Effect of Vasoactive Drugs on the Accuracy of Arterial Pressure-Based Cardiac Output Measurements in Open Heart Surgery

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ABSTRACT:

A new method for measurement of cardiac output has been invented utilizing the invasive arterial blood pressure waveform analysis, without external calibration, using a normal arterial cannula whether inserted in the radial artery or the femoral artery. It was imperative to understand the effect of vasoactive drugs , whether vasoconstrictors (e.g. norepinephrine) , or vasodilators (e.g. nitroglycerine) , on wall compliance and hence, on the accuracy of the reading, when compared with the thermodilution method of measurement.

In this prospective clinical study in National Heart Institute, 40 patients undergoing open heart surgeries for single valve replacement , with good ventricular functions (EF > 45%), and no pulmonary hypertension or ventricular hypertrophy. To each patient a radial arterial cannula and a pulmonary artery catheter (PAC) inserted and a series of readings were obtained simultaneously from both catheters , and compared . The patients were divided into 2 groups of 20 patients each , group I were treated after bypass by norepinephrine drips (up to 100 nanogram/kg/min) , and group II were treated after bypass with nitroglycerine drip (up to 1 microgram /kg/min). The readings were taken at 5 situations: after induction, before bypass, after weaning from cardiopulmonary bypass, at the end of operation and 2 hours postoperatively. The results of this study showed that there is no significant difference in most comparisons between the two modalities of measurement of cardiac output values (p-value around 1.000 and never < 0.05) in both groups. It was concluded that the use of arterial pressure -based cardiac output measurement FloTrac/Vigileo™ system (Version 3.02) is a reliable and accurate method of CO assessment in comparison to pulmonary artery catheter thermodilution method under normal hemodynamic conditions , and with the use of vasoactive drugs , whether vasoconstrictors or vasodilators when the mean pressure is kept in the range of (60-90 mm Hg).

KEY WORDS: Cardiac output measurement, Pressure wave based CO measurement, Vasoactive drugs.

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INTRODUCTION

In the quest for a less invasive method for measurement of cardiac output , a new method for measurement of cardiac output has been invented utilizing the invasive arterial blood pressure waveform analysis , without external calibration , using a normal arterial cannula whether inserted in the radial artery or the femoral artery.

The new arterial pressure-based cardiac output (APCO) device FloTrac/Vigileo™ system (Edwards Lifesciences, Irvine, CA, USA) allows the cardiac output to be determined continuously using pulse wave analysis without external calibration. It samples pressure wave signals using the radial or femoral artery via a standard arterial catheter. The standard deviation of pulse pressure is empirically correlated to the stroke volume based on patient demographic characteristics after automatic adjustment for actual vascular compliance and displayed as continuous cardiac output [1]. Initial evaluation studies on the FloTrac/Vigileo™ system revealed conflicting results [1-4].

Early studies comparing this new system and a reference technique had observed weak or only fair agreement, and this may be partly explained by the fact that adaption for changes of vascular compliance at 10 minute intervals may miss hemodynamic changes during that time window [5].

Consequently, the FloTrac/Vigileo™ system with its underlying algorithm has been improved and – as a major modification – the time window was reduced to one minute (Software version 1.07 and higher). Consecutive studies using a modified FloTrac/Vigileo™ system showed improved results [6-10].

It is supposed to estimate the arterial wall compliance and compensate for any change in vascular tone, by detecting characteristic changes in the waveform .In cardiac surgery patients, studies on the FloTrac/Vigileo™ system suggested that it reliably measures cardiac index when compared with the pulmonary artery catheter-derived measurement [7,11].whereas some other studies demonstrated an acceptable agreement [12].

Some limitations in cardiac surgery patients was that the FloTrac sensor is only indicated for adult use and has not been validated in patients with ventricular assist devices or intra aortic balloon pumps. Severe peripheral vasoconstriction during shock states or hypothermic episodes may influence values with radial arterial locations, consideration to femoral sites during these episodes or insertion of a pulmonary artery catheter may be considered[11-12].

This raises the question of the suitability of Arterial Based CO for critically ill patients with hemodynamic instability. In particular, the device could perform differently if the changes in cardiac output were related to volume expansion or to vasopressor or vasodilator administration.

The aim of the present prospective clinical study was to understand and test the effect of vasoactive drugs , whether vasoconstrictors (e.g. Norepinephrine) , or vasodilators (e.g.

Nitroglycerine) , on the accuracy of the reading of the FloTrac/Vigileo™ system (Software version 3.02), and their effect on the arterial wall compliance when compared with the thermodilution method of measurement of cardiac output in open heart surgery.

MATERIALS AND METHODS

The study protocol was approved by the institutional review board. All patients or their legal guardians consented for participation in this study. 40 patients undergoing single - valvular open heart surgery , with good ventricular functions (EF > 45 %) were chosen to be included in this study .

Exclusion criteria were reduced left and right ventricular function(EF < 45 %) , preoperative dysrhythmias, severe valvular heart diseases, intracardiac shunts, pulmonary artery hypertension, and severe arterial occlusion disease.

The sample size was determined on the hypothesis of an expected standard deviation of 8% for cardiac output values and an expected difference in the range of the standard deviation between the values of the different measurement techniques ($\alpha = 0.05$ and power > 0.9).

Anesthetic technique :

All usual cardiac medications required by the patient's underlying condition were continued until surgery. All patients received a standard premedication consisting of 1-3mg lorazepam, plus 150mg zantac orally on the evening of surgery and 0.15 mg/kg morphine intramuscular (I.M) given 30 min before the procedure. Prior to induction of anesthesia, pulse-oxymetry, ECG leads II and V5 were continuously recorded. After placement of peripheral intravenous (I.V) lines, and radial arterial line, anesthesia was induced with propofol 0.5-1.5 mg/kg then, 3-5 µg/kg fentanyl was given in 5 min. During fentanyl infusion, ventilation was assisted manually with 100% oxygen supplemented with sevoflurane. Neuromuscular blockade was achieved with 0.1 mg/kg pancuronium at induction and prior to CPB. After intubation, a continuous fentanyl infusion at 1-2µg/kg/hr was initiated and maintained until onset of CPB. Afterward, the fentanyl infusion was decreased to 0.5-1µg/kg/hr until the end of surgery. During CPB, propofol infusion 100µg/kg/min was substituted for sevoflurane. Controlled mechanical ventilation was adjusted to maintain end-tidal carbon dioxide between 35 and 40 mmHg.

To each patient a radial or femoral arterial cannula and a Becton Dickinson (Criticath ™ SP 5107HTD) pulmonary artery catheter were positioned for readings of cardiac output (HP Component Monitoring system M1094A (Hewlett Packard, Palo Alto, CA).

After surgery, patients were transferred to the ICU for postoperative ventilation .Sedation was achieved with propofol infusion 0.5- 2 mg/kg / hour and morphine boluses. Patients were extubated according to the standard criteria.

Radial and femoral arterial lines from a variety of manufacturers were connected to a new kit of FloTrac™ sensor and the cardiac output was determined using the algorithm used

in the Vigileo™ APCO system (Software version 3.02) ,in this study the device used is (Vigileo, Edward Lifescience , CA , USA) .

After entering the patient's personal data and demographics: age (years) ,gender, weight (kg) and height (cm), the FloTrac immediately calculates the stroke volume and starts displaying the continuous cardiac output and stroke volume index. Measurements were initiated after checking the arterial line waveform fidelity and zeroing the system at mid-axillary level to ambient pressure.

The Underling Principle:

Measurement of cardiac output by the FloTrac/Vigileo™ system is done by using special algorithms. These have been described in detail elsewhere [7]. In brief, the calculation of cardiac output by the FloTrac/Vigileo™ system is based on the contribution of pulse pressure on cardiac output being proportional to the standard deviation of arterial pulse pressure. The influence of vascular resistance and compliance on cardiac output is considered manually based on entered patient data. Thus, there is no need for external calibration[5], in contrast to the PiCCOplus™ method which relies on the work of Wesseling and colleagues [13]calculation of cardiac output by measuring the area under the curve of the systolic arterial pressure wave form and dividing this area by the aortic impedance after calibration by transpulmonary thermodilution.

Pulse wave analysis algorithms:

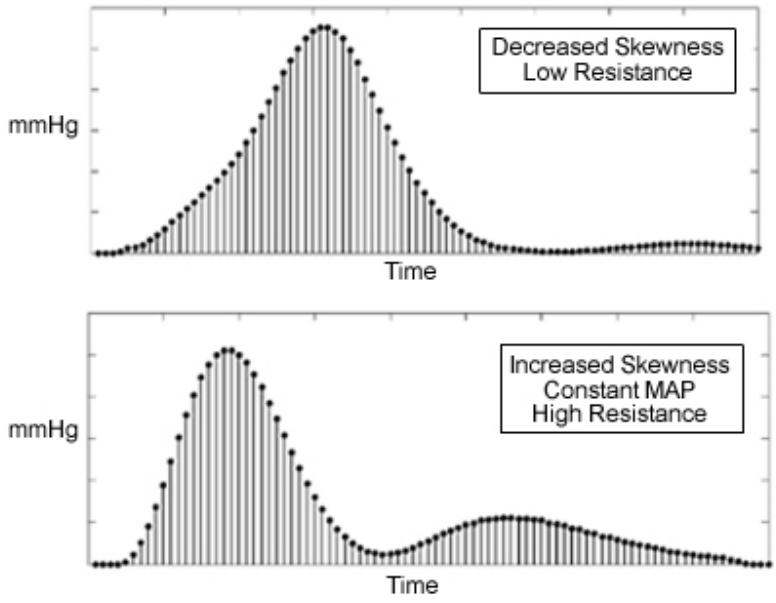
The Vigileo device differs from the trans pulmonary thermodilution device in two main points:

First, it does not take into account the area under the systolic part of the arterial curve, but does the standard deviation of the points contained by the arterial curve in a beat.

Second, it does not determine aortic impedance from any external calibration of CO, but estimates it from pressure-waveform characteristics, such as **skewness** and **kurtosis**, and from patient demographic data (age, gender, height, and weight). With the software we used in the present study(Version 3.02), the estimation of arterial compliance is updated on a rolling 60-second average.

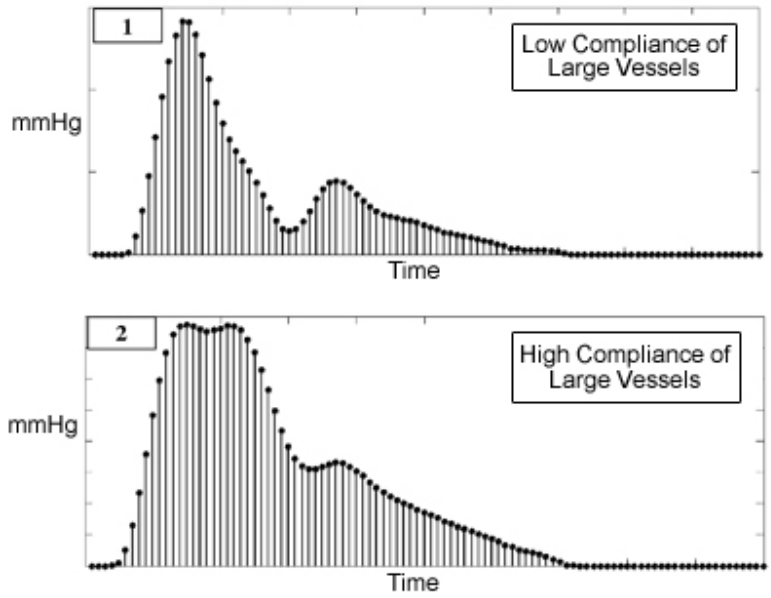
Skewness (a measure for lack of symmetry)

Symmetry characteristics on arterial pressure can indicate a change in vascular tone and/or resistance. Two different functions may have the same mean and standard deviation but will rarely have the same skewness. For example, an arterial pressure waveform in which the data points increase quickly in systole and fall slowly can result as an increase in vasoconstriction and would have increased skewness (Figure1).



(Figure1): Example of decreased and increased skewness[7].

Kurtosis (a measure of how peaked or flat the pressure data points are distributed from normal distribution)
Pressure data with high kurtosis has the pressure rise and fall very quickly relative to the normal pulse pressure and can be directly associated with large vessel compliance. (Figure2).
1) A high kurtosis value will indicate a distinct peak near the mean, with a drop thereafter, followed by a heavy “tail”.
2) A low kurtosis value will tend to indicate that the function is relatively flat in the region of its peak and suggests decreased central tone, as is often seen, for example, in the neonatal vasculature.



(Figure2): Example of high and low kurtosis [7].

Dynamic change: estimated by waveform analysis (skewness, kurtosis of the waveform). Measured as mL per beat/mm Hg will give an idea about beat-to-beat change in arterial resistance (skewness) and compliance (kurtosis).

The arterial pressure - based device provides an estimation of cardiac index (CI) from an analysis of the pulse waveform , but it does not require any external calibration because it estimates aortic impedance from certain characteristics of the arterial pressure waveform and from some demographic data .

Arterial blood pressure in mmHg is proportional to pulse pressure. Mean arterial pressure(MAP) is calculated by taking sum of sampled pressure point values over 20 seconds and dividing it by the number of pressure points. The algorithm is based on the principle that aortic pulse pressure is proportional to stroke volume (SV) and inversely related to aortic compliance.

The algorithm assesses pulse pressure by using the standard deviation of the arterial blood pressure [std(BP)] around the MAP value. This standard deviation of the pulse pressure is proportional to the volume displaced or the stroke volume. This is calculated by analyzing the arterial pressure waveform over 20 seconds at 100 times per second, creating 2,000 data points from which [std(BP)] is calculated:

CO = HR x SV

CO=Pulse Rate x [std(BP) x X factor]

Pulse Rate [PR] measured as beats per minute and the beats are identified by upslope of waveforms.

Advanced beat detection differentiates fully perfused beats computed from 20-second time period of beats, standard deviation of arterial blood pressure [std(BP)], and

Pulse pressure ∞ SV ∞ std(BP) measured as mm Hg computed on a beat-by-beat basis

The X factor compensates for differences in vascular compliance and resistance.

Patient-to-patient differences is estimated from biometric data.

Study protocol:

The patients were divided into 2 groups 20 patients each :

Group I were treated after bypass by norepinephrine drips (up to 100 nanogram/kg/ min) , to maintain a mean blood pressure not exceeding 90 mm Hg.

Group II were treated after bypass with nitroglycerine drip (up to 1 microgram /kg/min) to maintain a mean blood pressure not to drop below 60 mm Hg.

5 pairs of stroke volume index (SVI) and cardiac output (CO) readings were obtained simultaneously from both catheters , and compared .

The readings were taken at 5 situations: after induction (T1), before bypass (T2), after weaning from cardiopulmonary bypass (T3), at the end of operation (T4) and 2 hours postoperatively (T5).

Data consisted of :

a. SVI determined by pulmonary artery catheter (Swan Ganz) , at 5 measurement points in 20 patients .

b. SVI determined by Vigileo. At the same 5 measurement points in 20 patients .

c. CO by Swan Ganz , and

d. CO by Vigileo at the same points .

Giving us 5 pairs of reading for each parameter in each patient : with a total of 200 pairs of SVI readings in both groups (100 pairs in each group) and 200 pairs of CO readings for both groups (100 pair for each group) .

Statistical analysis:

All hemodynamic variables were recorded as a mean of three repeated measurements. Statistical analysis was performed using Statview 5.01® Software (SAS Institute Inc., Cary, NC, USA) and SPSS® 10.0 (SPSS Inc., Chicago, IL, UK). Cardiac output changes were calculated as percentage deviation of the previous measurements. Paired student's t-test was performed to compare cardiac output values obtained by Vigileo device and cardiac output assessed by intermittent thermodilution. Analysis of variance for repeated measurements (*post-hoc* Bonferroni correction) was used to assess differences of hemodynamic variables during the study period. Unless otherwise stated, data are presented as mean ± standard deviation. Results were considered significant when P values < 0.05.

RESULTS

All operations went on smoothly and patients were transferred to the ICU in good hemodynamic status (systolic blood pressure >100 mm Hg , HR between 60 and 110) ,CO was > 4 L/min by thermodilution method in most cases, and CVP exceeding 5cm water in all cases .

Readings were taken in the ICU , up to 2 hour postoperatively. Both groups were comparable regarding the perioperative characteristics, as shown in (Table 1).

Table 1 : **Demographic Data of both groups (Mean±SD):**

Demographics	Group I (n=20)	Group II (n=20)	P value
Number of females	14 (70 %)	11 (55 %)	P >0.05
Number of males	6 (30 %)	9 (45 %)	P >0.05
Age range	35 - 50	35 – 55	P >0.05
Weight	Mean 82 kg ± 6kg	Mean 79 ± 8kg	P >0.05
Type of surgery	Aortic valve : 7 Mitral valve: 13	Aortic valve : 5 Mitral valve : 15	
Cross clamp time	38 min ±9 min	43 min ± 7 min	P >0.05

No significant difference between the two groups.

The readings of SVI&CO measured by Swan Ganz and Vigileo of both groups in the five points of measurement in the study are presented in (Table 2).

Table 2 : The readings of SVI&CO measured by Swan Ganz and Vigileo on (Mean±SD):

Group I (Norepinephrine)	**T1**	**T2**	**T3**	**T4**	**T5**
SVI Swan Ganz	1.93 ± 0.19	2.18 ± 0.21	2.12 ± 0.30	2.06 ±0.20	2.45±0.17
SVI Vigileo	1.99 ± 0.21	2.19 ± 0.19	2.19 ± 0.23	2.23 ± 0.22	2.87±0.23
CO Swan Ganz	4.52 ± 0.58	4.68 ± 0.37	4.77 ± 0.41	4.75 ± 0.37	4.86 ± 0.5
CO Vigileo	5.65 ± 0.76	5.38 ± 0.37	5.38 ±0.30	5.34 ± 0.34	5.47 ± o.36
Group II (Nitroglycerine)	**T1**	**T2**	**T3**	**T4**	**T5**
SVI Swan Ganz	1.94±o.18	2.40±0.19	2.55±0.25	2.56±1.00	2.45±0.34
SVI Vigileo	1.95±0.21	2.50±0.58	2.60±0.38	2.69±0.41	2.87±0.50
CO Swan Ganz	4.76±0.48	5.25±0,47	4.68±0.37	5.39±0.43	4.88±0.28
CO Vigileo	5.76±0.052	6.10±0.58	5.81±0.45	6.03±0.29	5.54±0.50

SVI: Stroke Volume Index, CO: Cardiac Output,
T1= after induction, T2= before bypass, T3= after weaning from cardiopulmonary bypass,
T4= at the end of operation and T5= 2 hours postoperatively.

In order to compare the effect of the vasoactive drugs on the SVI&CO measurements , the mean reading for every measurement point from this table was then used as one reading for comparison of the different modalities of measurement.

Paired T- test was used to compare 10 pairs of SVI&CO measurements from the Swan Ganz catheter with those calculated from the Vigileo at the time points T1-T5 in norepinephrine group (Table 3),and in nitroglycerine group (Table 4).

Table 3 : Paired T-test : comparison between two modalities of measurement at each reading point(SVI& CO) when using norepinephrine :

Group I (Norepinephrine)		Paired Differences				
		Mean±SD	t	Significance (2-tailed)	95% confidence Interval of the difference	
					Lower	Upper
Pair 1	SVI Swan Ganz-SVI Vigileo at T1	-0.095±0.248	-1.712	0.103	-0.211	0.021
Pair 2	CO Swan Ganz-CO Vigileo at T1	-0.845±0.491	-7.689	0.101	-1.075	-0.615
Pair 3	SVI Swan Ganz-SVI Vigileo at T2	-0.200±0.296	-3.026	0.007*	-0.338	-0.062
Pair 4	CO Swan Ganz-CO Vigileo at T2	-1.130±0.437	-11.574	0.105	-1.334	-0.926
Pair 5	SVI Swan Ganz-SVI Vigileo at T3	-0.025±0.654	-0.171	0.866	-0.331	0.281
Pair 6	CO Swan Ganz-CO Vigileo at T3	-0.640±0.560	-5.107	0.001	-0.902	-0.377
Pair 7	SVI Swan Ganz-SVI Vigileo at T4	-0.125±0.547	-1.023	0.319	-0.131	-0.381
Pair 8	CO Swan Ganz-CO Vigileo at T4	-0.375±1.152	-1.456	0.162	-0.164	0.914
Pair 9	SVI Swan Ganz-SVI Vigileo at T5	-0.415±0.690	-2.690	0.015*	-0.092	-0.738
Pair 10	CO Swan Ganz-CO Vigileo at T5	-0.930±0.516	-8.058	0.001	-1.172	0.688

*** P value <0.05 =Statistical significance.**
No significant difference in most comparisons between the two modalities of measurement of cardiac output values (p-value around 1.000 and never < 0.05), but when the stroke volume index is compared , some significant difference becomes apparent (this difference which is in fractions , when multiplied by the heart rate becomes insignificant (p-value >0.05). SVI: Stroke Volume Index, CO: Cardiac Output, T1= after induction, T2= before bypass,
T3= after weaning from cardiopulmonary bypass, T4= at the end of operation and T5= 2 hours postoperatively.

Table 4 : Paired T-test : comparison between two modalities of measurement at each reading point (SVI& CO) when using nitroglycerine :

Group II (Nitroglycerine)		Paired Differences				
		Mean±SD	t	Significance (2-tailed)	95% confidence Interval of the difference	
					Lower	Upper
Pair 1	SVI Swan Ganz-SVI Vigileo at T1	-0.165±0.225	-2.582	0.107	-0.271	- 0.059
Pair 2	CO Swan Ganz-CO Vigileo at T1	-1.130±0.445	-11.312	0.603	-1.338	-0.922
Pair 3	SVI Swan Ganz-SVI Vigileo at T2	-0.255±0.136	-4.317	0.006*	-1.318	-0.192
Pair 4	CO Swan Ganz-CO Vigileo at T2	-0.705±0.286	-6.614	0.401	-0.839	-0.571
Pair 5	SVI Swan Ganz-SVI Vigileo at T3	-0.650±0.328	-2.312	0.103	-0.089	+0.219
Pair 6	CO Swan Ganz-CO Vigileo at T3	-0.610±0.352	-4.515	0.205	-0.775	-0.445
Pair 7	SVI Swan Ganz-SVI Vigileo at T4	-0.700±0.349	-2.712	0.013*	-0.094	+0.233
Pair 8	CO Swan Ganz-CO Vigileo at T4	-0.585±0.588	-4.542	0.153	-0.860	-0.310
Pair 9	SVI Swan Ganz-SVI Vigileo at T5	-0.175±0.351	-1.812	0.033*	+0.011	+0.339
Pair 10	CO Swan Ganz-CO Vigileo at T5	-0.610±0.609	-5.112	0.103	-0.895	-0.325

*** P value <0.05 =Statistical significance.**
No significant difference in most comparisons between the two modalities of measurement of cardiac output values (p-value around 1.000 and never < 0.05), but when the stroke volume index is compared , some significant difference becomes apparent (this difference which is in fractions , when multiplied by the heart rate becomes insignificant (p-value >0.05). SVI: Stroke Volume Index, CO: Cardiac Output, T1= after induction, T2= before bypass, T3= after weaning from cardiopulmonary bypass, T4= at the end of operation and T5= 2 hours postoperatively.

The accuracy of the Vigileo device, in measuring SVI over time, in the same case was statistically calculated by performing a **pairwise comparison with adjustment for multiple comparisons: Bonferroni,** between T1 , T2, T3, T4, & T5, (Table 6)

Table 6: Pairwise comparison between different times of Vigileo device readings of SVI with adjustment for multiple comparisons: Bonferroni, based on estimated marginal means.

(I)SVI Vigileo	(J)SVI Vigileo	Mean difference I-J	Stand. Error	p-value (a)	95% confidence interval for difference (a)	
					Lower bound	Upper bound
T 1	T2	-0.055	0,072	1.000	-0.283	0.173
	T3	-0.130	0.079	1.000	-0.379	0,119
	T4	-0.065	0.077	1.000	-0.309	0.179
	T5	-0.045	0.082	1.000	-0.214	0.304
T 2	T1	0.055	0.072	1.000	-0.173	0.283
	T3	-0.075	0.126	1.000	-0.474	0.324
	T4	-0.010	0.114	1.000	-0370	0.350
	T5	-0.100	0.103	1.000	-0.226	0.426
T 3	T1	0.130	0.079	1.000	-0.119	0.379
	T2	0.260	0.039	1.000	-0.324	0.474
	T4	-0.005	0.040	1.000	-0.289	0.419
	T5	-0.045	0.064	0.978	-0.144	0.494
T 4	T1	0.370	0.072	1.000	-0.179	0.309
	T2	0.265	0.044	1.000	-0.350	0.370
	T3	0.005	0.040	1.000	-0.419	0.289
	T5	-0.040	0.070	1.000	-0.260	0.480
T 5	T1	0.410	0.064	1.000	-0.304	0.215
	T2	0.305	0.063	1.000	-0.426	0.226
	T3	0.045	0.064	1.000	-0.494	0.144
	T4	0.040	0.070	0.978	-0.480	0.260

The pairwise comparison of the SVI reading along the case shows no significant difference in accuracy in the five different times of measurement (p-value equal to 1.00 in most of cases and always more than 0.05). (a) Adjustment for multiple comparisons: Bonferroni,
SVI: Stroke Volume Index, T1= after induction, T2= before bypass, T3= after weaning from cardiopulmonary bypass, T4= at the end of operation and T5= 2 hours postoperatively.

Also, the accuracy of the Vigileo device, in measuring CO over time, in the same case was statistically calculated by performing a **pairwise comparison with adjustment for multiple comparisons: Bonferroni,** between T1 , T2, T3, T4, & T5, (Table 7)

Table 7: Pairwise comparison between different times of Vigileo device readings of CO with adjustment for multiple comparisons: Bonferroni, based on estimated marginal means.

(I)CO Vigileo	(J)CO Vigileo	Mean difference I-J	Stand. Error	p-value (a)	95% confidence interval for difference (a)	
					Lower bound	Upper bound
T 1	T2	0.290	0.170	1.000	-0.248	0.828
	T3	0.070	0.111	1.000	-0.284	0.424
	T4	0.560	0.191	.086	-0.047	1.167
	T5	0.285	0.171	1.000	-0.259	0.829
T 2	T1	-0.290	0.170	1.000	-0.828	0.248
	T3	-0.220	0.134	1.000	-0.646	0.206
	T4	0.270	0.167	1.000	-0.289	0.829
	T5	-0.005	0.161	1.000	-0.517	0.507
T 3	T1	-0.070	0.111	1.000	-0.424	0.284
	T2	0.220	0.134	1.000	-0.206	0.646
	T4	0.490	0.175	.112	-0.064	1.044
	T5	0.215	0.167	1.000	-0.314	0.744
T 4	T1	-0.560	0.191	.086	-1.167	0.047
	T2	-0.270	0.176	1.000	-0.829	0.289
	T3	-0.490	0.175	.112	-1.044	0.064
	T5	-0.275	0.148	.796	-0.746	0.196
T 5	T1	-0.285	0.171	1.000	-0.829	0.259
	T2	0.005	0.161	1.000	-0.507	0.517
	T3	-0.215	0.167	1.000	-0.744	0.314
	T4	0.275	0.148	0.796	-0.196	0.746

The pairwise comparison of the CO reading along the case shows no significant difference in accuracy in the five different times of measurement (p-value equal to 1.00 in most of cases and always more than 0.05). (a) Adjustment for multiple comparisons: Bonferroni,
CO: Cardiac Output, T1= after induction, T2= before bypass, T3= after weaning from cardiopulmonary bypass, T4= at the end of operation and T5= 2 hours postoperatively.

DISCUSSION

Vasodilators and vasoconstrictor drugs are commonly used in cardiac surgery for hemodynamic management. In a device used to assess CO in cardiac surgical patients, it is important to evaluate the accuracy of that device in assessment of CO with the use of that vasoactive drugs, especially when that device is affected by the vasomotor tone in measurement of CO. The reliability of the pressure derived CO has been questioned by Sander et al [4], and by Compton and his coworkers [17].

When first introduced to the cardiac surgery theatre it was stated by Opdam and his coworkers[16] that the CO measurements obtained using the FloTrac CO monitor showed a limited correlation with those acquired using the PAC, that it showed relatively wide limits of agreement but no clear bias. He concluded with a recommendation that further evaluation is required before this device can be recommended for use in the clinical setting.

Similar results were met with by Biais and his coworkers [17] : in patients with lowered peripheral resistance undergoing liver transplantation the arterial-based CO measurement did not correlate well in low systemic vascular resistance (SVR) , the percentage error was 45% . This inaccuracy in low SVR is much less in the newer third generation Vigileo software , as proven by Compton et al [17], were the mean bias was found around 9%.

In particular, it has been suggested by Sakka and his associates [19] that the uncalibrated pressure-waveform analysis would not reliably track the changes in cardiac output when the arterial tone changes to a large extent they stated that “Pulse contour analysis-derived CO (Vigileo system) underestimates CO and is not as reliable as transpulmonary thermodilution in septic patients” during hyperdynamic states, and Biancofiore et al [20] deduced the same in liver cirrhosis patients , stating that “In cirrhotic patients with hyperdynamic circulation, the Vigileo system showed a degree of error and unreliability higher than that considered acceptable for clinical purposes.

Other studies reported conflicting results as Sakka and his associates [19] and Sander and his coworkers [4], and in particular, it has been suspected by Biais et al [18], that Vigileo could be inappropriate for estimating cardiac index (CI) in the case of low SVR or when the arterial waveform changes to a large extent.

Also, Jeong and his associates [20] did a study to compare the two methods of CO measurement and concluded that uncalibrated arterial pressure wave based CO (APCO) values do not agree with thermodilution continuous CO measurement and significantly overestimated the thermodilution continuous CO values in patients undergoing OPCAB surgery. They recommended that further evaluation is required to verify the clinical acceptance of FloTrac APCO in OPCAB surgery.

In another study by Manecke and Auger [1] reported a mean bias of 0.55 between the FloTrac/ VigileoTM device and the intermittent pulmonary artery thermodilution in 50 patients studied after cardiac surgery. Opdam and colleagues[16] reported data from 251 measurements in six patients. However, 66% of all measurements were done in only one patient. Therefore, their results are difficult to interpret. More recently, another study performed in 40 patients in a similar setting revealed a large mean bias of 0.46 [3].

In this study we evaluated cardiac output assessed by a modified version of the FloTrac/Vigileo™ (Version 3.02) and the bolus thermodilution – as reference technique – during hemodynamic changes induced by administration of Vasoactive drugs in patients after elective single - valvular open heart surgery.

The modified FloTrac/Vigileo™ system showed an improved performance as compared with the early version of the system and measurements were as reliable as those performed by Swan Ganz catheter. In both groups of the study , the vasoconstrictor (norepinephrine), and the vasodilator (nitroglycerine) groups , there were no significant difference in most comparisons between the two modalities of measurement of cardiac output values (p-value around 1.000 and never < 0.05). Also, in this study, the accuracy of the Vigileo device, in measuring CO over time, in the same case showed no significant difference in accuracy in the five different times of measurement (p-value equal to 1.00 in most of cases and always more than 0.05) with the use of norepinephrine and nitroglycerine.

Similar results was found by Compton and his coworkers [19] , that there is no correlation between norepinephrine dose and the accuracy of the Vigileo readings.

Button and his associates [7] did a prospective study that they concluded from that performance of the FloTrac/Vigileo system via radial as well as femoral access and the PiCCOplus monitoring for cardiac output measurement were comparable when tested against intermittent thermodilution in cardiac surgery patients.

When comparing the two methods of measurement of cardiac output and arterial - based CO measurement by the Vigileo , no significant difference was observed in most measurement points , this is in concordance with the findings of Zimmermann and his coworkers [21] ,Cecconi and his associates [22] , and Biais et al [23] .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, hemodynamic changes before the measurement periods - even under conditions of hemodynamic stability may have had a larger impact on measurements in the studies performed by Sander and colleagues[4] or Mayer and colleagues[3].

Most recent studies of De Backer et al [24] , and Biancofiore [25] and his associates proved that: The new software (Version 3.02) provided substantial improvements over the previous versions with better overall precision and trending ability. Further algorithm refinements will increase this technology's reliability to be extensively used in the highly complex setting of cirrhotic patients undergoing liver transplantation.

CONCLUSION

The net result of this study is that the use of arterial pressure -based cardiac output measurement FloTrac/Vigileo™ system (Version 3.02) is a reliable and accurate method of CO assessment in comparison to pulmonary artery catheter thermodilution method under normal hemodynamic conditions , and with the use of vasoactive drugs , whether vasoconstrictors or vasodilators when the mean pressure is kept in the range of (60-90 mm Hg). Further studies are needed to evaluate the accuracy of this system in times of relative and true hypovolemia , as in case of using higher doses vasodilator infusions, and immediately before bypass (loss of blood during aortic and venous cannulation) , and immediately following cross clamp release , before reinfusion of blood from the cardiotomy reservoir.

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