Supplement
THE SAYCARE STUDY

Obesity

Is the Measurement of Blood Pressure by Automatic Monitor in the South American Pediatric Population Accurate? SAYCARE Study

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Objective: This study aimed to test the validity of an automatic oscillometric device to measure the blood pressure (BP) in children ($n = 191$) and adolescents ($n = 127$) aged 3 to 18 years.

Methods: Systolic BP (SBP) and diastolic BP (DBP) levels were measured simultaneous by automatic device and mercury column with Y-connection. To verify the validity, Bland-Altman plots and limits of agreement of 95% (95% LOA), specificity and sensitivity of the device, and the grade of British Hypertension Society (BHS) criteria were used.

Results: The monitor measurements demonstrated lower measurement bias (mean difference [95% LOA]): 1.4 (−9.9 to 12.8) mmHg in children and 4.3 (−7.8 to 16.5) mmHg in adolescents for SBP. For DBP, it was 2.2 (−7.4 to 11.7) mmHg in children and 1.4 (−8.4 to 11.1) mmHg in adolescents. The sensitivity in children was 21.4 (95% CI = 16.3-26.6), and in adolescents, it was 20.0 (95% CI = 13.2-26.8); the specificity was 95.9 (95% CI = 93.4-98.4) in children and 100.0 (95% CI = 100.0-100.0) in adolescents. The monitor-tested ratings are Grade B for SBP in children and SBP and DBP in adolescents and Grade C for DBP in children.

Conclusions: The automatic monitor presented high values of specificity and lower values of sensitivity to the diagnosis of HBP; however, it can be considered accurate (lower measurement bias) and valid for epidemiological and clinical practice in accordance with BHS criteria.

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Introduction

In recent decades, mainly because of great industrial and technological advances, drastic behavioral changes have been observed, generating a high prevalence of the excessive intake of foods rich in salt and saturated fats. Together with physical inactivity, these are factors that are primary in explaining the epidemic of chronic noncommunicable diseases found in both developed and developing countries (1).

Among the several chronic noncommunicable diseases, arterial hypertension has been drawing the attention of the main public health organizations because it has a high prevalence in the world and causes enormous public expense in its treatment (2). In addition, arterial hypertension contributes substantially to the incidence of cardiovascular diseases and premature mortality (3).

Cardiovascular events occur more frequently during or after the fifth decade of life, but there has been some evidence from clinical and epidemiological studies to suggest that arterial hypertension and the pathophysiological precursors of cardiovascular diseases originate in childhood (4). In fact, some studies have shown that the occurrence of high blood pressure (HBP) levels observed during childhood is strongly associated with the presence of arterial hypertension in adulthood (5).

Given these factors, early and accurate identification of HBP levels is necessary for the development of preventive strategies (6). In the literature, there have been several methods for assessing BP; among them, the auscultatory method, either by aneroid sphygmomanometer or by mercury column, is the most commonly used. An alternative for the measurement of BP is the use of electronic devices. There is currently an increasing number of such devices on the market considering that, besides having affordable prices, they are easy to manipulate and eliminate the bias of an evaluator.

Verification and recognition of the quality of the equipment used are paramount for its legitimacy and reliability, so it is important that these devices are evaluated according to the validation standards required by international organizations such as the American Heart Association (AHA) (7) and British Hypertension Society (BHS) (8).

Thus, in view of the increasing frequency of HBP in childhood and adolescents and the negative repercussions that it can cause in the long term, it is important to develop studies that evaluate BP levels in this population because experiments using children and adolescents are still few, as most validations have been conducted with adult samples.

Thus, the purpose of this study is to validate the automatic oscillometric method of assessing BP by means of the Omron HEM-7200 (Omron Healthcare, Inc., Kyoto, Japan) device in children and adolescents of South America in accordance with international guidelines.

Methods

Study design

A cross-sectional, observational, multicenter feasibility study was undertaken by using data collected from the South American Youth/Child Cardiovascular and Environmental (SAYCARE) study. A detailed approach to the methodology of sampling, data collection, and quality control has been described in the first article of this supplement.

In this manuscript, children and adolescents (3-18 years old) were included from the following four cities that composed the SAYCARE study: São Paulo and Teresina (Brazil), Lima (Peru), and Medellín (Colombia). The exclusion criteria for this study consisted of pregnancy; an arm circumference that is inadequate to the size of the cuffs; an inability to respond to the questionnaire; and the absence of consent from parents, guardians, and/or the individual himself. The sample size was calculated based on experience in multicentric projects performed with children and adolescents in a previous study (9). The sample calculation was performed to verify the reliability and agreement between the two measurement methods (mercury column and automatic monitor) in the study population. For this calculation, the parameters used were α of 0.05 (bicaudal error type I), β or power (type II error) of 0.10, correlation coefficient and Cronbach's alpha (α) of 0.88, and concordance ratio of 95%.

BP measurement

Two evaluators following the recommendations of the AHA (10) performed all the BP measurements after a general training workshop as described in the first paper of this supplement (9). The inter-observer coefficients of variation were below 5% for both BP levels and both measurement methods (automatic monitor and mercury column). Because correct measurement requires appropriate cuff size to avoid the overestimating or underestimating of the true values of the BP (11), in our sample, we used three different cuffs according to the following anthropometric measurements of the arm: 12 to 21 cm (small), 22 to 32 cm (medium), and 33 to 42 cm (large).

The equipment to be validated was the Omron HEM-7200, an electronic and digital device for BP measurement in the arm, with automatic inflation and deflation, oscillometric measurement method, and a pressure variation of 0 to 299 mmHg. The Omron HEM-7200 monitor was Y connected with the mercury column. Before starting the measurement, both the mercury column and the automatic apparatus were properly calibrated, and the inflation mechanism was switched on.

Calibration was done before each collection with all automatic devices. The mercury column, automatic apparatus, arm simulator (can or glass bottle), and a triple connection were used.

Initially, unlocking the mercury column and turning down the black lock, the triple connection was connected to tip A on the mercury column, tip B on the cuff, and tip C on the automatic device. For calibration, it was noted that the triple connection was correctly fitted. After this check, the cuff was placed in the arm simulator, observing if the tap was open for all the tips, and all materials were supported on a rigid and flat surface. Afterwards, the start button of the automatic equipment was pressed to inflate the cuff. An observer looked directly at the mercury column and spoke loudly at 10 to 10 mmHg, while another looked at the display on the automatic device to make sure the values were the same.

This procedure was repeated as often as needed to make sure the equipment showed the same values. The measurements were performed on the right arm of the participants because of coarctation of the aorta, and the arm was supported at the level of the heart; all were placed in a quiet room. The children and adolescents were

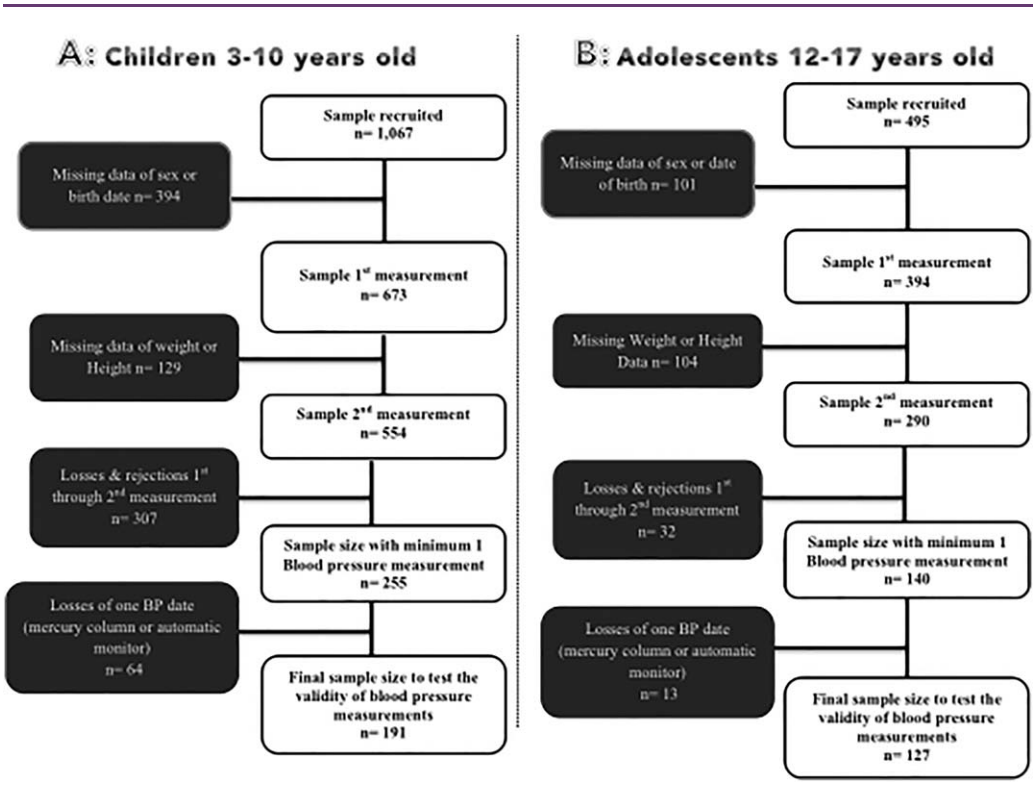

Figure 1 Flowchart of the final sample size to test the validity of an automatic oscillometric monitor by age group: SAYCARE study.

sitting, their backs resting on a chair, a relaxed arm resting on a rigid surface, and uncrossed feet resting on the floor. After 5 minutes of rest, the measurement was initiated.

The classification of the variation of the BP values provided by the device was made considering the differences in the reading records between the mercury column and the automatic device according to the procedures described by the AHA (7) and BHS (12). Two consecutive and simultaneous measures were performed with a 2-minute interval between them; if the difference between the two measurements was greater than 5% (difference of >5 mmHg between the first and second reading), a third measurement was carried out next.

The mean of these multiple readings is used because, for AHA, at least two readings should be taken at intervals of at least 1 minute, and the mean of those readings should be used to represent BP. In accordance with the BHS protocol, the devices must reach a minimum of a grade for systolic BP (SBP) and diastolic (DBP) to be valid instruments.

At the end of each measurement, the first observer recorded the BP values identified with the mercury column without knowing the values recorded by the automatic device reported by the second observer. Neither of them exchanged information (12).

To test the sensitivity and specificity of the Omron automatic monitor, we classified the children and adolescents by the presence or absence of HBP for both measurement methods. HBP was defined as SBP or DBP above the 95th percentile for sex, age, and height following the American Academy of Pediatrics protocol (11).

Statistical analyses

Descriptive analyses included the calculation of means, percentages, and 95% confidence intervals (CI). Agreement between the measurements was calculated by means of the intercalation coefficients for quantitative variables. The Bland-Altman concordance test was used to obtain reliability data. We calculated the sensitivity, specificity, and positive and negative predictive values through a 2×2 contingency table.

Sensitivity is the ability of a test to discriminate among those suspected of a pathology and those who are effectively ill in the two equipment pieces. Because the specificity (the true negative rate) measured the proportion of negatives that correctly classify an individual without HBP, positive predictive value and negative predictive value were also analyzed. For the analyses, Stata Software version 12.0 (Stata Corp., College Station, Texas) was utilized.

Results

Our final sample included pediatric populations (aged 3-18 years) of the following four South American cities: Lima (Peru), Medellin (Colombia), São Paulo, and Teresina (Brazil); in total, 191 children

TABLE 1 Descriptive analysis of characteristics of the sample grouped by gender and stratified by age group, SAYCARE study

Children ($n = 191$)	Mean or %	95% CI
Age		
3-5 y	41.9	32.8-49.5
6-10 y	58	50.5-65.2
Automatic oscillometric device		
Systolic blood pressure (mmHg)	95.9	94.5-97.4
Diastolic blood pressure (mmHg)	63.3	62.0-64.5
Mercury column		
Systolic blood pressure (mmHg)	94.5	93.1-95.9
Diastolic blood pressure (mmHg)	60.7	59.4-62.1
School type		
Public	53.4	45.9-60.8
Private	46.5	39.2-54.0
High blood pressure[a]		
Mercury column	2.7	1.3-5.7
Automatic oscillometric device	11.4	7.4-15.4
Adolescents ($n = 127$)		
Age		
11-14 y	52.3	42.8-61.6
15-17 y	47.7	38.4-57.2
Automatic oscillometric device		
Systolic blood pressure (mmHg)	108.6	106.6-110.4
Diastolic blood pressure (mmHg)	64.9	63.5-66.4
Mercury column		
Systolic blood pressure (mmHg)	104.2	102.2-106.3
Diastolic blood pressure (mmHg)	62.3	60.6-64.0
School type		
Public	30.3	22.3-39.7
Private	69.7	60.3-77.7
High blood pressure[a]		
Mercury column	1.4	0.4-5.6
Automatic oscillometric device	3.7	0.5-6.9

[a]High blood pressure was defined as systolic blood pressure or diastolic blood pressure above the 95th percentile for sex, age, and height.

(preschoolers and school children) and 127 adolescents participated in this paper (Figure 1). Characteristics of the analyzed subjects are described in Table 1.

In Table 2, the values recorded by the Omron HEM-7200 monitor are compared with those of the mercury column. According to the BHS (Supporting Information Table S1), in children, the device tested received Grade B for SBP and Grade C for DBP for ≤ 5 mmHg. Regarding adolescents, the device tested received Grade B for SBP and DBP for ≤ 5 mmHg. The ratings are Grade A for SBP in children and SBP and DBP in adolescents and Grade B for DBP in children for ≤ 10 mmHg. The ratings are Grade A for children and adolescents for ≤ 15 mmHg.

Table 3 shows that the values for sensitivity ranged between 20% and 21.43%, and the values for specificity ranged between 95.87% and 100%. The probability of an individual having HBP (positive predictive value) was 98.48%, while normal BP ($<$90th percentile for age and sex) (negative predictive value) was 96.99%. Table 4 presents the Bland-Altman plot and the mean (95% limits of agreement) difference between the mercury column and the monitor measurements for the two age groups. These results showed the automatic monitor measurement bias is lower (range between 1.4 and 4.3 mmHg) in both age groups.

Discussion

Early diagnosis of arterial hypertension in children and adolescents is fundamental for the early initiation of management and possible prevention of its occurrence in adult life (13). However, an adequate diagnosis by using internationally acceptable methods is essential. The use of a uniform international standard is desirable, as this improves the comparability of the data. We observed that the Omron HEM-7200 monitor presented high values of specificity and lower values of sensitivity for children and adolescents. Thus, the automatic monitor received the rating Grade A for children and adolescents without the disease, but it was inaccurate in detecting those children with HBP levels. However, results showed the Omron HEM-7200 monitor measurement bias is lower in both BP levels in children and adolescents.

All monitors in clinical settings should be tested for accuracy. These automated oscillometric monitors that provide SPB and DBP

TABLE 2 Comparison observed between the blood pressure values reported by the tested device (Omron HEM 7200) and those of mercury column according to BHS procedures (9), stratified by age group

	Variation monitor tests in comparison with mercury column		
	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Classification in children ($n = 191$)			
Systolic blood pressure	56.54% ($n = 108$)	91.04% ($n = 174$)	99.71% ($n = 190$)
Diastolic blood pressure	49.52% ($n = 95$)	77.14% ($n = 147$)	91.1% ($n = 174$)
Classification in adolescents ($n = 127$)			
Systolic blood pressure	52.75% ($n = 67$)	92.12% ($n = 117$)	99.99% ($n = 126$)
Diastolic blood pressure	52.75% ($n = 67$)	88.97% ($n = 113$)	95.27% ($n = 121$)

TABLE 3 Sensitivity and specificity of the Omron HEM7200 in diagnosis of high blood pressure in children and adolescents, SAYCARE study

	n	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	PNV (95% CI)
Children	191	21.43 (16.3-26.6)	95.87 (93.3-98.3)	40.0 (33.8-46.1)	98.4 (86.8-94.1)
Adolescents	127	20.00 (13.2-26.8)	100.00 (100.0-100.0)	100.00 (100.0-100.0)	96.99 (94.1-99.8)

PPV, positive predictive value; PNV, negative predictive value.

readings must be submitted to formal validation protocols by independent investigators. The two original protocols that are most widely accepted were developed by the Association for the Advancement of Medical Instrumentation in 1987 and the BHS in 1990, with revisions in 1993 and 2002. The present validation study showed that the Omron HEM-7200 monitor met the BHS criteria, obtaining Grade B and C for SBP and DBP, respectively, in children, and Grade B for SBP and DBP in adolescents. However, it is important to highlight that according the BHS standards of Grades A or B, the automatic device failed to detect DBP in children.

The device, as an identifier of HBP, was verified according to the parameters of sensitivity (efficiency in identifying the presence of HBP) and specificity (efficiency in identifying the absence of HBP). Sensitivity is the ability of a test to discriminate among those suspected of a pathology and those who are effectively ill. Despite our low sensitivity results, the Omron HEM-7200 monitor showed lower measurement bias (accurate for BP values) indicated by small mean differences and limits of agreement. In a recent review, Stergiou et al. (14) indicated that the mean differences have to be reported for validation of BP monitors in children. However, such results do not determine that either monitor is inadequate but are, rather, because of the characteristics of the population, as the results are classified as B within the international guidelines.

Our results demonstrated that the Omron HEM-7200 monitor has this condition in which a diagnostic test with a lower sensitivity and higher specificity could be solid evidence of the usefulness of this equipment in monitoring BP in clinical settings, a positive indicator for the use of the Omron HEM-7200. Higher specificity and lower sensitivity could be good when the aim is to establish the best available method to detect the presence or absence in survey or screening research (15). The Omron HEM-7200 monitor has the capacity to correctly classify an individual as disease-free, and the interobserver variability is automatically controlled by the device (16), and this does not happen in auscultatory measurement methods. However, it is important to emphasize that the HBP diagnosis by an oscillometric automatic monitor in children should be confirmed by auscultatory BP measurement by mercury column as recommended by American Academy of Pediatrics (11).

The BHS suggests the use of the methodology initially proposed by Bland and Altman in 1986 (17) to evaluate agreement between measures; this is also applied to validate digital BP measurement devices. The Bland-Altman plot indicates agreement between numerical data. In this study, high agreement was found between the BP values recorded by the two devices, and this fact was confirmed by the criteria established by the BHS being reached, including the highest grading (12), because the absolute difference between standard and test device should be < 5 mmHg.

Multicenter studies help to reach a sufficient number to meet a study goal; they produce more general findings, as participants are recruited from a larger population and may represent a situation more typical of future use. In order to maintain quality standards, it is necessary for centers to understand the definitions of the protocol (18).

The importance of the SAYCARE study strengthens the development of valid and accurate measurement methods to obtain information about BP, in addition to maximizing the quality of data collection and understanding these factors in different countries of South America, when developing joint methods that allow comparability for the measurement of cardiovascular health and associated factors. It is of great value because the standardization of the method in different South American countries, respecting the different cultures, can become a reference for analytical studies.

Conclusion

In summary, this automatic oscillometric monitor obtained Grade B for SBP in children and SBP and DBP in adolescents and Grade C

TABLE 4 Bland-Altman plot analysis for the mean values of the difference between the pressure systolic and diastolic apparatus, SAYCARE study

	Children		Adolescents	
Bland-Altman plot analysis	**Mean difference (mmHg)**	**95% LOA**	**Mean difference (mmHg)**	**95% LOA**
Systolic blood pressure	1.4	−9.9 to 12.81	4.3	−7.8 to 16.5
Diastolic blood pressure	2.2	−7.4 to 11.7	1.4	−8.4 to 11.2

95% LOA, limits of agreement of 95%.

for DBP in children according BHS criteria, and the Omron HEM-7200 monitor presented high values of specificity and lower values of sensitivity to the diagnosis of HBP in children and adolescents. However, the monitor can be considered accurate and valid for numerical data (BP values) because the absolute difference recorded by the two measurement methods is < 5 mmHg, so we conclude the monitor can be used for epidemiological and clinical practice.O

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