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Considering Spine Surgery: A web-based calculator for communicating estimates of personalized treatment outcomes

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Abstract

Study Design—Prospective evaluation of an informational web-based calculator for communicating estimates of personalized treatment outcomes.

Objective—To evaluate the usability, effectiveness in communicating benefits and risks, and impact on decision quality of a calculator tool for patients with intervertebral disc herniations, spinal stenosis, and degenerative spondylolisthesis who are deciding between surgical and non-surgical treatments.

Summary of Background Data—The decision to have back surgery is preference-sensitive and warrants shared decision-making. However, more patient-specific, individualized tools for presenting clinical evidence on treatment outcomes are needed.

Methods—Using Spine Patient Outcomes Research Trial (SPORT) data, prediction models were designed and integrated into a web-based calculator tool: <http://spinesurgerycalc.dartmouth.edu/calc/>. Consumer Reports subscribers with back-related pain were invited to use the calculator via email, and patient participants were recruited to use the calculator in a prospective manner following an initial appointment at participating spine centers. Participants completed questionnaires before and after using the calculator. We randomly assigned previously validated questions that tested knowledge about the treatment options to be asked either before or after viewing the calculator.

Results—1,256 Consumer Reports subscribers and 68 patient participants completed the calculator and questionnaires. Knowledge scores were higher in the post-calculator group

compared to the pre-calculator group, indicating that calculator usage successfully informed users. Decisional conflict was lower when measured following calculator use, suggesting the calculator was beneficial in the decision-making process. Participants generally found the tool helpful and easy to use.

Conclusions—While the calculator is not a comprehensive decision aid, it does focus on communicating individualized risks and benefits for treatment options. Moreover, it appears to be helpful in achieving the goals of more traditional shared decision-making tools. It not only improved knowledge scores but also improved other aspects of decision quality.

Introduction

Lumbar discectomy and lumbar spinal fusion are two of the ten most frequently performed surgical procedures in the United States.¹ In carefully selected patients with specific diagnoses of intervertebral disc herniations (IDH), spinal stenosis (SpS), and degenerative spondylolisthesis (DS) studies such as the Spine Patient Outcomes Research Trial (SPORT) show that patients tend to improve over time with both non-operative care and surgery, although the surgery group tends to experience greater and more rapid improvements.^{2,3,4,5} Whether or not to have surgery for such disorders is thus considered a preference-sensitive decision, and shared decision-making (SDM) is of critical importance in choosing a treatment. SDM is a method of communication between a physician and patient that empowers the patient to be more informed and more involved in making treatment decisions.⁶ Ideally, in SDM the physician explains relevant information about risks, benefits, and alternatives, the patient indicates his or her preferences and values that would make one treatment option preferable to another, and together they make a decision.⁷

How to best implement SDM in clinical practice is an area of ongoing research. Despite substantial data on the usefulness of formal decision aids in SDM, their use is far from routine in clinical practice.⁸ One barrier to more widespread use is the concern that data presented to patients contain clinical heterogeneity and do not answer the question of how overall results of a trial apply to the “*individual patient*.”⁹ An emerging option is to use risk calculators that aim to provide individuals with a “*personalized assessment*” of their expected outcomes for specific diseases and health outcomes. However, while some publicly available websites with calculators are popular, they can lead to patient misinformation due to failure to put the estimated risks in proper context, inadequate communication of uncertainty, and use of non-informative classifications, inconsistent risk estimates, and poorly documented risk models.^{10,11}

Our overall goal was to improve dissemination of the best clinical evidence on individualized outcomes for patients considering lumbar spine surgery for three specific diagnoses. To accomplish this, we first developed and validated prediction models for various outcomes among patients with IDH, SpS, and DS based on SPORT for a period of 8 years post-treatment. We then developed and validated quantitative treatment-decision calculators for each diagnostic group and implemented a user-friendly interface displaying individualized risks and benefits based on our prediction models. The refined calculator was

then evaluated with respect to its usability, effectiveness in communicating and benefits and risks, and impact on decision quality.

Materials and Methods

Calculator Development

The SPORT study has provided a rich source of data for understanding patient outcomes for treating lumbar spine disorders with either surgical or non-surgical treatment. SPORT was designed to evaluate the relative effectiveness of surgical and non-operative treatment for three common lumbar spine conditions: IDH, SpS, and DS.¹² While results from SPORT provide a potentially unique resource of information for patients considering spine surgery, the fact that the trials involved multiple outcomes, a complex study design, and longitudinal statistical analyses present challenges in communicating personalized results to enable patients to reach informed, values-based decisions regarding back surgery.

To cope with these complexities, SPORT cohorts were used to construct prediction models. Following development, validation, and assessment of accuracy of the prediction models, we developed a web calculator program to display individualized predictions based on important patient characteristics. Our goal was to provide estimates of patient-centered outcomes over time, accompanied by measures of the inherent accuracy of the predictions.

The calculator interface development began with researchers from Dartmouth and Consumer Reports (CR) conducting an assessment of user needs, followed by formal information architecture development. CR information architects created multiple iterations of the wireframes for stakeholder review. Near-final wireframes were tested in a physician panel as well as in cognitive interviews with patients. Following this usability feedback, subsequent adjustments, and successful internal testing, the final calculator (<http://spinesurgerycalc.dartmouth.edu/calc/>) was tested in a large web survey of CR subscribers and a smaller survey of patients seen in participating spine clinics.

Web-Based Surveys

Using pop-up web survey technology, survey participants were asked to answer a series of approximately 18 questions asking specifically about (1) helpfulness of features and content; (2) difficulties accessing, finding or understanding information; (3) whether or not this information would impact their own health decisions toward or against surgery; (4) decision quality; and (5) at what point in their personal history of having back pain would they most want to receive this information. The strength of the pop-up survey technology is that it permits asking questions about user experience interactively within a web-based application such as the calculator. To encourage participation, the number of questions as well as the length and format of individual questions were chosen to be as concise as possible. While the Decisional Conflict Scale (DCS) is a validated tool to assess patients' uncertainty in making the decision that is best for them,¹³ the time required to conduct the 16-item scale is a barrier to its widespread implementation.¹⁴ For this reason, we used the recently validated SURE scale to assess decision quality. This 4-item scale (*1. Do you feel SURE about the best choice for you? 2. Do you know the benefits and risks of each option? 3. Are you clear*

about which benefits and risks matter most to you? 4. Do you have enough support and advice to make a choice?) has a simple yes/no response format, is concise, easy to use, and correlates well with the longer DCS.¹⁵ Compared to the DCS as the gold standard, the SURE scale was found to have a sensitivity and specificity for clinically significant decisional conflict of 94% and 90% respectively.¹⁶ Validated questions measuring whether the calculator improved knowledge of risks and benefits of the treatments were included,¹⁷ and randomized such that half of the subjects were tested before viewing the calculator, and half were tested afterwards. Comparisons of the responses between the samples allowed for an estimate of knowledge gained without the effects of repeating the questions both before and after viewing the calculator, a process that might alter the interpretation of any differences detected.

In addition to the SURE scale questions, the pre-calculator survey asked patients if they were leaning towards a particular treatment, how far along they were with their decision, and who they thought should make the decision about whether or not to have surgery on a scale from “Totally You” to “Totally Your Health Care Provider.” Following the pre-calculator survey, patients were directed to the calculator itself, where patients were asked their age, sex, how often their health limits them in various activities, how often various symptoms have bothered them in the past week, and yes/no questions regarding past medical history. After patients went through the calculator results, they were then asked to complete a post-calculator survey with questions testing comprehension of material presented in the calculator, the same SURE scale questions, which treatment they are currently leaning towards, how far along they are with their decision, and who they felt should make the decision about surgery.

Survey Participants

The web-based calculator surveys targeted both on-line subscribers of Consumer Reports as well as patients presenting with IDH, SpS, or DS to providers at participating multidisciplinary spine centers.

The Consumer Reports subscribers’ cohort received an e-mail invitation to a web-link displaying the calculator. The clinical cohort of patients with IDH, SpS, and DS were invited to evaluate the calculator in a prospective manner. Providers at the Dartmouth-Hitchcock Medical Center Spine Clinic, OrthoCarolina, Washington University, and Beth Israel Deaconess Medical Center invited patients presenting with the appropriate diagnoses to view and evaluate the calculator. In clinic, providers distributed information cards containing a simple URL as well as a unique and anonymous login and confirmation code for accessing the study website.

Results

For the consumer participant group, a total of 2,282 eligible patients followed the web link and began the process, of whom 1,256 participants completed the calculator and questionnaires. For the patient participant group, a total of 77 patients signed into the website of whom 68 patients completed the calculator and questionnaires (Figure 1). The patient and consumer populations were different with respect to age and gender, but similar

with respect to race and ethnicity. As expected, the patients were demonstrably more symptomatic with respect to physical functioning, pain, sleep, and sex life disturbances compared to the consumers (Table 1).

Knowledge Questions

To assess knowledge gained from calculator use, knowledge scores (Table 2) were analyzed for both consumer and patient participants. For consumer participants with IDH, SpS, and DS, statistically significant differences were observed for all three diagnosis groups. Overall a higher percentage of participants answered knowledge questions correctly after using the calculator compared to the percentage of participants who answered pre-calculator knowledge questions correctly. For patient participants, the knowledge scores were statistically significantly higher in the post-calculator group for SpS, and were higher in the post-calculator group for IDH and DS, but did not reach statistical significance in this small sample.

Decision and Decisional Conflict Questions

To assess whether the calculator aided decision-making, SURE scale questions (Figures 2 and 3) were analyzed for both consumer and patient participants. For consumer participants, there was an increase post-calculator use in percentage of positive responses to all SURE scale questions (Figure 2a) that was statistically significant for 3 of the 4 questions. For patient participants, there was an increase post-calculator use in percentage of positive responses to feeling sure about the best choice, knowing the benefits and risks of each option, and being clear about which benefits and risks matter most to the individual patient, but only the latter reached statistical significance (Figure 2b).

Calculator Evaluation Questions

To garner participant feedback on the calculator itself, calculator evaluation questions (Table 3) were analyzed for both consumer and patient participants. Overall, participants found the preliminary images and descriptions of conditions included in the calculator to be helpful, were satisfied with the ease of use of the tool, felt providers should give calculators to their patients, and found the results pages useful.

Discussion

As the decision to treat specific low back disorders with surgery is preference-sensitive and ultimately up to the patient, SDM should be a fundamental component of choosing a treatment. However, integrating SDM into the treatment selection process is easier said than done. The use of formal decision aids is currently viewed as the gold standard of SDM. These aids outline treatment options, risks, and benefits, and are often supported by patient testimonials regarding specific treatment choices, and physician interviews describing procedural and recovery details. Patients are able to take these decision aids home and review them as many times as they please, so that they feel both informed about risks and benefits associated with each treatment option, and empowered to engage in a conversation with their physician regarding which treatment is best for them.

In isolation, the Back Treatment Outcomes Calculator is not intended as a complete decision aid. It does not go into detail about what is specifically entailed with either surgical or non-surgical treatment, nor does it comprehensively inform about all the risks and benefits associated with either treatment option. However, it does aid in the presentation and interpretation of complex evidence-based outcomes data tailored to an individual's characteristics, for three specific diagnostic groups. In this way, the calculator is a source of specific personalized information that could become a component of a more comprehensive decision support process.

The purpose of SDM is to ensure a patient feels comfortable with their knowledge of treatments available, and confident to make a decision that best suits them. Based on the SURE scale results, the calculator appears to assist users in feeling better about their likely decisions. Both consumer and patient participants felt more confident in their decisional leanings following calculator usage, which spurs patient engagement and empowerment in the treatment-decision dialogue between patient and physician.

However, there is some evidence that consumers and patients did not answer the SURE questions in the same way. Overall, both saw a positive percent difference post-calculator compared to pre-calculator in response to all SURE scale questions. However, patient participants had a higher percentage of positive responses for all SURE scale questions than consumer participants. Why the variability? The key difference between consumer and patient participants stems from the recruitment process of study participants: patients received access to the calculator after receiving a diagnosis from their physician, whereas not all consumers invited to participate were considering back surgery. Patient participants were recruited to the study after a provider confirmed their diagnosis; calculator information was distributed only to relevant patients. While the positive percent difference between post- and pre-calculator suggests that the calculator was beneficial for both participant groups, the differences between consumer and patients suggests that informational tools may be more beneficial when distributed further along in the decision-making process. The majority of patient participants felt the calculator would be most helpful after seeing a spine care specialist, and interestingly, only 7% of patients thought the calculator would be helpful prior to seeing any physician.

Patient recruitment was a limitation of the study, and ideally a larger patient population would be surveyed to determine if the understandability, usability, and helpfulness of the calculator hold true. Additionally, the majority of patient participants came from Dartmouth-Hitchcock Medical Center, and results were unable to be stratified based on centers. While some geographic variability in the rates of back surgery can be explained in the variance of SDM practices, we were unable to detect whether there was geographic variability in our evaluation of the calculator.

Although the question of geographic variance in back surgery warrants further investigation, more uniform practice of SDM will likely minimize unnecessary geographical variation. The question of how best to implement SDM does not have a simple answer. While an informational tool such as this calculator does not replace the need for formal decision aids, or interaction with a physician, the calculator may enhance SDM when distributed to

relevant patients at the appropriate time in their decision-making process. In general, the calculator appears to help patients feel informed, engaged, and confident in how they choose to treat their low back problems.

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Figure 1.
Study participants enrollment consort diagram.

Figure 2a.
SURE scale questions pre-calculator vs. post-calculator for consumers

Figure 2b.
SURE scale questions pre-calculator vs. post-calculator for patients

Table 1

Baseline demographic characteristics and health status measures*

	IDH			SPS			DS			All Condition		
	Consumers (n=401)	Patients (n=30)	P	Consumers (n=704)	Patients (n=26)	P	Consumers (n=151)	Patients (n=12)	P	Consumers (n=1256)	Patients (n=68)	P
Mean age (SD)	63.3 (10)	47.8 (16)	<0.001	69.3 (8.2)	67.3 (9.9)	0.23	66.1 (8.8)	68.8 (7.3)	0.29	67 (9.3)	59 (16)	<0.001
Female	108 (27%)	15 (50%)	0.013	176 (25%)	9 (35%)	0.38	52 (34%)	6 (50%)	0.44	336 (27%)	30 (44%)	0.003
Race, Caucasian [†]	373 (93%)	29 (97%)	0.70	661 (94%)	25 (96%)	0.96	136 (90%)	12 (100%)	0.53	1170 (93%)	66 (97%)	0.31
Ethnicity, non-Hispanic [†]	381 (95%)	30 (100%)	0.42	680 (97%)	26 (100%)	0.69	143 (95%)	12 (100%)	0.90	1204 (96%)	68 (100%)	0.16
Symptom duration > 6 months	391 (98%)	24 (80%)	<0.001	691 (98%)	25 (96%)	1	149 (99%)	6 (50%)	<0.001	1231 (98%)	55 (81%)	<0.001
SF-36 Physical Function score [§]	54.5 (26.2)	38.2 (21.2)	<0.001	49.2 (25.6)	32.5 (25.6)	0.001	48.5 (25.9)	45 (26.5)	0.65	50.8 (25.9)	37.2 (24)	<0.001
Sciatica/stenosis Bothersomeness Index [‡]	10.2 (6.5)	16.2 (5.8)	<0.001	11 (6.6)	15.4 (6.1)	<0.001	10.7 (6.9)	13 (5.9)	0.27	10.7 (6.6)	15.4 (5.9)	<0.001
Sleep well	163 (41%)	4 (13%)	0.006	307 (44%)	11 (42%)	0.94	57 (38%)	4 (33%)	1	527 (42%)	19 (28%)	0.031
Sex life unchanged	259 (65%)	7 (23%)	<0.001	462 (66%)	14 (54%)	0.30	89 (59%)	7 (58%)	0.79	810 (64%)	28 (41%)	<0.001

* Values presented are means (standard deviations), or numbers (%).

[†] Race or ethnic group was self-assessed. Caucasians and African Americans could be either Hispanic or non-Hispanic.[§] The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.[‡] The Sciatica/stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms.

SD indicates standard deviation; SF-36, 36-Item Short Form General Health Survey.

Table 2
Knowledge scores (percentage of correct answers) for pre- and post-calculator groups*

Condition	Group	Consumers (n = 1256)			Patients (n = 68)		
		N	% correct answers (SE)	P	N	% correct answers (SE)	P
IDH	Pre-calculator	183	24 (2)	<0.001	10	30 (9)	0.101
	Post-calculator	218	32 (2)		20	50 (7)	
SPS	Pre-calculator	340	22 (1)	<0.001	18	25 (6)	0.012
	Post-calculator	364	32 (1)		8	53 (9)	
DS	Pre-calculator	79	21 (2)	0.003	7	21 (7)	0.074
	Post-calculator	72	31 (3)		5	40 (6)	

* There were four knowledge questions and participants were randomly assigned to pre- or post-calculator knowledge question group. Knowledge score was defined as percentage of correct answers, which was calculated by number of correct answers divided by four, the total number of knowledge questions, and then times one hundred. Values presented are means (standard errors). T-tests were used to compare knowledge scores between pre- and post-calculator groups. SE indicates standard error.

Table 3

Calculator evaluation questions *

Question	Answer	Consumers (n = 1256)	Patients (n = 68)	P
How useful were the descriptions and images of Sciatica/Slipped Disc (Herniated Disc); Spinal Stenosis; and Slipped Vertebra (Degenerative Spondylolisthesis) in identifying your conditions?	Very useful	348 (28%)	32 (47%)	0.005
	Moderately useful	349 (28%)	16 (24%)	
	Somewhat useful	332 (26%)	14 (21%)	
	Not at all useful/Slightly useful	227 (18%)	6 (9%)	
How satisfied were you with the EASE OF USE of this computer-based tool?	Very satisfied	447 (36%)	32 (47%)	0.013
	Satisfied	513 (41%)	27 (40%)	
	Neutral	263 (21%)	5 (7%)	
	Dissatisfied/Very dissatisfied	33 (3%)	4 (6%)	
How important is it that health care providers give Calculators like this to their patients?	Extremely important	129 (10%)	11 (16%)	0.084
	Very important	424 (34%)	29 (43%)	
	Somewhat important	618 (49%)	26 (38%)	
	Not important at all	85 (7%)	2 (3%)	
At what point in the course of your back problem would this Calculator be most helpful?	Prior to seeing my primary care physician	241 (19%)	5 (7%)	<0.001
	Right after seeing my primary care physician	145 (12%)	4 (6%)	
	Just prior to seeing a spine care specialist	618 (49%)	26 (38%)	
	After seeing my spine care specialist	252 (20%)	33 (49%)	
Overall, how would you rate this Calculator?	Excellent	57 (5%)	8 (12%)	0.029
	Very good	365 (29%)	24 (35%)	
	Good	528 (42%)	26 (38%)	
	Fair	269 (21%)	8 (12%)	
	Poor	37 (3%)	2 (3%)	
How useful were the Results Pages in explaining the average expected results over time with surgical and non-surgical treatments?	Very useful	280 (22%)	27 (40%)	<0.001
	Moderately useful	365 (29%)	27 (40%)	
	Somewhat useful	380 (30%)	9 (13%)	
	Not at all useful/Slightly useful	231 (18%)	5 (7%)	
How useful were the Results Pages in explaining the chances of different results with surgical and non-surgical treatments?	Very useful	287 (23%)	27 (40%)	0.006
	Moderately useful	364 (29%)	20 (29%)	
	Somewhat useful	372 (30%)	11 (16%)	
	Not at all useful/Slightly useful	233 (19%)	10 (15%)	
How useful were the Results Pages in explaining the risks of surgical and non-surgical treatments?	Very useful	291 (23%)	23 (34%)	0.13
	Moderately useful	367 (29%)	21 (31%)	
	Somewhat useful	351 (28%)	16 (24%)	

Question	Answer	Consumers (n = 1256)	Patients (n = 68)	P
	Not at all useful/Slightly useful	247 (20%)	8 (12%)	

* Values presented are numbers (%).

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