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RESEARCH ARTICLE

Variation in blood pressure readings with mercury sphygmomanometer and automated device and to identify its impact on routine clinical practice: A comparative study

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ABSTRACT

Background: Accurate measurement of blood pressure (BP) is helpful and inevitable for clinical diagnosis. Mercury sphygmomanometer is a gold standard non-invasive BP measurement instrument. Recently, there is an increasing trend toward the use of automated devices for various reasons. BP readings with automatic devices rely on built-in electronic algorithm for several standard validation protocols have been developed. Thus, it is important to look into the functioning of such devices vis-à-vis the mercury sphygmomanometer. **Aims and Objectives:** The aim of the study was to estimate and compare BP reading obtained by the automated device with mercury sphygmomanometer. **Materials and Methods:** The study was carried on 500 subjects divided equally into five age groups. BP readings from the automated device (NUTEC BP09, based on oscillometric technique) were compared to the readings of mercury sphygmomanometer. BP was recorded twice on the left arm in the sitting position with each instrument. **Results:** The mean BP by mercury sphygmomanometer (HgBP) was 120.1 ± 12.9/81.7 ± 9.8 mmHg and mean BP by automated device (ABP) was 118.5 ± 15.9/72.0 ± 11.6 mmHg. There is a difference of about 1.5 mmHg in systolic BP (SBP) while there is a difference of about 9.7 mmHg in the diastolic BP (DBP). Similarly, the mean arterial pressure (MAP) value with the automated device is 7 mmHg less than the mercury sphygmomanometer. **Conclusion:** The present study concludes that there is a significant difference for SBP, DBP, and MAP values between the automated device and mercury sphygmomanometer measurement methods and automated BP device underestimate all the BP variables except SBP with more preponderance of DBP. Thus, automated device should be used with caution.

KEY WORDS: Blood Pressure; Mercury Sphygmomanometer; Automated Oscillometric; NUTEC BP09; Age

INTRODUCTION

Blood pressure (BP) is one of the basic windows to the healthy activity of the cardiovascular system. Accurate BP measurement is very essential and inevitable in the clinical diagnosis of various cardiovascular disorders. BP measurement is one of the first and inescapable tasks for patient diagnosis and management. It reflects the health of the cardiovascular system and also provides insight into the functioning of many other systems. It has its place in the diagnosis and management of hypertension, chronic kidney disease, vascular abnormalities, hormonal aberrations, etc. It is well researched that accurate measurement will help the clinician to pinpoint the problem and will guide its therapeutic management.[1] This will require proper training of the health personnel and the choice of the right kind of measuring device.

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Mercury sphygmomanometer has established its place as gold standard as a non-invasive BP measurement instrument because of its accuracy and reliability.[2] Recently, there is an increasing trend toward the use of automated devices for various reasons such as easy, less time consuming, and devoid of humane observational bias. The simplicity of automated device allows its use even by the paramedics and the general population. Second is the fear of the toxicity that is observed to the exposure to mercury.[3] Mercury being a neurotoxin poses serious health hazard,[4,5] and WHO has considered it an occupational hazard.[6] United Nations Environment Programme and various national governments have issued guidelines for the use of instruments that are containing mercury.[3] European Union and many other countries have suggested a widespread ban for the use of mercury based instruments.[4,5,7] Furthermore, less anxiety and apprehension among patients, when BP measured by technicians or by themselves lead to minimum chances of white coat hypertension with the use of the automated instrument.[8]

At such a juncture, it is imperative to look into the functioning of the automated devices. For the general use, the automated devices should offer the accuracy that is comparable to the mercury sphygmomanometer. Automated devices, to estimate BP, are based on various principles out of which oscillometric method is most widely used. The automated device uses cuff as a transducer to obtain a reading from oscillation transmitted from the artery. The signals received from cuff are then processed in device software by an algorithm, which is always proprietary and unique to each device manufacturer.[9,10] No scientific study can generalize finding of one device to another.[11] Oscillometric BP is calculated from oscillation generated due to pressure applied over the brachial artery by the inflating cuff, which is nearly equal to mean arterial pressure (MAP). The systolic BP (SBP) and diastolic BP (DBP) are then calculated indirectly from this mean in contrast to directly measured by sphygmomanometer.[9]

The reliability of automated devices can vary differently over the range of various characteristics, such as range of arm circumference[11] or level of BP.[12] Thus, validation protocols state that the devices should be tested over the large range of BP,[13] i.e., as per age categories, gender, body mass index, and arm circumference (small, medium, and large).[14]

The aim of the present study is to estimate BP in different age groups of normal healthy population of Bhavnagar city of Gujarat by automated device and compare its value with mercury sphygmomanometer readings.

MATERIALS AND METHODS

The study was carried at Government Medical College and Sir Takhatsinhji Hospital, Bhavnagar, Gujarat. Prior ethical approval from the Institutional Ethical Committee of Government Medical College, Bhavnagar, was obtained.

A total of 500 subjects were included in this study. Total five groups were made with each having 100 subjects. Five groups were created on the basis of to age; 15–25, 26–35, 36–45, 46–55, and >55 years of age. All the subjects were apparently healthy on the basis of clinical examination, without any symptoms/signs suggesting any major illness. The experimental protocol was explained to all the subjects and written informed consent was obtained.

Inclusion Criteria

Apparently, healthy subjects having age 15 years or above willing to give informed consent were included in the study. For adolescents, informed consent was taken from the parent or guardian.

Exclusion Criteria

Subjects having any known chronic illness, vascular disease, hypertension, etc., or not willing to give written consent were excluded from the study.

The automated device named NUTEC BP09 (Made by Nulife Global Medical Devices Pvt., Ltd., Mumbai) which functions on the oscillometric principle was used for the present study. It complies with European regulation guidelines and bears CE mark. It also confirms to EN 1060-1 standard for general requirements of the non-invasive sphygmomanometer; EN 1060-3 standard for supplementary requirements of the non-invasive sphygmomanometer and also to be the EN 1060-4 standard for overall system accuracy of ±3 mmHg. In automated device, systolic and DBP is represented as a certain percentage of the MAP.[9,10] The MAP is defined as the maximum of the envelope, a collection oscillometric waveform in the frequency domain produced due to oscillometric changes in the column of the blood. Many times oscillometric waveform has no clear envelop, which makes determining maximum difficult and far from accurate.

BP measurements were taken in the morning hour (9 AM–12 AM) to prevent the effect of diurnal variations on BP. Subjects were given 5 min rests before measuring the BP. The average of two readings was taken with a gap of 5 min between each measurement.

BP was taken by two methods; i.e., HgBP by mercury sphygmomanometer and ABP by the automated device. For the measurement by the mercury sphygmomanometer, the instrument was kept at the level of subject's heart, and commencement of Korotkoff sound phase-I was taken as SBP, and end of Korotkoff sound phase-V was taken as DBP.

BP was recorded on the left arm with subjects in a sitting position. The left arm was chosen as the cuff in the automated

instruments was for left arm only. Two readings were taken with each device. The person taking the BP with one device was blind to the reading of the other. Furthermore, there was a random allocation for the device to be used for the first reading.

Statistical Analysis

The data were analyzed in Microsoft Excel software program. Mean and standard deviation (SD) were calculated for the reading obtained by both the devices in each group. MAP was calculated for both the methods and student's *t*-test were applied to identify a significant difference between readings recorded by both devices.

RESULTS

Total five age groups were formed with each group having 100 subjects. A total number of subjects and distribution of male and female among different age groups are shown in Table 1.

MAP reflects the perfusion pressure in the tissues and is calculated by formula DBP + ⅓ pulse pressure (PP). Mean and SD were calculated for SBP, DBP, and MAP for both the devices and were compared in different age groups, as shown in Table 2.

DISCUSSION

The present study has identified variability in the BP reading by two different instruments in different age groups of normal healthy individuals. This study shows that the mean SBP measured with mercury sphygmomanometer increases with the advancement of age, on the contrary, mean SBP measured by the automated device does not shows any specific pattern. However, it is known that BP increases with the age due to many structural and physiological changes occurring with the progression of age, particularly in the cardiovascular system.[15,16]

As Table 2 shows when measured with mercury sphygmomanometer, there is an increase in DBP in relation to increasing in age except in age group of 45–55 years but readings obtained with automated device show decrease in DBP vis-à-vis age progression except after 55 years of age. Lin *et al*. observed an increase in SBP with the advancement of age but increased in DBP was observed only till 45 years of age, and after that a decrease was reported by them, justifying it by the physiological variability in arterial wall stiffness with advancing age (above 45 years).[16] Same findings were observed in our study when DBP readings by mercury sphygmomanometer were analyzed till 45 years of age, but after 55 years of age, DBP reading by both methods showed an increase. Framingham heart study, which followed patients for 30 years, agreed that SBP shows continuous increase between the age of 30 and 84 years or over and DBP has a varying pattern with aging, increasing until the 5th decade and slowly decreasing from the age of 60 to at least 84 years of age leading to steep rise in PP.[17] The present study also shows an increase in SMAP vis-à-vis age, but AMAP does not show a particular trend in relation to the age.

On observing the mean values of all 500 subjects combined, it is found that there is less difference in SBP (≈1.5 mmHg) while there is more difference in DBP (≈9.7 mmHg). The automated device shows lesser values as compared to the sphygmomanometer, and this may contribute to the underestimation of BP. Similarly, the MAP value with automated device is also less (≈7 mmHg) than the sphygmomanometer. A study by Landgraf *et al*. suggested that use of automated device may result in under-diagnosis and under-treatment of hypertension.[18]

Table 1: Distribution of subjects according to sex among different age groups

Gender	Age (in years)				
	15–25	26–35	36–45	46–55	>55
Male (n)	60	71	70	82	76
Female (n)	40	29	30	18	24
Subject (n)	100	100	100	100	100

Table 2: The mean±SD of SBP, DBP, and MAP obtained by both methods in subgroups and total subjects and comparison in different age groups

Age group (in years)	HgBP Mean±SD SBP/DBP (mm Hg)	ABP Mean±SD SBP/DBP (mm Hg)	SMAP/AMAP Mean±SD (mm Hg)	*P*-Value SBP (HgBP vs. ABP)	*P*-Value DBP (HgBP vs. ABP)	*P*-Value MAP (HgBP vs. ABP)
15–25	116.4±12.4/79.3±9.2	122.0±14.8/73.6±11.6	91.7±9.6/89.7±11.6	<0.0001*	<0.0001*	<0.01*
26–35	116.9±11.8/80.5±9.0	118.7±15.0/72.0±11.2	92.6±6.8/87.6±11.1	0.18	<0.0001*	<0.0001*
36–45	118.8±12.0/82.2±9.9	117.4±15.6/70.8±11.7	94.4±7.8/86.3±11.7	0.23	<0.0001*	<0.0001*
46–55	123.0±12.3/80.5±9.7	117.5±16.9/69.8±11.4	94.7±7.9/85.7±12.0	0.004*	<0.0001*	<0.0001*
>55	125.5±13.8/86.1±9.9	117.2±16.8/73.9±11.8	99.2±8.5/88.2±12.4	<0.0001*	<0.0001*	<0.0001*
Total	120.1±12.9/81.7±9.8	118.5±15.9/72.0±11.6	94.5±8.6/87.5±11.8	0.035*	<0.0001*	<0.0001*

HgBP: Blood pressure by mercury sphygmomanometer, ABP: Blood pressure by automated device, SMAP: MAP by mercury sphygmomanometer, AMAP: MAP by automated device, SD: Standard deviation. *Statically significant, SBP: Systolic blood pressure, DBP: Blood pressure, MAP: Mean arterial pressure

Table 2 also shows the comparison of different BP parameters among different age groups and level of significance with the application of student's *t*-test. There is a significant difference between the SBP recorded by two methods except in the age groups of 26–35 and 36–45 years (*P*-value 0.18 and 0.23, respectively). The difference in DBP and MAP is also highly significant in all the age groups. Mirdamadi and Etebari compared manual versus automated BP measurement in intensive care unit, coronary care unit, and emergency room and found significant difference between reading obtained by two methods and concluded that manual method in measurement of BP shows higher BP (up to 15 mmHg higher), and even more in critical condition.[19]

An automated oscillometric technique was mostly associated with lower BP values compared to mercury sphygmomanometer technique with the exception of SBP in young age groups. The variations in readings were more prominent in older subjects (>55 years). Findings in the present study are in conformity with the study of Heinemann *et al*., who also observed that automated oscillometric measurements underestimated both SBP and DBP.[20] van Ittersum *et al*. suggested that the oscillometric method might underestimate DBP in general population but might overestimate the MAP in diabetic patients.[21] Penny *et al*. observe underestimation of SBP and DBP by automated oscillometric BP monitors in women suffering from pre-eclampsia.[22]

In contrast, some studies have suggested that oscillometric readings compared sphygmomanometer reading might overestimate BP, Nelson *et al*. observed that automated monitor primarily overestimated DBP[23] and van Popele *et al*. reported overestimation of both SBP and DBP by oscillometric method compared to mercury sphygmomanometer.[24] The difference in the findings may be due to the variability in the use of different automated devices by the researchers.[10]

Various studies have found that the oscillometric BP instruments might underestimate or overestimate the BP when compared to mercury sphygmomanometer; depending on the level of BP itself.[10,18-24] Myer *et al*. even suggested to replace manual BP reading by validated automated BP recorder highlighting lower reading due to reduced observer-subject interaction may be more accurate estimate of BP.[25]

Analysis of the BP lowering treatment trialists collaboration study showed that even the reduction of 2 mmHg BP were associated with about a 20% reduction of stroke and reduction of cardiovascular mortality. In the present study, a difference of around 1.5 mmHg in SBP and a difference of around 9.7 mmHg in DBP have been observed between two methods. This underestimation of BP and more specifically of DBP by the automated device may seriously jeopardize the estimation of the prevalence of hypertension and its treatment outcome. Titration of antihypertensive medicines using automatic oscillometric techniques can lead to under-treatment, especially in the older population.[18]

Srinivasan *et al*. in their study concluded that manual instrument is more reliable over the digital for BP monitoring.[5] Shahbabu *et al*. also concluded that the specificity and sensitivity of digital sphygmomanometer are not up to the standards; thus, its use may lead misdiagnosis of hypertension in general population.[7]

Limitation

Restricted number of subject for each group and limited number of gender distribution for calculating the BP were one of the limitations. Usage of the single size cuff for different arm circumference was also limitation.

CONCLUSION

The present study observed significant difference for SBP, DBP, and MAP reading by both the methods. Automated device underestimates the BP values except for the SBP with more preponderance of DBP. The American college of physicians has strictly cautioned against managing patient solely on basis of readings obtained by an automated device; the present study does recommend the same that automated device is good for screening purpose as it is simple and fast but not reliable enough for diagnostic and treatment modalities. As the automated device uses an algorithm for the calculation of BP, it is imperative that these algorithms be designed in such a way that it takes into account the variables such as age, gender, body mass index and arm circumference to have better accuracy. Standard benchmarking, monitoring of accuracy, and more reliability are also advisable to make this instrument more useful. It may vary with age of the subject and comorbid conditions such as diabetes, obesity, and such other factors. "one size does not fit all."

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