Systematic Review

Fusion or Not for Degenerative Lumbar Spinal Stenosis: A Meta-Analysis and Systematic Review

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Background: Degenerative lumbar spinal stenosis (DLSS) is the main cause for chronic low back pain in the elderly. When refractory to conservative treatment, symptomatic patients commonly undergo surgery. However, whether or not fusion is a relatively better surgical option still remains unclear.

Objective: The purpose of the present study was to systematically review the clinical outcomes of spinal decompression with or without spinal fusion for DLSS.

Study Design: A systematic review of the therapeutic effect for DLSS with or without fusion.

Methods: A literature search of 5 electronic databases was performed including PubMed, EMBASE, MEDLINE, Cochrane Library, and CENTRAL from inception to August 2016. Only randomized controlled trials (RCTs) assessing the comparison between decompression and fusion surgery for DLSS were included.

Results: A total of 5 RCTs involving 438 patients met the inclusion criteria. Low-quality evidence of the meta-analysis was performed for the heterogeneity of the included studies. Pooled analysis showed no significant differences between decompression alone and fusion groups for the Oswestry Disability Index (ODI) scores at the baseline ($P = 0.50$) and 2 years follow-up ($P = 0.71$), and the satisfaction rate of operations was also similar for the groups ($P = 0.53$). However, operation time ($P = 0.002$), blood loss ($P < 0.00001$), and length of hospital stay ($P = 0.007$) were remarkably higher in the fusion group. Furthermore, there was no difference in the reoperation rate between these 2 groups at the latest follow-up ($P = 0.49$).

Limitation: The methodological criteria and sample sizes were highly variable. The studies were heterogeneous.

Conclusion: The present meta-analysis is the first to compare the efficacy of decompression alone and spinal fusion for the treatment of DLSS, including 5 RCTs. Our results demonstrate that additional fusion surgery seems unlikely to result in better outcomes for patients with DLSS, but it may increase additional risks and costs. High-quality homogeneous research is required to provide further evidence about surgical procedures for patients with DLSS.

Key words: Decompression, fusion, lumbar spinal stenosis, meta-analysis

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Degenerative lumbar spinal stenosis (DLSS) is caused by gradual narrowing of the spinal canal, which produces compression on neural elements and results in neurogenic intermittent claudication (1). The typical symptoms of DLSS present with radicular pain, during walking or standing, that resolves with lumbar flexion. DLSS exhibits high morbidity in the elderly, which severely decreases self-care ability and quality of life. Therefore, DLSS has become one of the most common degenerative diseases in orthopedic practice (2). Owing to the lack of high-quality clinical evidence, the latest systematic review cannot conclude whether surgical treatment or conservative approach is better for patients with DLSS (3). However, when refractory to conservative treatment, symptomatic patients commonly undergo surgery.

Currently, the standard surgical management for DLSS is single- or multi-level decompressive laminectomy. Despite some interspinous dynamic devices being designed to limit spinal extension to relieve symptoms, their clinical outcomes remain controversial compared with traditional decompressive surgery (4). In addition, lumbar fusion supplemented with decompression to minimize spinal instability is growing. A retrospective analysis demonstrated that the rate of simple fusion surgery for DLSS treatment has increased in the US (5). Decompression surgery without fusion has been proved to be beneficial for patients with DLSS without instability; however, some other studies have shown better clinical outcomes after laminectomy in combination with instrumented fusion (6). Liang et al (7) published a meta-analysis that provides evidence of better clinical outcome but a higher reoperation rate for spinal fusion, compared with decompression alone. In particular, some evidence included in their analysis is of low quality, and for the treatment of DLSS, there is no class I evidence to affirm that decompression accompanied with fusion is superior to decompression alone. Therefore, the present study aimed to systematically review clinical outcomes of randomized controlled trials (RCTs) for decompression alone or for decompression with fusion for DLSS and to provide further evidence to guide and standardize practice.

Methods

Literature Review

We performed this systematic review and meta-analysis following the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement (8). We conducted a systematic electronic search in PubMed, EMBASE, MEDLINE, Cochrane Library, and CENTRAL databases before July 2016. The preliminary search strategy was to use the following keywords: "decompression," "laminectomy," "spinal fusion," and "lumbar spinal stenosis," without any restrictions. A track search was performed in August 2016 to add any new publications.

The studies were selected by 2 independent reviewers (JLS and SXX). The inclusion criteria for the studies included in this meta-analysis were as follows: 1) studies had to be a RCT, 2) studies had to evaluate the comparison of the clinical outcomes of decompression with fusion and decompression alone for the management of DLSS, 3) a minimum of 30 patients in a study with a minimum follow-up period of 12 months, and 4) the end-point clinical outcome was required to be complete and detailed. The exclusion criteria included the following: 1) RCTs that reported disc replacement, interlaminar stabilization, epidural injection with procedures, or studies with a control group that was treated with non-surgical treatment, 2) studies that were not a clear comparison between decompression with or without fusion for DLSS, and 3) studies of patients with trauma, tumors, and previous spinal deformities.

Data from the initial screening of articles were independently extracted by 2 other investigators (SY and JH). The collected information included the study design, patients' characteristics (age and gender), sample size, follow-up time, interventions, and clinical outcomes. The quality of the included RCTs was assessed in accordance with the Cochrane Review criteria (9).

Statistical Analysis

The RevMan 5.2 (The Nordic Cochrane Centre for The Cochrane Collaboration, Copenhagen, Denmark) was used for the meta-analysis in the present study. Binary outcomes were calculated by risk ratios, and continuous outcomes were calculated by weighted mean differences (WMDs), along with 95% confidence intervals (CIs). The heterogeneity between studies was evaluated using the I^2-statistic, and a P value of < 0.01 for the chi-square test and < 30% for the I^2 test indicated consistent results. Homogeneous data were pooled using a fixed-effects model; heterogeneous data were assessed using a random-effects model.

SPSS Version 20.0 (IBM Corporation, Armonk, NY) was used for comparing the clinical outcomes by t-test for the analysis of metric scaled data and chi-square test for the analysis of categorical data. P values < 0.05 were considered statistically significant.

Results

Characteristics of Eligible Studies

After a complete systematic review, the initial search included 423 articles published between March 1976 and August 2016, of which 400 were excluded on the basis of the title, abstract, and keywords. Sixteen

Table 1. *Characteristics of the 5 included studies.*

Characteristic	Herkowitz & Kurz 1991 (10)	Grob et al 1995 (11)	Hallett et al 2007 (12)	Ghogawala et al 2016 (13)	Försth et al 2016 (14)
Study Design	RCT	RCT	RCT	RCT	RCT
Patients	50 patients (F/M: 36/14); Age: 64 yrs	45 patients (F/M: 24/21); Age: 67 yrs	44 patients (F/M: 20/24); Age: 57 yrs	66 patients (F/M: 53/13); Age: 67 yrs	233 patients (F/M: 155:78); Age: 67 yrs
Intervention	D: 25; D + F:25	D: 15; D + F:30	D: 14; D + F:30	D: 35; D + F:31	D: 120; D + F:133
Follow-Up Duration	3 yrs	28 mos	5 yrs	4 yrs	5 yrs
Outcomes	Satisfactory rate, pain in the back and lower limbs, radiographic findings	VAS score (overall pain), walking ability, operation time, blood loss, complications, reoperations; at 24 mos	Low back outcome score, RMDQ, operation time, blood loss, reoperations, costs; at 24 mos	SF-36; ODI score; blood loss, hospital stays, operation time	ODI score; EQ-5D score; VAS score for back and leg pain; ZCQ score; operation time; blood loss; satisfactory rate

D = decompression; F = fusion; VAS = visual analog scale; RMDQ = Roland Morris Disability Questionnaire; ODI = Oswestry Disability Index; SF-36 = 36-item short-form questionnaire; EQ-5D = quality of life measure; ZCQ = Zurich Claudication Questionnaire

articles were further excluded after viewing the full text because of the following reasons: original clinical outcomes were not defined, study designs were not RCTs, studies were case reports, or studies had duplicated data. Finally, 5 RCT studies were included according to the eligibility criteria (10-14). The detailed characteristics of the 5 included studies are illustrated in Table 1. The risk of bias assessment in accordance with the Cochrane Review criteria for all the included studies is shown in Table 2.

Assessment of Satisfaction and Oswestry Disability Index (ODI) Scores

The success rate of operations was defined as the proportion of patients who were satisfied with their outcomes. Three studies (10,11,14) also provided information regarding satisfaction rates for the 2 surgical approaches. Satisfaction rates were higher after fusion compared with only decompression (63.8% vs. 59.6%, respectively), but the results showed no statistical difference [WMD: -0.11, 95% CI: (-0.46, 0.24), $P < 0.00001$, $I^2 = 90\%$; $P = 0.53$] (Fig. 1).

Two studies reported ODI function scores (13,14). Pooled analysis showed no significant differences between decompression alone and spinal fusion at baseline [WMD: -1.12, 95% CI: (-4.4, 2.16), $P = 0.69$, $I^2 = 0\%$; $P = 0.50$] (Fig. 2) and at 2 years follow-up [WMD: 1.64, 95% CI: (-7.07, 10.36], $P = 0.003$, $I^2 = 89\%$; $P = 0.71$), respectively (Fig. 3). The quality of evidence was determined as low because of inconsistency.

Assessment of Operational Parameters

Obviously, the addition of fusion to decompression surgery increased the operation duration from 98.7 to 189.7 minutes, which indicated that the operation duration was significantly longer in the fusion group [WMD: -130.37, 95% CI: (-212.54, -130.37), $P < 0.00001$, $I^2 = 97\%$; $P = 0.002$] (Fig. 4). In parallel, blood loss was significantly higher in patients who underwent fusion operation [WMD: -461.78, 95% CI: (-639.15, -284.42), $P = 0.01$, $I^2 = 78\%$; $P < 0.00001$] (Fig. 5). Following their operations, patients who underwent only decompression had a significantly shorter hospital stay by 2.9 days [WMD: -2.9, 95% CI: (-3.78, -0.6), $P = 0.09$, $I^2 = 66\%$; $P = 0.007$] (Fig. 6). The quality of evidence for these outcomes was graded as moderate because of imprecision.

Assessment of Reoperation Rate

In regard to the reoperation rate, in the decompression group, 36 out of 166 (21.7%) patients required a second operation, compared with 30 out of 172 (17.4%) patients in the fusion group. Pooled analysis indicated that there were no significant differences in the reoperation rates between the 2 groups [WMD: 1.31, 95% CI: (0.61, 2.83), $P = 0.18$, $I^2 = 41\%$; $P = 0.49$] (Fig. 7).

Discussion

To the best of our knowledge, the present study is the first meta-analysis to assess the effectiveness of decompression alone and spinal fusion for the treatment of DLSS, including 5 RCTs, especially 2 high-quality RCTs published this year (13,14). Our analysis of 5 RCTs involving 438 patients showed that there were no significant differences between the 2 surgical procedures in terms of functional ODI scores at baseline and at 2-year follow-up, respectively. In addition, decompression alone had a similar satisfactory rate of operation with fusion

Table 2. *Quality assessment of studies.*

	Adequate Randomization	Allocation Concealment	Baseline Comparability	Blinding of Patient	Blinding of Care Provider	Blinding Outcome Assessor	Co-Interventions were Avoided	Acceptable Compliance between Groups	Drop-Out Rate is Described	Similar Timing of Outcome Assessment	Intention to Treat Analysis	Overall quality (max 11)
Herkowitz & Kurz 1991 (10)	No	No	Yes	No	No	Unknown	Yes	Yes	Yes	Unknown	Unknown	4
Grob ert al 1995 (11)	No	No	Yes	No	No	Unknown	Yes	Yes	Yes	Yes	Unknown	5
Hallett et al 2007 (12)	No	No	Yes	No	No	Unknown	Yes	Yes	Yes	Yes	Yes	6
Ghogawala et al 2016 (13)	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	9
Försth et al 2016 (14)	Yes	No	Yes	No	No	Unknown	Yes	Yes	Yes	Yes	Yes	7

surgery. However, due to the additional fusion, the operation time, blood loss, and hospitalization were all significantly higher in the fusion group. The final follow-up results demonstrated that the reported reoperation rate of decompression alone was equal to those treated with decompression plus fusion surgery.

Surgical interventions are commonly used for the treatment of symptomatic DLSS when conservative treatments are ineffective. The Spine Patient Outcomes Research Trial (SPORT) has found that surgery would be more beneficial for patients with DLSS without degenerative spondylolisthesis than for those who receive conservative treatment (15). However, there has long been a contentious issue for the choice of operation approach for DLSS. Decompression with fusion is performed to prevent the risk of progressive spinal instability (16), but our analysis revealed that there is little value in adding fusion to decompression surgery. In particular, all of the included RCTs had a vague definition of "stable" DLSS in the inclusion criteria. In the study by Ghogawala et al (13), patients were excluded if motion was > 3 mm at the level of listhesis, as measured on flexion-extension radiographs. However, a previous study has indicated that the findings of flexion-extension radiographs have low accuracy (17) and low reproducibility (18). Therefore, the bias in patient inclusion may weaken the efficacy of fusion surgery in the present meta-analysis. However, for the subgroup analysis of the study done by Försth et al (14), we found that they included patients with DLSS regardless of instability; they found that there was no additional benefit of fusion surgery.

Back/leg pain and walking ability are the 2 most important clinical parameters to assess the effect of DLSS treatment. Unfortunately, pooled analysis could not be performed for the lack of standardized expression in reporting these outcomes in primary studies. Herkowitz and Kurz (10) reported that patients having an arthrodesis had less residual pain in the back and lower limbs than those receiving decompression alone. On the contrary, the studies done by Grob et al (11) and Försth et al (14) demonstrated that there was no significant difference between decompression alone and fusion surgery in terms of pain relief. With respect to walking ability, Grob et al (11) reported that all of the patients showed significant improvement in walking distance at the final follow-up compared with the preoperative walking distance, but they did not perform comparisons between groups. In Försth et al's study, the results of a 6-minute walk test at the 2-year follow-up showed that improvement in walking ability did not differ between the treatment groups. Furthermore, the direct cost of each procedure was $6,800 higher in the fusion group than in the decompression alone group, as reported by Försth et al (14).

Additionally, limitations of the present meta-analysis should be taken into account when referring to the results. First, some important clinical indicators, such as visual analog scale (VAS) scores, walking ability, complications, and medical costs, could not be compared owing to the heterogeneity in outcomes in the primary

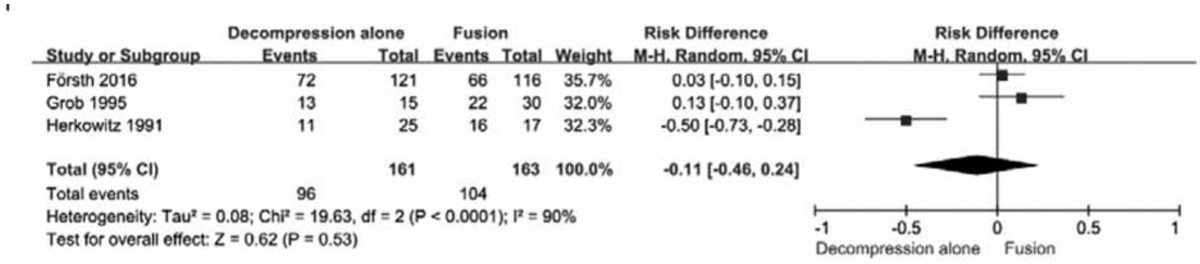

Fig. 1. *The satisfaction rate of operations.*

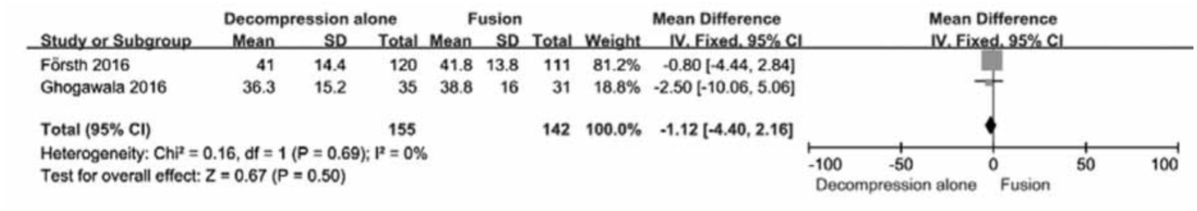

Fig. 2. *ODI scores at baseline.*

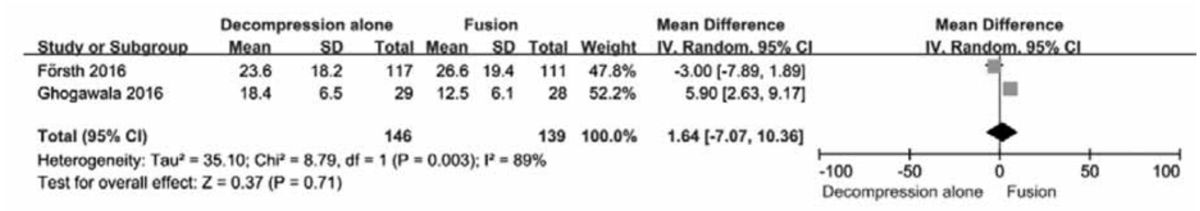

Fig. 3. *ODI scores at 2-year follow-up.*

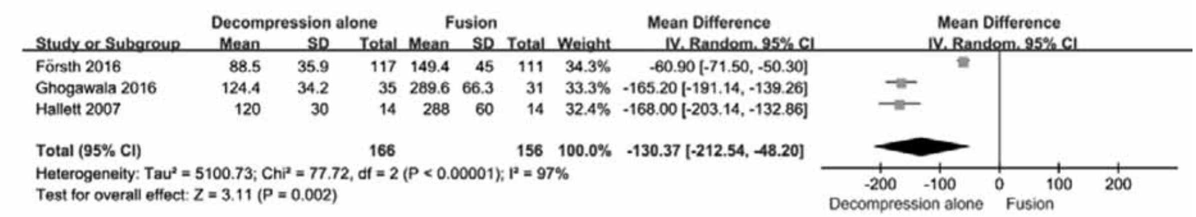

Fig. 4. *Duration of operation.*

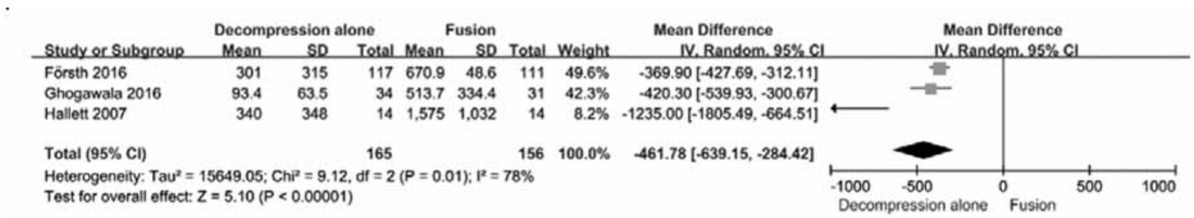

Fig. 5. *Blood loss.*

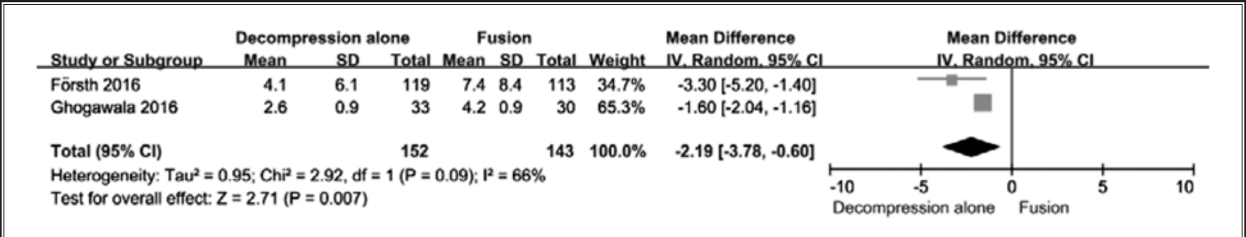

Fig. 6. *Length of hospital stay.*

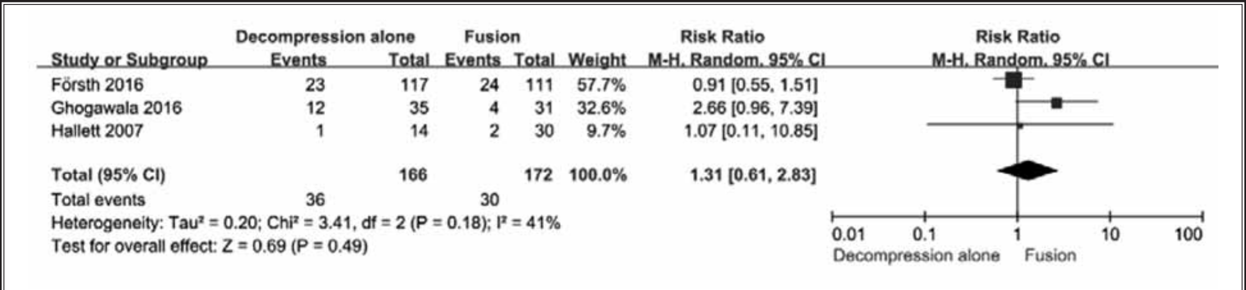

Fig. 7. *The reoperation rate.*

studies. For example, VAS scores reported by Herkowitz and Kurz (10), Grob et al (11), and Hallett et al (12) were not expressed in terms of mean ± standard deviation; as a result, no pooled analysis could be performed on these outcomes. We recommend that future RCTs report clinical outcomes following the Consolidated Standards of Reporting Trials (CONSORT) statement (19). Second, although the present meta-analysis included 5 RCT studies, the heterogeneity in these studies was poor. Three of the included studies were inadequate in terms of methodological quality, which is described in Table 2 (10-12). The difference in clinical heterogeneity may be because of the inclusion criteria, concrete surgical methods, follow-up time, etc. Even in the simple decompression surgery, some chose total laminectomy, whereas, others chose partial laminotomy, which could lead to the differences in postsurgical stability of the spinal column. To overcome the limitation of statistical heterogeneity, a random model was utilized to accommodate the high degree of heterogeneity between studies; otherwise, a fixed model was used in the present study.

Conclusion

In conclusion, the present review analyzed 5 RCTs consisting of 438 patients. Overall, these studies do not provide high-quality evidence regarding the efficacy of decompression alone versus fusion surgery. This analysis provides limited evidence that additional fusion surgery seems unlikely to result in better outcomes for patients with DLSS; however, fusion surgery may increase additional risks and costs. Finally, it needs to be emphasized that standardized criteria for inclusion should be established in further studies, especially for the diagnosis and prediction of spinal instablity.

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