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Minimal important difference in field walking tests in non-cystic fibrosis bronchiectasis following exercise training

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Summary
Background: The 6-min walk distance (6MWD) and incremental shuttle walk distance (ISWD) are clinically meaningful measures of exercise capacity in people with non-cystic fibrosis (CF) bronchiectasis, but the change in walking distance which constitutes clinical benefit is undefined. This study aimed to determine the minimal important difference for the 6MWD and ISWD in non-CF bronchiectasis.
Methods: Thirty-seven participants with mean FEV_1 70% predicted completed both field walking tests before and after an 8-week exercise program. The minimal important difference

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was calculated using a distribution-based and anchor-based method, with the global rating of change scale used.
Results: The mean change in 6MWD in participants who reported themselves to be unchanged was 10 m, compared to 36 m (small change) and 45 m (substantial change) ($p = 0.01$). For the ISWD, the mean change in participants who reported themselves to be unchanged was 33 m, compared to 54 m (small change) and 73 m (substantial change) ($p = 0.04$). The anchor-based method defined the minimal important difference for 6MWD as 24.5 m (AUC 0.76, 95% CI 0.61—0.91) and for ISWD as 35 m (AUC 0.88, 95% CI 0.73—0.99), based on participant's global rating of change. The distribution-based method indicated a value of 22.3 m for the 6MWD and 37 m for the ISWD. There was excellent agreement between the two methods for the 6MWD (kappa = 0.91) and the ISWD (kappa = 0.92).
Conclusions: Small changes in 6MWD and ISWD may represent clinically important benefits in people with non-CF bronchiectasis. These data are likely to assist in the interpretation of change in exercise capacity following intervention.

Introduction

For patients with non-cystic fibrosis (CF) bronchiectasis, chronic sputum production, fatigue, dyspnoea and reduced exercise tolerance are commonly reported symptoms [1—3]. Current guidelines for management recommend a variety of strategies, including both medical and physiotherapy treatment approaches [4]. Field walking tests including the 6-min walk test (6MWT) and incremental shuttle walk test (ISWT) are often applied as outcome measures to determine effects of interventions on exercise capacity and in bronchiectasis they have been used to evaluate treatment effects for antibiotic therapy [5], airway clearance techniques [6], inspiratory muscle training [7] and pulmonary rehabilitation [8—11].

Although a number of different therapies have significantly improved physical endurance in bronchiectasis [5,8,9,11], interpreting the clinical significance of these changes remains a challenge. The minimal important difference (MID) is defined as the smallest change in an outcome measure that is recognised to be beneficial by the patient and that would lead a clinician to consider a change in therapy [12,13]. Several methods can be used to determine this threshold of change and a combined approach is generally recommended [14]. One method utilises an external criterion (or anchor state) to estimate the MID [12,15], which involves comparing the magnitude of change in an outcome to another clinically relevant measure [15]. A common example of an external criterion is an ordinal rating of change perceived by the patient or clinician as improvement or decline [12,16]. Distribution-based methods compare the change in score to a measure of variability, which may be the standard error of measurement (SEM) or effect size (ES). This method analyses the statistical properties of the measures based on the study sample data for the outcome variable [17]. Because MIDs may vary across individuals, reporting a range of MIDs is appropriate [13]. This combined approach has been utilised to estimate the MID in other chronic respiratory disease populations [18—20].

The need for more clinical markers in bronchiectasis has been recently identified as a necessity to determine the effectiveness of treatment [21]. Both the 6MWT and ISWT are simple field walking tests, with the 6MWT measuring functional exercise capacity [22], and the ISWT being an incremental test, reflecting peak exercise capacity [23]. The performance of both may be influenced by the severity of lung disease [24,25]. To date, there is no accepted threshold for clinically relevant change in these two field walking tests in bronchiectasis. The aims of this study were to (1) prospectively determine MID for the 6MWT and the ISWT in patients with non-CF bronchiectasis and (2) to determine whether there is a difference in the MID calculated using both anchor and distribution-based methods.

Methods

Participants

Patients with non-CF bronchiectasis based on high resolution computed tomography (HRCT) were recruited from three tertiary hospitals. All were participants in a randomised controlled trial evaluating the efficacy of exercise training in this patient population [26]. Patients were eligible to participate if they reported dyspnoea on exertion (Modified Medical Research Council Dyspnoea grade of ≥ 1 [27] at baseline assessment and had no neurological and musculoskeletal comorbidities which compromised exercise training. Exclusion criteria were a diagnosis of chronic obstructive pulmonary disease (COPD) (based on the criterion of $FEV_1/FVC < 70$, smoking history of greater than 10 pack years and evidence of emphysema on HRCT) [28]), asthma, interstitial lung disease or CF and other conditions (orthopaedic, neurological, vascular) which limited the ability to safely or effectively undertake exercise. The study was approved by human research ethics committees at all institutions, with written informed consent obtained from all participants.

Study design

The 6-min walk distance (6MWD) and the incremental shuttle walk distance (ISWD) were measured on consecutive