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Original Article

Physiology Section

Automated versus Manual Blood Pressure Screening among Blood Donors: Agreement and Eligibility Outcomes

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ABSTRACT

Introduction: Blood Pressure (BP) measurement is a critical component of predonation screening to ensure donor safety and eligibility. Automated oscillometric devices are increasingly used due to ease of use and reduced observer variability; however, evidence regarding their agreement with manual auscultatory methods in blood donor settings remains limited.

Aim: To assess the agreement between automated and manual BP measurements and to evaluate their impact on donor eligibility classification.

Materials and Methods: A cross-sectional analytical study was conducted over a period of eight months (July 2024 to March 2025) among 200 blood donors at Sree Balaji Medical College and Hospital, Chennai, Tamil Nadu, India. BP was measured using both manual sphygmomanometer and a validated automated device following standard protocol. Agreement between both the methods was assessed using paired t-test, Pearson correlation, Intraclass Correlation Coefficient (ICC), and Cohen's kappa.

Results: The mean age of the participants was 34.09±9.05 years, with females constituting 53.5% and males 46.5% of the study population. The mean Systolic Blood Pressure (SBP) was 128.75±11.52 mmHg (manual) and 128.32±11.52 mmHg (automated), while Diastolic Blood Pressure (DBP) was 84.32±9.23 mmHg and 84.68±9.69 mmHg, respectively. A statistically significant but clinically negligible difference was observed for SBP (mean difference 0.43 mmHg, p-value <0.001), while no significant differences were noted for other parameters. ICC showed excellent agreement for SBP (0.997) and good agreement for Mean Arterial Pressure (MAP) (0.794), whereas DBP showed moderate agreement (0.528). Overall agreement in donor eligibility classification was 85.5% with moderate agreement (κ=0.69, p-value<0.001).

Conclusion: Automated BP devices demonstrate good agreement with manual methods and can be reliably used for blood donor screening, with minimal impact on donor eligibility classification, particularly in high-volume settings.

Keywords: Hypertension, Mass screening, Oscillometry, Sphygmomanometers

INTRODUCTION

Blood donor screening is a critical component of transfusion safety, designed to protect both donors and recipients from preventable adverse outcomes [1]. BP assessment is a mandatory component of predonation evaluation among blood donors, as abnormal values can predispose donors to vasovagal reactions and cardiovascular complications, and may also suggest undiagnosed hypertension. International and national transfusion guidelines recommend defined SBP and DBP ranges for donor eligibility [2]. Conventionally, BP among blood donors in blood banks has been measured using the manual auscultatory technique with mercury or aneroid sphygmomanometers, a method widely regarded as the clinical reference standard [3]. However, in recent years, automated oscillometric BP devices have increasingly replaced manual methods in many clinical and community settings due to ease of use, reduced observer variability, minimal training requirements, and improved feasibility in high-throughput screening environments such as blood donation camps [4].

Accurate measurement of BP is essential in blood donor screening, as eligibility decisions are based on strict BP thresholds and directly influence donor safety and deferral [5]. Traditionally, BP has been assessed using the manual auscultatory method, which serves as the clinical reference standard; however, automated oscillometric devices are increasingly adopted in blood bank settings due to their operational convenience [6]. Despite this shift, concerns persist regarding their diagnostic accuracy and agreement with manual measurements. Evidence from outpatient and primary care studies suggests a strong correlation between oscillometric and manual readings; however, agreement analyses such as ICCs indicate the presence of systematic biases, with automated devices tending to overestimate SBP and underestimate DBP [7,8].

Previous studies conducted in outpatient and primary care settings have demonstrated good correlation between automated oscillometric and manual auscultatory BP measurements, with minor systematic biases in systolic and diastolic values [4,7,8]. However, these studies were largely performed in clinical or hypertensive populations and did not specifically evaluate blood donor screening contexts, where strict eligibility thresholds and rapid high-volume assessments are critical. In contrast, the present study uniquely focuses on blood donor populations and additionally evaluated the impact of measurement agreement on donor eligibility classification, which has direct implications for deferral rates and blood bank operational efficiency. Therefore, the present study aimed to assess the agreement between automated and manual BP measurements among blood donors and to evaluate their impact on donor eligibility classification.

MATERIALS AND METHODS

A cross-sectional analytical study was conducted for a period of eight months from July 2024 - March 2025. The study was conducted after obtaining the Institutional Ethical Committee (IEC) approval (Approval Number: 002/SBMCH/IHEC/2024/2157) in the blood donation unit of Sree Balaji Medical College and Hospital in Chennai, Tamil Nadu, India. Data was collected during routine predonation screening of blood donors over a defined study period.

Study population: The study population consisted of individuals presenting for blood donation at the study site during the defined study period. Prior to enrollment, all participants underwent

routine eligibility screening in accordance with blood donation guidelines.

Inclusion criteria: Adults aged between 18-60 years, presenting for blood donation, who provided written informed consent to participate in the study were included in the study.

Exclusion criteria: Donors with a known diagnosis of hypertension and were on treatment, were excluded from the study.

Sample size: The sample size for the present study was calculated using the formula $N=Z^2pq/d^2$. The proportion (p) of donor deferral due to high BP was taken as 32% based on a previous study, with q=68%. Considering a 95% confidence level (Z=1.96) and 22% relative precision, the calculated sample size was approximately 200 including non response rate [9].

Study Procedure

The study variables included socio-demographic, clinical, and measurement-related variables. Socio-demographic variables comprised age and sex of the donors. Clinical variables included pulse rate of the blood donors. The primary measurement variables were SBP and DBP recorded using both manual sphygmomanometer and automated digital BP device. From these values, MAP was calculated using the formula MAP=DBP+(SBP-DBP)/3 [10]. Additional derived variables included differences between manual and digital SBP and DBP measurements and donor eligibility or deferral status based on BP criteria.

After obtaining informed consent, eligible donors underwent routine predonation screening. BP measurements were obtained using two different methods: manual sphygmomanometer (auscultatory method) and automated digital BP device (oscillometric method). Participants were seated comfortably with back support and BP measurements were taken after the donor had rested for at least five minutes. The arm was positioned at heart level during measurement.

Manual BP was measured using a calibrated sphygmomanometer (DIAMOND BPDL-237 Aneroid Blood Pressure Apparatus Bp Monitor) and stethoscope by trained healthcare personnel following standard auscultatory technique. Automated BP was measured by the same observer to ensure consistency using a validated digital device (Omron) placed on the same arm. Manual and digital BP measurements were taken sequentially with a 1-2 minute interval, and the order of measurement was kept consistent for all participants. MAP was calculated using the formula [11]:

MAP=DBP+(SBP-DBP)/3

Donor eligibility or deferral due to BP was determined using standard blood donation criteria. Donors were considered eligible if SBP ranged between 100-140 mmHg and DBP between 60-90 mmHg. Participants showing discordant values affecting eligibility classification were excluded from eligibility outcome analysis but retained for measurement agreement assessment. Values outside this range were classified as deferral due to BP [12]. BP measurement discordance was measured when there was a variation in the systolic BP difference of ±10 mm Hg between automated BP and manual BP monitoring [13].

STATISTICAL ANALYSIS

Data was entered and analysed using Statistical Package for the Social Sciences (SPSS) version 25.0. Continuous variables such as SBP, DBP, pulse rate, and MAP were summarised using mean and standard deviation. Categorical variables such as donor eligibility and deferral status were expressed as frequencies and percentages. Agreement between manual and automated BP measurements was evaluated using multiple statistical approaches. Paired sample t-tests were used to assess differences between mean SBP and DBP values obtained by the two methods. Pearson correlation analysis was performed to evaluate the relationship between measurements obtained by both methods. The level of agreement in donor eligibility classification between manual and automated BP measurements was assessed using Cohen's Kappa statistic. A Kappa value closer to one indicated stronger agreement between the two methods. A p-value < 0.05 was considered statistically significant.

RESULTS

The study included 200 blood donors, with a mean age of 34.09±9.05 years. The average previous donation count was 1.09±1.26, and the mean time since the last donation was 2.70±3.82 months. Donors reported an average sleep duration of 7.37±1.79 hours. The mean height was 165.33±11.17 cm, and the mean weight was 69.04±14.12 kg, suggesting a moderately varied body composition among the study participants.

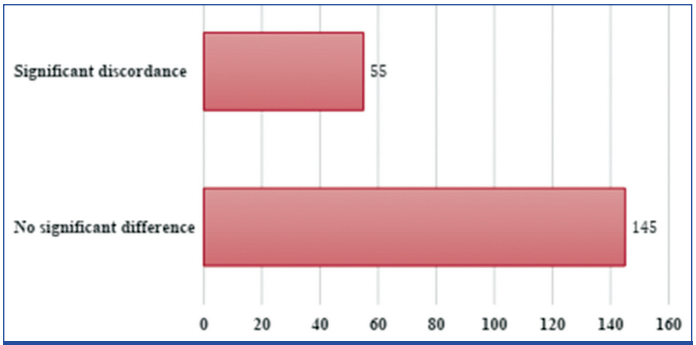
In present study, females constituted a slightly higher proportion 107 (53.5%) than males 93 (46.5%) among the donors. The majority had higher secondary education or above 124 (62%) and were employed 131 (65.5%). Nearly equal proportions of first-time 101 (50.5%) and repeat donors 99 (49.5%) were observed. Lifestyle characteristics such as smoking 94 (47%), alcohol intake 98 (49%), and recent physical activity 115 (57.5%) were almost evenly distributed, with 107 (53.5%) reporting a family history of hypertension [Table/Fig-1].

Variables	Category	n (%)
Gender	Male	93 (46.5)
	Female	107 (53.5)
Education	Up to middle school	55 (27.5)
	Up to high school	21 (10.5)
	Higher secondary school	64 (32.0)
	Graduates	60 (30.0)
Occupation	Employed	131 (65.5)
	Unemployed	69 (34.5)
First-time donor	Yes	101 (50.5)
	No	99 (49.5)
Smoking status	Yes	94 (47.0)
	No	106 (53.0)
Alcohol intake	Yes	98 (49.0)
	No	102 (51.0)
Family history of hypertension	Yes	107 (53.5)
	No	93 (46.5)
Smoking within last 30 minutes	Yes	95 (47.5)
	No	105 (52.5)
Physical activity within last 30 minutes	Yes	115 (57.5)
	No	85 (42.5)
Arm used for BP measurement	Left	79 (39.5)
	Right	121 (60.5)

[Table/Fig-1]: Socio-demographic characteristics of the study population (N=200).

Out of the total observations, the majority (145; 72.5%) showed no significant difference, while 55 (27.5%) demonstrated significant discordance [Table/Fig-2].

The comparison of BP measurements obtained using manual and digital methods showed very similar mean values. The mean SBP measured manually was 128.75±11.52 mmHg, while the digital method recorded a comparable mean of 128.32±11.52 mmHg. Similarly, the mean DBP was 84.32±9.23 mmHg using the manual method and 84.68±9.69 mmHg using the digital device. The mean pulse pressure was 44.44±10.15 mmHg with manual measurement and 43.64±2.33 mmHg with the digital method. Likewise, the MAP was nearly identical between the two methods, with 99.13±8.84 mmHg recorded manually and 99.23±10.27 mmHg recorded digitally [Table/Fig-3].



[Table/Fig-2]: Distribution of participants based on measurement discordance (N=200).

Parameters	Manual (Mean±SD)	Digital (Mean±SD)	p-value
Systolic BP (mmHg)	128.75±11.52	128.32±11.52	<0.001
Diastolic BP (mmHg)	84.32±9.23	84.68±9.69	0.576
Pulse Pressure (mmHg)	44.44±10.15	43.64±2.33	0.221
Mean Arterial Pressure (MAP) (mmHg)	99.13±8.84	99.23±10.27	0.819

[Table/Fig-3]: Blood Pressure (BP) measurements by manual and digital methods (N=200).

The paired t-test analysis comparing BP measurements obtained by manual and digital methods showed that the mean SBP difference was statistically significant (t=8.535, p-value<0.001). However, no significant differences were observed for the other parameters. [Table/Fig-4].

Parameters	Mean difference±SD	t value	p-value
SBP manual Vs SBP digital	0.43±0.71	8.535	<0.001
DBP manual Vs DBP digital	-0.37±9.20	-0.561	0.576
Pulse pressure difference	0.80±9.16	1.227	0.221
MAP difference	-0.10±6.16	-0.229	0.819

[Table/Fig-4]: Comparison of Blood Pressure (BP) measurements between methods using paired t-test.

The ICC analysis demonstrated varying levels of agreement between manual and digital BP measurements. The ICC for SBP was 0.997 (95% CI: 0.993-0.999, p-value<0.001), indicating excellent agreement between the two methods. The MAP also showed strong agreement, with an ICC of 0.794 (95% CI: 0.736-0.840, p-value<0.001). In contrast, DBP demonstrated moderate agreement, with an ICC of 0.528 (95% CI: 0.420-0.621, p-value<0.001). The pulse pressure showed poor agreement, with an ICC of 0.225 (95% CI: 0-090-0.352, p-value=0.001) [Table/Fig-5].

Parameters	ICC (Single measure)	95% CI	p-value
Systolic Blood Pressure (SBP)	0.997	0.993-0.999	<0.001
Diastolic Blood Pressure (DBP)	0.528	0.420-0.621	<0.001
Pulse pressure	0.225	0.090-0.352	0.001
Mean Arterial Pressure (MAP)	0.794	0.736-0.840	<0.001

[Table/Fig-5]: Intra-class correlation coefficient between Blood Pressure (BP) methods.

Based on BP eligibility classification, 171 of 200 donors (85.5%) showed concordant classification between manual and digital methods, whereas 29 donors (14.5%) were classified differently. Cohen's kappa demonstrated moderate agreement between the two methods (κ=0.69, p-value <0.001) [Table/Fig-6].

Binary logistic regression analysis [Table/Fig-7] was performed to identify factors associated with significant measurement discordance between manual and automated BP measurements. Although the overall logistic regression model was not statistically significant, first-time donors had lower odds of significant discordance compared to repeat donors (OR=0.42, 95% CI: 0.21-0.84, p-value=0.014). The model explained approximately 9.5% to 13.8% of the variance in discordance based on the Cox & Snell and Nagelkerke R^2 values.

Manual BP	Digital eligible	Digital deferred	Total
Eligible	117	10	127
Deferred	19	54	73
Total	136	64	200

[Table/Fig-6]: Agreement between manual and Digital Blood Pressure (BP) measurement deferral status (N=200).

Variables	Odds Ratio (OR)	95% CI	p-value
Gender	1.36	0.68-2.71	0.380
Occupation	1.46	0.71-2.97	0.305
First-time donor	0.42	0.21-0.84	0.014*
Smoking status	0.63	0.32-1.25	0.184
Alcohol intake	0.94	0.48-1.83	0.848
Family history of hypertension	0.66	0.33-1.31	0.231
Smoking (last 30 min)	0.62	0.31-1.24	0.179
Physical activity (last 30 min)	1.31	0.65-2.63	0.445

[Table/Fig-7]: Factors associated with measurement discordance using logistic regression (N=200).

DISCUSSION

The BP measurement is a critical component of predonation screening, as abnormal BP levels may increase the risk of adverse reactions during blood donation and may also indicate underlying cardiovascular disease [2,14]. In the present study, the mean SBP measured using the manual method was 128.75±11.52 mmHg, while the automated device recorded a very similar value of 128.32±11.52 mmHg. Similarly, the mean DBP values were 84.32±9.23 mmHg for manual measurement and 84.68±9.69 mmHg for digital measurement, indicating nominal difference between the two methods. Although the paired t-test showed a statistically significant difference for SBP, the absolute difference was only 0.43 mmHg, suggesting that the variation is clinically trivial.

Similar findings have been reported in several international studies. A study conducted in the United States by Gupta P et al., demonstrated strong agreement between automated oscillometric devices and mercury sphygmomanometers in clinical measurements, concluding that automated devices can reliably replace manual methods in routine screening settings [15]. Likewise, research conducted in European outpatient populations by Parati G et al., showed that automated devices produced systolic and diastolic readings that closely correlated with manual measurements, with only minimal systematic bias [16]. The results of the present study are consistent with these findings, particularly regarding the negligible mean difference in SBP. Minor variations between studies may be attributed to differences in device models, calibration standards, cuff size selection, and population characteristics, all of which can influence oscillometric measurements [17].

In the present study, the ICC coefficient analysis revealed excellent agreement for SBP (ICC=0.997) and good agreement for MAP (ICC=0.794) between manual and digital methods, whereas DBP showed moderate agreement (ICC=0.528) and pulse pressure demonstrated relatively poor agreement (ICC=0.225). In contrast, the relatively lower agreement observed for DBP compared to SBP may be attributed to the inherent limitations of oscillometric devices, which estimate diastolic values using algorithm-based calculations rather than direct auscultatory detection. Diastolic pressure is also more susceptible to physiological variability and observer-related factors, which may contribute to measurement discrepancies. This variation is clinically relevant, particularly when values lie near donor eligibility thresholds, as it may influence classification and deferral decisions.

Similar patterns have been documented in previous methodological research. For instance, Vischer AS and Burkard T reported that SBP tends to show stronger reproducibility between oscillometric and auscultatory methods compared with diastolic pressure [18]. This difference may be explained by the physiological characteristics of diastolic pressure detection, which is more susceptible to observer variability and algorithmic estimation in oscillometric devices. Additionally, transient physiological factors such as donor anxiety, recent physical activity, or environmental conditions in donation settings may contribute to variability in diastolic measurements [19-22].

Another important observation in the current study was the discordance in donor eligibility classification between manual and automated BP measurements. While most donors were classified similarly by both methods, a proportion of participants were categorised differently in terms of eligibility or deferral status. Comparable findings have been reported in international transfusion research. For example, Thibeault C et al., reported that differences in measurement techniques may occasionally lead to variations in donor deferral decisions, particularly when BP values lie close to the eligibility threshold [2]. Oscillometric devices may either slightly overestimate or underestimate certain BP components due to the mathematical algorithms used to derive systolic and diastolic values from oscillation amplitudes. Such variations are expected when comparing two fundamentally different measurement principles [20].

Furthermore, logistic regression analysis in the present study indicated that first-time donors had significantly lower odds of measurement discordance compared to repeat donors (OR=0.42, p-value=0.014), while other factors such as gender, smoking status, alcohol intake, and family history of hypertension were not significantly associated with discordance. Although limited research has examined predictors of measurement discordance in donor populations, some studies have suggested that repeated exposure to donation procedures may influence donor anxiety levels or physiological responses during screening, which could affect BP readings [21-23]. Differences across studies may also arise from variations in donor demographics, lifestyle characteristics, and screening environments. Overall, despite minor differences in specific parameters, the findings of the present study support the use of automated BP devices as reliable tools for donor screening, particularly in high-volume blood donation centres where rapid, standardised, and operator-independent measurements are advantageous [24,25]. The use of automated devices may also reduce observer bias and improve screening efficiency during high-volume blood donation camps.

Limitation(s)

The study had certain limitations. Being a single-centre study, the findings may not be generalisable to other settings. The use of convenience sampling may have introduced selection bias. Important confounders such as anxiety, hydration status, and environmental factors were not assessed.

CONCLUSION(S)

The present study demonstrated a high level of agreement between manual auscultatory and automated oscillometric BP measurements among blood donors, with minimal differences in mean SBP and DBP values. Automated devices showed excellent reliability for SBP and good agreement for MAP, although moderate variation was observed for diastolic pressure and pulse pressure. While minor discrepancies in donor eligibility classification were identified between the two methods, these differences were limited and unlikely to significantly impact overall donor screening outcomes. Therefore, automated BP devices can be considered a reliable and practical alternative to manual sphygmomanometer measurements for routine blood donor screening, particularly in high-volume blood donation settings where rapid, standardised and operator-independent assessments are required. Further research should focus on DBP variability, incorporate advanced analytical methods, and adopt longitudinal designs to assess the impact of measurement differences on donor safety and outcomes.

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