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HEALTH SERVICES RESEARCH

Psychometric Evaluation of a Decision Quality Instrument for Treatment of Lumbar Herniated Disc

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Study Design. Retrospective and prospective patient surveys and a physician survey using a sample from American Medical Association master file.

Objective. To evaluate the performance of a new instrument designed to measure the quality of decisions about treatment of herniated disc.

Summary of Background Data. There is growing consensus on the importance of engaging and informing patients to improve the quality of significant medical decisions, yet there are no instruments currently available to measure decision quality.

Methods. The herniated disc–decision quality instrument (HD-DQI) was developed with input from clinical experts, survey research experts, and patients. The HD-DQI produces 2 scores each scaled to 0% to 100%, with higher scores indicating better quality: (1) a total knowledge score and (2) a concordance score (indicating the percentage of patients who received treatments that matched their goals). We examined hypotheses relating to the acceptability, feasibility, validity, and reliability of the instrument, using data from 3 samples.

Results. The HD-DQI survey was feasible to implement and acceptable to patients, with good response rates and low missing data. The knowledge score discriminated between patients who had seen a decision aid or no decision aid (55% *vs*. 38%, $P < 0.001$) and between providers and patients (73% *vs*. 46%, $P < 0.001$). The knowledge score also had good retest reliability (intraclass correlation coefficient = 0.85). Most patients (78%) received treatments that matched their goals. Patients who received treatments that matched their goals were less likely to regret the decision than those who did not (13% *vs*. 39%, $P = 0.004$).

Conclusion. The HD-DQI met several criteria for high-quality patient-reported survey instruments. It can be used to determine the quality of decisions for treatment of herniated disc. More work is needed to examine acceptability for use as part of routine patient care.

Key words: shared decision making, patient-centered care, decision quality, quality measurement, lumbar herniated disc. **Spine 2012;37:1609–1616**

In 2009, the American Pain Society issued clinical practice guidelines for patients with low back disorders, including lumbar herniated disc. The guidelines recommend shared decision making (SDM) be used in the determination of treatment of low back pain.[1] The guidelines define SDM as a process that engages patients by providing them information about "trade-offs and uncertainties, so that decisions are consistent with their preferences, values, and goals."[1]

An international collaboration of SDM experts endorsed a definition of decision quality that focuses on 2 key areas: (1) the extent to which patients are informed and (2) the extent to which treatments match what is most important to patients.[2] To determine whether this is occurring in clinical practice, a valid and reliable survey instrument is needed. Although 2 studies have included a survey of patient knowledge for herniated disc and a single item for patients' treatment preference,[3,4] we could not find any published instruments available that would provide a comprehensive measure of decision quality for treatment of a herniated disc.

Sepucha *et al*[5–7] have proposed a method for developing decision quality instruments that measure knowledge and

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concordance (the match between patients' goals and treatments) and have developed instruments for several common surgical decisions, including breast cancer surgery and joint replacement for knee and hip. The current study evaluates the psychometric properties of the herniated disc–decision quality instrument (HD-DQI) using data from 3 samples: (1) a retrospective survey of patients who made a decision about treatment of herniated disc within the past year, (2) a prospective study of patients who completed the survey after viewing a patient decision aid (DA), and (3) a multidisciplinary group of clinicians who treat patients with herniated discs.

MATERIALS AND METHODS

Item Development

The HD-DQI development process began by reviewing clinical evidence regarding treatment options and was supplemented with findings from focus groups with patients who had been diagnosed with a herniated disc. A set of candidate facts and goals salient for the decision was reviewed and rated by a convenience sample of patients with a herniated disc (n = 33) and a multidisciplinary group of clinical experts (n = 21).[6] A draft survey was evaluated with cognitive interviews (n = 5). During the interviews, patients discussed their understanding of each question and reasoning behind their responses to ensure that the items were being interpreted and answered appropriately.

Study Samples and Procedures

Three samples provided complementary data on the performance of the instrument. The retrospective patient sample provided an "experienced" sample to evaluate the items and stability of responses. The prospective patient sample surveyed patients during the decision-making process after viewing a DA. These data were used to develop and validate the concordance model using goals and preferences from patients who had been exposed to standard information but who had not yet completed treatment. The physician sample provided additional evidence for validity.

1. *Retrospective patient sample*: Adults 30 to 60 years of age who had discussed surgery with their provider or had disc surgery within the past year were recruited through online and newspaper advertisements in 17 US cities. All respondents were screened by phone for eligibility and were randomized to receive either a herniated disc DA or no DA. The DA, "Herniated Disc: Choosing the Right Treatment for You," is a 38-minute DVD and booklet produced by Foundation for Informed Medical Decision Making and Health Dialog ©2008 (www.fimdm.org). All participants received study materials by mail. Nonresponders received a reminder packet about 2 weeks after initial mailing. Responders received a retest packet 4 weeks after completing the initial survey. A small incentive was provided ($30 for DA, $20 for no-DA, and $10 for retest, respectively).

   The study protocol was approved by the Institutional Review Board at the University of Massachusetts, Boston, Massachusetts General Hospital.
2. *Prospective patient sample:* From November 2009 to November 2010, the same DA described above was distributed to patients (age, 30–65 yr) referred from a spine center as part of usual clinical care. Patients watched the DA at home and completed a post-DA questionnaire. A reminder postcard was sent at 30 days. No financial incentives were offered. Chart review determined whether patients had discectomy within 6 months of being given the DA. The Committee for Protection of Human Subjects at Dartmouth-Hitchcock Medical Center approved the study protocol.
3. *Physician sample*. Primary care physicians and specialists (including spine-trained neurosurgeons and orthopedic surgeons and physical medicine, rehabilitation, and pain medicine physicians) were identified through the American Medical Association who practiced in the same 17 cities from the retrospective patient sample. Each provider was mailed a study packet with a $20 incentive. A phone reminder was made at 2 weeks and a mailed reminder was sent at 4 weeks. The provider study protocol was approved by the institutional review board at the Massachusetts General Hospital.

Measures

Herniated disc–decision quality instrument (HD-DQI): The HD-DQI contains 2 sets of items and results in 2 scores (a copy of the survey is available from the corresponding author):

1. Knowledge score: 13 multiple choice knowledge items. Each correct response received 1 point. Single items with multiple components had the individual component scores weighted equally for a total possible score of 1 for the item. Missing responses were scored as incorrect. A total knowledge score was standardized by dividing the number of correct responses by the number of items, resulting in scores from 0% to 100%.

2. Concordance score: Six goals and concerns were rated on an 11-point importance scale (*e.g.* "When you think about how to manage your back and leg pain, how important is it to you. .." 0 [Not at all important to me]–-10 [Extremely important to me]). Using data from the prospective patient sample, we examined whether having surgery was associated with each item using *t* tests. Then, we developed a multivariate logistic regression model with surgical treatment as the dependent variable. Missing responses from the goal items were imputed from the other available goal items using the EM algorithm.[8] The regression model generated a predicted probability of surgery for each patient controlling for baseline quality-of-life scores. Patients with a predicted probability of more than 0.5 who had surgery or those with a predicted probability of 0.5 or less who did not have surgery were classified as having treatments that "matched" their goals. This yielded a summary concordance score that ranged from 0% to 100%, indicating the percentage of patients whose treatment choice "matched" their goals. Higher scores indicate that more patients received treatments that matched their goals.

TABLE 1. Patient Characteristics for the Retrospective and Prospective Samples

	Retrospective Sample			Prospective Sample (N = 158)
	All (N = 183)	DA (N = 91)	No DA (N = 92)	
Sex, n (%)				
Female	99 (54)	49 (54)	50 (54)	71 (45)
Age, mean (SD)	45 (8.4)	44 (8.6)	46 (7.96)	48 (9.6)
Hispanic, n (%)	19 (10)	12 (13)	7 (8)	3 (2)
Race/ethnicity, n (%)				
White	139 (76)	66 (72.5)	73 (80)	148 (94)
Black	32 (17.5)	18 (20)	14 (15)	3 (2)
Asian	5 (3)	2 (2)	3 (3)	1 (0.6)
Other race	9 (5)	1 (1)	8 (8.5)	7 (5)
Education, n (%)				
≥College graduate	82 (45)	42 (46)	40 (43.5)	54 (34)
Some college	81 (44)	40 (44)	41 (45)	47 (30)
High school or less	20 (11)	9 (10)	11 (12)	54 (34)
Had back surgery, n (%)	11 (6)	4 (4.5)	7 (8)	42 (27)
Income, n (%)				
≤$30,000	65 (35)	32 (35)	33 (36)	NA
$30,001–$60,000	49 (27)	27 (30)	22 (24)	NA
>$60,001	64 (35)	30 (33)	35 (38)	NA
Quality-of-Life Scores				
MCS mean (SD)	37.6 (9.1)	38.9 (9.0)	36.3 (9.1)	48.4 (12.1)
PCS mean (SD)	36.85 (6.2)	36.6 (6.2)	37.1 (6.2)	31.2 (9.3)

DA indicates decision aid; NA, not available; MCS, mental component score; PCS, physical component score.

Treatment preference: Single item with possible responses: surgery, nonsurgical options, or unsure.

Decision regret: Single item assessed whether patients would choose same treatment again.

Patients in the retrospective sample completed the full set of measures. Patients in the prospective study completed fewer items to address clinician concerns about the length of survey for use in routine care. Prospective study patients completed the standard demographics and a brief version of the HD-DQI that contained 4 of the knowledge items, all 6 of the goals, and their treatment preference (surgery, nonsurgical options, or unsure). Patients in both samples also completed quality-of-life surveys—12-Item Short Form Health Survey (retrospective sample) and 36-Item Short Form Health Survey (prospective sample).[9] Physicians completed the HD-DQI knowledge items along with some demographic items.

Psychometric Analyses

The criteria set out by Fitzpatrick for high-quality patient-reported outcomes provided a framework for these analyses.[10]

Item retention and deletion: Items were examined for issues, such as difficulty, problematic format, redundancy, and floor or ceiling effects.

Acceptability and feasibility: Acceptability was examined using response rates. Feasibility was examined using rates of missing data for individual items and total scores.

Reliability: Test-retest reliability was assessed with the intraclass correlation coefficient (ICC) for the knowledge score and for the goals. Responses during the 4-week window were not expected to change for the retrospective sample, and the target was ICC ≥ 0.70. We also examined retest reliability and reproducibility of shorter HD-DQI screener with 5 knowledge items.

Validity: Because there is no "gold standard" for knowledge or concordance, hypothesis testing was used to provide evidence of validity.

1. Knowledge score discriminant validity hypotheses: (1) mean knowledge scores would be higher for physicians than patients and (2) in the retrospective sample, patients

TABLE 2. Provider Sample Characteristics

	All (N = 99)	Primary Care (N = 22)	Specialists (N = 77)
Sex, n (%)			
Male	83 (84)	19 (86)	64 (83)
Age, mean (SD), yr	51 (9.2)	56 (14.1)	50 (8.7)
No. of years in practice, mean (SD	20 (9.8)	23 (10.4)	18 (9.4)
Annual HD patient volume, median (IQR)	100 (35–200)	20 (7.25–40)	200 (82.5–300)
Hispanic, n (%)	4 (4)	0	4 (5.5)
Race/ethnicity, n (%)			
White	81 (82)	17 (77)	64 (83)
Black	2 (2)	0	2 (3)
Asian	13 (13)	4 (18)	9 (12)
Other	3 (3)	1 (4.5)	2 (2)
Professional training, n (%)			
PCP	22 (22)	22 (100)	0
Orthopedic surgeon	26 (26)	0	26 (34)
Neurological surgeon	21 (21)	0	21 (27)
Physical medicine and rehabilitation physicians	23 (23)	0	22 (29)
Other specialist	8 (8)	0	8 (10)

HD indicates herniated disc; IQR, interquartile range; PCP, primary care physician.

in the DA group would have higher scores than those in the control group (both tested with 2 sample *t* test).

2. Concordance score convergent validity hypothesis: patients who stated a preference for surgery would have higher predicted probability of having surgery from the regression model than those who were unsure, and those who were unsure would have higher predicted probability than those who stated a preference for nonsurgical approaches (using analysis of variance with planned comparisons with prospective sample).
3. Concordance score predictive validity hypothesis: patients who received treatment that matched their goals would have less regret than those who received treatment that did not match their goals (using χ^2 test with data from the retrospective sample).

Analyses for the patient and provider surveys were conducted using PASW Statistics 18.0 (SPSS Inc., Chicago, IL) and SAS version 9.2 (SAS Institute, Cary NC).

RESULTS

Patient and Physician Sample Characteristics

In the retrospective patient sample, 183 of 216 (85%) patients completed the initial survey and 150 (79%) patients completed the retest. In the prospective patient sample, 158 of 295 (54%) patients completed the survey. Data on age and sex were available for nonresponders in the prospective study. Responders were slightly older (mean age, 48 yr *vs.* 45 yr, $P = 0.007$) but did not vary by sex. Patient characteristics for both samples are summarized in Table 1. Among physicians, 99 of 182 (55%) completed the survey and their characteristics are summarized in Table 2.

Item Retention and Deletion

Two knowledge items were deleted for difficulty and 2 were revised. The patients' total knowledge scores ranged from 8% to 90%, with no evidence of a floor or ceiling effect. For the goals, "not be limited in what you can do" and "relieve your back and leg pain quickly," 62% and 59% respectively, selected 10 out of 10 (or extremely important) suggesting a ceiling effect. Both were kept because a high percentage of patients selected these as one of their top 2 most important concerns. The remaining analyses were conducted using a reduced set of 11 knowledge items (Table 3) and the full set of 6 goals and concerns (Table 4).

Acceptability and Feasibility

The response rate was higher for the retrospective sample (85%) than for the prospective sample (54%). There were few missing items; 1.7% (range, 0.5%–3%) and 4.3% (range, 2.5%–8%) for retrospective and prospective samples, respectively. Two items had more than 5% missing, but this was in the prospective sample only.

TABLE 3. Knowledge Items and Frequency of Correct Responses for Retrospective Patient and Physician Samples

Question (Correct Response)	%		
	DA N = 91	No DA N = 92	Physician N = 99
*,†1. For most people with a herniated disc, how likely is it that doing normal activities will make their herniated disc worse? (not very likely)	43	27	69
†,‡2. Over time, without surgery, does back and leg pain caused by a herniated disc usually get better, stay the same, or get worse? (gets better)	53	13	88
3. Over time, with surgery, does back and leg pain caused by a herniated disc usually get better, stay the same, or get worse? (gets better)	67	61	94
4 a. Can lots of bed rest help some people relieve the pain caused by a herniated disc? (No)	60	51	75
b. Can over-the-counter pain medicine help some people relieve the pain caused by a herniated disc? (Yes)	82	72	97
*,†5. Which treatment is most likely to provide faster relief from pain caused by a herniated disc? (Surgery)	53	36	74
6. Of 100 people who undergo surgery for a herniated disc, about how many will have the same or more back or leg pain after surgery? (10–29)	38.5	36	28
7. What are 3 common complications of surgery for herniated disc? (open-ended responses)	42	29	56
†8. Of 100 people who undergo surgery for a herniated disc, about how many will have a serious complication within the 3 mo after the surgery? (range: 1–5)	54	16	76
‡9. Without surgery, about how many people with a herniated disc develop permanent weakness that results in them not being able to walk at all? (Almost none)	44	21	77
†,‡10. After 5 years, which treatment is better at relieving pain caused by a herniated disc? (Both are about the same)	67	43.5	66
11. a. Are stomach ulcers a possible side effect of using over-the-counter pain medicine for a long time? (Yes)	93	95	98
11. b. Are migraine headaches a possible side effect of using over-the-counter pain medicine for a long time? (No)	47	56.5	64
11. c. Is a blood clot in the leg a possible side effect of using over-the-counter pain medicine for a long time? (No)	47	45	92
‡11. d. Is excessive bleeding a possible side effect of using over-the-counter pain medicine for a long time? (Yes)	86	67	90
11. e. Are kidney problems a possible side effect of using over-the-counter pain medicine for a long time? (Yes)	83	92	95

**P < 0.05 for DA versus no DA comparison.*

†Included in brief knowledge test version.

‡P < 0.01 for DA versus no DA comparison.

DA indicates decision aid.;

Reliability

The knowledge score had good retest reliability, ICC = 0.85 (95% confidence interval [CI], 0.79–0.89). A brief version with 5 items had high reproducibility with total knowledge score ($R = 0.91$, $P < 0.001$) and good retest reliability (ICC = 0.83 [95% CI, 0.76–0.87]). The retest reliability of the goals were as follows: relieve pain quickly, ICC = 0.79; not be limited in what you can do, ICC = 0.62; avoid a long recovery, ICC = 0.80; have fewest side effects, ICC = 0.79; avoid surgery, ICC = 0.80; and avoid taking medicine for a long time, ICC = 0.80.

Validity

1. *Knowledge score:* The total score discriminated between patients in the DA group and those in the control (55% *vs.* 38%, $P < 0.001$) and between physicians and patients (73% *vs.* 46%, $P < 0.001$). Patients in the DA

TABLE 4. Univariate and Multivariable Logistic Regression Analyses of Factors Associated With Treatment Received for Patients in Prospective Sample

	Surgery N = 40	Nonsurgical N = 115	Univariate	Multivariable*
Factor	**Mean (SD)**		***P***	**OR (95% CI)**
Quality of life†	29.9 (8.3)	31.4 (8.8)	0.34	
How important is it to you to…				
Relieve pain quickly	9.2 (1.4)	8.4 (2.1)	0.01	
Not be limited in what you can do	9.4 (1.1)	9.4 (1.3)	0.90	
Avoid surgery	3.7 (2.9)	6.8 (3.0)	<0.001	0.70 (0.61– 0.81)
Avoid prescription medicine	8.1 (2.4)	7.4 (2.9)	0.17	1.19 (1.02–1.40)
Avoid long recovery time	7.8 (2.4)	7.9 (2.3)	0.80	

Two factors were significant on multivariable analyses and were included in the model to develop the concordance score.

**The multivariable model fit was acceptable (c-statistic 0.78) and no evidence of lack of fit (Hosmer and Lemeshow goodness-of-fit test, P = 0.37).*

†SF-PCS: physical component score was used for quality of life. Assessment of quality of life was during the decision making process, before surgery.

OR indicates odds ratio of surgery with 95% confidence interval; CI, confidence interval.

group were more knowledgeable about benefits of surgery (53% *vs.* 36%, $P = 0.04$) and about the likelihood of serious complications within 3 months after surgery (54% *vs.* 16%, $P = 0.05$) compared with patients in the control group. The brief, 5-item version also demonstrated discriminant validity (54% *vs.* 27%, $P < 0.001$ for DA and control groups, respectively).

2. *Concordance score:* In univariate analyses, 2 factors, patients' desire to avoid surgery and their desire to relieve pain quickly, discriminated between those who underwent surgery and those who did not (Table 4). In the multivariable model, which controlled for baseline quality-of-life scores, patients' desire to avoid surgery remained significantly associated with not undergoing surgery and patients' desire to avoid taking medicine for a long time was associated with undergoing surgery. In the prospective sample, the majority of patients (78%) received treatments that were concordant with their goals. Of the 22% of patients who were discordant, most (17%) underwent surgery when the model predicted nonsurgical options and 5% had nonsurgical options when the model predicted that surgery would better fit their goals. The predicted probability generated by the model was able to discriminate among patients who stated a preference for surgery, those who were unsure, and those who preferred nonsurgical options (0.45 *vs.* 0.24 *vs.* 0.16, respectively, P , 0.008 for all pairwise comparisons).
3. Predictive validity was examined using the concordance model with data from the retrospective sample. The majority (90%) in the retrospective sample received treatments that matched those predicted by the model, and those who matched were less likely to regret the decision than those who did not (13% *vs.* 39%, $P = 0.004$).

DISCUSSION

The study examines the HD-DQI, the first comprehensive measure of decision quality for treatment of a lumbar herniated disc to our knowledge. High acceptability and feasibility of the instrument was found in the retrospective sample with a high response rate and low number of missing responses. The knowledge score was reliable and discriminated between providers and patients and between patients who have seen a DA or no DA. The concordance score provides a measure, at the group level, of the extent to which patients receive treatments that match their goals. Patients who matched were more likely to want to do the same thing again, indicating that they experienced less regret.

Patient knowledge scores varied widely and were low for patients who did not view a DA (38%). Other studies have found significant knowledge gaps for patients considering treatment of herniated disc.[11] The HD-DQI detected clinically important differences in knowledge comparable with the effect size from the Cochrane Systematic Review of Decision Aids.[12] The mean knowledge score from the patient sample who viewed the DA can be used to set a threshold for informed patients of 55%.

The concordance score indicated that the majority of patients received treatments that matched their goals. Two issues, patients' concerns about taking medication for a long time and their concerns about surgery, were significant in the multivariable model predicting treatment type. It is important to note that the concordance model was developed with data from patients in the prospective study. The goals and treatment preferences were assessed after patients viewed a DA but before they had experienced the treatments. Studies have shown that patients' goals and preferences can and do change with information and experience, and the timing of the assessment is important.[13–15] The difference in timing of

the assessment may explain some of the differences in rates of concordance for the prospective and retrospective samples. Further studies would be needed to examine how patients' goals and treatment preferences change over time.

In our multivariable model, quality-of-life scores were not significant predictors of choosing surgical treatment. Although important for tracking impact of disease and treatments, quality-of-life scores may not identify which individual should undergo surgery.[16] Studies in other symptom-driven diseases, such as benign prostate disease and osteoarthritis, have found that it is the level of bothersomeness of symptoms rather than the objective symptom score that was the stronger predictor of surgery in an informed patient population.[17,18] It is important for clinicians to consider patients' goals and concerns in addition to more objective symptom or functional status when deciding on treatment of herniated disc.

Studies have shown that DAs can promote SDM and improve decision quality for herniated disc. Phelan *et al*[3] found that a DA improved knowledge but did not have a significant impact on patients' preferences for surgery. Other DA studies found conflicting impact on discectomy rates, one found increased rates[19] and another decreased rates.[20] However, the purpose of SDM is not to increase or decrease rates of surgery but to ensure that the right patient is matched with the right treatment. A high-quality decision requires appropriate knowledge and the concordance between treatment received and patients' goals.

The patient samples illustrate potential uses of the instrument. As in the retrospective sample, the HD-DQI could audit the quality of decisions within or across group practices or hospitals by sampling a set of patients a short time after the decision is made. Alternatively, the HD-DQI may be prospectively integrated into clinical practice with patients surveyed before a visit to identify knowledge gaps and to elicit goals.[21] Providing feedback to clinicians about patients' responses to the HD-DQI may increase visit efficiency by focusing the discussion on knowledge gaps and patients' goals and concerns.

The evaluation of the HD-DQI has several limitations, including the retrospective nature of the first patient sample, the low response rate in the prospective patient sample, and limited ability to examine performance of the instrument in low literacy or underserved populations.

Given the increasing importance of engaging patients and families in significant medical decisions, there is a need for measures to assess the extent to which that is accomplished. The HD-DQI met many criteria for high-quality patient-reported surveys and can be used to determine whether patients have made informed decisions about treatment of a herniated disc that match their goals. Further work is warranted to examine acceptability in usual care across diverse populations. Collection of this type of information has been mentioned as part of meaningful use criteria set out for electronic health information technology,[22] can be tied to the provision of DAs or other decision support,[23] and may help organizations meet new priorities for patient-centered care set out in the health care reform legislation in the United States.[24,25]

➢ Key Points

- ❑ Although shared decision making is recommended for patients with a herniated disc considering surgical treatment, there are no instruments available to assess the quality of the decision.
- ❑ We evaluated the psychometric properties of a new instrument to measure decision quality for the treatment of a herniated disc.
- ❑ The instrument met several criteria for high-quality patient-reported surveys, including acceptability, reliability, and validity.

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