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BASIC SCIENCE

Minimal clinically important differences in the American Shoulder and Elbow Surgeons, Simple Shoulder Test, and visual analog scale pain scores after arthroscopic rotator cuff repair

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Background: Minimal clinically important differences (MCIDs) for different patient outcome scores have been reported for various shoulder diseases, including shoulder arthroplasty and the nonoperative treatment of rotator cuff disease. The purpose of this study was to assess the MCID for the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score, the Simple Shoulder Test (SST), and a visual analog scale (VAS) measuring pain, after arthroscopic rotator cuff repair.
Methods: A total of 202 patients who underwent arthroscopic rotator cuff repair were retrospectively reviewed. ASES, SST, and VAS pain scores were collected preoperatively and at 1 year postoperatively. The MCID was then calculated via a 4-question anchor–based method.
Results: The MCID results for the ASES, SST, and VAS pain scores were 27.1, 4.3, and 2.4, respectively. Age at time of surgery, sex, anteroposterior tear size, and worker's compensation status were not associated with MCID values ($P > .05$).
Conclusion: The MCID values determined in the current study are higher than those previously identified for the nonoperative treatment of rotator cuff disease using the same anchor questions. Use of these higher values should be considered when evaluating improvements of individual patients after rotator cuff repair, to determine comparative effectiveness of various rotator cuff repair techniques and to determine sample sizes for prospective comparative trials of rotator cuff repair methods.
Level of Evidence: Basic Science Study; Validation of Outcome Instrument

Keywords: Rotator cuff repair; minimal clinically important difference; Simple Shoulder Test; American Shoulder and Elbow Surgeons score; VAS pain; MCID

Institutional review board approval was obtained from the University of Utah School of Medicine before initiating this study (IRB 41649).

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Shoulder pain is the second most common musculoskeletal concern that accounts for millions of patient clinical visits each year.[1,12] Symptomatic rotator cuff tears, which are the most common cause for shoulder pain, and the functional limitations that may follow pose a significant economic burden on society. Although both conservative and surgical treatment have been shown to be successful in treating rotator cuff tears, surgical repair may reduce the overall burden.[10] Increasing emphasis has been placed on patient-reported outcomes and patient satisfaction when evaluating treatment effect for orthopedic conditions, including rotator cuff disease, and are increasingly linked to reimbursement policy.[7] As such, orthopedic clinical studies are relying more heavily on subjective patient outcome measures when determining treatment efficacy. Understanding clinically important changes in outcome measures is crucial in maximizing their utility.

Interpreting the relevance of results from clinical studies has remained difficult. Statistically significant results do not always equate into clinical relevance, as statistical significance is dependent on study size and variation of patient-perceived improvement.[14] Consequently, clinicians have begun to consider the minimal clinically important difference (MCID) when evaluating treatment effectiveness. The MCID is defined as ''the smallest difference in clinical outcome measure that a patient would perceive as beneficial and meaningful change by a given treatment'' and can be thought of as how much better quantitatively a patient needs to feel to appreciate treatment effect.[14] Additionally, use of MCIDs can help with interpretation and comparison of different clinical results in the literature.

Different methods of calculating MCIDs have been reported in the literature, including distribution, consensus, and anchor-based methods.[2,6,9] Currently there is no gold standard method, as each has its own advantages and disadvantages. Anchor-based methods rely on the relationship between an outcome measure and a separate measure of improvement and have been previously used to investigate shoulder disorders including rotator cuff disease.[16-18] MCIDs for visual analog scale (VAS) pain scores in nonoperative treatment of rotator cuff disease, hip and knee osteoarthritis, and patellofemoral pain have been previously reported.[3,16,18] The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) and Simple Shoulder Test (SST) scores have been shown to be valid and reliable outcome measures, and prior studies have determined MCIDs for the ASES and SST in the nonoperative treatment of rotator cuff disease and in shoulder arthroplasty.[5,11,15,17] Limited data exist on MCIDs after the surgical treatment of rotator cuff tears.

The purpose of this study was to quantify the MCIDs for ASES, SST, and VAS pain scores after arthroscopic rotator cuff repair using an anchor-based approach. Various patient factors were also evaluated to determine their effect on MCIDs.

Materials and methods

Two hundred thirty-eight patients underwent arthroscopic rotator cuff repair and were retrospectively reviewed after institutional review board approval was obtained. All patients between May 2007 and April 2016 who underwent arthroscopic rotator cuff repair by 3 surgeons were potential candidates for inclusion. A total of 2191 arthroscopic rotator cuff repairs were performed by the 3 surgeons during that time period and were potential candidates. Patients had been asked preoperatively to fill out a baseline questionnaire that included the ASES, SST, and VAS pain scores. The SST is a 12-question survey specifically focused on shoulder function and activity intolerance, whereas the ASES is a mixed-outcome patient-reported instrument focused on joint pain, instability, and activities of daily living.[8,13] For the VAS pain, patients were asked to assess shoulder pain in 1-digit increments from a 0-10 level, with 0 being none and 10 being disabling. Inclusion criteria consisted of patients who had baseline, preoperative ASES, SST, and VAS pain scores available, advanced imaging consistent with a full-thickness posterosuperior rotator cuff tear, and those who underwent an arthroscopic rotator cuff repair. Exclusion criteria included any patient undergoing revision surgery or surgical repair of a partial-thickness rotator cuff tear only.

All procedures were performed by 3 shoulder and elbow or sports medicine fellowship-trained surgeons at our institution. The patients underwent arthroscopic rotator cuff repair with a variety of fixation methods dependent on tear size and morphology, including single- and double-row techniques. In addition to rotator cuff repair, other pathology such as biceps tendinopathy was addressed concomitantly when indicated. Standard postoperative protocol included 6 weeks of shoulder immobilization in a sling with instructions for pendulums and passive range of motion exercises during that time. Formal physical therapy was typically started at the 6-week postoperative mark and progressed to strengthening exercises at 3 months postoperatively. When patients returned for their 1-year postoperative visit, they were again asked to fill out the questionnaire consisting of the ASES, SST, and VAS pain scores along with a 4-item anchor question regarding their improvement after repair. Patients were recruited if they returned for follow-up and had complete preoperative data as well as completed the follow-up questionnaires.

The 4-item anchor question was used to evaluate the MCID on the 3 measurement outcomes ASES, SST, and VAS pain between preoperative and 1-year postoperative assessment. This anchor question, originally designed by Tubach et al,[18] was previously used by Tashjian et al[17] to determine MCIDs in shoulder arthroplasty and in the nonoperative treatment of rotator cuff disease. Patients were asked, ''Since your shoulder rotator cuff repair, please rate your response to treatment: none—no improvement (A); poor—some improvement but unsatisfactory (B); good—satisfactory improvement (C); and excellent—ideal outcome (D).''

All magnetic resonance images were independently reviewed by an orthopedic surgeon not involved in any of the repairs. Anteroposterior tear size (mm) of the posterosuperior

rotator cuff was measured using the most lateral sagittal image including the entire greater tuberosity on the T2 sequences.

Statistical analysis

The anchor question was used to classify the patients in study cohort as having no change (combined group A [None] and group B [Poor]) or change (group C [Good]). The group D (Excellent) was not included in the analysis as this was considered beyond minimal change. We summarized and compared the distributions of patient characteristics (ie, sex, age, tear size, and worker's compensation) and SST, VAS, and ASES measurement at baseline and follow-up between the ''unchanged'' and ''changed'' groups. We applied a new anchor-based MCID calculation approach using the potential outcome framework. The new approach allowed us to compare differences in the score changes between the ''unchanged'' and ''changed'' groups after accounting for the patient baseline characteristics, including sex, age, tear size, and worker's compensation. We used the median regression approach to evaluate the effects of age, sex, worker's compensation, and AP tear size on the average treatment effect for the ASES, SST, and VAS pain scores.

Results

During the study period, 202 patients were evaluated at 1 year postoperation with functional outcome scores as well as the anchor question (85% follow-up). Eighty-nine patients rated their postoperative shoulder improvement as ''good'' and thus represented the changed group, whereas 10 and 3 patients rated their improvement postoperatively as ''poor'' and ''no improvement,'' respectively, representing the unchanged group (Table I). The remaining 100 patients rated their improvement as ''excellent.'' The mean preoperative/postoperative ASES, SST, and VAS pain scores for the ''excellent'' group were 52.7/92, 5.1/11, and 4.4/1.3. No differences were identified in age at the time of surgery ($P = .59$), sex ($P = .75$), worker's compensation status ($P = .15$), and AP tear size ($P = .33$) between the changed and unchanged groups. There was no difference in preoperative SST, VAS pain, or ASES scores between the groups, but there was a significant difference in final 1-year postoperative outcomes with worse ASES, SST, and VAS pain scores in the unchanged group compared with the changed group (Table I). The average treatment effect, which are considered the MCIDs for the ASES, SST, and VAS pain scores, were 27.13, 4.32, and 2.37, respectively. Results of median regression models investigating the association of sex, age at the time of surgery, worker's compensation status, and AP tear size on each of the change scores (average treatment effect) for the ASES, SST, and VAS pain did not find any linear associations (Table II).

Table I Demographic information comparing the changed and unchanged groups

	Unchanged (n = 13)	Changed (n = 89)	*P* value
Sex, n (%)			.75
Female	3 (23)	28 (31)	
Male	10 (77)	61 (69)	
Age at surgery			
Mean (SD)	57.8 (11.2)	59.5 (9.4)	
Median (IQR)	54 (50-68)	60 (54-66)	.59
Range	42-73	31-83	
Worker's compensation, n (%)			.15
No	10 (77)	80 (91)	
Yes	3 (23)	6 (7)	
AP tear size			
Mean (SD)	2.2 (1.3)	2.5 (1.4)	
Median (IQR)	1.8 (1.2-3.1)	2.2 (1.5-3.6)	.33
Range	0.8-4.8	0.1-6.1	
Preoperative SST score			
Mean (SD)	4.4 (3.4)	4.3 (3)	
Median (IQR)	3 (2-7)	4 (2-7)	.99
Range	0-10	0-11	
Preoperative VAS pain score			
Mean (SD)	5 (2.2)	4.7 (2.5)	
Median (IQR)	5 (3.5-6.2)	4.9 (3-6.8)	.7
Range	1.6-9	0-10	
Preoperative ASES score			
Mean (SD)	45.9 (15.6)	46.8 (18.8)	
Median (IQR)	43.3 (40-58.3)	45 (33.3-60.8)	.91
Range	18.3-68.3	11.6-85	
1-year postoperative SST score			
Mean (SD)	5.8 (3.4)	9.7 (2)	
Median (IQR)	6 (4-8)	10 (9-12)	<.001
Range	0-12	4-12	
1-year postoperative VAS pain score			
Mean (SD)	4.5 (2.8)	1.8 (2)	
Median (IQR)	5 (3-7)	1 (0.3-2.5)	<.001
Range	0-9	0-9	
1-year postoperative ASES score			
Mean (SD)	53.2 (21.4)	80.8 (14)	
Median (IQR)	55 (38.3-60)	83.3 (75-91.6)	<.001
Range	23-100	41.7-100	

SD, standard deviation; *IQR*, interquartile range; *AP*, anteroposterior; *SST*, Simple Shoulder Test; *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form.
P values <.05 were considered significant.

Table II Median regression results (*P* values) investigating the effects of sex, age at surgery, worker's compensation status, and AP tear size on MCIDs for the SST, VAS pain, and ASES scores

	SST (*P* value)	VAS pain (*P* value)	ASES (*P* value)
Intercept	.04	.09	.01
Sex	.18	.58	.77
Age at surgery	.90	.74	.46
Worker's compensation	.49	.35	.17
AP tear size	.28	.86	.24

AP, anteroposterior; *MCIDs*, minimal clinically important differences; *SST*, Simple Shoulder Test; *VAS*, visual analog scale; *ASES*, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form.

Discussion

Currently, MCIDs of the ASES, SST, and VAS pain scores determined using patients with rotator cuff disease treated nonoperatively have been used for analysis of patients after rotator cuff repair or in analysis of studies of rotator cuff repairs.[15,16] Treatment method (operative or nonoperative) may potentially influence MCIDs. Our anchor-based determination indicated that a minimum of 27.13, 4.32, and 2.37 point improvements in the ASES, SST, and VAS pain scores, respectively, were necessary for the patient to ascertain a clinically important benefit after arthroscopic rotator cuff repair. These values are larger than our previously reported MCIDs for the nonoperative treatment of rotator cuff disease, supporting the theory that patients require greater degrees of improvement to reach the MCID after operative as opposed to nonoperative treatment for rotator cuff disease.[15,16] Similar to our prior studies, age and sex did not have a significant effect on MCIDs which was also seen in the current study with AP tear size and Worker's Compensation status.[15]

MCIDs have been previously reported for the various outcome scores in patients treated for rotator cuff disease.[4,15,16] Gagnier et al[4] published the results of their study assessing MCIDs for the ASES and Western Ontario Rotator Cuff Index (WORC) in 222 patients with full-thickness rotator cuff tears that were treated both operatively and conservatively. After 64 weeks of follow-up, they determined the MCIDs for the ASES to be 21.9 and the WORC to be –282.6 using an anchor-based method when the surgical and conservative patient groups were combined. Interestingly, when the operative and conservative groups were analyzed separately using the anchor-based method, they found that the MCIDs for the ASES and WORC scores were approximately twice as high for the surgical group as it was for the conservatively treated group (39 vs 17 and –481.5 vs –178.8). When using a distribution-based method, they found an MCID of 17.9 for the ASES and –392.5 for the WORC score. They also found that sex, age, and comorbidity score were not associated with MCIDs. A possible reason for the large ASES MCID for surgical patients that was reported in this study could be attributed to their very small surgical patient group (n = 5), which also may limit the reliability of the MCIDs derived for the surgical group. Tashjian et al[15,16] assessed MCIDs for the ASES, SST, and VAS pain scores in patients with rotator cuff disease that were treated nonoperatively. They determined MCIDs to be 1.4 for VAS pain scores, approximately 2 points for SST and between 12-17 points for the ASES score using 15- and 4-item anchor questions. Age and sex were also not associated with MCIDs although a longer duration of follow-up was associated with a greater MCID.[15] The current results support, in the context of the Tashjian et al[15,16] and Gagnier et al[4] data, that MCIDs for the ASES and SST scores of surgically treated patients are larger by approximately 5-10 points (ASES), 3 points (SST), and 1 point (VAS pain) compared with nonoperatively treated patients. Potential reasons for smaller MCIDs in the nonoperatively treated group compared with surgically repaired group include greater expectations for improvement with surgery vs nonoperative treatment or surgical patients biasing their preoperative scores toward a lower range to convince themselves of the need for surgical repair.

MCIDs have also been determined for the ASES and SST for the treatment of other shoulder disorders. Simovitch et al,[14] Werner et al,[17] and Tashjian et al[19] have all examined MCIDs after shoulder arthroplasty. Simovitch et al[14] specifically calculated MCIDs for the ASES and Constant scores, University of California Los Angeles shoulder rating scale, SST, Shoulder Pain and Disability Index score, and VAS pain among other metrics assessing global shoulder function and range of motion in 466 patients undergoing both anatomic and reverse total shoulder arthroplasty using a 4-item anchor–based method modeled after that of Tashjian et al.[17] Specifically for the ASES, SST, and VAS pain scores, they found that changes of 13.6 ± 2.3, 1.5 ± 0.3, and 1.6 ± 0.3, respectively, were needed for the patient to perceive their treatment as successful. They also found that female sex and reverse TSA were associated with lower MCID values. Werner et al[19] focused on calculating the MCID as well as the substantial clinical benefit for the ASES score only after both anatomic and reverse total shoulder arthroplasty in 490 patients who had 2-year follow-up. Similar to Simovitch et al,[14] they found the MCID for the ASES score to be 13.6 ± 4.5. They also found reverse total shoulder arthroplasty, higher preoperative ASES scores, and having a diagnosis of rheumatoid arthritis to be independent predictors of not achieving an MCID for the ASES at the 2-year follow-up mark. Tashjian et al[15,16] found the MCID for the ASES to be slightly higher than either of the 2 previous studies, and in addition to the ASES score they also calculated the MCIDs for the VAS pain score and the SST. Their study population included 326 patients undergoing hemiarthroplasty, anatomic total shoulder arthroplasty, and reverse total shoulder arthroplasty. Using an anchor-based method and the same 4-item anchor question

used in the current study, they found the MCIDs to be 20.9, 2.4, and 1.4 for the ASES, SST, and VAS pain scores, respectively, and found that although type of arthroplasty did not have a significant effect on MCIDs, younger age correlated with larger MCIDs for all scores.[15,16] The arthroplasty studies of Simovitch et al[14] and Tashjian et al[17] both demonstrate a relationship between age and sex after arthroplasty not seen in the current study after rotator cuff repair. These findings may be due to innate differences between the surgeries or the changes in certain functional abilities that one procedure may provide over another that may or may not be influenced by age and sex. Also, comparing the overall size or magnitude of MCIDs after rotator cuff repair and shoulder arthroplasty, the MCIDs were higher in the current study than those of the Tashjian et al[17] study, suggesting that patients undergoing rotator cuff repair may require greater improvements compared with arthroplasty patients to consider their improvement clinically important. The differences may be explained by a generally younger patient population undergoing rotator cuff repair compared with shoulder arthroplasty, and expectations of pain and functional improvement after shoulder surgery likely differ between these 2 patient populations.

Our study had numerous limitations, including its retrospective nature, limited follow-up, and use of anchor questions that have not been validated. Given the prolonged nature of recovery after rotator cuff repair, there is a possibility that longer follow-up could have affected our results. The intraoperative decision to address concomitant pathology other than the rotator cuff tear was made at the individual surgeon's discretion. This could be considered a variable that could affect patient-perceived outcome, though we did not specifically examine it.

Conclusion

The MCID values determined in the current study are higher than those previously identified for the nonoperative treatment of rotator cuff disease using the same anchor questions. Use of these higher values should be considered when evaluating improvements of individual patients after rotator cuff repair, to determine comparative effectiveness of various rotator cuff repair techniques, and to determine sample sizes for prospective comparative trials of rotator cuff repair methods.

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