A clinical evaluation report of the performance of the OMRON digital blood pressure monitor, HBP-1320, on accuracy as compared to the value measured by auscultation with a mercury sphygmomanometer

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Abstract

The present study aimed to validate the accuracy of blood pressure (BP) measurements by the OMRON HBP-1320 according to the American National Standards Institute, Inc./ Association for the Advancement of Medical Instrumentation/ International Organization for Standardization 81060-2:2013 (ANSI/AAMI/ISO) guideline. This study was performed in 88 subjects. The results showed that readings of the OMRON HBP-1320 fulfilled both criterion 1 and criterion 2 of the guideline. Therefore, the OMRON HBP-1320 fulfilled the requirement of the ANSI/AAMI/ISO guideline.

1. Purpose

The present study aimed to validate the accuracy of an upper arm BP monitor, the OMRON HBP-1320 according to ANSI/AAMI/ISO guideline.

2. Methods

Device

The standard type of the OMRON HBP-1320 (Omron Healthcare Co, Ltd. Kyoto, Japan) device was provided by the manufacturer. The OMRON HBP-1320 is designed to measure blood pressure by healthcare professionals in clinic or hospital. It is able to select the oscillometric mode or the auscultation mode to measure BP at the upper arm, and the oscillometric mode was used in this study. Five sizes of cuffs of extra-small (SS), small (S), medium (M), large (L) and extra-large (XL) were used in subjects with an arm

circumference of 12 to 18cm, 17 to 22cm, 22 to 32cm, 32 to 42cm and 42 to 50cm, respectively.

Subject selection

This study was approved by the institutional review board of the Biwako Chuo Hospital (Shiga, Japan). The study was performed in the measurement room in the Omron Healthcare Co, Ltd. (Kyoto, Japan), and written informed consent was obtained from each subject. In cases of child subject, it was obtained from both of the child subject and his/her parent. This device measures BP in adults and children with the same algorithm. Therefore, this study validated to measure BP with children and adults. Based on the ANSI/AAMI/ISO guideline, this study consisted of more than 85 subjects, including more than 35 children (aged 3 to 12 years)

Procedure

This study was performed according to "same arm sequential method" of ANSI/AAMI/ISO guideline using the BP mode of the devise in a single arm. The subjects were seated in a quiet room with comfortable room temperature and humidity, and they were instructed to avoid talking during the procedure. The BP measurements started after taking 5 minutes rest. The subjects sat in a chair with their legs uncrossed and their feet flat on the floor. The chair had a supportive back as well as elbow and forearm rests.

Trained two observers auscultated using a calibrated standard mercury sphygmomanometer. Diastolic BP (DBP) used fourth phase (K4) and fifth phase (K5) of Korotkoff sounds. An interval of at least 1 minute was taken between the measurements.

The situations below were excluded from this study.

- Subjects who has arrhythmia.
- When body motion is observed during measurement.
- Korotkoff sound of poor quality.
- Subject's arm circumference is outside the range of designated cuff size.
- Subject's systolic BP (SBP) readings differ by more than 12 mmHg, and those of DBP differ by more than 8 mmHg between the 2 observers.
- Subject offered to stop on the way of testing.

3. Analysis

Data were analyzed according to the requirements and criteria as described in ANSI/AAMI/ISO guideline.

All data for the analysis were presented as the mean ± standard deviation (SD).

4. Results

4.1 Subjects distribution

The subjects' requirements of ANSI/AAMI/ISO guideline were fulfilled in this study.

Table 1. Screening and recruitment details

Total Screened	111
Total Excluded	23
Arrhythmias	1
Poor quality sounds	2
Cuff size mismatch	0
Body movements	10
Blood pressure variation	10
Observers' determination with difference	0
Others	0
Total Recruited	88

4.1.1 Number of subjects

We screened 111 subjects for this study. After excluding 23, 88 subjects were evaluated (Table 1). K5 was used in all subjects (Table 2).

Number of subjects that were evaluated 3 data was 88 (100%) (Table 3).

4.1.2 Gender

Forty-four men (50 %) and 44 women (50 %) were included in this study (Table 2).

4.1.3 Age

The mean age of subjects was 31.3 ± 22.6 years old (range, 4– 70 years old) (Table 2).

4.1.4 Arm circumference range

The mean arm circumference was 26.8 ± 8.7 cm (range, 14.1 – 48.2 cm). The number of subjects was 11 (12%), 22 (25%), 31 (35%), 14 (15%) and 10(11%) in extra-small (SS), small (S), medium (M), large (L) and extra-large (XL), respectively (Table 4).

Table 2. Subject details

Gender	Male : Female	At least 30%	44 : 44(50% : 50%)
Age (years)	Range (Low : High)		4 : 70
	Mean (SD)		31.3 (22.6)

Arm Circumference (cm)		
Range (Low : High)	14.1 : 48.2	
Mean (SD)	26.8 (8.7)	
Korotkoff sounds		
K5	88	
K4	0	

Table 3. Data validation

Three valid determination pairs	88	100%
Two valid determination pairs	0	0%
Total	88	

*No more than 10% of the subjects shall have fewer than three valid determination pairs.

Table 4. Subject requirements

	Requirements	Children	Adults	Total
Number	at least 85 subjects	38	50	88
Gender male : female (%)	at least 30% in each gender	19 : 19	25 : 25	44 : 44 (50% : 50%)
Cuff size (adapted range)				
SS size (12-18cm)	at least 9 subjects	8	3	11
S size (17-22cm)	at least 9 subjects	21	1	22
M size (22-32cm)	at least 9 subjects	7	24	31
L size (32-42cm)	at least 9 subjects		14	14
XL size (42-50cm)	at least 9 subjects		14	10

*Children are between 3 years to 12 years.

4.1.5 BP range

When measured by the mercury sphygmomanometer, the mean values of the 264 data were 117 ± 28.8 mmHg (range, 77 – 213 mmHg) for SBP and 73 ± 17.9 mmHg (range, 47 – 117 mmHg) for DBP. The percentages for high SBP (≥ 160 mmHg), medium SBP (≥ 140 mmHg), and Low SBP (≤ 100 mmHg) were 7% (criteria; ≥ 5%), 22% (criteria; ≥ 20%), and 46% (criteria; ≥ 5%), respectively. The percentages for high DBP (≥ 100 mmHg), medium DBP (≥ 85 mmHg), and Low DBP (≤ 60 mmHg) were 11% (criteria; ≥ 5%), 28% (criteria; ≥ 20%), and 33% (criteria; ≥ 5%), respectively, all fulfilling the criteria (Table 5).

Table 5. Blood pressure distribution

SBP (mmHg)	Requirement	Readings	%	DBP (mmHg)	Requirement	Readings	%
≧ 160	At least 5%	19	7%	≧ 100	At least 5%	28	11%
≧ 140	At least 20%	58	22%	≧ 85	At least 20%	73	28%
≦ 100	At least 5%	121	46%	≦ 60	At least 5%	86	33%
Range (Low : High)		77 : 213		Range (Low : High)		47 : 117	
Mean (SD)		117 (28.8)		Mean (SD)		73 (17.9)	

4.2 Reference BP

The differences between the two observers were 0.2 ± 1.4 mmHg (range, -4 – 4 mmHg) and 0.5 ± 1.8 mmHg (range, -4 – 4 mmHg) for SBP and DBP, respectively (Table 6).

Table 6. Reference determination

	SBP (mmHg)	DBP (mmHg)
Observer 2 - Observer 1		
Range (Low : High)	-4 : 4	-4 : 4
Mean (SD)	0.2(1.4)	0.5 (1.8)

4.3 Measurement accuracy

The OMRON HBP-1320 fulfilled the validation criteria, criterion 1 and 2 of the ANSI/AAMI/ISO requirements (Table 7).

4.3.1 Criterion 1

The mean differences between the two observers and the OMRON HBP-1320 were 1.6 ± 5.8 mmHg (range, -16.3 – 20.5 mmHg) for SBP and -0.4 ± 5.3 mmHg (range, -16.3 – 13.5 mmHg) for DBP. These data fulfilled the ANSI/AAMI/ISO requirements to be ≤ 5 ± ≤8 mmHg.

4.3.2 Criterion 2

The mean differences between the observers and the OMRON HBP-1320 were 1.6 ± 4.3 mmHg (range, -11.5 – 14.4 mmHg) for SBP and -0.4 ± 4.6 mmHg (range, -12.0 – 10.4 mmHg) for DBP. Thereby, the SD for SBP is calculated to be less than 6.76 mmHg and for DBP 6.93mmHg by criterion 2. These results fulfilled requirement of the ANSI/AAMI/ISO guideline.

Table 7. Data analysis

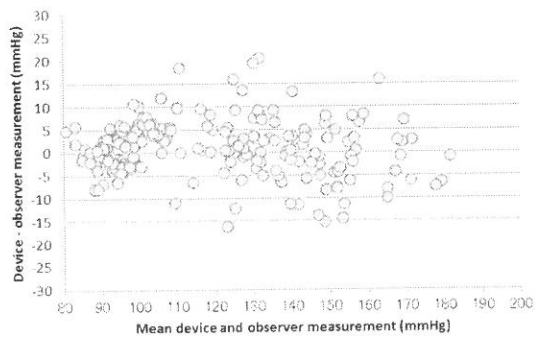
	Adult (N=50)		Children (N=38)	
	SBP (mmHg)	DBP (mmHg)	SBP (mmHg)	DBP (mmHg)
a) Criterion 1				
Range (Low : High)	-16.3 : 20.5	-14.0 : 13.5	-8.0 : 18.5	-16.3 : 10.5
Mean (SD)	0.8(6.5)	0.8(5.2)	2.6(4.4)	-2.0(5.2)
b) Criterion 2				
Range (Low : High)	-11.5 : 14.2	-12.0 : 10.4	-3.2 : 14.4	-11.1 : 8.0
Mean (SD)	0.8(4.7)	0.8(4.5)	2.6(3.6)	-2.0(4.4)

	All (N=88)	
	SBP (mmHg)	DBP (mmHg)
a) Criterion 1		
Range (Low : High)	-16.3 : 20.5	-16.3 : 13.5
Mean (SD)	1.6 (5.8)	-0.4 (5.3)
b) Criterion 2		
Range (Low : High)	-11.5 : 14.4	-12 : 10.4
Mean (SD)	1.6 (4.3)	-0.4 (4.6)

5. Discussion

This study aimed to validate the accuracy of the BP monitor, the OMRON HBP-1320 according to ANSI/AAMI/ISO guideline. It is able to measure BP of both of adults and children with same algorithm. The results of the present study fulfilled both subject requirements and two criteria. The results show that the OMRON HBP-1320 readings are accurate enough compared with the reference BP value. Therefore, the present study confirmed that the OMRON HBP-1320 was sufficiently accurate.

a)



b)

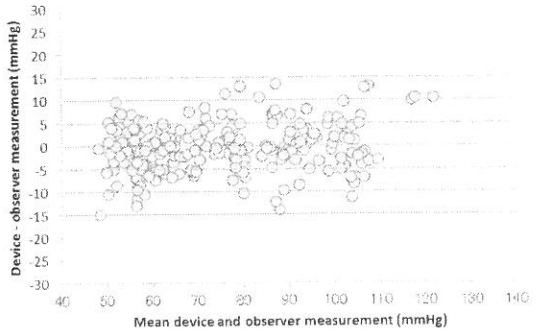


Figure. Bland–Altman plots for the differences between OMRON HBP-1320 readings and

the observer measurements for systolic blood pressure (a) and diastolic blood pressure (b).

6. Conclusion

The OMRON HBP-1320 fulfilled requirements of ANSI/AAMI/ISO guideline.

7. Reference

1. Association for the Advancement of Medical Instrumentation. American National Standard. ANSI/AAMI/ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type. 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633, USA: AAMI; 2013.

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