A meta-analysis on the clinical efficacy of fire dragon cupping in the treatment of lumbar disc herniation

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\textbf{Author contributions}

MHX and MD was responsible for conceptualization and methodology. MHX was responsible for formal analysis and writing-original draft preparation. LB was responsible for software, validation. ZXK also reviewed, edited and supervision. MHX and LB was responsible for resources and data curation. All authors have read and agreed to the published version of the manuscript.

\textbf{Competing interests}

The authors declare no conflicts of interest.

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\textbf{Abbreviations}

LDH, lumbar disc herniation; TCM, traditional Chinese medicine; VAS, visual analogue scale; NRS, numerical ratings scale; JOA, Japanese Orthopaedic Association; RCT, randomized controlled trial; RR, relative risk; CI, confidence intervals; SMD, standardized mean difference; MD, mean difference.

\textbf{Citation}


\textbf{Abstract}

\textbf{Background}: The incidence of lumbar disc herniation (LDH) is notably high. Consensus among experts highlights non-surgical treatments as the primary therapeutic approach for LDH. Contemporary medicine frequently employs pharmacotherapy and epidural injections in such treatments, which are associated with numerous adverse effects. Prolonged use can severely impair the liver and kidney functions of patients. Hence, the role of safe and effective traditional Chinese medicine techniques becomes pivotal. Among various traditional Chinese medicine approaches for treating LDH, fire dragon cupping, renowned for its remarkable efficacy, cost-effectiveness, and ease of application, is extensively utilised in clinical settings for managing LDH. Nonetheless, there is a scarcity of systematic and standardised evidence from evidence-based medicine studies. Therefore, conducting a meta-analysis is imperative. \textbf{Methods}: A comprehensive computerised search was conducted in databases including China National Knowledge Infrastructure, WanFang Data, VIP, China Biology Medicine disc, PubMed, EMbase, The Cochrane Library, Web of Science, and CINAHL. The search aimed to gather randomised controlled trials on fire dragon cupping therapy for LDH, spanning from the inception of these databases until December 2023. Two researchers independently screened the literature according to inclusion and exclusion criteria, extracted data, and assessed the methodological quality of the studies included, utilising RevMan 5.3 software for meta-analysis. \textbf{Results}: The results show that the fire dragon cupping therapy group had better clinical effectiveness (relative risk = 1.23, 95% confidence interval (CI) (1.14, 1.33), \(P < 0.00001\)), less pain (standardized mean difference = −1.33, 95% CI (−1.49, −1.16), \(P < 0.00001\)), and some improvement in lumbar function (Japanese Orthopaedic Association scores: mean difference = 3.37, 95% CI (2.31, 4.43), \(P < 0.00001\)). \textbf{Conclusion}: The fire dragon cupping therapy significantly alleviates LDH, warranting its extensive application. However, considering the limitations in the number and quality of studies included, the aforementioned conclusion necessitates further validation through more high-quality research.

\textbf{Keywords}: fire dragon cupping therapy; lumbar disc herniation; lumbar spine; meta-analysis; randomized controlled trial
Background

Lumbar disc herniation, abbreviated as LDH, arises from the localised displacement of certain tissues within the lumbar intervertebral disc, surpassing the normal margins of the disc. The protruding tissues may encompass the cartilaginous endplate, fibrous annulus, nucleus pulposus, or a combination thereof. When the protrusion of lumbar intervertebral disc tissues culminates in clinical manifestations such as weakness, numbness, pain, and functional impairment within the corresponding neural distribution area [1]. Lumbago is frequently the first symptom of the clinical presentation, then symptoms like radiating pain and numbness in the lower limbs appear. In severe cases, pain and sensory impairment may manifest in both the lower extremities and the perineal area, accompanied by disturbances in bladder and bowel function [2].

Studies in epidemiology conducted abroad reveal that the incidence of LDH is approximately in the range of 2% to 3%. For males aged 35 and above, the incidence rate stands at approximately 4.8%, while for females, it hovers around 2.5%. Moreover, it is worth noting that at least 95% of cases manifest at the L4-5 and L5-S1 levels [3, 4]. In our country, research indicates a steady annual increase in its incidence, which is approximately 7.62%. The highest incidence is observed among individuals aged 25 to 55, and the affected population is growing, leading to a wider prevalence and a more prolonged course of the disease. Its detrimental effects are progressively worsening, not only impacting patients’ daily lives, work, and studies but also exerting adverse influences on their physical and mental well-being [5, 6]. LDH is a prevalent ailment in clinical practice. Presently, clinical interventions for LDH can be broadly categorised into surgical and non-surgical modalities. Surgical treatment typically yields expedited and substantial amelioration of symptoms. However, it is important to note that surgical procedures are not only governed by stringent criteria but also entail a protracted period of postoperative recuperation, often accompanied by lingering lumbar and leg discomfort.

Hence, non-surgical therapy stands as the frontline approach for managing LDH [2]. In recent years, traditional Chinese medicine (TCM) has become more popular as a way to treat LDH because it has few harmful side effects, is cheap, works quickly, is easy to administer, and can change all of a patient’s bodily functions [7, 8]. The fire dragon cupping therapy represents an integrated natural healing approach within TCM, encompassing techniques such as Tuina, Gua Sha, massage, acupuncture, and moxibustion. The resultant infrared radiation can penetrate the skin and infiltrate the body, transmitting thermal energy along the meridians and acupoints to reach various tissues and organs systemically. This method uses the meridian-viscera interaction to its fullest, affecting both the outside and the inside. This makes it easier to control vital energy, improve blood flow, boost Yang (in Chinese philosophy, the masculine, active and positive principle, characterized by light, warmth, dryness, activity, etc.) energy, and adjust visceral functions. The utilisation of ten distinct manipulative techniques, including kneading, rolling, pushing, pressing, pinpointing, rocking, flashing, vibrating, ironing, and scalding, amplifies the intensity of stimulation at meridian points. This serves to harmonise the Yin and Yang (Yin and Yang refer to the two basic properties of things and things that are opposed to each other) equilibrium and promote the smooth flow of vital energy, particularly efficacious in addressing ailments of the cold and damp nature. Its remarkable efficacy in treating patients with LDH has earned it considerable favour among patients [9, 10].

In recent years, while there have been clinical investigations and scholarly reports concerning the comprehensive moxibustion therapy with fire dragon cupping for the treating of LDH, there remains a dearth of empirical evidence supporting its efficacy. Consequently, the primary objective of this study is to conduct a systematic and quantitative meta-analysis of the outcomes from multiple independent studies on the topic of comprehensive moxibustion therapy for LDH. This organised study aims to find out how well fire dragon cupping comprehensive moxibustion works as a treatment for LDH by giving us objective evidence to back up our claims. By applying the best available evidence to guide clinical decisions, this endeavour seeks to foster the enhancement of medical quality.

Materials and methods

Inclusion and exclusion criteria

The inclusion criteria of this study were formulated according to the PICOS principles as follows: (1) The subjects met the diagnostic criteria for lumbar disc herniation and their age was not limited. (2) The experimental group needs to use the fire dragon cupping intervention for lumbar disc herniation. (3) The control group received conventional treatment without fire dragon cupping (e.g., TCM therapy, ordinary acupuncture, massage, moxibustion, auricular seed pressure, rehabilitation, and so on, without limitation on intervention time). (4) The outcomes were clinical efficacy rate, pain intensity, and lumbar function. Pain was evaluated using the visual analogue scale (VAS) and the numerical ratings scale (NRS). Lumbar function was evaluated using the Japanese Orthopaedic Association (JOA) scoring system. (5) The study type was a randomized controlled trial (RCT). The exclusion criteria are as follows: (1) literature inaccessible or lacking original data; (2) duplicate publications; (3) literature quality rated as Grade C; (4) non-Chinese or non-English literature.

Literature retrieval strategy

We conducted a comprehensive digital search across multiple databases, including the China National Knowledge Infrastructure, WanFang Data, VIP Chinese Journal Service Platform, Chinese Biomedical Literature Database, and international databases such as PubMed, EMBase, The Cochrane Library, Web of Science, and Cinahl. Our aim was to collate RCTs concerning the integrative moxibustion treatment of LDH using Huolongguan therapy. The search spanned from the inception of each database until December 2023. Additionally, we manually searched key orthopaedic journals to supplement and enrich our collection of pertinent literature. The search terms in English included: fire dragon cupping, comprehensive moxibustion with Huolong cupping; lumbar disc herniation, lumbar disc protrusion, intervertebral disc displacement, intervertebral disc degeneration, lumbar disc herniation, lumbar disk herniation, lumbar disc protrusion, lumbar herniated disk, lumbar intervertebral disc herniation, lumbar intervertebral disc prolapse, prolapse of lumbar intervertebral disc, lumbosacral radiculopathy; randomized controlled trial, randomized control, randomized, random, randomly (Supplementary Table S1).

Literature screening and data extraction

Two researchers independently conducted literature screening and data extraction based on predefined inclusion and exclusion criteria, followed by a meticulous cross-verification process. In cases of discrepancies, a third researcher was consulted for a decisive adjudication. The screening process began with an initial review of titles and abstracts to eliminate obviously irrelevant studies, proceeding thereafter to a thorough examination of the full texts to ascertain their final inclusion. The extracted information primarily included: the lead author, publication date, sample size, gender, age, intervention measures, duration of intervention, and outcome indicators.

Quality assessment of included literature

Two researchers independently evaluated the quality of the included studies using the Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0, as a guide [11]. In instances of disagreement, a third researcher was called upon to assist in reaching a consensus. The evaluation criteria encompassed aspects such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, completeness of outcome data, selective reporting, and other potential

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e8:e24011. https://doi.org/10.53388/IMD202408011
sources of bias. Each criterion was judged as ‘low risk of bias’, ‘high risk of bias’, or ‘unclear risk of bias’. Studies meeting all criteria were designated as Grade A, indicating low bias; those meeting some criteria as Grade B, denoting moderate bias; and those not meeting any as Grade C, signifying high bias.

Statistical analysis
Meta-analysis was conducted using RevMan 5.3 software [12]. We talked about binary outcomes using relative risk (RR) and 95% confidence intervals (CIs). For continuous outcomes, we used the weighted mean difference and 95% CIs if the measurement tools were the same, or the standardized mean difference (SMD) and 95% CIs if they were not. Study heterogeneity was assessed using $P$-values and the $I^2$ test: heterogeneity was considered significant if $P \leq 0.1$ and $I^2 \geq 50\%$, prompting the use of a random-effects model for data analysis; otherwise, a fixed-effects model was applied. When the source of heterogeneity could not be determined, descriptive analysis was employed in lieu of meta-analysis. Subgroup analyses were conducted to explore sources of heterogeneity, with a significance level of $\alpha = 0.05$ and a threshold of $P \leq 0.05$ for statistical significance.

Results

Literature screening process and outcomes
Following the pre-established search strategy and data collection methods, an initial search yielded 66 relevant publications. After deduplication, 39 articles remained. A review of the titles and abstracts of these 66 articles led to the exclusion of 48 that did not align with the study’s inclusion criteria regarding research type and intervention measures. This preliminary screening resulted in 18 articles meeting the criteria, for which full texts were downloaded. Further scrutiny of these full texts, based on inclusion criteria, outcome measures, and data completeness, led to the final inclusion of 9 RCTs [13–21], encompassing a total of 697 patients, with 349 in the experimental group and 348 in the control group. The process and results of the literature screening are depicted in Figure 1.

Basic characteristics and bias risk assessment of included studies
The fundamental characteristics of the included studies are detailed in Table 1, and the risk of bias assessment for the included studies is as follows.

Selection bias due to inadequate generation of random sequences: of the nine studies included, three mentioned the use of random number tables, thus assessed as ‘low risk’; one mentioned using a two-color ball random method; one did not specify the randomization method; and the remaining studies merely mentioned randomization without detail, assessed as ‘unclear’. Selection bias due to inadequate concealment of allocation: none of the nine studies mentioned allocation concealment, thus assessed as ‘unclear’. Performance bias: none of the studies mentioned the implementation of blinding, thus being assessed as ‘unclear’. Detection bias: all studies failed to mention blinding of outcome assessors, thus assessed as ‘unclear’. Attrition bias: one study talked about dropouts but only looked at those who were actually supposed to be in the study. The amount of missing data in the outcome measures wasn’t high enough to have a clinically relevant effect on the estimate of the intervention effect, so it was called “low risk.” The rest of the studies had no incomplete data, hence being assessed as ‘low risk’. Reporting bias: none of the studies could provide the original study protocols, but the published reports included all expected outcomes, thus being assessed as ‘low risk’. Other sources of bias: all studies were unable to ascertain the presence of other sources of bias affecting the outcomes, thus being assessed as ‘unclear’. The basic characteristics of the included studies are presented in Table 1, and the risk of bias assessment results for the included RCT studies are shown in Table 2.

Figure 1 The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart of study selection. RCT, randomized controlled trial.
Table 1 Basic characteristics of the included studies

<table>
<thead>
<tr>
<th>Included studies</th>
<th>Participants (Experimental group/Control group)</th>
<th>Gender (Male/Female)</th>
<th>Age (year)</th>
<th>Intervention Experimental group</th>
<th>Control group</th>
<th>Duration (days)</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qiu 2021 [16]</td>
<td>T: 63, C: 63</td>
<td>T: 12/43</td>
<td>T: 44.32 ± 10.11</td>
<td>Fire dragon</td>
<td>Conventional</td>
<td>10 d</td>
<td>2: NRS</td>
</tr>
</tbody>
</table>

T, experimental group; C, control group; NRS, numerical ratings scale; VAS, visual analogue scale; ①, clinical efficacy rate; ②, pain; ③, lumbar function.

Table 2 Methodological quality assessment of the included literature (n = 9)

<table>
<thead>
<tr>
<th>Included studies</th>
<th>Random sequence</th>
<th>Allocation concealment</th>
<th>Blinding of subjects/researchers</th>
<th>Blinding outcome assessors of Complete data reporting</th>
<th>Selective reporting</th>
<th>Other bias sources</th>
<th>Evidence level (Grade)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen 2021 [15]</td>
<td>Low risk</td>
<td>unclear</td>
<td>unclear</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>B</td>
</tr>
<tr>
<td>Qiu 2021 [16]</td>
<td>Low risk</td>
<td>unclear</td>
<td>unclear</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>B</td>
</tr>
<tr>
<td>Lu 2021 [17]</td>
<td>Low risk</td>
<td>unclear</td>
<td>unclear</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>B</td>
</tr>
<tr>
<td>Gou 2021 [18]</td>
<td>Low risk</td>
<td>unclear</td>
<td>unclear</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>B</td>
</tr>
<tr>
<td>Wu 2021 [19]</td>
<td>Low risk</td>
<td>unclear</td>
<td>unclear</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>B</td>
</tr>
<tr>
<td>Yang 2022 [20]</td>
<td>Low risk</td>
<td>unclear</td>
<td>unclear</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>B</td>
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<tr>
<td>Huang 2022 [21]</td>
<td>Low risk</td>
<td>unclear</td>
<td>unclear</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>B</td>
</tr>
</tbody>
</table>

Meta-analysis results

Clinical efficacy rate

Five studies [13, 14, 16, 18, 19] encompassing a total of 401 participants explored the clinical efficacy rate of fire dragon cupping in treating LDH. Homogeneity was observed among the studies (P = 0.92, I² = 0%). Consequently, a fixed-effect model was employed for the pooled analysis. The results revealed a statistically significant higher overall clinical efficacy rate in the experimental group compared to the control group (Z = 5.11, RR = 1.23, 95% CI (1.14, 1.33), P < 0.00001), as detailed in Figure 2.

Pain scores

Nine studies [13-21] investigated the effect of fire dragon cupping on pain in patients with LDH, involving a total of 697 participants. The pain scores were assessed using the VAS and NRS scales. Due to the variability in assessment tools, the SMD was utilized to process numerical variables. Homogeneity was observed among these studies (P = 0.81, I² = 0%), leading to the use of a fixed-effect model for the
Combined analysis. The results indicated that the pain scores in the experimental group were significantly lower than those in the control group \(Z = 15.74, \text{SMD} = -1.33, 95\% \text{CI} (-1.49, -1.16)\), \(P < 0.00001\), as elaborated in Figure 3.

**Lumbar function**

Six studies \([13, 14, 16, 18-20]\) investigated the effect of fire dragon cupping on lumbar function in patients with LDH, assessed using the JOA scoring system. The research encompassed 461 participants. Significant heterogeneity was observed across the studies \((P < 0.00005, I^2 = 87\%)\), necessitating the use of a random effects model for the meta-analysis. The results indicated a statistically significant improvement in JOA scores in the experimental group compared to the control group \((Z = 6.23, \text{mean difference (MD)} = 3.37, 95\% \text{CI} (2.31, 4.43), P < 0.00001)\). A sensitivity analysis, excluding the studies by Guo Y \([18]\) and Wu L. \([19]\), showed a significant reduction in heterogeneity \((P = 0.45, I^2 = 0\%)\), leading to a fixed-effect model meta-analysis of the remaining studies. This analysis confirmed the significant superiority of the experimental group in JOA scores \((Z = 13.76, \text{MD} = 3.27, 95\% \text{CI} (2.81, 3.74), P < 0.00001)\), as detailed in Figure 4.

**Publication bias**

Due to the inclusion of only nine studies in this research, funnel plot analysis was not conducted. Instead, robustness analysis was employed to test for publication bias. Following the exclusion of each study individually, the outcome indicators remained unaffected, suggesting the absence of publication bias.

**Figure 2 Forest plot of the clinical efficacy rates.** CI, confidence interval.

**Figure 3 Forest plot of the pain scores.** CI, confidence interval; SD, standard deviation.

**Figure 4 Forest plot of the JOA score.** JOA, Japanese Orthopaedic Association; CI, confidence interval; SD, standard deviation.

**Discussion**

**Methodological quality of included RCT studies**

This study incorporates nine RCTs involving 697 patients. As shown in Figure 2 and Figure 3, a Cochrane quality assessment of these RCTs revealed generally poor methodological quality. Most researchers described their methods of generating random sequences using vague terms like “random” or “random grouping,” making it challenging to determine the authenticity and correctness of the methods. Out of the...
nine included studies, seven [15–20] mentioned the use of random number tables, while only two [13, 14] were described simply as “random”. None of the studies discussed sample size estimation, with sample sizes in different RCTs ranging from 50 to 126. The lack of proper sample size estimation or small sample sizes can reduce the test power of RCTs, leading to false-negative results and unnecessary waste of resources. Accurate sample size estimation is crucial to ensuring the reliability and authenticity of RCT results. In terms of allocation reporting, none mentioned concealed allocation or the use of sealed envelopes. Inadequate concealment of allocation can exaggerate treatment effects, thus distorting the results. To reduce implementation and measurement bias in clinical research, blinding of researchers, participants, and outcome assessors is essential. Due to the specificity of fire dragon cupping, most studies exhibited implementation bias. Studies correctly applying blinding to outcome assessors helped avoid measurement bias and ensure result authenticity. Regarding outcome data completeness, only one study [18] reported dropouts and conducted an intention-to-treat analysis, while others reported no missing data. None of the studies reported clinical registration, but it was evident that the published reports included all expected outcome indicators. As for other sources of bias, the included studies reported none. Comprehensive reporting of study protocol details can reduce the reporting bias caused by selective reporting. Overall, the quality of the included studies in this research is moderate, and the meta-analysis results hold some reference value for clinical practice. However, high-quality studies are needed for further validation in the future.

Efficacy analysis of fire dragon cupping

Impact of fire dragon cupping on clinical efficacy rate in LDH patients

Analysis of five studies [13, 14, 16, 18, 19] shows that fire dragon cupping can improve the clinical efficacy rate in LDH patients. The results of this study indicate that the intervention group’s efficacy rate is higher than the control group’s (RR = 1.23, 95% CI (1.14, 1.33), P < 0.001). Studies show that fire dragon cupping affects blood cell cytokine levels [19], increasing TNF-α and IL-6 and IL-1β levels, thereby modulating inflammation, enhancing patient immunity, and reducing inflammatory factors [19, 22].

Impact of fire dragon cupping on pain in LDH patients

Analysis of studies reveals that fire dragon cupping can alleviate pain in LDH patients. This study used VAS and NRS scores to evaluate pain changes pre- and post-intervention. The intervention group had less pain than the control group (VAS: MD = -1.01, 95% CI (-1.14 to -0.88), P < 0.0001; NRS: MD = -1.03, 95% CI (-1.26 to -0.8), P < 0.00001), showing that VAS and NRS scores were similar when measuring pain after the intervention. Fire dragon cupping, integrating massage, scraping, acupressure, moxibustion, and other TCM techniques, applies ten different methods, including kneading, rolling, pushing, pressing, and tapping. This approach avoids the discomfort associated with scraping and the negative pressure of cupping, as well as the side effects of blood stasis and embolism typical in traditional cupping therapies, thus offering pain relief advantages [23]. Studies suggest that the burning of moxa in fire dragon cupping can suppress abnormal activation of related signaling pathways, reduce inflammation factor release, thereby slowing disease progression, and enhance immune levels; the heat from moxa warms the shoulders, and the properties of mugwort boost Qi (Qi refers to the basic substance that constitutes the human body and maintains life activities, and is the unity of substance and function) and blood circulation, thereby alleviating pain [24].

Impact of fire dragon cupping on lumbar function in LDH patients

It was found that the fire dragon cupping intervention group had better lumbar nerve function than the control group, with lower levels of lumbar dysfunction (JOA: MD = 3.37, 95% CI (2.31–4.43), P < 0.0001). Six studies compared JOA scores, but significant heterogeneity was present (P = 0.00005, I² = 78%; P < 0.00005, I² = 87%). Sensitivity analysis, excluding studies by Guo Y [18] and Wu L [19], showed a significant reduction in heterogeneity (P = 0.45, I² = 0%), leading to a fixed-effect model meta-analysis of the remaining studies. This analysis confirmed the significant superiority of the experimental group in JOA scores (Z = 13.76, MD = 3.27, 95% CI (2.81, 3.74), P < 0.00001). LDH is primarily affected by compression from protrusions or stimulation of the nerve roots, resulting in a significant increase in nerve excitability.

Limitations

To the best of our knowledge, this meta-analysis is the first to definitively show that fire dragon cupping interventions can significantly improve therapeutic effects, JOA scores, and pain scores. However, there are some limitations to this study: (1) because the number of included studies limited the ability to detect publication bias, the possibility of publication bias cannot be ruled out. (2) There was no uniform measurement instrument for the same outcome index. Although SMD was chosen as the effect size indicator, caution is needed when interpreting the results. (3) Sensitivity analysis was conducted, and subgroup analysis was conducted on important factors such as intervention time, intervention method, gender, and age, but no sources of heterogeneity were found. (4) All the included studies originated in China. Therefore, more high-quality, multi-center, and large-sample randomized controlled trials are needed to confirm the effects on LDH patients in the future and further validate the results of this study.

Conclusion

The fire dragon cupping therapy demonstrates significant efficacy in treating LDH and is worthy of widespread application. The fire dragon cupping therapy significantly reduce pain scores, alleviates LDH, warranting its extensive application.

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