

Long-Term Clinical Outcome of Minimally Invasive Versus Open Single-Level Transforaminal Lumbar Interbody Fusion for Degenerative Lumbar Diseases with a Minimum Follow-Up of 2 Years: A Meta-Analysis Protocol

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Abstract

Minimally invasive surgical transforaminal lumbar interbody fusion (MIS-TLIF) is a relatively new approach for fusion of the lumbar spine. It was developed in addition to traditional open transforaminal interbody fusion (O-TLIF) to minimize iatrogenic soft tissue damage and prevent denervation and atrophy of the paraspinal trunk musculature. Potential disadvantages of MIS-TLIF are inadequate neural element decompression and higher risk of cage migration, resulting in persistent symptoms and a need for reoperation. Other disadvantages include inadequate visualization of bony landmarks for instrumentation, and less robust postero-lateral arthrodesis than open approaches, which may affect fusion rates. Several studies have reviewed the differences between both treatments for degenerative lumbar disease, but they mainly focused on the peri-operative and short-term post-operative outcomes. Since the potential disadvantages of MIS may be expected after a longer follow-up, we performed a meta-analysis comparing MIS-TLIF with O-TLIF for long-term outcomes.

Questions/purposes

In this systematic review, we compared clinical outcome of MIS and open single level TLIF for degenerative lumbar disease with a minimum follow-up of 2 years, with regard to (1) clinical outcomes (VAS pain scores and Oswestry Disability Index [ODI]), (2) adverse events (reoperation, revision, readmission, implant failure rate, infection, cage migration, cage extrusions), and (3) Fusion rate.

Conclusion

This meta-analysis will provide a detailed summary of the long-term clinical outcome of minimally invasive versus open single-level transforaminal lumbar interbody fusion for degenerative lumbar diseases. Previous meta-analyses have been published, but all focused on the peri-operative or short-term outcomes. This meta-analysis is the first in including only studies with a minimum follow-up of 2 years.

Keywords: Meta-analysis, degenerative spine disease, transforaminal lumbar interbody fusion, TLIF, MIS-TLIF, minimally invasive surgical transforaminal lumbar interbody fusion, O-TLIF, open transforaminal interbody fusion, long-term, clinical outcome

Introduction

Degenerative spinal diseases are one of the most common comorbidities in elderly patients, potentially leading to back pain, radiculopathy and spinal instability. In case of clinical deterioration of neurologic deficits or failed conservative management, surgery should be considered. This may occur in the form of decompression, stabilization, or both. In transforaminal lumbar interbody fusion (TLIF), decompression and cage placement are generally performed through a unilateral approach, which provides exposure of the disc space while reducing potentially harmful retraction of the thecal sac and nerve root when compared with a posterior lumbar interbody fusion (PLIF) approach.(1) The first described TLIF was an open procedure (O-TLIF). This results in an extensive muscle dissection of the back with possible denervation and atrophy of the paraspinal trunk musculature. This has been suggested as the major cause for persistent or recurrent postoperative pain.

Because of the multi-segmental anatomy of the stabilizing posterior paravertebral muscles, chronic damage to these muscles might also influence the development or progression of adjacent segment degeneration or sagittal imbalance. (2) More recently, the minimally invasive surgery TLIF (MIS-TLIF) was developed, to minimize iatrogenic soft tissue damage and decrease the risk on atrophy of the multifidus or longissimus muscle.(3) This procedure has become more popular in recent years, since it may have some potential advantages.

It aims to achieve the same clinical results as the O-TLIF, however with smaller wounds, fewer soft tissue damage, reduced blood loss, reduced postoperative pain, faster recovery time and shorter hospital stay.(4) The main drawback of MIS-TLIF is the potentially longer operating times, a steeper learning curve, higher intraoperative radiation exposure due to reliance on bi-planar fluoroscopy to compensate for diminished surgical exposure and visualization, a potentially higher risk for cage and pedicle screw misplacements and potentially higher risk for cage migrations.(5) There are also persisting concerns regarding inadequate neural decompression, resulting in persistent symptoms and a need for reoperation, because an open approach may be associated with improved deformity reduction.(6) Although numerous studies on the differences between MIS-TLIF and O-TLIF have been performed, most of these studies have focused on peri-operative and short post-operative outcomes. Differences in mid- to long-term outcomes in MIS-TLIF vs O-TLIF are still inconclusive and, therefore, require more research.(7) The aim of this meta-analysis is to compare the long-term clinical outcomes between the MIS-TLIF and O-TLIF in single-level degenerative lumbar diseases with a minimum follow-up of 2 years in terms of (1) clinical outcomes (VAS back/ leg pain scores or Oswestry Disability Index [ODI]), (2) Fusion rate and (3) adverse events (revision, readmission, adjacent segment disease, implant failure rate, pseudoarthrosis, cage migration, cage extrusions).

Objective

To evaluate the clinical outcome, measured by VAS back/leg pain or ODI, of patients with degenerative lumbar diseases treated with single-level TLIF (open vs MIS) with a minimum follow-up of 2 years.

Methods

The systematic review will be conducted following the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions (version 5.1.0 from 2011) to insure quality (8). We accessed the EQUATOR (Enhancing the QUALity and Transparency Of health Research) Network to find the right guideline for accurate reporting of our systematic review (<http://www.equator-network.org/>) and the correct checklists for accessing the quality of the included studies. (9) To strengthen the methodological quality of our systematic review we used the PRISMA-P guideline for protocols. (10) The protocol will be registered in the international register of systematic reviews to strengthen the transparency and reliability (<http://www.crd.york.ac.uk/PROSPERO>). (11) The systematic review will be performed in accordance with the *PRISMA guideline 'Preferred Reporting Items for Systematic reviews and Meta-Analyses'* to secure proper reporting and improve methodological quality of our review.

Review Inclusion Criteria

Types of studies: RCT, prospective and retrospective observational studies.

Randomized controlled trials (RCTs), prospective and retrospective observational studies will be included. Case-control designs and studies without original data will be excluded.

Types of participants: Patients with degenerative lumbar disease.

Studies will be included if they include patients with degenerative lumbar disease, for which they received a single-level TLIF. Degenerative lumbar disease encompasses conditions such as spondylosis, degenerative spondylolisthesis, degenerative disc degeneration and lumbar spinal stenosis. Studies describing a population treated with TLIF because of traumatic or congenital disorders will be excluded.

Type of intervention: Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF).

Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) is a surgical technique first described by Schwender et al. in 2005 (3). The MIS-TLIF procedure was developed to achieve neural decompression and interbody arthrodesis, while offering the advantages of reducing soft tissue trauma and reducing recovery time when compared to the open techniques. However, MIS-TLIF is a technically challenging procedure and the main drawback has been increased intra-operative radiation exposure due to reliance on biplanar fluoroscopy that is required to compensate for diminished surgical exposure and visualization. There are also persisting concerns regarding inadequate neural decompression and higher risk for cage migrations, resulting in persistent symptoms and a need for reoperation.

Type of comparison: Open transforaminal lumbar interbody fusion (O-TLIF).

The O-TLIF technique was introduced to reduce the risks associated with a PLIF procedure. For an O-TLIF, a unilateral transforaminal route to the intervertebral space is used, with a unilateral facetectomy and insertion of one cage which reduces potentially harmful retraction of neural structures. The advantage of an O-TLIF when compared with MIS-TLIF is the extensive surgical exposure allowing visualization of key landmarks for facetectomy and screw placement. The main drawback of the O-TLIF technique is that it still requires extensive soft tissue preparation, which may result in denervation and atrophy of the paraspinal trunk musculature, more intraoperative blood loss and more postoperative pain. (5)

Types of outcome measures:

Primary outcomes

Clinical outcome, as measured by:

- Visual Analogue Scale (VAS), Oswestry Disability Index (ODI).

Secondary outcomes

- Fusion rate
- Pseudoarthrosis
- Lower extremity pain relief
- Back pain
- Neurological deficits
- Revision
- Readmission
- Implant failure rate
- Cage migration
- Cage extrusions

Literature Search Strategy

With help of a clinical librarian (Lisa Marks), a search strategy will be developed. For our literature search strategy, we will combine the terms: “minimally invasive”, “open”, “transforaminal lumbar interbody fusion”, “TLIF”, “treatment outcome” and “complication”, as either key words or MeSH terms. Details about the search strategy are presented in Appendix 1.

Electronic Searches

An electronic search of the literature will be conducted in the following databases from their dates-of-inception to 7-1-2019:

- Pubmed
- MEDLINE
- CENTRAL (Cochrane Register of Controlled Trials)
- Ovid EMBASE
- Scopus
- Web of Science
- ClinicalTrials.gov

Searching Other Resources

The following strategies will also be used to ensure a comprehensive search:

- 1) Reference lists will also be hand searched for further relevant studies.
- 2) Searching of the main electronic sources of ongoing trials (National Research Register, meta-Register of Controlled Trials; Clinical Trials)

Study Screening and Selection

All retrieved articles will be uploaded in the online program Rayyan (<http://rayyan.qcri.org>) after deletion of the duplicates. (12) Title and abstract of all articles will be screened against predetermined selection criteria and potential eligible studies will be independently selected by two authors (JH and OA). After this initial assessment, we will obtain full-text copies of all studies considered to be potentially relevant. Two review authors (JH and OA) independently will check the full papers for eligibility. Disagreements will be resolved by discussion. A third review author (KA) will be contacted if disagreements persist. We will record all reasons for exclusion of studies. We will complete a PRISMA flowchart to summarize this process. For final inclusion, all eligibility criteria had to be fulfilled.

We will not have a restriction on language.

Abstracts, case reports, conference presentations, editorials, reviews and expert opinions will be excluded.

Inclusion criteria	Adult patients diagnosed with degenerative lumbar disease
	Treated with one level MIS-TLIF or one level open TLIF
	Outcomes in terms of back and leg pain measured with VAS or ODI
	With a minimal follow-up of 2 years
Exclusion criteria	TLIF for other reasons than degenerative lumbar disease
	Reviews
	Case-control studies
	Abstracts
	Case reports
	Conference presentation
	Editorials
	Expert opinions
	Overlapping cohort
	Studies with insufficient data

Table 1: Inclusion and exclusion criteria.

Data Extraction and Management

All outcomes will be extracted from full-length article texts, tables, or figures. A standardized data extraction form will be prepared in Excel and will be used to extract data from the included papers. Two review authors (JH & OA) will be independently extract the data. Discrepancies between the two reviewers (JH & OA) will be resolved by discussion and consensus. A third review author (KA) will be consulted if disagreements persist. If studies will be found with overlapping cohorts from individual institutions, only the complete report will be included.

The following data will be extracted:

- Country of origin
- Year of publication
- Study design
- Number of participants
- Age
- Sex
- Type of degenerative lumbar disease
- Description of interventions
- Duration of follow-up
- Reported outcome
- Adverse effects (Pseudoarthrosis, Lower extremity pain, Neurological deficits, Revision, Readmission, Implant failure rate, Infection, Cage migration, Cage extrusions)
- Fusion rate

Critical Appraisal and Assessing of Bias

The risk of bias for each RCT study will be assessed using the revised tool to access risk of bias in randomized trials (RoB 2 tool).(13) It included the following domains: (1) random sequence generation, (2) allocation concealment, (3) blinding of participant and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other bias. Each domain will be measured as low bias, unclear bias, or high bias. The risk of bias of observational studies will be assessed using the ROBINS-I tool (Risk of Bias

In Non-randomized Studies - of Interventions).(14) It accesses bias in the following domains: (1) Bias due to confounding, (2) Bias in selection of participants into the study, (3) Bias in classification of interventions, (4) Bias due to deviations from intended interventions, (5) Bias due to missing data, (6) Bias in measurement of outcomes and (7) Bias in selection of the reported result. The response options for each domain-level are low risk of bias, moderate risk of bias, serious risk of bias, critical risk of bias and no information on which to base a judgement.

Risk of bias will be assigned to each article independently by 2 reviewers (JH & OA). Disagreements among any of the above data points will be resolved through discussion among the authors. A third review author (KA) will be consulted if disagreements persisted.

Strategy for Statistical Analysis

Data will be analyzed using Review Manager, version 5.3 or Rstudio (2016).(15, 16) Clinical outcomes will be assessed using the relative risk (RR) for dichotomous variables or weighted mean difference (WMD) and their 95% confidence interval (CI) for continuous variables. Pooled results will be assessed for heterogeneity using the Cochrane Q test and I^2 tests. Cochrane Q test will be used to test heterogeneity between studies.

Heterogeneity will be considered as statistically significant when the P value derived from Cochrane Q is <0.1 . I^2 statistic will be used to quantify the percentage of total variation across studies, owing to heterogeneity rather than chance.(17) Heterogeneity will be defined as absent when I^2 is between 0 and 25%; low, between 25.1 and 50%; moderate, between 50.1 and 75%; or high, between 75.1 and 100%. Fixed-effects meta-analysis will be performed when $P \geq 0.1$ and $I^2 \leq 50\%$; otherwise, random-effects meta-analysis will be performed.

Statistical tests will be two-sided; significance will be defined using the alpha threshold of 0.05, unless otherwise specified.

Grading the Evidence

We will access the overall quality of the evidence for each primary outcome. To accomplish this, we will use the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach .(18) The quality of the evidence on a specific outcome is based on the performance against six factors: study design, risk of bias, consistency and directness of results, precision of the data and non-biased reporting of the results across all studies that measured that particular outcome. The quality of evidence for each outcome will be assessed independently by two reviewers (JH and OA) Cases of discrepancy will be resolved through discussion. Each outcome will be rated as either high, moderate, low, or very low based on the studies on which the outcome is based and will be entered into the risk of bias table.

Publication Bias Assessment

Publication bias will be graphically assessed using the funnel plot and will be tested using the Egger's linear regression test and Begg's correlation tests. (19, 20) If the effect size will be symmetrical and P value drawn from Begg's test will be more than 0.05 indicated that there is no publication bias. Publication bias will be assessed using the procedure of "Metabias" in Rstudio.(16)

Conclusion

This meta-analysis will provide a detailed summary of the long-term clinical outcome of minimally invasive versus open single-level transforaminal lumbar interbody fusion for degenerative lumbar diseases. Previous meta-analyses have been published, but all focused on the peri-operative or short-term outcomes. This meta- analysis is the first in including only studies with a minimum follow-up of 2 years.

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