



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, pediatri 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 ($\alpha=0.10$) (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.

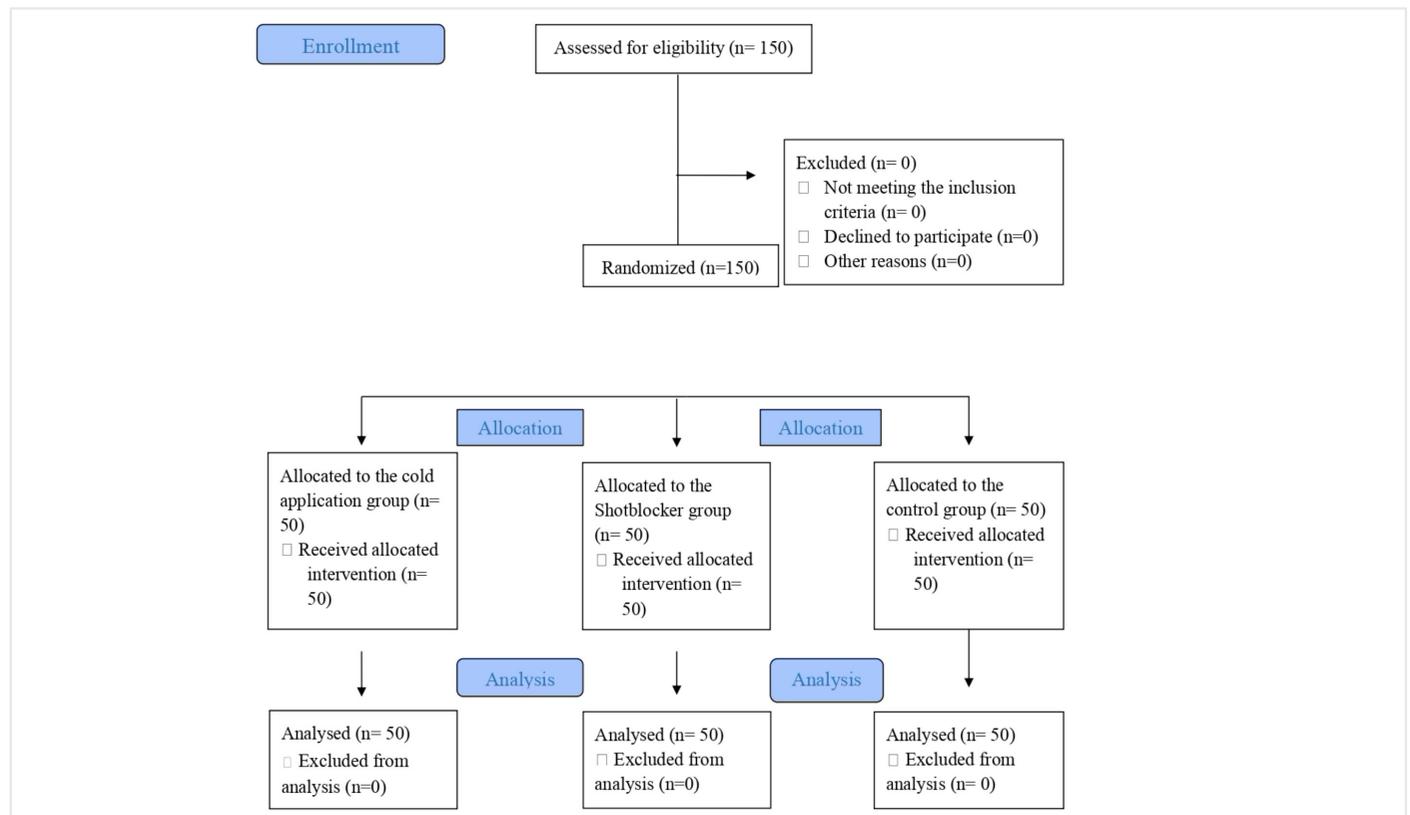


Figure 1. Study flow diagram

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)	x ²	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, Yılmaz 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 Yılmaz 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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References

- Hünseler C, Roth B, Pothmann R, Reinhold P. Intramuskuläre Injektionen im Kindesalter Notwendiges Ubel oder vermeidbare Körperverletzung? [Intramuscular injections in children]. *Schmerz*. 2005;19:140-3.
- Aydin E, Avşar G. Examining the effect of "Shotblocker" in relieving pain associated with intramuscular injection. *Complement Ther Med* 2019;47:102192.
- Kara D. The methods for reducing pain due to intramuscular injection. *Gümüşhane University Journal of Health Sciences*. 2013;2:169-82.
- Şanlıalp Zeyrek A, Takmak Ş, Kurban NK, Arslan S. Systematic review and meta-analysis: Physical-procedural interventions used to reduce pain during intramuscular injections in adults. *J Adv Nurs* 2019;75:3346-61.
- Bilge S, Aydin A, Gun C, Aldinc H, Acar YA, Yaylaci S, et al. Comparison of the efficacy of ShotBlocker and cold spray in reducing intramuscular injection-related pain in adults. A prospective, randomized, controlled trial. *Saudi Med J* 2019;40:996-1002.
- Canbulat Şahiner N, Türkmen AS. The Effect of Distraction Cards on Reducing Pain and Anxiety During Intramuscular Injection in Children. *Worldviews Evid Based Nurs* 2019;16:230-5.
- Yilmaz G, Alemdar DK. Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear Caused by Intramuscular Injection: A Randomized Controlled Trial. *J Emerg Nurs* 2019;45:502-11.
- Birnie KA, Noel M, Chambers CT, Uman LS, Parker JA. Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database Syst Rev* 2018;10:CD005179.
- Gad RF, Dowling DA, Abusaad FE, Bassiouny MR, Abd El Aziz MA. Oral Sucrose Versus Breastfeeding in Managing Infants' Immunization-

- Related Pain: A Randomized Controlled Trial. *MCN Am J Matern Child Nurs* 2019;44:108-14.
10. Uman LS, Birnie KA, Noel M, Parker JA, Chambers CT, McGrath PJ, et al. Psychological interventions for needle-related procedural pain and distress in children and adolescents. *Cochrane Database Syst Rev* 2013;CD005179.
 11. İnal S, Canbulat N. Çocuklarda işlemsel ağrı yönetiminde dikkati başka yöne çekme yöntemlerinin kullanımı. *Journal of Current Pediatrics* 2015;13:116-21.
 12. Canbulat Sahiner N, Turkmen AS, Acikgoz A, Simsek E, Kirel B. Effectiveness of Two Different Methods for Pain Reduction During Insulin Injection in Children With Type 1 Diabetes: Buzzy and ShotBlocker. *Worldviews Evid Based Nurs* 2018;15:464-70.
 13. Sivri Bilgen B, Balcı S. The Effect on Pain of Buzzy® and ShotBlocker® during the Administration of Intramuscular Injections to Children: A Randomized Controlled Trial. *J Korean Acad Nurs* 2019;49:486-94.
 14. Mackenzie A. Guideline statements on the management of procedure-related pain in neonates, children and adolescents. *J Paediatr Child Health* 2006;42:14-5.
 15. Göl I, Altuğ Özsoy S. Evidence-based applications to reduce pain in vaccine injections. *Türkiye Klinikleri J Public Health Nurs-Special Topics* 2017;3:39-45.
 16. ENA Clinical Practice Guideline Committee; ENA Board of Directors Liaisons;; Methodologist;; Staff Liaisons;; Administrative Staff;. Clinical Practice Guideline: Needle-Related or Minor Procedural Pain in Pediatric Patients. *J Emerg Nurs* 2019;45:437.e1-437.e32.
 17. Taddio A, Appleton M, Bortolussi R, Chambers C, Dubey V, Halperin S, et al. Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline. *CMAJ* 2010;182:E843-55.
 18. Göl I, Onarıcı M. Nurses' knowledge and practices about pain and pain control in children. *Journal of Hacettepe University Faculty of Nurs*. 2015;2:20-9.
 19. Zengin M, Yayan EH. A Comparison of Two Different Tactile Stimulus Methods on Reducing Pain of Children During Intramuscular Injection: A Randomized Controlled Study. *J Emerg Nurs* 2022;48:167-80.
 20. Srouji R, Ratnapalan S, Schneeweiss S. Pain in children: assessment and nonpharmacological management. *Int J Pediatr* 2010;2010:474838.
 21. Uman LS, Chambers CT, McGrath PJ, Kisely S. A systematic review of randomized controlled trials examining psychological interventions for needle-related procedural pain and distress in children and adolescents: an abbreviated cochrane review. *J Pediatr Psychol*. 2008;33:842-54.
 22. Drago LA, Singh SB, Douglass-Bright A, Yiadom MY, Baumann BM. Efficacy of ShotBlocker in reducing pediatric pain associated with intramuscular injections. *Am J Emerg Med* 2009;27:536-43.
 23. Çelik N, Khorshid L. The Use of ShotBlocker for Reducing the Pain and Anxiety Associated With Intramuscular Injection: A Randomized, Placebo Controlled Study. *Holist Nurs Pract* 2015;29:261-71.
 24. Cobb JE, Cohen LL. A randomized controlled trial of the ShotBlocker for children's immunization distress. *Clin J Pain* 2009;25:790-6.
 25. Çağlar S, Büyükyılmaz F, Coşansu G, Çağlayan S. Effectiveness of ShotBlocker for Immunization Pain in Full-Term Neonates: A Randomized Controlled Trial. *J Perinat Neonatal Nurs* 2017;31:166-71.
 26. Yıldız, T. The effect of the local ice applications to the pain of intramuscular injection of penicillin in children. Haliç University Institute of Health Sciences, 2014. Department of Child Health and Diseases Nursing. Master Thesis. Istanbul, Türkiye.
 27. Özcan S. The effects of cold application in reduction of acute pain due to injection of vaccination in children (Doctoral dissertation). İzmir: Ege University, Institute of Health Sciences, Department of Child Health and Diseases Nursing 2016.
 28. Gürdap Z, Cengiz Z. Comparison of cold spray and shotblocker to reduce intramuscular injection pain: A randomized controlled trial. *J Clin Pharm Ther* 2022;47:1249-56.
 29. Faul F. G*power version 3.1.9.2. [homepage on the Internet]. 2014 [cited 18 December 2019]. Available from: <http://www.gpower.hhu.de/>.
 30. Hasanpour M, Tootoonchi M, Aein F, Yadegarfar G. The effects of two non-pharmacologic pain management methods for intramuscular injection pain in children. *Acute Pain*. 2006;8:7-12.
 31. Gaikwad NS, Naregal PM, Mohite VR, Karale RB. A study to assess the effectiveness of ice application on pain response prior to intravenous procedures among children at tertiary care hospital. *AJPRHC* 2017;9:167-73.
 32. Susilawati S, Soetjningsih S, Arhana BNP, Subanada IB. Effectiveness of painaway on hepatitis B intramuscular injection in term neonates: a randomized controlled trial. *Paediatr Indones* 2010;50:214-9.
 33. Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatr Nurs* 1988;14:9-17.
 34. McMurtry CM, Noel M, Chambers CT, McGrath PJ. Children's fear during procedural pain: preliminary investigation of the Children's Fear Scale. *Health Psychol* 2011;30:780-8.
 35. Savcı C, Özkan B, Açıkarsı K, Solakoğlu GA. Effectiveness of Two Different Methods on the Perceived Pain and Satisfaction During Intramuscular Antibiotic Injection: ShotBlocker and Local Vibration. *Clin Nurs Res* 2022;31:812-9.
 36. Şahan S, Yıldız A. The Effect of ShotBlocker Application on Intramuscular Injection Pain in Adults: A Meta-Analysis. *Clin Nurs Res* 2022;31:820-5.
 37. Farhadi A, Esmailzadeh M. Effect of local cold on intensity of pain due to Penicillin Benzathin intramuscular injection. *Int. J Med Med Sci* 2011;3:343-5.
 38. Guevarra MAD. Efficacy of shotblocker in reducing pain associated with intramuscular injections in pre-school children. [homepage on the Internet]. [cited 18 December 2019]. Available from: <Http://Www.Bionix.Com/Pages/Medstudy1.Html>.
 39. Aykanat Girgin B, Aktaş E, Kılınç D, Gözen D. Let's prefer the pain reducing intervention, Buzzy or ShotBlocker: A Randomized Controlled Trial. *J Dr Behcet Uz Child Hosp* 2020;10:290-8.
 40. Tugrul, E, Nese, C, Khorshid L. Effects of ShotBlocker on relief of pain due to hepatitis B vaccine injection into deltoid muscle. *International Journal of Caring Sci* 2017;10:1669-75.
 41. Sparks L. Taking the "ouch" out of injections for children. Using distraction to decrease pain. *MCN Am J Matern Child Nurs* 2001;26:72-8.