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Clinical evaluation of the FloTrac/Vigileo™ system and two established continuous cardiac output monitoring devices in patients undergoing cardiac surgery†‡

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Background. Assessment of cardiac output (CO) by the FloTrac/Vigileo™ system may offer a less invasive means of determining the CO than either the pulmonary artery catheter (PAC) or the PiCCOplus™ *system*. The aim of this study was to compare CO measurements made using the FloTrac/Vigileo™ system with upgraded software (FCO, Edwards Lifesciences, Irvine CA, USA), the PiCCOplus™ system (PCO, Pulsion Medical Systems, Munich, Germany) and continuous CO monitoring using a PAC (CCO; Vigilance™ monitoring, Edwards Lifesciences, Irvine CA, USA) with intermittent pulmonary artery thermodilution (ICO). The study was conducted in patients undergoing elective cardiac surgery.

Methods. Thirty-one patients with preserved left ventricular function were enrolled. CCO, FCO, and PCO were recorded in the perioperative period at six predefined time points after achieving stable haemodynamic conditions; ICO was determined from the mean of three bolus injections. Bland–Altman analysis was used to compare CCO, FCO, and PCO with ICO.

Results. Bland–Altman analysis revealed a comparable mean bias and limits of agreement for all tested continuous CO monitoring devices using ICO as reference method. Agreement for all devices decreased in the postoperative period.

Conclusion. The performance of the FloTrac/Vigileo™ system, the PiCCOplus™, and the Vigilance™ CCO monitoring for CO measurement were comparable when tested against intermittent thermodilution in patients undergoing elective cardiac surgery.

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Cardiac output (CO) is monitored in critically ill patients to assess cardiac function with the primary goal of maintaining adequate tissue perfusion. In patients undergoing cardiac surgery, thermodilution using a pulmonary artery catheter (PAC) is still the most frequently applied technique. However, the value of the PAC has been questioned in recent years and its impact on outcome is a matter of debate;[1–4] several less invasive techniques which avoid the risks associated with the PAC have become available for routine CO monitoring.[5 6] One of these is pulse contour analysis using the PiCCOplus™ system (Pulsion Medical Systems, Munich, Germany). This records aortic pressure waveforms

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using a thermistor-tipped catheter. The CO is calculated using an algorithm based on the area under the systolic part of the pressure waveform after calibration by transpulmonary thermodilution.[7] This calibration is also used to adjust for individual vascular compliance. The system has extensively been evaluated and most studies demonstrate adequate results using the current device and software when compared with pulmonary artery thermodilution.[8–11]

Recently, a new pulse wave analysis device that does not require external calibration has become available.[12] The FloTrac/Vigileo™ system (Edwards Lifesciences, Irvine, CA, USA) obtains the pressure wave signal from any standard peripheral arterial line and the SD of pulse pressure is empirically correlated to the stroke volume (SV) based on patient characteristics (age, gender, body height, and weight) after automatic adjustment for actual vascular compliance. Early validation studies for this device showed conflicting results.[12–15] As a consequence, the FloTrac/Vigileo™ software with its underlying algorithm was improved and the time window for vascular adjustment was reduced.

The aim of this study was to evaluate the accuracy of CO measurements in patients undergoing elective cardiac surgery; the CO was determined using four devices: (1) the FloTrac/Vigileo™ system with upgraded software (FCO), (2) the PiCCOplus™ system (PCO), (3) continuous CO monitoring using a PAC (CCO, in combination with a Vigilance™ monitor, Edwards Lifesciences), and (4) intermittent pulmonary artery thermodilution.

Methods

Patients and setting

Patients undergoing elective coronary artery bypass grafting and/or valve surgery gave their informed consent to the study, which was approved by the local Ethics Committee. Exclusion criteria were reduced left and right ventricular function (ejection fraction $<40\%$), preoperative dysrhythmias, severe valve regurgitation, intracardiac shunts, pulmonary artery hypertension, severe arterial occlusive disease, and body weight <40 kg. A sample size of 25 patients was calculated on the basis of an expected difference of mean values between CO determination by the continuous measurement techniques and intermittent thermodilution of 0.3 litre min^{-1} ($\alpha = 0.05$ and power >0.9).

Routine perioperative management

Anaesthesia and postoperative management followed institutional standards. After tracheal intubation, the lungs were ventilated using volume-controlled mode to maintain normocarbia. In the postoperative period, the patients were extubated in the intensive care unit after the completion of the institutional weaning protocol. Routine monitoring (Philips IntelliVue™ Monitoring, Philips Medical Systems, Andover, MA, USA) during the entire perioperative period included pulse oximetry, 5-lead ECG, invasive blood pressure measurement via a peripheral radial arterial line, and central venous and pulmonary capillary wedge pressures (PCWPs) assessed by standard transducers (Truewave™ PX, Edwards Lifesciences). Postoperative pacing was used in all patients in an AOO or DDD mode at a minimal rate of 80 beats min^{-1}. Haemodynamic therapy was guided by values obtained from continuous CO monitoring using a PAC. I.v. fluids and blood products (target hematocrit $>25\%$), vasodilators (nitroglycerine/phentolamine), and catecholamines (norepinephrine/dobutamine) were used as appropriate to achieve and maintain a mean arterial pressure (MAP) of 65–75 mm Hg and a cardiac index of >2 litre $min^{-1}m^{-2}$.

CO monitoring

After induction of anaesthesia, a 7.5 F PAC (Swan-Ganz CCO/VIP PAC, Edwards Lifesciences) was introduced via right internal jugular vein access and attached to a Vigilance™ monitor (Version 6.3, Edwards Lifesciences). A CO monitoring set with a closed cold injectate delivery system (Edwards Lifesciences) used for intermittent thermodilution was connected to the proximal lumen of the PAC.

A 4F thermistor-tipped arterial catheter (Pulsiocath™ thermodilution catheter) was inserted into the left femoral artery, its tip advanced to the abdominal aorta, and connected to the stand-alone PiCCOplus™ computer (Version 6.0; Pulsion Medical Systems). Continuous CO measurement was initiated after the initial calibration of the system by a triplicate 20 ml ice-cold normal saline injection through an additional 7F central venous catheter (transpulmonary thermodilution). The calibration process was repeated according to the manufacturer's guidelines every 8 h.

A FloTrac™ sensor kit was connected to the arterial line and connected to the Vigileo™ monitor programmed with the 1.07 version of the software for this device (Edwards Lifesciences). Patient data (age, gender, body weight, and height) were entered and after checking the arterial line waveform fidelity, the system was zeroed and CO measurement initiated. The CO was recorded continuously for 24 h except for a short period when the patient was transferred from the operating room into the intensive care unit.

Pulse wave analysis algorithms

FloTrac/Vigileo™ system

The algorithm uses the basic equation (1) for measuring CO with heart rate (HR) being determined from the pressure waveform through conventional methods:

$$CO = HR \times SV. \quad (1)$$

The calculation of SV can be divided into two parts based on manually entered patient data (age, gender, body length, and weight):

(1) The contribution of pulse pressure to SV, which is proportional to the SD of arterial pulse pressure (SD_{ap}).

(2) The influence of vascular resistance and compliance on SV integrated into a single variable (χ). Thus, CO is calculated as follows (2):

$$CO = HR \times : SD_{ap} \times \chi. \quad (2)$$

Different characteristics of the blood pressure[16] are utilized in equation (3) for the derivation of χ from a multivariate regression model (M). These include Langewouter's aortic compliance (Cp),[17] MAP, the variance, skewness, and kurtosis of the pressure wave curve. Body surface area (BSA) also appears in the model. Further details of this proprietary algorithm are not disclosed by Edwards Lifesciences.

$$\chi = M(Cp, MAP, variance, skewness, kurtosis, BSA). \quad (3)$$

Pulse pressure is recorded at a frequency of 100 Hz and SD_{ap} is determined during a window of 20 s. After the early clinical experiences with this algorithm, the rate of the adjustment of χ was reduced from the initial interval of 10 to 1 min in the latest version of the software.

PiCCOplus™ system

The basics of the PiCCOplus™ method and its underlying algorithm have been described in detail elsewhere.[7] Briefly, CO is calculated every 3 s by measuring the area under the systolic part of the arterial pressure waveform and dividing this area by the aortic impedance.[18] For an adjustment of individual aortic compliance, calibration by transpulmonary thermodilution is required. Modification of the algorithm enhanced accuracy by the additional analysis of the shape of the pressure waveform.[10]

Study protocol

The CO data from all devices and standard haemodynamic data (HR, MAP, central venous pressure, and PCWP) were recorded by an observer not involved in the routine management of the patient at predefined time points before transpulmonary thermodilution measurements. Transpulmonary thermodilution measurements were made under stable haemodynamic conditions. Three injections of iced NaCl 0.9% (10 ml, 4–6°C) were made using a closed cold injectate delivery system and the mean value recorded. The measurements were free of interference from surgery or infusion boluses. Predefined measurement points were: T1=after induction of anaesthesia (study initiation), T2 =1 h post-initiation (after sternotomy), T3=4 h post-initiation (at skin closure), T4–6=8, 12, and 24 h post-initiation (after the transfer to the intensive care unit).

Statistics

Statistical analysis was done using StatView® for Windows version 5.01® (SAS Institute Inc., Cary, NC, USA) and SPSS for Windows Release 12.0.2 (SPSS Inc., Chicago, IL, USA). The data were tested for normality by the Kolmogorov–Smirnov test. ANOVA for repeated measurements (Bonferroni–Dunn) was done to assess the differences on haemodynamic variables between consecutive measurements. Bland–Altman analyses[19] and paired *t*-tests were done to compare CO values obtained by the different devices with CO assessed by intermittent pulmonary artery thermodilution. Unless otherwise stated data are presented as mean and SD.

Results

Thirty-one patients, mean age 67 (range 46–85 yr) yr, 26 male, BMI 28.2(5.3) kg m^{-2} with preserved left ventricular function [preoperative ejection fraction 62.4(12.2) %], undergoing elective cardiac surgery were enrolled. All patients were ASA physical status III and were in sinus rhythm before the induction of anaesthesia. Eleven patients (35%) underwent aortic valve replacement, one patient (3%) underwent mitral valve replacement, three patients (10%) underwent mitral valve reconstruction, three patients (10%) underwent coronary artery bypass grafting, and 13 patients (42%) underwent combined procedures.

The mean duration of mild hypothermic cardiopulmonary bypass was 100(11) min, mean operation time was 261(48) min, and mean ICU stay was 2(1) days. The measurement period was uneventful for all patients. After the removal of the PiCCO catheter, one patient (3%) developed arterial bleeding resulting in an inguino-scrotal haematoma requiring surgical intervention.

There was a significant increase in HR and CO assessed by all tested techniques during the observation period (Table 1). Systemic vascular resistance significantly decreased, whereas all other haemodynamic variables (MAP, MPAP, CVP, and PCWP) showed no significant changes over time.

CO assessed by the FloTrac/Vigileo™ and the PiCCOplus™ system was significantly higher for the first two measurements when compared with CO assessed by intermittent thermodilution. The CO values ranged between 2.4 and 7.5 litre min^{-1} during the intraoperative period and between 3.1 and 9.3 litre min^{-1} in the postoperative period.

Bland–Altman analysis (Figures 1 and 2, Table 2) revealed a consistently positive mean bias for the FloTrac/Vigileo™ system, the PiCCOplus™ system, and continuous CO monitoring by the PAC when compared with the intermittent pulmonary artery thermodilution at every measurement point during the intraoperative and the postoperative observation period. This finding indicates an overestimation of CO by all continuous measurement techniques. Agreement for all devices decreased early after the intervention (T3–4).

Discussion

In the present study, we tested a new pulse wave analysis device and two established systems for continuous CO

Table 1 Haemodynamics during the study period. T1=after induction of anaesthesia, T2=after sternotomy, T3=at skin closure, T4=after transfer to the ICU, T5–6=during ICU stay hours 12 and 24 after study initiation. HR, heart rate; MAP, mean arterial pressure; MPAP, mean pulmonary artery pressure; CVP, central venous pressure; PCWP, pulmonary capillary wedge pressure; SVR, systemic vascular resistance; CO, cardiac output; FCO, CO assessed by the FloTrac/Vigileo™ device; PCO, CO assessed by the PiCCOplus™ system; CCO, continuous CO measured by PAC using the Vigilance™ monitoring; ICO, CO determined by the intermittent pulmonary artery thermodilution. Data are presented as mean(SD). *$P<0.05$ compared with ICO, **$P<0.05$ compared with T1, ***$P<0.05$ compared with T2 (all comparisons with T3 and T4 not significant)

	Intraoperative measurements			**Postoperative measurements**		
	T1	**T2**	**T3**	**T4**	**T5**	**T6**
FCO (litre min^{-1})	4.7 (1.1)*	4.7 (0.9)	5.1 (0.9)	5.4 (1.2)	5.7 (1.1)**/***	5.5 (1.2)***
PCO (litre min^{-1})	4.7 (1.1)*	4.7 (1.2)*	5.3 (1.4)	5.5 (1.4)	5.8 (1.7)**/***	5.4 (1.9)***
CCO(litre min^{-1})	4.4 (1.2)	4.5 (1.2)	5.3 (1.6)	5.6 (1.6)	6.0 (1.5)**/***	6.0 (1.6)**/***
ICO (litre min^{-1})	4.2 (0.9)	4.3 (1.1)	5.0 (1.3)	5.3 (1.5)	5.6 (1.4)**/***	5.6 (1.2)**/***
HR (beats min^{-1})	64 (16)	67 (16)	82 (12)**/***	89 (7)**/***	88 (11)**/***	77 (12)**/***
MAP (mm Hg)	76 (12)	74 (11)	72 (7)	72 (8)	72 (8)	77 (9)
MPAP (mm Hg)	25 (9)	24 (10)	24 (7)	24 (6)	24 (6)	24 (6)
CVP (mm Hg)	12 (4)	10 (4)	12 (3)	11 (4)	11 (4)	12 (4)
PCWP (mm Hg)	16 (6)	16 (4)	16 (4)	15 (5)	15 (5)	16 (12)
SVR (dyn s cm^{-5})	1277 (276)	1252 (412)	1010 (251)***	1012 (274)***	921 (265)***	961 (154)***

monitoring and compared these with the clinical standard, intermittent pulmonary artery thermodilution, in patients with preserved left ventricular function undergoing elective cardiac surgery. The results show that the performance of the FloTrac/Vigileo™ system, the PiCCOplus™ system, and continuous CO monitoring by PAC were comparable.

Both the FloTrac/Vigileo™ and the PiCCOplus™ system are based on pulse pressure analysis. They calculate the flow from the arterial pressure waveform, which is itself the result of an interaction between the SV and the elastic properties of the systemic vascular system. Thus, resistance, compliance, and impedance at the site of the signal detection must be considered. The FloTrac/Vigileo™ system calculates CO by the analysis of the impact of vascular tone on pressure and adjustment for actual vascular tone based on waveform analysis and patient characteristics. In contrast to other available pulse contour techniques,[10 20] the system does not require an external reference method for calibration or subsequent correction. Therefore, it minimizes operator dependency and its automatic adjustment for the changes of vascular tone may eliminate drift phenomena.

Recently published studies investigating the FloTrac/Vigileo™ system showed inconsistent results.[12–15] Manecke and Auger[12] reported a mean bias of 0.55 (limits of agreement 1.96) litre min^{-1} between the FloTrac/Vigileo™ device and the intermittent pulmonary artery thermodilution in 50 patients studied after cardiac surgery. Opdam and colleagues[14] reported data from 251 measurements in six patients. Unfortunately, 66% of all measurements were done in only one patient. Therefore, their results are difficult to interpret. Sander and colleagues[15] observed an overall bias of 0.6 (limits of agreement 2.8) litre min^{-1} between the FloTrac/Vigileo™ system and intermittent thermodilution in 30 cardiac surgery patients. Most recently, another study performed in 40 patients in a similar setting revealed a large mean bias of 0.46 (limits of agreement 1.15) litre $min^{-1}m^{-2}$.[13] In our study, in contrast, better results for the FloTrac/Vigileo™ system were found in terms of a smaller bias or smaller limits of agreement for all measurements. These findings may be explained by the fact that the software has been modified recently. In order to better reflect the actual vascular status of the patient, the time window for vascular adjustment has been reduced from 10 to 1 min. Therefore, haemodynamic changes before the measurement periods—even under conditions of haemodynamic stability (i.e. after sternotomy)—may have had a larger impact on measurements in the studies performed by Sander and colleagues[15] or Mayer and colleagues.[13]

Overall bias and limits of agreement for the PiCCOplus™ system obtained in this study correspond to the data of previously published work.[8–11] In contrast to the FloTrac/Vigileo™ system, this system uses transpulmonary thermodilution for calibration. Inaccurate measurements as a result of variations in systemic vascular resistance were observed when the initial algorithm was used.[21] However, after the modification of the algorithm to better address the individual patient's aortic compliance, the majority of studies found a good agreement between the PiCCOplus™ values and the intermittent thermodilution.[8 10 11] The modified algorithm also appears to be more robust in the situations of haemodynamic changes.[9] Interestingly, recent studies evaluating this system in cardiac surgery patients revealed reliable measurements before cardiopulmonary bypass, but less accurate results if no recalibration was performed early after cardiopulmonary bypass.[22 23] In this period of surgery, temperature and fluid shifts and changes of vascular tone occur,[24] and early recalibration has been suggested to improve performance.[23] Despite the early recalibration in our study, we still observed a decreased agreement between the PiCCOplus™ system and the reference method in the postoperative period. This finding may be related to an increase in signal-to-noise ratio of

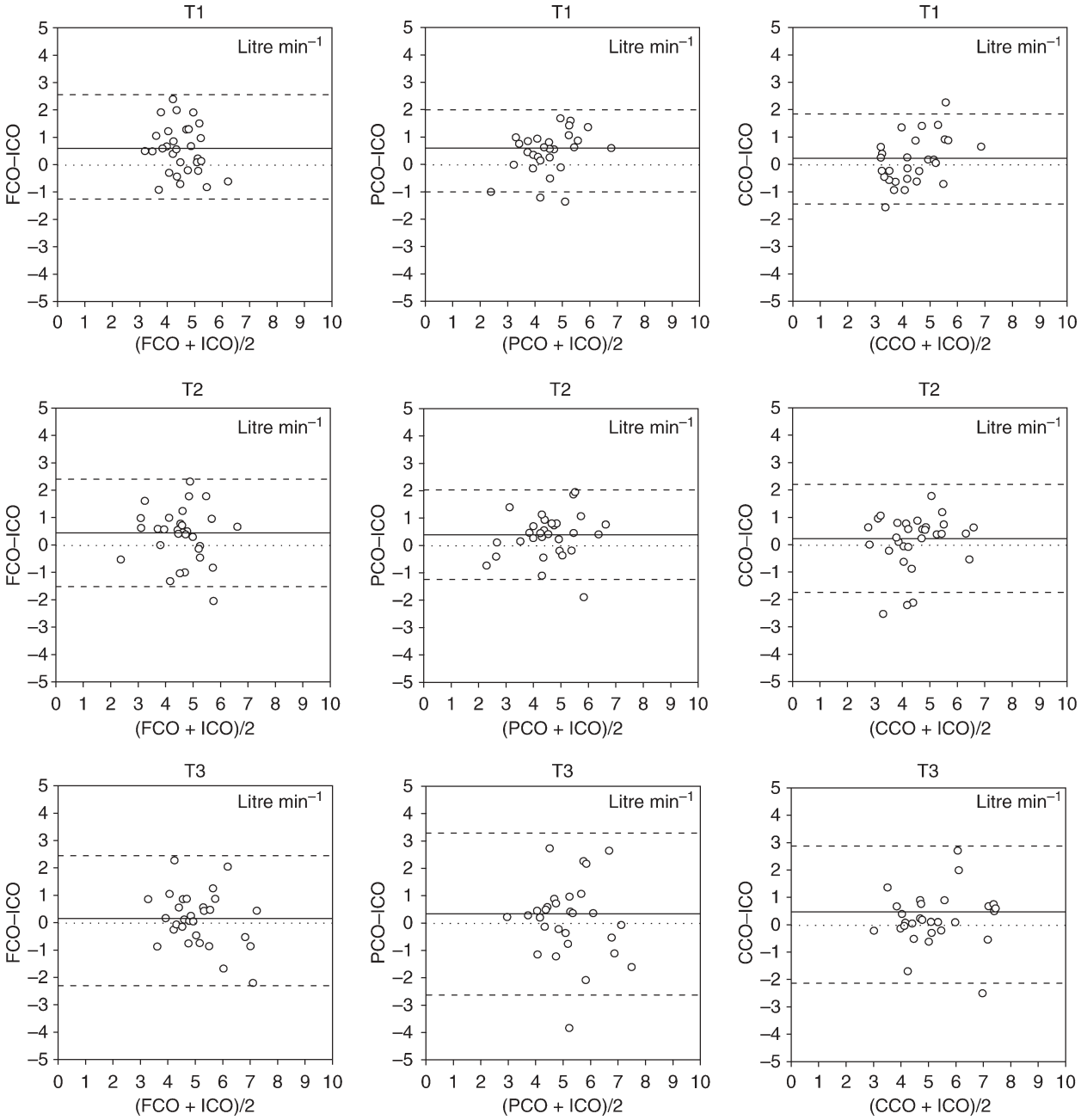

Fig 1 Bland–Altman analysis for CO measurements during the intraoperative period using the FloTrac/Vigileo™ system, the PiCCOplus™ system, and the PAC/Vigilance™ monitoring compared with the intermittent pulmonary artery thermodilution. T1=after induction of anaesthesia, T2=after sternotomy, T3=at skin closure; CO, cardiac output; FCO, CO by the FloTrac/Vigileo™ device; PCO, CO by the PiCCOplus™ system; CCO, continuous CO measured by PAC using the Vigilance™ monitoring; ICO, CO by intermittent pulmonary artery thermodilution (iced water bolus method). Solid line, mean bias; dashed lines, limits of agreement.

transpulmonary thermodilution because of potential thermal influences on this calibration technique after cardiopulmonary bypass. Therefore, calibration by means of thermodilution may not necessarily increase the accuracy of a CO monitoring device. Although the PiCCOplus™ system is considered a 'less-invasive' CO monitoring device, measurements are typically derived via a femoral catheter. Complications may occur, primarily ischaemia or bleeding related to femoral artery puncture and catheter use with an incidence up to 5%.[25] One of our patients enrolled in this study had a major bleeding complication requiring surgical intervention after removal of the PiCCO™ catheter.

Despite the development and the increased clinical use of different less invasive devices in the last years, continuous CO monitoring using the PAC remains the standard, especially when monitoring of pulmonary artery pressures is indicated. Corresponding to previous investigations,[22 26]

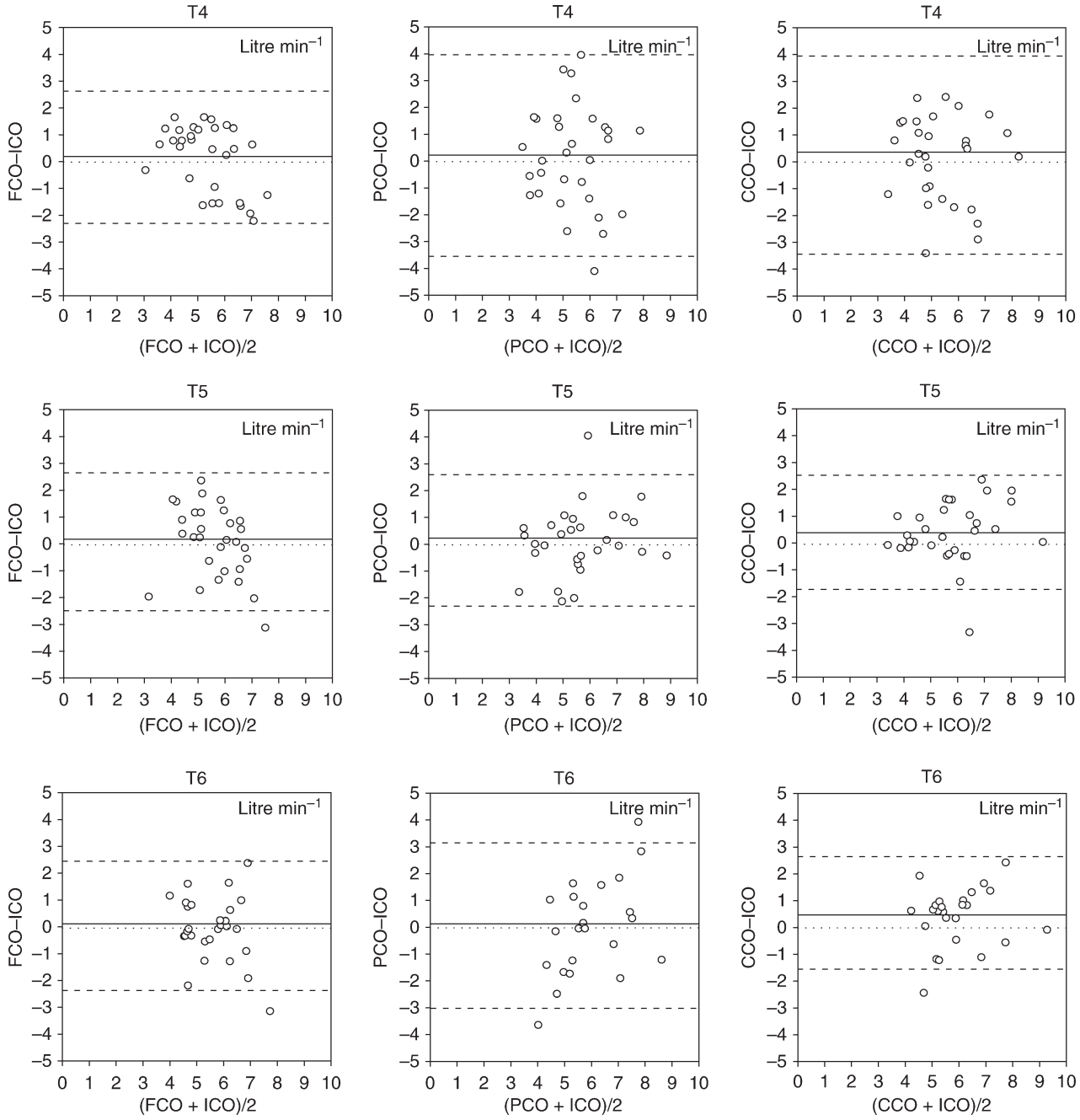

Fig 2 Bland–Altman analysis for CO measurements during the postoperative period using the FloTrac/Vigileo™ system, the PiCCOplus™ system, and the PAC/Vigilance™ monitoring compared with the intermittent pulmonary artery thermodilution. T4=after transfer to the ICU, T5–6=during ICU stay; CO, cardiac output; FCO, CO by the FloTrac/Vigileo™ device; PCO, CO by the PiCCOplus™ system; CCO, continuous CO measured by PAC using the Vigilance™ monitoring; ICO, CO by intermittent pulmonary artery thermodilution (iced water bolus method). Solid line, mean bias; dashed lines, limits of agreement.

we found a closer agreement between continuous CO monitoring and intermittent thermodilution in the pre-intervention period than in the early postoperative period. However, these changes of accuracy were less distinct than that reported previously.

Some limitations and methodological aspects have to be considered. The CO was assessed in low-risk cardiac surgical patients and values obtained were in a narrow range. Although the study revealed a comparable performance of the continuous CO monitoring systems, large limits of agreement were observed indicating that all continuous monitoring systems studied have limitations as regards their reliability and accuracy. Intermittent pulmonary artery thermodilution was used as a reference method for CO measurement. This technique is often referred to as the clinical standard, but it has well-known pitfalls related

Table 2 Bland–Altman analyses of measurements made with the FCO, PCO, and CCO systems compared in each case with intermittent CO measurements (ICO). T1=after induction of anaesthesia, T2=after sternotomy, T3=at skin closure, T4=after transfer to the ICU, T5–6=during ICU stay. CO, cardiac output; FCO, CO assessed by the FloTrac/Vigileo™ system; PCO, CO assessed by the PiCCOplus™ system; CCO, continuous CO measured by PAC using the Vigilance™ monitoring; ICO, CO determined by the intermittent pulmonary artery thermodilution. Data are presented as bias (limits of agreement), the limits of agreement being calculated as 2SD

	FCO-ICO (litre min^{-1})	PCO-ICO (litre min^{-1})	CCO-ICO (litre min^{-1})
Intraoperative period			
T1	0.6 (1.8)	0.5 (1.5)	0.2 (1.7)
T2	0.4 (1.9)	0.4 (1.7)	0.2 (2.0)
T3	0.1 (2.4)	0.3 (3.0)	0.4 (2.5)
Postoperative period			
T4	0.2 (2.5)	0.2 (3.8)	0.3 (3.7)
T5	0.1 (2.6)	0.2 (2.5)	0.4 (2.2)
T6	0.1 (2.4)	0.1 (3.1)	0.5 (2.2)

to operator variation, patient pathologies, and the indicator used.[27] While operator influences were minimized and patient pathologies known to induce bias were excluded, thermal influences in the postoperative period are likely to have influenced our results. Techniques independent of thermal influence or flow measurements as additional reference methods would have been of interest in this situation. Finally, Bland–Altman analysis is a widely accepted method to compare two methods measuring the same variable. However, it has often been applied in a misleading manner. Initially designed to compare single measurements,[19] it is increasingly used to compare repeated measurements. In such situations, an incorrect assumption is made that measurements are independent. However, it may be used for repeated measurements to calculate separate values and draw separate figures for each time point.

In conclusion, the performance of all continuous CO measurement devices, i.e. the FloTrac/Vigileo™ and the PiCCOplus system™, and continuous monitoring by PAC, was comparable in patients undergoing elective cardiac surgery. However, limitations regarding the reliability of all continuous cardiac techniques in this clinical situation should be borne in mind.

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