

### **Results of the SPORT Study for lumbar disc herniation**

**Introduction:** The SPORT study for lumbar disc herniation consisted of 2 separate studies- an observational cohort and a randomized controlled trial (RCT). Inclusion criteria were essentially identical for both studies. All had symptomatic, radiographically herniated lumbar disc, not responsive to at least 6 weeks of conservative non-operative management.

**The observational trial:** 743 patients were eligible for the RCT but refused. They elected, instead, to choose their own treatment (surgery or nonoperative care) based on their condition, preferences, and counseling from their physician. Ultimately, 528 patients underwent surgery and 191 patients received various, non-standardized forms of non-operative care.

The findings of the observational trial:

1. Patients who chose surgery had a much greater degree of pain and disability than those who chose non-operative care (e.g. Oswestry 56.7 operation, 35.9 non-operation)
2. Ultimately, 22% (48) of patients who initially chose non-operative management crossed over and had surgery.
3. Patients who had surgery had dramatic improvements in virtually all primary and secondary outcomes measures.
4. Patients treated with non-operative management also improved but not to the degree that surgery patients did.
5. The differences between surgery and non-surgery outcomes were highly significant.
6. Surgery was very safe with very few complications. Dural tear- 2%, recurrent hnp 7% at one year and 9% by two years. Mean op time 70 minutes with 50 ml average blood loss.

Conclusions and talking points:

1. The observational trial essentially reflects the 'real world' reality of the management of lumbar disc herniation. After consultation with their physician to gain knowledge and insight into their condition, treatment options, and expectations, patients make rational decisions regarding their choice of management. In essence, patients with much greater degrees of pain, disability, neurological deficit, and worsening pain chose surgery while those with less pain, improving pain, less disability, and less deficit chose non-operative management. 22% of these patients did not improve with non-operative management and crossed over to surgical treatment.
2. Interestingly, the group who refused entry to the RCT did so for 1 main reason. They wanted, based on their knowledge and symptoms, to choose their own treatment, rather than leave it to random chance in the RCT. Not surprisingly, those who chose surgery had high pain/disability and those who chose

nonoperative management had much lower pain/disability. Interestingly the average pain/disability score in the observational surgery group was substantially higher than those patients who agreed to be in the RCT. Conversely, the pain/disability scores of the nonoperative management group were substantially lower than the baseline scores of patients in the RCT. Thus, patients with very high pain/disability and those with very low pain/disability refused the RCT. However, because those who chose surgery outnumbered those who chose nonoperative management by almost 3 to 1, the average pain/disability scores of patients in the observational study was substantially higher than the average baseline scores in the RCT. This is important because it confirms our initial belief that patients with severe disease who are the patients most likely to obtain the greatest benefit from surgery will disproportionately opt out of the RCT. This leads to a bias toward the null in the RCT design.

**The randomized controlled trial (RCT):** 501 patients with symptomatic herniated lumbar disc herniation not improving after a minimum of six weeks of non-operative care were deemed eligible and agreed to participate in the RCT. 245 were assigned to undergo surgery and 256 were assigned to nonoperative care. Follow-up was two years

The findings of the RCT:

1. 45% (107) of patients randomized to nonoperative management crossed over and had surgery. The benefit of surgery to these crossover patients was attributed to nonoperative management (i.e. intent to treat).
2. 40% (92) of patients randomized to operative management crossed over to nonoperative treatment. The benefit of nonoperative treatment to these crossover patients was attributed to operative management (i.e. intent to treat).
3. Patients crossing over to surgery had higher pain/disability levels than those who stayed in the nonoperative group
4. Patients crossing over to nonoperative treatment had lower pain/disability levels than those who stayed in the surgery group
5. Those patients who underwent surgery had dramatic relief of their symptoms.
6. Surgery was extremely safe with minimal complications; csf leak- 4%, re-herniation-4%, 95% complication free. No mortality.
7. Those patients who ultimately received nonoperative care generally did well.

Conclusions and talking points of the RCT:

1. When analyzing the crossover patients it is clear that there was complete nullification of the randomization process by rational patient choice in the RCT study. Patients with high pain/disability generally chose surgery, whether or not they were randomized to the surgical treatment arm. The average baseline Oswestry and bodily pain scores were nearly identical in the patients randomized to surgery who had surgery (51.7, 24.1) and those randomized to conservative care who crossed over to have surgery (52.1, 24.1). Conversely, there were very similar Oswestry and bodily

pain scores in patients randomized to nonoperative care who remained in this group (41.6, 28.9) and those randomized to surgery who crossed over into the nonsurgery group (41.1, 31.7).

### Summary Assessment

1. Surgery is shown to be extremely safe and effective with dramatic improvements noted on average in patients who undergo surgery. **Evidence:** Both RCT and observational study.
2. Patients rationally chose the treatment option that is best for them based on their condition (e.g. pain/disability level/direction, duration, neurological deficit), knowledge of their condition obtained from physician consultation including the cause, natural history, and treatment options for their condition, and consistent with their own values and preferences.
3. Patients with severe or worsening pain or neurological deficit typically chose surgery and do well. **Evidence:** 1. Patients who opted out of the RCT and chose to have surgery in the observational cohort had very high pain/disability. 2. 45% of patients who agreed to RCT and were randomized to nonoperative management crossed over and received surgery. On average, these patients had substantially higher pain/disability scores than those patients who remained in the nonoperative group.
4. Patients with less severe or improving pain/disability usually chose and do well with non-operative treatment. If they don't, they chose surgery and do well. **Evidence:** 1. Patients who opted out of the RCT and chose nonoperative management had significantly lower baseline pain/disability scores than the patients who agreed to the RCT. 2. 22% of these patients did not improve with nonoperative management and crossed over to have surgery in the observational trial. 3. 40% of patients who agreed to RCT and were randomized to surgery chose not to have surgery and crossed over to the non-surgery group. The pain/disability scores were much lower in this group than in those patients who actually underwent surgery in the RCT.
5. There was complete nullification of the RCT randomization process by rational patient choice in the RCT study. Patients with high pain/disability generally chose surgery, whether or not they were randomized to the surgical treatment arm. The average baseline Oswestry and bodily pain scores were nearly identical in the patients randomized to surgery who had surgery (51.7, 24.1) and those randomized to conservative care who crossed over to have surgery (52.1, 24.1). Conversely, there were very similar Oswestry and bodily pain scores in patients randomized to nonoperative care who remained in this group (41.6, 28.9) and those randomized to surgery who crossed over into the nonsurgery group (41.1, 31.7).

**FAQ:**

1. Isn't it true that if you wait long enough everyone gets better and any differences between operative and non-operative treatment disappears?

A. In general, many but not all patients with painful herniated disc get better with nonoperative management. Such a benign natural history forms the basis of early conservative management of these patients. Patients are only offered surgery if they have severe unrelenting pain that does not improve with nonoperative care. Even patients randomized to conservative management in the SPORT RCT exercised their freedom of choice to have surgery when their pain/disability did not improve. We are not telling the patients to have surgery; they chose it! For those who cite Weber's data that by 4 years any treatment difference disappears they should be asked if patients should be forced to live with excruciating nerve pain for a prolonged period instead of undergoing a short, extremely safe, and reliable operation that consistently and dramatically relieves their pain. Both the 528 patients who volitionally opted out of the RCT to have surgery and the 107 patients in the nonoperative treatment arm of the RCT who crossed over to have surgery enjoyed remarkable immediate relief of their pain by exercising this personal choice.

2. What about the SPORT RCT, the strongest of all study designs, that concluded, "Between group differences in improvements were consistently in favor of surgery for all periods but were small and not statistically significant"? Doesn't that mean that surgery is not better than conservative management?

A. The SPORT RCT design was essentially nullified by patient rational choice. Patients chose treatment on the basis of their condition, not their randomization. The RCT design assumes a homogeneous disease but it is clear that symptomatic herniated lumbar disc is not. It varies with respect to severity, duration, and presence/severity of deficit, trend, and natural history. Non-operative care treated one type of patient in the observational and RCT trial while surgery treated another type of patient. In each study, patients gravitated to the treatment that was best for them and their condition. It's not a question of which treatment is better. Each treatment is different and is applied under different circumstances to different types of patients. Nonoperative care helps patients with lower and/or improving pain/disability but is not tolerated or effective in patients with persistent and/or severe pain. Surgery is very effective in patients with persistent and/or severe pain/disability but is not offered or chosen by patients with improving or mild/moderate pain/disability, unless they don't improve. To mix these two patient types into one large group and subject them to randomization (as the SPORT study intended to do) completely negates our ability to detect the differential effects and application of the surgery and ignores the heterogeneity of the condition under study. Fortunately, patients were rational enough to nullify the SPORT randomization process and chose the best treatment for them. Those patients with severe/persistent disease who chose surgery did extremely well. Most of those patients with mild/moderate disease who chose non-operative treatment did well. Those who didn't cross over to surgery and did well. Herniated lumbar disc is not a homogeneous condition and operation or nonoperative management are not interchangeable treatments.