To fuse or not to fuse: the elderly patient with lumbar stenosis and low-grade spondylolisthesis

Systematic review and meta-analysis of randomised controlled trials

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HIGHLIGHTS

- The optimum surgical intervention for LSS and LGDS in the elderly remains unknown.
- DA is not inferior to D+F for elderly patients with LSS and LGDS.
- No difference in pain at 2 years between PLF and open laminectomy in these patients.
- DA carries a lower risk hospital complications and fewer adverse events than D+F.
- Surgeons should consider the higher rate of post-op DS in patients undergoing DA.

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ABSTRACT

Background

The optimum surgical intervention for elderly patients with lumbar spinal stenosis (LSS) and low-grade degenerative-spondylolisthesis (LGDS) has been extensively debated. We conducted a systematic review and meta-analysis of randomised-controlled-trials (RCTs) comparing the effectiveness of decompression-alone against the gold-standard approach of decompression-with-fusion (D+F) in elderly patients with LSS and LGDS.

Methods

A systematic literature search was performed on published databases from inception to October-2021. English-language RCTs of elderly patients (mean age over-65) with LSS and LGDS, who had undergone DA or D+F were included. The quality and weight of evidence was assessed, and a meta-analysis performed.

Results

Six RCTs (n=531; mean age: 66.2 years; 57.8% female) were included. There was no difference in visual-analogue-scale (VAS) scores of back-pain (BP) or leg-pain (LP) at mean follow-up of 27.4 months between both DA and D+F groups (BP: mean-difference (MD)0.24, 95%CI: -0.38-0.85; LP MD:0.39, 95%CI: -0.34-1.11). No difference in disability, measured by Oswestry-Disability-Index scores, was found between both groups (MD:0.50, 95%CI: -3.31-4.31). However, patients in DA group had less hospital complications and fewer adverse events (total-surgical-complications OR:0.57, 95%CI: 0.36-0.90), despite a higher rate of worsening DS (OR:3.49, 95%CI: 1.05-11.65). No difference in BP or LP was found in subgroup-

analysis of open-laminectomy compared to posterolateral-fusion(PLF) (BP: MD: -0.24, 95%CI: -1.80-1.32; LP MD:0.80, 95%CI: -0.95-2.55).

Conclusions

DA is not inferior to D+F in elderly patients with LSS and LGDS. DA carries a lower risk of hospital complications and fewer adverse events, however, surgeons should weigh these findings with the increased risk of DS progressing post-operatively.

Keywords: Lumbar spinal stenosis; degenerative spondylolisthesis, decompression; fusion; back pain; leg pain

INTRODUCTION

Lumbar spinal stenosis (LSS) is the narrowing of the spinal and nerve root canals caused by hypertrophy of osseous and soft tissue structures within the lumbar vertebrae (Wu and Cruz, 2020) which compresses the spinal nerves and blood vessels exiting the foramen. It clinically manifests with long-term radiculopathy; specifically, back pain (BP) and bilateral radicular leg pain (LP) and paraesthesia, with progression to lower limb weakness (Siebert et al., 2009; Storm et al., 2002). Symptoms are aggravated by walking upright, standing or hyperextension due to further narrowing of the vertebral canal (Siebert et al., 2009). It is one of the most prevalent pathologies in the elderly population affecting 200,000 adults in the United States. It is estimated by 2025 that 64 million elderly people will be affected by the condition (Wu, Tong and Wang, 2016). In patients between the age of 40 to 49 years of age, the prevalence of LSS is estimated to be 3.8% in men and 1.4% in women increasing to 9.8% in men and 5.7% in women between ages 50 to 59 years (Ishimoto et al., 2012). LSS precipitates BP in both middle-aged and elderly patients resulting in loss of productivity and work hours in the working population and consequently significant economic burden (Alvarez and Hardy, 1998). Despite the dramatic decrease in quality of life (QoL) in those suffering and its overwhelming prevalence, an optimal treatment for elderly patients with both LSS and LGDS is yet to be definitively agreed. Surgical rates for LSS have grown significantly over the last decade, and currently, LSS is the most common reason for spinal surgery in patients 65 years and older (Lurie and Tomkins-Lane, 2016).

Recent studies have assessed the clinical effectiveness of DA and D+F in patients with LSS and LGDS. Two previous systematic reviews demonstrated that DA is not inferior to gold-standard D+F, irrespective of LGDS (Chang et al. 2017; Xu et al., 2019). However, a number of

recent studies have been published which may alter these conclusions. This study aims to determine whether DA is as effective as D+F in elderly patients, over the age of 65 years, with LSS and LGDS.

METHODS AND MATERIALS

A systematic review and meta-analysis of RCTs was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement guidance (Page et al, 2020).

Eligibility and study selection

The inclusion criteria for both comparisons included RCTs of elderly adult subjects (mean age over 65 years) with LSS and LGDS, comparing outcomes of interest between DA (by open laminectomy, bilateral laminotomy or micro-endoscopic decompression) and D+F (by posterolateral fusion (PLF), posterior lumbar interbody fusion (PLIF) or anterior lumbar interbody fusion (ALIF)).. There were no limitations on geographical location. Exclusion criteria included: samples with mean age less than 65 years, patients with degenerative spondylolisthesis (DS) alone without LSS or with foraminal stenosis and studies with sample sizes of less than twenty subjects. Studies which did not compare both groups or assessed specific techniques of decompression or fusion (such as cage fusions only), studies with patient cohorts who did not undergo any instrumented fusions in their D+F group and fusions where no autogenous bone graft was used, were excluded.

Outcome measures

Primary outcomes were postoperative BP and LP measured using Visual Analogue scale (VAS) scores ranging from 0 to 10; higher scores indicating greater degree of pain. Secondary outcomes: (a) degree of disability by Oswestry Disability Index (ODI) ranging from 0 to 100; higher score indicating greater degree of disability (Fairbank, Couper, and Davies, 1980) (b) QoL using 36-item short form (SF-36) survey: physical component summary (PCS) and mental component summary (MCS) scores (Saris-Baglama et al, 2010); (c) hospital complications: duration of operation, intra-operative blood loss and length of hospital stay and (d) adverse events: total number of surgical complications, incidence of dural tears, post-operative DS and reoperation rate.

Search strategy

Two authors [ANONYMOUS] independently performed a literature search using the databases Ovid Medline, EMBASE, Cochrane Register of Systematic Reviews, Cochrane Register of Controlled Trials (CENTRAL), PubMed and Web of Science databases from inception to June 2020. A manual search of reference lists of relevant reviews and their included studies was carried out.

Data extraction

Search strategies are shown in **Supplementary File 1**. Titles and abstracts were independently screened according to the PICOS criteria (**Table 1**) by two authors [ANONYMOUS] and full-text articles independently screened and assessed for eligibility. A third author [ANONYMOUS] resolved any discrepancies at title, abstract and full-text screening stages. The extracted data included basic study characteristics including participant

age, gender, country of origin, surgical interventions and outcomes. Primary authors for all eligible trials were contacted to request missing data.

Quality Assessment

Two authors independently performed data extraction [ANONYMOUS] of included RCTs and three authors assessed risk of bias [ANONYMOUS] in accordance with the Cochrane Handbook for Systematic Reviews of Intervention version 2 (Higgins, Thomas, and Chandler, 2011). The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology was used by the aforementioned authors [ANONYMOUS] to assess the weight of evidence from the findings of the meta-analyses (Schünemann, Oxman, and Vist, 2011).

Data synthesis

Study heterogeneity was assessed for participant, intervention and study characteristics to determine if there was sufficient homogeneity of data pool. Where study homogeneity was assured by the review team, a meta-analysis was carried out. Meta-analysis results were expressed as weighted mean difference (MD) and 95% confidence intervals (CI), and dichotomous variables were reported as odd ratios (ORs) and 95% CI. Results were regarded as statistically significant if p-values were less than 0.05. Statistical heterogeneity was measured using the I^2 scores and a fixed-effects model was implemented. Subgroup analysis was performed for primary outcomes in patients undergoing open laminectomy (DA group) and PLF (D+F group) by excluding studies which used other techniques. Data were analysed using RevMan v.5.4 (Cochrane Collaboration, Oxford, UK) (RevMan, 2014).

RESULTS

Search results

The literature search (**Figure 1**) generated 6690 records. Full-text articles were reviewed for 107 studies and six RCTs were eligible (N=531).

Study characteristics

The characteristics of included studies are shown in **Table 2**. Mean follow-up was 27.4 months (range 24 months to 37.2 months). There were 256 patients and 275 patients within the DA and D+F groups respectively (mean age= 66.2 years; 57.8% female). The surgical techniques used were defined as shown in **Table 4**. All study participants had a diagnosis of LSS and LGDS based on clinical and radiological critieria (**Table 5**). Clinical criteria in all studies included the presence of typical symptoms of: neurogenic claudication or radiculopathic leg pain with associated neurological symptoms. Three studies used slippage of >3 mm to define LGDS (Forsth et al., 2016; Ghogawala et al., 2016; and Inose et al., 2018). One study used vertebral slippage exceeding 5% to define LGDS (Aihara et al., 2012) and two studies did not specify their criteria (Bridwell et al., 1993 and Grob et al., 1995). In the DA group, the surgical technique consisted of an open laminectomy in four studies (Ghogawala et al., 2016; Inose et al., 2018 and Bridwell et al., 1993), both open laminectomy (82%, n=98) and bilateral laminotomy (18%, n=22) in one study (Forsth et al.,2016), bilateral laminotomy only in one study (Grob et al., 1995) and micro-endoscopic decompression in one study (Aihara et al., 2012). In the D+F group, the surgical technique was PLF in all studies, however one study (Forsth et al., 2016) also carried out PLIF in 5% of patients (n=6) and non-instrumented fusion in 4% of patients (n=5). One study (Aihara et al., 2012) also carried out PLIF in 47% of patients (n=8) and ALIF in 6% of patients (n=1).

Quality appraisal

Three of the six studies did not perform or did not demonstrate good random sequence generation (Ghogawala et al., 2016; Grob et al., 1995 and Bridwell et al., 1993) (**Figure 2**). Only two studies demonstrated adequate allocation concealment (Inose et al., 2018; Aihara et al., 2012). Nevertheless, all studies demonstrated very low rates of attrition bias.

Results of meta-analysis

Primary outcome measures: Pain by Visual Analog Scale (VAS)

Three studies reported BP (Aihara et al., 2012; Försth et al., 2016 and Inose et al., 2018) and two studies reported LP (Försth et al., 2016 and Inose et al., 2018) using VAS scores. The data showed no difference in BP or LP by VAS scores between patients who had undergone DA versus D+F (BP: mean difference (MD) 0.24; 95% CI -0.38 to 0.85, p=0.45, N=329; LP: MD 0.39; 95% CI -0.34 to 1.11, p=0.29, N=279, GRADE: moderate) (**Table 3**). Similarly, a subgroup analysis comparing patients who underwent open laminectomy with those who underwent PLF showed no difference in post-operative BP and LP between the two groups at two years follow-up (BP: MD: -0.24, 95% CI: -1.80 to 1.32 p=0.76, N=51; LP MD: 0.80, 95% CI: -0.95 to 2.55, p=0.37, N=51, GRADE: moderate).

Secondary outcome measures:

Degree of disability

Two studies reported data on degree of disability by ODI scores (Försth et al., 2016 and Ghogowala et al., 2016). (**Table 3**). The data showed no difference in degree of disability between patients who had undergone DA compared to D+F (MD 0.50 95% CI -3.31 to 4.31, p=0.80, N=294, GRADE: moderate). Inose et al. (2018) reported no difference in post-operative disability scores, using Japanese Orthopaedic Association (JOA) scores, between patients who had undergone DA compared to D+F (MD -1.40; 95% CI -3.85 to 1.05; N=58).

Quality of Life

Only one study, Ghogowala et al. (2016), reported data on QoL using SF-36 scores. This study showed that those who had undergone a DA had lower PCS score than those who had undergone D+F at two years (MD -5.70; 95% CI 2.24 to 9.16; N=66, GRADE: moderate) and four years follow-up (MD -6.70; 95% CI -10.16 to -3.24; N=66, GRADE: moderate).

Hospital complications

Five studies reported duration of operation and volume of blood lost intra-operatively (Aihara et al., 2012; Försth et al., 2016; Ghogowala et al., 2016; Grob, Humke and Dvorak, 1995 and Inose et al., 2018) whilst four reported data on length of hospital stay (Aihara et al., 2012; Försth et al., 2016; Ghogowala et al., 2016 and Inose et al., 2018). There was shorter duration of operation (MD -68.84; 95% CI -76.03 to-61.66; p<0.00001, N=449, GRADE: low), less volume of intra-operative blood loss (MD -389.29; 95% CI -411.30 to-367.29, p<0.00001, N=434, GRADE: low) and shorter length of hospital stay (MD -43.04; 95% CI-52.82, -33.27, p<0.00001, N=404, GRADE: low) in patients who had undergone DA compared to D+F.

Adverse events

Six studies reported the total number of surgical complications (Aihara et al., 2012; Bridwell et al., 1993; Försth et al., 2016; Ghogowala et al., 2016; Grob, Humke and Dvorak, 1995 and Inose et al., 2018) whilst three studies reported the number of dural tears (Försth et al., 2016, Grob, Humke and Dvorak, 1995 and Inose et al., 2018), post-operative DS (Bridwell et al., 1993 and Inose et al., 2018) and five studies reported data on reoperation rate (Aihara et al., 2012; Bridwell et al., 1993; Försth et al., 2016; Grob, Humke and Dvorak, 1995 and Inose et al., 2018). The data showed that patients who had undergone DA had fewer total number of surgical complications than those who had undergone D+F (OR 0.57; 95% CI 1. 0.36 to 0.90, p=0.02, N=492, GRADE: moderate). However, those who had undergone DA had experienced more post-operative DS than patients who underwent D+F (OR 3.49; 95% CI 1.05 to 11.65, p=0.04, N=103, GRADE: moderate). There was no difference in incidence of dural tears or reoperation rate between the two groups (OR: 0.94; 95% CI 0.44 to 1.99, p=0.86, N=334, GRADE: moderate; OR 1.00; 95% CI 0.52 to 1.94, p=1.00, N=426, GRADE: low), respectively.

DISCUSSION

The results of this systematic review indicate that there is no difference in BP or LP postoperatively between elderly patients with LSS and LGDS, who had undergone DA compared to those who had D+F. Data for degree of disability showed no difference whether patients had undergone either type of operation. Patients who had DA experienced less hospital complications and lower total number of surgical complications despite higher rates of post-operative DS.

Recent evidence points towards the non-inferiority of DA for treatment of LSS and LGDS compared to D+F. This hypothesis is supported by findings of a recent Cochrane systematic review of 24 studies with 2352 participants with LSS and LGDS concluding that D+F is not superior to DA (Machado et al., 2016). Similarly, two previous systematic reviews demonstrated no difference in VAS pain or ODI scores between DA and D+F (Xu et al., 2019; Chang et al., 2017). Similarly, a large observational study by Försth, Michaëlsson and Sandén (2013) of 4259 patients included in the National Swedish Register for Spine Surgery (Swespine), concluded that there was no significant difference in mean VAS LP scores ($p=0.57$), ODI scores ($p=0.33$) or EQ-5D scores ($p=0.69$) between both treatment groups at two-years follow-up; regardless of the presence of pre-operative DS. A recent multicentre study of 306 patients enrolled in the Canadian Spine Outcomes and Research Network (CSORN) database showed clinically significant increased operative time, blood loss, length of hospital-stay and perioperative complications in the D+F group (Thomas et al., 2019). Nevertheless, both surgical interventions are not without their risks. DA was reported to be associated with post-operative vertebral instability (Burgstaller et al, 2015). On the contrary, albeit the lower rates of worsening of DS post-operatively, several studies have shown that D+F is associated with adjacent segment degeneration (Levin et al, 2007; Park et al, 2004). Another contentious issue is the economic burden of a fusion operation, having greater peri-operative cost implications as well as the economic consequences of higher complication rates ($p<0.001$) (Zino et al., 2020).

This comprehensive systematic review and meta-analysis has a number of strengths. It presents the most up-to-date evidence from RCTs comparing the effectiveness of D+F to

DA for elderly patients over 65 years with LSS and LGDS. We considered only experimental studies hence providing a higher level of evidence than if we had also included observational studies. The participants of studies represent a large demographic spread from various different healthcare systems which increases the generalisability and global applicability of our findings. All literature searches, data extraction, meta-analyses and quality appraisals were put through a rigorous cross-check by at least two independent researchers at every stage. This study also used the GRADE approach to evaluate the strength of the evidence allowing readers to appreciate the paucity of high-quality evidence on this subject area in the current literature. There are also some limitations worth highlighting. There was a high degree of heterogeneity in defining LGDS between included studies since different clinical and radiological criteria were used. Furthermore, surgical technique varied between studies, and within the patient cohorts of two studies (Aihara et al, 2012 and Forsth et al, 2016). We minimised this heterogeneity by clearly defining the acceptable surgical techniques in the inclusion criteria. Due to heterogeneity in follow-up time, there was an inadequate number of studies available to meta-analyse results at individual post-operative follow-up time points. In addition, there was a substantial lack of data with regards to walking ability and patient satisfaction in both comparisons.

Surgeons who operate on elderly patients with LSS and LGDS should be cognisant of the little benefit fusion provides for patients over a DA, as well as the increased risk of hospital complications and adverse events associated with fusion in this in age group. A thorough assessment of elderly patients with respect to their individual functional requirements as well as their comorbid conditions should be taken into account when justifying the addition of fusion in this age group. The clinical implication of the available evidence is substantially

limited by low to moderate quality literature, therefore, further research is necessary to provide high quality evidence-based recommendations. This can be improved by standardising outcome measures and increasing follow-up length in the literature to allow both comparability of studies and address paucity of long-term follow-up data.

CONCLUSION

D+F is not a superior intervention to DA for elderly patients with LSS and LGDS. Although DA was found to be associated with lower hospital complications and adverse events, surgeons should balance this with the increased risk of progression of DS post-operatively. Given the low to moderate quality of RCTs comparisons, higher quality RCTs are warranted to ascertain the most appropriate surgical approach in managing LSS with LGDS in elderly patients.

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3 10.1097/BRS.0000000000003250.
4
5 Turner J, Ersek M, Herron L, Deyo R. Surgery for lumbar spinal stenosis. Attempted meta-
6 analysis of the literature. *Spine (Phila Pa 1976).* 1992;17(1):1-8. doi: 10.1097/00007632-
7 199201000-00001.

Supplementary Tables, Figures and Files

Supplementary Table 1: Summary of findings (SOF) table for GRADE. Meta-analysis of primary outcome (back and leg pain VAS scores) for decompression alone versus decompression with fusion in elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis

Summary of findings:

Decompression alone versus decompression with fusion in elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis

Patient or population: Elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis
Setting: No restriction by setting
Intervention: Decompression alone
Comparison: Decompression with fusion

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DA	**Risk with D+F**				
Mean difference in back pain	The mean difference in back pain was **0.24**	MD **0.24 higher** (-0.38 lower to 0.85 higher)		329 (3 RCTs)	⨁⨁⨁◯ MODERATE [a,b]	
Mean difference in leg pain	The mean difference in leg pain was **0.39**	MD **0.39 higher** (-0.34 lower to higher 1.11)		279 (2 RCTs)	⨁⨁⨁◯ MODERATE [a,c]	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. The confidence in the estimate of effect decreased due to the magnitude of the potential biases present within the included RCTs. No blinding of participants was performed in Forsth et al., 2016 and this also remains unknown in Inose et al., 2018.
b. Lack of robust explanation for the large heterogeneity within this analysis of VAS back pain scores due to opposing conclusions between the included RCTs decreases the quality of the evidence.
c. Aihara et al, 2012 and Inose et al, 2018 both reported results very large confidence intervals (MD 0.60 95% CI -1.56 to 2.76 and MD -0.24 95% CI -1.80 to 1.32) respectively.

*GRADE= the grades of recommendation, assessment, development, and evaluation.

Supplementary Table 2: Summary of findings (SOF) table for GRADE. Subgroup meta-analysis of primary outcome (back and leg pain VAS scores) for decompression alone versus decompression with fusion in elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis

Summary of findings:

Decompression alone versus decompression with fusion in elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis

Patient or population: Elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis
Setting: No restriction by setting
Intervention: Decompression alone
Comparison: Decompression with fusion

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DA	**Risk with D+F**				
Mean difference in back pain	The mean difference in back pain was **-0.24**	MD **-0.24 higher** (-1.80 lower to 1.32 higher)		51 (1 RCT)	⨁⨁⨁◯ MODERATE [a]	
Mean difference in leg pain	The mean difference in leg pain was **0.80**	MD **0.80 higher** (-0.95 lower to higher 2.55)		51 (1 RCT)	⨁⨁⨁◯ MODERATE [a]	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. The confidence in the estimate of effect decreased due to the magnitude of the potential biases present within the included RCT. Further no blinding of participants was performed in Inose et al., 2018.

Supplementary Table 3: Summary of findings (SOF) table for GRADE. Meta-analysis of secondary outcomes for decompression alone versus decompression with fusion in elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis

Summary of findings:

Decompression alone versus decompression with fusion in elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis

Patient or population: Elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis
Setting: No restriction by setting
Intervention: Decompression alone
Comparison: Decompression with fusion

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DA	**Risk with D+F**				
Degree of disability	The mean degree of disability was **0.50**	MD **0.50 higher** (-3.31 lower to 4.31 higher)		294 (2 RCTs)	⨁⨁⨁◯ MODERATE [a]	
Duration of operation	The mean duration of operation was **-68.64**	MD **75.66 higher** (-76.03 higher to -61.66 higher)		449 (5 RCTs)	⨁⨁◯◯ LOW [c]	
Intra-operative blood loss	The mean intra-operative blood loss was **-389.29**	MD **-389.29 higher** (-411.30 higher to -367.29 higher)		434 (5 RCTs)	⨁⨁◯◯ LOW [b]	
Length of hospital stay	The mean length of hospital stay was **-43.04**	MD **-43.04 higher** (38.67 higher to 85.26 higher)		404 (4 RCTs)	⨁⨁◯◯ LOW [a, b]	
Total surgical complications	The mean total surgical complications was **0.57**	OR **0.57 higher** (0.36 higher to 0.90 higher)		492 (6 RCTs)	⨁⨁◯◯ LOW [d]	
Dural tears	The mean dural tears was **0.94**	OR **0.94 higher** (0.44 higher to 1.99 higher)		334 (3 RCTs)	⨁⨁⨁◯ MODERATE [e]	
Post-op DS	The mean post-op DS was **3.49**	OR **3.49 lower** (1.05 higher to 11.65 higher)		103 (2 RCTs)	⨁⨁⨁◯ MODERATE [e]	

Summary of findings:

Decompression alone versus decompression with fusion in elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis

Patient or population: Elderly patients with lumbar spinal stenosis and low-grade degenerative spondylolisthesis
Setting: No restriction by setting
Intervention: Decompression alone
Comparison: Decompression with fusion

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DA	**Risk with D+F**				
Reoperations	The mean reoperations was **1.00**	OR **1.00 higher** (0.52 higher to 1.94 higher)		426 (5 RCTs)	⨁⨁◯◯ LOW [d]	

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

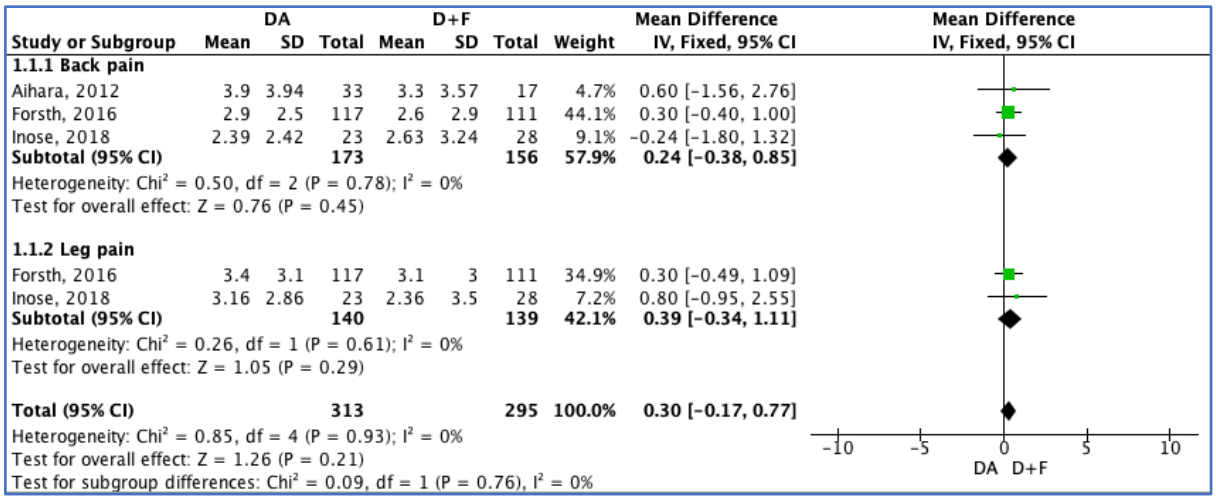
CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

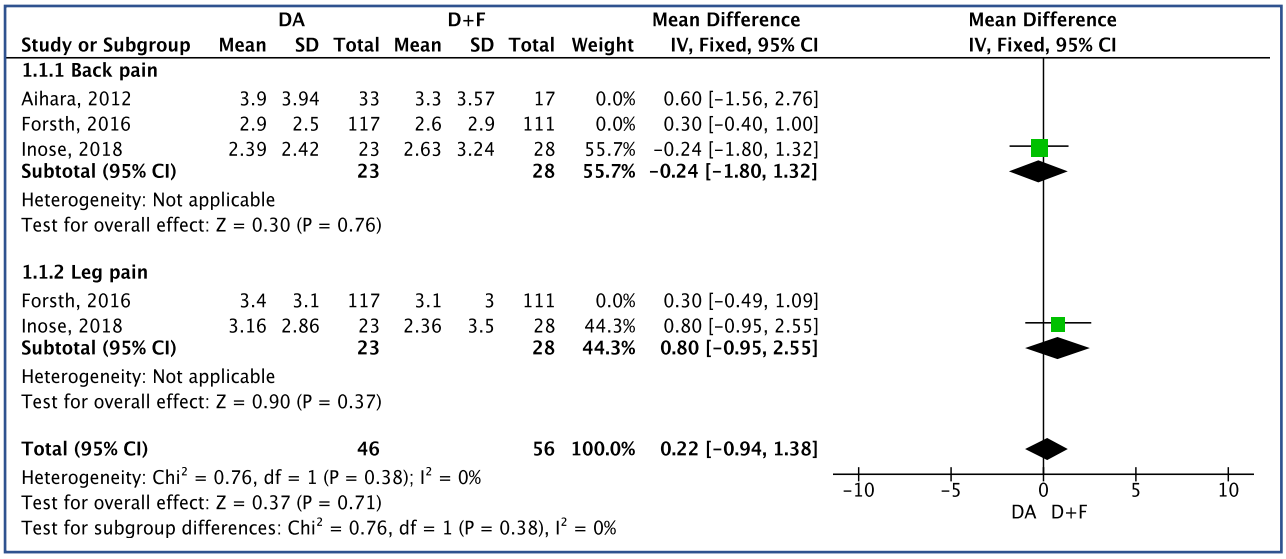
a. Risk of bias is serious due to blinding of participants, treatment provider and outcome assessment by Forsth et al. Blinding of treatment provider was not performed by Ghogawala et al. and other aspects of blinding remain unclear.
b. The confidence in the estimate of effect due to large risk of bias in included RCTs especially Grob et al with no random sequence generation and lack of blinding of participants or treatment provider.
c. The confidence in the estimate of the effect in adverse events; particularly with regards to total surgical complications, is very large due to significant selection and performance biases especially Grob et al and Bridwell et al.
d. Risk of bias is very serious due to the inclusion of Grob et al. which is a study with high selection and performance biases.
e. Risk of bias is very serious due to the inclusion of Bridwell et al. which is a study with high selection, reporting and performance biases.

Supplementary Figure 1: Forest plots of meta-analysis results for VAS scores of back (n=329) and leg pain (n=279) in DA group compared to D+F group; mean difference (MD) and corresponding 95% confidence intervals (CI) reported

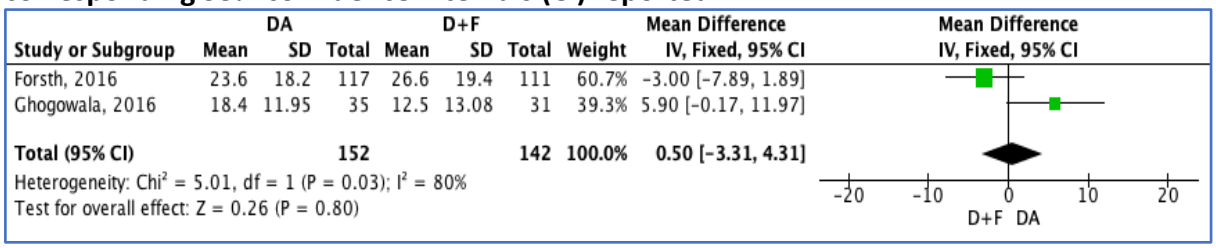


*VAS= Visual analogue scale, Decompression alone (DA), Decompression with fusion (D+F)

Supplementary Figure 2: Forest plots of subgroup meta-analysis results for VAS scores of back (n=51) and leg pain (n=51) in open laminectomy compared to posterolateral fusion; mean difference (MD) and corresponding 95% confidence intervals (CI) reported

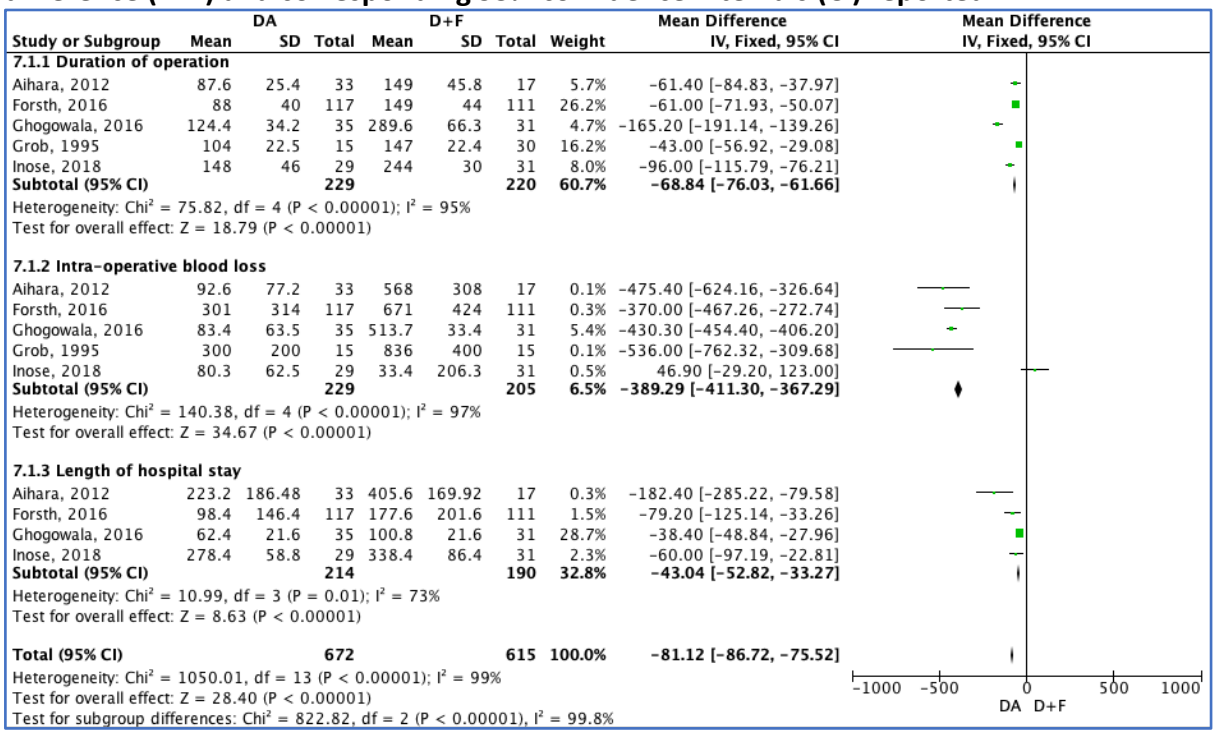


Supplementary Figure 3 Forest plots of meta-analysis results for degree of disability ODI scores (n=294) in DA group compared to D+F group; mean difference (MD) and corresponding 95% confidence intervals (CI) reported

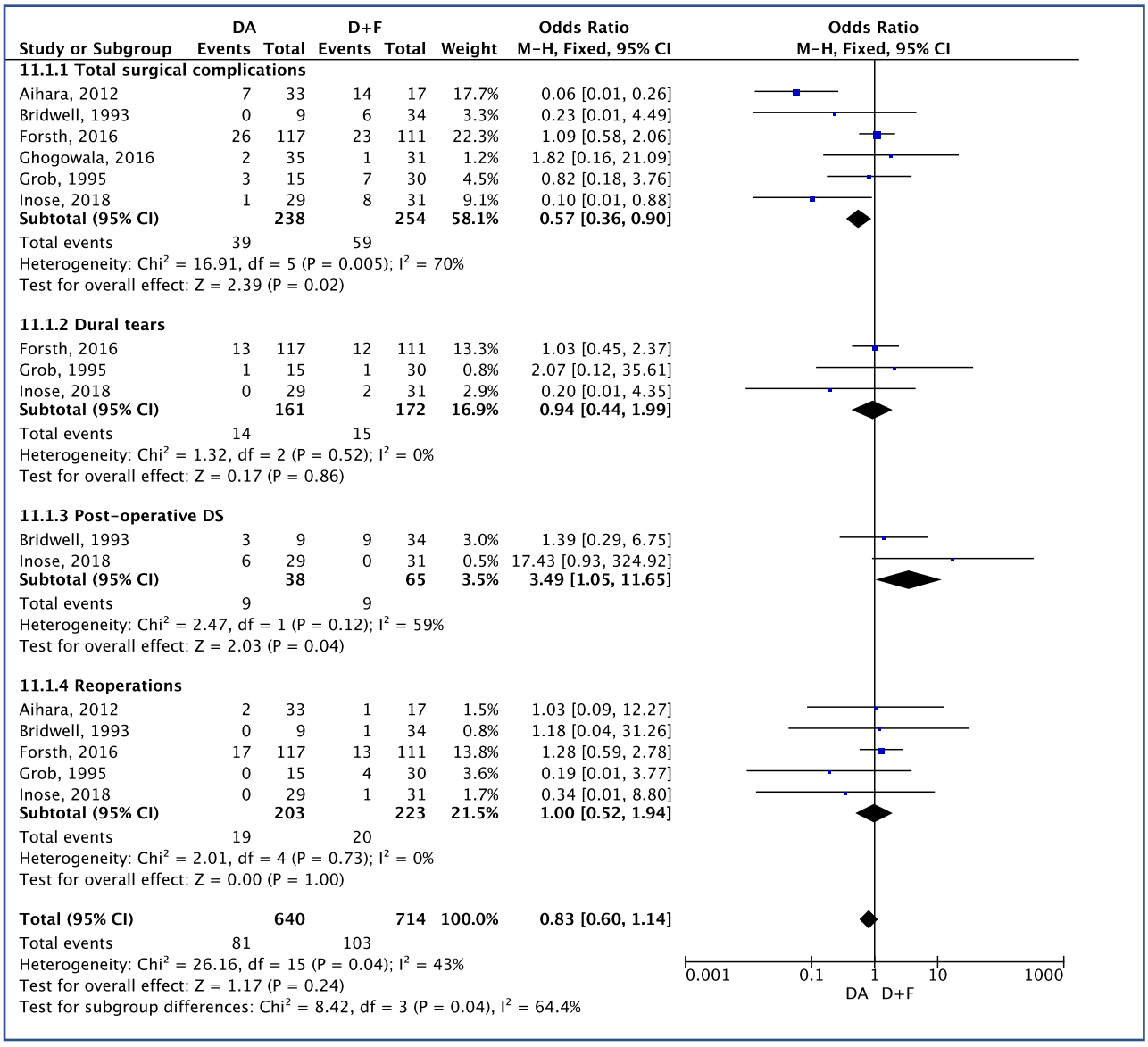


*ODI= Oswestry Disability Index, Decompression alone (DA), Decompression with fusion (D+F)

Supplementary Figure 4: Forest plots of meta-analysis results for duration of operation (n=449), IO blood loss (n=434) and LOS (n=404) in DA group compared to D+F group; mean difference (MD) and corresponding 95% confidence intervals (CI) reported



Supplementary Figure 5: Forest plots of meta-analysis results for surgical complications: total surgical complications (n=492), dural tears (n=334), post-operative DS (n=103) and reoperation rate (n=426) in DA group compared to D+F group; odds ratio (OR) and corresponding 95% confidence intervals (CI) reported



*Post-operative DS= Post-operative Degenerative spondylolisthesis, Decompression alone (DA), Decompression with fusion (D+F)

Supplementary File 1: Systematic review search strategy

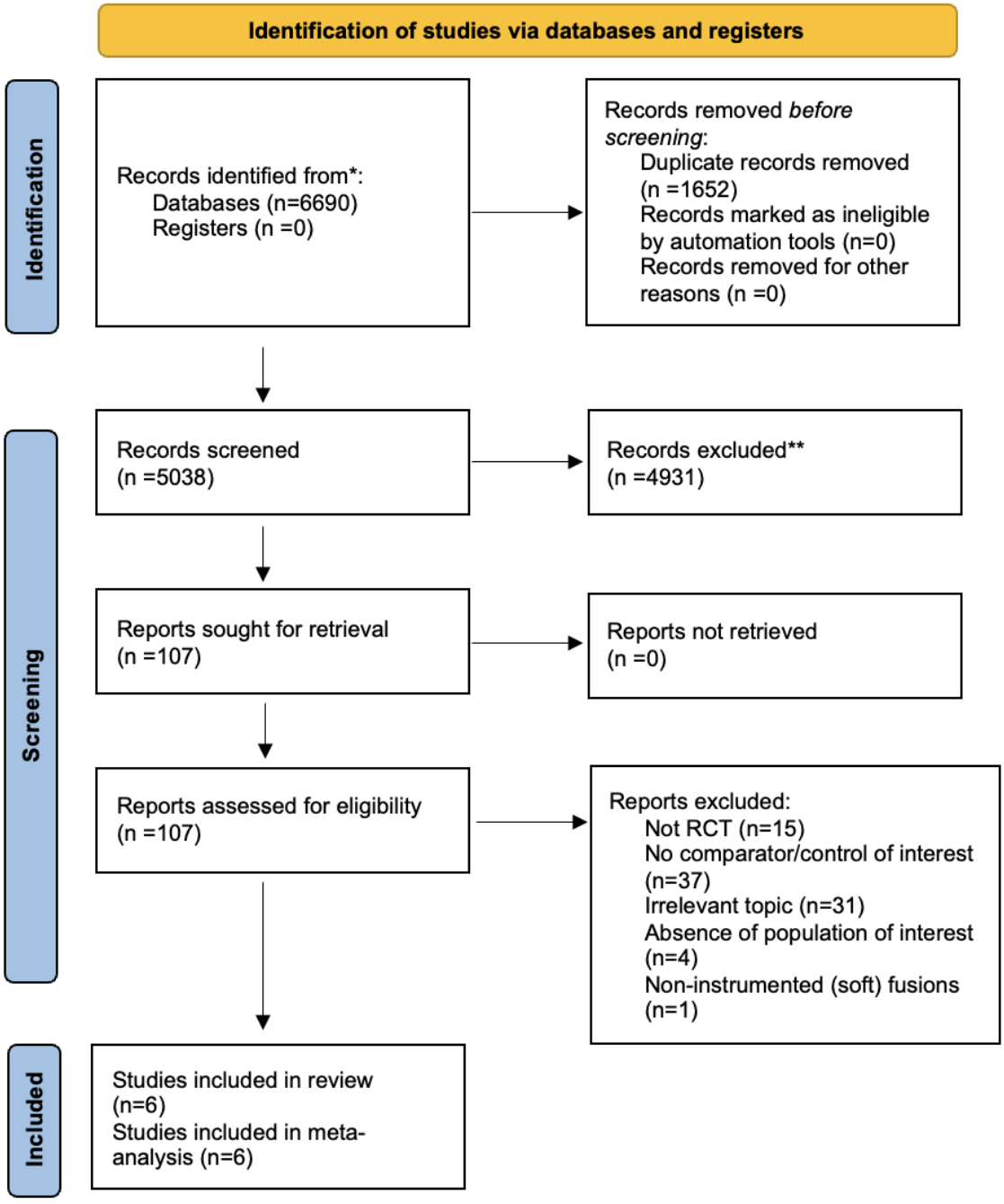
Databases: Ovid Medline, EMBASE, Cochrane register of systematic reviews, Cochrane register of controlled trials (CENTRAL), Web of Science, PubMed

EMBASE, Ovid MEDLINE, Cochrane Register of systematic reviews and Cochrane register of controlled trials (CENTRAL):
(exp laminectomy or exp vertebral canal stenosis or exp spinal cord decompression or laminotomy mp. OR laminectomy mp. or exp laminectomy OR fenestration mp. or exp fenestration OR hemilaminectomy mp. or exp laminectomy OR exp decompression surgery or exp spinal cord decompression or exp decompression or decompression mp. OR conventional laminectomy.mp. OR open laminectomy mp.) AND (exp spondylolisthesis or lumbar spondylolisthesis mp. OR lumbar spinal stenosis mp. or exp vertebral canal stenosis or exp lumbar spinal stenosis OR exp spondylolisthesis or degenerative lumbar spondylolisthesis mp. or exp spine fusion OR exp vertebral canal stenosis or exp lumbar spinal stenosis or lumbar canal stenosis mp.) AND (fusion mp. or spine fusion OR arthrodesis mp. or exp arthrodesis OR unilateral laminectomy mp. OR ULBD.mp. OR unilateral laminectomy for bilateral decompression mp. OR bilateral laminotomy mp. OR unilateral laminotomy.mp. OR microdecompression.mp. OR exp minimally invasive surgery) Limited to full-text, english-language, papers in human subjects, >18yo.

Web of Science
(laminectomy mp. OR decompression surgery mp. OR decompression mp. OR laminotomy mp. OR conventional laminectomy mp. OR open laminectomy mp.) AND (lumbar spinal stenosis mp. OR lumbar spinal stenosis mp. OR vertebral canal stenosis mp. OR lumbar canal stenosis mp. OR vertebral canal stenosis mp. OR lumbar canal stenosis mp.) AND (fusion mp. OR arthrodesis mp. OR spine fusion mp. OR unilateral laminectomy mp. OR ULBD mp. OR unilateral laminectomy for bilateral decompression mp. OR bilateral laminotomy mp. OR unilateral laminotomy mp. OR microdecompression mp. OR minimally invasive surgery mp.) Limited to full-text, english-language, papers in human subjects, >18yo.

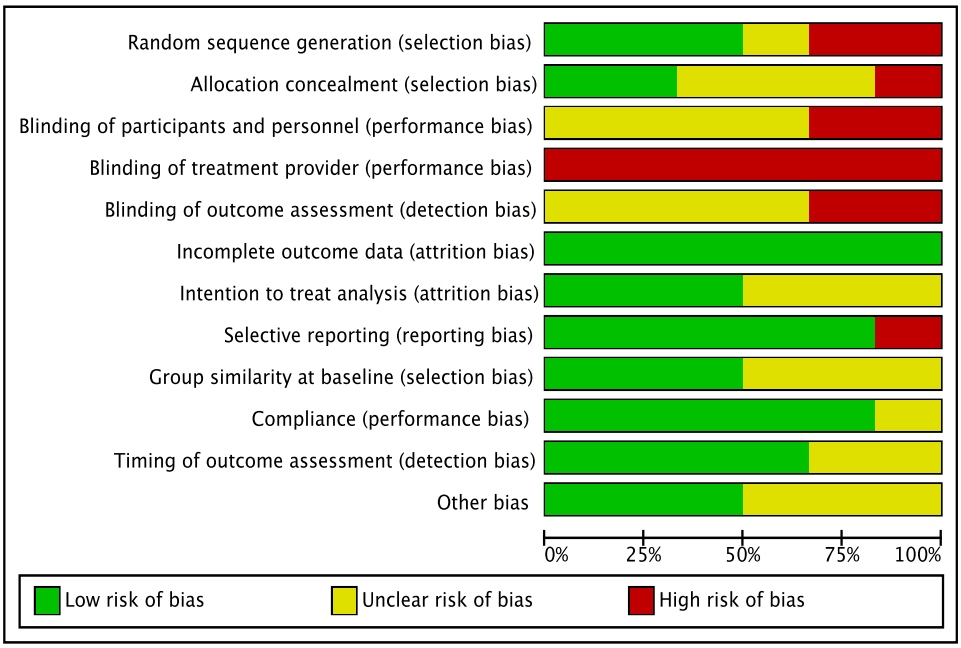
PubMed
(laminectomy mp. OR decompression surgery mp. OR decompression mp. OR laminotomy mp OR conventional laminectomy mp. OR open laminectomy mp. OR AND (lumbar spinal stenosis mp. OR vertebral canal stenosis mp. OR lumbar canal stenosis mp. OR vertebral canal stenosis mp. OR lumbar canal stenosis mp.) AND (fusion mp. OR arthrodesis mp. OR spine fusion unilateral laminectomy mp. OR ULBD mp. OR unilateral laminectomy for bilateral decompression mp. OR bilateral laminotomy mp. OR unilateral laminotomy mp. OR microdecompression mp. OR minimally invasive surgery mp.) Limited to full-text, english-language, papers in human subjects, >18yo.

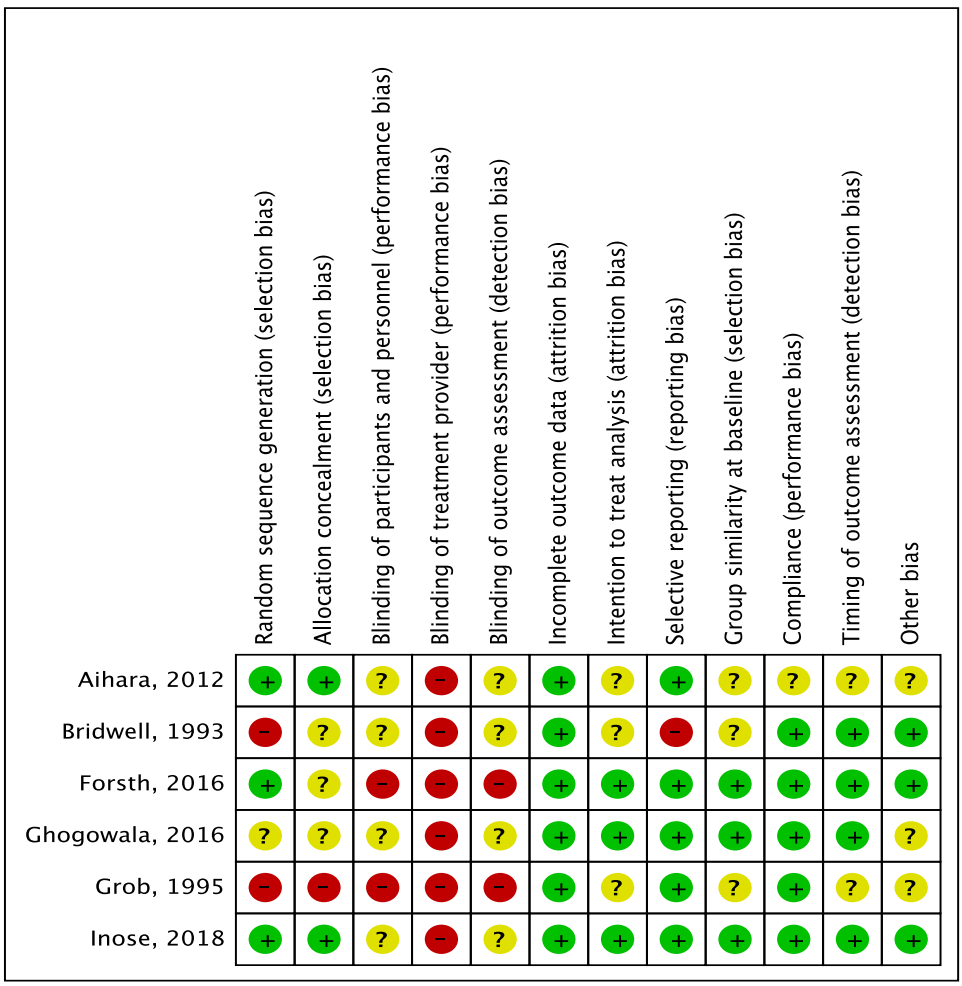
Figure 1: PRISMA Flow Diagram



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

Figure 2: Risk of bias graph and risk of bias summary





*The authors judgement of each risk of bias item for each included study was categorised by 'low risk' (+), 'unclear' (?) and 'high risk' (-).

Figure Captions

Figure 1: PRISMA Flow Diagram

Figure 2: Risk of bias graph and risk of bias summary

Table 1: PICOS diagram for inclusion and exclusion criteria

	Inclusion	Exclusion
Patient	Elderly patients defined as mean age above aged 65 years or older Lumbar Spinal Stenosis with Low-grade Degenerative Spondylolisthesis	Studies with mean age < 65 years old. <20 patients in the sample population Patients with non-degenerative spondylolisthesis alone (no mention of lumbar spinal stenosis) Patients with foraminal stenosis (and not vertebral canal stenosis)
Intervention	Decompression alone (DA) by open laminectomy, bilateral laminotomy or micro-endoscopic decompression.	Any study not assessing the comparison of decompression versus decompression with fusion Any study assessing techniques such as Coflex systems with no mention of DA and D+F.
Control	Decompression with fusion (D+F) by posterolateral fusion (PLF), posterior lumbar interbody fusion (PLIF) or anterior lumbar interbody fusion (ALIF).	No comparison to gold standard decompression with fusion. Papers that include only subgroups (e.g. cages only) Studies of purely non-instrumented or 'soft' fusion techniques used in all patients in the control arm Fusions where no autogenous bone graft was used
Outcomes	Postoperative back and leg pain (VAS score), degree of disability, QoL and hospital related outcomes: duration of operation, intraoperative blood loss, length of hospital stay, reoperation and surgical complications	Any study that does not assess the outcomes of interest in this study.
Study	Randomised controlled trials (or equivalent e.g. prospective randomised study/ randomised controlled study)	Any study methodology which does not adequately describe a randomised controlled trial methodology such as quasi-randomised trials, observational studies: retrospective analysis of RCT data, case reports, case-control, cross-sectional or cohort studies

Table 2: Characteristics of included studies

Study reference	Design	Participants (N=531)	Age (SD)	% female	Intervention (N=256)	Comparison (N=275)	Outcomes	Mean follow-up time
Inose, 2018	Multi-centre RCT, Japan	80 D 40 D+F 40	D 63.4 (8.6) D+F 61.2 (6.7)	D 41% D+F 65%	Open laminectomy (n=40)	PLF + autogenous iliac crest bone graft and pedicle screw fixation (n=40)	VAS pain score, JOA pain score, surgical parameters and hospital-related outcomes and surgical complications	24 months
Ghogawala, 2016	Multi-centre RCT, USA	66 D 35 D+F 31	D 66.5 (8.0) D+F 66.7 (7.2)	D 77% D+F 84%	Open laminectomy and medial facetectomy (n=35)	PLF (pedicle screws and titanium alloy rods) + autogenous iliac crest bone graft (n=31)	ODI score, SF-36 summary, and hospital-related outcomes	24 months
Forsth, 2016	Multi-centre RCT, Sweden	247 D 124 D+F 123	D 67.0 (7.0) D+F 68.0 (7.0)	D 59% D+F 39%	Open laminectomy (n=102) Bilateral laminotomy (n=22) (Total n=124)	PLF (n=111) PLIF (n=7) Non-instrumented fusions (n=5) + autogenous iliac crest bone graft (Total n=123)	VAS pain score, ODI score, EQ-5D, ZCQ, complications and reoperations	24 months
Aihara, 2012	Single-centre RCT, Japan	50 D 33 D+F 17	D 63.0 (10.2) D+F 65.0 (9.2)	D 33% D+F 45%	MED using tubular retractor with preservation of posterior structures (n=33)	PLF with pedicle screws (n=8) PLIF with inter body cages (n=8) ALIF (n=1) (Total n=17)	JOA back pain score	27 months
Grob, 1995	Single-centre RCT, Switzerland	45 D 15 D+F 30	D 66.0 D+F 71.0	D 60% D+F 50%	Laminotomy and medial facetectomy (n=15)	PLF with trans-laminar screws (n=14) Cotrel-Dubosset instrumentation (trans-pedicle) (n=16) + autogenous iliac crest bone graft (Total n=30)	Subjective patient-reported pain (poor, fair, good, very good), VAS pain score, hospital-related outcomes	28 months
Bridwell, 1993	Single-centre RCT, USA	44 D 9 D+F 34	D 72.3 D+F 64.6	D 72% D+F 69%	Open laminectomy with preservation of facets bilaterally (n=9)	PLF + autogenous iliac crest bone graft (n=34)	Categorical functional asses sment, hospital-related outcomes	37.2 months

*RCT= Randomised Controlled Trial, PLF= Posterolateral fusion, PLIF= Posterior Lumbar Interbody fusion, ALIF= Anterior Lumbar Interbody fusion, D= Decompression, D+F= Decompression with fusion, MED= Microendoscopic decompression, VAS= Visual analogue scale, ODI= Oswestry Disability Index, JOA= Japanese Orthopaedic Association, ZCQ= Zurich Claudication Questionnaire, EQ-5D= EuroQol-5D, SF-36= 36-item short form survey, RMDQ= Rolland-Morris Disability Questionnaire

Table 3: Summary of results from meta-analysis comparing outcomes in patients with lumbar spinal stenosis (LSS) with low-grade degenerative spondylolisthesis (LGDS) who had decompression alone (DA) versus patients who had decompression with fusion (D+F); mean difference (MD) for continuous variables, odds ratio (OR) for dichotomous variables and corresponding 95% confidence intervals (CI) reported

Outcome	**No. of participants (n)**	**Mean difference**	**95% CI**	**p-value**
Back pain (VAS)	329	0.24	-0.38, 0.85	0.45
Leg pain (VAS)	279	0.39	-0.34, 1.11	0.29
Disability (ODI)	294	0.50	-3.31, 4.31	0.80
Hospital complications				
		Mean difference	95% CI	p-value
Duration of operation	449	-68.84	-76.03, -61.66	<0.00001
Intra-operative blood loss	434	-389.29	-411.30, -367.29	<0.00001
Length of hospital stay	404	-43.04	-52.82, -33.27	<0.00001
Adverse events				
		OR	95%CI	p-value
Total surgical complications	492	0.57	0.36, 0.90	0.02
Dural tears	334	0.94	0.44, 1.99	0.86
Post-op DS	103	3.49	1.05, 11.65	0.04
Reoperation	426	1.00	0.52, 1.94	1.00
Subgroup analysis of PLF**				
Outcome		Mean difference	95% CI	p-value
Back pain (VAS)	51	-0.24	-1.80, 1.32	0.76
Leg pain (VAS)	51	0.80	-0.95, 2.55	0.37

*PLF= Posterolateral fusion; VAS= Visual analogue scale; ODI= Oswestry Disability Index; DS= Degenerative Spondylolisthesis.

**Subgroup analysis reflects results from only one study (Inose et al, 2018).

Table 4: Surgical technique for Decompression alone (DA) group (N=256) and Decompression with fusion (D+F) group (N=275)

Paper	DA Technique	D+F Technique
Inose, 2018	Open **laminectomy** (n=40)	Decompression and posterolateral fusion (**PLF**) + autogenous iliac bone graft and pedicle screw fixation (n=40)
Forsth, 2016	Open **laminectomy** by central decompression (82%, n=98) Bilateral laminotomies with preservation of midline structures (18%, n=22) (Total n=124)	Decompression and **PLF** (90% n=102), **PLIF** (5% n=6) and non-instrumented (**soft**) fusions (4% n=5) + autologous bone transplant from lamina or iliac crest for all fusions (Total n=123)
Ghogawala, 2016	Open **laminectomy** with complete laminectomy and partial medial (n=35)	Decompression and **PLF** (pedicle screws and titanium alloy rods across level of spondylolisthesis) + bone graft harvested from iliac crest (n=31)
Aihara, 2012	**Micro-endoscopic decompression** using tubular retractor while preserving the posterior structures (n=33)	Decompression and **PLF** with pedicle screws (n=8), **PLIF** with inter body cages (n=8) and **ALIF** (n=1) + autologous bone graft from iliac crest (Total n=17)
Grob, 1995	**Laminotomy** with widening of lateral recess and medial facetectomy (n=15)	Decompression and **PLF** with trans-laminar screws (n=14) or Cotrel-Dubosset instrumentation (trans-pedicle) (n=16) + autologous bone graft from iliac crest (n=30)
Bridwell, 1993	Open **laminectomy** with preservation of facets bilaterally (n=9)	Decompression and **PLF** (transverse process) with instrumentation with one-level or two-level pedicle fixation + autogenous iliac crest bone graft (n=34)
Total N=531	**Open Laminectomy n= 184/ 256**	**Posterolateral Fusion n=260/ 275**

Table 5: Diagnostic criteria for case definition of Lumbar Spinal Stenosis (LSS) and Low-Grade Degenerative Spondylolisthesis (LGDS)

Paper	Clinical Criteria	Radiological Criteria
Inose, 2018	Presence of typical symptoms (neurogenic claudication or radicular leg pain with associated neurological signs) and findings from MRI and/or CT myelograms at L4/5 level.	LGDS defined as the presence of >3 mm of spondylolisthesis of the L4 vertebra on a plain lateral radiograph.
Forsth, 2016	Presence of typical symptoms and findings on MRI.	MRI finding of LSS at one or two adjacent lumbar vertebral levels with cross-sectional area of dural sac measuring ≤75 mm^2. LGDS defined as the presence of a vertebra that had slipped forward ≥ 3mm in relation to the vertebra below it.
Ghogawala, 2016	Four standardised radiographic and MRI images for each patient to assess suitability by two neuroradiologists and one neurosurgeon to verify degenerative LSS with LGDS.	Grade I lumbar spondylolisthesis (defined as 3 to 14 mm) with LSS and neurogenic claudication with or without lumbar radiculopathy.
Aihara, 2012	Presence of typical symptoms (unilateral or bilateral neurological symptoms) and radiological findings.	Plain radiographs and imaging studies consisting of a myelogram and contrast-enhanced CT and MRI with LSS at the level of spondylolisthesis. Vertebral slippage exceeding 5% was considered to indicate LGDS.
Grob, 1995	Based on history, clinical examination and CT myelography or MRI scan.	Mid-saggital diameter of spinal canal of <11mm was considered stenotic. Instability of <5mm with rotational instability of <5mm.
Bridwell, 1993	Spinal claudication symptoms in all patients.	Coronal and lateral radiography, CT or CT myelography or MRI were used (criteria not specified).