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Variability of Four Home Blood Pressure Monitoring Devices: Insights from a 2024 Cross-Sectional Study

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Abstract
Home blood pressure monitoring (HBPM) is widely used for self-monitoring and managing hypertension. However, variations among devices may influence clinical decisions. This study aimed to evaluate the variability in systolic blood pressure (SBP) and diastolic blood pressure (DBP) readings across three commonly used upper-arm automated HBPM devices: Beurer Medical (BM 54), Citizen (CH-456), and Geratherm Smart (GT-1775) against a controlled, validated reference device, Omron M6 Comfort (HEM-7321-E). A total of 124 adult participants were recruited from King Abdulaziz University Hospital, Jeddah, Saudi Arabia. Trained medical students measured blood pressure using all four devices. Significant variations in SBP and DBP readings were observed among the four HBPM devices. Omron M6 Comfort recorded significantly lower SBP values (median = 112) compared to the Beurer Medical (median = 121), Geratherm Smart (median = 119), and Citizen (median = 119) devices, ($p < 0.001$). Conversely, Beurer Medical recorded significantly higher DBP values (median=85) compared to Omron M6 Comfort (median=80), Geratherm Smart (median = 76), and Citizen (median = 80), ($p < 0.001$). Although HBPM remains essential for hypertension management, these findings emphasize the need to select validated and reliable devices to ensure consistent and accurate blood pressure monitoring.

Keywords: Home Blood Pressure Monitoring, · Hypertension, · Blood Pressure, · Saudi Arabia.

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1. Introduction

Hypertension is a silent yet critical global health issue and a significant contributor to cardiovascular diseases. According to the latest World Health Organization (WHO) statistics from 2023, hypertension affects approximately 1.3 billion people (32%) worldwide. While global statistics are comprehensive, recent specific data on hypertension prevalence in Saudi Arabia remain scarce. However, a recent meta-analysis estimated the prevalence of hypertension to be 22.7%, based on a sample of 278,873 individuals in Saudi Arbia. [1] This underscores the substantial burden of hypertension in the region, as many cases remain undiagnosed. [2] The International Society of Hypertension (ISH) 2020 Global Hypertension Practice Guidelines define hypertension based on blood pressure (BP) thresholds, measured through various methods: office BP monitoring (OBPM), home BP monitoring (HBPM), and ambulatory BP monitoring (ABPM). For HBPM, hypertension is defined as systolic blood pressure (SBP) ≥ 135 mmHg and diastolic blood pressure (DBP) ≥ 85 mmHg. [3]

HBPM is widely recommended for effective hypertension management by leading health organizations, including the American Heart Association (AHA), European Society of Hypertension (ESH), and National Institute for Health and Care Excellence (NICE). These organizations emphasize the role of HBPM in confirming hypertension diagnosis, monitoring treatment effectiveness, improving patient compliance, and eliminating limitations associated with in-clinic measurements, such as the "white-coat" effect and masked hypertension phenomena. [3, 4]

However, the accuracy of HBPM devices varies considerably, making their reliability a critical factor for effective hypertension management. For example, a recent systematic review reported discrepancies in HBPM recordings compared to mercury sphygmomanometers, with inaccuracies ranging from 2.4 to 10.4 mmHg for SBP and 1.0 to 8.7 mmHg for DBP. [5] Another concern is the inherit variability in measurements across different monitors. For instance, a study comparing three HBPM devices—Microlife BP 3AC 1-1, Microlife BP3AG1, and Omron M4-I—among 65 participants found that the Omron M4-I recorded significantly lower SBP, DBP, and mean BP readings than Microlife devices. [6] These findings highlight the need for healthcare providers to exercise caution when selecting HBPM for their patients. These devices must be reliable and internationally certified by organizations such as the ESH, British Hypertension Society (BHS), Association for the Advancement of Medical Instrumentation (AAMI), and International Organization for Standardization (ISO).

The fundamental difference in measurement techniques is a primary source of variability between BP devices. Auscultatory devices (e.g., mercury or aneroid sphygmomanometers with a stethoscope) rely on the detection of Korotkoff sounds and are influenced by observer technique, hearing ability, and ambient noise. [5] In contrast, the vast majority of (HBPMs) and automated office devices employ the oscillometric method, which detects oscillations in cuff pressure and uses manufacturer-specific proprietary algorithms to derive systolic and diastolic blood pressure values. [5] Because these algorithms, sensor sensitivity, and signal processing differ substantially between manufacturers (and even between models from the same manufacturer), clinically meaningful systematic differences of 5–10 mmHg or more can occur between devices, [5] potentially leading to misclassification of hypertension status or treatment decisions.

Given the growing availability of HBPM devices on the market, ongoing research is essential to compare these tools with validated devices or the mercury sphygmomanometer, which is widely regarded as the gold standard for BP measurements. Therefore, this study aims to assess variations among the most commonly used HBPM devices in Jeddah, Saudi Arabia, focusing on their measurement variability in the adult population. This research will provide valuable insights for clinicians and patients, ultimately improving hypertension management.

2. Methods

This analytical cross-sectional study was conducted at King Abdulaziz University Hospital (KAUH) in Jeddah, Saudi Arabia. Participants were recruited from the clinic's waiting areas and hospital lobby. Participants were included if they were 18 years or older, attending KAUH, and willing to provide informed consent, regardless of any existing medical condition. The exclusion criteria included individuals younger than 18 years of age, pregnant individuals, and those unable to provide informed consent. The study procedures were clearly explained, and written informed consent was obtained from all participants before inclusion.

2.1 Participant preparation

To minimize the white-coat effect, participants were acclimatized for 10 minutes in a quiet environment before BP measurements were taken. During this period, sociodemographic and medical data were collected. Additionally, participants were informed that BP measurements were being collected strictly for research purposes.

A systematic random sample of 124 participants was collected from the visitor registry in the waiting area. Participants were selected using a fixed sampling interval, where **every 5th individual** listed in the registry was recruited after a random starting point. The collection period spanned May 2023 to October 2023,

with a recruitment rate of 3–4 participants per day over two days per week. Holidays and instances when eligible participants were unavailable were accounted for in the sampling schedule to ensure adherence to the inclusion criteria and maintain the integrity of the recruitment process.

2.2 Data collection procedures

Sociodemographic and medical data, including age, gender, body mass index (BMI), nationality, diabetics status, and hypertension history, were collected using a structured questionnaire and registered on Google Forms. BP measurements were conducted by trained medical students using four automated upper-arm cuff HBPM devices employing the oscillometric method: the Omron M6 Comfort (HEM-7321-E), Beurer Medical (BM 54), Citizen (CH-456), and Geratherm Smart (GT-1775). These devices, newly purchased from medical suppliers for this study, were used in a randomized sequence to eliminate measurement bias associated with the reading order. Measurements were recorded in Google Forms, and a standardized protocol, based on ESH guidelines and the literature, [7] were followed to ensure consistency. A five-minute interval between measurements was maintained to minimize the influence of prior readings. All measurements were taken in triplicate, with the results presented as means.

2.3 Study design and sample size

The study aimed to compare the variability in BP readings among three HBPM devices compared to a forth control device, Omron M6 Comfort (HEM-7321-E), which meets ESH 2010 standards. [8] A sample size of 124 participants was calculated using the Epi Info calculator, with a confidence level of 95% and power of 80%.

2.4 Data management and statistical analysis

Data from Google Forms were exported to Excel for initial organization and subsequently analyzed using SPSS version 20 (IBM Corp., Armonk, NY). Categorical variables were presented as frequencies and percentages, while numerical variables were summarized using means ± standard deviation for normally distributed data and as median with interquartile range for non-normally distributed data. The Friedman test was employed to identify significant influencing factors when comparing devices, while the Wilcoxon signed-rank test was used to compare each device's readings with the control device. Normality of readings was assessed prior to analysis, with a significance level of $\alpha = 0.05$ applied throughout.

2.5 Ethical considerations

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and approved by the Research Ethics Committee at King Abdulaziz University, Jeddah, Saudi Arabia (No: HA-02-J-008). All data were anonymized to ensure participant confidentiality and securely stored on Google Forms for two years, accessible only to the study authors.

3. Results

A total of 124 participants were recruited for the study between May 2023 and October 2023. The mean participant age was 31 ± 12 years, with a mean BMI of 25.9 ± 5.9 kg/m². Of the participants, 51.6% were male, and 80.6% were Saudi nationals. Pre-existing medical conditions included diabetes mellitus (9.7%), hypertension (8.1%), hypercholesterolemia (2.4%), and hyperthyroidism (0.8%). Additionally, 13.7% reported other chronic diseases (Table 1).

The Friedman test and the Wilcoxon signed-rank test were used to compare blood pressure measurements obtained from the four devices. These methods were chosen because the data were not normally distributed. The Friedman test was applied to compare SBP and DBP readings across the four devices, and the Wilcoxon signed-rank test was conducted for pairwise comparisons to determine which device pairs differed significantly.

3.1 Device comparisons: SBP

The Friedman test revealed statistically significant differences in SBP readings across the four devices, ($\chi^2 = 35.7$, $p < 0.001$*), indicating that at least one device recorded significantly different SBP values. Median SBP readings showed notable variation: the **Omron M6 Comfort** recorded a median of **112 mmHg**, whereas the **Beurer Medical BM 54, Geratherm Smart GT-1775**, and **Citizen CH-456** recorded higher median values of **121 mmHg, 119 mmHg,** and **119 mmHg,** respectively (Table 2).

3.2 Device comparisons: DBP

A similar pattern was observed for diastolic blood pressure measurements. The Friedman test identified significant differences among devices ($\chi^2 = 59.8$, $p < 0.001$), indicating inconsistent DBP readings (Table 2). The Omron M6 Comfort produced a median DBP of 80 mmHg, whereas the Beurer Medical BM 54 reported a higher median of 85 mmHg, and the Geratherm Smart GT-1775 recorded a lower median of 76 mmHg. The Citizen CH-456 showed a median value equal to the Omron (80 mmHg).

3.3 Pairwise comparisons

Pairwise comparisons using the Wilcoxon signed-rank test confirmed substantial variability in blood pressure measurements between the Omron M6 Comfort and the other devices (Table 3). For SBP, the Omron recorded significantly lower readings than all three comparison devices, with highly significant differences observed against the Beurer Medical BM 54 ($Z = –4.7$, $p < 0.001$), Geratherm Smart GT-1775 ($Z = –4.7$, $p <$

0.001), and Citizen CH-456 ($Z = –5.5$, $p < 0.001$). For DBP, the Omron also differed significantly from the Beurer device ($Z = –3.7$, $p < 0.001$), which produced higher DBP values, and from the Geratherm device ($Z = –4.9$, $p < 0.001$), which recorded lower DBP readings. In contrast, no significant difference in DBP was detected between the Omron and the Citizen device ($p = 0.73$).

4. Discussion

This study evaluated variability, rather than accuracy, among four automated upper-arm cuff HBPM devices employing the oscillometric method in adults in Jeddah, Saudi Arabia. Wrist devices were excluded due to their known inaccuracies and questionable reliability. [9] Among the tested devices, the Omron M6 Comfort (HEM-7321-E) and Beurer Medical (BM 54) met ESH standards, while the Citizen (CH-456) and Geratherm Smart (GT-1775) have no validation details in ESH, AAMI, BHS, or ISO reports. Nevertheless, the devices were selected based on their widespread use, representing a range of affordability from high-cost to budget options to ensure regional relevance.

Our main findings showed that the Beurer Medical, Geratherm Smart, and Citizen recorded significantly higher SBP readings than the Omron M6 Comfort by more than 7 mmHg. According to variation criteria established by the AAMI, ESH, and ISO, a mean difference exceeding ± 5 mmHg is suboptimal and generally not acceptable. [10] Such consistent variation could lead to clinical overestimation of SBP, potentially resulting in unnecessary management adjustments. These variations may be attributed to the oscillometric method, which relies on a fixed formula based on oscillation onset and maximum oscillation pressure. [9] This standardized approach may not account for individual physiological differences, contributing to variability compared to other measurement methods. [9] Additionally, differences may stem from unique manufacturer algorithms for calculating BP. [11] For DBP results, the Beurer Medical device recorded higher DBP readings than the Omron M6 Comfort by an average of 4 mmHg, while the Geratherm Smart recorded lower DBP readings compared to the Omron M6 Comfort by an average of 4 mmHg. Theses variations fall within the acceptable threshold of ± 5 mmHg.

Our findings align with previous studies, although reported inter-device variations were within acceptable limits. Varis and Kantola observed average differences of 2 mmHg in SDB and DBP among three devices (Omron M4-I and two Microlife devices, BP 3AC 1-1 and BP3AG1) tested on 65 Finnish participants (6). Similarly, Yarows and Brook evaluated 12 HBPM devices with two normotensive subjects. The devices, which included arm, wrist, and finger monitors, were compared against an Omron 712C upper arm monometer as well as to mercury and aneroid sphygmomanometers. [11] Among these devices, four arm monitors (Omron 711, Omron 725CIC, Omron HEM705CP, and A&D UA767) showed variations of less than 4 mmHg for both SBP and DBP measurements compared to the Omron 712c. [11] However, the limited scope of these studies and manufacturer homogeneity may restrict the generalizability of these findings. Having said that, findings from larger comparative studies support our results, demonstrating that automated oscillometric devices exhibit substantial inter-device variability. A metanalysis, analysed 24 studies with a total of 47,759 adults determined that the overall weighted mean difference between automated oscillometric devices and mercury sphygmomanometers was statistically significant but within the accepted clinical tolerance of 5 mmHg. However, this study revealed very high statistical heterogeneity among the included studies suggesting that BP estimating algorithms vary significantly depending on the manufacturer and product type. [12]

While OBMP is indispensable for hypertension follow-up and management, HBPM offers advantages such as minimizing white-coat anxiety, enhancing disease awareness, and promoting treatment adherence, thereby helping to reduce cardiovascular morbidity and mortality. [9] Despite this, most automated BP measuring devices sold on the global market have not been clinically validated, despite strong guideline endorsement for their use. The systemic challenge of inter-device variability is fundamentally linked to the oscillometric technique, as SBP and DBP are derived using proprietary, mathematical algorithms. The proprietary nature of these algorithms, combined with inherent sources of error like signal processing variations and estimation inaccuracies, makes it difficult to ascertain the cause of measurement inaccuracies in each automated BP device. [13] Furthermore, the historical use of multiple competing clinical validation protocols has fostered confusion, resulting in a lack of consensus, evidenced by the fact that multiple registries do not always agree on which HBPM are acceptable for clinical use. [13] To address this, recent global evidence underscores the need for a unified regulatory approach through the accelerated adoption of a single, universally accepted protocol namely, AAMI/ESH/ISO universal standard (ISO 81060-2:2018), to improve quality assurance and standardize requirements for accurate HBPM before devices reach the market. [14]

The study has some limitations. First, while many HBPM devices are available on the market, only four were evaluated, limiting the generalizability of the findings. However, these devices were selected for their regional popularity and affordability. Second, devices were not compared to a mercury sphygmomanometer due to the specialized training required for its use. Nonetheless, the study focused on inter-device variability rather than

absolute accuracy, with the control device meeting ESH standards. Third, external factors that could influence BP, such as caffeine consumption, medication, and tobacco use, were not controlled.

5. Conclusion

This study identified significant variability in SBP readings among four HBPM devices, with three devices exceeding the acceptable ±5 mmHg threshold compared to the Omron M6 Comfort, potentially leading to clinical mismanagement. These findings underscore the critical need for rigorous validation of HBPM devices to ensure their accuracy and reliability in clinical and home settings.

5.1 Conflict of Interest

The authors report no conflicts of interest.

5.2 Author Contributions

A.A., and H.B. developed the research idea, A.A., I.W. and H.B. designed the methodology, and provided supervision. S.ALG., R.A., S.ALA., S.S., and F.F. collected the data and wrote the manuscript. A.A. analyzed the data. A.A., I.W., and H.B. reviewed and edited the manuscript. All authors have read and approved the final version of the manuscript.

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8. Tables

Table 1: Demographic data of participants (N = 124). a: Mean ± Standard Deviation, BMI: Body mass index.

Variables	No. of subjects	Percent
Age (by years)	124	31 ± 12 a
BMI	124	25.9 ± 5.9 a
Gender		
Male	64	51.6
Female	60	48.4
Nationality		
Saudi	100	80.6
Non-Saudi	24	19.4
Previously diagnosed with:		
Diabetes mellitus		
Yes	12	9.7
No	112	90.3
Hypertension		
Yes	10	8.1
No	114	91.9
Hypercholesteremia		
Yes	3	2.4
No	121	97.6
Hyperthyroidism		
Yes	1	0.8
No	123	99.2
Other chronic diseases		
Yes	17	86.3
No	107	13.7

Table 2: Variation in HBPM devices for systolic and diastolic BP. a. Friedman Test, * p-value <0.05, ** < 0.01, and * < 0.001**

	SBP					DBP				
	Percentiles			Statistical test [a]		Percentiles			Statistical test	
	25th	50th (median)	75th	Chi-Square	p-value	25th	50th (median)	75th	Chi-Square	p-value
Omron M6 Comfort (mmHg)	102.25	112.00	123.5			74.00	80.00	85.00		
Beurer medical BM 54 (mmHg)	112.00	121.00	125.0			74.0	85.00	88.00		
Geratherm smart GT-1775 (mmHg)	110.25	119.0	127.75	**35.8**	**<0.001****	68.0	76.0	81.0	**59.8**	**< 0.001*****
Citizen CH-456 (mmHg)	111.00	119.0	130.0			73.0	80.0	86.0		

Table 3: Pairwise comparisons of measurements among HBPM devices. All comparisons were performed using the Omron M6 Comfort device as the reference standard a. Wilcoxon Signed Ranks Test, b. Based on positive ranks. *** p-value < 0.001

	SBP		DBP	
Device	**Statistical test [a]**			
	Z test	p-value	Z test	p-value
- Omron M6 Comfort Device2, Beurer medical BM 54	-4.7	***0.00	-3.7	***0.00
- Omron M6 Comfort Geratherm smart GT-1775	-4.7	***0.00	-4.9	***0.00
- Omron M6 Comfort Citizen CH-456	-5.5	***0.00	-0.3	0.73