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## To Have Surgery or Not? In Cases of Herniated Disk With Leg Pain, Dartmouth-led Landmark Studies Show Surgery Is Better Than Non-Operative Treatment

Lebanon, NH – The first in a series of groundbreaking papers that look at the efficacy of common back surgery over non-surgery shows that in cases of disk herniation with severe pain, patients who have surgery experience better outcomes than patients who undergo non-operative treatment. However, both surgical and non-surgical patients show considerable improvement in their functionality and quality of life one and two years after their initial symptoms.

The findings are part of the 5-year, \$15 million, 11 state Spine Patient Outcomes Research Trial (SPORT), funded by the National Institutes of Health. They are significant because they mark the first time the effectiveness of disk surgery has been measured in a unique trial involving both randomized and observational cohorts. They appear in the November 22<sup>nd</sup> issue of the Journal of the American Medical Association (JAMA).

“What we found is that for patients who come to us with severe back and leg pain and have surgery, there is an advantage in terms of how they feel overall one and two years out from the surgery,” said James N. Weinstein, DO, MSc, lead author and Chairman of the Departments of Orthopaedics at Dartmouth Medical School and Dartmouth-Hitchcock Medical Center.

However, he said, in cases where pain is tolerable and a patient’s lifestyle allows it, non-surgical treatment can be very effective. “In those cases, we saw that patients who did not have surgery, but treated their symptoms with physical therapy, over-the-counter pain medications and other non-surgical treatments, also improved substantially, reporting a quality of life close to what the surgical patients reported a year after their surgery.

“This new information will make it possible for physicians to share outcomes with their patients and allow them to make more informed choices about whether to have the surgery or not,” he said.

Lumbar discectomy is the most common surgical procedure in the United States for patients with back and leg pain. And back pain is one of the most frequent ailments in America, second only to the common cold as the cause of doctor visits and absences from work. 30 percent of Americans experience back pain on any given day; 80 percent of Americans will experience back problems at some time in life. The overall cost of back pain in direct medical charges and lost productivity is estimated to be between \$30-\$70 billion a year in the U.S.

And yet, up until now, there were only relatively small studies available to provide evidence specifically addressing whether discectomy and two other of the most commonly-performed back surgeries actually make a positive difference for patients over more conservative, non-surgical treatments. In 1999, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health (NIH), funded the SPORT study in hopes of measuring the efficacy and cost-effectiveness for these procedures. The disk herniation study results are the first to be published.

“As a surgeon who works with disk herniation patients, this research is extremely valuable,” Weinstein said. Clearly, those patients experiencing severe back and leg pain as a result of pressure on the nerve will benefit immediately and substantially from surgery. But for those patients where the pain is tolerable, they need to know that non-surgical treatment can yield longterm results that are close to what surgical patients experience. What it comes down to is a patient’s values, preferences, and what works for them in their life situation - *an informed choice.*”

The trial is unusual in that it followed a group of patients who allowed themselves to be “randomized” in traditional fashion (meaning that they agreed that a flip of the coin would decide if they received surgery or not), as well as an “observational” group, who would not agree to be randomized, but did agree to be followed and have their results reported as part of the trial. This unprecedented structure allowed the researchers to compare real-life patterns and outcomes with those of the randomized group.

What scientists found was that the trends and results were remarkably similar for the two groups. This is important because although randomized trials are considered to be the “gold standard” in clinical trials, people have questioned whether the population that will agree to be randomized are indeed representative of the population at large. The similarities between the two groups in this study add credibility to the findings, according to the authors.

Of the 1244 patients enrolled in the two groups, 760 had surgery and 484 did not. Because of crossovers – patients randomized to one arm of the study choosing to move to the other, largely because of changes in their condition, the findings are not considered conclusive. However, at every stage, the authors observed that patients who had surgery reported better outcomes.

Papers on the two other back conditions being studied – spinal stenosis and spinal stenosis with degenerative spondylolisthesis – are expected to be published in 2007.

Co-authors on the disk herniation study papers were Jon D. Lurie MD, MS, Tor Tosteson ScD, Jonathan A. Skinner PhD, Anna N.A. Tosteson ScD, Brett Hanscom MS, and William A. Abdu MD, MS, all of Dartmouth; Richard Deyo MD, MPH, University of Washington; Todd Albert MD and Alan S. Hilibrand MD, Rothman Institute at Thomas Jefferson University; Scott D. Boden MD, Emory University; Harry Herkowitz MD and Jeffrey Fischgrund MD, William Beaumont Hospital; Frank Cammisa MD, Hospital for Special Surgery.

Centers participating in the study in addition to Dartmouth were:

Wm. Beaumont Hospital, Royal Ok, MI  
Emory University, Atlanta, GA  
NYU/Hospital for Joint Diseases, New York, NY  
Hospital for Special Surgery, New York, NY  
Kaiser Permanente, Oakland, CA  
Nebraska Foundation for Spinal Research, Omaha, NE  
Rothman Institute @ Thomas Jefferson Hospital, Philadelphia, PA  
Rush Presbyterian-St. Luke's Medical Center, Chicago, IL  
University California-SF, San Francisco, CA  
University Hospitals of Cleveland/Case Western Reserve University, Cleveland, Ohio  
Washington University, St. Louis, MO  
Maine Spine and Rehabilitation, Scarborough, ME

For more information, go to: [www.dartmouth.edu/sport-trial](http://www.dartmouth.edu/sport-trial)