Comparison of cardiac output using invasive (Pulmonary Artery catheter Continuous cardiac Output), less invasive (FloTrac) and non invasive (Pulse Wave Transit Time) methods in patients undergoing off pump coronary artery bypass grafting

Yogesh N Zanwar1, Jubin T. J2, V R Shrotey3

1Assistant Professor, 2Resident, 3Professor and Head, Dept. of Anaesthesia, GMC & SSH, Nagpur, Maharashtra, India

Abstract

Aim and Objective: This study was undertaken in patients undergoing off-pump coronary artery bypass grafting (OPCABG) with aim of comparing cardiac output using invasive pulmonary artery catheter continuous cardiac output (PAC CCO), less invasive (FloTrac pulse contour based) and non invasive pulse wave transit time (PWTT) methods.

Materials and Methods: Longitudinal observational study carried out in the department of Anesthesiology (CVTS OT) of super speciality hospital tertiary care hospital run by state Government with total 995 data sets taken from 25 subjects undergoing off pump coronary artery bypass grafting. Swan Ganz pulmonary artery catheter was inserted through the right internal jugular vein through introducer sheath and attached to the Edward vigilance II continuous cardiac output monitor for continuous monitoring of cardiac output invasively. Similarly cardiac output was measured with less invasive (FloTrac) monitor attached to a dedicated left femoral artery line. Non invasive (Estimated Continuous cardiac output (esCCO) based on pulse wave transit time) monitor attached to ECG and Spo2 probe sensor & calibration done with non –invasive blood pressure (NIBP) and the required demographic characteristics entered.

Results: Mean cardiac output assessed by invasive, less invasive and non invasive method was 3.91 +/- 0.87, 5.71 +/- 0.87 and 6.03 +/- 0.99 L/min respectively. There was poor correlation between less invasive and the invasive with r=0.25 and also poor correlation between non-invasive and invasive with correlation coefficient of r=0.27. Both less invasive (FloTrac) and non invasive methods (PWTT) showed higher estimation when compared to the invasive (PAC CCO). The Bland Altman analysis showed poor agreement between less invasive (FloTrac) and the invasive (PAC CCO) method, whereas the non invasive (PWTT based esCCO) showed good agreement. Percentage error were 68% and 126% for non-invasive (PWTT based es CCO) and less invasive (FloTrac) respectively.

Conclusion: Cardiac output assessed with less-invasive method & non invasive method showed higher as well as lower estimates Both less and non invasive methods of cardiac estimation showed poor correlation with invasive method. Utilizing the current algorithms produces an unacceptable degree of error and its utility is doubtful for clinical/therapeutic decision making in patients undergoing off pump coronary artery bypass grafting.

Introduction

Insufficient tissue perfusion due to acute circulatory failure causes multiorgan failure in patients undergoing coronary revascularization surgery. Optimizing perioperative hemodynamic is important to maintain adequacy of tissue perfusion especially in high risk cardiac surgeries.1

Patients with coronary artery disease have a very poor cardiovascular reserve. Monitoring cardiac output has pivotal role apart from other hemodynamic parameters. Increase heart rate & contractility cause increase in myocardial oxygen demand. Hypotension causes reduction in perfusion. This demand supply mismatch leads to ischemia & detoriate cardiac status. Therefore monitoring their cardiac output (CO) and indirectly getting to know their myocardial perfusion status becomes a priority.

Monitoring CO holds prime importance in high risk, critically ill, surgical & Intensive care unit (ICU) patients population.2 Even in septic patients and other critically ill, the optimization of oxygen delivery (DO2) represents the most important aspect of goal-directed therapy.3 An ideal CO monitor should be minimally or non-invasive, continuous, cost effective, reproducible, reliable during various physiological states and have fast response time. Advances in the computer software and hardware have led to development of newer methods of CO monitoring with minimal or no vascular access.4 Although assessment of CO by the conventional intermittent thermo dilution technique widely hold the gold standard position, it is not reproducible & carry inherent risk.
due to placement of Swan Ganz pulmonary artery catheter (PAC). Changes in cardiovascular function is routinely monitored by continuously measuring cardiac output. As PAC is associated with risk due to its invasive nature, there is need to search alternative methods which will be less invasive or purely noninvasive. One of the described techniques which utilize pulse counter analysis principle is FloTrac CCO which still require placement of arterial line. Other method is based on principle of pulse wave transit time. Pulse wave transit time is time interval between R wave of electrocardiogram and upstroke of pulse plethysmograph. This method is truly noninvasive as it just need 3 ECG leads, Pulse oxymetry probe & noninvasive blood pressure monitoring cuff. It take in account the time taken by the pulse (heartbeat) to reach to another sensor on the arm, finger or leg.

The data related to estimation of CO by the 3 techniques simultaneously in the same patient and their comparison was not available in the literature and therefore there was a need for such an intraoperative study. Monitoring CO continuously is more relevant during off-pump coronary artery bypass (OPCAB) surgery because hemodynamic fluctuations are more in setting of off pump coronary artery bypass grafting (OPCABG). Therefore we carried out this study in patients undergoing off-pump coronary artery bypass surgery with aim and objective of comparison of cardiac output using invasive (Pulmonary artery catheter-Swan Ganz CCO), less invasive (FloTrac) and noninvasive (PWTT based esCCO) methods.

Materials and Methods

After obtaining the approval of the study from institutional ethics committee, the present longitudinal observational study was carried out in the department of anesthesiology (CVTS OT) of super specialty tertiary care hospital run by state government from October 2016 to November 2018 in patients undergoing off pump coronary artery bypass surgery. An inclusion and exclusion criterion for study was as follows:

**Inclusion Criteria**

1. Adult patients between the age group of 18 years to 70 years posted for elective off pump coronary artery bypass surgery
2. Patient with sinus rhythm

**Exclusion Criteria**

1. Patient with arrhythmias
2. Patients with associated valvular heart disease
3. Patients who succumb to death intraoperatively
4. Patient with peripheral vascular disease.
5. Patients requiring intra-aortic baloon pump (IABP) preoperatively & intraoperative

**Outcome Measures**

Assessment of cardiac output with three different techniques simultaneously.

**Sample Size Calculation**

Sample size was calculated considering correlation between less invasive (pulse contour analysis based FloTrac) and non invasive (esCCO based on PWTT), as described in Wacharasint et al., as the main outcome with power of 80% and confidence interval of 95%. Sample size was found to be 23. Therefore 25 subjects were included in this study.

**Methodology**

Preanaesthesia evaluation was carried out in details & patients were investigated as per hospital protocol for CABG and recorded in pre anesthesia checkup charts. All patients were assured that their identity would be held confidential.

All cardiac drugs which patients were previously taking were continued till morning of surgery. After confirming nil per oral status patient was taken in operation theatre. Standard noninvasive monitoring in form of electrocardiogram leads, NIBP cuff (on left arm) & SpO2 probe on left index figure attached. Peripheral line established with 16G IV cannula on the right upper limb. Patient sedated with 1 mic/kg Fentanyl & 0.05 mg/kg Midazolam. Right radial artery cannulated with 20 G jcelo under local anesthesia for continuous invasive blood pressure monitoring (IBP).

7.5 F Swan Ganz catheter was floated through right internal jugular vein through introducer sheath under local anesthesia taking all aseptic precaution. Continuous cardiac output was measured by the same catheter attached to the Edward Vigilance II Monitor based on continuous thermo dilution technique. All required demographic data like weight, height, age and gender were entered in monitor to get estimate of CO by PAC CCO method.

Left femoral artery cannulation was performed with 4 Fr Vygon femoral artery catheter and the same was attached to the Vigileo monitor from Edward life sciences FloTrac monitor. After entering the demographic data estimation CO by less invasive CCO FloTrac started.

With the already attached ECG, oxygen saturation probe and NIBP cuff, estimation of CCO (non-invasive esCCO) with Life Scope monitor from Nihon Kohden, was done after feeding the basic characteristics like weight, height, age and gender to the monitors. Baseline values of heart rate, IBP, pulmonary artery pressure, were taken.

Patients induced with inj IV Fentanyl 4 ug/kg, inj IV Propofol (1 mg/kg body weight) + i.v Vecuronium 0.15 mg/kg body weight. Patients were intubated and put on controlled ventilation. Anesthesia was maintained with air oxygen mixture and inhalational Isoflurane(MAC 0.6) Infusion of inj. Fentanyl 500 mcgs +inj. Atracurium 125mg + inj Midazolam 10mg in 50cc at the rate of 8-10 ml/hour infusion rate. The main goal was to maintain a stable haemodynamics especially during the anastomosis. A decrease in blood pressure (less than 60 mm Hg) if occurred was managed with change of table position, IV fluid administration (according to filling pressure) or an inotrope support (Dobutamine, Adrenaline, Noradrenaline according to hemodynamics of the patient). Any changes in heart rate such as sinus tachycardia (above 120/min) was treated with increasing depth of anaesthesia, adding Fentanyl and if not controlled then beta blocker was administered (Esmolol 5
mg in increments). Any variations in SVR or PVR were managed with appropriate inotrope & vasopressor.

Heart rate, blood pressure (systolic, diastolic & mean arterial pressure), pulmonary artery pressure (systolic, diastolic & mean pulmonary arterial pressure) every 5 minutes was taken and recorded. Cardiac output values through invasive (PAC-CCO), less invasive (FloTrac) and non-invasive techniques (esCCO) were recorded every 5 minutes. Edward Vigilance II Monitor was used for CCO monitoring. Vigileo monitor from Edward life sciences was used for less invasive (FloTrac) CO monitoring. Life Scope monitor from Nihon Kohden was used for non invasive CO monitoring (esCCO).

Statistical Analysis
Descriptive analysis included mean, standard deviation, and percentages. For inferential statistics, comparison of mean across the three groups (methods) was done by one-way ANOVA (Analysis of Variance). Pair-wise comparisons were performed by Bonferroni multiple comparison tests. Correlation between the methods was assessed by Pearson’s correlation coefficient (“r”). p value less than 0.05 was considered as statistical significance.

Bland and Altman plots were used to evaluate the agreement among two different methods or two measurement techniques. Data was analyzed in statistical software STATA, version 10.1.

Results
The present study was done on 25 subjects undergoing off pump coronary artery bypass grafting surgery. Total 995 pairs of data sets were obtained with each of three methods of cardiac output monitoring, invasive, less invasive and non invasive. Table 1 shows demographic variables of study subjects.

The mean cardiac output by invasive (PAC-CCO), less invasive (CO FloTrac) and non invasive (esCCO) method was 3.91 ± 0.87 L/min, 5.71 ± 0.97 L/min and 6.03 ± 0.99 L/min respectively, and difference in CO across 3 groups was found to be statistically highly significant (p<0.001) on ANOVA test. The post hoc analysis was done using Bonferroni Multiple Comparison test for the pair wise comparison of mean CO across the groups. All 3 between group comparisons showed statistically significant difference. Table 2 shows distribution of CO estimations in 995 data sets using three methods. Less as well as non invasive methods showed maximum estimations on higher side when compared to the gold standard, 940(94.47%) and 961(96.58%) respectively.

Table 1: Demographic variables of study subjects

| Parameter         | Mean   | SD    | Minimum | Maximum |
|-------------------|--------|-------|---------|---------|
| Age (years)       | 57.2   | 6.2   | 43      | 70      |
| Sex (n, %)        |        |       |         |         |
| Male              | 21(84%)|       |         |         |
| Female            | 04(16%)|       |         |         |
| Height (Cms)      | 160.6  | 9.1   | 140     | 175     |
| Weight (kg)       | 60     | 9.4   | 45      | 76      |

Table 2: Comparison of cardiac output estimations by Less invasive (FloTrac) and non invasive (esCCO) methods with invasive cardiac output method (CCO) (n=995)

| Estimation (In comparison to invasive) | Less invasive (FloTrac) | Non invasive (esCCO) | Result of paired comparison |
|---------------------------------------|-------------------------|----------------------|----------------------------|
|                                       | n=995 (data set) | %       | n=995 (data set) | %       | p value       |
| Same as invasive                      | 12                     | 1.21    | 1                    | 0.1     | 0.0022*       |
| Higher than invasive                  | 940                    | 94.47   | 961                  | 96.58   | 0.0228*       |
| Lower than invasive                   | 43                     | 4.32    | 33                   | 3.32    | 0.2421        |
| Total                                 | 995                    | 100     | 995                  | 100     |                |

*statistically significant

Correlation matrix showing pair-wise correlation between three methods was shown in table 3. Poor correlation was observed between PAC- CCO and CCO FloTrac as well as esCCO however moderate correlation was observed between CCO FloTrac and esCCO (r=0.3143). All the correlations across three methods were found to be significant.

Table 3: Correlation matrix for pair-wise correlation between three methods

| Method       | Pearson’s Correlation Coefficient (r) and P value (p) | CCO | CCO FloTrac | esCCO |
|--------------|------------------------------------------------------|-----|-------------|-------|
| CCO          | R                                                    | 1   | 0.2784      | 0.2509|
|              | P                                                    |     | 0.0001      | 0.0001|
| CCO FloTrac  | R                                                    | 0.2784 | 1     | 0.3143|
|              | P                                                    | 0.0001 |     | 0.0001|
| esCCO        | R                                                    | 0.2509 | 0.3143 | 1     |
|              | P                                                    | 0.0001 | 0.0001 |      |
Table 4: Absolute percentage error in estimating CO

| Variable   | n  | Median | 95% CI  | 95th Percentile | 95% CI  |
|------------|----|--------|---------|-----------------|---------|
| CO FloTrac | 995| 126.32%| 125.64 to 126.32| 138.46% | 135.71 to 140.00 |
| esCCO      | 995| 57.83% | 54.55 to 60.61  | 128.54% | 121.72 to 134.62 |

Fig. 1: Bland Altman plot for data for CCO vs FloTrac and FloTrac vs esCCO

Fig. 2: Bland Altman plot of data for CCO Vs esCCO

Bland Altman analysis of less invasive (FloTrac) and invasive methods (cco) of cardiac output measurements (Fig1) indicated presence of fixed bias and also existence of proportional bias was indicated as the two methods do not agree equally throughout the range of measurements. Hence, these 2 methods could not be used interchangeably. Similar proportional bias was also observed between non invasive (escco) and less invasive methods (Fig. 1). However Fig. 2 indicates absence of fixed bias and these two methods seem to agree equally throughout the range of measurements. Table 4 shows absolute percentage error in estimating CO as compared to gold standard invasive method. Percentage errors were 68% and 126% for non-invasive and less invasive respectively. Narrower 95% CIs also ensure more degree of reliability (precision) to escco measurements as compared to FloTrac.

Discussion
Monitoring of cardiac output provides a global assessment of the circulation, and in combination with other hemodynamic measurements (heart rate, IBP, CVP, PAP, and PCWP), from CO we can derive additional important circulatory variables, such as SVR, PVR, and ventricular stroke work. Newer techniques for cardiac output measurement are becoming less invasive and thus might provide benefit to many patients without the attendant risks of invasive monitoring. The advantages and disadvantages of each technique must be appreciated for proper clinical application.5

In the present study we compared the three methods of cardiac output, invasive (PAC CCO), less invasive (FLOTRAC) and non invasive (PWTT base esCCO) simultaneously in same patient. This study was done exclusively in OPCABG patients, as the maximum hemodynamics changes were seen in such surgeries.7 Total of 995 data sets were obtained from 25 patients. Similar studies on off pump CABG patients had been done by Thakre Amol et al,2 Smetkin et al,8 Ball et al9 and Chakravathy et al7 which showed similar mean cardiac output. Whereas in the studies done by Wacharasint et al,1 Sinha et al,6 Cannesson et al10 and Manecke et al11 the patients were those undergoing. On pump coronary artery bypass grafting. Few other studies done by McGee et al,12 Manecke et al11 and Ishihara et al13 were done in postoperative period of patients who underwent cardiac surgery. Hence the study population differs from our study population.

On Bland Altman analysis in present study it was found that there is underestimation of cardiac output by less invasive (FloTrac) as compared to invasive (CCO) showed existence of proportional bias and hence these two methods could not be used interchangeably. While Non invasive esCCO estimates of CO shows more higher estimations compared to invasive and absence of proportional bias. The two methods seem to agree equally throughout the range of measurements. Because of the bias free measurement, these two methods could be used interchangeably.

Similar to the present study Sinha et al10 also observed bias of 0.13 (2.27) L/min and precision of 6.56 (2.19) L/min for non invasive (esCCO). The 95% CI for bias and for
precision was 4.32-4.58 and 2.27-10.85 respectively. Percentage error was 69% between non invasive esCCO and CO (i.e.2 SD of bias divided by mean CO) which clearly showed limitation of accuracy of esCCO. Also it highlighted the need of improvement in protocols that were used in calculations. Findings of Ball et al14 also clearly reiterated the same point. They reported on comparison of non invasive (esCCO) and invasive methods mean bias value of 0.80 L/min and 95% CI -2.00-3.61 L/min. Large variations in the level of agreement of two methods, the clinical utility of non-invasive esCCO method was debatable. Less invasive (esCCO) is more convenient and provides continuous CO measurements. However it had wide limits of agreement and large percentage errors and consistently positive bias as compared to invasive method. Similar results were also obtained by Bataille et al14 and Ishihara et al.13

However good agreement between less and non invasive method as compared to invasive was shown in studies done by Wacharasint et al,1 Yamada et al,15 Tsuitsui et al,16 Chakravarthy et al,7 and Franchi et al.2 In this study correlation between non invasive (esCCO) and invasive (CCO) methods of CO estimation and between less invasive (FloTrac) and invasive (CCO) methods of CO estimation was poor (r = 0.2509 & 0.2784 resp.). This was in contradiction to that observed by Chakravarthy et al1 who reported correlation co-efficient (r) values of 0.6, 0.49 and 0.4 for CCO (invasive), FCCO (less invasive) and PiCCO (less invasive) respectively. This difference could be attributed to the calibration done with NIBP in the present study which was different from the study done by Chakravarthy et al.7 Bataille et al14 studied overall relationship between invasive method (COTTE) and non invasive (esCCO) which showed a significant correlation between the two (r=0.61, P=0.0001). Significant correlation between invasive and noninvasive cardiac output was observed by Thakre Amol et al,2 Franchi et al,3 Wacharasint et al1 and Sinha et al.5 These differences could be attributed to different study groups involved in study as well as differences in calibration methods. We have included patients undergoing OPCABG and calibrated with NIBP. However, Sakka et al17 in their study comparing less invasive with invasive, had linear regression analysis revealing r2=0.26 (P=0.0001), which showed non reliability of this less invasive method in their study group. However they have included only patients with septic shock on ventilator support in contrast to OPCABG patients in the present study.

In this study higher estimation of Cardiac output was found in 940 (94.47%) data sets by less invasive (FloTrac) compared to 961(96.58%) by non-invasive (esCCO). There were lower estimations in 43 (4.32%) data sets by less invasive (FloTrac) compared to 33 (3.32%) by non invasive (esCCO). The less invasive had same value of cardiac output as the invasive (CCO) in 12 (1.21%) data sets compared to 1(0.1%) by non-invasive. This was in contrast to that observed by Chakravarthy et al who found similar estimation by less invasive (FCCO) measurements as compared with invasive TDCO in 86.3% and underestimation in 8.2% data sets this might be due to difference in number of data sets involved in this study i.e. 995 as compared to 438 in study conducted by Chakravarthy et al.7 Thakre Amol et al2 showed lower estimate of cardiac output in non-invasive (PWTT based esCCO) than invasive (PAC-CCO) methods in 27.1% data sets and higher estimation of cardiac output in noninvasive (PWTT based esCCO) than invasive (PAC-CCO) methods in 71.9% data sets.

Thus in the present study the reason for non agreement of non invasive (PWTT based esCCO) method of estimation with invasive method (PAC CCO) could be due to a number of factors. Firstly, changes in the body position might occur during routine patient care in the operation theatre. These changes might had a significant effect on pulse wave transit time, & consequently ability of non invasive esCCO system to detect change.

Secondly, the non invasive (PWTT based esCCO) system might be in accurate in the presence of changes in the systemic vascular resistance (SVR).Therefore, apparent changes of SVR after the first cardiac output calibration might have a significant impact on non invasive esCCO values in some patients of the study. The other factors such as calibration, validation and differences in population and demographic characteristics too play an important role.

This study shows that noninvasive PWTT based esCCO and less invasive FloTrac methods of cardiac output estimation are not accurate as compared to invasive PAC CCO.

Conclusion
Cardiac output assessed with less-invasive method & non invasive method showed higher as well as lower estimates with significant difference between cardiac output estimation in clinically acceptable range by less and non invasive methods. Also both less and non invasive methods of cardiac estimation showed poor correlation with invasive method. However less invasive had better correlation as compared to non invasive method of cardiac output estimation and there was moderate correlation between less invasive and non invasive. However, utilizing the current algorithms based monitors produces an unacceptable degree of error and does not hold acceptable positions for therapeutic decision making in clinical practice.

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