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What are the Minimum Clinically Important Difference Values for the PROMIS and QuickDASH After Carpal Tunnel Release? A Prospective Cohort Study

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Abstract

Background To better define the clinical significance of patient-reported outcomes, the concept of a minimum clinically important difference (MCID) exists. The MCID is the minimum change that a patient will perceive as meaningful. Prior attempts to determine the MCID after carpal tunnel release are limited by methodologic concerns, including the lack of a true anchor-based MCID calculation.

Questions/purposes To address previous methodologic concerns in existing studies, as well as establish a clinically useful value for clinicians, we asked: What are the MCID values for the Patient-Reported Outcomes Measurement Information System (PROMIS) Upper Extremity (UE), PROMIS Pain Interference (PI), and the QuickDASH after carpal tunnel release?

Methods We conducted a prospective cohort study at an urban, Midwest, multihospital, academic health system. One hundred forty-seven adult patients undergoing unilateral carpal tunnel release between September 2020 and February 2022 were identified. PROMIS UE, PI, and QuickDASH scores were collected preoperatively and 3 months postoperatively. We also collected responses to an anchor-based question: "Since your treatment, how would you rate your overall function?" (much worse, worse, slightly worse, no change, slightly improved, improved, or much improved). Patients who did not respond to the 3-month postoperative surveys were excluded. A total of 122 patients were included in the final analysis (83% response proportion [122 of 147]). The mean age was 57 years (range 23 to 87 years), and 68% were women. The MCID was calculated using both anchor-based and distribution-based methods. Although anchor-based calculations are generally considered more clinically relevant because they consider patients' perceptions of improvement, an estimation of the minimum detectable change (which represents measurement error) relies on a distribution-based calculation. We determined a range of MCID values to propose a final MCID value for all three instruments. A negative MCID value for the PROMIS PI

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Ethical approval for this study was obtained from the Henry Ford Health System, Detroit, MI, USA (number 11361-29).
This work was performed at the Henry Ford Health System, Detroit, MI, USA.

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instrument represents a decrease in pain, whereas a positive value for the PROMIS UE instrument represents an improvement in function. A negative value for the QuickDASH instrument represents an increase in function.
Results The final proposed MCID values were 6.2 (interquartile range [IQR] 5.4 to 9.0) for the PROMIS UE, -7.8 (IQR -6.1 to -8.5) for the PROMIS PI, and -18.2 (IQR -13.3 to -34.1) for the QuickDASH.
Conclusion We recommend that clinicians use the following values as the MCID after carpal tunnel release: 6 for the UE, -8 for the PI, and -18 for the QuickDASH. Surgeons may find these values useful when counseling patients postoperatively regarding improvement. Future studies could examine whether a single MCID (or small range) for PROMIS instruments is applicable to a variety of conditions and interventions.
Level of Evidence Level II, therapeutic study.

Introduction

Recently, there has been an increasing emphasis on value-based care in orthopaedics [41, 53]. To objectively measure patients' responses to treatment, patient-reported outcomes (PROs) have been increasingly used [3, 37]. Two PRO instruments commonly used for patients with hand and upper extremity illness are the QuickDASH [5] and the Patient-Reported Outcomes Measurement Information System (PROMIS) [6, 9, 13, 51]. In contrast to the QuickDASH, which is a fixed-length questionnaire, PROMIS computer adaptive testing uses item-response theory to minimize the question burden and select the most appropriate questions in response to a patient's prior answers. The PROMIS has been widely used in orthopaedic surgery and has been validated for use in hand and upper extremity surgery [12, 37].

To better define the clinical importance of patients' improvements in terms of PRO scores, the concept of the minimum clinically important difference (MCID) emerged. The MCID is the minimal change that a patient will perceive as meaningful [29]. Although first described in 1989, there is still a lack of a standardized method to calculate the MCID [16, 29, 31]. Current methods to estimate the MCID are anchor-based or distribution-based [14, 22]. Anchor-based calculations pair a PRO of interest to a subjective scale of improvement or decline [17]. Distribution-based calculations are based on statistical parameters unique to a particular cohort, such as the standard deviation (SD) or effect size [22, 39]. Because MCID values for different PROs are being increasingly reported in orthopaedic research, review articles have commented on the wide variability in reported values, emphasizing the need for clear reporting of the methods used [16, 31].

A key component in the evaluation of MCID calculations is the minimum detectable change (MDC) [4, 49]. The MDC is a measurement error that represents the minimal change in a PRO that is not because of chance alone [4]. For an MCID value to be valid, it should be greater than the MDC value for the cohort of interest [49]. If the calculated MCID is less than the MDC value, the PRO instrument may not be sufficiently responsive to detect the MCID [19, 24]. More importantly, patients expect improvement from surgical intervention to be clinically appreciable, not merely detectable in numbers. Therein lies the entire concept of MCID.

Two previous studies have sought to calculate the MCID for the PROMIS after carpal tunnel release (CTR) [8, 33]. However, as highlighted in a commentary by Terwee [48], these studies have several methodologic limitations. Neither study calculated a true anchor-based MCID value for the PROMIS, and instead relied on distribution-based methods. Because distribution-based methods do not consider the patient's perspective, these calculations often underestimate what is considered a meaningful change to the patient [11, 22]. In addition, one study did not report an MDC value, which the authors recognized as a limitation and addressed as an important next step in future research pertaining to the MCID [8]. The second study reported MDC values that were greater than their MCID values [33].

Therefore, we asked: What are the MCID values for the PROMIS Upper Extremity (UE), PROMIS Pain Interference (PI), and QuickDASH after CTR?

Patients and Methods

Study Design and Setting

We conducted a prospective cohort study at an urban, Midwest, multihospital, academic health system.

Patients

A retrospective record review was performed to identify patients who underwent open or endoscopic CTR, based on Current Procedural Terminology codes for open and endoscopic CTR (64721 and 29848), by four fellowship-trained orthopaedic hand surgeons including the senior author (CSD) between September 2020 and February 2022. Patients who underwent bilateral CTR (staged or simultaneous), additional procedures at the time of CTR (including injections), or revision CTR were excluded. Patient demographics were recorded. At our institution, patients undergoing CTR use a tablet to complete preoperative questionnaires, including the PROMIS UE (version 2.0), PROMIS PI (version 1.1), and QuickDASH. Patients' responses are integrated into their

Table 1. Responses to the anchor question "Since your treatment, how would you rate your overall function?" (n = 122 responses)

Response to question: Since your treatment, how would you rate your overall function?	% (n)
Much worse	1 (1)
Worse	1 (1)
Slightly worse	4 (5)
No change	2 (2)
Slightly improved	20 (24)
Improved	33 (40)
Much improved	40 (49)

electronic medical record. Patients who completed preoperative questionnaires were included in the study and those who had incomplete preoperative questionnaires were excluded. At 3 months postoperatively, patients who met the inclusion criteria were prospectively sent questionnaires through the REDCap platform via an email that contained these three PRO instruments [25]. To calculate anchor-based MCIDs, patients were also asked to answer a seven-level anchor question: "Since your treatment, how would you rate your overall function?" (much worse [-3], worse [-2], slightly worse [-1], no change [0], slightly improved [+1], improved [+2], and much improved [+3]).

Participants' Baseline Data

A total of 147 unique patients met the inclusion criteria for this study; 83% (122 of 147) responded to the 3-month postoperative surveys. The mean age was 57 years (range 23 to 87 years), and 68% (83 of 122) were women. Forty-three percent of patients (52 of 122) underwent open CTR, and 57% (70 of 122) underwent endoscopic CTR. PRO instruments were completed at a mean 1.3 ± 1.2 months preoperatively. The mean time from surgery to completion of the postoperative survey was 4.1 ± 0.98 months.

Twenty-six percent (31 of 122 patients) of the cohort were included in the "nonimproved" group ("slightly worse [-1]," "no change [0]," and "slightly improved [+1]"), and 33% (40 of 122) were included in the "improved" group ("improved [+2]") (Table 1). There was improvement in scores from preoperatively to postoperatively for all three PRO instruments (Table 2).

Survey Instruments

PROMIS instruments were administered using computer adaptive testing [46]. The scores in PROMIS measures are computed to a T-score where a score of 50 represents the average level of the instrument for the United States general population and 10 is the SD.

The PROMIS UE (version 2.0) assesses upper extremity physical function in patients [51]. A lower score represents decreased function, and a higher score represents better function. The PROMIS PI (version 1.1) assesses pain severity [2]. A higher score represents increased pain levels while a lower score represents decreased pain.

The QuickDASH is an outcome measure that also attempts to quantify upper extremity function [5]. It is scored on a scale of 0 to 100, with 0 representing no dysfunction and 100 representing maximum dysfunction.

Analytic Approach

The MCID was calculated using both anchor-based and distribution-based methods. Although anchor-based calculations are generally considered more clinically relevant because they consider patients' perceptions of improvement, an estimation of the MDC (which represents measurement error) relies on a distribution-based calculation. Descriptive statistics were calculated (mean, median, range, and SD). Ninety-five percent confidence intervals were calculated using the mean ± 2*SD. Normality of continuous variables was assessed using the Shapiro-Wilk test. Preoperative and postoperative scores were compared using two-tailed paired t-tests for normal distributions and the Wilcoxon rank sum test for non-normal distributions. Statistical significance was set at a p value of < 0.05. All statistical analyses were performed with JMP® (Version 16.2.0, SAS Institute Inc).

Table 2. Preoperative, postoperative, and difference in scores for the PROMIS UE, PROMIS PI, and QuickDASH

Questionnaire	Preoperative score, mean ± SD	Postoperative score, mean ± SD	Mean difference (95% CI)	p value
PROMIS UE	36.3 ± 7.9	46.1 ± 11.3	9.8 (8.1 to 11.7)	< 0.01[a]
PROMIS PI	59.4 ± 7.0	49.4 ± 9.8	-10.0 (-8.2 to -11.8)	< 0.01[b]
QuickDASH	45.7 ± 17.6	18.1 ± 21.1	-27.6 (23.7 to 31.5)	< 0.01[b]

[a]Wilcoxon rank sum test
[b]Student paired t-test.

Table 3. PROMIS UE MCID estimates (n = 122)

Type	Method	Calculated MCID value	% of patients meeting the MCID threshold (n)
Anchor-based	Mean change difference	6.7	55 (67)
Anchor-based	Median change difference	6.2	57 (70)
Anchor-based	Mean change limit	18.3	22 (27)
Anchor-based	ROC curve	5.4	62 (76)
Distribution-based	0.5*SD	5.7	60 (73)
Distribution-based	0.8*SD	9	48 (59)
Distribution-based	MDC95	2.2	75 (91)

Sample Size Calculation

Currently, there is no consensus on what constitutes a sufficient sample size for an accurate calculation of the MCID [16]. However, we performed an a priori sample size calculation to detect a 5-point change in PROMIS UE and PI scores with a previously established SD of 10 (effect size of 0.5) [43] and setting power to 80% and $\alpha = 0.05$. We determined that approximately 25 patients in each group (baseline group reporting no improvement and a second group reporting improvement) were required. We also referenced two previous studies calculating the MCID for the PROMIS after CTR [8, 33] and decided to include a minimum of 100 patients in our total population.

Using Both Distribution-based and Anchor-based Methods

Although anchor-based calculations are generally considered more clinically relevant because they consider patients' perceptions of improvement [35], distribution-based methods still have utility. For example, an estimation of the MDC, a surrogate for the measurement error of a PRO, relies on a distribution-based calculation. Furthermore, there is general consensus that there is no gold standard for calculating an MCID and that both methods should be considered together to calculate a single value or a small range of MCID values [42, 54]. For these reasons, we used both distribution-based and anchor-based methods in our study.

Distribution-based Calculation Methods

Using the well-established 0.5 SD method, we calculated the MCID as one-half times the SD of the measured change in PRO scores [16, 39]. This is based on the finding that most health-related quality of life instruments have an effect size of roughly 0.495 [39]. We also performed a post hoc calculation of effect size between preoperative and postoperative scores after collecting data, and a large effect size was noted for all three PRO instruments (Cohen $d > 0.8$). A large effect size may represent a larger numerical change in the instrument used (rather than simply a large improvement), and thus a 0.8 times SD calculation was also performed to estimate the MCID as originally recommended by Cohen [15, 32, 39, 44].

We also estimated the lowest possible MCID using the MDC. We calculated the MDC_{95} (95% level of confidence) using established formulas (Supplemental Digital Content 1; http://links.lww.com/CORR/A958) [16, 45]. We obtained Cronbach alpha or r values representing the test-retest reliability coefficient of all three PRO instruments from previous studies specifically calculating these values

Table 4. PROMIS PI MCID estimates (n = 122)

Type	Method	Calculated MCID value	% of patients meeting the MCID threshold (n)
Anchor-based	Mean change difference	-7.8	58 (71)
Anchor-based	Median change difference	-8.5	53 (65)
Anchor-based	Mean change limit	-17.3	27 (33)
Anchor-based	ROC curve	-7.1	62 (76)
Distribution-based	0.5*SD	-5.1	67 (82)
Distribution-based	0.8*SD	-8.1	58 (71)
Distribution-based	MDC95	-6.1	64 (78)

Table 5. QuickDASH MCID estimates (n = 122)

Type	Method	Calculated MCID value	% of patients meeting the MCID threshold (n)
Anchor-based	Mean change difference	-22.3	61 (74)
Anchor-based	Median change difference	-18.2	73 (89)
Anchor-based	Mean change limit	-51.1	14 (17)
Anchor-based	ROC curve	-34.1	41 (50)
Distribution-based	0.5*SD	-10.3	79 (96)
Distribution-based	0.8*SD	-16.4	73 (89)
Distribution-based	MDC95	-13.3	77 (94)

(UE = 0.99 [51]; PI = 0.90 [10]; QuickDASH = 0.94 [40]), rather than calculating this value from our own dataset to avoid bias, because patients in our study underwent an intervention.

Anchor-based Calculation Methods

To calculate the MCID using anchor-based methods, we preemptively designated patients who reported "improvement" (+2) on the seven-level anchor question as the improved group (anchor) and patients who reported "slightly worse" (-1), "no change" (0), or "slight improvement" (+1) as the nonimproved (base) group [26]. Patients seldom responded with "no change" postoperatively in a previous study attempting to calculate the MCID after CTR [33] and in a study calculating the MCID after shoulder arthroplasty [26]. Because CTR has an extremely high rate of postoperative satisfaction among patients (mean of 8 on a 10-point Lickert scale) [36], we anticipated that designating "slightly improved" (+1) and "no change" (0) as the two groups would yield minimum sample sizes.

The mean change difference, median change difference, and mean change limit methods were used to calculate the MCID (Supplemental Digital Content 2; http://links.lww.com/CORR/A959) [16]. We also calculated the MCID using receiver operating characteristic curves to determine an optimal cutoff score in the anchor and base groups (by maximizing sensitivity and specificity using Youden index [55]).

Proposed Final MCID Values

For the seven different MCID values calculated for each PRO instrument, we determined whether the distribution of values exhibited a normal or skewed distribution. For all three instruments, a positively skewed distribution of MCID values was present. We calculated the median MCID value as well as the interquartile range (IQR) of the combined anchor-based and distribution-based estimates. Because of the skewed distribution, we report the median as the measure of central tendency and use the IQR to represent error (rather than the mean with a confidence interval for a normal distribution).

Ethical Approval

This study was approved by the institutional review board at our institution (number 11361-29).

Results

Anchor-based and distribution-based calculation methods yielded a wide range of MCID estimates for the PROMIS UE (Table 3), PROMIS PI (Table 4), and QuickDASH (Table 5). Our final proposed MCID values are as follows: PROMIS UE = 6.2 (IQR 5.4 to 9.0), PROMIS PI = -7.8 (IQR -6.1 to -8.5), and QuickDASH = -18.2 (IQR -13.3 to -34.1) (Table 6). A negative MCID value for the PROMIS PI instrument represents a decrease in pain, whereas a positive value for the PROMIS UE instrument represents

Table 6. Proposed MCID values for the PROMIS UE, PROMIS PI, and QuickDASH (n = 122)

Instrument	Median MCID (proposed) (IQR)	% of patient population meeting median MCID (n)
PROMIS UE	6.2 (5.4 to 9.0)	57 (69)
PROMIS PI	-7.8 (-6.1 to -8.5)	63 (77)
QuickDASH	-18.2 (-13.3 to -34.1)	67 (82)

A positive value for the PROMIS UE instrument represents an improvement in function. A negative MCID value for the PROMIS PI instrument represents a decrease in pain. A negative value for the QuickDASH instrument represents an increase in function.

an improvement in function. A negative value for the QuickDASH instrument represents an increase in function.

Discussion

The MCID revolves around that the idea that patients undergoing an intervention expect improvement to be clinically appreciable, not merely detectable by statistical means [35]. In this study, we comprehensively calculated MCID values for the PROMIS UE, PROMIS PI, and QuickDASH PRO instruments after CTR using anchor-based and distribution-based methods. We sought to address the methodologic concerns in existing studies and establish clinically useful values for clinicians. The MCID values for CTR in our study (PROMIS UE 6.6, PROMIS PI -7.0, and QuickDASH -15.3) were slightly larger than those reported (PROMIS UE 3.6 to 4.2, PROMIS PI -3.4 to -4.1, and QuickDASH -10.4) [8, 33].

Limitations

There are several limitations to our study. The ideal study for calculating MCID using anchor-based methods would use patients who responded "slightly improved" (+1) and "no change" (0) to the anchor question. This was not possible in our study owing to the very small number of patients falling into the "no change" category, given the overall high rate of satisfaction after CTR [36]. Therefore, we designated the "improved (+2)" response as the improved group and the combination of -1, 0, and 1 responses as the nonimproved groups, possibly resulting in a slight overestimation of the MCID. However, this method has been reported by other studies with similar limitations imposed by the condition or intervention itself during MCID calculation [26, 29]. Second, we did not exclude patients who experienced a ceiling effect, particularly for the PROMIS UE instrument, which may have also resulted in a slight underestimation of the MCID. Tyser et al. [51] demonstrated improved ceiling effects of the PROMIS UE version 2.0 (approximately 6.9% at a value of 61) compared with prior versions of the UE instrument. In our population, 2.5% (three of 122) of patients who fell into our two anchor classifications of "nonimproved" and "improved" met this ceiling effect preoperatively and 5% (six of 122) met this ceiling effect postoperatively. Because of the low percentage of patients meeting the ceiling effect in our population, we believe the effect on the MCID calculation was minimal.

The MCID values we calculated are the most applicable to patients who are demographically similar to those in our study. Other patient populations with racial, cultural, or demographic differences from our cohort may respond to the anchor question and PRO questionnaires differently. However, given our large sample size, more than 80% follow-up, and vigorous calculation methods, we believe our MCID values are accurate and can be confidently used in future studies. Our study was also underpowered to perform a subgroup analysis on whether men and women have different MCIDs after CTR. Therefore, our results are the most applicable to a population with a similar gender distribution to ours (68% women).

Another general limitation of MCID calculations that is applicable to our study is that the exact follow-up time period in which to readminister the PRO instruments has not been established. The responsiveness of PROMIS in the early postoperative period after CTR has been questioned by a recent study that showed that at 1 month after CTR, patients who reported subjective improvement had PROMIS scores reflecting declining function [7]. We also observed this phenomenon in our early postoperative data (not reported). However, patient improvement has been reported to peak at 6 months after CTR [23]. On the other hand, longer follow-up periods may portend a higher risk of anchoring bias and recall bias because anchor-based MCID calculations depend on patients recalling their preoperative state [21, 30, 50]. To avoid potential bias because of a too-early or too-late follow-up interval, we selected a 3-month follow-up period, which appears to be an appropriate time period to mitigate the effects of recall bias on anchor-based MCID calculations [1, 38].

MCID Values

In our study, the MCID values for PROMIS UE, PROMIS PI, and QuickDASH after CTR were greater than previously reported [8, 33]. Our findings suggest that a greater increase in function (PROMIS UE and QuickDASH) and a greater decrease in pain (PROMIS PI) than reported represents a "minimally" important change to a patient after this extremely prevalent surgery. One self-reported limitation of the two previous studies calculating MCID after CTR is that neither used a true anchor-based method. Several studies have reported that anchor-based and distribution-based methods can yield substantially different values [14, 16, 28]. Because distribution-based methods do not consider patient-reported change, these calculations may not accurately represent the clinical importance of the change, which is perhaps why our study resulted in larger MCID values [11, 16, 45, 52]. We addressed this limitation by incorporating anchor-based methods and modified distribution-based methods (considering the effect size of the change in score) in our MCID calculations. Although anchor-based MCID derivations tend to be viewed more favorably than distribution-based calculations, there is no universal standardized method of calculating the MCID. Therefore, we felt it was prudent to include both approaches, which allows

for a comparison of distribution-based MCID values with values in previous studies.

We also demonstrated the MDC_{95} was less than our proposed MCID value for the PROMIS UE, PROMIS PI, and QuickDASH, suggesting that our MCID values represent a clinically important change that is not simply because of random variation. If the MCID is smaller than the MDC, the measured change could be due to random chance [16, 18, 20]. Kazmers et al. [33] reported an MCID for the UE and PI instruments that was lower than their reported MDC, which suggests that their MCID may be too low. We believe this difference is likely because of the way the MDC was calculated. The MDC should be calculated with a standard error of measurement using Cronbach alpha (r value, test-retest probability) of the actual instrument rather than an r value calculated based on the change the study is measuring, because this introduces bias [11, 48]. Although there is almost universal agreement that the MDC should be factored into any calculation of the MCID, many studies on the MCID have not reported this [16, 20]. For future studies, we recommend reporting the MDC of the instrument alongside the actual MCID value to ensure that the calculated MCID is free from measurement error.

Previous studies have attempted to evaluate the MCID value of PROMIS instruments specific to a single condition using anchor-based approaches. Kazmers et al. [34] proposed an MCID of 4.2 to 4.8 for the PROMIS UE instrument after ligament reconstruction and tendon interposition for basilar thumb arthritis, and Hollenberg and Hammert [27] found an MCID of 6.8 for the PI after operative treatment of distal radius fractures. Overall, these values are similar to the values we proposed as the MCID after CTR in this study. Our findings, together with previous studies, suggest that a universal MCID value may be applicable to each PRO instrument rather than specific to a single pathologic condition. However, in the clinical setting, it is reasonable to hypothesize that the minimal improvement after treatment for trigger finger would be different than after a total elbow replacement. We believe MCID estimates depend on the pathology, intervention, and population, as has been shown before [47].

Conclusion

We suggest the following MCIDs after CTR: PROMIS UE 6, PROMIS PI -8, and QuickDASH -18. Surgeons could find these values useful when counseling patients postoperatively regarding their improvement. We believe these values represent a true improvement patients will recognize as a small but meaningful change. Our study also highlights that anchor-based and distribution-based MCID calculations can yield different values. Currently, there is not a universal consensus on whether one approach is the gold standard. Future studies should investigate the true differences between these different methods using multiple evaluations and determine whether one is truly superior to the other. In addition, future studies could examine whether a single MCID (or small range) for PROMIS instruments can be applicable to a variety of conditions and interventions.

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