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POSITION PAPER
Arterial hypertension

Cuffless Blood Pressure Monitoring Devices: Technical Foundations and Clinical Implications

Scientific Statement of the European Society of Cardiology (ESC) Working Group on e-Cardiology, the ESC Council on Hypertension, and the European Association of Preventive Cardiology of the ESC

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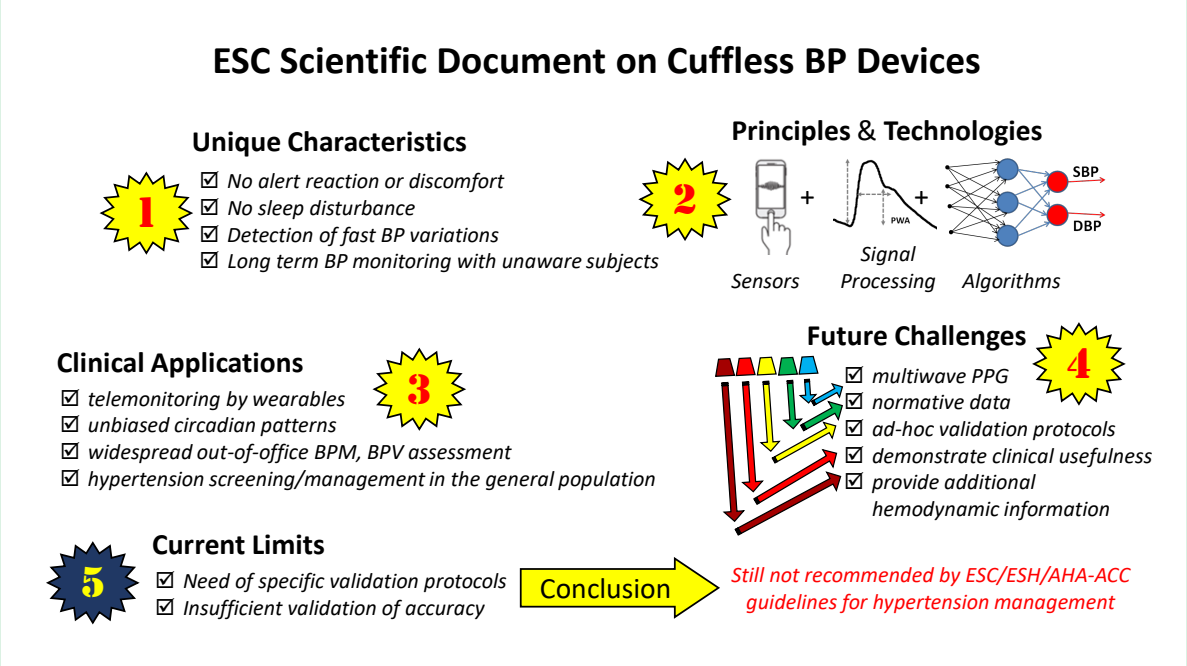
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Cuffless blood pressure (BP) monitoring devices represent a promising innovation in hypertension management. This scientific statement provides a comprehensive update on these emerging technologies, their specific validation requirements, their potential clinical applications, and their present and future challenges.

These devices generate considerable interest by enabling non-invasive BP measurement without arterial occlusion, thereby eliminating the discomfort associated with traditional cuff-based monitoring, particularly during sleep. The technologies on which these devices are based comprise a heterogeneous group, primarily utilizing pulse wave propagation time or waveform analysis through contact or non-contact sensors. They can be categorized as continuous or intermittent, automated or manual, calibration-free or requiring cuff/demographic calibration, and wearable or stationary. This technological diversity necessitates validation protocols distinct from those used for conventional cuff-based monitors, with specific requirements for each device category.

Potential clinical applications include widespread out-of-office BP monitoring, unbiased assessment of circadian BP patterns and BP variability, improved detection of nocturnal hypertension, enhanced treatment adherence and long-term BP control, and continuous monitoring in hospital settings. Additionally, their lower cost compared with conventional technologies could enhance the early detection of hypertension in resource-limited settings. However, due to insufficient accuracy validation, this scientific statement does not recommend their use in clinical decisions in spite of their potential interest, in line with international guidelines not recommending their use in hypertension management. Key challenges ahead include developing standardized validation protocols, establishing normative BP data, managing the resulting burden on clinicians in handling huge volumes of data, exploring additional haemodynamic parameters, and advancing sensor technology, mathematical models, and algorithms.

Graphical Abstract



Keywords

Accuracy • Calibration • Continuous • Cuffless blood pressure measurement • Cuffless blood pressure monitoring • Machine learning • Photoplethysmography • Pulse transit time • Smartwatch • Technology • Validation • Wearables

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Introduction

For many decades, non-invasive blood pressure (BP) measurements have been based on brachial artery occlusion by an arm cuff. Recent technological development has produced devices without an occluding cuff to improve hypertension screening and management in daily life. The speed of such developments, however, has not allowed the concomitant production of the scientific evidence to define their reliability and clinical applicability. Furthermore, most cuffless devices are marketed as fitness rather than medical devices, escaping the rigorous validation process

required by the European Medical Device Regulation or US Food and Drug Administration.

Therefore, new cuffless devices entered the market without evidence on their accuracy from properly conducted validation studies. Given their peculiar features, which promise BP tracking over time, specific validation protocols should be created by international regulatory authorities, a process currently ongoing that requires a considerable amount of time.[1] Nevertheless, these new techniques have rapidly generated interest because they avoid the inconvenience of repeated cuff inflations, offering either continuous or intermittent BP assessment without interfering substantially with daytime activities or nocturnal sleep.

These features have made cuffless BP devices interesting for hypertension management, leading the European Society of Hypertension (ESH) Working Group on Blood Pressure Monitoring and Cardiovascular Variability to start proposing specific procedures for their validation,[2] based on their technical characteristics. The more recent ESH and European Society of Cardiology (ESC) guidelines on hypertension[3,4] underlined that evidence on their accuracy and clinical usefulness must be obtained before proposing their implementation in clinical practice.

This scientific statement aims to provide an update of the latest ESH and ESC recommendations on cuffless BP devices[4] regarding their (i) unique characteristics; (ii) principles and main technologies; (iii) current validation and accuracy; (iv) intended clinical applications in the diagnosis, management, and follow-up of hypertension; and (v) limitations and future role. This clear-cut indication is required to face the confusion often generated in many clinicians by their difficulty in distinguishing between 'regulatory clearance' and 'clinical validation' of these tools. While regulatory clearance is a legal authorization from a regulatory body (such as the Food and Drug Administration (FDA) in the USA) to market and sell a device, a clinical validation is a scientific process aimed at proving the device's accuracy and reliability in assessing BP levels and tracking BP changes through rigorously conducted clinical studies, following specific international standards. Regulatory clearance may require the submission of technical documentation on design, manufacturing, and safety of a device, but does not necessarily require data on device accuracy from rigorous clinical studies. Thus, it does not automatically guarantee clinical validation, which, on the contrary, has to be based on device testing through *ad hoc* designed and internationally accepted validation protocols.

We anticipate that this scientific statement concludes that cuffless devices still lack adequate scientific validation and are not recommended for clinical decisions, despite the interest they are generating, in line with current guidelines on hypertension management.

Rationale for cuffless blood pressure measurement in clinical practice

According to the ESH and ESC hypertension guidelines,[3,4] diagnosis of hypertension should rely on repeated BP measures in the office using either auscultatory or oscillometric methods, combined with out-of-office home BP monitoring (HBPM) or 24 h ambulatory BP monitoring (ABPM), based on upper-arm cuff devices.[5,6] This is because all evidence regarding the clinical importance of hypertension and the benefits of its treatment was obtained by these approaches. Moreover, upper-arm cuff BP measurement is the reference standard when validating new BP measurement technologies.[2,7]

However, the compression of the upper arm is often associated with discomfort and might influence the measures, in particular when elevated BP levels require higher air pressure in the cuff.[8] Furthermore, accuracy of the cuff-based oscillometric technique depends on arterial stiffness, contributing to the need for separate validation of oscillometric devices to be used in conditions of modified arterial compliance, such as pregnancy (in particular when complicated by pre-eclampsia) and childhood.[9]

Another limitation of office and home cuff-based BP measuring methods is the need to perform the measurements under conditions of standardized rest.[10] The only non-invasive approach to track short-term BP variations in response to intrinsic (e.g. BP modulation by central oscillators and mental stress) or extrinsic (e.g. environmental) stimuli in daily life is represented by 24 h ABPM. Despite its limited sampling rate, this approach provides clinically relevant information on BP levels and their variability during the day and night. Nevertheless, also ABPM is based on repeated cuff inflations not always easily accepted by the patients, in particular during exercise, arm movement, and sleep, and when the 24 h ABPM has to be repeated over time. Cuff inflation when higher air pressure levels are required may be painful, introducing a measurement bias[11] and impairing the physiologic nocturnal BP dipping.[8,12,13] To limit cuff-related discomfort, it has been suggested to reduce the frequency of BP measurements, in particular during the night, at the cost to increase errors in the assessment of ambulatory BP levels and short-term BP variability. The advice is to set automated BP readings every 15 min in studies on BP variability[10] and every 20 min in the general clinical application of 24 h ABPM.[3,5] During daytime BP monitoring, the advice is to stop any physical activity at the time of cuff inflation, to avoid introducing movement artefacts and errors in BP detection, thus limiting the ability to provide an actual 'ambulatory' BP assessment in real daily-life conditions.[14]

To overcome these limitations, cuffless devices have been developed, providing either continuous or intermittent BP estimates. Some devices are aimed at measuring also BP short-term variations during daily activities or sleep, with higher sampling rates than conventional 24 h ABPM. Most[15] but not all[16] cuffless devices use wearable sensors. Their measurements can be automated or manual (requiring activation by the user or an operator). They may require an initial calibration, based on at least one cuff BP reading, or on anthropometric data ('demographic' calibration).[2] Some cuffless devices embed algorithms for signal sensing and processing in smartphones, smartwatches, or smart rings,[17-19] enabling their widespread use in hypertension screening campaigns or long-term follow-up of patients with hypertension, even in low-income settings,[20] given that cuffless devices may be based on less expensive technologies, not requiring extensive training, compared with traditional cuffed 24-h ABPM devices. Box 1 summarizes the unique characteristics of cuffless BP devices. Nevertheless, so far, none of these devices has proved to be reliable in accurately capturing a physiologically challenging parameter such as BP.

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Box 1. Unique characteristics of cuffless BP monitoring devices

- No discomfort or alert reaction due to limb compression
- No errors due to the size, shape, and positioning of the cuff by avoiding its use
- Minimal user's intervention during measurement
- User unawareness of the measurement taken
- No sleep disturbance or significant alterations of daily activities
- Record of rapid BP changes in response to physical and mental challenges
- Detailed and unbiased assessment of circadian BP patterns and variability
- Potential for being easily accessible in low-resource settings
- Additional haemodynamic information through machine learning techniques
- Possibility to offer multimodal association with other synchronized physiological signals such as heart rate, blood oxygen saturation, and body movements

Box 2. Potential clinical applications of cuffless BP monitoring devices

General population

Widespread out-of-office BP monitoring
Home BP telemonitoring through wearables and smartphones changing the model of healthcare delivery
Screening/diagnosis in the general population
Night-time BP monitoring without sleep disturbance
BP monitoring at work and without interference with daily life activities
Detailed and unbiased assessment of circadian BP patterns and variability

Patients with hypertension out of hospital

Self-monitoring at home, improving adherence to treatment
Treatment follow-up and long-term BP control
Telemonitoring and remote management of hypertension
Facilitation of regular patient–physician interaction

In-hospital patients and other clinical applications

- Continuous BP monitoring in intensive care units or during anaesthesia
- Continuous BP monitoring in patients with arrhythmias, orthostatic hypotension/syncope, hypertensive peaks, and other transient conditions affecting BP levels and variability
- Study of dizziness, pre-syncope, or postural tachycardia syndrome
- Assessment of BP variability

The potential clinical applications of cuffless devices include the diagnosis and management of hypertension, the assessment of circadian BP profiles, telemonitoring of BP levels, and in-hospital BP monitoring.

Hypertension screening/diagnosis in the general population. Because of their easy applicability, cuffless technologies embedded in smartphones/wearable devices hold potential for hypertension screening on a population basis. They might also help improve awareness and early treatment of hypertension in individuals with high BP.[19] Their relatively low cost compared with cuffed 24-h ABPM devices might be of interest in low- and mid-income settings.

Circadian BP patterns. A major advantage of cuffless devices is that the user may not be aware of the start of the BP measure because of the lack of discomfort associated with cuff inflation. This is advantageous when assessing night-time BP since cuff inflations may cause sleep interruption or fragmentation. Thus, cuffless devices, only if properly validated for their ability to track BP changes over time, might better represent the circadian BP changes. The important advantage of avoiding a disturbing inflating cuff must be weighed against the fact that wearable cuffless devices can be sensitive to motion artefacts to a greater or lesser extent depending on their technology, an aspect still insufficiently documented over the 24 h.

Out-of-hospital applications (telemonitoring of patients with hypertension). Coupling cuffless devices with smartphone applications enables BP self-monitoring by patients with hypertension at home, transmitting BP readings to their doctors. This may facilitate regular patient–physician interaction, improving patients' adherence to treatment and fighting physicians' inertia, thus increasing BP control rates in the long term.[19,21] Ancillary benefits in outpatients' daily life monitoring include screening for obstructive sleep apnoea or arrhythmias, facilitating early identification of these clinical conditions, thanks to their ability to provide beat-by-beat measurements and detect mismatches between cardiac contractions and amplitude of the subsequent pulse waves.

In-hospital applications (continuous short-term BP monitoring). Cuffless devices might be useful where continuous monitoring of short-term BP is required to evaluate the haemodynamic stability (e.g. during anaesthesia or in intensive care settings) or to monitor autonomic dysfunctions in which fast BP changes may be connected with clinical events (see Box 2).

Principles and technologies for cuffless blood pressure monitoring

Traditional non-invasive sphygmomanometers employ a cuff applied on a limb, which is inflated to interrupt the blood flow inside the artery. The flow is restored slowly releasing the air from the cuff, and BP is measured at each cuff inflation/deflation cycle by detecting the Korotkoff sounds (auscultatory method) or the amplitude of the air fluctuations within the cuff (oscillatory method). However, devices employing a flow-occluding cuff are not the only cuff-based devices for non-invasive BP measures. Semi-occlusive cuffs that more gently compress the artery without interrupting the flow are used by devices that measure BP through applanation tonometry, generally on the radial artery, or volume-clamp techniques on fingers.[18] This scientific statement focuses on cuffless devices and thus does not discuss techniques based on either occlusive

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or semi-occlusive cuffs. Furthermore, it considers devices for monitoring BP values, not those for notifying the presence of hypertension patterns only.[22]

Cuffless BP monitors represent a heterogeneous group of technologies. Most of them use specific sensors to detect the waveform of the pressure pulses of an artery or an arterial bed. Contact or non-contact sensors that detect alterations of different physical quantities can be used and implemented into wearable or non-wearable devices. Most are optical sensors detecting changes in light absorption due to changes in blood volume. Contact optical sensors consist of light-emitting diodes (LEDs) in photoplethysmograms (PPGs) and allow detection of pulse waves in different body sites,[23] while non-contact optical sensors are used in devices in which cameras extract pulse wave features from facial and/or hands video. Other contact sensors are mechanical transducers that detect changes in acceleration (ballistocardiogram), force, or heart sounds associated with the pulse wave,[23–25] or bioelectrical sensors for assessing bioimpedance or the electrocardiogram (ECG). Some devices detect beat-to-beat vascular changes by ultrasound transducers.[18] Other non-contact sensors detect body movements induced by the pulse wave with radar technologies.[26]

As to data analysis, some devices derive BP from the pulse transit time (PTT) between a proximal and distal artery. Others use an ECG lead to derive BP from the interval between the instant of ventricular depolarization (R wave on ECG) and the arrival of the pressure pulse at the distal artery site (pulse arrival time, PAT). Some devices derive BP from the alterations induced on the pulse waveform by BP changes, as the superposition of incident and reflected waves, with methods of pulse wave analysis (PWA). Since the pulse wave can be easily assessed by evaluating changes in arterial volume, currently most cuffless devices rely on the use of PPG sensors. They may consist in two PPG sensors, one proximal and one distal to the heart, for measuring PTT, or an ECG lead and a distal PPG sensor to measure PAT, or may consist of a single PPG sensor to derive BP from PWA. While PTT- or PAT-based systems have a clearer mechanistic link to BP, they need multiple sensors that limit their use in comparison to PPG-only systems, which are more commercially widespread due to their simplicity. However, the latter devices rely heavily on data-driven models, which make them more susceptible to inter-individual variability.

Most of these technologies use data-driven predictive algorithms for the transformation of measured variables into BP values, with or without pre-calibration. Calibrated methods detect one or more variables that correlate with BP, and calibrate these variable(s) to mmHg using either periodic cuff BP measurements or demographic inputs (such as age, sex, body height, and weight) to predict BP values by the system algorithms.[18,19] Blood pressure estimation can be done by machine learning[27,28] and deep learning, such as neural network algorithms.[29-31] Calibration-free methods do not require either type of calibration (*Figure 1*).

Cuff-calibrated devices. Cuffless devices requiring one or more cuff-BP measurements for initial calibration in general employ a validated automated upper-arm cuff-BP measurement device (manual auscultatory BP measurement by users is impractical). As different models of oscillometric devices do not give identical readings, the cuffless BP estimations are differently influenced. Hence, cuff-calibrated devices solely track BP changes relative to the preceding cuff BP measurement obtained for calibration and referred to as calibration BP. It remains unclear to what extent their readings depend on the calibration BP and whether they can reliably track actual BP changes after some time from calibration.[19]

Furthermore, the calibration BP may introduce a baseline error due to improper fitting of the calibration cuff, to the arm and body positioning, and to the inherent inaccuracy of the calibration device.[2] Moreover, spot BP measurements may not be representative of an individual's BP during the whole day, due to the intrinsic variability of these measures.[10] The frequency at which calibration should be repeated may vary according to the type of device, associated algorithms, and intended use. It may range from once every few weeks for devices used in outpatient settings to a few hours for devices used in anaesthesia/surgery.

Some cuffless devices require entering demographic variables, known to be correlated with BP values. In some devices, demographic data completely replace the cuff-based calibration. However, the accuracy and precision of calibration models entirely based on demographic data can be substantially lower in comparison with those based on cuff-BP measures.[32]

Although manufacturers recommend periodic recalibration of cuff-calibrated devices, independent studies to determine the frequency and conditions for calibrating cuffless devices are still lacking.[2] These studies should also repeatedly explore the accuracy of a cuffless device and retest it (static validation session) immediately before the recommended recalibration time (stability test) to determine whether the measurements between calibrations remain accurate over time.[16] *Table 1* summarizes major cuffless technologies needing calibration.

Calibration-free devices. Summarized in *Table 1*, they eliminate the need for periodic reference cuff use or demographic inputs. While calibration-free devices might appear simple as they do not require a cuff calibration procedure, more evidence supporting their accuracy is needed, and it may be more challenging to obtain accurate BP measurements.[19]

Interested readers may find an updated list of current cuffless BP devices on the market in Mukkamala *et al.*[39]

Limitations of cuffless devices

The development of cuffless devices has not been paralleled by clinical studies in support of their accuracy or defining the clinical indications for their use and the reference values for their clinical interpretation.[40] Because of serious issues with their accuracy, the 2021 ESH guidelines on BP measurement,[5] the 2023 ESH guidelines for hypertension management,[3] the 2024 ESC guidelines for the management of elevated BP and hypertension,[4] and the 2025 AHA/ACC guidelines on hypertension[41,42] recommend against using them in clinical practice.

Special patients' populations. It must be also considered that some categories of patients may present clinical characteristics that are incompatible with the operating principles of some cuffless devices. For instance, pregnancy, dialysis, or atrial fibrillation may cause calibration instability, which occurs when the vascular tone or the heart rhythm change rapidly, making the

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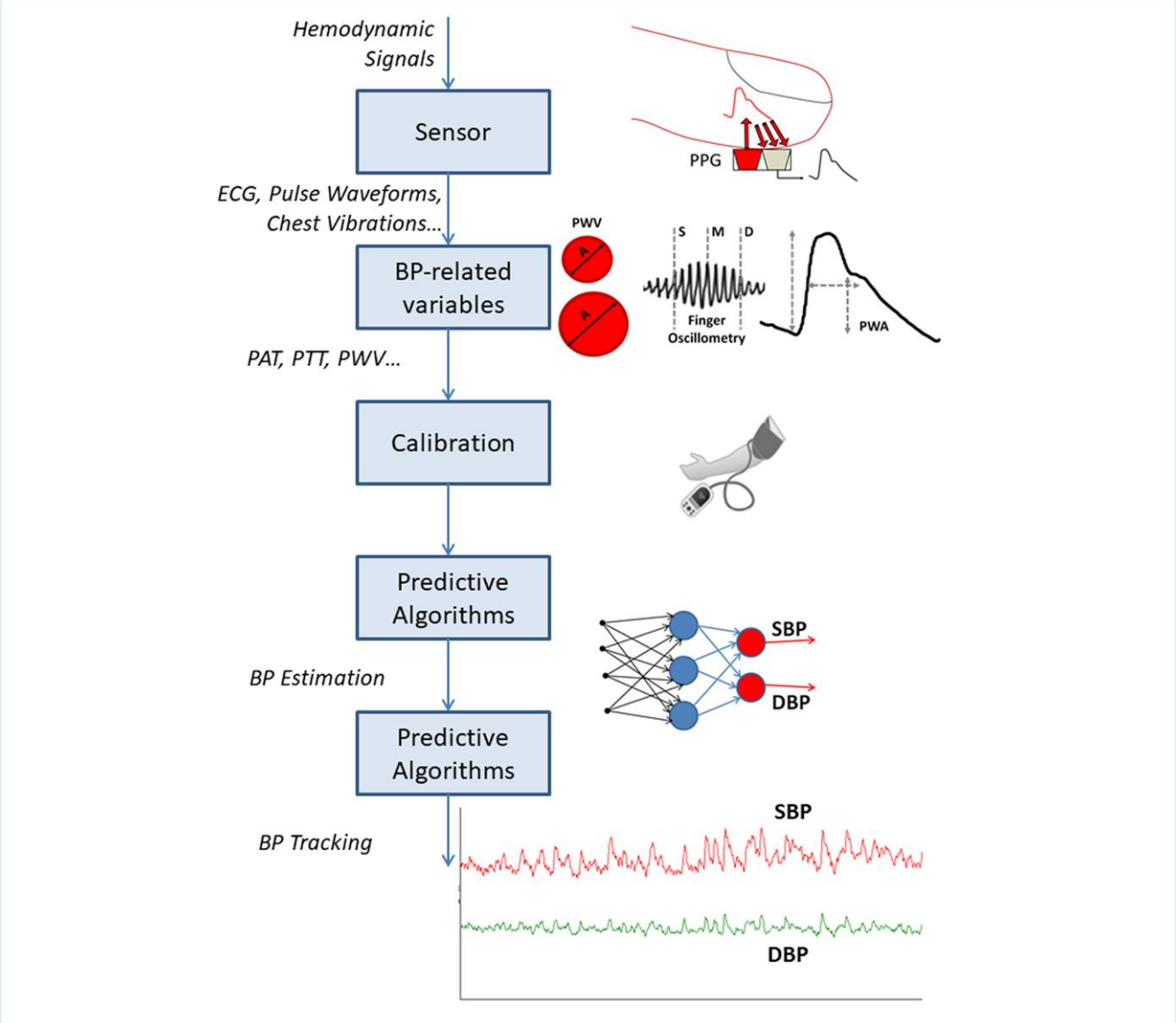


Figure 1 General scheme of cuffless blood pressure monitoring systems. 1) Haemodynamic signals are detected by one or more sensors: they may be optical (photodiodes and cameras), mechanical (accelerometers, tonometers, and microphones), or bioelectrical (electrodes for electrocardiogram or cardiac impedance) or may employ ultrasound or radar transducers. 2) The sensors' output is processed to derive blood pressure-related parameters, such as the pulse transit time between central and peripheral pulses, or the pulse arrival time from the electrocardiogram; pulse wave analysis or finger oscillometry features; or the pulse wave velocity from the pulsatile changes of the cross-sectional area of an artery. 3) Most systems require an initial calibration with an arm cuff or entering anthropometric data of the user (demographic calibration). 4) Data-driven predictive algorithms based on neural networks may be employed to estimate the blood pressure levels and track blood pressure changes over time.

calibration obsolete in hours. Moreover, a poor waveform quality, as in presence of frequent arrhythmias or altered vascular properties, can make the PTT or PAT measurements, or PWA, inaccurate. Further issues related to the use of cuffless devices in specific populations of patients are associated with algorithmic bias, which could affect machine learning–based models trained mostly or entirely on healthy individuals, and to the tendency of validation trials to exclude high-risk populations. *Table 2* summarizes specific problems in using cuffless devices in special patients' populations.

Initial calibration. Calibrated cuffless BP monitors, requiring initial cuff or demographic calibration and periodic cuff calibrations by users to follow BP changes over time,[19] rather than measuring devices should be considered as 'tracking devices' for BP changes. Thus, their ability to accurately estimate physiological BP fluctuations in daily life conditions appears questionable.

Drift. Over time, cuffless BP devices can gradually lose measurement accuracy due to several factors. These can be physiological changes in arterial stiffness, such as those due to

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Table 1 Principles of cuffless technologies with or without initial cuff calibration

Principle	Functioning	Advantages	Issues	Maturity
Calibration required				
Pulse transit time (PTT)	The time delay between proximal and distal arterial waveforms along the elastic aorta is inversely related to diastolic BP	PTT correlates to BP based on robust physical principles[18]	Carotid to femoral PTT is difficult to measure: the distal waveform is commonly detected at the finger site, being susceptible to smooth muscle contraction[33]	**Moderate technical maturity.** Considered a validated trend tracking, several CE/FDA-cleared systems are defined as 'BP monitors with periodic calibration' or as decision-support devices. They are still not accepted as stand-alone BP replacement
Pulse arrival time (PAT)	The time delay between the R-wave of the ECG and a distal arterial waveform is a surrogate of PTT, being PAT = PTT + pre-ejection period	Easier to measure than PTT	Susceptible to changes in the pre-ejection period uncorrelated to the BP level	
Pulse wave analysis (PWA)	The features of a measured arterial waveform are mapped into BP units via machine learning methods[18]	PWA requires a single sensor	Waveforms change with age[34] and are susceptible to smooth muscle contractions in the distal arm arteries[35]	**Moderate technical maturity with high commercial deployment**. Many consumer devices provide 'trending-only' values and are indicated for trend monitoring rather than diagnosis
Ultrasound velocimetry	It estimates the pulse wave velocity (PWV) as the ratio between changes in flow and cross-sectional area of the artery[36]; pulse pressure is then derived from PWV through physics equations	Pulse pressure provided without calibration	An operator is required. To infer systolic BP from the pulse waveform, it requires a cuff measure of diastolic BP (relatively stable along the vasculature)	**Advanced research and development.** The development of wearable ultrasound devices allows the technology to be integrated into portable/wearable systems, moving it out of the bulky, specialized laboratory setting
Calibration free				
Finger oscillometry	The finger is pressed against force and PPG sensors to measure volume variations as the finger transmural pressure decreases. BP is derived from the oscillogram.[37]	Easy to implement in smartphones	Not usable for sleep monitoring or in subjects with motor impairments	**Maturity level of system prototype demonstration**, particularly for smartphone-based, user-actuated cuff-less BP devices
Resonance sonometry	Acoustic waves stimulate the artery and ultrasound imaging determines its resonant frequency and dimensions. The wall tension is calculated from the artery dimension and resonance frequency, and Laplace's law derives BP from the wall tension.[38]	Calibration-free method not involving variable BP application. Central pulse BP may benefit cardiovascular risk stratification.	It requires operator interaction	**Late stage of research and early prototype development.** This technology is still being optimized, and significant work remains before it is ready for clinical application and commercialization

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Table 2 Problems in using cuffless devices in special patients' populations

Population	Main physiological issue	Impact
Atrial fibrillation	Irregular rhythm, variable stroke volume	Unreliable PTT/PAT, poor beat detection for PWA
Pregnancy (in particular when complicated by pre-eclampsia)	Changing vascular tone, oedema	Calibration drift, inaccurate BP trends
Advanced chronic kidney disease	Stiff calcified arteries, volume shifts	Loss of PTT–BP relationship
Peripheral vascular disease	Poor perfusion, waveform damping	Undetectable or distorted signals

ageing, atherosclerosis, or exercise training, that alter the relation between PTT and BP, or between PPG waveform and BP, independently of instantaneous BP. Changes in medication or disease progression that modify the vascular tone and compliance, or even shorter physiological changes affecting the relation between BP and PTT or PPG waveform, such as changes in temperature, hydration, stress, or posture[43] may also contribute to loss of accuracy over time. Therefore, validation protocols verifying the stability of the relationship between arterial properties and BP in different physiological and pathological conditions are needed. In addition, technical aspects such as changes in the position, orientation, tightness, and contact quality of the sensors, or algorithm updates, may contribute to generating measurement drifts.

Validation protocols. Limitations of cuffless devices could not be adequately addressed by conventional validation protocols designed to test automated cuff-based BP measuring devices, as these protocols do not include a procedure to track BP changes.[44] Only recently, expert institutions in charge of defining validation standards (i.e., the International Organization for Standardization (ISO) group) emphasized the need to assess the ability to track BP changes by *ad hoc* protocols that induce BP changes by pharmacological or non-pharmacological (e.g. physical aerobic or isometric exercise, slow breathing, and Valsalva manoeuvre) interventions. However, criticisms have been raised about this approach due to the impact of different interventions on cardiovascular physiology and the possibility that these interventions affect the quality of the measured variable, causing BP responses that vary widely among individuals.

The fact that some cuffless devices require the user to provide clinical or anthropometric data associated with BP levels to enable algorithms to predict BP values raises questions regarding the respective impact of the individual's data component and the measurement component on the estimated BP values. A simulation study revealed an even better agreement with reference BP values when the measurement component was eliminated.[19] In this context, it is interesting to note that the Microsoft 'Aurora' study showed no difference in baseline models where BP predictions were done using individuals' data-driven algorithms with no haemodynamic signals compared with those using PPG or tonometric signals.[45,46] raising doubts about the actual utility of those measurements to track BP changes at the individual level.

Posture, vasculature, and sensor positioning. Other factors may influence the accuracy of cuffless devices, such as body postures (e.g. lying, sitting, and standing), the distance between sensor position and the heart level (in particular for wrist/finger wearable devices), or changing environmental conditions. Changes in ambient temperature may induce vasoconstriction or vasodilation, both resulting in pulse waveform changes affecting the accuracy of cuffless technologies based on distal arterial waveform extraction.[47-50] Furthermore, skin properties such as thickness or tone may affect signal detection by PPG sensors.[51] Accuracy issues are summarized in Box 3.

Optimization of data analysis in validation studies. Studies including many individuals can yield small average differences between tested and reference BP measurement devices. However, considering individual subjects, tested and reference measurements may agree in a fraction of cases only, sometimes not greater than 50%. This raises the question of the relevance of cuffless BP estimates in different patients' phenotypes, where the reliability of long-term average BP changes is relevant for some, but

Box 3. Accuracy issues for cuffless BP measurement device validation

Physics and physiological assumptions

Lack of constant relationship between arterial properties and BP

Initial calibration

- Different types of oscillometric cuff BPM devices used for calibration
- Stability of successive measurements to be determined
- Ability to track BP changes after calibration to be demonstrated
- Frequency of calibration not yet determined
- Efficacy of device calibration only with demographic data to be determined

Validation protocols

- Cuffless and cuffed BP monitors require different validation protocols to ensure accuracy over time
- Cuffless devices for intermittent and continuous BP measurements require different validation protocols
- Most cuffless devices require validation during dynamic conditions

Posture, vasculature, and sensor positioning

- Influence of postural changes on the BP measure
- Influence of vasoconstriction/dilation on the peripheral BP waveform and thus on the accuracy of BP measures
- Measurement accuracy may depend on the distance of the sensors from the heart

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accurate detection of more rapid BP changes is relevant for others. This also brings up the issue of 'trust' in the tested device by both clinicians and patients and of the minimum accuracy level in estimating BP changes that these devices should guarantee. A reasonable requirement is that cuffless devices guarantee at least the accuracy of validated cuff-based methods.

Standards for validation of cuffless blood pressure measuring devices

The first attempts to define a standard for validating cuffless devices date back more than a decade ago.[52] Indeed, the validation procedure is different for cuffless than cuffed BP devices. However, developing a universal standard for their validation has turned out to be difficult. Even the most updated standards for cuffed device validation[44] should not be applied since cuffless devices need validation protocols tailored to their technology.

In spite of these considerations, most validation studies have been carried out with protocols for automated cuffed BP devices using manual auscultatory BP measurement as reference, an insufficient and potentially misleading approach.[19] In many reports, cuffless devices were compared with oscillometric or auscultatory methods in studies characterized by a large heterogeneity of sample size, measurement conditions, reference BP, statistical methods, and validation protocols, resulting in variable levels of agreement.[16] Moreover, in studies based on comparison of BP measures at rest, the static cuffless estimate is usually related to the calibration level entered with the initial measurements in individual patients. It does not assure that the devices reliably detect physiological BP changes over time.[19]

Specific protocols for validation of cuffless BP measurement devices have been recently issued, considering the complexity of cuffless devices and their BP tracking ability, such as the International Standard ISO 81060-3:2022(E).[53] However, there is still an imperative need to develop universally accepted validation standards specific to cuffless BP devices, an issue currently being addressed by an ISO Standard international team (ISO 81060-7 document in preparation).

Validation standards for continuous cuffless BP measurement devices. Considering that many cuffless devices promise to offer non-invasive estimation of BP values continuously, specific indications for their validation are provided by the International Standard ISO 81060-3:2022(E).[53] This document lists the requirements for clinical investigation of continuous BP measurement devices to ensure that their performance in estimating BP values guarantees an adequate level of accuracy, at least similar to the standards defined for intermittent automated non-invasive sphygmomanometers.[53] In particular, there is a separate description of procedures for assessing the accuracy of BP determination, the estimation of BP changes, and the stability of device performance. It also includes indications on how to validate continuous non-invasive cuffless automated devices that do not require to be calibrated before their first use. Although continuous cuffless automated non-invasive sphygmomanometers are unable to provide 'absolute' BP determinations, they should at least be accurate in tracking BP changes over time, and in such a case, they could be relevant for therapeutic applications. According to the ISO 81060-3:2022(E) document for cuffless continuous BP measurement devices, it is indeed only necessary to fulfil the requirements for demonstrating the accuracy of these devices in tracking BP changes and for evaluating the device stability.[53]

Since the standards for validation of continuous BP devices require the use of intra-arterial BP measurements as the reference, this protocol is reasonable for evaluating monitors to be used in critical care settings,[54] while it is less practical for evaluating devices intended for use in hypertension management. Further limitation of using such a standard is that the document, like all ISO standards, is not free of charge and is accessible only by payment.

Validation standards for intermittent cuffless BP measurement devices. To assess the accuracy of intermittent cuffless devices in the laboratory, the 2023 ESH validation standard document[2] proposed to induce BP changes by pharmacological or non-pharmacological interventions (*Table 3*). These would transform the validation procedure from observational to interventional, raising issues on feasibility, reproducibility, safety, and consistency.[2] The same document also suggests a pragmatic evaluation of the accuracy out of the laboratory setting, before and after titration of antihypertensive treatment, or during daily activities, including sleep. Treatment-induced BP changes may be compared with standard manual BP readings, while daily-life BP variations should be compared with a validated 24-h ABPM upper-arm cuffed device.[2,16] Along this line, clinical field studies may be conducted using cuff-based oscillometric BP measuring techniques (either in the office, at home, or in ambulatory conditions over 24 h) applied according to available guidelines as a reference and focusing more on BP changes rather than on absolute BP levels.[16,55]

Universal standard = same arm sequential reference-test BP measurement procedure for a general population according to the AAMI/ESH/ISO Universal Standard; details are in Stergiou *et al.*[2]

Box 4 summarizes the validation protocols for intermittent cuffless (IC) and continuous cuffless (CC) devices.

Current view of cuffless devices in hypertension guidelines

Cuffless BP devices are explicitly not recommended for hypertension management in most current hypertension guidelines,[4,41,56–60] except for improving hypertension awareness.[61] Although recent developments in cuffless BP technology might theoretically overcome important limitations of conventional BP measurement techniques, the accuracy of cuffless devices in providing reliable BP readings, in particular in the conditions for which they were developed (i.e. in dynamic conditions of daily life and for the assessment of night-time BP), has not yet been consistently explored nor demonstrated. Thus, current guidelines are in line with the conclusions reached in this paper, i.e. that cuffless BP device applications in clinical practice remain to date only potential. Before being recommended for clinical use, scientific evidence supporting their accuracy from dedicated and internationally acknowledged validation protocols, as well as sound evidence on the diagnostic and prognostic usefulness of their clinical application, are needed.[5,62]

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Table 3 ESH recommended validation tests for intermittent cuffless BP devices

Validation Test (*addressed issue*)	Rationale	Procedure
1 Static (*absolute BP accuracy*)	Not for cuff-calibrated devices if the calibrating cuff device has been validated according to the universal standard. The test is equivalent to the universal standard for validation of an automated cuff device against reference dual-observer manual auscultation	Universal standard validation procedure
2 Position (*hydrostatic pressure)*	To assess hydrostatic pressure effects for automated devices with sensors not at the heart level	Validation against reference dual-observer manual auscultation, sitting with arm resting on the table and at least another vertical position with respect to the heart
3 Treatment (*BP reduction accuracy*)	To be used for cuff-calibrated or demographic-calibrated devices. The test assesses the ability to track long-term and clinically important BP decreases	After initial calibration in uncontrolled hypertensive subjects, antihypertensive drug treatment is initiated or up-titrated. After 1–4 weeks, the device is tested against reference dual-observer manual auscultation before re-calibration
4 Awake/asleep (*BP change accuracy*)	To be used for automated cuff-calibrated or demographic-calibrated devices. The test assesses the ability to track BP changes during sleep, assessing accuracy under varying device positions, activity, and motion	Based on comparison with 24-h ABPM of the average awake/asleep BP changes. A single valid 24-h reference ABPM session should be considered for comparison
5 Exercise test (*BP increase accuracy*)	To be used for cuff-calibrated or demographic-calibrated devices. The test assesses the ability to track physiological BP increases induced by exercise, indirectly assessing the accuracy of BP measurements under motion	Immediately after sitting baseline measurements, submaximal exercise on a cycle ergometer will induce steady BP increases. Comparison is performed against manual auscultations taken at rest and during exercise
6 Recalibration (*calibration stability*)	To be used for cuff-calibrated devices requiring periodic calibration. The test assesses the calibration stability over time.	Universal standard validation procedure to be performed immediately before manufacturer instructions require recalibration

Box 4. Validation protocols for IC and CC devices

ISO 81060-3:2022(E) document[53]

- Specific indications for CC device validation
- CC devices should fulfil the requirements of two validation procedures respectively focusing on BP stability and BP change tracking
- Critical aspect: intra-arterial BP is difficult to apply as a reference measure in some research settings

2023 ESH document for the validation of IC BP measuring devices[2]

- Specific indications for IC device validation, according to their particular technical characteristics, functions, and need for calibration
- Lists specific, clinically meaningful, and pragmatic validation procedures for different types of IC devices
- Lists the procedures for assessing the accuracy of calibrated IC devices in tracking BP changes in the laboratory and/or in a clinical setting.

Future perspectives and challenges

Methodological aspects. A number of methodological issues need to be addressed concerning the use of cuffless BP measurement devices in clinical practice (Box 5). The recent ISO 81060-3 document on clinical investigation of continuous automated non-invasive sphygmomanometers and the expected ISO 81060-7 document on clinical investigation of intermittent cuffless measurement type should direct the validation efforts. Indeed, the high prevalence of hypertension represents an important stimulation for further increasing their accuracy, making them user-friendly and easily acceptable for daily life implementation, thus improving their role in population screening. Among the methodological issues that still need to be properly managed, three aspects deserve attention:

(1) Given that validation according to current standards does not suit their specific properties, it is required to assess them with a simulation of daily life conditions in the laboratory setting, as well as to assess their ability to track BP changes in real-life conditions during 24 h, including the wake–sleep cycle. Also their ability to track BP changes

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when antihypertensive medications are initiated or titrated is important to demonstrate their clinical usefulness.

(2) Validation studies should include the comparison of both average and individual data, through appropriate statistical tools. Indeed, when the analysis is focused on average data from a cohort, an apparently good agreement with a reference standard device may be obtained, because individual differences of opposite sign may result in small average discrepancies. In contrast, when individual data from each study participant are considered, discrepancies with reference devices may appear more clearly.[16] Systematic use of a Bland–Altman analysis should be recommended.

(3) The difference between BP values 'directly' measured and those estimated from an algorithm should be acknowledged, the latter only providing an indirect estimation of the variable being assessed.

Development of future technologies and protocols for their validation, and studies on the clinical value of cuffless devices, should consider these issues (Box 5).

Normative thresholds for hypertension diagnosis. Cuffless devices could be used in clinical practice only if normalcy levels are determined. As with other techniques, such as automatic office BP, ABPM, and HBPM, normalcy values and BP thresholds to identify a hypertensive condition should be determined for cuffless BP devices, considering the setting in which the device is intended to be used (i.e. doctors' office, patients' home, ambulatory daily life conditions, physical exercise, or recordings during sleep). Indeed, we need normative values for BP readings taken in 'non-standardized conditions,' such as those in which a cuffless device is likely to be used. Normative values will likely have to be defined for each class of devices, to take into account the different physical principles on which the measurements are based. All conventional devices have reference values for measurements taken in highly standardized conditions, with the partial exclusion of 24-h ABPM for which we have reference values for 24 h, day and night averages, but not for individual readings taken during different behavioural conditions of daily life. Furthermore, BP normality levels should be outcome driven, thus requiring prospective longitudinal studies.

Population screening and hypertension management. Future studies should specifically evaluate the ability of cuffless devices to act as a screening tool to identify individuals with BP elevation and to represent a novel approach to improve the awareness, treatment, and management of patients with arterial hypertension at a population level.

Management of big datasets. Cuffless devices are likely to yield a large amount of BP data. Given the possibility to obtain continuous and dynamic measures, these devices will end up with a large number of BP readings to be stored. A practical challenge is therefore optimizing the way these data are handled and stored, safely and accurately. From a clinician perspective, an additional issue regards managing and interpretation of such an amount of data.[55]

Haemodynamic information. In addition to methods for the estimation of stroke volume/cardiac output from PWA,[63] optical sensors might give useful haemodynamic information beyond the BP measurement. Indeed, PPG changes in vascular volume might be transformed into a pressure signal.[64] If models can be obtained to transform a finger PPG to a radial tonometric signal, then transfer function techniques may provide estimates of central aortic parameters.[65,66] Possible developments of cuffless devices might therefore offer a dynamic assessment of central aortic pressure.

Furthermore, microvascular damage is an early hypertension-mediated organ damage, with prognostic relevance,[3] but still not used in clinical practice because of difficulties related to its assessment. Optical PPG sensors operating across a broad spectrum of wavelengths might separate between volume changes due to arterioles (detected by longer wavelengths) and capillaries (by shorter wavelengths) and provide quantitative changes in peripheral vascular resistance.[67]

Box 5. Future challenges for cuffless BP devices

Validation

- Develop specific validation protocols for cuffless BP monitoring devices
- Validation in dynamic conditions (either in the laboratory or real-life conditions)
- Validation focusing both on average and within-individual comparisons between test and reference devices

Use

- Define normalcy levels and hypertension thresholds for different recording conditions
- Demonstrate their usefulness as screening tools
- Demonstrate their ability to improve the awareness, treatment, and management of patients with high BP
- Demonstrate their ability to predict outcome
- Provide additional haemodynamic information

Conclusions

Cuffless BP monitoring is rapidly evolving with potential to transform both clinical practice and public health approaches to hypertension management. While preliminary evidence suggests reasonable agreement with cuffed measurements under controlled conditions, available validation standards —originally designed for cuffed devices— may not adequately address the unique characteristics of these technologies to track BP changes over time. The true potential of cuffless monitoring indeed lies in its ability to provide unobtrusive measurements during daily activities, yet evidence supporting its accuracy in such dynamic conditions remains limited.[39] Therefore, due to insufficient

Box 6. Take-home message

- Cuffless devices are not ready for clinical use in hypertension
- Calibration and drifts remain major challenges
- Specific validation protocols should be used for each class of devices
- Algorithm transparency is required.

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accuracy validation, we cannot recommend their use in clinical decisions, in line with current international guidelines not recommending their use in hypertension management.

Future research must prioritize two critical areas: first, developing dedicated validation protocols that account for the specific features of cuffless technology, and, second, establishing the reliability of cuffless devices in daily life conditions. Optimizing data processing and interpretation by improving algorithms that employ artificial intelligence methods appears essential (Box 6).

Only after satisfactorily addressing these challenges we will be able to confidently recommend cuffless BP devices for widespread implementation in clinical practice and epidemiological research, ultimately fulfilling their promise of improving hypertension detection, monitoring, and management across diverse healthcare settings.

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