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An Updated Minimal Clinically Important Difference for the QoR-15 Scale

To the Editor:

We have previously reported the minimal clinically important difference for three quality of recovery (QoR) scales.[1] The minimal clinically important difference describes the smallest change in score that constitutes a meaningful change in health status—in our case, this pertains to QoR after surgery. We had estimated the minimal clinically important difference of the QoR-15 using an average (triangulation) of three distribution-based methods (0.3 SD, standard error of the measurement, and 5% range), and a standard anchor-based method,[2,3] resulting in an minimal clinically important difference of 8.0.[1] Distribution-based methods are based on the statistical variability of assessment scales, accounting for measurement error.[2] The anchor-based method uses repeat patient ratings that quantify the extent of change (*i.e.*, improvement or deterioration) of health status over time.[2,4–7] This method calibrates ("anchors") the change in health status—here quality of recovery measured by the QoR-15 scale—as perceived by patients relative to their previous state.

We have had an ongoing concern that our original estimation of minimal clinically important difference for the QoR-15 scale (minimal clinically important difference = 8.0) was too high. This is in part because of the discrepancy between the three distribution (mean minimal clinically important difference = 5.7) and anchor-based (minimal clinically important difference = 13) estimates in our original report[1] and experience in measuring patient outcomes after surgery in a recent large clinical trial evaluating dexamethasone in which patients reported less postoperative nausea and vomiting and less acute pain at rest.[8] This concern is further heightened when considering previous estimations of the responsiveness of the QoR-15,[9,10] which indicate very high ability to detect real change. There are several shortcomings of anchor-based methods, including that anchor questions used to establish minimal clinically important difference are rarely validated and are susceptible to recall bias[11] and will be affected by outliers. We have therefore undertaken further analysis.

An additional method of determining the minimal clinically important difference is to use receiver operating characteristic curve analysis.[12,13] A receiver operating characteristic curve plots the trade-off between the sensitivity and specificity of a binary diagnostic test, in this case correctly identifying whether minimal improvement (or greater) in QoR has occurred, according to change in QoR-15 score. We defined "minimal improvement" as a change from +1 to +2 or more (more than 1 point) on the 15-point Likert scale used in the original anchor-based method.[1] The area under the receiver operating characteristics curve (AUC) would equal 1 where a test has both perfect sensitivity and specificity, and an AUC of 0.5 represents discrimination that is no better than chance. When used for estimation of minimal clinically important difference, sensitivity is defined as the proportion of patients who report improvement based on the external criterion and have a patient-reported outcome—here at least minimal improvement in the QoR-15 score. The minimal clinically important difference is the point on the receiver operating characteristic curve that achieves the optimal trade-off between sensitivity and specificity, and the Youden index (maximal sensitivity + specificity − 1) provides an index of the improvement in sensitivity above chance at this point.[14]

Using this approach on the original dataset,[1] we found that the AUC was 0.83 (95% CI: 0.74 to 0.91), $P < 0.001$ (see fig. 1), indicating excellent discrimination.[15] A change in QoR-15 score of both 3.5 and 4.5 yielded the highest sensitivity (0.765 and 0.735, respectively) and specificity (0.758 and 0.788, respectively), resulting in a Youden's index of 0.52.

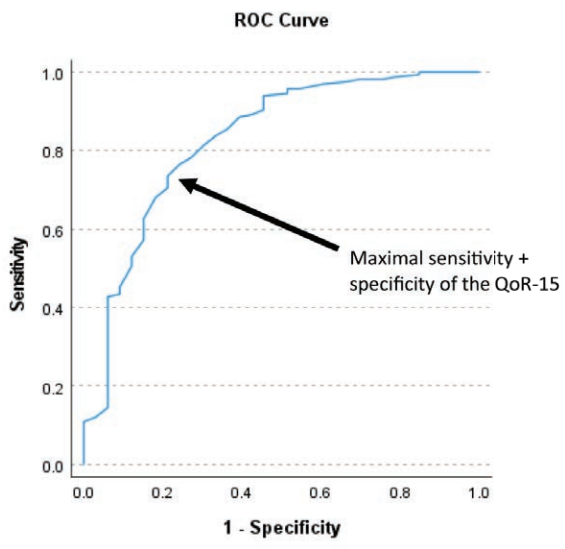

Fig. 1. The receiver operating characteristic curve (ROC) depicting sensitivity and specificity of a change in the QoR-15 score to predict minimal improvement in quality of recovery after surgery.

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If we now include the average of these values (4.0) in the previous averaged estimate using distribution and anchor-based methods,[1] the pooled mean minimal clinically important difference for the QoR-15 becomes 6.8 (median 5.7). However, given the consistency across distribution and ROC methods, we therefore recommend that the minimal clinically important difference for the QoR-15 scale be updated to a value of 6.0. We hope this can better guide sample size calculations for clinical trials and assist clinicians to interpret results of clinical studies.

Competing Interests

Dr. Paul S. Myles led the development and original validation of the QoR scales. Dr. Paul S. Myles is supported by a National Health and Medical Research Council (NHMRC) Practitioner Fellowship, Canberra, Australia. Mr. Daniel B. Myles is supported by the Australian Government Research Training Program, New South Wales Department of Health, Office of Responsible Gambling, Sydney, Australia. The authors declare no other competing interests.

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