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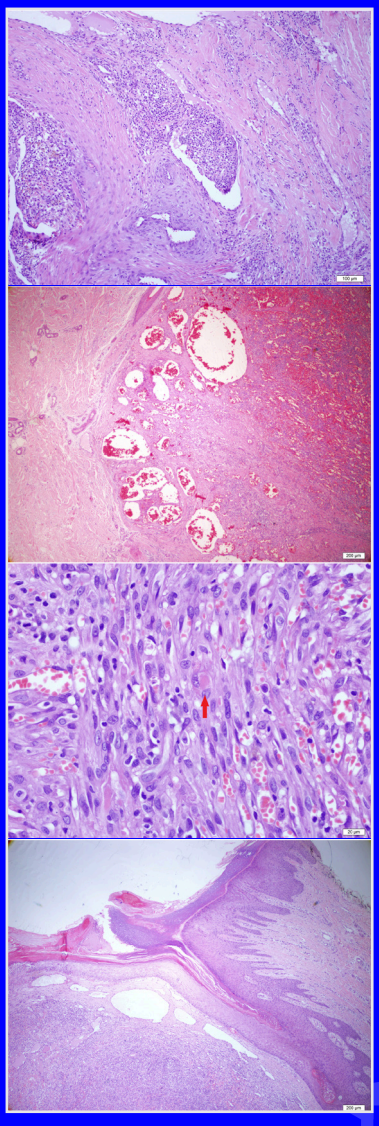

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EDITORIAL

Dear Readers;

The year 2024 means a new beginning and new hopes for our world and our country. Despite the advances in science and technology, humanity continues to experience problems more than ever before. We survived the earthquake disaster that occurred after the Covid pandemic in our country. Wars and human tragedies continue in various regions around the world. As the Bezmialem Science team, we continue to strive to find out how we can do better.

I think that last year has brought many successes for our journal, with our efforts increasing day by day. We're starting the new year with our new cover face.

In this issue, we have chosen the cover art from the article entitled "Our Five Years of Kaposi's Sarcoma Experience: Which Histopathological Parameters are More Valuable in Diagnosis?" by Benli Işık and Ölger Uzuner.

Kaposi sarcoma (KS) is a vascular proliferation associated with human herpesvirus 8. Although typical histopathological findings vary depending on the stage, it is characterized by vascular proliferation, inflammatory cell infiltration, extravasated erythrocytes and spindle cell proliferation. In the study, the clinical-histopathological features of the patients with KS were examined, and clinical and tumor characteristics and histopathological changes in the surrounding tissue were evaluated.

The articles selected in this issue are;

1- "Magnetic Resonance Imaging Findings of Suprapatellar Fat Pad Impingement Syndrome: A Retrospective Study" by Balkanlı B., et al.

2- "Evaluation of Filling Quality of Obturation Techniques in Internal Resorption Cavities Created with a Novel Methodology" by Özden İ., et al.

3- "One-year Body Mass Index Change in Adult Renal Transplant Recipients and Its Relationship with Glomerular Filtration Rate and Creatinine Level: A Retrospective Study " by Cebeci F., et al.

4- "Defining Effective Performance Management Strategies for Hospital with a Novel Fuzzy Decision-Making Model" by Uslu YD., et al.

We are honored by the increasing publication requests and are pleased to see articles coming from new domestic and international institutions.

This year, new friends joined our editorial board. I would like to thank our assistant editors and referees who supported us, and the entire Bezmialem Science team who worked hard behind the scenes, for their contributions, and I wish you a happy new year. I hope it will bring beauty to our country and our world.

See you in our next issue…

Kind regards
Prof. Dr. Adem AKÇAKAYA
Chief Editor

Commentary

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Hashimoto's Thyroiditis from the General Surgeon's Perspective

Genel Cerrah Bakışından Hashimoto Tiroiditi

Adem AKÇAKAYA

Bezmialem Vakıf University Faculty of Medicine, Department of General Surgery, İstanbul, Turkey

Dear Readers,

In this issue, I will talk about a general surgeon's perspective and approach to Hashimoto's thyroiditis (HT).

HT is one of the most common autoimmune diseases characterized by thyroid-specific autoantibodies. Although its etiology has not been fully elucidated, genetic elements, environmental factors and epigenetic effects are considered among the causes (1). The prevalence of HT varies between 5.8% and 14.2% depending on geographical locations (2). Cellular and humoral immunity play a key role in the development of the disease; therefore, inflammatory infiltration of T and B cells is often found. Histopathological features of the disease include lymphoplasmacytic infiltration, germinal-centered lymphoid follicle formation, and parenchymal atrophy. Additionally, the appearance of large follicular cells and oxyphilic cells or Askanazy cells is often associated with HT. Clinically, HT is characterized by systemic symptoms due to damage to the thyroid gland, and hypothyroidism often develops. The diagnosis of HT is mostly made clinically. Positivity of serum antibodies against thyroid antigens such as thyroid peroxidase (TPO) and thyroglobulin and lymphocytic infiltration in cytological examination are helpful parameters in diagnosis. The main principle of treatment is based on the treatment of hypothyroidism. The relationship between HT and a possible malignant transformation has been suggested in many studies and immunological/hormonal pathogenic effects are thought to be involved, but the specific correlation is still debated and needs to be further investigated in prospective studies (3).

In patients with HT, thyroid antibodies are formed through various immune processes. These antibodies attack thyroid tissues and fibrosis occurs, resulting in loss of thyroid function. Hypothyroidism develops due to this insult. Clinically, symptoms such as weight gain, constipation, increased sensitivity to cold, and dry skin occur. HT can cause cardiovascular diseases such as coronary heart disease. Additionally, HT is a risk factor for the development of thyroid cancer.

The prevalence of HT is increasing nowadays. It is known that genetic predisposition, environmental factors, immune system, cytokines and vitamin D deficiency play an important role in the pathogenesis of HT (4).

Factors Involved in Etiology and Pathogenesis

Genetic predisposition plays an important role in the pathogenesis of HT. Many studies have reported that there is a genetic predisposition to HT. For example, while the prevalence of HT is higher in Latin America, it is lower in Africa and Asians (5). Based on a Swedish twin study in which the HT concordance was shown to be 0.29 and 0.1 for monozygotic and dizygotic twins, respectively, and the heritability was 0.64, and the higher concordance rate for monozygotic twins than dizygotic twins confirmed that such disease sharing was dependent on common genes (5,6). Recombinant interleukin-2 receptor alpha, human leukocyte antigen (HLA), protein tyrosine phosphatase non-receptor type 22, and cytotoxic T lymphocyte-associated antigen-4 are susceptible sites for HT. These loci have the potential to

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disrupt T cell regulation and peripheral immune tolerance and play an important role in the pathogenesis of HT (7).

Environmental factors have an impact on the pathogenesis of HT. In autoimmune reactive diseases, an environment devoid of microbial agents and hygiene have been shown to have a strong relationship with the incidence of autoimmune diseases. One study suggested that women born in the summer months had a 2% higher incidence of HT compared to the general female population (8). Prolonged exposure to stressful situations may increase the incidence of HT. Meat, in particular, is an important nutritional factor that has been shown to increase the risk of thyroid autoimmunity, however, plant and fat-free foods containing fiber and antioxidants have been shown to reduce the risk of HT (4).

It is known that trace elements play an important role in the emergence of the disease. Iodine plays an important role, especially in thyroid diseases. Thyroid epithelial cells take up the iodine found in the blood and iodine tyrosine molecules by catalyzing it with hydrogen peroxide. The iodinated products are then converted into T3 and T4 by TPO (9). Studies have shown that increased iodine intake increases the risk of AITD. Both salt iodization programs and excessive supplementation can cause hypertension (10). The mechanisms currently discussed are: High iodine exposure may 1- increase the immunogenicity of thyroglobulin; 2- activate the autoimmune response and triggers signaling pathways that lead to apoptosis, which causes the destruction of thyroid tissue; 3- cause increased oxidative stress; 4- impair peripheral tolerance due to inhibition of regulatory T cells (Tregs) (9,11). Selenium is an essential micronutrient that plays an important role in immune-related diseases. The thyroid gland is the largest reserve of selenium in the body. SELENOS is a susceptibility gene for HT which is expressed in thyroid follicular cells. It encodes the family of selenoproteins which are involved in cellular stress and immune inflammatory responses. Selenium supplementation has an immune stimulating effect and can inhibit HLA-DR expression in thyroid cells, reduce thyroid autoimmunity, and this is evidenced by increased T and innate immune cell function. Therefore, selenium deficiency also plays a role in the pathogenesis of HT (12,13). Iron plays an important role in hemoglobin and myoglobin and is involved in many important metabolic processes. TPO can only be activated after binding to repaired "Hem I" and participates in thyroid hormone synthesis, therefore iron content affects T3-T4 synthesis. The thyroid-small intestine axis is closely related to HT. Hypothyroidism can cause digestive disorders, impaired bowel function, and decreased iron absorption. Iron deficiency affects the regulation of thyroglobulin with iodine, and combining of iotyrosine molecules, which causes a decrease in T3 and T4 production, causing hypothyroidism (9). HT is often associated with autoimmune gastritis, with large amounts of anti-parietal cell antibodies found in the serum. As the disease progresses, this evolves into severe atrophic gastritis and reduced gastric acid secretion, resulting in the body's inability to effectively absorb iron from food, resulting in iron malabsorption. Zinc is a trace element closely related to thyroid metabolism. It promotes the synthesis of hypothalamic thyrotropin-releasing hormone and thyroid-stimulating hormone (TSH), and is also a structural component of the T3 receptor. It also functions as a thyroid hormone-binding transcription factor that regulates the expression of thyroid hormones by regulating thyroid hormone deficiency. Dietary zinc deficiency and low serum zinc concentration can lead to changes in thyroid hormone metabolism and even thyroid structure. Zinc deficiency reduces free T3-T4 levels in serum. In addition, zinc and thyroid function may affect each other; zinc deficiency causes decreased thyroid function, and thyroid insufficiency leads to inadequate zinc absorption (14,15).

Vitamin D deficiency is one of the causes of HT. In this case, the greater the vitamin D deficiency, the higher the possibility of HT (16). Vitamin D concentration is positively associated with the cytokines TNF-α, IL-5, and IL-17, which regulate the cellular immune response against inflammation in patients with HT and are secreted from Th1 cells (17). Since cellular immunity is the main element of pathogenesis in patients with HT, the relationship between vitamin D and these cytokines suggests that vitamin D is involved in the pathogenesis of HT. Dysbiosis in the intestinal flora contributes to HT triggers.

Immunological factors are among the main factors that play a role in HT. As is known, HT is an autoimmune disease characterized by thyroid-specific autoantibodies. Inflammatory infiltration of T and B cells constitutes the main pathogenesis (5). In the context of genetic predisposition and environmental factors, errors in innate immune function produce antibodies against thyroid antigens, causing cytotoxic damage to thyroid cells and immune dysfunction. This causes cellular and humoral immune responses and destruction of thyroid epithelial cells, leading to disease. Cellular immunity; some autoreactive T cells escape immune regulatory control and enter peripheral tissues, leading to autoimmune disease. Activation of T cells stimulated by peripheral antigens, co-stimulatory factors or specific cytokines leads to the formation of different T cell subpopulations (18). T helper cells and Tregs are important T cells involved in the autoimmune response (19). Tregs and Th cells are key regulators of inflammation and play an important role in immune tolerance. CD4 is the main marker on the Th surface, and Th1, Th2, Th17, and follicular helper T cell subtypes are closely associated with the development of HT.

The Relationship between Autoimmune Thyroiditis and Cancer

Hashimoto's thyroiditis is also autoimmune aseptic inflammation. Research shows that chronic inflammation is a very important factor in the development of cancer (20). Therefore, more research institutes are investigating the relationship between HT and cancer. However, as research increases, debates and different opinions continue to emerge about whether HT is related to cancer development. In the meta-analysis study conducted by Hu et al. (2) in 2022, 12,917 patients and 60,509 control subjects in 11 case-control studies and 12 cohort studies were included. In the study conducted on patients with HT, 13

types of human cancer were examined: thyroid cancer, breast cancer, lung cancer, stomach cancer, liver cancer, colorectal cancer, uterine cancer, cervical cancer, ovarian cancer, prostate cancer, bladder cancer, kidney cancer and hematological cancers. Relative risk/probability ratios of cancer types in patients with HT were reported. The result of meta-analysis showed that the rate of thyroid cancer was highest in patients with HT. The rate of thyroid cancer in patients with HT in 21 studies ranged from 0.61% to 58.43%, with a mean rate of 25.01%. The mean rate of breast cancer 1.40% (0.99%, 1.82%), respiratory organs cancer 1.06% (0, 2.15%), genitourinary cancer was 1.2% (0.3%, 2.1%), digestive organs cancer 2.21% (0.46%, 3.95%), and leukemia 0.37% (0.13%, 0.61%). Only one document mentioned malignant lymphoma, and 2 patients were found among 2,036 patients with HT. Among 329 patients with HT, 3 patients of myeloma were found and no case was found in the control group (2).

There is no doubt about the relationship between AIT (autoimmune thyroiditis) and papillary thyroid carcinoma (PTC). Fiore et al. (21) analyzed the rate of PTC, high TSH levels and the presence of antithyroid antibody (ATA) in 13,738 patients with autoimmune thyroid disease (AITD) [3,914 on l-thyroxine (L-T4) treatment and 9,824 on no treatment]. The prevalence of PTC was found to be higher in patients with nodular-AIT than in those with nodular goiter. An increase in TSH levels has also been observed in patients with PTC. Both TSH level and PTC incidence were lower in patients receiving LT-4 treatment. Similar findings have been observed in other studies (21). Thyroid autoimmunity and high TSH levels are considered independent risk factors for thyroid cancer in different articles. A high prevalence of PTC was found in patients with chronic hepatitis C and mesothelioma, especially in the presence of autoimmune thyroiditis (22). Of patients with both PTC and AITD, 5-10% may develop aggressive disease and require systemic therapy.

Diagnosis of Hashimoto's Thyroiditis

Diagnosis of HT is based on clinical symptoms, ATA and histological features. Serum anti-TPO antibodies are considered the hallmark of HT and are present in approximately 95% of patients. Instead, anti-thyroglobulin antibodies are found in a lower percentage of patients (60-80%) and are therefore less reliable for diagnosis. It appears that anti-thyroglobulin antibodies may be an expression of an initial immune response, whereas anti-TPO antibodies may be a result of a later immune response. Clinical features include both local and systemic manifestations, as well as features specific to individual forms of HT. Local symptoms result from compression of cervical structures anatomically close to the thyroid gland and include dysphonia, dyspnea, and dysphagia. Systemic findings result from loss of function of the thyroid gland and subsequent primary hypothyroidism. Given the profound and broad influence of thyroid hormones on most organs and tissues, the signs and symptoms of hypothyroidism are numerous and variable.

The diagnosis of HT is currently made by a combination of clinical features, the presence of serum antibodies against thyroid antigens (mainly thyroperoxidase and thyroglobulin), and the appearance on a thyroid sonogram. Radioactive iodine uptake of the thyroid gland and cytological examination of thyroid aspirate are used less frequently.

Cytological examination is not routinely performed, but only when a thyroid nodule with suspicion of malignant transformation is found. Additionally, ultrasonographic features of HT may make nodule identification and aspiration difficult. Finding lymphocytes in contact with thyroid cells is considered the most important element in making the differential diagnosis between HT and thyroid tumors (23).

Radiological evaluation of HT is usually made with ultrasonographic examination. Neck ultrasound has become the most commonly used imaging tool in patients with thyroid diseases. It shows characteristically decreased echogenicity in HT. The normal thyroid gland, composed of thyroid follicles of various sizes making the lobes appear bright. In HT, on the contrary, thyroid follicles are destroyed and replaced by small aggregates of lymphocytes, so that the echogenicity of the thyroid parenchyma decreases markedly and becomes similar to that of the surrounding muscles. Various forms of HT have unique characteristics. For example, hypoechogenicity is more prominent in the IgG4-related variant, and in the fibrous variant it is accompanied by disorganization and nodularity, given the conspicuous accumulation of collagen fibers. Thyroid ultrasound can also measure the volume of the thyroid gland. Thyroid ultrasound can also be combined with Doppler or elastography. In addition, ultrasound is used to guide needle placement during fine needle aspiration into the thyroid nodule (24).

Thyroid Function Tests, Radioiodine Uptake and Fine Needle Aspiration

Evaluation of thyroid functions in patients with HT is performed by measuring serum thyrotropin (TSH) and free thyroxine (FT4) levels. TSH is the most important index for monitoring thyroid functions because its level fully adapts to even minimal changes in circulating thyroid hormones. Because results are variable, 24-hour thyroid radioactive iodine uptake is now rarely used to diagnose HT. However, it is beneficial in painless thyroiditis. During the hyperthyroid phase of this variant of HT, radioiodine uptake actually decreases (<5%) rather than increases. This is because the increase in circulating thyroid hormones is not due to increased function of the thyroid gland (hyperthyroidism), but rather to the destruction of thyroid follicles and the release of previously formed thyroid hormones (thyrotoxicosis).

When the patient has a thyroid nodule, fine needle aspiration is performed. Most thyroid nodules are true nodules and the majority are benign tumors. However, in the fibrous variant of HT, "pseudo-nodules" may be present, given that dense keloid-like fibrosis distorts the thyroid structure and gives the gland a lobular appearance. When thyroid antibodies and a nodule are present, it is difficult to determine whether the patient has two

concomitant thyroid diseases or just the fibrous variant of HT. Therefore, fine needle aspiration is performed and cytological results may be difficult to interpret. In HT, cytologic examination shows a polymorphic population of lymphoid cells (small mature lymphocytes, larger activated lymphocytes, and occasionally plasma cells) accompanied by Hurthle cells. Lymphocytes are often in contact with thyroid cell groups, and this feature is thought to be useful in distinguishing HT from thyroid neoplasms (25). However, some aspirates lack lymphoid cells and consist almost entirely of Hurthle cells, making it difficult to determine whether these are Hurthle cells found in HT or those found in other oncocytic lesions of the thyroid, such as oncocytic adenomatoid nodule.

Treatment of Hashimoto's Thyroiditis

Hashimoto's thyroiditis is essentially a medical disease. Its treatment is similar to the treatment of patients with goiter. The American Thyroid Association has guidelines for the management of thyroid disorders. It has been stated that medical options for goiter treatment primarily consist of iodine replacement, thyroid hormone replacement, thyroid hormone suppressive therapy and radioactive iodine (26).

The use of thyroid hormone (levothyroxine) in patients with iodine deficiency can cause the goiter to shrink by 15% to 40% in approximately 3 months. However, available literature indicates that goiter can be expected to return to its pretreatment size after discontinuation of thyroid hormone supplementation.

Levothyroxine replacement can be used and is routinely recommended to normalize high TSH levels due to hypothyroidism, which may be associated with a reduction in goiter size. In contrast, levothyroxine can also be used to suppress the serum TSH level below the lower limit of the normal range. This causes normal thyroid tissue to invert to a much greater extent than pathological thyroid tissue; therefore, its effectiveness in large goiters is limited and suppressive therapy is not routinely recommended. On the other hand, lifelong suppression is required, and such long-term TSH suppression therapy is associated with an increased risk of adverse side effects such as atrial fibrillation and osteoporosis, especially in postmenopausal women.

Radioactive iodine therapy is widely used to reduce goiter size in patients with non-toxic multinodular goiter. Patients who are considered risky surgical candidates and have goiters with compressive symptoms that range in size from medium to large may be suitable candidates for radioactive iodine. Radioactive iodine ablation has been associated with a reduction in goiter volume, but most of the reduction occurs in the first few months of treatment. However, there are complications associated with the treatment; (i) regrowth of goiter after treatment (15-25% potential increase in size) and narrowing of the trachea, (ii) transient thyrotoxicosis resulting from radiation thyroiditis; (iii) the subsequent development of subclinical or overt hypothyroidism; and (iv) the occurrence of secondary hyperthyroidism/Graves disease and radiation-induced malignancies (such as breast cancer), which have been reported in patients receiving radioactive iodine for ablation of euthyroid goiter.

Surgery

Surgery is rarely indicated for thyroiditis. Unlike medical treatment, which provides at best a partial reduction in goiter volume, surgery offers definitive treatment by removing the goiter, although it carries the risk of laryngeal nerve damage, hypoparathyroidism, bleeding or hematoma.

There are also publications advocating that surgical treatment for HT is contraindicated, except when the disease is associated with nodular lesions suggestive of malignancy (27).

The most basic surgical indication in HT is the presence of a nodule and the presence or suspicion of malignancy as a result of FNAB. Surgery may be performed in patients who do not show improvement in compressive symptoms despite long-term treatment with L-T4 and no decrease in goiter size, patients with shortness of breath and difficulty swallowing due to compression on the trachea or esophagus, growth of the nodule, localized progressive pain, for prevention of complications arising from extension to the mediastinum, or sometimes for cosmetic reasons.

The prevalence of thyroid cancer in patients with HT varies from 0.4% to 28% in different surgical series. However, there are studies arguing that the risk does not increase. A meta-analysis study has also been published concluding that HT is associated with all thyroid malignancies except follicular and anaplastic thyroid cancer. The risk of lymphoma in patients with HT is known. Although there are different opinions about the risk of cancer coexisting with thyroiditis, the surgeon treating thyroiditis should keep this risk in mind when determining the indication (27,28).

The recommended method of surgery is total thyroidectomy. If there is a risk of adhesion and injury to the recurrent laryngeal nerve (RLN), near total thyroidectomy can be performed.

Thyroidectomy is technically more difficult in patients with thyroiditis than patients without thyroiditis, because of requiring more operating time and longer hospital stay. Although some studies indicate no difference, most studies have found a higher risk of temporary or permanent hypocalcemia and/or RLN palsy. Surgery in patients with thyroiditis should be performed by a senior, specialist surgeon who is experienced in difficult thyroidectomies and can manage intraoperative difficulties such as bleeding and identification of the RLN and/or parathyroid gland. This will reduce post-operative complications.

Complications of surgery for HT are similar to complications experienced in other thyroid surgeries. These include bleeding, RNL injury, hoarseness, inability to raise the voice, and temporary or permanent hypoparathyroidism. Wound infection is rare. Intraoperative bleeding may be directly related to venous congestion. Rarely, pneumothorax may occur.

Postoperative calcium levels should be taken into consideration. Measurement of parathyroid hormone level in the postoperative period and, if necessary, the need for calcium supplements with

calcitriol should be determined before the patient is discharged. It is also important to start the patient on levothyroxine treatment after the surgery. The usual dose is 1.4-1.6 μg/kg per day (based on actual body weight), testing of TSH level should be planned 4-6 weeks after surgery and titration of döşe should be performed as necessary. Patient education at discharge should include signs/symptoms of hypocalcemia, hematoma, infection, or airway distress (29,30).

Last Words

To date, much progress has been made in the knowledge and treatment of HT. However, the mechanisms that lead to impaired tolerance of the immune system and the resulting autoimmune response against the thyroid gland and the onset of the disease are still controversial.

Although many genetic and environmental factors that can trigger an autoimmune response have been identified, the exact etiopathogenesis of HT is still unknown. Studies showing that excess iodine due to iodine added to foods in order to prevent iodine deficiency increases the formation of HT, and the warnings of the World Health Organization in this regard should be taken into consideration. The importance of epigenetic factors has been emphasized recently, but more studies are needed to fully understand their roles. Treatment of HT, currently focusing on the clinical symptoms of the disease, should in the future address the autoimmune mechanism that causes the destruction of the thyroid parenchyma and the resulting hypothyroidism. A better understanding of epigenetic modifications and autoimmune pathogenic mechanisms will contribute to a more accurate diagnosis of HT, a more adequate choice of treatment approach, and a more accurate prediction of treatment outcomes.

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Original Article

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Effect of Reaction Time Exercises on Physical Functionality and Quality of Life in Geriatrics: A Non-controlled Study

Geriatrik Bireylerde Reaksiyon Zaman Egzersizlerinin Fiziksel Fonksiyonellik ve Yaşam Kalitesi Üzerine Etkisi-kontrolsüz Bir Çalışma

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ABSTRACT

Objective: This study was conducted to investigate the effects of reaction time (RT) exercises on functional independence, static balance, fall risk, upper and lower extremity RT, and quality of life in older adults.

Methods: Forty participants aged 65-77 years were included in the study. Participants' functional independence was evaluated using the Functional Independence Scale, static balance using the Single-Leg-Squat Test, fall risks using the Morse Fall Scale, lower- and upper-extremity RT's using the Light Trainer Flash Light Exercise System (Model LTV2, Turkey, 2017), and their quality of life using the Short Form-36. RT exercises were performed using the Light Trainer Flash Light Exercise System for six weeks, three days a week. Measurements were repeated after the treatment.

Results: In the older adults examined, there was a significant difference between before and after the 6-week exercise protocol in functional independence, static balance, fall risk, upper- and lower-extremity RT, and quality of life ($p<0.05$).

Conclusion: The study showed that a 6-week RT exercise program had positive effects on functional independence, static balance, fall risk, upper- and lower-extremity RT, and quality of life in older adults. The results showed that reaction-time exercises can be added to rehabilitation protocols for older adults and can be used in clinical settings.

ÖZ

Amaç: Bu çalışma, geriatrik bireylerde reaksiyon zaman (RZ) egzersizlerinin fonksiyonel bağımsızlık, statik denge, düşme riski, üst ve alt ekstremite RZ ve yaşam kalitesi üzerindeki etkilerini araştırmak amacıyla yapılmıştır.

Yöntemler: Çalışmaya, 65-77 yaş aralığında 40 geriatrik birey dahil edildi. Geriatrik bireylerin sosyodemografik özellikleri kaydedildikten sonra fonksiyonel bağımsızlıkları, Fonksiyonel Bağımsızlık Ölçeği ile, statik dengeleri Tek Ayak Üzerinde Durma Testi ile, düşme riskleri Morse Düşme Ölçeği ile, alt ve üst ekstremite RZ'ler, Light Trainer Flash Light Exercise System (Model LTV2, Türkiye, 2017) ile yaşam kaliteleri Kısa Form-36 ile değerlendirildi. Bireylere altı hafta süreyle, haftada üç gün Light Trainer Flash Light Exercise System ile RZ egzersizleri yaptırıldı ve 6 hafta sound değerlendirme parametreleri bakımından ölçümler tekrarlandı.

Bulgular: Geriartrik bireylerde, altı haftalık RZ egzersiz ve sonrası sonuçları arasında fonksiyonel bağımsızlık, statik denge, düşme riski, bilişsel beceri, üst ve alt ekstremite RZ ve yaşam kalitesi bakımından anlamlı fark olduğu görüldü ($p<0,05$).

Sonuç: Çalışma, 6 haftalık RZ egzersiz programının yaşlı yetişkinlerde fonksiyonel bağımsızlık, statik denge, düşme riski, üst ve alt ekstremite RZ'si ve yaşam kalitesi üzerinde olumlu etkileri olduğunu gösterdi. Sonuçlar, RZ egzersizlerinin yaşlı yetişkinler için

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ABSTRACT

Keywords: Geriatrics, exercise, functional status

ÖZ

rehabilitasyon protokollerine eklenebileceğini ve klinik ortamlarda kullanılabileceğini gösterdi.

Anahtar Sözcükler: Geriatri, egzersiz, fonksiyonel durum

Introduction

The term aging refers to all the structural and functional changes that occur over time at the level of cells, tissues, organs, and systems in an organism with chronological, biological, social, and psychological dimensions (1). The population aged 65 years and over is increasing rapidly throughout the world and in Turkey. The number of people aged 65 and over, reported as 703 million in 2019, is expected to reach 1.5 billion by 2050 (1).

Functional deficiencies can often develop in older adults because of age-related physiological changes, social factors, or diseases (2). The presence of functional deficiencies in these individuals may have negative effects on activities of daily living (3). A decline in physical performance and cognitive abilities with aging causes progressive deterioration in muscle strength, coordination, and balance (3).

Balance is fundamental to the ability to stand and move (4). Deterioration in body functions due to aging causes a decrease in the ability to maintain the center of gravity on the support base and an increase in the swing area in response to postural changes (5). This deterioration in balance functions may cause a decline in the activities of daily living and an increase in the frequency of falling (5). Falling emerges as a major health issue in older adults, in terms of its medical and economic consequences, and is among the factors that cause the highest rates of mortality and disability (6).

Falls are the primary cause of injury in older adults and can lead to reduced quality of life and high personal, social, and health costs (7). A person who falls may experience pain, hospitalization, surgery, decreased activities of daily living, lower quality of life, or fear of falling (7). Factors such as loss of muscle mass, prolongation of reaction time (RT), decrease in balance ability, and decline in muscle strength and endurance that occur with aging increase the risk of falling (7).

RT is the time between the stimulus reaching the central nervous system, its evaluation, and the appropriate response after the relevant arrangements are made. There are many factors affecting this parameter (8). Ageing is one of these factors, and with aging, the capacity of the nervous system to process information and activate a response decreases (9).

These factors affect the quality of life of older adults, a term that includes well-being rather than only health, and reduce their active participation in life (7). Increasing the level of physical activity helps minimize these negative factors, and it is known to be an important intervention to protect and maintain health in older adults (7). Therefore, these factors pave the way for both the preservation of quality of life and functional independence of the older population.

Exercise training for people aged 65 years has a positive effect on muscle strength and balance, increases bone mineral density, improves cognitive functions, and is an effective method for preventing falls, reducing risk factors for falls, and increasing quality of life (10). Resistance exercise programs, programs aiming to increase flexibility, balance, and endurance, tai-chi, ai-chi, and aqua therapy are among the most effective exercise methods for older adults (10). While there are numerous studies in the literature that examine the effects of physical activity on individuals aged 65 years and older, no study has investigated RT exercises aimed at activating cognitive functions during physical activity and enhancing engagement in exercise. Therefore, this study aimed to determine the effects of RT exercises on functional independence, balance, risk of falling, RT, and quality of life in the elderly population.

Methods

Study Design: Prospective Cohort Study

Participants

This study was conducted with 43 adults (26 female, 14 male) over 65 years of age who could walk independently and applied to the Üsküdar University Physical Therapy and Rehabilitation Center. The exclusion criteria were as follows: being diagnosed with Alzheimer's or dementia, having a history of cerebrovascular accident, a physical disability such as amputation, visual impairment, active cancer, advanced joint contracture, acute inflammatory problems, or having undergone any musculoskeletal surgery.

Ethics committee approval was obtained from the Non-Invasive Ethics Committee of Üsküdar University (no: 61351342/2020-231). Participants were informed about the purpose and procedures of the study. The "Informed voluntary consent" form was signed. This study was conducted according to the principles of the Declaration of Helsinki.

Assessment Tools

After recording the participants' sociodemographic and medical data, such as gender, age, height, weight, allergy status, chronic diseases, and drug use, the following parameters were evaluated.

Physical Functionality

Functional Independence Level

The functional independence levels of the participants were evaluated using the Functional Independence Measure (FIM). FIM is a scale used to evaluate individuals' daily life activities and independence levels. Küçükdeveci et al. (11) conducted a

Turkish validity and reliability study of the scale. The higher the score an individual receives because of the evaluation, the higher the level of independence. The scale was filled by the face-to-face interview method.

Static Balance Assessment

The static balance of individuals was evaluated using the Single-Leg-Squat Test (SLST). The validity and reliability study of the SLST test was performed by DiMattia et al. (12). In the test, participants were asked to lift one foot with their eyes open so that it would not touch the supporting leg and maintain this position. The test was terminated in those who stood on one leg independently for 30 s. Touching the supported leg, foot touching the floor, jumping or bouncing on the supporting leg, or the participant touching any object in the environment for support were determined as the termination criteria of the test. Three measurements were made, and the average of the participants' standing on one leg was recorded in seconds.

Fall Risk Assessment

Participants' risk of falling was assessed using the Morse Fall Scale (MFS). The Turkish validity and reliability study of the scale was conducted by Demir and İntepeler (13). The scale includes 6 items: history of falling, presence of additional disease, getting help while walking, receiving intravenous treatment, walking style, and mental status. 0-24 is considered "low risk", 25-50 "moderate fall risk", 51 and above "high risk of falling". The scale was filled by the face-to-face interview method.

Reaction Time Measurement

The participants' lower and upper extremity RT's were measured using the Light Trainer Flash Light Exercise System (Model LTV2, Turkey, 2017) before and after the intervention. These assessments were repeated 3 times for 30 s in randomized mode, the results were recorded, and the test parameters were completed.

Upper Extremity Reaction Time Measurement

For this measurement, the participants were seated on a chair at point A, which coincided with the middle of the modules. The participants were placed in a position with their hands on the table. Four light reaction modules were placed in front of the participants. The distance from the midpoint of the modules to point A was set as 50 cm, and the distance between the modules was set as 15 cm. Before the test, each participant was given a trial and informed about the test content. Afterward, when the participants were ready, they were positioned at the starting point for the test. After the start command was given, the participant waiting at point A was asked to react to any burning module and switch it off by hand as soon as possible. It was reported that the participant should switch off the maximum number of modules within 30 s, and at the end of the measurements, their best scores were recorded as upper extremity RT (14).

Lower Extremity Reaction Time Measurement

Participants were positioned on the line at point A in the test field, with both feet in contact with the ground, for lower extremity RT measurement. Four light reaction modules were placed in front of the participants. The distance from the midpoint of the modules to point A was 50 cm, and the distance between the modules was set to 15 cm. Before the test, each participant was given a trial and informed about the test content. Afterward, when the participants were ready, they were positioned at the starting point for the test. Afterward, when the participants were ready, they were positioned at the starting point for the test. After the start command was given, the participant waiting at point A was asked to react to any burning module and switch it off by hand as soon as possible. It was reported that the participant should switch off the maximum number of modules within 30 s, and at the end of the measurements, their best scores were recorded as lower extremity RT (14).

Quality of Life Assessment

The participants' quality of life was evaluated using Short Form-36 (SF-36). A validity and reliability study of the scale in the Turkish population was performed by Koçyiğit et al. (15). The scale consists of 36 items evaluated under 8 sub-headings: Physical Functioning, Social Functioning, Role Limitations due to Physical Problems, Role Limitations due to Emotional Problems, Vitality, Bodily Pain, General Health Perceptions, and General Mental Health. The higher the score for each item in SF-36, the higher the individual's health-related quality of life.

Exercise Protocol

After the evaluations, the participants were given exercise training for 40 minutes, 3 days a week, for 6 weeks. Before each session, a 10-min warm-up exercise consisting of 3 sets of 10 repetitions of flexion-extension movements was performed for the neck, shoulders, elbows, knees, hips, and ankle regions. Then, with the Light Trainer Flash Light Exercise System (Model LTV2, Turkey, 2017), RT exercises were performed for 20 min using four modules in a randomized light mode (Figure 1, 2). After each session, a 10-min cool-down exercise including pectoral stretching, upper trapezius stretching, hamstring stretching, hip flexor stretching, and breathing exercises was performed (10).

Participants were re-evaluated for the same parameters after 6 weeks of exercise training.

Statistical Analysis

Sample Size Calculation

The G*Power version 3.1.7 program was used for sample size and effect size calculations. In the study, the minimum number of people to be included was determined as 40, with an acceptable margin of error of 5% and a confidence level of 95%. The effect size level for this sample group to provide a sampling power of 0.83 was 0.30.

Statistical analysis was performed using SPSS version 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, IBM Corp., New York, USA).

Descriptive statistics are presented with mean and standard deviation values. The normal distribution of the variables was analyzed using the Kolmogorov-Smirnov test. The Wilcoxon sign test was used to examine the differences in the pre-test and post-test measurements of the parameters. P values 0.05 were considered significant in the study.

Results

Initially, 43 participants volunteered for the study. The study was completed with 40 participants, excluding 2 participants who did not attend 3 consecutive sessions and 1 participant who did not attend 4 sessions in total (Figure 3).

Figure 1. Reaction time exercises for the upper extremities with a Light Trainer Flash Light Exercise System

Figure 2. Reaction time exercises for the lower extremities with a Light Trainer Flash Light Exercise System

The sociodemographic and medical characteristics of 40 participants included in the study are given in Table 1.

There was a significant difference between the results of FIM, SLSL, MFS, UEOrtRT, and LEOrtRT of older adults before and after 6 weeks of exercise training ($p<0.05$), (Table 2).

It was determined that there was a statistically significant difference between the measurement values of the participants before and after the exercise training between Physical Functioning, Social Functioning, Role Limitations due to Physical Problems, Role Limitations due to Emotional Problems, Vitality, Bodily Pain, General Health Perceptions, and General Mental Health ($p<0.05$), (Table 3). Comparisons of the SF-36 quality of life variables of older adults before and after exercise training are shown in Table 3.

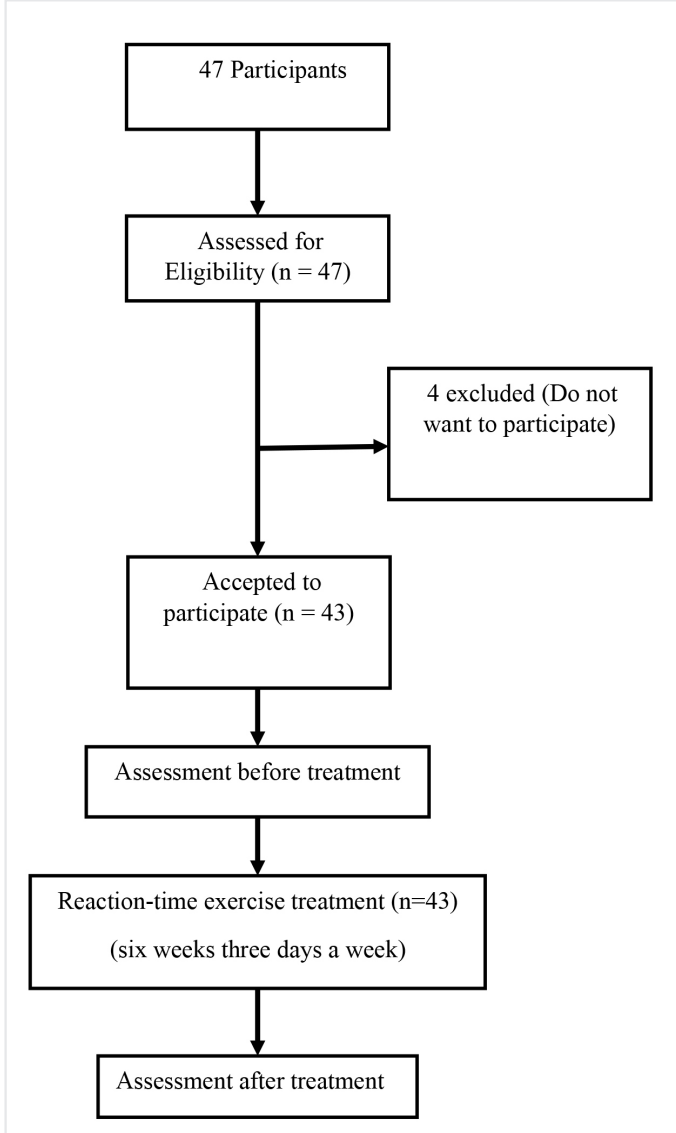

Figure 3. Study flowchart

Table 1. Sociodemographic characteristics of the participants

Age years (X ± SD)	72.48±5.13
Height (cm) (X ± SD)	165.84±9.42
Weight (kg) (X ± SD)	69.92±15.8
Gender (n/%)	
Woman	26 (65%)
Man	14 (35%)
Chronic disease (n/%)	
No	9 (22.5%)
Yes (HT/ DM)	31 (77.5%)

%: Percent, N: Participant number, X ± SD: Mean ± Standard deviation

Discussion

This study examined the effect of RT exercises on functional independence, balance, risk of falling, RT, and quality of life in the elderly population. The study findings showed that RT exercises applied to older adults had positive effects on functional independence, balance, fall risk, and quality of life in these individuals.

RT is a reliable indicator of processing speed, as it reflects the perception of stimuli by the central nervous system and its response in the form of a motor reaction. It can determine a person's alertness, as an individual's response to a stimulus is dependent on their RT (16). RT is more adversely affected in older adults than in younger individuals. This condition leads to a decline in functional capacity and an increase in the rate of falls. According to the findings of Okubo et al.'s (17) systematic review, stepping exercises have been shown to reduce RT and the

Table 2. Comparison of participants' Functional Independence measures, Single-Leg-Squat tests, Morse Fall Scale, and Upper and Lower Extremity Reaction Time scores before and after exercise training

Assessments	T1 (n=40) M ± SD (min-max)	T2 (n=40) M ± SD (min-max)	p value
FIM	111.52±7.51 (96-123)	117.19±6.42 (104-126)	**<0.001***
SLST	19.84±10.24 (5-38)	22.11±10.03 (11-48)	**<0.001***
MFS	33.19±23.17 (0-70)	23.86±18.8 (0-55)	**0.003***
UEOmnRT	1.68±0.36 (1.02-2.18)	1.20±0.29 (0.85-1.87)	**<0.001***
LEOmnRT	1.70±0.35 (0.96-2.11)	1.34±0.29 (0.81-1.74)	**<0.001***

LEOmnRT: Lower extremity mean reaction time, UEOmnRT: Upper extremity mean reaction time, FIM: Functional independence measure, MFS: Morse Fall Scale, SLST: Single-Leg-Squat Test, T1: Before treatment, T2: After treatment, M ± SD: Mean ± standard deviation, min-max: Minimum-maximum, *Wilcoxon sign test, p<0.05

Table 3. Comparison of participants' SF-36 scores before and after exercise training

SF-36	T1 (n=40) M ± SD (min-max)	T2 (n=40) M ± SD (min-max)	p value
Physical functioning	57.35±20.70 (20-90)	70.00±19.76 (40-100)	**<0.001***
Role limitations due to physical problems	61.76±26.68 (0-100)	77.35±23.39 (25-100)	**0.006***
Role limitations due to emotional problems	70.59±26.04 (33.33-100)	84.37±23.86 (33.33-100)	**0.015***
Vitality	44.75±21.58 (20-85)	59.41±18.69 (40-95)	**<0.001***
General mental health	66.11±11.41 (44-88)	76.00±9.79 (60-96)	**<0.001***
Social functioning	64.11±19.24 (25-100)	78.82±15.46 (50-100)	**0.002***
Bodily pain	52.35±20.52 (22.50-90)	74.26±14.10 (55-100)	**<0.001***
General health perceptions	48.75±19.27 (18.89-80)	58.82±18.83 (30-95)	**<0.001***

SF-36: Short Form-36, M ± SD: Mean ± standard deviation, min-max: Minimum-maximum, T1: Before treatment, T2: After treatment, *Wilcoxon sign test, p<0.05

incidence of falls. The moderate or intense supervised exercise training thrice-weekly for 12 weeks exercise intervention applied by Morrison et al. (18) on elderly individuals with type II diabetes reduced the RT and therefore the risk of falling. The aim of the current study was to shorten the RT of elderly individuals and reduce the risk of falling with a RT exercise program. In this respect, this study complies with the current literature. Because of the study, individuals' RT's and risk of falling decreased.

Although there are many studies on the functionality of older adults, there is still a need to develop multi-component rehabilitation programs to increase functional independence (19). Kocic et al. (20) demonstrated that a group-based Otago exercise program combining 6-month strengthening and balance exercises is effective in improving balance and functional mobility in older adults staying in nursing homes, and a significant improvement was achieved in the level of functional independence. The virtual reality-based Tai Chi exercise program implemented by Hsieh et al. (21), which included 60 older adults, increased the functional independence level and cognitive performance of these individuals. Silva et al. (22), on the other hand, investigated the effectiveness of aquatic exercise in older adults, and as a result, it was determined that depression and anxiety levels decreased in these individuals and that the level of balance and functional independence showed a positive improvement. The Multi-system Physical Exercise program created by Chittrakul et al. (23) includes balance, coordination, muscle strength, and RT exercises. RT exercises were performed for 15 repetitions each, and participants were instructed to maintain the movements for 10 s. Rest periods between each set were determined as 10 s. According to the results of the study, individuals' functional independence, health-related quality of life, muscle strength, proprioception, and postural sway improved significantly (23). In the current study, we observed that the functional independence level of older adults increased with RT exercises. The difference between the RT exercises applied in the current study and the RT exercises applied in Chittrakul et al.'s (23) study is that the training was given with the Light Trainer Flash Light Exercise System (Model LTV2, Turkey, 2017). Thus, the study differs from the literature. We believe that this result may be due to the fact that RT exercises were performed with the Light Trainer Flash Light Exercise System (Model LTV2, Turkey, 2017) including parameters such as functionality, balance, coordination, attention, and skill.

Balance is the key element of maintaining posture, standing upright, and the ability to move. Balance training plays an important role in preventing falls (24). Most studies investigating the risk of falls in older adults have stated that physical activity and even leisure time exercises are effective methods to maintain balance control and prevent falls (24). In a review that analyzed different types of exercises aimed at increasing static balance in older adults, interventions such as resistance exercise programs, aerobic exercise, balance training, T-bow and balance board training, aerobic steps, exercises with a stability ball, pilates, and Wii Fit training have been shown to be effective exercise programs in increasing balance ability (5,25). In the current study, it was observed that the balance levels of older adults increased and the risk of falling decreased with RT exercises, which was consistent with the literature. In addition to many exercise types in the literature, it is thought that RT exercises can be an effective approach to improving balance in older adults.

Providing good postural control in older adults plays a crucial role in preserving cognitive and functional capacity (26). Although balance exercises are considered to be one of the most effective modalities in rehabilitation programs aimed at reducing falls, there is no consensus in the literature on this issue (26). In a study conducted by Bumin et al. (27), it was stated that while almost half of the participants had a history of falling in older adults staying in nursing homes, balance, walking problems, and other risk factors increased the risk of falling, and falls made older adults more dependent. Schoene et al. (3) stated that falling and the fear of falling reduce the quality of life and affect it negatively. In this study, we believe that increasing the balance in the participants with the RT exercises reduces the risk of falling. We believe that this situation provides older adults with the opportunity to act more freely and without fear and plays an important role in increasing functional independence.

Prolongation of the RT, reduction in protective reflexes, and more fragile body systems increase the possibility of injury (5). Hunter et al. (28) investigated changes in RT with aging and the relationship between reaction speed, strength, and physical exercise in 270 healthy women. They found a significant difference between physically active and inactive women and concluded that there was an improvement in RT with exercise (28). Mohamed et al. (29) determined that corrective exercises applied together with biofeedback had positive effects on the RT in individuals with forward head posture between the ages of 40 and 60 years. In another study, it was determined that whole body vibration and balance exercises applied to individuals with diabetic peripheral neuropathy had positive effects on RT and muscle strength (30). The current study determined that the reaction speed of older adults increased with RT exercises. Increasing the reaction speed enables older adults to react more easily to external stimulation. We believe that results such as an increase in the speed of reaction, an increase in the level of balance, and a decrease in the risk of falling will pave the way for an increase in the quality of life. We also believe that the automatic activation of attention-concentration skills and the fact that these exercises are fun, short, and effective play a role in the recovery of these functions.

Health problems associated with aging and the psychological and physical aspects of life can affect the quality of life of older adults (31). In a review investigating the effect of exercise training programs on the quality of life in older adults, it was stated that there were improvements in the quality of life in these individuals after exercise training (32). In this review, various exercises such as balance, strengthening, aerobics, Tai chi, and group-based and aquatic exercises were examined within the exercise programs (32). To the best of our knowledge, no study has examined the effect of RT exercises on quality of life parameters in older adults. Because of this study, it was determined that the subheadings

of quality of life, physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, vitality, bodily pain, general health perceptions, and general mental health were improved in older adults who were subjected to RT exercises.

Study Limitations

There are some limitations to this study. First, it was non-controlled, and second, it was non-randomized. These conditions may affect the interpretation of the results. Further research is needed to investigate the effects of RT exercises on physical functionality and quality of life using a randomized controlled study protocol. In addition, the sample size in this study was not sufficient to assess the correlation between lower and upper extremity RT, static balance, and fall risk. In future studies, the appropriate sample size should be calculated to evaluate the correlation between lower and upper extremity RT, static balance, and fall risk. The results of a future study comparing different exercise training methods with RT exercises may bring different perspectives to the subject.

Conclusion

In conclusion, this study showed that RT exercises applied to older adults have positive effects on functional independence levels, balance, fall risk, upper and lower extremity RT, and quality of life. RT exercises can be added to existing rehabilitation protocols in the clinical practice of older adults.

Ethics

Ethics Committee Approval: Ethics committee approval was obtained from the Non-Invasive Ethics Committee of Üsküdar University (no: 61351342/2020-231). This study was conducted according to the principles of the Declaration of Helsinki.

Informed Consent: Participants were informed about the purpose and procedures of the study. The "Informed voluntary consent" form was signed.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: B.E.O., Concept: Y.E., B.E.O., Design: Y.E., B.E.O., Data Collection or Processing: B.E.O. Analysis or Interpretation: Y.E., B.E.O., Literature Search: B.E.O., S.S., Writing: Y.E., B.E.O., S.S., F.B.

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Original Article

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The Turkish Adaptation of the COVID-19 Perinatal Perception Questionnaire: Validity and Reliability Study

COVID-19 Perinatal Algı Ölçeği'nin Türkçe'ye Uyarlanması: Gerçeklilik ve Güvenirlik Çalışması

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ABSTRACT

Objective: Women during the perinatal period are more vulnerable to environmental stressors. However, there is no Turkish scale that evaluates the perinatal perception of coronavirus disease 2019 (COVID-19) pandemic-related stressors. This methodological study aimed to adapt the COVID-19 Perinatal Perception Questionnaire (COVID-19-PPQ) to Turkish.

Methods: The sample consisted of 150 pregnant women and 150 postpartum women in Turkey. Data were collected using an individual information form, pregnancy scale and postpartum scale of the COVID-19-PPQ, the Fear of COVID-19 Scale (FCV-19S), and the Edinburgh Postpartum Depression Scale (EPDS). Validity was assessed with language, content, and construct validity. Cronbach's alpha, equivalent-form reliability, and item analysis were used for reliability.

Results: The pregnancy scale fits well with eight items, while the postpartum scale fits well with ten items. Each scale has a three-factor structure. Moreover, the scales have acceptable fit index values, confirming the model. The pregnancy scale has a Cronbach's alpha of 0.85, while the subscales "risk of infection," "contact," and "future" have Cronbach's alpha values of 0.74, 0.65, and 0.87, respectively. The postpartum scale has a Cronbach's alpha of 0.81, while the subscales "first postpartum week," "COVID-19 measures," and "fear for infection" have Cronbach's alpha values of 0.84, 0.84, and 0.90, respectively. Significant correlations between the pregnancy scale, the FCV-19S (r=0.459, p<0.001), the postpartum scale and the EPDS (r=0.166, p=0.042) scores indicate that the scale is reliable.

ÖZ

Amaç: Perinatal dönemde kadınlar çevresel stresörlere karşı daha savunmasızdır. Ancak koronavirüs hastalığı 2019 (COVID-19) pandemisine bağlı stresörlere ilişkin perinatal algıyı değerlendiren Türkçe bir ölçek bulunmamaktadır. Bu metodolojik çalışmada COVID-19 Perinatal Algı Ölçeği'nin (C-19PAÖ) Türkçe'ye uyarlanması amaçlanmıştır.

Yöntemler: Örneklemi Türkiye'de yaşayan 150 gebe ve 150 postpartum kadın oluşturmuştur. Veriler bireysel bilgi formu, C-19PAÖ'ye ait gebelik ölçeği ve postpartum ölçeği, COVID-19 Korku Ölçeği (C-19KÖ) ve Edinburgh Postpartum Depresyon Ölçeği (EPDÖ) kullanılarak toplanmıştır. Ölçek geçerliliği dil, içerik ve yapı geçerliliği ile değerlendirilmiştir. Ölçek güvenirliği için Cronbach alfa, eşdeğer form güvenirliği ve madde analizi kullanılmıştır.

Bulgular: Gebelik ölçeği sekiz madde ile, postpartum ölçeği ise on madde ile iyi uyum sağlamıştır. Her ölçek üç faktörlü bir yapıya sahiptir. Ayrıca, ölçekler modeli doğrulayan kabul edilebilir uyum indeksi değerlerine sahiptir. Gebelik ölçeğinin Cronbach alfa değeri 0,85 iken, "enfeksiyon riski", "temas" ve "gelecek" alt ölçeklerinin Cronbach alfa değerleri sırasıyla 0,74, 0,65 ve 0,87'dir. Postpartum ölçeğinin Cronbach alfa değeri 0,81 iken "doğum sonrası ilk hafta", "COVID-19 önlemleri" ve "enfeksiyon korkusu" alt ölçeklerinin Cronbach alfa değerleri sırasıyla 0,84, 0,84 ve 0,90'dır. Gebelik ölçeği ile C-19KÖ (r=0,459, p<0,001), postpartum ölçeği ile EPDÖ (r=0,166, p=0,042) puanları arasındaki anlamlı korelasyonlar ölçeğin güvenilir olduğunu göstermektedir.

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ABSTRACT

Conclusion: The Turkish version of the COVID-19-PPQ is valid and reliable for Turkish pregnant and postpartum women.

Keywords: COVID-19 Perinatal Perception Questionnaire, factor analysis, validity, pandemic, reliability, scale

ÖZ

Sonuç: CV-19PAÖ Türkçe versiyonu, Türk gebeler ve postpartum dönemdeki kadınlar için geçerli ve güvenilirdir.

Anahtar Sözcükler: COVID-19 Perinatal Algı Ölçeği, faktör analizi, geçerlilik, pandemik, güvenilirlik, ölçek

Introduction

The coronavirus outbreak was declared as a pandemic in March 2020 (1). The pandemic caused health problems and negatively affected societies biopsychosocially (2,3). The pandemic may affect perinatal women more because they are more vulnerable to environmental stressors (4-6). In addition, pregnant women are more affected by the adverse consequences of coronavirus disease 2019 (COVID-19) concerning decreased pulmonary capacity in pregnancy, altered immunity, and response to viral infections (7). According to the Centers for Disease Control and Prevention, pregnant women are more likely to be hospitalized, be admitted to intensive care units, receive mechanical ventilation support, and die from COVID-19 than women of reproductive age with COVID-19 (8). COVID-19 obstetric complications in pregnant women result in an increased need for emergency cesarean section and potential neonatal infection (5,7).

In addition to all these adverse conditions, women in the perinatal period are particularly disadvantaged during the COVID-19 pandemic due to more frequent emotional fluctuations and psychological changes (8). Pregnant women experience more mental health problems because they are afraid of contracting the coronavirus and are concerned about the potential effects of the virus on the fetus and newborn. Research has shown that stress, depression, and anxiety are more common among pregnant and postpartum women during the COVID-19 pandemic than before (6,9-13). During this period, almost seven in ten pregnant women experienced anxiety and depression (14,15). The prevalences of anxiety and depression among Turkish pregnant women during the pandemic were 63.9-64.5% and 27.7-56.3%, respectively (3,16).

In the context of perinatal health care during the pandemic, healthcare professionals should physiologically assess women and understand COVID-19-related stressors that affect their mental health. However, there is no Turkish scale to measure the perinatal perception of COVID-19 stressors. The COVID-19 Perinatal Perception Questionnaire (COVID-19-PPQ) was developed by Hulsbosch et al. (6) to determine COVID-19-related stressors affecting prenatal and postnatal Dutch women. This study was evaluated the Turkish validity and reliability of the questionnaire.

Methods

This methodological study was conducted between October 1, 2021, and June 30, 2022, in the antenatal and newborn clinics of a Health Services Practice and Research Hospital in Turkey.

Participants

It is recommended to take a sample of 5 to 10 times the number of items on a scale for adaptation (17). Therefore, the sample consisted of 150 pregnant women and 150 postpartum women admitted to the antenatal and newborn clinics of the hospital.

Inclusion and Exclusion Criteria: The inclusion criteria were; speaking Turkish, living in Turkey, being over 18 years of age, being in the 12th gestational week to 8-10 weeks postpartum (18), having no mental problems (anxiety disorder, depression, severe psychosocial problems, etc.). The exclusion criteria were; failing to fill out the data collection tools and wanting to withdraw from the study.

Data Collection Tools

The Individual Information Form (IIF) was based on a literature review (4-6,11-13,15). The form consisted of two parts, each with 11 items on individual and obstetrical characteristics. Pregnant women filled out the first part, while postpartum women filled out the second part. A pilot study was conducted, and the items were revised based on the results.

The COVID-19 Perinatal Perception Questionnaire (COVID-19-PPQ): The scale was developed by Hulsbosch et al. (6) to measure COVID-19 perinatal perception during pregnancy and postpartum period. The questionnaire allows researchers to determine COVID-19-related stressors. The four-point Likert-type scale consists of 19 items. It has two scales: pregnancy (nine items; min score =0, max score =27) and postpartum (ten items; min score= 0, max score =30). The pregnancy scale has three subscales: risk of infection, contact, and future. The postpartum scale also has three subscales: first postpartum week, COVID-19 measures, and fear of infection. Seven postpartum scale items (3-9) are reverse scored. Higher scores indicate higher rates of negative COVID-19-related stress perceptions during pregnancy and postpartum. The pregnancy and postpartum scales have Cronbach's alpha (α) values of 0.71 and 0.64, respectively (6).

The Fear of COVID-19 Scale (FCV-19S): It was developed by Ahorsu et al. (19). It was adapted to Turkish by Bakioğlu et al. (20). The five-point Likert-type scale consists of seven items. Higher scores indicate greater fear of COVID-19 (min score= 7, max score= 35). The Turkish version's Cronbach's alpha value is 0.84 (20). Cronbach's alpha values were 0.87 (pregnancy) and 0.90 (postpartum period) in the present study.

The Edinburgh Postpartum Depression Scale (EPDS): It was developed by Cox et al. (21), and adapted to Turkish by

Aydin et al. (22). The American College of Obstetricians and Gynecologists (2015) recommends using the EPDS to screen for perinatal depression during pregnancy and postpartum period (23). The instrument consists of ten items, with higher scores indicating a higher risk for depression (min score =0, max score =30) (22). The Turkish version's Cronbach's alpha value is 0.72 (22). The Cronbach's alpha values were 0.84 (during pregnancy) and 0.87 (postpartum period) in the present study.

Ethical Approval

This study was approved by the National Ministry of Health, the Health Services Practice and Research Hospital (approval number: E-93596471-010.01-116695) and Ethics Board (ethics approval number: 2022/02/11). Electronic written consent for this study's use of the scales were taken for the COVID-19-PPQ and the FCV-19S. Informed consent was obtained from all participants included in this study.

Procedure

This study had three stages: language and content validity, implementation, and analysis (Figure 1).

Language and Content Validity: Two translators translated the scale from English into Turkish. A third translator reviewed the original scale and the two translated versions and translated the scale from English into Turkish again. A fourth translator (a native English speaker) translated the document from Turkish back into English (24). Finally, a draft was created.

Lawshe's (25) method was used to assess content validity. Thirteen experts were consulted and asked to rate each item on a scale of 1 to 3 for items clarity/essentiality (1= not clear/essential, 2 =item needs some revision/useful, but not essential, and 3 =very clear/essential) (25). The items were revised based on expert feedback and were evaluated by experts in terms of conformity to Turkish.

Implementation: A pilot study was conducted with 15 pregnant and 15 postpartum women randomly selected based on the inclusion criteria. The sample of the pilot study was not included in the main study. The purpose of the pilot test was to evaluate the intelligibility and relevance of the IIF and the COVID-19-PPQ. After the pilot study, the researchers finalized the scale.

The researchers briefed all women in the antenatal (n=330) and newborn clinics (n=355) about the research purpose and procedure. They explained the inclusion criteria after they were invited to the study. The pregnant women filled out the IIF, the pregnancy scale of the COVID-19-PPQ, the FCV-19S, and the EPDS (n=150). The postpartum women filled out the IIF, the postpartum scale of the COVID-19-PPQ, the FCV-19S, and the EPDS (n=150).

Analysis: The data were analyzed using the Statistical Package for Social Sciences (SPSS, IBM version 26, Chicago, IL, USA) and Analysis of Moment Structures at a significance level of 0.05. Number (n), percentage (%), mean, and standard deviation were used for descriptive statistics. Content and construct validity were assessed. Cronbach's alpha, equivalent-form reliability, and item analysis methods were used to assess the scale's reliability.

Content validity ratios (CVRs) allow researchers to keep or remove items from a scale. The minimum values of the CVRs and the content validity index (CVI) should be 0.54 because the number of experts was 13. After determining which items to include in the scale, the CVI was computed for the total scale. The CVI is the CVR's average value of the retained items (25).

A confirmatory factor analysis (CFA) was conducted to construct validity. The CFA revealed factor loadings and path coefficients, which should be greater than 0.50 to obtain an acceptable scale structure (26). The ratio of chi-square to the degree of freedom

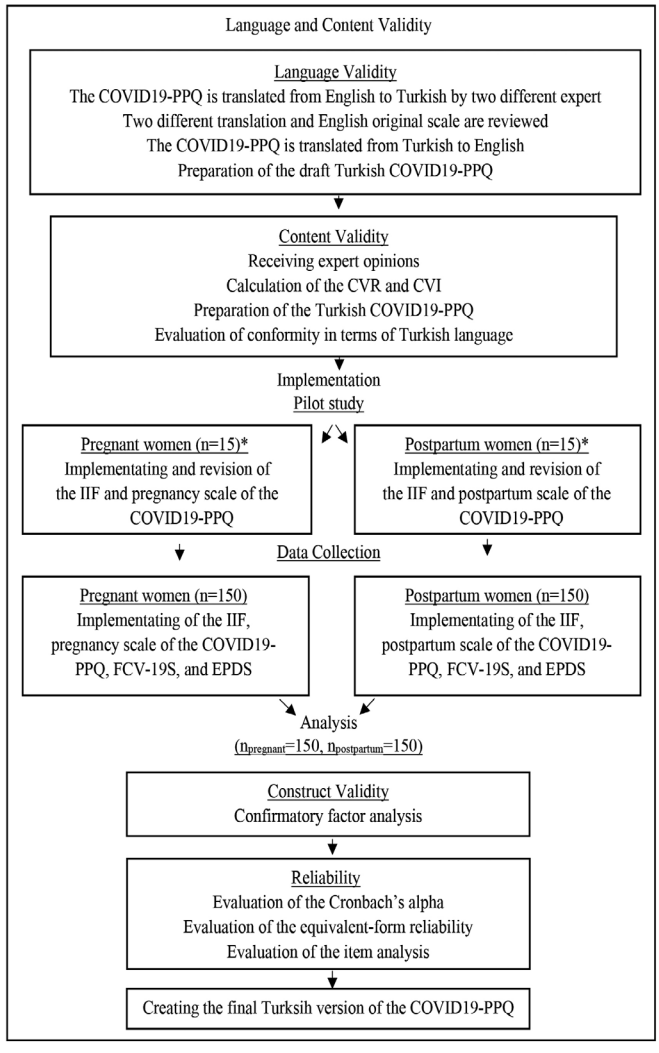

Figure 1. Flow diagram

**The data obtained here were not included in the analysis.*

COVID-19-PPQ: The COVID-19 Perinatal Perception Questionnaire, CVR: Content validity ratio, CVI: Content validity index, IIF: Individual Information Form, FCV-19S: The Fear of COVID-19 Scale, EPDS: The Edinburgh Postpartum Depression Scale, COVID-19: Coronavirus disease 2019

(x^2/df) is used to identify the conformity of the model to the data. x^2/df should range from 2 to 5. The Root Mean Square Error of Approximation (RMSEA) should range from 0 to 0.08. The Goodness of Fit Index (GFI) has a cut-off point of 0.90. A Standardized Root Mean Square Residual (SRMR) as high as 0.08 is deemed acceptable. A Comparative Fit Index (CFI) ≥0.95 indicates a good fit (27). The Tucker Lewis Index (TLI)/Not-Normed Fit Index (NNFI) close to 1 indicates a good fit, while values below 0.90 indicate a need to respecify the model. The Incremental Fit Index (IFI) should be ≥0.90 for an acceptable model (28).

Cronbach's alpha indicates internal consistency. Methodologists recommend a minimum Cronbach's alpha value of 0.65 and regard a Cronbach's alpha of less than 0.50 as unacceptable. A maximum value of 0.90 is recommended (29).

Equivalent forms have identically functioning items. The FCV-19S and the EPDS were equivalent forms in this study. Each participant's score should be correlated to achieve a stable tool. A Pearson's correlation coefficient (r) of less than 0.3 indicates a weak correlation, and 0.3< r <0.5 indicates a moderate correlation. An r greater than 0.5 indicates a strong correlation (30).

An item analysis allows researchers to determine which items to keep, revise, or remove (31). This study evaluated the relationship between the items and the total score in item analysis (especially corrected item-total correlation). The item discrimination index (>0.30= good, 0.10-0.30= fair, and <0.10= poor) is the correlation between an item and a test (32).

Results

Participants

All participants were Turkish. Pregnant women had a mean age of 29.33±6.94 years. More than half of the pregnant women had high school degrees (70%). Most pregnant women did not work in a paid job (82.7%). Eleven pregnant women experienced COVID-19. When the characteristics of postpartum women were analyzed, postpartum women had a mean age of 29.91±6.04 years. More than half of the postpartum women had high school degrees (63.9%). Most pregnant women did not work in a paid job (84.7%). Four postpartum women experienced COVID-19 (2.6%) (Table 1).

Pregnant women had a mean pregnancy scale score of 12.22±5.68 (range 0-24). Postpartum women also had a mean postpartum scale score of 19.63±5.42 (range 0-30) (Table 2). Table 3 shows all participants' FCV-19S and EPDS scores.

Validity

Content validity: On the pregnancy scale, all items but 9 had CVRs of 0.54 to 1.00. Item 9 had a CVR of 0.23. The acceptable minimum value of CVR and CVI was 0.54. Therefore, item 9 was removed from the scale, and CVI was recalculated. The scale had a CVI of 0.77. Of the postpartum scale, all items had CVR and CVI values greater than 0.54 (Table 4).

Construct validity: The pregnancy and postpartum scales of the COVID-19-PPQ consist of three factors. Therefore, a CFA was performed for the three-factor structure. The measurement model established to confirm the scale structures was analyzed (Figure 2). The pregnancy scale had factor loadings of 0.52 to 0.90. The postpartum scale had factor loadings of 0.69 to 0.93 (Table 4). There was no item factor loading lower than 0.5. Therefore, model fit indexes were examined. χ^2/sd >2.0, RMSEA and SRMR ≤0.08, GFI, TLI/NNFI, and IFI >0.90, CFI ≥0.95 for the pregnancy and postpartum scales. These results confirmed the model (Table 5).

Table 1. Distribution of women by characteristics

Characteristics	Pregnant women (n=150)		Postpartum women (n=150)	
	Mean (SD)		Mean (SD)	
Age, years	29.33 (6.94)		29.91 (6.04)	
Gestational age, weeks	29.13 (7.91)		37.27 (3.43)	
Total pregnancy number	2.21 (1.51)		2.24 (1.41)	
	n	%	n	%
Education				
High school ↓	105	70.0	96	63.9
High school and ↑	45	30.0	54	36.0
Paid job				
Yes	26	17.3	23	15.3
No	124	82.7	127	84.7
Economical status				
Low income	25	16.7	26	17.3
Middle income	99	66.0	107	71.3
High income	26	17.3	17	11.3
Experience of COVID-19				
Yes	11	7.3	4	2.6
No	139	92.7	146	97.4
Planned pregnancy				
Yes	91	60.7	98	65.3
No	59	39.3	52	34.7
Abortion in previous pregnancy[a]				
Yes	36	46.8	31	35.6
No	41	53.2	56	64.4
Chronic disease in previous pregnancy[a]				
Yes	13	16.9	14	16.1
No	64	83.1	73	83.9
Medical problem in previous birth[a]				
Yes	0	0.0	6	6.9
No	77	100.0	81	93.1

SD: Standard deviation, N: number, %: Percentage
[a]$n_{pregnant}$=77, $n_{postpartum}$=87

Table 2. Distribution of women's the pregnancy scale & postpartum scale of the COVID19-PPQ, subscales' scores and Cronbach's alpha values

COVID19-PPQ	Items	Min-max	Score		Cronbach's alpha
			Mean	SD	
Pregnancy scale	1-8	0-24b	12.22	5.68	0.85
Risk of infection	3,4,5	0-9	4.95	2.36	0.74
Contact	1,2,6	0-9	4.11	2.39	0.65
Future	7,8	0-6	3.15	1.97	0.87
Postpartum scale	1-10	0-30[b]	19.63	5.42	0.81
First postpartum week	(6,7,8,9)[a]	0-12	7.93	2.83	0.85
COVID-19 measures	(3,4,5)[a]	0-9	6.92	2.02	0.84
Fear for infection	1,2,10	0-9	4.77	2.84	0.90

COVID-19-PPQ: The COVID-19 Perinatal Perception Questionnaire, min: minimum, max: maximum, SD: Standard deviation
[a]It is reverse scored, [b]Higher scores indicating a more negative COVID-19-related stress perception

Table 3. Distribution of women's the FCV-19S & EPDS scores and Cronbach's alpha

Equivalent form	Items	Min-max	Period	Score		Cronbach's alpha
				Mean	SD	
FCV-19S	1-7	7-35	Pregnancy	17.50	6.24	0.87
			Postpartum	16.93	6.95	0.90
EPDS	1-10	0-30	Pregnancy	8.36	5.49	0.84
			Postpartum	5.64	5.22	0.87

FCV-19S: Fear of COVID-19 Scale, COVID-19-PPQ: COVID-19 Perinatal Perception Questionnare, min: Minimum, max: Maximum, SD: Standard deviation, EPDS: Edinburgh Postpartum Depression Scale

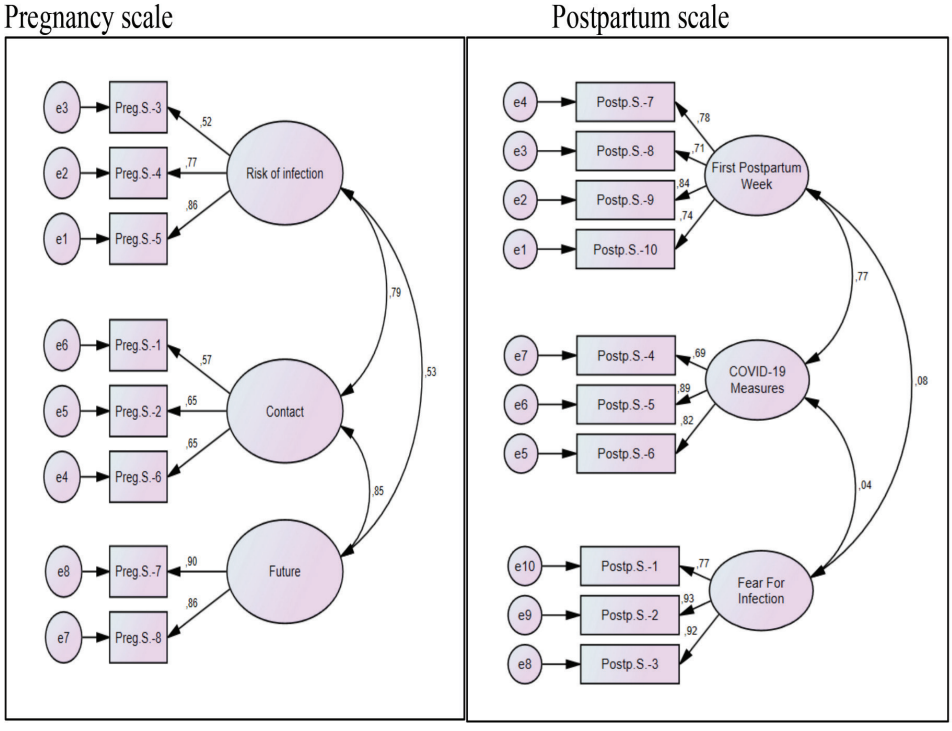

Figure 2. Path diagram of the COVID19-PPQ
Preg.S.: Pregnancy scale, Postp.S.: Postpartum scale,
COVID-19: Coronavirus disease 2019

Table 4. The pregnancy scale & postpartum scale of the COVID19-PPQ CVR values, and item analysis values

COVID19-PPQ	CVRs	Factor loads	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Pregnancy scale						
Item 1	0.69	0.57	10.97	25.96	0.53	0.84
Item 2	0.54	0.65	10.57	24.36	0.60	0.83
Item 3	1.00	0.52	11.00	26.95	0.48	0.85
Item 4	0.69	0.77	10.25	26.20	0.55	0.84
Item 5	0.69	0.86	10.46	24.26	0.65	0.83
Item 6	0.69	0.65	11.01	25.23	0.60	0.83
Item 7	0.54	0.90	10.69	24.16	0.68	0.82
Item 8	0.54	0.86	10.59	24.55	0.63	0.83
CVI	0.77					
Postpartum scale						
Item 1	1.00	0.77	18.16	24.62	0.34	0.87
Item 2	1.00	0.93	17.88	24.19	0.40	0.81
Item 3	0.85	0.92	18.07	24.63	0.37	0.81
Item 4	0.85	0.69	17.33	24.83	0.49	0.80
Item 5	1.00	0.89	17.32	24.45	0.57	0.79
Item 6	0.85	0.82	17.31	24.24	0.61	0.79
Item 7	0.85	0.78	17.70	23.54	0.57	0.79
Item 8	0.85	0.71	17.60	24.15	0.58	0.79
Item 9	1.00	0.84	17.63	24.08	0.59	0.79
Item 10	0.69	0.74	17.65	23.88	0.53	0.79
CVI	0.89					

COVID19-PPQ: COVID-19 Perinatal Perception Questionnare, CVRs: Content validity ratios, CVI: Content validity index

Table 5. Fit indexes of the pregnancy scale & postpartum scale of the COVID19-PPQ for construct validity

Fit index	COVID-19-PPQ	Value	Acceptable threshold levels
χ^2/sd	Pregnancy scale	2.48	2.0-5.0
	Postpartum scale	2.33	
RMSEA	Pregnancy scale	0.08	≤0.08
	Postpartum scale	0.08	
GFI	Pregnancy scale	0.94	≥0.90
	Postpartum scale	0.92	
SRMR	Pregnancy scale	0.05	≤0.08
	Postpartum scale	0.04	
CFI	Pregnancy scale	0.95	≥0.95
	Postpartum scale	0.95	
TLI/NNFI	Pregnancy scale	0.91	≥0.90
	Postpartum scale	0.93	
IFI	Pregnancy scale	0.95	≥0.90
	Postpartum scale	0.95	

COVID19-PPQ: COVID-19 Perinatal Perception Questionnare, χ^2/sd: Ratio of chi square to the degree of freedom, RMSEA: Root meansquare error of approximation, GFI: Goodness of fit index, SRMR: Standardised root mean square residual, CFI: Comparative fit index, TLI/NNFI: Tucker lewis index/Not-normed fit index, IFI: Incremental fit index

Table 6. Pearson's correlation between the pregnancy scale & postpartum scale of the COVID-19-PPQ and the FCV-19S & the EPDS scores

COVID-19-PPQ	FCV-19S	EPDS
Pregnancy scale	r=0.459[b], p<0.001	r=0.141, p=0.084
Risk of infection	r=0.489[b], p<0.001	r=0.169[a], p=0.038
Contact	r=0.348[b], p<0.001	r=0.083, p=0.312
Future	r=0.315[b], p<0.001	r=0.103, p=0.209
Postpartum scale	r=0.002, p=0.981	r=0.166[a], p=0.042
First postpartum week	r=-0.253[b], p=0.002	r=0.031, p=0.709
COVID-19 measures	r=-0.260[b], p=0.001	r=0.020, p=0.812
Fear for infection	r=0.439[b], p<0.001	r=0.272[b], p<0.001

COVID19-PPQ: The COVID-19 Perinatal Perception Questionnare, FCV-19S: Fear of COVID-19 Scale, EPDS: Edinburgh Postpartum Depression Scale, r: Pearson's correlation
[a]p<0.05, [b]p<0.01

Reliability

Cronbach's alpha coefficient: The total pregnancy scale and subscales had Cronbach's alpha values of 0.65 to 0.87. The total postpartum scale and its subscales had Cronbach's alpha values of 0.81 to 0.90 (Table 2). The Cronbach's alpha was acceptable as it was greater than 0.65 and less than 0.90.

Equivalent-form reliability: There was a positive correlation between the scores of the pregnancy scale and the FCV-19S (r=0.459, p<0.001). Moreover, there was a positive correlation between the scores of the postpartum scale and the EPDS (r=0.459, p<0.001). Table 6 shows the correlations between the subscale scores and FCV-19S or EPDS scores.

Item analysis: The corrected item-total correlation values ranged from 0.33 to 0.68, indicating that all items had "good" discrimination. Table 4 shows the scale means if the item is deleted, the scale variance if the item is deleted, and the squared multiple correlation values of the pregnancy and postpartum scales.

Discussion

The COVID-19 pandemic significantly impacted the mental well-being of vulnerable women during the perinatal period (2,33). This study adapted the COVID-19-PPQ to Turkish to measure COVID-19-related stressors during pregnancy and postpartum period.

Some experts assessed item 9 of the pregnancy scale as "not essential or item needs some revision." They thought that item 7 and item 9 measured the same construct, and that item 7 was not about pregnancy. Item 9 was removed from the scale because it had a CVR of 0.23. Content validity was achieved because the total scale had a CVI of 0.77 (CVI >0.54) (25).

The CFA results showed that the models for the pregnancy scale (eight items; three subscales) and postpartum scale (ten items; three subscales) had acceptable fit indices. Therefore, the models seemed fit (27,28). The original pregnancy and postpartum scales also have adequate, and excellent model fits, respectively (6).

Item 3 (factor loading: 0.52), and item 1 (factor loading: 0.57) had factor loadings close to the lower limit. The items were acceptable because they had factor loadings of greater than 0.50 (26). Hulsbosch et al. (6) reported that items 1 and 3 had factor loadings of 0.64 and 0.51, respectively. These items are about antenatal visits. Pregnant women are hesitant to attend antenatal visits because they are worried about the "risk of infection" and "contact" (item 3 in factor 1. Risk of infection, and item 1 in factor 2. contact). Turan et al. (34) also found that half of the pregnant women made fewer antenatal visits during the COVID-19 pandemic, which might affect women's responses to these items.

In addition, these factors had Cronbach's alpha values close to the cut-off value (Factor 1. Risk of infection α=0.74, Factor 2. Contact α=0.65). In this study, all subscales had Cronbach's alpha values of 0.65 to 0.90, indicating high internal consistency for the pregnancy and postpartum scales (29,35). Hulsbosch et al. (6) reported similar Cronbach's alpha values, suggesting that the COVID-19-PPQ was reliable.

The pregnancy scale has three subscales. The subscale "the risk of infection" concerns testing positive for COVID-19 during pregnancy. The subscale "contact" concerns cancellations of ultrasounds, having ultrasounds alone, and family and friends not visiting. The subscale "future" is about financial and work-related concerns. All three subscales focus on fear or worry (6). Our results showed that the pregnancy scale and its subscales significantly correlated with the FCV-19S. Hulsbosch et al. (6) also reported that the pregnancy scale and its subscales significantly correlated with pregnancy-specific distress symptoms. Research also showed that pregnant women were more worried and afraid of COVID-19 (10,11). However, the present study has no significantly correlated total pregnancy scale and the EPDS.

Similarly, Boekhorst et al. (36) did not document any findings regarding the increased prevalence of depression among pregnant women during the pandemic. There was a significant correlation between the "infection" subscale and the EPDS. However, the other two subscales (contact and future) were not correlated with the EPDS. This suggests that pregnant women are more negatively affected by the possibility of having COVID-19 than by the indirect effects of COVID-19, such as lack of visits from friends and financial problems.

The postpartum scale has three subscales. The subscale "first postpartum week" refers to the perception of COVID-19-related changes due to fewer visits. The subscale "COVID-19 measures" concerns the perception of measures and guidelines during delivery. The subscale "fear for infection" is about concerns regarding getting infected (self, baby, or partner) with COVID-19 during delivery or in the first postpartum week (6). These subscales were correlated with the FCV-19S. The subscale "fear for infection" was significantly correlated with the EPDS, suggesting that the first postpartum week and COVID-19 measures were about visits and the birth period. In the postpartum period, labor is over, and the woman focuses on her baby and breastfeeding. Therefore, she might move away from the stressors of COVID-19. Hulsbosch et al. (6) stated that the "first postpartum week" subscale was not correlated with symptoms of postpartum depression and anxiety.

Strengths and Limitations of the Study

The study had three strengths. First, this is the first study to adapt the COVID-19-PPQ to Turkish. Thus, this scale can be used in clinical practices in perinatal health services during the COVID-19 pandemic. Second, the COVID-19-PPQ is a user-friendly scale that includes both pregnancy and postpartum scales. Therefore, it can be used as a screening tool in all areas where antenatal and postnatal healthcare is offered in Turkey during the COVID-19 pandemic. Thus, this study contributes to develop a national perinatal care policy and strategy for this vulnerable group. Third, validity and reliability were established face-to-face in the hospital during the COVID-19 pandemic.

Study Limitations

The study had three limitations. First, the results were sample-specific and could not be generalized. Second, the study was conducted in a city in Turkey. Third, women with healthy pregnancies and healthy babies were included in the study. Perception might change in high-risk pregnancies, and this was also true in the postpartum period. It was also suggested to validate the COVID-19-PPQ in other regions of Turkey.

Conclusion

The COVID-19-PPQ is a valid and reliable scale used to assess perinatal COVID-19-related stress perception. Future research should examine the use of the scale in clinical practice during the COVID-19 pandemic. It is recommended to adapt the COVID-19-PPQ to other countries.

Ethics

Ethics Committee Approval: This study was approved by the National Ministry of Health, the health Services Practice and Research Hospital (approval number: E-93596471-010.01-116695) and Ethics Board (ethics approval number: 2022/02/11). Electronic written consent for this study's use of the scales were taken for the COVID-19-PPQ and the FCV-19S.

Informed Consent: Informed consent was obtained from all participants included in this study.

Peer-review: Externally peer reviewed.

Authorship Contributions

Concept: H.A., S.K., Design: H.A., S.K., Data Collection or Processing: B.Ö.G., Analysis or Interpretation: H.A., B.Ö.G., S.K., Literature Search: H.A., Writing: H.A., S.K.

Conflict of Interest: No conflict of interest was declared by the authors.

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Attitude and Knowledge of Intensive Care Nurses About Organ Donation

Yoğun Bakım Hemşirelerinin Organ Bağışı Hakkındaki Tutum ve Bilgisi

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ABSTRACT

Objective: Intensive care nurses make a significant contribution to the donation process by providing communication between donor and recipient families. Hence, their knowledge and attitude are important to increase the rate of organ donation. This research aimed to determine the knowledge and attitudes of intensive care nurses about organ donation.

Methods: The study was a cross-sectional design. The aim of this study was to determine the knowledge and attitudes of intensive care nurses about organ donation. The number of samples was determined according to the nurse layer weight of these hospitals: 311 volunteer intensive care nurses formed the sample. The data were collected using a valid and reliable "Organ Donation Attitude Scale" and "Organ Donation Information Scale".

Results: The mean age of the nurses was 27.28±6.08. The majority of the intensive care nurses included in the study were young, their attitudes towards organ donation were positive, and their knowledge on organ donation was at a good level. Most of the nurses did not have an organ donor card (98.4%). Positive organ donation attitude score in young nurses (p=0.012), male nurses (p=0.049), nurses with low-education level (p=0.002), nurses working in a private university or training/research hospital (p=0.007) and nurses working in neurosurgery, emergency intensive care (p=0.001) was lower. ODI score was higher in nurses with undergraduate and higher education (p=0.001), nurses working at education/research university hospital and state university hospital (p=0.003). There

ÖZ

Amaç: Yoğun bakım hemşireleri verici ve alıcı aileler arasında iletişim sağlayarak, bağış sürecine önemli katkı sağlarlar. Bu nedenle bilgi ve tutumları organ bağış oranının artırılmasında önemlidir. Bu araştırma, yoğun bakım hemşirelerinin organ bağışı konusundaki bilgi ve tutumlarını belirlemeyi amaçlamaktadır.

Yöntemler: Çalışma kesitsel bir tasarımdır. Çalışma İstanbul'daki düzey 3 yetişkin hasta yoğun bakımı olan üniversite hastanelerinde yapıldı. Örneklem sayısı hastanelerin hemşire tabaka ağırlığına göre belirlendi; 311 gönüllü yoğun bakım hemşiresi örneklemi oluşturdu. Veriler, "Organ Bağışı Tutum Ölçeği ve "Organ Bağışı Bilgi Ölçeği" kullanılarak toplandı.

Bulgular: Hemşirelerin yaş ortalaması 27,28±6,08 idi. Araştırmaya alınan yoğun bakım hemşirelerinin çoğu gençti, organ bağışı tutumları olumluydu, organ bağışı konusundaki bilgileri iyi düzeydeydi. Hemşirelerin çoğunun organ bağışçısı kartı yoktu (%98,4). Pozitif organ bağışı tutum puanı; genç (p=0,012), erkek (p=0,049), düşük eğitim düzeyli (p=0,002), özel üniversite ya da eğitim/araştırma hastanesinde çalışan (p=0,007) ve nöroşirürji servisinde ve acil yoğun bakımında çalışan (p=0,001) hemşirelerde daha düşüktü. Organ bağışı bilgi puanı lisans ve üzeri eğitimli (p=0,001) ile eğitim/araştırma üniversite hastanesinde ve devlet üniversite hastanesinde çalışan hemşirelerde (p=0,003) daha yüksekti.

Sonuç: Hemşirelerin organ bağışı tutumunda bazı klinik ve sosyodemografik karakteristiklerin rolü önemlidir. Ancak organ

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ABSTRACT

was an inverse correlation between negative and positive attitude about organ donation (p=0.029).

Conclusion: Some clinical and sociodemographic characteristics of nurses are important in organ donation attitudes. However, although it is recommended that nurses with a high level of education work in this field to have a high level of knowledge about organ donation, this is not enough. Continuous training of nurses on this subject is required after graduation.

Keywords: Organ donation, knowledge, attitudes, intensive care unit nurse

ÖZ

bağışı konusundaki bilgi düzeyleri için eğitim düzeyi yüksek hemşirelerin bu alanda çalışması önerilse de bu yeterli değildir. Hemşirelerin mezuniyet sonrası bu konuda sürekli eğitimleri gereklidir.

Anahtar Sözcükler: Organ bağışı, bilgi, tutum, yoğun bakım hemşiresi

Introduction

Organ donation begins with determining which patients can be suitable donors (1,2). In UK, the rate of donations from donors after brain death is 99% and the rate of processing families for donation is 91% (3). According to a research in Turkey, which covers the period between 2013 and 2017, organ donation could not be made in 74.3% of the patients with brain death, because their legal relatives did not give permission (4). According to the 2021 data of the Turkey Health Services General Directorate, Department of Tissue, Organ Transplantation and Dialysis Services, only 300 families of patients with brain death (1,370 patients) allowed organ donation (5).

Intensive care nurses play an important role in identifying and increasing the number of potential organ donors (1,2,6,7). The Organ Transplant Coordination System is largely run by nurses in the USA and entirely in the UK. In this area, intensive care unit (ICU) specialists and nurses work together in Spain, where the organ transplantation process is globally regarded as a best practice (8,9). Turkey, which ranks first in terms of live organ donation in Europe and in the world (53.02 pmp), follows the example set by Spain in order to solve cadaveric organ donation (7.54 pmp) deficiency (9-11). There is a big deficit between patients waiting for transplants and organ donors and the reason for this can be rooted in legal, religious or educational matters. However, health professionals' knowledge levels and behaviours in regard to, and attitudes towards organ donation and transplantation have a positive impact on organ donation rates. Especially ICU nurses play a special role in the organ donation process from the point of identifying and assessing potential donors and supporting their families (8,12-14). These nurses can communicate with relatives of patients with brain death and encourage them to donate organs (1,15). These expectations have increased the academic interest in ICU nurses' attitudes towards and knowledge in term of organ donation. Currently, there are studies on the key role played by nurses in the organ donation process, particularly with regard to their roles as an organ donation counsellor (7,12,15). If nurses are not aware of their own feelings towards organ donation, they may not be effective in term of obtaining consent for organ donation from a family in grief. Nurses who have personal donors cards can present a more convincing approach for the relatives of the patient (8,14-17).

Studies draw attention to the importance of knowledge and skill levels of nurses in terms of extending potential donor pool (3,7,16,18). This is because while nurses provide care for patients, they can take early action at the onset of brain death, using the data which they gather.This means timely medical treatment and maintenance (i.e. mechanical ventilation and vasopressor support) in order to preserve the organs to be transplanted. In this way nurses contribute to the increased the number of organs transplanted per donor (6,16). In the current literature, there are studies that draw attention to the importance of nurses' knowledge and attitude about organ donation in increasing the donor ratio (6,19-23). However, studies on this topic in Turkey are limited (2) and the sample sizes of those studies are small. Therefore, this study aimed to provide data which that would shed light on ICU nurses' active role in organ donation by determining their knowledge and attitudes about organ donation in Turkey.

Research Questions

The ICU nurses'

- What is attitude about organ donation?
- What is the level of organ donation knowledge?
- Do sociodemographic characteristics have an effect on the organ donation attitudes?
- Do clinical characteristics have an effect on the organ donation attitudes?
- Do clinical and sociodemographic characteristics have an effect on the knowledge about organ donation?
- Is there a correlation between the organ donation attitude score and knowledge scores?

Methods

Design

This is a cross-sectional and descriptive study.

Study Settings

This study was conducted in the hospitals located in European sides of İstanbul in the north-western Turkey. In the period of

the study (June 2018-February 2020), there were 125 university hospitals in İstanbul. In most of these hospitals especially in private hospitals, there were no ICUs or there were a few beds. Therefore, the universe of the study consisted of 1,623 nurses working in ICUs of 14 hospitals which had quality certificate, and employing 30 or more ICU nurses. The hospitals where the study was conducted were hospitals with a university mission: state university hospital of the Higher Education Institution, private and public university hospitals of the Ministry of Health (education and research hospitals of the Ministry of Health).

Organ transplantations are performed in these hospitals with III level ICUs. Nurses working in these units encounter more organ donation cases. The knowledge and attitudes of these nurses on organ donation can provide important data for donor care nursing. That's why this study was performed especially on these nurses.

The selection criteria for hospitals was the existence of a level 3 ICU, working in an adult ICU for at least one year, voluntarily participating in the study, and speaking Turkish. Paediatric ICUs were not included in this study. In order to determine the organ donation attitude of a nurse working for organ donation in the paediatric ICU, it was necessary to reach nurses working longer. This did not meet the sample selection criteria.

Exclusion criteria from the sample: personal or family history of organ transplantation, incomplete filling of the data form.

Dependent variables were organ donation attitude and organ donation knowledge. Independent variables were age, gender, marital status, educational status, having an organ donation card, characteristics of hospital and ICU and intensive care experience.

Participants

The sample was created by considering the number of working nurses in the state university hospital, public university hospital, and private university hospital sectors. Weights of the stratum of the university hospitals were 0.18, 0.62 and 0.21, respectly. The number of volunteer nurses to be reached in each hospital was calculated.

The size of the sample was calculated with n=Nt2pq/d2(N – 1) + t2pq (t=1.96, d=0.05, p=50%, q=1-p) formula and it was aimed to reach 311 ICU nurses. It was necessary to reach 143 nurses from the state university hospital, 58 nurses from the private university hospital and 110 nurses from the public university hospital.

In the research, targeted number of nurses (n=311) was reached in 18 months (June 2018-February 2020).

Data Collection

The researchers interviewed the nurses face-to-face. They explained them the purpose of the research and introduced the data forms. The researchers asked the nurses to fill in the data forms. The data forms of these nurses were given to the manager nurses in a closed envelope. Manager nurses gave the forms to these nurses and asked them to fill in. The nurses handed the envelopes closed to the delivery manager nurses. The researcher received the data forms from the manager nurse.

Study Instruments-Validity and Reliability

Researchers used two scales in the study. The first of these scales was developed by Parisi and Katz (24) in 1986. The scale is the organ donation attitude scale (ODAS) adapted by Kent and Owens (20) in 1995. The validity and reliability study for revised the scale was conducted by Yazici Sayin (25) in 2016 in Turkey. The revised ODAS includes 46 items (23 positive, 23 negative items) which indicate attitudes about organ donation. Each item of the scale is in a 6-point Likert scale format, ranging between *completely agree and completely disagree.*

Researchers presented the Turkish scale within a questionnaire form. The first part of this form contains socio-demographic data. In the second part, there are 40 items (20 positive, 20 negative items) which determine the organ donation attitude. The revised ODAS subscale "philanthropy and moral values and beliefs" [positive attitudes about organ donation: (PAOD)] consists of 20 items (*for example: A person willing to donate is almost a hero, People have a moral responsibility to donate some of their body parts to people in need, By agreeing to donate my organs after death, I am giving some people hope for survival, Organ donation benefits the whole of philanthropy,….*). The score that can be obtained from PAOD is between 20 and 120 points. Negative attitudes about organ donation (NAOD) include 2 subscales. The first of these subscales is "fear of medical negligence" (FMN) (*for example: Organ donors cannot control which organs will be taken even when specified in advance, Medical school researchers who remove organs do not treat the body in a dignified manner, A person will be less likely to receive adequate medical care after signing a donor card,…*). The second is "fear of bodily injury" (FBI) (for example: Organ donation leaves the body disfigured, an intact body is needed for the next life ...). The FMN is about lack of knowledge of health services and distrust of health workers. The FBI is about religious beliefs, attitudes, and values. The FMN and FBI sections include 10 questions each and their scores vary between 10 and 60 points. The total NAOD score ranges between 20 and 120 points. High-positive and low-negative scores indicate strong voluntary attitudes about organ donation. The questions in this part are not mandatory to determine the participants' attitude. However, researchers can add their own questions here. The Cronbach's α was 0.85 for PAOD (Cronbach's α =0.92) and Cronbach's α was 0.91 for NAOD (20). In the present study, the Cronbach's α values were 0.94, 0.97 and 0.85, respectively for ODAS, PAOD and NAOD, respectively.

The second scale used in the study was the "organ donation information (ODI) scale" for the participants. This scale was developed by Emiral et al. (26) through a review of national and international literature and contemporary educational content. It includes a total of 17 questions which consist of correct and incorrect answers (9 correct, 8 incorrect). The questions consist of two subgroups. The first subgroup involves donor characteristics (age, definition of organ donation, cadaveric and live donor type, brain death and medical death, recipient and donor characteristics), while the second subgroup involves ethical, legal and medical conditions (permission from the patient and their

family for organ donation...). Score distribution is between 0 and 17 points. An increasing score means the level of knowledge is evaluated as positive, and a decreasing score connotes negative evaluation. The Cronbach's α was 0.88 (22). In the present study, the Cronbach's α for ODI was 0.69.

Statistical Analysis

We performed the data analysis using the SPSS 24.0 package software. We performed the Kolmogorow-Smirnow test to follow data distribution of the data. The data often did not demonstrate a normal distribution. Researchers conducted nonparametric statistical analyses for the study sample. For continuous variables, researchers expressed the data as mean ± standard deviation (SD), median, and range (minimum-maximum). Researchers used proportions for categorical variables. Researchers evaluated the results at a 95% confidence interval, and the significance at the $p<0.05$.

Ethics

This study respected the principles of research and publication ethics. Researchers obtained approvals from the Bezmialem Vakıf University Clinical Research Ethics Committee, under the code IRB#04.07.2017-12/192. Researchers took written permissions from the Provincial Directorate of Health, hospitals and volunteers for the research. Researchers informed ICU nurses that the information which they shared for this research was only intended for scientific purposes. Written permission was obtained from the authors who developed the ODAS and ODI for this study.

Results

Table 1 shows ICU nurses' sociodemographic characteristics. Of all the ICU nurses including in the study, 86.5% were between the ages of 20-34, 13.5% were older than 34, the mean age was 27.28±6.08 (min-max: 20-55) years, 77.2% were women, 59.5% had bachelor's degree, 46.0% were working in public/university hospital, 35.4% were working in private university hospitals, 18.6% were working in the state university hospital, 34.1% were in anaesthesia reanimation and postoperative care units. Of the nurses, 65.9% had 1-3 years and 8.7% had 11 years or more of ICU experience [mean ± SD (min-max)] 4.59±3.32 (1-20). Most of nurses (98.4%) did not have a donor card.

Table 2 shows the nurses' knowledge and attitude regarding organ donation according to the sociodemographic characteristics.

Based on the nurses' age groups, the PAOD score was statistically higher in nurses older than 34 years compared to those under the age of 34 years (95.95±24.58, 85.72±29.99; p=0.012). The nurses who held master's/doctorate and bachelor degree had higher PAOD and ODI scores compared to those with high school and associate degrees (91.49±28.43, 87.86±30.17; p=0.002, 14.49±1.69, 13.47±2.01; p=0.001). NAOD scores were low for all nurses. But the negative attitude scores were higher in nurses who held bachelor' and master's/doctorate degrees, compared to those with high school and associate degree graduates (57.71±20.98, 52.01±17.99; p=0.023). This difference was correlated with concerns of both bodily injury and medical negligence (26.58±10.54, 25.25±9.64; p=0.040, 28.50±12.14, 26.76±10.13; p=0.038).

Table 3 shows the nurses' knowledge and attitude regarding organ donation according to the clinic characteristics. Only the PAOD and ODI scores of the nurses working in a state university hospital were significantly higher than that of those working in a private and public university hospitals (95.07±25.32, 85.05±28.01, 81.81±31.83; p=0.007). The PAOD (67.97±28.11; p=0.001)

Table 1. Sociodemographic characteristics of intensive care unit nurses (n=311)

Age (years)	Number	%
(Mean ± SD) (min-max): 27.28±6.08 (20-55)		
20-34	269	86.5
35 and +	42	13.5
Gender		
Male	270	77.2
Female	71	22.8
Marital status		
Married	100	32.2
Single	211	67.8
Education		
High school graduate	68	21,9
Associate degree	22	7.1
Bachelor degree	185	59,5
Master/doctorate	36	11,6
University hospitals		
State*	58	18.6
Public	143	46.0
Private	110	35.4
Intensive care unit		
ARU/PCU	106	34.1
CVS and coronary	95	30.5
General adult	75	24.1
Neurosurgery/neurology, emergency	35	11.3
ICU experience (years)**		
(Mean ± SD) (min-max): (4.59±3.32) (1-20)		
1-3	205	65.9
4-10	79	25.4
11 and +	27	8.7
Organ donor card		
Yes	5	1.6
No	306	98.4
Which organ donation type the nurses supported		
Cadaveric	252	81.0
Living donor	59	19.0

*All the participants hold bachelor, master's or doctorate degree
**63.7% of nurses were working in a state university hospital for more than 4 years.
ARU: Anaesthesia reanimation unit, PCU: Postoperative care units, CVS: Cardiovascular surgery, SD: Standart deviation, min: Minimum, max: Maximum

and the NAOD (47.25±12.99, p=0.010) scores of the nurses working in neurosurgery/neurology and emergency were lower than the nurses working in the other ICUs. These differences were statistically significant. The PAOD and NAOD scores of the nurses did not show a statistical difference according to the years of work in the ICU (p>0.05).

In the present study, the nurses' PAOD scores (87.10±24.49), (philanthropy and moral values and beliefs) were higher than their NAOD scores (53.99±19.24) (Table 2). The correlation between PAOD and NAOD was negative (r=-0.124; p=0.029). The relationship between PAOD and ODI was positive, but not statistically significant (r=0.099; p=0.080). The relationship between NAOD and ODI was negative but not statistically significant (r=-0.101; p=0.060). However, the relationship between FBI and ODI was negative and statistically significant (r=-0.112; p=0.049) (Table 4).

Discussion

Our study shows that ICU nurses need in-service training for their attitudes about organ donation.

Sociodemographic Characteristics

The present study showed that hospitals in the metropolitan city of İstanbul worked with ICU nurses who were young and single, had bachelor's degree, worked in a public hospital, and had little working experience. Nurses may encounter with brain death cases, as they mostly work in critical areas such as anaesthesia-reanimation and postoperative, CVS/coronary, and general adult ICUs. Although Karaman and Akyolcu (11) did not only take university hospitals into account, they showed that ICU nurses had similar demographics (age, gender, educational level, institution where they work) in Istanbul in Turkey. In their study, even 23.3% of ICU nurses who worked less than 1 year were reported to have experience in cases of brain death and 53.1% faced the decision to transplant organs (11). According to the present study and the data collected by Karaman and Akyolcu (11) about 6 years ago, the fact that most ICU nurses did not increase their working time showed that nurse stability could not be achieved in ICU hospitals in İstanbul. This is noteworthy for the future of organ donation roles of ICU nurses and requires precautions.

The Attitude and Knowledge on Organ Donation

Some studies have shown that nurses' organ donation knowledge and attitudes may be related to sociodemographic (7,27) and clinical characteristics (28). In a study conducted in Tabriz, Shahsavarinia et al. (29) reported that age, gender, marital status and the characteristics of ICU had no effect on nurses' organ donation attitudes. In the present study, as the education level of the nurses increased, the PAOD ve ODI scores increased, and the NAOD score (fear of medical neglect and FBI) decreased. As the age of the nurses increased, the PAOD and NAOD (fear of medical neglect and FBI) scores increased, and the ODI score decreased. These findings suggest that nurses may have concerns about organ donation even if they have positive attitudes as their knowledge about organ donation decreases. It could be concluded that the positive attitudes of the male nurses in the study about organ donation were higher than that of the female nurses, but their ODI score was lower than that of the female nurses, which might be related to their education or working time and experience in this field. This situation can be explained

Table 2. The knowledge and attitude about organ donation according to the sociodemographic characteristics of the nurses (n=311)

Characteristics	PAOD	NAOD	FMN	FBI	ODI
	Mean ± SD (min-max)	Mean ± SD (min-max)	Mean ± SD (min-max)	Mean ± SD (min-max)	Mean ± SD (min-max)
Age*					
20-34	85.72±29.99 (27-120)	53.98±19.28 (22-117)	26.18±10.09 (10-58)	27.79±10.91 (10-59)	14.14±1.87 (7-20)
35 years old and over	95.95±24.588 (26-120)	54.04±19.24 (25-97)	26.02±10.32 (13-47)	28.02±11.13 (10-54)	13.57±2.36 (6-17)
Test & p	-2.510; 0.012	-0.129; 0.891	-1.293; 0.195	-0.397; 0.690	-1.367; 0.171
Gender*					
Female	85.18±30.15 (26-120)	54.45±19.33 (22-117)	26.58±10.05 (10-58)	27.86±10.76 (10-59)	14.08±1.96 (8-20)
Male	93.59±26.35 (27-120)	52.46±19.00 (25-106)	24.76±10.24 (11-54)	27.70±11.53 (12-54)	13.98±1.90 (6-16)
Test & p	-1.966; 0.049	-0.703; 0.481	-1.529; 0.121	-0.487; 0.623	0.563; 0.577
Education*					
High school and associate degree	87.86±30.17 (26-120)	57.71±20.98 (24-117)	26.58±10.54 (12-58)	28.50±12.14 (10-59)	13.47±2.011 (6-16)
Bachelor's and master's/ doctorate degree	91.49±28.43 (35-120)	52.01±17.99 (22-109)	25.25±9.6 (10-54)	26.76±10.13 (10-56)	14.49±1.69 (9-20)
Test & p	-3.114; 0.002	-2.279; 0.023	-2.053; 0.040	-2.072; 0.038	-5.715; 0.001
Total	87.10±29.49 (26-120)	53.99±19.24 (22-117)	26. 16±10.11 (10-58)	27.82±10.92 (10-59)	14.06±1.95 (6-20)

*Mann-Whitney U Test, PAOD: Positive attitudes towards organ donation, NAOD: Negative attitudes towards organ donation, FBI: Fear of bodily injury, FMN: Fear of medical negligence, ODI: Organ donation information, ICU: Intensive care unit

by the duration of experience with age. In addition, it is known that nurses with a high level of education are generally employed in critical ICU (such as Cardiovascular surgery and coronary ICU and postoperative ICU). Therefore, nurses with higher education may have worked more with organ donation patients. Although it was not statistically significant, the PAOD score (philanthropy and moral values and beliefs) of male nurses was higher than that of female nurses. The higher ODI score of male nurses may have played a role in this result.

The years of work in ICU of the nurses had no effect on the organ donation attitude. This can be explained by the fact that nurses are young and have less ICU experience. It was observed that the institution where the nurses worked and the characteristics (neurosurgery and postoperative ICU, cardiovascular ICU…) of the ICU affected the organ donation attitudes of the nurses. At this point, the facts that state university hospitals generally include a wider variety of patient characteristics, employ nurses with higher education levels and more frequently organize in-service training, congresses and symposiums can rather positively influence the perspective on organ donation. Findings demonstrate that nurses working in these hospitals are better suited to assume leading roles in terms of organ donation.

Table 3. The knowledge and attitude about organ donation according to the clinical characteristics of the nurses (n=311)

Characteristics	PAOD Mean ± SD (min-max)	NAOD Mean ± SD (min-max)	FMN Mean ± SD (min-max)	FBI Mean ± SD (min-max)	ODI Mean ± SD (min-max)
Institution of work*					
Training and research hospital	81.81±31.83 (27-120)	55.23±19.85 (23-117)	26.72±10.30 (10-58)	28.51±11.45 (10-59)	14.48±1.78 (8-20)
Private university hospital	85.05±28.01 (26-120)	53.48±20.43 (25-109)	26.08±10.64 (11-53)	27.39±11.35 (10-56)	13.52±1.88 (8-16)
Public university hospital	95.07±25.32 (36-120)	52.66±17.82 (22-11)	25.49±9.61 (12-56)	27.17±9.99 (10-55)	14.48±1.78 (8-20)
Test & p	9.843; **0.007**	0.886; 0.644	0.535; 0.768	1.107; 0.586	11.84**; 0.003**
ICU*					
ARU and PCU	88.30±31.09 (26-120)	58.08±19.68 (22-109)	28.24±10.44 (12-54)	29.83±11.14 (10-59)	13.93±2.08 (6-17)
CVS and coroner	91.25±27.09 (35-120)	52.02±18.81 (25-109)	24.61±9.63 (11-54)	27.41±10.99 (10-56)	14.14±1.68 (8-17)
General adult intensive care	89.09±27.85 (38-120)	53.86±20.58 (23.117)	26.56±10.69 (10-58)	27.30±11.75 (10-59)	14.24±1.94 (8-20)
Neurosurgery/ neurology, emergency	67.97±28.11 (38-116)	47.25±12.99 (29-99)	23.25±7.78 (13-48)	24.00±6.37 (11-44)	13.86±2.25 (7-17)
Test & p	**16.677; 0.001****	**11.287; 0.010**	**9.774; 0.021**	7.499; 0.058	0.513; 0.911
ICU working duration*					
1-3 years	87.10±30.11 (27-120)	53.51±19.49 (22-117)	25.94±10.22 (10-58)	27.57±11.09 (10-59)	14.05±1.93 (6-20)
4-10 years	85.70±29.12 (36-120)	54.60±18.93 (24-104)	26.51±9.67 (13-54)	28.08±10.91 (11-59)	14.15±2.13 (8-17)
10+	91.22±26.33 (26-120)	55.85±18.73 (32-91)	26.81±10.79 (13-47)	29.03±9.83 (17-54)	13.89±1.55 (10-16)
Test & p	0.985; 0.611	0.561; 0.753	0.383; 0.823	0.803; 0.665	2.424; 0.293
Total	87.10±29.49 (26-120)	53.99±19.24 (22-117)	26.16±10.11 (10-58)	27.82±10.92 (10-59)	14.06±1.95 (6-20)

*Kruskal-Wallis test, PAOD: Positive attitudes towards organ donation, NAOD: Negative attitudes towards organ donation, FBI: Fear of bodily injury, FMN: Fear of medical negligence, ODI: Organ donation information, ICU: Intensive care unit, ARU: Anaesthesia reanimation unit, PCU: Postoperative care units, CVS: Cardiovascular surgery, min: Minimum, max: Maximum

Table 4. The relationship between the knowledge and attitudes of intensive care nurses about organ donation (N=311)

Characteristics	PAOD **r and p value**	NAOD **r and p value**	FMN **r and p value**	FBI **r and p value**	ODI **r and p value**
PAOD	-	-0.124; **0.029**	-0.149; **0.008**	-0.130; **0.022**	0.099; 0.080
NAOD	0.124; **0.029**	-	-	-	-0.106; 0.060
FMN	-0.149; **0.008**	-	-	0.571; 0.001	-0.100; 0.070
FBI	-0.130; **0.022**	-	0.571; **0.001**	-	-0.112; **0.049**

ICU: Intensive care unit, PAOD: Positive attitudes towards organ donation, NAOD: Negative attitudes towards organ donation, FMN: Fear of medical negligence, FBI: Fear of bodily injury, ODI: Organ donation information, r: Spearman's rho

Although Turkey is the country to perform the highest number of organ transplants in the world according to the IRODaT 2020 report (18), it also ranks last in terms of cadaveric donors. In the present study, ICU nurses support cadaveric donation as a donor type. However, almost all of the nurses did not have an organ donation card. Most of them were young, they might fear medical neglect, their FBI might prevent them from donating their organs. Knowledge and attitudes of healthcare professionals impact to willingness to donate organs (4,6,12,21,27). In Turkey, where there is a general voluntariness in terms of becoming live donors for relatives (9), education and training regarding organ donation must start during nursing education years. The positive attitude score of the nurses was higher than negative attitude score, and there was an inverse relationship between knowledge and negative attitude. Although these data indicated that nurses had positive thoughts about organ donation, they had some fears. Nurses might have a fear of medical neglect, and it might be difficult for them to express this fear. Nurses' fear of medical neglect can be explained by lack of knowledge. FBI may be related to both religious beliefs and attitudes and lack of knowledge. Also, some nurses may have encountered some malpractice events in ICU.

The organ donation knowledge alone not be sufficient to create positive attitudes. Planned, repetitive training sessions rich in content (brain death, donor management, transplantation, communication, religious myths) increase ICU nurses' advocacy for organ donation and their commitment to the process, for improving their behaviours (7,28,29). Lomero et al. (30) and Foong et al. (27) reported that the attitudes of nurses/ICU nurses, who were not sufficiently convinced of brain death, were also negative. For example, it has been reported that ICU nurses who are aware of the organ donation legislation in the country have more positive attitudes independent of their own values and beliefs (27,30).

The ODI scores of the nurses in this study were not low. In addition, the ODI scores of the young and university graduate nurses were higher (although not statistically significant) than the others. However, this score was not high enough for an ICU nurse to be a consultant on organ donation. Nurses are expected to know death, grief counselling, hospital policies and procedures, brain death criteria, organ and tissue healing processes very well (22,30).

Today, the curricula in most nursing education institutions include certain content regarding organ transplant, but few provide instructions regarding the consent process and the role of the nurse (31-34). For critical care nurses in the field, continuing education is needed to enhance skills, knowledge, and sensitivity to organ donation (6,33-35).

Study Limitations

There were two limitations in the research. The first limitation was that bureaucratically process required to collect data took very long time (12 months), wasting time with corporate correspondence. The second limitation was that the data network being irregularly distributed in Istanbul, a very large city, and because of financial constraints, no interviewer assistance, other than that of the researcher's own efforts, could be used for data collection. This led to hospitals with level 2 intensive care processes being left out of the scope of the study. The lack of access to nurses working in these institutions limited generalization of study findings. However, since researchers had to make a selection, researchers chose to prioritize the attitudes and knowledge of the level 3 ICU nurses who assumed more critical roles and responsibilities in terms of organ donation, and attitude about organ donation. The reason being, the findings with these nurses can shed a light on other nurses' situation regarding the subject matter. However, the results should be limited to the study group.

Relevance to Clinical Practice

The findings drew attention to the relationship between the attitudes and information of intensive care nurses about organ donation and clinical characteristics. Also, data have shown that there is a need for comprehensive knowledge of the transplantation process. The study suggests that younger nurses need comprehensive training (brain death, transplantation and legislation, families, grief counselling, patients and community awareness) and clinical experience, through a perspective which fits their generational life views. Thus, they can be motivated for more active roles in Organ Donation Associations and Centres.

Conclusion

According to study data, the ICU nurse profile in the university hospitals in Istanbul is of young age, which leads to a short ICU clinical experience. Nurses' sociodemographic (age, education) and clinic characteristics (Institution of work, ICU; anaesthesia reanimation unit, postoperative care units) may be affect their PAOD and ODI scores. Researchers can say that nurses with higher education degrees and working in state/puplic university hospitals may specifically assume more active roles in terms of organ donation. Although it is recommended that nurses with a high level of education work in this field for their level of knowledge on organ donation, this is not enough. Continuous training of nurses on this subject is required after graduation. Nurses in Turkey need comprehensive professional training on brain death, organ donation process, grief counselling and organ donation legislation. To maintain duty continuity of ICU nurses is of utmost importance for organ donation roles and attitudes. It is recommended to further the subject in future with new studies.

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Ethics

Ethics Committee Approval: This study respected the principles of research and publication ethics. Researchers obtained approvals from the Bezmialem Vakıf University Clinical Research Ethics Committee, under the code IRB#04.07.2017-12/192.

Informed Consent: Researchers took written permissions from the Provincial Directorate of Health, hospitals and volunteers for the research. Researchers informed ICU nurses that the information which they shared for this research was only intended for scientific purposes. Written permission was obtained from the authors who developed the ODAS and ODI for this study.

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Authorship Contributions

Surgical and Medical Practices: Y.S., M.D., S.Y., Concept: Y.S., M.D., S.Y., Design: Y.S., M.D., S.Y., Data Collection or Processing: Y.S., M.D., S.Y., Analysis or Interpretation: Y.S., S.Y., Literature Search: Y.S., M.D., S.Y., Writing: Y.S., S.Y.

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Original Article

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Magnetic Resonance Imaging Findings of Suprapatellar Fat Pad Impingement Syndrome: A Retrospective Study

Suprapatellar Yağ Yastığı Sıkışma Sendromunda Manyetik Rezonans Görüntüleme Bulguları: Retrospektif Çalışma

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ABSTRACT

Objective: Peripatellar fat pads are extrasynovial intracapsular fat tissues. Suprapatellar, perifemoral, and infrapatellar (Hoffa fat pad) fat pads are included in the peripatellar fat pad. This study aimed to describe the magnetic resonance imaging (MRI) signs of suprapatellar fat pad impingement syndrome, describe their prevalence and pattern, and look into the relationship between their MRI and clinical signs.

Methods: Two radiologists retrospectively analyzed 5,700 patients' knee MRI data between December 2010 and December 2015. We documented the MRI findings that were associated with suprapatellar fad pad impingement syndrome. The correlations between age, osteoarthritis, chondromalacia, and the patellofemoral joint were evaluated using Pearson's correlations.

Results: In our study group, the prevalence of suprapatellar fat pad impingement was 5.3%. Of the patients 52% were men and 48% were women. Patients who were admitted to the clinic complained of non-specific pain in 80.3% of patients. Twenty-seven patients (8.9%) presented with isolated suprapatellar impingement syndrome; 185 (60.9%) showed an increase in intra-articular fluid; 4 (1.3%) had synovitis findings; 17 (5.6%) had medial collateral ligament tears; 107 (35.2%) had quadriceps femoris tendinitis; 8 (2.6%) had patellar tendinitis; 80 (26.3%) had a

ÖZ

Amaç: Peripatellar yağ yastıkçığı, ekstrasinovyal intrakapsular yağ dokusudur. Ekstrasinovyal intrakapsüler yağ dokuları, peripatellar yağ yastıklarıdır. Suprapatellar, perifemoral ve infrapatellar (Hoffa yağ yastığı) yağ yastıkları, peripatellar yağ yastığını oluşturmaktadır. Bu çalışma, suprapatellar yağ yastığı sıkışma sendromunun manyetik rezonans görüntüleme (MRG) bulgularını tanımlamayı, bunların prevalansını ve paternini tanımlamayı ve MRG ile klinik belirtileri arasındaki ilişkiyi incelemeyi amaçlamıştır.

Yöntemler: Aralık 2010 ile Aralık 2015 arasında 5.700 hastanın diz MRG verilerini geriye dönük olarak 2 radyolog tarafından analiz edildi. Suprapatellar yağ yastığı sıkışma sendromu ile ilişkili MRG bulguları değerlendirildi. Yaş, osteoartrit, kondromalazi ve patellofemoral eklem arasındaki korelasyon Pearson korelasyonu kullanılarak değerlendirildi.

Bulgular: Çalışma grubumuzda suprapatellar yağ yastığı sıkışması prevalansı %5,3 olarak bulundu. Hastaların %52'si erkekti ve %48'i kadındı. Kliniğe başvuran hastaların %80,3'ünde non-spesifik ağrı şikayeti vardı. Yirmi yedi hastanın (%8,9) izole suprapatellar impingement sendromu vardı, 185 hastada (60,9%) eklem içi efüzyon mevcuttu, 4 hastada (%1,3) sinovitis bulguları vardı, 17 (%5,6) hastada medial kollateral bağ yaralanması vardı, 107 (%35,2) hastada kuadriceps femoris tendiniti vardı, 8

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ABSTRACT

medial meniscus tear; 23 (7.6%) had Baker's cyst; and 30 (9.9%) had soft-tissue edema. Medial meniscus degeneration was observed in 51 (16.8%) patients, Hoffa edema was observed in 31 (10.2%) patients, and anterior cruciate ligament tears in 3 (1%) patients. There were positive correlations between age and osteoarthritis (r=0.4660, p<0.05), between chondromalacia and the grade of the chondromalacia (r=0.5198, p<0.05), and between lateral subluxation and lateral tilt as opposed to the normal patellofemoral relationship (r=0.3171, p<0.05).in patients with suprapatellar fat pad impingement.

Conclusion: The most common symptom of suprapatellar impingement, that is one of the major causes of anterior knee pain, is non-specific pain. The most common additional MRI findings are increased intra-articular fluid and quadriceps femoris tendinitis.

Keywords: Suprapatellar fat pad impingement syndrome, knee MRI, knee pain, quadriceps fat pad

ÖZ

(%2,6) hastada patellar tendinit vardı, 80 (%26,3) hastada medial menisküs yırtığı vardı, 23 (%7,6) hastada Baker kisti vardı ve 30 (%9,9) hastada yumuşak doku ödemi vardı. Medial meniskus dejenerasyonu 51 (%16,8) vakada, Hoffa ödemleri 31 (%10,2) olguda ve ön çapraz bağ yırtığı 3 (%1) olguda gözlenmiştir. Suprapatellar yağ yastığı sıkışması olgularında yaş ile osteoartrit arasında (r=0,4660, p<0,05), kondromalazi ile kondromalazinin derecesi arasında (r=0,5198, p<0,05) ve normal patellofemoral ilişkinin aksine lateral sublüksasyon ile lateral tilt arasında pozitif korelasyon vardı (r=0,3171, p<0,05).

Sonuç: Ön diz ağrısının başlıca nedenlerinden biri olan suprapatellar sıkışmanın en sık görülen semptomu non-spesifik ağrıdır. En yaygın ek MRG bulguları eklem içi sıvı artışı ve kuadriseps femoris tendinitidir.

Anahtar Sözcükler: Suprapatellar yağ yastığı sıkışma sendromu, diz MRG, diz ağrısı, kuadriseps yağ yastığı

Introduction

The knee is a complex joint with movements in multiple planes and along multiple axes. Many anatomical structures cause complex motion in the knee. The peripatellar fat pads are one of the most significant soft tissues of the knee. The synovium is separated from the joint capsule by fat pads (1). Fat pads consist of deformable fat and fibrous tissues. Fat pads adapt during movement in the knee and protect the joint from stress by displacing it. It increases the synovial surface and acts as a lubricant (2,3). The suprapatellar fat pad, perifemoral fat pad, and infrapatellar (Hoffa fat pad) fat pads are all parts of the peripatellar fat pad (2). The suprapatellar fat pad is triangular in the anterior knee. It is the smallest of the fat pads on the front knee. On average, the suprapatellar fat pad is 7-8 mm thick (4). It occupies the anatomical space between the quadriceps tendon insertion and the posterior superior portion of the quadriceps tendon.

Trauma, inflammation, tumors, infection, and congenital anatomical abnormalities can cause soft tissue injuries. Impingement syndrome occurs due to 2 main reasons in lower extremity pathologies. The first are bone deformities, the second are soft tissue abnormalities, or combinations thereof. Magnetic resonance imaging (MRI) is a suitable imaging method for evaluating bone and soft tissue components in the evaluation of impingement syndrome. This study aimed to characterize the MRI findings of suprapatellar fat-pad impingement syndrome, define its prevalence and pattern, and investigate the correlation between its clinical findings and MRI findings.

Methods

Between December 2010 and December 2015, 5,700 patients' knee MRIs were reviewed retrospectively. All knee MRIs were performed with 1.5 Tesla and 3 Tesla systems (Magnetom Symphony and Skyra; Siemens Healthineers, Germany) equipped with a knee coil with 15 channels. Supine position according to standard knee MRI protocol 10-15º flexion and 15º external rotation were also applied. The radiology information system was evaluated with PACS (Evorad Research PACS). The knee MRI protocol included PD-weighted sequences (sagittal, coronal, and axial) with fat-saturation and T1-weighted coronal and T2-weighted fat-sat sagittal sequences.

Suprapatellar fat pad impingement was detected in 304 patients. The age, gender, physical activity history (whether they participated in sports regularly or not), trauma, tumor, and arthroscopic surgery history were all investigated. The clinical symptoms were divided into three categories: anterior knee pain, meniscus pain (pressing and sticking sensations), and non-specific pain. Chondromalacia (types, if any), patellofemoral joint relationship (normal, lateral subluxation, lateral tilt), and other associated findings [intra-articular fluid, synovitis, medial collateral ligament (MCL) tear, quadriceps femoris tendinitis, patellar tendinitis, medial or lateral meniscus tear, anterior cruciate ligament (ACL) tear, medial meniscus degeneration, Hoffa's edema, Baker's cyst, soft-tissue edema] were defined.

The patients were evaluated together by two radiologists (8 years and 20 years of musculoskeletal MRI experience). The study was approved by the Acıbadem University Institutional Ethics Committee (approval number: 2022-11/38). In patients with suprapatellar impingement syndrome, Pearson's correlations were used to assess the age-osteoarthritis-chondromalacia-patellofemoral joint relationship. This study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki.

Statistical Analysis

Statistical analysis was performed using the IBM SPSS Statistics 23.0 package program (SPSS Corp; Armonk, NY, USA). The

correlation between age, osteoarthritis, chondromalacia, and the patellofemoral joint were analyzed using Pearson's correlations. P<0.05 was considered statistically significant.

Results

Suprapatellar impingement was identified on MRI in 304 patients (Table 1). Two hundred ten (69%) patients were visualized in a 1.5 Tesla and 94 (31%) patients in a 3 Tesla MRI device. In patients with suprapatellar fat pad impingement, there was a positive correlation between age and the presence of osteoarthritis (r=0.4660, p<0.05), between the presence of chondromalacia and its grade of chondromalacia (r=0.5198, p<0.05), and between the presence of lateral subluxation and lateral tilt instead of the normal patellofemoral relationship (r=0.3171, p<0.05). No significant difference was observed between 1.5 Tesla and 3 Tesla devices.

The prevalence of suprapatellar fat pad impingement in our study group was 5.3%. One hundred fifty-eight (52%) patients were female, and 146 (48%) patients were male (Table 1). Anterior knee pain was present in 44 (14.5%) of the patients, while pain from meniscus degeneration and ACL rupture were reported in 16 (5.2%) of the patients (difficulty pressing, stuck feeling). Two hundred fourty four (80.3%) patients were admitted to the clinic with the complaint of non-specific pain (Table 2).

While 296 (97.3%) of 304 patients with suprapatellar impingement did not participate in sports regularly, 8 (2.7%) did. There were 23 (7.56%) patients with a history of trauma, 2 (0.66%) patients with a history of malignancy, and 10 (3.3%) patients with a history of arthroscopic surgery (Table 1). Osteoarthritis was observed in 65 (21.3%) patients (Table 2).

Chondromalacia patella (CP) was not found in 138 (45.4%) patients: grade 1 CP in 28 (9.2%) patients, grade 2 CP in 24 (7.9%) patients, grade 3 CP in 44 (14.5%) patients, and grade 4 CP in 70 (23%) patients. The patellofemoral joint relationship was observed as lateral subluxation in 60 (19.7%) patients, lateral tilt in 10 (3.3%) patients, and normal in 234 (77%) patients (Table 3). A contrast-enhanced knee MRI was performed in 6 patients. In all of the patients, contrast enhancement was observed.

Isolated suprapatellar impingement syndrome was observed in 27 (8.9%) of the patients, intra-articular fluid increase in 185 (60.9%), synovitis findings in 4 (1.3%), MCL tears in 17 (5.6%), quadriceps femoris tendinitis in 107 (35.2%), patellar tendinitis in 8 (2.6%), medial meniscus tear in 80 (26.3%), Baker's cyst in 23 (7.6%), and soft-tissue edema in 30 (9.9%). Medial meniscus degeneration was detected in 51 (16.8%), Hoffa edema in 31 (10.2%), and ACL tear in 3 (1%) patients (Table 2).

Table 1. Details of the patients

MRI (n=5700)	(n)	(%)
Normal MRI	5396	94.7
Suprapatellar impingement MRI	304	5.3
Mean age		
Female	158	52
Male	146	48
Sport activity (-)	296	97.3
Sport activity (+)	8	2.7
Trauma	23	7.5
Tumor	2	0.6
Arthroscopic surgery	10	3.3

n: Number of patients, %: Percentage of patient, MRI: Magnetic resonance imaging

Table 2. Distribution of knee symptoms and MRI findings with SIPS

Knee symptoms (n=304)	(n)	(%)
Anterior knee pain	44	14.5
Pain caused by intra-articular pathology	16	5.2
Non-specific pain	244	80.3
MRI findings with SPIS	**(n)**	**(%)**
Isolated SPIS	27	8.9
Osteoarthritis	65	21.3
Intra-articular effusion	185	8.9
Synovitis	4	1.3
ACL rupture	3	1
MCL rupture	17	5.6
Quadriceps femoris tendinitis	107	35.2
Patellar tendinitis	8	2.6
Medial meniscus tear	80	26.3
Medial meniscus degeneration	51	16.8
Baker cyst	23	7.6
Hoffa edema	31	10.2

n: Number of patients, %: Percentage of patient, SPIS: Suprapatellar impigement syndrome, ACL: Anterior cruciate ligament, MCL: Medial collateral ligament

Table 3. Distribution of chondromalesia and patellafemoral joint pathology

Chondromalesia with SPIS (n=304)	(n)	(%)
Chondromalesia grade 0	138	45.4
Chondromalesia grade 1	28	9.2
Chondromalesia grade 2	24	7.9
Chondromalesia grade 3	44	14.5
Chondromalesia grade 4	70	23
Patellafemoral joint with SPIS (n=304)	**(n)**	**(%)**
Normal	234	77
Lateral subluxation	60	19.7
Lateral tilt	10	3.3

n: Number of patients, %: Percentage of patient, SPIS: Suprapatellar impingement syndrome

Discussion

In this study, we aimed to evaluate and characterize the MRI findings of suprapatellar fat pad impingement syndrome, define its prevalence and pattern, and evaluate the correlation between its clinical findings and MRI findings. Non-specific knee pain is the most prevalent clinical finding in suprapatellar fat pad impingement syndrome, but anterior knee pain is also a significant clinical finding. In addition, no significant relationship was found between suprapatellar impingement syndrome and gender, sports activities, or trauma. The most common accompanying MRI findings in this study were increased intra-articular fluid and quadriceps femoris tendinitis.

In the study of Tsavalas and Karantanas (5), no significant relationship was established between anterior knee pain and suprapatellar impingement syndrome. This finding suggests that injury to the suprapatellar fat pad after repetitive microtrauma and overuse does not exceed the threshold for pain. Edema of the suprapatellar fat pad and anterior knee pain are controversial issues. Studies show that 12-14% of patients undergoing knee MRI have suprapatellar fat pad edema (5-7). Some studies found a relationship between suprapatellar fat pad volume and knee pain (7). However, some studies did not find a relationship between suprapatellar fat pad with pain (8). Suprapatellar impingement syndrome was found in 304 (5.3 %) of 5700 knee MRIs of patients in our study. The most common clinical finding with suprapatellar impingement syndrome was non-specific knee pain in 244 patients (80.3%). The second most common symptom was anterior knee pain in 44 (14.5%) patients. Anterior knee pain was found to be similar to previous studies. The association between suprapatellar impingement syndrome and knee pain requires more research.

In the study of Lapègue et al. (3) and Nouri et al. (9), repetitive compression, trauma, and instability of the patellofemoral joint are all known to cause inflammation and metaplasia of the fat pad. After metaplasia, fibrotic tissue is formed. This causes anterior knee pain (3,9). Publications are showing that edema-like changes in the suprapatellar fat pad seen on knee MRIs are rarely associated with anterior knee pain (10). In our study, 23 (7.56%) patients had a history of trauma, 2 (0.66%) patients had a history of tumors, and 10 (3.3%) patients had a history of arthroscopic surgery.

Suprapatellar fat pad edema is thought to result from repetitive friction against the trochlea during knee flexion (7,11). The terms suprapatellar fat pad impingement and suprapatellar fat pad edema impingement are interchangeable (12). However, there is no evidence to support it. In retrospective studies, no relationship was found between suprapatellar fat pad edema and patellar maltracking (5-7). In our study group, patella lateral subluxation was found in 60 (19.7%) patients, patella lateral tilt in 10 (3.3%) patients, and patellofemoral joint pathology in 224 (77%) patients. Suprapatellar fat pad edema and patellofemoral degeneration have been linked in recent publications (13). The relationship between suprapatellar fat pad size and osteoarthritis is unclear. Wang et al. (14) found a positive association with femorotibial osteoarthritis in their study. Shabshin et al. (1) found no association between patellofemoral osteoarthritis and suprapatellar fat pad size. Osteoarthritis was found in 65 (21.3%) of the participants in our study.

Quadriceps tendon edema has been observed in patients with suprapatellar fat pad edema in the literature (15). In our study, isolated suprapatellar impingement syndrome was observed in 27 (8.9%) patients, an intra-articular fluid increase was observed in 185 (60.9%) patients, and synovitis findings were observed in 4 (1.3%) patients. Quadriceps femoris tendinitis was found in 35.2% of the patients, patellar tendonitis in 8 (2.6%), and soft tissue edema in 30 (9.9%). In the study of Roth et al. (7), no significant relationship was found between chondromalacia and suprapatellar fat pad. In our study, CP was found in 138 (45.4%) patients, grade 1 CP in 28 (9.2%) patients, grade 2 CP in 24 (7.9%) patients, grade 3 CP in 44 (14.5%) patients, and grade 4 CP in 70 (23%) patients.

Study Limitations

There were certain limitations to our research. To begin with, our study was a retrospective, single-center study. Multicenter prospective studies should back up our findings. Since our study included a large patient population, all patients might not be adequately and objectively screened for clinical symptom evaluation. Our paper included a heterogeneous patient group. The study's strengths included a large-scale analysis of comprehensive MRI data with a large patient cohort.

Conclusion

Non-specific pain was the most common symptom in the suprapatellar impingement, it was one of the most significant causes of anterior knee pain. No significant relationship was found between suprapatellar impingement and gender, sports, and trauma. Increased intra-articular fluid and quadriceps femoris tendinitis were the most prevalent additional MRI findings.

Ethics

Ethics Committee Approval: The study was approved by the Acıbadem University Institutional Ethics Committee (approval number: 2022-11/38).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: B.B., A.A., H.M.Ö., Ö.B., Concept: B.B., A.A., H.M.Ö., Ö.B., Design: B.B., A.A., H.M.Ö., Ö.B., Data Collection or Processing: B.B., A.A., H.M.Ö., Ö.B., Analysis or Interpretation: B.B., A.A., O.Ö., H.M.Ö., Ö.B., Literature Search: B.B., A.A., H.M.Ö., Ö.B., Writing: B.B., A.A., H.M.Ö., Ö.B.

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Original Article

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Assessment of Pharmacy Students' Knowledge, Attitudes and Practices on Self Medication

Eczacılık Öğrencilerinin Kendi Kendine İlaç Kullanımı Konusunda Bilgi, Tutum ve Uygulamalarının Değerlendirilmesi

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ABSTRACT

Objective: This study aimed to evaluate the knowledge, attitudes and practices of Süleyman Demirel University Faculty of Pharmacy students about self-medication in Turkey.

Methods: This cross-sectional online survey study was conducted to investigate the knowledge, attitudes, and practices of Süleyman Demirel University Faculty of Pharmacy students regarding self-medication between 22 September and 22 October 2022.

Results: The questionnaires were answered by 336 students (76%). Most of the students (79.2%) correctly defined self-medication and 9.5% of students declared that self-medication was a part of self-care. Only 4.2% of students reported that they recommended self-medication to others. Female students had better knowledge and more negative attitudes about self-medication than male students ($p<0.05$). Approximately 79% of the students stated that they used self-medication in the last 6 months. About half of the participants (54.4%) stated that they had taken painkillers without a prescription in the last 6 months. The students declared that they had used drugs without a prescription for headache (36.3%), common cold (14.8%) and menstrual problems (10.4%) in the last 6 months, respectively.

Conclusion: Most of the students had good knowledge about self-medication, but the majority of them had negative attitudes. The study also showed that self-medication was common among these students. Pharmacists make an important contribution to the public health system. Pharmacy students should continue to be educated about responsible self-medication as future pharmacists.

Keywords: Knowledge, attitude, practice, pharmacy students, self-medication

ÖZ

Amaç: Bu çalışma, Türkiye'de Süleyman Demirel Üniversitesi Eczacılık Fakültesi öğrencilerinin kendi kendine ilaç kullanımı konusundaki bilgi, tutum ve uygulamalarını değerlendirmeyi amaçlamaktadır.

Yöntemler: Bu kesitsel çevrimiçi anket çalışması, 22 Eylül-22 Ekim 2022 tarihleri arasında Süleyman Demirel Üniversitesi Eczacılık Fakültesi öğrencilerinin kendi kendine ilaç kullanımlarına ilişkin bilgi, tutum ve uygulamalarını araştırma amacıyla yapılmıştır.

Bulgular: Anketler 336 öğrenci (%76) tarafından cevaplanmıştır. Öğrencilerin çoğu (%79,2) kendi kendine ilaç kullanımını doğru tanımlamıştır. Öğrencilerin %9,5'i kendi kendine ilaç kullanımının kişisel bakımın bir parçası olduğunu belirtmiştir. Öğrencilerin sadece %4,2'si kendi kendine ilaç kullanımını başkalarına tavsiye ettiğini bildirmiştir. Kız öğrencilerin kendi kendine ilaç kullanımı konusunda erkek öğrencilere göre daha iyi bilgi düzeyine ve daha fazla olumsuz tutuma sahip oldukları görülmüştür ($p<0,05$). Öğrencilerin yaklaşık %79'u son 6 ayda kendi kendine ilaç kullandığını belirtmiştir. Katılımcıların yaklaşık yarısı (%54,4) son 6 ayda reçetesiz ağrı kesici aldığını belirtmiştir. Öğrenciler son 6 ayda sırasıyla baş ağrısı (%36,3), soğuk algınlığı (%14,8) ve adet sorunları (%10,4) için reçetesiz ilaç kullandıklarını beyan etmişlerdir.

Sonuç: Öğrencilerin çoğu kendi kendine ilaç kullanımı hakkında iyi bilgiye sahiptir, ancak çoğunluğunun olumsuz tutumları vardır. Ayrıca kendi kendine ilaç tedavisi bu öğrenciler arasında yaygındır. Eczacılar halk sağlığı sistemine önemli katkılarda bulunurlar. Eczacılık öğrencileri, geleceğin eczacıları olarak sorumlu "kendi kendine ilaç kullanımı" konusunda eğitim almaya devam etmelidir.

Anahtar Sözcükler: Bilgi, tutum, uygulama, eczacılık öğrencileri, kendi-kendine ilaç kullanımı

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Introduction

Self-medication is prevalent around the world. The World Health Organization defines self-medication as individuals' choice and use of drugs to treat self-recognized diseases or symptoms (1). Taking medication without a doctor's prescription and using a prescription for recurring symptoms are examples of self-medication (2). Having no time to go to the physician, urgency, mild illness, the distance of hospitals from home, and easy access to over-the-counter (OTC) medicines from markets are the causes of self-medication (3,4). Convenient access to medicine and illness information, especially on the internet, encourages patients to self-medicate (5). Painkillers, antibiotics, cold syrups and nutritional supplements are frequently used in self-medication (6). Herbal preparations are generally considered to be safe. However, like medicines, herbal medicines also cause adverse reactions (7).

Responsible self-medication comprises the use of approved OTC drugs. When they are used to treat self-diagnosed disorders or symptoms, they are considered comparatively safe and effective drugs. Self-medication may prevent mild illness and decrease the financial costs of health care (8). Therefore, responsible self-medication encourages the rational use of drugs (9). Responsible self-medication has advantages such as reduced doctor visits, reduced burden on the health system, and access to effective treatment (10). Conversely, irresponsible self-medication leads to misdiagnosis, adverse drug reactions and drug-drug interactions (11).

According to studies, self-medication rates in Turkey changes between 58.9% and 83.1%. The studies were carried out in medical faculty students, university students, the general population and pharmacists (12-15).

As pharmacy students will be the pharmacists of the future and the counsellors and drug suppliers to patients, it is important to determine their knowledge, attitudes and practices in this regard (1). It is also important because self-medication is more common in developing countries (16). As far as we know, there is no study conducted on this subject among pharmacy students in Turkey. For this reason, the study aimed to evaluate the knowledge, attitudes and practices of Süleyman Demirel University Faculty of Pharmacy students about self-medication.

Methods

Study Area and Study Design

This cross-sectional online survey study was conducted to investigate the knowledge, attitudes, and practices of Süleyman Demirel University Faculty of Pharmacy undergraduate students regarding self-medication between 22 September and 22 October 2022. This study was approved by the Süleyman Demirel University Clinical Research Ethics Committee (approval number: 246/20.09.2022). A faculty administration permission was also obtained.

Data Collection

The survey was created via Google form. The survey link was distributed to the students via the WhatsApp. On the first page of the questionnaire, it was stated that the participation of the students was on a voluntary basis and the data would be kept confidential. Each student gave consent before answering the questionnaire.

The questionnaire was created by revising a previous study (3). The survey was translated into Turkish. Expert opinion was obtained from 2 pharmacologists. Some questions were removed. The questionnaire was tested on 30 students for clarity and readability. These students were selected from different academic years. Some questions were minor revised to make it more understandable to create the final version of the questionnaire.

The survey included 26 questions. The first 4 questions were about demographic information, questions between 5 and 10 were about knowledge, questions between 11 and 15 were about attitude, and questions between 16 and 26 were about practice.

Sample Size

The sample size was calculated by 206 with Raosoft sample size calculator with 5% of margin of error and 95% of confidence interval, 50% of response rate (17).

Statistical Analysis

Data were analyzed by using the SPSS version 20.0. Quantitative and qualitative variables were defined as median-interquartile range (IQR), mean ± standard deviation (SD) and percentage, respectively. Quantitative variables were compared with the Mann-Whitney U test if they were not normally distributed (for two-group comparison). The chi-square test was performed to compare categorical variables. P value <0.05 was considered statistically significant.

For the knowledge questions, a 3-point Likert scale was used. The answers to the knowledge questions consisted of "Yes", "No" and "Don't know." Correct answers were scored as 1, wrong answers and "Don't know" answers were scored as 0. The maximum knowledge score was 6, as there were 6 questions. More than >50% of the total score was considered good knowledge, and ≤50% was considered poor knowledge. A 5-point Likert scale was used for attitude questions. Attitude responses were calculated as 5 points for "Strongly disagree" answer, 4 for "Disagree" answer, 3 for "Uncertain" answer, 2 for "Agree" answer and 1 for "Strongly agree" answer. Attitude questions consisted of 5 questions and the maximum score was 25. Since we gave high scores to items such as "strongly disagree" and "Disagree" on a 5-point Likert scale, high scores indicated a negative attitude. More than ≥50% of the total score was associated with a negative attitude, and less than <50% was associated with a positive attitude.

In order to evaluate the practical level of the students, questions such as what type of drugs that the students used for self-medication, for which condition they used them, and whether they had any side effects or not were asked.

Results

Internal consistency of the study was calculated with the Cronbach's alpha score. Cronbach's alpha scores were 0.77 for knowledge and 0.52 for attitude and were acceptable (18).

The questionnaire was sent to all students studying in the faculty of pharmacy, but it was answered by 336 students (76%). Of the students participating in the study 243 (72.3%) were female and 93 (27.7%) were male and median age was 21 (IQR: 20-22). The 1st and 4th grades had the highest participation (21.7%) in the survey. Only 11% of the students had a chronic disease. Demographic characteristics are shown in Table 1.

Knowledge

The mean ± SD knowledge level of the students was 5.21±0.924. Most of the students (79.2%) correctly defined self-medication. More than half of the students (59.2%) knew that all drugs could have side effects. The majority of the students (97.3%) were aware that they should contact the doctor or pharmacist in the condition of adverse effects, and the majority (97.9%) of them knew that the use of drugs with unidentified substances was unsafe in patients with liver or kidney disease. Most of the students (89%) knew that self-medication could mask the signs and symptoms of certain diseases. In addition, students (97%) knew that increasing or decreasing the dose of the drug without consulting a doctor or pharmacist could be dangerous. Table 2 shows students' knowledge about self-medication. Students who were female had better knowledge level than male students ($p<0.05$) (Table 3).

Attitude

The mean ± SD attitude level of the students was 15.84±2.8. Figure 1 shows the attitudes of pharmacy students toward the self-medication. Only 9.5% of students declared that self-medication was a part of self-care. The majority of the students (82.5%) believed that there was a need for education about self-medication. Only 4.2% of students reported that they recommended self-medication to others.

Students who were female had more negative attitudes than the male students ($p<0.05$) (Table 3).

Practices

Table 4 shows the practice of pharmacy students in self-medication. Approximately 79% of the students stated that they used self-medication in the last 6 months. The rates of self-medication were 22.8% in 4th grade students, 21.6% in 3rd grade students, 20.5% in 2nd grade students, 17.9% in 5th grade students and 17.2% in 1st grade students. Students who had chronic disease in the last 6 months used more self-medication than the students who did not have. There was a statistically significant difference between different classes in terms of using self-medication ($p<0.05$), and there was no difference between genders in terms of using self-medication ($p>0.05$). About half of the participants (54.4%) stated that they had taken painkillers without a prescription in the last 6 months. The students declared that they had used drugs without a prescription for headache (36.3%), common cold (14.8%) and menstrual problems (10.4%) in the last 6 months, respectively. 80.1% of the students knew whether the drugs they used required a prescription or not. More than half of the students stated that pharmacists (59.2%) and doctors (18.5%) were the sources of information about self-medication. Most of the students (68%) knew about the possible side effects of the drugs they self-medicated. Awareness of the side effects of self-medication was highest in the 5th grade students (23.4%), and this was followed by 3rd grade students

Table 1. Demographic characteristics of respondents

Variables	n (%)
Gender	
Female	243 (72.3)
Male	93 (27.7)
Age median (IQR)	21 (20-22)
Year of study	
First year	73 (21.7)
Second year	64 (19)
Third year	66 (19.6)
Fourth year	73 (21.7)
Fifth year	60 (17.9)
Do you have any chronic disease?	
Yes	37 (11)
No	299 (89)

IQR: Interquartile range

Table 2. Knowledge of pharmacy students on self-medication

Questions	Item	n (%)
Self-medication is defined as self-consumption of medicine without advice of a physcian.	Yes[a]	266 (79.2)
	No	41 (12.2)
	Don't know	29 (8.6)
Do all drugs (prescription/non-prescription) have adverse effects?	Yes[a]	199 (59.2)
	No	59 (17.6)
	Don't know	76 (22.6)
Do you think it is dangerous to increase or decrease the dose of the drug without consulting the doctor or pharmacist?	Yes[a]	326 (97)
	No	4 (1.2)
	Don't know	6 (1.8)
In case of adverse effects, the doctor or pharmacist should be contacted.	Yes[a]	327 (97.3)
	No	-
	Don't know	9 (2.7)
It is dangerous to use drugs with unknown substances in patients with liver and kidney disease	Yes[a]	329 (97.9)
	No	2 (0.6)
	Don't know	5 (1.5)
Self-medication can mask the signs and symptoms of some diseases.	Yes[a]	299 (89)
	No	10 (3)
	Don't know	27 (8)

[a]: Correct answer

(22.9%), 4th grade students (21.2%), 2nd grade students (19.9%), and 1st grade students (12.6%). The students mostly stated that the most important causes for self-medication were that the health problem was not serious (36.9%) and it was a time-saving method (19.9%). A few of the students (11.1%) stated that they experienced adverse effects of self-medication.

Discussion

To the best of our knowledge, this is the first study to evaluate the knowledge, attitudes, and practices of pharmacy students in self-medication in Turkey. Our study presents the perspective of a pharmacy faculty in Turkey on this issue.

In our study, most of the students (95.5%) had good knowledge of self-medication, but the attitude level of most of them (88.4%) was negative. In the last 6 months, 79.2% of the students practiced self-medication.

In some of the studies on self-medication, the level of knowledge of the students was good (19-21) as in our study, but it was found to be poor in some studies (22-24). In our study, as in the

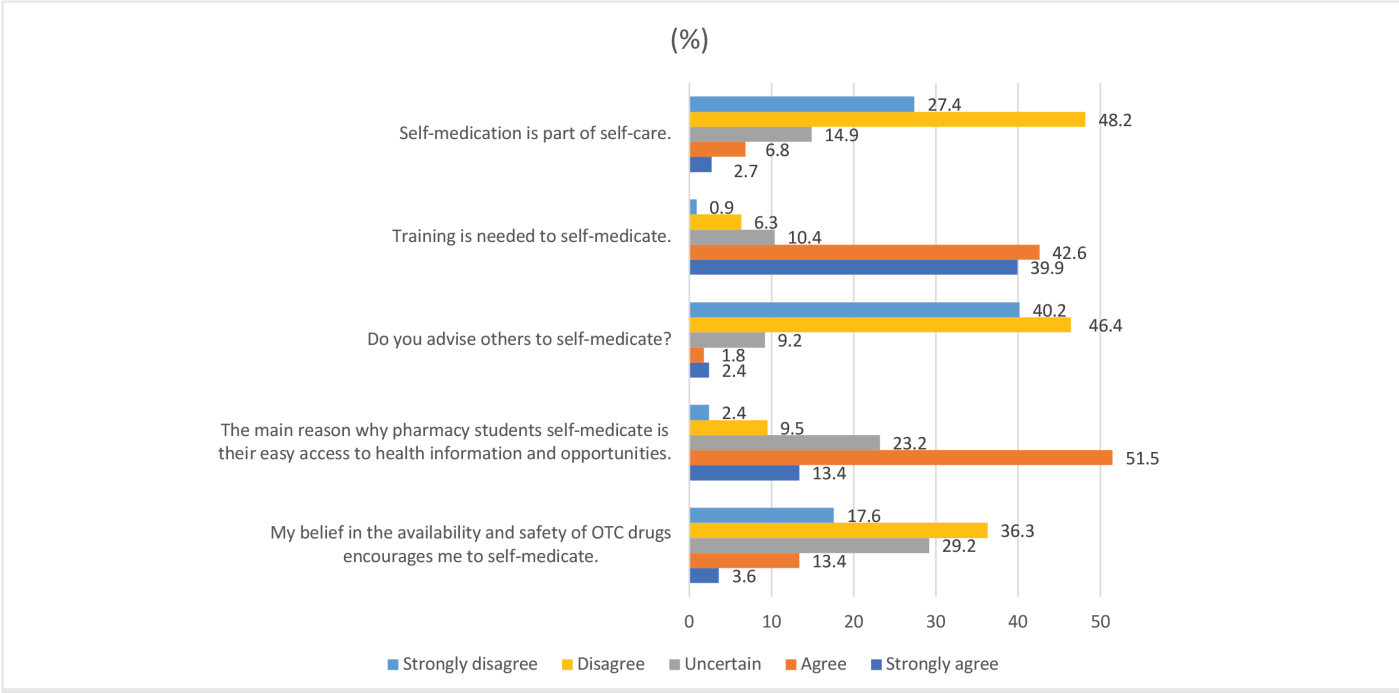

Figure 1. Percentage of pharmacy students' attitudes towards self-medication

Table 3. The relationship between the demographic characteristics of pharmacy students and their knowledge and attitude about self-medication

Variables	Knowledge level			Attitude level		
	Poor, n (%)	Good, n (%)	p	Negative, n (%)	Positive, n (%)	p
Gender						
Male	8 (8.6)	85 (91.4)	0.035	73 (78.5)	20 (21.5)	0.001
Female	7 (2.9)	236 (97.1)		224 (92.2)	19 (7.8)	
Age, years (median-IQR)	20 (19-22)	21 (20-22)	0.081	21 (20-22)	21 (20-22)	0.392
Year of study						
First year	5 (6.8)	68 (93.2)	0.28	65 (89)	8 (11)	0.851
Second year	3 (4.7)	61 (95.3)		58 (90.6)	6 (9.4)	
Third year	2 (3)	64 (97)		58 (87.9)	8 (12.1)	
Fourth year	5 (6.8)	68 (93.2)		62 (84.9)	11 (15.1)	
Fifth year	0 (0)	60 (100)		54 (90)	6 (10)	
Chronic disease						
Yes	2 (5.4)	35 (94.6)	0.675	30 (81.1)	7 (18.9)	0.169
No	13 (4.3)	286 (95.7)		267 (89.3)	32 (10.7)	

IQR: Interquartile-range. The cut-off score for the knowledge section is 3 and for attitude it is 12.5

Table 4. Practices of pharmacy students on self-medication

Questions	Item	n (%)
Have you self-medicate in the last 6 months?	Yes	255 (79.2)
	No	70 (20.8)
How frequently did you visit the pharmacy to purchase drugs without a prescription for yourself in the last 6 months?	1	168 (50)
	2	61 (18.2)
	≥3	37 (11)
Which of the following drug did you take without a prescription in the last 6 months?	Painkillers	183 (54.4)
	Antibiotics	7 (2.1)
	Antipyretics	4 (1.2)
	Antihistamines	10 (3)
	Cold and flu preparations	33 (9.8)
	Antiacid drugs	3 (0.9)
	Others	26 (7.7)
	None	70 (20.8)
For which of the following indication did you take medications without prescription during the last 6 months?	Headache	122 (36.3)
	Common cold	50 (14.8)
	Fever	7 (2.1)
	Allergy	9 (2.7)
	Digestive system disorder	7 (2.1)
	Acne/skin diseases	10 (3)
	Menstrual problems	35 (10.4)
	Other	26 (7.7)
	None	70 (20.8)
Do you know if the drugs you use require a prescription?	Yes	269 (80.1)
	No	30 (8.9)
	Don't know	37 (11)
What is your source of information about self-medication?	Relatives	20 (6)
	Friends	11 (3.3)
	Internet	42 (12.5)
	Television	2 (0.6)
	Advised by doctors but sold without prescription	62 (18.5)
	Pharmacist	199 (59.2)
Do you know the potential adverse reactions of the drug with which you have self-medicated?	Yes	231 (68.8)
	No	67 (19.9)
	Don't know	38 (11.3)
Where do you get the medicine when you are going to self-medicate?	Pharmacy	326 (97)
	Street market	3 (0.9)
	Herbal store	1 (0.3)
	Friend	6 (1.8)
What is the most important reason for you to self-medicate?	To save money	4 (1.2)
	To save time	67 (19.9)
	Privacy	5 (1.5)
	Urgency	130 (38.7)
	No healthcare facility nearby	5 (1.5)
	Health problem not serious	124 (36.9)
	Embarrassed of discussing own symptoms	1 (0.3)
Have you ever experienced the negative side effects of self-medication?	Yes	39 (11.6)
	No	297 (88.3)
If yes which was it?	Drug side effects	24 (7.1)
	Disease recurrence	8 (2.4)
	Development of drug resistance	4 (1.2)
	Drug-drug interactions	3 (0.9)

study of Alves et al. (23), female students' knowledge level was better than male students. In our study, similar to other studies, the definition of self-medication was correctly defined by most students (79.2%) (3,24). The vast majority of students (97.9% and 89%, respectively) believed that it was dangerous to use drugs containing unknown substances in patients with liver or kidney disease, and that self-medication could mask the symptoms of some diseases. Although these rates were higher than the study of Siraj et al. (25) (65.1% and 57.1%, respectively), they were similar to the results of the study of Alduraibi and Altowayan (3) (97.5% and 88.3%, respectively).

The attitudes of the students in our study were mostly negative. This shows that students may be careful about self-medication because their knowledge level is good. However, despite this negative attitude, this situation contradicts the results of high practice (79.2%). This negative attitude may result from their ignorance of the concepts of responsible self-medication and irresponsible self-medication. In addition, since there were few questions about attitude, we might not measure the real attitude level of the students. Contrary to our study, the attitude level was positive in most of the studies (19,24,25). Only 9.5% of the students agreed that self-medication was a part of self-care, and only 4.2% stated that they recommended self-medication to others. In the study by Siraj et al. (25), this rate was 35.3% and 46.2%, respectively.

Self-medication rates vary between studies. While it was 57.1% in a study conducted among pharmacy and medical students in Iran (8), it was 63.9% in a study conducted in Saudi Arabia (3) and 38.5% in Ethiopia (26). In addition, in studies conducted among medical school students in India (27), Egypt (28) and Bahrain (29), the rates of self-medication use were found as 78.6%, 55% and 44.8%, respectively. In studies conducted in European countries in medical students in Serbia (30) and in Slovenia (31) in health care and non-health care students, the rates of self-medication were found to be 81.3% and 92.3%, respectively. These differences may result from the methods of studies, data collection methods, welfare levels of countries, and access to health services. In a study conducted with medical school students in Turkey, self-medication use was 83.1% (13) and 63.4% among university students (12). The reason for the high rate of self-medication among health department students and health professionals may be the well-known knowledge of medicine and pharmacology and the ease of access to this information (32). In our study, students who had chronic disease in the last 6 months used more self-medication than the students who did not have. There was a statistically significant difference between different classes in terms of using self-medication, and there was no difference between genders in terms of using self-medication. In some studies, the male gender was found to use more self-medication (8), while in some others the female gender was found to use more self-medication (26). In our study, the use of self-medication in the 4th and 3rd grades was higher than in the other classes, and this situation may be related to the higher level of drug and pharmacology knowledge than 1st and 2nd grades. In addition, there may be an increase in stress-related headaches and an increase in the use of painkillers depending on these headaches, as these are the two most difficult courses in the faculty of pharmacy (33).

In our study, the most commonly used drugs for self-medication among students were painkillers (54.4%). This situation was similar to many studies (3,26,28,34,35). In Turkey, analgesics such as paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) can only be sold in pharmacies with or without a prescription (36). Opioid-derived analgesics are only sold in pharmacies with a red prescription (37). In many countries in Europe, analgesics such as paracetamol and NSAIDs can be sold non-pharmacy outlet in Denmark, Ireland, Slovenia, Czech Republic, United Kingdom, Hungary, and Poland (38). In the United States, there are two groups of non-prescription drugs: restricted and unrestricted unrestricted OTC drugs can be sold outside the pharmacy without pharmacist supervision (39). While there are some risks to self-medication, there are advantages such as reduced government health expenditures, reduced unnecessary physician consultations, and greater patient involvement. Community pharmacists have an important role in providing accurate information and counseling to patients about OTC drugs. As the pharmacists of the future, pharmacy students should also be conscious of this issue (40). For example, overuse of OTC painkillers can lead to medication overuse headache. Pharmacy students should be informed about the harms of excessive use of analgesics (41). Self-medication with antibiotics was also found to be high in some studies (8,42,43). This situation is very dangerous as it can lead to antibiotic resistance (44). In our study, antibiotic use was 2.1%. This might result from the student did not have knowledge about antibiotic drugs and thought another drug was an antibiotic. Also it can be due to using leftover antibiotics at home.

In our study, students mostly used self-medication for headache (36.3%), common cold (14.8%), and menstrual problems (10.4%). Headache and cold were also indications for self-medication in most other studies (20,34,43,45).

In our study, the most important cause for self-medication was that the health problem was not serious (36.9%). This was in line with the results of most studies (20,26,35,46).

Study Limitations

There were some limitations in our study. 1st and 2nd-year students were unacquainted with some terminology and may have had difficulty with some questions. In our study, the Cronbach's alpha score for the attitude section was low. This might be due to the low number of questions and we may not have measured the actual knowledge and attitude levels. In addition, the generalizability of our study was limited as it was conducted in a single center.

Conclusion

According to the results of this study, most of the students had good knowledge of self-medication, but the majority of them

had negative attitudes. It also showed that self-medication was prevalent among these students. Pharmacists make an important contribution to the public health system. Although the students' knowledge level was good in our study, pharmacy students should continue to receive training in responsible self-medication as future pharmacists.

Ethics

Ethics Committee Approval: This study was approved by the Süleyman Demirel University Clinical Research Ethics Committee (approval number: 246/20.09.2022).

Informed Consent: Each student gave consent before answering the questionnaire.

Peer-review: Externally peer-reviewed.

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Original Article

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The Reliability and Validity Study of the Turkish Version of Yale-Brown Obsessive-compulsive Scale Modified for Body Dysmorphic Disorder for Adolescents

Adölesanlar için Geliştirilmiş Olan Yale Brown Obsesif-kompulsif Ölçeği Beden Dismorfik Bozukluğu Modifikasyonunun Türkçe Versiyonunun Geçerlilik ve Güvenirlik Çalışması

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ABSTRACT

Objective: Body dysmorphic disorder (BDD) is defined as a highly disturbing condition characterized by the patient developing an excessive anxiety and repetitive behaviors. The prevalence of BDD in the orthodontic patients is still not well known. The aim of this study was to evaluate reliability and validity study of the Turkish version of the Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder (TR-YBOCS-BDD) for adolescents.

Methods: This study consisted of two groups, the study group and the control group. The study group consisted of 126 patients who were admitted with aesthetic complaints (n=126). The control group consisted of 126 participants who were admitted with non-aesthetic complaints such as dental calculus, caries and pain. Turkish versions of YBOCS-BDD and Body Image Disturbance Questionnaire (T-BIDQ) were administered to 252 patients in total for reliability and validity studies.

Results: The internal consistency coefficient of the TR-YBOCS-BDD scale was 0.903. The scores of the subareas of the TR-YBOCS-BDD scale were analyzed with Principal Components Factor Analysis and it was concluded that 8 factors corresponded to 62.104% of the total variance. The test re-test analysis was carried

ÖZ

Amaç: Beden dismorfik bozukluğu (BDB), hastanın aşırı kaygı ve tekrarlayıcı davranışlar geliştirmesiyle karakterize, oldukça rahatsız edici bir durum olarak tanımlanmaktadır. Ortodontik hastalarda BDB prevalansı hala tam olarak bilinmemektedir. Bu çalışmanın amacı, Yale-Brown Obsesif-Kompulsif Ölçeği BDB modifikasyonunun adölesanlar için Türkçe versiyonunun (YBOKB-BDB) geçerlik ve güvenirlik çalışmasının değerlendirilmesidir.

Yöntemler: Bu çalışma, çalışma grubu ve kontrol grubu olmak üzere iki gruptan oluşmaktadır. Çalışma grubu estetik şikayet ile başvuran 126 hastadan oluşurken, kontrol grubu ise diş taşı, çürük veya ağrı gibi estetik olmayan şikayetlerle başvuran 126 hastadan oluşturulmuştur. Güvenilirlik ve geçerlilik çalışmaları için YBOKB-BDB ve Beden Görünüşü Rahatsızlığı Testi (BGRT) toplam 252 hastaya uygulandı.

Bulgular: YBOKB-BDB'nin iç tutarlılık katsayısı 0,903'tür. YBOKB-BDB ölçek puanlarının alt alanları Temel Bileşenler Faktör Analizi ile analiz edilmiş ve 8 faktörün toplam varyansın %62,104'üne karşılık geldiği sonucuna varılmıştır. Test tekrar test analizi, YBOKB-BDB ölçeği 126 kişiye uygulanarak ve aynı test birer hafta arayla tekrar uygulanarak yapılmıştır. İlk toplam ölçek

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out by applying the TR-YBOCS-BDD scale to 126 participants and same test re-test was made at one-week interval. High positive correlation was found between the first total scale results and the total score calculated one week later (rho =0.986, p<0.001).

Conclusion: The Turkish translation of the BDD-YBOCS has content and construct validity and is also reliable method. The clinicians can apply this test to adolescents in the Turkish-speaking countries.

Keywords: Adolescent psychiatry, body dysmorphic disorder, orthodontics

ÖZ

sonuçları ile bir hafta sonra hesaplanan toplam puan arasında yüksek pozitif korelasyon bulundu (rho =0,986, p<0,001).

Sonuç: YBOKB-BDB'nin Türkçe çevirisi içerik ve yapı geçerliğine sahip olup güvenilir bir yöntemdir. Klinisyenler bu testi Türkçe konuşulan ülkelerde bulunan adölesanlarda uygulayabilirler.

Anahtar Sözcükler: Adelösan psikiyatrisi, beden dismorfik bozukluğu, ortodonti

Introduction

Body dysmorphic disorder (BDD) was first defined in 1886 as "dysmorphophobia" by a psychiatrist named Morselli (1,2). Later, in 1980, BDD was defined as "atypical somatoform disorder" in the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV). The American Psychiatric Association classified this "problem" as "Body Dysmorphic Disorder" in the DSM-IV in 1987 (3). BDD is now included in contemporary classification systems with the DSM-V (4). BDD is a highly disturbing disorder characterized by the patient's concern about imaginary or mild physical defects perceived by the patient. Some of the common behaviors in patients with BDD are: Comparing the patient's appearance with other individuals, repeated inspection or direct examination of mirrors or other reflective surfaces for detected defects, extreme self-care (for example, hair combing, hair styling, shaving, plucking or pulling hair), camouflage (for example, repeatedly applying make-up or covering disliked areas with a hat, clothing, make-up or hair), seeking reassurance about what perceived defects look like, touch undesirable areas to check, exercising excessively or lifting weights, searching for cosmetic procedures (5). Because patients with BDD are unaware of the true nature of the problem, they often seek solutions in non-psychiatric treatments and aesthetic procedures (6,7). Patients tend to hide their disease and often refer to plastic surgeons (1,8), dentists (9) or dermatologists (10) instead of being treated.

High percentage of suicidal tendencies is found in patients with severe BDD symptoms. These rates were observed in clinics, not in the general population (11-13). The prevalence of BDD in the general population is still not well known. Previous studies reported that BDD affected only 2% of general population (1,14,15) and 12% of psychiatric patients (1,16). Major depression, social phobia, drug addiction and Obsessive-Compulsive-related disorder (OCD) are accompanying disorders found with BDD. Previous studies reported that BDD shared the basic disorder features of OCD. They were similar in terms of high comorbidity, increased family history and treatment response (4). Differential diagnosis are; concerns about normal appearance and obvious physical defects, eating disorders, other obsessive-compulsive and related disorders, illness anxiety disorder, major depressive disorder, anxiety disorders, psychotic disorders (5).

Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder (YBOCS-BDD) is a 12-item, semi-structured, physician-administered scale which is assessing BDD severity (17). Adapted from YBOCS which is a scale used to measure OCD severity (18). The aim of this study was to test the reliability and validity of the Turkish translation of the Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder (TR-YBOCS-BDD) on adolescents, which was applied to adults in the previous study (19). This test provides easier to understand the prevalence of BDD and facilitate the diagnosis in Turkey and Turkish-speaking areas. The null hypothesis is there is no differences between groups.

Methods

This study was approved by the Bezmialem Vakıf University Local Ethics Committee (decision no: 20/375, date: 22.10.2019). The necessary permissions were obtained for the scale to be adapted into Turkish. The original version of this scale was translated from English to Turkish by native English speakers. Translation was checked by an orthodontist, an oral and maxillofacial surgeon, and two psychiatrists. The meanings of the words were arranged in a way that adolescents could understand. Later, the scale was translated back into the native language by two independent translators. The English version of the scale was checked by the same board and compared with the original scale to correct any possible errors during back translation. As a result, the final version of the test was decided.

The Turkish translation of the Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder and Beck Depression Inventory (BDI) were applied to 252 adolescent patients. Patients aged 13-18 years were included in the study. The gender distributions between the groups were chosen very close to each other. A voluntary consent form was obtained from each patient for participating in this study. One hundred twenty six of the adolescent patients were admitted to our faculty with aesthetic expectations, the other 126 adolescent patients were admitted to the faculty with non-aesthetic complaints such as pain, calculus and caries. Participants were selected on a voluntary basis. Exclusion criteria for both groups of participants were: inability to understand the issue of scale, severe physical disorders caused by syndromes, pre-diagnosed BDD and

another psychiatric illness. TR-YBOCS-BDD was applied to the participants twice, one-week apart. In this study, the validity and reliability of the TR-YBOCS-BDD scale were compared in both control and study groups. They answered 33 questions for TR-YBOCS-BDD and 21 questions for BDI. Participants were asked to write numerically how much they participated with the questions in TR-YBOCS-BDD from 0 to 4, and from 0 to 3 with the statements in the BDI. The scales were administered directly to the patients by the researchers, over the phone, on the internet, and during a dental appointment. The content validity method was applied to the area of the items in the scale and their relationship with other items. BDI scale was used for equivalence analysis. Statistical significance was accepted as $p<0.05$.

Statistical Analysis

Shapiro-Wilks test (Q-Q graphs) statistics was used for evaluation of the data distribution. The two independent group comparisons were performed. In these comparisons, the independent two-sample t-test was performed for analyzing of normally distributed data, and the Mann-Whitney U test was performed for the analyzing of non-normally distributed data. Spearman correlation analysis was used to test the compatibility of the two quantitative data sets. Factor analysis was performed for the factorial structure. Principal Component Analysis was performed as factor extraction method. Additionally, factor score was determined by Bartlett test and Kaiser-Meyer-Olkin (KMO) test. Varimax rotation method was performed for factor rotation analysis. The validity analyzes for YBOCS were examined under 2 main headings: construct validity and content validity. The methods used in construct validity analysis can be defined as 4 different methods; examining the differences between subscale scores and total scale scores of the study group (group differences and construct validity analysis, examining correlations between sub-domains, calculation of factor analysis results and calculation of internal consistency coefficient and Regarding validity. BDOC was used as an alternative form in criterion validity analysis, it was based on the concurrent validity analysis specified in the literature. The Cronbach alpha reliability coefficients were checked out for each subfield and whole scale in the internal consistency method for evaluation of the YBOCS reliability analyses. Moreover, inter-item correlation and item-total score correlation coefficient average were analyzed. Additionally, the equivalence method was performed by analyzing the correlation with the BDOCS scale. YBOCS reliability analyses were tested under 3 categories: test-retest, intra correlation coefficient (ICC), concordance correlation coefficient (CCC), Bland Altman Plot and. The R 3..6..2 program and TURCOSA (Turcosa Analytics Ltd. Co., Turkey, www.turcosa.com.tr) statistics software were used for analyzing of the data. Statistical significance was accepted as $p<0.05$.

Results

The findings were examined under two main headings, validity and reliability.

Content Validity

The content validity analysis of YBOCS was carried out at the following stage: The adaptation stage of the scale was adjusted in terms of cultural conformity by based on the original version. Validity was examined under 4 subgroups. As a result of their analysis, the following findings were obtained.

Calculating the Internal Consistency Coefficient (Cronbach Alpha)

The total scores of the patient group in sub-areas of the YBOCS scale and throughout the scale were found to be higher

Table 1. Examining differences between the healthy participant group and the group in terms of the YBOCS-BDD scale subscale scores and total scale scores

Scale fields	Group Control (aesthetic concern) median (25p-75p)	Patients median (25p-75p)	p value
YBOCS-BDD 1	1.00 (0.00-1.00)	1.00 (1.00-2.00)	0.011
YBOCS-BDD 2 total	2.00 (0.00-7.00)	7.00 (4.00-9.25)	<0.001
YBOCS-BDD 3	0.00 (0.00-1.00)	1.00 (0.00-1.00)	0.367
YBOCS-BDD 4	0.00 (0.00-1.00)	0.00 (0.00-1.00)	0.988
YBOCS-BDD 5	0.00 (0.00-1.00)	1.00 (0.00-1.00)	0.725
YBOCS-BDD 6 total	3.00 (1.00-5.00)	7.00 (3.75-11.00)	<0.001
YBOCS-BDD 7	0.00 (0.00-1.00)	1.00 (0.00-1.00)	<0.001
YBOCS-BDD 8	0.00 (0.00-1.00)	1.00 (0.00-1.00)	**0.109**
YBOCS-BDD 9	0.00 (0.00-1.00)	1.00 (0.00-1.00)	**0.364**
YBOCS-BDD 10	0.00 (0.00-1.00)	1.00 (0.00-1.00)	**0.208**
YBOCS-BDD 11	1.00 (0.00-1.00)	1.00 (0.00-1.00)	**0.397**
YBOCS-BDD 12	0.00 (0.00-1.00)	1.00 (0.00-1.00)	<0.001
YBOCS-BDD total scale	11.00 (5.00-21.25)	10.30 (11.00-29.25)	**0.006**

YBOCS-BDD: Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder

than the scores of the healthy group (p<0.001) (Table 1). Evidence for construct validity on the scale studies is the high internal consistency coefficient (Cronbach's alpha). In this study, the internal consistency coefficient for the YBOCS scale was found to be 0.903, providing evidence for the construct validity.

The Correlation Coefficients

The correlation coefficients between the YBOCS scale subdomains of the participants in both groups and the whole scale were analyzed using the Spearman correlation coefficient. According to the analysis results, there was a correlation between the YBOCS2 and all YBOCS score of the control participants with aesthetic expectations. (rho =0.766 and p<0.001). Moreover, there was a correlation between the YBOCS6 total score scale and the total YBOCS scores of the control participants with aesthetic expectations (rho =0.733 and p<0.001). There was a correlation between YBOCS2 and total YBOCS scores of patients with unaesthetic expectations (rho =0.774 and p<0.001). Also there was a correlation between YBOCS6 total score scale and total YBOCS scores of patients with unaesthetic expectations (rho =0.812 and p<0.001). At this stage, correlation analysis between the sub-domains of the YBOCS scale was performed for both groups of participants. For control participants, there was moderate, positive and statistically significant correlation between the YBOCS2 participation domain and YBOCS6 (rho =0.472, p<0.001). Additionally, similar correlation was observed between the compact subdomain and the emotional state subdomain (rho =0.533, p<0.001).

Calculating Factor Analysis Results

The KMO was used for examination of the suitability of the sample and the adequacy of the number of samples was also controlled. With a KMO value of 0.869 sampling efficiency was found to be very good. The test results of Bartlett were found as p<0.001. The sub-areas of the scale scores were performed with the Principal Component Factor Analysis. The 8 factors corresponded to 62.104% of the total variance andan Eigen value above 1.00 emerged according to the results of the analysis. The results of the factorization of the items were determined by Varimax rotation. The 1st factor had YBOCS 2.8, the 2nd factor had YBOCS5 items based on the results of the axis rotation analysis. YBOCS 6.12 substances were included in 3rd factor and 8th factor. Table 2 and 3 shows these results.

Regarding Validity

In the internal consistency sub-analysis of the YBOCS reliability, the average of item-total score correlation coefficients, inter-item correlation coefficients, and Cronbach Alpha method results are presented in Table 4, 5.

Reliability Analysis

Equivalence Analysis

The alternative form method was applied and the comparable form BDI scale was used. The correlation analysis was performed for the comparisons of these two scales, and a moderately significant positive correlation was found among the patient and control groups. These analyzes are shown in Table 6.

Test-retest Analysis

Another criterion used in the estimation of the reliability coefficient of the YBOCS was test-retest analysis. The YBOCS was applied to 126 participants, after a one-week break, and then applied to the same participants again. It was observed that there was a high positive correlation among the first total scale score of this scale and the total scale score one week later (rho =0.986, p<0.001). According to these results, the test was found to be reliable.

Intra Correlation Coefficient and Concordance Correlation Coefficient

The CCC between the first measurement of YBOCS and the second measurement of YBOCS was found to be 0.9913. There was significant interclass correlation coefficient results (95% confidence interval) for all factors.

Bland Altman Plot

Testing the reliability of the scale was done with Bland Altman charts. It was observed that there was no difference between the test-retested first measurement of YBOCS and the second test measurement of YBOCS.

Table 2. The Eigen values and variance percentages of the YBOCS-BDD factors

Factor	Eigen value	Percentage of variance	Cumulative percentage of variance
Factor I	8.597	26.052	26.052
Factor II	3.158	9.570	35.622
Factor III	2.414	7.314	42.935
Factor IV	1.676	5.078	48.013
Factor V	1.345	4.076	52.089
Factor VI	1.172	3.550	55.639
Factor VII	1.085	3.289	58.927
Factor VII	1.048	3.176	62.104

YBOCS-BDD: Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder

Table 3. Factor evaluations of the YBOCS-BDD scale items

Factor	Item numbers	Mean	Standard deviation	Corrrected item-total correlation	Cronbach's alpha if item deleted	Factor loading	ICC (95% CI)
Factor I	YBOCS-BDD 2.8	2.90	0.65	0.767	0.843	0.813	0.876 (0.85-0.90)
	YBOCS-BDD 2.6	2.90	0.66	0.692	0.853	0.778	
	YBOCS-BDD 2.9	2.97	0.61	0.638	0.860	0.748	
	YBOCS-BDD 2.7	2.88	0.71	0.664	0.857	0.706	
	YBOCS-BDD 2.10	2.93	0.63	0.581	0.867	0.667	
	YBOCS-BDD 2.5	2.88	0.68	0.635	0.861	0.620	
	YBOCS-BDD 2.4	2.94	0.62	0.622	0.862	0.568	
Factor II	YBOCS-BDD 5	2.44	0.77	0.597	0.681	0.752	0.753 (0.70-0.80)
	YBOCS-BDD 6.1	2.52	0.72	0.579	0.690	0.714	
	YBOCS-BDD 3	2.40	0.79	0.592	0.682	0.667	
	YBOCS-BDD 4	2.37	0.88	0.383	0.766	0.538	
	YBOCS-BDD 6.2	2.56	0.72	0.476	0.724	0.495	
Factor III	YBOCS-BDD 6.12	1.59	0.59	0.633	0.676	0.761	0.757 (0.71-0.80)
	YBOCS-BDD 6.13	1.58	0.61	0.583	0.692	0.747	
	YBOCS-BDD 6.11	1.58	0.60	0.576	0.695	0.680	
	YBOCS-BDD 6.10	1.56	0.63	0.490	0.726	0.611	
	YBOCS-BDD 7	1.44	0.68	0.369	0.773	0.435	
Factor IV	YBOCS-BDD 6.7	1.27	0.69	0.688	0.644	0.776	0.767 (0.71-0.81)
	YBOCS-BDD 6.9	1.36	0.63	0.535	0.729	0.728	
	YBOCS-BDD 6.6	1.24	0.71	0.552	0.721	0.693	
	YBOCS-BDD 6.8	1.31	0.67	0.503	0.745	0.547	
Factor V	YBOCS-BDD 2.2	2.21	0.61	0.663	0.643	0.755	0.754 (0.70-0.80)
	YBOCS-BDD 2.3	2.17	0.64	0.558	0.693	0.640	
	YBOCS-BDD 2.1	2.03	0.74	0.566	0.689	0.619	
	YBOCS-BDD 1	1.72	0.74	0.444	0.760	0.499	
Factor VI	YBOCS-BDD 6.4	1.02	0.67	0.583	0.531	0.769	0.703 (0.36-0.541)
	YBOCS-BDD 6.3	0.84	0.74	0.552	0.573	0.765	
	YBOCS-BDD 6.5	1.04	0.62	0.436	0.708	0.583	
Factor VII	YBOCS-BDD 9	1.55	0.95	0.510	0.547	0.739	0.673 (0.60-0.74)
	YBOCS-BDD 10	1.60	0.83	0.478	0.591	0.671	
	YBOCS-BDD 8	1.53	0.91	0.474	0.594	0.659	
Factor VII	YBOCS-BDD 12	0.85	0.80	0.452	-	0.725	0.452 (0.35-0.55)
	YBOCS-BDD 11	0.73	0.82	0.452	-	0.712	

YBOCS-BDD: Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder, ICC: Intra correlation coefficient, CI: Confidence interval

Table 4. Inter-item correlation analysis results for the YBOCS2 communication subfield

	YBOCS-BDD 2.1	YBOCS-BDD 2.2	YBOCS-BDD 2.3	YBOCS-BDD 2.4	YBOCS-BDD 2.5	YBOCS-BDD 2.6	YBOCS-BDD 2.7	YBOCS-BDD 2.8	YBOCS -BDD 2.9
YBOCS-BDD 2.1									
YBOCS-BDD 2.2	0.591**								
YBOCS-BDD 2.3	0.473**	0.679**							
YBOCS-BDD 2.4	0.491**	0.488**	0.551						
YBOCS-BDD 2.5	0.454**	0.454**	0.403	0.558**					
YBOCS-BDD 2.6	0.280**	0.357**	0.365	0.431**	0.531**				
YBOCS-BDD 2.7	0.346**	0.310**	0.361	0.405**	0.500**	0.560**			
YBOCS-BDD 2.8	0.391**	0.435**	0.439	0.390**	0.550**	0.633**	0.614**		
YBOCS-BDD 2.9	0.321**	0.330**	0.344	0.468**	0.351**	0.510**	0.502**	0.569**	
YBOCS-BDD 2.10	0.295**	0.336**	0.367	0.373**	0.411**	0.473**	0.375**	0.549**	0.540**

YBOCS-BDD: Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder; Spearman's Rho Analysis, **p<0.01.

Table 5. Inter-item correlation analysis results for the YBOCS6 communication subfield

	YBOCS-BDD 6.1	YBOCS-BDD 6.2	YBOCS-BDD 6.3	YBOCS-BDD 6.4	YBOCS-BDD 6.5	YBOCS-BDD 6.6	YBOCS-BDD 6.7	YBOCS-BDD 6.8	YBOCS-BDD 6.9	YBOCS-BDD 6.10	YBOCS-BDD 6.11
YBOCS-BDD 6.1											
YBOCS-BDD 6.2	0.517**										
YBOCS-BDD 6.3	0.358**	0.428**									
YBOCS-BDD 6.4	0.197**	0.314**	0.550**								
YBOCS-BDD 6.5	0.227**	0.298**	0.356**	0.396**							
YBOCS-BDD 6.6	0.207**	0.260**	0.379**	0.377**	0.412**						
YBOCS-BDD 6.7	0.172**	0.299**	0.299**	0.367**	0.325**	0.497**					
YBOCS-BDD 6.8	0.272**	0.324**	0.339**	0.326**	0.353**	0.385**	0.554**				
YBOCS-BDD 6.9	0.207**	0.190**	0.232**	0.238**	0.220**	0.358**	0.445**	0.440**			
YBOCS-BDD 6.10	0.215**	0.193**	0.322**	0.368**	0.237**	0.226**	0.299**	0.343**	0.448**		
YBOCS-BDD 6.11	0.062	0.168**	0.242**	0.249**	0.278**	0.269**	0.324**	0.403**	0.456**	0.489**	
YBOCS-BDD 6.12	0.157*	0.227**	0.212**	0.358**	0.272**	0.262**	0.406**	0.302**	0.380**	0.419**	0.618**

*p<0.05; **p<0.01. YBOCS-BDD: Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder; Spearman's Rho Analysis

Table 6. Correlation coefficients indicating the relationship between between YBOCS-BDD and BDI scale for participants and control Spearman's Rho analysis (r)

	YBOCS scale- BDI scale	
Group	rho	p
Control	0.451	<0.001*
Patients	0.602	<0.001*

YBOCS-BDD: Yale-Brown Obsessive-Compulsive Scale modified for Body Dysmorphic Disorder, BDI: Beck Depression Inventory *p<0.05.

Discussion

Adolescence (the period between the ages of 10 and 24) is a term of life specified by increased sensitivity to social life and an increased need for human relations (20). Adolescents turn to various treatment options to make better their appearance, one of which is orthodontic treatment. This situation results in increasing of the generality of BDD in orthodontic patients. The identification of BDD in orthodontic patients is very critical in terms of evaluating the treatment flow and results. The definitive diagnosis of BDD in adolescents should be made in psychology clinics, but the application of the TR-YBOCS-BDD may raise awareness in terms of providing an insight for clinicians. Previous study reported the Turkish validation of TR-YBOCS-BDD in adults, and the scale was tested in adolescents in this study, and it was aimed to better understand and guide adolescents with BDD in orthodontic treatments. The aim of this study was to investigate the prevalence of BDD in adolescents in the Turkish population with TR-YBOCS BDD and to raise awareness by changing our approach to patients with BDD symptoms.

The BDD-YBOCS psychometric properties of subjects was investigated by Philips for evaluation the reliability. Test-retest reliability (n=64) were examined. There was found that excellent inter-inter and test-retest reliability of intraclass correlation coefficients; internal consistency was strong. Of the variance 66% was determined by principal components factor analysis. The analyses of depression, social disability, and psychosocial functioning measures were resulted in a good convergent and discriminant validity. The significant decrease in average BDD-YBOCS scores with treatment indicates sensitivity to changes (21).

The diagnosis of BDD in clinical practice may be difficult. Patients with BDD are mostly preoccupied about their head and

face. For example, acne, wrinkles, scars, facial asymmetry, and disproportions are the conditions that worry patients (2,10). In addition, cheeks, teeth, lips and jaws are also concerns mentioned by these patients. The reasons why patients with BDD go to dentists are mostly; teeth whitening, jaw surgery and orthodontic treatment (22). Most of the patients with BDD undergoing dental or orthodontic treatment are dissatisfied with the treatment results and tend to visit other dentists repeatedly with similar concerns. To understand the expects of patients and psychological evaluation is a critical stage of the treatment. It allows us to make sense of the problems that may occur during the treatment process, to make more realistic treatment plans and to explain this situation to the patient (23). It has been documented that patients with BDD who are admitted to the orthodontics department have unrealistic expectations about treatment (24). Hepburn and Cunningham (25) reported that 7.5% of orthodontic patients were positive for BDD in their study of 40 adult orthodontic patients. In another study, 62 (5.2%) of 1,184 orthodontic patients were diagnosed as having BDD. Furthermore, it was reported that the rates of whitening and orthodontic treatment were nine times higher in those with BDD (24). Therefore, the clinicians must have the knowledge to clearly assess and manage patients with BDD (26). The probability of encountering patients with BDD in orthodontic practices is high. These patients should be referred to a psychiatrist for diagnosis and treatment. In order to achieve this, orthodontists should be familiar with this issue (2).

YBOCS-BDD is widely used as a gold-standard measurement of BDD symptoms (4). Researchers in various countries around the world have translated YBOCS-BDD into their own languages and performed reliability and validity tests. There were published studies on the prevalence of YBOCS-BDD between orthodontic patients. For example, in a study conducted at the Universidade Federal de São Paulo Plastic Surgery Outpatient Clinic in Brazil, YBOCS-BDD was translated into Brazilian Portuguese for the cultural adaption of the Brazilian Portuguese version of YBOCS-BDD. Thirty patients participated in the study. To analyze reliability and construct validity in patients, the final version was tested. The total Cronbach's alpha =0.918, ICC =0.934; ($p<0.001$) was found as a result of the study. Significant differences in BDD-YBOCS scores were found between patients with and without BDD symptoms ($p<0.001$), and among patients with different levels of BDD severity ($p<0.001$). The Brazilian Portuguese version of the YBOCS-BDD was proven to be a reliable scale that demonstrated aspect, content, and construct validity (27). In another study, YBOCS-BDD translated into Persian was applied to 100 students (50 males, 50 females) selected by stratified cluster sampling from Isfahan University. The Cronbach's alpha range ranged from 0.78 for the "strength of thought control" factor to 0.93 for the "obsessive thoughts and behaviors" factor. YBOCS-BDD was found to have reliability and validity in Persian (28). This study demonstrates the psychometric investigation of the adolescent version of the TR-YBOCS-BDD in Turkish population. There are following various findings emerged as a result of this study. The results were promising (Tables 1-5).

Hepburn and Cunningham (25) reported that 7.5% of orthodontic patients were positive for BDD and they found BDD in 2.9% of the population (2). In another study, 62 (5.2%) of 1184 orthodontic patients were diagnosed as having BDD (2). Yassaei et al. (7) reported that 15 patients (5.5%) were positive. Because of the high probability of come across such patients in orthodontists' offices, it is necessary to refer these patients. Therefore physicians should be familiar with BDD (2).

The Turkish version of the scale, validated in a sample of patients (n=252), showed excellent internal consistency (Cronbach's alpha coefficient of 0.93 vs 0.80 in the original measure) and test-retest reliability (0.986 vs 0.88 in the original instrument) (17). The BDD-YBCOS can be performed for diagnosing patients who are not satisfied with their physical appearance, but do not meet diagnostic criteria for BDD. There is no definitive cut off score for YBOCS-BDD in the literature, but a score of 20 or above usually indicates moderate BDD (12). We can transfer this situation to daily clinical practice as follows: When the patient is diagnosed as having OCS, then they can be referred to a psychiatrist for the examination of BDD.

There were three main factors explaining the 60% of the total variance reported by Phillips: Factor-1 as core symptoms, Factor-2 as compulsions and Factor-3 as resistance and control of thoughts. While evaluating the validity in Turkish population, successful results were gathered with both tests. There was significant correlation, allowing to make a factor analysis. Therefore, we could evaluate the construct validity. The remarkable correlations might be performed among communication subdomain and the emotional state subdomains. These outcomes had good convergent and discriminant validity like previous studies (29). The strengths of this study were; general examination of issues and numerous aspects of reliability-validity, and the large sample size. This was also the first study to test the relationship of TR-YBOCS-BDD with adolescents in Turkish population.

Study Limitations

Relatively small sample size for analyzing of TR-YBOCS-BDD in adolescents was a limitation of the study. This test was applied to adolescents without gender discrimination. Furthermore, there are certain differences in terms of BDD rates in boys versus girls (30), and future studies should investigate predisposition of BDD according to gender. It was also important to understand that patients in this study came from patients undergoing routine dental clinical procedure and therefore might restrict the generalizability of the study. Because, all adolescents with BDD in Turkish population may not be admitted to orthodontic treatment, they may be obsessed with another part of their body. The results of this study should not be generalized to Turkish population. Divergent validity is a method to analyze the factorability of the scale. This was not performed in the study.

Conclusion

This is the first study for evaluation of the TR-YBOCS-BDD in adolescent patients. The scale has strong internal consistency, a

two-factor structure and good converent. The adolescent version of TR-YBOCS-BDD have strong psychometric properties. The research trials with adolescents are supported by the study. Thus, clinicians and academicians in Turkish-speaking populations will be able to benefit from this TR-YBOCS-BDD.

Ethics

Ethics Committee Approval: This study was approved by the Bezmialem Vakıf University Local Ethics Committee (decision no: 20/375, date: 22.10.2019).

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Authorship Contributions

Surgical and Medical Practices: E.D.Ş., S.Y., N.K., T.Y., Concept: E.D.Ş., S.Y., T.Y., G.E., Design: E.D.Ş., S.Y., T.Y., G.E., Data Collection or Processing: E.D.Ş., S.Y., T.Y., Analysis or Interpretation: E.D.Ş., S.Y., N.K., T.Y., G.E., Literature Search: E.D.Ş., S.Y., N.K., T.Y., G.E., Writing: E.D.Ş., S.Y., N.K., T.Y., G.E.

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Original Article

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Effect of Chronic Non-specific Neck Pain on Aerobic Capacity in Females

Kadınlarda Kronik Non-spesifik Boyun Ağrısının Aerobik Kapasiteye Etkisi

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ABSTRACT

Objective: To examine the effect of chronic non-specific neck pain (NSNP) on maximal aerobic capacity (VO_{2max}) in females.

Methods: This study evaluated a total of 104 participants including 52 females aged 20-40 years who were diagnosed with chronic NSNP for at least 1 year (patient group) and 52 healthy females (control group). Mean age of the patient group was 31.04±5.65 years and of the control group was 31.33±5.10 years. Pain severity was evaluated with visual analog scale (VAS), neck disability degree with Neck Disability Index (NDI), and VO_{2max} with Bruce Protocol Treadmill Test.

Results: Mean VAS score was 5.86±1.11 cm and mean disease duration was 4.72±4.20 years in the patient group. There was no significant difference in terms of VO_{2max} level between the two groups (p>0.05). However, in the patient group, there was a moderate negative significant correlation between NDI value and VO_{2max} level (r=-0.344, p=0.012). In addition, there was a moderate positive significant relationship between pain duration (hours/day) and NDI value in the patient group (r=0.308, p=0.026).

Conclusion: As a result of the study, it was seen that there was no difference between the patient and healthy groups in terms of aerobic capacity. However, in the patient group, aerobic capacity decreased as the degree of neck disability increased. In the treatment of patients with neck pain, considering the respiratory dysfunction and the factors that cause it may contribute to the treatment processes.

Keywords: Cardiopulmonary exercise testing, disability evaluation, neck pain, pain measurement, respiration

ÖZ

Amaç: Bu çalışmanın amacı kadınlarda kronik non-spesifik boyun ağrısının aerobik kapasite üzerine etkisini incelemektir.

Yöntemler: Çalışmada non-spesifik boyun ağrısı tanısı almış, 20-40 yaş arası, en az 1 yıldır boyun ağrısı şikayeti olan 52 kadın ile 52 sağlıklı kadın olmak üzere toplam 104 birey değerlendirilmiştir. Hasta grubunun yaş ortalaması 31,04±5,65 yıl, kontrol grubunun yaş ortalaması 31,33±5,10 yıldı. Olguların, ağrı şiddeti; Görsel Ağrı Skalası, özürlülük düzeyleri; Boyun Özür Göstergesi (BÖG) ve aerobik kapasiteleri (VO_{2maks}); Bruce Treadmil Test Protokolü ile değerlendirilmiştir.

Bulgular: Hasta grubunda ağrı şiddeti ortalaması 5,86±1,11 cm, hastalık süresi ortalaması ise 4,72±4,20 yıldı. Hasta grup ile sağlıklı grup arasında VO_{2maks} değerleri arasında anlamlı farklılık yoktu (p>0,05). Ancak kronik boyun ağrılı bireylerde, BÖG skorları ile VO_{2maks} değerleri arasında negatif yönlü anlamlı ilişki bulundu (p=0,012). Ayrıca hasta grubunda gün içinde yaşanan ağrı süresi ile BÖG skorları arasında pozitif yönlü anlamlı ilişki tespit edildi (p=0,026).

Sonuç: Çalışma sonucunda hasta ve sağlıklı grup arasında aerobik kapasite açısından fark olmadığı fakat hasta grubunda boyun özürlülük derecesi arttıkça aerobik kapasitenin azaldığı görülmüştür. Boyun ağrılı hastalara yaklaşımlarda respiratuvar etkilenim ve buna neden olan faktörlerin göz önünde bulundurulması tedavi süreçlerine katkı sağlayabilir.

Anahtar Sözcükler: Kardiyopulmoner egzersiz testi, özürlülük değerlendirmesi, boyun ağrısı, ağrı değerlendirmesi, solunum

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Introduction

Neck pain is one of the most common complaints of the musculoskeletal system. Worldwide, 288.7 million cases of prevalent neck pain were reported in 2017 (1). Its annual prevalence ranges between 16.7% and 75.1% (2), with the prevalence increasing over time (3). Although the course of neck pain is usually characterized by exacerbation, symptoms do not completely resolve in most patients and the conditions in 5-10% of the patients become chronic (4). The state of pain and disability lasting for >12 weeks is classified as chronic neck pain (3). In cases wherein the underlying cause or specific disease cannot be identified in the vast majority of individuals with neck pain, non-specific neck pain (NSNP) leads to significant health and care costs, employee absenteeism and loss of productivity (5).

Chronic NSNP is a multifactorial disease that is associated with various dysfunctions in the cervical region and the adjacent structures (6). Because there is a close anatomical, musculoskeletal and neural connection between the cervical region and thoracic spine, it is reported that chronic neck pain may affect respiratory functions by causing biomechanical changes in the thoracic spine and thorax (7). In patients with neck pain, muscle weakness and fatigue, limitation of normal joint range of motion (ROM) in the cervical region, changing muscle activation patterns, pain, postural changes, loss of proprioception, and psychological conditions (such as anxiety, depression and kinesiophobia) can cause changes in vital capacity, functional vital capacity, respiratory muscle strength, blood chemistry, and rib cage/breathing pattern (8,9). Dimitriadis et al. (8), in their review in 2016; stated that changes in respiratory parameters such as maximal voluntary ventilation, partial arterial carbon dioxide pressure ($PaCO_2$), respiratory muscle strength and thoracic mechanics were consistently observed in all studies on neck pain and respiratory dysfunction, although there are respiratory indices for which the evidence provided conflicts. In another review conducted in 2017; a significant difference was observed in terms of maximal inspiratory pressure (PI_{max}), and maximal expiratory pressure (PE_{max}), in patients with chronic neck pain compared to asymptomatic patients, and it was reported that respiratory volumes and $PaCO_2$ were lower. Muscle strength, muscle endurance, cervical ROM, and psychological states; were found to be significantly associated with respiratory parameters. A significant relationship has been shown between chest expansion and neck pain (9).

VO_{2max}, an indicator of physical fitness, is mainly defined as the transport of O_2 and the ability of muscles to use O_2. It is associated with the functionality of cardiovascular, respiratory, and muscular systems as well as hematological components (10-12). Conditions affecting the function of these systems may also lead to changes in VO_{2max} in the long run. Given the respiratory effects in patients with neck pain, we think that aerobic capacity will decrease in patients with NSNP. There are studies in the literature that examine the relationship between neck pain and respiratory functions, insufficient data to examine the relationship between chronic NSNP and VO_{2max}. This study aimed to investigate the effect of chronic NSNP on VO_{2max}.

Methods

Study Design and Ethics

This cross-sectional study was conducted between February 2017 and May 2018. The study was conducted in accordance with the Helsinki Declaration. Ethics approval was received from Pamukkale University Non-Interventional Clinical Research Ethics Committee (date: 13.12.2016, number: 22). A written informed participant consent form was received from each participant in the study.

Participants

One hundred forty participants were evaluated in the study (patient group: 52 participants, control group: 52 participants).

Inclusion criteria for the patient group

- Diagnosis of chronic NSNP at the Brain and Nerve Surgery Outpatient Clinic of Pamukkale University Training and Research Hospital

- Chronic NSNP for ≥1 year

- Female, age between 20-40 years

- Pain severity of ≥4 the visual analog scale (VAS)

Inclusion criteria for the control group

- Age of 20-40 years and healthy

- Female sex

Exclusion criteria for the study

- Diagnosis of cardiopulmonary diseases

- Smoking habit

- Presence of traumatic cervical injuries

- Upper or lower respiratory tract infection within the past month

- Having received any physical therapy within the past year

- Regularly exercising habit

- Undergoing spinal and thoracic surgery

- Being obese [body mass index (BMI) ≥40 kg/m^2]

- Presence of clinical abnormalities of the thoracic cage and vertebral column

- Presence of neurological disease, diabetes mellitus and malignancies

- Presence of professional industrial risks or severe comorbidities

Regarding the patient group, the records of 4.538 females who presented to the Brain and Nerve Surgery Outpatient Clinic of Pamukkale University Training and Research Hospital due to neck pain during the past five years were reviewed. There were

438 patients who met the exclusion and inclusion criteria. Each patient was called and invited to participate in the study. Among these, the records of 56 females who agreed to participate were evaluated. Two of these patients were excluded from the study because they experienced pain in the lower back and knee during VO_{2max} testing. Additional two patients were excluded from the study because VO_{2max} measurement was not completed due to a technical problem of the device. The study was completed with a total of 52 patients (Figure 1).

Regarding the control group, 53 healthy females who met the criteria and agreed to participate in the study were evaluated. Among these, one female was excluded because VO_{2max} measurement could not be completed due to a technical problem of the device. The study was completed with 52 healthy participants (Figure 1).

Assessment Scales

Information such as age, sex, body weight and height, BMI, medications taken, disease history, working status, smoking and alcohol use and exercising habits of all participants was recorded using a prepared sociodemographic form. In addition, the frequency of pain (day/week) and duration of pain experienced during the day (hour/day) were recorded by questioning.

VAS was used to evaluate pain severity, Neck Disability Index (NDI) was used to evaluate the degree of neck disability and Bruce Protocol Treadmill Test was used to evaluate VO_{2max}.

VAS

VAS was used to assess pain severity. VAS is a valid and reliable measurement scale of chronic pain severity (13). VAS usually comprises two lines representing the extreme ends of pain severity (e.g., no pain and excessive pain) and a 100 mm distance between these two lines. Patients assess pain severity by leaving a mark on the line, representing pain severity. VAS scores are given by measuring the distance from the "no pain" end of the line (14).

NDI

To determine the degree of neck disability in patients with chronic neck pain, NDI was used. The Turkish version of this index, which was developed by Vernon and Mior (15) in 1991, was created by Aslan et al. (16) in 2008. NDI comprises ten parts: pain severity, personal care, lifting loads, reading, headache, concentration, work life, driving, sleep, and leisure. There are six possible answers for each part, with scores between 0 (no pain and no functional limitation) and 5 (worst pain and maximum limitation). At the end of the survey, the scores of the selected options are summed and the incapability's of the patients are determined. A score between 0 and 4 points indicates no disability, a score between 5 and 14 points indicates mild disability, a score between 25 and 34 points indicates severe disability and a score of >35 indicates complete disability (15,16).

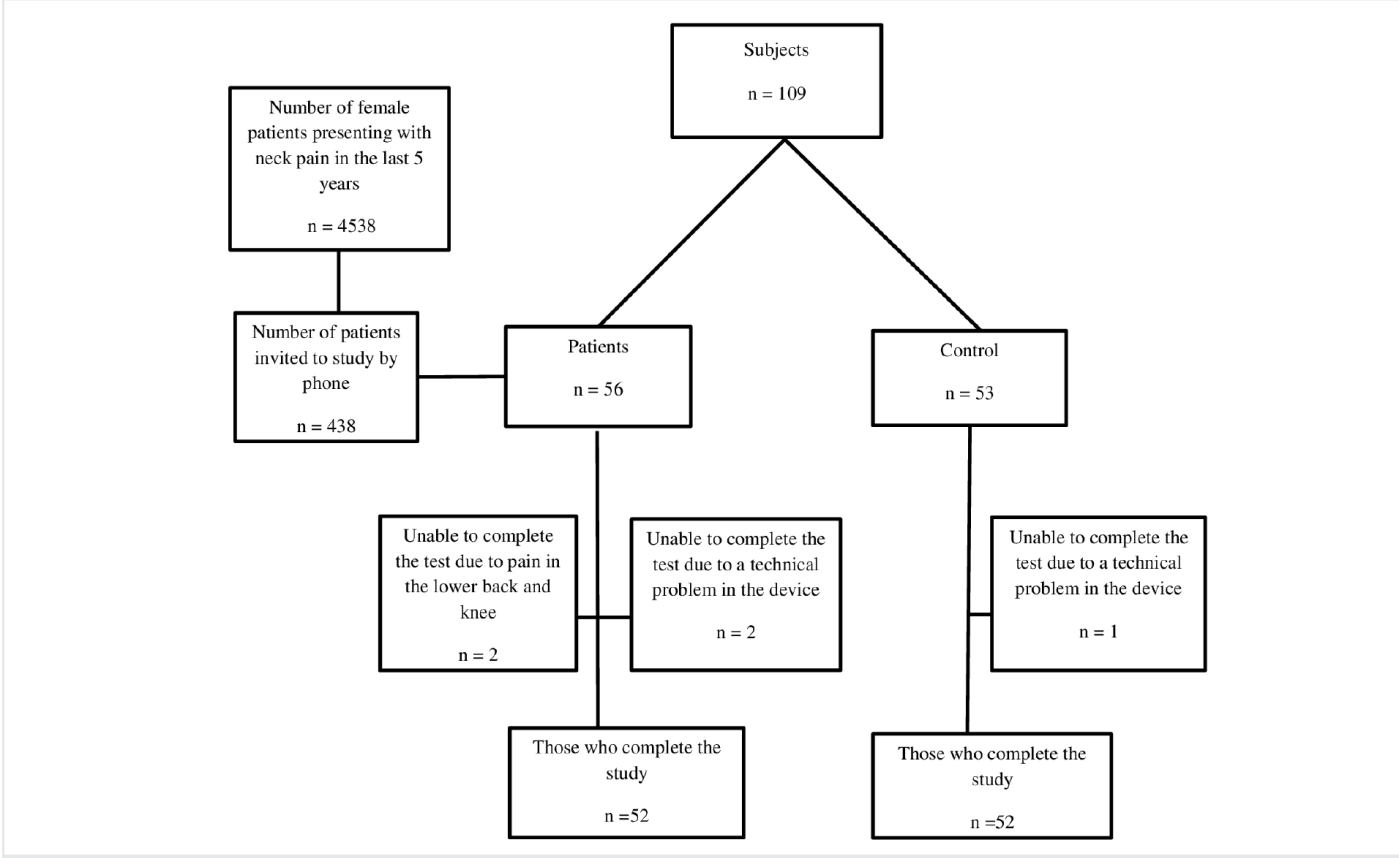

Figure 1. Flow chart of participant selection

Bruce Protocol Treadmill Test

The Bruce Protocol Treadmill Test was developed in 1963 by Bruce et al. (17). This protocol is one of the most common protocols used in clinics for the measurement of non-invasive estimated VO_{2max}. In the Bruce Protocol Treadmill Test, treadmill speed increases with 2-3 MET increments every three min (2% increase in slope). During this test, the participant is expected to reach the maximum possible speed (17-19).

After applying the Bruce Protocol Treadmill Test, the estimated VO_{2max} was calculated using this formula:

VO_{2max} (mL/kg/min) = 132.853 - (0.0769 × body weight) - (0.3877 × age) + (6.315 × sex) - (3.2649 - duration) - (0.156 x heart rate)

where body weight is measured in kilogram, female is scored 0 and male is scored 1, and duration is measured in min.

Before starting the test, the participants were provided the necessary information, and their blood pressure, resting heart rate, and oxygen saturation were measured. At the end of each level and at the end of the test, these measurements were repeated. Their heart rate at the end of the test was considered the maximum heart rate. The age-dependent VO_{2max} norm values for female gender are provided in Table 1.

Statistical Analysis

Data were analyzed using SPSS for Windows version 21.0 (IBM SPSS, Armonk, NY: IBM Corp.). Continuous variables are expressed as mean ± standard deviation and categorical variables as numbers and percentages. The normal distribution of data was examined by the Kolmogorov-Smirnov test. Because parametric test-based assumptions of all data were provided, the independent samples t-test was determined to compare differences between independent groups. Pearson's correlation analysis was performed to examine the relationship between continuous variables. In all analyses, a p value of <0.05 was considered statistically significant. The sample size was calculated using G*Power 3.1 (University Dusseldorf, Germany) software. In a study performed by Dimitriadis et al. (20), a significant difference was shown in the maximum voluntary ventilation values between subjects with chronic neck pain and healthy controls, with an effect size of 0.58. Accordingly, we calculated that a total of 104 subjects (patient group: 52, control group: 52) should be included with 95% confidence level and 90% power in this study.

Results

The demographic and clinical characteristics of the participants are given in Table 2. There were no significant differences between the two groups in terms of demographic data (p≥0.05, Table 2).

VO_{2max} level was measured in both groups, and VO_{2max} levels were grouped according to age range. Accordingly, in the patient group, 22 participants (42.3%) had moderate VO_{2max} level, 14 (26.9%) had adequate VO_{2max} level, 14 (26.9%) had good VO_{2max} level and 2 (3.8%) had low VO_{2max} level (Table 2). In the control group, 20 participants (38.5%) had moderate VO_{2max} level, 15 (28.8%) had adequate VO_{2max} level, 15 (28.8%) had good VO_{2max} level and 2 (3.8%) had low VO_{2max} level (Table 2). The mean VO_{2max} level of the patient group (31.82±6.37) was slightly lower than the control group (32.06±5.97) and there were no a significant difference (p=0.943; Table 2).

In the patient group, there was a moderate positive correlation between NDI value and pain duration (r=0.308, p=0.026). In addition, there was a moderate negative correlation between NDI value and VO_{2max} level (r=-0.344, p=0.012; Table 3).

Discussion

This study focused on investigate to the aerobic capacity in people with chronic NSNP complaints by comparing them to healthy people. In this study, a significant positive relationship was found between the degree of neck disability and the duration of pain experienced during the day. When the VO_{2max} was examined, a negative relationship was observed between the degree of neck disability and VO_{2max} in the patient group, although there was no difference between the groups in terms of VO_{2max}. The increase in the degree of neck disability appears to be associated with a decrease in aerobic capacity.

In this study, the entire patient group had a mild to severe degree of neck disability. In addition, the increased degree of neck disability was associated with increased pain duration during the day. Several studies have reported that various physical and biomechanical factors are associated with the degree of neck disability (21-24). Yip et al. (22) found that increased forward head position was moderately associated with the degree of neck

Table 1. Age-dependent VO_{2max} levels for females

VO_{2max} (mL/kg/min) Age groups (years)	Low level	Adequate level	Moderate level	Good level	High level
20-29	<24	24-30	31-37	38-48	>49
30-39	<20	20-27	28-33	34-44	>45
40-49	<17	17-23	24-30	31-41	>42
50-59	<15	15-20	21-27	28-37	>38
60-69	<13	13-17	18-23	24-34	>35

VO_{2max}: Maximal aerobic capacity, mL: Milliliter, kg: Kilogram, min: Minimum

disability. Tsang et al. (23) compared the muscle activations of healthy people and people with neck pain during movement and found significant differences in the activation patterns of multiple cervical and thoracic muscles. They reported that this was significantly associated with pain level and functional limitation. Young et al. (24) showed that psychological conditions such as depression and somatization were strongly associated with disability (NDI) in patients with neck pain. In our study, as the duration of pain experienced during the day increased in people with neck pain, it may have caused a limitation in daily activities

Table 2. Demographic and clinical characteristics of the participants

Demographic and clinical characteristics	Patient group (n=52)	Control group (n=52)	
	X ± SD	X ± SD	p*
Age (years)	31.04±5.65	31.33±5.10	0.417
Weight (kg)	64.76±10.54	66.67±12.25	0.428
Height (cm)	164.38±5.75	162.46±5.84	0.993
Body mass index (kg/m²)	23.93±3.56	25.23±4.52	0.205
Occupation			
Student	7 (13.5%)	6 (11.5%)	0.953
Housewife	20 (38.5%)	20 (38.5%)	
Employee	25 (48.1%)	26 (50%)	
Disease duration (years)	4.72±4.20	n/a	-
Pain duration (hours/day)	19.54±13.46	n/a	-
VAS (cm)	5.86±1.11	n/a	-
NDI	13.92±4.91	n/a	-
Degree of neck disability			
No disability	-		
Mild disability	26 (50%)		
Moderate disability	25 (48.1%)		
Severe disability	1 (1.9 %)	n/a	-
Complete disability	-		
VO_{2max} (mL/kg/min)	31.82±6.37	32.06±5.97	0.943
VO_{2max} level			
Low level	2 (3.8%)	2 (3.8%)	0.983
Adequate level	14 (26.9%)	15 (28.8%)	
Moderate level	22 (42.3%)	20 (38.5%)	
Good level	14 (26.9%)	15 (28.8%)	
High level	-	-	

SD: Standart deviation, NDI: Neck Disability Index, VAS: Visual analog scale, kg: Kilogram, cm: Centimeter, VO_{2max}: Maximal aerobic capacity, n/a: Not applicable
*Independent samples t-test

Table 3. Relationship between VO_{2max} level, disease duration, pain duration, pain severity and NDI value in the patient group

Variable	Disease duration (years)	Pain duration (hours/day)	Pain severity	NDI value
Disease duration (years)				
Pain duration (hours/day)	r=−0.048 p=0.735			
Pain severity	r=0.226 p=0.107	r=0.153 p=0.278		
NDI value	r=0.095 p= 0.503	**r=0.308*** **p=0.026**	r=0.245 p=0.080	
VO_{2max}	r= 0.047 p=0.743	r=-0.211 p=0.134	r=-0.101 p=0.477	**r=-0.344*** **p=0.012**

NDI: Neck Disability Index, VO_{2max}: Maximal aerobic capacity
* Pearson correlation analysis

by causing avoidance of movement, and thus an increase in disability.

In this study, it was found that there was a decrease in VO_{2max} level due to an increased degree of neck disability in the patient group. For aerobic capacity, it is necessary to evaluate all the factors that determine the effectiveness of the oxidative mechanisms of the muscles during physical activity, such as the functionality of the cardiovascular, respiratory and muscular systems, and hematological components (10-12). Therefore, changes in the function of the respiratory system can also affect aerobic capacity (10-12,25). Some studies have shown a strong relationship between the cervical region and associated pathologies and respiratory dysfunctions in chronic NSNP. PImax, PEmax, inspiratory capacity, expiratory volume, FEV1 and FVC values and $PaCO_2$ significantly decreased in individuals with chronic NSNP compared with healthy individuals (9,26-30). Chronic neck pain by hyperventilation, leading to respiratory dysfunction; may cause a blood chemistry compensation similar to that observed in chronic respiratory patients (8). Impairment of oxidative mechanisms at any level leads to a decrease in O_2 intake (12). The decrease in the amount of O_2 carried in the blood can cause premature fatigue in the respiratory muscles and affect VO_{2max} over time (8).

In addition, respiratory dysfunction may also develop due to psychological conditions such as anxiety, depression, kinesiophobia, or catastrophobia and accompanying changes such as altered breathing pattern. Patients' avoidance of cervical movements due to pain and psychological factors may lead to movement inhibition, resulting in changes in thoracic cage mechanics and respiratory dysfunction (8). This avoidance may also affect aerobic capacity by causing a decrease in the physical activity level of individuals. Although not evaluated in our study, we think that physical inactivity may be one of the reasons for the decrease in VO_{2max} level with the increase in the degree of neck disability in the patient group in this study. Mihailova and Kaminska (31) reported that the amount of weekly physical activity in students aged 20-36 years has a positive correlation with VO_{2max} and high lung volumes. In addition, in a 1-year prospective cohort study; It was reported that there was a negative significant relationship between the number of daily walking steps and the onset of neck pain in sedentary workers (32).

In this study, it was found that there was a decrease in VO_{2max} level due to increased degree of neck disability in the patient group but there was no difference between the patient and healthy groups in terms of VO_{2max}. To the best of our knowledge, there is only one study investigating the relationship between chronic NSNP and VO_{2max}. Yalcinkaya et al. (33) examined physical fitness parameters in 80 patients with chronic NSNP and 80 matched healthy individuals and similarly noted that there was no difference in terms of VO_{2max} levels among females in both groups. We believe that the reason why there was no difference between the two groups in our study may be because the pain severity was not very high in the patient group. In a study published in 2018, moderate/severe disabled patients with chronic NSNP, mildly disabled patients and healthy individuals were compared in terms of cervical motor function and respiratory muscle strength, and it was reported that there was a difference between only moderate/severe disability group and healthy group (34). Perry et al. (35) showed that severe pain in females with chronic NSNP is associated with decreased VO_{2max} level. In addition, the very young age group included in our study may be the reason why no difference was found with healthy controls. VO_{2max}; it is a parameter that changes depending on age, and physical activity, which decreases with increasing age, also has an effect. Pulmonary function and aerobic capacity decrease by about 40% between the ages of 25 and 80. Studies show that VO_{2max} decreases between 0.2 and 0.5 mL.min-1kg-year-1 (~0.5% per year) after the age of 30, and this decrease may accelerate after the age of 40-50 (25).

The strength of the present study is that, to the best of our knowledge, it is the first study to examine the relationship among pain parameters, degree of neck disability and VO_{2max} in chronic NSNP. It was conducted only among females, which increases its importance in the literature. It has been reported in the literature that female gender is one of the risk factors for NSNP (3). The prevalence of chronic neck pain, the burden of neck pain and the number of years lived with disability are higher in female gender than male gender (36,37). In addition, VO_{2max} level decreased with advanced age (25). In this regard, the enrolment of a young population is important to eliminate the effect of other factors that reduce VO_{2max} level. The limitations of present study are that there is no comparison between the genders, the fatigue levels of the individuals are not evaluated, and the severity of pain in our patient group is moderate. Patients with a higher mean pain severity should be included in future.

Conclusion

In conclusion, it has been found that aerobic capacity decreases due to an increase in the degree of neck disability in people with chronic NSNP complaints. Effects of respiratory dysfunction should be taken into account in approaches for people with chronic NSNP. Chronic NSNP and associated respiratory effects may lead to a decrease in the physical activity levels in daily lives due to reasons such us pain, kinesiophobia, catastrophobia and muscle fatigue, thereby reducing VO_{2max} level in the long run. Because there is insufficient data in the literature to examine the relationship between chronic NSNP and VO_{2max}, further randomized controlled studies are needed to cover this deficiency.

Ethics

Ethics Committee Approval: Ethics approval was received from Pamukkale University Non-Interventional Clinical Research Ethics Committee (date: 13.12.2016, number: 22).

Informed Consent: A written informed participant consent form was received from each participant in the study.

Peer-review: Externally peer reviewed.

Authorship Contributions

Concept: Ö.M., F.A., O.T.A. Design: Ö.M., F.A., O.T.A. Data Collection or Processing: Ö.M. Analysis or Interpretation: Ö.M., F.A. Literature Search: Ö.M. Writing: Ö.M., F.A.

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Original Article

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The Effects of Virtual Reality and Kaleidoscope on Pain and Fear During Blood Draw in Children: A Randomized Controlled Trial

Çocuklarda Kan Alma Sırasında Sanal Gerçeklik ve Kaleideskopun Ağrı ve Korkuya Etkisi: Randomize Kontrollü Bir Çalışma

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ABSTRACT

Objective: This study was carried out to determine the effect of cartoon watching with virtual reality (VR) glasses and kaleidoscope used during blood draw on the pain and fear of children.

Methods: The universe of this randomized controlled study was composed of 7-12-year-old children who were admitted to blood draw unit of a hospital between January-April 2020. Data of the study were collected by using "Participant Information Form", "Visual Analog Scale", "Wong-Baker FACES Pain Rating Scale" and "The Children's Fear Scale (CFS)."

Results: Mean pain scores of the children in kaleidoscope and VR groups were found to be significantly lower than the ones in the control group in the study ($p<0.05$). Mean fear scores of the children in kaleidoscope and VR groups were significantly lower than the control group based on CFS ($p<0.05$).

Conclusion: It was concluded that kaleidoscope and VR methods were found to be effective in alleviating pain and fear among 7-12-year-old children during blood draw.

Keywords: Acute pain, virtual reality, kaleidoscope, vascular access, child, nursing

ÖZ

Amaç: Bu araştırma çocuklara kan alma işlemi esnasında uygulanan kaleidoskop ve sanal gerçeklik (VR) gözlüğü ile çizgi film izletme yöntemlerinin, çocukların ağrı ve korku durumuna etkisini belirlemek amacıyla yapılmıştır.

Yöntemler: Bu randomize kontrollü çalışmanın evreni bir hastanenin çocuk kan alma birimine Ocak-Nisan 2020 tarihleri arasında başvuran 7-12 yaş arası çocuklar oluşturmuştur. Araştırmanın verileri "Tanıtıcı Bilgi Formu", "Visual Anolog Scale", "Wong-Baker Yüz İfadeleri Derecelendirme Ölçeği" ve "Çocuk Korku Ölçeği (ÇKÖ)" ile toplanmıştır.

Bulgular: Araştırmada kaleidoskop grubu ve VR gözlüğü grubundaki çocukların ağrı puan ortalamaları kontrol grubuna göre anlamlı derecede düşük bulunmuştur ($p<0,05$). Kaleidoskop grubu ve VR gözlüğü grubundaki çocukların ÇKÖ'ye göre puan ortalamaları kontrol grubuna göre anlamlı derecede düşük bulunmuştur ($p<0,05$).

Sonuç: Yedi-on iki yaş arası çocuklara kan alma işlemi sırasında uygulanan kaleidoskop ve VR gözlüğü yöntemlerinin çocukların ağrı ve korku düzeylerini azaltmada etkili olduğu bulunmuştur.

Anahtar Sözcükler: Akut ağrı, sanal gerçeklik, kaleideskop, damar yolu, çocuk, hemşirelik

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Introduction

Children's reactions to the hospital environment and the disease are closely related to the painful medical procedures applied for diagnosis and treatment (1). Children who fear the unknown and perceive that their control is under threat experience the fear that the medical procedures performed on them in the hospital will hurt them and they worry that these procedures will harm them (2). Children are exposed to many medical procedures such as venous blood draw during their lives. Pain, that is experienced during invasive interventions, is generally perceived as a scary experience by the children and shapes future pain responses of the individual (3). It is highly important to make pain experiences less traumatic during childhood. Non-pharmacological methods are among the techniques that can be applied effectively for acute pain as well as chronic pain (4,5). Distraction is an active coping strategy whereby a patient diverts his or her attention from nociceptive stimuli to decrease awareness of the pain. Distraction is often used during medical procedures for managing pain (6). In literature review, many studies have been found to support positive effects of various distraction methods in the alleviation of pain and fear created by invasive procedures (3,7,8). Among these methods, there are watching cartoon, inflating balloon, distracting with non-interventional conversations, using virtual reality (VR) glasses, listening to music, using kaleidoscope and distraction cards (3,8-10). Kaleidoscope is a playing material where colorful patterns are seen inside (11). VR glasses are technological products that are attached to the patient's head to isolate him/her from real life and that enable to watch the prepared images inside larger and clearer in 3-dimensions with its special lenses (4,8). They have a relaxing and pain-relieving effect on the patient due to its distractive ability (11,12). Although it has been supported with the studies in the literature how these methods should be according to cognitive development level, the search for the most suitable ones according to the age groups still continues. In this context, there are a limited number of studies in the literature on reducing the pain and fear of school-age children through distraction techniques. It is known that children in this age group, unlike previous age groups, need detailed information about procedures in addition to family support. In addition, it is important to choose distraction techniques to be used in this age group, which is interested in technological tools and willing to learn. It is important that the methods to be chosen appeal to more than one sense, arouse curiosity and be interesting (2,13). Therefore, this study was carried out to determine the effects of kaleidoscope and cartoon watching using the VR glasses on the pain and fear states of children during blood draw.

Methods

Study Design

This study was planned as a three-group randomized controlled intervention trial.

Setting and Sample

This study was carried out with 7-12-year-old children who were admitted to blood draw unit of a hospital in Turkey between January 21-April 21, 2020. G*Power 3.0.10 program was used to calculate sample size. Power of the study was determined as 0.95 at a confidence interval of 0.95, significance level of 0.05 and an effect size of 0.1 (small effect) by using One-Way ANOVA to compare three groups through G*Power 3.0.10 program. Sample size was calculated as 156 including 52 individuals per each group in the study. However, 2 children were lost in all groups due to the inability to draw blood with one entry and data were completed with a total of 150 children. Groups were generated by using randomization method. Randomization method was determined by using an online program provided that the number of children in study and control groups regardless of the characteristics of the children such as age and sex. The variables of age (7-12 years), gender (girls and boys) were used for block randomization. The blocks were repeated five times in each group, and 50 participants were assigned to each. A 5X2X5 blocked randomization list was developed using an online randomization tool (14). The researcher was not blinded to the group allocation because she performed the randomization herself. Randomization list was prepared by a third individual and given to the researcher only during the implementation.

The inclusion criteria were (1) being between the ages of 7 to 12 years, (2) being literate, and (3) requiring blood tests. The exclusion criteria were (1) having chronic diseases, (2) hospital stay for treatment, (3) visual, audio, or speech impairments, (4) mental disorders, (5) history of sedative, analgesic, or narcotic use within 24 h before admission.The study protocol prepared on the basis of the literature (4,6,8) was reviewed and the trial was registered through Clinical Trials.gov (NCT05564260)."

Hypotheses of the Study

H_0: There are no significant differences in the mean pain and fear scores of the children who have used kaleidoscope and watched cartoon using VR glasses.

H_1: Mean pain and fear score of the children who have used kaleidoscope during blood draw is lower than the ones who have not.

H_2: Mean pain and fear score of the children who have used VR glasses during blood draw is lower than the ones who have not.

Data Collection

Participant Information Form: This form included sociodemographic characteristics (age, sex, presence of chronic disease) of the children.

Visual Analog Scale (VAS): VAS developed by Hayes and Patterson (15) is used to measure and monitor pain intensity. VAS, which is used to measure severity of pain consists of a horizontal or vertical ruler at a length of 10 cm or 100 mm which has "no pain" on one side and "the most severe pain possible" on the other side. While there is "no pain" expression on the left side of the ruler, there is "unberable pain" expression on the right side. VAS is described as understandable and easy-to-use for the children over 7 years old (16). Its validity and reliability have been shown in the previous studies (17-19).

Wong-Baker FACES Pain Rating Scale (FACES): The scale is commonly used for children aged 3 to 18 years (20). Besides, the psychometric properties of the Wong-Baker is suitable for evaluating parent proxy (21). It has been translated into many languages including Turkish (22). In this numerical rating scale, scores given by the child range between 0 and 10. Faces show emotions from smiling (0= very happy/no pain) to crying (10= the most painful) (14). In this study, children were assessed by the researcher and nurse in the clinic during post-procedure period. FACES is a commonly used scale to evaluate pain in pediatric group in Turkish population (11,13).

The Children's Fear Scale (CFS): This is a one-item self-report scale which is used to measure pain-associated fear. CFS was developed by McMurtry et al. (23), and adapted to Turkish by Özalp Gerçeker et al. (9). This one-item scale is composed of five neutral faces in terms of sex. There is a face showing no fear on the left and a face showing extreme fear on the right. The response of the evaluator shows the level of fear. It can be used by the parents and researchers before and during the procedure for the children aged 5-10 years old (23,24). Psychometric properties of the scale in Turkish population were carried out by Özalp Gerçeker et al. (24). Fear scale was assessed before and after the blood draw by the child, parent and researcher during the study (24).

Kaleidoscope

Kaleidoscope is an instrument that shows colorful patterns when viewed. When looked inside, patterns that are retrieved by the reflection of light from two mirrors adjacent to each other with an angle of 60 degrees are seen. Created using mirrors and reflected light, these patterns continuously change as glass is turned. These patterns in different shapes draw the attention of the children and provide distraction (11,25).

Virtual Reality Glasses

VR are technological products that provide 360-degree audio visual simulation that surround the user and allow them to look around in all directions (2,5). In this study, the VR intervention was performed using a smartphone (Samsung Note 4), VR glasses BOX 3D/Fuchsia7/20x11x13 in./weigh 550 g) and a headset (Samsung Galaxy, microphone, Bluetooth, wired). While using VR, there is no need for any power or connection unit other than the phone. All children in the study were made to watch the same video (Puss in Boots The Three Musketeers/Looney Tunes Road Runner) recommended by the experts based on children ages. Five children between 7-12 years old were made to watch selected videos before starting the study. There was no negative feedback.

Procedures

Before venous blood draw: The method to be used during blood draw was explained to the child and parent by the researcher; and measurement tools to be scored were introduced during the procedure. The parents were told to be with their children in the room and to observe them during the procedure. CFS scoring was done by the children, one parent and the researcher in all groups before blood draw. Intervention groups were introduced kaleidoscope and VR and they were told how to use them and they would watch these materials during the procedure.

At 2-3 minutes before blood draw: Children in the kaleidoscope group were given kaleidoscope and they were made to watch it during the procedure. VR group was made to choose one of the different videos/cartoons found in the phone for the implementation of VR glasses. The glasses were put on as soon as the child sit on the armchair and he/she was made to watch 3D video during the procedure. The parts of the device which were in contact with children's faces were cleaned before each practice. Control group received routine venous blood draw in the clinic and no other intervention was made.

Following venous blood draw: Children in all groups were made to score VAS and FACES for pain level and CFS for fear level during the procedure. A parent and researcher who stayed besides the children and observed them determined their pain and fear levels and scored FACES for pain and CFS for fear. Venous blood draw was performed by an experienced nurse in all groups (Figure 1).

Ethical Considerations

The study was conducted after formal permissions for the study were obtained from the Directorates of the Ondokuz Mayıs University Hospitals and the Ethic Commission of university hospital (approval number: KAEK 2019/846, date: 12.12.2019).

Before the launch of the research, parents and children were informed about the subject and the objectives of the research and parents' written consent and children's verbal assents were obtained (clinicaltrials: NCT05564260).

Statistical Analysis

Data were analyzed by IBM SPSS V23 (SPSS Inc., Chicago, IL, USA). Normality assumption was tested by Kolmogorov-Smirnov and Shapiro-Wilk tests. Chi-square was used to compare categorical variables between the groups. Mann-Whitney U test was used to compare non-parametric variables in two independent groups. Non-parametric quantitative data in three and more groups were compared by Kruskal-Wallis test. Moreover, Wilcoxon test was used to compare non-parametric variables before and after the procedure within the groups. Dunnett's T3 pairwise comparison post hoc test was used to determine significant differences in the case of unequal variances. Significance level was considered as $p<0.050$.

Results

It was determined that the distribution of sex and age of the children according to the groups was homogenous (Table 1).

Table 2 shows the comparisons of mean pain scores. When VAS values were compared between the groups, it was determined that mean pain scores of kaleidoscope and VR groups were lower than the control group and the difference was found to be statistically significant ($p<0.001$). When FACES pain scores were compared between the groups, mean pain score of the control group was found to be higher than the other groups and the difference was found to be statistically significant ($p<0.001$) (Table 2).

Table 3 shows the comparisons of mean fear scores of the child, parent and researcher. Accordingly, no statistically significant difference was observed between the groups before blood draw according to the child, parent and researcher (p>0.05). It was found that mean fear score was higher in the control group compared to the other two groups following blood draw, and the difference was statistically significant (p<0.05). The statistically significant difference was found between the fear scores before and after the procedure in each group. It was determined that the mean fear score was the lowest in the VR group followed by the kaleidoscope group and the control group, respectively (p<0.001).

Discussion

In this study, the effects of kaleidoscope and VR glasses methods used during blood draw on the pain and anxiety of 7-12-year-old children were investigated and some of the distraction methods found in the literature which were used in various areas such as blood draw and other invasive procedures were discussed.

In the study, it was determined that VR group was more effective than control group in alleviating pain and fear. Similar results have been reported in many studies in the literature. It was also found that interventions such as VR reducing pain during the blood draw was effective in reducing perceived pain in children of various age groups (8,12,26,27). Özalp Gerçeker et al. (13) compared two different VR methods and revealed that both methods were effective in alleviating pain of children during blood draw based on the reports by the child, parent and researcher. In the study by Gold and Mahrer (12) which was carried out with 143 children and adolescents between 10-21 years, it was found that pain scores of the children in the study group using VR glasses were lower than the scores of children in the control group. Also in the study by Piskorz and Czub (28) with pediatric nephrology patients between 7-17 years, VR was found to decrease pain intensity and stress level significantly. Moreover, Dumoulin et al. (6) reported that VR was effective in reducing pain among 8-17-year-old children during blood draw in the emergency service. VR was also reported to be effective in

Table 1. Sex and age characteristics of the children according to the groups

Characteristic		Kaleidoscope group		VR group		Control group		X^2	p
		n (%)		n (%)		n (%)			
Sex	Female	27 (54.0)		25 (50.0)		26 (52.0)		0.160[1]	0.923
	Male	23 (46.0)		25 (50.0)		24 (48.0)			
		$\bar{X}$ ± SD	Min.-max.	$\bar{X}$ ± SD	Min.-max.	$\bar{X}$ ± SD	Min.-max.		
Child's age		9.2±1.6	7-12	8.9±1.4	7-12	9.1±1.4	7-12	0.590[2]	0.745

$\bar{X}$ ± SD: Mean ± standard deviation, min.: Minimum, max.: Maximum, [1]Chi-sqaure test, [2]Kruskal-Wallis test, p<0.05, VR: Virtual reality

Table 2. Comparisons of mean VAS, FACES scores between kaleidoscope, VR and control groups

Characteristic	Kaleidoscope group[a]; mean ± SD (min.-max.)	VR group[b]; mean ± SD (min.-max.)	Control group[c]; mean ± SD (min.-max.)	Test statistic, (p)
VAS	0.8±1.3 (0-7)	1±1.7 (0-8)	3±2.5 (0-9)	KW: 35.750, p<0.001 *a<b, p>0.909 *a<c, p=0.000 *b<c, p=0.000
FACES-child reported	0.6±0.9 (0-4)	0.4±0.7 (0-3)	1.9±1.5 (0-5)	KW: 36.836, p<0.01 *a>b, p>0.691 *a<c, p=0.000 *b<c, p=0.000
FACES-parent reported	0.8±0.9 (0-4)	0.6±0.8 (0-3)	2±1.5 (0-5)	KW: 25.366, p<0.01 *a>b, p>0.793 *a<c, p=0.000 *b<c, p=0.000
FACES-researcher reported	0.8±1 (0-4)	0.5±0.8 (0-4)	1.9±1.6 (0-5)	KW: 26.927, p<0.001 *a>b, p>0.272 *a<c, p=0.000 *b<c, p=0.000

*Post-hoc test=Dunnett T3 p<0.05, VAS: Visual Analog Scale, FACES: Wong-Baker FACES Pain Rating Scale, VR: Virtual reality, KW: Kruskal-Wallis, SD: Standard deviation, min.: Minimum, max.: Maximum

Table 3. Comparisons of mean CFS scores between kaleidoscope, VR and control groups

CFS		Kaleidoscope group[a]; mean ± SD (min.-max.)	VR group[b]; mean ± SD (min.-max.)	Control group[c]; mean ± SD (min.-max.)	Test statistic, (p)
Self reported	Pre	2.0±1.1 (0-4)	2.4±1.1 (0-4)	2.2±1.1 (0-4)	3.564; 0.168
	Post	0.8±0.9 (0-4)	0.3±0.6 (0-3)	1.5±1.3 (0-4)	**23.961; <0.001** *a>b, p>0.016 *a<c, p=0.009 *b<c, p=0.000
	Diff.	1.2±1.3 (-2-4)	2.1±1.1 (0-4)	0.7±0.8 (-1-3)	36.782; <0.001
Parent reported	Pre	2.4±1.3 (0-4)	2.2±1.1 (0-4)	2.4±1.2 (0-4)	0.622; 0.733
	Post	1.0±1.0 (0-4)	0.6±0.7 (0-3)	2.4±1.2 (0-4)	**10.889; 0.004** *a>b, p>0.103 *a<c, p=0.049 *b<c, p=0.000
	Diff.	1.4±1.4 (-2-4)	1.6±1.1 (-1-4)	0.8±0.9 (0-3)	13.391; <0.001
Observer reported	Pre	2.5±1.3 (0-4)	2.3±1.1 (0-4)	2.2±1.1 (0-4)	1.488; 0.475
	Post	0.9±1.1 (0-4)	0.5±0.7 (0-3)	1.4±1.4 (0-4)	**14.850; <0.001** *a>b, p>0.039 *a<c, p=0.122 *b<c, p=0.000
	Diff.	1.5±1.4 (-3-4)	1.8±1.1 (0-4)	0.8±0.8 (0-3)	21.120; <0.001

*Post-hoc test=Dunnett T3 p<0.05, SD: Standard deviation, KW: Kruskal-Wallis, CFS: Children's Fear Scale, VR: Virtual reality, SD: Standard deviation, min.: Minimum, max.: Maximum

alleviating pain, fear and anxiety during some invasive procedures such as vaccination, dental procedures and changing dressing in wound and burn cases (29-31). Our research findings are similar to the results reported in the literature.

In the study, it was determined that distraction by using kaleidoscope during blood draw was effective in alleviating the level of perceived pain. Also in the previous studies, various distraction methods and kaleidoscope were reported to be effective in alleviating pain, anxiety and fear among children during blood draw (6,11,25,32,33). Karakaya and Gozen (25) reported that distraction by using kaleidoscope during blood draw from 7-12-year-old children was effective in alleviating their perceived pain. Kunjumon and Upendrababu (32) also showed that kaleidoscope was effective in managing pain during intravenous cannulation among 4-6-year-old children. Canbulat et al. (11) found that distraction cards and kaleidoscope were effective in alleviating perceived pain compared to control group among 7-11-year-old children. Moreover, the study by Prajapati (33) showed that kaleidoscope was more effective in alleviating pain during blood draw compared to the control group. In their study, Tüfekçi Güdücü et al. (34) determined that kaleidoscope method was effective in reducing pain during blood draw among school age children. Also, Bulut et al. (35) investigated the effects of music therapy, hand massage and kaleidoscope use following circumcision on nausea, vomiting, fear and stress in their study; and reported that mean postoperative pain scores in kaleidoscope and music group were lower than the control group and fear and anxiety scores were lowest in the kaleidoscope group. In addition, Koç Özkan and Polat (36) reported that kaleidoscope and VR use during blood draw had positive effects on pain and anxiety compared to control group among 4-10 year old children.

Our results showed that VR was an effective method that helped reduce venipuncture fear in children. In the study by Koç Özkan and Polat (36), it was found that VR was more effective on the pain and anxiety compared to kaleidoscope according to the child, parent and researcher. In a randomized clinical trial by Walther-Larsen et al. (37), the effect of VR pain reduction during venipuncture was investigated in children aged 7 to 16 years, and it was found not effective on pain. A systematic review and meta-analysis of the effect of VR on pain and anxiety in children conducted and suggested that more research was warranted (38). In addition, most VR manufacturers do not recommend the use of VR in children younger than the age of 6 years due to their neurodevelopmental characteristics (39). Therefore, it can be concluded that VR is more effective in children aged 7 years and older.

Study Limitations

There were some limitations in this research. First of all, the study was carried out at a single hospital and on 7-12-year-old children, which made the generalization of the study results limited. Secondly, before conducting the study, children in the VR group were informed by the researcher about the purpose of the study. This explanation might have relieved children's fear about the procedure, so they might have experienced less pain. Third, the sample size was small, and therefore, the results were sample-specific and not generalizable to all venipuncture procedures in children.

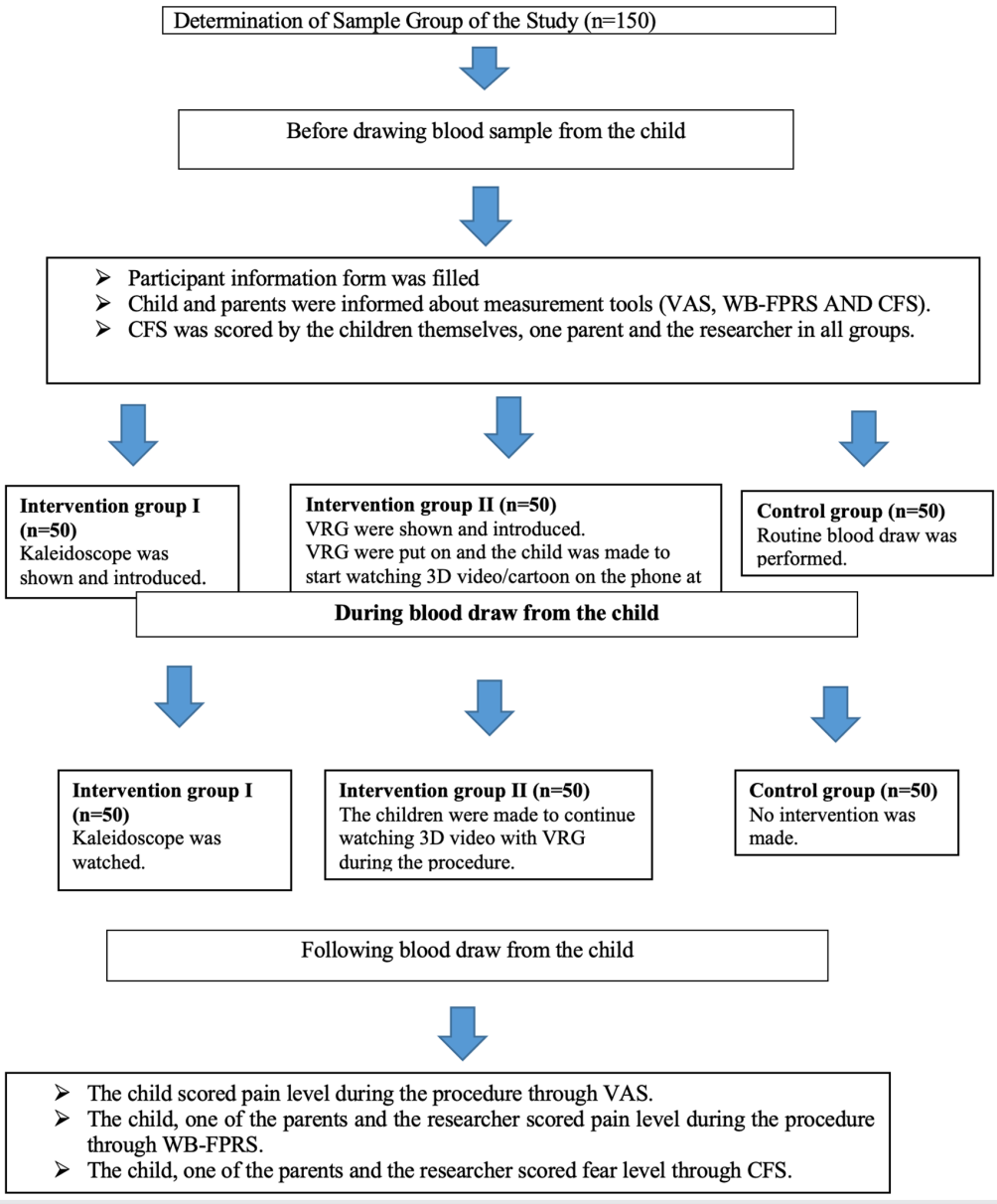

Figure 1. Flowchart based on the CONSORT diagram

VAS: Visual Analog Scale, WB-FPRS: Wong Baker-FACES Pain Rating Scale, CFS: Children's Fear Scale, VRG: Virtual reality glasses

Conclusion

In the study, kaleidoscope and VR groups were found to be effective in alleviating pain and fear levels compared to the control group according to the child, parent and researcher. Moreover, VR was observed to be more effective in reducing fear levels compared to the kaleidoscope group. Although VR was an effective tool, it would be more efficient to use it together with another non-pharmacological or/and pharmacological method so that the method could give more favorable results. Many relevant studies in the literature have reported similar outcomes; and it can be stated that kaleidoscope and VR can be safely used as a distraction method for alleviating pain and fear in children during invasive procedures.

The results of the present study might contribute to the use of evidence-based and non-pharmacological pain management methods for pediatric nurses. Based on the results, it is recommended to inform nurses and other healthcare professionals working in the pediatric units about the use of VR and kaleidoscope, to make the use of them more common during invasive procedures and to conduct evidence-based studies. Randomized controlled trials are required to increase the level of evidence of VR and kaleidoscope method. Further research should be conducted in different age groups, and VR and kaleidoscop effect should be compared with other distraction methods.

Ethics

Ethics Committee Approval: The study was conducted after formal permissions for the study were obtained from the Directorates of the On Dokuz Mayıs University Hospitals and the Ethic Commission of university hospital (approval number: KAEK 2019/846, date: 12.12.2019).

Informed Consent: Before the launch of the research, parents and children were informed about the subject and the objectives of the research and parents' written consent and children's verbal assents were obtained.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: N.T., Concept: E.T.B., Design: E.T.B., Data Collection or Processing: N.T., E.T.B., Analysis or Interpretation: N.T., E.T.B., Literature Search: N.T., E.T.B., Writing: N.T., E.T.B.

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Original Article

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Evaluation of Filling Quality of Obturation Techniques in Internal Resorption Cavities Created with a Novel Methodology

Yeni Bir Metodoloji ile Oluşturulan İnternal Rezorpsiyon Kavitelerinde Dolum Tekniklerinin Doldurma Kalitesinin Değerlendirilmesi

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ABSTRACT

Objective: The aim of this study was to evaluate the impact of filling irregularly bounded internal resorption cavities created by acid demineralization using different filling techniques on the quality of the filling.

Methods: A total of 54 extracted single-rooted teeth were sectioned mesiodistally. Each tooth segment was subjected to 5% nitric acid for 12 hours followed by 8% sodium hypochlorite for 10 minutes. Samples were rinsed with distiled water between the two solutions. The demineralization protocol was renewed every 24 hours and applied for 11 days. At the end of the process, the teeth were reassembled, and randomly divided into six groups, each containing 9 samples:

1. Group 1: AH Plus + Cold Lateral Condensation Technique,
2. Group 2: AH Plus + Thermoplastic Injection Technique,
3. Group 3: T-Endo Bioserra + Cold Lateral Condensation Technique,
4. Group 4: T-Endo Bioserra + Thermoplastic Injection Technique,
5. Group 5: GuttaFlow 2,
6. Group 6: GuttaFlow 2 + Single-Cone Technique.

Filling quality was evaluated by determining the percentage of gutta-percha, sealer, and remaining voids in the resorption cavities through stereomicroscopic examination.

ÖZ

Amaç: Bu çalışmanın amacı; asit demineralizasyonu ile oluşturulan düzensiz sınırlı iç rezorpsiyon kavitelerinin farklı dolum teknikleri ile doldurulmasının, dolum kalitesi üzerindeki etkisini değerlendirmektir.

Yöntemler: Toplamda 54 adet çekilmiş tek köklü diş mesiodistal olarak ikiye ayrıldı. Her iki diş segmentine önce 12 saat 5% nitrik asit; ardından 10 dakika 8% sodyum hipoklorit uygulandı. İki solüsyon arasında örnekler distile su ile yıkanarak temizlendi. Demineralizasyon protokolü 24 saatte bir yenilenerek 11 gün boyunca uygulandı. Sürecin sonunda dişler yeniden bir araya getirildi ve her grupta 9 örnek olacak şekilde rastgele 6 gruba ayrıldı. Gruplar;

Grup 1: AH Plus + Soğuk Lateral Kondenzasyon Tekniği,

Grup 2: AH Plus + Termoplastik Enjeksiyon Tekniği,

Grup 3: T-Endo Bioserra + Soğuk Lateral Kondenzasyon Tekniği,

Grup 4: T-Endo Bioserra + Termoplastik Enjeksiyon Tekniği,

Grup 5: GuttaFlow 2,

Grup 6: GuttaFlow 2+ Tek Kon Tekniği.

Dolum kalitesi, stereomikroskopik inceleme yoluyla rezorpsiyon boşluklarındaki gutaperka, kanal patı ve kalan boşluk miktarlarının belirlenmesiyle değerlendirildi.

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ABSTRACT

Results: The group filled with AH Plus sealer using the cold lateral condensation technique showed a significantly higher gutta-percha percentage compared to the other groups ($p<0.05$). The GuttaFlow 2 group, applied with the single-cone technique, exhibited the highest gutta-percha percentage (99.01%). When the cold lateral condensation and thermoplastic injection techniques were compared based on sealer contents, no statistically significant difference in gutta-percha percentage in the resorption cavities was observed ($p=0.136$).

Conclusion: Our study demonstrated that none of the obturation techniques used achieved complete filling in the resorption cavities. However, the use of GuttaFlow 2 with the single-cone technique showed superior filling quality, demonstrating excellent adaptation to the root canal walls and ease of application.

Keywords: GuttaFlow 2, internal root resorption, root canal obturation

ÖZ

Bulgular: Soğuk lateral kondensasyon tekniği kullanılarak AH Plus kanal patı ile doldurulan grup, diğer gruplara göre anlamlı olarak daha yüksek pat yüzdesi gösterdi ($p<0,05$). Tek kon tekniğiyle uygulanan GuttaFlow 2 grubu, en yüksek gutaperka yüzdesini sergiledi (%99,01). Soğuk lateral kondenzasyon ve termoplastik enjeksiyon tekniklerin pat içeriklerine göre karşılaştırıldığında, rezorpsiyon boşluklarında pat yüzdesinde istatistiksel olarak anlamlı farklılık gözlenmedi ($p=0,136$).

Sonuç: Çalışmamız, kullanılan hiçbir obtürasyon tekniğinin rezorpsiyon kavitelerinde boşluksuz dolumu başaramadığını ortaya koymuştur. Bununla birlikte, master kon ile uygulanan GuttaFlow 2'nin kullanımı, kök kanal duvarlarına mükemmel uyum ve uygulama kolaylığı göstererek üstün doldurma kalitesi sergilemiştir.

Anahtar Sözcükler: GuttaFlow 2, iç kök rezorpsiyonu, kök kanal dolumu

Introduction

The American Endodontic Society provides a definition of resorption as a condition linked to a physiological or pathological process that results in the loss of dentin, cementum, or bone (1). Resorption involves non-infectious damage caused by the activity of osteoclastic cells, leading to the loss of dental hard tissue (2,3). Root resorptions are categorized as internal or external based on their location on the root surface. Internal root resorption refers to a clinical condition characterized by the gradual destruction of dentin along the walls of the root canal, typically caused by chronic infection or trauma (4,5). Although internal root resorption is rarely identified in clinical settings, histological studies have reported varying incidence rates ranging from 0.01% to 55%, depending on the inflammatory condition of the pulp (6).

Filling the root canal hermetically in cases of internal resorption is an important step in successful treatment (7). However, the irregular structure of the resorption cavities poses a challenge for physicians. Therefore, the efficacy of various techniques and materials in sealing internal root resorption cavities has been evaluated through *ex vivo* study designs.

Obturation of the root canal system is indeed one of the most critical stages of endodontic treatment (8). The primary objective of root canal treatment is to achieve a hermetic seal, thereby preventing apical and coronal leakage. While various methods have been introduced over the years, each method comes with its own set of advantages and disadvantages.

One widely used technique is the cold lateral condensation method, which proves suitable for many clinical conditions. This approach involves filling the gaps between the dentin walls and the gutta-percha by employing auxiliary cones after placing a master gutta-percha cone that corresponds to the canal preparation. However, it may be inadequate in completely filling irregularities within the canal and fails to provide a uniform filling compared to alternative systems (9).

The thermoplastic injection method was initially introduced by Michanowicz and Czonstkowsky in 1984. With this approach, the gutta-percha is heated and softened, and then pressure is applied using specialized devices to place it into the root canal. Injectable gutta-percha has been reported to effectively fill anatomical variations such as intracanal irregularities, internal resorption, C-shaped canals, lateral canals, and branching foramina (10).

Studies have demonstrated that the thermoplastic injection technique is significantly more effective than cold lateral condensation in achieving three-dimensional canal filling (11-13). A recently introduced method, known as the cold-fluid filling technique, is also under evaluation for its potential use in cases of internal resorption. GuttaFlow 2, a cold, flowable, and self-curing root canal filling material, contains polydimethylsiloxane and gutta-percha powder with particle sizes less than 30 μm (14). Due to its reduced viscosity under shear stresses, it exhibits remarkable flow properties. While it can be used with lateral or vertical compaction techniques, it is commonly recommended for single-cone application without mechanical compression (15).

In existing literature, experimental resorption cavities were mechanically created using various types and sizes of burs (15-18). However, in natural resorption cavities, which are formed as a result of clastic cell activity, the demineralized areas exhibit irregular cavity boundaries (19). No study has been found in the literature that evaluates the quality of filling in internal resorption cavities formed through this chemical process.

The aim of this study was to evaluate the effect of different obturation techniques on the quality of filling internal resorption cavities that were created through acid demineralization. Furthermore, the study seeked to assess the extent of resin and bioceramic sealer coverage within these cavities.

This study represents the first investigation in the literature to solely evaluate filling quality based on sealer contents, irrespective of the obturation technique employed.

The null hypothesis of our study is that the relatively newer technique of cold-flow obturation (GuttaFlow 2) may provide more successful filling in terms of internal resorption quality when compared to the traditional cold lateral condensation technique, simple single-cone technique, and thermoplastic injection technique.

Methods

The study obtained ethical approval from the Marmara University Faculty of Dentistry Ethics Committee under decision number: 2022/45, dated 24.02.2022, as human tissues were utilized for the *in vitro* study. After receiving approval from the ethics committee, a total of 54 single-rooted human teeth, extracted for reasons such as caries or periodontal issues, were selected for the study. The inclusion criteria included teeth with single and straight root canals.

Teeth exhibiting complete root development without fractures, cracks, resorption, or anatomical variations were chosen after examination under x25 magnification.

To prepare the specimens, the crowns of each tooth were removed using a diamond bur, resulting in a standardized root length of 12 mm. The teeth were mounted on acrylic blocks (Figure 1). In the next step, the specimens were bisected in the mesiodistal direction using a diamond disc (Buehler Diamond Cut-Off Wheels 114243; Buehler, Lake Bluff, IL) attached to a chainsaw (IsoMet Low Speed Saw; Buehler) with water cooling. Metal discs, measuring 2 mm in width and 2 mm in height, were placed in the middle third of the root length in both segments of the tooth. These discs were securely fixed with the aid of a gingival barrier (Gingiva Shield VLC, PrevestDenPro, India) and the tightness was ensured (Figure 2).

The demineralization protocol for creating the resorption cavity spanned a duration of 11 days. The protocol involved three steps: first, the application of a 5% nitric acid solution for 12 hours; second, the exposure to an 8% sodium hypochlorite (NaOCl) solution for 10 minutes; and finally, another 12 hour application of a 5% nitric acid solution (19). Distilled water was used for rinsing between each solution, and throughout the entire duration, the samples were stored at a temperature of -1 °C (+/-3 °C) (Figure 3). At the conclusion of this period, the metal rings were removed from the root surface, and any residues were thoroughly cleaned. Liquid adhesive was applied to the acrylic surfaces, allowing the parts to be assembled in such a way that the resorption areas on both root surfaces were opposite each other. This prepared the samples for root canal preparation.

The working length of the root canals was determined by using a no.15 K-file (Mani, Japan), and 0.5 mm was subtracted from the length visible at the apical foramen. For cleaning and shaping the root canals, rotary nickel-titanium instruments (ProTaper, Dentsply Maillefer) were employed, with an X2 file attached to a torque-controlled reduction handpiece (X-Smart, Dentsply Maillefer). Irrigation was performed between each instrument using 2.5 mL of 2.5% NaOCl. Following the completion of the preparation, the root canals were rinsed with 5 mL of 2.5% NaOCl for 1 minute. The samples were randomly divided into 6 groups, with 9 samples in each group (Table 1). The Calamus Dual Obturation System (Dentsply Maillefer, Ballaigues, Switzerland) was used to the thermoplastic injection technique.

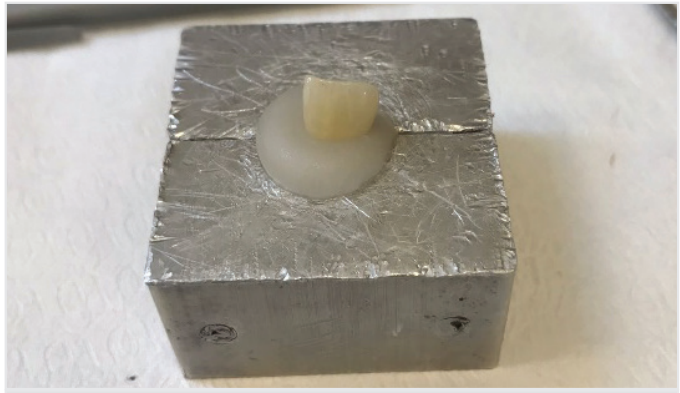

Figure 1. Samples preparation

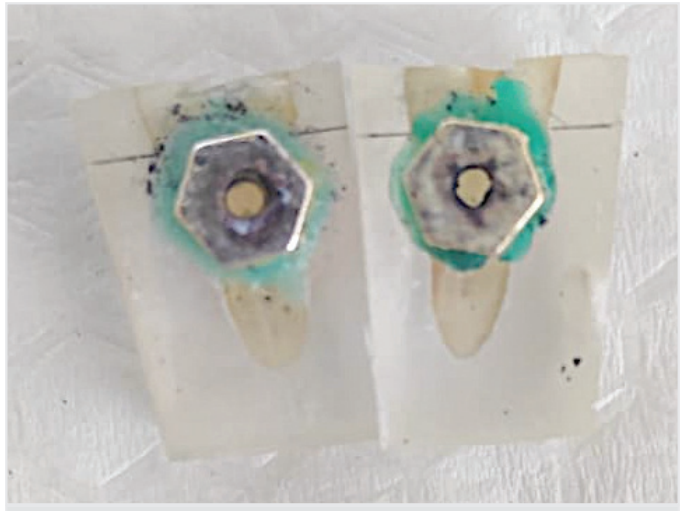

Figure 2. Preparation of resorption cavities

Figure 3. Resorption cavities

After storing the samples at room temperature for 7 days, a 7 mm section was obtained from each tooth for analysis. The root sections were then examined under a Leica MZ 7.5 stereomicroscope (Leica, Germany) at 25x magnification. Microscope images were captured and loaded into computer-based image analysis software (ImageJ and NIH Image Software; National Institutes of Health, Bethesda, Md) (Figure 4). A software program was utilized to calculate the percentages of sealer, gutta-percha, and voids present in the root sections of each group (Figure 5).

Statistical Analysis

Statistical analyses were performed using the SPSS28 software (IBM Corp., Armork, NY,USA). The Kruskal-Wallis and Mann-Whitney U tests were utilized to determine any significant differences between the groups. A p value below 0.05 was considered statistically significant.

Results

The Kruskal-Wallis test was utilized to examine the differences between the groups. The results of the Kruskal-Wallis test indicated a statistically significant difference in the percentages of gutta-percha and sealer within the resorption cavities ($p<0.05$). However, no significant difference was found between the groups in terms of the percentage of voids present in the cavities ($p>0.05$) (Table 2). Table 3 and Table 4 present the results of the study, comparing the percentages of gutta-percha and sealer within the resorption cavities among the different groups.

Further analysis of the stereomicroscope images revealed that group 1 had a significantly higher percentage of sealer compared to the other groups ($p<0.05$). Group 6 exhibited the highest percentage of gutta-percha. When comparing the first four groups with each other in terms of sealer content, no statistically significant difference was observed in the percentage of sealer within the resorption cavities ($p>0.05$).

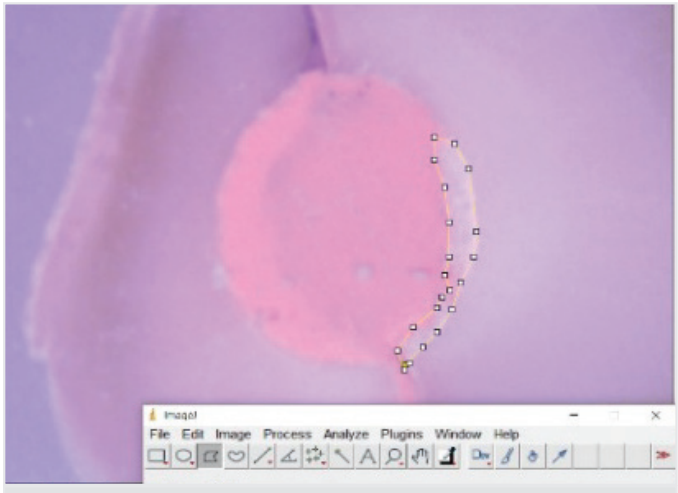

Figure 4. ImageJ data

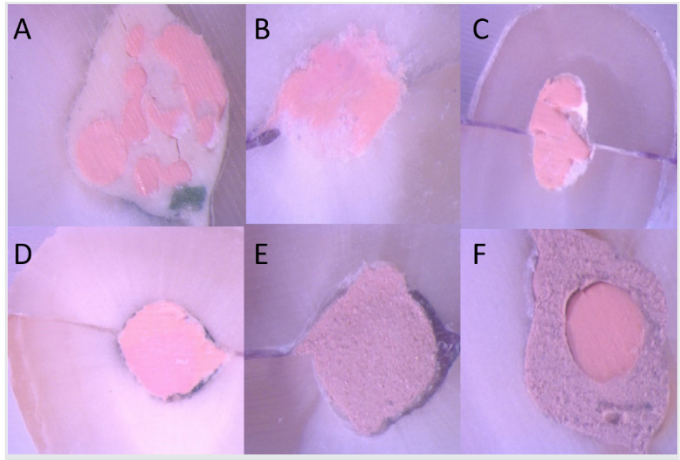

Figure 5. Stereomicroscopic images of the samples (25x magnification)

5A: Group 1 (AH Plus Sealer + Cold Lateral Condensation Technique), **5B:** Group 2 (AH Plus Sealer + Thermoplastic Injection Technique), **5C:** Group 3 (T-Endo Bioserra Sealer + Cold Lateral Condensation Technique), **5D:** Group 4 (T-Endo Bioserra Sealer + Thermoplastic Injection Technique), **5E:** Group 5 (GuttaFlow 2), **5F:** Group 6 (GuttaFlow 2 + Single Cone Technique)

Table 1. Groups of the study

	Obturation technique	Sealer
Group 1	Cold Lateral Condensation	AH Plus
Group 2	Thermoplastic Injection Technique	AH Plus
Group 3	Cold Lateral Condensation	T-Endo Bioserra
Group 4	Thermoplastic Injection Technique	T-Endo Bioserra
Group 5	Gutta Flow 2	Gutta Flow 2
Group 6	Single Cone Technique	Gutta Flow 2

Table 2. The percentages of gutta-percha, sealer and void in the cavities

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	p
Gutta Percha	47.00	87.22	64.98	79.92	93.06	96.57	<0.001
Sealer	40.00	7.76	23.20	18.45	-	-	<0.001
Void	5.57	1.99	8.23	4.91	6.94	3.43	0.136

Table 3. Comparisons of obturation percentages of resorption cavities with gutta-percha among groups

Groups	p
Group 1-Group 3	0.338
Group 1-Group 4	0.045
Group 1-Group 2	*0.002*
Group 1-Group 5	<0.001
Group 1-Group 6	<0.001
Group 3-Group 4	0.294
Group 3-Group 2	0.35
Group 3-Group 5	<0.001
Group 3-Group 6	<0.001
Group 4-Group 2	0.287
Group 4-Group 5	0.012
Group 4-Group 6	0.001
Group 2-Group 5	0.150
Group 2-Group 6	0.31
Group 5-Group 6	0.472

Table 4. Comparisons of obturation percentages of resorption cavities with sealer among groups

Groups	p
Group 2-Group 4	0.277
Group 2-Group 3	0.018
Group 2-Group 1	<0.001
Group 4-Group 3	0.245
Group 4-Group 1	0.002
Group 3-Group 1	0.049

Discussion

The success of root canal treatment can be negatively affected in the presence of voids that provide a space for microbial colonization within the cavity. If the resorption cavity is not completely filled, these voids can serve as focal points for microbial colonization, leading to contamination and microleakage, which can have a detrimental effect on treatment success (20). In our study, we evaluated the percentage of area covered by resin and bioceramic-based sealers after filling the cavities using two different sealers in cases involving irregular cavities such as internal resorption.

In our study, the experimental resorption cavities were positioned in the middle one-third of the roots of maxillary central incisors, considering the higher prevalence of internal root resorption in this region and its frequent occurrence in the middle and apical thirds of the root (21,22).

Unlike previous *in vitro* studies (15-18), our study followed a methodology similar to the one conducted by da Silveira et al. (19) in 2014. We created irregular demineralized areas using nitric acid and NaOCl, aiming to simulate actual internal resorption cavities more accurately. These chemically formed cavities were designed to closely resemble the characteristics of real internal resorption cavities. For filling the artificial internal root resorption cavities in our study, we employed three preferred obturation techniques. The first technique used was the cold lateral condensation technique, which was the most commonly used and widely practiced technique in the clinic (23,24). The second technique chosen was Calamus Dual Obturation System, a system that utilized injectable thermoplasticized gutta-percha. Studies have indicated that the thermoplastic injection technique is significantly superior to cold lateral condensation, providing better three-dimensional canal filling (25-27). In our study, GuttaFlow 2 (Micromega, Coltene Whaledent, USA), a flowable filling material at room temperature, was utilized. It was evaluated in two groups: one group involved the use of a master cone, while the other group did not use a master cone.

For the evaluation of the obtained images, stereomicroscope analysis was chosen in our study. This method was preferred to obtain a clearer view of the surface, which would then be transferred to the image analysis software for further analysis.The advantages of using a stereomicroscope include not requiring any pre-processing of the samples, providing a three-dimensional view, and eliminating human errors that may occur during the interpretation of parameters (24). However, a disadvantage of the stereomicroscope is that it examines and evaluates only a certain cross-sectional area of the resorption cavity, leaving other areas unassessed (25). The necessity of obtaining sections from the samples is also seen as a disadvantage due to the potential irreversible damage it may cause (26).

For image analysis in our study, we used ImageJ, a Java-based image processing and analysis program. ImageJ provides the capability to calculate area and pixel value statistics for user-defined selections. Additionally, it enables measurements of distances and angles. It is preferred for its support of standard image processing functions and the ability to perform geometric transformations such as measurements (27).

The null hypothesis was accepted in our study. None of the filling techniques used completely filled the resorption cavities. But when evaluating the percentage of cavity filling with sealer or gutta-percha, the group filled with AH Plus sealer using the cold lateral condensation technique had the highest sealer percentage (40.40%), while the group treated with GuttaFlow 2 using the master cone technique had the highest gutta-percha percentage (96.57%).

When the percentages of void areas in the experimental groups were ranked according to medians, the highest percentage of voids was observed in the group filled with T-endo Bioserra sealer (Dentac, Istanbul, Turkey) using the cold lateral condensation technique (8.23%), while the lowest percentage of voids was found in the group filled with AH Plus sealer (Dentsply De Trey Gmbh, Konstanz, Germany) using the thermoplastic injection technique (1.99%). However, the difference observed between the groups was not statistically significant. These findings align with the existing literature on the subject (28,29).

Most studies in the literature have consistently demonstrated the advantages of the thermoplastic injection technique in

effectively filling internal resorption cavities. These studies have reported that the root canal filling should ideally contain a higher proportion of gutta-percha and a lower amount of sealer. Gençoğlu et al. (13) compared various filling techniques for the filling of mechanically created internal resorption cavities in their study. The researchers found that Obtura II (Obtura Spartan, Fenton, MO) with the thermoplastic injection technique filled the resorptive area significantly better than the cold lateral condensation technique using Obtura II. Similarly, *in vitro* studies with similar methodologies comparing different filling techniques for filling internal resorption cavities have concluded that the thermoplastic injection method creates higher quality fillings compared to cold lateral condensation (8,15,18). Additionally, the literature has documented successful outcomes associated with the utilization of warm obturation techniques for the treatment of teeth exhibiting internal resorption (30,31). The evaluation of gutta-percha amounts in the resorption cavities in our study revealed that the group with the highest gutta-percha filling was the one treated with GuttaFlow 2 and the simple single-cone technique. Our results are consistent with the findings of Naseri et al. (28), Gençoğlu et al. (13), and Goldberg et al. (22) in the literature. The group treated with the thermoplastic injection technique using T-endo Bioserra sealer showed a significantly lower percentage of gutta-percha filling within the cavities compared to the group treated with GuttaFlow 2 using the master cone technique. This finding differs from some studies in the literature. In a study by Anantula and Ganta (24) these two techniques were compared and it was reported that the thermoplastic injection provided a more compatible filling to the canal walls and resulted in fewer voids compared to the groups treated with GuttaFlow. Similarly, in a study by Kumar et al. (32), the filling capacities of GuttaFlow 2, thermoplastic injection technique, and cold lateral condensation technique were compared. The researchers found that the thermoplastic injection technique provided significantly better filling than the other groups. We believe that the difference between the results of our study and the results of other studies in the literature may be due to differences in methodology. While previous studies evaluated the adaptation to the canal walls of mechanically created cavities, our study evaluated irregular demineralized areas created to simulate patients encountered in clinical practice.

In another study, researchers compared GuttaFlow 2 with the cold lateral condensation technique to assess apical microleakage. The findings of the study revealed that when GuttaFlow 2 was applied with the master cone technique, it resulted in the least amount of dye penetration in comparison to the cold lateral condensation technique (33).

Study Limitations

Our study had limitations including its *in vitro* design, minimal loss of tooth structure due to sectioning of tooth segments, and filling of created voids with paste. However, this study was the first to evaluate the filling of root canals in internal resorption cavities created by acid demineralization using GuttaFlow 2. We believe that our results will contribute to the literature and provide insights for further studies in this area.

Conclusion

In conclusion, our study revealed that none of the obturation techniques used in the treatment of resorption cavities were able to completely fill the defects. However, the GuttaFlow 2 applied with the master cone demonstrated superior filling quality, offering good adaptation to the root canal walls and ease of use. Significantly, this study is the inaugural examination in the literature to exclusively evaluate filling quality based on the resorption cavity content, irrespective of the obturation technique employed. Therefore, further investigations involving *in vivo* and long-term assessments are necessary.

Ethics

Ethics Committee Approval: The study obtained ethical approval from the Marmara University Faculty of Dentistry Ethics Committee under decision number: 2022/45, dated 24.02.2022, as human tissues were utilized for the *in vitro* study.

Informed Consent: *In vitro* study.

Peer-review: Externally peer reviewed.

Authorship Contributions

Concept: İ.Ö., H.S.Ö., Design: İ.Ö., H.S.Ö., Data Collection or Processing: İ.Ö., H.S.Ö., Analysis or Interpretation: İ.Ö., Literature Search: İ.Ö., Writing: İ.Ö., H.S.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

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Original Article

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Bezmialem Science 2024;12(1):78-83

One-year Body Mass Index Change in Adult Renal Transplant Recipients and Its Relationship with Glomerular Filtration Rate and Creatinine Level: A Retrospective Study

Yetişkin Böbrek Nakli Alıcılarında Bir Yıllık Vücut Kitle İndeksi Değişimi ve Bu Değişimin Glomerüler Filtrasyon Hızı, Kreatinin Değerleri ile İlişkisi: Retrospektif Bir Çalışma

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ABSTRACT

Objective: Renal transplantation is a challenging process for the recipients. One of the important problems in this process is unwanted weight gain. This study aimed to determine the change in body mass index (BMI) and to evaluate the effect of recipient characteristics on BMI during one-year period after renal transplantation.

Methods: The article was conducted in a retrospective design. In the study, files of 170 patients who underwent renal transplantation between 2015 and 2016 were reviewed retrospectively. T-test, ANOVA, and correlation analysis were used in the analysis of data.

Results: It was determined that the patients had a tendency to have increased BMI after transplantation, with a higher rate in the first three months. The increase in BMI was higher in singles than in married participants ($p=0.01$ and $p<0.05$), and in men than in women ($p=0.01$ and $p<0.05$). It was determined that there was no significant relationship between BMI values and glomerular filtration rate, and creatinine levels of adult renal transplant recipients ($p>0.05$).

Conclusion: In the study, it was determined that the increase in BMI was higher especially in the first three months after renal transplantation. For this reason, it is an important requirement to address the counseling and support to patients and their relatives regarding weight management in the early period.

Keywords: Body mass index, kidney transplantation, obesity, transplant recipients, weight gain

ÖZ

Amaç: Renal transplantasyon, alıcılar için zorlu bir süreçtir. Bu süreçteki önemli sorunlardan biri de istenmeyen kilo alımıdır. Bu çalışmada, böbrek nakli sonrası bir yıllık süreçte vücut kitle indeksindeki (VKİ) değişimin belirlenmesi ve alıcı özelliklerinin VKİ'ye etkisinin değerlendirilmesi amaçlanmıştır.

Yöntemler: Makale retrospektif olarak yürütülmüştür. Çalışmada 2015-2016 yılları arasında böbrek nakli yapılan 170 hastanın dosyaları retrospektif olarak incelenmiştir. Verilerin analizinde t-testi, ANOVA ve korelasyon analizi kullanılmıştır.

Bulgular: Hastaların nakil sonrası VKİ'de ilk üç ayda daha fazla artış eğilimi olduğu belirlenmiştir. VKİ artışı bekarlarda evlilere göre ($p=0,01$, $p<0,05$), erkeklerde kadınlara göre ($p=0,01$, $p<0,05$) daha yüksektir. Glomerüler filtrasyon hızındaki VKİ değişiklikleri ile kreatinin ölçümleri arasında anlamlı bir ilişki olmadığı saptanmıştır ($p>0,05$).

Sonuç: Çalışmada böbrek nakli sonrası özellikle ilk üç ayda VKİ artışının daha fazla olduğu belirlenmiştir. Bu nedenle kilo yönetimi konusunda hasta ve yakınlarına danışmanlık ve desteğin erken dönemde verilmesi önemli bir gerekliliktir.

Anahtar Sözcükler: Vücut kitle indeksi, böbrek nakli, obezite, nakil alıcıları, kilo alımı

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Introduction

Renal transplantation constitutes 12.97% of the treatment options in end-stage renal disease (1). According to the United States Renal Data System, approximately more than a quarter (25.7%) of patients who have been waiting for a kidney transplant for 1 year have received a kidney transplant (2). It is reported that renal transplantation has increased in Turkey over the years, and 3,621 individuals were transplanted in 2022 (3).

Renal transplantation is a challenging process for patients and their relatives. One of the encountered problems in this process is weight gain. It is known that there is a three-fold increase in the risk of obesity and a two-fold increase in the risk of morbid obesity in the post-transplant period. Therefore, determining the weight gain status in renal transplant recipients is important to support weight management. Maintaining a normal weight by regulating the lifestyles of patients is of great importance in terms of the functions of the transplanted organ, and it is important in increasing the success of treatment (4). In a study by Kim et al. (5), renal functions decreased as body mass index (BMI) increased, especially in the first three months after transplantation. It was reported that death and graft defects were more common in patients with a BMI above 30 kg/m^2 one year after transplantation (6). In another conducted research, it was observed that the risk of short-term complications in the 90-day period after transplantation was higher in obese individuals (7).

Graft failure and morbidity in the first three years after transplantation may not be associated with morbid obesity (8). But, it is stated that obesity is a serious problem in renal transplant recipients, and there is an important relationship between increased BMI and decreased graft functions (9). In addition, the pre-transplant weight status of patients also affects post-transplantation (10). There were no studies in the literature that were similar to our study when it was being prepared. Considering the data in the literature, the purpose of this study was to determine the BMI changes of patients after renal transplantation in one-year period.

Research Questions

1. What are the changes in BMI of adult renal transplant recipients over one-year period?

2. Do the demographic characteristics of adult renal transplant recipients affect BMI changes in the first one year?.

3. Is there a relationship between BMI values, glomerular filtration rate (GFR), and creatinine levels of adult renal transplant recipients?

Methods

Study Population and Design

The Organ Transplantation Center at a University Hospital's patient files from January 2015 to 2016 were retrospectively analyzed. When renal transplant recipients came for control, their height, weight, blood pressure, liver, and renal functions were recorded in their files. Study data were obtained from patient files. The records of adult renal transplant recipients followed up in the Organ Transplantation Center constituted the population of the study. A purposeful sampling method was used. The file data of the patients who underwent transplantation in the center for the years 2015-2016 constituted the sample. One hundred eighty eight patient records were included in one year, with missing data on study size. Adults (aged ≥18 years old) and patients who died at least one year after renal transplantation were included. However, patients who died within one year and patients with files with missing data were excluded. Eighteen files were excluded due to insufficient medical records in terms of authorization bias.

In this study, dependent variables were BMI, creatinine level, and GFR. The independent variables of the research were defining features (age, gender, educational status, marital status, donor type, transplantation time). Research data were collected through the data collection form, which was created by using the literature (4,6,8). The data collection form consisted of questions measuring the degree of the relation of the living donor, age, gender, educational status, marital status, donor type, BMI, transplantation time, creatinine level, and GFR. The form was planned in such a way that all data about the patient could be taken from the patients' files. Research data were collected after obtaining institutional permissions and ethics committee approval and continued until all patient records within the specified date range were reached. The Clinical Research Ethics Committee's approval and the hospital's institutional permission were obtained in order to carry out the study (dated 20.02.2016, ıssue no: 70904504/77, decision no: 101).

Statistical Analysis

Data were evaluated with the IBM SPSS 23 program in an electronic environment for analysis of data. Descriptive statistics were displayed as frequency, percentage, mean, standard deviation, maximum and minimum values. Missing data were not included in the analyses. Patients' BMI changes in 1st, 3rd, 6th, 9th and 12th months were calculated based on pre-transplant BMI levels [ΔBMI (BMI x. month-BMI baseline/BMI baseline)]. Independent t-test analyzes between patients' BMI change, gender, age, marital status and transplant type were performed. ANOVA test was used to compare patients' BMI changes according to education level. Repeated analysis of variance was performed to examine whether BMI levels differed between 1st, 3rd, 6th, 9th and 12th months and pre-transplantation period. Sidak pairwise comparison test was applied to examine the different measurement times. Correlation analysis was applied to examine the relationship between BMI changes, GFR, and creatinine level. P values less than 0.05 were considered statistically significant in the study.

Results

The data obtained as a result of the retrospective study were analyzed with the statistical methods mentioned above. The

findings obtained as a result of the analysis of the data are explained below.

Our study consisted of 170 (48 female and 122 male) patient data. 85.3% of the recipients were transplanted from a living donor. Before transplantation, 53% of patients were normal weighted. The mean BMI of the patients before transplantation was found to be 23.05±4.74 kg/m^2 (Table 1).

While the mean BMI was 24.29±4.81 kg/m^2 in the first month, it was determined as 27.04±5.33 kg/m^2 at the end of the 12th month and it was found gradually increased. It was found that the increase in BMI was higher in males than in female patients (Figure 1).

Table 1. Sociodemographic characteristics of the patients (n=170)

Donor type	n	%
Living donor	145	85.3
Deceased donor	25	14.7
Living donor	n	%
First degree relative	68	40.0
Second degree relative	34	20.0
Fourth degree relative	60	35.3
Cross	8	4.7
Education	**n**	**%**
Primary	94	55.3
High school	48	28.2
Bachelors	28	16.5
Marital status	n	%
Married	116	68.2
Single	54	31.8
Age	**Mean ± SD**	**Min-max**
	41.45±12.75	20-77
Sex	**n**	**%**
Female	48	28.2
Male	122	71.8
BMI before transplantation	**n**	**%**
Underweight	29	17.1
Normal weight	90	52.9
Pre-obesity	32	18.8
Obese	19	11.2
BMI	**Mean ± SD**	**Min-max**
Before transplantation	23.05±4.74	13.36-36.21
First month after transplantation	24.29±4.81	13.25-42.53
12th month after transplantation	27.04±5.33	14.49-44.41

Min: Minimum, Max: Maximum, SD: Standard deviation, BMI: Body mass index

When the patients' BMI changes according to age were examined in the first year after transplantation, it was found that increase in BMI was 0.21±0.17 kg/m^2 in patients aged 40 and below, and increase in BMI was 0.16±0.15 kg/m^2 in patients aged 41 and above. These changes were determined to be statistically significant (p=0.03). A statistically significant difference was found between changes in patients' marital status and BMI at 1st, 3rd, 6th, 9th, and 12th months (p=0.01, p<0.05). BMI increases in single patients were higher than in married patients. There was no statistical difference between the education levels and donor types of the patients and the BMI changes in the 1st, 3rd, 6th, 9th, and 12th months (p>0.05). It was observed that BMI changes in the 1st, 3rd, 6th, 9th, and 12th months of the living and transplanted patients were similar (p>0.05).

GFR measurements of the patients were 15.60±20.54 mg/dL before transplantation and 73.39±25.97 mg/dL at 12 months. While the mean of creatinine levels before transplantation was 5.95±3.72 U/L, the average of creatinine level at the end of the 12th month was 1.34±0.97 U/L. It was determined by the correlation analysis that the BMI changes of the patients according to the months did not have a significant relationship with the GFR and creatinine level (p>0.05). We found statistically different levels of change in patients in 1st, 3rd, 6th, 9th, and 12th months according to their pre-transplant BMI values, which were shown in Table 2 (p=0.01 and p<0.05). It was observed that there was no difference between the 9th and 12th month BMI changes of the patients, and there was an increasing trend between the other months. It was determined that the BMI changes of the patients in the 1st, 3rd, 6th, 9th, and 12th months were different according to their genders (p=0.01). It was observed that BMI changes in the 1st, 3rd, 6th, 9th, and 12th months of male patients were higher than those of female patients. It was determined that female patients' BMI increases between 1-12 months were lower than those of male patients (Figure 1). The patients' marital status and the changes in their BMI in the 1st, 3rd, 6th, 9th, and 12th months were found to differ statistically (p=0.01 and p<0.05). It was observed that the BMI changes of the single patients in the 1st, 3rd, 6th, 9th, and 12th months were higher than the married patients.

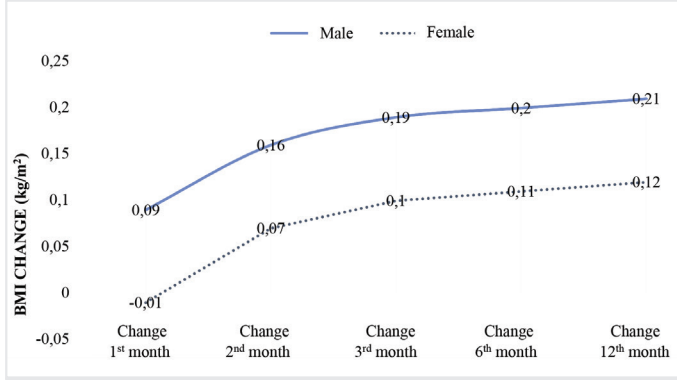

Figure 1. BMI changes by gender at 1st, 3rd, 6th, 9th, and 12th months

BMI: Body mass index

Table 2. BMI Changes in the 1st, 3rd, 6th, 9th, and 12th months (n=170)

BMI changes (n=170)	X ± SD	p**	Difference***
Δ 1st month	0.06±0.13	0.01*	1<2<3<4=5
Δ 3rd month	0.14±0.14		
Δ 6th month	0.17±0.15		
Δ 9th month	0.18±0.15		
Δ 12th month	0.19±0.16		

Δ= (Month Measurement-Baseline)/Baseline x100,
*Significant difference
**Repeated analysis of variance was applied
***Sidak test was applied for pairwise comparison test
BMI: Body mass index, SD: Standard deviation

Discussion

Weight gain in transplant recipients causes an adverse cardiovascular profile. Weight gain is becoming an important factor in the evaluation of graft dysfunction after transplantation. Weight increase following a transplant is linked to ischemic heart disease, hypertension, diabetes, and dyslipidemia (11-14). Regardless of their nutritional status prior to transplantation, about 50% of patients gain weight afterward. There are studies reporting weight gain in patients within one year after renal transplantation (4,5,10,15-18). Significant increases are observed in the weight of individuals after renal transplantation, especially in the 3rd and 12th months (11,16,19,20). In our study, the average BMI was 23.05±4.74 kg/m^2 before transplantation, 24.29±4.81 kg/m^2 in the 1st month after transplantation, and 27.04±5.33 kg/m^2 in the 12th month. In a study, the mean weight gains in the first 12 months after transplantation was 4.4±9.6 kg. It was stated that the weight gains of the group with a BMI of ≥35 kg/m^2 before transplantation was 9.8±7.02 kg in one year after transplantation [Liese et al. (21)]. However, there are also studies showing that the increase in the first years is not significant or that this increase is not statistically significant (10,18). In a two-year observational study by Wołoszyk et al. (22), in patients who were initially overweight and obese, their BMI did not significantly change after two years. In a study evaluating living donor transplantations, it was reported that 40 of 427 patients who were obese and normal weighted (BMI <30) before transplantation had post-transplant weight gain (11).

The mean BMI in our study was 23.05±4.74 kg/m^2 before transplantation and 27.04±5.33kg/m^2 in the 12th month after transplantation. According to the obtained data, the BMI levels of the transplant recipients increased by 19% at the end of the first year (Figure 1). This increase may be due to intensive immunosuppressive therapy after transplantation, it is important to carefully monitor weight, especially in the first months, and to handle weight management by a multidisciplinary team approach. In case of need, it is an important requirement to examine the cultural factors in detail that affect weight gain in patients.

In our study, it was determined that the BMI changes of the patients differed according to gender (p=0.01) and that the increase in BMI of male patients was higher in the one year after transplantation. There are different results in studies on the effect of gender on BMI changes. In the literature, there were studies that found a statistically significant difference between BMI and gender (21,23) and there were also studies that showed no difference (11,24). Our study supports literature data showing significant differences between BMI and gender. It is thought that this situation is related to the eating habits and lifestyles of male and female patients, and cultural differences affect this situation.

In our study, it was determined that single renal transplant recipients gained more weight than married ones. In our country, married individuals lead a more regular life than singles (25). Our result was thought to be related to a regular life with marriage, the culture of preparing food at home, and the decrease in the consumption of ready-made/processed food.

Donor type and monthly variations in BMI did not differ from one another (p>0.05). In other words, BMI changes in the 1st, 3rd, 6th, 9th, and 12th months of living and deceased donor transplant recipients were similar. Liese et al. (21), reported no significant difference between BMI and donor type in a five-year retrospective study. Uysal et al. (26), reported no statistically significant difference between cadaver donor and living donor in terms of the BMI changes of the recipients in the 6th and 12th months. In this respect, our findings are similar to the literature.

In the study, it was found that patients younger than 40 years of age (n=81) had a higher BMI change in the first year after transplantation than those over 40 years of age (n=89) (p=0.03). In the study of Bardonnaud et al. (27), unlike our study, it was stated that the average age of obese patients was higher after transplantation. In a retrospective study, there was no significant difference between recipient age and BMI (BMI ≤29.9, BMI 30-34.9, BMI ≥35) (p=0.597) Liese et al. (21) evaluated five-year renal transplantation data. Different results in age and BMI comparison may be due to cultural habits and lifestyle.

A major risk factor that reduces the GFR value is obesity, which occurs between 3 and 6 months following renal transplantation (28). In our study, there was no statistically significant distinction between BMI changes and GFR changes in the 1st, 3rd, 6th, 9th, and 12th months before and after transplantation (p>0.05). In a study, obesity was not seen as a permanent risk factor in one year but became a risk factor again in two and three years (28). In the study of Kim et al. (5), a negative significant correlation was found between BMI and GFR. In this study, it was determined that the only independent factor explaining the decrease in GFR between the pre-transplantation and the first month after transplantation was the increase in BMI (5). In a five-year retrospective study by Liese et al. (21), 12 months after transplantation, the GFR value was found to be significantly lower in obese patients than in non-obese patients (32.76 mL/min), (p=0.005). Being overweight and obese was associated with annual GFR decline (29). Contrary to these studies, Forte et al. (15), revealed that post-transplant weight changes did not affect the GFR level.

In our study, the mean creatinine value of the patients at the end of the first year was 5.95 mg/dL and the mean BMI was 27.04±5.33 kg/m^2 at the end of the first year. Nevertheless, there was no statistically significant difference between BMI changes and creatinine levels over the first 12 months (p>0.05). Contrary to our study; in a study, the mean creatinine level of the groups with BMI ≤29.9, 30-34.99, and ≥35 kg/m^2 in the 12 months after renal transplantation were determined as 1.76±0.81, 2.04±0.10 and 2.1±0.66 mg/dL, respectively, and a statistically significant difference was found between them (p=0.036) (23). In the study of Malgorzewicz et al. (24), a positive, moderately significant correlation was found between BMI and creatinine level (r=0.38, p<0.05) in the early post-transplant period (30-180 days).

Study Limitations

There were various limitations to our study. The limitations of the study were that it was a single-centered study, there were missing file data, and the data obtained were limited to the ones in the file.

Conclusion

In summary, as a result of the research, patients experienced weight gain, especially in the first six months after transplantation. Male patients had a higher tendency to have increased BMI than women and single patients compared to married ones. There was no effect of BMI changes on GFR and creatinine level in the one-year post-transplantation period. From this point of view, it may be recommended to focus especially on the first months in terms of weight gain, and to increase information, support and counseling during these months. In addition, socio-cultural factors affecting weight gain in the first months after transplantation may need to be addressed and investigated. It is the responsibility of the entire post-transplant team to evaluate the post-transplant habits of the patients in detail and to make attempts to improve them.

Ethics

Ethics Committee Approval: Akdeniz University Faculty of Medicine, Clinical Research Ethics Committee (number: 70904504/77).

Informed Consent: Retrospective study.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: R.Ç., Concept: F.C., Design: D.S., Ç.E., D.D.B., Data Collection or Processing: D.S., Ç.E., D.D.B., Analysis or Interpretation: D.S., Ç.E., D.D.B., Literature Search: D.S., Ç.E., D.D.B., R.Ç., Writing: F.C., D.S., Ç.E., D.D.B.

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Original Article

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The Influence of Varicocelectomy Age on Semen Parameters and Fertility Rates

Varikoselektomi Yaşının Semen Parametreleri ve Fertilite Üzerine Etkisi

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ABSTRACT

Objective: Varicocele is the most frequently observed correctable cause of infertility in men. In this study, we aimed to evaluate the influence of age at the time of varicocelectomy on semen parameters and fertility.

Methods: Infertile men who underwent microsurgical varicocelectomy between January 2012 and December 2019 were retrospectively evaluated. Patients were divided into 4 age groups as follows: group 1 including patients aged ≤25 years old, group 2 including patients aged ≥26 and ≤30 years old, group 3 including patients aged ≥31 and ≤35 years old, and group 4 including patients aged ≥36 years old.

Results: A total of 138 infertile men were divided into 4 groups. There were 18 men in group 1, 58 men in group 2, 44 men in group 3, and 18 men in group 4. There were significant improvements in the mean sperm concentration, progressive motility, and total motile sperm count values in all groups after surgery. Significant improvement in sperm morphology was detected only in groups 1 and 2 (p=0.007 and p=0.005, respectively). There was no significant difference between the groups in terms of preoperative and postoperative sperm parameters. Total fertility rate and the number of patients having children with natural conception or assisted reproductive techniques were lower in group 4 but these differences were not statistically significant (p=0.083 and p=0.454, respectively).

Conclusion: Varicocelectomy can be recommended for all infertile men regardless of age. There was no difference in postoperative semen parameters and fertility rates between the age groups.

Keywords: Age, infertility, varicocelectomy, semen parameters

ÖZ

Amaç: Varikosel erkeklerde en sık görülen düzeltilebilir infertilite nedenidir. Varikoselektomi sonrası postoperatif semen parametrelerinin düzeldiği ve gebelik oranlarının önemli ölçüde arttığı birçok çalışma ile gösterilmiştir. Literatürde yaşın postoperatif sonuçlara etkisini bildiren az sayıda çalışma vardır ve sonuçlar çelişkilidir. Bu çalışmada varikoselektomi sırasındaki yaşın semen parametreleri ve fertilite üzerine etkisini değerlendirmeyi amaçladık.

Yöntemler: Ocak 2012 ile Aralık 2019 tarihleri arasında mikrocerrahi ile varikoselektomi yapılan infertil erkekler retrospektif olarak değerlendirildi. Hastalar 4 yaş grubuna ayrıldı: Grup 1≤ 25 yaş hastaları, grup 2≥26 ve ≤30 yaş hastaları, grup 3 ≥31 ve ≤35 yaş hastaları ve grup 4 ≥36 yaş hastaları içermekteydi.

Bulgular: Toplam 138 infertil erkek 4 gruba ayrıldı. Grup 1'de 18 erkek, grup 2'de 58 erkek, grup 3'te 44 erkek ve grup 4'te 18 erkek vardı. Sadece grup 1 ve 2'de sperm morfolojisinde anlamlı iyileşme saptandı (sırasıyla, p=0,007 ve p=0,005). Ameliyat öncesi ve sonrası sperm parametreleri açısından gruplar arasında anlamlı fark yoktu. Toplam fertilite oranı ve doğal konsepsiyon veya yardımcı üreme teknikleriyle çocuğu olan hasta sayısı grup 4'te daha düşüktü ancak bu farklar istatistiksel olarak anlamlı değildi (sırasıyla, p=0,083 ve p=0,454).

Sonuç: Yaşına bakılmaksızın tüm infertil erkeklere varikoselektomi önerilebilir. Yaş grupları arasında postoperatif semen parametreleri ve doğurganlık oranları açısından fark yoktur.

Anahtar Sözcükler: Yaş, infertilite, varikoselektomi, semen parametreleri

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Introduction

Varicocele is the pathological dilatation of the venous plexus of testes and it is the most frequently observed correctable cause of male infertility (1). The incidence of varicocele is around 15% in the general population but this rate rises to 35-40% and 69-81% in primary and secondary infertile men, respectively (2,3). Although several hypotheses like reflux of adrenal metabolites, increased oxidative stress and scrotal temperature have been suggested, the exact mechanism of how varicocele impairs semen parameters has still not been fully elucidated (4-6). Sclerotherapy, embolization, open or laparoscopic surgery are the main treatment options for varicocele but microsurgical varicocelectomy is accepted as the most successful technique (7). It has been shown by several studies that semen parameters improve and pregnancy rates significantly increase postoperatively (8-11). The current European Association of Urology guideline recommends surgery in infertile patients with any abnormality in semen parameters, and clinical varicocele if the spouse has a good ovarian reserve to increase fertility rates (12). It has been shown that parameters like volume, motility, and morphology are affected by aging (13,14). In current guidelines, there are no lower or upper age limits recommended for varicocelectomy in infertile adults and there is no age group stated in which varicocelectomy is more successful.

In this study, we investigated the influence of age at the time of varicocelectomy on semen parameters and fertility. Patients were divided into 4 different age groups and changes in semen parameters after microscopic varicocelectomy and fertility rates were compared. There are a limited number of studies reporting the impact of age on postoperative results in the literature and reports are conflicting. In most of these studies, patients were divided into 2 or 3 groups depending on the ages of the patients. Also, in some studies the effect of the spouse's age on fertility was not investigated and fertility rates were not reported. The differences of this study from the previous ones were that we grouped patients into 4 different age groups, we evaluated the effect of the age of the spouse and reported the fertility rates after varicocelectomy.

Methods

Infertile men who had microsurgical varicocelectomy due to clinically palpable varicocele between January 2012 and December 2019 were evaluated retrospectively. Failure to conceive after one year of regular unprotected sexual intercourse was defined as infertility. Medical histories and findings of physical examinations were obtained from the patient files. Age, duration of infertility and follow-up, fertility status, sides of the varicocele, and ages of the spouses were noted. The diagnosis of varicocele was verified by Scrotal Doppler ultrasonography in all patients. Two semen analyses at least 4 weeks apart were obtained from each patient, after 3-5 days of abstinence. Analysis with better parameters was accepted as preoperative baseline semen analysis.

Semen analysis was carried out in accordance with the World Health Organization (WHO) laboratory manual for the examination and processing of human semen, 5th edition (WHO, 2010) to measure semen volume, sperm concentration, progressive motility, non-progressive motility, normal morphology, and vitality (15). The same staff member performed all semen analyzes. Total motile sperm count (TMSC) was calculated by using the formula: ejaculate volume (mL) x concentration per mL x motile fraction. Patients with subclinical varicoceles, with associated female factor infertility, patients with a follow-up duration of less than one year, and with hormonal pathology that might affect sexual function were excluded from the study. Microsurgical inguinal varicocelectomy was performed in all patients. Control semen analysis was carried out six months after the operation. Patients were evaluated in 4 groups based on their ages: group 1 (GR1) including men aged ≤25 years, group 2 (GR2) including men aged ≥26 and ≤ 30 years, group 3 (GR3) including men aged ≥31 and ≤35 years, and group 4 (GR4) including men aged ≥36 years. Median ages, duration of infertility, duration of follow-up, fertility rates, sides of the varicoceles, ages of the spouses, preoperative and postoperative sperm parameters were compared.

Statistical Analysis

The SPSS (Statistical Package for the Social Sciences) 24.0 program was used for statistical analysis. The Kruskal-Wallis test was performed for group comparisons of three or more parameters with no normal distribution. The difference between groups was evaluated by using the Mann-Whitney U test. Comparisons of preoperative and postoperative measurements were performed by using the Wilcoxon Signed-Rank test. The relationship between the measurements was determined by using the Spearman's rank-order correlation analysis. Binary regression analysis was used to evaluate the effect of varicocelectomy age on fertility rates. A p value <0.05 was considered to be statistically significant. All results were shown as median and interquartile ranges (IQR). This study was approved by the Institutional Ethics Committee (approval number: 2021/333). Owing to the study design patient consent was waived.

Results

A total of 138 infertile men who underwent varicocelectomy met the criteria and were divided into 4 groups based on their age at the time of surgery. There were 18 men in GR1 (≤25 years old), 58 men in GR2 (≥26 and ≤30 years old), 44 men in GR3 (≥31 and ≤35 years old), and 18 men in GR4 (≥36 years old). Patient characteristics are shown in Table 1. There was no significant difference in the median duration of follow-up between groups (p=0.081). The median spouse age in GR4 [33 years (IQR =31.75-36.5)] was significantly higher compared to GR1 [22 years (IQR =21-23.25)], GR2 [26 years (IQR =25-28)], and GR3 [28 years (IQR =28-29)] (p=0.001). Significant improvements in the median sperm concentration, progressive motility, and TMSC values were detected in all groups after surgery (p=0.007, p=0.026 and p=0.004, respectively for

Table 1. Detailed characteristics of the patients

	GR1 (n=18)	GR2 (n=58)	GR3 (n=44)	GR4 (n=18)	p
Age (years)	24 (23-25)	28.5 (27-29)	32 (31-33)	38 (36.75-40)	0.001
Duration of infertility (months)	13.5 (12-24)	18 (12-24)	22 (13-36)	24 (18-51)	0.002
Laterality (n, %)					0.221
Left	12 (66.7)	30 (51.7)	25 (56.8)	14 (78)	
Bilateral	6 (33.3)	28 (48.3)	19 (43.2)	4 (22)	
Duration of follow-up (months)	67.5 (61.5-84)	70 (62-81.5)	66 (57.5-82)	61 (56-68.5)	0.08
Age of the spouse (months)	22 (21-23.25)	26 (25-28)	28 (28-29)	33 (31.75-36.5)	0.001

All values are median (interquartile range)

GR1; p=0.001, p=0.04 and p=0.001, respectively for GR2; p=0.007, p=0.001 and p=0.001, respectively for GR3 and p=0.002, p=0.02 and p=0.035, respectively for GR4) (Table 2). Significant improvement in sperm morphology was detected only in GR1 and GR2 (p=0.007 and p=0.005, respectively). The changes in sperm morphology in GR3 and GR4 were not statistically significant (p=0.121 and p=0.143, respectively). There was no significant difference between the groups in terms of preoperative and postoperative sperm parameters (Table 3 and 4). Detailed fertility rates are shown in table 5. Thirteen patients (72.22%) in GR1, 41 (70.7%) patients in GR, 29 (65.9%) patients in GR3, and 7 (38.89%) patients in GR4 had children within the specified follow-up periods. Total fertility rate, number of patients having children with natural conception, and number of patients having children with ART were lower in GR4 but these differences were not statistically significant. When the whole cohort was evaluated, no significant correlation was found between age at varicocelectomy and postoperative semen volume, sperm concentration, progressive motility, TMSC, and sperm morphology (Spearman's rho =-0.103/p=0.228, Spearman's rho =0.157/p=0.066, Spearman's rho =-0.028/p=0.746, Spearman's rho= -0.027/p=0.754, and Spearman's rho =-0.030/p=0.725, respectively). Also, no significant relationship was found between the age of the spouse and fertility (p=0.984). We performed a binary regression analysis to evaluate the effect of varicocelectomy age on fertility rate and no relationship was found between the age of varicocelectomy and the fertility rate [Exp (B): -0.053, 95% confidence interval (0.86-1.03), p=0.948]

Discussion

Today, it is widely accepted that varicocele repair positively affects semen parameters and fertility rates. However, there is a paucity of data about the effects of patient age on these parameters. Some authors suggest that varicocele has progressive toxic effects on the testis and several studies reported a significant decrease in sperm concentration and motility in men with untreated varicoceles (2,16). The higher incidence of varicocele in patients with secondary infertility supports this suggestion. Therefore, varicocele repair can be expected to be more successful in younger patients and men with a shorter duration of infertility.

Hassanzadeh-Nokashty et al. (17) evaluated 67 men divided into 4 age groups as patients aged <25 years (n=17), patients aged between 25-29 years (n=18), patients aged between 30-34 years (n=17), and patients aged ≥35 years (n=15). They reported significant improvements in total sperm count, motility, and morphology in all age groups after varicocelectomy. The highest improvements were observed in men <25 years old, but they didn't evaluate the fertility rates and there was no information about the age of the spouse. Hsiao et al. (18) evaluated semen parameters after varicocelectomy in men divided into 3 age groups: Men aged <30 years, men aged between 30 and 39 years, and men aged ≥40 years. The mean spouse age was significantly higher in men aged ≥40 years (25.7±0.5, 32.2±0.3, and 37.7±0.5, respectively). Significant improvements were detected in sperm concentration and total sperm count in all groups but interestingly significant change in motility was detected only in men aged between 30 and 39 years old and no significant change was detected in sperm morphology in any group. They reported pregnancy rates of 33.3% in men aged <30 years, 39.2% in men aged between 30 and 39 years, and 24.1% in men aged ≥40 years. Bolat et al. (19) evaluated the impact of varicocelectomy in men who were ≤20 years old, men between 21-30 years old, and men ≥31 years old. They reported an increase in mean TMSC and percentage of sperms with normal morphology in all groups but no difference in natural fertility rates. Yazdani et al. (20) compared semen parameters and pregnancy rates of men younger than 30 years with men older than 30 years. Significant improvements were detected in the mean sperm concentration, motility, and morphology postoperatively in both groups. The increase in sperm concentration in the younger group was significantly higher compared to the older group. There were no statistically significant differences in other semen parameters and pregnancy rates (51.1% and 44.7% for group 1 and group 2, respectively) between the two groups. Kimura et al. (21) found that improvement in sperm concentration and motility was greater in men ≤37 years old and younger age was a predictor of early improvement in TMSC. However, Palmisano et al. (22) evaluated 228 men who underwent left microscopic varicocelectomy and reported a significant improvement in sperm concentration only in men ≥35 years old.

Table 2. Comparison of preoperative and postoperative sperm parameters in each group

	GR1 (n=18)			GR2 (n=58)			GR3 (n=44)			GR4 (n=18)		
	Pre.	Post.	p	Pre.	Post.	p	Pre.	Post.	p	Pre.	Post.	p
Sperm volume (mL)	3.61 (2.31-4.46)	3.45 (2.37-5.12)	0.845	3.58 (2.57-4.63)	3.97 (3.08-4.74)	0.201	3.38 (2.62-4.76)	3.9 (2.85-4.75)	0.07	3.75 (2.42-4.99)	3.34 (1.61-4.59)	0.078
Sperm conc. ($x10^6$/mL)	5.14 (2.8-9.25)	13 (3.2-24.5)	**0.007**	6.3 (2.75-10)	15.76 (3.9-25)	**0.001**	6.9 (2.03-16.5)	12.2 (6.05-19.55)	**0.007**	7.9 (3.5-30.5)	23 (5-36.75)	**0.002**
Progressive motility (%)	30 (23-38)	39.5 (25.25-48.25)	**0.026**	36 (20.75-42.5)	40 (27-47)	**0.04**	31.5 (13-42)	35.5 (24.25-50.5)	**0.001**	28.5 (13.5-37.5)	35 (29-41.5)	**0.020**
Non-progressive motility (%)	8.67 (6.75-10)	7.05 (5-9)	0.208	7 (6-9)	7 (5.75-9)	0.582	8 (6.25-10)	7 (6-10.75)	0.486	7.5 (6-9)	8.5 (6.75-10.2)	0.645
Non-motile sperm (%)	61.38 (55.5-69.25)	55 (46.5-65.75)	0.118	56.5 (49.5-68.25)	53 (46.75-63)	0.037	60 (49-78)	55.5 (44-66)	**0.001**	62 (53.5-75.5)	57 (51-62.25)	**0.014**
TMSC ($x10^6$)	6.87 (2.71-14.55)	19.32 (4.31-39.06)	**0.004**	7.73 (1.73-15.91)	16.12 (3.97-46.85)	**0.001**	8.29 (1.2-19.38)	17 (5.58-32.01)	**0.001**	5.25 (4.02-27.2)	15.64 (4.66-44.3)	**0.035**
Morphology (% of normal forms)	0 (0-1)	1 (0-2)	**0.007**	0.5 (0-1)	1 (0-2)	**0.005**	0 (0-1)	0.5 (0-2)	0.121	0 (0-1.25)	1 (0-1.5)	0.143

Pre.: Preoperative, Post.: Postoperative, Conc.: Concentration, TMSC: Total motile sperm count
All values are median (interquartile range)

Zini et al. (23) retrospectively analyzed 115 infertile men older than 40 years old and 466 infertile men younger than 40 years old. Sixty-three percent of the men younger than 40 years old underwent varicocelectomy and 52% of the men older than 40 years underwent varicocelectomy. The mean age of the spouse was 37.7±3.7 in men older than 40 years old and 33.2±4 in men younger than 40 years old and this difference was statistically significant. Spontaneous pregnancy rates in men older than 40 years old and in men younger than 40 years old were 49% and 39%, respectively. No significant difference was detected. We detected improvements in sperm concentration, motility, and TMSC in all age groups similar to the results in the literature. However, contrary to the data in the literature, change in the morphology was only significant in men ≤30 years old (GR1 and GR2); no significant change in morphology was detected in men >30 years old (GR3 and GR4). Also, there was no significant difference in postoperative semen parameters between groups in our study. We detected similar fertility rates in group 1 (72.22%), group 2 (70.6%) and group 3 (65.9%). However, the fertility rate of GR4 (38.89%) was lower compared to other groups, but this difference was not statistically significant (p=0.083). The median duration of infertility and the median age of the spouse values were also significantly higher in GR4. The number of patients in this group was small. This might prevent a healthy comparison and a significant difference could be found if there were more patients.

The fertility status of the spouse is also important when evaluating male infertility. Men with partners who have fertility problems are excluded from the studies investigating the pregnancy rates after varicocelectomy. However, the age of the spouse is a crucial factor affecting fertility rates. Fertility potential decreases to 50% at age 35 compared to the fertility potential of a 25-year-old woman (24). Fırat and Erdemir (25) investigated the outcome of varicocelectomy in 3 groups. In group 1 both men and their partners were ≥35 years old, in group 2 men were ≥35 and their partners were <35 years old, and in group 3 both men and their partners were <35 years old. The median age of the spouse was 36 (35-38) in group 1, 30 (21-34) in group 2, and 25 (21-33) in group 3. No significant difference was detected in pregnancy rates between the groups. In their prospective study with 120 men, Zhang et al. (26) stated that ages of the patient and spouse were not associated with spontaneous pregnancy rate after varicocelectomy. We determined the median age of spouses in each group as well. The median age of the spouse was lowest for GR1 (23.22±3.69) and highest for GR4 (33.66±4.79) as expected. The difference in the median age of spouses between the groups was statistically significant (p=0.001) but no significant relationship was found between the age of the spouse and fertility (p=0.984).

Study Limitations

This study had a few important limitations. Firstly, it was a retrospective study. The low number of patients in GR1 and GR4 was another limitation. It would be more valuable if patients over the age of 40 could be evaluated in a separate group. The highest median age of the spouse was in GR4, but this value was below 35. A study including the evaluation of fertility rates in a group of men with a median spouse age >35 years will be more useful.

Table 3. Comparison of preoperative semen parameters between groups

	GR1 (n=18)	GR2 (n=58)	GR3 (n=44)	GR4 (n=18)	p
Sperm volume (mL)	3.61 (2.31-4.46)	3.58 (2.57-4.63)	3.38 (2.62-4.76)	3.75 (2.42-4.99)	0.957
Sperm concentration (x10^6/mL)	5.14 (2.8-9.25)	6.3 (2.75-10)	6.9 (2.03-16.5)	7.9 (3.5-30.5)	0.493
Progressive motility (%)	30 (23-38)	36 (20.75-42.5)	31.5 (13-42)	28.5 (13.5-37.5)	0.368
Non-progressive motility (%)	8.67 (6.75-10)	7 (6-9)	8 (6.25-10)	7.5 (6-9)	0.609
Nonmotile sperm (%)	61.38 (55.5-69.25)	56.5 (49.5-68.25)	60 (49-78)	62(53.5-75.5)	0.415
TMSC (x10^6)	6.87 (2.71-14.55)	7.73 (1.73-15.91)	8.29 (1.2-19.38)	5.25 (4.02-27.2)	0.977
Morphology (% of normal forms)	0 (0-1)	0.5 (0-1)	0 (0-1)	0 (0-1.25)	0.579

TMSC: Total motile sperm count
All values are median (interquartile range)

Table 4. Comparison of postoperative semen parameters between groups

	GR1 (n=18)	GR2 (n=58)	GR3 (n=44)	GR 4 (n=18)	p
Sperm volume (mL)	3.45 (2.37-5.12)	3.97 (3.08-4.74)	3.9 (2.85-4.75)	3.34 (1.61-4.59)	0.293
Sperm concentration (x10^6/mL)	13 (3.2-24.5)	15.76 (3.9-25)	12.2 (6.05-19.55)	23 (5-36.75)	0.437
Progressive motility (%)	39.5 (25.25-48.25)	40 (27-47)	35.5 (24.25-50.5)	35 (29-41.5)	0.853
Non-progressive motility (%)	7.05 (5-9)	7 (5.75-9)	7 (6-10.75)	8.5 (6.75-10.2)	0.265
Non-motile sperm (%)	55 (46.5-65.75)	53 (46.75-63)	55.5 (44-66)	57 (51-62.25)	0.915
TMSC (x10^6)	19.32 (4.31-39.06)	16.12 (3.97-46.85)	17 (5.58-32.01)	15.64 (4.66-44.3)	0.916
Morphology (% of normal forms)	1 (0-2)	1 (0-2)	0.5 (0-2)	1 (0-1.5)	0.631

TMSC: Total motile sperm count
All values are median (interquartile range)

Table 5. Comparison of fertility rates between groups

	GR1 (n=18)	GR2 (n=58)	GR3 (n=44)	GR4 (n=18)	p
Overall fertility (%)	13 (72.22)	41 (70.7)	29 (65.9)	7 (38.89)	0.083
Way of fertility					0.454
Natural conc. (%)	8 (44.44)	18 (31.03)	14 (31.8)	5 (27.78)	
ART (%)	5 (27,78)	23 (56.09)	15 (34.09)	2 (11.11)	

Conc: Conception, ART: Assisted reproductive techniques

Conclusion

In literature, various age groups were used in different studies. There is no standardized age-group distinction. In some studies, patients were divided into only two groups and men with large age differences were evaluated in the same group. Although these factors make it difficult to reach a certain conclusion, it is generally accepted that in all age groups semen parameters significantly improve after varicocelectomy, and there is no difference in fertility rates between the age groups. This study also supports these results. Varicocelectomy can be recommended to all infertile men regardless of age. However, the age of the spouse should be considered as fertility potential decreases significantly after the age of 35 in women.

Ethics

Ethics Committee Approval: This study was approved by the Institutional Ethics Committee (approval number: 2021/333).

Informed Consent: Owing to the study design patient consent was waived.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: A.İ., C.E., B.D., S.K., İ.O., M.A., Concept: A.İ., Design: A.İ., C.E., B.D., S.K., İ.O., M.A., Data Collection or Processing: A.İ., C.E., B.D., S.K., İ.O., M.A., Analysis or Interpretation: A.İ., C.E., B.D., S.K., İ.O., M.A., Literature Search: A.İ., C.E., B.D., S.K., İ.O., M.A., Writing: A.İ., C.E., B.D.

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Original Article

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Our Five Years of Kaposi's Sarcoma Experience: Which Histopathological Parameters are More Valuable in Diagnosis?

Beş Yıllık Kaposi Sarkomu Deneyimimiz: Hangi Histopatolojik Parametreler Tanıda Daha Değerlidir?

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ABSTRACT

Objective: Kaposi's sarcoma (KS) is a vascular proliferation associated with Human Herpes Virus 8. Typical histopathological findings of KS are characterized by vascular proliferation, inflammatory cell infiltration, extravasated erythrocytes and spindle cell proliferation, although it varies according to the stage. In this study, the clinical-histopathological features of patients with KS were examined. The value of histopathological parameters in the diagnosis was investigated.

Methods: Patients with KS diagnosed in University of Health Sciences Turkey, Samsun Training and Research Hospital Medical Pathology Department between 2016-2020 were retrospectively scanned. Clinical and tumor features and histopathological changes in the surrounding tissue were evaluated.

Results: The most common histopathological features belonging to tumor were extravasated erythrocytes, spindle cell changes, fascicle formation, slit-like space; the most common epidermal features were hyperkeratosis and acanthosis; the most common peritumoral features were the presence of large vessels and ectatic vessels in the periphery. There was a significant relationship between the promontory sign and the lymphangioma-like area and ulcer. Also there was a significant relationship between nuclear atypia and lymphangioma-like area.

ÖZ

Amaç: Kaposi sarkomu (KS), human herpes virüs 8 ilişkili vasküler bir proliferasyondur. Tipik histopatolojik bulguları, evreye göre değişmekle birlikte; vasküler proliferasyon, inflamatuvar hücre infiltrasyonu, ekstravaze eritrositler ve iğsi hücre proliferasyonu ile karakterizedir. Çalışmamızda KS olgularının klinik-histopatolojik özellikleri incelendi. Histopatolojik parametrelerin tanıdaki değeri araştırıldı.

Yöntemler: Sağlık Bilimleri Üniversitesi Samsun Eğitim ve Araştırma Hastanesi Tıbbi Patoloji Bölümü'nde 2016-2020 yılları arasında tanı alan KS olguları retrospektif olarak tarandı. Klinik, tümör özellikleri ve çevre dokudaki histopatolojik değişiklikler değerlendirildi.

Bulgular: En sık görülen tümöre ait histopatolojik özellikler ekstravaze eritrositler, iğsi hücre değişikliği, fasikül oluşumu, yarık benzeri boşluk; epidermise ait özellikler hiperkeratoz ve akantoz; peritümöral özellikler ise periferde büyük damar ve çevrede ektatik damar varlığıdır. Promontuvar belirti ile lenfanjiom benzeri alan ve ülser arasında; nükleer atipi ile lenfanjiyom benzeri alan arasında anlamlı ilişki saptanmıştır.

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ABSTRACT

Conclusion: While most of the histopathological features are characteristic for KS, none of them alone is specific. They should be evaluated together with all structural, tumoral and peritumoral features during the diagnostic approach.

Keywords: Kaposi's sarcoma, vascular tumor, histopathology, human herpes virus 8, HHV-8, promontory sign

ÖZ

Sonuç: Histopatolojik özelliklerin çoğu KS için karakteristik olmakla birlikte, hiçbiri tek başına spesifik değildir. Tanısal yaklaşım sırasında tüm yapısal, tümöral ve peritümöral özellikler birlikte değerlendirilmelidir.

Anahtar Sözcükler: Kaposi sarkomu, vasküler tümör, histopatoloji, human herpes virüs 8, HHV-8, promontuvar belirti

Introduction

Kaposi's sarcoma (KS) is a vascular proliferation associated with human herpes virus 8 (HHV-8), and is still contoversial whether it is a true sarcoma or not. It's worldwide estimated incidence is 0.6/100,000 person-year (1). Four different clinical/epidemiological subtypes of KS have been defined: classic, epidemic [acquired immunodeficiency syndrome associated], endemic (African type), and iatrogenic (transplantation-associated) KS (1-3). All these types show similar histomorphological spectrum. The histopathological development of the tumor occurs in clinically distinguishable patch, plaque and nodule stages. In addition to the usual type of KS, there are many histopathological subtypes defined in the literature such as anaplastic, lymphedematous, lymphangioma-like, lymphangiectatic, bullous, telangiectatic, hyperkeratotic, keloidal, micronodular, pyogenic granuloma-like, ecchymotic, intravascular, and regressed KS (2,4,5).

Typical histopathological findings of KS are characterized by vascular proliferation, inflammatory cell infiltration, extravasated erythrocytes and spindle cell proliferation, although it varies according to the stage. Apart from these well-known features, what other histological changes are observed in the tumor and surrounding tissue, and which ones are more valuable in making the diagnosis?

In our study, answers to these questions were sought, and detailed histopathological analysis of patients with KS diagnosed in the Medical Pathology Department of University of Health Sciences Turkey, Samsun Training and Research Hospital during the 5-year period covering the years 2016-2020 was carried out. Clinical and tumor features and histopathological changes in the surrounding tissue were evaluated. The value of histopathological parameters to making the diagnosis was investigated.

Methods

Case Selection

Patients with KS diagnosed in University of Health Sciences Turkey, Samsun Training and Research Hospital, Medical Pathology Department between 2016-2020 were retrospectively scanned from the hospital information management system (HIMS). Fourty three patients who had excisional or punch biopsies were detected. The slides of the patients were removed from the archive. Three patients were excluded because there was no slide or block in the archive. The clinical data of the patients (age, gender, localization of the lesions) were compiled from HIMS. Histopathological evaluation was performed using hematoxylin/eosin stained slides, immunohistochemical (HHV-8 in all patients) and histochemical (PAS in some patients) materials. One patient was not found to be compatible with KS after re-evaluation and was excluded from the study.

The study was approved by the Non-invasive Clinical Research Ethics Committee of University of Health Sciences Turkey, Samsun Training and Research Hospital (decision no: 2019/3/4) and performed in accordance with the Helsinki Declaration.

Histomorphological evaluation

The slides of the lesions included in the study were re-evaluated by double observers. Epidermal parameters (hyperkeratosis, acanthosis, papillomatosis, vesicle/bulla, ulcer), tumor features (vascular horizontal location, presence of miniature vessels in the center, lymphangioma-like area, hemangioma-like area, promontory sign, collagen fiber dissection, erythrocyte extravasation, hemosiderin/hemosiderin-laden macrophage, presence of spindle cell, slit-like space, fascicle formation, presence of hyaline globule, nuclear atypia, mitosis, necrosis, inflammatory infiltrate) and peritumoral features (large vessel in the periphery, ectatic vessel in the periphery) were evaluated. Mitosis was counted in 10 high power fields. Inflammatory infiltrate was graded as dense, moderate, mild, and the predominant cell component (lymphocyte, plasma, neutrophil) was determined. All other parameters were classified as present/absent.

Statistical Analysis

The SPSS 15.0 for Windows (SPSS Inc., Chiago, Illinois, USA) program was applied for statistical analysis. Descriptive statistics were given as numbers and percentages for categorical variables. Numerical variables were given as mean, standard deviation, minimum and maximum. Comparison of rates in independent groups was made with the chi-square test. Since the numeric variables showed normal distribution, comparisons of independent two groups were made with Student's t-test. Statistical alpha significance level was accepted as $p<0.05$.

Results

Of the 39 patients included in the study, 28 (71.8%) were male and 11 (28.2%) were female. The mean age ± standard deviation of the patients was 71.8±8.5, and the age range was between 49

and 92 years. Tumors were located in the lower extremity in 25 (65.8%) patients, in the upper extremity in 12 (31.6%) patients, and in the scrotum in 1 (2.6%) patient. Thirty two (82.1%) of the evaluated materials were excisional materials and 7 (17.9%) of them were punch biopsy materials. The stages of the patients were detected as "patch" in only 2 patients and as "nodul" in the others.

The histopathological parameters we evaluated and their incidence rates are shown in Table 1.

The most common finding we determined from the features of the tumor was the presence of extravasated erythrocytes (n=38), and the most common finding among the epidermis parameters was hyperkeratosis (n=34).

The rate of detection of spindle cell changes, fascicles, peripheral large vessels, slit-like spaces, and ulcers was statistically significantly lower in punch biopsies than excisional biopsies (Table 2).

Table 1. Results

	n	(%)
Features of tumor		
Erythrocyte extravasation	38	97.4%
Spindle cell change	36	92.3%
Fascicle	34	87.2%
Slit-like space	28	71.8%
Hemosiderin laden macrophages	21	53.8%
Nuclear atypia	12	30.8%
Promontory sign	11	28.2%
Collagen fiber dissection	10	25.6%
Hemangioma-like area	7	17.9%
Hyaline globule	6	15.4%
Vascular horizontal location	6	15.4%
Miniature vessels in the center	5	12.8%
Lenfangioma-like area	3	7.7%
Necrosis	1	2.6%
Parameters of epidermis		
Hyperkeratosis	34	87.2%
Acanthosis	25	64.1%
Papillomatosis	20	51.3%
Ulcer	19	48.7%
Vesicle/bulla	1	2.6%
Peritumoral features		
Large vessel in the periphery	29	74.4%
Ectatic vessel in the periphery	26	66.7%

When the findings were compared according to localization, no significant difference was found between the findings.

When the relationship between the parameters was examined;

- The rate of ulceration in sarcomas with promontory sign was statistically significantly higher than those without promontory sign (p=0.010) (Table 3).

- Presence of lymphangioma-like area in those without nuclear atypia was statistically significantly higher than those with nuclear atypia (p=0.024) (Table 4).

- The mean mitosis of patients with spindle cell changes, fascicles, peripheral great vessels, slit-like spaces, and ulcers were statistically significantly higher than those without them (Table 5).

- No significant difference was found in the findings of patients with or without hyaline globules.

A feature that caught our attention was the presence of moderate or intense mixed type lymphoplasmacytic inflammatory cell infiltration in each patient (Table 6).

Pictures of some of the histopathological parameters are given in Figure 1.

Discussion

Kaposi's sarcoma is an HHV-8-associated vascular proliferation primarily involving the skin, most commonly located in the lower extremities (1). Most of the studies which were reported until now on KS were related to demographic and clinical data, and studies examining histopathological features were in the minority. In our study, histopathological features as well as demographic data were discussed in detail.

When the demographic data of the patients included in our study were compared with the literature, no difference was found.

The mean age of onset of KS may differ according to the subtype (6-8). However, the mean age in classical KS has been reported to be between 65 and 75 in most studies (3,4,6,9). In our study, the mean age of the patients was 71.8 (age range between 49 and 92), which was similar to the literature.

The female/male ratio was reported at different rates between studies. While the M/F ratio was 2.36 in the study of Demirel et al., (4) 2.11 in the study of Kandemir et al., (5) 4.07 in the study of Errihani et al., (10) and this ratio was 6.5 in the study of Wu et al. (11). In our study, the male/female ratio was 2.54.

Typical histopathological findings of KS vary according to the stage. Patch-stage lesions are characterized by thin endothelial cell proliferation that breaks down collagen (1,2,4). The extension of small proliferating vascular structures towards to larger vessel lumens causes the appearance called "promontory sign" (2). Early stage lesions may be accompanied by promontory sign. Plaque stage lesions are more cellular and are characterized by dense dermal vascular infiltrate and spindle cell proliferation.

Table 2. Comparison of histopathological parameters according to biopsy type

	Biopsy type				
	Excision		Punch		
	n	%	n	%	p
Spindle cell change	32	100.0%	4	57.1%	**0.004**
Fascicle	30	93.8%	4	57.1%	**0.032**
Hyperkeratosis	28	87.5%	6	85.7%	1.000
Large vessel in the periphery	27	84.4%	2	28.6%	**0.007**
Slit-like space	26	81.3%	2	28.6%	**0.012**
Ectatic vessel in the periphery	22	68.8%	4	57.1%	0.566
Acanthosis	23	71.9%	2	28.6%	0.075
Papillomatosis	18	56.3%	2	28.6%	0.235
Ulcer	19	59.4%	0	0.0%	**0.008**
Collogen fiber dissection	8	25.0%	2	28.6%	1.000
Hemangioma-like area	7	21.9%	0	0.0%	0.313
Vascular horizontal localization	5	15.6%	1	14.3%	1.000
Miniature vessels in the center	3	9.4%	2	28.6%	0.213
Lenfangioma-like area	3	9.4%	0	0.0%	1.000
Vesicle/bulla	1	3.1%	0	0.0%	1.000

Table 3. Comparison of histopathological parameters according to promontory sign

	Promontory sign				
	Presence		Absent		
	n	%	n	%	p
Spindle cell change	11	100.0%	25	89.3%	0.545
Fascicle	10	90.9%	24	85.7%	1.000
Hyperkeratosis	11	100.0%	23	82.1%	0.296
Large vessel in the periphery	9	81.8%	20	71.4%	0.693
Slit-like space	10	90.9%	18	64.3%	0.130
Ectatic vessels in the periphery	9	81.8%	17	60.7%	0.276
Acanthosis	9	81.8%	16	57.1%	0.266
Papillomatosis	6	54.5%	14	50.0%	0.798
Ulcer	9	81.8%	10	35.7%	**0.010**
Kollogen fiber dissection	3	27.3%	7	25.0%	1.000
Hemangioma-like area	4	36.4%	3	10.7%	0.083
Vascular horizontal localization	3	27.3%	3	10.7%	0.323
Miniature vessels in the center	1	9.1%	4	14.3%	1.000
Lenfangioma-like area	3	27.3%	0	0.0%	**0.018**
Vesicle/bulla	1	9.1%	0	0.0%	0.282

Other expected findings are hyaline globules, siderophages, and slit-like spaces containing erythrocytes (1,2). Nodule stage lesions are much more cellular. The spindle cells form fascicles and slit-like spaces are common. Hyaline globules and mitoses can be seen (1,2).

Almost all of our patients were in the nodule stage, and in accordance with this, the most frequent tumor-related features we detected were extravasated erythrocytes, spindle cell changes, fascicles, slit-like space and hemosiderin-laden macrophages. Among the peritumoral features, the presence of large vessels in the periphery was a remarkable feature in KS with 74% of cases.

It has been reported in the literature that promontory sign is frequently seen in early-stage lesions (1,2). Since almost all of our patients were in the nodule stage in our study, we could not compare the relationship between the stage and the promontory sign. However, we observed that the promontory sign was not less in the nodule stage. In addition, we found that there was a statistically significant positive correlation between the

Table 4. Comparison of nuclear atypia and other histopathological parameters

	Nuclear atypia				
	Present		Absent		
	n	%	n	%	p
Spindle cell change	26	96.3%	10	83.3%	0.219
Fascicle	24	88.9%	10	83.3%	0.634
Hyperkeratosis	22	81.5%	12	100.0%	0.299
Large vessel in the periphery	21	77.8%	8	66.7%	0.693
Slit-like space	19	70.4%	9	75.0%	1.000
Ectatic vessels in the periphery	18	66.7%	8	66.7%	1.000
Acanthosis	16	59.3%	9	75.0%	0.477
Papillomatosis	15	55.6%	5	41.7%	0.423
Ulcer	12	44.4%	7	58.3%	0.423
Collogen fiber dissection	7	25.9%	3	25.0%	1.000
Hemangioma-like area	5	18.5%	2	16.7%	1.000
Vascular horizontal localization	2	7.4%	4	33.3%	0.060
Miniature vessels in the center	2	7.4%	3	25.0%	0.159
Lenfangioma-like area	0	0.0%	3	25.0%	**0.024**
Vesicle/bulla	1	3.7%	0	0.0%	1.000

Table 5. Comparison of the relationship between the number of mitosis and other histopathological parameters

		Mitosis … /10 HPF		
		Mean ± SD	Min-max	p
Spindle cell cgange	Positive	11.39±6.95	1-31	**0.012**
	Negative	0.67±1.15	0-2	
Fascicle	Positive	11.59±7.00	1-31	**0.020**
	Negative	3.60±5.41	0-13	
Hiperkeratosis	Positive	10.94±7.62	0-31	0.406
	Negative	8.00±3.87	3-12	
Large vessel in the periphery	Positive	11.97±7.14	1-31	**0.039**
	Negative	6.50±6.35	0-17	
Slit-like space	Positive	13.14±6.60	4-31	**<0.001**
	Negative	4.00±4.22	0-13	
Ectatic vessels in the periphery	Positive	11.04±6.71	1-31	0.572
	Negative	9.62±8.52	0-27	
Acanthosis	Positive	11.68±6.61	1-31	0.205
	Negative	8.57±8.22	0-27	
Papillomatosis	Positive	11.00±8.30	1-31	0.707
	Negative	10.11±6.23	0-23	
Ulcer	Positive	14.26±6.54	6-31	**0.001**
	Negative	7.05±6.23	0-23	
Collogen fiber dissection	Positive	8.00±6.09	0-17	0.200
	Negative	11.45±7.54	0-31	
Hemangioma-like area	Positive	10.57±4.04	3-15	0.998
	Negative	10.56±7.86	0-31	
Vascular horizontal localization	Positive	11.50±5.96	0-17	0.737
	Negative	10.39±7.56	0-31	

Table 5. Continued				
Miniature vessels in the center	Positive	5.80±5.26	0-13	0.118
	Negative	11.26±7.33	0-31	
Lenfangioma-like area	Positive	18.00±11.27	11-31	0.065
	Negative	9.94±6.72	0-27	
Vesicle/bulla	Positive	14.00	14-14	-
	Negative	10.47±7.35	0-31	

SD: Standart deviation, Min: Minimum, Max: Maximum

Table 6. Inflammatory infiltrate status in our patients

		n (%)
Inflammatory response	Severe lymphocyte predominant	24 (61.5%)
	Moderete lymphocyte predominant	12 (30.8%)
	Severe plasma cell predominant	2 (5.1%)
	Severe lymphocyte = plasma cell	1 (2.6%)

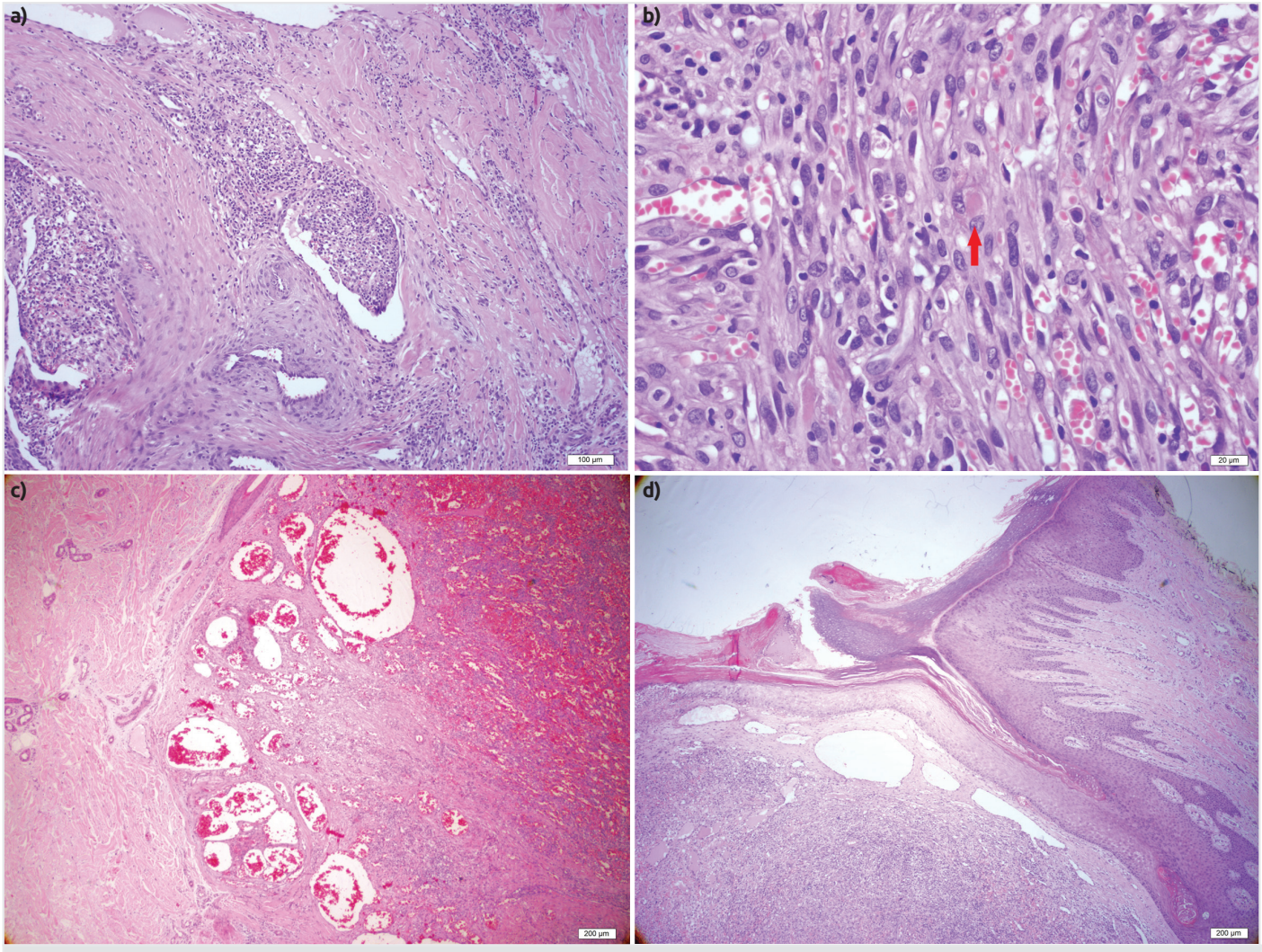

Figure 1. a) Promontory sign is seen. Its called for the extension of small proliferating vascular structures towards to larger vessel lumens (hematoxylin & eosin x100), b) Hiyalen globule is seen (hematoxylin & eosin, x400), c) Hemangioma-like area is seen (hematoxylin & eosin, x40), d) Ectatic vessel in the periphery (hematoxylin & eosin, x40)

promontory sign and the presence of ulcer. In the approach to an ulcerated skin lesion, the presence of promontory sign should raise suspicion in terms of KS. However, it should be noted that the promontory sign is not pathognomonic for KS. It has been emphasized that it is not an uncommon feature in patch or plaque stage of angiosarcomas (12), and it has been reported that it can also be seen in reactive benign vascular proliferations (13).

It has been reported that promontory sign is observed more frequently in lymphangioma-like subtype (2,5). Consistent with this, we also observed the presence of promontory sign in 3 of our 3 patients with lymphangioma-like areas.

In our study, some histopathological features such as spindle cell change and the presence of fascicles were found to be significantly lower in punch biopsies compared to excisional biopsies. These findings, which are strongly suggestive for diagnosis, may be observed less frequently in small biopsies, which may lead to missed diagnosis or delays in diagnosis.

Nuclear atypia and high mitosis are not common findings in KS. They can be observed more frequently in advanced lesions. In our study, we found a significant relationship between nuclear atypia and the presence of lymphangioma-like areas. Presence of lymphangioma-like area in those without nuclear atypia was statistically significantly higher than those with nuclear atypia. When we searched the literature, we did not find any study reporting a relationship between atypia and lymphangiomatous area. In this sense, our study presents a new finding.

When the relationship between the number of mitosis and histopathological changes was compared; we found a significant relationship between mitosis and spindle cell change, fascicle formation, large vessels in the periphery, slit-like space and ulcer. Considering that spindle cell changes, slit-like space and fascicle formation were more common findings in the nodule stage; it would not be wrong to say that the number of mitoses might be high in advanced lesions.

Conclusion

In this study, the clinical-histopathological features of patients with KS were examined. The most common histopathological features belong tumor were extravasated erythrocytes, spindle cell changes, fascicle formation, slit-like space; the most common epidermal features were hyperkeratosis and acanthosis; the most common peritumoral features were the presence of large vessels and ectatic vessels in the periphery. There was a significant relationship between the promontory sign and the lymphangioma-like area and ulcer. Also there was a significant relationship between nuclear atypia and lymphangioma-like area. Mitosis was found to be high in advanced lesions.

While most of the histopathological features were caracteristic for KS, none of them alone was specific. They should be evaluated together with all structural, tumoral and peritumoral features during the diagnostic approach. In addition, it should not be forgotten that the diagnosis could be missed, especially in punch biopsies; and small biopsies should be examined carefully.

Ethics

Ethics Committee Approval: The study was approved by the Non-invasive Clinical Research Ethics Committee of University of Health Sciences Turkey, Samsun Training and Research Hospital (decision no: 2019/3/4) and performed in accordance with the Helsinki Declaration.

Informed Consent: Since it was a retrospective study, patient consent was not obtained.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: C.B.I., Concept: C.B.I., H.Ö.U., Design: C.B.I., Data Collection or Processing: C.B.I., Analysis or Interpretation: C.B.I., H.Ö.U., Literature Search: C.B.I., Writing: C.B.I.

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Original Article

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Shotblocker or Cold Application; Which One is More Effective in Reducing Anxiety and Pain Associated with the Intramuscular Injection in Children?: A Randomized Controlled Trial

Shotblocker veya Soğuk Uygulama; Çocuklarda Intramusküler Enjeksiyona İlişkin Anksiyete ve Ağrıyı Azaltmada Hangisi Daha Etkilidir?: Randomize Kontrollü Çalışma

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ABSTRACT

Objective: Pain is associated with most invasive interventions in childhood and considered as an unpleasant condition; thus, it should be relieved. This study aimed at investigating the effect of two different non-pharmacological pain-relief methods on reducing the pain and anxiety associated with intramuscular (IM) injection in children.

Methods: This study was a prospective experimental randomized controlled trial. The sample of the study comprised 150 children aged 7 to 12 years who were brought to the pediatric injection room in a university hospital and had IM injection. The children were randomized into the Shotblocker (n=50), cold application (n=50) and control (n=50) groups.

Results: The children in the control group felt pain more than did the children in the ShotBlocker and cold application groups. The difference was statistically significant. Assessment of the anxiety level during the IM injection demonstrated that the children in the control group experienced anxiety statistically significantly more than did the children in the ShotBlocker group.

ÖZ

Amaç: Çocukluk çağında invaziv girişimlere bağlı olan ağrı, hoş olmayan bir durum olarak tanımlanmakta ve giderilmesi gerekmektedir. Çalışma, çocuklarda intramusküler (İM) enjeksiyona bağlı ağrının azaltılmasında iki farklı non-farmakolojik ağrı giderme yönteminin çocukların ağrı ve anksiyete düzeyine etkisini değerlendirmek amacı ile yapıldı.

Yöntemler: Bu çalışma ileriye dönük randomize kontrollü deneysel bir çalışmadır. Araştırmanın örneklemini bir üniversite hastanesinin çocuk enjeksiyon odasına getirilen ve İM enjeksiyon yapılan 7-12 yaş arası 150 çocuk oluşturdu. Çocuklar, Shotblocker (n=50), soğuk uygulama (n=50) ve kontrol (n=50) gruplarına randomize edildi.

Bulgular: Kontrol grubundaki çocukların, ShotBlocker ve soğuk uygulama grubuna göre daha fazla ağrı yaşadığı ve aralarındaki farkın anlamlı olduğu belirlendi. Araştırmada İM enjeksiyon sırasındaki anksiyete durumunu değerlendirildiğinde, kontrol grubunda yer alan çocukların, ShotBlocker grubuna göre daha fazla anksiyete yaşadığı ve aralarındaki farkın anlamlı olduğu belirlendi.

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ABSTRACT

Conclusion: The children in the ShotBlocker and cold application groups experienced pain less than did the children in the control group during the IM injection. When compared to the Cold Application method, ShotBlocker method is more effective in reducing IM injection-related pain and fear.

Keywords: Children, intramuscular injection, pediatric nurse, pain management

ÖZ

Sonuç: ShotBlocker ve soğuk uygulama gruplarında yer alan çocukların İM enjeksiyon sırasında kontrol grubundaki çocuklara göre daha az ağrı yaşadığı belirlendi. ShotBlocker, soğuk uygulama ile karşılaştırıldığında İM enjeksiyonla ilişkili ağrı ve korkuyu azaltmada daha etkilidir.

Anahtar Sözcükler: Çocuklar, kas içi enjeksiyon, pediyatri hemşiresi, ağrı yönetimi

Introduction

Throughout their life from birth to death, people undergo many invasive interventions and experience pain and anxiety associated with these interventions. Children, the most affected group by such interventions, also face various sources of pain and anxiety during their developmental period (1). The pain experienced in this period affects behaviors, interaction with family, diet and growth negatively and may create negative impacts on children. The intramuscular (IM) injection is one of these unpleasant experiences not only for children but also for parents and healthcare professionals.

IM injection, one of the parenteral drug administration methods, is a common nursing intervention used in clinical practice (2-4). The invasive procedures involving the IM injections are routinely carried out in healthcare settings, and especially children with chronic disease face many painful procedures during the diagnosis and treatment. Being defined as an invasive hospital intervention causing serious pain, IM injection is also perceived as a frightening intervention by children (5-7).

In the period from childhood to adulthood, two-thirds of children experience injection fear due to the agonizing and painful experiences (8,9). While the injection fear experienced in childhood often leads to the unwillingness to medical procedures in the child and parents; in later ages, it may result in the rejection of treatment and the failure or delay of some required examinations (10-13). Many pains and fears experienced in childhood can cause fear and avoidance while medical care is received in adulthood. In the literature, it has been reported that about 25% of adults have the injection fear and, moreover, this fear is caused by the needle interventions applied in childhood (14,15). It has also been reported that there is a relationship between pain and anxiety; therefore, reducing the anxiety can affect the child's perception towards pain during and after the painful procedures (16).

In the literature, pain is considered as the fifth vital sign, and minimizing pain is considered as a basic human right. Considering the fact that the most common iatrogenic pains experienced by children are caused by the IM injections, the pain control provided at the appropriate time during the painful interventions to children will increase their tolerance for the future procedures (17-19). It is also important to focus on reducing pain and anxiety together in pain management (16). Therefore, many approaches involving the pharmacological and non-pharmacological methods have been being used alone or in combination to reduce the pain and anxiety possible to be experienced by children during the medical interventions. In recent years, non-pharmacological methods have been preferred due to the fact that they are noninvasive, cheap, reliable, one of the independent nursing interventions, and have no side effects (20). Today, non-pharmacological supportive methods, cognitive/behavioral methods, and physical methods are being applied to manage the pain and anxiety associated with the invasive procedures in children (7,12,15,21).

Most of the non-pharmacological methods used to reduce pain associated with IM injections in children are considered during vaccinations; however, methods only used during the IM applications are limited in number (7,12,13,22). ShotBlocker, a plastic device approved by Food and Drug Administration and used for pain control in the IM injection, is a nondrug and noninvasive method suitable for all age groups (23). It has been reported that it reduces pain by preventing the pain from being perceived and transmitted to the central nervous system by means of applying temporary blockage to the peripheral nerve ends (7,22-25). One of the methods used to reduce the IM injection pain is the local cold application on the injection site. With its anti-inflammatory, anti-spasmodic, and analgesic effects, it has an important place in non-pharmacological pain relief methods as being easy to implement and being cheap (3,26-28).

Pain-reducing intervention strategies used in pain management should be evidence-based. Therefore, it is important to conduct well-designed studies in which various non-pharmacological modalities are compared and their efficacy is investigated in pain management in children of different age groups. Our literature review demonstrated that there was no randomized controlled study in which the effects of both ShotBlocker and cold application on pain reduction in children having IM injections were demonstrated. In the light of this information, we conducted this randomized controlled experimental study to determine the effects of methods such as cold application and Shotblocker on the pain and anxiety levels of children in reducing the pain associated with IM injection.

Methods

Design

The present study was designed as a prospective randomized controlled experimental research to determine the effects of methods such as cold application and Shotblocker on the pain and anxiety level of the children in reducing the pain associated with IM injection. Before the study was started, all the children and parents were informed about what the purpose of the study was, how the study would be carried out, and how the data of the study would be used, verbal consent from the children and written consent from the parents (clinical trials: NCT05070325).

Hypotheses of the Study

The hypotheses of the study are as follows:

Hypothesis 1. Using ShotBlocker during IM injection reduces the pain and anxiety experienced by the child.

Hypothesis 2. Applying cold to the injection site prior to IM injection reduces the pain and anxiety experienced by the child.

Hypothesis 3. ShotBlocker is more effective than cold application in reducing pain and anxiety of children

Sample

The population of the present study consisted of children within the age range of 7-12 years who presented to the injection room in the pediatrics clinic of a university hospital between November 2017 and June 2018. Of these children, 150 who met the case-selection criteria and agreed to participate in the study were included in the study sample. The sample selection criteria of the study were as follows: (a) being in the age group of 7-12 years, (b) requiring penicillin (procaine penicillin), (c) having no developmental retardation/disability, (d) having no communication difficulty, (e) having no chronic disease, (f) having taken no analgesic drug within the last 6 hours.

In the Power analysis carried out based on the literature (7,13,25), the sample size of the study was determined as 150 (α=0.10) (Figure 1). The sample was calculated as minimum 50 patients per group (effect size: 0.5 power 0.95) (29). The sample size in a similar study was determined as 50 in each group, comprising a total of 150 (13).

The children in the sample were randomly assigned to the following groups: Cold application, Shotblocker, and control groups. In order to determine which patient to include in which group, the numbers were randomly distributed to the 3 groups without repetition using a software. The children included in the study were distributed to groups by stratified randomization method according to gender. A gender (girl/boy) group was created. In each group set, the order in which the sample would be distributed among the groups was determined. In the study, the sample size for each of the 3 groups, that is, cold application group (n=50), Shotblocker group (n=50), and control group (n=50) was determined as 50.

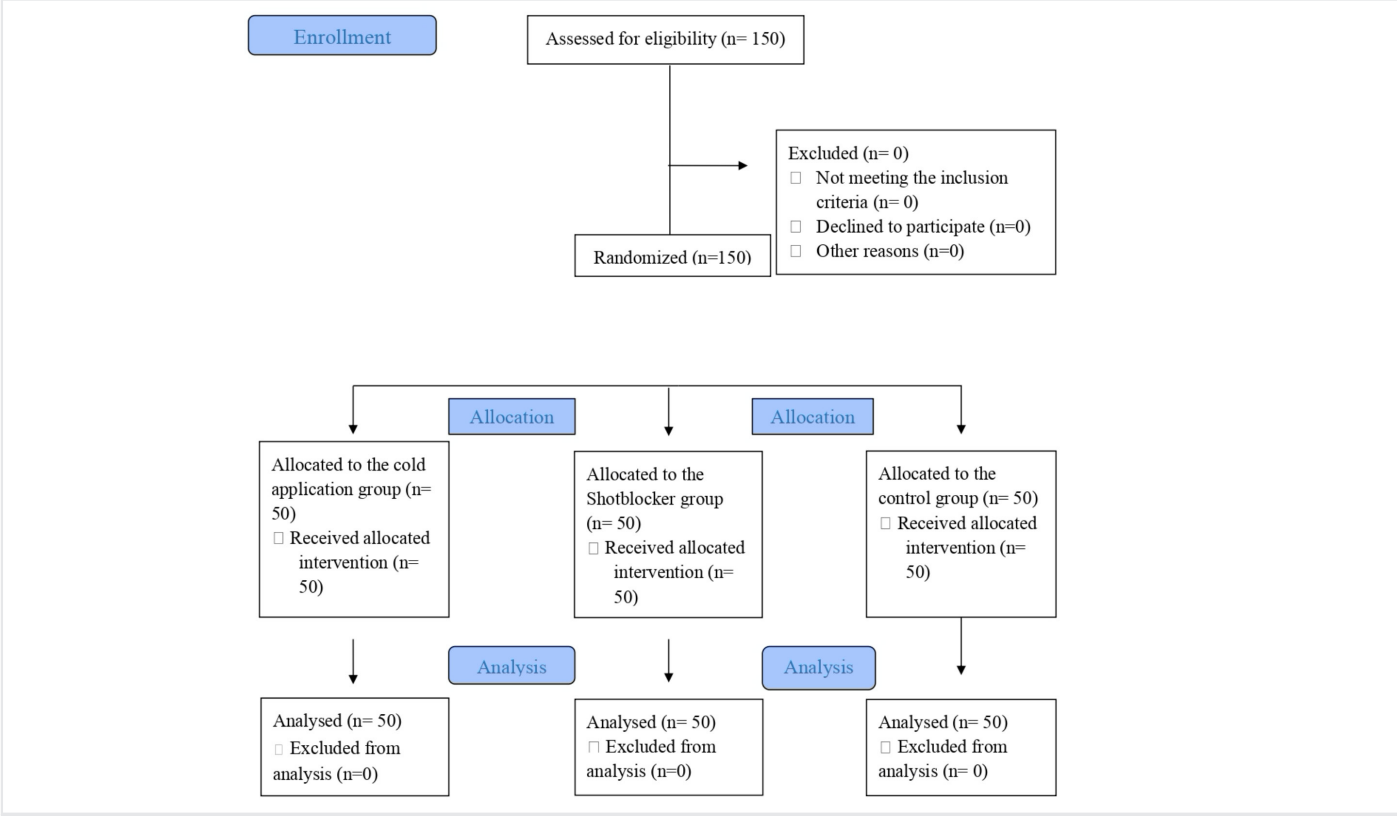

Figure 1. Study flow diagram

Data Collection

IM injection was carried out in the pediatric injection room of a university hospital. Patients who were prescribed IM injections by a pediatrician as part of the necessary medical care of pediatric patients and admitted to the injection room were included in the study. Before the intervention, the parents and children were met, they were informed about the study, and they were asked whether they would accept to participate in the study. The written and verbal consent was obtained from the parents and the children, respectively. In order to ensure reliability in the study results, IM injection was given by the same nurse having at least 5 years of working experience throughout the study, and the pain behavior and anxiety levels of the children were evaluated by the same researcher. This situation was discussed in the limitations section of the research. The parents were allowed to stay with their children during IM injection.

The following information was obtained from the children and parents who agreed to participate in the study using the Child **Information form:** Socio-demographic characteristics of the children and parents, previous history of IM injection, previous history of being subject to a painful intervention, whether the child took an analgesic drug within the last 6 hours, the body mass index (BMI), etc. Prior to IM injection, the children's body weight and height were measured and recorded. The same medicine (procaine penicillin) was administered to all the children.

During IM injection, it was ensured that the environmental factors (temperature, light, noise, etc.), the injection site, and the antiseptic solution (70% alcohol) were standardized. The injection site was wiped using an antiseptic (batticon/chlorhexidine) cotton ball (antiseptic [batticon/chlorhexidine] cotton wool by gently pressing from center to periphery. It was ensured that the child was in the appropriate position, that is, in the prone position, with the toes facing inward. Prior to the injection, Shotblocker or the cold gel pad was introduced to the children in the experimental group and they were informed of how they would be used. Furthermore, the children and parents were informed about the Wong-Baker FACES® Pain Rating Scale and Children's Fear Scale (CFS) to be used in the study. The parents and children who volunteered to take part in the study were informed of the scale scoring. Which parent would take part in the study was left to the choice of parents to take participate. The CFS scale was evaluated preoperatively after consent was obtained from the children and parents and the information form was filled in. The pain evaluation was made by the children, parents, and observers right after the procedure. When the scales were administered, a particular attention was paid so that the children, parents and observers would not see each other's evaluation and not affect one another. Before the injection, the anxiety level was evaluated by the child, parent, and researcher using the CFS. After the injection; the pain level was evaluated by the child, parent, and researcher using the Wong-Baker FACES® Pain Rating Scale, and the anxiety level was evaluated by the parent and researcher using the CFS. In assessing the pain level, the child was asked to choose the face that best expressed his or her feelings on the scale, and the parents were also asked to evaluate their child's pain level.

Cold application group (Group 1): Cold gel pad, with the dimensions of 8.89 cm x11.43 cm, is suitable for the child's age group and thanks to the fine-grained gel it contains, it can easily adapt to the shape of the application site. It can be used for both hot and cold applications and is offered in the form of various animal characters (Figure 2). The cold application eliminates the edema and muscle spasm by means of vasoconstriction and is effective in relieving the pain by blocking the transmission by peripheral nerves (30,31).

In the children in this group, the injection site was cleaned before the injection using an antiseptic cotton ball (antiseptic cotton wool) and then the gel pad was placed on the injection site. In line with the literature, the cold gel pad was applied to the IM injection site for 30-45 seconds before the injection and then the injection was delivered. The children were told to breathe in deeply and not to tense their muscle during the injection. CFS was used to evaluate the anxiety level in children before the injection. Wong-Baker FACES® Pain Rating Scale was used to assess the child's pain level after the injection, and CFS was used again to assess the fear level.

ShotBlocker group (Group 2): ShotBlocker is a nondrug, noninvasive, small, flat, yellow, and plastic patented device that is suitable for all age groups. It is used by pressing against the skin during injection and has no side effects. ShotBlocker has short, blunt, and 2 mm-thick points touching the skin and an opening in the middle to expose the injection site.[2] In IM injection, it works by the mechanism of preventing the pain from being perceived and transmitted to the central nervous system by means of applying temporary blockage to the peripheral nerve ends. This feature of ShotBlocker is designed in line with the principles of Gate Control Theory (2,22-24,32). Approval for using ShotBlocker in this study was received from Turkish Medicines and Medical Devices Agency.

The injection site was cleaned using an antiseptic cotton ball (antiseptic cotton wool). The Shotblocker with the contact

Figure 2. Cold gel pad

points was placed on the site just before the injection in a way not to contaminate the injection point. Injection was carried out through the opening in the middle of ShotBlocker. The children were told to breathe in deeply and not to tense their muscle during the injection. After the injection was completed, ShotBlocker was removed from the skin. CFS was used to evaluate the anxiety level in children before the injection. Wong-Baker FACES® Pain Rating Scale was used to assess the child's pain level after the injection, and CFS was used again to assess the fear level.

Control Group (Group 3): The routine IM injection was applied to the children in this group. The injection site was cleaned using an antiseptic cotton ball (antiseptic cotton wool). The children were told to breathe in deeply and not to tense their muscle during the injection. CFS was used to evaluate the anxiety level in children before the injection. Wong-Baker FACES® Pain Rating Scale was used to assess the child's pain level after the injection, and CFS was used again to assess the fear level.

Data Collection Tools

The study data were collected using the Child Information Form, the Wong-Baker FACES® Scale, and CFS.

Child Information Form: This form prepared by the researcher to get information about the children selected for the sample contains 12 questions on the child's age, gender, weight, length, BKI, whether the child has a health problem that affects her/his perception of pain, previous history of IM injection, injection duration, and whether the child has injection fear, etc.

Wong-Baker FACES® Scale (WB-FACES): This scale developed by Wong and Baker (33) is used to assess the level of pain in the children at the age of 3-18 years. In this scale, there are six faces representing the pain in an increasing order of intensity from zero to five from left to right. The leftmost face has a smile on it, representing "no pain"; whereas the rightmost face is a crying face, representing "the most intense pain." As the score obtained from the scale increases, the pain tolerance decreases, and vice versa. In practice, the child is asked to choose the face that best expresses her/his feelings. Before the scale is administered, the child is told that each face belongs to a person, and the faces represent a happy person with no pain or a sad person feeling a little or too much pain (33).

Children's Fear Scale (CFS): The scale developed by McMurtry et al. (34) is used to measure the levels of fear and anxiety in children. The child is shown a picture of 5 facial expressions, each having a score between "0" and "4" points. This scale can be easily administered by both researchers and families to measure the fear and anxiety before and during the applications. In the scale, while "0" refers to "no fear and anxiety"; "4" refers to "the highest level of fear and anxiety" (34).

Statistical Analysis

The data obtained in the present study were analyzed using IBM Statistical Package for the Social Sciences 22 (IBM SPSS, Turkey). The fitness of the parameters to normal distribution was evaluated by the Shapiro-Wilks test. In the evaluation of the data, in addition to the descriptive statistical methods (arithmetic mean, standard deviation, frequency), the one-way analysis of variance (ANOVA) test was used for the comparisons of three or more groups with normal distribution, and Tamhane's T2 was used for the paired comparisons. On the other hand, the chi-square test was used for the comparison of the qualitative data. The statistical significance was set at $p<0.05$.

Ethical Considerations

Permission was obtained from the clinical research ethics committee (29.07.16/2016-41) and from the relevant institution to carry out the study. We registered the trial at the Turkey Registry of Clinical Trials-Turkish Medicines and Medical Devices Agency, Ministry of Health in 2016 (2016-080). The study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2010. Before the study was started, all the children and parents were informed about what the purpose of the study was, how the study would be carried out, and how the data of the study would be used, verbal consent from the children and written consent from the parents were obtained through the Voluntary Informed Consent Form. Furthermore, they were informed that they could withdraw from the study at any time without giving any reason. This randomized controlled trial was performed according to the CONSORT guidelines, and registered as a clinical trial (NCT05070325).

Results

In the study, 76 girls (50.7%) and 74 boys (49.3%) were included. The mean age of the children was 10.28±1.94 years. The children included in the study were randomly divided into three groups: cold application (n=50), Shotblocker (n=50), and control (n=50). The children's characteristics were given in the Table 1. As can be seen in the Table 1, variables such as age, sex, BMI, and the duration of the procedure were similar in all the groups.

The pain levels of the groups were given in the Table 2. The comparison of the mean scores in the cold application, Shotblocker, and control groups based on the evaluations made by the child, parent, and researcher demonstrated that there was a statistically significant difference between the groups ($p<0.05$, Table 2). The analysis conducted to find out from which group the difference stemmed demonstrated that the difference stemmed from the Shotblocker group.

The evaluations on the anxiety levels of the groups were given in the Table 3. In the evaluations made by the child, parent, and researcher, it was found that there was a statistically significant difference between the groups in terms of the mean anxiety scores obtained in the cold application, Shotblocker, and control groups ($p<0.05$, Table 3). Intra-group comparisons made by the researcher revealed that there was no significant difference between the cold application group and the control group. However, there was a significant difference between the evaluations made by the parent and researcher. The anxiety levels of the children in the shotblocker group were significantly lower than those in the control and cold application groups.

Table 1. Baseline characteristics and pre-procedural anxiety scores of the study groups

	Cold application group (n=50)	ShotBlocker group (n=50)	Control group (n=50)	x²	p†
Sex					
Girls	26 (52%)	25 (50%)	25 (50%)	0.399	2.956
Boys	24 (48%)	25 (50%)	25 (50%)		
	Cold application group (n=50)	**Shotblocker group (n=50)**	**Control group (n=50)**	**F**	**p††**
Age (years)	10.54±1.87	10.16±1.74	10.14±2.21	0.665	0.516
BMI	17.78±2.28	17.37±3.30	17.11±4.64	0.418	0.659
Pre-procedural anxiety levels					
Self-reported	1.14±0.57	1.90±1.35	0.98±0.14	1.702	0.186
Parent-reported	0.66±0.65	0.48±0.57	0.74±0.44	2.754	0.067
Observer-reported	1.34±0.91	0.04±0.19	0.10±0.30	0.808	0.448

Data are represented as number (percentage) or mean ± standard deviation, where appropriate.
†Pearson's chi-square test - x2, ††One-way analysis of variance - F
BMI: Body mass index, p<0.05

Table 2. Comparison of procedural pain scores of the study groups

Procedural pain scores according to WB-FACES	Cold application group[1] (n=50)	ShotBlocker group[2] (n=50)	Control group[3] (n=50)	F	p†	Group 1-2††	Group 1-3††	Group 2-3††
Self-reported	4.12±2.43	3.68±3.13	6.20±3.60	9.758	***<0.001***	0.820	***0.003***	***0.001***
Parent-reported	3.36±1.63	1.96±1.68	4.12±2.30	16.626	***<0.001***	***<0.001***	0.170	***<0.001***
Observer-reported	2.76±1.66	1.52±1.87	3.16±1.46	13.034	***<0.001***	***0.002***	0.496	***<0.001***

Data are represented as mean ± standard deviation. WB-FACES, Wong Baker Faces
†One-way ANOVA test-F, ††Tamhane's T2, p<0.05

Table 3. Comparison of procedural anxiety scores of the study groups

Procedural anxiety scores	Cold Application group[1] (n=50)	ShotBlocker group[2] (n=50)	Control group[3] (n=50)	F	p†	Group 1-2††	Group 1-3††	Group 2-3††
Parent-reported	1.40±1.08	0.24±0.65	0.98±0.14	31.651	***<0.001***	***<0.001***	***0.027***	***<0.001***
Observer-reported	1.00±0.85	0.08±0.27	0.98±0.14	49.916	***<0.001***	***<0.001***	0.998	***<0.001***

Data are represented as mean ± standard deviation.
†One-way ANOVA test - F, ††Tamhane's T2, p<0.05

Discussion

Pain is associated with most invasive interventions in childhood and referred to as an unpleasant condition; thus, it should be relieved (3,35,36). The effective evaluation and elimination of pain in children is the first requirement of pain management and one of the basic elements of nursing care (26,28,36). The American Society of Pain Management Nursing also states that nurses are responsible for using the pharmacological and non-pharmacological methods in pain management before, during, and after the procedure in individuals exposed to painful procedures (34). Nurses have an important role in pain management and control. The quality of pain management depends on the nurse's knowledge, attitude, and skill regarding painful interventions (2,23,35). In the present study, the effects of ShotBlocker and local cold application performed to reduce pain and anxiety in children who received IM injection were investigated and compared. The children participating in the study were assigned into three groups. There was no statistically significant difference between the participating children in terms

of variables such as age, sex, body mass index, and pre-procedural anxiety (Table 1). These results suggested that the groups were similar in terms of demographic variables that might affect their perceptions of pain and anxiety.

One of the non-pharmacological methods used to reduce the IM injection pain is the local cold application to the injection site. Cold application has been used as a topical pain reliever for many years. Although the cold application is not widely used to relieve the pain during the invasive procedures in the literature, this method is a natural, cost-effective, easily accessible, and ideal intervention to reduce pain in children without any negative effects, and it exerts its anesthetic effect on the skin quickly. Cold application works by the mechanism of slowing down the transmission by peripheral nerves (31). In their study, Hasanpour et al. (30) investigated the effect of two non-pharmacological methods on the IM injection pain in 90 children aged 5-12 years, and they asserted that the local cold application relieved the pain associated with the injection. In their study, Gaikwad et al. (31) reported that the local cold application was a practical, comfortable and cost effective method in reducing the pain during the intravenous procedures in children. In their study, Farhadi and Esmailzadeh (37) investigated the effect of local cold application on pain associated with IM penicillin injection in the participants aged 15-50 years, and they stated that the local cold application was effective in reducing the pain associated with the injection. In their study, the self-reported evaluations showed that the procedural pain scores of the cold application group were significantly lower than were those of the control group. The results obtained in the present study indicating that the local cold application was effective in reducing pain associated with injection on children were consistent with those obtained in studies conducted by Hasanpour et al. (30), Gaikwad et al. (31), and Farhadi and Esmailzadeh (37). However, the effect of the local cold application was less effective than was that of the Shotblocker method. In order to evaluate this difference in parent-reported and observer-reported evaluations, there is a need for different large-scale studies. In our study, statistical significance was determined between the WB-FACES score averages evaluated by the children in the evaluation of pain levels between the cold application and control groups, although the WB-FACES score averages evaluated by the parents and the researcher were lower than the control group, but no statistical significance was determined. It is thought that this difference is due to the group sizes considered within the scope of the study.

ShotBlocker is another non-pharmacological method recently being used to reduce pain during invasive procedures in children. In the literature, it has been reported that the Shotblocker's asserted mechanism of action works as follows: the pressure applied to the skin stimulates the nerve ends that transmit signals faster and have smaller diameters, slower pain signals during the injection are temporarily blocked, and thus the gates to the central nervous system are closed, and as a result, the pain is reduced (22,23,36). In the literature, while in some studies, it was revealed that the ShotBlocker had positive effects during the various painful procedures such as the IM injection in both children and adults (23,25,35,36,38,39), and that; in some other studies, its effect was not fully specified (19,32,40). In their study, Yilmaz and Alemdar (7) asserted that Shotblocker was more effective than the bubble-blowing in reducing the pain during the IM applications in the pediatric emergency unit. Sivri Bilgen and Balcı (13) reported that Buzzy, followed by ShotBlocker, was the most effective method in reducing the pain associated with IM injection in the children aged 7-12 years. In their study, Aykanat Girgin et al. (39) reported that ShotBlocker and Buzzy methods were effective in reducing pain and fear in children and increasing parental satisfaction during IM injection. In their study on using ShotBlocker in reducing the IM injection pain in children, Drago et al. (22) found that the children's pain scores dropped in the evaluations made by the nurses and caregivers; however, there was no difference according to the evaluations made by the children. Cobb and Cohen (24) asserted that ShotBlocker was not effective in relieving pain associated with the IM injection into the deltoid muscle in children. The differences between the results of the studies might be due to the fact that the studies were conducted in children of different age groups, in different environments, or that they were used together with different non-pharmacological methods. These results were similar to those of studies by Yilmaz and Alemdar (7), Sivri Bilgen and Balcı (13), Aykanat Girgin et al. (39) in terms of reducing the pain during the IM injection.

Other parameters examined in the present study were the fear and anxiety. It has been reported in the literature that the anxiety and fear increase the level of pain perceived, and as a result, the high anxiety levels may cause more pain response in children (16,41). In the post-IM injection evaluations made by the parents and researchers in our study, we found that there was a statistically significant difference between the groups in terms of the mean anxiety scores ($p<0.05$). In the intragroup paired comparison of the evaluation made by the researcher, there was no significant difference between the cold application group and the control group; whereas in the paired comparisons of the evaluations made by both the parent and researcher, there was a significant difference. The anxiety levels of the children in the Shotblocker group were significantly lower than those in the control and cold application groups. In their study in which they investigated the effectiveness of two different methods during the insulin injection in the children aged 6-12 years, Canbulat Sahiner et al. (12) asserted that the children in the Shotblocker group experienced less anxiety. In their study carried out with children aged 6-11 years who received IM injection, Canbulat Şahiner and Türkmen (6) reported that the distracting cards caused a statistically significant decrease in the pain and anxiety levels of the children. Sivri Bilgen and Balcı (13) also reported that there was a statistically significant decrease in the fear and anxiety levels of the children in all the three groups. In our study, the effectiveness of the ShotBlocker method was more significant in reducing fear and anxiety experienced during IM injections both in the researcher's and parent's evaluations, whereas there was no difference between the cold application and control group in the researcher's evaluations, which made us think that the ShotBlocker method was more effective than the cold application method. The findings of our study were similar to

those of the studies in the literature in terms of reducing the fear and anxiety associated with the IM injections (6,12,13).

Study Limitations

In our study, the observer researcher, child and parent were not blind to the intervention, which might create a prejudice in the evaluations of the observer researcher, child and parent. In addition, the children in the study might give different reactions to pain due to their physical, emotional state, socioeconomic status and cultural background.

Implications for Nursing Practice

Reducing or relieving pain is undoubtedly one of the most important objectives of the nursing care. The ability of nurses to minimize the emotional and physical effects of pain on children during the painful procedures is important in terms of children's development. Therefore, it is thought that the Shotblocker and cold application methods, which are used to reduce pain, can be applied in more clinics due to the fact that they are not only practical, inexpensive, and effective pain relievers but also they are easy to use and preferable by nurses. Furthermore, the Shotblocker and cold application methods are one of the independent nursing interventions that can be carried out by nurses in relieving pain in children.

Nurses should be aware that children having IM injections may suffer pain and thus they should use a pain reliever method accordingly. Therefore, training of healthcare professionals is the first step in reducing pain in pediatric patients. Nurses and other healthcare professionals responsible for children can be informed about the importance of pain relief through in-service training within the scope of the protocols of the hospitals where they work, and about the use and effectiveness of easy and low-cost devices such as local cold application and ShotBlocker. The usefulness of these methods can be further demonstrated in studies in which other painful procedures are implemented in different age groups.

Conclusion

The findings of our study based on the evaluations made by the child, parent, and observer demonstrated that both the ShotBlocker group and the cold application group experienced less pain, respectively, than did the control group during IM injection. ShotBlocker was more effective than the cold application in reducing the pain associated with IM injection. According to the researcher's and parent's evaluations, the ShotBlocker method was more effective on reducing anxiety during IM injection than was the cold application method.

Based on these results, we recommend that nurses be aware of the pain and anxiety associated with the short painful procedures such as IM injections in children, have knowledge about various non-pharmacological pain-relief methods, and use these methods in clinics. We also recommend that the effectiveness of ShotBlocker and cold application be supported with the future evidence-based studies to be carried out in different painful procedures and in different age groups.

Ethics

Ethics Committee Approval: Permission was obtained from the clinical research ethics committee (29.07.16/2016-41) and from the relevant institution to carry out the study. We registered the trial at the Turkey Registry of Clinical Trials-Turkish Medicines and Medical Devices Agency, Ministry of Health in 2016 (2016-080).

Informed Consent: Before the study was started, all the children and parents were informed about what the purpose of the study was, how the study would be carried out, and how the data of the study would be used, verbal consent from the children and written consent from the parents (clinical trials: NCT05070325).

Peer-review: Externally peer reviewed.

Authorship Contributions

Concept: D.Y., S.O.A., H.N.P.K., Design: D.Y., S.O.A., H.N.P.K., Data Collection or Processing: D.Y., Analysis or Interpretation: D.Y., Literature Search: D.Y., S.O.A., H.N.P.K., Writing: D.Y., S.O.A., H.N.P.K.

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Original Article

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Fetal Health Anxiety: A Validity and Reliability Study of the Turkish Version of the Fetal Health Anxiety Inventory

Fetal Sağlık Kaygısı: Fetal Sağlık Kaygı Envanteri Türkçe Versiyonu Geçerlilik ve Güvenilirlik Çalışması

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ABSTRACT

Objective: In the present study, it was aimed to adapt the fetal health anxiety inventory (FHAI) into Turkish and to analyze the validity and reliability of the scale among pregnant women.

Methods: Explanatory factor analysis (EFA) was applied to 370 pregnant women in Sample I and confirmatory factor analysis (CFA) was applied to 200 pregnant women in Sample II. The Prenatal Distress Questionnaire (NuPDQ) was used to test criterion-related validity of the FHAI. The reliability of the inventory was examined with Cronbach's alpha reliability coefficient, item-total score correlation coefficient and test-retest analysis.

Results: As a result of EFA applied to Sample I, it was determined that the 14-item FHAI covered a single factor, and the scale demonstrated good fit indices (χ2/standard deviation =3.148, comparative fit index =0.907, standardized root mean squared residual =0.000, root mean square error of approximation =0.089, and p value =0.000) as a result of the CFA applied to Sample II. A statistically significant positive correlation was found between the FHAI and NuPDQ (r=0.851, p<0.01). Cronbach's alpha internal consistency coefficient of the inventory was 0.85, and item-total score correlation coefficients were found to range between r=0.34-0.59 (p<0.001). In the test-retest analysis, a statistically significant and positive correlation was found between the total scores of

ÖZ

Amaç: Bu çalışma, Fetal Sağlık Kaygı Envanteri (FSKE) Türkçe'ye uyarlamayı ve ölçeğin gebelerde geçerlilik ve güvenilirliğini değerlendirmeyi amaçlamaktadır.

Yöntemler: Örnek 1'de yer alan 370 gebeye açıklayıcı faktör analizi (AFA), Örnek 2'de yer alan 200 gebeye doğrulayıcı faktör analizi (DFA) uygulanmıştır. FSKE'nin ölçüt-bağıntılı geçerlik testi için Prenatal Distres Ölçeği (PDÖ) kullanıldı. Envanterin güvenirliği Cronbach's alfa güvenirlik katsayısı, madde-toplam puan korelasyon katsayısı ve test-retest analizi ile incelendi.

Bulgular: Örnek 1'e uygulanan AFA sonucunda 14 maddelik FSKE'nin tek faktörü kapsadığı ve Örnek 2'ye uygulanan DFA sonucunda ölçeğin iyi uyum indeksleri (χ2/standart sapma =3,148, karşılaştırmalı uyum indeksi =0,907, artıkların standart sapması veya kök ortalama kare hatası =0,000, kök ortalama karekök hatası =0,089 ve p değeri =0,000) gösterdiği belirlendi. FSKE ile PDÖ arasında istatistiksel olarak pozitif yönde anlamlı ilişki olduğu saptandı (r=0,851, p<0,01). Envanterin Cronbach's alfa iç tutarlık katsayısının 0,85 olduğu ve madde-toplam korelasyon katsayılarının r=0,34-0,59 arasında değiştiği bulundu (p<0,001). Test-tekrar test analizinde, iki farklı uygulamada elde edilen envanterin toplam puanları arasında istatistiksel olarak pozitif yönde anlamlı ilişki bulundu (r=0,568, p=0,001).

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ABSTRACT

the inventory obtained in two different applications (r=0.568, p=0.001).

Conclusion: The current study supported the use of 14-item FHAI as a valid and reliable tool to measure fetal health anxiety of Turkish pregnant women.

Keywords: Anxiety, fetal health, reliability, validity

ÖZ

Sonuç: Bu çalışma, 14 maddeden oluşan FSKE'nin Türk gebe kadınlarda fetal sağlık kaygısını ölçmek için geçerli ve güvenilir bir araç olarak kullanımını desteklemiştir.

Anahtar Sözcükler: Anksiyete, fetal sağlık, geçerlilik, güvenilirlilik

Introduction

Stress and mental illnesses experienced during pregnancy may have negative effects on both the mother and the developing infant (1-4). The physiological changes required for the growth of fetus and development of fetal health as well as response to these physiological changes take place throughout pregnancy, and these changes are accompanied with dread and uncertainty. The well-being of the pregnant woman is very important both for herself and for the health of the developing fetus. If the expectant mother cannot cope with her anxiety, the risk of mental and psychological disorders increases and the anxiety negatively affects the mechanisms that enable the adaptation process to take place in a healthy way (1,2).

There are many studies in the literature showing negative birth outcomes such as low birth weight in infants, small head circumference, which is an indicator of brain development, and preterm labor associated with the stress experienced during pregnancy (5-7). At the same time, there are findings showing that the preterm is negatively affected in neurodevelopmental, emotional, and behavioral areas (8). Concerns over the health of the mother's growing fetus are referred to as fetal health anxiety (4,9). Fetal health is affected by maternal, fetal, placental, and external factors. Early diagnosis and treatment of problems that may adversely affect fetal health minimize fetal mortality and morbidity (10). Pregnant women should be examined in order to determine fetal health concerns during pregnancy. Using a qualitative methodology, Harpel (4) investigated the influence of ultrasonography on the experiences of fetal health concerns among 30 pregnant women. According to the findings, ultrasonography can help women feel less anxious about their fetuse's health, especially when they can see the image and hear positive comments (4). At the same time, it is stated in the literature that the knowledge that the fetus is healthy following an ultrasound reduces the anxiety levels of parents (11,12).

Although there are many measurement tools and studies that analyze the mother's anxiety level during pregnancy (13-16), the fetal health anxiety cannot be determined because there is no measurement tool that determines it. The fact that fetal issues are widely acknowledged emphasizes the necessity to address the measuring techniques that may be employed to test for this issue. In actuality, it's crucial to examine whether the measuring techniques to be employed for this goal are appropriate for various cultural frameworks. By adapting the Fetal Health Anxiety Inventory (FHAI) to Turkish in terms of determining fetal health anxiety, creating strategies to eliminate anxiety, and defining it more specifically and objectively, the current study aimed to test the validity and reliability of the FHAI in Turkish population.

Methods

Study Design and Participants

The current research was designed in methodological type. The study involved expecting mothers who were enrolled in a public hospital's pregnancy course in eastern Turkey. Records showed that the researchers contacted pregnant women who satisfied the inclusion requirements and told them about the study. Women who accepted to take part in the study were asked to complete a web-based survey. The study questionnaires were created with the help of the Google Forms program (https://docs.google.com/forms), and links to the surveys were distributed to the expectant mothers via social media such as WhatsApp, and Facebook Messenger. On the first page of the online survey, there was information on the study and a consent form for participants. The data collection phase was completed by filling out the questionnaires, which took approximately 5-10 minutes.

The sample size for the current investigation was decided upon using the standards proposed by Comrey and Lee (16). Comrey and Lee (16) advised the following sample size guidelines for factor analysis: Very poor was defined as 50, poor as 100, moderate as 200, good as 300, very good as 500, and excellent as 1,000 or above. Participants in the research included 570 pregnant women. Two separate sample groups were subjected to confirmatory factor analysis (CFA) and exploratory factor analysis (EFA). Three hundred seventy pregnant women from sample I were given EFA, while 200 pregnant women from sample II were given CFA. To determine if the sample size was enough, a post hoc power analysis was carried out. Web-based and publicly available statistical software OpenEpi version 3.01 was used for power analysis (17). The study's power was determined to be 95% for 570 pregnants that were part of the sample, with a 5% margin of error, bipolar significance level, and a 95% confidence interval.

The data from Sample I was collected between the dates of August and October, 2021, and the data from Sample II was collected in December, 2021 (Figure 1). Pregnant women who met the inclusion criteria were randomly selected from the records. The inclusion criteria were being a healthy pregnant woman who was older than 18 years of age, without any psychiatric disease or depressive symptoms.

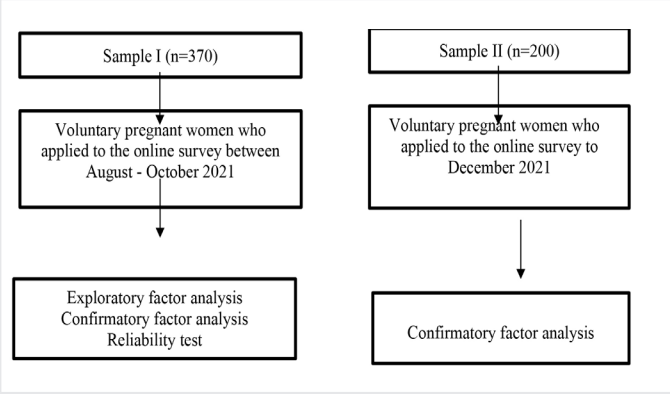

Figure 1. Study design, grouping and modeling

Data Collection Tools

Personal Information Form

It is a form consisting of questions to determine the sociodemographic characteristics of pregnant women (such as age, educational level, employment status) and obstetric characteristics (parity, the status of having a planned/desired pregnancy, trimester) (1,4,10).

Prenatal Distress Questionnaire (NuPDQ)

It was created by Yali and Lobel (18) to gauge pregnant women's prenatal discomfort levels. A 17-item version was developed by Lobel (19) as a result of revision studies, and by Yuksel et al. (20), its Turkish validity and reliability study was established. The questionnaire determines the physical and emotional symptoms that may occur during pregnancy, the levels of anxiety and concern experienced by women in matters related to motherhood, body image, and pregnancy. The questionnaire consists of four subscales: "Physical and Social Changes related to Pregnancy, Concerns regarding the Baby and Labor", "Concerns regarding the Quality of Healthcare and Health Status", "Concerns regarding the Baby-care and Postpartum Life", and "Financial Concerns". A minimum of 0 points and a maximum of 34 points can be obtained from the entire questionnaire. An increase in the scores of the questionnaire and its subscales indicates that the level of distress perceived by pregnant women increases. After doing their research, Yuksel et al. (20) discovered that the questionnaire's internal consistency coefficient was 0.85. The scale's internal consistency coefficient according to Cronbach's alpha was estimated to be 0.77 in the current investigation.

Fetal Health Anxiety Inventory (FHAI)

Reiser and Wright (21) created the FHAI, and this study examined its validity and reliability. The survey gauges pregnant women's worry over the fetus's well-being. There are no subscales in the FHAI and it consists of 14 items. Each item consists of 4 statements that best deal with the experiences of the pregnant women in the past weeks. Items on the inventory are scored between 0 (no symptoms) and 3 (severe symptoms), and the sum of the items gives the total score of fetal health anxiety (0-42), while the higher the score, the higher the fetal health anxiety level (21) (Appendix 1).

Process of the Cultural Adaptation

The main task of cultural adaptation was to translate the FHAI into Turkish. The stages of language validity, content validity, and pilot implementation made up the cultural adaptation phase.

Language validity: In the process of adapting the FHAI to Turkish, first of all, permission was obtained from Wright, who developed the scale, via e-mail. The scale was translated into Turkish during the language validation phase of the test by two faculty members and two independent linguists (lecturers in the field of midwifery, obstetrics, and gynecology nursing). The researchers looked over the translations and developed the Turkish version that most accurately reflected each item. Two separate, qualified linguists translated the generated Turkish text back into English and checked for compatibility between the two languages. It was discovered that the back translation form and the original inventory were identical.

Content Validity Index for Items (I-CVI)

Content validity was performed for language and content control of the items of the inventory (22,23). There are two most common methods used for content validity. One of them is the Lawshe technique and the other is the Davis technique. Davis technique was used for the content validity index in our study. In the Davis technique, experts are asked to evaluate their opinions with one of four degrees. In this scoring, the statements are 1 point for "not appropriate", 2 points for "somewhat appropriate, the item needs correction", 3 points for "quite appropriate but minor changes are necessary", and 4 points for "very appropriate" (22). To determine the content validity of the scale, five faculty members, four in midwifery and one in obstetrics and gynecology, were asked to rate each item of the scale from 1 to 4. After examining the average scores given by the experts for each item of the scale, it is recommended to completely remove or rearrange the items that are at least below the agreement limit or least compatible (24). The "content validity index (CVI)" of the item is obtained by dividing the number of experts marking the options in this technique by the total number of experts. As a result of the evaluation of expert opinions using Davis method; while the statements that the experts found very appropriate were accepted without changing, the statements that the experts did not find appropriate or wanted to be corrected were revised and corrected. A CVI greater than 0.80 means that the content validity of the scale is statistically significant. As a result of the expert evaluations of the scale; the CVI calculated with the CVI formula was found to be quite high (CVI =0.95, Table 1). It was seen that the scores obtained from the experts were not statistically different and there was a consistency between the experts. The level of agreement with the expert opinions was examined with the Kendall W analysis, which was a non-parametric test (25). In line with expert opinions, the draft version of the FHAI inventory was completed.

Pilot implementation: In the next stage, the trial Turkish form of the inventory was applied to 10 pregnant women and they were asked to identify the unclear expressions. The findings obtained were not included in the results of the present research. There were no misunderstood items in the pilot implementation, and the Turkish version of the FHAI was completed.

Psychometric Testing of the FHAI

During the adaptation to Turkish of the FHAI validity-reliability analyses were performed for psychometric analysis.

Validity

Exploratory Factor Analysis

First, the applicability of the dataset was assessed in order to assess the construct validity of the FHAI. Kaiser-Meyer-Olkin (KMO) and Barlett's test of sphericity were applied for this. The KMO must exceed 0.60 in order for the data to be appropriate for factor analysis, and Bartlett's test of sphericity results must be statistically significant (26). For the inventory's construct validity, explanatory and confirmatory factor analyses were carried out.

EFA was used to identify the scale's fundamental elements. A high variance ratio as a result of EFA indicates that the factor structure power of the scale is high. A total explained variance above 50% indicates that there is strong construct validity (27). It is advised to remove goods with factor loading below 0.30 from the inventory as this is the maximum value for factor loading (28). EFA was used to analyze the data from Sample I (n=500).

Confirmatory Factor Analysis

By comparing the results of one or more measurement tools that are assumed to measure the same feature with the score of the measurement tool that is meant to assess the desired feature as a standard, criterion-related validity/concurrent validity is produced. Similar results show that the measurement tool has criterion-related validity when the measurement tool's validity has been studied and compared to the measurement tool of which validity has already been established (29). Pregnant women were subjected to the NuPDQ in order to assess the FHAI's criterion-related validity.

CFA is an analysis in which a previously defined and limited structure is tested to whether it is validated as a model (30). CFA was applied to test the structure obtained after EFA. For CFA studies, the FHAI was applied to sample II and the obtained data was analyzed. Multiple fit indices were used for CFA and chi-square goodness, comparative fit index (CFI), Standardized Root Mean Square Residual (SRMR), Root Mean Square Error of Approximation (RMSEA), and p value for testing the null hypothesis's fit indices were examined. In the fit indices, $\chi 2/df < 5$, $0.90 \leq$ CFI, $0.05 <$ SRMR ≤ 0.10, $0.05 \leq$ RMSEA ≤ 0.10, and p value <0.05 were regarded as acceptable criteria (31).

Reliability

Cronbach's Alpha Reliability Coefficient

The reliability of the FHAI was measured by calculating the Cronbach's alpha internal consistency coefficient, determining item-total score correlations, and test-retest reliability. Internal consistency increases as the coefficient approaches 1, and in order to say that a scale is reliable, the calculated coefficient must be at least 0.70 (32).

Item-total Score Correlation Coefficient

The item-total score correlation coefficients were looked at in order to look at the link between the scores acquired from the FHAI's items and the overall score of the inventory. The item-total score correlation coefficient provides details on how the assessment tool's items relate to one another. It is advised that the

Table 1. Content validity index scores for FHAI

Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Item CVI
FHAI1	3	4	4	4	4	1.00
FHAI2	3	2	3	3	4	0.80
FHAI3	3	3	3	4	3	1.00
FHAI4	3	3	4	4	3	1.00
FHAI5	3	2	4	4	3	0.80
FHAI6	3	4	4	4	3	1.00
FHAI7	3	3	4	4	2	0.80
FHAI8	3	3	4	4	4	1.00
FHAI9	3	3	4	3	3	1.00
FHAI10	3	3	4	3	3	1.00
FHAI11	3	3	4	4	4	1.00
FHAI12	3	3	4	4	3	1.00
FHAI13	3	3	4	4	3	1.00
FHAI14	3	4	4	4	4	1.00
I-CVI total	-	-	-	-	-	0.96

1 point for "not appropriate", 2 points for "somewhat appropriate, the item needs to be adjusted", 3 points for "quite appropriate but minor changes are necessary", 4 points for "very appropriate", CVI: Content validity index

acceptable item selection coefficient be higher than 0.20 (33).

Test-retest Analysis

In order to determine the invariance of the FHAI over time, the consistency of the responses of the individuals to the items of the measurement tool by applying the measurement tool to the same individuals at different times shows the invariance of the measurement tool against time. In the literature, it is stated that at least 30 participants should be reached for the test-retest (34), and the scale was applied to 30 women for the second time to be retested 15 days later. The correlation coefficient between the values obtained at the end of the two applications gives the reliability coefficient of the scale. As this value takes values between 0 and 1 and gets closer to 1, the reliability of the correlation value increases (35).

Statistical Analysis

The SPSS 25.0 (SPSS Inc., Chicago, IL, USA) and AMOS 24 (Multivariate Software, Inc., Los Angeles, CA, USA) were used to analyze the study's data (36). The Kolmogorov-Smirnov test was performed to examine the results of all scale values utilized in this study in order to verify the normalcy assumptions. Due to the data's normal distribution, parametric tests were applied. Descriptive statistics including frequency, percentage, mean, and standard deviation were used to describe the characteristics of the pregnant women. To examine the content validity of the inventory, Kendall's W-test was applied. The data's acceptability for factor analysis was assessed using KMO analysis, and the sample size's appropriateness was determined using Bartlett's test of Sphericity. EFA and the Promax Rotation technique were used to investigate the factor structure of the inventory. To validate the structure of the inventory discovered by factor analysis, CFA was carried out. The Pearson product-moment correlation analysis was used to look at the correlation between the FHAI and NuPDQ as part of the criterion-related validity/concurrent validity investigation of the inventory. In the reliability analyses of the inventory, the item analysis and test-retest analysis were investigated using Pearson correlation analysis, and the internal consistency of the inventory was examined with Cronbach's alpha reliability coefficient. Explanatory factor analysis produced the main findings. Additionally, analyses of the content validity, confirmatory factor analysis, criterion-related validity, and reliability were carried out.

Ethical Issues

Wright, who created the scale, was contacted by email to provide his consent to translate the FHAI into Turkish. Additionally, approval from the Scientific Research and Publication Ethics Committee of the İnönü University (decision number: 2020/915) was acquired prior to data collection. On the first page of the online questionnaire, which served as the study's consent form, all pregnant women who agreed to participate in it were informed about the research before it began. Included were those who freely took part in the study.

Results

A total of 2% of pregnant women with high-risk pregnancies (such as cardiac conditions and gestational diabetes) were cut from the study's sample of EFA (n=377) due to inclusion requirements. Of pregnant women with hazardous pregnancies (including placenta previa, intrauterine growth retardation, and high blood pressure) 4% were eliminated from the research after the target sample (n=208) was checked for CFA inclusion requirements. Two hundred pregnant women in Sample II of the study's CFA and 370 pregnant women in Sample I of its EFA were both included in the analysis.

Participants' Characteristics

The mean gestational week of Sample I included in the study was 36.72±4.53, 64.3% of them were between the ages of 18 and 30, 36.5% were university graduates, 78.6% were unemployed, 84.1% had the moderate level of income, 88.4% had planned pregnancy, 97.6% had the desired pregnancy, 95.4% were in the third trimester, and 62.2% were multiparas. The mean gestational week of Sample II was 30.62±9.53, 65.5% of them were between the ages of 18 and 30, 50.0% were university graduates, 65.5% were unemployed, 73.5% had moderate level of income, 82.5% had planned pregnancy, 91.5% had desired pregnancy, 74.5% were in the third trimester, and 68.5% were multiparas (Table 2).

Validity

Exploratory Factor Analysis

The items evaluated as a result of the expert views reviewed by the Kendall W analysis were not significantly different from one another for the content validity of the scale (Kendall W =0.851; p>0.05), and the expert opinions were consistent. Following the application of EFA to Sample I, the KMO value of FHAI was 0.851 and the results of Barlett's test of sphericity were X^2 =1955.003 and p=0.001, respectively. According to the results of the investigation, the sample size was suitable for factor analysis. According to the EFA findings, the sole factor with an eigenvalue above 1 was found for 14 FHAI components. Between 0.4 and 0.69 factor loadings accounted for 37.120% of the overall variation (Table 3).

Table 2. Demographic and obstetric characteristics of the pregnant women (n=570)

Variables	Sample I (n=370) n (%)	Sample II (n=200) n (%)
Age		
Between the ages of 18 and 30	238 (64.3)	131 (65.5)
31 years and older	132 (35.4)	69 (34.5)
Educational level		
Primary school	128 (34.6)	36 (18.0)
High school	107 (28.9)	64 (32.0)
University	135 (36.5)	100 (50.0)
Employment status		
Employed	79 (21.4)	69 (34.5)
Unemployed	291 (78.6)	131 (65.5)
Income level		
Low	28 (7.6)	9 (4.5)
Moderate	311 (84.1)	147 (73.5)
Good	31 (8.4)	44 (22.0)
Is it a planned pregnancy?		
Yes	327 (88.4)	165 (82.5)
No	43 (11.6)	35 (17.5)
Is it a desired pregnancy?		
Yes	361 (97.6)	183 (91.5)
No	9 (2.4)	17 (8.5)
Parity		
Primipara	140 (37.8)	83 (41.5)
Multipara	230 (62.2)	117 (58.5)
How would you rate your general well-being during your pregnancy?		
Bad	5 (1.4)	17 (8.5)
Mediocre	128 (34.6)	118 (59.0)
Good	237 (64.1)	65 (32.5)
Gestational week	**Mean ± SD**	
	36.72±4.53	30.62±9.53

SD: Standard deviation

Confirmatory Factor Analysis

To ascertain the FHAI's criteria-dependent validity, the NuPDQ was used as the criterion. According to the results of the correlation analysis, there was a statistically significant positive association between the FHAI total score and the NuPDQ overall score as well as its subscale total scores (p=0.01; Table 4).

According to the results of CFA performed on Sample II, the values of $\chi 2$/sd (cmin/df) =3.148, CFI =0.907, SRMR =0.000, RMSEA =0.089, and p value =0.000 were determined for the FHAI (Table 4; Figure 2). It was found that there was a satisfactory fit between the measurement model and the data after looking at the numbers in the fit indicators (Table 5).

Reliability

Cronbach's Alpha Reliability Coefficient

The FHAI was found to have an internal consistency coefficient of Cronbach's alpha of 0.85 (p<0.001; Table 3).

Item-total Score Correlation Coefficient

It was discovered that each of these items had a correlation coefficient with the overall score derived from the inventory items that ranged from r=0.34-0.59 and that this connection was statistically significant (p<0.001; Table 3).

Table 3. Factor loadings, means, item-total correlations and Cronbach's alpha of the Fetal Health Anxiety Inventory (Sample I, n=370)

Item	Factor	Mean ± SD	Corrected item-total correlations	Cronbach's alpha if item deleted
4	0.69	1.08±0.58	0.59	0.83
3	0.68	0.97±0.64	0.59	0.80
5	0.65	0.85±0.57	0.57	0.83
13	0.63	0.84±0.54	0.55	0.83
11	0.63	0.86±0.65	0.53	0.83
9	0.57	0.86±0.47	0.48	0.83
10	0.57	0.94±0.63	0.48	0.83
1	0.56	1.05±0.50	0.47	0.83
6	0.56	0.41±0.55	0.46	0.83
2	0.55	1.60±0.80	0.46	0.84
7	0.55	0.44±0.67	0.45	0.84
8	0.54	0.17±0.42	0.45	0.84
12	0.50	0.74±0.48	0.40	0.84
14	0.41	1.04±0.41	0.34	0.84
Total of item				
Variance 37.120				
Cronbach's alpha 0.85				

All correlations are significant at p<0.01 (2-tailed)
SD: Standart deviation

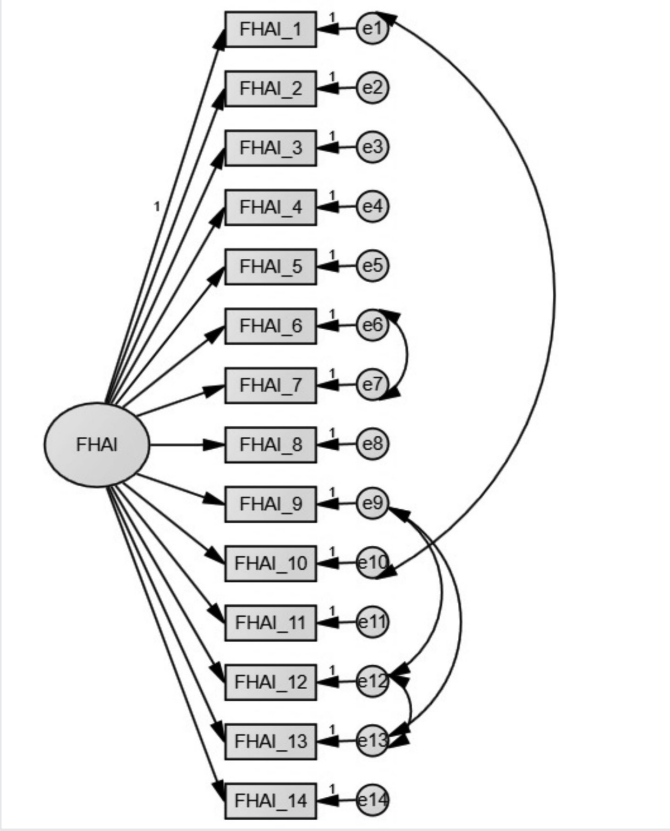

Figure 2. FHAI -standardized factor loadings and interfactor (Sample II, n=200)

Test-retest Mean Scores of the FHAI

A statistically significant positive correlation between the total mean scores of the inventory was discovered when the first and second measurement correlation findings of the FHAI administered with a three-week interval were assessed (r=0.568, p=0.001).

Discussion

Chronic stress is one of the most common modifiers of fetal and postnatal development with lifelong effects on health (37). There is no scale to determine fetal anxiety stress in Turkey. The FHAI was modified for Turkish use in the current study, and the instrument's reliability and validity were assessed. With a sample of Turkish pregnant women, the FHAI showed overall high validity and reliability. The CFA in this study verified that the single-factor construct had good fit indices and its reliability values were in an acceptable range. The EFA in this study suggested that a pregnant mother's worry for the health of her growing fetus might be analyzed as a single-factor construct. It was found that the factor loads of the FHAI in the Turkish adaption research were distributed similarly to how they were in the original form. The data of the CFA fit index, which was used to check whether the items were compatible with the data in the original FHAI (21), was not used, but the results of the analysis we used in the Turkish version were in the right range of values, ensuring the construct validity of the inventory (31,36,38).

Table 4. Correlation between the FHAI and NuPDQ

Scales	1	2	3	4	5	6
1.FHAI	-	0.851**	0.474**	0.743**	0.633**	0.353**
2. NuPDQ	-	-	0.230**	0.423**	0.309**	0.311**
3. Physical and social changes related to pregnancy, concerns regarding the baby and labor	-	-	-	0.214**	0.160**	0.104*
4. Concerns regarding the quality of healthcare and health status				-	0.537**	0.248**
5. Concerns regarding the baby-care and postpartum life					-	0.277**
6. Financial concerns						-
Mean ± SD	12.29±3.53	10.88±3.73	7.50±2.20	0.57±0.86	1.50±1.16	1.30±0.91

**Correlations are significant at p<0.01 (2-tailed).
*Correlations are significant at p<0.05 (2-tailed).
SD: Standart deviation

Table 5. CFA fit indices for FHAI (Sample II, n=200)

Fit criteria	Good fit	Acceptable fit	Model results	Fit
$\chi 2/df$ (c_{min}/df)	0< x2/df <3	<5	3.148	Acceptable fit
CFI	≥0.95	0.90≤ CFI ≤0.97	0.907	Acceptable fit
SRMR	0≤ SRMR ≤0.05	0.05< SRMR ≤0.10	0.000	Good fit
RMSEA	0< RMSEA <0.05	0.05≤ RMSEA ≤0.10	0.089	Acceptable fit
p value	<0.05		0.000	Good fit

CFI: Comparative fit index, SRMR: Standardized root mean square residual, RMSEA: Root mean square error of approximation, CFA: Confirmatory factor analysis

In the present study, factor loads of the FHAI varied between 0.41-0.69 according to the results of EFA. Similarly, factor loading values of the FHAI were found to be between 0.51 and 0.77 in the original inventory (22). It was discovered that the distribution of the items in the Turkish inventory, which was made up of the initial 14 items, was the same. As a result of the EFA applied in the original Reiser and Wright's (21) inventory, it was possible to divide the inventory into two subscales titled Disease Probability and Body Attention, but in a two-factor structure, item 1 (time worrying about your baby's health) and item 7 (ability to take the mind off of thoughts of baby's health) indicated that the factors were not distributed appropriately. Considering this inconsistency, it was suggested that items 1 and 7 might not be loaded on individual subscales as expected, and they could be used as a unitary inventory as well as subscales of the FHAI (21). In the present study, it was determined that Reiser and Wright's single-factor model fitted the Turkish FHAI data more appropriately. Additionally, it was discovered that the KMO, Barlett's test of sphericity, and explained variance values in this investigation were comparable to those in the initial study. The data in the current investigation showed an adequate distribution for factor analysis, according to the results of KMO and Barlett's test of sphericity (39). The overall variance of the inventory can be deemed sufficient when 30% or more of the variation rate described in scale adaptation experiments is regarded sufficient (28).

Strong relationships between prenatal distress (NuPDQ total score, including the subscale of concerns regarding the baby) and the FHAI total score were found, indicating high concurrent validity (40). Additionally, Reiser and Wright (21) showed relationships between the FHAI and measures of anxiety related to pregnancy, anxiety related to maternal health, general anxiety, anxiety sensitivity, and uncertainty intolerance. Numerous studies in the literature demonstrate the detrimental short- and long-term consequences of anxiety on the mother and unborn child during pregnancy (41-43). The significance of the function that fetal health anxiety can play in mother's and child's health has been shown when taking into account the association between prenatal distress and fetal health anxiety in the current investigation.

In the current study, the FHAI showed good internal consistency. The FHAI, developed by Reiser and Wright (21), was also reported to have a high level of reliability when Cronbach's alpha value was examined. In addition, the item-total score correlation coefficients in the current study were found to be similar to those in Reiser and Wright's (21) study, and it was determined that the coefficients of all items were above the acceptable value (r≥0.20 for all items in the inventory) for item selection (33). To prove that the FHAI was invariant over time, the inventory was re-administered to 30 pregnant women three weeks after the first application. The high correlation value between the first and second application scores indicates that the inventory gives consistent results and is invariant over time.

Given these findings, it can be concluded that the FHAI, of which Turkish validity and reliability research we have conducted, and the original of this inventory are in agreement, making it a valid and reliable instrument for assessing pregnant women's fetal health anxiety.

Study Limitations

The present study had certain shortcomings. First off, pregnant women from other institutions were not included in this study since it only included pregnant women who were registered at one public hospital. The findings of this study might not apply to all pregnant women because it only included pregnant women who were admitted to the hospital. Another drawback was that the FHAI validity and reliability analyses were conducted without taking gestation and trimester into account. Future research may advocate doing the validity and reliability tests of the inventory independently based on gestational age and trimester. Regarding the measurement, web-based questionnaires were applied to pregnant women, and the reports were in the form of self-reports. This variable was susceptible to bias.

Conclusion

The FHAI is a potential tool for detecting fetal health anxiety during pregnancy, as well as for application in research and clinical practice, according to the study's findings. Due to the harmful effects that may occur on maternal and fetal health of those who experience fetal health anxiety intensely, healthcare professionals can make a better analysis of the expectant mothers' anxiety levels in order to be aware of the anxiety levels experienced by women during pregnancy, and they can enable the mother and fetus to have a better pregnancy period. This may also assist in developing specific initiatives to meet the needs of individual care. The FHAI can be applied as a rapid and accurate pre-screening tool to assess fetal health anxiety levels in the clinics and studies.

Acknowledgement: We thank all pregnant women who participated in the research.

Ethics

Ethics Committee Approval: Wright, who created the scale, was contacted by email to provide his consent to translate the FHAI into Turkish. Additionally, approval from the Scientific Research and Publication Ethics Committee of the İnönü University (decision number: 2020/915) was acquired prior to data collection.

Informed Consent: On the first page of the online questionnaire, which served as the study's consent form, all pregnant women who agreed to participate in it were informed about the research before it began.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: N.G, Z.B, T.U., Concept: N.G, Z.B., Design: N.G, Z.B., Data Collection or Processing: N.G, Z.B., Analysis or Interpretation: : N.G, Z.B, T.U., Literature Search: N.G, Z.B., Writing: N.G, Z.B, T.U.

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Appendix 1. Turkish version of the Fetal Health Anxiety Inventory (FHAI)

1. (a) I do not worry about my baby's health.
(b) I occasionally worry about my baby's health.
(c) I spend much of my time worrying about my baby's health.
(d) I spend most of my time worrying about my baby's health.

2. (a) If I notice pains/discomforts, I rarely worry about what this means for my baby.
(b) If I notice pains/discomforts, I sometimes worry about what this means for my baby.
(c) If I notice pains/discomforts, I often worry about what this means for my baby.
(d) If I notice pains/discomforts, I always worry about what this means for my baby.

3. (a) As a rule I am not concerned about how my own bodily sensations/changes are related to my baby's health.
(b) Sometimes I am concerned about how my own bod- ily sensations/changes are related to my baby's health.
(c) I am often concerned about how my own bodily sensations/changes are related to my baby's health.
(d) I am constantly concerned about how my own bodily

4. (a) Resisting thoughts of my baby having a health problem is never a problem.
(b) Most of the time I can resist thoughts of my baby having a health problem.
(c) I try to resist thoughts of my baby having a health problem but am often unable to do so.
(d) Thoughts of my baby having a health problem are so strong that I no longer even try to resist them.

5. (a) As a rule I am not afraid that my baby has a serious health problem.
(b) I am sometimes afraid that my baby has a serious health problem.
(c) I am often afraid that my baby has a serious health problem.
(d) I am always afraid that my baby has a serious health problem.

6. (a) I do not have images (mental pictures) of my baby having a health problem.
(b) I occasionally have images of my baby having a health problem.
(c) I frequently have images of my baby having a health problem.
(d) I constantly have images of my baby having a health problem.

7. (a) I do not have any difficulty taking my mind off thoughts about my baby's health.
(b) I sometimes have difficulty taking my mind off thoughts about my baby's health.
(c) I often have difficulty taking my mind off thoughts about my baby's health.
(d) Nothing can take my mind off thoughts about my baby's health.

8. (a) I am lastingly relieved if my doctor tells me there is nothing wrong with my baby.
(b) I am initially relieved but the worries sometimes return later.
(c) I am initially relieved but the worries always return later.
(d) I am not relieved if my doctor tells me there is nothing wrong with my baby.

9. (a) If I hear about a health problem in developing babies I never think my baby has it.
(b) If I hear about a health problem in developing babies I sometimes think that my baby has it.
(c) If I hear about a health problem in developing babies I often think my baby has it.
(d) If I hear about a health problem in developing babies I always think that my baby has it.

10. (a) If I have a bodily sensation or change I rarely wonder what it means for my baby.

(b) If I have a bodily sensation or change I often wonder what it means for my baby.

(c) If I have a bodily sensation or change I always wonder what it means for my baby.

(d) If I have a bodily sensation or change I must know what it means for my baby.

11. (a) I usually feel at very low risk for my baby developing a serious health problem.

(b) I usually feel at fairly low risk for my baby developing a serious health problem.

(c) I usually feel at moderate risk for my baby developing a serious health problem

(d) I usually feel at high risk for my baby developing a serious health problem.

12. (a) I never think that my baby has a serious health problem.

(b) I sometimes think that my baby has a serious health problem.

(c) I often think that my baby has a serious health problem.

(d) I usually think that my baby has a serious health problem.

13. (a) If I notice an unexplained bodily sensation that is (or could be) related to my baby's development I don't find it difficult to think about other things.

(b) If I notice an unexplained bodily sensation that is (or could be) related to my baby's development I sometimes find it difficult to think about other things.

(c) If I notice an unexplained bodily sensation that is (or could be) related to my baby's development I often find it difficult to think about other things.

(d) If I notice an unexplained bodily sensation that is (or could be) related to my baby's development I always find it difficult to think about other things.

14. (a) My family/friends would say I do not worry enough about my baby's health.

(b) My family/friends would say I have a normal attitude about my baby's health.

(c) My family/friends would say I worry too much about my baby's health.

(d) My family/friends would say I am extreme in my worries about my baby's health.

Original Article

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Defining Effective Performance Management Strategies for Hospital with a Novel Fuzzy Decision-Making Model

Yeni Bir Bulanık Karar Verme Modeli ile Hastane için Etkili Performans Yönetim Stratejilerinin Tanımlanması

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ABSTRACT

Objective: This study aimed to identify the most significant issues for the effective performance management of hospitals.

Methods: Accordingly, seven indicators were selected based on the literature review results. An analysis was carried out using the Spherical fuzzy TOP-DEMATEL method to determine the most important ones among these criteria.

Results: The main contribution of this study was that the prior indicators of effective performance management in the hospitals were identified. With the help of this issue, hospitals can take actions to improve performance without having too much costs. Moreover, the main methodological originality of this study is that a new decision-making model is proposed by the name of TOP-DEMATEL.

Conclusion: Effective supply chain is found as the best factor that affects the performance of the hospitals. Additionally, advanced technology also plays a key role in this framework. Nevertheless, qualified personnel criterion is on the last rank. Supply network refers to the process of providing medical supplies, medicines, equipment, and other resources for healthcare institutions. These resources are of great importance for the performance of hospitals as they are needed to deliver the service.

Keywords: Health management, performance management, hospitals, fuzzy logic

ÖZ

Amaç: Bu çalışma, hastanelerin etkin performans yönetimi için en önemli konuları belirlemeyi amaçlamaktadır.

Yöntemler: Buna göre, literatür taraması sonuçlarına dayalı olarak yedi kriter seçilmiştir. Bu kriterlerden en önemlilerini belirlemek için küresel bulanık TOP-DEMATEL yöntemi kullanılarak bir analiz yapılmıştır.

Bulgular: Bu çalışmanın temel katkısı, hastanelerde etkin performans yönetiminin ön göstergelerinin belirlenmesidir. Bu konu sayesinde hastaneler çok fazla maliyete katlanmadan performans artırıcı aksiyonlar alabilirler. Ayrıca bu çalışmanın ana metodolojik özgünlüğü, TOP-DEMATEL adıyla yeni bir karar verme modeli önerilmiş olmasıdır. Etkili tedarik zinciri, hastanelerin performansını etkileyen en iyi faktör olarak bulunmuştur. Ayrıca ileri teknoloji de bu çerçevede önemli bir rol oynamaktadır. Ancak nitelikli eleman kriteri son sırada yer almaktadır.

Sonuç: Tedarik ağı, sağlık kurumları için tıbbi malzeme, ilaç, ekipman ve diğer kaynakların sağlanması sürecini ifade eder. Bu kaynaklar, hizmeti sunmak için ihtiyaç duyulduğu için hastanelerin performansı için büyük önem taşımaktadır.

Anahtar Sözcükler: Sağlık yönetimi, performans yönetimi, hastaneler, bulanık mantık

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Introduction

Measuring performance is a process used to measure the degree to which a company has achieved its goals. In this context, it is aimed to determine both the operational and financial performance of the company. On the other hand, monitoring this measured performance in the future and determining the areas that need improvement are other stages involved in this process. Financial results are important in the performance management of businesses. In this framework, matters such as the company's profit, liquidity power and asset size play an important role. In addition, customer satisfaction is a key issue in terms of performance management (1). In this process, the opinions of customers about the business can be measured by conducting surveys. Performance management also includes the processes of evaluating the work performance of the personnel working in an enterprise. The main purpose here is to improve the performance of the personnel whose performance is evaluated. In this context, while highlighting the areas where the personnel are successful, improvement suggestions are offered for the issues they are deemed deficient in. There are several stages in the performance measurement system. First, measurable goals are set with both the employee and their manager. After that, the performance of the personnel in a period is compared with the target set. In this way, it is determined how far the personnel can reach these targets. In this process, feedback is given to the personnel regarding the issues that are thought to be missing (2). In this context, the superior aspects of the employee are also highlighted. As a result, development planning is carried out for the performance of the employee. In this way, it is aimed to improve the missing aspects of the employee until the next performance period.

Performance measurement is very important for businesses in many ways. First of all, effective performance management should be done in order to measure whether the enterprise can effectively reach its goals. In this way, it is possible to take corrective action when necessary. Performance measurement also enables businesses to produce the right strategies. In other words, businesses will be able to use business resources more effectively by considering performance management results (3). Moreover, measuring performance helps the company identify its strengths and weaknesses. Considering this information, it is more possible to create action plans to improve performance. In this context, together with the effective actions to be taken, businesses can take the necessary steps to improve their weak areas. Performance management is important for businesses in many ways. Thanks to successful performance management practices, it is possible to identify employees with good performance in businesses (4). In this way, a fairer incentive system can be applied to the personnel. Moreover, thanks to performance management processes, the communication of employees with their managers becomes stronger. In this process, employees often receive feedback from their managers regarding their performance. Thanks to this feedback, employees can both get suggestions for improving their shortcomings and understand their good points.

Measurement of performance is of great importance for hospitals. Measuring the performance of hospitals allows them to provide better quality service. Thanks to effective performance management, it is possible for hospitals to comply more with quality standards. On the other hand, patient safety can be ensured with successful performance management. Factors such as infection rates and medical errors are included in performance management processes. Moreover, performance management enables hospitals to use their resources more effectively (5). As a result of effective performance management, existing problems in hospitals may arise. In this way, hospitals can evaluate their resources more successfully by taking this information into account. Thus, efficiency in the operations of hospitals will be ensured, and this contributes significantly to effective cost management. Furthermore, the performance of health personnel will be clearly determined in this process. The performance of these personnel is very important in terms of providing quality and safe health services. Therefore, the performance management mechanism allows hospital staff to operate more successfully (5). Thus, it is much more possible to increase the quality of services provided by hospitals.

Performance management is a very important issue in hospitals. In this context, hospitals need to take actions to improve performance management. On the other hand, it is not financially possible for hospitals to improve on all these factors (6). In this context, the most important issues should be determined and given priority. The purpose of this study is to identify the most important issues for the effective performance management of hospitals. Accordingly, 7 criteria are determined based on the literature review results. An analysis has been carried out using the Spherical fuzzy TOP-DEMATEL method to determine the most important ones among these criteria.

The main contributions of this study are given as follows. (i) The prior indicators of effective performance management in the hospitals are identified. This situation helps to propose more prior strategies. With the help of this issue, hospitals can take actions to improve performance without having too much costs. (ii) A new decision-making model is proposed by the name of TOP-DEMATEL. There are lots of criticism to the classical DEMATEL technique. To overcome this issue, the final steps of TOPSIS are integrated into DEMATEL and a new approach is created.

Literature review is given in the second part. The methodology is shared in the next part. Analysis results are indicated in the fourth part. The final part gives information about the conclusions and discussions.

Literature Review

Hospitals are institutions responsible for providing health services. Health services should be provided 24/7 without interruption. Therefore, health institutions have a very dynamic structure. Accordingly, it becomes difficult to measure the performance of health institutions. One of the factors affecting the performance of health institutions is technology. Advanced technologies help increase the quality of service by contributing to the diagnosis and treatment processes. In addition, the processes carried out can be automated and resource efficiency can be achieved thanks to advanced technologies. Wanke et al. (7) conducted a study to

reveal how social welfare conditions affected performance. In the study, where the number of beds, the number of employees and the number of doctors had a significant effect on productivity, the importance of following the technology for the success of performance management was also emphasized. Jiang et al. (8) conducted a study with multi-criteria decision-making techniques to determine key performance indicators in hospital performance management. In the study, it was stated that one of the main performance indicators for hospitals was technology.

Another issue affecting the performance of health institutions is the quality of the service provided. It refers to meeting patient expectations. Apart from this, issues such as the accuracy of the treatments applied, ensuring patient safety, access to health services for those in need, and reducing medical errors are the factors that determine the quality of the service provided. Kennedy et al. (9) conducted a study on performance management and improvement of health service quality. It was identified that there was a direct relationship between the quality of service provided and the performance of the institution in the study conducted by qualitative interviews with 31 employees working in primary health care and surgical departments. Abdullah et al. (10) conducted a study on health performance management using the FUCOM-MARCOS approach. It was determined that service quality affects performance success.

The quality of the working personnel is another issue that affects the performance process. Employees play a key role in achieving the goals of the organization. Expertise and competencies of the employees, communication skills and sense of responsibility are the skills that are important in reaching the determined targets. Accordingly, it is important for a hospital that wants to achieve its goals to have qualified personnel. Kedikli et al. (11) made a study to improve hospital performance. According to the study conducted on 12 criteria, the quality of employees was one of the important issues affecting hospital performance. Another issue that affects the performance of health institutions is to have a strong supply network. The supply network of a healthcare business consists of drugs, equipment, and medical supplies. This equipment is needed to provide health services. Therefore, hospitals need to supply the materials and equipment needed at the right time and at the right cost. Accordingly, a strong supply network is needed for effective performance management. Cristofaro et al. (12) conducted an empirical study to measure health performance in the era of digitalization. In the study, which drew attention to the factors affecting the performance of health enterprises, it was stated that the supply network was an important criterion. In addition, health outcomes also affect the performance of hospitals. Health outcomes refer to the effectiveness of the services provided by hospitals. Issues such as the recovery time of patients, the scope of services and the range of services provided fall within the scope of health outcomes. Noto et al. (13) made a study to overcome the nasty problems in the performance management of public health. From the study, in which COVID-19 vaccination strategies were analyzed empirically, it was concluded that health outcomes affected performance.

The determined evaluation is another issue that affects the success of health institutions. In particular, whether the criteria to be determined are national or international is an important point of distinction in revealing the performance status of health institutions. Accordingly, clinical quality criteria such as mortality/morbidity rate and complication rate, efficiency measures such as waiting times and cost control, and patient experience criteria such as patient satisfaction will be decisive at this point. Peixoto et al. (14) conducted a study to measure the performance management of the Brazilian Federal University hospital. Data Envelopment and Principal Component analyzes were used in the study. In the study, the importance of the performance criteria determined for the success of performance management was emphasized. The performance of hospitals is also directly related to a well-defined organizational structure. Effective decision-making processes, communication channels and the distribution of responsibilities are factors within the scope of the organizational structure. These factors are also important criteria that affect the performance of the business. Yokota et al. (15) conducted a study examining the performance management systems of Japanese companies. Aiming to design a performance management system beyond the balanced scorecard, the authors contacted 1,700 companies traded on the Tokyo Stock Exchange through a survey. Accordingly, it was stated that the organizational structure of enterprises was an important factor in performance evaluations.

The research subject of optimization is to determine the most important criterion in line with a goal. One of the optimization issues is multi-criteria decision-making techniques. DEMATEL method is a multi-criteria decision-making technique used to determine the most important criteria. This method is used when numerical measurement is not possible. In other words, it is a method that rates criteria based on expert opinions. It involves ambiguity in the linguistic expressions used for expert opinions. Fuzzy numbers were preferred to include this uncertainty in the analysis.

As a result of the literature review, the following conclusions can be reached.

(i) The issue of performance management is important for health institutions.

(ii) In addition, ensuring the effectiveness of performance management also affects the quality of the services provided.

(iii) However, it may not be possible for the hospital management to intervene in all of these criteria at the same time. Therefore, with this study, it is necessary to weight the criteria for hospitals to provide effectiveness in performance management.

(iv) However, there is a limited number of studies in literature addressing this issue.

In this study, it is aimed to determine the most important strategies to be taken to carry out the performance management of hospitals effectively. In this context, an analysis has been carried out with fuzzy decision-making techniques.

Spherical Fuzzy TOP-DEMATEL Methodology

The classical DEMATEL method has been criticized in many ways. The first step in response to these criticisms was fuzzy numbers developed by Zadeh (16). The uncertainty in expert opinions in multi-criteria decision making was included in the analysis with the help of fuzzy numbers. However, this was also insufficient. A new method was developed in this study in order to eliminate the deficiencies mentioned in these criticisms (17). In this context, a new method has been created by including the last stages of the TOPSIS technique into the DEMATEL method (18). This new method is named TOP-DEMATEL because it is obtained as a result of the integration of both methods (19). The steps of this new technique are given below.

Quantitative Analysis

Step 1: The evaluations are provided from the experts by considering the questions related to the criteria. In this framework, the fuzzy numbers in Table 1 are taken into consideration. In this process, μ refers to the membership degree whereas η and υ give information about non-membership hesitancy degrees.

A matrix of expert opinions is created. Expert opinions are given in Table 1. In this context, Equation (1) is used.

$$D\,i = \lceil \lfloor 0 \cdots (\mu\,1n\,i, \eta\,1n\,i, v\,1n\,i) \vdots \ddots \vdots (\mu\,n1\,i, \eta\,n1\,i, v\,n1\,i) \cdots 0 \rceil \rfloor \quad (1)$$

Step 2: With the help of equation (2), the decision matrix (D) is formed by taking the average of the expert opinions. The decision matrix is shown by equation (3). The weights in equation (2) are considered as 1/k. k is number of experts. Weighted arithmetic mean (SFAM) in spherical fuzzy numbers is calculated by equation (3).

$$SFWAM_w(\tilde{D}_1, \tilde{D}_2, \ldots \tilde{D}_k) = \left\{ \begin{array}{c} \left[1 - \prod_{i=1}^{k}\left(1-\mu_{D_i}^2\right)^{\frac{1}{k}}\right]^{\frac{1}{2}}, \\ \prod_{i=1}^{k}\eta_{D_i}^{\frac{1}{k}}, \\ \left[\prod_{i=1}^{k}\left(1-\mu_{D_i}^2\right)^{\frac{1}{k}} - \prod_{i=1}^{k}\left(1-\mu_{D_i}^2-v_{D_i}^2\right)^{\frac{1}{k}}\right]^{\frac{1}{2}} \end{array} \right\} \quad (2)$$

Table 1. Linguistic expressions

	μ	η	υ
4	0.85	0.15	0.45
3	0.6	0.2	0.35
2	0.35	0.25	0.25
1	0	0.3	0.15
0	0	0	0

$$D = \begin{bmatrix} 0 & \cdots & \left(\mu_{1n}^d, \eta_{1n}^d, v_{1n}^d\right) \\ \vdots & \ddots & \vdots \\ \left(\mu_{n1}^d, \eta_{n1}^d, v_{n1}^d\right) & \cdots & 0 \end{bmatrix} \quad (3)$$

Step 3: For each component in the spherical fuzzy numbers, 3 separate submatrices are created. Then, each submatrix is normalized with equations (4) and (5). X is normalize matrix.

$$X = sD \quad (4)$$

$$s = \min\left[1 \_ \max i \sum j{=}1\ n\ |d\,ij|,\ 1 \_ \max j \sum i{=}1\ n\ |d\,ij|\right] \quad (5)$$

After normalization, the 3 submatrices are expressed by equation (6).

$$X^{\mu} = \begin{bmatrix} 0 & \cdots & \mu_{1n} \\ \vdots & \ddots & \vdots \\ \mu_{n1} & \cdots & 0 \end{bmatrix} \quad X^{\eta} = \begin{bmatrix} 0 & \cdots & \eta_{1n} \\ \vdots & \ddots & \vdots \\ \eta_{n1} & \cdots & 0 \end{bmatrix} \quad X^{v} = \begin{bmatrix} 0 & \cdots & v_{1n} \\ \vdots & \ddots & \vdots \\ v_{n1} & \cdots & 0 \end{bmatrix} \quad (6)$$

Step 4: Using equation (7), the total relationship matrices (T) are calculated over each sub-matrix.

$$T = X^*(1 - X) - 1 \quad (7)$$

Euclidean normalization is then applied to the 3 calculated sub-matrices.

Step 5: The 3 calculated subtotal relationship matrices are combined and the spherical fuzzy sum relationship matrix ($\tilde{T}$) is obtained. The details of this matrix are shown in equation (8).

$$\sim T = \lceil \lfloor 0 \cdots (\mu\,1n\,T, \eta\,1n\,T, v\,1n\,T) \vdots \ddots \vdots (\mu\,n1\,T, \eta\,n1\,T, v\,n1\,T) \cdots 0 \rceil \rfloor \quad (8)$$

Step 6: With equation (9), the score function is calculated. This score value is used for the clarification method.

$$Score = \mu\,2 - \eta\,2 - \nu\,2 \quad (9)$$

Step 7: After clarification of the spherical fuzzy T matrix, criteria importance degrees (W) are obtained using equation (10)-(16). C

matrices express the sum of the Euclidean distances of the columns to ideal values. R matrices express the sum of the Euclidean distances of the row to ideal values. While S^- indicates sum of the negative ideal distance, S* indicates the sum of the positive ideal distance.

$$C*j = \sqrt{\sum_{i=1}^{n} \left(t\,i - \max j\,t\,i\right)2} \quad j = 1,2,..n \qquad (10)$$

Table 2. Criteria list

Criteria	Literature
Advanced Technology (DVTG)	Wanke et al. (7)
Service Quality (SVQY)	Kennedy et al. (9)
Qualified Personnel (QDNN)	Kedikli et al. (11)
Effective Supply Chain (EPPC)	Peixoto et al. (14)
Defining Appropriate Performance Indicator (DAPI)	Yokota et al. (15)
Organizational Effectiveness (GZNS)	Jiang et al. (8)
Successful Health Outputs (SHTP)	Abdullah et al. (10)

$$C-j = \sqrt{\sum_{i=1}^{n} \left(t\,i - \min j\,t\,i\right)2} \quad j = 1,2,..n \qquad (11)$$

$$R*i = \sqrt{\sum_{j=1}^{n} \left(t\,j - \max i\,t\,j\right)2} \quad i = 1,2,..n \qquad (12)$$

$$R^-_i = \sqrt{\sum_{j=1}^{n} \left(t\,j - \max i\,t\,j\right)2} \quad i = 1,2,..n \qquad (13)$$

$$Si* = Ci* + Ri* \qquad (14)$$

$$Si- = Ci- + Ri- \qquad (15)$$

$$Wi = Si-\_Si- + Si* \qquad (16)$$

Table 3. Expert evaluations

Expert 1

	DVTG	SVQY	QDNN	EPPC	DAPI	GZNS	SHTP
DVTG	0	4	4	4	3	4	4
SVQY	3	0	4	3	3	4	3
QDNN	2	3	0	4	4	4	4
EPPC	3	4	4	0	4	4	3
DAPI	4	4	4	3	0	4	3
GZNS	3	4	4	4	3	0	3
SHTP	3	4	4	3	3	4	0

Expert 2

	DVTG	SVQY	QDNN	EPPC	DAPI	GZNS	SHTP
DVTG	0	4	4	3	4	4	4
SVQY	4	0	4	3	4	3	4
QDNN	4	4	0	4	4	4	4
EPPC	3	4	3	0	3	3	3
DAPI	4	4	4	3	0	4	4
GZNS	4	4	4	4	4	0	4
SHTP	4	4	4	3	4	4	0

Expert 3

	DVTG	SVQY	QDNN	EPPC	DAPI	GZNS	SHTP
DVTG	0	4	4	4	2	2	3
SVQY	4	0	4	4	4	4	4
QDNN	4	4	0	3	4	4	3
EPPC	4	4	3	0	3	4	3
DAPI	2	3	3	2	0	2	3
GZNS	2	4	4	4	2	0	3
SHTP	4	4	4	3	4	3	0

Analysis Results

In the analysis process, firstly, the criteria set is defined. In this context, literature review results are taken into consideration. As a result, seven criteria are defined as in Table 2.

An expert team was created with three experts who had the necessary experience in this area. The questio ns were created from the comparison of the criteria. The evaluations of the experts are provided as in Table 3. After that, decision matrix is created as in Table 4.

Normalized sub matrixes are generated in the following process as in Table 5.

In the following process, total relation matrix is generated as in Table 6.

The weights are calculated in the final stage. The details are indicated in Table 7.

Effective supply chain is found as the best factor that affects the performance of the hospitals. Additionally, advanced technology also plays a key role in this framework. Nevertheless, qualified personnel criterion is on the last rank.

Study Limitations

This study was carried out only in the health sector and experts were selected in the health sector. Separate studies could be done

Table 4. Decision matrix

	DVTG			SVQY			QDNN			EPPC			DAPI			GZNS			SHTP		
DVTG	0.00	0.00	0.00	0.85	0.15	0.45	0.85	0.15	0.45	0.80	0.17	0.48	0.68	0.20	0.38	0.77	0.18	0.50	0.80	0.17	0.48
SVQY	0.80	0.17	0.37	0.00	0.00	0.00	0.85	0.15	0.45	0.72	0.18	0.37	0.80	0.17	0.37	0.80	0.17	0.48	0.80	0.17	0.37
QDNN	0.77	0.18	0.27	0.80	0.17	0.37	0.00	0.00	0.00	0.80	0.17	0.48	0.85	0.15	0.45	0.85	0.15	0.45	0.80	0.17	0.48
EPPC	0.72	0.18	0.37	0.85	0.15	0.45	0.72	0.18	0.49	0.00	0.00	0.00	0.72	0.18	0.49	0.80	0.17	0.48	0.60	0.20	0.35
DAPI	0.77	0.18	0.50	0.80	0.17	0.48	0.80	0.17	0.48	0.54	0.22	0.35	0.00	0.00	0.00	0.77	0.18	0.50	0.72	0.18	0.37
GZNS	0.68	0.20	0.38	0.85	0.15	0.45	0.85	0.15	0.45	0.85	0.15	0.45	0.68	0.20	0.38	0.00	0.00	0.00	0.72	0.18	0.37
SHTP	0.80	0.17	0.37	0.85	0.15	0.45	0.85	0.15	0.45	0.60	0.20	0.35	0.80	0.17	0.37	0.80	0.17	0.48	0.00	0.00	0.00

Table 5. Normalized Sub matrixes

μ	DVTG	SVQY	QDNN	EPPC	DAPI	GZNS	SHTP
DVTG	0.0000	0.1703	0.1703	0.1594	0.1361	0.1542	0.1594
SVQY	0.1594	0.0000	0.1703	0.1438	0.1594	0.1594	0.1594
QDNN	0.1542	0.1594	0.0000	0.1594	0.1703	0.1703	0.1594
EPPC	0.1438	0.1703	0.1438	0.0000	0.1438	0.1594	0.1202
DAPI	0.1542	0.1594	0.1594	0.1077	0.0000	0.1542	0.1438
GZNS	0.1361	0.1703	0.1703	0.1703	0.1361	0.0000	0.1438
SHTP	0.1594	0.1703	0.1703	0.1202	0.1594	0.1594	0.0000
η	DVTG	SVQY	QDNN	EPPC	DAPI	GZNS	SHTP
DVTG	0.0000	0.1385	0.1385	0.1524	0.1807	0.1642	0.1524
SVQY	0.1524	0.0000	0.1385	0.1678	0.1524	0.1524	0.1524
QDNN	0.1642	0.1524	0.0000	0.1524	0.1385	0.1385	0.1524
EPPC	0.1678	0.1385	0.1678	0.0000	0.1678	0.1524	0.1847
DAPI	0.1642	0.1524	0.1524	0.1989	0.0000	0.1642	0.1678
GZNS	0.1807	0.1385	0.1385	0.1385	0.1807	0.0000	0.1678
SHTP	0.1524	0.1385	0.1385	0.1847	0.1524	0.1524	0.0000
μ	DVTG	SVQY	QDNN	EPPC	DAPI	GZNS	SHTP
DVTG	0.0000	0.1554	0.1554	0.1662	0.1317	0.1731	0.1662
SVQY	0.1268	0.0000	0.1554	0.1283	0.1268	0.1662	0.1268
QDNN	0.0927	0.1268	0.0000	0.1662	0.1554	0.1554	0.1662
EPPC	0.1283	0.1554	0.1696	0.0000	0.1696	0.1662	0.1208
DAPI	0.1731	0.1662	0.1662	0.1216	0.0000	0.1731	0.1283
GZNS	0.1317	0.1554	0.1554	0.1554	0.1317	0.0000	0.1283
SHTP	0.1268	0.1554	0.1554	0.1208	0.1268	0.1662	0.0000

Table 6. Total relation matrix

	DVTG		SVQY		QDNN		EPPC		DAPI		GZNS		SHTP							
DVTG	0.36	0.35	0.36	0.39	0.38	0.41	0.39	0.38	0.40	0.39	0.38	0.41	0.39	0.38	0.40	0.39	0.38	0.41	0.39	0.38	0.41
SVQY	0.39	0.37	0.36	0.36	0.35	0.32	0.39	0.37	0.36	0.39	0.37	0.36	0.39	0.37	0.36	0.39	0.37	0.37	0.39	0.37	0.36
QDNN	0.40	0.37	0.37	0.39	0.37	0.37	0.37	0.34	0.33	0.40	0.36	0.38	0.40	0.36	0.38	0.40	0.36	0.37	0.40	0.37	0.38
EPPC	0.36	0.39	0.39	0.37	0.39	0.39	0.36	0.40	0.40	0.34	0.37	0.35	0.36	0.39	0.40	0.37	0.39	0.39	0.36	0.40	0.39
DAPI	0.37	0.40	0.41	0.36	0.40	0.40	0.37	0.40	0.40	0.36	0.40	0.39	0.34	0.38	0.35	0.36	0.40	0.40	0.36	0.40	0.40
GZNS	0.38	0.38	0.38	0.38	0.38	0.38	0.38	0.38	0.37	0.39	0.38	0.38	0.38	0.38	0.37	0.35	0.36	0.33	0.38	0.38	0.37
SHTP	0.39	0.37	0.37	0.39	0.37	0.37	0.39	0.37	0.37	0.38	0.38	0.37	0.39	0.37	0.37	0.39	0.37	0.37	0.36	0.35	0.33

Table 7. Weights

Criteria	S*	S-	w
DVTG	0.1940	0.1980	0.1503
SVQY	0.2132	0.1780	0.1353
QDNN	0.2214	0.1808	0.1337
EPPC	0.1708	0.1797	0.1525
DAPI	0.1787	0.1702	0.1451
GZNS	0.1789	0.1778	0.1483
SHTP	0.1972	0.1635	0.1348

for other sectors. Apart from this, the criteria determined were generally based on the results of the literature review. These criteria could be generated based on a program or theory.

Discussions and Results

The aim of this study was to determine the most important issues for the performance management of hospitals to be effective. Accordingly, 7 criteria determined based on the literature were selected. An analysis was carried out using the global fuzzy TOP-DEMATEL method to determine the most important ones among these criteria. The results showed that both methods gave consistent results. As a result, the most important criteria to effectively manage the performance management process of hospitals were found to be supply network and technology.

Supply network refers to the process of providing medical supplies, medicines, equipment, and other resources for healthcare institutions. These resources are of great importance for the performance of hospitals as they are needed to deliver the service. If the necessary resources are not available, people's lives can be put at risk. Therefore, having a good supply network directly affects the health service provided. Cristofaro et al. (12) conducted a study investigating the challenges and prospects in the management of health services. In the study, which stated that the emphasis of performance management in health services evolved from an output or result-based approach to a system-based approach, the importance of having a good supply network for performance management was also mentioned. Çiftçi and Özkan (20) made a study examining the effects of the COVID-19 pandemic on the health sector in terms of global and Turkey. Stating that the pandemic affected many sectors such as education, military, and agriculture, especially the health sector, the article emphasized the importance of the supply network in terms of the continuity of health services.

Technological tools are needed to provide health services. In addition, innovative devices used in taste and treatment processes are important for resource efficiency. In addition, innovative technological devices are important in terms of providing more accurate diagnosis and treatment. Therefore, following technology directly affects the delivery of health services and the performance of hospitals. Korhonen et al. (21) conducted a study investigating the effect of new technology application on the financial aspect of health services. In a study to calculate the financial impact of introducing new digital technologies to elderly care in a Scandinavian city, it was stated that technological developments affected the performance of hospitals. Çınaroğlu (22) conducted a study using the PATH analysis developed by the World Health Organization for performance management in health institutions. According to the results of the study, it was stated that besides many factors, technological developments should be followed to improve the performance of health systems.

McDermott et al. (23) conducted a study in Ireland to improve the performance of hospitals. The results of the study indicated that an effective coordination system would improve performance. Ippolito et al. (24) examined the relationship between performance management and technology in the healthcare sector. It is stated that technological infrastructure has an important place in performance management. Lu et al. (25) investigated the place of data mining applications in the performance management of public hospitals. The results of the study conducted in China indicated that technological applications such as data mining positively affected performance. Kim et al. (26) examined the impact of managers' knowledge levels on hospital performance. The study was conducted by surveying 1,000 senior managers from American hospitals. The results of the study showed that the level of knowledge affected performance. Vaz et al. (27) conducted a study to improve the performance of healthcare providers in the Middle East. It was emphasized that the satisfaction and motivation of managers and employees should be ensured. Zheng et al. (28) and Kokko and Laihonen (29) pointed out that performance management was important for hospitals.

The factor that most affected the process was found to be the establishment of an effective supply network in the study. Accordingly, hospitals need to be careful in their supplier relationships to increase their performance. Apart from this, the supply network for hospitals also includes pharmaceutical and medical device processes. Therefore, it is important to avoid any problems in the supply network to ensure continuity of services. The second most important factor was that hospitals had advanced technology. Therefore, hospitals need to keep up with developing technology and use new technologies for their performance.

Conclusion

The most important contribution of this study to the literature was to determine the most important factors affecting the performance management process of health institutions. It is not financially possible for health institutions to improve all the factors affecting the process at the same time. By determining the factors that affect the performance of health institutions, priority strategies can be determined for improving performance management and it will be possible to keep costs at a reasonable level. The most important limitation of this study was that it dealed with the issue of performance management in health in general. In future studies, more specific strategies can be developed by considering technology or supply network specific issues.

Ethics

Ethics Committee Approval: Ethics committee approval was not required for this study.

Peer-review: Externally peer reviewed.

Authorship Contributions

Concept: S.Y., H.D., Design: S.Y., H.D., Data Collection or Processing: S.Y., S.E., Analysis or Interpretation: Y.D.U., S.Y., S.E., H.D., Literature Search: Y.G., Writing: Y.D.U., Y.G., S.Y., S.E., H.D.

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Original Article

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Experiences of Healthcare Professionals Providing Women's Health Services to Asylum Seeking Women at the Hospitals

Hastanelerde Sığınmacı Kadınlara Kadın Sağlığı Hizmeti Sunan Sağlık Profesyonellerinin Deneyimleri

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ABSTRACT

Objective: This study aimed to describe the experiences of healthcare professionals providing women's health services to asylum seeking women at hospitals.

Methods: A qualitative design was used in this study. The data were collected from thirty-four healthcare professionals providing women's healthcare services to asylum seeking women through semi-structured, face-to-face, individual in-depth interviews. The data were evaluated using Colaizzi's seven-step analysis method in the NVivo12 package program.

Results: Three themes were identified (1) challenges, (2) reflections, and (3) needs. Healthcare professionals evaluated the process of providing women's healthcare services to asylum seeking women from a positive and negative point of view. They stated that they should be supported personally, professionally, and as a health team in improving this experience.

Conclusion: This study narrows the gap in the literature and expands the scope of existing knowledge concerning the healthcare professionals experience about asylum seeking women health care.

Keywords: Asylum seekers, qualitative research, women's health

ÖZ

Amaç: Bu araştırma, hastanelerde sığınmacı kadınlara sağlık hizmeti veren sağlık profesyonellerinin deneyimlerini tanımlamayı amaçlamıştır.

Yöntemler: Araştırmada nitel araştırma tasarımı kullanılmıştır. Veriler, yarı yapılandırılmış, yüz yüze, bireysel derinlemesine görüşmeler yoluyla sığınmacı kadınlara kadın sağlığı hizmeti veren otuz dört sağlık profesyonelinden toplanmıştır. Veriler, NVivo12 paket programında Colaizzi'nin yedi aşamalı analiz yöntemi kullanılarak değerlendirilmiştir.

Bulgular: Araştırma sonucunda (1) zorluklar, (2) yansımalar ve (3) ihtiyaçlar olmak üzere üç tema belirlenmiştir. Sağlık Profesyonelleri, sığınmacı kadınlara kadın sağlığı hizmeti sunma sürecini olumlu ve olumsuz bir bakış açısıyla değerlendirmiştir. Bu deneyimin geliştirilmesinde kişisel, mesleki ve sağlık ekibi olarak desteklenmeleri gerektiğini belirtmişlerdir.

Sonuç: Araştırmanın sonuçları, literatürdeki boşluğu daraltmakta, sağlık çalışanlarının sığınmacı kadın sağlığı hizmetlerine ilişkin deneyimlerinin anlaşılmasına yardımcı olmakta ve bu deneyimlere ilişkin mevcut bilgilerin kapsamını genişletmektedir.

Anahtar Sözcükler: Kadın sağlığı, nitel araştırma, sığınmacılar

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Introduction

One of the top priorities of the United Nations Sustainable Development Goals 2030 is to reduce inequalities within and between countries for disadvantaged populations. The basis of this goal is the necessity of accepting health as the most basic human right, regardless of the gender, race, religion, social class and political orientation of the individual (1). Despite all regulations in the world and Turkey, it is reported that especially women who migrate experience barriers to accessing this right. When these barriers to accessing the service are evaluated holistically, the individual characteristics of asylum seekers, the health system, health policies, the geographical location of the country, and cultural social factors and discrimination are emphasized (2). Studies trying to explain migration from the perspective of asylum seeking women benefiting from health services have focused on asylum seeking women's health problems, prenatal and postnatal care experiences, migration experiences and the effects of migration on women's health (3,4). Studies on the effects of migration on women's health focused on maternal health and emphasized that the access of pregnant women who migrated to antenatal care was often delayed (5,6). Additionally, these studies focused on the negative experiences of asylum seeking women during their pregnancy (7,8).

When evaluated in terms of health care providers to asylum seeking women, it is quite difficult to provide adequate and culturally appropriate gynecological and obstetric health care services to minority ethnic groups. In order to overcome this difficulty, it is imperative to examine and understand the views of health professionals on the care of asylum seeking women. So far, research in this perspective has focused on the barriers healthcare professionals face in providing services. These obstacles are; inability to coordinate care, cope with cultural diversity, and communication barriers (9-11). Studies generally focused on communication barriers, were carried out with a single group of health professionals or were carried out in a descriptive design. However, a multidisciplinary perspective and qualitative design are very important in revealing the experiences of health professionals holistically.

This study aimed to describe the experiences of healthcare professionals providing women's health services to asylum seeking women. The results of the study, which examines the experience of providing women's health to asylum-seeking women from a multidisciplinary perspective, present the process not only in terms of obstacles, but also in a broader framework. It is thought that it will contribute to the development of women's health services, especially in the regions where refugee women live and in the hospitals they are admitted to.

Methods

Study Design, Participants, and Setting

This study aimed to phenomenologically describe the working experiences of doctors, nurses, and midwives health care for asylum seeking women through a qualitative design. A snowball sampling method was used. The inclusion criteria for this study were (a) being a nurse, a midwife, or obstetricians and gynecologists working on the frontline, (b) providing women's health care services to asylum seeking women and working at obstetric and gynecology service and delivery room (c) having more than six months of experience. Other healthcare professionals who had less than six months of experience were excluded. Following the literature for phenomenological studies, the absence of new information in the interviews was accepted as an indicator of data saturation (12). The study was completed with 34 healthcare professionals (12 nurses, 15 midwives, and 7 physicians). This study was carried out in four state hospitals, each with a capacity of 150 beds, located in the border districts of Şanlıurfa, where temporary accommodation centers were located, and a training and research hospital with 500 beds in the city center.

Ethical Considerations

Approval was obtained from the Istanbul University Social Sciences and Humanities Research Ethics Committee to conduct the study (date: 26.06.2018, number: 66934). The participants were provided with necessary explanations about the study (objective, content, and the data obtained would be used only within the context of this study; they had the right to leave the study). Consent was obtained from the participants who agreed to participate in the study. The participants were given a number, and data confidentiality and anonymity were ensured. The data obtained from the interviews were kept in encrypted files that only the researchers could access. This study was carried out in line with the Declaration of Helsinki, 1964.

Interview Guide

Following the objective and question of this study, a semi-structured interview guide, which was prepared with support from the literature, was used (3,13,14). Two experts on qualitative research methods evaluated the interview guide, and the questions were tested with two pilot interviews. The required revisions were made following expert views and pilot interviews, and the interview guide was finalized (Table 1).

Data Collection

The semi-structured, face-to-face and individual in-depth interview methods were used to collect data. The first participant who met the inclusion criteria in the study was reached by contacting the managers of hospitals and the other potential participants were determined in line with snowball sampling. The participants were informed about the study's aim, scope,

Table 1. Key questions

What are the women's health services provided to Syrian migrant women?
What problems do you encounter in this process?
How do you spend a working day in this hospital/in your unit?
How do you feel when you leave the hospital/your unit at the end of the day?
Could you tell us about an incident that you experienced with Syrian migrant women that affected you and left a trace on you?

and process. Interview time and place were determined by the participants who agreed to participate in the study. The first researcher conducted the interviews, and each was recorded with a voice recorder with the participant's consent. The duration of the interviews varied between 32 and 53 minutes (41 minutes on average). In this study, data collection and analysis processes were conducted in parallel, and a codebook was created to help determine the time to reach data saturation. In the 34th interview of the study, it was decided that data saturation was reached. There weren't repeat interviews carried out. The interviews were carried out between January 2019 and April 2019. All researchers on the research team were academics in nursing and had Ph.D. degrees, and they were female.

Statistical Analysis

In analyzing the data obtained from the study, Nvivo 12 software package and (15) Colaizzi's seven-step method (1978) were used (Table 2). Within the scope of trustworthiness, this study tried to meet four criteria: credibility, transferability, dependability, and confirmability (16). In this context, the NVivo12 software package used to analyze the data ensured credibility. The researchers discussed the confirmation of the participants, the process of the research through frequent meetings, and the inclusion of the qualifications of the researchers in the text. The research sample, environment, and process were presented clearly and precisely to ensure transferability. Statements of the participants were directly quoted in the text. For reliability, the researchers created the codes and themes using Colaizzi's seven-step method (15). An expert outside the research evaluated the consistency between the researchers and the suitability of codes and themes, and the results were validated. Different researchers coded data to ensure confirmability. Lastly, the consolidated criteria for reporting qualitative research checklist was followed in reporting (17).

Results

In the study group, 30 of the 34 healthcare professionals were females, and their ages varied between 23 and 48. Twelve participants were nurses, 15 were midwives, and 7 were obstetricians and gynecologists. While the participants' experiences in their current institution varied between 6 months and 11 years, their total experience varied between 6 months and 30 years. Thirteen of the participants were married. All participants worked in the gynecology/obstetric units (Table 3).

As a result of data analysis, reached the three main themes: (1) Challenges, (2) reflections, and (3) needs. Table 4 shows each theme's sub-themes, codes, and example quotations.

Discussion

The experience of caring for asylum seeking women is full of uncertainties and obstacles. The risk of experiencing these problems will continue due to rapid changes in world dynamics and forced migration movements. This study aimed to describe the working experiences of doctors, nurses, and midwives in health care for asylum seeking women through a qualitative design.

Discussion section is presented by discussing under each theme.

Challenges

According to the participants, the physical structure of the hospital they worked in and the equipment when providing women's healthcare services to asylum seeking women was

Table 2. Colaizzi's seven-step method

	How it was used in the study
1st step: Understanding the general meaning of transcribed texts	The interviews were recorded with a voice recorder and they were backed up. The interviews were transcribed and a 132-page document was created. The consistency between the records and written documents was read and checked by GTU and U.B. by reading a number of times. All interviews were listened to three times and read six times.
2nd step: Finding out all meaningful expressions in transcriptions	The two researchers collected meaningful expressions from the transcriptions independently and formed a table. 34 important quotations. The quotations were recorded with participant code, line and page numbers.
3rd step: Formulating the meanings of meaningful quotations	Codes were assigned to expressions and comprehensive code book was prepared. Following this, the similarities and differences between the expressions defined by independent coders were discussed until the research team reached a consensus.
4th step: Organizing the codes created from formed meanings into themes and sub-themes	The relationships between the codes obtained from the data were evaluated and sub-themes and themes were categorized. The researchers discussed on the codes until they reached a consensus and the codes were classified under 9 sub-themes and 3 themes.
5th step: Making a comprehensive explanation of the studied phenomenon **6th step:** Describing the basic structure of the phenomenon	A comprehensive description (5) and basic structure (6) of the phenomenon were created.
7th step: Feedback to the participants	The codes and themes were sent to three randomly chosen participants with the interview transcripts to evaluate the relevance of the findings and feedback was received.

insufficient. The participants emphasized that they had problems, especially with the delivery room, operating room, inpatient units, blood bank, and neonatal intensive care unit, and beds were insufficient for the patients referred to the hospital. Another study conducted in Turkey stated that almost half of the healthcare services in public hospitals in cities close to the Syrian border experienced capacity problems in terms of physical conditions and healthcare professionals because of the services provided to asylum seekers (18). Other causes of the problems are that most asylum seekers ignore the chain of referrals and refer to hospitals by skipping primary healthcare centers due to insufficient resources, equipment, and beds (19). Asylum seekers receiving health services in Sweden, on the other hand, expressed their dissatisfaction with emergency services (20). This information can be considered as an indication that hospitals are not ready for the dense population of asylum seeking patients with different health backgrounds.

The participants emphasized negative working conditions as an essential source of problems experienced when providing women's

Table 3. Socio-demographic characteristics of participant

Participant	Gender	Age	Marital status	Education background	Profession	Experiences of current institution (year)	Total experience (year)
1	Female	26	Single	Bachelor	Midwife	2	2
2	Female	30	Single	Bachelor	Nurse	5	6
3	Female	25	Single	Bachelor	Midwife	1	2
4	Female	26	Single	Bachelor	Midwife	2	4
5	Female	26	Single	Bachelor	Midwife	1	1
6	Female	26	Single	Bachelor	Nurse	1	1
7	Female	24	Single	Bachelor	Midwife	1	1
8	Female	23	Single	Bachelor	Midwife	1	1
9	Female	26	Married	Bachelor	Nurse	1.5	3
10	Female	25	Married	Bachelor	Nurse	1	4.5
11	Female	25	Single	Bachelor	Nurse	1	3
12	Female	23	Single	Bachelor	Nurse	1	1
13	Male	40	Married	Higher degrees	Doctor	3	10 l
14	Female	30	Married	Bachelor	Midwife	11	18
15	Female	28	Single	Bachelor	Midwife	1.5	8
16	Female	31	Married	Bachelor	Midwife	5	7
17	Female	32	Married	Bachelor	Nurse	3	10
18	Male	30	Married	Higher degrees	Doctor	1	5
19	Female	30	Single	Bachelor	Midwife	1.5	3
20	Female	24	Single	Bachelor	Nurse	1	1
21	Female	27	Married	Higher degrees	Doctor	1	5
22	Female	40	Married	Bachelor	Midwife	1.5	20
23	Female	48	Married	Bachelor	Midwife	1	30
24	Male	32	Married	Higher degrees	Doctor	1	3
25	Female	27	Single	Bachelor	Nurse	3	6
26	Female	30	Single	Higher degrees	Doctor	1	7
27	Male	31	Single	Higher degrees	Doctor	1	5
28	Female	24	Married	Bachelor	Nurse	2	2
29	Female	29	Single	Bachelor	Midwife	9	9
30	Female	28	Single	Bachelor	Nurse	1	5
31	Female	29	Single	Bachelor	Nurse	2	6
32	Female	26	Single	Bachelor	Midwife	2	4
33	Female	23	Single	Bachelor	Midwife	1	1
34	Female	34	Married	Higher degrees	Doctor	3	10

healthcare services to asylum seekers. Especially, nurse and midwife participants reported that they worked more than normal working hours, experienced a lack of healthcare professionals, and could not maintain their professional development during this process. Following these results, different studies also showed that after Syrian asylum seekers came there was an increase in patient circulation, lack of nurses and increase working hours, and a decrease in the time allocated to patients (18,21). In a similar study, physicians working in areas with too many asylum seekers stated that professional development training, career, and promotion opportunities were insufficient and they tended to leave the region in which they worked (22).

The participants described the women's healthcare services they provided to asylum seekers women as unsafe healthcare and treatment. The participants emphasized that patient and employee safety were not provided with the effect of an unsafe healthcare service environment when providing women's healthcare services to asylum seekers women. Also, in terms of patient safety, they stated that experiencing problems while getting information for anamnesis and informed consent due to the insufficiency of translator services caused problems in making the correct diagnosis, applying, and completing effective care treatment.

Participants stated that they had difficulty in getting information for anamnesis and had problems obtaining informed consent for cesarean section and hysterectomy operations. In a study with similar findings, problems were experienced in receiving informed consent from patients who would undergo an operation or

Table 4. Themes, categories, codes and sample quotations identified in interviews with participants

Theme 1	Sub-theme	Codes	Quotations
Theme 1: Challenges	1.1. Unsuitable physical environment and lack of equipment	Delivery room	*"…Delivery room is not sufficient, I wish we had more beds and comfort, but this is what we have, we have to make use of them in the best possible way…" (P1).*
		Blood bank	*"…We don't have a blood bank, I don't know if we get a certain number monthly, but when I say I want blood products to this patient, I get the blood product in one and a half hour. But as I heard, blood products such as thrombocyte suspension are not found even in the centre of Urfa, they come from Antep. Antep is four hours from here (P21).*
		Inpatient units	*"…The patients wait in the delivery room for 12 hours, they can't get in the service because all our beds are full. Right now there are 40 beds in the service, 20 beds in the opposite service, 60 in total. Although we had 80 beds before, this was not enough. (P33).*
		Neonatal intensive care	*"…Since there is no neonatal intensive care unit in our hospital, we have to refer a large number of our patients to another place. I can say that a large number of babies who are referred after delivery are the babies of migrant mothers…" (P21).*
	1.2. Negative working conditions	Working too much	*"… We are assigned to different units, we work too much, we have limited leave, we have shifts every other day and migrant women have a big effect on this workload…" (P4).* *"…We work too much and I feel the need to check what we do all the time …" (P13).*
		Lack of health manpower	*"…This is one of the places with the highest number of births in Turkey, but we have very few nurses, midwives and doctors. I think that increasing the number of healthcare professionals will contribute to providing a more efficient service to migrants and Turkish patients…" (P3).*
		Not being able to maintain professional development	*"…I feel really sorry because I could not develop myself professionally during this process and because I could not add anything to my education life in one and a half year. Because I have limited opportunities and I cannot find time" (P5).*
	1.3. Unsafe health care and treatment practices	Failure to ensure patient safety	*"…We experienced problems with a patient in whom the anamnesis was wrong, the patient had not told us that she had had caesarean section, but thanks God, nothing happened to the patient…" (P31).* *"…They don't want to have caesarean section, why? Because previous caesareans will be a problem, she'll have second caesarean section, too and be able to give birth three or four times …" (P34).* *…There were migrant women who used each other's identities and who seemed to deliver twice in the same year, thanks God, we did not have any problems. Everyone says that they are emergency patients and they generally refer to the emergency service, but when you examine, you see that they can be followed in the outpatient clinic… (P11).*
		Failure to ensure employee safety	*"…We experience verbal arguments, this is mostly due to language problems, delivery is a painful process, we sometimes get beaten, sometimes bitten, everything may happen during delivery…" (P3).* *"…Since we cannot make pre-evaluation, we don't have any information about the patient's previous diseases, we don't know what has happened to them …" (P22).* *"…It creates a risky environment, imagine that we cannot get anamnesis properly, but we have to make an emergency intervention, we don't know if the patient has HIV or hepatitis?..." (P21).*

Table 4 (Continued). Themes, categories, codes and sample quotations identified in interviews with participants

Theme 2	Sub-theme	Codes	Quotations
Theme 2: Reflections	2.1. Providing transcultural health care	Feeling insufficient	*"…Professionally, I feel insufficient, especially not knowing the language, not being able to communicate with the other party is a very big deficit, and communication through translators is not very healthy…" (P25).*
		Feeling unsafe	*"…In fact, it is unsafe because we don't know the culture exactly, some patients tell things which show that they don't trust us …" (P16)*
	2.2. Emotions	Astonishment	*"…I want to tell about a memory. While I was giving breastfeeding training, a migrant woman took out her breast and began to show how she breastfed and then she said that she was breastfeeding for 10 years. I thought she had given birth with short intervals, but it turned out she breastfed each child for 10 years. I can't tell you how surprised I was…" (P1).*
		Anxiety	*"…It causes anxiety because we feel anxious mostly because we don't know about patients' anamnesis and we cannot communicate, we wonder if there's something we are missing. We cannot know their anamnesis completely, for example, we don't know if they had caesarean section or normal birth before, the treatment and the process will be different according to this, therefore, you feel anxious…" (P20).*
		Hopelessness	*"…How can I say, I feel hopeless…" (P23).*
	2.3. Professional experience	Positive Professional experiences	*"…I have seen different patients here, my communication skills have improved and I have developed myself professionally. I have seen different cases, I mean we have improved ourselves, it has more advantages for us…" (P3)*
			"…There is a continuous crisis professionally, we are always in an effort to solve problems. I would feel comfortable even if I encountered very complex cases…" (P27).
			"…It brought great contributions professionally. I don't think that I can have such an experience in any place in Turkey. Not just in terms of gynaecology, but I also had lots of humanly experiences …" (P31).
		Negative Professional experiences	*"…Now I feel less patient. I have asked myself why I have changed, but it is very easy to say when you are on the outside, things are more different when you are on the inside…" (P10).*
			"…I was more patient before I came here. I think I had more tolerance before. Now I feel more rigid. I mean I used to love those differences more in the past, but not now…" (P15).
			"…I feel professionally exhausted. I regret that I did my chosen profession in this way…" (P34).

Table 4 (Continued). Themes, categories, codes and sample quotations identified in interviews with participants

Theme 3	Sub-theme	Codes	Quotations
Theme 3: Needs	3.1. Individualy	Motivation	*"…Here, we need to be motivated to provide an effective health service. But we haven't seen any initiative regarding this so far. The salary paid can never be a source of motivation on its own…" (P24).*
	3.2. Professionaly	Education and training	*"…Transcultural knowledge is not just knowledge to be acquired in professional life. For this, there must be initiatives that start from our education lives. Compulsory courses, compulsory training, continuous assessment…" (P2).*
	3.3. As a team	Multidisciplinary team	*"…The most critical deficiency among our multidisciplinary team is a professional translator. We are aware of this deficiency, Are patients or managers aware of this?..." (P6).*

interventional procedures (23). Lastly, the participants reported that asylum seeking women referred to institutions using the identities of other women, and this situation was a significant threat to patient safety. According to the literature, the lack of identity numbers and identity impersonation to get medication by many patients create suspicion in healthcare professionals (23). The demand for identity information correctness gives healthcare professionals the responsibility of bureaucratic procedures such as checking identities (24). In addition to its adverse impacts on patient safety, it can be said that this situation is reflected in the relationship between the patient and the healthcare professionals, with healthcare professionals losing their confidence in patients.

Regarding employee safety, the participants stated that they were afraid of being exposed to violence and that there was a risk of infectious diseases since they did not know the patients' anamnesis. In the literature, violent behaviors against healthcare

professionals have been closely associated with communication with patients and their relatives and the language barrier (14). Another issue the participants mentioned relating to their safety was that they were at risk since asylum seekers had infectious diseases frequently, but since they could not learn their anamnesis, the diagnosis of these diseases made after the intervention put them at risk. In the literature, the infectious diseases of asylum seekers who experience migration under negative conditions and struggle for their lives under unsuitable conditions are among the situations that scare the host country most (25).

Reflections

While the participants described their experiences in providing healthcare services to individuals from different languages and cultures as unhealthy communication with translators, they also stated that they felt insufficient and unsafe. Similarly, in a study conducted on nurses providing care to asylum seeking women, nurses stated that they felt insufficient (21). In a study that examined the difficulties experienced by healthcare professionals providing women's healthcare services to pregnant women with different languages and cultures, it was concluded that healthcare professionals felt insufficient since they could not communicate with women (26).

While the participants stated that they experienced different emotions when providing service to asylum seeking women, they described these emotions as astonishment, sadness, anxiety, and despair towards different practices and beliefs of women. However, they emphasized that their emotions did not affect their service. In their study, Dias et al. (27) found that healthcare professionals had positive emotions and attitudes toward asylum seekers, while Zhou et al. (28) expressed that the negative emotions nurses developed for asylum seeking patients were due to workload and communication problems. In a study conducted in Iran, nurses stated that they felt hopeless, anxious, and fearful while providing care to patients from different cultures (29).

Lastly, the participants stated that providing healthcare services to asylum seekers contributed positively and negatively. The participants mostly evaluated dealing with patients from a different society as positive in terms of having increased self-confidence, gaining experience in managing crises and patients, and getting rid of biases. In contrast, they evaluated the fatigue and burnout created by negative working conditions, getting impatient with people, and having decreased tolerance as negative. Following these results, it was found in the literature that nurses working in regions where Syrian asylum seekers lived intensely had increased self-confidence, acted more patient and careful, were cautious and courageous, had increased awareness about creativity, and cared about different patients during this process (21). According to the results of studies that focused on the negative impacts of this experience, it was found that nurses and midwives who lived in an area where Syrian asylum seekers lived intensely had higher burnout levels (22,30).

Needs

Participants stated that they needed to effectively provide women's healthcare services to women from different cultures. First, they thought that it was essential to ensure their individual motivation and that this could not be achieved only with financial motivation sources. Many factors such as political, economic, social, cultural, and technological factors affect the motivation of health workers. However, most work motivation theories focus on micro factors (31). These reflections are also seen in practice. However, it is necessary to determine health professionals' working conditions and focus on these conditions and motivation factors specific to individuals.

They expressed their education and training needs that would enrich the transcultural health service provision professionally. Studies continue to make these training programs compulsory in disciplines such as business administration, medicine, and nursing.

The name and content of intercultural courses in medicine and nursing undergraduate programs in Turkey differ, and there is no standardization (32,33). The situation in the world is no different. It was found that intercultural nursing course was compulsory in only 31.6% of nursing programs in Korea (34). It has been reported that medical curricula in Europe are culturally inadequate and that the programs do not evolve in line with the increasing migration (35). It is recommended that the barriers, strengths, weaknesses, and opportunities associated with the different cultures that health professionals serve are determined by SWOT analysis. In other words, what is the process in practice besides the theoretical information? Answering the question is of vital importance.

Finally, they mentioned that the importance of working as a multidisciplinary team in addition to their individual and professional needs and stated that the presence of a professional translator in this team was vital. In the literature, the most difficulties are experienced in the process of giving care to patients from different cultures (36). Aygün et al. (37) stated that physicians providing healthcare services to asylum seekers were unsure whether translators could tell the problems correctly and to what extent they could translate the recommendations and treatment they gave. It is thought that translations not made by professionals are not generally accurate, symptoms are not explained correctly, and essential details are skipped (38). In a different study, it was emphasized that the lack of professional translators, healthcare professionals not having language education, and language barriers when providing health services to asylum seekers were obstacles to patient rights including reproductive rights (39). Patients from different cultures create uncertainty and anxiety for healthcare professionals. Although the presence of an interpreter is considered the gold standard in ensuring intercultural communication, it should not be forgotten that the essential point is health communication. Linguistic and cultural knowledge alone is not sufficient to decide an individual's situation. While it has been suggested that individual efforts cannot overcome language barriers, professional steps should be taken by including the parties receiving and providing service. Also, it is advocated that the presence of effective translators will provide a correct medical interaction, thereby contributing to patient outputs (40,41).

Study Limitations

The data were collected with in-depth interviews, which limited the findings to the expressions of the participants. The majority of the study participants were females (n=30); only four males were recruited for this study. Thus, the experience of the males may not have been adequately explored in this study.

Conclusion

This study narrows the gap in the literature and expands the scope of existing knowledge concerning the healthcare professionals' experience with asylum-seeking women's health care. The results obtained in the study were collected under three themes (1) challenges, (2) reflections, (3) needs. Our results revealed that many factors, especially the language barrier, cultural differences, and ignorance, affected the effectiveness of these services. In addition to the effectiveness of the service provided, the meanings attributed by health professionals to their experiences during this process differ. In conclusion, it was found that the healthcare professionals thought providing healthcare to individuals with different languages and cultures created inadequacy and professional insecurity, they experienced adaptation problems during the whole process, and they had problems with the physical structure and equipment of the hospital they worked in, they worked under negative working conditions, they evaluated the whole process as an unsafe healthcare and treatment service process, they thought the host country was not ready to provide healthcare services to patients with different language and cultures. They stated they should be supported personally, professionally, and as a health team in improving this experience. Our results may help health institutions, managers and policymakers understand healthcare professionals' challenges, emotions, needs and also determine strategies for improving healthcare delivery.

Ethics

Ethics Committee Approval: Approval was obtained from the Istanbul University Social Sciences and Humanities Research Ethics Committee to conduct the study (date: 26.06.2018, number: 66934).

Informed Consent: The participants were provided with necessary explanations about the study (objective, content, and the data obtained would be used only within the context of this study; they had the right to leave the study).

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: G.T.Ü., Ü.B., Design: G.T.Ü., Ü.B., Data Collection or Processing: G.T.Ü., Analysis or Interpretation: G.T.Ü., Ü.B., Literature Search: G.T.Ü., Writing: G.T.Ü.

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Review

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Non-pharmacological Methods in the Management of Postoperative Sore Throat in Patients Undergoing Endotracheal Intubation: A Systematic Review

Endotrakeal Entübasyon Uygulanan Hastalarda Ameliyat Sonrası Boğaz Ağrısının Yönetiminde Non-farmakolojik Yöntemler: Sistematik Derleme

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ABSTRACT

The aim of this study was to determine and compare non-pharmacologic methods for the management of postoperative sore throat in adult patients undergoing endotracheal intubation. This study used a systematic review of clinical trials. Articles published between 2010 and 2022 in PubMed, Scopus, Web of Science, MEDLINE, EBSCOHost databases were included. The review was organized according to Cochrane Collaboration guidelines and reported using Preferred Reporting Items for Systematic Reviewsand Meta-Analyses. A total of 857 articles were retrieved in the initial search. After reviewing the articles according to the inclusion and exclusion criteria, a final set of seven articles was evaluated. It was observed that ASA I-II patients in whom elective surgery was planned were mostly included in the studies. It was determined that cold vapor, ice cube, licorice gargle, luo han guo (Monk fruit) herbal tea and tube warming were used as non-pharmacological methods. Interventions were performed preoperatively in five of the studies and postoperatively in two. Numeric pain scale was frequently used to assess sore throat. Patients' sore throat was most commonly evaluated in the second, fourth and 24th hours after extubation. Cold vapor, licorice gargle, luo han guo herbal tea and tube warming were found to be effective in reducing sore throat. Several reliable non-pharmacological methods are available for managing a sore throat in patients undergoing endotracheal

ÖZ

Bu çalışmanın amacı, endotrakeal entübasyon uygulanan yetişkin hastalarda ameliyat sonrası boğaz ağrısının yönetiminde non-farmakolojik yöntemleri belirlemek ve karşılaştırmaktır. Bu çalışmada klinik çalışmaların sistematik bir incelemesi kullanılmıştır. PubMed, Scopus, Web of Science, MEDLINE, EBSCOHost veri tabanlarında 2010 ve 2022 yılları arasında yayınlanan araştırmalar dahil edilmiştir. İnceleme Cochrane Collaboration kılavuzlarına göre düzenlenmiş ve Preferred Reporting Items for Systematic Reviewsand Meta-Analyses kullanılarak raporlanmıştır. İlk aramada 857 makaleye ulaşıldı. Bulunan makaleler dahil etme ve hariç tutma kriterlerine göre gözden geçirildikten sonra, yedi makaleden oluşan son bir set değerlendirildi. Araştırmalara çoğunlukla ASA I-II ve elektif cerrahi planlanan hastaların dahil edildiği görüldü. Hastalara non-farmakolojik yöntem olarak soğuk buhar, buz küpü, meyan kökü gargarası, luo han guo (Monk meyvesi) bitki çayı ve tüp ısıtılması kullanıldığı saptandı. Araştırmaların beşinde girişimler ameliyat öncesi, ikisinde ameliyat sonrası uygulandı. Boğaz ağrısını değerlendirmek için sıklıkla numerik ağrı skalası kullanıldı. Hastaların boğaz ağrısı en fazla ekstübasyon sonrası ikinci, dördüncü ve 24. saatlerde değerlendirildi. Soğuk buhar, meyan kökü gargarası, luo han guo bitki çayı ve tüp ısıtılmasının boğaz ağrısını azaltmada etkili olduğu bulundu. Endotrakeal entübasyon

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ABSTRACT

intubation. However, more research is needed to determine the most effective non-pharmacological approach.

Keywords: Intubation, surgical patient, sore throat, non-pharmacologic methods

ÖZ

uygulanan hastalarda boğaz ağrısının yönetiminde birçok güvenilir non-farmakolojik yöntem kullanılmıştır. Bununla birlikte, en etkin non-farmakolojik yöntemi belirlemek için daha fazla araştırmaya ihtiyaç vardır.

Anahtar Sözcükler: Entübasyon, cerrahi hasta, boğaz ağrısı, non-farmakolik yöntemler

Introduction

Postoperative sore throat (POST) is a common complication. The incidence of POST varies between 18% and 65% and lasts for 12-24 hours after surgery (1,2). It is caused by local tissue trauma and pharyngeal mucosal inflammation (2). The risk factors of POST include head and neck surgery, female gender, nausea and vomiting, cuff pressure and difficult intubation (3). POST affects the healing process by negatively affecting the nutrition and fluid intake of the patients. On the other hand, reducing postoperative complications reduces the length of hospital stay and increases patient satisfaction (4,5).

Due to the extensive etiologies of POST, several methods are used to prevent and reduce it. These methods usually include pharmacological (1,3) and clinical applications. Some of the clinical applications include acupuncture, cuff pressure, difficult intubation interventions, soaking the endotracheal tube (ET) with water-soluble gel, and nerve block (6-9). However, the routine use of these applications is limited, and there is no clinical standard (10).

Postoperative pain control includes nursing interventions as well as pharmacological and clinical applications. Hot and cold applications such as cold vapor (4,11), licorice (2) and luo han guo (12) are among the nursing interventions. These limited studies are novel and include easy-to-apply nursing interventions for the prevention and reduction of POST (2,4,11,12). However, a systematic review calculating the effect size of these interventions has not been found in the literature.

Methods

Aim

To determine and compare non-pharmacologic methods in managing POST in adult patients undergoing endotracheal intubation.

Design

The research question is "What is the effect of non-pharmacological methods in managing sore throat as a result of a postoperative endotracheal intubation?" This research complied with the principles of the Cochrane Guideline (13) and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Two independent researchers (HO, TY) reviewed the titles and abstracts of the studies according to the inclusion criteria (Figure 1). The researchers (HO, TY) analyzed the data one by one. At all stages, discrepancies were resolved through consensus and collaboration of the researchers (HO, TY).

Inclusion and Exclusion Criteria

Inclusion Criteria

Experimental studies meeting the PICOS criteria were included in the study:

Patients: Adult patients undergoing intraoperative endotracheal intubation and elective surgery.

Intervention: Non-pharmacological interventions in POST management.

Comparison: Intervention and control group.

Outcome: POST.

Study design: Only full-text English articles that contain experimental research published between 2010 and 2022 were included in this review.

Exclusion Criteria

Congress abstracts without full-text articles,

Editorial letters,

Non-English articles,

Studies with pediatric patients,

Pharmacological studies,

Other clinical studies (acupuncture, cuff pressure measurement, difficult intubation interventions, nerve blocking).

Definition of Outcome Measures

The outcomes of the study were the severity and incidence of postoperative sore throat. These outcomes were evaluated in the postoperative care unit (PACU) between the first 24 hours and the third day after surgery.

Literature Search Strategy

PubMed, Scopus, MEDLINE, Web of Science and EBSCOhost databases were used in this study. The databases were searched between January 1, 2010 and February 1, 2022, with no restrictions on article status (abstract or full text, etc.). Search terms included "sore throat", "endotracheal intubation", "postoperative complication" and "hoarseness". The search was performed by combining indexed (e.g. MESH) and free text (sore throat* OR postoperative sore throat) terms using "AND" as follows: (endotracheal intubation) AND (postoperative

complication* OR hoarseness). The study followed the PRISMA guideline recommendations (14).

Study Selection

A total of 857 articles were found in the initial review. After eliminating duplicates and non-English language studies, the number of studies selected for the final survey was 338. The abstracts of these articles were reviewed for exclusion criteria. After excluding letters to the editor (n=1), pharmacological (n=237) and pediatric studies (n=35), the remaining 65 articles were subjected to an additional full-text evaluation to decide which articles to use. Finally, 58 articles about clinical practice were excluded and seven articles about nursing intervention were included (Figure 1).

Data Extraction and Analysis

Two reviewers (HO, TY) independently extracted data from the included studies using a pre-designed data extraction form. The extracted data included study design, study location(s), sample size, patient characteristics, the measurement tool used to assess the severity of sore throat, and the effect of the non-pharmacologic method on POST (Table 1).

Quality Appraisal

This review used the Cochrane tool for assessing risk of bias (RoB) in randomized trials (15), which consists of five domains: Randomization process, Deviations from intended interventions, Missing outcome data, Measurement of outcome, and Selection of reported outcome. Table 2 summarizes the results of the RoB assessments.

Results

Study Characteristics

Two of these studies were conducted in Turkey (4,11) two in China (10,12) one in Austria (2) and two in Korea (16,17). One of these studies was quasi-experimental (11), one was single-blind, and five were double-blind randomized controlled studies.

Characteristics of the Patients

The total number of patients in all studies was 1.092. However, 1.067 patients were included in the study sample since 14 patients from the study of Tan et al. (12) and 11 patients from the study of Yu et al. (18) dropped out after the initial selection.

Regarding the sociodemographic characteristics of the participants, the mean age of the patients was 51.37±13.84 years and the mean body mass index was 25.59±5.12 kg/m^2. Most of the patients in the studies were female. Inclusion criteria were similar among the included studies: The patients were over the age of 18, planned for elective surgery under general anesthesia, without preoperative sore throat and hoarseness, had ASA scores I-II (2,4,10,17), had Mallampati Score I-II (4), had Body Mass Index <30 kg/m^2 (16), had Cormack-Lehane Grade I-II (12). The included patients underwent general surgery, lumbar disc herniation, hysterectomy, thoracic surgery and nasal surgery.

Exclusion criteria included difficult intubation or multiple intubation history (2,11,12), steroid drug therapy (10-12), difficulty in co-operation, chronic respiratory system disease (2,11,12,17), psychiatric diagnosis, ASA score ≥III, Mallampati score ≥II-III, presence of nasogastric catheter (4,12), head and neck surgery history, operation time <30 min (4,10,17), a surgery

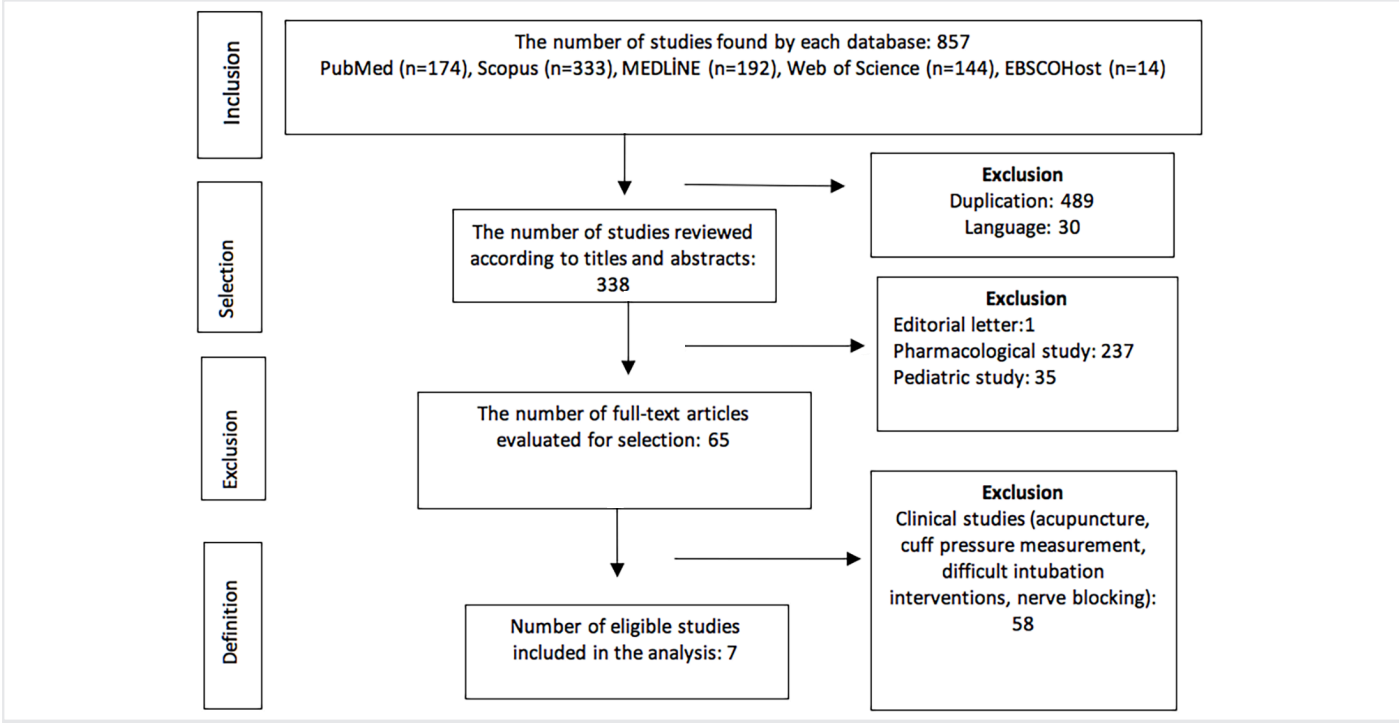

Figure 1. PRISMA flow chart

Table 1. Study summary

Sample size/ group	Sample size/ group	Type of surgery	Intervention		Instrument		Study findings
			Type of non-pharmalogical intervention	Duration and frequency	Name	Reliability	
Sahbaz and Khorshid (4) RCT	120 EG1: 30 EG2: 30 EG3: 30 CG: 30	General surgery	EG1: Cold vapor EG2: 25 g of ice cube EG3: Cold vapor and 25 g of ice cube CG: No intervention	At 0, 2, 6, 24 hours postoperative	VAS	NI	Significant reduction at 6th (p<0.000) and 24 h (p<0.000) postoperatively.
Bulut et al. (11) quasi-experimental	60 EG1: 20 EG2: 20 CG: 20	Lumbar disc herniation	EG1: Cold vapor EG2: Cold vapor and oxygen group CG: No intervention	Pre-interventional, postoperative 2, 4, 8, 12 hours	Yes-No	NI	There was no statistically significant difference between pre-intervention (p=0.803), 2nd hour (p=0.415), 4th hour (p=0.091), 8th hour (p=0.057) and 12th hour (p=0.235)
Wang et al. (10) double-blind RCT	138 EG: 69 CG: 69	Elective hysteroscopic surgery	EG: Before transferring to the operating room, the intervention group chewed sugar-free herbal gum for two minutes in the pre-operative waiting area CG: They were just asked to swallow twice with no additional treatment	At 2, 6, and 24 hours postoperative	NRS	0.325	Significant reduction in sore throat at 2 hours (p=0.001), 6 hours (p=0.001) and 24 hours (p=0.010) postoperatively
Ruetzler et al. (2) double-blind RCT	235 EG: 118 CG: 117	Elective thoracic surgery	EG: 30 mL of the mouthwash (1 min) prepared with licorice, 5-minutes pre-operatively CG: 30 mL mouthwash with a licorice-like flavor (1 min)	At 30 min, 1.5, and 4 hours Postoperatively	11-point Likert scale	0.46	Significant reduction in sore throat at postoperative 30th min (p=0.005), 1.5 h (p=0.001) and 4th hour (p=0.0001)
Seo et al. (17) double-blind parallel group RCT	140 EG: 70 CG:70	Elective thoracic surgery	EG: The distal part of double-lumen tubes between the bronchial tip and the proximal edge of the tracheal cuff was immersed in sterile normal saline in a bottle for 10 minutes pre-tracheal intubation. The saline temperature was manually maintained at 40 °C for the intervention group using an aseptic thermometer (Ewha Biomedics, Seoul, Korea) CG: The temperature was at operating room temperature for the control group	The sore throat was evaluated on the 1st, 2nd, and 3rd days postoperatively	None= no sore throat; Mild= pain with swallowing; Moderate= persistent pain increasing with swallowing; Severe= pain that prevents eating and requires analgesic medication	0.95	On the first postoperative day, the incidence of sore throat was 20% in the intervention group and 38% in the control group. There was no difference on the 2nd and 3rd days

Table 1. continued

Sample size/ group	Sample size/ group	Type of surgery	Intervention		Instrument		Study findings
			Type of non-pharmalogical intervention	Duration and frequency	Name	Reliability	
Tan et al. (12) double-blind RCT	203 EG: 102 CG: 101 189 patients were included in the final analysis: 94 in the intervention group and 95 in the control group	Patients with cervical cancer scheduled for tracheal intubation during general anesthesia for laparoscopic radical hysterectomy	EG: 6 hours postoperatively, the intervention group received 30% oral decoction of luo han guo (300 g of dried luo han guo was boiled in 1000 ml of water for 10 minutes) [0.5-1.0 g/kg/day; 30 mL bolus, three times daily (08:00, 12:00, 16:00) for 48 hours] CG: The control group received black tea according to their condition and dry mouth symptoms	The sore throat was evaluated at the 2nd, 12th, 24th, and 48th hours postoperatively	Visual Analogue Scale	NI	Sore throat scores did not differ significantly between the intervention and control groups 2 hours postoperatively (p=0.971) However, the scores of the intervention group were significantly lower than those of the control group at the 12th, 24th, and 48th hours postoperatively
Yu et al. (16) double-blind RCT	n=196 EG: 96 CG: 94 Analyzed: EG: 94 CG: 91	Elective nose surgery	EG: The air in the tube was vacuumed, and the distal part of the tube was immersed in a sterile bottle of normal saline for 10 minutes pre-intubation. The temperature of normal saline was kept at 40 °C for the intervention group CG: The temperature of normal saline was at operating room temperature for the control group	The sore throat was evaluated at 1st and 24th hours postoperatively	The Sore throat was evaluated with NRS (0-10 points: 0: no pain, 10: worst pain imaginable)	At 1st hour postoperatively NA NA At 24th hours postoperatively NA	In conclusion, ETT intubation after thermal softening reduced the incidence and severity of sore throat at 1st hour postoperatively compared to ETTs without thermal softening (p<0.01)

history within last month (2), BMI >40 kg/m^2, nonsteroidal anti-inflammatory drug use within last 24 hours (2,10), and having cervical spine diseases (17).

Control of Sore Throat

Table 1 shows the details of interventions for sore throat due to intubation in the studies. In these studies, the interventions administered to patients in the intervention group for the management of sore throat were cold vapor-ice cube cold vapor, oxygen administration with cold vapor, licorice extract, luo han guo and thermal softening of ET (2,4,11,12,16,17). As for control groups, three studies had no-intervention control groups (4,10,11), one study applied a placebo with licorice-like taste (2), one study applied black tea (12), and two studies kept the ET at operating room temperature (16,17).

The severity of POST was assessed using scales such as Visual Analog Scale, Numerical Rating Scale and subjective questions (none, mild, moderate, severe). Pain levels were assessed at 2, 4, 6, 12, 24 hours and 3 days postoperatively at the postoperative recovery unit. The results showed that "cold vapor" and "cold vapor-oxygen combination" were not statistically significantly effective in reducing sore throat (11). "Cold vapor-ice cubes-cold vapor combination" and "ice cubes" application were not effective in reducing the severity of sore throat at zero and second hours after surgery, but were effective at 6th and 24th hours (4). While licorice reduced the severity of sore throat 30 minutes, 1.5 hours and 4 hours after surgery (2), luo han guo was found to reduce the severity at the 12th, 24th and 48th hours after surgery (12). Furthermore, thermal softening of ET significantly reduced the incidence of POST (16,17).

Table 2. The Cochrane's risk of bias assessment

Study	D1	D2	D3	D4	D5	Over all		
Sahbaz and Khorsid (4)	!	+	+	+	!	+	+	Low risk
Bulut et al. (11)	!	+	+	!	-	!	!	Some concerns
Wang et al. (10)	+	+	+	+	!	+	-	High risk
Ruetzler et al. (2)	+	+	-	+	!	+		
Seo et al. (17)	+	+	+	+	!	+		
Tan et al. (12)	+	+	+	+	!	!		
Yu et al. (16)	+	+	+	+	!	!		
Low risk of bias	5	7	6	6	0	4		
Some concerns	2	0	0	1	6	3		
High risk of bias	0	0	1	0	1	0		

D1: Randomization process, D2: Deviations from the intended interventions, D3: Missing outcome data, D4: Measurement of the outcome, D5: Selection of the reported result

Discussion

Intubation tubes are commonly used to maintain breathing in patients undergoing surgery under general anesthesia. However, difficult intubation can cause airway damage. Moreover, ET cuff pressure is an important factor in mucosal irritation and inflammation. Therefore, different postoperative complications associated with ET are common. POST is one of these complications (2,16,19,20). It has been reported that the frequency of POST peaks between the 2nd and 6th hours after extubation and decreases over time (21,22). Although pain management in postoperative period is among nursing interventions, studies are inadequate. There are different practices in POST management. These practices generally aim to reduce tissue trauma and prevent inflammation during intubation (2,4,16,17).

Thermal softening of the ET allows the ET to form easily and thus reduces physical trauma to the larynx. Seo et al. (17) used saline heated at 40 °C and a softened intubation tube for the patients undergoing elective thoracic surgery. They observed that the incidence of POST was significantly reduced by 20% on the first day. Yu et al. (18) similarly found that thermal softening of ET reduced the incidence and severity of sore throat in the first hour after surgery. These findings show that thermal softening is a simple and easily applied method in POST. Wang et al. (10) used chewing gums to reduce physical trauma for the management of POST and found that sore throat decreased at the 2nd, 6th, and 24th post-operative hours. Chewing gum increases salivation and reduces intubation-related trauma by lubricating the oral cavity (10). The results suggest that thermal softening of ETs and the use of chewing gum may be among the nursing interventions to reduce POST with an interdisciplinary approach.

Hot and cold applications reduce inflammation in patients undergoing endotracheal intubation. Herbal teas are presented as hot applications in the literature. Licorice was used in this systematic review and meta-analysis (23). The researchers used herbal teas prophylactically and reported that herbal teas significantly reduced sore throat within 30 minutes, 1 hour and 4 hours postoperatively. Licorice contains glycyrrhizin and has anti-inflammatory and antiallergic effects. Glycyrrhizin reduces prostaglandin secretion and inhibits inflammation by slowing platelet aggression (24,25). Tan et al. (12) used luo han guo to reduce POST and observed that sore throat was reduced in the 12th, 24th and 48th postoperative hours. Luo han guo is an anti-inflammatory, antibacterial herb widely used in Traditional Chinese Medicine to moisturize the lungs, relieve heat and alleviate cough (26,27). These findings suggest that anti-inflammatory herbal teas can be cost-effective applications in

nursing interventions to reduce POST. However, the correct use of herbs may require further knowledge. Therefore, integrative applications are recommended.

Cold applications affect POST by reducing the capillary permeability, controlling edema, reducing the risk of hematoma formation and bacterial activity, preventing the transfer of pain stimulus to the upper centers, and eliminating painful spasms (28). It is observed that "cold vapor" and "ice cube" applications are used to cope with POST (4,11). In the literature, it has been reported that cold vapor can relieve complications such as hoarseness, cough, dry throat and sore throat due to laryngeal damage (29-33). Sahbaz and Khorshid (4) also suggested that cold vapor application, which was easy to apply, had no side effects and low drying cost, might reduce sore throat in the first hours after surgery. However, some studies showed that the effect of cold applications (such as cold vapor and ice cubes) in managing POST was not statistically significant.

Bulut et al. (11), applied cold vapor to the patients in the intervention group for 15 minutes in the first hour after admission to the PACU, while no intervention was applied to the patients in the control group. No statistically significant difference was found between the incidence of sore throat in the intervention and control group patients at the 2nd, 4th, 8th and 24th hours. Similarly, in the study of Özsoy et al. (34), cold vapor was applied to the patients in the intervention group at 0, 2 and 6 hours after surgery. No intervention was applied to the control group. As a result, no statistical difference was found between the POST levels of the patients in the intervention and control groups. Özsoy et al. (34), attributed the similarity between the two groups to the short operation time, successful intubation placement in the first attempt, appropriate ET use and postoperative analgesic doses (34). The time of starting oral intake, frequency of cold application, duration of application and cuff pressure within the normal range may affect the difference between the groups in cold applications.

Study Limitations

This systematic review had several limitations. It included only English-language experimental studies and addressed only the adult patient group. Furthermore, this review was not recorded and published in a specific protocol due to time constraints and limited resources.

Conclusion

POST is a common complication in adult patients undergoing elective surgery. However, interventions mainly include pharmacological and other clinical interventions (acupuncture, cuff pressure, difficult intubation methods, etc.). Nursing interventions with thermal softening, chewing gum and herbal teas significantly reduce POST. However, cold applications that prevent inflammation (cold vapor, etc.) provide only an insignificant decrease in the severity of POST. There are limited number of studies on nursing interventions and more randomized controlled trials are needed.

Ethics

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: H.Ö., T.Y., Concept: H.Ö., T.Y., Design: H.Ö., T.Y., Data Collection or Processing: H.Ö., T.Y., Analysis or Interpretation: H.Ö., T.Y., Literature Search: H.Ö., T.Y., Writing: H.Ö., T.Y.

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Case Report

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Our Unpredicted Difficult Airway Experience in Tracheobronchopathia Osteochondroplastica Patient: A Case Report

Trakeobronkopatia Osteokondroplastika Hastasında Öngörülemeyen Zor Hava Yolu Deneyimimiz: Olgu Sunumu

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ABSTRACT

Difficult airway is a serious condition that can be fatal and is frequently encountered during general anesthesia applications. Tracheobronkopathy osteochondroplasty (TBO) is a rare benign disease that is one of the causes of unpredictable difficult airway. A 45-year-old male patient with no comorbidities was transferred to the operating room for elective cholecystectomy. He couldn't be intubated after standard monitoring and induction of anesthesia. The patient, who had papillomatous lesions in the trachea detected by bronchoscopy, was awakened to be scheduled for rigid bronchoscopy. TBO was detected in pathological examination of the samples taken in rigid bronchoscopy. TBO is a rare benign disease. Its etiology is unknown. It may be asymptomatic or may present with persistent dry cough, hemoptysis, dyspnea, recurrent lower respiratory tract infection, atelectasis and difficult intubation. Some patients may be diagnosed for the first time in the operating room due to difficult intubation.In cases with advanced tracheal stenosis, invasive airway intervention may be required or it may have a fatal course. The use of a laryngeal mask in the perioperative period may be an ideal option in a patient known to have TBO before. Unexpected difficult airway management in the operating room is important for anesthesiologists. According to the difficult airway society algorithm, waking the patient from a planned operation is the safest way until the problem is detected. We did not need invasive intervention because our patient also had elective

ÖZ

Zor hava yolu genel anestezi uygulamaları sırasında sık karşılaşılan ölümcül seyredebilen ciddi bir durumdur. Trakeobronkopatia osteokondroplastika (TBO), öngörülemeyen zor hava yolu nedenlerinden biri olan nadir görülen iyi huylu bir hastalıktır. Kırk beş yaşında ek hastalığı olmayan erkek hasta elektif kolesistektomi ameliyatı için ameliyathaneye alındı. Standart monitörizasyon ve anestezi indüksiyonu sonrası entübe edilemedi. Bronkoskopi ile trakeada papillomatöz lezyonlar görülen hasta rijid bronkoskopi planlanmak üzere uyandırıldı. Rijid bronkoskopide alınan örneklerin patolojik incelemesinde TBO saptandı. TBO nadir görülen benign bir hastalıktır. Etiyolojisi bilinmemektedir. Asemptomatik olabilir ya da inatçı kuru öksürük, hemoptizi, nefes darlığı, tekrarlayan alt solunum yolu enfeksiyonu, atelektazi ve zor entübasyon görülebilir. Bazı hastaların tanısı ilk kez zor entübasyon nedeniyle ameliyathanede koyulabilir. İleri derecede trakeal darlığı olan olgularda invaziv hava yolu girişimi gerekebilir ya da mortal seyredebilir. Önceden TBO olduğu bilinen bir hastada perioperatif dönemde laringeal maske kullanımı ideal bir seçenek olabilir. Ameliyathanede beklenmedik zor hava yolu yönetimi anestezistler için önemlidir. Zor hava yolu derneği algoritmasına göre hastayı planlı bir operasyondan uyandırmak sorun tespit edilene kadar en güvenli yoldur. Bizim hastamızın da elektif cerrahi olması ve ventilasyonunun zor olmaması nedeniyle invaziv girişime gerek duymadık. Ayrıca ameliyathane şartlarında fiberoptik bronkoskopi

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ABSTRACT

surgery and ventilation was not difficult. In addition, we think that it is an important decision to make a diagnosis using fiberobtic bronchoscopy in operating room conditions and to wake up our patient with sugammadex without repeated attemps of tracheal intubation and delay elective surgery. In coclusion, it should be kept in mind that TBO may be one of the unpredictable causes of difficult intubation in the operating room.

Keywords: Traceobroncopatia osteocondroplastica, difficult airway, fiberobtic broncoscopy

ÖZ

kullanarak tanı koymamız ve reentübasyon denemelerinde bulunmadan hastamızı sugammadeks ile uyandırarak elektif cerrahiyi ertelememizin önemli bir karar olduğunu düşünmekteyiz. Sonuç olarak nadir görülmekle birlikte TBO ameliyathane, yoğun bakım ve acil servislerde öngörülemeyen zor entübasyon nedenlerinden biri olarak akılda tutulmalıdır.

Anahtar Sözcükler: Trakeobronkopatia osteokondroplastika, zor hava yolu, fiberoptik bronkoskop

Introduction

Difficult airway is a serious condition that is frequently encountered during general anesthesia and can be fatal. According to the analysis of Difficult Airway Society (DAS) 2016-2021 data, it was stated that 50% of difficult airway events were unexpected (1).

Tracheobronkopathy osteochondroplasty (TBO) is a disease characterized by the protrusion of submucosal nodules originating from bone and cartilage tissue in the tracheobronchial wall into the lumen. Nodules can cause stenosis and complete obstruction over time (2). It was first encountered in 1,875 by Wilks in the autopsy of a patient who died due to tuberculosis. Its etiology is unknown (3).

We aimed to present a patient with TBO, one of the rare causes of unpredictable difficult airway, who we detected in our clinic, in the light of the literature.

Case Report

A 45-year-old male patient was transferred to the operating room for laparoscopic cholecystectomy due to cholelithiasis. He had no additional disease in his medical history. The American Society of Anesthegiology score was evaluated as 1. There was no history of previous surgery. There were no findings on physical examination that would suggest a difficult airway. In preoperative evaluation, sternomental distance, thyromental distance and mouth opening, which were among the parameters we used to predict the possibility of a difficult airway, were evaluated as normal. Mallampati score 2 was calculated. Standard monitoring was applied to the patient (non-invasive blood pressure, SpO_2, ECG). After premedication was provided with 0.01 mg/kg iv midazolam, 1 mg/kg iv lidocaine, 2 mg/kg iv propofol and 1 mcg/kg iv fentanyl were administered for anesthesia induction. After effective ventilation was achieved with a mask, 0.6 mg/kg rocuronium was administered iv. Mask ventilation was continued for 2 minutes to ensure the muscle relaxant effect. It was detected as Cormack Lehane Class 1 on direct laryngoscopy. Orotracheal intubation was attempted with a size 8.0 endotracheal tube (ETT). After the vocal cords were passed, the ETT could not be pushed forward. Then, orotracheal intubation was tried by the specialist anesthesiologist with ETT numbers 7.0, 6.0 and 5.0, respectively. However, ETT could not be pushed forward again after passing the vocal cords. It was determined that the ETT could not be pushed forward due to resistance at the level just below the vocal cords. After mask ventilation with 100% oxygen for 3 minutes, the vocal cords were passed and the tracheal lumen was visualized using a 2.8 mm inner diameter and 3.7 mm outer diameter pediatric fiberoptic bronchoscopy. Diffuse nodular lesions protruding inward, narrowing the lumen, were observed on the tracheal wall (Figures 1, 2). Intubation attempts were not repeated to avoid complications such as edema and bleeding in the narrowed lumen. The patient was consulted to the thoracic surgery clinic during the procedure, and it was decided to wake him up to plan a rigid bronchoscopy at a later date under elective conditions. After 4 mg/kg sugammadex was administered iv to reverse the neuromuscular blockade, the patient, whose muscle activity fully returned, was transferred to the post-anesthesia care unit. The patient, whose SpO_2 level was around 90% and had intercostal retractions during follow-up, was

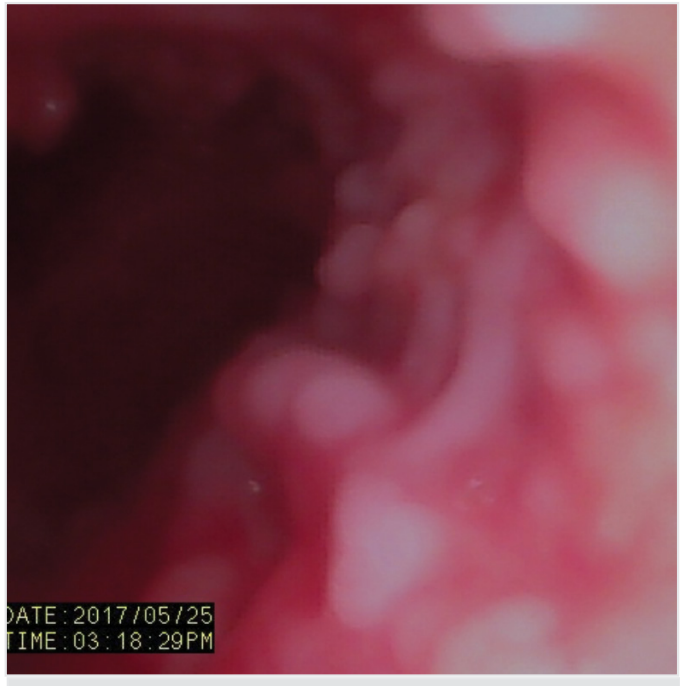

Figure 1. Multiple nodules protruding into the tracheal lumen

administered 1 mg/kg iv prednisolone, inhaler bronchodilator and cold steam therapy to prevent edema in the airway and for bronchodilation. The patient, whose SpO_2 in room air was 100% and who had no respiratory distress, was transferred to the ward. The posterior anterior chest radiograph performed before the operation of the patient, who had no respiratory complaints in the preoperative evaluation, was re-evaluated. It was observed that the tracheal lumen was irregularly limited.

Rigid bronchoscopy performed electively revealed many hard papillamatous lesions starting just below the vocal cords and extending to the main bronchi. Lesions narrowing the lumen were excised. By pathological examination of the samples taken, the diagnosis of TBO was made. A cholecystectomy was planned one week after the diagnosis. After routine preoperative monitoring and standard anesthesia induction, intubation was attempted with a size 7 ETT. The patient, whose intubation was successful, was extubated without any problems after the operation and transferred to the ward.

Discussion

Tracheobronchopathia osteochondroplastica is a rare benign disease. Its etiology is unknown. It may be asymptomatic. Persistent dry cough, hemoptysis, shortness of breath, recurrent lower respiratory tract infection, atelectasis and difficult intubation may occur. The diagnosis of some patients can be made in the operating room due to difficult intubation (2,4). Patients with severe tracheal stenosis may require invasive airway intervention or may have fatal course (5,6). In patients with previously known TBO, the use of a laryngeal mask in the perioperative period may be an ideal option (5). Ishii et al. (5) presented a patient who was to undergo elective hepatectomy. They could not push forward the ETT after passing the vocal cords, just like us, and they woke the patient up, thinking that the lesions might be due to malignancy and could lead to bleeding. When the patient underwent surgery again after the diagnosis of TBO was made, they completed the surgery safely using a laryngeal mask when the tube could not be pushed forward (5). Our patient was not previously diagnosed as having TBO and we had no idea about the characteristics of the lesions. Therefore, we did not consider using a laryngeal mask. Since there was a risk of laryngeal edema and bleeding after repeated intubation attempts, we chose to wake our patient.

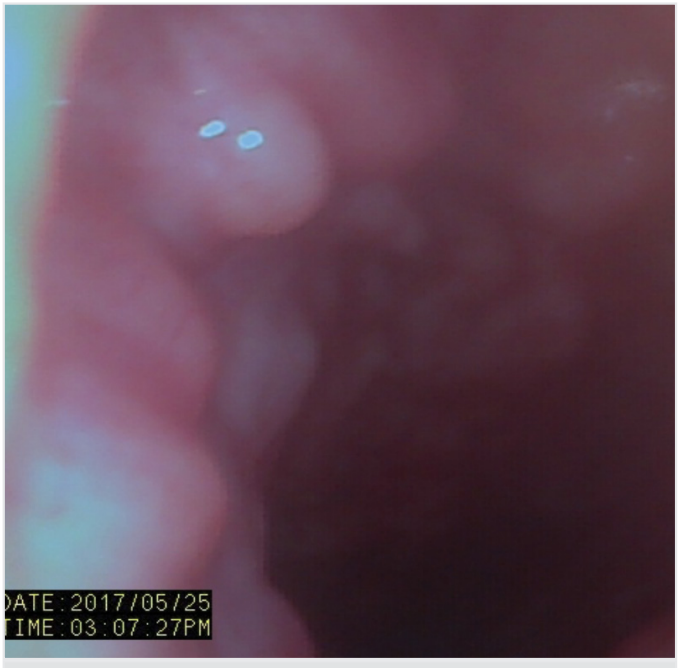

Figure 2. Multiple nodules protruding into the tracheal lümen

Warner et al. (4) could not push forward ETT during laryngoscopy in a patient who was to undergo elective prostatectomy, similar to our patient, and they preferred to wake the patient. In the postoperative period, they diagnosed TBO first with CT and then with bronchoscopy. They argued that bronchoscopy would be useful in the diagnosis of TBO and in relieving obstructive symptoms by excising the lesions (4). Based on this, we think that it is important to first visualize papillomas, which are the cause of unexpected difficult airway, using a fiberoptic bronchoscope under operating room conditions, and then to relieve airway access by excising the lesions with planned rigid bronchoscopy.

We would also like to draw attention to the importance of the posterior anterior chest radiography performed in the preoperative evaluation. In our patient, we noticed that the trachea was irregularly bordered by careful retrospective examination. A more careful examination in the preoperative period can prevent unexpected situations.

Unexpected difficult airway management in the operating room is important for anesthesiologists. According to the DAS algorithm, waking the patient from a planned operation is the safest way until the problem is detected (7). As a result of our patient's comfortable mask ventilation, we provided adequate oxygenation and did not require invasive airway intervention. Additionally, since he was going to have an elective planned surgery, we woke our patient as indicated by DAS as safe.

As a result, although TBO is a rare disease, it may cause difficult intubation. Knowledge and experience regarding difficult airway management come to the fore, especially in patients encountered in operating room conditions. We think that our patient will contribute to unexpected difficult airway management.

Ethics

Informed Consent: The patient was asked to sign a voluntary consent form to parcipate in the case report study, stating that his identiy information would not be shared.

Peer-review: Externally peer reviewed.

Authorship Contributions

Surgical and Medical Practices: S.Y., O.C.A., Concept: S.Y., K.K., Design: A.Ş., S.Y., K.K., Data Collection or Processing:

A.Ş., Analysis or Interpretation: A.Ş., S.Y., Literature Search: A.Ş., Writing: A.Ş.

Conflict of Interest: No conflict of interest was declared by the authors.

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