

Randomized Controlled Trial

# Comparison of Different Treatment Regimens of Extracorporeal Shockwave Therapy in Chronic Low-back Pain: A Randomized Controlled Trial

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**Background:** Extracorporeal shockwave therapy (ESWT) has shown its efficacy in treating chronic pain. Previous evidence has proven that ESWT in patients with chronic low-back pain (CLBP) results in significant reductions in pain. However, the optimal regimen for conducting ESWT in these patients remains unknown.

**Objectives:** This study aimed to investigate, under the same total energy dose, the effectiveness and safety of low-intensity versus medium-intensity ESWT on CLBP.

**Study Design:** A prospectively registered, randomized controlled trial in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement. The study was registered at the Chinese Clinical Trial Registry (No. ChiCTR2100049871). This study was approved by the ethics committee of our hospital (No.2021-193).

**Setting:** A tertiary hospital in China.

**Methods:** Sixty-nine patients with CLBP were randomly allocated into either the low-intensity (LI) or the medium-intensity (MI) group. In a 2-week treatment course, patients in the LI group received 6 sessions of ESWT (0.03 millijoules [mJ]/mm<sup>2</sup>) and patients in MI group received 2 sessions of ESWT (0.09 mJ/mm<sup>2</sup>). Outcome assessments included the Visual Analog Scale (VAS) at rest and at movement, the Oswestry Disability Index (ODI), and the Hospital Anxiety and Depression Scale (HADS). Follow-up visits were scheduled at 2 weeks, 4 weeks, 6 weeks, and 3 months after randomization. The primary outcome was the 11-point VAS at movement reported at 4 weeks after randomization. Adverse events were recorded. Overall therapeutic satisfaction on a 5-point Likert scale was collected at the last follow-up.

**Results:** From August 2021 through December 2021, 69 eligible patients were enrolled in the randomized controlled trial; 68 patients completed the whole treatment. Compared with baseline, both the LI group and MI group manifested significant improvement in VAS, ODI, and HADS scores at each follow-up time point (all  $P < 0.05$ ). The between-group comparison indicated that the LI group had lower VAS scores at movement at 2 weeks, 4 weeks and 6 weeks after randomization (all  $P < 0.05$ ), while the VAS score at rest was significantly lower in the LI group than in the MI group ( $P = 0.018$ ) at 6 weeks after randomization. The ODI score in the LI group was significantly lower than the MI group at 2 weeks and 6 weeks after randomization (both  $P < 0.05$ ). In addition, the HADS score was lower in the LI group than the MI group at 2 weeks after randomization ( $P = 0.021$ ). However, at 3-months follow-up, no significant difference in VAS, ODI, or HADS were observed between the 2 groups. No notable shockwave-related side effects occurred in either group.

**Limitation:** The limitations of our study include the small sample size and the lack of an untreated control group.

**Conclusion:** Low-intensity ESWT treatment with more sessions is more effective in relieving pain and improving disability in the short-term than medium-intensity treatment with fewer sessions under the same total energy dose.

**Key words:** Low back pain, extracorporeal shockwave therapy, randomized controlled trial, rehabilitation

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Low back pain is a common, recurrent, and disabling musculoskeletal disorder in all age groups; its lifetime prevalence is estimated to be as high as 84% and the point prevalence is 25% (1,2). The global burden of low back pain has not shown any signs of decrease in the past decades, and the population will probably continuously experience elevated rates of disability as life expectancy increases (3). Chronic low back pain (CLBP) is commonly defined as low back pain lasting longer than 12 weeks. Most current practice guidelines are in general agreement and advise physical activity and pharmacotherapy combined with multidisciplinary, psychosocial, and behavioral approaches. Despite active treatment, symptoms might recover within 12 months in one-third to two-thirds of treated patients, indicating the need for more effective treatment options (4,5).

Extracorporeal shockwave therapy (ESWT), a non-invasive approach that passes pressure waves through the skin to the affected area, has shown efficacy in treating chronic painful musculoskeletal conditions due to its anti-inflammatory, tissue repair, and regeneration induction effects (6). Our previous systematic review proved that ESWT in patients with CLBP results in significant and quantifiable reductions in pain and disability in the short-term, along with negligible side effects (7). However, the optimal regimen in conducting ESWT in patients with CLBP remains unknown. An *ex vivo* study has shown that a low-intensity approach with a greater number of shocks is more favorable for enhancing cellular activities than high-intensity waves with fewer shocks under the same total energy (8). We therefore hypothesize that under the same total energy dose, low-intensity ESWT is more effective in treating CLBP than a higher-dosage regimen in clinical practice.

Therefore, the aim of the current study was to prospectively compare the effectiveness and safety of 2 different therapeutic regimens, *i.e.*, a low-intensity regimen with a greater number of courses versus a medium-intensity regimen with fewer courses, in treating patients with CLBP.

## METHODS

### Study Design

This study is a registered randomized controlled trial with a 1:1 allocation ratio, designed and implemented in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement (9). The pro-

ocol of this study was approved by the Institutional Review Board and Ethics Committee of Peking University First Hospital (No. 2021-193), and all patients signed a written informed consent. This trial was prospectively registered at the Chinese Clinical Trial Registry (No. ChiCTR2100049871). From August 13, 2021 through December 21, 2021, a total of 69 eligible patients were enrolled.

### Patients

Patients aged 18 to 65 years with nonspecific low back pain for more than 3 months and a Visual Analog Scale (VAS) pain score of the low back area of at least 5 were considered as eligible. The exclusion criteria were as follows: lumbar radicular symptoms or cauda equina syndrome; specific spinal diseases (lumbar degenerative diseases with compression of the lumbar nerve roots or the dural sac, grade 2–4 lumbar spondylolisthesis, scoliosis, spinal trauma, malignant tumour, rheumatic diseases); history of lumbar surgery; uncontrollable systemic diseases; coagulation disorders; mental disorders; and cognitive impairment.

### Randomization and Blinding

The patients were randomly assigned into either the low-intensity (LI) or the medium-intensity (MI) group with an equal allocation ratio (1:1) according to a computer-generated randomization sequence created by Excel 2019 (Microsoft). A researcher (FHY) blinded to all clinical data performed the allocation, and the allocation was concealed in a sequentially numbered, sealed, opaque envelope. The statistician who performed the analyses (YL) was also blinded to group allocation. The therapist or the patients were not blinded due to the obvious differences in treatment regimens.

### Intervention

The patients assigned to the shockwave treatment groups were positioned prone. Their trigger point was recognized by palpation and then marked with a pen. ESWT was performed on the marked area without local anesthesia (Fig. 1). The MedizinSysteme enPuls (ZimmerGroup) was applied for ESWT treatment in this trial. In the LI group, the ESWT treatment was delivered with energy flux density (EFD) of 0.03 millijoules(mJ)/mm<sup>2</sup> in 4,000 pulses, with a total of 3 sessions per week during a 2-week treatment period. In the MI group, EFD was 0.09 mJ/mm<sup>2</sup> in 4,000 pulses; these patients received one session of ESWT per week during a 2-week treatment period. Oral medication or other

treatment approaches were not routinely prescribed; however, medication was prepared as a supplementary treatment if the patient experienced aggravation of symptoms or discontinued the trial.

### Outcomes

Outcome assessments were patient-reported outcomes, including VAS scores at both rest and at movement, the Oswestry Disability Index (ODI), and the Hospital Anxiety and Depression Scale (HADS). Follow-up visits were scheduled at 2 weeks, 4 weeks, 6 weeks and 3 months after randomization.

The primary outcome was the 11-point VAS at movement reported at 4 weeks after randomization. The secondary outcome included VAS at movement at 2 weeks, 6 weeks, and 3 months after randomization; VAS at rest, ODI score, and HADS score at each follow-up time point; and overall therapeutic satisfaction on a 5-point Likert scale at the last follow-up.

### Sample Size

Based on our previous study, the mean VAS in the ESWT group and control group at one-month follow-up were 2.83 and 3.80, respectively (7). Based on this, with a 2-sided 2.5% significance level and power of 80%, the estimated minimum sample size was 31 patients per group. Considering a 10% loss to follow-up rate, a sample size of 69 randomized patients in total was finally determined for this trial.

### Statistical analysis

All personal identifying data were redacted and tabulated into an Excel spreadsheet (Microsoft) for statistical analysis. Continuous variables were described as the mean  $\pm$  standard deviation if variance was equal, and analyzed using a pairwise t-test for intragroup comparison / independent t-test for intergroup comparison. Data of unequal variance or order variance were described as median (Q1, Q3) or proportion, and were analyzed by Wilcoxon's signed rank test for non-parametric intragroup comparison / Mann-Whitney U test for intergroup comparison. Moreover, categorical variables were described as proportion, and were analyzed by the  $\chi^2$  test or Fisher's exact test.

Analysis was only conducted in patients who completed the originally allocated treatment. SPSS 27.0 (IBM) was used for statistical calculations, and graphs were produced using GraphPad Prism version 9.0 (GraphPad Software). All results were considered statistically significant at the  $P < 0.05$  level.

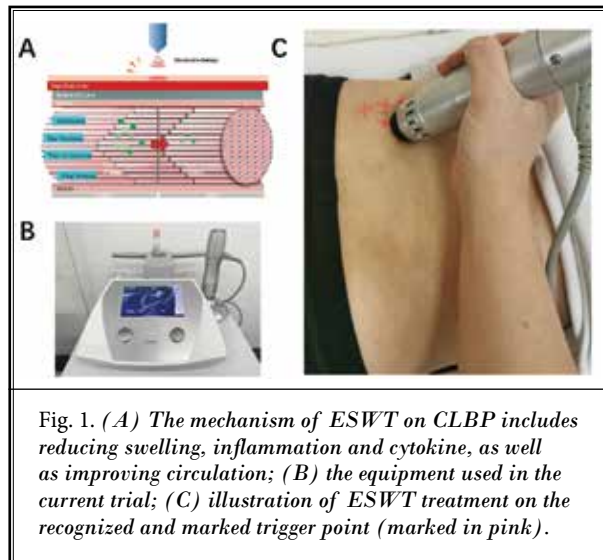


Fig. 1. (A) The mechanism of ESWT on CLBP includes reducing swelling, inflammation and cytokine, as well as improving circulation; (B) the equipment used in the current trial; (C) illustration of ESWT treatment on the recognized and marked trigger point (marked in pink).

## RESULTS

### Patient Recruitment

A total of 102 patients were screened for eligibility. Among them, 23 patients were excluded due to insufficient duration of symptoms or specific causes of LBP; 10 eligible individuals refused to participate in the trial. As a result, 34 patients were allocated to the LI group and 35 patients were allocated to the MI group according to the computer-generated randomization sequence. During the entire process, only one patient in the LI group discontinued the intervention one week after randomization due to COVID-19 quarantine and was considered as dropped out (Fig. 2).

### Baseline Characteristics

The patients' demographic characteristics are shown in Table 1. There were no significant differences between the groups in terms of age, gender distribution, height, weight, body mass index, or duration of symptoms. Baseline magnetic resonance imaging showed no differences in lumbar lordosis, disc degeneration grade, incidence of Modic change or incidence of a high-intensity zone in the posterior annulus of the disc at all lumbar intervertebral discs between the 2 groups. In addition, the distributions of Pfirrmann disc degeneration grading of L1/2, L2/3, L3/4, L4/5, and L5/S1 were similar between the 2 groups (all  $P > 0.05$ ), (Supplemental File 1).

### Comparison of Clinical Outcomes

At baseline, the patient-reported outcomes (VAS

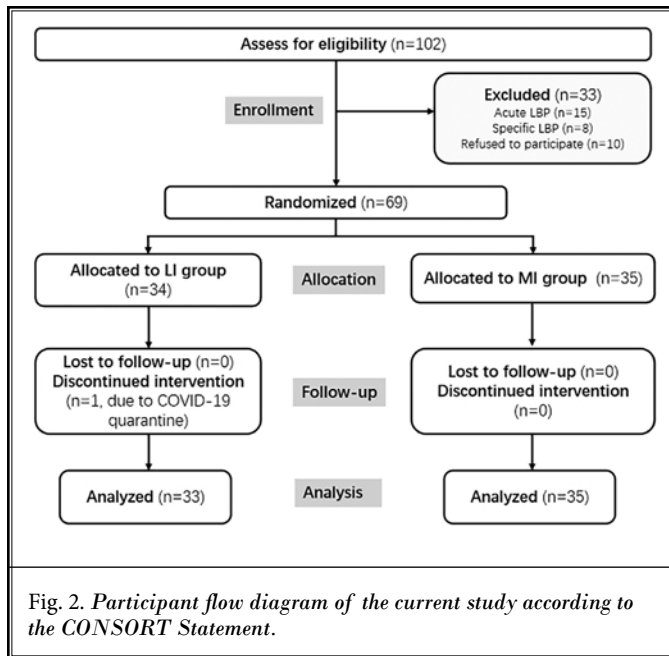


Table 1. Demographic and baseline characteristics of patients in the LI, and MI groups.

	LI group (n = 33)	MI group (n = 35)	P value
Age (years)	36.52 ± 13.35	35.74 ± 10.62	0.792
Gender (women/total)	20/33	24/35	0.492
Height (m)	1.69 ± 0.09	1.68 ± 0.08	0.609
Weight (kg)	66.03 ± 13.07	65.77 ± 15.14	0.940
BMI (kg/m <sup>2</sup> )	22.94 ± 2.95	22.55 ± 5.72	0.726
Duration of symptoms (mos)	15.09 ± 16.83	15.23 ± 10.90	0.968
Lumbar lordosis (degree)	33.27 ± 8.86	37.31 ± 8.34	0.057
Modic change	10/165	7/175	0.384
HIZ on posterior annulus	7/165	7/175	0.910

Abbreviations: BMI = body mass index, HIZ = high-intensity zone, LI = low intensity, MI = medium intensity.

at rest and VAS at movement, ODI, and HADS) were similar between the LI group and the MI group (all  $P > 0.05$ ). The primary analysis showed that the VAS at movement at 4 weeks after randomization was significantly lower in the LI group in contrast to the MI group (3 [2,3] vs 3 [2,3],  $P = 0.016$ ). Secondary analysis indicated that the LI group showed lower VAS scores at movement at 2 weeks and 6 weeks after randomization (all  $P < 0.05$ ) (see Fig. 3), while the VAS score at rest was also significantly lower in the LI group ( $P = 0.018$ ) at 6

weeks after randomization (Fig. 4). In addition, the ODI score in the LI group was significantly lower than the MI group at 2 weeks (24 [20, 26] vs 28 [24, 34],  $P = 0.002$ ) and 6 weeks (12 [8, 14] vs 14 [12, 18],  $P = 0.004$ ) (Fig. 5). The HADS score was also lower in the LI group than the MI group at 2 weeks after randomization (1 [0, 2] vs 2 [1, 3],  $P = 0.021$ ) (Fig. 6). All patient-reported outcomes were similar at 3 months after randomization between the 2 groups. In addition, the Likert scale was similar in the LI group and the MI group at the last follow-up ( $P = 0.07$ ).

The results of intragroup comparisons indicate that at each follow-up time point, compared with the baseline level, both the LI and MI groups showed significantly improved clinical outcomes in terms of VAS at rest, VAS at movement, ODI, and HADS scores (all  $P < 0.001$ ).

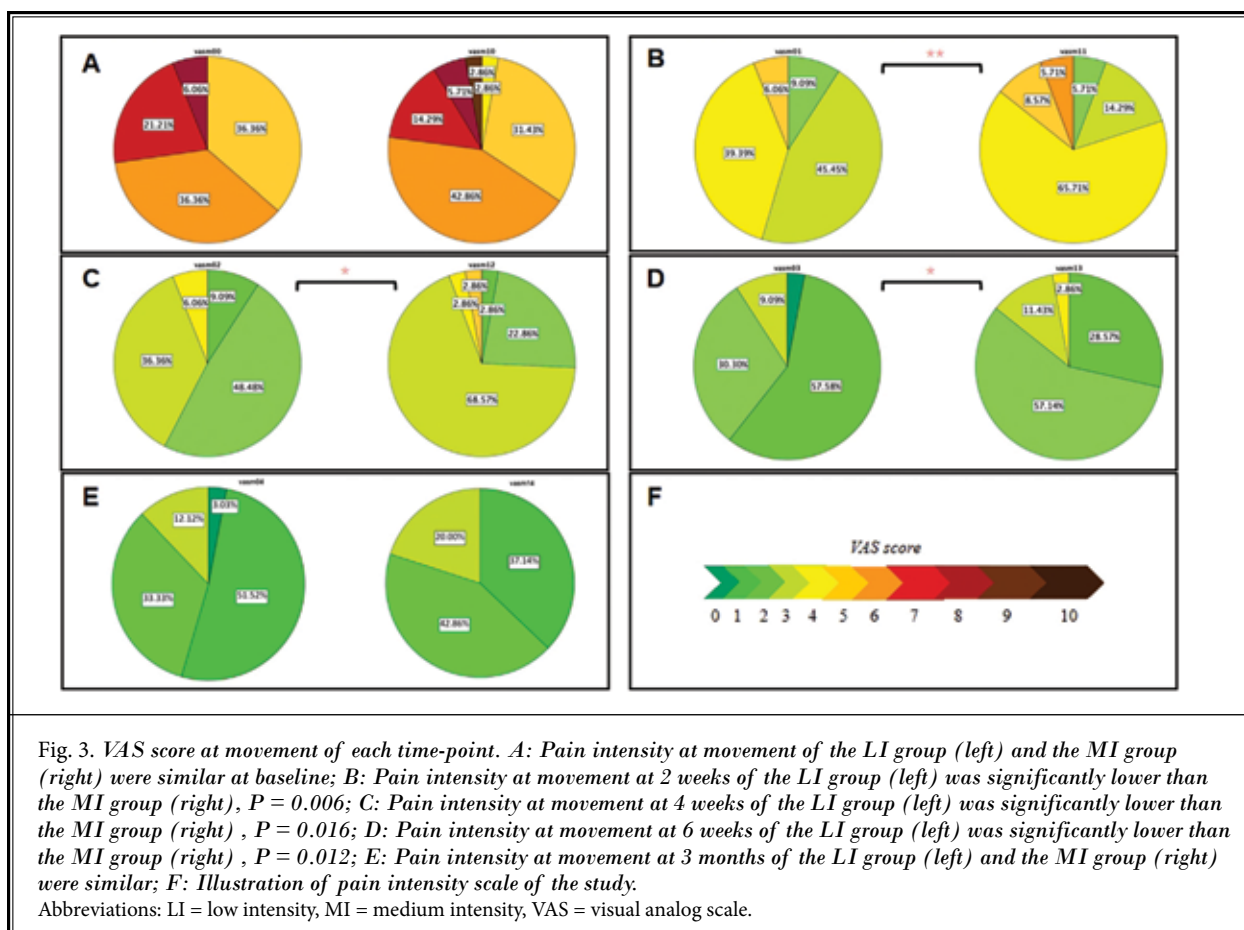
### ESWT-related Side Effects

Throughout the entire process, no treatment-related side effects, e.g., hematoma, bruise, pain in the treated area, or any other adverse events requiring intervention occurred in any of the groups.

### DISCUSSION

This is the first randomized trial to investigate the optimal ESWT regimen for the treatment of CLBP. The current study shows that ESWT treatment significantly reduced pain intensity, improved disability status, and relieved anxiety during the 3-month follow-up period, compared with baseline levels. Noteworthy, under the same total energy dosage, low intensity with more sessions showed more preferable therapeutic effects in reducing pain and improving functional status in up to 6 weeks, compared with medium intensity with fewer sessions; however, the superior efficacy of the LI group was no longer noticed at 3-months follow-up. Furthermore, treatment EFD from 0.03 to 0.09 mJ/mm<sup>2</sup> was shown to be safe given that no side effects were reported by the patients.

Although ESWT has still not been recommended by guidelines, its effectiveness and safety on CLBP, either delivered as a standalone therapy or in combination with other active therapies, has been demonstrated by previous trials (10-12). Our previous systematic review and meta-analysis provided low-quality evidence that, compared with the control, the ESWT group significantly lowered pain intensity (standardized mean difference [SMD] -0.81; 95%CI -1.21 to -0.42) and disability



score (SMD -1.45; 95%CI -2.68 to -0.22) at one-month follow-up; there was also moderate-quality evidence that ESWT achieved better clinical ODI scores at 3 months of follow-up (SMD -0.69; 95%CI -1.08 to -0.31) compared with control (7).

The current study also showed that compared with baseline levels, patients treated by ESWT reported significantly lower VAS, ODI, and HADS scores at each follow-up time point since randomization without risks of treatment-related side effects. In musculoskeletal conditions, ESWT is defined as high (> 0.28 mJ/mm<sup>2</sup>), medium (0.08–0.28 mJ/mm<sup>2</sup>), and low intensity (0.08 mJ/mm<sup>2</sup>) (13). Previous studies have mostly applied medium intensity at 0.10–0.15 mJ/mm<sup>2</sup> for treating CLBP (10-12,14-16); however, in spite of satisfactory clinical results, the study by Kang et al (16) encountered local pain in some patients during treatment at an EFD of 0.15 mJ/mm<sup>2</sup>. In the current study, no ESWT-related side effects were observed at the EFD range of 0.03-0.09 mJ/mm<sup>2</sup>, indicating that this is a safe ESWT dose range for treating CLBP.

The effect of shockwave therapy is dose- and time-dependent according to multiple in vivo studies and clinical trials (17-19), which means that the efficacy of ESWT relies on the principle of an energy accumulation effect. Tam et al (8) noted that total energy dose (intensity multiplied by the number of total shocks) was a better reference for determining the shockwave effect. Previous studies seem to agree that in musculoskeletal scenarios, ESWT is more effective in higher energy (20,21). However, the randomized trial by Taheri et al (22) showed that, compared with single high-intensity treatment, multiple low-dosage ESWT achieved more favorable therapeutic effects at 12 weeks of follow-up (22).

Here, our results showed that under the same total energy dose, the single EFD of 0.03 mJ/mm<sup>2</sup> ESWT more substantially reduced VAS and ODI scores compared with single EFD of 0.09 mJ/mm<sup>2</sup> in up to a 6-week follow-up period. Apart from the energy accumulation effect theory, the merits of a low-intensity treatment

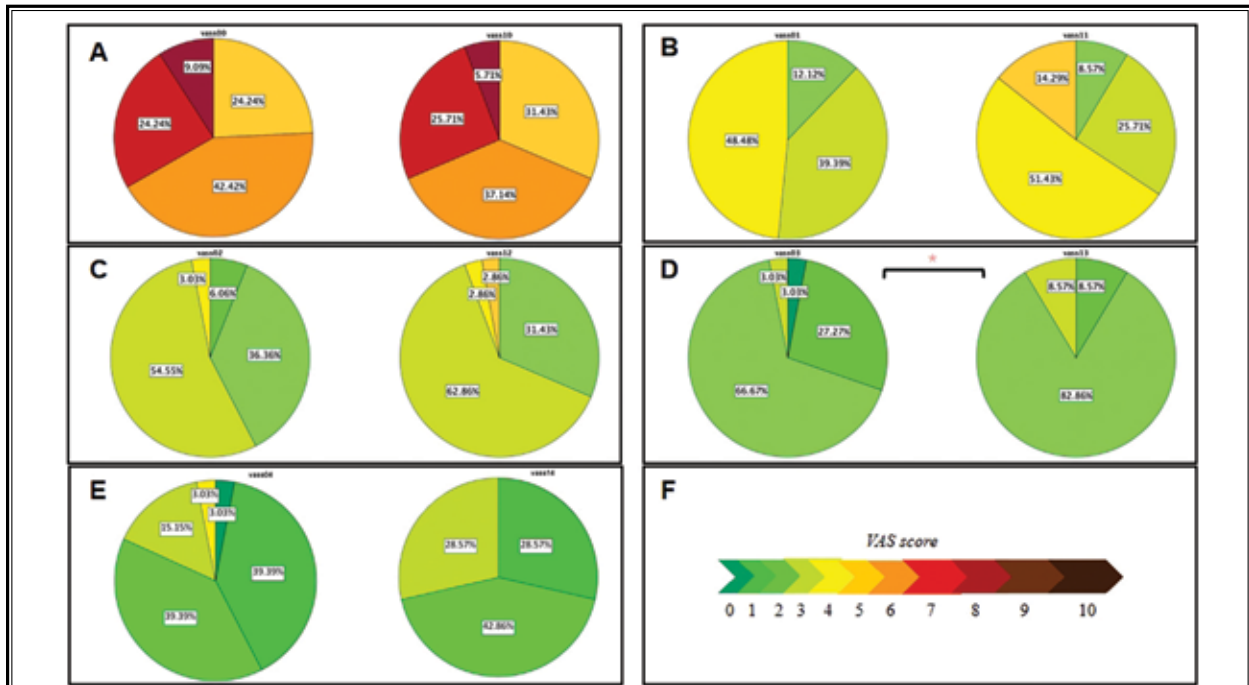


Fig. 4. VAS score at rest of each time-point. A: Pain intensity at rest of the LI group (left) and the MI group (right) were similar at baseline; B: Pain intensity at rest at 2 weeks of the LI group (left) and the MI group (right) were similar; C: Pain intensity at rest at 4 weeks of the LI group (left) and the MI group (right) were similar; D: Pain intensity at rest at 6 weeks of the LI group (left) was significantly lower than the MI group (right),  $P = 0.018$ ; E: Pain intensity at rest at 3 months of the LI group (left) and the MI group (right) were similar; F: Illustration of pain intensity scale of the study. Abbreviations: LI = low intensity, MI = medium intensity, VAS = visual analog scale.

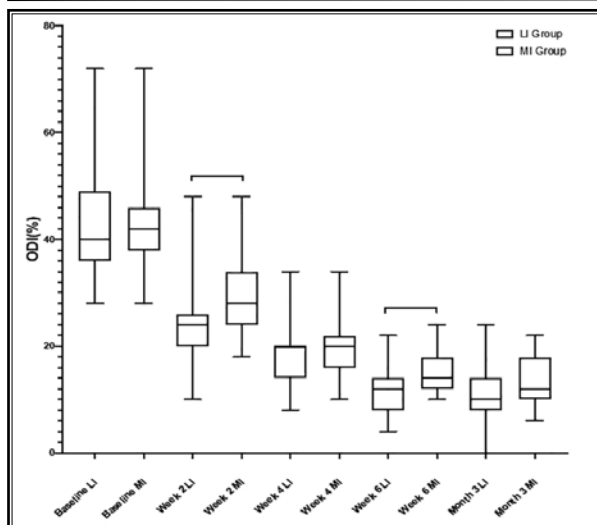


Fig. 5. ODI score at movement of each time-point. The ODI score of the LI group was significantly lower than the MI group at 2 weeks ( $P = 0.002$ ) and 6 weeks ( $P = 0.004$ ); the ODI scores of both groups at each time-point after treatment were lower than baseline (all  $P < 0.001$ ). Abbreviations: LI = low intensity, MI = medium intensity, ODI = Oswestry Disability Index.

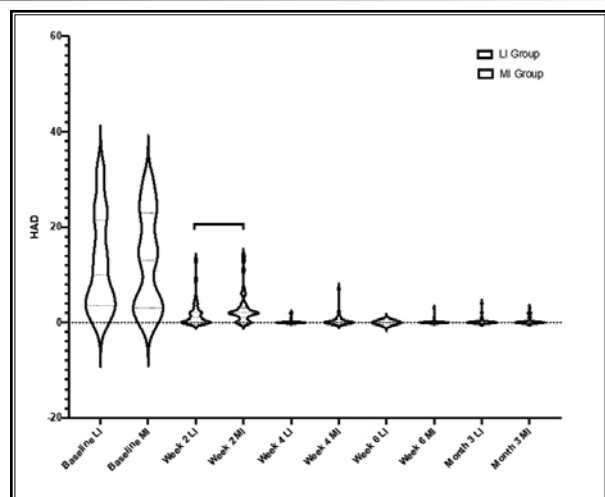


Fig. 6. HADS score at movement of each time-point. The HADS score was lower in the LI group than the MI group at 2 weeks ( $P = 0.021$ ); the HADS scores of both groups at each time-point after treatment were lower than baseline (all  $P < 0.001$ ). Abbreviations: LI = low intensity, MI = medium intensity, HADS = Hospital Anxiety and Depression Scale.

regimen might also be explained by its avoidance of potential tissue damage due to a relatively lower dose of acoustic waves (23). Our study therefore introduces new ideas for the application of EWST in low back pain treatment, and we expect high-quality evidence to confirm our results.

This study has several limitations. First, although our study obtained clinical outcomes up to 3 months after randomization, a longer follow-up period would undoubtedly provide a better understanding of the difference between the 2 regimens. Second, a control group was not set in this trial, which impeded the complete rationale of the analgesic efficacy of ESWT treatment. Third, the sample size was small and the patients enrolled were recruited from a single institution. Lastly, we only included patients with nonspecific CLBP diagnosed by trigger point palpation; however, other CLBP

types, such as facet-mediated pain, sacroiliac joint pain, or discogenic pain, were not included, which limits the generalizability of the findings. Despite these limitations, we still believe that our study provides robust evidence that low-intensity ESWT treatment provides better clinical efficacy on CLBP under the same total energy dose.

## CONCLUSION

Under the same total energy dose, low-intensity ESWT treatment with more sessions is more efficient in relieving pain and improving disability than medium-intensity ESWT with fewer sessions in the short-term.

## Availability of Data and Materials

Raw data are available on reasonable request from the corresponding author.

Supplementary material available at [www.painphysicianjournal.com](http://www.painphysicianjournal.com)

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Supplementary Table 1. *Comparison of disc degeneration grade of each lumbar segment.*

	<b>L1/L2</b>	<b>L2/L3</b>	<b>L3/L4</b>	<b>L4/L5</b>	<b>L5/S1</b>
Z value	-1.39	-1.171	-0.593	-1.909	-1.381
P value	0.165	0.242	0.553	0.056	0.167