Evidence-Based Recommendations for Spine Surgery

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**STUDY BACKGROUND**

There has been a growing interest in minimally invasive surgical approaches to the spine. Minimally invasive surgery (MIS) has been suggested to hasten recovery, decrease complications, and improve outcomes in patients when compared with traditional surgical procedures. The literature, however, has not proven this and often reports greater complications. The far-lateral or transpsoas approach to the interbody space has been developed as an alternative to traditional retroperitoneal anterior lumbar interbody fusion (ALIF) procedures. The authors of this article sought to describe the intraoperative and early postoperative complications associated with “extreme lateral interbody fusion” (XLIF), a proprietary version of the transpsoas approach.

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Acknowledgment date: November 29, 2011. Acceptance date: December 5, 2011.

The device(s)/drug(s) that is/are the subject of this manuscript is/are not FDA approved for this indication and is/are not commercially available in the United States.

No funds were received in support of this work.

One or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript: e.g., honoraria, gifts, consultancies, royalties, stocks, stock options, decision making position.

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DOI: 10.1097/BRS.0b013e3182454ef0

**METHODOLOGICAL REVIEW**

The study design was a retrospective review of a prospectively collected database. Unfortunately, the study lacked detail and transparency on how the complications were collected and how strict the surveillance was. The population from which these 600 patients were drawn was not described. The inclusion and exclusion criteria were not well defined. The inclusion criterion seemed broad and included any patient who the primary author treated with a spinal fusion in the lumbar spine. It included patients treated for many spinal conditions and patients treated at multiple levels. The type of implants used or specific spinal levels fused were not reported. Five hundred eleven patients underwent XLIF and posterior fixation, 84 XLIF and lateral fixation, and 5 underwent XLIF alone. Treatment strategy for 1 method of fixation compared with another was not defined.

The outcome of interest was a description of medical and surgical complications. The authors also commented on hemoglobin level, length of stay, visual analogue scale (VAS) pain, and satisfaction. The description of neurological complications included only motor deficits (weakness), postoperative leg pain, paresthesias, or dysesthesias. Other commonly reported complications were not included. Complications occurring beyond the first 6 weeks after surgery were also excluded. The authors did not use an independent assessor to identify and record complications despite 1 or both authors being conflicted, although this was appropriately recognized as a limitation in the article.

Descriptive statistics summarized complication data. Although logistic regression was used in an effort to identify predictors of complications, there was no mention of odds ratios and corresponding confidence intervals for those predictor variables (age, sex, obesity, diagnosis, comorbidities, and number of levels fused).

The authors conclude with several key points, 1 of which states that the L4–L5 level is associated with more complications. However, the frequency of surgery at specific spinal levels was not provided in detail, and therefore the reader cannot adequately assess this as a risk factor.

**CLINICAL REVIEW**

The authors identified 37 complications for a perioperative complication rate of 6.2%. The authors identified inclusion
of the L4–L5 level and prior surgery as risk factors for perioperative complications. The distribution of patient diagnoses varied widely from disc herniation to scoliosis. Despite the wide array of diagnoses, the authors do not provide detail on the criteria of these patients for spinal fusion. As such, it is difficult for the reader to adequately ascertain the population of patients this study could be applied to as well as the true incidence of complications that are reported.

The retrospective nature of the study, as noted by the authors, may lead to an under-reporting of complications. In addition, the authors excluded hip flexor weakness and thigh pain, numbness, or paresthesias as defined complications. Other reports of similar far-lateral or transpsoas approaches have classified these as potential complications. The authors note in the discussion that these neurological findings are “nearly universal” and “always transient.” This statement is not supported by the article, given that these data were neither collected nor reported objectively.

Additional limitations of the article also need to be addressed. It should be noted that the treating surgeons in this study are very experienced with the XLIF technique and, as such, results should be generalized to other settings with caution. In addition, 1 or more of the authors have a financial interest in the product being investigated in their study. Unintended bias, which was not adequately controlled for, may therefore exist, which would further downgrade the methodology and limit the impact of the study findings.

The authors conclude their article by stating that complications associated with the XLIF technique are less than that with traditional open procedures and that the XLIF procedure offers “great hope of reducing the morbidity, cost, and recovery time for patients who need spinal fusion surgery.” However, no comparative arm in the study exists, no cost data are presented, and objective measures of recovery time are not presented in this article. As such, these statements are a hyperbole that is not supported by data and, as such, should not influence surgical care.

RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE

The authors summarized intraoperative and early postoperative complications from a large case series of XLIF patients. Given the limitations of this large, 2-surgeon case series, the far-lateral, or transpsoas, approach to interbody fusion is a surgical option with an unverified complication profile. As a consequence, no change to clinical practice can be justified on the basis of this study.


STUDY BACKGROUND

Low back pain is a ubiquitous clinical problem with enormous public health costs across the world. The diagnosis of a singular pain generator can be difficult for low back pain. Discogenic low back pain has been defined as pain related to disc degeneration, although strict criteria for diagnosis and management are limited. Surgical treatment of discogenic back pain is common, although the efficacy of surgical intervention is controversial. In an attempt to address this question, the authors compared nonsurgical treatment with surgical treatment in a carefully selected group of patients with discogenic low back pain.

METHODOLOGICAL REVIEW

The clearly stated purpose was to compare the effectiveness of nonsurgical and surgical therapies. Because of the controversies and challenges surrounding the evaluation and treatment of chronic low back pain, the authors have appropriately chosen to do an efficacy study. This is a study with optimal internal validity and limited external validity or generalizability. The authors achieve this by rigorously selecting their subjects. Inclusion and exclusion criteria are specified and suit the goals of the study while eliminating confounding factors (multilevel disease, workers compensation, etc.) The authors define concordant discogram pain response and an anesthetic response as diagnostic for discogenic back pain. No control discs were included and details on the discogram technique (pressure and volumetric rate of injection) were provided.

The study design is a randomized trial comparing nonsurgical care and surgery in the form of an ALIF. The patients and investigators were not blinded, and it is unclear whether the evaluators of subjective outcomes were blinded. The randomization method was not defined in sufficient detail. After randomization, if an ALIF was deemed technically dangerous due to the overlying great vessels, then a posterior lumbar fusion (third group) was performed. Nonsurgical care involved monthly physician visits with a regimented exercise program. The nonsurgical care was clearly described and replicable. There was no consideration given to counterintervention. Patients may have engaged in others forms of therapy during the 2-year follow-up period; however, this lends generalizability to the control group.

The included outcome measures, including the VAS, Japanese Orthopaedic Association (JOA), and Oswestry Disability Index (ODI), were appropriate for the question asked; however, there was no primary outcome identified a priori. Baseline comparability between groups was documented with regard to VAS, JOA, and ODI scores as well as age and duration of symptoms. The authors applied statistical tests appropriately. Given that there was no primary outcome measure, there was no a priori consideration given to sample size requirement before the study. In addition, treatment arms included a small numbers of patients, so power may have been limited, although significant differences were found.

CLINICAL REVIEW

Given the baseline similarities across the 3 groups, the authors’ randomization scheme, while not clearly described, seems effective. The authors reported 100% follow-up at 2 years and 100% compliance with all treatment arms. This strengthens the findings of the article, but generalizability or
applicability to a broader group of patients has not yet been determined. Despite the small number of patients, the authors were able to show significant differences between treatment and control groups, with the numbers included. The significant differences noted are clinically meaningful (example: VAS scores 7.4 pretreatment and 1.3 post-treatment), with statistically greater improvements in VAS, JOA, and ODI scores at 1 and 2 years in surgically treated versus nonsurgically treated patients. The only significant limitation to this study is lack of blinding to control for patient expectations—the placebo effect. This effect can be modified by beliefs or philosophies unique to a particular culture. In surgical studies, however, blinding is difficult, if not impossible to achieve, due to ethical and patient participation issues.

RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE
This high-impact, well-executed, and clearly written study provides high-quality evidence into the treatment of rigorously selected patients with chronic discogenic low back pain. Attempts should be made to replicate these study results in a broader patient population. We make a strong recommendation for surgical treatment of discogenic low back pain in patients strictly meeting the inclusion criteria used in this study. Until the findings of this study are replicated and performed in a broader patient population, more generalizable recommendations cannot be made.


STUDY BACKGROUND
Postoperative wound infections represent a potentially devastating complication of spinal procedures, including posterior thoracolumbar fusions. The prophylactic administration of intravenous antibiotics, such as the cephalosporins, prior to surgery is generally considered to be the standard of care for reducing the incidence of surgical site infections secondary to gram-positive bacteria. Unfortunately, the increasing prevalence of resistant organisms in recent years has led to higher rates of postoperative wound infections, which may necessitate reoperations or prolonged antibiotic regimens that are both invasive and expensive.

The local delivery of antibiotics within the operative site is a relatively well-accepted practice in the fields of joint replacement and orthopedic trauma, but the results of this technique have only recently been reported for spinal applications. It has been suggested that the combination of vancomycin powder with bone graft material may decrease the risk of surgical site infections. In their retrospective review of a large series of posterior instrumented thoracolumbar fusions, Sweet *et al* attempted to assess the safety and efficacy of vancomycin powder implanted within the wound as an adjunctive method for decreasing the incidence of postoperative infections compared with a standard regimen of parenteral antibiotics alone.

CLINICAL SUMMARY
This study sample consisted of 1732 consecutive posterior instrumented thoracolumbar fusions performed by 3 surgeons at a single institution. The first 821 subjects received 2 g of intravenous cefazolin within 1 hour of the incision, whereas the second cohort of 911 subjects was also treated with the direct application of 2 g of vancomycin powder into the wound; approximately 1 g was mixed with autogenous iliac crest autograft and the remainder was sprinkled throughout the deep and superficial tissues, including any exposed dura. Blood samples were also obtained from the surgical drains of 178 subjects in the vancomycin group to determine drug levels in the perioperative period. In addition to routine radiographic examinations, ODI and 36-Item Short Form Health Survey scores were collected preoperatively, immediately postoperatively, and at the latest visit. The mean follow-up was 3.4 and 2 years for the control and vancomycin cohorts, respectively.

Individuals suspected of having a wound infection underwent deep aspiration to confirm the diagnosis. Superficial infections involving the skin and subcutaneous tissues were initially addressed with oral antibiotics and local wound care measures; these were not considered in the subsequent analysis. In contrast, those with deep infections localizing below the level of the fascia were treated with open surgical debridement, with intravenous antibiotics directed toward the causative organisms.

METHODOLOGICAL REVIEW
This investigation represents a retrospective, single-center, multisurgeon comparative time series cohort study. Of the 1778 consecutive patients eligible for inclusion, follow-up data were available for 1732 subjects. There were no notable patient- or procedure-specific disparities between the demographic characteristics of the 2 cohorts. There were 21 documented infections in the control group compared with only 2 in the vancomycin group (2/6% vs. 0.2%); this difference was determined to be statistically significant (*P* < 0.0001) based on a study power of 95% and an alpha level of 0.01. In the majority of these cases, the isolated organism was either *Staphylococcus aureus* or coagulase negative staphylococcus. Both of the infections in the vancomycin cohort developed more than 4 weeks after surgery subsequent to other infectious events (i.e., septic diverticulitis and urosepsis). There were no significant disparities between the clinical outcome measures, pseudarthrosis rates, or adverse events recorded for the 2 groups; in particular, the implantation of vancomycin locally within the surgical site did not seem to bring about any instances of systemic hypotension or renal toxicity. The mean vancomycin concentration measured in the fluid acquired from the surgical drains was highest on postoperative day 0 and decreased steadily to day 3; although therapeutic levels of vancomycin were generally present in these local samples, this antibiotic was unable to be
detected in the serum samples of 80% of these patients. Of the remaining 20%, the peak mean serum vancomycin level was 1.6 μg/mL on postoperative day 1 (range, 0.7–5.9 μg/mL).

The purpose of this study is explicitly stated, which the authors attempt to address using a retrospective cohort design. Although both of the groups are similar in terms of their demographic data as well as any potential confounding variables and the investigation is appropriately powered, there are still several methodologic flaws. The surveillance of infection is performed retrospectively and does not incorporate any independent evaluation; although the diagnosis of infection may generally be established in an objective fashion, there is an inherent reporting bias. For instance, some subacute cases may have been missed after discharge, and it is possible that some superficial infections may have been inadvertently excluded, which could have progressed to involve the deeper tissues. The other major limitation is the sequential manner in which the cohorts were established. All of the fusions augmented with vancomycin powder were performed in 2006 or later, and it is conceivable that there may have been changes in surgical technique, the operating room environment, or postprocedural care, which could have influenced the rate of wound infection. Nevertheless, when considering the primary research aim, these results are still very compelling, given the reasonably large sample size, significant effect change, and relative safety of this strategy.

RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE
This study is clearly limited by its nonblinded, retrospective, single-center, sequential design. Although the significant difference in infection rate coincided with the direct application of vancomycin powder to the wound, other aspects of the clinical care or surgical technique used for these patients could have contributed to the observed effect. Taking into account the dramatic effect size that is reported for this intervention as well as the considerable morbidity and economic costs associated with surgical site infections, we think that these findings may have an impact on the treatment of these types of cases. Because higher quality evidence derived from a prospective, randomized, controlled trial would necessarily require a large number of subjects and entail a tremendous investment of resources in order to corroborate the safety and efficacy of this protocol, we conclude that the results of this investigation justify a weak recommendation for the prophylactic administration of vancomycin directly into the surgical wounds of patients undergoing posterior thoracolumbar instrumented fusions who are at higher risk for infection.


STUDY BACKGROUND
ALIF is a common surgical procedure that is intended to treat a wide range of pathology and is generally performed through a retroperitoneal abdominal approach. One relatively rare but serious complication that is known to be associated with this operation is retrograde ejaculation, which develops as a result of iatrogenic injury to the superior hypogastric plexus. This structure is generally located in close proximity to the bifurcation of the great vessels and is most often disrupted during an exposure of the lower lumbar segments. The reported rates of postoperative retrograde ejaculation vary from 0% to almost 50%, but the true incidence is likely dependent upon several different factors, including surgical technique, type of pathology, extent of the dissection, and the method of detection.

The bone morphogenetic proteins (BMPs) are soluble growth factors that have been shown to stimulate the osteoblastic differentiation of pluripotential stem cells. Recombinant human BMP-2 (rhBMP-2, INFUSE; Medtronic, Memphis, TN) is a commercially available bone graft substitute that has been approved by the Food and Drug Administration (FDA) for ALIF in conjunction with a threaded cage. However, a wide range of adverse events have been reported with the use of this product for both “on-label” and “off-label” spinal applications, including local inflammation leading to osteolysis, seroma formation, heterotopic ossification, radiculitis, and swelling of the soft tissues. Although none of the original publications specifically identified an increased risk of retrograde ejaculation in the INFUSE cohort compared with control subjects receiving iliac crest autograft, other studies have reported that this complication may occur more frequently with this biologically active graft material because of either ectopic bone formation or an inflammatory reaction affecting the anterior disc space. In an attempt to further characterize the incidence of retrograde ejaculation after the use of rhBMP-2, Carragee et al. completed a retrospective analysis of a consecutive series of ALIF cases performed with and without INFUSE.

CLINICAL SUMMARY
The study sample consisted of male individuals with spondylosis, spondylolisthesis, recurrent disc herniations, or discectomy pain who underwent ALIF at 1 or 2 levels of the lower lumbar spine (L5–S1 vs. L4–S1, respectively) at a single institution between 2002 and 2004. All of the retroperitoneal exposures were performed by the senior author (EJC), and with few exceptions a structural femoral ring allograft filled with either 2 collagen sponges soaked in 4.2 mg of rhBMP-2 or autogenous bone combined with a demineralized bone matrix was inserted into the disc space. The clinical data from these surgeries were prospectively collected and registered into a database so that it could be retrospectively accessed to determine how many of the subjects developed postoperative retrograde ejaculation.

The control and INFUSE cohorts comprised 174 and 69 patients, respectively. Retrograde ejaculation was diagnosed in 5 subjects receiving INFUSE compared with only 1 in the control group (7.2% vs. 0.6%, P = 0.0025); for single-level ALIF procedures at the L5–S1 level, the rates were 6.7% versus 0% (P = 0.0233). The radiographs of 3 of the 5 individuals with July 2012
rogressive ejaculation who had been treated with rhBMP-2 demonstrated changes consistent with early osteolysis. At the 1-year follow-up, 3 of the 6 cases of retrograde ejaculation were found to have resolved (2 INFUSE, 1 control).

METHODOLOGICAL REVIEW
In this retrospective, single-center, sequential time series investigation, 243 patients were identified who had undergone 1- or 2-level ALIF procedures for degenerative pathology that included the L5–S1 disc. The first 174 control subjects were treated with autograft, whereas the subsequent 69 subjects received rhBMP-2. Although retrograde ejaculation events were identified from the database, the method of their determination, including when and by whom, was not well elucidated. The authors do not discuss whether the patients were specifically asked prior to surgery about the presence of symptoms, which could be indicative of pre-existing retrograde ejaculation. Similarly, the prevalences of other potential risk factors for this condition, such as diabetes mellitus, history of prostate surgery, or certain medications (e.g., antihypertensives, antidepressants, or antipsychotics), which may independently bring about retrograde ejaculation were not thoroughly investigated. In addition, there is little data regarding the number of revision ALIF procedures in each cohort, which could certainly affect the incidence of this complication.

Finally, the time points at which these subjects were diagnosed with retrograde ejaculation are not specified. One would expect retrograde ejaculation that arises secondary to an inflammatory process to occur in a subacute fashion, whereas the later onset of this disorder may reflect a different pathophysiological mechanism unrelated to an iatrogenic injury to the superior hypogastric plexus. However, patients may not resume sexual activity immediately after an ALIF, and therefore it may not be possible to accurately determine when this condition may have developed, making it difficult to differentiate between surgical and other nonoperative etiologies.

RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE
Although the incidence of retrograde ejaculation was significantly higher among patients undergoing ALIF procedures with rhBMP-2 compared with those treated with autogenous bone, we think that the limitations in the study design and the reporting of the results preclude the establishment of a direct causal role for rhBMP-2. The results, however, corroborate the original FDA-approved randomized controlled investigational device exemption (IDE) study regarding the incidence of retrograde ejaculation. The seriousness of this complication certainly warrants further investigation as 2 controlled studies (FDA IDE study-level 1 and this study, level III) both report similar potential increased risk of retrograde ejaculation. When these findings are placed in the context of the myriad of concerns already raised regarding other adverse events associated with the implantation of rhBMP-2 that have been reported in the literature, we offer a weak recommendation to seriously consider this potential complication when determining whether to employ rhBMP-2 as a graft material in an on-label application. This potential complication needs to be discussed in great detail with any male patient, in which this growth factor is considered.


STUDY BACKGROUND
Lumbosacral radiculopathy syndromes are some of the most common conditions encountered by spine surgeons worldwide. Although they often carry a favorable prognosis even without surgical intervention, a minority of patients will require surgical decompression. Surgical techniques for nerve root decompression and subtotal discectomy have evolved since Walter Dandy’s first report in 1929. Mixter and Barr compiled all available surgical case reports in 1934, describing a procedure with generous laminectomy and transdural removal of the offending disc herniation. Since that time, surgical progress has been predicated on technologies that have helped reduce invasiveness. Caspar and Yasargil independently published use of the operating microscope for lumbar disc surgery in 1977. Although initially met with skepticism, this technique has become a popular method of the treatment for operative herniated lumbar discs, and numerous series have since described surgical success rates to be in the range of 88% to 98.5%. In 1997, Foley and Smith introduced the technique of transmuscular tubular discectomy, incorporating a muscle-splitting technique that was expected to reduce tissue trauma, reduce postoperative pain, and accelerate recovery without compromising effectiveness. In 2009, Arts et al presented the results of their prospective, multicenter, double-blind randomized trial comparing tubular discectomy with conventional microdiscectomy. Their results from that study emphasized differences in clinical outcome and recovery time and suggested that tubular discectomy does not confer significant benefit in terms of functional disability, perceived recovery, or back and leg pain at 1-year postoperation. This study draws on that same data, more specifically examining indicators of muscle injury in these 2 populations. They report serum creatine kinase (CPK) levels and multifidus muscle cross-sectional area (CSA) on magnetic resonance imaging (MRI).

METHODOLOGICAL REVIEW
This study is a subgroup analysis from a double-blind randomized controlled effectiveness superiority trial. The study was performed at 7 general hospitals in the Netherlands from January 2005 to October 2006. Eligibility criteria are not explicitly outlined, but they are implied in the same authors’ prior report. A total of 328 patients aged 18 to 70 years who had persistent leg pain (>8 wk) due to lumbar disc herniation were included in the original study. A total of 216 patients had CPK measurements perioperatively, of whom 140 patients also had MRI analyses performed. These data were
collected at only 3 of the 7 study centers without explanation for this decision, although this subgroup is posited to be comparable with the parent group. CPK measurements were recorded preoperatively and 1 day postoperatively; the CPK ratio was compared. MRI CSA measurements were recorded preoperatively and 1 year postoperatively, and once again the CSA ratios were compared. Multifidus atrophy was graded on a scale from 0 (normal) to 3 (severe). No establishment of minimal clinically important difference was provided for any of these measurements, and it was implied that any difference, if statistically significant, is clinically important. VAS score for low back pain was provided.

The mean preoperative CPK measurements were 105.8 IU/L and 107.1 IU/L for the tubular discectomy and microdiscectomy groups, respectively, whereas the postoperative measurements were 255.7 IU/L and 268.1 IU/L, respectively. There was no statistical difference in these measurements between the 2 groups. Multifidus CSA measurements are provided for both groups at 2 time points: preoperatively and at 1-year postoperatively. The CSA ratio is noted to be significantly lower in the tubular discectomy group (0.99 ± 0.14) than in the conventional microdiscectomy group (1.05 ± 0.19), with P = 0.04. Atrophy scores were not statistically different. The CPK and CSA ratios did not correlate significantly with recorded VAS scores.

The authors concluded that tubular discectomy and conventional microdiscectomy demonstrated comparable invasiveness and soft-tissue effects as indicated by CPK release and multifidus atrophy measurements.

**CLINICAL INTERPRETATION**

Arts et al should be commended for performing a thoughtful and meticulous comparison between tubular discectomy and conventional microdiscectomy. The proliferation of MIS spine techniques has been predicated on a number of assumptions, including the belief that tubular retraction reduces muscle trauma. This study represents an investigation of this particular belief, using perioperative serum CPK levels and paravertebral muscle atrophy as indicators of muscle trauma. Although the original study was designed as a superiority trial, this subgroup analysis is performed as a noninferiority comparison by surgeons who were facile with both techniques, and treatment selection was performed for a mainstay treatment for multilevel disease; however, in a selected subset of patients with multilevel CSM, laminoplasty may offer lower morbidity, decreased cost, and greater preservation of physiological motion. This study by Highsmith et al compares the outcomes and costs associated with laminoplasty and laminectomy with fusion for patients with CSM.

**STUDY BACKGROUND**

Multilevel cervical stenotic myelopathy (CSM) is a common clinical condition that responds favorably to surgical decompression. Although anterior and posterior surgical approaches are available, multilevel disease involving more than 3 levels is most often treated posteriorly. Methods for achieving this goal include laminectomy, laminectomy with posterior instrumented fusion, and laminoplasty. Isolated laminectomy without fusion has been well established to increase the risk of late neurological deterioration, progressive kyphosis, segmental instability, and perineural adhesion. As a consequence, it is rarely indicated as an optimal treatment strategy. Laminectomy with fusion has become a mainstay treatment for multilevel disease; however, in a selected subset of patients with multilevel CSM, laminoplasty may offer lower morbidity, decreased cost, and greater preservation of physiological motion.

**RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE**

In aggregate, although this is an interesting subgroup analysis extracted from an important article, the conclusions had inherent methodological flaws. As a consequence, no change to clinical practice can be justified on the basis of this study.


**CLINICAL REVIEW**

The authors retrospectively reviewed 56 patients surgically treated for CSM, of whom 30 underwent open door laminoplasty and 26 underwent laminectomy with instrumentation and iliac crest autograft. Patients with significant spondylolisthesis or kyphosis were excluded from this study and the authors noted that demographic characteristics were similar between the 2 groups. Importantly, treatment selection was performed by surgeons who were facile with both techniques, and the authors indicated that clinical differences existed between patients in the 2 treatment arms, for example, “more facet pathology” typically prompted a decision to perform laminectomy with fusion. Patients undergoing fusion were noted to...
have significantly greater preoperative neck pain ($P < 0.01$), lower preoperative Nurick score ($P < 0.05$), a greater number of operative levels ($P < 0.01$), a higher likelihood of having a decompression extending through C7, and a higher likelihood of having instrumentation cross the cervicohoracic junction. A minimum 12-month follow-up was required and a mean follow-up of about 42 months was achieved.

Patients in both treatment groups had improvement in myelopathy scores postoperatively. Nurick scores improved significantly in both treatment groups by an average of 1.4 points although preoperative scores were significantly higher in the laminoplasty group. Similarly, mJOA scores improved significantly in both treatment groups. Although patients in the fusion group had greater preoperative neck pain, they had a significant improvement in their neck pain postoperatively (VAS-Neck scores of 5.8 preoperatively and 3.0 postoperatively; $P < 0.01$). Patients in the laminoplasty group had a slight and statistically insignificant increase in neck pain postoperatively (VAS-Neck scores of 3.2 preoperatively and 3.4 postoperatively; $P = 0.50$). Odom outcomes were comparable between the 2 groups. Reoperation rates were higher in the fusion group (27% vs. 13%; $P < 0.01$). The reoperation rate in the fusion subgroup without extension beyond the cervicohoracic junction was 13% comparable with the laminoplasty group. The overall infection rate in this study was 11%, and the authors indicated that this is explained by the higher rate of comorbidities seen in their study population. These were all managed effectively, with no patient requiring instrumentation explantation. Radiographical outcomes were similar between the 2 groups, with general preservation of lordosis despite a 3° to 4° loss of lordosis postoperatively in both groups. The authors reported a 92% fusion rate at 2 years in the fusion group with no patient developing a symptomatic pseudarthrosis. Finally, the authors performed a cursory, if compelling, cost analysis, indicating that hardware costs for laminoplasty were $4200 compared with $12,000 for fusion constructs of the same length, excluding cross-connectors.

**METHODOLOGICAL REVIEW**

This study represents a retrospective cohort study without an explicit hypothesis; as such, it should be treated as a hypothesis-generating study and not a hypothesis-testing study. The clinical background and study rationale are summarized simply and adequately. Although the 2 cohorts are reported to have comparable demographic characteristics, specifics are not presented with the exception of age. Especially, because they recorded relatively high complication rates attributable to higher observed comorbidities, these details may have allowed the reader to better define the generalizability of these results. There are no specific details on how these 56 patients were selected, for example, timeframe, setting, comprehensive inclusion/exclusion criteria, number of similarly treated patients not included, and so forth. It is likely that between all of the authors more than 56 patients with CSM have been allocated to 1 of these 2 treatment arms. Treatment allocation was performed by the surgeons, and there was significant clinical disparity between these 2 cohorts. Minimal details on allocation criteria are provided. As such, these patients do not seem to be equal candidates for laminectomy/fusion and laminoplasty; this is a significant methodological limitation. Outcome measures employed were appropriate and extensive, including Nurick score, mJOA score, VAS for neck pain, Odom outcome grade, radiographical lordosis measurements, and recorded complications. Details of how these measures were recorded are not provided. Finally, although cost comparison was a central objective of this study, no discussion is provided on how costs were estimated over time. They seem to have singularly focused on the implant cost difference, which is only a small portion of aggregate cost.

**RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE**

Although the authors have presented a thoughtful retrospective study, it had significant methodological flaws as outlined earlier. No recommendation to change clinical practice can be made on the basis of this study.

**References**

14. Smoljanovic T, Siric F, Bojanic I. Six-year outcomes of anterior lumbar interbody arthrodesis with use of interbody fusion cages and


