

Modified 1-min sit-to-stand test for evaluating exercise capacity in pulmonary fibrosis

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Shareable abstract (@ERSpublications)

The modified 1-min sit-to-stand test, taking into account the recovery phase, is an easier alternative to the 6-min walk test as a measure of exercise performance in pulmonary fibrosis. It could be used for patient follow-up and prognostic assessment. https://bit.ly/407I4Jm

Cite this article as: Berger I, Mortada S, Gachie C, et al. Modified 1-min sit-to-stand test for evaluating exercise capacity in pulmonary fibrosis. *ERJ Open Res* 2025; 11: 00745-2024 [DOI: 10.1183/23120541.00745-2024].

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Received: 25 July 2024 Accepted: 5 Oct 2024

Abstract

Question The reference test for the functional evaluation of pulmonary fibrosis (PF) during exercise is the 6-min walk test (6MWT). However, the 6MWT involves temporal and spatial constraints that the 1-min sit-to-stand test (1-MSTST) does not have. Previous studies have not validated 1-MSTST use in this context, mainly because of far less oxygen desaturation. We hypothesise that the modified 1-MSTST (m1-MSTST), taking into account the recovery phase, could compensate this shortcoming.

Patients and methods This was a randomised, crossover, single-centre trial conducted in 36 patients with PF. A 6MWT and 1-MSTST were performed 30 min apart for each patient in a randomised order. An equivalence test was performed on the peripheral oxygen saturation (S_{pO_2}) nadir.

Results The 36 patients comprised eight with idiopathic PF, five with nonspecific idiopathic pneumonia, eight with collagen tissue disease-associated PF, four with hypersensitivity pneumonitis, two with sarcoidosis and nine with other PF. Mean \pm sD nadir desaturation was 84.9 \pm 4.3% for the 6MWT and 88 \pm 3.5% for the m1-MSTST, with a strong correlation between both tests. 33 patients (91.7%) had concordant results in the two tests regarding significant desaturation (S_{pO_2} delta >4% or nadir <88%), which is a known prognosis factor.

Conclusion The m1-MSTST, taking into account the recovery phase, is a sensible compromise to the 6MWT in measuring exercise performance in people with PF. As many clinical endpoints transfer from hospital to outpatient care, the m1-MSTST is technically easier and more practical for patients. Further studies are warranted to determine the minimal clinically important difference and norms in healthy subjects.

Introduction

Fibrotic interstitial lung diseases (ILDs), or pulmonary fibrosis (PF), represent a heterogeneous group of progressive pulmonary diseases that cause significant morbidity and mortality [1]. Clinicians need a reliable method to assess the severity of such diseases. Impaired gas exchange is routinely assessed at rest by measuring the diffusing capacity of the lung for carbon monoxide (D_{LCO}), peripheral oxygen saturation (S_{PO_2}) and arterial blood gases. These markers are used to assess prognosis and during follow-up [2]. Evaluating functional exercise capacity is also crucial for prognosis and patient follow-up. The most widely used and validated test for functional evaluation during exercise in PF is the 6-min walk test (6MWT) [3, 4]. The 6MWT is routinely used in the management of all types of PF, although most studies of its value have been conducted in patients with idiopathic pulmonary fibrosis (IPF) [5]. This test can be used to assess a patient's prognosis: there is an increased risk of mortality in the event of S_{PO_2} nadir <88% or S_{PO_2} delta >4% [6–8]. It can be used to evaluate disease progression, notably in terms of distance walked. There is some variability across studies and methods to determine the minimum clinically





important difference (MCID); however, based on the large evidence database now available, we can be confident that the MCID lies between 25 and 33 m [9].

However, the 6MWT has some limitations. Its results are subject to intra-individual variability [4]. International experts and guidelines recommend performing two 6MWTs and considering the results of the best trial only [9], which is rarely done in practice. In addition, the 6MWT has both time and space constraints: 15–20 min are required to perform it, including patient conditioning and the recovery phase. It also requires an unobstructed corridor of at least 30 m [3].

Other field tests for assessing functional exercise capacity have been developed, such as the 30-second, 1-min and 3-min sit-to-stand tests, stepper tests, step tests and stair tests [10]. Among these, the 1-min sit-to-stand test (1-MSTST) is the best evaluated. It involves sitting down and standing up from a chair as many times as possible in 1 min. The primary criteria measured are desaturation and the number of repetitions. The fundamental advantage of the 1-MSTST over the 6MWT is that it eliminates temporal and spatial constraints: it takes only a few minutes and can be performed in a medical office. While the 1-MSTST appears promising, there are still challenges in replacing the 6MWT with the 1-MSTST for PF, mainly due to lower oxygen desaturation. Given that clinically important thresholds of oxygen desaturation are established with the 6MWT, this problem does not allow us to conclude that the two tests are equivalent. Interestingly, Tremblay Labrecque *et al.* [11] showed that peak oxygen consumption and $S_{\rm PO_2}$ nadir were reached at the end of the 6MWT, but occurred during the recovery phase of the 1-MSTST.

The primary objective of our study was to assess the correlation between S_{pO_2} nadir during the 6MWT and the modified 1-MSTST (m1-MSTST). The hypothesis tested in our trial was that the m1-MSTST, taking into account the recovery phase, could be comparable to the 6MWT for the functional evaluation of PF during exercise.

Methods

Trial design

We conducted an investigator-initiated, single-centre, randomised crossover trial to compare the m1-MSTST with the 6MWT in order to detect desaturation. Patients were recruited from the pulmonology department of the Hôpitaux Paris Saint-Joseph & Marie Lannelongue, Paris, France. The trial protocol was approved by the relevant ethics committee (Comité de protection des Personnes des Hôpitaux du Sud-Ouest et Outre Mer III (2022-A01196-37)). The authors vouch for the completeness and accuracy of the data and for the fidelity of the trial to the protocol.

The study protocol was registered at ClinicalTrials.gov (identifier NCT05449431).

Trial participants

We included consecutive patients with PF if they fulfilled all of the following inclusion criteria: 1) aged ≥18 years, 2) diagnosis of PF based on a multidisciplinary discussion and 3) French-speaking patient. Exclusion criteria were as follows: 1) exacerbation of PF in the preceding 6 months, 2) inability to perform either the 6MWT or the 1-MSTST, 3) distance walked <200 m in the 6MWT (to avoid patients with very severe PF, and some marginal results) and 4) hypoxaemia requiring long-term oxygen therapy.

All the participants provided written informed consent.

Procedures and follow-up

Clinical characteristics were recorded on the same day as the pulmonary function tests and both exercise tests. After pulmonary function assessment, each participant was included in the two-period controlled crossover treatment comparing the m1-MSTST with the 6MWT, separated by a 30-min rest period allowing heart rate and dyspnoea to return to their baseline values.

The 6MWT was performed following recommendations from the international guideline [3]. Participants were asked to walk as far as possible within 6 min, on a marked 30-m indoor corridor. S_{pO_2} and pulse rate were measured with a pulse oximeter before the test, every minute during the test and at the end of the test. The walking distance was recorded. Dyspnoea was assessed using the modified Borg scale before and at the end of the test.

The 1-MSTST was performed according to OZALEVLI *et al.* [12]. We used a standard-height chair (between 44.5 and 48 cm), without armrests, positioned against a wall. Patients were asked to sit with their legs hip-width apart and flexed at 90°, hands still on hips, without using hands or arms to assist movement.

They were asked to stand up, standing completely upright and touching the chair with their buttocks as they sat, without having to sit completely on the chair. Patients were asked to perform as many repetitions as possible for 1 min. The number of completed repetitions was recorded. S_{pO_2} and pulse rate were measured with a pulse oximeter before, during and at the end of the test; during the 1-min recovery; and at the end of 1 min of recovery. The test that takes into account the recovery phase is named the modified 1-MSTST (m1-MSTST).

Patients were scheduled for two similarly structured outpatient visits separated by 6 months (visit (V) 1=month (M) 0 and V2=M6). At each visit, patients underwent clinical examination and pulmonary function tests, followed by the 6MWT and the m1-MSTST. Spirometry and the $D_{\rm LCO}$ measurements were performed in accordance with recommended techniques, using reference equations from the Global Lung Function Initiative [13, 14].

Patients were followed up for 12 months after inclusion. According to the international clinical practice guideline, progression was defined by the composite of progression, exacerbation or death [1].

Outcomes

The primary outcome was the correlation between S_{pO_2} nadir during the 6MWT and S_{pO_2} nadir during the m1-MSTST.

The secondary outcomes were as follows:

- the comparison between the S_{pO_2} delta during both tests,
- the number of patients with a significant desaturation (S_{pO_2} delta >4% or nadir <88%),
- the correlation between the distance walked during the 6MWT and the number of repetitions during the m1-MSTST,
- the correlation between the heart-rate increase observed with both tests,
- the correlation between the dyspnoea (modified Borg scale score) experienced by patients with both tests,
- the correlation between the S_{PO_2} nadir during the m1-MSTST and the features of the pulmonary function tests (forced vital capacity (FVC) and D_{LCO}).

The exploratory outcomes were as follows:

- the correlation between changes (M6–M0) in both tests at 6 months,
- the correlation between a significant desaturation (S_{PO_2} delta >4% or nadir <88%) at M0 during the m1-MSTST and the occurrence of progression at M12.

Randomisation

The randomisation list was generated by the study statistician. Patients were randomly assigned in a 1:1 ratio by the physician using an electronic case report form (REDCap). Random assignment was block-balanced with variable block sizes of 2 or 4.

Statistical analysis

We determined that a sample of 36 participants was necessary to test equivalence of means using two one-sided tests on data from a 2×2 crossover design to achieve 80% power at a 5% significance level. When the true difference between the means is 0, the SD of the paired differences is 0.1, and the equivalence limits are -0.05 and 0.05 (PASS 20 software [15]).

The trial results are reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement (extension to randomised crossover trials) [16].

All the participants who underwent randomisation were included in the primary analysis.

Continuous variables are reported as mean±sp or median (interquartile range), according to the distribution, and discrete variables as numbers (proportions). The Spearman correlation coefficient was calculated for the primary outcome, which was tested using equivalence test for paired data (R package TOSTER, version 0.8.2). For other outcomes, the Spearman correlation coefficient was used to estimate the relationship between two variables; a correlation of >0.6 was considered to be strong. The Bland–Altman plot was also used to compare the two methods [17]. Briefly, a Bland–Altman plot consists of a plot of the difference between paired readings of two variables (i.e. 6MWT and 1-MSTST values) over the average of these two readings. The ±2 sp lines are the confidence interval (CI) parallel to the mean difference and

define the credibility interval. The presence of carry-over and period effects was sought with paired t-tests. Linear regression was used to estimate the relationship between $S_{\rm PO_2}$ nadir after the 6MWT and $S_{\rm PO_2}$ nadir after the m1-MSTST. Missing data were not replaced. No adjustment was made for test multiplicity.

All analyses were performed with R software, version 4.2.2 (www.r-project.org/).

Results

Participant characteristics

Between 31 August 2022 and 14 December 2022, 36 patients with PF were included and completed the two tests. No patient was excluded from analysis at V1 (M0), but four patients were either lost to follow-up (n=2) or died (n=2) at V2 (M6). Patients' characteristics and pulmonary function are described in table 1.

Primary outcome

The results of the 6MWT and the m1-MSTST are shown in table 2. At M0, the $S_{\rm pO_2}$ nadirs were 84.9±4.3% and 92±2.8% during the 6MWT and the 1-MSTST, respectively. During m1-MSTST (taking into account 1 min of recovery), the $S_{\rm pO_2}$ nadir was 88±3.5%. The correlation between the $S_{\rm pO_2}$ nadir value obtained during the 6MWT and that obtained during the 1-MSTST (r=0.35, p=0.035) was significant, but lower than the correlation between the $S_{\rm pO_2}$ nadir value obtained during the 6MWT and that obtained during the m1-MSTST (r=0.68, p<0.0001) (figure 1a and b).

At M6, the $S_{\rm pO_2}$ nadirs were 84.2±5.0% and 90.6±3.3% during the 6MWT and the 1-MSTST, respectively. During the m1-MSTST, the $S_{\rm pO_2}$ nadir was 86.4±3.7%. The correlation between the $S_{\rm pO_2}$ nadir value obtained during the 6MWT and that obtained during the m1-MSTST was high (r=0.79, p<0.0001) (figure 1c).

Convergent validity (Bland-Altman analysis)

capacity of the lung for carbon monoxide.

At M0, the mean difference and the limits of agreement for the $S_{\rm pO_2}$ nadir were -7.07 (90% CI -8.32-5.87) between the 6MWT and the 1-MSTST (figure 2a) and -3.06 (90% CI -3.97-2.14) between the 6MWT and the m1-MSTST (figure 2b). At M6, the mean difference and the limits of agreement for the $S_{\rm pO_2}$ nadir were -2.26 (90% CI -4.15-0.37) between the 6MWT and the m1-MSTST (figure 2c). For all comparisons, the differences between the two tests differed significantly from 0 and there was no evidence of an increase in the difference with increasing values of the measurement. Visual inspection of the Bland–Altman plots shows a high individual dispersion in the two comparisons between the 6MWT *versus* the 1-MSTST and the 6MWT *versus* the m1-MSTST, but it is lower for the 6MWT *versus* m1-MSTST comparison.

Characteristic	Value
Age, years	68.3±10
Male sex	28 (78)
Smoking status	
Current smoker	2 (5.6)
Never smoker	17 (47)
Former smoker	17 (47
Number of pack-years	27.4±15
ype of ILD	
Idiopathic pulmonary fibrosis	8 (22)
Nonspecific ILD	5 (14)
Collagen tissue disease-associated ILD	8 (22)
Hypersensitivity pneumonitis	4 (11)
Sarcoidosis	2 (6)
Other	9 (25)
Pulmonary function test	
FVC, L	2.57±0.
FVC, % predicted	70.8±16
D _{LCO} , % predicted	38.7±10

TABLE 2 Results of the 6-min walk test and the 1-min sit-to-stand test			
Result	Value		
6-min walk test			
Distance, m	514.7±76.2		
Distance, % predicted	89.6±19		
S _{pO₂} nadir, %	84.9±4.3		
S _{pO₂} delta, %	9.7±4.5		
Peak heart rate, beats per minute	118.9±21.5		
Peak modified Borg score	4.1±2		
1-min sit-to-stand test			
Number of completed repetitions	24.6±7.9		
S _{pO₂} nadir during the test, %	92±2.8		
S _{pO₂} nadir during the recovery phase, %	88±3.5		
S _{pO₂} delta during the recovery phase, %	7.1±2.5		
Peak heart rate during the test	ND		
Peak heart rate during the recovery phase	ND		
Peak modified Borg score	4.3±1.6		

Data are presented as mean \pm sp. ND: not done due to too many missing data. S_{pO_2} : peripheral oxygen saturation.

Secondary outcomes

The differences between the initial and the minimum S_{pO_2} values were 9.7±4.5% and 7.0±2.5% with the 6MWT and the m1-MSTST, respectively (difference between the two methods: 2.6, 95% CI 1.4–3.8).

If we categorise $S_{\rm PO_2}$ according to the threshold of significant desaturation ($S_{\rm PO_2}$ delta >4% or nadir <88%), which is considered to be a prognostic factor, there is good agreement between the 6MWT and the m1-MSTST (kappa: 0.62, 95% CI 0.23–1.00) (table 3).

The mean number of repetitions performed by the whole population during the m1-MSTST was 25 ± 7.9 . The mean distance walked during the 6MWT was 458 ± 100 m. The number of repetitions during the m1-MSTST was well correlated with the distance walked during the 6MWT (r=0.61, p<0.0001) (figure 3).

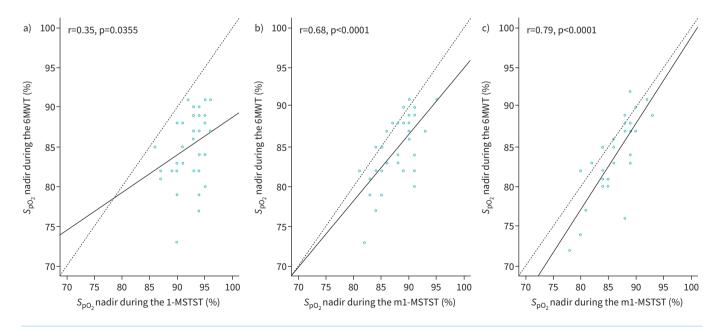


FIGURE 1 Correlation between the peripheral oxygen saturation (S_{pO_2}) nadir values measured: a) during the 6-min walk test (6MWT) and during the 1-min sit-to-stand test (1-MSTST) at month (M) 0, b) during the 6MWT and during the modified 1-MSTST (m1-MSTST) at M0 and c) during the 6MWT and during the m1-MSTST at M6.

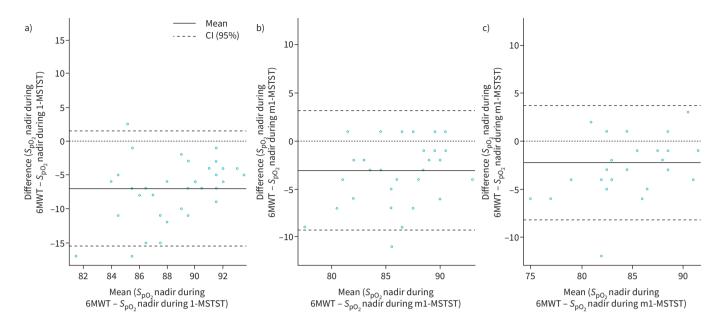


FIGURE 2 Bland–Altman plot of mean over difference between paired readings of the peripheral oxygen saturation (S_{pO_2}) nadir obtained: a) during the 6-min walk test (6MWT) and during the 1-min sit-to-stand test (1-MSTST) at month (M) 0, b) during the 6MWT and during the modified 1-MSTST (m1-MSTST) at M0 and c) during the 6MWT and during the m1-MSTST at M6.

Unfortunately, the analysis of the increase in heart rate could not be done because of missing data.

The scores of the modified Borg dyspnoea scale at the end of the two tests were well correlated (r=0.63, p<0.0001), with scores of 4.1 ± 2 with the 6MWT and 4.3 ± 1.6 with the m1-MSTST (figure 4).

The $S_{\rm pO_2}$ nadir obtained during the m1-MSTST was not correlated with $D_{\rm LCO}$ (r=0.27, p=0.11) or with FVC (r=0.03, p=0.85).

Exploratory outcomes

The correlations between the M6–M0 differences for both 1) the distance walked in the 6MWT and the number of repetitions in the m1-MSTST and 2) $S_{\rm PO_2}$ nadir after each test are weak (r=0.20 and r=0.47, respectively). However, neither the change in the 6MWT distance (-6.2 m, 95% CI -24.9–12.4) or in the number of repetitions during the m1-MSTST (1.5, 95% CI -0.3–3.2) nor the change in the $S_{\rm PO_2}$ nadir for the 6MWT (-0.7, 95% CI -2.2–0.7) or for the m1-MSTST (-1.6, 95% CI -2.6–0.7) were clinically significant.

Agreement between the presence of a significant desaturation (S_{pO_2} delta >4% or nadir <88%) at M0 and the occurrence of progression (see above, "Procedures and follow-up") at M12 is shown in table 4. Patients without significant desaturation with both tests did not progress.

Discussion

To our knowledge, this study is the first to prospectively compare the 6MWT with the m1-MSTST in a cohort of fibrotic ILD patients, including both IPF and other fibrotic ILDs, while also considering the

TABLE 3 Agreement in the diagnosis of significant desaturation" as measured by the 6-min walk test (6MWT) and by the modified 1-min sit-to-stand test (m1-MSTST)

	6MWT significant desaturation (n)	6MWT nonsignificant desaturation (n)		
m1-MSTST significant desaturation	30	1		
m1-MSTST nonsignificant desaturation	2	3		
#: peripheral oxygen saturation difference of >4% or desaturation of <88%.				

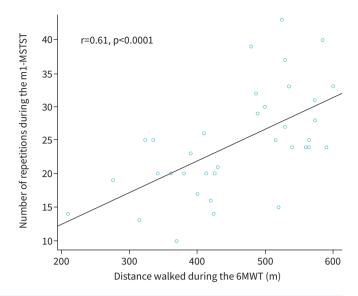


FIGURE 3 Correlation between number of repetitions during the modified 1-min sit-to-stand test (m1-MSTST) and the distance walked during the 6-min walk test (6MWT).

recovery phase. This study reveals that the m1-MSTST is better than the 1-MSTST for estimating exercise-induced oxygen desaturation in patients with fibrotic ILDs. This is evidenced by a better correlation between the $S_{\rm pO_2}$ nadir values in the m1-MSTST and the 6MWT. Our results suggest that, like 6MWT, the m1-MSTST enables effective patient follow-up and could be used to assess patient prognosis. In addition, the m1-MSTST has the major advantage of being feasible in a medical office.

The 1-MSTST has been studied primarily in patients with COPD. In COPD, there is a strong correlation between the number of repetitions in the 1-MSTST and the distance walked in the 6MWT [18, 19], although the $S_{\rm PO_2}$ nadir tends to be higher with the 1-MSTST [12, 20]. Interestingly, a Canadian study showed that maximum desaturation and peak oxygen consumption in this population occurred during the recovery phase after the test ended [21].

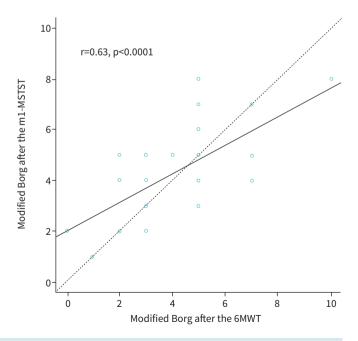


FIGURE 4 Correlation between the modified Borg scale score after the modified 1-min sit-to-stand test (m1-MSTST) and after the 6-min walk test (6MWT) at month (M) 0.

TABLE 4 Relationship between the degree of desaturation[#] during the 6-min walk test (6MWT) and during the modified 1-min sit-to-stand test (m1-MSTST) at month (M) 0 and the disease evolution at M12

	Progression (n=8)	Stable disease (n=27)
Significant desaturation after 6MWT at M0		
Yes (n=31)	8 (100)	23 (85.2)
No (n=4)	0 (0.0)	4 (14.8)
Significant desaturation after m1-MSTST at M0		
Yes (n=30)	8 (100)	22 (81.5)
No (n=5)	0 (0.0)	5 (18.5)

Data are presented as n (%). #: significant desaturation is defined by a peripheral oxygen saturation difference of >4% or a desaturation of <88%.

Comparing the 6MWT with the 1-MSTST among those with fibrotic ILD has been studied previously, but data are limited and inconsistent [11, 22–25]. Two prospective studies showed excellent test–retest reliability for the 1-MSTST, indicating that a single trial is sufficient for an accurate assessment [11, 23]. Analysing the correlation of S_{PO} , nadir between the two tests yields interesting results.

The same previous Canadian team of Tremblay Labrecque *et al.* [11] performed a study combining the 6MWT and 1-MSTST with ergocycle exercise testing in 15 patients with fibrotic ILD. Similar to their findings among patients with COPD [21], they observed that the peak cardiorespiratory response occurs after test completion, resulting in a delayed recovery period. The $S_{\rm pO_2}$ nadir was achieved 31±26 s after the end of the 1-MSTST. Accounting for this recovery period, the authors found no significant difference between the $S_{\rm pO_2}$ nadir reached during the 1-MSTST and that reached during the 6MWT: 88±4% and 85±5%, respectively. Our cohort yielded very similar results. By contrast, a French study of 33 patients with IPF found significantly less oxygen desaturation during the 1-MSTST, without accounting for the recovery time, than during the 6MWT ($S_{\rm pO_2}$, was higher by \approx 5%) [23].

Three other studies found a good correlation between the $S_{\rm pO_2}$ value during the 6MWT and that during the 1-MSTST, but raised issues regarding the subtype and the severity of ILD. An Indian study of 60 patients with ILD reported very similar $S_{\rm pO_2}$ nadirs between the two tests, but the nadirs were unusually high (91±2.7% and 92±2.5% for the 6MWT and 1-MSTST, respectively) [25]. Explanations for this result are various. Their population included non-fibrotic ILD and exercise was probably suboptimal (6MWT distance of 332±67 m, compared with 514.7±76.2 m in our cohort). Briand *et al.* [22] studied 107 patients with ILD, including only 51 with fibrotic ILD. They found a strong correlation between the $S_{\rm pO_2}$ nadir values in the 6MWT and 1-MSTST, with the $S_{\rm pO_2}$ nadir in the 1-MSTST being 2% higher than in the 6MWT. As in the Indian study, their population included mild ILD with $S_{\rm pO_2}$ nadir during the 6MWT of 90±7%, very different from the one of our cohort. Interestingly, the agreement on $S_{\rm pO_2}$ nadir between the two tests was lower among those with fibrotic ILD than among those with non-fibrotic ILD. Finally, OISHI *et al.* [24] studied 116 patients with fibrotic and non-fibrotic ILD and found a very strong correlation between the $S_{\rm pO_2}$ nadir during the 6MWT and that during the 1-MSTST. However, like the previous studies and unlike our cohort, their population had mild ILD, with an $S_{\rm pO_2}$ nadir during the 6MWT of 91%.

Analysis of these studies suggests that the benefit of the strong correlation in S_{pO_2} nadirs obtained with the 6MWT and 1-MSTST (or m1-MSTST) is most relevant for patients with sufficiently severe desaturation.

The latest IPF management recommendations have established prognostic criteria based on the $S_{\rm pO_2}$ nadir (<88%) and the $S_{\rm pO_2}$ delta (>4%) during the 6MWT, which are considered significant desaturation [7]. In our study, there was no significant difference between the two groups in the number of patients with significant desaturation, suggesting that the same criteria can be used to assess prognosis with the m1-MSTST.

In usual practice, the 6MWT takes around 15 to 20 min to complete, including rest and post-test time. With the 1-min recovery time, the m1-MSTST takes around 5 min. Furthermore, the m1-MSTST can be conducted in a limited space and uses readily available equipment (a standardised chair and stopwatch). This could generate an economic gain. The ability to perform exercise testing in a medical office (*e.g.* by the general practitioner) allows us to screen patients needing ILD specialist advice. Its application as a tele-assessment could be used for home monitoring.

The strengths of our study include its prospective and randomised design, involving various types of PF with moderate severity. It also has several limitations. Firstly, there is only one study reporting 1-MSTST results in a healthy population of 6926 people aged 20–79 [26]. Unfortunately, only the number of repetitions is reported, with no data on $S_{\rm PO_2}$ or dyspnoea. Secondly, because more severe patients were excluded, we cannot draw conclusions about the validity of the m1-MSTST in these patients. However, our population comprised more severe patients than in most previous studies of the 1-MSTST among those with ILD. In addition, our data come from a single centre and involve a relatively small sample size, which may limit external validity. However, our results are very similar to those of Tremblay Labrecque *et al.* [11], giving consistency to our findings.

In conclusion, the m1-MSTST, which takes into account the recovery phase, is a sensible alternative to the 6MWT as a measure of exercise performance in people with PF. Further studies in healthy subjects are needed to establish norms, and more research on patients with PF is required to better assess the long-term prognostic value of the test and its MCID.

Provenance: Submitted article, peer reviewed.

Data availability: Individual participant data will be available (including data dictionaries). All of the individual participant data collected during the trial, after deidentification, will be available, as well as the study protocol, statistical analysis plan, informed consent form, clinical study report and analytic code immediately following publication with anyone who wishes to access the data for any purpose. The data are available from jmnaccache@ghpsj.fr.

This clinical trial is prospectively registered with ClinicalTrials.gov as NCT05449431.

Ethics statement: Approval of the trial protocol was received from the relevant ethics committee (Comité de protection des Personnes des Hôpitaux du Sud-Ouest et Outre Mer III; 2022-A01196-37). All the participants provided written informed consent.

Conflict of interest: The authors have nothing to disclose.

Support statement: This study was supported by the Saint-Joseph Foundation.

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