Original Research

Defining minimal clinically important difference, patient acceptable symptomatic state and substantial clinical benefit for the visual analog scale pain score after arthroscopic rotator cuff repair

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ABSTRACT

Introduction: Patient satisfaction after arthroscopic rotator cuff repair (RCR) is commonly assessed with patient-reported outcome measures (PROMs), and there is an increased need to establish clinical relevance within these measures. The purpose of this study was to (1) define minimal clinically important difference (MCID), patient acceptable symptomatic state (PASS), and substantial clinical benefit (SCB) for the visual analog scale (VAS) pain score in patients undergoing arthroscopic RCR, and (2) identify preoperative predictors of achieving each of these threshold values.

Methods: Data from consecutive patients who underwent primary arthroscopic rotator cuff repair study between 2010 and 2016 were prospectively collected. Baseline data and VAS pain scores were collected preoperatively and at 1 year and 2 years postoperatively. MCID, PASS and SCB were determined using an anchor-based approach, with anchor questions assessing postoperative satisfaction and expectation fulfillment. Multivariate logistic regression analysis was also used to identify preoperative predictors for achieving MCID, PASS, and SCB.

Results: A total of 286 patients were included in the final analysis, with an average age of 60.2 ± 10.4 and the majority being female (61.2%). The values for the VAS pain score identified to represent MCID, PASS, and SCB, respectively, at 1-year postoperatively were: 5, 2, and 1. The rates of achieving clinically significant improvement based on VAS were 60.5%, 63.3%, and 57.2%, respectively. A higher preoperative VAS was predictive for achieving MCID (odds ratio [OR], 1.84; P < 0.01).

Conclusion: This study identified threshold VAS pain scores of 5, 2, and 1 for achieving MCID, PASS, and SCB, respectively, at 1-year follow-up after arthroscopic rotator cuff repair. A higher preoperative VAS pain score was also identified as a statistically significant predictor of attaining MCID after arthroscopic rotator cuff repair.

Level of Evidence: II.

What are the new findings?

- Threshold visual analog scale pain scores for achieving minimum clinically important difference was 5, at 1-year follow-up after arthroscopic rotator cuff repair.
- Threshold visual analog scale pain scores for achieving patient’s acceptable symptomatic state was 2, at 1-year follow-up after arthroscopic rotator cuff repair.
- Threshold visual analog scale pain scores for achieving substantial clinical benefit was 1, at 1-year follow-up after arthroscopic rotator cuff repair.

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INTRODUCTION

Outcome reporting after rotator cuff repair (RCR) is heavily reliant on patient-reported outcome measures (PROMs), and therefore, there is an increased need to establish clinical relevance within these measures [1]. Arthroscopic RCR leads to robust improvements in PROMs for most patients, with marked changes occurring up to 1 year postoperatively [2]. However, one of the challenges with the use of such measures is determining the value of any differences observed, as well as interpreting and translating these scores to the clinical response of an individual patient [3].

As such, there has been increasing interest in defining clinically meaningful measures in patients undergoing arthroscopic RCR [4]. Clinically significant measures include the minimal clinically important difference (MCID), patient acceptable symptomatic state (PASS) and substantial clinical benefit (SCB). These established measures are able to reflect patient benefit and satisfaction after surgery [5]. They can be used to assess whether the study results for a particular surgery are clinically meaningful and to help determine the appropriate sample size or power in designing the study [6,7].

The minimal clinically important difference (MCID) is defined as the smallest change in an outcome that a patient would identify as important [3]. It establishes the change in outcome score that results in the smallest, appreciable clinical improvement after surgery.

The patient acceptable symptomatic state (PASS) is the highest threshold of symptoms beyond which patients consider themselves well, and are thus satisfied with the treatment. This is also identified as the 75th percentile of scores of patients who report a clinically significant improvement by the anchoring question [8,9].

Substantial clinical benefit (SCB) is a similar concept to the MCID, except the difference in change scores is between no change and substantial change on an anchor question instead of the difference between no change and minimal change, which is used for the MCID [10]. SCB is defined as the minimum amount of change in an outcome measurement that allows a patient to feel “sufficiently better” after treatment, while MCID is the minimum amount of change in an outcome measurement that allows a patient to feel “better” after treatment [11].

Representative studies on MCID, PASS, and SCB have been reported for the nonsurgical treatment of rotator cuff disease [12] and arthroplasty [13]. However, there is a paucity of literature on the visual analog scale (VAS) pain score threshold required to achieve meaningful clinical outcome, and on predictors for achieving clinically meaningful outcomes after arthroscopic RCR.

Therefore, the aim of this study was to (1) define MCID, PASS, and SCB for the VAS pain score in patients undergoing arthroscopic RCR, and (2) identify preoperative predictors of achieving each of these threshold values. We hypothesized that meaningful MCID, PASS, and SCB values could be derived for the VAS pain score, and that the preoperative VAS pain score would have a good predictive value of clinically significant outcomes after arthroscopic RCR.

MATERIALS AND METHODS

Patient selection and study design

We conducted a prospective cohort study of patients who underwent unilateral rotator cuff repair at a tertiary hospital between 2010 and 2016. The study was approved by the institutional review board prior to commencement (Institutional review board reference: CIRB 2019/2777).

Inclusion criteria were patients aged 21 years or older with a full-thickness rotator cuff tear documented on the preoperative shoulder ultrasound or shoulder MRI, who failed nonoperative treatment, underwent primary RCR, and had at least a 2-year follow-up. Patients with traumatic tears, isolated subscapularis tears, concomitant adhesive capsulitis, or glenohumeral instability were excluded from this study.

All patients, while under general anesthesia, underwent arthroscopic double-row rotator cuff repair with subacromial decompression by a single fellowship-trained shoulder surgeon. Their surgeries were performed in the beach chair position, with standard posterior, anterior, and lateral arthroscopic portals.

All patients underwent the same postoperative rehabilitation protocol. Postoperatively, they were placed in an arm sling and started on pendulum exercises. The sling was discontinued at 4 weeks, and active shoulder range of motion (ROM) was started. Strengthening exercises were started 8 weeks after surgery.

Outcome measures

Baseline demographics, including age, gender, and BMI, were noted preoperatively. VAS pain score, satisfaction score, and expectation fulfillment were scored preoperatively and at 1 and 2 years postoperatively.

The VAS pain score is a patient-based outcome scale that allows the evaluation of pain in the involved shoulder on a Likert scale of 0–10, with 0 points representing no pain at all and 10 points representing the worst pain ever felt.

For the anchor question to evaluate patient satisfaction, patients were asked, “How would you rate the overall results of treatment for your shoulder condition?”, and patients who answered “Excellent,” “Very good,” or “Good” were considered to be satisfied, while those who answered “Fair,” “Poor,” or “Terrible” were considered to be unsatisfied. MCID was defined as the smallest change in VAS score at 1 year postoperatively, at which patients were satisfied. PASS was defined as the absolute VAS score at 1 year postoperatively below which patients were satisfied. PASS was also defined as the 75th percentile of VAS scores at 1 year postoperatively among patients who were satisfied, as was previously also defined by Tubach et al. [14] The corresponding difference between the “Excellent” group and “Fair” group was used to define SCB.

For the anchor question to evaluate expectation fulfillment, patients were asked, “Has the surgery for your shoulder condition met your expectations so far?,” and patients who answered “Totally,” “Almost totally,” or “Quite a bit” and “More or less” were considered to as having their expectations fulfilled, while those who answered “No not quite” or “Far from it” and “Not at all” were considered to not have their expectations fulfilled. MCID was defined as the smallest change in VAS score at 1 year postoperatively, at which patients had their expectations fulfilled. PASS was defined as the absolute VAS score at 1 year postoperatively below which patients had their expectations fulfilled. PASS was also defined as the 75th percentile of VAS scores at 1 year postoperatively among patients who had their expectations fulfilled. The corresponding difference between the “Totally” group and “More or less” group was used to define SCB.

Statistical analysis

Statistical analyses were carried out in consultation with a statistician using SPSS software (version 23.0; IBM, Armonk, NY) and the R package (version 3.4.2 [2017]; R Foundation for Statistical Computing, Vienna, Austria).

The change in VAS pain scores from baseline to follow-up for each patient was calculated. MCIDs were determined utilizing an anchor-based technique described by Tubach et al. [14] Patients were classified based on their responses to anchor questions assessing postoperative satisfaction and expectation fulfillment.

Dichotomized responses were used as an external criterion in receiver operating characteristics (ROC) analysis to define each threshold value. An area under the curve >0.8 was considered predictive of patients who did or did not achieve MCID, PASS, and SCB. The cut-off point was defined using the Youden Index. In addition, the 75th percentile approach was used to determine PASS. 75th percentile scores were determined by calculating the univariate distribution of variables. All values were rank ordered, and percentiles were then applied.
To determine whether there are preoperative patient characteristics that may predict achieving the MCID, PASS, and SCB, multivariate logistic regression analysis was performed. Preoperative variables used in the correlation and regression analyses were age, sex, BMI, and preoperative VAS score. Descriptive statistics for all continuous variables were reported as means ± standard deviations and level of significance was taken as p < 0.05.

RESULTS

Patient demographics

We identified 286 cases of arthroscopic RCR between 2010 and 2016, which met our inclusion criteria and had two-year follow-up data. The majority of patients were female (61.2%), and the study group had a mean age of 60.2 ± 10.4 years and a BMI of 25.5 ± 4.4 kg/m² (Table 1).

Most patients had preoperative VAS pain scores ranging from 5 to 8 out of 10, which showed statistically significant improvement at 1 year and 2 years postoperatively. Patients who were more satisfied had higher VAS scores preoperatively (p = 0.003) and lower VAS scores at 2 years postoperatively (p = 0.034). Likewise, patients who had their expectations fulfilled also had lower VAS scores at 2 years postoperatively (p = 0.026) (Table 2).

The MCID for change in VAS at 1 year postoperatively was identified as −4.5 (AUC 0.65, 95% CI 0.54–0.76) and −3.5 (AUC 0.65, 95% CI 0.55–0.75) based on the satisfaction and expectation anchor methods, respectively (Fig. 1). The proportion of patients attaining MCID of −4.5 and −3.5 were 60.5% (n = 173) and 71.3% (n = 204), respectively (Table 3).

The PASS for the absolute VAS score at 1 year postoperatively was identified as 1.5 based on both satisfaction (AUC 0.71, 95% CI 0.62–0.80) and expectation (AUC 0.69, 95% CI 0.60–0.78) anchor methods (Fig. 1). The 75th percentile approach method was also utilized, and yielded the same values as via the ROC approach. The proportion of patients attaining PASS was 63.3% (n = 181) (Table 3).

The SCB for VAS score at 1 year postoperatively was identified as 1.5 (AUC 0.82, 95% CI 0.71–0.93) and 0.5 (AUC 0.71, 95% CI 0.59–0.83) based on the satisfaction and expectation anchor methods, respectively (Fig. 1). The proportion of patients attaining SCB of 1.5 and 0.5 were 71.0% (n = 203) and 66.4% (n = 190), respectively (Table 3).

Hence, the values for VAS pain score identified to represent MCID, PASS, and SCB, respectively, at 1-year postoperatively were 5, 2, and 1. The rates of achieving clinically significant improvement based on VAS were 60.5%, 63.3%, and 57.2%, respectively (Table 3).

Predictors of attaining clinically significant outcomes

A higher preoperative VAS pain score was predictive for achieving MCID (odds ratio [OR], 1.84; P < 0.01) (Table 4), but not PASS or SCB. Other preoperative variables of age, gender, and BMI were not statistically significant predictors of attaining clinically significant outcomes.

Table 2

Distribution of responses in relation to the anchor question used for assessment of postoperative satisfaction.

<table>
<thead>
<tr>
<th>Response</th>
<th>Preoperative VAS</th>
<th>1-year VAS</th>
<th>2-year VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction rating$^a$</td>
<td>0.80</td>
<td>0.71</td>
<td>0.69</td>
</tr>
<tr>
<td>Expectation fulfillment$^b$</td>
<td>0.76</td>
<td>0.71</td>
<td>0.69</td>
</tr>
</tbody>
</table>

VAS = visual analog scale for pain.

$^a$ Boldface indicates statistical significance.

$^b$ Anchor question for evaluation of patient satisfaction was “How would you rate the overall results of treatment for your shoulder condition?”, and patients who answered “Excellent”, “Very good” or “Good” were considered to be satisfied.

$^c$ Anchor question for evaluation of expectation fulfillment was, “Has the surgery for your shoulder condition met your expectations so far?”, and patients who answered “Totally”, “Almost totally” or “Quite a bit” and “More or Less” were considered to be satisfied.

DISCUSSION

The main finding of this study was that the values for the VAS pain score were identified to represent MCID, PASS, and SCB, respectively, at 1-year postoperatively were 5, 2, and 1, for patients undergoing arthroscopic RCR.

Patients who attain an improvement in VAS pain score of at least 5 points at 1 year postoperatively would be considered to have achieved clinically significant improvement in outcome after arthroscopic RCR. In contrast, Kim et al. [11] found that the MCID, SCB, and PASS values were 1.5, 2.5, and 1.7, respectively, for the VAS pain score after arthroscopic RCR. Another study by Tashjian et al. [8] determined that MCID in patients undergoing arthroscopic RCR would be an improvement of at least 1.4-cm on a 10-cm VAS pain scale, with older patients requiring a larger change in order to obtain a clinically important difference as compared to younger patients. As such, the higher MCID obtained in the present study could be attributed to the higher average age of patients in the present cohort (60.2 ± 10.4 years vs. 51 years, range 19–88), requiring a greater improvement in the VAS pain score to be considered clinically significant. The limitation of using MCID is that the timing of anchor questions, method of deriving values, and target scores differ among such studies and the results should thus be interpreted and compared with care. If sufficient MCID, SCB, and PASS data are collected after the same treatment, a general consensus can be drawn for each treatment [11].

The rates of attainment of clinically significant outcomes in terms of MCID, PASS, and SCB were 60.5%, 63.3%, and 57.2%, respectively, at 1 year postoperatively. A similar study by Manderle et al. [15] of 203 patients undergoing arthroscopic RCR also found that the majority of patients achieved MCID (82.92%), PASS (59.28%), and SCB (77.01%) after RCR for the three PROMs used in the study: ASES, SANE, and subjective constant score. The mean time required for achievement of MCID was 5.77 ± 1.79 months for ASES, 6.25 ± 2.42 months for SANE, and 6.94 ± 3.85 months for constant score postoperatively. This timeline aligns well with that of previous studies on RCR that have demonstrated that most improvement is reached within 1 year postoperatively [7].
Another key finding of the present study was that preoperative VAS was a statistically significant predictor of achieving MCID after arthroscopic rotator cuff repair. Several studies have also reported that higher baseline pain levels and poorer preoperative functional scores predict for MCID attainment after shoulder surgery [11,16]. The worse the preoperative score, the higher the potential change in the score, which may account for the higher probability of attaining MCID [11]. Furthermore, smaller differences may be clinically significant when symptoms are more severe [17]. Conversely, better preoperative shoulder function (in terms of higher subjective constant scores, or SANE scores) has been shown to be statistically significant predictors of delayed attainment of clinically significant outcomes [15]. Kim et al. [11] also identified other statistically significant factors related to attaining clinically meaningful outcomes. Large to massive tears and retears were found to have a
negative role in improving clinical symptoms, likely due to the slower recovery associated with larger tears. The male gender was also found to be predictive of attaining PASS for the VAS pain score, possibly due to the effect of hormonal differences on rotator cuff healing [18]. However, in the present study, gender was not identified as a statistically significant predictor of MCID, PASS, or SCB after arthroscopic RCR. This is corroborated by other studies [12,19] of patients with full-thickness rotator cuff tears (undergoing operative and nonoperative treatment), which have found that patient sex, age, and comorbidity scores do not predict for attaining MCID of PROMs such as the WORC and ASES. As such, further studies are needed to better delineate the role of gender and other preoperative variables in achieving clinically significant outcomes after arthroscopic RCR. Such information would be a useful tool in patient selection, patient education, and interpretation of reported changes in PROMs to evaluate the achievement of clinical significance.

The present study has several strengths. Firstly, the data represents patients operated on by a single surgeon, thus reducing heterogeneity in surgical technique and postoperative rehabilitation. Secondly, our robust and systematic follow-up protocol allowed for the serial measurement of outcome scores at fixed intervals postoperatively with no loss to follow-up. Third, the present study includes a relatively large patient cohort of 286, which is comparable to or greater than that of other similar studies on this topic [1,11,19,24].

LIMITATIONS

However, this study also has its limitations. First, the anchor question was applied at 1 year. This study did not aim to investigate the final results of surgery, but rather the improvement of clinical symptoms. Therefore, we used the 1-year follow-up as the baseline for this study as previous studies have shown statistically significant improvement in PROMs after arthroscopic RCR for most patients up to 1 year post-operatively [2]. Other studies have derived MCID, SCB, and PASS values at different time points, including 6 weeks [12], 3 months [20], 6 months [21], 12 months [2], and 24 months [22]. If future studies derive MCID, SCB, and PASS values for various time points and scores, comparisons among studies and the formation of a consensus will be of further value to clinicians. Second, the present study did not consider other preoperative variables, such as the size of rotator cuff tears and the presence of concomitant biceps pathology [23], which could potentially influence and predict the attainment of clinically significant outcomes after arthroscopic RCR.

CONCLUSION

This study identified threshold VAS pain scores of 5, 2, and 1 for achieving MCID, PASS, and SCB, respectively, at 1-year follow-up after arthroscopic rotator cuff repair. A higher preoperative VAS pain score was also identified as a statistically significant predictor of attaining MCID after arthroscopic rotator cuff repair.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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