Original Article

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The Efficacy of Acupressure Therapy on Chronic Mechanic Low Back Pain

Kronik Mekanik Bel Ağrısında Akupresör Tedavisinin Etkinliği

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ABSTRACT

Objective: Chronic mechanical low back pain, defined as lasting more than 3 months, is an important health burden causing loss of function and work capacity. The aim of the study was to determine the effectiveness of acupuncture treatment in patients with chronic low back pain.

Methods: Sixty patients with chronic mechanical low back pain were randomly divided into two groups. While acupuncture was applied to the first group, the second group received transcutaneous electrical nerve stimulation (TENS) and infrared therapy. All patients in both groups were included in the exercise program containing strengthening of abdominal, low back and back muscles. The effectiveness of treatment modalities were evaluated with low back range of motion parameters, pain with back movements, milligram test, visual analogue scale values of rest and activity pain, Oswestry low back pain disability and Roland-Morris functional assessment scales and short-form 36, at baseline, at the end of treatment and at 1st month follow-up.

Results: Significant improvement was observed in favor of acupuncture treatment group not only in the early period in terms of pain with back movements and patient self-reported pain parameters but also especially at the second visit in terms of disability-functional values. Quality of life was also found to be better in acupuncture group.

Conclusion: Ten sessions of acupressure application was found to be superior to 10 sessions of TENS combined with infrared therapy. The favorable effect lasted at 1st month follow-up after the end of the treatment.

Keywords: Chronic low back pain, acupressure, pain, alternative medicine, treatment

ÖZ

Amaç: Üç aydan uzun süreli olarak tanımlanan kronik mekanik bel ağrısı, fonksiyon ve iş kapasitesi kaybına neden olan önemli bir sağlık yüküdür. Çalışmanın amacı, kronik bel ağrısı olan hastalarda akupunktur tedavisinin etkinliğini belirlemektir.

Yöntemler: Kronik mekanik bel ağrısı olan altmış hasta rastgele iki gruba ayrıldı. Birinci gruba akupunktur uygulanırken, ikinci gruba transkütanöz elektriksel sinir stimülasyonu ve infrared terapi uygulandı. Her iki gruptaki tüm hastalar karın, bel ve sırt kaslarının güçlendirilmesini içeren egzersiz programına dahil edildi. Tedavi modalitelerinin etkinliği başlangıçta, tedavi sonunda ve 1. ay takiplerinde bel hareket açıklığı parametreleri, sırt hareketleri ile ağrı, milligram testi, istirahat ve aktivite ağrısı görsel analog skala değerleri, Oswestry bel ağrısı özürlülük ve Roland-Morris fonksiyonel değerlendirme ölçekleri ve kısa-form 36 ile değerlendirildi.

Bulgular: Sırt hareketleri ile ağrı ve hastanın kendi bildirdiği ağrı parametreleri açısından sadece erken dönemde değil, özellikle ikinci vizitte özürlülük-fonksiyonel değerler açısından da akupunktur tedavi grubu lehine anlamlı iyileşme gözlendi. Yaşam kalitesi de akupunktur grubunda daha iyi bulunmuştur.

Sonuç: On seans akupresür uygulaması, kızılötesi ile kombine edilmiş 10 seans transkütanöz elektriksel sinir stimülasyonuna göre daha üstün bulunmuştur. Olumlu etki tedavi bitiminden sonraki 1 aylık takipte de devam etmiştir.

Anahtar Kelimeler: Kronik bel ağrısı, akupresör, ağrı, alternatif tıp, tedavi.

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Introduction

Low back pain is the second most frequent type of body pain after headache in developed countries (1). Ten percent of back pain becomes chronic and almost 1% of the population is handicapped due to chronic low back pain (CLBP) (2). The aims of the chronic mechanic LBP (CMLBP) treatment are to release the pain, to increase the life quality and functional capacity and to prevent disability. The conservative treatment includes rest, medical treatment, physical treatment and rehabilitation techniques such as acupuncture, manipulation and exercises (3).

Another approach of CMLBP treatment is acupressure. Acupressure is an established treatment method of traditional Chinese medicine. The principle of the acupressure treatment is to press manually on the particular acupuncture points and painful body parts. The major aim here is to stimulate these points by various maneuvers and consequently release the blockings. This cheap and trustworthy treatment method decreases the pain threshold by the mechanisms of speeding up the energy (chi) flow, increasing the temperature, speeding up the circulation, relaxing the muscles and ligaments and increasing the secretion of endorphin (4,5). In recent years, there have been optimistic randomized controlled research reports, especially coming from Far East about the effectiveness of acupressure treatment on patients with different types of CLBP (6-9). The purpose of the study is to evaluate the effectiveness of acupuncture treatment for CLBP.

Methods

Selection of the patients

Sixty-two patients aged between 20 and 60 years, who were admitted to Physical Medicine and Rehabilitation Department of Trakya University Hospital, with low back pain lasting for 3 months or longer and diagnosed as having CMLBP by clinical evaluation and lumber radiographs were accepted to this research. Patients having CLBP caused by non-mechanic etiology were excluded and only patients with local CMLBP were included in the study for randomization. Patients' age, sex, height, weight, education, job and marital status were questioned and recorded.

The exclusion criteria were being younger than 20, older than 60; having prior lumbar spine surgery; having severe spinal diseases such as infectious spondylodiscitis, spinal malignity and inflammatory sacroiliitis-spondylitis; having concomitant pathological conditions, having skin lesions, having open wounds and irregular skin sense; being treated with acupressure before and pregnancy.

The study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the Scientific Research and Ethics Committee of Trakya University (approval no: 2006/167, date: 02.11.2006). All participants gave written informed consent.

Sample Size

Patients were randomized with the n, n+1 principle and the ones with the odd numbers were taken to the first group to be treated by acupressure and the other ones with the even numbers were taken to the second group to be treated by transcutaneous electrical nerve stimulation (TENS) + infrared (IR) therapy. Patients in the first group (intervention group) were given 15 minutes of lumbar acupressure as the treatment regime, while patients in the second group (control group) were applied 20 minutes of TENS and IR heating. Additionally, patients in both groups were given exercise programs to strengthen abdominal and dorsal muscles and instructed to take preventive measures to avoid back pain. The patients were advised to take paracetamol if needed. Each patient in both groups was treated once a day, five days a week and totally 10 sessions.

The treatment regime was applied to all the patients in the first group by the same doctor and to the second group (control group) patients by the therapists. Randomization, acupressure and evaluation were performed by the same doctor.

Acupressure Treatment

Patients were asked to lie in prone position with a pillow under their stomach and relax. Lower extremity regions from feet to thigh, upper extremity regions from hand to elbow and low back region were denuded. Seventeen points were chosen in total. While choosing these points, traditional acupuncture points were considered and the ones which are valuable for the acupressure treatment on CMLBP patients were chosen. These are the chosen acupressure points:

1. Lumbar acupressure points: Bilateral BL-23 Shen shu point; on 1.5 cun (1 cun=3.3cm) lateral to the 2nd lumbar vertebra, bilateral BL-24 Qiaishu point; on 1,5 cun lateral to the 3rd lumbar vertebra, bilateral BL-25 Dachangshu point; on 1.5 cun lateral to the 4th lumbar vertebra, on the same level with upper limit of iliac crest, bilateral BL-26 Guangyuanshu point; on 1.5 cun lateral to the 5th lumbar vertebra (5).

2. Lower extremity points: BL-40 Weizhong point; in the middle of transverse line on popliteal fossa. BL-57 Chengshan point; on the middle line of the leg, at the conglutination point of gastrocnemius and calcaneus tendons. BL-60 Kunlun point; in the cavity between calcaneus tendon and external malleolus (5).

3. Upper extremity points: LI-4 Hegu point; between the 1st and 2nd metacarpal bones, in the middle. If the thumb and the forefinger are united, it is at the highest point of adductor pollicis muscle. LI-11 Quchi point; on the lateral part of the transversal cubital line while the elbow is flexed 90 degrees. PC-6 Neiguan point; 2 cun up from the wrist, between palmaris longus flexor carpi radialis tendons. Chosen acupressure points are shown in Figure 1.

Acupressure treatment was applied to the patients in the first group at these chosen points. The treatment was applied according to the principle of starting with gentle touch, getting harder and faster later and ending with soft, gentle touch (5). One session lasted 15 minutes. It was performed once a day, 5 times a week, for two weeks, makes up a total of 10 sessions.

TENS

Acupuncture-like TENS was applied to the lumbar region. (TENS device model: Med 4, serial no: 0349ND, Brazilian). TENS was applied as the patients lie prone with a pillow under their stomach. Four TENS electrodes were placed on the painful parts of the low back. TENS was applied with current passage time of 200-300 ms, the frequency of 2-4 Hz and amplitude enough to make muscle contractions noticeable with bare eyes. 20-minute sessions were applied once a day, 5 times a week, for 2 weeks, 10 times in total. The phrase of "acupuncture-like" is used for describing intense-low frequency model. Severe rhythmic muscle contractions occur without any paresthesia.

IR

IR was applied on naked skin with the dose enough to make the patient feel warm. IR was applied with a perpendicular angle to the area. It was applied once a day for 20 minutes, 10 sessions in total. IR is a superficial heater. Beam spectrum of these lamps is about 350-4000 nm. Most of the beams are around 1000 nm wavelength. These reach the superficial fascias. Heat speeds up the healing and helpful with chronic pain.

Medical Treatment

Every patient participating on the research was instructed to take 500 mg paracetamol tablets, maximum up to 1500-3000 mg when they had pain. The amount of tablets they needed was noted. The patients were asked not to have any medical treatment before the visits.

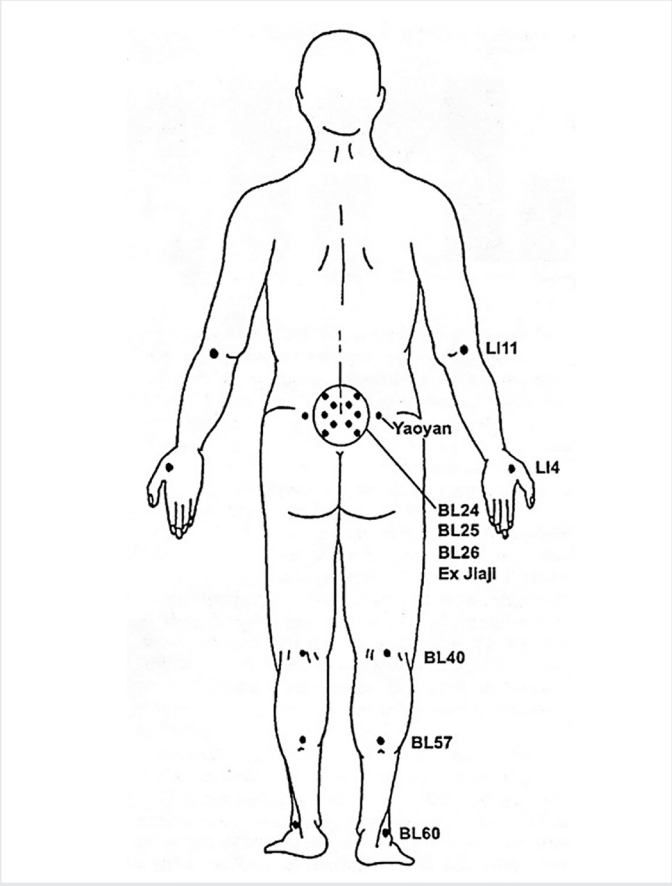

Figure 1. Acupressor points

Outcome Assessment

The clinical examination, consisting pain and function evaluation were performed at baseline before treatment; at the end of the treatment (1st control); and 30 days after the end of the treatment (2nd control).

The evaluation parameters of physical examination were: low back motion range, pain on back motions, visual analogue scale (VAS) values of pain, milligram test, nerve tension tests, and neurological examination. Severity of the pain was evaluated by VAS, functional state by Roland-Morris functional assessment forms and Oswestry low back pain disability and life quality by short-form 36 (SF-36).

Oswestry Low Back Pain Disability Score:

Patients were asked to rate 10 questions on the form from 0 to 5. The sum of the rates was multiplied by 2 and the result was used as the percent (10).

Roland-Morris Functional Assessment Scala:

Patients were asked to answer the questions beginning with "because of my low back pain" as yes/no. Every "yes" was counted 1 and every "no" was counted 0 and the sum of 24 questions was calculated. Higher score is worse for this survey (10).

Visual analog scale:

Was used to evaluate pain and SF-36 was used to evaluate quality of life at the patient's first and second visits (11).

Statistical Analysis

Statistical evaluations were made in statistical 7.1 and serial number program (AXA507C775506FAN3). The conformity of the data to the normal distribution was examined with the one-sample Kolmogorov-Smirnov test. In the comparison of the values of the treatment and control groups, the t-test was used in independent groups for normally distributed variables, and non-parametric type of the same test was used for non-normally distributed variables. Chi-square was used to investigate the intergroup differences of categorical variables. ANOVA was used for repetitive measurements to compare the measurements with normal distribution in the comparison of repetitive measurements within the groups, and Friedman's ANOVA tests were used for the measurements that did not show normal distribution. Wilcoxon test was used when significant difference was found. McNemar chi-square test was used to compare the values of categorical variables within the groups. The statistical significance limit was chosen as $p<0.05$.

Results

As two patients dropped out of the program because of incompatibility, the research was carried on 60 patients. Thirty patients were included in the first group and the other 30 in the second group. The mean ages were 53.6±10.28 and 53.5±9.29

in the first and the second groups, consecutively. There was no statistically significant difference between the age means of these two groups (p=0.979). In the first group, 17 patients out of 30 were female (56.7%) and 13 patients were male (43.3%). In the second group, 21 patients out of 30 were female (70.0 %) and 9 patients were male (30.0 %). There were no statistically significant difference between these two groups in terms of gender (p=0.284). The mean body mass index (BMI) of the first group was 27.51±39 and for the second group it was 28.78±07. There was no significant difference in terms of mean BMI between the groups (p=0.249). The average durations of the symptoms were 95.24±90.40 months in the first group and 109.50±87.89 months in the second group with no significant difference in between (p=0.538).

Comparison of the Clinical Assessment Parameters Between Two Groups at Baseline Before the Treatment

We did not observe significant difference between the two groups in terms of hand-finger ground distance values; left and right lateral flexion, right and left rotation and extension ranges which are used for measuring limits of the low back motion before the treatment (p>0.05). Milligram test positivity, VAS values of the pain while resting and moving, OLBPDF, RMFAS and life quality parameters valued by SF-36 were not found to be significantly different, either (p>0.05).

Evaluation of the Efficiency of the Treatment Within the Groups

Clinical changes among baseline and first-second controls after the treatment were compared within the groups. There were significant differences between evaluations before the treatment and first and second controls after the treatment in terms of left and right lateral flexion values for the first group (p<0.05), however there were no significant difference for the second group (p>0.05). Significant improvements in terms of hand-finger ground distance were found between baseline evaluation and first-second controls after the treatment for all groups (p<0.05) (Table 1).

There were significant differences between baseline and first control in terms of left/right rotation and extension values in the first (the acupressure treatment) group (p<0.05), however, a significant difference was observed only for extension in the second group. The change was parallel with these results for the second control.

Milligram test changed significantly in the first group beginning from baseline, in advance to the first and second control visits (p<0.05). No such change was observed in the second group (p>0.05).

Pain evaluation using VAS values while resting and moving revealed significant improvement for both groups beginning from baseline proceeding to the first and second control visits (p<0.05). Such significant longitudinal change in terms of OLBPDF and RMFAS was found out only in the first acupressure treatment group (p<0.05) (Table 2).

Life quality parameters measured by using SF-36 were analyzed and changes between baseline visit and second control visit were analyzed in both groups. In the first group significant changes were determined in terms of physical function, role limitations due to emotional problems, body pain, general mental health, role limitations due to physical problems, general perception of health, social function and state of health scores compared to last year (p<0.05); however, there was no difference in terms of energy/vitality scores between the two visits from baseline to the second visit after treatment (p>0.05) (Table 3). In the second group, significant changes were observed in role limitations due to physical problems, body pain and state of health scores compared to last year (p<0.05); however physical function, social function, general mental health, role limitations due to emotional problems, general perception of health and energy/vitality scores did not change significantly between baseline visit and the second after treatment (p>0.05) (Table 3).

There was no difference between the patients' need for paracetamol during the treatment period (the period between the beginning of the treatment and the end of the 2nd control (p>0.05).

Discussion

CMLBP lasts three months or longer, increases with physical activity and decreases with rest and consequently limits the use

Table 1. Variation of lumbar range of motion values with treatment in the first and second groups

Group 1 (n=30)	Group 1 (acupressure) Median ± SD			
Variables	**Pretreatment**	**First control**	**Second control**	**p-value**
Right lateral flexion (cm)	52.20±5.75	48.93±5.77	48.47±5.81	0.027*[ab]
Left lateral flexion (cm)	52.13±5.70	48.97±5.79	48.43±5.81	0.031*[ab]
Fingertip-to-floor test (cm)	24.80±8.02	12.10±5.07	9.53±4.73	0.000*[abc]
Group 2 (n=30)	**Group 2 (TENS + IR) Median ± SD**			
Variables	**Pretreatment**	**First control**	**Second control**	**p-value**
Right lateral flexion (cm)	52.10±5.00	50.30±5.29	49.13±9.77	0.263
Left lateral flexion (cm)	52.00±4.94	50.33±5.37	50.63±5.09	0.412
Fingertip-to-floor test (cm)	29.07±10.29	18.27±7.59	18.87±6.07	0.000*[ab]

SD: Standard deviation, TENS: Transcutaneous electrical nerve stimulation, IR: Infrared, *: p<0.05, [a]: There is a difference between pretreatment and 1st control, [b]: There is a difference between pretreatment and 2nd control, [c]: There is a difference between 1st control-2nd control

of low back or whole physical activities (12). Our purpose with this research was to compare two different treatments applied with exercises at the same time on CMLBP patients.

There are many treatment options for CMLBP, one of which is acupressure. It is a treatment method which is as old as humanity. It's known that people have been pressing and massaging the painful spots to kill the pain since the beginning of the mankind (5,13). The principle of the acupressure treatment is to press to definite acupuncture points which are on the meridians of body surface and painful parts by the hand, manually and to stimulate these points by various maneuvers. By releasing blockages, we can speed up the energy (chi) flow, increase the temperature and relax the muscles and ligaments by protecting the balance between yang and yin or by fixing it if it's imbalanced. Mechanism of the treatment is the composition of all these effects. This theory encourages the hypothesis of acupressure that the intervention may be stimulating the nerve system to block the pain impulses before they reach the brain. Another theory suggests that stimulating acupressure points increases the secretion of opioid proteins which reduces the pain, activates hypothalamus and pituitary, regulates the blood circulation, and changes the immune system and effects secretion of neurohormones. Acupressure treatment handles the whole body unlike a local treatment (4,5,14).

It has been reported systemically that acupressure is found efficient on pain and function in CLBP patients when compared with placebo and other physiotherapy approaches (15). The efficiency of the treatment especially on pain is evaluated by using VAS and the other methods. Hsieh et al. (15) formed two groups and applied acupressure to 69 patients and physiotherapy to 77 patients who were chosen randomly from 146 patients with CLBP. Both of the groups had 6 sessions during 4 weeks and each session lasted 15 minutes for the acupressure group.

Table 2. Variation of Visual analog scale values, oswestry low back pain disability questionnaire scores and Roland-Morris functional assessment scores with treatment

Group 1 (n=30)	Group 1 (acupressure) Median ± SD			
Variables	**Pretreatment**	**First control**	**Second control**	**p-value**
Pain at rest	29.50±18.11	8.00±12.14	2.00±6.10	0.000*[abc]
Pain with activity	71.93±15.46	42.00±10.30	33.67±13.77	0.000*[abc]
OLBPDQ	48.80±21.66	35.73±17.83	31.00±17.77	0.002*[ab]
RMDQ	13.33±5.44	10.93±9.70	8.03±4.90	0.017*[ab]
Group 2 (n=30)	Group 2 (TENS + IR) Median ± SD			
Variables	Pretreatment	First control	Second control	p-value
Pain at rest	29.03±17.43	18.33±18.21	20.33±17.71	0.033*[a]
Pain with activity	69.33±12.58	59.73±83.53	50.00±9.82	0.000*[abc]
OLBPDQ	49.27±18.73	42.00±20.52	46.60±18.86	0.345
RMDQ	14.90±8.66	11.60±8.83	12.60±9.72	0357

SD: Standard deviation, TENS: Transcutaneous electrical nerve stimulation, IR: Infrared, OLBPDQ: Oswestry Low Back Pain Disability Questionnaire, RMDQ: Roland-Morris Disability Questionnaire, *: p<0.05, [a]: There is a difference between pretreatment and 1st control, [b]: There is a difference between pretreatment and 2nd control, [c]: There is a difference between 1st control-2nd control

Table 3. Changes of Quality of Life (Short-Form 36) scores with treatment between pretreatment and second control in both groups

Variables	Group 1 (n=30) Acupressure Median ± SD			Group 2 (n=30) TENS + IR Median ± SD		
	Pretreatment	**Second control**	**p-value**	**Pretreatment**	**Second control**	**p-value**
Physical function	44.76±19.70	60.33±19.57	0.000*	41.57±23.33	49.16±20.60	0.138
Roles limited by physical problems	23.33±29.31	47.50±31.03	0.000*	15.83±27.45	30.83±29.86	0.006*
Pain	36.90±15.89	50.23±10.87	0.000*	30.93±16.24	42.47±20.80	0.004*
Social function	56.90±19.17	67.40±20.89	0.007*	64.93±85.99	56.43±18.75	0.321
General health	56.53±22.17	49.06±20.12	0.018*	50.53±19.32	50.53±19.32	0.773
Emotional well-being	23.53±29.67	49.67±29.99	0.000*	28.80±34.73	26.53±36.42	0.718
Vitality	67.36±21.92	55.20±24.12	0.061	48.50±21.78	50.50±19.08	0.522
Roles limited by emotional problems	37.67±19.77	45.17±21.19	0.034*	37.13±18.68	32.17±17.40	0.101
Health change	37.33±22.61	56.50±23.49	0.000*	27.50±16.54	38.33±26.04	0.021*

SD: Standard deviation, TENS: Transcutaneous electrical nerve stimulation, IR: Infrared, *: p<0.05

Routine physiotherapy (thermotherapy, infrared, electrical stimulation, pelvic manual traction and exercise) was applied to the second group. Pain scores were evaluated by short-form pain questionnaire before the treatment, right after the treatment and 6 months after the end of treatment and as a result, acupressure treatment was found more efficient.

According to the researches, acupressure treatments applied more than 4 sessions were more efficient and advised. (16) We applied a treatment program including 10 sessions, once a day, for 15 minutes to explore the probable efficiency on CMLBP. Our findings showed that there was a significant difference in favor of acupressure in both rest and movement pain in the medium term, but it showed that the relief in pain at rest was at an earlier stage. Despite of some methodological differences, another research which had parallel results with ours was performed by Yip et al. (16) in Hong Kong analyzing the efficiency of acupressure treatment on 51 patients diagnosed with CLBP. According to the results of this study, the acupressure treatment applied by using aromatic lavender essential oil as a lubricating agent was more effective than acupoint stimulation in terms of a short-term pain relief. Although massage with lavender oil causes regular motions and pain relief in patients with multiple sclerosis and although some may attribute acupressure's positive effects to the use of lavender oil, we did not use lavender oil throughout the study while having results in favor of acupressure.

There are some other researches showing that acupressure is efficient not only on pain but also on disability and functional situation. Lisa Li-Chen Hsieh et al. (17) planned a randomized controlled trial including 129 patients with CLBP to compare the efficiency of acupressure and physiotherapy. Acupressure was applied on 64 patients and physiotherapy on 65 patients. Each patient from acupressure group was treated with 6 sessions of acupressure in a month. Patients in the other group were treated with routine physiotherapy 6 times a month. The outcome parameters were VAS assessment of pain, OLBPDF and RMFAS. The evaluations at baseline before the treatment, right after the treatment and six months after the treatment revealed that acupressure was more efficient than physiotherapy. And also, the state of improvement after acupressure treatment continued six months after the research. Similarly within our research, acupressure group recovered better than TENS+IR group especially on second visits according to OLBPDF and RMFAS.

The SF-36, a reliable and valid measure of life quality, is used by many researches for the evaluation of patients with CLBP (18,19). Quality of life parameters measured with SF-36 varied significantly between baseline and second visits in both groups in our study. In the acupressure group, we had positive results in almost every sub-parameter of the quality of life, except for the energy/vitality parameter. According to this result, we can say that acupuncture treatment improves the quality of life in many ways.

Study Limitations

The limitations of this study can be listed as follows: Limited amount of patients included, short follow up period, not arranging a personal treatment program and addition of medical treatment and exercises. We could have avoided the medical treatment and exercise to eliminate the confusing effects of other treatments and get more pure results but it would be unethical if we had left the patient without these types of treatment. That's why we advised both of the groups to take paracetamol when needed. Exercise programs were instructed to each group and control group was applied IR in addition to TENS.

Acupressure treatments have to be customized because acupressure handles the whole body instead of just being a local treatment (5,14). Acupressure is stated as an effective control implement for low back pain, headache and neck pain, etc. It's quite hard to handle a randomized controlled trial, aiming to control specifically the low back pain because of the heterogeneity in practice. Our research is based on a randomized controlled trial and asserts the efficacy of acupressure on reducing the pain. At the same time, the efficiency of acupressure or any kind of manipulation treatment are related to the technique and experience of the therapist or the doctor. The applications of acupressure and physiotherapy have to be standard so that the comparison of these two treatments can be certain. It is hard to standardize acupressure as there are limited number of doctors and physicians who are able to apply acupressure. That's why acupressure is applied by only one doctor during our research to avoid the different attitudes. In addition to that, it's arguable if the pain reduces because of the treatment or the psychological interaction between doctor and the patient. The relationship between doctor and the patient may be an important factor for the interaction (5,14,15).

Conclusion

This research shows that acupressure treatment is effective on reducing pain and increasing the life quality. This improvement seems to be continuous in different visits during the short-term scenario of the study. This evidence supports acupressure to be used as a complementary treatment on CMLBP patients because it is a simple and non-invasive technique. According to the results of our research, acupressure treatment is more effective than TENS+IR treatment in CMLBP patients. Acupressure should rather be taken as a complementary technique to heal CMLBP.

Ethics

Ethics Committee Approval: The study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the Scientific Research and Ethics Committee of Trakya University (approval no: 2006/167, date: 02.11.2006).

Informed Consent: All participants gave written informed consent.

Footnotes

Authorship Contributions

Surgical and Medical Practices: M.R., Concept: M.R., M.B., N.T., K.U., Design: M.R., M.B., N.T., Data Collection or Processing: M.R., N.T., K.U., Analysis or Interpretation: M.R., M.B., N.T., G.E., E.U., Literature Search: M.R., M.B., K.U.,

E.U., Writing: M.R., M.B., N.T., G.E., E.U.

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

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