Continuous non-invasive arterial pressure shows high accuracy in comparison to invasive intra-arterial blood pressure measurement

Sackl-Pietsch E., Department of Anesthesiology, Landeskrankenhaus Bruck an der Mur, Austria

I. INTRODUCTION

Continuous blood pressure (BP) monitoring is required in a multitude of clinical settings, especially in perioperative care. For inpatient surgeries, the American Society of Anesthesiologists (ASA) requires continuous perioperative blood pressure monitoring at least for patients with severe systemic disease; this necessitates the invasive placement of an intra-arterial catheter. In all other cases intermittent non-invasive blood pressure monitoring (NBP) is the standard of care. Therefore, the patients` blood pressure may not be monitored at all times.

A recent representative survey(1) among Austrian and German physicians (N=198) provides evidence that, in 82% of inpatient surgeries, non-invasive blood pressure monitoring is used. However, in 25% of these cases, especially in surgeries where hemodynamic instabilities can be expected or where aggressive management of blood pressure might be required (e.g. in urologic, extended laparoscopic, orthopaedic or vascular surgeries, in surgeries in gynecology and obstetrics, in medium to extended intestinal surgery and elective or urgent trauma surgery(2)), anesthetists would prefer a non-invasive continuous blood pressure monitoring to have better control over the patient's hemodynamics. In the remaining 18% of inpatient surgeries, BP is measured continuously using invasive catheters (IBP), mainly in patients where cardiovascular instability is expected and thus ASA guidelines specifically require continuous BP measurement and/or where repeated blood gas analysis is needed. Note that, in 26% of these cases the invasive catheter is inserted only to enable continuous blood pressure monitoring. However, this is a time-consuming and cost-intensive procedure, causing pain for the patient and including the risk of infection, and thus should be replaced by a non-invasive method if possible.

There are a number of studies stressing the importance of continuous perioperative blood pressure monitoring: e.g., more than 20% of all hypotensive episodes during surgeries may be missed by intermittent upper-arm blood pressure readings and another 20% may be detected with a delay(3). This in turn may prevent immediate treatment or even lead to missing complete hypotensive episodes. It has been shown that intraoperative hypotension preceeds 56% of perioperative cardiac arrests(4) and is associated with a significant increase of the 1-year post surgical mortality rate(5), indicating that intermittent NBP monitoring can be insufficient.

Consequently, there seems to be a discrepancy between the number of cases where continuous blood pressure monitoring is needed and those cases where it is actually used: Due to its invasive nature and associated risks, intra-arterial catheters can only be justified in a limited number of patients whereas anesthetists would like to perform risk-free continuous BP monitoring in a greater number of cases. For exactly these situations CNAP™ has recently become available(6, 7, 8, 9, 10, 11). CNAP™ is designed for anesthetists who look for more control in situations when continuous blood pressure is desirable, but the risks and burden of an arterial line are not justified. CNAP™ provides continuous, non-invasive and risk-free beat-to-beat blood pressure measurement.

The aim of the present report was to evaluate the accuracy of CNAP™ in a real-life perioperative setting by comparing simultaneous measurements of CNAP™ to continuous intra-arterial pressure monitoring.

II. METHODS

DATA RECORDING

The measurements were conducted in a perioperative setting at the Department of Anesthesiology at Landeskrankenhaus Bruck an der Mur (Austria). In all patients included in this report, continuous BP monitoring was indicated by clinical safety standards. Arterial pressure was measured simultaneously with an invasive catheter (Edwards Life Sciences™ Pressure Monitoring Set, Irvine, USA, connected to Datex Ohmeda S/5 monitor, GE, Helsinki, Finland) and the CNAP™ Monitor 500i (CNSystems Medizintechnik AG, Graz, Austria) in fifteen patients undergoing orthopedic, cardiac and vascular surgeries (seven female and eight male patients, mean age of 71 years, range 33 to 82 years, ASA classifications I-III: I in 1 case, II in 12 cases, III in 2 cases). The arterial catheter was placed ipsi-laterally (n=5) or contra-laterally (n=10) to the CNAP™ finger cuff in the A. radialis or A. brachialis, depending on indication and requirements. The surgery durations averaged 1h39min with a minimum of 44min and a maximum of 3h01min, the total duration of recordings obtained was approx. 25 hours.

DATA PROCESSING

From the IBP as well as from the CNAP™ signal, systolic, diastolic and mean pressure values were derived for each second. If one of the signals was missing (e.g. due to transmission faults or artifacts) for one data point, all other measurements for that data point were consequently discarded. Otherwise, no further data processing was performed and a total of 75,485 data points were included into the statistical comparison.

DATA COMPARISON

For a comprehensive evaluation of CNAP™, its underlying mechanisms have to be considered: CNAP™ is an integrated solution where relative BP changes are measured at the finger sensor which are turned into absolute values based on initial readings from its integrated NBP-unit. This fact needs to be taken into consideration when comparing the blood pressure readings recorded by CNAP™ and IBP.

Since three measurement positions are combined in this comparison (CNAP™ finger sensor, CNAP™ NBP-unit and IBP catheter), some physiological facts have to be taken into account: namely, transformations of BP amplitudes and waveforms as illustrated in figure 1. This implies that a systematic offset between CNAP™ and IBP can be expected.

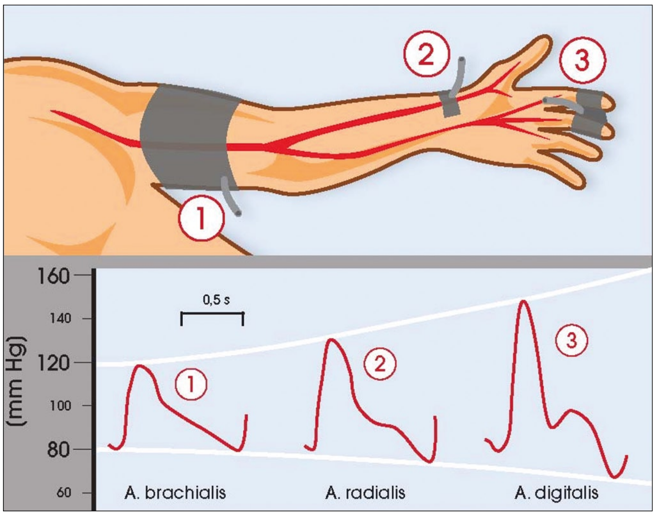

Figure 1: Different blood pressure waveforms and amplitudes in the (1) A. brachialis, (2) A. radialis and (3) A. digitalis, resulting in different systolic and diastolic values

Thus, it is not surprising that even the AAMI-SP10 standard recommended by the FDA reports substantial differences between indirect NBP and direct intra-arterial measurements[12]. A meta-analysis with the results of nine studies totaling 330 patients was performed which quantifies this systematic offset: The average differences between arterial and NBP-cuff systolic BP ranged from 0.8 to 13.4 mmHg with standard deviations (SD) ranging from 0 to 13.0 mmHg. Diastolic BP showed average differences from 0.8 to 18.0 mmHg with SDs ranging from 0.0 to 10.2 mmHg.

This offset may be even magnified when IBP and NBP recordings are taken on contra-lateral arms. Note that in 10 out of the 15 patients reported on here, CNAP™ and IBP were placed on contra-lateral arms.
Therefore, the following differences between CNAP™ and IBP can be expected:
(i) Differences between the two BP waveforms.
(ii) The characteristic offset between the absolute values of systolic, diastolic and mean pressure.

III. RESULTS

WAVEFORM COMPARISON

Figure 2 shows blood pressure waveforms recorded by CNAP™ compared directly to intra-arterial blood pressure waveforms. The upper graph shows a short episode of stable blood pressure. The bottom-up arrows indicate rising and the top-down arrows indicate falling BP ramps considered as results of volume status, the Frank-Starling mechanism and autonomic regulation[13]. The lower graph shows BP changes caused by perioperative treatment or patient movement. Due to the fact that data was recorded in the clinical routine, no further information about the patient`s treatment at this special time slice is available. Nevertheless, the good accordance of waveforms indicates that CNAP™ can follow fast blood pressure variations changes as well as IBP.

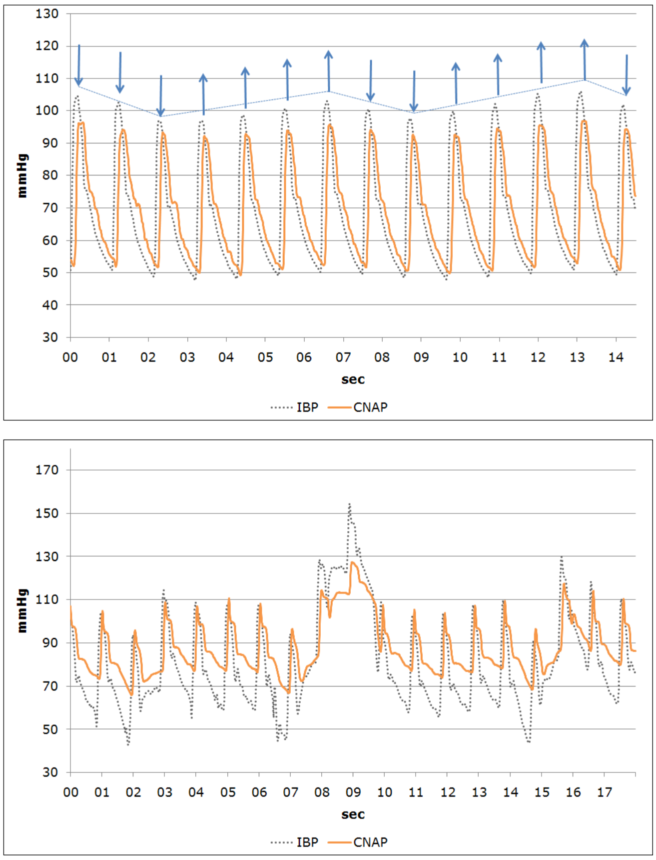

Figure 2: Blood pressure tracings showing the agreement of CNAP™ (solid line) with IBP (dotted line) during anesthesia.

HEMODYNAMIC CHANGES

For clinical application it is important to ensure that CNAP™ is able to monitor fast hemodynamic changes. In figure 3 an example is displayed where short-term hemodynamic variability during 25 minutes of orthopedic surgery can be observed clearly: CNAP™ and IBP display a parallel hemodynamic trend with the typical offset between indirect and direct measurement methods.

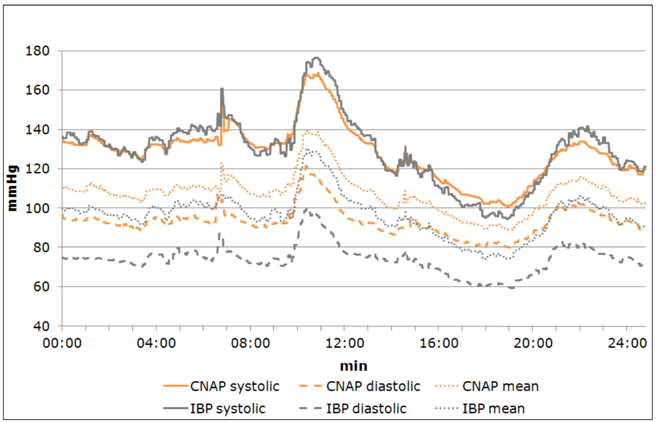

Figure 3: Comparison of short-term trends of systolic, diastolic and mean blood pressure measurements from CNAP™ (solid lines) and from IBP (dotted lines) during 25 min of anesthesia.

BOXPLOTS FOR ALL PATIENTS' DATA SETS

Figure 4 shows boxplots for all 15 data sets, for mean BP values. This graph illustrates that most of the patients show a characteristic offset between CNAP™ and IBP.

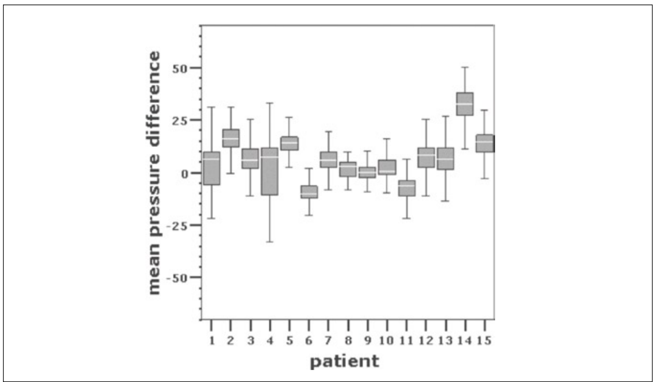

Figure 4: Boxplots of differences between CNAP™ and IBP values for all 15 patients (mean BP (mmHg)). The boxes contain the middle 50% of the data, the horizontal lines show the median. The upper and lower edges of the boxes indicate the 75th and 25th percentiles, respectively. The 5-95% range of the data is indicated by the ends of the vertical lines.

BLAND-ALTMAN-PLOTS FOR THE COMPLETE DATA SET

The differences of CNAP™ and IBP data points were computed for every data point (n = 75,485) and plotted vs. their average, resulting in the Bland-Altman-plot of Figure 5. No distinct trend of blood pressure difference in relation to the absolute mean values of pressure can be detected, i.e. the diffe difference between the two recording methods is the same over the whole range of values.

Furthermore, table 1 shows mean values and standard deviations of differences of CNAP™ to IBP for systolic, mean and diastolic pressure for each patient separately as well as for the whole sample.

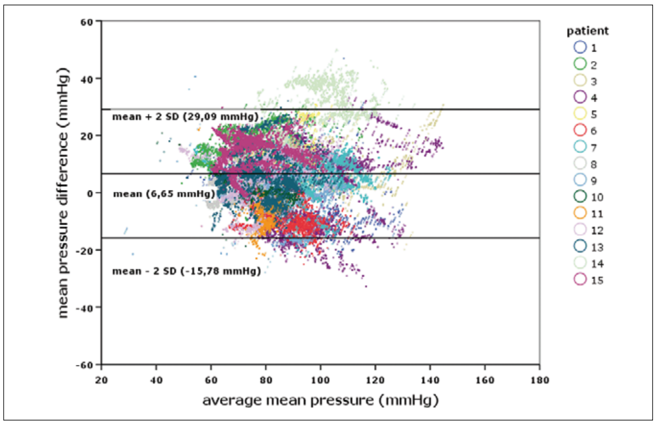

Figure 5: Bland-Altman-plot of differences vs. average of all data points (CNAP™ vs. IBP values, n=75,485) for mean BP (mmHg).

TABLE 1: Means and standard deviations (SD) of differences between CNAP™ and IBP (mmHg).

	Systolic BP		Mean BP		Diastolic BP	
patient	mean	SD	mean	SD	mean	SD
1	-10,03	13,83	4,29	9,87	8,80	6,80
2	2,56	7,54	16,09	5,82	19,24	5,88
3	-2,81	7,17	6,99	6,51	12,27	7,21
4	-7,82	12,06	1,88	12,62	9,94	14,11
5	1,31	6,63	14,41	5,88	20,25	4,70
6	-16,43	5,11	-9,44	4,15	-3,99	4,38
7	-1,33	8,00	5,44	6,15	14,46	5,07
8	-10,77	5,69	1,91	3,71	7,34	2,86
9	-11,20	7,78	-0,81	6,71	3,75	6,91
10	-9,93	7,82	1,93	3,86	7,16	3,22
11	-25,82	8,37	-7,48	4,62	0,22	3,89
12	-1,45	6,95	6,52	7,73	10,95	6,41
13	0,24	11,62	6,81	7,91	11,09	7,34
14	33,55	4,59	32,00	7,10	37,77	5,77
15	2,89	10,49	13,58	5,84	19,69	4,99
Total	-2,96	13,81	6,66	11,23	12,36	10,91

IV. DISCUSSION

Within an every day clinical setting, CNAP™ and IBP readings were recorded simultaneously during inpatient surgeries. The results of this perioperative comparison indicate that CNAP™ has a high usability during anesthetic care: the overall statistical analyses of systolic, mean and diastolic blood pressure show small differences and standard deviations between the two methods. The graphical comparison of BP waveforms and short-term trends during anesthesia indicates that CNAP™ can follow hemodynamic variability as fast as IBP. These results give strong support to a high accuracy of the non-invasive CNAP™ device in comparison to the invasive measurement.

The waveforms of CNAP™ and IBP shown in figure 2 comply well with the physiological expectations (see section "Methods"). As can be seen, CNAP™ corresponds to the IBP signal both in resting conditions as well as in movement.
For perioperative usability of the CNAP™ system, it is essential to show that CNAP™ can deal with hemodynamic changes as well as IBP: The trends of systolic, diastolic and mean BP depicted in figure 3 show excellent visual accordance between the two devices.

To illustrate the overall agreement between CNAP™ and IBP, figures 4 and 5 sum up the results for all 15 patients. The validation of CNAP™ with a total observation duration of about 25 hours and 75,485 data points is very acceptable: The mean values and standard deviations of differences to the intra-arterial recordings comply with the results of the meta-analysis recommended by the FDA.

As can be seen in figure 4, all patients have their own characteristic offset between CNAP™ and IBP. Only patient no. 14 seems to slightly deviate from the rest with a higher pressure difference which may be explained by the patients' arteries: in patient no. 14 the vessels were described by the clinician as 'stiff' and the IBP readings as 'dependent on bedding', thus making the arterial reference less reliable and the results surprisingly good. On the other hand, not even in the case where a patient's peripheral perfusion was described by the physician as "poor" (patient no. 11) did the CNAP™ system fail to quickly find a suitable BP waveform and the results compared to IBP are very satisfactory.

The individual, physiologically-determined offset can also be seen clearly in the cluster of data points of each patient in figure 5 (e.g., note patient no. 14 in the upper right-hand corner). Nevertheless, the Bland-Altman-plot between CNAP™ and IBP shows no distinct trend of mean pressure difference in relation to the average values of pressure, i.e. the difference between the two recording methods is the same over the whole range of values. This indicates that CNAP™ measurement is reliable in normal, hypotensive and hypertensive episodes.

The mean values and standard deviations of differences between CNAP™ and IBP reported in table 1 confirm the findings of the meta-analysis in the current ANSI standard. These results are very satisfactory considering the patient sample included in this report. Note that data was recorded in patients with severe systemic disease or during higher-risk surgeries where the placement of an invasive catheter was motivated by safety considerations.

Although the results of this report indicate a high clinical usability of CNAP™, some remarks have to be made about the comparison to IBP measurements: There is common agreement that "true" blood pressure is best determined directly using a reliable, calibrated transducer in an artery. Nevertheless, there is also consensus that the direct intra-arterial measurement is fraught with its inherent set of issues, including variability with radial position, vasoconstriction, the effects of flow-velocity changes and the frequency response of amplifier and transducer. Taking this into account, the results of this present report are even more remarkable.

V. CONCLUSION

On the whole, the reported results provide clear evidence of an excellent clinical feasibility and high accuracy of the non-invasive BP measurement device CNAP™ in comparison to IBP.

With intermittent measurement of oscillometric sphygmomanometers (NBP), short-term but clinically relevant hemodynamic changes during anesthesia are not satisfactorily detectable. Therefore, the demand from anesthetists for a system providing non-invasive, continuous beat-to-beat BP is increasing.

CNAP™ provides patient comfort and usability similar to a standard upper-arm NBP and clinical data shows that its accuracy is comparable to IBP. Thus, CNAP™ is the convenient solution for anesthetists who want to have comprehensive hemodynamic control to ensure highest patient safety.

VI. REFERENCES

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