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RESEARCH ARTICLE

A Comparative Accuracy Study of Touch-based Non-invasive Blood Pressure Feature of Device- H360

Rahul Rastogi, Neha Rastogi, Ashish Saini*, Ojasavi Nirav, Charul Gaur, Itra Singh

Agatsa Software Pvt Ltd., Noida, Uttar Pradesh, India.

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ABSTRACT

Background: To take blood pressure (BP) measurements repeatedly is beneficial for managing the control of hypotension and hypertension. Now present readings depend on cuff-based technology. This study compared blood pressure readings taken with new device without cuff photo plethysmography – PPG with a typical mercury-based sphygmomanometer apparatus.

Purpose:A comparative accuracy study of the touch-based non-invasive blood pressure (NIBP) feature of device H360 compared with a mercury-based sphygmomanometer.

Material and method: The study was conducted among 95 participants (Above 18 years) at Apex Heart Institute, Ahmedabad from 08th December 2022 to 07th January 2023. We concluded the study on three major factors like age, gender, and health status of participants with hypertensive (n=12), hypotensive (n=18) and normotensive (n=65). Hypotensive and normotensive).

Results: According to our observations, the results of the study revealed substantial variations between the three groups in terms of the standard deviation (STD), mean value of systolic blood pressure (SBP) and diastolic blood pressure (DBP), as measured by both the H360 and the mercury sphygmomanometer work on the principle that measures blood pressure by constricting the brachial artery with an inflatable cuff. The cuff is inflated until blood flow stops, then slowly deflated until a tapping sound is heard, indicating blood flow resumption. The pressure at which the sound is heard is the systolic blood pressure, while the pressure at which it disappears is the diastolic blood pressure. The mean values of SBP and DBP were highest in the hypertensive group, followed by the normotensive group, and lowest in the hypotensive group.

Conclusion: The study concluded that the device H360 device and mercury sphygmomanometer were effective in measuring blood pressure in hypertensive, hypotensive, and normotensive individuals. However, the H360 showed better accuracy and consistency in measuring blood pressure with a mercury sphygmomanometer.

Keywords: Blood pressure monitoring, Cuff less-NIBP monitoring, Systolic-diastolic blood pressure.

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INTRODUCTION

When determining a person's physical condition, whether inside or outside of a health center or hospital, blood pressure is the minimally necessary measurement that is taken.[1] It has been established for over 50 years that abnormal blood pressure levels of systolic blood pressure have been linked physically to an increased chance of cardiovascular disease.[2,3] Mainly used BP instruments are based on the manometer method for blood pressure measurement.

This type of procedure is challenging, unreliable, and susceptible to measurement errors due to a variety of factors, including different cuff sizes, a failure to adhere to established measurement standards, and a lack of regular calibration.[4-9] The fundamental step in taking someone's blood pressure is to teach them how to operate the instrument so that they can take an accurate reading.[10] Thus, these challenges and the reality that hypertension is the most prevalent cardiovascular risk factor worldwide.[11,12] The American Heart Association (ACC/AHA) offers important recommendations regarding the measurement of blood pressure at small healthcare settings and self-monitoring. Blood pressure readings are still required in typical medical settings, and cardiology is commonly used in therapy. Blood pressure is measured at the physician's workplace with outpatient or at-home tracking to verify the identification of the condition that causes high blood pressure and to adjust the dosage of medications that lower it[12-15]. There is a need for straightforward, non-invasive, cuff-less, and wireless monitoring devices to implement

*Author for Correspondence: ashish.saini@agatsa.com

future plans for proper home care, pre-hospital treatment, and hospital care, assuring prompt detection and avoidance of any cardiovascular risk. To reduce the type of risk related to heart disease, Agatsa Software Pvt Ltd developed a touch base blood pressure monitoring device (H360) that measures blood pressure without a cuff and is less expensive than any other device. The main advantage of this device is to monitor ECG, HRV and SpO_2 as well at your office, at home and in small clinical settings.

RESULTS

Patient Characteristics

A total of 95 people in total were enrolled in the research. Their blood pressure values divided participants into hypertensive (n=12), hypotensive (n=18), and normotensive. We define hypertension as having a systolic blood pressure more than 140 mmHg and for diastolic more than 90 mmHg. As for hypotension, it was described as SBP 90 mmHg, DBP 60 mmHg, and norm tension as SBP 140 mmHg, DBP 90 mmHg.

The study's findings revealed a sizable disparity in the three groups' mean SBP and DBP readings, as determined by the mercury sphygmomanometer and the H360. The normotensive group had the greatest mean values of SBP, DBP, and the hypotensive group had the lowest mean values of these measurements (Tables 1 and 2).

Similarity Between Device Measurements

For the H360 device, the mean SBP values for the hypertensive, normotensive, and hypotensive groups were 152, 126 and 86 mmHg, respectively (Table 2). The mean DBP values were 96, 88 and 51 mmHg, respectively (Table 2).

For the mercury sphygmomanometer, the mean SBP values for same three groups were 149, 128 and 82 mmHg, respectively (Table 1). For mean DBP values for the same groups were 101, 82 and 56 mmHg, respectively.

The standard deviation (STD) of SBP and DBP, was also compared between the three age groups. The results showed that the hypertensive group had the highest SD values for all three parameters and the hypotensive group had the lowest SD values, followed by the group that was normotensive.

DISCUSSION

The 2017 guidelines from the American College of Cardiology/ American Heart Association (ACC/AHA) recommend changes to the technique by which arterial hypertension is treated. They recommend a thorough approach that makes use of team-based treatment, typical at-home and outdoor blood pressure monitoring and highlights the value of regular, accurate, and standardized blood pressure readings.[13-15] As a result of modifications to the recommendations' definition of hypertension, the proportion of adults with the condition has sharply increased across Asia and North America.[16,18]
Recent estimates indicate that more than 50 million persons globally have an SBP of 140 mmHg or above. Hypertension, linked to stroke, cardiovascular disease, heart failure, and chronic renal disease, is the second-leading preventable cause of mortality in Asia, and its consequences are expected to worsen. According to the study's findings, individuals with hypertension, hypotension, and norm tension had significantly different blood pressure parameters.[19-23] The greatest mean SBP and DBP were found in the hypertension group, which was considered to have hypertension. The normotensive group had intermediate values and the hypotensive group had the lowest systolic and diastolic values.

The findings of this research highlight the value of precise. Blood pressure readings are used to detect and treat hypertension. Identifying hypertensive patients early and instituting appropriate treatment to prevent cardiovascular complications is imperative.

The results of this study suggest that touch-based NIBP measurement using PPG technology can be a reliable alternative to standard cuff-based mercury sphygmomanometer. The high sensitivity and specificity of touch-based Non-invasive blood pressure (NIBP) measurement indicate that the technology can accurately detect hypertension. However, the study also found that touch-based NIBP measurement was less accurate in measuring DBP compared to SBP.[24]

The standard deviation (STD) of SBP and DBP was also compared between the three age groups (Figure 1). As we individually study the blood pressure parameter on gender category for hypertension, hypotension, and normal participants (Table 3).

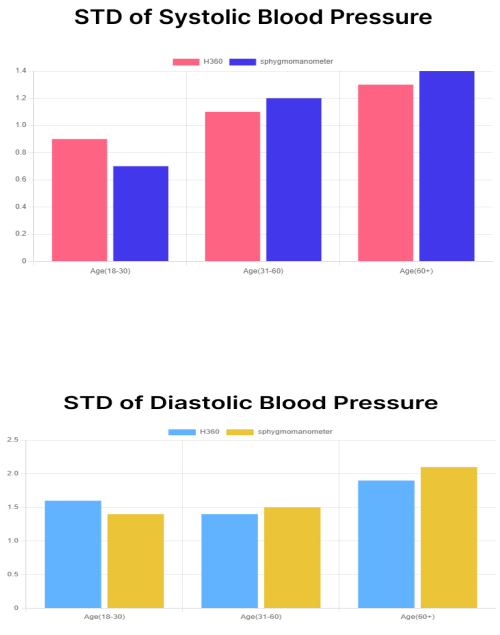

Figure 1: STD comparsion of 2 device on different age group

Table 1: Data analysis of SBP

	Range	Method	STD	Mean (mm/Hg)	STD Accuracy
Systolic Blood Pressure	<90 mm/Hg (Hypotensive)	Sphygmomanometer	1.9	82	± 1.2
		H360	3.1	86	
	90–140 mm/Hg (Normotensive)	Sphygmomanometer	2.0	128	± 0.9
		H360	2.9	126	
	> 140 mm/Hg (Hypertensive)	Sphygmomanometer	4.1	149	± 2.3
		H360	6.4	152	

Table 2: Data analysis of DBP

	Range	Method	STD	Mean (mm/Hg)	STD Accuracy
Diastolic Blood Pressure	<60 mm/Hg (Hypotensive)	Sphygmomanometer	6.0	56	± 1.2
		H360	7.2	51	
	60–90 mm/Hg (Normotensive)	Sphygmomanometer	4.5	82	± 1.5
		H360	6.0	88	
	>90 mm/Hg (Hypertensive)	Sphygmomanometer	3.2	101	± 1.8
		H360	5.0	96	

Table 3: Data distribution

Gender	Total Participants	Hypertensive	Hypotensive	Normotensive
Male	71	10	13	48
Female	24	2	5	17

This research's relatively small sample size is one of its limitations, which may restrict the generalizability of the results. Additional research involving bigger sample sizes is required to confirm the precision of touch-based NIBP measurement across a range of populations and clinical contexts.

MATERIAL AND METHOD

The measurement of blood pressure (BP) will be repeated to improve hypertension and hypotension management. Present day measurements are mainly depending on the device which have cuff. The main motive of this study was to analyse blood pressure measurement use a non-invasive cuff less photo plethysmography device with a common mercury sphygmomanometer device. Men and women who visit the hospital for a routine examination are recruited for the study. One measurement was performed for each person using devices based on a sphygmomanometer and on photoplethysmography device. The device was considered if the standard deviation (SD) was no greater than 12 mmHg and the mean difference (MD) between the two measures was less than 15 mmHg. The analysis of the research included 95 participants. There were no negative effects during the research.

Material

A comparative accuracy study of touch based non-invasive blood pressure feature of device H360 conducted at the Apex Heart Institute from 8th December 2022 to 7th January 2023 at Ahmedabad, India. A total of 95 study participants aged more than 18 years participated in this study.

- Touch based blood pressure monitoring device.
- Cuff less BP monitoring device.
- Less expensive

Method

The study was conducted among 95 participants, where we compared the accuracy level of device H360 (Figure 2). We measured the participants' blood pressure in the sitting and relaxed position and noted the result on the consent form as shown on the device display. Simultaneously we measured the blood pressure of participants with mercury-based sphygmomanometer based on the principle that measures blood pressure by constricting the brachial artery with an inflatable cuff (Figure 3). The cuff is inflated until blood flow stops, then slowly deflated until a tapping sound is heard, indicating blood flow resumption. The pressure at which the sound is heard is the systolic blood pressure, while the pressure at which it disappears is the diastolic blood pressure in the presence of a health physician.

While during the study we followed the participation criteria (for the participants which have inclusion and exclusion).

Inclusion Criteria

- Health status of participants with hypertension and hypotension disorder
- Based on their gender (Male/Female).
- Different age groups (18–30), (30–60) and (above 60)
- Lifestyle factors
- Based on the medication of participants.

Front View	Side View

Figure 2: H360 device

Figure 3: Dial based mercury sphygmomanometer

Exclusion Criteria

- Participants with recent exercise
- The participant who is pain or in discomfort
- Consumption of heavy meals/alcohol/smoking.
- Arrhythmiatic patients
- White coat hypertension patients
- Pregnant women

Each participant underwent blood pressure measurements once, with a 2 minute interval between both devices. The order of measurement was randomized to minimize the effect of order bias. For data processing, the measurement's average was used. The mean SBP, DBP, and standard deviation values were compared between the three age categories.

H360 device

The device is a handheld device used for measuring blood pressure readings, systolic and diastolic and same thing is displayed on the device screen. The technology for measuring BP is based on PPG (Figure 2). The same PPG is used for measuring SPO2 blood and heart rate levels. The majority of commercially available devices transmit red light at 660 nm and infrared light at 780 nm, emitting wavelengths through the tissue of the index finger. On the opposite side of the device, we place a detector that absorbs the transmitted light, with each of these wavelengths having a different pattern of absorbing light. This is mainly upon to the interaction with oxy- and de-ox hemoglobin. The detector tracks the fluctuating absorbance at each wavelength, allowing it to isolate pulsed arterial blood alone from venous blood, muscle fat, bones, and the skin in order to determine the absorbance values.

The light source (a Light Emitting Diode, or LED) and sensor area are located towards the back of the device thanks to a special reflecting PPG technology used by the H360. Some of the light that LEDs transmit into tissue of index finger is reflected from the tissue and is picked up by a photodiode detector. The device's excellent quantitative and temporal resolution makes it possible to record even the smallest variations in tissue reflectance and calculate numerous crucial functions that are derived from the pulse contour, including sophisticated hemodynamic metrics like tracking variations in blood pressure.

Reference Device

We use dial based mercury sphygmomanometer as a reference device for our study. The mercury sphygmomanometer work on principle that measures blood pressure by constricting the brachial artery with an inflatable cuff. The cuff is inflated until blood flow stops, then slowly deflated until a tapping sound is heard, indicating blood flow resumption (Figure 3). The pressure at which the sound is heard is the systolic blood pressure, while the pressure at which it disappears is the diastolic blood pressure in the presence of a health physician.

Informed Consent

The individual participants included in this study go through with procedure which includes a consent form and pre and post-procedure activities.

CONCLUSION

Our study demonstrated that both H360 device and the mercury sphygmomanometer were effective in measuring blood pressure in hypertensive, hypotensive, and normotensive individuals. However, the H360 showed accuracy and consistency in measuring blood pressure parameters. Therefore, it is essential to consider the type of device used for measuring blood pressure and the individual's blood pressure status when making clinical decisions. Further study is needed to evaluate the long-term effects of H360 device on patient outcomes.

The technology of touch-based (NIBP) devices has great potential for future development and application in various healthcare settings. Some future aspects of this technology are:

- Remote patient monitoring: The development of touch-based NIBP devices with wireless connectivity will enable healthcare providers to remotely monitor patients' blood pressure readings. This will be particularly beneficial for patients with chronic conditions such as hypertension who require regular monitoring of their blood pressure levels.
- Telemedicine: Using touch-based NIBP devices in telemedicine will allow patients to receive remote consultations with healthcare providers. This will be particularly useful for patients living in remote areas or with limited healthcare services.
- Personalized healthcare: Integrating touch-based NIBP devices with machine learning algorithms will enable healthcare providers to provide more personalized healthcare interventions to patients. The technology will allow for the early detection of potential health problems and the identification of individual risk factors for hypertension.
- Real-time data analytics: Using touch-based NIBP devices with real-time data analytics will enable healthcare

providers to access real-time data on patients' blood pressure readings. This will facilitate faster decision-making and the delivery of more effective treatments.

Patient empowerment: The use of touch based NIBP devices will empower patients to take control of their health by enabling them to monitor their blood pressure levels at home. Patients will be able to track changes in their blood pressure readings and take appropriate action, such as contacting their healthcare provider if their blood pressure levels are outside of normal ranges.

In conclusion, touch based NIBP devices have enormous potential for future development and application in healthcare. The technology will enable healthcare providers to deliver more personalized and effective treatments and empower patients to take control of their health. As the technology continues to evolve, we can expect to see even more advanced and sophisticated touch based NIBP devices that will revolutionize the way we monitor blood pressure.

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