Systematic Review and Meta-Analysis

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Efficacy and safety of extracorporeal shock wave on low back pain

A systematic review and meta-analysis

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Abstract

Background: Extracorporeal shock wave therapy (ESWT) is a relatively new type of treatment for many musculoskeletal disorders. However, ESWT for low back pain remains controversial as the pain relieve benefit is questionable. We performed this systematic review and meta-analysis to explore the effectiveness and safety of ESWT interventions on pain and disability in patients with low back pain (LBP).

Methods: In this meta-analysis, we searched electronic databases in the Pubmed, Embase, Cochrane's library, China National Knowledge Infrastructure, and Wanfang Database to determine the equivalence of ESWT and placebo for the treatment of LBP up to April 4, 2022. A number of other outcomes were measured, including functional status, quality of life, and psychological outcomes measured by the Oswestry Disability Index. Weighted mean differences were calculated for continuous outcomes, while risk ratios were calculated for binary outcomes. Stata 12.0 software was used for statistical analysis.

Results: Thirteen randomized controlled trials included for further analysis. Compared with control, the ESWT group showed lower pain intensity at month 1 ($P < .05$), as well as lower disability score at month 1 ($P < .05$) and at month 3 ($P < .05$). There was no statistically significant difference between ESWT and control groups in terms of the pain intensity at month 3 ($P > .05$). No serious adverse events related to treatment were reported. Sensitivity analysis demonstrates that the conclusions from this analysis were robust.

Conclusions: ESWT is effective in alleviating pain and improving the functional outcomes for patients with LBP. However, there remains a lack of high-level evidence to verify their effectiveness and safety and support their clinical application.

Abbreviations: ESWT = extracorporeal shock wave therapy, GRADE = Grading of Recommendations Assessment, Development and Evaluation, LBP = low back pain, ODI = Oswestry Disability Index, RCTs = randomized controlled trials.

Keywords: extracorporeal shock wave therapy, low back pain, systematic review and meta-analysis

1. Introduction

Low back pain (LBP) is the second leading cause of disability among adults in USA accounting for 149 million days of work lost and costing 100-200 billion dollars annually.[1] A survey of Saskatchewan farmers revealed that 84% of respondents had experienced at least one episode of back pain in their lifetime.[2,3] According to the 2002 US National Health Interview Study, 26.4% of the 30,000 participants had at least one full day of back pain in the previous three months.[4] LBP was the most common complaint among German adults insured by the public health care system in 2010 (26%).[5] As a result, LBP causing significant personal and social burden.[6] Approximately $33 billion is spent annually on evaluating and treating LBP in the United States.[7] Approximately $100 billion USD is spent each year on back pain in the United States of America.[8] A variety of methods have been proposed to treat LBP, including pharmaceutical analgesics, acupuncture, manual therapy as well as physical therapy, sports medicine, etc.[9]

Current pharmacologic treatment options focus on relieving pain in LBP patients. However, long-term use of pharmacologic drugs is limited by both tolerability and serious adverse events.[10]

Non-pharmacological and noninvasive managements are recommended by current related guidelines, including exercise therapy, cognitive behavioral therapy and education.[11]

Among all the therapies mentioned above, extracorporeal shock wave therapy (ESWT) is a physiotherapy technique that has been shown to be effective in different pathologies such as plantar fasciitis, lateral epicondylitis of the elbow, calcific tendinopathies of the shoulder, nonunion of long bone fractures.[12] Currently, ESWT is administered for musculoskeletal system diseases, but studies of the effects of ESWT on chronic LBP are

CL and ZX contributed equally to this article.

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rare, and few studies have examined its effects on pain, disability, and depression.[13,14] Despite the widespread use of therapeutic ultrasound as one of the most popular and commonly used modalities in the field of physiotherapy for LBP patients, there is still limited evidence of its effectiveness.[15] Currently, clinical trials have reported extracorporeal shock wave for the treatment of LBP, but the effectiveness and safety has not been proved by systematic review.

This meta-analysis will address the problem that whether ESWT could alleviate pain and improving the functional outcomes for patients with LBP, and will provide evidence for clinical decision making.

2. Materials and Methods

The present meta-analysis was conducted according to the recommendations of the Cochrane Collaboration and the Quality of Reporting of Meta-analyses guidelines and A MeaSurement Tool to Assess systematic Reviews 2 (AMSTAR2). This meta-analysis was registered in the Research Registry (https://www.researchregistry.com/browse-the-registry#registryofsystematicreviewsmeta-analyses/; No. reviewregistry1418).

2.1. Search strategy

The preferred reporting items for systematic reviews and meta-analyses (PRISMA statement) guidelines were used to perform this meta-analysis. Two independent investigators searched for original randomized controlled trials (RCTs) related to the ESWT in LBP published before April 4, 2022, in Pubmed, Embase, Cochrane's library, China National Knowledge Infrastructure, and Wanfang Database. In all three databases the following three categories of keywords (and related synonyms) were used to build a sensitive search strategy and to provide a systematic search: "extracorporeal shock wave therapy" and "low back pain." When selecting studies, there were no restrictions on language, year of publication, patient follow-up duration, or status of the publication.

The Boolean search method was used in PubMed to combine the keywords and MeSH words. Search terms were truncated using an asterisk (*) to find all terms beginning with a specific word. After the initial electronic search, we retrieved relevant articles and bibliographies from the studies identified.

2.2. Inclusion criteria and study selection

An independent review and selection process was conducted by two investigators (C.L. and Z.X.), based upon predefined inclusion/exclusion criteria. We read titles and abstracts; if suitability was not determined, the full article was evaluated.

We identify eligible studies according to the PICOS (population, intervention, control, outcomes, and study design) principle in order to ensure the systematic search of available literature. Population: LBP patients; Intervention: ESWT; Control: placebo, medications, physical exercise and so on; Outcome: Visual Analog Scale, numeric rating scale, Oswestry Disability Index (ODI) score, and adverse events or complications; and Study: RCTs.

Studies were excluded according to following criteria: non-RCTs, including cohort studies or review; animal studies,

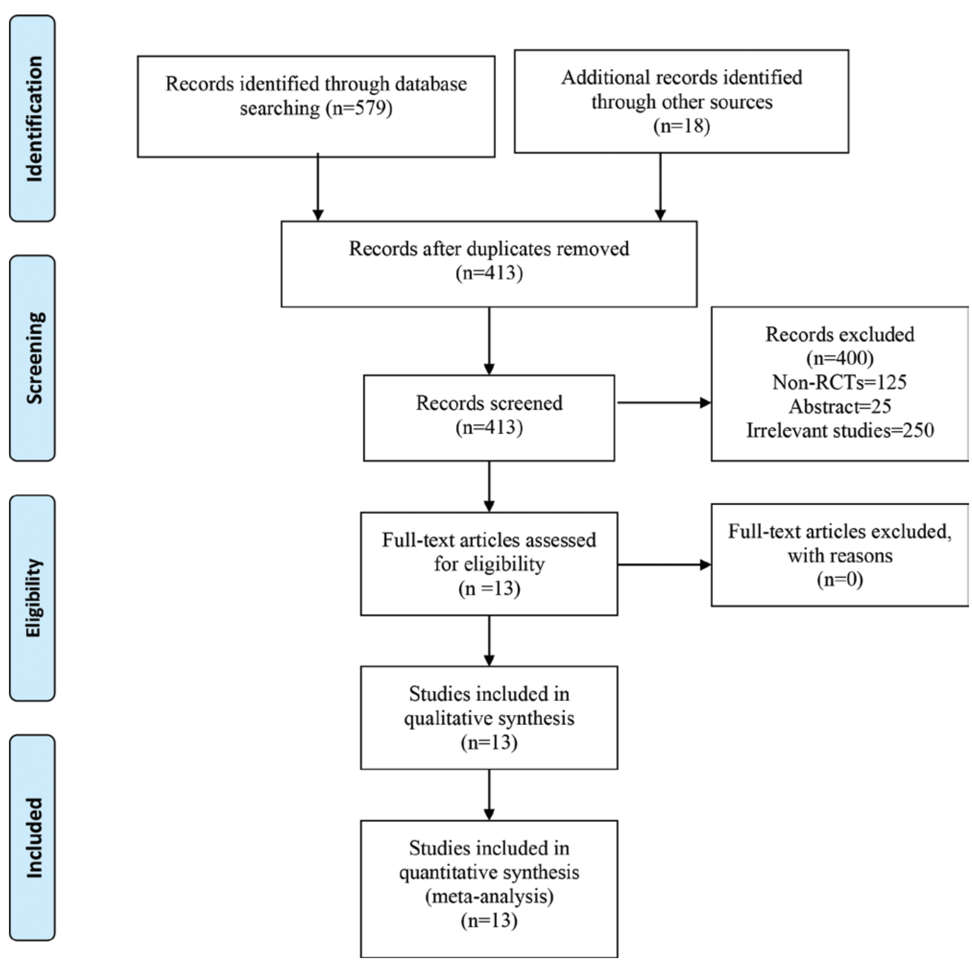

Figure 1. Flow chart of the literature search. RCTs = randomized controlled trials.

cadaver studies, or laboratory studies; study without comparing WSWT and placebo; and without outcomes.

Those two authors independently assessed each full study report to see whether it met the inclusion criteria, and authors were contacted for more information and clarification of data as necessary. We consulted with two other independent reviewers (L.C. and S.P.) in case of doubt or concern, and if necessary, a third reviewer (C.L.) resolved disagreements.

2.3. Methodological quality

Two investigators independently applied the Cochrane Collaboration tool for the risk of bias to assess the methodological quality of the included RCTs and evaluate the possibility of bias in the design of each included study. The following 6 domains of the Cochrane Collaboration's tool were selected to evaluate the risk of bias: random sequence generation and allocation concealment for selection bias, blinding of participants and personnel for performance bias, blinding of outcome assessment for detection bias, incomplete outcome data for attrition bias and selective reporting for reporting bias. Each item of which was classified into three levels: high, unclear and low risk.

The Cochrane Collaboration Network GRADE (The Grading of Recommendations Assessment Development and Evaluation) will be utilized to grade the quality of evidence as very low, low, moderate or high.

2.4. Data extraction

Study selection, screening, and quality assessment were conducted independently by two authors. Related information was also extracted. The following data of all eligible trials were extracted: study

Table 1

General characteristic of the included studies.

Study (year)	Mean symptom duration (ESWT/control)	No. ESWT/ control	Male patients (ESWT/control)	Mean age (ESWT/control)	Mean BMI (ESWT/control)	Mean follow-up time	Outcomes
Yang 2015	5.06/5.26 mo	29/29	3/2	32.27/33.27	NS	5 wk	VAS score
Wu 2016	6.32/7.42 wk	28/26	17/14	46.14/48.77	20.91/20.61	4 wk	VAS score, ODI score
Moon 2017	20.42/17.7 mo	14/11	3/1	54.42/59.18	NS	4 wk	NRS score, ODI score
Walewicz 2019	9.8/9 yr	20/20	6/5	51.1/55.8	NS	3 mo	VAS score, ODI score
Çelik 2019	36/33 mo	25/20	15/8	40.76/40.25	NS	6 wk	NRS score, ODI score
Schneider 2018	25.2/18.9 mo	15/15	NS	NS	NS	3 wk	VAS score
Walewicz 2019	8.5/7.6 yr	20/20	6/0	51.1/55.8	NS	17 wk	VAS score, ODI score
Eftekharsadat 2020	NS	27/27	7/10	44.74/45.04	27.47/26.20	4 wk	VAS score, ODI score
Elgendy 2020	NS	15/15	10/10	32.73/33.26	24.93/25.56	6 wk	VAS score
Guo 2021	NS	47/48	25/23	34.9/36.0	22.3/22.7	4 wk	NRS score
Kang 2015	5.2/3.9 yr	22/21	NS	43.1/42.5	NS	8 wk	VAS score, ODI score
NAHAS 2018	15.6/13.4 mo	15/15	0/0	29.40/29.20	26.68/25.81	4 wk	VAS score
Taheri 2021	6.7/5.8 yr	19/19	6/9	42.5.37.1	27.1/26.8	12 wk	VAS score, ODI score
Zheng 2013	7.52/6.89 yr	33/33	18/25	45.84/47.39	NS	2 wk	VAS score

BMI = body mass index, ESWT = extracorporeal shock wave therapy, NRS = numeric rating scale, ODI = Oswestry Disability Index, VAS = Visual Analog Scale.

Table 2

General characteristic of the included studies.

Study (year)	Parameters of ESWT					Control
	Radial or focused	Pulse	Energy	Frequency (Hz)	Treatment interval/times	
Yang 2015	Focused	1800–2500	NS	1.5	3–4 d/6	Celebrex (0.2 g each time, twice a day)
Wu 2016	Radial	2000	1.8–2.5 bar	8–10	4–5 d/4	Sham ESWT
Moon 2017	Focused	2000	0.09–0.25 mJ/mm^2	3	Single session	Sham ESWT
Walewicz 2019	Radial	2000	2.5 bar	5	3–4 d/10	Sham ESWT
Çelik 2019	Radial	1500	0.12 mJ/mm^2	2.5	3–4 d/12	placebo ESWT (0.08 mJ/mm^2)*
Schneider 2018	Focused	NS	NS	15–42	2/wk	Myofascial trigger therapy
Eftekharsadat 2020	Focused	1500	0.1 mJ/mm^2	10–16	1/wk	Sham ESWT
Elgendy 2020	Focused	2000	0.1 mJ/mm^2	5	2/wk	Physical exercise
Guo 2021	Radial	4000	NS	15	1/wk	Celebrex
Kang 2015	Radial	1000	0.15 mJ/mm^2	4	1/wk	Conservative treatment
NAHAS 2018	Radial	2000	2 bar	10	2/wk	Physical exercise
Taheri 2021	Focused	1500	0.15 mJ/mm^2	4	1/wk	Sham ESWT
Zheng 2013	Radial	2000	1.6–3 bar	8–12	Once a day	Sham ESWT

ESWT = extracorporeal shock wave therapy.

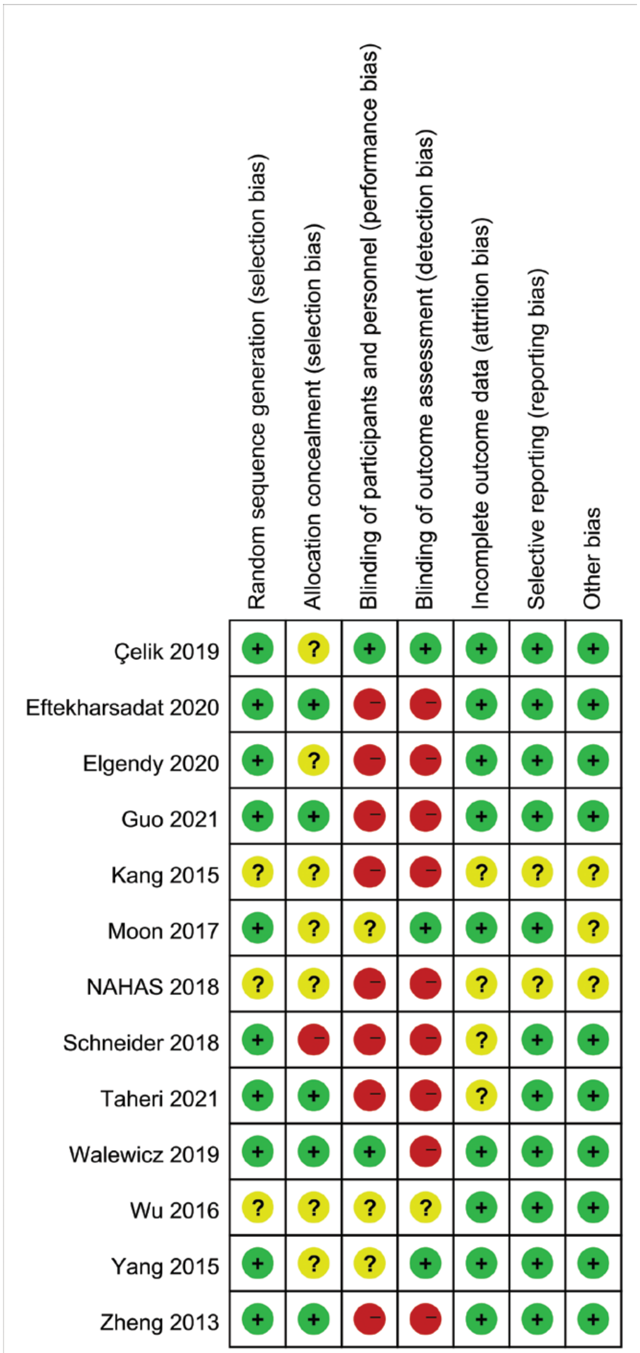

Figure 2. Risk of bias summary of the included studies.

information: general characteristic of the patients, including year of publication, symptom duration, number of patients, male patients, mean age of patients, bone mass index of patients and follow up duration; study population; intervention methods (radial or focused, pulse, energy, frequency and interval/times) applied on the different group; and outcomes, including pain score at 1 and 3 months, ODI score at 1 and 3 months.

2.5. Statistical analysis

Inconsistencies among the clinical studies were estimated using the chi-squared heterogeneity test and quantified using I^2. A value above 50% was considered substantial. The random-effects model was used, when there was significant heterogeneity between-studies; otherwise, the fixed-effects model was employed. For all comparisons, risk ratio (RR) and 95 % confidence intervals (CI) were calculated for binary outcomes, while mean difference (MD) and 95 % CI were calculated for continuous outcomes. A P value less than .05 was thought statistically significant. Statistical analysis was performed using Stata Version 12.0 (Stata Corporation, College Station, TX)

3. Result

3.1. Study inclusion

A total of 597 studies were identified through initial search (579 through electronic database, 18 through other sources). After removal of duplicate, 413 records were identified and 400 of which were excluded for no direct comparison between ESWT and control groups and the lack of uniformed measurement of outcome. The full texts of remaining 13 articles were reviewed for more details. Eventually, 13 RCTs[16–28] were included in this meta-analysis. The flow diagram of study selection procedure was shown in Figure 1.

3.2. Study characteristics

The selected 13 studies included 329 patients in ESWT group and 319 patients in control group. Only 3 studies did not report the mean symptom duration and the rest studies all reported the symptom duration. Symptom duration ranged from 5.06 to 36 months. All included studies compared the pain intensity before and after intervention. The detailed sample size and measured parameters was shown in Table 1. Besides, the parameters (pulse, frequency, energy, treatment intervals, and times) used in ESWT group as well as in the control group from different studies were collected in Table 2.

3.3. Risk of bias assessment and quality of the included studies

The risk of bias in the 13 included studies was presented in Figures 2 and 3. Ten studies reported the random sequence generation clearly, indicating a low risk of selection bias in these studies. As for allocation concealment, it was clear in 5 studies and vague in 7 studies. Blinding method included two parts: blinding of participants and personnel (performance bias) and blinding of outcome assessment (detection bias). Two studies were double-blinded, and low risk of detection and performance bias existed in the two studies. While the blinding method was not clear in the other three studies, and there was insufficient information to permit judgement of "low risk" or "high risk." Thus, unclear risk of detection and performance bias existed in the two studies. As for incomplete outcome data (attrition bias), there was no missing outcome data or missing data with similar reasons balanced in numbers across intervention groups in nine studies. The selection bias and other bias were was low in eleven studies.

3.4. Pain score at 1 month

Thirteen studies including 606 patients reported pain score at 1 month. High heterogeneity existed between the included thirteen studies (I^2 = 91.7%, P = .000; Fig. 4). So, we conducted a random-effects model. And meta-analysis showed significant difference between two groups (WMD = −1.51, 95% CI: [−2.06, −0.95], P = .000; Fig. 4).

3.5. Pain score at 3 months

Seven studies including 353 patients reported pain score at 3 months. Moderate heterogeneity existed between the two

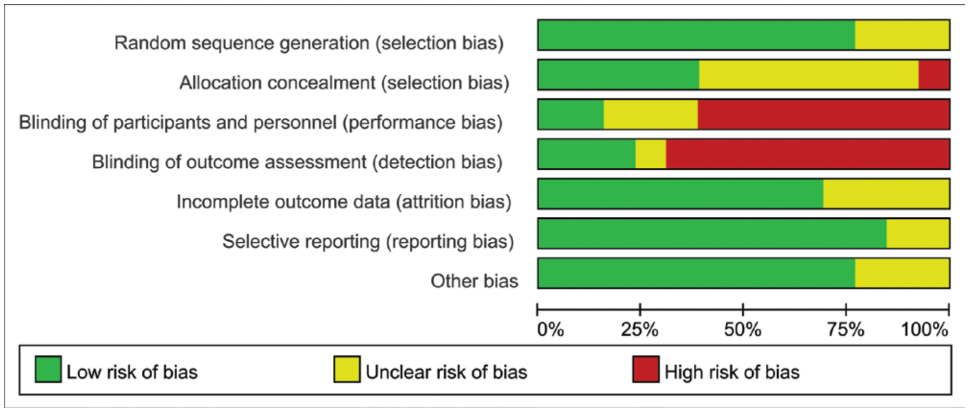

Figure 3. Risk of bias graph of the included studies.

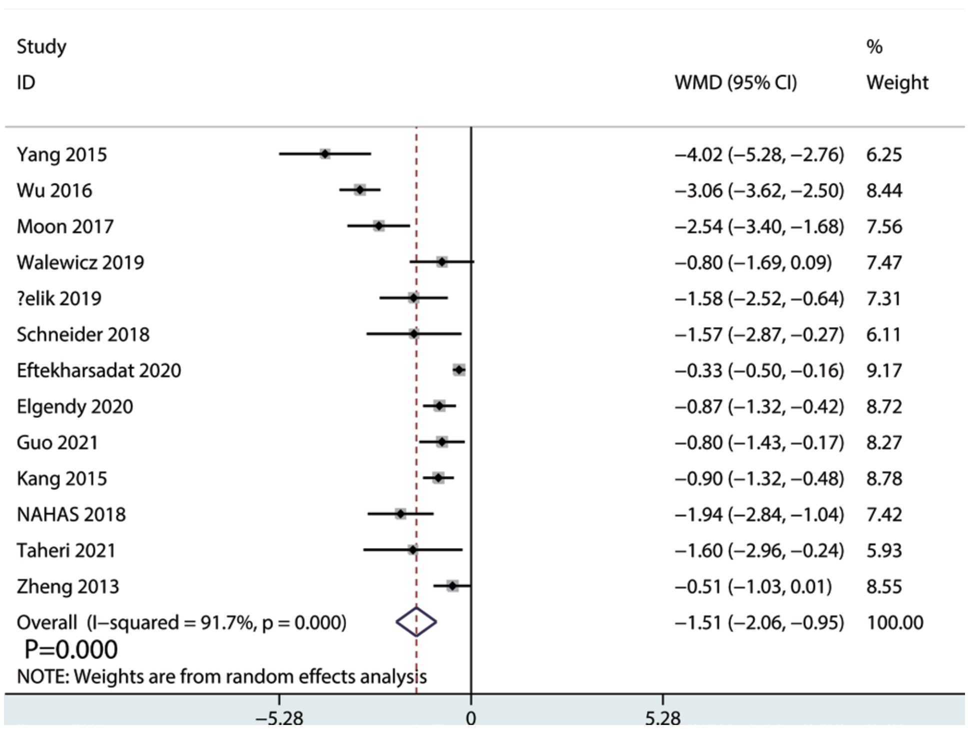

Figure 4. Forest plot analysis of Pain sores at 1 month in patients with LBP after treatment between the ESWT and control group. CI = confidence intervals, ESWT = extracorporeal shock wave therapy, LBP = low back pain.

studies (I^2 = 61.0%, P = .017, Fig. 5). We conducted a random-effects model, and the meta-analysis showed a significant difference between two groups (MD = -0.54, 95%CI: [-1.07, -0.02], P = .042; Fig. 5).

3.6. ODI score at 1 month

We compared the ODI score at 1 month after treatment. Eight studies including 357 patients reported ODI score at 1 month. High heterogeneity existed between the two studies (I^2 = 91.6%, P = .000, Fig. 6). We conducted a random-effects model, and the meta-analysis showed a significant difference between two groups (WMD = –4.31, 95% CI: [–5.63, –2.99], P = .000; Fig. 6).

3.7. ODI score at 3 months

We compared the ODI score at 3 months after treatment. Eight studies including 369 patients reported ODI score at 3 months. Moderate heterogeneity existed between the eight studies (I^2 = 42.4%, P = .095, Fig. 7). We conducted a random-effects model, and the meta-analysis showed a significant difference between two groups (WMD = –3.53, 95% CI: [–4.64, –2.42], P = .000; Fig. 7).

3.8. Sensitivity analysis

Sensitivity analysis was conducted by removing one study in turn to see if the single study could have significant impact on the pooled effects for LBP. Overall heterogeneities and results were stable (Fig. 8).

3.9. Publication bias

To detect publication bias, funnel plot and Begg test were performed. Funnel plot and Begg test showed no publication bias (Fig. 9).

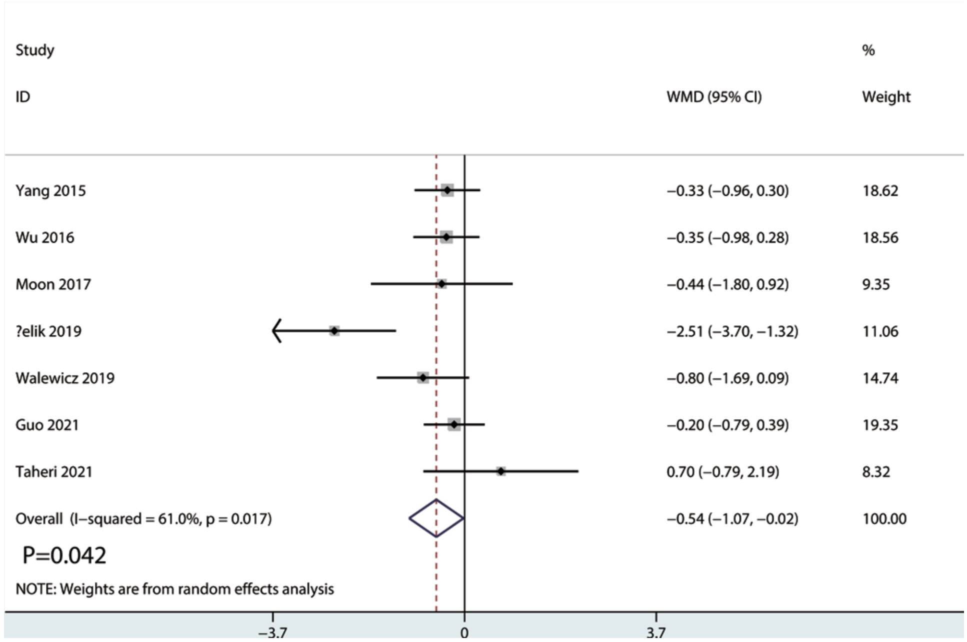

Figure 5. Forest plot analysis of Pain sores at 3 months in patients with LBP after treatment between the ESWT and control group. CI = confidence intervals, ESWT = extracorporeal shock wave therapy, LBP = low back pain.

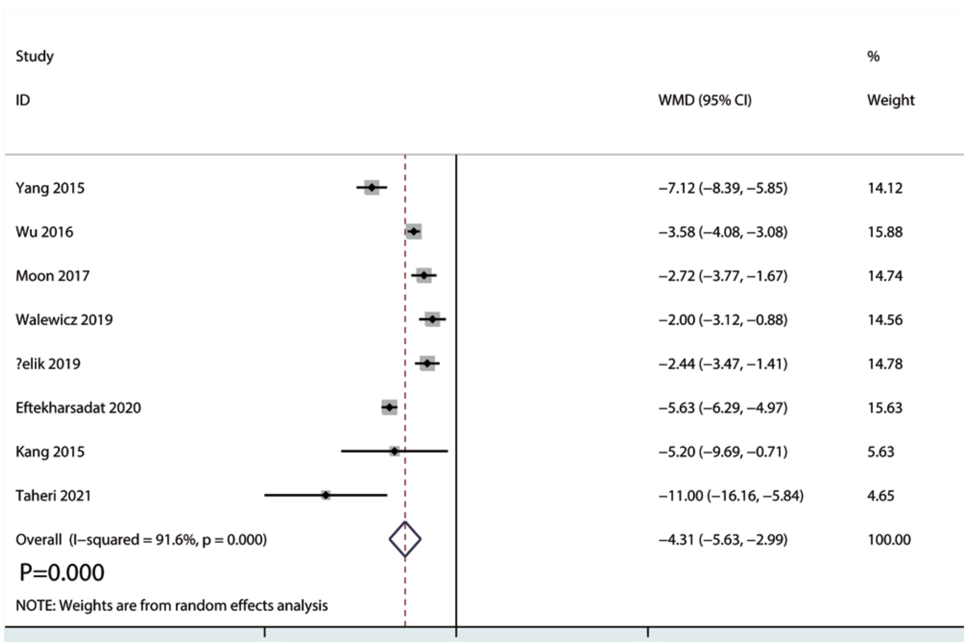

Figure 6. Forest plot analysis of ODI sores at 1 month in patients with LBP after treatment between the ESWT and control group. CI = confidence intervals, ESWT = extracorporeal shock wave therapy, LBP = low back pain, ODI = Oswestry Disability Index.

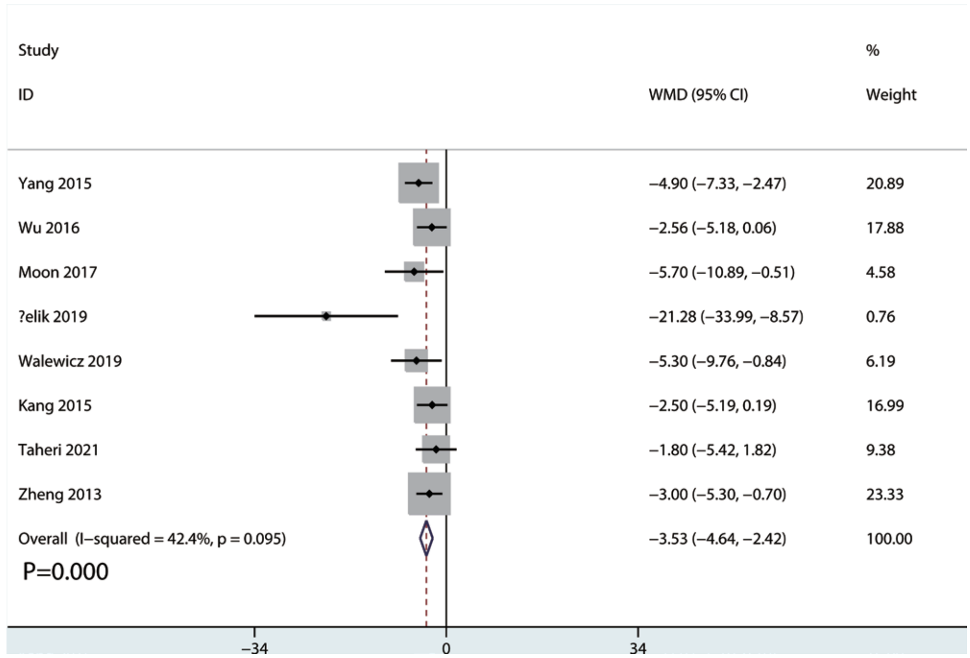

Figure 7. Forest plot analysis of ODI sores at 3 months in patients with LBP after treatment between the ESWT and control group. CI = confidence intervals, ESWT = extracorporeal shock wave therapy, LBP = low back pain, ODI = Oswestry Disability Index.

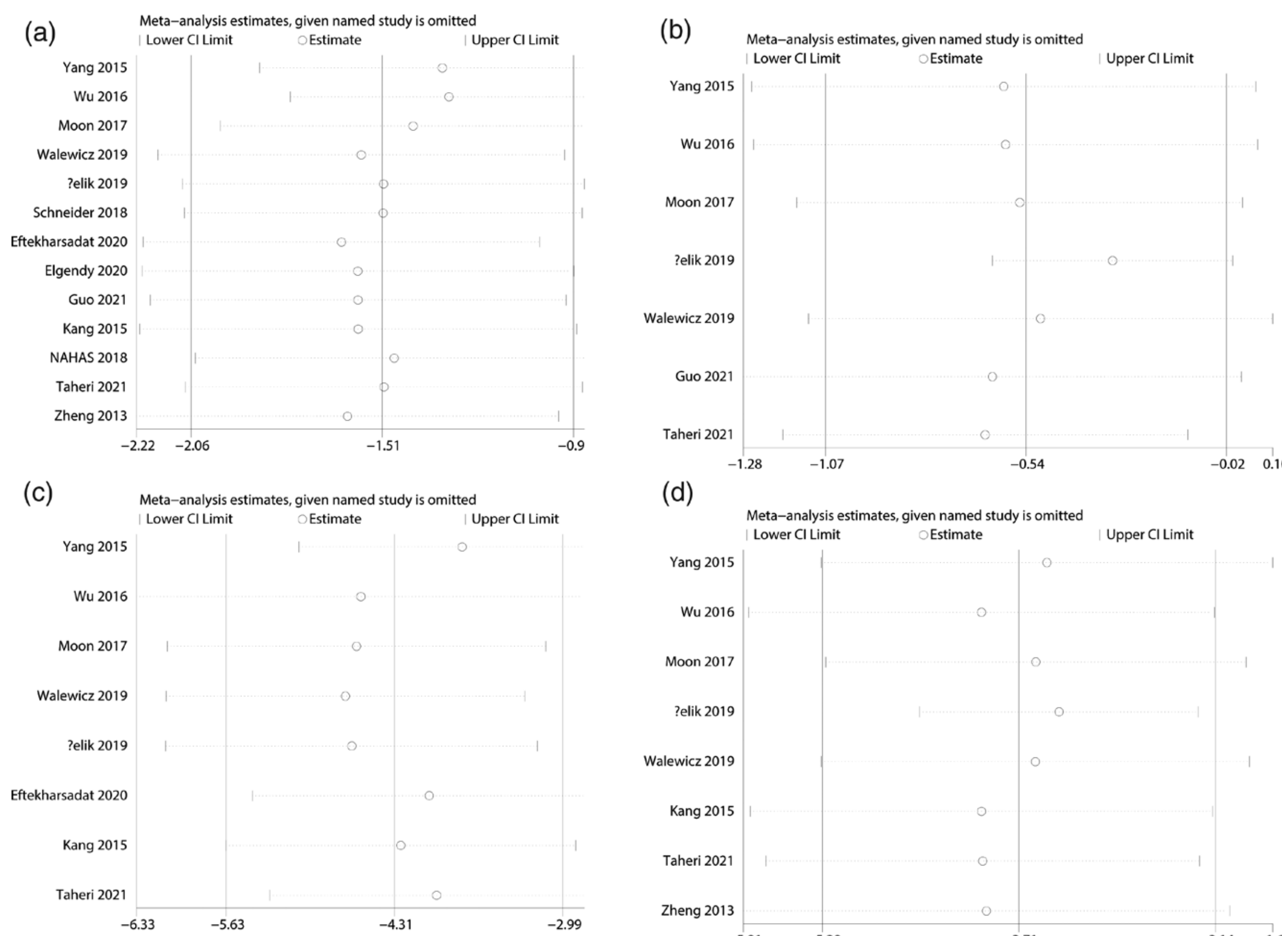

Figure 8. Sensitivity analysis of pain score at 1 month (A), 3 months (B), ODI at 1 month (C) and 3 months (D). CI = confidence intervals, ODI = Oswestry Disability Index.

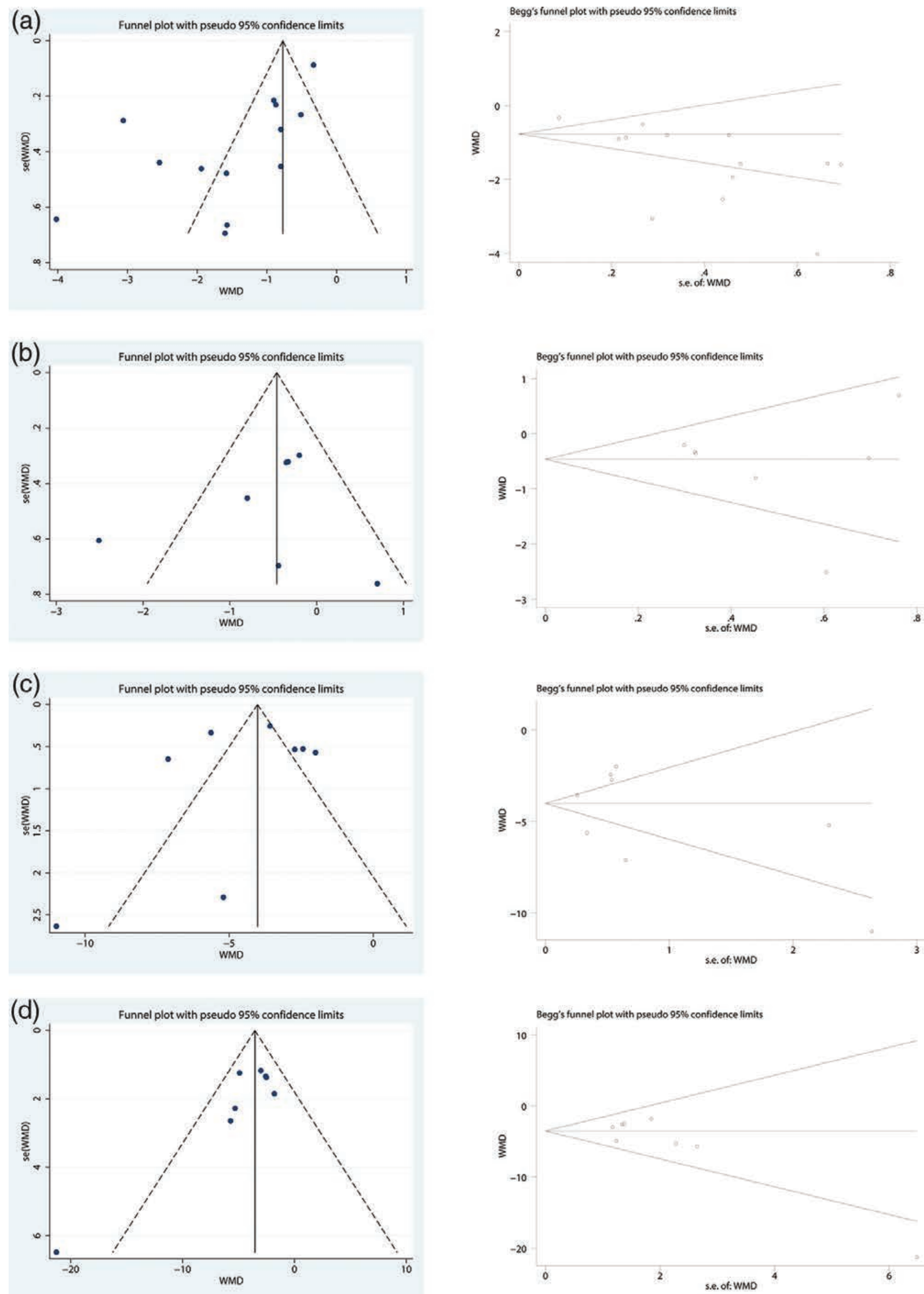

Figure 9. Sensitivity analysis of pain score at 1 month (A), 3 months (B), ODI at 1 month (C) and 3 months (D). CI = confidence intervals, ODI = Oswestry Disability Index.

4. Discussion

4.1. Main findings

To our knowledge, this is the first meta-analysis that comparing ESWT versus placebo for LBP patients. Our main finding in this meta-analysis is that ESWT could significantly reduce the pain score and ODI score in LBP patients than that of control group.

4.2. Strength of this meta-analysis

A major strength of this meta-analysis was that this is the first meta-analysis that comparing ESWT versus placebo for LBP patients. To increase the robustness of this meta-analysis, we applied sensitivity analysis to assess the impact of random error and repetitive testing.

4.3. Comparison with other meta-analyses

Only one meta-analysis on the topic have been published. Although the main finding of our meta-analysis was consistent with previous meta-analysis, differences between ours and the previous ones should be noted. First, previous meta-analysis included no more than ten trials and 455 patients. In comparison, our current meta-analysis included 13 trials totaling 648 patients. Our current meta-analysis was the latest and the most comprehensive one, which generally concurs and further reinforces earlier results of previous meta-analyses. Finally, we evaluated the quality of evidence for outcomes using GRADE to help health-care professionals make clinical decisions.

4.4. Implication and explanation of findings

A variety of bone and muscle diseases have been treated with ESWT, including external epicondylitis of the humerus, plantar fasciitis, bone nonunion.[29–31] Recently, ESWT have been investigated, but the mechanisms of action are not well understood. According to general knowledge, extracorporeal shock waves induce characteristic changes within living tissues due to the conversion of mechanical signals into biochemical signals. Study results suggest that ESWT first stimulates the expression of multiple cytokines and then promotes cell proliferation through its mechanism based on studies in animals. Additionally, ESWT decreases the expression of pain-related calcitonin gene-related peptide in the dorsal root ganglion, and increases the pain threshold at peripheral sensory nerve ends.[32] ESWT also produces hyperstimulation analgesia, which some scholars believe is responsible for alleviating pain in insertional tendinopathy.[33] Another hypothesis was that motor simulation of the muscles and tendons with extracorporeal shock waves may be effective in killing pain and improving muscle strength.[34] Even though ESWT seems to have many beneficial effects on the human body, its effectiveness and safety are questioned when its use is promoted comprehensively for clinical purposes.[35]

The pain score at 1 month and 3 months was significantly lower in patients who underwent ESWT with LBP. An analysis of sensitivity was conducted by excluding one study at a time to determine whether one study had a substantial impact on overall WMD estimates.

4.5. Limitations

However, several limitations inevitably exist in our meta-analysis. Currently, there was only five RCTs were finally included in this study and the number was relatively small. Thus, additional research is required to support or refute the present findings before any firm conclusions can be drawn. The funnel plots produced showed no evidence of publication bias but are limited by the small number of studies, and hence we accept that a risk publication bias may be present. In some studies, there was significant differences in age, gender, body mass index, and preoperative ASA class, which made general characteristic of the two groups incomparable. Heterogeneity existed between the selected studies, although it was impossible to determine all sources of heterogeneity.

5. Conclusion

This systematic review and meta-analysis revealed that ESWT was effectiveness for relieving pain and disability in LBP patients. The safety of ESWT was still unclear in current meta-analysis. However, due to the small number of included studies, limited quality of available study data and the fact that the data was not meta-analyzed, the results of the review should be interpreted with caution. Due to these limitations, the combined results of this meta-analysis should be cautiously accepted, and high-quality RCTs with long term follow-up and large sample size are needed.

Author contributions

CL and ZX conceived and designed the study. LC and SP searched and selected relevant studies. CL and ZX extracted and interpreted data. LC and SP analyzed the data. LC and SP wrote the paper. CL and ZX critically reviewed and approved the final manuscript.

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Validation: Zhibo Xiao.
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Writing – review & editing: Zhibo Xiao.

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