



## Research

# In adults with advanced lung disease, the 1-minute sit-to-stand test underestimates exertional desaturation compared with the 6-minute walk test: an observational study

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## KEY WORDS

Exercise testing 6MWT  
1-min STS Lung disease  
Physical therapy

## ABSTRACT

**Question:** In adults with advanced lung disease, do the 6-minute walk test (6MWT) and 1-minute sit-to-stand test (1minSTS) elicit similar cardiorespiratory responses? Can the 6-minute walk distance (6MWD) be estimated from the 1minSTS result? **Design:** Prospective observational study using data collected during routine clinical practice. **Participants:** Eighty adults (43 males) with advanced lung disease, a mean age of 64 years (SD 10) and a mean forced expiratory volume in 1 second of 1.65 L (SD 0.77). **Outcome measures:** Participants completed a 6MWT and a 1minSTS. During both tests, oxygen saturation (SpO<sub>2</sub>), pulse rate, dyspnoea and leg fatigue (Borg 0 to 10) were recorded. **Results:** Compared with the 6MWT, the 1minSTS resulted in higher nadir SpO<sub>2</sub> (MD 4%, 95% CI 3 to 5), lower end-test pulse rate (MD -4 beats/minute, 95% CI -6 to -1), similar dyspnoea (MD -0.3, 95% CI -0.6 to 0.1) and greater leg fatigue (MD 1.1, 95% CI 0.6 to 1.6). Among the participants who demonstrated severe desaturation (SpO<sub>2</sub> nadir < 85%) on the 6MWT (n = 18), five and ten participants were classified as moderate (nadir 85 to 89%) or mild desaturators (nadir ≥ 90%), respectively, on the 1minSTS. The relationship between the 6MWD and 1minSTS was: 6MWD (m) = 247 + (7 × number of transitions achieved during the 1minSTS) with poor predictive ability (r<sup>2</sup> = 0.44). **Conclusion:** The 1minSTS elicited less desaturation than the 6MWT and classified a smaller proportion of people as 'severe desaturators' on exertion. It is therefore inappropriate to use the nadir SpO<sub>2</sub> recorded during a 1minSTS to make decisions about whether strategies are needed to prevent severe transient exertional desaturation during walking-based exercise. Further, the extent to which performance on the 1minSTS can estimate a person's 6MWD is poor. For these reasons, the 1minSTS is unlikely to be helpful when prescribing walking-based exercise. [Watson K, Winship P, Cavalheri V, Vicary C, Stray S, Bear N, Hill K (2023) In adults with advanced lung disease, the 1-minute sit-to-stand test underestimates exertional desaturation compared with the 6-minute walk test: an observational study. *Journal of Physiotherapy* ■:■–■] © 2023 Australian Physiotherapy Association. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## Introduction

Adults diagnosed with advanced lung disease who attend respiratory medicine outpatient clinics are often referred to participate in pulmonary rehabilitation programs (PRPs), which include supervised exercise training. These programs reduce dyspnoea and improve health-related quality of life and functional capacity in adults with a range of chronic respiratory conditions.<sup>1</sup> Prior to commencing a PRP, the response to exercise is often evaluated using a 6-minute walk test (6MWT).<sup>2</sup> During this test, several measures are collected, including peripheral capillary oxygen saturation (SpO<sub>2</sub>) and pulse rate, using a pulse oximeter, and dyspnoea and leg fatigue, using the Modified Borg category ratio scale.<sup>2,3</sup> These measures are used in the prescription of exercise. Specifically, 6-minute walk distance

(6MWD) is often used to develop a 20-minute walking goal.<sup>4</sup> Marked desaturation during the 6MWT may trigger an evaluation for ambulatory oxygen prescription<sup>5,6</sup> and SpO<sub>2</sub>, pulse rate and symptom responses during the 6MWT are also useful in monitoring disease progression.

In recent times, due to the COVID-19 pandemic, physiotherapists have needed to balance the requirement to evaluate the response to exercise by supervising the person whilst they perform a 6MWT with the restrictions related to the pandemic such as lock-downs, personal protective equipment requirements and physical distancing. The transition of many services to telehealth due to such restrictions has led to an increased reliance on assessments such as the 1-minute sit-to-stand test (1minSTS).<sup>7</sup> Over the last decade, few studies have compared cardiorespiratory and symptom responses

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measured during the 6MWT with the 1minSTS in people with a chronic lung condition. Some<sup>8–10</sup> but not all of these studies<sup>11</sup> have demonstrated greater desaturation (~3%) during the 6MWT compared with the 1minSTS. However, most of the earlier studies excluded people who required long-term oxygen therapy (LTOT) and/or supplemental oxygen on exertion.<sup>8,9,11</sup> It is therefore difficult to generalise these results to PRP in Australia, where > 80% of programs have access to supplemental oxygen during exercise testing and training.<sup>5</sup> Further, no study has collected responses after 1 minute of the 6MWT and compared these with responses elicited during the 1minSTS. Such a comparison will help to elucidate whether any difference in SpO<sub>2</sub> or end-test pulse rate relates mainly to differences in test duration.

The aim of this study was, in a large sample of adults known to the advanced lung disease service at a tertiary hospital (Fiona Stanley Hospital, Perth, Western Australia) to: explore the agreement between measures of SpO<sub>2</sub>, pulse rate, dyspnoea and leg fatigue elicited during the 6MWT and 1minSTS; and explore the extent to which the 6MWD could be estimated using the results of the 1minSTS. Therefore, the research questions for this prospective observational study using data collected during routine clinical practice were:

1. In adults with advanced lung disease, do the 6-minute walk test (6MWT) and 1-minute sit-to-stand test (1minSTS) elicit similar cardiorespiratory responses?
2. Can the 6-minute walk distance (6MWD) be estimated from the 1minSTS result?

## Methods

This study presents an analysis of data collected prospectively during routine clinical practice on all adults known to the advanced lung disease service at Fiona Stanley Hospital who completed a 6MWT and 1minSTS test between September 2021 and January 2022. Adults referred to the advanced lung disease service had a chronic lung disease and were being considered for specialist interventions (eg, lung transplant) or enrolment in pharmaceutical trials. All adults were exacerbation-free at the time of assessment, and the 6MWT was performed prior to the 1minSTS with at least 20 minutes of rest between tests. Variables of interest that were recorded were: participant characteristics (eg, age, gender, height, weight and lung function); nadir SpO<sub>2</sub>, pulse rate, dyspnoea and leg fatigue collected on completion of the 6MWT and 1minSTS; and SpO<sub>2</sub> and pulse rate, measured at the end of the first minute of the 6MWT (ie, iso-time responses). For both tests, SpO<sub>2</sub> and pulse rate were monitored continuously using the Massimo Rad-V pulse oximeter (Massimo Australia Pty Ltd, NSW, Australia) and the sensor placement was standardised between tests. For those who had been prescribed supplemental oxygen, interface and dose were kept identical between tests. Those who used supplemental oxygen during the 6MWT transported the cylinder on their own using a trolley or wheeled walker. Dyspnoea and leg fatigue were measured on test completion using the modified Borg category ratio scale (0 to 10).<sup>3</sup> Approval to undertake and submit these analyses for publication was granted through the Governance Evidence Knowledge Outcomes (GEKO) system (approval number 42614).

### 6-minute walk test

This test was undertaken in accordance with the current technical standard for field-based walking tests, with the exception of a track length equal to 25 m due to space limitations.<sup>12</sup> Only one 6MWT was performed, as 89% of the participants included in this study had previously performed a 6MWT, with 83% having performed a 6MWT within the preceding 3-month period. Given the absence of data demonstrating the safety profile of desaturation to < 80% at the facility during exercise testing, participants who desaturated to < 80%

were instructed to stop and rest and were permitted to recommence once their SpO<sub>2</sub> was ≥ 85%.<sup>12,13</sup>

### 1-minute sit-to-stand test

The testing procedures were informed by recommendations from a systematic review of the literature.<sup>14</sup> Participants were instructed to transition between sitting and standing as many times as possible in 1 minute. The height of the chair was kept between 45 and 48 cm and participants were encouraged not to use their arms to facilitate the transitions.

### Data analyses

Data were analysed using commercial software<sup>a</sup>. The distribution of data was assessed using frequency histograms. Data are expressed as mean ± standard deviation. Agreement in measures was explored using the methods described by Bland-Altman, including Bland-Altman plots and limits of agreement (LOA).<sup>15</sup> Mean differences between tests are reported along with the corresponding 95% confidence interval. The study also explored the extent to which the two tests produced a response that would classify each participant as either a mild desaturator (nadir ≥ 90%; included non-desaturators), moderate desaturator (nadir 85 to 89%) or severe desaturator (< 85%). These desaturation thresholds, albeit arbitrary, are consistent with earlier work that describes desaturation responses during exercise.<sup>16,17</sup> Cohen's kappa was used to assess agreement (interpretation: < 0.2 poor, 0.2 to < 0.4 fair, 0.4 to < 0.6 moderate, 0.6 to < 0.8 substantial, 0.8 to < 1 almost perfect).<sup>18</sup> To explore differences in sub-groups, participants were grouped according to their primary respiratory diagnosis as having either obstructive disease (alpha-1 antitrypsin deficiency, asthma, bronchiectasis, chronic obstructive pulmonary disease (COPD), cystic fibrosis; n = 31), restrictive disease (asbestosis, interstitial lung diseases; n = 28) or other disease (bronchiolitis obliterans, pulmonary arterial hypertension, post lung transplant; n = 21). Participants were also grouped according to whether they used supplemental oxygen during the tests. Differences between groups were explored using one-way analysis of variance (ANOVA). Linear regression was used to determine the extent to which 6MWD could be estimated using the results of the 1minSTS.

## Results

Data were available on 80 participants. The 6MWD was (mean ± SD) 419 ± 104 m and the number of transitions achieved during the 1minSTS was 24 ± 10. Participant characteristics are presented in Table 1.

### Agreement

The SpO<sub>2</sub> measured during the tests is presented in Figure 1a. Regarding SpO<sub>2</sub>, the nadir was higher during the 1minSTS compared with the 6MWT (mean difference [MD] 4%, 95% CI 3 to 5). This difference in nadir SpO<sub>2</sub> between the tests was slightly greater in those who used supplemental oxygen compared with room air by 2% (95% CI 1 to 4). The difference in nadir SpO<sub>2</sub> measured during the tests in participants with 'obstructive disease' was 3% (95% CI 2 to 5), 'restrictive disease' was 6% (95% CI 4 to 7) and 'other disease' was 3% (95% CI 1 to 4). The Bland-Altman plot is presented in the Figure 2a; LOA ranged from -4 to 12%.

The SpO<sub>2</sub> measured 1 minute into the 6MWT was similar to the nadir measured during the 1minSTS (MD 1%, 95% CI 0 to 2). Agreement between the two tests in classifying participants as mild, moderate or severe desaturators, using nadir SpO<sub>2</sub>, is presented in Table 2. Individual participant data are presented in Table 3 on the eAddenda. Agreement between the two tests was fair (κ = 0.26, 95% CI 0.09 to 0.36). Of those who demonstrated severe desaturation on the 6MWT (n = 18), 5 and 10 were classified as moderate or mild

**Table 1**  
Participant characteristics.

Characteristic	(n = 80)
Age (yr), mean (SD)	64 (10)
Body mass index ( $\text{kg}/\text{m}^2$ ), mean (SD)	28 (6)
Sex, n (%) male	43 (54)
Ethnicity, n (%)	
Caucasian	72 (90)
Asian	6 (8)
ATSI	2 (3)
Primary respiratory diagnosis, n (%)	
Alpha-1 antitrypsin deficiency/asthma/COPD	27 (34)
cystic fibrosis or non-cystic fibrosis bronchiectasis	4 (5)
interstitial lung disease	13 (16)
interstitial pulmonary fibrosis	14 (18)
pulmonary arterial hypertension	7 (9)
post lung transplant	9 (11)
other	6 (7)
FEV <sub>1</sub> (L), mean (SD)	1.65 (0.77)
FVC (L), mean (SD)	2.58 (0.84)
On LTOT, n (%)	42 (52)
O <sub>2</sub> flow rate used during both tests, n (%)	
room air	38 (48)
1 to 4 L/min	26 (33)
5 to 8 L/min	11 (14)
9 to 12 L/min	2 (3)
13 to 15 L/min	1 (1)
Required at least one rest during the 6MWT, n (%)	7 (9)
Used a four-wheeled walker during the 6MWT, n (%)	15 (19)

ATSI = Aboriginal/Torres Strait Islander; COPD = chronic obstructive pulmonary disease; FEV<sub>1</sub> = forced expiratory volume in 1 second; FVC = forced vital capacity; LTOT = long-term oxygen therapy; 6MWT = 6-minute walk test. Some percentages do not sum to 100 because of rounding.

desaturators on the 1minSTS, respectively. Of those who demonstrated moderate desaturation on the 6MWT (n = 25), 20 were classified as a mild desaturators on the 1minSTS test.

The pulse rate measured on completion of both tests is presented in Figure 1b. The end-test pulse rate was slightly lower during the 1minSTS compared with the 6MWT (MD -4 bpm, 95% CI -6 to -1). There was no difference in end-test pulse rate measured between the tests in those who used supplemental oxygen compared with those who breathed room air (0 bpm, 95% CI -5 to 4). The difference in end-test pulse rate measured during the tests in participants with 'obstructive disease' was -3 bpm (95% CI -7 to 1), 'restrictive disease' was -5 bpm (95% CI -10 to -1) and 'other disease' was -6 bpm (95% CI -11 to -1). The Bland-Altman plot is presented in Figure 2b; LOA ranged from -25 to 16 bpm. The pulse rate measured 1 minute into the 6MWT was lower than end-test pulse rate measured during the 1minSTS (MD -8 bpm, 95% CI -11 to -5).

Regarding dyspnoea, the scores reported on test completion were similar for the 6MWT and the 1minSTS (MD -0.3, 95% CI -0.6 to 0.1). The Bland-Altman plot is presented in Figure 2c; LOA ranged from -3 to 3. Regarding leg fatigue, the score reported on test completion was greater during the 1minSTS compared with the 6MWT (MD 1.1, 95% CI 0.6 to 1.6). The Bland-Altman plot is presented in Figure 2d; LOA ranged from -3 to 5.

### Linear regression

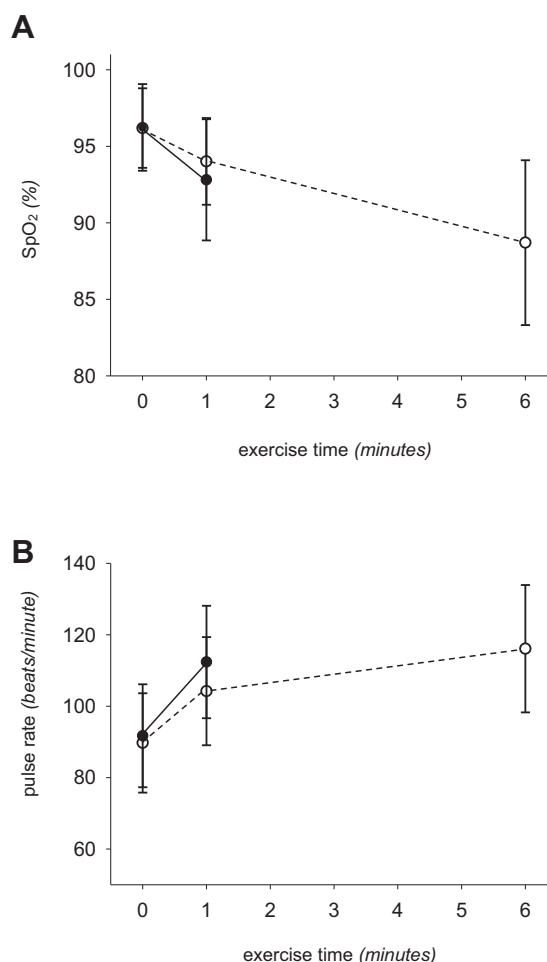
The association between 6MWD and performance on the 1minSTS was  $r = 0.66$  (Figure 3). The equation that represented this relationship was:

$$6\text{MWD (m)} = 247 + (7 \times \text{number of transitions achieved during the 1minSTS}).$$

This equation has poor predictive ability ( $r^2 = 0.44$ ).

### Discussion

This study explored cardiorespiratory responses during the 6MWT and 1minSTS in a large sample characterised by moderate to severe

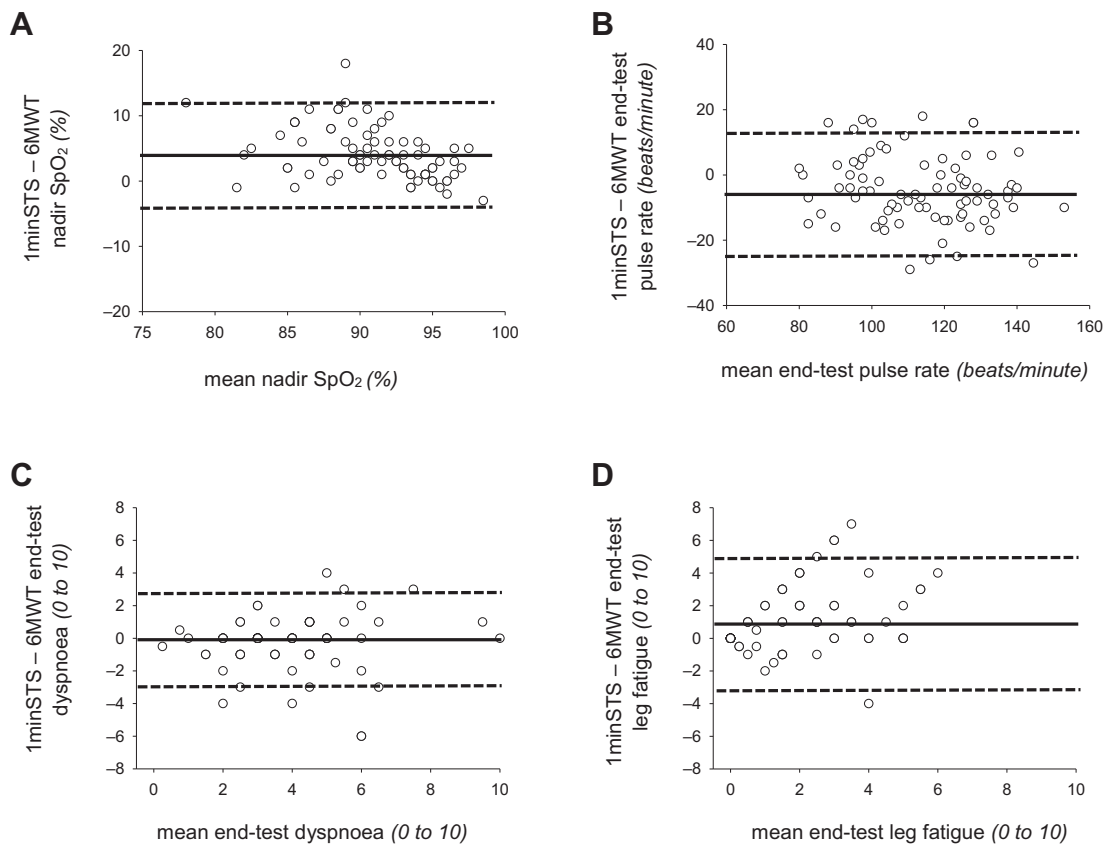


**Figure 1.** Measures of peripheral capillary oxygen saturation (SpO<sub>2</sub>) (1A) and pulse rate (1B) measured at rest and after 1 minute of exercise in both tests, and after 6 minutes of exercise during the 6-minute walk test. Data are mean and standard deviation. Open circles and dashed lines indicate 6-minute walk test; filled circles and solid lines indicate 1-minute sit-to-stand test.

lung disease who were known to the advanced lung disease service at Fiona Stanley Hospital. The data demonstrated that in this clinical population, when compared with the 6MWT, the 1minSTS elicited less desaturation, a lower end-test pulse rate, similar dyspnoea and greater leg fatigue. The true mean difference in nadir SpO<sub>2</sub> between the tests is likely to be between 3 and 5%. Although this difference might seem small, when the nadir SpO<sub>2</sub> was used to develop thresholds to classify people as mild, moderate or severe desaturators, 83% of those who were classified as severe desaturators on the 6MWT were classified as only mild or moderate on the 1minSTS. Similarly, 80% of those who were classified as moderate desaturators on the 6MWT were classified as mild desaturators on the 1minSTS. In addition, the LOA were wide, indicating that nadir seen during the 1minSTS may be as much as 12% greater than the nadir seen during the 6MWT.

The mechanisms underpinning the differences in desaturation between these tests have not been elucidated. The most likely reason is simply that the 6MWT is of longer duration than the 1minSTS and therefore people with chronic lung disease are exposed to a longer period of increased ventilatory demand, dynamic hyperinflation and greater V/Q mismatching.<sup>19</sup> Our findings that the SpO<sub>2</sub> measured 1 minute into the 6MWT was similar to the SpO<sub>2</sub> measured on completion of the 1minSTS and that SpO<sub>2</sub> continued to decrease during the 6MWT suggest that exercise time was an important determinant of the difference between tests.

This study did not enable comment on whether adults with chronic lung disease demonstrate different nadirs in SpO<sub>2</sub> with



**Figure 2.** Bland-Altman plots for demonstrating agreement between the measures collected during the 6-minute walk test (6MWT) and 1-minute sit-to-stand test (1minSTS). These measures are: A) nadir peripheral capillary oxygen saturation measured via pulse oximeter ( $\text{SpO}_2$ ); B) end-test pulse rate; C) end-test dyspnoea score; and D) end-test leg fatigue score. Solid lines represent bias and dashed lines represent limits of agreement.

walking and sit-to-stand exercise. This is because the work done during the two tests was not assessed and is unlikely to be equivalent. Despite this consideration, it is possible that, at equivalent rates of oxygen uptake, adults will demonstrate less desaturation with sit-to-stand exercise than walking exercise. This is because earlier work has shown that when people with COPD exercise at equivalent rates of oxygen uptake, cycle-based exercise elicits less desaturation than walking-based exercise<sup>20,21</sup> and mechanisms underpinning this finding may also be applicable to exercise that involves transitioning between sitting and standing; that is, compared with walking exercise, for a similar amount of work, transitioning between sitting and standing is likely to elicit greater lactate.<sup>22,23</sup> This is because unlike walking, which is a whole-body exercise, the exercise load is borne almost exclusively by muscles of the lower limb, namely the quadriceps, when transitioning between sitting and standing. Of note, following the 1minSTS, earlier work has shown that > 70% of people with COPD demonstrate contractile fatigue of the quadriceps, which

**Table 2**

Classification of each participant as a mild, moderate or severe desaturator using the nadir  $\text{SpO}_2$  measured during the two tests.

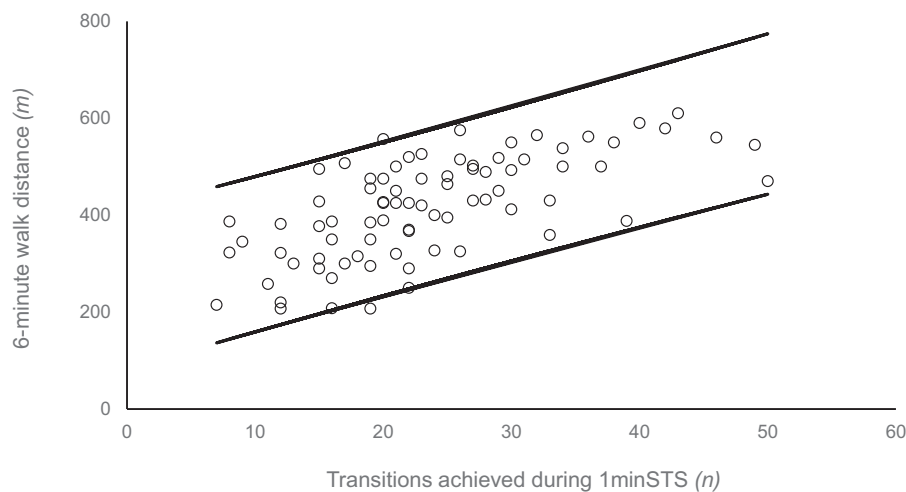
		1-minute sit-to-stand test			Total sample
		Mild desaturator	Moderate desaturator	Severe desaturator	
6-minute walk test	Mild desaturator	37	0	0	37 (46%)
	Moderate desaturator	20	5	0	25 (31%)
	Severe desaturator	10	5	3	18 (23%)
	Total sample	67 (84%)	10 (12%)	3 (4%)	80

'Mild desaturator' = nadir  $\text{SpO}_2 \geq 90\%$ ; 'Moderate desaturator' = nadir  $\text{SpO}_2$  85 to 89%; 'Severe desaturator' = nadir  $\text{SpO}_2 < 85\%$ ;  $\text{SpO}_2$  = peripheral capillary oxygen saturation measured via pulse oximeter.

aligns with our finding that the 1minSTS elicited greater leg fatigue than walking.<sup>24</sup> This higher lactate associated with overloading the quadriceps is a potent ventilatory stimulant.<sup>22,23</sup> Compared with walking-based exercise, people with COPD achieve greater peak ventilation during cycle-based exercise, as they are able to fix their arms on the handlebars and use accessory muscles of respiration and adopt a forward lean position to optimise the mechanical advantage and pressure-generating capacity of the diaphragm.<sup>25</sup> The greater levels of ventilation achieved during cycle-based exercise minimise desaturation.<sup>22</sup> Unlike walking, which necessitates arm swing, people can fix their arms against their body during the 1minSTS (eg, place their hands in their pockets or press them against their trunk). Although this effect may seem less potent than the advantages offered during cycle-based exercise (ie, using the handlebars and adopting a forward lean position), an earlier study reported that people with COPD reached a similar peak rate of minute ventilation during the 1minSTS when compared with a ramp cycle ergometry test.<sup>24</sup> This mechanism may minimise desaturation during sit-to-stand exercise.<sup>21</sup> To further explore this idea, ventilation and lactate responses and at iso-work (or similar peak rates of oxygen uptake) between the exercise modalities need to be evaluated.<sup>22</sup>

The role of supplemental oxygen therapy in people with chronic lung disease who do not qualify for LTOT is contentious and there is very little evidence that transient exertional desaturation is dangerous.<sup>26</sup> Nevertheless, people who do not qualify for LTOT but who demonstrate transient exertional desaturation are often considered for supplemental oxygen on exertion on the basis that laboratory studies have shown that supplemental oxygen during a single bout of exercise reduces minute ventilation at equivalent work rates. This in turn delays the onset of dynamic hyperinflation and the associated dyspnoea in people with COPD who have severe disease.<sup>27</sup> However, it is notable that within the context of PRPs, providing supplemental oxygen during exercise training to those who do not qualify for LTOT but demonstrate transient exertional desaturation





**Figure 3.** Scatter plot showing the 95% prediction interval for the relationship between the 6-minute walk distance and number of transitions achieved during the 1-minute sit-to-stand test (1minSTS).

does not produce any advantage in walking-based outcomes of exercise capacity on program completion.<sup>16</sup> Similarly, in this group, providing supplemental oxygen for home use does not produce convincing gains in health-related quality of life or participation in physical activity.<sup>28–30</sup> Despite this controversy, clinicians who run PRPs strive to minimise severe transient exertional desaturation<sup>5</sup> and our data demonstrate that relying on the 1minSTS to screen for moderate or severe transient desaturation is problematic.

Our finding of a relationship ( $r = 0.66$ ) between the performance on the 1minSTS and 6MWD is consistent with earlier work.<sup>8,9,11,31</sup> We present an equation that characterised this relationship. Although clinicians may be tempted to use this equation to estimate the 6MWD using the number of transitions achieved during the 1minSTS, it explained < 50% of the variance in the measure of 6MWD and so the estimate derived using this method is poorly predictive for use in clinical practice.

A strength of this study was its pragmatic approach to include data from all people known to the advanced lung disease service at Fiona Stanley Hospital. In contrast with earlier work in this area, which recruited people who met pre-specified inclusion and exclusion criteria,<sup>8–11</sup> our data are likely to have greater generalisability to the population of adults who have been referred to a tertiary centre for management of their lung disease. The use of the facility protocol for the 6MWT in which participants who demonstrated a  $\text{SpO}_2 < 80\%$  were instructed to stop and rest until their  $\text{SpO}_2 \geq 85\%$  may be seen as a limitation to this study. This is because imposing rests to minimise severe desaturation is likely to have reduced the disparity in nadir  $\text{SpO}_2$ . A small study with 38 participants being assessed for lung transplant, which did not appear to impose rests during the 6MWT, demonstrated very large differences in test nadir (end-test  $\text{SpO}_2$  73% [75 to 89] 6MWT vs 88% [81 to 92] 1minSTS).<sup>32</sup> It is therefore likely our estimate of the difference was conservative. A small number (11%) of participants were naïve to the 6MWT at the time of testing and only performed one test; performing a second test may have improved their performance. It is also acknowledged that the gold standard method for quantifying arterial oxygen saturation requires direct sampling of arterial blood, but this is beyond the scope of routine clinical practice.

In conclusion, this study demonstrated differences in cardiorespiratory and symptom responses between the 6MWT and 1minSTS in adults referred to an advanced lung disease service. Of importance, the data revealed that using the nadir  $\text{SpO}_2$  recorded during a 1minSTS to make decisions about whether strategies are needed to prevent severe transient exertional desaturation during walking-based exercise is inappropriate in this population. Further, the extent to which performance on the 1minSTS can estimate a person's

6MWD is limited and so the 1minSTS is unlikely to be helpful when prescribing walking-based exercise.

**What was already known on this topic:** In people with chronic lung disease, a 6-minute walk test (6MWT) is typically used to evaluate the response to exercise prior to commencing a pulmonary rehabilitation program. The transition of many pulmonary rehabilitation services to telehealth due to such restrictions imposed during the COVID-19 pandemic has led to increased use of the 1-minute sit-to-stand test (1minSTS) instead of the 6MWT.

**What this study adds:** The 1minSTS elicited less desaturation than the 6MWT and classified a smaller proportion of patients as 'severe desaturators' on exertion. It is therefore inappropriate to use the nadir  $\text{SpO}_2$  recorded during a 1minSTS to make decisions about whether strategies are needed to prevent severe transient exertional desaturation during walking-based exercise. Further, the extent to which performance on the 1minSTS can estimate a person's 6MWT distance is poor. For these reasons, the 1minSTS is not helpful when prescribing walking-based exercise.

**Footnotes:** <sup>a</sup> Stata version 16, StataCorp, College Station, USA.

**eAddenda:** Table 3 can be found online at <https://doi.org/10.1016/j.jphys.2023.02.001>

**Ethics approval:** The South Metropolitan Health Service Human Research ethics committee waived the need for ethics approval because the data were collected as part of normal clinical practice.

**Competing interests:** Nil.

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