Validity of an Arterial Pressure Waveform Analysis Device: Does the Puncture Site Play a Role in the Agreement With Intermittent Pulmonary Artery Catheter Thermodilution Measurements?

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Objective: **The measurement of cardiac output is a key element in the assessment of cardiac function. Recently, a pulse contour analysis-based device without need for calibration became available (FloTrac/Vigileo, Edwards Lifescience, Irvine, CA). This study was conducted to determine if there is an impact of the arterial catheter site and to investigate the accuracy of this system when compared with the pulmonary artery catheter using the bolus thermodilution technique (PAC).**

Design: **Prospective study.**

Setting: **The operating room of 1 university hospital.**

Participants: **Twenty patients undergoing cardiac surgery.**

Interventions: **CO was determined in parallel by the use of the Flotrac/Vigileo systems in the radial and femoral position (CO_rad and CO_fem) and by PAC as the reference method. Data triplets were recorded at defined time points. The primary endpoint was the comparison of CO_rad and CO_fem, and the secondary endpoint was the comparison with the PAC.**

Measurements and Main Results: **Seventy-eight simultaneous data recordings were obtained. The Bland-Altman analysis for CO_fem and CO_rad showed a bias of 0.46 L/min, precision was 0.85 L/min, and the percentage error was 34%. The Bland-Altman analysis for CO_rad and PAC showed a bias of −0.35 L/min, the precision was 1.88 L/min, and the percentage error was 76%. The Bland-Altman analysis for CO_fem and PAC showed a bias of 0.11 L/min, the precision was 1.8 L/min, and the percentage error was 69%.**

Conclusion: **The FloTrac/Vigileo system was shown to not produce exactly the same CO data when used in radial and femoral arteries, even though the percentage error was close to the clinically acceptable range. Thus, the impact of the introduction site of the arterial catheter is not negligible. The agreement with thermodilution was low.**

KEY WORDS: cardiac output, arterial waveform analysis, pulmonary artery catheter, thermodilution

THE MEASUREMENT OF cardiac output (CO) is a key element in the assessment of cardiac function. It is frequently used in the intensive care unit (ICU) and the operating room, especially in the management of patients undergoing cardiac surgery. The intermittent thermodilution bolus technique using a pulmonary artery catheter is still accepted as a standard method, despite its invasive character and associated risks.[1-3] Recently, less invasive methods and hardware to assess cardiac output became available. One of these alternatives is the FloTrac/Vigileo system (Edwards Lifescience, Irvine, CA), which determines CO by analyzing the peripheral arterial waveform of any artery. It is easy to install, safe to use, and does not need any specific catheter or external calibration. It is based on the following equation: stroke volume = pulsatility × kappa. Pulsatility is calculated by using the standard deviation of a peripheral arterial pressure wave; kappa as a number represents the vascular tone of the patient's arterial tree and takes into account the age, weight, height, and sex. This factor is recalculated every minute by software version 1.07, which was used in this study. The algorithm may misinterpret the curve in case of modifications of the arterial resistance, waveform, or location of measurement, which is of major interest for the clinician in the operating room who does regularly modify blood pressure by vasopressors and can be confronted with complex valve diseases.[4,5] Moreover, he/she has to decide individually where to insert arterial catheters for patients' blood pressure monitoring.

This system was tested in several studies with conflicting results concerning the agreement with the thermodilution bolus technique via pulmonary artery catheter,[4,6-9] although a newer algorithm seems to correlate better with the reference method.[10] So far, no studies examined the impact of the puncture site on the accuracy of the cardiac output measurements by the FloTrac/Vigileo system as a primary endpoint in patients undergoing cardiac surgery in whom particular strong modifications of the arterial waveform can occur (eg, by replacing valves or by administration of vasopressors). The cardiac surgery itself has a highly incisive character to patients' hemodynamics, which is partly predictable. This stands in contrast to cardiac output monitoring in an ICU, where in general there are rapid and strong perturbations of patients' hemodynamics less often.

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The impact of the arterial puncture site is not negligible, when the FloTrac/Vigileo system is used to measure hemodynamic data. Compared with the thermodilution bolus technique using the pulmonary artery catheter, large differences were observed. Therefore, the use of this device should be questioned in cardiac surgery.

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Taking these points together, the authors conducted a study in patients undergoing cardiac surgery and who were monitored by a pulmonary artery and 2 arterial catheters. The primary endpoint was the comparison of simultaneous measurements of the FloTrac/Vigileo system at 2 different sites (ie, the radial and femoral artery). The secondary endpoint was to compare the cardiac output measurements of the FloTrac/Vigileo system with those obtained by the pulmonary artery catheter. Because of the perioperative setting of this study, measurements could be obtained under a wide range of hemodynamic situations and in a subsequent analysis also separately before and after CPB.

METHODS

After approval of the ethics committee and written informed consent of the patients, 20 patients scheduled for cardiac surgery with cardiopulmonary bypass (CPB) (coronary artery bypass grafting, valve repair and replacement, and surgery of the thoracic aorta) were enrolled. Inclusion criteria were the situations requiring the use of a pulmonary catheter following the guidelines of the authors' university hospital such as left ventricular dysfunction (ejection fraction $<40\%$), left ventricular dilatation, expanded abnormalities of the segmental contractility, ventricular wall resection, surgery of the thoracic aorta, mitral valve surgery, pulmonary hypertension, right ventricular dysfunction, CPB >2.5 hours, deep hypothermia, combined operations (coronary artery bypass graft surgery and mitral valve replacement), and severe comorbidities (renal insufficiency and chronic obstructive lung disease). The only additional procedure compared with standard anesthesia was the second arterial catheter, which was inserted once the patient was anesthetized.

Anesthesia was induced with etomidate at 0.2 mg/kg body weight, vecuronium at 0.1 mg/kg body weight, and fentanyl with an absolute dose of 1,000 μg before sternotomy. Anesthesia was maintained following the authors' institutional standards with isoflurane and midazolam and was in no way modified by the study. Before induction, 1 of the 2 arterial catheters, Seldicath 3F (Plastimed, Saint-Leu-La-Forêt, France), was inserted in either the radial or the femoral artery and connected to the FloTrac transducer (Edwards Lifescience LLC). After induction, the patient's trachea was intubated, and his lungs were ventilated to achieve normocapnia. The second artery catheter was placed in the nonpunctured artery. A pulmonary artery catheter (Swan Ganz, Edwards Lifescience LLC) was introduced via the right internal jugular vein and installed in the wedge position. Central venous pressure was measured and recorded continuously. The intermittent thermodilution bolus technique using the pulmonary artery catheter was conducted in the usual way, 3 injections during apnea; the monitoring device (Philips IntelliVue) calculated the mean values of the cardiac output and the subsequent hemodynamic values. Two Vigileo monitors (Edwards Lifescience LLC, software version V1.07) were used for the simultaneous recordings in the radial and femoral artery. They were connected to 1 of the 2 output lines of the FloTrac system; the second output line was connected to the Philips monitor. Hemodynamic data calculated by the Vigileo systems were recorded continuously by a connected laptop personal computer using the recording software MDL (Edwards Lifesciences Multi-Data Logger version 4.0). A mean value was calculated from 3 values that were chosen exactly 2 seconds before each injection of the thermodilution method.

The measurements and the data collection were performed by an independent observer who was not involved in the anesthesia care of the patient. Four different intraoperative time points were chosen (the measurements were realized during a hemodynamically stable phase, not directly after vasopressor bolus or modification): (1) after induction of anesthesia and before sternotomy (T0), (2) after sternotomy and before aortic cannulation (T1), (3) after complete decannulation of CPB and before closure of the pericardium (T2), and (4) after sternal closure (T3). In addition, measurements could be performed when irregular situations occurred (eg, during anaphylactic shock).

The results were analyzed in a comparison of all time points between the Vigileo/FloTrac systems in the radial and femoral positions and between each of the Vigileo/FloTrac systems and the thermodilution bolus technique. To see if the strong perturbations of CPB detectably affect the fit among the different methods to measure cardiac output, an analysis before and after the CPB was performed. The statistical analysis was performed by using the JMP 5.1 statistical package (SAS Institute Inc, Cary, NC). The Bland-Altman method was applied to compare CO values between the 2 puncture sites and the pulmonary artery catheter. Data are presented as bias, precision (standard deviation), and limits of agreement (1.96 standard deviation). Critchley and Critchley[11] defined in 1999 the percentage error = 2 standard deviations/mean CO, which is a useful tool when comparing 2 methods of CO measurement. A percentage error of 30% or less indicates an interchangeability of the 2 methods. Values higher than 30% are considered as clinically not acceptable. Therefore, the present authors calculated and displayed the percentage error for each of the comparisons. The sample size had been determined by a power analysis. To obtain a power $>90\%$ with an estimated difference between groups of 10% using cardiac output, a total sample size of 20 patients had been determined with a type I error of 0.025. This power analysis was made for an initially planned statistical analysis by analysis of variance.

RESULTS

Three women and 17 men were included in this study; the mean weight was 74 kg ($\pm$15 kg), the mean height was 170 cm ($\pm$9 cm), and the mean age was 64 years ($\pm$14 years). The mean CPB time was 112 minutes ($\pm$42 minutes). The different operations were distributed as follows: 4 aortic valve replacements, 1 combined with a maze intervention, and 2 with coronary bypasses. Ten patients had mitral valve repairs or replacement, 3 combined with a maze intervention, 1 with coronary bypasses, and 1 with pulmonary lobectomy. Four patients had aortic repair, and 2 had triple coronary bypasses. Eight of the patients had aortic regurgitation degree I and II, and 3 patients had minimal aortic regurgitation at intraoperative transesophageal echocardiography before CPB.

Vasopressor support after CPB was ensured by the use of norepinephrine, dobutamine, epinephrine, and dopamine in usual clinical doses and depending on each individual. Ephedrine and phenylephrine were generally used before CPB and given as a bolus. Two data measurements dropped out because intermittent arterial catheter obstruction occurred.

Primary Endpoint Comparison of the Radial and Femoral Cannulation Sites

Overall Analysis

The primary aim was to compare CO data between the Vigileo/FloTrac system in the femoral (CO_fem) and the radial (CO_rad) positions; The Bland-Altman analysis for CO_fem and CO_rad showed a bias of 0.46 L/min, precision of 0.85 L/min, and percentage error of 34% (n = 78) (Fig 1).

Analysis Before and After CPB

The subanalysis of the data was separated in the data pairs obtained before and after CPB.

CO_fem versus CO_rad. Before CPB, the bias was 0.2 L/min, and the precision (standard deviation) was 0.73 L/min.