Responsiveness of standard spine outcome tools: do they measure up?

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OBJECTIVE Over the past 2 decades, spine outcome research has become more standardized in response to recommendations from Deyo and others. By using the same generic and condition-specific patient-reported outcome (PRO) measures across studies, results are more easily compared. Given the challenges of maintaining high-quality data in clinical research studies, it would be important to evaluate the contribution of each PRO to confirm that it merits the respondent burden. This study aimed to examine the spine PROs' association with clinically important change and relative responsiveness in explaining variance in patients' global assessment of change (GAC).

METHODS This prospective longitudinal cohort study included adults recruited from 4 active spine surgery practices at a Toronto-based hospital. Patients were diagnosed with a degenerative lumbar spinal condition and underwent spinal decompression and/or fusion surgery. Participants completed the RAND-36 (to generate the physical component score [PCS] and mental component score [MCS]), Oswestry Disability Index (ODI), the numeric rating scale (NRS) for pain, Patient-Reported Outcomes Measurement Information System (PROMIS) pain interference, and a GAC item. Random-effects models were used to investigate the sensitivity of PROs to the GAC and their responsiveness over time (i.e., PRO main effects and PRO-by-time interactions, respectively).

RESULTS The study sample included 168 patients (mean age 61 years, 50% female) with preoperative and up to 12 months of postoperative data. Random-effects models revealed significant main effects for all PROs. Significant time-by-PRO interactions were detected for the PCS, PROMIS, ODI, and NRS ($p < 0.0005$ in all cases), but not for the MCS. Further examination revealed different sensitivity of the PROs to the GAC at different times. The NRS, PROMIS, and PCS showed higher sensitivity early after surgery, and the PCS evinced a marked drop in sensitivity to the GAC at about 8 months postsurgery.

CONCLUSIONS All PROs currently included in the spine outcome core measures are associated with patients' subjective assessment of a clinically important change, and all but the MCS scores are responsive to such change. Based on these findings, the core spine PROs could be reduced to include fewer estimates of pain. The authors suggest replacing the less responsive measures with tools that help to characterize factors that are driving the patients' subjective assessment of change and that meaningfully address some of the higher levels in the hierarchy of quality-of-life outcomes.

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KEYWORDS spine; quality of life; patient-reported outcomes; responsiveness; redundancy

SPINE outcome research has progressed in important ways over the past 2 decades. On Deyo and colleagues' recommendations of using a standard spine outcome battery of patient-reported outcomes (PROs),⁷ study results across clinics and investigators became more directly comparable. This standardization has enabled a more evidence-driven research base on which to make de-

cisions about treatment choices.^{1,17} Nonetheless, the passage of time has led to a larger selection of measures and methods for detecting outcomes and change over time in clinical research studies. Given the challenges of maintaining high-quality data in clinical studies, it would be important to evaluate the contribution of each PRO to confirm that it merits the corresponding respondent burden

ABBREVIATIONS GAC = global assessment of change; HIPAA = Health Information Portability and Accountability Act; MCS = mental component score; NRS = numeric rating scale; ODI = Oswestry Disability Index; PCS = physical component score; PRO = patient-reported outcome; PROMIS = Patient-Reported Outcomes Measurement Information System.

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and to consider whether relevant domains are missed or not measured as well as they could be.

Interest in interpreting change over time in PROs has led to a helpful body of research defining responsiveness³⁶ and examining methodological differences in characterizing the change over time^{22,34} and theoretical work highlighting its nuances.^{33,35} Generally speaking, one characterizes the responsiveness of a tool using external indicators of change (i.e., anchors) and/or distribution-based methods (e.g., one-half standard deviation^{6,23}). The most widely used anchor-based method is the patient's global assessment of change (GAC),³⁷ whereby the patient answers whether their health or functional status is better, the same, or worse compared with the 3 months prior. This query thus operationalizes the patient's perspective on whether a noticeable or meaningful change has occurred.³⁷ Distribution-based methods might utilize one of many available responsiveness formulas that are ratios of signal to noise (i.e., numerator is mean change, denominator is variation).⁹ These formulas can then be summarized in terms of effect size,³¹ and it is generally accepted that a medium effect size is clinically meaningful.²¹

With a growing empirical base, researchers have documented that responsiveness is not a static attribute of a measure but rather is a contextualized attribute that varies as a function of who is being analyzed, which scores are being contrasted, and what type of changes are being quantified.⁴ This contextual quality makes it difficult to hone in on a single value for a minimum clinically important difference (MCID). For this reason, the published MCIDs for spine outcome measures are variable.^{23,24,30} Indeed, MCID has been reported as moderate to large in early stages of recovery from spine surgery; over time smaller and smaller changes become important.²⁹

Given the importance of evaluating the benefit of spine surgery using measures that are not only standardized but also nonredundant and responsive, we aimed to examine the spine PROs' association with clinically important change, and relative responsiveness in explaining variance in patients' GAC.

Methods

Sample and Design

This longitudinal study included adults who were recruited from 4 active spine surgery practices from an academic teaching hospital. Patients older than 18 years who were scheduled to undergo elective surgery for degenerative lumbar spinal disorder of disc herniation, neurogenic claudication, degenerative spondylolisthesis, or lytic spondylolisthesis were included. Patients were excluded if they had prior lumbar surgery at the same level or were unable to understand and complete the survey-related documents in the English language. Eligible patients were recruited consecutively, and study participation was thoroughly explained. All patients provided written informed consent prior to completing any questionnaires. Data were collected online or by mail preoperatively (up to 2 baselines) and at approximately 6 weeks, 3 months, 6 months, and 12 months postsurgery using a secure, Health Information Portability and Accountability Act (HIPAA)-compliant

interface (surveygizmo.com). The study was reviewed and approved by the Sunnybrook Health Sciences Centre's institutional review board.

Outcome Measures

Self-Report Measures

The Medical Outcomes Study Short-Form (RAND-36)¹⁰ was used to assess physical and emotional functioning via the physical component score (PCS) and mental component score (MCS). Spine-specific disability was measured using the 10-item Oswestry Disability Index (ODI).⁸ Pain impact was measured using 4 numeric rating scale (NRS) items to assess pain at rest, pain with activity, back pain, and leg pain,⁵ and the 6-item Patient-Reported Outcomes Measurement Information System (PROMIS) pain interference short form² was scored using standardized scoring tables provided in the PROMIS manual. To facilitate interpretation of the PRO measures, all were rescored such that high scores reflect better functioning; i.e., ODI, NRS, and PROMIS pain interference scores were reverse-scored to achieve this orientation. The NRS summary score was computed by taking the sum of the 4 items and subtracting it from 40 (the maximum total). The PROMIS pain interference score was then subtracted from 100. Clinically important change was assessed using an anchor-based technique, the GAC item, "Compared to three months ago, how would you rate your health in general now?" Response options were recoded to make intuitive sense, with a range from -2 (much worse) to +2 (much better) and a score of 0 indicating same/no change. An option to decline to answer was coded as missing. This item was included in all but the first baseline data collection timepoints. Demographic characteristics were included for descriptive purposes and to serve as control variables.

Statistical Analysis

Random-effects models¹² were used to investigate the relationship of each PRO in predicting GAC over time. This relationship can be separated into its *sensitivity* (as reflected by PRO main effects) and its *responsiveness* to clinically important change (i.e., differential change in GAC over time as reflected by its PRO-by-time interaction). Analyses were conducted on the subsample of patients with at least 2 follow-up records ($n = 168$). The PRO independent variables were standardized for use in multivariable analysis (mean 50, SD 10) to facilitate comparison of parameter estimates. The patient identifier was treated as a random effect, while PRO, time, and PRO-by-time interaction were treated as fixed effects. For the purpose of the random-effects models, time was expressed in days, and for plotting results, in months. Thus, time remained a continuous variable to reflect the varying windows separating different timepoints. We began by testing simple main effects of PRO scores and time in predicting GAC scores over time, and then added the PRO-by-time interactions. Final models were selected on the basis of a type I error rate of 0.05. Stata (version 15, StataCorp), R (release 3.4), and/or IBM SPSS (version 26, IBM Corp.) were used for all analyses.

Results

Sample

The surgical indication was leg pain with or without back pain. Table 1 shows the distribution of diagnoses and primary procedures and the demographic characteristics of the sample. The patients had a mean age of 61 years (SD 16 years) and an equal number of males and females. The sample had an average of almost 2 comorbidities among the 14 presented (range 0–7), with the most common being high blood pressure and osteoarthritis. BMI averaged a high 28.5. The majority of the sample had more than a college degree, and about one-third was retired. Less than 5% reported being on workers' compensation currently or in the recent past.

Table 2 shows descriptive statistics for the GAC and PRO scores at baseline, reflecting a sample that endorsed being slightly worse off prior to surgery and with poor scores on measures of physical and mental functioning and pain. Figure 1 shows the mean GAC over follow-up. As expected, patients reported substantial improvement soon after surgery up to about 6 months postsurgery. After that, patients reported incremental improvements that were smaller in magnitude.

Relationship of PROs to GAC Scores

Table 3 shows results of the random-effects models testing the main effects of time and each of the 5 PRO scores. All PROs were associated over time with the GAC scores, but time was not consistently related to the GAC score in any linear fashion. Only in the main-effects model including the NRS pain score was time associated with the subjective endorsement of improvement ($p < 0.03$).

Responsiveness of PROs

Random-effects models revealed significant time-by-PRO interactions in predicting GAC scores over time for the PCS, PROMIS pain interference, ODI, and NRS ($p < 0.0005$ in all cases), but not for the MCS (Table 3). Figure 2 displays the standardized regression coefficients (betas) for the main effects and interaction terms using time in months. This illustrates that the PRO most associated with GAC as a main effect was the NRS, but the largest responsiveness (interaction) effect was with the PROMIS pain interference.

Thus, in the longitudinal models, PROs all had significant associations with GAC. For main effects, the NRS score was the most sensitive, while the PCS was the least (Fig. 2 bars). There were also significant time-by-PRO interactions. Of note, PROs showed different sensitivity to GAC at different time periods (Fig. 2 line). To elucidate the substantive meaning of these interactions, we created a series of figures. Supplemental Fig. 1 shows scatterplots of GAC by PRO at each timepoint, including best-linear-fit lines. Figure 3 draws on Supplemental Fig. 1, showing how the slope coefficients (main effects) reflected there varied over time (interactions). These figures suggest different sensitivity of the PROs to GAC at different times. The NRS, PROMIS, and PCS all evinced a “bump” early after surgery, suggesting higher sensitivity at that time window. In contrast, ODI and MCS had less of a “bump.”

TABLE 1. Descriptive statistics of study sample

Variable	Value
Age, yrs	
Mean (SD)	60.59 (16.12)
Range	18–91
Comorbidities (of 14 presented)*	
Mean (SD)	1.96 (1.77)
Range	0–7
BMI (n = 159)	
Mean (SD)	28.54 (5.34)
Range	17–40
Follow-up time, days	
Mean (SD)	255 (117)
Range	41–595
Sex	
Male	84 (50)
Female	84 (50)
Missing	0
Primary diagnosis(es)†	
Disc herniation	60 (36)
Radiculopathy/sciatica	25 (15)
Spinal stenosis w/ neurogenic claudication	108 (64)
Spondylolisthesis (lytic or NOS)	8 (5)
Spondylolisthesis (degenerative)	36 (21)
Scoliosis—deformity	8 (5)
Primary procedure(s)‡	
Laminectomy	91 (54)
Discectomy	102 (61)
Fusion	52 (31)
Laminectomy & discectomy	59 (35)
Laminectomy & fusion	24 (14)
Discectomy & fusion	10 (6)
Specific comorbidities (back pain excluded)*	
Anemia or other blood disease	4 (2)
Cancer	8 (5)
Depression	14 (8)
Diabetes	12 (7)
Heart disease	15 (9)
High blood pressure	46 (27)
Kidney disease	1 (1)
Liver disease	1 (1)
Lung disease	7 (4)
Osteoarthritis, degenerative arthritis	45 (27)
Other	49 (29)
Rheumatoid arthritis	12 (7)
Ulcer or stomach disease	3 (2)
Marital status	
Married	111 (70)
Widowed	8 (5)
Living w/ significant other	10 (6)
Single (never married)	17 (11)

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TABLE 1. Descriptive statistics of study sample

Variable	Value
Marital status (<i>continued</i>)	
Divorced/separated	11 (7)
Civil union/domestic partner	1 (1)
Missing	10
Race	
American Indian or Alaskan Native	1 (1)
Asian	6 (4)
Black or African American	1 (1)
Native Hawaiian or other Pacific Islander	0 (0)
White	153 (95)
Missing	7
Education	
Less than high school	8 (6)
Graduated from high school or GED	23 (16)
Some college or technical school	31 (22)
Graduated from college	42 (30)
Postgraduate school or degree	3 (27)
Missing	26
Employment status*	
Working	48 (29)
On leave of absence	8 (5)
Retired (not due to ill health)	52 (31)
Disabled &/or retired because of ill health	7 (4)
Homemaker	5 (3)
Unemployed	4 (2)
Student	2 (1)
Other	10 (6)
Not working	32 (19)
Smoking status	
Never smoked/used tobacco	80 (50)
Used to smoke/use tobacco	68 (43)
Current smoker/use tobacco	12 (8)
Missing	8
Legal action*	
Not considering any legal action	165 (98)
My legal action is pending	2 (1)
My legal action has been resolved in my favor	1 (1)
Workers' compensation status*	
I am not planning to apply for workers' compensation	161 (96)
I used to receive it, but do not now	0 (0)
I am planning to apply for it	1 (1)
I have applied for it	1 (1)
I am currently receiving workers' compensation	5 (3)

GED = General Educational Development; NOS = not otherwise specified.

Percentages are based on the number of patients with existing data.

* For these topics, a nonresponse was counted as the absence of the event in question (e.g., no disease, not working, no legal action).

† Values may sum to greater than 100% because more than one may apply.

TABLE 2. Descriptive statistics of PROs at baseline

Item or (Sub)scale	Mean	SD	Min	Max
GAC (recoded) (n = 164)	−0.50	1.07	−2	2
RAND-36 PCS (n = 162)	29.88	6.81	14	46
RAND-36 MCS (n = 162)	40.42	10.58	15	61
PROs PROMIS pain interference (n = 161)*	34.92	7.40	22	59
ODI (n = 164)*	56.15	16.01	12	100
NRS (n = 164)*	16.32	8.71	0	38

PRO raw scores are shown here, whereas statistical models utilized standardized scores (mean 50, SD 10) to facilitate comparisons.

* Rescaled so that higher scores reflect better functioning.

Of note, the PCS evinced a marked drop in sensitivity to GAC at about 8 months postsurgery.

Discussion

All of the PROs currently included in the spine outcome core measures are associated with patients' subjective assessment of clinically important change, and all but the MCS are responsive at most time windows to clinically important change. Three measures show substantial similarity in their relationship with the GAC (i.e., the NRS, ODI, and PROMIS pain interference scores), all of which are focused on pain.

Based on these findings, the core spine PROs could be reduced to include fewer estimates of pain. Deciding on which PRO to drop would depend on one's emphasis. For example, the NRS (for back or leg pain only) or the more multidimensional ODI would be the PRO of choice if one emphasizes consistent sensitivity to the GAC subjective indicator of change. The only time window during which the PROMIS pain interference's sensitivity is comparable to the NRS' or ODI's is soon after surgery.

The two composite scores from the generic RAND-36 show the least sensitivity to the GAC. While this generic measure is helpful in characterizing patient samples according to large population- and diagnostic-subgroup norms, it does not seem particularly informative about postsurgical recovery.

This finding may suggest that spine outcome researchers consider including a briefer generic health measure, such as the PROMIS-10, and allocating space in their PRO data collection to capturing other valuable information. For example, in our clinic we have found that including measures of cognitive appraisal processes that underlie patient responses to PRO measures has been helpful for understanding group differences in self-assessed change²⁹ and for detecting response-shift effects.^{13,28} Measuring appraisal processes can help to clarify the patient's emphases and values and create a better understanding between surgeon and patient. We have found, for example, that early after surgery, about one-quarter of patients disagree with their surgeon's assessment of change postsurgery and that these patients tended to have worsened mental health and leg pain.²⁶ Having more information about patients' underlying cognitive appraisal processes—frame of refer-

FIG. 1. Mean GAC over follow-up. As expected, patients reported substantial improvement soon after surgery up to about 6 months postsurgery. After that, patients reported improvements that were smaller in magnitude. Figure is available in color online only.

TABLE 3. Longitudinal random-effects models predicting the GAC score based on PROs

	Main-Effects Model			Interaction Model		
	β	SE	p Value	β	SE	p Value
RAND-36 PCS						
Time (days)	0.00037	0.00040	0.359	0.01234	0.00229	<0.0005
PRO	0.04125	0.00560	<0.0005	0.06105	0.00654	<0.0005
Time-PRO interaction				-0.00023	0.00004	<0.0005
RAND-36 MCS						
Time (days)	0.00066	0.00036	0.073	0.00408	0.00209	0.053
PRO	0.04340	0.00570	<0.0005	0.04966	0.00681	<0.0005
Time-PRO interaction				-0.00007	0.00004	0.099
PROMIS pain interference*						
Time (days)	-0.00032	0.00040	0.425	0.01577	0.00208	<0.0005
PRO	0.06494	0.00527	<0.0005	0.09393	0.00612	<0.0005
Time-PRO interaction				-0.00030	0.00004	<0.0005
ODI*						
Time (days)	-0.00053	0.00037	0.150	0.01367	0.00209	<0.0005
PRO	0.08170	0.00546	<0.0005	0.10383	0.00601	<0.0005
Time-PRO interaction				-0.00027	0.00004	<0.0005
NRS*						
Time (days)	-0.00074	0.00034	0.030	0.01046	0.00186	<0.0005
PRO	0.09738	0.00457	<0.0005	0.10976	0.00481	<0.0005
Time-PRO interaction				-0.00021	0.00003	<0.0005

Each PRO is standardized to have a mean 50 (SD 10). Boldface type indicates statistical significance.

* Score recoded such that high scores reflect better functioning.

FIG. 2. PROs' relationships with GAC. The standardized regression coefficients (betas) are shown for the main effects and interaction terms using time in months. This illustrates that the PRO most associated with GAC as a main effect was the NRS, but the largest responsiveness (interaction) effect was with the PROMIS pain interference. Figure is available in color online only.

ence, standards of comparison, sampling of experience, and patterns of emphasis—can help to improve doctor-patient communication^{18,19} and the interpretation of PROs over time.²⁷

Our findings may also suggest that the current mea-

sures in the standard spine outcome battery may miss assessment of key constructs. For example, since the MCS did not evince strong responsiveness over time, it might be worthwhile to consider testing other measures of well-being or wellness in the battery. In her seminal paper con-

FIG. 3. Slope coefficients (main effects) over time. There was different sensitivity of the PROs to GAC at different times. The NRS, PROMIS, and PCS all evinced a "bump" early after surgery, suggesting higher sensitivity at that time window. In contrast, ODI and MCS had less of a "bump." Of note, PCS evinced a marked drop in sensitivity to GAC at about 8 months postsurgery. Figure is available in color online only.

ceptualizing quality of life, Smith³² compared this multidimensional construct to Maslow's hierarchy of needs,^{14–16} with lower layers (e.g., physical functioning) serving as a necessary foundation for higher-level concepts, such as role performance, adaptability, and eudaemonic well-being. While physical functioning and pain are clearly important foundational outcomes for spine surgery, an improved sense of ability to perform desired roles (i.e., role performance), confidence in one's ability to deal with the challenges of life postsurgery (e.g., environmental mastery), and an enhanced sense of purpose in life and social connection (i.e., eudaemonic well-being) are also indicative of a fuller recovery.

While this study has clear advantages in its longitudinal data of spine clinic patients, its limitations should be acknowledged. The study has the advantage of including patients with a broad range of spinal pathologies/procedures; its findings do not, however, differentiate by pathology or procedure. Another limitation is that, largely because of sample size, we did not fully explore study findings that reflect nonlinear relationships over time (e.g., the inverted-U-shaped pattern shown in Fig. 3). Also, the PRO redundancy detected in our findings may suggest that patients found the survey burdensome and reacted by answering mechanically or in other undesirable ways that biased results. For example, straightlining is a common survey response whereby the individual selects the same response option regardless of the question.²⁵ Such response biases can affect validity and power.²⁵ Research by members of our group has indicated, however, that patients do not experience even long surveys as burdensome if they are varied and comprehensive.³ Finally, there is growing recognition that responsiveness is mediated by attitudinal, behavioral, and framing effects.³³ Attitudinal mediators would include, for example, social desirability (e.g., what do patients think their provider wants to hear?). Behavioral mediators would include, for example, implicit theories of change,²⁰ effort justification, or cognitive dissonance.³³ Framing effects might involve the way the time frame is grouped (i.e., past day, week, or month) and/or what symptoms are considered when answering a GAC.³² In terms of evaluating the success of lumbar spine surgery using the GAC, it may be beneficial to reference the health condition for which the surgery was recommended when formulating the question in order to reduce response ambiguity and ensure clinical relevance.¹¹ These dynamics were not addressed in the current study. Future research might evaluate the impact of these mediators on spine surgery outcomes.

Conclusions

The present work supports the responsiveness of most of the spine PROs but suggests that several provide little additional information about recovery. Although all PROs were associated with GAC, they differed in their responsiveness over time. We suggest replacing the less responsive measures with tools that help to characterize factors that are driving the patients' subjective assessments of change, and that meaningfully address some of the higher levels in the hierarchy of quality-of-life outcomes.

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Disclosures

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Author Contributions

Conception and design: Schwartz, Finkelstein. Acquisition of data: Balasubramaniam, Shrikumar, Wasim, Finkelstein. Analysis and interpretation of data: Schwartz, Stark, Finkelstein. Drafting the article: Schwartz, Stark. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Schwartz. Statistical analysis: Schwartz, Stark. Administrative/technical/material support: Balasubramaniam, Shrikumar, Wasim, Finkelstein. Study supervision: Schwartz, Finkelstein.

Supplemental Information

Online-Only Content

Supplemental material is available with the online version of the article.

Supplemental Fig. 1. <https://thejns.org/doi/suppl/10.3171/2019.12.SPINE191367>.

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