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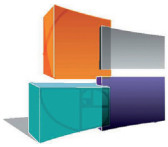

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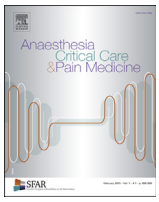

Original Article

Comparison of Proaqt/Pulsioflex® and oesophageal Doppler for intraoperative haemodynamic monitoring during intermediate-risk abdominal surgery

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ABSTRACT

Objective: To compare cardiac index (CI) between Proaqt/PulsioFlex® and oesophageal Doppler (OD) and the ability of the PulsioFlex® to track CI changes induced by fluid challenge and secondly to assess the impact of the time interval between two auto-calibrations of PulsioFlex® on the accuracy of the measured CI.
Methods: In a single hospital, 49 intermediate-risk oncologic abdominal surgery patients were included in an observational study. We measured the cardiac Index (CI) provided by OD and by the Proaqt/PulsioFlex® before and after internal calibration, which were performed randomly at specific intervals after the initial one (30, 60, 90 and 120 min). The ability to track fluid responsiveness was evaluated by measuring stroke volume variation, pulse pressure variation (PPV) and CI before and after a 250 ml fluid challenge and assessed by a receiver operating characteristic curve analysis.
Results: The percentages of error before calibration were 51, 58, 82, 81% for 30, 60, 90 and 120 min, they were 39, 57, 65, and 54% after calibration. Trending ability is assumed by a 93% concordance rate after applying a 15% exclusion zone. The trend interchangeability rate was 13.75%. The area under the curve for fluid responsiveness measured by PPV and SVV PulsioFlex were respectively 0.67 [0.57–0.77], $P < 0.01$ and 0.75 [0.47–0.66], which was not clinically relevant.
Conclusions: The Proaqt/Pulsioflex® system is not equivalent to OD for haemodynamic monitoring during non-vascular abdominal surgery in intermediate-risk patients. More studies are required to define the effect of the auto-calibration on the system.

1. Introduction

Fluid management guided by intraoperative monitoring of haemodynamic parameters may be beneficial to patients [1]. The choice of the monitoring technique should be adapted to the clinical scenario [2]. In the perioperative setting, limited invasiveness should be an important criterion when choosing the monitoring system. For example, Oesophageal Doppler (OD) is one of the less invasive technique of monitoring known to improve haemodynamic control and guide fluid replacement in comparison to conventional parameters such as heart rate, central venous pressure, arterial blood pressure and urine output [3]. Also, in this regard, pulse contour analysis devices may be of particular interest since they estimate cardiac output with a minimal invasiveness (an arterial catheter) [2] and measure some respiratory-induced changes in surrogates of stroke volume, which allow clinicians to predict fluid responsiveness [4].

Among such devices, the Proaqt/PulsioFlex® system (Pulsion Medical Systems, Munich, Germany, called hereafter PulsioFlex®) uses a pulse contour analysis algorithm that is similar to that of the Pulse Index Continuous Cardiac Output (PiCCO2) device, which is well established [4]. Nevertheless, unlike the PiCCO2 device, pulse contour analysis by the PulsioFlex® is not calibrated by transpulmonary thermodilution. The cardiac output value at the beginning is determined by a newly developed "start algorithm" that provides an automatic start value based on patient

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characteristics and details of the pressure curve. In addition, this auto-calibration can be performed at any time by the user by simply clicking the "on" button. A previous study showed that the Pulsioflex® has the capacity to guide goal-directed therapy during the perioperative period up to 28 days [5] however the trend interchangeability rate and the effect of additional calibration has not been yet assessed.

Our primary purpose was to compare the cardiac index obtained using Pulsioflex® and oesophageal Doppler (CIPX and CIOD) during intermediate-risk oncologic abdominal surgery. Secondly, we assessed the ability of Pulsioflex® to track haemodynamic changes during fluid challenge and finally we evaluated the effect of time interval between two auto-calibrations on the accuracy of Pulsioflex®.

2. Materials and methods

2.1. Patients

We conducted a prospective study from January to July 2013 in a teaching hospital. The study methodology complies with the STROBE statement [6] and was approved by the regional Ethics Committee (CPP Île-de-France 7, ref SC12-015). Written informed consent was obtained preoperatively for all patients. Patients younger than 18 years of age or those exhibiting contraindications to the use of OD such as: oesophagus, oropharynx or larynx disease including cancer or mediastinal disease such as thoracic aorta aneurysm, and those having contraindications to pulse contour analysis were excluded. All consecutive patients undergoing intermediate-risk oncologic abdominal surgery requiring intraoperative monitoring of the cardiac index in accordance with our local haemodynamic protocol were screened for inclusion.

2.2. Measurements and interventions

All patients were initially monitored using pulse oximetry, capnography, non-invasive arterial pressure, bispectral index, ECG, neuromuscular transmission and temperature monitoring. After induction of general anaesthesia (propofol 2.5 mg/kg, remifentanil effect-site perfusion starting at 3 ng/ml and atracurium 0.5 mg/kg), the patients were intubated and mechanically ventilated. Tidal volume was 8 mg/kg (ideal body weight) and the respiratory frequency was adapted for an end-tidal carbon dioxide value between 35 and 40 mmHg. Anaesthesia was maintained with inhaled desflurane for a bispectral index between 40 and 60 and the remifentanil infusion titrated according to patient response.

A radial artery catheter was inserted before surgery (Arterial Leader-Cath 20 G, Vygon, Ecouen, France). It was connected to a ProAQT sensor, which was plugged to the PulsioFlex® monitor. As the system did not have a quality index for the arterial signal, a check for damping was performed by performing a fast flush test with one min pause and verification before any measurement [7]. The ProAQT start algorithm used the biometric values (age, height and weight). Additionally, the dynamic circulatory parameters (mean blood pressure and heart rate) are used and an abstract value of CI is calculated from the blood pressure curve using a proprietary algorithm of the manufacturer by using a statistical approach which is not based on a classical physiological model such as the Windkessel model but rather the result of analysis of a manufacturer's own database.

An OD probe CardioQ® (Deltex Medical, Gamida, Eaubonne, France) was inserted. The signal was optimized at each measurement by adjusting the position until a sharp Doppler sound and optimal velocity-time wave were obtained [8]. As OD had the most evidence regarding improving outcome for intermediate-risk surgery patients [9], it was used for our perioperative haemodynamic management protocol which was partly inspired by Cannesson et al. [10]. According to our local protocol, fluid therapy consisted in a continuous infusion of balanced crystalloid (5 ml/kg/h) and in additional fluid boluses (250 ml of colloid [Voluven®; Fresenius, France] over five minutes when the stroke volume decrease was > 15% of the initial OD value reference). A patient could get several fluid challenges with different status (negative fluid challenge and positive one). Haemodynamic and anaesthesia management were not modified for the purpose of the study. For hyperthermic intraperitoneal chemotherapy (HIPEC) patients, no measurements were performed during and after the hyperthermia period.

Haemodynamic data (CI measured by the PulsioFlex® [CIPx], CI measured by oesophageal Doppler [CIOD], pulse pressure variation [PPV] and stroke volume variation [SVV] measured by the PulsioFlex® and mean arterial pressure [MAP]) were recorded before and one minute after fluid boluses that were decided by the anaesthesiologist within the protocol as needed. No personal interpretation was permitted. These values were used to assess trending ability of the PulsioFlex®.

In addition, auto-calibration of the PulsioFlex® was reinitiated by clicking the "on" button for calibration by the anaesthetist in charge at either 30, 60, 90 or 120 minutes after the initial auto-calibration. The sequencing of time intervals was distributed at random to each patient the interval between calibrations was not necessarily identical for each patient but all patients had 4 calibrations. Averaging of the Pulsioflex® was through a period of 30 sec within 4 window of 7.5 s while Doppler values were collected beat per beat and averaged post hoc within the same period of 30s. We used a repeatability coefficient of 8% for OD [11].

We recorded the haemodynamic data just before and one minute after each of these additional auto-calibrations. Two analyses were realised with these by values. First, the values recorded were pooled and used to assess the agreement between CIPx and CIOD under the best possible conditions, which was after the internal calibration. Second, four groups were created according to the time elapsed since the last internal calibration. Then the percentage error was calculated for each group, using pre and post calibration values. This analysis was used to provide information on the ability of the auto-calibration to improve the reliability of the device.

The normality of data distribution was tested with the Kolmogorov–Smirnov test. The results are presented as means (SD) for parametric continuous variables, median interquartiles for nonparametric or numbers (%) for qualitative variables, as required.

2.3. Statistical analysis

Comparison of the absolute values, agreement between measures and percentage of error were made by modified Bland and Altman plot for repeated measures for each patient [12], using Critchley and Critchley recommendation [13] defining the reliability of a technique as a percentage of error of less than 30%, this method evaluates agreement between two measurements techniques rather than validating the new technique. The percentage of error was calculated as 1.96 SD of bias divided by mean cardiac output [14]. The influence of population characteristics on the bias was assessed using a Wilcoxon test.

An analysis of trending ability was performed using two methods. The first one was plotting the % change in CIOD versus the % change in CIPx on a 4-quadrant plot. Trending ability was assessed through the analysis of directional changes. The concordance rate of the direction of change between consecutive readings from the CardioQ® and the PulsioFlex® was scored as the

percentage of measurements for which both devices detected changes in the same direction. We excluded changes in the cardiac index below 15% [15] and the concordance rate was defined as good when it was higher than 90% [15,16]. The second method was the recently described trend interchangeability method (TIM) developed by Fischer et al. [17]. Briefly, two steps were used. First, each CI change, measured by the PulsioFlex® over a fluid challenge, was classified as un-interpretable or interpretable, using the repeatability coefficient of the reference method of 8% (OD in our case). Then, using a predicted precision interval of the reference method, each change was described as either non-interchangeable, in the grey zone or interchangeable. An interchangeability rate was calculated (number of interchangeable changes divided by the total number of interpretable changes).

To categorise patients with positive or negative fluid challenge we used values obtain from OD.

The ability to provide information regarding fluid responsiveness as a therapeutic intervention was assessed using ROC curves.

The following variables obtained from the PulsioFlex® were used SVV, PPV, ΔCI (px), ΔSV. The AUC of the ROC curves with 95% CI was calculated according to Hanley and Mc Neil method, a grey zone approach with bootstrap methodology was used, and Younden's index was calculated as previously described [10].

We used Graphpad Prism 5.01 (Graphpad Software Inc., La Jolla, CA, USA) and Medcalc V15.8 (Mariakerke, Belgium) for statistical analyses. The Excel datasheet for the calculation of the Trend interchangeability method is open accessed (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4998299/bin/medi-95-e3530-s002.xlsx). A $P < 0.05$ was considered significant.

3. Results

3.1. Population

Forty-nine patients were included (12 males/37 females). Calibration and fluid bolus timeline (design of the study) is presented in Fig. 1. The mean age was 55 (13) years and the body mass index was 24 (4) kg/m^2. Twenty-three patients underwent intermediate-risk abdominal surgery (HIPEC, sarcoma surgery, hepatectomy, pancreatic surgery) and 26 underwent intermediate-risk gynaecological surgery (advanced ovarian cancer surgery). The patients had minimum 3 and maximum 4 measurements. Patient physiological data according to the responder status for the fluid challenge are shown in Table 1. There was no statistically significant bias related to the following parameters: ASA score, history of heart failure, hypertension, coronary syndrome, peripheral arterial disease, chronic kidney disease, diabetes mellitus, and smoking status.

Table 1
Haemodynamic characteristics of the patients regarding their status (positive or negative) for the fluid challenges.

Fluid challenge	Positive	Negative
Number of fluid challenges	72	43
Tidal volume (mL/kg)	8 ± 0.57	8 ± 0.6
Heart rate		
Before	83.1 ± 15.1	83.2 ± 20.5
After	84.6 ± 14.5	82.1 ± 20.1
MAP		
Before	72 ± 14.6	75.4 ± 12.3
After	76.4 ± 15.9	77.7 ± 11.6
SV		
Before	73.5 ± 23.4****	82.2 ± 24.6
After	95.8 ± 27.2*	80.9 ± 21.9
CI		
Before	3.53 ± 1.1****	4.16 ± 1.51
After	4.75 ± 1.29	4.07 ± 1.39
ΔCI		
OD (%)	36.4 +/23.7-	−0.89 ± 11.7
PulsioFlex® (%)	14.7 ± 14.4	14.47 ± 15.1
PPV		
Before FC (%)	10.3 ± 5.6**	8.2 ± 5.3
After	8.6 ± 4.5***	8.3 ± 5.3

MAP: mean arterial pressure; FC: fluid challenge; bpm: beat per minute; ΔFC: percentage of variation before/after fluid challenge; SV: stroke volume; ΔCI: percentage of variation before/after fluid challenge for cardiac index; OD: oesophageal Doppler.
* $P < 0.005$ vs. negative.
** $P < 0.001$ vs. negative.
*** $P < 0.03$ vs. PPV before FC.
**** $P < 0.05$ before vs. after FC

Comparison of all absolute values of CIOD and CIPX, before and after a fluid challenge, was performed using a Bland and Altman graph for repeated measures for each patient. It showed a bias of 0.7 L/min/m^2 with a limit of agreement (−1.8 to 3.3). The percentage of error was 78.6% (Fig. 2).

3.2. Comparison of changes in CIOD and CIPX

We analysed 114 CI pairs acquired before and after fluid challenge. The four quadrant plots with the exclusion zone are shown in Fig. 3: without the exclusion zone of 15%, the correlation coefficient was 0.33 ($P < 0.0001$) and the concordance rate was 84%. With an exclusion zone of 15%, the correlation coefficient was 0.19 ($P = 0.08$). The concordance rate after applying the exclusion zone of 15% was 92%.

Trend interchangeability method: with the repeatability coefficient of the OD at 8%, 39/114 (34%) changes were

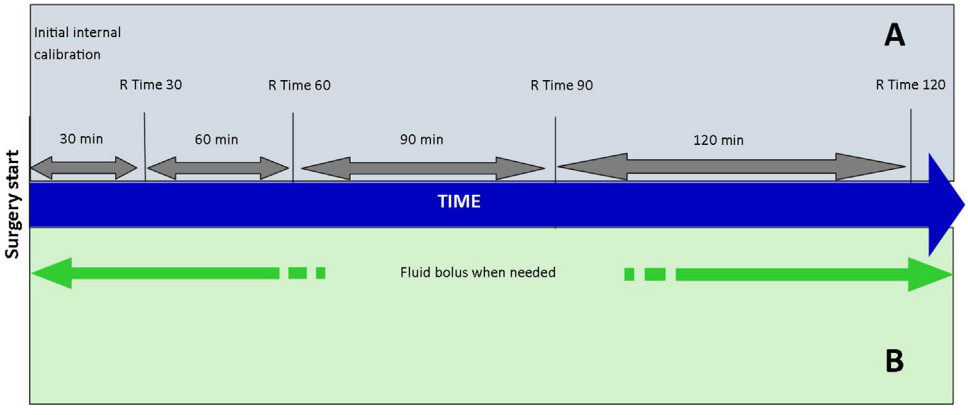


Fig. 1. The design of the study. The sequencing of time intervals was random for each patient the interval between calibrations was not necessarily identical for each patient but all patients had 4 calibrations.

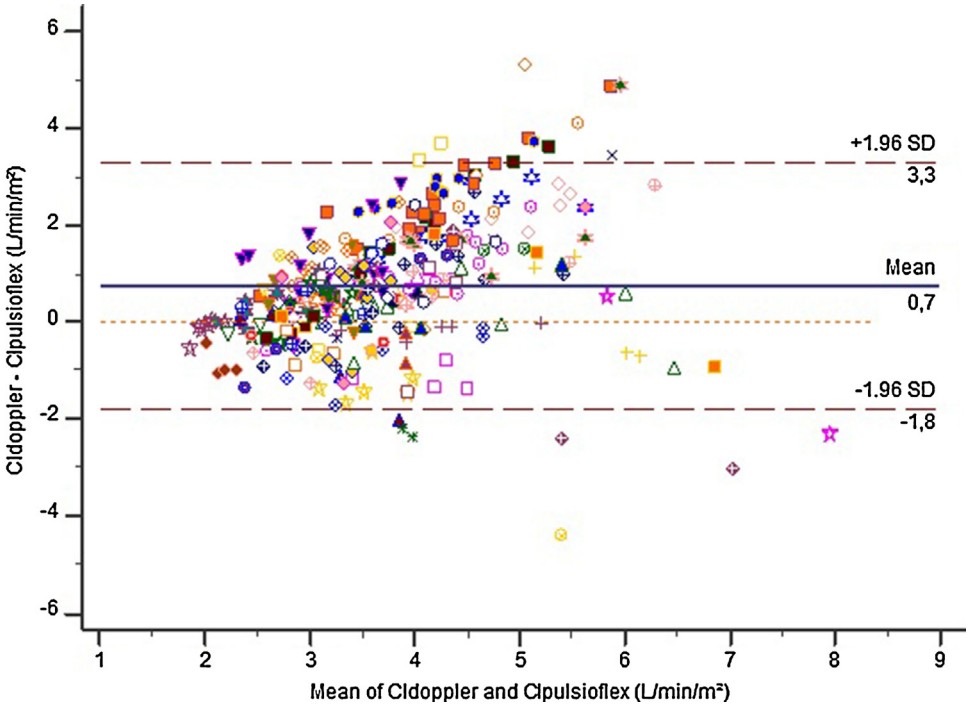


Fig. 2. Bland and Altman graph for repeated measurements for each patient before and after fluid challenge.

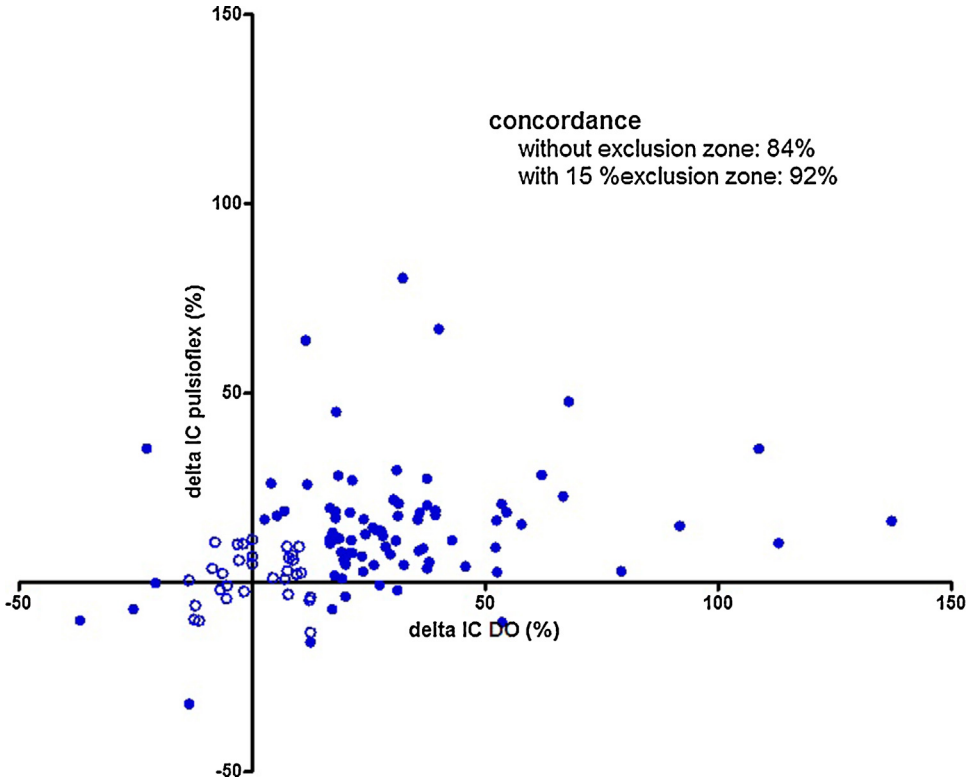


Fig. 3. Trending ability of the Pulsioflex® to detect changes in the cardiac index during fluid challenge, based on four quadrant concordance analysis. A 15% exclusion zone was applied (hollowed circles).

un-interpretable, 38/114 (33%) were non-interchangeable, 26/114 (23%) were in the grey zone and 11/114 (10%) were interchangeable. The graphical representation (trend interchangeability plot) is shown in Fig. 4. The trend interchangeability rate was 11/(114–38) = 13.75%.

3.3. Assessment of fluid responsiveness

The receiver operating characteristic (ROC) curves analysis is displayed in Fig. 5. The AUC of SVV is not significantly different from the non-discriminative line.

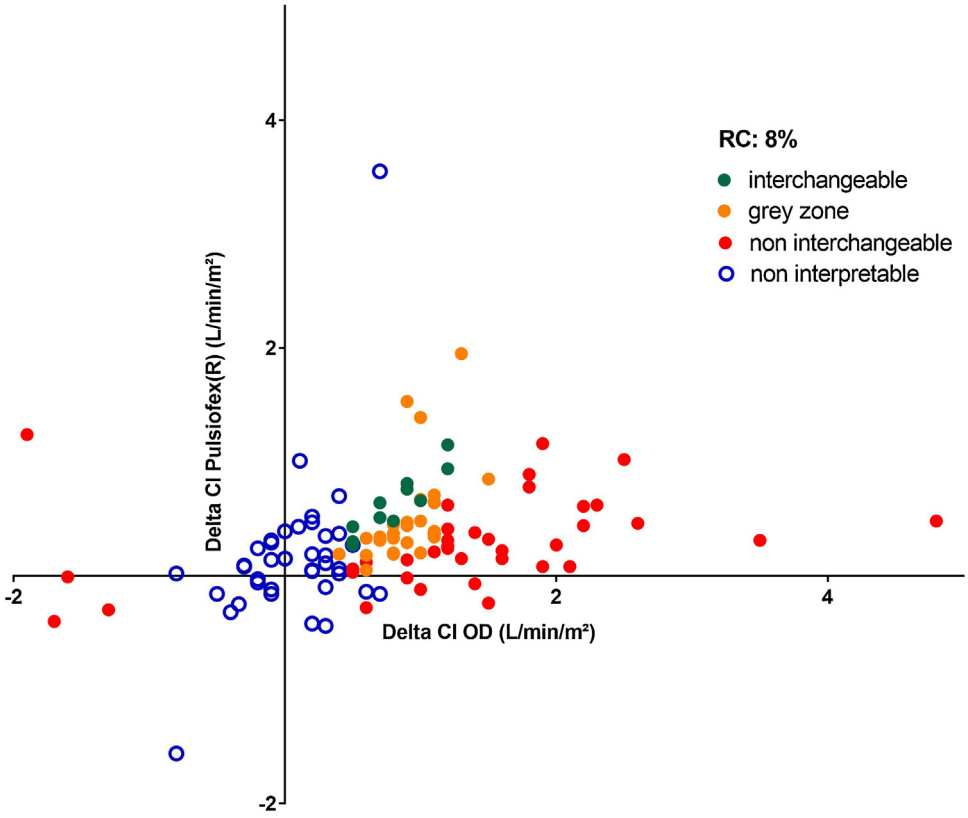
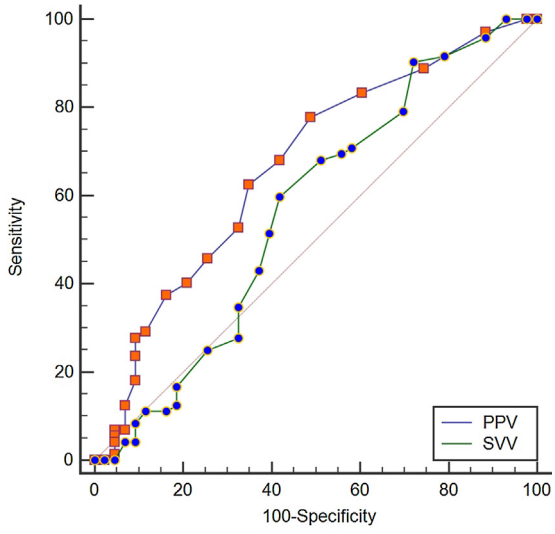


Fig. 4. The trend interchangeability rate plot.



	AUC	95% CI	*p*	SE	SP
PPV	0.67	0.57–0.75	< 0.01	77.8	51.2
SVV	0.57	0.47–0.66	ns		

Fig. 5. Receiver operating characteristic (ROC) curve analysis and area under the curve (AUC) table.

A cut-off value of 6% for the PPV helped to predict the fluid challenge. The AUC was 0.67 (0.57–0.75) with a sensitivity (SE) of 78% and a specificity (SP) of 52%. A grey zone was determined between 5 to 13%, 45% of the patients were within the grey zone. ΔCI had an AUC of 0.75 (0.66–0.82); the cut-off value was of 7%, with an SE of 74% and an SP de 70%. The grey zone extended from 3 to 18% with 54% of the samples within the interval. And finally, ΔSV had an AUC of 0.57 (0.47–0.66) with a cut-off of 4%. The SE was of 80% and the SP 58%. The grey zone was 4 to 15% with 46% of values within the zone.

3.4. Repercussion of auto-calibration on agreement between CIPx and CIOD values

When all the pairs of values were analysed together, the percentage error was 65.26% before calibration and 54.1% after calibration. Table 2 shows bias values and the percentage error before and after each calibration and each time interval.

4. Discussion

To our knowledge, this is the first study about trending ability of the CI using the PulsioFlex® in the operating room and comparing it to the OD technique in non-cardiac surgery. The main result is that the PulsioFlex® was not interchangeable with OD for monitoring cardiac output in intermediate-risk oncologic abdominal surgery. When OD values were used as references, internal calibration appeared to improve the accuracy of the CIpx values. Finally, we found that the shorter the duration between two internal calibrations, the smaller was the percentage error.

We found that the performances of the PulsioFlex® were not adequate enough whether for absolute values, trending ability or fluid challenge responsiveness.

Our results were somewhat similar to already published studies. Peyton conducted a meta-analysis on minimally invasive cardiac output monitors in 2010 and reported a mean percentage error of 41.3% for pulse contour devices (Flotrac®/Vigileo and PiCCO2®) and 42.1% for OD [18]. In another recently published meta-analysis Joosten et al. reported an overall pooled bias for non-invasive monitoring of 47%[19]. For the new fourth generation of Flotrac®/Vigileo devices, a recent study showed a bias of

Table 2
Bias and percentage error before and after each calibration and each time interval.

	Bias	Limits of agreement	% error
30 min			
Before calibration	−0.70	−2.30 to +0.89	51.09
After calibration	−0.67	−1.68 to +0.33	39.71
60 min			
Before calibration	−0.66	−3.32 to +2.00	58.58
After calibration	−0.38	−3.01 to +2.24	57.15
90 min			
Before calibration	−0.70	−3.28 to +1.88	82.13
After calibration	−0.70	−3.01 to +1.51	65.34
120 min			
Before calibration	−0.50	−4.92 to +3.92	81.92
After calibration	−0.11	−2.28 to +2.06	54.70

Oesophageal Doppler values are used as reference for bias calculation.

-0.66 ± 1.89 L/min and a percentage error of 55.4% [20]. In another investigation, Monnet et al. compared PulsioFlex® with Flotrac®/Vigileo device and a trans-pulmonary thermodilution device. Percentage error for Pulsioflex® was 40% and concordance rate 79% during a volume expansion [21]. More recently, Grensemann [7] found similar results with the Bland and Altman methods and percentage of errors. They used a polar plot approach finding the same conclusions as ours with trend interchangeability method [7].

One could notice that most of the works, concerning haemodynamic monitors' evaluation, used trans-pulmonary thermodilution as a reference [15]. Although we choose OD for reference, our results are similar with studies using invasive monitoring.

Statistical methods to assess the performance of CI monitors are subject to debate. The four quadrants graphics as well as the polar plot have their own limits [15,17,22]. We also used a new method which takes into account the guidelines for reporting reliability and agreement studies [17,23] nevertheless we cannot undermine limitation and bias for most of non-invasive monitoring system [24].

The most important point to us was that whatever methods used the conclusion is the same and enhanced by the results of the ability to provide information regarding fluid responsiveness, nevertheless the AUC of the significant variables of the ROC curves (PPV and ΔPPV are beyond values considered as being clinically relevant).

In our study, additional auto-calibration improved the percentage of error of the Pulsioflex® however, we acknowledge that the percentage of errors is still far from 30%. Percentage errors were better when the time elapsed from previous auto-calibration was shorter. The impact of auto-calibration is not well known. In their study, Monnet et al. [21], showed similar percentage of errors before and after auto-calibration (40 and 39% respectively). Their study protocol was quite different from the one we used. The auto-calibration "before" and "after" sets of measurements were performed after a therapeutic intervention (fluid challenge or change in the norepinephrine perfusion). But a reset (i.e. auto-calibration) was performed at the beginning of the protocol sequence. So, the effect of the time elapsed since previous internal calibration was not specifically observed. Our findings regarding the effect of the time are similar to those observed with trans-pulmonary thermodilution. Previous studies showed that prolonging the interval between two calibrations increased the percentage error [25] and recalibration is necessary after therapeutic manoeuvre-free periods more than 1 hour without calibration and after fluid challenges or alterations in norepinephrine infusion rates [26]. These studies were performed in intensive care units with calibration free periods ranging from 1 to 24 h. This similarity is logical as the same algorithm is used for continuous pulse contour analysis. Nevertheless, regular scheduled auto-calibrations are beneficial in addition to those required for vascular tone variations [27,28].

The main limit of our study is that we did not use a more reliable reference method such as trans-pulmonary thermodilution. However, despite its low complication rate [2] trans-pulmonary thermodilution still remain an invasive method, thus we chose to use OD which has been used as an alternative reference method for validation as it is suggested for this purpose in some studies [29]. Moreover, trans-pulmonary thermodilution is not recommended as the standard monitoring method for intermediate-risk surgery patients. OD is frequently the reference method for perioperative studies in terms of accuracy of fluid responsiveness and trend but not for CI accuracy [30,31]. Several studies have demonstrated that OD was adequate and could be recommended for intraoperative fluid management [2]. Secondly, fluid challenge per se may affect the performance of the OD monitoring. Changes in aortic diameter impact the accuracy of the OD, especially if a large increase in arterial pressure occurs [28] nevertheless OD is extremely useful as a trend monitor when used with attention and care [3]. In our study, surgery did not have any repercussion on the distribution of blood flow between the descending aorta and the supra-aortic vessels. Moreover, we did not observe any significant increase in mean arterial pressure during the study. Finally, heterogeneity of the types of surgery (HIPEC, sarcoma, gynaecological) performed in our population sample could have altered the measurement of agreement between the 2 devices [32] while other confounding factors such as the amount, the choice or the time of fluid challenge may also have partly contributed to the large difference between the amplitude of changes observed in the present study. Similar uncertainties were also observed in postoperative cardiac surgery setting using calibrated pulse contour cardiac index [19]. We chose to investigate a large sample of patients submitted to laparotomic intermediate-risk surgery. This population reflected daily practice in our institution and thus enhanced the external validity of the results.

Finally, authors describing the methods also used a repeatability coefficient of 8% to measure the cardiac index by thermodilution. We also decided to use this value based on data available for OD [11]. Obviously this has an importance as the authors demonstrated that higher value implicate a higher number of measurements being un-interpretable but will improve the trend interchangeability rate. In addition the repeatability coefficient affect the acceptable percentage of error (PE) according to the formula: PE = repeatability × square root of 2 [13], thus by using 8% repeatability coefficient we settled for a PE of less than 10% instead of 30% as usually accepted but this was not an issue since we found values far above both of these numbers.

In conclusion during non-vascular abdominal surgery in intermediate-risk surgery patients, the performances of the PulsioFlex® are similar to those of recent pulse contour analysis monitoring without auto-calibration. More studies are required to define the effect of the additional auto-calibration on the system reliability.

Disclosure of interest

Xavier MONNET is a member of the medical advisory board of Pulsion medical systems. All other authors declare that they have no competing interest.

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