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## **Randomized Study Indicates That Patients With Herniated Disk Improved With or Without Surgery**

CHICAGO – Patients with lumbar disk herniation who had surgery or nonoperative treatments showed similar levels of improvement in the reduction of pain over a 2-year period, according to a randomized trial in the November 22/29 issue of *JAMA*. In all cases patients who had surgery did slightly better.

Lumbar discectomy (surgical removal, in part or whole, of an intervertebral disk) is the most common surgical procedure performed in the United States for patients having back and leg pain. The vast majority of the procedures are elective. However, lumbar disk herniation (protrusion from its normal position) is often seen on imaging studies in the absence of symptoms and can regress over time without surgery, according to background information in the article. High variation in regional discectomy rates in the U.S. and lower rates internationally raise questions regarding the appropriateness and effectiveness of some of these surgeries, compared to nonoperative care, with evidence inconclusive on the optimal treatment.

James N. Weinstein, D.O., M.Sc., of Dartmouth Medical School, Hanover, N.H., and colleagues compared the outcomes of surgical and nonoperative treatment for lumbar intervertebral disk herniation in the Spine Patient Outcomes Research Trial (SPORT), which included both a randomized trial study group and an observational study group who declined to be randomized in favor of designating their own treatment.

The randomized clinical trial enrolled patients between March 2000 and November 2004 from 13 multidisciplinary spine clinics in 11 U.S. states. The participants included 472 patients (average age, 42 years; 42 percent women) who were candidates for surgery, with imaging-confirmed lumbar intervertebral disk herniation and persistent signs and symptoms of radiculopathy (involvement of the spinal nerve roots characterized by pain that radiates from the spine, such as down the leg) for at least 6

weeks. Patients were randomized to undergo discectomy (n = 232) vs. nonoperative treatment (n = 240), which included physical therapy, education/counseling with home exercise instruction, and nonsteroidal anti-inflammatory drugs, if tolerated. There was follow-up at 6 weeks, 3 months, 6 months, and 1 and 2 years.

The researchers found that adherence to assigned treatment was limited: 50 percent of patients assigned to surgery received surgery within 3 months of enrollment, while 30 percent of those assigned to nonoperative treatment received surgery in the same period. Intent-to-treat analyses (in which group outcomes were assessed based on the therapy to which the patient was initially assigned) demonstrated substantial improvements for all primary (pain and physical function measures) and secondary outcomes (sciatica severity, satisfaction with symptoms, self-reported improvement, and employment status) in both treatment groups. The intent-to-treat analysis likely underrepresents the true treatment effect, while the as-treated analysis likely overestimates the true treatment effect.

“Patients in both the surgery and nonoperative treatment groups improved substantially over the first 2 years,” the authors write. “Between-group differences in improvements were consistently in favor of surgery for all outcomes and at all time periods but were small and not statistically significant except for the secondary measures of sciatica severity and self-rated improvement. Because of the high numbers of patients who crossed over in both directions, conclusions about the superiority or equivalence of the treatments are not warranted based on the intent-to-treat analysis alone.”

(*JAMA*. 2006;296:2441-2450. Available pre-embargo to the media at [www.jamamedia.org](http://www.jamamedia.org).)

Editor’s Note: Please see the article for additional information, including other authors, author contributions and affiliations, financial disclosures, funding and support, etc.

## **Observational Study Demonstrates that Patients Who Chose Surgery Had Greater Improvement**

In the companion article, which was the observational study of SPORT, patients with persistent sciatica who had discectomy or usual care reported improvement over 2 years, although patients who chose surgery experienced greater improvement.

The observational study group, treated at 13 spine clinics in 11 U.S. states between March 2000 and March 2003, included patients who met SPORT eligibility criteria but declined randomization. Of the 743

patients enrolled in the observational cohort, 528 patients received surgery and 191 received usual nonoperative care.

At 3 months, patients who chose surgery had greater improvement in the primary outcome measures of bodily pain, physical function, and on a disability index. These differences narrowed somewhat at 2 years.

“In this nonrandomized evaluation of patients with persistent sciatica from lumbar disk herniation who had operative or usual care, both treatment groups improved considerably over 2 years. Nonrandomized comparisons of self-reported outcomes are subject to potential confounding and must be interpreted cautiously. Nevertheless, patients who underwent discectomy had significantly better self-reported outcomes than those who had usual care,” the authors conclude.

(*JAMA*. 2006;296:2451-2459. Available pre-embargo to the media at [www.jamamedia.org](http://www.jamamedia.org).)

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