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# Validation of cardiac output monitoring based on uncalibrated pulse contour analysis *vs* transpulmonary thermodilution during off-pump coronary artery bypass grafting

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## Editor's key points

- Uncalibrated pulse contour analysis (UPCA) derived from the arterial pressure signal might provide beat-to-beat cardiac index (CI) monitoring.
- Determination of CI by UPCA demonstrated an acceptable degree of agreement with results of intermittent transpulmonary thermodilution.
- The ability of UPCA to follow trends in cardiac output was poor.

**Background.** Cardiac output monitoring, as a part of a goal-directed haemodynamic management, has been shown to improve perioperative outcome in high-risk patients undergoing major surgical interventions. However, thorough validation of cardiac output monitoring devices in different clinical conditions is warranted. The aim of our study was to compare the reliability of a novel system for cardiac index (CI) monitoring based on uncalibrated pulse contour analysis (UPCA) with transpulmonary thermodilution (TPTD) during off-pump coronary artery bypass grafting (OPCAB).

**Methods.** Twenty patients undergoing elective OPCAB were enrolled into the study. CI measured by means of UPCA ($CI_{UPCA}$) was validated against CI determined with TPTD technique ($CI_{TPTD}$). Parallel measurements of CI were performed at nine stages during the surgery and after operation. We assessed the accuracy and the precision of individual values and the agreement of trends of changes in CI.

**Results.** Totally, 180 pairs of data were collected. There was a significant correlation between $CI_{UPCA}$ and $CI_{TPTD}$ ($\rho$=0.836, $P<0.01$). According to a Bland–Altman analysis, the mean bias between the methods was $-0.14$ litre min$^{-1}$ m$^{-2}$ with limits of agreement of $\pm 0.82$ litre min$^{-1}$ m$^{-2}$ and a percentage error of 31%. A polar plot trend analysis revealed acceptable angular bias ($-0.54^{\circ}$), increased radial limits of agreement ($\pm 52.7^{\circ}$), and decreased polar concordance rate (74%).

**Conclusions.** In OPCAB, UPCA provides accurate and precise CI measurements compared with TPTD. However, the ability of this method to follow trends in cardiac output is poor.

**Clinical trial registration.** NCT01773720 (ClinicalTrials.gov).

**Keywords:** cardiac output; haemodynamic monitoring

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Cardiac output monitoring, as a part of a goal-directed haemodynamic management, has been shown to improve perioperative outcome in high-risk patients undergoing major surgical interventions, including off-pump coronary artery bypass surgery (OPCAB).[1–5] According to Vincent and colleagues,[6] the 'ideal' haemodynamic monitoring system should provide assessment of relevant variables, accurate and reproducible measurements, and interpretable data. It should also be readily available, operator-independent, and easy to use, have a rapid response-time, cause no harm, be cost-effective, and provide information that might be used to guide therapy. However, a system fulfilling all these requirements is not available yet. In clinical practice, the selection of monitoring device is influenced by several factors including invasiveness, technical limitations, heart rhythm, validity, accuracy, and repeatability of measurements. Moreover, the level of operator's experience and the availability of additional haemodynamic variables might be of significance.[7]

Cardiac index (CI) is one of the most important variables to monitor during cardiac surgery. Traditionally, CI is monitored by means of either pre-pulmonary or transpulmonary thermodilution (TPTD) techniques.[8] Both methods have demonstrated an acceptable accuracy and have been included in different protocols of goal-directed therapies.[2 3 9–14] At the same time, thermodilution techniques are not fully operator-independent and require repeated injections of the thermal indicator.[15 16] Moreover, the pre-pulmonary thermodilution technique utilizes a pulmonary artery catheter, and its use is controversial due to a low benefit to risk ratio.[17–19] Therefore, alternative less invasive techniques have been developed.[7 20]

Recently, a novel system for CI monitoring (Professional Arterial Flow Trending, ProAQT, Pulsion Medical Systems, Germany) based on uncalibrated pulse contour analysis (UPCA) became available for clinical practice. This technology allows the operator to use a special sensor with an existing arterial pressure catheter to provide a beat-to-beat CI monitoring. The system does not require external calibration but uses an operator-activated automatic initial CI determination, which is based on characteristics of the patient combined with details of the systemic arterial pressure curve, as assessed by sampling at 250 Hz. The subsequent calculations of CI are performed by continuous analysis of the waveform of the arterial pressure curve by using the established PiCCO algorithm.

However, this novel system has not been validated yet in different clinical settings. Therefore, our aim was to compare the reliability of uncalibrated CI monitoring based on analysis of the systemic arterial pressure waveform with TPTD in patients undergoing off-pump coronary artery bypass grafting.

## Methods

### Patients

The study was conducted in compliance with the Helsinki Declaration. The protocol and the informed consent form were approved by the Ethics Committee of the Northern State Medical University, Arkhangelsk, Russian Federation, and registered with ClinicalTrials (ref: NCT01773720). Written informed consent was obtained from every patient.

The study was performed at the Department of Anaesthesiology and Intensive Care Medicine of the Northern State Medical University and the City Hospital #1 of Arkhangelsk (Arkhangelsk, Russian Federation). From October 2011 to April 2012, 21 adult patients with coronary artery disease, ranked ASA II–III, and undergoing elective OPCAB were enrolled. Exclusion criteria were age $<18$ and $>80$ yr, preoperative ejection fraction $<0.35$, severe cardiac valve dysfunction, peripheral vascular disease confirmed by preoperative ultrasound, permanent form of atrial fibrillation, and simultaneous interventions (carotid endarterectomy, aneurysm repair, etc.). The exclusion criteria were used to make the study population more homogenous, to prevent complications resulting from femoral artery puncture and catheterization, and to avoid misinterpretation of results of CI measurements due to arrhythmias. The study was discontinued in patients transferred to cardiopulmonary bypass during the intervention.

### Anaesthesia and surgery

After establishing routine haemodynamic monitoring with ECG including ST segment analysis, non-invasive arterial pressure, and oxygen saturation obtained by pulse oximetry (LifeScope, Nihon Kohden, Japan), anaesthesia was induced with i.v. midazolam (Dormicum, F. Hoffmann-La Roche Ltd, Switzerland) 0.07 mg $kg^{-1}$, propofol (Diprivan, AstraZeneca, UK) 1 mg $kg^{-1}$, and fentanyl (Fentanyl, Moscow Endocrine Factory, Russian Federation) 3–4 $\mu g\ kg^{-1}$. Neuromuscular block was induced with pipecuronium (Arduan, Gedeon Richter, Hungary) 0.1 mg $kg^{-1}$ and maintained with repeated doses of pipecuronium 0.015 mg $kg^{-1}\ h^{-1}$, i.v. Anaesthesia was maintained with sevoflurane 0.5–3.0 vol% and fentanyl 1–3 $\mu g\ kg^{-1}\ h^{-1}$. Mechanical ventilation in the operating theatre was performed using a semi-closed anaesthetic circuit (Fabius, Dräger, Germany) with $F_{IO_2}$ 0.5, tidal volume 7–8 ml $kg^{-1}$, respiratory rate 12–14 bpm, positive end-expiratory pressure 4 cm $H_2O$, and a fresh gas flow of 1 litre $min^{-1}$.

Fluid therapy included an infusion of Ringer's lactate at rates of 6–7 ml $kg^{-1}\ h^{-1}$ before and during surgery and 2–3 ml $kg^{-1}\ h^{-1}$ during the first 6 h after operation. If the patients presented with hypovolaemia (global end-diastolic index $<680$ ml $m^{-2}$), a 500 ml bolus of 6% hydroxyethyl starch 130/0.42 (6% Tetraspan, B.Braun, Germany) was infused over a period of 30 min aiming at global end-diastolic index within the range of 680–800 ml $m^{-2}$. If needed, the bolus infusion was repeated once up to a total volume of 1000 ml. All the patients were operated by the same team of surgeons using an Acrobat SUV OM-9000S (Guidant, Santa Clara, CA, USA) device for stabilization of the heart during revascularization.

### Measurements and data collection

After induction of anaesthesia, an 8.5 F four-lumen 20 cm central venous catheter was inserted into the internal jugular vein. The femoral artery was catheterized with a 5 F arterial thermodilution catheter (Pulsiocath PV2015L20, Pulsion). This catheter was connected to the $PiCCO_2$ monitor (Pulsion Medical Systems) for intermittent TPTD measurements and monitoring of CI ($CI_{TPTD}$), global end-diastolic volume index (GEDVI), extravascular lung water index (EVLWI), mean arterial pressure (MAP), systemic vascular resistance index (SVRI), and stroke volume variation (SVV). The thermodilution measurements were performed in triplicate with a cooled ($<8^{\circ}C$) 5% dextrose solution injected via the central venous catheter. The average of three measurements with $<10\%$ variation was used for data analysis.[21] In parallel, the same femoral thermodilution catheter was connected to the ProAQT monitor for continuous measurements of CI based on UPCA ($CI_{UPCA}$).

The haemodynamic variables registered simultaneously with both monitors were recorded after induction of anaesthesia, after sternotomy, at the restraint of the heart surface using a stabilizing device, after restoration of blood flow via the coronary grafts, at the end of surgery, and at 2, 4, 6, and 24 h after operation. These perioperative time-points were selected for the TPTD measurements and repeated activations of automatic-based CI determination. Initially, the system requires that the patient-related data (age, sex, height, weight) are entered. At all stages, we flushed and zeroed the pressure line followed by activation of the inner algorithm assessing mathematically the arterial pressure waveform with 250 Hz sampling.

### Statistical analysis

For data collection and analysis, we used SPSS software (version 14.0; SPSS Inc., Chicago, IL, USA), MedCalc software (version 12.3, MedCalc Software bvba, Belgium), and SigmaPlot software (version 11.0, Systat Software, Inc., USA). The data