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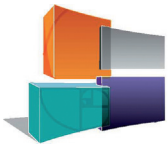

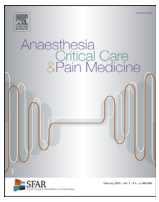

Original Article

Assessment of changes in cardiac index with calibrated pulse contour analysis in cardiac surgery: A prospective observational study

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ABSTRACT

Objectives: To assess the trending ability of calibrated pulse contour cardiac index (CI_{PC}) monitoring during haemodynamic changes (passive leg raising [PLR] and fluid loading) compared with transpulmonary thermodilution CI (CI_{TD}).
Method: Seventy-eight mechanically-ventilated patients admitted to intensive care with calibrated pulse contour following cardiac surgery were prospectively included and investigated during PLR, and after fluid loading. Fluid responsiveness was defined as a $\geq$ 15% CI_{TD} increase after a 500 ml bolus. Areas under the empiric receiver operating characteristic curves (ROC_{AUC}) for changes in CI_{PC} (ΔCI_{PC}) during PLR to predict fluid responsiveness and after fluid challenge to predict an increase at least 15% in CI_{TD} after fluid loading were calculated.
Results: Fifty-five patients (71%) were classified as responders, 23 (29%) as non-responders. ROC_{AUC} for ΔCI_{PC} during PLR in predicting fluid responsiveness, its sensitivity, specificity, and percentage of patients within the inconclusive class of response were 0.67 (95% CI = 0.55–0.77), 0.76 (95% CI = 0.63–0.87), 0.57 (95% CI = 0.34–0.77) and 68%, respectively. Bias, precision and limits of agreements and percentage error between CI_{PC} and CI_{TD} after fluid challenge were 0.14 (95% CI: 0.08–0.20), 0.26, –0.37 to 0.64 l min^{-1} m^{-2}, and 20%, respectively. The concordance rate was 97% and the polar concordance at 30° was 91%. ROC_{AUC} for ΔCI_{PC} in predicting an increase of at least 15% in CI_{TD} after fluid loading was 0.85 (95% CI: 0.76–0.92).
Conclusion: Although ΔCI_{PC} after fluid loading could track the direction of changes of CI_{TD} and was interchangeable with bolus transpulmonary thermodilution, PLR could not predict fluid responsiveness in cardiac surgery patients.
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Abbreviations: CI, cardiac index; CI_{PC}, calibrated pulse contour cardiac index; CI_{TD}, transpulmonary thermodilution cardiac index; CVP, central venous pressure; DAP, diastolic arterial pressure; ICU, intensive care unit; MAP, mean arterial pressure; PP, pulse pressure; PLR, passive leg raising; ROC, empiric receiver operating characteristic curve; ROC_{AUC}, areas under the empiric receiver operating characteristic curve; SAP, systolic arterial pressure; SV, stroke volume; SVR, systemic vascular resistance.

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1. Introduction

Cardiac index (CI) monitoring during the perioperative period could decrease both morbidity and length of hospital stay and has been recommended in high-risk surgical patients [1–4]. Theoretically, the ideal CI monitor should not only accurately measure CI but also guide haemodynamic optimisation by assessing fluid responsiveness during therapeutic manoeuvres [5]. At the bedside, the real-time tracking of the direction of changes in CI could be more useful than the ability to give a highly accurate single measurement under stable haemodynamic conditions [6]. CI measurement with pulse contour analysis (CI_{PC}) is a continuous, mini-invasive, operator-independent, widely used and cost-effective technique, which could be helpful to assess changes in CI during various haemodynamic manoeuvres as passive leg raising (PLR) or fluid loading. However, the ability to track changes in CI with uncalibrated CI_{PC} is poor [7,8], since acute changes in vascular resistance (as produced by norepinephrine) affect the precision of the CI measurements [9]. Although calibrated CI_{PC} could produce better results than uncalibrated CI_{PC} [7], those reported with the $PiCCO_2$ device (Pulsion Medical System, Munich, Germany) are controversial [9–12]. Thus, further studies are clearly needed before definitely recommending a wider use of calibrated CI_{PC} to adequately track dynamic changes in CI at the bedside.

The present prospective observational study was designed to assess changes in CI with calibrated CI_{PC} during PLR and after fluid loading in patients following elective cardiac surgery. The hypotheses tested were that changes in CI_{PC} during PLR could accurately predict a positive response to fluid loading, and that changes in CI_{PC} after fluid loading could reliably track changes in CI after fluid loading when compared with transpulmonary thermodilution CI (CI_{TD}).

2. Patients and methods

2.1. Patient population

After approval by the local Ethics Committee (No. A10-D16-VOL. 10, Nord Ouest III CPP, Caen University Hospital, France (Chairman: Dr C. Bazin) on 15 July 2010), all consecutive adult patients admitted from January 2011 to May 2012 to the intensive care unit (ICU) following elective cardiac surgery with cardiopulmonary bypass and receiving advanced haemodynamic monitoring by transpulmonary thermodilution were eligible for the study. As data were collected during routine care administered according to standard procedures currently used in our institution, a waiver of consent was granted. Preoperative verbal consent was however obtained from all study participants. Patients were included postoperatively if the attending anaesthesiologist decided that fluid administration was indicated. In accordance with our institutional standards, this decision was mainly based on the presence of at least one of the following clinical criteria: $CI \leq 2.2$ l/min/m^2, systolic arterial pressure (SAP) < 90 mmHg, urinary output < 0.5 ml/kg/h for at least 2 h, and/or the presence of skin mottling. Patients with arrhythmia during the study period were excluded. An appointed anaesthesiologist acquired the data. The study methodology followed the STROBE Statement [13].

2.2. Perioperative management

At the time of the study, all patients were intubated, ventilated (volume-controlled regimen) and sedated with propofol and remifentanil to maintain the Ramsay score above 5 [14]. For each eligible patient, a femoral 5F thermistor-tipped arterial catheter (Pulsiocath thermodilution catheter PV2015L20N [Pulsion medical system, Munich, Germany]) and a jugular central venous catheter were put in the operating room after induction of general anaesthesia. The Pulsiocath thermodilution catheter was connected to the stand-alone $PiCCO_2$ computer PC8500 version 2.0 (Pulsion Medical Systems, Munich, Germany). All pressure monitors were zeroed at the midaxillary line. To calibrate the pulse contour analysis, bolus transpulmonary thermodilution was measured by a triplicate 15 mL ice-cold normal saline injection through the central venous catheter at the arrival in the ICU, and just before the PLR test [15]. The CI_{PC} was continuously displayed on the monitor and the value was updated every 12 s. CI_{PC} assessment has been well described elsewhere [16]. Briefly, CI was obtained from the arterial waveform analysis using the 3-element Windkessel model. In this model, the area under the arterial pressure tracing is related to the SV according to the following formula: $SV = \kappa \times {}_{\text{end-diastole}}\int^{\text{end-systole}} [P(t)/SVR + C(p) \times dP/dt]dt$, where κ represents a calibration factor, P(t) the arterial pressure at any time, SVR systemic vascular resistance, C(p) aortic compliance, and dP/dt instantaneous pressure changes. Both compliance and SVR are updated beat-to-beat according to a proprietary algorithm. The CI is then computed according to the usual formula: CI = (Heart rate × SV)/body surface area.

2.3. Study protocol

Once the decision to give fluid (hydroxyethyl starch 6% 130/0.4, 500 ml over 15 min) within the first 6 h after surgery was made by the attending anaesthesiologist, 4 consecutive data sets were recorded for each patient:

- at baseline in the 45° semi-recumbent position;
- when CI_{PC} reached the maximum during a 90 s PLR, which consisted of simply pivoting the entire bed by automatic pivotal motion, as previously described [11];
- at return to baseline in the 45° semi-recumbent position; and iv) 10 min after fluid loading as described above.

The detailed study protocol is shown in Fig. 1. The positive response to fluid administration was defined as an increase in CI using bolus transpulmonary thermodilution (ΔCI_{TD}) of at least 15% repeated at the end of study period, just after recording the CI_{PC} following fluid loading (Fig. 1) [15]. All haemodynamic parameters were recorded at each step. The highest SAP, diastolic arterial pressure (DAP), mean arterial pressure (MAP), pulse pressure (PP) and CI values during PLR were taken into account for the data set analysis. During the study, ventilatory patterns (volume-controlled regimen), sedation and vasoactive drugs remained unchanged.

2.4. Endpoints

The primary endpoint was discrimination of changes in CI_{PC} during PLR to predict a positive response to fluid loading. Secondary endpoints were the ability of CI_{PC} to reliably track changes in CI after fluid loading, and discrimination of CI_{PC} in predicting an increase in CI_{TD} after fluid loading.

2.5. Statistical analysis

Considering an area under the empiric receiver operating characteristic curve (ROC_{AUC}) > 0.75 as good discrimination [17], we calculated that at least 23 patients per group (responders and non-responders) were required for the study (α risk = 0.05 and β risk = 0.10). Subsequently, we decided to include other patients until the smallest group reached 23 patients. Data are expressed as mean (standard deviation) (SD) or median (interquartile range) for not-normally distributed variables (Kolmogorov-Smirnov test) or number (percentage), as appropriate. Continuous variables were

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