VIA MEDICA

PRACE ORYGINALNE I KLINICZNE

Anestezjologia Intensywna Terapia
2017, tom 49, numer 3, 181–186
ISSN 0209–1712
www.ait.viamedica.pl

Comparison of the ability of esCCO and Volume View to measure trends in cardiac output in patients undergoing cardiac surgery

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Abstract

Background: Cardiac output (CO) is a physiological variable that should be monitored during cardiac surgery. The purpose of this study was to assess the trending ability of two CO monitors, esCCO (Nihon Kohden™, Tokyo, Japan) and Volume View (VV) (Edwards Lifesciences, Irvine, USA).

Methods: A total of 19 patients were included in the study. Before cardiopulmonary bypass (CPB), CO was measured simultaneously using both esCCO and VV devices before and after three CO-modifying manoeuvres (passive leg raise [PLR], the end expiratory occlusion test [EEOT] and positive end expiratory pressure [PEEP] at 10 cm H_2O). Five CO values for esCCO and three for VV were averaged and compared during a one-minute period of time before and after each manoeuvre.

Results: A total of 114 paired readings were collected. Median CO values were 4.3 L min^{-1} (IQR: 3.8; 5.2) and 3.8 L min^{-1} (IQR: 3.5; 4.5) for esCCO and VV, respectively. The precision error was 1.4% (95% CI:1.0–1.7) for esCCO and 2.2% (95% CI: 1.8–2.7) for VV. The bias between esCCO and VV values was normally distributed ($P = 0.0596$). Between esCCO and VV, the mean bias was +0.6 L min^{-1} with a Limit of Agreement (LOA) of –1.8 L min^{-1} and +3.0 L min^{-1}. The concordance rate was 43% (95% CI: 29–58) between esCCO and VV.

Conclusion: Both single and trended measurements of CO using esCCO and VV were not in agreement. This large discrepancy leads one to the conclusion that any outcome study conducted with one of these devices cannot be applied to the other.

Anestezjologia Intensywna Terapia 2017, tom 49, nr 3, 181–186

Key words: non-invasive monitoring, cardiac output, cardiac surgery, general anaesthesia

Cardiac output (CO) is a powerful physiological variable that should be monitored within the operating room for high-risk patients and in cardiac surgery [1]. Once measured, it should be subsequently used to assess and guide therapeutic decisions. For many years, the pulmonary arterial catheter was considered to be the reference method used to determine CO. However, this technique is invasive and can lead to critical complications, which have resulted in its decreased use over the past 10 years [2–3]. As a result, several minimally and non-invasive CO monitors have emerged on the market. One of these emerging technologies is the estimated continuous cardiac output monitor (esCCO, Nihon Kohden, Tokyo, Japan) which estimates CO in a completely non-invasive way using only an electrocar-

Należy cytować wersję anglojęzyczną: Dache S, Van Rompaey N, Joosten A et al. Comparison of the ability of esCCO and Volume View to measure trends in cardiac output in patients undergoing cardiac surgery. Anaesthesiol Intensive Ther 2017, vol. 49, no 3, 175–180, doi 10.5603/AIT.2017.0043.

diogram (ECG), a plethysmographic waveform, as well as non-invasive blood pressure management. As described more in depth elsewhere [4], this technology is based on the temporal relationship between arterial blood pressure changes secondary to cardiac systole, measured by the time difference between the R wave on the ECG to the noted changes in the SpO_2, and the arterial blood pressure waveform. This temporal relationship, or pulse wave transit time (PWTT), is closely related to the stroke volume (SV) [4–6]. Alternatively, the Volume View (VV) (Edwards Lifesciences, Irvine, CA, USA) is a minimally invasive device which uses bolus trans-pulmonary thermodilution and pulse contour analysis to intermittently and continuously measure CO [7]. As expected, the ability of both the esCCO and VV monitors to measure CO has been compared to intermittent bolus or continuous thermodilution and transthoracic echocardiography with varying results, biases and conflicts of interest [5, 8–10]. Moreover, most of the published studies have tracked the ability of these technologies to determine absolute CO values. Despite their easy-to-use approach, we feel that more attention should be paid to the ability to trend the evolution of CO changes over time. Although neither is considered a gold standard for CO measurement, the outcome of this study was to compare CO measured by esCCO and VV devices with special attention given to their trending abilities in patients undergoing cardiac surgery. As these devices will likely never be used concurrently, the ultimate goal of our study was to determine whether these devices were interchangeable or consistently produce different measurements.

METHODS

PATIENTS

The study was conducted in accordance to the current Declaration of Helsinki. The study was approved by the local ethics committee (Comité d'éthique de l'Hôpital Erasme, Bruxelles, Belgique N° P2013/181) and registered on clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT02964663) After obtaining a written informed consent, 19 patients scheduled for elective cardiac surgery were included in this study between November 2013 and March 2014. Exclusion criteria were the following: patients younger than 18 years; known or potential pregnancy; arrhythmias; known significant tricuspid or aortic valve insufficiency; left or right ventricular dysfunction; peripheral arteriopathy; or a low perfusion index.

The patients were premedicated with alprazolam (0.5 mg) one hour before anaesthesia induction. In the operating room, standard monitoring was put in place (non-invasive blood pressure, ECG, pulse oximetry, bispectral index [BIS]) and esCCO monitoring. An intravenous line and a femoral artery catheter (VolumeView™ catheter) were inserted before anaesthesia induction under local anaesthesia. Anaesthesia was induced with a plasmatic target-controlled infusion of remifentanil (4–6 μg mL^{-1}) and propofol (2–3 μg mL^{-1}). The maintenance of anaesthesia was obtained with a plasmatic target-controlled infusion of propofol (1–2 μg mL^{-1}) to maintain a BIS value between 40 and 60, as well as a plasmatic target-controlled infusion of remifentanil between 3 and 5 μg mL^{-1} to achieve sufficient hemodynamic stability upon presenting a noxious stimulus. All patients received a loading dose of cisatracurium (0.2 mg kg^{-1}) before endotracheal intubation followed by a continuous infusion of cisatracurium (6 mg h^{-1}). The mechanical ventilation conditions were the following: volume-controlled ventilation with tidal volumes of 8 mL kg^{-1} ideal body weight at a respiratory frequency of 12–15 breaths per minute to maintain an end-tidal CO_2 between 30 and 35 mm Hg. A triple lumen 16 cm 8.5 Fr central venous catheter (Arrow International Inc.) was then placed into the right internal jugular vein. Pressure transducers were placed on the midaxillary line and fixed to the operating table in order to keep the transducer at the right atrial level throughout the study protocol. All transducers were zeroed to atmospheric pressure. Normothermia was maintained during the entire duration of the operation. The use of inotropic agents was left to the discretion of the attending physician.

DEVICES AND MEASUREMENTS

Measurements were performed before and after three CO-modifying interventions before initiating cardiopulmonary bypass (CPB). Collected data points were CO measured via esCCO (esCCO-CO) and VV (VV-CO).

ESCCO MEASUREMENTS

The esCCO device was calibrated initially by a non-invasive arterial pressure cuff after three minutes of stable ECG and SpO_2 signals. The esCCO can be calibrated in two different ways [5, 6]. The first one is by only entering patient information (age, gender, height and weight) and using non-invasive arterial pressure cuff while the second approach requires a CO value obtained from a different invasive CO device. For practical reasons, we decided to calibrate esCCO using the first approach because in a practical setting, another CO device would not be used simultaneously. ECG, the pulse oximetry wave, non-invasive arterial blood pressure and the pulse wave transit time were obtained using a BSM-3000 bedside monitor (Nihon Kohden™, Tokyo, Japan). The algorithm calculating CO-esCCO continuously has been previously described [6]. However, esCCO-CO is calculated using the following equation:

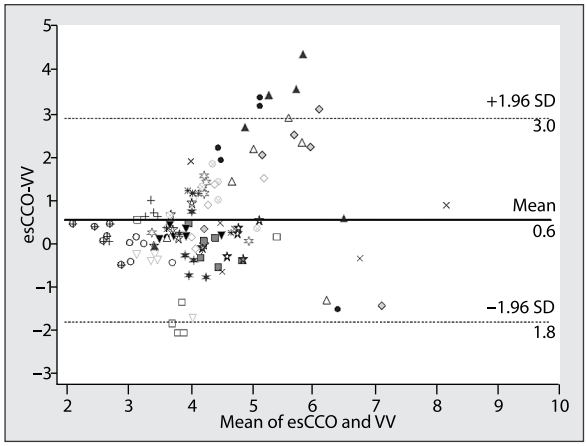

Figure 1. Bland and Altman plots between changes in CO obtained using esCCO and VV. The continuous line shows the mean difference (bias of 0.6 L min^{-1}) and the dotted lines show the 95% limit of agreement of ± 2.4 L min^{-1} (± 1.96*SD) of the bias. Each symbol represents a different patient

$$esCCO\text{-}CO = K \times (\alpha \times PWTT \times \beta) \times HR$$

Where α is a fixed value determined experimentally from previous esCCO clinical studies [6]. K and β are constants calculated from patient data (age, sex, height and weight) and data obtained by calibration (PWTT, HR and arterial pressure).

VOLUME VIEW MEASUREMENTS

Before the start of surgery, the VV-CO variable was calibrated using transpulmonary bolus thermodilution using the average of five successive measurements omitting the maximum and minimum values obtained by the injection of 15 mL cooled 0.9% NaCl at 4°C.

STUDY DESIGN

Before CPB, CO was measured simultaneously using esCCO and VV before and after three CO-modifying manoeuvres [passive leg raise (PLR), the end expiratory occlusion test (EEOT) and positive end expiratory pressure (PEEP) at 10 cm H_2O]. Five CO values for esCCO and three for VV were averaged and compared during a one-minute period of time before (T1, T3 and T5) and after each manoeuvre (T2, T4 and T6). The precision error and its 95% confidence interval (CI) that corresponds to the least significant change (LSC) were calculated and averaged within each period of time (T1, T2, T3, T4, T5, and T6) [11].

The PLR test was performed using the semi-recumbent method over one minute [12]. The modified EEOT was performed during one minute using the disconnection of the ventilation with a PEEP of 5 cm H_2O. The third manoeuvre was a one-minute period of 10 cm H_2O PEEP. A minimum 3-minute stabilization phase was allowed between each manoeuvre. Recordings were started only if no vasoactive drug modifications were made in the 10 minutes before the protocol started.

STATISTICAL ANALYSIS

Distributions of values were evaluated by a Kolmogorov-Smirnov test. Values were expressed in mean [Standard Deviation (SD)] or median [Interquartile Range (IQR)] according to their distribution.

PRECISION OF THE TECHNIQUE

The CO precision error (%) of each device at each time point for each patient was calculated using:

$$\text{Precision error} = 1.96 \times \frac{CV}{\sqrt{n}}$$

where CV is the coefficient of variation of each measurement ($CV = \frac{SD}{mean}$) and n is the number of replications kept for each measurement at each time point for each patient [12–14]. In order to ensure that trending CO was not biased by the precision of the technique (i.e. the minimum change between successive measurements that can be considered a real change and not due to random error with a probability of 95%), we calculated the LSC of CO proposed by Cecconi [12, 13] adapted from previous studies [15, 16] where LSC (%) = precision error × $\sqrt{2}$. The mean and SD or Median and IQR, and the precision error, as well as LSC were then calculated according to mean values of each time plot for each patient.

AGREEMENT AND RESPONSIVENESS

The agreement between the measurements obtained with the tested devices (esCCO and VV) was assessed using the Bland and Altman method [17]. The measurements corresponded to the mean of each of the three to five replicates carried out at T1, T2, T3, T4, T5, and T6. After checking the normality of Bland and Altman bias by the Kolmogorov-Smirnov test, the level of agreement (1.96*SD of the bias) between the methods of measurement with multiple observations per individual was calculated [18]. The percentage of error between esCCO and VV was calculated according to the following formula: 1.96*SD of the bias/mean of both CO values (%).

TRENDING ABILITY

Agreement of the change in CO (ΔCO) between ΔesCCO-CO and ΔVV-CO DesCCO-CO and DVV-CO_(ΔCO: difference of the measurements between T1 and T2, between T3 and T4, and between T5 and T6) was assessed using the four-quadrant plot approach recently refined by Saugel [19]. Values presenting a ΔCO < 10% for both methods were excluded for the analysis (central exclusion zone) [20] This central exclusion corresponds to the noise of the device, due to the insufficient precision of the technique. As the precision error of each technique was *a priori* less than 5%, a potential variation of CO > 10% was considered as a true detection of CO, and is currently considered as a threshold to guide fluid therapy [21]. Changes in CO values were calculated by subtracting the previous CO value from the cur-

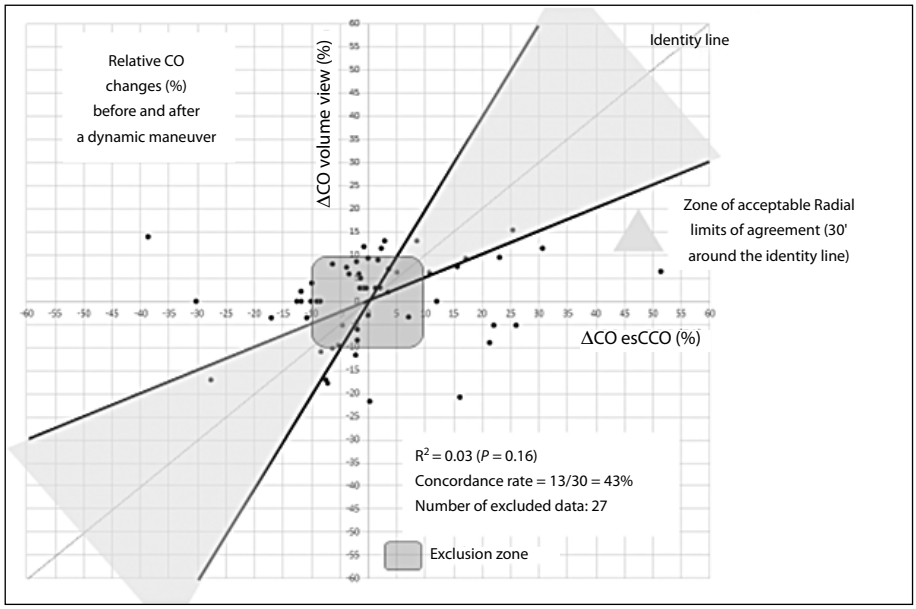

Figure 2. Four-quadrant trend plots with central exclusion zone (10%) for assessing the ability of the esCCO and the VV to trend CO

rent CO value, accordingly: T2-T1 (before and after passive leg rising), T4-T3 (before and after end expiratory occlusion test) and T6-T5 (before and after a positive end expiratory pressure of 10 cm H_2O).

We calculated the angular bias between ΔesCCO-CO and ΔVV-CO with the four-quadrant plot graph (Fig. 2), wherein the 45° line corresponds to the line of identity. The more the plot is far from this line, the higher the radial angle [19]. With ΔesCCO-CO values in the x axis and ΔVV-CO in the y axis, radial angle is positive when ΔesCCo-CO < ΔVV-CO, and radial angle is negative when DesCCO-CO < DVV-CO, whatever the direction of the mean ΔCO (increase or decrease). The mean difference of the radial angle corresponds to the angular bias. An angular bias no greater than ± 5° and radial limits agreement no greater than ± 30° were defined to likely represent a good trending ability [22].

The concordance rate was also calculated according to the four-quadrant plot (proportion of data points in which both methods demonstrate change within an angle < 30°). The 95% CI for the concordance rate was calculated usin $SD = \sqrt{n \times p \times (1-p)}$ where *n* is the number of ΔCO pairs and *p* is the concordance rate.

SAMPLE SIZE

We calculated that 30 triplicate sets of ΔCO data would be sufficient to obtain a concordance rate of 0.8 with a 95% CI < 10%. Based on this estimation and the knowledge that a hemodynamic change would induce a change of CO > 10% in more than 50% of the sets, at least 19 patients were needed for our study. All the analysis was carried out using the MedCalc Statistical Software version 14.8.1 (MedCalc® Software bvba, Ostend, Belgium). An Excel spreadsheet was used for the Polar coordinate format. (Microsoft® Office Excel 2013; 2012 Microsoft Corporation, Redmond, VA, USA).

RESULTS

A total of 19 patients were included in this study. The patient's characteristics are shown in Table 1. The precision error could not be calculated for five patients for esCCO and for four patients for VV.

BLAND AND ALTMAN ANALYSIS

A total of 114 pairs of CO reading collected. Median CO values were 4.3 L min^{-1} (IQR: 3.8; 5.2) and 3.8 L min^{-1} (IQR: 3.5; 4.5) for esCCO and VV, respectively. The bias between esCCO and VV was normally distributed ($P = 0.0596$) according to the Kolmogorov-Smirnov test. A Bland and Altman analysis (Fig. 1) showed a mean bias between esCCO and VV of +0.6 L min^{-1} with an LOA of –1.8 L min^{-1} and +3.0 L min^{-1}. The precision error was 1.37% (95% CI: 1.04–1.69) for esCCO and 2.22% (95% CI: 1.75–2.70) for VV. The percentage error for CO measurement was 54%.

TRENDING ABILITY

Pairs of ΔCO (Fig. 2) were analyzed and the mean ΔCO angle was determined to be +14° (IR: –33, +32°, ranging from –49 to +83°). The concordance rate between esCCO and VV was also found to be 43% (95% CI: 29–58). The upper left and lower right quadrants of Figure 2 demonstrate instances where recorded CO changes were in opposite directions when comparing the two devices.

Table 1. (Baseline) demographic data

Patient Characteristics, n = 19	
Age (Yr)	69 (50–87)
Sexe (M/F)	18/1
BMI (kg m^{-2})	28 (22–39)
ASA I/I/II/III/IV	0/0/18/1
Euroscorell	1,089
Type of surgery	
Coronary artery bypass	15 (80%)
Off-pump coronary arterybypass	1 (5%)
Aortic valve replacement	2 (10%)
Combined surgery	1 (5%)
Inotropic support	
Norepinephrine	15(80%)
Dobutamine	0
Epinephrine	0
Dosage of norepinephrine (pg kg^{-1} min^{-1})	0,052

Yr — Year, M: Male, F: Female, BMI: Body Mass Index, Euroscore: European System for Cardiac Operative Risk Evaluation

DISCUSSION

This study is the first to assess two minimally invasive devices, and which are easy to use in patients undergoing cardiac surgery. The large LOA and the weak trending ability between esCCO and VV demonstrate that these two attractive devices are not interchangeable. These results cannot be explained by the intrinsic variations of CO calculations as the reproducibility of each technique was excellent, with a worst precision error less than 3%. Moreover, it cannot be explained by the time delay of each technique. Indeed, we waited one minute after each manoeuvre to record CO values. With an esCCO average CO of 64 beats and VV at 20 seconds, the timing was acceptable. These large discrepancies between both devices can essentially be explained by two different approaches of the CO, namely the PWTT for the esCCO and the pulse contour analysis for the VV. Regarding the first published correlations between PWTT and SV, it is noteworthy that PWTT shows a weak correlation with SV ([4] IEEE).

Under our study conditions, non-invasive (esCCO) and minimally invasive (VV) measurements of CO are not in agreement and display insufficient trending ability in patients undergoing cardiac surgery. Our results are in accordance with others studies comparing the esCCO device to a "gold standard" (pulmonary artery catheter and/or transpulmonary bolus thermodilution techniques). Our percentage error was 54 %, which is in the same range as other published studies. Indeed, Biais *et al.* [23] reported a percentage error of 61% with a bias of –0.7 L min^{-1}, LOA of –4.4 to 2.9 L min^{-1} and –0.5 L min^{-1}, LOA of –4.2 to 3.2 L min^{-1} before and after therapeutic manoeuvres, respectively, when esCCO was compared with transthoracic echocardiography. This comparison was used also by Bataille *et al.* [8] who demonstrated a percentage error of 49%. Moreover, Thonnerieux *et al.* [24] compared esCCO to the pulmonary thermodilution method and found a bias of 0.7 L min^{-1} with an LOA of –2.1 to 3.5 L min^{-1}. In addition to its accuracy and the precision not being reliable, the ability of the esCCO to track changes in CO was also inaccurate. Specifically, esCCO was not able to track changes in CO induced by CO-modifying manoeuvres. In our study, the low concordance rate (43%) is also alarming; however, we cannot speculate which device is in error as we did not use a reference method or a gold standard in order to measure CO. However, with the high dispersion of the bias radial angle, any protocol implemented with the VV can definitely not be applied with the esCCO. Indeed, only four significant variations of VV would be detected with the same direction with the esCCO. We tried to analyze the trending ability according to Saugel *et al.* [19] This method implements the polar plot approach proposed by Critchley [22] and implements it in a four-quadrant plot graph. The advantage of this method is that it is easier to understand within the graph while the opposite variations of CO are also analyzed. However, determination of the angle is not straightforward and cannot be simply calculated as Saugel [19] has proposed.

They are several limitations in this study. The most important one consists of the fact that we did not use a reference method (gold standard) based on bolus pulmonary thermodilution or transpulmonary thermodilution in order to compare CO as measured by the esCCO and the VV devices. Secondly, we cannot speculate which device is 'wrong' when assessing their accuracy and the trending ability. Another limitation is that we tested a non-invasive technique in a population (cardiac surgery patients) where non-invasive CO devices should not be utilized. Although the study was conducted prior to CPB, the medical history of such a population with hypertension, diabetes and arterial stiffness can engender potential peripheral hypoperfusion and thus lead to an erroneous PWTT for the esCCO device. One could argue that esCCO should be used in moderate risk surgery with patients at moderate risk. At least, the dynamic manoeuvres (PLR, OCC, PEEP) did not significantly alter the CO. One must keep in mind that, despite 58 variations of CO, we could analyze only 30 statistically significant pairs.

CONCLUSION

In patients undergoing cardiac surgery, measurement of CO by esCCO and VV displays poor agreement and trending ability. The large discrepancy between the two methods indicates that these two devices are not interchangeable and that any outcome study conducted with one cannot be applied to the other.

ACKNOWLEDGEMENTS

1. Source of funding: none.
2. Conflict of interest: none.

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Przyjęto: 17.12.2016 r.
Zaakceptowano: 22.05.2017 r.