Original Article

V-CHEK Clinical Trial: A Comprehensive Evaluation of Cuffless Blood Pressure Monitoring Device in a Large-scale Indian Patient with Cardiovascular Diseases

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Abstract

Background: Conventional blood pressure (BP) measurement devices using inflatable cuffs offer limited snapshots of BP profiles. Cuffless BP technologies enable continuous monitoring, potentially revolutionizing hypertension management by providing comprehensive daily data. **Objective:** To compare the accuracy of a commercially available cuffless BP monitor (V-CHEK device) against a mercury sphygmomanometer and pulse oximeter for measuring BP, heart rate, and oxygen saturation (SpO_2) in resting conditions. **Methods:** In this cross-sectional study at Sri Jayadeva Institute of Cardiovascular Sciences and Research, 250 patients underwent daytime BP, heart rate, and SpO_2 measurements using both the V-CHEK device and a mercury sphygmomanometer/pulse oximeter. Statistical analysis included Bland-Altman agreement assessment with 95% confidence intervals (CIs). **Results:** BP: No significant difference between devices; bias: −0.377 mmHg (95% CI: −0.758 to 0.004) Heart rate: Bias: −0.078 bpm (95% CI: −0.253 to 0.098). SpO_2: Marginal bias: 0.173% (95% CI: −0.23 to −0.103). All parameters showed strong agreement, with SpO_2 demonstrating slightly lower concordance. **Conclusion:** The V-CHEK cuffless device provides BP, heart rate, and SpO_2 measurements comparable to traditional sphygmomanometry in resting conditions, supporting its potential for clinical and ambulatory use.

Keywords: Cuffless blood pressure, hypertension, photoplethysmography, sphygmomanometer

Introduction

In the era of advanced digital health technology, the approach to blood pressure (BP) monitoring is undergoing a paradigm shift from traditional methods, such as in-office and home BP monitoring, toward cuffless and wearable technology. This shift is driven by the limitations of traditional cuff-based methods, which can be cumbersome, inconvenient, and potentially inaccurate, especially for frequent measurements or individuals with limited mobility.

Traditional cuff-based BP monitoring methods face several challenges. The American Heart Association statement on BP measurement[1] emphasizes that cuff-based devices are reliable only when multiple physician-and patient-related variables are considered, including proper cuff size, placement, and patient technique.[2,3] In addition, many users lack the knowledge of correct cuff usage, which can lead to erroneous BP readings, potentially impacting the diagnosis and management of hypertension (HTN). The traditional cuff-based method, introduced by Scipione Riva-Rocci almost 125 years ago, has remained largely unchanged.[4] This cumbersome nature of cuff-based methods, along with the growing need for frequent BP monitoring, has motivated researchers to explore cuffless BP monitoring techniques. Advancements in sensor technology, signal processing techniques, and machine learning algorithms have opened up opportunities for newer cuffless methods. These methods aim to establish precise relationships between biomedical signals, such as pulse transit time or photoplethysmography (PPG), and changes in BP, offering a more convenient and user-friendly approach to BP monitoring.

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Some cuffless BP monitoring devices have the potential to address the limitations of traditional methods and provide a more accessible, convenient, and accurate approach to BP monitoring.[1] V-CHEK has designed and developed noninvasive, cuffless BP monitor that measures BP, heart rate, and oxygen saturation (SpO2) parameters. V-CHEK measures BP data following an initialization process using sphygmomanometer [Figure 1].[5-7] Optical sensors embedded in an integrated hardware and software solution, and it measures BP by capturing physiological signals at the user's fingertip. Waveforms obtained by these sensors are analyzed by V-CHEK algorithms to determine systolic BP (SBP) and diastolic BP (DBP) changes relative to the calibration point. The measured BP data are displayed on the device and the smartphone application using Bluetooth. This device requires no patient interaction, making it a comfortable and convenient option for daily home BP measurements.

Recognizing the need for more accessible, convenient, and accurate BP monitoring solutions, the present study aims to evaluate the clinical performance of V-CHEK, a cuffless BP monitoring device designed to overcome the shortcomings of traditional methods. Developed by leveraging innovative technologies, V-CHEK offers a noninvasive and user-friendly approach to BP measurement, allowing for seamless integration into daily life and routine monitoring by patients in home settings.

The primary objectives of this study are twofold: first, to assess the accuracy and reliability of V-CHEK in comparison to traditional BP measurement devices, including mercury-based sphygmomanometers, when used by trained staff, is considered gold standard; and second, to evaluate the usability and feasibility of V-CHEK for routine self-monitoring of BP by patients. By conducting a comprehensive evaluation of V-CHEK's performance and usability, this study aims to provide valuable insights into its potential role in transforming BP monitoring practices and improving patient outcomes. Through rigorous testing and analysis, we seek to demonstrate the clinical validity and utility of V-CHEK as a reliable tool for BP measurement in diverse patient populations.

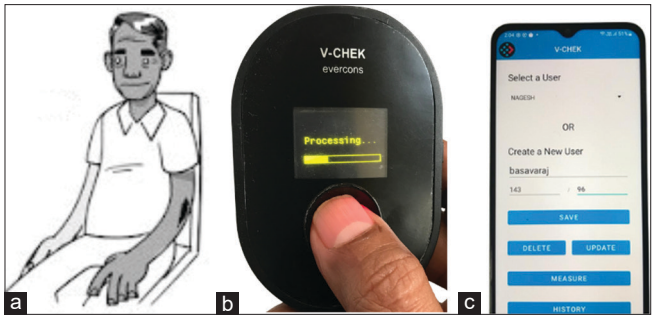


Figure 1: Test set up – V-CHEK device and mobile App. (a) Patient set up. (b) V-CHEK device. (c) patient details on V-CHEK mobile App

Methods

Study population

A clinical trial involving 250 patients with cardiovascular diseases was conducted in Bangalore, India. Patients admitted to the hospital were enrolled and their BP, heart rate, and SpO2 were measured multiple times using both a reference mercury sphygmomanometer and the V-CHEK device. The mercury manometer has long been considered the gold standard for BP measurement, with decades of established use in clinical practice and research. Its historical significance as a reference standard provides valuable context for evaluating the accuracy and reliability of new BP measurement technologies. Government of India has come up with a gradual phasing out mercury manometer. While recognizing the limitations associated with the use of mercury manometers, including safety concerns and practical constraints, we acknowledge these factors in our study. While the mercury manometer may not be commonly used in contemporary practice, its clinical validity as a reference standard remains undisputed. The inclusion of the mercury manometer comparison enhances the scientific rigor of our study by adhering to recognized standards and methodologies for validation research. In the absence of a universally accepted alternative gold standard for BP measurement, the mercury manometer was chosen as the comparator in our study to provide a robust benchmark.

More than 80% of the subjects were inpatients admitted to the hospital. Some factors while choosing the subjects include logistical consideration – need for the close monitoring of the patient's condition over the period of time, controlled environment, and the clinical relevance – inpatients often present with a range of medical conditions and comorbidities that may impact BP readings differently than stable outpatient populations. BP measurements were taken between 9–10 am, 12 pm and 2 pm, and in the evening 7 pm to 8 pm. These readings were taken by staff nurses in the presence of duty doctors.

The sample size of 250 patients was determined based on statistical power calculations to ensure adequate representation and robustness of the study findings. A power analysis was conducted to estimate the sample size required to detect significant differences or effects with a predefined level of statistical power (typically 80% or higher) and a significance level (alpha) of 0.05. Other factors include previous studies, clinical relevance, and resource constraints such as available resources, time constraints, and feasibility.

Table 1 shows the demographic and clinical characteristics of the enrolled patients:

The clinical trial was approved by the local ethics committee and all patients provided written informed consent.

Inclusion criteria were:

- Patients with HTN
- Patients with cardiovascular disease including atrial fibrillation

- Healthy employees of the institution
- Patients with comorbidities and
- Geriatric patients.

Exclusion criteria was:

- Pregnant women
- Severe cardiovascular or respiratory diseases that could interfere with the study procedures
- History of recent myocardial infarction, stroke, or unstable angina
- Patients below 18 years.

Measurements with blood pressure modalities

Cuffless BP monitoring devices have the potential to address the limitations of traditional methods and provide a more accessible, convenient, and accurate approach to BP monitoring. However, robust validation of these devices is crucial to ensure their reliability and efficacy, particularly in diverse populations like India with unique demographic and physiological characteristics. This study aims to validate the efficacy of a new cuffless and finger-based BP monitor device against the existing gold standard, the mercury-based sphygmomanometer, in the Indian population. The study will also evaluate the device's ability to measure heart rate and SpO2 (blood SpO2) accurately compared to the best instruments used by hospitals in India.

Materials and Methods

This study was a prospective, observational study designed to evaluate the accuracy of a new cuffless and finger-based BP monitor device against the existing gold standard, the mercury-based sphygmomanometer, in the Indian population. The study also evaluated the device's ability to measure heart rate and SpO2 (blood SpO2) accurately compared to the best instruments used by hospital.

A clinical trial conducted at 3rd, 4th, and 5th floor General wards, Sri Jayadeva Institute of Cardiovascular Sciences and Research, Jayanagar 9th Block, Bannerghatta Road, Bangalore-560 069, Karnataka, India.

Table 1: The demographic table of the subjects

Variable (demographic)	Levels	Frequency (%)
Sex	Female	109 (43.6)
	Male	141 (56.4)
Food habit	Nonveg	210 (84)
	Veg	40 (16)
Smoke	No	200 (80)
	Yes	50 (20)
Alcohol	No	192 (76.8)
	Yes	58 (23.2)
Family history of HT	No	43 (33.08)
	Yes	87 (66.92)
Variable (clinical characteristics)	***n***	**Mean±SD**
Age (years)	250	51.55±13.06
Duration of diabetes (years)	249	3.63±5.86
Duration of HT (years)	249	3.9±5.42
SBP (mmHg) (standard)	248	122.78±20.35
DBP (mmHg) (standard)	248	79.35±12.11
PR (bpm) (standard)	248	80.36±13.18
SpO_2 (%) (standard)	248	97.23±1.59

HT: Hypertension, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, PR: Pulse rate, SpO_2: Oxygen saturation, SD: Standard deviation

Study design

Operating protocol

Observer training and measurement

Before the commencement of the clinical trial, two experienced medical professionals were trained to get familiar with the data-collecting procedure and device operation including Android Mobile App usage.

Subject selection and description of participants

A total of 250 patients were participated in the clinical trial. Out of 250, 24 participants were the employees of the institute, and the remaining participants were the patients admitted in the Institute. Each participant's name, age, sex, urban/rural, income, marital status, alcoholic habit, Gutkha/drugs, HTN (years), diabetes (years), family history of HTN, current medication, and medical history were collected and recorded in the Pro forma.

Calibration protocol

1. Before calibration, patients were rested for 5 min in a seated position with their hand open and relaxed and legs uncrossed as shown in Figure 1a. Below is the setup.
2. BP reference measurement using mercury-based sphygmomanometer
   i. In the mobile app, create a unique patient profile by entering your name before proceeding with the reference BP measurement as shown in Figure 1b and 1c
   ii. Perform three reference BP measurements (designated Ref1, Ref2, and Ref3) and record the SBP and DBP values in mmHg units
   iii. Calculate the average of the three SBP and DBP values obtained from the reference measurements
   iv. Enter the averaged SBP and DBP values in the systole and diastolic fields within the mobile app [Figure 2].

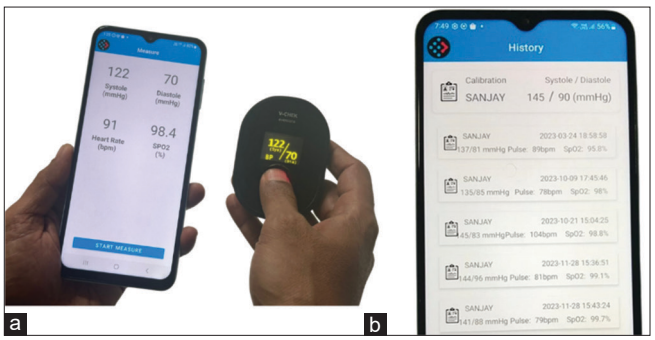


Figure 2: Result storage and display on V-CHEK device and the App. (a) Readings displayed in V-CHEK and APP. (b) Readings stored in APP

3. Test device (V-CHEK) measurement
   i. Immediately after the reference measurement is completed (within 60 s), perform the V-CHEK measurement. Follow the calibration instructions in the V-CHEK Android application, which involve selecting a username and entering reference values in the designated text boxes [Figure 5]
   ii. Place the patient's right index finger or thumb gently on the sensor, avoiding excessive pressure. Users should maintain steady finger pressure on the PPG sensor and remain silent during the measurement
   iii. V-CHEK will display the calibration progress and show a success message once completed. Keep the finger on the sensor until all four vital signs are displayed: heart rate, SpO2, SBP), and DBP. This typically takes 40–60 s, depending on the quality of the PPG signal
   iv. Note that BP values continuously update on the V-CHEK device and the Android App until the finger lifts. The reading closest to the reference measurement will be automatically selected.

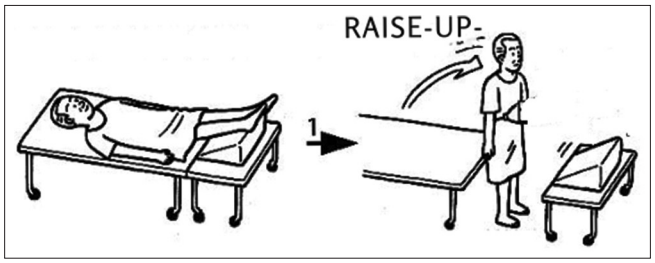


Figure 3: Changing the body position for inducing blood pressure values

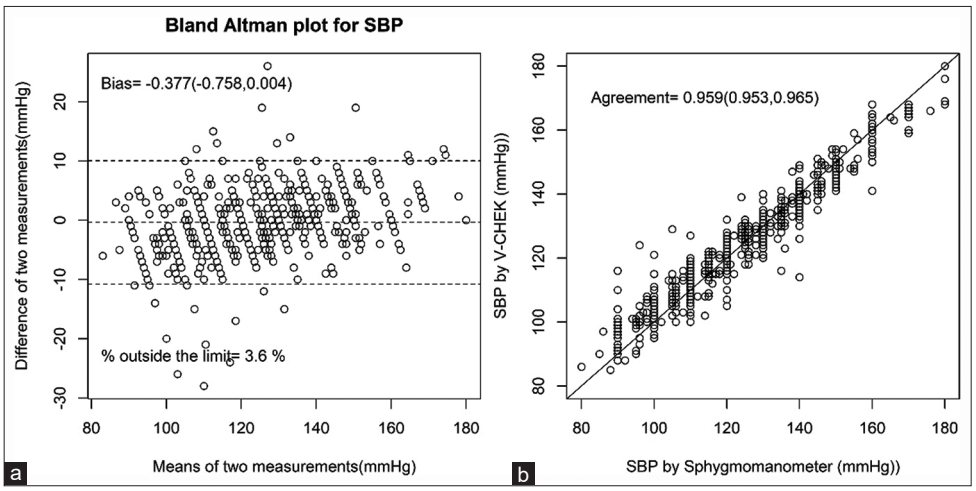


Figure 4: (a) Bland altman plot and statistics that plotted difference in measurements of systolic blood pressure (SBP) by two method against means of these two measurements along with dotted lines indicates bias (middle) and limit of agreement (outer) (b) Scatter plot of SBP by V-CHEK against the same by sphygmomanometer on the line of prefect agreement with embedded Pearson's correlation coefficient as a measure agreement. SBP: Systolic blood pressure

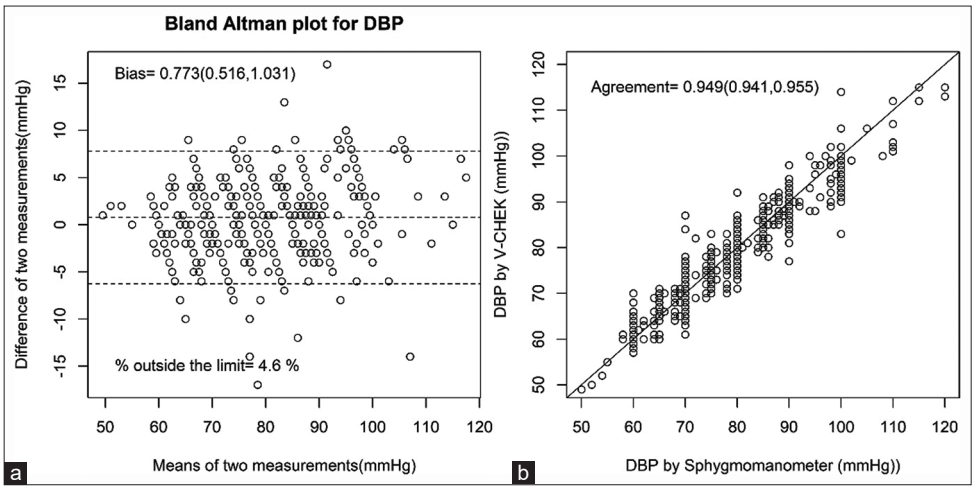


Figure 5: (a) Bland altman plot and statistics that plotted difference in measurements of diastolic blood pressure (DBP) by two method against means of these two measurements along with dotted lines indicates bias (middle) and limit of agreement (outer). (b) Scatter plot of DBP by V-CHEK against the same by sphygmomanometer on the line of prefect agreement with embedded Pearson's correlation coefficient as a measure agreement. DBP: Diastolic blood pressure

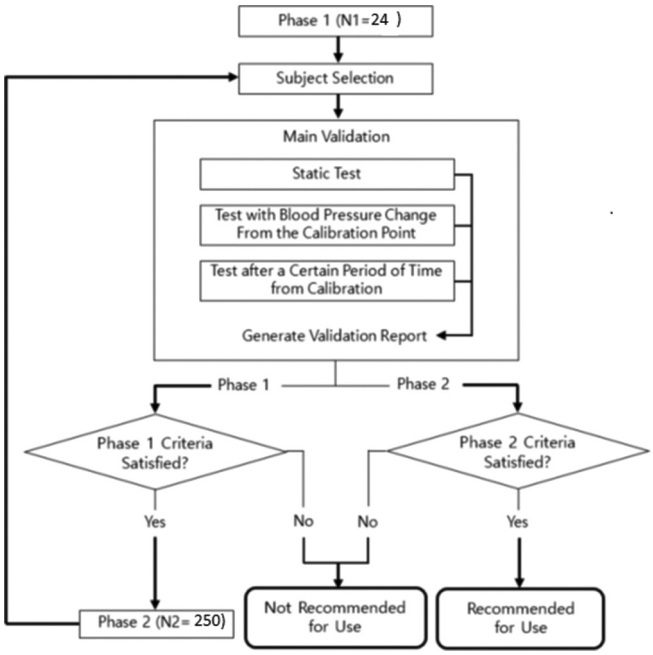
Static testing

Static testing was conducted under resting conditions as shown in Figure 1a and at room temperature. It has been done in two phases. In Phase 1, only 24 subjects were recruited to assess the device's accuracy. Twenty employees of the institute were healthy and four subjects were patients of the institute to check the accuracy of the device at the very early stage. Accuracy criteria were set to assess the accuracy of the device.

Validation criteria

To analyze the data in Phase 1, mean absolute difference (MAD) and mean absolute percentage difference were calculated to assess the accuracy. The MAD calculated as,

$$MAD = \frac{\Sigma \left| \chi_i - \bar{\chi} \right|}{n}$$



Flowchart 1: Testing methodology

Where x_i is the V-CHEK measurement, mean x is the reference device measurement, and n is the sample size.

In Phase 1, MAD is less than 7 which means the clinical trials can be moved to Phase 2 where evaluation of the remaining 226 patients is to be conducted. Evaluation for Phase 2 was conducted similar to Phase 1.

Test with blood pressure change by changing the body posture

To evaluate whether a device has been properly calibrated and whether the cuffless device can track physiological BP changes dynamically, test procedure to induce BP externally or naturally. Since test has to be performed on patients admitted at the hospital, interventions for decreasing and even increasing BP may pose a risk to patients. Hence, test procedure to induce BP variation naturally, i.e., by changing posture, standing position, or lying on the bed depending on the patient's health condition. The objective is to induce BP change from the point of calibration as shown in Table 2. Select patients whose BP value change more than 4 mmHg (>4 mmHg) compared to calibration. Patients with BP values less than 4 mmHg will not be considered for validation.

Precondition

Subject/patient shall be in supine rest position for at least 5 min and should complete Phase 1/Phase 2 test.

i. Instruct the patient to stand up for 30 s or instruct the patient to change the posture as shown in Figure 3
ii. Perform BP measurements using a reference sphygmomanometer and V-CHEK in a standing position and record SBP, DBP, and heart rate values.

Test after a certain period of time

This test was required to validate whether the calibration of the V-CHEK device ages and the long-term stability of the test device readings. The minimum time for the test calibration shall be 6 h and more. Patients who are going to stay in the hospital for at least 24 h.

- Precondition: (i) To proceed, the patient must complete static testing and have calibration done at least 6 h beforehand, (ii) select patients who are on medication

Table 2: Subject selection characteristics

Number of subjects: 250 (24 subjects for phase 1; 226 subjects for phase 2)					
BP classification	**BP ranges**				
	SBP (mmHg)		**DBP (mmHg)**	**Subjects in phase 1**	**MAD criteria for phase 1**
Normal	<120	and	<80	20	< 7
Prehypertension	120–139	or	80–89	3	
Stage 1 hypertension	140–160	or	90–100	1	
Stage 2 hypertension	≥160	or	≥100	0	
Gender					
11 males and 13 females					
Age					
Between 24 years and 58 years					

BP: Blood pressure, MAD: Mean absolute difference, SBP: Systolic BP, DBP: Diastolic BP

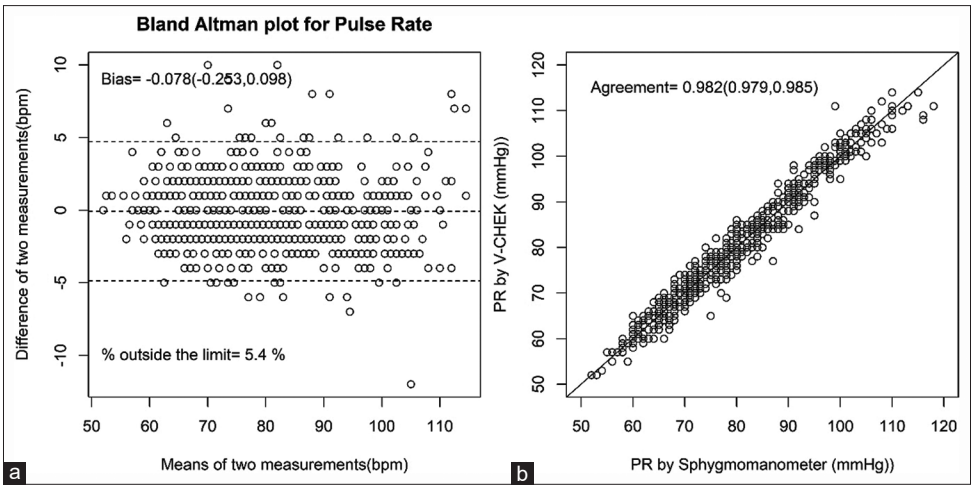


Figure 6: (a) Bland altman plot and statistics that plotted difference in measurements of PR by two method against means of these two measurements along with dotted lines indicates bias (middle) and limit of agreement (outer). (b) Scatter plot of PR by V-CHEK against the same by sphygmomanometer on the line of prefect agreement with embedded Pearson's correlation coefficient as a measure agreement. PR: Public relations

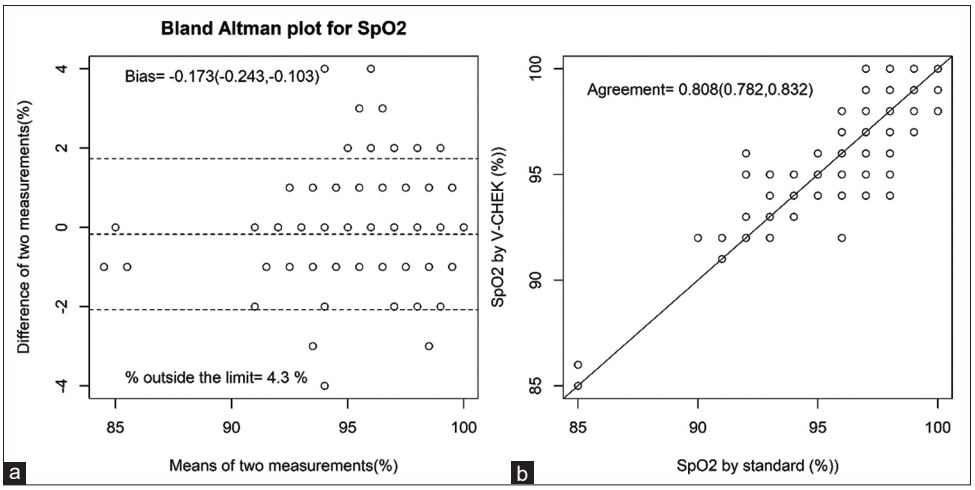


Figure 7: (a) Bland Altman plot and statistics that plotted difference in measurements of oxygen saturation (SpO2) by two method against means of these two measurements along with dotted lines indicates bias (middle) and limit of agreement (outer). (b) Scatter plot of SpO2 by V-CHEK against the same by sphygmomanometer on the line of prefect agreement with embedded Pearson's correlation coefficient as a measure agreement. SpO2: Oxygen saturation

for HTN and/or diabetis and other cardiovascular diseases and are goint to stay in the hospital for at least 24 h

- Condition: (i) This test shall be conducted in resting conditions as performed in static testing. Conduct measurements on both the reference sphygmomanometer and V-CHEK device and record the BP readings.

Study location

The study has been conducted at Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bangalore, Karnataka.

Technical information

- Reference device:
  Diamond mercurial sphygmomanometer and stethoscope. DIAMOND Industrial Electronic and Allied Products 34, Electronic Co-op Estate, Pune-Satara Road, Pune– 411009 Maharashtra, India
- Device Under Test:

V-CHEK cuffless blood pressure monitor device: Blood pressure, heart rate, and oxygen saturation

Evercons Technologies Pvt. Ltd., 999/30, 1st Main, 4th Cross, Vijaya Nagar, Bangalore-560 040, Karnataka, India.

Clinical trial conducted at 3rd, 4th, and 5th floor General wards, Sri Jayadeva Institute of Cardiovascular Sciences and Research, Jayanagar 9th Block, Bannerghatta Road, Bangalore-560 069, Karnataka, India. Generally.

Statistical analysis used

Statistical method

Continuous measurements were summarized by mean and standard deviation; categorical parameters were summarized

by frequency and percentage. Bland–Altman statistics and plot were used to assess the validity of the measurement by V-CHEK in comparison with gold standard instruments. The estimated bias was reported with 95% confidence. Pearson's product-moment correlation coefficient was used for measuring the degree of agreement between the two methods with visualization in a scatter plot. The same sign of both the limits of confidence can be considered statistically significant estimates. Statistical software R version 4.2.3 (R Core Team, 2023, Vienna, Austria) was used for data analysis.

Results

There were 250 participants, BP, HR, and SpO2 were measured three times for each of the participants by both standard and V-CHEK. Out of all participants, 56.4% were male and 43.6% were female. The average age was 51.6 ± 13.1 years, 84% were nonvegetarian, and 20% reported smoker and 23.2% reported consume alcohol. 66.9% reported a family history of HT. 105 participants had diabetes and 154 had HT with an average duration of 8.5 ± 6.3 and 6.3 ± 5.7 years, respectively. The average SBP and DBP by the standard instrument were 122.8 ± 20.4 and 79.4 ± 12.1 mmHg, respectively. The HR and SpO2 were 80.4 ± 13.2 bpm and 97.2 ± 1.59%, respectively.

Data were collected from three different types of tests: static test, test with BP change from the calibration point, and test after a certain period from calibration.

Separately for each of the test methods, statistical analysis has been performed, and the outcomes are reported below.

- Validation of Test Method 1: Static test
- Test Method 2: Test with BP change from the calibration point as shown in Figure 4 and Figure 5
- Test Method 3: Test after a certain period from calibration as shown in Figure 6 and Figure 7.

Note that, in the original data set, each participant's SBP and DBP were measured several times separately using each of the instruments, i.e., sphygmomanometer and V-CHEK. Hence, at the analysis time, average BP measurements for everyone were calculated and considered as the overall instrumental BP measurement for each of those instruments.

After analyzing the distribution of mean deviations of both SBP and DBP, between two instruments, capability potentials were calculated based on the appropriate distribution, and in all cases, it followed normal.

The analysis was performed in three stages, one is for overall, and the other two are subset analysis, stratified by age groups and gender of the participants, respectively.

Validation of blood pressure measurement

The Blant–Altman plot of SBP indicates a good agreement between the two methods with negligible bias of −0.377 with 95% confidence interval (CI) (−0.758, 0.004). Only 3.6% of the measurements were found outside the limit of agreements as shown in Table 3. On the other hand, the scatter plot also shows very high agreement between them with Pearson's correlation coefficient of 0.959 (95% CI: 0.953–0.965).

Similar pattern was observed for DBP as shownon Table 4, Bland Altman statistics also estimated very negligible bias of 0.773 with 95% CI: 0.516-1.031 and only 4.6% measurements were outside the limit of agreement. The Pearson's correlation coefficient was 0.949 with 95% CI: 0.941-0.955, close to perfect agreement.

Validation of pulse rate measurements

Bland Altman statistics estimated very negligible bias for pulse rate too by V-CHEK in comparison with sphygmomanometer as shown in Table 5. The estimated bias was −0.078 with 95% CI: −0.253–0.098. 5.4% measurements where outside the limit agreement. The scatter plot depicted very strong alignment with line of perfect agreement with correlation coefficient 0.982 (95% CI: 0.979–0.985).

Validation of SpO2 measurements

When SpO2 measurements by V-CHEK were compared against standard instrument used my respective hospital, the estimated bias by Bland Altman statistics was-0.173 with 95% CI (-0.23,-0.103) and only 4.3% were outside the lime of agreement. Pearson's correlation was 0.808 with 95 CI: 0.782-0.832. Though overall agreement measured little low, but considering very low bias and only few points outside limit of agreement indicates fair measurement of SpO2 by V-CHEK.

Table 3: Summary table for blood pressure, pulse rate, and oxygen saturation

Parameter	Bias (95% CI) (Bland Altman)	Outside limit of agreement (%)	Agreement (Pearson correlation)
SBP	−0.38 (−0.76–0.004)	3.6	0.96
DBP	0.77 (0.52–1.03)	4.6	0.95
PR	−0.08 (−0.25–0.09)	5.4	0.98
SpO_2	−0.17 (−0.24–−0.10)	4.3	0.81

CI: Confidence interval, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, PR: Pulse rate, SpO_2: Oxygen saturation

Table 4: Summary table for pulse rate

Parameter	Bias (95% CI) [Bland Altman]	Outside limit of agreement (%)	Agreement (Pearson correlation)
PR	−0.08 (−0.25–0.09)	5.4	0.98

PR: Pulse rate, CI: Confidence interval

Table 5: Summary table for oxygen saturation

Parameter	Bias (95% CI) (Bland Altman)	Outside limit of agreement (%)	Agreement (Peason correlation)
SpO_2	−0.17 (−0.24–−0.10)	4.3	0.81

CI: Confidence interval, SpO_2: Oxygen saturation

Conclusions

V-CHEK offers a compelling alternative for daytime BP monitoring in resting conditions, exhibiting accuracy comparable to the sphygmomanometer.

Key findings

No significant differences: V-CHEK demonstrated no statistically significant differences in resting SBP and DBP compared to the traditional sphygmomanometer.

Minimal bias: The bias between V-CHEK and the sphygmomanometer was negligible for BP (-0.377 mmHg), heart rate (-0.078 bpm), and SpO2 (0.173%).

Marginal variation: A slightly lower line of agreement bias was observed for SpO2 with V-CHEK compared to the pulse oximeter.

Overall, this study suggests that V-CHEK provides daytime BP measurements during resting conditions that are comparable to the traditional sphygmomanometer. This highlights the device's potential as a promising tool for cuffless BP monitoring in clinical settings and for individuals seeking convenient and continuous BP assessment in daily life.

However, further research is warranted to:

Evaluate the accuracy of V-CHEK during activities and under different physiological conditions (e.g., exercise, sleep) and stability testing for longer duration (one week to 4 weeks). Examine the performance using larger sample sizes and longer study durations to enhance generalizability. Compare V-CHEK's performance to ambulatory BP monitoring methods for a more comprehensive evaluation.

The V-CHEK device represents a novel and innovative approach to BP monitoring, particularly with its cuffless and non-invasive design. Given its unique technology, the study was designed as a Pilot study to assess the feasibility and initial performance of the V-CHEK device in measuring BP across a range of hypertensive conditions. Despite the small sample size, valuable insights were gained that can guide future research and development efforts. We acknowledge the importance of more effective follow-up strategies for patients with stage 2 HTN. In the next Study, we will plan for the broader spectrum of Hypertensive conditions, including Stage 2 HTN.

In conclusion, V-CHEK offers a compelling alternative for daytime BP monitoring in resting conditions, exhibiting accuracy comparable to the sphygmomanometer. Further research into diverse contexts (e.g., Pregnant women which is not included in our study) and broader sample size are required to refine its accuracy and pave the way for its broader adoption in clinical practice.

Table 6: Phase 1 mean absolute difference result

Type of test	MAD (mmHg)	
	SBP	DBP
Static testing	6.83	6.21

MAD: Mean absolute difference, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

Table 7: Requirements on the blood pressure change by body posture

Changes of BP from the point of calibration (mmHg)	
SBP	DBP
−20–−10	−15–−10
−10–0	−10–0
0–10	0–10
10–20	10–15

BP: Blood pressure, SBP: Systolic BP, DBP: Diastolic BP

Key messages

Cuffless V-CHEK device demonstrates comparable daytime BP measurements to traditional sphygmomanometers in resting conditions, suggesting potential for continuous BP monitoring in daily life for capturing change in BP.

Discussion

In the present study, we aimed to evaluate the clinical performance of V-CHEK, a commercially available finger-based cuffless BP monitor, compared to a traditional mercury-based sphygmomanometer.

Comparison with Mercury-based sphygmomanometer

On a population-level, our findings demonstrate a high level of agreement between V-CHEK and standard instruments for measuring BP, Heart Rate (HR), and SpO2 across a diverse patient population. The Bland-Altman plots and Pearson correlation coefficients indicate negligible biases and high correlations for all three parameters.

BP: The bias for SBP and DBP was −0.377 and 0.773, respectively, with <5% of measurements falling outside the limits of agreement. This suggests that V-CHEK provides accurate and reliable BP measurements comparable to standard instruments in rested position as shown in Table 6.

HR: The bias for HR was-0.078, with only 5.4% of measurements outside the limits of agreement, indicating high accuracy and reliability for HR measurement using V-CHEK as shown in Table 7.

SpO2: The bias for SpO2 was-0.173, with a slightly lower Pearson correlation coefficient (0.808) compared to BP and HR. However, only 4.3% of measurements were outside the limits of agreement, suggesting that V-CHEK provides a fair measure of SpO2 with acceptable accuracy as shown in Table 8.

Ease of use and patient satisfaction

In the clinical trial, patients across all age groups, including older adults, reported that V-CHEK was easy to learn and use without requiring any assistance. This highlights the user-friendly nature of V-CHEK, making it suitable for self-monitoring at home or on-the-go. The non-invasive, portable, and easy-to-use features of V-CHEK offer significant advantages over

Table 8: Overall summary table of Validation of test method 1: Static test

Variable	*n*	Total	Mean	SD	Median	Minimum	Maximum	IQR
Validation of test method 1: Static test								
Age	248	12,757	51.44	13.05	53	17	81	41.00–62.00
Sphygmomanometer (SBP)	248	30,324	122.27	17.99	121	86	178.67	108.33–135.00
Sphygmomanometer (DBP)	248	19,399	78.22	11.02	78.33	52	115	69.33–87.42
V-CHEK (SBP)	248	30,419.33	122.66	16.26	120.83	86.33	174	110.00–132.75
V-CHEK (DBP)	248	19,203.33	77.43	10.4	76.67	50.33	113.33	69.25–85.67

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Table 9: Summary table of Validation of test with BP change from the calibration point

Age	135	6921	51.27	13.69	53	17	81	39.00–62.50
Sphygmomanometer (SBP)	135	16,427	121.68	19.75	122.5	85	175	105.00–135.00
Sphygmomanometer (DBP)	135	10,426	77.23	11.76	77.5	51	107.5	67.50–87.50
V-CHEK (SBP)	135	16,584.5	122.85	17.04	122.5	87	167.5	108.00–134.75
V-CHEK (DBP)	135	10,410.5	77.11	11.04	77	49.5	107	68.50–86.00

AQ16

Table 10: Summary table of Validation of test after a certain period from calibration

Age	101	5272	52.2	12.36	54	29	78	45.00–60.00
Sphygmomanometer (SBP)	101	12,804.67	126.78	19.74	125.67	63.33	178.67	113.33–136.67
Sphygmomanometer (DBP)	101	8139.67	80.59	12.41	80	41.67	115	69.33–88.33
V-CHEK (SBP)	101	12,807	126.8	17.67	126	68.33	174	115.33–137.33
V-CHEK (DBP)	101	8055.33	79.76	11.43	78.67	43	113.33	71.33–86.67

traditional cuff-based BP monitoring devices, enhancing patient convenience and compliance with regular monitoring routines.

Clinical impact

The study demonstrates the precise performance of V-CHEK across diverse patient populations, including those with or without HTN, diabetes, or a family history of these conditions. This has promising implications for early detection and intervention, promoting regular BP monitoring among patients. Additionally, V-CHEK enables long-term data collection, offering clinicians readily accessible information for accurate diagnosis and ongoing HTN management. These findings underscore its potential to improve patient outcomes and mitigate cardiovascular risks.

Limitations

Despite the valuable insights gained from this study, several limitations should be acknowledged. Firstly, the sample size of 250 patients may be considered relatively small for a comprehensive evaluation of V-CHEK's performance across all patient groups. Additionally, the distribution of patients with stage 2 HTN was limited, which may affect the generalizability of the findings to this specific population. Furthermore, while the study compared V-CHEK with the mercury manometer, it did not include a comparison with aneroid meters, which are commonly used in clinical settings. Future research endeavours should aim to address these limitations by expanding the sample size, ensuring a more balanced representation of hypertensive patients, longer testing intervals such as 7,15 and 30 days to validate stability tests and including comparisons with other standard conventional BP measurement devices.

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Conflicts of interest

There are no conflicts of interest.

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Author Queries???

AQ9: As per correction we have rearranged the reference citations in chronological order and list. Kindly check and confirm.

AQ16: Kindly provide the table citation 9 and 10 in the text part.