Brief Communication

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The Minimum Important Difference of the Incremental Shuttle Walk Test Distance in Patients with COPD

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Abstract

We aimed to describe the minimum important difference (MID) of the ISWT in patients with COPD using both distribution- and anchor-based methods. Two cohorts were used (n=613) with eligibility criteria of a clinical diagnosis of COPD, an $FEV_1/FVC<70\%$, and an ISWT (after familiarisation) before and after a seven week course of pulmonary rehabilitation (PR). The MID of the ISWT using the distribution method was 36.1m. The area under the curve to discriminate between perceived 'improvement' or 'no improvement' post-PR for a change in ISWT of 35m was 0.66 [0.58–0.73]. The MID of the ISWT is therefore between 35.0-36.1m.

Introduction

Understanding the minimum important difference (MID) of outcome measures is essential for evaluating the effectiveness of clinical interventions. There are a number of recognised approaches to define the MID which are selected depending upon the purpose. Across a variety of exercise tests different approaches have been employed to define the MID for example distribution- and anchor-based methods (1). An inconsistent approach in MID methodology introduces bias particularly when interventions are being assessed against different thresholds. The MID for the 6MWT is 25 - 35m using either the anchor and distribution methods (2-4), whilst the MID for the ISWT is 48m and has only been described using an anchor based approach with a global ratings of change score (5).

We therefore aimed to further describe the minimum important difference (MID) of the ISWT in patients with COPD using both the distribution- and anchor-based methods.

Methods

Two databases were used: the original cohort (n=327) developed to describe the minimum clinically important improvement of the ISWT (5) (cohort 1) and a further cohort of patients (n=286) developed to describe the 'iBODE' (cohort 2)(6). All included participants had a clinical diagnosis of COPD, a FEV_1/FVC <70%, and completed an ISWT (after familiarisation) before and after a seven week course of pulmonary rehabilitation (PR) previously described (5). In cohort 1, after performing their final ISWT, participants were asked how they felt compared to when they completed the test at the start of PR using a global ratings of change score (5;7): 1. much better, 2. a little better, 3. about the same, 4. a little worse and 5. much worse. Categories 1 and 2 were combined to represent a group who perceived 'improvement' and categories 3,4 & 5 were combined and represented 'no improvement'.

The databases were combined to describe the MID using the distribution method. For the anchor-based method, the MRC dyspnoea scale grade (cohort 1) and the Chronic Respiratory Questionnaire - Dyspnoea domain (CRQ-D) (cohort 2) were used.

Statistical analysis

The baseline demographics were described as mean (SD) for normally distributed data and median [IQR] for non-normal data. The change in ISWT distance (m) before and after PR was assessed using paired t-tests. The distribution-based method (effect size) was calculated using 0.5 x the SD of the change in the ISWT distance (m) (8). Multiple linear regression was used to analyse the association between the change in ISWT and the potential anchors adjusted for age, gender and FEV_1, and to be an anchor an r value of >0.3 was required (7). The sensitivity and specificity for the change in ISWT between those who felt they had 'improved' versus 'not improved' were calculated and a receiver operatory curve constructed.

An AUC of at least 0.7 has previously been suggested as acceptable for other measures of health status (9).

Results

The demographics of the participants in both cohorts are shown in Table 1. Over 95% of the participants had an ISWT <400m.

Table 1. Patient demographics and baseline data for both cohorts

	Cohort 1 (n=327)	Cohort 2 (n=286)
Age (yr)	68.8 [9.3]	69.5 [8.4]
Gender (% male)	55.2	56.5
FEV_1 (L)	1.07 [0.51]	0.95 [0.43]
FEV_1/FVC	44.2 [12.3]	45.1 [11.1]
MRC grade †	4.0 [3.0 to 5.0]	4.0 [3.0 – 5.0]
CRQ-Dyspnoea domain	2.2 [1.1]	NA
ISWT (m)	180 [100 - 280]	180 [90 - 260]

Mean [SD] unless † median [IQR], yr: year, FEV_1: Forced Expiratory Volume in 1 second, FVC: Forced Vital Capacity, MRC: Medical Research Council, CRQ: Chronic Respiratory Questionnaire, ISWT: Incremental Shuttle Walk Test distance.

The mean [SD] change in ISWT (m) after pulmonary rehabilitation was 63.2 [72.1] m, ($p<0.001$) for both cohorts. The MID of the ISWT using effect size was therefore 36.1 m.

There was no relationship between baseline ISWT distance and the change in ISWT distance with PR $r = -0.067$, $p=0.061$, as previously described (10) therefore only the absolute change in ISWT distance was used and not the percent change from baseline. There was no correlation between the change in ISWT distance and the change in MRC grade after PR, r =

0.136, p < 0.364, and either no correlation or a weak correlation between the change in ISWT and the four domains of the CRQ: CRQ-Dyspnoea r = 0.162, p=0.203; CRQ-Fatigue r = 0.226, p = 0.008; CRQ-Emotional Function r = 0.214, p = 0.015; CRQ-Mastery r = 0.128, p = 0.538. These outcome measures could therefore not be used as anchors.

The global rating scale was combined into 'improved' (80.7%, n= 264) or 'not-improved' (19.3%, n=63) with a mean [SD] change in ISWT distance of 66.7 [54.8] m and 21.6 [46.4] m, respectively. The receiver operator curve for the change in ISWT distance (m) to discriminate between those that had improved or not is shown in Figure 1. The area under the curve (AUC) was 0.73 [0.66 – 0.80], p<0.001. The sensitivity and specificity for a change in ISWT of 25 m to discriminate 'improvers' or 'non-improvers' were 0.76 and 0.53 (AUC 0.64 [0.56 – 0.71]) and for a change of 35m were 0.70 and 0.67 (AUC 0.66 [0.58 – 0.73]), respectively.

Discussion

Different approaches to derive the MID are evident in the literature and almost inevitably result in different values. In isolation, this is not problematic and clinicians or researchers should choose the MID that best reflects their purpose. We describe the minimum important improvement in the ISWT as 36 m using the distribution method and a similar 35m using ROC analysis with a global ratings of change score as an anchor. Both these methodologies for an MID will enable more accurate calculation for sample sizes comparing an intervention versus usual care than the existing MID.

Describing the attainment of an MID can enable comparison between different tests for example in meta-analyses, but until now the MIDs across different exercise tests have been

calculated with different methodology and are not precisely comparable. Exercise tests are routinely used as outcome measures for rehabilitation programmes to identify high quality services; the recent National COPD Pulmonary Rehabilitation (PR) audit predefined a successful outcome on the attainment of the MID for ISWT or the 6MWT with the best estimate of the MID available at the time (11).

The methodology in the current report matches that used for the 6MWT where the MID was described as 25m (2). The size of the population in the current report is much larger than previously described (5) and provides a robust MID for the ISWT with a typical range of exercise values observed in a rehabilitation population. However, caution is advised for extrapolation to less disabled cohorts or other patient populations. We also highlight that the AUC of 0.66 for a cut-point of 35m is less than 0.7 described as adequate for measures of health status (9) which needs to be considered when interpreting the described MID. We were unable to establish the MID in this cohort using the MRC dyspnoea scale grade or the CRQ-dyspnoea domain as anchors.

Our report enables a consistent approach to describe the MID for the two most commonly used field walking tests for the first time. We advise any sample size calculations, meta-analyses or future benchmarking of services use the MID of 36 m for the ISWT particularly if using the MID 6MWT distance of 25m.

Figure legend

Figure 1. Receiver operating curve of the change in ISWT distance with pulmonary rehabilitation using patient ratings of change.

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