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Original Article

Evaluation of effectiveness of osteopathic visceral manipulation in patients with chronic mechanical low back pain: A multi-center, single-blind, randomized-controlled study

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ABSTRACT

Objectives: In this study, we aimed to evaluate the effectiveness of osteopathic visceral manipulation (OVM) combined with physical therapy in pain, depression, and functional impairment in patients with chronic mechanical low back pain (LBP).

Patients and methods: A total of 118 patients with chronic mechanical LBP were assessed, and 86 who met the inclusion criteria were included in the randomized-controlled study between January 2021 and August 2022. The patients were randomized to either Group 1 (n=43), which underwent physical therapy (5 days/week, for a total of 15 sessions) combined with OVM (2 days/week with three-day intervals), or Group 2 (n=43), which underwent physical therapy (5 days/week, for a total of 15 sessions) combined with sham OVM (2 days/week with three-day intervals). Both groups were assessed before and after treatment and at the fourth week post-treatment.

Results: Seven patients were lost to follow-up, and the study was completed with 79 patients (25 males, 54 females; mean age: 46.87±14.12 years; range, 19 to 75 years). Pain, depression, and functional impairment scores were all improved in both groups (p=0.001 for all). This improvement was sustained at week four after the end of treatment. However, improvement in the pain, depression, and functional impairment scores was significantly higher in Group 1 than in Group 2 (p=0.001 for all).

Conclusion: The results suggest that OVM combined with physical therapy is useful to improve pain, depression, and functional impairment in patients with chronic mechanical low back pain. We believe that OVM techniques should be combined with other physical therapy modalities in this patient population.

Keywords: Chronic mechanical low back pain, depression, functional impairment, osteopathic visceral manipulation, pain, physical therapy.

Low back pain (LBP) is a common musculoskeletal problem in the industrialized world, and nearly 80% of individuals experience an episode of LBP during their lifetime.[1,2] It is the most common condition among chronic diseases and adversely affects the daily living activities of individuals, leading to workforce loss.[1-3] Chronic LBP is defined as LBP lasting for more than three months.[3] The majority of cases (97%) is of mechanical origin.[4] Mechanical LBP is mainly characterized by axial symptoms caused by excessive use, strain, trauma, or deformation of the spine and the supporting soft tissues surrounding the

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spine.[4-6] The main causes of chronic mechanical LBP include disc herniation, lumbar spondylosis, vertebral compression fractures, acute or chronic traumatic injury, repetitive trauma, and overuse.[6] Several studies have shown that visceral dysfunction may be implicated in the etiology of LBP and contribute to the increased severity of pain.[7-9] Surgical interventions, adhesions, or inflammatory processes that affect the visceral connective tissue mobility, such as the fascia, may lead to visceral dysfunction.[8,9]

Visceral dysfunction is altered mobility of visceral organs and their fascial, neural, skeletal, vascular, and lymphatic components.[10] These restrictions may adversely affect the spinal nerve innervation related to dysfunctional viscera. As the visceral innervation arises from the thoracic and lumbar regions via the sympathetic nervous system, the state of the abdominal and pelvic viscera may segmentally restrict the mobility of structures in the distant parts of the body, contributing to the development or continuation of chronic LBP in some cases[8,9] or increased severity of symptoms or widespread and localized pain.[11]

Currently, three mechanisms have been proposed by which the altered movement relationship between organs and supporting connective tissues can potentially manifest as LBP: visceral, central sensitization, and local fascial alterations. Visceral disorders may be the triggering factor or exacerbating factor for LBP through one of these mechanisms.[9] Some authors have suggested that visceral mobilization may be effective in the treatment of LBP.[7,12-14]

Osteopathic visceral manipulation (OVM) is used in the treatment of musculoskeletal system, vascular, nervous, urogenital, respiratory, gastrointestinal, and lymphatic dysfunction, improving the functional and structural imbalances.[9] It is a gentle manual therapy that helps to relax the fascial constraints between the visceral organ and related connective tissue to restore the normal mobility of the visceral organs than the surrounding tissues and maintain mechanical, vascular, and neurological visceral function by eliminating movement restrictions.[8,15,16] Despite the widespread use of physical therapy modalities in the treatment of chronic LBP,[17,18] the number of studies using OVM is limited in the literature.[7,10,11]

A review of the literature reveals only two studies combining OVM and physical therapy.[8,19] There are discrepancies between these studies in terms of the methodology, number of patients, and follow-up duration. In the present study, we aimed to evaluate the effectiveness of OVM combined with physical therapy in pain, depression, and functional impairment in patients with chronic mechanical LBP.

PATIENTS AND METHODS

This multicenter, single-blind, prospective, randomized-controlled study was conducted at the Physical Therapy and Rehabilitation outpatient clinics of four healthcare centers between January 2021 and August 2022. Patients who were admitted with LBP, diagnosed with chronic mechanical LBP, and scheduled for physical therapy in the outpatient setting were screened. Inclusion criteria were as follows: age between 18 and 75 years; having chronic mechanical LBP lasting for more than three months; receiving no physical therapy and rehabilitation within the past six months; receiving no nonsteroidal anti-inflammatory drugs during the study period; having normal complete blood count, erythrocyte sedimentation rate, and C-reactive protein values; having pain (≥4 based on the Visual Analog Scale [VAS]). Exclusion criteria were as follows: acute disc hernia and sciatalgia with neurological symptoms, severe structural deformities, acute vertebral fractures, malignancies, spinal and visceral organ surgery within the past six months, inflammatory back pain, metabolic and endocrinologic bone diseases, pregnancy, psychiatric disorders affecting patient compliance and symptoms, receiving anti-platelet drugs, and previous osteopathy treatment.

In this study, 118 patients with chronic mechanical LBP were assessed, and 86 who met the inclusion criteria were recruited. The patients were recruited according to the randomization order in four study centers and divided into two groups. The patients were not informed about which treatment group they were allocated. The patients were randomized to either Group 1 (n=43), which underwent physical therapy (5 days/week, for a total of 15 sessions) combined with OVM (2 days/week with three-day intervals), or Group 2 (n=43), which underwent physical therapy (5 days/week, for a total of 15 sessions) combined with sham OVM (2 days/week with three-day intervals). Physical therapy consisted of hot pack application to the lumbar region for 20 min, conventional transcutaneous electrical nerve stimulation for 20 min, and ultrasound 1.5 W/cm^2 for 10 min.[20] Group 1 received additional OVM for two days a week with three-day intervals.[19] In Group 2, sham OVM was applied by performing light pressure and touches with the palm of the hand on the selected points for OVM without the intention of treating the patient.[19] Four experienced clinicians from four centers who performed OVM in this study completed their osteopathy training and received the Republic of Türkiye, Ministry of Health, Osteopathy Certificate. The OVM was applied on 10 regions in the abdomen by these clinicians.

Selection of regions

The pylorus, sphincter of Oddi, duodenojejunal flexure (DJF), ileocecal valve, sigmoid colon, liver, intestines, diaphragm, and kidneys were included in the study. A large part of the duodenum is fixed by the peritoneum to structures in the posterior abdominal wall at the level of the lumbar (L)1-3 vertebrae.[21] It is continuous with the pylorus and distally with the DJF. The sphincter of Oddi (hepatopancreatic ampulla) is located where the bile and main pancreatic ducts open. The mesentery, a fan-shaped fold of peritoneum, connects the convolutions of the jejunum and ileum with the posterior wall of the abdomen. The ileocecal valve on it divides the small and large intestines from each other. The sigmoid colon begins as a continuation of the descending colon and is connected to the anterior surface of the sacrum by the mesocolon. The liver is associated with the diaphragm by its diaphragmatic surface, with the right kidney and adrenal gland and with the duodenum by the hepatoduodenal ligament.[21] As a result of an ulcer in the pylorus, spasms usually occur. Pyloric spasms stop gastric motility and cause spasms of the descending duodenum, impairing the passage of digestive juices from the pancreas and gallbladder.[22] Hardening occurs secondary to pyloric spasms. The pylorus, sphincter of Oddi, gallbladder, DJF, and ileocecal junction are reflexogenic sites.[22]

According to Barral,[23] if one of the main sphincters of the digestive tract is in spasm, the rest would likely be very tense as well. Therefore, if the pylorus needs to be treated, the sphincter of Oddi, duodenojejunal junction, and ileocecal junction should be also evaluated.[23] The perirenal fascia is the collagenous connective tissue sheath which surrounds the perirenal space, including the kidney and adrenal gland. It is divided into anterior and posterior and joints with the medial diaphragm, iliac, phrenic, quadratus lumborum, and psoas major fascia. It is continuous with the anterior layer of the thoracolumbar fascia attached medially to the anterior surfaces of the lumbar transverse processes.[13] The lumbar portion of the diaphragm is attached to the anterior L1-4 vertebrae on the right and L1-2 vertebrae on the left.[24] Considering these fascial and anatomical connections between these visceral structures and the surrounding dorsolumbopelvic structures, we included these 10 regions in our study.

Anatomic localization

Pylorus is approximately 6 to 7 cm (five fingers) above the navel, slightly to the right of the midline.[23,25] The sphincter of Oddi is on the right midclavicular line, approximately two to three fingers above the navel. The DJF is on the left midclavicular line, two to three fingers above the navel. The ileocecal valve is located where the line drawn from the right spina iliaca anterior superior to the umbilicus intersects the right midclavicular line and is 2 cm above the McBurney point. The sigmoid colon is in the left iliac fossa and runs along the outer edge of the left psoas muscle, joining the rectum at the level of sacral (S)3 vertebra. The liver is located in the right costal arch and extends over the diaphragm to the fifth intercostal space. The small intestine starts at the pylorus and ends at the ileocecal valve. The kidneys are at the level of thoracic (T)11-L3 vertebrae, and the right kidney is 1 to 2 cm lower at the level of the navel, while the left kidney is 1 cm above the navel.[23,25] The diaphragm is attached laterally to the 11th and 12th ribs.[24]

In Group 1, pylorus, sphincter of Oddi, DJF, ileocecal valve, sigmoid colon, liver, small intestine, kidneys,[8,9] and diaphragm mobilization were applied.[25] Each technique was applied for 1 min.[8,9,25]

Application of techniques

Except for small intestine mobilization, the patients were placed in the supine position with their knees pulled with a pillow under their heads to reduce the tension on the abdominal wall during the application of other techniques.[8] For the pylorus, the practitioner stood on the left side of the patient, and small circular mobilizations were performed with the index and middle fingers following the loosening of the deep structures and the fascia slowly over the pylorus and entering posteriorly until the 0.5 to 1 cm pylorus was palpated. For the sphincter of Oddi, the practitioner stood on the right side of the patient, and small circular mobilizations were performed with the index and middle fingers over the sphincter of Oddi, slowly entering the posterior cranial by following the relaxation of the deep structures and fascia. For the DJF, the practitioner stood on the left side of the patient, and small circular mobilizations were performed with the index and middle fingers, following the gradual opening of the intestines and loosening of the fascia and entering posteriorly until a 0.5 to 1 cm pressure-sensitive point was palpated over the DJF. For the ileocecal valve, the practitioner stood on the right side of the patient, and small circular mobilizations were applied by entering posteriorly with the index and middle fingers over the ileocecal valve, slowly following the loosening of the deep structures and fascia until a firm, 0.5 to 1 cm, roughly hazelnut-sized, pressure-sensitive point was palpated. For the sigmoid colon, the practitioner stood on the right side of the patient, and the sigmoid colon was slowly mobilized from the lateral sigmoid to the navel by descending slowly from the medial of the left ilium to both hands. For the liver, the practitioner stood on the left side of the patient, and the liver was mobilized using the patient's legs in the frontal plane. For the small intestine, the patient was placed on their left side with the legs bent. Standing behind the patient, the abdomen was entered from the medial of the descending colon and the lateral of the small intestines with both hands pointing posteriorly. The small intestines were mobilized towards the right shoulder of the patient. For the kidneys, stood on the opposite side of the kidney to be mobilized. The right kidney was mobilized craniomedially from roughly the level of the patient's ileocecal valve along the medial side of the ascending colon while the patient was exhaling. The left kidney was mobilized craniomedially from roughly the level of the patient's sigmoid colon along the medial edge of the descending colon as the patient exhaled. For the diaphragm, the practitioner stood on the side of the patient, and pressure was applied by grasping the ribs from below with both hands and mobilized indirectly over the thorax, alternately to the right and left (Figure 1).[25]

Outcome measures and assessment

All patients were evaluated before and after treatment and at week four after the end of the treatment. A detailed inquiry and physical examination of all patients were performed. The pain severity was assessed using the VAS on a 10-cm line, with 0 indicating no pain and 10 the worst pain.[26]

The Beck Depression Inventory (BDI) was used to assess depression, which was developed by Beck et al.[27] The validity and reliability studies of the scale in the Turkish population were conducted by Hisli[28] Beck Depression Inventory is a 21-item, self-report scale that evaluates the symptoms and severity of depression. The score ranges from 0 to 63: 0-13, no depression; 14-19, mild depression; 20-28, moderate depression; 29-63, severe depression.[28]

The Roland-Morris Low Back Pain and Disability Questionnaire (RMDQ) was used to evaluate functional disability and was developed by Roland and Morris.[29] The validity and reliability studies of the scale in the Turkish population were conducted by Küçükdeveci et al.[30] It is a 24-item self-report questionnaire with binary questions. Each "Yes" answer is given 1 point, and a "No" answer is given 0 points, with a total score ranging from 0 to 24. Higher scores indicate more severe disability.[29]

Statistical analysis

A power analysis and sample size calculation were performed using the G*Power version 3.1.7 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). In the study of Villalta Santos et al.,[8] minimum 39 patients in each group were required (total n=78) to achieve 80% study power according to the pre- and post-treatment RMDQ scores. Considering a 10% dropout rate, a total of 43 patients in each group were recruited.

Statistical analysis was performed using Number Cruncher Statistical System version 20 software (NCSS LLC, Kaysville, UT, USA). Descriptive data were expressed as mean ± standard deviation (SD), median (min-max), or number and frequency. The Shapiro-Wilk test was used to check for the normality of the distribution of quantitative variables. Repeated measures of variance analysis was used to compare repeated measures of quantitative variables with normal distribution, and the Bonferroni test was used for post hoc evaluations. The Friedman test was used to compare repeated measures of VAS and RMDQ variables that were nonnormally distributed, and the Dunn test was used for post hoc comparisons. Student's t-test was used to compare two independent groups with normal distribution. The Mann-Whitney U test was used in the comparison of two independent groups that were nonnormally distributed. The Pearson chi-square test, Fisher precision test, and Fisher-Freeman-Halton precision tests were used to compare qualitative variables. A p-value <0.05 was considered statistically significant.

RESULTS

In Group 1, three patients (one male and two females) withdrew from the study due to the increased severity of pain (one patient during the third session). Two patients also withdrew from the study after the treatment and at week four after the treatment, respectively, due to the lack of attendance to the follow-up visits. In Group 2, four patients (one male and three females) withdrew from the study due

Figure 1. The application of the techniques.

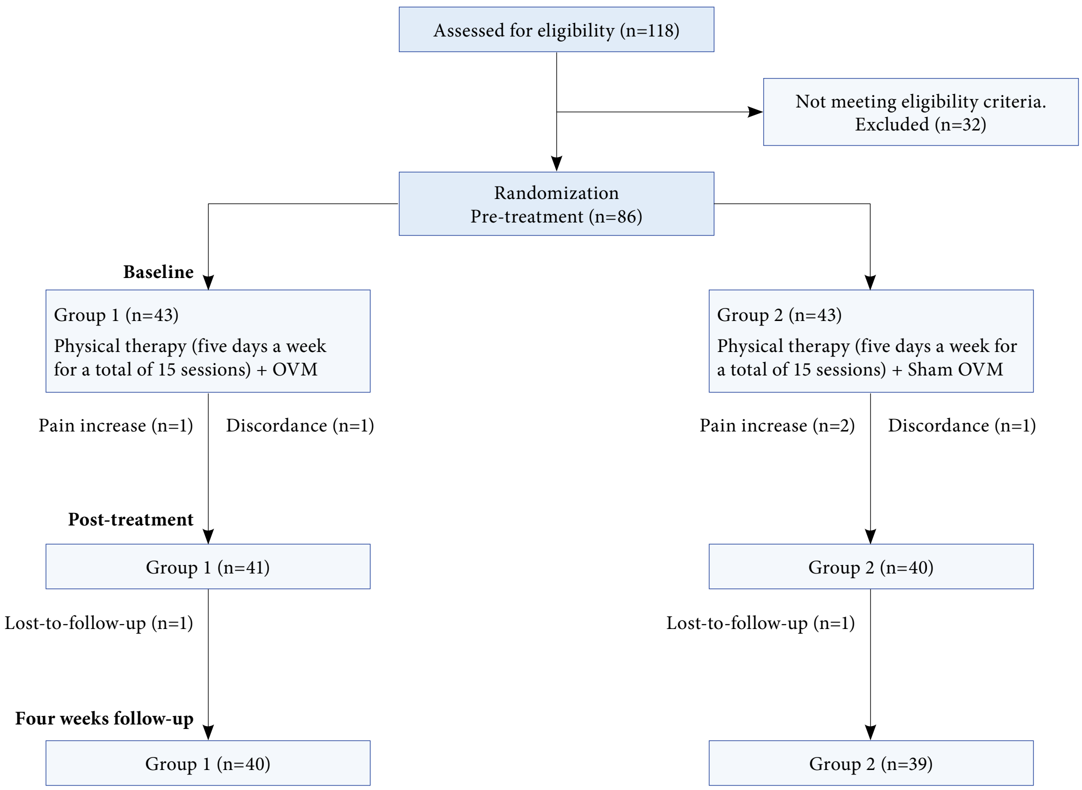

Figure 2. Flow chart of the study sample.

TABLE 1
Descriptive characteristics of patients

	n	%	Mean±SD	Median	Min-Max
Age (year)			46.9±14.1	47	19-75
Sex					
Female	54	68.4			
Male	25	31.6			
Employment status					
Worker	21	26.6			
Housewife	24	30.4			
Retired	21	26.6			
Other	13	16.5			
Education status					
Primary school	31	39.2			
Secondary/high school	23	29.1			
University	25	31.6			
Marital status					
Single	27	34.2			
Married	52	65.8			
Height (cm)			165.03±7.30	165	152-185
Body weight (kg)			69.52±10.08	68	42-94
Body mass index (kg/m²)			25.59±3.21	25.6	15.4-32.9
Disease duration (month)			18.06±17.01	12	4-72

SD: Standard deviation.

TABLE 2
Descriptive characteristics of patients according to groups

	Group 1					Group 2					
	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max	*p*
Age (year)			46.9±13.4	48	25-75			46.9±15.0	46	19-74	0.987[c]
Sex											0.869[a]
Female	27	67.5				27	69.2				
Male	13	32.5				12	30.8				
Employment status											1.000[b]
Worker	11	27.5				10	25.6				
Housewife	12	30.0				12	30.8				
Retired	10	25.0				11	28.2				
Other	7	17.5				6	15.4				
Education status											1.000[b]
Primary school	16	40.0				15	38.5				
Secondary/high school	12	30.0				11	28.2				
University	12	30.0				13	33.3				
Marital status											1.000[a]
Single	14	35.0				13	33.3				
Married	26	65.0				26	66.7				
Height (cm)			165.18±7.42	164.5	152-185			164.87±7.26	165	153-183	0.855[c]
Body weight (kg)			70.03±10.28	68.5	42-94			69.00±9.99	68	46-94	0.654[c]
Body mass index (kg/m²)			25.62±2.85	25.6	15.4-31.2			25.57±3.58	25.6	17.1-32.9	0.944[c]
Disease duration (month)			17.98±16.49	12	4-60			18.15±17.74	12	4-72	0.961[d]

SD: Standard deviation; [a] Pearson Chi-Square test; [b] Fisher-Freeman-Halton test; [c] Student T-test; [d] Mann-Whitney U test.

TABLE 3
Visual analog scale scores according to groups

	Pre-treatment		Post-treatment		Week 4 post-treatment			
VAS scores	Median	Min-Max	Median	Min-Max	Median	Min-Max	p^a	Post hoc Dunn test†
Group 1	6	4-10	3	1-6	1	0-5	0.001*	1>2, 3 2>3
Group 2	6	4-10	5	2-10	4	1-6	0,001*	1>2, 3 2>3
p	0.867‡		0.001*‡		0.001*‡			

VAS: Visual Analog Scale; † Friedman test, post hoc Dunn test; ‡ Mann-Whitney U Test * p<0.01.

TABLE 4
Beck Depression Inventory scores according to groups

	Pre-treatment	Post-treatment	Week 4 post-treatment		
	Mean±SD	Mean±SD	Mean±SD	*p*†	Post hoc Bonferroni
Group 1	15.43±5.83	7.70±3.93	3.15±2.73	0.001*	1>2. 3 2>3
Group 2	15.26±5.30	11.64±4.26	8.41±3.39	0.001*	1>2. 3 2>3
p	0.893‡	0.001*‡	0.001*‡		

BDI: Beck Depression Inventory; SD: Standard deviation; † Repeated Measures test post hoc Bonferroni test; ‡ Student t-test; * p<0.01.

TABLE 5
Roland-Morris Low Back Pain and Disability Questionnaire scores according to groups

	Pre-treatment		Post-treatment		Week 4 post-treatment			
RMDQ	Median	Min-Max	Median	Min-Max	Median	Min-Max	*p*†	Post hoc Dunn test
Group 1	14,5	4-24	7	1-15	3	0-9	0.001*	1>2, 3 2>3
Group 2	15	4-20	12	2-16	9	1-14	0.001*	1>2, 3 2>3
p	0.867‡		0.001*‡		0.001*‡			

RMDQ: Roland-Morris Disability Questionnaire; † Friedman test, post hoc Dunn test; ‡ Mann-Whitney U test; * p<0.01

to the increased severity of pain (one patient during the fourth session and one patient after the seventh session). Two patients also withdrew from the study after the treatment and at week four after the treatment, respectively, due to the lack of attendance to the follow-up visits. Three patients who withdrew from the study due to severe pain were referred to the neurosurgery department and were operated. The study was completed with 79 patients (25 males, 54 females; mean age: 46.9±14.1 years; range, 19 to 75 years; Figure 2).

Demographic and clinical characteristics of the patients are summarized in Table 1. Table 2. There was no significant difference in the age, sex, occupation, education status, marital status, body weight, body mass index, and height between the groups (p>0.05).

There was no significant difference in the mean VAS scores between the groups before the treatment (p=0.955). However, the intragroup analysis showed a significant difference in the VAS scores before and after treatment and at week four in both groups (p=0.001). The intergroup analysis showed a significant difference in the VAS scores after the treatment and at week four compared to pre-treatment scores, with a higher difference in Group 1 than in Group 2 (p=0.001, Table 3).

There was no significant difference in the mean BDI scores between the groups before the treatment (p=0.893). However, the intragroup analysis showed a significant difference in the BDI scores before and after treatment and at week four in both groups (p=0.001). The intergroup analysis showed a significant difference in the BDI scores after the treatment and at week four compared to pre-treatment scores, with a higher difference in Group 1 than in Group 2 (p=0.001, Table 4).

There was no significant difference in the mean RMDQ scores between the groups before the treatment (p=0.867). However, the intragroup analysis showed a significant difference in RMDQ scores before and after treatment and at week four in both groups (p=0.001). The intergroup analysis showed a significant difference in the RMDQ scores after the treatment and at week four compared to pre-treatment scores, with a higher difference in Group 1 than in Group 2 (p=0.001, Table 5).

DISCUSSION

In the present study, we evaluated the effectiveness of OVM combined with physical therapy in pain, depression, and functional impairment in patients with chronic mechanical LBP. Despite widespread use of physical therapy modalities in these patients,[17,18] there is a limited number of studies investigating the effectiveness of OVM in the literature.[7,8,10,12-14,19,31] Some authors have proposed that OVM is effective in the treatment of chronic LBP,[7,10,12-14,31] while others have concluded that OVM does not provide an additional contribution with a minimal pain relief.[8,19]

Some studies selected different visceral organs.[8,12-14,19,31,32] Namely, kidneys,[13,14] sigmoid colon,[10] thorax, subdiaphragmatic, abdomen, pelvis,[19] liver, thorax, diaphragm, pelvic base,[31] cardia, pylorus, sphincter of Oddi, DJF, ileocecal valve, sigmoid colon, liver, global hemodynamic, and respiratory parameters[8] were chosen. Considering there is no consensus on the selection of body regions for OVM in LBP, treatment may yield different results.

In the study of Panagopoulos et al.,[19] standard physiotherapy combined with thoracic, subdiaphragmatic, abdominal, and pelvic OVM was compared with sham OVM. At weeks 2, 6, and 52, there was no significant difference in pain, disability, and function scores between the groups. In another study, standard physical therapy modalities combined with OVM for the cardia, pylorus, sphincter of Oddi, DJF, ileocecal valve, sigmoid colon, and liver, global hemodynamic and respiratory inspiration and expiration were compared, and no significant difference in the pain perception and functionality was observed between the OVM and sham OVM groups.[8] However, OVM improved lumbar spine movement and specific functionality over time. Although the vast majority of visceral organs used in the aforementioned studies are similar to ours, the pain and functional disability scores are different. This can be attributed to the different patient groups, age range, body weight, and treatment protocols. In addition, different training and experience levels of the clinicians may have played a role in obtaining different results.

In a systematic review, Mirza et al.[7] reported that visceral manipulation and mobilization were effective in pain relief. In another systematic review investigating the effect of visceral mobilization on nonspecific LBP symptoms, OVM was shown to be effective and could improve the visceral motion.[10]

In a study, Tamer et al.[31] compared physiotherapy modalities, such as osteopathic manual therapy (OMT), spinal stabilization, and strengthening and stretching exercises, and concluded that visceral OMT improved pain, functional disability, and quality of life of patients. In this study, visceral OMT was shown to be more effective than OMT to improve quality of life. In another study, Tozzi et al.[13] reported a lower rate of kidney motility in patients with LBP than in asymptomatic individuals. The authors concluded that OVM was an effective manual technique in improving kidney motility and pain perception in the short term. Furthermore, the studies of Lo Basso et al.[14] and Tozzi et al.[13] showed that manipulation techniques significantly increase the motility of the right kidney, decrease pain perception in the short term, and improve the motility of the lumbar spine in patients with nonspecific LBP related to urinary tract infection. Similar to these studies, we evaluated the kidneys in our study. The outcomes for pain and functional status of our study are also consistent with these studies. In our study, OVM was applied to the pylorus, sphincter of Oddi, DJF, ileocecal valve, sigmoid colon, liver, small intestines, diaphragm, and kidneys, considering the fascial and anatomic connections between the visceral organs and the surrounding dorsolumbarpelvic structures, consistent with the literature.

A previous study showed that there were viscerosomatic interactions between the lumbosacral joint of the uterus and muscles of the L2 vertebra and surroundings.[33] Therefore, the uterus should be included in women with LBP. As both male and female patients were included in our study, the uterus was not selected for OVM application.

A review of the literature reveals no study investigating the effect of OVM on depression in chronic mechanical LBP. However, it has been shown that chronic pain significantly affects psychological well-being and is associated with depression symptoms in 30 to 60% of cases.[1] The prevalence of major depression is three- to four-fold higher among chronic LBP patients compared to the general population,[34] and depression symptoms are the leading cause of disability in LBP patients.[35] Altogether, the effectiveness of OVM in the treatment of chronic mechanical LBP and depression appears beneficial in providing pain relief and improving depression symptoms.

The relatively short follow-up is the main limitation of this study. The main strengths of the study are its multicenter, randomized-controlled design and adequate sample size.

In conclusion, OVM combined with physical therapy is useful to improve pain, depression, and functional impairment in patients with chronic mechanical LBP. We believe that the widespread use of OVM may contribute to the treatment success by improving pain, functional disability, and depression and may provide additional benefits in patients with chronic LBP who are unresponsive or do not respond adequately to conventional physical therapy modalities. Further large-scale multicenter studies investigating different OVM techniques or the combination of OVM with different modalities are warranted to establish the value of OVM in the treatment protocol of LBP.

Ethics Committee Approval: The study protocol was approved by the Clinical Research Ethics Committee (date: 18.11.2020, no: 2020/0661). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article. All authors read and approved the final manuscript.

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