

The Effectiveness of Moxibustion for Treating of Lumbar Disc Herniation(LDH): A Protocol for Systematic Review and Meta-ananlysis

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Abstract

Background: Lumbar disc herniation (LDH) refers to lumbar disc degeneration or external pressure, resulting in annulus fibrosus rupture, nucleus pulposus protrusion or bulging, compression of nerve roots, cauda equina nerve, and then some clinical symptoms of a clinical syndrome, clinical symptoms are often manifested as unilateral or bilateral lumbar pain, leg numbness. L3/L4, L4/L5, and L5/S1 intervertebral disc herniations are common in the lesion sites of lumbar disc herniations, and the incidence rate is as high as 90%. Typical manifestations are tenderness at the corresponding surface of the body. This disease is a common and frequently-occurring disease in the department of rehabilitation and acupuncture of the hospital, and is a common cause of lumbago and leg pain. At present, the common external treatment for LDH includes many methods, mostly acupuncture and moxibustion

Methods: We're going to use systematic electronic search, including PubMed, MEDLINE, Cochrane library, SinoMed, CNKI, WF, VIP and checked references of retrieved articles. Randomized controlled trials (RCTs) on acupotomy treatment in LDH patients will be searched for independently by 2 reviewers in the databases from their inception to August 2020. We will combine data from clinically homogenous studies in a fixed effect meta-analysis using RevMan V.5.3.5, and the evidence level will be assessed by using the method for Grading of Recommendations Assessment, Development, and Evaluation (GRADE).

Discussion: The results of this review will provide reliable evidence for effectiveness and safety of moxibustion for treating LDH.

Systematic review registration: CRD42020187626

1. Background

Lumbar disc herniation (LDH) is a clinically common degenerative spinal disease, which adversely affects patients' quality of life and work ability^[1]. The clinical symptoms of the disease are localized low back pain or lower extremity radioactive neuralgia, which is distributed in a region corresponding to the dermal nodes of the associated nerve roots^[2], LDH mainly affects 1–3% of the general population, and most of the patients are aged 30–50 years old. Meanwhile, the common lesion site of LDH is the lumbar disc between L4/L5 and L5/S1, which has become a common occupational health problem and brought severe test to the medical security system^[3]. The treatment of LDH includes surgery and conservative modalities, nowadays, more and more attention has been paid to conservative treatment, One study showed that less than 2% of patients with low back pain receive LDH surgery^[4]. However, only 15–20% of LDH patients need operative intervention because of severe neurological symptoms^[5]. Surgical treatment of LDH has certain risks, its applicability is not high, and there are many uncertain factors in the treatment process^[6]. Efficacy of non-operative interventions including various physiotherapy treatments have been evaluated and reported^[7]. Although physical therapy modalities are often recommended, some studies discourage the use of modalities such as spinal decompression therapy, transcutaneous electrical neuromuscular stimulation (TENS), ultrasound, and biofeedback, which

possess uncertain effectiveness for managing acute lumbar impairment^[8-10]. Moxibustion, which is almost widely used in all dynasties of China, has a significant effect on analgesia of LDH, in which suspended moxibustion, Thunder fire moxibustion, mild moxibustion, and needle warming moxibustion are routinely used as treatment modalities^[11]. Nowadays, the indications for moxibustion are gradually expanded because of its function and practicality, The heat generated by moxibustion can effectively play the role of replenishing Yang and dispelling cold, promoting blood circulation and removing blood stasis, and warm the meridians and collaterals^[12].

Moxibustion, as an ancient treatment method under the guidance of traditional Chinese medicine theory, mainly uses the heat generated by moxibustion to stimulate specific acupoints or surface parts of the body to stimulate the related functions of acupoints, and stimulates the meridians and vital energy to regulate the zang-fu organs, so as to treat many kinds of disease including LDH^[13]. Previous studies showed that moxibustion alleviated chronic pain by protecting against oxidative damage in skeletal muscle, alleviating cardiac injury, and reducing the serum proinflammatory cytokines in rats^[14-16]. One study had investigated the effect of moxibustion on behavioral activities. Cytokines mRNA expression of IL-1b, IL-6, and TNF-a in the hippocampus was detected by RT-PCR, and these cytokines content was measured by ELISA. The study found that moxibustion could attenuate exercise-induced fatigue and inhibits inflammation in the hippocampus in fatigue rats exposed to chronic exhaustive exercise^[17].

We strongly believe that systematic reviews and meta-analyses could be advantageous for assessing clinical efficacy and developing clinical guidelines^[18]. However, to date, no systematic review or meta-analysis has specifically concentrated on moxibustion therapy for LDH. In this study, evidence-based medicine will be used to analyse and evaluate clinical randomized controlled trials (RCTs) on the use of moxibustion for LDH. As the research progresses, you will find an interesting phenomenon. Some studies on the treatment of LDH with conventional drugs have shown that drug resistance and adverse reactions are increasingly impossible to ignore. Meanwhile, some studies based on surgical therapy have reported severe postoperative reactions and unsatisfactory low efficiency. Hence, this systematic review and meta-analysis aimed to assess the quality of RCTs, so as to evaluate the effectiveness and safety of moxibustion for treating LDH patients and further enhancing the clinical efficacy of acupuncturists and physicians in the treatment of LDH patients.

Objectives

We will conduct a systematic review to critically assess the efficacy and safety of recent clinical evidence of moxibustion for LDH.

2. Methods

2.1. Study registration

This systematic review and meta-analysis will be performed according to the guidelines of the Cochrane Handbook for Systematic Reviews and Meta-Analysis Protocol (PRISMA-P) ^[19]. This protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 5 July 2020 and registration number is CRD42020187626, and it could be found at https://www.crd.york.ac.uk/prospERO/display_record.php?ID=CRD42020187626. Any changes in the full text will be described.

2.2. Inclusion and exclusion criteria

2.2.1. Types of study

There is no restriction on blinding or publication type, all RCTs published in both Chinese and English on moxibustion in the treatment of LDH can be included.

2.2.2. Type of participants.

Patients with all types of LDH who were diagnosed with internationally recognized criteria are eligible for inclusion. There will be no restrictions on diagnostic criteria, race, gender, economic situation and education level.

2.2.3. Type of interventions.

Studies that involved any form of moxibustion (including suspended moxibustion, Thunder fire moxibustion, mild moxibustion, and needle warming moxibustion) as the sole treatment or as a major part of a combination therapy with other interventions (e.g. conventional drugs, etc.) will be included. Importantly, no restrictions are placed on the number of acupoints, the method of moxibustion, duration, and frequency. However, studies will be excluded if moxibustion is used as an adjuvant therapy.

2.2.4. Type of comparator (s)/control

The comparative interventions will be sham moxibustion, placebo, no treatment, or other active treatments. The following treatment comparisons will be performed:

- (1) moxibustion vs no treatment
- (2) moxibustion vs placebo or sham moxibustion
- (3) moxibustion vs other active therapies
- (4) moxibustion + active therapy vs the same active therapy

2.2.5. Types of outcome measurements

2.2.5.1. Main outcomes.

The primary outcomes of interest will be verbal rating scale (VRS) and functional disability.

2.2.5.2 Additional outcomes.

The secondary outcomes of interest will include McGill pain questionnaire, quality of life, muscle tension, muscle strength and recurrence rate.

2.3. Search methods for identification of studies

We will electronically search the following databases for literature, regardless of publication status and language: the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; China National Knowledge Infrastructure (CNKI); Chinese Biomedical Literature Database (CBM); Chinese Scientific Journal Database (VIP database); and Wan-Fang Database. In order to ensure the comprehensiveness and accuracy of the literature retrieval, we will combine the Suggestions of evidence-based medicine experts with the actual situation in the literature retrieval process to formulate the retrieval strategy, and make corresponding records to find the most appropriate retrieval strategy. The reference lists and the citation lists of studies meeting the inclusion criteria and relevant systematic reviews will also be searched to identify further studies for inclusion. Before this review completed, the two reviewers will conduct the searching once again to ensure the latest studies could be included.

The search will be restricted to human subjects, while there is no restriction on any specific languages. The proposed search strategy for PubMed is presented in Table 1.

2.4. Data collection and analysis

2.4.1 Pilot search.

The authors of review conducted pre-testing in order to improve the consistency of literature selection criteria and reduce unnecessary problems in the literature selection process. We obtained the results through article screening and summarized the potential causes of inconsistencies, thus greatly improving the understanding of all authors on inclusion criteria and exclusion criteria.

2.4. 2 Studies selection

Studies will be identified using NoteExpress 3.0. After the initial removal of duplicate studies, two reviewers (ZNW and YY) will independently screen titles and abstracts based on the eligibility criteria. Full-text studies will be retrieved for all potentially includable systematic reviews (SRs) or SR protocols. If studies contain insufficient information to make a decision about eligibility, QSX will try to contact authors of the original reports to obtain further details. During the procedure, disagreements will be resolved by discussion or consensus with the third reviewer (YY). Study selection will be performed in accordance with the PRISMA flowchart (Fig. 1).

2.4.3 Data extraction

Two researchers (ZNW and YY) extracted the literature information according to the inclusion and exclusion criteria, including the following aspects:

- (1) Study characteristics: author, year, study design, sample size and follow-up time;
- (2) Patient characteristics: age, sex, and type of LDH;
- (3) Intervention: intervention measures in the experimental group, intervention measures in the control group);
- (4) Outcome of the study: Two researchers (YY and QSX) cross-examined the results of extraction of the included literature. In case of differences, a third party (JX) should be consulted to resolve them.

Reporting will be assessed for completion by utilising the Standards for Reporting Interventions in Controlled Trials of Moxibustion (STRICTM) checklist ^[20].

2.4.4 Evaluation of the methodological and reporting quality of the included studies

For each systematic Reviews that meets the inclusion criteria, two reviewers (ZNW and YY) will use the Assessment of Multiple Systematic Reviews-2 (AMSTAR-2) Measurement Tool ^[21] and PRISMA to assess methodological quality and report quality. At the same time, differences arising during the evaluation process will be discussed by two reviewers and arbitrated by a third author (JX).

(1) AMSTAR-2 consists of 16 items, 7 of which are critical areas. The 16 criteria are rated as "yes" (clearly completed), "no" (clearly not completed), "cannot report" (unclear completion), or "not applicable" based on the information provided by the reviewer to the system review when the criteria are met.

(2) PRISMA: This is a 27-item list. Each checklist item will be evaluated as yes, no, or partially Yes to indicate compliance.

2.4.5 Evaluation of the evidence quality of the included studies

After the evidence is evaluated by the Grading of Recommendations Assessment, Development and Evaluation (GRADE), the quality of the evidence, the weights of strengths and weaknesses, and the patient's values and preferences will be carefully considered by Two authors (ZNW and YY) to develop preliminary recommendations. This proposal will be reviewed by 2–3 rounds of Delphi process ^[22], which will then be submitted to other two authors (GXX and ZYZ) for approval. We will use the GRADE Grid instrument ^[23] to review each recommendation one by one to group it into one of five options, including "strong recommendation", "weak recommendation", "unclear recommendation", "weak no recommendation" and "strong no recommendation". The aim is to reach a better consensus. If 75 percent

of the experts agree on an option, there is consensus on the recommendation. Otherwise, the project goes to the next Delphi process to discuss the disputed project again.

2.4.6 Dealing with lost data

When we find insufficient or unspecified data in the published SRs, it will be necessary to contact the author by phone or email with the necessary information. If the data we need cannot be collected completely, it will be considered useless and abandoned. After that, we will analyze the existing data and discuss the potential impact of missing data

2.4.7 Synthesis of data

Two of our researchers (QSX and ZNW) will use the bias risk tool provided by the Cochrane Collaboration to evaluate the quality of the literature using RevMan 5.3 software. This recommended tool includes 7 important items: sequence generation, allocation concealment, blinding of participants and personnel, blinding of results evaluation, incomplete result data, selective result reporting, and other biases. Make "Low risk," "High risk," and "unclear risk" judgments for each research literature. Finally, a "risk of deviation" summary and a chart are generated to show the results. As with the previous process, it will be independently assessed by 2 researchers. If there is disagreement, it will be discussed with the 3rd researcher (JX).

RevMan 5.3.3 software was used for Meta analysis of the research objects. Counting data were represented by relative risk (RR) and its 95%CI, and measurement data were represented by mean difference (MD) and its 95%CI. Heterogeneity among all included studies was detected by χ^2 test. When statistical homogeneity was found among the results ($P > 0.1$, $I^2 < 50\%$), a fixed effect model was used for meta-analysis of the results. If statistical heterogeneity exists among the results ($P < 0.1$, $I^2 > 50\%$), the source of heterogeneity needs to be analyzed. If statistical heterogeneity exists between the two results and the difference is not statistically significant, a random-effects model should be used for Meta analysis. When there is too much heterogeneity among the results of various studies, statistical methods such as subgroup analysis, sensitivity analysis and descriptive analysis can be used to treat the heterogeneity.

2.4.8 Subgroup analysis.

If the necessary data are available, we will carry out subgroup analysis in line with the type of LDH, the duration or dosage of moxibustion, treatment frequency, and the type of intervention in the control group or the study group

2.4.9 Sensitivity analysis.

If there is significant heterogeneity, a sensitivity analysis will be conducted from the aspects of sample size, the quality of research, methodological elements, and characteristic of research. In the meantime, we will get rid of low-quality or small sample studies to evaluate whether the conclusions are stable. If sensitivity analysis changes the results, we must be more careful in reaching conclusions.

3. Discussion

We have developed this study based on the principles and standards of evidence-based medicine, in collaboration with multidisciplinary experts, which will facilitate the treatment of LDH by clinicians, as well as for teaching and educating patients.

Based on what we know so far, we have found some limitations of this Protocol:(1)Most of the sites included in the study are in China;(2)The application of moxibustion in other countries and regions needs further study.(3)At the same time, the differences of moxibustion operation methods between different countries should also need be considered.

This study has a number of Contributions:(1)to the best of our knowledge, this is the first protocol to assess moxibustion therapy for patients with LDH;(2)the results of this protocol will be beneficial to acupuncturists and physicians to make decisions the optimal method of treating the disease, and help patients with LDH seeking optimal treatment.;(3)the results are helpful to find out the correct operation method of moxibustion for treating LDH and the relationship between the therapeutic effect, the time of moxibustion and the total amount of moxibustion,effectively improving the efficacy and safety of LDH with moxibustion.

Abbreviations

LDH = Lumbar disc herniation; TENS = transcutaneous electrical neuromuscular stimulation ; RCTs = randomized controlled trials ; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocol; VRS = Verbal Rating Scale;SRs = systematic reviews;AMSTAR-2 = Assessment of Multiple Systematic Reviews-2 ; GRADE = Grading of Recommendations Assessment, Development and Evaluation; RR = relative risk ; MD = mean difference.

Declarations

Ethics approval and consent to participate

Ethical approval will not be required as this is a protocol for a systematic review. The systematic review will evaluate the current evidence regarding moxibustion therapy for Lumbar disc herniation. Findings will be disseminated through peer-reviewed publications and conference presentations.

Consent for publication

Results will be disseminated on peer-reviewed publication and conference presentations

Availability of data and materials

Not applicable.

Competing interests

The authors have no conflicts of interest to declare.

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Author contributions

Conceptualization: Xu GuiXing , Jun Xiong, ZhengYun Zuo.

Data curation: Xu GuiXing , XingYu Yu, ZeNanWu.

Formal analysis: XingYu Yu,QingShan Xie.

Investigation: Jun Xiong, Xu GuiXing .

Methodology: Jun Xiong, XingYu Yu, ZeNan Wu.

Software: Xu GuiXing , QingShan Xie.

Supervision:Jun Xiong, ZhengYun Zuo.

Writing – original draft: Jun Xiong, Xu GuiXing , XingYu Yu, ZeNan Wu.

Writing – review and editing: ZhengYun Zuo, Xing Yu Yu, QingShan Xie.

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Availability of data and materials

Not applicable.

Declaration of Competing Interest

The authors have no conflicts of interest to declare.

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Tables

Table 1: Search strategy (PubMed)

Order	Strategy
#1	Search " Lumbar Disc Herniation "[Mesh] OR " disc displacement, intervertebral "[Mesh] OR " herniated disk "[Mesh] OR " disk prolapse "[Mesh]
#2	Search ((((((Lumbar Disc Herniation [Title/Abstract]) OR disc displacement, intervertebral [Title/Abstract]) OR herniated disk [Title/Abstract]) OR disk prolapse [Title/Abstract]) OR intervertebral disc chemolysis [Title/Abstract]) OR Sciatica [Title/Abstract]) OR Slipped Disk [Title/Abstract]
#3	#1 OR #2
#4	Search" moxibustion "[Mesh]
#5	Search ((((((moxibustion [Title/Abstract]) OR suspended moxibustion [Title/Abstract]) OR Thunder fire moxibustion [Title/Abstract]) OR taiyi miraculous moxa roll [Title/Abstract]) OR acupoint[Title/Abstract]) OR mild moxibustion [Title/Abstract]) OR needle warming moxibustion [Title/Abstract]
#6	#4 OR #5
#7	Search" Systematic Reviews as Topic"[Mesh] OR "Systematic Review"[Publication Type]
#8	Search((((Systematic Reviews[Title/Abstract]) OR Systematic Review[Title/Abstract]) OR SR[Title/Abstract]) OR SRs[Title/Abstract]) OR Review[Title/Abstract])
#9	Search (systematic[Title/Abstract]) AND review[Title/Abstract]
#10	Search"Meta-Analysis"[Publication Type] OR "Meta-Analysis as Topic"[Mesh]
#11	Search ((Meta-Analysis[Title/Abstract]) OR meta-analysis[Title/Abstract]) OR meta- analy*[Title/Abstract]
#12	#7 OR #8 OR #9 OR #10 OR #11
#13	#3 AND #6 AND #12

Figures

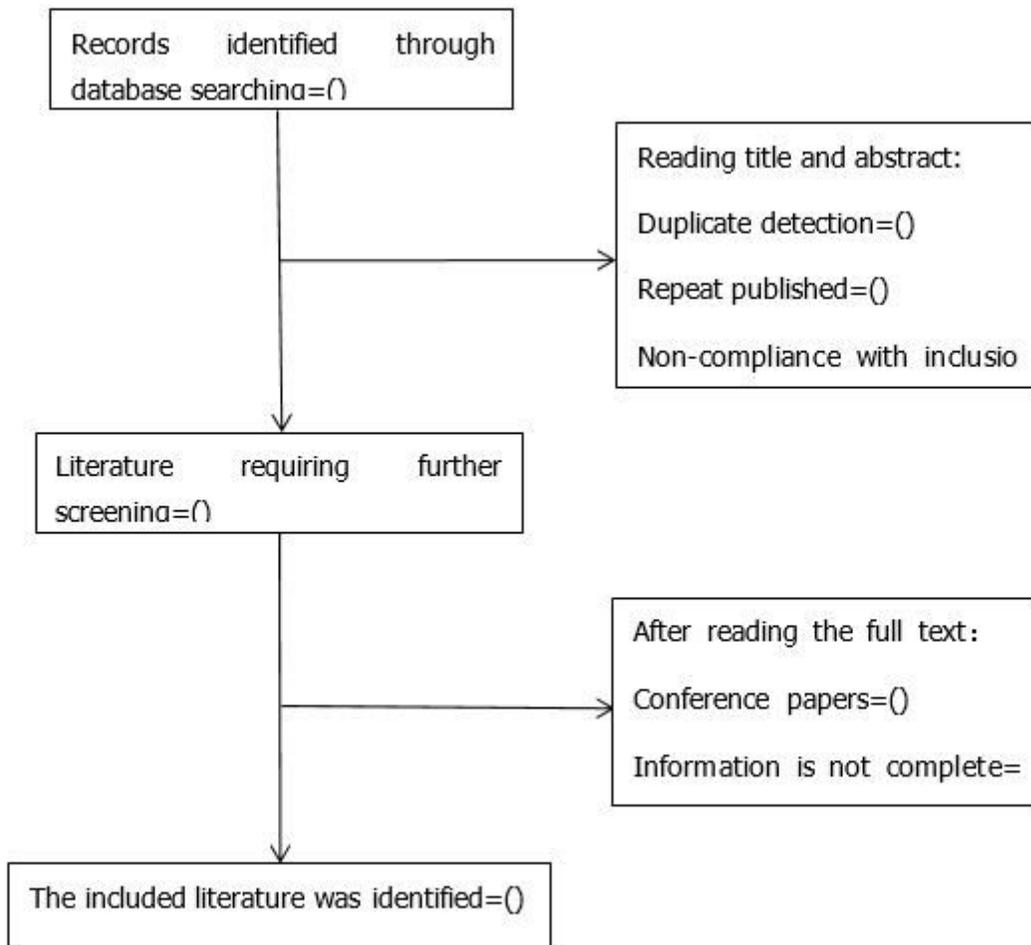


Figure 1

Figure 1

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