

CARDIOVASCULAR

Non-invasive assessment of fluid responsiveness using CNAP™ technology is interchangeable with invasive arterial measurements during major open abdominal surgery

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Abstract

Background. Dynamic variables of fluid responsiveness (FR), such as pulse pressure variation (PPV), have been shown to predict the response to a fluid challenge accurately. A recently introduced non-invasive technology based on the volume-clamp method (CNAP™) offers the ability to measure PPV continuously (PPV_{CNAP}). However, the accuracy regarding the prediction of FR in the operating room has to be proved.

Methods. We compared PPV_{CNAP} with an invasive approach measuring PPV using the PiCCO technology (PPV_{PiCCO}). We studied 47 patients undergoing major open abdominal surgery before and after a passive leg-raising manoeuvre and i.v. fluid resuscitation. A positive response to a volume challenge was defined as $\geq 15\%$ increase in stroke volume index obtained with transpulmonary thermodilution. Bootstrap methodology was used with the grey zone approach to determine the area of inconsistency regarding the ability of PPV_{PiCCO} and PPV_{CNAP} to predict FR.

Results. In response to the passive leg-raising manoeuvre, PPV_{PiCCO} predicted FR with a sensitivity of 81% and a specificity of 72% [area under the curve (AUC) 0.86] compared with a sensitivity of 76% and a specificity of 72% (AUC 0.78) for PPV_{CNAP}. Regarding the volume challenge in the operating room, PPV_{PiCCO} predicted FR with a sensitivity of 87% and a specificity of 100% (AUC 0.97) compared with a sensitivity of 91% and specificity of 93% (AUC 0.97) for PPV_{CNAP}. The grey zone approach identified a range of PPV_{PiCCO} values (11–13%) and PPV_{CNAP} values (7–11%) for which FR could not be predicted reliably.

Conclusions. Non-invasive assessment of FR using PPV_{CNAP} seems to be interchangeable with PPV_{PiCCO} in patients undergoing major open abdominal surgery.

Clinical trial registration. NCT02166580.

Key words: anaesthesia, general; arterial pressure, measurement; equipment; haemodynamics; pulse pressure

Editor's key points

- Goal-directed fluid therapy has the potential to improve outcomes after major surgery.
- Fluids are administered on the basis of a measured parameter that predicts responsiveness of haemodynamic parameters.
- Pulse pressure variation (PPV) is a dynamic variable that accurately predicts responsiveness to a fluid challenge.
- The authors compared a non-invasive with an invasive technique of PPV assessment.

During recent decades, dynamic variables of fluid responsiveness (FR), such as pulse pressure variation (PPV), have gained increasing impact regarding perioperative fluid optimization.¹ The underlying principle is based on a cyclic change in cardiac preload induced by mechanical ventilation, attributable to the intermittent decrease in venous return. Observing and analysing the resulting effects on stroke volume (SV) or its surrogates, such as pulse pressure, is the main concept of what is known today as functional haemodynamic monitoring.² Typically, an increase of $SV \geq 15\%$ attributable to a volume shift is claimed to be adequate. The value of PPV, in the operating room (OR) and the intensive care unit (ICU), has been highlighted in several meta-analyses.³⁴ Consequently, the optimization of fluid resuscitation regarding timing and amount of fluids is necessarily linked to the concept of FR. Moreover, dynamic variables have progressively gained a central role in the design of intraoperative goal-directed haemodynamic optimization protocols.⁵ However, most of the studies predominantly used invasive monitoring tools for the assessment of FR. Today, numerous completely non-invasive haemodynamic monitoring technologies are available, which offer some promising alternative perspectives. The recently introduced non-invasive CNAPTM technology, based on the volume-clamp method, enables continuous measurement of blood pressure, SV, cardiac output (CO), and PPV (PPV_{CNAP}).^{6–8} Regarding the accuracy of blood pressure recordings in comparison to continuous invasive measurements, the results are conflicting.^{9–11} With respect to PPV_{CNAP}, Monnet and colleagues¹² were able to show that PPV was valuable in predicting FR in critically ill patients on the ICU; however, the values were calculated offline. Recently, a 'grey zone' approach has been introduced in order to assess more clearly the inconclusive values of dynamic variables around a defined cut-off value, helping to optimize fluid resuscitation on the basis of dynamic variables.^{13 14} The ability of the continuous, beat-to-beat measurement of PPV_{CNAP} to predict FR in the OR accurately has to be proved.

The aim of our prospective observational study was to assess the predictive accuracy of non-invasive PPV_{CNAP} compared with an invasive measurement of PPV using the grey zone approach in patients undergoing elective, major open abdominal surgery.

Methods**Patients**

The study complies with the Declaration of Helsinki and was conducted in accordance with the Guidelines for Good Clinical Practice, approved by our institutional ethics committee (Ethikkommission UKSH Kiel – AZ 106/12, Christian-Albrechts-

Table 1 Characteristics of the study population (n=54)

Parameter	Value
Age (yr; median [range])	74 [25–89]
Sex (female/male)	29/25
Weight [kg; mean (SD)]	73 (16.3)
Height [cm; mean (SD)]	169 (9.1)
Body mass index [kg m ⁻² ; mean (SD)]	25.5 (5)
ASA grade (II/III)	24/30
Tidal volume [ml kg ⁻¹ ; mean (SD)]	8.6 (2.0)
Total PEEP [cm H ₂ O; mean (SD)]	5 (3.0)
Surgery (gastrointestinal/cystectomy)	44/10

University Kiel, Schwanen-weg 20, D 24105 Kiel, Germany), and registered at <https://clinicaltrials.gov> (NCT02166580). After written informed consent, 54 patients who were to undergo elective major abdominal surgery under general anaesthesia were recruited into the study. Exclusion criteria were pregnancy, patients receiving vasoactive or inotropic support before induction of anaesthesia, <18 yr of age, and atrial fibrillation, ventricular arrhythmias, or both distorting the variation in pulse pressure readings. All measurements were assessed during surgery, after induction of anaesthesia. Patients received midazolam 3.75–7.5 mg orally 30 min before induction of anaesthesia. After admission to the operation theatre, ECG and pulse oximetry were applied to every patient. After induction of anaesthesia and injection of rocuronium (0.6 mg kg⁻¹) as a neuromuscular blocking agent, the trachea was intubated, and patients were ventilated with the ADU S5 ventilator (Datex Ohmeda, GE Healthcare, Munich, Germany) in a volume-controlled mode with a PEEP of 5 cm H₂O, an inspiratory-to-expiratory ratio of 1:1.5, and a mean (SD) tidal volume of 8.6 (2.0) ml kg⁻¹. The respiratory rate was adjusted to achieve normocapnia (partial pressure of CO₂ of 4.5–5.5 kPa). Respiratory settings were not changed throughout the measurements. Patients' characteristics are summarized in Table 1.

Continuous non-invasive arterial pressure measurement

The CNAP system (CNAPTM Monitor 500; CNSystems Medizintechnik AG, Graz, Austria) is able to measure the arterial pressure continuously and non-invasively. It consists of a double finger cuff, applied to the index and the middle finger, a pressure transducer, and a non-invasive arterial pressure cuff for calibration. The double finger cuff is used for automatic switches between fingers every 5–60 min, set to 30 min in our study, as recommended by the manufacturer. The upper arm non-invasive arterial pressure cuff serves for calibration of the device every 6–60 min, set to 15 min in our study.

This technology in principle is based on the 'volume-clamp method' first introduced in the early 1970s by Jan Penáz.¹⁵ With a double finger cuff, a pressure transducer fixed on the forearm, and a non-invasive arterial pressure cuff for calibration, this technology offers the ability to measure blood pressure and PPV continuously (beat to beat). The basic principle of the volume-clamp method, in brief, is that the diameter of a finger artery under the finger cuff is 'clamped' to keep the diameter of the artery constant ('set-point'), naturally in the presence of dynamic beat-to-beat changes in arterial pressure. Now, changes in the

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