

Journal Review II

By Ron Feise, DC

Spinal Surgery Cost-Effective?

Søgaard R, Bungert CE, Christiansen T, Høy K, Eiskjaer SP, Christensen FB. Circumferential fusion is dominant over posterolateral fusion in a long-term perspective: cost-utility evaluation of a randomized controlled trial in severe, chronic low-back pain. *Spine* 2007;32:2405-2414.

SYNOPSIS: This was a randomized, controlled trial that examined cost issues. A total of 146 patients were randomized to posterolateral or circumferential fusion and were followed 4 to 8 years after surgery. The mean age of the cohort was 46 years (range, 20 to 65 years); 61% were females; 49% were smokers; 30% had primary diagnosis of isthmic spondylolisthesis; 35% had disc

degeneration and no previous surgery; and 35% had disc degeneration and previous surgery. Eighty-two percent of patients had symptoms for more than 2 years, and 50% were out of the labor market because of sickness. Costs were calculated for 2004 U.S. dollars.

Table 1. Summary of Costs in a Long-term Perspective of 4 to 8 Years of Follow-Up in Patients Having Lumbar Spinal Fusion

Mean Cost per Patient in Surgical Group (*values are discounted 2004 U.S. dollars*)

Cost Perspective	Posterolateral (n=73)	Circumferential (n=73)
Primary health care	8,196	5,053
Secondary health care	30,240	20,940
Patient costs	26,558	25,157
Society costs	3,363	4,473
Total	68,567	55,624

RESEARCH QUALITY:

Overall, this study had reasonable methodological rigor.

Quality Details: This study used the following: 1) appropriate design; 2) clearly stated inclusion and exclusion criteria; 3) concealed randomization assignment; 4) treatment methods described; 5) valid, reliable, and relevant outcome measures; 6) suitable measurement period; 7) acceptable sample size; 8) groups clinically similar at the start of the trial; and 9) acceptable loss to follow-up.

CONCLUSION: Circumferential fusion is less costly than instrumented posterolateral fusion.

COMMENTS: *Previous research findings question the cost-effectiveness of lumbar fusion.¹ Regardless of which surgical procedure is performed, these interventions have a hefty price tag. Health care costs for lumbar fusion are between \$26,000 and \$38,000 per patient over a 4- to 8-year time frame. Using conservative numbers (\$25,993 for health care costs over a 6-year period), these patients use \$4,332 per year per patient for health care. This would equate to over 61 visits to a chiropractic office every year for a 6-year period (chiropractic office visit=\$70). Moreover, spinal surgery is without convincing data of effectiveness.²*

The Medicare Evidence Development and Coverage Advisory Committee convened in November 2006 to provide recommendations to the Centers for Medicare and Medicaid Services on the quality and strength of evidence for the benefits and risks of spinal fusion surgery for chronic low-back pain from lumbar degenerative disc disease in the Medicare population.²

The committee identified 4 randomized, controlled trials that yielded mixed results. Three of 4 studies did not show a clinically important benefit. Only one study demonstrated clinical benefit.³ Other data presented were from low-quality studies such as case series and cohorts. Additionally,

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there was a paucity of data regarding safety. The advisory committee stated that the likelihood of improvement in clinical outcomes from fusion compared with conservative treatment during short-term (<2 years) and long-term (>2 years) follow-up was not superior. The panel's vote of uncertainty reflected the lack of scientific evidence of effectiveness.

This conclusion is supported by previous research. To date, fusion has failed to demonstrate effectiveness sufficiently large to meet the FDA threshold for a clinically meaningful benefit in a consistent manner, and there are no data suggesting how to select patients for a favorable outcome.^{4,5} Moreover, structured rehabilitation with a cognitive

behavioral component demonstrated superiority over surgery in terms of pain and function with no complications.^{6,7}

The rationale for performing fusion is that it should reduce abnormal motion and, therefore, reduce pain and reduce the need for additional surgery. Lumbar reoperation is an unwanted result, indicating unremitting symptoms, advancement of the underlying disease, or complications related to the initial operation. Moreover, second surgeries frequently yield even worse results than the initial operation.⁸ Thus, surgeons and their patients generally aim to prevent the need for a repeat lumbar operation. A recent study, however, found a 19% reoperation rate.⁹ Moreover, patients who had lumbar surgery for

degenerative disease in the late 1990s were more likely to undergo a repeat operation than patients who had surgery in the early 1990s.¹⁰ Additionally, another research team found that fusion techniques have not improved disability or complication rates.¹¹

America has the highest rate of spinal surgery in the world, about 5 times greater than the United Kingdom.^{12,13} Moreover, lumbar fusion surgery rates in the United States increased 220% from 1990 to 2001.¹³⁻¹⁵ Considering the failure of spinal fusion to demonstrate effectiveness, cost-effectiveness, or safety for lumbar degenerative disc disease and its overutilization, surgery should be avoided.

Spinal Injections Lack Scientific Support

Abdi S, Datta S, Trescot AM, Schultz DM, Adlaka R, Atluri SL, Smith HS, Manchikanti L. Epidural steroids in the management of chronic spinal pain: a systematic review. *Pain Physician* 2007;10:185-212.

SYNOPSIS: This was a systematic review to evaluate the effect of various types of epidural steroid injections for chronic spinal pain in the neck and low-back regions. Data sources included relevant literature in English and manual searches of bibliographies of known primary and review articles and abstracts from scientific meetings. Three reviewers independently assessed the trials for the quality of their methods.

RESEARCH QUALITY:

Overall, this study had poor methodological rigor.

Quality Details: This study used the following: 1) a focused question; 2) stated inclusion and exclusion criteria; 3) a clearly described, thorough search of the literature; 4) multiple independent reviewers appraising the studies; 5) an assessment of the studies; and 6) a description of the data extraction process.

This study failed with the following: 1) This review combined quality studies with poor-quality studies. This is inappropriate for systematic reviews and is by itself a fatal flaw that negates the authors' conclusions. Including studies of inferior quality on the same foundation as those of elevated quality is unac-

ceptable (the "garbage in, garbage out" phenomenon); 2) The authors did not define clinical benefit. Thus, we have no idea if 1 point, 10 points, or 20 points of improvement on a 100-point scale demonstrates clinical benefit in the eyes of these reviewers.

CONCLUSION: The authors concluded that there was evidence supporting the use of epidurals.

COMMENTS: Previous reviews do not support this current review. In a systematic review for low-back pain and sciatica, Koes found that quality studies showed inconsistent results for epidural steroid injections and concluded that the efficacy of epidural steroid injections has not been established.¹⁶ Another systematic review found that the effectiveness

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of epidural steroids in common low-back pain and sciatica was inconsistent (5 trials demonstrated greater pain relief within the first month in the steroid group as compared to the control group, but 8 trials found no measurable benefits).¹⁷ A Cochrane review of injection therapy for subacute and chronic benign low-back pain concluded that convincing evidence is lacking regarding the effects of injection therapy on low-back pain.¹⁸ More recently, an international research team concluded that at present, there is no evidence to support the use of corticosteroid injections as treatment options for lumbosacral radicular symptoms.¹⁹ Additionally, numerous potential adverse reactions have been associated with cervical epidural steroid injections. Although the vast majority are minor and transient in nature, seri-

ous complications, including death, may also result.²⁰

In the absence of data supporting the effectiveness of injection, a worrisome trend is occurring. Between 1994 and 2001, there was a 271% increase in lumbar epidural steroid injections and a 231% increase in facet injections.²¹ Claims of effectiveness of epidural steroids are based on lower-quality research designs, not double-blinded, randomized clinical trials. Convincing evidence is lacking regarding the effects of injection therapy on spinal pain.

Warning. Practitioners should not automatically use information from research studies to make decisions about patient care, because health care literature suffers from inconsistent quality and frequently distorts research findings. Before relying on the findings of a research study, a practi-

tioner should perform a critical appraisal to determine whether the conclusion is supported by the study's data. He or she should also locate and examine previous relevant research in order to integrate the current findings and form a conclusion based upon the preponderance of quality evidence. Even conclusions from multiple studies do not provide a definitive answer. Rather, they indicate the *direction* of the evidence. ■

These reviews are excerpts from Direction of the Evidence, published by the Institute of Evidence-Based Chiropractic, whose aim is the integration of science into chiropractic practice in order to improve patient outcomes. Dr. Feise can be reached at rjf@chiroevidence.com.

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