Comparison of continuous non-invasive finger arterial pressure monitoring with conventional intermittent automated arm arterial pressure measurement in patients under general anaesthesia


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Editor’s key points

- Continuous but non-invasive arterial pressure measurement offers some advantages during and after surgery.
- This study evaluated such a device in patients with stable haemodynamics and found it performed satisfactorily.
- Non-invasive continuous arterial pressure measurement might reduce the need for arterial cannulation in selected cases.
- Non-invasive continuous arterial pressure measurement might provide more complete monitoring during and after surgery.

Background. For a majority of patients undergoing anaesthesia for general surgery, mean arterial pressure (MAP) is only measured intermittently by arm cuff oscillometry (MAPiNIAP). In contrast, the Nexfin® device provides continuous non-invasive measurement of MAP (MAPcNIAP) using a finger cuff. We explored the agreement of MAPcNIAP and MAPiNIAP with the gold standard: continuous invasive MAP measurement by placement of a radial artery catheter (MAPinvasive).

Methods. In a total of 120 patients undergoing elective general surgery and clinically requiring MAPinvasive measurement, MAPiNIAP and MAPcNIAP were measured in a 30 min time period at an arbitrary moment during surgery with stable haemodynamics. MAPiNIAP was measured every 5 min.

Results. Data from 112 patients were analysed. Compared with MAPinvasive, modified Bland–Altman analysis revealed a bias (sd) of 2 (9) mm Hg for MAPcNIAP and 2 (12) mm Hg for MAPiNIAP. Percentage errors for MAPcNIAP and MAPiNIAP were 22% and 32%, respectively.

Conclusions. In a haemodynamically stable phase in patients undergoing general anaesthesia, the agreement with invasive MAP of continuous non-invasive measurement using a finger cuff was not inferior to the agreement of intermittent arm cuff oscillometry. Continuous measurements using a finger cuff can interchangeably be used as an alternative for intermittent arm cuff oscillometry in haemodynamically stable patients, with the advantage of beat-to-beat haemodynamic monitoring.

Clinical trial registration. NCT 01362335 (clinicaltrials.gov).

Keywords: Nexfin; NIAP; non-invasive arterial pressure; volume clamp

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Mean arterial pressure (MAP) monitoring, along with pulse oximetric assessment of heart rate and arterial oxygen saturation, is mandatory in patients undergoing surgery, irrespective of the type of anaesthesia the patient receives. During major surgical procedures or in high-risk patients, continuous (invasive) arterial pressure measurement using an indwelling arterial catheter is preferred to closely monitor ‘beat-to-beat’ changes in MAP. In addition, this method can be regarded as the clinical ‘gold’ standard for monitoring of MAP (MAPinvasive). However, placement of an indwelling arterial catheter is prone to several complications. Thus, MAPinvasive use is limited to patients in whom the advantage of continuous MAP measurement outweighs the risk of placement of the arterial catheter or when frequent arterial blood sampling is required.

In most cases, conventional non-invasive intermittent measurement of MAP by arm cuff oscillometry (MAPiNIAP) with an interval of 3–5 min is considered appropriate. In addition, it is not considered harmful (i.e. non-invasive) and easy to perform. Nevertheless, its accuracy is dependent on appropriate positioning of the patient, correct cuff positioning, and adequate cuff size, and may be impaired by patient conditions such as arrhythmia and obesity. MAPiNIAP has been validated with the cuff placed around the upper arm; but since the upper...
arm may be inaccessible in some patients (due to wounds, fractures, oedema, vascular access), cuff locations on the calf or thigh are considered as alternative measurement sites, although they decrease measurement accuracy considerably.\(^5\) On the top of decreased accuracy, MAP\textsubscript{iNIAP} does not allow continuous, ‘beat-to-beat’ monitoring of MAP as it takes time to in- and deflate the cuff. Moreover, because cuff deflation takes several seconds, the determined systolic and diastolic values originate from different heartbeats and may therefore be inaccurate in situations where there is significant pulse pressure variation.\(^6\)

The Nexfin device (Edwards Lifesciences, Irvine, CA, USA), introduced in 2007, is based on the volume clamp method first introduced by the Czech physiologist Jan Penaz in 1967.\(^7\) It allows continuous non-invasive arterial pressure measurement (MAP\textsubscript{iNIAP}) using a photoplethysmograph and an inflatable cuff placed around a finger.\(^8\) Based on the input from the photoplethysmograph, the cuff pressure is adjusted 1000 times per second to keep the arterial volume constant during the cardiac cycle. Thus, the artery is clamped at a diameter where the transmural pressure is zero, and therefore the cuff pressure is equal to the arterial pressure. This ‘volume clamping’ allows measurement of an arterial pressure waveform. Finally, brachial arterial pressure is reconstructed from finger arterial pressure and displayed.\(^9\)

Multiple studies\(^10\) –\(^12\) have already investigated the accuracy of arterial pressure measurement by this device and compared it with invasively obtained measurements with various results. Yet, the vast majority of patients undergoing surgery is monitored solely using intermittent non-invasive measurements, and therefore, it is of interest whether MAP\textsubscript{cNIAP} would be a valuable adjunct or could ultimately replace MAP\textsubscript{iNIAP} in the intraoperative setting.

Therefore, we explored in the current study in patients under general anaesthesia, the agreement of both MAP\textsubscript{cNIAP} and MAP\textsubscript{iNIAP} with the clinical standard of arterial pressure measurement\(\text{MAP}\textsubscript{invasive}\) in a beat-to-beat fashion on the Nexfin monitor. Values of MAP\textsubscript{cNIAP} and other haemodynamic data (heart rate, cardiac index, systemic vascular resistance index, dP/dT) were recorded in a beat-to-beat fashion on the Nexfin monitor. Values of MAP\textsubscript{cNIAP} and MAP\textsubscript{iNIAP} were imported into Microsoft Excel 2010\(^6\) (Microsoft, Redmond, WA, USA) and synchronized. After graphical representation of these values, a visual inspection was performed to correct for obvious atypical values caused by artifacts (mostly resulting from blood sampling and iNIAP cuff inflation).

**Statistical analysis**

All statistics were performed using Microsoft Excel 2010\(^6\) and PASW Statistics 18 (SPSS Inc., Chicago, IL, USA). A 30 s running median with 1 s steps was calculated for MAP\textsubscript{invasive} and MAP\textsubscript{cNIAP}. The normality of continuous variables was assessed using the Kolmogorov–Smirnov test. Data were expressed as mean (SD), median (range), or number of patients (%). The distribution (median, 2.5th and 97.5th percentile) of the difference with MAP\textsubscript{invasive} of MAP\textsubscript{cNIAP} or MAP\textsubscript{iNIAP} minus MAP\textsubscript{invasive} was plotted for the 30 min time period. The Mann–Whitney U-test was performed to test whether the difference in the bias of both methods was significantly different. A modified Bland–Altman analysis for repeated measurements\(^13\) –\(^15\) was performed for comparison of all data points of MAP\textsubscript{cNIAP} with MAP\textsubscript{invasive} and of MAP\textsubscript{iNIAP} with MAP\textsubscript{invasive} at a 5 min time interval. In a case where cuff inflation influenced continuous measurements, these variables were determined just before inflation of the cuff and correlated with the subsequent MAP\textsubscript{cNIAP} value. Here, the bias (SD) is calculated together with the limits of agreement [LOA=bias (1.96 SD)]. As a measure of precision,\(^16\) coefficients of error (CE) were calculated as the SD of the bias divided by the mean of

In all patients, anaesthesia was induced with propofol and sufentanil or remifentanil. Anaesthesia was maintained with propofol or sevoflurane, in combination with either sufentanil or remifentanil, as clinically required.

Before data recording, a radial artery was cannulated using a 20 G catheter and connected with a disposable pressure transducer (Truwave PX-600F, Edwards Lifesciences LLC). MAP\textsubscript{iNIAP} was measured using cuff oscillometry at the upper arm according to routine clinical practice with the cuff size adapted to body weight and posture, as recommended by the manufacturer. The MAP\textsubscript{iNIAP} measurement interval was set at 5 min.

The Nexfin cuff was placed at the intermediate phalanx, ipsi- or contralateral to the radial artery catheter, at the most accessible side.

To correct for hydrostatic pressure differences between the finger and the heart, the heart reference system (HRS\textsuperscript{TM}) is provided with the Nexfin device. Both the HRS\textsuperscript{TM} and the arterial pressure transducer were located at the level of the right atrium.

MAP\textsubscript{invasive} and MAP\textsubscript{cNIAP} data were recorded at a 1 s and 5 min interval, respectively, using RugLoop II data-manager software (Demed, Temse, Belgium), connected to the anaesthesia monitor (Philips MP70; Philips, Eindhoven, The Netherlands). MAP\textsubscript{cNIAP} and other haemodynamic data (heart rate, cardiac index, systemic vascular resistance index, dP/dT) were recorded in a beat-to-beat fashion on the Nexfin monitor. Values of MAP\textsubscript{cNIAP} and MAP\textsubscript{iNIAP} were imported into Microsoft Excel 2010\(^6\) (Microsoft, Redmond, WA, USA) and synchronized. After graphical representation of these values, a visual inspection was performed to correct for obvious atypical values caused by artifacts (mostly resulting from blood sampling and iNIAP cuff inflation).

**Methods**

This observational study was approved by the local medical ethics committee (METc 2011.052, University Medical Center Groningen, The Netherlands) and was registered at clinicaltrials.gov (NCT: 01362335).

A total of 120 patients, undergoing elective abdominal, neurosurgical, oncological, and vascular surgery under general anaesthesia and for which placement of a radial artery catheter was required on clinical grounds, were included (Fig. 1). Measurements took place at an arbitrary moment of stable haemodynamic conditions during surgery with a total measurement period of 30 min. At least 24 h after the operation, written informed consent was obtained for analysis of the recorded data and patients were included for data analysis.
As subsequently, percentage errors for MAP_{cNIAP} and MAP_{iNIAP} compared with MAP_{invasive} were calculated as: $2.0 \times CE \times 100$; here CE is from either MAP_{cNIAP} or MAP_{iNIAP} bias.\textsuperscript{17}

Currently, two guidelines apply to validation of arterial pressure measurement by the Nexfin: one from the European Working Group for the Validation of Blood Pressure Measuring Devices (ESH criteria) and one from the Association for the Advancement of Medical Instrumentation (AAMI).\textsuperscript{18, 19} The requirements for validation by the ESH criteria are summarized in the legend of Table 1. Furthermore, AAMI criteria consider a device acceptable if its estimated probability of tolerable error is at least 85%, suggesting that a predefined estimated sample mean error of 5 mm Hg should have a concomitant standard deviation below 8 mm Hg. We used this criterion to test for non-inferiority. Sample size calculation for our study was based on the AAMI criteria and was calculated in order to detect a mean difference of 5 mm Hg. For an estimated SD of MAP values of 9 mm Hg, a power of 98% and an $\alpha$-error of 0.05, at least 106 patients should be included. Therefore, we included 120 patients in total. Statistical significance was assumed if $P<0.05$.

### Results

A total of 120 patients were included in this study (Fig. 1). Eight patients were excluded from data analysis because of unwillingness or inability to sign informed consent ($n=7$) or technical reasons ($n=1$). Of the 112 patients analysed in total, two data sets could not be used for the comparison of MAP_{cNIAP} with MAP_{invasive} and 11 data sets could not be used for the comparison of MAP_{iNIAP} with MAP_{invasive}, all because of technical difficulties with recording MAP_{cNIAP} or MAP_{iNIAP}, respectively. Characteristics of the studied patients ($n=112$) were normally

### Table 1

| Requirements for arterial pressure measurement validation as set by the European Working Group for the Validation of Blood Pressure Measuring Devices (ESH criteria). Shown is the required minimal percentage of MAP measurements being either very accurate, slightly inaccurate, or inaccurate. In order to determine whether a device passes the ESH criteria, either two of three minimal accuracy requirements (step 1) or all three minimal accuracy requirements (step 2) should be achieved |
|---|---|---|
| Very accurate ($<5$ mm Hg) (%) | Slightly inaccurate ($<10$ mm Hg) (%) | Inaccurate ($<15$ mm Hg) |
| Pass all three | 65 | 81 | 93 |
| Pass two of three | 73 | 87 | 96 |
distributed and are shown together with the main haemo-
dynamic variables in Table 2.

Figure 2 shows the individual differences with MAP_{invasive} values of MAP_{cNIAP} (Fig. 2a) and MAP_{iNIAP} measurements (Fig. 2b) for the 30 min measurement period of all patients together with its median and concomitant 2.5th and 97.5th percentile.

The median difference (2.5th/97.5th percentile) of MAP_{cNIAP} at the start of measurements was 1 (−13/8) mm Hg and was 3 (−8/11) mm Hg after 30 min. The median difference of MAP_{iNIAP} was −2 (−18/14) mm Hg at the start of measurements and was −2 (−18/8) mm Hg after 30 min. For all data points, the bias of MAP_{cNIAP} was significantly different from that of MAP_{iNIAP} (P<0.001, Mann–Whitney U-test).

In Figure 3 and Table 3, the bias (sd) and LOAs, as derived from the modified Bland–Altman analysis for repeated measurements, are shown for the 30 min time period with a time interval of 5 min. Also in Table 3, CE and percentage errors for both MAP_{cNIAP} and MAP_{iNIAP} are shown. The original modified Bland–Altman plot, including all available data points, is shown in Supplementary Figure S1.

The performance of both MAP_{cNIAP} and MAP_{iNIAP} measurement as an alternative for MAP_{invasive} is shown in Table 1 for both steps of the ESH reliability criteria. Neither MAP_{cNIAP} nor MAP_{iNIAP} measurements succeeded to match any of these criteria. Both measurement methods also failed to meet the AAMI criteria (Table 3).

### Influence of measurement side and absolute MAP_{invasive} value on MAP_{cNIAP} bias

The Nexfin® cuff was attached to the index finger ipsilateral to the inserted radial artery catheter in 70 patients (63%), whereas it was attached to the contralateral side in 42 patients (37%). The modified Bland–Altman analysis for repeated measurements revealed no differences in agreement of MAP_{cNIAP} with MAP_{invasive} between both measurement sides: bias (sd) was 2 (9) (LOA: −16/20 mm Hg for ipsilateral and 2 (8) (LOA: −14/18 mm Hg for contralateral measurements.

Figure 4 shows the influence of MAP_{invasive} on MAP_{cNIAP} accuracy. Values are shown for all data points (n=765) in the 30 min measurement period with an interval of 5 min. There was no correlation between the two variables, indicating that MAP_{invasive} had no effect on the accuracy of cNIAP.

### Discussion

The agreement of the Nexfin device with invasive arterial pressure measurement as a gold standard has been studied in several recent studies, with varying results. However, much as replacement of invasive by non-invasive measurement has important advantages, most patients undergoing anaesthesia are monitored in a non-invasive fashion, and may benefit from accurate and precise continuous non-invasive monitoring. To the best of our knowledge, this is the first study investigating the potential benefit of the Nexfin to monitor arterial pressure for these patients.

In the current study in patients under general anaesthesia, the main purpose was to quantify the accuracy and precision of continuous non-invasive MAP measurement using the Nexfin device (MAP_{cNIAP}) and using conventional intermittent cuff oscillometry (MAP_{iNIAP}), comparing both methods with the gold standard, that is, continuous invasive measurement of MAP (MAP_{invasive}). Only periods of stable haemodynamic conditions were recorded and included for further analysis.

In this phase, the Nexfin-derived MAP_{cNIAP} showed an agreement with invasive measurements which was not inferior to the agreement of automated cuff oscillometry-derived MAP_{iNIAP}. This suggests that this method is at least a valuable adjunct to measure MAP and might even be used as an alternative to MAP_{iNIAP} in patients undergoing anaesthesia. We observed however that both MAP_{cNIAP} and MAP_{iNIAP} showed some imprecision with respect to invasive MAP measurement (MAP_{invasive}) and that both methods failed to meet the AAMI criteria and the ESH criteria for arterial pressure measurement validation.

The accuracy of Nexfin-derived MAP_{cNIAP} measurements has been studied in a number of previous studies and showed close correlations with MAP_{invasive} in patients undergoing cardiothoracic surgery, and was considered reliable enough to replace invasive arterial pressure monitoring in most patients.

MAP_{cNIAP} and MAP_{iNIAP} accuracy have until now only been compared in awake—non-anaesthetized—patients, and in these studies, they were not compared with any gold standard.

Studies comparing MAP_{cNIAP} with MAP_{iNIAP} in supine patients, in acutely ill patients at an emergency department, in pregnant women for longitudinal tracking of arterial pressure, or in patients during autonomic function testing demonstrated adequate accuracies.

We however did not investigate the relationship between MAP_{cNIAP} and MAP_{iNIAP} measurements as in our opinion, it is more relevant—in patients receiving (general) anaesthesia—to directly compare both MAP_{cNIAP} and MAP_{iNIAP} measurements.
with the gold standard of continuous invasive MAP measurement (MAP_{invasive}). Surprisingly, we found that both non-invasive measurement methods failed to meet the AAMI criteria because the precision—as an indication of measurement reproducibility—exceeded the pre-defined precision of 8 mm Hg. Nevertheless, MAP_{cNIAP} values were more closely related to MAP_{invasive} values than the MAP_{iNIAP} values, which was also true for the agreement data provided in Tables 1 and 3. While statistically significant, the small absolute difference does not entail a clinically significant superior accuracy. There are, up to our knowledge, no other studies in which the accuracy of both MAP_{cNIAP} and MAP_{iNIAP} measurements were compared with MAP_{invasive} measurements and therefore, these findings require confirmation in future studies, particularly in conditions of haemodynamic instability and during vasopressor use.

A second point of major clinical importance is that while the difference in accuracy of both non-invasive methods is small and arguably not clinically significant, MAP_{cNIAP} monitoring has the obvious advantage of providing MAP measurements both faster and in a continuous ‘beat-to-beat’ fashion. In this view, although inevitably less accurate than MAP_{invasive}, showing non-inferiority of absolute measurement of the MAP_{cNIAP} relative to MAP_{iNIAP} would be sufficient to advocate its use.

As pointed out in a recent study, MAP_{cNIAP} was able to detect significantly more periods of hypo- and hypertension in patients undergoing surgery compared with the use of MAP_{iNIAP} monitoring. Additionally, the Nexfin device can also obtain flow-based haemodynamic variables such as cardiac output, although reports on the accuracy of these variables are sparse. Since MAP_{cNIAP} is acquired at the finger, and the MAP_{invasive} at the radial artery, while MAP_{iNIAP} is measured at the brachial level, one may ask whether the reported superior agreement with invasive measurements is merely a

Fig 2 The evolution in individual patients of the differences with MAP_{invasive} of the continuous measurement of MAP_{cNIAP} (A) and the intermittent measurements of MAP_{iNIAP} (B) over the 30 min period in mm Hg. Individual patients (thin pink lines) and median values (green line) are shown together with the 2.5th and 97.5th percentile (blue lines).
consequence of the reference point. The Nexfin algorithm however performs a waveform transformation to reconstruct the arterial waveform and values, and therefore, MAPcNIAP and MAPiNIAP values should be considered brachial MAP. In addition, since the higher errors in MAPiNIAP consist of overestimations and underestimations (Fig. 2), a difference in reference point is an unlikely reason for the divergent accuracy.

Still, non-inferiority of MAPcNIAP compared with MAPiNIAP does not necessarily result in improved patient outcome, but a faster diagnosis implicates a significant potential for improved patient monitoring. An additional advantage is likely in patients where brachial measurements may be difficult such as obese patients or patients with brachial injuries or dialysis shunts. However, it has to be shown if the additional costs of measuring MAPcNIAP justify the benefits of its use described above, also in view of a recent change in the distributor of the device.

**Study limitations**

All measurements were performed in patients at arbitrary moments during general anaesthesia. The most important limitation therefore is that during these observation periods, no particularly considerable changes in arterial pressure occurred and therefore the accuracy and precision of both MAPcNIAP and MAPiNIAP during substantial variations in arterial pressure cannot be answered by this study. It has been demonstrated that the use of continuous non-invasive measurements decreases the total time of hypotension or hypertension during anaesthesia significantly, but the accuracy of either assessments compared with a gold standard was not investigated in that study.

Secondly, our measurements took place in patients with MAPinvasive at randomly selected moments during anaesthesia. We did not specifically analyse the influence of changes in vascular tone, for example, induced by changes in temperature or use of vasoactive drugs. This is, however, in accordance with normal clinical practice where reliability of MAPinvasive may also be dependent on a variety of physiological conditions. Although the Physiological algorithm of the Nexfin monitor is developed to compensate for any changes in vascular tone due to peripheral hypothermia or other induced changes in local perfusion, we may not exclude a decrease in accuracy of finger-based methods in such cases. Therefore, our conclusions are only valid for normothermic, haemodynamically stable patients not requiring (high doses of) vasoactive medication.

It is well known that pulse oximetry becomes less accurate in the case of hyperpigmentation, low blood oxygen saturation, or certain intoxications because pulse oximetry is based on differential absorption of two distinct wavelengths. The plethysmographic measurement used for the volume clamp method, however, does not rely on such delicately distinct wavelength absorptions (it uses one wavelength only) and is therefore very unlikely to be less reliable in such circumstances, although no reports have confirmed this yet.
Despite the reliability of MAP\textsubscript{cNIAP} compared with MAP\textsubscript{iNIAP}, our results also show that the agreement of MAP\textsubscript{cNIAP} with MAP\textsubscript{iNIAP} is not sufficient to advocate replacing MAP\textsubscript{iNIAP} in any case. Therefore, high-risk patients undergoing major procedures, that is, conditions where hypothermia or high vasopressor need may occur, will still require invasive MAP monitoring for most reliable arterial pressure monitoring and arterial blood sampling.

Furthermore, insufflation of the MAP\textsubscript{iNIAP} cuff is known to induce alterations in the vascular compliance due to endothelial activation and vasodilation. Our previous research demonstrates a sustained influence on distal limb physiology for several minutes after intermittent MAP\textsubscript{iNIAP} cuff insufflation.\textsuperscript{31} It is still the subject of debate whether these microvascular changes are induced by ischaemia, congestion, or other physiological phenomena, but it is conceivable that these local changes may influence the compliance of the vascular wall and therefore the accuracy of the MAP\textsubscript{cNIAP} measurements. Contrarily, inter-arm anatomical differences can also cause different arterial pressure readings.\textsuperscript{32} Therefore, we measured MAP\textsubscript{cNIAP} either ipsilaterally and contralaterally with regard to MAP\textsubscript{iNIAP}. Since there was no blinded randomization on this matter, this may have influenced our results. However, a subanalysis comparing data received from the ipsilateral vs contralateral side did not reveal any significant differences. Hence, we decided to group all data without further differentiating the side of MAP\textsubscript{cNIAP} measurement.

Finally, all analyses were performed on MAP values, since these are most commonly used in comparing different monitoring devices\textsuperscript{13} and also for guiding therapy. Comparison of systolic arterial pressure values may vary somewhat from our results, although these were not reported for conciseness.

**Conclusion**

This study shows that in a haemodynamically stable phase in patients under general anaesthesia, the agreement with invasive MAP measurements of Nexfin-derived MAP\textsubscript{cNIAP} was found to be non-inferior to conventional MAP\textsubscript{iNIAP} measurements. Although influence on outcome was not investigated, this study demonstrates that MAP\textsubscript{cNIAP} has significant potential to improve patient monitoring in haemodynamically stable patients undergoing anaesthesia where MAP\textsubscript{iNIAP} is at present being clinically used.

**Supplementary material**

Supplementary material is available at *British Journal of Anaesthesia* online.

**Authors’ contributions**


**Declaration of interest**

M.M.R.F.S. is an editor for the *British Journal of Anaesthesia*, but had no role in the handling of this manuscript.
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