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Implications of the Spine Patient Outcomes Research Trial in the clinical management of lumbar disk herniation

SPORT could not answer the question it posed, but it does give us some guidance

THE ARTICLE BY Mazanec and Okereke in the current issue of the *Cleveland Clinic Journal of Medicine*¹ critically evaluates the recently published Spine Patient Outcomes Research Trial (SPORT),^{2,3} which compared the surgical and nonoperative management of patients with lumbar disk herniation. As these authors point out, because a large number of patients in the randomized arm of the study did not actually receive the treatment they were randomized to receive, SPORT did not achieve its stated goal of accurately comparing surgical with nonoperative treatment of lumbar disk herniation and therefore could not provide the answer to the question it posed.

So what information does SPORT offer for patients with lumbar radiculopathy? And as importantly, what guidance does it provide to clinicians who treat these patients?

■ RESULTS FROM THE SPORT RANDOMIZED ARM

The randomized arm of SPORT² encountered a significant crossover from the nonoperative group to the surgery group. By 3 months, 30% of those randomized to nonoperative management had undergone surgery, and by 2 years the number had risen to 45%. In addition, there were significant demographic and symptomatic differences between patients crossing over to surgery and those who remained in the originally assigned nonoperative group. These differences make head-to-head comparisons of the outcome of the two groups potentially inaccurate.

Furthermore, only 60% of patients assigned to the surgical group actually had

surgery within the 2-year study period. This crossover between both groups was significant, such that there was a difference in surgery rates between the two groups of only 14% to 20% at every evaluation period. This contaminated the results and made it difficult to draw conclusions about the efficacy of surgery relative to nonoperative treatment.

The data were analyzed in two ways: as an *intention-to-treat analysis* and as an *as-treated analysis*.

The intention-to-treat analysis evaluated outcomes based on the original group to which patients were assigned, regardless of whether or not they crossed over to the other group or failed to undergo the treatment to which they were assigned. This analysis showed no statistically significant treatment effect for the primary outcome measures (Short Form-36 bodily pain and physical function scales and the Oswestry Disability Index), although there was a trend towards better outcome with surgery. There was a statistically significant advantage for surgery for some secondary outcome measures (sciatica severity and self-reported improvement).

The as-treated analysis, which evaluated outcomes based upon the treatment actually received, showed a statistically significant advantage for surgery at all follow-up periods.

■ RESULTS FROM THE SPORT OBSERVATIONAL ARM

SPORT also included an observational arm, consisting of a cohort of patients who chose not to be randomized.³ Patients in this cohort chose either surgery or nonoperative care, and

their outcomes were followed for 2 years.

Demographic differences between the two groups might have affected outcome. Interestingly, more patients choosing surgery in the observational cohort actually had it, compared with those randomized to surgery in the randomized trial (96% vs 60%). Similarly, fewer patients choosing nonoperative care in the observational cohort crossed over to surgery than those in the randomized trial (22% vs 45%). Outcome measures were statistically significant in favor of surgery at all follow-up periods between 3 months and 2 years, although the treatment effects narrowed by 2 years.

The results of the observational arm were comparable to those of the randomized arm on the as-treated analysis. However, patients in the observational arm had more symptoms and were more functionally impaired than those in the randomized arm, making direct comparisons between the two cohorts difficult.

■ RESULTS FROM A DUTCH TRIAL

A recent, randomized 1-year clinical trial from the Hague Spine Intervention Prognostic Study Group also evaluated and compared surgery and conservative treatment for sciatica.⁴ Like SPORT, that study analyzed outcome according to the intention-to-treat principle and had a high crossover rate (39%) for patients assigned to conservative treatment. Unlike in SPORT, a large majority (89%) of patients assigned to the surgical group in this study did undergo surgery. At 1 year of follow-up there were no significant differences between the two treatment groups for any outcome measure.

It should also be understood that nearly all randomized studies, including SPORT, tend to underestimate the effect of conservative or nonoperative treatment for patients with acute sciatica. Patients in such trials are preselected, since they have already failed to improve after a period of nonoperative treatment (lasting at least 6 weeks in SPORT and 6 to 12 weeks in the Dutch study) before being randomized into a clinical trial. Since many patients with sciatica show improvement within 6 to 12 weeks of the onset of symptoms,

randomized trials typically eliminate those patients who have responded to nonoperative treatment.

■ WHAT CAN WE LEARN?

What important points can we learn from SPORT,^{2,3} the Dutch study,⁴ and other randomized studies^{5,6}?

Lumbar disk herniation is generally a benign and self-limited condition. Nearly all studies that looked at the outcome of lumbar disk herniation have reported that the long-term outcome is favorable, regardless of how it is treated. Although most studies show that surgically treated patients do better than nonoperative patients initially, the difference between the two treatments diminishes over time, although ultimate clinical outcome in many studies, including the observational arm of SPORT, slightly favors surgery. Therefore, unless a patient has the very unusual condition of cauda equina syndrome causing bowel and bladder impairment, or unless he or she has progressive lower extremity weakness, there is no harm in pursuing nonoperative treatment rather than surgery. None of the nonoperative patients in SPORT experienced any catastrophic event, such as cauda equina syndrome.

The size and type of herniation should not play a major role in the decision for or against surgery. Although not addressed in SPORT, this point was mentioned in the Dutch study. Many patients are advised to have surgery if a large disk fragment (extruded or sequestered disk) is identified by magnetic resonance imaging. But in fact, large free fragments seem more likely to resorb spontaneously and therefore not to require surgery than smaller, well-contained disk herniations.

We should tell patients that the risks of surgery are minimal. The complication rate for lumbar microdiscectomy is very low, being less than 5% in the randomized arm of SPORT and 1.6% in the Dutch study. Dural tear was the most common adverse event, ranging in incidence from 4% to less than 1%.

We should explain to patients that they are making a lifestyle decision: either they temporarily modify their lifestyle to accommodate the pain from the disk herniation or they

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modify their back (ie, with surgery) to return more quickly to the lifestyle they wish to live. Either of the two choices is correct, and there is no evidence that either decision will compromise the long-term outcome.

In summary, patients need to know the generally favorable natural history of lumbar disk herniation in order to make an informed treatment decision. Unless there is bowel or bladder impairment or a progressive neurologic deficit, there is no imperative for surgery. Although surgery offers the patient a speedier recovery and a quicker return to normal activities than does nonoperative treatment, patients treated without surgery can expect to have a satisfactory outcome in the long term. ■

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CORRECTION

Obstructive sleep apnea

(JANUARY 2007)

The article, "The effect of obstructive sleep apnea on chronic medical disorders" by Dr. Nancy Collop (*Cleve Clin J Med* 2007; 74:72-78) contained a typographical error. On page 75, in a study by Turkington et al (*Thorax* 2004; 59:367-371) the mortality rate in stroke patients with obstructive sleep apnea was given as 5%. The rate was actually 45%.