International Journal of Research in Medical Sciences
Kiron V et al. Int J Res Med Sci. 2026 Mar;14(3):965-968
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20260611

Original Research Article

Comparative evaluation of a novel multisensor device EYVA versus standard clinical sphygmomanometry for blood pressure measurement: a paired observational study

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Received: 23 July 2025
Revised: 20 August 2025
Accepted: 27 January 2026

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ABSTRACT

Background: Reliable and accessible blood pressure (BP) monitoring is vital for effective hypertension management. EYVA, a novel multisensor device, aims to provide accurate, non-invasive BP measurement. We evaluated EYVA's accuracy compared with standard clinical sphygmomanometry.
Methods: A paired observational study involving 442 adult participants was conducted from June 2022 to August 2022. Blood pressure was sequentially measured using EYVA and a standard-of-care (SOC) sphygmomanometers under resting conditions. Paired t-tests, Pearson correlation and Bland-Altman analyses assessed agreement and consistency between methods.
Results: EYVA showed strong agreement with standard of care (SOC) for both systolic and diastolic BP. Mean systolic BP was 127.69±16.29 mmHg with EYVA and 126.77±16.90 mmHg with SOC, with a bias of 0.93 mmHg ($p<0.001$) and Pearson correlation $r=0.94$. Diastolic BP averaged 84.19±11.74 mmHg (EYVA) and 83.45±12.48 mmHg (SOC), with a bias of 0.74 mmHg ($p<0.001$) and correlation $r = 0.95$. Bland-Altman analysis indicated limits of agreement of ±11.25 mmHg for systolic and ±7.64 mmHg for diastolic measurements.
Conclusions: The EYVA device demonstrates clinically acceptable agreement with standard BP measurements, supporting its utility for clinical and home-based BP monitoring.

Keywords: Blood pressure, Digital health, EYVA, Hypertension, Multisensor device, Sphygmomanometer, Validation

INTRODUCTION

Systemic arterial hypertension or essential hypertension is a global epidemic, and India is home to more than 220 million adults with hypertension. Over two-thirds of those patients are undiagnosed, only one in five receives treatment regularly and only one in twelve achieves adequate BP control.[1] Hypertension, often termed the 'silent killer', remains asymptomatic until major complications arise and can affect multiple organs and systems, making early detection and management pivotal.[2] In the realm of cardiovascular health, hypertension not only accelerates arterial damage but also serves as a precursor to kidney dysfunction and retinal harm. Its prevalence highlights the urgent need for innovative approaches to treatment and monitoring.[2]

Two clinically accepted gold-standard methods for blood pressure measurement are invasive arterial catheterization and the non-invasive cuff sphygmomanometer.[3] While invasive measurement is reserved for the critically ill, the non-invasive cuff device is the most common method in routine practice. There is growing interest in remote monitoring and shared decision-making in the

management of hypertension, necessitating the development of reliable home-based monitoring devices.[4] Photoplethysmography (PPG)-based cuff-less BP monitors are emerging as key players in digital health due to their accuracy and ease of use.[5] Beyond remote monitoring, emerging technologies such as telemonitoring platforms and artificial-intelligence driven predictive tools are being explored to enhance hypertension management.[6]

EYVA is a novel multisensor wearable device that utilizes photoplethysmography (PPG), tonometry, and machine learning algorithms to estimate BP non-invasively. This study aimed to validate EYVA against standard sphygmomanometry in a tertiary-care setting, with the goal of determining its agreement, reliability, and potential for clinical integration. The release of the 2025 AHA/ACC Hypertension Guidelines has renewed focus on accurate, reproducible, and home-based BP monitoring to improve hypertension detection and control.[7] These updates reinforce the need to evaluate emerging technologies like EYVA for both clinical and home applications.

Objective

This study aimed to compare the accuracy of the EYVA multisensor device with a standard digital sphygmomanometer for measuring blood pressure in adults. We hypothesized that EYVA would provide BP values that agree closely with those obtained using standard clinical sphygmomanometry.

METHODS

Study design and data collection

Subjects involved in the study were invited to the T-hub Health Centre, Hyderabad, India between June 2022 and August 2022, where data collection was supervised by trained professionals. Prior to enrolment, participants were educated on how to use EYVA and were required to have completed at least 30 practice scans. After providing informed consent, participants recorded their name, age, and gender into the EYVA app. On the study day, participants were seated comfortably in a chair and instructed to obtain paired blood-pressure measurements from EYVA and from a standard digital blood-pressure monitor. The cuff of the reference device was placed on the participant's left arm, and three consecutive readings were taken; the average of these readings was used as the reference BP. Participants then obtained three consecutive EYVA scans through their profile in the EYVA application, and the average of these three values was considered the EYVA BP measurement. The study adhered to the principles of the Declaration of Helsinki, and informed consent was obtained from all participants.

Participants

A convenience sample of 442 participants with an equal distribution of male (221) and female (221) participants was recruited. Ages ranged from 12 to 85 years (mean 49.67 years). Individuals under 12 years of age, those unable to hold the EYVA gadget with a steady posture, or patients with uncontrolled hypertension requiring immediate medical attention were excluded. Twenty-one subjects meeting these exclusion criteria were not enrolled. Demographic and clinical characteristics are summarized in Table 1.

Technology

Digital blood-pressure monitor

The digital sphygmomanometer uses an oscillometric method. An inflatable cuff is wrapped around the upper arm and inflated via a pump until arterial flow is occluded. Pressure is then gradually released through a digitally controlled valve. The pressure at which arterial pulsations first appear corresponds to the systolic pressure and the pressure when pulsations disappear corresponds to the diastolic pressure. These readings are displayed automatically by the device. Digital BP monitors have been widely accepted by regulatory agencies such as the FDA, EMA, MHRA and CDSCO, making them suitable as reference markers for this study.[8]

EYVA multisensor device

EYVA is a non-invasive multisensor health-tracking gadget that can measure blood glucose, HbA_1c, blood pressure, ECG, oxygen saturation and heart rate. For this study, only the blood-pressure functionality was analyzed. Participants placed both thumb tips on the EYVA sensors, having sanitized their hands and ensured a calm environment. The device acquires a PPG signal from the fingertips. Ambient light artefacts are cancelled, baseline drift and motion artefacts are removed and a peak-detection algorithm identifies systolic and diastolic peaks. Signals with inconsistent peaks awee discarded. After peak detection, the signal's second derivative is computed and a proprietary algorithm calculates blood pressure values. Filtering of the PPG signal is crucial for accurate BP estimation.[9]

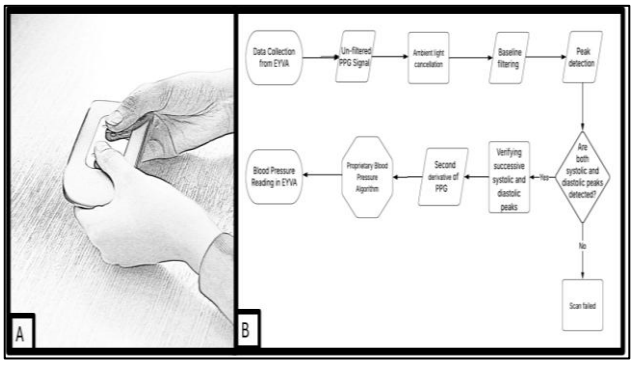

Figure 1: (A) EYVA- the world's first metabolic health tracker. (B) Flow chart of the algorithm to measure blood pressure in EYVA.

Statistical analysis

Descriptive statistics were calculated for demographic and clinical variables. Mean and standard deviation (SD) were used for continuous variables and counts and percentages for categorical variables. Agreement between EYVA and SOC measurements was assessed using paired t-tests, Pearson correlation coefficients and Bland-Altman plots. Statistical significance was set at $p<0.05$.

RESULTS

Table 1 shows the demographic and clinical characteristics of the study participants. Half of the participants were male and half were female. The mean age was 49.67 years with a range of 12 to 85 years. More than half of participants (54.5%) were receiving antihypertensive medication, 38.9% were diabetic and 26.5% had a systolic BP≥140 mmHg.

Table 1: Demographic and clinical characteristics of the study participants.

Characteristic	Statistic	Value
Participants	N	442
Mean age years (range)	49.67 (12-85)	
Male sex	N (%)	221 (50)
Female sex	N (%)	221 (50)
On antihypertensive medication	N (%)	241 (54.5)
Diabetes	N (%)	172 (38.9)
Systolic BP≥140 mmHg	N (%)	117 (26.5)

Table 2: Comparison of blood-pressure measurements obtained with EYVA and the standard digital sphygmomanometer.

Parameter	EYVA mean±SD (mmHg)	SOC mean±SD (mmHg)	Bias (mmHg)	Pearson r	P value	Limits of agreement (mmHg)
Systolic BP	127.69±16.29	126.77±16.90	0.93	0.94	<0.001	−11.25 to +11.25
Diastolic BP	84.19±11.74	83.45±12.48	0.74	0.95	<0.001	−7.64 to +7.64

Table 2 summarizes the paired BP measurements obtained with EYVA and the standard digital sphygmomanometer. EYVA showed strong agreement with SOC for both systolic and diastolic BP. The mean difference (bias) was less than 1 mmHg for both parameters, and Pearson correlation coefficients were 0.94 for systolic and 0.95 for diastolic readings ($p<0.001$ for both). The 95% limits of agreement were ±11.25 mmHg for systolic and ±7.64 mmHg for diastolic measurements.

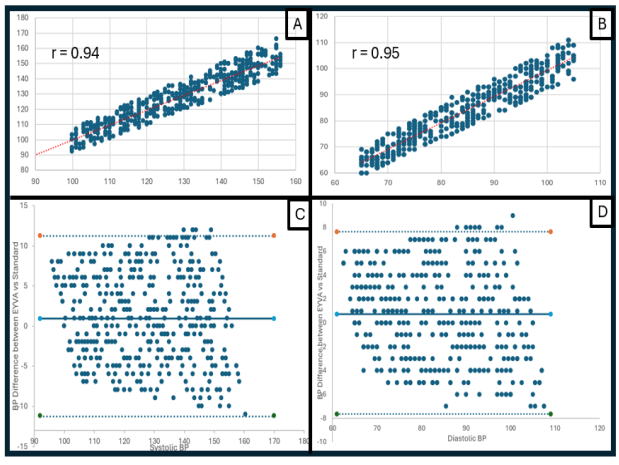

Figure 2: (A) Correlation plot of systolic blood pressure, (B) correlation plot of diastolic blood pressure, (C) Bland-Altman plot of systolic blood pressure, (D) Bland-Altman plot of diastolic blood pressure.

DISCUSSION

In this validation study, the EYVA multisensor device demonstrated tight agreement with standard sphygmomanometry. The mean bias of <1 mmHg and high correlation coefficients (>0.94) indicate strong consistency and clinical comparability. These results align favorably with prior studies evaluating cuff-less BP devices.

A 2022 systematic review and meta-analysis evaluating 15 cuff-less BP devices reported a pooled mean difference of 3.42 mmHg for systolic and 1.16 mmHg for diastolic BP when compared to reference standards. The authors concluded that although results were promising, variability across devices and calibration protocols remained a concern.[10] EYVA's smaller bias and narrower LoA suggest comparable or superior accuracy within current validation thresholds.

The European Society of Hypertension (ESH) 2023 Working Group recommendations emphasize that cuff-less BP device validation requires a comprehensive framework, including six tests- static accuracy, device position robustness, treatment test (BP decrease), awake/asleep accuracy, exercise response, and recalibration stability.[11] EYVA's validation in this study primarily addressed static accuracy under resting conditions. Future research should incorporate the full validation spectrum to meet international standards (ISO 81060-3:2022).[12]

The 2025 AHA/ACC Hypertension Guidelines reiterate that reliable home BP monitoring is integral to diagnosis and management. These guidelines classify normal BP as <120/80 mmHg, elevated BP as 120-129/<80 mmHg, and hypertension as ≥130/80 mmHg. The new guidelines also highlight the clinical importance of early BP control to mitigate cognitive decline and cardiovascular risk. EYVA's ease of use positions it well for long-term monitoring and telemedicine-based hypertension programs.

While the 2025 AHA/ACC hypertension guidelines currently state that cuff-less BP devices are not yet recommended for diagnostic use (class III: no benefit, level of evidence C-LD), the field is evolving rapidly.[7] Ongoing refinement of calibration algorithms, sensor fidelity, and machine-learning correction factors could soon close this gap, especially if devices consistently meet validation criteria across physiological conditions.

Limitations of this study include the absence of dynamic validation tests (e.g., exercise, posture changes, recalibration stability), and potential variability due to environmental or individual physiological factors. EYVA's performance under ambulatory or long-term use conditions remains to be assessed. This was a cross-sectional study and the clinical use in guiding antihypertensive therapy has not been studied.

In context, our findings demonstrate that EYVA performs within acceptable clinical limits and may bridge the gap between conventional cuff-based and continuous monitoring systems. Strengths of this study include a large sample size and robust paired comparison methodology. Its application could complement existing hypertension management protocols and aligns with global trends emphasizing accessible, patient-centered monitoring solutions.

CONCLUSION

The EYVA multisensor device shows strong agreement with standard sphygmomanometric BP measurements under resting conditions. Despite certain limitations inherent to cuff-less technology, EYVA's high correlation and minimal bias underscore its potential as a reliable adjunct for home and telehealth monitoring. Future studies integrating full validation frameworks (per ESH and ISO standards) are warranted.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kiron V, Navuluri SK, Nadiminti CS. Comparative evaluation of a novel multisensor device EYVA versus standard clinical sphygmomanometry for blood pressure measurement: a paired observational study. Int J Res Med Sci 2026;14:965-8.