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Effectiveness of a Decision-Making Protocol for the Surgical Treatment of Lumbar Stenosis with Grade 1 Degenerative Spondylolisthesis

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■ BACKGROUND: **Addition of fusion to decompression for stenosis with grade 1 degenerative spondylolisthesis is a controversial topic, and the question remains if fusion provides any benefit to the patient that warrants the increased health care utilization and perioperative morbidity. There is no consensus on indications for use of fusion over decompression alone.**

■ METHODS: **Patients received fusion or decompression according to a decision-making protocol based on their pattern of complaints, location of the compression, and facet angles and effusion as proven predictors of postoperative instability. Propensity score matching of patients was done for baseline data.**

■ RESULTS: **The study comprised 102 patients in 2 equally sized groups. No intergroup differences in numeric rating scale and Oswestry Disability Index were detected at any follow-up point (all *P* > 0.05). Duration of surgery, length of stay, estimated blood loss, and radiation doses were higher in the fusion group (all *P* < 0.001). Cumulative reoperation rate was similar with 6% for fusion and 8% for decompression (*P* > 0.05), as was the complication rate (8% vs. 6%, *P* > 0.05). Postoperative iatrogenic progression of spondylolisthesis requiring fusion surgery was seen in only 2% in the decompression group.**

■ CONCLUSIONS: **Use of a decision-making protocol led to a low rate of iatrogenically increased spondylolisthesis after decompression, while retaining outcomes. These data suggest that a decision-making protocol based on clinical history, location of nerve root compression, and proven radiologic predictors of postoperative instability assigns patients to fusion or decompression in a safe and effective manner.**

INTRODUCTION

In recent years, spinal fusion surgery has become a standard treatment for lumbar degenerative spondylolisthesis (DS), with an increase in patients in the United States treated with interbody fusion from 14% in 1999 to 37% in 2011.[1] Conversely, the proportion of patients with DS treated by isolated decompression decreased from 12% to 4% in that same period.[1] For high-grade DS,[2] there is little doubt as to the superiority of fusion surgery versus decompression alone, but in cases with grade 1 DS, benefits of additional fusion are unclear.[3-8] This controversy is further complicated by the paucity of standardized prognostic tools to assess the risk of increasing spondylolisthesis after decompression alone.[9,10] In addition, because of the higher perioperative burden for the patient and the additional costs, it is unclear if fusion surgery adds any value for the patient.[5,6,11,12]

Ghogawala et al.[6] and Försth et al.[5] recently published 2 prominent randomized controlled trials comparing decompression and decompression with additional fusion. The first trial found a slight but statistically significant benefit in 1 of the patient-reported outcome measures (PROM), whereas the latter found no additional benefits to added fusion.[5,6,12] It was concluded that, with the exception of a lower rate of reoperation for postoperative instability, there is little evidence supporting

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Key words
- Decision making
- Decompression
- Neurogenic claudication
- Spinal fusion
- Spondylolisthesis
- Stenosis

Abbreviations and Acronyms
ASA: American Society of Anesthesiologists
BMI: Body mass index
DS: Degenerative spondylolisthesis
NRS-BP: Numeric rating scale for back pain
NRS-LP: Numeric rating scale for leg pain

ODI: Oswestry Disability Index
PROM: Patient-reported outcome measures

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additional fusion for DS with stenosis, and for this reason additional fusion should be used cautiously.[12]

Although fusion surgery may not be better for the treatment of stenosis with grade 1 DS in the general patient population, there are subsets of patients who would truly profit from the addition of fusion to decompression alone. However, identifying these subsets in a clinical setting is difficult. Instability, usually identified in flexion-extension radiographs, is often used as a selection criterion, but the evidence considering its usefulness is conflicting.[12-14] Rather, the patient's pattern of complaints, the location of the compression, and the risk of postoperative iatrogenically increased spondylolisthesis may be critical considerations when selecting patients. Over the past years, we have devised and used a simple decision-making protocol for the selection of patients with lumbar stenosis and grade 1 DS. The aim of this protocol is to provide good PROM, while minimizing the proportion of patients who require reoperation for iatrogenically increased DS after decompression alone. In this study, we analyze the effectiveness of this decision-making protocol in 102 propensity score–matched patients.

MATERIALS AND METHODS

Patient Population
Data were collected in a prospective database containing 280 lumbar interbody fusions and 488 lumbar laminectomies. All patients were operated on by the senior neurosurgeon (M.L.S.) in a specialized spine surgery clinic, and selection into the 2 groups was achieved by use of the decision-making protocol (Figure 1). Inclusion criteria were the presence of grade 1 DS[2] on magnetic resonance imaging, previous single-level fusion or decompression, complete baseline data, and a minimum follow-up threshold of 12 months. Malignancy, fractures, severe scoliosis (coronal Cobb angle >30°), and other severe comorbidities were flags for exclusion. Owing to local insurance policies, patients >80 years old, patients with an American Society of Anesthesiologists

(ASA)[15] score >2, and patients with a body mass index (BMI) >33 were never considered for surgery. The last-mentioned patients were first required to lose weight, and patients who smoked were strongly encouraged to stop smoking before surgery.

Follow-up included the Oswestry Disability Index (ODI),[16] numeric rating scale for back pain (NRS-BP), numeric rating scale for leg pain (NRS-LP), and any revisions and reoperations. Data were collected at follow-up visits and via mailed questionnaires. Perioperative data were also gathered. Estimated blood loss and radiation dose (dose area product) were present in most, but not all, cases. Complications were consistently recorded in a separate database. At the time of this writing, all patients had a scheduled telephone interview to assess if they had received reoperations elsewhere.

Surgical Technique
Transforaminal Lumbar Interbody Fusion. In prone position, the proper vertebral level was fluoroscopically identified, and a 25-mm paramedian incision was made on the clinically most symptomatic side. A Kirschner wire was placed on the facet joint, and dilating tubes were advanced over the Kirschner wire, splitting the musculature and creating a working channel. Using a bayonet punch, the facet joint and the ligamentum flavum were resected, and the nerve roots were decompressed. After debulking the disc space, the endplates were curetted. A Crescent or Cornerstone cage (Medtronic plc., Dublin, Ireland) was filled with locally harvested bone chips, as was the remaining disc space. A T-frame and fiducial array were fixated to the patient's spine. Using
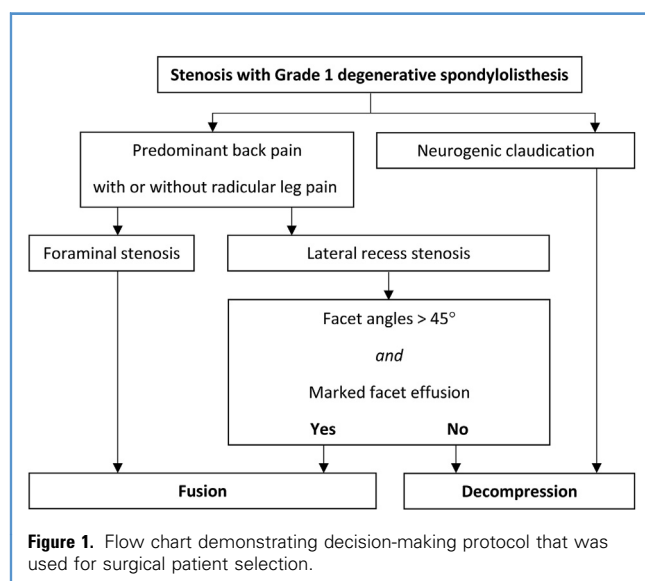

Figure 1. Flow chart demonstrating decision-making protocol that was used for surgical patient selection.

Table 1. Baseline Patient Characteristics

Characteristic	Fusion (n = 51)	Decompression (n = 51)	P
Age, years	53.5 ± 11.1	52.7 ± 8.4	0.708*
BMI, kg/m²	25.6 ± 3.5	25.5 ± 3.2	0.925*
Weight, kg	77.1 ± 14.1	75.4 ± 12.1	0.599*
Height, cm	173.1 ± 9.8	170.4 ± 9.9	0.245*
Male sex	25 (49)	22 (43)	0.551†
ASA I	22 (43)	22 (43)	0.999†
Active smoker	18 (35)	14 (28)	0.393†
PROM at baseline			
NRS-BP	6.3 ± 2.6	5.5 ± 2.8	0.144‡
NRS-LP	6.8 ± 2.3	6.5 ± 2.5	0.486‡
Oswestry Disability Index	38.3 ± 18.5	36.2 ± 17.2	0.634‡

Categorical data are reported as number (%), and continuous data are reported as mean ± SD.
BMI, body mass index; ASA, American Society of Anesthesiologists; PROM, patient-reported outcome measures; NRS-BP, numeric rating scale for back pain; NRS-LP, numeric rating scale for leg pain.
*Independent *t* test.
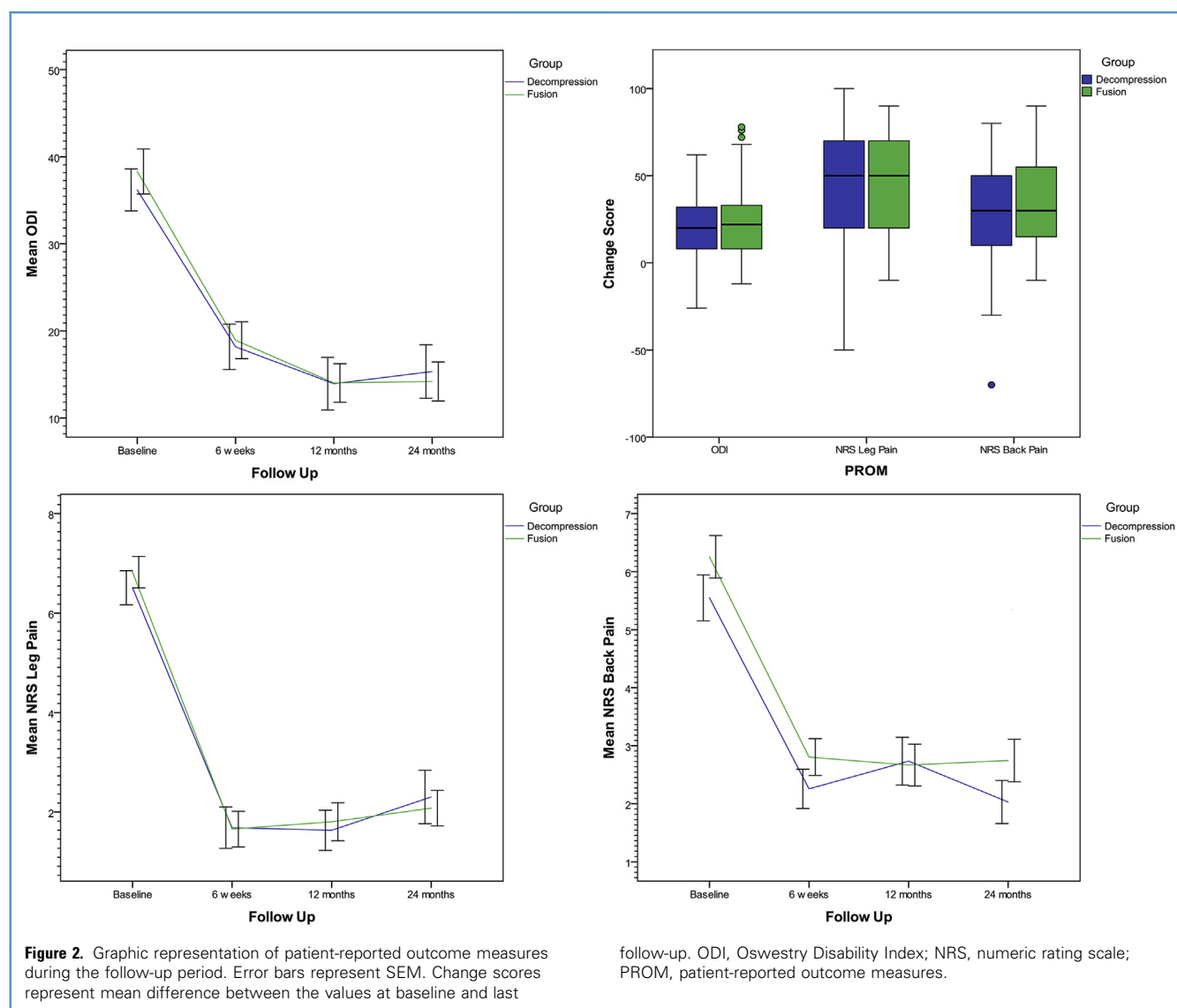†χ² test.
‡Mann-Whitney *U* test.

fluoroscopy, the patient's current spinal anatomy was matched to the trajectories that were preplanned on computed tomography images. Kirschner wires were inserted percutaneously under guidance of the SpineAssist robot (Mazor Robotics Ltd., Caesarea, Israel) under fluoroscopic control. Pedicle screws were inserted over the wires. Using the Sextant system (Medtronic plc.), reduction was achieved, if necessary, and 2 curved rods were inserted percutaneously.

Decompression. In knee-elbow position, a 50-mm midline incision was made after fluoroscopic identification of the proper vertebral level. Via a muscle-splitting approach, a mini-open retractor was placed. The interspinous ligament was cut, and the spinous process was partially resected. Bilateral partial hemilaminectomy was then performed. The interspinous ligament was deliberately resected to contralaterally undercut the hypertrophic ligamentum

flavum and osteophytes. The facet joints were left untouched wherever possible to preserve biomechanical integrity.[17] If needed, only their hypertrophic medial part was partially resected. The lateral recesses and foramina were further opened until the nerve roots appeared to be fully released. Discectomy was performed only in cases of significant nerve root compression by a bulging disc at the index level.

Statistics

Patients who met inclusion and exclusion criteria were pooled, and 2 optimal groups were constructed using nearest-neighbor propensity score–based matching. This was achieved using the MatchIt[18] code for R (R Foundation for Statistical Computing, Vienna, Austria; https://www.R-project.org/).[19] Patients were matched for age; BMI; sex; ASA score; smoking status; and baseline NRS-BP, NRS-LP, and ODI. Categorical data are

Figure 2. Graphic representation of patient-reported outcome measures during the follow-up period. Error bars represent SEM. Change scores represent mean difference between the values at baseline and last follow-up. ODI, Oswestry Disability Index; NRS, numeric rating scale; PROM, patient-reported outcome measures.

reported as numbers and percentages, and continuous data are reported as mean ± SD. For statistical testing, normality of continuous data was assessed using the Shapiro-Wilk test. Intergroup comparisons were performed using χ^2 tests, independent t tests, or Mann-Whitney U tests, according to the type of data. Longitudinal data were assessed using the Wilcoxon signed rank test. All analyses were performed using version 3.4.0 of R.[19] A 2-tailed $P < 0.05$ was considered significant.

RESULTS

Patients

We matched 102 patients who fit the inclusion and exclusion criteria into 2 equally sized groups. Both groups had highly comparable baseline criteria (all $P > 0.05$) regarding BMI; weight; height; sex; ASA score; smoking status; and baseline ODI, NRS-BP, and NRS-LP scores (Table 1).

Patient-Reported Outcome Measures

The mean follow-up length was 21.7 months ± 4.8, and 84 (82%) patients had a complete 24-month follow-up. In both groups, all PROM improved markedly from baseline to the last follow-up (all $P < 0.001$). All PROM showed a pronounced decrease from baseline to the 6-week follow-up (all $P < 0.001$) (Figure 2). Only ODI progressed from 6 weeks to 12 months ($P = 0.002$), whereas both NRS-BP and NRS-LP showed no further decrease or increase (both $P > 0.05$). No further changes were observed between 12-month and 24-month follow-up (all $P > 0.05$). There were no intergroup differences in PROM at any stage during the follow-up period (all $P > 0.05$) (Table 2). PROM change scores were equal between the 2 groups ($P > 0.05$).

Perioperative Parameters

The duration of surgery was longer for fusion (161.0 minutes ± 45.9) than for decompression (25.7 minutes ± 11.2, $P < 0.001$), as was length of stay (54.0 hours ± 15.0 vs. 28.5 hours ± 13.2, $P < 0.001$) (Table 3). Estimated blood loss was available for 73 patients (72%) and was significantly higher in the fusion group (443.3 mL ± 452.1 vs. 142.7 mL ± 108.4, $P < 0.001$). Blood transfusions were not needed in either group. Similarly, the radiation dose, measured as dose area product in cGy · cm², was also higher in the fusion group (354.4 cGy · cm² ± 144.4 vs. 122.0 cGy · cm² ± 73.6, $P < 0.001$). In both groups, L4-5 was the most common surgical index level. However, L3-4 was more prevalent in the laminectomy group, whereas L5-S1 was more frequent in the fusion group ($P = 0.001$).

The complication rate was similar for the fusion (8%) and decompression (6%) ($P = 0.695$) groups. Incidental durotomy was seen in 3 and 2 cases, respectively. Each group included 1 patient who experienced transient partial extensor pareses postoperatively. Both cases improved spontaneously throughout the follow-up period. No cases of spondylodiscitis or wound infection were encountered.

Reoperations

The cumulative rate of reoperations was similar for fusion (6%) and decompression (8%, $P > 0.05$) (Table 4). Iatrogenic progression of spondylolisthesis was seen in only 1 case (2%) in

the decompression group. Two reoperations (4%) in the fusion group were for synovial cysts at the index level, and 1 (2%) patient in that group received additional fixation for degeneration of an adjacent level. Other reoperations in the decompression group were done for disc herniation (2%) and exploration of a suspected dural defect (2%) at the index level with a negative finding. Finally, 1 patient (2%) in the decompression group had to undergo vertebrectomy and insertion of an expandable cage after an osteopenic compression fracture of the index vertebral body. No screw-related revisions were needed.

Table 2. Patient-Reported Outcome Measures at 6 Months, 12 Months, 24 Months, and Last Follow-Up

Characteristic	Fusion (n = 51)	Decompression (n = 51)	P
PROM at 6 months			
Number	41 (80%)	35 (69%)	
NRS-BP	2.8 ± 2.0	2.3 ± 2.0	0.213
NRS-LP	1.7 ± 2.3	1.7 ± 2.5	0.939
ODI	18.9 ± 13.6	18.2 ± 15.5	0.514
PROM at 12 months			
Number	51 (100%)	30 (59%)	
NRS-BP	2.7 ± 2.6	2.7 ± 2.3	0.702
NRS-LP	1.8 ± 2.7	1.6 ± 2.2	0.663
ODI	14.0 ± 15.8	13.9 ± 16.6	0.821
PROM at 24 months			
Number	51 (100%)	33 (65%)	
NRS-BP	2.8 ± 2.6	2.0 ± 2.1	0.241
NRS-LP	2.1 ± 2.6	2.1 ± 3.1	0.961
ODI	14.2 ± 16.0	15.3 ± 17.7	0.943
PROM at last follow-up			
Follow-up length, months	24.0 ± 0.0	19.3 ± 5.9	
NRS-BP	2.8 ± 2.6	2.4 ± 2.2	0.656
NRS-LP	2.1 ± 2.6	2.1 ± 2.9	0.941
ODI	14.2 ± 16.0	16.2 ± 17.8	0.642
PROM change at last follow-up			
NRS-BP change score	3.5 ± 2.7	3.2 ± 3.0	0.706
NRS-LP change score	4.8 ± 2.9	4.4 ± 3.5	0.793
ODI change score	24.1 ± 20.8	20.0 ± 18.8	0.594

All patients had at least 1 follow-up evaluation at ≥12 months. Last follow-up is defined as last completed follow-up evaluation, with most patients (82%) having 24 months as last follow-up. Change score indicates mean difference between baseline and PROM at last follow-up. Data are reported as mean ± SD.

PROM, patient-reported outcome measures; NRS-BP, numeric rating scale for back pain; NRS-LP, numeric rating scale for leg pain; ODI, Oswestry Disability Index.

Table 3. Perioperative Parameters

Characteristic	Patients	Fusion (n = 51)	Decompression (n = 51)	P
Duration of surgery, minutes	102 (100%)	161.0 ± 45.9	25.7 ± 11.2	<0.001*†
Length of stay, hours	102 (100%)	54.0 ± 15.0	28.5 ± 13.2	<0.001*†
Estimated blood loss, mL	73 (72%)	443.3 ± 452.1	142.7 ± 108.4	<0.001*†
Dose area product, cGy · cm^2	48 (47%)	354.4 ± 144.4	122.0 ± 73.6	<0.001*†
Vertebral index level	102 (100%)			
L3-L4		1 (2)	22 (43)	0.001*‡
L4-L5		30 (59)	27 (53)	
L5-S1		20 (39)	2 (4)	

Categorical data are reported as number (%), and continuous data are reported as mean ± SD.
*P < 0.05.
†Mann-Whitney U test.
‡χ^2 test.

DISCUSSION

In this propensity score—matched controlled cohort study, 102 patients were assigned to either fusion or decompression alone by means of a simple decision-making protocol. This protocol is based on the patient's pattern of complaints, the localization of the compression, and on facet angles and facet effusion as proven radiologic predictors of postoperative iatrogenically increased

Table 4. Complications and Reoperations During Follow-Up Period

Characteristic	Fusion (n = 51)	Decompression (n = 51)	P
Complications	4 (8)	3 (6)	0.695
Durotomy	3 (6)	2 (4)	
Transient paresis	1 (2)	1 (2)	
Wound infection	0 (0)	0 (0)	
Spondylodiscitis	0 (0)	0 (0)	
Reoperations	3 (6)	4 (8)	0.695
Synovial cyst	2 (4)	0 (0)	
Progression of spondylolisthesis	0 (0)	1 (2)	
Adjacent level degeneration	1 (2)	0 (0)	
Disc herniation	0 (0)	1 (2)	
Exploration for dural defect	0 (0)	1 (2)	
Compression fracture	0 (0)	1 (2)	
Implant failure	0 (0)	—	

Data are reported as number (%).

spondylolisthesis. Only 1 patient (2%) in the decompression group required reoperation for postoperative instability during the follow-up period of 21.7 months ± 4.8. No intergroup differences in PROM, complication rates, and reoperation rates were observed. As expected, fusion surgery had a higher perioperative burden for the patient.

The decision-making protocol that we describe in this study appears to effectively assign patients requiring surgical treatment for lumbar stenosis with grade 1 DS to either fusion or decompression alone. This assignment led to a low rate of revision surgery for iatrogenically increased spondylolisthesis after decompression alone, while retaining favorable PROM in both groups. The rationale of this decision-making scheme is based on the clinical history, location of the compression, and proven radiologic predictors of iatrogenically increased DS.[9,13,20,21] Neurogenic claudication is usually generated by central stenosis, accompanied by central compression of 1 or multiple nerve roots. However, predominant back pain with or without radicular symptoms is probably generated by facet joint degeneration, discopathy, and stenosis of the neural foramen or lateral recess. The aforementioned mechanisms of pain generation lead to 2 distinct patterns of complaints that are well separated. In most cases, patients with neurogenic claudication are helped by decompression alone. However, surgical decision making for patients with low-grade DS who present with back pain as the predominant complaint can be more challenging. If the nerve root compression is located inside the neural foramen, part of the facet joint must intrinsically be removed to access the foramen and to allow for sufficient decompression. This usually justifies fusion surgery. In case of stenosis of the lateral recess, decompression alone is sufficient, but the risk of postoperative, iatrogenically increased DS must be considered. If patients present with both sagittally aligned facets (facet angles >45°) and marked facet effusion, this predicts increasing DS, and it may be justified to add a fusion procedure for patients who demonstrate both of these signs. The rationale of this approach to diagnostically classifying patients is similar to the system described by Glassman et al.,[22]

which is also based on symptoms and location of the compressive pathology.

Fusion surgery did not provide any improved clinical outcomes at any follow-up length when compared with decompression alone. This corresponds to the results seen in most recent trials. The study by Försth et al.[5] is only 1 among many studies that came to the same conclusion.[3,12,23] Ghogawala et al.[6] observed a small outcome difference in 36-Item Short Form Health Survey physical component summary scores at 2, 3, and 4 years, but not at 1 year. The latter randomized controlled trial was well designed, but the authors themselves acknowledged that this is not a disease-specific outcome measure and that the analysis of this outcome measure was probably not sufficiently powered considering the number of patients who were seen at the aforementioned follow-up dates. Both trials concluded that such modest improvements, if any, do not warrant the higher costs of an additional fusion procedure. Therefore, there is little valid evidence that supports any kind of superiority in clinical outcomes of additional fusion over decompression alone for stenosis with grade 1 DS.

Because the surgical technique does not seem to matter for PROM, we believe that it would be ill-advised to recommend 1 technique over the other for the general patient population. Rather, surgical treatment of stenosis with grade 1 DS should be tailored to the patient's history on a case-by-case basis. The addition of fusion has its place in the treatment of back pain caused by significant instability or in isthmic spondylolisthesis. However, there is no consensus yet on criteria and assessment tools for instability. Moreover, an association between preoperative instability and iatrogenic progression of spondylolisthesis is still to be proven.[8,9,13,14]

In this cohort, flexion-extension imaging was not used on a regular basis. Rather, we tried to assess the risk of iatrogenic progression of spondylolisthesis after decompression alone by looking at facet effusion and angles.[9,13,20,21] Moreover, low back pain and radiculopathy that prevailed over pure neurogenic claudication was a prerequisite for selection for fusion surgery. Apparently, this selection process was effective at reducing reoperations for postoperative instability after decompression alone. This rate was 2% at a 2-year follow-up, which compares favorably to the rates reported in the literature of 0.81%–34%.[5,6,8] This may be partly explained by regional and cultural differences in decision making for reoperation.[12] The shorter follow-up in our study compared with the literature specifically looking at the reoperation rate may also be a contributing factor. Nonetheless, selection that is in particular based on the patient's history, localization of the compression, and proven radiologic predictors evidently has the potential to reduce the rate of iatrogenic progression of spondylolisthesis to a bare minimum.[9]

As expected, patients in the fusion group experienced significantly more blood loss and intraoperative radiation, while also having a prolonged duration of surgery and length of stay.[3-6] However, the length of stay in this series was comparatively low in both groups, 1.2 days and 2.3 days respectively, which may be explained by the use of minimally invasive surgery.[24-28] The addition of fusion just "to be on the safe side" probably does not warrant the added health resource utilization in the general patient population, even when using minimally invasive techniques.[5,6,12] However, there are subsets of patients for whom the addition of fusion surgery to simple decompression provides added value.

Limitations

This study is limited by its retrospective nature. Although all data were prospectively collected in a dedicated database, this leaves room for potential selection bias. Furthermore, this study lacks randomization. However, randomization would not be a useful tool for demonstrating the effectiveness of a decision-making protocol, and the applied matching procedure created 2 highly comparable groups that allowed for a secure analysis. Although group sizes may seem moderate with 51 cases each, a post hoc power analysis indicated that to detect a 12-point intergroup difference on the ODI at a power of $1 - \beta = 0.8$ and a significance level of $\alpha = 0.05$, the minimum sample size would be 42 patients.[5] This indicates that our analysis was appropriately powered. Operative index levels differed between the groups, which is explained by the fact that back pain was more commonly the prevailing symptom at the lumbosacral junction. However, it is inconceivable that better matched index levels would have changed the findings of this study in any way. Complete data were available for most variables, but blood loss and radiation data were unavailable in some cases. Such subgroup analyses must always be viewed with skepticism. Comorbidities were not systematically recorded and could constitute possible undetected confounders. Owing to local policies enforced on specialized outpatient spine clinics, we included only low-risk patients (age ≤80 years, BMI ≤33, ASA score ≤2). This means that this decision-making protocol may provide different results in geriatric and high-risk patients. The mean follow-up length was 21.7 months ± 4.8. The follow-up threshold was 12 months, and most patients (82%) had complete 24-month follow-up. Although the PROM are unlikely to further change after 2 years, the follow-up length influences the rate of reoperation.[6] Lastly, this was a single-surgeon study.

CONCLUSIONS

In patients with stenosis and grade 1 DS, outcome measures were equal between fusion surgery and decompression alone at all follow-up lengths. A fusion procedure was associated with a significantly higher perioperative burden for the patient. The rate of reoperation for iatrogenic progression of spondylolisthesis after decompression alone was comparatively low at 2%. The data suggest that a decision-making protocol based on the clinical history, location of the nerve root compression, and proven radiologic predictors of postoperative instability assigns patients to fusion or decompression in a safe and effective manner.

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