



An Observational Comparative Study of Cardiac Index Estimated By FloTrac and Intermittent Thermo Dilution in Off-Pump Coronary Artery Bypass Grafting

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Abstract

Objective: The purpose of this study was to determine the correlation between cardiac index (CI) measurements made using intermittent thermodilution (ITD) technique by pulmonary artery catheter (PAC) and arterial pulse-contour analysis by FloTrac.

Design: Prospective observational study.

Setting: Cardiac surgery unit in a 350 bedded tertiary care hospital in India. Participants: 31 adult patients undergoing elective off-pump coronary artery bypass grafting (OPCABG) Interventions: CI measurements performed by the two different methods at six time points during the surgery (before skin incision, during grafting of left anterior descending artery, obtuse marginal artery and right coronary/ posterior descending artery, after protamine administration and after shifting the patient to recovery room).

Measurements and results: The techniques a weak correlation at all six time points during the OPCABG. The mean bias of 0.85 L/min/m² and precision of 0.55 was found in the study population. The percentage error calculated using Critchley's criteria was found to be 46%.

Conclusion: CI measurements obtained using FloTrac showed a limited correlation with those acquired by ITD technique at different stages of OPCABG. Further studies are required in other patient populations and clinical situations.

Keywords: FloTrac; Bypass grafting; Coronary artery

Abbreviations: CO: Cardiac Output; ITD: Intermittent Thermo Dilution Technique; PAC: Pulmonary Artery Catheter; IABP: Intra-Aortic Balloon Pump; LOA: Limits of Agreement; CI: Cardiac Index; OPCABG: Off-Pump Coronary Artery Bypass Grafting

Introduction

The use of Off Pump Coronary Artery Bypass Grafting (OPCABG) is gaining widespread acceptance as the preferred choice for myocardial revascularization [1,2]. However, during OPCABG, hemodynamic instability is common and thus, maintaining an adequate cardiac output (CO) plays a pivotal role in the peri-operative management of these patients [3-5]. Traditionally, CO monitoring has been accomplished by the Intermittent Thermodilution Technique (ITD) using Pulmonary Artery Catheter (PAC) [6]. Considering its potential advantage of providing additional information about cardiac filling pressures, pulmonary artery pressures and mixed venous oxygen saturation, PAC still remains the favored technique by many clinicians [7]. However, the routine use of PAC has been questioned in the literature for the lack of statistical evidence of its benefit and associated problems such as longer time required for its placement, cost, intermittent nature leading to potential for delay and rare complications like pulmonary artery rupture [8].

Various lesser invasive techniques have been developed such as transthoracic bioimpedance, pulse dye densitometry, Doppler and pulse wave contour analysis [7,9]. FloTrac by Edwards Life sciences is one of such devices based on the pulse contour analysis that estimates the cardiac output by beat to beat stroke volume analysis, based on Windkessel model described by Otto Frank in 1899 [10].

Major advantages with the device are the ability to measure cardiac output using any existent arterial line and elimination of the need for system calibration. The drawbacks include inability to provide other hemodynamic parameters as measured by PAC and limitation of its use in situations of arterial wave artifacts, aortic incompetence, severe peripheral vasoconstriction, irregular pulse and patients on Intra-Aortic Balloon Pump (IABP) [11].

Numerous studies in literature have produced inconsistent results with cardiac output measured using the conventional ITD and newer FloTrac methods in different clinical settings. The present study was aimed at analysis of clinical agreement between the ITD technique and FloTrac device for the estimation of cardiac index (CI).

Material and Methods

The study was approved by the hospital ethics committee and written informed consent was taken from all the patients enrolled in the study. The study included patients planned for elective OPCABG.

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Patients with concomitant valvular heart disease, arrhythmias or intra-aortic balloon pump during pre-operative and intra-operative period were excluded from the study. The patient group for the study comprised of 32 consecutive patients planned for elective OPCABG in our institution without the concomitant problems. In all the study patients, CO was monitored using both the techniques in question i.e. by ITD method and FloTrac technique. Pre-operative evaluation of the patients was performed a day before surgery. Patients were reassured and premedicated with oral lorazepam 2 mg and ranitidine 150 mg at the bed time and on the morning of surgery. For the patients on beta blockers, half the regular dose was given on the morning of surgery. All other cardiac medications including anti-hypertensive and nitrates were continued till the morning of surgery. In the operating room, routine monitoring was started with 5 lead ECG and pulse oximetry. Under local anaesthesia with 1% lignocaine, a 14/16G cannula was inserted in right antecubital vein and right radial artery was cannulated with 20G cannula which was connected to FloTrac sensor for cardiac output estimation. The anesthesia was induced with midazolam 0.03mg/kg, fentanyl 4 mcg/kg and propofol 1% in the dose of 1.5-2 mg/kg. Endotracheal intubation was facilitated with rocuronium 0.6 mg/kg. After induction 7.5 Fr PAC was inserted into the right internal jugular vein and right femoral artery was cannulated with 16G cannula. Other intra-operative monitoring included nasopharyngeal temperature and end tidal CO₂. Anesthesia was maintained with 0.5-2% isoflurane with oxygen-air mixture in ratio of 1:1, fentanyl and rocuronium. Normothermia was maintained throughout the procedure with the help of warm intravenous fluids, forced air warmers and circulating warm water mattress under the patient. Heparin was administered in the dose of 1500 IU/Kg and repeated as required to maintain the activating clotting time more than 250 seconds during myocardial revascularization. Medtronic octopus was used to stabilize the heart during beating heart surgery. During the grafting, the inotropes, intravenous fluids or vasodilators were used to maintain the hemodynamics as per the discretion of the attending anesthesiologist. On completion of revascularization, protamine was used to neutralize the effect of heparin. The patients were shifted to cardiac recovery room on completion of surgery and extubated as per the institutional weaning protocol.

For the purpose of the study, cardiac output values were estimated by thermo dilution Method by PAC and by FloTrac. Cardiac index values were derived and termed as CI by Thermo dilution Technique

(CITD) and CI by FloTrac Technique (CIFT). The measurements were recorded at six time points (T1-T6) i.e. before skin incision (T1), during grafting of left anterior descending artery (T2), obtuse marginal artery (T3) and right coronary Artery/posterior descending artery (T4), after protamine administration (T5) and just after shifting the patient to cardiac recovery room (T6). During grafting, CI values were obtained after the arteriotomy and placement of the shunt. For CITD by PAC, an average of 3 values was taken not deviating more than 20% that were obtained within 3 minutes. For each injection, 10 ml of 0.9% normal saline at room temperature was used and each injection was completed in less than 3 seconds. CIFT was directly recorded from the Vigileo monitor.

Statistics

The results obtained were analyzed by MedCalc 11.0 and SPSS 16.0 software for windows. Bland and Altman analysis, which is used for assessing the agreement between 2 measurements of the same clinical variable by two different techniques, was used [12]. According to it, bias is defined as the average difference between the two measures and limits of agreement (LOA) is 2SD (standard deviation) of the bias. A paired t-test was applied to test the mean difference between the two groups. A p-value of <0.05 depicted statistically significant difference between the CI values recorded by two different techniques.

Critchley's criteria were also applied [13]. According to it, the limit of acceptance for calculated Percentage error is 30% and the value more than 30% indicates poor agreement between the two techniques.

Results

A total of 32 patients were included in the study. One patient was electively converted to On-pump CABG because of poor quality of target vessels and thus was excluded from the Study. Thus the study group included 31 adult patients who underwent OPCABG at our Institution. Left anterior descending artery was grafted in all the patients. Anastomoses to obtuse marginal and right coronary artery/posterior descending artery were performed in 28 and 24 patients respectively.

The demographic profile and patient characteristics are as shown in (Table 1). There were 23 males and 8 females. The mean left ventricular ejection fraction was $48.87 \pm 7.7\%$ (Figure 1).

Represents the mean values of CI plotted against their respective

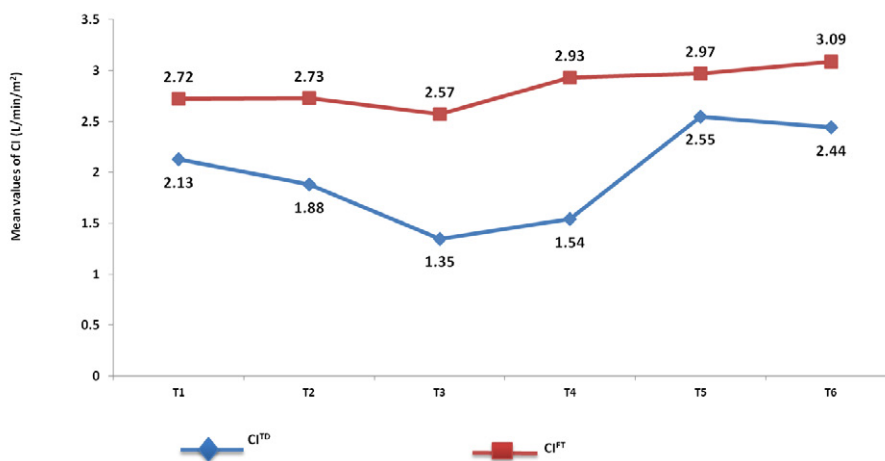


Figure 1: Graph showing mean values of CI at different time points.

time points. The mean values of CI at all six time points during our study and correlation between these 2 sets of values are as mentioned in (Table 2). It is evident that the 2 techniques exhibit a weak correlation at all the six stages of the surgery. A paired t-test to test the mean difference between the 2 study techniques shows p-values of much lesser than 0.05, suggesting a statistically significant difference between the CI values calculated by the 2 methods at all six time points. Bland-Altman analysis of CITD and CIFT showed the mean bias and limits

of agreement (2 SD) expressed in L/min/m² at their respective time points to be 0.59 ± 0.95, 0.85 ± 1.14, 1.22 ± 1.20, 1.39 ± 0.99, 0.42 ± 1.23, and 0.65 ± 1.17 (Table 3). Figures 2-7 show the Bland-Altman plots, where the differences between CI values measured by the 2 methods are plotted against their mean values. The mean bias of 0.85 L/min/m² and precision of 0.55 was found in the study population. The overall CI in the present study was 2.41 ± 0.48 L/min/m². The percentage error using the calculation recommended by Critchley is 46% which is well above the accepted limit of 30%.

	Mean ± SD
Age (yrs.)	65.65 ± 10.14
Weight (kg)	66.58 ± 11.42
Height (cm)	166.26 ± 8.75
Body surface area (m ²)	1.74 ± 0.17
Left ventricular ejection fraction (%)	48.87 ± 7.71
Sex (Male: Female)	23:08

Table 1: Demographic data and patient characteristics.

Discussion

The present study on 31 patients showed a weak correlation and a statistically significant difference between the two methods of CO monitoring at six different stages of OPCABG. OPCABG is increasingly being performed as an alternative to the standard CPB assisted procedure and aims at reduction in peri-operative morbidity [14]. This new approach requires accurate hemodynamic monitoring because surgical

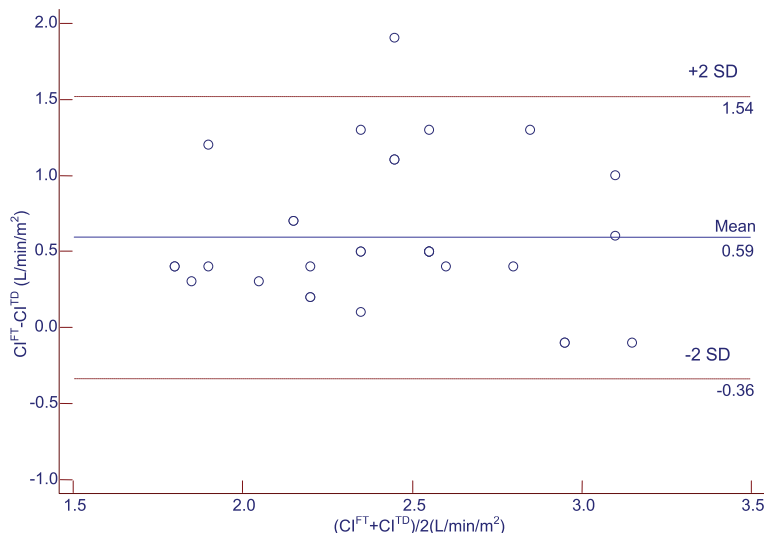


Figure 2: Bland-Altman analysis for CI measurements using FloTrac (CIFT) and intermittent thermodilution (CITD) before skin incision.

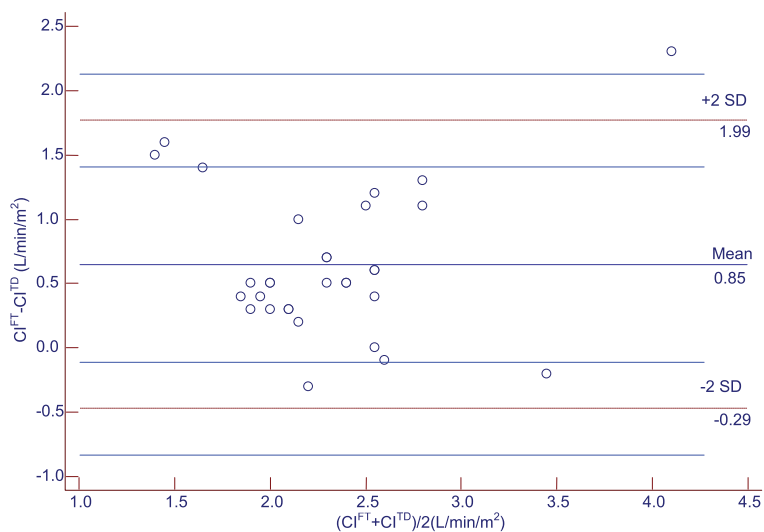


Figure 3: Bland-Altman analysis for CI measurements using FloTrac (CIFT) and intermittent thermodilution (CITD) during grafting of left anterior descending artery.

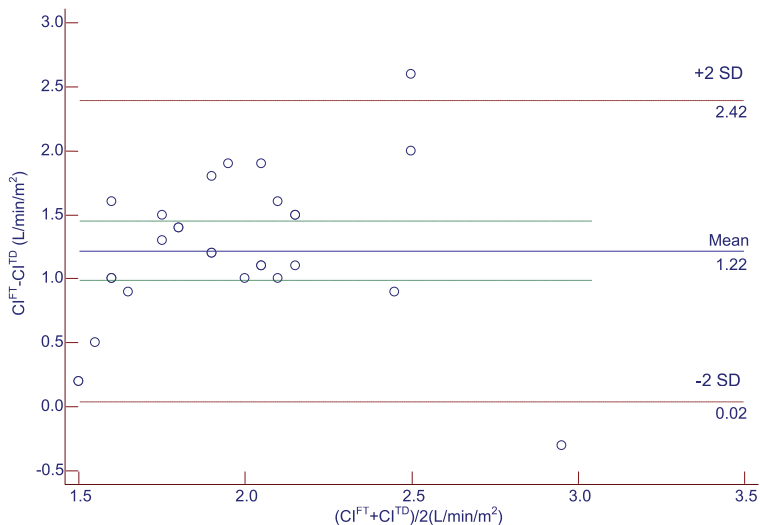


Figure 4: Bland-Altman analysis for CI measurements using FloTrac (CI^{FT}) and intermittent thermodilution (CI^{TD}) during grafting of obtuse marginal artery.

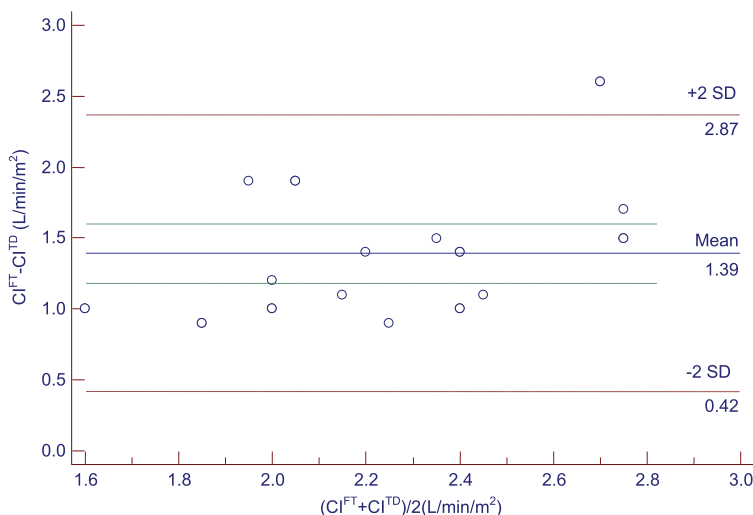


Figure 5: Bland-Altman analysis for CI measurements using FloTrac (CI^{FT}) and intermittent thermodilution (CI^{TD}) during grafting of right coronary/posterior descending artery.

Variable → Time points ↓	CI ^{TD} (L/min/m ²)	CI ^{FT} (L/min/m ²)	Correlation Coefficient
T1 (n = 31)	2.12 ± 0.46	2.72 ± 0.45	0.46
T2 (n = 31)	1.89 ± 0.63	2.73 ± 0.58	0.56
T3 (n = 28)	1.35 ± 0.42	2.57 ± 0.49	0.14
T4 (n = 24)	1.54 ± 0.31	2.92 ± 0.52	0.38
T5 (n = 31)	2.55 ± 0.56	2.97 ± 0.41	0.22
T6 (n = 31)	2.44 ± 0.62	3.09 ± 0.41	0.42

(Abbreviations: CI^{TD}- Cardiac index measured by intermittent thermodilution technique, CI^{FT}- cardiac index measured by FloTrac, T1- before incision, T2- left anterior descending artery grafting, T3- obtuse marginal grafting, T4- right coronary/ posterior descending artery grafting, T5- after protamine administration, T6- after shifting the patient to recovery room)

Table 2: Correlation between CI^{TD} and CI^{FT} at different time points

manipulations, unprotected myocardial ischemia and use of stabilizers on the beating heart can provoke abrupt hemodynamic changes. As a principal determinant of oxygen delivery and perfusion pressure,

CO represents an important hemodynamic variable. Its measurement offers potentially useful information to the cardiac anesthesiologists in the peri-operative period in the patients undergoing cardiac surgical procedures [9,15].

Since being introduced in 1970, intermittent thermo dilution technique by PAC has been considered the gold standard for the measurement of CO [10]. Apart from calculating CO, PAC provides data about the cardiac filling pressures such as central venous pressure, pulmonary artery pressure, pulmonary artery occlusion pressure, systemic vascular resistance, pulmonary vascular resistance and mixed venous oxygen saturation. This additional information can be a valuable tool particularly in the management of hemodynamically unstable patients [7]. The use of PAC has been increasingly criticised because of its invasiveness and unclear evidence of its benefit. CO estimation by ITD method fails to detect rapid and transient hemodynamic changes that may occur especially during OPCABG [16]. Other limitations of ITD technique include the potential for development of arrhythmias,

Variable→ Time Points I ↓	No. of Data Pairs	CI (L/min/m ²) (Mean ±SD)	Bias (Limits of Agreement) (2SD) (L/ min/m ²)	95% Confidence Interval of the Difference (L/min/m ²) Upper Lower		p-value
T1	31	2.42 ± 0.455	0.59 (0.95)	0.76	0.42	0.000
T2	31	2.31 ± 0.60	0.85 (1.14)	1.06	0.64	0.000
T3	28	1.96 ± 0.45	1.22 (1.20)	1.45	0.98	0.000
T4	24	2.23 ± 0.42	1.39 (0.99)	1.60	1.18	0.000
T5	31	2.76 ± 0.48	0.42 (1.23)	0.64	0.19	0.001
T6	31	2.76 ± 0.52	0.65 (1.17)	0.86	0.43	0.000

(Abbreviations: T1- before incision, T2- left anterior descending artery grafting, T3- obtuse marginal grafting, T4- right coronary/ posterior descending artery grafting, T5- after protamine administration, T6- after shifting the patient to recovery room)

Table 3: Statistical analysis of comparison of CI^{TD} and CI^{FT}.

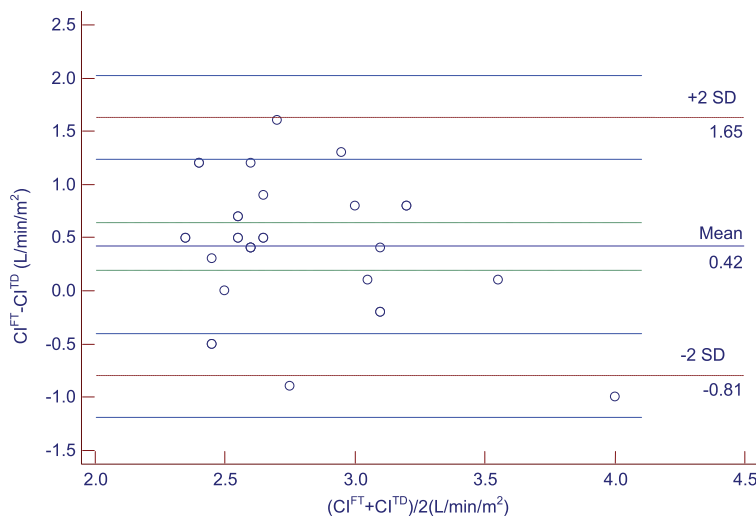


Figure 6: Bland-Altman analysis for CI measurements using FloTrac (CIFT) and intermittent thermodilution (CITD) after protamine administration.

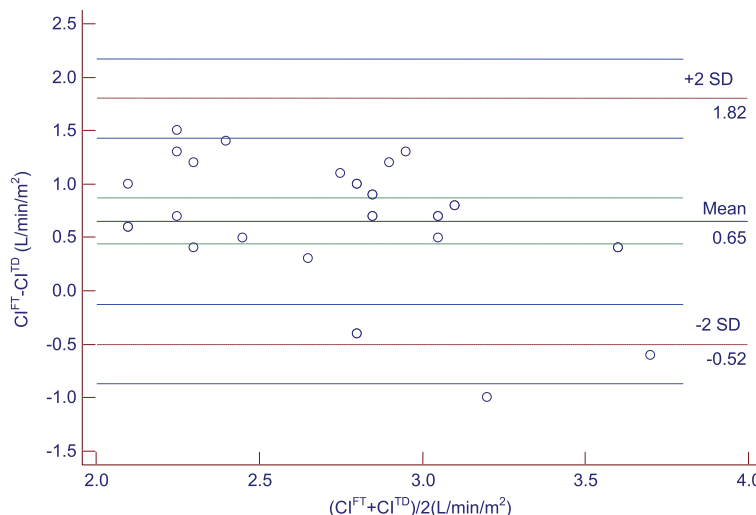


Figure 7: Bland-Altman analysis for CI measurements using FloTrac (CIFT) and intermittent thermodilution (CITD) after shifting the patient to recovery room.

valvular lesions and rupture of pulmonary artery [17]. Sandham et al. demonstrated that the use of PAC was associated with an increased risk of pulmonary embolism in patients undergoing major cardiac surgery [18]. The accuracy of CO by ITD method can be influenced by factors such as timing of injection within the respiratory cycle, temperature of

injectate, speed of injection and placement of catheter [19,20]. These limitations along with the desire for lesser invasive technologies have driven the development of various arterial pulse contour based devices.

The arterial pressure waveform analysis has come a long way from the description of Windkessel model by Otto Frank in 1899 to the model

by Erlangen and Hooper (1904) and Wesseling et al. [13]. Most of the pulse contour analysis techniques are explicitly or implicitly based on this Windkessel model [11]. In 2005, Edwards Life sciences introduced a novel device naming FloTrac for arterial pressure waveform CO estimation [10]. It consists of a special transducer that can be attached to an existing arterial cannula on one end and to a processing/display unit (Vigileo) on the other end. CO is calculated from an arterial pressure based algorithm that utilizes the relationship between pulse pressure and stroke volume. The arterial pressure waveform is assessed at 100 hertz and standard deviation of pulse pressure is determined over 20 seconds window. The algorithm takes two additional factors into account, i.e., vessel compliance (influenced by age, gender, height and weight) and peripheral resistance effects (determined from arterial waveform characteristics) [21]. The FloTrac has some unique features that are appealing to the clinician. First, the system can theoretically be used with any arterial line and there is no need to put a specifically designed proprietary catheter. The second major feature is the fact that FloTrac system does not require external calibration. The FloTrac analysis algorithm does its own calibration based on patient demographics and waveform characteristics [9]. Possible limitations of this device may be the inability to measure CO in situations of arterial wave artifacts, aortic incompetence, and severe peripheral vasoconstriction, compromise of arterial catheter and irregular pulse as in dysrhythmias and concomitant use of IABP [11].

Many studies have been published in the literature questioning the efficacy of FloTrac in a variety of cardiac operations and critical care units. Critchley and Critchley proposed that the acceptance of any method of determination of CO should be judged against the accuracy of the reference method which is till date considered being the ITD method obtained by PAC [22]. Since the measurement of this physiological variable generally lacks precision, error of +10-20% are common even for the reference method. Applying the same error limit to the new method results in a combined percentage error of +28.3% (calculated using Pythagorean approach). Thus it was recommended that limits of agreement between the new and the reference technique of up to +30% should be accepted. In our study, we analyzed 176 pairs of CI measured by FloTrac and ITD at six stages of OPCABG in 31 patients. A statistically significant ($p < 0.05$) weak correlation was found between the two methods at all the six time points. On applying the Critchleys criteria, a percentage error of 46% was revealed in the study that is well above the accepted limit.

One of the earliest studies done by Sander et al in 30 patients undergoing CABG analyzed 108 pairs of CO measured by FloTrac and ITD [23]. It measured a high bias (0.6 L/min, (LOA) of - 2.2 to 3.4 L/min). Percentage error in this study using Critchleys criteria is 30% that is such higher than the accepted limit of 30%. Another study by Manecke and Auger reported a positive correlation between the 2 techniques with a mean bias of 0.55 (LOA-1.96) L/min in 50 post-operative cardiac surgical patients [24]. Opdam et al. in their pilot study involved 251 measurements in 6 patients and showed limited correlation [21]. Our study also showed similar results with limited correlation at all six stages of surgery, with a mean bias of 0.85 L/min/m² and a precision of 0.55. However the major limitation in the study by Opdam was that 66% of all the calculations were done in only one patient. Mehta et al compared the CO values estimated by FloTrac and ITD in 12 patients undergoing OPCABG at various time points and concluded that good agreement existed between the 2 techniques [11]. However, the percentage error found in this study was 29% that is again closer to the accepted limit of 30%. The major limitation of the study was a small number of patients. Zimmermann et al. analyzed 192 data

pairs of CO estimated by FloTrac and ITD at seven predefined time points during elective CABG [25]. They concluded that FloTrac seems sufficiently accurate when considering 30% limit of agreement and not applying the 20% criteria. Mayer et al. measured CI in 40 patients undergoing elective cardiac surgery and analyzed 244 data pairs and found the high percentage error of 46% [7]. de Waal and colleagues also compared ITD and FloTrac and found a percentage error of 33% [26]. Lorsomradee et al. compared FloTrac with continuous thermo dilution method (CCO) and found that pulse contour analysis was able to reflect CO measured with CCO technique in patients undergoing uncomplicated CABG [27]. However, the pulse contour was less reliable in some situations like during sternotomy and phenylephrine administration. Similar alterations were also observed when the arterial pressure waveform is changed as in patients with aortic insufficiency and in patients on IABP. Many other studies involving other different subsets of patients have produced inconsistent results when the CO was measured with thermodilution and pulse contour analysis techniques [4-6,14-16,22,28-32]. Thus, although FloTrac method has many potential advantages including non-invasiveness, simplicity, no need for external calibration and minimal operator intervention, it still has many limitations in a variety of situations. Also the higher bias found particularly during settings of acute hemodynamic changes further questions the use of this technology in the dynamic settings of OPCABG.

Thus we conclude that CO estimation by FloTrac does not appear to adequately agree with ITD technique in patients undergoing OPCABG. However, it can be particularly recommended in situations where invasive CO monitoring is not an option and tracking of changes in CO are more important than absolute values of CO such as in management of hemodynamically unstable patients in emergency department. As the study population in our study was relatively small, more studies are required in the future to authenticate the usefulness of pulse contour analysis method.

Limitations of the Study

We must acknowledge some of the limitations in our study. A limitation of our study is that we do not know the true CI. We only assume that CO calculated by ITD method represents a reliable estimation of the true CI. Another limitation of this study is that the use of radial artery for estimation of CI by FloTrac and vasopressor administration for maintaining the hemodynamics in the intra-operative period might have influenced the accuracy of CO estimation due to vasoconstriction in variety of situations during OPCABG. Our study also suffers from the potential weakness that all the measurements made by these methods may not have been in real time with respect to each other as ITD involves 3 different injections and CO is then averaged over these 3 values.

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