Accuracy and trending ability of the fourth-generation FloTrac/ EV-1000 system in patients with severe aortic valve stenosis before and after surgical valve replacement

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Background and Goal of Study: Patients with severe aortic valve stenosis (AS) show reduced hemodynamic stability during general anaesthesia and surgery. Continuous monitoring of cardiac output (CCO) may guide appropriate treatment and outcome in this patient group. The fourth-generation FloTrac/EV-1000 system (Edwards Lifesciences, Irvine, CA) is a promising, and when compared to pulmonary artery catheter (PAC), less invasive device to measure CCO by pulse contour analysis. The goal of this study was to determine the level of agreement and trending ability of CCO values in patients with severe AS when FloTrac/EV-1000 values (CCO-FT) were compared with continuous thermodilution PAC measurements (CCO-PAC) during general anaesthesia before and after surgical valve replacement with a bioprosthesis.

Materials and Methods: After ERB approval and written informed consent, 20 patients (59-82 yrs) with AS and scheduled for elective surgical valve replacement with cardiopulmonary bypass (CPB), were enrolled in this study. CCO-FT and CCO-PAC values were recorded every 30 seconds after induction of general anaesthesia before and after CPB until end of surgery. If hemodynamic stability was given, value pairs were selected every 5 to 15 minutes for further analyses. Data were analysed separately before and after CPB. Bland-Altman analyses, and trending analyses (4-quadrant plot, half circle polar plot) were performed. The limit for clinical acceptance was set to a percentage error < 30%. Good trending ability was defined as concordance rates and angular concordance rates > 90%.

a. Regression analyses

b. Bland-Altman analyses

c. 4-quadrant plot

d. Polar plot

Results and Discussion: Recording time before cardiopulmonary bypass (CPB) was 62 ± 36 minutes (mean $\pm$ SD) and 48 ± 17 minutes after CPB. Bland-Altman analyses (fig. 1A) provided the following results (before and after CPB, resp.): Percentage errors 70.2% and 59.8%, bias 0.69 l/min and -0.09 l/min, limits of agreement (-2.5, 3.8) and (-3.6, 3.4). The trending analyses (half circle polar plot, fig. 1B) revealed concordance rates of 50.9% and 57.1%, and angular concordance rates of 48.7% and 61.9%.

Conclusion: This study revealed poor accuracy and trending ability of the FloTrac/EV-1000 system compared to CCO-PAC in patients with severe aortic stenosis. Although there was a slight improvement after surgical valve replacement, the results were far behind acceptable limits for clinical application.