Lack of reliability of cardiac output measurements derived from arterial pressure waveform analysis in on-pump cardiac surgery patients

S. Eleftheriadis[1], M. Heringlake[2], K.-U. Berger[2] , H.V. Groesdonk[2],and J.Schoen[2]

[1] Department of Anesthesiology, University General Hospital, Alexandroupolis, Greece
[2] Department of Anesthesiology, University of Luebeck, Luebeck, Germany

Abstract—

The arterial pressure waveform-based device for cardiac output (CO) measurement FloTrac/Vigileo™ offers the possibility of minimal-invasive CO monitoring without the need for invasive calibration. The agreement of the results of this device with bolus thermodilution remains controversialas is the choice of the best arterial cannulation site

After approval of the local ethics committee 14 Patients scheduled for elective cardiac surgery with cardiopulmonary bypass were enrolled. Routine arterial access inone radial and one femoral artery were used for CO measurement with the FloTrac/Vigileo device Pulmonary artery catheter was inserted for determination of CO with thermodilution bolus technique. All CO was indexed to body surface area resulting in CI_FEM, CI_RAD and CI_PAC. Measurements were performed at least four times before and three times after CPB.

A total of 262 data pairs were analysed. Including all data before and after CPB bias and precision for CI_PAC vs. CI_FEM were 0,09 L $min^{-1}m^{-2}$ and ±1,01 $Lmin^{-1}m^{-2}$, with a percentage error of 40%. For CI_PAC vs. CI_RADbias and precision were 0,34 $Lmin^{-1}m^{-2}$ and ±1,08 $Lmin^{-1}m^{-2}$ with a percentage error of 45%. CI_FEM vs. CI_RAD revealed a bias of -0,25 $Lmin^{-1}m^{-2}$ and a precision of ±0,48 $Lmin^{-1}m^{-2}$ resulting in a percentage error of 20%. Subgroup analysis of data pairs obtained before CPB showed a percentage error of 32% and 34% for CI_PAC vs. CI_FEM and CI_PAC vs. CI_RAD respectively. After CPB percentage error was 46% for CI_PAC vs. CI_FEM and 55% for CI_PAC vs. CI_RAD.

We conclude that the agreement between CO measured with the FloTrac/Vigileo™ device and the thermodilution bolus method is not sufficient for clinical diagnosis and therapy guidance in the setting of cardiac anesthesia with CPB.

Keywords— **Cardiac output, pulse pressure, arterial pressure, pulmonary artery catheter, hemodynamic monitoring**

I. Introduction

The determination of cardiac output (CO) in patients undergoing cardiac surgery is of high importance for diagnosis and therapy. The most common device used is the pulmonary artery catheter (PAC) with intermittent thermodilution bolus method. The unclear risk/benefit ratio of this highly invasive technique[1,2] has lead to the development of less invasive methods of measuring CO. The arterial pressure waveform-based device for cardiac output (CO) measurement FloTrac/Vigileo™ offers the possibility of non-invasive CO monitoring without the need for invasive calibration. This device is using an arterial pressure-based algorithm including individual demographic data for estimation of vessel compliance and arterial waveform characteristics for estimation of peripheral resistance effects.

The interchangeability of the results of this device with the invasive measurement by bolus thermodilution remains controversial[3,4,5]. It also remains unclear, whether the peripheral radial artery or femoral artery might show best agreement between invasive and arterial pressure waveform-based CO measurement[4,6]. This study was designed to evaluate the agreement of invasive CO measurement using PAC compared to the non-invasive arterial pressure waveform based FloTrac/Vigileo™ device either in the radial or in the femoral artery in patients undergoing cardiac surgery.

II. Methods

After approval of the local ethics committee and written informed consent 14 patients scheduled for elective cardiac surgery with cardiopulmonary bypass (CPB) were enrolled in the study.

After premedication all patients were equipped with two arterial catheters, one in right or left radial and one in the right or left femoral artery according to standard institutional practice and received standardized general anesthesia. The Vigileo™ monitor (Edwards Lifesciences, Irvine, CA; software version 1.10) was connected to the arterial access via the FloTrac™ pressure transducer with the possibility to change the connection from the femoral artery to the radial artery catheter. A pulmonary artery catheter (PAC) (7,5F, Edward, Irvine, CA) was placed after induction of anesthesia.

Cardiac output measurements by bolus thermodilution and the FloTrac/Vigileo device in two localizations were

O. Dössel and W.C. Schlegel (Eds.): WC 2009, IFMBE Proceedings 25/VII, pp. 559–562, 2009.
www.springerlink.com

obtained at least four times before and three times after CPB.

For every measurement the mean CO value of the Vigileo monitor was documented and then the thermodilution CO measurements were performed using constant injections of 10ml cold 0,9% saline solution for three consecutive measurements and the mean CO was calculated. Subsequently the measuring site for the arterial waveform analysis was changed and after stabilization of the signal the CO value for the other arterial access was recorded. The radial and femoral artery catheter were used at random order. All CO values were indexed to the body surface area (CI) resulting in thermodilution CI (CI_PAC), femoral artery CI (CI_FEM) and radial artery CI (CI_RAD).

Statistical analysis was performed using the method described by Bland and Altman[7]. Bias was defined as mean difference between CI_PAC and CI_FEM, CI_PAC and CI-RAD, and CI_FEM and CI_RAD respectively. Precision was defined as the upper and lower limits of agreement. The percentage error (2 standard deviation of the bias/mean CI) was calculated according to Critchley and Critchley[8] and a percentage error of <30% was set as acceptable for interchangebility of the methods.

Bias and precision as well as percentage error were calculated for all obtained data pairs and for the time range before and after CPB accordingly.

III. Results

Of the 14 patients included in the study, 12 patients had coronary artery bypass grafting (CABG), one had aortic valve replacement and CABG and one patient had mitral valve replacement. Basic demographic data are shown in table 1.

Including all data pairs (n=262) CI_PAC ranged from 1,5 to 6,3 L min^{-1} m^{-2} (mean 2,6 ± 0,76 L min^{-1} m^{-2}), CI_FEM ranged from 1,5 to 4,7 L min^{-1} m^{-2} (mean 2,5 ± 0,59 L min^{-1} m^{-2}), and CI_RAD ranged from 1,4 to 4,5 L min^{-1} m^{-2} (mean 2,3 ± 0,57 L min^{-1} m^{-2}).

The results for bias and precision are shown in table 2. Bias and precision for CI_PAC versus CI_FEM were 0,09 L min^{-1} $m^{-2}$and ± 1,01 L min^{-1} m^{-2}, with a percentage error of 40%. For CI_PAC versus CI_RAD bias and precision were 0,34 L min^{-1} $m^{-2}$and ±1,08 L min^{-1} m^{-2} with a percentage error of 45% (see figure 1). Comparing CI_FEM and CI_RAD revealed a bias of -0,25 L min^{-1} m^{-2} and a precision of ±0,48 L min^{-1} m^{-2} resulting in a percentage error of 20%.

Subgroup analysis of the data obtained before CPB showed for CI_PAC versus CI_FEM a bias of 0,04 L min^{-1} m^{-2} and a precision of ±0,78 L min^{-1} m^{-2}. The percentage error was 32%. CI_PAC versus CI_RAD had a bias of 0,27 L min^{-1} m^{-2} and a precision of ±0,79 L min^{-1} m^{-2}, resulting in a percentage error of 34%. Comparing CI_FEM and CI_RAD showed a bias of 0,22 L min^{-1} m^{-2} and a precision of ±0,34 L min^{-1} m^{-2}, the percentage error was 15%.

Analysis of the data obtained after CPB showed a bias of 0,18 L min^{-1} m^{-2} and a precision of ±1,28 L min^{-1} m^{-2} for CI_PAC versus CI_FEM, resulting in a percentage error of 46%. CI_PAC versus CI_RAD revealed a bias of 0,50 L min^{-1} m^{-2} and a precision of ±1,44 L min^{-1} m^{-2}, resulting in a percentage error of 55%. For CI-FEM versus CI_RAD bias was 0,30 L min^{-1} m^{-2} and precision was ±0,64 L min^{-1} m^{-2}, percentage error was 25% (see figure 2).

Table 1Demographic data. If not mentioned otherwise, data are given as mean ± standard deviation. BSA: Body surface area.

Gender (m/f)	n=10/n=4
Age (years)	60,57 ± 10,7
Height (cm)	164,71 ±13,7
Weight (kg)	85,61 ± 21,9
BSA (m^2)	1,92 ± 0,31

Table 2 Results of Bland Altman analysis

Time range	Methods	Bias	Precision	Percentage error
before CPB	CI_PAC vs. CI_FEM	0,03578	0,78	32%
	CI_PAC vs. CI_RAD	0,2658	0,79	34%
	CI_FEM vs. CI_RAD	0,2190	0,34	15%
after CPB	CI_PAC vs. CI_FEM	0,1793	1,28	46%
	CI_PAC vs. CI_RAD	0,5030	1,44	55%
	CI_FEM vs. CI_RAD	0,2968	0,64	25%
total	CI_PAC vs. CI_FEM	0,09059	1,01	40%
	CI_PAC vs. CI_RAD	0,3490	1,08	45%
	CI_FEM vs. CI_RAD	-0,2485	0,48	20%

IV. Discussion

This study was designed to evaluate the agreement between the thermodilution bolus technique and the CO measurement derived from arterial pressure waveform analysis with the FloTrac/VigileoTM device in the radial and the femoral artery and to determine the

interchangeability of the CO by Vigileo device between the different arterial measurement sites.

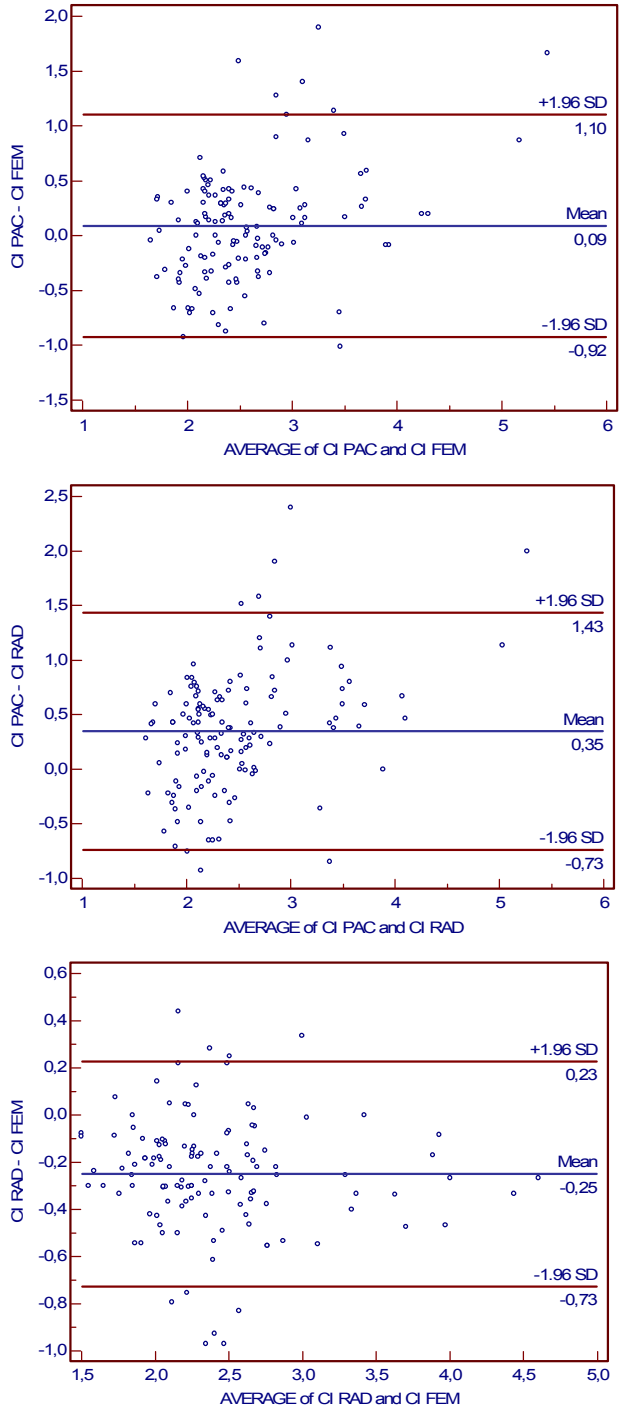

Figure 1: Bland-Altman-Plots for all obtained data

The arterial pressure waveform-based device for cardiac output (CO) measurement FloTrac/VigileoTM is using an arterial pressure-based algorithm. This algorithm includes individual demographic data for estimation of vessel compliance and arterial waveform characteristics for estimation of peripheral resistance effects. This device is able to measure CO without calibration with an invasive method.

Several studies have been published with the aim to evaluate the accuracy of the device in comparison to the "gold-standard" of thermodilution bolus technique via pulmonary artery catheter in different settings[3,5,6,9-12]. The results are conflicting, ranging from underestimation of CO by the VigileoTM device[3,10] to overestimation of CO[12]. Mayer et al[11] found clinically acceptable percentage errors below 30%[8] with the new software version V01.10, whereas the same group published low accuracy of the device with the older software versions[5].In the study presented we also used the software version V01.10 and found low agreement between thermodilution bolus technique and the Vigileo^{TM} device. With percentage errors of 40% for PAC versus Vigileo in the radial artery and 45% in the femoral artery the agreement was not clinically acceptable according to Critchley and Critchley[8]. The subgroup analysis of data obtained before and after CPB revealed a considerable increase in differences between the devices supporting the thesis of Breukers[12] et al, that the Vigileo^{TM} device is especially sensitive to rapid changes in vascular tone.

As the arterial pressure in the radial artery in relation to the femoral artery can change significantly after CPB[13], we measured CO with the Vigileo device in both radial and femoral artery. Here our data showed good agreement between both measuring sites with 15% percentage error before and 25% percentage error after CPB. A relevant limitation of our design is, that we did not measure simultaneously in the radial and femoral artery and thermodilution bolus injection was performed between both measurements. It is possible, that significant changes in hemodynamic situation occurred even in this short period of time.

III. CONCLUSIONS

Keeping in mind the limitations of the relatively small sample size of the presented study we conclude, that the FloTrac/Vigileo^{TM} device can not replace the measurement of CO with the PAC during cardiac surgery.

Acknowledgment

The author M. Heringlake receives horonaria for lectures and scientific support from Edwards Lifesciences, Irvine, CA.

References

1. Sandham JD, Hull RD, Brant RF, et al (2003) A randomized controlled trial of the use of pulmonary-artery catheter in high-risk surgical patients. N Engl J Med 348:45-14
2. Connors AF, Speroff T, Dawson NV, et al. (1996). The effectiveness of right heart catheterization in the initial care of critically ill patients. JAMA 276: 889-97
3. Sander M, Spies CD, Grubitzsch H, et al (2006). Comparison of uncalibrated arterial waveform analysis in cardiac surgery patients with thermodilution cardiac output measurements. Crit Care 10:R164.
4. Manecke GR Jr, Auger WR (2007). Cardiac output determination from the arterial pressure wave: clinical testing of a novel algorithm that does not require calibration. J Cardiothorac Vasc Anesth 21: 3-7
5. Mayer J, Boldt J, Schollhorn T, et al (2007) Semi-invasive monitoring of cardiac output by a new device using arterial pressure waveform analysis: a comparison with intermittent pulmonary artery thermodilution in patients undergoing cardiac surgery. Br J Anaesth 98: 176-82.
6. Opdam HI, Wan L, Bellomo R (2007). A pilot assessment of the FloTrac™ cardiac output monitoring system. Intensive Care Med 33: 344-349.
7. Bland JM, Altman DG (1986). Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1: 307-310.
8. Critchley LAH, Critchley JAJH. (1999). A meta-analysis of studies using bias and precision statistics to compare cardiac output measurement techniques. J Clin Monit Comput 15: 85-91.
9. Zimmermann A, Kufner C, Hofbauer S, et al (2008). The accuracy of the Vigileo/FloTrac continuous cardiac output monitor. J Cardiothorac Vasc Anesth 22(3): 388-393.
10. Delle Rocca G, Costa MG, Chiarandini P, et al (2008). Arterial pulse cardiac output agreement with thermodilution in patients in hyperdynamic conditions. J Cardiothorac Vasc Anesth 22(5): 681-687.
11. Mayer J, Boldt J, Wolf MW, et al (2008). Cardiac output derived from arterial pressure waveform analysis in patients undergoing cardiac surgery: Validity of a second generation device. Anesth Analg 106: 867-872.
12. Breukers RMBGE, Sepehrkhouy S, Spiegelenberg SR, et al (2007). Cardiac output measured by a new arterial pressure waveform analysis method without calibration compared with thermodilution after cardiac surgery. J Cardiothorac Vasc Anesth 21(5): 632-635.
13. Baba T, Goto T, Yoshitake A, et al (1997). Radial artery diameter with increased femoral to radial arterial pressure gradient during cardiopulmonary bypass. Anesth Analg 85: 252-258.

Author: Dr Julika Schön
Institute: Department of Anesthesia, University of Luebeck
Street: Ratzeburger Allee 160
City: 23538 Luebeck
Country: Germany
Email: julika.schoen@t-online.de