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REVIEW

Wearable cuffless blood pressure monitoring devices: a systematic review and meta-analysis

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Aims High blood pressure (BP) is the commonest modifiable cardiovascular risk factor, yet its monitoring remains problematic. Wearable cuffless BP devices offer potential solutions; however, little is known about their validity and utility. We aimed to systematically review the validity, features and clinical use of wearable cuffless BP devices.

Methods and results We searched MEDLINE, Embase, IEEE Xplore and the Cochrane Database till December 2019 for studies that reported validating cuffless BP devices. We extracted information about study characteristics, device features, validation processes, and clinical applications. Devices were classified according to their functions and features. We defined devices with a mean systolic BP (SBP) and diastolic BP (DBP) biases of <5 mmHg as valid as a consensus. Our definition of validity did not include assessment of device measurement precision, which is assessed by standard deviation of the mean difference—a critical component of ISO protocol validation criteria. Study quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies version 2 tool. A random-effects model meta-analysis was performed to summarise the mean biases for SBP and DBP across studies. Of the 430 studies identified, 16 studies (15 devices, 974 participants) were selected. The majority of devices (81.3%) used photoplethysmography to estimate BP against a reference device; other technologies included tonometry, auscultation and electrocardiogram. In addition to BP and heart rate, some devices also measured night-time BP ($n = 5$), sleep monitoring ($n = 3$), oxygen saturation ($n = 3$), temperature ($n = 2$) and electrocardiogram ($n = 3$). Eight devices showed mean biases of <5 mmHg for SBP and DBP compared with a reference device and three devices were commercially available. The meta-analysis showed no statistically significant differences between the wearable and reference devices for SBP (pooled mean difference $= 3.42$ mmHg, 95% CI: -2.17, 9.01, I^2 95.4%) and DBP (pooled mean $= 1.16$ mmHg, 95% CI: -1.26, 3.58, I^2 87.1%).

Conclusion Several cuffless BP devices are currently available using different technologies, offering the potential for continuous BP monitoring. The variation in standards and validation protocols limited the comparability of findings across studies and the identification of the most accurate device. Challenges such as validation using standard protocols and in real-life settings must be overcome before they can be recommended for uptake into clinical practice.

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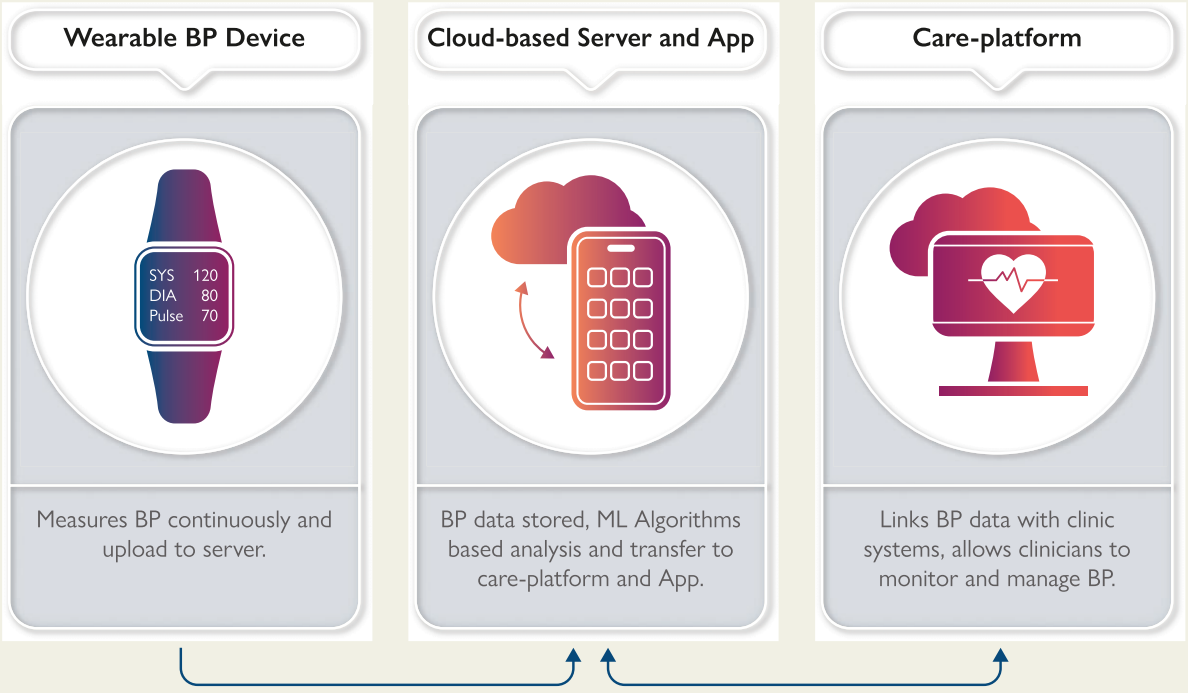
Graphical Abstract



Wearable BP device system.

Keywords Hypertension • Cardiovascular disease • Blood pressure (BP) • Validation • Digital health • Non-invasive

Introduction

High blood pressure (BP) is the most common modifiable risk factor causing the largest burden of diseases globally,[1] including stroke, cardiovascular disease, and end-stage renal disease. In 2015, 1.13 billion adults had high BP leading to over 19% of all deaths.[1,2] Among those diagnosed with high BP, more than 80% have uncontrolled BP leading to increased morbidity and mortality.[3] A recent global survey on >1.5 million adults reported that among those on treatment for high BP, >71% had uncontrolled BP (>130/80 mmHg).[4] High BP is also a leading risk factor for disability, accounting for 122.2 million disability-adjusted life years.[5] Over the past decades, population growth, increasing life expectancy, unhealthy lifestyle and an aging population have led to an increase in the global burden of high BP.[1] The actual burden is likely to be even higher as more than one-third of people worldwide with high BP remain undiagnosed.[6]

An effective approach to reduce hypertension-related disease burden is early detection and initiation of treatment, including lifestyle modification, and ongoing monitoring.[7] Despite significant advancements in healthcare and the availability of low-cost, effective therapies, overall progress in BP control has been slow due to the large number of undiagnosed cases of high BP and lack of regular BP assessment over time. Conventional management strategies rely on physician-centric diagnosis and BP assessment in clinics, which has several limitations, including measurement errors, 'white-coat hypertension' and failing to measure the circadian and seasonal variations in BP.[8] Additionally, clinic BP measurements often fail to detect masked hypertension (i.e. high BP at home and outside the clinic but not in the clinic)—which is present in 20–40% of people and an essential marker for CVD risk [9]—leading to inadequate treatment and incomplete follow-up. Twenty-four-hour ambulatory BP monitoring (ABPM) is essential for accurate detection of hypertension but is costly and subject to user discomfort.[10,11] Home monitoring overcomes these limitations but only records periodic resting BP and requires manual input from individuals, which reduces feasibility.

New approaches are needed for continuous monitoring of BP that is simple and unobtrusive, acceptable to users and clinicians, and enables better tracking of treatment response, and hence a greater ability to manage and titrate treatments. Recent developments in sensor technologies offer the promise to monitor BP throughout daily life, over prolonged periods, and across many individuals.[12,13] 'Cuffless' technologies such as photoplethysmography (PPG), electrocardiogram (ECG), ballistocardiography,[14] microelectromechanical,[15] magneto-plethysmography,[16] bioimpedance,[17] ultrasound image processing,[18] and mobile phone sensors[19] can be used to estimate BP from pulse transit time (PTT), pulse wave velocity (PWV), and pulse arrival time parameters.[20] These wearable cuffless BP devices could enable long-term monitoring to support enhanced BP management.[13] A review on wearable BP devices summarized developments, research trends, and prospects for clinical use[21] but did not review measurement validity. Recent work and position statements have highlighted the problems with inaccurate BP measurement and

the lack of formal validation of devices according to established standards.[22,23] Currently, there is a dearth of information about the features, validity and clinical application of wearable BP devices. Moreover, there is no consensus regarding BP measurement accuracy standards of cuffless devices. While different methods claim superiority, no systematic reviews have compared the validity of these devices. Therefore, we aimed to systematically review the features and validity of wearable BP devices that have the potential for application in clinical settings.

Methods

We conducted a systematic literature search following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[24]

Search strategy

MEDLINE, Embase, IEEE Xplore, and the Cochrane Database of Systematic Reviews were searched from inception to December 2019 without language restriction. The following related terms and phrases were used: (Cuffless) OR (Wearable OR Body OR wear*) AND (Blood pressure OR BP OR blood pressure monitor* OR BP monitor* OR blood pressure measur* OR BP measur*). The Medline Ovid search strategy is presented in Supplementary material online, *Table S1* and was adapted as required for other databases. Relevant reviews and meta-analyses were hand-searched to identify additional studies. Two reviewers (S.M.S.I. and R.D.) also hand-searched bibliographies of included articles and reviewed the grey literature (i.e. Google Scholar, conference proceedings, and relevant websites https://www.stridebp.org, https://medaval.ie/and https://bihsoc.org/bp-monitors/which provide the most comprehensive independent international device registry and database for BP monitors) to identify additional studies.

Eligibility criteria

Inclusion criteria were as follows: eligible studies described the validation of wearable cuffless BP devices against a reference device in humans. For the purpose of this review, wearable cuffless BP devices were broadly defined as those worn on or non-invasively attached to the body that did not require inflation of a pneumatic cuff to determine BP. This includes cuffless devices with calibration step requiring cuff BP.

Exclusion: We excluded studies that did not include a reference device for assessing validity, described devices that used a pneumatic cuff or invasive sensing components, or evaluated devices using animal, simulation models, presented only algorithms, or did not have full text. We also excluded studies that described only methodological concepts or lacked sufficient information to determine eligibility.

Study selection

Two reviewers (S.M.S.I. and N.S.) independently screened titles and abstracts for potential eligibility. Full papers of potentially eligible articles were retrieved and assessed. Information from eligible articles was entered into a predesigned electronic spreadsheet developed for this review. Devices were included in this review if they met all the inclusion criteria, and the reasons for exclusion were recorded (*Figure 1*). Any disagreements were resolved by discussion and consultation with other authors (R.M. and C.K.C.).

Data extraction and analysis

Before data extraction, a set of features considered essential or desirable in wearable BP devices was developed based on literature reviews and expert opinion. We extracted the following information: characteristics of the included studies (name of the device, author/year, sample size, country of the study, study population and recruitment strategies), characteristics of the wearable BP devices (anatomical location of the sensors, mechanism of BP measurement), reference device, validation protocol, BP data from test and reference devices, clinical application and additional features and prototype or commercial availability, and practical and functionality features of the wearable BP devices (ease of use, battery life, costs, alerts/reminders, data storage, data viewing, data transfer/sharing and related app). Where possible, additional information (e.g. device features and cost) were extracted from manufacturers' websites. Devices that were described in two or more publications were summarised as a single device. Features that could not be ascertained were considered absent. Differences in data extraction were resolved by consensus and in consultation with another researcher (C.K.C. and R.M.). While the IEEE guideline[25] recommends that for a cuffless device to be valid, the mean absolute difference (MAD) between test and reference device should be <7 mmHg for both systolic BP (SBP) and diastolic BP (DBP), this was not possible due to lack of MAD data from the included studies. Therefore, for the purpose of this study, we defined devices with a mean SBP and DBP biases of <5 mmHg as valid as a consensus. Our definition of validity did not include assessment of device measurement precision, which is assessed by standard deviation of the mean difference (MD) and is a critical component of ISO protocol validation criteria.

Data were analysed using IBM SPSS version 22.0 (IBM Corporation). Device characteristics and features are presented as means or medians for continuous data and as frequencies and proportions for categorical data. We classified the cuffless BP devices based on their additional clinical functions and types of sensors used to measure BP. The MD between SBP and DBP between the test and reference devices was calculated and compared for assessing the validity of cuffless BP devices. The mean biases for SBP and DBP were pooled across all included studies using MATLAB.[26] The meta package in R was used to perform random-effects model to pool effect sizes as we anticipated considerable between-study heterogeneity. We used the restricted maximum likelihood estimator[27] to calculate the heterogeneity variance τ^2. The Knapp–Hartung adjustments[28] was used to calculate the confidence interval around the pooled effect. We calculated pooled mean and standard deviation for secondary analyses using following equations:

$$mean_z = \frac{1}{n}\sum_{i=1}^{n} z_i.$$

$$SD_z = \sqrt{\frac{1}{n}\sum_{i=1}^{n}(z_i - mean_z)^2}.$$

Where, $z \in \{SBP,\ DBP\}$ and Z_i is the reported measurement of average SBP or DBP for i^{th} study, n is the total number of studies used in the pool analysis. Finally, $mean_z$ and SD_z represent the pooled mean and standard deviation of SBP and DBP values. We then calculated the difference between the pooled mean bias and the mean bias of individual studies for both SBP and DBP measurements. Sensitivity analysis was performed by removing studies with high heterogeneity/differences in mean bias between test and reference device.

Assessment of risk of bias and methodological quality

Study quality was assessed by two independent reviewers (R.D. and S.M.S.I.) using the Quality Assessment of Diagnostic Accuracy Studies version 2 (QUADAS-2) tool,[29] which has been widely used in systematic reviews to evaluate the risk of bias and applicability of primary diagnostic

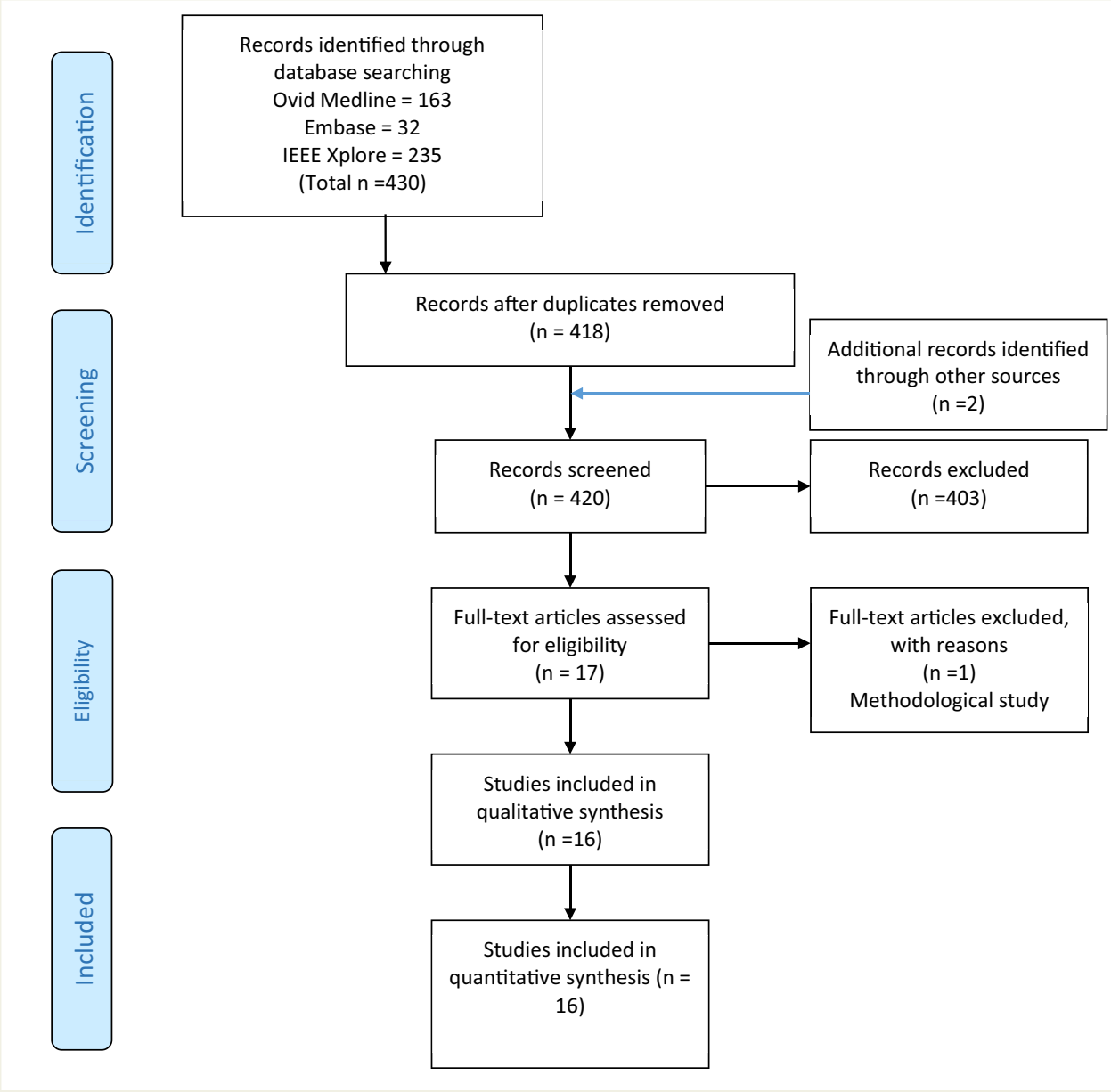


Figure 1 Study flow diagram.

accuracy studies. Quality Assessment of Diagnostic Accuracy Studies version 2 consists of four key domains: patient selection, index test, reference standard, and flow and timing. Each domain was assessed in terms of risk of bias (low, high, or unclear) and the first three in terms of concerns regarding applicability. Results were expressed as the frequency of each response. Any disagreement was resolved by consensus and consultation with a third author (C.K.). We used tabular and graphical displays in Review Manager 5.3[30] to summarize the QUADAS-2 appraisals.

Results

The search identified 430 study records, of which 16 studies, including 15 devices and 974 participants (range $n = 4$–313), were included in the review (*Figure 1*). Studies were conducted in 12 countries (2 each in South Korea, India, China and Netherlands, one each in Hong Kong, Japan, Greece, the UK, the USA, Spain, Italy, and Australia). All studies except one[31] were single-centre studies. Studies included mixed normotensive and hypertensive ($N = 6$), normotensive only ($N = 7$), and hypertensive only ($N = 1$) participant cohorts. Two studies did not specify the participants' BP status. The characteristics of the included studies are presented in *Table 1*.

Technologies to estimate blood pressure

Most of the wearable devices used PPG sensors to estimate BP ($N = 13$, of which 6 also included ECG sensors). Three devices used other sensor technologies such as magneto-plethysmography, seismocardiography and digital auscultation. Sensors were used to detect PWV, tonometry, seismocardiogram, ECG and PPG waves at different anatomical locations, including the wrist ($N = 7$), fingers ($N = 6$), chest ($N = 4$), and over the carotid artery ($N = 1$). Devices used

Table 1 Characteristics of included studies

Author, year (device name)	Sample Size	Country	Population	Recruitment
Kim *et al.*,[32]	34	South Korea	Hypertensive Age: 52.8 ± 15.62 years; female (64.7%)	Recruited from a hospital (not randomized)
Nabeel *et al.*,[33]	35	India	Normotensive Age: 28 ± 4.5 years; female (34.2%)	Volunteers (location: N/A)
Park *et al.*,[34]	163	South Korea	Normotensive and hypertensive Age: 20–60 years; female (89.5%)	Volunteers (from a public health centre)
Nabeel *et al.*,[35]	83	India	Normotensive and hypertensive Age: 57 ± 12 years; female (24%)	Randomized from people visiting a clinic for a health check-up.
Zheng *et al.*,[36]	10	Hong Kong	Normotensive Age: 27 ± 3 years; no info on gender.	N/A
Noda *et al.*,[37]	12	Japan	Normotensive Age: 22.9 ± 5.1 years; female (50%)	N/A
Boubouchairopoulou *et al.*, (Freescan)[38]	313	Greece	Normotensive and hypertensive Age: 49.3 ± 12.3 years; female (43.7%)	Attending a hypertension clinic and healthy volunteers
Cohen et.al.,[39]	4	UK	N/A	N/A
Peng *et al.*,[40]	32	China	Normotensive Age: 20–31 years; female (21.8%)	N/A
Schoot *et al.*, (Checkme)[41]	37	Netherlands	Normotensive and hypertensive Age: 54.1 ± 14.5; Female (51.3%)	Volunteers from outpatient of a university medical centre
Xin *et al.*,[42]	70	China	Normotensive and hypertensive (Age, gender: N/A).	Randomised (location- N/A)
Garcia-Ortiz *et al.*, (B-pro)[31]	104	Spain	Normotensive Age: 50.44 ± 11.02; female (68.3%)	Random sampling from among PEPAF[a] cohort study participants (multicentre: primary care centres of hospitals)
Bilo G *et al.*, Somnotouch-NIBP[43]	33	Italy	Normotensive and hypertensive Age: 63.5 ± 11.9; female (33.3%)	Inpatients and outpatients, Cardiology Unit of San Luca Hospital
Carek *et al.* (SeismoWatch)[44]	13	USA	Normotensive Age: 23 ± 3; female (38.5%)	Young and healthy volunteers
Islam *et al.* (T2-Mart)[45]	20	Australia	Normotensive Age: 20.3 ± 5.4; female (50%)	Young and healthy volunteers recruited from university and community settings in Melbourne, Australia
Ogink *et al.* (Checkme)[46]	11	Netherlands	N/A Age: 57 ± 11.5; female (36%)	Hypertension outpatient clinic of an academic hospital in The Netherlands

[a]PEPAF (Multicenter Assessment of Experimental Programme Promoting Physical Activity) cohort

different algorithms to estimate BP; only three studies described these algorithms.

Device validation

Only six studies reported using a standardized international BP validation protocol (*Table 2*). Included studies used a variety of reference BP devices, including ABPM ($N = 3$), mercury sphygmomanometer ($N = 3$), and automated pneumatic cuffs worn on the finger ($N = 2$), wrist ($N = 2$), upper arm ($N = 2$), and undisclosed anatomical locations ($N = 3$). All of the reference devices were approved devices based on international protocols and used according to standards of BP determination. Ten wearable devices required calibration before use; three did not require calibration, and calibration requirements were not reported for the remaining three studies.

Practical and functional usability features of the wearable blood pressure devices

In addition to BP and heart rate, some devices also measured nighttime BP ($n = 5$), sleep monitoring ($n = 3$), oxygen saturation ($n = 3$), temperature ($n = 2$), and ECG ($n = 3$). Wearable BP devices were classified based on the clinical application as either (i) basic devices ($N = 10$) that provided basic BP and heart rate measurement, or (ii) advanced devices ($N = 6$) which also provided customizable and interactive features such as BP statistics over-time, data sharing, and multiple user support. Only three devices: B-Pro,[31] Somnotouch-NIBP[47] and T2-Mart[45] were commercially available as consumer products (*Table 2*).

Reported device battery life varied from 7 days to 6–8 h. The cost of commercially available devices ranged from $50 to $3000; costs were not available for prototype devices. Three devices provided reminders to measure BP and alerts for high BP, and seven devices had onboard data storage; it was unclear whether remaining devices could store data. Most devices included displays to show BP measurements ($N = 13$). Nine devices had data transfer/sharing capacity, including five that could connect with mobile apps while others displayed/stored BP data on the device. The main usability of the wearable devices would be long-term BP measurement in daily living conditions, but only six devices were suitable for such use.[31,32,34,38,44,45] (*Table 3*)

Measurement validity and meta-analysis

Eight devices showed mean biases of <5 mmHg for SBP and DBP compared with a reference device. Only two devices: Somnotouch-NIBP by Somnomedics[43] and Freescan by Maisense[38] are currently included in the STRIDE BP Validated Cuffless BP Monitor list (https://stridebp.org/bp-monitors).

Data on mean (SD) biases between test and reference devices were available for only 12 studies. The pooled effect size estimates did not show statistically significant differences between wearable cuffless BP devices and a reference device in measuring both systolic [MD (95% CI): 3.42 (−2.17, 9.01)] and DBP [MD (95% CI): 1.16 (−1.26, 3.58)] (*Figure 2*). Regarding heterogeneity, the between-study heterogeneity variance was estimated at $\tau^2 = 25.99$ (95% CI: 9.14–175.18), with an I^2 value of 95.4% (95% CI: 92.3–97.2%) for SBP. The prediction interval ranged from MD = −11.92 to 18.76, indicating that negative intervention effects cannot be ruled out for future studies (*Figure 1*). Similarly, for DBP, the between-study heterogeneity variance was $\tau^2 = 3.88$ (95% CI: 1.10–37.15), with $I^2 = 87.1\%$ (95% CI: 74.3–93.5%). The prediction interval ranged from MD = −4.82 to 7.15, indicating that negative intervention effects cannot be ruled out for future studies (*Figure 2*).

One study [35] showed large biases for both SBP and DBP. Excluding this study, the pooled mean biases were 3.16 ± 4.13 mmHg (range: −1.80 to 13.19 mmHg) for SBP and 1.22 ± 2.25 mmHg (range: −1.00 to 5.86 mmHg) for DBP (see Supplementary material online, *Figure S1*). A sensitivity analysis removing two studies with extreme mean BP difference[35,39] showed the pooled mean biases in SBP and DBP of 2.54 ± 4.21 mmHg (range: −1. 80 to 13.19 mmHg) and 0.93 ± 2.22 (range: −1.00 to 5.86 mmHg) (see Supplementary material online, *Figure S2*). The mean biases between the devices using PPG for SBP and DBP were 12.09 ± 14.30 mmHg (range: −1.80 to 38.0 mmHg) and 3.27 ± 2.25 mmHg (range −0.33 to 5.86 mmHg) and for devices using PPG + ECG for SBP and DBP was 2.18 ± 1.01 mmHg (range: 0.50 to 3.20 mmHg) and 0.40 ± 1.56 mmHg (range: −0.80 to 2.60 mmHg) (See Supplementary material online, *Figure S3* and *S4*).

Risk of bias of the included studies

The quality of the studies varied (*Figure 3*). Risk of bias regarding patient selection was judged to be low in seven studies [31–33,35,38,42,45] and high in three studies.[34,44,46] Increased risk of bias was associated with insufficient data on patient enrolment and inappropriate exclusion criteria. The risk of bias regarding the index test and reference standards was low in all studies as all studies included validated devices. Five of the 16 studies did not report sufficient information regarding participant flow and timing, while this risk of bias was judged to be low in 10 studies.[31,35,36,39–41,43–46] Studies that used standardised validation protocols (e.g. European Society of Hypertension) had a lower risk of bias than studies that used custom validation protocols. Regarding the applicability for index and reference standards, all studies had a low risk of bias since data were generated by the test and reference devices without any human interpretations. Overall, seven studies showed a low risk of bias across all domains and the remaining nine studies were assessed as having a moderate risk of bias. In addition, all studies showed low concern regarding applicability.

Discussion

Our review identified a number of cuffless BP devices utilising different approaches for BP measurement, which were mostly prototypes and not available commercially. These devices used a range of different BP sensor technologies, but it remains unclear which sensors offer superior validity. While the clinical utility of cuffless BP devices is yet to be established, the ability to obtain accurate BP data with a device that captures this throughout daily living offers potential for cardiovascular risk assessment and management. Our findings may inspire further research and help pushing BP management in a new direction.

This systematic review and meta-analysis is the first to report the measurement accuracy of wearable cuffless BP devices. We found substantial variation in sensor technologies and validation

Table 2 Characteristics of wearable cuffless blood pressure devices

Author, year (device)	Sensors used for BP measurement	Device location (sensor position)	Comparison (reference device)	Validation protocol	Clinical applications (additional features)	Availability (prototype/ commercial)
Kim *et al.*,[32]	Magneto-plethysmography	Wrist	Auscultatory (Accoson Greenlight 300) and oscillatory (Omron HEM-7121) devices	IEEE standards	Bluetooth and App enabled (Tele monitoring).	Prototype
Nabeel *et al.*,[33]	PPG	Chest and finger	Brachial BP (automated oscillometric BP apparatus, SunTec 247™)	N/A	HR	Prototype
Park *et al.*,[34]	Radial artery tonometry pressure Sensor/PPG	Wrist	Wrist type BP device (OMRON-R6)	N/A[a]	BP	New method/Prototype
Nabeel *et al.*,[35]	PPG	Sensors placed on carotid artery	Automatic sphygmomanometer (SunTech 247, SunTech Medical, USA)	N/A	BP measurement and hypertension screening	Prototype
Zheng *et al.*,[36]	PPG and ECG	Arm and thorax	Oscillometric ambulatory BP monitor (SunTech Medical)	N/A	Night-time BP	Prototype
Noda *et al.*,[37]	PPG and ECG	Chest and finger	Oscillometric ambulatory BP monitor (FB-270, Fukuda denshi, Japan)	N/A	Sleep/night-time BP	Algorithm-based BP detection from ABPM
Boubouchairopoulou *et al.*, (Freescan)[38]	PPG and ECG	Wrist	Mercury sphygmomanometer	2013 ANSI/AAMI/ISO.	Pocket-size cuffless BP device, 60 grams	Prototype (Freescan, Maisense Inc., Taiwan)
Cohen et.al.,[39]	PPG	Ring (finger blood flow)	Cuff-based oscillometric device (NONIN 2120)	N/A	Ring-type sensor device, Oxygen saturation, HR	Prototype
Peng *et al.*,[40]	Auscultation sensors connected to smartphone	Chest (microphone sensors)	Using finger cuff Fiometer MIDI, Model II, Finapres Medical Systems B.V., The Netherlands	N/A	BP from heart sounds via mobile phone sensors	New method/Prototype
Schoot *et al.*, (Checkme)[41]	PPG (2)	Fingers (index, thumb and middle) and palm	Oscillometric BP monitor (Vital Signs Monitor 300, Welch Allyn, USA)	ESH International Protocol	BP, skin temperature, HR, oxygen saturation, ECG, sleep monitoring	Prototype (Checkme Health Monitor, Viatom Technologies, China)
Xin *et al.*,[42]	PPG	Wrist	Traditional Mercury BP device	N/A	Continues non-invasion BP and HR detection	Prototype
Garcia-Ortiz *et al.*,(B-pro)[31]	Tonometry	Wrist	SphygmoCor	ESH, AAMI and BHS (healthy Caucasians).	Night-time BP, Central augmentation index, carotid intima-media thickness,	Commercially available

Continued

Table 2 *Continued*

Author, year (device)	Sensors used for BP measurement	Device location (sensor position)	Comparison (reference device)	Validation protocol	Clinical applications (additional features)	Availability (prototype/ commercial)
				Previously validated in other population and hypertensives	ankle-brachial index, central aortic systolic pressure, peripheral BP and the radial augmentation index	
Bilo G *et al.*, Somnotouch-NIBP[43]	PPG	Finger	Standard wrist BP device	ESH-IP	Night-time BP, Continuous BP	Somnotouch-NIBP (Somnomedics GmbH, Germany) Commercially available
Carek *et al.* (SeismoWatch) [44]	PPG and Seissmo-cardiogram	Wristwatch	Finger-cuff BP sensor using volume clamp (ccNexfin)	N/A	ECG, HR	Prototype
Islam *et al.* (T2-Mart)[45]	PPG	Wrist	24-hours ambulatory BP device	IEEE	Night-time BP, Continuous BP, HR, Sleep	Commercially available
Ogink *et al.* (Checkme)[46]	PPG and ECG	Fingers (index, thumb, and middle) and palm	In hospital BP	N/A	BP, skin temperature, HR, oxygen saturation, ECG, sleep monitoring	Prototype (Checkme Health Monitor, Viatom Technologies, China)

N/A, not applicable or not clear; ECG = electrocardiogram; PPG = photoplethysmography; HR = heart rate; ANSI/AAMI/ISO = American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization; ESH = European Society of Hypertension; ESH-IP = ESH International Protocol; ABPM = ambulatory blood pressure monitoring; SBP = systolic blood pressure
[a]MAP and PP were within limits for the AAMI SP 10 criteria, and the results of SBP and DBP were not within limits for the AAMI SP 10 criteria. # STRIDE BP Validated Cuffless BP Monitor

Table 3 Practical and functional usability features of the wearable cuffless blood pressure BP devices

Author, year (device)	Calibration required	Long use time (battery life)	Costs	Alerts/ reminders	Data storage	Data viewing	Data transfer/ sharing	Related app
Kim *et al.*,[32]	Needed (at the beginning)	Yes	N/A	N/A	N/A	Via smartphone	Yes	Yes
Nabeel *et al.*,[33]	Needed (at the beginning)	N/A	N/A	N/A	N/A	Yes (external display unit, e.g., tablet)	N/A	N/A
Park *et al.*,[34]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Nabeel *et al.*,[35]	Not required	N/A	N/A	N/A	N/A	Yes (external display unit, e.g., tablet)	Yes	N/A
Zheng *et al.*,[36]	Only once	Every 30 min, Over 24-h	N/A	Yes	Yes	No	N/A	N/A
Noda *et al.*,[37]	Not-required	Continuous over 30-min	N/A	N/A	N/A	Yes (device's display screen)	N/A	N/A
Boubouchairopoulou *et al.*, (Freescan)[38]	Individualised initial calibration using standard BP monitor/+ last 2 BP	N/A	N/A	N/A	Yes	Yes (device's display screen)	N/A	N/A
Cohen et.al.,[39]	Pre-calibration	24-h (day and night) use possible	Low-cost	Yes	N/A	Yes (using an Arduino UNO microcontroller with a display screen)	Yes (Bluetooth/radio frequency/ internet)	N/A
Peng *et al.*,[40]	Not clear	Continuous	Low-cost	N/A	N/A	Yes (via smartphone)	N/A	N/A
Schoot *et al.*, (Checkme)[41]	Patient-specific calibration	N/A	N/A	N/A	N/A	Yes (device's screen)	Yes (via Bluetooth to mobile or tablet)	Yes
Xin *et al.*,[42]	N/A	Continuous (7D/ 24-h)	N/A	Yes	Yes	Yes (touch screen, as well as on multi-terminal ending e.g., phone using IoT)	Yes	Yes
Garcia-Ortiz *et al.*, (B-pro)[31]	Pre-use calibration by an arm-based oscillometric monitor.	Scheduled every 15-min over 24-h	High (~$3000)	N/A	Yes	Via device/computer	Yes	N/A
Bilo G *et al.*, Somnotouch-NIBP[43]	Initial calibration required	N/A	N/A	N/A	Yes	Via device/computer	Yes	N/A
Carek *et al.* (SeismoWatch)[44]	Required	BP at rest only	N/A	N/A	Yes		Bluetooth to mobile device	N/A
Islam *et al.* (T2-Mart)[45]	Not required	7–10 days battery life	$50	No	Yes	Via mobile phone app	No	Yes (Wearfit)
Ogink *et al.* (Checkme)[46]	Calibration required	N/A	N/A	N/A	N/A	Yes (device's screen)	Yes (via bluetooth to mobile or tablet)	Yes

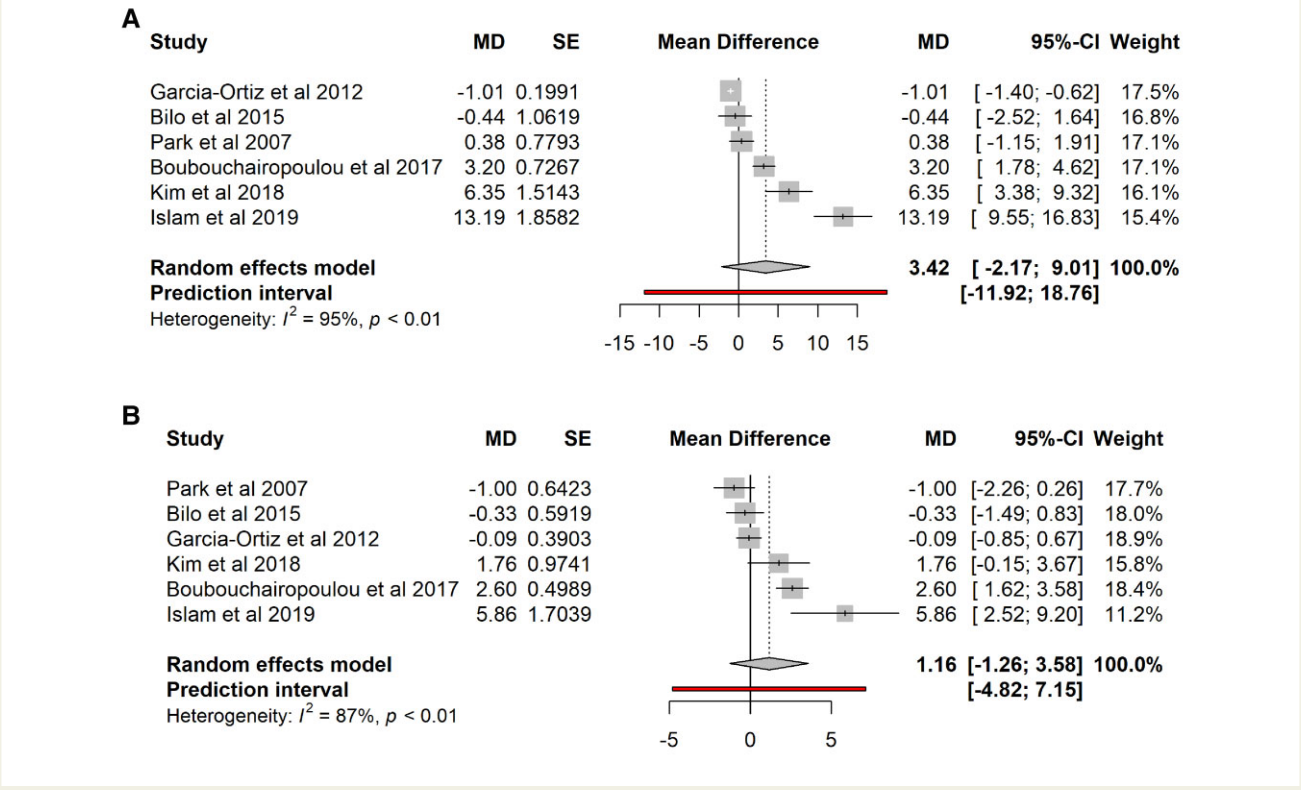


Figure 2 Pooled effects of bias in systolic and diastolic blood pressure measurement in various wearable devices. (*A*) Pooled effects of bias in SBP. (*B*) Pooled effects of bias in DBP.

approaches of these devices that limited their direct comparison. A challenge to the validation of these devices is that many of the cuffles devices obtained long-term measures or multiple measures over a shorter period. Yet the majority of validation used static ESH or AAMI protocols, which may not be suited to the cuffless device.[48]. This inhibits their recommended for current clinical use. An alternative approach would be to compare wearable BP data with long-term measurements, such as in a hospital or the clinic with an intra-arterial recording or continuous finopemter.

The majority of wearable cuffless devices included in this review estimated BP from measurements of PTT, PPG, finometer and PPG + ECG. Our results suggest that devices that used PPG + ECG to estimate BP performed better than those that used only PPG, which is in line with a study by Nitzan showing that PTT calculated using ECG + PPG had a better correlation with SBP than the PTT derived from PPG alone.[49] However, obtaining ECG can be problematic as it requires electrodes to be connected to the wearable device making it less suitable for use during daily activities. PPG is a simple technology based on measurement of changes in light absorption with a light-emitting diode to illuminate the skin and a photodetector which can be integrated into portable devices.[50]

The main usability of the wearable devices is to measure BP during activities of daily living and over-time to which is important for managing high BP. However, BP varies throughout the day and is affected by temperature, daily activities, including eating, physical activity or sedentary time and different exercise conditions.[51] It is not clear how the wearable devices in this review adjusted for these various conditions as detailed algorithms for BP measurements were not provided by the majority of the studies. Most of the included devices required BP to be measured at rest and not during exercise or continuously and measurements were affected by body movements and active noises, thereby limiting their use. Battery life is a critical feature for wearable devices, especially for long-term BP measurement, which could inform clinical decisions about medication use and titration by a better understanding of BP patterns and stability.

While some PPG-based wearable cuffless devices appear to measure BP within 5 mmHg of reference device, there are opportunities for improvement. First, BP detection algorithms need to consider movement artefacts and individual physiological variations to represent true BP.[52] Although individual physiological variations can be taken into account via the calibration this has not been clearly mentioned in the included studies. Second, BP measurement algorithms should be based on large cohorts of participants from diverse populations.[50] Finally, there is need to report measurement precision.

Although the primary function of devices in this review was to measure BP, several devices were capable of measuring other vital signs, including heart rate, ECG, oxygen saturation, physical activity and sleep. These additional functions can provide contextual data to guide interpretation of BP status. In addition, mobile connectivity offers opportunities to deliver context-aware BP-related alerts and reminders directly to participants, connect with clinicians and web-based care platforms for long-term BP management. These additional features could further improve management of high BP and

Study	RISK OF BIAS				APPLICABILITY CONCERNS		
	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD	FLOW AND TIMING	PATIENT SELECTION	INDEX TEST	REFERENCE STANDARD
Kim et al., 2018	☺	☺	☺	?	☺	☺	☺
Nabeel et.al., 2017	☺	☺	☺	?	☺	☺	☺
Park et al., 2007	☹	☺	☺	?	☹	☺	☺
Nabeel et.al., 2018	☺	☺	☺	☺	☺	☺	☺
Zheng et al., 2014	?	☺	☺	☺	?	☺	☺
Noda et.al., 2014	?	☺	☺	?	?	☺	☺
Boubouchairopoulou et.al., 2017	☺	☺	☺	?	☺	☺	☺
Cohen et al., 2017	?	☺	☺	☺	☺	☺	☺
Peng et al., 2015	?	☺	☺	☺	☺	☺	☺
Schoot et.al., 2016	?	☺	☺	☺	☺	☺	☺
Xin et.al., 2017	☺	☺	☺	?	☺	☺	☺
Garcia-Ortiz et al., 2012	☺	☺	☺	☺	☺	☺	☺
Bilo G et al., 2015	?	☺	☺	☺	☺	☺	☺
Carek et al. 2017	☹	☺	☺	☺	☹	☺	☺
Islam et al. 2019	☺	☺	☺	☺	☺	☺	☺
Ogink et al. 2019	☹	☺	☺	☺	☺	☺	☺

☺ Low Risk ☹ High Risk ? Unclear Risk

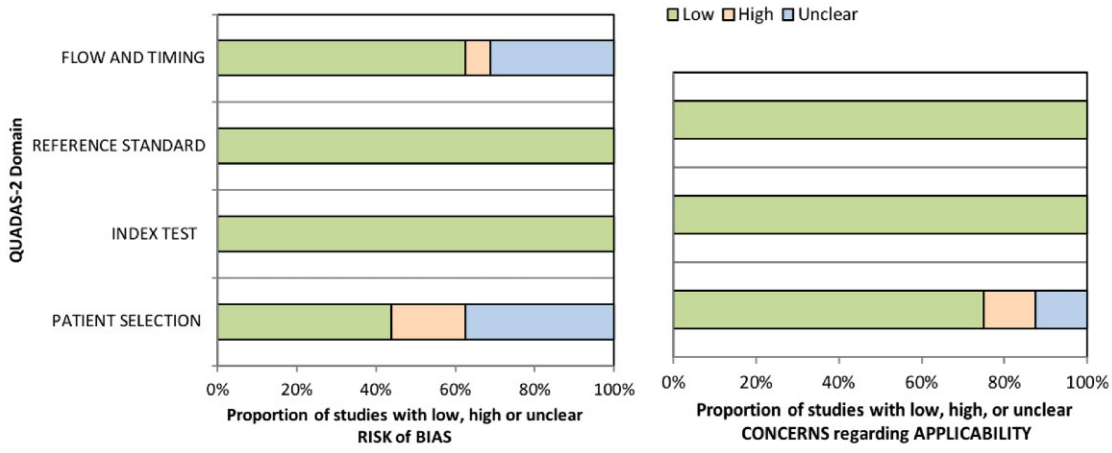


Figure 3 Risk of bias assessment using the QUADAS-2.

represent significant advantages over traditional BP devices.[53] Previous studies have reported that the wearable BP devices were easy to use and acceptable among users,[46] and healthcare providers found the utility of the devices for clinical use if the measurements were accurate.[45] Despite these positive findings, the use of wearable BP device in clinics has yet to be initiated.

This review has some limitations. First, studies used a broad range of BP measurement protocols and reference devices due to a lack of consensus on wearable BP device validation. While we extracted data measuring BP at rest, methodological differences and uncertainty in reporting protocol adherence made it difficult to directly compare the accuracy between different types of sensor technologies (e.g. PPG vs. non-PPG, PPG vs. ECG), location (e.g. wrist, finger, chest), and devotion to IEEE standards. Second, our indicator definition of BP validity <5 mmHg for SBP and DBP represents a significant data limitation. This specification was 'chosen' due to the lack of

more nuanced metrics for wearable BP device validation in international guidelines (IEEE standards for cuffless BP devices). Our definition of validity did not include assessment of device measurement precision, which is assessed by standard deviation of the MD and is a critical component of ISO protocol validation criteria. Therefore, the results of the study should be interpreted with caution.Third, only three studies provided detailed algorithms for BP measurements. The lack of details pertaining to the underlying sensing methods and algorithms—aspects which dictate calibration requirements are limitations of this study and barriers for widespread adoption of the technology. In addition, it is not clear how the calibration free devices accounted for individual physiological differences. Fourth, evaluation of the overall sensitivity, specificity, and ROC curves were not possible because of the absence of specific cut-off points for BP differences between studies. Therefore, the pooled analysis does not represent effect size but rather how well an individual devices in general perform against other devices. Fifth, SD was not reported by 8 studies and 3 studies reported SD for SBP only, which is a significant limitation of the individual study methods and reporting. Finally, the majority of studies measured BP among young people in clinical and supervised settings, and their validity for use in activities of daily living and in older people remains unclear.

Advances in recent technologies have improved power efficiency and battery life in wearable devices leading to development of more efficient devices. In 2020, Samsung Galaxy device and health monitor app received clearance from South Korea's Ministry of Food and Drug Safety which has substantial utility for BP measurement. The Seismo watch measured BP using seismocardiography by placing the watch against the sternum to detect micro-vibration of the chest wall associated with the heartbeat.[44] Other wearable BP devices, for example, the Glabella used a pair of wearable spectacles [54] and Naptics used a wearable short to assess BP[55]. Long-term BP measurement could enhance diagnosis of hypertension among at-risk populations, help medication titration and enable appraisal of BP regulation in response to physiological factors. Thus, wearable devices could improve BP management by using machine learning and providing new treatment strategies.[56–60] However, more user-centric designs in diverse population groups and robust trials are needed to demonstrate the effectiveness and cost-effectiveness for long-term BP measurement. There is a need for developing universal standards for wearable BP device validation, reporting, and interpretation. Future wearable BP device studies should provide the detailed of calibration methods, number of BP measurements, MD, standard deviations, measurement precision, and algorithms based on international standards.[61]

Conclusion

Wearable cuffless devices are a promising tool for long-term BP measurement. However, challenges such as validation using standard protocols and in real-life settings must be overcome before they can be recommended for uptake into clinical practice. The current review suggests wearable cuffless BP devices are still in their infancy as most were prototypes and not available commercially, yet the area is moving rapidly. Current devices use a range of different BP sensor technologies, but it remains unclear which sensors offer superior validity. Further studies comparing different wearable BP devices using a standardized validation protocol are required. Research into the role and clinical utility of these devices and particularly whether they can augment and improve BP management are needed.

Lead author biography

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Supplementary material

Supplementary material is available at *European Heart Journal – Digital Health*

Author's contributions

S.M.S.I.: concept, study protocol development, data analysis, and drafting; C.K.C.: concept, supervision, and reviewing; R.D.: data extraction and review; N.S.: searching and review; J.R.: interpretation, review, and drafting; C.K.: data analysis, T.T.: meta-analysis and review; G.L.: concept and review; R.M.: supervision and review.

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Data availability

Data is available from First author on request.

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