The Minimal Clinically Important Difference of the Patient-Rated Wrist Evaluation Score for Patients with Distal Radius Fractures: A Prospective Cohort Study

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Purpose: The purpose of this study was to determine the minimal clinically important difference (MCID) of the Patient-Rated Wrist Evaluation (PRWE) score in patients with distal radius fractures.

Methods: We prospectively included 102 patients with a median age of 59 years (interquartile range, 48-66). All participants completed the PRWE questionnaire during two separate visits. Additionally, patients were asked to indicate the degree of clinical change they appreciated on a scale from -5 (much worse) to +5 (much better) through 0 (no change). Accordingly, patients were categorized into two groups: (1) minimally improved or (2) no change. These groups were used to "anchor" the changes observed in the PRWE to patients' perspective of what is clinically important. We determined the MCID according to the ROC (receiver operating characteristic curve) method. In this context, the change in PRWE is considered a diagnostic test and the anchor (minimally improved or no change) is the gold standard. The optimal ROC cutoff point reflects the value of the MCID.

Results: The majority of patients indicated they experienced marked improvement and the PRWE score between the first and the second measurement differed significantly (P <0.001, Wilcoxon signed rank test). The MCID of the PRWE was 11.5 points.

Conclusion: A change of 11.5 points on the PRWE represents a clinically important difference for patients with distal radius fractures. We recommend using this value to interpret treatment effects and for sample size calculations.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.