INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effect of full-endoscopic cervical laminectomy and decompression versus anterior cervical decompression with fusion in the treatment of patients with cervical spondylotic myelopathy: A protocol for systematic review and meta-analysis

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Review question / Objective: **This systematic review aims to comprehensively assess the efficacy and safety of full-endoscopic cervical laminectomy and decompression versus anterior cervical decompression with fusion in treating cervical spondylotic myelopathy (CSM) patients.**
Condition being studied: **Cervical spondylotic myelopathy (CSM) is a degenerative disease associated with cervical cord compression, which has increased significant health-related social costs and derived disabilities. Anterior cervical discectomy and fusion (ACDF) is the "gold standard" for the treatment of CSM. However, the application of ACDF may cause some complications. Recently, full-endoscopic cervical laminectomy and decompression have shown potential therapeutic effects for CSM. However, no systematic review or meta-analysis has focused on the effects of full-endoscopic cervical laminectomy and decompression in the treatment of CSM. This systematic review aims to comprehensively assess the efficacy and safety of full-endoscopic cervical laminectomy and decompression versus anterior cervical decompression with fusion in treating CSM patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 August 2021 and was last updated on 09 August 2021 (registration number INPLASY202180034).

INTRODUCTION

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cervical spondylotic myelopathy (CSM) patients.

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METHODS

Search strategy: #1 "Spondylosis"[Mesh] OR cervical spondylosis[Title/Abstract] OR cervical spondylotic myelopathy[Title/Abstract] OR cervical myelopathy[Title/Abstract] OR cervical stenosis[Title/Abstract] OR CSM[Title/Abstract] OR Intervertebral disc degeneration[Title/Abstract]; #2 Anterior cervical decompression with fusion[Title/Abstract] OR anterior decompression with fusion[Title/Abstract] OR anterior cervical decompression and fusion[Title/Abstract] OR anterior decompression with fusion[Title/Abstract] OR anterior cervical discectomy with fusion[Title/Abstract] OR anterior cervical corpectomy with fusion[Title/Abstract] OR anterior decompression with fusion[Title/Abstract] OR anterior cervical discectomy and fusion[Title/Abstract] OR anterior cervical corpectomy and fusion[Title/Abstract] OR ACDF[Title/Abstract] OR ADF[Title/Abstract] OR ACCF[Title/Abstract]; #3 "Laminectomy"[Mesh] OR full-endoscopic laminectomy[Title/Abstract] OR full-endoscopic cervical laminectomy[Title/Abstract] OR full-endoscopic laminectomies[Title/Abstract] OR full-endoscopic laminotomy[Title/Abstract] OR full-endoscopic laminotomies[Title/Abstract] OR full-endoscopic cervical laminectomies[Title/Abstract] OR full-endoscopic cervical laminotomy[Title/Abstract] OR full-endoscopic cervical laminotomies[Title/Abstract] OR ((endoscopes[Title/Abstract] OR endoscope[Title/Abstract]) AND (cervical laminectomy[Title/Abstract] OR cervical laminectomies[Title/Abstract] OR cervical laminotomy[Title/Abstract] OR cervical laminotomies[Title/Abstract])) OR full-endoscopic cervical laminectomy and decompression[Title/Abstract] OR full-endoscopic cervical laminectomy with decompression[Title/Abstract]; #4 #1 AND #2 AND #3.

Participant or population: We will include patients over 18 years old diagnosed with CSM receiving full-endoscopic cervical laminectomy and decompression or anterior decompression with fusion treatment.

Intervention: All patients in the experimental group received full-endoscopic cervical laminectomy and decompression for their treatment. There are no restrictions on the frequency and duration of the intervention.

Comparator: The participants in the control group received anterior decompression with fusion treatment, whether or not combined with usual care.

Study designs to be included: We will include randomized controlled trials, controlled clinical trials, or cohort studies with interventions comprising full-endoscopic cervical laminectomy and decompression versus anterior decompression with fusion in the treatment of patients with CSM. Any other types of studies, such as animal studies, case reports, case series, noncomparative studies, and reviews will all be excluded.

Eligibility criteria: We will include randomized controlled trials, controlled

clinical trials, or cohort studies with interventions comprising full-endoscopic cervical laminectomy and decompression versus anterior decompression with fusion in the treatment of patients with CSM. We will exclude studies with the following characteristics (1) patients with previous cervical surgery; (2) patients with tumors, trauma, or infections; (3) patients undergoing a combined full-endoscopic cervical laminectomy with decompression or anterior decompression with fusion and other surgical approaches.

Information sources: We will perform a comprehensive literature search using PubMed, Embase. com, the Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, China National Knowledge Infrastructure (CNKI), Wan Fang, and SinoMed from databases inception to August 31, 2021. We will also manually search the references of relevant systematic reviews and meta-analyses and related articles to identify additional trials. There is no restriction on the publication language. The search strategy has been developed and tested through an iterative process by an experienced librarian researcher in consultation with the review team.

Main outcome(s): The outcomes include the Japanese Orthopaedic Association (JOA) scores for the cervical spine, operation time, neck disability index (NDI) scores, neurological recovery rates calculated by Hirabayashi's method, cervical alignment data; surgical complications (e.g., dysphagia, hoarseness, and infection), and reoperation rates.

Data management: Two reviewers will independently extract the data using a standardized form, which covered the following items: (1) basic characteristics, including author, year, country, funding, and study design; (2) patients characteristics, including grouping and sample size, age and sex of patients; (3) intervention characteristics, including experimental and control methods, basic treatments, treatment duration, and length of follow-up; (4) outcomes of interest, including preoperative and postoperative JOA scores, operation time, NDI scores, neurological recovery rates, any surgical complications, and reoperation rates. We will solve disagreements through discussion with the third reviewer.

Quality assessment / Risk of bias analysis: We will use the Newcastle-Ottawa quality assessment scale (NOS) to assess the quality of the included case-control clinical trials or cohort studies. We will consider studies with more than 7 stars as high quality, 5-7 stars as moderate quality, and lower than 5 stars as low quality. We will assess the risk of bias of included randomized controlled trials using a revised version of the Cochrane tool for assessing the risk of bias in randomized trials (RoB 2.0). The assessment list including the following domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported result. We will rate each domain as either: low risk of bias, some concerns—probably low risk of bias, some concerns—probably high risk of bias, or high risk of bias. We will rate trials at high risk of bias overall if one or more domains are rated as some concerns—probably high risk of bias, or as high risk of bias and as low risk of bias overall if all domains are rated as some concerns—probably low risk of bias or low risk of bias. In our study, one reviewer will rate the risk of bias of each study according to the scale and another will review it. Reviewers will resolve discrepancies by discussion and, when not possible, with adjudication by a third party.

Strategy of data synthesis: We will use the Review Manager (version 5.4) to perform random-effects meta-analysis using the inverse variance statistical method. We will estimate pooled risk ratio (RR) with 95% confidence intervals (CIs) for the dichotomous variables and the mean differences (MDs) with 95% CIs for continuous variables. The statistical level of significance will be set at $P < 0.05$. We

will assess the heterogeneity using Cochran's Q test and I2 statistic, and I2 values of less than 25%, 26% to 50%, and more than 50% are considered as low, moderate, and high degrees of heterogeneity, respectively. If high degree of heterogeneity exists, we will explore the heterogeneity by performing subgroup analysis, sensitivity analysis, and meta-regression analysis.

Subgroup analysis: We will perform predefined subgroup analyses on different regions of patients and types of CSM.

Sensitivity analysis: We will conduct sensitivity analysis by excluding trials of high risk of bias. We will also use Stata 14.0 (Stata Corporation, College Station, TX) to conduct univariate meta-regression analyses to explore whether the outcome or the heterogeneity is associated with the prespecified variables: publication year, mean age, proportion of females, treatment duration, and comorbidity.

Language: English.

Country(ies) involved: China.

Keywords: Cervical spondylotic myelopathy, Full-endoscopic cervical laminectomy and decompression, Anterior cervical decompression with fusion, Efficacy, Safety, Meta-analysis.

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