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The Effect of Expectations on Treatment Outcome for Lumbar Intervertebral Disc Herniation

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Abstract

Study Design—Secondary analysis of randomized and non-randomized prospective cohorts.

Objective—To examine the effect of patient treatment expectations on treatment outcomes for patients with intervertebral disc herniation.

Summary of Background Data—Patient expectations about treatment effectiveness may have important relationships with clinical outcomes.

Methods—Sub-group and re-analysis of the Spine Patient Outcomes Research Trial, a randomized trial and comprehensive cohort study enrolling patients between March 2000 and November 2004 from 13 multidisciplinary spine clinics in 11 US states. Overall 501 randomized and 744 observational patients (1244 total) who were surgical candidates with radiculopathy and imaging confirmed lumbar intervertebral disc herniation were enrolled. The primary study compared surgical discectomy to usual non-operative care; this sub-group analysis reassessed outcomes based on treatment expectations at baseline. Expectations about symptomatic and functional improvement for both surgery and non-operative care were assessed on 5-point scales (1="No Chance (0%)" to 5="Certain (100%)"). Outcomes were assessed using longitudinal regression models analyzed by treatment received.

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Results—Among 1244 IDH SPORT participants, 1168 provided data on both outcomes and baseline expectations and were included in the current analysis: 467 from the randomized and 701 from the observational cohort. Low expectations of outcomes with surgery predicted poorer outcome regardless of treatment. High expectations of outcomes with non-operative care predicted better non-operative outcomes but did not affect surgical results. These differences were of similar magnitude to the difference in outcomes between surgery and non-operative care.

Conclusions—High expectations of treatment benefit had clinically significant positive associations with outcomes.

Keywords

lumbar spine; patient expectation; lumbar herniated disc; surgery; non-operative treatment; functional outcomes; pain; disability; physical function; patient-reported outcomes

INTRODUCTION

Patients' expectations about treatment effectiveness have been shown to have complex relationships with clinical outcomes and satisfaction. Overall, patient expectations for spine surgery have been shown to be quite high.[1,2] Unrealistically high expectations may contribute to unmet expectations and decreased patient satisfaction.[1–5] On the other hand, high expectations may result in improvement in symptoms and function through placebo effects, increased motivation for improvement, and improved compliance with treatment recommendations.[3,6–8]

The SPORT database provides a unique opportunity to examine the relationship between patients' treatment specific expectations, actual therapeutic choices, and treatment outcomes from both surgery and non-operative care. At the time of initial enrollment in the SPORT study, we assessed: a) patients' expectations about surgical/non-surgical treatments; b) potential benefit with respect to pain; c) potential benefit with respect to function; d) possible risks. We have previously looked at the relationship between patients' treatment expectations and their baseline treatment preferences.[9] In that study, baseline expectations had strong and consistent correlations with patient preference. The specific aim of this project was to examine the effect of patient treatment expectations on treatment outcomes for patients with intervertebral disc herniation (IDH). We hypothesized that expectations of improved outcomes for surgical and non-surgical treatment would correlate with improved outcomes for patients treated surgically and non-surgically, respectively.

MATERIAL AND METHODS

The Spine Patient Outcomes Research Trial (SPORT) is a large multicenter clinical trial designed to compare surgery to non-operative treatment for patients with IDH, spinal stenosis (SpS), and degenerative spondylolisthesis (DS); it is described in detail elsewhere.[10–13] SPORT contains a randomized component as well as prospective cohorts in which patients met all inclusion and exclusion criteria but were unwilling to be randomized and instead received the treatment of their choice.

All patients in the IDH arm of SPORT were over 18 years of age, had radicular pain for at least six weeks with a positive nerve root tension sign and or neurologic deficit, and a confirmatory cross-sectional imaging study demonstrating IDH at a level and side corresponding to their symptoms. Exclusion criteria included cauda equina syndrome, progressive neurological deficit, malignancy, significant deformity, prior back surgery and other established contra-indications to elective surgery. All subjects were deemed surgical candidates by the enrolling surgeon,[11,13] and all signed an IRB-approved consent form. Baseline preference and expectation data were acquired at the time of enrollment, and are representative of the patients' knowledge and understanding of their condition and treatment options immediately following their initial presentation for care by a spine specialist and before exposure to the study's standardized informed consent process.[11,13] Patient expectation for improvement in symptoms and function was assessed pre-treatment using measures of expected benefit from surgery and from non-operative treatment. These expectations were quantified on a 5-point scale as: No Chance, Small Chance, Moderate Chance, Substantial Chance, or Certain (100%); high expectations were defined as responses of 'substantial chance' or 'certain.' Specific questions asked were, "What is your best guess about the chance that you will be free of symptoms like pain, stiffness, numbness, weakness" and "What is your best guess about the chance that you will be able to work at your usual job or activities" for both surgery and non-surgical treatment.

For this analysis, the surgery group consists of all patients receiving surgery within 3 months of enrollment; the non-operative group included patients with later surgery or who never received surgery. Post-treatment outcome measures included the Short Form-36 (SF-36) Bodily Pain Scale, the SF-36 Physical Function Scale, and the Oswestry Disability Index (AAOS/MODEMS version). The two SF-36 scales range from 0 to 100 with higher scores and positive change scores representing better health. The Oswestry Disability Index (ODI) ranges from 0 to 100 with lower scores and negative change scores representing better health. Post-treatment outcomes were collected at 6 weeks, 3 months, 6 months, 1 year, and 2 years. However, given the definition of the surgery group as those receiving surgery within the first 3 months, only the outcomes at 6 months, 1 year and 2 years are relevant to this analysis as earlier time points may have occurred prior to or immediately after surgery in the surgery group.

Baseline comparisons between expectations and treatment received were analyzed using Chi-squared tests. Outcomes analyses were performed using longitudinal regression models with covariate adjustment for potentially confounding factors previously shown to be associated with expectations including cohort (randomized vs observational), education, baseline outcome score, symptom duration, and factor cited as influencing treatment preference (ability to participate in leisure activities.[9] Computations were done using SAS procedures PROC MIXED for continuous data and PROC GENMOD for binary and non-normal secondary outcomes (SAS version 9.1 Windows XP Pro, Cary, NC). Statistical significance was defined as $p < 0.05$ based on a two-sided hypothesis test with no adjustments made for multiple comparisons

RESULTS

Among 1244 IDH SPORT participants, 1191 provided data on baseline expectations; 1168 also had data on treatment outcome and were included in the outcome analysis: 467 from the randomized and 701 from the observational cohort.

Expectations

Overall 63% (753/1191) of patients had high expectations for surgery at baseline compared to 16% (196/1191) with high expectations for non-operative care. Expectations were associated with treatment received and these relationships were similar between the randomized and observational cohorts. In the combined cohorts, half of the non-operative patients had high expectations for surgery while 76% of the surgery group had high expectations for surgery. For non-operative expectations, 30% of the non-operative group and only 7% of the surgery group expected a substantial chance of improvement with non-operative care (Table 1).

Expectations in the randomized cohort showed a significant and somewhat complicated association with treatment outcomes. Overall, patients who had high expectations of improvement from the treatment they received, independent of which treatment that was, had improved outcomes compared to those with lower expectations for the treatment they received (BP $p<0.001$, PF $p<0.001$, ODI $p=0.002$; data not shown).

In both the randomized and the observational cohorts, the expected benefit from surgery showed significant positive effects on the outcomes of both surgery and non-operative treatment. Given the similarity in results between the two cohorts, a combined analysis was done and is summarized in Table 2. At all three time points and for all three main outcome measures, patients with high expectations of improvement with surgery did significantly better following surgery than those with lower expectations. Similarly, in both the randomized and observational cohorts there was a significant association between surgical expectations and non-operative outcomes with those patients in the non-operative group who had high expectations of improvement with surgery doing better than those with lower surgical expectations. Surgical expectations thus had an effect on outcome that was relatively independent of treatment.

The effects of non-operative expectations were also similar in both the randomized and observational cohorts; the analysis combining both groups is summarized in Table 3. Patients with higher expectations of non-operative benefit showed a trend toward better surgical outcomes at 6 months (BP 47.1 vs 40.1, $p=0.07$; ODI −40.4 vs −34.7, $p=0.07$) but no significant differences at 1 or 2 years (Table 2). In contrast, non-operative expectations showed a consistent statistically significant association with non-operative outcomes in both the randomized and observational cohorts. Those expecting a substantial chance of improvement in non-operative care had significantly better outcomes for each outcome measure at each time point. The treatment effect for surgery, however, was not statistically different based on non-operative expectations at any time point.

Adjusted Treatment Outcomes

In the primary analyses from the SPORT study, the high rate of cross-over made it difficult to draw conclusions from the intention-to-treat analysis alone and as-treated analyses were also performed.[11,13,14] These analyses, however, lose the protection from confounding offered by randomized intention-to-treat analysis. In particular, because the trial was not blinded (no sham procedure control) and the outcomes were subjective patient reports of pain and function, a significant potential exists for patient expectations to confound the study results. [15] We therefore undertook additional analyses that looked at the as-treated outcomes of surgery compared to non-operative treatment, while controlling for baseline expectations, in order to assess their potential confounding effects.

As with the specific expectations analyses reported above, the results in the randomized and observational cohorts were very similar. Figure 1 shows the longitudinal results for Bodily Pain from the primary study as-treated analysis and then controlling for baseline expectation for the treatment received. As anticipated, controlling for baseline expectations mitigated the apparent effect of surgery. In the analysis ignoring expectations, the relative treatment effect of surgery compared to non-operative treatment was statistically significant for all time periods; however, after controlling for the effect of expectations, the treatment effect at 1 and 2 years was no longer statistically significant.

Figure 2 shows the results for functional disability measured by the ODI. The benefit of surgery is also somewhat blunted for the ODI; however, the effect of controlling for expectations is smaller and the outcomes remain statistically significantly in favor of surgery out to 2 years. Results for the SF-36 PF scale were similar to the results for ODI (data not shown).

DISCUSSION

Expectations showed a significant relationship with treatment outcomes. Patients with high expectations for surgery did significantly better than those with low surgical expectations independent of treatment received. In other words, patients who don’t expect to do well with surgery tend not to do well with surgical or non-surgical treatment. However, expectations for non-operative care had a more treatment-specific effect. High or low non-operative expectations did not significantly affect the outcomes of surgery but those with high expectations for non-operative care had much better non-operative outcomes than those with low non-operative expectations.

The interaction between non-operative expectation and treatment did not reach statistical significance, meaning that despite the differential effect of expectation on outcomes by treatment, the treatment effects were not statistically different between expectations groups. This may be related to a small subgroup (n=44) with high non-operative expectations who ended up having surgery. Non-operative expectations had previously been shown to be an important predictor of patient treatment preference.[9] Our current findings reinforce the importance of patients’ non-operative treatment expectations and suggest that setting appropriate expectations for non-operative outcomes should be a major focus of educational efforts and decision aids for patients with lumbar disc herniation.

Several prior studies have looked at the relationship of treatment expectations and outcome. In a randomized trial comparing massage therapy and acupuncture for low back pain, Kalauokalani et al. found that patients who had higher expectations of benefit from the treatment they received had improved outcomes compared to those who were assigned to a treatment for which they had lower expectations.[16] General optimism for improvement had no effect on outcome in that study. In a similar study with contrasting results, Myers et al. found that higher general expectations were significantly associated with disability reduction but that specific expectations of patients' chosen therapies were not associated with disability reduction. [17] Similar to Kaluokalani and Myers, we did find a strong association between higher expectations and treatment received and outcome. For non-operative expectations, the effect was relatively specific to non-operative treatment; however, for surgical expectations the effect appeared to be generally independent of treatment.

Lutz et al. found that patients who expected more rapid recovery with surgery for sciatica were more satisfied than patients who expected a slower recovery but had similar functional outcomes.[18] Similarly, Sherman et al. found that general and specific expectations for the effectiveness of acupuncture resulted in improved functional scores but after adjusting for baseline bothersomeness scores and patient demographics there were no significant differences in outcome with regard to expectations. [19] Unlike Lutz and Sherman, we found a strong and consistent relationship between higher expectations for surgery and improved pain and functional outcomes. The reason for the general effect of surgical expectations on surgical and non-surgical treatment is uncertain and is without obvious precedent in the literature. However, one might speculate that the observed effect was less about those with high expectations for surgery but rather about those with low expectations from surgery. An alternative way to frame the finding for surgical expectations is that those patients who did not particularly expect to do well with surgery, tended not to do well with either treatment. Whether this is an effect of pessimism affecting outcome or an accurate estimation by those with more intractable symptoms is unclear.

Mannion et al. looked at anticipated improvement in 100 patients undergoing decompressive spine surgery for either herniated disc or spinal stenosis. It is difficult to directly compare results with this study since they measured patients' anticipated health state change rather than expectancy (expected chance of improvement). [20] Nonetheless, they did not find a significant association between anticipated health state change and actual change in symptoms or function. Similarly, Toyone et al. evaluated patients' anticipated health state change prior to spine surgery and found no association with pain and functional outcomes.[21] On the other hand, Yee et al. looked at expectancy in 155 patients undergoing spine surgery for a variety of degenerative conditions of the spine. Similar to our results, they found those with higher surgical expectations had greater improvement in the SF-36 PF scale, though apparently not in the BP or ODI.[22] It is interesting to note that across these studies expectancy (predicted probability of achieving a particular outcome) seems to be predictive of pain and functional outcomes while anticipated health state or anticipated health state change does not. The reasons for this are unclear and may represent a fruitful area for further investigation.

In addition to their effect on pain and functional outcomes, many authors have separately looked at the association of patient expectations on patient satisfaction with the outcomes achieved. Mannion et al., Yee et al., and Toyone et al. all found that having expectations met was an important predictor of patients' satisfaction with their outcomes. We are unable to look at our data in this way since we measured formal expectancy rather than anticipated health state. Expectancy, which is a probability estimate, cannot be technically 'met' or 'not met'. Nonetheless, we agree with Mannion et al. that attempts to manipulate expectations in order to have a 'low bar' that is easy to reach in order to try to achieve higher satisfaction is not a realistic approach in clinical practice. Rather, careful and consistent education of patients in the evidence regarding their treatment options to allow them to reach informed and realistic expectations will be critical in achieving the best decisions and the best outcomes of treatment. This should include the evidence from this study that those with reasonable expectations of a good outcome from non-operative care have excellent non-operative outcomes with very little additional advantage to be gained by undergoing surgery.

The analysis of the SPORT outcomes controlling for baseline expectations yielded interesting results. First, it substantiated some early concerns about the potential placebo effects of patient expectations regarding surgery in that controlling for their expectations mitigated the apparent beneficial effects of surgery. This effect was greater for the outcome of bodily pain than for functional disability, with pain no longer being significantly different between surgery and non-operative treatment at 1–2 years but with surgery maintaining an advantage in terms of functional outcomes. This finding is consistent with the results of Hrobjartsson and Gotzsche's meta-analysis of trials that contained both a placebo control and an additional 'no intervention' control.[23] In that meta-analysis they found a consistent positive effect of placebo compared to no-treatment only for subjective continuous outcomes and in particular for measures of pain. It suggests that pain measures may be particularly sensitive to the effects of expectations and that functional status, even when collected as patient self-report, may be somewhat more 'objective.' This reinforces the importance of including uniform functional status measures in the assessment of painful conditions in general and in studies of back pain and other spinal disorders in particular. [17] What has not yet been controlled for in assessing this potential placebo effect is the quality of prior knowledge patients have pertaining to treatment options and likely outcomes, and how this may influence both expectations and ultimate outcomes.

Several limitations of this study must be considered. Expectations were only measured at baseline, but these are clearly not static traits and will change along with the patient's experience. For this reason, we included only those receiving surgery within the first 3 months in the surgery group for this analysis as it is unclear to what extent the baseline expectations would still apply to someone having surgery 6 or 9 months later. Also, there is no gold standard or any validated instrument to measure expectations, but the need for such instruments is well described. [17] As discussed we measured formal expectancy rather than anticipated health states. The questionnaires have significant face validity and extensive investigations of the relationships between baseline expectations and preferences showed that they behaved in a reasonable manner.[9] Finally, in this observational study, we cannot comment on the cause of the observed relationship between expectation and outcome. While higher expectations may affect patient outcomes, through placebo or compliance

mechanisms, or their reporting of their outcomes, it may also reflect accurate predictions on the part of patients as to how well they will do with specific treatments.

In summary we found a significant association between treatment-specific expectations (specifically expectancy) on pain and functional outcomes. Controlling for baseline expectations in the as-treated analysis of this unblinded study diminished the apparent advantage of surgery such that there was no longer a statistically significant difference in pain at 2 years; however functional status continued to show a significant advantage for surgery. These results suggest the importance in unblinded studies of spinal interventions of measuring functional outcomes and of adequately informing patients and then including their informed expectations in the decision-making process in order to optimize their treatment outcomes.

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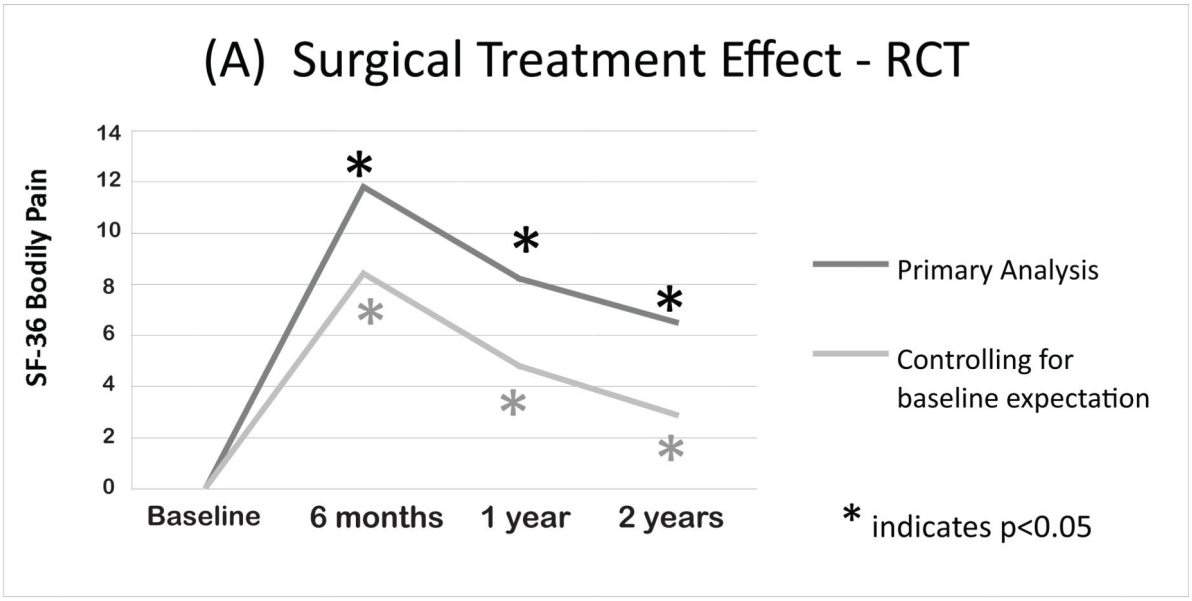


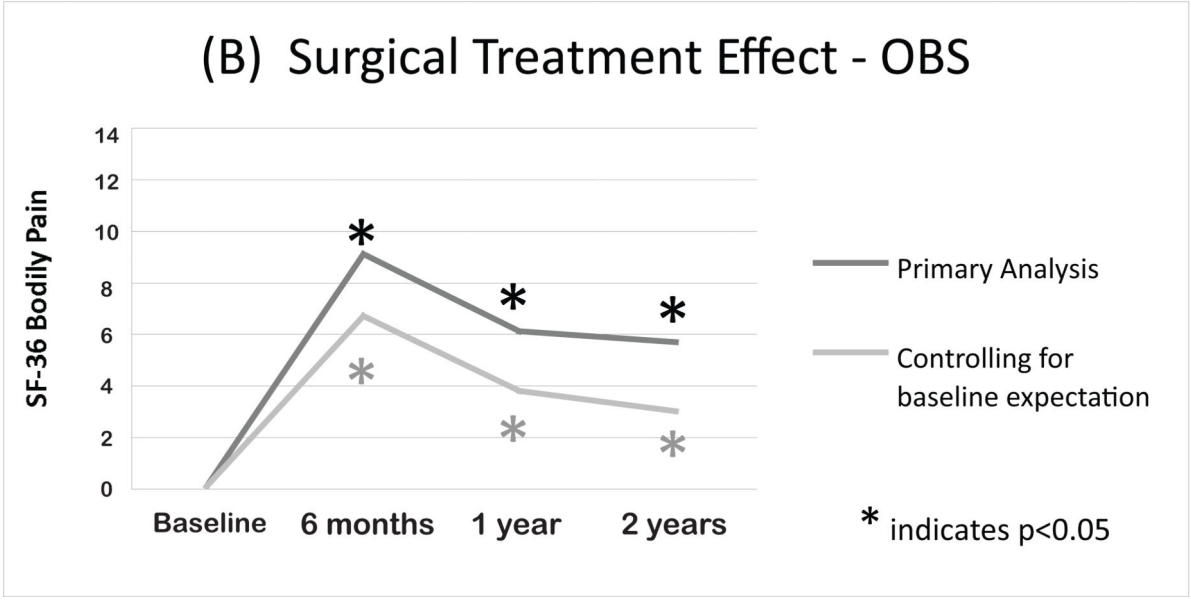
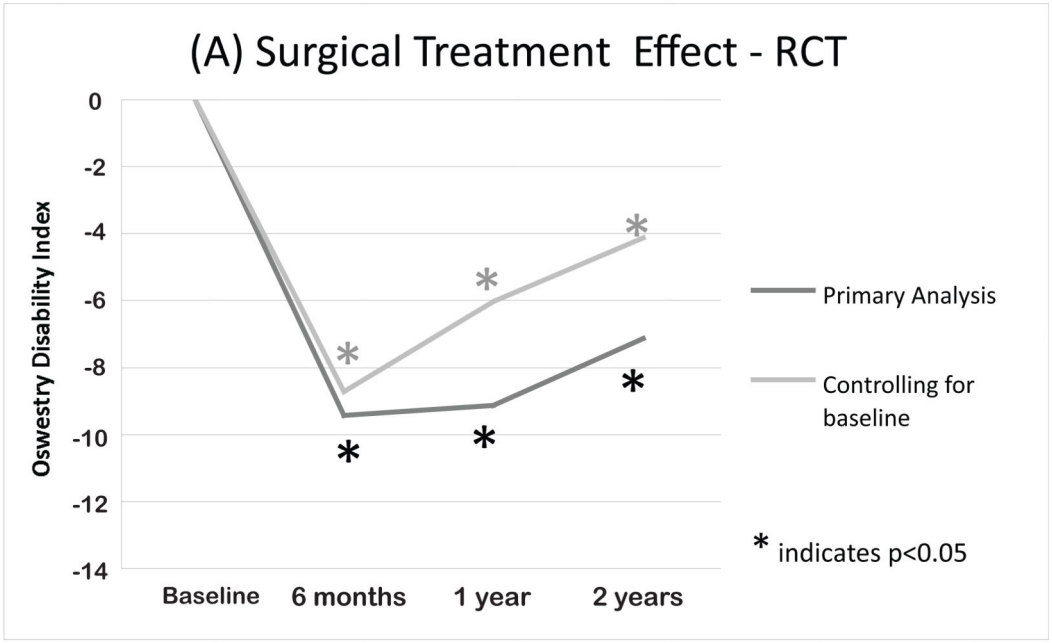


Figure 1.
SPORT primary as-treated SF-36 BP outcomes with and without controlling for baseline expectations for treatment received.



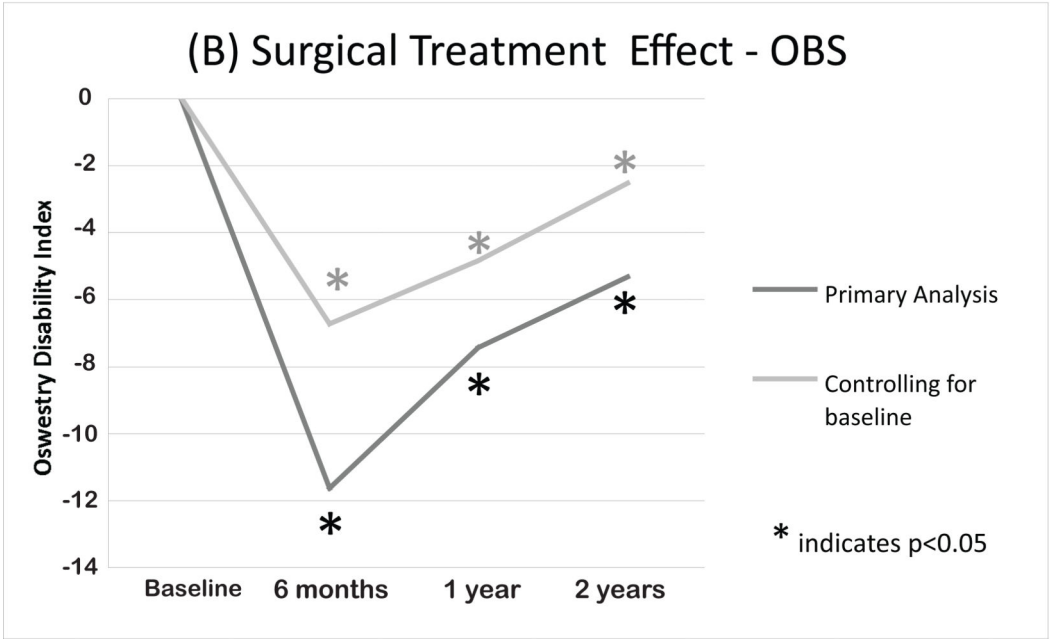


Figure 2.
SPORT primary as-treated Oswestry Disability outcomes with and without controlling for baseline expectations for treatment received.

Table 1

Baseline expectation and preference by treatment received within 3 months for 1191 SPORT participants with IDH.

	Randomized Cohort			Observational Cohort			Combined Cohorts		
	Surgery* (n=185)	Non-op (n=287)	p-value	Surgery* (n=496)	Non-op (n=223)	p-value	Surgery* (n=681)	Non-op (n=510)	p-value
Expected benefit from surgery			0.002			<0.001			<0.001
Big	125 (69%)	154 (54%)		377 (78%)	97 (44%)		502 (76%)	251 (50%)	
Moderate/Small	56 (31%)	130 (46%)		105 (22%)	121 (56%)		161 (24%)	251 (50%)	
Expected benefit from non-op			0.005			<0.001			<0.001
Big	28 (15%)	76 (27%)		16 (3%)	76 (35%)		44 (7%)	152 (30%)	
Moderate/Small	155 (85%)	208 (73%)		472 (97%)	143 (65%)		627 (93%)	351 (70%)	

*Surgery group consists of all patients who underwent surgery within 3 months of enrollment.

Table 2

Outcomes stratified by expectation of benefit from Surgery for the combined randomized and observational cohorts

Outcome	Improvement Expectancy With Surgery	6 months			1 Year			2 years		
		Surgery*	Non-Op	Treatment Effect	Surgery*	Non-Op	Treatment Effect	Surgery*	Non-Op	Treatment Effect
BP	Big Chance	43 (1.1)	35.2 (1.6)	7.8 (3.9, 11.6)	44.6 (1.1)	38.3 (1.6)	6.3 (2.4, 10.2)	44.3 (1.1)	39.8 (1.6)	4.5 (0.5, 8.4)
	< Big Chance	32.6 (1.9)	26 (1.6)	6.5 (1.6, 11.5)	33.1 (2)	32.5 (1.6)	0.6 (−4.3, 5.6)	35.2 (2)	34.2 (1.6)	1 (−4, 6.1)
	p-value	<0.001	<0.001	0.69	<0.001	0.008	0.068	<0.001	0.012	0.28
PF	Big Chance	43.2 (1.1)	31.4 (1.5)	11.9 (8.1, 15.6)	45.3 (1.1)	35.2 (1.5)	10 (6.3, 13.8)	45 (1.1)	37.2 (1.6)	7.8 (4, 11.6)
	< Big Chance	33.3 (1.9)	21.9 (1.5)	11.4 (6.6, 16.2)	35.5 (1.9)	28.9 (1.5)	6.6 (1.7, 11.4)	36 (1.9)	31.5 (1.6)	4.6 (−0.3, 9.5)
	p-value	<0.001	<0.001	0.87	<0.001	0.003	0.25	<0.001	0.008	0.29
ODI	Big Chance	−37 (0.9)	−28.3 (1.3)	−8.7 (−11.9, −5.5)	−37.5 (0.9)	−29 (1.3)	−8.4 (−11.6, −5.2)	−37.5 (0.9)	−31.6 (1.3)	−5.8 (−9.1, −2.6)
	< Big Chance	−28.7 (1.6)	−20.2 (1.3)	−8.4 (−12.6, −4.3)	−29.4 (1.6)	−24.7 (1.3)	−4.6 (−8.8, −0.5)	−29.4 (1.6)	−26.7 (1.3)	−2.7 (−6.9, 1.5)
	p-value	<0.001	<0.001	0.91	<0.001	0.016	0.14	<0.001	0.007	0.23

Longitudinal model covariates: cohort (randomized vs observational), education, baseline outcome score, symptom duration, and factor cited as influencing treatment preference (ability to participate in leisure activities)

*Surgery group consists of all patients who underwent surgery within 3 months of enrollment

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Table 3

Outcomes stratified by expectation of benefit from Non-operative Treatment

Outcome	Improvement Expectancy with Non-Op	6 months			1 Year			2 years		
		Surgery*	Non-Op	Treatment Effect	Surgery*	Non-Op	Treatment Effect	Surgery*	Non-Op	Treatment Effect
BP	Big Chance	47.1 (3.7)	33.7 (2)	13.4 (5.1, 21.7)	47.1 (3.7)	39.6 (2)	7.5 (−0.7, 15.7)	46.2 (3.8)	41.6 (2)	4.6 (−3.7, 13)
	< Big Chance	40.1 (1)	29.7 (1.4)	10.5 (7, 13.9)	41.3 (1)	33.8 (1.4)	7.5 (4, 10.9)	42 (1)	35.6 (1.4)	6.4 (3, 9.9)
	p-value	0.073	0.094	0.52	0.13	0.014	1	0.28	0.013	0.69
PF	Big Chance	47.7 (3.6)	32.2 (2)	15.5 (7.4, 23.5)	47.2 (3.6)	36.2 (1.9)	11 (3, 18.9)	42.8 (3.6)	38.2 (2)	4.7 (−3.5, 12.8)
	< Big Chance	40.5 (1)	24.5 (1.3)	15.9 (12.6, 19.3)	42.7 (1)	30.7 (1.3)	12 (8.6 , 15.3)	42.9 (1)	33.1 (1.3)	9.8 (6.4, 13.2)
	p-value	0.054	<0.001	0.92	0.23	0.018	0.82	0.98	0.031	0.24
ODI	Big Chance	−40.4 (3.1)	−28.1 (1.7)	−12.3 (−19.1, −5.5)	−40.3 (3)	−29.7 (1.7)	−10.5 (−17.3, −3.8)	−37.9 (3.1)	−32.8 (1.7)	−5.1 (−12, 1.8)
	< Big Chance	−34.7 (0.8)	−22.8 (1.1)	−11.9 (−14.7, −9)	−35.1 (0.9)	−26 (1.1)	−9.1 (−12, −6.2)	−35.4 (0.9)	−27.9 (1.1)	−7.5 (−10.4, −4.6)
	p-value	0.07	0.006	0.91	0.10	0.059	0.70	0.45	0.015	0.52

Longitudinal model covariates: cohort (randomized vs. observational), education, baseline outcome score, symptom duration, and factor cited as influencing treatment preference (ability to participate in leisure activities).

*Surgery group consists of all patients who underwent surgery within 3 months of enrollment