Abstract: Different methods exist to continuously measure cardiac output by minimally invasive means, most of them based on arterial pulse contour analysis like FloTrac/Vigileo, PiCCO, LiDCO/PulseCO, PRAM and Modelflow. 90 comparative studies between these devices and the accepted reference method, pulmonary artery catheter thermodilution, were included in our analysis. The majority of studies show acceptable accuracy during stable hemodynamic conditions, only few appear sufficiently accurate during changing hemodynamics. 41 studies provided adequate data for a pooled weighted analysis yielding a pooled bias of 0.28±1.14 l/min, percentage error of 39% and a correlation of r=0.69. Reliable use of these semiinvasive systems for critical therapeutic decisions requires further improvement and/or validation.

Keywords: cardiac output, pulmonary artery thermodilution, pulse contour analysis

Introduction

A pulmonary artery catheter PAC enables the invasive assessment of cardiac output (CO_PAC) or stroke volume (SV) by thermodilution (TD). Significant complications have been associated [1,2] with the use of a PAC, resulting in increased morbidity [3] and mortality [4]. As a consequence, several so-called less invasive techniques have been developed as alternatives to CO_PAC, which still represents the clinical reference of choice in non pediatric patients. [5]. We reviewed published data (range and mean cardiac output, bias, percentage error, software versions and study population) in order to allow a detailed analysis when comparing CO_PAC and PC based CO measurement systems.

Methods

Prospective studies and available reviews on the comparison of the pulse contour (PC) approach with CO_PAC were enclosed in our literature search using the keywords "cardiac output, (pulmonary) thermodilution CO, semi-invasive and minimal invasive CO, Vigileo, FloTrac, PiCCO, PRAM, LiDCO, PulseCO, Modelflow, and CO reference".

We searched electronic data bases including Medline (from 1990) Web of Science and Scopus (from 1992). The search and bibliographic review covered peer-reviewed journals and was limited to studies comparing simultaneous measurements of CO or cardiac index (CI) by one or more semi-invasive CO measurement systems with intermittent bolus right heart TD. - The used keywords led to 224 hits - effective March 2013. After screening the abstracts for appropriateness, 144 studies were selected. All studies were checked in respect of eventual retraction and, if so, excluded (N=3). Out of 141 studies, 77 papers with 90 studies compared at least one of the semiinvasive systems with the intermittent bolus TD CO: N=24/12/6/9/39 for PiCCO/ LiDCO/ Modelflow/ PRAM/ FloTrac. - Number of patients, age range and number of datapoints for each study, mean CO±standard deviation (SD), CO range, bias±SD (semi invasive system versus intermittent bolus TD), percentage error (PE), correlation coefficient (r), software version, study population, arterial access site, study design (blinded or non-blinded observers), study limitations reported by the authors and obvious limitations, were collected. In case certain values (e.g. PE) were not reported, they were calculated from other values if possible. To fulfill the Critchley and Critchley criterion (C&Cc) [6], a PE <=30% between the new CO-measurement technique and CO_PAC has to be achieved. The PE was calculated as two times the SD of the bias divided by the mean CO. [6]If mean CO or range of CO were not stated explicitly, it was estimated from the graphs. 7 studies quoted only CI; then CO was calculated via the body surface area (BSA). If BSA was not provided, a value of 1.9 m² was assumed. Statistical analysis: For each of the 5 semi-invasive CO devices, mean CO, bias, SD of the bias, and correlation coefficient (r) were included in a pooled weighted analysis and weighted according to standard formula. Pooled weighted PE was calculated as two times the pooled weighted SD of the bias over the mean pooled weighted CO. In the FloTrac/Vigileo (CO_F) studies, sub-group analysis of the 3 different software releases (1st, 2nd and 3rd generation) was performed to check whether software modifications correlate with improvements. Data are presented as mean±SD with p<0.05 considered significant.

Results

In 90 analysed studies of CO determination by arterial PC analysis, the majority shows acceptable accuracy during stable hemodynamic conditions, only few demonstrate sufficient accuracy when hemodynamic situations vary in major ranges. 40 studies (45%) provided adequate data
for a pooled weighted meta-analysis and resulted in a total pooled bias of -0.52±1.65 l/min, PE of 39% with r=0.69. Remarkably, just 2 of 5 semi-invasive methods (LiDCO and ModelFlow) fulfilled the ±30% PE limit [3], PiCCO exceeded it marginally (PE=32%), FloTrac/Vigileo and PRAM grossly deviated (PE of 55 and 44% respectively). (Fig. 1)

Figure 2: Pooled weighted bias (top) and PE (bottom) showing agreement of CO measured by the 5 semi-invasive systems (including FloTrac sub-group analysis for 1st, 2nd and 3rd software generation) and the reference CO\textsubscript{PAC}

Discussion

For monitoring the perioperative period and in the critical care setting, systems based on PC measurement are increasingly used and considered a more-or-less accurate and safe alternative to the highly invasive Swan-Ganz PAC. In accordance with several literature reviews, from our analysis a strong recommendation for or against a single system cannot be given yet, also for the reason that the analysis was limited by significant heterogeneity in the number of studies evaluating the different CO devices. CO\textsubscript{PAC} as reference: In spite of the fact that CO\textsubscript{PAC} is still accepted as the clinical reference of choice for CO determination, the method itself suffers from several limitations. Besides its invasiveness and the concomitant risks, the accuracy of the method also depends on external factors: At low cardiac output levels overestimations have been reported. Valve insufficiency, fluid discontinuation and shunting, ventilation, transition from cardiopulmonary bypass and operator experience may also influence the result of bolus TD. Triplicate injections are usually required to achieve acceptable accuracy. [8] When taking into account all these factors, an overall accuracy of CO\textsubscript{PAC} as a reference may be, at best, about ±15%. Therefore the question of the clinically acceptable error has to be raised. When comparing two methods with a ±20% error, a deviation of up to 28% may result leading to the conclusion, that a deviation of <=30% still could be clinically acceptable when comparing a new CO measurement system to CO\textsubscript{PAC}[6]. The idea that finding a PE of <= 30% between two CO systems was challenged since quoting the PE as an adequate criterion without reporting the precision of the reference technique or the confidence intervals may lead to inappropriate conclusions. In case one might consider the absolute CO value of less importance than to correctly follow trends in CO, recently Vigileo, PiCCO, biotome impedance, Doppler sound and PC were carefully analyzed. However, if these devices are used to track changing CO, e.g. induced by preload changes, care must be taken to avoid influences from altered vascular tone.

Conclusions: In various clinical situations CO measurement based on continuous arterial PC analysis shows only limited agreement with intermittent bolus TD. For reliable use of these seminvasive systems, especially when considered to guide critical therapeutic decisions, further improvement seems to be necessary.

Bibliography