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ORIGINAL ARTICLE

Defining Substantial Clinical Benefit for Patient-Rated Outcome Tools for Shoulder Impingement Syndrome

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Abstract

Objective: To define for 2 shoulder outcomes scales the substantial clinical benefit (SCB)—a metric that defines the change amount associated with patient perception of a large meaningful improvement and that can be used to interpret change over time in the outcome score.

Design: Cohort.

Setting: Clinic.

Participants: Patients (N=74) with shoulder impingement syndrome.

Interventions: Standardized exercise and manual therapy for 6 weeks, and outcome measures completed at initial evaluation, discharge, and 6 to 8 weeks postdischarge.

Main Outcome Measures: Disabilities of the Arm, Shoulder and Hand (DASH), Pennsylvania Shoulder Score (Penn), and a 13-point Global Rating of Change (GROC). Patients were classified as "substantially improved" when they reported "quite a bit better" (11) or greater on the GROC at discharge and again 6 to 8 weeks after discharge. Patients with GROC <11 at discharge or follow-up were classified as "non-substantially improved." The percentage and raw points change in the Penn and DASH that corresponded with patient-rated substantial improvement was determined with receiver operator characteristic (ROC) analyses.

Results: ROC analyses revealed the SCB for the DASH was 40% (area under the curve [AUC]=.79; confidence interval [CI], .69−.89) and 11 points (AUC=.63; CI, .50−.76); and for the Penn, 20% (AUC=.76; CI, .65−.87) and 21 points (AUC=.80; CI, .69−.90).

Conclusions: The SCB of 40% for the DASH, and 20% and 21 points for the Penn represents substantial improvement over 6 weeks of care, which was sustained at 12 weeks. The SCB of 11 points for the DASH is not recommended for use because of poor discrimination. The SCB can be used to enable clinical decision-making and in future clinical trials. Alternative approaches such as the within- and between-group change values can produce different SCB values.

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Patient-rated outcome measures are used to assess patient-perceived change in health status. The Disabilities of the Arm, Shoulder and Hand (DASH)[1] is an arm region-specific measure of upper extremity disability, while the Pennsylvania Shoulder Score (Penn)[2] is a shoulder-specific measure of shoulder pain and function. These outcome tools can be used in both clinical trials and clinical practice to determine patient-perceived response to treatment; however, their usefulness is dependent on knowing how much change in their scores is meaningful important change.

Meaningful patient-rated change is defined in multiple ways. The minimal clinically important difference (MCID)[3] is the minimal or smallest amount of change that is perceived by the patient as meaningful or important, and not just the result of random variation. The MCID metric defines only the minimal patient-rated important change. The substantial clinical benefit (SCB)[4] is the amount of change associated with substantial or large patient-perceived meaningful improvement. SCB values can be

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useful to interpret clinical trial results and aid in treatment decision-making for individual patients. The MCID has been reported as 10.2 points for the DASH and 11.4 points for the Penn in patients with shoulder pain,[2,5] but the SCB has not. The SCB metric can assist clinicians and researchers in interpreting the change in outcome scores to determine patient-perceived improvement. Both the MCID and SCB can enable our ability to define patient meaningful improvement, by using the MCID value to identify minimal important change and the SCB to recognize when large meaningful change has occurred. Moreover, the MCID and SCB can be used to calculate estimates of effect size and sample size in future clinical trials.

Determining a threshold for patient-perceived improvement with treatment is complex. The Global Rating of Change (GROC) scale[6] is a transitional scale used to define patient-perceived change. The GROC has been used previously[4,7] as an external criterion measure to define the SCB or a very similar metric known as the major clinically important improvement. Defining patient-perceived improvement with the GROC identifies those patients who perceive their condition has improved, and how much improvement they perceive has occurred. Patient management can be aided by knowing the amount of change in an outcome measure that indicates a patient-perceived substantial improvement. Clinicians can use the SCB to identify when it is appropriate to discharge a patient from care, and have confidence that the patient will remain improved in the short-term. The SCB as defined can assist in this clinical decision-making.

The purpose of this study was to determine the SCB values using a receiver operating curve analysis of a sensitivity-specificity approach for the DASH and Penn in patients with shoulder impingement syndrome who received a standard rehabilitation program. We hypothesized that there would be SCB for the DASH and Penn that discriminates between those with and without a substantial improvement, as defined by patient-perceived, meaningful, large improvement reported after care (discharge) and remaining improved at short-term follow-up.

Methods

Participants

Consecutive patients (N=74) with shoulder pain indicating shoulder impingement syndrome presenting to physical therapy were recruited for a clinical trial to examine the effects of a standardized rehabilitation program consisting of stretching, strengthening, and manual therapy.[8] Patients were recruited from 12 outpatient clinics. Demographics and characteristics of the patients are described in table 1. To be entered in the study, patients had to meet all 4 inclusion criteria: (1) shoulder pain; (2) positive Hawkins-Kennedy test or Neer sign; (3) positive painful arc; and (4) pain or weakness indicating a positive Jobe "empty can" test, or pain or weakness indicating a positive resisted external rotation test (resisted external rotation at the side). Exclusion criteria were as follows: (1) shoulder surgery; (2) previous rehabilitation for this episode of shoulder pain; (3) positive Spurling test; (4) primary diagnosis of traumatic shoulder dislocation or instability in the past 3 months; (5) shoulder pain reproduction with active or passive cervical range of motion; and (6) clinical presentation of adhesive capsulitis, defined as a loss in passive shoulder range of motion greater than 50% compared with the uninvolved side in at least 2 shoulder motions.

List of abbreviations:

AUC	**area under the curve**
CI	**confidence interval**
DASH	**Disabilities of the Arm, Shoulder and Hand**
GROC	**Global Rating of Change**
ICC	**intraclass correlation coefficient**
MCID	**minimal clinically important difference**
Penn	**Pennsylvania Shoulder Score**
ROC	**receiver operating characteristic**
SCB	**substantial clinical benefit**

Procedures

Patients completed an informed consent form approved by the primary author's institutional review board, demographics, DASH, and Penn at the initial evaluation. At discharge, after a maximum of 10 visits over 8 weeks of rehabilitation (mean, 9 visits over 5wk), patients completed the DASH, Penn, and GROC. At 12 weeks after initial evaluation, patients completed the GROC again and were blinded to their GROC score from discharge. Data collection is depicted in figure 1. Rehabilitation consisted of a standardized impairment-based treatment of exercise and manual therapy.[8] Exercises were aimed at stretching and strengthening the muscles and soft tissues about the shoulder and spine. Manual therapy included manual stretching and thrust and nonthrust manipulation aimed at improving pain and motion of the shoulder and spine. Patients performed a daily home exercise program of stretching and strengthening exercises, which they were instructed to continue after discharge. Systematic reviews[9,10] indicated exercise and manual therapy are effective to reduce pain and disability.

Disabilities of the Arm, Shoulder and Hand

The DASH is a 30-item, region-specific, patient-rated outcome tool for upper extremity disability.[1] There are 21 items rated on a 5-category Likert scale for level of difficulty (1, no difficulty; 2, mild difficulty; 3, moderate difficulty; 4, severe difficulty; 5, unable); 3 questions on the impact on social activities, usual work, and sleep (1, not limited at all; 2, slightly limited; 3, moderately limited; 4, very limited; 5, unable); 5 questions on symptom severity (1, none; 2, mild; 3, moderate; 4, severe; 5, extreme); and 1 question on confidence with use of the upper extremity (1, strongly disagree; 2, disagree; 3, neither agree nor disagree; 4, agree; 5, strongly agree). The DASH score is calculated by ([sum of n response/n] − 1) × 25, where n is the number of questions answered. The score is valid if 27 or more of the 30 questions are answered. The DASH ranges from 0 to 100 points (0, no disability). The DASH has excellent reliability (intraclass correlation coefficient [ICC]=.92, .96)[1,11] and responsiveness.[5,11-13] The minimal detectable change with 90% confidence interval (CI) weighted average is 10.5[14] (6.6−12.2),[5,11,15] with an MCID of 10.2 points.[5]

Pennsylvania Shoulder Score

The Penn, a shoulder-specific outcome tool,[2] contains 3 sections: pain, satisfaction, and function. The pain section has 3 questions about pain at rest, with normal daily activities, and with strenuous activities. Each item is rated on an 11-point numeric pain rating scale (0, no pain; 10, worst possible pain). The pain section is scored as follows: 10 − raw score for each item, then summing the 3 scores for a score from 0 to 30 (30, no pain). The satisfaction