Reliability of Cardiac Output Measurements Using LiDCOrapid™ and FloTrac/Vigileo™ Across Broad Ranges of Cardiac Output Values

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* Conflicts of Interest:  
  This study is a consignment study from Nihon Kohden Corportation (Tokyo, Japan), the provider of LiDCOrapidTM in Japan. Nihon Kohden Corportation supported our study by providing four LiDCOrapidTM catheters and lending us LiDCOrapidTM for 2 years. Edwards Lifesciences Corporation (Irvine, California) provided us five CO-Set+TM (closed injectate delivery system).   
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**IRB:** This study was reviewed and approved by the local ethics committee of The University of Tokyo Hospital (Tokyo, Japan, #3926).

Abstract

Background

Knowing a patient’s cardiac output (CO) is important for safe, optimized hemodynamic control during surgery. Precise CO measurements can serve as a guide for resuscitation therapy, catecholamine use, differential diagnosis, and intervention during a hemodynamic crisis. Despite its invasiveness and intermittent nature, the thermodilution technique via pulmonary artery catheter (PAC) remains the accepted gold standard for CO measurements. LiDCOrapid™ (LiDCO, UK) and FloTrac/Vigileo™ (Edwards Lifesciences, Irvine, CA) are less invasive continuous CO monitors that use arterial waveform analysis. Their calculations are based on arterial waveform characteristics and need no calibration. We evaluated LiDCOrapidTM and FloTrac/VigileoTM during off-pump coronary artery bypass graft (OPCAB) and living-donor liver transplantation (LDLT) surgery.

Methods

This observational, single-center study included 21 patients (11 OPCAB and 10 LDLT). We performed simultaneous measurements of CO at the fixed sample points during surgery with both devices (LiDCOrapid™ version 1.04-b222 and FloTrac/Vigileo™ version 3.02) and used the thermodilution technique via PAC as a benchmark. LiDCOrapid™ and FloTrac/Vigileo™ were used in an uncalibrated fashion. We analyzed the measured cardiac index using modified Bland–Altman analysis and polar plot method.

Results

One OPCAB patient was excluded because of intra-aortic balloon pumping used during surgery, and 20 patients (10 OPCAB and 10 LDLT) were enrolled. We obtained 149 available triplet measurements that ranged over wide areas of cardiac index and systemic vascular resistance index. Bland–Altman analysis revealed biases (FloTrac/Vigileo™ vs. PAC and LiDCOrapid™ vs. PAC: 0.71 L/min/m2 and 0.53 L/min/m2, respectively) and percentage errors (80.8% and 55.1%, respectively). The polar plot method showed angular bias (FloTrac/VigileoTM vs. LiDCOrapidTM: 8.1° vs. 6.0°, respectively) and radial limits of agreement [(−61.0, 77.1) vs. (−36.1, 48.0)].

Conclusions

Both devices tended to underestimate when the cardiac index was high. These tendencies produced large percentage errors in our study setting. Neither device showed good trending abilities when we used a reported criterion.

# Introduction

It is important to know a patient’s cardiac output (CO) for safe, optimized hemodynamic control during surgery. Precise CO measurements can serve as a guide for resuscitation therapy, catecholamine use, differential diagnosis, and intervention during a hemodynamic crisis[1,2]. Although thermodilution technique via a pulmonary artery catheter (PAC) is an invasive and intermittent technique, it still remains the accepted gold standard for CO measurements[3]. LiDCOrapid™ (LiDCO, UK) and FloTrac/Vigileo™ (Edwards Lifesciences, Irvine, CA) are examples of are less invasive and continuous CO monitors using an arterial waveform analysis. Their calculations are based on arterial waveform characteristics and need no calibration. The evaluation and comparison of these low-invasion CO estimation monitors are invaluable in the rational selection of CO measurement methods[3], with many research projects having been carried out in this field[4-8].

This study focused on the use of live-donor liver transplant (LDLT) recipients and off-pump coronary artery bypass graft (OPCAB) cases for comparing the devices. LDLT recipients exhibit a hyperdynamic state in cirrhosis hemodynamics, with low systemic vascular resistance (SVR) and high CO[9,10]. The OPCAB cases, on the other hand, have high SVR due to arteriosclerosis and low CO due to coronary ischemia[11,12]. We hypothesized that, using LDLT and OPCAB surgical patients, we could verify CO measurements across a broad range of CO and SVR.Methods

**Institutional Review Board/Consent:**

This research was approved by the ethics committee of the University of Tokyo Hospital (#3926). All patients provided written informed consent.

**Clinical Trial Registration:**

This research project is an observational study. Because the research design had no allocation, no clinical trial registration was implemented.

Subjects

This research is based on observations at a single facility of OPCAB and LDLT patients undergoing planned surgeries between November 2012 and February 2014 (a total of 21 cases; 11 cases of OPCAB and 10 cases of LDLT). The following exclusion criteria were implemented during presurgical application: 1) atrial fibrillation (Af) rhythm, 2) emergency surgery, 3) moderate/severe valvular diseases, 4) significant intracardiac shunts, 5) significant arterial occlusions, 6) artificial vessel replacements, 7) massive ascites (>10% of the body weight), and 8) any other disease that may influence CO measurements.

FloTrac/VigileoTM

The FloTrac/VigileoTM system estimates CO without correction, using arterial pressure waveforms and the patient’s age, sex, height, and weight. FloTrac/VigileoTM-derived CO is calculated by multiplying heart rate by stroke volume. The stroke volume is averaged and displayed every 20 s, and the CO displayed on the monitor represents a 5-min moving average. We used version 3.02 of the software in this study.

LiDCOrapidTM

LiDCOrapidTM is similar to the FloTrac/VigileoTM system in that it facilitates CO measurements without correction using invasive arterial pressure waveforms and the patient’s age, sex, height, and weight. LiDCOrapidTM uses the PulseCO algorithm, which is characterized by its ability to measure CO per beat. In this research, we used version 1.04-b222 of the software.

Data Collection

All data were taken in the supine position, and the transducer (TruWave transducer; Edwards Lifesciences) was positioned at the midaxillary line. After an arterial catheter was inserted into the radial artery and attached to the FloTracTM device, arterial pressure waveforms were sent simultaneously to VigileoTM and LiDCOrapidTM. A central venous catheter and 9-Fr sheath introducer (AK-09903-JJ; Teleflex Inc, Reading, PA) were positioned in the right internal jugular vein and an 8-Fr PAC (777HF8; Edwards Lifesciences) was inserted through the introducer. The PAC was inserted using the tip pressure as a guide, with confirmation by either chest radiography (LDLT) or transesophageal echography (OPCAB). The CO was measured using a cold saline dilution from the central venous catheter, after confirming 1) that the hemodynamics was stable for 5 min, 2) that rapid infusion (>1000 mL/h) was not taking place, and 3) a minimum of 30 min had passed since the previous measurement. The cold water dilution method was implemented using saline cooled to 0°C with a closed injectate delivery system (CO-Set+TM; Edwards Lifesciences). The temperature of the cooled saline delivered was input to VigilanceTM (Edwards Lifesciences) using a dedicated cable. If the CO measured three times by cold saline dilution showed a disassociation of 15% or greater, the measured values were discarded. We used an average of three values of the cardiac index (CI) through PAC (PAC-CI) as the benchmark. The following sample points were determined in advance:

OPCAB

(T1) After insertion of a PAC

(T2) After vertical incision of the sternum

(T3) During harvesting of a graft

(T4) During anastomosis to LAD

(T5) During anastomosis to HL/IM

(T6) During anastomosis to LCX

(T7) During anastomosis to RCA

(T8) Before closure of the sternum

(T9) After closure of the sternum

LDLT

(U1) After insertion of a PAC

(U2) Before the start of surgery

(U3) One hour from the start of surgery

(U4) Two hours from the start of surgery

(U5) After complete removal of the liver

(U6) At anastomosis of the clamped IVC and the hepatic vein

(U7) At anastomosis of the portal vein

(U8) After recirculation of the portal vein

(U9) Thirty minutes after reperfusion of the portal vein

(U10) After anastomosis and recirculation of the hepatic artery

(U11) After reconstruction of the bile duct

(U12) Abdominal closure

At the point at which 1)-3) were confirmed during surgery, CO measurement was additionally conducted (Tx, Ux). The FloTrac/VigileoTM system-derived CI (FT-CI), LiDCOrapidTM-derived CI (LiD-CI), mean arterial pressure, central venous pressure, and body temperature measurements were made before and after the three thermodilutions through PAC. If the variations of FT-CI, LiD-CI, and mean arterial pressure during thermodilution were 15% or greater, the measured values were not used in the analysis.

Statistical Analysis

The CI and SVR index (SVRI) were used for the analysis to eliminate the effect of physical size. A Bland–Altman analysis was performed with a correction for repeated measurements[13]. Furthermore, trending ability was examined using the polar plot method[14] (cutoff value: 0.5 L/min/m2, half-moon method), and we used a reported criterion for good trending ability of an angular bias no greater than ±5° and radial limits agreement no greater than ±30°[14]. The statistical software package R version 3.1.2 (R: A Language and Environment for Statistical Computing; R Foundation for Statistical Computing, Vienna, Austria) was used.Results

One case of OPCAB required an intra-aortic balloon pump during surgery and was excluded. Descriptive data are presented as the means ± standard deviations for normally distributed data. Patient backgrounds are shown in Table 1 (overall mean age was 60.8 ± 14.3 years, mean height was 159.3 ± 10.7 cm, and mean weight was 61.2 ± 13.6 kg; the mean MELD score for those undergoing LDLT was 18.4 ± 6.8 and the average bypass number for those with OPCAB was 4.3 ± 1.4). In total, 91 pieces of CI were taken from the LDLT patients (9.1 ± 2.2 per case, 82 fixed-time-point and 9 other-time-point data) and 58 pieces of CI from the OPCAB cases (5.8 ± 2.8 per case, 54 fixed-time-point and 4 other-time-point data). When the data were plotted on a graph showing the relationship between SVRI and CI (PAC-CI), it was clear that data for a wide range of SVRI and CI had been obtained (Figure 1). The results of Bland–Altman analysis are shown in Figures 2 and 3. Neither logarithmic transformation nor coordinate transformation was used. With FloTrac/VigileoTM, the increased CI produces an accompanying decrease of FT-CI (correlation coefficient in a Bland–Altman plot, R = −0.71). Bias and percentage error, which is an indicator of the replaceability[15], were −0.71 L/min/m2 and 80.8%, respectively. A similar relationship was noted using LiDCOrapidTM, although it was weaker than that identified using FloTrac/VigileoTM (correlation coefficient in a Bland–Altman plot, R = −0.53), with bias and percentage error of −0.53 L/min/m2 and 55.1%, respectively. The results of the polar plot method are shown in Figures 4 and 5. FloTrac/VigileoTM had an angular bias of 8.1° and radial limits of agreement of −61.0°–77.1°. LiDCOrapidTM had an angular bias of 6.0° and radial limits of agreement of −36.1°–48.0°. When we used reported criteria[15,14], neither device had acceptable accuracy or good trending abilities.

Discussion

This study is the first study to include surgical patients with two physiologically different circulatory conditions, allowing verification of the devices using a broad range of CO and blood vessel resistance values (Fig 1). We hypothesized that performing verification in two conditions that demonstrate extremes of both CO and SVR would allow all other circulatory physiological conditions to be interpolated and explained. With FloTrac/VigileoTM, the results of previous reports[4,7,8,6,5] were consistent with this research, indicating that the expectations of this study were met. Under these conditions, neither the FloTrac/VigileoTM system nor LiDCOrapidTM achieved replaceability of Critchley’s criteria[15]. LiDCOrapidTM had a smaller percentage error than the Flotrac/VigileoTM system, indicating that it measures CI more accurately. As has been reported to date, the FloTrac/VigileoTM system has broad radial limits of agreement and its trending ability is low. This indicates that LiDCOrapidTM has lower radial limits of agreement than the FloTrac/VigileoTM system and offers better trending ability. In both FT-CI and LiD-CI, there was a tendency to underestimate CI in line with increased CI and reduced SVRI. Results indicate that this may be a problem unique to CO measurement using arterial pressure waveform analysis.

The three types of CO measurement methods require different times for completing CO measurement and the reflected CO. In the thermodilution using a PAC, the CO obtained during roughly 3 min, which is the time required from the start of measurement to completion, was the average CO for the 3 min. The FloTrac/VigileoTM system uses two parameters, at 1 min and 20 s, respectively, before displaying the measured value. LiDCOrapidTM measures CO per heartbeat. To rationally compare these three type of CO measurements, we decided to exclude any data that demonstrated a variation of 15% or more in the measurement parameters between the point when thermodilution was started after hemodynamics had been stable for 5 min or more and when thermodilution was completed. Furthermore, the CI of the FloTrac/VigileoTM system and LiDCOrapidTM were averaged before and after thermodilution.

Limitations

We acknowledge several limitations of this study. First, it was performed at a single institution, and all the subjects were Japanese. As a result, it is impossible to rule out the effect of the facility on the applicability of OPCAB and LDLT in this study, and our results may only be applicable to Asian people. Next, the patients involved had particular circulatory physiology in the forms of OPCAB and LDLT. Although we believe that a broad range of CO and blood vessel resistance can be interpreted based on these two conditions, great care will be required when determining its emphasis. Furthermore, it was not possible to clarify whether CO or blood vessel resistance had a greater impact on either the FloTrac/VigileoTM system or LiDCOrapidTM because the subjects were surgical patients, and from the perspective of maintaining mean arterial pressure, it was necessary to increase the blood vessel resistance if the CO was low, whereas it was necessary to increase the CO if the blood vessel resistance was low.

Conclusion

We found both devices tended to underestimate when CIs were higher. These tendencies produced large percentage errors in our study setting. Both devices did not show acceptable accuracy and good trending abilities when we used reported criteria.

# Table

Table 1. Patient Demographic Data

|  |  |  |
| --- | --- | --- |
|  | LDLT | OPCAB |
| Age (years) | 51.6 ± 14.6 | 69.9 ± 5.7 |
| Height (cm) | 158.8 ± 10.3 | 159.8 ± 11.7 |
| Weight (kg) | 61.0 ± 15.2 | 61.5 ± 12.7 |
| Sex (male/female) | 4/6 | 7/3 |
| Mean arterial pressure (mm Hg) | 62 ± 9 | 77 ± 15 |
| Central venous pressure (mm Hg) | 9 ± 4 | 10 ± 4 |
| Mean CI (L/min/m2) | 5.5 ± 1.5 | 2.0 ± 0.7 |
| Mean SVRI (dyn·s/cm5/m2) | 859 ± 392 | 2809 ± 1072 |

LDLT = living-donor liver transplantation; OPCAB = off-pump coronary artery bypass graft; CI = cardiac index; SVRI = systemic vascular resistance index.

Data are expressed as means ± standard deviations.

# Figures and Illustrations

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# Figure 1. All analyzed data were plotted with the cardiac index (CI) on the horizontal axis and the systemic vascular resistance index (SVRI) on the vertical axis. The red circles represent off-pump coronary artery bypass graft (OPCAB) cases and the black circles represent living-donor liver transplantation (LDLT) cases. OPCAB demonstrated low CI and high SVRI, whereas LDLT demonstrated high CI and low SVRI. This indicates that the combination of the two types of surgical patients allowed verification of the devices using a broad range of CI and SVRI.

# Figure 2. The Bland–Altman plot of pulmonary artery catheter (PAC)-measured cardiac index (PAC-CI) and FloTrac/VigileoTM-derived CI (FT-CI). In line with the increase in (PAC-CI + FT-CI)/2, FT-CI was estimated to be higher than the actual value (R = −0.71). ULA = upper limits of agreement; LLA = lower limits of agreement; PE = percentage error.

# Figure 3. The Bland–Altman plot of pulmonary artery catheter (PAC)-measured cardiac index (PAC-CI) and LiDCOrapidTM-derived CI (LiD-CI). There was a tendency for overestimation when the increase of (PAC-CI + LiD-CI)/2 was less than that for FloTrac/VigileoTM. LiDCOrapidTM also had a smaller percentage error. ULA = upper limits of agreement; LLA = lower limits of agreement; PE = percentage error.

# Figure 4. The trending ability for FloTrac/VigileoTM was also evaluated by the polar plot method (n = 93). The cutoff value was 0.5 L/min/m2. The angular bias was 8.1°, and the angular limits of agreement were from −61.0° to 77.1°.

# Figure 5. The polar plot method for LiDCOrapidTM (n = 88). The angular bias was 6.0°, and the angular limits of agreement were from −36.1° to 48.0°. LiDCOrapidTM demonstrated a better trending ability than FloTrac/VigileoTM.

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