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Cardiac output measured by the FloTrac/Vigileo system: Does the „plug and play“ principle work?

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Abstract

Background: Determination of cardiac output by the classic thermodilution technique is widely accepted to be the gold standard, but it is not without additional risks due to invasive catheterisation. Therefore, we compared it with the less invasive FloTrac™/Vigileo™-system based on an automated pulse contour analysis.

Methods: 34 patients who underwent cardiac surgery with extracorporeal circulation were included. In each patient, four measurements were performed. A software update split the patients into two groups: 19 of them were measured using software version V1.07, 15 were measured using software version V1.10.

Results: Overall, 120 measurements were performed. Software version V1.07 showed a bias of $-0.45\text{l}\cdot(\text{min}\cdot\text{m}^2)^{-1}$ and a precision of $0.53\text{l}\cdot(\text{min}\cdot\text{m}^2)^{-1}$. The percentage error was 45%. Software version V1.10 showed a bias of $-0.26\text{l}\cdot(\text{min}\cdot\text{m}^2)^{-1}$ and a precision of $0.42\text{l}\cdot(\text{min}\cdot\text{m}^2)^{-1}$, the percentage error was 36% in this case. The differences were statistically significant with respect to the bias but not to the precision.

Conclusion: Although software version V1.10 led to an improvement in the concordance with thermodilution technique, the percentage error exceeds the acceptable threshold of 28.28%. Therefore, in the setting of cardiac surgery the FloTrac™/Vigileo™-system cannot replace the thermodilution technique at present.

Key words: pulmonary artery catheter, thermodilution, cardiac output, pulse contour analysis, semi-invasive

Introduction

Thermodilution-based determination of cardiac output (CO) using a pulmonary artery catheter (PAC) has been widely accepted to be the clinical reference method since its introduction in last century's seventies. However, some studies have shown that its risks might outweigh its benefits [1-3]. Ever since, several attempts have been undertaken to establish less invasive techniques with compara-

ble accuracy, e. g. the PICCO system (Pulsion, Munich, Germany), doppler or bioimpedance techniques [4]. In 2005, a new, semi-invasive technique has been launched by Edwards Lifesciences (Irvine, CA, USA). It is based upon the analysis of the arterial pressure waveform derived from a standard arterial catheter. The present study compares this method to the right ventricular bolus thermodilution in the setting of cardiac surgery with cardiopulmonary bypass. The results

published by other investigators so far are inconsistent, whereas the software versions used are not mentioned in all studies. However, there is a tendency to better agreement with recent software versions (i. e. > V1.07) [5-9].

Methods

After approval of the local ethics committee and written informed consent, thirty-four patients anticipating cardiac surgery with CPB were enrolled in the study. Standard operating procedures of our department advise the use of a pulmonary artery catheter solely in cases of aortocoronary bypass surgery with reduced left ventricular function, in cases of valvular surgery or combination of both. Therefore, all patients recruited from these groups. Patients with severe arrhythmias or intra-aortic balloon pump were excluded. Age varied from 52 to 86 years, ASA classification was III in all patients. Patients received an oral premedication of 2mg flunitrazepam and 30mg morphine. General anesthesia was induced by injection of 0.2-0.3 $\mu\text{g}\cdot\text{kg}^{-1}$ sufentanil, 0.05-0.1 $\text{mg}\cdot\text{kg}^{-1}$ midazolam and 0.1 $\mu\text{g}\cdot\text{kg}^{-1}$ pancuronium bromide. Patients were intubated orally afterwards and ventilated volume-controlled (Draeger Primus anesthesia workstation, Luebeck, Germany) targeting at a PaCO_2 of 34-44 mmHg. Maintenance of anesthesia was achieved by use of sufentanil (25 μg bolus injections) and isoflurane (0.3-1.0 Vol%). During and after CPB, anesthesia was maintained by use of propofol (3-4 $\text{mg}\cdot\text{kg}^{-1}\cdot\text{h}^{-1}$), sufentanil (25 μg bolus injections) and midazolam (5mg bolus injections as necessary). Invasive hemodynamic monitoring consisted of cannulation of the left or right radial artery with a standard arterial catheter and a pulmonary artery catheter inserted via the right internal jugular vein (PAVIP+catheter, Nr. 831F75, Edwards Lifescience, Irvine, CA, USA). CPB was performed in moderate hypothermia (t_{rectal} approx. 33°C) with non-pulsatile flow (2.4l/min/m²) and a membrane oxygenator (Sorin 41, Sorin, Turin,

Italy). For priming of the extracorporeal circulation, 2000ml Ringer's solution and 250ml 5% albumin solution were used. Cardioplegic arrest was achieved by blood cardioplegia (Buckberg). Before end of CPB, patients were rewarmed to 37°C.

The FloTrac™-sensor was connected directly to the arterial line without interposed lengthening. Each measurement was performed in the supine position after prior zero and height adjustment of the pressure sensor to the middle to upper third of the thorax. Hemodynamic measurements were taken at four points during the course of the procedure in a standardised way: T0 after induction of anesthesia, T1 prior to onset of CPB, T2 after end of CPB and T3 after sternal closure. CO was determined simultaneously by bolus thermodilution measurements (CO_{TD}) and by the FloTrac™/Vigileo™-system (CO_{AP}) and related to the body surface area (CI_{TD} , CI_{AP}). For CO_{TD} , the average of three subsequent measurements was calculated, during the middle measurement CO_{AP} shown on the Vigileo™-monitor was noted.

A software-update by the FloTrac™/Vigileo™'s manufacturer divided the patients into two groups: Of 34 patients 19 were measured using software version V1.07 and 15 using software version V1.10 (with improved algorithms regarding analysis of the pulse contour). To investigate whether the FloTrac™/Vigileo™-system shows sufficient agreement with the thermodilution technique and whether the software update leads to improved accuracy, the following statistical methods were used: Data analysis was performed as recommended by Bland und Altman [10]. Bias describes the mean of the differences between thermodilution and FloTrac™/Vigileo™-measurements, precision describes the standard deviation of the differences. Additionally, a regression analysis between the methods was performed. Subsequently, the agreement of the methods was assessed as recommended by Critchley and Critchley [11]. For this purpose, not only the error of the method to be evaluated is taken into account, but also the error of the refer-

ence method. The standard deviation of the differences of both methods is divided by the mean of all measurements (i. e. of both methods), resulting in the percentage error. In clinical practice, an inaccuracy of 20% is regarded to be acceptable. Comparing two methods each with an inaccuracy of 20% results in a maximum tolerable error of 28.28% ($((0.22+0.22)^{1/2})$). Differences between the software versions were addressed by an unpaired t-test (regarding bias) and a F-Test (regarding precision).

Results

In total, 122 measurements were obtained. Among these, in 62 cases software version V1.07 and in 60 software version V1.10 was used. There were no significant differences within the groups regarding demographic or hemodynamic values (Table 1 and 2). In the V1.07 group, the Bland-Altman-analysis showed a bias of $-0.45 \text{ l} \cdot (\text{min} \cdot \text{m}^2)^{-1}$ and a precision of $0.53 \text{ l} \cdot (\text{min} \cdot \text{m}^2)^{-1}$ (Fig. 1). Regression analysis between Cl_{TD} and Cl_{AP} resulted in a correlation coefficient of $r=0.46$ ($p<0.01$)

Table 1: Demographic data and preoperative ejection fraction. Shown is Mean \pm SD.

Age [years]	Gender [m:f]	Height [cm]	Weight [kg]	ASA I/II/III/IV	EF preoperative [%]
Group 1 (Software V1.07)					
74 \pm 7	11:8	168 \pm 10	83 \pm 12	0/0/19/0	62 \pm 18
Group 2 (Software V1.10)					
70 \pm 10	8:7	178 \pm 8	78 \pm 15	0/0/15/0	65 \pm 16
Both groups together					
72 \pm 8	19:15	169 \pm 9	81 \pm 13	0/0/34/0	63 \pm 17

Table 2: Hemodynamic parameters. Shown is Mean \pm SD.

Parameter	Unit	Group 1 Software 1.07	Group 2 Software 1.10	Both groups
Cl_{TD}	$\text{l} \cdot (\text{min} \cdot \text{m}^2)^{-1}$	2.16 \pm 0.56	2.14 \pm 0.69	2.17 \pm 0.57
Cl_{AP}	$\text{l} \cdot (\text{min} \cdot \text{m}^2)^{-1}$	2.61 \pm 0.45	2.38 \pm 0.47	2.53 \pm 0.42
HF	min^{-1}	79 \pm 17	81 \pm 16	80 \pm 16
MAP	mmHg	73 \pm 12	73 \pm 10	73 \pm 11
MPAP	mmHg	23 \pm 6	25 \pm 11	24 \pm 9
PCWP	mmHg	12 \pm 5	15 \pm 7	14 \pm 6
CVP	mmHg	9 \pm 5	10 \pm 5	9 \pm 5
SVR	$\text{dyn} \cdot \text{s} / \text{cm}^5$	1373 \pm 527	1347 \pm 475	1360 \pm 500
PVR	$\text{dyn} \cdot \text{s} / \text{cm}^5$	226 \pm 146	219 \pm 147	221 \pm 147

(Cl_{TD} = thermodilution cardiac index, Cl_{AP} = FloTrac/Vigileo-system cardiac index, HF = heart frequency, MAP = mean arterial pressure, MPAP = mean pulmonary arterial pressure, PCWP = pulmonary capillary wedge pressure, CVP = central venous pressure, SVR = systemic vascular resistance, PVR = pulmonary vascular resistance)

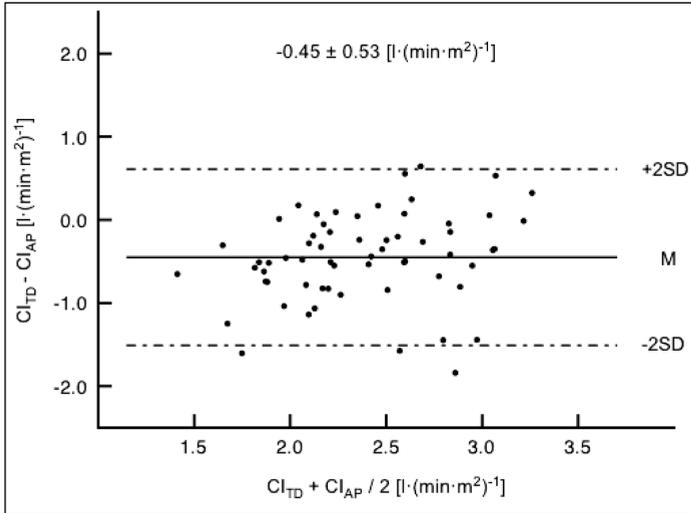


Figure 1: Bland-Altman-graph of group 1 (software version V1.07). Shown is cardiac index (CI) determined by the FloTrac™/Vigileo™-system (CI_{AP}) and by thermodilution measurement (CI_{TD}). Plotted is the mean of the values of both methods ($(CI_{TD} + CI_{AP})/2$) against their differences ($CI_{TD} - CI_{AP}$). The solid line marks the mean of the differences, the dotted line the 95%- confidence intervals of the differences (twofold standard deviation of the differences). Displayed are also bias and precision in $l \cdot (\text{min} \cdot \text{m}^2)^{-1}$.

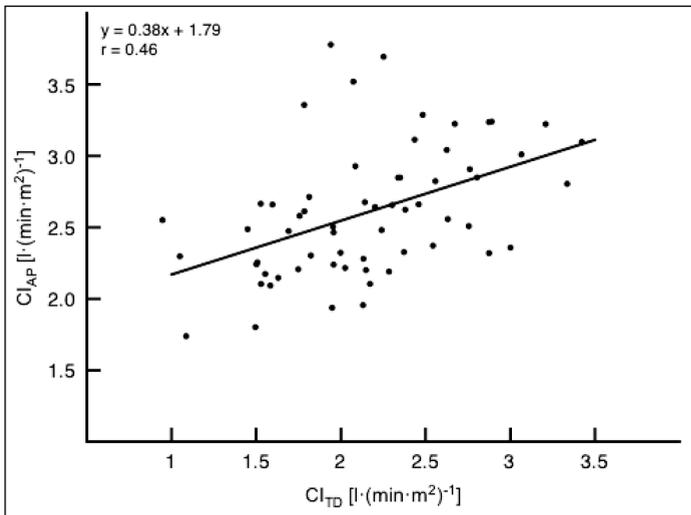


Figure 2: Regression analysis of group 1: CI_{AP} is plotted against CI_{TD} . The equation of the regression line ($y = ax + b$) and the correlation coefficient (r) are displayed, $p < 0.01$.

(Fig. 2) and a percentage error of 45%. The improved algorithms of V1.10 resulted in a bias of $-0.26 \text{ l} \cdot (\text{min} \cdot \text{m}^2)^{-1}$ and a precision of $0.42 \text{ l} \cdot (\text{min} \cdot \text{m}^2)^{-1}$ (Fig. 3). Regression analysis between CI_{TD} and CI_{AP} resulted in a correlation coefficient of $r=0.72$ ($p < 0.01$) (Abb. 4) and a percentage error of 36%. The results of each respective measurement point are displayed in table 3. Comparison of the bias of both groups by use of an unpaired t-test revealed a level of significance of $p=0.032$,

whereas analysis of the precision resulted in a level of significance of $p=0.067$. Consequently, a statistically significant difference between the elder and the newer software version can only be proven for bias, not for precision.

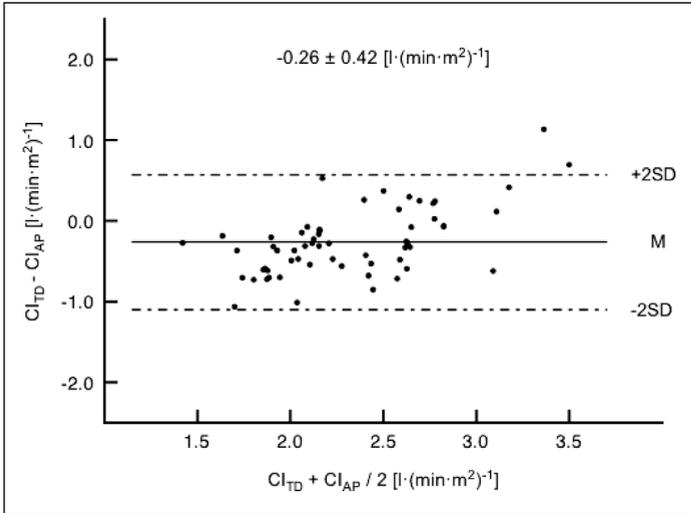


Figure 3: Bland-Altman-graph of group 2 (software version V1.10). Shown is cardiac index (CI) determined by the FloTrac™/Vigileo™-system (CI_{AP}) and by thermodilution measurement (CI_{TD}). Plotted is the mean of the values of both methods ($(CI_{TD} + CI_{AP})/2$) against their differences ($CI_{TD} - CI_{AP}$). The solid line marks the mean of the differences, the dotted line the 95%- confidence intervals of the differences (twofold standard deviation of the differences). Displayed are also bias and precision in $l \cdot (\text{min} \cdot \text{m}^2)^{-1}$.

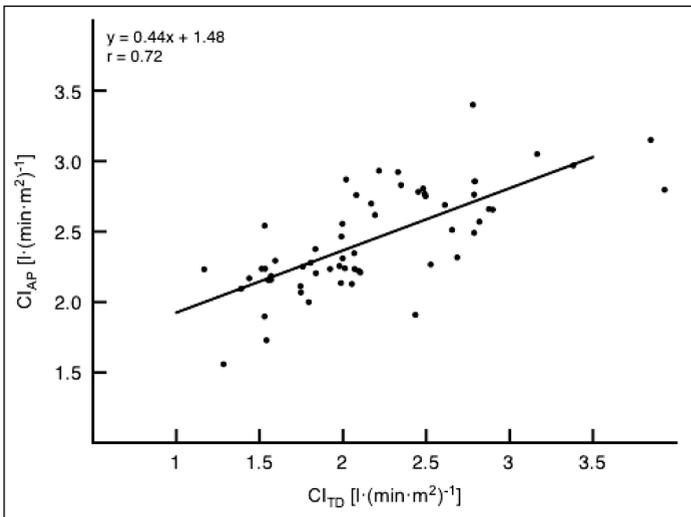


Figure 4: Regression analysis of group 2: CI_{AP} is plotted against CI_{TD} . The equation of the regression line ($y = ax + b$) and the correlation coefficient (r) are displayed, $p < 0.01$.

Table 3: Bias (and Precision) of the FloTrac/thermodilution measurements.

	T0	T1	T2	T3	T0-3
Group 1 Software V1.07	-0.55 (0.41)	-0.52 (0.53)	-0.21 (0.52)	-0.51 (0.62)	-0.45 (0.53)
Group 2 Software V1.10	-0.34 (0.33)	-0.31 (0.42)	0.01 (0.48)	-0.39 (0.36)	-0.26*(0.42)

*= $p < 0.05$ vs. group 1.

Discussion

Determination of cardiac output by the classic thermodilution method requires either catheterisation of the pulmonary artery or the insertion of a central venous catheter. Because these procedures are not free from risks [1-3], many attempts have been undertaken to provide the clinician with less invasive but just as well instruments for cardiac output determination. The analysis of the arterial pressure waveform enables conclusions on stroke volume, its variability and cardiac output. However, systems like the PiCCO system (Pulsion Medical Systems, Munich, Germany) or the LiDCO™-plus-system (Lidco Ltd., Cambridge, UK) require calibration by either transpulmonary thermo- or lithium-dilution and therefore depend upon a central venous catheter. Moreover, it has been shown that frequent re-calibration is necessary to achieve reliable measures under circumstances of changing vascular tone [12]. The FloTrac™/Vigileo™-system (Edwards Lifescience, Irvine, CA, USA) does not require calibration, is therefore very easy to use and – provided that an arterial catheter is available – is equivalent to some kind of „plug & play“ in medical engineering.

The basic principles of cardiac output are fundamental for the technique used by the FloTrac™/Vigileo™-system. Cardiac output is calculated on the basis of the arterial pressure waveform (CO_{apw}) with the formula $CO_{apw} = \text{pulse frequency} \cdot \text{stroke volume}$. Therefore, the system has to estimate stroke volume by analysing the form of the arterial pulse wave at a frequency of 100 Hz over a 20 sec time frame. It calculates σAP – the standard deviation of the arterial pressure – out of the resulting 2000 data points, taking age, height, weight and gender into account. Finally, σAP is multiplied by the factor χ (χ), which is a multivariate parameter containing estimations of resistance and compliance of the vascular system. The result is the estimated stroke volume.

The algorithm is under continuous development resulting in different software ver-

sions. During our investigation, the configuration changed from software version V1.07 to V1.10. The most important features of the updated version were a wider range of the χ -factor, an improved range of the algorithm with respect to pulse pressure and an improved stroke detection. The first software version (version V1.03) could not convince in any way [6]. The second version was used for the first 19 patients in the present study, the third one (version V1.07) was used for the remaining 15 patients. The percentage error improved from 45 to 36% with the software update, but still exceeds the threshold of 28.28% recommended by Critchley and Critchley [11]. Nevertheless, improvements in the measuring techniques used can improve accuracy, albeit the software versions in the present study differed significantly with respect to bias but not with respect to precision.

The precise estimation of the vascular tone – in which the factor χ merges – is crucial for the FloTrac™/Vigileo™-technique. The luxury of the lacking need for calibration is achieved at the price of limitations due to circumstances influencing the vascular tone. Similar results have been found by other investigators [13]. Because the software version used is not mentioned in all studies, a general recommendation cannot be given at this time. Other studies using software version V1.10 partly showed better values of the percentage error [7,14]. Additionally, one has to keep in mind the variety of clinical settings investigated so far: It is obvious that e. g. vascular tone after cardiac surgery behaves different than in septic shock or during liver transplantation. In our scenario, V1.10 could not convince. The next software version was investigated by Eleftheriadis et al. in the setting of cardiac surgery. Again, the percentage error remained above 30% and the question of the clinical usefulness of the FloTrac™/Vigileo™-system outlasts [15]. At least, the catheterisation site seems irrelevant. Kim et al. found no difference between radial and femoral catheterisation site [16]. But there is a flicker of hope: All investigations of the Flo-

Trac™/Vigileo™-system have one thing in common, namely improvements in accuracy due to optimisation of the algorithms. Many of the FloTrac™/Vigileo™-system's relatives have never found entrance to clinical routine. Maybe further improvements of the algorithms are the clue to prevent the FloTrac™/Vigileo™-system to suffer the same fate of sinking into obscurity.

The evolution of the non- or semi-invasive methods for measuring cardiac output continues and a heir to the throne – occupied by the PAC for decades – has not evolved yet.

Speculations

It is unchallenged that critically ill and high risk patients require more invasive monitoring techniques than average patients [17,18]. Whether the use of the FloTrac™/Vigileo™ - system makes sense in these patients has to be decided on an individual basis. This decision process should take into account whether the waiver of central venous catheterisation is advantageous and whether the moderate agreement with the reference method is acceptable.

Disclosure

Except for the author PD Dr. M. Mueller who received fees for scientific lectures from Edwards Lifesciences Germany GmbH there is no conflict of interest to be declared.

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