Inaccuracy of the FloTrac/Vigileo™ System in Patients With Low Cardiac Index

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Objectives: **The goal of this study was to compare cardiac output derived from the FloTrac/Vigileo™ system (CO_{FT}) with cardiac output measured by 3-dimensional transesophageal echocardiography (CO_{3D}) in patients with severe heart failure undergoing cardiac resynchronization therapy. The impact of preoperative systemic vascular resistance index on the accuracy of the FloTrac/Vigileo™ system also was investigated.**

Design: **Prospective clinical study.**

Setting: **Cardiac surgery operating room of a single cardiovascular center.**

Participants: **Forty-one patients undergoing elective cardiac resynchronization therapy lead implantation.**

Interventions: **CO_{3D} as the reference method and CO_{FT} were determined simultaneously after induction of anesthesia.**

Measurements and Main Results: **Linear regression analysis showed a poor correlation between CO_{3D} and CO_{FT} ($R^2 = 0.16$). Bland–Altman plots showed wide limits of agreement between CO_{3D} and CO_{FT}. Bias was 0.60 ± 0.63 L/min with a high percentage error of 58.2%. Subgroup analysis showed that the percentage error between CO_{3D} and CO_{FT} was 74.1% in patients with a cardiac index <2.2 L/min/m^2 and 17.2% in patients with a cardiac index ≥ 2.2 L/min/m^2. Systemic vascular resistance index was significantly higher in patients with a cardiac index <2.2 L/min/m^2 ($3,037 \pm 820$ *v* $2,461 \pm 878$; $p = 0.039$).**

Conclusions: **The FloTrac/Vigileo™ system is not accurate in patients with low cardiac output, especially those with a cardiac index <2.2 L/min/m^2. A high systemic vascular resistance index in patients with low cardiac index may contribute to this inaccuracy.**

KEY WORDS: ***cardiac output, intraoperative monitoring, thermodilution, pulse-wave analysis, low cardiac output syndrome, heart failure***

CARDIAC OUTPUT (CO) commonly is measured in critically ill patients using a thermodilution technique. However, complications of pulmonary artery catheter (PAC) insertion, such as arterial puncture, arteriovenous fistula, arrhythmias, and right heart valvular damage, cannot be justified in every case. An alternative to PAC, the FloTrac/Vigileo™ (Edwards Lifesciences, Irvine, CA), is less invasive and allows pulse pressure-derived CO measurement without external calibration.

Previous studies of CO measurement using the first and second versions of the FloTrac/Vigileo™ showed poor agreement with the thermodilution method for patients with low systemic vascular resistance (SVR),[1–2] such as those cases with intracranial hemorrhage or cirrhosis and those who are critically ill and require hemodynamic monitoring. The new, third-generation FloTrac/Vigileo™ has been shown to provide improved CO measurement in cirrhotic patients compared with previous versions.[3] However, some reports have shown that even the third software algorithm did not improve the accuracy of CO measurement,[4,5] especially in high-SVR states induced by high-dose vasopressor support or aortic cross-clamping.

Patients suffering from severe heart failure may have high SVR, which may lead to inaccuracies in CO measurement with the FloTrac/Vigileo™. While an indwelling PAC can provide useful monitoring information for patients suffering from severe heart failure, its use cannot be justified in minor surgery. The FloTrac/Vigileo™ is less invasive and may be used to monitor the CO of patients suffering from severe heart failure in minor surgeries. However, little information exists regarding the accuracy of FloTrac/Vigileo™-derived CO in patients with a low cardiac index (CI). High SVR also may affect CO measurements by the FloTrac/Vigileo™.

Recent advances in computer processing and transducer technology have enabled more precise assessment of left ventricle (LV) function using 3-dimensional (3D) transesophageal echocardiography (TEE).[6–9] The LV ejection fraction measured by 3D-TEE has been reported to correlate well with that measured by magnetic resonance imaging (MRI).[10,11] Therefore, the present study evaluated the validity of FloTrac/Vigileo™-derived cardiac index (CI_{FT}) by comparing it with the CI determined using 3D transesophageal echocardiography (CI_{3D}) in patients with low CO who underwent cardiac resynchronization therapy (CRT) lead implantation surgery. In addition, the authors investigated the impact of using preoperative, rather than intraoperative, systemic vascular resistance index (SVRI) on the accuracy of the FloTrac/Vigileo™.

METHODS

After obtaining approval from the ethics committee and informed consent, 41 patients who underwent CRT lead implantation surgery from March 2010 to March 2012 were studied prospectively.

CRT is indicated for patients with New York Heart Association functional class III-IV heart failure with a QRS complex ≥ 130 ms and an ejection fraction $\leq 35\%$ estimated by echocardiography.

Patients who had (1) more than mild mitral regurgitation (MR), (2) more than mild aortic regurgitation, or (3) arrhythmias were excluded from the present study. CRT leads were implanted using a transvenous approach under general anesthesia. Anesthesia was induced with fentanyl (1.5-2.0 μg/kg) and propofol (1 mg/kg). All patients were intubated and maintained under anesthesia with sevoflurane (0.7%-1.0%) and remifentanil (0.1-0.2 μg/kg/min). All patients were ventilated mechanically with a tidal volume of 8 to 10 mL/kg body weight at a frequency of 8-12 breaths per minute to keep end-tidal carbon dioxide between 35 and 40 mmHg. The radial artery was cannulated using a 22-gauge catheter (BD Angiocath ™; Becton Dickinson Infusion Therapy Systems Inc., Sandy, UT) after induction of anesthesia, and hemodynamic monitoring was performed with the

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1053-0770/2601-0001$36.00/0

http://dx.doi.org/10.1053/j.jvca.2014.04.013

FloTrac/Vigileo™ system (version 3.02). A TEE probe (X7-2t transducer; Philips Medical Systems, GmbH; Andover, MA) was inserted after endotracheal intubation. A series of 3D full-volume images were obtained 15 minutes after induction of anesthesia with stable hemodynamics during suspended breathing using a Philips iE-33 system (Philips Medical Systems, GmbH). The images were obtained by acquisition of 4 cardiac cycles for offline full-volume reconstruction. CI data from the FloTrac/Vigileo™ and standard hemodynamic data (heart rate [HR] and mean arterial pressure) were recorded. The images then were analyzed by an investigator, who was blind to the intraoperative values, using QLAB 6.2 semiautomatic 3D volume-tracing software, and stroke volume (SV), CO, and CI were calculated using the following formulae:

$$\text{SV} = \text{end-diastolic volume (EDV)} - \text{end-systolic volume (ESV)},$$
$$\text{CO} = \text{HR} \times \text{SV},$$
$$\text{CI} = \text{CO}/\text{body surface area}$$

Agreement between CI_{3D} and CI_{FT} was assessed using Bland-Altman plots. Linear regression analysis was used to examine the relationship between CI_{3D} and CI_{FT} by calculating the coefficient of determination (R^2).

The FloTrac/Vigileo™ system calculates SV using arterial pulsatility (standard deviation [SD] of the pulse pressure over a 20-second interval), resistance, and compliance. CO was calculated as follows:

$$\text{CO} = \text{HR} \times \text{SV}$$
$$\text{SV} = K \times \text{pulsatility}$$

where K is a constant quantifying arterial compliance and vascular resistance. It was derived from a multivariate regression model that included the Langewouters model of aortic compliance, mean arterial blood pressure, and variance, skewness, and kurtosis of the pressure curve.[12] The rate of adjustment of K was 1 minute.

Offline LV volume analysis employing semiautomatic border detection with biplane projections was conducted using QLAB version 6.2 software (Philips). After inputting 5 specific identification points (1 at the apex and 4 at the mitral annulus), the software automatically fits the data points to a geometric model. A quad screen displaying 2 orthogonal views (upper left and right), 1 short-axis view (lower left), and a mold of the LV cavity (lower right) is shown in Figure 1. After adjusting the LV 4-chamber and orthogonal views, the appropriate 4-chamber view allows high-quality LV quantification. Afterward, the point of intersection of the displayed horizontal and vertical lines in the middle of the LV cavity is located. Subsequently, the LV end-diastolic volume (EDV) (defined as occurring on the R-wave of the QRS complex) and end-systolic volume (ESV) (defined as occurring at the end of the T-wave) frames are determined. Five identification points are marked on both the end-diastolic and end-systolic frames. The software then automatically delineates the LV endocardial border and creates an LV mathematical model. If the delineation of the endocardial border was insufficient, it was manually adjusted. LVEF and SV were derived from the LV volume measurements.

All results are expressed as mean ± SD unless indicated otherwise. Linear regression analysis was used to evaluate the relationship between CI_{3D} and CI_{FT} for all data. High correlation does not imply agreement between the 2 methods; for this reason, the authors adopted the Bland-Altman method to quantify agreement.[13] Bias (mean difference between CI_{3D} and CI_{FT}) represents the systematic error between methods. Precision (SD of the bias) represents the random error or variability between techniques. Limits of agreement (LOAs) were calculated as bias ± 2SD and defined the range in which 95% of the differences between methods were expected to lie. The percentage error was calculated as the ratio of 2SD of the bias to mean CO and was considered clinically acceptable if it was below 30%, as proposed by Critchley et al.[14] Bias, LOA, and percentage error between CI_{3D} and CI_{FT} were calculated for all data.

To examine the effect of low CO on the association between CI_{3D} and CI_{FT}, the authors divided the patients into 2 groups according to measured CI_{3D} for subanalysis. Patients with $CI_{3D} < 2.2$ L/min/m^2 were assigned to group A, and those with $CI_{3D} \geq 2.2$ L/min/m^2 to group B.[15] To assess the effect of vascular resistance on CI_{FT}, the authors evaluated SVRI during preoperative cardiac catheterization.

RESULTS

Forty-one patients (6 women, 35 men) were involved in this study. Patient characteristics are shown in Table 1. All patients were in sinus rhythm before the induction of anesthesia and during surgery. Thirty-seven patients had trivial MR, and none had AR. Twenty-five patients had $CI_{3D} < 2.2$ L/min/m^2 (group A), and 16 patients had $CI_{3D} \geq 2.2$ L/min/m^2 (group B). Hemodynamic data are summarized in Table 2.

Linear regression showed a poor but significant correlation between CI_{3D} and CI_{FT} ($R^2 = 0.16$, $p = 0.01$) (Fig 2A). Bland-Altman analysis showed poor agreement between CI_{3D} and CI_{FT} (Fig 2B). Bias was 0.60 ± 0.63 L/min/m^2 with LOAs of −0.65 L/min/m^2 and 1.85 L/min/m^2. The percentage error was 58.2%.

Subgroup analysis of the linear regression showed a poor correlation between CI_{3D} and CI_{FT} ($R^2 = 0.067$, $p = 0.21$) in group A (Fig 3A). However, linear regression showed a good correlation between CI_{3D} and CI_{FT} ($R^2 = 0.59$, $p < 0.001$) in group B (Fig 4A).

Subgroup analysis of the Bland-Altman method also showed poor agreement between CI_{3D} and CI_{FT} in group A with a high percentage error of 74.1% (Fig 3B). Bias was 0.87 ± 0.67 L/min/m^2 with LOAs of −0.44 L/min/m^2 and 2.2 L/min/m^2. However, Bland-Altman plots showed acceptable agreement between CI_{3D} and CI_{FT} in group B with a low percentage error of 17.2% (Fig 4B). Bias was 0.18 ± 0.24 L/min/m^2 with LOAs of −0.29 L/min/m^2 and 0.65 L/min/m^2. Perioperative SVRI was significantly higher in group A than in group B (3,037 ± 820 *v* 2,461 ± 878, respectively; $p = 0.039$) (Table 2).

DISCUSSION

The main finding of the authors' study was that CI_{FT} showed wide LOAs with CI_{3D} in patients with low CI, especially for CI less than 2.2 L/min/m^2. The acceptance of a new method should be judged against the ± 10% to 20% accuracy of the current reference method. However, Critchley et al recommended that limits of agreement between the new and the reference technique of up to ± 30% be accepted.[14] The percentage error between CI_{3D} and CI_{FT} was 58.2%, which, at ≥30%, was not acceptable.[14] However, subgroup analysis of Bland-Altman methods showed that group B (CI ≥2.2 L/min/m^2) had an acceptable percentage error of 17.2%. The perioperative SVRI of group A was significantly higher than that of group B (3,037 ± 820 *v* 2,461 ± 878, respectively; $p = 0.039$). The high SVRI in group A might have contributed to the discrepancy between CI_{FT} and CI_{3D}.

To compensate for reduced CO, endocrine feedback mechanisms try to maintain normal arterial pressure by constricting arterial (resistance) vessels through activation of the sympathetic adrenergic nervous system, thereby increasing systemic vascular resistance. Thus, patients who suffer from severe heart