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Age and Gender Confound PROMIS Scores in Spine Patients With Back and Neck Pain

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Abstract

Study Design: This was a single-center retrospective review.

Objectives: To explore how age and gender affect PROMIS scores compared with traditional health-related quality of life (HRQL) in spine patients.

Methods: Patients presenting with a primary complaint of back pain (BP) or neck pain (NP) were included. Legacy HRQLs were Oswestry Disability Index (ODI), Neck Disability Index (NDI), and Visual Analogue Scale (VAS). PROMIS Physical Function (PF), Pain Intensity (Int), and Pain Interference (Inf) were also administered to patients in a clinical setting. Patients were grouped by chief complaint, age (18-44, 45-64, 65+ years) and gender. Two parallel analyses were conducted to identify the effects of age and gender on patient-reported outcomes. Age groups were compared after propensity-score matching by VAS-pain and gender. Separately, genders were compared after propensity-score matching by age and VAS-pain.

Results: A total of 484 BP and 128 NP patients were matched into gender cohorts (n = 201 in each BP group, 46 in each NP group). Among BP patients, female patients demonstrated worse disability by ODI (44.15 vs 38.45, $P = .005$); PROMIS-PF did not differ by gender. Among NP patients, neither legacy HRQLs nor PROMIS differed by gender when controlling for NP and age. BP and NP patients were matched into age cohorts (n = 135 in each BP group and n = 14 in each BP group). Among BP patients, ANOVA revealed differences between groups when controlling for BP and gender: ODI ($P < .001$), PROMIS-PF ($P = .018$), PROMIS-Int ($P < .001$) PROMIS-Inf ($P < .001$). Among NP patients, matched age groups differed significantly in terms of NDI ($P = .032$) and PROMIS-PF ($P = .022$) but not PROMIS-Int or PROMIS-Inf.

Conclusions: Age and gender confound traditional HRQLs as well as PROMIS domains. However, PROMIS offers age and gender-specific scores, which traditional HRQLs lack.

Keywords

health-related quality of life measures, NDI, ODI, Patient-Reported Outcomes Measurement Information System, back pain, neck pain

Introduction

Back pain (BP) is the number one cause of disability worldwide, according to the 2010 Global Burden of Disease Study.[1] It is estimated that up to 84% of adults are afflicted with BP at least once in their lives.[2] Similarly, neck pain (NP) is the fourth most common disability that patients experience chronically.[3] Physician-based outcome metrics for spine patients are

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inherently biased because progress largely depends on patients' perceived pain levels—an outcome that scans and physical exam tactics cannot capture.[4]

Consequently, patient-reported health-related quality of life measures (HRQLs) have grown especially popular among orthopaedic spinal surgeons to evaluate patient progress.[5-7] HRQL measures not only improve doctor-patient communication, but also track patient recovery over time and allow straightforward comparisons of health outcomes across diverse populations and between research studies.[8,9] Thus, understanding the effectiveness of these metrics is essential to optimizing patient outcomes.

Traditionally, popular HRQL measures among spinal surgeons include the Oswestry Disability Index (ODI), Neck Disability Index (NDI), and the Visual Analogue Scale for pain (VAS-pain).[10,11]

More recently, the Patient Reported Outcomes Measurement Information System (PROMIS) was developed by the National Institutes of Health to assess domains such as physical functioning, pain intensity, and pain interference in patients using computer adaptive testing (CAT) software.[4] PROMIS is actively pursued because of its short completion times and low floor and ceiling effects.[12]

Previous studies have reported on the confounding variables of traditional spine HRQLs. Disability metrics such as ODI are influenced by factors such as age, gender, race, and socioeconomic status.[13,14] Furthermore, NDI is affected by both psychosocial and physical impairments.[15] Both age and socioeconomic status confound VAS scores.

Although the literature often controls for some of the aforementioned variables during statistical analysis, there is limited data on confounders of PROMIS scores. To date, no study evaluates confounders of PROMIS domains in the spine patient population. To provide optimal care, we must investigate factors that influence PROMIS scores. The aim of this study is to explore how confounding variables such as age and gender affect PROMIS as compared with traditional HRQLs in patients who complain of BP or NP.

Materials and Methods

Inclusion Criteria

Following approval from the institutional review board, retrospective analysis was performed on a database of prospectively collected patient-reported outcomes measures at a single-institution in a large urban area from December 2016 to April 2017. Inclusion criteria were age >18 years and a primary complaint of BP or NP.

Outcome Metrics

Patient records were deidentified. Demographic and outcome data was collected for each patient by chart review. Demographic data was limited to age and gender only because survey analyses were anonymous. Age was recorded using 6 age groups: group 1 (<35 years), group 2 ($35 \leq$ age < 45 years), group 3 ($45 \leq$ age < 55 years), group 4 ($55 \leq$ age < 65 years), group 5 ($65 \leq$ age < 75 years), and group 6 (age ≥ 75 years). In addition to demographic information, outcomes data was also obtained from each patient in the form of several health-related outcome metrics.

The legacy outcomes included in this analysis were the following: ODI, NDI, Visual Analog Score (VAS) BP, VAS NP, VAS Leg pain, and VAS Arm pain. PROMIS-CAT domains included Physical Function (PF), Pain Intensity (Int), and Pain Interference (Inf). Questionnaires were administered via tablet before clinic visits and were completed by patients in random order. ODI and NDI questionnaires each contain 60 questions. The resulting scores range from 0 to 100, with larger numbered outcomes representing more back or neck disability, respectively.[13,15]

The VAS is a single question that asks patients to rate pain on a 10-cm line. The chosen point corresponds to a score that ranges from 0 to 10, with scores closer to 10 demonstrating worse pain.[16]

The PROMIS CAT algorithm results in *t*-scores standardized to a normative US population. Brodke et al[17] demonstrated that the PROMIS-PF domain uses, on average, 4.15 questions in spine patients. PROMIS scores range from 0 to 100, with a mean score of 50 representing the population average and 10 points set as the SD. PROMIS-PF scores closer to 100 indicate higher function, whereas scores close to 100 for PROMIS-Int or PROMIS-Inf indicate worse outcomes. PROMIS scores were compared with legacy outcome metrics (ODI and VAS) for their ability to capture pain and disability.

Statistical Analysis

The patient cohort was grouped based on complaint, age category (18-44, 45-64, 65+ years), and gender (male or female). Propensity score matching (PSM) was performed between the age groupings while controlling for pain level (VAS) and gender. Groups were matched by gender while controlling for age and pain level (VAS) control for age and VAS. To compare between legacy HRQL measures and PROMIS-CAT, independent samples *t*-tests were performed. ANOVA was used for multivariate comparisons. All statistical analysis was conducted using the Statistical Package for Social Sciences (SPSS Version 23, IBM Corp, Armonk, NY). $P < .05$ was used to indicate statistical significance for all findings.

Results

Patients presenting with a chief complaint of BP or NP were identified between December 2016 and April 2017. A total of 612 patients who completed all necessary HRQLs were included. Of this sample, 484 (79.1%) patients consulted for BP and 128 (20.9%) patients were seen for NP complaints. A summary of the demographic characteristics and HRQL scores of the study population can be found in Table 1. The mean age of both BP and NP patients fell between 45 and 55 years. The

BP patient cohort was 50.60% female, and 51.20% of neck patients were female. Back patients reported worse PF and more pain than NP patients (PROMIS-PF 37.40 vs 41.15, PROMIS-Int 54.79 vs 52.99, PROMIS-Inf 64.33 vs 62.42; Table 1).

Table 1. Demographic and HRQL Score Characteristics of the Study Population, by Complaint.[a]

	Back Pain (n = 484)	Neck Pain (n = 128)
Age (years)	3.4 ± 1.6	3.1 ± 1.5
Gender (female)	50.1%	51.2%
VAS Back	6.9 ± 2.3	4.5 ± 3.0
VAS Leg	5.2 ± 3.3	2.5 ± 2.9
VAS Neck	3.1 ± 3.2	6.1 ± 2.5
VAS Arm		4.3 ± 3.1
ODI	41.4 ± 19.2	
NDI		38.0 ± 19.2
PROMIS: Physical Function	37.4 ± 8.1	41.2 ± 9.4
PROMIS: Pain Intensity	54.8 ± 7.0	53.0 ± 7.7
PROMIS: Pain Interference	64.3 ± 6.9	62.4 ± 7.3

Abbreviations: HRQL, health-related quality of life measures; VAS, Visual Analog Scale; ODI, Oswestry Disability Index; NDI, Neck Disability Index; PROMIS, Patient-Reported Outcomes Measurement Information System.
[a] Values are reported as mean ± SD or percentage.

To more effectively explore the effect of gender on HRQLs of BP and NP patients, a PSM analysis was performed to mitigate the uneven distribution of age and VAS pain scores. BP and NP patients were matched into gender cohorts (n = 201 in each group and 46 in each group, respectively). To compare the effect of age on HRQLs of BP and NP patients, PSM analysis was performed to control for the uneven distribution of gender and VAS pain scores. BP and NP patients were matched into age cohorts (n = 135 each and n = 14 each, respectively). Mean scores for the age analysis were compared between cohorts aged 18 to 44, 45 to 64, and >65 years old.

Among BP patients, female patients demonstrated significantly worse disability in terms of ODI (44.15 vs 38.45, $P = .005$; Table 2), whereas PROMIS-PF, PROMIS-Int, and PROMIS-Inf did not exhibit differences by gender ($P > .05$; Table 2). When comparing age groups, ANOVA revealed differences between groups when controlling for VAS BP and gender across all measured HRQLs. The lowest ODI disability scores were found in patients aged 18 to 44 years, and the highest disability in patients aged 45 to 64 years, with patients older than 65 years scoring in-between the other age cohorts (36.21 vs 44.99 vs 44.28, $P < .001$; Table 2). PROMIS-PF (40.24 vs 36.73 vs 34.82, $P < .001$; Table 2), PROMIS-Int (53.54 vs 55.93 vs 54.99, $P = .018$; Table 3), and PROMIS-Inf (62.56 vs 65.33 vs 65.12, $P < .001$; Table 2) demonstrated similar results.

Table 2. Comparison Between Gender and Age Groups for Back Pain Cohort.[a]

	Gender Analysis			Age (years) Analysis			
	Male (n = 201)	Female (n = 201)	*P*	18-44 (n = 135)	45-64 (n = 135)	65+ (n = 135)	*P*
ODI	38.5 (CI: 35.9-41.1)	44.2 (CI: 41.5-46.9)	.005b	36.2 (CI: 32.9-39.5)	45.0 (CI: 41.7-48.3)	44.3 (CI: 41.3-47.3)	<.001b
PROMIS Physical Function	38.3 (CI: 37.1-39.4)	37.0 (CI: 35.9-38.1)	.122	40.2 (CI: 38.8-41.6)	36.7 (CI: 35.4-38.0)	34.8 (CI: 33.5-36.0)	<.001b
PROMIS Pain Intensity	54.2 (CI: 53.3-55.1)	55.4 (CI: 54.4-56.4)	.077	53.5 (CI: 52.3-54.8)	55.9 (CI: 54.8-57.0)	55.0 (CI: 53.9-56.1)	.018b
PROMIS Pain Interference	63.7 (CI: 62.8-64.6)	64.7 (CI: 63.7-65.7)	.151	62.6 (CI: 61.3-63.9)	65.3 (CI: 64.2-66.4)	65.1 (CI: 64.0-66.2)	<.001b

Abbreviations: ODI, Oswestry Disability Index; PROMIS, patient-reported outcomes measurement information system.
[a] Values are reported as means with 95% CIs in parentheses.
[b] Statistically significant ($P < .05$).

Table 3. Comparison Between Gender Groups for Neck Pain Cohort.[a]

	Gender Analysis			Age (years) Analysis			
	Male (n = 46)	Female (n = 46)	*P*	18-44 (n = 14)	45-64 (n = 14)	65+ (n = 14)	*P*
NDI	37.0 (CI: 31.6-42.4)	37.2 (CI: 31.1-43.3)	.967	24.7 (CI: 16.5-32.9)	43.6 (CI: 31.9-55.3)	37.4 (CI: 28.5-46.3)	.032b
PROMIS Physical Function	41.7 (CI: 38.9-44.5)	42.3 (CI: 39.4-45.2)	.770	50.0 (CI: 44.2-55.8)	39.7 (CI: 34.0-45.4)	43.6 (CI: 37.8-49.4)	.022b
PROMIS Pain intensity	53.2 (CI: 50.5-55.9)	52.2 (CI: 50.4-54.1)	.556	51.2 (CI: 47.6-54.8)	53.4 (CI: 47.6-59.2)	53.4 (CI: 48.1-58.7)	.787
PROMIS Pain Interference	62.3 (CI: 60.1-64.5)	62.0 (CI: 59.6-64.4)	.843	57.3 (CI: 53.3-61.3)	63.3 (CI: 58.3-68.3)	63.4 (CI: 59.4-67.4)	.104

Abbreviations: NDI, Neck Disability Index; PROMIS, Patient-Reported Outcomes Measurement Information System.
[a] Values are reported as means with 95% CIs in parentheses.
[b] Statistically significant ($P < .05$).

Among NP patients, no significant differences were found between genders in traditional HRQLs or PROMIS domains when controlling for VAS NP and age ($P > .05$; Table 3). When comparing age cohorts, comparison of matched age groups revealed significant differences in NDI ($P = .032$) and PROMIS-PF ($P = .022$), but neither for PROMIS-Int nor PROMIS-Inf ($P > .05$). NDI scores demonstrated the least disability in neck patients between 18 and 44 years of age and most disability in patients 45 to 64 years old, with patients older than 65 years scoring in between (24.71 vs 43.57 vs 37.43, $P = .032$; Table 3). PROMIS-PF indicated highest functioning in patients 18 to 44 years old and lowest function in the 45- to 64-year-old cohort, with patients >65 years old scoring in between (50.03 vs 39.74 vs 43.56, $P = .022$; Table 3).

Discussion

There is little published literature that exposes confounding variables of spine HRQL scores. Although some studies have shown that there are variables that influence HRQLs, we are unaware of any research study that aims specifically to discover confounders of back and neck PROMIS scores.[13-15,18-21] As the American health care climate shifts to a value-based approach, the use of patient-reported outcomes that quantify disability and health improvement becomes essential in medical practice.[22-24] Studying confounders of HRQLs such as PROMIS, therefore, is essential to providing well-informed care.

The present study reveals that many of the most commonly used spine HRQLs are influenced by a BP or NP patient's age and/or gender. ODI was significantly different in gender cohorts of BP patients, with female patients reporting more disability. With respect to age, ODI, PROMIS-PF, PROMIS-Int, and PROMIS-Inf were different in age cohorts of BP patients, whereas NDI and PROMIS-PF were different in age cohorts of NP patients. Unsurprisingly, the youngest cohort consistently reported the least amount of disability or pain and the highest level of PF. However, the greatest amount of disability or pain and the lowest amount of PF was found not in the oldest cohort but rather among the middle-aged cohort (45-64 years). Literature is generally lacking regarding the effect age has on spine HRQLs in nonpediatric populations. Although McGirt et al[16] and Patel et al[25] recently reported an association between older age and traditional spine HRQLs, our study extends this relationship to PROMIS scores as well.

Given that the present study has validated the influence of age and gender on spine HRQLs, our data suggests that physicians should be mindful when using these HRQLs in the future. This caution pertains to the use of ODI, NDI, and PROMIS-PF, PROMIS-Int, and PROMIS-Inf domains when comparing across age and gender groups because all were affected by either age or gender.

It is notable that PROMIS domains were less affected by age and gender than traditional HRQLs. PROMIS scores were not significantly different between gender cohorts, unlike traditional HRQLs such as ODI. Moreover, whereas both NDI and ODI demonstrated differences between age-matched cohorts, PROMIS-Int and PROMIS-Inf were not significantly different between age cohorts of neck patients. It is for this reason that we suggest using PROMIS domains to track outcomes of spine patients.

The PROMIS data collected in the present study used scores centered on the 2000 US Census with respect to relevant population demographics.[26] Although not used in this study, there are additional PROMIS scores that center data on subpopulation norms of age or gender. Cook et al[27] and Molton et al[28] studied normative data generated from these subgroups. The subpopulation norms divide the relevant population to aid in interpretation of scores.[27,28] Although age and gender are confounders of traditional HRQLs, as well as PROMIS domains, the PROMIS CAT does offer age- and gender-specific scores that traditional patient-reported outcome measures lack. By accounting for confounding variables, PROMIS may be considered a superior research measure for spine patients. It is our hope that this conclusion guides clinical reasoning and choice of spine HRQLs in the future.

Limitations of this study include the small sample size and retrospective nature of the methodology. As with any retrospective review, there is a possibility of selection bias that we must recognize. However, HRQLs were administered to any patient presenting with neck or BP older than 18 years. Additionally, we must recognize the heterogeneity of the pathologies that may have instigated pain. Further studies should increase sample size and perhaps focus on specific BP or NP etiologies. Prospective studies are also needed to investigate the effects of other confounding variables. Despite these limits, the present study provides evidence as to how age and gender confound common spine HRQLs, filling a gap in the literature.

Authors' Note

Internal review board approval was obtained prior to study initiation.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article:

Charla R. Fischer: Dr Fischer reports personal fees from Expert Connect and personal fees from Stryker, outside the submitted work.

Aaron J. Buckland: Dr Buckland reports personal fees from EOS imaging, personal fees from K2 M, and personal fees from NuVasive, outside the submitted work.

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