Effectiveness and safety of moxibustion in treatment of lumbar disc herniation: a systematic review and Meta-analysis

Wang Yang, Zhang Huiling, Xia Liping, Sun Zhiling, Xu Xiao, Du Shizheng

METHODS: Four Chinese databases and three English databases were searched from their inception to April 2018. Randomized controlled trials (RCTs) were included if moxibustion was used as the sole treatment or as a part of combination therapy with other treatments in patients with LDH. Two reviewers independently extracted the data and assessed the methodological quality using the Cochrane criteria for the risk of bias. The Meta-analysis was performed using Review Manager 5.3 software.

RESULTS: In total, 16 RCTs including 1186 patients with LDH were analyzed. The Meta-analysis showed favorable effects of moxibustion in combination with massage therapy on the visual analog scale score compared with massage therapy alone [mean difference (MD) = −1.32, 95% confidence interval (CI) (−2.12, −0.51), P = 0.001]. The subgroup Meta-analysis failed to show favorable effects of electro-acupuncture plus moxibustion on the efficacy rate compared with electro-acupuncture alone [relative risk (RR) = 1.06, 95% CI (0.98, 1.14), P = 0.15]. However, acupuncture or massage therapy plus moxibustion improved the efficacy rates compared with acupuncture or massage therapy alone [RR = 1.33, 95% CI (1.18, 1.49), P < 0.000 01] [χ² = 2.76, P = 0.25, I² = 27%], [RR = 1.15, 95% CI (1.06, 1.25), P = 0.001] [χ² = 0.00, P = 0.95, I² = 0%]. With respect to the Japanese Orthopaedic Association (JOA) scores, acupuncture or massage therapy in addition to moxibustion produced results different from those of acupuncture or massage therapy alone [MD = 5.58, 95% CI (4.15, 7.00), P < 0.000 01] [χ² = 0.58, P = 0.45, I² = 0%], [MD = 3.61, 95% CI (3.01, 4.21), P < 0.000 01]. There were no significant differences in the JOA score for subjective symptoms, objective symptoms, daily living ability, and other parameters. In six RCTs, no adverse reactions occurred during moxibustion.

CONCLUSION: Whether moxibustion is an effective intervention for LDH is unclear because of the small sample size of qualified RCTs and the high risk of bias. More high-quality RCTs that
overcome the methodological shortcomings of the existing evidence are needed.

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**Keywords:** Moxibustion; Intervertebral disc displacement; Review; Meta-analysis; Randomized controlled trial

**INTRODUCTION**

Lumbar disc herniation (LDH) refers to lumbar intervertebral disc degeneration, fibrous ring rupture, nucleus pulposus stimulation, or compression of the spinal cord, nerve roots, or cauda equina.\(^1\) van Tulder et al.\(^2\) reported that LDH is the origin of the severe and disabling forms of low back pain, and LDH is now a known cause of low back pain and sciatica.\(^3\) LDH often leads to high treatment costs, restricted functioning, an inability to work, and a reduction in health-related quality of life,\(^4\) therefore causing social concern.\(^5\) The incidence of LDH is approximately 5 per 1000 adults annually.\(^6\) Thus, the incidence of LDH is high. The currently available therapeutic methods for LDH include nonsurgical and surgical treatments. In most young patients, the LDH condition improves with conservative treatment; however, conservative treatment lacks efficacy in a small number of patients, who eventually need surgical treatment.\(^7\) Many patients with sciatica will improve over time. However, surgery is frequently considered for patients with severe or persistent symptoms.\(^7\) Researchers have recently indicated that surgery generally does not increase the rate of patients’ return to work compared with conservative interventions. Conservative treatment methods for LDH are diverse. The main methods of conservative treatment are bed rest, traction, physiotherapy, massage, epidural injection of adrenal cortical hormone, and chemical dissolution of the nucleus pulposus.\(^8\) However, whether the efficacy of conservative treatment is superior to the natural progression of disc herniation or if it is a safe and economical treatment option remains controversial.\(^9,10\)

A large amount of research has focused on the role of moxibustion in treating rheumatic conditions, including rheumatoid arthritis,\(^11\) osteoarthritis,\(^12\) and knee osteoarthritis.\(^13,14\) Several systematic reviews of interventional studies have been conducted to detect evidence of the efficacy of moxibustion in the treatment of cancer-related fatigue,\(^15,16\) inflammatory bowel disease,\(^17\) primary dysmenorrhea,\(^18\) cancer care,\(^19\) irritable bowel syndrome,\(^20,21\) stroke rehabilitation,\(^22\) pain,\(^23,24\) and ulcerative colitis.\(^25\) Moxibustion can effectively treat the symptoms of patients with knee osteoarthritis.\(^26\)

Several randomized controlled trials (RCTs) have been performed to examine the effects of moxibustion in the treatment of LDH, and their conclusions were some-what inconsistent with one another.\(^27,28\) However, one review of RCTs indicated that heat-sensitive moxibustion plays a certain positive role in LDH.\(^29\) The limitation of the former review is that it did not focus exclusively on moxibustion as the interventional theme of LDH. No systematic reviews have specifically focused on moxibustion as treatment for LDH, resulting in less clinical significance. Hence, the purpose of this Meta-analysis was to evaluate the efficacy and safety of moxibustion for LDH.

**MATERIALS AND METHODS**

**Inclusion criteria**

All RCTs published worldwide, whether blinded or not, were included in the study, including those trials published in the form of dissertations and abstracts. There were no language restrictions.

**Study subjects**

As more diagnostic criteria for LDH, those who met the criteria were included in the study.

**Interventions**

The patients in the treatment group underwent direct or indirect moxibustion therapy. Moxibustion alone or moxibustion combined with other treatments for LDH were included in the study, but moxibustion was required to be the only variable. Moxibustion combined with acupuncture and other related technologies was allowed. The control group could be treated by other means such as acupuncture, massage, Western Medicine, electro-acupuncture, and cupping.

**Outcome measures**

The outcome measures were the Japanese Orthopaedic Association (JOA) score, the visual analog scale (VAS) score, the efficacy rate, and the incidence of adverse events.

The JOA score was developed to assess treatment for low back pain by members of the JOA in 1986.\(^30\) The JOA score, which consists of four parts (14 projects), was evaluated for pain and function in the present study. The four parts are subjective symptoms, which include low back pain, leg pain, or tingling gait (scores range from 0 to 9 points); clinical signs, which include straight leg elevation, test sensory disturbance, and dysesthesia (scores ranged from 0 to 6 points); restricted activities, including lying, standing, washing, tilting forward, sitting for about 1 h, lifting or holding weights, and walking (scores range from 0 to 14 points); and finally, bladder function (scores range from 0 to 6 points). The total score of the questionnaire is 6 to 29 points, with higher scores indicating better conditions.\(^31\) The VAS score was determined by the patients placing a mark on a line from 0 cm (no pain) to 10 cm (or 100 mm) (worst pain imaginable), indicating their present pain intensity.\(^32\)
Finally, the efficacy rate and incidence of adverse events were calculated.

**Exclusion criteria**

Studies in which the outcome was not assessed by the effectiveness of moxibustion were excluded (such as studies that used an unproven therapeutic effect in the control group or moxibustion in two different forms of comparisons).

**Search strategy**

We reviewed the four main Chinese databases: the China National Knowledge Infrastructure, Chinese Biological Literature Database, China Science and Technology Journal Database, and Wanfang Digital Journal. We also reviewed three English databases: PubMed, Web of Science, and the Cochrane Library. The search terms fell into three categories: 1#moxibustion (“moxibustion,” “moxa,” “moxa-moxibustion,” or “mugwort”), 2#LDH (“lumbar disc herniation,” “LDH,” “intervertebral disk displacement,” or “intervertebral disc displacements”), and 3#RCTs (“randomized controlled trials,” “controlled clinical trials,” or “random”). 1#AND2#AND3#. The databases were searched from their inception to April 2018.

**Evaluation method**

For the data extraction, two reviewers (Wang Yang and Zhang Huiling) independently reviewed the articles and abstracts, independently selected relevant literature according to the inclusion and exclusion criteria, and excluded apparently unrelated literature. The reviewers read the full text of the trials that potentially met the inclusion criteria to determine if they could truly be included. The two reviewers cross-checked the results of the included trials, and disagreements regarding inclusion were resolved either by discussion or by a third reviewer (Du Shizheng).

In the clinical outcome measurement, the primary outcome was the efficacy rate and the secondary outcomes were the JOA score, VAS score, and incidence of adverse events.

**Quality evaluation**

Two reviewers evaluated the RCTs according to the Cochrane Handbook for Systematic Reviews of Interventions Version 5.0 quality evaluation standard, which includes the following evaluation criteria: (a) random distribution methods; (b) allocation concealment; (c) blinding of participants, practitioners, and outcome assessors; (d) complete outcome data; (e) selective outcome reporting data; and (f) other bias sources. Each of the research results were judged explicitly by these criteria as follows: Yes (low risk of bias), No (high risk of bias), or Unclear (uncertain risk of bias). Criteria (a), (b), and (e) were used to evaluate the risk of bias of each included study, and the other three criteria were used to evaluate the research results according to the different assessments, emphasizing the different degrees of the influence of bias on the study results from the same paper. Two decision-makers (Wang Yang and Zhang Huiling), double-checked the evaluation results by exchanging with each other. The eligibility of the trials was assessed through discussion to resolve disagreements regarding inclusion, or the decision was made by the third decision-maker (Du Shizheng).

The data were analyzed using Review Manager (Version 5.3) provided by the Cochrane network.1 The included studies were inspected for heterogeneity, and \( P < 0.1 \) was taken as the inspection standard. If no heterogeneity was present among the trials, a fixed-effects model was applied to the Meta-analysis. If heterogeneity was present among the trials, the source of heterogeneity was determined. If no clinical or methodological heterogeneity was present, a random-effects model was used in the Meta-analysis. Dichotomous data are summarized as relative risk (RR). Continuous data are reported as mean difference (MD). Their effect sizes are expressed as 95% confidence intervals (CIs) throughout, and \( P \leq 0.05 \) was considered statistically significant. If obvious clinical heterogeneity existed in the trials, a descriptive analysis was performed. If necessary, a sensitivity analysis was performed to check the stability of the test results.

**RESULTS**

**Search outcomes**

According to the search strategy, the initial screening resulted in 1306 potentially relevant citations. No additional records were identified through other sources. After omission of 103 duplicate citations, the remaining 1203 records were filtered. In total, 1147 citations were removed based on the title and abstract and the remaining 56 papers were read and screened. Finally, 16 articles were included in the quantitative Meta-analysis. The specific retrieval strategy is shown in Figure 1.

**Characteristics of the included studies**

Type of study: all studies were RCTs. Fourteen RCTs adopted a two-arm parallel control design,27,28,35-46 and two RCTs used a three-group parallel control design.47 All RCTs originated from China.

Study object: the study participants were outpatients and/or hospitalized patients. Seven trials used the National Traditional Chinese Medicine disease diagnosis and treatment standard of Chinese medicine promulgated by the State Administration of Traditional Chinese Medicine in 1994.27,29,31,34,40,41,44 The remaining eight trials used different diagnostic standards.35,36,42-45 Only one trial did not report the diagnostic standards.47 Thirteen trials reported the inclusion and exclusion criteria.27,28,35,36,38,40,42-45 Interventions: moxibustion was applied in the treatment group either alone or combined with other tradi-
tional Chinese therapies (e.g., acupuncture, massage, electro-acupuncture, or rehabilitation training). The control group was treated by acupuncture in six trials,\textsuperscript{27,28,36,37,39,40} electro-acupuncture in three trials,\textsuperscript{28,37,39} cupping in one trial,\textsuperscript{28} massage in three trials,\textsuperscript{41,44,46} Western Medicine plus acupuncture in one trial,\textsuperscript{48} rehabilitation training in one trial,\textsuperscript{43} and oral drug therapy in one trial.\textsuperscript{42}

Key data regarding the 16 included RCTs\textsuperscript{27,28,35-48} are summarized in Table 1.

Methodological quality: risk assessment was performed in all trials (Figure 2). Among all 16 trials, 2 used a computer-generated random sequence,\textsuperscript{35,45} 9 used a random table method,\textsuperscript{27,28,35,36,43,45,46,48} and 3 used appropriate methods;\textsuperscript{38,40,44} the other trials referred to randomization only and did not specify the methods. Only two trials reported allocation concealment,\textsuperscript{35,41} and only two trials used single blinding.\textsuperscript{35,41} Nine trials reported cases of shedding, but none of them used intention-to-treat analysis.\textsuperscript{35,38,40,42,47,48} Two trials included a follow-up report.\textsuperscript{41,44} All trials described the baseline conditions and comparability. A specific risk assessment chart for each trial is shown in Figure 3.

**VAS score**
Six RCTs ($n = 500$) used the VAS score as a measure of the effects of a particular therapy on improvement in LDH.\textsuperscript{35,38,40,44,46,48} The results of the Meta-analysis showed that compared with massage therapy, moxibustion combined with massage therapy had significantly favorable effects in improving LDH conditions [$MD = -1.32$, 95\%CI ($-2.12$, $-0.51$), $P = 0.001$] (Figure 4).

Because of large differences in control interventions, the remaining three trials\textsuperscript{28,36,47} were not included in the Meta-analysis. One trial showed that compared with cupping, moxibustion did not significantly improve the status of patients with LDH.\textsuperscript{47} Two trials showed that moxibustion or moxibustion combined with acupuncture had significantly favorable effects in improving LDH conditions compared with acupuncture therapy alone.\textsuperscript{35,36}

**Efficacy rate**
Twelve RCTs ($n = 516$) used the efficacy rate as a measure of the effects of a particular therapy on improving LDH.\textsuperscript{35,38,40,42,48}
Moxibustion + electro-acupuncture vs electro-acupuncture: three RCTs (n = 152) assessed the efficacy of electro-acupuncture versus electro-acupuncture plus moxibustion in patients with LDH. All three studies showed no statistically significant difference in the efficacy rate between the groups. The subgroup analysis suggested that compared with electro-acupuncture alone, electro-acupuncture plus moxibustion had no statistically significant favorable effects on the efficacy rate [RR = 1.06, 95% CI (0.98, 1.14), P = 0.15] (Figure 5).

Moxibustion + acupuncture vs acupuncture: three RCTs (n = 230) assessed the efficacy of acupuncture combined with moxibustion compared with acupuncture alone in patients with LDH. Two of these studies showed a significant difference in the efficacy rate between the groups, while the other study did not. The result of the subgroup analysis suggested that...
Moxibustion + massage vs massage: two RCTs \((n = 260)\) assessed the efficacy of massage plus moxibustion compared with massage therapy in patients with LDH.\(^{24,66}\) One trial showed a significant difference in the efficacy rate between the groups,\(^{66}\) while the other study did not.\(^{24}\) The result of the subgroup analysis suggested that compared with massage therapy alone, moxibustion plus massage therapy had significantly favorable effects in improving the efficacy rate \([RR = 1.15, 95\% CI (1.06, 1.25), P = 0.001]\) with low heterogeneity \([\chi^2 = 0.00, P = 0.95, I^2 = 0\%]\) (Figure 5).

Because of large differences in control interventions, four trials were not included in the Meta-analysis.\(^{24,37,47,48}\) One trial implied that compared with cupping, moxibustion did not significantly improve the status of patients with LDH in terms of the efficacy rate.\(^{47}\) One trial indicated that compared with Western Medicine plus acupuncture, moxibustion had significantly favorable effects in improving LDH conditions.\(^{48}\) One trial showed that compared with oral drug therapy (yao-tongning), moxibustion had significantly favorable effects.\(^{48}\) Another single trial indicated that moxibustion combined with rehabilitation training had significantly favorable effects in improving LDH conditions compared with rehabilitation training alone.\(^{49}\)

**JOA score**

Eight RCTs \((n = 620)\) used the JOA score as a measure of the effects of a particular therapy on improving LDH.\(^{27,28,36,39,42,46,46,47}\)

Moxibustion vs acupuncture: two RCTs \((n = 100)\) assessed the efficacy of moxibustion compared with acupuncture in patients with LDH.\(^{27,28}\) Both studies showed a statistically significant difference in the JOA score between the groups. However, their conclusions were opposite. The subgroup analysis suggested that compared with acupuncture, moxibustion had no significantly favorable effect with respect to the JOA score \([MD = 0.02, 95\% CI (-6.15, 6.19), P = 0.99]\) (Figure 6).

Moxibustion + acupuncture vs acupuncture: two RCTs \((n = 140)\) assessed the efficacy of acupuncture plus moxibustion compared with acupuncture in patients with LDH.\(^{29,30}\) Both studies showed a statistically significant difference in the JOA score between the groups. The result of the subgroup analysis suggested that compared with acupuncture alone, moxibustion plus acupuncture had significantly favorable effects in improving the JOA score \([MD = 5.58, 95\% CI (4.15, 7.00), P < 0.00001]\) with low heterogeneity \([\chi^2 = 0.58, P = 0.45, I^2 = 0\%]\) (Figure 6).

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**Table 1**

<table>
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<th>Study or Subgroup</th>
<th>Experimental</th>
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<td>2.07</td>
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<tr>
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<td>5.11</td>
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<td>100.0</td>
<td>-1.32 [-2.12, -0.51]</td>
<td>-1.32 [-2.12, -0.51]</td>
</tr>
</tbody>
</table>

Heterogeneity: \(T^2 = 0.25, \chi^2 = 25.63, df = 2 (P = 0.00001), P = 92\%

Test for overall effect: \(Z = 3.22 (P = 0.001)\)

**Figure 3** Summary of the risk of bias of the included trials

**Figure 4** Meta-analysis of the visual analog scale score
Figure 5 Subgroup analysis of the efficacy rate

Figure 6 Subgroup analysis of the Japanese Orthopaedic Association score

Figure 7 Subgroup analysis of the Japanese Orthopaedic Association score of each item
Moxibustion + massage vs massage: two RCTs assessed the efficacy of moxibustion plus massage therapy compared with massage therapy in patients with LDH. Both studies showed a statistically significant difference in the JOA score between the groups. The result of the subgroup analysis suggested that compared with massage therapy alone, moxibustion plus massage therapy had significantly favorable effects in improving the JOA score \([MD = 3.61, 95\% \, CI \,(3.01, 4.21), P < 0.0001]\) (Figure 6).

The study results also indicated that the effectiveness of moxibustion plus acupuncture or acupuncture alone, massage therapy (or acupuncture) were superior to those of acupuncture (or massage therapy) alone. Compared with Western Medicine plus acupuncture or acupuncture alone, moxibustion had a therapeutic advantage. However, confirmation of these findings requires an expanded sample. It was also difficult to determine the safety of moxibustion because of the lack of assessment of adverse effects in the trials. Moxibustion may lead to allergic reactions, burns, and infections. Six of the 16 included studies reported that adverse reactions did not occur during treatment, but the remaining studies did not mention assessment of adverse reactions. With respect to moxibustion safety, none of the 16 investigators described any adverse events due to moxibustion. Hence, there is not enough evidence to prove that moxibustion is unsafe for patients with LDH.

Because of the nature of the individual or complex interventions, it was difficult to fully determine whether the inclusion of moxibustion in the treatment strategy was beneficial for LDH. Numerous factors can influence the efficacy of moxibustion treatment, including the application method (direct or indirect), duration of moxibustion therapy, frequency of moxibustion treatment, moxibustion treatment periods, moxibustion points, moxibustion distance, and others. Direct moxibustion treatment was not employed in the RCTs in this Meta-analysis. In 20% of the included studies, the participants underwent a median of 15 d of moxibustion treatment; however, this was not always a daily therapy, and the treatment duration varied. In addition, all of the included studies were conducted in China, and the moxibustion interventions investigated in these trials are thus likely to reflect common moxibustion practice in China. All of these factors should be considered before making any judgments or recommendations regarding moxibustion for patients with LDH. If the efficacy of moxibustion as a treatment for LDH is acknowledged, the underlying mechanism would draw much attention. Interest in research regarding the underlying mechanisms of moxibustion has grown in recent decades through animal experiments. In modern research, the most widely accepted view of the mechanisms underlying moxibustion involves anti-inflammation and immunoregulation theory. Another hypothesis is the thermal stimulation effect theory. Heat stimulated by burning moxa is transferred to the skin and recognized by the thermal sensory receptors as invasive stimulation. When this stimulation activates the thermal sensory receptors, the signal is propagated to the central nervous system through nerve fibers, producing a therapeutic effect. However, none of these theories are currently more than speculation.

Our review has several limitations that must be acknowledged. First, this systematic review had a high risk of bias, which seemed to result in the positive results we found. To avoid bias, we suggest that the authors of future studies refer to the recent extension of the Consolidated Standards of Reporting Trials statement for trials of moxibustion interventions. In addition, the total numbers of RCTs and participants involved were too small to draw concrete conclusions regarding the therapeutic effect of moxibustion. Second, most of the outcomes were subjective symptom scales,
such as the VAS score and efficacy rate. The tendency toward subjective judgements weakened the credibility of the conclusions regarding the effectiveness of moxibustion. Future trials must consider the use of a pragmatic design not only for subjective patient-reported outcome measures but also for objective outcome measures such as the use of medications or other health services. Second, all included RCTs that reported positive results came from China, where reports of positive results are common, casting some doubt on the data validity. In addition, because all of the included studies were conducted in Asia, our conclusions are relevant only to Asian populations. Our conclusions should be further verified in future studies. All of these limitations increase the difficulty in drawing overall conclusions.

In conclusion, whether moxibustion is an effective intervention for treating LDH remains unclear because of the small sample sizes of the eligible RCTs and the high risk of bias among the available RCTs. Further rigorous RCTs are warranted to confirm our findings.

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