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Correlation of PROMIS CAT instruments with Oswestry Disability Index in chiropractic patients

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ABSTRACT

Background: The inefficiency associated with collecting standard validated instruments has been a barrier to routine use. We utilized computer adaptive testing (CAT) instruments available through Patient-Reported Outcomes Measurement Information System (PROMIS) and correlated these with the Oswestry Disability Index (ODI).

Methods: All measurements were collected at a routine chiropractic visit. The ODI assessment was used for comparison as a widely used patient reported outcomes instrument.

Results: The average time to complete all questions during an office visit was 170 ± 67 s (average ± Stdev) to answer 25 ± 6 questions. Regression analysis revealed a good linear fit between ODI and both PROMIS pain behavior and physical function with R^2 values of 0.5219 and 0.6754 respectively, and a good linear fit between anxiety and depression with R^2 values of 0.5236.

Conclusions: PROMIS CAT instruments can be efficiently administered during routine clinical visits and correlations values found validate the utility when compared to ODI.

1. Introduction

Patient outcomes following chiropractic care are highly variable, and substantial debate continues regarding the effectiveness of chiropractic care in a number of treatment areas [1–4]. In order for patients, payers, legislators and other stakeholders to make well informed decisions regarding the role of chiropractic care in the overall healthcare landscape more reliable and standardized outcome metrics are needed. The routine use of patient based outcome instruments in chiropractic patients may be one such metric [5,6]. Integrating routine collection of patient reported outcome measures (PROs) into clinical practice would facilitate the evaluation of treatment strategies based on direct feedback from the patient. Recently the National Institutes of Health (NIH) supported the development of the Patient-Reported Outcomes Measurement System (PROMIS). This system includes computer adaptive testing (CAT) based instruments used to measure health outcomes from the patient's perspective. The CAT allows for far fewer questions to be asked of the patient since subsequent questions are algorithmically chosen based on responses to those already answered. Also no more questions are asked once a high degree of measurement certainty is reached. While these instruments are validated in several populations [7–15] and have the potential to provide quantitative outcome measures in spinal disorders [11,16], they have not been validated in a chiropractic care setting nor have they been compared to previously validated legacy measures of spine pain and disability in such a setting. The Oswestry Disability Index (ODI) is currently a well-established and highly regarded PRO measure of disability in those with in low back pain disability. While the PROMIS scales are broadly validated in the general population, the case must be made that the broad domains are sensitive when compared to disease specific and/or injury specific outcome measures to show that they are useful in a particular population. Previous research has shown that chiropractic patient populations can have unique sociodemographic and functional attributes [17,18]. This study assessed the feasibility of simultaneously obtaining PROMIS and ODI measurements from a cohort of patients seen in a private practice chiropractic office, and measured the correlation of specific PROMIS measures with the legacy instrument, ODI. We also examined the correlation between

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well documented patient outcome domains in chiropractic such as pain and physical function [6,19–22] with those of mental distress (depression and anxiety) that have not been as well documented [23,24].

Very little research has been done using PROMIS assessments to study chiropractic care [11,25–28]. We hypothesize that there is a significant correlation between a patient's PROMIS (physical function and pain behavior) scores and their ODI score in those patients suffering back pain. With a decrease in physical function and an increase in pain behavior being associated with higher ODI scores. Previous research has found a variety of age and gender effects on outcomes associated with low back pain [29–32]. We therefore wanted to establish that these correlations based on gender and age.

2. Materials and methods

The study was approved by a local Institutional Review Board prior to any data collection. Data was collected from a private chiropractic office affiliated with the institution. All patients seeing the chiropractor for a newly diagnosed acute care treatment for any condition who were at least 18 years old, were asked to participate in the study. Patients seeing the doctor that were not able to read or understand English, or were not able to provide informed consent were excluded. Patients involved in medico-legal or workman's compensation cases were also excluded. This was designed as a pragmatic evaluation of chiropractic patients as generally seen by the clinician, therefore no set time points or specific treatment modalities were delineated. The PROMIS physical function assessment acts to identify the physical abilities of individuals' in carrying out physical activities of daily living. This definition has been broadened from the earlier descriptions of disability domains to allow for abilities to be quantified both above and below the population mean [9,10,33]. The PROMIS pain behavior assessment acts to self-identify verbal complaints of pain and suffering, non-language sounds, facial expressions, body posturing and gesturing, and limitations in activities [9,33,34]. The PROMIS anxiety assessment acts to identify symptoms that reflect autonomic arousal and the experience of threat exemplified by, among other, things fear, worry, and nervousness [9,14,33]. The PROMIS Depression assessment acts to identify depressive symptoms exemplified by, among other, loneliness, sadness and worthlessness [9,15,33]. The scoring scale for each PROMIS instruments is a T-score, where a score of 50 represents the normal adult population of the United States, and 10 points on this scale would represent 1 standard deviation from the mean. For the physical function scores above 50 represent patient improvement, while for pain behavior, anxiety, and depression a decrease would represent patient improvement.

The ODI is one of the most widely used spine specific outcome measures, and is used by both clinicians and researchers [5,21,35,36]. The ODI is used to measure the physical function disability related to disorders of the spine. It was originally introduced in 1976 by Obrien et al. and was published in 1980 [37]. A recent PubMed search for “Oswestry Disability Index” returned over 2500 scientific articles involving the ODI. The ODI has been used to validate a multitude of low back specific pain/disability scales [38–41], and it has shown high correlation with general pain/function outcome measures [22,42]. ODI scores are presented as percentages of disability, Minimal (0–20%), Moderate (21–40%), Severe (41–60%), Crippled (61–80%), and Exaggerated (81–100%) [35].

Phase one of data collection included approximately 19 months of data collection, patients who agreed to participate were evaluated by administering the PROMIS (physical function, pain behavior, anxiety, and depression) instruments on a tablet device (iPad 2) during a routine office visit. Phase 2 of data collection included the subsequent 16 months, patients who agreed to participate were evaluated by administering the PROMIS (physical function, pain behavior, and ODI) in the same manner. While the ODI was collected on all subjects in phase 2, only those with reported back pain are used in calculations involving ODI. Using the PROMIS CAT instruments available through the Assessment Center (www.assessmentcenter.net), custom assessments was created to include the physical function (version 1.2); pain behavior (version 1.1); anxiety (version 1.1); depression (version 1.1); a custom instrument was also created to include the ODI separately. In this manner the PROMIS assessments and/or the ODI questionnaire were completed in succession on the same tablet device during each of the patient's office visits during the collection period.

2.1. Feasibility

In order to assess the feasibility of introducing the PRO measures into the daily operations of a private chiropractic clinic the clinician was asked to evaluate the acceptability, implementation, and practicality of data collection during the study duration [43]. This evaluation was provided both by objective measures of time to fill out the assessments and by the descriptive experiences as described by the clinician and staff. Acceptability focused on the welcome or unwelcome responses of the clinician and staff administering the PROs, as well as the patients asked to participate. A description of the implementation process and any alterations needed to maintain office efficiency was also provided. The assessment of practicality focused on any additional resources, time, and/or commitment needed to complete the data collection.

2.2. Statistical analysis

A repeated measures ANOVA using age and gender as fixed factors was used to evaluate average score in those patients completing 6 visits. All time points collected for each patient were used to calculate the correlation between days in treatment and each outcome measure, as well as the correlation between ODI assessments and individual PROMIS assessments. These correlations were quantified using Pearson's correlation coefficient, using linear bivariate regression analysis, with each office visit used as the unit of measure. Separate correlation coefficients were calculated for subsets of patients based on sex and age. Age groups were determined post hoc. Scatter plots of the data suggested a linear shape for prediction models across all subjects as well as in each of the patient subsets. Comparisons made between individual bivariate correlations were based on calculated 95% confidence intervals (CI) of the coefficients. Differences were deemed significant when there was no overlap of the CIs for the coefficients being compared [44].

3. Results

A total of 1108 unique visits from 117 (49 Male; 68 Female) patients with an average age of 40.8 ± 15.0 years were collected. Additional demographics of individual groups are summarized in Table 1. Of the 125 patients asked to participate 117 were willing to do so (93.6%), which can be taken as an indication of acceptability. The average time to complete all questions during an office visit was 170 ± 67 s (average $\pm$ Stdev) to answer 25 ± 6 questions, a breakdown of timing for individual instruments is given in Table 2. Completion time for each of PROMIS assessments was significantly shorter than that of the ODI ($p < 0.01$).

The repeated measures analysis of longitudinal data (Fig. 1)