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Which is More Accurate in Measuring the Blood Pressure? Comparison of An manual Aneroid Sphygmomanometer, manual mercury or Digital Automated in Hypertension

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Abstract

Aim: The aim of this study was to compare the accuracy of blood pressure (BP) readings with manual aneroid sphygmomanometer (MAS), manual mercury (MM) and an automated office digital blood pressure (AODBP) device.

Subjects and methods: A cross-sectional study based on 1154 patients included sociodemographics, life-style habits, anthropometric measurements, and clinical biochemistry parameters. The sleep quality of participants was measured using the Pittsburgh Sleep Quality Index (PSQI) test. The Bland-Altman plot analysis is used to compare two measurements' agreement against a mercury sphygmomanometer (MS).

Results: Out of 1154 subjects, 528 (47.6%) were men and 626 (52.4%) were women. The study revealed significant differences between gender for age, educational, occupational, income, smoking, exercise, sport activities and fatigue, respectively. The present study showed that accurate measurement of BP is MAS readings which were slightly higher than AODBP estimates. Compared to the gold standard MM, the MAS provides better accuracy, valid and reliable readings than the AODBP device. Similarly, the biochemistry parameters regarding vitamin D, blood glucose, HbA1c, creatinine, bilirubin, albumin, total cholesterol, LDL-C, uric acid, and blood pressures revealed significantly gender differences. Multivariate stepwise logistic regression analysis revealed that the vitamin D deficiency ($p<0.001$), lack of sleep ($p<0.001$), lack of physical activity, ($p<0.001$), systolic blood pressure, mmHg ($p=0.002$), diastolic blood pressure, ($p=0.005$), obesity ($p=0.006$), smoking ($p=0.015$), and fatigue ($p=0.032$) were considered at higher risk as a predictors for hypertension patients.

Conclusion: The present study showed that accurate measurement of BP is MAS readings, which were slightly higher than AODBP estimates. Compared to the gold standard MM, the MAS provides better accuracy, valid and reliable readings than the AODBP device.

Keywords: Blood pressure, diastolic, systolic, mercury, digital, sphygmomanometer, diagnostic errors, epidemiological factors

Introduction

With advances in technology, people spend less physical effort in daily life and when nutritional habits are added to this situation. There is an increase in the prevalence of obesity, diabetes

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and hypertension, which affect each other. Hypertension is typically diagnosed and managed in family medicine, primary health care and hospital setting and it is one of the most common reasons for visits to physicians in Turkey. Accurate blood pressure measurement is the most important foundation of optimal screening, diagnosis and treatment of hypertension. Blood pressure measurements are often mistaken. The main reasons for incorrect measurements are due to non-compliance with protocols and the accuracy of the meter. Patients are misdiagnosed as hypertension due to erroneous high measurements and they are deprived of treatment with false low measurements. Automated digital blood pressure (AODBP) measuring devices are becoming very popular among clinicians and patients who self-monitor their BP at home or in the office [1-4]. However, the systolic and diastolic blood pressure results obtained from these devices are not the result of measurement since they work with the oscillometric method. They are the results of the calculation algorithm of the device and there are differences in algorithms between brands and models. Therefore, the results of the automatic measuring device were compared with the gold standard mercury sphygmomanometer and aneroid sphygmomanometer in the study. The patients some characteristic may have an impact on the BP measurements have also been reported [5]. Meanwhile, a MM and an AODBP measurement differences were found to be slightly higher than in an experimental setting [6-8]. Further, the accuracy of the AODBPs has been subject to criticism [9-12]. Some studies reported [13-14] the difference is approximately between 2-5 mm Hg, which is usually allowed in epidemiological studies. Furthermore, several studies [3,7-8,15-16] have reported that the AODBP comparison with the MM in hypertension screening produced significantly underestimated or not accurate readings. The aim of the current study was to compare the accuracy of readings of blood pressure with MAS, MM and using AODBP devices to determine hypertensive patients.

Material and methods

This cross sectional study was carried out among the hypertensive outpatient patients registered in hypertension and endocrinology clinics of the Istanbul Medipol University, Medipol Teaching Hospitals. Patients were aged between 25-65 years during the study period from August 2020 to December 2020. Institutional Ethics Committees (IEC) or IRB approval was provided by the Istanbul Medipol University (Research Project # 10840098-772.02.01-E.49746).

Data collection methods Questionnaire and Blood Pressure Measurement

The assumed prevalence of hypertension in Turkey was based on prior studies, which indicate it to be between 20.0% - 24.0% [17-19]. Sample size formula ($n = N * [Z^2 * p * (1-p)/e^2] / [N - 1 + (Z^2 * p * (1-p)/e^2]$) and calculation is based on the following parameters: margin error = 2.65%, Z= confidence level= 99%, the prevalence likely to be considered P=24%, then the required sample size was approximately to be 1644. A total of 1644 patients of both genders, between the ages of 25-65, were approached and 1154 (70.2%) subjects participated voluntarily in this study. Exclusion criteria, patients who could not respond due to a physical or mental illness and whose body measurements could not be made were not included in the study.

The questionnaire gathered data on socio-demographics, anthropometrics, lifestyle habits, physical activities, smoking and biochemistry parameters.

To measure the sleep quality of participants, the Pittsburgh sleep quality index (PSQI) test was used and classified as good, average and poor sleeping. Content validity, face validity and reliability of the questionnaire were based on 100 patients. The test revealed a high level of validity, and high degree of repeatability Cronbach's alpha value was 85%.

Blood Pressure Measurement

Blood pressure was measured two times on the right arm of the selected subject using Manual Mercury [ERKAMETER 3000 Mercury Sphygmomanometer – Made in Germany], Manual Aneroid sphygmomanometer (MAS) [Erka Perfect Aneroid, German made] and AODBP device (OMRON M2 Intellisense Hem-7121-E). An MAS and a digital instrument were selected for the purpose and were judged with respect to a properly calibrated mercury sphygmomanometer (Gold standard). The average of two readings was used. Definition and criteria of hypertension was taken according to the 2017 American College of Cardiology and American Heart Association [1,20-21]. Blood pressure categories in the new guideline are; Normal: Less than 120/80 mm Hg, Elevated: Systolic between 120-129 mm Hg and diastolic less than 80 mm Hg, Stage 1 Systolic between 130-139 mm Hg or diastolic between 80-89 mm Hg, Stage 2: Systolic at least 140 or diastolic at least 90 mm Hg.

Blood collection and laboratory measurements

A blood sample of 10 ml was collected from each subject after fasting for 10 hours at the Medipol Hospital, Medipol International School of Medicine.

Vitamin D, glucose, HbA1c, calcium, urea, creatinine, bilirubin, albumin, cholesterol, triglycerides, HDL-C, LDL-C and uric acid levels of the participants in the study were measured.

Serum 25-OH D was measured using a direct competitive chemiluminescent immunoassay (Elecsys; Roche Diagnostics, Germany). Vitamin D patients were classified into three cut-off as; 1) vitamin D deficiency, 25(OH)D<20 ng/ml, 2) insufficiency, 25(OH)D 20-29 ng/m and normal/optimal level which is between 30-80 ng/ml on the basis of previous recommendations [19,22-24].

ROCHE COBAS 6000 auto-analyser (Roche Diagnostics, Germany) was used for the analysis. Plasma glucose, total cholesterol, triglyceride, low and high density lipoprotein cholesterol (HDL & LDL), were measured by an auto-analyser (ROCHE COBAS 6000). Glycosylated, hemoglobin, (HbA1c) was

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analysed using a high-performance liquid chromatography (HPLC) method [19,24].

The Bland-Altman (mean-difference or limits of agreement) plot and analysis

In clinical or medical studies, we often need to compare two methods of measurement or a new method with an established one, to determine whether these two methods can be used interchangeably or the new method can replace the established one [25-26]. The following details come from Zou [27].

This plot analysis is a simple way to evaluate a bias between the mean differences and to estimate an agreement interval.

The data was analysed using SPSS 21 Statistics (IBM Corp Armonk, NY, USA). The significance of differences between the mean values of two continuous variables was determined by the Student´s t and paired t test. The Chi-square test performed for the differences between two or more categorical variables or groups. We have performed Bland and Altman [25-26] analysis, based on the quantification of the agreement between two quantitative measurements. The Multivariate stepwise logistic regression analysis method was used to assess the relationship between blood pressure as dependent and socio-demographics and life-style habits gender; age groups in years, BMI groups, educational level, occupational status, smoking habits, nargile shesha smoking and physical exercising as independent variables to determine risk factors for the presence of hypertension. The level $p<0.05$ was considered as the cut-off value for significance.

Results

Table 1 is on the comparison of socio-demographic and lifestyle characteristics of the participants. Out of 1154 patients, 528 (45.8%) were male and 626 (54.2%) were female. The mean age of males was 51.89±14.82 and females was 49.02±14.25 ($p=0.004$). There were statistically significant differences between gender; age groups in years, BMI groups, educational level, occupational status, smoking habits, nargile shesha smoking, physical exercising and sport activities.

Table 2 shows the comparison between the mean clinical biochemical characteristics of the hypertensive patients by gender. As can be seen from this table, there were statistically significant differences between males and females regarding co-morbid complications, associated symptoms, treatment mode and PSQI as good, average and poor sleeping and Vitamin D respectively.

Table 3 shows the comparison between the mean clinical biochemical characteristics of the gender subjects. As can be seen from this table, gender showed significant difference for age and biochemistry parameters regarding vitamin D, blood glucose, HbA1c, calcium, urea, creatinine, bilirubin, albumin, cholesterol, LDL-C, uric acid, systolic and diastolic blood pressures, hours of sleeping and BMI respectively. Figures 1-6 provides comparisons of systolic and diastolic blood pressure by MAS, AODBP and MM devices for blood pressure.

Table 1. Comparison of Socio-demographic characteristics of the participants by gender (N=1154).

Variables	Male= 528 n (%)	Female=626 n (%)	P value
Age in years			
30-39	113(21.4)	176(28.1)	
40-49	124(23.5)	150(24.0)	0.018
50-59	120(22.7)	141(22.5)	
60 and above	171(32.4)	159(25.4)	
Marital status:			
Single	99(18.8)	120(19.2)	0.856
Married	429(81.2)	506(80.8)	
Body mass index (**BMI**)**:**			
<25 (kg/m^2)	134(25.6)	217(34.7)	
25-29.9 (kg/m^2)	219(44.5)	238(38.0)	0.002
30 (kg/m^2) and above	175(33.1)	171(27.3)	
Level of education:			
Elementary	90(17.0)	125(20.0)	
Intermediate	137(25.9)	144(23.0)	0.002
Secondary	170(32.2)	153(24.4)	
University	131(24.8)	204(32.6)	
Occupational status:			
Housewife	0(0.0)	152(24.3)	
Sedentary	137(25.9)	169(27.0)	
Manual	166(31.4)	113(18.0)	0.001
Businessman	83(15.7)	73(11.7)	
Arm/police/security	41(7.8)	50(8.0)	
Clark	101(19.1)	69(11.0)	
Household income			
Low	175(33.1)	223(37.2)	
Medium	213(40.3)	229(36.6)	0.299
High	140(26.5)	164(26.2)	
Eating frequency:			
2 times	131(24.8)	174(27.8)	0.252
3 times	397(75.2)	452(78.2)	
Smoking status:			
Yes	104(19.7)	79(12.6)	0.015
No	424(80.3)	547(87.4)	
Nargile - Sheesha smoking:			
Yes	94(17.8)	61(9.7)	<0.001
No	434(82.2)	565(90.3)	
Alcohol use			
Yes	23(4.4)	32(5.1)	0.548
No	505(95.6)	594(94.9)	
Physical exercise:			
Yes	155(29.4)	151(24.1)	0.045
No	373(70.6)	475(75.9)	
Sport activity:			
Yes	37(7.0)	74(11.8)	0.006
No	491(93.0)	552(88.2)	

Table 4 gives multivariable stepwise logistic regression analysis of independent predictors for the risk factors of hypertension. Vitamin D deficiency [OR 3.95 95% CI 1.93-4.84, $p<0.001$], lack of physical activity [OR 4.25 95% CI 3.16-5.71, $p<0.001$], lack of sleep [OR 2.83 95% CI 1.65-4.57, $p<0.001$], systolic blood pressure, mmHg [OR 1.45 95% CI 1.18-1.85, $p=0.002$], diastolic blood pressure, mmHg [OR 2.78 95% CI 1.34-5.24,

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Table 2. Clinical Characteristics of the studied subjects by gender (N=1154).

Variables	Males n=528 n(%)	Females n=626 n(%)	P value
Co-morbid complications			
Hypoglycemia	129(24.4)	141 (22.5)	0.446
Gastrointestinal	45(8.5)	77(12.3)	0.038
Respiratory	51(9.7)	51(8.1)	0.367
Headache	119(22.5)	127(20.3)	0.352
Dizziness	49(9.3)	94(15.0)	0.003
Vision problem	109(20.6)	92(14.7)	0.008
Stroke	48(9.1)	55(8.6)	0.856
Nervousness	45(8.5)	56(8.9)	0.800
Chest pain	67(12.7)	52(8.3)	0.015
Coronary Heart Disease	79(15.0)	59(9.4)	0.004
Fatigue	65(12.3)	113(18.1)	0.004
Stress	40(7.6)	79(12.6)	0.005
Sweating	58(11.0)	98(15.7)	0.021
Associated symptoms			
Excessive passing of urine	98(18.6)	85(13.6)	0.021
Excessive hungry	82(15.5)	95(15.2)	0.888
Excessive thirst	113(21.4)	95(15.2)	0. 006
Weight loss	94(17.8)	99(15.8)	0.363
Loss of appetite	149(28.2)	134(21.4)	0.007
Dry mouth	66(12.5)	81(9.7)	0.136
Hypertension treatment mode			
Herbal plant	90(17.0)	143(22.8)	0.015
Vigorous activity	155(29.4)	151(24.1)	0.045
Garlic use	91(17.2)	107(17.1)	0.949
Drug tablet use	81(15.3)	131(20.9)	0.015
Green tea use	87(16.5)	151(24.1)	0.001
Supplement vitamin	84(15.9)	135(21.6)	0.136
Pittsburgh Sleep Quality Index			
Good (**PSQI**<5)	178(33.7)	258(41.2)	
Average (6<**PSQI**≤8)	153(29.0)	195(31.2)	0.001
Poor (**PSQI**>8)	197(37.3)	173(27.6.0)	
Vitamin D levels			
Deficiency 25(OH)D 10-19 ng/ml	241(45.6)	368(58.8)	
Insufficiency 25(OH)D 20-29 ng/ml	198(37.5)	144(23.0)	0.001
Sufficiency 25(OH)D 30-80 ng/ml	89(16.9)	114(18.2)	

p=0.05], obesity [OR 2.65 95% CI 1.81-4.48, p=0.006], smoking [OR 1.81 95% CI 1.22-2.64, p=0.015] and fatigue [OR 1.77 95% CI 1.39-2.86, p=0.032] were considered at higher risk as a predictors of hypertension.

Discussion

The current study revealed a small difference between the

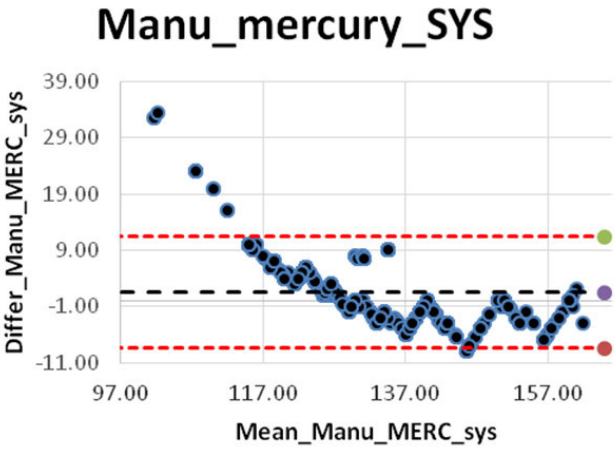

Figure 1. Bland & Altman graph for difference between manual aneroid and manual mercury systolic.

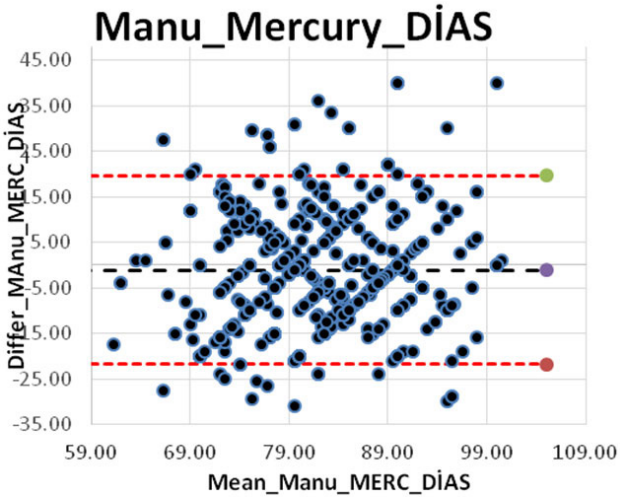

Figure 2. Bland & Altman graph for difference between manual aneroid and manual mercury diastolic.

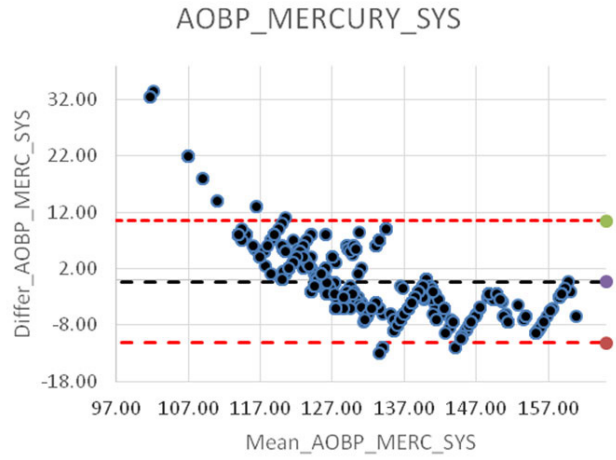

Figure 3. Bland & Altman graph for difference between AODBP and manual mercury systolic.

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Table 3. The comparison of clinical biochemistry characteristics and blood pressures among subjects by gender (N=1154).

Biochemistry investigations	Males Mean ± SD	Females Mean ± SD	Mean differences	P value *
Age in year	51.89±14.82	49.02±14.25	2.68(0.99, 4.80)	0.004
Vitamin D	21.01±8.62	19.40±9.95	1.92(0.8, 3.01)	0.001
Blood glucose(mmol/L)	8.82±0.90	9.04±1.48	-0.32(-0.56, -0.08)	0.003
HbA1c	9.60±1.13	9.36±1.17	0.22(0.09, 0.56)	0.006
Calcium (mmol/L)	2.00±0.12	1.95±0.10	0.05(0.02, 024)	0.001
Urea (mmol/L)	5.42±2.81	5.13±2.10	0.29(0.14, 0.58)	0.045
Creatinine(mmol/L)	76.47±13.84	72.49±15.72	3.98(2.26, 5.70)	0.001
Bilirubin (mmol/L)	7.20±2.71	7.72±2.50	-0.52(-0.82, -0.52)	0.002
Albumin (mmol/L)	43.15±5.97	41.15±3.70	2.00(1.43, 2.56)	0.001
Cholesterol (mmol/L)	4.90±0.93	4.68±0.74	0.21(0.11, 0.31)	0.001
Triglycerides (mmol/L)	1.62±0.67	1.63±0.71	-0.01(-0.09, -0.07)	0.738
HDL-C (mmol/L)	1.10±0.26	1.09±0.27	-0.01(-0.03, -0.02)	0.892
LDL-C (mmol/L)	1.81±0.93	1.99±0.94	-0.20(-0.31, 0.07)	0.002
Uric acid (mmol/L)	288.7±66.0	274.3±68.2	14.52(6.70, 22.55)	0.001
Blood pressure (BP)				
Aneroid Systolic BP (mmHg)	131.1±8.67	133.1±9.72	-2.19(-3.27, -1.10)	0.001
Aneroid Diastolic BP (mmHg)	80.8±7.98	82.7±8.82	-1.24(-2.26, -0.26)	0.013
Mercury Systolic BP (mmHg)	129.3±12.42	132.1±13.35	-2.08(-4.36, -1.36)	0.001
Mercury Diastolic BP (mmHg)	82.3±8.22	82.9±8.31	-0.44(-1.41, 0.51)	0.364
Auto Dig Systolic BP (mmHg)	129.4±8.53	131.4±9.72	-2.02(-3.02, -0.95)	0.001
Auto Dig Diastolic BP (mmHg)	79.1±7.95	80.1±9.21	-0.94(-1.958,0.55)	0.064
Hours of Sleep	6.49±1.01	6.66±0.90	-0.15(-0.26, 0.04)	0.006
Body Mass Index (kg/m^2)	27.96±4.50	27.33±4.70	0.63(0.52, 1.16)	0.005

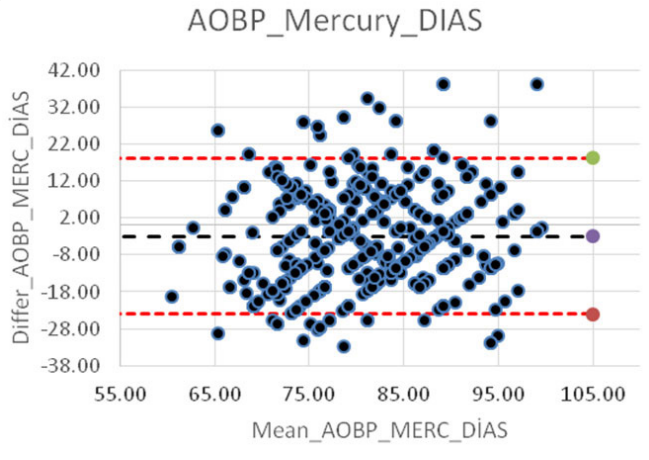

Figure 4. Bland & Altman graph for difference between AOBP and manual mercury diastolic.

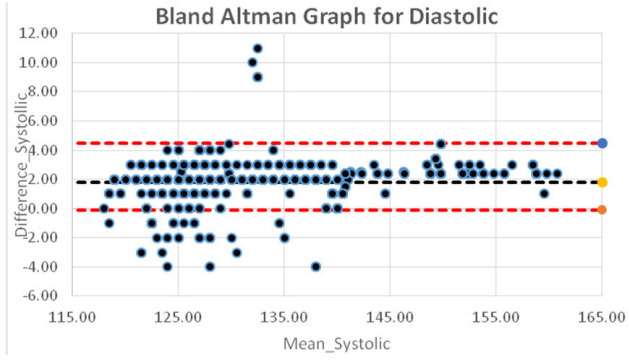

Figure 5. Bland & Altman plot of the differ between manual aneroid and AOBP systolic.

accuracy of readings of manual aneroid and the AODBP with reference to mercury sphygmomanometers (gold standard) and determined the hypertensive patients correctly. The present study confirmed the previous reported studies [3,7-15]. This is very important to classification the hypertensive patient accurately and reliable to get the opportunity to receive treatment correctly.

The study conducted in India by Shahbabu et al. [13] showed the agreement between the mercury and aneroid device in classifying hypertension. Then, Lim et al. [3] reported AODBP devices are practiced to be popular among both clinicians and patients which their accuracy has been validated [1,20-21]. However, it is very important and practical using AODBP device outside hospitals. Meanwhile, it should be taken to calculate the average of at least blood pressure to obtain an appropriate reliable reading. Despite small differences in the mean values, the agreement and reliability between the

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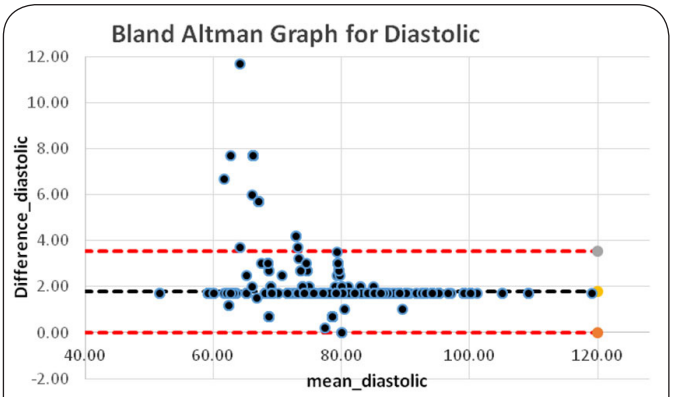

Figure 6. Bland & Altman plot of the differ between manual aneroid and AOBP diastolic.

Table 4. Multivariate stepwise logistic regression analysis for predictors risk factors of hypertension.

Independent Variables	Odds Ratio	95% Confidence Interval	P-value
Vitamin D deficiency	3.95	1.93-4.84	0.001
Lack of physical activity	4.25	3.16--5.71	0.001
Lack of sleeping	2.83	1.65-4.57	0.001
Systolic blood pressure, mmHg	1.45	1.18-1.85	0.002
Diastolic blood pressure, mmHg	2.78	1.34-5.24	0.005
Obesity (kg/m^2)	2.65	1.81-4.48	0.006
Smoking	1.81	1.22-2.64	0.015
Fatigue	1.77	1.39-2.86	0.032

manual and AODBP were not good enough to recommend.

The study conducted in Canada by Myers *et al.* [4] compared between an automated and manual sphygmomanometer in a population survey, compared blood pressures and suggested using mercury sphygmomanometer could be replaced by a validated, automated recorder. However, the study conducted by Myers et al. [4] have not been supported and confirmed by Turner and van Schalkwyk [7]. Also, we observed our results and conclusion is not consistent with the study conducted by Myers et al. [4].

Most studies do not report calibrating their instruments before the use of blood pressure device. Several authors [4,7,28,29] reported calibrating their instruments before the study started, otherwise it could be inaccurate. Further, the meta-analysis review [6] stated that the difference in blood pressure between the AODBP and mercury differences was considered as 5 mmHg. Furthermore, the Bland and Altman [25-26] methods and plot comparing two blood pressure measurements agreement is a more accurate, valid and reliable method, since the detection of hypertension which is extremely sensitive to systematic errors in BP measurements [11]. This is supported and confirmed by the current study.

The present study has some limitations. Firstly, the design of the study was cross-sectional, which does not allow the determining of any cause-effect relationship. Secondly, the study was conducted within the outpatient patients registered in hypertension and endocrinology clinics. The patients selection might be bias due to studying patients seeking health service only. Thirdly, socio-demographics or other clinical parameters that might have affected the blood pressure readings.

Conclusion

The present study showed that accurate measurement of BP is manual aneroid readings which were slightly higher than AODBP estimates. The manual aneroid BP provides better accuracy, valid and reliable readings compared to the AODBP as compared to the mercury sphygmomanometer golden standard.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Authors' contributions	AB	BS	CCB	AT
Research concept and design	√	√	√	--
Collection and/or assembly of data	√	√	√	--
Data analysis and interpretation	√	√	√	√
Writing the article	√	√	√	√
Critical revision of the article	√	√	√	√
Final approval of article	√	√	√	√
Statistical analysis	--	√	--	√

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