Validity, responsiveness and minimum clinically important difference of the incremental shuttle walk in idiopathic pulmonary fibrosis: a prospective study

ABSTRACT

The incremental shuttle walk (ISW) is well validated in COPD but limited psychometric data restrict its use in idiopathic pulmonary fibrosis (IPF). Study 1: 50 patients performed the ISW and 6 min walk test (6MWT). Study 2: 72 patients completed the ISW before and after pulmonary rehabilitation (PR). The ISW correlated strongly with 6MWT distance ($r=0.81, p<0.0001$). Mean (95% confidence interval) improvement in ISW with PR was 54 (38 to 70) m with an effect size of 0.29. Distribution-based and anchor-based minimum clinically important difference (MCID) estimates ranged from 31 to 46 m. The ISW is valid and responsive in IPF, with an anchor-based MCID estimate similar to that observed in chronic obstructive pulmonary disease.

Trial registration number Pre-results; NCT02530736, NCT02436278.

INTRODUCTION

The incremental shuttle walk (ISW) test is an externally paced maximal exercise test, which shows good reliability and construct validity in people with chronic obstructive pulmonary disease (COPD), heart failure and cystic fibrosis.¹ In COPD, it has also been shown to be responsive to intervention² and is widely used to measure outcome following pulmonary rehabilitation (PR).³ However, limited data exist on the validity, responsiveness and minimum clinically important difference (MCID) of the ISW in people with idiopathic pulmonary fibrosis (IPF), where the 6 min walk test (6MWT) is the most established field walking test.

The 6MWT and the ISW have similarities and differences. Both are field walking tests, simple to perform and do not require expensive equipment. They are commonly used as functional outcome measures, particularly in PR. In the 6MWT, the patient is asked to walk as far as possible in 6 min along a flat course. Although there are standardised instructions/encouragement, the test is essentially self-paced and may be considered submaximal. In contrast, the ISW is both incremental (patients have to walk faster as the test progresses) and externally paced

(by pre-recorded beeps). Whereas the ISW requires a straight 10-metre course, the 6MWT is now standardised to be conducted on a straight, 30-metre, unobstructed course,⁴ which may not be practical in some healthcare settings.

To determine the validity of the ISW in IPF, we evaluated the relationship between the ISW and 6MWT in a cohort of outpatients with IPF. In a separate cohort of patients with IPF undergoing an 8-week outpatient PR programme, we tested the responsiveness of the ISW. As the MCID (the smallest change that is considered beneficial or detrimental) helps interpret outcomes in clinical and research settings, we further estimated the MCID of the ISW using distribution-based and anchor-based methods.

METHODS

In two prospective observational cohort studies, we recruited participants from respiratory outpatient clinics at the Royal Brompton and Harefield NHS Foundation Trust, UK between February 2015 and July 2016. We included people diagnosed with IPF by a specialist interstitial lung disease multidisciplinary team according to international guidelines⁵ and excluded those with significant comorbidities that would limit exercise capacity or make it unsafe. The studies were approved by the London Riverside Research Ethics Committee (14/LO/2247, 15/LO/0015) and registered on clinicaltrials.gov (NCT02530736, NCT02436278 (pre-results)). All participants provided informed consent.

For study 1, spirometry, body mass index (BMI), the Medical Research Council (MRC) dyspnoea scale,⁶ ISW⁴ and 6MWT⁴ were measured in 50 outpatients with IPF. For study 2, we assessed the ISW⁴ and Chronic Respiratory Questionnaire (CRQ),⁷ before and after an 8-week PR

programme as previously described.⁸ At the post-PR assessment, prior to the measurement of the other outcome measures, participants also completed a five-point Global Rating of Change Questionnaire (GRCQ) comprising the question: 'How do you feel overall after PR?'. Responses were rated on a five-point Likert scale, ranging from '1: much better' to '5: much worse'.

We used Pearson's correlation coefficient to evaluate the relationship between the ISW and 6MWT and simple linear regression to predict 6MWT from ISW data. We compared outcomes and effect size following PR using paired t-test and Cohen's d, respectively. We compared the change in ISW according to GRCQ responses using the one-way analysis of variance test. Distribution-based estimates of the MCID used $0.5 \times \text{standard deviation (SD)}$ and standard error of measurement (SEM) using the formula $SEM = SD \times \sqrt{1 - (\text{test} - \text{retest reliability})}$, assuming an intraclass correlation of 0.80.⁹ For the anchor-based method, we estimated the MCID to be the mean change in ISW for those who reported feeling '2: a little better' on the GRCQ.

RESULTS

For study 1, 64 people were invited to participate: 11 declined, three did not meet the inclusion criteria and 50 enrolled. The baseline characteristics were 36 (72%) males; mean (SD) age: 75 (7) years; BMI: 26.9 (4.6) kg/m²; forced vital capacity (FVC) 2.17 (0.68) L; FVC% predicted: 70.0 (19.9); MRC dyspnoea scale: 3 (1); long-term oxygen therapy (LTOT): 8%; ambulatory oxygen therapy (ABOT): 12%; ISW: 264 (146) m and 6MWT: 342 (145) m. There was a strong correlation between the ISW and 6MWT ($r=0.81, p<0.0001$) (figure 1). The formula to predict 6MWT

Figure 1 Correlation between the incremental shuttle walk (ISW) and 6 min walk test (6MWT).

using ISW data was: mean (95% confidence interval (CI)): $6\text{MWT}=0.69$ (0.54 to 0.84)*ISW+160.30 (116.30 to 202.20) m; $r^2=0.65$, $p<0.0001$.

For study two, 82 people were invited: five declined, two did not meet the inclusion criteria and 77 were enrolled. Seventy-two participants (93.5%) completed PR. Baseline characteristics were 50 (69%) male; mean (SD) age: 74 (7) years; BMI: 27.9 (4.9) kg/m²; FVC: 2.3 (0.7) L; FVC% predicted: 76.7 (19.8); MRC dyspnoea scale: 3 (1); LTOT: 8%; ABOT: 15%; ISW: 285 (175) m; CRQ dyspnoea domain: 16.7 (5.8) and CRQ total: 85.7 (22.4).

The respective mean (95% CI) changes in ISW, CRQ dyspnoea and CRQ total were 54 (38 to 70) m, 4.2 (2.7 to 5.7) and 9.9 (6.1 to 13.6), with corresponding effect sizes of 0.29 for the ISW, 0.68 for CRQ dyspnoea and 0.49 for CRQ total. For distribution-based methods, the ISW MCID estimate was 35 m using $0.5 \times \text{SD}$ and 31 m using SEM. The distribution of response to the GRCQ was '1: much better' in 46%, '2: a little better' in 42%, '3: the same' in 9%, '4: a little worse' in 3% and '5: much worse' in 0%. Due to the small number of participants, responses 3–5 were combined. The mean (95% CI) changes in ISW for responses 1, 2 and 3–5 were 69 (47 to 92) m, 46 (18 to 74) m and 14 (–34 to 61) m, respectively ($p=0.03$) (figure 2).

DISCUSSION

To our knowledge, this study is the first to assess the validity, responsiveness to PR and provide estimates of the MCID of the ISW in IPF-specific cohorts. This research was undertaken in respiratory outpatient clinics and a PR unit that adheres to UK and international PR guidelines, suggesting our results would be generalisable, but future studies are necessary to corroborate our

findings. The strong correlation between the ISW and 6MWT provides evidence for construct validity for the ISW in IPF and supports previous data demonstrating significant correlation between ISW and distance walked on a treadmill in patients with IPF.¹⁰ Our anchor-based estimate of the MCID of the ISW in IPF also corroborates the previously reported anchor-based estimate of the MCID in COPD.²

We did not use the 6MWT as an anchor in our responsiveness study because the ISW is used in the participating PR programme, although, for future studies a comparison between both tests following PR would be informative. However, our use of the GRCQ follows an established anchor for determining the MCID, in line with the method used by Singh *et al* to determine the MCID of the ISW in COPD.² There were also few patients reporting deterioration with PR; hence, our data findings support the MCID for improvement and not deterioration. Although there is no gold standard technique or consensus on method of determining the MCID,¹¹ our study used both distribution-based and anchor-based methods to provide a range of MCID estimates. We favour the anchor-based approach as it may capture the patient experience better than statistically derived, distribution-based estimates. Reassuringly, our anchor-based estimate of the MCID for the ISW (46 m) was very similar to the MCID observed in COPD (47.5 m).²

In summary, the ISW is valid and responsive to PR in people with IPF with MCID estimates from 31 to 46 m.

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Figure 2 Mean (95% CI) change in the incremental shuttle walk (ISW) following pulmonary rehabilitation according to the Global Rating of Change Questionnaire.

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