Cardiac Output Measurement by Bioimpedance and Noninvasive Pulse Contour Analysis Compared With the Continuous Pulmonary Artery Thermodilution Technique

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Objective: **The aim of the present study was to compare 2 noninvasive cardiac output measurement methods with the continuous cardiac output thermodilution (CCO-TD) method.**

Design: **A single-center prospective design.**

Setting: **A university hospital.**

Participants: **Fifty-three consecutive patients scheduled for elective, non-emergent cardiac surgery.**

Interventions: **With each participant the cardiac output was measured using 3 methods: CCO-TD, the Endotracheal Cardiac Output Monitor (ECOM), and the Nexfin monitor.**

Measurements and Main Results: **Measurements were performed simultaneously at 7 time points: After induction, before cardiopulmonary bypass, after cardiopulmonary bypass, after protamine, after arrival in the intensive care unit, and before extubation on postoperative day 1. Statistical analysis was performed using Pearson's correlation, Bland-Altman, percent error, and polar plots. Compared to CCO-TD, ECOM showed significant correlation of R0.619 with a bias of -0.13 L/min (95% confidence interval -2.19-1.93 L/min), a percent error of 40%, and trending ability of 87% and 97% within 0.5 L/min and 1.0 L/min, respectively. The Nexfin monitor showed significant correlation of R0.535 with a bias of −0.35 L/min (95% confidence interval −3.36-2.66 L/min), a percent error of 58% and trending ability of 84% and 97% were within 0.5 L/min and 1.0 L/min limits of agreement.**

Conclusions: **Neither the ECOM nor the Nexfin had the ability to replace the thermodilution-based continuous cardiac output monitor. The ECOM did not have acceptable accuracy or trending ability and only could be utilized for intubated patients. The Nexfin lacked reliability and trending ability. Also, the Nexfin did not provide consistent results.**

KEY WORDS: cardiac output, hemodynamic monitoring, noninvasive measurement, cardiac output monitor, Swan-Ganz, ECOM, Nexfin

FOR MONITORING AND OPTIMIZATION of cardiovascular function in certain patient categories, cardiac output (CO) measurement is often crucial. The ideal CO monitor should be reliable, continuous, noninvasive, operator-independent, operator-friendly, cost-effective, quickly-responsive (beat-to-beat), and without increased morbidity or mortality.[1] The pulmonary artery thermodilution technique provides information on preload, afterload, CO, and stroke volume. This technique is still considered by many as the gold standard in monitoring cardiovascular function, although expensive, invasive, operator-dependent, and associated with some morbidity and mortality.[2] Therefore, the development of reliable, continuous, noninvasive, operator-friendly, and cost-effective alternatives is of great value. Previously studied alternatives such as transesophageal Doppler, echocardiography, and transpulmonary thermodilution with pulse contour analysis all have considerable limitations.[1,3–6] Recently, several noninvasive, continuous cardiac output monitors were introduced. The endotracheal CO monitor (ECOM, ConMed, Irvine, CA) calculates the CO via bioimpedance, and the Nexfin (BMEYE, Amsterdam, Netherlands) uses noninvasive pulse contour analysis to calculate CO.[7,8] To the authors' knowledge, there are no studies comparing both methods simultaneously with the pulmonary artery thermodilution technique. Therefore, this study was set up to compare the accuracy of these 2 methods to the thermodilution technique at several time points during and after cardiac surgery. The authors' hypothesis was that both the ECOM and the NEXFIN CO measurements were equivalent to the thermodilution method.

METHODS

The study was approved by the institutional review board, and written informed consent was obtained from all patients. A consecutive group of patients undergoing cardiac surgery were included. All patients undergoing elective coronary artery bypass surgery (CABG) and/or valve replacement surgery were included. The exclusion criteria were emergency cardiac surgery and patients under the age of 18. General anesthesia was induced according to standard institutional protocol. After induction, the patients were intubated with the ECOM endotracheal tube, which was connected to the monitor and to the arterial line in order to calibrate the system, according to the manufacturers' recommendations. The ECOM is a CE-approved device, calculating the CO via bioimpedance. The cuff of the ECOM tube contains 7 electrodes, which generate a localized, 10-cm diameter, low-voltage electrical field. In this field, impedance changes due to pulsatile flow in the ascending aorta are processed by the ECOM computer as a measure for volume change in the aorta. With every heartbeat, the distention of the ascending aorta is detected, and the monitor calculates a beat-to-beat cardiac output.[7] Apart from stroke volume and CO, the ECOM monitor also calculates the cardiac index (CI) and the systemic vascular resistance (SVR). In addition, all studied patients received a Nexfin cuff around their right index finger, which was connected to the Nexfin monitor. The cuff was placed at midaxillary level. The cuff size selection was based on the diameter of the patients' finger and adjusted until a stable signal was displayed on the monitor. The Nexfin is a noninvasive blood pressure and CO measuring system based on pulse contour analysis of small arteries in the digits. Stroke volume and CO are determined by dividing the pulsatile systolic area of each beat by impedance, which is estimated from the patient-specific aortic vascular characteristics based on sex, age, length, and weight.[8,9] Lastly, all patients received a 7.5F pulmonary artery catheter (Swan-Ganz Oximetry TD catheter, Baxter Edwards Critical Care, Irvine, CA) via the right internal jugular vein, which was connected to a Vigilance monitor (Edwards Lifesciences

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Vigilance VGS Monitor, Edwards Lifesciences, Irvine, CA) for displaying the continuous CO thermodilution (CCO-TD). Even though the gold standard is the intermittent CO with single-shot thermodilution, the authors chose to connect the catheter to the CCO-monitor because this seemed the most acceptable way to collect data from all 3 devices without much time delay. Patients' height and weight were entered to calculate body mass index and body surface area. Calibration was performed at midaxillary level. On 7 time points, the authors awaited 2 consecutive CO values from the Vigilance and simultaneously noted the CO calculated by the ECOM and Nexfin monitors; the 2 values were averaged for every method. The 7 time points were (1) immediately after induction, (2) just before cardiopulmonary bypass (CPB), (3) 5 minutes after CPB, (4) 5 minutes after the administration of protamine, (5) 5 minutes after arrival in the intensive care unit, (6) just before extubation, and (7) on the first postoperative day at 8 a.m. No data was collected for the ECOM monitor at this last time point because the patient had been extubated. All data were collected simultaneously by the same person (SM) at the predetermined time points. The ease of intubation, postoperative hoarseness, and laryngeal symptoms of the patients were recorded by postoperative interviews with the patient and the anesthesiologist.

Power analysis showed that 49 patients had to be studied to reach a statistical significance of 90% with an alpha error of 0.05, assuming a limit of agreement of 30% as relevant. Critchley and Critchley stated that, because of the inherent error up to 20% in thermodilution, the percent error is acceptable up to 30% for a new monitor compared to thermodilution monitoring.[10] All data were collected in an SPSS 18.0 (IBM Corp., Armonk, NY) database. For statistical analysis, Pearson's correlation coefficient and Bland-Altman for the limits of agreement and bias were used.[11] Pearson's correlation measures the strength of a linear relationship between 2 variables. In the Bland-Altman analysis, a negative value signifies that the estimate of CO by ECOM is higher than that with the Vigilance, whereas a positive value means that the Vigilance estimate is higher than the ECOM estimate.[12] Percent error (2 standard deviation bias/mean CO) also was calculated using the method described by Critchley and Critchley.[10] In addition, the data were copied to an Excel spreadsheet (Microsoft Office Excel 2007, Microsoft Corp., Redmond, WA) in order to create the data for the polar plots as described by Critchley et al.[13] The actual polar plots were generated using the software graph drawing program, SigmaPlot 12.5 (Systat Software, Inc., San Jose, CA). The polar plots provide information on the trending ability. The data that agree will come close to the horizontal axis, whereas data with little agreement will approach the vertical axis. With good trending, the data point will lie within the 0.5 L/min boundaries, which represents 10%. With acceptable trending, the mean CO will lie within 1.0 L/min.[13]

RESULTS

Fifty-three consecutive patients were included, and 50 datasets were obtained. In 2 patients, the pulmonary artery catheter was removed because it caused dangerous arrhythmias, and in 1 patient, technical problems with the Vigilance monitor occurred. In Table 1, demographic data are shown. The population included 38 (76.0%) men, and the average age in the study group was 69.8 (48-86) years. Patients underwent coronary artery bypass grafting (n = 42), aortic valve replacement (n = 3), mitral valve replacement (n = 1) or combined surgery (n = 4). During the 7 specific measuring time points, 325 measurements were collected from the Vigilance and 304 from the Nexfin. The ECOM had 6 time points, and 295 measurements were collected. For the comparison of the Vigilance with the ECOM, the authors had 220 pairs of data and 225 pairs of data with the Nexfin. The mean ECOM CO was 5.08 L/min (range 2.15-8.25 L/min). The mean Nexfin was 4.84 L/min (range 1.35-9.85). The mean Vigilance was CO 5.20 L/min (2.20-9.80 L/min). Results for both methods per measurement are shown in Table 2. Results from the Pearson's correlation and the Bland-Altman analysis are displayed in Figures 1 and 2. In Figure 3, the polar plots for the ECOM and Nexfin can be seen.

The overall results for the ECOM revealed a significant correlation of 0.619, a bias of −0.13 L/min (95% confidence intervals −2.19-1.93 L/min), and a percent error of 40%. The best results were seen after CPB and before extubation. Poor correlation results were seen when the CO exceeded 6 L/min. The polar plot shows poor trending, with 87% of the data points scattered within the limits of good agreement (<0.5 L/min) and 97% of the CO changes within acceptable agreement (<1.0 L/min).[13] Anesthesiologists assessed every intubation with the ECOM endotracheal tube. They considered the tube stiff but non-traumatic with 9 patients (18%). Furthermore, there were no vocal cord or other complications detected in the authors' study population.

Results for the Nexfin monitor showed a significant correlation of 0.535, a bias of −0.35 L/min (95% confidence intervals −3.36-2.66 L/min), and a percent error of 58%. Best correlations were seen after CPB. Poor correlation was observed before CPB, in the ICU, and when the CO exceeded 5 L/min. The polar plot presents poor trending for the Nexfin, with 84% of CO changes within 0.5 L/min and 97% within 1.0 L/min. At several time points, in particular in the ICU, the Nexfin, was unable to obtain a signal and calculate the cardiac output. Multiple attempts to use different fingers or cuff sizes were often unsuccessful.

DISCUSSION

In the present study, the accuracy of 2 noninvasive CO monitors was evaluated in clinical practice. Complications of the use of these systems were not observed. It has been reported that optimizing cardiac output is associated with positive effects on morbidity and length of stay in the intensive care unit.[14,15] The main advantage of the pulmonary artery thermodilution technique is the provision of a large dataset

Table 1. Demographics

Population n = 50	% (n)
Sex	
Male	76% (38)
Female	4% (12)
Procedure	
CABG*	84% (42)
AVR†	6% (3)
MVR‡	2% (1)
Combined	8% (4)
Age (years)	
Average	69.8
Range	42-86
LVEF(n = 45)	
Mean	52.7

* Coronary artery bypass surgery.
† Aortic valve replacement.
‡ Mitral valve replacement.