

# Continuous noninvasive arterial pressure measurement using the volume clamp method: an evaluation of the CNAP device in intensive care unit patients

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**Abstract** The CNAP system allows continuous noninvasive arterial pressure measurement based on the volume clamp method using a finger cuff. We aimed to evaluate the agreement between arterial pressure measurements noninvasively obtained using the CNAP device and arterial catheter-derived arterial pressure measurements in intensive care unit patients. In 55 intensive care unit patients, we simultaneously recorded arterial pressure values obtained by an arterial catheter placed in the abdominal aorta through the femoral artery (criterion standard) and arterial pressure values determined noninvasively using CNAP. We performed Bland–Altman analysis and calculated the percentage error. The mean difference ( $\pm$ standard deviation, 95 % limits of agreement, percentage error) between noninvasive (CNAP) and invasively assessed arterial

pressure was for mean arterial pressure  $+1$  mmHg ( $\pm 9$  mmHg,  $-16$  to  $+19$  mmHg, 22 %), for systolic arterial pressure  $-10$  mmHg ( $\pm 16$  mmHg,  $-42$  to  $+21$  mmHg, 27 %), and for diastolic arterial pressure  $+7$  mmHg ( $\pm 9$  mmHg,  $-10$  to  $+24$  mmHg, 28 %). Our results indicate a reasonable accuracy and precision for the determination of mean and diastolic arterial pressure by noninvasive continuous arterial pressure measurements using the volume clamp method compared with the criterion standard (invasive arterial catheter). Systolic arterial pressure is determined less accurately and precisely.

**Keywords** Blood pressure · Critical care · Hemodynamic monitoring · Vascular unloading technology · Photoplethysmography

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## 1 Introduction

Accurate and continuous arterial pressure (AP) measurement is of outstanding importance in the treatment of intensive care unit (ICU) patients. In the critically ill patient, the criterion standard method for obtaining continuous AP is the measurement with an arterial catheter. However, this invasive technique implicates risks like bleeding, infection, and limb or digital ischemia [1, 2].

In contrast, the volume clamp method allows continuous noninvasive AP measurements [3]. The CNAP<sup>TM</sup> system (CNSystems Medizintechnik AG, Graz, Austria) uses this method for AP measurement. The system detects blood flow oscillations and keeps the volume in the finger arteries constant by using an inflatable finger cuff regulated by the CNAP<sup>TM</sup> controller placed on the patient's forearm [4]. From the cuff pressure needed to keep the volume in the finger artery constant throughout the cardiac cycle, the AP

waveform can be derived indirectly. The CNAP<sup>TM</sup> system calibrates the finger AP values measured with the volume clamp method to the AP values obtained by oscillometric upper arm cuff measurements. This calibration is performed mathematically by amplifying and shifting the finger sensor-derived values to systolic and diastolic AP values obtained by oscillometry using a proprietary transfer function while the mean AP is adjusted accordingly. The technology is easy to apply and—in contrast to invasive arterial catheters—bears no risk of infection, bleeding, or limb ischemia.

The CNAP<sup>TM</sup> system has already been evaluated and compared with invasive measurements from an arterial catheter during anesthesia and in surgical ICU patients [5–7]. Data on the AP measurement performance of this system in critically ill patients treated in the medical ICU are missing. Therefore, we aimed to evaluate the agreement (accuracy and precision) of the CNAP<sup>TM</sup> device with AP readings from a catheter placed in the abdominal aorta through the femoral artery (criterion standard) in medical ICU patients.

## 2 Materials and methods

### 2.1 Study design, inclusion/exclusion criteria, AP measurements

The ethics committee of our university hospital (Ethikkommission der Fakultät für Medizin der Technischen Universität München, Munich, Germany) approved this study. We obtained written informed consent from all conscious patients or a patient's legal surrogate in case of patients lacking decision-making capacity. According to the approved study protocol and considering the noninvasiveness of the study measurements, unconscious patients could also be enrolled and asked for their consent if their condition allowed doing so in the course of their disease.

We prospectively obtained AP data in patients who were treated in the ICU of our university hospital (Klinikum rechts der Isar der Technischen Universität München, Munich, Germany) and compared AP measurements obtained with the CNAP<sup>TM</sup> system with invasively assessed AP derived from an arterial catheter (PulsioCath; Pulsion Medical Systems SE, Feldkirchen, Germany).

Patients who were monitored with a catheter placed in the abdominal aorta through the femoral artery for clinical indications unrelated to the present study were eligible for study inclusion. Exclusion criteria were a patient's age <18 years or significant finger edema. Before starting the AP measurements, oscillometric AP was determined on the right and on the left upper arm and only differences of <10 mmHg in systolic AP were accepted for study enrollment.

In order to preserve realistic clinical conditions during study measurements, episodes of AP recordings during interventions like fluid administration or changes in vasopressor and antihypertensive therapy were deliberately included in the analysis.

For each patient, we analyzed invasive and noninvasive AP measurements simultaneously recorded over a total time period of 15 min (split into three intervals of 5 min) for the present method comparison analysis.

Calibration of the CNAP<sup>TM</sup> finger sensor-derived values to upper arm oscillometric values was performed at the beginning of each 5-min AP measurement interval.

### 2.2 Patients

In total, AP measurements were performed in 57 patients. AP recordings of two patients could not be analyzed due to technical reasons and were therefore excluded. AP data of 55 patients were finally used for statistical evaluation. Clinical characteristics of these patients extracted from the medical records are summarized in Table 1.

### 2.3 Data recording and processing

Both invasively and noninvasively recorded AP waveforms were displayed on the patient monitor (Datex-Ohmeda S/5<sup>TM</sup> Critical Care Monitor and Datex-Ohmeda S/5<sup>TM</sup> Compact Critical Care Monitor; GE Healthcare, Helsinki, Finland). The values for systolic, diastolic, and mean AP derived from both methods were collected through a PC serial interface cable into a laptop by using the software S/5<sup>TM</sup> Collect (Datex-Ohmeda) and were time synchronized for the subsequent data analysis.

Before statistical analyses, apparent artifacts were excluded from invasively and noninvasively obtained AP measurements by visual inspection of both AP waveforms. These artifacts were mainly caused by arterial line flushing and excessive movements of the upper extremities in non-sedated patients. For comparative statistical analyses, AP data recorded with the CNAP<sup>TM</sup> device and the arterial catheter were averaged over a time period of 10 s. After excluding 0.99 % of AP measurements because of apparent artifacts, a total of 4891 averaged 10-s episodes of simultaneous noninvasive and invasive AP recordings were analyzed.

### 2.4 Statistical analyses

For patient characteristics, we present either the median and interquartile ranges (i.e., 25–75 % percentile range) or absolute frequencies with percentages. We calculated the mean  $\pm$  standard deviation (SD) for AP values assessed either by the invasive arterial catheter or by the CNAP<sup>TM</sup> system. For the comparison of AP values we used Bland–

**Table 1** Patient and clinical characteristics

<i>Patient characteristics (n = 55)</i>	
Age (years)	60 (52–71)
Sex, male [n (%)]	36 (65)
Height (m)	1.75 (1.68–1.80)
Weight (kg)	80 (70–88)
Body mass index (kg m <sup>-2</sup> )	26.1 (24.0–27.9)
Atrial fibrillation [n (%)]	4 (7)
<i>Reason for intensive care unit admission</i>	
Pneumonia, respiratory insufficiency [n (%)]	14 (25)
Liver cirrhosis, liver failure [n (%)]	12 (22)
Sepsis [n (%)]	10 (18)
Acute pancreatitis [n (%)]	7 (13)
Gastrointestinal bleeding [n (%)]	3 (5)
Peritonitis [n (%)]	2 (4)
Other [n (%)]	7 (13)
<i>Clinical characteristics at day of study measurement</i>	
Mechanical ventilation [n (%)]	26 (47)
Norepinephrine therapy [n (%)]	19 (35)
Midazolam therapy [n (%)]	11 (19)
<i>Advanced hemodynamic monitoring data</i>	
Cardiac index (L/min)	4.1 (3.3–5.0)
Cardiac power index (W/m <sup>2</sup> )	0.7 (0.6–0.9)
Central venous pressure (mmHg)	14 (9–18)
Global end-diastolic volume index (mL/m <sup>2</sup> )	768 (690–906)
Extravascular lung water index (mL/kg)	9 (8–13)
Pulmonary vascular permeability index	1.5 (1.2–2)
Systemic vascular resistance index (dyn s cm <sup>-5</sup> m <sup>2</sup> )	1378 (1011–1722)
<i>Intensive care unit scores</i>	
Acute Physiology and Chronic Health Evaluation II Score (points)	22 (18–26)
Sequential Organ Failure Assessment score (points)	8 (5–11)
Simplified Acute Physiology Score II (points)	17 (10–28)

Data are presented as the median and interquartile ranges (25–75 % percentile) or as absolute frequencies with percentages

Altman analysis for repeated measurements in the same subject [8]. The mean of the differences (=bias), SD, and 95 % limits of agreement (=bias ± 1.96\*SD) were computed to evaluate the accuracy and precision of the non-invasive AP monitoring technology. The differences between CNAP<sup>TM</sup>-derived and invasive AP measurements were calculated by subtracting the invasively assessed AP values from the CNAP<sup>TM</sup>-derived AP values. We calculated the percentage error as 2 × SD of the differences/mean of measurements [9].

In addition, we computed Bland–Altman plots showing the patients' individual mean AP measurements, the intra-individual AP variability, the individual mean difference, and the intra-individual mean difference variability as described previously [10, 11].

Data analysis was performed using the statistical software package R (The R Foundation for Statistical Computing, Vienna, Austria) and IBM SPSS Statistics 21 (SPSS Inc., Chicago, IL, USA).

### 3 Results

#### 3.1 AP measurements with CNAP<sup>TM</sup> and the criterion standard

For the CNAP<sup>TM</sup>-derived AP values, the mean value (±SD) for mean, systolic, and diastolic AP was 84 mmHg (±16 mmHg), 115 mmHg (±24 mmHg), and 67 mmHg (±12 mmHg), respectively. For AP values measured invasively by an arterial catheter the corresponding values were 83 mmHg (±14 mmHg), 125 mmHg (±21 mmHg), and 60 mmHg (±10 mmHg), respectively.

#### 3.2 Comparison CNAP<sup>TM</sup> versus arterial catheter

The Bland–Altman analysis resulted in a mean difference (±SD; 95 % lower and upper limits of agreement) between invasively assessed AP values and AP values obtained by the CNAP<sup>TM</sup> system with the use of upper arm calibration

of +1 mmHg ( $\pm 9$  mmHg,  $-16$  to  $+19$  mmHg) for mean AP,  $-10$  mmHg ( $\pm 16$  mmHg,  $-42$  to  $+21$  mmHg) for systolic AP, and  $+7$  mmHg ( $\pm 9$  mmHg,  $-10$  to  $+24$  mmHg) for diastolic AP (Bland–Altman plots are presented in Fig. 1). The percentage error of CNAP<sup>TM</sup>-derived AP measurements was 22, 27, and 28 % for mean, systolic, and diastolic AP, respectively.

In Fig. 2 we present Bland–Altman plots showing the individual patients' mean AP measurements, the intra-individual AP variability, the individual mean difference, and the intra-individual mean difference variability.

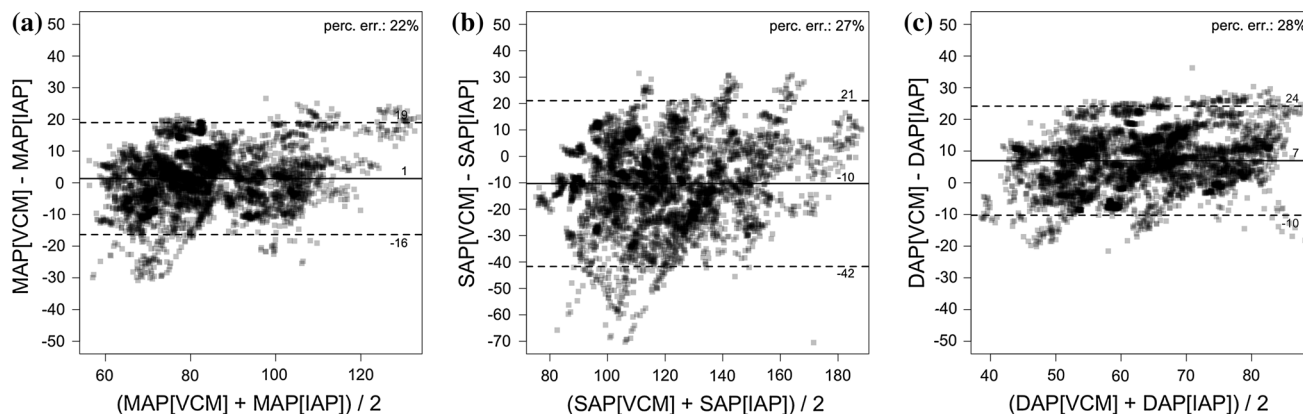
#### 4 Discussion

The main findings of the present study can be summarized as follows: Noninvasive continuous AP monitoring with the volume clamp method using the CNAP<sup>TM</sup> device is feasible in critically ill patients in the medical ICU and provides mean and diastolic AP with reasonable accuracy and precision when compared with invasive AP as criterion standard. Systolic AP is determined less accurately and precisely by CNAP<sup>TM</sup>.

Until now, data comparing invasively assessed AP measurements with noninvasive AP measurements using the volume clamp method in medical ICU patients are still missing. Several previous studies evaluated the volume clamp method using the CNAP<sup>TM</sup> device intraoperatively during anesthesia [5, 6, 12, 13]. For example, Jeleazcov

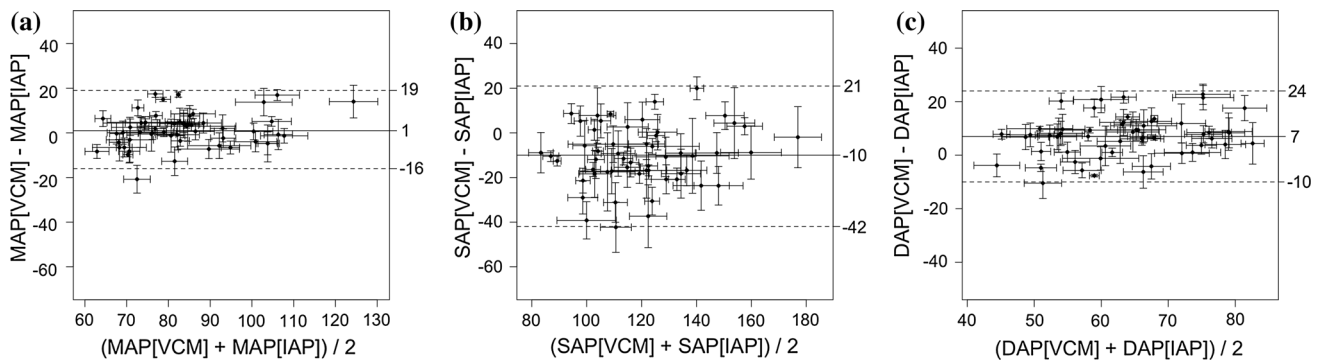
et al. [6] investigated the accuracy and precision of the CNAP<sup>TM</sup> system during anesthesia in 88 patients undergoing different surgical procedures. Their study revealed a bias ( $\pm$ SD) of  $-1.6$  mmHg ( $\pm 11$  mmHg),  $+6.7$  mmHg ( $\pm 14$  mmHg), and  $-5.6$  mmHg ( $\pm 11$  mmHg) for mean, systolic, and diastolic AP, respectively [6]. Further studies evaluating the CNAP<sup>TM</sup> device during general anesthesia provided similar results for accuracy and precision compared with the findings of Jeleazcov et al. [5, 12, 13]. Especially during unstable clinical conditions, e.g., induction of anesthesia and endotracheal intubation, a decrease in accuracy and precision as well as in the capability of tracking AP changes has been recently demonstrated [14].

Although the present work was conducted in medical ICU patients, our results showing a bias ( $\pm$ SD) of  $-1$  mmHg ( $\pm 9$  mmHg),  $10$  mmHg ( $\pm 16$  mmHg), and  $-7$  mmHg ( $\pm 9$  mmHg) for mean, systolic, and diastolic AP, respectively, are comparable with the results obtained in the mentioned previous studies evaluating the CNAP<sup>TM</sup> system during surgery in anesthetized patients [5, 12, 13]. In contrast, we included both sedated and awake critically ill patients. Considering the use of CNAP<sup>TM</sup> in nonsedated ICU patients, it must be taken into account that a higher frequency of artifacts caused by motion of the study limb might be observed. Nevertheless, the occurrence of motion artifacts is common in all AP measurement methods. Careful identification of unreliable AP values in order to avoid critical diagnostic errors in ICU patients is of high importance—irrespective of the AP monitoring method



**Fig. 1** **a** Comparison between arterial pressure measurements using the volume clamp method (VCM) with invasively obtained arterial pressure (IAP) measurements for mean arterial pressure (MAP[VCM] vs. MAP[IAP]). Bland–Altman plots with a mean bias (*continuous horizontal line*) of +1 mmHg and 95 % limits of agreement [(1.96\*SD); *dashed horizontal lines*] of  $-16$  to  $+19$  mmHg in 55 patients are shown. The percentage error was 22 %. **b** Comparison between arterial pressure measurements using the volume clamp method (VCM) with invasively obtained arterial pressure (IAP) measurements for systolic arterial pressure (SAP[VCM] vs. SAP[IAP]). Bland–Altman plots with a mean bias (*continuous*

*horizontal line*) of  $-10$  mmHg and 95 % limits of agreement [(1.96\*SD); *dashed horizontal lines*] of  $-42$  to  $+21$  mmHg in 55 patients are shown. The percentage error was 27 %. **c** Comparison between arterial pressure measurements using the volume clamp method (VCM) with invasively obtained arterial pressure (IAP) measurements for diastolic arterial pressure (DAP[VCM] vs. DAP[IAP]). Bland–Altman plots with a mean bias (*continuous horizontal line*) of  $+7$  mmHg and 95 % limits of agreement [(1.96\*SD); *dashed horizontal lines*] of  $-10$  to  $+24$  mmHg in 55 patients are shown. The percentage error was 28 %



**Fig. 2** Modified Bland–Altman plots showing individual mean arterial pressure (AP) measurements, the intra-individual AP variability, the individual mean difference, and the intra-individual mean difference variability for the mean AP (MAP, **a**), systolic AP (SAP, **b**), and diastolic AP (DAP, **c**). The *continuous line* shows the mean of the differences (=bias), the *dashed lines* show the upper and lower

95 % limits of agreement (=1.96\*SD). One data point represents one patient’s mean AP value. In addition, the intra-individual AP variability (SD in parallel to the x-axis), the individual mean difference, and the intra-individual mean difference variability (SD in parallel to the y-axis) are presented. *VCM* volume clamp method, *IAP* invasive arterial pressure

used. Another issue that needs to be taken into account when applying the CNAP™ finger cuff in critically ill ICU patients is the presence of finger edema. Distinct finger edema is a known contraindication for the use of the volume clamp method using a finger cuff because it can cause a downward drift in the AP waveform over time. Despite conscientiously excluding all patients with distinct edema, we noticed downward drifts of the CNAP™ AP signal over time when visually checking the AP waveforms during data analysis. Therefore, we performed regression analysis (data not shown) and revealed a decrease in the noninvasively measured AP of ≥10 % during at least one 5-min measurement interval that was not detected by the criterion standard (invasive AP) in 23 patients. The presence of clinically hard to identify finger edema or an increase in tissue fluid due to increased capillary permeability that occurs in various medical conditions in ICU patients must be kept in mind when interpreting these drifts observed in CNAP™-derived AP measurements. Furthermore, the question whether finger edema induced by venous obstruction from the finger cuffs of the CNAP™ device might influence the noninvasive AP measurements is not fully answered yet.

A common observation of previous studies and our study was that the mean AP was measured with the highest accuracy compared with systolic and diastolic AP. In accordance with the results by Jeleazcov et al. [6] we also observed that the CNAP™ device underestimates systolic AP and overestimates diastolic AP. This reduction in CNAP™-derived pulse pressure might be indicative for ‘arterial waveform damping’ when using the CNAP™ system for recording of the peripheral arterial waveform. One possible solution might be an adjustment of the transfer function used for calibrating the finger AP values to the oscillometrically obtained upper arm cuff AP values. Further research is therefore needed to

systematically evaluate this problem in different patient populations. To improve the technology’s measurement performance for systolic AP (e.g., by improving the calibration method) is especially of importance considering that systolic AP is crucial for the detection of hypotension and hypertension and for the assessment of fluid responsiveness based on systolic pressure variation and pulse pressure variation.

Another technology for completely noninvasive AP monitoring is the radial artery applanation tonometry. A method comparison study performed in a quite similar ICU patient population revealed comparable results [15]. This also included high accuracy and precision for MAP and a higher bias and wider limits of agreement for SAP in comparison to the invasive femoral catheter derived AP values.

Adequate interchangeability criteria for noninvasive continuous AP measurement devices still need to be defined. The Association for the Advancement of Medical Instrumentation standards for noninvasive AP measurement (ANSI/AAMI SP10) defined clinically acceptable agreement as a bias of ±5 mmHg and a SD of 8 mmHg [16]. However, this AAMI standard does not cover finger cuff AP measurement devices and can therefore not be applied as an interchangeability criterion in our study. In addition, for method comparison, the percentage error can be calculated to describe the agreement between two methods. The percentage error of the CNAP™-derived AP measurements was 22, 27, and 28 % for mean, systolic, and diastolic AP, respectively. For cardiac output monitors, Critchley and Critchley [9] defined a percentage error cut-off value of 30 % to define clinically acceptable agreement. However, because this 30 % threshold for the percentage error was explicitly defined to compare different technologies for cardiac output determination it cannot be simply transferred to AP measurement comparison

analyses. No established percentage error cut-off value exists to define clinically acceptable agreement between two technologies providing continuous AP data [17].

In contrast to the previous studies mentioned above evaluating the CNAP™ system in surgical patients in comparison to invasive AP readings from the radial artery [5, 6, 12, 13], we used the femoral artery for invasive AP measurements. It has been demonstrated that the invasive AP varies dependent on the site of measurement [15, 18, 19]. This fact must also be kept in mind when regarding the observed mean differences between the CNAP™ system and invasive AP values in our study. One might speculate that the difference between the CNAP™ AP measurements and the invasively assessed central aortic AP measurements might be influenced by respiratory phase differences between the measurement sites.

The CNAP™ device that we used in our study to assess noninvasive continuous AP measurement based on the volume clamp method provides AP after calibration to oscillometric brachial AP whereas our invasive AP recordings were obtained using an abdominal catheter placed through the femoral artery. Again, the observed bias might be influenced by the physiological difference between AP measured in the brachial artery and abdominal aorta.

Our study has limitations that need to be mentioned. Study measurements were performed in a relatively heterogeneous ICU patient population. The number of study patients was too small to perform subgroup analysis in order to identify specific influencing factors on the CNAP™ technology's measurement performance. Further, we did not study a specific intervention in order to systematically evaluate the trending ability of the CNAP™ device. Undistinctive finger edema and potential capillary leakage syndrome in ICU patients remain possible limitations for the noninvasive measurements using the CNAP finger cuff technology in this study.

The CNAP™ system providing noninvasive continuous AP measurements could be a useful device for the improvement of patient safety in procedures where invasive AP measurements are not definitely indicated or not possible but occurrence of hemodynamic instability is likely due to the patient's age or medical condition [20].

Conceivable situations of application are therefore medical interventions requiring patient sedation (i.e., endoscopy, short surgical procedures) or clinical monitoring of patients in the emergency department.

## 5 Conclusions

In conclusion, in ICU patients, the CNAP™ system shows reasonable accuracy and precision for the determination of

mean and diastolic AP compared with the criterion standard (invasive arterial catheter). Systolic AP is determined less accurately and precisely.

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