

Assessment of accuracy of mercury sphygmomanometer and automated oscillometric device of blood pressure measurement in population of normal individuals



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ABSTRACT

Background: Blood pressure (BP) measurement is the most common investigation performed nearly on all patients' for diagnosis and treatment of hypertension. Accuracy of the measurement device is crucial for timely diagnosis. However, sphygmomanometer requires medical expertise whereas automated oscillometric device needs only careful observations in measuring BP. **Aims and Objectives:** The objective of the present study is to determine the comparative accuracy of mercury sphygmomanometer and automated oscillometric device of measuring BP and the limit of agreement between the two devices. **Materials and Methods:** A cross-sectional study designed and carried out at MGM Medical College, Indore among 438 normal individuals. Age, weight, height, body mass index, history and BP were recorded. An average of three recording of BP measurement by both the devices was used. **Results:** Out of a total, 52.3% were male and 47.7% were female. Average SBP (130.78 ± 17.31 mmHg) and DBP (86.96 ± 10.26 mmHg) measured by automated instrument were significantly elevated than SBP (126.32 ± 13.47 mmHg) and DBP (81.70 ± 8.63 mmHg) by mercury sphygmomanometer while the mean differences in SBP and DBP (5.16 ± 4.40 and 5.57 ± 3.30 mmHg) were statistically significant ($p = 0.000$). Hypertension reported in more patients with automated (79.0%) compared to sphygmomanometer (76.0%). Bland-Altman plots indicated a positive linear trend for BP readings between two instruments. Differences were more in SBP reading than DBP within three categories. Measurement of agreement indicated strong statistically significant ($p = 0.000$) mutual agreement between the rate of judging hypertension by two apparatuses. The coefficient of determination for SBP ($R^2 = 0.95$) and DBP ($R^2 = 0.87$) were very high when manual readings compared to automated. **Conclusion:** Present research suggests that BP readings obtained by automated and sphygmomanometer is comparable however as compared to mercury sphygmomanometer oscillometric device gives slightly higher readings of SBP. Looking towards the simplicity of measurement and freedom from environmental toxicity automated oscillometric device may be recommended as a primary tool for early detection and management of high BP.

Key words: Blood pressure measurement; Sphygmomanometer; Hypertension; Automated Oscillometric device; Systolic blood pressure; Diastolic blood pressure

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INTRODUCTION

Early diagnosis of hypertension is essential for timely management and prevention of its complication. Accuracy of the BP measurement plays a crucial role in curbing the menace of hypertension and to decrease associated morbidity which a matter of great public health concern.¹ High blood pressure is ranked as the third most important risk factor of attributable burden of disease in south Asia (2010) and the prevalence for hypertension in India was 29.8%² and, is directly responsible for 57% of all stroke deaths and 24% of all coronary heart disease deaths.³

Therefore, to reduce burden of deaths from coronary heart diseases and other diseases timely diagnosis of hypertension is must which is dependent on accuracy of the BP measurement device. Falsely underestimated or overestimated readings both put the patient to risk. An underestimated reading, the patient is at a risk of hypertension related diseases, which can significantly reduce life expectancy whereas an over estimated reading exposes the patient to the hazards of treatment of hypertension. Therefore an accurate reading is essential.⁴ There are different invasive and non-invasive methods available to measure blood pressure.⁵ The blood pressure should be measured in both the arms because differences exist and measurement in only one arm may lead to under diagnosis of hypertension.^{6,7} However, the inter-arm blood pressure difference is efficient diagnostic tool for diagnosis of hypertension and disorders related to hypertension.⁸

There are three non-invasive modalities commonly used to check BP throughout the world such as manual mercury sphygmomanometer, aneroid meter and the automated oscillometric device (digital). The manual mercury sphygmomanometer is considered to be the gold standard.⁹ Mercury sphygmomanometers had been used by healthcare professionals over the last 100 years in both hospital and ambulatory settings as a gold standard.¹⁰ But, there is no long-term future for these mercury based devices¹¹ due to potential environmental toxic effects of mercury (Hg). These devices banned in European countries such as Sweden and Netherlands as well as in the United States.¹²⁻¹³

An approach is necessary to identify the alternative device which is easier and competent in measuring BP. Non-mercury sphygmomanometers like aneroid and more recently, digital ones have replaced the use of traditional mercury instruments in many settings. This device translates arterial pressure into oscillometric wave and with system built algorithm display readings.¹⁰

Oscillometric devices are gaining fame since these devices are considered environmentally safe and have a significant

advantage over their manual counterparts (mercury or aneroid) and they don't require a trained professional to measure BP. Among the various advantages of the available replacements of mercury devices, aneroid instrument has the portability¹⁴, while that of digital instruments are ease of use and they obviate the need of auscultation skill of the examiner.¹⁵ Thus these devices are recommended and used in various population surveys of BP recording.¹⁶ Moreover they are also useful for ambulatory BP recordings and for monitoring blood pressure at home,¹⁷ to add further they are free from the bias of white coat hypertension thus give more accurate readings.^{18,19}

Keeping the above in mind the present study was performed to identify the accuracy of automated oscillometric (digital) measuring devices of measuring blood pressure as compared to mercury sphygmomanometer (manual) and the limit of agreement between the two devices.

Objective of the study

The present study aims to compare the accuracy of BP measurement by mercury sphygmomanometer and automated oscillometric measuring device and to find out limits of agreement between the two devices. The findings of the study were analyzed and discussed.

MATERIALS AND METHODS

Background and study design

A cross sectional study designed and carried out at Mahatma Gandhi Memorial Medical College, Indore (M. P.), India among normal healthy individuals.

Participants and data collection method

Out of a total of 612, four hundred thirty eight (N=438) normal individuals selected randomly for the study. Ethical approval and prior informed consent from the subjects were obtained. Individuals aged between 20 and 84 years of both the sexes but without diseases were participated in the study. Age in completed years, sex, weight by digital weighing scale with accuracy of 50 grams, height in centimeter by stadiometer, body mass index (BMI), and blood pressure by two devices were recorded using standard protocol. An average of three recordings of blood pressure measurement by both the devices was used for analysis.

Blood pressure measurements

All normal individuals who were the attendees of patients were assessed by one trained doctor experienced in collecting clinical data. Following 5 minutes of rest in supine position, both palpatory and auscultatory methods were used to record the BP using validated standard sphygmomanometer and automated oscillometric measuring device with appropriately sized cuffs in right

arm. Three readings for systolic blood pressure (SBP) and diastolic blood pressure (DBP) were noted for specified arm and the average of BPs was used for further analysis. All the measurements were taken between 10:00 AM to 1:00 PM.

Statistical analysis

The data analyzed by using SPSS 17.0 trial version. Descriptive and inferential statistics were used. Results for continuous variables presented as mean \pm standard deviation while categorical as numbers (%). This was assumed that the observations recorded for a continuous variable had followed a normal distribution. Z-test and one way analysis of variance used to compare the mean values of BP recordings. Cohen's kappa statistic used to measure the agreement between two measuring devices.

Regression analysis was also computed to project the relationship between the automated oscillometric and manual blood pressure readings. The probability value $p \leq 0.05$ was considered as significant while $p \leq 0.01$ and above were considered as highly/strongly significant.

RESULTS

Out of a total of 438 normal individuals, 229 (52.3%) were male and 209 (47.7%) were female. The age of all subjects were obtained with a span of 21 to 83 years with a mean spread of age was 40.79 ± 14.77 years. The characteristics of the studied subjects depicted in Table 1.

Table 1 showed that large numbers of patients (214, 48.8%) between 20-40 years. 175 (40.0%) patients aged 40-60 years while the 60-80 year age group included 45 (10.3%) patients. Some (4, 0.9%) normal individuals were above and equal to 80 year. The body mass index of most of the individuals (281, 64.2%) was normal. 142 (32.4%) individuals diagnosed as overweight. Few (11, 2.5%) had obesity whereas only four (0.9%) were underweight. Hypertension was reported in more individuals (79.0%) when measured by using a standard validated sphygmomanometer as compared to automated instrument (76.0%).

Table 2 showed the features and characteristic of the selected population comprised of 229 males and 209 females. Average age of individual's was 40.79 ± 14.77 years within range of 21-83 years. Range of body mass index was from 17.58 to 31.45 kilogram/meter² with an average of 23.97 ± 2.98 kilogram/meter² whereas the mean weight and height also reported in table. The mean difference between recordings of automated oscillometric and manual systolic and diastolic BPs were 5.16 ± 4.40 mmHg and 5.57 ± 3.30 mmHg respectively. The ranges for differences in automated and manual systolic and diastolic BPs found to be -8 - +19 and -8 - +16 mmHg respectively.

Table 3 highlights the measurement of BP of normal individuals between manual and automated instruments. Average (Mean \pm SD) SBP (130.78 ± 17.31) and DBP (86.96 ± 10.26 mmHg) measured by automated instrument found to be significantly greater as compared to SBP

Table 1: Distribution of age, body mass index and hypertension

Parameter	Variables	Frequency N=438	Percentage (%)
Age	20-40 year	214	48.8
	40-60 year	175	40.0
	60-80 year	45	10.3
	≥ 80 year	4	0.9
Body Mass Index (kg/m ²)	<18.5 (Underweight)	4	0.9
	18.5-24.9 (Normal Weight)	281	64.2
	25-29.9 (Over Weight)	142	32.4
	≥ 30 (Obesity)	11	2.5
Hypertension	Present (Sphygmomanometer)	346	79.0
	Present (Automated)	333	76.0

Table 2: Subject's characteristics

Characteristics (N = 438)	Mean or frequency	Standard deviation	Range
Age (Year)	40.79	14.77	21-83
Sex (Male/Female)	229/209	-	-
Weight (Kilogram)	60.42	7.87	41-90
Height (Centimeter)	158.81	6.59	137.16-185.82
Body Mass Index (Kilogram/Meter ²)	23.97	2.98	17.58-31.45
Difference between two apparatuses (mmHg)			
Systolic Blood Pressure	5.16	4.40	-8 - +19
Diastolic Blood Pressure	5.57	3.30	-8 - +16

Table 3: Significance of blood pressure reading between the two apparatuses (manual and automated)

Parameter and apparatus	Scatter for blood Pressure	95% CI of the mean		Z-statistic	p-value (LOS)
	Mean ± SD	LB	UB		
SBP (mmHg)					
Sphygmomanometer	126.32±13.47	125.05	127.58	18.40	p=0.000 [#]
Automated	130.78±17.31	129.15	132.40		
Mean Difference	4.46 mmHg				
DBP (mmHg)					
Sphygmomanometer	81.70±8.63	80.89	82.51	29.16	p=0.000 [#]
Automated	86.96±10.26	85.99	87.92		
Mean Difference	5.26 mmHg				

[#]The mean differences are highly/strongly significant at the 0.000 levels of significance. [CI-Confidence Interval; UB-Upper Bound; LB-Lower Bound; LOS-Level of Significance]

(126.32±13.47) and DBP (81.70±8.63 mmHg) measured by manual sphygmomanometer.

However, the mean differences of 4.46 mmHg in SBP and of 5.26 mmHg in DBP were statistically significant (p=0.000). The statistical agreement of 95.0% confidence limits for SBP and DBP noted using digital instrument (129.15 to 132.40 mmHg and 85.99 to 87.92 mmHg) was significantly raised than manual instrument (125.05 to 127.58 mmHg and 80.89 to 82.51 mmHg).

Bland-Altman difference plot (Figures, 1 and 2) showed the limits of agreement between two devices of measuring BP which displays a scatter diagram of the differences plotted against the averages of the two measurements. However, horizontal lines are drawn at the mean difference and at the limits of agreement of the differences.

Amount of bias between mean systolic and diastolic blood pressures noted on automated and manual sphygmomanometer apparatuses were 4.46 (-5.48 to 14.42 mmHg) and 5.25 (-2.14 to 12.65 mmHg).

Difference between digital and manual readings for both pressures found to elevate subsequently the average BP was also rose which known as the error of electronic measurement is shown in next table four. Plots in Figures, 1 and 2 reported that there was a significant agreement between automated oscillometric and manual devices. Nevertheless, the Bland-Altman plots indicated a positive linear trend for both, SBP and DBP readings between automated and manual measurements.

Table 4 shows the variations in the differences in BP measurement among normal healthy individuals between automated and manual instruments. Subjects explored for three categories of BP based on manual reading (<120 mmHg, 120 -140 mmHg and >140 mmHg) in order to observe the trend of differences. It was found to be dependent on increment in BP. An increase in SBP and DBP readings between digital and manual measurements was significantly (p=0.000) accompanied with an increment

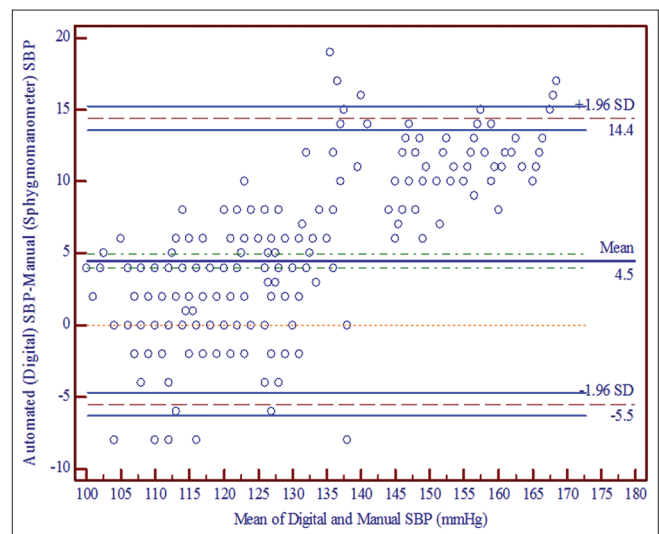


Figure 1: Bland-Altman plot showing the reading difference and limits of agreement of SBP between automated and manual apparatuses

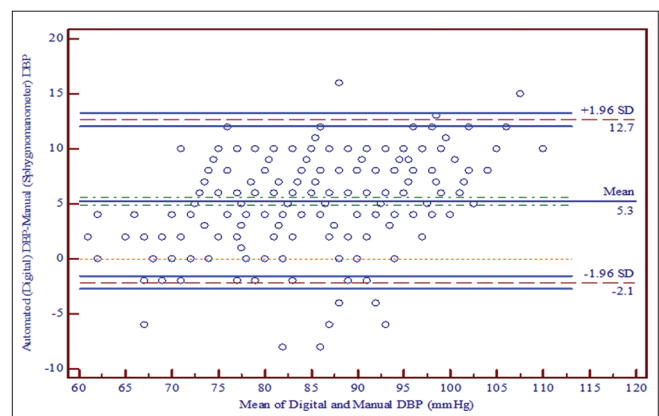


Figure 2: Bland-Altman plot showing the reading difference and limits of agreement of DBP between automated and manual apparatuses

in their difference recordings with respect to these categorizations. However, the differences found to be more in SBP than DBP within three categories.

An average of differences of SBP measured between automated and manual instruments was significantly (p=0.000) elevated among those who had a manual systolic

Table 4: Categorized blood pressure difference between the two apparatuses (automated and manual)

Parameter and Variable	Difference of Blood Pressure Mean±SD	95% CI of the Mean		F-statistic	p-value (LOS)
		LB	UB		
SBP (mmHg)					
< 120 mmHg	1.34±3.21	0.75	1.93	199.33	p=0.000#
120-140 mmHg	3.40±4.13	2.87	3.94		
> 140 mmHg	11.05±2.93	10.45	11.66		
DBP (mmHg)					
< 120 mmHg	3.85±3.59	3.19	4.51	26.48	p=0.000#
120-140 mmHg	5.09±3.61	4.62	5.56		
> 140 mmHg	7.45±3.45	6.73	8.16		

#The mean differences are highly/strongly significant at the 0.000 levels of significance. [CI-Confidence Interval; UB-Upper Bound; LB-Lower Bound; LOS-Level of Significance]

Table 5: Measure of agreement between two blood pressure measuring modalities in terms of detection rate of hypertension

Characteristic	Variable	Hypertension (Automated)		Total
		Absent	Present	
Hypertension (Manual)	Absent	332 75.8%	14 3.2%	346 79.0%
	Present	1 0.2%	91 20.8%	92 21.0%
	Total	333 76.0%	105 24.0%	438 100.0%
	Value of Kappa is 0.90 and P=0.000#			

#Limits of agreement are highly/strongly significant at the 0.000 levels of significance

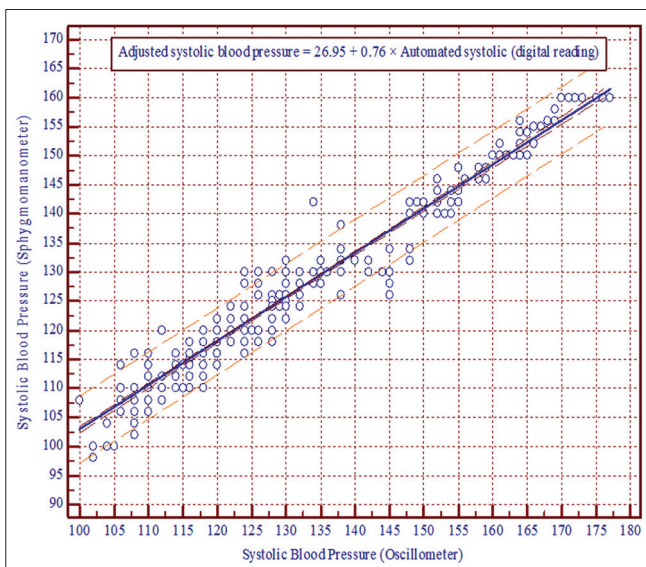


Figure 3: Regression analysis shows the prediction of manual SBP using automated SBP

reading of above 140 mmHg (11.05±2.93 mmHg) as compared to those who had readings between 120 mmHg and 140 mmHg (3.40±4.13 mmHg) and below 120 mmHg (1.34±3.21 mmHg).

Average differences of DBP measured between automated and manual instruments was significantly (p=0.000) elevated among those who had a manual systolic reading of above 140 mmHg (7.45±3.45 mmHg) as compared

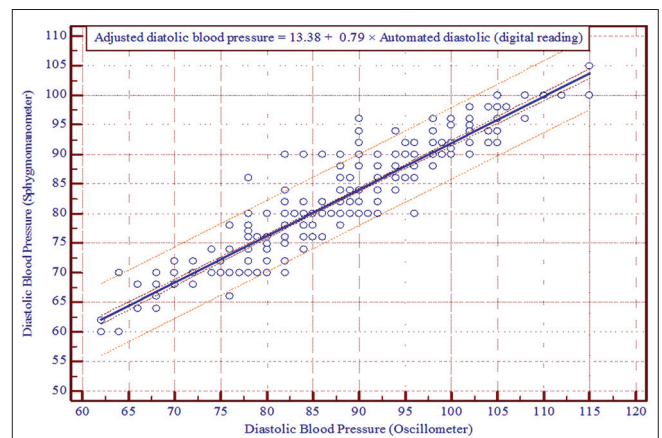


Figure 4: Regression analysis shows the prediction of manual DBP using automated DBP

to those who had readings between 120 mmHg and 140 mmHg (5.09±3.61 mmHg) and below 120 mmHg (3.85±3.59 mmHg).

Cohen's kappa statistic used to measure the agreement between two apparatuses in order to compare the detection rate of hypertension among population which can be seen in Table 5. However, a BP recordings of normal healthy individuals of <140/90 mmHg reported as absence of hypertension as per WHO diagnosis criteria to detect hypertension whereas recordings of >140/90 mmHg used as presence of hypertension.

Table 5 demonstrates that the automated apparatus found with significant agreement of reporting approximately similar degree of measurement of BP in detecting hypertension when compared to sphygmomanometer among normal healthy individuals. Measurement of agreement using Cohen's Kappa found to be high (0.90). However, statistically highly significant ($p=0.000$) mutual agreement of more than 95% confidence was judged between the rate of detection of hypertension by two apparatuses.

Relationship between manual and automated BP readings had reported using regression analysis when automated BP readings considered as the independent variable.

The coefficient of determination for SBP ($R^2=0.95$) was very high when manual readings of BP compared to automated apparatus. In Figure 3, linear regression analysis showed that the automated SBP is the significant predictor ($\beta = 0.76$, $p=0.000$) of SBP noted manually with a regression equation [Adjusted SBP = $26.95 + 0.76 \times$ automated SBP (digital)].

The coefficient of determination for DBP ($R^2=0.87$) was high when manual BP readings compared to automated apparatus (digital). Figure 4 shows that DBP noted on automated was also the significant predictor ($\beta = 0.79$, $p=0.000$) of DBP measured manually with a regression equation [Adjusted DBP = $13.38 + 0.79 \times$ Automated DBP (digital)].

Discussion: Scientific research studies conducted during the last decades have clearly showed that automated oscillometric device do not require skilled expertise for BP measurement and they can be used as a primary tool for early diagnosis and management of high BP. In the similar context, the present study had evaluated the role of automated BP measuring devices in early health care for the management of high BP among normal population.

Mercury sphygmomanometers have been considered as a gold standard for measuring blood pressure reading for a long time. However, in the recent past oscillometric equipment had gain importance.²⁰ Present study demonstrated the difference between digital and manual readings. Both SBP and DBP pressures found to increase and subsequently the average BP was also elevated which is known as the error of electronic measurement but there was a significant agreement between automated and manual devices as shown by table four.

However, results of the present study indicated a positive linear trend for both, SBP and DBP readings between automated and manual measurements which is in agreement with the results of a study carried out by

Mansoor *et al* in 2016 observed that there was a positive linear trend for SBP reading as the average SBP is raising, the difference between manual and electronic readings (subsequently called the error of electronic measurement) is also rising.¹⁷

Present study demonstrated that the mean difference in SBP was 5.16 mmHg and 5.57 mmHg for DBP between automated and manual apparatuses were statistically significant which is in agreement with the recent study conducted by Sujanitha in 2018, observed that the mean difference of the mercury and oscillometric readings in SBP is 4.18 mmHg in right arm and 3.66 mmHg in left arm which are statistically significant.²¹

Myers MG *et al* reported that there is a higher level of discrepancy when using these devices on hypertensive patients.¹⁶ Results of the present study revealed that automated apparatus found with significant agreement of reporting approximately similar degree of measurement of BP in detecting hypertension when compared to manual. Further, study explored for three categories of BP based on manual reading and was found to be dependent on increment in BP which is correlated with the results of the study conducted by Mansoor *et al* showed that the differences between manual and electronic readings for the two groups were statistically significant.¹⁷

Estimates of the cut-point for normal BP for routine manual versus automated values are still preliminary but Beckett, and Godwin suggested that conventional office BP at 140/90 mm Hg is equivalent to an automated reading of 135/85 mm Hg taken in the office with subjects resting alone in a quiet room.²² In the present study, 346/79.0% and 333/76.0% individuals reported hypertensive using manual and automated techniques respectively according to a cut-point of <140/90 mm Hg for normal manual BP. However, research carried out by Ma Y *et al* showed that variation in BP readings by two instruments within participant/technician accounts for most of the variation.²³

The performance of mercury and digital models was similar and significantly better than aneroid models. However, digital devices requiring no expertise at all showed better accuracy as compared to mercury sphygmomanometer.¹⁴

Automated apparatus found with significant agreement of reporting approximately similar degree of measurement of BP in detecting hypertension when compared to sphygmomanometer among normal healthy individuals. Measurement of agreement found to be high was in agreement with the study showed that the agreement of measurement between aneroid and gold standard (mercury

instrument) and between digital and gold standard (mercury instrument) was analyzed using kappa coefficient were 0.88 and 0.39 for the aneroid and digital devices respectively and both were statistically significant.¹⁵

Study demonstrated that the hypertension detected in more (79.0%) individuals using a sphygmomanometer as compared to automated (76.0%) instrument which is correlated with the findings suggested by Shahbabu *et al* (2016), showed that the aneroid device has diagnosed more (86.7%) hypertensive as compared to digital device (80.0%).

However in a study Nelson *et al* observed that automated or digital BP monitors are easy to use. Once the patient and cuff are positioned properly, the operator needs only to press a button on the unit to begin measuring BP with the oscillometric technique. No stethoscope is needed and BP and pulse readings are displayed on the unit's screen and this was noted that automated wrist and arm manometers are being used in health care settings and by many individuals in their homes.²⁴

Nevertheless, the SBP reading found with small average difference of 5.16 mmHg whereas 5.57 mmHg was noted for DBP between automated and manual apparatuses and thus both the apparatuses can be used interchangeably but while caution particularly in diagnosing hypertension with using an automated blood pressure recording device. Study alarmed that the automated devices should be used with care, and their standardization should be done from time to time.

Implications

Study highlights that the BP reading noted on automated device is comparable with the recordings of mercury devices, and are useful in detection and management of high blood pressure. Its operation is simple and do not require expertise of auscultation. However, the readings of automated devices may be slightly on higher side. Present study evaluated that automated oscillometric BP measuring devices may be considered as a primary tool to detect high BP without medical skill.

CONCLUSION

Present study evaluated that automated oscillometric BP measuring devices are simple to operate, free from environmental toxicity. Readings of these devices are comparable to mercury devices but readings of SBP are slightly higher as compared to mercury devices. They may be considered as a primary tool to detect high BP without medical help and consequently helpful in early diagnosis of diseases. Moreover, automated apparatus found to

be statistically similar in detecting hypertension when compared to sphygmomanometer.

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Authors Contribution:

RW- Design of the study, data collection, reviewed the literature, manuscript preparation and critical revision of the manuscript; **NS**- Conceptualized study, review of literature and helped in preparing first draft and critical revision of manuscript, literature search; **BKS**-Concept, literature search, statistically analysed, interpreted, prepared first draft of manuscript and critical revision of the manuscript.

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