Validation of the Raycome RBP-1200 upper-arm pulse wave device in children aged 3 – 12 years according to the Association for the Advancement of Medical Instrumentation protocol

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Objective To validate the accuracy of Raycome RBP-1200 used for blood pressure (BP) measurements in Chinese children aged 3–12 years according to the Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization 81060-2:2013(E) protocol.

Methods A prospective observational study was carried out using 'the same arm sequential method' as described in the AAMI protocol. Eighty-seven children participated in this examination and 255 paired-determinations were analyzed.

Results The BP difference between the RBP-1200 and the mercury sphygmomanometer device was − 0.9 ± 5.3 mmHg for systolic BP and − 1.1 ± 5.0 mmHg for diastolic BP, which were within the range of ± 5 ± 8 mmHg as required by criterion 1 of the AAMI protocol. The SD of the averaged difference for each participant was 4.1 mmHg for systolic BP and 3.9 mmHg for diastolic BP, which were also within the requirement of criterion 2 of the AAMI protocol.

Conclusion The Raycome RBP-1200 device fulfills the requirements of the AAMI protocol and it can be recommended for BP measurements in Chinese children aged 3–12 years with low or normal BP values. Blood Press Monit 22:40–43 Copyright © 2017 Wolters Kluwer Health, Inc. All rights reserved.

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Introduction

Hypertension has become a major public health issue in China. The blood pressure (BP) values and prevalence of elevated BP among Chinese children have increased considerably in recent years [1]. Hypertensive children have a higher risk of developing target organ damage including arterial stiffness and left ventricular hypertrophy compared with children with normal BP [2]. Actually, epidemiological studies have indicated that BP can moderately track from childhood into adulthood [3]. Therefore, screening and identification of hypertension among asymptomatic children are important to reduce the risk of target organ damage in childhood and cardiovascular events in adulthood.

Because of observer bias (e.g. terminal digit preference) and environmental pollution, the mercury sphygmomanometer, which is considered the gold standard device for BP measurements, has been substituted by several other techniques, such as an oscillometric device [4,5]. However, only a few BP devices used in Chinese children have been validated on the basis of international protocols [6]. Hence, this study aimed to validate the accuracy of Raycome RBP-1200 in Chinese children aged 3–12 years according to the Association for the Advancement of Medical Instrumentation (AAMI)/ International Organization for Standardization 81060-2:2013(E) protocol [7].

Methods

Tested device

The Raycome RBP-1200 upper-arm pulse wave device (Shenzhen Raycom Health Technology Co. Ltd, Shenzhen, China) is fully automated for clinical BP measurements. It can measure BP values ranging from 0 to 270 mmHg and pulse rates from 40 to 180 beats/min. The size of this device is about 16.5 × 10.9 × 6.1 cm (length × width × height). The device is powered by a Li battery (DC 3.7V) and can measure more than 200 times after being fully charged. The Raycome RBP-1200 innovatively combines a pulse wave detector at the downstream position of the pressurized cuff, which is used to detect changes in the pulse wave to determine systolic blood pressure (SBP) and to sense the real-time changes in the blood flow pulse to determine diastolic blood pressure (DBP). In this study, three devices were provided by the manufacturer, and one of them was chosen randomly for the purpose of validation. Three sizes of cuff were designed: extra-small (15–18 cm), small (18–22 cm), and standard (23–32 cm).

Protocol

In our study, the protocol of AAMI 2013 edition was followed. For SBP and DBP, the mean value of the differences between the observers' determinations and the RBP-1200 readings should be within or equal to ± 5.0 mmHg, with a SD no greater than 8.0 mmHg (criterion 1). The SD of the averaged differences for each participant should fulfill criterion 2 described in the AAMI protocol.

Participants

Children aged 3–6 years were recruited from the inpatients in the Department of Cardiology, Children's Hospital Affiliated to Capital Institute of Pediatrics, and those aged 6–12 years were recruited from Beijing Jingshan School in the Dongcheng District of Beijing, China. Participants who had heart arrhythmias or abnormal Korotkoff sound, or had wounds of both upper arms,including vaccination in both arms in the past week, were excluded.

Observers

The validation team included three individuals: two observers and one supervisor. Two observers who were blinded to each other and to the device were responsible for BP measurements using a mercury sphygmomanometer as the reference; the supervisor took charge of BP measurements using RBP-1200 and evaluation of the agreement (≤ 4 mmHg) between the two observers.

Before the study started, observers were trained by an experienced professional, and took about 2 weeks to become familiar with the use of the mercury sphygmomanometer, RBP-1200, and the procedure.

BP measurements

Before the test, each component of the instruments involved in was checked carefully, and each participant's arm circumference was measured to select the suitable cuff size as well as to ensure that $\frac{1}{2n}$ (n is the number of cuff sizes) participants were tested for each size of cuff.The entire procedure was completed in a quiet and comfortable environment. Participants were seated with their legs uncrossed, their left arms were supported at the heart level, and they had rested for at least 5 min before BP measurements. During the entire measurements,participants were recommended to be relaxed and avoid talking. DBP was determined by the last audible Korotkoff sound (K5), except when the Korotkoff sound was still audible with the cuff deflated to 0; then, the fourth phase sound (K4) was used.

Procedure

Validation was performed according to the 'same arm sequential method' as recommended by the AAMI protocol. An initial BP measurement using a sphygmomanometer was performed for the basic BP and RBP-1200 was used for the second BP measurements. Then, subsequent BP readings were recorded using both devices alternately, with at least a 1 min rest for the participants between two BP measurements. For each measurement using the mercury sphygmomanometer, the BP values from two observers were averaged for determination of this measurement. The preceding and following two observers' determinations were averaged and used as a reference BP determination. The device reading between the two manual measurements and the reference BP determination were considered as a pair of BP determination.

Statistical analysis

Data were entered using Microsoft Excel 2010 (Microsoft Corp., Redmond, Washington, USA) and SPSS 19.0(SPSS, Inc., Chicago, Illinois, USA) and analyzed according to the criteria described by the AAMI protocol.

Ethical statement

This study was approved by the Ethics Committee of the Capital Institute of Pediatrics. Written informed consents were obtained from all the participants' guardians.

Results

Five children were excluded initially because of their SBP determinations' difference more than 12 mmHg or DBP determinations' difference more than 8 mmHg. For 87 recruited participants (boys, 50.6%), six participants (≤ 10%) had two compliant consecutive determination pairs for each one and the remaining 81 had three determination pairs per participant. The initial SBP was 97.6 ± 7.0 mmHg (ranging from 86 to 115 mmHg) and DBP was 60.6 ± 6.1 mmHg (ranging from 47 to 78 mmHg) for the participants included. Eight participants used K4 and 79 participants used K5 as DBP. Arm circumferences ranged from 15.0 to 32.0 cm. Among these, 20 participants used the extra-small cuff and 29 used the small cuff (Table 1).

Table 1 Basic characteristices of the study population

Sex(n)	
Male:female	44:43
Age(years)	
Range(low:high)	3:12
Mean (SD)	22.2(4.1)
Cuffs for RBP-1200(n)	
Extra-small:small:standard	20:29:38
Recruitment BP(mmHg)	
SBP	
Range(low:high)	86:115
Mean(SD)	97.6(7.0)
DBP	
Range(low:high)	47:78
Mean(SD)	60.6(6.0)

BP,blood pressure;DBP,diastolic blood pressure;SBPsistolice blood pressure

The observer difference was 1.3 ± 2.1 mmHg for SBP and 0.5 ± 2.3 mmHg for DBP. For SBP, the mean value of observers' determinations was 95.2 ± 7.3 mmHg and the mean value measured by RBP-1200 was 94.3 ± 7.5 mmHg; for DBP, the mean value of observers'determinations was 60.0 ± 6.0 mmHg and the mean value measured by RBP-1200 was 59.5 ± 6.0 mmHg. The mean difference in automated-manual measurements was − 0.9 ± 5.3 mmHg for SBP and − 1.1 ± 5.0 mmHg for DBP, which were within values of ± 5 ± 8 mmHg (criterion 1). Scatter plots were performed for SBP and DBP,respectively, according to the Bland–Altman method,where the y-axis shows the differences between device values and reference BP values and the x-axis represents the average values obtained from the observers and Bland–Altman plots of the SBP (a) and DBP (b) between the difference and the mean of

the findings. The x-axis shows the mean values of the RBP-1200 readings and the reference blood pressure values (mmHg),and the y-axis represents the differences between values obtained from the RBP-1200 and the mercury sphygmomanometer (mmHg). DBP, diastolic blood pressure; SBP, systolic blood pressure.

Fig. 1

(a)
(b)
Mean device and observer measurement (mmHg)
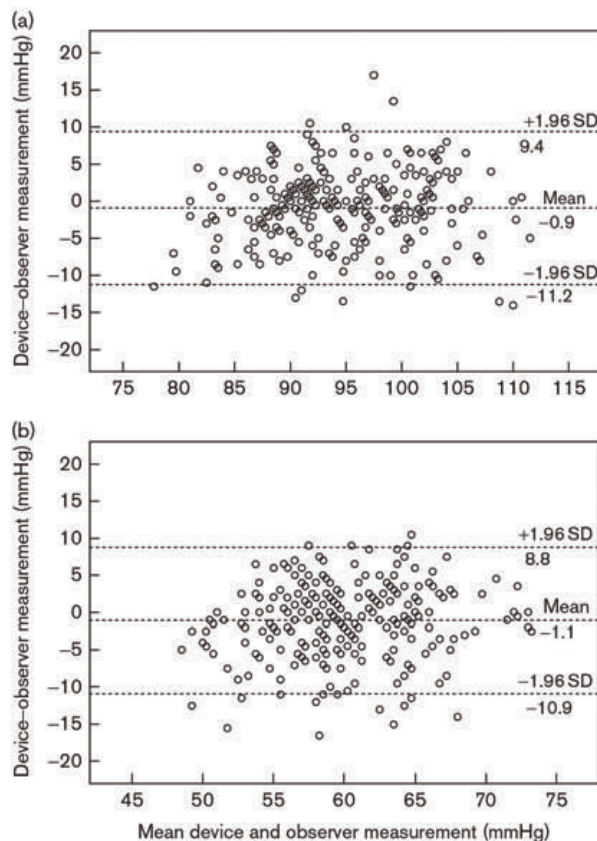
device measurements (Fig. 1). There was no pattern of BP overestimation or underestimation on the basis of the plots' distribution.

For each of the 87 participants, analysis of the averaged paired-determinations per participant using the RBP-1200 and mercury sphygmomanometer showed an SD value of 4.1 mmHg (≤ 6.88 mmHg) for SBP and 3.9 mmHg (≤ 6.86 mmHg) for DBP (criterion 2),respectively.

Discussion

The accuracy of Raycome RBP-1200 was validated in Chinese children aged 3–12 years compared with a standard mercury sphygmomanometer, and the results showed that the Raycome RBP-1200 fully complied with the first and second criteria of the AAMI validation protocol for both SBP and DBP.

Our study had two strengths. First, to our knowledge, the validation of Raycome RBP-1200 was first performed in children aged 3–12 years according to the AAMI protocol.Because of the increasing prevalence of elevated BP in children, it is important to monitor BP status in pediatric population using convenient devices. However,

to date,few validated BP monitor devices have been provided for children. We believe that our validated RBP-1200 will be useful for screening of elevated BP in children. Second,the pulse wave technology is an innovative method for BP measurement in children aged 3–12 years. The use of this electronic device will avoid observer bias such as digit preference.

Our study is subject to one limitation. The accuracy of the device may be inconsistent in children with high BP levels. In our study, the maximum SBP/DBP was 115/78 mmHg, but in clinical practice, a proportion of children's BP values may exceed this range. Therefore, a careful judgment should be made when a high BP value is recorded by this device. Future studies are needed to explore the accuracy of this device in children with high BP values.

Conclusion

The Raycome RBP-1200 upper-arm pulse-wave device fulfills the requirements of the AAMI 2013 protocol and it can be useful for BP measurements in Chinese children aged 3–12 years within the validated BP range.

Conflicts of interest

There are no conflicts of interest.

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