Establishment of the Minimal Clinically Important Difference (MCID) for the Ankylosing Spondylitis Quality of Life (ASQoL) scale

RWD185

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Introduction

Axial Spondyloarthritis (axSpA) is an inflammatory rheumatic disease affecting the spine, sacroiliac and peripheral joints. AxSpA has significant implications for daily life of patients. The main goal of treatment is to control symptoms of the disease and to improve patients' quality-of-life (QoL).

Many studies designed to test **therapies for axSpA focus on the assessment of their impact on QoL of patients**. In majority of cases, the observed changes on health-related outcomes are analysed solely by the application of statistical 'significance' tests applied to the differences between pre- and post-intervention time points. Although it is important, it is increasingly recognised that the evidence of statistical 'significance' is not sufficient to prove that the intervention is effective [1] and clinical relevance must also be demonstrated [2].

The concept that captures this important issue is **Minimal Clinically Important Difference (MCID)** [3]. MCID refers to the amount of change observed in the outcome corresponding to the noticeable improvement (or sometimes deterioration) of patient's condition following the intervention [5].

Objectives

The primary objective of the current study was to determine the MCID value for one of the most commonly used quality-of-life measures for axSpA patients, which is **Ankylosing Spondylitis Quality of Life (ASQoL)**, an 18-item self-reported instrument proved to be valid, reliable, and responsive [4].

The secondary objective of the study was to compare MCID values obtained by the application of various methods.

Data and participants

The data used in this study were historical electronic patient records collected by Royal National Hospital for Rheumatic Diseases, Bath, UK on its patients attending the RNHRD axSpA rehabilitation programme.

Data included 290 patients (228, 79% males) who attended at least two assessments scheduled (a) just before the rehabilitation course and (b) 2 weeks later, after the course. Majority of patients (187; 61%) were 50yo+.

All patients met ASAS classification criteria.

Methods

There are a number of methods in the literature used to determine MCID [5]. In general, they can be classified into one of two categories: (i) distribution-based methods and (ii) anchor-based methods [6]. Each group has its strong advocates and critics and there is still no consensus amongst researchers on how the MCID should be operationalised. In a growing number of studies, the pragmatic approach is adopted by researchers who determine MCID as the average of the MCID-values obtained from a number of applied methods, both from distribution- and anchor-based groups [7]. This approach was also used in the current study, using three common and best justified anchor-based methods (1-3) and three distribution-based methods (4-6).

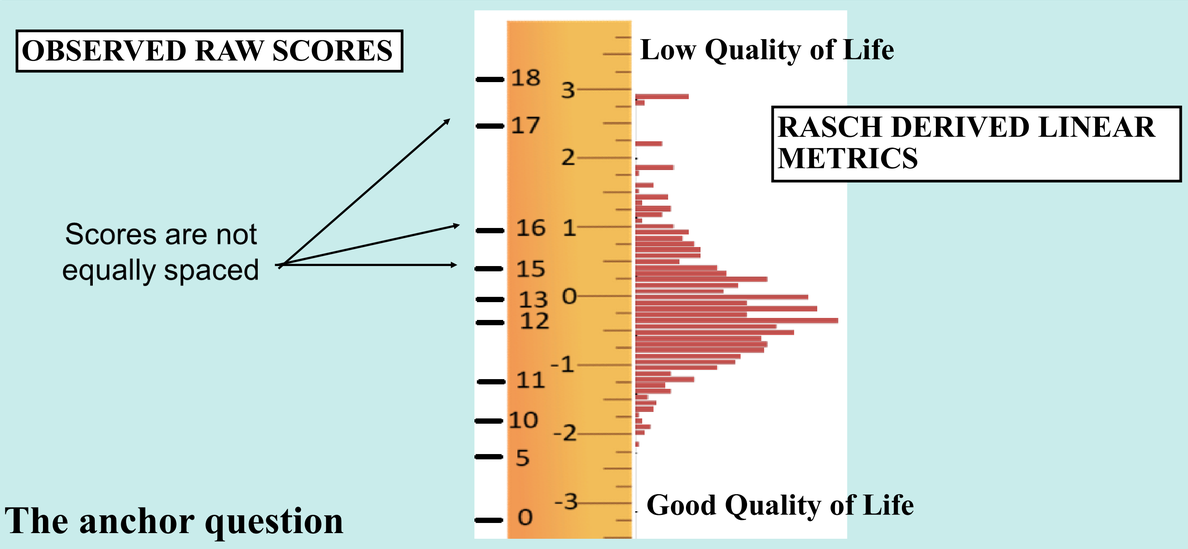
Distribution-based methods	Anchor-based methods
1. MCID is a value corresponding to the Cohen's effect size of 0.50 [8].	**4. MCID value is identified as the difference between the average scale change of responders and the average score change of non-responders.**
2. MCID is equal to 0.50 of standard deviation (SD) value of change score computed as the difference between the observed values on baseline and follow-up timepoints [9].	**5. MCID value is derived from ROC curve analysis. It is determined at the point of the ROC curve in which sensitivity and specificity are maximised.**
3. MCID is a change on outcome variable larger than standard error of measurement (SEM): SEM=SD√(1-reliability) [10].	**6. MCID is defined as the coefficient associated with the unit change on anchor variable in the regression model predicting the change score (difference between baseline & follow-up).**

Results

The Rasch transformation

All the MCID values were calculated on the ASQoL measure in its Rasch transformed version (interval-level scale with logit unit). Rasch analysis applied to the patient data has confirmed good psychometric properties of ASQoL, proving that its items and patients can be mapped onto the single axis (unidimensionality).

Rasch measures used for the purpose of MCID calculations have advantage over observed raw (sum) scores, as they have truly linear metrics (with equal unit over the whole QoL continuum). Also, raw scores are not equally spaced which exclude them from the analyses requiring continuous variables as an input, such as those used for determining MCIDs.



The anchor question

A ***general health*** question was used as an 'anchor' in the anchor-based methods. It asked patients about the recent activity of disease on a 0 to 10 scale with labelled ends (none to severe, respectively). This question was presented to patients before and after the rehabilitation course and the improvement/deterioration on this item defined categories of 'responders' and 'non-responders'.

The MCID values for ASQoL Rasch measure derived from application of the different methodological approaches presented in Table 1. Results for anchor-based methods present lower variability. Those obtained by Change Difference and ROC curve approaches tend to converge for improvement and deterioration which may suggest that the patients' subjective perception of improvement and getting worse are symmetrical phenomena. However, it is not confirmed by the results obtained within the regression analysis approach.

Table 1. MCID values for ASQoL measure obtained from different methods

	Anchor-based methods			Distribution-based methods		
	1. Change difference	2. ROC curve	3. Regression analysis	4. Cohen's Effect size =0.50	5. Std error of measurement (SEM)	6. ½SD
Improvement*	0.603	0.345	0.284	0.869	0.246	0.597
Deterioration	0.577	0.372	0.026			

Following the pragmatic approach, the average of the MCID-thresholds obtained from all applied methods was computed. The average MCID for anchor-based improvement and distribution-based methods was 0.49 logit. The average value for anchor-based deterioration and distribution-based methods was 0.45 logit. Both numbers are very close and if rounded to a single decimal are both 0.50 logit.

Conclusions

The MCID value for ASQoL measure both for improvement and deterioration is 0.50 logit. It is a clear and robust value and finds support both on empirical and theoretical grounds.

References

[1] Draak et al., 2019; [2] Sedaghat, 2019; [3] Jaeschke et al., 1989; [4] Doward, 2003; [5] Crosby et al., 2003; [6] Mouelhi et al., 2020 [7] Sinha et al., 2019; [8] Cohen, 1988) ; [9] Norman et al., 2003; [10] Wyrwich et al., 2002.

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