

Feasibility of continuous noninvasive arterial pressure monitoring in a prehospital setting, measurements during emergency transfer

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Objectives In severely injured or acutely ill patients close monitoring of blood pressure (BP) can be crucial. At the prehospital scene and during transfer to hospital, the BP is usually monitored using intermittent oscillometric measurements with an upper arm cuff every 3–5 min. The BP can be monitored noninvasively and continuously using the continuous noninvasive arterial pressure (CNAP) device. In this study, we investigated the feasibility of a CNAP device in a prehospital setting.

Patients and methods The study was an observational convenience study. The CNAP device was applied to the patient once in the ambulance and measurements were carried out during transfer to hospital. The primary object was the number of patients in whom the CNAP device could monitor the BP continuously in a prehospital area en route to hospital.

Results Fifty-nine patients were enrolled in this study. Fifty-four (92%) patients had their BP monitored continuously by the CNAP device. The main reasons for missing data were a mean BP below the detectable range,

reduced pulse wave caused by constricted arteries in the fingers, or patients' excessive movements. The CNAP device provided continuous measurements after a median of 164.5 s. No complications and no adverse events were observed.

Conclusion Continuous measurement of the BP obtained by the CNAP device is feasible and safe in a prehospital setting under potentially difficult conditions. *European Journal of Emergency Medicine* 26: 334–339 Copyright © 2018 The Author(s). Published by Wolters Kluwer Health, Inc.

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Introduction

Blood pressure (BP) is one of the most important parameters in several clinical settings. In a prehospital emergency setting, the measurement of BP is of utmost importance to facilitate early, targeted therapy and provide initial triage of patients. In studies with both trauma and unselected medical patients, the BP measured before hospital arrival was found to be correlated to morbidity and mortality [1,2].

Noninvasive blood pressure (NBP) can be measured with an oscillometric upper arm cuff. This is currently the first choice in the prehospital field. The Association for the Advancement of Medical Instrumentation standard is BP measurement once every 3–5 min [3]. In critically ill patients, identification of hemodynamic events may be missed or delayed because of these intermittent measurements. The gold standard of measurement of BP,

continuous invasive BP measurement by an arterial line (IAP), is an exception in the prehospital field [4].

A new device has made it possible to measure BP continuously without using invasive techniques. The continuous noninvasive arterial pressure (CNAP) device uses the vascular unloading technique described by Peñáz [5].

The accuracy of the CNAP device has been compared with IAP measurements in-hospital. Both perioperatively [6,7] as well as in patients admitted to the ICU, acceptable agreement between CNAP and IAP measurements has been shown [8,9]. Furthermore, in an emergency department, the CNAP device proved to be superior to intermittent BP measurements in detecting hemodynamic events [10]. To our knowledge, the CNAP device has never been tested in a prehospital field. Thus, we carried out this study to evaluate the feasibility of the CNAP device in a prehospital setting.

Patients and methods

This prospective, open, single-centre convenience study was carried out at The Mobile Emergency Care Unit (MECU) in Odense in The Region of Southern Denmark. This prehospital physician-manned unit in

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Odense, Denmark, operates in a three-tiered system supplementing the ordinary ambulance or paramedic. The MECU services a population of 260 000 citizens. The longest transportation distance encountered is 50 km from the outskirts of the catchment area to Odense University Hospital. One study investigator participated in the MECU runs and enrolled eligible patients on an availability basis.

All prehospital patients treated on scene by the MECU physician and subsequently requiring emergency transfer to hospital were potentially eligible for enrolment in this study.

Exclusion criteria were age younger than 18 years or patients with vascular implants at the site of the CNAP/NBP measurement (upper extremities).

The primary objective was to assess the number of patients where CNAP monitoring was feasible during the emergency transport. The secondary objective was to evaluate the time elapsed from the placement of the CNAP device to the first continuous readings by the device. Finally, we aimed to evaluate the number of valid versus invalid readings during the measurement period of the CNAP device compared with the standard intermittent NBP device.

This study was considered a low-risk nonintervention study. The Ethical Committee in Region of Southern Denmark approved this study as a quality control study and waived the need for written informed consent (registration number S-20132000-37). Data were anonymized.

Study materials

The technology evaluated in this study is the CNAP Monitor 500 (CNSystems Medizintechnik AG, Graz, Austria). A double finger cuff encompassing two neighbouring fingers is used for continuous BP monitoring; an upper arm cuff derives the measurement of oscillometric BP. Thus, BP is measured in two ways: as absolute BP values (oscillometric measurement) and as continuous BP changes (CNAP Technology, CNSystems Medizintechnik AG, Graz, Austria). The trend of the latter is correlated automatically to the absolute values of the oscillometric device derived at the beginning of the measurement [5]. Figure 1 shows an image of the CNAP equipment set up in an ambulance and Fig. 2 shows the CNAP device screen in the same setting.

The life pack 12 (LP12), developed by Physio Control (Redmond, Washington, USA), was the standard equipment used to measure intermittent NBP in the participating ambulances and provided a standard of comparison in our study.

Study measurements

The investigators received 30 min of training before patient enrolment. This included secure placement of

Fig. 1



An image of the CNAP device equipment set up in an ambulance. The device is securely mounted on the wall beside the patient. CNAP, continuous noninvasive arterial pressure.

Fig. 2



The CNAP device screen in the same setting as in Fig. 1. CNAP, continuous noninvasive arterial pressure.

the device in the ambulances, choice of appropriate cuff size, equipment placement, proper use of the device and data extraction. If needed, the CNAP device producer could be consulted for further questions or training.

After patient enrolment, the CNAP device was placed on the upper arm opposing the arm where the ambulance personnel measured the NBP. The investigator chose the appropriate size of finger cuff and upper arm cuff (both available in three sizes). After correct placement of the equipment, the calibration of the device was initiated automatically. Time from placement of the CNAP device

to first continuous reading of the device was measured with a separate timer. Patient data (age, sex and medical history) were collected en route to hospital. The pre-hospital preliminary diagnosis was noted on the patient sheet along with mode of transportation (speed and road conditions), possible patient's movements and possible treatments initiated, for example, fluid administration or vasopressor therapy.

The investigator did not provide patient care beside placement of the CNAP device. No treatment was initiated or changed because of measurements made by the CNAP device.

The NBP were measured automatically by the ambulance personnel every 3–5 min according to standard procedure or at the discretion of the attending physician.

A NBP measurement was considered valid whenever a BP value was displayed on the screen of the LP12. A CNAP measurement was considered valid if the CNAP device showed one or more BP values within 20s before the LP12 measurement was displayed. All the LP12 measurements were analysed within 20s of continuous BP measurement made by the CNAP device, thereby allowing us to compare single measurements obtained by LP12 to continuous measurements made by the CNAP device.

Data collection and statistical analyses

CNAP measurements were stored automatically on the CNAP device. Data were transferred by a USB memory card and stored as a Microsoft Excel file (Microsoft Corporations, Redmond, Washington, USA).

The NBP measurements were stored automatically on the ambulances' LP12. At the end of the ambulance transfer, the investigator received a printout of the LP12 measurements. Synchronizing points of time were noted in both the CNAP file and on the LP12 printout. The LP12 measurements along with patients' data were added manually to the Microsoft Excel file by the investigators afterwards. Data analyses were carried out in Microsoft Excel. Graphic illustrations were performed in STATA 14 (StataCorp, College Station, Texas, USA). Patient characteristics and study results are presented as absolute numbers with percentage, median or 25–75% quartiles when appropriate.

Results

Patients' characteristics are shown in Table 1.

Enrolment of patients was performed on an investigator availability basis on 45 separate dates from October 2013 until May 2015. Sixty-three patients were eligible for study inclusion. Three patients were not included as a choice of the attending physician, who prioritized evident lifesaving procedures and as a result needed the extra space around the patient. One patient was excluded

Table 1 Patients' and clinical characteristics (N=59)

	N (%)
Sex (male)	25 (42)
Age ^a (years)	61.5 (39.8–77.3)
Reason for emergency response	
Traffic accident	15 (25)
Other trauma	5 (8)
Pneumonia/respiratory insufficiency	10 (17)
Seizure/unconsciousness	10 (17)
Chest pain	7 (12)
Sudden severe headache	3 (5)
Heart failure	2 (3)
Abdominal pain	2 (3)
Other causes	6 (10)

^aDisplayed as median with 25–75% quartiles.

Table 2 Summary of concurrently valid continuous noninvasive arterial pressure device and life pack 12 measurements

LP12	CNAP		Total [n (%)]
	Valid	Not valid	
Valid	280	5	285 (93)
Not valid	18	2	20 (7)
Total [n (%)]	298 (98)	7 (2)	305 (100)

CNAP, continuous noninvasive arterial pressure; LP12, life pack 12.

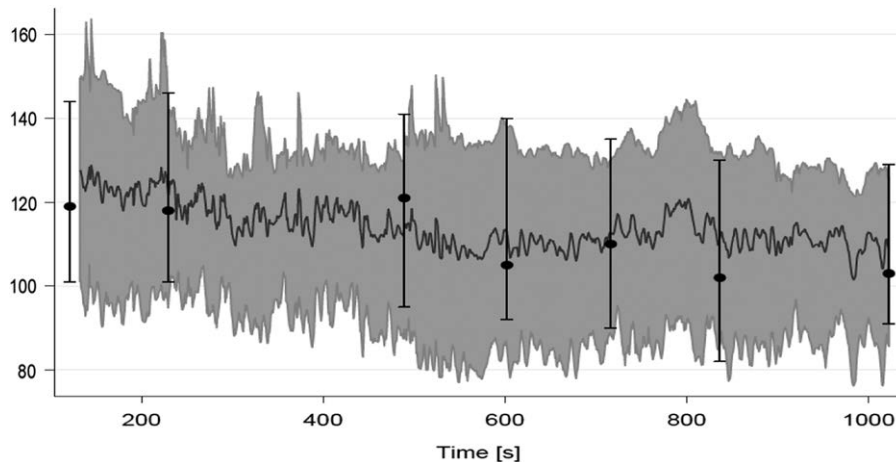
from the study because she resisted having her BP measured by any means during ambulance transfer. Fifty-nine out of 63 eligible patients were included in the study. One patient was excluded from the analyses of valid/invalid BP readings because the measurement made by the LP12 and the CNAP device could not be synchronized because of a technical error.

Fifty-four out of the 59 (92%) included patients had their BP measured continuously by the CNAP device during ambulance transfer. The CNAP device provided continuous BP measurements after a median time of 164.5s (25–75% quartiles; 144–191s). In four cases, the initial finger cuff chosen for the patient had to be exchanged to another size and in another two cases, the finger cuff had to be repositioned to a different set of fingers. Valid versus invalid BP measurements are shown in Table 2. One example of the information provided by the two devices to the healthcare providers is compared in Fig. 3.

Discussion

We have found that the CNAP device is as a feasible monitor of BP in a prehospital setting, with 54 out of 59 (92%) patients included having their BP measured continuously by the device. This corresponds to an in-hospital trial in an ICU that reported a success rate of 91% [8]. The CNAP feasibility is also reported in another study where CNAP monitoring was compared with intermittent BP measurements in the Emergency Department. This study enrolled 150 patients and reported a success rate of 93%. In this study, Wagner *et al.* [10] concluded that continuous noninvasive AP measurements enable immediate recognition of clinically relevant hypotensive

Fig. 3



An example of information provided by the two devices (CNAP and LP12). CNAP shows a continuous graph, whereas prehospital standard measurements with the LP12 device only provide intermittent information. The blood pressure is measured in mmHg. CNAP, continuous noninvasive arterial pressure; LP12, life pack 12.

episodes where recognition would either be delayed or missed with intermittent AP measurements. In a prehospital setting, immediate recognition of changes in BP is highly relevant to improve outcome in critically ill patients.

When performing point-of-care monitoring, it is vital to reduce unnecessary on-scene time, that the monitor can be used en route and, whenever possible, that it is noninvasive [11]. When continuous BP readings are important in-hospital, for example, in the ICU, an invasive arterial line is often used. This method appears to be superior to NBP measurements as the possibility for obtaining arterial blood gas analyses is therefore also present. Wildner *et al.* [4] have evaluated the feasibility of the invasive AP method in a prehospital setting. Here, insertion of an arterial line with subsequent continuous IAP en route was achieved in 83.9% of the cases. In this study, they noted a need for 2 min to achieve the invasive line and another 3 min to prepare the equipment for the monitoring. In comparison, the CNAP device only needs to be fastened like a regular upper arm BP cuff as well as two fingers placed in another cuff, which is fastened afterward to the forearm. These fast procedures leave more valuable time to other important initiatives on scene compared with IAP measurements.

Because of generally short ambulance transfer times in Denmark, we only see the IAP measurement as a feasible alternative to the currently used NBP in a few selected cases. However, in the unselected group of patients in the prehospital field, the CNAP device appears to be a feasible alternative to the apparently more risky [12] and time-consuming IAP in presenting continuous BP readings to the healthcare providers. In addition, the

placement of an invasive arterial line requires specific skills and training. We expect that the use of a CNAP device only requires 30 min of information and training of the healthcare personnel before implementation in the prehospital environment.

The CNAP device weighs 11.4 kg including wall mounting for secure placement in the ambulance. In our study, no problems with handling and placement were observed. Furthermore, no adverse event or complications were observed. Other CNAP studies have not reported serious adverse events because of the CNAP device [9,10] and the device appears to be a safe alternative to the present methods used for BP monitoring [12].

Thiele states the need for defining the minority of patients where the CNAP device is not applicable [13]. In our study, the CNAP device failed to provide continuous BP readings in five cases including three cases with very low BP. In these three cases, the LP12 initial measured a BP of 85/50, 75/40 and 80/40, respectively. If the initial CNAP calibration fails and very low BP is suspected, we suggest that the CNAP device, instead of continuous BP values, may be set to measure regular upper arm BP values. In this way, the CNAP device could initially work as a conventional upper arm BP device until later adding continuous readings, for example, when BP is higher because of treatment. This approach seems to be an acceptable alternative in cases where continuous readings cannot be obtained at first. This approach was not implemented in this study, but the CNAP device should be considered a noninvasive device capable of measuring both regular upper arm BP values as well as adding the continuous BP trend.

One patient in our study had a mean BP of ~85 mmHg, but the finger cuff noted insufficient BP wave signals. The patient had been exposed to cold weather 20 min before the measurements. We assume that the patient's peripheral circulation was compromised because of hypothermia and consequently, the CNAP device finger cuff could not obtain a proper signal.

The investigators noticed that the CNAP device calibration failed more frequently or the calibration time was prolonged if patient or ambulance movements were made during calibration time. In one patient in this study, we could not obtain continuous BP readings because of initially excessive limb movement and subsequent calibration failure.

After calibration, the CNAP device appears to be nearly insensitive to movements and a BP trend line was displayed irrespective of patients' movements, low BP, use of vasopressors or rapid changes in BP. During ambulance accelerations/decelerations as well as driving on bumpy roads and the ambulance taking curves very fast, the CNAP device showed continuous BP readings after initial calibration. As the CNAP device appears to be stable during these circumstances, it might also be of value in the critical care aviation medicine, where accelerations/decelerations, etc. are unavoidable.

In four (7%) patients, an equipment placement error was noted, all related to the finger cuff. The investigators chose a finger cuff size too small in two cases and two large in two cases. When replaced by a larger/smaller size, there was no problem with continuous measurements afterwards. In Table 3, suggestions to CNAP device troubleshooting are presented.

A calibration time of median 164.5s was needed in our study to provide continuous data from the CNAP device. When mounted correctly, the CNAP device optimizes the signal in the finger cuff before making a regular upper arm oscillometric BP measurement for calibration. Consequently, the CNAP device does not show a BP measurement until after the calibration. A median time of 164.5s seems like a long wait to get the first BP, which may affect the initial treatment of an emergency prehospital patient. Our suggestion would be to have the CNAP device measuring a regular upper arm

BP before calibration. This has to be initiated manually. Thereby, the first BP measurement would be available fast and a continuous measurement would be available after ~3 min. Consequently, targeted treatment might be initiated sooner.

The agreement of the two devices was not evaluated. This was not an objective of the study as some patients only had two or three LP12 measurements made during their emergency transfer (short transfer time) and none of the two methods of measuring BP is considered the gold standard. One in-hospital study showed that the intermittent BP is more inaccurate than the CNAP device compared with IAP, especially in very high or very low BP [14]. One objective of our investigation was the comparison of the failure rate of the two devices (Table 2). The LP12 failed in 20 of 305 attempted measurements. At the same time, only seven CNAP device measurements failed. In only two of 305 cases the LP12 and the CNAP device failed at the same time. The reason for CNAP device failure to obtain measurements was often a BP too low for cuff signal detection. Also, the CNAP device needs a renewed upper arm cuff calibration every 30 min or whenever a permanent change is introduced in hand/finger cuff placement compared with the patient's upper arm cuff level. During this calibration, no continuous BP values are displayed by the CNAP device; hence, it 'fails' compared with the LP12 measurements made at these times. This was the case in one out of the seven times the CNAP device failed according to our study objectives defined before patient enrolment.

The reason for missing LP12 measurements was not investigated further, but might be because of low BP or artefacts such as patient or vehicle movement.

Despite not showing absolute BP values in case of severe hypotension, the CNAP trend line was still visible because a measurement was made every time the BP increased above the detection level. At these times, the waveform also reappeared in the CNAP device display, showing a BP high enough for finger cuff detection. It is conceivable that when treating patients in a prehospital setting, the BP trend will often be more valuable to the physician than a display of an exact BP number. A decrease in BP below cuff signal detection will often indicate a BP too low, leading to a risk of organ hypo

Table 3 Suggestions for continuous noninvasive arterial pressure device troubleshooting

Problems	Possible solution
Display indicates 'low cuff signal'	Change to a smaller finger cuff (if possible) Change finger cuff to a different set of fingers
Display indicates 'calibration fails'	Consider risk of BP below finger cuff detection and measure an upper arm BP
Prolonged calibration period (no pulse wave displayed >1 min)	Reduce patient movement during upper arm cuff measurement for calibration (if possible) Consider risk of BP below cuff detection or compromised peripheral circulation and measure an upper arm BP
Permanent change in finger cuff placement that necessitates upper arm recalibration	In case of current patient/vehicle excessive movements, consider using trend changes instead and recalibrate when more steady situation

BP, blood pressure.

perfusion, hence the need for intervention(s) to increase the BP.

Study limitations

Our aim was to evaluate the CNAP monitor during emergency transfers of potentially unstable patients. A clear threshold of which patients were considered too stable for inclusion was not made before patient inclusion. This was a subjective decision made by the investigator. However, most of the included patients had stable BP values during transfer after initial treatment on scene. Future studies that include more critically unstable patients would further strengthen the evidence of CNAP device feasibility in a prehospital environment.

Some of our emergency transfers lasted less than 10 min and left little time to measure BP. Future studies might include longer distances to increase the data quantity. This was not possible in our study because of short transfer distances.

Application of the CNAP device was undertaken by the study investigator and not the healthcare personnel in our study. The device's usability might be reduced when application and troubleshooting need to be undertaken by the healthcare personnel in addition to present tasks. Nevertheless, the CNAP device is very easy to apply as well as operate, which might further increase if the CNAP device was installed as an additional function in the prehospital standard equipment. In this way, one would not need an additional device including wall mounting, batteries, etc. and only one upper arm cuff would need to be applied.

Conclusion

Our study indicates that continuous BP measurement made by the CNAP device is feasible in a prehospital setting under potentially difficult conditions. The utility of the CNAP device in the prehospital environment appears to be correlated closely with previous in-hospital studies. Motion artefact does not appear to affect the device once calibrated. Several practical troubleshooting solutions to prehospital challenges have been identified and form the basis of further studies.

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Conflicts of interest

Louise H. Hansen received refunds for travel expenses from CNSystems Medizintechnik AG to one congress participation when presenting preliminary data from this study. For the remaining authors there are no conflicts of interest.

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