Validation of the Omron HEM 742 Blood Pressure Monitoring Device in Adolescents

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Summary

Background: Accurate blood pressure measurement is fundamental for scientific investigation or clinical decision-making. In this sense, it is important to verify the values provided by electronic devices.

Objective: To validate the Omron HEM 742 blood pressure monitoring device in adolescents according to criteria suggested by the British Hypertension Society.

Methods: A total of 150 adolescents aged between 10 and 16 years participated in the study. The automated Omron HEM 742 monitor was connected in Y to the mercury column auscultatory device, then three simultaneous measurements were taken, and the differences between the readings of the two devices were calculated. The intraclass correlation coefficient and Bland-Altman plot (agreement) were used to verify the relationship between both devices. Specificity and sensitivity of the device were determined by using the ROC curve.

Results: The comparison between the measurements showed an equal to or lower than 5mmHg difference in 67.3% of the systolic values, and 69.3% of the diastolic values; an equal to or lower than 10mmHg difference occurred in 87.3% and 90.6% of the systolic and diastolic values, respectively; an equal to or lower than 15mmHg difference was found in 96.6% of the systolic values and 97.3% of the diastolic values. These findings are consistent with a grade A according to the British Hypertension Society protocol. A marked consonance was observed between the values obtained by the automated monitor and this device was proven to be capable of identifying the presence or absence of high blood pressure.

Conclusion: The Omron HEM 742 monitor was proved valid for blood pressure measurement in adolescents according to the criteria suggested by the British Hypertension Society. (Arq Bras Cardiol 2009;92(1):9-14)

Key words: Blood pressure; blood pressure monitors/utilization; adolescent.

Introduction

The prevalence of high blood pressure (BP) has increased steeply among adult men and women from various countries[1], and is a cause of concern for health care professionals, since this condition is considered one of the major risk factors for the development of cardiovascular diseases[2,3]. However, national data show that children and adolescents may present significantly increased BP levels[4,5], which is also disturbing, considering that the risk conditions during childhood and adolescence tend to be expressed in adulthood[6].

Accurate and reliable BP measurements, whether in the clinical practice or for experimental purposes, are indispensable to help in the diagnosis or interpretation of findings. In this sense, the literature points out several forms of BP measurement[7]. Among these methods, the auscultatory technique is the one that has been most commonly used, whether by means of aneroid or mercury sphygmomanometers. However, the accuracy of this method may be affected by factors relative to the observer.

Thus, an alternative for BP measurement is the utilization of electronic devices. To date, a growing number of such devices has been found in the market, considering that they are affordable and easy to use. However, it is important to evaluate these devices according to validation rules required by international entities such as the British Hypertension Society (BHS)[8]. Data available in the literature regarding the validity of automated devices were mainly obtained from samples of adult individuals. Trials involving children and adolescents are fewer and thus suggest further investigation.

Therefore, the objective of the present study was to validate the Omron HEM 742 oscillometric automated BP monitoring device in children and adolescents according to the protocol proposed by the BHS, and to evaluate its efficacy in the classification of individuals within this age range in relation to resting BP values.

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Methods

Sample

Data were collected in an institution of the state education system. The school unit was selected by convenience for meeting all the requirements pre-established by the researchers

a) proximity to the Higher Education Institution;

b) facilities adequate for measurement taking;

c) authorization from the principal in charge of the school unit;

d) meeting the age range previously defined by the researchers).

All subjects who, according to information provided by their guardians, had arrhythmias or atrial fibrillation, had ingested caffeine 30 min prior to the assessment or were using chronotropic or inotropic agents were excluded from the sample analyzed. All sample subjects informed not to be tobacco smokers and they did not perform physical activities on the day their blood pressure was measured. Thus, the sample was comprised of 150 adolescents (77 males and 73 females).

All guardians signed a written informed consent agreeing with the participation of the subjects in the study, according to instructions contained in Resolution 196/96 of the National Health Council for studies in humans. The study was approved by the Ethics Committee of the Higher Education Institution.

Anthropometric measurements

The chronologic age of the adolescents was determined in the hundredth form using the date of birth and day of assessment. Body mass and height were measured to characterize the sample. For this purpose, a portable digital scale (graduation: 100g and maximum capacity: 150Kg) and a metal stadiometer fixed to the wall (accuracy: 0.1cm and maximum height: two meters) were used. All measurements were taken with the individuals barefoot and dressing light clothes, according to the protocol suggested by Gordon et al[9]. Based on this information, the body mass index (BMI) was calculated, and the values were expressed as kilograms per square meter (kg/m^2).

Blood pressure measurements

For BP measurement of the adolescents, two types of cuffs were used according to the arm circumference (6mm x 12mm [child size], and 9mm x 18mm for adolescents 14-16 years old and those younger but who had a greater body size]), following the recommendations of the American Heart Association[7]. All blood pressure measurements were taken in the right arm of each individual. The device to be tested was the Omron HEM 742, which consists of an electronic and digital device for arm BP measurement with automated air inflation and deflation. This device uses the oscillometric measurement method, with pressure range from 0-280mmHg.

The oscillometric device was connected in "Y" to the mercury sphygmomanometer. The inflation mechanism of the device was activated to perform three consecutive measurements with a two-minute interval between each. At the end of each measurement, an observer recorded systolic (SBP) and diastolic blood pressure (DBP) readings identified in the mercury column, blind to the readings identified in the automated device and recorded by another observer.

Before being assessed, the individuals remained sitting at rest for five minutes with their trunk leaning against a chair and the arm relaxed. The mercury column and the automated device were duly calibrated before the measurements were taken. The time spent for the full assessment of each sample subject (anthropometric and blood pressure assessment) was approximately 10 minutes.

A total of 450 simultaneous assessments were made with both BP measurement devices. Classification of the variation of BP values provided by the device was made considering the differences of the reading records between the mercury manometer and the automated device according to the procedures described by the BHS. The BHS protocol suggests that devices should achieve at least grade B for SBP and DBP to be deemed valid. The respective grades and their values are described in Box 1.

Statistical analysis

Initially, the Kolmogorov-Smirnov test was used to verify data distribution. Then, descriptive analysis was performed using mean and standard deviation (SD) values, since all the variables analyzed fit the Gaussian distribution model. Analysis of variance for repeated measures (with Greenhouse-Geisser correction when the sphericity assumption was violated) and the Student's t test for paired samples were used for comparisons between the mean BP values found by the two devices. In order to verify the relationship between the BP values provided by the automated device and those provided by the mercury device, the intraclass correlation coefficient (ICC) was used. Agreement measurements were tested using the Bland-Altman plot (numeric values), and the parameters provided by the ROC curve (sensitivity, specificity and area under the curve [AUC]) indicated the power of diagnosis of high blood pressure values of the oscillometric device. Significance values lower than 5% were considered statistically significant. The statistical software programs used were MedCalc and SPSS version 13.0.

Results

The overall sample characteristics grouped according to gender are shown in Table 1. No statistically significant differences were found between the variables analyzed.

Box 1 - Criteria used by the British Hypertension Society for differences between the device tested and the mercury device

Classification	Variation in comparison with the mercury device		
	≤ 5 mmHg	≤10 mmHg	≤15 mmHg
Grade A	60%	85%	95%
Grade B	50%	75%	90%
Grade C	40%	65%	85%
Grade D	Lower than Grade C		

Table 1 - Overall characteristic of the sample distributed according to gender

Variables	Male (*n*= 77)	Female (*n*= 73)	*t*	*p*
	Mean (SD)	Mean (SD)		
Age (years)	12.8 (1.4)	12.8 (1.2)	-0.024	0.981
Weight (kg)	48.4 (11.7)	49.9 (10.3)	-0.874	0.383
Height (m)	1.55 (0.8)	1.57 (0.8)	-1.477	0.142
BMI (kg.m^{-2})	19.6 (3.2)	19.9 (3.3)	-0.541	0.590
SBP (mmHg)*	109.8 (8.6)	110.8 (9.5)	-0.673	0.502
DBP (mmHg)*	64.5 (6.2)	66.3 (6.7)	-1.661	0.099

**- values obtained from the third blood pressure measurement with the mercury device; SD - standard deviation; SBP - systolic blood pressure; DBP - diastolic blood pressure; BMI - body mass index.*

The results presented in Table 2 show the differences between the measurements obtained by the automated and the mercury devices in percentage values. According to the results found, the device tested received grade A both for SBP and DBP, as per the criteria established by the BHS.

The comparisons and the ICC for SBP and DBP values are shown in Table 3. Significant differences for SBP values were found between the devices used and in all three measurements. However, for DBP, difference was found only in the first measurement. For both devices, no statistically significant differences were found for SBP and DBP values between the three measurements taken. As regards gender, the correlation values for SBP observed between the devices ranged from moderate to high (ICC = 0.74 and ICC = 0.88). For DBP, in turn, moderate values were observed (ICC = 0.50 and ICC = 0.79). In both circumstances, no differences were found between genders that could compromise the use of the device.

The Bland-Altman plot (Figure 1) was used as an agreement indicator for BP values provided by both devices. For SBP values, only 2.2% of the 450 measurements were observed to be out of the 95% confidence interval set for the mean of the differences observed. For DBP values, in turn, only 2.4% of the measurements were out of this confidence interval.

After classification of the individuals according to their hemodynamic behavior at rest (normal blood pressure / high BP), the efficacy of the automated device in diagnosing the presence of high BP was tested in the 450 measurements (Table 4).

Table 2 - Variation observed between blood pressure values obtained with the device tested (Omron HEM 742) and those obtained with the mercury device

Assessments		Variation in comparison with the mercury device		
		≤ 5 mmHg	≤10 mmHg	≤15 mmHg
SBP	n= 450	67.3%	87.3%	96.6%
DBP	n= 450	69.3%	90.6%	97.3%

SBP - systolic blood pressure; DBP - diastolic blood pressure.

Table 4 shows that in the three measurements high values of sensitivity (correct indication of the presence of the endpoint variable), of specificity (correct indication of the absence of the endpoint variable) and, consequently, of AUC (overall coefficient of the diagnosis, derived from the interaction between sensitivity and specificity) were observed.

Discussion

The purpose of this study was to validate the Omrom HEM 742 oscillometric automated device for BP measurement in children and adolescents according to the protocol proposed by the BHS, and to evaluate its efficacy in the classification of individuals of this age range in relation to BP values at rest, considering that this device has been validated only in adult individuals[10] and that the majority of the studies involving the validation of other automated devices for BP measurement was also performed with adult populations[11-14]. Additionally, with the increasing occurrence of high BP values at rest that has been observed among children and adolescents[4,5], studies with younger populations are also required so as to create strategies to facilitate BP measurement and its interpretation in this population, both in the clinical practice and in research.

Thereby, we should point out that automated inflation and deflation devices are light, portable and easy to use and interpret, thus reducing the occurrence of reading errors by the observer, which is relatively often seen with the auscultatory method. Therefore, the use of automated devices seems to be an interesting strategy for BP measurement, especially when related to a better home blood pressure control by hypertensive populations.

For a device to be validated for use in special populations, the BHS[8] suggests that it should be previously validated in adults, as is the case of the Omron HEM 742 device validated by Coleman et al[10], and also that different BP values ranging from 100mmHg to 240mmHg for SBP and from 60mmHg to 120mmHg for DBP should be evaluated. However, this was a study limitation, since our values ranged from 98mmHg to 135mmHg, and from 53mmHg to 86mmHg for SBP and DBP, respectively. Nonetheless, this variation verified in the present investigation is similar to that found in other studies of validation of devices for BP measurement in young populations[15,16], in which values higher than 140mmHg for SBP and 90mmHg for DBP were not found.

This is mainly due to the fact that prevalence rates of hypertension are lower in this age range[17,18] in comparison to the adult population[18-22]. Also, we should point out that the diagnosis of hypertension in the young population is based on percentiles considering gender, age and height, unlike the diagnosis in adults for which there are pre-established SBP and DBP values.

In the present study, in all three measurements taken in the sample, the SBP values provided by the device tested were significantly higher when compared with the values obtained by the mercury column device. These higher values obtained with the oscillometric device may have resulted from lower measurements obtained by the observer using the auscultatory method and/or they may have really been higher values obtained with the test device[23]. However, a definitive

Table 3 - Mean blood pressure levels grouped according to both devices used in the study

Measurements	Oscillometric device	Mercury device	t	p*	ICC (95%CI)	
	Mean (SD)	Mean (SD)			Male	Female
SBP I	112.6 (8.3)	110.3 (9.3)	5.213	0.001	0.81 (0.71 - 0.87)	0.80 (0.70 - 0.87)
SBP II	112.4 (8.6)	110.8 (8.9)	4.595	0.001	0.87 (0.81 - 0.92)	0.88 (0.82 - 0.92)
SBP III	112.6 (8.9)	110.3 (9.1)	4875	0.001	0.74 (0.62 - 0.82)	0.83 (0.75 - 0.89)
	p= 0.896	p= 0.579				
DBP I	65.7 (6.9)	64.7 (6.8)	2.529	0.012	0.62 (0.46 - 0.74)	0.79 (0.69 - 0.86)
DBP II	64.8 (6.4)	64.1 (6.2)	1.715	0.088	0.50 (0.31 - 0.65)	0.73 (0.60 - 0.82)
DBP III	66.1 (6.6)	65.4 (6.5)	1.397	0.164	0.63 (0.48 - 0.75)	0.67 (0.52 - 0.77)
	p= 0.202	p= 0.158				

*SD - standard deviation; ICC - intraclass correlation coefficient; 95%CI - 95% confidence interval; SBP - systolic blood pressure; DBP - diastolic blood pressure; * statistical significance between*

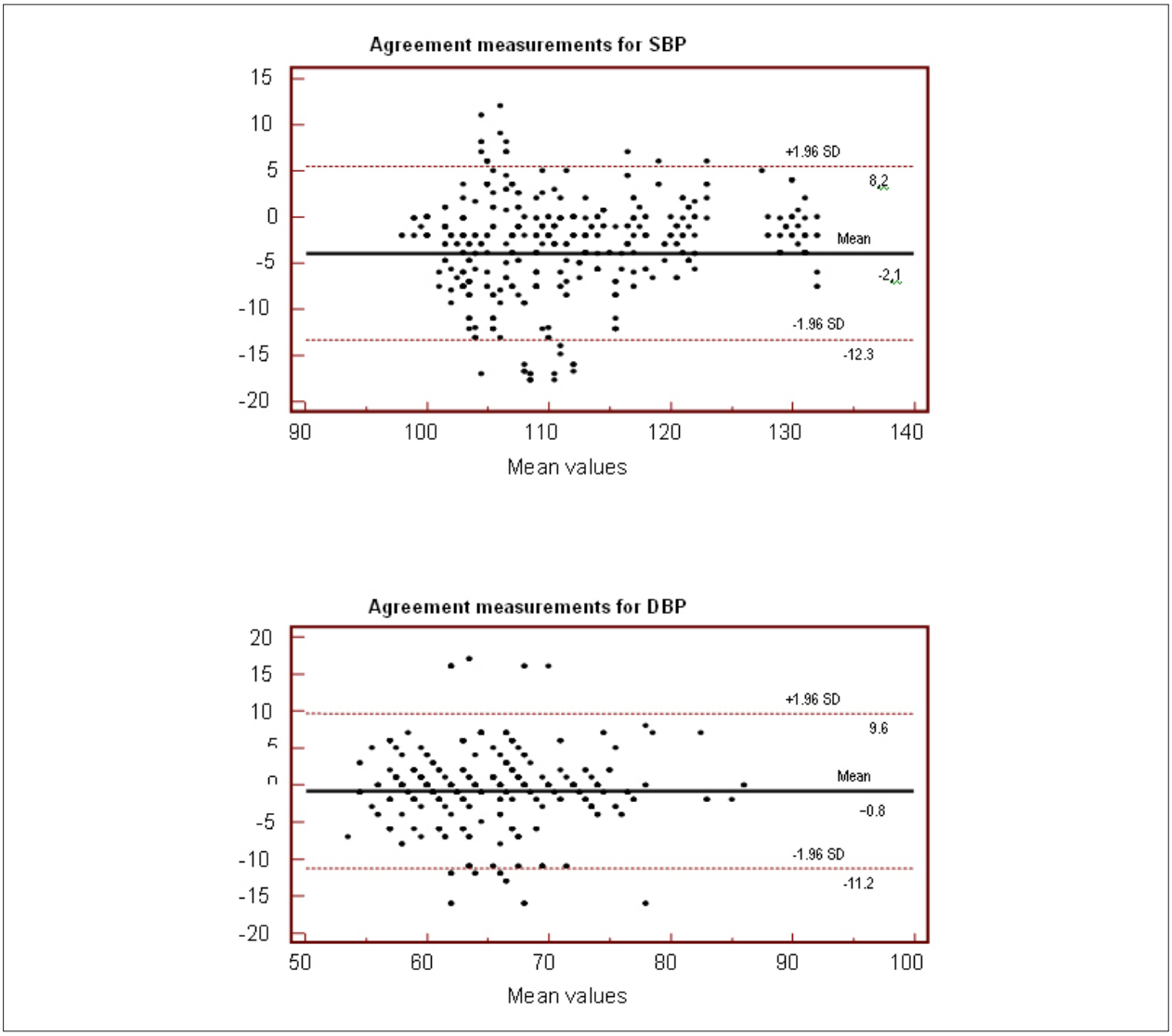

***Figure 1 -** Bland-Altman plot for the mean values of the difference between the devices regarding systolic blood pressure values (upper) and diastolic blood pressure (lower). SD - standard deviation*

Table 4 - Sensitivity and specificity values for the detection of high blood pressure in the sample (n = 150)

	Oscillometric Device		
	SENS (95%CI)	SPE (95%CI)	AUC (95%CI)
Measurement I	100 (79.2-100)	100 (97.3-100)	100±0.001 (97.1-100)
Measurement II	100 (75.1-100)	98.5 (94.8-99.8)	99.3±0.016 (97.1-100)
Measurement III	100 (83-100)	100 (97.2-100)	100±0.001 (97.5-100)

SENS - sensitivity; SPE - specificity; 95%CI - 95% confidence interval; AUC - area under the curve

explanation for this behavior has not been fully defined in the literature. On the other hand, in relation to DBP, a significant difference was only found in the first measurement. Despite these differences, the SBP and DBP values provided by the Omron HEM 742 and by the mercury device were not significantly different between the three measurements when compared with each other, thus suggesting good data reproducibility in both devices.

The ICC was significant and showed moderate/high values in all measurements, both for SBP and DBP, thus indicating a good relationship between the values observed for both devices. That is, the higher the value obtained with a device, the higher the value found by the other device for the same individual. However, this statistical procedure is only a relationship measurement and does not indicate the agreement between these two devices and, consequently, does not detect possible extreme variations between them. This limitation is overcome by the use of the Bland-Altman plot which does indicate the agreement between numeric data. In the present study, low disagreement was observed between the BP values found by both devices. This fact was confirmed when we verified that the criteria proposed by the BHS[8] had been met and, also, that the highest grade had been achieved.

These positive indicators shown by the ICC and by the Bland-Altman plot are important information on the reliability of the use of the device tested. However, these are numeric values and, therefore, they are not able to indicate the efficacy of the device in the clinical practice, more specifically in the detection of high BP values. To this end, the use of the ROC curve is required. Thus, the parameters provided by the ROC curve showed that the Omron HEM 742 device was highly capable of detecting both the presence (sensitivity) and the absence (specificity) of high BP levels in the sample studied.

Conclusion

The Omrom HEM 742 device has good reliability for use in the assessment of adolescents, since it was validated according to international recommendations of the BHS[8], and achieved grade A for SBP and DBP analyses, in addition to having presented good sensitivity and specificity in the diagnosis of blood pressure levels in individuals within this age range.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

There were no external funding sources for this study.

Study Association

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