INPLASY PROTOCOL

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Conflicts of interest:

The authors have no conflicts of interest to disclose.

INTRODUCTION

Review question / Objective: The incidence and characteristics of percutaneous endoscopic lumbar discectomy complicated with dural tear.

Dural tears of percutaneous endoscopic lumbar discectomy for lumbar disc herniation: A protocol for systematic review and metaanalysis

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Condition being studied: This is a systematic review, and the meta-analysis will be carried out as conditions permit. Since this is a systematic review based on original research, no ethics committee approval is required. In addition, our team includes two medical doctors and a graduate student.

Information sources: Electronic databases include PubMed, Embase, Web of Science, and Cochrane Library. Contact with authors.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 November 2020 and was last updated on 17 December 2020 (registration number INPLASY2020110069).

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includes two medical doctors and a graduate student.

METHODS

Search strategy: (transforaminal fullendoscopic lumbar discectomy) or (transforaminal lumbar discectomy) or (percutaneous endoscopic interlaminar discectomy) or (percutaneous endoscopic transforaminal discectomy) or (percutaneous endoscopic lumbar discectomy) AND (Dural tear).

Participant or population: Lumbar disc herniation is the main diagnosis.

Intervention: Percutaneous endoscopic lumbar discectomy.

Comparator: Comparison only exists in subgroup analysis.

Study designs to be included: Randomized controlled trials, cohort studies, case-control studies, and case series.

Eligibility criteria: Participant or population: Lumbar disc herniation is the main diagnosis. Intervention: Percutaneous endoscopic lumbar discectomy. Study designs to be included: Randomized controlled trials, cohort studies, casecontrol studies, and case series.

Information sources: Electronic databases include PubMed, Embase, Web of Science, and Cochrane Library. Contact with authors.

Main outcome(s): Number of cases of dural sac tear.

Quality assessment / Risk of bias analysis: The risk assessment of the bias will be independently taken by 2 reviewers based on the extracted data information. Any inconsistencies will be discussed and resolved with the third author. This process will be based on the Cochrane Collaboration's tool for assessing risk of bias. Assessment items according to the information of random sequence generation, assignment hiding, blind to

patients and researchers and blind measurement, data integrity, selective reporting, other bias. The results of the assessment will be shown as high risk, unclear, and low risk. The outcome of the assessment of risk of bias will be presented in tabular form or a specific figure made by using Review Manager 5.3 software.

Strategy of data synthesis: If the clinical heterogeneity between the included clinical trials is significant, or the data from the original study cannot be extracted, we will perform descriptive analysis or narrative synthesis. Only when the apparent clinical heterogeneity between studies is excluded and the data are sufficiently similar and homogeneous, the meta-analysis is conducted. Chi-square test will be used to test the heterogeneity and I2 statistic will be used to test the size of heterogeneity. There is heterogeneity when the P-value of the Chi-square test≤0.1, but no heterogeneity while the Chi-square test Pvalue>0.1. We define l2≤50% for acceptable heterogeneity in multiple studies. In this case, the fixed model will be applied to calculate mean differences (MDs) by inverse variance and risk ratios (RRs) by Mantel-Haenszel method. When I2>50%, high heterogeneity between studies is considered. In this case, the causes of heterogeneity such as the age, the severity of the condition will be analyzed and subgroup analysis will be used. If there still have higher heterogeneity after the above methods processed, random model will be conducted in meta-analysis. MDs and 95% confidence intervals (CIs) will be used for the effect size of the numerical variable, and RRs and 95% CIs for the effect size of dichotomous variable. The effect size will be measured by Z test, and the P-value ≤ 0.5 is statistically significant. The results of the meta-analysis will be presented as forest plots by RevMan 5.3. Subgroup analysis will be performed according to age, the operation section, surgical approach.

Subgroup analysis: Subgroup analysis will be performed according to age, the operation section, surgical approach.

Sensibility analysis: We will use sensitivity analysis to test the stability and reliability of meta-analysis. It will be conducted by 2 methods: eliminating each study one by one; using random-effect model (DerSimonian & Laird method) to test the results after using the fixed effect model.

Country(ies) involved: China.

Keywords: percutaneous endoscopic lumbar discectomy, lumbar disc herniation, dural tear, systematic review.

Contributions of each author:

Author 1 - Juan Wang. Author 2 - Deshui Yu.