Validity, reproducibility and responsiveness of the two minute step test in frail cardiac patients

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1. Studying validity of the 2MST in comparison with CPET2. Studying reproducibility of the 2MST by test-retest3. Studying responsiveness of the 2MST to changes in physical fitness

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49400

Source
ToetsingOnline

Brief title
Validity 2 minute step test in frail cardiac patients

Condition

- Cardiac valve disorders

Synonym
Aorta Valve Replacement, frailty

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,NWO

Intervention

Keyword: Cardiac rehabilitation, Frailty, Step test, Validity

Outcome measures

Primary outcome

Validity of 2MST: Intraclass correlation coefficient (ICC) between VO2-peak CPET and VO2-peak 2MST

Reproducibility of 2MST: ICC between NoS T1 and NoS T2, and between VO2-peak T1 and VO2-peak T2

Responsiveness of 2MST: minimal clinically important difference (MCID) for NoS T3.

Secondary outcome

quality of life (KVL-H), level of daily activities (KATz-ADL), physical functioning (Short Physical Performance Battery), metabolic equivalents level (Specific Activity Scale), self perceived effect. Possible associations with performance on exercise testing: for sarcopenia: fat-free mass (Bio Impedance Assessment and CT-scan), grip strength (JAMAR), risk of malnutrition (SNAQ); for cardiac anxiety: CAQ-DV, rate of perceived exertion (BORG-RPE); for comorbidity (Charlson comorbidity index); and for frailty (Edmonton frailty scale).

Study description

Background summary

Cardiac rehabilitation (CR) is considered standard of care after hospital admission or intervention for cardiac disease, and is preceded by exercise testing. The objective of exercise testing is to assess the safety of exercise and to assess baseline fitness level of patients. The baseline fitness level is used for personalising exercise prescription and evaluation of changes in fitness during CR. The gold standard for exercise testing is a lab-based cardiopulmonary exercise test (CPET). However, for frail patients, CPET is burdensome and complex. A less complex, non lab-based, preferentially home-based exercise test is potentially better suited to frail patients with cardiac disease. Field-tests such as the six-minute walk test and shuttle walk test have been suggested as an alternative, but are often not feasible in the home setting. The two-minute step test (2MST), which uses the number of steps to assess maximal exercise capacity, has been shown to be feasible in the home setting in elderly patients. However, the 2MST has not been validated in frail patients with cardiac disease and responsiveness to change is unknown.

Study objective

1. Studying validity of the 2MST in comparison with CPET
2. Studying reproducibility of the 2MST by test-retest
3. Studying responsiveness of the 2MST to changes in physical fitness

Study design

This is an observational validation study in which we will compare the performance of the two minute step test (2MST) to the gold standard in exercise testing, i.e. a cardiopulmonary exercise test with gas exchange measurement (CPET).
Subjects will be included during hospital admission after the TAVI procedure. Subjects will be tested on three occasions, see figure 1. Initially, the subjects will perform a CPET two to three weeks after dismissal from the hospital. This is part of the usual intake for cardiac rehabilitation. Additionally, after an hour of rest, they will perform the first step test (2MST-1) with gas-exchange measurement. For reproducibility of the test, within two to five days, a second step test (2MST-2) will be performed at home together with mobile gas exchange measurement to assess VO2-peak. Finally, to test responsiveness, at the end of their regular cardiac rehabilitation, a third step test (2MST-3) will be performed together with mobile gas exchange measurement to assess VO2-peak.

Study burden and risks

The 2MST is a submaximal exercise test. Performance of comparable submaximal exercise tests (eg. 6-minute walk test) is part of standard care in CR and

considered safe. However musculoskeletal complaints have been reported after performance of exercise testing. The 2MST brings no additional risk for patients who are indicated for cardiac rehabilitation.

Contacts

Public
Hogeschool van Amsterdam

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Hogeschool van Amsterdam

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Undergo a Transcatheter Aortic Valve Implantation (TAVI) in the AUMC
Age >= 70 years
Able to walk prior to TAVI (immobility due to aortic stenosis excepted)
Absence of any comorbid disease leading to inability to walk.
Eligible and motivated to participate in cardiac rehabilitation

Exclusion criteria

Unstable ischemic heart disease
Inability or any contra-indication to perform physical exercise
Life expectancy < 6 months

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-09-2021
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL70174.018.19