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CNAP® does not reliably detect minimal or maximal arterial blood pressures during induction of anaesthesia and tracheal intubation

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Background: CNAP® provides continuous non-invasive arterial pressure (AP) monitoring. We assessed its ability to detect minimal and maximal APs during induction of general anaesthesia and tracheal intubation.
Methods: Fifty-two patients undergoing surgery under general anaesthesia were enrolled. Invasive pressure monitoring was established at the radial artery, and CNAP monitoring using a finger sensor recording was begun before induction. Statistical analysis was conducted with the Bland–Altman method for comparison of repeated measures and intraclass correlation coefficient (ICC).
Results: Patients' median age was 67 years [interquartile range (59–76)], median American Society of Anesthesiologists score was 3 [interquartile range (2–3)]. Bias was 5 and –7 mmHg for peak and nadir systolic AP (SAP), with upper and lower limits of agreement of (42:–32) and (27;–42), respectively. The corresponding ICC values were 0.74 [95% confidence interval (CI) = 0.57–0.84] and 0.60 (95% CI = 0.44–0.73). Time lags to reach these values were 7.5 s (95% CI = –10.0 to 60.0) for the highest SAP and 10 s (95% CI = –12.5 to 72.5) for the lowest SAP. Bias, lower and upper limits of agreement for diastolic, and mean AP were –14 (–36 to 9) and –12 (–37 to 13) for the nadir value and –7 (–29 to 15) and –2 (–28 to 25) for the peak value.
Conclusions: The CNAP monitor could detect acute change in AP within a reasonable time lag. Precision of its measurements is not satisfactory, and therefore, it could only serve as a clue to the occurrence of changes in AP.

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Penáz et al.[1] opened the way to non-invasive measurement of beat-to-beat arterial pressure (AP) using a plethysmanometer. Since then, several devices have been proposed; among them, CNAP® (CNSystems Medizintechnik AG, Graz, Austria) is one of the latest that provides high-resolution, real-time AP waveform after calibration with the built-in standard oscillometric measurement of AP. After applying this scaling operation, CNAP values correspond to the values measured at the brachial artery.[2]

The accuracy of CNAP during anaesthesia has recently been studied,[3–6] and promising applications have been reported. As the monitoring of AP is particularly useful in case of haemodynamic instability, the focus should be on the period with acute large modifications of AP. Its accuracy during induction of anaesthesia and intubation, a time that is frequently associated with both significant and rapid falls and rises in AP, has not previously been examined. Despite progress in anaesthetic drugs and anaesthetic management, these 'valleys' and 'peaks' persist often with amplitudes that vary from one case to another, sometimes unpredictably. Insertion of an arterial line is usual in high-risk patients; in other cases, non-invasive beat-to-beat AP measurement could be useful in detecting acute changes in AP.

The purpose of this study was to evaluate the ability of the non-invasive measurement of AP with the CNAP monitor to detect minimal and maximal APs during induction of general anaesthesia and tracheal intubation.

Study performed in the Department of Anaesthesiology, Hôpital Foch, Suresnes, France.

Methods

After approval by the Ethics Committee and informed written consent had been obtained, all consecutive adult patients managed by OT or KS, and undergoing major scheduled surgery were investigated. Presence of cardiac arrhythmia was a non-inclusion criterion.

In the operating room, a 20-gauge intravenous (IV) catheter was inserted into the radial artery under local anaesthesia and was connected to the S/5™ monitor (Datex-Ohmeda, Helsinki, Finland). Briefly, the CNAP is a non-invasive beat-to-beat AP measurement device based on vascular unloading. Finger cuff pressure is continuously changed through the systolic and diastolic blood pressure cycle so that blood volume flowing through the finger arteries is held constant. Therefore, the cuff pressure corresponds to the pressure in the finger at any time. The CNAP is calibrated by standard non-invasive blood pressure via the upper arm cuff. It was used as recommended by the manufacturer, with two appropriately sized cuff sensors placed on the patient's index and middle fingers ipsilateral to the radial artery catheter. The device was connected to the S/5 monitor on a second arterial input and was calibrated just before anaesthetic induction.

General anaesthesia was induced and maintained using propofol and remifentanil target control infusions.[7] Tracheal intubation was facilitated by injection of atracurium.

The S/5 monitor was connected via an RS 232 port to the ToolBox 95 version 4.8 system (Département d'Anesthésie-Réanimation et Département de Calcul Scientifique, Hôpital Universitaire Erasme, ULB, Brussels, Belgium),[8] which was used to store systolic AP (SAP), diastolic AP (DAP) and mean AP (MAP) simultaneously measured invasively and non-invasively at 5-s intervals from 2 min before the induction to 5–10 min after tracheal intubation. For each patient, SAP and DAP were measured by the two methods just before the induction of anaesthesia (baseline SAP, MAP and DAP), at the nadir (nadir SAP, MAP and DAP) and at the peak (peak SAP, MAP and DAP). Then, the differences between the two methods in absolute value and in time to reach the nadir and the peak were calculated.

Statistical analysis

Results are expressed as median and first and third quartiles, or counts and percentages. For agreement between the invasive and the non-invasive method, Bland–Altman analysis was applied, calculating bias as the mean difference between both methods and limits of agreement as the range in which 95% of the differences between the two methods are expected to lie. The intraclass correlation coefficient between the two methods was also estimated. Agreement was studied for individual peak and nadir values ($n = 52$) using the standard Bland–Altman approach, whereas agreement between the two samples using all measured values ($n = 5174$) was studied using repeated measures techniques.[9] Lastly, we assessed percentage error according to Critchley and Critchley.[10] Comparison of continuous variables was made using the Wilcoxon's rank test. A two-sided P-value of 0.05 was considered significant. All analyses were performed with R 2.13.0 statistical software (R Foundation for Statistical Computing, Vienna, Austria).

Results

Fifty-two consecutive patients (33 males, median age 67) were included for a total of 5174 pairs of invasive AP and CNAP measurements. Their main characteristics are reported in Table 1. Actual representations of AP curves obtained by the two techniques are displayed in Fig. 1. Bland–Altman graphical representation of agreement between the two methods over all pairs of measurement is dis-

Table 1

Patient characteristics data.

Variable	$n = 52$
Age (years)	67 (59–76)
Male sex	33 (63%)
Hypertension	34 (65%)
Heart failure	8 (15%)
Diabetes mellitus	13 (25%)
COPD	11 (21%)
Obesity (body mass index > 35 kg/m^2)	10 (19%)
Long term medication	
Beta-blocker	16 (37%)
Calcium channel blocker	18 (35%)
Renin angiotensin system blocker	12 (23%)
Statin	22 (42%)
Baseline systolic arterial pressure (mmHg)*	135 [125–145]
Baseline diastolic arterial pressure (mmHg)*	80 [70–90]
ASA score	3 [2–3]
Scheduled surgery	
Cardiac surgery	32 (62%)†
Urological surgery	12 (23%)
Vascular surgery	3 (6%)
Digestive surgery	3 (6%)
Thoracic surgery	1 (2%)
Neurosurgery	1 (2%)

*Based on invasive measurements.
†Including 14 coronary artery bypass grafts.
Data are given as median (interquartile range) or count (percentage).
COPD, chronic obstructive pulmonary disease; ASA, American Society of Anesthesiologists.

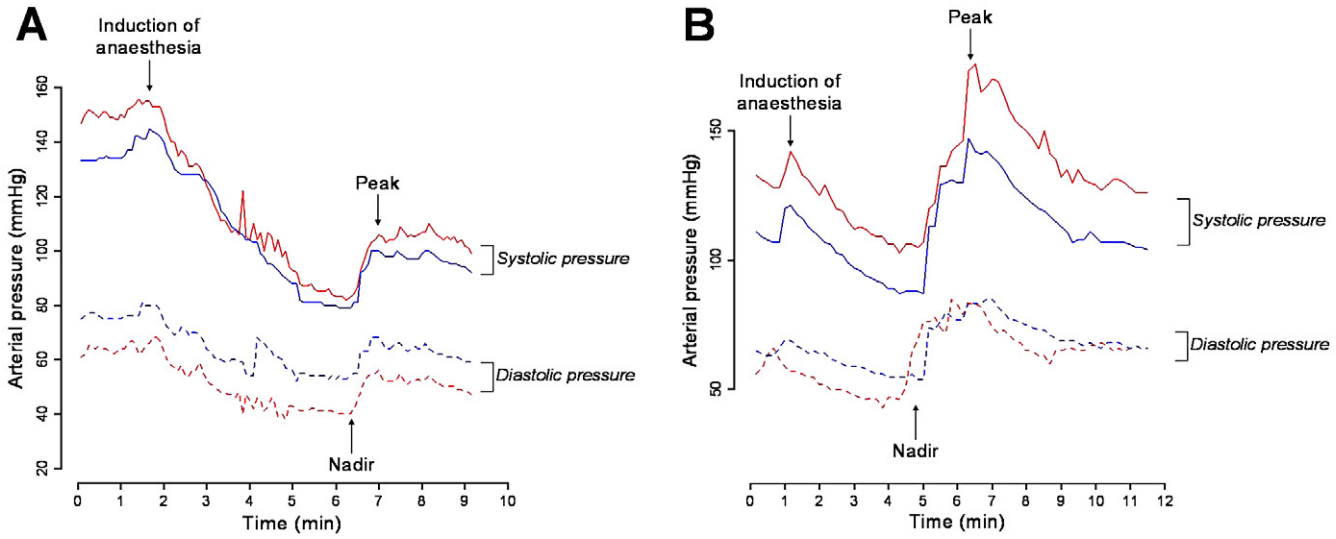

Fig. 1. Representation of arterial pressure trends in two different patients. The red lines depict the invasive measurements and the blue line the non-invasive ones, using the CNAP® device. In both cases, the time to peak and nadir are similar between invasive and non-invasive measurements, although there is bias in diastolic pressure measurement (A) and in systolic pressure measurement (B).

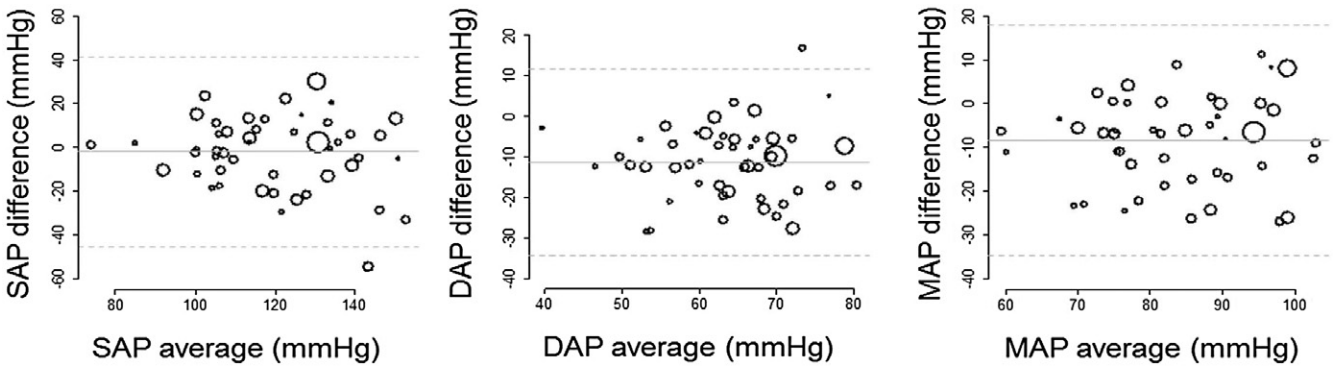

Fig. 2. Bland–Altman graphical representation of concordance for repeated measurements among the 52 patients [systolic arterial pressure (SAP),diastolic arterial pressure (DAP), mean arterial pressure (MAP)]. Difference corresponds to the value obtained by the invasive method minus the one obtained by the non-invasive method. Area of circle is proportional to number of measures. Grey continuous line represents the bias and the dashed grey lines the upper and lower limits of agreement, respectively.

played in Fig. 2 and in Fig. 3 for individual peak (A panel) and nadir values (B panel) obtained by the two methods during induction of general anaesthesia. Bland–Altman parameters and percentage errors of repeated measurements are shown in Table 2. All concordance results for individual values are shown in Table 3. The median time lags between the two methods were 7.5 s (95% CI = –10.0 to 60.0) for the highest SAP and 10 s (95% CI = –12.5 to 72.5) for the lowest SAP. Of note, the invasive method was the fastest in both cases.

Table 2

Concordance parameters for multiple measurements ($n = 5174$ in the 52 patients).

	Bias* (LLA; ULA)	Percentage error (%)
Systolic arterial pressure	–2 (–45; 41)	37
Diastolic arterial pressure	–11 (–34; 12)	37
Mean arterial pressure	–8 (–35; 18)	32

*Corresponds to mean difference between invasive measurement minus non-invasive method.
LLA, lower limit of agreement; ULA, upper limit of agreement.

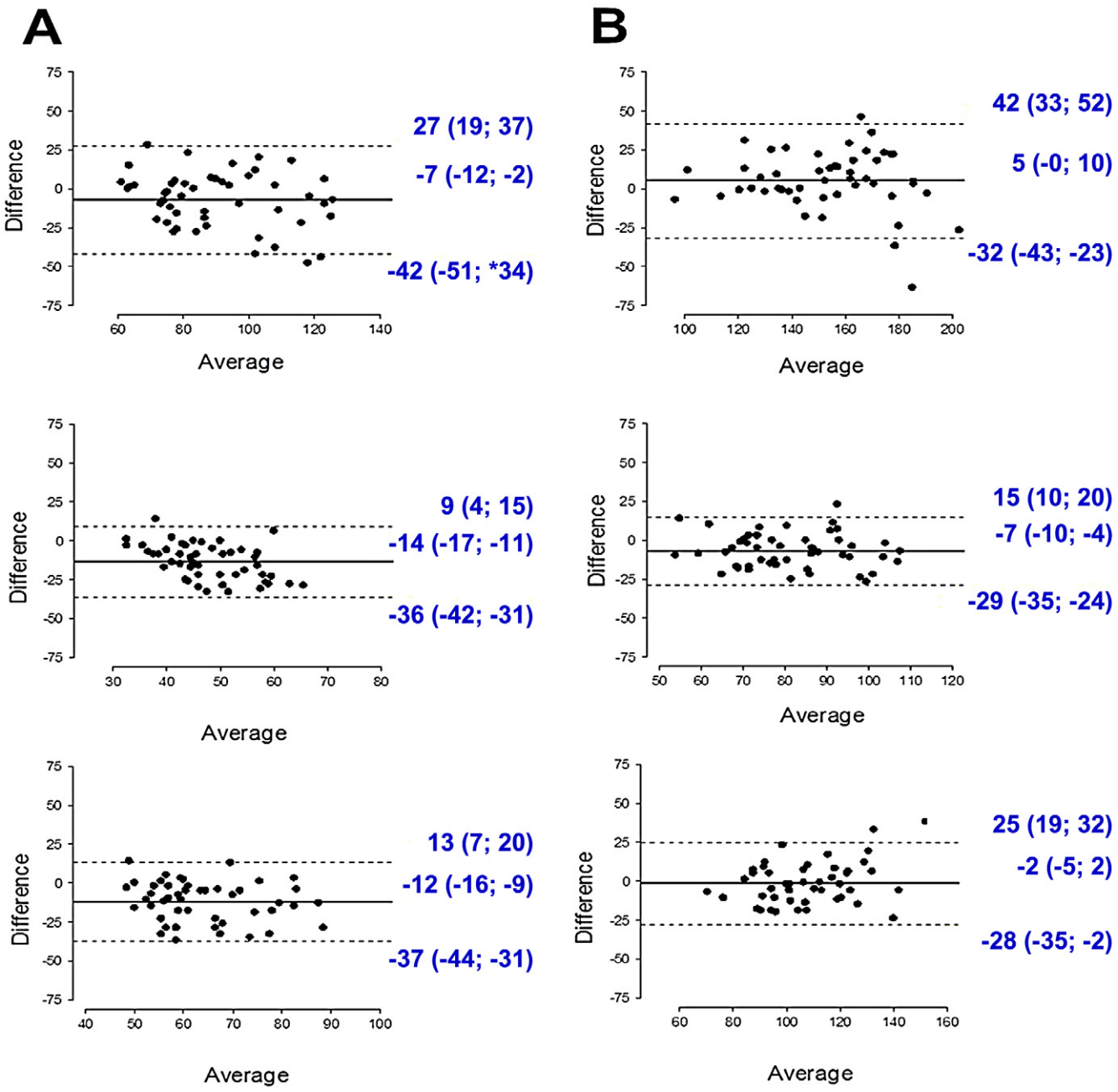

Fig. 3. Bland–Altman graphical representation of concordance for individual value of peak and nadir pressures between invasive and non-invasive measurements during induction of general anaesthesia. Difference corresponds to the value obtained by the invasive method minus the one obtained by the non-invasive method. (A) represents concordance of the peak values, while (B) represents concordance of nadir values.

Discussion

Two recent studies evaluated the accuracy of CNAP to measure AP in comparison with invasive measurement,[3,4] and one compared respiratory-induced pulse pressure variations obtained with an arterial line or CNAP to predict fluid responsiveness in anaesthetised patients.[7] The validation studies reported a small bias around 5–7 mmHg for SAP and DAP, and –2 mmHg for MAP but a large limit of agreement between the measurements. Other studies confirmed those results showing limited bias but relatively large limits of agreement.[11] However, their conclusions were quite different, as

Table 3

Concordance results between invasive and non-invasive measurements of blood pressure (one value of nadir and of peak pressures for each of the 52 patients).

	Bias* (95% CI)	LLA (95% CI)	ULA (95% CI)	Percentage error (%)	ICC coefficient (95% CI)
Systolic arterial pressure					
Individual nadir values	–7 (–12; –2)	–42 (–51; –34)	27 (19; 37)	39	0.60 (0.44–0.73)
Individual peak value	5 (0; 10)	–32 (–42; –23)	42 (33; 52)	25	0.74 (0.57–0.84)
Diastolic arterial pressure					
Individual nadir values	–14 (–17; –11)	–36 (–42; –31)	9 (4; 15)	48	0.17 (0.06–0.28)
Individual peak value	–7 (–10; –4)	–29 (–35; –24)	15 (10; 20)	28	0.66 (0.54–0.75)
Mean arterial pressure					
Individual nadir values	–12 (–16; –9)	–37 (–44; –31)	13 (7; 20)	41	0.33 (0.15–0.48)
Individual peak value	–2 (–5; 2)	–28 (–35; –22)	25 (19; 32)	25	0.76 (0.66–0.83)

*Corresponds to mean difference between invasive measurement minus non-invasive method.
ULA, upper limit of agreement; LLA, lower limit of agreement; ICC, intraclass coefficient; CI, confidence interval.

Jeleazcov et al.[4] stated that 'CNAP provides real-time estimates of AP comparable with those generated by an invasive intra-arterial catheter', while Biais et al.[3] affirmed that the CNAP system seems more accurate for MAP measurement than for SAP and DAP.

No study has focused on the period of induction of general anaesthesia. Ilies et al.[12] recently reported their comparison between CNAP monitoring and invasive pressure monitoring during induction and maintenance of general anaesthesia, but the induction period was defined as the period between the beginning of the IV anaesthetic administration and skin incision. This approach blurs the significant but transient changes in blood pressure, adverse haemodynamic effects of anaesthetic agents and intubation.

Consequently, these studies were not designed to respond to the major issue that can be summarised as follows: can a non-invasive method of AP measurement detect an acute change as rapidly and with the same magnitude as invasive measurement? A device, which achieves this goal, would be an alternative to invasive measurement in numerous cases where the placement of an arterial catheter before anaesthesia is judged inadequate.

Concerning the difference between the two methods, the Association for the Advancement of Medical Instrumentation ANSI/AAMI SP10 considers a mean difference of ± 5 mmHg between the test device and the reference method as a clinically acceptable disagreement.[13] Our results show that bias between the two methods was just at this limit regarding peak values, while bias was greater for nadir values, particularly for DAP. But, comparability cannot be summarised by bias, and our results show very large limits of agreement as do previous studies.[3,4] Compared with other concordance parameters, percentage errors have been less reported in studies assessing CNAP. This parameter is most frequently used to assess cardiac output monitor, and a cut-off of 30% is considered acceptable in this setting.[10] In our study, percentage errors analyses showed contrasting results with values below 30% for all peak APs but above this cut-off for all nadir values.

Concerning time lags, CNAP took twice as long to reach the lowest SAP compared with the highest, but these time intervals are short, the maximal confidence interval being in the order of 1 min. This allows for quick reaction, with an appropriate pharmacological vasoactive drug response.

More recently, Ilies et al. investigated the ability of CNAP to detect hypotension during Caesarean section in a cohort of 80 women.[14] They compared CNAP with oscillometric AP measurement. Unfortunately, they did not show concordance results, but they concluded that continuous non-invasive monitoring using CNAP led to detect a significantly higher number of hypotensive episodes.[14] The ability of CNAP to predict fluid responsiveness has also been studied in several studies with consistent results, suggesting excellent ability of the device to predict this.[15,16] Those results suggest that CNAP is probably a valuable tool more to assess AP semi-quantitatively and to detect hypotension or response to fluid expansion than to precisely measure AP.

Limitations of the study

We compared our results to AAMI standards. However, the AAMI standards for the evaluation of non-invasive blood pressure devices clearly state

that monitors measuring blood pressure on the finger are not covered and if intra-arterial measurements are compared with non-invasive devices, the radial artery should not be used as the reference device because a systematic bias has to be expected. This problem has been reported in previous work on this topic.[4,12] We did not assess the discrepancies between invasive measurements and the automatic oscillometric cuff method nor between CNAP and the automatic oscillometric cuff method. The sample size of the study could be considered as limited, and no sample size calculation was performed. This limits the power of the study, and our results should be confirmed in a larger sample before being broadly generalisable.

In conclusion, our study shows that CNAP could detect acute change in AP within a reasonable time lag, but the magnitude of its measurements should only serve as guidance.

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