Evidence-Based Recommendations for Spine Surgery

Charles G. Fisher, MD,* Alexander R. Vaccaro, MD, PhD,† Peter G. Whang, MD,‡ Srinivas K. Prasad, MD,† Peter D. Angevine, MD, MPH,§ Kishore Mulpuri, MBBS, MHSc,¶ Kenneth C. Thomas, MD, MHSc,|| and Alpesh A. Patel, MD,**

Preventing Surgical-Site Infections in Nasal Carriers of Staphylococcus aureus.


The development of nosocomial infection has been a long-standing issue facing health care providers and patients. The risks and the cost of infections are significant and are coming under increased scrutiny. In an attempt to reduce the rate of infection, the authors investigate a protocol for screening and treatment of Staphylococcus aureus (S. aureus) bacteria. The authors question whether rapid identification of S. aureus nasal carriers by means of a real-time polymerase chain reaction assay, followed by treatment with mupirocin nasal ointment and chlorhexidine soap, reduces the risk of hospital-associated S. aureus infection.

STUDY SUMMARY

The study is a randomized, double-blind, placebo-controlled, multicenter trial conducted at three university hospitals and two general hospitals in the Netherlands. Subjects were patients admitted to the departments of surgery and internal medicine. Of a total of 6771 patients screened on admission, 1251 patients were positive for S. aureus. They enrolled 917 of these patients in the intention-to-treat analysis, of whom 808 (88.1%) underwent a surgical procedure. Patients were randomly assigned to either active treatment with mupirocin ointment 2% (Bactroban, GlaxoSmithKline Brentford, Middlesex, UK) in combination with chlorhexidine gluconate soap, 40 mg/mL (Hibiscrub, Mölnlycke Health Care, Gothenburg, Sweden), or placebo ointment in combination with placebo soap. The rate of S. aureus infection, as defined by the treating surgeon and confirmatory cultures, was 3.4% (17 of 504 patients) in the mupirocin-chlorhexidine group, as compared with 7.7% (32 of 413 patients) in the placebo group (relative risk [RR] of infection, 0.42; 95% confidence interval [CI]: 0.23–0.75). The effect of mupirocin–chlorhexidine treatment was most pronounced for deep surgical-site infections (RR: 0.21; 95% CI: 0.07–0.62). There was no significant difference in all-cause in-hospital mortality between the two groups. The time to the onset of nosocomial infection was shorter in the placebo group than in the mupirocin-chlorhexidine group (P = 0.005). The authors conclude that a protocol for S. aureus screening and mupirocin-chlorhexidine treatment can reduce the rate of infection.

METHODOLOGICAL REVIEW

The authors should be congratulated for completing this prospective, randomized, double-blind, placebo-controlled, multicenter trial. The authors originally planned to enroll 1800 subjects for randomization to achieve a power of 80% with a two-tailed Type I error rate of 0.05 and a reduction of 50% in the incidence of serious S. aureus infections. After 860 patients had been enrolled, a perceived change in the cumulative incidence of serious S. aureus infections was reported in one of the participating centers. A sequential analysis was conducted which showed a significant difference. This should be taken into account while interpreting the results. There is no mention about an a priori interim analysis or stopping rules in the study methods and therefore, by reducing the number of study subjects, this introduces potential error into the methodology.

The authors also mention the impact of the experimental protocol on surgical site infections and mortality, specifically mentioning deaths associated with cardiothoracic surgery. The majority of patients enrolled were surgical patients and, therefore, an accurate comparison of surgical and nonsurgical patients is not feasible. Although cost analysis was not an outcome or research question in this study, failure to address
this issue at a minimum in the discussion is concerning given that the cost of universal screening and targeted treatment remains unknown. The cost-effectiveness of this protocol needs further clarification. By not accounting for the costs of screening, the authors have biased the interpretation of the results of their study to favor universal screening. Why were these costs not accounted for? The presence of a financial conflict cannot be excluded as an intended or unintended cause of this methodological flaw and therefore justifies downgrading the methodological quality of this study.

**RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE**

Given the significant implications of *S. aureus* infections, the authors’ article provides one treatment protocol that is reported to have a very low complication rate with a statistically significant effect of infection reduction. On the basis of the strength of the study, we recommend that screening of high-risk patients for *S. aureus* be considered by the treating physicians and that treatment for positive carriers be initiated. Patients typically at higher risk for infection include the following: revision procedures, smokers, prior or recent spinal infection, and recent nonspinal infections. The cost-effectiveness of this protocol remains to be clarified before universal screening can be performed and before a singular standardized treatment protocol can be strongly recommended.

**Chlorhexidine–Alcohol Versus Povidone–Iodine for Surgical-Site Antisepsis**


There is growing emphasis on the reduction of postsurgical infections. The health implications to the patient and the significant costs to hospitals and payers are focusing health research on this problem. The authors investigate the effectiveness of one antisepsis regimen to another in preoperative patients. The study hypothesis is that preoperative skin cleansing with chlorhexidine-alcohol is more protective against surgical-site infection than povidone-iodine scrub and paint.

**STUDY SUMMARY**

This is a prospective, randomized clinical trial conducted between April 2004 and May 2008 at six university-affiliated hospitals in the United States. Patients aged 18 years or older who were undergoing clean-contaminated surgery (i.e., colorectal, small intestinal, gastroesophageal, biliary, thoracic, gynecologic, or urologic operations performed under controlled conditions without substantial spillage or unusual contamination) were eligible for enrollment. Of 1003 eligible patients, 897 were randomly assigned to have the skin at the surgical site either preoperatively scrubbed with 2% chlorhexidine gluconate and 70% isopropyl alcohol (Chlora-Prep, Cardinal Health) or preoperatively scrubbed and then painted with an aqueous solution of 10% povidone-iodine (Scrub Care Skin Prep Tray, Cardinal Health). The overall rate of surgical-site infection was significantly lower in the chlorhexidine-alcohol group than in the povidone-iodine group (9.5% vs. 16.1%; *P* = 0.004; RR: 0.59; 95% CI: 0.41–0.85). Chlorhexidine-alcohol was significantly more protective than povidone-iodine against both superficial incisional infections (4.2% vs. 8.6%, *P* = 0.008) and deep incisional infections (1% vs. 3%, *P* = 0.05) but not against organ-space infections (4.4% vs. 4.5%). Both the intention-to-treat analysis and the per-protocol analysis showed lower rates of surgical-site infection in the chlorhexidine-alcohol group than in the povidone-iodine group for each of the seven types of operations studied. The authors concluded that preoperative cleansing of the patient’s skin with chlorhexidine-alcohol is superior to cleansing with povidone-iodine for preventing surgical-site infection after clean-contaminated surgery.

**METHODOLOGICAL REVIEW**

The authors completed a prospective randomized clinical trial with appropriate power, sample size calculations, baseline characteristics, comparisons and log of all eligible subjects. While there were minimal statistical limitations, the authors’ interpretation of results may be over-reaching and does not account for limitations in the study design.

The two treatment protocols being compared, as noted by the author, are not equivalent. The authors present supporting references, which have demonstrated a greater antibacterial efficacy, potentially because of the alcohol component of one antisepsis agent. The comparison, despite the authors’ statements, does not adequately compare the effectiveness of chlorhexidine versus povidone-iodine based agents. A more appropriate comparison would be between chlorhexidine-alcohol and iodine-alcohol antiseptic agents or between chlorhexidine and iodine antiseptic agents. All agents are widely available in the US market. This limitation in study design should have been discussed in the body of the discussion to educate readers on the potential limitations of the generalizability of the authors’ findings.

With regards to infection reduction, this study primarily identified an effect on RR for superficial site infections. Although not a primary measure of the study, the discussion does not address cost issues which raises an important potential limitation: financial bias. All of the investigators receive financial support from the company (Cardinal Health) while one of the investigators is a direct employee of the company. Though the same company produces both treatment products, the authors do not define the cost difference between the two. A brief online search identified listed price differences of 20 times or greater for the 2% chlorhexidine gluconate and 70% isopropyl alcohol when compared to the 10% povidone-iodine treatment. The potential financial benefit to the sponsoring company cannot be ignored. This combined with the authors’ conflict of interest, the role of the company in study design, and the omission of cost data downgrades the quality and limits the impact of the study.

**RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE**

The authors identify a potential treatment protocol to reduce the rate of postsurgical infections, most notably superficial...
skin and deep incisional infections. Through a statistically sound study, the potential financial conflicts diminish the impact of this study. Therefore, only a weak recommendation for change in clinical practice can be made. A study comparing the effectiveness of more similar antiseptic agents while better controlling for financial conflicts of interest by including cost-effectiveness data would be more beneficial and may have a greater impact on clinical practice.

**Vertebroplasty Versus Conservative Treatment in Acute Osteoporotic Vertebral Compression Fractures (Vertos II): An Open-Label Randomized Trial.**


The management of osteoporotic vertebral compression fractures remains a controversial subject with recent, good-quality literature yielding conflicting results. Given the high incidence of compression fractures in an aging population, optimal management remains an important, but unresolved, issue. The present study represents the latest contribution to this body of work, addressing some of the methodological and clinical concerns presented by recent literature. Important differences include an emphasis on management of acute fractures only, inclusion of more rigorous radiological criteria, incorporation of a true conservative group without sham intervention and inclusion of both quality of life and cost analyses. Unlike the original Vertos trial, this study achieved completion without undue high crossover; unfortunately, limitations around volunteer bias persist.

**STUDY SUMMARY**

Klazen *et al.*, published a prospective, randomized (randomized clinical trial [RCT]), nonblinded study of the clinical and economic outcomes of vertebroplasty compared to nonoperative management of acute osteoporotic vertebral compression fractures. Two hundred and two (29%) patients were randomized of 708 eligible patients seen at six academic centers in the Netherlands and Belgium over a 2½-year study period. Patients were eligible if they were at least 50 years old, had back pain for 6 weeks or less with a confirmed vertebral compression fracture at or caudal to T5, a visual analog scale (VAS) score of five or more, bone edema at the fracture level on magnetic resonance imaging, and a T score of –1 or less. The primary outcome measure was the change in VAS scores between 1 month and 1 year after treatment. Secondary outcomes were estimated cost-effectiveness at the same time points. Tertiary outcomes were quality of life measures using Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) and Roland-Morris disability questionnaires.

Ninety-three of the 101 patients randomized to receive vertebroplasty underwent the procedure at a mean of 5.6 weeks after the onset of symptoms. One-month and 1-year follow-up data were obtained for 93% and 80% of patients, respectively. The incremental VAS benefit for vertebroplasty compared to nonoperative management was 2.6 at 1 month and 2.0 at 1 year. Both differences were statistically significant and suggest that patients undergoing vertebroplasty enjoyed quicker and more significant pain reduction than conservatively treated patients. There were no major complications encountered with vertebroplasty. Cost measures in the Netherlands revealed that vertebroplasty was associated with a marginal cost of €2474 at 1 month and €2450 at 1 year. On the basis of cost-effectiveness analysis, vertebroplasty is considered cost-effective in the study nations with 70% certainty if society is willing to pay €30,000 or more per quality adjusted life year. Development of new compression fractures was not significantly different between the two groups.

**METHODOLOGICAL REVIEW**

The authors completed a multicenter RCT with well-defined, appropriate inclusion/exclusion criteria. Unlike recently described RCTs, the authors in this investigation defined very strict inclusion criteria for enrollment—duration of disease and imaging confirmation—to identify acute compression fractures and eliminate old fractures, healed fractures, fracture nonunion, and patients unrelated or nonspecific back pain. Unlike the similarly designed VERTOS I study which was terminated because of high crossover, this study had a much lower crossover rate. In the vertebroplasty group there were three crossovers to nonoperative management and three patients who had spontaneous improvement in their pain. Five of the 101 patients assigned to nonoperative treatment crossed over to undergo vertebroplasty. As with other vertebroplasty RCTs, volunteer bias is high with only 29% of eligible patients consenting. There is no attempt to compare the outcomes of all eligible patients who did and who did not participate, nor discuss this limitation in the discussion of the article.

The validity of any nonblinded RCT is potentially reduced. An additional limitation of this study is that no sham procedure was performed. Both factors make the results susceptible to the criticism that a placebo effect or patient expectations may be responsible for the difference in outcome between the interventions. Finally, the cost analysis is acutely sensitive to health care climates and, as such, may not be generalizable to all readers.

**RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE**

This is a well-executed study designed to mimic regular clinical practice. The study enhances the literature through a clearly and strictly defined cohort in which vertebroplasty appears to be both safe and efficacious for acute vertebral compression fractures. Nevertheless, the absence of blinding and low participation introduces important biases that potentially undermine the final conclusion. In aggregate, this evidence supports a weak recommendation to incorporate these findings into clinical practice.

**Trends, Major Medical Complications, and Charges Associated with Surgery for Lumbar Spinal Stenosis in Older Adults.**


US health care expenditure continues to grow at an alarming rate, prompting exhaustive examination of our complex...
health care system and institution of policies designed to contain these expenditures. Centrally, the mission of health care reform is to balance access, quality, and cost control—the so-called “iron triangle” of health care—in an effort to maximize efficiency in health care utilization. Princeton health care economist Uwe Reinhardt promotes a more structured corollary: maximizing efficiency in any health care system requires that we are deriving the maximum number of quality adjusted life years as a society for each incremental dollar spent. This is a powerful model that should serve as an ideological ground truth in the noisy narrative of health care reform. Fundamentally, no meaningful discussion of health care efficiency can singularly examine costs without examining outcomes, and vice versa.

STUDY SUMMARY
Deyo et al conducted a retrospective review using Medicare data between 2002 and 2007. In particular, the authors examine surgical treatment rendered to all Medicare beneficiaries older than 65 years of age for the primary diagnosis of lumbar stenosis. Primary diagnosis information was supplemented with available information about coincident scoliosis and/or spondylolisthesis. Surgical intervention was stratified by complexity into three types: decompression alone, decompression with “simple” fusion (1–2 levels, using single approach) and decompression with “complex” fusion (three or more levels; 360° fusions including posterior lumbar interbody fusion [PLIF] and transforaminal lumbar interbody fusion [TLIF]). Principal outcome measures included: rates for each of these three types of surgery, major complications, rehospitalization rate, mortality, and resource utilization. Only rates of surgery were recorded across the full interval from 2002 to 2007; the remainder of the measures was only recorded for the 2007 cohort.

The absolute number of operations and the rate per 100,000 beneficiaries declined between 2002 and 2007, from 137.4 per 100,000 to 135.5 per 100,000. Rates of decompression alone and “simple” fusion declined over the interval, although raw data are not presented. The rate of “complex” fusion procedures increased, as did overall hospital charges. In 2007, 78% of surgical patients carried diagnoses of stenosis alone, while 22% carried additional diagnoses of scoliosis and/or spondylolisthesis. Of patients with stenosis alone, 79% had decompression without fusion and 21% had decompression with either “simple” or “complex” fusion. Of patients with scoliosis and/or spondylolisthesis, 25% had decompression alone while 75% had some type of fusion.

Complication data were only presented for the 2007 cohort. Major medical complications occurred in 3.1% of patients; wound complications occurred in 1.2%; mortality was 0.4% within 30 days of discharge. The proportion of patients with a major medical complication increased with increasing comorbidity score and complexity of surgery. The findings demonstrate appropriate trends given the current evidence based indications for these procedures and the limitations of data derived from an administrative data set.

METHODOLOGICAL REVIEW
The essence of any study distills to the rationale and subsequent research question or purpose. The question then dictates the appropriate study design. Deyo et al set out to enhance more “individualized decision making” for the surgeon and patient by answering three questions: one, trends in the use of surgical procedures; two, variables influencing complications; and three, health care utilization associated with lumbar spinal stenosis surgery. The methodology chosen to answer these research questions was through the use of an operational, administrative data set with all its attendant limitations. This data set was not collected for research purposes and, as such, has limited clinical information and no disease-specific outcome measures. This unfortunately is not the ideal design to provide answers to facilitate individualized decisions about patients with spinal stenosis.

A retrospective study using International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis and procedure codes in patients aged 65 years or older who underwent surgery for lumbar spinal stenosis during the study period were identified. Complications for surgeries performed between January 1, 2007, and December 1, 2007, were analyzed for major medical complications, wound complications and mortality. Adjustments were made for comorbidities, and resource use was estimated from the MedPAR data.

The proliferation of administrative medical databases and ready access to powerful computers and software make this type of retrospective observational study relative easy to perform, and similar studies have been published.3–11 These administrative databases are designed to answer questions around general trends and resource allocation. Extreme caution must be exercised in their interpretation or attempts to answer clinical questions, however, as the amount of clinically relevant information contained in the databases is generally minimal. International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis coding does not include any information regarding patients’ symptoms, for example, which is central to treatment decision-making. Secondary diagnoses were not included in the analysis of the 2002 group, adding potential error in the comparison. Also, nonclinician coding technologists are responsible for data entry, and may not include all relevant data. Finally, there are no data regarding patient clinical outcomes. Despite the authors’ comments to the contrary, the clinical effectiveness of the different treatments administered is unknown.

RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE
This study offers a very narrow, retrospective view of one aspect of spine care during a 5-year period for the elderly segment of the population. The authors have mined an exhaustive database and presented very selective information. For example, although the authors report a significant increase in fusion rate between 2002 and 2007 for complex surgical procedures, they have not presented secondary diagnosis information (scoliosis and/or spondylolisthesis) for the 2002 cohort. Our review of the presented 2007 data indicates
that 79% of stenosis patients underwent a decompression alone in the absence of scoliosis and spondylolisthesis. It is impossible to determine the indications for fusion that were employed in the remaining 21%. In addition, the method used to stratify surgical complexity appears arbitrary, potentially confounding results. Other confounding factors, such as changes in nonsurgical management, are not discussed. One example is that of lumbar epidural steroid injections, which have increased significantly within Medicare recipients, potentially reducing the number of borderline surgical candidates.12 The patients treated operatively may be those with more complex problems or more recalcitrant symptoms. Despite this and other confounding factors, the authors assume, without supporting data, that the patient population from 2007 is exchangeable with that from 5 years earlier; this central assumption may, in fact, be erroneous. Finally, without clinical outcomes data it is impossible to perform any meaningful comparison of the treatment choices in question. This descriptive, retrospective study of an administrative database is interesting but, given the significant limitations, should have no impact on either clinical practice or health care policy.

Factors Associated with Recurrent Back Pain and Cyst Recurrence after Surgical Resection of One Hundred Ninety-Five Spinal Synovial Cysts.

Xu R, McGirt MJ, Parker SL, et al. Spine 2010;35:1044–53. Synovial or ganglion-type cysts frequently arise from the facet joints and are most prevalent in the lumbar spine. Although their pathogenesis remains a matter of some debate, these cysts are thought to develop as a consequence of progressive degeneration and/or segmental instability. Depending upon their specific location within the spine, synovial cysts may bring about a myriad of symptoms including axial back pain, radicular deficits, neurogenic claudication, or even cauda equina syndrome. While it may be reasonable to attempt a trial of nonoperative care, a significant proportion of these cysts may ultimately require surgical intervention consisting of any number of decompressive techniques (most commonly laminectomy) with or without concomitant arthrodesis. The literature is rife with case reports and small series of synovial cysts, which were treated with a wide range of operative procedures; unfortunately, it has been difficult to glean any definitive therapeutic guidelines from this disparate collection of studies. In an attempt to further elucidate the natural history of these pathologic lesions and compare the outcomes associated with different surgical methods, Xu et al published the results of a large retrospective analysis of patients with symptomatic intraspinal synovial cysts who subsequently underwent surgical excision.13

STUDY SUMMARY

The study sample consisted of 167 consecutive individuals who presented to a single institution over a 19-year period for the surgical treatment of 195 symptomatic synovial cysts with mean follow-up of 16 ± 9 months; the vast majority of which localized to the lumbar spine (most commonly at the L4-L5 level). These patients were further segregated into one of four cohorts according to the operative procedure that had been performed to address these lesions—unilateral hemilaminectomy, bilateral laminectomy, facetectomy with in situ fusion, or facetectomy with instrumented arthrodesis. The incidence of postoperative cyst recurrence was 3%, all of which were observed in patients who had undergone an isolated decompression. The risk of recurrence was found to be significantly higher for the bilateral laminectomy group compared to those undergoing facetectomy with arthrodesis. While both axial and radicular pain initially improved regardless of the type of surgical intervention, a significant proportion of patients were found to have developed recurrent symptoms—21.6% recurrent back pain and 11.9% with recurrent radicular pain. The fusion groups demonstrated significantly lower rates of recurrent back pain compared to the decompression groups. On the basis of these results, the authors suggest that a decompression alone may confer a greater risk of recurrent back pain and cyst reformation which may be reduced with the addition of an instrumented arthrodesis.

METHODOLOGICAL REVIEW

The authors elucidated the outcomes of surgical decompression of symptomatic synovial cysts using a large series of cases compiled from multiple surgeons at a single institution. In this study, patients were retrospectively assigned into four different cohorts based on the review of operative reports (hemilaminectomy, bilateral laminectomy, facetectomy with in situ fusion, and facetectomy with instrumented fusion). Prognostic stratification was unable to be employed because these individuals were categorized post hoc. The baseline characteristics of the various groups appeared to vary widely limiting the ability to compare between cohorts; for instance, 68% of the patients undergoing instrumented arthrodesis were noted to have a spondylolisthesis deformity compared to only 7.8% of the hemilaminectomy cohort.

The fact that multiple different surgeons performed these procedures raises the possibility that there may have been considerable disparities in the care of these individuals, some of whom may have received additional therapy or medication during the postoperative period (i.e., cointervention). Although all of these patients were accounted for after their operations, the length of follow-up ranged from 1 to 36 months; in fact, 24-month data were only able to be collected for 71 of the 195 cases (36.4%).

The clinical outcomes that were recorded included rate of reoperation, cyst recurrence, and the presence of either mechanical low back or radicular pain; however, the manner in which these were quantified was largely undefined in the methodological section. As an example, the authors do not describe how cyst recurrence was diagnosed or the level of pain was measured. In addition, it has previously been shown that the retrospective evaluation of complications is less than ideal and tends to underestimate the true incidence of adverse events.14,15

Finally, there are no fewer than 42 P values reported in this study, which raises concerns about multiple comparisons that...
are being made as part of this analysis. As more and more statistical tests are utilized, the probability of finding a difference due to mere chance also increases.

RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE

Given the prevalence of these facet cysts, the optimal method for treating these lesions is of clear interest to spine practitioners. The authors have compiled the largest published series of patients with synovial cysts. Nevertheless, taking into account the inherent limitations of the experimental design, a lack of baseline comparability between the different cohorts, and the relative ambiguity of the clinical outcome measures, we do not recommend any changes in clinical practice based on the results of this investigation. To definitively determine which surgical procedure is best for addressing symptomatic intraspinous cysts, individuals will need to be prospectively and randomly assigned to each treatment group and followed for a minimum of 2 years. Furthermore, postoperative outcomes should be assessed using validated instruments and the effect size of each intervention should be more precisely represented by calculating appropriate CIs. In the meantime spine surgeons must rely on their clinical experience and expertise along with indirect evidence to effectively treat this condition.

Does an Interspinous Device (Coflex™) Improve the Outcome of Decompressive Surgery in Lumbar Spinal Stenosis? One-Year Follow-up of a Prospective Case Control Study of 60 Patients.


While laminectomy has been shown to be generally effective for relieving neurogenic claudication secondary to spinal stenosis, interspinous devices have recently been introduced as a potential alternative to decompression with or without arthrodesis as a treatment for this condition. The Coflex device (Paradigm Spine, New York, NY) is a compressible “U”-shaped titanium implant which is designed to be placed between two consecutive spinous processes following a microsurgical decompression where it is intended to unload the facet joints, maximize foraminal height, and stabilize the spinal column. Because the Coflex is thought to protect the degenerative segment while limiting the forces on adjacent levels, it has been suggested that the insertion of this device may preclude the need for a fusion. The Coflex implant is currently being evaluated in the United States as part of a multicenter Food and Drug Administration Investigational Device Exemption (FDAIDE) trial but this technique has already been employed in Europe as an adjunct to lumbar decompression for spinal stenosis. Nevertheless, up to this point there has been a paucity of data derived from prospective, randomized investigations establishing the safety and efficacy of this device. Richter et al report the findings of a prospective study comparing the outcomes of patients treated with a simple decompression for one or two levels of spinal stenosis to those treated with a simple decompression and introduction of the Coflex device.

STUDY SUMMARY

In this prospective cohort investigation in which there was no randomization, the study population consisted of 60 subjects enrolled at a single institution who underwent a one- or two-level microsurgical decompression either alone or in conjunction with the implantation of Coflex devices for symptomatic spinal stenosis with or without stable Grade 1 degenerative spondylolisthesis deformities. Postoperatively, both cohorts demonstrated significant improvements in pain and disability scores at all time points (3, 6, and 12 months) regardless of the operation that had been performed; however, at 1-year follow-up there were no statistically significant differences between the clinical outcomes recorded for the two groups. Thus, the authors conclude that the implantation of the Coflex device did not appear to confer any additional benefits relative to an isolated decompression for the treatment of patients with spinal stenosis and symptomatic neurogenic claudication.

METHODOLOGICAL REVIEW

With the prospective cohort design of this study, patients were allocated to one of the two intervention groups according to the judgment of the surgeon at the time of the operation; however, the rationale for making these decisions is not discussed. It should also be noted that a total of 150 individuals were initially followed in this investigation but only 60 subjects were actually included in the analysis, leaving a significant number of patients who are not accounted for in the methodological section. Furthermore, the baseline characteristics of the two treatment groups are not elucidated in any great detail, which raises concerns about their comparability. Although multiple outcome measurements were assessed such as the Oswestry Disability Index, Roland-Morris score, VAS, and pain-free walking distance, the authors did not utilize a patient-driven instrument that is specific to a diagnosis of spinal stenosis (e.g., Zurich Claudication Questionnaire). Finally, given that there were no significant differences between the clinical results of the two cohorts at 1 year, the sample sizes and study power must be shown to be adequate to ensure that a null result does not simply represent a Type II (i.e., “false negative”) error; unfortunately, these critical issues were not addressed in this investigation.

RECOMMENDATION ON IMPACT TO CLINICAL PRACTICE

This study has extensive limitations and although some degree of safety has been established, efficacy has not. Efficacy may be definitively established by the results of long-term, prospective, randomized research investigations, which are currently underway in the United States as part of a FDA IDE trial; however, it is unusual for a prospective series to show equivalence (assuming power) and a randomized trial superiority. Until this high-quality evidence becomes available, we do not believe that these findings warrant any change to clinical practice and further data is necessary to justify the adoption of this technique.
References

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