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Original article

Defining patient acceptable symptom state thresholds for commonly used patient reported outcomes measures in general orthopedic practice

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ABSTRACT

Background: Patient reported outcomes measures are distributed regularly within musculoskeletal physical therapy practice in an effort to track patient progress and response to treatment. A number of studies have reported on the amount of change necessary to identify the minimal clinically important difference. Few studies have identified thresholds signifying patient satisfaction with treatment and what patient specific factors may be influential in identifying patient satisfaction.
Objectives: To identify thresholds amongst commonly used patient reported outcomes measures associated with the patient acceptable symptom state (PASS). To identify the confounding effects of demographic and psychosocial variables on reported PASS estimates.
Design: Prospective cohort study.
Method: A sample of convenience consisting of consecutive patients referred for outpatient physical therapy for general orthopaedic conditions fulfilling the eligibility criteria were included. All patients completed baseline demographic information as well as baseline pain and functional outcomes measures. The PASS question was used as the anchor in this study to identify patient thresholds. Patients completed outcomes measures every 2 weeks and at patient discharge. PASS thresholds were identified using receiver-operating curves maximizing sensitivity and specificity.
Results: PASS thresholds were found to vary depending on baseline pain levels, functional status, socioeconomic status, educational level, and psychosocial status.
Conclusions: Multiple factors are influential in determining patient success following treatment. Clinicians should be aware of patient baseline pain and functional status as well as socioeconomic status, educational level, and psychosocial status and stratify patients accordingly when determining patient prognosis and developing a plan of care.

1. Introduction

Patient reported functional outcomes measures (FOM) are commonly used amongst clinicians to track patient response to treatment and help inform clinical decision-making. In order to be meaningful, a level of interpretability must be established to help define a clinically meaningful difference. Previous authors (Binkley et al., 1999; Angst et al., 2001; Salaffi et al., 2004; Abbott and Schmitt, 2014) have defined the minimal clinically important difference (MCID) score as the minimal amount of change necessary to define a clinically meaningful change in patient status as perceived by the patient. A recent study by Abbott and Schmitt (2014), defined the MCID of four region-specific outcome measures and a pain rating scale amongst patients attending physical therapy for

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musculoskeletal disorders. As an example, small patient-perceived improvements in the Lower Extremity Functional Scale (LEFS) was defined as an increase of nine points; small improvements in the Numeric Pain Rating Scale (NPRS) was defined as a decrease of 1.5 points (Abbott et al., 2014).

The Patient Acceptable Symptom State (PASS) is a slight variation of the MCID concept in that it defines an end point at which patients consider themselves *well* as compared to *better*. Previously, the PASS was designed to capture the patients' satisfaction with their current state and has been used to gather outcome data in patients following treatment for impairments associated with rheumatoid arthritis, ankylosing spondylitis, and osteoarthritis (Tubach et al., 2005, 2006; Heiberg et al., 2008; Maksymowych et al., 2010). While the MCID and PASS concepts are complementary in terms of interpreting patient reported outcomes at the population level, we believe identified PASS estimates may be a more appropriate treatment target as the PASS is anchored to the personal experience of the patient and is thought to be a more robust measure of the patient's overall satisfaction and adaptation. In addition, identified PASS estimates may help to determine treatment effectiveness and whether a specific treatment is likely to result in a satisfactory state of health. Several authors have previously developed cut points for commonly used patient reported and physical performance outcomes in knee and hip osteoarthritis (Tubach et al., 2005, 2006; Wright et al., 2011), rheumatoid arthritis (Heiberg et al., 2008), and ankylosing spondylitis (Maksymowych et al., 2010) corresponding to PASS. We are unaware of PASS related cut-points identified for more region and dimension specific outcome measures including the Lower Extremity Functional Scale (LEFS), Numeric Pain Rating Scale (NPRS), and Global Rating of Change (GROC) Scale for patients undergoing conservative management (physical therapy) of musculoskeletal related conditions. An identified target among commonly used outcome measures would be useful to clinicians when creating long term goals and establishing a discharge plan.

Current literature suggests that patient satisfaction may be influenced by additional factors unrelated to treatment. Previously identified determinants of patient satisfaction include age, ethnicity, anxiety, depression, education, socioeconomic status (SES), co-morbidities, interpersonal communication skills, process of care, embodiment, and workers' compensation (Carr and Moffett, 2005; Hekkert et al., 2009; Young et al., 2009; Hush et al., 2011; Marks et al., 2011; Hush et al., 2012; Gong and Dong, 2014; Liddle et al., 2014). As an example, patients with lower SES generally report poorer outcomes in terms of health and well-being; (Carr and Moffett, 2005; Finsen, 2014) adequate treatment duration, low waiting times, and effective communication and empathy have been associated with better overall health outcomes (Hush et al., 2011).

According to the World Health Organization (WHO), depression is the leading cause of disability for both males and females. Interestingly, for women depression is the leading cause of disease burden for women of low, middle, and high income countries (World Health Organization, 2008). Multiple studies infer a relationship between depression and decreased functional performance (Goodwin, 2006; Yanagita et al., 2006; Conradi et al., 2008). The specific effect of depression on self report functional outcome measures has not been well defined.

These findings suggest patient outcomes are influenced by a number of factors that should be considered by clinicians when developing a treatment plan, and defining patient response to treatment. Improved understanding of these determinants can be useful to clinicians, optimizing patient outcomes by addressing components of care that patients find most important.

2. Purpose

The aim of this prospective cohort study was to identify PASS estimates for three main domains of patient reported outcomes used in a general outpatient musculoskeletal physical therapy clinic: pain, functional impairment, and patient's global rating of change. We also sought to investigate the influence of potential confounding variables including SES, educational level and depression on these estimates and whether clinicians should consider stratifying patients based on socioeconomic status when determining patient outcomes.

3. Materials and methods

3.1. Participants

We conducted a prospective cohort study utilizing a sample of convenience. The study's sample consisted of consecutive patients referred to outpatient physical therapy for general orthopedic conditions fulfilling the eligibility criteria from May 2012 to March 2014 at The University of Chicago Medicine. Patients were eligible to participate if they where $\geq$18 years of age and reported suffering from a pathology of the cervical spine, lumbar spine, upper or lower extremity, warranting a referral for physical therapy services. Exclusion criteria included those who were $\leq$18 years of age, pregnant, and illiterate or non-English speaking patients who would be unable to independently read and complete a FOM. The University of Chicago Medicine's Institutional Review Board approved this study (Protocol # 12-0197).

3.2. Examination procedures

Upon the initial evaluation, patients were educated on the details of the study and those interested in participating signed the IRB approved informed consent document. Enrolled patients then completed baseline demographic intake forms entailing socioeconomic information including education and household income. Education level was divided into four categories: *less than high school; high school; college; and postgraduate*. Household income levels were separated into five categories: *Less than $20K(USD); $25–$35K(USD); $35–$50K(USD); $50–$70K(USD); and > $70K(USD)*. These breakdowns were derived from previous studies investigating SES (Valencia et al., 2011).

To screen for depressive symptoms, the Whooley questionnaire was administered (Whooley et al., 1997). The Whooley questions were developed as 2 questions from the Patient Questionnaire of the Primary Care Evaluation of Mental Disorders (PRIME-MD) for screening for depressive symptoms. The 2-question instrument asks: (1) "During the past month, have you often been bothered by feeling down, depressed, or hopeless?" and (2) "During the past month, have you often been bothered by little interest or pleasure in doing things?" Answering "yes" to either question is considered a positive test for depression, with a 96% sensitivity and 57% specificity.

The treating therapist decided which FOM was most appropriate for the patient based on their injury or ailment. FOMs were completed at baseline and every 2 weeks there after until discharged from physical therapy. Upon discharge patients were required to complete a PASS, GROC and final FOM. See Fig. 1.

3.3. Assessment tools

The PASS at discharge was used as the anchor in this study. The PASS is a measure of patient opinion that asks patients to rate their satisfaction with their current state of being and thus, their treatment. At the final visit, patients' opinions of their state was