Correlation of Cardiac Output Estimation by Analysis of Arterial Blood Pressure Waveforms versus Continuous Pulmonary Artery Thermodilution in Post Cardiac Surgery Intensive Care Unit Patients

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Abstract

Purpose

We sought to assess agreement of cardiac output estimation between continuous pulmonary artery catheter (PAC) guided thermodilution (CO-CTD) and a novel method that performs an analysis of multiple beats of the arterial blood pressure waveform (CO-MBA) in post-operative cardiac surgery patients.

Methods

PAC obtained CO-CTD measurements were compared with CO-MBA measurements from analysis of arterial blood pressure waveforms using the Argos monitor (Retia Medical; Valhalla, NY, USA), in prospectively enrolled adult cardiac surgical intensive care unit patients. Correlation between paired values of CO-CTD and CO-MBA was computed, and agreement was assessed via Bland-Altman analysis. Subgroup analysis was performed on data segments identified as arrhythmia.

Results

927 hours of monitoring data from 79 patients was analyzed, of which 26 had arrhythmia. Mean CO-CTD was 5.29 ± 1.14 L/min (bias ± precision), whereas mean CO-MBA was 5.36 ± 1.33 L/min, (4.95 ± 0.80 L/min and 5.04 ± 1.07 L/min in the arrhythmia subgroup). Mean of differences was 0.04 ± 1.04 L/min, 95% limits of agreement: -2.00 to 2.08 L/min, and a percentage error of 38.2%. In the arrhythmia subgroup, mean of differences was 0.14 ± 0.90 L/min, 95% limits of agreement: -1.63 to 1.91 L/min and percentage error of 35.4%. Paired observations showed a moderate correlation throughout the cohort (r = 0.64).

Conclusion

CO measurements using a novel multi-beat analysis of the arterial pressure waveform are reasonably correlated with traditional more-invasive continuous PAC thermodilution guided cardiac output measurements in adult patients after cardiac surgery including in those with arrythmias.

1. Introduction

Cardiac surgery patients show dynamic and complicated changes in hemodynamics. Initially developed about five decades ago, pulmonary artery catheters (PACs) have long been used for invasive hemodynamic monitoring in these patients. [1] Evidence for mortality, length of stay, cost, survival benefit, infectious morbidity and other complications have been mixed with this intervention. [1–5] Recently, the continuous cardiac output pulmonary artery catheter has been shown to pass interchangeability criteria compared to the intermittent thermodilution method. [6]

Pulse contour analysis devices are a class of minimally-invasive methods which analyze the arterial blood pressure wave form to determine stroke volume and cardiac output. [7] These devices employ algorithms that often model the arterial tree as a two-element Windkessel model. This model considers the compliance of large arteries and resistance of smaller arteries as two components thereby meaning that during diastole, blood pressure would decay in an exponential manner. [8] However, a smooth exponential decay in diastole is rarely seen in clinical practice due to distortions caused by wave reflections from the periphery. Multi-Beat Analysis (MBA™) is a novel method that aims to account for the confounding wave reflection. Here multiple beats are used to model the circulation, following which an exponential function is fit to the tail end of the arterial tree impulse response, after the distortions due to wave reflection have vanished. [8] In theory, this allows an accurate characterization of systemic vascular resistance and thus cardiac output.

The Argos monitor, (Retia Medical; Valhalla, NY, USA) utilizes this proprietary Multi-Beat Analysis (MBA™) algorithm to allow for beside cardiac output monitoring. Here cardiac output is estimated and displayed every 5 seconds. This technique was examined in 31 patients in the intensive care unit following off pump coronary artery bypass (OPCAB) surgery against a reference standard of intermittent thermodilution with an overall error of 40.7% and a concordance of 88% thereby determined to be reasonable agreement and trending ability. [9]. During OPCAB surgery, the monitor was 89% concordant with intermittent thermodilution.[10] In non-cardiac surgery, the MBA method was 93% concordant with the transesophageal Doppler method during both fluid and vasopressor administration. [11]

To the best of our knowledge there is no examination of cardiac output measurements using the multi beat analysis method against a reference of continuous cardiac output thermodilution via the pulmonary artery catheter in patients recovering from cardiac surgery. Furthermore, correlation of these techniques including presence of arrhythmias has not been done. Here we prospectively assess the agreement between a traditional continuous pulmonary artery catheter guided thermodilution method and cardiac output estimation using a novel method that analyses multiple beats of the arterial blood pressure waveform including in those critically ill patients with arrythmias after on-pump cardiac surgery.

2. Methods

2.1 Study design and setting

This study was reviewed and approved by the Wake Forest School of Medicine Institutional Review Board (IRB number and date of approval: Wake Forest School of Medicine (IRB00065503); 6/18/2020). The IRB also determined that this research met the criteria for a waiver of consent entirely according to 45 CFR 46(d). The purpose of this work was to compare CO measurements between the multi-beat analysis method (MBA™) and the continuous thermodilution (CTD) method via a pulmonary artery catheter. The study was conducted from July – December 2020 in the cardiovascular surgical intensive care unit of the Wake Forest Baptist Medical Center, a tertiary academic care center part of the Wake Forest School of Medicine.

2.2 Inclusion and exclusion criteria

Adult patients scheduled for elective cardiac surgery (both coronary artery bypass and or valve surgery) on cardiopulmonary bypass, and who received a radial arterial catheter and a pulmonary artery catheter per clinical indications were included in this study. Exclusion criteria included patients less than 18 years of age, those with mechanical circulatory support (e.g., LVADs, ECMO or intra-aortic balloon pumps) or patients with moderate to severe aortic regurgitation, per the contraindications of the Argos monitor.

2.3 Study measurements

After receiving patients in the ICU, standard blood pressure monitoring was continued via the previously established radial arterial catheter and via a transducer to a bedside multi-parameter monitor (Philips Intellivue, Cambridge, MA). 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. The Argos monitor (Retia Medical LLC., Valhalla, NY, USA) received the radial blood pressure waveform from the bedside monitor via a reusable cable. Patient demographics were entered into the Argos monitor and cable connections were checked to ensure that the blood pressure waveform was being received correctly by the Argos monitor. Subsequently, the front screen of the Argos monitor was covered, so monitoring data was acquired in a user blinded fashion. Research personnel performed intermittent checks of the integrity of the recording system. No patient interventions were performed based on cardiac output numbers on the Argos monitor. Monitoring and data collection continued till patient discharge from the intensive care unit or discontinuation of the arterial line or failure of the arterial line, whichever came first.

Cardiac output readings from the pulmonary artery catheter were calculated by the HemoSphere monitor (Edwards Lifesciences, Irvine, CA, USA) and were continuously recorded by a connected data capture system (Capsule Medical Device Information Platform, Andover, MA). The Argos monitor records CO-MBA measurements once every 5 seconds, while the Capsule system records CO-CTD once every minute. After each patient's ICU stay, data from the Argos monitor and the Capsule system were exported to a computer for further analysis. Data synchronization was ensured by matching the timestamps from the two sources.

2.4 Data processing

100 patients were enrolled, of which 6 were excluded due to unavailability of cardiac output data from the pulmonary artery catheter (CO-CTD). Another 2 subjects were excluded due to removal of the pulmonary artery catheter before application of the Argos monitor. Another 2 subjects were excluded due to blood pressure waveforms unavailable to the Argos monitor (CO-MBA), potentially due to a loose cable connection. One subject was excluded because minute-by-minute CO-CTD could not be extracted from the Capsule system due to technical reasons.

Blood pressure waveforms and continuous thermodilution measurements were visually inspected to determine any artifact or improperly damped waveforms. While the appearance of non-physiological signals is clear, inadequate damping is more difficult to assess. Overdamping, where the blood pressure waveform shows a progressive narrowing of pulse pressure, can be clinically easier to detect and correct, as the cause is often a kink or an air bubble in the transducer tubing [12]. Underdamping, results in systolic and diastolic overshoots, causes widening of the pulse pressure and can be more difficult to detect [12]. We inspected the fast flush response when available [13], the waveform morphology, and the maximum systolic slope (dP/dt max) of the BP waveform to determine inadequately damped data, which were excluded from further analysis [14]. Data from 89 subjects was available for further analysis, of which we identified 10 subjects (11%) as having consistently underdamped BP signals and were excluded. In 31 of the remaining 79 subjects, data were partially excluded due to artifact or inadequate damping. After all exclusions, 927 hours of data, corresponding to 55599 CO-CTD and CO-MBA data pairs, were available from 79 subjects. Blood pressure waveform segments were visually inspected by two anesthesiologists blinded to cardiac output measurements, to determine persistent arrhythmia or extrasystoles. These data segments constituted the arrhythmia subgroup. Of these, 4555 data pairs in 26 patients were marked with an arrhythmia or extrasystole label.

2.5 Statistical analysis

Continuous thermodilution cardiac output has been shown to have a delayed response, especially under unstable hemodynamic conditions [15]. For the data collected in this study, plotting CO-CTD and CO-MBA onto the same graph revealed that the delay in continuous thermodilution was maximally up to 24 minutes (supplementary Fig. S1 A and S1 B).

Supplementary figures: Examples comparing the time delay in CO-CTD to CO-MBA are shown in Fig. S1. The time delay can be variable (Fig. S1(A) and S1(B)). If this time delay is not considered, the results can be erroneous. For e.g. in Fig S1(A), comparing CO-MBA to CO-CTD at 2300 hrs. leads to CO-MBA = 3.5 L/min and CO-CTD = 5.1 L/min, with a difference of 1.6 L/min between the two. We used a simple 1-hr moving average over both signals (CO-CTD and CO-MBA) to reduce the influence of these errors.

Accordingly, we averaged the continuous thermodilution cardiac output over one hour to average out any instabilities and delays. CO-MBA was similarly averaged and then resampled to one measurement every minute to allow paired comparisons with CO-CTD.

Patient demographic distributions were summarized as mean ± standard deviation for continuous quantities (age, height, weight, and BMI) and as integers for the Male/Female distribution. CO-CTD and CO-MBA distributions over all patients were summarized as mean ± standard deviation. CO-CTD and CO-MBA data pairs were analyzed according to correlation and Bland-Altman statistics, considering multiple observations within subjects [16, 17]. We calculated the mean and standard deviation of the paired difference between CO-CTD and CO-MBA (bias and precision), the 95% limits of agreement (bias ± 1.96 x precision), and the percentage error [18]. All analyses were performed in MATLAB (Mathworks Inc., Natick, USA)

3. Results

Patient demographic distributions are summarized in Table 1.

Table 1
Baseline patient characteristics. Data are shown as absolute and relative frequencies or mean and standard deviation.

Number of included patients, n	**79**
Age (years)	66 ± 9
Sex, female [n (%)]	21 (27)
Height (cm)	173 ± 10
Weight (kg)	87 ± 23
BMI (kg/m^2)	29.1 ± 6.6

Correlation between CO-CTD and CO-MBA was moderate (r = 0.64, Fig. 1). Mean value of CO-CTD across all subjects was 5.29 ± 1.14 L/min. Mean CO-MBA was 5.36 ± 1.33 L/min. Mean difference between CO-CTD and CO-MBA (bias ± precision) per Bland-Altman analysis was 0.04 ± 1.04 L/min. Limits of agreement were − 2.00 to 2.08 L/min (Fig. 2). The percentage error was 38.2%.

In the arrhythmia subgroup, mean value of CO-CTD across all subjects was 4.95 ± 0.80 L/min. Mean CO-MBA was 5.04 ± 1.07 L/min. Correlation between CO-CTD and CO-MBA is shown in Fig. 3 (r = 0.64). Mean difference between CO-CTD and CO-MBA (bias ± precision) per Bland-Altman analysis was 0.14 ± 0.90 L/min. Limits of agreement were − 1.63 to 1.91 L/min (Fig. 4). The percentage error was 35.4%.

4. Discussion

This prospective analysis of 927 hours of data from post-operative cardiac surgery patients recovering in the intensive care unit showed a moderate correlation between the gold standard of measurement (CO-CTD via the pulmonary artery catheter) and the CO-MBA method using the peripheral arterial waveform.

Intermittent pulmonary artery thermodilution uses injection of several fluid boluses with a known volume and temperature into the right atrium. The temperature change detected by a distal thermistor is then used to calculate the cardiac output [19]. In contrast, continuous pulmonary artery thermodilution uses a thermal filament in the right ventricle, without the need for manual injections [19]. This method has been proven to be as accurate and reliable as standard bolus thermodilution, and both methods are used clinically to manage the hemodynamic status of critically ill patients [20]. This report is the first analysis of agreement between the continuous cardiac output Swan-Ganz catheter (CO-CTD) and the novel multi-beat analysis of arterial waveform (CO-MBA). Animal data and retrospective analysis from ICU data comparing cardiac output with the CO-MBA against a reference calibrated standard have reported good agreement.[7, 21, 22]

A debate about the merits of PAC placement has been ongoing with multiple large scale studies both showing and failing to show an overall clinical benefit to placement [1]. Adverse events ranging in severity from self-limiting arrhythmia to pulmonary artery rupture have been reported in the literature with an incidence from two to seventeen percent [2]. Less invasive methods of cardiac output determination, such as the CO-MBA, may allow the intensivist to avoid the PAC and supplement it in other situations where extended periods of monitoring may be necessary. Multiple studies have compared various pulse contour cardiac output methods to intermittent bolus thermodilution cardiac output via the PAC and have shown good correlation, concordance, and lower percentage errors [23–28] Accuracy of measurement is critical, and our analysis showed a percentage error of 38.2% and a mean of differences 0.04 ± 1.04 L/min, 95% limits of agreement: -2.00 to 2.08 L/min, in the full cohort and a percentage error of 35.2% and a mean of differences 0.14 ± 0.90 L/min, 95% limits of agreement: -1.63 to 1.91 L/min in the in the arrhythmia cohort respectively. Although the CO-MBA agreement with CO-CTD reported here, is outside the 30% error limit set by the well-known Critchley and Critchley analysis [18] other meta analyses of a combination of calibrated and uncalibrated methods have found that the error in clinically used pulse contour devices is about 42%. [29]

Greiwe and colleagues also specifically compared the CO-MBA during off pump coronary artery bypass graft surgery and in the intensive care unit using intermittent thermodilution in a method comparison study afterwards.[9] They had a smaller sample size than our report (167 comparison points; 31 patients) and performed bolus thermodilution cardiac output measurements at seven pre-defined time points. Furthermore, this was not a real time data collection with a bedside monitor, rather was an offline analysis where arterial blood pressure waveforms were fed into the Argos monitor retrospectively. Percentage error reported was 40.7% and not very different from the 35–38% range in our cohorts. Our results are also consistent with the CO-MBA technique method comparison analysis reported in the cardiac operating room by Saugel and colleagues [10]. CO estimations showed reasonable agreement and trending ability between the two methods, with a concordance rate of 89%. [10] Another recent study comparing the Argos and FloTrac monitors, showed that Argos was more accurate with a higher concordance rate, and thus may prove valuable in CO trending. Although, both devices were not interchangeable with thermodilution for absolute CO measurement due to high percentage errors of 50% . [30] We identified 10 subjects (11%) as having consistently underdamped blood pressure signals on the arterial line and were excluded. For comparison, other investigators have previously excluded 9 out of 40 subjects (23%) and found 92 out of 300 subjects (31%) to have underdamping or resonant arterial lines in similar patient populations. [9] [14]

Up to a third of patients have atrial and ventricular arrhythmias after cardiac surgery.[31] Some of these rhythm changes last for a significant amount of time and are associated with hemodynamic instability. This may result in periods of under perfusion and trigger organ system injury We specifically analyzed a subgroup of patients with rhythm disturbances identified by two anesthesiologists and found moderate correlation here as well. The reliability of cardiac output measurements during rhythm instability shown in this work is of critical significance. Even though we only had 26 patients in this subgroup, our work serves as hypothesis generating for future analysis where specific types, times and durations of rhythm changes could be analyzed in larger cohorts.

This work is novel and has several advantages. We had a large dataset with highly granular comparative data with CO-MBA measurements recorded once every 5 seconds, and CO-CTD recorded once every minute, generating 55599 CO-CTD and CO-MBA data pairs, and over 900 hours of usable data. Furthermore, we performed post processing, where we averaged out the CO-CTD over an hour and the CO-MBA to once every minute, to compensate for the difference in response time between the CO-MBA and the continuous cardiac output swan-Ganz. Patients were prospectively enrolled into the study, with broad inclusion criteria, and data for the CO-MBA and the CO-CTD was recorded real-time at the bedside. The CO-MBA was blinded, alarms silenced, and clinicians followed standard management protocols with the pulmonary artery catheter. Our bedside ICU nurses routinely check the integrity of the arterial line using the 'fast-flush test' which allowed us an assurance that the data generated was accurate.[13, 32, 33] In addition, visual inspection of available data by two experienced anesthesiologists let us exclude segments of over damped or under damped arterial line morphology. Rhythm disturbances being common after cardiac surgery, this analysis was the first comparison of agreement with a subgroup of patients with these elements, in addition to being the first analysis to use the continuous cardiac output from the PAC as a comparator.

There are some limitations to this analysis as well. While we allowed for adjustments for CO response time differences between the two comparison methods by averaging both methods over a one-hour time scale, this may have the effect of reducing the variance in both methods. We are unsure of the clinical validity and relevance of an earlier detection of a change in cardiac output, however, our delay in response time reported (12–24 minutes) for the continuous thermodilution swan-Ganz is not different from published work reporting a response time of 10 minutes or more. [15]Furthermore, the arrythmia subgroup involved a small sample size, was of uncertain clinical significance including the actual hemodynamic changes involved, and the specific nature or duration of the rhythm disturbances. This was novel all the same, and relevant since rhythm disturbances are very common in the post-operative cardiac surgery patient. While removing artifactual and underdamped or overdamped arterial line waveforms and data was crucial, we could have introduced a selection bias and made this data non-representative of the real world where such periods of less-than-optimal monitoring constitute a non-trivial part of the total monitoring time of a critically ill patient in the ICU. In CO method comparison studies with intermittent thermodilution as the reference method, a four-quadrant concordance analysis is often suggested as a way to assess the trending agreement. Here, because the reference method was continuous thermodilution with consecutive samples being one minute apart, a meaningful four-quadrant analysis could not be performed. In addition, we did not plan for comparisons at specific interventions such fluid loading or rapid changes in inotropy or afterload and could not perform a trending analysis. Finally, this work comes from a single center and may be reflective of local practice patterns precluding generalizability.

5. Conclusions

Cardiac output estimations using a multi-beat analysis of the radial arterial blood pressure waveform show a reasonable agreement compared with continuous thermodilution cardiac output measurements in adult patients recovering in the intensive care unit after on-pump coronary artery bypass surgery including those with arrhythmia. There may be an opportunity to use less invasive technology to measure cardiac output continuously and accurately in critically ill cardiac surgery patients in the post-operative period to supplement and extend monitoring beyond the duration of a swan-Ganz catheter.

Glossary of Abbreviations

Intensive care unit (ICU)

Body mass index (BMI)

Acute kidney injury (AKI)

Kidney Disease: Improving Global Outcomes (KDIGO)

Declarations

Acknowledgments:

None

Conflicts of interest:

HA is an employee at Retia Medical, the manufacturer of the Argos monitor. AKK consults for Medtronic, Edwards Life Sciences, Philips 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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Ethics approvals:

This research meets the criteria for a waiver of consent entirely according to 45 CFR 46(d)

IRB number and date of approval: Wake Forest School of Medicine (IRB00065503); 6/18/2020

Informed Consent Statement:

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

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Figures

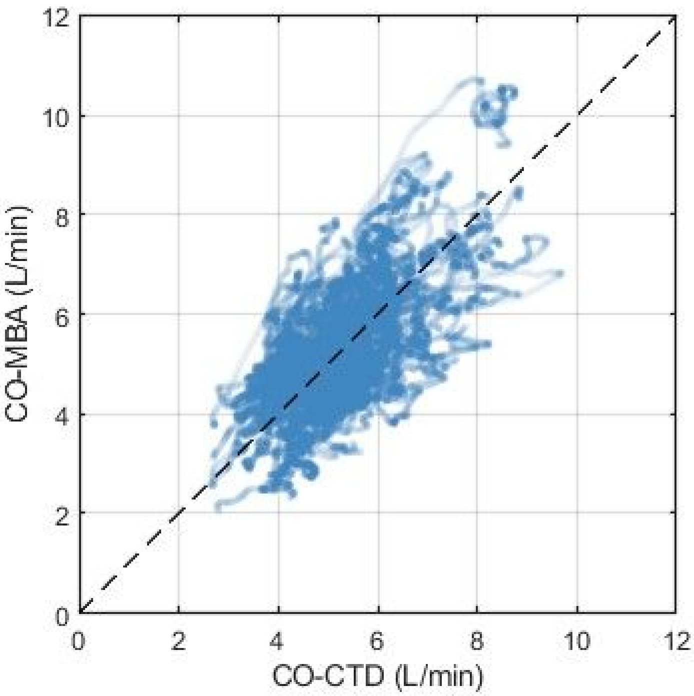

Figure 1

Correlation plot between CO-CTD and CO-MBA.

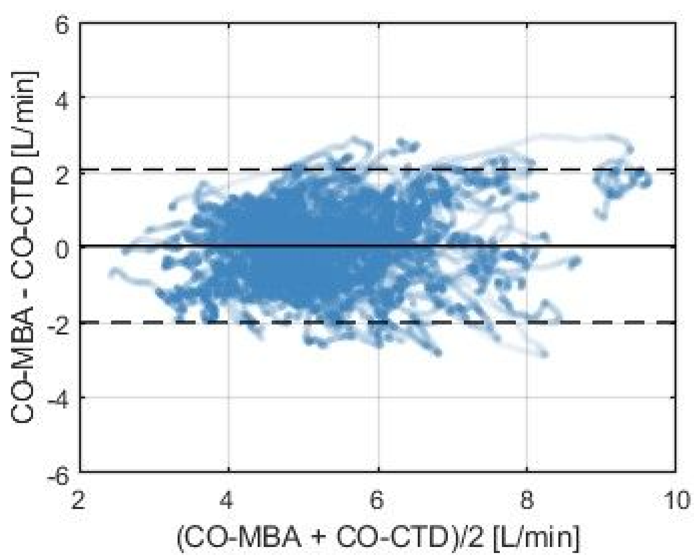

Figure 2

Bland-Altman plot showing agreement between CO-CTD and CO-MBA. Bold horizontal line indicates bias, and dashed lines indicate 95% limits of agreement.

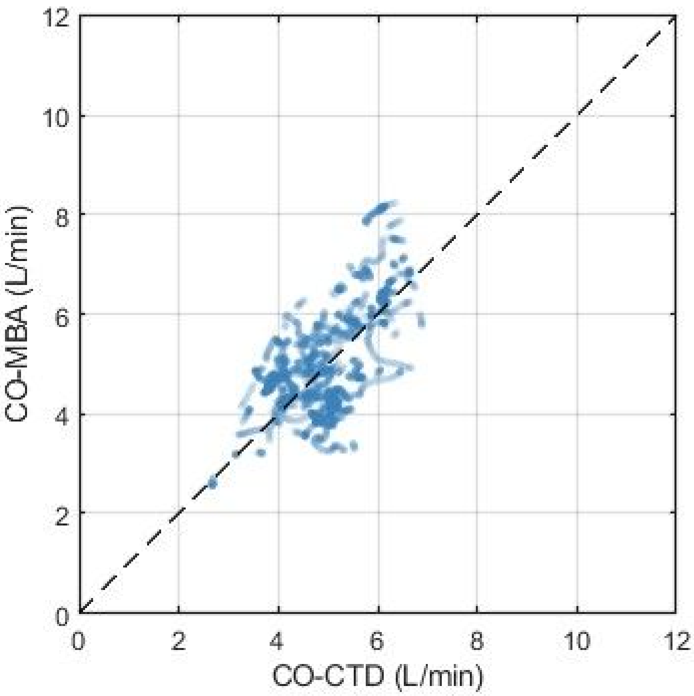

Figure 3

Correlation plot between CO-CTD and CO-MBA for the arrhythmia subgroup.

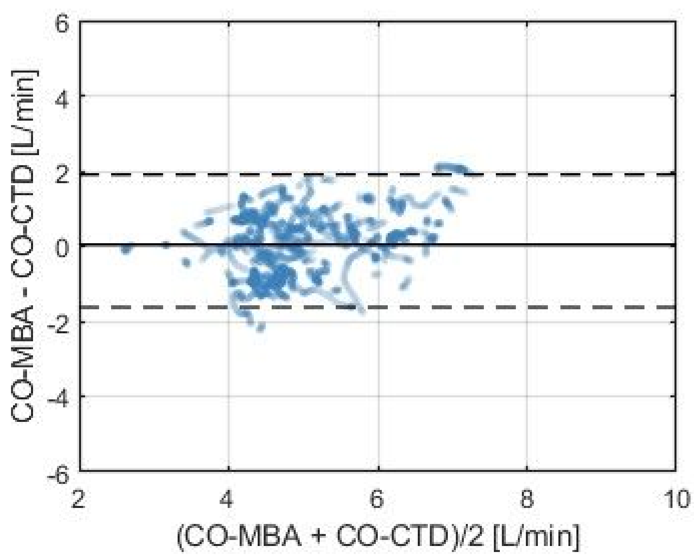

Figure 4

Bland-Altman plot showing agreement between CO-CTD and CO-MBA for the arrhythmia subgroup. Bold horizontal line indicates bias, and dashed lines indicate 95% limits of agreement.

Supplementary Files

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- FigS1.jpg