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Noninvasive BP Monitoring in the Critically Ill Time to Abandon the Arterial Catheter?



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Although its reliability is often questioned, noninvasive BP (NIBP)-monitoring with an oscillometric arm cuff is widely used, even in critically ill patients in shock. When correctly implemented, modern arm NIBP devices can provide accurate and precise measurements of mean BP, as well as clinically meaningful information such as identification of hypotension and hypertension and monitoring of patient response to therapy. Even in specific circumstances such as arrhythmia, hypotension, vasopressor infusion, and possibly in obese patients, arm NIBP may be useful, contrary to widespread belief. Hence, postponing the arterial catheter insertion pending the initiation of more urgent diagnostic and therapeutic measures could be a suitable strategy. Given the arterial catheter-related burden, fully managing critically ill patients without any arterial catheter may also be an option. Indeed, the benefit that patients may experience from an arterial catheter has been questioned in studies failing to show that its use reduces mortality. However, randomized controlled trials to confirm that NIBP can safely fully replace the arterial catheter have yet to be performed. In addition to intermittent measurements, continuous NIBP monitoring is a booming field, as illustrated by the release onto the market of user-friendly devices, based on digital volume clamp and applanation tonometry. Although the imperfect accuracy and precision of these devices would probably benefit from technical refinements, their good ability to track, in real time, the direction of changes in BP is an undeniable asset. Their drawbacks and advantages and whether these devices are currently ready to use in the critically ill patient are discussed in this review. CHEST 2018; 153(4):1023-1039

KEY WORDS: BP; critical care; monitoring

Arterial BP is often measured with an automated brachial cuff (arm noninvasive BP [NIBP]).¹ Indeed, intermittent arm NIBP is the first-line monitoring technique during prehospital care, in the ED, at ICU admission, or even during the entire ICU stay.²⁻⁴ Despite the widespread use of intermittent NIBP, its fundamental operating principles are not familiar to many physicians. This situation may partially explain why the reliability of intermittent NIBP is sometimes questioned, in particular in the critically ill, encouraging invasive

ABBREVIATIONS: AUC_{ROC} = area under the receiver-operating characteristics curve; ISO = International Organization for Standardization; NIBP = noninvasive BP; PPV = pulse pressure variation

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measurements.⁵ However, the superiority of the arterial catheter over NIBP is uncertain⁶ and has been questioned.^{4,7} It is also noteworthy that most of the current knowledge regarding BP cutoffs in patients with hypertension is derived from intermittent NIBP measurements.¹ Similarly, via the analysis of large databases that mostly include NIBP measurements, a recent international consensus emphasized that a systolic BP < 100 mm Hg represents an alert signal during sepsis.⁸

NIBP is a fast-evolving field, as illustrated by the development, over the last decade, of several devices displaying continuous measurement of BP that are now entering the clinical arena. They might soon offer an elegant compromise between noninvasive (although intermittent) NIBP monitoring and beat-to-beat (although invasive) intraarterial monitoring.

The historic auscultatory method, currently nearly abandoned in the setting of critical care, is not covered in the present review. Because we discuss several proprietary devices and technologies, it is important to underscore that none of the authors has or has had any association with the relevant companies or with the development of the devices discussed.

Brachial Cuff Oscillometric Measurements

How Does It Work?

The development of oscillometry goes back to the late 19th century when it was discovered that the arterial pulse oscillations of the human forearm could be transmitted to a surrounding air-filled cuff.⁹ Since then, it took several decades before the physical principles governing the transmission of BP oscillations to the air cuff were understood and before the translation of cuff pressure oscillations into BP values were mathematically modeled.¹⁰ With the arrival of microprocessors, oscillometric devices were released onto the market in the late 1970s, even before the most recent knowledge and modeling could be fully embedded.¹¹

Most oscillometric devices measure the amplitude of pressure oscillations in the air-filled arm cuff during gradual deflation, over 30 to 40 s, from a pressure well above systolic BP (collapsing the brachial artery) down to atmospheric pressure (Fig 1). As the cuff deflates below systolic BP, blood flows through the reopening



Figure 1 – Oscillometric, volume-clamp, and applanation tonometry technologies. DBP = diastolic BP; MBP = mean arterial BP; SBP = systolic arterial BP.

Mean and diastolic BP measurements are often accurate and precise with modern NIBP devices. Mean BP readings should be preferred over systolic BP to guide therapy.

NIBP reliably identifies hypotensive (mean BP <65 mm Hg or systolic BP <90 mm Hg) and hypertensive patients (mean BP >140 mm Hg).

Arm NIBP reliably tracks therapy-induced changes in BP (>10% increase in mean BP).

Even in specific circumstances such as arrhythmia (provided that triplicates are averaged), hypotension, vasopressor infusion and possibly in obese patients (provided that the cuff is carefully selected), arm NIBP could be useful.

NIBP measurements are less accurate if the cuff is placed at the ankle or the thigh rather than at the arm.

Mean and diastolic BP measurements are consistently more accurate than systolic BP measurements. Mean BP readings should therefore be preferred over systolic BP to guide therapy.

Whether continuous NIBP measurements are accurate & precise is uncertain.

Provided that close recalibrations are automatically or manually performed, these fast-response devices may allow an early and reliable detection of acute changes in BP as alert signals, but may be misleading when considering the magnitude of the BP change in the event of abrupt changes.

Figure 2 – Key messages for clinical practice. NIBP = noninvasive BP.

brachial artery and induces arterial wall oscillations that increase until the counterpressure exerted by the cuff allows minimal arterial wall tension and maximal arterial volume change. The cuff pressure at this point of maximal oscillation determines the mean BP. Notwithstanding some artifacts, including the imperfect consideration of the slow decrease of pressure in the deflating cuff, mean BP measurements were later found to be accurate to a few millimeters of mercury.^{12,13}

Systolic and diastolic BPs are not directly measured but are mathematically derived.¹ Empirical algorithms, owned by manufacturers, analyze the oscillometric envelope (Fig 1) and determine systolic and diastolic BPs either at fixed ratios of maximal oscillation or at varying inflexion points on the ascending and descending parts of the envelope, respectively.¹⁴

How and to what extent oscillometric algorithms evolved over the recent decades while the physics of arterial and air-filled systems became better understood is not known.¹⁰ Ideally, for accurate BP determination, these algorithms should do the following: (1) take into account the dynamic compliances of the air-cuff and of the underlying soft tissues, as well as their changes during cuff deflation; (2) operate across a broad range of arterial stiffness levels; (3) sufficiently filter and amplify the BP oscillatory signal; (4) cope with irregular beats during arrhythmia; and (5) recognize artifacts such as a patient's movements or vibrations during ambulance or helicopter transport.^{15,16} Failure to fulfill one or several of these requirements may account for the observed inaccuracies of some first-generation or even more recent devices; for example, in elderly patients or those with hypertension or diabetes (with increased arterial stiffness), obese patients (with thick soft tissues dissipating pressure waves), and in patients with low-flow states or drug-induced vasoconstriction.¹⁷

To what extent can clinicians trust recent devices and use them in everyday critical care practice? Before addressing this practical question, it is worth reviewing some basic issues. First, because existing algorithms best operate within a certain range of cuff compliance, the cuff size is of paramount importance (more specifically, the cuff length-to-width ratio [ideally 2:1] and the cuff width-to-arm circumference ratio [ideally 40%]).^{1,18,19} Cuffs that are too large expose to underestimation of BP, whereas too small cuffs expose to overestimation.¹⁷ In everyday practice, manufacturer instructions, often printed on the cuff itself, are helpful for a thorough choice of cuff. Second, because mean BP represents the perfusion pressure of most organs, studies not reporting mean BP when testing NIBP devices are of poor value for critical care practitioners. Third, oscillometric systolic BP measurement is the BP component with the poorest agreement with the intraarterial reference.^{5,20,21} In addition to the drawbacks inherent to empirical algorithms of BP determination, pathophysiologic considerations may account for the "error" (bias) observed between systolic NIBP and the invasive reference. Indeed, systolic BP amplifies from the aorta to peripheral arteries,²² and arm NIBP measures BP at the brachial level, whereas invasive measurements are mostly taken in the radial artery.²³ Of note, systolic NIBP remains a cornerstone of triage for acutely ill patients; for instance, systolic NIBP is one of the three criteria of the quick Sequential Organ Failure Assessment, a recently recommended triage tool.⁸ Finally, even invasive BP as displayed by bedside ICU monitors may exhibit inaccurate measurements.²⁴ Indeed, artifacts due to inappropriate dynamic response of the fluid-filled monitoring systems such as underdamping/resonance phenomena²⁵ are frequent in the clinical setting.^{26,27}

Today, Does Arm NIBP Provide Acceptable Accuracy and Precision?

According to the Association for the Advancement of Medical Instrumentation, NIBP and intraarterial BP devices are deemed interchangeable if the mean bias between the two techniques (accuracy) and its SD (precision) do not exceed 5 and 8 mm Hg, respectively. In their last update, the so-called International Organization for Standardization (ISO) standard 81060-2, the criteria of the Association for the Advancement of Medical Instrumentation were slightly refined to take into account the variability of the intraarterial measurements.^{28,29}

In retrospective analyses of large databases, the ISO standard was not fulfilled by intermittent arm oscillometric NIBP.^{5,30} Mean BP measurements seemed less inaccurate than systolic and diastolic BP measurements. However, paying particular attention to avoid technical factors biasing BP measurements regardless of the technique (eg, level of the arterial line pressure transducer, pressure signal overdamping or underdamping, size of the brachial cuff, cuff placement), prospective studies have shown that mean and diastolic BP measurements with arm NIBP fulfilled the ISO standard^{21,31,32} (ie, reported a mean bias of \leq 5 mm Hg, with sufficient precision). Thus, if correctly applied, the performance of oscillometry can be good.

Can Arm NIBP Be Relied on to Detect Hypotension or Hypertension?

Most of the studies have focused on NIBP accuracy and precision via Bland-Altman analysis, but few have addressed the practical issue of detection of BP values beyond thresholds relevant to patients and clinicians. During the very first hours of critical illness, when invasive BP is not yet available, hypotension, a common trigger for urgent therapy, should be accurately detected. Remarkably, arm NIBP detection of mean BP < 65 mm Hg was associated with a high diagnostic performance as assessed by the area under the receiver-operating characteristics curve (AUC_{ROC}).^{20,21,31,33} By plotting the true positive rate (sensitivity) as a function of the false-positive rate (1 – specificity) of a binary diagnostic tool, those curves enable global assessment of the tool, combining sensitivity and specificity. An AUC_{ROC} of 0.5 indicates a total lack of diagnostic performance, whereas an AUC_{ROC} of 1.0 indicates a perfect diagnostic tool. Hence, NIBP assessed as a diagnostic tool to identify patients with hypotension (with invasive mean BP <65 mm Hg) found very high values of AUC_{ROC} (0.89-0.98).

Generally, detection of chronic hypertension is not a primary concern in critical care. However, pain-, disease-, or vasopressor-induced hypertension, for instance, should be reliably diagnosed because it can be harmful during conditions such as arterial hemorrhage or myocardial infarction. The AUC_{ROC} for the identification of patients with a systolic BP >140 mm Hg with arm NIBP was 0.88 to 0.94.^{29,33}

Of note, optimal thresholds of NIBP readings that best detect hypotension or hypertension may differ across oscillometric devices and depend on whether clinicians choose to favor specificity or sensitivity.²⁰ In this regard, our opinion is that the value of 70 mm Hg for mean NIBP as a target when caring for patients in shock may offer a clinically relevant compromise; that is, allowing ruling out of low invasive mean BP (< 65 mm Hg) with strong confidence while not exposing patients to deleteriously high BP levels.

What About Measurements of Changes in BP With Arm NIBP?

Changes in arm NIBP have sufficient accuracy to provide good detection of a significant increase in invasive mean BP, enabling identification of BP responders to urgent therapy (AUC_{ROC} of 0.89-0.98 for a 10% mean BP increase cutoff).^{20,21,31,33} When using BP change to track cardiac output change during fluid challenge, arm NIBP was not less performant than intraarterial BP.³⁴

Reliability of *NIBP* in *Situations Frequently Encountered* in the ICU

Contrary to widespread belief, several studies have shown that vasopressor agents have little impact on arm NIBP performance.^{5,20,21} In the most recent study, although the investigators judged NIBP measurements of insufficient accuracy based on other criteria, diastolic and mean arm NIBP passed the ISO criteria.³⁵

Hypotension does not seem to cause flawed arm NIBP measurements.^{5,20,21,31} During extreme hypotension, arm NIBP may fail to display a value, but along with other signs of shock, this finding prompts urgent therapy.

In obese patients, provided that the cuff is carefully selected and positioned, arm NIBP can be considered reliable to detect hypertension.³⁶ However, either poor or fair accuracy was reported in the critically ill obese patient, probably depending on the NIBP device used.^{32,37,38}

Cardiac arrhythmia (atrial fibrillation)-induced beat-tobeat variability of the pulse wave is commonly deemed to hinder the reliability of NIBP measurements,¹ but few data support this belief. Cardiac arrhythmia compared with regular cardiac rhythm in some studies did not cause flawed NIBP measurements^{31,39,40} provided that three consecutive measurements were averaged.

In summary, those clinical factors potentially unfavorable to NIBP measurements should not, on their own, restrict clinicians from using brachial cuff NIBP. However, because these potentially unfavorable factors may be encountered concomitantly in the same patient, caution and clinical judgment should always apply.

What if the Brachial Cuff <mark>Cannot Be Placed</mark> at the Arm?

The common practice of a lower limb cuff placement² has only recently been evaluated. Possibly for anatomical reasons, NIBP measurements were less accurate if the

cuff was placed at the ankle or the thigh rather than at the arm.²¹ However, ankle and thigh NIBP still reliably detected hypotensive and therapy-responding patients $(AUC_{ROC} = 0.93 \text{ and } 0.96, \text{ respectively}).$

Are There Discrepancies From One Device to Another?

In the same population, accuracy and precision vary significantly from one oscillometric device to another³³ or even within one device, from an older to a newer software version.⁴¹ This may herald future improvements of NIBP.

What Are the Risks of Arm NIBP?

The wider the interval between two intermittent NIBP measurements, the higher the risk of delaying the detection of sudden changes of BP, especially when vasopressor agents are infused. However, closer intervals expose patients to discomfort and to cuff inflation-induced injuries of the skin, vessels, and nerves.⁴²⁻⁴⁴

Noninvasive Continuous Monitoring of BP

Numerous commercial devices have been developed, relying on two distinct technologies. First are the finger cuff devices, such as <u>CNAP (CNSystems)</u> and <u>Nexfin</u> (recently rebranded as <u>ClearSight</u> [Edwards Lifesciences Corporation]). The <u>Finapres Nova</u> finger cuff system (FMS), which recently received clearance from the US Food and Drug Administration, is a development of older devices such as the Ohmeda Finapres (Ohmeda) or the Finometer (FMS). The second technology comprises tonometers, of which the T-Line System (Tensys Medical) is the most studied.⁴⁵ Via beat-to-beat measurements, the promise of these "next-generation" devices is a rapid and reliable detection of acute changes in BP, a detection that could be delayed or even missed with intermittent NIBP. Have these promises been kept?

How Does It Work?

Finger Cuff Devices: The volume clamp technique was described several decades ago. The patient's finger is wrapped in an inflatable cuff including a photoplethysmograph. The finger <u>cuff keeps the finger</u> blood volume constant during each pulse wave by keeping constant the photoplethysmographic absorbance adjusting cuff pressure in real time. Hence, the finger <u>cuff inflates</u> during <u>systole</u> and <u>deflates</u> during <u>diastole</u> (increasing and decreasing pressure in the cuff), using fast electronic retrocontrol loops to keep the photoplethysmographic signal constant.^{46,47} Instant changes in the counterpressure exerted by the finger cuff

reflect the finger BP waveform (Fig 1). The <u>brachial BP</u> is then <u>mathematically reconstructed</u> and, for the CNAP but not the Nexfin/ClearSight system, calibrated against arm oscillometric NIBP.

Tonometers: Arterial applanation tonometry consists of placing, over the skin, a pressure transducer that gently compresses (ie, applanates) the underlying artery. This action allows the reconstruction of the BP waveform, using a proprietary algorithm taking into account the soft tissue-related signal loss. Hence, a tonometer, through estimating the arterial wall tension, quantifies the arterial pulse that physicians otherwise subjectively assess through radial palpation. Contrary to several of its predecessors, the T-Line device is user friendly and free of user bias because the sensor is housed by a wrist bracelet rather than handheld by a health-care provider. Within the bracelet, the sensor is automatically moved over the radial artery until maximal pulse pressure (ie, the optimal waveform) is recorded. No external calibration is required.^{48,49}

Do Continuous NIBP Devices Provide Acceptable Accuracy and Precision?

Because the aforementioned ISO standard does not cover continuous NIBP,²⁸ acceptability of the accuracy and precision lacks consensual definition. The ISO standard has been proposed for various settings, from ambulatory to health-care facility use. In the critically ill, the ISO criteria are not so stringent and could be seen as maximal limits of tolerability.²⁹ However, even using these rather loose tolerance boundaries (5 mm Hg and 8 mm Hg for mean bias and its SD, respectively) to compare continuous NIBP with invasive BP, a 2014 systematic review and meta-analysis concluded that continuous NIBP was not sufficiently reliable.⁴⁵ More recent reports with the latest hardware and software versions of these devices may slightly nuance this conclusion and refine the current knowledge. Detailed information about the numerous recent studies performed with those devices is summarized in Table 1.^{33,47-86}

First, whatever the device, <u>mean</u> and, to a lesser extent, <u>diastolic</u> BP measurements were consistently <u>more</u> <u>accurate</u> and precise than <u>systolic</u> BP measurements. <u>Mean BP</u> readings should therefore be <u>preferred</u> over <u>systolic</u> BP to guide therapy.

Second, in most evaluations of the T-Line device, measurements of mean BP fulfilled the ISO criteria. However, the T-Line device has only been studied in small size studies (20-30 patients), often from the same group,^{48,80-82,84} during a short observation period of relative hemodynamic stability, mostly with normal BP values. Therefore, the encouraging performance of the T-Line device has to be confirmed in larger studies before drawing any enthusiastic conclusion.

Third, for the Nexfin/ClearSight and CNAP devices, the fulfilment of the ISO criteria was variable, with several studies reporting insufficient accuracy and/or precision (Table 1).

Fourth, beyond different case mixes, methodologic issues may account for the heterogeneous performances reported. Electronical extraction of measured values to average them, and the manual elimination of outliers, often subjectively (presumably corresponding to patient motion, arterial line flushing, or device calibration), could have artificially improved the agreement between noninvasive and invasive BP in some studies. For the CNAP system, BP readings struggle with drifting between two oscillometric calibrations, especially in case of changes in the hemodynamic status.³³ Therefore, the interval to last calibration should have been more often mentioned in study reports because it affects the accuracy of CNAP readings.^{33,66}

Last, the detection of BP values above or below a critical cutoff, which is one of the clinically relevant questions addressed to those devices, has been assessed in only one study.³³ During the 4 min following calibration, the CNAP reliably detected mean BP < 65 mm Hg.

Continuous NIBP to Track Changes in BP

Trending ability denotes the capacity of the device to accurately follow BP changes over time. This denotation implies that the device should be able to detect and take into account major confounders such as disease- or therapy-induced changes in the vasomotor tone of the upper limb. Some devices perform periodical recalibrations of the BP waveform via changes in finger cuff pressure and contemporaneous analysis of the plethysmogram changes (Nexfin/ClearSight)⁴⁷ or via upper arm NIBP (CNAP system).⁴⁶

The ability of the Nexfin/ClearSight and the CNAP devices to indicate the direction of changes in actual BP has often been reported to be good (Table 1).^{51,54,56,57,59,64} In other words, an increase (a decrease) in the BP displayed by a finger cuff system reliably reflects an increase (a decrease) in the actual BP. Nevertheless, beyond this gross evaluation, firm conclusions about the precise trending ability of these

Study	Year of Publication	Device and Version	Setting	Cardiac Arrhythmia	Patients	Pairs	Mean Bias \pm SD SBP	Mean Bias \pm SD DBP	Mean Bias \pm SD MBP	Trending	Comment
Nexfin/ ClearSight											
Schramm et al ⁵⁰	2017	Nexfin ^a	OR (neurosurgery)	NA	35	280	$14\pm19^{\rm b}$	$25\pm15^{\rm b}$	$23\pm16^{\rm b}$	Concordance rate for MBP: 84% during fluid bolus and 41% during sitting up (exclusion zone 10%)	Recordings made in supine and in sitting position Norepinephrine in 33 patients (0.017 µg/kg/min [IQR, 0.0-0.04])
Balzer et al ⁵¹	2016	ClearSight	OR (orthopedic)	0%	20	120	-5.2 ± 16	5.07 ± 12	0.8 ± 13	Polar plot: within the acceptable range of angle/angular bias $\pm 30^{\circ}$	Measurements at the beginning and end of surgery Vasopressors NA
Heusdens et al ⁵²	2016	ClearSight	OR (carotid)	NA	25	3,782	-3.3 ± 10.8	6.1 ± 5.7	3.5 ± 5.2	NA	Ephedrine, phenylephrine, and/or norepinephrine in all patients
Vos et al ⁵³	2014	ClearSight	OR (general)	NA	112	758	NA	NA	2 ± 9	NA	Vasopressors NA
Ameloot et al ⁵⁴	2014	Nexfin	ICU (medico- surgical)	NA	45	675	8.3 ± 13.8	-9.4 ± 6.9	-1.8 ± 5.1	Concordance rate 85% (10% exclusion zone) Polar plot: 97% of the data points lie within the 10% lines	Trending analysis with mean of 3 measurements Norepinephrine in 78% (0.20 \pm 0.17 μ g/kg/min)
Martina et al ⁵⁵	2014	Nexfin ^a	ICU (surgical)	NA	29	8,700	-7.6 ± 5.8	-7.0 ± 5.2	-6.9 ± 5.1	NA	Continuous flow LVAD in all patients Norepinephrine in 14% (dosage NA)
Weiss et al ⁵⁶	2014	Nexfin	OR (general)	0%	31	3,479	$\textbf{3.8} \pm \textbf{16.5}$	$\textbf{8.8} \pm \textbf{10.8}$	5 ± 12 to -9 ± 15	Concordance rate (SBP and DBP) 100% (no exclusion zone) High bias and/or LOA for changes in SBP or DBP	Recordings from 1 min before the induction to 10 min after tracheal intubation 58% ephedrine and 9.7% phenylephrine

TABLE 1] Overview of Studies Comparing, in Adults, Nexfin/ClearSight, CNAP, and T-Line Noninvasive and Invasive Intraarterial Measurements of Arterial BP

	N/ 5			0				NA 81	14 51		
Study	Year of Publication	Device and Version	Setting	Cardiac Arrhythmia	Patients	Pairs	Mean Bias ± SD SBP	Mean Bias ± SD DBP	Mean Bias ± SD MBP	Trending	Comment
Hofhuizen et al ⁵⁷	2014	ClearSight	ICU (after cardiac surgery)	0%	20	54	2.7 ± 11.5	4.9 ± 6.9	4.2 ± 7.0	Concordance rate 100% (exclusion zone, 5%) Mean polar angle 10.4°, SD of 10.3° 100% between the 30° radial limits	28 fluid challenges in 19 patients Norepinephrine in 40% (0.03 μg/kg/ min [IQR, 0.01- 0.08])
Hohn et al ⁵⁸	2013	Nexfin	ICU (surgical)	0%	25	117	-9 ± 25	NA	6 ± 12	NA	Norepinephrine in 72% (0.13 \pm 0.11 μ g/kg/min)
Broch et al ⁵⁹	2013	Nexfin ^a	OR (elective coronary)	0%	50	514	6.5 ± 17.5 to 15.1 ± 17.9	6.2 ± 11.7 to 13.5 ± 11.3	9.3 ± 15.8 to 13.7 ± 12.1	Concordance rate MBP 86 to 94% (15% exclusion zone)	Recordings during "off-pump" periods. Body temperature 35.5°C-35.9°C Agreement with IABP differed according to IABP site (femoral or radial) and to timing of measurements (before or after cardiopulmonary bypass) Vasopressors NA
Martina et al ⁴⁷	2012	Nexfin ^a	OR (cardiothoracic)	NA	50	9,000	-0.5 ± 6.7	2.8 ± 6.4	2.2 ± 6.4	NA	Recordings during "off-pump" periods Vasopressors NA
Fischer et al ⁶⁰	2012	Nexfin	ICU (after cardiac surgery)	0%	44	220	-5.7 ± 14.7	$\textbf{8.9}\pm\textbf{6.9}$	4.6 ± 6.5	NA	Norepinephrine in 44% (0.01-0.1 µg/kg/min)
Monnet et al ⁶¹	2012	Nexfin	ICU (medical and surgical)	13%	38	76	NA	NA	-2 ± 11	NA	All patients had signs of acute circulatory failure Norepinephrine in 45% (0.4 μg/kg/ min [IQR, 0.21-0.60])
Stover et al ⁶²	2010	Nexfin	ICU (surgical)	0%	10	80	NA	NA	-2 ± 8 ^b	NA	Norepinephrine in all patients (12 \pm 12 μ g/min)

Study	Year of Publication	Device and Version	Setting	Cardiac Arrhythmia	Patients	Pairs	Mean Bias ± SD SBP	Mean Bias ± SD DBP	Mean Bias \pm SD MBP	Trending	Comment
CNAP											
Lakhal et al ³³	2016	Infinity SmartPod CNAP	ICU (surgical and medical)	37%	182	546	-4.3 ± 13.8	-9.7 ± 7.8	7.2 ± 6.4	Concordance rate 67% (exclusion zone 10%) Cardiovascular intervention: important drift	Agreement reported in this table has been analyzed during the 3 min following calibration Trending was analyzed between 2 calibrations Norepinephrine in 61% (0.3 [IQR, 0.1–0.4] µg/kg/ min)
Wagner et al ⁶³	2015	CNAP ^a	ICU (medical)	AF 7%	55	4,891	-10 ± 16	7 ± 9	1 ± 9	NA	Mechanical ventilation 47%, norepinephrine 35% (dosage NA)
Smolle et al ⁶⁴	2015	CNAP 500 ^a	ICU (medical)	AF15%	40	7,200	-3.2 ± 10.1	7.0 ± 6.7	4.6 ± 6.7	Concordance rate 95% (exclusion zone, 10%) Polar concordance rate of 99.5% within 10% limits	All patients sedated and under mechanical ventilation Norepinephrine in 70% (0.16 µg/kg/min [IQR, 0.08–0.25])
Kumar et al ⁶⁵	2015	Infinity SmartPod CNAP	OR (cardiac)	0%	60	1,200	-6.0 ± 10.4	3.7 ± 6 .1	0.0 ± 5.7	NA	Recordings during anesthesia induction Vasopressors NA
Ilies et al ⁶⁶	2014	CNAP 500 v3.5ª	ICU (after cardiovascular surgery)	15%	104	11,222	-4.3 ± 11.6	9.4 ± 8.0	6.1 ± 7.6	NA	Epinephrine or norepinephrine in some patients (number NA)
Tobias et al ⁶⁷	2014	CNAP 500	OR (bariatric)	NA	18	2,159	-0.3 ± 14.2	1.3 ± 9.5	0.6 ± 8.6	NA	Obese patients (BMI, 38-75 kg/ m ²) Cuff, for calibration against oscillometric NIBP, was placed around the upper arm (n = 9) or the forearm (n = 9) Vasopressors NA

(Continued)

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Study	Year of	Device and Version	Setting	Cardiac Arrhythmia	Patients	Pairs	Mean Bias ±	Mean Bias ±	Mean Bias ±	Trending	Comment
Schramm et al ⁶⁸	2013	CNAP 500 v3.5 R01 (hardware revision R06)	OR (TAVR)	27%	33	152,000	$\begin{array}{c} \text{Overall:}\\ -6.3 \pm 18.9\\ \text{Severe}\\ \text{hypotension:}\\ 11.8 \pm 14.5 \end{array}$	$\begin{array}{c} \text{Overall:}\\ \text{7.4} \pm 10.5\\ \text{Severe}\\ \text{hypotension:}\\ 13.8 \pm 12.4 \end{array}$	$\begin{array}{c} \text{Overall:}\\ 4.0 \pm 11.3\\ \text{Severe}\\ \text{hypotension:}\\ 12.9 \pm 12.4 \end{array}$	NA	Episodes of severe hypotension were induced by rapid pacing
Hahn et al ⁶⁹	2012	CNAP 500 V3.0 and V3.5	OR (orthopedic)	6%	100	524, 878	$\begin{array}{c} \text{V3.0:} \\ -3.4 \pm 16 \\ \text{V3.5:} -0.9 \pm \\ 13 \end{array}$	$\begin{array}{c} \text{V3.0:} \\ \text{4.4} \pm 10.8 \\ \text{V3.5:} \ 2.8 \pm \\ \text{8.6} \end{array}$	$\begin{array}{c} \text{V3.0:}\\ \text{2.9} \pm 10.6\\ \text{V3.5:} \text{ 3.1} \pm \\ \text{9.5} \end{array}$	NA	Two software versions were tested (3.0 and 3.5) Vasopressors NA
Jagadeesh et al ⁷⁰	2012	Infinity SmartPod CNAP	ICU (cardiac)	NA	30	3,600	10.4 ± 5.8	-5.3 ± 3.0	0.04 ± 2.0	NA	Vasopressors NA
Ilies et al ⁷¹	2012	CNAP 500 ^a	OR (major abdominal, vascular, or thoracic)	NA	85	16, 843	Induction: 3.3 ± 20.3 Maintenance: -4.2 ± 16.5	$\begin{array}{l} Induction:\\ 10.8\pm12.6\\ Maintenance:\\ 5.8\pm6 \end{array}$	Induction: 10.2 ± 13.1 Maintenance: 4.3 ± 10.4	NA	Separate analysis of recording during induction and maintenance of anesthesia Vasopressor in some patients (number NA and dosage NA)
Monnet et al ⁷²	2012	CNAP 500	ICU (medical)	0%	39	195	2 ± 14.8	-11 ± 12.8	4.8 ± 11	NA	All patients had signs of acute circulatory failure Norepinephrine in 64% (0.7 [IQR, 0.1–2.4] to 1.1 [IQR, 0.6–2.0] μg/kg/min)
Gayat et al ⁷³	2012	CNAP 500	OR (general)	0%	52	5,174	2 ± 22	11 ± 12	8 ± 13	NA	Recordings from before the induction to 5-10 min after tracheal intubation Vasopressors NA
Schramm et al ⁷⁴	2011	CNAP v2.94	OR (TAVR)	NA	29	48,691	-11 ± 18	6 ± 16	-0.8 ± 15	NA	Vasopressors NA
Biais et al ⁷⁵	2010	Infinity SmartPod CNAP	OR (vascular)	0%	25	1,452	7.2 ± 12.7	-7.5 ± 10.1	-1.8 ± 10.3	Concordance rate 80% (exclusion zone, NA)	Ephedrine used in 756 measurements
Jeleazcov et al ⁷⁶	2010	Infinity SmartPod CNAP (V2.9.14) ^a	OR	0%	78	156,000	6.7 ± 13.9	-5.6 ± 11.4	-1.6 ± 11.0	NA	Vasopressors NA

	Voor of	Dovice and		Cardiac			Moon Ring J	Moon Ring J	Moon Rise J		
Study	Publication	Version	Setting	Arrhythmia	Patients	Pairs	SD SBP	SD DBP	SD MBP	Trending	Comment
T-Line											
Lin et al ⁷⁷	2017	TL-300	OR (neurosurgery)	NA	23	4,381	1.3 ± 5.9	2.8 ± 6.4	1.8 ± 4.2	NA	Retrospective study Vasopressors NA
Sun et al ⁷⁸	2017	TL-300	OR (colic)	NA	30	1,538	-0.9 ± 7.6	4.3 ± 7.4	3.1 ± 6.5	Concordance rate MBP 85% (exclusion zone, 4 mm Hg)	
Greiwe et al ⁷⁹	2016	TL-200pro	OR (bariatric surgery)	NA	28	201,907	3.4 ± 13.0	3.7 ± 9.9	4.0 ± 9.4	Concordance rate MBP 74% (exclusion zone, 3 mm Hg)	$\begin{array}{l} \text{BMI 49.4} \pm 9.7 \text{ kg/} \\ \text{m}^2 \\ \text{Norepinephrine in} \\ \text{all patients} \\ (\text{maximal dose,} \\ 0.05 \pm 0.03 \ \mu\text{g/} \\ \text{kg/min}) \end{array}$
Langwieser et al ⁸⁰	2015	TL-200pro ^a	ICU (cardiac)	AF 20%	30	7,304	-6 ± 11	4 ± 7	2 ± 6	Concordance rate MBP 88% (exclusion zone, 3 mm Hg)	Mechanical ventilation in 63% Norepinephrine in 23% (0.29 [IQR, 0.03–0.45]) µg/ kg/min Epinephrine in 33% (0.13 [IQR, 0.09–0.21]) µg/ kg/min
Meidert et al ⁶¹	2014	TL-200 or TL- 200pro ^a	ICU (medical)	AF 25%	24	2,993	-3 ± 15	5 ± 7	2 ± 6	NA	Mechanical ventilation in 46%; norepinephrine in 25% (dosage NA)
Meidert et al ⁸²	2013	TL-200pro ^a	ICU (medical)	AF 4%	23	2,879	-3.3 ± 11.2	4.9 ± 7.0	1.0 ± 5.5	Concordance rate MBP 85% (exclusion zone, 3 mm Hg)	Mechanical ventilation in 50%; norepinephrine in 39% (dosage NA)
Colquhoun et al ⁸³	2013	TL-200	OR (spine surgery)	NA	21	NA	3.1 to 7.1 SD NA	4.9 to 7.0 SD NA	3.5 to 6.4 SD NA	Concordance rate MBP: 82%- 90% (exclusion zones, 2.5-12.5 mm Hg)	Bias varied according to applied filters Vasopressors NA

TABLE 1	(Continued)
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Study	Year of Publication	Device and Version	Setting	Cardiac Arrhythmia	Patients	Pairs	Mean Bias ±	Mean Bias ±	Mean Bias ±	Trending	Comment
Saugel et al ⁴⁸	2013	TL-200pro ^a	ICU (medical)	AF 18%	34	4,502	-1.4 ± 8.8	4.4 ± 6.6	0.7 ± 5.1	Concordance rate MBP 88% (exclusion zone, 3 mm Hg)	Mechanical ventilation in 50%; norepinephrine in 32% (0.09 µg/kg/ min [IQR, 0.02– 0.20])
Saugel et al ⁸⁴	2012	TL-200	ICU (medical)	AF 32%	28	76,826	-9.0 ± 14.5	5.2 ± 9.5	0.5 ± 8.7	Concordance rate MBP 67% (exclusion zone, 3 mm Hg)	Mechanical ventilation in 54%; norepinephrine in 50% (0.11 µg/kg/ min [IQR, 0.04– 0.16])
Dueck et al ⁴⁹	2012	TL-200 ^a	OR (general)	NA	19	4,747	2.3 ± 7.8	1.7 ± 6.2	2.3 ± 5.9	NA	Vasopressors NA
Szmuk et al ⁸⁵	2008	TL-100 ^a	OR (spine surgery)	NA	22	5,450	0.0 ± 7.9	1.6 ± 5.6	1.6 ± 5.3	NA	Vasopressors NA
Janelle and Gravenstein ⁸⁶	2006	TL-100 ^a	OR (general)	NA	25	17,009	1.7 ± 7.0	2.3 ± 6.9	1.7 ± 5.3	NA	Vasopressors NA

Mean bias indicates noninvasive minus invasive BP. Concordance rate indicates the percentage of invasive and noninvasive data points with the same direction of change (after excluding central data of the plot, which tend to be randomly distributed [ie, after the application of an exclusion zone]). Standardization standard criteria are provided in bold characters. AF = atrial fibrillation; DBP = diastolic BP; IABP = intraarterial BP; IQR = interquartile range; LOA = limits of agreement; LVAD = left ventricular assist device; MBP = mean BP; NA = not available; NIBP = noninvasive BP; OR = operating room; SBP = systolic BP; TAVR = transcatheter aortic valve replacement. Mean bias ($\leq 5 \text{ mm Hg}$) and SD ($\leq 8 \text{ mm Hg}$) validating the International Organization for

^aConflict of interest (COI) with the tested device, as declared by the authors. COI is reported in this table if at least one of the authors received research grants, travel fees, and/or is member of the advisory board or is employee of the manufacturer. Simple loan of device is not reported as COI in this table.

^bWhether bias was calculated as noninvasive minus invasive or vice versa is unclear.

devices cannot yet be drawn, for several reasons. First, for finger cuff devices, the trending ability has been mostly evaluated during periods of relative hemodynamic stability. Therefore, events of significant changes in BP retained in the analyses were scarce, even among very large datasets,^{54,64} after exclusion of minimal changes in BP possibly reflecting random noise.⁸⁷ Second, the detection of the magnitude of changes in BP, rather than the simple increase or decrease, has rarely been addressed, but encouraging findings have been reported.^{51,54,56,57,64} Third, the detection of abrupt changes in BP should also be specifically tested. Indeed, in studies reporting good trending ability, recalibrations of the device occurred during the observation period. Thus, these studies tested calibration rather than trending.^{54,57,64} In one of the few studies evaluating the trending ability in between calibrations, the effects of a cardiovascular intervention (eg, volume expansion, change in vasopressor dosage, passive leg raising) were poorly detected by the CNAP monitor.³³ Similarly, during induction of anesthesia and tracheal intubation, BP changes were detected within a reasonable time lag by the CNAP or the Nexfin/ ClearSight, but the magnitude of these changes was poorly estimated.^{56,73} For the detection of a fluid bolusinduced increase in BP, the Nexfin/ClearSight tracking ability was only fair⁵⁰ or, at best, correct.⁵⁷

Likewise, studies addressing the trending ability of the T-Line System investigated the detection of the direction of changes in BP (fair to honorable performance) but not the magnitude of these changes. In addition, disease-or therapy-induced abrupt changes in BP were not studied.^{48,78-80,82-84}

In summary, provided that close recalibrations are automatically or manually performed, these fast-response devices may allow an early and reliable detection of acute changes in BP as alert signals. However, they may be <u>misleading</u> when considering the <u>magnitude</u> of the BP change in the event of <u>abrupt</u> <u>changes</u>. Specific studies are needed to refine this conclusion.

Limitations to Continuous NIBP in ICU Patients

Important peripheral vasoconstriction (related to hypothermia, to the disease, or to a high dosage of vasopressor agent⁵⁸) may account for failure of finger cuff technology to display any measurement, as observed in up to 15% to 17% of studied ICU patients.^{33,61,72} Whether excessive vasoconstriction also alters BP

waveform reconstruction by the T-Line algorithm is unclear.

Movements of the limb equipped with the device hamper the accuracy of BP measurements. This outcome is particularly true for the T-Line System in nonsedated patients, as the optimal placement of the sensor could be lost.⁴⁸

The impact of several pathophysiologic conditions on continuous NIBP should be better explored: cardiac arrhythmia⁶⁶ and even obesity and upper limbs edema,⁵⁸ which can promote a marked attenuation of the BP signal and yield insufficient precision of the device.^{67,79} Some studies excluded patients with obesity⁶⁴ or finger edema.^{63,64,66} This approach may also contribute to the between-study reported differences.

Other Applications for Continuous NIBP Monitors

Prediction of Fluid Responsiveness: <u>Instant changes</u> in BP waveform are sufficiently <u>well detected</u> to guide fluid management according to the noninvasive measurement of respiratory pulse pressure variations (PPVs). In the operating room⁸⁸⁻⁹¹ or in the ICU,^{72,92} several studies (except for one⁹³) reported that noninvasive and invasive PPV have similar performance to <u>predict fluid responsiveness</u>. Naturally, all the limitations of invasive PPV (eg, arrhythmia, spontaneous breathing efforts, limited tidal volume)⁹⁴ also apply to noninvasive PPV.

Cardiac Output: The CNAP, Nexfin/ClearSight, and T-Line systems, in their latest versions, also provide a noninvasive determination of cardiac output via pulse contour analysis without invasive calibration, an exciting perspective.⁹⁵ Discussing the accuracy of these cardiac output measurements is outside the scope of the present review.

Arterial Line, Intermittent NIBP, or Continuous NIBP?

Can NIBP Fully Replace the Arterial Catheter? Probably <mark>Yes</mark>

NIBP is already widely used in nonseverely ill patients, in patients whose critical illness has been partially resolved, and even in more severely ill patients before an arterial line is placed.² Postponing the arterial line insertion could be a suitable strategy because arterial catheter insertion may be difficult during hypotension or vasoconstriction. Furthermore, urgent insertion of indwelling devices may not be compatible with appropriate measures to prevent intravascular catheter-related infections. In addition, urgent insertion of an arterial catheter may delay more urgent measures such as patient transfer, imaging and therapeutic invasive procedures, initiation of antimicrobial agents, and transfusion. Because NIBP provides rather accurate measurements of mean BP, or at least a reliable detection of hypotension, hypertension, or response to urgent therapy,^{20,21,31,33} we believe that NIBP can be used to postpone the arterial catheter insertion. This approach can be considered safe because, in case of persistent shock, invasive measurement may correct any inaccuracy in initial management, whereas among patients with improved circulatory status, catheterization might be avoided. Such a strategy of delayed catheter insertion may be prospectively tested to confirm our hypothesis.

To go even further, critically ill patients may be safely managed completely noninvasively with respect to BP monitoring. The arterial catheter is used for both BP monitoring and blood sampling for laboratory testing. However, despite its widespread use for decades, there is no evidence that the arterial catheter is associated with improved outcomes in the ICU.⁶ Two observational studies addressed this issue. In hemodynamically stable patients who are mechanically ventilated, Hsu et al⁴ reported the lack of association between survival and arterial catheter use. A similar finding was reported by Gershengorn et al^7 in a primary cohort of patients who were mechanically ventilated and in eight of nine secondary cohorts. In the cohort of patients receiving vasopressor agents (almost 11,000 patients), arterial catheter use was even associated with increased mortality.

The wide variation in arterial catheter utilization illustrates the uncertainty regarding its benefits.^{2,3} Indeed, as mentioned earlier, even invasive BP monitoring is prone to inaccuracies.²⁶ Furthermore, arterial lines encourage excessive laboratory blood testing,⁹⁶ promoting anemia, transfusion, and their respective complications, whereas the benefit of repeated blood sampling is often questionable.⁶ Lastly, patient discomfort from repeated percutaneous vascular punctures or frequent BP cuff inflations should be balanced with the life-threatening risks related to arterial catheters (eg, limb ischemia, bloodstream infection²³). As emphasized by Garland,⁶ there is an urgent need for rigorous studies assessing the usefulness of arterial catheters in the ICU, as performed earlier for the pulmonary artery catheter.

Can Continuous NIBP Replace Intermittent NIBP? Possibly Yes

Only few studies provided comparisons of continuous NIBP with both intermittent NIBP and invasive BP. The Nexfin/ClearSight⁵³ and the CNAP³³ systems were no less accurate than the compared intermittent NIBP while providing beat-to-beat measurements. Again, this finding may depend on the oscillometer model and on the time to last calibration. To limit the drift and improve the trending ability of the CNAP system, setting a shorter between-calibration interval is a possibility. However, this method may question the added value of the CNAP device over frequent intermittent measurements.

No finger or wrist complications have been reported during the short-term use of continuous NIBP devices.^{84,97} Future studies should aim at confirming that replacing intermittent NIBP with continuous NIBP is a safe and suitable option. Ideally, the end points should be patient-centered outcomes.⁶

Some clues may herald future improvements of all NIBP devices as hardware or software updates increase their accuracy^{48,69} or were proposed for this purpose.³³ This underscores the ongoing progress that may render the future of noninvasive monitoring even brighter than the current widespread use of intermittent NIBP for patients' resuscitation.

Conclusion

Key messages are summarized in Figure 2. In our opinion, during the care of the critically ill, intermittent NIBP measurements, with their good ability to detect hypotension and therapy-induced BP changes may safely replace invasive measurements until arterial catheterization is eventually viewed as an unescapable need. The next few years will tell us if, provided that technical refinements arise, continuous NIBP can emerge as a suitable alternative to continuous invasive BP monitoring.

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