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Effects of Viewing an Evidence-Based Video Decision Aid on Patients' Treatment Preferences for Spine Surgery

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Abstract

Study Design-Secondary analysis within a large clinical trial

Objective—To evaluate the changes in treatment preference before and after watching a video decision aid as part of an informed consent process.

Summary of Background Data—A randomized trial with a similar decision aid in herniated disc patients had shown decreased rate of surgery in the video group, but the effect of the video on expressed preferences is not known.

Methods—Subjects enrolling in the Spine Patient Outcomes Research Trial (SPORT) with intervertebral disc herniation (IDH), spinal stenosis (SPS), or degenerative spondylolisthesis (DS) at thirteen multidisciplinary spine centers across the US were given an evidence-based videotape decision aid viewed prior to enrollment as part of informed consent.

Results—Of the 2505 patients, 86% (n=2151) watched the video and 14% (n=354) did not. Watchers shifted their preference more often than non-watchers(37.9% vs. 20.8%, p < 0.0001) and more often demonstrated a strengthened preference (26.2% vs. 11.1%, p < 0.0001). Among the 806 patients whose preference shifted after watching the video, 55% shifted toward surgery (p=0.003). Among the 617 who started with no preference, after the video 27% preferred non-operative care, 22% preferred surgery, and 51% remained uncertain.

Conclusion—After watching the evidence-based patient decision aid (video) used in SPORT, patients with specific lumbar spine disorders formed and/or strengthened their treatment preferences in a balanced way that did not appear biased toward or away from surgery.

Introduction

Shared decision-making is the process of engaging patients in treatment decisions in order to arrive at informed, values-based choices among two or more medically reasonable alternatives. 1 Decision aids are increasingly used to foster this process. A recent Cochrane Collaboration Review identified over 200 decision aids and over 34 randomized trials evaluating decision aids. 2 In these trials, decision aids improved knowledge, created more

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Elective lumbar spine surgery is an example of preference-sensitive care,3 where reasonable people with similar indications for spine surgery might chose different treatments. For many spine conditions non-operative outcomes are generally good, and the treatment choice between surgical and non-operative care depends greatly on the patients' values regarding their degree of pain and functional impairment and trade-offs between rapidity of improvement and potential risks of surgery. A randomized study of a decision aid for patients with either intervertebral disc herniation or spinal stenosis showed a statistically significant reduction in surgery rates among disc herniation patients receiving an evidence-based decision aid, whereas a trend towards higher rates of surgery was seen among spinal stenosis patients who received a decision aid.4

The Spine Patient Outcomes Research Trial (SPORT) is a multi-center clinical trial comparing the outcomes of surgery and non-operative treatment for patients with one of three lumbar spinal disorders. Patients enrolling in this trial viewed a diagnosis-specific videotape decision aid as part of their informed consent process. In this study, we compared the patients' expressed treatment preferences before and after being given the video decision aid.

Methods

SPORT was conducted at 13 multidisciplinary spine practices in 11 states across the U.S. Each participating institution's human subjects committee approved a standardized protocol. An independent Data Safety and Monitoring Board monitored the study. All patients in SPORT were over 18 years old with a clinical diagnosis of either intervertebral disc herniation (IDH) or spinal stenosis (SPS) - with or without degenerative spondylolisthesis (DS) - that was confirmed by imaging. 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 had had symptoms for a minimum of 6 weeks in the IDH group and 12 weeks in the SPS/DS groups and were deemed surgical candidates by the enrolling surgeon.

Patients identified as candidates for the study answered the question "What is your current preference for how to treat your spine-related problem?" on a 5-point scale (1-definitely prefer to have non-surgical treatment; 2-probably prefer to have non-surgical treatment; 3 - I'm not sure what treatment I prefer at this time; 4-probably prefer to have surgery; 5 - definitely prefer to have surgery). All patients were given an evidence-based video decision aid as part of their informed consent process; there were two separate video decision aids, one for the IDH group and another for the SPS and DS groups. A small percentage of the patients chose not to watch the video. After enrollment patient preferences (including those of non-watchers) were again assessed using the same scale.

These videos were adapted for this trial from decision aids developed by and available through the Foundation for Informed Medical Decision Making. Each decision aid included basic information on the condition itself, testimonials by patients who had the condition and had chosen each of the options, and a summary of the available data on outcomes and potential harms of each of the treatment options derived from the literature.

Initial analyses compared changes in preference for those who did and did not see the video to establish a baseline for patient preference stability. Change in preference was evaluated in terms of movement toward or away from: 1) surgery and 2) certainty. For example if someone stated that they probably preferred non-operative care before the video and was

unsure of their preference after the video, they were considered to have moved their preference toward surgery and away from certainty. Alternatively if they started out stating that they probably preferred surgery before the video and definitely preferred surgery after the video, they were considered to have moved their preference toward surgery and toward certainty. If they started out definitely preferring surgery before the video and probably preferring surgery after the video, then they were considered to have moved their preference away from surgery and away from certainty.

Changes among those seeing the entire video were evaluated relative to patient demographics, diagnosis, and pre-video preference using chi-square for categorical and t-tests for continuous variables. For these analyses, the pre-video preference scale was collapsed into 3 categories by combing the definitely prefer and probably prefer categories for each treatment resulting in the following categories – prefer surgery, uncertain, and prefer non-op. Evaluation of differences in patient demographics and functional health status within each cohort relative to preference shift (toward surgery, no shift, away from surgery) was analyzed using chi-square for dichotomous and analysis of variance (ANOVA) for continuous outcomes. While analyses used the full five category scale, for readability in Table 1, the 5 preference categories at baseline were collapsed into 3 categories by combining the definitely prefer and probably prefer categories for each treatment resulting in three categories and probably prefer categories for each treatment resulting in three categories and probably prefer categories for each treatment resulting in three categories and probably prefer categories for each treatment resulting in three categories – prefer surgery, uncertain, and prefer non-op.

Results

Overall, 2151/2505 patients (86%) watched the video. Comparison of the characteristics of watchers vs. non-non-watchers revealed them to be quite similar except that watchers were: 1) less likely to be "very dissatisfied" with their symptoms at baseline (73% vs. 86%; p<0.001); 2) more likely to shift their treatment preference after enrollment, i.e. after being offered the video (38% vs. 21%; p<0.001); and 3) more likely to demonstrate a strengthened preference (increased certainty) post-enrollment (26% vs.11%; p<0.001).

Table 1 summarizes the pre-to-post video preference shift for watchers, stratified by diagnosis (IDH vs. SPS/DS). Overall, among 806 watchers who shifted their preference post-video, slightly more moved their preference toward surgery (55% vs. 45%; p=0.003). However, among the 304 who started with no preference pre-video and who expressed a preference post-video, slightly more developed a preference for non-operative care than for surgery (55% vs. 45%; p=0.012). Only a small percentage (4%) of patients who had an expressed preference for one treatment or the other pre-video changed their preference enough to end up preferring the other treatment post-video. Preference shifts post-video did not differ significantly between IDH and the SPS/DS groups.

Table 2 summarizes differences in selected patient demographics and functional health status measures relative to their pre- to post-video shift in preference, stratified by diagnosis (IDH vs. SPS/DS). Those IDH patients who shifted their preference toward surgery had worse baseline bodily pain (SF-36 Bodily Pain score 24 vs. 30; p=0.003), physical function (SF-36 Physical Function score 33 vs. 47; p<0.001), disability (Oswestry Disability Index 53 vs. 43; p<0.001), and greater dissatisfaction with their symptoms (very dissatisfied 85% vs. 71%; p=0.006) than those who shifted their preference toward non-operative care. A similar comparison among the SPS/DS patients revealed similar findings of worse symptoms, lower function and greater disability among those who shifted their preference toward surgery; however, in addition, SPS/DS patients who shifted their preference toward surgery were more likely to be female; to be receiving disability compensation; to have previously received an epidural steroid injection; and were less likely to have diabetes mellitus. Other clinical and demographic characteristics (race, ethnicity, educational attainment, marital

status, work status, BMI, smoking status, duration of symptoms, leg pain bothersomeness, SF-36 Mental component summary score, prior physical therapy, and baseline symptom trajectory (getting worse versus getting better)) did not significantly differ between those shifting and those not shifting their preference in either diagnosis group.

Discussion

There was a significant change in treatment preference for patients after watching the videotape decision aids used in the SPORT trial. Those who watched the video that was provided as part of the informed consent process were more likely to shift their treatment preference than those who chose not watch it. The video helped those patients who were uncertain at baseline to form a preference, and helped those patients who started with an initial preference to strengthen their preference. There was no consistent trend in preference shifts either toward or away from surgery, suggesting that the decision aid had a balanced effect on treatment preferences (i.e. it did not appear to be biased either for or against one treatment approach).

A similar decision aid with much of the same content had been previously studied in a randomized trial comparing a videodisc plus a booklet to the informational booklet alone. Patients were not randomized to treatment but chose their treatment after exposure to one of the two decision aids.4.5 In that trial, the videodisc group demonstrated improved knowledge scores compared to the booklet-only group and a larger proportion of the videodisc group rated the material as easy to understand. Furthermore, patients with IDH in the videodisc group underwent surgery significantly less often (32% vs. 47%).

Interestingly, in the current study, patients with IDH were somewhat more likely to shift their preference toward surgery rather than away from it. In addition, the previous trial found an apparent difference in the effect of the videodisc based on diagnosis – disc herniation patients in the videodisc group were less likely to get surgery while spinal stenosis patients in the videodisc group were somewhat more likely to receive it. We found that the effect of the video on preference was similar in the disc herniation and the two spinal stenosis groups.

Several factors could explain this apparent difference. We looked at expressed preference while Deyo et al. looked at actual treatment choice. Patient treatment preference is only one factor in determining the ultimate choice of treatment. Those factors might play out differently in the context of a clinical trial than in clinical practice. Additionally, the current study, being in the context of a large multicenter clinical trial, had strict clinical and imaging criteria for entry that may have selected a different group of patients than the smaller study by Deyo et al. which included all patients considered for surgery at two sites. Finally, since most of the preference shifts post-video were a strengthening of patients' baseline preference, differences in the baseline preferences of patients in the two studies might explain the difference in results.

The major limitation of this study is that the videos were supplied to all subjects and we do not have a randomized comparison group that did not receive the decision aid. As a result, we are able to describe the changes in preference; however, there were other aspects to the informed consent process that may have contributed to the differences seen. The patients who chose not to view the tape serve as a partial control group but the effects might be confounded by unmeasured differences between those who chose to watch the tape and non-watchers.

In conclusion, the informational video decision aids used in SPORT appeared to help patients with IDH and SPS/DS form or strengthen their treatment preferences. The decision

aids provided uniform information across all sites, allowing all patients to have evidencebased information as part of the SPORT informed consent process. Unbiased, evidencebased decision aids such as these can be useful tools to help patients with lumbar spine disorders participate with their physicians in making an informed choice regarding whether or not to have spine surgery.

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Table 1

Percentage and Direction of Preference Shift Post-Video from Baseline

	Prefer	ence Shift P	ost Video - IDH	
Baseline Preference	Toward Surgery n=229	No Shift n=636	Away Surgery n=161	P Value
Non-op (n=349)	37%	34%	30%	< 0.001
Uncertain (n=293)	33%	23%	44%	
Surgery (n=384)	30%	43%	26%	

	Preferen	ice Shift Pos	st Video – SPS/DS	1
	Toward Surgery n=216	No Shift n=685	Away Surgery n=200	P Value
Non-op (n=381)	41%	36%	22%	< 0.001
Uncertain (n=324)	29%	24%	48%	
Surgery (n=396)	30%	40%	30%	

Table 2

Summary of differences in selected demographics and health status measures by cohort and shift in treatment preference after viewing the video decision aid

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	Variable [*]	Toward Surgery n=229	No Shift n=636	Away Surgery n=161	P value
HCII	Age [Mean (SD)]	41.2 (11)	41.8 (11.6)	42 (11)	0.74
	Gender (%Female)	46%	44%	38%	0.24
	Disability Compensation (% Yes)	18%	16%	18%	0.78
	Diabetes (% Yes)	4%	3%	4%	0.60
	Received Epidural Injection (% Yes)	52%	49%	43%	0.20
	Bodily Pain [Mean (SD)]	23.5 (17.1)	26.7 (18)	29.7 (18.7)	0.003
	Physical Function [Mean (SD)]	33.4 (24.4)	39.2 (25.9)	46.8 (26.1)	<0.001
	ODI [Mean (SD)]	52.8 (21)	48.6 (21.8)	42.7 (21.6)	<0.001
	Symptoms (% Very Dissatisfied)	85%	78%	71%	0.006
	Variable [*]	Toward Surgery n=216	No Shift n=685	Away Surgery n=200	P value
SD/SqS	Age [Mean (SD)]	65.1 (11.9)	65.3 (10.5)	67.1 (11.2)	0.08
	Gender (%Female)	52%	58%	42%	<0.001
	Disability Compensation (% Yes)	13%	6%	6%	<0.001
	Diabetes (% Yes)	10%	14%	22%	0.004
	Received Epidural Injection (% yes)	64%	53%	52%	0.013
	Bodily Pain [Mean (SD)]	30.1 (17)	31.2 (16.6)	35.1 (18.9)	0.006
	Physical Function [Mean (SD)]	31.5 (21.5)	35 (23.5)	37.2 (23.5)	0.038
	ODI [Mean (SD)]	44.4 (17.5)	41.8 (18.2)	38 (18.4)	0.001
	Symptom (%Very Dissatisfied)	71%	%69	59%	0.013