Noninvasive Assessment of Cardiac Output in Advanced Heart Failure and Heart Transplant Candidates Using the Bioreactance Method

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Title:

Non-invasive assessment of cardiac output in advanced heart failure and heart transplant candidates using the bioreactance method

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Validity of bioreactance in heart failure

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Declaration of Interest: None

Abstract

Objective(s): The aim of the present study was to assess the validity and trending ability of the bioreactance method in estimating cardiac output at rest and in response to stress in advanced heart failure patients and heart transplant candidates.

Design: This was a prospective single-centre study.

Setting: Study was conducted at the heart transplant centre at the Freeman Hospital, Newcastle upon Tyne UK.

Participants: Eighteen patients with advanced chronic heart failure due to reduced left ventricular ejection fraction (LVEF, 19±7%), and peak oxygen consumption 12.3 ± 3.9 ml/kg/min.

Interventions: participants underwent right heart catheterisation using the Swan-Ganz catheter.

Measurements and Main Results: Cardiac output was measured simultaneously using thermodilution and bioreactance at rest and during active straight leg raise test to volitional exertion. There was no significant difference in cardiac index values obtained by thermodilution and bioreactance methods (2.26±0.59 vs 2.38±0.50 L/min, $p>0.05$) at rest, and peak straight leg raise test (2.92±0.77 vs 3.01±0.66 L/min, $p>0.05$). In response to active leg raise test, thermodilution cardiac output increased by 22% and bioreactance by 21%. There was also a strong relationship between cardiac outputs from both methods at rest ($r=0.88$, $p<0.01$) and peak straight leg raise test ($r=0.92$, $p<0.01$). Cartesian plot analysis shows good trending ability of bioreactance compared to thermodilution (concordance rate=93%)

Conclusions: Cardiac output measured by the bioreactance method is comparable to that from thermodilution method. Bioreactance method may be used in clinical practice to assess

hemodynamics and improve management of advanced heart failure patients undergoing heart transplant assessment.

Keywords: Bioreactance, Cardiac Monitoring, Cardiac Output, Heart Failure, Thermodilution.

Registration: European Clinical Trials Database (Number: 2016-005264-34)

Introduction

Assessment of cardiac output and pulmonary and systemic vascular resistance are pivotal for decision making in advanced heart failure patients who are candidates for transplant or circulatory support. Hemodynamic measures are strong predictors of mortality in heart failure patients [1,2].

The reference methods for evaluation of advanced heart failure patients who are considered for heart transplant or mechanical circulatory support involve right heart catheterisation and use of thermodilution, and direct Fick's methods to assess cardiac output [3]. These methods are however invasive, require specialized training to perform and may be associated with complications such as infection, arrhythmia, and bleeding. Furthermore, thermodilution have been shown to underestimate cardiac output in patients with moderate to severe tricuspid regurgitation [4–6]. These complications limit cardiac output monitoring in routine practice despite its benefit in heart failure patients [7,8].

Bioreactance is a non-invasive cardiac output measurement method which is based on an analysis of beat by beat changes (phase shifts) of an electric current that occur as that current travels through the thoracic cavity [9]. Phase shifts occur due to pulsatile blood flow majorly from the aorta. Volume changes in the thoracic cavity produce variations in electrical capacitance and inductance referred to as bioreactance [10]. This is unlike bioimpedance which works on the principle that the thoracic cavity is perfused with blood which has a specific resistivity to a high frequency low amplitude current [11]. Bioreactance addresses the limitations of bioimpedance technique which include sensitivity to body size, large surface area electrode contact on skin and poor signal quality due to physical factors that impact on electrode conductivity such as temperature and humidity [12]. Several studies have compared bioreactance with other non-invasive cardiac output monitoring techniques [13–15] and in various clinical situations, especially in critically ill patients [16–18]. Previous studies showed that bioreactance is

more precise for determining hemodynamic changes than thermodilution [17,19,20] with both sensitivity and specificity reported to be 93% [19]. Furthermore, some studies have reported strong relationship between bioreactance cardiac output and other relevant physiological measures such as peak oxygen consumption, ventilatory efficiency and peak cardiac power [21,22]. However, literature on the trending ability of bioreactance in advanced heart failure patients is lacking despite its potential application, especially for risk stratification. Trending ability is defined as a feature of a new technology to accurately detect changes in cardiac output [23] Accordingly, the aim of the present study is to compare validity and trending ability of bioreactance and thermodilution methods at rest and during exercise in patients with advanced heart failure. Based on previous studies which report good agreement between both methods at rest, we hypothesise that cardiac output changes during exercise will be accurately detected by both methods with an acceptable margin of error.

Methods

This was a prospective single-centre study from the UK heart transplant centre at the Freeman Hospital, Newcastle upon Tyne. Eighteen patients with advanced chronic heart failure reduced left ventricular ejection fraction (as defined by the European Society of Cardiology [24] were admitted into the hospital for a three day pre-transplant assessment. Patients were excluded from the study if they had a myocardial infarction or cerebrovascular event within 30 days preceding the study, uncontrolled arrhythmias, symptomatic severe aortic stenosis, or taking part in another research study. All study procedures were approved by the UK National Health Research Authority Research Ethics Committee 6 (17/WA/0066) and performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants. Measurements of hemodynamics were performed simultaneously using thermodilution and bioreactance at rest. After resting measurements were taken, subjects were asked to perform

straight leg raise (SLR) test while supine, by raising each leg alternately at about 45°. Patients were encouraged to perform SLR until volitional exertion.

Thermodilution is reduction in temperature of a liquid that occurs when it is introduced to a colder liquid. In clinical settings, it is a method of measuring ventricular blood volume and cardiac output. A bolus of solution of known volume and temperature is injected into the right atrium, and the resultant change in blood temperature downstream over duration of time is detected by a thermistor previously placed in the pulmonary artery with a catheter. Thermodilution was performed using Swan-Ganz catheter (Edwards Lifesciences, Irvine, CA, USA) which is inserted through the internal jugular vein into the right pulmonary artery by a cardiologist. The catheter was advanced to the pulmonary artery and was guided by X-ray imaging, ensuring that the catheter injection port is located directly on top of the tricuspid valve. Bolus injected was 0.9% saline Sodium Chloride (NaCl) cooled to ice-cold temperature (0°C - 6°C) by means of storing the bolus in an ice bath insulated with Styrofoam to increase the signal to noise ratio. Temperature-time curve was then recorded from the beginning of the injection until the point when temperature returned to baseline, pre-injection level. Cardiac output is then calculated automatically.

Bioreactance method was performed using NICOM hemodynamic monitoring system (Cheetah Medical, Delaware, USA). The NICOM system is based on an analysis of relative phase shifts of an oscillating current that occurs when traversing the thoracic cavity. It comprises a radiofrequency generator that creates a high-frequency current that is transmits across the thorax, 4 dual surface electrodes that are used to establish electrical contact with the body, a receiving amplifier for recording the transthoracic voltage in response to the injected current, and circuitry for determining the relative phase-shift between the injected current and the recorded voltage. While one end of the electrodes was used to introduce high frequency (75 kHz) current to the body, the other was used as a voltage input amplifier. Signals are recorded

from the left and right sides of the thorax; these signals are processed separately and averaged after digital processing. After electrode placement, the device was calibrated and stable signals generated before were measurements taken. The signal processing unit of the system determines the relative phase shift between the input signal relative to the output signal. Phase shifts are due to changes in blood flow in the aorta. The complete mechanism of the bioreactance method has been described previously [9].

Statistical Analysis

All statistical analyses were performed using SPSS version 24 (IBM, Chicago, IL, U.S.). Cardiac output data from thermodilution and bioreactance were then analysed for association using two-sided student t-test and Pearson's correlation. Statistical significance was indicated if $p<0.05$. Bland-Altman plots were used to assess agreement between the methods. Percentage error was calculated using the formula ($\frac{\pm 2S}{M}$ *100) where 'S' is the standard deviation of the measurement and M is the mean cardiac output.

Trending ability was assessed using two methods: Cartesian plot and polar plot. In both plots, we excluded SLR-resting cardiac output difference (ΔCO) of below 0.5l/min as they could be attributed to device error [23,25]. A Cartesian plot was constructed by plotting ΔCO between thermodilution and bioreactance. Concordance rate was then calculated as the percentage of data points located within the quadrant containing the line of identity (y=x) compared to total data points. A concordance rate of >90% indicated good trending ability [23].

Data was transformed using methods described by Critchley and colleagues [23] using Microsoft Excel (Version 1905, Microsoft) and plotted using SigmaPlot 13 (Systat Software, Inc., California, USA). Trending ability was analysed from the plot of inclusion rate against radial sector size. 95% inclusion rate at ≤35° indicates acceptable limit of agreement.

Results

Patient characteristics are presented in Table 1. Mean LVEF and pulmonary arterial pressure were 19±7% and 26±11mmHg respectively, and 56% were categorized as NYHA class IV. One patient demonstrated severe, and two patients moderate tricuspid regurgitation. All subjects completed both measurements during rest and SLR test. Resting and stress test parameters are presented in Table 2. Resting cardiac output was not significantly different between thermodilution and bioreactance methods at rest (TD: 4.7±1.4; BR: 4.9±1.21 $lmin^{-1}$, p=0.17) and during SLR (TD: 6.0±1.7; BR: 6.2±1.36 $lmin^{-1}$, p=0.29) with a strong positive relationship between cardiac output measured by both methods (figure 1). Bland-Altman analysis at rest and SLR showed a mean bias of 0.23 $lmin^{-1}$ with lower and upper limits of agreement between -1.1 to 1.55 $lmin^{-1}$ and mean bias of 0.18 $lmin^{-1}$ with lower and upper limits of agreement of -1.71 to 1.53 $lmin^{-1}$ respectively (figure 2). Percentage error of measurement at rest and SLR was 28% and 22% respectively. Cartesian plot analysis (Figure 3) showed good trending ability of bioreactance when compared to thermodilution. The concordance rate between the two methods was 93% (14/15 data points). Further analysis using polar plot showed mean angular bias of 7° and radial limits of agreement of 41°. Four data points were excluded from the analysis due to small change CO (Exclusion zone: 0.5l/min).

Discussion

The main finding of this study indicates that in heart failure patients, cardiac output measurement obtained by bioreactance method is comparable to that obtained by thermodilution method. Bland-Altman analysis showed small bias, narrow limits of agreement, and acceptable percentage error [26]. Additionally, the bioreactance method could detect changes in cardiac output with acceptable accuracy compared to thermodilution as shown by high concordance rate and polar plot result. The present study findings support the use non-invasive

bioreactance as complementary method for evaluation of haemodynamics and cardiac output in heart failure patients.

The gold standard Fick's and thermodilution methods for cardiac output measurement, is not always easy to use as it is invasive, requires extensive training, and has been associated with several risks, i.e. hematoma, arrhythmias and infection [27]. In contrast, bioreactance is more versatile, non-invasive, and does not require as much operator training as thermodilution. Furthermore, bioreactance is easily repeatable over a number of hours as clinical settings change. The result of the present study suggests that bioreactance is a potential non-invasive supplement for on-going care in patients with advanced chronic heart failure. The decision to use bioreactance as a continuous monitoring device will depend on a number of factors including patient's clinical situation, presence of cardiac devices and overall risk to benefit ratio.

Squara and colleagues proposed a theoretical framework for the validation of the cardiac output devices and suggested four quality criteria i.e. accuracy, precision, short response time and accurate amplitude response [28]. In the present study we used appropriate statistical methods to evaluate and demonstrate validity of bioreactance method to assess cardiac output.

The present study CO results are similar to a previous study in heart failure patients [29] that reported resting cardiac output of 4.5l/min and 5l/min for thermodilution and Fick's methods respectively. A multicentre study by Raval and colleagues [17] incorporating 111 subjects demonstrated that cardiac output measurement using bioreactance correlates better with thermodilution compared to bioimpedance, with a bias of only -0.09 $lmin^{-1}$. Additionally, bioreactance has been shown to be comparable to Pulse Contour Analysis and thermodilution [30]. Our study further substantiates the evidence that cardiac output measured by bioreactance is comparable to thermodilution in heart failure patients. Furthermore, the present study

A few studies have reported opposing results. In critically ill patients, a percentage error of 85% was reported with bioreactance during passive leg raise exercise [18]. Fagnoul and colleagues [16] while investigating critically ill patients (i.e. cardiogenic, septic, and distributive shock) also showed wide agreement between thermodilution and bioreactance. Both studies remarked that results were due to extensive lung injury and fluid accumulation in the thoracic cavity. However, Squarra and colleagues[19] while studying post-cardiac surgery patients showed that sensitivity and specificity of the NICOM for detecting significant directional hemodynamic changes was 93% respectively and concluded that bioreactance had acceptable accuracy, precision, and responsiveness in a wide range of circulatory situations. From our results and available literature it is reasonable to suggest that bioreactance is reliable method in perioperative care.

The present study also conducted trending ability analysis of bioreactance compared to thermodilution using two methods: 4-axis cartesian plot and polar plot. The result of the cartesian plot demonstrated that bioreactance has good trending ability, with a concordance rate of 93%. A previous study showed that bioreactance could track cardiac output changes with strong linear correlation when compared with other non-invasive methods [31]. However, these devices have markedly different bias and precision values relative to each other making it unrealistic to validate new devices based on results from prior studies which used a single technique to estimate cardiac output. Recent approaches to functional hemodynamic monitoring now involve use the dynamic change in cardiac output response, such as passive leg raise or in the present study straight leg raise, to define volume responsiveness.

This study is not without limitations. Firstly, the sample size used in the present study is small. Although sample size calculation in validation studies is controversial [32], a bigger sample size would potentially reduce limits of agreement and increase the accuracy seen in the Bland-Altman plot. Also, measurements were done only twice, meaning that only one ΔCO (SLR-

Resting) could be extracted. The following limitations of bioreactance method should be noted. Firstly, the ability of the device to measure cardiac output might be limited by variations in thoracic impedance due to variations in thoracic blood volume resulting from respiration, arrhythmias, and cardiogenic shock). Furthermore, strength of the electrical signal could be diminished due to interference with cardiac devices, such as pacemakers or ventricular assist devices.

Conclusions

The result of the present study demonstrates that bioreactance is a valid method in measuring cardiac output in advanced heart failure patients. The method can also accurately detect changes in cardiac output in response to dynamic exercise and presents a simple, inexpensive method to supplement clinical evaluation of patients with chronic heart failure. Future studies are warranted to evaluate clinical- and cost-effectiveness of bioreactance in heart failure clinical practice.

Author contributions:

Study conceived and designed by DGJ, GAM

Data collection performed by GAM, NCO, BAWP, AK, NBC, OGF

Data extraction and analyses performed by BAWP, NCO, DGJ.

Interpretation of data and preparation of manuscript performed by DGJ, BAWP, NCO, CE, NBC, OGF LV, AK.

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Table 1. Patient demographic and clinical characteristics n=18

Characteristics	**Result**
Age	52 ± 9
Weight (kg)	92.8 ± 15.8
Height (cm)	174.2 ± 8.6
Body Mass Index (kg m^{-2})	30.49 ± 4.3
Body Surface Area (m^2)	2.07 ± 0.2
Systolic Blood Pressure (mmHg)	100 ± 17
Diastolic Blood Pressure (mmHg)	65 ± 10
Left Ventricular Ejection Fraction (%)	19 ± 7
Peak oxygen consumption (ml/kg/min)	12.3 ± 3.9
NYHA Class	
III	8 (44%)
IV	10 (56%)
Medications, n (%)	
Beta Blockers	17 (94%)
Diuretics	16 (89%)
Spironolactone	14 (78%)
ACE Inhibitor	13 (72%)
Angiotensin Receptor Blocker	3 (16%)

Data are presented as mean ± SD or frequency (%). ACE: Angiotensin Converting Enzyme. NYHA: New York Heart Association.

Table 2. Resting and stress test hemodynamic parameters (mean ± SD).

	Thermodilution	Bioreactance	P Value
Rest			
Cardiac Output ($lmin^{-1}$)	4.72 ± 1.42	4.94 ± 1.21	ns
Cardiac Index ($lmin^{-1}$)	2.26 ± 0.59	2.38 ± 0.50	ns
Stroke Volume (ml)	64.6 ± 21.46	67.6 ± 18.31	ns
Straight Leg Raise			
Cardiac Output ($lmin^{-1}$)	6.04 ± 1.7	6.22 ± 1.36	ns
Cardiac Index ($lmin^{-1}$)	2.92 ±0.77	3.01 ± 0.66	ns
Stroke Volume (ml)	70.7 ± 26.47	72.6 ± 21.87	ns

Figure 1

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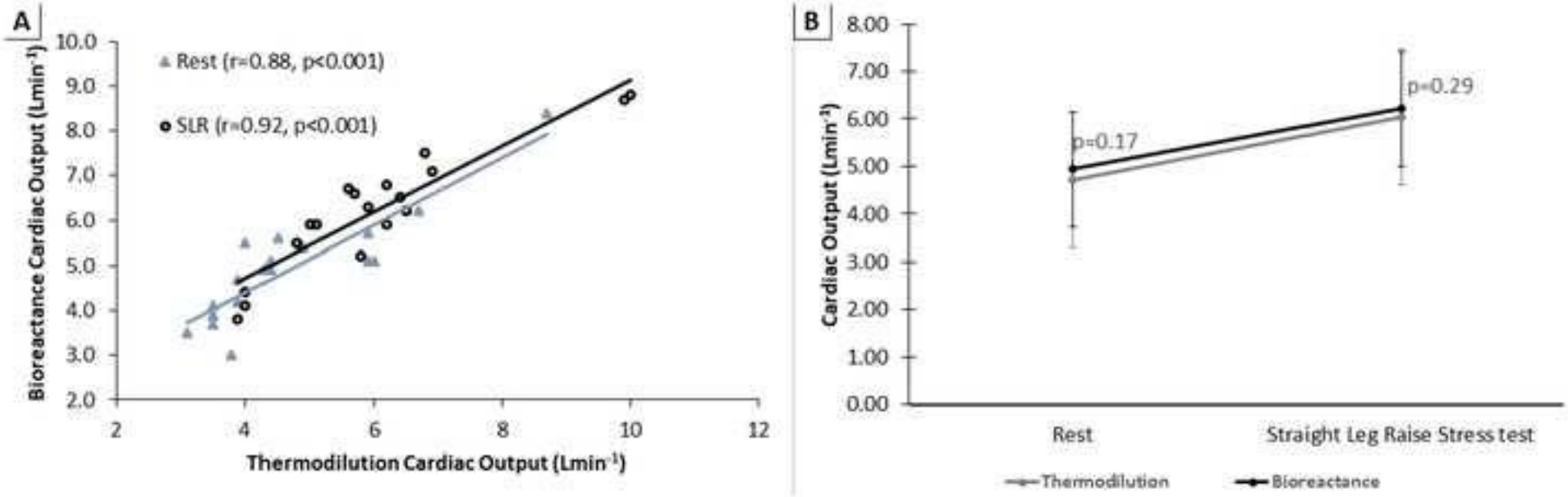

Figure 2

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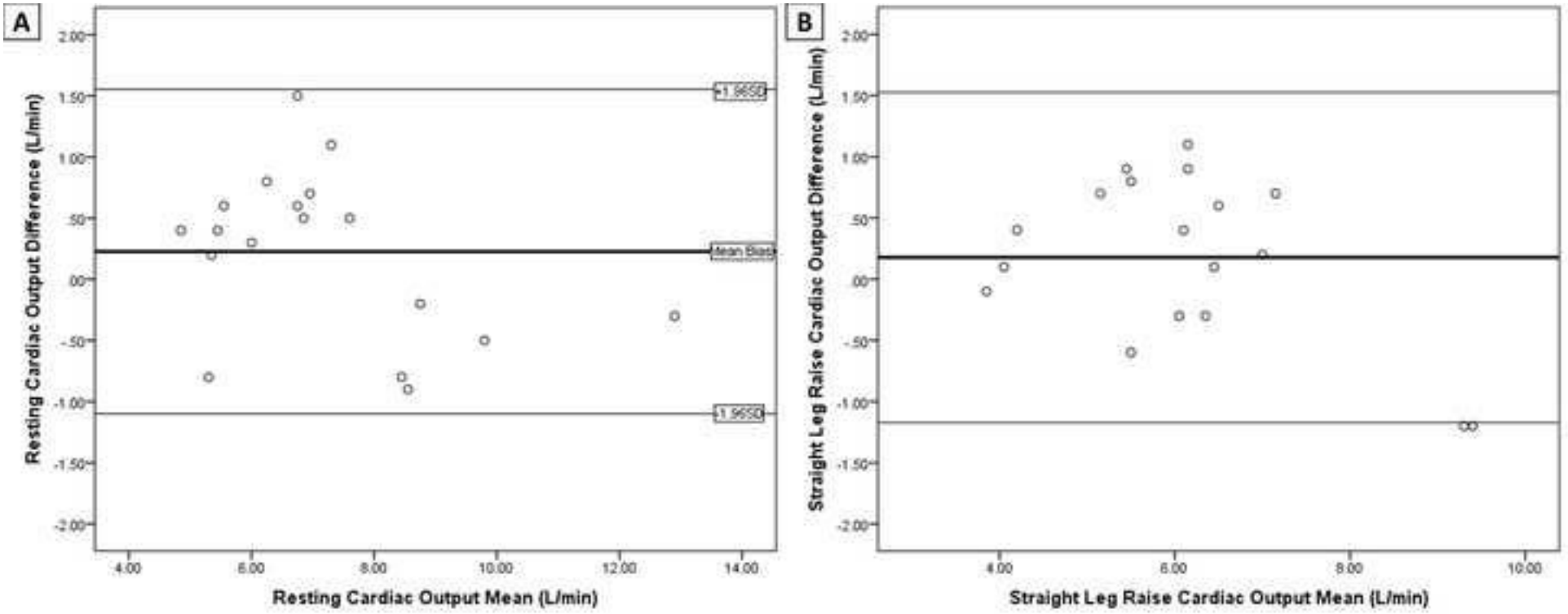

Figure 3

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