Improved Performance of the Fourth-Generation FloTrac/Vigileo System for Tracking Cardiac Output Changes

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Objectives: The aims of this study were to compare cardiac output (CO) measured by the new fourth-generation FloTrac™/Vigileo™ system (Version 4.00) (CO_{FVS}) with that measured by a pulmonary artery catheter (CO_{REF}), and to investigate the ability of CO_{FVS} to track CO changes induced by increased peripheral resistance.

Design: Prospective study.

Setting: University Hospital.

Participants: Twenty-three patients undergoing cardiac surgery.

Interventions: Phenylephrine (100 µg) was administered.

Measurements and Main Results: Hemodynamic variables, including CO_{REF} and CO_{FVS}, were measured before and after phenylephrine administration. Bland–Altman analysis was used to assess the discrepancy between CO_{REF} and CO_{FVS}. Four-quadrant plot and polar-plot analyses were utilized to evaluate the trending ability of CO_{FVS} against CO_{REF} after phenylephrine boluses. One hundred thirty-six hemodynamic interventions were performed. The bias shown by the Bland–Altman analysis was −0.66 L/min, and the percentage error was 55.4%. The bias was significantly correlated with the systemic vascular resistance index (SVRI) before phenylephrine administration ($p < 0.001$, $r^2 = 0.420$). The concordance rate determined by four-quadrant plot analysis and the angular concordance rate calculated using polar-plot analysis were 87.0% and 83.0%, respectively. Additionally, this trending ability was not affected by SVRI state.

Conclusions: The trending ability of the new fourth-generation FloTrac™/Vigileo™ system after increased vasomotor tone was greatly improved compared with previous versions; however, the discrepancy of the new system in CO measurement was not clinically acceptable, as in previous versions. For clinical application in critically ill patients, this vasomotor tone-dependent disagreement must be decreased.

KEY WORDS: FloTrac/Vigileo system, cardiac output, systemic vascular resistance, pulmonary artery catheter, thermodilution

EARLY GOAL-DIRECTED THERAPY (EGDT) in high-risk surgery has been associated with reduced postoperative morbidity and mortality[1] along with a decrease in cardiac complications, particularly arrhythmias.[2] Hemodynamic management in EGDT aims to optimize cardiac output (CO) and deliver adequate oxygen to the tissues. Pulmonary artery catheterization with thermodilution has become the clinical standard for CO monitoring, but it causes increased cardiovascular complications compared with less-invasive CO monitors, such as arterial pressure waveform analysis and echocardiography.[3–5] Therefore, the use of less-invasive CO monitors is supported when conducting perioperative EGDT.[2]

The FloTrac™/Vigileo™ system (Edwards Lifesciences, Irvine, CA) is an arterial pressure waveform analysis method for continuous CO monitoring first introduced in 2005. In the last 5 years, the FloTrac™/Vigileo™ system algorithms for CO measurement have been improved repeatedly, as early validation studies demonstrated poor agreement between the FloTrac™/Vigileo™ system (first and second generations) and reference method.[6,7] Recent data on the third-generation FloTrac™/Vigileo™ system indicated further improvement in CO measurement in states of low systemic vascular resistance (SVR);[8] however, its reliability in tracking CO changes after hemodynamic interventions remains a major concern. Some studies have reported clinically unacceptable accuracy of this system after acute SVR changes.[9,10] Recently, a new fourth-generation software algorithm was introduced that uses a new correction factor to adjust for acute SVR changes, designed to improve the reliability of this system for tracking CO changes after increased vascular tone.

The aims of this study were to compare CO measured by the fourth-generation FloTrac™/Vigileo™ system with that measured by pulmonary artery catheterization, and to investigate the ability of the fourth-generation FloTrac™/Vigileo™ system to track CO changes induced by increased peripheral resistance.

METHODS

After institutional review board approval, 23 patients undergoing elective cardiac surgery were enrolled in this study. Patients with cardiac arrhythmias and intracardiac shunt were excluded. Written informed consent was obtained from all enrolled patients. The dosage of anesthetic drug was decided based on the ideal body weight. General anesthesia was induced with propofol (0.5–2.5 mg/kg), midazolam (0.01–0.15 mg/kg), fentanyl (2–8 µg/kg), and rocuronium (1–1.2 mg/kg). After tracheal intubation, general anesthesia was maintained with sevoflurane (1%–2.5%), fentanyl (20–35 µg/kg total dose), and rocuronium (15–30 mg/hr). All patients were mechanically ventilated with a tidal volume of 6-to-10 mL/kg body weight at a frequency of 7-to-12 breaths per minute to maintain end-tidal carbon dioxide concentrations between 35 and 45 mmHg. An arterial pressure catheter was inserted into the radial artery and connected to the

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FloTrac™/Vigileo™ system (Version 4.00, Edwards Lifesciences, Irvine, CA). Then, the central venous catheter and the pulmonary arterial catheter (PAC) were inserted into the right internal jugular vein, and their positions were confirmed by pressure waves and transesophageal echocardiography. The PAC was connected to the Vigilance™ monitor (Edwards Lifesciences, Irvine, CA).

A conventional PAC thermodilution technique with ice-cold saline (10-mL bolus injection) was used as a reference method for CO measurement. The authors performed three consecutive CO measurements with PAC, and the average value of those measurements was used for CO analysis. Systemic vascular resistance index (SVRI) was calculated as follows: SVRI = (mean arterial blood pressure [MAP] – central venous pressure) $\times$ 80/cardiac index.

A new fourth-generation algorithm (Version 4.00) was developed to further improve the performance of the FloTrac™/Vigileo™ system. In the FloTrac analysis, CO = PR $\times$ SD (blood pressure [bp]) $\times$ χ, where PR is the pulse rate, SD (bp) is the standard deviation of the arterial pressure, and χ is the auto-calibration factor that is part of a proprietary algorithm with Edwards to incorporate the assessment of vascular tone based on waveform morphology analysis and patient characteristics. In the third-generation FloTrac algorithm, PR and SD (bp) were calculated every 20 seconds, while χ was calculated every minute. When vascular tone changed suddenly, χ consequently lagged in response. In the fourth-generation FloTrac algorithm, a new component K_{fast} that is inversely proportional to pressure[11] is added to χ and the new component is calculated every 20 seconds.

In the third-generation FloTrac algorithm: $\chi = K3$

In the fourth-generation FloTrac algorithm: $\chi = K4 \times K_{fast}$

$K3$ and $K4$ are both averaged every minute and are multivariate polynomial equations of waveform variables such as skewness and kurtosis. This change allows the fourth-generation FloTrac™/Vigileo™ system to respond faster and track closer to the changing vascular tone.

All hemodynamic data were obtained before cardiopulmonary bypass. All 23 patients demonstrated MAP below 70 mmHg during anesthesia. When MAP decreased below 70 mmHg, phenylephrine (100 μg) was administered to increase it. CO measurements using PAC and the FloTrac™/Vigileo™ system were performed simultaneously before and 2 minutes after phenylephrine boluses. Then, hemodynamic indices, including MAP, central venous pressure, mean pulmonary arterial pressure, heart rate, CO_{REF}, CO_{FVS}, and SVRI, were recorded. The time points before and after drug administrations were set as T0 and T1.

Data are expressed as mean and standard deviation. For all statistical analysis, SigmaPlot 11.2 (Systat Software Inc., San Jose, CA) and StatFlex version 6.0 software (Artech. Co., Ltd, Osaka, Japan) were used. Hemodynamic variables before and after interventions were compared using the two-sided paired Student's *t*-test and Mann–Whitney *U* test. The authors used Bland–Altman analysis to assess the bias and percentage error (PE; 2SD of the bias divided by mean CO of the reference method) between CO_{REF} and CO_{FVS}.[12] When the PE was below 30%, the tested method (CO_{FVS}) was regarded as interchangeable with the reference measurement method (CO_{REF}), as indicated by Critchley and colleagues.[13] In the Bland–Altman analysis, the authors made repeated-measurement adjustment for each subject, as shown by Myles and Cui.[14]

The authors performed four-quadrant plot analysis and polar-plot analysis to compare the trending abilities of CO_{REF} and CO_{FVS} after hemodynamic interventions. Four-quadrant plot analysis was used to assess the concordance rate between ΔCO_{REF} (percent changes in CO_{REF} between T0 and T1) and

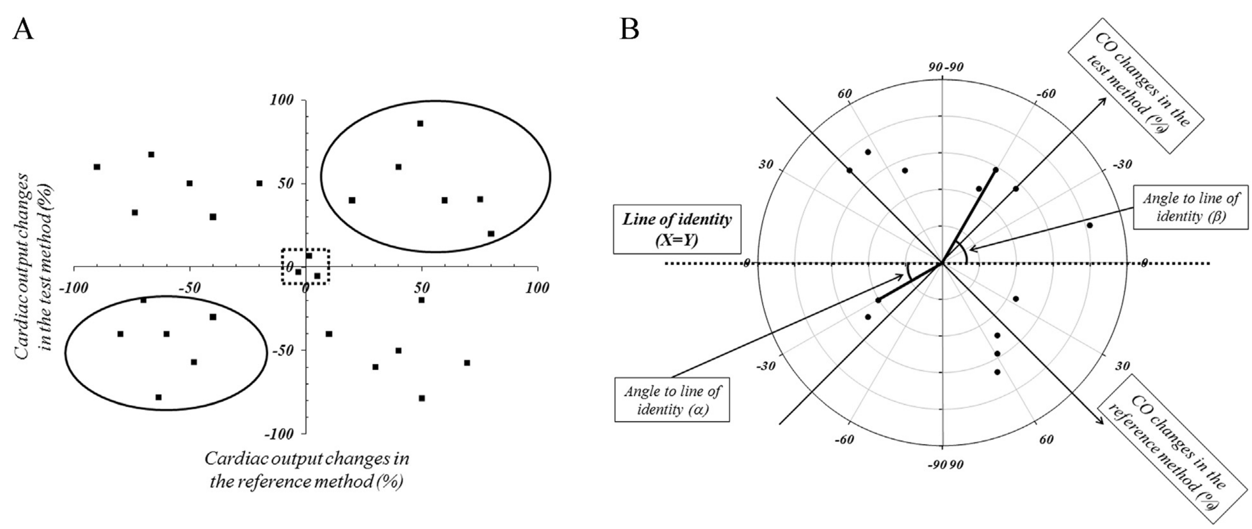

Fig 1. (A) Diagram of the four-quadrant plot analysis. Four-quadrant plot analysis was used to assess the concordance rate between cardiac output changes by the reference method and that by the test method. The concordance rate was defined as the percentage of the total number of points in the lower left or upper right quadrant of the four-quadrant plot (the points within the circles). In this figure, the concordance rate is 50%. The plots at the center are excluded as an exclusion zone. (B) Diagram of the polar-plot analysis. Polar-plot analysis requires a data rotation of the four-quadrant plot of 45° in the clockwise direction. This analysis shows the vector of changes after hemodynamic interventions as an angle from the line of identity (X = Y), and represents the agreement between the reference and tested methods as an angle from the axis (0°; positive in the clockwise direction). In this figure, the angle of α is -30°, while that of β is -60°.