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Original Article

Effects of physical therapy agents on pain, disability, quality of life, and lumbar paravertebral muscle stiffness via elastography in patients with chronic low back pain

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ABSTRACT

Objectives: This study aims to evaluate early effects of combined hot pack (HP) and transcutaneous electrical nerve stimulation (TENS) treatment and therapeutic ultrasound (US) on pain, quality of life, disability, and the multifidus muscle stiffness.

Patients and methods: Between December 2016 and March 2017, a total of 69 patients (36 females, 33 males; mean age 48.9±10.9; range, 27 to 73 years) were included in this randomized-controlled study. The patients were divided into three groups as HT + TENS (Group H+T, n=23), HP + TENS + US (Group H+T+U, n=23), and controls (control group, n=23). All patients filled out the Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), and Short Form-36 (SF-36) questionnaire at baseline and at the end of treatment. The left multifidus muscle strain ratio at fourth lumbar spinal level was obtained from the upper, middle, and lower parts of the muscle along the longitudinal axis on the first and last days of treatment.

Results: There was a significant improvement in the NRS, ODI, and SF-36 physical function, physical role function, pain, and general health perceptions in the H+T and H+T+U groups, compared to the control group ($p<0.05$). However, there was no significant difference between the H+T and H+T+U groups. The H+T+U group showed an improvement in the SF-36 social role function and emotional role function. There was no significant difference in the multifidus muscle strain ratios among the groups.

Conclusion: Our study results suggest that H+T treatment has a beneficial effect on pain, disability, and certain subscales of the quality of life. However, US seems not to have an additional benefit.

Keywords: Chronic low back pain, elastography, multifidus, physical therapy, ultrasound.

Superficial heat therapy, electrical current, and therapeutic ultrasound (US) are widely used for the treatment of chronic low back pain, although the benefits of all these treatment modalities still remain controversial.[1,2] Both superficial heat and deep heating agents increase the collagen extensibility owing to their thermal effects.[1,3] Increased skeletal muscle temperature has been reported to decrease gamma efferents and type II muscle spindle afferents, while increasing the Golgi tendon organ type 1b afferent fiber firing rates and decreasing the skeletal muscle tone.[4,5] Ultrasound has been also shown to enhance flexibility and reduce stiffness of connective tissue as well as muscle spasms.[2,6] Conventional transcutaneous electrical nerve stimulation (TENS) is used to attenuate pain perception via subsequent interruption of pain transmission at the dorsal horn via the gate control mechanism.[7]

Sonoelastography is a newly introduced US technique which evaluates the mechanical properties of tissues and is a quantitative method for measuring the muscle stiffness.[8,9] Although it was first developed in the 1990s, it has been increasingly used for muscle imaging in recent years.[10] This technique is based on the principle that stiff tissues exhibit a lower strain than soft tissues.[8,11] In strain elastography, which

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is a type of sonoelastographic method, mechanical stress is manually applied by compressing the skin with a transducer.[12] Tissue stiffness can be measured semi-quantitatively using strain elastography by calculating the strain ratio (SR), which is an index of the relative elasticity between an objective region of interest (ROI) and a reference ROI.[9]

Previous studies have demonstrated increased stiffness of the paravertebral muscle fibers in chronic low back pain.[13,14] It has been also reported that the multifidus muscle is stiffer in patients with chronic low back pain than in asymptomatic patients with reference to elastographic measurements.[15] However, to the best of our knowledge, there is no study investigating the effects of superficial heat and therapeutic US on stiffness of the paravertebral multifidus muscles, as assessed by elastography.

In the present study, we aimed to evaluate early results of combined superficial heat therapy, TENS, and the additional effect of therapeutic US to this combination on pain, disability, quality of life, and multifidus muscle stiffness in patients with chronic lower back pain.

PATIENTS AND METHODS

Patient selection and enrollment

This randomized-controlled trial (RCT) included a total of 75 patients with chronic low back pain admitted to the outpatient clinic of the Physical Medicine and Rehabilitation Department of Gaziosmanpasa Education and Research Hospital between December 2016 and March 2017. Six patients were excluded from the study, as they did not meet inclusion criteria or were not willing to participate in the study. Finally, 69 patients (36 females, 33 males; mean age 48.9±10.9; range, 27 to 73 years) were included. A written informed consent was obtained from each patient. The study protocol was approved by the Gaziosmanpaşa Taksim Training and Research Hospital Clinical Investigations Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

All patients were classified according to their gender and were further divided into three groups as HT + TENS (Group H+T, n=23), HP + TENS + US (Group H+T+U, n=23), and controls receiving no treatment (control group, n=23) using the allocation of an equal number of patients to each group at a ratio of 1:1:1 by an electrotherapist. After allocation of the groups, the electrotherapist performed treatments. Both the physiatrist delivering the questionnaires and the radiologist measuring SR were blind to the study groups and treatments. The effect size was calculated based on the preliminary analysis results. Minimum 23 patients were needed for an effect size of 0.39 for the Oswestry Disability Index (ODI), 80% power, and 5% type 1 error.

The treatment groups were comprised of patients with non-specific chronic lower back pain lasting more than three months. The control group consisted of those with chronic lower back pain having no specific sign, compared to the other two groups. *Inclusion criteria for all groups were as follows: (i)* age ≥18 years; *(ii)* ability to provide an informed consent; and *(iii)* having low back pain for more than three months. *Exclusion criteria for all groups were as follows: (i)* the use of any physical therapy agent for low back pain over the last year; *(ii)* a history of trauma, fracture, operation, or presence of scar tissue at the lumbar region; *(iii)* presence of a disease which may affect stiffness of the muscle tissue such as collagen tissue diseases, hemiplegia, multiple sclerosis, or myopathies; *(iv)* any degree of myotomal weakness of the lower extremities which may affect the paravertebral muscles by innervation of the same muscle root; *(v)* malignancy, pregnancy, or severe hypertension; *(vi)* presence of a systemic disorder (i.e., liver or kidney insufficiency or endocrinopathies); *(vii)* previous or existing sacroiliitis; and *(viii)* diseases which may affect lumbar mobility and pain at baseline, such as leg length discrepancy, hip replacement, or scoliosis.

Physical therapy and outcome evaluation

All patients were prescribed paracetamol 500 mg three times a day during the study period, and they were advised not to exercise until the end of the treatment to prevent increases in the muscle stiffness, consistent with the literature showing alterations in the elastographic muscle stiffness of relevant muscles with exercise.[16-18] The patients in the control group did not undergo any therapy for three weeks. The patients in the second group were treated with HP for 20 min along with conventional TENS at 100 Hz (Chattanooga Intelect Advanced Monochromatic Combo, Chattanooga Medical Supply Inc., TN, USA) for 30 min in the lumbar region daily, five days a week for 15 sessions in total. The patients in the third group received US therapy in a circular motion at the paravertebral muscles of the lumbar region for 10 min (5 min at the left side and 5 min at the right side) at 1 MHz, 2 watt/cm^2 (Chattanooga Intelect

Advanced Monochromatic Combo, Chattanooga Medical Supply Inc., TN, USA), in addition to HP and TENS daily, five days a week for 15 sessions in total. All patients were asked to fill out the Numeric Rating Scale (NRS) for movement, rest, and night, ODI,[19] and Short Form-36 (SF-36) v.2.0 questionnaire[20] at baseline and at the end of treatment.

Elastographic evaluation

The SR was measured by an experienced radiologist using an US machine (Aplio 500, Toshiba Medical Systems Corp., Tochigi, Japan) on the first and last days of the study. The patients were asked to lie prone on a couch, and a small pillow was placed below the abdomen to optimally position and minimize movements of the lumbar spine. The tip of the spinous process of the L4 vertebra was located by palpation, confirmed with a longitudinal scan, and cross-sectional images of the multifidus muscles on the left side of the L4 vertebra were acquired (Figure 1). The echogenic tip of the spinous process in the middle and vertebral lamina of the L4 vertebra at the anterior margin of the multifidus muscle served as a consistent landmark for locating multifidus muscle. After locating the multifidus muscle, the probe was longitudinally turned onto it, and the strain of the left multifidus muscle from the upper, middle, and lower parts of the fourth lumbar spinal level was considered objective ROI, and the strain of the subcutaneous fat tissue at the same level was considered reference ROI (Figures 2a-c). Three SRs were acquired at these levels and the mean value was calculated. The SR was calculated as the reference ROI strain divided by the multifidus muscle ROI strain. Therefore, a higher SR indicated a stiffer muscle.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive statistics were expressed as mean ± standard deviation for variables with normal distribution; mean ± standard deviation, median, minimum-maximum, IQR for non-normal distributed variables; and frequency and percentage (n, %) for categorical variables. Distribution of variables was analyzed using the Kolmogorov-Smirnov test.

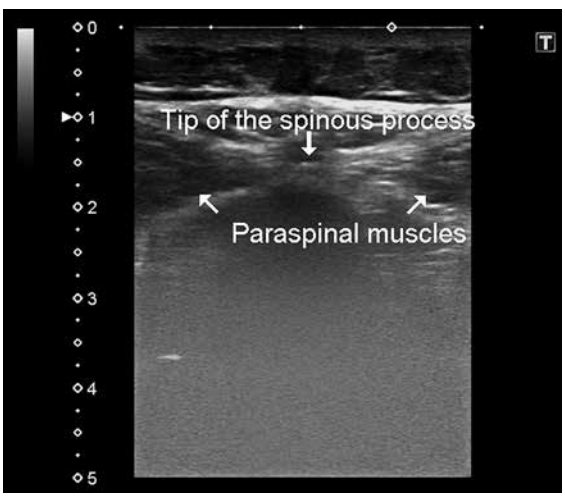

Figure 1. A transverse scan of the fourth lumbar vertebra showing the tip of the spinal process and adjacent paravertebral muscles.

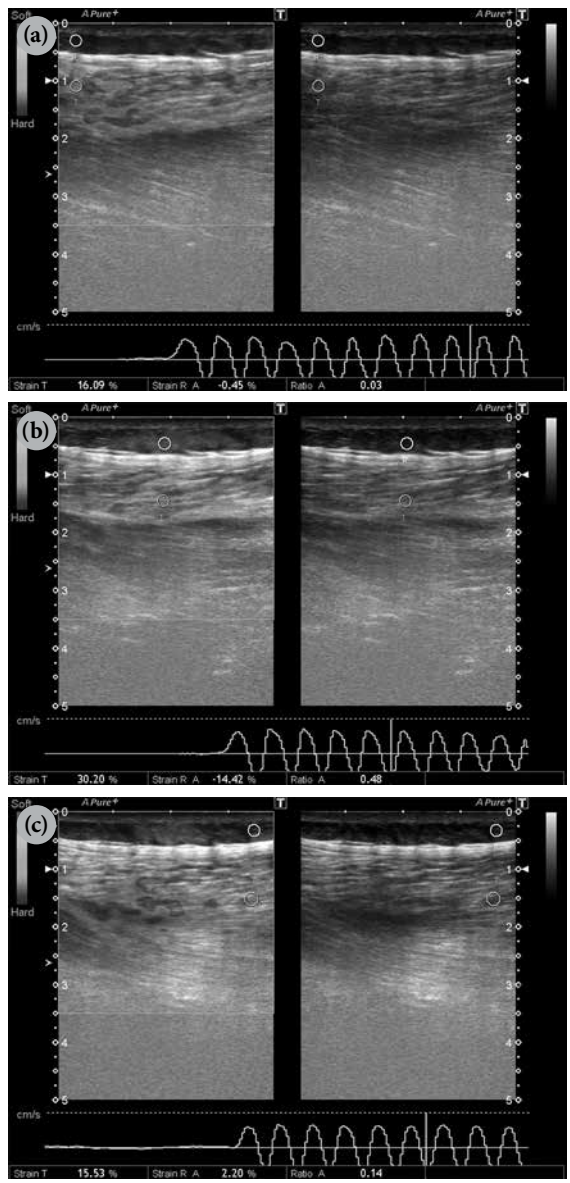

Figure 2. Elastogram of the multifidus muscle. Strain ratio from the **(a)** upper, **(b)** middle, and **(c)** lower part of the muscles acquired using a longitudinal scan.

Table 1. Demographic characteristics of study population

	Control group				H+T group				H+T+U group				
	n	%	Mean±SD	Median	n	%	Mean±SD	Median	n	%	Mean±SD	Median	*p*
Age (year)			46.3±10.7	45.0			51.7±10.7	52.0			48.6±11.0	47.0	0.249*
Gender													1.000†
Female	12	52			12	52			12	52			
Male	11	48			11	48			11	48			
Height (m)			1.7±0.1	1.7			1.6±0.1	1.6			1.6±0.1	1.6	0.314*
Weight (kg)			73.7±15.3	72.0			77.0±14.1	80.0			76.5±12.6	78.0	0.698*
BMI (kg/m^2)			26.3±3.9	26.3			29.2±5.3	29.4			28.3±4.1	29.1	0.090*
Martial status													0.853†
Single	2	9			2	9			3	13			
Married	21	91			21	91			20	87			
Educational status													0.070†
Elementary school	10	43			14	61			17	74			
Secondary school	10	43			0	0			2	9			
High school	4	17			7	30			3	13			
University	3	13			2	9			1	4			
Occupational status													0.124†
Office	10	43			2	9			7	30			
Ambulatory	5	22			7	30			6	26			
Not working	8	35			14	61			10	43			
Pain duration (months)			71.0±98.2	24.0			79.6±75.5	48.0			49.3±70.5	12.0	0.144‡

H+T: Hot pack and TENS treatment; H+T+U: Hot pack, TENS and therapeutic ultrasound treatment; SD: Standard deviation; BMI: Body Mass Index; * ANOVA; † Chi-square test; ‡ Kruskal-Wallis test.

Table 2. Numeric Rating Scale, Oswestry Disability Index, and strain ratios before and after treatment among study groups

	Control group				H+T group				H+T+U group				
	Mean±SD	Median	Min-Max	IQR	Mean±SD	Median	Min-Max	IQR	Mean±SD	Median	Min-Max	IQR	p^*
NRS movement													
Before treatment	6.2±2.5	8.0	0-10	2	6.2±1.7	6.0	4-9	2.5	5.9±1.8	6.0	2-9	2	0.751
After treatment	6.2±2.4	6.0	4-8	1	4.5±2.0	5.0	2-8	2.5	4.0±1.5	4.0	0-6	1.5	**0.008**
BT/AT change	0.0±1.0	0.0			-1.7±1.5	-2.0			-1.9±1.5	-2.0			**<0.001**
BT/AT change (p)		0.891†				**<0.001**†				**<0.001**†			
NRS rest													
Before treatment	4.3±2.6	4.0	0-8	2	3.8±2.1	4.0	0-8	4	3.5±2.3	4.0	0-8	2	0.576
After treatment	4.5±2.6	4.0	1-4	2	2.9±1.8	3.0	0-8	3.5	2.1±1.9	2.0	0-6	4	**0.007**
BT/AT change	0.2±1.2	0.0			-0.9±1.3	-1.0			-1.4±1.3	-1.0			**<0.001**
BT/AT change (p)		0.339†				**0.003**†				**0.001**†			
NRS night													
Before treatment	4.3±2.4	5.0	0-10	3.5	4.0±2.9	4.0	0-10	4	4.2±3.1	4.0	0-9	5	0.878
After treatment	4.1±2.4	4.0	0-6	1	2.2±2.0	2.0	0-8	3.5	2.0±2.2	1.0	0-7	4	**0.005**
BT/AT change	-0.2±1.0	0.0			-1.8±2.4	-1.0			-2.3±2.4	-2.0			**0.002**
BT/AT change (p)		0.319†				**0.002**†				**0.001**†			
Oswestry													
Before treatment	40.7±14.0	44.0	14-64	20	45.6±12.9	48.0	26-72	18	42.9±16.3	44.0	12-76	20.5	0.592
After treatment	37.4±14.9	32.0	14-64	24	29.3±16.0	20.0	12-72	27	22.9±8.6	24.0	2-50	13	0.007
BT/AT change	-3.3±10.4	0.0			-16.3±16.8	-18.0			-20.0±14.5	-20.0			**<0.001**
BT/AT change (p)		0.144†				**0.001**†				**<0.001**†			
Strain ratio													
Before treatment	0.8±1.4	0.3	0.03-6.90	0.60	0.6±0.9	0.3	0.11-4.12	0.22	0.6±0.4	0.5	0.12-1.81	0.46	0.279
After treatment	1.3±1.8	0.4	0.05-8.88	1.58	0.6±0.8	0.3	0.00-3.51	0.64	0.6±0.6	0.5	0.07-2.07	0.75	0.302
BT/AT change	0.6±1.9	0.0			0.0±1.2	0.0			0.1±0.5	-0.1			0.288
BT/AT change (p)		0.136†				1.000†				0.761†			

H+T: Hot pack and TENS treatment; H+T+U: Hot pack, TENS and therapeutic ultrasound treatment; SD: Standard deviation; Min: Minimum; Max: Maximum; IQR: Interquartile range; NRS: Numeric Rating Scale; BT: Before treatment; AT: After treatment; * Kruskal-Wallis test (Mann-Whitney U test); † Wilcoxon test.

Table 3. Short-Form 36 results

	Control group				H+T group				H+T+U group				
SF-36	Mean±SD	Median	Min-Max	IQR	Mean±SD	Median	Min-Max	IQR	Mean±SD	Median	Min-Max	IQR	*p**
Physical function													
Before treatment	52.8±21.6	50	10-85	30	48.3±19.9	45	15-85	20	53.3±25.7	50	10-90	40	0.682
After treatment	48.7±21.2	55	0-80	25	64.1±24.5	70	15-85	32.5	69.8±20.8	70	15-100	37.5	**0.007**
BT/AT change	-4.1±19.1	0			15.9±19.3	15			16.5±21.9	10			**0.001**
BT/AT change (p)		0.476†				**0.001**†				**0.001**†			
Physical role function													
Before treatment	32.6±33.2	25	0-100	50	30.4±38.4	0	0-100	25	30.4±35.3	25	0-100	50	0.889
After treatment	30.4±39.9	0	0-100	75	45.4±38.2	25	0-100	75	51.5±33.1	50	0-100	50	**0.002**
BT/AT change	-2.2±30.1	0			15.0±26.8	25			21.1±24.9	25			**0.002**
BT/AT change (p)		0.601†				**0.009**†				**0.001**†			
Pain													
Before treatment	34.8±23.5	32	0-74	29	31.7±15.0	22	10-61	19.5	39.7±21.5	32	0-84	25	0.442
After treatment	36.8±21.5	32	0-100	36.75	46.3±20.3	51	0-84	20	58.0±22.5	51	12-100	26	**0.003**
BT/AT change	2.0±7.5	0			14.6±17.9	10			18.3±16.3	16			**0.002**
BT/AT change (p)		0.304†				**0.003**†				**<0.001**†			
General health perceptions													
Before treatment	39.1±15.7	40	10-72	19.5	34.5±18.5	30	0-82	20	39.8±23.7	42	0-85	30.5	0.073
After treatment	40.2±16.1	47	5-82	15.75	50.1±19.4	50	0-76	23.5	54.7±18.9	50	22-92	24.5	**0.002**
BT/AT change	2.8±12.9	0			7.8±13.1	10			14.2±19.7	5			**0.009**
BT/AT change (p)		0.366†				**0.008**†				**0.002**†			
Vitality													
Before treatment	41.7±21.1	40	10-90	30	30.0±16.6	30	5-60	22.5	41.7±21.6	40	10-95	20	0.091
After treatment	41.1±19.8	45	5-85	20	34.6±19.1	35	0-75	27.5	45.4±24.0	40	10-90	37.5	0.288
BT/AT change	-0.7±16.7	0			4.6±15.5	0			3.7±19.7	0			0.714
BT/AT change (p)		0.984†				0..253†				0.420†			
Social role function													
Before treatment	54.3±30.3	50	0-100	44	53.7±26.2	50	0-100	38	54.6±28.5	62	12-100	38	1.000
After treatment	59.7±29.2	50	12-100	43.75	56.8±25.5	50	12-100	38	63.4±25.3	62	25-100	44	0.727
BT/AT change	5.4±18.9	0			3.2±17.7	0			8.8±20.8	12			0.301
BT/AT change (p)		0.217†				0.523†				**0.037**†			
Emotional role function													
Before treatment	40.2±29.9	33	0-100	49.5	49.0±33.1	33	0-100	33	31.7±29.2	33	0-100	26	0.156
After treatment	37.4±32.1	33	0-100	66	43.2±35.4	33	0-100	49.5	46.1±32.9	33	0-100	33	0.689
BT/AT change	-2.8±30.0	0			-5.7±35.7	0			14.4±29.8	0			0.115
BT/AT change (p)		0.809†				0.475†				0.029†			
Mental health													
Before treatment	48.0±21.5	52	0-88	20	45.4±17.5	48	12-80	22	51.1±20.0	52	16-100	33	0.649
After treatment	52.2±15.2	52	24-88	20	47.5±18.6	48	8-92	18	57.4±18.2	60	24-96	30	0.229
BT/AT change	4.2±14.0	4			2.1±14.7	0			6.3±16.7	8			0.689
BT/AT change (p)		0.161†				0.599†				0.069†			

H+T: Hot pack and TENS treatment; H+T+U: Hot pack, TENS and therapeutic ultrasound treatment; SD: Standard deviation; Min: Minimum; Max: Maximum; IQR: Interquartile range; NRS: Numeric Rating Scale; BT: Before treatment; AT: After treatment; * Kruskal-Wallis test (Mann-Whitney U test); † Wilcoxon test.

One-way analysis of variance (ANOVA) (Tukey test), Kruskal-Wallis test, and Mann-Whitney U test were used to analyze quantitative data. Qualitative data were compared using the chi-square test. A p value of <0.05 was considered statistically significant.

RESULTS

The control group included 23 patients (12 females and 11 males) with a mean age of 46.3±10.7 years, a Body Mass Index (BMI) of 26.3±3.9 kg/m^2, and a pain duration of 71±98.2 months. The H+T group included 23 patients (12 females and 11 males) with a mean age of 51.7±10.7 years, a BMI of 29.2±5.3 kg/m^2, and a pain duration of 79.6±75.5 months. The H+T+U group included 23 patients (12 females and 11 males) with a mean age of 48.6±11.0 years, a BMI of 28.3±4.1 kg/m^2, and a pain duration of 49.3±70.5 months. There were no significant differences among the three groups in terms of gender, mean age, mean height, mean weight, mean BMI, marital status, extent of education, or mean pain duration. Demographic characteristics of all patients are presented in Table 1.

There was a significant decrease in the NRS movement scores of the patients in the H+T and H+T+U groups after treatment, compared to baseline, whereas there was no change in the control group. However, decreases in the H+T and H+T+U groups were not statistically significant. In the NRS at rest, a significant decrease was observed in the H+T and H+T+U groups after treatment, compared to baseline, whereas there was no change in the control group. However, decreases in the H+T and H+T+U groups did not differ significantly. In the NRS at night, there was a significant decrease in the H+T and H+T+U groups after treatment, compared to baseline, whereas there was no significant difference in the control group. However, changes in the H+T and H+T+U groups did not differ significantly. Comparison of the changes in the NRS movement, at rest, and at night scores are presented in Table 2.

Using the ODI, a significant decrease was seen in the H+T and H+T+U groups after treatment, compared to baseline, whereas there was no significant difference in the control group. However, changes in the H+T and H+T+U groups did not differ significantly (Table 2).

In terms of the SR, there was no significant change in any of the groups after treatment, compared to baseline (Table 2).

In addition, there was no significant improvement in the SF-36 subscales (i.e., physical function, physical role function, pain, general health perceptions, vitality, social role function, emotional role function, and mental health) in the control group. However, in the H+T group, physical function, physical role function, pain, and general health perceptions improved after treatment compared to baseline. Similarly, in the H+T+U group, physical role function, pain, general health perceptions, social role function, and emotional role function improved after treatment, compared to baseline. However, there was no significant difference in the improvement of physical function, physical role function, pain, and general health perceptions between the H+T and H+T+U groups. The SF-36 results in all subscales are shown in Table 3.

DISCUSSION

In the present study, we evaluated the effects of combined hot pack and TENS treatment as well as the additional effect of therapeutic US on pain, disability, quality of life, and SR of the multifidus muscles as measured using elastography in patients with chronic low back pain. Although superficial heat therapy, TENS, and US are widely used for chronic low back pain, evidence-based guidelines for the treatment of chronic low back pain do not recommend any of these therapies due to lack of evidence.[21,22] According to our results, the combined superficial heat therapy and TENS treatment improved pain on movement, at rest, and at night, disability, physical functioning, physical role functioning, pain, and general health perception of the quality of life in patients with chronic low back pain. Addition of therapeutic US to the treatment, however, did not change the effects of the combined HP and TENS treatment on the aforementioned parameters, whereas it showed an additional benefit only on the social role functioning and emotional role functioning.

Chan et al.[15] investigated the change in multifidus muscle stiffness in patients with chronic lower back pain. They examined 12 male patients with chronic lower back pain and 12 healthy male controls using shear wave elastography and demonstrated that the multifidus muscles were stiffer in the patient group, compared to healthy controls. It is speculated that both superficial and deep heating agents reduce muscle tone and stiffness via their thermal effects.[2,5] In addition, a recent study by Turo et al.[23] suggested that stiffness of the taut bands in myofascial pain syndrome could be reduced by pain relief following dry needling, and this change in stiffness could be assessed using elastography. Therefore, in the present study, we hypothesized that superficial heat therapy and

therapeutic US would reduce the multifidus muscle stiffness by relieving pain. However, our results did not confirm our hypothesis. To the best of our knowledge, there is no study available suggesting the normal range or values for multifidus muscle elastography. Although a change in the multifidus muscle stiffness would have allowed us to evaluate the effect of the therapy objectively, such a change was not be accomplished. To the best of our knowledge, this is the first study to evaluate the effects of physical therapy agents on the mechanical features of the paravertebral muscles.

In their study, Masaki et al.[24] examined the relationship between lower back pain and muscle stiffness in young and middle-aged medical workers. This study included 23 healthy controls and nine medical workers with lower back pain. The authors evaluated muscle stiffness using shear wave elastography from the lumbar erector spinae, quadratus lumborum at L3 level, and multifidus muscle at L4 level. Multiple regression analysis showed that only height and multifidus muscle stiffness were independent determinants of lower back pain and shear wave elastography showed higher stiffness in workers with lower back pain than asymptomatic control workers in a prone position. The authors, eventually, concluded that muscle spasm due to pain might be a possible reason for higher multifidus stiffness in lower back pain.[24] Similar to our study, the aforementioned authors also used the ODI and static and dynamic NRS to evaluate the status of lower back pain. In addition, we evaluated the quality of life using the SF-36 scale, while Masaki et al.[24] only demonstrated higher elastographic muscle stiffness with chronic lower back pain, but did not evaluate how the muscle stiffness changed after intervention.

In a Cochrane systemic review, Ebadi et al.[25] investigated the efficacy of therapeutic US alone and included seven RCTs comparing US treatment to other treatment methods or placebo. According to the results of three studies (n=100), there was moderate-quality evidence that US improved function related to back pain. Two trials (n=58) revealed moderate-quality evidence that US treatment did not improve the extension range of motion, while the remaining two studies (n=79) demonstrated low-quality evidence that the addition of US to exercise did not improve pain, function, and lumbar flexion range of motion, compared to exercise alone. The authors concluded that therapeutic US alone was not superior to placebo with regard to short-term pain improvement.[25] Another Cochrane systematic review including four placebo-controlled RCTs (n=585) by Khadilkar et al.[26] showed that there was no evidence that TENS could relieve symptoms and reduce disability in chronic low back pain. Similarly, our study results demonstrated that the addition of US treatment to HP + TENS did not change the outcome in terms of pain, disability, and quality of life; however, the present study did not include a treatment group with US or TENS alone. Therefore, it is not possible to suggest that US treatment alone does not have an effect or improvement can be attributed to TENS alone.

In a study, Koldaş et al.[27] compared home-based exercises alone, a combination of physical therapy agents (HP, TENS, and US treatment) and home-based exercises, and aerobic exercises alone to evaluate their effects on chronic low back pain and found that pain significantly decreased in all groups, whereas patients treated with physical therapy and home-based exercises experienced greater improvements in disability and physical disturbances at one month of follow-up. Differently from our study, there was no control group in this study. Our study also showed the short-term effects of combination therapy on pain, disability, and quality of life. Interestingly, our results support an improvement in the emotional role functioning and social role functioning, consistent with the results of the aforementioned study.

Guillemin et al.[28] studied short- and long-term effects of superficial heat therapy in patients with chronic low back pain. They used SPA therapy as superficial heat source and demonstrated an improvement in the spine mobility, functional scores, daily pain duration, pain intensity, and drug consumption. They also showed a moderate long-term effect after nine months. As their short-term effects are consistent with our results and our study did not include long-term outcomes, we were unable to conclude that the therapies we applied have long-term effects.

The neuroscience of pain has suggested three possible mechanisms for chronic low back pain: central sensitization, nociceptive, and neuropathic mechanisms.[29] On the contrary, TENS treatment is thought to be operating by facilitating the interruption of neural transmission of pain.[30] In our study, HP and TENS combination did not demonstrate a reduction of multifidus stiffness in patients with chronic lower back pain, although this combination relieved pain, thus putting central sensitization or neuropathic mechanisms forward as possible reasons for chronic

low back pain. Therapeutic US is considered a potential tool for nociceptive pain, but is considered of limited or no use for central pain or chronic pain exacerbated by neuroplastic remodeling.[1] This may be the reason why US did not have an additional benefit for relieving chronic lower back pain.

The main limitations of our study include lack of long-term follow-up results and lack of a sham therapy group. Another limitation is its relatively small sample size. The sample size in this study was established according to power analysis of a clinical questionnaire (using ODI); however, the results in terms of elastographic muscle stiffness would be different with a larger sample size.

In conclusion, our study results demonstrate that combined superficial heat therapy and TENS treatment has a beneficial effect on pain, disability, and certain subscales of quality of life in the short term. In addition to this combination, US treatment, however, does not have an additional benefit in terms of pain, disability, physical function, physical role function, or general health perceptions of quality of life. Nonetheless, it may have a beneficial effect on social role functioning and emotional role functioning; however, as these functions are affected by various social factors, it is not possible to conclude that this is an effect of US alone, solely based on our study findings. Conversely, the combined HP+TENS treatment or HP+TENS+US treatment have no beneficial effects on stiffness of the multifidus muscles, although they can provide pain relief. In this context, muscle stiffness may not be the major reason for pain in patients with chronic low back pain, and physical treatment agents may alleviate pain through other mechanisms. We recommend further large-scale and long-term studies to confirm these findings.

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