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Improved adjusted minimal important change took reliability of transition ratings into account

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Abstract

Objectives: The anchor-based minimal important change (MIC), based on the receiver operating characteristic (ROC) analysis or predictive modeling, is biased by the proportion of improved patients. The adjusted MIC, published in 2017, adjusts the predictive MIC for this bias but does not take the reliability of the transition ratings (i.e., the anchor) into account. The aim of this study was to examine whether the transition ratings reliability affects the accuracy of the adjusted MIC and, if so, whether the adjustment can be improved.

Study Design and Setting: Multiple simulations of patient samples involved in anchor-based MIC studies with different characteristics of patient-reported outcome scores were used to determine the impact of reliability of the transition ratings on the MIC estimate. An improved adjustment formula was derived in an exploration set of simulated samples (number of samples = 19,440) and validated in a different set of simulated samples (number of samples = 12,960). The effect of sample size (100−1,000) was also evaluated in simulated datasets.

Results: Reliability of the transition ratings biased the MIC estimate if the proportion improved was different from 0.5. The improved adjustment formula performed well, especially if the proportion improved was between 0.3 and 0.7. Smaller sample sizes were at the expense of the precision of the MIC estimates.

Conclusion: We provide an improved formula for calculating the adjusted MIC, taking into account the proportion of improved patients and the reliability of the transition ratings.

Keywords: Adjusted minimal important change; Minimal important difference; Receiver operating characteristics; Predictive modeling; Proportion improved patients; Reliability of transition ratings

1. Introduction

The minimal important change (MIC) is the smallest change in a patient-reported outcome measure (PROM) score that patients on average consider important [1,2]. As change can refer to improvement or deterioration, for simplicity we will limit the present discussion to one direction of change: improvement. The MIC can be conceptualized as the PROM change score that corresponds to the mean of patients' individual thresholds for a meaningful or important improvement [3]. It is assumed that people have their individual MICs and we denote the group mean individual MIC as the "genuine MIC" [3]. Various methods are used to estimate MIC values; these can be categorized in two groups: distribution-based methods and anchor-based methods [2]. Because distribution-based methods do not relate to the patient perspective of an important change [4], we will focus on anchor-based methods. The anchor represents an external criterion of what constitutes a (minimally) important change. The most frequently used anchor is a single-item patient-reported "transition question" (also called a "patient global impression of change") by which patients rate their perceived

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Conflicts of interest: None.

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What is new?

Key findings

- The (un)reliability of transition ratings amplify the bias in minimal important change (MIC) estimates based on predictive modeling due to the proportion improved if the proportion improved is smaller or greater than 50%.

- The predictive MIC estimate can be simultaneously adjusted for both the proportion improved and the (un)reliability of the transition ratings using an improved formula.

What this adds to what was known?

- The method to adjust the predictive MIC for the proportion improved has now been extended to adjust additionally for the (un)reliability of the transition ratings.

What is the implication and what should change now?

- MIC estimates based on predictive modeling should be adjusted for the proportion improved and the (un)reliability of transition ratings if the proportion improved deviates from 50%.

change on an ordinal scale (e.g., ‘‘much better,’’ ‘‘a little better,’’ ‘‘about the same,’’ ‘‘a little worse,’’ and ‘‘much worse’’) [5]. Transition rating scales are used with 5, 7, up to 15 response options [6]. The most popular methods to link the change score to the anchor are the mean change method [7,8], receiver operating characteristic (ROC) analysis [9], and predictive modeling [3,10]. The mean change method simply takes the mean of the change scores in the group scoring ‘‘a little better’’ on the anchor as the MIC. Drawbacks of this method are the relatively small number of patients on which the MIC is based and the fact that this method does not really estimate the (mean) threshold for a meaningful change (i.e., the genuine MIC) because all patients scoring ‘‘a little better’’ have passed their thresholds [11]. The ROC method defines MIC as the change score cutoff that optimally classifies improved and not-improved patients. The predictive modeling method defines MIC as the change score that is equally likely to occur in the improved and not-improved groups [10]. The ROC method and predictive modeling method require that the transition ratings (i.e., the anchor) are dichotomized into ‘‘improved’’ and ‘‘not-improved’’. Both methods provide an accurate estimate of the genuine MIC if the improved and not-improved groups are equally sized (i.e., if the proportion improved is 0.5) [3]. If the proportion improved is greater than 0.5, the ROC and predictive modeling MICs will be overestimated relative to the genuine MIC, and conversely, if the proportion improved is smaller than 0.5 the MICs will be underestimated [3]. However, based on simulations, the predictive modeling MIC proved suitable to be adjusted for the bias induced by the proportion improved (but the ROC-based MIC is too imprecise to make adjustment feasible) [3]. In other words, the ‘‘adjusted MIC’’, which is the topic of this article, identifies the genuine MIC (i.e., the mean of the individual MICs) irrespective of the proportion improved.

The performance of the adjusted MIC was tested in simulated samples that varied with respect to the mean and variance of the (true) baseline PROM score, the mean and variance of the (true) PROM change score, the mean and variance of the individual MICs, and the reliability of the PROM. The simulations (implicitly) assumed that the transition ratings were valid and reliable indicators of the true change between baseline and follow-up. However, this assumption might be problematic, because it was recently shown that the reliability of transition ratings in four real datasets ranged from 0.27 to 0.48 [12]. This finding raises the question whether the (un)reliability of transition ratings affects the predictive MIC and whether the adjusted MIC is able to identify the genuine MIC in the face of less than perfect reliability of the transition ratings. In case the current adjustment formula does not suffice, an additional question is whether the formula can be improved.

This article is organized as follows. Section 2 examines the effect of transition ratings reliability on the predictive and adjusted MIC estimates in simulated datasets. Section 3 derives an improved formula for the adjusted MIC, based on simulated datasets. Section 4 examines the effect of sample size on the improved adjusted MIC estimates in samples with various proportions improved and transition ratings reliability values. Section 5 discusses implications and limitations of the improved adjusted MIC method.

2. Effect of transition ratings reliability

In the present section we examine whether transition ratings reliability affects the predictive and adjusted MICs in simulated datasets (for the simulation design: Supplement, Chapter 1). For comparison, we examine also the effect on the ROC-based MIC. The advantage of using simulations is that the true MIC, which is unknown in real data, can be simulated, after which the results of methods to estimate the MIC can be evaluated as to the extent to which the method is able to recover the true (as simulated) MIC.

We simulated datasets varying only the proportion improved and the transition ratings reliability (the R-code is provided in the Supplement, Chapter 7). The mean and standard deviation (SD) of the true baseline (T1) scores were (arbitrarily) set to 40 and 10, respectively. The reliability of the observed T1 score was (arbitrarily) set to 0.80. The genuine MIC was (arbitrarily) set to 15. The

SD of the true change score was (arbitrarily) set equal to the SD of the true T1 score. Given fixed values for the individual MICs and the SD of the true change score, the mean true change score determines the proportion improved (i.e., the proportion of patients whose true change score exceeded their individual MIC). Therefore, to obtain varying proportions improved between 0.2 and 0.8, the mean true change score was varied between 7 and 23 in steps of one. No correlation between the true T1 score and the true change score was simulated. Finally, the reliability of the perceived change (which equals the reliability of the transition ratings, Supplement, Chapter 1) was varied across the values 1, 0.7, and 0.4. We generated 150 samples for each of the 17 (levels of proportion improved) * 3 (levels of the transition ratings reliability) = 51 different combinations of sample parameters, yielding a total number of 7,650 samples. In each sample, we estimated the predictive MIC [10], the adjusted MIC [3], and the ROC-based MIC [9] (Supplement, Chapter 2: for the details of calculating the predictive MIC and the adjusted MIC). The ROC-based MIC was determined as the optimal ROC cutoff point as per the Youden criterion [13].

Fig. 1 shows the relationship between the predictive and adjusted MICs with the proportions improved, for different transition ratings reliability values. Note that the horizontal scale shows the log odds of improvement (i.e., the natural logarithm of the odds of improvement) instead of the proportion improved because the relationship with the proportion improved is nonlinear, whereas the relationship with the log odds of improvement is practically linear [3]. Log odds values of −1, 0, and 1 correspond to proportions improved of 0.27, 0.50, and 0.73, respectively. The upper panel of Fig. 1 shows that the estimated predictive MIC values decreased as the proportions improved decreased, and conversely, the predictive MIC values increased as the proportions improved increased. In addition, this effect on the predictive MIC was amplified by (un)reliability of the transition ratings. Only when the proportion improved was 0.5, the estimated MIC accurately identified the genuine MIC (indicated by the horizontal dashed lines in Fig. 1). The ROC-based MIC is affected in the same way by the proportions improved and the (un)reliability of the transition ratings (Supplement, Chapter 3). The lower panel of Fig. 1 shows that the adjusted MIC worked reasonably well for correcting the biasing effect of the proportion improved, but it failed to correct for the additional effect of transition ratings reliability.

3. Updating the adjusted minimal important change

In this section, we present an updated formula for the adjusted MIC to account for both the biasing effect of the proportion improved and the reliability of the transition ratings. Furthermore, we examine the performance of the improved adjusted MIC formula with respect to recovering the genuine MIC across two large sets of simulated samples.

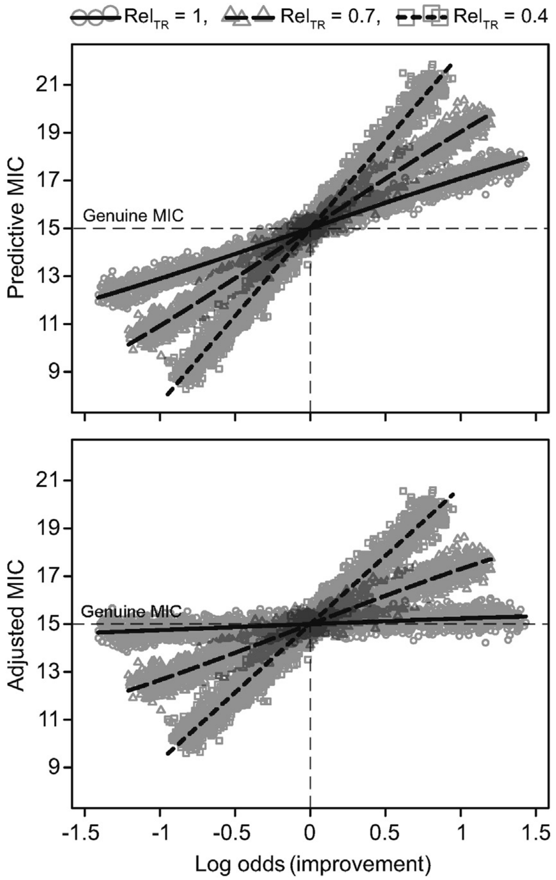

Fig. 1. Associations of the estimated predictive MIC (upper panel) and the adjusted MIC (lower panel) with the log odds (i.e., the natural logarithm of the odds) of improvement and the reliability of the transition ratings ($\mathrm{Rel}_{\mathrm{TR}}$) across 7,650 simulated samples in which the genuine MIC was fixed at 15 (indicated by horizontal dashed lines).

For the adjusted MIC formula derivation and validation we followed a similar analytical strategy as in our previous study [3]. We simulated two sets of samples, one set to derive the updated adjusted MIC formula, called the "exploration set" ($n = 19{,}440$ samples), and the other set to validate the formula, called the "validation set" ($n = 12{,}960$ samples; details of the analyses are provided in the Supplement, Chapter 4).

The updated adjusted MIC formula, derived from the exploration set through a linear regression analysis, is shown in Box 1. The formula shows that the adjusted MIC takes the predictive MIC and subtracts the term $[(0.8/\mathrm{Rel}_{\mathrm{TR}} - 0.5) * \mathrm{SD}_{\mathrm{change}} * Cor * \text{log odds (imp)}]$. Note that the value of the subtracted term is in the metric of the PROM scale, thanks to the inclusion of $\mathrm{SD}_{\mathrm{change}}$. Assuming that *Cor* is positive (as it should be if the change score and the transition ratings are scored in the same direction), the term is positive if the proportion improved is greater than 50% (i.e., if log odds (imp) is positive), and the adjusted MIC will become smaller than the predictive MIC.

Box 1 Formula for calculating the adjusted MIC

$\text{MIC}_{\text{Adjusted}} = \text{MIC}_{\text{Predictive}} - (0.8/\text{Rel}_{\text{TR}} - 0.5) * \text{SD}_{\text{change}} * \mathit{Cor} * \text{log odds(imp)}$

Explanation:

$\text{MIC}_{\text{Adjusted}}$ = Improved adjusted minimal important change.

$\text{MIC}_{\text{Predictive}}$ = Predictive minimal important change.

Rel_{TR} = Reliability of the transition ratings.

Cor = Point biserial correlation between the PROM change score and the dichotomous transition ratings.

$\text{SD}_{\text{change}}$ = standard deviation of the PROM change score.

log odds(imp) = natural logarithm of [proportion improved/(1 − proportion improved)].

However, if the proportion improved is smaller than 50% (i.e., if log odds (imp) is negative), the term becomes negative, and the adjusted MIC will become larger than the predictive MIC.

Table 1 shows the residual statistics of the genuine MIC minus the adjusted MIC across both the exploration and validation set of simulated samples. The mean difference between the genuine MIC and the adjusted MIC was zero, indicating that the adjusted MIC was an unbiased estimate of the genuine MIC. The adjusted MIC was in some samples a little off the mark but in 95% of the samples this was less than 1.3 point on a scale of approximately 100 points. The root mean square error indicated that the average deviation of the adjusted MIC (either above or below) from the genuine MIC across all samples was about 0.6 points. However, it is important to note that this degree of precision depends on the sample size.

We examined the effect of the correlation between the transition ratings and the change scores on the accuracy and precision of the adjusted MIC estimates. In the validation set, the mean (point biserial) anchor-change correlation was 0.41 (range: 0.13−0.69). In 2,710 samples (21%) the correlation was smaller than the minimally recommended 0.30; in these samples the bias in the adjusted MIC estimate was −0.01 and the root mean square error was 0.79 (these numbers can be compared with Table 1). So, small anchor-change correlations do not pose a big problem for the accuracy (i.e., bias) of the adjusted MIC estimation, but they do so for its precision.

Table 1. Residual statistics for the adjusted MIC as predictor of the genuine MIC

Statistic	Exploration set	Validation set
Mean (bias)	−0.00	0.00
Minimum	−4.46	−4.71
Maximum	5.75	5.94
95% confidence interval	−1.27, 1.27	−1.19, 1.22
Variance	0.39	0.35
Mean square error (bias^2+variance)	0.39	0.35
Root mean square error	0.62	0.59

4. Effect of sample size and proportion improved

To assess the effect of sample size on the adjusted MIC, we simulated samples with various sample sizes (100, 200, 500, and 1,000) and proportions improved (between 0.2 and 0.8 in steps of 0.1) under different transition ratings reliability values (0.30 and 0.60). For each specific combination of parameters 1,000 samples were created. Other specifications of the samples were mean true T1 score = 40, SD true T1 score = 10, reliability of the T1 score = 0.80, SD true change score = 10, correlation between true T1 score and true change score = −0.30, mean of the individual MICs (genuine MIC) = 5, and SD of the individual MICs = 0.5 (the R-code is provided in the Supplement, Chapter 7). The estimated adjusted MICs are shown in Table 2 for transition ratings reliability of 0.30 and in Table 3 for transition ratings reliability of 0.60. The results show that the adjusted MIC accurately recovered the genuine MIC if the proportion improved was between 0.3 and 0.7. However, if the proportion improved was outside that interval, the adjusted MIC tended to become somewhat biased, depending on the transition ratings reliability. This is probably due to the bias not being a strictly linear effect of the log odds of improvement and the reliability of the transition ratings. The precision of the adjusted MIC estimate decreased as the total sample size decreased (as can be expected) and also as the proportion improved deviated further from 0.5 (i.e., if improved and not-improved groups were unequally sized). That is because the precision of the estimate is largely determined by the size of the smallest group.

In Section 2 we showed that the predictive MIC is only biased by the proportion improved and the transition ratings reliability if the proportion improved is not 0.5. Therefore, if the proportion improved is (close to) 0.5 using the simpler formula for the predictive MIC (Supplement, Chapter 2) [10] instead of the adjusted MIC results in a significant gain in precision of the MIC estimate. For instance, in Table 2 the 95% confidence interval (CI) of the adjusted MIC estimate for a sample size of 100 and a proportion improved of 0.5 was 0.6−9.5, whereas the 95% CI of the predictive MIC across the same samples was much narrower: 2.9−7.2.

5. Discussion

The adjusted MIC published in 2017 did not take the reliability of the transition ratings into account. However, like all measurements, transition ratings are subject to measurement error. This study showed that the measurement

Table 2. Estimated adjusted MIC values with 95% confidence intervals, by proportion improved and sample size (genuine MIC = 5, reliability of transition ratings = 0.3, number of samples per estimate = 1,000)

	Sample size			
Proportion improved	**100**	**200**	**500**	**1,000**
0.20	4.1 (−3.9, 14.0)	4.0 (−2.1, 10.4)	4.1 (0.3, 8.3)	4.1 (1.6, 6.9)
0.30	4.8 (−0.8, 11.3)	4.8 (0.7, 9.7)	4.9 (2.1, 8.0)	4.9 (3.0, 6.9)
0.40	5.0 (0.8, 10.7)	5.0 (1.8, 8.6)	5.1 (3.1, 7.4)	5.0 (3.6, 6.6)
0.50	5.0 (0.6, 9.5)	4.9 (1.7, 8.0)	5.0 (3.1, 6.9)	5.0 (3.7, 6.4)
0.60	4.8 (−0.8, 9.2)	4.9 (0.7, 8.2)	5.0 (2.8, 7.1)	4.9 (3.4, 6.4)
0.70	4.9 (−2.3, 10.8)	5.1 (−0.2, 9.4)	5.1 (2.1, 7.9)	5.2 (3.2, 6.9)
0.80	5.9 (-3.1, 14.4)	5.8 (-1.1, 11.7)	5.9 (1.8, 9.5)	5.9 (3.3, 8.5)

error in transition ratings has an aggravating effect on the bias caused by the proportion of improved patients. If the proportion improved is (close to) 0.5, the transition ratings reliability causes no bias in the predictive MIC estimate. Therefore, if the proportion improved is (close to) 0.5, the predictive MIC will recover the genuine MIC accurately. For that reason, when designing an MIC study, a proportion improved of 0.5 is preferably targeted. However, in many cases the proportion improved is not under the control of the researcher. If the proportion improved deviates from 0.5, we recommend applying the improved adjustment formula presented in Box 1. The (improved) adjusted MIC appeared to perform well in samples with proportions improved between 0.3 and 0.7. Outside that range there will remain some residual bias, depending on the reliability of the transition ratings.

Calculating the adjusted MIC requires the estimation of the transition ratings reliability, which can be performed using a confirmatory factor analysis [12]. In the Supplement we provide an R-code to estimate the reliability of transition ratings and the adjusted MIC with 95% CIs in real datasets (Supplement, Chapter 5). Moreover, we have developed an R-package MIC [14] (Supplement, Chapter 6 shows a demo).

Because it was impossible to simulate any conceivable combination of sample parameters, we provide an online MIC simulation tool (https://iriseekhout.shinyapps.io/MICvalidation/) that allows researchers to simulate a user-specified number of samples with user-specified characteristics (including the genuine MIC) and observe the mean ROC-based, predictive, and adjusted MIC estimates with their 95% CIs. This tool can be used to examine the MIC estimates and observe their accuracy and precision with respect to recovering the genuine MIC under various circumstances. Researchers can also use the tool to simulate their data (or data they are planning to collect) to examine the validity of their MIC estimates using the methods provided.

An important limitation of the adjusted MIC method is that it assumes normally distributed PROM scores and PROM change scores. Future studies need to examine the performance of the adjusted MIC in samples with skewed PROM scores and floor or ceiling effects.

If we wish to recover the sample mean of the hypothetical individual MICs (i.e., the genuine MIC), in principle, the ROC method and the predictive modeling method are eligible if the proportion improved is 0.5. However, both methods are subject to bias if the proportion improved is smaller or greater than 0.5. Moreover, the ROC method is much more imprecise than the predictive modeling method. The adjusted MIC, however, is able to adjust the bias in the predictive MIC, recovering the genuine MIC irrespective of the proportion improved. Therefore, we recommend replacing the ROC method by the predictive MIC method if the proportion improved is (close to) 0.5 and by the adjusted MIC method if the proportion improved deviates from 0.5. Other MIC

Table 3. Estimated adjusted MIC values with 95% confidence intervals, by proportion improved and sample size (genuine MIC = 5, reliability of transition ratings = 0.6, number of samples per estimate = 1,000)

	Sample size			
Proportion improved	**100**	**200**	**500**	**1,000**
0.20	4.6 (0.3, 9.6)	4.6 (1.8, 8.0)	4.6 (2.5, 6.9)	4.6 (3.3, 6.0)
0.30	5.1 (1.8, 9.0)	5.0 (2.7, 7.8)	5.0 (3.5, 6.8)	5.0 (3.9, 6.2)
0.40	5.1 (2.1, 8.5)	5.0 (2.9, 7.2)	5.1 (3.8, 6.4)	5.1 (4.1, 6.0)
0.50	5.0 (1.9, 8.0)	4.9 (2.9, 7.1)	5.0 (3.7, 6.4)	5.0 (4.2, 5.9)
0.60	4.8 (1.6, 7.6)	4.9 (2.5, 7.2)	4.9 (3.4, 6.2)	4.9 (4.0, 5.8)
0.70	4.8 (0.9, 8.1)	4.9 (2.3, 7.3)	5.0 (3.2, 6.5)	5.0 (3.9, 6.0)
0.80	5.3 (0.1, 9.9)	5.4 (1.6, 8.6)	5.4 (3.2, 7.3)	5.5 (4.0, 6.8)

methods, such as the mean change method, do not target the genuine MIC. Thus, published MIC values (most frequently based on the mean change method and the ROC method) are difficult to compare with the adjusted MIC method. How the mean change method compares to the adjusted MIC method could be examined in future research.

The strength of an anchor is usually expressed in the anchor-change score correlation. This correlation is determined by (a) the substantive correspondence between the anchor question and the PROM construct, (b) the measurement error in the anchor, and (c) the measurement error in the PROM change scores. The reliability of the transition ratings reflects the combined impact of (a) and (b). Stronger anchors are associated with higher precision of the MIC estimates, but weaker anchors do not necessarily produce inaccurate estimates. A large sample size can partly compensate for the loss of precision due to a weak anchor. Knowledge of the genuine MIC value can help clinicians to evaluate the relevance of individual and group (mean) PROM change scores [11]. However, when interpreting individual change scores the clinician should take into account that the MIC of a specific individual patient may be greater or smaller than the group average MIC (i.e., the genuine MIC) and that PROM change scores inevitably come with measurement error.

CRediT authorship contribution statement

Berend Terluin: Conceptualization, Formal analysis, Methodology, Writing - original draft, Writing - review & editing. **Iris Eekhout:** Software, Writing - review & editing. **Caroline B. Terwee:** Methodology, Supervision, Writing - review & editing.

Supplementary data

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