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Comparison between a Fully-Automated and Mercury Sphygmomanometer for Measuring Blood Pressure in Adult Indian Females

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ABSTRACT: The use of gold standard mercury sphygmomanometers in clinical and research studies is in decline due to recent concerns about the mercury toxicity and its ill effects on the environment and health. This has led to the widespread use of automated sphygmomanometers. Despite this change, only few studies have compared the mercury and automated blood pressure (BP) measurements. This research work evaluated the performance of a fully-automated sphygmomanometer against a standard mercury sphygmomanometer, before implementing a study-wide transition to the fully-automated sphygmomanometer. BP of 50 normotensive and 24 hypertensive individuals was measured in random order, under standardized conditions. The study found no statistically significant difference between systolic BP (SBP) and diastolic BP (DBP) measurements of both sphygmomanometers. Regression analysis demonstrated that the measurements of fully-automated sphygmomanometer have positive and statistically strong correlation with the mercury measurements. Bland-Altman plot also showed a perfect agreement between the measurements of both sphygmomanometers. The conclusion from this study is that the mercury BP measurements can be replaced by measurements taken using a validated, fully-automated sphygmomanometer in research settings. The slightly lower readings obtained with fully-automated sphygmomanometer (in the context of reduced observer-subject interaction) may be a more accurate estimate of BP.

KEYWORDS: blood pressure, blood pressure determination, mercury sphygmomanometer, fully-automated sphygmomanometer, BPMR-112, OMRON HEM-7203.

I.INTRODUCTION

A few risk factors account for a large contribution to global loss of healthy life. Overall, 26% of the world population had hypertension in 2000 and 29% are projected to have this condition in 2025 [1]. Hypertension has been recognized as the third most important cause for global burden of disease and as the leading global risk factor for mortality, accounting for over 7 million deaths yearly [2].

Accurate BP measurement is essential for optimal diagnosis and treatment of hypertension, which is underpinned by the need for a reliable and highly accurate sphygmomanometer [3].

The conventional approach to BP measurement is based on the use of standard mercury sphygmomanometer, which has been regarded as the “gold standard” for BP measurement since its first description in 1896. However, environmental concerns about the toxicity of mercury have led to an attempt to replace the mercury sphygmomanometers with non-mercury sphygmomanometers, of which aneroid devices are the leading contenders [4]. However, an aneroid sphygmomanometer has moving parts compared to mercury sphygmomanometer and are subjected to fatigue which is a major source of errors in aneroid measurements [5]. Therefore, an aneroid sphygmomanometer should be inspected for physical defects and calibrated for accuracy against a standard mercury sphygmomanometer at 6-months interval to prevent inaccurate BP measurements [6]. However, observer bias is the important source of error in auscultatory BP measurement technique [7]. Thus, another alternative for BP measurement is the utilization of automated sphygmomanometers. To date, a growing number of such devices have been found in the market, considering that they are affordable and easy to use. Although, the British Hypertension Society (BHS), and the Association for the

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Advancement of Medical Instrumentation (AAMI) have developed laboratory protocols to evaluate automated sphygmomanometers [8, 9]. However, the validity of these devices was mainly obtained from samples of healthy adult individuals. The clinical and research studies involving their evaluation in other populations and clinical conditions are fewer and thus suggest further investigations. We therefore conducted the present study to compare the performance of a fully-automated sphygmomanometer against a mercury sphygmomanometer within two different groups of subjects, namely (i) normotensives, and (ii) hypertensives.

II.MATERIALS AND METHODS

A) *PARTICIPANTS*

The sample used for this study consisted of 74 females from Sant Longowal Institute of Engineering and Technology (SLIET), Deemed-University, Longowal, District Sangrur, Punjab, India. From the total sample of 74 subjects, subjects with specific characteristics were placed into two different groups: a group of 50 were normotensive, and a group of 24 who were hypertensive. To be eligible participants had to over 18 years of age. We excluded the female subjects who were pregnant and who had arrhythmias [3]. The institutional research committee approved the research protocol and all participants gave written consent before participation.

B) *ANTHROPOMETRIC DATA COLLECTION*

The age of the participants was determined from their date of birth registered in the institute. A portable digital scale and a metal stadiometer fixed to wall was used to determine the weight and height respectively. All the measurements were taken with the individuals barefoot and dressing light clothes [10]. Based on the values of weight and height, the body mass index (BMI) was calculated, and the values were expressed as Kg/m2. For the measurement of mid upper arm circumference (MUAC), a subject was instructed to stand erect with feet together and the left arm flexed at 90º at the elbow, as demonstrated in Fig.1. Using an inelastic tape, the midpoint of the upper arm was determined by measuring the length of the arm between the acromium and olecranon process (between the shoulder and elbow). The mid-point of the upper arm was then marked with a temporary marker and the bare arm circumference, to the nearest 0.1 cm, was measured at the mid-point.

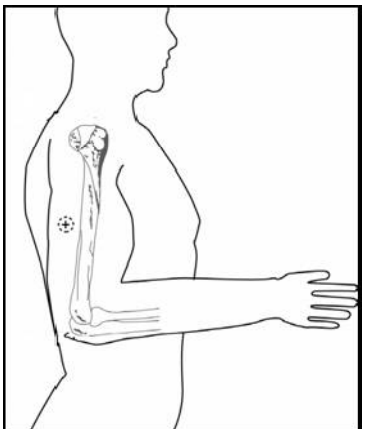

Fig.1MUAC measurement

C) *SPHYGMOMANOMETERS USED FOR BP MEASUREMENT*

(i) Mercury sphygmomanometer:- The mercury sphygmomanometer (BPMR-112), manufactured by Industrial Electronic & Allied Products, Maharashtra, India, as represented in Fig. 2, was used as a standard sphygmomanometer in this research work. It works onthe principle of auscultation with a BP measurement range of 0-300mmHg. SBP and DBP measurements are displayed on mercury column. Accuracy of measurements is ±3mmHg. Cuffs available are: small adult (for MUAC: 22-26cm), adult (for MUAC: 27-34cm) and large (for MUAC: 35-44cm). This sphygmomanometer is validated in many clinical circumstances against direct intra-arterial BP measurements [11].

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Fig. 2Mercury sphygmomanometer (BPMR-112)

(ii) Fully-automated sphygmomanometer:- The fully-automated sphygmomanometer (OMRON HEM-7203), as shown in Fig. 3, was manufactured by OMRON Healthcare Co., Ltd., Kyoto, Japan. It records brachial BP oscillometrically with a BP measurement range of 0-299mmHg and heart rate range of 40-180 beats/min. SBP, DBP and heart rate are displayed on a liquid crystal display (LCD) read-out. Accuracy of measurements is: pressure: ±3mmHg, pulse: ±5% of display reading. Cuffs available are: small (for MUAC: 17-22cm), medium (for MUAC: 22-32cm) and large (for MUAC: 32-42cm). Both inflation and deflation of the cuff are automatic. OMRON BP monitors are clinically validated according to the protocols of three major standards developing organizations: European Society of Hypertension (ESH), British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) [12].

Fig. 3Fully-automated sphygmomanometer (OMRON HEM-7203)

D) ***BP MEASUREMENT PROCEDURE***

The present study was carried out in Bio-electric Signal Processing Laboratory of Electrical and Instrumentation Engineering (EIE) Department at SLIET, Deemed University, Longowal, Distt. Sangrur, Punjab, INDIA.

The observers involved in the study were trained using the BHS's BP measurement training materials [13].

Subjects were advised to avoid alcohol, cigarette smoking, coffee/tea intake, and exercise for at least thirty minutes prior to their BP measurement. They were also instructed to empty their bladder prior to measurements and remove any constrictive clothing and jewellery that may interfere with the cuff placement. Moreover, they were asked not to talk and move during measurement.

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Before starting BP measurement, the participants were made to rest for five minutes to allay anxiety. The measurements were performed in standard sitting posture of the subject, as illustrated in Figure 3.6, with the measurement arm supported at heart level, back supported by back support of the chair, legs uncrossed and feet flat on the ground, as these are the potential confounding factors [3].
To eliminate the error due to wrong-size cuff, an appropriate size of cuff was determined from the mid-arm circumference of each subject [14]. To eliminate the order effect, the order of the use of sphygmomanometer type (mercury or fully-automated) for measurement was based on each subject's personal identification number (assigned when the consent for participation in the study was obtained from the subjects). Subjects with odd study numbers were assigned the order mercury-automated, and subjects with even study numbers were assigned the order automated-mercury. All measurements were taken on left arm of the subject to eliminate difference between BP of the two arms [15].

To improve the reliability of measurements, the measurement protocol was repeated for seven consecutive days, which results in a set of seven mean BP measurements for each subject [3]. All measurements were obtained under similar conditions except for the different sphygmomanometers. Hence, all measurements were obtained under similar measurement conditions except for the use of different sphygmomanometers.

E) ***DATA ANALYSIS***
Data were expressed as mean±SD. A paired t-test was used to determine whether mercury and fully-automated observations differ from each other in a significant way. A univariate linear regression analysis was used to examine the relationship between BP measurements of both sphygmomanometer. Bland-Altman analysis was used to determine the agreement between measurements of two sphygmomanometers. Probability (p) value of less than 0.05 was deemed significant in data analysis.

III.RESULTS AND DISCUSSION

Anthropometric characteristics such as age, height, weight, BMI and MUAC of the participants are presented in Table 1.

Table 1- Anthropometric characteristics of the enrolled participants

Anthropometric Characteristics	***Normotensive subjects (Number, N = 50)**	***Hypertensive Subjects (Number, N = 24)**
Age (years)	23.1±1.233 (21-28)	50.583±11.348 (28-80)
Height (m)	1.6±0.042(1.435-1.68)	1.648±0.101 (1.51-1.832)
Weight (kgs)	55.275±7.004 (39-70.9)	73.604±9.522 (50.3-92)
BMI (kg/m2)	21.576±2.455 (15.172-26.386)	27.075±2.281(21.572-30.458)
Arm Circumference (cm)	27.540±2.015 (22-31)	29.167±1.845 (24.5-31)

*expressed as mean±SD (range)

Mean value of BP (SBP/DBP) taken with OMRON HEM-7203 was 103.745/68.156 compared to 103.747/68.168 with BPMR-112 for normal and 117.161/75.442 compared to 117.192/75.466 for hypertensive subjects. It was observed that the mean value of BP measurements taken by using OMRON HEM-7203 sphygmomanometers was very close to the BPMR-112 sphygmomanometer's measurements that indicated high accuracy of measurements.

A) ***ASSESSMENT OF THE PAIRED DIFFERENCE BETWEEN MEASUREMENTS OF SPHYGMOMANOMETERS***
A two-tailed paired t-test was used to evaluate whether observed mean difference between measurements of sphygmomanometers in a pair, was statistically significantly different from zero. The null and alternative hypothesis was stated as follows:

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Null hypothesis: No statistically significant difference existed between paired BP measurements of sphygmomanometers.

Alternative hypothesis: A statistically significant difference existed between paired BP measurements of sphygmomanometers.

Level of significance (α) was set at 5%.

The critical value of t-statistics t(critical) is ±2.0096 and ±2.0639 for 49 and 24 degree of freedom (DOF), respectively, at 5% level of significance.

In normotensive as well as hypertensive subjects, t(calculated)<t(critical) when BP measurements of BPMR-112 sphygmomanometer were compared against OMRON HEM-7203 in all cases, as shown in Table 2. The calculated p-value was found to be greater than 5% or 0.05 revealed that the null-hypothesis was accepted. In other words, there was no statistically significant difference existed between SBP and DBP measurements of both sphygmomanometers.

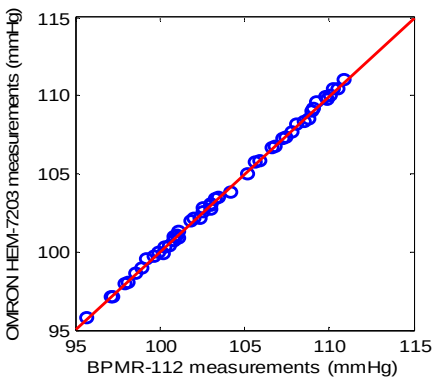
Table 2- Results of paired t-test for assessment of the paired difference between measurements of both sphygmomanometers

Participants	*Mean difference±SD	*t	*p-value
Normal	0.0019±0.1494/0.0114±0.1043	0.0908/ 0.7730	0.93/0.44
Hypertensive	0.0318±0.1094/0.0238±0.0952	1.4261/ 1.2239	0.17/0.23

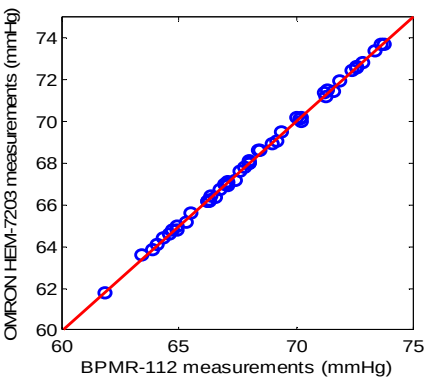
*expressed as SBP/DBP.

B) ***ASSESSMENT OF THE RELATIONSHIP BETWEEN PAIRED MEASUREMENTS OF SPHYGMOMANOMETERS***

For the assessment of relationship between BP measurements of both sphygmomanometers, a scatter plot was drawn first with the measurements of BPMR-112 and OMRON HEM-7203 sphygmomanometer on x-axis and y-axis, respectively. Pattern of data points around the least-square fit line revealed a positive and linear relationship between the BP measurements with negligible deviations between the least-square fit line and BP measurements, as presented in Fig. 4 and 5, for normotensive and hypertensive subjects respectively.



(a) SBP measurements



(b) DBP measurements

Fig. 4Scatter plots between SBP and DBP measurements of BPMR-112 and OMRON HEM-7203 sphygmomanometer in normotensive subjects

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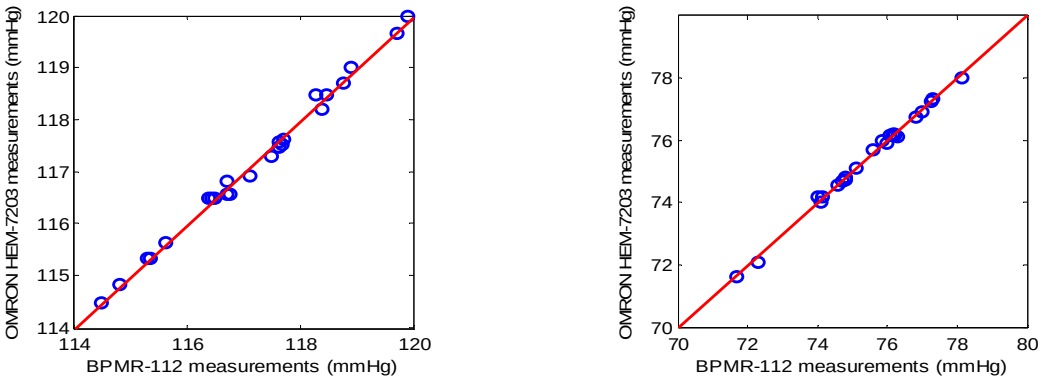

(a) SBP measurements (b) DBP measurements

Fig. 5Scatter plots between SBP and DBP measurements of BPMR-112 and OMRON HEM-7203 sphygmomanometer inhypertensive subjects

Furthermore, linear regression analysis was used for determination of the correlation between measurements of both sphygmomanometers. The null and alternative hypothesis was stated as follows:

Null-hypothesis: slope of regression line is zero.

Alternative hypothesis: slope of regression line is not zero.

Level of significance (α) was set at 5%.

A positive, high and very high correlation was observed between paired measurements of sphygmomanometers, as the value of R was found very close to 1, illustrated in Table 3. Moreover, measurements of OMRON HEM-7203 sphygmomanometer were significant predictor of BPMR-112's BP measurements as the calculated p-value was <0.001, which meant results were extremely significant. Hence, the null-hypothesis was rejected or we accepted that the slope of regression line between BP measurements of BPMR-112 and OMRON HEM-7203 sphygmomanometer was not zero.

Table 3- Results of linear regression analysis for assessment of the relationship between paired measurements of sphygmomanometers in normotensive and hypertensive subjects

Participants	***Regression equation**	***R**	***p**
Normal	y=0.101+0.999x / y=0.414+0.994x	0.99/0.99	<0.001/<0.001
Hypertensive	y=0.264+0.997x/ y=0.0383+0.999x	0.99/0.99	<0.001/0.001

*expressed as systolic/diastolic.

The clinically insignificant bias (mean difference) and narrow limits of agreement demonstrated a perfect agreement between the measurements of two sphygmomanometers. Moreover, there is no clear trend in the data to suggest a specific cut point where the two sphygmomanometers become discordant. And 95% of discrepancies for SBP and DBP measurements were between limits of agreement, as shown in Fig. 5 and 6 for normontensive and hypertensive individuals respectively, the required features of the Bland-Altman analysis for the results to be generalizable [16]. Table 4 summarized the results of Bland-Altman analysis of the data.

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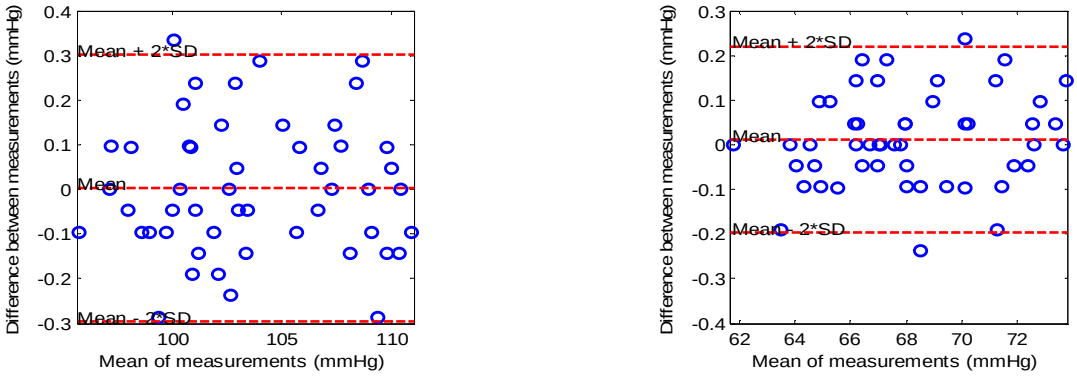
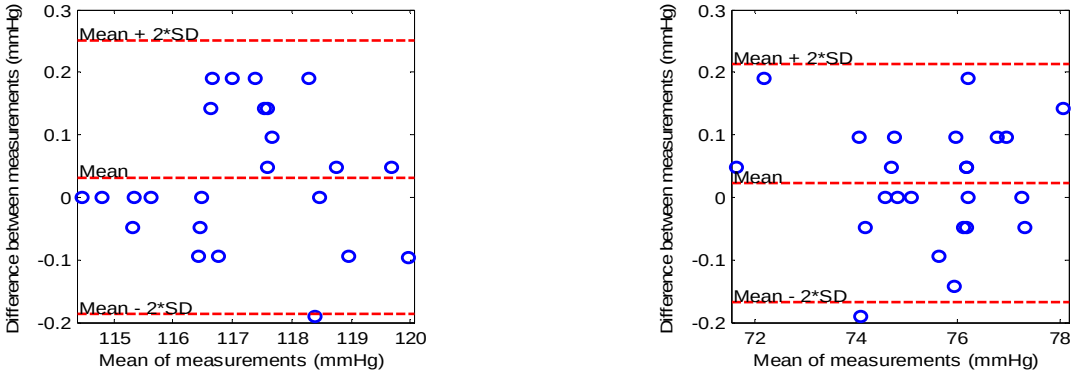


(a) SBP measurements (b) DBP measurements

Fig. 5 Bland-Altman plots between SBP and DBP measurements of BPMR-112 and OMRON HEM-7203 sphygmomanometer in normotensive subjects



(a) SBP measurements (b) DBP measurements

Fig. 6 Bland-Altman plots between SBP and DBP measurements of BPMR-112 and OMRON HEM-7203 sphygmomanometer in normotensive subjects

Table 4- Results of Bland-Altman analysis for assessment of the agreement between paired measurements of sphygmomanometers in normotensive and hypertensive subjects

Measures of Bland-Altman analysis (SBP/ DBP)	
Bias±SD	**Limits of agreement**
0.0019±0.1494/0.0114±0.1043	(0.3006, -0.2968)/(0.2201, -0.1973)
0.0318±0.1094/0.0238±0.0952	**(0.2506, -0.1869)/(0.2142, -0.1666)**

Bold values indicate measures of Bland-Altman analysis for hypertensive subjects

VI.CONCLUSION

In conclusion, this study documented that OMRON HEM-7203 can be used as non-mercurial alternative for BP measurement in normotensive and hypertensive subjects in research settings, although we support further research in this area.

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