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RESEARCH ARTICLE

Variability in digital blood pressure measurement and normal sphygmomanometer – A randomized study

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ABSTRACT

Background: Hypertension is one of the most common comorbidity across the whole world so its true measurement is important for its diagnosis as well as management. For diagnosis of estimating blood pressure (BP), the most common non-invasive modalities are manual mercury sphygmomanometer and digital BP monitor device. **Aim and Objective:** The objective of the study was to comparative evaluation between normal sphygmomanometer and digital BP instrument in normal healthy volunteers. **Materials and Methods:** The study begins after obtaining permission from the Institutional Ethics Committee. The written consent of the individual was obtained. Persons above 18 years of age, who gave their written consent and receiving antihypertensive treatment, are included in the study. Persons having diabetes, severe hypertension, psychiatric disorders, and smoked before 30 min are excluded from the study. BP is measured according to JNC-8 criteria. The study was a cross-sectional observational study. **Results:** A total of 102 individuals were analyzed age group accordingly. The data were analyzed by unpaired *t*-test for comparing BP measured by mercury and digital sphygmomanometer with a significance value set at $P < 0.05$ as significant. The comparison of each modality was done using an unpaired *t*-test and *P* values were found as follows: Systolic BP, $P = 0.1856$ and diastolic BP, $P = 0.891$. **Conclusion:** BP is one of the most common and must necessary medical procedure done in each and every person before any medical and surgical procedure. As there is no significant difference between digital and manual sphygmomanometer, so we can use digital as an alternative option of manual carefully as per need.

KEY WORDS: Automated Method; Blood Pressure Measurement; JNC-8; Manual Method; Variability

INTRODUCTION

Hypertension is called a sustained rise in blood pressure (BP) of 140/90 mmHg or higher. Blood pressure is the pressure of circulating blood on the walls of blood vessels.[1]

BP measurement is one of the most common medical procedures done on thousands of patients every day. Hypertension is the most common cardiovascular disease. Increased arterial pressure causes hypertrophy of the chambers of heart and also alters blood vessel's endothelial cells too. There are four main vitals reading body temperature, respiratory rate, pulse rate, and BP. BP is one of the main vital signs routinely monitored by healthcare professionals. An accurate BP measurement is vital in giving appropriate treatment ranging from dehydration in diarrhea patients with low readings to vascular disease patients with elevated readings. As a consequence, hypertension is the principal cause of various complications such as transient ischemic attack, coronary artery disease, peripheral vascular disease, heart failure, myocardial infarction, and sudden cardiac death, renal insufficiency, and dissecting aneurysm of the aorta.[2]

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High BP is a health risk factor and considered as one of the highest causes of morbidity, one of the main leading causes for cardiovascular disease and social worldwide burden, in addition to the high-cost burden to the global health service providers. BP is affected by external and internal factors. Age, gender, and heredity are factors which are unmodifiable but external factors such as smoking, salt restriction, eating habits, and regular medication, we can manage.[3,4] Globally, the overall prevalence of raised BP in adults aged 25 and above was around 40%. Raised BP is a condition that causes around half of all deaths from stroke and heart disease. The WHO also reported that 54% of cases of strokes, 47% of cases of ischemic heart diseases, and 13.5% of cases of all mortality worldwide were attributable to elevated BP.[5]

Mercury sphygmomanometer was once a gold standard but the use is drooping down. Due to fear of potential mercury toxicity and the problems of disposal of mercury, it has led to decrease in the use of mercury instruments worldwide. For this same reason, the European Union issued a directive for the phaseout of mercury instruments. Non-mercury sphygmomanometers are now the future. They are based on the oscillometric technique, which detect mean arterial pressure. Other methods include ultrasound and the finger cuff method.[6]

Moreover, digital BP monitor reading can be stored in a monitor's memory and ability to review it later on. It's easy to use, portable decreases human error and is much better for people with hearing or vision loss. However, it has some drawbacks such as fragility, the complexity of its mechanism, and delicate parts. Device accuracy must be checked beforehand; then, it should be applied to the user. Body movements also can influence their accuracy. It is expensive; it requires batteries, an AC adapter for large arm cuffs, also may require factory repair and readjustment when it becomes faulty. Requires careful choosing of the cuff and accurate arm positioning is required for perfect measurements. Some models are designed, particularly for the right or left arm. Hence, it is very crucial and important to measure the variability in two BP measurement methods.[7]

Thus, there are some benefits and some drawbacks of both measurements, so our goal of the research study is to evaluate the accuracy between both measurements and feasible use of it. Our methods of study: Digital BP measurement and normal sphygmomanometer using manual mercury sphygmomanometer and digital BP.

Objective

The objective of the study was to evaluate the variation in the digital BP measurement and normal sphygmomanometer in a randomized group of people.

MATERIALS AND METHODS

The study begins only after obtaining permission from the Institutional Ethics Committee. The study was a cross-sectional study conducted from March 2018 to June 2018 in Ahmedabad. The written consent of every individual was obtained in their vernacular language. The participants were recruited in the study based on selection criteria [Figure 1]. BP of the consenting persons was measured and informed that their participation is entirely voluntary and that they can draw back their participation from the study at any given point of time if they want. Moreover, the confidentiality of the data will be maintained properly. Male and female patients' data were enrolled irrespective of their ethnicity. The site of this study was the community.

The instruments used for this study include manual mercury sphygmomanometers, Littmann Classic II Stethoscope, and Omron digital meter valid by association for the advancement of medical instruments. All of these instruments will be checked, standardized, and calibrated by experts.[8]

The standard location for BP measurement is the arm where the brachial artery is located. A common measurement is 120/80. The number is normally given in units of millimeters of mercury (mmHg). The following selection criteria were applied for the study.

Randomization

Two groups of studies were performed using odd and even randomization.

Standard Operating Procedure for the Measurement of BP was followed:[9]

Subjects should refrain from smoking or ingesting caffeine during the 30 min preceding the measurement. BP was measured on the dominant arm in seating position using mercury and digital sphygmomanometers, at least 2 times for each device at an interval of 10 min. In the even group, first, digital readings were taken first followed by a normal sphygmomanometer. Moreover, in the second odd group, first, normal sphygmomanometer readings were taken followed by digital meter readings.

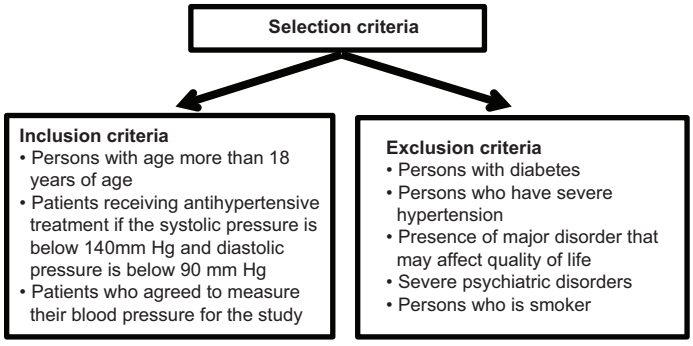

Figure 1: Selection criteria

The standard operating procedure for measuring BP was followed by according to JNC-8 criteria. It was made sure that the study persons were relaxed beforehand at-least for 5–10 min before the measurements and we also ensured that they were seated with legs uncrossed and back supported at heart level before the readings. BP of participant will be measured twice by each instrument using appropriate cuff size and average was taken.

A total no of the subject is 102. Sample size was obtained through random sampling method. The data were analyzed using the unpaired *t*-test for comparing the values of BP with significance $P < 0.05$. Mercury sphygmomanometer technique of measurement and digital BP was used which was based on AHA guidelines.[10]

Accuracy Checking of Instruments

All the instruments are certified by the manufacturer as BHS/EHS complaint [European Society of Hypertension (EHS) and British Hypertension Society (BHS)].

For the reduction of selection bias, a systematic random sample was used. To reduce measurement bias, we have used a validated, standardized, and calibrated sphygmomanometers reduced instrument variation. New batteries were used and they were replaced frequently. To reduce subject physiologic variation, as well as the known regression to mean with repeated BP measurement phenomenon, the standard BP was measured within a few minutes before or after the pragmatic BP. All BP measurements were obtained by a single investigator at predefined time only.

Statistical Analysis

All the data were collected and compiled in MS Excel 2016 and Statistical Package for Social Sciences version 25.0 was used for analysis. The average value of both readings was taken. Mean and standard deviation of the systolic BP (SBP) and diastolic BP (DBP) measurements from each instrument was compared to each other using paired and unpaired *t*-test and *P* values were found out. $P = 0.05$ or less will be considered to be significant.

RESULTS

A total of 102 individuals were analyzed age group accordingly. In the adult age group (21–40 years), maximum number of individuals has been noted. Their mean BP was taken out. Mean and standard deviation was taken out individually for normal systolic, normal diastolic, digital systolic, and digital diastolic. The mean value of normal systolic pressure is 116.95 mmHg. The mean normal diastolic pressure is 73.27 mmHg. The mean value of automated systolic pressure is 119.09 mmHg. The mean value of automated diastolic pressure is 73.10 mmHg. The mean pulse rate of the individuals is 82. The comparison of each modality was done using an unpaired *t*-test and *P* values were found as follows: Systolic BP, $P = 0.1856$ and diastolic BP, $P = 0.891$ [Tables 1 and 2].

DISCUSSION

The objective of the study was to evaluate the pinpoint accuracy of digital sphygmomanometer in comparison to mercury sphygmomanometer in a randomized group of people. Our study highlights on sensitivity and specificity of digital sphygmomanometers, though it is portable, feasible to use, requiring no medical expertise in it but still not up to standard.

A similar study done in Iran stated that the mercury method of BP measurement of BP frequently shows higher BP. The findings of this were varying from that of this study. This could be due to different study setting, a different model of meter and also due to different environmental conditions.[11]

Another Indian study done on normal healthy individuals showed that the average SBP and DBP were measured by the automated instrument which was higher. It suggests that BP measurement readings acquired by automated sphygmomanometer is comparable to mercury sphygmomanometer. The results of our study were comparable with the results of this study.[12]

Another study conducted in Bandung stated that there was no difference between the SBP and DBP of mercury and digital

Table 1: Comparison of normal and automated readings

Variables	Normal	Digital	*P*-value
Age	37.01±15.88		
Body WT	64.96±13.90		
Pulse rate	82.18±9.29		
SBP1	116.74±11.09	118.24±12.23	0.3599
DBP1	73.13±8.021	72.86±10.03	0.8321
SBP2	117.15±11.17	119.94±12.09	0.0885
DBP2	73.41±7.46	73.33±10.39	0.9497
Mean SBP	116.95±11.13	119.09±12.16	0.1856
Mean DBP	73.27±7.74	73.10±10.21	0.8910

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, $P<0.05$ was considered as statistical significant

Table 2: Age group frequency

Age group	Frequency
0–20	10
21–40	49
41–60	33
61–80	10
Total	102

measurement readings. Hence, the study concluded that a digital sphygmomanometer can be used to replace mercury sphygmomanometer in a community setting as well.[9]

In contrast, another study conducted in Australia concluded that automated instruments under-read both systolic and diastolic BPs and they also concluded that the systolic BP can be said to be equivalent in both instruments but there was a difference in diastolic BP.[13]

In a study done by NHANES, the difference of SBP and DBP was minimal.[14] However, there is also some contradiction in findings which may attributed to the use of different make of the digital sphygmomanometer.[15]

In another study involving 604 sphygmomanometers reported only, around 80% of the aneroid models were able to give accurate measures, while 88% of digital devices were accurate, considering the acceptable error of 3 mmHg.[16]

Hence, the conclusion of the study was that the BP measured using digital sphygmomanometer varies some level of difference from the mercury manometer and showed some levels of inaccuracy and hence, it should be used with caution in the clinical setting. As we can see, hypertension is a major risk factor among the population nowadays. The positive point of our study was to identify the correct device which could be used for measuring BP. BP is one of the most common and must necessary medical procedure done in each and every person before any medical and surgical procedure. Thousands of patients every day and even at home BP are being monitored, so it becomes a necessity to clinically evaluated and choose a standardized measuring instrument that could correctly measure the BP. This is, particularly important to patients of hypertension and other cardiovascular diseases. Several guidelines have been published with the aim of improving the accuracy of BP measurements by standardized procedures.[15]

With the advancement of the technologies, newer devices are being introduced but their measurement should be comparable with the gold standard mercury sphygmomanometer. Hence by this study, the difference in the BP of normal and digital meters is been clearly noted.

The limitations of our study are that BP being a highly variable entity, the readings may vary with the condition of the body and many other factors also. Second, our study setup being a community there might be variation (such as one season, changing temperature, and climate) than that which could have been done in the hospital. Third, due to the smaller sample size, there might be chances of error in standardization. Fourth, there might be differences in different models of the measuring devices and therefore, it is not possible to conclude the overall effectiveness of the instrument.

The future work in our study would be to conduct the study on larger sample size and also include the patients in the hospital and to also compare other devices also (such as oscillometric, auscultatory, and aneroid).

The possible reason for inaccuracy in the measurement of BP could be due to acute ingestion of food, general device inaccuracy, cuff size, clothing effect, and many more according to a study conducted on this. Since the SBP is a higher value than DBP, the differences could arise.

CONCLUSION

The conclusion of our study is that automated BP measurements are found to produce discrepancies in reading in clinical settings. The reliability and accuracy of the automated devices are questionable. Although digital BP monitors have more convenience-based advantages over manual methods, their usage should be done with increased caution.

As we can see, there are minor variations between manual and automated BP measurements, and mean pressure is almost the same, so we can choose automated monometer as an alternative to manual monometer. There are benefits of automated instruments like it is easy to carry, easy to use, no expertise is required, any person with some basic knowledge can use it, so it makes doctors work easy and it saves time also. Moreover, its data can be stored directly in the monitor, so data record is maintained immaculately. Therefore, primary healthcare workers and the community health-care staff's access become easy and accurate. Our study also highlights the sensitivity and specificity of both the measurement methods. However, there are some drawbacks related to accuracy compared to manual, as we mentioned so careful and consciously use is needed.

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