The Intrarater and Interrater Reliability of Measures Derived from Cardiopulmonary Exercise Testing in Patients with Abdominal Aortic Aneurysms

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Running Head: Reliability of CPET in vascular patients

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Summary

Introduction: Patients with abdominal aortic aneurysms (AAA) often have low exercise tolerance due to comorbidities and advance age. Cardiopulmonary exercise testing (CPET) is predictive of post-operative morbidity and mortality in patients with AAA**.** We aimed to assess the intra- and inter-rater reliability of both treadmill and cycle ergometer based CPET variables.

Methods: Patients with a AAA (>3.5cm) were randomised to treadmill or bike CPET. Participants were asked to perform two separate CPET tests seven days apart after a familiarisation protocol. All CPETs were carried out using a ramp cycle or modified Bruce treadmill protocol with breath-by-breath gas analysis.

Results: Twenty-two male and 2 female patients, aged 73.6 ± 6.0, completed the study. Intra-rater analysis (intraclass correlation coefficients) demonstrated high reliability on both the treadmill and bike for VAT (r = 0.834 and r = 0.975, respectively). All other CPET variables demonstrated high intra-rater reliability on both modalities bar the highest point for VE/VO_2 on the treadmill (substantial agreement r = 0.755). Further, inter-rater reliability demonstrated high agreement for VAT on both the treadmill and cycle (r = 0.983 and 0.905, respectively). All other CPET variables demonstrated high intra-rater reliability on both modalities, with the exception of VO_{2PEAK} on the cycle ergometer (fair agreement r = 0.400).

Discussion: CPET in AAA patients is reliable on short-term repeat testing patients and between CPET test reviewers for common testing modalities/protocols. These findings provide further support for the use of CPET, especially treadmill walking, as a clinical measure of peri-operative cardiorespiratory fitness in patients with AAA.

Introduction

Abdominal aortic aneurysms (AAA) affect approximately 5% of men over 65 years old and in the United Kingdom surgical repair is usually offered when the diameter exceeds 5.5cm [1]. Surgical repair may involve open or endovascular repair, with in hospital mortality rates for open and endovascular procedures 3.1% and 0.6% respectively [2]. However it is evident that where patients have pre-existing medical conditions or are elderly the risk may be much higher [3].

Cardiopulmonary exercise testing (CPET) is a widely used non-invasive tool to identify aerobic capacity and cardiorespiratory pathology in the preoperative setting [4-6]. CPET provides a wealth of information on the integrated cardiovascular, ventilatory and metabolic responses to exercise [7]. Several important prognostic markers have been established, including peak oxygen uptake (VO_{2Peak}), ventilatory anaerobic threshold (VAT), VE/VCO_2 slope, and ventilatory equivalents [8]. $VO_{2Peak,}$ VAT and VE/VCO2 slope up to the VAT are independent predictors of survival after elective aneurysm repair [5]. The above CPET measures provide superior prediction of postoperative complications compared to other scoring systems and biochemical markers [4]. The anaerobic threshold also has the additional benefit of being obtainable from submaximal effort up to volitional exhaustion, rather than physiological maximal effort, which is more achievable for elderly or frail patients [3, 5, 9]. Further to predicting postoperative complications, CPET can also predict length of hospital stay and mid-term mortality risk [3, 5, 9].

The reliability of CPET results are dependent on four main factors: alteration in patient fitness level, reliability of CPET equipment, intra and inter observer measurements and intra-user learning effect [10]. Significant clinical decisions may be based upon the results of preoperative CPET testing, and therefore an understanding of the inherent reliability of the test is required for adequate risk categorisation on a per patient basis.

Despite its routine use there is little evidence on reliability of interpretation between clinicians. Only one previous study in patients with abdominal aortic aneurysms have reported good intra-reliability of cycle ergometry based VAT based on a reported intra-class correlation [10]. No studies assessing treadmill as an exercise modality could be identified. In addition there are no studies whereby measures such as VE/VCO_2, VE/VO_2 and the total time able to exericse have been compared for reliability.

Therefore this study aimed to investigate the intra and inter-rater reliability of all CPET measurements on both a cycle ergometer and motorised treadmill in AAA patients.

Methods

This randomised study was undertaken in a university teaching hospital with a tertiary vascular surgery referral service covering 1.2 million patients [11]. Ethical approval was granted by the local Research Ethics Committee (16/LO/0785) and the trial was conducted in accordance with the ethical standards of the Committee on Human Experimentation from the Declaration of Helsinki 1975. The study was also prospectively registered on clinicaltrials.gov (NCT02973308). All participants provided written informed consent prior to any trial procedure.

Participants

All patients had a known AAA, and had been reviewed and referred to the study by a consultant vascular surgeon. Inclusion criteria included age over 60 years, ability to walk unaided and AAA >3.5cm. Severe cardiovascular, musculo-skeletal or pulmonary illness precluding ability to partake in CPET, active cancer treatment, and patients not able to give informed consent were exclusion criteria.

Randomisation

Patients were randomised in a simple 1:1 ratio using an online randomisation tool (Sealedenvelope.com, London, UK) to either motorised treadmill walking or cycle ergometer CPET.

Testing Protocols

A symptom-limited motorised treadmill or ramp-incremental cycle ergometer test (MedGraphics Ultima™ CardioO_2; Medical Graphics, St Paul, MN, USA) was performed, following a detailed medical history. All participants took part in a familiarisation session of their randomised testing modality to limit any learning effect between subsequent testing visits.

For ventilatory gas analysis, patients were fitted with a soft facemask, covering both the nose and the mouth and was tested for adequately sealed. The gas exchange analysis software used was the Breeze Suite software (Medical Graphics, St Paul, Minnesota, USA). Calibration of airflow, volumes and oxygen and carbon dioxide analysers took place before each exercise test. The temperature, barometric pressure and humidity within the laboratory were utilised in separate calibration's. The calibration of ventilatory volumes was achieved using a mass flow sensor and involves injecting a repeated (10 injections) 3L volume of air from a syringe according to manufacturer's instructions. This volume calibration is accurate to ±3% of the 3L volume.

A twelve-lead ECG with concurrent ST segment analysis (Mortara mobile ECG system, Medical Graphics, St Paul, Minnesota, USA) was monitored from the start to termination of the exercise test. Continuous, real-time computer display was implemented to contribute to test safety. In order to minimise any confounding factors, testing was carried out at the same time each day and in the same environment a maximum of one week apart.

Motorised Treadmill Protocol

The Modified Bruce protocol consists of three-minute incremental minute stages [12] commencing with walking at 1.7 miles per hour (mph) on a 0% gradient and progressing to a upper stage of walking at 5.5mph on a 20% gradient .

Cycle Ergometer Protocol

The cycle protocol was based on the following stages [13];

- Stage 1; 0 – 2 minutes, free-wheeling (0 watts resistance)
- Stage 2; Increase of 15-$W.min^{-1}$ increments until the patient reached their limit of tolerance
- Stage 3; recovery / cool down

Patients were asked to maintain a cycle speed of between 60 – 70 revolutions per minute to maintain consistency. The CPET was terminated prematurely if the patient reported any chest pain, chest tightness, severe dyspnoea or more than 2 mm ST change in any lead. If the CPET was terminated early these results were not included in the final data set. All tests were performed with trained medical staff in attendance and resuscitation equipment immediately available.

Gas-exchange measures

Gas exchange variables were determined via breath-by-breath analysis. Erroneous breaths were excluded from analysis (coughing, swallowing etc), and time-averaging of 15 seconds were applied. The variables recorded for each CPET assessments were as follows; peak oxygen consumption (VO_{2peak} ml/kg/min^{-1}) [within the last 30 seconds of exercise], ventilatory anaerobic threshold (VAT - ml/kg/min^{-1}) determined via the V-slope method[14] , total time to exhaustion (TTE) and ventilatory slopes for oxygen (V_E/VO_2) and carbon dioxide (V_E/VCO_2).

Outcome measures

The primary outcome was intra and inter-rater reliability for the measurement of VAT. Intra-rater refers to within patient testing and inter-rater refers to the consistency of agreement between clinicians.

Secondary outcomes included intra and inter-rater reliability of VO_{2Peak}, Ventilatory Equivalents for Carbon Dioxide (VE/VCO_2) at VAT and Total Time to Exhaustion (TTE).

Sample Size

The sample size for this study was based on the desired precision of estimation of the measurement error; which is determined on the number of participants and tests [15]. This resulted in a sample size of 24 in total or 12 patients per group. ***Statistical Analysis***

Mean and standard deviation were calculated using Microsoft Excel 2015 (Microsoft Washington, USA). Further statistical analysis was performed in IBM SPSS Professional Edition v24.0 (IBM, New York, USA: SPSS). The Shapiro-Wilk test was performed to assess for normality. Interclass correlation coefficient (ICC) test was performed using a two-way mixed model on VAT, VO_{2Peak} and VE/VCO_2 slope. For ICC, an r value of 0.21-0.40 was taken to indicate a fair agreement, 0.41-0.60 a moderate agreement, 0.61-0.80 a substantial agreement and 0.80-1.00 a high agreement [16]. A paired t-test was used to compare all variables between repeat testing, with significance set at $p < 0.05$.

Results

24 patients (2 female) were recruited, all of whom completed 2 CPET assessments. There were no adverse events or complications to symptom-limited exercise testing and CPET data from all participants were analysed. The baseline demographic data is presented in tables I and II and CPET data in table III.

Intra-Rater reliability

There were no significant differences in the VAT analysed by the same clinician for the test-retest group in either the cycle ergometer (p=0.395) or treadmill (p=0.473). The ICC for the VAT showed excellent intra-rater reliability on both the motorised treadmill (r=0.834 [95% CI 0.215,0.975]; p = 0.010) and cycle ergometer (r=0.959 [95% CI 0.741,0.994]; p = 0.000) group. The typical within-patient error was 9.6% with a 0.2 standard error the mean.

There were no significant differences in VO_{2Peak}, VE/VCO_2, TTE or VE/VO_2 when determined by the same clinician on test-retest analysis in the motorised treadmill or cycle ergometer group. In addition, VO_{2PEAK} had a 7.1% co-efficient of variance and a 0.3 standard error of the mean. All intra-group values had a high correlation with the exception of VE/VO2 on the treadmill which demonstrated substantial agreement (table IV).

Inter-Rater Reliability

There were no significant differences in the VAT analysed by clinician A and B for either the treadmill (p=0.783) or cycle (p=0.549). The ICC value showed high agreement between AT values measured at the first and second visit for both the motorised treadmill (*r*=0.983 [95% CI 0.785,0.999]; *p* =0.002) and cycle ergometer (*r*=0.905 [95% CI 0.508,0.986]; *p*=0.003).

All ICC values within the inter-rater analysis showed high correlation, except for TTE which had a moderate but non significant correlation on the cycle ergometer (table V)

Discussion

The aim of this study was to investigate the intra-rater and inter-rater reliability of CPET measurements undertaken on both a cycle ergometer and motorised treadmill within a small representative cohort of patients with AAA disease. Our findings demonstrate high agreement between two independent observers investigating the same patient on two separate test days (inter-rater reliability) and the same reviewer investigating the same patient on different days (intra-rater reliability) for almost all routine CPET measures.

Ventilatory Anaerobic Threshold

The ventilatory anaerobic threshold (VAT), determined by gas exchange analysis using the V-slope methodology, is considered as one of the most important measures derived from a CPET[10]. This study demonstrated that intra-rater reliability for VAT showed a high agreement for both the cycle (r = 0.959) and treadmill (r = 0.834) protocols. Furthermore, despite a small change in the mean AT between tests (insert delta difference in VO2) in all groups there was no significant difference in either the cycle groups (*p* = 0.473) or treadmill groups (*p* = 0.780). In addition, to a high intra-class correlation, the coefficient of variation (CV) for each testing modality was 9.4% and 9.6% for the cycle and treadmill respectively, with a small standard error of the mean. These reliability values are consistent with a prior study reporting a 10% coefficient of variance within 18 with abdominal aortic aneurysm[10]. On evaluating CPET scores, clinicians should be aware of this potential measurement variability and a 10% window should be used when assessing patients with one CPET prior to operation. However, this study should give confidence to clinicians that VAT can be accurately gauged in a single visit, saving both clinical and patient time[17].

CPET Variables

There are a number of other important variables that can be ascertained from a CPET including; VO_{2PEAK}, VE/VCO_2 slope, VE/VO_2 at VAT and TTE; with VE/VCO_2 linked to pulmonary post-operative complications [3]. Although some of these measures are much more reliant on patient motivation they still provide valuable information to the clinician. There were no significant differences between any variable collected for groups A/C in either modality. The intra-rater reliability demonstrated high agreement for all variables ($r > 0.80$) with the exception of VE/VO_2 at VAT which demonstrated substantial agreement ($r = 0.755$). In addition to a high intra-class correlation; the coefficient of variance for $_{VO2PEAK}$ for each modality was 6.9% and 7.1% for the cycle and treadmill respectively, with a small standard error of the mean.

Inter-rater reliability demonstrated no significant differences between tests for any the other CPET measures (VO_{2Peak}, VE/VCO_2, VE/VO_2 and TTE) for both the cycle ergometer and the treadmill group. Moreover, all inter-rater variables demonstrated high agreement with the exception of VO_{2PEAK} and TTE in the cycle ergometer group which both demonstrated only fair agreement ($r = 0.400$, and $r = 0.417$, $p = 0.197$; respectively). Variation in these results may be due to inconsistency in patient motivation and effort and supports the view by Hartley *et al.* (2012) that patient effort is likely to reflect negatively on the reproducibility of CPET results in AAA cohort's [9]. Test supervisors should be mindful of the effect of patient effort on test outcome. In order to minimise these effects; particularly when multiple clinicians are performing CPETs; certain criteria should be applied to determine whether a patient has given maximal effort. These criteria include; >85% maximum heart rate, failure to increase VO_2 >150ml/min with increasing workload, respiratory exchange ratio >1.10 and rating of perceived exertion using the Borg scale >17[7]. If patients fail to achieve these criteria this should be noted on outcome reports-but recent reports in healthy adults indicate that secondary criteria for maximal exertion may be age-dependent [18].

Test Modality

There appears to be limited reseearch on the use of treadmill testing in patients with AAA; perhaps because patients are deemed to be too high risk, or that the testing modality is not safe [19]. However, in the present study all patients tolerated testing well on both ergometer protocols and no adverse events were recorded. This suggests that for patients with no associated contradindications, and who are amenable to walking, treadmill testing can be used. Perhaps most importantly the inter-rater reproducibiltiy of VO_{2PEAK} measurement appears to be greater when treadmill testing is used in comparison to cycle ergometer testing (r = 0.798 versus r = 0.400). Other advantages of treadmill testing over cycle ergometer testing include familiarity to activity and larger muscle mass work and therefore higher peak O_2 uptake. One caveat that is important to note is that, should treadmills be used, holding on must be discouraged where possible, as it decreases the metabolic cost associated with the workload [20].

Limitations

It is important to take into consideration the reproducibility of CPET-derived measurements when undertaking clinical exercise tests. Factors that may contribute to variability in these measurements include patient motivation and ability, time of day, testing procedures and equipment and / or calibration errors. Meticulous care was taken during the study to ensure that every factor that may contribute to the measured exercise response was controlled as much as possible. All patients were invited to come back for follow-up testing at the same time of day as the previous visit(s), and no tests were performed if there was an error with equipment or calibration.

Although we achieved the sample size required for this study, there is a relatively small sample of patients (12 per arm). More patients would be required to further assess the reliability of exercise testing in this cohort.

Conclusion

In summary, these results demonstrate that CPET measures within elderly AAA patients appear to show robust intra-rater and inter-rater reliability using either a cycle-ergometer or motorised treadmill protocols. Both the measurement error, coefficient of variance and interclass correlation coefficient should give clinicians confidence that single CPET assessments may be accurate and reliable. The gas exchange measures derived from CPET may be used to inform risk stratification and clinical decisions prior to surgical intervention. However, clinicians should be mindful that VO_{2PEAK} on a cycle ergometer appears to have less reproducibility than other CPET measures. Care should be taken to encourage patients to give maximal effort when undertaking CPET testing using the specified criteria.

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Figure I:

Table I: Patient Anthropometric Data

Characteristic	Cycle Ergometer (*n*=12)	Treadmill (*n*=12)	*p Value*
Demographics			
Age (years)	73.3±5.9	75.4±5.5	.312
Gender (female)			
Height (cm)	176.2±6.5	175.2±4.3	.675
Weight (kg)	94.6±22.1	89.3±14.9	.268
BMI (kg/m^2)	31.9±7.2	29.1±4.2	.282
Aortic diameter (cm)	5.07±0.87	5.09±0.9	.957
Resting values			
Heart rate (bpm)	81±10	76±12	.309
Blood pressure (mmHg)			
Systolic	141.1±13.4	144.8±17.8	.624
Diastolic	84.8±9.9	81.8±8.9	.453
Mean arterial pressure	103.7±9.9	102.7±11.3	.834
Medication			
Statin	7	9	.102
Aspirin	6	8	.414
Blood Pressure control	8	7	.221
Beta-Blocker	5	5	1.000

cm = centimetres, kg = kilograms, BMI = Body Mass Index, kg/m^2 = kilograms per meters squared, bpm= beats per minute, mmHg = millimeters of mercury

Table II. Comorbidites of patients completing the study

Condition	**Cycle Ergometer**	**Treadmill**	***p Value***
Angina	3	2	.253
Previous MI	2	2	1.00
Hx of cardiac failure	1	1	1.00
Previous CAS	2	4	.889
HTN	8	8	1.00
COPD	3	3	1.00
Active smoker	2	1	.537
DM	1	3	.590
CKD ≥ 3	1	1	1.00

MI = Myocardial infarction; Hx = history; CAS = Coronary artery stenting; HTN = Hypertension; COPD = Chronic obstructive pulmonary disease; DM = diabetes mellitus; CKD = Chronic kidney disease

Table III. Mean CPET variables on cycle and treadmill

Variable	Cycle Ergometer	Cycle Ergometer (2)	Treadmill	Treadmill (2)
VO_{2peak} ml/kg/min^{-1}	12.3±4.1	11.4±2.7	17.2±4.9	16.0±3.1
VAT ml/kg/min^{-1}	8.4±2.3	8.8±2.7	13.25±3.1	12.3±2.3
VE/VO_2 slope	30±4	30±3	32±7	30±7
VE/VCO_2 slope	31±5	33±3	35±8	32±7
TTE (secs)	515±225	467±283	486±211	412±214
RPE	17±2	18±1	18±2	17±1
RER	1.00±0.12	0.95±0.10	0.96±0.13	0.92±0.11

VAT = Ventilatory Anaerobic Threshold, TTE = Total Time to Exhaustion, RPE = Rate of Perceived Exertion, RER = Respiratory Exchange Ratio, %PMHR = Predicted Maximum Heart Rate

Table IV. ICC (intra-rater) for selected cardiorespiratory variables from repeat cycle and treadmill CPET

		95% confidence interval		
	ICC R value	**Lower**	**Upper**	***p* value**
Cycle				
VO_{2PEAK}	0.984	0.888	0.999	0.000
VE/VCO_2 slope	0.800	0.114	0.969	0.015
VE/VO_2 slope	0.816	0.160	0.972	0.013
TTE	0.894	0.428	0.984	0.003
Treadmill				
VO_{2PEAK}	0.927	0.576	0.990	0.001
VE/VCO_2	0.923	0.557	0.989	0.001
VE/VO_2	0.755	0.001	0.962	0.025
TTE	0.967	0.785	0.995	0.000

Table V. ICC (inter-rater) for selected cardiorespiratory variables from repeat cycle and treadmill CPET

		95% confidence interval		
	R value	**Lower**	**Upper**	***p* value**
Cycle				
VO_{2PEAK}	0.400	-0.891	0.851	0.025
VE/VCO_2 slope	0.976	0.828	0.997	0.001
VE/VO_2 slope	0.952	0.706	0.993	0.001
TTE	0.417	-0.623	0.896	0.197
Treadmill				
VO_{2PEAK}	0.978	0.392	0.999	0.000
VE/VCO_2	0.843	-0.004	0.989	0.015
VE/VO_2	0.957	0.506	0.997	0.003
TTE	0.969	0.729	0.998	0.003