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Title:

Validity of hemodynamic monitoring using inert gas rebreathing method in patients with chronic heart failure and those implanted with a left ventricular assist device.

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Abstract

Objective. The present study assessed agreement between resting cardiac output estimated by inert gas rebreathing (IGR) and thermodilution methods in patients with heart failure and those implanted with a left ventricular assist device (LVAD).

Methods and results. Haemodynamic measurements were obtained in 42 patients: 22 with chronic heart failure and 20 with implanted continuous flow LVAD (34 males; aged 50 ± 11 years). Measurements were performed at rest using thermodilution and inert gas rebreathing methods. Cardiac output derived by thermodilution and IGR were not significantly different in LVAD (4.4±0.9 vs 4.7±0.8 l/min; P=0.27) or heart failure patients (4.4±1.4 vs 4.5 ± 1.3 l/min; P=0.75). There was a strong relationship between thermodilution and IGR cardiac index (r=0.81, p=0.001) and stroke volume index (r=0.75, p=0.001). Bland-Altman analysis showed acceptable limits of agreement for cardiac index derived by thermodilution and IGR i.e. mean difference (lower and upper limits of agreement) for heart failure patients -0.002 (-0.65 - 0.66) l/min/m^2, and -0.14 (-0.78 - 0.49) l/min/m^2 for patients with LVAD.

Conclusion: Inert gas rebreathing is a valid method for estimating cardiac output and should be used in clinical practice to complement evaluation and management of chronic heart failure and LVAD patients.

Keywords: Cardiac output; Heart failure; Inert gas rebreathing; Thermodilution

Introduction

Cardiac output (CO) monitoring plays a vital role in the hemodynamic management of critically ill patients and assessment of patients with advanced heart failure undergoing evaluation for heart transplantation or mechanical circulatory support [1]. In the field of cardiovascular dynamics, minimally invasive and non-invasive innovative technologies for CO monitoring are increasingly available [2]. Consequently, the number of studies comparing these techniques with a reference methods, such as thermodilution or direct Fick, are rapidly growing [3–6].

Inert gas rebreathing (IGR) estimates CO from the rate of clearance of an inert gas (nitrous oxide) from pulmonary capillary circulation. IGR is based on the principle that pulmonary capillary circulation and estimation of pulmonary blood flow, which in the absence of pulmonary shunt, equals cardiac output [7,8]. IGR has been validated against direct Fick's method in pulmonary hypertension patients [9] and in heart failure patients under resting and exercise conditions [10–12]. The IGR use in patients with chronic heart failure implanted with a left ventricular assist device (LVAD) have also been reported [13–15]. LVADs are used as an effective therapeutic strategy in advanced heart failure patients, either as a bridge to transplantation, as destination therapy, or in some patients, as a bridge to recovery [16]. Limited number of studies have evaluated validity of IGR for assessing cardiac output in LVAD patients [17]. Therefore, the aim of the present study was to assess the agreement of CO measurement using IGR and thermodilution methods in patients with chronic heart failure and those implanted with LVAD.

Methods

This was a single centre, prospective study comparing hemodynamic measurements obtained from thermodilution and IGR in patients with chronic heart failure and those implanted with

continuous flow LVADs (Medtronic, Minneapolis USA). In total, 42 patients (20 LVAD and 22 chronic heart failure patients) admitted at the Freeman Hospital (Newcastle upon Tyne, United Kingdom) for a heart transplant assessment between August 2017 and October 2018 were included in the study. Patients who were decompensated, had unstable ventricular arrhythmias or with known intrapulmonary shunt were excluded from the study. The study was conducted in accordance with the Helsinki declaration, was approved by the Ethical Committee Wales Research Ethics Committee 6 and registered in the European Clinical Trials Database (Number: 2016-005264-34). All participants provided a written informed consent.

Study Protocol and Measurements

The study included clinical examination and hemodynamic assessment using thermodilution and IGR techniques. Thermodilution was performed supine via pulmonary artery catheterization using a Swan Ganz catheter with central venous access through the right internal jugular vein. CO was also assessed with the inert gas (N_2O) rebreathing method using non-invasive Innocor system (Innovision, Odense, Denmark), and following procedure previously described by Okwose et al. [18]. Rebreathing was performed in a closed system. The participants rebreathed 0.5% nitrous oxide, N_2O (blood soluble gas), 0.1% sulphur hexafluoride, SF_6 (blood-insoluble gas) and 28% oxygen diluted in atmospheric air, from a 5L rubber anaesthesia bag. Rebreathing lasted between 8-12 seconds and was typically performed over 5-8 breaths. CO and stroke volume measurements from thermodilution and IGR were obtained under same conditions within two hours and then indexed to body surface area.

Statistical analyses

Data are expressed as mean ± standard deviation (SD) unless otherwise stated. Normality of distribution was evaluated using a Kolmogorov–Smirnov test. Pearson's correlation coefficient was used to evaluate the relationship between cardiac outputs from both techniques. Paired t-

tests were also used to assess differences in hemodynamic measurements while the agreement between the two techniques was analyzed using the Bland–Altman plots [20]. The difference in CO between the two techniques was summarized as the mean ± 1.96 SD which represented 95% limits of agreement [20]. Percentage error was calculated as 1.96 SD divided by the cumulative mean of average CO from both techniques and was considered clinically acceptable if it was ≤ 30%, as described previously [21]. All statistical analyses were carried out using SPSS version 22.0 (SPSS Inc., Chicago, IL, USA).

Results

Twenty patients with LVAD and 22 patients with heart failure completed the study. All patients successfully carried out the rebreathing manoeuvre and no adverse events occurred throughout the study. Patient demographics and clinical characteristics are displayed in Table 1. In both patients groups, mild to severe right ventricular dysfunction occurred in approximately 60% of patients. Sixteen (80%) patients with LVAD had normal aortic valve opening and median number of days from post implantation to recruitment into the study was 385 days. There was no significant difference between thermodilution and IGR cardiac outputs, and stroke volumes (Table 2), with strong positive correlation found between the two methods (Figure 1A & 1B). Bland–Altman analysis revealed acceptable agreement between thermodilution and IGR with mean difference (lower and upper limits of agreement) for cardiac index in chronic in heart failure patients; -0.002 (-0.65 - 0.66) L/min/m^2, and in LVAD patients of -0.14 (-0.78 - 0.49) L/min/m^2. When data from all patients (heart failure and LVAD) were combined, the mean difference and limits of agreement for cardiac index was -0.06 (-0.73 - 0.59) L/min/m^2 (Figure 1C), and for stroke volume index 0.5 (-12.8 – 13.9) ml/m^2 (Figure 1D). The percentage error was 29% for all patients combined. LVAD speed was set up at 2520 ± 250 revolutions per minute and LVAD flow (3.72 ± 0.88 L/min) and flow index (1.97 ± 0.48 l/min/m2) were significantly lower than that obtained by thermodilution and inert gas rebreathing (Table 2).

Discussion

The major findings of the present study indicate non-significant difference, acceptable agreement and strong positive relationship between CO measured by inert gas rebreathing and thermodilution methods in patients with chronic heart failure and those implanted with a continues flow LVAD. There was acceptable agreement between the two methods for estimating CO, with percentage error falling within acceptable range as defined by Critchley and Critchley [21]. HeartWare ventricular assist device significantly underestimates flow thus necessitating alternative methods of haemodynamic monitoring of LVAD patients. To the best of our knowledge, this is the first study to assess agreement between IGR and thermodilution methods in evaluation of cardiac output in LVAD patients.

Compared to the native heart, patients implanted with continuous flow LVAD exhibit an un-physiological response to haemodynamic changes due to reduced preload sensitivity and tracking of right ventricular flow [22,23].

Although routine measurement of CO is not imbedded in heart failure clinical practice, reduced CO is an indicator of advanced heart failure, and its measurement is recommended in patients undergoing heart transplantation or ventricular assist device implantation [24]. Cardiac index is an independent predictor of all-cause mortality and heart transplantation in ambulatory patients with advanced heart failure [25,26].

Similar to findings of the present study, Hassan et and colleagues [12] also demonstrated small difference in cardiac index (0.03 l/min/m^2) with limits of agreement of ±0.6 l/min/m^2 between IGR, magnetic resonance imaging and thermodilution methods in patients with heart failure. Another study compared IGR and impedance cardiography in 50 stable chronic heart failure patients, and reported mean resting cardiac index of (2.3 ±0.7) l/min/m^2 from IGR which is similar to the present study [27]. IGR derived CO in the present study showed strong positive

correlation with thermodilution method and supports previous findings demonstrating significant positive relationship between IGR and invasive methods i.e. Fick's and thermodilution [19,28,29] and non-invasive i.e. bioreactance and cardiac magnetic resonance imaging methods [18,30].

Although there was a significant difference in heart rate between IGR and thermodiltion in heart failure group, it did not affect the overall CO. Slightly higher heart rate (5 beats per minute) produced during IGR is potentially due to fact that rebreathing manoeuvre may require increase in oxygen uptake of respiratory muscles. As the rebreathing procedures may last up to 15 seconds, the first mechanism to respond to increased metabolic demand is likely to be heart rate. In addition, IGR measurements were performed in the sitting position compared to supine position during thermodilution measurements. This could have increased heart rate and lead to slightly higher but insignificant CO value observed with IGR. A previous study also showed that sitting or supine position did not significantly affect CO in heart failure patients although there were differences pulmonary artery and ventricular filling pressures [31]

It has previously been suggested that a potential source of error in the determination of CO using IGR may arise from intrapulmonary shunt. However, when oxygen saturation is normal (i.e. 94% or above) as was the case in the present study, error from intrapulmonary shunt is small and IGR provides a good estimate of cardiac output in patients with heart failure [9,19].

The present study is limited by relatively small sample size. However, major results are consistent with other studies evaluating validity of non-invasive methods for CO determination.

In conclusion, this study demonstrates that inert gas rebreathing is a valid non-invasive method for assessing CO in patients with chronic heart failure and those implanted with a LVAD. Inert

gas rebreathing is safe and easy to use method and should be incorporated into clinical practice for evaluation and management of chronic heart failure and LVAD patients.

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Table 1. Demographics and Clinical Characteristics of Study Population

	Heart Failure N=22	LVAD N=20	P-Value
Age, years	53.8 ± 8.80	46.7 ± 13.40	0.05
Male, n (%)	15 (68)	19 (95)	0.07
Height (cm)	173.9 ± 8.60	173.8 ± 7.60	0.95
Weight (kg)	91.7 ± 15.10	74.8 ± 11.20	0.00
BSA	2.1 ± 0.20	1.9 ± 0.20	0.00
LVEF	19.6±6.8	20.3±10.1	0.80
NYHA (%)	II/III (36/64)	I/II/III (5/60/35)	
Systolic BP (mmHg)	106±16	98±11	0.09
Diastolic BP (mmHg)	66±13	66±9	1.00
Right atrial Pressure (mmHg)	6.9±4.2	7.4±5.9	0.73
Systolic pulmonary artery P (mm Hg)	45.1±22.5	38.1±17.8	0.27
Diastolic pulmonary artery P (mm Hg)	19.2±15.8	14.9±10.1	0.31
Mean pulmonary artery P (mm Hg)	26.4±11.5	23.6±11.7	0.44
Pulmonary artery wedge P (mm Hg)	16.8±8.3	13.8±8.4	0.25
Pulmonary arterial oxygen saturation (%)	65.6±11.0	64.6±8.6	0.74
Arterial oxygen saturation (%)	97.0±1.8	96.0±4.8	0.39
Medications, n (%)			
Beta blockers	21 (95)	16 (80)	0.29
ACEI/ARB	16(77)	13 (65)	0.59
Sacubitril/Valsartan	5 (23)	0 (0)	0.07
Spironolactone/Eplerenone	17 (74)	8 (40)	0.01
Diagnosis, n (%)			
Ischemic heart disease	8 (36)	5 (25)	
Dilated cardiomyopathy	9 (41)	10 (50)	
Other (sarcoidosis, myocarditis)	3 (14)	1 (5)	
Restrictive cardiomyopathy	2 (9)	0 (0)	
Congenital heart disease	1 (4)	4 (20)	
Transplant, n (%)	1 (4)	1 (5)	
VAD after assessment, n (%)	2 (9)		

ACEI, Angiotensin converting enzyme inhibitor; ARB, Angiotensin receptor blocker; BSA, Body surface area; LVEF, Left ventricular ejection fraction; NYHA, New York heart association; P, pressure

Table 2. Comparison between haemodynamic variables measured by thermodilution and inert gas rebreathing methods.

Parameter	Thermodilution	IGR	P	r
Heart Failure Patient (n=22)				
CO (l/min)	4.40 ± 1.40	4.50 ± 1.32	0.75	0.90
CI (l/min/m^2)	2.15 ± 0.60	2.20 ± 0.60	0.98	0.84
SV (ml)	60.70 ± 21.40	57.60 ± 18.0	0.60	0.92
SVI (ml/m^2)	28.80 ± 9.20	27.40 ± 7.70	0.57	0.91
HR (beats/min)	73 ± 7	79 ± 10	0.01	0.57
LVAD patients (n=20)				
CO (l/min)	4.40 ± 0.90	4.70 ± 0.80	0.27	0.78
CI (l/min/m^2)	2.30 ± 0.50	2.50 ± 0.40	0.31	0.76
SV (ml)	64.30 ± 18.80	65.20 ± 18.60	0.88	0.60
SVI (ml/m^2)	34.00 ± 10.10	34.40 ± 9.30	0.89	0.57
HR (beats/min)	71 ± 13	75 ± 15	0.36	0.75
All Patients (n=42)				
CO (l/min)	4.40 ± 1.20	4.60 ± 1.10	0.40	0.90
CI (l/min/m^2)	2.20 ± 0.60	2.30 ± 0.50	0.56	0.84
SV (ml)	62.40 ± 19.80	61.20 ± 18.30	0.77	0.92
SVI (ml/m^2)	31.30 ± 9.80	30.70 ± 9.00	0.78	0.75
HR (beats/min)	72 ± 10	77 ± 12	0.03	0.57

HeartWare LVAD flow compared with Thermodilution and IGR cardiac outputs

	LVAD	Thermodilution	IGR	P
Flow (l/min)	3.72 ± 0.88	4.40 ± 0.90	4.70 ± 0.80	*ŧ
Flow index (l/min/m2)	1.97 ± 0.48	2.30 ± 0.50	2.50 ± 0.40	*ŧ
Speed (revs/min)	2520 ± 250			

CI, Cardiac Index; CO, Cardiac output; HR, Heart rate; HVAD, HeartWare ventricular assist device; IGR, Inert gas rebreathing; LVAD, Left ventricular assist device; SV, stroke volume; SVI, Stroke volume index; P, p-value between thermodilution and IGR; r, Spearman's correlation between thermodilution and IGR ($P < 0.05$); *, $p<0.05$ between HVAD and thermodilution ŧ, $p<0.05$ between HVAD and IGR.

Figure Legend

Figure 1. Relationship between thermodilution and inert gas rebreathing (IGR) cardiac index, CI (A), stroke volume index, SVI (B) and Bland-Altman plots showing the agreement between thermodilution and inert gas rebreathing (IGR) cardiac index, CI (C), and stroke volume index, SVI (D).

Figure

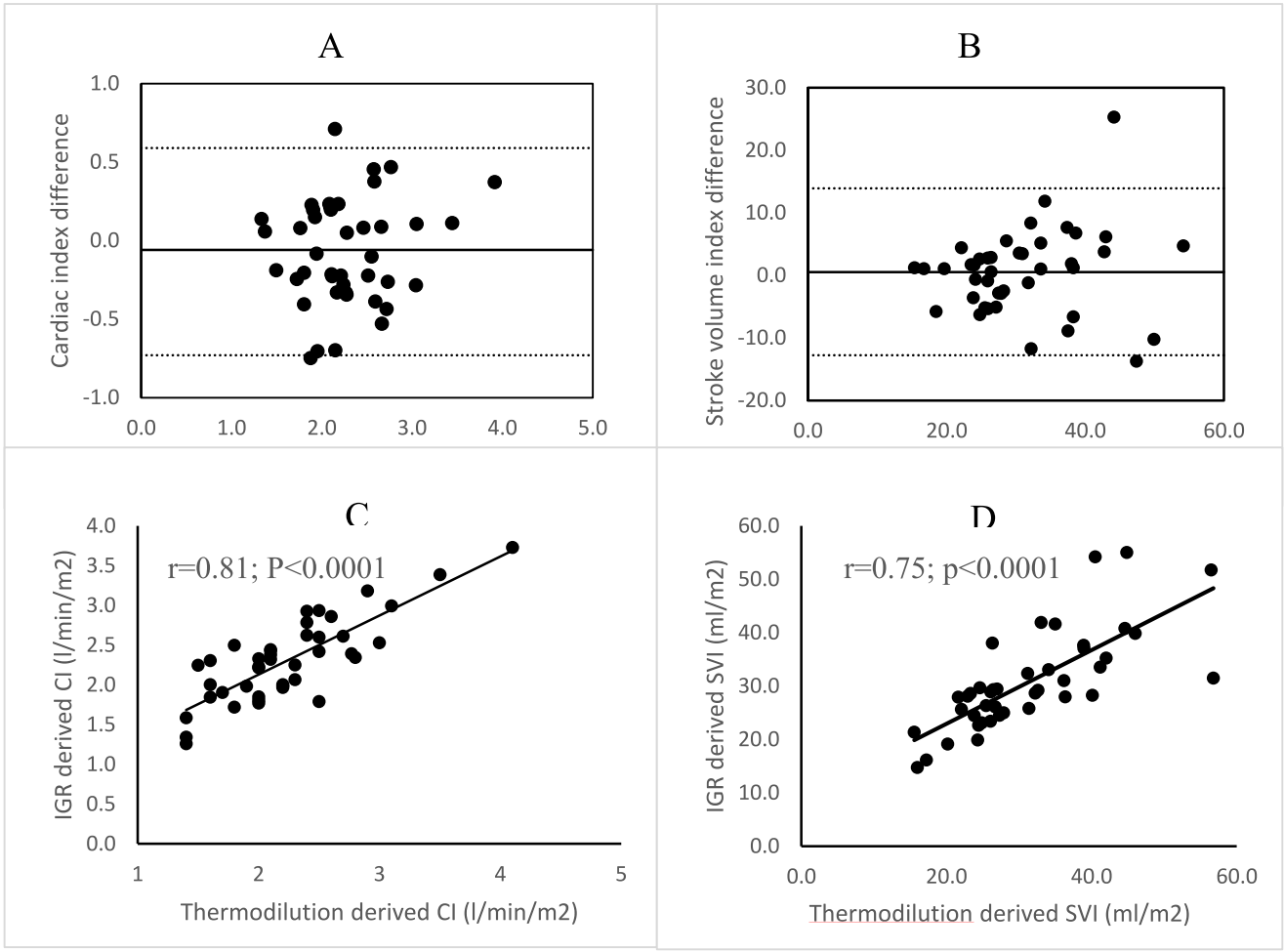

Figure 1. Relationship between thermodilution and inert gas rebreathing (IGR) cardiac index, CI (A), stroke volume index, SVI (B) and Bland-Altman plots showing the agreement between thermodilution and inert gas rebreathing (IGR) cardiac index, CI (C), and stroke volume index, SVI (D). Bold lines represent mean difference while dashed lines represent upper and lower limits of agreement (±1.96 SD), n=42.