INPLASY PROTOCOL

To cite: Feng et al. The use of a annular closure device in lumbar discectomy: a meta-analysis of clinical outcomes. Inplasy protocol 202320044. doi: 10.37766/inplasy2023.2.0044

Received: 11 February 2023

Published: 11 February 2023

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Support: **China Elder Health Care Association (CAWA20210528163 7000503382-09).**

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

Conflicts of interest:
None declared.

The use of a annular closure device in lumbar discectomy: a meta-analysis of clinical outcomes

Feng, CZ[1]; Xie, YZ[2]; Wang, YT[3]; Zhang, ZY[4].

Review question / Objective: **The purpose of this study is to comprehensively analyze the effectiveness and safety of the ACD device applied in lumbar discectomy.**
Condition being studied: **Lumbar disc herniation (LDH) refers to a clinical syndrome which protruding nucleus pulposus irritates or compresses nerve roots. Various causes(injury, degeneration, strain and so on) generate the annulus fibrosus (AF) partially or completely ruptured, and result in and the nucleus pulposus tissue protruding backward from the rupture. Cummins et al reported that the mean age of patients with disc herniation was 41 years, and was more common in males than females, with proportions of 57% and 43 %. 。 Although conservation treatment is the first choice of most patients, they sill will choose the various surgical discectomy (e.g. microdiscectomy , endoscopic and open discectomy) to relieve symptom after failure of non-operation therapy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 February 2023 and was last updated on 11 February 2023 (registration number INPLASY202320044).

INTRODUCTION

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METHODS

Participant or population: People with Lumbar Disc Herniation.

Intervention: Diskectomy and ACD device.

Comparator: Diskectomy only.

Study designs to be included: Utilizing a standard form to extract all data (text, figures and tables) from available full text reports. Data extracted from the articles include: (1) study characteristics which covers study period, institution and country of study, average length of follow up, study size and vertebra level involved; (2) patients' baseline traits covering age, weight and gender; (3) mean pre- and post-operation Oswestry Disability Index (ODI); (4) mean pre- and post-operation visual analogue scale (VAS) for back and legs; (5) outcome of surgery focusing on symptomatic disc re-herniation; and (6) post-operat.

Eligibility criteria: Literature selection was done in strict accordance with PICOS principles: (P) Population: people with LDH[20]; (I) Intervention: Diskectomy and ACD device; (C) Comparator: Diskectomy only; (O) Outcomes: clinical outcomes for people with LDH. (S) Study type: RCTs.

Information sources: Literature search was conducted according to Cochrane Manual and PRISMA guidelines. Retrieved electronic database include Ovid Medline, Embase, Web of Science and PubMed. Aiming to obtain the highest possible sensitivity, the search terms used were a combination of "annular closure device", "annular repair", "annulus device", "Diskectomy, Percutaneous" and "Percutaneous Diskectomies". The date of the search is from the beginning of the database build to October 31, 2022. Further review of the reference list of all related articles was performed to identify potential studies. All relevant articles were assessed systematically based on the inclusion and exclusion criteria.

The search strategy was constructed around the PICOS tool: (P) Population: people with LDH; (I) Intervention: Diskectomy ; (C) Comparator: control group with only Diskectomy; (O) Outcomes: clinical outcomes for people with LDH. (S) Study type: RCTs.

Main outcome(s): Re-herniation; reoperation; serious adverse events; disc height; VAS; ODI; SF-12.

Quality assessment / Risk of bias analysis: Two researchers independently assessed the risk of bias (ROB), in accordance with the Cochrane Handbook version 5.1.0 tool for assessing ROB in RCTs. The following seven domains were considered: (1) randomized sequence generation, (2) treatment allocation concealment, blinding of (3) participants and (4) personnel, (5) incomplete outcome data, (6) selective reporting and (7) other sources of bias. Trials were categorized into three levels of ROB by the number of components for which high ROB potentially existed: high risk (five or more), moderate risk (three or four) and low risk (two or less).

Research manuscripts reporting large datasets that are deposited in a publicly available database should specify where the data have been deposited and provide the relevant accession numbers. If the accession numbers have not yet been obtained at the time of submission, please state that they will be provided during review. They must be provided prior to publication.

Interventionary studies involving animals or humans, and other studies that require

ethical approval, must list the authority that provided approval and the corresponding ethical approval code.

Strategy of data synthesis: The variables of the statistics include dichotomous and continuous variables. Continuous variables are expressed as means with standard deviation (SD) . Continuous variables in the study will be reported as mean difference (MD = absolute difference between the means of two groups, defined as the difference in means between the treatment and control groups and calculated using the same scale) or standardised mean difference (SMD = mean difference in outcome between groups/standard deviation of outcome between subjects, used to combine data when trials with different scales) with 95% confidence intervals (CI) and analysis.
The weighted mean difference (WMD) and odds ratio (OR) were used as summary statistics. Both fixed- and random-effect models were tested. In the fixed-effects model, it was assumed that treatment effect in each study was the same, whereas in a random-effects model, it was assumed that there were variations between studies. X2 tests were used to study heterogeneity between trials. I2 statistic was used to estimate the percentage of total variation across studies, owing to heterogeneity rather than chance, with values greater than 75% considered as substantial heterogeneity. I2 can be calculated as :I2 = 100% × (Q – df)/Q, with Q defined as Cochrane's heterogeneity statistics and df defined as degree of free-dom. In the present meta-analysis, the results using the random-effects model were presented to take into account the possible clinical diversity and methodological variation between studies.

Subgroup analysis: None.

Sensitivity analysis: None.

Country(ies) involved: China.

Keywords: Lumbar disc herniation, Lumbar discectomy, Microdiscectomy, Annular closure device, Annular repair, Barricaid, Lumbar intervertebral disc, Meta-analysis.

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