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REVIEW

Lumbar disc herniation: what has the Spine Patient Outcomes Research Trial taught us?

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Abstract

Introduction Intervertebral disc herniation (IDH) can cause back pain and/or radiculopathy and accounts for a significant portion of patients having spinal surgery in the USA. One of the most impactful and well-executed randomized trials to study diagnosis, treatments, and outcomes in patients with three commonly treated spinal conditions was the Spine Patient Outcomes Research Trial (SPORT). This study and the subsequent data analyses have resulted in numerous publications related to IDH. The purpose of this review is to summarize SPORT publications with IDH results to better understand what we have learned from this important landmark trial.

Methods Publications utilizing SPORT data that reported findings related to IDH patients were identified from Medline, PubMed, and PubMed Central. The primary findings pertaining to IDH were summarized.

Results There were 25 studies identified reporting findings related to IDH from the SPORT data published between 2004 and 2017. Publications in the following areas were summarized: epidemiology and baseline patient characteristics (1), treatment preferences and expectations (2), radiological and MRI (3), primary study objectives at two years (2), four years (1) and eight years (1), subgroup analyses (13), cost-effectiveness (1), and reherniation (1).

Conclusions This report reviewed the current state of SPORT publications related to IDH to identify and summarize what we have learned about diagnosis, patient characteristics, treatments, outcomes, and cost-effectiveness in patients with lumbar disc herniations. Many important findings are now published from this robust trial's data. Clinicians should incorporate these results into their clinical decision-making and during counseling patients presenting with lumbar disc herniations.

Keywords Lumbar disc herniation · Spine Patient Outcomes Research Trial (SPORT) · Patient outcomes

Introduction

Intervertebral disc herniation is a spinal condition that can cause back pain and/or radiculopathy and accounts for a large portion of patients having spine surgery in the USA annually [1]. In 2000, most of the reported outcomes and clinical data related to common surgical spinal conditions were based on cohort studies with inherent flaws compared to higher level evidence research [2]. At that time, there was one previous randomized controlled trial reporting outcomes of surgical versus nonsurgical treatment of lumbar disc herniations [3]. The lack of robust scientific basis behind treatment decisions paved the way for designing and implementing the Spine Patient Outcomes Research Trial (SPORT) in 2000 [2].

SPORT was designed to assess the outcomes and relative efficacy of treatments for three spinal conditions that account for a significant proportion of patients treated surgically: intervertebral disc herniation (IDH), spinal stenosis (SPS), and degenerative spondylolisthesis (DS) [2]. The trial simultaneously performed three multi-center randomized controlled trials (RCT) comparing surgical and nonsurgical treatments of IDH, SPS, and DS. Concurrently, they studied patients who declined to be in the RCT and reported treatments, outcomes,

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and costs of this observational cohort. The last objective was to formally estimate the cost-effectiveness between treatment groups for these conditions. There were 13 participating sites in 11 US states and enrollment began in 2000 with the first two year follow-up results published in 2006.

Since that time, there have been numerous subgroup analyses performed for all three study groups from both the randomized and observational cohorts. Results from four year and eight year follow-ups have also been published. There were initially 501 patients in the randomized cohort [4] and 743 in the observational cohort [5]. The data and analyses from SPORT have led to a better understanding of operative and non-operative treatments, the factors impacting outcomes, and the cost-effectiveness of treating these three spinal conditions.

The purpose of this review is to examine the SPORT publications pertaining to IDH and summarize the findings to better understand what has been learned about lumbar disc herniation treatments and outcomes.

Materials and methods

The number of publications stemming from the SPORT data continues to grow even at the time of this publication. Reports vary in their objectives from comparing the three spinal conditions (IDH, SPS, and DS), to assessing baseline characteristics, examining accuracy of diagnosis, and a plethora of subgroup analyses assessing differences in outcomes.

We utilized Medline, PubMed, and PubMed Central to identify publications that utilized the SPORT dataset. Publications related only to SPS or DS were excluded. This report summarizes major findings related to IDH from existing SPORT publications. Full results can be found within each individual publication. We are limiting our reporting to the primary findings related to IDH unless discussing the comparison between study groups provides meaningful insight to the IDH results.

Results

There were 25 studies identified reporting findings related to IDH from the SPORT data published between 2004 and 2017. These studies are summarized below based on their area of focus.

Epidemiology of patients with intervertebral lumbar disc herniation

One of the first reports publishing SPORT results studied 1417 patients enrolled in the observational cohort of the three study groups by Cummins et al. [6]. Their objective was comparing baseline demographic characteristics and healthcare utilization between IDH, SPS, and DS. IDH patients were the youngest (mean age 41 years) compared with SPS (64 years) and DS (66 years) patients. IDH patients had the highest baseline pain scores and were the most impaired. Chiropractic care, emergency room visits, and opiate use were the highest in IDH. This study demonstrated the significant symptomology, healthcare utilization, and disability IDH produces compared to two other common spinal conditions.

Treatment preferences and expectations

In 2008, Lurie et al. studied the IDH observational cohort [7]. By definition, these patients declined to be randomized and instead chose their treatments. Due to highly complex association of patient expectations and expected results with clinical outcomes and satisfaction, the authors aimed to better define the characteristics of patients that selected surgical versus non-surgical treatments. They found 67% of patients elected for surgery, and this group was younger and had lower levels of education and higher unemployment/disability. In addition, they had higher pain, worse functional scores, more back pain–related disability, longer duration of symptoms, and more opiate use. Expectations of the potential benefit from non-operative care were the most powerful single predictor of treatment preference [7]. This information has important implications for clinicians during the informed decision counseling process.

A more recent publication by Lurie et al. in 2016 reanalyzed all IDH subjects from both the randomized (467) and observational (701) cohorts that had baseline expectations and outcome data [8]. Sixty-three percent of patients had high expectations with surgery compared with only 16% of non-operative patients having high expectations. They found that regardless of treatment, expectations of surgery had a significant relationship with outcomes. In particular, low surgical outcome expectations were associated with poorer outcomes regardless of treatment. High expectations with nonsurgical treatment were associated with better non-operative outcomes but had no effect on surgical outcomes. These findings again emphasize the importance of understanding and addressing treatment expectations and the impact on outcomes in IDH patients.

Magnetic resonance imaging: interpretation reliability and surgical outcomes

One radiological study from the IDH cohort used 50 randomly selected baseline MRI studies to determine the interpretation reliability related to herniation morphology and neural element compression [9]. They found a high concordance for classifying the disc morphology with only moderate agreement related to thecal sac compression and nerve root impingement. This reliability assessment was the first step in

potentially further classifying whether radiographic features can guide treatment decisions and prognosis.

A second publication in 2009 compared radiologist and clinician descriptions of MRI disc herniations [10]. They found excellent concordance in identifying herniation level and location; however, several radiologist reports fail to provide full detail about the disc herniation morphology. When morphology details were present, there was only fair agreement between radiologist and clinician evaluations.

The last radiologic study was published five years after the initial reliability study. The goal was to better define the relationship between MRI findings in IDH cases and surgical treatment outcomes [11]. Their primary findings included greater surgical treatment effect in patients with ≥ 1/3 thecal sac compression and/or nerve root compression or displacement compared to patients without these radiographic findings.

Surgical versus nonsurgical treatment: two year, four year, and eight year results

The landmark SPORT publications reporting the primary study objectives were published in 2006 [4, 5], 2008 [12], and 2014 [13]. In 2006, Weinstein et al. published results from both the randomized [4] and observational [5] cohorts with two year outcomes. In the randomized cohort, there was a substantial crossover with 30% of patients in the nonoperative arm receiving surgery within three months. Both surgical and nonsurgical patients showed significant improvements at two years. In this study, intent-to-treat analyses were performed and due to the high crossover, the differences between groups were small, however favoured surgical treatment on secondary outcomes [4]. In the observational study group, again both surgical and nonsurgical patients showed significant improvement; however, those that chose operative intervention had greater improvements than subjects choosing non-operative care [5].

In 2008, Weinstein et al. published the four year outcomes for IDH patients. Both the observational and randomized cohorts were combined, and as-treated analyses were performed [12]. The primary findings demonstrated patients that underwent surgical intervention for IDH had greater improvement across all outcomes. The one exception was the percentage of patients working was similar between operative and non-operative groups.

At eight year follow-up, Lurie et al. published a follow-up study using the same IDH cohort and found similar findings as the four year report with minimal degradation of outcomes for either surgical or nonsurgical groups between the time points [13]. They again demonstrated greater improvements with surgery compared to nonsurgical treatments across all outcomes using an as-treated analysis.

Subgroup analyses

Several subgroup analysis publications have come out of SPORT to better understand specific variables impacting treatments and outcomes. In 2015, Koerner et al. published a review of SPORT disc herniation studies reporting variables that impact patient outcomes [14]. Their objective was to answer three specific questions related to IDH patient outcomes. We expand on their publication in this section and analyze many of the subgroup analysis publications to report the primary IDH findings.

Location and morphology of herniation

One of the easily and most objective elements of disc herniation evaluation that may impact outcomes is the location and morphology of the pathology. While the original randomized and observational cohort studies only provided descriptive data about the location of the herniations, a few years after the initial publications, Lurie et al. examined whether lumbar level impacted outcomes between operative and non-operative treatments [15]. They studied IDH patients from both the randomized and observational cohorts to identify outcome differences when analyzing patients based on herniation level. The results had strong evidence that patients with upper level herniations (L2–3, L3–4) had greater surgery treatment effects with surgery compared to non-operative care compared to L5-S1 herniations. There was a similar trend for better treatment effect for L4–5 compared to L5-S1; however, the only outcome measure that was significantly different was SF-36 physical functioning. Their findings were consistent with previous reports and give clinicians a better understanding of which IDH patients may have the greatest treatment effect with surgical intervention compared to non-operative management.

Another 2008 publication by Pearson et al. examined the effect of herniation zone and morphology [16]. Their main interest was not lumbar level, but rather if there was a difference between outcomes for herniations in different zones (central, posterolateral, foraminal, or far lateral). In addition, they classified the herniation morphology as protrusion, extrusion, or sequestration. One of the primary variables was back pain versus leg pain relief, and this was one of the first studies to report back pain metrics for IDH patients. For all herniation types and zones, both non-operative and operative groups had relief of back and leg symptoms; however, consistent with the other SPORT findings, the surgical patients had greater relief at three months and two years. Interestingly, patients with central zone herniations had more back pain at baseline than the other zones, and regardless of the herniation zone, patients having discectomy had greater relief of back pain compared with non-operative patients. When comparing groups based on morphology, protrusions, extrusions, and

sequestrations had similar back pain at baseline and had equal improvement with surgery.

The findings from these subgroup analyses help clinicians better appreciate the nuances of surgical level, herniation zones, and morphology and how these characteristics may impact outcomes for patients presenting with IDH.

Duration of symptoms

One critical question that surgeons commonly ask at first presentation is the duration of symptoms. This time course can help delineate potential causation and gain understanding of symptom progression and may shed light on the underlying symptom severity. In addition, symptom duration may have substantial impact on the treatment effects. Some spinal conditions benefit from early intervention while others may have no difference in outcomes regardless of treatment timing. Rihn and colleagues performed a subgroup analysis study in 2011 to help better answer these questions in IDH patients [17].

Their study utilized the combined randomized and observational cohorts and compared them based on whether they had symptoms for 6 months or less compared to those with symptoms for more than 6 months. For both operative and non-operative groups, patients with less than or equal to six months of symptoms had better improvements across all outcome measures compared with patients with greater than six months of symptoms. They did not find a significant difference in treatment effect based on symptom duration between groups, suggesting again that surgical treatment offers advantages over nonsurgical management regardless of duration of symptoms. These are unique findings that surgeons can utilize when counseling patients and may help guide the conversations about symptom duration and treatment timeliness. Certainly, if patients are considering or pursuing operative treatment, interventions prior to six months of symptom duration may optimize their outcome potential.

Diabetes and obesity

Comorbid conditions must be understood and incorporated into decision-making when considering surgical treatment for many conditions. Research related to how comorbidities impact spinal procedure treatments and outcomes is an important area of interest and can impact recommendations and preoperative optimization protocols.

The landmark articles reporting two, four and eight year follow-up outcomes provided descriptive details about patient demographics and comorbidities, however did not perform in-depth subgroup analyses based on these groups. Three studies have been published from the SPORT analyzing specific comorbidities and the impact on outcomes in IDH treatment.

One study by Freedman et al. in 2011 analyzed patient outcomes for all SPORT participants with diabetes [18]. In the IDH group, there were 40 diabetic patients (3.4% of the overall cohort). These patients were older and had higher BMI and higher incidence of stroke and hypertension than nondiabetics. Baseline SF-36 and ODI scores were no different between groups. Their most important findings showed that nondiabetic patients had significantly greater improvement with surgery compared with diabetics. In addition, for diabetic patients only, there was no difference in outcomes for pain and function between surgical and non-surgical treatments.

The second study by Rihn et al. from 2013 analyzed outcomes between groups based on BMI < 30 kg/m^2 (nonobese) and BMI ≥ 30 kg/m^2 (obese) for the SPORT IDH cohort [19]. Significantly more obese patients underwent surgical intervention compared with nonobese (73% vs 63%). Obese patients had longer operative time, higher blood loss, and longer hospital stays. At four year follow-up, obese patients had significantly less outcome improvement with both operative and non-operative treatments compared with nonobese patients.

The third study was published in 2014 by McGuire et al. and examined the effect of extreme obesity on outcomes in SPORT [20]. They expanded on Rihn's analyses by examining patients with BMI < 30 kg/m^2 (nonobese), 30 kg/m$^2 \leq$ BMI < 35 kg/m^2 (obese), and ≥ 35 kg/m^2 (extremely obese). The extremely obese group had the highest level of comorbidities and lowest baseline SF-36 scores in the IDH group. Operative time was related to BMI and the highest in the extreme obesity group. While all groups improved with surgical treatment, the extremely obese group had the highest treatment effect with surgery likely due to the lowest improvements with non-operative care compared with the other groups.

These three studies provide important information for surgeons and patients regarding the differences in expected outcomes and peri-operative metrics in patients with diabetes and obesity.

Education level and workers' compensation

Two studies have been published related to workers' compensation (WC) and one related to educational level in IDH patients. A 2007 publication by Atlas et al. examined patients with lumbar radiculopathy from two large databases, one being SPORT, to identify baseline socioeconomic differences associated with WC in patients with IDH and SPS [21]. They found notable differences between WC and non-WC patients. WC patients were more likely to be younger, male, nonwhite, less educated, and smokers; had longer work hours, less weeks worked over the previous year, and more strenuous work activities; and were more likely to have legal action taken. WC patients had lower annual income and had more often depleted their financial reserves because of their back problem. Lastly, the WC patients were less likely to expect to be able to return to work and more often felt surgery was necessary. This publication shed light on the concept that

WC patients are fundamentally different at baseline than non-WC patients and this may be the underlying reason for differences in outcomes.

In 2010, Atlas et al. again studied the impact of WC on outcomes in more detail using only the SPORT IDH patients [22]. They used both the randomized and observational cohorts to compare differences between WC and non-WC patients. Their primary findings demonstrated similar surgical treatment benefit for both groups in the short term; however, in the WC population, there was no difference in surgical versus nonsurgical treatments at two years for all outcomes while the non-WC group had significantly greater improvements with surgical treatment at all time points.

In 2013, Olson et al. studied the SPORT IDH cohort and analyzed outcomes based on education levels [23]. Their findings showed significant improvement in outcomes across all education levels with surgery. The main differences reported showed that the higher educational attainment was associated with significantly better nonsurgical outcomes at four years compared to the lower education groups.

Opioid use

Patients with symptomatic IDH often are prescribed multiple medications for symptom management which may include opioid pain medications. This can be problematic for multiple reasons, and surgeons may find difficulty in adequately treating post-surgical pain in patients presenting on opioid pain medications. In addition, the addictive nature of the medicines and the growing opioid epidemic have prompted considerable attention in the literature regarding the amount and frequency of opioid use as well as whether patients continue using these medications in the long term.

A 2010 study by Krebs et al. utilized the entire SPORT cohort including all spinal conditions to determine predictors of long-term opioid use [24]. Although they studied all three spinal pathology groups (IDH, SPS, and DS), they identified several interesting findings specific to the IDH group. The IDH group had the highest frequency of patients using opioids at baseline. Within the IDH group, those that chose to be in the observational group were more likely to use opioids. When studying the entire cohort, they found that smoking and nonsurgical management were the prevailing risk factors that predicted opioid continuation at 12- and 24-month follow-up. Certainly, these findings should be interpreted in the context of all patient factors; however, the results should be considered in discussions with patients electing for nonsurgical IDH treatment, especially if they smoke or are using opioids at the baseline visit.

In 2013, Radcliff et al. studied the SPORT IDH patients from both the randomized and observational cohorts to determine differences based on opioid use [25]. There were 520 patients in the nonopioid group and 542 in the opioid group. The opioid group had worse baseline pain, function, and disability scores and had a significantly higher percentage of patients receiving surgery. They found no difference in outcomes between opioid groups at four years and reported 16% of patients using opioids at baseline were still using them at four years, compared with only 5% using opioids in the nonopioid group.

Incidental durotomy

A well-known but infrequent complication associated with IDH surgeries is incidental durotomy. Studies have demonstrated controversial effects on long-term outcomes when this is encountered during spinal procedures with reported rates between 1 and 17% and factors such as increased patient age, revision procedures, and lower surgeon experience are associated with higher durotomy rates. Short-term effects of a durotomy may include spinal headaches, pseudomeningocele formation, and dural-cutaneous fistulas.

Given inconsistent results of outcomes after incidental durotomies following lumbar disc procedures, Desai et al. attempted to better answer this question utilizing the SPORT IDH surgical cohort in 2011 [26]. They studied 799 patients that underwent first-time discectomy and identified 25 incidental durotomies (3.1%). There was no difference in patient characteristics in patients with and without durotomies including age, sex, race, BMI, smoking, diabetes, hypertension, or herniation level/type. The differences that were identified are consistent with previous studies and included increased operative time, estimated blood loss, and hospital length of stay. Analyzing data from multiple follow-up points, they found no difference in nerve root injury, postoperative mortality, additional surgery rate, SF-36 scores, or ODI scores at one, two, three or four year follow-up.

This study provides robust information that can be used during patient counseling regarding the risks and complications associated with IDH surgical intervention. Durotomy rates reported from this study were 3.1% and resulted in increased operative time, blood loss, and hospital stay; however, there was no effect on long-term patient-reported outcomes compared to patients without a durotomy.

Cost-effectiveness of intervertebral disc herniation treatments

In 2008, Tosteson et al. published a cost-effectiveness study related to IDH treatment over two years using SPORT data [27]. The details of the complex costing and quality-adjusted life year (QALY) data can be found in the full publication. They found that although surgery is more expensive than non-operative care, health outcomes were better over two years for those treated surgically. They estimated cost per QALY gained with surgery ranged from $34,355 to $69,403 depending on

the surgery cost. These figures represent a reasonably cost-effective healthcare intervention compared to other common healthcare expenditures and demonstrate IDH surgical intervention is a relatively cost-effective intervention.

Recurrent intervertebral disc herniation

A common patient question when discussing surgical intervention is whether recurrent herniation can occur, how often this might happen, and what are the risk factors for recurrent IDH. Abdu et al. attempted to answer this question in 2017 using the SPORT data [28]. They studied all patients who underwent primary discectomy and found that 9.1% underwent re-operation for reherniation by four years. They identified younger age, lack of motor or sensory deficits, and higher baseline ODI as risk factors for reherniation. For patients that underwent revision surgery for reherniation, they showed significant improvements in outcomes, but less improvement than with primary discectomy. Other studies since SPORT have identified factors such as transitional vertebra, hypermobile discs on flexion-extension films, and potentially endoscopic versus open surgical techniques may impact reherniation rates [29, 30]. Recurrent disc herniation and the potential causes may not have been fully elucidated with SPORT; however, continued clinical research aims to better understand this unfortunate outcome after primary discectomy for IDH.

Conclusions

This report reviewed the current state of SPORT publications related to IDH to identify and summarize what we have learned about diagnosis, patient characteristics, treatments, outcomes, and cost-effectiveness in patients with lumbar disc herniations. Many important findings are now published from this robust trial's data. Clinicians should incorporate these results into their clinical decision-making and during counseling patients presenting with lumbar disc herniations.

Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interest.

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