Original Article

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Public Health Section

Do the Readings of Digital and Aneroid Sphygmomanometer Concur? A Clinic-based Study in an Urban Area of South Kolkata

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ABSTRACT

Introduction: Hypertension is a major risk factor for cardiovascular and cerebrovascular diseases. Thus, regular and accurate measurement of Blood Pressure (BP) is essential for its early diagnosis and follow-up. There is a surge in popularity of digital sphygmomanometer due to its convenience of use and functionality. In contrast, the traditional universally accepted sphygmomanometer is aneroid type, hence there arose a need for comparison of digital and universally accepted aneroid sphygmomanometer in terms of agreement and correlation.

Aim: To evaluate the agreement and correlation between blood pressure measurement by digital and aneroid sphygmomanometer.

Materials and Methods: The clinic based cross-sectional study was conducted in the Out Patient Department (OPD) of Urban Heath Centre, All India Institute of Hygiene and Public Health, Kolkata, West Bengal, India. Adults visiting the OPD on two chosen days of the week, between June 2019 to July 2019 were selected using systematic random sampling. A total of 400 participants were included. Agreement and correlation between BP measurements by digital and aneroid sphygmomanometer was analysed by Cohen's Kappa, Bland Altman Plot along with sensitivity, specificity and predictive values using Microsoft Excel and Statistical Package for the Social Sciences (SPSS) version 16.0. The p-value <0.05 was considered significant for the statistical test in the analysis.

Results: Cohen's Kappa value (0.59) revealed these two tools had moderate agreement in diagnosing hypertension. Sensitivity and specificity of digital sphygmomanometer taking aneroid sphygmomanometer as gold standard is 86% and 83.1% respectively. The BP readings of these two-tools showed moderate correlation as Intraclass Correlation Coefficient (ICC) for Systolic BP (SBP) and Diastolic BP (DBP) were 0.804 and 0.624, respectively. Bland Altman plot showed gross disagreement of SBP findings and disagreement between DBP findings was also noted.

Conclusion: Digital device was found to be less accurate in detecting hypertension. Therefore, more similar research work is solicited to verify the accuracy of the very easy to use, the digital BP monitor.

Keywords: Accuracy, Agreement, Blood pressure, Hypertension, Sensitivity, Specificity

INTRODUCTION

Hypertension poses serious health risk which can be life-threatening and can lead to co-morbidities including cardiovascular and cerebrovascular diseases [1]. Hypertension is sometimes referred to as the "silent killer" because it often remains undetected or in latent form until a dangerous health incident, such as stroke or premature death occurs [1,2]. Therefore, accurate and regular measurement of BP has enormous importance for early diagnosis and management of hypertension [3].

For more than a century, BP measurement was conducted using the ineradicable standard of the mercury sphygmomanometer which was also considered as the "gold standard" until recent decades [4]. International hypertension societies concluded that the risk of toxicity of Mercury outpaced the benefits of using mercury based BP devices [4].

So, the reliance over mercury sphygmomanometer was curtailed leading to a revolution in BP measurement in past several years. Later, there was transition from widespread use of manual aneroid sphygmomanometers (which require trained personnel for accurate measurement) to a more convenient device such as fully automated BP monitors that are capable of giving out precise BP readings [5].

Aneroid sphygmomanometers (mechanical types with a dial) are in common use, they are considered safer than mercury sphygmomanometers because of the lack of mercury and its performance being akin to its mercury counterpart [5].

In recent years, automated (digital) BP machines have become the preferred choice in most hospitals. Reasons being automated machines are more comfortable to use, allow continuous or intermittent BP monitoring and some machines even allow pulse rate and oxygen saturation levels to be taken simultaneously [5]. As no stethoscope is needed for measurements and calculations, automatic BP machines can be used in noisy settings like Out Patient Departments, Emergency Room etc. Moreover, measurement of BP with digital sphygmomanometer needs less expertise so that even the Accredited Social Health Activist (ASHAs) and other frontline workers can very much participate in screening, diagnosis and monitoring of high BP at the community level. This popularity of digital sphygmomanometer very much necessitates for establishing its validity and reliability. However, the main limitation of digital BP monitors is that their accuracy is compromised during physical activity when there may be considerable movement artifact. This makes home monitoring of BP particularly in elderly patients with tremors of the extremities more difficult [6].

There are very few studies available for evaluating the concurrence of readings derived by aneroid and digital sphygmomanometer [7]. There is an immediate need for such studies that will try to ascertain the validation of digital instrument's readings in comparison with aneroid sphygmomanometer since accurate diagnosis of hypertension entails better prevention and cure. In this context present study was conducted to evaluate validity of digital for BP measurement using aneroid sphygmomanometer as gold standard.

MATERIALS AND METHODS

This clinic-based cross-sectional study was conducted at the general Out Patient Department (OPD) in urban field practice area of All India Institute of Hygiene and Public Health, Kolkata, West Bengal, India. Adults visiting that OPD on two chosen days of the week for a period of two months (June 2019-July 2019) were selected. This study was approved by Institutional Ethics Committee of AIIH&PH with IEC certificate no. PSM/ IEC/ 2018/7.

Inclusion criteria: Adults aged more than 18 years that visited the general OPD were included.

Exclusion criteria: Those people who did not give informed written consent were excluded from the study.

Sample size calculation: Sample size was calculated using the formula provided by Temel G and Erdogan S [8], where k=estimated kappa value (0.90), β=type II error (0.20), $Z_{1-\alpha/2}$=standard normal deviate in a specified α level and π=probability of disagreement (0.05), and Z=1.96 for 95% confidence interval, minimum sample size was 397. So, total 400 participants were included in this study.

Study Procedure

For measuring BP, two types of sphygmomanometers, i.e., digital sphygmomanometer (Omron HEM- 7121J-IN manufactured by Omron Healthcare manufacturing Vietnam. Co., Ltd.,) and aneroid sphygmomanometer (Diamond A127798-9™) in combination with stethoscope (Littman classic III™ by 3M, USA) were used. All the instruments used in the study were checked, standardised and calibrated by experts.

The research's purpose and objective were explained to the participants and, informed written consent from each subject was obtained before data collection. Privacy and confidentiality of data was maintained.

Method of data collection: Sociodemographic data i.e., age and sex was collected. Same instruments were used throughout the study and all the readings were measured by single person, who was a trained medical professional, all the standard operating procedures were followed keeping in mind all the minute details in recording the data which reduced chances of errors in our findings.

Measurements of BP was done in each subject by two sphygmomanometers (digital and aneroid) where BP readings were obtained using standardised procedures for each device and preliminary preparation for both devices [9,10]. Before starting the BP measurements, the respondents were seated for at least five minutes in a relaxed state. The respondents were told to avoid eating, smoking, or exercising for at least 30 minutes before having a measurement taken. They were made to sit with the back straight in a chair with her/his feet flat on the floor and the respondent's arm was placed on a table so that the cuff was at the same level as the heart. Palm of the respondent's hand was placed facing upward. The lower margin of the cuff placed approximately 1 to 2 cm above the elbow. It was made sure that there were no kinks in the air tubing. When the measurement was complete, the arm cuff was completely deflated and the BP readings were displayed and the same was recorded [9].

After five minutes interval, another measurement using aneroid BP monitor was done. Cuff of appropriate size were used and was fully deflated before starting the procedure. Cuff was inflated until pulsation disappeared and was deflated to estimate SBP. Cuff was again inflated to 30 mmHg above the estimated systolic level to occlude the pulse, then placing the stethoscope diaphragm over the brachial artery. The cuff was deflated at a rate of 2-3 mm/sec until regular tapping sounds were heard, measured SBP (first sound) and DBP (disappearance of the sound) [10]. Readings were documented as systolic and DBP in mmHg by both instruments at 2 mmHg precision scale level. Two measurements were made and the average was recorded. Instruments and observer were same for all the study participants. Hypertension is defined as SBP ≥140 mmHg and/or DBP ≥90 mmHg as per JNC 7 criteria [3].

STATISTICAL ANALYSIS

Data were analysed in MS Excel 2010 and Statistical Package for the Social Sciences (SPSS for Windows, version 16.0, SPSS Inc. Chicago, USA). Wilcoxon Signed-Rank test was used to find out the difference of median BP measured by these two instruments as data was not normally distributed. Agreement of measurement was analysed by Cohen's Kappa coefficient for detection of hypertension and by Intra-class Coefficient (ICC) for two-way mixed model for absolute agreement. Bland Altman plots are drawn with 95% confidence interval. Sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of digital sphygmomanometer for detection of hypertension were calculated considering aneroid sphygmomanometer as gold standard.

RESULTS

Total number of study participants was 400. The mean age of study participants was 46.28±14.55 years. Most of them (68.8%) were females.

Findings of Blood Pressure (BP) measurement by the two instruments: Total 86 patients (21.5%) were found to be hypertensive when BP was measured by aneroid. But digital sphygmomanometer found 127 persons (31.7%) as hypertensive. Cohen Kappa value (0.59) revealed that these two tools had a moderate agreement between them in diagnosing hypertension. The sensitivity and specificity of digital sphygmomanometer taking aneroid sphygmomanometer as the gold standard was 86% and 83.1%, respectively. However, this tool's Positive Predictive Value (PPV) was 58.3%, i.e., nearly half of the hypertensive cases diagnosed by digital sphygmomanometer were false positive. But Negative Predictive Value (NPV) revealed that this tool could successfully identify 95.6% non-hypertensive cases) [Table/Fig-1].

Blood Pressure (BP) range		Aneroid: Hypertensive number	Aneroid: Not hypertensive number
Digital	Hypertensive number (%)	74	53
	Not hypertensive number (%)	12	261
Instruments		**Proportion of hypertension n (%)**	
Aneroid		86 (21.5)	
Digital		127 (31.7)	
Agreement Statistics			
Cohen's Kappa value			0.590
Diagnostic accuracy For digital device in gold standard of aneroid device			
Sensitivity			86.0%
Specificity			83.1%
Positive predictive value			58.3%
Negative predictive value			95.6%

[Table/Fig-1]: Agreement and validity of digital sphygmomanometer with aneroid sphygmomanometer in detection of hypertension (N=400).

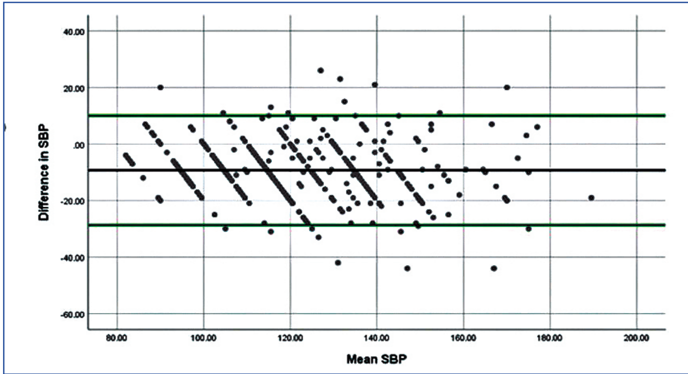
Median SBP measured by aneroid and digital sphygmomanometer was 110 and 125 mmHg respectively. This difference was statistically significant (p<0.001). Similarly, differential median DBP was noted in aneroid and digital sphygmomanometer readings (70 and 78 mmHg respectively), which was statistically significant (p<0.001) [Table/Fig-2].

Intra-Class Correlation Coefficients (ICC) was also calculated for absolute agreement in a two-way mixed model. ICC of SBP and DBP were 0.804 and 0.624, respectively [Table/Fig-2]. Good agreement was present between the two instruments in recording SBP and DBP.

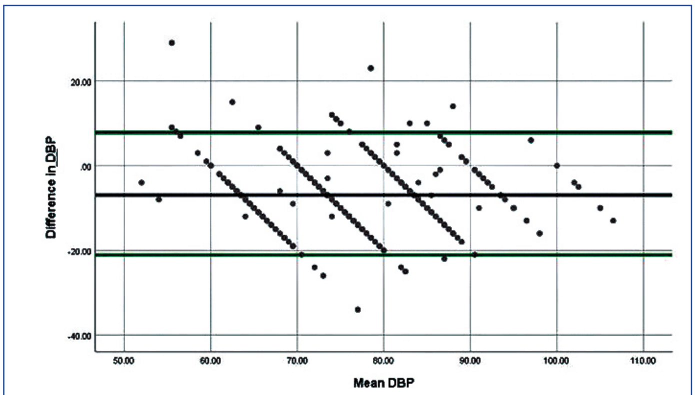
Variable	SBP (mmHg)	DBP (mmHg)
Median (in aneroid)	110	70
Median (in digital)	125	78
p-value for difference between aneroid and digital reading	<0.001*	<0.001*
Intraclass correlation coefficient	0.804	0.624

[Table/Fig-2]: Correlation and agreement of Blood Pressure (BP) measurement with aneroid and digital sphygmomanometer (N=400).
Wilcoxon Signed Rank Test was done; *p-value <0.001- statistically highly significant

Bland Altman plot showed gross disagreement of SBP findings mostly between 120 to 140 mmHg [Table/Fig-3]. Similarly, Disagreement in DBP findings was mostly between 70 to 90 mmHg [Table/Fig-4].



[Table/Fig-3]: Bland Altman plot showing disagreement of SBP in aneroid and digital sphygmomanometer (N=400).
Black horizontal line represents mean difference of SBP; Two green lines represent Mean+SD (11.58 mmHg) and mean-SD (-28.42 mmHg) of difference



[Table/Fig-4]: Bland- Altman plot showing disagreement of DBP in aneroid and digital sphygmomanometer (N=400).
Black horizontal line represents mean difference of SBP; Two green lines represent Mean+SD (6.8 mmHg) and mean-SD (-20.5 mmHg) of difference

DISCUSSION

Findings in current study provided moderate agreement for Cohen's Kappa (0.59) for both systolic and DBP. Hence, Digital machine can be used with caution for self-monitoring but not for clinical diagnosis. In the present study, readings on the digital BP machine were significantly higher for both systolic and DBP, which is not similar to study done by Srinivasan MK et al., which showed minimal bias this could be due to usage of different models of Digital BP monitors (Omron Healthcare Manufacturing Vietnam Company, Singapore) [11].

As per the current study findings, the Aneroid and Digital devices showed moderate agreement in classifying hypertension (Kappa =0.590, p-value <0.001), which is similar to findings of a study done by Shahbabu B et al., which showed very high agreement between Mercury and Aneroid devices in classifying hypertension (kappa=0.881) [12]. Moderate agreement with kappa value (0.397) was observed between mercury and digital sphygmomanometer. This showed aneroid instrument is better to measure whether a person is hypertensive or normotensive.

In the current study, Bland Altman plot showed a disagreement between SBP and DBP readings which are against the study by Heinemann M et al., where accuracy and reliability of the automated machine was tested against US Association for the Advancement of Medical Instrumentation (AAMI), British Hypertension Society (BHS) and Bland-Altman plot criteria. Comparison of mean differences in BP measures in those machines showed the automated machine consistently over-read both systolic and DBP [5]. Thus, it can be concluded that automated monitors can be used with some degree of confidence to measure SBP in an adult general patient.

In a study done by Mansoor K et al., the Bland Altman plots showed disagreement between automated and manual devices that is concordant to our findings [13].

As per the present study ICC of SBP and DBP between Aneroid and Digital devices were 0.804 and 0.624 respectively indicating good agreement. This differs from the study done by Cao X et al., in which Omron HBP-1300 showed ICC of 0.94 and 0.92 for SBP and DBP measurements, while same using a mercury sphygmomanometer were 0.98 and 0.95, respectively [14]. Reliability statistics of Omron HBP-1300 and mercury sphygmomanometer were 0.87, 0.88, and 0.87 for each SBP measurement and 0.87, 0.95, and 0.92 for each DBP measurement, respectively. However, the present study did not use any mercury sphygmomanometer due to policy of mercury-free healthcare facility [15].

Limitation(s)

Only one instrument of each type was used for carrying out the study so it is a detriment to assess the overall efficacy of the results as there should be multiple devices (as done in institutions for the reason that multiple batches could give varied results) for validation before deriving a conclusion that can be generalised.

CONCLUSION(S)

As per the current study findings there is a moderate agreement between digital and aneroid sphygmomanometer. Considering aneroid sphygmomanometer as gold standard, digital device has varied readings. Therefore, it may be concluded that just based on the readings derived from digital BP monitors could be misleading for diagnosis of hypertension. Thus, cautious usage of digital BP machine is warranted in healthcare facilities. Further, multi-centric studies with ample sample size should be directed to validate these findings in community level with use of multiple devices of same model.

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