

THE EFFECT OF LUMBAR STABILIZATION EXERCISES ON CHRONIC LOW BACK PAIN PATIENTS

KRONİK BEL AĞRILI HASTALARDA LOMBER STABİLİZASYON EGZERSİZLERİNİN ETKİSİ

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Öz

Amaç

Bu çalışmanın amacı kronik bel ağrısı olan hastalarda lomber stabilizasyon egzersizlerinin (LSE) ağrı, fonksiyonel kapasite, yaşam kalitesi ve denge üzerine etkisini araştırmak, ayrıca lomber multifidus kası kesitsel alanına etkisini değerlendirmektir.

Gereç ve Yöntem

Çalışmaya kronik bel ağrısı tanısı alan 66 hasta alındı. Hastalar randomize edilerek iki gruba ayrıldı. Birinci gruba (Grup 1, n=28) lomber stabilizasyon egzersizleri, TENS ve Hotpack tedavileri, ikinci gruba (Grup 2, n=37) ise sadece TENS, Hotpack tedavileri verildi. Hastalar tedavi öncesi ve tedavi sonrası 8. haftada değerlendirildi. Ağrı için Visuel Analog Skala (VAS), fonksiyonel dizabilite için Roland Morris Sorgulama Anketi ve Oswestry Özürlülük İndeksi, yaşam kalitesi için Kısa Form-36 (SF-36) ile değerlendirme yapıldı. Denge değerlendirmesinde Tetrax® posturografi cihazı (SunlightMedicalLtd, İsrail) kullanıldı ve düşme indeksi (FI) hesaplandı. Multifidus kası kesit alanı ultrasonografi ile ölçüldü.

Bulgular

Gruplar arası karşılaştırıldığında multifidus kası kesitsel alanı, SF-36'nın fiziksel rol güçlüğü, ağrı, ruhsal

sağlık ve enerji/vitalite/ canlılık alt parametrelerinde LSE alan hastalarda daha anlamlı iyileşme gözlemlendi (p<0.05). Düşme indeksi, VAS skorları, Roland Morris Sorgulama Anketi ve Oswestry Özürlülük İndeksi skorlarında gruplar arasında anlamlı farklılık saptanmadı.

Sonuç

Lomber stabilizasyon egzersizleri, kronik bel ağrısı olan hastalarda multifidus kesit alanını ve yaşam kalitesini olumlu yönde etkilemektedir. Bizim örneklemimiz için lomber stabilizasyon egzersizlerinin konvansiyonel fizik tedavi programına eklenmesi denge, ağrı ve dizabilite açısından ek katkı sağlamamaktadır.

Anahtar Kelimeler: Denge, Kronik bel ağrısı, Lomber stabilizasyon egzersizleri, Multifidus kası, Yaşam kalitesi

Abstract

Objective

The aim of this study is to investigate the effect of lumbar stabilization exercises (LSE) on pain, functional capacity, quality of life, and balance in patients with chronic low back pain (CLBP), and also to evaluate the effect on the cross-sectional area of the lumbar multifidus muscle.

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Material and Method

Sixty-six patients with CLBP were enrolled, randomized, and divided into two groups. LSE, transcutaneous electrical nerve stimulation (TENS), and hot pack treatments were performed in Group 1 (n=28). In Group 2 (n=37), TENS and hot pack treatments were performed only. Pre and 8-week post-treatment assessments were made. Visual Analog Scale (VAS) was used to evaluate pain. Modified Oswestry Disability Index (ODI) and Roland Morris Disability Questionnaire (RMDQ) were used to evaluate the functional disability. Short Form-36 (SF-36) was used to measure the quality of life. In the assessment of balance, a Tetrax® posturography device (Sunlight Medical Ltd, Israel) was used and fall index (FI) was calculated. The cross-sectional area of multifidus muscles was measured by ultrasonography.

Results

Significant improvements regarding the cross-

sectional area of multifidus muscles and sub-parameters of SF-36 named physical role, pain, mental health, and energy/vitality were determined in Group 1 compared to Group 2 ($p < 0.05$). No significant difference was present between the groups regarding FI, VAS score, RMDQ, ODI, and balance.

Conclusion

Lumbar stabilization exercises in patients with chronic low back pain multifidus positively affects cross-sectional area and quality of life. For our sample, the addition of lumbar stabilization exercises to the conventional physical therapy program does not provide an additional contribution in terms of balance, pain and disability.

Keywords: Lumbar stabilization exercises, chronic low back pain, quality of life, balance, multifidus muscle

Introduction

Low back pain (LBP) is the most significant disorder leading to severe productivity loss and disability (1). Although the annual incidence of LBP is 5%, it is the second most common cause of presentation to a physician, with a lifetime prevalence of 75-85% (2). In addition, those over 30 years of age, obese, or having various psychosocial disorders are at risk for LBP (3). Management of LBP is a controversial topic. Cochrane reviews of different treatment modalities have concluded that no significant differences were present among treatments (4-6). In a very recent collaborative study conducted in 18 countries, despite its commonness, the prevalence of disabling LBP showed substantial differences among similar workgroups of different countries; these variations were attributed to the general propensity to musculoskeletal pain rather than spine disorders (7).

Multifidus muscles (MM) are responsible for proprioception, and especially in segmental stabilization, MM and Transversus abdominis muscles (TrAM) take a significant part. In a systematic review article by Goubert et al., written by analyzing 15 eligible studies, both MM and paraspinal muscles were reported to be atrophied in chronic LBP patients but not in those with recurrent or acute LBP (8). A recent clinical commentary on the stability concept in LBP concluded that instability was active in iatrogenic LBP (9).

The core stabilization exercises (CSE) are based on the development of MM and TrAM, which are responsible for spinal stabilization. It has been suggested that people with chronic low back pain experience a reduction in the cross-sections of the MM and TrAM and balance control (10). In chronic LBP, the effects of MM on pain and balance were investigated by looking at the cross-sectional measurements of the MM in chronic LBP (11). LSE has recently gained popularity in chronic LBP with the emergence of the segmental stabilization concept. Training muscles in the para-lumbar region were suggested to directly lead to a more favorable outcome regarding pain compared to conventional treatment methods (12). A recent systematic review by Nascimento et al. concluded that these exercises reduced pain, improved functional capacity, and increased MM size in chronic LBP patients (13).

This study aimed to investigate the effects of CSE on MM mass, pain, quality of life, functional capacity, and balance in patients with chronic LBP.

Material and Method

Prior to the study, the Local Ethics Committee approval (09.12.2016/E.54082) and informed written consent from all patients were obtained.

Patients who applied to the outpatient clinic with chronic low back pain between November 2015 and

December 2016 were evaluated. Sixty-six patients with chronic LBP were included. One patient left prematurely, whereas 65 patients completed the study. The criteria for inclusion were being 18-65 years, having continuous mechanical LBP for at least 12 weeks, and compliance with a scheduled exercise program. Exclusion criteria were the presence of a neurological deficit, spinal deformity, congenital malformation, pregnancy, severe osteoporosis/osteomalacia, comorbidities such as cardiovascular or chronic obstructive pulmonary disorder, spondylolysis/spondylolisthesis, lumbar surgery, chronic infectious or inflammatory disorder, malignancy, and electrotherapy received in the last six months. Randomization was done as n: n+1 principle by random allocation process. The study flowchart was given in Figure 1.

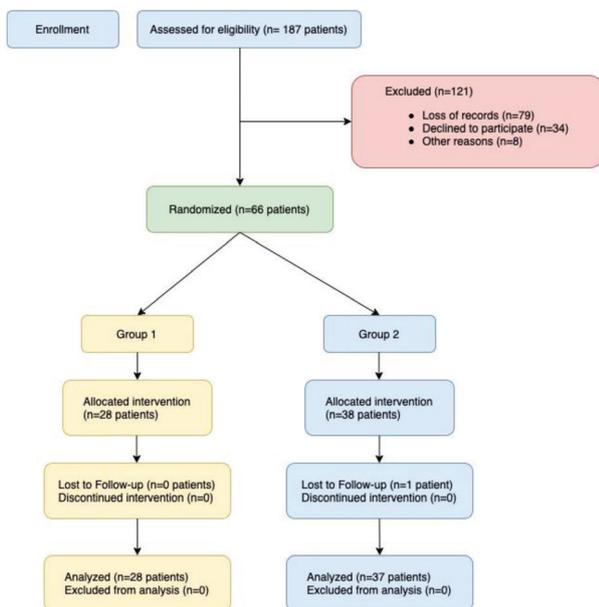


Figure 1
Consolidated Standards of Reporting Trials Flow Diagram Used In The Design Of The Trial

Group 1 (Study Group): Dynamic lumbar stabilization exercises (LSE) started with neutral positioning. Exercises performed in the supine position involved abdominal muscle strengthening with/without upper extremities, partial curl-up, bridge position, and leg elevation in the bridge position. Exercises performed in the prone position involved the elevation of extremities one by one. Exercises performed in the tetrapodesis position involve elevating one upper extremity or one upper and one lower extremity while in the tetrapodesis position. These exercises were demonstrated by a physiotherapist in charge of this task. The exercises were initially five times, then

gradually increased to 15 repetitions. Sufficient time has been set for relaxation. Exercises were performed two times a day and in 3 sets with 10-15 repetitions. An informed consent form was obtained from the patients that these exercises would be performed as demonstrated. Patients were requested to perform LSE twice daily at home for eight weeks.

Twenty sessions of 30-minute conventional TENS applications were made using the Chattanooga Monochromatic Stim device. During the TENS application, patients were kept in the prone position. A pillow was placed under the patient's abdomen to reduce lumbar lordosis. Four electrodes were used; two channels to the right and left. Active electrodes were placed at the level of 3-5 Lumbar vertebrae and 1.5cm lateral to midline. Passive electrodes were placed 3cm distal to active electrodes. Attention was paid to avoiding discomfort and pain during the TENS application. Additionally, a 30-minute hot pack application was made.

Group 2 (Control Group): Twenty sessions of 30-minute conventional TENS applications were made by same device and the same procedural steps were applied during the TENS and hot pack application as in Group 1.

Patients were tested before and after treatment for pain severity, functional disability, quality of life, body balance, and cross-sectional areas (CSA) of lumbar MM. Pain severity was assessed by scoring between 0 and 10 while resting (RVAS) and in motion (MVAS) according to the visual analog scale (VAS). Functional insufficiency was evaluated using the Turkish version of the modified Oswestry Disability Index (ODI) Questionnaire (14).

Functional disability was assessed using the Roland Morris Disability (RMD). The questionnaire, modified from Sickness Impact Profile, and validated for Turkish, comprised 24 items (15-16). Quality of life was evaluated by Short Form-36 (SF-36) (17).

The balance and fall risks were assessed using the fall risk assessment device (FRAD) brand-named Tetrax Interactive Balance and Coordination System-2006 (Sunlight Lab, Israel). It is a device in which postural oscillation is measured, and the individual's fall risk is calculated eventually. It involves two balance platforms at each side comprising finger points and heel points of both feet and software. For accurate pressure measurement, the patient should stand in an upright posture, feet should be placed on pre-defined sites, and arms should hang down loosely

on both sides. Differences in pressure displacement centers are detected with the help of pressure receivers. For balance parameters, measurements lasting for 32 seconds each are made at eight different positions. Eyes-open position (NO) is the reference measurement. At the eyes-closed position (NC), the effect of the visual system on balance is evaluated. At eyes-open and on pillow position (PO), the somatosensorial system is restricted by pillows. At the eyes-closed and on-pillow position, only the vestibular system is evaluated. At the eyes closed and head turned, either right (HR) or left (HL) position, both the somatosensorial and vestibular systems are assessed. The central and peripheral vestibular systems are evaluated while the eyes are closed and the head either bent-30°-backward (HB) or 30°- flexed (HF). With FRAD, four balance parameters, overall balance, weight percentage, weight distribution index, Fourier transformations of postural oscillations, and synchronized pressure parameters between the heel and fingers of the foot, and between the right and left feet, are evaluated. Data is compared to the reference value according to the individual's age and gender, and FI between 0-100 is obtained; 0-36% is interpreted as low, 37-58% as moderate, and 59-100% as high (18).

Hides et al. reported in 1995 that USG was as reliable as MRI in evaluating MM size and activation (19). With USG, the status of MM was reliably studied in patients with LBP and lumbar spondylolisthesis (20-22). To measure CSA of lumbar MM, a USG device brand-named ESAOTE- Mylab70, was used with a 5 MHz-convex probe, covering a field 50mm in length (Figure 2). The patient was placed in the prone position with both arms extended freely at both sides, and a pillow was placed under the hips to reduce lumbar lordosis. The spinous process of the L5 vertebra was palpated and marked with a grease pencil, starting from the sacrum, and moving cranially. Then, by palpating in the cranial direction, the spinous process of the L4 vertebra was marked. The convex USG probe was placed at midline and transversally to spinous processes. The probe was moved to either right or left. The most distinct image was obtained to clarify MM. The vertebral lamina was considered as the border for the deep portion of MM. When the lateral border of MM could not be visualized, the patient was asked to elevate, and then relax the ipsilateral leg. USG was reperformed at rest (23).

While evaluating the findings obtained in the study, the "Statistical Package for Social Sciences (SPSS) for Windows 17.0" package program was used for statistical analysis. The conformity of the variables

to the normal distribution was examined using visual (histogram and probability) and analytical methods (Kolmogorov-Smirnov and Shapiro-Wilk tests).

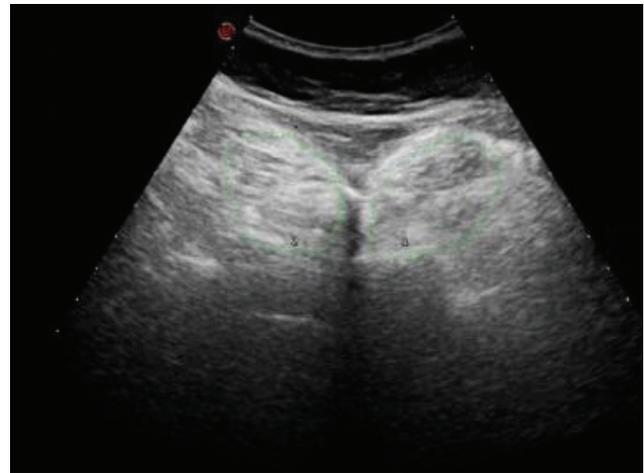


Figure 2
The Ultrasonographic Cross-Sectional Image Of Lumbar Multifidus Muscles

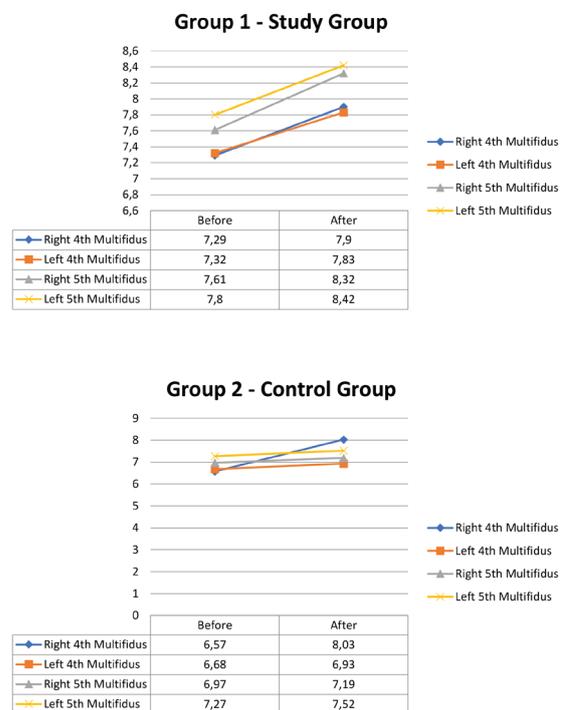


Figure 3
The Distributions of The Differences In Cross-Sectional Areas of The Right And Left 4th And 5th Multifidus Muscles Occurring With Treatment In Groups 1 And 2

Descriptive statistics of the data, normally distributed for continuous data for variables (mean±standard deviation) and as [median (minimum: maximum)] for non-normally distributed variables. Independent Samples “t” test and within-group comparisons were made for the comparison of two independent groups for normally distributed, continuous data. Paired-Samples “t” test was used for before-after comparisons. For non-normally distributed, continuous data, the MannWhitney U test was used to compare two independent groups, and the Wilcoxon Signed Ranks Test was used for before-after comparisons for within-group comparisons. Chi-square test was used to compare categorical variables used. The statistical

significance limit was accepted as 0.05.

Results

The sociodemographic data and pretreatment parameters of 28 patients who performed lumbar stabilization exercises in addition to TENS & hot pack treatment (Group 1) and 37 patients who received only TENS & hot pack treatment (Group 2) were presented in Table 1. When two groups were compared regarding gender, the higher ratios of female gender in Group 1 and male gender in Group 2. The other sociodemographic data were comparable.

Table 1

The distributions and comparison of sociodemographic data and pretreatment parameters of the groups in both genders

		Study Group (Group 1) n=28		Control Group (Group 2) n=37		p
Age (years)	Woman	17	41.06 (13.62)	11	37.00 (14.34)	0.457
	Man	11	37.36 (13.70)	26	40.92 (13.78)	0.477
Height (cm)	Woman	17	163.29 (8.42)	11	161.82 (5.64)	0.614
	Man	11	178.36 (5.14)	26	173.38 (5.49)	0.015*
Weight (kg)	Woman	17	68.76 (12.47)	11	77.64 (17.22)	0.126
	Man	11	80.00 (70.00;118.00)	26	79.50 (45.00;120.00)	0.222
BMI (kg/m ²)	Woman	17	25.81 (4.32)	11	29.62 (6.11)	0.064
	Man	11	27.00 (3.58)	26	26.49 (4.41)	0.738
Duration (months)	Woman	17	35.00 (32.30)	11	45.00 (35.27)	0.447
	Man	11	12.00 (3.00;240.00)	26	33.00 (3.00;180.00)	0.350
FI	Woman	17	45.41 (23.71)	11	53.27 (23.58)	0.398
	Man	11	34.00 (14.00;74.00)	26	35.00 (2.00;100.00)	0.881
Right 4 th Multifidus	Woman	17	6.93 (.99)	11	6.62 (.95)	0.412
	Man	11	7.85 (1.10)	26	6.55 (1.22)	0.004*
Left 4 th Multifidus	Woman	17	6.86 (.92)	11	6.56 (.80)	0.377
	Man	11	7.41 (6.57;11.30)	26	6.59 (5.02;9.04)	0.007*
Right 5 th Multifidus	Woman	17	7.31 (1.12)	11	7.27 (1.35)	0.938
	Man	11	7.44 (5.65;10.70)	26	6.73 (4.60;10.66)	0.013*
Left 5 th Multifidus	Woman	17	7.33 (1.28)	11	7.47 (1.35)	0.793
	Man	11	8.06 (6.53;11.76)	26	6.97 (4.05;10.53)	0.028*
RVAS	Woman	17	7.00 (2.00;8.00)	11	7.00 (2.00;10.00)	0.427
	Man	11	6.00 (2.00;9.00)	26	6.00 (0.00;10.00)	0.260
MVAS	Woman	17	8.00 (6.00;10.00)	11	10.00 (7.00;10.00)	0.247
	Man	11	8.00 (4.00;10.00)	26	8.00 (3.00;10.00)	0.537

Table 1
continue

The distributions and comparison of sociodemographic data and pretreatment parameters of the groups in both genders

RMD	Woman	17	11.47 (4.39)	11	11.45 (6.20)	0.994
	Man	11	9.00 (3.90)	26	10.65 (5.59)	0.379
ODI	Woman	17	22.82 (6.86)	11	25.73 (6.72)	0.280
	Man	11	17.27(6.77)	26	20.00(9.70)	0.403
SF-36 / PF	Woman	17	50.61 (19.16)	11	37.34 (19.41)	0.087
	Man	11	50.00 (11.10;77.70)	26	66.60 (5.50;94.40)	0.249
SF-36 / PRD	Woman	17	0.00 (0.00;75.00)	11	0.00 (0.00;75.00)	0.767
	Man	11	25.00 (0.00;100.00)	26	37.50 (0.00;100.00)	0.698
SF-36 / P	Woman	17	37.79 (17.96)	11	42.27 (18.76)	0.532
	Man	11	40.23 (17.37)	26	42.98 (25.25)	0.744
SF-36 / SF	Woman	17	62.50 (12.50;87.50)	11	62.50 (25.00;87.50)	0.513
	Man	11	64.77 (18.39)	26	61.06 (25.08)	0.661
SF-36 / MH	Woman	17	46.12 (24.25)	11	45.82 (18.19)	0.972
	Man	11	57.45 (16.52)	26	56.50 (21.01)	0.894
SF-36 / ERD	Woman	17	0.00 (0.00;100.00)	11	33.30 (0.00;100.00)	0.959
	Man	11	66.60 (0.00;100.00)	26	33.30 (0.00;100.00)	0.740
SF-36 / EVL	Woman	17	31.47 (24.09)	11	35.00 (17.75)	0.680
	Man	11	45.91 (21.43)	26	42.31 (19.09)	0.616
SF-36 / GHP	Woman	17	36.76 (11.45)	11	43.64 (11.85)	0.138
	Man	11	49.09 (19.60)	26	49.81 (19.77)	0.920

*: Statistically significant; BMI: Body mass index, FI: Fall index, RVAS: Resting visual analog scale, MVAS: Movement visual analog scale, RMD: Roland Morris disability score, ODI: Oswestry disability index, SF-36: Short form- 36, PF: Physical functioning, PRD: Physical role difficulty, P: Pain, SF: Social functionality, MH: Mental health, ERD: Emotional role difficulty, EVL: Energy/Vitality/Liveliness, GHP: General health perception. Data were presented as mean \pm standard deviation or median (minimum; maximum).

The differences between pre and post-treatment values in Groups 1 and 2, together with comparisons of the groups were shown in Table 2 and Figure 3. No statistically significant difference was present between the groups regarding the difference in FI occurring with treatment ($p=0.449$).

It was found that the increases in CSA of right and left 4th, and 5th MM was statistically significantly higher in Group 1 compared to Group 2 ($p<0.05$). The increase determined in the right/left 4th/5th MM of patients in Group 1 compared to patients in Group 2 was statistically significant.

When the groups were compared regarding the differences occurring in RVAS and MVAS scores, no statistically, significant differences were present ($p=0.171$, and $p=0.620$, respectively). No statistically

differences were present between groups regarding the differences occurring in the RMD Questionnaire and ODI scores also ($p=0.424$, and $p=0.161$, respectively)

When the two groups were compared regarding differences in sub-parameters of SF-36, it was found that improvements in physical role difficulty, pain, mental health, and energy/vitality/liveliness sub-parameters in Group 1 were statistically more significant than in Group 2 ($p=0.004$, $p=0.016$, $p=0.020$, and $p=0.048$, respectively).

Discussion

This study aimed to investigate LSE in chronic LBP. Since the patient groups were similar regarding sociodemographic characteristics and pre-treatment values of most of the study parameters, we were

Table 2

The distribution of the differences between the posttreatment and pretreatment values of the study parameters in Groups 1 and 2, together with the comparisons of the two groups

	Group 1	Group 2	p
FI	-7 (-36;28)	0 (-52;32)	0.449
Right 4 th Multifidus	0.62 (-1.35;2.41)	0.17 (-1.56;45.79)	<0.05*
Left 4 th Multifidus	0.51 (-2.08;2.04)	0.14 (-1.07;2.09)	<0.05*
Right 5 th Multifidus	0.60 (-0.20;2.44)	0.08 (-0.93;1.60)	<0.05*
Left 5 th Multifidus	0.64 (-0.58;1.87)	0.07 (-0.95;2.29)	<0.05*
RVAS	-2.82 (2.45)	-2.03 (2.16)	0.171
MVAS	-2.5 (-10;1)	-2 (-8;2)	0.620
RMD	-4 (-18;5)	-3 (-19;5)	0.424
ODI	-7.5 (-27;8)	-5 (-36;8)	0.161
SF-36 / PF	18.65 (21.08)	11.41 (20.28)	0.166
SF-36 / PRD	25 (0;100)	0 (-25;100)	0.004*
SF-36 / P	25 (-25;67.5)	10 (-12.5;65)	0.016*
SF-36 / SF	12.5 (-25;50)	12.5 (-50;75)	0.072
SF-36 / MH	16 (-24;40)	4 (-12;32)	0.020*
SF-36 / ERD	33.3 (-33.3;100)	0 (-66.7;100)	0.430
SF-36 / EVL	16.42 (18.6)	8.37 (13.59)	0.048*
SF-36 / GHP	10 (-25;50)	0 (-45;30)	0.153

able to investigate differences between the groups occurring with different modes of therapy and reach significant conclusions. We determined that MM mass increased with the quality life of indices, and conventional physical therapy plus LSE was superior to only conventional physical therapy. However, the body balance did not improve with LSE.

Several significant and insignificant results were determined regarding comparing the differences between the posttreatment and pretreatment status. There were no significant differences between the pre/post-treatment FI scores in both groups. But a study by Hlaing et al. showed positive effects of stabilization exercises on balance (24).

In various studies, similar findings were reported regarding RVAS and MVAS scores when LSE was performed. In the study by Kumar et al., a comparison of LSE and placebo in LBP patients revealed a significant difference in VAS score in the group that performed LSE (25). A meta-analysis of five studies showed that LSE was superior to general exercises

as the VAS score was reduced further (26). In another recent meta-analysis, the effect of stabilization exercises on pain was found to be superior to stretching and McKenzie exercises (27). However, in a study by Bae, stabilization exercises and sit-up exercises were found to be similar to each other in terms of pain (28). In another study, stabilization exercises and manipulative exercises showed similar effects in terms of pain control in chronic low back pain (29). Similarly, Unsgaard-Tondel et al. compared exercises for lumbar stabilization and abdominal strengthening and reported significantly more improvement in VAS score in the group that performed LSE (30).

We determined a significant increase in CSA of MM with LSE. Kim and Kin measured the dimensions of MM by CT in chronic LBP patients and compared conventional physical therapy with LSE. They reported that, while no change was observed in the group that received physical therapy, LSE increased the CSA of MM (31). In the study conducted by Hides et al., MM was evaluated by USG, and an increased CSA of MM was observed with LSE (32).

We did not determine any significant difference in improvement between the groups regarding RMD and ODI scores. We did not meet any study comparing LSE with the TENS application. However, Cho et al. compared CSE to conservative physical therapy and reported that the ODI score of the group that performed CSE was superior to the other group (33). In another study conducted by Ferreira et al., RMD Questionnaire was used as a functional disability index, and significant superiority of LSE was determined (29). In another study using only ODI, considerable improvement was observed in the ODI score of the group performing LSE compared to conventional exercises (34).

We determined that significantly more improvement occurred in patients performing LSE compared to control patients regarding sub-parameters of SF-36 named physical role difficulty, pain, mental health, and energy/vitality. Unfortunately, we did not encounter any study in which SF-36 was used to assess the quality of life in patients treated with LSE. Another study compared LSE to Pilates exercises by evaluating the differences in SF-36 subgroup scores obtained after three and six months of exercise. Statistically, significant improvements were reported in favor of the Pilates group for mental and general health within the third month and physical function within the sixth month (35).

Home exercises and the low number of patients are the study's limitations, so larger sample-sized prospective studies are required to assess the effectiveness of CSE better in chronic LBP patients.

In conclusion, the CSA of MM increases with LSE. However, despite increased MM mass, improvement in the body balance may not occur. Additionally, LSE offers an alternative treatment route effective on pain, functional recovery, and quality of life.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Ethical Approval

Prior to the study, the Local Ethics Committee approval (09.12.2016/E.54082, No: 13) were obtained from Kahramanmaraş Sütçü İmam University Social and Humanities Ethics Committee.

Consent to Participate and Publish

Written informed consent to participate and publish was obtained from all individual participants included in the study.

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Availability of Data and Materials

Data available on request from the authors.

Authors Contributions

KB: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Validation; Visualization; Writing-original draft.

ET: Conceptualization; Formal analysis; Investigation; Methodology; Project administration; Supervision; Validation; Writing-review & editing.

OFS: Investigation; Validation; Writing-original draft.

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