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ACCURACY OF BLOOD PRESSURE RECORDING BY MANUAL AND AUTOMATED DIGITAL DEVICES: A CLINICAL GUIDELINE

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ABSTRACT

Introduction: The Mercury sphygmomanometer, a global gold standard Blood Pressure (BP) recording device is being replaced by Automated Wrist, Arm and Finger devices due to the hazardous effect of mercury on health. The present study was conducted to test the accuracy of blood pressure measurements taken with two Automated blood pressure devices (Arm and Wrist) keeping Mercury sphygmomanometer as the Gold Standard.

Materials & Methods: A cross sectional comparative study was done in April 2016 on 120 employees of Rehman Medical College aged 20-69 years (mean age 34.39 ± 10.49 years), based on convenience sampling and informed consent; known hypertensive cases and those on anti-hypertensive medication were excluded on account of lability of blood pressure recordings. Two readings were obtained from both arms and wrists by three trained researchers through calibrated Mercury and Automated Arm and Wrist devices using standard techniques. Data were analyzed by SPSS 15.0. Comparisons were done using T tests and ANOVA, keeping $p \leq 0.05$ as significant.

Results: Differences in Systolic Blood Pressures (SBP) of right and left arms were not significant ($p>0.05$) for each device. However significant differences were obtained ($p=0.043$) for the right and left upper arm mean Diastolic Blood Pressures (DBP) by Mercury sphygmomanometer. The Automated devices differed significantly ($p<0.05$) from the Mercury device by reporting higher BP values and diagnosing many more cases of Systolic and Diastolic hypertension.

Conclusion: The Mercury device provided more accurate and consistent BP readings than the automated ones. The left upper arm should be the preferred location for blood pressure measurements in clinical practice.

Keywords: Blood Pressure; Arterial Pressure; Blood Pressure determination; Sphygmomanometers; Hypertension.

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INTRODUCTION

The most common risk factor for many cardiovascular diseases is hypertension which is usually diagnosed and treated by taking blood pressure readings in a hospital.[1] In most hospitals and clinical settings around the world, blood pressure (BP) is measured by using a cuff which is fastened around a patient's arm, then filled with air; the pulse is checked manually by Palpatory technique, then the clinician places the stethoscope over the already palpated brachial artery and listens to the sounds while observing the mercury levels in the sphygmomanometer and deflating the cuff. This method was developed by Riva-Rocci in 1896; the only improvement is in the Auscultatory method which was developed by Sergei Korotkoff (1904-1905), and to fasten the cuff with the help of Velcro.[2,3] Measuring of blood pressure has a very important role in the field of diagnostic medicine as well as for the maintenance of health. On a regular basis, it is measured by non-invasive procedures including the Auscultatory technique (Korotkoff sounds) with the pressure in the cuff measured using mercury sphygmomanometer, which is still considered as the "*Gold Standard* ".[4,5]

However due to the finding that mercury is a hazard for occupational life, environment and health, the use of Mercury sphygmomanometers has been restricted worldwide.[6] United Nations environment program and WHO stated mercury pollution as a serious human health problem and also dangerous for global environment. Many countries including Sweden, Argentina and Philippines have banned mercury sphygmomanometers; European Union is also considering a ban. The American Hospital

Association agreed in 1998 that they will stop the usage of mercury sphygmomanometer by 2005.[7]

The automated blood pressure devices which are commonly available nowadays use oscillometric method. These include automated spot check devices, or arm devices and wrist devices. The arm device consists of an electronic monitor with a digital display and an upper arm cuff having pressure sensor; when started, the device inflates and deflates the cuff automatically giving the Systolic and Diastolic readings. The wrist device also has an electronic monitor and a pressure sensor; function of the device is similar to arm device as an electronically driven pump is attached to wrist cuff and the pulse is also recorded in these devices.[8]

These automated devices have been preferred over the manual sphygmomanometer because they are mercury free, light weight, compact, easy to use and carry, no observer bias and having increased patient comfort. Along with these advantages they also have many disadvantages as these automated devices are not suitable for everyone like patients having arrhythmias, pre-eclampsia and vascular diseases and also that the reading in these devices depend on the position of wrist to the heart. Wrist devices tends to be less accurate than upper arm devices.[9]

A study by the name of "Automated versus manual blood pressure measurement: a randomized crossover trial" was done in Australia in year 2013.[10] Aim of the study was to test the accuracy and reliability of measurements in hospital-admitted patients with similar medical and surgical problems to answer the research question (a test of null hypothesis stating that the Dinamap 8100 and a manual mercury sphygmomanometer showed no significant changes in Systolic and Diastolic blood pressures). Sample was taken with a similar proportion of males and females of ages 19-93 years; sample consisted of 63 patients out of 138, as only these agreed to participate. Results showed positive correlations on all four measures (two manual and two automated) showing high agreement between the nurses (range 0.64-0.79). Level of agreement on automated Diastolic measure was lower (0.64) than others.[10]

A related study took place in America in 2008;[11] the purpose of the study was to determine if automated manometers were as accurate as mercury sphygmomanometer. In this study, a sample size of 94 (ages 19 years and above) was taken and blood pressure was measured by four devices, all measurements were taken from left arm with five minutes intervals. Results of the study showed that there is little difference for pulse reading between the two methods; however Systolic readings by the wrist manometer were unreliable and the automated arm monitor gave different Diastolic readings in one age group as compared to control and all devices showed low reliability for age 50 years.[11]

Another study took place in America in 2010.[12] The purpose of the study was to determine the accuracy of automated oscillometric readings. Blood pressure was taken from the same site with the same cuff. Sample was taken from patients coming to cardiology department consisting of 337 patients comparing mercury manometer with automated device. The mean Systolic BP (133 ± 20.0 mmHg) and Diastolic BP (72 ± 11.0 mmHg) were greater with mercury manometer than automated device (Systolic 131 ± 18.0 mmHg and Diastolic 70 ± 12.0 mmHg, $p<0.0001$). Discrepancies in Systolic BP were seen in 22%, while in Diastolic BP were seen in 20% of all patients. The mean of the discrepancy between the 2 techniques was 1.95 ± 5.0 mmHg (range 1 to 26) for Systolic BP and 1.3 ± 4.0 mmHg (range 1 to 25) for Diastolic BP. The

discrepancies were greater in patients more than 65 years of age. In conclusion, the mercury manometer technique resulted in consistently greater BP values than oscillometric devices.[12]

No published data on this topic are available in Pakistan making this the first study from Pakistan to compare automated and manual devices.

The present study was carried out to test the accuracy of blood pressure measurements taken with two automated blood pressure devices (Arm and Wrist) keeping Mercury sphygmomanometer as the Gold Standard. It was hypothesized that the Automated blood pressure devices would show less accurate recordings as compared to Mercury manual sphygmomanometer.

MATERIALS & METHODS

The present cross sectional comparative study was carried out at Rehman Medical College, Peshawar during April 2016. Study subjects were all available employees of the college regardless of gender or age, who could be accessed by convenience sampling and after obtaining informed consent. Employees found to be previously hypertensive or those taking anti-hypertension medications were excluded, as blood pressure readings in these patients were likely to be more labile compared to non-hypertensive individuals, thus introducing unneeded bias in the readings. A final total of 120 employees became available for the study.

Data collection was based on use of three blood pressure determination apparatuses:

1. The Manual Mercury sphygmomanometer
2. Automated Arm device
3. Automated Wrist device

The Mercury sphygmomanometer was kept as the Gold Standard (Reference) device, comparing its readings with the two automated devices to determine the accuracy of the latter. Details of the devices are as below:

1. Manual mercury sphygmomanometer: For the calibration of a standard commonly used Mercury sphygmomanometer, readings were taken by all the three Observers and the Experienced Supervisor with intervals of 5 minutes. Acceptable observer performance was defined as obtaining the same readings as the Supervisor.

2. Arm device: (Upper arm monitor), Digital BP Monitor Model BP 20A (Belivia), Machine # IF 45329 REV: - 15.9.2011, Medium size cuff (22-32 cm Arm). Instructions: 1-2 cm above the cuboidal area with air hose in middle of arm.

3. Wrist device: Width 7 cm, Omron Health Care Co, Ltd Kyoto Japan (quality pass), Machine # 20121002720 VF Model # R2 HEM-6113-E (V). Instructions: Grip and monitor on radial side / flexor surface.

Data Analysis

Data were entered in SPSS version 15.0 for analysis; calculations of frequencies, proportions, percentages, means and standard deviation were done. One-way ANOVA and Repeated Measures ANOVA were performed for comparisons for the three instruments; $p \leq 0.05$ denoted significance.

RESULTS

Tables 1-5 depict the data obtained from the 120 study subjects. Demographic data of Table 1 show that there were 74(61.7%) males and 46(38.3%) females with ages ranging from 20 – 69 years; most subjects (51, 42.5%) were in the younger age group of 20-29 years, followed by 36(30.0%) in the 30-39 years age group, 18(15.0%) in the 40-49 years age group and 15(12.5%) aged 50-69 years. The mean age was 34.39 ± 10.49 years.

Table 1: Demographic data of subjects (n=120).

#	Demographic variables	No. of subjects	Percentage
1	**Gender**		
	Males	74	61.7
	Females	46	38.3
2	**Age Groups (Years)**		
	20 – 29	51	42.5
	30 – 39	36	30.0
	40 – 49	18	15.0
	50 – 59	13	10.8
	60 – 69	02	01.7
Total		**120**	**100.0**
Mean Age (Years)		34.39 ± 10.49	

Table 2 provides data of Systolic Blood Pressure (SBP) recordings of both upper limbs by the three devices. Differences are seen between the three devices for the same sided limb, with the Wrist and Arm devices appearing less consistent with the Mercury device and more consistent among each other. BP recording differences are also observed between the left and right arms; however, the observations of the Arm and Wrist devices are more consistent among themselves, whereas the Mercury device shows greater variation across the limbs.

Regarding the diagnosis of Systolic Hypertension (SBP > 140 mmHg), the Mercury device detected 06(5.0%) cases from the right upper arm and validated 03(02.5%) of these cases from the left upper arm. The Arm device recorded 25(20.8%) cases of Systolic hypertension from the right upper arm, validated 12(10.0%) of these cases from the left upper arm, and detected 09(7.5%) additional cases from the left upper arm, giving a total of 36(30.0%) cases. The Wrist device recorded 19(15.8%) cases of Systolic hypertension from the right limb, validated 09(7.5%) of these cases in the left limb, and identified 11(09.2%) additional cases from the left limb, giving a total of 30(25.0%) hypertensive readings. Thus the Arm and Wrist devices are more consistent with each other than with the Mercury device.

Table 2: Distribution of Systolic Blood Pressure recordings of both upper limbs (n=120).

BP Groups (mmHg)	RIGHT UPPER LIMB (mmHg)			LEFT UPPER LIMB (mmHg)		
	Mercury n (%)	Arm n (%)	Wrist n (%)	Mercury n (%)	Arm n (%)	Wrist n (%)
60 - 80	-	-	05 (04.2)	-	-	04 (03.3)
81 - 100	30 (25.0)	05 (04.2)	05 (04.2)	33 (27.5)	04 (03.3)	07 (05.8)
101 - 120	59 (49.2)	43 (35.8)	50 (41.6)	50 (41.6)	44 (36.7)	47 (39.2)
121 - 140	25 (20.8)	47 (39.2)	41 (34.2)	34 (28.3)	51 (42.5)	42 (35.0)
141 - 160	04 (03.3)	21 (17.5)	16 (13.3)	03 (02.5)	19 (15.8)	16 (13.3)
161 - 180	01 (0.8)	03 (02.5)	03 (02.5)	-	02 (01.7)	03 (02.5)
181 - 200	01 (0.8)	01 (0.8)	-	-	-	01 (0.8)

Table 3 displays the mean Systolic blood pressure recordings of both arms by the three devices. Significant differences exist in the overall mean SBP recordings between the three devices within the right and left upper limb, with the exception of the mean left upper limb SBP recordings for Arm and Wrist devices, which show no significant difference (p=0.308). It is noteworthy that mean SBP recordings for the three individual devices are consistent across the right and left sided upper limbs.

Table 3: Mean Systolic Blood Pressure recordings of both upper limbs (n=120).

BP Groups (mmHg)	RIGHT UPPER LIMB (mmHg)			LEFT UPPER LIMB (mmHg)		
	Mercury Mean ± SD	Arm Mean ± SD	Wrist Mean ± SD	Mercury Mean ± SD	Arm Mean ± SD	Wrist Mean ± SD
Males (n=74)	119.46 ± 17.14	132.08 ± 17.18	126.27 ± 19.27	118.68 ± 14.33	130.65 ± 13.69	127.46 ± 19.52
Females (n=46)	111.13 ± 14.95	119.96 ± 16.65	113.78 ± 15.47	110.13 ± 15.23	116.30 ± 16.21	113.87 ± 16.11
Overall (n=120)	116.27 ± 16.77[a]	127.43 ± 17.92[b]	121.48 ± 18.85[c]	115.40 ± 15.20[d]	125.15 ± 16.23[e]	122.25 ± 19.39[f]

P<0.001 for right arm mean overall SBP (Mercury a & Arm b); p=0.002 for right arm mean overall SBP (Mercury a and Wrist c); p=0.022 for right arm mean overall SBP (Arm b and Wrist c); p<0.001 for left arm mean overall SBP (Mercury d and Arm e); P<0.001 for left arm mean overall SBP (Mercury d and Wrist f); p=0.309 for left arm mean overall SBP (Arm e and Wrist f).

Table 4 shows the frequency distribution of Diastolic Blood Pressure (DBP) recordings for the upper limbs, as measured by three devices. The DBP recordings showed variations for same and opposite sides; the wrist device showed the most consistency for opposite limb recordings.

The Mercury device recorded 12(10.0%) cases of Diastolic hypertension (DBP > 90 mmHg) for the right upper arm, validated 10(8.3%) of them in left upper arm recordings, and did not detect any new cases. The Arm device recorded 30(25.0%) cases of Diastolic Hypertension for the right upper arm, validated 18(15.0%) of them in left upper arm, and recorded additional 06(05.0%) cases from the left upper arm, giving a total of 36(30.0%) cases of Diastolic hypertension recorded by it. The Wrist device recorded 28(23.3%) cases of Diastolic hypertension for the right limb, validated 22(18.3%) of them in left limb, and recorded additional 05(4.2%) cases from the left limb, giving a total of 33(27.5%) cases of Diastolic hypertension recorded by it.

Table 4: Distribution of Diastolic Blood Pressure recordings of both upper limbs (n=120).

BP Groups (mmHg)	RIGHT UPPER LIMB (mmHg)			LEFT UPPER LIMB (mmHg)		
	Mercury n (%)	Arm n (%)	Wrist n (%)	Mercury n (%)	Arm n (%)	Wrist n (%)
< 50	-	01 (0.8)	01 (0.8)	-	-	-
50 - 70	46 (38.3)	27 (22.5)	25 (20.8)	38 (31.7)	25 (20.8)	25 (20.8)
71 - 90	62 (51.7)	62 (51.7)	66 (55.0)	72 (60.0)	72 (60.0)	68 (56.7)
91 - 110	12 (10.0)	27 (22.5)	23 (19.2)	09 (7.5)	22 (18.3)	21 (17.5)
111 - 130	-	03 (02.5)	02 (01.7)	01 (0.8)	01 (0.8)	03 (02.5)
>130	-	-	03 (02.5)	-	-	03 (02.5)

Table 5 shows the values for the mean DBP recordings of both upper limbs given by the three devices. Similar to the SBP recordings, the mean DBP recordings show significant variations between the three devices, particularly for the same sided upper limb. However, the recordings for the same device across the limbs are more consistent with each other, and the right limb recordings show more variations than the left limb.

Table 5: Mean Diastolic Blood Pressure recordings of both upper limbs (n=120).

BP Groups (mmHg)	RIGHT UPPER LIMB (mmHg)			LEFT UPPER LIMB (mmHg)		
	Mercury Mean ± SD	Arm Mean ± SD	Wrist Mean ± SD	Mercury Mean ± SD	Arm Mean ± SD	Wrist Mean ± SD
Males (n=74)	81.12 ± 11.64	83.55 ± 13.36	87.50 ± 15.95	81.24 ± 11.84	83.89 ± 10.99	88.95 ± 15.15
Females (n=46)	70.67 ± 09.71	75.48 ± 10.72	75.37 ± 13.98	72.91 ± 08.86	73.72 ± 09.84	73.93 ± 14.93
Overall (n=120)	77.12 ± 12.03[a]	80.46 ± 12.98[b]	82.85 ± 16.28[c]	78.05 ± 11.50[d]	79.99 ± 11.64[e]	83.19 ± 16.70[f]

P=0.002 for right arm mean overall DBP (Mercury a and Arm b); P<0.001 for right arm mean overall DBP (Mercury a and Wrist c); P=0.321 for right arm mean overall DBP (Arm b and Wrist c); P=0.089 for left arm mean overall DBP (Mercury d and Arm e); P=0.002 for left arm mean overall DBP (Mercury d and Wrist f); P=0.061 for left arm mean overall DBP (Arm e and Wrist f); P=0.043 for the right and left (Mercury a and d) arm mean DBP; Other differences for right and left arm are not significant (p>0.05).

Table 6 provides the correlation data for the SBP and DBP recorded by the three devices in both upper limbs. Although all correlations are statistically significant, a greater correlation is seen between the Mercury and Arm devices for both right and left upper limb recordings. This is particularly evident in the Right Arm DBP, Left Arm SBP, and the Left Arm DBP recordings. In general, weaker correlations are seen between the Mercury and Wrist devices, as well as between the Arm and Wrist devices for all recordings.

Table 6: Correlation between the three devices for right and left upper limb recordings (n=120).

S. #	X-Axis Variable	Y-Axis Variable	r value	r^2	p value of r
1.	Right arm SPB Mercury	Right arm SBP Arm device	0.574	0.329	<0.001
2.	Right arm SPB Mercury	Right arm SPB Wrist device	0.316	0.10	<0.001
3.	Right arm SPB Arm device	Right arm SPB Wrist device	0.473	0.224	<0.001
4.	Right arm DBP Mercury	Right arm DBP Arm device	0.650	0.423	<0.001
5.	Right arm DPB Mercury	Right arm DPB Wrist device	0.439	0.193	<0.001
6.	Right arm DPB Arm device	Right arm DPB Wrist device	0.411	0.169	<0.001
7.	Left arm SPB Mercury	Left arm SBP Arm device	0.665	0.442	<0.001
8.	Left arm SPB Mercury	Left arm SPB Wrist device	0.429	0.184	<0.001
9.	Left arm SPB Arm device	Left arm SPB Wrist device	0.421	0.178	<0.001
10.	Left arm DBP Mercury	Left arm DBP Arm device	0.651	0.423	<0.001
11.	Left arm DPB Mercury	Left arm DPB Wrist device	0.414	0.171	<0.001
12.	Left arm DPB Arm device	Left arm DPB Wrist device	0.494	0.244	<0.001

DISCUSSION

Most of the study subjects were young, healthy males and females below the age of 40 years (72.5%); the overall mean age was 34.39 ± 10.49 years, thereby providing for anticipated normal consistency in blood pressure readings. Despite this, both frequency distribution and mean values of both SBP and DBP showed significant variations by devices in same-sided limbs and in both-sided limb measurements (Tables 2-5).

For the right upper limb, systolic values obtained by the Arm device showed 67.7% concordance with the Mercury device (ROC, SPSS), whereas the Wrist device showed 61.7% concordance. Diastolic values showed the Arm device to have 49.0% concordance and the Wrist device to have 55.1% concordance with the Mercury device.

For the left upper limb, systolic values obtained by the Arm device showed 66.4% concordance, while the Wrist device showed 60.6% concordance. For Diastolic values, the Arm device showed 50.0% concordance, while the Wrist device showed 53.2% concordance.

Systolic BP readings showed greater variation than Diastolic readings. Similar conclusion was reached by Nelson D (2008)[11] in a study on 94 subjects (aged 19+ years) where he noted that "Systolic readings by automated wrist manometers were the most unreliable". The Mercury readings differed significantly from the automated readings, tending to have lower values and lesser variation for SBP and DBP. This has also been reported by Nelson D (2008.)[11] The Arm and Wrist devices tended to maintain consistency of recordings with each other rather than the Mercury device. Mercury readings were more consistent across left and right sides than the automated readings. No other studies have compared left and right sided measurements; hence these are the original findings of this study.

In terms of detecting cases of Systolic or Diastolic hypertension, BP recordings showed great variability by the three devices. Consistently, the automated devices labeled many more cases as hypertensive, compared to the Mercury device (Tables 2 & 4). This has implications for clinical practice, and if the Mercury device is not to be taken as the gold standard, many spurious cases of hypertension would require needless medication. Moreover, interpretation of right and left sided diagnosis of hypertension is also insufficiently consistent with all three devices, as wide variations in the frequencies of diagnosed cases were obtained based on the side recorded.

A further clinical consideration is which device and which limb to use for BP recording in clinical settings. Based on the correlations obtained (Table 6), the choice of the Mercury device is obvious, followed by the Arm device. This may be because both devices are measuring at the same arm level, whereas the Wrist device is recording values more distally. In a study on normal subjects from Brazil (2009),[13] the Wrist device showed 80% sensitivity and 90% specificity when compared to the Mercury device; however this concordance was for SBP and was lower for DBP. Moreover, the sample of subjects did not include people with hypertension, so the validity in patients and clinical settings could not be ascertained.

A recent study from West Bengal (Mar 2016)[14] identified the aneroid device as more accurate than the digital devices when compared to the Mercury device. The authors further recommend the use of aneroid devices for diagnosis of hypertension in preference to the digital devices.

The choice of the Left upper limb appears justified, as there were lesser variations and more consistent recordings from the left upper limb compared to the right.

CONCLUSIONS

The Mercury device provided more accurate and consistent BP readings than the Automated ones. Moreover, upper arm readings showed greater consistency compared to the Wrist readings.

RECOMMENDATIONS

The left arm should be the preferred location for blood pressure measurements in clinical practice. Further in depth studies on larger sample sizes are required to validate findings of current study.

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