

Feasibility and accuracy of the 40-steps desaturation test to determine outcomes in a cohort of patients presenting to hospital with and without COVID-19

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Feasibility and accuracy of the 40-steps-desaturation-test to determine outcomes in a cohort of patients presenting to hospital with and without COVID-19

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SCHOLARONE™ Manuscripts Feasibility and accuracy of the 40-steps-desaturation-test to determine outcomes in a cohort of patients presenting to hospital with and without COVID-19

Abstract

Desaturation on exercise has been suggested as predictive feature for deterioration in COVID-19. The objective of this paper was to determine the feasibility and validity for the 40-steps-desaturation test.

A prospective observational cohort study was undertaken in patients assessed in hospital prior to discharge. 152 participants were screened between November 2020 and February 2021 and 64 were recruited to perform a 40-steps-desaturation test. Patients who were able to perform the test were younger and less frail. 4 patients were readmitted to hospital and one patient died within 30 days.

The majority of patients showed little change in saturations during the test, even with pre-existing respiratory pathology. Change in saturations, respiratory rate, heart rate and breathlessness were not predictive of death or readmission to hospital within 30 days. Of 13 patients who had a desaturation of 3% or more during exercise none was readmitted to hospital within 30 days.

Not enough patients with COVID-19 could be recruited to the study to provide evidence for the safety of the test in this patient group.

The 40-steps-desaturation test requires further evaluation to assess clinical utility.

Background

Hypoxaemia in COVID-19

Since the emergence of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV2), the features of its causative disease, COVID-19 have been extensively studied and described (1). One feature of the disease that gained prominence is the phenomenon of "silent hypoxia", based on observations that critically ill patient with COVID-19 appeared to display minimal features of respiratory distress despite profound hypoxia (2,3). This led to an intense focus on identifying hypoxaemia early in suspected COVID-19, which was compounded by preliminary findings that hypoxaemia in the context of COVID-19 could be an early indicator of clinical deterioration (4–6). In addition it has been suggested that exercise induced desaturation may also be a prominent early feature to indicate clinical deterioration in COVID-19 (7,8).

Exercise testing in COVID-19

The recognition of exertional hypoxaemia as a feature in COVID-19 linked to clinical deterioration has made testing for exertional hypoxaemia integral to the triage of patients presenting to healthcare services with acute dyspnoea (9,10): The 6-Minute Walking Test was used in a small study of patients with COVID-19 at discharge and only completed in full by half of participants due to desaturation below 90% (11). A shorter, 3-minute walk test has linked 2% desaturation to diagnosis of pulmonary embolism, and poor outcome within 14-days in acute dyspnoea in participants desaturating below 90% during the test (12,13). Both 30 second and 5 repetition variation of a sit-to-stand test have been linked to future risk of acute exacerbations in COPD (14), but there is little research that has focused on short term outcomes of relevance in COVID-19. There are number of tools that present different physiological stress and implementation challenges and to date none of these tests have been clearly validated in the context of prediction of outcome for COVID, or feasibility of implementation(15).

One of the proposed tests appearing in National Health Service (NHS) guidance for both emergency departments and primary care settings (16,17,21) is the 40-step-test, a short exercise test involving 40 steps of walking on a flat surface, with peripheral oxygen saturations being measured before and after the test. A drop in saturation of 3% has been proposed as significant to trigger further investigation, and/or consideration of admission to hospital (15). A negative test, where a patient does not desaturate, is used as an indication that the patient can be discharged safely.

Currently it is unclear which exertional test may offer the better prediction and be suitable for ease of delivery in a potentially small space is as crucial in suspected COVID-19 patients where isolation from other patients is necessary.

Aim

The present study aimed to establish safety and feasibility of performing the 40-steps desaturation test before discharge in a population of medical emergency admissions. The secondary outcome for the study were to establish normal values for the 40-steps-test and describe the predictive value of physiological responses in patients with and without Covid-19 for future deterioration.

Methods

Study design

We performed a prospective cohort study in a single district general hospital.

Screening

Adult participants were screened, the emergency department (ED), Acute Medical Unit (AMU) and five medical wards on 30 days. Days of screening were chosen pragmatically based on availability of the researchers (TW, GHR).

Eligibility

Inclusion and exclusion criteria are listed in Appendix A. Patients were recruited prior to discharge and were required to be independently mobile. Patients were excluded if they were post-operative, had minor injuries, were electively admitted, were non-mobile patients or had abnormal physiological parameters at rest (SpO2 <95%, HR >100bpm or RR >25/min).

Baseline characteristics

During the index visit age, gender, ethnicity, working diagnosis, COVID-19 status, a past-medical history of heart failure, COPD, asthma, or interstitial lung disease were collected for each participant.

Physiological monitoring

Baseline observations of oxygen saturation (SpO₂), heart rate (HR), respiratory rate (RR), blood pressure (BP), and temperature were recorded from the patient's vital signs chart, with readings performed within four hours accepted. In addition, the patient was asked to give a numerical dyspnoea score from 0 to 10 using a word-anchored, pictorial numerical rating scale (Appendix B).

Dyspnoea score, RR (calculated by visually counting breaths), SpO_2 and HR were re-recorded immediately at completion of the 40-steps-test and at 2 minutes after the test was completed.

40-steps-test

The national recommendation for the 40-steps-test does not include specifications. For this study the test was standardised by walking on the spot, to enable reproducibility and testing in locations with limited space. Participants were asked to walk 40 steps on the spot at a self-paced walking pace. The test was discontinued if the participant expressed that they could not continue for reasons including breathlessness, light-headedness, or chest pain during the test. Saturations were measured during the test with a spot-check monitor (General Electrics, CarescapeTM V100).

No changes to medication were undertaken for the test.

Follow up/Outcome

The following outcomes were collated from medical records: Rehospitalisation within 30-days, mortality within 30-days, subsequent COVID-19 diagnosis within 7 days of taking part of the test, clinical deterioration within 7 days and changes in decision to discharge.

Safety and Feasibility

Safety was determined by the number of adverse events, feasibility by number of eligible patients, and usability as the number of patients able to complete the test as a proportion of the number of invited patients.

Data Analysis

Data was uploaded to Microsoft Excel and IBM SPSS version 26 for data analysis.

The percentage of predicted heart rate achieved by participants in the 40 step on the spot test using the maximum HR equation (220-age), $[208 - 0.7 \times age.]$ was used to estimate the exercise intensity achieved by participants during the 40-steps-test (18).

All variables were tested for normality. Normal distributed variables were reported as mean and standard deviation, non-normal distributed variables were reported a median and interquartile range. The Chi-square test was used for categorical variables. Significance was assumed for p<0.05. No adjustments were undertaken for multiple comparisons.

The 'Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies' (19) was used for the reporting of the results.

The sample size was based pragmatically on availability of investigators. No formal sample size estimate was undertaken. The study was closed due to an inability to recruit further patients.

Registration and Ethics

The study protocol was designed in collaboration with clinicians and scientists at Oxford Brookes University, Betsi Cadwaladr University Health Board (BCUHB) and Bangor University. The study was registered with the Health Research Authority (IRAS reference 283998) and ethical approval was obtained (REC 20/WA/0286). All participants provided written informed consent. No external funding was received.

Results

Screening

152 participants were screened between November 2020 and February 2021 and 64 (42%) were recruited to the study. The attrition of patients screened to participants recruited and their outcomes are summarised in Figure 1, with reasons for exclusion outlined. Participants in older age groups were more likely to meet criteria for exclusion. The mean age of included participants was significantly younger at 63 years (range 19-90) vs excluded participants at 71 years (range 24-98, p=0.008).

Demographics

50% of participants were recruited from inpatient wards, 36% from the medical admissions unit, and 14% from the emergency department. The mean age of patients recruited was 62.5 (18.7). The sample included 35 female participants and 29 male participants. 61 participants were Caucasian, one Asian, one Black/African-Caribbean and one Arabic (Table 1).

Pre-existing co-morbidities potentially affecting cardiopulmonary exercise were presented in 22 (34%) patients (16% COPD, 19% asthma, 2% pulmonary fibrosis, and 3% heart failure). Eleven COVID-19 positive patients were included (17%), of whom two had pre-existing asthma and one COPD had a co-morbid lung condition.

Safety

Of the 64 participants recruited, 100% completed the 40-steps-test in full. There were no adverse events or early terminations of the test recorded. One participant was identified as requiring physiotherapy after appearing unsteady during the exercise test. Several participants were noted to need to hold on to a surface to stabilise themselves during or immediately after the test.

Exercise intensity of the 40 steps test

Using the standard calculation for maximum predicted heart rate (HRmax), 17% of the cohort generated a HR less than 50% their predicted maximum (light intensity) during the 40-steps-test. Most participants (66%) exercised to a moderate intensity during the 40-steps-test (HR 50-70% of maximum predicted), and a further 17% were vigorously exercising during the test (>70%). Mean percentage of maximum predicted HR during the test was 60%, SD 11.51 (Figure 2).

Physiological variables during exercise

The mean starting SpO₂ was 97%, with a mean decrease in SpO₂ of 1% at the end of the 40 steps test. Mean oxygen saturation at 2-minutes was also 96%. The mean starting HR for all participants was 82 bpm, increasing a mean of 11 bpm to 93 bpm at completion of the 40 steps test, before recovering to a mean of 88 bpm at 2-minutes. The mean resting RR in our cohort was 18, which rose to 19 breaths/minute after the 40 steps and returned to a mean of 18 breaths/min at 2 minutes. The mean numerical dyspnoea score given at rest was 2 out of 10. This increased by an average of 1 to a mean of 3 at test completion, before decreasing to a mean of 2 at 2-minutes.

Patients with COVID-19

In the cohort of patients with COVID-19, mean pre-exercise saturation was 96%, with a mean post-exertion saturation of 94%. Mean SpO_2 2-minutes after completing the test was 97%. The mean oxygen desaturation in COVID-19 patients was 2%, however there was wide clinical variability (Figure 3).

The difference in SpO_2 at baseline, test completion and 2-minutes between COVID-19 and non-COVID-19 patients was not statistically significant. The difference between the mean SpO_2 change from baseline to test completion in the COVID-19 positive and negative cohort was <1%, (p=0.656).

COVID-19 positive and COVID-19 negative patients had a similar mean baseline heart rate, but COVID-19 positive patients had a mean increase of HR 16 bpm by test completion compared to 10 bpm in non-COVID-19 participants.

The mean baseline RR in COVID-19 positive patients was higher than the COVID-19 negative group, however, the difference in respiratory rate change observed following the 40-steps-test was less than 1 breath/min between COVID-19 and non-COVID-19 cases.

The difference in baseline, end-test and 2-minute numerical dyspnoea score between COVID-19 and non-COVID-19 patients were all significant at the 5% level (p=0.021, p=0.029, p=0.042), with COVID-19 positive patients reporting dyspnoea scores on average twice as high as non-COVID-19 patients. However, the difference in change of dyspnoea score prompted by the 40-steps-test in the two groups was 0.2, which was not statistically significant (p=0.584).

A third of COVID-19 positive patients required further inpatient hospital stay after the 40 steps test was completed, 9% were readmitted, 27% were investigated further, and 18% clinically deteriorated.

30-day follow-up

No deaths were recorded during 30-day follow-up.

Same day discharge occurred in 49 (76.6%) participants. Fifteen (23.4%) participants required further inpatient hospital stay; 5 were discharged the following day (7.8%), 9 within 7 days (14.1%), and 1 (1.6%) within 14 days of the 40-steps-test.

Three participants (mean desaturation 4%, all COVID-19 positive, range -10-0%) had further investigations as inpatients following the 40-steps-test: one had a D-dimer test to assess for PE following marked desaturation on the 40 steps test (due to 10% desaturation), one had repeat chest imaging which confirmed a hospital-acquired pneumonia, and another had a COVID-19 test which confirmed COVID-19. Only one patient (2%) experienced clinical deterioration while still in hospital and was diagnosed with hospital-acquired pneumonia.

Four participants were re-hospitalised (6%) within 30-days of taking part in the study, including one who presented to the ED and was then discharged. The reasons for readmission included worsening symptoms of metastatic cancer, COVID-19 related diarrhoea and vomiting, and back pain. None of the physiological parameters measured during the 40-steps-test showed a significant association with readmission to hospital within the period studied, including the change in HR, RR, SpO_2 and dyspnoea.

Same day discharge

Of the COVID-19 patients, the oxygen saturation changes from baseline to test completion ranged from -10% to +2% in those hospitalised further, and in the COVID-19 negative cohort SpO_2 change ranged from -5% to +1%. The observed mean differences in SpO_2 at baseline, test completion and 2-minute, between those hospitalised further and those discharged on the day of the test as planned were less than 1%. The mean change between SpO_2 at the end of the test from baseline was -2% in those further hospitalised, compared to -1% in those discharged on the same day.

The HR values for those hospitalised further were on average lower than those discharged on the same day, and both groups increased HR by a mean of 11 bpm during the 40 steps test. End-test RR was 2 breath/minute lower in the same day discharge group which was statistically significant (p=0.038), but the difference in change in RR during the test between the groups was <1 breath/min. Dyspnoea scores did not differ significantly between the groups.

Physiological thresholds

Using an SpO₂ threshold of 3% as currently recommended for admission to be considered (16), we found that 27% of COVID-19 positive patients desaturated more than 3% compared to 18% of COVID-19 negative patients. None of the readmitted patients desaturated more than 3% during the 40-steps-test. In those who continued to be hospitalised despite planned discharge, 27% had desaturated \geq 3% during the test. 36% of COVID-19 positive patients in the study were hospitalised further following the 40 steps test, of whom 50% had desaturated 3% during the test (Table 2).

The area under the Receiver Operator Characteristic Curve (AUROC) for changes in SpO_2 for readmission at 30 days was 0.72 (confidence interval 0.532 to 0.872). AUROC for patients without COVID was 0.697 and for those with COVID it was 0.700. There were not higher AUROCS for changes in RR, HR, dyspnoea for any of the measured outcomes including deterioration within 7 days or need for further investigations.

Discussion

What we have found

To our knowledge this is the first study to assess the 40 steps on the spot desaturation test: Our study indicates that the 40 steps test is feasible and safe in mobile patients within the acute setting and could potentially be applied in a pathway as a pre-discharge tool. We found that many patients

were unable to undertake the test. Without a pre-described pace exercise was often sub-maximal, with moderate or above levels of exertion achieved by over 75%.

In this small cohort we did not find an association between desaturation during the test and a diagnosis of COVID-19 or any other outcomes including readmission and clinical deterioration.

Heart rate change was higher in COVID-19 positive at the end of the 40 steps test and at 2-minutes, with a HR increase of 15 bpm or more seen more commonly in patients with COVID-19. Higher dyspnoea scores were observed in participants with COVID-19 diagnosis, and those further investigated, continued to be hospitalised, and who clinically deteriorated.

In our sample previously recommended thresholds for desaturation were not found to be predictive of clinical deterioration, and further work is needed to establish valid thresholds for change in HR, RR and dyspnoea.

Limitations

Despite being one of the shortest, less vigorous exercise tests within the literature many patients had to be excluded from participating in the study, mainly due to poor mobility. This limits the potential wider applicability of the 40-steps-test as a widespread screening tool. Predictive modelling is challenging with the small numbers and the main finding of our study is the limitation of the 40-step test in an elderly population while there is still an absence of the predictive performance of the 40-step test in younger patients.

Discharge from hospital is a complex process, especially in frail patients with limited mobility. Some hospitals have developed checklists to support the process (20) but thresholds for mobility are often poorly defined.

Due to the small sample size obtained, we were unable to assess validity of the test as a predicator or future deterioration, readmission or indeed mortality. Consequently, to substantiate our findings, further studies with a larger sample size is desirable, especially in COVID-19 patients.

What others have found

In a scoping review into the use of exercise testing in the acute setting (submitted for publication), we found limited evidence for using desaturation as a clinical decision tool in acute conditions including COVID-19. Desaturation predicted diagnosis of Pulmonary embolism (both in COVID-19 and non-COVID-19) (11,13), Pneumocystis pneumonia (21), clinical deterioration, and hospital

readmission within 14-days (12) in various small studies involving 6MWT, 3MWT and bicycle stepper tests. In a COVID-19 study measuring post-exertion desaturation following a non-standardised period of exertion, we identified modest evidence linking 3% desaturation and 30-days outcome in a select group of patients with oxygen saturations above 94% at rest (9). Similarly mixed results were seen using the 10-feet-desaturation-test, in COVID-19 (22); a higher proportion of patients who deteriorated clinically or died desaturated more than 3%, however 51% of the stable cohort also met this criterion.

Dyspnoea as a symptom in COVID-19 at admission has also been linked to deterioration from the disease (23,24). These are intriguing findings given the widespread focus on silent hypoxaemia.

Implications for clinical practice

As one of the shortest tests ever recommended in the clinical setting, it is likely that the 40-steps-test is not sufficiently challenging to elicit exertional desaturation. Importantly, not desaturating during the test did not rule out future clinical deterioration or readmission, and therefore other clinical features should be considered alongside the presence or absence of desaturation during 40-steps-test when deciding to discharge.

More evidence linking dyspnoea scoring and outcomes is required to assess whether there is a link between perceived dyspnoea and COVID-19 outcomes.

Implications for research and or policy

Given the inclusion of the 40-steps-test in national guidance as well as its widespread clinical use, analysis of a larger sample assessed for discharge using the 40 steps desaturation test is required to conclusively provide insight into the relevance of desaturation and clinical deterioration in COVID-19.

Our study was open for recruitment in UK hospitals and several hospitals had started the sign-up process but without readily available funding and infrastructure felt unable to contribute to the data collection despite using the test for clinical purposes. The urgency of the pandemic dictated the deployment of 'imperfect' solutions. Drug trials benefited from the existing NHS research infrastructure(25). Studies in acute care were challenged by the lack of readily available skilled teams that could conduct such work at scale. Our findings might highlight the need for infrastructure funding for acute care research.

Conclusion

We demonstrated that the 40-steps-test is a safe and feasible sub-maximal test for use in the acute setting, in mobile patients. However, it may not be achievable for a significant proportion of hospitalised patients. Therefore, the evidence to support the use of very-short exertional tests to predict outcomes and facilitate safe discharge from hospital remains limited.



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Table 1 – Demographic data 40 steps study.

Data for age, gender, and ethnicity was collected, as well as patient location, cardio-pulmonary comorbidity, and COVID-19 status. The distribution of these participants is displayed according to all outcome measures studied. The three participants investigated further included one patient having a d-dimer test which was normal, one Chest X-Ray which confirmed a hospital-acquired pneumonia, and one who had a COVID-19 PCR result which was positive. The patient who clinically deteriorated was the patient who diagnosed with a hospital-acquired pneumonia.

	Total	Readmission	No readmission (n=60)	
	n=64	(n=4)		
Gender: n (%)				
Male	29 (45.3)	0 (0.0)	29 (48.3)	
Female	35 (54.7)	4 (100.0)	31 (52.7)	
Age:				
Mean (SD)	62.5 (18.7) 19-90	76.3 (19.6)	61.7 (18.5)	
Range		47-88	19-90	
Ethnicity: n(%)				
White	61 (95.3)	4 (100.0)	57 (95.0)	
African-Caribbean	1 (1.6)	0	1 (1.7)	
Asian	1 (1.6)	0	1 (1.7)	
Arab	1 (1.6)	0	1 (1.7)	
Other	0 (0.0)	0	0	
Location: n(%)				
ED	9 (14.1)	2 (50.0)	7 (11.7)	
AMU	23 (35.9)	1 (25.0)	22 (36.7)	
Ward	32 (50)	1 (25.0)	31 (51.7)	
Ambulance	0 (0.0)	0	0	
Primary care	0 (0.0)	0	0	
Co-morbidity: n(%)				
COPD	7 (10.9)	0	7 (11.7)	
Asthma	9 (14.1)	0	9 (15.0)	
COPD and asthma	3 (4.7)	0	3 (5.0)	
Pulmonary fibrosis	1 (1.6)	0	1 (1.7)	
Heart Failure	2 (3.1)	0	2 (3.3)	
COVID-19: n(%)				
Positive	11 (17.2)	1 (25.0)	10 (16.7)	
Negative	49 (76.6)	3 (75.0)	46 (76.7)	
Not tested	4 (6.2)	0	4 (6.7)	

COPD; Chronic obstructive pulmonary disease, COVID-19; Coronavirus disease, ED; Emergency department, AMU; Acute Medical Unit, SD; Standard deviation.

Table 2 – Using physiological thresholds during the 40 steps test to predict outcome

Thresholds refer to the change in SpO2, HR, RR, and dyspnoea from the baseline measurement to the measurement immediately after completing the 40 steps test. Frequency of participants by outcome measure are displayed.

	Covid-19		Readmission		Same day discharge		Further Investigation		Clinical Deterioration	
	Υ	N	Υ	N	Υ	N	Υ	N	Υ	N
Desaturation ≥3%	3	9	0	13	9	4	2	11	0	13
Desaturation <3%	8	40	4	47	40	11	1	50	1	50
HR ≥15 bpm	5	13	0	18	14	4	0	18	1	17
HR <15 bpm	6	36	4	42	35	11	3	43	0	46
RR ≥4/min	3	9	1	12	9	4	1	12	1	12
RR <4/min	8	40	3	48	40	11	2	49	0	51
Dyspnoea ≥3	3	11	0	15	10	5	0	15	1	14
Dyspnoea <3	8	38	4	45	39	10	3	46	0	49

Bpm; beats per minute, Chi²; Chi square statistic, COVID-19; Coronavirus disease, HR; heart rate, RR; respiratory rate

Figure 1 – CONSORT flow diagram 2010 for 40 steps to safety study at one District General Hospital. Details the number of participants screened, excluded/recruited, completed the intervention, and followed up.

Attrition of patients 40 steps study

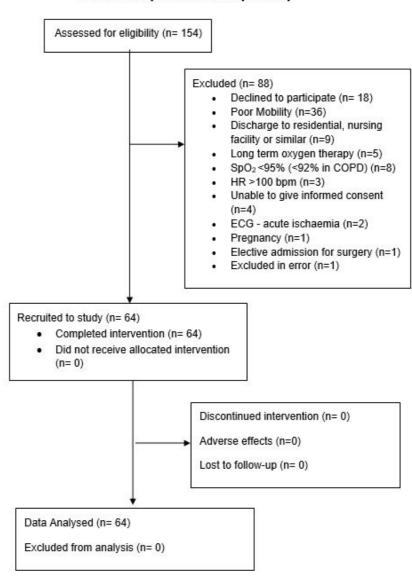


Figure 2 – Distribution of percentage of maximum predicted HR as elicited by the 40 steps test.

Histogram showing the percentage of the maximum predicated heart rate according to their age each participant achieved at completion of the 40 steps test with the majority achieving moderate exercise intensity (50-70%).

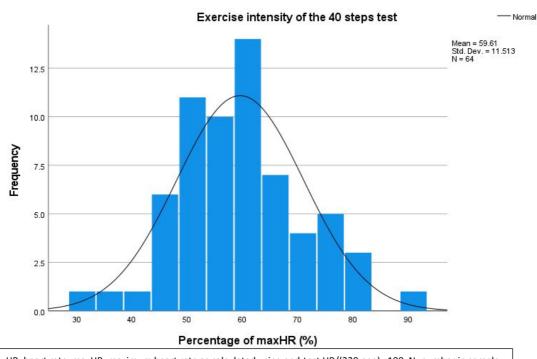


Figure 3 – Post exertional saturation changes according to COVID-19 status

Stacked histogram showing the change in oxygen saturation from baseline to immediately after completion of the 40 steps on the spot test in coronavirus disease (COVID-19) positive, negative and untested participants.

