Cardiac output determination by thermodilution and arterial pulse waveform analysis in patients undergoing aortic valve replacement

[Détermination du débit cardiaque par thermodilution et par analyse du contour de pression artérielle chez des patients subissant un remplacement de la valve aortique]

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Purpose: To compare the accuracy of cardiac output (CO) measurement by arterial pulse waveform analysis (CO_{PW}) to thermodilution assessments in patients with aortic stenosis, a high-risk patient group who may benefit from extended hemodynamic monitoring.

Methods: In 30 patients with aortic stenosis, CO was assessed in triplicate by thermodilution via pulmonary artery catheterization (CO_{PAC}), and by arterial pulse waveform analysis (CO_{PW}), before and after valve replacement. The techniques were compared by assessing the repeatability coefficient of each method and by calculating the percentage error, bias, and the limits of agreement between methods.

Results: The repeatability coefficients of CO_{PAC} and CO_{PW} were 0.89 $L \cdot min^{-1}$ and 1.04 $L \cdot min^{-1}$ respectively after induction of anesthesia, which corresponded to 24% of CO_{PAC} and 26% of CO_{PW}, and increased to 33% of CO_{PAC} and 32% of CO_{PW} immediately after extracorporeal circulation. A systematic error between methods was not observed. The limits of agreement were bias $\pm$ 1.42 $L \cdot min^{-1}$ after anesthesia induction, corresponding to a 36% percentage error. The scattering of differences between methods increased markedly after termination of extracorporeal circulation (percentage error 56%).

Conclusion: The repeatability of CO_{PAC}, as well as of CO_{PW}, is reduced in patients with aortic stenosis. The repeatability of both methods, as well as the agreement between methods, decreased markedly immediately after termination of cardiopulmonary bypass.

***Objectif** : Comparer la précision de la mesure du débit cardiaque (CO) par analyse du contour de la pression artérielle (CO_{PW}) aux évaluations par thermodilution chez les patients présentant une sténose aortique, un groupe de patients à haut risque qui pourraient bénéficier d'un monitorage hémodynamique étendu.*

***Méthode** : Le CO a été mesuré en triplicata par thermodilution, via un cathéter de l'artère pulmonaire (CO_{PAC}), et par analyse du contour de la pression artérielle (CO_{PW}), chez 30 patients souffrant de sténose aortique avant et après le remplacement valvulaire. Les techniques ont été comparées en évaluant le coefficient de reproductibilité de chaque méthode et en calculant le pourcentage d'erreur, le biais et les limites de la concordance des méthodes.*

***Résultats** : Les coefficients de reproductibilité de CO_{PAC} ET CO_{PW} étaient de 0,89 $L \cdot min^{-1}$ et 1,04 $L \cdot min^{-1}$ respectivement après induction de l'anesthésie, ce qui correspond à 24 % de CO_{PAC} et 26 % de CO_{PW}, et ont augmenté à 33 % de CO_{PAC} et 32 % de CO_{PW} immédiatement après la circulation extracorporelle. Aucune erreur systématique entre les méthodes n'a été observée. Les limites de la concordance étaient un biais de $\pm$ 1,42 $L \cdot min^{-1}$ après l'induction de l'anesthésie, soit un pourcentage d'erreur de 36 %. La distribution des différences entre les méthodes a considérablement augmenté après la fin de la circulation extracorporelle (pourcentage d'erreur 56 %).*

***Conclusion** : La reproductibilité de CO_{PAC} ainsi que de CO_{PW} est réduite chez les patients souffrant de sténose aortique. La reproductibilité des deux méthodes, ainsi que la concordance entre les méthodes, ont considérablement diminué après la fin de la circulation extracorporelle.*

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IN view of recurrent discussions about the usefulness and dangers of the pulmonary artery catheter (PAC), alternative techniques of hemodynamic monitoring have been developed and evaluated.[1] Several devices use the analysis of the arterial pressure curve to estimate left ventricular stroke volume. However, changes in the pressure curve, due to changes in the peripheral arterial vascular tone, might influence the determination of stroke volume, as we observed in a previous study evaluating pulse contour analysis.[2]

Recent studies of a new method, the cardiac output (CO) measured by pulse waveform analysis (CO_{PW}), give inconsistent results,[3–7] which may be related to the software version used, the patient populations studied, or the statistical methods used. Further investigation of this method is therefore needed. We compared CO measured by thermodilation via PAC (CO_{PAC}), with CO_{PW} in patients suffering from aortic stenosis who were undergoing replacement of the aortic valve. In this high risk patient population, the noninvasive assessment of stroke volume may be a valuable part of hemodynamic monitoring during surgery and intensive care. Pulse wave morphology is altered in these patients due to the underlying valvular disease, and may be further altered after valvular replacement. The influence of these phenomena on CO_{PW} (not previously investigated) should be of interest to anesthesiologists. Accordingly, this study was undertaken to compare the repeatability of CO_{PW} with CO_{PAC}, and to quantitate the agreement between methods during changes in CO and blood pressure.

Methods

The study was approved by the local Ethics Committee, and all patients gave written informed consent. Thirty subjects, 16 male, aged 45 to 81 yr (mean age 73.6 yr, mean height 166 ± 8 cm, mean weight 76.6 ± 14.1 kg), who were scheduled for elective aortic valve replacement for aortic stenosis, were investigated. Patients were excluded if previous echocardiographic investigation revealed evidence of co-existent aortic regurgitation, or if the cardiac rhythm was other than normal sinus. Patients were premedicated with temazepam 10–20 mg orally. Anesthesia was induced with sufentanil, etomidate and pancuronium, and was maintained with sevoflurane and supplemental sufentanil as required. A 20G arterial cannula (Leader-Cath™, VYGON GmbH, Aachen, Germany) was inserted into the left radial artery, and connected to the FloTrac™ sensor/Vigileo™ Monitor (Edwards LifeSciences, Irvine, CA, USA) and to the standard hemodynamic monitor (Marquette Hellige GmbH, Freiburg, Germany). A 7 Fr PAC (Edwards LifeSciences Irvine, CA, USA) was introduced into the pulmonary artery via the right internal jugular vein. Cardiac output was measured by the conventional pulmonary artery thermodilution technique (Marquette Hellige, Freiburg, Germany), and by analysis of the pressure wave registered in the radial artery (FloTrac™ sensor/Vigileo™ Monitor). Cardiac output, measured by thermodilution via PAC and $CO_{PW,}$ was assessed by averaging the results of three measurements randomly distributed over the respiratory cycle, and carried out within a three-minute time interval. Cardiac output, measured by thermodilution via PAC, was measured using 10 mL cooled 0.9% sodium chloride solution injected in less than four seconds through the proximal lumen of the PAC. The measurements were accepted if the thermodilution curve showed a typical morphology without indication of artefacts. Cardiac output measured by pulse waveform analysis was calculated in time intervals of 20 sec, and was registered simultaneously with the CO_{PAC} measurements.

Cardiac output was determined during clinical steady state conditions at four sample times: after induction of anesthesia (sample point A); after sternotomy (sample point B); five minutes after the end of extracorporeal circulation (sample point C); and after closure of the chest (sample point D). Thus, we assessed CO twice before valve replacement, and twice after valve replacement, during different clinical conditions.

Statistical analysis

In previous experiments, we determined a mean CO_{PAC} of 4.0 $L \cdot min^{-1}$ and a variance of 1.0 $(L \cdot min^{-1})^2$ in patients with aortic stenosis. Selecting a statistical power of 0.8, and assuming that a bias of 0.5 $L \cdot min^{-1}$ between methods is of clinical relevance, (i.e., an effect size of 0.5) we calculated that a minimal sample size of 30 patients was required.

The coefficients of variation (SD/mean × 100%) were calculated for the triplicate CO determinations and were used as a measure of the scattering of methods. Additionally, the repeatability coefficient, which reports the range in which 95% of replicate measurements are expected to lie, was calculated for the three measurements in accordance with the suggestions of Bland and Altman.[8] Agreement between methods was also calculated according to the method described by Bland and Altman.[9] The bias between CO_{PAC} and CO_{PW} was calculated as the mean difference between CO measurements by each method. The upper and lower limits of agreement, which define the range in which 95% of the differences between methods are

TABLE Repeatability and precision of cardiac output measurement and hemodynamic data at the different sample points. Data are reported as mean ± SD. A $P < 0.025$ is regarded as significant due to adjustment of the alpha error for repeated measurements.

Sample point	*A*	*B*	*P value A vs B*	*C*	*D*	*P value C vs D*
Heart rate (min^{-1})	58.7 ± 10.5	69.2 ± 12.3	0.001	87.7 ± 6.7	88.3 ± 3.9	0.56
Systolic blood pressure (mmHg)	108.0 ± 17.0	119.0 ± 15.3	0.005	114.1 ± 13.4	115.2 ± 16.5	0.75
Diastolic blood pressure (mmHg)	52.4 ± 8.8	56.0 ± 12.6	0.049	59.3 ± 8.9	63.7 ± 10.9	0.027
Mean blood pressure (mmHg)	72.3 ± 10.7	80.0 ± 12.8	0.01	77.8 ± 10.2	82.6 ± 12.7	0.075
CO_{PAC} ($L \cdot min^{-1}$)	3.77 ± 0.83	4.63 ± 1.08	0.001	5.14 ± 1.45	4.58 ± 1.33	0.001
Cardiac index$_{PAC}$ (($L \cdot min^{-1} \cdot m^{-2}$)	2.02 ± 0.43	2.48 ± 0.56	0.001	2.72 ± 0.63	2.43 ± 0.60	0.001
CV CO_{PAC}	6.9	8.9		9.6	7.6	
CO_{PAC} Repeatability coefficient ($L \cdot min^{-1}$)	0.89	1.42		1.63	1.03	
CO_{PW} ($L \cdot min^{-1}$)	3.93 ± 0.66	4.57 ± 0.99	0.001	4.88 ± 1.07	4.82 ± 0.91	0.64
Cardiac index$_{PW}$ ($L \cdot min^{-1} \cdot m^{-2}$)	2.10 ± 0.24	2.43 ± 0.42	0.001	2.60 ± 0.51	2.57 ± 0.37	0.60
CV CO_{PW}	6.3	9.7		10.8	6.3	
CO_{PW} Repeatability coefficient ($L \cdot min^{-1}$)	1.04	1.39		1.60	1.12	
Mean CO ($L \cdot min^{-1}$)	3.85 ± 0.66	4.60 ± 0.93	0.001	5.01 ± 1.05	4.70 ± 1.00	0.005
Mean cardiac index ($L \cdot min^{-1} \cdot m^{-2}$)	2.06 ± 0.33	2.45 ± 0.42	0.001	2.66 ± 0.43	2.50 ± 0.41	0.005
Bias [95% CI] ($L \cdot min^{-1}$)	0.16 ± 0.71 [-0.11 to 0.42]	-0.06 ± 0.91 [-0.40 to 0.28]		-0.26 ± 1.43 [-0.79 to 0.27]	0.24 ± 1.09 [-0.17 to 0.64]	
Upper limit of agreement [95% CI] ($L \cdot min^{-1}$)	1.55 [1.09 to 2.01]	1.72 [1.13 to 2.31]		2.54 [1.62 to 3.46]	2.37 [1.66 to 3.08]	
Lower limit of agreement [95% CI] ($L \cdot min^{-1}$)	-1.24 [-1.70 to -0.78]	-1.84 [-2.43 to -1.25]		-3.06 [-3.98 to -2.14]	-1.90 [-2.60 to -1.19]	
Percentage error (%)	36	39		56	46	

CO_{PAC} = cardiac output measured by thermodilution via pulmonary artery catheter; CO_{PW} = cardiac output measured by pulse waveform analysis; CV = coefficient of variation. Sample points: A = after induction of anesthesia; B = after sternotomy; C = five minutes after the end of extracorporeal circulation; D = after closure of the chest.

expected to lie, were calculated as bias ± 1.96 SD. The precision of the bias, and of the limits of agreement, are reported as a 95% confidence interval. As the scattering of the differences between CO_{PAC} and CO_{PW} increased with increasing CO, especially in the post-bypass period, bias analysis was additionally performed with logarithmically transformed data. The antilog transformed data of the limits of agreement report the range in which one method is expected to differ from the other for 95% of cases.[9] Additionally, the percentage error, (1.96 SD of the bias between methods divided by the mean CO, expressed as percentage), which is used as a measure of the relative error between methods, was calculated as proposed by Critchley and Critchley.[10]

Statistical analysis was performed using commercially available software (SPSS for Windows 12.0.1., SPSS Inc., Chicago, IL, USA). After the assessment of normal distribution by the Lilliefors modification of the Kolmogorov-Smirnov test, and visual assessment of the histograms and the probability plots (Q-Q plots), the two-tailed Student's *t* test for paired

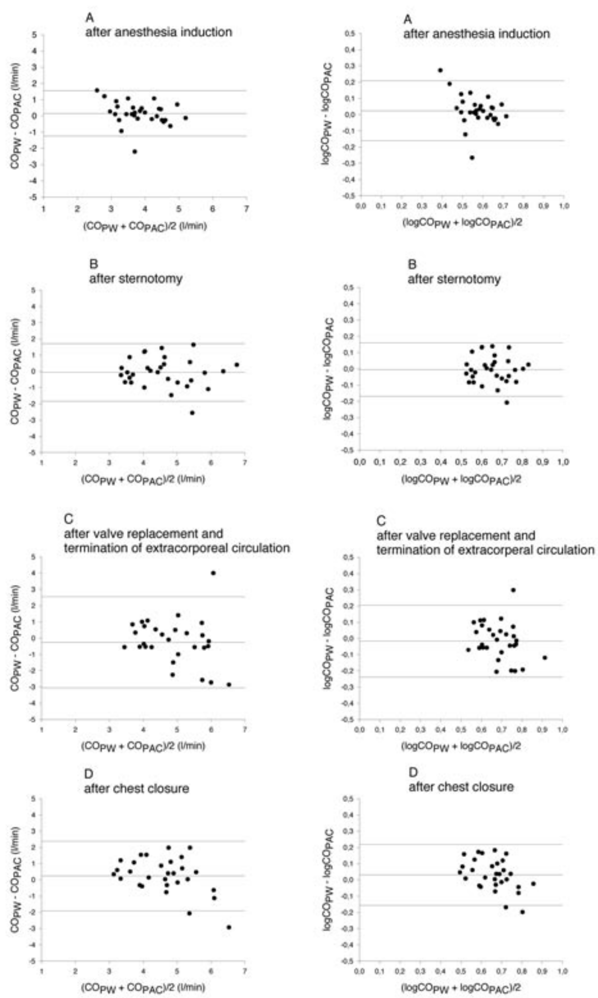

FIGURE 1 Bland-Altman analysis for CO_{PAC} and CO_{PW} (left) and for the logarithmic transformed data of CO_{PAC} and CO_{PW} (right) at the four sample points. The bias and the limits of agreement (± 1.96 SD of bias) are indicated. CO_{PAC} = cardiac output measured by thermodilution via pulmonary artery catheter; CO_{PW} = cardiac output measured by pulse waveform analysis; A = after induction of anesthesia; B = after sternotomy; C = five minutes after the end of extracorporeal circulation; D = after closure of the chest.

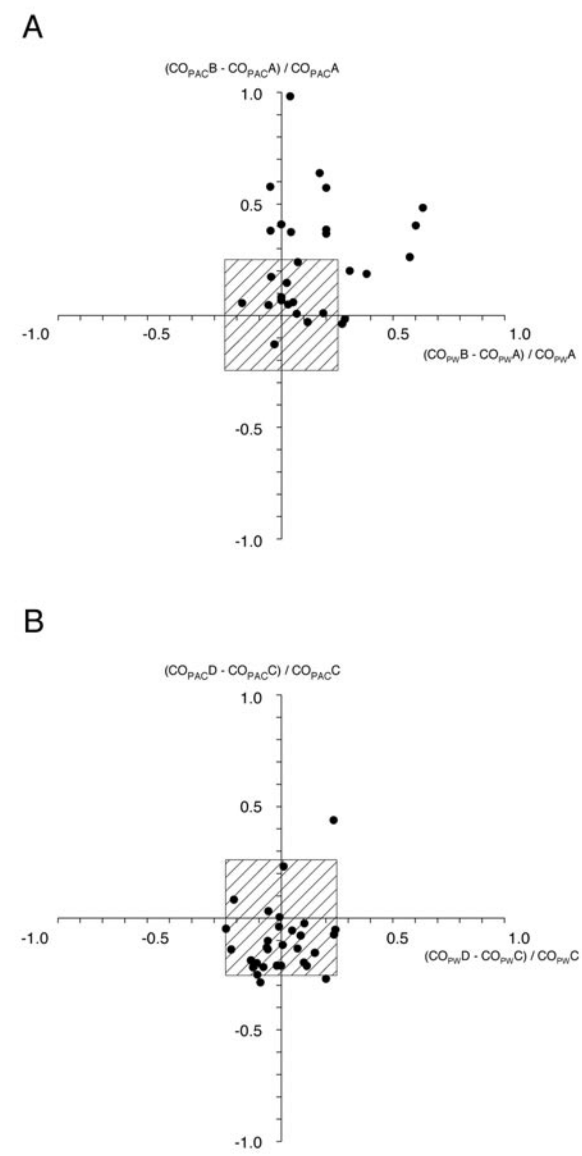

FIGURE 2 Fractional changes in CO_{PAC} and CO_{PW} from sample point A to B (A) and from sample point C to D (B). The shaded area marks the 25% error of methods. Refer to Figure 1 legend for abbreviations.

data was used to compare variables. A $P < 0.05$ was regarded as significant. As we performed two significance tests on hemodynamic data (sample points A *vs* B and C *vs* D) the alpha error was adjusted in accordance with the Bonferroni method, and a $P < 0.025$ was regarded as significant for these comparisons.

Results

All patients completed the study protocol. The hemodynamic data obtained at the different sample points, and the details of CO measurement and analysis, are reported in the Table. Heart rate, blood pressure and both CO_{PAC} and CO_{PW} increased significantly from sample point A to sample point B. Heart rate and blood pressure remained stable from sample points C to D. Cardiac output measured by pulse waveform analysis remained stable, but CO_{PAC} decreased from C to D.

The coefficient of variation, as well as the repeatability coefficient, was lowest after induction of anesthesia, (sample point A). The repeatability coefficient of the two methods corresponded to 24% of CO_{PAC} and 26% of CO_{PW} at this sample point. The repeatability coefficient increased after sternotomy, (sample point B), and after termination of extracorporeal circulation, (sample point C), (31% of CO_{PAC}, 30% of CO_{PW}, and 32% of CO_{PAC}, 33% of CO_{PW}, respectively). Repeatability returned to the initial values at sample point D (22% of CO_{PAC}, 23% of CO_{PW}).

The bias between CO_{PAC} and CO_{PW}, and the upper and lower limits of agreement, are presented in Figure 1. The bias between CO_{PAC} and CO_{PW} was not significantly different from zero at all sample points. The agreement between methods was highest at sample point A with a percentage error of 36%. The percentage error increased markedly at sample points C and D. The antilog of the limits of agreement, which reveals the extent to which the methods differ for 95% of cases, showed that CO_{PAC} differed from CO_{PW} by 32% below to 61% above at sample point A, by 33% below to 44% above at sample point B, by 58% below to 60% above at sample point C, and by 31% below to 65% above at sample point D. The fractional changes from CO_{PAC} and CO_{PW} from A to B, and from C to D are presented in Figure 2. The shaded area marks the 25% error of methods. The graph demonstrates that the reference and the test method did not report changes in CO from A to B in opposite directions. However, increases in CO_{PAC} were not always reflected by increases in CO_{PW}. The changes in CO from sample point C to D were mostly in the range of the 25% error of the methods.

Discussion

There are three main findings of the present study. Firstly, the repeatability of CO assessments evaluated in triplicate by CO_{PAC} and as CO_{PW}, is limited in patients with aortic stenosis, and decreases further in the period immediately after cardiopulmonary bypass. Secondly, there is no significant bias between CO_{PAC} and CO_{PW} assessments. Finally, the percentage error between CO_{PAC} and CO_{PW} methods of assessment is about 35% in patients with aortic stenosis. After extracorporeal circulation, the agreement between methods decreases markedly.

The repeatability of CO_{PAC} and CO_{PW}

Based on the data from 14 clinical studies, Stetz and coworkers[11] calculated that the error of CO determination by the thermodilution technique was 22% for single measurements and 13% for the average of triplicate measurements. These results were supported by Mackenzie and colleagues[12] who found that the 95% confidence limit for CO determination by thermodilution had a value between 21% and 33% of CO under *in vitro* conditions with a pulsatile flow of 5 $L \cdot min^{-1}$. According to the study by MacKenzie,[12] the physiological limit of precision for CO measurement by thermodilution has frequently been reported with 1 $L \cdot min^{-1}$. Based on these calculations, it has been proposed that the limits of agreement between a new technique for the determination of CO and thermodilution as the gold standard should not exceed the 10–20% error of the thermodilution method.[13] However, Critchley pointed out that it is advisable to combine the errors of the test and the reference method, and calculated a value of 28%.[10]

In the present study, we observed a repeatability coefficient of about 1 $L \cdot min^{-1}$ at the sample points A and D for both methods. However, these patients with severe aortic stenosis had COs which were clearly lower than the mentioned reference value of 5 $L \cdot min^{-1}$, resulting in a relative error of about 25%. As a consequence, the reproducibility of CO determination was decreased in our patients with aortic stenosis when compared to previously published data.[10,11,13]

In addition, methodological limitations may have contributed to this phenomenon, as the three measurements of CO were randomly distributed over the respiratory cycle. This approach is associated with an increase in the physiological error of CO measurement. Stevens *et al.*[14] observed that the coefficient of variation was greater than 10% if the injections for the measurement of CO were randomly distributed over the respiratory cycle, compared to 4% for the injection in the expiratory pause. On the other hand, a method which averages the stroke volume over a time period of 20 sec, such as arterial pulse waveform analysis, should not show this dependence on the respiratory cycle.

After termination of extracorporeal circulation, the repeatability of CO determination decreased further. An increasing error in CO determination by thermodilution may have been caused by shifts in blood temperature, a well-known phenomenon after cardiopulmonary bypass.[15] However, decreased reproducibility was likewise observed in CO_{PW}, which should not be influenced by blood temperature. It is possible that the decrease in reproducibility may be attributed to changes in hemodynamic conditions immediately after termination of extracorporeal circulation, even under the clinical impression of steady state conditions. This assumption is supported by the fact that the repeatability coefficient returned to the initial value after sternal closure, (i.e., about 15 to 30 min after sample point C). Our results underline the well-known inaccuracies when determining CO in the period after cardiopulmonary bypass, regardless of the method used.

Bias between CO_{PAC} and CO_{PW}

In a previous study we observed that increases in blood pressure, due to an increase in peripheral resistance, caused an erroneous increase in the estimation of CO by pulse contour analysis.[2] This phenomenon caused a marked bias to CO_{PAC}, and may be explained by changes in arterial input impedance influencing the contour of the pulse wave.[16] The current device estimates CO by analyzing the pulse waveform without individual calibration.[17] In the present study, we did not observe a significant bias between CO_{PAC} and CO_{PW} at any sample point despite the blood pressure increasing significantly from sample point A to B. Additionally, changes in the morphology of the arterial pressure curve, before and after valve replacement, did not cause any systematic error between methods. Cardiac output measured by thermodilution via PAC was slightly increased, compared to CO_{PW}, after termination of extracorporeal circulation; but the bias was not significantly different from zero. An overestimation of CO_{PAC} in the immediate period after termination of cardiopulmonary bypass has been reported by other authors when comparing thermodilution with Doppler - CO.[18] As already mentioned above, instability of blood temperature was discussed as the cause of the inaccuracy of CO measurement by thermodilution in the post-bypass period.[18]

The precision of CO determination by CO_{PAC} and CO_{PW}

It has been proposed that the limits of agreement between a new technique for the determination of CO and thermodilution as the gold standard should not exceed the 10–20% error of the thermodilution method.[13] However, Critchley and Critchley[10] pointed out that the combined error of two methods can be calculated from the error of each method following a Pythagorean approach. Referring to an inherent error of 20%, Critchley and Critchley stated that the limits of agreement between a reference and a test method should be lower than 30%, in order to accept the methods as interchangeable. Due to the fact that the inherent error of thermodilution was increased to about 25% in our patients with aortic stenosis, a percentage error between methods of 36% should be acceptable. However, one should be aware of the large relative limits of agreement between methods calculated with the logarithmically transformed data.

In the post-bypass period the combined error would be expected to be in the range of 45%, according to the criterion suggested by Critchley and Critchley.[10] The actually observed percentage error of 56% indicates lack of agreement between methods post-bypass, which is underlined by the rather large relative limits of agreement. Thus, our study indicates poor agreement between the methods after extracorporeal circulation, which is at least partly related to the poor repeatability of the methods in this period.

Comparison with previous studies evaluating pulse waveform analysis

Several previous studies demonstrated a significant bias and large limits of agreement when comparing CO_{PAC} and CO_{PW} in the cardiac surgery setting.[3–5] Whereas Opdam *et al.*[3] analyzed repeated measures of only six postoperative cardiac surgery patients, Mayer *et al.*[5] investigated 40 cardiac surgery patients and found a percentage error of 46% for all confidence interval data (mean CI_{PAC} 2.3 $L \cdot min^{-1} \cdot m^{-2}$, mean CI_{PW} 2.8 $L \cdot min^{-1} \cdot m^{-2}$) and a bias ± SD of 0.46 ± 1.15 $L \cdot min^{-1} \cdot m^{-2}$. Obviously, the error of CO measurement increased proportionally to the magnitude of CO. The percentage error between methods increased up to 51% when analyzing a subgroup with low CO.[5] Sander *et al.*[4] studied 30 patients during coronary bypass surgery and observed a maximum bias of 1 $L \cdot min^{-1}$ (SD ± 1.8 $L \cdot min^{-1}$) after sternotomy, (mean CO_{PAC} 5.7 $L \cdot min^{-1}$, mean CO_{PW} 4.7 $L \cdot min^{-1}$), which corresponded to a percentage error of 70%. In contrast to these results, we did not find a significant bias between the methods. Our data demonstrate a marked improvement in precision, halving the limits of agreement, and reducing the percentage error up to 36% after anesthesia induction. The improvement in the agreement of methods may be caused by a software modification in the pulse waveform analysis which was not available in the above-mentioned studies.

Manecke and coworkers[6] investigated the same improved algorithm of arterial pulse wave analysis in postoperative cardiac surgical patients, and observed a minimal bias between methods and an SD of the bias of 0.98 $L \cdot min^{-1}$. McGee and colleagues[7] compared repeated measurements of CO_{PAC} and CO_{PW} in a heterogeneous patient group and calculated a bias of 0.20 $L \cdot min^{-1}$ and a SD of the bias of ± 1.28 $L \cdot min^{-1}$, which was interpreted as an acceptable agreement between methods. The data demonstrate an increase in the scattering of the differences between CO_{PAC} and CO_{PW} with increasing CO, which limits the significance of the calculated agreement between methods.[7] It is not known whether the authors corrected for the repeated measurement of CO as suggested by Bland and Altman.[8]

When compared to the results of Manecke,[6] our data demonstrate a slightly improved agreement between methods in the period before extracorporeal circulation, and similar results in the period after sternal closure. The results reported by McGee *et al.*[7] seem to be comparable to the analysis of the percentage error and the limits of agreement of log-transformed data which we obtained at sample points A and B.

In contrast to previously reported criteria for the thermodilution method, we found that in patients with aortic stenosis, repeatability of both CO_{PAC} and CO_{PW} is reduced. A systematic error between methods was not observed. These results indicate that the alteration of arterial pulse wave morphology due to aortic stenosis does not have an adverse impact on the precision of CO estimation. The repeatability of both methods, as well as the agreement between methods, decreased markedly after termination of cardiopulmonary bypass. These data underline the difficulty in obtaining CO values that are stable and accurate during this period of increased hemodynamic fluctuations. In conclusion, our study indicates that arterial pulse waveform analysis may be useful in providing extended hemodynamic monitoring from existing arterial lines in high risk patients with aortic stenosis.

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