INPLASY PROTOCOL

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None declared.

Effects of Posterior Lumbar Non-fusion Surgery with Isobar Devices Versus Posterior Lumbar Interbody Fusion Surgery on Clinical and Radiological Features in Patients with Lumbar Degenerative Diseases: A Meta-Analysis

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Review question / Objective: **The aim of this study was to systematically evaluate the efficacy of posterior lumbar isobar non-fusion with Isobar devices versus posterior lumbar interbody fusion in the treatment of patients with lumbar degenerative diseases.**
Condition being studied: **The effectiveness and safety of the isobar non-fusion surgery have been verified by a large number of biomechanical studies and clinical researches, including some randomized controlled trials.**
Information sources: **Referring to the search strategy of Cochran assistance network, we searched PubMed, Ovid, EMBASE, Web of Science, MEDLINE, China National Knowledge Internet (CNKI), VIP and Wan Fang databases from inception to June 2021.At the same time, we traced the references of the included literatures and the meta-analysis related to this research, screened, and evaluated the references to determine potential research.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 November 2021 and was last updated on 17 November 2021 (registration number INPLASY2021110059).

INTRODUCTION

Review question / Objective: **The aim of this study was to systematically evaluate the efficacy of posterior lumbar isobar non-fusion with Isobar devices versus posterior lumbar interbody fusion in the treatment of patients with lumbar degenerative diseases.**

Condition being studied: The effectiveness and safety of the isobar non-fusion surgery have been verified by a large number of biomechanical studies and clinical researches, including some randomized controlled trials.

METHODS

Participant or population: The subjects included patients with lumbar degenerative diseases, including lumbar instability, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, etc. The patients had obvious symptoms of low back pain, which were diagnosed by CT or MRI, and had been treated conservatively for at least 6 months.

Intervention: Posterior Lumbar Non-fusion Surgery.

Comparator: Posterior Lumbar Interbody Fusion Surgery.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: To qualify for inclusion, a study had to be a randomized controlled trial (RCT) comparing isobar non-fusion surgery versus PLIF surgery in the treatment of lumbar degenerative diseases and have compared clinical and radiological outcomes directly and differed only in surgical methods. The subjects included patients with lumbar degenerative diseases, including lumbar instability, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, etc. The patients had obvious symptoms of low back pain, which were diagnosed by CT or MRI, and had been treated conservatively for at least 6 months. Studies of individuals who underwent procedures that used other instruments (e.g., Dynesys, N-Flex, an interspinous device, and/or GRAF)were not eligible. Biomechanical, single arm studies, literature review, case report, dissertation, conference summary also was eligible.To qualify for inclusion, a study had to be a randomized controlled trial (RCT) comparing isobar non-fusion surgery versus PLIF surgery in the treatment of lumbar degenerative diseases and have compared clinical and radiological outcomes directly and differed only in surgical methods. The subjects included patients with lumbar degenerative diseases, including lumbar instability, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, etc. The patients had obvious symptoms of low back pain, which were diagnosed by CT or MRI, and had been treated conservatively for at least 6 months. Studies of individuals who underwent procedures that used other instruments (e.g., Dynesys, N-Flex, an interspinous device, and/or GRAF)were not eligible. Biomechanical, 1single-treament-arm studies, literature review, case report, dissertation, conference summary also was eligible.

Information sources: Referring to the search strategy of Cochran assistance network, we searched PubMed, Ovid, EMBASE, Web of Science, MEDLINE, China National Knowledge Internet (CNKI), VIP and Wan Fang databases from inception to June 2021.At the same time, we traced the references of the included literatures and the meta-analysis related to this research, screened, and evaluated the references to determine potential research.

Main outcome(s): A total of 201 relevant literatures were obtained through preliminary search, including 66 PubMed, 12 Ovid, 13 EMBASE, 10 web of science, 10 MEDLINE, 46 CNKI, 24 VIP and 68 WanFang. After eliminating duplicate literatures, reading topics and abstracts and full-text re screening, 7 RCT studies with 394 patients were finally included.

Quality assessment / Risk of bias analysis: Due to the particularity of surgical treatment and ethical requirements, the patients' right to know and personal will must be fully respected when grouping, so neither the patient nor the surgeon can implement blinding. Therefore, the included 3 studies were high-risk in terms of randomization, allocation concealment, and blinding of participants and personnel.

None of the 7 studies withdrew or was lost to follow-up, and the data was complete. This study used the Cochrane risk bias tool for quality evaluation. This tool includes evaluations in seven aspects: random sequence generation, allocation hiding, blinding of participants and implementers, blinding of outcome evaluators, incomplete outcome data, selective reporting, and other biases. The risk of bias in each area is judged as low risk, high risk, or unknown risk. The quality of the studies was evaluated by two researchers.

Strategy of data synthesis: All statistical tests were performed using Review Manager 5.3 software (The Cochrane Collaboration), and the results were represented by forest map. Heterogeneity test shall be conducted during data consolidation. If there is no obvious heterogeneity between the data ($I^2 \leq 50\%$), using fixed-effect model to consolidate data. When there is heterogeneity ($I^2 > 50\%$), the random-effects models were used. If the heterogeneity could not be removed, the random effect model was used for descriptive analysis of obvious clinical heterogeneity. The measurement data are expressed by mean difference (MD) and its 95% confidence interval (CI); Odds ratio (or) was used as the efficacy analysis statistic. All tests were 2-sided, and any p value less than 0.05 was deemed significant. We assessed publication bias by visual inspection of funnel plots.

Subgroup analysis: This study did not perform subgroup analysis.

Sensitivity analysis: The heterogeneity of operation time (I2 = 98%), blood loss (I2 = 98%) and surgical segment ROM (I2 = 97%) is high. The included literature is excluded one by one, and the remaining literature is combined to show high heterogeneity, indicating that the results of this meta-analysis are reliable, and the heterogeneity may be related to operation technology of surgeons, postoperative nursing measures in the hospital and the psychological character of patients.

Country(ies) involved: China.

Keywords: Isobar device, lumbar non-fusion surgery, posterior lumbar interbody fusion, Meta-analysis.

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