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COMPARATIVE EVALUATION OF SENSITIVITY OF BLOOD PRESSURE MEASURING EQUIPMENT OF DIFFERENT MAKES USED BY HEALTH FACILITIES IN A CAPITAL CITY OF SOUTHEAST-NIGERIA

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ABSTRACT

Accurate blood pressure (BP) measurement is fundamental for diagnosing and managing hypertension disease. Cases of high blood pressure (HBP) and cardiovascular accident are on the increase, therefore, sensitive, accurate and high precision equipment is panacea for the proper management of the disease. The objective of this study is to compare the diagnostic accuracy between digital (Omron), semiautomatic sphygmomanometer (Aneroid) verses Mercury sphygmomanometer in normotensive subjects. Three blood pressure measuring equipment from different makes; Omron M3 (Digital-automated), A&D Medical UA-767S (Manuel-anerod) and Accoson Greenlight 300 (mercury calibration), were used serially for two consecutive times for each. The choice of these three makes was based on manufactures credibility, common accessibility and use among health facilities in our study area.The result of our finding shows variability in sensitivity, (accuracy and precision) among the three devices. Systolic and diastolic readings of Omron M3 and A&D Medical UA-767S showed significant difference ($p \leq 0.05$) from the readings of Accoson Greenlight 300 which we used as standard to compare the other two. More inconsistencies (significantly lack of precision) were recorded with Omron M3 and A&D Medical UA-767S than with Accoson Greenlight 300.

KEYWORDS: Comparative, Evaluation, Measuring equipment.

INTRODUCTION

Blood pressure (BP) results from the blood on the walls of arterial vessels at the systemic circulation (Albert & Ortega, 2016).It depends on cardiac output ,arterial elasticity, blood viscosity and systemic peripheral vascular resistance (Mourad, 2002). The average reference values in adults are 120/80mmHg for Systolic (SBP) and Diastolic (DBP)

respectively (Blanc0, 2012). Mean Arterial Pressure (MAP) is the average pressure in the arteries during cardiac cycle and is calculated using the formular MAP=[(SBP)+(DBPX2)]/3 (Introduction to Hemodynamics, 2021). European Society of Cardiology (ESC, 2024) introduced the category of Elevated Blood Pressure, defined as SBP of 120-139mmHg or DBP of 70-89mmHg. BP is a basic vital sign in physical examination (Method off verification for mercurial and aneroid sphygmomanometers, 2018) that provides data to diagnose and treat multiple pathologies (Jaramillo-Ramirez, et al, 2018). The American Heart Association (AHA, 2017) recommends blood pressure levels below 130/80mmHg and stresses the importance of timely interventions to prevent cardiovascular complications.

Therefore, blood pressure (BP) measurement is a fundamental clinical practice used for diagnosing and managing of cardiovascular diseases, making the accuracy, precision and sensitivity of BP measuring equipment a critical and reliable to be, (Muntner et al, 2020). The precision of this device determines its clinical reliability, particularly for conditions such as hypertension, where small measurement errors can significantly impact patient management, (Stergiou et al, 2018). Various BP measurement devices exist, including manual mercury sphygmomanometers, and automated digital monitors. However, discrepancies among these devices have been reported in several comparative studies, raising concerns about their sensitivity, accuracy and reliability, (Uhlig et al, 2019).

Traditional mercury sphygmomanometers are considered the gold standard for BP measurement due to its high accuracy and long- term stability, (Picone, et al, 2017). However, concerns regarding mercury toxicity have led to the gradual phasing out of this device in favour of aneroid and digital sphygmomanometers, (O'Brien et al, 2020). Aneroid devices though commonly used, are prone to mechanical calibration errors which may affect their sensitivity, (Palatini & Asmar, 2018). On the other hand, digital BP monitors have gained widespread use in both clinical and home settings due to their convenience and ease of operation, (Shimbo et al, 2020). Despite its advantages, some digital devices show considerable variations in accuracy when compared to standard mercury sphygmomanometer, often requiring validation studies to confirm their clinical suitability, (Mengden et al, 2018). The sensitivity of BP measurement equipment is influenced by various factors, including cuff size, arm position and patient characteristics such as obesity and vascular stiffness, (Pickering et al, 2019). Device calibration and validation protocols also play a crucial role in maintaining measurement accuracy, (Stergiou et al, 2021). A systematic review by Bilo et al, (2020) found that some digital BP monitors failed validation tests against the mercury standard, leading to concerns about their clinical utility. Additionally, environmental factors such as temperature fluctuations and electromagnetic interference may impact the performance of electronic BP monitors, (Myers et al, 2019).

Several studies have compared the sensitivity and accuracy of BP measurement devices. A multicenter trial conducted by Omboni et al (2018) revealed significant differences in BP readings between digital and aneroid devices, with digital monitors demonstrating higher variability. Similarly, a study by Nerenberg et al, (2020) found that home-use BP monitors often underestimate systolic BP by 5-10 mmHg when compared to mercury sphygmomanometers. Conversely, some high-end automated devices, such as oscillometric monitors have demonstrated accuracy and comparable to manual BP measurement when properly calibrated, (Stergiou et al, 2021). A meta-analysis by Kario et al, (2019) revealed that home monitors exhibited greater variability than clinical-grade monitors. Devices such as Omron and Beurer maintained sensitivity within 5 mmHg, whereas lower cost brands exhibited discrepancies exceeding 10 mmHg, (Cohen et al, 2022).

The sensitivity of BP measurement devices varies significantly across different manufacturers due to differences in sensor technology, calibration stability and validation protocols, (Verberk et al, 2019). Clinical-grade devices such as Welch Allyn and Omron, exhibit higher sensitivity compared to budget brands, (O'Brien et al, 2020). Calibration frequency plays a crucial role in maintaining accuracy as seen in aneroid and digital monitors requiring periodic adjustments, (Muntner et al, 2020). Ambulatory blood pressure monitor (ABPM) devices provide continuous BP readings over 24 hours, improving sensitivity for detecting white-coat hypertension (WCH) and masked hypertension (Kario et al, 2019). Brands such as Spacelabs and Welch Allyn have shown superior reliability in multiple studies, (O'Brien et al, 2020).

Regular calibration is essential to maintain BP monitors sensitivity. A study by Bilo et al (2016) showed that uncalibrated aneroid devices deviated by to 7 mmHg over six months use. Digital monitors showed a mean error of 3 mmHg when used without periodic recalibration, (Mieke et al, 2018).

The variability in sensitivity across different BP measurement devices has profound implications for hypertension diagnosis and management. Incorrect BP readings may lead to misdiagnosis, inappropriate treatment, or failure to detect hypertensive crises, (Whelton et al, 2018). Therefore, international guidelines emphasize the importance of using validated BP devices that meet standardized accuracy criteria set by organizations such as the Association for the Advancement of Medical Instrumentation (AAMI), the European Society of Hypertension (ESH), and the British Hypertension Society (BHS), (Stergiou et al, 2021).

It is this outlook in which we speculate on future directions for a reliable BP device research agenda, emphasizing the expanding efforts in improving calibration and re-calibration strategies to reflect the actual BP of human subjects especially in home settings where these new BP devices are commonly used.

METHODS

This study employed an experimental comparative design aimed at evaluating and comparing the sensitivity (accuracy and precision) of three different makes of blood pressure (BP) measurement devices under standardized conditions.

The study was conducted at the clinical physiology laboratory department of Ebonyi State University where controlled environmental conditions (temperature: 22-25oc, low noise levels and good sitting position) were maintained throughout the procedure.

Eighty-seven apparently healthy adult volunteer subjects, aged between 18-60 years, 30 females and 57 males were randomly selected through purposive sampling.

Inclusion criteria

- No prior history of cardiovascular disease
- No ongoing medication that could affect blood pressure
- Consent to participate in the study
- Subjects above thirteen years of age
- Apparently healthy subjects without any signs or symptoms of any sickness or illness

Exclusion criteria

- Subjects suffering from hypertension or with history of cardiovascular disease
- Subjects on medications that can affect blood pressure
- Subjects below thirteen years of age
- Pregnant or breast feeding mothers
- Subjects with any form of sickness or illness

Measurement of study population blood pressure and reading were done under these following standardized conditions:

- Subjects were well seated on a back padded seat, relaxed, arm supported at heart level, and feet on the floor.
- Measurements were done on bare arm and no-tight clothing after the subject was allowed to rest and relax for at least 5 minutes
- Proper cuff placement, inflation and deflation rate were maintained and two readings taken per a subject within an interval of 1-2 minutes, and the average taken.

Three different makes of BP measurement devices were: M3 (Digital -automated), A&D Medical UA-767S (Manual Aneroid) and Accoson Greenlight 300 (Mercury calibration) which was used as our standard to compare the other two. Each device used for the study was earlier calibrated using standard mercury sphygmomanometer (Gold standard) which was validated according to British Hypertension Society (BHS) and European Society of Hypertension (ESH) protocols.

For each measuring device, two readings were taken at different times to address the intrinsic variability of BP. Subsequently, the average data were used to calculate in order to obtain a final representative value of each measurement. Therefore, we obtained 174 measurements of each device which represented a total of 522 SBP, DBP, and 261 MAP evaluations. The order of device use was randomized using simple randomization table to eliminate bias. We maintained an interval of 1 minute between successive measurements to obviate venous congestion or arm fatique.

RESULTS

Table 1.Mean and standard deviation of blood pressure readings of the three devices.

	Device	Mean &Std deviation of systolic reading	Mean &Std deviation of diastolic reading
1	Aneroid	112.00± 9.69	75.50 ± 7.04
2	Omron	117.12 ± 5.72	70.46± 10.66
3	Mercury	109.46± 12.26	74.65± 8.69

The analysis showed that the Omron sphygmomanometer recorded the highest average systolic pressure (117.12mmHg), followed by Aneroid (112.00mmHg), while the Mercury sphygmomanometer recorded the lowest mean systolic pressure (109.46mmHg). The same pattern of differential mean and standard deviation values were seen in diastolic pressure readings of the three BP measurement devices (Table 1).

Statistically compared readings (systolic and diastolic) of the three studied blood pressure measuring equipment were shown in Fig.1.

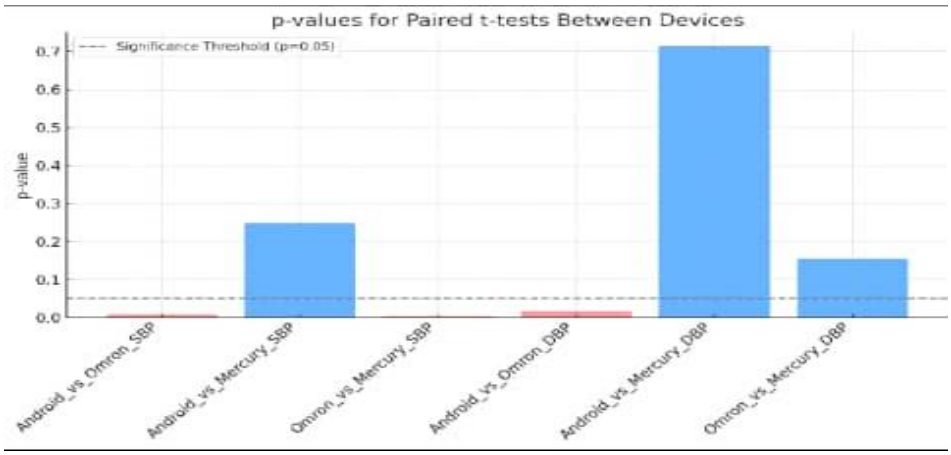

Fig. 1: Statistically comparison of the blood pressure readings of the three studied devices.

DISCUSSION

Accurate and reproducible blood pressure measurement device that gives international acceptable values is sine quanon for optimum treatment and management of high blood pressure disease. Cardiovascular disease and other high blood pressure diseases are on the increase following global economic crises and new emerging disease entities.

The finding of our study corroborated with multiple studies that earlier evaluated the accuracy and reliability of various BP measurement devices. Our work shows statistically significant difference both in systolic and diastolic between Omron and Android and Omron and Mercury but non-significant difference between Android and Mercury ($p \leq 0.05$). The mean value of Omron device is at variance with its standard deviation indicating non-reproducibility (precision) of the device. This finding is line with the work of Stergiou et al, (2018) that digital BP monitors, although convenient, may introduce systematic bias, particularly in diastolic values compared to auscultatory methods such as mercury sphygmomanometers. Moreso, Omboni et al (2016), reported in his work that automated oscillometric devices such as Omron were more prone to variability due to patient movement and arm positioning. This corroborates high standard deviation owned to Omron device observed in our work. This is a show of inaccurate and lower precision compared to Aneroid and Mercury sphygmomanometer. It is also reported that it gives erroneous reading in cases of hypotension, (What is sphygmomanometer, 2024). However, this biometric device has advantage of easy to inflate and deflates, easy to use, and giving out fast results. Moreso, it does not necessary need a skilled health professional and hence its home use. Semiautomatic sphygmomanometer (Aneroid), includes a bulb to inflate the cuff, with deflation and automatic determination of BP (Method of verification for mercurial and aneroid sphygmomanometers, 2018). IT senses arterial flow in which pulses received through the cuff are filtered, amplified, processed and applied to an algorithm to estimate systole and diastole values, (Martinez et al, 2008).It is easy to use and suitable for screening, saves clinical time and resources and needs less expertise and training when used in lack of an experienced health worker,(Ortega et al, 2018).

Despite higher accuracy and precision of semiautomatic sphygmomanometer, ix t is expensive and requires constant battery replacement, (Gorostidi et al, 2020).

The mercury sphygmomanometer which we used to compare the other biometric devices is cost-effective, does not require electricity or batteries, gives reliable readings in both hypertension and hypotension cases, but needs constant calibrations and there is a risk of noise interference, (Martinez et al,2008). However, it has been gradually discontinued

by WHO, (2020), because mercury has actually been considered as a risk factor for environmental pollution, (Panamericana de la Salud O.WHO, 2020). It also needs the ability to reduce evaluators bias and requires more time and effort from health workers. Mercury sphygmomanometer has a moderate level of accuracy and identifies hypertension with a 79% sensitivity and a 91% specificity, (Muniyandi et al, 2022). Moreso, WHO recommends evaluating the hearing capacity and the accuracy of the measurements of professionals on a regular basis since deficiencies in vision, hearing or manual dexterity are factors that contribute to inaccurate BP measurements when using the mercury sphygmomanometer, (Panamericana de la Salud O.WHO, 2020).

Recently, vital signs monitor which displays vital signs graphically, including invasive and non-invasive BP is invoke, (Patel et al,2016). It is the most frequently used device in intensive care units since it measures BP automatically at scheduled times. The monitor has a moderate level of accuracy and identifies arterial hypertension (SAH) with similar sensitivity and specificity to Mercury sphygmomanometer, though it has disadvantage of its results being affected by external factors such as patient movement, electromagnetic interference and incorrect use of device, (Diaz,2023).

Inasmuch as BPMDs are critical for diagnoses, and treatment of BP some commercially available BPMDs are not independently evaluated using a valid protocol, (Stergiou et al, 2021).Using inaccurate BPMD can lead to overdiagnosis and unnecessary treatment or underdiagnosis and exposure to preventable cardiovascular disease, (Stergiou et at, 2021). Therefore, a reliable sphygmomanometer is required in terms of sensitivity and specificity to provide security in clinical results.

Blood pressure digital biomedical device, in our study showed less sensitivity and specificity and, therefore, should be reserved for home use and monitoring of already established cases, while semiautomated sphygmomanometer and mercury sphygmomanometer showed higher sensitivity and specificity, and are recommended for clinical use, though with caution following WHO report on mercury.

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