

Is spinal surgery effective for back pain?

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Abstract

There have only been a few randomized controlled trials of surgical treatment of chronic low back pain caused by degenerative disc disease. Fusion surgery has been compared primarily with nonoperative treatment, whereas disc arthroplasty has been compared with fusion surgery. The results for either of the two surgical procedures are modest in terms of pain relief and improved function.

Introduction and context

Surgical procedures are quite commonly used as a treatment for chronic low back pain assumed to originate from the intervertebral disc. Although there are a large number of outcome studies, only a few randomized controlled trials have been performed. Randomized controlled trials are important since they offer the strongest evidence for treatment effect. Randomization reduces biases from known and unknown confounders, and typically (but not always), randomized trials are more rigorous in their collection of data and in measuring outcomes and reporting them. Because it is difficult to conduct placebo-controlled trials of surgical procedures and difficult to conduct sham trials, most studies compare surgery with nonoperative care or one surgical procedure with another. Surgery and nonoperative care are often treated as 'black boxes', that is, they are treated without regard to variations in technique and skills, and adaptations to different patients. Additionally, the risk of undertreatment in the comparison group can occur, and - not infrequently - there may be variation in cotreatment between groups. Problems also arise following crossover between treatment groups, as this tends to systematically reduce differences in outcomes between control and experimental subjects, reducing the value of randomization. The preferred statistical analysis is an intention-to-treat analysis, in which outcomes are analysed based on the assigned treatment arm. Although

this does preserve the value of randomization, it raises the question of whether it is appropriate to consider a patient surgical if he or she actually did not have a surgical procedure.

Recent advances

Three randomized controlled trials of fusion for low back pain and two controlled trials of disc arthroplasty have been published in recent years. These studies provide data that allow an appraisal of how effective surgery is for the treatment of chronic low back pain.

The study of Fritzell and colleagues [1] showed that fusion was more effective than conservative care. The study of Brox and colleagues [2] found fusion to be no more effective than cognitive therapy and exercises. The study of Fairbank and colleagues [3] found fusion to be minimally more effective than a rehabilitation program. Improvements in Oswestry Disability Index (ODI) were from 47.3 to 35.7 in the Fritzell study, from 42 to 26 in the Brox study, and from 46.5 to 34 in the Fairbank study.

As pointed out by Mirza and Deyo [4], the mean improvements in ODI achieved in two of these studies [1,3] were less than the threshold of 15 points that the US Food and Drug Administration considers to be the minimal clinically important change (MCIC). The Brox

study exceeded this threshold by 0.6 points. In the Fritzell study, only 29% of patients rated themselves as 'much better'. No patient was reported as having been rendered free of pain. The other two studies did not report this outcome. The Fairbank study reported a change in mean scores for bodily pain from 28.6 to 48.1. In the Brox study, pain scores improved by 20 points (from 60 to 40), which barely equals the MCIC for back pain.

Blumenthal *et al.* [5] compared disc arthroplasty, using a particular device, with a form of anterior lumbar interbody fusion. Zigler *et al.* [6] compared arthroplasty, using a different device, with circumferential fusion. Although the Blumenthal study found disc arthroplasty to be not inferior to fusion, the outcomes of arthroplasty were modest. Mean pain scores improved by 40 points (from 70 to 30), which exceeds the MCIC of 20 points, and ODI improved from 50 to 25. But 64% of patients treated by surgery still took opioids, and although 64% returned to work, 53% had been working before surgery. These latter figures do not attest to any decrease in the burden of illness; surgery did not seem to alter the patients' use of other health care services, or their ability to work.

The Zigler study found disc arthroplasty to be slightly more effective, on average, than circumferential fusion, but it too reported only modest results for both surgical treatments. For arthroplasty, ODI improved from 63.4 at inception to 34.5 at 24 months, but with a standard deviation of 24.8. This latter figure indicates that a substantial proportion of patients were still substantially disabled. Pain scores improved from just above 70 to 37, with a standard deviation of 30.1. This study judged outcomes as a success if the ODI improved by 15 points. On this basis, a 72% success rate was claimed. But this misrepresents MCIC. The MCIC does not amount to the least value at which success occurs. It is no more than the least value that patients equate with a detectable level of improvement. The study did not report the proportion of patients rendered substantially better or free of pain. Of patients considered to have a successful outcome, 39% still took opioids, which seems contradictory.

These results from controlled trials of arthroplasty are starkly inferior to those of a well-reported descriptive study. In the study of Bertagnoli *et al.* [7], mean pain scores improved from 7.5 to 3 and ODI improved from 54 to 29. At 2 years, 32% of patients had no back pain, 59% had only occasional pain, 90% took no opioids, and only 41% required nonsteroidal anti-inflammatory drugs for pain.

Implications for clinical practice

Surgeons and others believe that surgery is effective for back pain. They base this belief either on their own experience or on observational studies. This belief is, by and large, not vindicated by the outcomes in well-reported clinical trials. Those trials indicate that only a small proportion of patients do well from surgery. If surgeons achieve better outcomes than those reported in the controlled trial literature, the community would benefit from the publication of those outcomes. In the absence of contradicting evidence, the benefits of surgery must be regarded as small. Because improvements from surgery are small and because not all patients benefit, it becomes critically important to carefully select patients in whom fusion surgery is performed for chronic back pain. Furthermore, it is important that patients have a clear understanding of the procedure and its potential results and complications so that they can participate in the decision.

Differences in results from one study to another may be explained by the selection of patients, but the surgical procedure itself and its performance are likely to influence outcomes as well. In an editorial, Fritzell [8] posed the question: 'is surgical treatment consistent with evidence-based medicine?', and answered it with: 'yes, in selected patients'. But surgeons have not yet articulated the definition of the correctly selected patient, and tested it prospectively. The reputation of surgery rests on the observation, after treatment, that some patients sometimes do well, with some procedures. That is little solace to the majority of patients who do not do well, who suffer complications, or who are rendered worse by surgery.

Abbreviations

MCIC, minimal clinically important change; ODI, Oswestry Disability Index.

Competing interests

The authors declare that they have no competing interests.

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