Evaluation of the Accuracy of the Omron Hem - 907 Blood Pressure Device

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SUMMARY

A study was undertaken to assess the accuracy of the Omron HEM-907 blood pressure measuring device for use in community studies. A modified version of the British Hypertension Society (BHS) and American Association for the Advancement Medical Instrumentation (AAMI) protocol for measuring the accuracy of a blood pressure measuring device was used. A total of 104 subjects were recruited from two clinics. Observer-observer agreement for readings within the 5 mmHg was good; 80.8% and 84.6% of systolic blood pressure (SBP) and diastolic blood pressure (DBP) agreement respectively. Of the two, the better observer-device agreement readings within the 5 mmHg were 66.4% and 50.0% for SBP and DBP respectively, giving an overall grade B. The mean differences and standard deviation of the differences were within ≤5 mmHg with a standard deviation (SD) of ≤8 mmHg. The Omron HEM-907 satisfied both the AAMI and BHS protocols for accuracy for a non-invasive blood pressure monitoring device using single observer readings.

KEY WORDS:
Blood pressure determination, Validation studies

INTRODUCTION

Various blood pressure measuring devices are available in the market. The Omron HEM-907 blood pressure measuring device has been tested previously for accuracy using various protocols[1,2]. In order to assess its accuracy for use in local community studies as a screening tool for hypertension, a validation study was undertaken.

The study aimed to determine the accuracy of the Omron HEM-907 blood pressure measuring device under local conditions, specifically to measure the limits of agreement between observers and the limits of agreement between the test device and the standard device.

MATERIALS AND METHODS

Background

The Omron HEM-907 device determines blood pressure by oscillometric measurement and displays systolic blood pressure (SBP), diastolic blood pressure (DBP) and pulse rate using an LCD digital monitor[2]. It is small, portable, electric and easy to carry during field surveys.

For assessing the accuracy of a blood pressure measuring device, various validation protocols are available, the British Hypertension Society (BHS) protocol, the European International protocol, and the American Association for the Advancement Medical Instrumentation (AAMI) protocol[3,4,5]. All protocols use the mercury sphygmomanometer as the standard device. Our study was based on both the AAMI and BHS validation protocols with some modifications.

Study Design

The AAMI protocol requires a heterogeneous sample of not less than 85 subjects. At least 10% of the subjects are required to have a systolic blood pressure of >160 mmHg and <100 mmHg respectively, as well as 10% >100 mmHg and <60 mmHg diastolic blood pressure respectively based on the reference device. In addition, 10% of the subjects are also required to have a mid-arm circumference of >35 cm and <25 cm respectively.

The study was conducted over a period of three weeks. Subjects were determined for eligibility based on a set of predetermined inclusion and exclusion criteria. We included subjects aged 18 and older, to match those in possible intended community studies. Patients who had a history of mastectomy, lymphadenectomy, a susceptibility to easy bruising, peripheral nerve damage to the upper extremities, arterio-venous fistula, shunt or irregular cardiac arrhythmias were excluded. In order to ensure that a sample size of not less than 85 was achieved, we included all eligible subjects. As such, a total of 104 subjects were recruited during the study period.

Subjects were interviewed by trained interviewers using a structured questionnaire. They were asked if they were hypertensive and if medication had been taken prior to that particular clinic visit. This was followed by blood pressure and anthropometric measurements.

Study Subjects

Eligible subjects for the study were recruited from the Shah Alam Community Polyclinic and the Hypertension clinic at the Kuala Lumpur Hospital. Verbal consent for participation was obtained.

Blood Pressure Measurement

A specially separated room within the clinics was organized to conduct the study. This ensured minimal interference within the room while the tests were being carried out. However, since the area outside the room where the subjects waited for their turns was the common waiting area for the outpatient services, it was noisy and busy. Two trained public health nurses were recruited as observers for the study. A third

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trained person measured the subjects' blood pressure using the test device (Omron HEM-907). Blood pressure was measured on the same arm of each subject using the test and standard devices sequentially. The two observers used a double-headed teaching stethoscope for measuring the blood pressure. The Korotkoff phase I and phase V sounds were taken to measure systolic and diastolic blood pressures respectively.

Prior to the study, the observers involved in the study were tested for a normal audiogram before being trained by the investigators using the BHS blood pressure measurement training materials[6].

Analyses
Data documented on the case report forms included the subject's socio-demographic and clinical characteristics, as well as the test device and standard device readings.

The limits of agreement between the two observers and between the test device and the standard device were measured using the Bland-Altman method[7]. The level of agreement between the two observers was also gauged by calculating to see if at least 95% of the differences between the observers were within ± 10 mmHg and at least 80% within ± 5 mmHg with a standard deviation (SD) of 8 mmHg each.

RESULTS

Subjects
The device gave successful (i.e., no error readings) blood pressure readings for all the 104 subjects. The subjects comprised a wide range of ages, height, weight, arm circumference and blood pressure (Table I). The mean age of the studied subjects was 41.8 ± 15.4 years. There were 50 male (48.1%) and 54 female (51.9%) subjects. Twelve point five percent and 20.8% of the subjects had an arm circumference of <25 cm and >35 cm respectively. The other anthropometrical and clinical characteristics are as shown in Table I. The subjects studied were in the following blood pressure ranges: 15.4% with SBP <100 mmHg, 10.8% with SBP >160 mmHg; 11.5% with DBP <60 mmHg and 10.7% with DBP >100 mmHg. These readings satisfied the conditions as stipulated in the AAMI Guidelines.

Observers' Agreement
The two blood pressure readings of each subject by trained nurses were compared for the observers' agreement; the limits of agreement are as shown in Figure 1a (SBP) and 1b (DBP). The mean differences between the two observers were -0.3 ± 4.5 mmHg for the SBP and -0.7 ± 4.0 mmHg for the DBP respectively. The proportions of readings within 5, 10 and 15 mmHg were calculated and as shown in Table II. Approximately 80.8% of SBP and 84.6% of DBP readings obtained by the two observers were within the 5 mmHg agreement. Similarly, 94.2% and 99.0% of SBP and DBP readings were within the 10 mmHg agreement and 98.1% and 99.0% of SBP and DBP readings were within the 15 mmHg agreement respectively.

Observers-Device Agreement
The observer 1-device agreements were -0.3 ± 7.9 mmHg for the SBP and -0.7 ± 7.7 mmHg for the DBP respectively (Table II). In reference to Table II, it was noted that 66.4% of systolic and 50.0% of diastolic readings obtained by the Omron HEM-907 automated blood pressure measuring device were within 5 mmHg of the observer 1 readings. The analysis also revealed that 81.7% and 79.8% of the SBP and DBP readings were within the 10 mmHg agreement. As for the observer-device agreement within 15 mmHg, it was 92.3% and 93.3% for the SBP and DBP respectively.

The observer 2-device agreements were -0.5 ± 36.5 mmHg for the SBP and -1.4 ± 8.4 mmHg for the DBP respectively (Table II). It was noted that 51.0% of systolic and 46.2% of the diastolic readings obtained by Omron HEM-907 automated blood pressure measuring device were within 5 mmHg of the observer 2 readings. The findings showed that 75.0% and 76.0% of the SBP and DBP readings were within the 10 mmHg agreement, while 86.5% and 93.2% of the SBP and DBP readings were within the 15 mmHg agreement respectively (See Appendix A for BHS grading criteria).

Between observer 1 and observer 2, the readings from observer 1 were found to be more consistent with the device readings. Therefore observer 1 was taken as the better observer. The limits of agreement between the better observer and the Omron HEM-907 automated blood pressure measuring device readings are as shown in Figures 2a (SBP) and 2b (DBP).

Test Device and the Better Observer
The average and difference scores for the SBP and DBP between the better observer and the device are as shown in Table III.

The Better Observer-Device Agreement by Blood Pressure Ranges
As shown in Table IV, the grades for DBP across the three ranges consistently falls within the grade B limits. For SBP at low pressure range, the differences fall within the grade A limits. However at medium and higher pressure levels, the differences fall within the grade C limits.

DISCUSSION AND CONCLUSION

Reliable and valid measurements are essential for the interpretation of epidemiological data on blood pressure, as well as for comparability of studies.

Our study showed that more than 80% of the differences in both SBP and DBP measurements between observers 1 and 2 fell within 5 mmHg, fulfilling the BHS protocol requirement. For the within 10 mmHg category, the difference in DBP met the 95% requirement (99.0%), however for the SBP, the difference fell marginally below (94.2%).

Based on the findings of the difference between each of the observers and the device, the readings of observer 1 were found to be more consistent with the device compared to observer 2. Using the BHS grading criteria, observer 1 gave readings within the grade B limits, while the readings from observer 2 fell within grade C. Therefore, observer 1 was chosen as the better observer for subsequent analyses in line with the BHS recommendation.

Table I: Characteristics of the Study Population

Characteristics	Values	
I. Demographic Characteristics		
Age (years):		
• Mean (SD)	41.8 (15.4)	
• Median (Min ,Max)	42.0 (18.0 – 79.0)	
	No (n)	%
Gender:		
• Male	50	48.1
• Female	54	51.9
Ethnicity:		
• Malay	70	67.3
• Chinese	6	5.8
• Indian	26	25.0
• Others	2	1.9
II. Clinical Characteristics	**Mean (SD)**	
Height (cm)	159.6 (138.6 - 180.1)	
Weight (kg)	68.2 (33.3 - 121.9)	
Mid-arm circumference (cm)	30.6 (18.8 - 47.0)	
Pulse rate (beats / min)	75.0 (41.0 - 130.0)	
Systolic blood pressure (mmHg)	133.6 (86.0 - 233.0)	
Diastolic blood pressure (mmHg)	81.4 (50.0 - 148.0)	

Table II: Grading, Mean and Mean of Differences for the Test Device and Observers

	Differences between standard and test device (mmHg) (%)				Mean ± SD (mmHg)	Mean ± SD of differences (mmHg)
	Grade	5	≤10	≤15		
Observer 1						
SBP	B	66.35	81.70	92.30	133.5 (31.4)	-0.3 (7.9) *
DBP	B	50.00	79.81	93.27	81.1 (17.5)	-0.7 (7.7) *
Observer 2						
SBP	C	50.96	75.00	86.54	133.7 (32.0)	-0.5 (36.5) *
DBP	C	46.15	75.96	93.23	81.7 (17.5)	-1.4 (8.4) *
Observer comparison						
SBP	A	80.77	94.23	98.08	133.6 (31.6)	-0.3 (4.5) #
DBP	A	84.62	99.04	99.04	81.4 (17.3)	-0.7 (4.0) #

* difference between test device and observer
\# difference between observer 1 and observer 2

Table III : Average and Differences Between Observer 1 and Omron HEM-907

Parameters	Systolic Blood Pressure		Diastolic Blood Pressure	
	Average : Device & Observer 1	Difference : Device - Observer 1	Average : Device & Observer 1	Difference : Device - Observer 1
Mean	133.3	0.3	80.7	-0.7
SD	30.4	8.0	0.8	7.7

Table IV: Grading for the Test Device at Low, Medium and High Pressure Levels for the Better Observer (Observer 1) according to the British Hypertension Society Criteria

		Differences between standard and test device (mmHg) (%)			
	Grade	5	≤10	≤15	n
Low pressure range (< 130 / 80 mm Hg)					
SBP	A	76.00	94.00	100	50
DBP	B	55.10	77.55	97.96	49
Medium pressure range (130-160 / 80 – 100 mm Hg)					
SBP	C	54.29	68.57	85.71	35
DBP	B	51.11	86.67	93.33	45
High pressure range (> 160 / 100 mm Hg)					
SBP	C	63.16	73.68	85.01	19
DBP	B	50.00	90.00	100	10

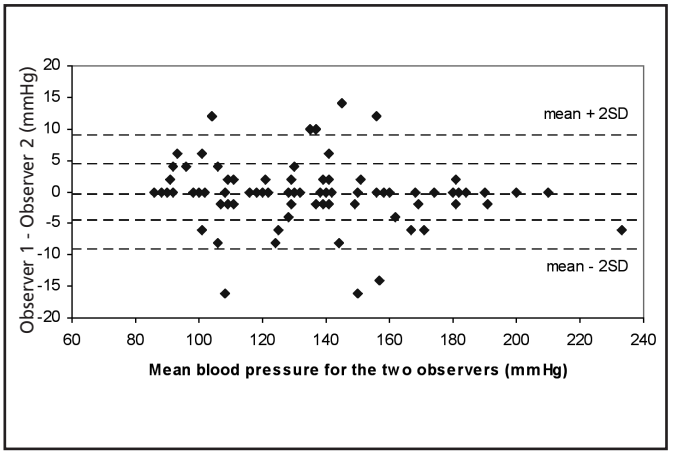

Fig. 1a: Plot of Systolic Blood Pressure Between Observers and the Average Blood Pressure for the Two Observers.

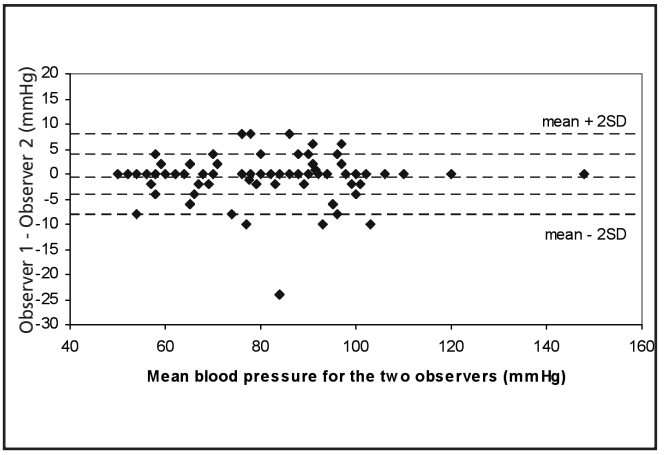

Fig. 1b: Plot of Diastolic Blood Pressure Between Observers and the Average Blood Pressure for the Two Observers.

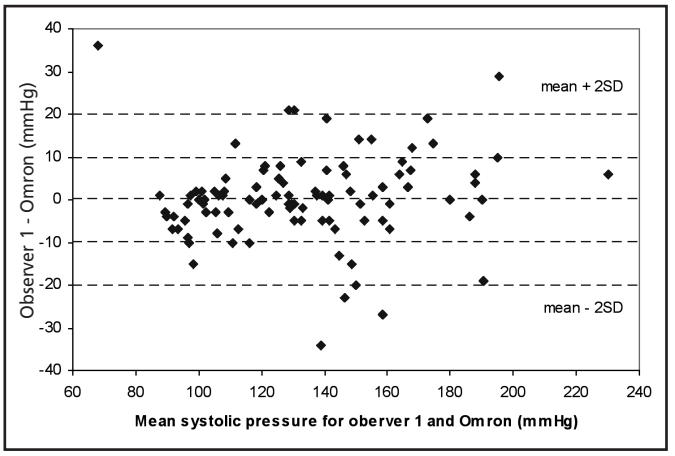

Fig. 2a: Plot of Systolic Blood Pressure Difference Between Observer 1 and the Test Device and Mean Systolic Pressure for Observer 1 and the Test Device.

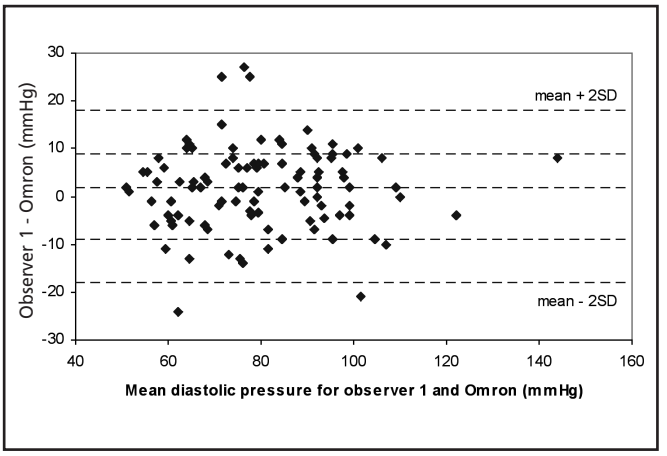

Fig. 2b: Plot of Diastolic Blood Pressure Difference Between Observer 1 and the Test Device and Mean Diastolic Pressure for Observer 1 and the Test Device.

For both SBP and DBP, the mean difference between the device and observer 1 readings were ≤5 mmHg with a SD of ≤8 mmHg, therefore fulfilling the AAMI recommendations.

The accuracy of all non-invasive oscillometric devices tends to decrease at extremes of blood pressure, however the degree of error varies[8,9]. Various studies have shown that the observer-device limits of agreement widened at higher SBPs[1,2]. Our study showed similar findings. For the DBP, the gradings were consistent (grade B) for the three blood pressure ranges. However, for the SBP there was wider variation in the gradings, with grade A at the low pressure range and grade C for both medium and high pressure ranges.

Based on a single observer and device comparison, the findings were found to be satisfactorily fulfilling both the AAMI and BHS protocols. However, the findings of the study must be interpreted with caution. The findings could be attributed to several factors. Blood pressure measurement using the mercury sphygmomanometer is highly subjective and based on the interpretation of the observer. Factors such as experience, skill and background noise affect the assessment of blood pressure. Although the observers were trained, their limited experience of exposure to a clinical setting prior to the study and the environmental conditions where the study was conducted must be considered. It is recommended that the study be repeated under stricter conditions including re-training of the observers. The results of this study should not be generalized to other types of devices.

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Appendix A: British Hypertension Society grading criteria

Grade	**Absolute difference between standard and test device (mmHg)**		
≤	**≤5**	**≤10**	**≤15**
Cumulative percentage of readings			
A	60	85	95
B	50	75	90
C	40	65	85
D		Worse than C	

Grades derived from percentages of readings within 5, 10 and 15 mmHg. To achieve a grade all three percentages must be equal to or greater than the tabulated values