Comparison of Decompression Alone and Decompression Combined with Fusion for Treating Lumbar Degenerative Spondylolisthesis

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Abstract

Background To assess the necessity or not of the addition of fusion to decompression for lumber degenerative spondylolisthesis patients.

Method Potential publications were selected from PubMed, Web of Science and Cochrane Library. Gray relevant studies were manually searched. We set the searching time spanning from the creating date of electronic engines to August 2019. STATA version 11.0 was exerted to process the pooled data.

Results Six RCTs were selected in our analysis. A total of 650 participants were divided into 275 in the decompression group and 375 in the fusion group. Our meta-analysis showed negative results generally. No statistic differences were found in VAS score for low back pain (WMD, -0.045; 95%CI, -1.259 to 1.169; P=0.942) and leg pain (WMD, 0.075; 95% CI, -1.201 to 1.35; P=0.908), ODI score (WMD, 1.489; 95% CI, -7.232 to 10.211; P=0.738), EQ-5D score (WMD, 0.03; 95% CI, -0.05 to 0.12; P=0.43), Odom's classification (OR, 0.353; 95%CI 0.113, 1.099; P=0.072), postoperative complications (OR, 0.437; 95% CI, 0.065 to 2.949; P=0.395), secondary operation (OR, 2.541; 95% CI 0.897, 7.198; P=0.079) and postoperative degenerative spondylolisthesis (OR=8.59,P=0.27). Subgroup analysis in VAS score on low back pain (OR=0.77, 95% CI, 0.36 to 1.65; P=0.50) was demonstrated as no meaning as well.

Conclusion The overall efficacy of the combination of decompression and fusion is not found to be superior to decompression alone. At the same time, more evidence-based performance is needed to supplement this opinion.

Background

Lumber degenerative spondylolisthesis (LDS) belongs to a common disease in spinal surgery. Anatomically, it presented as one vertebral body displace the latter from the anterior sagittal orientation while remaining intact arch, and accompanied by spinal stenosis in most conditions[1, 2]. Meanwhile, L4-5 was impaired frequently among all centrums[2, 3], which seems to be explained by where the main force places when people stand upright. Clinically, it manifested by radiating pain from buttock to leg and mechanical backache in the lower part[3, 4]. It is reported that LDS accounts for 4.1% in the general population[5], with women and the aged over 60 mostly involved[6, 7]. SPORT (The Spine Patient Outcomes Research Trial)[8] verified that surgery treatment advantages over non-operative ones, and decompression alone is the initially emerged surgical procedure[9], which benefits the patients with less invasive operations[10] and relief from the suffering of neural compression symptoms[3]. As new technique arising, some operators combined decompression with lumbar fusion in today's operations. A study conducted in the United States showed that the rate of it is high up to 96%[11]. To their satisfaction, the fusion with or without instrumented assistance brought about good clinical outcomes (such as decreased pain, longer relaxed term), which seems to be superior to the single decompression approach[12, 13]. Undoubtedly, the expenses go up as the procedures get complicated. Furthermore, there are some other hesitations on account of the uncertain comparing results between two approaches[12, 14]. Hence, we will seek superiorities yet inferiorities of these methods in this article by expounding the clinical efficacy between decompression alone and decompression combined with lumbar fusion for LDS patients.

Methods

Data sources & searches

Our review work was restricted closely along with the PRISMA guidelines[15]. The online search engines, such as PubMed (1970.01-2019.08), Web of Science (1970.01-2019.08), and Cochrane Library (1970.01-2019.08) are used to search potential studies. The searching terms are as follows: fenestration or hemilaminectomy or laminotomy or laminectomy or decompression, lumbar canal stenosis or lumbar spomdylolisthesis or lumbar spinal stenosis or degenerative lumbar spondylolisthesis, arthrodesis or fusion. Meanwhile, previous relevant references and related original researches were manually searched as well.

Inclusion & exclusion criteria:

Our analysis is limited to (I) Randomized controlled trials (RCTs); (II) Topics on the comparison between decompression alone and decompression combined with lumbar fusion; (III) English language; (IV) contents consist of at least one aspect in the clinical efficacy and/or complications;

In contrast, (I) Animal trials, conference or commentary articles, letters, systematic review, meta-analyses, case reports and series; (II) Studies without comparison between groups; (III) The included items < 10; (IV) Patients with diseases such as spinal tumor, bone fracture, systemic diseases, and other irrelevant diseases; (V) Articles focusing on the surgical techniques and internal fixed instruments, are excluded from our analysis.

Data extraction and outcome measures

We assigned two reviewers independently completed this part. A third author will join the extraction process in case of disagreements. The basic demographic information (the age, gender, diagnosis, the number of included cases, stenosis degree at the moment of grouping, follow-up time, and outcomes) was extracted based on preplanned form. The primary outcomes involved patients' satisfaction (Odom's classification), restored walking ability, the improvement ratio of European Quality of Life-5 Dimensions (EQ-5D), of the visual analog scales (VAS) score, of Oswestry Disability Index (ODI) for low back pain and leg pain. The secondary outcomes referred to the complications (the secondary operation, operation time, adjacent segment degenerative/disease (ASD), bleeding amount, and the development of centrum slippage after an operation.

Risk of bias and Quality Assessment

Cochrane Handbook for Systematic Review of Interventions (version 5.0) was used to evaluate the quality of related controlling factors of included literature. Specifically, each study was accessed for random sequence generation, blinding of participants and personnel, allocation concealment, selective reporting, blinding of outcome assessment, incomplete outcome data, and other sources of bias.

Data synthesis and analysis

All meta-analyses of eligible results were conducted using the STATA version 11.0 (Stata Corporation, College Station, Texas, USA). Heterogeneity among studies was estimated using a $\chi 2$ test, the I^2 value was identified to describe the percentage variance in trials attributable to heterogeneity. We regarded I^2 >50% as high heterogeneity, and a random-effect model was conducted. Otherwise, the fixed-effect model was used. The continuous outcomes (VAS score, ODI score, and EQ-5D score) were presented as weighted mean difference (WMD) with 95% confidence intervals (CIs). For binary variables (Odom's classification, complications, re-operation) odds ratios (ORs) with 95% CIs were applied for the evaluation. A p-value < 0.05 was regarded as statistically significant.

Result

Search results

A total of 2437 studies via searching electronic databases presented, there were 997 articles after removed the duplicates. Strictly along with our inclusion and exclusion criteria, 33 studies were included, afterward, we retained 10 full-text articles assessed for eligibility. 6 studies [2-4, 12, 16, 17] were eventually accepted.

Quality assessment and demographics

Two-thirds of the included studies showed a low risk of bias for sequence generation and selective reporting, all showed low risk for blinding of outcome assessment and incomplete outcome data. Herkowitz's study[12] assessed the allocation concealment as high risk, the other five studies didn't mention this criterion. The results of the quality assessment of trials were provided in Table1. A total of

650 patients diagnosed with LDS were enrolled, hailing from the USA, Sweden, and Japan. Of these 650 patients, 275 were randomized to the decompression (D) group versus 375 to the decompression combined with fusion (D+F) group. Recruitment periods approximately ranged from 3 to 7 years. No statistic value was found in average age (P=0.99) and gender (P=0.47) between D and D+F groups. More details were depicted in Table2.

Outcomes

VAS score

VAS grades from 0, meaning no pain, to 10, representing maximal pain[18]. There were four RCTs[3, 4, 12, 16] mentioned the improvement ratio of the VAS score of low back pain before and after given decompression or fusion treatment. Postoperative pain easement assessed by VAS didn't show significant value in our study (WMD, -0.045; 95% CI, -1.259 to 1.169; P=0.942, Figure2), and the heterogeneity is non-negligible (I^2=75.1%; p=0.007). Two RCTs[3, 4] worked out no statistic difference between two groups on the number of those who got improved VAS scores after taking surgery (OR, 0.77; 95% CI, 0.36 to 1.65; P=0.50). Three trials[3, 4, 12] described the VAS score of the leg pain pre- and post-operation, and we worked out the postoperative easement between groups as no significant difference (WMD, 0.075; 95% CI, -1.201 to 1.351; P=0.908, Figure3).

ODI score and EQ-5D score

ODI ranges from 0 to 100, EQ-5D ranges from 0 to 1, respectively, ODI score is parallel with the severity of the disability, so is EQ-5D score with the quality of life [19]. Two RCTs [4, 17] referred to ODI and EQ-5D indicators. However, our meta-analysis via random effect model performed no statistic difference between the D and D+F groups in ODI score (WMD, 1.489; 95% CI, -7.232 to 10.211; P=0.738; Figure4) and EQ-5D score (WMD, 0.03; 95% CI, -0.05 to 0.12; P=0.43).

Odom's classification

Postoperative patients' satisfaction was evaluated by Odom's classification. Our meta-analysis worked out no statistical difference between the D and D+F groups (OR, 0.353; 95% CI, 0.113 to 1.099; P=0.072; Figure5). Restored walking ability was only seen in Forsth's literature[4], and reported no statistical difference in the number of patients in the increase of walking distance at 2 years as well.

Complications

Five articles[2-4, 16, 17] recorded the incidence of complications, among which there were two articles[4, 17] mentioned ASD. Forsth's trial[4] was eliminated because of recording both spondylolysis and non-spondylolysis. Analysis towards the other four articles was regarded as no statistic difference between the D and D+F groups (OR= 0.437; 95% CI, 0.065 to 2.949; P=0.395; Figure6). Ghogawala et al.[17] recorded the cases of ASD in two groups respectively as 12 and 4, both were adjacent segment disease and took the secondary surgery.

Re-operation

Three publications[2, 16, 17] reported the incidence of re-operation. The average rates in the D group were 18.2%, while that one in the D+F group was 7.3%. No statistical difference was found between two groups (OR, 2.541; 95% CI, 0.897 to 7.198; P=0.079; Figure7).

Postoperative degenerative spondylolisthesis progression

In both groups, a certain proportion of postoperative degenerative spondylolisthesis happened at follow-up and immediate post-operation. Two RCTs[2, 12] referred to the number of degenerative spondylolisthesis progression and were verified no statistics difference (OR=8.59，P=0.27).

Discussion

Clinicians never stop inventing new and advanced techniques to defeat diseases. In terms of LDS, ongoing debates on the issue of decompression and/or fusion treatment have been strongly intense. The new emerging application of decompression combined with the fusion, came with a concern of cost performance. Whereas it is lack of big data support, given this, we perform this meta-analysis, including 6 RCTs, quantifying and comparing the clinical outcomes. Regrettably, our result showed that decompression plus fusion treatment is not found to be superior to decompression alone.

LDS patients may get an iatrogenic slip or increased spondylolisthesis degree after taking decompression surgery alone[20, 21]. Though lacking consensus on LDS, it is deemed to be an unsteady state, and surgeons may choose decompression plus fusion as a potential mean of avoiding postoperative instability and restenosis. Besides, some publications believe that the efficacy of decompression alone is significantly better than the one of fusion[22]. Forsth et al[4] performed a trial involving 247 patients and found no clinical benefit even adding fusion to decompression treatment after two years at the cost of higher hospital charges. Meanwhile, several cohort studies have concluded no substantial benefit in taking decompression plus fusion method[22-25].

Compared with preoperative, Forsth's trial demonstrated no significant difference was found in postoperative low back pain relief[4]. Similarly, our result showed no significant value on VAS scores evaluating low back pain. Furthermore, we performed a subgroup analysis of postoperative VAS scores and showed meaningless results. Same consequence came to the evaluation of leg pain. Based on three RCTs, our analysis demonstrated negative results, which might be ascribed to the limitation of sample size, or be explained by the quality of included RCTs, or truly indicate that the addition of fusion treatment is clinically valueless. Given the evaluation implementation of VAS, largely affected by doctors and/or patients' subjective judge, we should combine it with other results to achieve a comprehensive understanding.

Ghogawala et al. wrote a paper published in *N Engl J Med* and concluded that no significant difference in reduction of ODI scores was observed between two groups[17], and they found more than twice on improvement of ODI scores for decompression plus fusion compared to decompression alone[26]. Nevertheless, our results demonstrated that there was no significant statistical difference between the two groups, which was similar to Brodke et al.'s conclusion[27]. ODI scores could get influenced by the high loss rate of follow-up in 4-5 years, while the short-term follow-up was usually limited by small sample size. Thus, we used EQ-5D, referencing to the included two RCTs mentioned above, to evaluate the postoperative quality of life, and no significant value was shown between the D and D+F groups. Though most cases presented as one or two segments got spondylolisthesis, fusion failed to significantly improve patients' lives. Fusion could cause an increase in the amount of blood loss and operation time. In a word, the meaningless results could be indicated by the redundancy of fusion based on decompression.

Odom's classification was applied in our meta-analysis due to four articles[2-4, 12] evaluated the Odom's degree. It covers an item of excellent, good, fair and poor. We defined the excellent and the good as the standard of meeting the patients' needs. The negative result may indicate the uselessness of fusion treatment at patients' subjective perceptions. Restored walking ability was usually regarded as a primary outcome after an operation, and it was reported that the loss for walking speed is 1.6% yearly among the elder[28]. No statistic difference was found between two groups in terms of the increase in the postoperative walking distance within two years. This may be explained by the relatively low loss of walking ability or the independence between the improvement of walking ability and the surgery method, which means fusion is not necessary for LDS patients.

Complications involve surgery relevant complications such as intraoperative dural rupture, loose internal fixation, and systemic complications like pulmonary embolism and myocardial infarction. The major complication attributes to ASD (80%), followed by relapse or non-alleviation (15%) and internal fixation (5%). It would be completer to do further analysis of the complication category, but this part was restrained due to the small sample size. It was reported that the increase both on spondylolisthesis degree and age were risk factors for the high incidence of complications[29, 30]. Ghogawala et al. calculated the re-operation rates in 4 years after surgery[17], in the decompression group it is 34% while in the fusion group it is 14%. Dailey et al.[31] deemed no association between re-operation rates of surgical segments and adjacent segments and the surgical methods. Similarly, we illustrated no statistic difference between the two groups. Re-operation is more likely to be a surgeon's suggestion than a patient’s appeal. A veteran surgeon would not put re-operation on the schedule unless there was no treatment option remained, and the patient’s satisfaction is inversely proportional to the re-operation event to some extent. Though fusion technique may improve the unstable condition of lumbar spondylolisthesis, it holds the possibility of incurring more complications and a second operation as well.

There were some limitations existing in our study as well. Not all indexes were compared between the pre- and post- operative group owing to not all included RCTs collected preoperative data. More vertical comparison studies were needed for further RCTs. Though low back pain and leg pain presented as the primary symptoms of LDS, a specific definition of the involved body part is a lack of consensus, which might slightly affect the outcome. The age of included patients varied from 63 to 73, we didn’t perform a smaller age span analysis due to the unavailability of original data. It was a rationale to assume that proper surgery procedures maximized the benefit for patients of a certain age.

Conclusion

Based on the present results, the addition of fusion on decompression failed to reach anticipated outcome satisfying to the price patients paid, in other words, decompression alone seems to be sufficient to solve the problem. Given that the limitations arose from this analysis, a growing number of high qualities of RCTs are needed, at better with larger sample size and longer follow-up years.

Abbreviations

CIs = confidence intervals; RCT = Randomized Controlled Trial;

D = Decompression; D+F = Decompression Combined with Fusion

LDS = Lumber Degenerative Spondylolisthesis; ORs = Odds Ratios;

EQ-5D = European Quality of Life-5 Dimensions; VAS = Visual Analog Scales;

PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses;

ODI = Oswestry Disability Index; SPORT = Spine Patient Outcomes Research Trial;

WMD = Weighted Mean Difference; ASD = Adjacent Segment Degenerative/Disease.

Declarations

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Availability of data and materials

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Authors’ contributions

All authors planned and designed the study. WXQ and QQX conducted the articles search, selection of studies, extraction of data and risk of bias assessment supervised by XYY. All authors have participated sufficiently in the writing work.

Competing interests

The authors have declared that no competing interests exist.

Consent for publication

Not applicable. This manuscript does not involve data from any individual person.

Ethics approval and consent to participate

Not applicable. This manuscript does not include any animal or human data.

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Tables

Table 1: Cochrane Collaboration's tool for quality assessment in the included studies.

Trials	Sequence Generation	Allocation Concealment	Blinding of Outcome Assessors	Incomplete Outcome Data	Selective Outcome Reporting	Others
Herkowitz et al.	Low	High	Low	Low	Low	Low
Bridwell et al.	Low	Unclear	Low	Low	Low	Low
Aihara et al.	High	Unclear	Low	Low	Unclear	Low
Kleinstuect et al.	Unclear	Unclear	Low	Low	Unclear	Unclear
Ghogawa et al.	Low	Unclear	Low	Low	Low	Low
Forsth et al.	Low	Unclear	Low	Low	Low	Low

Table 2. Overview of Included Studies.

Author	Country	Years	Type of Study	Recruitment period	Participants (n)		Gender (M/W)		Age (mean ± standard)	
					D	D+F	D	D+F	D	D+F
Herkowitz et al.	USA	1991	RCT	NA	25	25	1.50	0.25	65.0	63.5
Bridwell et al.	USA	1993	RCT	1985.2~1990.3	9	34	0.28	0.31	72.3	64.6
Aihara et al.	Japan	2012	RCT	2005.5~2008.8	33	17	1.36	0.55	63.0±10.2	65.0±9.2
Kleinstueck et al.	Sweden	2012	RCT	2004.3~2008.5	56	157	0.70	0.29	73.0±8.0	67.4±9.4
Ghogawa et al.	USA	2016	RCT	2002.3~2009.8	35	31	0.30	0.19	66.5±8.0	66.7±7.2
Forsth et al.	Sweden	2016	RCT	2006.10~2012.6	117	111	0.41	0.61	67.0±7.0	68.0±7.0

Note. NA= not available; RCT= randomized controlled trial; M/W= man/woman; D= decompression; D+F= fusion.

Table 3. Meta-analysis results

Outcome	Studies	Groups		Overall effect			Heterogeneity	
		Decompression	Fusion	Effect estimate	95% CI	p-Value	I^2(%)	p-Value
LBP VAS score	4	231	310	-0.045	-1.259, 1.169	0.942	75.1%	0.007
LP VAS score	3	198	293	0.075	-1.201, 1.351	0.908	82.8%	0.003
ODI score	2	173	268	1.489	-7.232, 10.211	0.738	74.9%	0.046
Odom’s classification	3	77	82	0.353	0.113, 1.099	0.072	76.4%	0.005
Complications	5	250	350	0.437	0.065, 2.949	0.395	78.5%	0.003
Re-operation	3	77	82	2.541	0.897, 7.198	0.079	0.0%	0.613

Note: LBP= low back pain; LP= leg pain; VAS= visual analog scales; ODI= Oswestry Disability Index; EQ-5D= European Quality of Life-5 Dimensions.

Figures

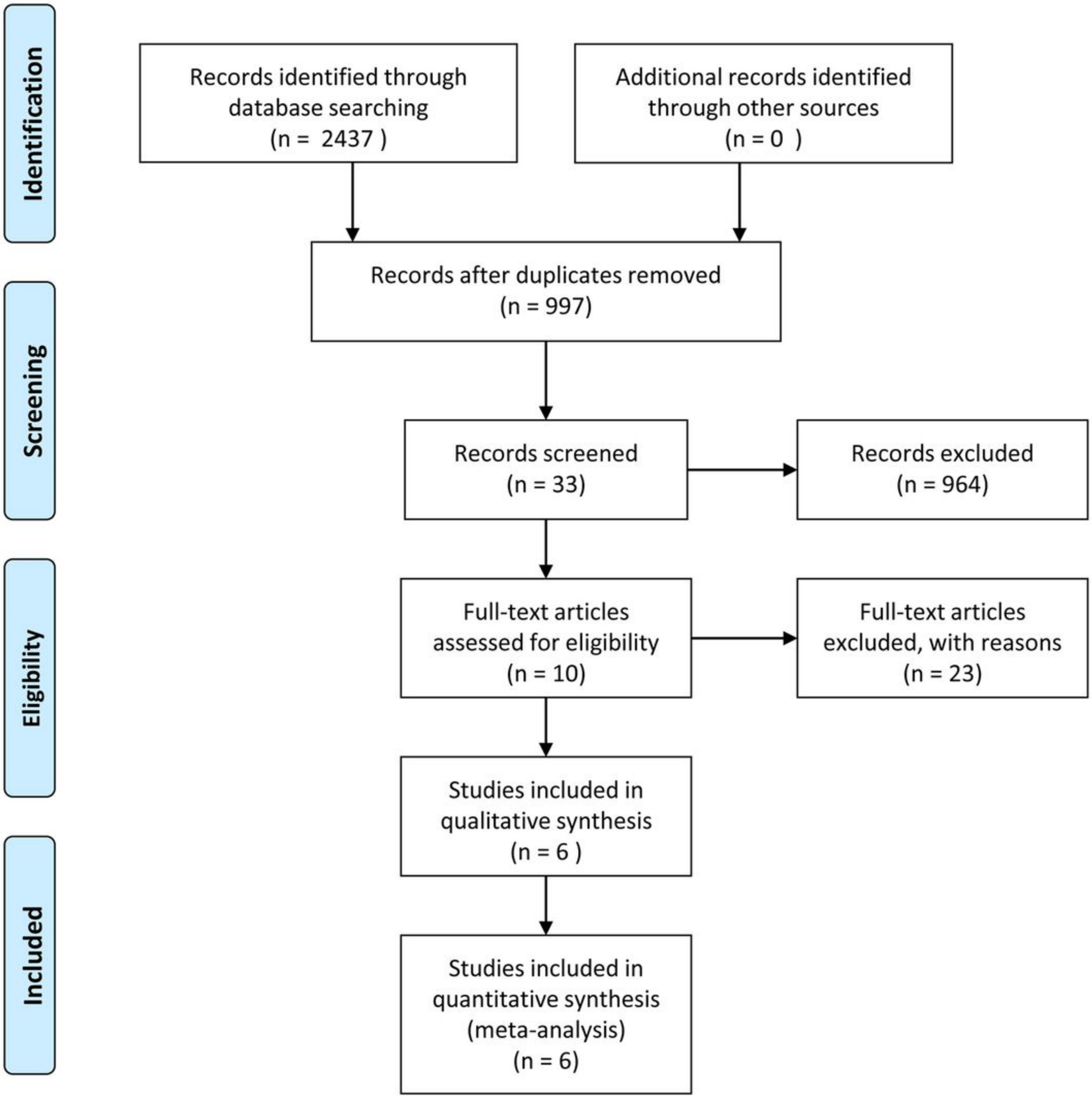

Figure 1

Flowchart of the study selection process.

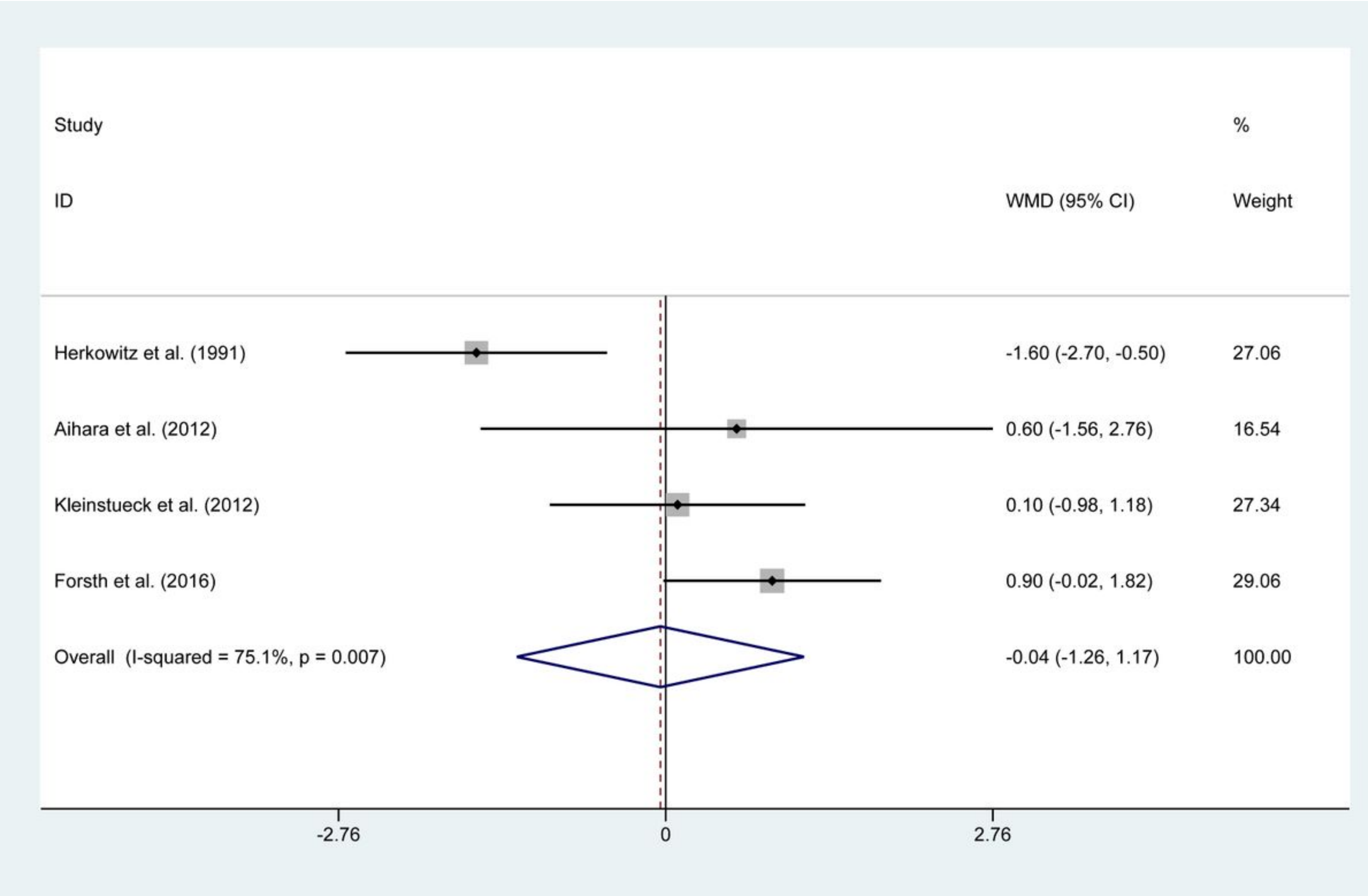

Figure 2

Forest plot of weighted mean difference (WMD) of VAS score of low back pain improvement with decompression vs. decompression combined with fusion.

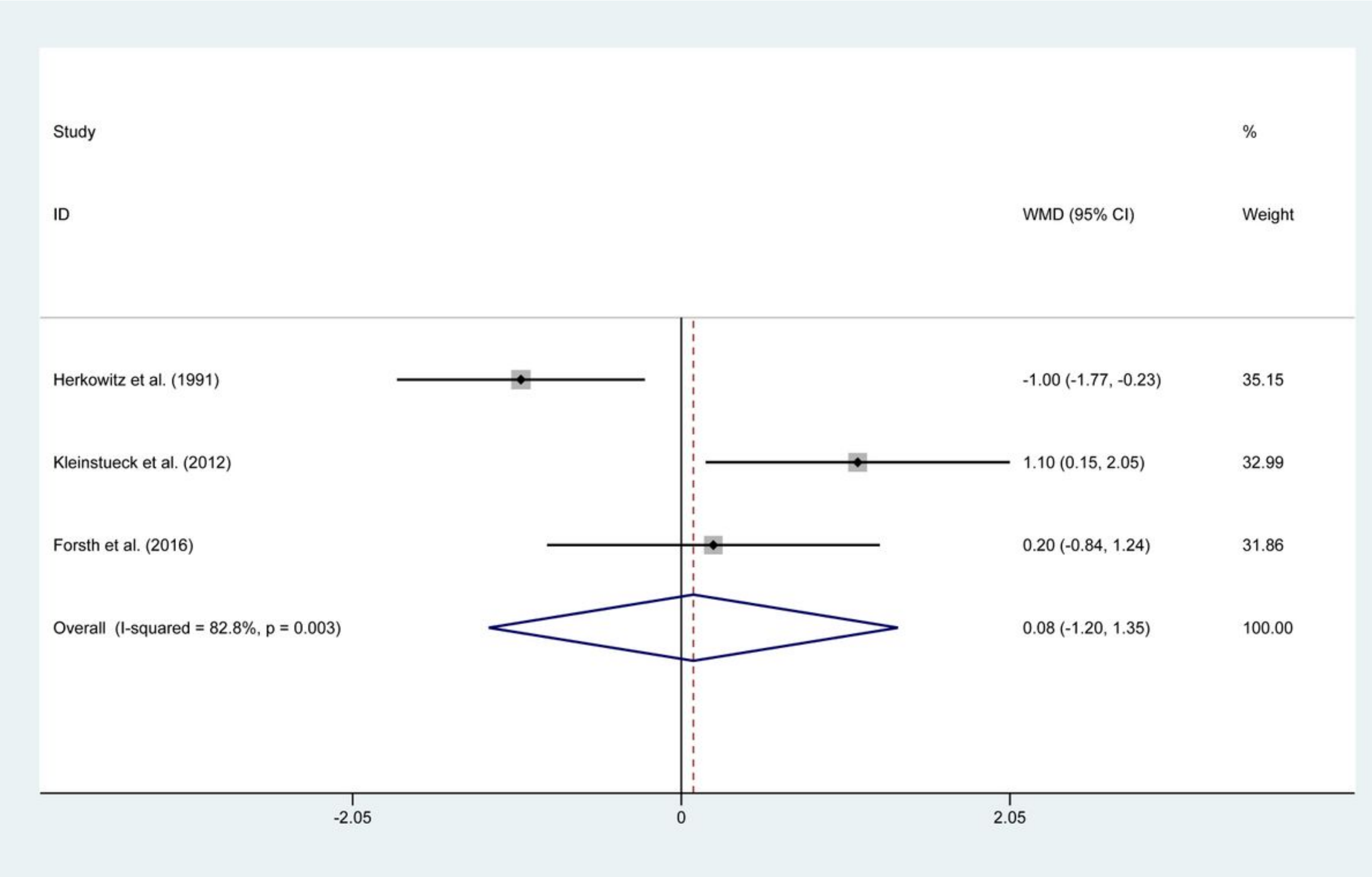

Figure 3

Forest plot of weighted mean difference (WMD) of VAS score of leg pain improvement with decompression vs. decompression combined with fusion.

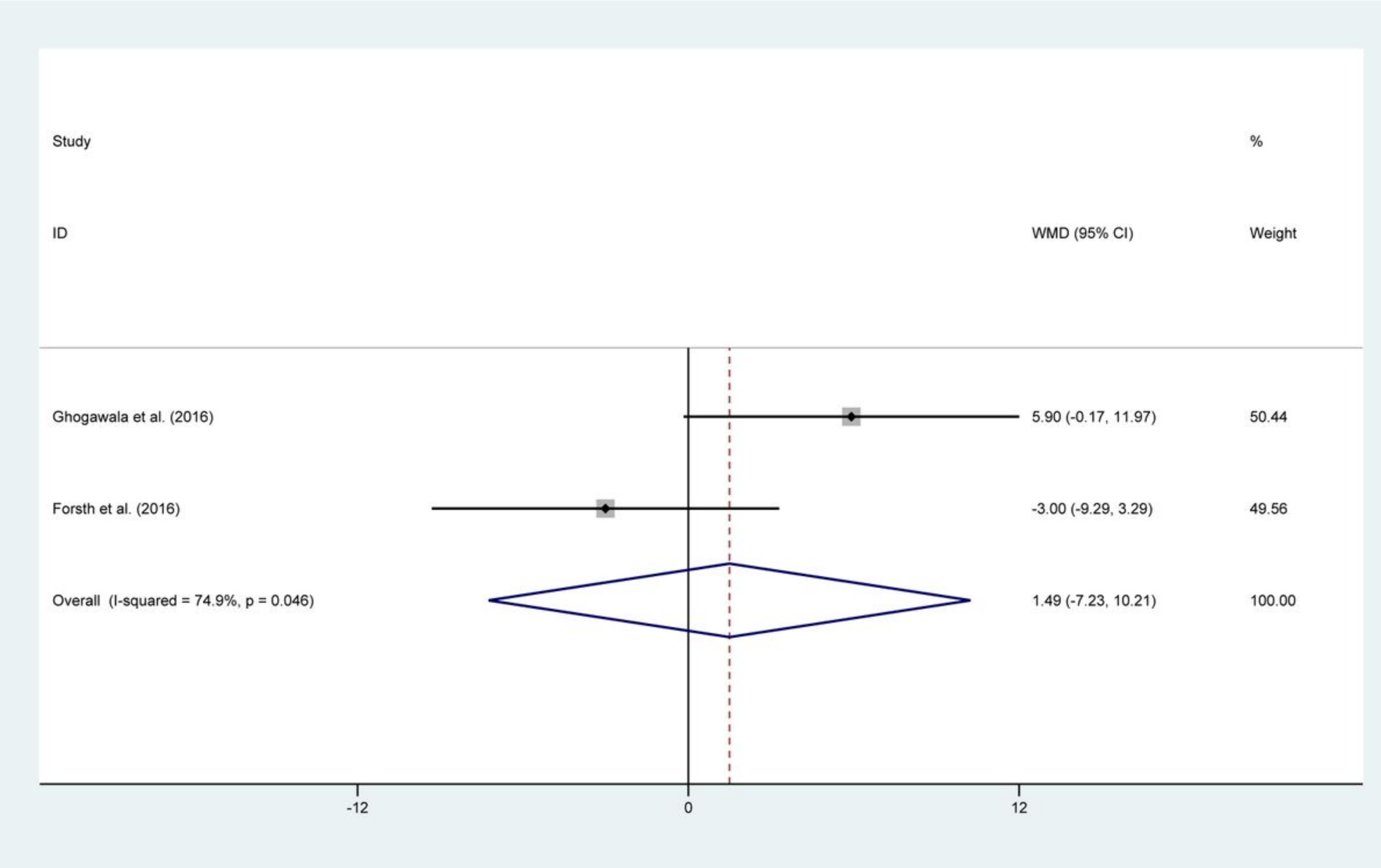

Figure 4

Forest plot of weighted mean difference (WMD) of ODI score improvement with decompression vs. decompression combined with fusion.

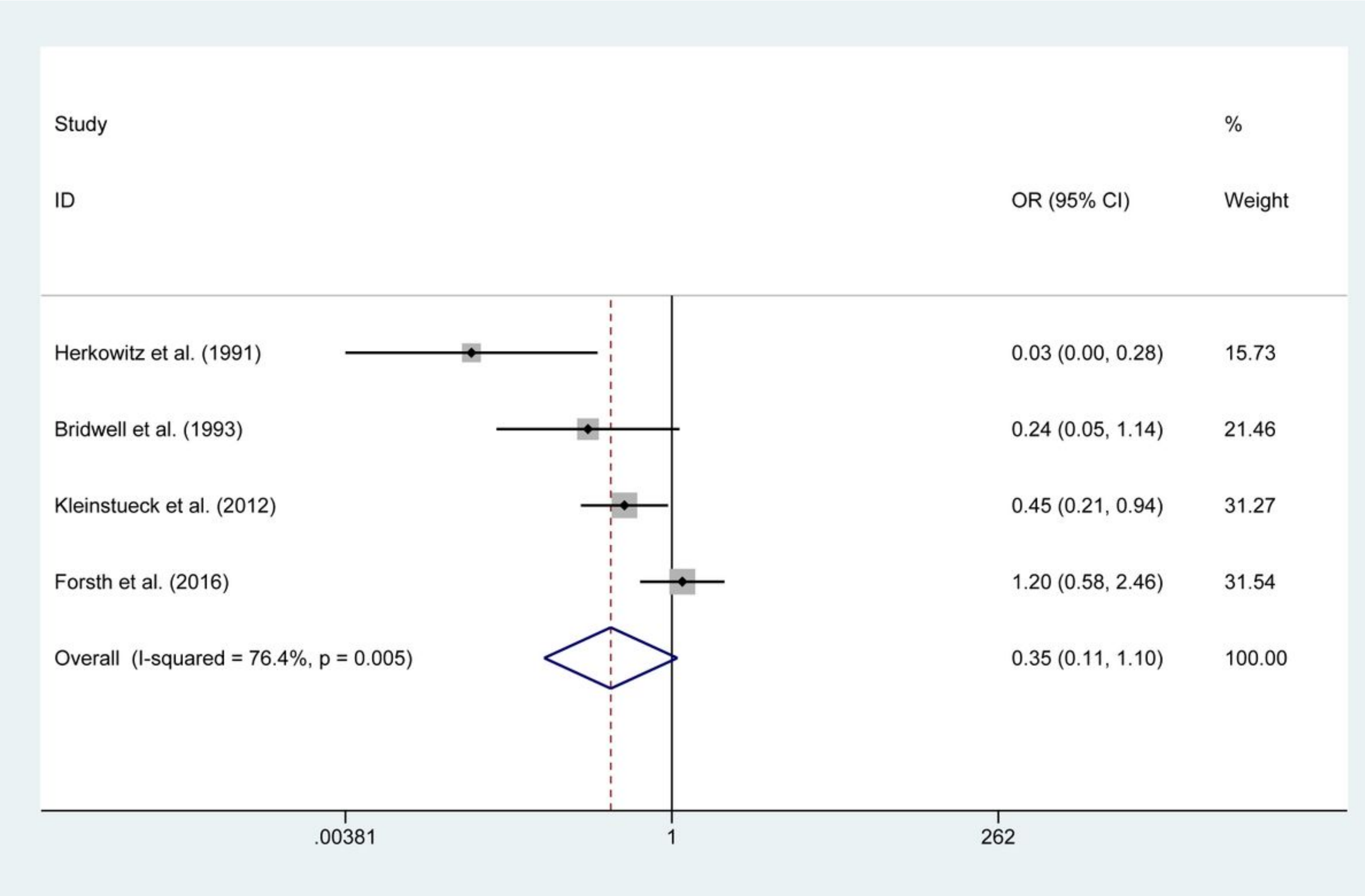

Figure 5

Forest plot of odds ratio (OR) of postoperative patients' satisfaction with decompression vs. decompression combined with fusion.

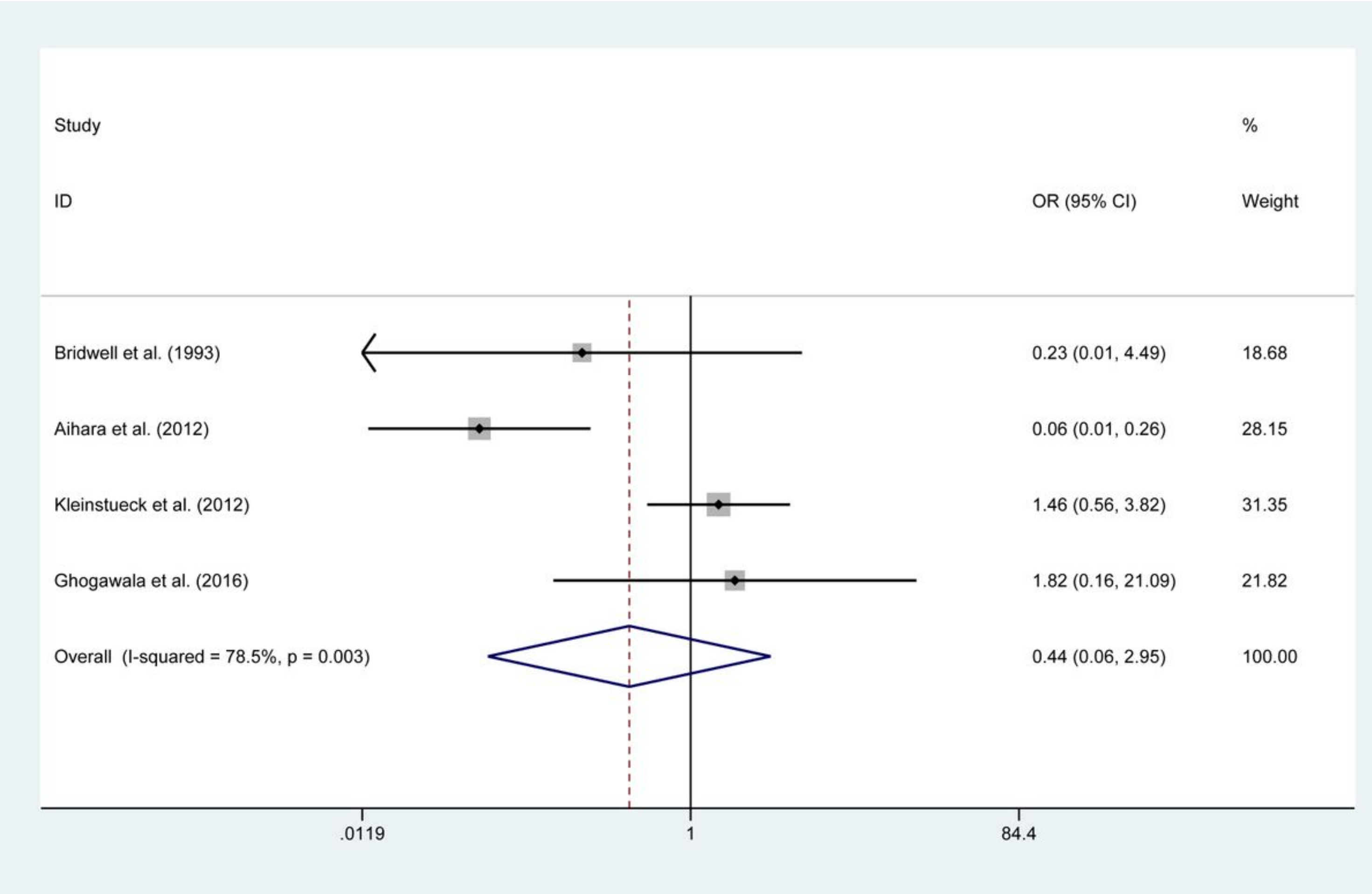

Figure 6

Forest plot of odds ratio (OR) of the incidence of postoperative complications with decompression vs. decompression combined with fusion.

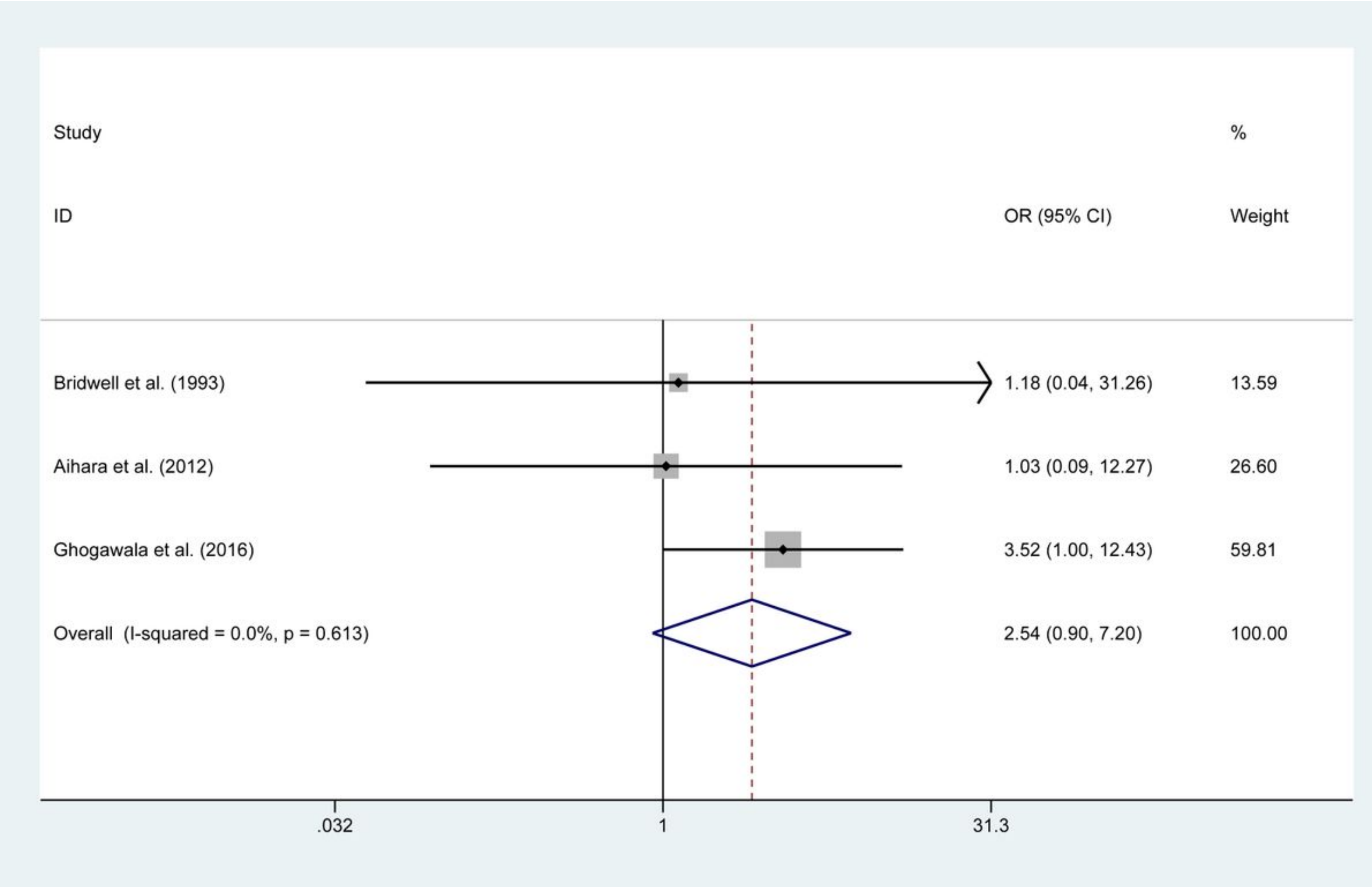

Figure 7

Forest plot of odds ratio (OR) of the rates of re-operation with decompression vs. decompression combined with fusion.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- PRISMAChecklist.doc