Minimal clinically important differences in average, best, worst and current intensity and unpleasantness of chronic breathlessness

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ABSTRACT

Background: Chronic breathlessness has devastating consequences. The minimal clinically important difference (MCID) for current intensity has been estimated as 9 mm on a 100-mm visual analogue scale (VAS). We aimed to determine MCIDs for commonly used dimensions and recall periods: the current unpleasantness and current, average, best and worst intensity of the past 24 h for chronic breathlessness.

Methods: This was a secondary analysis of a randomised controlled trial of morphine *versus* placebo over 7 days in people with chronic breathlessness from severe disease. The breathlessness scores were self-reported using a diary each evening on 100-mm VAS. The MCID for improvement in each score was estimated using anchor-based and distribution-based methods.

Results: 283 participants (mean age 74.2 years; 63% male; 58% COPD; 87.0% modified Medical Research Council (mMRC) score 3–4) were included. Anchor-based MCIDs for breathlessness scores ranged from −13.9 mm to −9.5 mm. The MCIDs were similar when using different anchors and across all participants, and participants with more severe breathlessness (mMRC 3–4). Distribution-based effect sizes were classed as small (−4.7−6.3 mm), moderate (−9.4−12.5 mm) and large (−15.0−20.0 mm) effect. Sample sizes for trials using the different scores were proposed. MCIDs of absolute change were more stable than using relative change from baseline.

Conclusion: An improvement of ∼10 mm on a 100-mm VAS is likely to be clinically meaningful across commonly used measures of chronic breathlessness (current intensity, unpleasantness, and average, best and worst intensity over the past 24 h) to evaluate clinical benefit and effects in therapeutic trials.