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ORIGINAL RESEARCH

Agreement between cardiac output estimation with a wireless, wearable pulse decomposition analysis device and continuous thermodilution in post cardiac surgery intensive care unit patients

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Abstract

Purpose Pulse Decomposition Analysis (PDA) uses integration of the systolic area of a distally transmitted aortic pulse as well as arterial stiffness estimates to compute cardiac output. We sought to assess agreement of cardiac output (CO) estimation between continuous pulmonary artery catheter (PAC) guided thermodilution (CO-CCO) and a wireless, wearable noninvasive device, (Vitalstream, Caretaker Medical, Charlottesville, VA), that utilizes the Pulse Decomposition Analysis (CO-PDA) method in postoperative cardiac surgery patients in the intensive care unit.

Methods CO-CCO measurements were compared with post processed CO-PDA measurements in prospectively enrolled adult cardiac surgical intensive care unit patients. Uncalibrated CO-PDA values were compared for accuracy with CO-CCO via a Bland-Altman analysis considering repeated measurements and a concordance analysis with a 10% exclusion zone.

Results 259.7 h of monitoring data from 41 patients matching 15,583 data points were analyzed. Mean CO-CCO was 5.55 L/min, while mean values for the CO-PDA were 5.73 L/min (mean of differences +- SD 0.79 ± 1.11 L/min; limits of agreement − 1.43 to 3.01 L/min), with a percentage error of 37.5%. CO-CCO correlation with CO-PDA was moderate (0.54) and concordance was 0.83.

Conclusion Compared with the CO-CCO Swan-Ganz, cardiac output measurements obtained using the CO-PDA were not interchangeable when using a 30% threshold. These preliminary results were within the 45% limits for minimally invasive devices, and pending further robust trials, the CO-PDA offers a noninvasive, wireless solution to complement and extend hemodynamic monitoring within and outside the ICU.

Keywords Pulse decomposition analysis · Cardiac output · Hemodynamics · Wireless · Monitoring · Cardiac surgery · Postoperative · Intensive care unit

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1 Introduction

Accurate hemodynamic management and assessment is an important part of care for the hospitalized inpatient. Devices for this purpose are mostly invasive and come with additional technical complexities. This may restrict their use to care areas such as the operating room and the ICU.

However, changes in hemodynamics are common outside the ICU. One example is the emergency department, where invasive technologies such as arterial and Swan-Ganz catheters are rarely found, yet the need for assessing and adjusting fluid status is of extreme importance. Even when used in the critically ill, benefits for mortality, length of stay, cost, survival benefit, infectious morbidity, and other complications have not been conclusive with the PAC [1]. Another example is the general hospital floor where nearly half of all changes in blood pressure at a mean pressure less than 65mmHg are missed due to the lack of continuous monitoring [2]. Several noninvasive devices have attempted to fill this need, but introduction has been limited because of size, technical complexities, patient comfort, and cost issues [3, 4]. There remains a need for clinically validated wireless and small-footprint technologies that can be utilized quickly and effectively in different clinical care settings.

One approach to continuous, noninvasive measurement of blood pressure and cardiac output uses Pulse Decomposition Analysis (PDA). This physiological model uses the structure of an arterial pressure pulse and is based on the concept that two central reflection sites are responsible for the shape of the pressure pulse envelope [5–7]. These sites, one located at the aortic juncture of thoracic and abdominal aortas, the other at the iliac bifurcation, reflect the primary left ventricular ejection pulse to give rise to two additional, reflected, component pulses. Within the pulse pressure envelope of each cardiac cycle, quantification of the spatio-temporal behavior of these three component pulses that arrive sequentially in the arterial periphery, is used to monitor hemodynamic states and trends.

The Vitalstream®, the platform on which PDA runs, is a wireless, wrist-worn, continuous, noninvasive, physiological monitor (Caretaker Medical LLC, Charlottesville, Virginia) that is FDA-cleared for the measurement of heart rate (HR), continuous, noninvasive blood pressure (BP), respiratory rate, as well as cardiac output and or stroke volume, left ventricular ejection time, and heart rate variability [8, 9]. Using PDA to analyze the peripheral pulse at a distal site, typically the finger, the device tracks central aortic blood pressure, using a ,. low constant pressure [30–40 mmHg], pump-inflated, finger cuff that pneumatically couples arterial pulsations via a pressure line to the wrist-worn Vitalstream® device. PDA is also used to determine cardiac output (CO), which utilizes a linear model that incorporates arterial stiffness estimation, impedance correction [10], and integration over the "systolic" area of the pressure pulse, since knowledge of the structure of the pressure pulse plays a central role in determining CO in the PDA as well as other pulse analysis approaches [11–14]. Specifically, this entails determination of the pulse area corresponding to the actual left ventricular ejection pulse, as opposed to the overlapping contributions of reflected and trailing pressure pulses, which other approaches include by using the "dicrotic notch" incisura as the demarcation between systolic and diastolic phase [12].

The objective of this study was to prospectively assess the agreement between post-processed CO measurements obtained from the commonly used continuous pulmonary artery catheter (PAC)-based thermodilution method (CCO) and from the Vitalstream® PDA-based CO algorithm in ICU patients after on-pump cardiac surgery, without any calibration of the Vitalstream data to the reference system.

2 Methods

2.1 Study design and setting

This study was reviewed and approved by the Wake Forest University School of Medicine Institutional Review Board (IRB00074289;6/10/2021). Enrollment was conducted from October 2021 through December 2021 in the cardiovascular surgical ICU of the Wake Forest Baptist Medical Center. Informed consent was obtained retrospectively, once the subject completed their immediate post-surgical critical care period, and Vitalstream® use had ended. Retrospective consent was requested due to the passive nature of data collection in this study. Standard of care was maintained for enrolled patients and was not affected by the Vitalstream® monitor. Further, the Vitalstream® monitor was not used for any clinical decisions, nor were Vitalstream® alarms deployed at any stage. For the purpose of this analysis we report interchangeability thresholds in relationship to the 30% limits per Critchley and Critchley and 45% limits suggested for minimally invasive calibrated devices by Peyton and Chong criteria [2, 15, 16]. Continuous CO from the PAC, while not regarded as a reference gold standard, has been shown to pass interchangeability criteria compared to the intermittent thermodilution method and is the standard of care at our institution [17].

2.2 Inclusion and exclusion criteria

Included in the study were adult post-cardiac surgery patients requiring cardiopulmonary bypass and use of the PAC (following coronary artery bypass graft (CABG),

valve, heart transplant, major aortic and other vascular surgery, and a combination of CABG and valve procedures), and who were admitted to the ICU with a PAC (continuous thermodilution cardiac output) and an arterial catheter for blood pressure monitoring as standard of care.

Patients without an appropriately positioned or functioning PAC admitted to the cardiac ICU after surgery, as well as patients on left ventricular assist device support, extracorporeal membrane oxygenation, or an intra-aortic balloon pump were excluded from the study.

2.3 Measurements

Cardiac surgery ICU patients subject to standard BP monitoring via previously established invasive arterial catheters and CO monitoring via PAC were assessed for eligibility. Standard ICU standards and protocols were followed of leveling the pressure transducer to the right atrium and confirming zero of the system to atmospheric pressure. Square wave tests were performed if deemed necessary. Continuous reference thermodilution (CO-CCO) was recorded with the HemoSphere® monitor (Edwards Lifesciences), per institutional standard of care. Blood pressure and CO data were provided by a data capture system (Capsule Medical Device Information Platform, Andover, MA) with a 1-minute resolution.

The arterial pressure pulse signal was continuously measured, beat-by-beat and noninvasively, using the Vitalstream® device. This device was placed on the patient's wrist during the procedure setup, with the finger cuff coupled to the middle member of the middle finger, and data transmission was verified. Operation of the device would commence after an initial BP self-calibration procedure, lasting approximately 25 s, during which time the device would scan the finger cuff's coupling pressure from 0 to 250 mmHg while collecting the pressure-modulated arterial pressure pulse signal. At the end of the pressure scan, systolic and diastolic BPs were calculated from the processed signal envelope. Thereafter, the device was programmed to perform self-calibration scans at 15-minute intervals, operating in between in the continuous tracking mode with the finger cuff pressure collecting pulse data at a fixed baseline cuff pressure of between 20 and 45 mmHg. The coupling pressure for continuous operation was determined as part of the self-calibration procedure and held constant until the next procedure. Collected data were sent via Wi-Fi interface to an Android tablet for storage. The Vitalstream® device alarms were silenced, and data recorded passively.

Monitoring with the Vitalstream® monitor was started immediately in the post-operative period once the patient reached the ICU and discontinued once patient stay in the ICU exceeded 8 h, or if the arterial catheter had been removed, or if the patient left the ICU before 8 h.

2.4 Data processing

Data analyses were performed using post-processed Vitalstream® cardiac output data, meaning the cardiac output values were obtained by processing the recorded Vitalstream® arterial pulse signal as well as recorded Vitalstream® vital signs, such as heart rate, blood pressures etc. Time alignment of the Vitalstream® and reference data was established via time stamps in the EMR and by matching heart rate spectra from both systems.

Quality assessment of the reference data for the PDA was not possible because of the absence of arterial waveform data, which can be investigated for evidence of over- and under-damping as well as motion artifacts. In the case of the Vitalstream® data, a custom signal/noise factor (SNF) was used to identify poor quality data sections, which were excluded. The factor is based on the standard ratio of the variances of the physiological signal band to the noise band and obtained using Fourier spectral analysis over an 8-second window with 1-second overlap. The frequency range of the band associated with the physiological signal was set to 1–10 Hz, based on data by the authors and results by others [18], while the noise band was set to the 100–250 Hz frequency range, which is subject to ambient noise, but contains no signal relevant to the base band phenomena of the arterial pressure pulse or its propagation characteristics. Data sections with an $SNF < 80$ were excluded from the analysis.

2.5 Statistical analysis

We compared the accuracy of the Vitalstream®'s absolute CO values without calibration to the CCO values, as well as the trending ability, i.e., changing CO values of the Vitalstream® physiological monitor compared to those of the reference [19]. The analysis was performed using the MATLAB software package (Natick, USA). The accuracy against reference CO-CCO measurements was assessed via Bland-Altman analysis of the CO values and standard concordance analysis of the changing CO values (with a 10% exclusion zone). The Bland-Altman analysis took repeated measurements per subject into account [20].

Correlation and Bland-Altman analyses, i.e., mean of differences, +-standard deviation and the 95%-limits of agreement, were calculated for Vitalstream® data comparisons with the CCO reference.

Considering the well-known significant time delays associated with CO-CCO measurements [21], sensitivity and specificity for predicting significant CO changes [22],

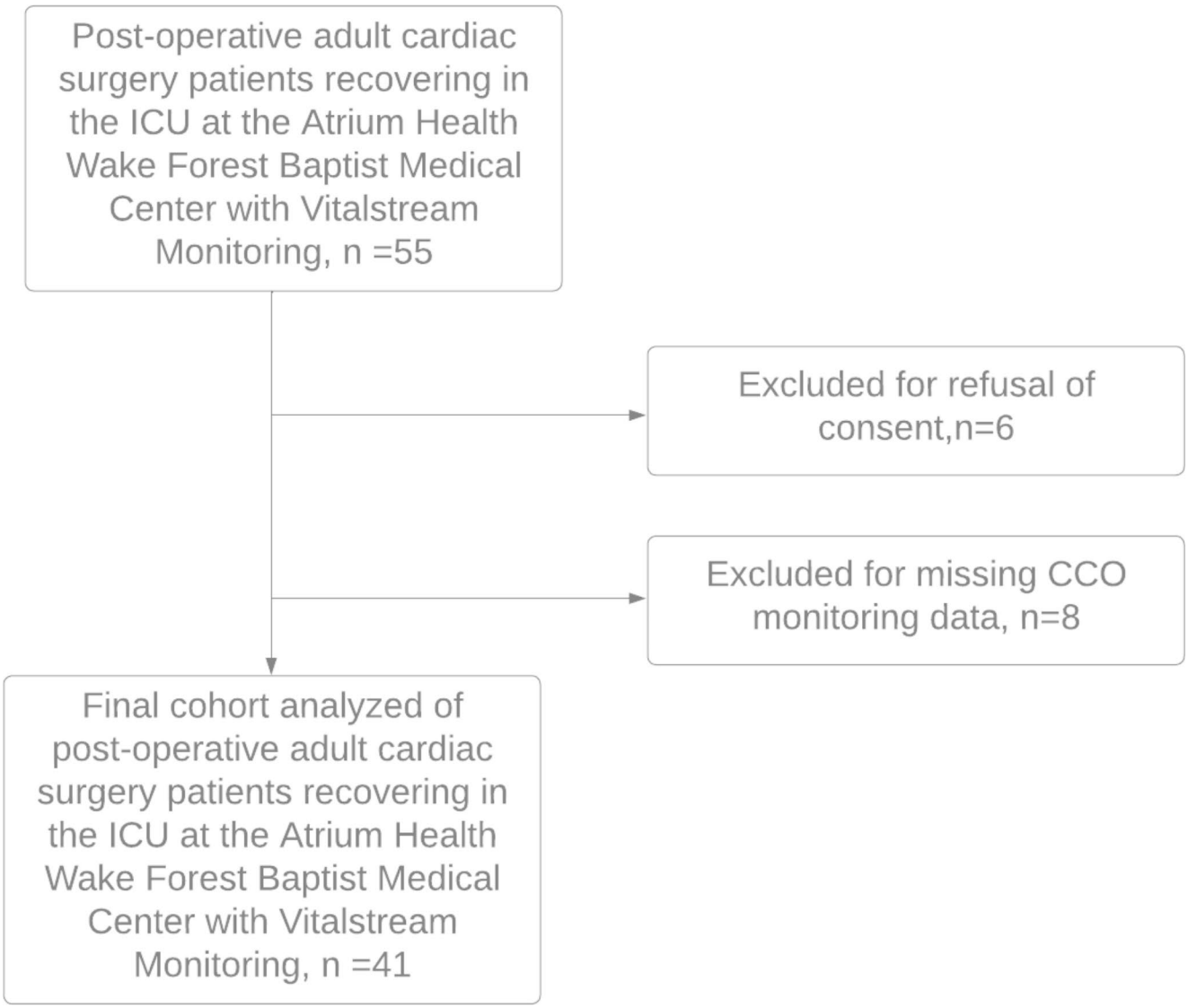

Fig. 1 Patient recruitment flowchart

defined as larger than 0.5 L/min, were investigated for different time delays using receiver operator curve (ROC) analyses. Optimal time delays were determined through cross correlation of the two trend data sets and then categorized relative to different delay thresholds. Sensitivity and specificity were determined from the resulting plot of true positive rate (TRP) against false positive rate (FRP). Numerical integration yielded the under-the-curve (AUC) value or discriminatory power.

3 Results

Discrete comparison CO data from 41 patients were analyzed. Patient recruitment flowchart is shown in Fig. 1. The Capsule data capture system and Vitalstream® data comparison yielded 15,583 data pairs, covering 259.7 h (median: 351 h; 5.85 h/patient, range: 3.5–8.91 h/patient). Since the Vitalstream® generates beat-by-beat CO data, the data points within a 20-second window bracketing the CCO reading were averaged to generate a comparison data point. Patient demographics are presented in Table 1. Figure 2 presents the correlation and Bland-Altman results for the CO data analysis. Correlation was moderate (0.54). Mean

Table 1 Baseline patient characteristics

	41 patients
Characteristic	Mean (SD) or N (%)
Age – mean (std) – yr.	64.5 (9.9)
Height – mean (std) – cm	173.5 (11.5)
Weight – mean (std) - kg	92.2 (22.4)
Male Sex – no. (%)	27 (65.8%)
BMI (kg/m2)	30.5 (6.38)

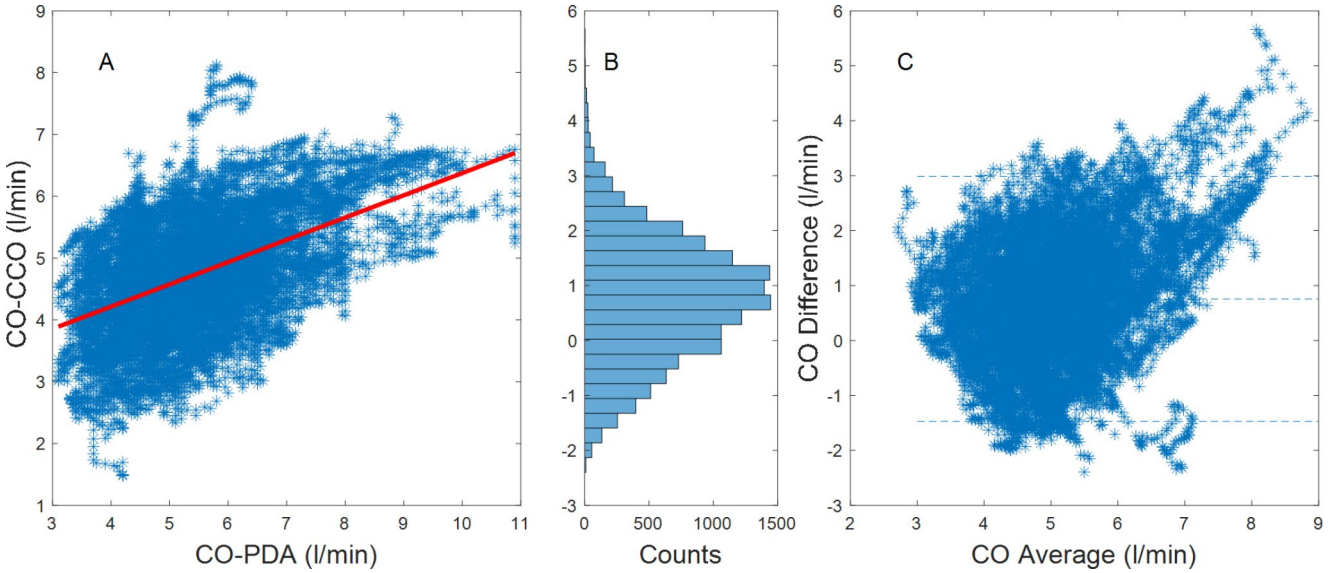

Fig. 2 Correlation and Bland-Altman analysis results. Correlation: 0.54, SD +-: 1.11 L/min, mean of differences = 0.79 L/min, error: 37.5%

value of CCO was 5.55 L/min, while the mean values for the Vitalstream® was 5.73 L/min. mean of differences ± SD per Bland-Altman analysis was 0.79 ± 1.11 L/min with limits of agreement − 1.43 to 3.01 L/min. The percentage error was 37.5%. Concordance was 0.83 and is shown with the trend graph presented in Fig. 3, which presents the trend data, with a 10% exclusion zone, as the surface plot of a 3D histogram to visually better resolve the trend data distribution.

Sensitivities and specificities for predicting CO changes larger than 0.5 L/min peaked for a time delay of 9 min, with discriminatory power (area under curve (AUC) of 0.96 and corresponding specificity and sensitivity, respectively, of 0.93 and 1.0. However, even for larger delays these measures remained significant. Specifically, at a time delay of 20 min, AUC, sensitivity, and specificity were, respectively, 0.89, 0.88, and 0.87.

4 Discussion

The results of this post-processed CO comparison study that examined measurements obtained with the noninvasive Vitalstream® CO-PDA with those of the reference CO-CCO, show that the absolute agreement between CO-PDA and CO-CCO was 35% and this was not clinically acceptable within the interchangeability limits of 30% set by Critchley and Critchley. However, this was acceptable within the 45% limits suggested for minimally invasive calibrated devices by Peyton and Chong criteria [2, 15, 16] .

These results are in line with those of comparison studies using other noninvasive as well as invasive technologies [3, 4, 23]. It is important to note that invasive monitoring technology are usually less, or not at all, subject to the interferences that affect pulse analysis-based and noninvasive technologies, such as physiology- or environment-induced low perfusion, motion or vibrational issues, as well as issues related to vascular tone changes. However, the trade-off for these is the allowance for difference clinical applications such that non-invasive devices may be used in the more mobile critically ill patient and transition to care outside the ICU. Furthermore, non-invasive devices may not necessarily be interchangeable for invasive ones in at least some of these patients.

Previously the PDA model, has been used in clinical comparison studies of blood pressure [24, 25]. We now report cardiac output determination with the Vitalstream® that utilizes PDA-provided parameters of the systolic area of the pressure pulse envelope. Other traditional waveform analysis approaches have utilized the “dichrotic” notch to separate systolic and diastolic phases [12]. However, these methods may be inaccurate since such categorization yields integration over both the actual systolic component pulse area as well as sections of reflected component pulses that complete the pulse envelope [8]. This is particularly important because the area of the first reflection pulse, or the renal reflection, is highly blood pressure dependent. Concordance rate of our results were also comparable with those obtained with other referenced technologies [23], suggesting that the CO-PDA offers value in continuous CO trending. This is clinically relevant and especially so in the patient who is being actively titrated on vasopressors-inotropes and fluids.

The merit of this work is the novel wireless, wearable technology being examined in a clinically relevant setting of the postoperative cardiac surgical patient. While there is enough invasive monitoring performed as standard of care in this patient population, this is also rapidly de-escalated as

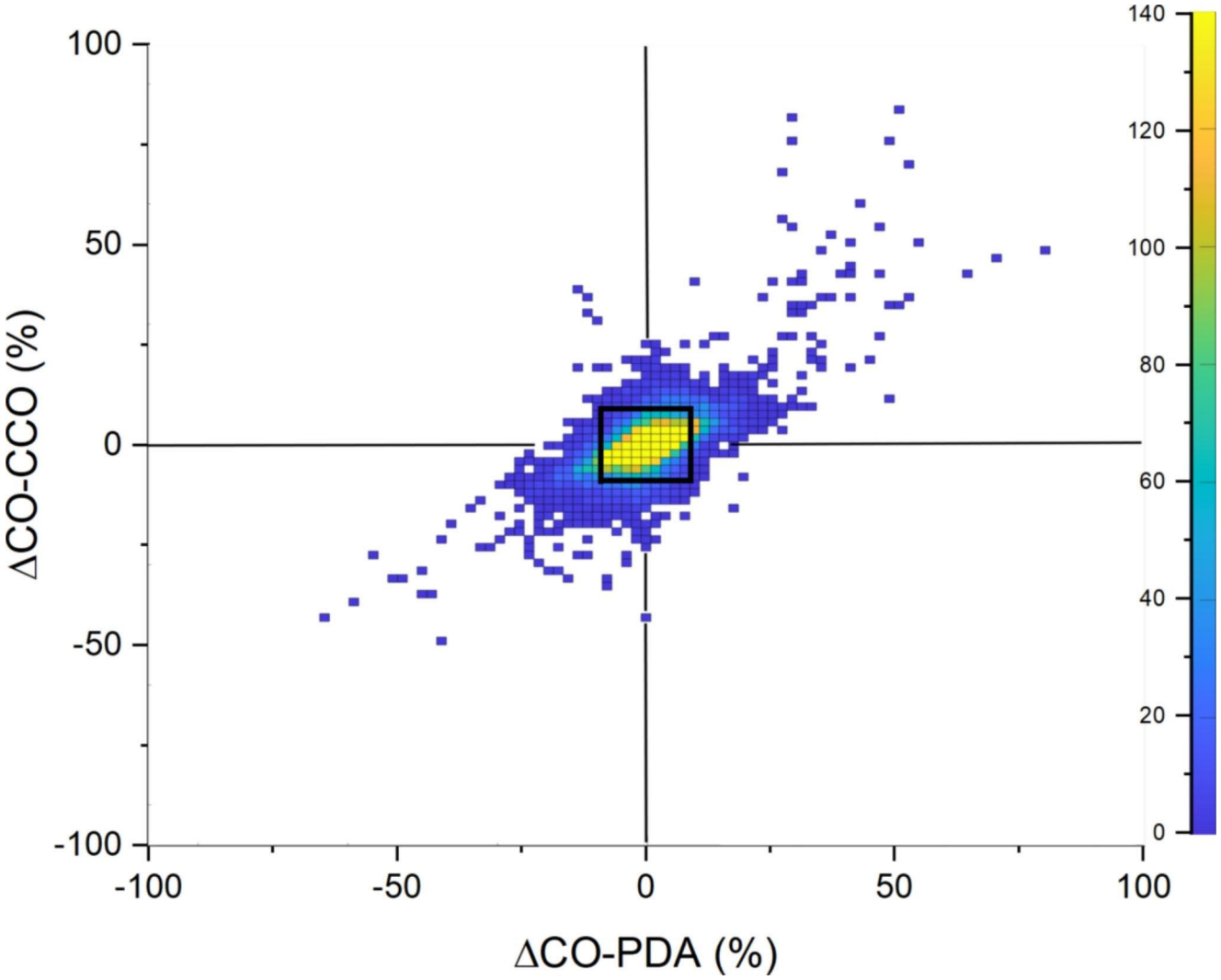

Fig. 3 Results of trend analysis. Concordance: 0.83. Presented is a surface plot of a 3D histogram with a resolution of 0.325% in both dimensions. Also shown is the 10% exclusion zone, which is signified by the black square

the patient recovers. Here the PDA guided portable CO could provide a bridge of enhanced monitoring over and above traditional blood pressure as these patients transition out of the ICU. We included a myriad of cardiac surgical patients, with data both during deeply sedated mechanical ventilated states and spontaneously breathing awake patients and captured dense, granular 1-minute sampled information from the reference monitors. While we did not specifically ask the question the portable monitoring device was well tolerated by awake patients and none of our patients asked for this to be removed before the 8 h monitoring period ended.

Our analysis is limited by a small sample size and single center experience limiting generalizability. Other method comparison studies have used a similar number of patients in the cardiac surgery ICU. Despite 41 patients, we had over 15,000 comparison data points because of the ability to capture bedside vitals at 1-minute sampling windows. Continuous cardiac output Swan-Ganz measurements are used very commonly in clinical practice. However, some data suggests that there is delay in response time reported from 10 to 12–24 min for the continuous thermodilution PAC [28, 29]. We are unsure of how this time lag would have affected our analysis. Furthermore, while arrhythmias, specifically atrial fibrillation, are common after cardiac surgery, only three patients displayed arrhythmias, because of this we did not specifically look at the influence of this rhythm disturbance on the performance of the PDA. We did not have waveform data from the CO-CCO. However, we excluded patients who had obviously misplaced PACs on arrival to the ICU and our clinicians and ICU nurses do check Swan-Ganz waveform quality at the bedside per institutional protocol. Even then, it is possible that patients with inappropriately positioned PAC during ICU stay or those with occlusions to the distal end resulting in erroneous CO

calculations could have been included in the analysis. Such periods of less-than-optimal monitoring would be minimal if any. Our reference method was continuous thermodilution with one minute sampling and while we did do a four-quadrant concordance trending analysis, this may not be as meaningful as when the reference would be an intermittent thermodilution done at a certain specific time point. On the same lines, we could not generate data for a trending analysis specific to clinical interventions in the ICU such rapid changes in intravascular volume, contractility, or a combination. Finally, with the ready availability of bedside transesophageal echocardiography (TEE) in the cardiac surgical ICU and accurate estimation of cardiac output derived from an appropriately performed exam, validation against and utility compared with the TEE should be looked at in future studies.

There is concern that some motion-artifact compromised reference data for the PDA were included in the analysis, since reference arterial catheter waveform data were not available. While the usual concern is underdamped or resonant response (a problem other investigators have found to be the case on the order of 25% [30, 31], analysis of arterial catheter waveforms would have further facilitated identification of interferences that, given the reference data's granularity, was only possible based on the Vitalstream®'s pulse waveform data.

5 Conclusions

In ICU patients recovering after cardiac surgery, compared with the CO-CCO Swan-Ganz, cardiac output measurements obtained using the CO-PDA did not agree with the 30% thresholds set by Critchley and Critchley but agreed with the 45% limits suggested for minimally invasive calibrated devices by Peyton and Chong criteria. Pending robust interventional trials, these preliminary results may allow us to complement and extend traditional invasive monitoring as we expand access to effective, wireless, portable, and readily implemented hemodynamic management monitoring tools to patients within and outside hospital sections previously not covered.

Abbreviations

ICU	Intensive care unit
BMI	Body mass index
AKI	Acute kidney injury
KDIGO	Kidney Disease: Improving Global Outcomes
SD	Standard Deviation

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Author contributions AKK: Investigation, Conceptualization, Writing - Review & Editing; JG: Data Collection, Writing – Editing AS: Data Collection, Writing – Editing; MB: Data Analysis, Writing – Editing LH: Data Collection, Writing – Editing RSM: Data Collection, Writing – Editing. All authors reviewed the manuscript.

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Declarations

Ethics approval and consent to participate This research meets the criteria for a waiver of consent entirely according to 45 CFR 46(d).

Informed Consent Wake Forest University School of Medicine?s IRB granted a waiver of consent for this study.

Competing interests MB is an employee at Caretaker Medical the manufacturer of the Vitalstream monitor. AKK consults for Medtronic, Edwards Life Sciences, Philips Research North America, GE Healthcare, Potrero Medical, Retia Medical and Caretaker Medical. He is also funded with a Clinical and Translational Science Institute (CTSI) NIH/NCTAS KL2 TR001421 award for a trial on continuous postoperative hemodynamic and saturation monitoring. The department of anesthesiology is supported by Edwards Lifesciences under a master clinical trials agreement. He is a founding member of the BrainX group.

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