INPLASY PROTOCOL

To cite: Gong et al. The safety of endoscopic lumbar discectomy for lumbar disc herniation: A protocol for systematic review and network meta-analysis. Inplasy protocol 202160025. doi: 10.37766/inplasy2021.6.0025

Received: 08 June 2021

Published: 08 June 2021

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Support: **No support.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

The safety of endoscopic lumbar discectomy for lumbar disc herniation: A protocol for systematic review and network meta-analysis

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Review question / Objective: **The purpose of our systematic review is to systematically compare the complication rates of PTED, PIED, and MED for LDH based on RCTs using two classification schemes (general classification that includes intraoperative and post-operative complications, and modified Clavien–Dindo classification). The results will provide a higher level of clinical evidence and clinical surgical decisions for surgeons and patients.**
Condition being studied: **Overall complication rate and complications in two different classification schemes (General classification and Clavien–Dindo classification).**
Information sources: **MEDLINE, PubMed, Web of Science, EMBASE, Clinicaltrials.org, Cochrane Library, China National Knowledge Infrastructure Database (CNKI), Wan fang Database, China Biology Medicine Database (CBM), VIP Science Technology Periodical Database, and Chinese Clinical Trial Registry.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 June 2021 and was last updated on 08 June 2021 (registration number INPLASY202160025).

INTRODUCTION

Review question / Objective: **The purpose of our systematic review is to systematically compare the complication rates of PTED, PIED, and MED for LDH based on RCTs using two classification schemes (general classification that includes intraoperative and post-operative complications, and modified Clavien–Dindo classification). The results will provide a higher level of clinical evidence and clinical**

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Condition being studied: Overall complication rate and complications in two different classification schemes (General classification and Clavien–Dindo classification).

METHODS

Participant or population: Patients are confirmed as LDH by imaging and clinical symptoms; 6-week conservative treatment is ineffective for patients; cauda equina syndrome or a progressive neurological deficit requiring urgent surgical intervention; firstly, undergo surgery; patients aged 18-65 years.

Intervention: Patients are confirmed as LDH by imaging and clinical symptoms; 6-week conservative treatment is ineffective for patients; cauda equina syndrome or a progressive neurological deficit requiring urgent surgical intervention; firstly, undergo surgery; patients aged 18-65 years.

Comparator: Percutaneous transforaminal endoscopic discectomy (PTED), percutaneous interlaminar endoscopic discectomy (PIED), and microendoscopic discectomy (MED).

Study designs to be included: The studies included are two arms or three arms. The treatment performed reported on lumbar discectomy by PTED, PIED, and MED.

Eligibility criteria: Patients are confirmed as LDH by imaging and clinical symptoms; 6-week conservative treatment is ineffective for patients; cauda equina syndrome or a progressive neurological deficit requiring urgent surgical intervention; firstly, undergo surgery; patients aged 18-65 years.

Information sources: MEDLINE, PubMed, Web of Science, EMBASE, Clinicaltrials.org, Cochrane Library, China National Knowledge Infrastructure Database (CNKI), Wan fang Database, China Biology Medicine Database (CBM), VIP Science Technology Periodical Database, and Chinese Clinical Trial Registry.

Main outcome(s): Overall complication rate and complications in two different classification schemes (General classification and Clavien–Dindo classification). 1. Overall complication: all the complications related to various discectomy surgeries. 2. Intraoperative general complications: mortality, thrombosis, and hepatitis. 3. intraoperative specific complications: durotomy, bleeding, nerve root injury, surgical error. 4. post-operative general complications: urinary tract infection, miction disturbances (catheter required), pulmonary complication, deep venous thrombosis leg. 5. Modified Clavien–Dindo classification: type I: conservative treatment, without intervention or pharmacologic treatment; type II: pharmacologic treatment; type III: invasive intervention under general anesthesia; type IV: intensive care unit management; type V: death.

Quality assessment / Risk of bias analysis: Two reviewers evaluated bias risk independently. The evaluation process was based on the "bias risk assessment" tool developed by the Cochrane Collaboration Network. The evaluation contents include the random allocation method, hidden allocation scheme, and blinding method for the subjects and implementers of the treatment scheme. The evaluation results were divided into three categories: "low bias risk," "high bias risk," and "uncertainty of bias risk," which were presented in the form of a chart using RevMan.

Strategy of data synthesis: Direct pairwise meta-analysis. Pairwise meta-analysis will be performed with RevMan (Review Manager 5.3 version. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.). Heterogeneity will be tested using Q test, and based on the results, heterogeneity is quantitatively estimated using I2. If I2 was 75%, there is a greater heterogeneity. If the heterogeneity of the results of each study is large, the causes of heterogeneity can be analyzed by related subgroups or a sensitivity

analysis. 3.5.2 Network meta-analysis. Statistical analysis software STATA (release 15, Stata-Corp LLC, TX) was used for performing the NMA. The DerSimonian and Laird random-effects model will be used to analyze data. We will report direct comparisons parameter (pooled estimates of odds ratio (OR) and 95% confidence intervals (CI)) and direct comparisons parameter (95% credible intervals (CrI)). NMA results are also assessed by means of forest plots. The evaluation of inconsistency of treatment is an important aspect of NMA, which will be evaluated by Node-splitting results. Surface under cumulative ranking curve (SUCRA) results will be used to evaluate the relative rank of each discectomy technique under different complication outcomes.

Subgroup analysis: Subgroup analysis will be performed according to different subtypes of lumbar disc herniation and intervention of operation.

Sensitivity analysis: Dealing with zero-events studies and sensitivity analysis Zero-events studies may occur in some of the outcomes, and for double-zero studies classical methods did not synthesis them in the meta-analysis by default. However, research have documented that simply exclude double-zero studies is unreasonable and may change the conclusions. Therefore, we will use the Zero Framework proposed by Xu et al as a solution to deal with zero-events problems. In the framework, they listed all available methods that could be used to synthesis the evidence from double-zero studies, which includes the Bayesian models, generalized mixed models. Current study we will used the Bayesian method to deal with zero-events studies. Sensitivity analysis will be used to detect the stability, reliability of the results of meta-analysis by dealing with zero-events studies.

Country(ies) involved: China.

Keywords: minimally invasive spine surgery, lumbar disc herniation, lumbar disc herniation, complications, systematic review.

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