INPLASY PROTOCOL

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Comparison of the efficacy of different conservative measures in lumbar spinal stenosis: A protocol for an overview of systematic review and network meta-analysis

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Review question / Objective: **Which conservative treatment measure is the most effective and whether the combined application can enhance the efficacy.**
Condition being studied: **Randomized controlled trials (RCTs) that compared the effect among different conservative measures in lumbar spinal stenosi will be included in this NMA. We will exclude publications that were not peer-reviewed or cannot retrieve relevant data, such as letters, comments, and conference proceedings.**
Information sources: **PubMed, Embase, Web of Science, Cochrane Library and other databases were comprehensively searched.There is no limit to the search. This paper will search the grey literature and the references contained in the published literature. The retrieval formula is constructed by combining medical subject headings (MeSH) and free words with Boolean logic operators. And according to each database different place to carry on the appropriate modification to the retrieval formula.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 September 2021 and was last updated on 08 September 2021 (registration number INPLASY202190025).

INTRODUCTION

Review question / Objective: **Which conservative treatment measure is the most effective and whether the combined application can enhance the efficacy.**

Rationale: **Lumbar spinal stenosis (LSS) is a common degenerative disease of the spine, which is one of the common causes of functional disorders such as lumbar leg pain and neurogenic intermittent claudication. About one-fifth of patients over 65 years old have symptoms of**

neurogenic intermittent claudication, and this disease has become the most common cause of spinal surgery in patients over 65 years old, which significantly affects the activity ability and quality of life of patients. At present, there are many non-surgical treatments for LSS. However, which conservative treatment measure is the most effective and whether the combined application can enhance the efficacy is still controversial.

Condition being studied: Randomized controlled trials (RCTs) that compared the effect among different conservative measures in lumbar spinal stenosi will be included in this NMA. We will exclude publications that were not peer-reviewed or cannot retrieve relevant data, such as letters, comments, and conference proceedings.

METHODS

Search strategy: The PubMed, EMBASE and Cochrane Library databases were systematically searched. Two independent reviewers assessed the trials for eligibility and quality and extracted data. #1 “Spinal Stenosis”[Mesh] #2 “Spinal Stenoses” [Title/Abstract] #3 “Stenoses, Spinal”[Title/Abstract] #4 “Stenosis, Spinal”[Title/Abstract] #5 “osteophytosis”[Title/Abstract] #6 “neurogenic claudication” [Title/Abstract] #7 “lumbar radicular pain” [Title/Abstract] #8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 | #9 “Lumbar Vertebrae”[Mesh] #10 “Lumbar” [Title/Abstract] #11 #9 OR #10 | #12 "Randomized Controlled Trial" [Publication Type] #13 “controlled trial, randomized”[Title/Abstract] #14 “randomised controlled study”[Title/Abstract] #15 “randomised controlled trial”[Title/Abstract] #16 “trial, randomized controlled”[Title/Abstract] #17 “Placebo”[Title/Abstract] #18 #12 OR #13 OR #14 OR #15 OR #16 OR #17 | #19 #8 AND #11 AND #18.

Participant or population: We will include patients with lumbar spinal stenosis were diagnosed using any recognized diagnostic criteria,such as the evidence-based clinical guideline on the diagnosis and treatment of degenerative lumbar spinal stenosis by the North American Spine Society (NASS).But, patients with a lumbar surgery history, infection, tuberculosis, tumors, and other diseases will be excluded.

Intervention: Randomized controlled trials (RCTs) that compared the effect among different conservative measures in lumbar spinal stenosi will be included in this NMA. We will exclude publications that were not peer-reviewed or cannot retrieve relevant data, such as letters, comments, and conference proceedings.

Comparator: Randomized controlled trials (RCTs) that compared the effect among different conservative measures in lumbar spinal stenosi will be included in this NMA. We will exclude publications that were not peer-reviewed or cannot retrieve relevant data, such as letters, comments, and conference proceedings.

Study designs to be included: Randomized controlled trials (RCTs) that compared the effect among different conservative measures in lumbar spinal stenosi will be included in this NMA. We will exclude publications that were not peer-reviewed or cannot retrieve relevant data, such as letters, comments, and conference proceedings.

Eligibility criteria: 2.3.2. Inclusion criteria(1) Participations: The patients with lumbar spinal stenosis were diagnosed using any recognized diagnostic criteria, such as the evidence-based clinical guideline on the diagnosis and treatment of degenerative lumbar spinal stenosis by the North American Spine Society (NASS), were included in our study. But, patients with a lumbar surgery history, infection, tuberculosis, tumors, and other diseases will be excluded.(2) Intervention: All conservative treatments for lumbar spinal stenosis.(3) Comparator: Different types of conservative treatments for lumbar spinal stenosis.(4) Outcomes: The main outcomes were disability and pain intensity. (5) Articles published in Chinese or English.(6) Randomized controlled trials (RCTs) that compared the effect among different

conservative measures in lumbar spinal stenosis.2.3.3. Exclusion criteria(1) Animal research(2) Letters, conference papers(3) Descriptive research(4) Full text is not available(5) Repeated publications(6) Important data are missing and cannot be obtained after contacting the authors.

Information sources: PubMed, Embase, Web of Science, Cochrane Library and other databases were comprehensively searched.There is no limit to the search. This paper will search the grey literature and the references contained in the published literature. The retrieval formula is constructed by combining medical subject headings (MeSH) and free words with Boolean logic operators. And according to each database different place to carry on the appropriate modification to the retrieval formula.

Main outcome(s): The main outcomes were disability and pain intensity.

Data management: All the searched literatures were imported into Endnote X7 software. We identified 432 records through database searching, removed 195 duplicate records, and then excluded 183 records by reading the title and abstract. There are 54 items to be further screened by reading the full text. All the screening process was completed by 2 reviewers independently. The difference will be determined after discussion with the third reviewer. Finally, the included RCTs were used for direct meta-analysis and indirect network meta-analysis.

Quality assessment / Risk of bias analysis: 2.5. Methodological quality assessment of included articles. Because low-quality SRs may affect the reliability of the results, it is necessary to evaluate their quality. Assessing the Methodological Quality of Systematic Reviews-2 (AMSTAR2) is an instrument for rigorously evaluating the systematic review of randomized controlled clinical trials which contains 16 items and 7 of them are critical items. It can be evaluated as "Yes," "Partial Yes," "No" or "No meta-analysis conducted." SRs results can be divided into four levels according to the score: high, medium, low and very low. The evaluation process will be completed independently by two reviewers, and If there are any objections during the process, they will be discussed and resolved with the third reviewer. 2.6. Risk of bias assessment and quality of evidence assessment. We used the Cochrane risk of bias tool and Confidence in Network Meta-Analysis (CINeMA) to assess the risk bias of the included studies. The Cochrane risk of bias tool consists of 7 domains: random sequence generation, allocation concealment, blinding of participants and experimenters, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. The classification of the judgement for each domain was low risk of bias, high risk of bias, or unclear risk of bias. CINeMA is a web application that simplifies the evaluation of confidence in the findings from network meta-analysis. It is based on a methodological framework described in which it considers six domains: within-study bias, reporting bias, indirectness, imprecision, heterogeneity and incoherence. Two authors independently used the CINeMA to assess the quality of evidence.

Strategy of data synthesis: 2.7.3. Direct meta-analysis (DMA). The statistical analyses were carried out using Stata software version 14.0 (Stata Corporation, College Station, TX). The odds ratio (OR) and mean differences (MD) along with the 95% confidence interval (CI) were estimated for dichotomous and continuous outcomes, respectively. The point estimate of the OR value was considered statistically significant at $P < 0.05$. The point estimate of the MD value was considered statistically significant at $P < 0.05$. They were then pooled across studies using a random effects model if heterogeneity was present (Cochrane's Q Test $P \leq 0.05$ or $I2 \geq 25\%$). If $I2 \geq 50\%$, we believe that the heterogeneity was large, and sensitivity analysis was performed accordingly. If sensitivity analysis did not reveal a source of heterogeneity, we manually excluded the included studies one by one to observe changes in heterogeneity. We did not use a

funnel plot to identify possible publication bias because the number of included studies in one comparison was not larger than 10. 2.7.4. Network meta-analysis (NMA). All statistical analyses were conducted using the R Software Version 3.4.1(R Foundation for Statistical Computing. Vienna, Austria), plots depicting the network geometry were generated using Stata version 14.0. Bayesian NMA and the random-effects model were adopted throughout our analysis, due to the large heterogeneity of clinical trials. Dichotomous results were expressed as odds ratio (OR) with 95% confidence interval (CI), as for continuous outcomes, the mean difference (MD) was used to evaluate the treatment effects. Furthermore, each therapy at each endpoint was ranked according to their surface under the cumulative ranking curve (SUCRA), which indicated the performance of each treatment.

Subgroup analysis: 2.9. Sensitivity analysis and subgroup analysis. According to the problems encountered in the analysis process, we will analyze different subgroups such as quality of articles, degree of disease, etc. If possible, we will do some additional subgroup analyses based on the results of heterogeneity and inconsistency. If the heterogeneity is large (I2≥50), we will conduct a sensitivity analysis to exclude those important data missing, low quality or small studies, and high risk of bias trials to ensure the stability of the results.

Sensitivity analysis: 2.9. Sensitivity analysis and subgroup analysis. According to the problems encountered in the analysis process, we will analyze different subgroups such as quality of articles, degree of disease, etc. If possible, we will do some additional subgroup analyses based on the results of heterogeneity and inconsistency. If the heterogeneity is large (I2≥50), we will conduct a sensitivity analysis to exclude those important data missing, low quality or small studies, and high risk of bias trials to ensure the stability of the results.

Language: We only want articles in English and Chinese.

Country(ies) involved: China.

Keywords: lumbar spinal stenosis, network meta-analysis, conservative treatment, systematic review.

Contributions of each author:
Conceptualization: Xin Wang, Peng-zhong Fang. Data curation: Jin-Lei Chen, Rui-Rui Wang, Dong-Liang Li. Methodology: Xin Wang. Software: Jin-Lei Chen, Rui-Rui Wang. Writing – original draft: Jin-Lei Chen. Writing – review & editing: Jin-Lei Chen.
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