The necessity or not of the addition of fusion to decompression for lumbar degenerative spondylolisthesis patients

A PRISMA compliant meta-analysis

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Abstract

Background: The new emerging application of decompression combined with fusion comes with a concern of cost performance, however, it is a lack of big data support. We aimed to evaluate the necessity or not of the addition of fusion for decompression in patients with lumbar degenerative spondylolisthesis.

Methods: Potential studies were selected from PubMed, Web of Science, and Cochrane Library, and gray relevant studies were manually searched. We set the searching time spanning from the creating date of electronic engines to August 2020. STATA version 11.0 was exerted to process the pooled data.

Results: Six RCTs were included in this study. A total of 650 patients were divided into 275 in the decompression group and 375 in the fusion group. No statistic differences were found in the visual analog scales (VAS) score for low back pain (weighted mean difference [WMD], –0.045; 95% confidence interval [CI], –1.259–1.169; P = .942) and leg pain (WMD, 0.075; 95% CI, –1.201–1.35; P = .908), Oswestry Disability Index (ODI) score (WMD, 1.489; 95% CI, –7.232–10.211; P = .738), European Quality of Life-5 Dimensions (EQ-5D) score (WMD, 0.03; 95% CI, –0.05–0.12; P = .43), Odom classification (OR, 0.353; 95% CI 0.113–1.099; P = .072), postoperative complications (OR, 0.437; 95% CI, 0.065–2.940; P = .395), secondary operation (OR, 2.541; 95% CI 0.897–7.198; P = .079), and postoperative degenerative spondylolisthesis (OR = 8.59, P = .27). Subgroup analysis of VAS score on low back pain (OR = 0.77, 95% CI, 0.36–1.65; P = .50) was demonstrated as no significant difference as well.

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

Abbreviations: ASD = adjacent segment degenerative/disease, CIs = confidence intervals, D = decompression, D+F = decompression combined with fusion, EQ-5D = European Quality of Life-5 Dimensions, LDS = lumbar degenerative spondylolisthesis, ODI = Oswestry Disability Index, ORs = odds ratios, PRISMA = preferred reporting items for systematic reviews and meta-analyses, RCT = randomized controlled trial, SPORT = spine patient outcomes research trial, VAS = visual analog scales, WMD = weighted mean difference.

Keywords: decompression alone, decompression combined with fusion, lumbar degenerative spondylolisthesis
1. Introduction

Lumbar degenerative spondylolisthesis (LDS) belongs to a common disease in spinal surgery. Anatomically, it presents as one vertebral body displace the latter from anterior sagittal orientation while remaining intact arch, and accompanied by spinal stenosis in most conditions.\(^1\),\(^2\) Meanwhile, the L-4–5 is impaired frequently among all centrum,\(^3\),\(^4\) which seems to be explained by where the main force places when people stand upright. Clinically, it manifests by radiating pain from buttock to leg and mechanical backache in the lower part.\(^3\),\(^4\) It is reported explained by where the main force places when people stand upright. The spine patient outcomes research trial (SPORT)\(^7\) verified that the surgery advantages were over conservative treatment and decompression alone. As an initially emerged surgical procedure, it benefits the patients with less invasive operations\(^8\) and relieved them from suffering of neural compression symptoms.\(^3\) Some surgeons combined decompression with lumbar fusion in today’s operations. Recent systemic reviews on this issue have supported that decompression plus fusion brings about promising clinical outcomes.\(^9\),\(^10\) The fusion with or without instrumented assistance also yields good clinical outcomes (such as decreased pain and longer relaxed term).\(^11\),\(^12\) It is widely used and even as the “golden standard.”\(^13\) A study conducted in the United States showed that the rate of combined treatment is high up to 96%.\(^14\) However, different voices are existing: whether fusion is the necessary option still ignites great controversy.\(^15\),\(^16\) Notably, the expenses go up as the procedures get complicated. Besides, there are some other hesitations on account of the uncertain comparing results between the procedures.\(^11\),\(^17\) Therefore, we aimed to seek the superiorities yet inferiorities of these 2 groups by expounding the clinical efficacies between decompression alone and decompression combined with lumbar fusion for LDS patients.

2. Materials and methods

2.1. Data sources and searches

This review work is restricted closely along with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.\(^18\) The online search engines including PubMed (1970.01–2020.08), Web of Science (1970.01–2020.08), and Cochrane Library (1970.01–2020.08) are searched for potential studies. The searching terms are shown as follows: fenestration or hemilaminectomy or laminotomy or laminectomy or decompression, lumbar canal stenosis or lumbar spondylolisthesis or lumbar spinal stenosis or degenerative lumbar spondylolisthesis, arthrodensis or fusion. Besides, previous relevant references and related original studies are manually searched as well.

2.2. Inclusion and exclusion criteria

The inclusion of this analysis is limited to randomized controlled trials (RCTs); topics on the comparison between decompression alone and decompression combined with lumbar fusion; English language; contents consist of at least one aspect in the clinical efficacy and/or complications.

In contrast, animal trials, conference or commentary articles, letters, systematic review, meta-analyses, case reports and series; studies without comparison between 2 groups; the included items <10; patients with isthmic spondylolisthesis or other diseases such as the spinal tumor, bone fracture, systemic diseases, and other irrelevant diseases during the recruitment period; articles focusing on the surgical techniques and internal fixed instruments are excluded from our analysis.

2.3. Data extraction and outcome measures

We assigned 2 authors to independently complete this part. A third author would join the extraction process in case of disagreements. The basic demographic information (the age, sex, diagnosis, the number of included cases, stenosis degree at the moment of grouping, follow-up time, and outcomes) was extracted based on a preplanned form. The primary outcomes included patients’ satisfaction (Odom classification), restored walking ability postoperative, 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).

2.4. 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.

2.5. Data synthesis and analysis

All meta-analyses of eligible results were conducted using the STATA version 11.0 (Stata Corporation, College Station, TX). Heterogeneity among studies was estimated using a Chi-squared 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 differences (WMD) with 95% confidence intervals (CIs). For binary variables (Odom classification, complications, reoperation), odds ratios (ORs) with 95% CIs were applied for the evaluation. A $P$-value $<.05$ was regarded as statistically significant.

3. Result

3.1. Search results

A total of 2437 publications were presented via searching electronic databases, there were 997 publications after removing duplicates. Strictly along with our inclusion and exclusion criteria, 33 studies were included. Afterward, we retained 10 full-text articles assessed for eligibility. Six studies\(^1\),\(^3\),\(^4\),\(^11\),\(^19\),\(^20\) were eventually accepted. More details were shown in Fig. 1.

3.2. Quality assessment and demographics

Two-thirds of the included studies showed a low risk of bias for sequence generation and selective reporting, all showed a low risk...
A total of 650 patients diagnosed with LDS were enrolled, hailing from USA, Sweden, and Japan. Of these 630 patients, 275 were randomized to the decompression (D) group versus 375 to the decompression combined with the fusion (D+F) group. Recruitment periods approximately ranged from 3 to 7 years. No

Table 1: Cochrane Collaboration 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    |
| Kleinstueck 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    |
statistic value was found in average age and sex between the D and D+F groups. More details were depicted in Table 2.

### 3.3. Outcomes

#### 3.3.1. VAS score

VAS grades varied from 0, meaning no pain, to 10, representing maximal pain. There were 4 RCTs that mentioned the improvement ratio of the VAS score of low back pain before and after receiving decompression or fusion treatment. Postoperative pain easement assessed by VAS did not show significant value in this study (WMD, –0.045; 95% CI, –1.259–1.169; \( P = .942 \), Fig. 2), and the heterogeneity was non-negligible (\( I^2 = 75.1\% \); \( P = .007 \)). Two RCTs worked out no statistic difference on the number of those who got improved VAS scores after taking surgery between the 2 groups (OR, 0.77; 95% CI, 0.36–1.65; \( P = .50 \)). Three trials described the VAS score of the leg pain pre- and postoperation, and this meta-analysis worked out the postoperative easement between the 2 groups as no significant difference (WMD, 0.075; 95% CI, –1.201–1.351; \( P = .908 \), Fig. 3).

#### 3.3.2. 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. Two RCTs referred to ODI and EQ-5D indicators. But this meta-analysis used random-effect model and performed no statistic difference between the D and D+F groups in ODI.

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**Table 2**

Overview of included studies.

| Author          | Country | Years        | Type of study | Recruitment period | Participants (n) | Gender (M/W) | Age (mean ± standard) |
|-----------------|---------|--------------|---------------|--------------------|------------------|--------------|-----------------------|
| Herkowitz et al | USA     | 1991         | RCT           | NA                 | 25               | 25           | D 25.0 ± 0.25          |
| Bridwell et al  | USA     | 1993         | RCT           | 1985.2–1990.3      | 9                | 34           | D+F 0.28 ± 0.31        |
| Aihara et al    | Japan   | 2012         | RCT           | 2005.5–2008.8      | 33               | 17           | D+F 1.36 ± 0.55        |
| Kleinstueck et al | Sweden | 2012         | RCT           | 2004.3–2008.5      | 56               | 157          | D+F 0.70 ± 0.29        |
| Ghogawa et al   | USA     | 2016         | RCT           | 2002.3–2009.8      | 35               | 31           | D+F 0.30 ± 0.19        |
| Forsth et al    | Sweden  | 2016         | RCT           | 2008.10–2012.6     | 117              | 111          | D+F 0.41 ± 0.61        |

D+F = decompression combined fusion, D = decompression, M/W = man/woman, NA = not available, RCT = randomized controlled trial.
score (WMD, 1.489; 95% CI, –7.232–10.211; P = .738; Fig. 4) and EQ-5D score (WMD, 0.03; 95% CI, –0.05–0.12; P = .43).

3.4. Odom classification

Postoperative patients’ satisfaction was evaluated by Odom classification. Our meta-analysis worked out no statistical difference between the D and D+F groups (OR, 0.353; 95% CI, 0.113–1.099; P = .072; Fig. 5). Restored walking ability was only seen in Forsth literature,⁴ and reported no statistical difference in the incidence of patients in the increase of walking distance at 2 years as well.

3.5. Complications

Five articles⁴,¹³,¹⁹,¹⁹,¹⁹ recorded the incidence of complications, among which there were 2 articles¹³,¹⁹ mentioned ASD. Forsth trial⁴ was eliminated because of recording both spondylolysis and non-spondylolysis. Analysis towards the other 4 publications was regarded as no statistic difference between the D and D+F groups (OR = 0.437; 95% CI, 0.065–2.949; P = .395; Fig. 6). Ghogawala et al¹⁹ recorded the cases of ASD in the 2 groups respectively as 12 and 4, both were adjacent segment disease and took the secondary surgery.

3.6. Reoperation

Three publications¹¹,¹⁹,¹⁹ reported the incidence of reoperation. The average rate in the D group was 18.2%, while another one in the D+F group was 7.3%. And no statistical difference was found between the 2 groups (OR, 2.541; 95% CI, 0.897–7.198; P = .079; Fig. 7).

3.7. Postoperative degenerative spondylolisthesis progression

In both groups, a certain proportion of postoperative degenerative spondylolisthesis happened at follow-up and immediate postoperation. Two RCTs⁴,¹¹ showed the number of degenerative spondylolisthesis progression and were verified no statistics difference (OR = 8.59, P = .27). More details about the outcomes were shown in Table 3.

4. Discussion

Clinicians never stop inventing new and advanced techniques to defeat diseases. In the 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 comes with a concern of cost performance. Whereas it is a lack of big data support, given this, we perform this meta-analysis, including 6 RCTs, quantifying and comparing the clinical outcomes. Our result showed that decompression plus fusion treatment was not found to be superior to decompression alone. LDS patients may get an iatrogenic slip or increased spondylolisthesis degree after taking decompression surgery.
Figure 4. Forest plot of weighted mean difference (WMD) of Oswestry Disability Index (ODI) score improvement with decompression versus decompression combined with fusion.

Figure 5. Forest plot of odds ratio (OR) of postoperative satisfaction of patients with decompression versus decompression combined with fusion.
Figure 6. Forest plot of odds ratio (OR) of the incidence of postoperative complications with decompression versus decompression combined with fusion.

Figure 7. Forest plot of odds ratio (OR) of the rate of reoperation with decompression versus decompression combined with fusion.
alone.\textsuperscript{[23]} Though lacking consensus on LDS, it is deemed to be an unstable state, and surgeons may choose the decompression plus fusion as a potential therapy for avoiding postoperative instability and restenosis. Besides, some publications believe that the efficacy of decompression alone is significantly better than the one of fusion.\textsuperscript{[24]} Forsth et al\textsuperscript{[4]} performed a trial involving 247 patients and found no clinical benefit even adding fusion to decompression treatment after 2 years at the cost of higher hospital charges. Meanwhile, several cohort studies have concluded no substantial benefit in taking decompression plus fusion method.\textsuperscript{[24–27]}

Compared with preoperative, Forsth trial demonstrated no significant difference was found in postoperative low back pain relief.\textsuperscript{[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 found meaningless results. Same consequence came to the evaluation of leg pain. According to 3 RCTs, our analysis demonstrated negative results, which might be due to the limitation of sample size, or be explained by the quality of included RCTs, or truly indicated that the addition of fusion treatment was 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\textsuperscript{[20]} wrote a paper published in N Engl J Med and concluded that no significant difference was revealed in the reduction of ODI scores between the 2 groups, and they illustrated more than twice on the improvement of ODI scores for the decompression plus fusion compared with decompression alone.\textsuperscript{[23]} Nevertheless, our results demonstrated that there was no significant statistical difference between the 2 groups, which was similar to the conclusion of Brodke et al.\textsuperscript{[29]} ODI scores could get influenced by the high loss rate of follow-up in 4 to 5 years, while the short-term follow-up was usually limited by a small sample size. Thus, we used EQ-5D, referencing the included 2 RCTs mentioned above, to evaluate the postoperative quality of life, and no significant value was shown between the 2 groups. Though most cases presented as 1 or 2 segments got a 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 classification was applied in this meta-analysis based on 4 articles\textsuperscript{[1,3,4,11]} evaluated Odom degree. It covered the 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 was 1.6% yearly among the elder.\textsuperscript{[10]} No statistical difference was found between the 2 groups in terms of the increase in the postoperative walking distance within 2 years. It 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/non-alleviation (15%) and internal fixation (5%). It would be more complete 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 in both spondylolisthesis degree and age were risk factors for the high incidence of complications.\textsuperscript{[31,32]} Ghogawala et al calculated the reoperation rates in 4 years after surgery.\textsuperscript{[20]} in the decompression group it was 34% while in the fusion group it was 14%. Dailey et al\textsuperscript{[33]} deemed no association between reoperation rates of surgical segments and adjacent segments and the surgical methods. Similarly, we illustrated no statistical difference between the 2 therapy. Reoperation is more likely to be a surgeon’s suggestion than a patient’s appeal. A veteran surgeon would not put reoperation on the schedule unless there was no treatment option remained, and the satisfaction of patients is inversely proportional to the reoperation event to some extent. Though fusion technique could improve the unstable condition of lumbar spondylolisthesis, it holds the possibility of incurring more complications and a second operation as well.

There were 2 meta-analyses similar to our work, 1\textsuperscript{[34]} included 5 RCTs with 438 patients. Another\textsuperscript{[35]} included 4 RCTs and 14 non-RCTs with 77,994 patients. Both of them concluded that there are no significant differences between the 2 groups for the ODI score, EQ-5D score, the degree of satisfaction and the rate of reoperation, which is similar to our results. Given these 3 publications, if counting our work in, it is truly a hesitation to perform fusion or not in addition to only decompression for LDS patients! There were some limitations existing in our study as well. Not all indexes were compared between the pre- and postoperative 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 was a lack of consensus, which might slightly affect the outcome. The age of included patients varied from 6.3 to
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