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The Effect of Ultrasound-Mediated Drug Delivery Combined with Core Muscle Group Training on the Lumbar Spine of Patients with Chronic Low Back Pain

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Abstract: *Objective*: To investigate the effects of ultrasound-mediated drug delivery combined with core muscle group training on lumbar spine function, pain intensity, and muscle function in patients with chronic low back pain (CLBP), providing evidence-based support for clinical treatment. *Methods*: A total of 120 CLBP patients admitted to the Department of Orthopedics in our hospital from January 2023 to December 2024 were selected as research subjects. They were randomly divided into a control group (n = 60) and an observation group (n = 60) using a random number table method. The control group received ultrasound-mediated drug delivery treatment alone, while the observation group received a combination of ultrasound-mediated drug delivery and core muscle group training. Both groups underwent continuous treatment for 8 weeks. The Visual Analogue Scale (VAS) scores, Oswestry Disability Index (ODI), and clinical efficacy were compared between the two groups before treatment, at 4 weeks, and at 8 weeks after treatment. *Results*: Before treatment, there were no statistically significant differences in VAS scores, ODI, or lumbar spine range of motion between the two groups ($p > 0.05$). After 4 and 8 weeks of treatment, both groups showed a significant decrease in VAS scores and ODI compared to before treatment ($p < 0.05$), with the observation group having lower scores than the control group ($p < 0.05$). The total effective rate in the observation group after 8 weeks of treatment was 93.33% (56/60), which was higher than the 78.33% (47/60) in the control group, with a statistically significant difference ($p < 0.05$). *Conclusion*: Ultrasound-mediated drug delivery combined with core muscle group training can effectively alleviate pain intensity, improve lumbar spine function and range of motion, enhance core muscle strength, and demonstrate good safety in CLBP patients. It is worthy of clinical promotion and application.

Keywords: Chronic low back pain; Ultrasound-mediated drug delivery; Core muscle group training; Lumbar spine function

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1. Introduction

Chronic low back pain (CLBP) is a common clinical condition in orthopedic surgery, characterized by lumbar pain or discomfort lasting more than 12 weeks, often accompanied by symptoms such as restricted lumbar mobility and radiating pain in the lower extremities, which severely impacts patients' quality of daily life and work capacity [1]. Epidemiological surveys indicate that the global incidence of CLBP is approximately 18–45%, and it has shown a trend of affecting younger populations in recent years, imposing a significant burden on social healthcare resources [2]. Currently, conservative treatments are the mainstay for CLBP management, including pharmacological therapy, physical therapy, and rehabilitation training. However, the efficacy of a single treatment modality is often limited: while pharmacological therapy alone can provide short-term pain relief, its long-term use is prone to causing gastrointestinal adverse reactions; physical therapy alone, such as ultrasound therapy has a weak effect on improving lumbar stability; and rehabilitation training alone is associated with slow pain relief [3].

Ultrasound drug delivery technology is a novel physical therapy modality that utilizes the mechanical vibration and thermal effects of ultrasound to disrupt the stratum corneum barrier of the skin, facilitating the targeted penetration of drug molecules into the affected area, achieving "targeted drug delivery" and combining the dual advantages of physical and pharmacological therapies [4]. The core muscle group, which includes the erector spinae, transverse abdominis, and multifidus muscles, is a critical structure for maintaining lumbar stability. Weakened or imbalanced function of the core muscle group is an important pathophysiological basis for the onset of CLBP [5]. Based on this, the present study proposes a synergistic treatment approach combining "ultrasound drug delivery with core muscle group training," hypothesizing that the two modalities can achieve a therapeutic effect greater than the sum of their individual effects ($1 + 1 > 2$) through a progressive mechanism of "pain relief-lumbar stabilization-repair." This study aims to compare and analyze the effects of ultrasound drug delivery alone versus the combined treatment on lumbar function and pain intensity in patients with CLBP, providing high-quality evidence-based data for optimizing clinical treatment strategies for CLBP.

2. Materials and methods

2.1. General information

Patients with CLBP admitted to the Orthopedics Department of our hospital from January 2023 to December 2024 were selected as the study subjects. The sample size was estimated based on the results of a preliminary experiment: setting $\alpha = 0.05$ and $\beta = 0.20$, and assuming a 15% difference in the overall response rate between the two groups, a sample size of 52 patients per group was required. Considering a 15% dropout rate, the final sample size was determined to be 60 patients per group, totaling 120 patients, continuous variables were expressed as $\bar{x} \pm s$ (mean ± standard deviation).

2.1.1. Inclusion criteria

(1) Meeting the diagnostic criteria for CLBP in the "Guidelines for the Diagnosis and Treatment of CLBP (2022 Edition)": persistent low back pain lasting ≥ 12 weeks with a Visual Analog Scale (VAS) score ≥ 4

(2) Aged between 25 and 65 years

(3) Exclusion of organic diseases such as lumbar fractures, tumors, tuberculosis, and severe lumbar disc herniation (protrusion compressing nerve roots with decreased muscle strength) based on lumbar imaging examinations (X-ray, CT, or MRI)

(4) No history of lumbar injection therapy, physical therapy, or rehabilitation training in the past month.

2.1.2. Exclusion criteria

(1) Patients with severe cardiovascular and cerebrovascular diseases, hepatic and renal insufficiency, or coagulation disorders
(2) Patients with skin allergies or skin damage, infection, or eczema on the lumbar area which may affect ultrasound-mediated drug delivery
(3) Pregnant or lactating women
(4) Patients with severe cognitive impairment, mental illness, or those unable to cooperate with the training
(5) Patients with contraindications to core muscle group training, such as severe osteoporosis or abdominal hernia). There were no statistically significant differences in general information such as gender, age, disease duration, body mass index (BMI), and pain location between the two groups ($p > 0.05$), indicating comparability (**Table 1**).

Table 1. General information

Indicator	Control group (n = 60)	Observation group (n = 60)	t/χ^2	p
Gender (Male/Female, n)	32/28	34/26	0.133	> 0.05
Age (years, $\bar{x} \pm s$)	45.62 ± 8.35	46.18 ± 7.92	0.382	> 0.05
Disease Duration (years, $\bar{x} \pm s$)	3.85 ± 1.26	4.02 ± 1.31	0.701	> 0.05
BMI (kg/m², $\bar{x} \pm s$)	23.85 ± 2.16	24.12 ± 2.08	0.683	> 0.05
Pain Location (n)				
Lumbosacral Region	38	36	0.568	> 0.05
Lumbodorsal Region	22	24		

2.2. Methods

Both groups of patients received basic nursing care: avoiding prolonged sitting or standing, lifting heavy objects with a bent waist, and being instructed on proper sitting and sleeping postures (using a thin pillow under the waist when lying supine), with a daily water intake of ≥ 1500 mL.

2.2.1. Control Group: Ultrasound-mediated drug delivery therapy alone

(1) Equipment and medication

The DS-UCMF2B ultrasonic electroconductive directional drug delivery therapy device from Nanjing Dingshi (frequency: 1.0 MHz, adjustable output power: 0–3 W/cm²) was used. The medication selected was Qingpeng Ointment (Tibet Qizheng Tibetan Medicine Co., Ltd., National Medical Product Approval Number Z54020140, specification: 55 g/tube).

(2) Operational method

The patient was positioned prone, exposing the painful area of the waist. A sterile gauze (8 cm × 10 cm) soaked in the medication was placed over the painful point. After applying a coupling agent to the ultrasonic probe, it was placed on the gauze. The probe was adjusted to be perpendicular to the skin, with the output power set at 1.5 W/cm². The treatment duration was 20 minutes per session, once daily, five times per week, for a continuous period of eight weeks. During the treatment, the patient's skin condition was closely monitored. If redness, swelling, or a stinging sensation occurred, the treatment was immediately suspended.

2.2.2. Observation group: Ultrasonic drug delivery combined with core muscle group training

The ultrasonic drug delivery procedure was conducted once daily in the morning, following the same protocol as that of the control group.

The core muscle group training was performed every afternoon under the guidance of rehabilitation therapists. The training program was designed in accordance with the Guidelines for Rehabilitation Medicine (2nd Edition) and implemented over a total period of eight weeks, progressing through three stages of increasing difficulty, each lasting two weeks.

Phase I (Weeks 1–2, Basic Activation Phase) focused on activating and improving control of the deep core muscles to enhance trunk stability. Exercises included Diaphragmatic Breathing, performed in a supine position with knees bent and hands placed on the abdomen. Patients inhaled slowly through the nose, allowing the abdomen to rise, and exhaled through the mouth while the abdomen fell, completing 10 repetitions per set, 3 sets per day. Then, Gluteal Bridge Exercise, performed by lying supine with knees bent and feet flat on the ground. The hips were slowly lifted until the torso and thighs formed a straight line, held for 3 seconds, and then lowered, for 15 repetitions per set, 3 sets per day. Next is the Bird-Dog Exercise, performed in a quadruped position. Patients extended the opposite arm and leg simultaneously, maintaining trunk stability, held for 2 seconds, then returned to the starting position, alternating sides for 10 repetitions per side, 3 sets per day.

Phase II (Weeks 3–4, Muscle Strength Enhancement Phase) aimed to further strengthen the abdominal and back muscles. The exercises included the Dead Bug Exercise, performed by lying supine with hips and knees at 90° and arms extended upward. The opposite arm and leg were lowered simultaneously until close to the ground, held for 1 second, then returned, alternating sides for 12 repetitions per side, 3 sets per day. Next is the Side Bridge Exercise, in which patients supported their body on one elbow, lifting the hips to form a straight line, held for 5 seconds, then lowered, for 10 repetitions per side, 3 sets per day. Besides, the Superman Exercise, performed in a prone position, lifting the chest and legs 5–10 cm off the bed, holding for 3 seconds, then lowering, for 12 repetitions per set, 3 sets per day.

Phase III (Weeks 5–8, Endurance Strengthening Phase) emphasized improving muscular endurance and dynamic stability. The exercises included Plank Exercise, performed by supporting the body with elbows and toes, maintaining a straight alignment for 30–60 seconds per repetition, 5 repetitions per set, 2 sets per day. Single-Leg Glute Bridge Exercise, performed supine with one knee bent and the other leg extended. The hips were lifted until the torso and supporting leg formed a straight line, held for 5 seconds, then lowered, for 12 repetitions per side, 3 sets per day, and the Dynamic Bird-Dog Exercise, performed from a four-point kneeling position, extending the opposite arm and leg, then bringing them toward the body until the elbow and knee touched, before returning to the start position, for 10 repetitions per side, 3 sets per day.

Throughout the training process, rehabilitation therapists provided real-time supervision to ensure correct posture and prevent compensatory movements such as excessive lumbar extension or pelvic sagging. If any participant experienced lumbar pain with a Visual Analog Scale (VAS) score of 6 or higher, training was immediately suspended and reassessed before continuation.

2.3. Observation indicators

2.3.1. Pain assessment

The Visual Analog Scale (VAS) is used for assessment: On a 10 cm line, the left end is labeled “0 points” (no pain) and the right end is labeled “10 points” (severe pain). Patients mark their perceived pain level on the line, and the

distance from the left end to the marked point is the VAS score. Assessments are conducted before treatment, at 4 weeks of treatment, and at 8 weeks of treatment.

2.3.2. Lumbar spine function assessment

The Oswestry Disability Index (ODI) was used for assessment, encompassing 10 dimensions including pain intensity, activities of daily living, lifting, walking, sitting, standing, sleeping, sexual life, social activities, and traveling. Each dimension was scored from 0 to 5, with a total score ranging from 0 to 50. A higher score indicates more severe lumbar spine dysfunction. Assessments were conducted before treatment, at 4 weeks of treatment, and at 8 weeks of treatment.

2.3.3. Clinical efficacy evaluation

The clinical efficacy evaluation result was formulated in accordance with the "Diagnostic and Therapeutic Efficacy Criteria for TCM Diseases and Syndromes" and was generally classified into four categories.

(1) Cure

Complete disappearance of low back pain, with a VAS score ≤ 1 point, an ODI score ≤ 5 points, and the restoration of normal lumbar spine range of motion (flexion ≥ 80°, extension ≥ 30°, lateral flexion ≥ 35°), enabling normal daily life and work

(2) Significant improvement

Marked relief of low back pain, with a VAS score reduction ≥ 50%, an ODI score reduction ≥ 40%, and an increase in lumbar spine range of motion by ≥ 30% compared to before treatment

(3) Effective

Some relief of low back pain, with a VAS score reduction of 25% to 49%, an ODI score reduction of 20% to 39%, and an increase in lumbar spine range of motion by 10% to 29% compared to before treatment

(4) Ineffective

Failure to meet the aforementioned criteria for effectiveness. The overall effectiveness rate = (Number of cured cases + Number of significantly improved cases + Number of effective cases) / Total number of cases × 100%. The therapeutic effect was evaluated at 8 weeks post-treatment.

2.4. Statistical methods

Data analysis was performed using SPSS 26.0 statistical software. Continuous variables were expressed as "$\bar{x} \pm s$". For variables that follow a normal distribution and exhibit homogeneity of variance, paired *t*-tests were used for within-group comparisons before and after treatment, while independent sample *t*-tests were used for between-group comparisons.

Categorical variables are expressed as "number of cases (%)", and comparisons were made using the χ^2 test. Ranked data (therapeutic efficacy) were compared using the rank-sum test. A *p*-value of < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of VAS scores before and after treatment in both groups

Before treatment, there was no statistically significant difference in VAS scores between the two groups ($p > 0.05$). After 4 and 8 weeks of treatment, VAS scores in both groups significantly decreased compared to before

treatment ($p < 0.05$), with the observation group having lower scores than the control group, and the difference was statistically significant ($p < 0.05$) (**Table 2**).

Table 2. Comparison of VAS scores before and after treatment in both groups

Group	n	Before treatment	4 weeks of treatment	8 weeks of treatment
Control	60	6.85 ± 1.02	4.23 ± 0.85	2.96 ± 0.71
Observation	60	6.92 ± 1.05	3.15 ± 0.78	1.58 ± 0.63
t-value	-	0.352	6.824	11.267
p-value	-	0.725	< 0.05	< 0.05

3.2. Comparison of ODI index between the two groups before and after treatment

Before treatment, there was no statistically significant difference in the ODI index between the two groups ($p > 0.05$). After 4 and 8 weeks of treatment, the ODI index in both groups significantly decreased compared to that before treatment ($p < 0.05$), with the observation group showing a lower index than the control group, and the difference was statistically significant ($p < 0.05$) (**Table 3**).

Table 3. Comparison of ODI index between the two groups before and after treatment

Group	n	Before treatment	4 weeks of treatment	8 weeks of treatment
Control	60	32.56 ± 4.28	21.35 ± 3.86	15.82 ± 3.15
Observation	60	33.12 ± 4.35	15.68 ± 3.24	8.95 ± 2.67
t-value	-	0.673	8.251	12.834
p-value	-	0.502	< 0.05	< 0.05

3.3. Comparison of clinical efficacy between the two groups

After 8 weeks of treatment, the total effective rate in the observation group was 93.33%, which was higher than the 78.33% in the control group, and the difference was statistically significant ($p < 0.05$) (**Table 4**).

Table 4. Comparison of clinical efficacy between the two groups

Efficacy Grade	Control Group (n = 60)	Observation Group (n = 60)
Cured (n)	8	22
Markedly Effective (n)	18	25
Effective (n)	21	9
Ineffective (n)	13	4
Total Effective Rate (%)	78.33	93.33
Z-value	-	2.853
p-value	-	0.004

4. Discussion

The ultrasound-mediated drug delivery technique promotes drug penetration through a dual mechanism of "cavitation effect" and "thermal effect": The mechanical vibration of ultrasound can disrupt the lipid bilayer of the stratum corneum, forming temporary "pores" and increasing skin permeability. Simultaneously, the local thermal effect generated by ultrasound can dilate capillaries, accelerate blood circulation, and provide the driving force for the diffusion of drug molecules [6]. The results of this study indicate that the VAS scores and ODI index in the observation group were significantly lower than those in the control group after 4 and 8 weeks of treatment, with a total effective rate of 93.33%. This suggests that the combined treatment regimen has significant advantages in the treatment of CLBP.

The core muscle group serves as the "internal scaffold" for maintaining lumbar spine stability. Weakening of its function can lead to biomechanical imbalance in the lumbar spine, increasing intervertebral disc pressure and facet joint wear, thereby forming a vicious cycle of "pain-muscle atrophy-dysfunction" [7,8]. The stepped core muscle group training program adopted in this study adheres to the rehabilitation logic of "activation–enhancement–strengthening".

In the first stage, actions such as abdominal breathing and gluteal bridge are employed to activate deep core muscle groups, including the transverse abdominis and multifidus, thereby improving muscle recruitment capabilities. In the second stage, exercises like the dead bug and side plank are utilized to enhance the strength of the core muscle groups, thereby boosting the lumbar spine's resistance to load. In the third stage, actions such as plank and single-leg gluteal bridge are used to strengthen muscular endurance, maintaining long-term stability [9].

While simple ultrasound drug delivery can provide short-term pain relief, it fails to improve lumbar spine stability, leading to a high likelihood of recurrence after medication cessation. In the early stages of simple core muscle group training, patient compliance is often poor due to pain, limiting training effectiveness. However, the combined treatment achieves "complementary advantages": ultrasound drug delivery rapidly alleviates pain, enhancing patient tolerance to training; core muscle group training strengthens lumbar spine stability, reducing pain recurrence, and creating a virtuous cycle of "pain relief–training–spinal stabilization - pain reduction" [10]. Additionally, core muscle group training promotes blood circulation in the lumbar region, accelerating the excretion of drug metabolites and reducing the risk of drug accumulation. Ultrasound drug delivery relieves muscle spasms, providing a more favorable environment for core muscle contractions and further enhancing training effectiveness.

The clinical value of this study lies in first, proposing a synergistic treatment approach combining "physical therapy + rehabilitation training," offering a new option for conservative treatment of CLBP; then employing a stepped core muscle group training program that balances safety and effectiveness, suitable for patients with varying functional levels.

This study has the following limitations, where this study consists with a sample size of only 120 cases and being a single-center study, selection bias may exist, and the generalizability of the results requires validation through multi-center, large-sample studies. Besides that, the follow-up period is only 8 weeks, failing to observe long-term efficacy such as recurrence rates at 6 months and 1 year, necessitating further extension of the follow-up period. Moreover, the study did not analyze efficacy differences among patients with varying disease durations and ages. Subsequent research could conduct subgroup analyses to provide evidence for individualized treatment.

5. Conclusion

In conclusion, the combination of ultrasound-mediated drug delivery and core muscle group training can

effectively alleviate pain in patients with CLBP, improve lumbar spine mobility, enhance the muscle strength and stability of the core muscle group, and demonstrate good safety. This combined treatment approach is simple to operate and cost-effective, making it suitable for promotion and application in primary-level hospitals. It can serve as one of the preferred conservative treatment options for patients with CLBP.

Disclosure statement

The author declare no conflict of interest.

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