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ORIGINAL ARTICLE

Establishing minimally important differences for the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index in patients with full-thickness rotator cuff tears

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Background: The American Shoulder and Elbow Surgeons (ASES) score and the Western Ontario Rotator Cuff Index (WORC) are frequently used measures in clinical research for patients with rotator cuff tears (RCTs). The minimally important differences (MIDs) for these measures have not been established in patients with RCTs. The purpose of this study was to establish the MIDs for patients with known RCTs treated both surgically or nonsurgically.

Methods: We included 222 subjects with full-thickness RCTs. The WORC and ASES were collected at baseline and at 4, 8, 16, 32, 48, and 64 weeks, as was an end of study form with questions about change in the condition after treatment. We calculated anchor-based and distribution-based MIDs. We used regression modeling to determine change in MIDs as predicted by several variables.

Results: For the anchor-based method, we found an MID of 21.9 for the ASES and −282.6 for the WORC. When using the distribution-based method of ½ and ⅓ the standard deviation, we arrived at an MID of 26.9 and 17.9 points for the ASES and −588.7 and −392.5 points for the WORC. No variables predicted MID changes.

Conclusion: This is the first study to report MIDs for the ASES and WORC in a population of patients with only full-thickness RCTs. This information will directly improve our ability to determine when patients with RCTs are changing in a meaningful manner and accurately power clinical studies using these outcome measures.

Level of evidence: Basic Science Study; Validation of Outcome Instruments

Keywords: Minimally important difference; Western Ontario Rotator Cuff Index (WORC); American Shoulder and Elbow Surgeons (ASES) score; rotator cuff tears; patient-reported outcomess; minimal clinically important difference

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Rotator cuff disease is one of the most common musculoskeletal disorders in the adult population. Nearly 20 million Americans reported shoulder pain in 2005 alone, establishing shoulder pain second only to knee pain in prevalence.[1] There also appears to be an age-related prevalence of rotator cuff tears (RCTs).[15,18,39] For example, imaging and cadaveric studies have revealed that >30% of individuals older than 60 years will have a full-thickness RCT, with a dramatic increase in the probability of disease thereafter.[22,27,33,44] With the aging of the baby boomer generation, we can expect the prevalence of rotator cuff disorders to increase significantly during the next 2 decades.[1]

Shoulder dysfunction is associated with high societal cost and patient burden. In 2007, a reported 76,000 work-related shoulder injuries and illnesses involving days away from work occurred in the United States.[3] In 2000, the direct costs for the treatment of shoulder dysfunction in the United States totaled $7 billion. As the most common cause of shoulder dysfunction, rotator cuff disease accounted for the greatest proportion of this burden.[25] It is estimated that between 75,000 and 250,000 rotator cuff operations take place annually in the United States.[23,24,40]

RCTs are a significant cause of disability in adults and are associated with chronic pain, weakness, and dysfunction of the upper extremity.[11] Rotator cuff disorders substantially affect quality of life, including disordered activities of daily living (ADL), altered sleep patterns, and adverse impact on work and recreation.[11] Patient-reported outcomes suggest that rotator cuff dysfunction is associated with a compromise in an individual's health status similar to that seen in major medical diseases, including congestive heart failure, acute myocardial infarction, diabetes mellitus, and clinical depression.[11]

There are many ongoing clinical trials focusing on rotator cuff disease, with the number of new clinical studies, randomized and observational, increasing each year.[6] Also, it appears that these studies are using a wide array of outcome measures for assessing the included patients,[16,43] making it difficult to perform meta-analyses as well as undermining the applicability of any such findings. Furthermore, it has been suggested that there are few outcome measures focusing on rotator cuff injuries that possess adequate measurement properties.[6,10,12]

It is generally agreed that health status measurement instruments of any kind must possess adequate psychometric properties (eg, reliability, validity, responsiveness) to be useful instruments for research or patient care purposes.[5,28,29,35] Responsiveness is the ability to detect clinically important change in the underlying construct over time, even if the changes are small. One measure of responsiveness is the minimally important difference (MID).[19]

A threshold approach to individual health assessment questionnaire scores can be based on the concept of clinically important change.[7,15,18,41] The MID, sometimes called the minimal clinically important difference, is the smallest detectable change in a score that is deemed relevant or meaningful. The MID is an obviously patient-centered approach in that it allows the patients themselves to determine the level of improvement or worsening deemed important and relevant.[7,14,17,32,42] The MID is expressed in the same units as the outcome measure.

Whereas MIDs have been reported in the literature for the Western Ontario Rotator Cuff Index (WORC) and the American Shoulder and Elbow Surgeons (ASES) score, they are in heterogeneous groups of patients, are on small samples, and use questionable methods. Specifically, the MID for the WORC, 245.26 points or 11.7%, was established in a small sample of patients (N = 44, resulting in wide confidence intervals [CIs]) who had cuff tendinosis without tears, were undergoing treatment for subacromial injection, and were followed up for only 3 months.[21] Another study of corticosteroid injections for 128 patients with rotator cuff disease followed up for 6 weeks reported an MID of 275 points (13.1%).[8]

For the ASES, an MID has been reported in two separate studies.[17,37] The first study included 63 patients observed up to 4 weeks with varying diagnoses—impingement syndrome (n = 25), instability/dislocation (n = 2), rotator cuff syndrome (n = 2), adhesive capsulitis (n = 5), hemiarthroplasty (n = 1), shoulder weakness (n = 2), humeral fracture (n = 5), rotator cuff and adhesive capsulitis (n = 6), status post surgery (n = 15)—and used receiver operating characteristic curves to establish an MID.[37] Whereas the investigators reported an MID of 6.4 ASES points, this is an obviously heterogeneous group of patients who were not observed for a long period and who received varying treatments, none of which was accounted for in the analysis. In the second study, a total of 81 patients with tendinitis or a tear of the rotator cuff, treated nonoperatively, were evaluated at a minimum of 6 weeks on the ASES and for the MID.[17] For the ASES subscales of function and pain and the 4-item assessment, the investigators found MIDs of 12.01-point, 16.92-point, and 16.72-point change in the ASES score from baseline. They also reported that age, sex, initial baseline scores, and hand dominance did not predict the MID but that a longer duration of follow-up after treatment was associated with a greater MID. They did not examine MID changes by diagnosis and had relatively short follow-up periods. In 2 other studies,[38,41] the MID was determined in patients undergoing shoulder arthroplasty, and MIDs of 13.5 and 20.9 were found.

Therefore, the MIDs reported thus far in the literature for the WORC and ASES do not seem to be robust, are not applicable to RCT patients undergoing arthroscopy or rehabilitation, do not have sufficiently long follow-up periods, and fail to determine MID changes relative to comorbidities. All of these variables suggest a need to further evaluate the MID of the ASES and WORC. The purpose of this study was to establish the MIDs for patients with known RCTs treated both surgically and nonsurgically.