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CLINICAL RESEARCH

What is the Minimum Clinically Important Difference in Grip Strength?

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Abstract

Background Grip strength reflects functional status of the upper extremity and has been used in many of the clinical studies regarding upper extremity disease or fracture. However, the smallest difference in grip strength that a patient would notice as an improvement resulting from treatment (defined as the minimum clinically important difference [MCID]), to our knowledge has not been determined.

Questions/purposes We asked (1) how 1-year postsurgery grip strength compares with preinjury values; (2) if grip strength correlated with patient's ratings; (3) what the MCID is in the grip strength; and (4) if these values are equivalent to or greater than what can be explained by measurement errors in patients treated for distal radius fracture.

Methods Fifty patients treated by volar locking plate fixation for a distal radius fracture constituted the study cohort. Grip strengths were measured 1 year after surgery on the injured and uninjured sides using a dynamometer. Grip strengths before injury were estimated using the grip strengths of the uninjured side with consideration of hand dominance. Patients were asked to rate their subjective level of grip strength weakness at 1 year postoperatively. Receiver operator characteristic curve analysis was used to determine MCIDs. Minimal detectable change in grip strength, which is a statistical estimate of the smallest change between two measurement points expected by measurement error or chance alone, also was determined using the formula $1.65 \times \sqrt{2} \times$ standard error of measurement.

Results One year after surgery, grip strength (23 kg; 95% CI, 20–27) was less compared with calculated preinjury values (28 kg; 95% CI, 25–31; $p < 0.001$). Patients' rating of grip strength and measured grip strength changes correlated well ($\rho = 0.56$). MCIDs were 6.5 kg for grip strength and 19.5% for percentage grip strength. The MCID was not less than the minimum detectable change for grip strength (also 6.5 kg).

Conclusions The MCID of the grip strength was a decrease of 6.5 kg (19.5%). We believe the MCID of grip strength is useful for evaluating effectiveness of new treatments and for determining appropriate sample size in clinical trials of distal radius fractures.

Level of Evidence Level III diagnostic study. See the Instructions for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

Two types of instruments, patient-reported and clinician-rated, are used for clinical outcome evaluations of upper extremity diseases or fractures. Patient-reported instruments take into account the patient's concerns such as symptoms, function, satisfaction with the results of treatment, and quality of life [8]. Patient-reported instruments for upper extremity outcomes include the Boston Carpal Tunnel Syndrome Questionnaire [13], The DASH questionnaire [7], and the Patient-Rated Wrist Evaluation questionnaire [14]. However, clinician-rated instruments including measurements of ROMs and grip strength have a longer history in clinical research compared with patient-reported instruments. Grip strength reflects functional status of the upper extremity, and this has been used in clinical studies regarding upper extremity disease or fracture.

The minimum clinically important difference (MCID) is the smallest difference in the score of an outcome instrument that a patient would perceive as important. Patient-reported instruments are being used increasingly in clinical research because such questionnaires are suitable for evaluating treatment outcomes from the patient's perspective, and the findings are not influenced much by the views of clinicians who were involved in treatment [18]. The MCIDs of some patient-reported instruments for upper extremity outcomes have been reported [9, 10], however, those of clinician-rated instruments for upper extremity outcomes, such as grip strength, have rarely been reported.

Minimal detectable change (MDC) is defined as an estimate of smallest change between two measurement points expected by chance alone or measurement error [17]. If the value of the MCID is less than that of the MDC, the MCID is within the limit of measurement errors or chances. Therefore, the MCID represents true clinical change when the value of the MCID is more than that of the MDC [9].

The purpose of our study was to investigate (1) how 1-year postsurgery grip strength compares with preinjury values; (2) if grip strength correlated with patient's ratings; (3) what the MCID is in the grip strength; and (4) if these values are equivalent to or greater than what can be explained by measurement errors in patients treated for a distal radius fracture.

Patients and Methods

Patients

This study was approved by our institutional review board. Our study group consisted of patients who were older than 20 years treated with volar plate fixation for a distal radius fracture. Exclusion criteria were bilateral wrist fractures, concomitant upper extremity fracture, neurologic or inflammatory disease, and history of wrist fracture.

Between November 2011 and March 2012, we identified 73 patients who received volar plate fixation. Among these patients, 11 (15%) were excluded using the above criteria. Three patients (4%) refused participation and nine (12%) were lost during follow up, leaving 50 subjects (68%) in our study cohort who completed 1 year of follow up. The mean patient age was 55 years (range, 26–68 years; SD, 13.4), and there were 12 (24%) male patients and 38 (76%) female patients.

Measurement

Assessments were performed by a trained physiotherapist at 1 year after surgery. Grip strengths were measured on both sides using a Jamar® dynamometer (Lafayette Instrument Company, Lafayette, IN, USA). Patients were instructed to maximally squeeze the handle of a dynamometer, sitting on a chair without armrests, both feet flat on the ground, shoulders in the neutral position, and elbows flexed to 90° with neutrally rotated forearm [2, 11]. Grip strength was measured twice and averaged. The ipsilateral and contralateral grip strengths were measured in an alternative manner with a 1-minute rest interval, during which the examiner reset the dynamometer to 0.

Grip strengths before injury were estimated by calculating from grip strengths of uninjured sides. Regarding grip strength calculations, 10% greater strength was assessed for the dominant hand when the right hand was dominant, but no compensation was applied when the left hand was dominant [4, 15]. In other words, when the right wrist was injured in a right hand-dominant patient, the grip strength before injury of the right hand was estimated by multiplying the grip strength of the left hand by 1.1, and when the left wrist was injured in a right hand-dominant patient, grip strength before injury of the left hand was estimated by multiplying the grip strength of the right hand by 0.9. However, in left hand-dominant patients, the grip strength of the uninjured hand was regarded as the grip strength before injury; both hands were considered to have equivalent grip strength.

We also calculated grip strengths as percentages of estimated grip strength before injury.

We asked the patients an anchor question, that is, "How do you feel about the current grip strength of your injured hand as compared with before injury?" at the time of grip strength measurement. The patients could answer with one of four options, and they were categorized according to their answer. When patients answered, "no different from grip strength before injury", they were assigned to Group A; when they answered "slightly weaker, but little difference", they were assigned to Group B; when they answered "definitely weaker," they were assigned to Group C; and when they answered "much weaker", they were assigned to Group D.

Statistical Analysis

The grip strength data of our study was normally distributed, analyzed by the Shapiro-Wilk test, a statistical test for normality. The estimated preinjury grip strength and the grip strength measured 1 year after surgery were compared using a paired sample t-test.

We used ANOVA and post hoc Tukey's test to examine whether change of grip strength was different according to patients' responses to a transition question.

The Spearman rank correlation test was used to examine associations between changes in grip strength and responses to the transition question. A correlation coefficient of 0.3 to 0.6 was taken to indicate moderate correlation and greater than 0.6 was considered a strong correlation [6].

We estimated the MCID in two ways: one was using an anchor-based method that compares changes in scores from the instrument when the patient-reported changes compared with the patient's own experienced baseline; and the other was a distribution-based method that evaluates minimal difference in excess of that expected by random sample variation or by instrument measurement errors.

Receiver operator characteristic (ROC) curve analysis was used to determine the MCID for the anchor-based method. To construct a ROC curve, the patients were separated into two groups according to their response to the transition question. Those who responded "no different" or "slightly weaker, but little difference" were assigned to a group with no change in grip strength, and those who responded "definitely weaker" or "much weaker" were assigned to a group with weakened grip strength. A ROC curve was drawn by plotting sensitivity (y-axis) against 1-specificity (x-axis) for all possible cut-off points of grip strength change. Sensitivity was calculated by dividing the number of patients who had weakened grip strength by the number of patients with a grip strength change greater than the cut-off point. Specificity was calculated by dividing the number of patients who had no change in grip strength by the number of patients with a grip strength change less than the cut-off point. The most efficient cut-off value, regarding specificity and sensitivity, is associated with the point closest to the top left corner of the ROC curve. We made each ROC curve and estimated each MCID for grip strength and percentage of grip strength. The greater the area under the ROC curve, the greater the ability of the scale to differentiate between patients with clinically important change and those without. If the area under the curve (AUC) is 0.5, the test is not predictive, whereas an area close to 1.0 indicates better differentiation [17].

As a distribution-based method, we used the MDC. For a conventional confidence level of 90%, the minimal detectable change is defined as $1.65 \times \sqrt{2} \times$ standard error of measurement. The standard error of measurement is the error estimate for a single measurement of grip strength and is related directly to the reliability of the scale. It is calculated using the standard error of measurement formula $= \text{SD} \times \sqrt{(1-\alpha)}$, where SD is the SD of grip strength before injury and α is the test-retest reliability coefficient of grip strength. The SD of preinjury grip strength was 10.5. According to Bohannon and Schaubert [3], the coefficient of test-retest reliability of grip strength in community-dwelling elderly patients showed a range of 0.91 to 0.95. We used 0.93, which is the middle value of this range, as the test-retest reliability coefficient of grip strength.

Results

At one year after surgery, grip strength (23 kg; 95% CI, 20–27) was less compared with calculated preinjury values (28 kg; 95% CI, 25–31; $p < 0.001$). Mean percentage grip strength compared with the contralateral intact sides was 84% (95% CI, 78%–90%) at 1 year after surgery.

One year after surgery, there were 9 patients in Group A, 18 patients each in Groups B and C, and 5 patients in Group D.

Mean value for grip strength change comparing grip strength 1 year after surgery with estimated preinjury grip strength in each group showed an increase of 0.9 kg (95% CI, increase of 2.3 to decrease of 4.6) in Group A, a decrease of 4.1 kg (95% CI, 2.1–6.3) in Group B, a decrease of 7.0 kg (95% CI, 4.0–9.9) in Group C, and a decrease of 10 kg (95% CI, 2–17) in Group D (Table 1). ANOVA showed that changes in grip strength for each group had significant differences ($p < 0.001$), and the post hoc analysis revealed that the mean grip strength change for Group A was significantly different from that of Group C ($p = 0.003$) and Group D ($p = 0.004$).

The mean percentage grip strengths were 104% (95% CI, 94%–114%) in Group A, 86% (95% CI, 78%–95%) in Group B, 75% (95% CI, 65%–86%) in Group C, and 68% (95% CI, 46%–85%) in Group D. ANOVA showed that percentage grip strength for each group also was significantly different ($p < 0.004$), and post hoc analysis showed that percentage grip strength for Group A was significantly different from that of Group C ($p = 0.003$) and Group D ($p = 0.004$).

Table 1. Grip strength changes

Group	Grip strength 1 year after surgery (kg)	Estimated preinjury grip strength (kg)	Grip strength change (kg)	Percentage grip strength (%)
A	27 (95% CI, 21–33)	26 (95% CI, 21–32)	−0.9 (95% CI, −2.3 to 4.6)	104 (95% CI, 94–114)
B	24 (95% CI, 18–29)	28 (95% CI, 23–33)	4.1 (95% CI, 2.1–6.3)	86 (95% CI, 78–95)
C	21 (95% CI, 14–27)	27 (95% CI,, 22–32)	7.0 (95% CI, 4.0–9.9)	75 (95% CI, 65–86)
D	19 (95% CI, 12–24)	28 (95% CI, 22–33)	10 (95% CI, 2–17)	68 (95% CI, 46–85)

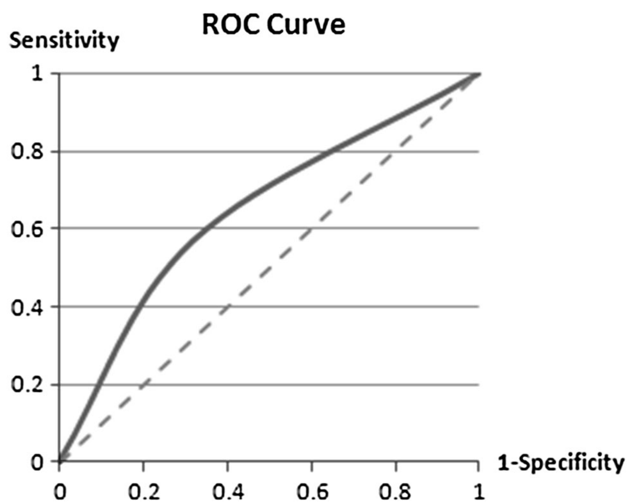

Fig. 1 The ROC curve for grip strength shows the sensitivity was 0.57 and 1-specificity was 0.32 for optimal cut-off points (6.5 kg).

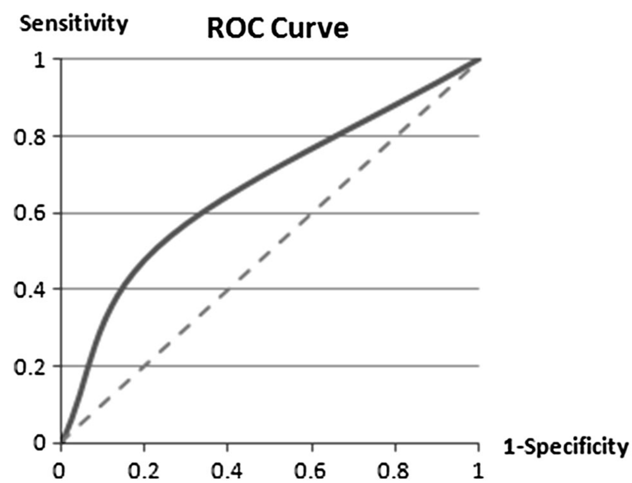

Fig. 2 The ROC curve for the percentage grip strength shows the sensitivity was 0.51 and 1-specificity was 0.23 for optimal cut-off points (19%).

The Spearman Rank correlation test showed a significant correlation between changes in patients' rating of grip strength ($\gamma = 0.56$; $p < 0.001$) and percentage changes in grip strength ($\gamma = 0.51$; $p < 0.001$).

The ROC curve for grip strength showed that the MCID of grip strength was 6.5 kg (Fig. 1), and the AUC was 0.76 ($p < 0.001$; 95% CI, 0.62–0.90). The ROC curve for percentage grip strength showed that the MCID of the percentage grip strength was 19.5% (Fig. 2), and the AUC was 0.77 ($p < 0.001$; 95% CI, 0.63–0.90).

For grip strength, the MCID was not less than the MDC (both were 6.5 kg).

Discussion

Determination of the MCID is important in two aspects. It provides important information to clinicians regarding the effectiveness of a new treatment. When an expensive, risky, or unproven new treatment is introduced for a specific disease, the improvement should reach a point that a patient is able to perceive the clinical change before any requests for payment are made or the patient is exposed to the risk of uncertainty. Measuring the MCID explicitly renders the idea that statistical significance and clinically important difference are different. Even though there is a small but significant statistical difference in a large given sample size, it is possible for a patient to perceive no difference in conditions less than the MCID. In addition, when a new study is initiated, the MCID of the primary outcome variable is used to determine the sample size of a study [5].

Our study has several limitations. First, our results were based on distal radius fractures treated by plate fixation and, thus, the majority of study subjects were older women. The MCID in our study may not apply to other conditions and other populations because it depends on the study population and disease condition. Second, an anchor-based MCID estimation contains an anchor question that reflects patients' perspectives on clinical change, but it has an inherent limitation in that the answers provided for transition are arbitrary and are affected by recall bias [9, 10]. On the contrary, a distribution-based MCID estimation is less variable to study population and disease condition because it usually reflects the measurement error of the instruments. However, it does not reflect the patients' perspectives on clinical change. Third, we did not measure the preinjury grip strength; rather, we estimated preinjury grip strength by using the grip strength of the contralateral wrists and adjusted for dominance. However, large normative data have been reported for grip strength in both hands [4, 15], therefore we can estimate preinjury grip strength without loss of precision as long as the contralateral side has no previous injury.

In this study, we calculated the MCID in a traumatic condition, such as a distal radius fracture, using grip strength as a comparable instrument, because with grip strength the preinjury condition can be estimated using the contralateral grip strength. Two conditions are necessary to obtain meaningful MCID values. One is that the study population has a relatively even distribution in terms of the number of clinically changed and unchanged patients. In other words, if the majority of the study participants experienced clinical deterioration, or by contrast experienced clinical improvement, the calculated MCID would be meaningless. The other is that the initial status of the patient should be addressed. With a traumatic condition such as a fracture or dislocation, when the initial status is defined as a patients' condition immediately after trauma, the majority of patients would show clinical improvements after all. It is difficult to find patients who with no clinical change from their initial status immediately after trauma. However, the initial status rarely is addressed when it is considered the status before trauma. For these reasons, the MCID, to our knowledge, has not been addressed in traumatic conditions before [12].

The MCID in our study is based on worseness of the clinical condition. The MCID for patient-reported instruments has been evaluated for nontraumatic diseases. Because trauma occurs unexpectedly, it is not possible to obtain data before injury using patient-reported instruments, and it is impossible to calculate the MCID without data before injury. By contrast, with nontraumatic diseases, it is not difficult to obtain initial data using patient-reported instruments. Therefore, MCIDs for patient-reported instruments address clinical improvements in nontraumatic diseases, because treatment is administered with the expectation of an improvement. The MCID of the DASH was used to determine sample size for study designs in a couple studies of distal radius fractures [1, 16]. However, as the MCID of the DASH is based on improvements of the clinical outcome in patients with nontraumatic conditions, we believe it is inappropriate to use it for patients with distal radius fractures. We suggest using the MCID of our study which is based on worsening of clinical conditions.

In our patients, the MCID of grip strength was 6.5 kg, which was equivalent to the MDC of grip strength. To ensure that the MCID values are free of measurement errors, the MCID should not be less than the MDC. In our study, the MCID and MDC of grip strength were equivalent, which suggests that the observed MCID is representative of true changes in clinical status. The MCIDs for the patient-reported questionnaires have been reported for nontraumatic upper extremity disease [9, 10]. The MCIDs for wrist disease were 17 for the Patient-Rated Wrist Evaluation and 13.5 for the DASH. The MDCs for wrist disease were 7.7 for the Patient-Rated Wrist Evaluation and 9.3 for the DASH [10]. The MCID for the Boston Carpal Tunnel Questionnaire was 0.9 and the MDC was 0.58 [9].

We found the MCID of grip strength to be a decrease of 6.5 kg or a decrease of 19.5%, and these values were found to represent the patients' perception of clinically meaningful reductions in grip strength. Our study provides new insight for the MCID based on worseness of clinical outcome in traumatic conditions, and we believe the MCID for grip strength should be used to evaluate effectiveness of new treatments and to calculate appropriate sample size in clinical trials of distal radius fractures.

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