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INTERPRETING THE SPINE PATIENT OUTCOMES RESEARCH TRIAL

Medical vs surgical treatment of lumbar disk herniation: Implications for future trials

ABSTRACT

The Spine Patient Outcomes Research Trial (SPORT) consisted of two parallel studies: an observational study and a randomized comparison of medical and surgical treatment of disk herniation. In the long term, patients did well with either treatment, and an intention-to-treat analysis found no difference in outcomes. However, at 2 years 40% of patients in the surgical group of the randomized study still hadn't had surgery, and 40% of the medical patients did have surgery, muddying the results. Surgery was superior according to an analysis by the treatment patients actually received, but the study has been criticized for methodologic shortcomings, and the topic remains controversial.

KEY POINTS

Patients with lumbar disk herniation and radiculopathy may improve with either medical or surgical treatment.

Surgical treatment may result in more rapid improvement than medical therapy but the differences diminish with time.

Patient preferences and comorbidities are important factors in the choice of treatment.

THE SPINE PATIENT OUTCOMES RESEARCH TRIAL (SPORT) was designed to compare the outcomes of surgical and nonsurgical treatment in patients who had had radicular pain for at least 6 weeks.[1,2] This multicenter trial found that both surgically and nonsurgically treated groups improved substantially over the 2-year study period. Though designed as an intention-to-treat study comparing medical and surgical outcomes, the study was compromised by a large number of patients who "crossed over" to the alternative treatment.

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SPORT has generated considerable discussion about the efficacy of medical vs surgical treatment in patients with lumbar radiculopathy and how best to manage patients with this relatively common disorder.

BEFORE SPORT

Lumbar disk herniation with radiculopathy is a common clinical problem, with a prevalence of 1% to 3% in adults.[3] Most patients who do not have cauda equina syndrome or progressive weakness are initially managed medically. However, if symptoms persist and are intolerable, surgical diskectomy is usually recommended. Diskectomy remains the most commonly performed lumbar surgical procedure in the United States, but rates vary by more than eightfold in different regions of the country.[4]

Before SPORT, only two randomized tri-

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als had compared medical and surgical treatment of diskogenic lumbar radiculopathy.

In a classic but dated study, in 1970 and 1971 Weber[5] randomized 126 patients to undergo surgery or physical therapy after a 2-week trial of bed rest in the hospital, and followed their outcomes for 10 years. Surgical patients had statistically superior outcomes at 1 year, but by the 4th and 10th years, the difference was no longer significant. The rates of recurrence and of recovery of muscle strength were the same in both groups.

Both surgical and medical treatments have evolved since then, as have the instruments available to measure outcome. In addition, 17 (28%) of the 60 patients in the medical group in the Weber study received surgical treatment.

Osterman et al,[6] in a smaller, more recent randomized trial, compared microdiskectomy and continued conservative management, consisting of physical therapy instruction and isometric exercises. The surgical patients recovered more quickly, but at 2 years the groups did not differ in a clinically significant way in terms of intensity of leg or back pain, subjective disability, or health-related quality of life.

Up to 1/3 of healthy people have disk herniations on imaging

Butterman,[7] in another recent randomized trial, compared epidural steroid injection (both fluoroscopically guided and blind) and surgical diskectomy in 100 patients with lumbar disk herniation who had not improved with noninvasive treatment. Though surgical treatment was clearly superior to epidural injection at 3 years, almost half of the epidural-injection group had a successful nonsurgical outcome.

Atlas et al[8] performed a large prospective, nonrandomized cohort study of patients recruited from multiple surgical and nonsurgical practices in Maine. Surgical patients reported greater satisfaction than the medical patients did at 10 years. However, no significant difference in work disability status or predominant symptom (back or leg pain) was found.

In these and smaller cohort trials, medical ("conservative") treatment was typically nonstandardized and poorly described.

Saal and Saal,[9] in an older retrospective study of 347 patients with lumbar radiculopathy treated with well-characterized aggressive medical treatment alone, found that 90% had "good to excellent" outcomes and 92% returned work. No significant difference in outcome was found in patients with weakness or disk extrusion compared with the overall group. Aggressive treatment included stabilization exercise training, nonopioid analgesics, and epidural steroid injections.

These studies, though flawed, suggest that surgical patients improve faster, but that in the end both medical and surgical treatment may be effective in many patients.

Imaging is not helpful in radiculopathy

Imaging is not helpful in guiding decisions about therapy in patients with radiculopathy. If we would perform magnetic resonance imaging in a population of people without any back problems whatsoever, we would find lumbar disk herniations in 20% to 36% of them, so, from a diagnostic perspective, the risk of attributing symptoms to clinically unimportant imaging findings is significant.[10,11]

Furthermore, imaging findings in patients with symptoms do not predict the outcome of nonsurgical treatment. A prospective trial in 246 patients with acute low back pain or radiculopathy found no relationship between herniation type, size, or behavior over time and outcome of medical treatment.[12] Another cohort trial followed 21 medically treated patients with lumbar radiculopathy with serial imaging for up to 7 years.[13] Herniation size decreased in 20 of 21 patients (95%), and no correlation between disk herniation morphology and clinical outcome was observed.

SPORT STUDY DESIGN: TWO PARALLEL STUDIES

SPORT was initiated in 2000 to compare the results of medical and surgical treatment in patients with spinal disorders, including disk herniation, spinal stenosis, and spondylolisthesis. The trial was conducted in 13 US spine centers between March 2000 and November 2004.

Two parallel studies were performed. The first compared the outcomes of patients who

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TABLE 1

Exclusion criteria in SPORT

- Prior lumbar surgery
- Cauda equina syndrome
- Scoliosis > 15 degrees
- Segmental instability
- Vertebral fractures
- Spine infection or tumor
- Inflammatory spondyloarthropathy
- Pregnancy
- Comorbid conditions contraindicating surgery
- Inability or unwillingness to have surgery within 6 months

SPORT = Spine Patient Outcomes Research Trial[1,2]

TABLE 2

Baseline patient characteristics in the randomized trial*

	SURGICAL GROUP (N = 232)	MEDICAL GROUP (N = 240)
Mean age (years)	41.7	43
Women	101 (44%)	93 (39%)
Working	142 (61%)	148 (62%)
Receiving compensation	36 (16%)	40 (17%)
Neurologic deficit	170 (73%)	177 (74%)
Positive ipsilateral SLR	143 (62%)	147 (61%)
Dermatomal radiation	223 (96%)	234 (98%)
Herniation level		
L4-5	80 (34%)	85 (35%)
L5-S1	136 (59%)	138 (57%)
SF-36 scores (mean)		
Bodily pain	27.1	26.7
Physical function	39.7	39.2
Mental	46.3	45.5

SPORT = Spine Patient Outcomes Research Trial[1,2]; SLR = straight leg-raising test; SF-36 = Short Form 36, range of possible scores 0–100; higher scores indicate less severe symptoms.
*Patients who completed at least one follow-up visit and were included in the analysis.

ADAPTED FROM WEINSTEIN JN, TOSTESON TD, LURIE JD, ET AL. SURGICAL VS NONOPERATIVE TREATMENT FOR LUMBAR DISK HERNIATION. THE SPINE PATIENT OUTCOMES RESEARCH TRIAL (SPORT): A RANDOMIZED TRIAL. JAMA 2006; 296:2441–2450.

agreed to be randomized to undergo either surgery or continued medical management.[1] The second was an observational cohort study of patients who declined to enroll in the randomized trial but who agreed to undergo regular follow-up to assess the treatment they chose.[2]

Patients all had radicular pain, disk herniation

All patients had imaging-confirmed lumbar disk herniation with corresponding radicular pain despite at least 6 weeks of nonsurgical treatment, which was not standardized. All patients had evidence of nerve root irritation: either a positive result on a nerve tension test (a straight leg-raising test or a femoral stretch test) or an appropriately located neuromuscular deficit (reflex loss, weakness, dermatomal sensory loss). All patients were considered surgical candidates. **TABLE 1** lists specific exclusion criteria.

A total of 1,244 patients were enrolled; 743 in the observational cohort study and 501 in the randomized trial. Baseline patient characteristics in the randomized trial are listed in **TABLE 2**. In the observational cohort, the patients who underwent surgery did not differ significantly from those who received medical therapy in terms of age, compensation status, disk herniation level, or nerve tension signs.

Treatment: Discectomy vs 'usual care'

In the randomized trial, the surgical group (n = 245) were assigned to undergo a standard open diskectomy with examination of the involved nerve root. The nonsurgical treatment group (n = 256) was to receive "usual care," which was not standardized. Nonsurgical treatments provided were prospectively tracked. **TABLE 3** lists the nonoperative treatments provided in the randomized trial.

In the nonrandomized, observational cohort study, 528 patients had surgery and 191 received continued medical management.

Study measures

The primary outcome measures were the Short Form-36 bodily pain and physical function scales and the Oswestry Disability Index.

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TABLE 3

Nonoperative treatments in SPORT

	NUMBER (N = 323)	(%)
Education/counseling	299	93
NSAIDs	193	60
Physician visit	195	60
Injections	180	56
Narcotics	147	46
Physical therapy	142	44
Muscle relaxants	66	20
Orthopedic pillow	38	12
Chiropracter	36	11
Brace/corset	27	9
Oral steroids	15	5
Acupuncture	13	4
TENS device	12	4
Magnets	12	4

SPORT = Spine Patient Outcomes Research Trial[1,2]; NSAIDs = nonsteroidal anti-inflammatory drugs; TENS = transcutaneous electrical nerve stimulation

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At 2 years, 40% of the surgical group in SPORT hadn't had surgery

The Short Form-36 is a health status questionnaire consisting of 36 items focusing on physical functioning, physical restrictions, emotional restrictions, social functioning, somatic pain, general mental health, vitality, and general health perception. A higher score correlates with the perception of less bodily pain and more physical function.[14]

The Oswestry Disability Index is a 10-item questionnaire designed for back patients, focusing on different aspects of function; the score equals the percentage of perceived disability. This score correlates linearly with the degree of perceived disability, which is rated as minimal, moderate, severe, crippled, or bedbound.[15]

Changes in the measures from baseline were assessed at 6 weeks, 3 months, 6 months, and 1 and 2 years after enrollment.

STUDY RESULTS

Randomized trial: Poor adherence to randomization

Adherence to the randomized treatment was poor. At 3 months, only 50% of patients assigned to surgical treatment had undergone the procedure, and 30% of those in the medical group had been treated surgically. Compliance with the protocol remained poor throughout the trial (TABLE 4).

The patients in the surgical group who never actually had surgery were significantly older, had higher incomes, were more likely to have an upper lumbar herniation, and had less physical disability than those who did have surgery. Patients crossing over to surgical treatment from the medical group had lower incomes and greater disability and were more likely to view their symptoms as worsening at enrollment than those who stayed with medical therapy.

On intention-to-treat analysis, the groups did not differ significantly in the primary outcome measures at any time point. Two secondary outcome measures, the sciatica bothersomeness index[14] and patient self-reported progress, showed significant advantages for the surgical group. The sciatica bothersomeness index rates the frequency (0 = not at all, 6 = always) and bothersomeness (0 = not bothersome, 6 = extremely bothersome) of back and leg symptoms. The total score therefore ranges from 0 to 24.

In view of the many patients who did not adhere to their randomly assigned treatment, an "as-treated" analysis was performed, comparing patients according to the treatment they actually received. In contrast to the intention-to-treat analysis, this comparison showed statistically significant advantages for surgery at all follow-up points up to 2 years in primary and secondary outcomes.

The most common surgical complication was dural tear (4%). Nine patients (4%) required reoperation within 1 year.

Observational cohort

In contrast to the randomized trial, 91% of the patients in the observational cohort study who chose surgery had the procedure by 6 weeks. Of the 222 patients who initially chose med-

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ical treatment, 9% had undergone surgery by 3 months, 16% by 6 months, and 22% by 2 years.

There were significant differences in baseline characteristics of the two treatment groups in the observational cohort. Fewer patients who chose surgery were working, more of them were involved in workers' compensation claims, more of them rated their symptoms as worsening, and they had more disk extrusions on imaging.

Though both groups in the observational cohort improved, surgically treated patients had significantly superior bodily pain scores, physical function, and Oswestry scores at 3 months. The difference in treatment effect had diminished by 2 years but remained significant.

Surgical complications in the observational study were similar to those in the randomized trial. Dural tears occurred in 2% of patients, and 7% of patients needed a repeat operation by 1 year.

TABLE 4

Deviation from randomization protocol in SPORT

TIME	% DEVIATION FROM ASSIGNED TREATMENT	
	SURGICAL GROUP	MEDICAL GROUP
3 months	50	30
6 months	43	39
1 year	41	43
2 years	40	45

SPORT = Spine Patient Outcomes Research Trial[1,2]

CONTROVERSIES

Intention-to-treat analysis was confounded by crossovers in treatment

The SPORT investigators used an intention-to-treat design in an attempt to minimize bias in the comparison of the effects of medical and surgical treatment. In such a trial, patients are analyzed in the groups into which they were randomized, irrespective of the treatment they actually received. Randomization is preserved, balancing both known and unknown variables between the treatment groups.

Such an analysis is confounded, however, when a substantial number of patients do not receive the assigned treatment.[16] In SPORT, large numbers of patients in both groups crossed over to the alternative treatment, effectively negating the randomization process and leading to a secondary, as-treated analysis. In essence, this converted the randomized portion of the trial into another observational cohort study, with greatly increased potential for bias. Patients crossing over to surgical treatment had more baseline disability and pain than those who stayed with medical treatment, suggesting a poorer prognosis. As a result, one might speculate that the study underestimates the surgical treatment's effect in comparison with medical treatment.

However, other unrecognized variables, perhaps in the psychosocial realm, may have affected outcomes. As a result of the large number of crossovers in SPORT, these variables may no longer be equally distributed in the treatment groups, and no definitive conclusion can be drawn as to the comparable efficacy of medical and surgical therapy.

Medical treatment was not standardized

Unlike the surgical treatment in SPORT, the medical treatment was not standardized. The protocol "recommended" that the medical treatment include "at least active physical therapy, education/counseling with home exercise instruction, and nonsteroidal anti-inflammatory drugs, if tolerated."[1] However, the medical treatment the patients actually received was extremely variable; eg, only 44% received physical therapy (TABLE 3). The authors attempted to justify this approach by suggesting that there is "limited evidence regarding efficacy for most nonoperative treatments for lumbar disk herniation and individual variability in response."

The SPORT design assumes that all forms of medical treatment are comparable. However, recent evidence suggests that some specific forms of physical therapy, for example, are more effective for lumbar radiculopathy.[17,18] Indeed, the study by Saal and Saal[9] referred to earlier suggests that a well-structured, aggressive, nonsurgical treatment

Some types of physical therapy may be more effective than others

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approach may be very effective in these patients.[9]

For these patients, medical therapy had already failed

An even more fundamental issue with the design of SPORT is the inclusion criterion requiring failure of nonoperative treatment for at least 6 weeks. As a result, patients for whom medical treatment had failed were randomized to either surgery or continued medical treatment, which was not necessarily different from the failed treatment already received. These patients' conditions may have been more refractory to continued medical treatment, shifting the bias in favor of the surgery. In fact, of the 44% of patients who received active physical therapy during the study, 67% had received it before randomization.

UNANSWERED QUESTIONS

Do medical and surgical outcomes differ in the long term? Unfortunately, SPORT didn't answer this fundamental issue. As with earlier nonrandomized trials, the as-treated analysis of the randomized study and the observational data suggest earlier benefit with surgical treatment. Whether this difference disappears with long-term follow-up (4–10 years), as in the Weber trial,[5] is unknown.

Either medical or surgical treatment may be effective in many patients

Findings from the SPORT observational cohort suggest that differences in the Oswestry Disability Index and SF-36 pain and physical function scores between medically and surgically treated patients diminished but remained significant at 2 years.

What is the most effective medical treatment for radiculopathy? Since the medical treatment was not standardized, the efficacy of the wide array of medical treatments used in the medical patients cannot be compared.

How do the costs of medical and surgical treatment compare over time? If the long-term outcomes of medical and surgical treatment do not differ very much, the answer to this question becomes more important in clinical decision-making. As Carragee has noted,[19] other factors, such as family responsibilities and personal economic constraints, may drive patients to choose surgery, which would resolve the problem more rapidly.

IMPLICATIONS FOR MANAGEMENT

Though the SPORT data are inconclusive in comparing medical and surgical treatment, the study does provide useful clinical information from a well-defined population of patients with diskogenic lumbosacral radiculopathy.

Reinforcing the conclusions of earlier studies, SPORT demonstrates that patients may improve with either medical or surgical treatment. The randomized arm and the observational cohort demonstrated significant improvement in both the medically and the surgically treated groups.

Also consistent with other trials, the SPORT observational cohort study found that surgical treatment relieves symptoms and improves function faster than medical treatment. Longer-term trials suggest that, over time, the differences in outcome between medical and surgical patients continue to narrow.

Surgical complications and risks were low. However, exclusion criteria eliminated patients with radiculopathy at higher risk of complications and poor outcomes, such as those with previous surgery.

Since we still do not have data clearly favoring medical or surgical treatment for diskogenic radiculopathy, patient preferences, comorbidity, coping style, previous experience with surgery, and other individual factors are important in selecting treatment. Patients can be offered either medical or surgical treatment for lumbar radiculopathy with reasonable confidence in a favorable outcome. Those with more severe, incapacitating pain may be more inclined to opt for earlier surgical intervention, while those with significant comorbidity may favor a more conservative nonsurgical approach.

IMPLICATIONS FOR FUTURE TRIALS

The failure of SPORT to conclusively address the differences in long-term outcomes of medical and surgical treatment of lumbar disk herniation suggests that several things should be done differently in the next (hopefully definitive) trial:

- Patients should be randomized before receiving any treatment.

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- Medical treatment should be standardized and based on the highest quality evidence available.
- An intention-to-treat design is preferred, but a vigorous attempt to minimize crossover and preserve randomization is crucial.
- Long-term outcomes (at least 4 years) should be compared, as should the costs of treatment and lost productivity.

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