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ACCURACY OF A NOVEL APPROACH TO MEASURING ARTERIAL THERMODILUTION CARDIAC OUTPUT DURING INTRA-AORTIC COUNTERPULSATION

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ABSTRACT. Objective. To assess the agreement between a novel approach of arterial and the pulmonary artery bolus thermodilution for measuring cardiac output in critically ill patients during aortic counterpulsation. **Methods.** Eighteen male patients aged 37–80 years, undergoing preoperative insertion of an intra-aortic balloon pump (IABP) and elective coronary artery bypass grafting. A thin 1.3FG thermistor was introduced through the pressure lumen to the tip of an 8FG IABP catheter, and the pump rate was set at 1:1. After arrival in the intensive care unit cardiac output (CO) was measured under haemodynamic steady-state conditions hourly for 8–11 h, and arterial bolus thermodilution (BCO_{iabp}) and pulmonary artery bolus thermodilution (BCO_{pulm}) were determined after the patients' admission to the intensive care unit. **Results.** A total of 198 data pairs were obtained: 177 with aortic counterpulsation and 21 without. During aortic counterpulsation, median CO was 6.8 l/min for BCO_{iabp} and 6.1 l/min for BCO_{pulm}, without aortic counterpulsation; corresponding values were 7.1 l/min for BCO_{iabp} and 6.5 l/min for BCO_{pulm} with aortic counterpulsation. Mean bias was +0.77 l/min, limits of agreement (± 2 SD) were −1.27/+2.81 l/min, and mean error (2 SD/[(BCO_{iabp} + BCO_{pulm})/2] was 31.4%. Without aortic counterpulsation, corresponding values were +0.43 l/min, −1.03/+1.87 l/min, and 22.4%. **Conclusions.** Agreement between BCO_{iabp} and BCO_{pulm} was satisfactory for CO values between 2.0 and 10 l/min only without aortic counterpulsation. BCO_{iabp} CO measurements during aortic counterpulsation after coronary artery bypass grafting cannot be recommended at the present time.

KEY WORDS. arterial thermodilution, intra-aortic counterpulsation, cardiac surgical intensive care unit.

INTRODUCTION

Use of an intra-aortic balloon pump (IABP) before, during or after cardiac surgery has gained widespread clinical acceptance for patients with unstable angina, myocardial infarction, or low cardiac output (CO) syndrome [1]. To determine the improvement in CO and to monitor the point at which weaning from aortic counterpulsation seems possible, CO has to be measured at close intervals. Bolus thermodilution with a pulmonary artery catheter (BCO_{pulm}) is currently considered the technique with which the accuracy of new CO-monitoring techniques should be compared. The accuracy of BCO_{pulm} has been confirmed at our institution [2]. However, the indications for and effect of right heart catheterization on outcome have been questioned because of the technique's invasiveness and the associated risk of complications [3, 4]. In 1996, arterial bolus thermodilution (BCO_{art}) was introduced as a less invasive method for CO monitoring (PiCCO; Pulsion Medical Systems, Munich, Germany) combined with arterial pulse contour analysis, and the algorithm for pulse contour analysis has been continually refined [3–5]. Details of the method have been reported elsewhere [6].

Many investigators have validated BCO_{art} in relation to BCO_{pulm} [6–11]. To our knowledge, BCO_{art} during intra-aortic counterpulsation has not been investigated in humans. In pigs, Janda et al. [12] recently reported good agreement between BCO_{art} (using the PiCCO device) and BCO_{pulm} during aortic counterpulsation (mean bias, 0.26 l/min; limits of agreement, −0.26/+0.78 l/min); agreement between the two techniques was similar, with or without IABP. The authors concluded that BCO_{art} measurement with PiCCO might be a valid alternative to BCO_{pulm} during IABP support.

The aim of this study was to compare the accuracy of BCO_{art} using a thermistor introduced into the pressure lumen of an IABP catheter (BCO_{iabp}) with that of BCO_{pulm} during intra-aortic counterpulsation in patients undergoing coronary artery bypass grafting (CABG). The accuracy of BCO_{iabp} during intra-aortic counterpulsation is a prerequisite for the development of a new algorithm to analyze the biphasic systolic peak pulse contour in a thermistor integrating an IABP catheter.

METHODS AND MATERIALS

With approval of the institutional ethics committee and written informed consent of the study participants, patients with poor left ventricular function scheduled for preoperative IABP insertion prior to elective CABG surgery or significant left main stem, proximal circumflex and/or left anterior coronary artery stenosis were enrolled in this prospective, nonrandomized, open and single-center study. Exclusion criteria were non-German-speaking patients, unstable haemodynamics, arrhythmias, age <18 years, refusal to participate in the trial, pregnancy, weight <50 or >110 kg, and contraindication for femoral arterial cannulation (such as dissection or peripheral arterial occlusive disease) or contraindication for insertion of a pulmonary artery catheter such as an artificial pulmonary valve or pulmonary artery thrombosis. Criteria for ending a subject's participation were significant arrhythmias (e.g., atrial fibrillation) and perfusion disturbances of the leg where the IABP catheter had been introduced.

Standard instrumentation was applied, either before induction of anaesthesia in the operating theatre or preoperatively in the intensive care unit (ICU). It consisted of a 2-channel ECG (leads II and V_5) (Hellige SMU 612 monitor, Marquette Hellige, Freiburg i.Br, Germany), continuous arterial blood pressure monitoring via a fluid-filled catheter system (Baxter Healthcare Corp. Cardiovascular Group, Irvine, CA) connected to the non dominant radial artery, a triple-lumen central venous catheter (Arrow International, Reading, PA) and a 7.5FG thermistor-tipped, flow-directed pulmonary artery catheter (IntelliCath; Baxter Healthcare Corp., Edwards Critical Care Division), introduced through an 8.5FG introducer (Arrow International), inserted in the right jugular vein and connected to a CO computer system (9520A; Baxter Healthcare Corp.). Then an 8FG Fidelity IAB intra-aortic balloon catheter with a balloon size of 40 cc (Datascope Cardiac Assist Div., Fairfield, NJ) was inserted preferential in the left femoral artery and connected with the IABP system 95 or system 98 (Datascope Cardiac Assist Div.). For the thermodilution measurement, a 1.3FG, 92-cm-long prototype thermistor probe (PV2011-92; Pulsion Medical Systems) was introduced via a special sheath into the pressure lumen of the balloon catheter and connected to a CO computer (PiCCO-plus, V6.0; Pulsion Medical Systems). The thermistor's flexible, soft tip was placed 2 cm beyond the proximal opening of the balloon catheter. Because the inserted thermistor did not allow unimpeded reading of the aortic pressure curve, additional pressure monitoring was performed by standard radial arterial line. Intra-aortic counterpulsation was started with a pump rate of 1:1 preoperatively, either before induction of anaesthesia or in the ICU.

Postoperatively, after arrival of the cardiac surgery patients in the ICU, CO measurements were performed hourly for 8–11 h. BCO_{pulm} was measured by injecting 10 ml of iced saline 0.9% with a closed injectate system (CO-set; Baxter Healthcare Corp.). Injections were distributed randomly throughout the respiratory cycle. Thermodilution curves were displayed on a recorder and accepted as correct if the shape of the curve fulfilled the criteria of Levett and Replogle [13] and if the injectate temperature was <10 °C. Thereafter, 15 ml of iced saline 0.9% was injected through the inline-sensor lumen (PV4046; Pulsion Medical Systems) connected to the distal lumen of the central venous line, and the temperature change over time was detected via the tip of the thermistor probe at the proximal opening of the IABP catheter pressure lumen to measure BCO_{iabp}. For both methods, three to five thermodilution measurements were carried out for every patient, and the mean CO value was used for comparison. Thermodilution measurements were considered acceptable when they were within 10%. Pump rate, trigger modus (electrocardiogram, arterial pressure or pacemaker), pulse rate, central venous pressure, mean pulmonary artery pressure, pulmonary capillary wedge pressure, mixed venous saturation ($Sv{O_2}$), haematocrit, haemoglobin and continuously administered haemodynamic active drugs were documented hourly under steady-state conditions.

The power calculation revealed that 15 patients were necessary to estimate variation between and within subjects with an accuracy of at least 15%. Bland-Altman analysis [14] was applied to assess mean bias and limits of agreement (LOA) (±2 SD of mean bias). LOA were considered clinically acceptable if the mean error (2 SD/[(BCO_{iabp} + BCO_{pulm})/2] was <30% [15]. Multiple regression analysis was performed to assess whether age, body mass index, ejection fraction, pulse rate, mean pulmonary artery pressure, haemoglobin, anaesthesia time, surgery time, cardiopulmonary bypass (CPB) time, aortic clamping time or continuously applied drugs such us dobutamine, epinephrine, norepinephrine and milrinone significantly influenced the mean bias of BCO_{iabp} and BCO_{pulm}.

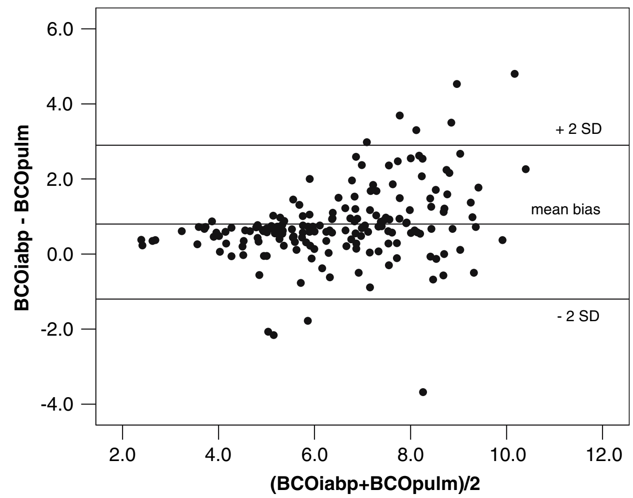

Fig. 1. Agreement between BCO_{iabp} and BCO_{pulm} of 177 data pairs during aortic counterpulsation. Mean bias, +0.77 l/min; limits of agreement, −1.27/+2.81 l/min; mean error (2 SD/[(BCO_{iabp} + BCO_{pulm})/2]), 31.4%.

RESULTS

Eighteen patients were enrolled in the study; their characteristics, haemodynamic data, and intraoperative data are listed in Table 1. Of 198 data pairs for BCO_{iabp} and BCO_{pulm}, 177 were available with IABP and 21 without IABP. Median (range) BCO_{iabp} and BCO_{pulm} with IABP were 6.8 (2.5–12.6) and 6.1 (2.2–10.1) l/min, respectively; and without IABP were 7.1 (4.4–8.7) and 6.5 (4.0–9.8) l/min, respectively. During intra-aortic counterpulsation, mean bias of BCO_{iabp} and BCO_{pulm} was +0.77 l/min, and LOA were −1.27/+2.81 l/min with a mean error of 31.4% (Figure 1). Without intra-aortic counterpulsation, mean bias was +0.43 l/min, and LOA were −1.03/+1.87 l/min with a mean error of

Table 1. Patients' characteristics, haemodynamic data and intra-operative data[a]

No. of patients	18
Age, year	63.5 ± 12.6 (37–80)
Male/female	18/0
Body mass index, kg/m^2	27.4 ± 3.5 (21.8–35.2)
Ejection fraction, %	52.8 ± 18.8 (20–79)
Surgery	
On pump	10
Beating heart	4
Off pump	4
Bypasses	4.1 ± 0.8 (3–5)
Anesthesia time, min	426.2 ± 56.7 (330–550)
Surgery time, min	277.1 ± 55.3 (200–385)
CPB time, min	132.1 ± 28.3 (94–195)
Aortic clamping time, min	76.2 ± 26.7 (50–138)

[a] Values are expressed as mean ± SD (range).

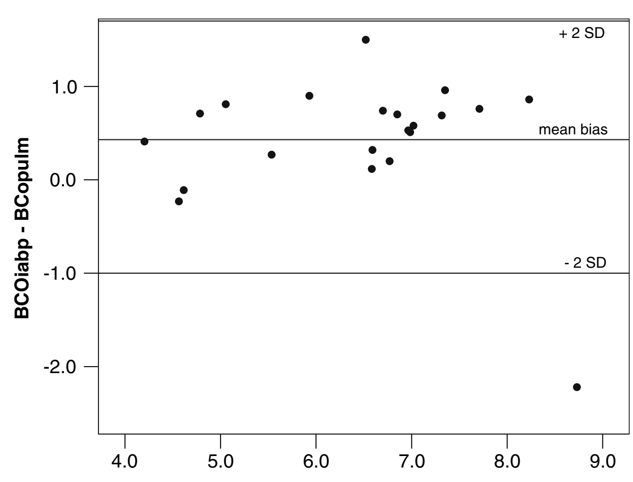

Fig. 2. Agreement between BCO_{iabp} and BCO_{pulm} of 21 data pairs without aortic counterpulsation. Mean bias, +0.43 l/min; limits of agreement, −1.03/+1.87 l/min; mean error (2 SD/[(BCO_{iabp} + BCO_{pulm})/2]), 22.4%.

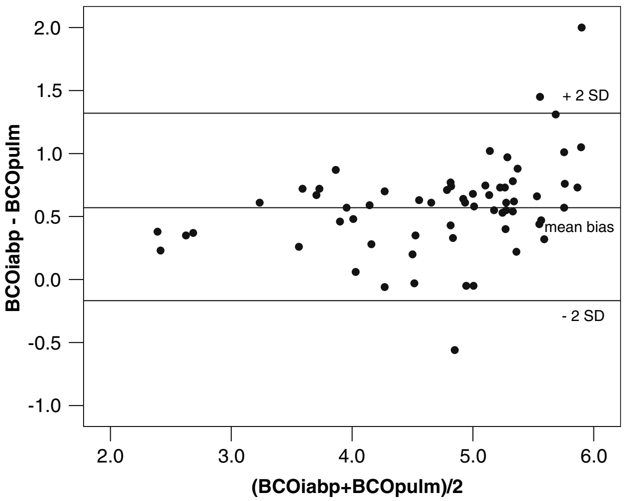

Fig. 3. Agreement between BCO_{iabp} and BCO_{pulm} of 47 data pairs at BCO_{pulm} ≤ 5.5 l/min during aortic counterpulsation. Mean bias, +0.57 l/min; limits of agreement, −0.18/+1.32 l/min; mean error (2 SD/[(BCO_{iabp} + BCO_{pulm})/2]), 15.9%.

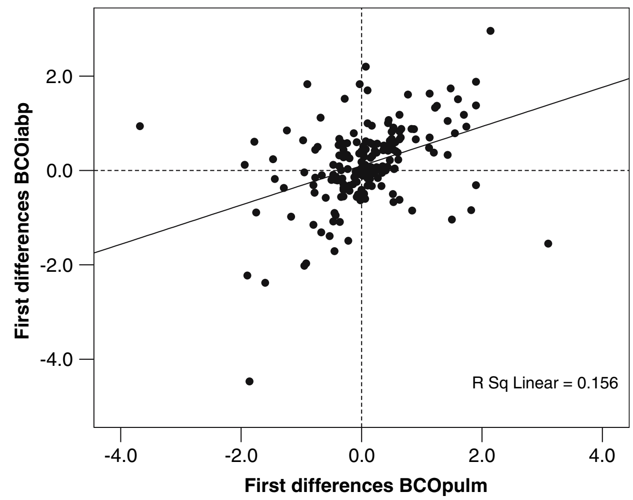

Fig. 4. First differences of BCO_{iabp} and BCO_{pulm} (166 data pairs) (R^2 = 0.156; p > 0.001).

22.4% (Figure 2). During intra-aortic counterpulsation and at BCO_{pulm} ≤ 5.5 l/min, mean bias was +0.57 l/min, and LOA were −0.18/+1.32 l/min with a mean error of 15.9% (Figure 3); during intra-aortic counterpulsation and at BCO_{pulm} >5.5 l/min, mean bias increased to +0.88 l/min, and LOA were −1.58/+3.34 l/min with a mean error of 33%. With or without IABP support, BCO_{iabp} values were always higher than BCO_{pulm} values. No correlation was found between mean bias of BCO_{iabp} and BCO_{pulm} with age, body mass index, ejection fraction, pulse rate, mean pulmonary artery pressure, haemoglobin, anaesthesia time, surgery time, CPB time, aortic clamping time, or continuously applied drugs. Only a moderate correlation was found in the first differences of BCO_{iabp} and BCO_{pulm} during aortic counterpulsation (Figure 4), with sensitivity of 76% and specificity of 63%.

DISCUSSION

The main findings of this study are that (i) with or without IABP support, BCO_{iabp} consistently overestimated CO; (ii) without counterpulsation, the agreement of BCO_{iabp} and BCO_{pulm} was satisfactory; (iii) during counterpulsation at BCO_{pulm} values ≤5.5 l/min, the mean bias of BCO_{iabp} and BCO_{pulm} was only moderate, but the LOA were small and the mean error was low; and (iv) during counterpulsation at BCO_{pulm} >5.5 l/min, agreement of the two methods was poor.

(i) Several investigators have validated BCO_{art} against BCO_{pulm} or the direct Fick method in animals, in critically ill patients, during sepsis, and during and after cardiac surgery [10, 16–23]. In accordance with our observations, most of these studies found that BCO_{art} values were consistently higher than those obtained with BCO_{pulm}. For the BCO_{art} technique, the loss of thermal indicator during its passage through the lungs, left side of the heart and aorta may explain this overestimation [20]. Particularly after cardiac surgery with CPB, disturbances of the barrier function of membranes facilitate efflux of fluid from the vascular system [24, 25]. It has been estimated that approximately 3–9% of the indicator may be lost during its passage through the pulmonary circulation, resulting in a higher arterial CO than that of the pulmonary artery [24–26]. Some investigators, however, did not confirm these findings [8, 27]. Inconstant blood temperature states in the pulmonary artery are also well known because of baseline variation and baseline drift during spontaneous and controlled respiration [28]. Because of heating and humidification of inspired gas during mechanical ventilation, the baseline variation of pulmonary artery blood temperature in mechanically ventilated patients is negligible. However, particularly during the first hours after arrival in the ICU, cardiac surgery patients suffer imbalances of blood and tissue temperatures, which may have more impact on the BCO_{pulm} measurement because of the short distance between the site of injection and that of the indicator detection. Alternatively, transient slowing of the heart rate at the time of cold fluid injection by impeding the sinus node will clearly reduce BCO_{pulm} CO to a greater extent than BCO_{art} CO and could contribute to the observation of higher CO by BCO_{art} [20, 29].

(ii) In the present study, the mean bias of BCO_{iabp} and BCO_{pulm} in patients without intra-aortic counterpulsation was comparable to results of other investigators. Gust and coworkers [30] reported a consistent overestimation of CO by BCO_{art} (bias of + 0.46 l/min) but higher LOA in patients after CABG surgery. In contrast to our study, they used smaller injection volumes for BCO_{art} (10 ml of iced saline 0.9%) and did not use the IABP pressure lumen approach. Sakka and coworkers [10] reported good agreement between BCO_{art} and BCO_{pulm} in critically ill patients without intra-aortic counterpulsation using thermodilution with the COLD-Z021 device. In that study, LOA were comparable to our findings (−0.56/+1.72 l/min), but BCO_{art} considerably overestimated CO compared to BCO_{pulm} (mean bias, +0.68 l/min).

(iii) In contrast to previous investigations, we introduced an intra-aortic balloon catheter in the aortic vessel. Janda and coworkers [12], who investigated the impact of intra-aortic counterpulsation on CO determination by BCO_{art} and BCO_{pulm} in pigs, concluded that BCO_{art} is suitable for CO measurement during intra-aortic counterpulsation. In our novel approach—using a thermistor inserted via the IABP pressure lumen in patients after CABG surgery—analysis of all data during intra-aortic counterpulsation showed only a moderate agreement between BCO_{iabp} and BCO_{pulm}. The mean bias in the subgroup with $BCO_{pulm} \leq 5.5$ l/min was twice that of Janda and coworkers [12], but the LOA were only slightly higher.

(iv) Our main finding during intra-aortic counterpulsation was a considerable increase of the mean bias as well as the LOA at BCO_{pulm} values >5.5 l/min. No association was found between this observation and the time course of intra-aortic counterpulsation. We did not measure the patients' body temperature at the time points of data collection, but the lack of interrelation of the increased mean bias with time course renders temperature dependence improbable. Also, the finding was not explained by the effect of outliers. To determine BCO_{art} during intra-aortic counterpulsation in pigs, Janda and coworkers [12] used a thermistor introduced into the femoral artery, downstream of the IABP catheter, whereas in our study the variation of blood temperature after bolus injection of iced saline 0.9% for BCO_{iabp} was detected at the tip, upstream of the IABP catheter. Some investigators using a transcranial Doppler device [31, 32] found an inverse flow velocity in the middle cerebral artery during the late diastole or early systole in patients with intra-aortic counterpulsation. Theoretically, this flow reversal may lead to an admixture of warm cerebral blood to the aortic blood volume, reducing the area under the temperature curve. This effect could be more pronounced at higher CO values. In contrast to Janda and coworkers [12], who determined CO simultaneously, we performed our thermodilution measurements consecutively because of different injection volumes for both methods. This procedure may also contribute to the differences between our results and those of Janda et al. although our measurements were performed during haemodynamic stability.

Limitations of this study are the decision not to measure body temperature at the various time points of data collection and the possibility of interobserver variability in a study involving three investigators. Another limitation is the reduced count of data pairs of BCO_{art} and BCO_{pulm} in patients without intra-aortic counterpulsation. Considering the amount and comparability of data without IABP already present in the literature, we doubt that this limitation had any influence on our data interpretation. A methodological limitation is the fact that placing a 92-cm-long, 1.3FG thermistor at the tip of a IABP catheter is a tricky procedure. Although in all cases the thermistor was placed in the balloon catheter at its full length, we cannot exclude the possibility that the tip of the thermistor was not placed outside the tip of the balloon catheter in the free-flowing aortic blood. We also cannot exclude coiling of the thermistor in the balloon catheter lumen, because radiographic control was not possible given the size of the thermistor. However, even if the tip of the catheter lies in free-flowing aortic blood, unimpeded thermodilution measurement with correct calculation of BCO_{iabp} is possible. In high-CO states and during high-flow counterpulsation, the indicator passes more rapidly, so a partially hidden or obstructed thermistor has a lag in response time and thus can affect the accurate measurement of CO.

CONCLUSIONS

The agreement between arterial thermodilution CO measured by a thermistor inserted into an IABP catheter pressure lumen and CO measured by pulmonary arterial thermodilution in patients without intra-aortic counterpulsation was satisfactory for CO values ranging from 2.0 to 10 l/min. Arterial thermodilution CO measurements using this approach cannot be recommended for use during intra-aortic counterpulsation in patients after CABG surgery. Future investigations will show whether a change in technique may correct for the differences, particularly at high CO values.

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