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Minimal clinically important difference of Liverpool Elbow Score in elbow arthroplasty

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Background: The minimal clinically important difference (MCID) that allows the interpretation of small but meaningful changes after intervention has not been reported for the Liverpool Elbow Score (LES). This study aimed to determine the MCID for the LES in patients undergoing total elbow replacement.
Methods: This observational study is based on preoperative and 1-year postoperative clinical outcome of total elbow replacement (Discovery Elbow System) in 71 patients using the LES. A 4-point Likert-like transition scale was used to evaluate patient satisfaction after total elbow replacement. A combination of distribution-based methods (standard deviation [SD] of change in the LES, standard error of mean, smallest detectable change [SDC]) and anchor-based methods (receiver operating curve, difference of mean of change in LES) was used to determine range of MCID values.
Results: The mean change in the LES value was 2.4 (SD, 2.1). The estimated SDC value with upper limit of 90% confidence interval was 1.5. The mean change in LES of "satisfied" and "somewhat satisfied" patient groups was 2.4 (SD, 2.1) and 1.1 (SD, 1.4), respectively, and the difference between both means (MCID based on difference of mean in 2 subgroups) was 1.3. According to receiver operating curve analysis, the value of MCID was 1.6.
Conclusion: The MCID value for the LES was estimated to range between 0.7 and 1.8. The estimated SDC value was 1.5. We propose that the "true" MCID value of the LES would be between 1.6 and 1.8 to ensure that the value is higher than the measurement error of the LES.

The Liverpool Elbow Score (LES) is a region-specific outcome score that is completed by both the clinician and the patient. Validation study by the developers of the score demonstrated that the LES is valid, reliable, and responsive to change in clinical condition of the patient in different elbow conditions.[30] The LES has demonstrated satisfactory responsiveness after total elbow replacement arthroplasty.[39] The LES has found support from other research groups and has been used by independent groups other than the developers of the score. The LES has been used in assessment of functional outcome after total elbow arthroplasty (TEA) in arthritis,[1,3] functional outcome after arthroscopic arthrolysis and hyaluronan gel in post-traumatic elbow stiffness,[25] difference in functional outcome in a randomized controlled trial comparing platelet-rich plasma and autologous whole blood in chronic tennis elbow,[34] functional outcome after internal fixation of severe olecranon fracture,[23] and functional outcome after internal fixation of intra-articular distal humerus fracture.[26]

Establishing the minimal clinically important difference (MCID) for clinical outcomes scores is an important component of outcomes research to understand treatment effectiveness, particularly from the patient's perspective. The MCID is defined as the smallest change in the value of an outcome instrument that patients perceive as important, beneficial, or harmful.[20] In other words, MCID value differentiates patients who improve from those who do not improve after a therapeutic intervention.[18] The concept of MCID assists in differentiating statistical significance from clinical significance. A statistical test might reveal a significant difference between preoperative and postoperative scores of an outcome instrument; however, if the difference is lower than the MCID value of the outcome instrument, this statistically significant difference is not

Sefton Research Ethics Committee approved this study: REC No. 08/H1001/109. Trust Study No. 3735. All participants gave written consent for participating in the study and for operative intervention.

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deemed to be clinically significant. The MCID value is also helpful in evaluating cost-effectiveness, estimating appropriate sample size for randomized controlled trials, and evaluating power of a nonrandomized study.[20]

To our knowledge, the MCID value has not been determined for the LES. Hence, this study aimed to critically evaluate the MCID of the LES in a large cohort of patients who underwent TEA for various underlying pathologic processes.

Methods

A prospective database of patients who had undergone TEA using the Discovery Elbow System (Biomet Inc, Warsaw IN, USA) was reviewed to identify patients with completed preoperative LES and 1-year postoperative LES and satisfaction questionnaire. Identified patients had undergone TEA for degenerative arthritis (osteoarthritis, post-traumatic arthritis), inflammatory arthritis (rheumatoid arthritis, hemophiliac arthropathy, and psoriatic arthritis), comminuted distal humerus fracture, and loosening of previous elbow prostheses using the Discovery prosthesis between April 2003 and March 2013. Patient demographics are presented in the Results section. All identified cases (N = 71) were operated on and followed up in a single upper limb center.

Outcome assessment

Clinical and functional outcome after TEA was assessed using the LES. Before the operation and at 1-year follow-up, patients first completed the patient-answered questionnaire of the LES (PAQ-LES), followed by completion of the clinical assessment part of the score (CAS-LES) by independent research fellows. PAQ-LES includes 9 questions representing domains of pain (1 question), functional ability to do activities of daily living (7 questions), and functional ability to participate in sporting and recreational activities (1 question). These questions are answered on a 5-point adjectival scale from 0 (maximum disability) to 4 (no functional disability). The CAS-LES includes assessment of range of motion (4 items), muscle strength (1 item), and ulnar nerve function (1 item). The points from PAQ-LES and CAS-LES are then entered individually in a mathematical formula to determine the total LES. In this scoring system, 0 and 10 points indicate the worst and best outcome, respectively.[30,31]

As there is no "gold standard" external criterion to assess change and improvements in the clinical condition of the patient, a 4-point Likert-like transition scale was used to evaluate patient satisfaction after TEA. The options on this scale were very satisfied, satisfied, somewhat satisfied, and unsatisfied. Patients answered this question at postoperative follow-ups.

Estimation of MCID

There is no gold standard method to measure MCID, which can be estimated using either anchor-based or distribution-based methods. It has been recommended that studies use both anchor-based and distribution-based methods to give range of values for MCID and finally triangulate to converge on possible MCID value.[7,42] It is also suggested that anchor-based methods be given greater weight than distribution-based methods for converging on a single value or to narrow the range of possible MCID values. Distribution-based methods are solely used only when suitable external anchors have not been used or are not available for use.[28]

This study determined the MCID using both anchor-based and distribution-based methods. Patient satisfaction was used as a global transition external anchor. This is in accordance with a similar approach by previous studies to estimate clinically meaningful change.[6,32] Adjusting for the change in unsatisfied patients, the MCID can be calculated as the mean change score for satisfied patients minus the mean change score for somewhat satisfied patients.[6,14,32,37] Receiver operating curve (ROC) analysis is then used to evaluate the point that is closest to the upper left-hand corner of the curve representing MCID.[37,40] A diagonal is drawn from the upper left corner of the ROC to the lower right corner. The point at which this diagonal intersects the curve is considered to be the point closest to the upper left corner, and hence the value of change in the LES at this site of intersection represents the MCID.[37] For ROC analysis, patients who were unsatisfied and somewhat satisfied were grouped into the "not improved" group, and those who were satisfied and very satisfied were grouped into the "improved" group. The entire cohort was included in the ROC analysis rather than just the values adjacent to the point of dichotomy, as this has been shown to increase precision of MCID estimation.[36] Sensitivity is the proportion of patients who are definitely satisfied and whose change in LES is above the threshold MCID value. Specificity is the proportion of patients who are not definitely satisfied and whose change in LES is below the threshold MCID value.

For the distribution-based approach, we first estimated the standard error of mean (SEM) and smallest detectable change (SDC). It has been reported that estimates based on measurement precision of outcome measurement (SEM) are better than estimates based on sample variation (effect size) or those based on statistical significance (paired *t*-test).[9] SEM is an indicator of random error during single use of an outcome instrument and is believed generally to be stable across different populations and different studies.[9,10] SDC or minimum detectable change (MDC) refers to the smallest change in the value of an outcome instrument that is greater than random measurement error associated with use of the instrument.[10] Both SEM and SDC are determined in a stable subgroup of patients in the study cohort. These patients either have perceived no change in clinical condition after an intervention or have experienced negligible or minimal change in their clinical condition.

Repeated application of an outcome instrument in the same patient should give a similar value if the condition has remained stable with no change. However, this is infrequently seen, and more often repeated application gives rise to slight changes in the value of the outcome instrument. This minimum change in value is likely to be due to the measurement error of the outcome instrument. SDC or MDC represents the threshold value beyond which any increase in the score of the outcome instrument is likely to indicate "true" change in clinical condition instead of error due to repeated administration of the outcome tool. A change in the value of an outcome instrument lower than the value of SDC might not indicate true change in the clinical condition, as this is likely to be due to the measurement error of the outcome instrument.

In this study, SEM was calculated as SEM = [standard deviation (SD) of baseline preoperative LES] × [square root of 1 – α], wherein α represents the reliability coefficient of the test-retest value of the outcome instrument in a stable group of patients[5,10,17,19]; α can be represented as either Cronbach α or the intraclass correlation coefficient. Commonly, 90% confidence limit is chosen for MDC and is calculated as $MDC_{90} = (1.65) \times (\text{square root of } 2) \times (\text{SEM})$.[5,10,17,19] Cronbach α based on standardized items was used to measure the reliability coefficient of test-retest in a stable group of patients.[19] Based on patients' response to the 4-point Likert-like satisfaction scale, those patients who felt somewhat satisfied after the TEA were considered to be stable patients, as they probably did not have significant change in their clinical condition. Various threshold values have been reported for the estimation of clinically meaningful change based on SEM including 1 SEM,[41] 1.96 SEM, and 2.77 SEM.[22] Norman et al[24] observed that a value of half the SD of the change in score of the outcome instrument was equal to MCID in a variety of studies, although it is believed that this is a conservative estimate of MCID. SPSS version 18 (SPSS Inc., Chicago, IL, USA) was used to do the statistical analysis.

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