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REVIEW ARTICLE/BRIEF REVIEW

Semi-invasive measurement of cardiac output based on pulse contour: a review and analysis

Mesure semi-invasive du débit cardiaque basé sur le contour du pouls: étude et analyse

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Abstract

Purpose *The aim of this review was to provide a meta-analysis of all five of the most popular systems for arterial pulse contour analysis compared with pulmonary artery thermodilution, the established reference method for measuring cardiac output (CO). The five investigated systems are FloTrac/Vigileo®, PiCCO®, LiDCO/PulseCO®, PRAM/MostCare®, and Modelflow.*

Source *In a comprehensive literature search through MEDLINE®, Web of Knowledge (v.5.11), and Google Scholar, we identified prospective studies and reviews that compared the pulse contour approach with the reference method ($n = 316$). Data extracted from the 93 selected studies included range and mean cardiac output, bias, percentage error, software versions, and study population. We performed a pooled weighted analysis of their precision in determining CO in various patient groups and clinical settings.*

Principal findings *Results of the majority of studies indicate that the five investigated systems show acceptable accuracy during hemodynamically stable conditions. Forty-three studies provided adequate data for a pooled weighted analysis and resulted in a mean (SD) total pooled bias of -0.28 (1.25) $L{\cdot}min^{-1}$, percentage error of 40%, and a correlation coefficient of $r = 0.71$. In hemodynamically unstable patients ($n = 8$), we found a higher percentage error (45%) and bias of -0.54 (1.64) $L{\cdot}min^{-1}$.*

Conclusion *During hemodynamic instability, CO measurement based on continuous arterial pulse contour analysis shows only limited agreement with intermittent bolus thermodilution. The calibrated systems seem to deliver more accurate measurements than the auto-calibrated or the non-calibrated systems. For reliable use of these semi-invasive systems, especially for critical therapeutic decisions during hemodynamic disorders, both a strategy for hemodynamic optimization and further technological improvements are necessary.*

Résumé

Objectif *Le but de cette revue était de fournir une méta-analyse des cinq systèmes les plus connus d'analyse de contour du pouls artériel comparativement à la thermodilution artérielle pulmonaire, la méthode de*

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Author contributions *Thomas Schlöglhofer* and *Hermann Gilly* contributed equally to this work. *Thomas Schlöglhofe*r and *Heinrich Schima* developed the concept and aim of the study. *Thomas Schlöglhofer* and *Hermann Gilly* performed the literature research and evaluated the search results; they also performed the quantitative synthesis and analysed the results. *Thomas Schlöglhofer, Hermann Gilly,* and *Heinrich Schima* wrote the manuscript.

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référence actuelle de mesure du débit cardiaque (DC). Les cinq systèmes étudiés sont: FloTrac/Vigileo®, PiCCO®, LiDCO/PulseCO®, PRAM/MostCare® et Modelflow.

Source *Une recherche étendue des publications dans les bases de données MEDLINE®, Web of Knowledge (v.5.11), et Google Scholar, nous a permis d'identifier les études prospectives et les analyses qui comparaient l'approche par le contour de pouls avec la méthode de référence (n = 316). Les données extraites de 93 études sélectionnées incluaient les valeurs de l'étendue et de la moyenne du débit cardiaque, les biais de mesure, les erreurs de pourcentages, les versions des logiciels et la population des études. Nous avons réalisé une analyse groupée et pondérée de leur précision à déterminer le DC chez différents groupes de patients et dans divers contextes cliniques.*

Constatations principales *Les résultats de la majorité des études indiquent que les cinq systèmes analysés affichent une précision acceptable dans les situations hémodynamiquement stables. Quarante-trois études ont fourni des données convenables pour une analyse groupée et pondérée; elles ont abouti à un biais groupé total moyen (É.T.) de −0,28 (1,25) L·min^{-1}, une erreur de pourcentage de 40 % et un coefficient de corrélation r = 0,71. Chez des patients hémodynamiquement instables (n = 8), nous avons trouvé une plus grande erreur de pourcentage (45 %) et un biais de −0,54 (1,64) L·min^{-1}.*

Conclusion *Au cours d'un épisode d'instabilité hémodynamique, la mesure du DC basée sur l'analyse continue du contour du pouls artériel ne montre qu'une concordance limitée avec la thermodilution par bolus intermittents. Les systèmes calibrés semblent procurer des mesures plus précises que les systèmes auto-calibrés ou les systèmes non calibrés. Pour une utilisation fiable de ces systèmes semi-invasifs, en particulier pour des décisions thérapeutiques critiques au cours des troubles hémodynamiques, il est nécessaire de définir une stratégie d'optimisation hémodynamique et de bénéficier d'améliorations technologiques.*

A pulmonary artery catheter (PAC) is a device utilized in intensive care units (ICU) to measure the pressures in the superior vena cava, right heart, and pulmonary artery. It also enables the invasive assessment of cardiac output (CO_{PAC}) or stroke volume (SV) by thermodilution (TD). The use of a PAC is declining[1] as significant complications have been associated with the procedure[2,3] which have resulted in an increase in mortality[4,5] and have raised doubts about its possible benefits.[5] In contrast, a recent report concluded that the use of a PAC did not alter the mortality, general ICU or hospital length of stay, or cost for adult patients in intensive care.[6] Furthermore, it has been emphasized that inappropriate clinical decisions and/or inaccurate hemodynamic data may well constitute a greater risk to the patient than all other PAC-related complications.[7] Thus, for many investigators, measuring cardiac output (CO) using a PAC still represents the clinical reference method of choice[8-11] when evaluating the accuracy or trending capability of less invasive techniques for measurement of CO.

Less invasive CO techniques are mostly based on arterial pulse contour analysis (PCA), which has been investigated for more than a century[12] as a method for estimating and monitoring the SV on a beat-to-beat basis. In 1904,[13] it was pointed out that SV is proportional to pulse pressure (the difference between systolic and diastolic blood pressure). At present, systems based on the pulse contour concept[14,15] are far from being generally accepted as a reference method because other factors influence the pulse wave (e.g., underdamping/resonance artifacts frequently affect blood pressure measurement)[16] and because of technical problems (e.g., proper calibration).[17]

For the assessment of CO by arterial pulse contour analysis (CO_{PCA}), an arterial catheter is required (usually already in place in critically ill patients). The invasiveness of these systems depends on the different calibration requirements.[18] So-called calibrated pulse pressure analysis systems have to be referenced to another accepted (invasive or non-invasive) method. Calibration via transpulmonary (TP) TD (PiCCO/PiCCOplus),[11] lithium indicator dilution (LiDCO), or bolus TD (Modelflow) requires central venous access. The Edwards FloTrac/Vigileo needs no invasive calibration but refers to an autocalibration algorithm based on the patient's demographic data, as detailed in patent applications,[A,B] with the aim of adjusting for different hemodynamic situations. With the LiDCO system, the new LiDCOrapid also offers the possibility of autocalibration via a patient-specific scaling factor.[C] In contrast, the PRAM/MostCare system provides a quasi continuous cardiac output (CCO) readout requiring only a catheter in the radial or femoral

[A] *Hatib F, Roteliuk L, Pearce J* (inventors). Pulse contour method and apparatus for continuous assessment of a cardiovascular parameter. International patent publication WO 2006/113337 A2, 2006 Oct. 26.

[B] *Roteliuk L* (inventor). Arterial pressure-based automatic determination of a cardiovascular parameter. International patent publication WO2005/055825 A1, 2005 June 23.

[C] *LiDCO Ltd*. User's Manual LiDCO Rapid-Fluid management just got easier. http://www.lidcorapid.co.uk/pdfs/english-rapid-v1.04-user-manual.pdf (accessed February 2014).

Table 1 Competing pulse contour-based technologies in clinical cardiac output assessment

Group	Device	PAC	TD necessary	Indicator dilution	Special equipment	Cont. CO	Recalibration necessary
Auto-Calibrated	FloTrac/ Vigileo	No	No	No	Yes, arterial sensor	Yes	No
Calibrated	PiCCO	No	Yes, TP TD	No	Yes, thermistor tipped arterial sensor	Yes, after calibration	Every 3 to 4 hr
	LiDCOplus	No	No	Yes	Yes, lithium dilution set	Yes, after calibration	Every 4 to 6 hr
	Modelflow	Maybe	Yes, or Doppler	No	No	Yes	No
Non-Calibrated	PRAM	No	No	No	Yes, arterial sensor	Yes	No

CO = cardiac output; PAC = pulmonary artery catheter; TD = thermodilution; TP = transpulmonary

artery without any calibration. An overview is presented in Table 1 (see Appendix 1 for further technical details).

In this work, we present an extensive review of five semi-invasive systems, tested over a span of 20 years, their underlying technologies, and how they correspond with CO_{PAC}. Other recent reviews[9,10,18-26] focused on only a single system or excluded at least one of the systems based on arterial pulse contour analysis. This review includes all of the five most popular commercially available systems and also provides technical details (based on their underlying patents) of the individual CO measurement systems. Furthermore a comprehensive pooled weighted analysis of their precision in various patient groups and clinical settings was performed and compared with that of CO_{PAC}. In previously published studies, meta-analyses were performed for only a single system,[22] or the data of different pulse contour systems were analysed as a pooled unit.[23] Our systematic analysis also explores possible differences between calibrated and non-calibrated systems, software generations, and performance differences during hemodynamically stable and unstable conditions. Nevertheless, because of incomplete data in the studies, not all of the reviewed studies were included in the analysis.

Methods

This systematic review was carried out in accordance with recommended methods as established by the Cochrane Methods Group on Screening and Diagnostic Tests, and this review also fulfils the criteria as set by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) group (http://www.prisma-statement.org/).

A literature search covering the topic of semi-invasive CO measurement was performed using the keywords "cardiac output, (pulmonary) thermodilution CO, semi-invasive and minimally invasive CO, Vigileo, FloTrac, PiCCO, PRAM, LiDCO, PulseCO, Modelflow, and CO gold standard". We searched electronic data bases up to August 2013, including MEDLINE (from 1990), Web of Knowledge (v.5.11) (from 1990), and Google Scholar. The search strategy included the following free-text and index terms: "arterial pressure-based cardiac output" or "arterial pressure waveform cardiac output" or "cardiac output" or "FloTrac" or "pulmonary artery thermodilution" or "thermodilution" and not "experimental" and not "pediatric" and not "animal". In review articles, the bibliography was screened additionally for clinical reports and investigations of CO_{PAC} *vs* CO_{PCA}.

Two of the authors (T.S. and H.G.) carefully evaluated the search results ($n = 416$) to select the eligible articles for inclusion (see Appendix 2). First, obviously irrelevant items were excluded by reviewing the title and/or abstract of the records. Next, the full-text articles of the remaining papers ($n = 238$) were retrieved and checked to determine if they met the following eligibility criteria: 1) The study was published in a peer-reviewed journal written in English or German; 2) It was not retracted for any reason ($n = 3$); 3) It was performed in adults; 4) The study described a clinical investigation using one or more semi-invasive CO measurement systems to compare simultaneous measurements of CO or cardiac index with measurements using intermittent bolus right heart TD; and 5) Studies that did not use continuous CO measurements (e.g., Vigilance, Edwards Lifesciences) instead of CO_{PAC} as the reference method. After additionally screening the full-text articles as described, 108 clinical studies were selected for the review (see Fig. 1).

As the intention of this work was to focus on CO data based on arterial pulse contour analysis, we did not analyse derived parameters (e.g., systemic vascular resistance) or volumetric parameters (e.g., extravascular lung water) offered by the EV1000/Volume View from Edwards

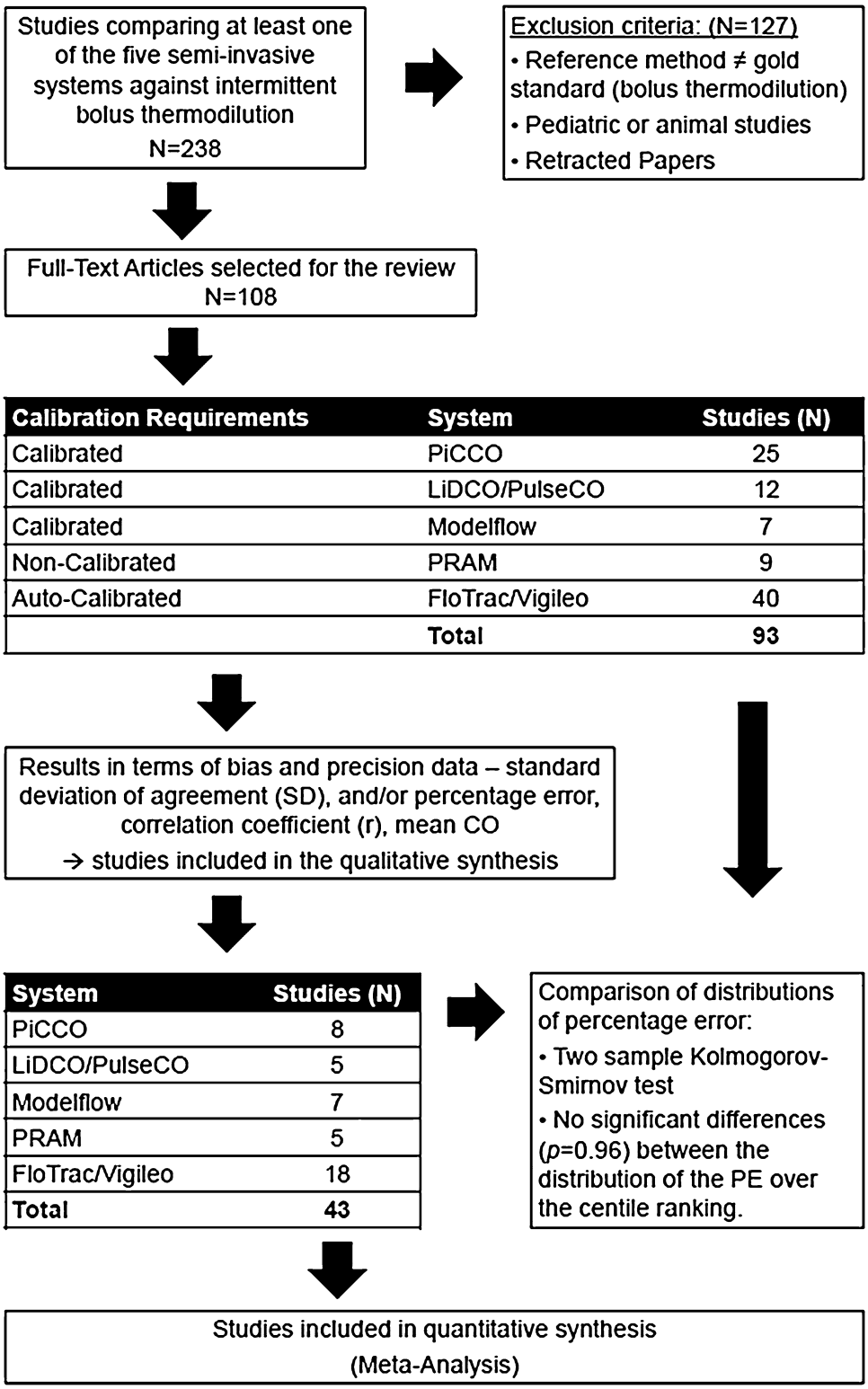

Fig. 1 Flow diagram describing the search strategy to identify papers suitable for analysis

Lifesciences or by the PiCCO systems or LiDCOrapid for perioperative SV optimization and fluid administration. Other methods, like the Fick principle applied to carbon dioxide re-breathing techniques, esophageal Doppler velocimetry, or CO measured by bioimpedance, were excluded as well. The newly introduced Nexfin (BMEYE, The Netherlands), a photoplethysmographic technology which also offers the ability to measure CO noninvasively, was excluded because only two studies[27,28] were found that supplied adequate data. In addition, noninvasive blood

pressure monitoring with Nexfin did not seem to be sufficiently accurate to replace intra-arterial invasive blood pressure measurements in critically ill patients,[29] a result that *a priori* questions its usefulness for noninvasive CO assessment.

Finally, out of these 108 studies, 80 publications with multiple (93) comparisons were analysed to assess the agreement of any of the five semi-invasive systems with intermittent bolus TD CO. In five publications, two or more systems were simultaneously compared with CO_{PAC}, and in five publications, two different software versions/generations were used. The five systems, PiCCO, LiDCO, Modelflow, PRAM and FloTrac, contributed 25, 12, 7, 9, and 40 trials, respectively, to the 93 comparisons. The following data were collected from the 80 publications: number of patients, age range and data points for each study, mean CO (SD), CO range, bias (SD) (semi-invasive system *vs* intermittent bolus TD), percentage error (PE), correlation coefficient (r), software version, study population, arterial access site, study design (blinded or non-blinded observers), and study limitations reported by the authors of the publications. In addition, we collected our own observations of study limitations. In case certain values (e.g., PE) were not reported, they were calculated from other values where possible. To fulfil the Critchley and Critchley criterion (C&Cc),[30] a PE of $\leq 30\%$ between the new CO measurement technique and CO_{PAC} had to be achieved. The PE was calculated as twice the SD of the bias divided by the mean CO.[30] If the mean CO or the range of CO measurements was not stated explicitly in tables or text, it was estimated from the graphs. In seven studies, only the cardiac index was quoted, and we calculated CO from the body surface area (BSA). If BSA was not provided by the authors, a value of 1.9 m^2 was assumed.

Statistical analysis

For each of the five semi-invasive CO measuring systems, mean CO, bias, SD of the bias, and correlation coefficient (r) were included in a pooled weighted analysis and weighted according to equation 1[23] and equation 2[31] on the number of measurements in each trial (see Appendix 3).

The pooled weighted PE was calculated as twice the pooled weighted SD of the bias over the mean pooled weighted CO. The pooled weighted analysis was done for all semi-invasive systems and separately for each system. In the FloTrac/Vigileo (CO_{FT}) studies, sub-group analysis of the three different software releases – first generation (V1.0-V1.03), second generation (V1.07-V1.14), and third generation (V3.0 and higher) – was performed to investigate whether software modifications are reflected in performance improvements. The PiCCO system is initially calibrated with TP TD. The performance of the PiCCO system strongly depends on the re-calibration interval;[32,33] on the one hand, the interval is not always given by the authors, and on the other hand, different intervals have been suggested depending on the investigating group.[34-36] Therefore, studies comparing PiCCO with TP TD as the reference method were excluded to avoid false positive distortion of the results relating to precision.

To verify whether the studies selected for the pooled weighted analysis are a representative selection of all 93 studies, the PE distribution of the studies in the pooled weighted analysis and that of all studies (if reported or at least calculable) were compared with a two-sample Kolmogorov-Smirnov test.

Additionally, a forest plot was drawn in order to provide further information for 14 studies dealing with hemodynamically unstable conditions. The 14 studies could not be included in the pooled weighted analysis because of incomplete data.

The statistical analysis was performed with SPSS® for Windows Release 20.0.0 (SPSS Inc., Chicago, IL, USA). Data are presented as mean (SD) or bias (SD) with a value of $P < 0.05$ considered significant.

Results

All 93 trials investigating the agreement of the five semi-invasive CO systems with intermittent bolus TD are listed in Appendix 4. The systems are grouped according to their different calibration methods (auto-calibrated, calibrated, and non-calibrated). Studies examining the same system are sorted by publication date in descending order.

FloTrac/Vigileo system

First-generation software (N = 10)

Nine out of ten studies investigated the performance of the first FloTrac generation (CO_{FTg1}) in cardiac surgery patients during fairly stable hemodynamic conditions. Although eight trials (80%) referred to the C&Cc, only four authors stated the mean or range of CO measurements. In five studies, different arterial access sites were used and the data were pooled.

Six studies[37-42] classified the performance of the CO_{FTg1} as not satisfactory and demonstrated poor accuracy, with

the PE (40-55%) clearly exceeding the 30% limit of acceptability. Only three studies[43-45] reported a PE < 40%, and the smallest PE of 33% with a bias of 0.55 (0.98) L·min^{-1} was reported in a study of 50 postoperative cardiac surgery patients.[43] The only study[46] using solely femoral arterial access found a bias of −0.15 (0.33) L·min^{-1} with CO_{FTg1}, and neither mean CO nor PE was mentioned. None of the ten studies fulfilled the C&Cc.

Second-generation software (n = 24)

Most of the FloTrac studies ($n = 24$) used the second-generation software (CO_{FTg2}). In 21 (88%) of the studies, PE was presented or calculable. In contrast with the CO_{FTg1} evaluations, the second-generation studies were performed in various patient cohorts. Two authors[45,47] consider modifications between the first- and second-generation software to have resulted in better accuracy in the CO measurements. Only six studies (four studies in cardiac surgery, one in liver transplant, and one in septic shock patients)[45,48-52] using the second-generation software reported acceptable precision with a PE < 30%. During/after cardiac surgery,[53-57] liver transplantation,[58] and during septic shock,[59] PE was < 50% (32-48%) with correlation coefficients ranging from r = 0.32-0.90. On the other hand, a high PE > 60% during cardiac surgery,[60,61] in hyperdynamic cirrhotics,[62] and in patients undergoing liver transplantation[63] points to the fact that CO_{FTg2} may deviate considerably from CO_{PAC}.

Up to now, four studies[51,58,62,64] have reported a (logarithmic) relationship between the bias of CO_{FTg2} and systemic vascular resistance (SVR), with the observation, the higher the bias, the lower the SVR.

Third-generation software (n = 6)

In two studies evaluating the FloTrac third-generation software (CO_{FTg3}), only poor agreement with CO_{PAC} was found during liver transplantation[65,66] and in one study with septic shock patients.[67] In contrast, in another study with septic patients[51] and with cardiac surgery,[68] CO_{FTg3} and the CO_{PAC} reference agreed, with a PE of 29% and 22%, respectively.

When compared with the second generation, the third-generation software seems to be less sensitive to a changing SVR, thus resulting in improved overall precision and trending ability.[51,66] Nevertheless, after living-donor liver transplantation, the bias between CO_{FTg3} and CO_{PAC} still became apparent when SVR was < 1,000 dyne·sec·cm^{-5}.[69]

According to the manufacturer,[D] the site of arterial access[55] should not affect FloTrac/Vigileo results. Almost all studies investigated FloTrac performance via radial artery access (see Appendix 4). Five studies compared the radial *vs* the femoral access site. The results of two studies[43,60] point to a modest but not negligible influence of the arterial access site. With a PE difference < 5%,[51,55,68] arterial site-independent results were observed with CO_{FTg2} and CO_{FTg3}. Two other studies using femoral access[70,71] reported only limited agreement with CO_{PAC} during cardiac surgery.

PiCCO/PiCCOplus system (n = 25)

Twenty-five studies were identified that supplied adequate data in terms of bias and precision, and 21 of them were in cardiac surgery patients. The PE was revealed by the authors or calculable on the basis of other values in only 14 trials (58%). Range and mean CO were quoted in eight trials (32%). In 21 (88%) trials, the PiCCO catheter was inserted via the femoral artery.

The recalibration interval and the influence of the SVR on PiCCO-derived CO (CO_{PiCCO}) are still discussed controversially in the literature. According to two studies,[70,72] changes in SVR do not affect the accuracy of CO_{PiCCO} if a recalibration is performed every four hours. Another study in hemodynamically stable patients[73] emphasizes that recalibration of PiCCO is not necessary more often than every three hours and that CO_{PiCCO} is clinically acceptable (PE not stated). Nevertheless, the same authors recommend additional studies with PiCCO in septic shock patients or during the use of vasoactive drugs. Three studies[34-36] concluded that recalibration of the PiCCO is necessary at least after marked changes in SVR. The requirement of frequent recalibration, especially in the presence of vasopressors, is also discussed by other authors.[74,75] Remarkably, excellent results were found when CO_{PiCCO} and CO_{PAC} were compared in stable cardiac surgery patients,[76] as long as there were no significant changes in SVR[36] [bias (SD) of 0.23 (0.50) L·min^{-1} and PE 20%]. When the whole study period was evaluated, however, the PE of 36% exceeded clinical acceptability. Without any recalibration, a high bias > 1.0 L·min^{-1} and SD > 2.0 L·min^{-1} of CO_{PiCCO} was observed.[77,78] When initial calibration was performed with CO_{PAC} instead of TP TD CO (CO_{TPTD}), PiCCO results were not comparable with the reference method: CO_{PiCCO} was underestimated and low correlation coefficients (r < 0.40) were found and, if calculable, PE was beyond clinical acceptability.[21,46,71,79]

[D] *Edwards*. Lifesciences Inc. FloTrac System 3rd Generation Software. Available from URL: http://www.edwards.com/eu/products/mininvasive/Pages/flotrac3g.aspx (accessed February 2014).

In hemodynamically stable cardiac surgery patients, comparable but not interchangeable results (PE 34-43%) were observed. The PiCCO system was acknowledged to be useful to monitor trends, but intermittent bolus TD remained the method of choice for measuring CO.[55,80,81] In similar patients,[82,83] CO_{PAC} and CO_{PiCCO} did not agree and showed large discrepancies (PE > 50%). Just a few authors reported a PE < 30%, indicating interchangeable results of CO_{PiCCO} and CO_{PAC}.[45,76,84-86]

Several studies[35,46,47,87-89] performed only in cardiac surgery patients reported a small bias < 0.5 $L \cdot min^{-1}$ with a SD > 0.5 $L \cdot min^{-1}$ and correlation coefficients up to r = 0.93. Although the authors argue that CO_{PiCCO} is a reliable alternative to CO_{PAC}, it has to be emphasized that important information (PE and mean) is not given.

LiDCO/PulseCO system (n = 12)

Nine of 12 studies comparing LiDCO-derived CO (CO_{LI}) with CO_{PAC} reported the PE. Eighty-three percent of the investigators used radial artery access to measure the arterial lithium concentration. Up to now, the new LiDCOrapid system has been evaluated only in animal studies or compared with other CO measurement methods but not with bolus CO_{PAC}, therefore, the studies were not included in our analysis. CO_{LI} showed good agreement with CO_{PAC} during hemodynamically stable conditions post cardiac surgery,[90-93] after liver transplantation,[94] and in patients with severe pre-eclampsia.[95] Three studies showed clinical acceptability of LiDCO (PE < 30%), although initial calibration was performed with intermittent bolus TD instead of the manufacturer recommended lithium dilution technique.[21,71,96] Nevertheless, with initial CO_{PAC} calibration and without any recalibration, CO_{LI} overestimated CO_{PAC} during cardiac surgery.[97] Two studies (22%) postulated that LiDCO cannot be used interchangeably with CO_{PAC} in liver transplant patients[63] or in a mixed study population, including septic patients[42] CO_{LI} clearly failed to show acceptable accuracy (PE of 76% and 40%, respectively).

Modelflow system (n = 7)

In six of the studies evaluating CO with the Modelflow system (CO_{MF}), the PE was stated or at least calculable, and met the 30% limit. All studies but two[98,99] were performed in rather small patient groups ($n < 30$ patients). After calibration with CO_{PAC}, CO_{MF} showed high accuracy with pressure signals obtained from a radial or femoral artery and was able to replace intermittent bolus TD during cardiac surgery[21,99,100] and in septic shock patients.[101] Nevertheless, the C&Cc was not fulfilled during liver transplantation.[98] After aortic diameter calibration[102] instead of TD calibration, CO_{MF} showed clinical acceptability (PE = 12%). Interestingly, even with noninvasive pressure signal monitoring after ultrasound calibration, a small bias and small SD was reported in critically ill ICU patients.[103]

PRAM/MostCare system (n = 9)

The nine studies suitable for analysis can be divided into studies with excellent and comparable results for CO measured by PRAM (CO_{PRAM}) and CO_{PAC} and into studies which show only poor agreement between the two methods. The PRAM technique was reliable in patients undergoing left or right heart catheterization.[104,105] Pressure in both studies was recorded via an aortic catheter and not from a peripheral arterial line. Excellent performance of CO_{PRAM} was also reported during[106,107] and after cardiac surgery[108] and in patients with an intra-aortic balloon pump.[109] Despite these findings, differences between CO_{PAC} and CO_{PRAM} became evident at extremely high or low CO values.[105,106] In septic shock patients,[110] there appeared to be no correlation between SVR and bias, and the C&Cc was met (PE = 25%). The results of two post cardiac surgery studies[111,112] are in clear contrast with those of other studies.[104-110] It should be pointed out that the latter studies were performed either by the same group or by authors cooperating with this group. The reason for the enormous discrepancy between these two groups of studies (PE > 73%) is not clear, especially since study sizes and participants were comparable.

Pooled weighted analysis

Forty-three (46%) of 93 trials listed in Appendix 4 provided adequate data for a pooled weighted analysis of mean CO, bias (SD), and PE: eight (32%) studies on PiCCO, five (42%) studies on LiDCO/PulseCO, seven studies (100%) on Modelflow, five studies (56%) on PRAM, and 18 studies (45%) on FloTrac/Vigileo (n = 4/9/5 trials with the first/second/third-generation software, respectively).

The PE distribution of the 43 selected studies for the pooled analysis (Table 1) and of all studies compiled in Appendix 4 showed no significant differences ($P = 0.96$) across the percentile ranking (two-sample Kolmogorov-Smirnov test).

The calculated mean weighted pooled data are presented in Table 3. The 43 studies (5,780 measurements in total) resulted in a pooled weighted bias of −0.28 (1.25) $L \cdot min^{-1}$ and a pooled weighted PE of 40%. Thus, our findings are in concordance with another meta-analysis[23] reporting a pooled PE of 42.1% in 21 studies with pulse contour systems. The pooled bias points to underestimation of CO_{PAC} in all systems with the exception of PRAM (Fig. 2A). Worth highlighting, the widest range in bias was observed with CO_{FTg3}. The pooled PE was lowest for CO_{LI} (27%) and

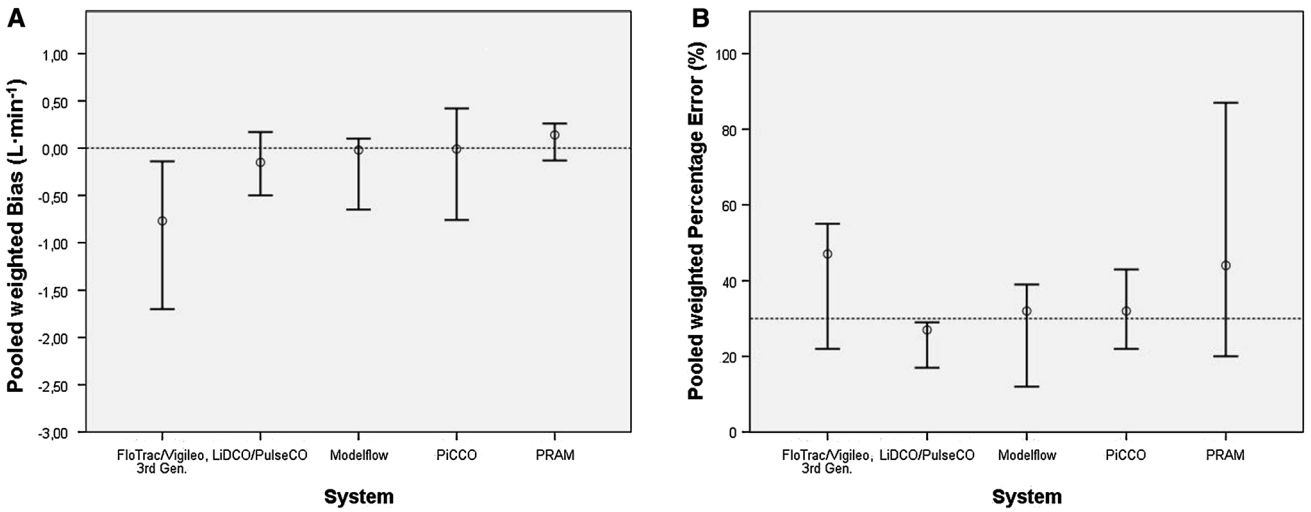

Fig. 2 Pooled weighted bias (A) and percentage error (B) showing agreement of cardiac output measured by five semi-invasive systems (FT_{g3}: $n = 5$; LiDCO: $n = 5$ Modelflow: $n = 7$; PiCCO: $n = 8$; PRAM: $n = 5$) and intermittent bolus thermodilution. ° Mean pooled weighted bias and PE (cardiac output $[CO]_{method}$ *vs* CO_{PAC}); bars indicate range of bias and PE, respectively. Broken lines represent zero bias (A) and the 30% Critchley & Critchley criterion (C&Cc) (B). CO_{PAC} = cardiac output assessed using a pulmonary artery catheter; PE = percentage error

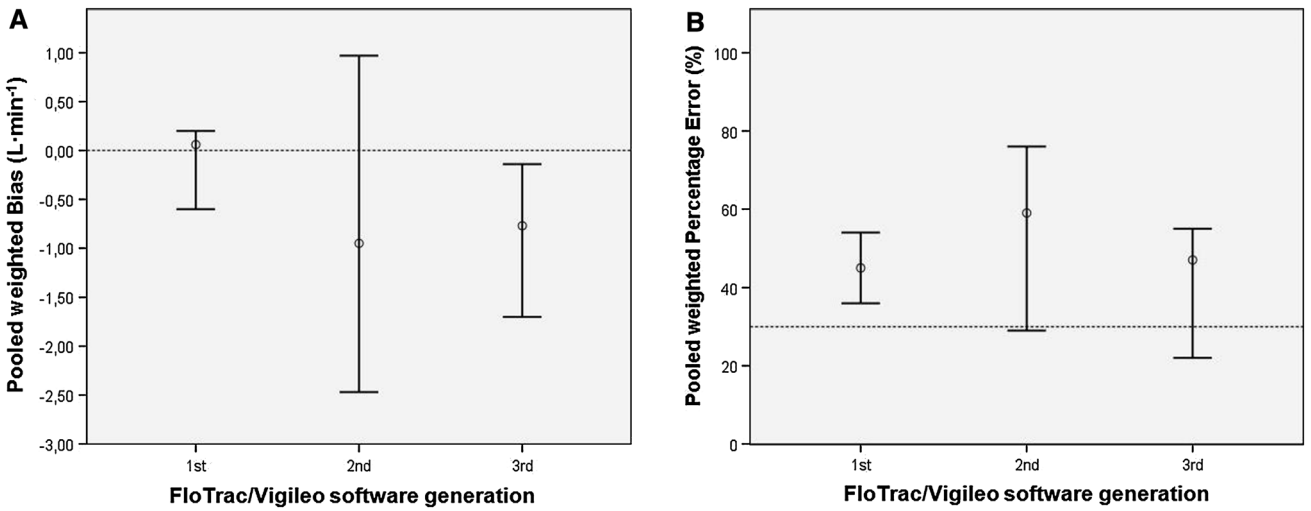

Fig. 3 Pooled weighted bias (A) and percentage error (B) showing agreement of cardiac output measured by FloTrac, first, second, and third ($n = 4/9/5$, respectively) software generation and intermittent bolus thermodilution. ° Mean pooled weighted bias and percentage error (PE) (CO_{FT} *vs* CO_{PAC}); bars indicate range of bias and PE, respectively. Broken lines represent zero bias (A) and the 30% Critchley & Critchley criterion (C&Cc) (B). CO_{FT} = cardiac output assessed using the FloTrac system; CO_{PAC} = cardiac output assessed using a pulmonary artery catheter

highest for CO_{FT} (52%; in subgroup FT_{g2} 59%). Only LiDCO fulfilled the C&Cc; PiCCO and Modelflow exceeded it marginally (PE = 32%), FloTrac/Vigileo (third-generation software) and PRAM grossly exceeded the 30% limit (PE 47% and 44%, respectively), as also shown in Fig. 2B. In the CO_{FT} subgroup analysis (see Table 3 and Fig. 3), the lowest bias of 0.06 (1.31) L·min^{-1} and the lowest PE (45%) in this group were found in the first-generation software.

Eight of these 43 studies were performed in liver transplant and septic shock patients and used for a sub-analysis to investigate the differences in performance in hemodynamically unstable situations (Fig. 4). With 1,911 measurements in total, the five semi-invasive systems

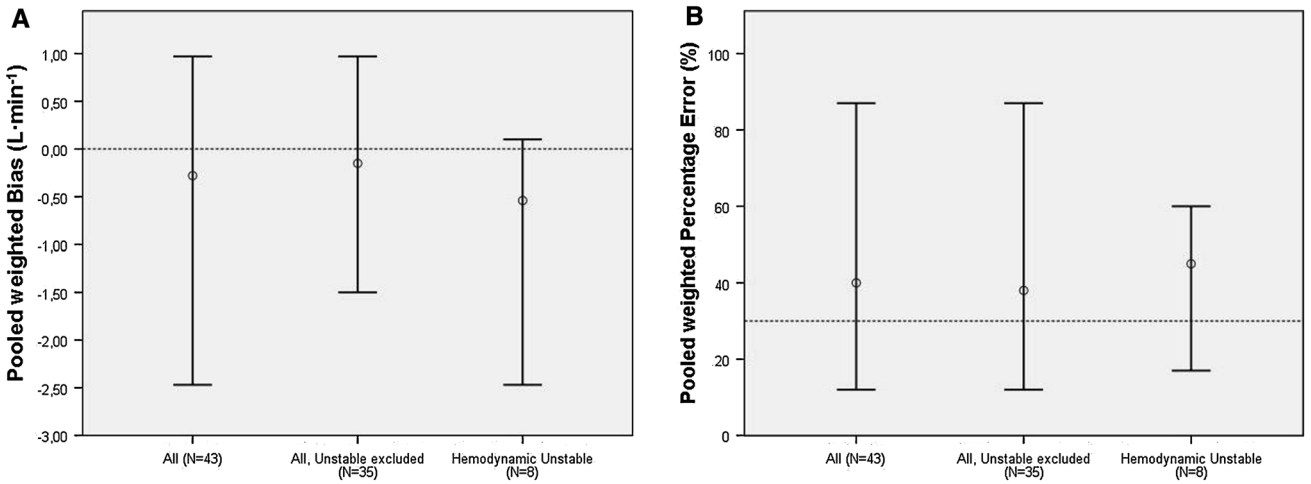

Fig. 4 Pooled weighted bias (A) and percentage error (B) showing agreement of all studies included in the analysis ($n = 43$); studies excluding hemodynamically unstable conditions ($n = 35$); and those studies referring to hemodynamically unstable conditions ($n = 8$). ° Mean pooled weighted bias and percentage error (PE) (cardiac output $[CO]_{method}$ *vs* CO_{PAC}); bars indicate range of bias and PE, respectively. Broken lines represent zero bias (A) and the 30% Critchley & Critchley criterion. CO_{PAC} = cardiac output assessed with a pulmonary artery catheter

(PiCCO/ LiDCO/ Modelflow/ PRAM/ FloTrac) contributed with $n = 0/1/2/0/5$ trials, respectively, to the hemodynamically unstable cohort. This cohort yielded a pooled weighted bias of -0.54 (1.64) $L{\cdot}min^{-1}$ (Fig. 4A) and a pooled weighted PE of 45.3% (Fig. 4B) with $r = 0.75$. Compared with all studies included in the analysis, hemodynamic instability results in a slightly higher PE (5% higher) and bias. The exclusion of the eight studies performed in unstable patients yielded a smaller bias of -0.15 (1.04) $L{\cdot}min^{-1}$ and a smaller PE (38%) compared with all studies in the pooled analysis (Table 2).

Thirty-nine studies (Table 4) met the criteria for pooled weighted analysis of the correlation between the five systems and bolus TD. The highest correlation was found for CO_{LI} ($r = 0.88$) and the lowest for CO_{FT} ($r = 0.54$; in the subgroup FT_{g1} $r = 0.50$). A correlation coefficient was given in only one study with CO_{FTg3} ($r = 0.67$). For all semi-invasive studies, the pooled weighted correlation resulted in $r = 0.71$ and was slightly lower than in a recently published analysis including only 12 pulse contour studies ($r = 0.75$).[23]

In order to show the results obtained in hemodynamically unstable patients, we also analysed the bias and confidence intervals in those studies; however, because of incomplete data, the results could not be included in the pooled analysis. These results are compiled in the forest plot (Fig. 5) covering FloTrac ($n = 5$, second generation and $n = 4$, third generation), PiCCO ($n = 1$), LiDCO ($n = 2$), and Modelflow ($n = 2$). All but two pulse contour systems underestimated CO compared with CO_{PAC}.

Discussion

For monitoring in the perioperative period and in the critical care setting, systems based on pulse contour measurement have recently been offered as a more-or-less accurate and safe alternative[113] to the highly invasive Swan-Ganz PAC. Despite continued efforts to introduce improved products to the market, the main outcome of our analysis is that a clear recommendation cannot be given for any single system that can accurately monitor hemodynamically unstable patients. This limitation also applies to reliable intraoperative monitoring during surgery accompanied by hemodynamic instability. The informative value of CO_{PCA}-based monitoring during hemodynamically stable conditions should be questioned, since CO data provided by these monitors parallel the arterial pressure as long as the compliance and resistance remain unaffected.

From the technical point of view, it is important to be aware of the inherent limitations of the mathematical models/algorithms implemented. Important model parameters might have been derived from patient cohorts that might not always fully match the critical care patients to be monitored. It is therefore necessary to readjust these parameters, especially during hemodynamic instability. We

Table 2 Studies included in the pooled weighted analysis comparing different systems for measuring cardiac output with the intermittent bolus TD as reference

References	*n*	Cardiac output		PE (%)	r**	Software version
		Mean (SD) ($L \cdot min^{-1}$)	Bias (SD) ($L \cdot min^{-1}$)			
Auto-calibrated						
FloTrac/Vigileo						
Sander *et al.*[39]	30/108	5.5 (1.1)	−0.60 (1.40)	54	0.53	1st
Opdam *et al.*[40]	6/218		0.41 (1.00)	40	0.35	1st
Prasser *et al.*[41]	20/164	5.9 (1.2)	−0.02 (1.48)	49	0.58	1st
Breukers *et al.*[44]	20/56	5.5 (0.9)	0.14 (1.00)	36 §	0.74	1st
Chakravarthy *et al.*[46]	15/438		−0.15 (0.33)		0.49	1st
McGee *et al.*[37]	84/561	5.9 (?)	0.20 (1.28)	43		1st
Cannesson *et al.*[53]	11/166	4.7 (1.0)	0.26 (0.87)	37 §	0.66	2nd
Mehta *et al.*[48]	12/?	4.5 (1.3)	−0.26 (0.66)	29		2nd
Biais *et al.*[58]	20/400	5.5 (1.0)	−0.80 (1.35)	43		2nd
Della Rocca *et al.*[50]	18/126		−0.95 (1.41)	26	0.68	2nd
Biancofiore *et al.*[62]*	29/261	7.4 (1.7)	−2.47 (2.66)	60	0.39	2nd
Eleftheriadis *et al.*[70]	16/80		0.40 (0.87)		0.51	2nd
Slagt *et al.*[59]	5/86		−1.60 (1.60)	48	0.32	2nd
	4/73		−1.20 (1.10)	32	0.90	2nd
Maxeiner *et al.*[57]	19/62	5.0 (1.0)	0.87 (1.02)	45	0.46	2nd
	15/60	4.7 (1.0)	0.51 (0.82)	36	0.72	2nd
Saraceni *et al.*[61]	15/96	6.56 (?)	0.19 (2.50)	76 §	0.63	2nd
	6/45	7.48 (?)	−0.97 (1.83)	49 §	0.72	2nd
Junttila *et al.*[64]	16/407	6.0 (1.7)	−1.50 (2.00)	58		2nd
Biancofiore *et al.*[66]*	21/210	8.2 (1.9)	−0.74 (1.60)	52	0.67	3rd
Akiyoshi *et al.*[69]	20/138	6.3 (?)	−0.89 (1.35)	38		3rd
Tsai *et al.*[65]	20/200	5.9 (1.8)	−0.22 (1.67)	55		3rd
Vasdev *et al.*[68]	38/342	4.8 (?)	−0.14 (0.55)	22		3rd
Slagt *et al.*[67]	19/314	6.8 (2.0)	−1.70 (2.40)	53		3rd
Calibrated						
PiCCO/PiCCOplus						
Irlbeck *et al.*[87]	20/165		−0.09 (0.85)		0.93	1.x
Buhre *et al.*[72]	12/36	4.4 (?)	0.003 (0.63)	29 §	0.88	1.x
Zöllner *et al.*[73]	19/228		0.31 (1.25)		0.88	
Mielck *et al.*[80]	22/96	6.6 (1.7)	−0.40 (1.30)	39		
Gödje *et al.*[35]	24/517		−0.20 (1.15)		0.88	4.1
Della Rocca *et al.*[86]	62/186	7.8 (?)	0.04 (0.84)	22 §	0.94	4.1
Felbinger *et al.*[88]*	20/360		0.27 (0.63)		0.93	
Della Rocca *et al.*[84]	58/318	6.1 (?)	0.08 (0.72)	24 §		4.1
Sujatha *et al.*[36]	60/480	4.4 (?	0.42 (0.86)	36		
Halvorsen *et al.*[81]	30/252	6.0 (?)	−0.76 (1.17)	43		5.1
Chakravarthy *et al.*[46]	15/438		−0.13 (1.12)		0.40	
de Wilde *et al.*[21]	24/199	4.7 (?)	−0.14 (0.87)	37 §		
LiDCO/PulseCO						
Linton *et al.*[90]	40/160		−0.25 (0.5)		0.97	
Garcia-Rodriguez *et al.*[91]	31/93	5.55 (?)	−0.5 (0.7)	24 §		
Hamilton *et al.*[92]	20/100		0.05 (0.6)		0.86	
Costa *et al.*[94]	23/151	7.7 (?)	−0.29 (1.09)	17	0.85	
Missant *et al.*[96]	20/149	4.9 (?)	−0.03 (0.65)	29	0.84	

Table 2 continued

References	*n*	Cardiac output		PE (%)	r**	Software version
		Mean (SD) ($L \cdot min^{-1}$)	Bias (SD) ($L \cdot min^{-1}$)			
de Wilde *et al.*[21]	24/199	5.0 (?)	0.17 (0.69)	28 §		
Mora *et al.*[93]	30/220	6.2 (1.9)	−0.28 (0.84)	27	0.86	
Modelflow						
Wesseling *et al.*[100]	8/76	4.7 (0.4)	0.09 (0.36)	15 §		
Jellema *et al.*[101]	15/137	8.9 (3.0)	−0.10 (0.80)	18 §		
Hirschl *et al.*[103]*	29/175	6.3 (?)	−0.65 (1.25)	19 §		
Jansen *et al.*[99]	54/436	4.9 (0.9)	−0.13 (0.47)	19 §		
de Vaal *et al.*[102]	24/24	5.4 (?)	−0.08 (0.70)	12	0.83	
de Wilde *et al.*[21]	24/199	4.8 (?)	0.00 (0.37)	15 §		
Nissen *et al.*[98]	39/1309	7.8 (2.6)	0.10 (1.50)	39 §	0.81	
Non-calibrated						
PRAM						
Romano *et al.*[105]*	50 / ?	5.1 (1.1)	−0.06 (0.80)	31 §	0.85	
Romano *et al.*[107]	32 / 128	4.0 (0.7)	0.07 (0.40)	20 §	0.87	
Zangrillo *et al.*[108]*	28 / 28	5.1 (1.1)	−0.13 (0.78)	30	0.72	
Paarmann *et al.*[111]	23 / 46		0.00 (2.26)	87	0.31	
Scolletta *et al.*[109]	15 / 106		0.20 (0.98)	24	0.90	
Franchi *et al.*[110]	30 / 90	7.7 (?)	0.26 (0.98)	25	0.93	
Maj *et al.*[112]	41/123	4.6 (?)	0.25 (1.66)	73	0.08	

n = patients / measurements; PE = percentage error; ? = value not given

* Cardiac index converted to CO with body surface area of 1.9 ($L \cdot min^{-1} \cdot m^{-2}$); ** Some values converted from r^2 to r; § PE not mentioned and therefore calculated according to Critchley & Critchley[30]

found no explicit evidence that suggested calibration intervals were strictly followed. If this were the case, it seems clear that the calibrated systems would provide more accurate CO data than the non-calibrated or auto-calibrated systems.

Table 3 Pooled weighted data showing agreement between the five semi-invasive CO systems and intermittent bolus thermodilution

System	Studies *n*	Mean CO ($L \cdot min^{-1}$)	Bias (SD) ($L \cdot min^{-1}$)	PE (%)
FloTrac/Vigileo	18	6.0	−0.62 (1.56)	52
$FloTrac_{FTg1}$	4	5.8	0.06 (1.31)	45
$FloTrac_{FTg2}$	9	6.0	−0.95 (1.75)	59
$FloTrac_{FTg3}$	5	7.4	−0.77 (1.72)	47
PiCCO	8	5.6	−0.01 (0.90)	32
LiDCO/PulseCO	5	5.9	−0.15 (0.80)	27
Modelflow	7	6.8	−0.02 (1.11)	32
PRAM	5	5.2	0.14 (1.13)	44
Semi-invasive total	**43**	**5.9**	**−0.28 (1.25)**	**40**
Hemodynamically stable	35	5.5	−0.15 (1.04)	38
Hemodynamically unstable	8	7.3	−0.54 (1.64)	45

CO = cardiac output; PE = percentage error

This is in line with our results showing the calibrated systems to be more accurate (LiDCO, Modelflow, and PiCCO) than the auto-calibrated FloTrac or the non-calibrated PRAM (see Fig. 2). It is noteworthy that almost all systems failed to fulfil the C&Cc in both hemodynamically stable and hemodynamically unstable scenarios (Table 3).

Table 4 Pooled weighted correlation between the five semi-invasive CO systems and intermittent bolus thermodilution

System	Studies *n*	r
FloTrac/Vigileo	17	0.54
$FloTrac_{FTg1}$	6	0.50
$FloTrac_{FTg2}$	10	0.56
$FloTrac_{FTg3}$	1	0.67
PiCCO	8	0.79
LiDCO/PulseCO	5	0.88
Modelflow	2	0.81
PRAM	7	0.68
Semi-invasive total	39	0.71
Hemodynamically stable	35	0.69
Hemodynamically unstable	4	0.75

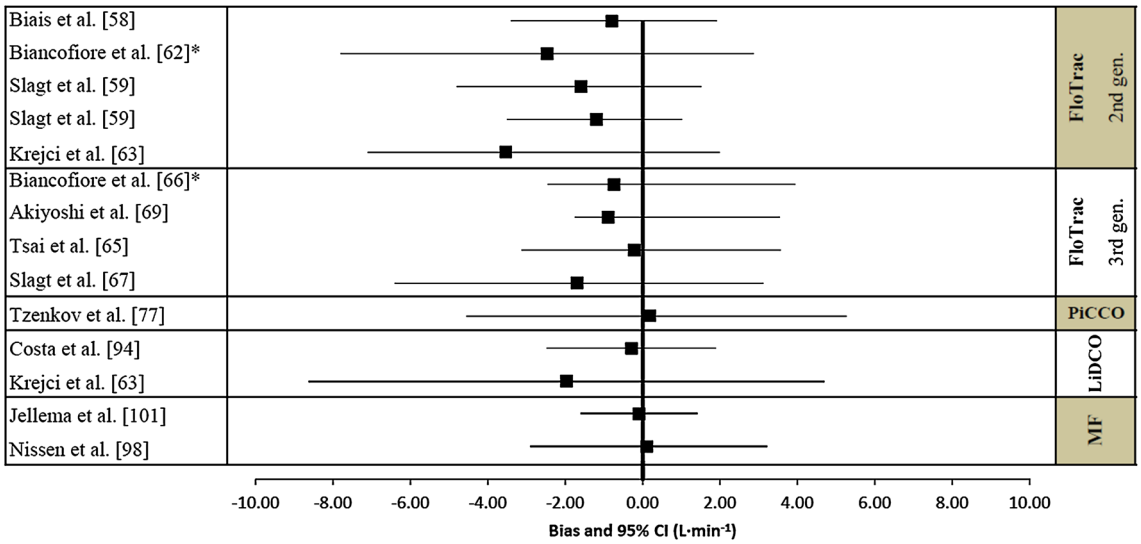

Fig. 5 Forest plot showing the agreement of cardiac output measured by five semi-invasive systems with intermittent bolus thermodilution in 14 studies referring to hemodynamically unstable conditions. ■ bias (cardiac output $[CO]_{method}$ *vs* CO_{PAC}); bars indicate the 95% confidence interval. CO_{PAC} = cardiac output assessed with a pulmonary artery catheter. *Cardiac index converted to cardiac output with body surface area of 1.9 ($L \cdot min^{-1} \cdot m^{-2}$). The 14 selected studies include the eight from Fig. 4 designated as unstable plus those six studies in which neither the mean cardiac output (CO) nor the number of data points were stated. Notice that studies with septic patients and with liver transplant patients characterized as "hemodynamically stable" by the author or studies in which the bias was given in % are excluded (see Appendix 4)

CO_{PAC} as reference method of choice

Although CO_{PAC} was long the "gold standard" and is still widely accepted as the reference method of choice for CO determination,[114,115] the method itself suffers from several limitations. Besides its invasiveness and the concomitant risks, the accuracy of the method also depends on external factors, e.g., overestimates have been reported at low CO levels.[116] Other factors that may influence the accuracy of bolus TD are valve insufficiency, fluid discontinuation and shunting,[117] ventilation,[118] transition from cardiopulmonary bypass,[119] and operator experience. Triplicate injections are recommended to achieve acceptable accuracy,[117,120] although it has also been shown that four CO measurements in series must be averaged in order to be 95% confident that the result is within 5% of the "true" CO.[121] When all these factors are taken into account, the overall accuracy of the TD reference CO_{PAC} may be ± 15% at best (in a recent *in vitro* study, the PE was shown to range from 13-15.3%).[122] In light of this basic limitation, the question of clinically acceptable error has to be raised. When C&C analysed 34 studies (23 bioimpedance *vs* CO_{PAC}, 11 Doppler *vs* either CO_{PAC} or Fick CO_2 rebreathing),[30] they found differences between the methods, i.e., up to 37% in the PE for PAC/Fick and up to 65% higher for Doppler measurements. The authors considered an error of 20% acceptable for clinical practice. When methods with a 20% error are compared, a deviation of up to 28.3% will result. Therefore, C&C[30] concluded that a deviation of < 30% would still be acceptable when comparing a new CO measurement system with CO_{PAC}. This position has also been challenged[123] because quoting the PE as an adequate criterion without reporting the precision of the reference technique[124] or the confidence intervals[125] could lead to erroneous conclusions. It has been proposed to enlarge the acceptable PE to 45%,[123] which would mean that the tested method would show a precision of only 42.4% and 40.3%, respectively, when assuming a precision of 15% or 20% for the reference method.

Limitations with respect to the accuracy of the chosen reference method

When aiming at a sufficiently close estimate of the "true" precision of the tested method, it is important to be clear about the accuracy of the reference method. We were not able to define the averaged precision of the reference method for the pooled 43 studies, as the relevant data on the reference were only sparsely described or not reported. If the reference technique had been performed with less precision than the generally accepted 20%, then this would have resulted in a smaller PE for the tested semi-invasive method[124] and in the acceptance of the studied technique based on a questionable level of precision. None of the investigators stated the predicted level of precision for the tested technique at the start of their study.

Limitations in our analysis with regard to available data

First, with respect to our analysis, we appreciate that the number of studies varied considerably for the different systems (from seven Modelflow up to 40 FloTrac/Vigileo studies). No more than 43 reports (46%) out of 93 trials in our extensive literature search provided adequate data for a pooled weighted analysis, a fact which considerably reduced the available data pool for a thorough evaluation and thus weakened the statistical power. Furthermore, due to shortage of data we could not perform a detailed sub-analysis regarding the influence of vasoactive drugs, reasons for hemodynamic instability, or differences with respect to peri-, intra-, and postoperative CO conditions.

Second, the significant heterogeneity in the number of data pairs evaluating the different CO devices impairs the strength of our analysis.

Third, in seven papers cardiac index but not CO data were reported. Assuming a body surface area of 1.9 m^2 could possibly have modified our overall results; however, we consider such modification to be insignificant.

Fourth, studies that compare these systems with other reference methods were explicitly excluded (as outlined in our Methods section), reducing the available body of knowledge on the performance of CO_{PCA} methods. For example, we excluded several studies comparing the FloTrac/Vigileo with CCO[69,123,126-130] as well as with TP TD[131-133] or esophageal Doppler.[134] We also excluded the few available studies comparing LiDCO with TP TD[135] or CCO[136] as well as an evaluation of the PRAM system *vs* CCO.[109] A single study evaluated the Modelflow device using graded lower body negative pressure.[137]

Comparison of systems

For the FloTrac/Vigileo system, 18 applicable studies using different software versions were selected, and only two studies[48,65] met the C&Cc. If the software version was not stated, we inferred the version from another study.[22] Remarkably, the smallest PE (45%) in the pooled analysis of FloTrac data was found in the studies using devices with first-generation software but in hemodynamically stable conditions (see Fig. 3B). The highest pooled PE (59%) was found in studies using the second-generation software, but these investigations were performed in patients in hemodynamically less stable conditions. When the manufacturer introduced the third-generation software, it was claimed to take enhanced account of changing hemodynamic conditions.[E] Though there is a modestly smaller bias in the third-generation software than in the second (see Figs. 3 and 5); nevertheless, it is important to be aware that CO_{FTg3} may grossly deviate from CO_{PAC} or CCO during hemodynamic instability[138] and particularly in extreme conditions of vasoconstriction or vasodilation.[123] As yet, the FloTrac/Vigileo algorithm for autocalibration apparently adjusts insufficiently for gross changes.

For the PiCCO system, only eight of 25 studies included sufficient data to be included in the pooled weighted analysis. The lowest reported PE was 20%;[36] however, this was measured in the pre-induction phase of anesthesia. In the pooled analysis, PiCCO exceeded the PE criterion only marginally (PE = 32%). Since almost all data were obtained in hemodynamically stable conditions, it must be concluded, based on the available data, that it is not possible to judge the reliability of PiCCO under hemodynamically unstable conditions.

Many studies assessing the three other CO measurement systems (LiDCO, PRAM, and Modelflow) show a PE of 30%; however, one should note that most of these studies were performed in only three centres (Modelflow as well as PRAM). For the PRAM system, two studies from external centres report high PEs of 87%[111] and 73%,[112] respectively, yielding a pooled weighted PE of 44%. The PRAM device was the only system showing a pooled bias overestimation (0.14 $L \cdot min^{-1}$), while all other devices underestimated CO_{PAC}. Remarkably, with a pooled PE of 27% (LiDCO), just one of the five semi-invasive systems fulfilled the C&Cc, and the highest pooled correlation coefficient was found with LiDCO (r = 0.88). On the other hand, a most recent LiDCO study performed in animals[139] highlights a large bias between CO_{LI} and CO_{PAC} and identifies a number of drugs used in perioperative medicine that influence the accuracy of the LiDCO sensor *in vitro*.[140] As we found no comparisons with CO_{PAC} in humans, LiDCOrapid studies were not included in our analysis. This auto-calibrated system[C] was validated against the commonly used LiDCO indicator dilution-based calibration and a correlation of r = 0.88 was reported. According to the manufacturer, the scaling factor estimate may not be as precise as an independent calibration with a well-performed indicator dilution method. It therefore remains highly questionable whether the auto-calibrated LiDCOrapid system would successfully replace the lithium indicator calibrated measurement. Special care should be taken when using LiDCOrapid, especially in patients with severe peripheral vasoconstriction with the particular requirement of high-fidelity pressure recording.[C]

Tracking changes

With respect to measuring trends in CO, the capabilities of various CO measurement devices (Vigileo, PiCCO, bioimpedance, Doppler sound, and pulse contour) were carefully analysed in a recent review.[141] If these devices

[E] *Edwards*. FloTrac Sensor. Available from URL: http://ht.edwards.com/scin/edwards/sitecollectionimages/products/mininvasive/flotracbrochurear05917.pdf (accessed February 2014).

are used to track changes in CO, induced for instance by preload changes, care must be taken to ensure there are no additional influences from altered vascular tone.[24] A most recent study[142] emphasizes the rather poor performance of the Vigileo system in tracking changes in CO induced by increased vasomotor tone: the concordance rates between CO_{PAC}- and CO_{PCO}-changes were 67.5%, 28.8%, and 7.7% in the low, normal, and high SVRI states, respectively.

A recent report[143] emphasizes that, in clinical practice, the dynamic response (trending) to interventions is more important and critical than absolute values of CO. More serious consideration should be given to the ability to track (induced) CO changes[144] as well as the impacts of time and repetitive measurements over time.[145] Accordingly, future studies should include the analysis of trending ability using three different statistical techniques:[66] by correlation coefficients between the system under evaluation and the particular reference method, by a modified Bland and Altman analysis using ΔCO data (ΔCO representing the change between sequential readings), and by plotting Δsemi-invasive CO against ΔCO_{PAC} on a four-quadrant plot.[146]

When to use semi-invasive PCA systems?

Unstable hemodynamics appears to be a general problem for pulse contour analysis.[38] In unstable conditions, intraoperatively, and in the ICU, our results show a 7% higher PE and a larger bias (-0.54 *vs* -0.15 L·min^{-1}) than in the hemodynamically stable cohort (Fig. 4). In such situations, a more reliable and invasive technology (CO_{PAC})[143] or CCO[123] should be considered.

The pulse contour measurement of CO is strongly influenced by factors independent of true changes in CO such as those affecting the arterial pressure (e.g., vascular tone, compliance, and the arterial site).[24] Further validation studies, particularly covering a wide CO range, are required[147] to assess the reliability of the currently implemented algorithms which tend to either under- or overcompensate for prominent increases (or decreases) in vascular tone and compliance. The algorithms implemented in these devices are primarily based on the model described by Wesseling.[100] Besides age, sex, and body mass index, this model is based on a strict mathematical relationship between (aortic) compliance and pressure and can hardly take into account real changes in vessel compliance due to vasoactive drugs or mediators. This rather inflexible model will fail during hemodynamic instability. The deficiency in the model can be compensated by repeated calibration. To date, studies are lacking that explicitly provide the calibration intervals needed to maintain the accuracy of the CO_{PCA} measurements. This information would be helpful for proper analysis, particularly since the producers of semi-invasive monitoring systems market them as having signal stability over time.

Physicians should keep in mind the limitations of these technologies, especially in unstable critically ill patients. Although a recent study concluded that only 39% of patients undergoing surgical procedures met the criteria for semi-invasive hemodynamic monitoring,[148] CO_{PCA} systems may have their place in postoperative intensive care medicine when the administration of fluids and vasopressors is guided to specific therapeutic endpoints ("goal-directed therapy"). Nevertheless, only a few studies showed reduced mortality and morbidity[149,150] or reduced length of hospital stay[151,152] (but not reduced ICU stay)[152] when hemodynamic monitoring and therapy were coordinated.

Positive reports on the clinical suitability of presently available semi-invasive pulse contour systems for continuous CO measurement are increasingly found in the literature. These systems are gaining in popularity despite the fact that the measured CO in various clinical situations shows only limited agreement with intermittent bolus TD. Further improvements and validation studies are required. There is also a need to show whether there is a resulting healthcare benefit if these monitors are used in regular clinical practice. In the interim, the physician should be aware of the inaccuracy of currently available CO monitoring devices based on PCA and should not be guided solely by CO data. The physician providing care must also adhere to a hemodynamic optimization strategy that includes all relevant clinical parameters for secure therapeutic decision-making.

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Conflicts of interest None declared.

Appendix 1

FloTrac/Vigileo system

The FloTrac/Vigileo system (Edwards Lifesciences, Irvine, CA, USA) comprises the FloTrac pressure sensor attached to a radial or femoral arterial line using a standard arterial catheter and the Vigileo monitor. After the patient's age, height, weight, and sex have been entered and the device connected to the artery, SV and arterial CO are continuously estimated. In general, the system is used without the Venous Arterial blood Management Protection (VAMP) blood sampling kit in the operating room. For intensive care application, the FloTrac sensor should be used with a special VAMP system.[D]

The algorithm is based on the premise that SV is proportional to pulse pressure and is inversely related to aortic compliance.[153,154] The algorithm calculates arterial pulsatility (= standard deviation [SD] of the pressure wave).[155] According to the patent, the algorithm accounts for vascular resistance and compliance on SV,[47] and a variable κ is calculated without any external calibration. These parameters for calculation include 1) the aortic compliance described in the study by *Langewouters et al.*[156] 2) the mean arterial pressure (providing information about resistance changes), 3) the variance of the pressure wave as pulsatility, 4) the skewness, and 5) the kurtosis.[A,B] The calibration factor κ was recalculated every ten minutes in the first-generation software. The interval of ten minutes was reduced to one minute in the second-generation software (first used in V1.07), and a larger human database was implemented. The newest third-generation software (since V3.0) claims a new dynamic tone technology with automatic factor adaptation to patient vascular tone and also claims to have been validated for hyperdynamic patient conditions, including sepsis[59,137] and liver transplantation.[62,63] It is also asserted that another key feature of the third-generation software is better performance during arrhythmia.[124]

The EV1000 Clinical Platform is indicated for use primarily for critical care patients to assess the balance between cardiac function, fluid status, and vascular resistance. Analysis of the intermittent and transpulmonary thermodilution curve provides data on intravascular and extravascular fluid volumes. Whereas the PULSION PiCCO System calculates the volume parameter based on a mean transit time algorithm, the Edwards EV1000 system relies on the decay time of the thermodilution curve. When the EV1000 Clinical Platform is used with the VolumeView System, it measures and/or calculates hemodynamic parameters such as systemic vascular resistance, manually calibrated CO, extravascular lung water, etc. When connected to a FloTrac sensor, the EV1000 Clinical Platform continuously measures/calculates arterial pressure CO.[F]

PiCCO system

The PiCCO technology (PiCCO, PULSION Medical Systems, Munich, Germany) is a hemodynamic monitoring system combining a transpulmonary thermodilution technique for calibration and arterial pulse contour analysis. The PiCCO system consists of a monitor, an inline injectate temperature sensor connected to a central venous catheter, and a 4-French thermistor-tipped catheter for pressure and temperature measurement in a large peripheral artery (femoral, axillary, and brachial). The PiCCO algorithm has been described elsewhere.[11] A central venous injection of a cold saline bolus and the time course of the temperature in a peripheral artery are used for the calibration of the system. In older software versions of the PiCCO device, an algorithm was used which was previously described for determination of CO.[157,158] With this algorithm, the SV is computed by integrating the systolic area under the arterial pressure waveform. The specific aortic impedance is required for calibration, which is calculated by comparison between the systolic area and the CO measured by transpulmonary thermodilution.[G] The second-generation software uses an adapted algorithm which analyzes the shape of the pressure waveform, and it also claims to take into account the individual compliance and systemic vascular resistance. However, transpulmonary thermodilution is also needed with the new software version to assess the patient-specific compliance.[35,159]

LiDCOplus/PulseCO system and LiDCOrapid

The LiDCOplus/PulseCO system (LiDCO Ltd, Cambridge, UK) includes a minimally invasive lithium dilution technique for calibration. A central or peripheral venous access is required for indicator injection. A small dose of lithium chloride (0.002-0.004 $mmol \cdot kg^{-1}$) is injected. To avoid pharmacological or even toxic effects, the manufacturer recommends an upper limit of 3 $mmol \cdot day^{-1}$. Cardiac output is calculated from the amount of injected lithium and the arterial concentration time curve which is measured by an ion-selective electrode located in a peripheral artery.[160,161] After calibration, the PulseCO performs a beat-to-beat estimate of the cardiac output. The algorithm is assumed to be independent of the arterial measurement site. For the analysis of the pressure trace, a three-step transformation is described.[161] Briefly, the first step is the transformation of the arterial pressure signal into a standardized volume-time waveform (done by an algorithm "compliance" with a lookup table).[H] Second, in order to obtain cardiac output, the duration of the cardiac cycle and the SV are calculated by autocorrelation (the autocorrelation of the standardized volume waveform results in a net effective beat power factor which is proportional to the nominal stroke volume).[14] Third, this result is calibrated by comparison with a LiDCO-measured value which the manufacturer recommends to be done every four to six hours.[160] This calibration factor corrects for the arterial compliance for a given arterial blood pressure and for variations between individuals.[14] Further

[F] *Edwards Lifesciences Inc.* EV1000 Clinical Platform 510(k) Summary. Available from URL: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100709.pdf (accessed February 2014).

[G] *Joeken S, Fahle M, Pfeiffer UJ* (inventors). Devices for in-vivo determination of the compliance function and the systemic blood flow of a living being. US patent US 6315735 B1.

[H] *Band DM, Linton RA, O'Brien TK* (inventors). Method and apparatus for the measurement of cardiac output. International patent publication WO 97/24982 A.

details for the exact calculation are not provided, not even in the patent description.[I]

The LiDCOrapid can be calibrated by entering a known value for CO (with dilution calibration) or with a nomogram-based estimate of a patient-specific calibration factor. This calibration factor was developed using *in vivo* calibration data from post-surgical patients providing radial arterial blood pressure waveform data. The nomogram estimate was then validated in an independent cohort of medical ICU patients. A correlation of $r = 0.88$, no bias, and acceptable limits of agreement ($\pm$ 26%) were found when compared with indicator dilution-based calibration.[C]

Modelflow system

The Modelflow system (Finapres Medical Systems, Amsterdam, The Netherlands) computes the beat-to-beat CO from the radial artery pressure after an initial calibration (thermodilution or ultrasound for velocity and aortic diameter determination). The aortic flow pulsations from arterial blood pressure are computed by simulating a nonlinear time-varying three-element model of aortic input impedance (modified Windkessel model).[100] The Modelflow system simulates the interaction between the cardiac ejection and the aortic and peripheral systemic input impedance and the resulting reflected pressure.[159] The nonlinear characteristics of the model parameters were studied post-mortem in human aortae;[162] however, considerable individual variations of the aortic cross-sectional area (up to 30%) were found.[159] Therefore, calibration against thermodilution or an aortic diameter calibration[101] is required. A more detailed description of the underlying model is to be found in the study by *Bogert et al.*[163]

PRAM/Mostcare

With PRAM (Mostcare FIAB SpA, Florence, Italy) beat-to-beat values of CO are calculated. This system is based on the mathematical analysis of changes in the arterial pressure profile.[J] The PRAM/Mostcare system includes a standard arterial radial or femoral catheter with no need for calibration. Pressure signals and estimated flow values are displayed on the monitor screen in real time. Calibration with other techniques is not required. The algorithm is based on the "principle of perturbations"[164] with a beat-to-beat analysis of the whole arterial pressure wave morphology (instead of just the pulsatile systolic area) with a sampling rate of 1 kHz.[155] The diastolic minimum, the systolic pressure, the dicrotic notch, and points of perturbance are evaluated. PRAM claims to consider aortic impedance, compliance, and systemic vascular resistance, which affect the pressure signal. For further details, see these references.[104,155,165,J]

Appendix 2

The following explicit search terms in Web of Science yielded 382 hits.

Title=(arterial pressure-based cardiac*) OR Title=(Arterial pressure waveform cardiac*) OR Title=(Vigileo) OR Title=(FloTrac) OR Title=(pulmonary artery thermodilution) OR Title=(thermodilution) NOT Topic=(experimental) NOT Topic=(pediatric) NOT Topic=(pediatric) NOT Topic=(animal) OR Topic=(PICCO) OR Topic=(LiDCO) OR Topic=(PRAM) AND Topic=(cardiac output*gold standard)

Refined by: Research Areas=(CARDIOVASCULAR SYSTEM CARDIOLOGY OR ANESTHESIOLOGY OR SURGERY OR CRITICAL CARE MEDICINE) AND Document Types=(ARTICLE) AND Research Domains=(SCIENCE TECHNOLOGY)

Timespan=1990-2013.

Search language=Auto

Appendix 3

Formulas used for calculating mean cardiac output, bias, standard deviation of the bias, and correlation coefficient

$$x_{pooled} = \sum_{i=1}^{i=N} \left\{ \frac{x_i(n_i - 1)}{\sum_{i=1}^{i=N} (n_i - 1)} \right\} \quad (1)$$

$$r_{pooled} = \frac{\sum_{i=1}^{N} n_i r_i}{\sum_{i=1}^{N} n_i} \quad (2)$$

where n_i is the number of measurements, x_i is the variable for pooled calculation (bias, mean cardiac output, precision), and r_i is the correlation coefficient to be pooled in the study i of total n studies for the analysis.

[I] *Band MS, Linton WM, Linton RA, O'Brien KT* (inventors). Verfahren und Vorrichtung zum Messen der Herzleistung. DE patent 697 23 847 T2. 2004 Jun. 03.

[J] *Romano S* (inventor). Method and apparatus for measuring cardiac output. US patent US 6758822 B2.

Appendix 4

References[#]	*n*	Age (yr) mean (SD) or range	Mean (SD) ($L \cdot min^{-1}$)	Range ($L \cdot min^{-1}$)	Bias (SD) ($L \cdot min^{-1}$)	PE (%)	r**	Software version	Cardiac output			Listed / obvious limitations explanatory notes
									Population	Access site	Blinded observers	
Auto-calibrated												
FloTrac/Vigileo												
Sander *et al.*[39]	30/108	67 (8)	5.5 (1.1)	x	−0.60 (1.40)	54	0.53	1.03	Cardiac surgery (OP/ICU)	rad	N/A	Range not given
Button *et al.*[47]	31/185	46-85	x	2.4-9.3	0.25 (1.13)	x	x	1.07	Cardiac surgery (OP/ICU)	rad	N/A	Mean values, PE not given; only gold standard range mentioned
Manecke and Auger[43]	50/295	61 (14)	x	2.8-9.6	0.55 (0.98)	33	x	1.03	Post cardiac surgery (ICU)	rad/fem	N/A	Mean CO not given; hemodynamic stable patients; different access sites
Opdam *et al.*[40]	6/218	56-85	x	x	0.41 (1.00)	40	0.35	1.03	Post cardiac surgery (ICU)	rad/fem	N/A	Mean CO and range not given; small number of patients; varying replicates of CO determination
Prasser *et al.*[41]	20/164	16-74	5.9 (1.2)	3.4-9.8	−0.02 (1.48)	49	0.58	1.03	Neurosurgical (ICU)	rad/fem	N/A	Small and varying number of CO estimations performed for each patient; constant vascular tone
Prasser *et al.*[49]	20/158	64 (9)	x	x	−0.01 (0.82)	27	x	1.10	Post cardiac surgery (ICU)	rad	Yes	Mean and range values of CO not given
Breukers *et al.*[44]	20/56	72 (9)	5.5 (0.9)	3.3-8.8	0.14 (1.00)	36 §	0.74	1.03	Post cardiac surgery (ICU)	rad	N/A	PE not given; rise in vascular tone over time cannot be excluded because of vasoactive drugs
Chakravarthy *et al.*[46]	15/438	x	x	1.0-6.9	−0.15 (0.33)	x	0.49	N/A	Cardiac surgery (OP)	fem	N/A	Mean CO, software version, patient age, and PE not given; small number of patients
Cannesson *et al.*[53]	11/166	58-83	4.7 (1.0)	1.9-8.2	0.26 (0.87)	37 §	0.66	1.07	Cardiac surgery (OP/ICU)	rad	N/A	PE not given; small number of patients; no vasoactive drugs applied
McGee *et al.*[37]	84/561	24-84	5.9 (?)	3.1-9.2	0.20 (1.28)	43	x	1.01	After cardiac surgery (ICU)	rad/fem	N/A	SD of mean CO not given; different access sites
Staier *et al.*[54]	30/120	45-81	x	3.9-4.9	0.02 (1.04)	44	x	1.07	Cardiac surgery (OP)	rad	N/A	Mean and range values of CO not given, therefore estimated from graphs
Mehta *et al.*[48]	12/?	45-75	4.5 (1.3)	2.8-7.7	−0.26 (0.66)	29	x	1.07	Cardiac surgery (OP)	rad	Yes	Number of measurements not given; small sample size; only male patients; exclusion of study: peripheral vascular disease
Biais *et al.*[58]	20/400	51 (9)	5.5 (1.0)	2.1-9.5	−0.80 (1.35)	43	x	1.07	Liver transplant (OP/ICU)	rad	Yes	Reference method: instantaneous TD instead of gold standard
Zimmermann *et al.*[38]	30/174	51-80	x	2.7-10.7	−0.13 (1.53)	46	0.56	1.01	Cardiac surgery (OP/ICU)	rad/fem	Yes	Mean CO not given; 3 different monitors used for determination of TD CO
Della Rocca *et al.*[50]	18/126	36-67	x	3.1-11.5	−0.95 (1.41)	26	0.68	1.10	Liver transplant (ICU)	rad	N/A	Mean CO not given; hemodynamic stable patients
Biancofiore *et al.*[62]*	29/261	19-64	7.4 (1.7)	5.8-15.2	−2.47 (2.66)	60	0.39	1.10	Liver transplant (OP/ICU)	rad	N/A	Observers were not blinded; cardiac index values but BSA not mentioned
Eleftheriadis *et al.*[70]	16/80	62 (10)	x	3.5-7.0	0.40 (0.87)	x	0.51	1.14	Cardiac surgery (OP)	fem	N/A	PE and mean CO not given; only male patients

continued

References[#]	*n*	Age (yr)mean (SD) or range	Mean (SD) ($L \cdot min^{-1}$)	Range ($L \cdot min^{-1}$)	Bias (SD) ($L \cdot min^{-1}$)	PE (%)	r**	Software version	Cardiac output			Listed / obvious limitations explanatory notes
									Population	Access site	Blinded observers	
Senn *et al.*[45]	25/100	65 (11)	x	5.0-6.1	−0.1 (1.12)	38	x	1.03	Post cardiac surgery (ICU)	rad	N/A	Low-risk cardiac surgical group; mean CO not given; 1.03 and 1.07 data obtained in different patients (CO differences up to 20%)
	25/100	67 (8)	x	4.3-5.8	−0.3 (0.71)	22	x	1.07	Post cardiac surgery (ICU)	rad	N/A	
Zimmermann *et al.*[52]	24/138	x	x	x	0.04 (1.09)	x	x	1.10	Cardiac surgery (OP/ICU)	rad	N/A	Reported in a letter, therfore only limited information
Hofer *et al.*[55]	26/?	67 (10)	x	2.4-9.1	0.20 (1.05)	40 §	x	1.07	Cardiac surgery (OP/ICU)	rad	N/A	Mean CO and PE not given; low risk cardiac surgical group; thermal influences
Schramm *et al.*[60]	20/78	64 (14)	x	3.0-9.0	−0.35 (1.88)	76	x	1.07	Cardiac surgery (OP)	rad	N/A	Small sample size (and only 3 female patients); mean and range values of CO not given; range estimated from graphs
Slagt *et al.*[59]	5/86	65 (6)	x	3.6-7.1	−1.60 (1.60)	48	0.32	1.07	Septic shock (ICU)	rad	N/A	Mean CO not given; small sample size; systemic vascular resistance varied by 30% / 47% during monitoring
	4/73	65 (6)	x	3.3-10.8	−1.20 (1.10)	32	0.90	1.10	Septic shock (ICU)	rad	N/A	
Maxeiner *et al.*[57]	19/62	52-86	5.0 (1.0)	x	0.87 (1.02)	45	0.46	1.07	Cardiac surgery (OP)	rad	N/A	No cardiac output range mentioned; left or right radial artery access
	15/60	52-86	4.7 (1.0)	x	0.51 (0.82)	36	0.72	1.10	Cardiac surgery (OP)	rad	N/A	
Hadian *et al.*[71]	17/?	54-82	6.1 (1.9)	x	0.43 (1.69)	59	0.28	1.07	Post cardiac surgery (ICU)	rad/fem	Yes	Number of measurement and CO range not given; calibration with PAC-TD; different access sites; reference method: CCO and TD-CO
Cecconi *et al.*[42]	29/203	24-83	x	3.7-10.8	−1.10 (2.85)	55	x	1.03	Patients on ICU	rad	N/A	Mixed medical surgical population in which many were septic; no mean CO
Krejci *et al.*[63]	19/97	56 (9)	7.2 (1.8)	x	−3.54 (?)	69	x	1.10	Liver transplant (OP)	rad	N/A	Range and SD of bias not given; study was limited to the dissection phase
Saraceni *et al.*[61]	15/96	31-80	6.56 (?)	3.5-11.8	0.19 (2.50)	76 §	0.63	1.07	Patients on ICU	rad	N/A	SD of mean CO and PE not given; heterogeneous patient group: trauma, septic, cardiac
	6/45	44-67	7.48 (?)	5.4-10.4	−0.97 (1.83)	49 §	0.72	1.10	Patients on ICU	rad	N/A	SD of mean CO and PE not given; heterogeneous patient group: trauma, septic, cardiac
Vetrugno *et al.*[56]	20/360	70 (9)	x	2.4-7.7	0.50 (0.86)	37	x	1.10	Cardiac surgery (OP/ICU)	rad	Yes	Mean CO not given; left or right radial artery access
Junttila *et al.*[64]	16/407	54 (13)	6.0 (1.7)	x	−1.50 (2.00)	58	x	1.14	Intracranial hemorrhage (ICU)	rad	N/A	Range not given; bolus TD performed by different persons
Biancofiore *et al.*[66]*	21/210	32-60	8.2 (1.9)	3.8-14.8	−0.74 (1.60)	52	0.67	3.02	Liver transplant (OP/ICU)	rad	N/A	Single bolus TD measurement taken as CO reference

References[#]	*n*	Age (yr) mean (SD) or range	Mean (SD) ($L \cdot min^{-1}$)	Range ($L \cdot min^{-1}$)	Bias (SD) ($L \cdot min^{-1}$)	PE (%)	r**	Software version	Cardiac output			Listed / obvious limitations explanatory notes
									Population	Access site	Blinded observers	
De Backer *et al.*[51]	58/401	62 (14)	6.5 (1.5)	2.5-14.4	0.2% (1.05)	30	x	1.14	Septic patients (ICU)	rad/fem	Yes	Bias stated in %; different access sites
	58/401	62 (14)	7.3 (2.1)	2.5-17.0	−10.3% (1.10)	29	x	3.02	Septic patients (ICU)	rad/fem	Yes	Bias stated in %; different access sites
Akiyoshi *et al.*[69]	20/138	55 (9)	6.3 (?)	x	−0.89 (1.35)	38	x	3.00	Liver transplant (OP/ICU)	rad	N/A	SD of mean CO and range not given; single bolus TD taken as CO reference
Tsai *et al.*[65]	20/200	x	5.9 (1.8)	2.8-10.9	−0.22 (1.67)	55	x	3.02	Liver transplant (OP)	rad	Yes	Age not given; Asian study population, but Vigileo patient demographics have been derived mostly from western countries
Vasdev *et al.*[68]	38/342	58 (9)	4.8 (?)	2.0-8.5	−0.14 (0.55)	22	x	3.02	Cardiac surgery (OP)	rad	No	Only 4 female patients; low-risk cardiac surgical group
Slagt *et al.*[67]	19/314	62 (15)	6.8 (2.0)	4.0-13.7	−1.70 (2.40)	53	x	3.02	Septic shock (ICU)	rad/fem	N/A	Different access sites

n = patients / measurements; PE = percentage error; OP = operative; ICU = intensive care unit; rad = radial access site; fem = femoral access site; rad/fem = radial and femoral access site; bra = brachial access site; N/A = not available; A = aorta pressure signal; axi = axillary access site; ni = non invasive; BSA = body surface area; CCO = continuous cardiac output; CO = cardiac output; PAC = pulmonary artery catheter; TD = thermodilution; x = value not given

[#] References sorted by year of publication

* Cardiac index converted to CO with body surface area of 1.9 [$L \cdot min^{-1} \cdot m^{-2}$]; ** Some values converted from r^2 to r; § PE not mentioned and therefore calculated according to Critchley & Critchley[30]

References #	n	Age (yr) Mean (SD) or Range	Mean (SD) (L·min^{-1})	Range (L·min^{-1})	Bias (SD) (L·min^{-1})	PE (%)	r**	Software version	Condition of the participants	Access site	Blinded observers	Listed /obvious limitations explanatory notes
Calibrated												
PiCCO/PiCCOplus												
Irlbeck *et al.*[87]	20/165	x	x	x	−0.09 (0.85)	x	0.93	1.x	Patients on ICU	rad/fem	N/A	Age, mean CO, range, and PE not given; different access sites
Buhre *et al.*[72]	12/36	46-66	4.4 (?)	1.6-9.2	0.003 (0.63)	29 §	0.88	1.x	Cardiac surgery (OP)	fem	N/A	SD of mean CO and PE not given; small number of patients and measurements
Rödig *et al.*[34]	26/308	44-82	x	2.3-12.6	0.18 (1.24)	x	x	1.x	Cardiac surgery (OP/ICU)	fem	N/A	Bias (SD) obtained from another study; mean CO and PE not given
Gödje *et al.*[35]	24/204	41-81	x	3.0-11.8	0.07 (0.70)	x	0.92	x	Post cardiac surgery (ICU)	fem	N/A	Mean CO, PE, and software version not given; no recalibration for 24hr
Zöllner *et al.*[73]	19/228	34-76	x	3.0-15.7	0.31 (1.25)	x	0.88	x	Post cardiac surgery (ICU)	fem	N/A	Mean CO, PE, and software version not given; hemodynamically stable patients
Rauch *et al.*[79]	25/380	42-77	x	1.9-11.6	−0.14 (1.16)	x	x	1.x	Cardiac surgery (OP/ICU)	fem	N/A	Mean CO and PE not given; initial calibration with PAC TD, only one recalibration in 12 hours
Mielck *et al.*[80]	22/96	49-74	6.6 (1.7)	2.6-11.4	−0.40 (1.30)	39	x	x	Post cardiac surgery (ICU)	fem	N/A	Software version not given; hemodynamically stable patients
Gödje *et al.*[35]	24/517	46-88	x	2.7-14.1	−0.20 (1.15)	x	0.88	4.1	Post cardiac surgery (ICU)	fem	N/A	Mean CO and PE not given; influences of arrhythmias on the accuracy of PiCCO
Della Rocca *et al.*[86]	62/186	24-66	7.8 (?)	3.0-13.0	0.04 (0.84)	22 §	0.94	4.1	Liver transplant (OP)	fem	N/A	SD of mean CO and PE not given, stable hemodynamic conditions
Felbinger *et al.*[88]*	20/360	x	x	x	0.27 (0.63)	x	0.93	x	Post cardiac surgery (ICU)	fem	No	Age, mean CO, range, PE, and software version not given
Tzenkov *et al.*[77]	35/314	x	x	1.3-19.0	0.18 (2.41)	x	x	4.1	Liver transplant (OP)	fem	N/A	Age, mean CO and PE not given; no recalibration
Della Rocca *et al.*[84]	58/318	x	6.1 (?)	2.7-12.0	0.08 (0.72)	24 §	x	4.1	Lung transplant (OP)	fem	N/A	SD of mean CO and age not given
Sander *et al.*[82]	45/?	62 (1)	6.5 (0.3)	2.5-12.5	−1.40 (1.70)	52 §	0.63	5.2.2	Cardiac surgery (OP)	fem	N/A	PE, number of measurements and values of the total study period not given, therefore 15 min after aorta decannulation
Wouters *et al.*[78]	23/224	65 (?)	x	x	1.08 (0.75)	x	0.80	x	Cardiac surgery (OP)	bra	N/A	SD of mean age, mean CO, range, PE, and software version not given; single bolus TD CO as reference method
Sujatha *et al.*[36]	60/480	40-75	4.4 (?)	x	0.42 (0.86)	36	x	x	Cardiac surgery (OP)	fem	N/A	Mean bias not given; stated bias was recalculated over total study period; range and software version not given
Ostergaard *et al.*[83]	25/?	42-79	4.8 (?)	3.8-6.1	−0.07 (1.10)	50	x	x	Cardiac surgery (OP/ICU)	fem	N/A	Number of measurements, SD of mean CO, and software version not given; hemodynamically stable patients
Halvorsen *et al.*[81]	30/252	39-86	6.0 (?)	5.0-7.1	−0.76 (1.17)	43	x	5.1	Cardiac surgery (OP)	fem	N/A	SD of mean CO not given; stated values during period 1, as no values of total study period were given

References #	n	Age (yr) Mean (SD) or Range	Mean (SD) (L·min^{-1})	Range (L·min^{-1})	Bias (SD) (L·min^{-1})	PE (%)	r**	Software version	Condition of the participants	Access site	Blinded observers	Listed /obvious limitations explanatory notes
Chakravarthy *et al.*[46]	15/438	x	x	1.0-6.9	−0.13 (1.12)	x	0.40	x	Cardiac surgery (OP)	fem	N/A	Age, mean CO, PE, and software version not given; small number of patients; initial calibration with PAC TD
de Wilde *et al.*[21]	24/199	x	4.7 (?)	2.1-9.7	−0.14 (0.87)	37 §	x	x	Cardiac surgery (OP)	rad	N/A	Initial calibration with PAC TD; no age, SD of mean CO, PE, or software version mentioned
Button *et al.*[47]	31/185	46-85	x	2.4-9.3	0.28 (1.30)	x	x	6.0	Cardiac surgery (OP/ICU)	fem	N/A	Mean CO and PE not given
Yamashita *et al.*[85]	20/?	68 (7)	3.0 (0.8)	x	−0.14 (0.34)	23 §	0.98	x	Prior cardiac surgery (OP)	fem	N/A	Number of measurements, range, PE, and software version not given; stated values after prostaglandin administration
Senn *et al.*[45]	25/100	65 (11)	x	4.9-5.8	−0.20 (0.82)	25.5	x	6.0	Post cardiac surgery (ICU)	fem	N/A	Mean CO not given; low-risk cardiac surgical group
Hofer *et al.*[55]	26/?	67 (10)	x	2.4-9.1	0.20 (1.10)	34 §	x	5.2.2	Cardiac surgery (OP/ICU)	fem	N/A	Number of measurements, mean CO, and PE not given; low-risk cardiac surgical group; thermal influences
Hadian *et al.*[71]	17/?	54-82	5.4 (1.5)	x	−0.24 (1.10)	41	0.33	x	Post cardiac surgery (ICU)	rad/fem	N/A	Measurements, range and software version not given; calibration with PAC-TD; different access sites; reference method: CCO and TD-CO
Staier *et al.*[76]	30/30	59 (11)	4.1 (0.9)	x	0.12 (?)	28	x	x	Cardiac surgery (OP)	fem	N/A	Range, bias SD, and software version not given; small sample size
LiDCO/PulseCO												
Linton *et al.*[90]	40/160	x	x	x	−0.25 (0.5)	x	0.97	x	Post cardiac surgery (ICU)	N/A	N/A	Age, range, mean CO, and PE not given; results from LiDCO but not PulseCO
Garcia-Rodriguez *et al.*[91]	31/93	42-80	5.55 (?)	2.4-11.5	−0.5 (0.7)	24 §	x	x	Post major surgery (ICU)	rad	N/A	SD of mean CO and PE not given; hemodynamically stable patients; results from LiDCO but not PulseCO
Hamilton *et al.*[92]	20/100	64 (2)	x	3.4-8.5	0.05 (0.6)	x	0.86	x	Post cardiac surgery (ICU)	rad	N/A	Mean CO, and PE not given; low-risk cardiac surgical group
Yamashita *et al.*[97]	23/?	68 (9)	x	1.5-4.5	0.76 (1.93)	x	0.74	x	Cardiac surgery (OP)	rad	N/A	Mean CO not given; PAC TD used for initial calibration of PulseCO; no PE, no recalibration
Costa *et al.*[94]	23/151	37-68	7.7 (?)	3.4-13.2	−0.29 (1.09)	17	0.85	x	Liver transplant (ICU)	rad	N/A	SD of mean CO not given
Missant *et al.*[96]	20/149	68 (12)	4.9 (?)	x	−0.03 (0.65)	29	0.84	x	Cardiac surgery (OP)	rad	N/A	SD of mean CO and range not given; PAC TD (instead of LiDCO) used for initial calibration of PulseCO
de Wilde *et al.*[21]	24/199	x	5.0 (?)	2.5-8.9	0.17 (0.69)	28 §	x	x	Cardiac surgery (OP)	rad	N/A	Age, SD of mean CO, and PE not given; PAC TD (instead of LiDCO) used for initial calibration of PulseCO

References #	n	Age (yr) Mean (SD) or Range	Mean (SD) (L·min^{-1})	Range (L·min^{-1})	Bias (SD) (L·min^{-1})	PE (%)	r**	Software version	Condition of the participants	Access site	Blinded observers	Listed /obvious limitations explanatory notes
Krejci *et al.*[63]	19/107	56 (9)	8.2 (?)	x	−1.97 (?)	76	x	x	Liver transplant (OP)	rad	N/A	SD of mean CO, SD of bias, and range not given; only one recalibration every 24 hours; calibration before induction of anesthesia
Hadian *et al.*[71]	17/?	54-82	5.4 (1.6)	x	0.18 (0.78)	29	0.60	x	Post cardiac surgery (ICU)	rad/fem	N/A	Measurements and range not given; calibration with PAC-TD; different access sites; reference method: CCO and TD-CO
Cecconi *et al.*[42]	29/203	24-83	x	3.5-13.6	0.50 (2.00)	40	x	x	Patients on ICU	rad	N/A	Mean CO not given; mixed medical surgical population including septic patients
Dyer *et al.*[95]	16/?	x	5.0 (?)	3.6-9.4	−0.58 (0.77)	22 §	x	x	Severe pre-eclampsia	rad	N/A	Measurements, SD of mean CO, age, and PE not given; central venous calibration; stable monitoring conditions
Mora *et al.*[93]	30/220	68 (13)	6.2 (1.9)	2.6-10.8	−0.28 (0.84)	27	0.86	x	Post cardiac surgery (ICU)	rad	Yes	PAC TD and PulseCO values assessed with a small time delay
Modelflow												
Wesseling *et al.*[100]	8/76	x	4.7 (0.4)	3.1-6.9	0.09 (0.36)	15 §	x	x	Cardiac surgery (OP)	N/A	N/A	Age and PE not given; small number of patients; TD calibration
Jellema *et al.*[101]	15/137	19-74	8.9 (3.0)	x	−0.10 (0.80)	18 §	x	x	Septic shock (ICU)	rad/fem	N/A	Range not given; no PE; PAC TD calibration
Hirschl *et al.*[103]*	29/175	61 (16)	6.3 (?)	2.5-13.9	−0.65 (1.25)	19 §	x	x	Critical ill patients (ICU)	ni	N/A	SD of mean CO and PE not given; PAC TD calibration
Jansen *et al.*[99]	54/436	43-78	4.9 (0.9)	3.0-7.7	−0.13 (0.47)	19 §	x	x	Cardiac surgery (OP)	N/A	N/A	No PE; anesthesia regimen differed slightly; PAC TD calibration
de Vaal *et al.*[102]	24/24	35-79	5.4 (?)	3.1-8.8	−0.08 (0.70)	12	0.83	x	Post cardiac surgery (ICU)	ni	N/A	SD of mean CO not given; aortic diameter calibration with ultrasound echo system
de Wilde *et al.*[21]	24/199	x	4.8 (?)	2.5-7.1	0.00 (0.37)	15 §	x	x	Cardiac surgery (OP)	rad	N/A	Age, SD of mean CO and PE not given
Nissen *et al.*[98]	39/1309	23-66	7.8 (2.6)	2.1-16.4	0.10 (1.50)	39 §	0.81	x	Liver transplant (OP)	fem	N/A	No PE mentioned; PAC TD calibration

References #	n	Age (yr) Mean (SD) or range	Mean (SD) ($L \cdot min^{-1}$)	Range ($L \cdot min^{-1}$)	Bias (SD) ($L \cdot min^{-1}$)	PE (%)	r**	Software version	Condition of the participants	Access site	Blinded observers	Listed / obvious limitations explanatory notes
Non-calibrated												
PRAM												
Romano and Pistolesi[104]*	18 / ?	32-48	4.9 (1.1)	3.2-7.6	−0.29 (0.67)	27 §	0.88	x	Heart catheterization (ICU)	A	N/A	Number of measurements and PE not given; pressure signal recorded in the aorta not in the peripheral artery
Giomarelli *et al.*[106]	28 / 112	66 (3)	x	2.3-7.4	0.03 (0.89)	x	0.88	x	Cardiac surgery (OP)	rad	N/A	Mean (SD) CO and PE not given; low-risk patients during stable hemodynamic situations; hypothermia during ECC
Romano *et al.*[105]*	50 / ?	62 (14)	5.1 (1.1)	3.0-8.0	−0.06 (0.80)	31 §	0.85	x	Heart catheterization (ICU)	A	N/A	Number of measurements and PE not given
Romano *et al.*[107]	32 / 128	44-81	4.0 (0.7)	x	0.07 (0.40)	20 §	0.87	x	Cardiac surgery (OP)	rad	Yes	Range and PE not given; low-risk patients; hypothermia during extracorporeal circulation
Zangrillo *et al.*[108]*	28 / 28	63 (10)	5.1 (1.1)	3.0-8.3	−0.13 (0.78)	30	0.72	x	Post cardiac surgery (ICU)	rad	N/A	Measurement with artefacts were excluded without definition of criteria on the signal quality
Paarmann *et al.*[111]	23 / 46	51-82	x	2.6-9.2	0.00 (2.26)	87	0.31	x	Post cardiac surgery (ICU)	rad	N/A	Mean (SD) CO not given; stable hemodynamic conditions
Scolletta *et al.*[109]	15 / 106	x	x	x	0.2 (0.98)	24	0.90	x	Post cardiac surgery (ICU)	N/A	N/A	Age, mean (SD) CO, and range not given; patients with intra-aortic balloon pump
Franchi *et al.*[110]	30 / 90	21-81	7.7 (?)	4.5-13.5	0.26 (0.98)	25	0.93	x	Septic shock (ICU)	rad	N/A	SD of mean CO not given: stable hemodynamic conditions
Maj *et al.*[112]	41/123	66 (12)	4.6 (?)	x	0.25 (1.66)	73	0.08	x	Post cardiac surgery (ICU)	rad/fem	N/A	Different access sites; median instead of mean CO; range not given

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