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Int J Spine Surg 2021, 15 (6) 1060-1065
doi: https://doi.org/10.14444/8191
https://www.ijssurgery.com/content/15/6/1060

The International Journal of Spine Surgery
2397 Waterbury Circle, Suite 1,
Aurora, IL 60504, Phone: +1-630-375-1432

International Journal of Spine Surgery, Vol. 15, No. 6, 2021, pp. 1060–1065
https://doi.org/10.14444/8191

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ABSTRACT

Background: Patient-reported outcome measures (PROMs) are increasingly used for spinal surgery and may place additional burden in terms of time needed to complete. Few studies address the impact of time to complete (TTC) on PROMs.

Purpose: To determine whether length of TTC Patient-Reported Outcomes Measurement Information System physical function (PROMIS-PF) surveys impact scores in patients undergoing minimally invasive surgery (MIS) for lumbar decompression (LD).

Methods: We conducted a retrospective review of LD patients from 2015 to 2020. Inclusion criterion was primary, single-level MIS LD. Patients undergoing multilevel procedures and patients without preoperative PROMIS-PF survey data were excluded. PROMIS-PF, and visual analog scale (VAS) for back and leg pain were all evaluated at preoperative, 6 weeks, 12 weeks, 6 months, and 1 year time points. A minimum clinically important difference was evaluated for PROMIS-PF and VAS back and leg. TTC was calculated as the difference in start and stop time for completed questionnaires. Improvement in outcome scores was determined using a *t* test. Differences in mean TTC among time points were assessed using 1-way analysis of variance. Correlation between PROMIS-PF and TTC or VAS back and leg was determined using Pearson correlation and categorized as: $0.1 \leq |r| < 0.3$ = weak; $0.3 \leq |r| < 0.5$ = moderate; $|r| \geq 0.5$ = strong.

Results: The study cohort included 91 patients. Mean age was 47 years, and 64.7% of patients were male. PROMIS-PF, VAS back, and VAS leg significantly improved at all postoperative time points. TTC did not significantly differ at any time point. PROMIS-PF and TTC were not significantly correlated at any time point (all $P > 0.05$), but PROMIS-PF was correlated with VAS back and leg ($P < 0.015$).

Conclusion: PROMIS-PF significantly improved through 1 year. TTC did not significantly differ at any time point and was not correlated with PROMIS-PF scores. This suggests PROMIS-PF consistently places relatively low burden on patients and remains a valid measure to evaluate outcomes after LD.

Clinical Relevance: The utility of PROM surveys is increasingly appreciated in the context of spinal surgery; expansion of their use places additional burden on patients to complete surveys accurately and in a timely fashion. Length of TTC PROMIS-PF surveys does not impact scores in patients undergoing LD.

Level of Evidence: 4.

Lumbar Spine

Keywords: lumbar decompression, patient-reported outcomes, Patient-Reported Outcomes Measurement Information System, physical function, time to complete, outcomes

INTRODUCTION

Minimally invasive lumbar decompression (MIS LD) surgery is a common spinal procedure used to treat lumbar spinal stenosis and neurological claudication that has demonstrated low reoperation rates with few adverse events at 2-year follow-up.[1,2] To reflect postoperative improvement, traditional outcome measures often included the assessment of objective surgical factors,[3,4] which relied on clinical data such as radiographic imaging and neurological findings to assess a patient's quality of life.[5] However, this approach may fail to account for a patient's own experiences regarding the efficacy of treatment, pain, physical function, or quality of life and may be inherently biased.[3,5,6]

As modern healthcare shifts toward a patient-centered and cost-effective approach, there has been an increased interest in utilizing patient-reported outcome measures (PROMs) to assess and quantify postoperative outcomes based on patient perceptions following surgical procedures.[6] Two commonly used health-related quality of life assessments are the Medical Outcomes Study Short Form (SF-12) and Veterans RAND 12-Item Health Survey (VR-12). SF-12 and VR-12 measure physical, social, and mental functions and are generalizable across several disease states, allowing for

assessment of general health outcomes of a diverse patient population.[3,6,7] However, the so-called legacy PROMs such as VR-12 and SF-12 are not without their own shortcomings and may overburden patients due to their time-consuming nature and inclusion of potentially irrelevant questions, which may collectively lead to reduced data quality.[4,8–11] The effects of these factors may also extend to providers, as it has been suggested that use of an efficient patient-reported outcome can reduce cost, reduce physician burden, and minimize disruption to clinical workflow.[12]

In an effort to reduce burden, Patient-Reported Outcomes Measurement Information System (PROMIS) was developed to utilize computer adaptive testing (CAT), which may allow patients to complete surveys in significantly less time than lengthier legacy PROMs.[12] CAT presents patients with a minimum of 4 and a maximum of 12 questions. The answer to the first general question is used to determine the administration of the next question, the second used to determine the third, and so on until a threshold standard error is met or the patient has completed the maximum number of questions.[4] Using this system, Iyer et al reported a median time to complete (TTC) of 37 seconds and an average of 4 questions answered, compared with median TTC of 154 and 97 seconds for SF-36 physical component score and Neck Disability Index, respectively.[13] More efficient question administration can allow for shorter surveys, which are associated with higher response and completion rates and possibly quality.[14] However, given the variability in number of questions answered to complete PROMIS, the effects of questionnaire length and TTC on outcome scores are yet to be investigated.

While previous research has established the validity of PROMIS as an outcome measure following lumbar decompression (LD) procedures,[15–19] other studies highlighted possible risk factors for decreased PROMIS completion rates.[20] Additionally, questionnaire length, frequency of sampling, and even question layout may all contribute to response burden and consequently quality of data.[21] As the use of PROMs continues to increase within the clinical space, it remains prudent to evaluate all aspects that may impact outcome scores. Few studies currently exist that assess associations between TTC and PROMIS outcome scores, particularly for common spinal procedures such as LD. Therefore, this study aims to assess the impact of completion times on Patient-Reported Outcomes Measurement Information System physical function (PROMIS-PF) outcome scores in patients undergoing MIS LD.

METHODS

Patient Population

Prior to this study, IRB approval (Office of Research Affairs #14051301) and patient consent were obtained. A prospectively maintained surgical database was retrospectively reviewed for patients who underwent a lumbar procedure from 2015 to 2020. Inclusion criteria involved patients who underwent primary elective single-level LD surgery. Patients were removed from the study if they met the following exclusion criteria: surgery indicated for infection, malignancy, or trauma or not completing a preoperative PROMIS-PF survey. All patients had their procedure performed at a single institution by a single attending physician.

Data Collection

Demographic characteristics for included patients were collected at the preoperative time point. Collected demographic data included age, body mass index (BMI), smoking status, diabetic status, American Society of Anesthesiologists physical classification, Charlson Comorbidity Index, insurance type, and pain severity by way of visual analog scale (VAS) for leg and back. In addition to demographics, recorded spinal pathologies and operative characteristics were also collected, which included operative duration (skin incision to closure in minutes) and estimated blood loss (in milliliters). To assess physical function improvements following LD, PROMIS-PF (version 1.2)[22] scores were recorded at preoperative and 6 weeks, 12 weeks, 6 months, and 1 year postoperative time points. Back and leg pain were also collected using the VAS at the same time points. A minimum clinically important difference (MCID) was calculated by comparison of the difference in outcome scores from their respective preoperative values with established thresholds from the literature: 3.0 (PROMIS-PF),[18] 1.2 (VAS back),[23] and 1.6 (VAS leg).[23]

Surveys included in this study were completed either during clinic appointments through a tablet or on personal devices through an online portal. Using electronic survey data, TTC PROMIS-PF was determined by calculating the difference in beginning and ending times for each instance of survey completion. Outlier screening was performed to avoid the use of extreme values as a result of uncompleted surveys or patients being away from the computer or inactive for lengthy periods of time, all of which may not reflect the true nature of completion times. This involved exclusion from analysis for values that fell outside of 3 standard deviations.

Table 1. Demographics of patients undergoing lumbar decompression (n = 91).

Demographic	Total (n = 91)
Age (mean ± SD)	46.7 ± 13.2
Gender, n (%)	
Female	33 (36.3%)
Male	58 (64.7%)
BMI, n (%)	
< 30 kg/m^2	53 (58.2%)
≥ 30 kg/m^2	38 (41.8%)
Smoking status, n (%)	
Nonsmoker	80 (87.9%)
Smoker	11 (12.1%)
Diabetes, n (%)	
Diabetic	3 (3.3%)
Nondiabetic	88 (96.7%)
ASA score, n (%)	
≤2	30 (33.0%)
>2	61 (67.0%)
CCI score, n (%)	
<1	31 (34.1%)
≥1	60 (65.9%)
VAS back	
<7	50 (54.9%)
≥7	41 (45.1%)
VAS leg, n (%)	
<7	51 (56.0%)
≥7	40 (44.0%)
Worker's compensation, n (%)	
No	83 (91.2%)
Yes	8 (8.8%)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; VAS, visual analog scale.

Statistical Analysis

Demographic characteristics, spinal pathologies, and operative variables were all summarized using descriptive statistical analysis. To determine the improvement in mean PROMIS-PF, VAS back, and VAS leg scores from baseline values, a paired Student t test was performed at each postoperative time point. Comparison of TTC values at all time points, both preoperative and postoperative, was performed using a 1-way analysis of variance. A post hoc Tukey test was performed to determine at which time points a difference in mean TTC was observed. The relationship between the time it took to complete PROMIS-PF surveys and outcome scores was investigated at preoperative and postoperative time points using Pearson correlation analysis. Additionally, the relationship between PROMIS-PF and both VAS back and VAS leg was also evaluated using Pearson correlation analysis. In order to qualify the strength of relationship between TTC and PROMIS-PF as well as VAS back and VAS leg with PROMIS-PF, Pearson correlation coefficients were categorized into the following: $0.1 \leq |r| < 0.3$ = weak; $0.3 \leq |r| < 0.5$ = moderate; $|r| \geq 0.5$ = strong. Significance for all statistical analysis was set at $P = 0.05$.

Table 2. Operative characteristics of patients undergoing lumbar decompression (n = 91).

Operative Characteristic	Total (n = 91)
Spinal pathology, n (%)	
Herniated nucleus pulposus	76 (83.5%)
Degenerative spondylolisthesis	5 (5.5%)
Isthmic spondylolisthesis	2 (2.2%)
Operative time (min), mean ± SE	41.9 ± 11.8
Estimated blood loss (mL), mean ± SE	25.8 ± 6.6

RESULTS

This study included a total of 91 patients who underwent primary elective single-level LD surgeries. The patient cohort had a mean age of 46.7 years; 64.7% were male, 58.2% were nonobese (BMI < 30 kg/m^2), and 91.2% used either private or Medicare/Medicaid insurance (Table 1). A majority of the cohort had a spinal pathology of herniated nucleus pulposus (83.5%) and had a mean operative time of 41.9 and mean estimated blood loss of 25.8 mL (Table 2).

Physical function demonstrated significant improvements from preoperative baseline values at 6 weeks ($P < 0.001$), 12 weeks ($P < 0.001$), 6 months ($P = 0.002$), and 1 year ($P < 0.001$). A similar result was demonstrated for both VAS back and VAS leg where a significant improvement was observed at all postoperative time points ($P \leq 0.023$, all) (Table 3). Majority of patients achieved an MCID at all postoperative time points for PROMIS-PF, VAS back, and VAS leg (Table 3). Preoperative baseline TTC was 69.0 ± 61.7 seconds and reached a maximum of 72.0 ± 39.8 seconds at 12 weeks postoperatively. Comparative analysis of mean TTC did not demonstrate significant differences from preoperative baseline values at all postoperative time points (all $P > 0.05$; Table 3). Pearson correlation analysis demonstrated a positive relationship between TTC and PROMIS-PF at all time points but did not reach statistical significance (all $P > 0.05$). Further investigation of the relationship between TTC and PROMIS-PF revealed a low strength but positive relationship at the 6-week ($r = 0.213$; $P = 0.129$) and 12-week ($r = 0.159$; $P = 0.400$) postoperative time points (Table 4). PROMIS-PF did demonstrate significant and strong or moderate relationships with VAS back at all time points ($P \leq 0.015$, all) and with VAS leg from the preoperative to 12-week time point ($P \leq 0.007$, all) (Table 4).

DISCUSSION

Traditional methods of assessing patient outcomes entailed radiographic and physical examinations;

Table 3. Improvement in Patient-Reported Outcomes Measurement Information System physical function after lumbar decompression.

Outcome Measure	Mean ± SD	n	MCID Achievement	*P* Value[a]
PROMIS-PF				
Preoperative	37.4 ± 6.8	91	-	-
6 wk	43.4 ± 8.2	64	64.8%	**<0.001**
12 wk	50.3 ± 10.2	39	84.8%	**<0.001**
6 mo	43.8 ± 7.0	20	68.4%	**0.002**
1 y	46.5 ± 9.0	21	70.0%	**<0.001**
VAS back				
Preoperative	6.2 ± 2.5	76	-	-
6 wk	2.7 ± 2.6	62	72.6%	**<0.001**
12 wk	1.7 ± 2.3	25	88.0%	**<0.001**
6 mo	2.9 ± 2.9	17	76.5%	**<0.001**
1 y	2.8 ± 3.0	16	68.7%	**0.023**
VAS leg				
Preoperative	6.0 ± 2.9	76		-
6 wk	3.0 ± 2.9	62	65.5%	**<0.001**
12 wk	1.7 ± 2.6	25	76.0%	**<0.001**
6 mo	1.6 ± 2.0	17	70.6%	**<0.001**
1 y	2.6 ± 2.9	16	62.5%	**0.006**
TTC (sec)				*P* value[b]
Preoperative	69.0 ± 61.7	87	-	-
6 wk	66.8 ± 52.2	53	-	0.999
12 wk	72.0 ± 39.8	30	-	0.999
6 mo	55.0 ± 40.1	12	-	0.912
1 y	70.6 ± 23.6	17	-	0.999

Abbreviations: LD, lumbar decompression; MCID, minimum clinically important difference; PROMIS-PF, Patient-Reported Outcomes Measurement Information System physical function; TTC, time to complete; VAS, visual analog scale.
[a]*P* values calculated using paired *t* test.
[b]*P* values calculated using 1-way ANOVA post hoc Tukey.

however, more recently, a shift toward evidence-based, patient-centered medicine has placed an emphasis on PROMs. While this shift in practice benefits patients by promoting their involvement in determining outcomes, requiring completion of surveys at multiple time points may simultaneously place additional burden on patients.

Table 4. Correlations of Patient-Reported Outcomes Measurement Information System physical function (n = 91).

Outcome Measure	Pearson, |*r*|	*P* Value[a]
TTC		
Preoperative	0.048	0.656
6 wk	0.213	0.129
12 wk	0.159	0.400
6 mo	0.096	0.765
1 y	0.058	0.823
VAS back		
Preoperative	0.477	**<0.001**
6 wk	0.512	**<0.001**
12 wk	0.593	**0.006**
6 mo	0.654	**0.015**
1 y	0.595	**<0.001**
VAS leg		
Preoperative	0.316	**0.005**
6 wk	0.528	**<0.001**
12 wk	0.577	**0.007**
6 mo	0.273	0.365
1 y	0.583	0.059

Abbreviations: TTC, time to complete; VAS, visual analog scale.
Boldface indicates statistically significant finding.
[a]*P* value calculated using Pearson coefficient.

This study aimed to quantify the burden of completion time that PROMIS-PF imposes on the patient and assess whether this may impact reported outcomes in the postoperative setting.

A number of physical function PROMs exist in today's clinical setting, including VR-12, SF-12, and PROMIS-PF. Although these surveys each have similar goals of accurately representing a patient's perception of their physical function, the questionnaires differ in both length and content. Previous studies have established that on average, both VR-12 and SF-12 require up to 3 minutes to complete.[12,24] Our study reported that mean TTC for PROMIS-PF survey ranged from 55.0 to 72.0 seconds, which is similar to values observed in PROMIS validation studies.[12,25] Relative to other PROMs, this TTC represents a substantial amount of time saved, especially when the increasing number of questionnaires administered at each preoperative and postoperative time point is considered.

In addition to reducing time needed to complete, effective PROMs should accurately depict a patient's perceptions of the desired outcome. Our study was able to demonstrate that PROMIS-PF scores significantly increased through 1 year postoperatively, which was previously established in a study by Purvis et al that strongly correlated PROMIS-PF scores with other well-studied PROMs in LD patients.[17] Given that PROMIS-PF has been used extensively with LD patients[15–17] and validated in a number of spine surgery studies,[6,12,13,17] it was also important to determine whether the questionnaire increased response burden for patients. For the purposes of this study, we assessed burden by way of TTC and demonstrated a consistently low TTC with no significant differences in mean times between all postoperative time points. A similar study focusing on comparison of PROMIS to other legacy PROMs also reported a similar completion time through the 3-month postoperative time point.[12] This may suggest that PROMIS-PF does not substantially add to the burden of surveys on patients and further validates its use as an appropriate outcome measure for patients undergoing LD.

Well-validated legacy PROMs can add value to the assessment of a patient's postoperative progress, but with the time constraints faced by today's physicians and patients, surveys that take up to 5 or even 10 minutes may have less of a role.[24] While the use of PROMIS-PF addresses the time constraint, the impact of varying TTC values on outcome scores has not been well established. Our study was able to demonstrate that through the 1-year postoperative time point, TTC

did not significantly vary and was not significantly correlated with PROMIS-PF scores. This suggests that the improvements in physical function reflected by PROMIS were not influenced by the time taken to complete the survey and again further validates the use of PROMIS as an efficient and effective measure for LD patients.[26,27]

Limitations

There are several limitations associated with this study. The patient population included was from a single institution, and all underwent procedures performed by a single surgeon. As such, this may select for a specific cohort and limits the ability to generalize our findings regarding the impact of TTC on PROMIS scores to other populations. Additionally, the use of self-reported surveys to assess patient outcomes has the potential to introduce response bias.

CONCLUSION

PROMs continue to be an increasingly important aspect of patient-centered medical practice. As studies continue to validate their use and establish their permanency among assessments of postoperative progress, the commitment required of patients and clinical staff to survey completion will likewise grow. Our study is one of few that investigates the impact time taken to complete PROMs has on actual outcome scores. We were able to demonstrate that TTC PROMIS-PF did not differ through 1 year postoperatively and did not influence reported outcomes in the postoperative setting. Our findings suggest that the use of PROMIS-PF imposes a relatively small burden on patients in terms of time commitment while also providing an accurate measure to track postoperative improvement in physical function.

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Funding: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Declaration of Conflicting Interests: The authors report no conflicts of interest with respect to the research, authorship, and/or publication of this article.

IRB Approval: Office of Research Affairs #14051301

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Published 24 December 2021