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Meta-analysis of prospective cohort studies that compare outcomes of minimally invasive and open transforaminal lumbar interbody fusion in surgical treatment of patients with lumbar spine degenerative disease

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Purpose To conduct a meta-analysis based on the results of prospective cohort clinical studies that compare the outcomes of minimally invasive and open transforaminal lumbar interbody fusion in surgical treatment of patients with lumbar spine degenerative disease. **Material and methods** Pubmed, EMBASE, ELibrary and Cochrane Library databases were searched for randomized clinical trials published from 2008 to November 2018, which compared the results of minimally invasive (MIS-TLIF) and open (O-TLIF) techniques of transforaminal interbody fusion in treating patients with degenerative diseases of the lumbar spine. For dichotomous variables, the relative risk and 95% confidence interval were calculated; in turn, a standardized difference in mean values and their 95 % confidence intervals were used for continuous variables, using the random effects model. **Results** This meta-analysis included 14 prospective cohort studies, three of which were randomized controlled clinical trials. The results of surgical treatment of 1,324 patients with degenerative diseases of the lumbar spine were assessed. In the MIS-TLIF group, a reliably lower level of pain in the lumbar spine ($p < 0.00001$), better functional status by ODI ($p < 0.0001$), lower number of adverse effects ($p = 0.01$) were verified. At the same time, the rate of fusion ($p = 0.98$) and of secondary surgical procedures ($p = 0.52$) between the compared groups had no significant differences. **Conclusion** The MIS-TLIF method has significantly better long-term clinical outcomes in comparison with the O-TLIF method in terms of pain relief and functional status and a lower risk of consequences. There were no statistically significant differences in the rates of interbody fusion and repeated surgical interventions between the compared groups of respondents.
Keywords: lumbar spine, degenerative diseases, transforaminal interbody spinal fusion, transpedicular stabilization, minimally-invasive spinal surgery, meta-analysis, prospective cohort studies, randomized controlled studies

INTRODUCTION

Degenerative diseases of the lumbar spine are diagnosed in the individuals of working age and are accompanied by pain in the lower back and lower limbs, syndrome of neurogenic intermittent claudication and a decrease in functional activity [1, 2].

Transforaminal interbody fusion and transpedicular fixation are the most common surgical treatment options for most degenerative diseases of the lumbar spine [3, 4]. Open dorsal rigid stabilization (O-TLIF) is commonly accompanied by significant damage to the paravertebral muscles, high risks of infectious complications, pronounced postoperative pain, significant intraoperative blood loss and long-term functional recovery [5, 6]. As an alternative, to reduce iatrogenic damage to soft tissues, a method of minimally invasive transforaminal interbody fusion and transcutaneous transpedicular stabilization fixation (MIS-TLIF) has been developed [7, 8]. Despite better clinical outcomes of using such technologies, there are conflicting data on the comparative effectiveness of O-TLIF and MIS-TLIF in the current specialized literature sources which are based on a long learning curve, limited area of surgical manipulations, and a high number of complications associated with the use of additional equipment [9, 10]. All of the above reasons motivated us to conduct this meta-analysis.

The **purpose** of the study was to conduct a meta-analysis based on the results of prospective cohort clinical studies that compare the use of minimally invasive and open transforaminal interbody fusion techniques for treating patients with degenerative diseases of the lumbar spine.

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MATERIAL AND METHODS

Search and selection of literature sources

Pubmed, EMBASE, ELibrary and Cochrane Library databases were searched for randomized clinical trials published from 2008 to November 2018, which compared the results of minimally invasive (MIS-TLIF) and open (O-TLIF) techniques of transforaminal interbody fusion in treating patients with degenerative diseases of the lumbar spine. Two researchers performed the search of available literature. If disagreements arose regarding the inclusion of studies in the meta-analysis, the decision was made collectively with the participation of the entire group of authors. The study was performed in accordance with international recommendations for writing systematic reviews and meta-analyzes PRISMA [11].

At the first stage, the keywords "degenerative disease", "lumbar spine", "transforaminal interbody fusion", "TLIF", "minimally invasive spine surgery", "MIS", "open", "clinical outcomes" , "radiological outcomes" for English-language and their equivalents for Russian-speaking systems were used for search; selection of Russian articles by title was also manual. At the second stage, the abstracts of the articles were read and publications that did not meet the research criteria were excluded. At the third stage, full texts of selected articles were reviewed for compliance with the inclusion criteria and a list of references for relevant studies (**Fig. 1**).

Inclusion Criteria

The following criteria for literature source correspondence were defined in order to compare these two surgical interventions:

1) included articles: a prospective cohort clinical study assessing the results of the use of minimally invasive and open transforaminal interbody fusion techniques in adult patients with degenerative lumbar spine disease and clinical neurological symptoms;

2) types of surgical interventions: studies comparing minimally invasive and open transforaminal interbody fusion techniques using various implants;

3) outcomes: studies analyzing clinical and instrumental results of the implementation of these types of surgical interventions; quality of life of patients associated with the index of movement restrictions in the lumbar spine ODI (Oswestry Disability Index), severity of pain in the lumbar spine with Visual Analogue Scale (VAS), adverse events, interbody spondylodesis, surgical re-interventions;

4) minimum postoperative follow-up period at least 24 months;

5) availability of a full-text article in English or Russian.

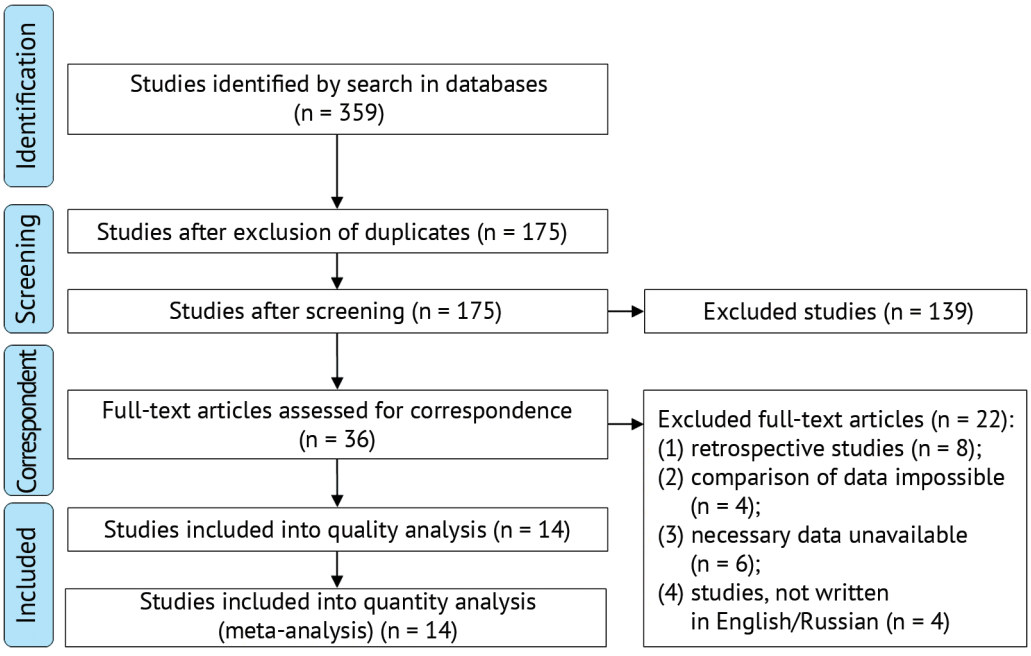

Fig. 1 Strategy for searching and selecting literature data for inclusion in meta-analysis

Assessing the risk of research bias

Each randomized clinical trial included in this meta-analysis was evaluated using the Review Manager 5.3 software option (Assessing the risk of research bias) of the Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014, Copenhagen, Denmark) by the following parameters: 1) data sequence generation, 2) hiding research data, 3) use of blinding procedure, 4) incomplete list of study findings, 5) selective presentation of study results, and 6) other bias parameters (**Fig. 2**). The total estimated risks of bias for all studies are divided into "low", "not defined" and "high" (**Fig. 3**). The Newcastle-Ottawa Scale [12] was used to evaluate the methodological quality of non-randomized prospective clinical studies.

For dichotomous variables, the relative risk (RR) and 95 % confidence interval (CI) were calculated. In turn, standard mean difference (SMD) and 95 % CI using random effects model (REM) were used for continuous variables. The degree of heterogeneity was estimated using the I^2 coefficient. Studies were considered homogeneous if I^2 value was less than 25 %; values from 25 to 50 % were of low heterogeneity, from 50 to 75 % of moderate one and more than 75 % of high heterogeneity. The asymmetry of the study was analyzed by constructing a funnel plot graph the Egger linear regression test. Tree-shaped diagrams were created using the Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, 2014, Copenhagen, Denmark). Differences with $p \leqslant 0.05$ were considered significant.

Parameters of Bias	Studies		
	Wang, 2010	Rodriguez-Vela, 2013	Yang, 2015
Data sequence generation	+	+	+
Hiding research data	?	?	?
Use of blinding procedure	–	–	+
Incomplete list of study findings	+	+	+
Selective presentation of study results	+	+	+
Other	?	?	?

+ – low risk ? – not defined risk – – high risk

Fig. 2 Assessment of risk of bias for each study included in meta-analysis

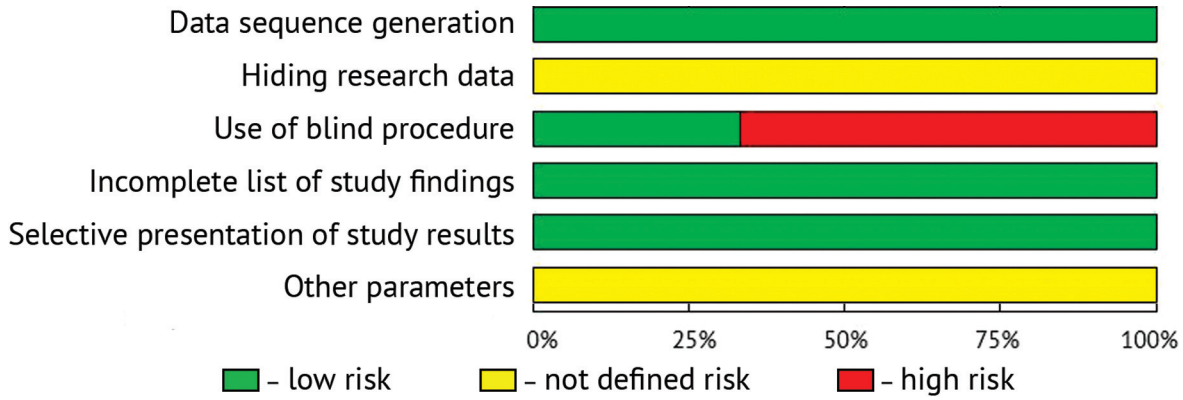

Fig. 3 Summarized risks of bias for all studies included into meta-analysis

RESULTS

Search for studies

According to criteria, fourteen prospective cohort studies with a minimum follow-up period of 24 months were included in this meta-analysis, of which three were randomized controlled clinical trials, with results of surgical treatment of 1324 patients with degenerative diseases of the lumbar spine. General characteristics of the studies included in this meta-analysis are presented in Table 1.

All studies that met the criteria for inclusion in this meta-analysis reflected the main clinical and instrumental parameters. These papers provide information on the use of minimally invasive and open transforaminal interbody fusion.

Table 1

General characteristics of the studies included in the meta-analysis

	Year	Country	Study types	Number of patients		Mean age (years)		Gender (m/f.)		Follow-up period (months)	Score Newcastle-Ottawa
				MIS-TLIF	O-TLIF	MIS-TLIF	O-TLIF	MIS-TLIF	O-TLIF		
Peng CW [13]	2009	Singapore	PCS	29	29	54.1 (26.4–73.6)	52.5 (23.8–71.3)	5/24	5/24	24–48	7
Shunwu F [9]	2010	China	PCS	32	30	51.4 ± 7.2	52 ± 6.4	18/14	14/16	24	6
Wang J [14]	2010	China	PCS / RCS	42	43	47.9 ± 8.5	53.2 ± 10.6	13/19	16/27	26.3	–
Wang HL [10]	2011	China	PCS	41	38	51.4 ± 15.3	57.3 ± 12.1	24/17	23/15	24	8
Lee KH [15]	2012	Singapore	PCS	72	72	52.2 ± 13.8	56.6 ± 14.6	20/52	22/50	24	8
Rodriguez-Vela J [16]	2013	Spine	PCS / RCS	21	20	41.81 ± 8.7	43.15 ± 7.3	14/7	13/7	36-54	-
Seng C [17]	2013	Singapore	PCS	40	40	56.6 ± 1.63	56.8 ± 1.67	7/33	7/33	60	8
Parker SL [18]	2013	USA	PCS	50	50	53.5 ± 12.5	52.6 ± 11.6	16/34	18/32	24	7
Wong AP [19]	2014	China/ USA	PCS	144	54	61	58	61/83	25/29	45	7
Sulaiman WA [20]	2014	USA	PCS	57	11	61.1	56.4	17/40	4/7	24	7
Wang J [21]	2014	China	PCS	42	39	56.4 ± 10.7	54.2 ± 9.1	13/29	12/27	36.1 (23–57)	6
Yang Y [22]	2015	China	PCS / RCS	50	50	58.0 ± 13.4	56.1 ± 11.0	18/32	23/27	24	–
Tian W [23]	2017	China	PCS	30	31	48.21 ± 9.1	48.9 ± 8.89	16/14	23/8	25.6	6
Wu AM [2]	2018	China	PCS	79	88	58.1 ± 12.80	55.3 ± 14.0	33/46	38/50	24	8

Note: PCS - a prospective cohort study; RCT – randomized clinical trial; MIS-TLIF – minimally invasive transforaminal lumbar interbody fusion with transcutaneous transpedicular fixation from paramedian approach; O-TLIF – transforaminal lumbar interbody fusion with open transpedicular fixation from the middle approach

Severity of pain in the lumbar spine on VAS

Information on the severity of pain in the lumbar spine after operations of rigid stabilization of the lumbar spine using VAS was presented in 13 prospective cohort studies [2, 9, 10, 14–23]. There was a significantly lower severity of pain in the lumbar spine at follow-up in the MIS-TLIF group (SMD = -0.25, 95 % CI: -0.56, 0.06, p <0.00001; I^2 = 84 %; **Fig. 4**).

Quality of life assessed with ODI

All prospective cohort studies included in this meta-analysis provided information on the quality of life of patients according to ODI after rigid stabilization. High values of the patients' quality of life were verified by ODI at the long-term follow-up in the MIS-TLIF group (SMD = -0.15, 95 % CI: -0.27, -0.03, p <0.0001; I^2 = 70 %; **Fig. 5**).

Adverse events

Information on the frequency of adverse events in patients who underwent transforaminal interbody fusion and transpedicular stabilization was presented in all studies included in this meta-analysis [2, 9, 10, 14–23]. Adverse events frequency was lower in the MIS-TLIF group (SMD= 0.47, 95 % CI: 0.34, 0.65, p = 0.010; I^2 = 53 %; **Fig. 6**).

Reoperations

Data on repeated surgical interventions were presented in eight prospective cohort clinical studies [2, 10, 13–15, 18, 19, 23]. A combined analysis of the results of these studies showed no significant differences in re-interventions between the MIS-TLIF and O-TLIF groups (RR = 0.64, 95 % CI: 0.37, 1.11, p = 0.52; I^2 = 0 %; **Fig. 7**).

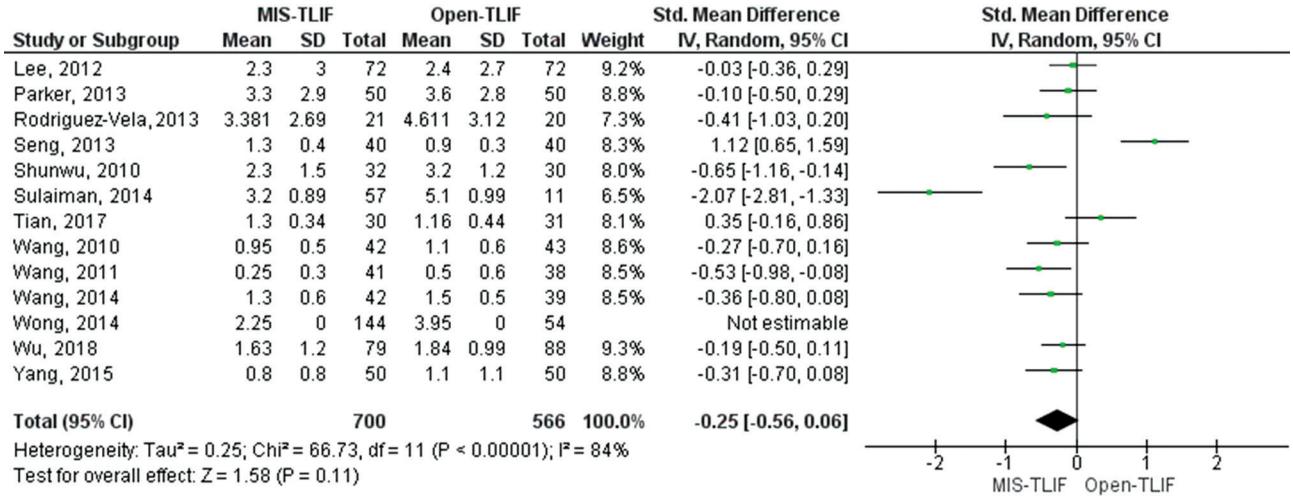

Fig. 4 Tree diagram of severity of pain in the lumbar spine according to VAS. Note. Mean – average value; SD – standard deviation; Weight – weighted effect size; Total is the total number of patients; Std. Mean Difference – standardized difference of mean values; Random – random effects model; 95 % CI – 95 % confidence interval

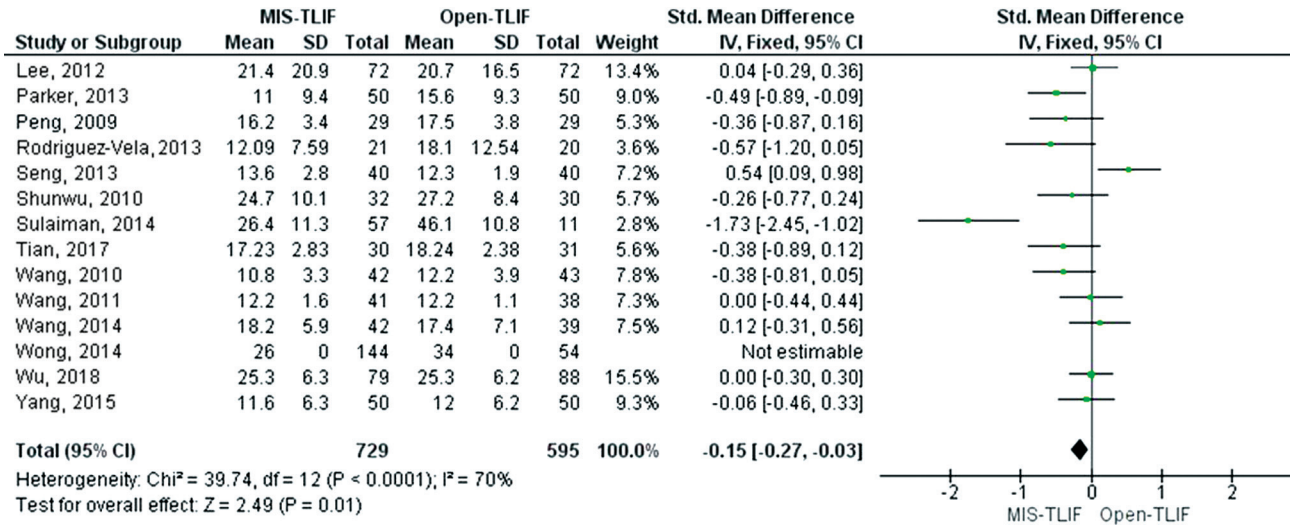

Fig. 5 Tree diagram of the level of quality of life of patients associated with the ODI functional status. Note. Mean – average value; SD – standard deviation; Weight – weighted effect size; Total – total number of patients; Std. Mean Difference – standardized difference of average values; Random – random effects model; 95 % CI – 95 % confidence interval

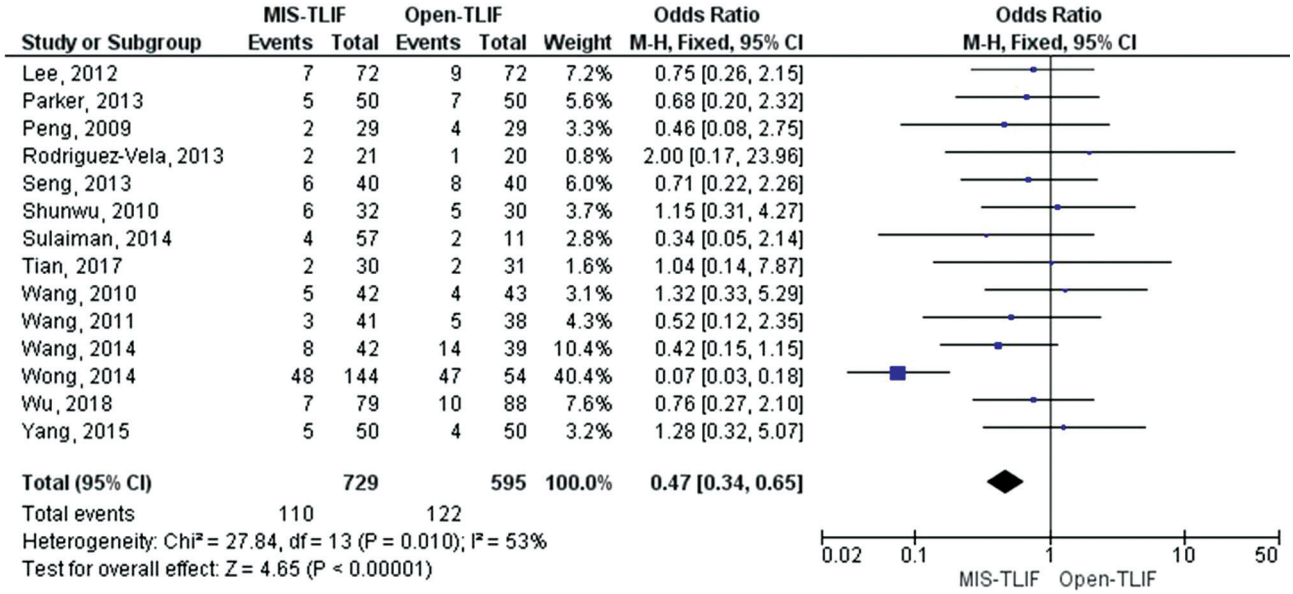

Fig. 6 Tree diagram of adverse events. Note: Events - number of cases; Total - total number of patients; Weight – weighted effect size; Odds Ratio – odds ratio; M-H – Mantel-Henzel test; Random – random effects model; 95 % CI – 95 % confidence interval

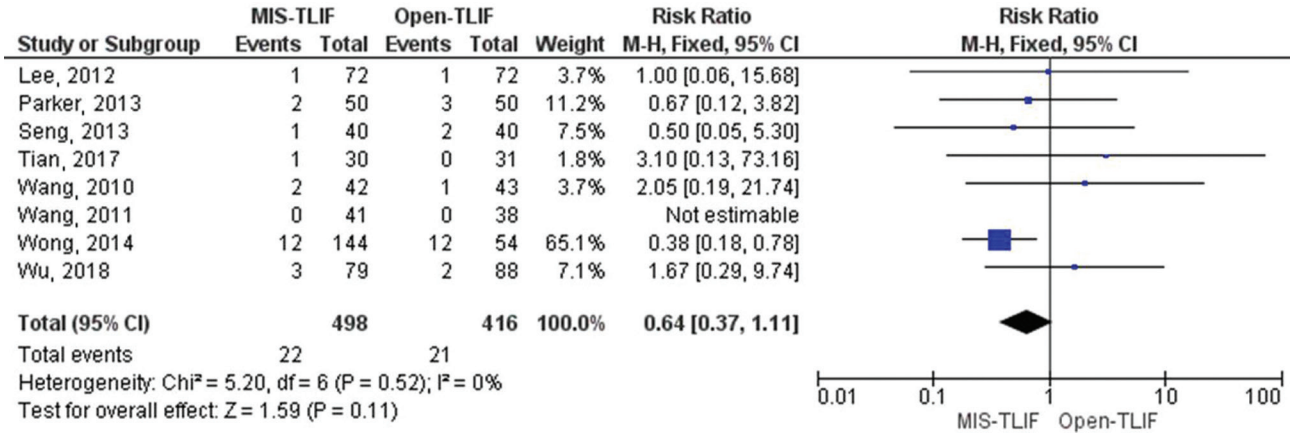

Fig. 7 Tree diagram of re-operations. Note. Events – number of cases; Total – total number of patients; Weight – weighted effect size; Risk Ratio – relative risk; M-H – Mantel-Henzel test; Random – random effects model; 95 % CI – 95 % confidence interval

Rates of interbody fusion

The data are presented in 10 prospective clinical studies in patients who underwent MIS-TLIF and O-TLIF operations [9, 10, 13–15, 17–19, 22, 23]. The meta-analysis of the results of these studies clearly demonstrated comparable information on the rate of spinal fusion in the analyzed groups (SMD = 0.98, 95 % CI: 0.50, 1.94, p = 0.98; I^2 = 0 %; **Fig. 8**).

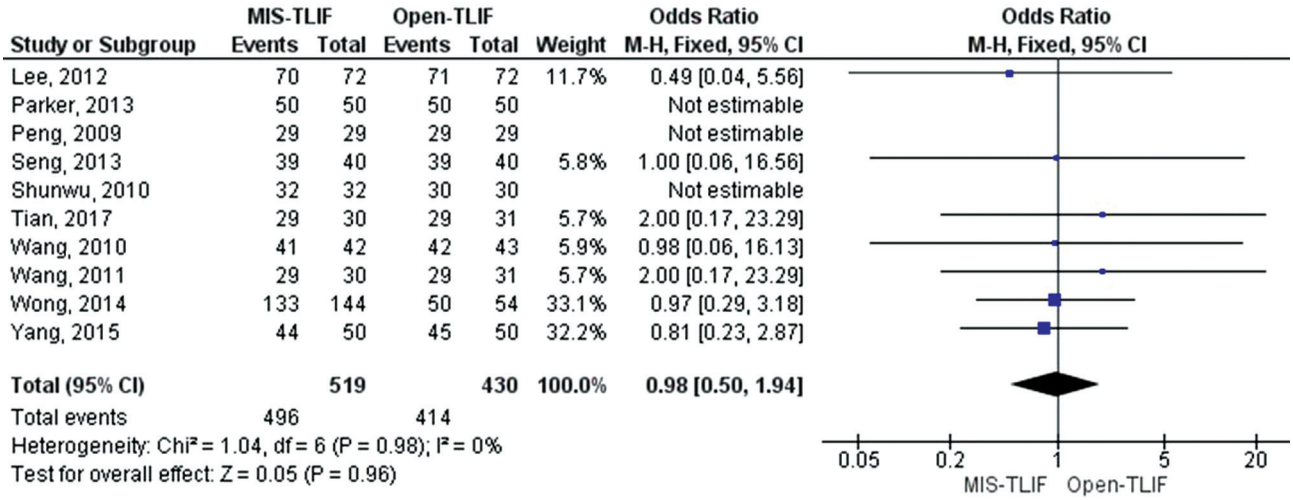

Fig. 8 Tree diagram of interbody fusion. Note: events – number of cases; Total – total number of patients; Weight – weighted effect size; Odds Ratio – odds ratio; M-H – Mantel-Henzel test; Random – random effects model; 95 % CI – 95 % confidence interval

DISCUSSION

The search of literary sources in various databases identified several meta-analyzes studying the comparison of the effectiveness of using MIS-TLIF and O-TLIF in the surgical treatment of patients with degenerative diseases of the lumbar spine.

Xie L. et al. [24] found a significantly lower postoperative pain using VAS and better ODI functional status in the MIS-TLIF group, which was most likely due to objectively less intraoperative trauma and early full rehabilitation. Khan N. et al. [25] indicate a significant improvement in clinical parameters after using both methods of rigid stabilization with no significant difference in outcomes in the late postoperative period. These results are attributed by the authors to high heterogeneity of the studies included in the meta-analysis, as well as to the absence of time periods regulated by the study protocol for measuring clinical parameters.

According to the results of the present meta-analysis, pain relief in the lumbar spine and the level of quality of life in the late postoperative period in the MIS-TLIF group were significantly better versus the O-TLIF group. Thus, a minimized operative invasiveness using tubular retractors, reduced dissection of the paravertebral muscles or their atrophy contributed to a significant decrease in postoperative pain and to restoration of functional activity in the MIS-TLIF group.

The findings of Lin Y. and co-authors [26] indicate that the most frequent complications of both MIS-TLIF and O-TLIF are postoperative liquorrhea, damage to the spinal nerve, infection in the surgical area and pseudarthrosis. The authors did not find intergroup differences in perioperative adverse events (RR = 0.94; 95 % CI, 0.69–1.28). However, Li A. et al. [27] pointed out lower risks of complications in the MIS-TLIF group. It was most likely associated with a smaller area of the wounded surface and advanced training of spinal surgeons.

The present study analyzed the total number of adverse effects. Fewer complications were reported in the MIS-TLIF group compared with O-TLIF.

Tian N. et al. [28] noted comparable data on the frequency of re-operations in the MIS-TLIF and O-TLIF groups. Total rates of repeated surgical interventions did not exceed 0.5 % for each of the included studies. The dominant causes of these interventions were the migration of a pedicle screw or cage, pseudarthrosis and an epidural hematoma.

We also did not reveal a statistically significant difference in surgical re-interventions between the MIS-TLIF and O-TLIF groups.

Full interbody fusion is one of the conditions for achieving a good clinical outcome. Many studies established there was no significant difference in the rates of fusion formation between the minimally invasive and open dorsal fixation [24, 27, 29].

Our study also confirms the comparable frequency in the formation of effective spinal fusion after applying the methods of MIS-TLIF and O-TLIF.

A lot of spinal surgeons prefer minimally invasive surgical techniques to open ones due to smaller incisions and faster functional recovery [2, 5]. However, the learning curve with MIS-TLIF is much longer than with O-TLIF [10]. It is also believed that the MIS-TLIF is technically more complex and requires the use of additional specialized equipment as compared to O-TLIF [27].

The goal of minimally invasive surgical techniques is not only reducing damage to the paravertebral tissues, reducing blood loss and reducing treatment time, but also a better clinical outcome as opposed to open surgical interventions [1, 21, 29]. Thus, at present, it is promising to use low invasive methods of decompression and stabilization, which provide effective stabilization of the segments involved and a lesser degree of iatrogenic aggression against soft tissues.

Limitations of the study

The study has a number of shortcomings that must be pointed out. First, the meta-analysis included patients with various degenerative diseases of the lumbar spine without details on the dominant pathology (instability, deformity, or stenosis). Second, most of the studies included in the meta-analysis had a short follow-up period, which significantly reduces the reliability of the results obtained. And, third, only three randomized trials that met the inclusion criteria were found. All had no low risk of bias in all parameters, which could also affect the results of the meta-analysis.

CONCLUSION

This meta-analysis showed that the MIS-TLIF method compared with the O-TLIF method has significantly better long-term clinical outcomes in regard of pain relief and functional status, less risk of adverse events. There were no statistically significant differences in the rate of interbody fusion and repeated surgical interventions between the compared groups of respondents. It is necessary to further conduct meta-analyses, including methodologically qualitative randomized clinical studies with long-term follow-ups after surgical procedures of MIS-TLIF and O-TLIF performed for degenerative diseases of the lumbar spine.

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Conflict of interest The authors of this study have no any conflict of interest to be reported.

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