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AO Spine Clinical Practice Recommendations for the Surgical Management of Degenerative Spondylolisthesis: When to Decompress Alone and When to Fuse

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Abstract

Study Design: Literature review.

Objective: To provide a concise review of outcomes of decompression and fusion (D + F) vs decompression (D) alone for degenerative lumbar spondylolisthesis (DLS).

Methods: 6 articles were selected, including 3 randomized clinical trials (RCT), 2 meta-analyses, and 1 radiographic cohort study. Summarized factors affecting the outcomes of D + F vs D alone for DLS and provide expert level clinical recommendations.

Results: Ghogawala included DLS patients showing improved SF-36 scores ($P = 0.046$) and lower re-operation rates ($P = 0.05$) in D + F patients compared to D alone. Forsth, included patients with stenosis both with and without DLS, and showed no difference in any reported outcome measure or reoperation rate. Austevoll included DLS patients that found that D alone was non-inferior to D + F in the primary outcome measure of ODI reduction at 2-year after surgery. Gadjradi included studies showing higher morbidity in the D + F group, as compared to D alone. Shukla included studies which found there was no difference in the raw patient outcome scores at final follow-up. Blumenthal included DLS patients who received D and reported disc height of >6.5 mm, facet angle >50°, and dynamic motion >1.25 mm were associated with high re-operation rates (45%, 39%, and 54% respectively).

Conclusions: The RCT's and meta-analyses report contradictory conclusions and no blanket statement regarding the efficacy of D + F vs D alone can be made for all patients with DLS. Surgeons should closely review pre-operative imaging for signs of instability in order to better identify appropriate patients for each indication.

Keywords

degenerative, lumbar, spondylolisthesis, decompression, fusion, outcomes

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Introduction

Degenerative lumbar spondylolisthesis (DLS) is a common spinal pathology in the aging population. Surgical treatment algorithms are marred with controversy due to variable evidence for instrumented decompression and fusion (D + F) compared to decompression (D) alone. Recently, several high-quality studies have attempted to shed light on the outcomes of both treatment strategies as well as factors related to treatment failure. The purpose of this review is to provide a concise summary of the recent literature and a recommendation regarding utilization of the evidence and consensus expert opinion.

Methods

The steering committee from the AO Spine Knowledge Forum Degenerative selected 6 key articles on the topic of surgical management of degenerative spondylolisthesis. This included three randomized clinical trials (RCT's), two meta-analyses of RCT's and prospective cohort studies, and one radiographic cohort study which aimed to define objective parameters associated with instability. Articles were chosen at the discretion of the knowledge forum steering committee based on the quality of the included data, recency, and topic relevance. Each article was summarized by a small group of three Knowledge Forum members. The summaries were incorporated into a single document by the first author, and all 23 members of the knowledge forum reviewed the final manuscript. Consensus was obtained for the final clinical recommendations after a virtual meeting reviewing the summaries.

Ghogawala Z, Dziura J, Butler WE, Dai F, Terrin N, Magge SN, Coumans JV, Harrington JF, Amin-Hanjani S, Schwartz JS, Sonntag VK, Barker FG 2nd, Benzel EC

Laminectomy plus Fusion vs Laminectomy Alone for Lumbar Spondylolisthesis.

The New England Journal of Medicine, 2016

Study Summary

The Spinal Laminectomy vs Instrumented Pedicle Screw (SLIP) trial was a randomized, controlled trial comparing D + F to D alone in patients with symptomatic grade I DLS without instability (defined as less than 3 mm motion on dynamic radiographs). The primary outcome measure was the change in the physical-component summary score of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) at 2 years after surgery, with secondary outcomes including the Oswestry Disability Index (ODI) score with a follow-up of 4 years.

A total of 66 patients (mean age, 67 years; 80% women) were randomized, with a follow-up rate of 68% at 4 years. The D + F group showed a significantly greater increase in SF-36 physical-component summary scores at 2 years compared to the D alone group (15.2 vs 9.5, difference 5.7, 95% CI 0.1 to 11.3, $P = 0.046$), which persisted at 3 and 4 years (6.7-point difference at 4 years; $P = 0.02$). However, there were no significant differences in the reduction of ODI scores between the groups at 2 years ($P = 0.06$). The D + F group experienced higher rates of blood loss, longer procedural times, and longer hospital stays than the decompression-alone group ($P < 0.001$).

The cumulative reoperation rates were lower in the D + F group (14% vs 34%, $P = 0.05$). In the D + F group, all revisions were performed at the adjacent lumbar level, whereas in the D alone group, all revisions were performed at the index level due to subsequent clinical instability. Based on the above findings, the authors concluded that among patients with grade I DLS without instability, stabilizing the lumbar spine after decompressive laminectomy was associated with slightly greater but clinically meaningful improvement in overall physical health-related quality of life compared to laminectomy alone for up to 4 years following surgery despite increased surgical complexities and recovery challenges associated with fusion surgery.

Methodological Review

Patients were enrolled from five centers between March 2002 and August 2009. A significant proportion (51 out of 106) were enrolled at a single site, potentially affecting the generalizability of the findings. Most patients were enrolled at academic centers, possibly causing selection bias and affecting generalizability due to the focus on complex spine issues and recruitment of patients with more severe symptoms. Patients with grade I DLS (3 to 14 mm) with lumbar stenosis and neurogenic claudication, with or without lumbar radiculopathy, were eligible.

Exclusion criteria included patients with instability (>3 mm translation on flexion-extension radiographs); patients judged by the enrolling surgeon to have lumbar instability based on a history of mechanical low back pain with axial loading; patients with previous lumbar spinal surgery; or patients with American Society of Anesthesiologists (ASA) class IV or higher disease. The second exclusion criterium might introduce selection bias due to surgeon subjectivity on what constituted lumbar instability. Furthermore, the degree of stenosis, duration of symptoms, and prior pain management strategies were not used in the eligibility criteria which might have confounded the trial results.

Strategies to reduce bias were employed, including imaging reviews by two neuroradiologists and one neurosurgeon for diagnosis confirmation and independent review of postoperative CT scans for protocol adherence. A sample size of 64 patients (32 per group) was estimated to provide 80% power to detect a between-group difference of 7.5 points in SF-36 scores at a two-sided significance level of 0.05. The analysis strategy was developed post-trial completion but pre-data examination. D alone involved a complete laminectomy with partial removal of the medial facet joint. The D + F group also had pedicle screws and titanium alloy rods implanted, with bone graft harvested from the iliac crest. The trial did not evaluate bone morphogenetic protein (BMP), interbody devices, or minimally invasive decompressive or fusion techniques.

There were marginal, nonsignificant differences in the baseline variables between the patients in the decompression-alone group and those in the fusion group which might have impacted the observed outcomes. Initially, both the 1-year and 2-year SF-36 score changes were primary outcomes. Follow-up was restricted to 4 years due to funding limitations and high dropout rates, despite the initial 5-year plan. The study aimed to enroll 100 patients, randomly assigning at least 64, with funding for 40 patients in a parallel registry for those who declined randomization. Data were managed at the Wallace Clinical Trials Center, with no industry involvement. The reliance on mailed assessments and the need for multiple follow-up attempts might introduce biases related to the accuracy of responses. High dropout rates after 4 years and the inclusion of data from patients who underwent reoperations without censoring might affect reliability of the results.

The sample size was sufficient to yield meaningful results, demonstrating improved quality of life (QoL) and SF-36 scores. At 1-year post-surgery, no significant difference was observed between treatment groups. However, at 2, 3, and 4 years, the fusion group showed greater improvements in SF-36 physical-component summary scores, indicating sustained benefits over time (6.7-point difference at 4 years; $P = 0.02$).

Recommendation Regarding Impact on Clinical Practice

While this study shows some benefits of D + F over D alone for stable grade I DLS, there are some important caveats. Notably, D + F carries a significantly higher morbidity risk than D alone, and D + F may not be a good option for comorbid patients. Furthermore, the surgeons performed a traditional complete laminectomy with partial medial facetectomies. It is not clear if a less invasive midline sparing technique, such as laminotomy/foraminotomy instead of a total laminectomy, may have resulted in lower reoperation rates in the D alone group. Lastly, while the overall reoperation rate for fusion patients was lower, the revisons occured at the adjacent level, thus propagating the cycle of adjacent level disease. Overall, more studies are needed to better understand which specific patient or surgical factors influence outcomes after D alone, and ideally surgeons would offer fusions only to the patients most likely to develop post-operative instability or severe mechanical back pain. We find the quality of evidence in this article to be Moderate, and provide a Conditional

recommendation that compared to laminectomy alone, fusion may be considered in patients with grade 1 spondylolisthesis for improved physical function.

Försth P, Ólafsson G, Carlsson T, Frost A, Borgström F, Fritzell P, Öhagen P, Michaëlsson K, Sandén B.

A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis.

The New England Journal of Medicine, 2016

Study Summary

The Swedish Spinal Stenosis Study (SSSS) was a multicenter, open-label, clinical superiority trial in which patients were randomized in a 1:1 ratio to either D + F or D-alone after being stratified according to absence or presence of DLS. The study included patients 50-80 years of age suffering for >6 months from pseudoclaudication in one or both legs and back pain with a visual-analogue score (VAS) > 30, and MRI images showing 1 or 2 adjacent stenotic segments between L2-S1, with cross-section area of the dural sac $\leq$75 mm^2. Exclusion criteria included the presence of spondylolysis, degenerative scoliosis, non-degenerative stenosis, stenosis from a herniated disk, rheumatic disease, neoplasm, neurologic disorder, previous lumbar surgery, history of vertebral compression fractures in affected segments, and psychological disorders that rendered participation inappropriate. The primary outcome was ODI and the secondary outcomes were EQ-5D, VAS for back pain and leg pain; and Zurich Claudication Questionnaire (ZCQ) values. In addition, the patients responded to four questions related to overall satisfaction, a global assessment of back pain and leg pain, and walking ability. The patient reported outcome measures (PROMs) were collected by postal questionnaire preoperatively, at 2 and 5 years postoperatively. A 6-minute walk test (to serve as an objective analysis) was also performed at baseline and at 2 years. Data on complications and reoperations was collected from medical files. Direct and indirect costs were calculated.

For the 228 patients who received interventions and completed the 2-year follow-up, 111 were randomized to D + F (67 with DLS) and 117 to D-alone (66 with DLS). At 5 years, data for 138 patients was available: 65 in D + F (39 with DLS), and 73 in D-alone (41 with DLS). There were no significant differences between the two treatment groups in any of the preoperative variables and baseline characteristics. At both two and five years follow-up, there were no statistically significant differences between D + F and D-alone groups in any of the nine PROMs nor the 6-min walking test, indirect costs, incidence of complications, or in the rate of reoperations. This result was maintained even after stratification according to the absence or presence of DLS. Post hoc analysis for patients with vertebral slip ranging from 7.4 to 14.3 mm showed no difference in ODI or VAS scores between the two treatment groups at baseline or at 2 years. However, fusion surgery was associated with significantly longer hospital stays, increased intraoperative bleeding, and direct costs.

The study authors concluded that D + F does not provide additional clinical benefit over D-alone for patients with lumbar spinal stenosis, even in the presence of degenerative spondylolisthesis.

Methodological Review

Randomization was stratified by the presence or absence of preoperative degenerative spondylolisthesis, ensuring balanced groups for comparison. This stratification is important given that spondylolisthesis is often considered an indicator for fusion surgery. However, many surgeons have questioned why patients without spondylolisthesis were included in the study at all. The indications for adding a fusion to patients without spondylolisthesis may include trauma, tumor, and deformity, but these patient populations were explicitly excluded from the trial. Other potential indications for fusion such as foraminal stenosis or severe mechanical back pain are not described by the authors and it is not clear whether they were present or not, or at what frequency. This lack of specificity in the patient population makes comparing this trial against others that evaluated only patients with spondylolisthesis more difficult and may limit the generalizability. Further, the applied surgical techniques were not pre-standardized and left to the determination of the operating surgeons as per the study protocol. Thus, the heterogeneity in the fusion (posterolateral, interbody, or non-instrumented) and decompression (central or midline-preserving) techniques may also represent confounding factors for the outcomes, especially considering the heterogeneity in pathology as previously mentioned.

The study does have multiple strengths. The trial's use of a web-based system for random treatment assignment minimized selection bias. The authors summarized the enrollment, randomization, and follow-up of the study participants using a Consolidated Standards of Reporting Trials (CONSORT) flow diagram. The use of the National Swedish Register for Spine Surgery (Swespine) to collect preoperative, perioperative, and postoperative data ensured a high level of data integrity and completeness. The follow-up periods of two and five years allowed for an evaluation of both short-term and long-term outcomes. The statistical analysis was robust, with the primary analysis conducted on a per-protocol basis, excluding patients who did not receive the assigned treatment or lost to follow-up.

Additionally, the trial included both stratified and exploratory post-hoc analyses to ensure comprehensive evaluation across different subgroups. The use of multiple imputation for missing data in the health economic evaluation added rigor to the analysis. However, data for cost evaluation was obtained only from a single participating center, which can't be accurately reflective for the variability in practices, policies, and financial modules within other centers locally or internationally. In accordance with the trial protocol, data on patient costs were not collected after two years, leaving the

costs for most of the reoperated fusion cases underreported as the mean reoperation time was 37 months. The data for the health economic evaluation is not provided either in the main manuscript or in the appendices.

Recommendation Regarding Impact on Clinical Practice

Given the heterogenous patient population that included both patients with and without spondylolisthesis, non-standardized surgical interventions, and uncertainty about presence of dynamic instability or foraminal stenosis, these results cannot be applied broadly to all patients with DLS. The authors did attempt to stratify based on the presence or absence of DLS, and it seems likely that in properly indicated patients a less invasive strategy of D alone may be appropriate. However, this study did not fully elucidate the appropriate indications for D alone, and the additional morbidity of a fusion may be appropriate for selected patients in whom post-operative instability is likely. Overall, we find the quality of evidence in this study to be Moderate, and provide a Conditional recommendation that patients with spinal stenosis with predominant leg pain undergo midline sparing decompression surgery, and that both D and D + F are options for patients with DLS.

Austevoll IM, Hermansen E, Fagerland MW, Storheim K, Brox JI, Solberg T, Rekeland F, Franssen E, Weber C, Brisby H, Grundnes O, Algaard KRH, Böker T, Banitalebi H, Indrekvam K, Hellum C; NORDSTEN-DS Investigators.

Decompression with or without fusion in degenerative lumbar spondylolisthesis

The New England Journal of Medicine, 2021.

Study Summary

This open-label, multicenter, noninferiority trial assessed single level decompression with or without fusion in patients with lumbar spinal stenosis and spondylolisthesis of 3 mm or more. The null hypothesis was that the percentage of patients who had a reduction of at least 30% in the ODI score (ie, had a clinically important improvement in functioning) would be at least 15 percentage points lower in the D alone group than in the D + F group.

Patients were between 18 and 80 years of age (mean of 66 years) with magnetic resonance imaging (MRI) confirmed spinal stenosis combined with neurogenic claudication or radicular symptoms in the lower limbs, and degenerative spondylolisthesis of at least 3 mm on standing radiographs. The authors specifically included patients with dynamic motion on flexion-extension radiographs, but this group was not stratified or analyzed separately from the stable DLS patients. Patients with foraminal stenosis (defined as deformation of the nerve root on MRI) were excluded. All patients had 3 months of conservative care prior to surgery. Patients were randomly assigned in a 1:1 ratio to undergo decompression surgery alone or decompression surgery with instrumented fusion. All decompressions were midline sparring. Individuals were assessed every 3 months up to 2 years postoperatively.

A total of 267 patients (134 to D alone, 133 to D + F) were recruited. 89.9% of the 267 patients (240 patients) had available data at 2-year follow-up. For the primary outcome in the per-protocol analysis, 75.5% of the D alone group and 75.5% of the D + F group had at least 30% reduction in ODI. In the secondary outcomes, there were no significant difference between groups in terms of Score on Zurich Claudication Questionnaire (ZCQ) (symptom severity, physical function, and patient satisfaction), Numeric Rating Scale (NRS) back and leg pain, the global perceived scale, or EQ-5D.

The mean duration of surgery (174 vs 104 minutes), mean length of hospital stay (5 days vs 3.3 days), blood loss (429 vs 141 mL), and incidence of dural tears (13.3% vs 5.3%), were higher in the D + F group as compared to D alone ($P < 0.05$ for each). Reoperation was performed in 12.5% of the D alone group and 9.1% of the D + F group, but this did not reach significance (95% CI of −4.6 to 11.5). There was no significant difference in the incidence of other medical or surgical complications between groups. In Table 2 the authors did report that the fusion group trended towards better improvement for both NRS leg pain and back pain in the D + F group, but this did not reach statistical significance.

Methodological Review

The authors report that 20% of the patient population had dynamic instability on pre-op flexion-extension radiographs. However, patients were not stratified based on the presence or absence of dynamic instability and it is unclear if this cohort behaved differently from the patients with stable DLS. The incidence of re-operation was higher in the D alone group, but the authors note they were not powered to definitively report on whether these differences were statistically significant.

Randomization and data collection methodology was robust. For the D alone group, midline preserving decompressions were performed. For the D + F group, the posterior midline structures were not preserved and implantation of pedicle screws and rods were used. Intervertebral fusion device was optional (38% incidence). Fusion was assessed by computed tomography by 2 surgeons and a radiologist but the criteria used to determine fusion status were not reported. Adequate numbers of patients were recruited in order to achieve statistical power. Both intention-to-treat and per-protocol analyses were done. However, in the per-protocol analysis they excluded patients who required a re-operation, which likely biases the results in favor of the D alone group.

Recommendation regarding Impact on Clinical Practice

D alone was non-inferior to D + F in the primary outcome measure of ODI reduction at 2-year after surgery. Of note, the authors followed up this cohort and recently published 5-year

results with very similar outcomes as in this manuscript.[1] A trend towards improved back pain improvement in the fusion group requires further investigation. Overall, we find the quality of evidence to be High, and provide a Conditional recommendation that for patients with magnetic resonance imaging (MRI) confirmed spinal stenosis combined with neurogenic claudication or radicular symptoms in the lower limbs, and degenerative spondylolisthesis of at least 3 mm on standing radiographs, a midline sparing decompression alone be offered as first choice for surgery.

Gadjradj PS, Basilious M, Goldberg JL, Sommer F, Navarro-Ramirez R, Mykolajtchuk C, Ng AZ, Medary B, Hussain I, Härtl R

Decompression alone vs decompression with fusion in patients with lumbar spinal stenosis with degenerative spondylolisthesis: a systematic review and meta-analysis

European Spine Journal, 2023.

Study Summary

The purpose of this study was to systematically review RCT's and prospective studies comparing outcomes between D alone and D + F for DLS. The search strategy identified 2403 studies, of which 7 were included (5 RCT's and 2 prospective studies). A meta-analysis of the included trials showed no significant between-group differences in terms of ODI, SF36, VAS or walking improvements at two years after surgery. However, the group undergoing D alone exhibited significantly lower blood loss, shorter hospital stays, reduced costs, and a similar reoperation rate compared to D + F. In contrast, D + F was associated with higher direct costs and complications. Although reported by only two studies, patients undergoing D alone showed statistically significant slip progression compared to those receiving D + F. Most studies included exhibited either low or unclear risk of selection bias and primarily targeted low-grade DS.

Methodological Review

The authors followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and registered their review protocol in the international prospective register of systematic reviews (Prospero) under the ID CRD42021291603. They performed a robust literature review with an experienced librarian and key inclusion and exclusion criteria. The authors included all posterior decompression and/or fusion techniques, whether conducted before or after fusion or during the same surgical session. The choice of fusion devices, grafts, and any additional instrumentation was left to the discretion and preference of the surgeon. Although this approach allowed for higher flexibility, it may introduce confounding. Indeed, this study employed only three different techniques, which were performed using a minimally invasive approach. This might not represent the entirety of the current practice and therefore cannot be inferred as a universal assumption. Data extraction and outcome measures were aligned with the study aims and hypotheses, were independently extracted, and discrepancies were resolved through consensus.

Risk of bias in included RCTs was assessed according to Cochrane Collaboration guidelines assessing selection bias, performance bias, attrition bias, detection bias, and selective outcome reporting bias. On the other hand, no evaluation was performed in the prospective studies due to a higher risk of bias expected. Although theoretically true, several scales have been designed with the aim of specifically assessing non-randomized studies. Due to the low number of included studies, a low or high risk of bias in the two prospective studies would significantly contribute to the overall quality of the evidence, especially within the GRADE framework.

Data analysis was performed including RCTs only, which affects the level of the evidence but risks excluding important data. This is particularly relevant considering the small number of included studies and their relatively high risk of bias. Continuous outcomes were reported as mean differences with 95% confidence intervals. Reoperation risk was assessed using odds ratios. All analyses employed a random-effects model based on the DerSimonian and Laird approach. The statistical heterogeneity was examined by inspecting the Forest plot and formally tested by the Q-test (chi-square) and I^2. The quality of evidence for primary and secondary outcomes was assessed using the GRADE method, which categorizes evidence from high to very low based on study design limitations, result inconsistencies, indirectness, imprecision, and other factors such as publication bias. We evaluated this systematic review with the use of the AMSTAR2 criteria,[2] and with this tool the level of evidence was found to be LOW.

Recommendation Regarding Impact on Clinical Practice

Overall, this systematic review and metanalysis indicated no differences in terms of functional, pain, and clinical outcomes between D alone and D + F in patients with low-grade DLS at two years of follow-up. D alone is associated with reduced blood loss, length of stay, and complications rate. On the other hand, D + F may halt the progression of DLS, and the review found higher rates of post-operative instability in the D alone group. Overall, we find the quality of evidence to be Low and provide a Conditional recommendation that decompression alone be considered non-inferior to decompression with fusion as a treatment option for low-grade DS, but given the higher slip progression observed in the D alone group, that fusion be considered in patients with signs of pre-op instability.

Shukla GG, Chilakapati SS, Matur AV, Palmisciano P, Conteh F, Onyewadume L, Duah H, Griffith A, Tao X, Vorster P, Gupta S, Cheng J, Motley B, Adogwa O.

Laminectomy with fusion is associated with greater functional improvement compared with laminectomy alone

for the treatment of degenerative lumbar spondylolisthesis: a systematic review and meta-analysis.

Spine, 2023.

Study Summary

The authors did a systematic review following PRISMA guidelines of 90 996 DLS patients from 23 studies, of which 10 267 (11.3%) underwent D alone while 80 729 (88.7%) underwent D + F. Overall, D + F was found to have significantly increased operative time, hospital stay, blood loss and complication rates compared to D alone, with similar raw scores in outcome measures at final follow-up including the NRS, ODI, and EQ5-D. However, the improvement from pre-op to final follow-up in ODI and NRS leg and NRS back pain was higher in the D + F group, and this was true in both the overall cohort as well as in a sub-analysis of patients with stable degenerative spondylolisthesis (defined as less than 3 mm motion on flexion-extension x-rays). Therefore, the authors concluded that D + F resulted in greater functional improvement compared to D alone, both in stable and unstable DLS.

Methodological Review

The authors searched PubMed, Scopus and EMBASE databases for English-language studies on surgical management of DLS published since inception through August 6, 2022. They included both RCTs and cohort studies that included a minimum of 5 patients and included 23 articles. The primary outcomes of interest were duration of hospital stay, reoperation rate, major complications, change of ODI, and change of NRS for leg and back pain. The authors compared these variables using all papers taken in aggregate, for randomized controlled trials only, and for papers that included only stable spondylolisthesis. The results from the included studies were summarized using the standard mean difference (SMD), which is a summary statistic used in meta-analyses when the outcome measures of the included studies are collected in a variable way. The SMDs express the size of the treatment effect in each study relative to the variability observed in that study. This finding highlights the importance of reporting a mean change in the outcome measure. The authors base their primary conclusions on this statistic, and report that the improvement from baseline in ODI was higher in the D + F cohort compared to the D alone (SMD: −0.38, 95% CI: [−0.57, −0.19], $P < 0.01$). Similarly, the SMD for NRS Leg (SMD: −0.11, 95% CI: [−0.21, −0.01], $P = 0.04$) and NRS Back pain (SMD: −0.45, 95% CI: [−0.66, −0.23], $P < 0.01$) favored D + F over D alone. Therefore, the authors argue that the patients undergoing D + F typically are more disabled at baseline, with worse starting ODI and NRS pain scores, and thus the fact that the final follow up ODI and NRS scores are similar implies a greater functional benefit for D + F as compared to D alone.

In the sub-analysis of patients with stable spondylolisthesis (defined as less than 3 mm of dynamic motion), there was no difference in complication rates between D + F and D alone (OR: 1.12, 95% CI: [0.34, 3.65], $P = 0.86$), but the D + F group had a higher mean change in ODI (SMD: −0.57, 95% CI: [−0.98, −0.17], $P = 0.0054$). There was a trend towards lower re-operation rates in the D + F group, but this did not reach statistical significance (OR: 0.53, 95% CI: [0.28, 1.29], $P = 0.063$).

In the second sub-analysis of patients only from RCT's, the authors note that reporting methodology varied across the studies, and this prevented a pooled analysis of functional outcomes. They provide a table reviewing the available outcome data, and two studies reported trends towards greater functional improvement,[3,4] without statistical significance. The authors were able to pool data on complications, and found that complication rates were higher in the D + F group, compared to D alone.

The study has several weaknesses. It does not list the excluded studies from the literature review. We also have concerns regarding the heterogeneity in the included studies in terms of the patient population, measurement of instability, grading of DLS, and variations in the actual surgical procedures involved. The included RCT's had different data reporting, which prevented a pooled analysis of the level 1 data. The meta-analysis of intraoperative parameters, reoperations, ODI, and NRS back had high heterogeneity ($I^2 > 40\%$). This heterogeneity introduces significant confounders and given the small effect sizes on which the authors based their conclusions raises concerns regarding the veracity of their result. We evaluated this systematic review using the AMSTAR2 criteria,[2] and using this tool the level of evidence was graded as LOW.

Recommendation Regarding Impact on Clinical Practice

The quality of this systematic review is primarily affected by the inclusion of level 4 retrospective cohort studies in contrast to the *Gadjradj et al* study[5] which included only prospective studies. The study does not clearly differentiate the cause of the higher baseline disability in the D + F cohort, which makes it difficult to generalize the findings. Ideally, fusions would be offered in a curated way only to those patients for whom the higher morbidity of the operation is justified, and thus determining the factors behind that disability is a critical element that is needed to better inform surgeon decision making. Nonetheless, the findings support offering D + F to patients with DLS, particularly those with greater baseline disability. Given the methodological concerns noted above, we find the quality of evidence to be Low and provide a Conditional recommendation that surgeons consider equally between D and D + F in patients with DLS for the majority of patients,

but consider offering fusions to those with greater baseline disability and back pain.

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Radiographic predictors of delayed instability following decompression without fusion for degenerative grade I lumbar spondylolisthesis

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Study Summary

This prospective single center study reported on 40 patients aged 50-80 years with stable (defined as less than 3 mm motion on flexion-extension radiographs and the absence of severe mechanical back pain) Grade I spondylolisthesis with neurogenic claudication. All patients were treated with D alone. Multiple baseline radiographic parameters (degree of slippage, disc height, facet angle, segmental motion on flexion-extension X-rays, and sagittal rotation angle) were examined. Reoperation was performed in 15 (37%) patients for mechanical back pain presumptively due to instability at the index level during a mean follow-up time of 3.6 years. A disc height of >6.5 mm led to a reoperation in 45%, a facet angle >50° was associated with a reoperation rate of 39%, and patients with motion at spondylolisthesis of more than 1.25 mm were associated with a 54% reoperation rate. Patients with all three risk factors had a reoperation rate of 75%, while patients without any of these risk factors had a 0% reoperation rate.

Methodological Review

The study was performed prospectively in a single center, but the 40 patients were not consecutively enrolled. The study was conducted with a single treatment arm without a control group or an alternative treatment option. Therefore, the study appears to be a retrospective single center study with prospectively collected data. The disc height and facet angle were measured in the preoperative CT, while all other parameters were determined in lateral lumbar radiographs. The disc height measured on CT may be less reliable than the measurement on X-ray, particularly if one is looking at the mechanical stress effect on the disc height. The authors did not explain why they applied a multivariate forward selection with a stepwise logistic regression and setting the threshold *P*-value of 0.35. A mean follow-up time for reoperation appears not to have been set prior to the study but was described as 3.6 years. The primary efficacy endpoint is the reoperation rate. However, the criteria for reoperation were missing. Finally, the impact of minimally invasive surgical techniques was not included in this study. Therefore, significant methodological concerns exist which may hamper the generalizability of the study findings. The level of evidence was very low.

Recommendation Regarding Impact on Clinical Practice

The results of this study suggest that significant risk factors for re-operation after D alone for DLS include segmental motion >1.25 mm, disc height >6.5 mm, and facet angle >50°, as patients with a combination of all three of those radiographic parameters had a 75% reoperation rate, and the presence of at least one parameter resulted in a re-operation rate of 39%–54%. The small sample size and non-standardized outcomes limit the generalizability of these results. Nonetheless, surgeons should thoroughly evaluate the patients pre-operative imaging for markers of instability in order to identify patients who may benefit from adding a fusion to the planned decompression. Given that this is a level 4 retrospective study, we find the quality of evidence to be Low and provide a Conditional recommendation that evaluation of radiographic parameters may aid surgeons in determining when to add fusion to a planned decompression for DLS.

Discussion

Interestingly, the three RCT's each report similar results in terms of ODI, which showed no difference at final follow-up between D + F and D alone groups across any of the studies. The North American SLIP trial[3] used the physical component of SF36 as its primary outcome measure, and reported better improvement in the D + F group, but SF36 was not commonly used in the European RCT's.[4,6] The studies differ in their reporting of index-level re-operation rates, with the SLIP trial[3] and NORDSTEN-DS[4] trials reporting higher reoperation rates in the D alone group, whereas SSSS[6] trial reported no difference. Surgical techniques were not standardized across the studies, with variable use of midline-sparing decompressive techniques and this confounds some of the comparisons. The two recent meta-analyses also drew contradictory conclusions,[5,7] but the magnitude of functional improvement seems to be higher in D + F patients as compared to D alone.[7]

Given the mixed results of these recent RCT's and meta-analyses, no succinct conclusion regarding the efficacy of D + F vs D alone for the surgical treatment of DLS as a whole can be made. It appears that degenerative spondylolisthesis is not a homogeneous pathology and is probably in simplest terms stable, unstable, or potentially unstable with decompression alone as an operative intervention. While it is clear that D alone is appropriate in many patients, it is equally clear that there is a subset of patients with DLS for whom D alone is likely to lead to instability or enhance existing instability and thus reoperation at the index level.

Conclusion

The constellation of these articles warrants a strong recommendation that both D alone and DF can be considered in the

surgical management of DLS, a recommendation that could not have been made a decade ago. Precisely determining what patients require D alone or DF is not clear, but possible clinical and radiographic parameters for evaluating this risk have been proposed. Future research will hopefully shed light on specific patient, imaging and technical factors that contribute to post-operative instability, and ideally fusions would be performed selectively in patients for whom the instability justifies the additional morbidity of the fusion operation.

Declaration of conflicting interests

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Ethical Statement

Ethical Approval

Institutional Review Board approval was not required for this study as it did not meet the standards for human research.

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