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Transcutaneous Electrical Nerve Stimulation Improves Low Back Pain during Pregnancy

E.A. Keskin[a] O. Onur[b] H.L. Keskin[c] I.I. Gumus[a] H. Kafali[a] N. Turhan[a]

Departments of [a]Obstetrics and Gynecology, [b]Physical Therapy and Rehabilitation, Fatih University, Faculty of Medicine, and [c]Department of Obstetrics and Gynecology, Atatürk Education and Research Hospital, Ankara, Turkey

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Key Words
Low back pain, pregnancy · Transcutaneous electrical nerve stimulation · Exercise · Acetaminophen

Abstract
Background: To compare the efficiency of transcutaneous electrical nerve stimulation (TENS) with those of exercise and acetaminophen for the treatment of pregnancy-related low back pain (LBP) during the third trimester of pregnancy. ***Methods:*** This prospective study included 79 subjects (≥32 gestational weeks) with visual analog scale (VAS) pain scores ≥5. Participants were divided randomly into a control group (n = 21) and three treatment groups [exercise (n = 19); acetaminophen (n = 19); TENS (n = 20)]. The VAS and the Roland-Morris disability questionnaire (RMDQ) were completed before and 3 weeks after treatment to assess the impact of pain on daily activities. ***Results:*** During the study period, pain intensity increased in 57% of participants in the control group, whereas pain decreased in 95% of participants in the exercise group and in all participants in the acetaminophen and TENS groups. Post-treatment VAS and RMDQ values were significantly lower in the treatment groups ($p < 0.001$). VAS and RMDQ scores indicated a significantly greater degree of pain relief in the TENS group than in the exercise and acetaminophen groups ($p < 0.001$). No adverse effect of TENS application on pregnant women was observed during the study. ***Conclusion:*** TENS is an effective and safe treatment modality for LBP during pregnancy. TENS improved LBP more effectively than did exercise and acetaminophen.

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Introduction

Low back pain (LBP) is a common problem for all women, but an increased incidence is associated with pregnancy [1].

The prevalence of back pain in pregnancy is reported to be approximately 50% and increases as pregnancy advances up to 75%, especially in the last trimester [2–5]. The back pain is serious in 25% of pregnant women, and disabling in a further 8% [4, 6]. In a study, 61.8% of women who suffered from LBP during pregnancy claimed the pain was at least moderately severe; 9% claimed they were completely disabled by the pain [7]. This form of pain can result in serious morbidity, reducing the health-related quality of life.

In one third of pregnant women, back pain is a severe problem compromising normal everyday life [3, 4]. The

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Dr. H. Levent Keskin
Birlik Mah. 450. Cad. 499. sok. 3/ 5 Cankaya
TR–06610 Ankara (Turkey)
Tel. +90 505 357 43 59
E-Mail hlkeskin@yahoo.com

majority of pregnant women with LBP have sleep disturbances (58%) secondary to the pain. Over half (57%) of women with LBP complained that LBP impaired their daily activities and prevented them from performing tasks that caused them the greatest difficulties such as climbing stairs (47%), running (40%), heavy work (28%), and participating in exercise (30%). 10% of all pregnant women with LBP were forced to take time off from work because of LBP symptoms [4].

The etiology of pregnancy-related LBP remains unclear, but it is believed to arise from hormonal, mechanical, and/or circulation causes [1]. These factors may include ligamentous laxity (loosening of the pelvic ligaments) caused by relaxin, a polypeptide hormone produced by the corpus luteum, fluid retention within the connective tissue or sacroiliac dysfunction. Pregnant women may adopt postural changes to balance the anterior weight shift, leading to increased lumbar lordosis (an increase in the natural inward curvature of the lower spine) and further increasing stress on the lower back. Bone mass density changes have an etiological role in back pain during pregnancy, and the pain symptoms are associated with a greater fall in BMD at the os calcis [1, 5, 8, 9].

Prevention and treatment of this condition are fundamental for the women and for the society to improve quality of life, reduce public health costs, and increase productivity [3, 10].

Although conservative management of LBP is preferred during pregnancy for obvious reasons, available treatments usually have a low success rate and consist mainly of lifestyle adjustments and bed rest [1]. Various pharmacological and nonpharmacological treatment, including transcutaneous electrical nerve stimulation (TENS), or alternative therapy options are available to relieve back pain during pregnancy [1, 8, 11–14].

Electrical stimulation, including TENS, controls pain noninvasively and nonpharmacologically, and has a wide range of clinical applications. The TENS unit emits low-voltage electrical impulses that vary in frequency and intensity. These electrical pulses are thought to stimulate nerve pathways in the spinal cord, thereby blocking the transmission of pain. Although the precise mechanism of this treatment is not well understood, several theories have been proposed to explain its analgesic effect. First is the 'gate control theory' of pain [15]. After the description of 'gate control theory' of pain in 1965 by Melzac and Wall, TENS became the most common and important form of electroanalgesia. According to this theory, the transmission of pain is inhibited by the stimulation of large, afferent nerve fibers which carry impulses towards the central nervous system. When afferent nerves are stimulated, the pathway for other painful stimuli is closed by the operation of a 'gate' in the spinal cord that controls transmissions to the brain. The mechanism of action of TENS is based on the fact that a noxious stimulation can inhibit pain produced by another noxious stimulation. When applied to the lower back, the TENS unit emits electrical impulses which excite afferent nerves, and thus inhibits the transmission of painful stimuli arising from the region [16].

Second, it is suggested that painful stimuli result in chemical changes in the brain and cerebrospinal fluid which mediate the experience of pain. TENS is thought to complement this chemical process [17, 18]. More recent theories suggest that the varied factors influencing the experience of pain are likely to be interactive [19, 20].

Proposed indications of TENS are numerous. Primarily, TENS is used for the relief of pain for all types of musculoskeletal pain including LBP of any etiology. TENS has been increasingly and safely used especially for pain relief during labor and delivery [20–25].

This prospective study explored the use of TENS as an alternative treatment option for LBP during the third trimester of pregnancy. We compared the efficiency of this treatment method with those of exercise and acetaminophen.

Materials and Methods

This prospective, randomized study was conducted from August 2008 through February 2011 among women with uncomplicated pregnancies (≥32 gestational weeks) who presented at the Antenatal Care Unit of the Department of Obstetrics and Gynecology, Medicine of Faculty, Fatih University for routine antenatal care. Study participants had reported LBP during routine antenatal care or had been referred from another center due to this complaint. This study was approved by the Local Ethics Committee of the University, and all participating women provided informed consent before being enrolled in the study.

No participant had a history of LBP or lumbar pathology before pregnancy. Participants with a history of diseases related to bony structures or lumbar intervertebral discs and those with pain caused by nonmusculoskeletal factors (e.g. urinary tract infection, obstetric complication) were excluded from the study.

Baseline visual analog scale (VAS) evaluations were performed to assess the severity of pain on an intermittent scale from 0 ('no pain') to 10 ('worst pain imaginable'). Participants with VAS scores ≥5 underwent consultation in the Physical Therapy Clinic. All participants completed the 24-item Roland-Morris Disability Questionnaires (RMDQ) before treatment to assess the impact of LBP on daily activities [26]. The minimum score was 0, and the maximum score was 24.

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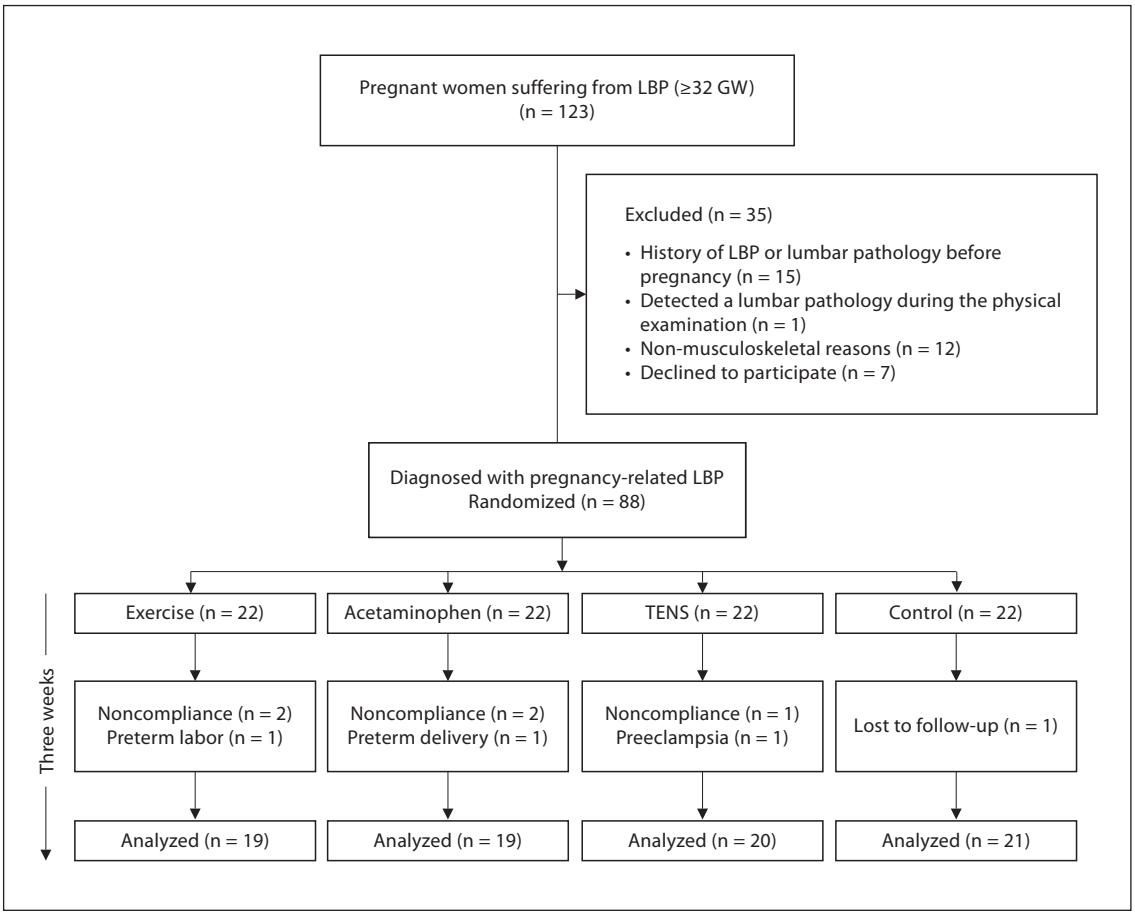

Fig. 1. Flow chart of the study. GW = Gestational weeks.

Physical examinations were performed by an experienced physical medicine and rehabilitation specialist. The clinical examination methods described by Albert et al. [27] were used to discriminate pregnancy-related low back and pelvic joint pain from other painful conditions. The pelvic region was evaluated by two main groups of tests, topographic/palpation tests to observe anomalies in pelvic alignment and pain provocation tests. Range of motion in the lumbar vertebrae was measured, and pain in this region was assessed verbally. Detailed neurological examinations of the lower extremities were performed to exclude patients with lumbar nerve irritation. Differential diagnosis was completed without the use of imaging techniques.

A total of 88 pregnant women with no pathology except for joint mobility were diagnosed with pregnancy-related LBP and agreed to participate in this study. Following informed consent, each patient was randomized to one of four groups (control, exercise, acetaminophen, TENS; n = 22 each) by drawing sealed, opaque envelopes, prepared by one author (H.L.K.), containing group names, from a box. The envelopes were opened by another author (E.A.K.), who was blind to the contents of the envelopes, on inclusion to the treatment.

The pregnant women in the exercise group were given a home exercise program by a physical therapist as the treatment modality. This program consisted of pelvic tilt exercises, stretching for the lower extremity muscles, posture exercises, and mild isometric abdominal contractions. Patients were instructed to repeat each exercise 10 times per session, and to complete the program twice daily for 3 weeks.

Patients in the acetaminophen group were prescribed one 500-mg paracetamol tablet twice daily for 3 weeks.

TENS was administered to patients in the third treatment group using a dual-channel portable TENS unit (Intelect TENS; Chattanooga Medical Supply Inc., Taiwan). Four 5 cm^2 surface electrodes were placed on the painful lumbar region of each patient. Our protocol used continuous waves of stimulation at a frequency of 120 Hz and duration of 100 μs. The intensity was adjusted to produce a tingling sensation approximately 2–3 times above the sensory threshold. Patients received a total of six TENS therapy sessions (twice weekly) during 3 weeks. After 3 weeks, the data of 79 participants (exercise: n = 19; acetaminophen: n = 19; TENS: n = 20; control: n = 21) who completed the study were analyzed. Nine cases were excluded from analysis for various reasons. Five patients

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Table 1. Descriptive statistics in each group

	Control (n = 21)	Exercise (n = 19)	Acetaminophen (n = 19)	TENS (n = 20)	p
Age, years[a]	29.2 ± 4.0	30.7 ± 4.3	29.7 ± 4.2	29.1 ± 5.0	0.626
Gravida[b]	2 (1)	1 (2)	1 (1)	1 (1)	0.768
Parity[b]	1 (1)	0 (2)	0 (1)	0 (1)	0.771
GW at initiation of treatment[b]	32.0 (1.0)	32.0 (1.0)	32.0 (1.0)	32.0 (1.0)	0.938
Weight gain, kg[b]	14 (5)	11 (3)	12 (4)	12 (4)	0.069
GW at delivery[b]	38.7 (1.4)	38.7 (1.4)	38.3 (2.9)	39.1 (1.9)	0.859
Birthweight, g[a]	3,455 ± 391	3,253 ± 303	3,244 ± 313	3,262 ± 320	0.141
Mode of delivery					0.936
Vaginal	12	10	9	11	
Cesarean	9	9	10	9	

GW = Gestational weeks.
[a] Mean ± SD.
[b] Median (interquartile range).

with study periods shorter than 3 weeks were excluded. One of them has left the TENS method because of discomfort sense. In the acetaminophen group, one of the women stopped taking the tablets because of anxiety that it does damage to the fetus, and another woman because of gastric intolerance. In the exercise group, two women quit the exercises because of laziness. The compliance rate for all treatment methods was over 90% (fig. 1).

Age of the subjects, number of gravidity and parity, gestational week at the beginning of treatments and at delivery, weight gained during pregnancy, mode of delivery and birthweight were compared between groups. The severity of pain and disability were reassessed by the participants after 3 weeks of treatment using the VAS and RMDQ instruments. Differences between pre- and post-treatment VAS and RMDQ scores were compared within and among groups.

Statistical Analyses

Before the study was carried out, a minimal number of 16 patients per group was determined to conform to the following statistical requirements: type 1 error (α) = 0.05, type 2 error (β) = 0.10, power = 90%, and effect size (f) = 25% difference in within- and between-group proportions of patients with decreasing pain intensity during the study period. G*Power v3.0.10 software (University of Kiel, Germany) was used for sample size calculation. Because we expected problems associated with patient compliance and pregnancy complications during the 3-week follow-up period, we included 22 patients in each group to allow for a 25% exclusion rate.

The normal distribution of variables was evaluated using the Shapiro-Wilk test. No variables except age and birthweight were distributed normally ($p \leq 0.05$). Descriptive values of the variables distributed normally were indicated as mean ± SD, and values of the variables that did not distribute normally as median (interquartile range – IQR). Because the VAS and RMDQ scores were not distributed normally, nonparametric tests were used for comparisons. The Kruskal-Wallis test was used to compare independent sample values between groups. For multiple comparisons among groups, the Mann-Whitney test was used with post-hoc corrections. The Wilcoxon test was used to compare related values within groups. Results are reported as median (IQR) values.

The SPSS statistical software package (v11.5; SPSS, Inc., Chicago, Ill., USA) was used to perform statistical analyses. Statistical significance was set at $p \leq 0.05$. For post-hoc comparisons using the Mann-Whitney test, p values were calculated as p/number of compared groups.

Results

The mean age of the total sample was 29.7 ± 4.4 years, the median gestational week at the time of treatment onset was 32.0 (1.0) weeks, and the median weight gain from the time of pregnancy until enrollment in the study was 12.0 (4.0) kg. The mean gestational week at delivery was 38.9 (1.6) weeks, and the mean birthweight was 3,307 ± 341 g. The vaginal delivery rate was 53.2% (n = 42/79). Age, gestational week at initiation of treatment, gravidity, parity, weight gain (kg), gestational week at delivery, mode of delivery and birthweight were similar among groups ($p > 0.05$; table 1). The rate of primigravida participants (54.4%; n = 43) was similar among groups (p = 0.667). No adverse effect of TENS application on pregnant women was observed during the study.

Median pre-treatment VAS scores differed significantly among groups (p = 0.004; Kruskal-Wallis test). These scores were significantly higher in the TENS group than in the control (p = 0.002; post-hoc Mann-Whitney

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Table 2. Comparison of pre- and post-treatment VAS and RMDQ scores within and between groups

	Control (n = 21)	Exercise (n = 19)	Acetaminophen (n = 19)	TENS (n = 20)	p (χ^2)[a]
VAS score					
Before treatment	6 (1)	7 (1)	6 (1)	7 (1)	0.004 (13.099)
After treatment	7 (1)	6 (1)	5 (2)	4 (1)	
Difference	1 (1)	–1 (1)	–1 (1)	–4 (1)	<0.001 (66.162)
p (Z)[b]	0.003 (2.952)	<0.001 (3.804)	<0.001 (3.946)	<0.001 (4.005)	
RMDQ score					
Before treatment	14 (1)	15 (4)	14 (3)	15 (5)	0.051 (7.749)
After treatment	15 (3)	13 (3)	12 (3)	7 (2)	
Difference	1 (2)	–2 (3)	–3 (2)	–8.5 (5)	<0.001 (60.544)
p (Z)[b]	0.002 (3.031)	<0.001 (3.641)	<0.001 (3.847)	<0.001 (3.928)	

[a] Kruskal-Wallis test.
[b] Wilcoxon test.

test) and acetaminophen (p = 0.009) groups, but did not differ significantly among the other groups (p > 0.0125; table 2).

Median pre-treatment RMDQ values were similar in all groups (p = 0.051; Kruskal-Wallis test; table 2).

Comparison of Pre- and Post-Treatment VAS and RMDQ Scores within Groups

At the end of the study period, pain intensity had increased in 57% and was unchanged in 38% of participants in the control group, whereas it decreased in 95% of patients in the exercise group and in all patients in the acetaminophen and TENS groups (fig. 2).

Post-treatment VAS and RMDQ scores were significantly higher than pre-treatment scores in the control group [VAS = 7 (1) vs. 6 (1), p = 0.003; RMDQ = 15 (3) vs. 14 (1), p = 0.002; Wilcoxon test]. However, the treatment groups (exercise, acetaminophen and TENS) showed significant improvement in both scores after treatment. Post-treatment VAS and RMDQ scores were significantly lower than pre-treatment scores in all treatment groups (p < 0.001; table 2, fig. 3 and 4).

Comparison of the Differences in Pre- and Post-Treatment VAS and RMDQ Scores among Groups

Differences in pre- and post-treatment scores among groups indicated the pain relief achieved by the treatment methods. The differences in pre- and post-treatment VAS and RMDQ scores were significant among the three treatment groups (VAS; p < 0.001; RMDQ, p < 0.001; Kruskal-Wallis test). This difference was caused by markedly higher scores in the TENS group than in the other two treatment groups (p < 0.001 for both comparisons; post-hoc Mann-Whitney test). However, the differences in scores between the exercise and acetaminophen groups were not significant (VAS, p = 0.694; RMDQ, p = 0.506; table 2).

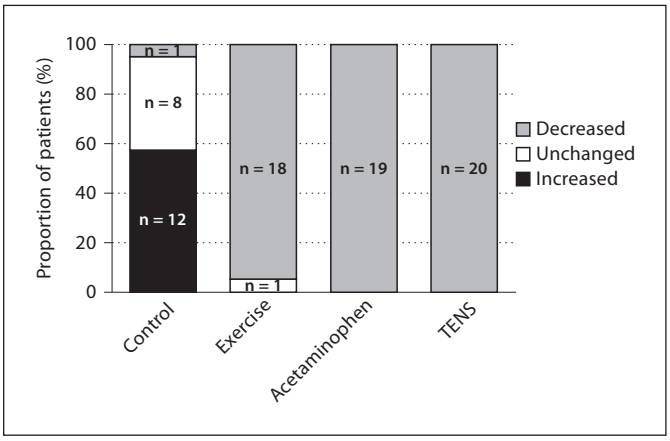

Fig. 2. Change in pain intensity over time in control and treatment groups during the study period.

Discussion

The reported prevalence of pregnancy-related LBP has varied among studies. This difference depends on the type of study conducted, the diagnostic criteria used, and the precision of methods used to characterize the pain.

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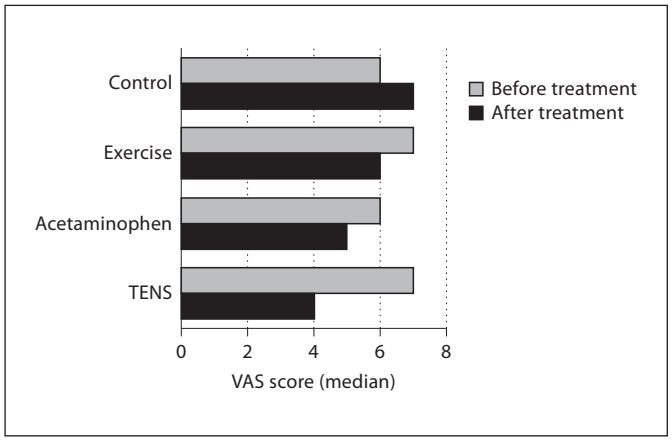

Fig. 3. Median pre- and post-treatment VAS scores (0–10) for pain intensity in control and treatment groups.

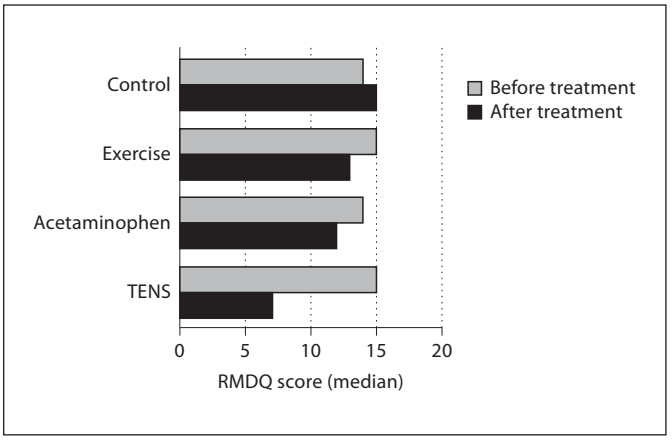

Fig. 4. Median pre- and post-treatment RMDQ scores (0–24) for disability in daily activities in control and treatment groups.

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Some researchers have distinguished pelvic pain from back pain in pregnancy [8, 28]. Diagnosis of LBP in pregnancy is usually based on symptoms, because few diagnostic tests are available that do not risk harming the fetus. The evaluation of this condition is difficult because the pain is subjective and usually results from a combination of problems [1].

The present study used the tests described by Albert et al. [27] to distinguish back pain from pelvic pain and other causative syndromes. Physical examinations were performed to distinguish posterior pelvic pain from lumbar pain. The posterior pelvic pain provocation test (administered while the patient stood on one leg) and the Patrick's Fabere test were used to elicit pelvic pain. Both tests manipulated the patients' legs to put pressure on the pelvic joints. Palpation of soft tissue in the sacroiliac, pubic symphysis, and gluteal regions distinguished pelvic pain from tenderness in the back above the waist. Studies have demonstrated the effectiveness of both methods in diagnosing posterior pelvic pain, although pain provocation tests are considered to be more reliable than topography/palpation tests [27].

A thorough assessment of pain is paramount in selecting the most appropriate tools to manage existing pain and prevent it from worsening. Accurate and recorded assessment of pain is important to monitor the outcomes of any suggested intervention and to assess change over time. The VAS is an effective method for understanding the objective value and subjective meaning of pain. For this reason, we choose this method to evaluate pain intensity in our study.

Most women consider back pain and discomfort to be a normal part of pregnancy and do not seek treatment from a health-care professional. Only 32% of women with symptoms of LBP reported these symptoms to their prenatal care providers [4]. Women who rate their pain higher on a VAS are more likely to see a physician. Of the women who see a physician, 70% are treated, and the majority of treated women have reported that they received more than one type of treatment [29]. However, Wang et al. have reported that 75% of prenatal providers did not recommend any treatment to manage symptoms. Most of the suggestions given by the 25% of prenatal care providers who made management recommendations were stretching/exercise (10.4%), frequent rest (9.8%) and combinations of other therapies from various complementary and allopathic treatments [4].

Data on the effectiveness of acetaminophen and TENS are limited, although numerous studies have examined alternative methods, such as exercise programs and acupuncture, for the treatment of pregnancy-related LBP [13, 20].

Pregnancy-specific exercise programs and physiotherapy added to usual prenatal care appear to reduce back or pelvic pain. Pregnant women participating in a strengthening exercise program reported that the intensity of their back pain decreased significantly. Pelvic tilts, knee pulls, straight-leg raises, curling up, lateral straight-leg raises, and Kegel exercises have been shown to be most effective [30]. Good posture is also mandatory for pregnancy-related pain relief. Exercise, particularly pelvic tilts during the second half of pregnancy, decreases pain

dramatically [30]. Suputtitada et al. [31] found that women who participated in an exercise program that included seated pelvic tilts reported better pain relief (measured using VAS) after 8 weeks of exercise.

In a study comparing pregnant women enrolled in an exercise program with those who were not, a decrease in postural changes and pain severity has been demonstrated in the exercise group [32]. The program used in these studies was designed to address core strength, flexibility, and muscular endurance, particularly abdominal strength. In our study, the women in the exercise group performed pelvic tilt and posture exercises, stretching of the muscles of the lower extremities, and mild isometric abdominal contractions for 3 weeks. Significant relief of LBP after these exercise therapies was reported.

Our second treatment modality used acetaminophen. This treatment is an acceptable over-the-counter medication to relieve pain during pregnancy, whereas aspirin and ibuprofen are not [1]. Acetaminophen can be used for relief of all back pain, regardless of pregnancy [13]. With a regime of 500 mg twice daily, we found a significant decrease in VAS and RMDQ scores at the end of treatment.

Our third treatment modality used TENS. This treatment has been used to relieve both acute and chronic pain in a variety of settings and for a range of conditions, including dysmenorrheal, labor pain, and back pain in pregnancy [13, 20]. We found that TENS application reduced LBP during the third trimester of pregnancy more effectively than did exercise and acetaminophen.

No adverse effects of TENS application have been reported in mothers or newborns [20, 21]. TENS performed to the back has been compared with control groups and various modalities during labor pain, and there was no significant difference between TENS and other groups in the number of women undergoing cesarean section or assisted vaginal delivery [22, 23, 25]. Chao et al. [24] have reported that, while TENS used during labor pain did not increase the cesarean rate, it tended to significantly increase assisted delivery (RR: 4.50).

No significant differences were found in fetal heart rate tracings and neonatal outcomes (fetal distress, Apgar scores and cord blood pH) between the TENS group and other groups who used different forms of pain management during labor [21, 23, 24].

Kvorning et al. [13] have used TENS in a small group (6 patients) in late pregnancy to relieve LBP, and they did not report any adverse effect of TENS on pregnant women and pregnancy prognosis in those patients. In our study, no adverse effect of TENS on pregnant women or pregnancy outcomes was detected. The mode of delivery was not different from the other treatment or control groups.

In conclusion, LBP is a common problem during pregnancy. Established treatments may be inadequate in relieving the symptoms. Therefore, better treatments are needed. Although any of the treatments tested in this study can relieve LBP in pregnancy, we prefer TENS administration as the most effective, easy-to-apply and safe treatment modality for this disorder. Although this study was conducted after calculating the minimum sample size statistically, the number of the cases can be seen as few. For this reason, before the results of our study could be generalized, further studies with more samples, perhaps only comparing TENS with control, are required to prove the efficiency of TENS in the relief of back pain during pregnancy.

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