

Equivalence of Bioimpedance and Thermodilution in Measuring Cardiac Output and Index in Patients with Advanced, Decompensated Chronic Heart Failure Hospitalized in Critical Care

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Background

- Heart Failure (HF) is a debilitating condition that leads to frequent rehospitalization
- Nearly one-quarter of patients admitted for decompensated HF require close monitoring and aggressive treatment either in an intermediate (stepdown) or critical care setting¹
- Pulmonary artery catheters (PAC) are frequently used in the management of patients with acutely decompensated advanced HF
- PACs provide sequential hemodynamic measurements to guide and measure care decisions
- PAC use is associated with an increased risk of morbidity and mortality
- In a study that compared continuous versus sequential bolus cardiac output (CO) value determination via PAC, continuous CO led to significantly more treatment decisions and decreased hospital median length of stay by two days²
- Continuous, non-invasive hemodynamic monitoring that provides accurate CO and cardiac index (CI) values might reduce morbidity and mortality associated with PACs and facilitate treatment decisions that could impact HF morbidity, mortality and cost of care

Aims

The purposes of this study were to:

- Determine the relationship between CO/CI measurements by thermodilution and impedance cardiography (ICG) in patients with decompensated advanced systolic HF
- Determine if differences between CO/CI measurement techniques could be explained by structural and functional heart alterations associated with advanced HF

Methods

Sample and Setting

Convenience sample; retrospective medical records data collection after assessment of correlation between CO obtained by thermodilution bolus and impedance cardiography by BioZ[®] ICG Monitor (CardioDynamics Inc., San Diego, CA)

- Institutional Review Board approved as a retrospective chart review
- Conducted at a large university-based teaching hospital
- 33 patients admitted to the HF intensive care unit (HF-ICU) who had hemodynamic monitoring with a PAC as part of their standard of care were studied

Inclusion criteria are as follows:

- Patients with a diagnosis of acutely decompensated systolic left ventricular dysfunction as evidenced by an ejection fraction less than 35%
- Stable status as evidenced by ability to be placed in a supine position with the head of the bed flat to 20-degree elevation
- Patient provided verbal informed consent to have ICG monitor attached, be monitored for 10-20 minutes and have hemodynamic data recorded as part of product assessment for possible purchase

Exclusion criteria are as follows:

- Unstable clinical status; in cardiogenic shock requiring an intra-aortic balloon pump or other ventricular assist device therapies

Procedure: Impedance Cardiography Preparation and Monitoring

- Two RN's with extensive experience in hemodynamic monitoring conducted all procedures related to assessing agreement with CO techniques between thermodilution and ICG methods
- Patients were placed in a supine position at a 20-degree angle prior to having the ICG monitoring system (software version 2.26) applied

- Right atrial pressures and pulmonary artery wedge pressures were obtained with the PAC and entered into the ICG monitor (rather than using the default values of six and ten, respectively)
- Due to PAC placement and occlusive dressing over the right internal jugular vein, the upper ICG monitoring sensors were placed 180-degrees opposite each other with the right sensor placed behind the ear lobe and the left sensor placed in front of the ear lobe
- The principal investigator completed sensor placement on all patients
- Prior to monitoring and recording data, the ECG and electrical impedance signal strength were assured To improve signal strength:
 - The ECG vector was changed to the option providing the strongest signal
 - The pacemaker "on/off" indicator was used if the patient was pacemaker dependent
 - Sensors were assessed for adhesion to skin
- The ICG system provided updated hemodynamic values using a 30 beat data averaging process and a 30-second screen update interval. Measurements were continually displayed

Procedure: Bolus Thermodilution

- 10 ml of 5% dextrose water was injected through a standard CO injection kit connected to the right atrial port of the PAC in under four seconds
- There was a two minute minimum wait time between each bolus injection
- Bolus injections were not correlated with the respiratory cycle
- CO values were deemed invalid if their respective curves were abnormal or if there was a prolonged injection time
- The second RN recorded the ICG variables: CO, CI, systemic vascular resistance, thoracic fluid content and stroke volume from the ICG monitor for each CO injection
- Counterbalancing techniques (alternating the order of recording ICG immediately before or after bolus measurements were obtained) was utilized
- Mean CO and CI were calculated from valid thermodilution bolus values and impedance cardiography values
- Vital signs were recorded from the bedside monitor
- RN's were not blinded from observing each other's actions or either monitor
- Retrospective chart review provided:
 - Demographics
 - Medical history
 - HF etiology
 - Echocardiographic data

- Electrocardiographic data was obtained directly from the monitor at the time of the data collection and used to analyze heart rhythm and QRS duration
- Four patients were excluded from data analysis because the impedance signal was inadequate
- Data analysis conducted in 29 patients; 1 set of paired data per patient

Data Analysis

- Required sample size was determined using power analysis of established ICG data from other reports. For an alpha of 0.05 and a power of 0.80, a minimum of 16 patients was required to determine a clinically significant mean difference of 0.1 L/min
 - Sample set at 30 patients for adequate assessment of predictors of variation between CO methods
- Concordance correlation coefficient (r) was calculated to assess agreement between paired mean bolus and ICG CO and CI measurements
- Bland and Altman method was used to determine the mean bias, standard deviation and the 95% confidence limits of agreement between CO methods
- Absolute percent differences of greater than 15% between bolus and ICG CO and CI were considered clinically significant and the rate and possible cause of these occurrences were examined
 - Multivariate logistic regression analysis was used to identify predictors for patients with high variation

Results

- In 29 patients, mean left ventricular ejection fraction was $16.8 \pm 7.5\%$
- 34% of patients had 3-4+ mitral regurgitation and 24% had 3-4+ tricuspid regurgitation
- Intravenous agents included inotropic, 45%; vasodilators, 31%; and inoavasodilator, 14%
- Pacemakers were present in 41% and cardioverter-defibrillator in 34% of patients
- Table 1 provides patient demographic and cardiac structure, and function variables
- Table 2 provides patient hemodynamic data at the time the study was conducted
 - Mean CO by TD and ICG was 5.48 and 5.40 L/min ($r = 0.89, P < 0.0001$)
 - Mean CI by TD and ICG was 2.69 and 2.65 L/min/m² ($r = 0.82, P < 0.0001$)

Figure 1 provides concordance correlation plots for CO
 Mean bias (95% confidence interval) between data pairs:

- CO: 0.08 (-0.18 to 0.35) L/min ($P = 0.53$)
- CI: 0.03 (-0.097 to 0.16) L/min/m² ($P = 0.61$)

Precision (limits of agreement) and 95% level of confidence:

- CO: 1.38 L/min; ± 0.46 L/min
- CI: 0.68 L/min/m² ± 0.22 L/min/m²

Six data pairs (21%) had an absolute percent difference > 15%. Of these, 60% had a higher bolus reading

Fig 1: CO by TD and ICG with Line of Equality

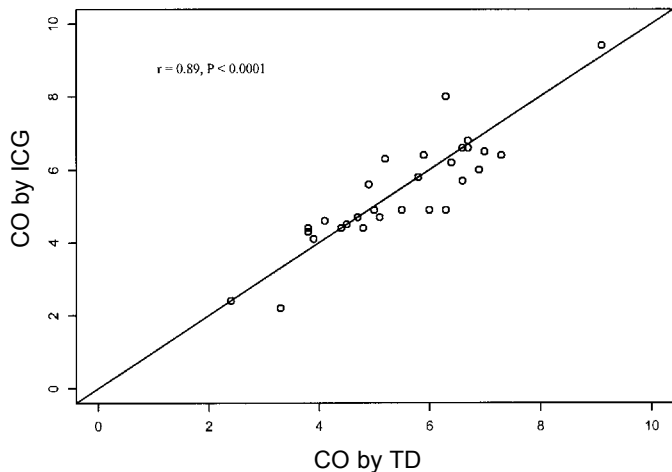
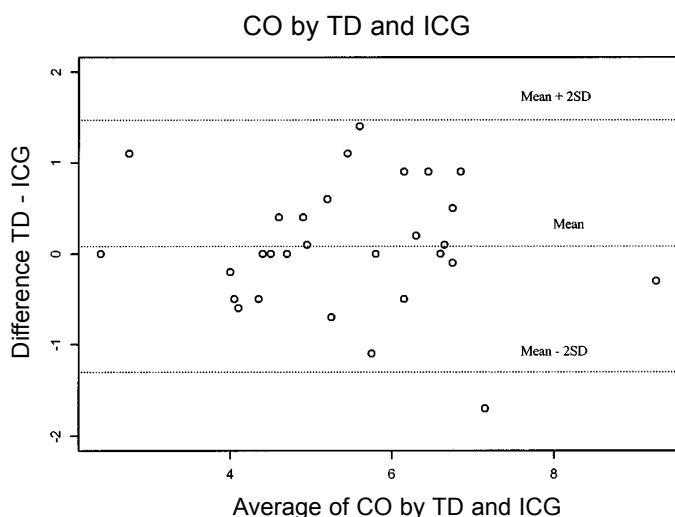


Figure 2: Bland-Altman plot of differences of cardiac output (CO) by thermodilution and ICG versus the mean with bias, upper and lower 95% levels of agreement



Of the 6 patients with greater than 15% difference between CO values (bolus thermodilution versus ICG), the following variables were related:

Variable	Estimate	Standard Error	Wald Chi-Square	P
Low Temperature	-5.7148	2.8205	4.1053	0.0427
Ejection Fraction	-2.0779	1.1726	3.1401	0.0764

Summary: Patients with lower temperature and lower ejection fraction are likely to be different.

Of the 6 patients with greater than 15% difference between CI values (bolus thermodilution versus ICG), the following variables were related:

Variable	Estimate	Standard Error	Wald Chi-Square	P
Atrial fibrillation	4.1900	1.8487	5.1368	0.0234
Temperature	-3.6224	1.7824	4.1303	0.0421

Summary: Patients with atrial fibrillation and lower temperature are likely to be different.

Conclusions

- CO and CI in ICG and thermodilution were significantly correlated ($P < 0.0001$)
- Clinically acceptable accuracy of cardiac output by ICG was demonstrated in patients hospitalized with advanced, decompensated heart failure
- ICG can potentially benefit hospitalized patients by:
 - Providing hemodynamic monitoring without risk for infection, arrhythmias, bleeding, and deconditioning due to bed rest status
 - Providing hemodynamic guided care without need for an intensive care unit stay; thereby, potentially decreasing cost of care
 - Providing continuous hemodynamic monitoring (versus snapshots) that might decrease hospital length of stay if continuous data increases decision-making and treatments/actions by healthcare providers

Table 1. Demographic and Cardiac Structure and Function Data, n = 29.

Variable	Mean ± SD or percent
Age (years)	57.6 ± 11.0
Male	83%
Race (Caucasian)	82%
Body mass index, kg/m ²	28.7 ± 6.1
Ischemic cardiomyopathy	76%
Dilated cardiomyopathy	17%
Hypertensive heart failure	0%
Alcoholic cardiomyopathy	7%
Diabetes	41%
Chronic obstructive pulmonary disease	21%
Asthma	21%
Atrial fibrillation	10%
Ventricular tachycardia/premature ventricular complexes	0%
Hypercholesterolemia	62%
Renal insufficiency (creatinine > 2.0 mg/dL)	17%
Pacemaker	41%
Implantable cardioverter defibrillator	34%
Hemoglobin	11.2 ± 1.9
Drug use:	
Angiotensin converting enzyme inhibitor	62%
Hydralazine	41%
Oral nitrate	45%
Angiotensin II receptor blocker	7%
Beta-blocker	21%
Digoxin	69%
Amiodarone	28%
Spironolactone	24%
Oral loop diuretic	17%
Intravenous loop diuretic (int bolus/continuous)	72%
Intravenous nitrate drip	31%
Intravenous nesiritide drip	7%
Intravenous dobutamine drip	28%
Intravenous milrinone drip	14%
Intravenous dopamine drip	3%
Left ventricular ejection fraction	16.9 ± 7.5
Left ventricular end-systolic diameter (n = 27)	5.8 ± 1.4
Left ventricular end-diastolic diameter (n = 27)	6.4 ± 1.2
Left atrial diameter (n = 21)	4.9 ± 0.9
Mitral valve regurgitation, 3-4+	34%
Mitral valve stenosis	11%
Tricuspid valve regurgitation, 3-4+	24%
Aortic valve regurgitation, 3-4+	7%
Aortic valve stenosis	22%

Table 2. Hemodynamic Data, n = 29.

Variable	Mean ± SD or percent
Respiratory rate, breaths per minute	19.8 ± 2.4
Heart rate, beats per minute	84.9 ± 17.0
Systolic blood pressure, mm Hg	101.6 ± 17.0
Diastolic blood pressure, mm Hg	53.0 ± 6.8
Core blood temperature, centigrade*	36.9 ± 0.6
Pulmonary artery systolic pressure, mm Hg*	45.9 ± 13.7
Pulmonary artery diastolic pressure, mm Hg*	20.7 ± 7.2
Pulmonary artery wedge pressure, mm Hg*	18.2 ± 7.1
Right atrial pressure, mm Hg*	11.8 ± 7.4
Mixed venous oxygen saturation (%)	60.2 ± 8.1
Arterial oxygen saturation (%)	95.3 ± 2.7
Pulmonary vascular resistance, dynes/sec/cm ⁻⁵ *	208.9 ± 122.0
Systemic vascular resistance, dynes/sec/cm ⁻⁵	
Thermodilution	837.9 ± 266.8
Impedance cardiography (ICG)	859.2 ± 281.7
Cardiac output, L/minute	
Thermodilution	5.48 ± 1.43
Impedance cardiography (ICG)	5.40 ± 1.48
Cardiac Index, L/minute/m ²	
Thermodilution	2.69 ± 0.57
Impedance cardiography (ICG)	2.65 ± 0.57
Thoracic fluid content**	42.91 ± 9.32
Stroke volume**	64.8 ± 18.2
Acceleration contractility index**	69.97 ± 23.32
Right ventricular systolic pressure, mm Hg [†]	41.8 ± 11.8

*, calculated with thermodilution cardiac output;

** , calculated with impedance cardiography;

†, obtained from echocardiogram

References:

1 Scios, Inc. ADHERE™ Acute Decompensated Heart Failure National Registry. 2nd Quarter 2002 Benchmark Report. San Diego, CA, Scios, Inc.

2 Albert NM, Spear BT, Hammel J. Agreement and clinical utility of two techniques for measuring cardiac output in patients with low cardiac output. *Am J Critical Care.* 1999;8:464-474.