

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.

Part 7: intractable low-back pain without stenosis or spondylolisthesis

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Recommendations

Standards. Lumbar fusion is recommended as a treatment for carefully selected patients with disabling low-back pain due to one- or two-level degenerative disease without stenosis or spondylolisthesis.

Guidelines. There is insufficient evidence available to support a treatment guideline.

Options. An intensive course of physical therapy and cognitive therapy is recommended as a treatment option for patients with low-back pain in whom conventional medical management has failed.

Rationale

Lumbar spinal fusion procedures are presently being provided as a treatment for patients with low-back pain due to lumbar degenerative disease without stenosis or spondylolisthesis. These procedures are associated with significant cost and the potential for complications. There has been considerable debate regarding the role, if any, of lumbar fusion for the treatment of patients with low-back pain without deformity or neurological deficit. The pur-

pose of this review is to evaluate the published literature regarding the use of lumbar fusion in this patient population.

Literature Search

The database of the National Library of Medicine was searched using the search terms “spinal fusion and randomized clinical trial,” “lumbar fusion and randomized clinical trial,” “spinal fusion and outcomes,” “lumbar fusion and outcomes,” and “lumbar fusion and physical therapy.” The Cochrane Central Register of Controlled Trials was searched using the search term “spinal fusion.” Reference lists from relevant papers as well as from the Cochrane Review⁴ were reviewed, and all randomized clinical trials comparing lumbar fusion with nonoperative management were identified. Both of these trials are identified in Table 1. A number of case series, cohort studies, and studies evaluating different fusion techniques were also identified and provide supportive scientific evidence.

Scientific Background

In 1999, Gibson, et al.,⁴ published an evidence-based review of the literature regarding the surgical treatment of lumbar spondylosis by using the protocol developed by the Cochrane Review. These authors identified 26 RCTs dealing with surgical management of lumbar spondylosis

Abbreviations used in this paper: GFS = General Function Scale; ODI = Oswestry Disability Index; PLF = posterolateral fusion; RCT = randomized controlled trial; VAS = visual analog scale.

TABLE 1

*Summary of studies involving patients with intractable, chronic low-back pain**

Authors & Year	Class	Description	Comment
Fritzell, et al., 2001	I	RCT of fusion vs conservative care in patients w/ CLBP. All 3 fusion groups fared better on all outcome measures.	Lumbar fusion is an effective treatment for CLBP in patients who fail conservative measures.
Brox, et al., 2003	III	RCT of intensive physiotherapy vs instrumented PLF in patients w/ CLBP. No significant difference noted in primary outcome measure; however, patients in op group did better in terms of leg & back pain. Patients in physiotherapy group did better on psychological assessments & in flexibility testing. Small sample size precludes definitive conclusions.	Intensive physiotherapy may be effective alternative to instrumented PLF in patients w/ CLBP who fail conservative measures.

* CLBP = chronic low-back pain.

including disc herniation and degeneration. None of the trials identified specifically involved the issue of lumbar fusion compared with conservative management of patients with low-back pain. Because of the absence of Class I medical evidence regarding the efficacy of lumbar fusion, the authors concluded that "There is no scientific evidence on the effectiveness of any form of surgical decompression or fusion for degenerative lumbar spondylosis compared with the natural history, placebo, or conservative management."

In 2001, Fritzell and colleagues³ published the results of a multicenter RCT from the Swedish Lumbar Spine Study Group. In their study, 294 patients with disabling back pain thought to be surgical candidates were randomized to conservative care (physical therapy supplemented with education and other pain-relieving technologies at the discretion of the treating physician), or one of three surgical treatments. Patients were required to have suffered from low-back pain for at least 2 years and were required to have radiographic and clinical evidence of spondylosis at L4–5, L5–S1, or both levels. Surgery was performed by one of 26 participating surgeons and consisted of either PLF, PLF supplemented with pedicle screw fixation, or interbody fusion supplemented with PLF and pedicle screw fixation. The groups were comparable in all measured demographic variables with the exception of a higher incidence of medical comorbidity in the surgical group. Patients were followed for 2 years with intermediate evaluations at 6 months and at 1 year following treatment. Results were assessed using multiple well-validated outcome measures including pain VASs, the ODI for low-back pain, the Million VAS, the GFS, Work Status, a patient satisfaction survey, and an independent functional assessment by a second spine surgeon.³

Follow up was achieved in 98% of the patients enrolled in the study. Appropriate statistical analysis was performed based on the type of data derived from the different outcome measures. The surgical group did statistically significantly better than the conservatively treated group in terms of pain relief, degree of disability as measured by the ODI, Million, and GFS, return-to-work status, and degree of satisfaction reported by the patients and by the independent observer. The authors' statistical analysis was rigorous and included "intention to treat" as well as "worst case" scenarios. All primary outcome measures evaluated in the study were statistically significantly better in patients ran-

domized to the surgical group compared with the nonsurgical group.³ This study provides Class I medical evidence that demonstrates that lumbar fusion is associated with better outcomes than conservative care for appropriately selected patients with disabling low-back pain. Consideration for surgery should be reserved for those patients with persistent pain thought to arise from one or two motion segments despite the best medical management available to the patient.

The study by Fritzell and colleagues,³ despite its rigorous design and robust results, has been criticized by proponents of various specific therapies. Mooney,⁷ for example, commented that the study was unfairly biased against conservative care because a trial of the same type of therapy had already failed in the enrolled patients prior to entry into the study.

In 2003, Brox, et al.,² conducted a smaller randomized study evaluating the relative efficacy of instrumented PLF compared with a specific protocol of cognitive intervention and physical therapy. In their study, patients were required to have suffered low-back pain for 1 year and have an ODI score of 30 to 100 and radiographic evidence of degeneration at L4–5, L5–S1, or both. The primary outcome measure used was a modified ODI (modified for the Norwegian population). This particular outcome measure was previously studied in the target population and found to be reliable, although the authors specifically stated that up to a 12-point difference on the scale may be attributed to random error.^{1,5,6} Secondary outcome measures included pain VASs, daily use of medication, GFS, the Waddell Fear Avoidance Belief Questionnaire, and a patient satisfaction score. Outcomes were assessed by physical therapists or rehabilitation physicians at 1 year following initiation of treatment.

Patients randomized to the surgical arm were treated with instrumented PLF. Postoperative physical therapy was variably used at the discretion of the surgeon and was not codified. The patients enrolled in the physical therapy arm underwent a program specifically designed for patients with low-back pain that was thought to be more effective than standard conservative care based on a previous study.¹ This more comprehensive program included significant cognitive therapy designed to lower patient fear as well as supervised physical therapy averaging 25 hours per week for 8 weeks. Because of the intensity of the program, most patients stayed at the treatment center in patient hotels. This