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Accuracy of the Spacelabs 90217 Ambulatory Blood Pressure Monitor in a Pediatric Population

Karen M. Redwine, MD, MPH[1], **Laura P. James, MD**[2], **MaryAnn O'Riordan, PhD**[3], **Janice E. Sullivan, MD**[4], **Jeffrey L. Blumer, PhD, MD**[5], and **the Network of Pediatric Pharmacology Research Units**[6]

[1]Department of Pediatrics, Division of Pediatric Nephrology University of Arkansas for Medical Sciences & Arkansas Children's Hospital

[2]Department of Pediatrics, Section of Clinical Pharmacology and Toxicology University of Arkansas for Medical Sciences & Arkansas Children's Hospital

[3] Department of Pediatrics, Division of Pediatric Critical Care Case Western Reserve University Hospitals

[4] Departments of Pediatrics and Pharmacology and Toxicology Divisions of Pediatric Critical Care and the Kosair Charities Pediatric Clinical Research Unit University of Louisville

[5] Department of Pediatrics University of Toledo

[6]National Institute of Child Health and Human Development

Abstract

Ambulatory Blood Pressure Measurement (ABPM) techniques provide unique advantages for diagnosing hypertension although few devices have been independently validated in the pediatric population. We sought to validate the accuracy of the Spacelabs 90217 ABPM in children using a modified British Hypertension Society protocol. A total of 112 children, age 6-17 years, completed the study at one of 3 participating centers. Overall, the monitor earned an “A” for systolic blood pressure and “B” for diastolic blood pressure. It performed slightly better among 6-12 year olds (“A/A”) than 13-17 year olds (“A/B”). We conclude that the Spacelabs 90217 monitor is in an appropriate monitor for use in children 6 years of age and older.

Keywords

Ambulatory Blood Pressure Monitoring; Validation; Children; Adolescents

Corresponding author and reprint requests: Karen M. Redwine, MD, MPH Division of Pediatric Nephrology University of Arkansas for Medical Sciences 1 Children's Way, Slot 512-14 Little Rock, AR 72202 Phone: (501) 364-1847 Fax: (501) 364-1780 redwinekarenm@uams.edu.

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Introduction

Accurately diagnosing hypertension (HTN) in children and adolescents presents a challenge for medical practitioners. Ambulatory blood pressure monitoring (ABPM) techniques, which capture multiple blood pressure (BP) measurements in a patient's natural environment, provide multiple advantages over standard office-based measurements[1]. Most notably, they capture the natural variability that occurs in BP over an extended time period. ABPM also correlates more closely to morbidity and mortality associated with HTN and to secondary target organ damage in children.

Despite the large variety of ambulatory monitors commercially available and their widespread use among pediatric specialists, very few have been independently validated in children[2-4]. The Spacelabs 90217 ABPM (Issaquah, WA) is a light weight oscillometric monitor with a wide range of BP cuff sizes making it an ideal monitor for use in a diverse pediatric population. The current study aimed to independently validate the accuracy of this monitor for use in pediatric patients using a modified British Hypertension Society (BHS) protocol[5].

Methods

Study Population and Enrollment

Children aged 6 to less than 18 years were enrolled from three participating sites within the Network of Pediatric Pharmacology Research Units. Eligible subjects were required to be free from previously diagnosed cardiac arrhythmias, conditions which might alter normal circulation (i.e. AV fistula or unrepaired congenital heart disease), and anatomic anomalies preventing BP measurement in the non-dominant arm. Subjects were also asked to refrain from ingesting caffeine, being exposed (actively or passively) to tobacco, and strenuous exercise for 30 minutes prior to BP measurements. Informed parental consent was obtained from all participants and subject assent was obtained for all children ≥ 7 years of age. All protocols and procedures were approved by the committee for the protection of human subjects at each of the participating institutions.

Enrollment was aimed at generating a cohort of subjects with a wide range of age, BP, and arm circumferences. Thus, subjects were recruited with a goal of having equal enrollment within each of 2 age groups (6 – 12 years and 13 – <18 years). In addition, a minimum of 16.7% of subjects within each age group were expected to have a qualifying systolic BP (SBP) < 1 standard deviation (s.d.) below the subject's mean BP for age, height, and gender[6]; a qualifying SBP > 1 s.d. above this mean; a qualifying diastolic BP (DBP) < 1 s.d. below this mean, and a qualifying DBP > 1 s.d. above this mean. Finally, a minimum of 16.7% of subjects within each age group were also required to fit into one of three cuff sizes (child, small adult, and adult for the younger cohort; small adult, adult, and large adult for the older cohort).

Study Procedures

Height, weight, mid-arm circumference, and a brief medical history were performed on all subjects. BP was measured while in a seated position using an appropriate sized cuff in the

non-dominant arm of each subject alternating between standard auscultatory measures and the Spacelabs device per BHS protocol. Cuff selection was based on the mean of three mid-arm circumference measurements and the larger cuff was used when mid-arm circumference fell within the suggested range for two separate cuffs. All auscultatory measurements were obtained simultaneously by 2 blinded observers using calibrated aneroid devices. The first and fifth Korotkoff sounds were used to define systolic and diastolic BP respectively. American Heart Association (AHA) recommendations for measurement of BP[7] were followed throughout the study. Observers responsible for obtaining auscultatory measurements completed centralized training in AHA recommendations and serial measurements were validated against a single investigator prior to initiating the study.

Statistical Analysis

Nominal demographic characteristics are described using frequencies and percents. Continuous variables (age) are described using the median and range.

Differences in readings between the two devices were calculated for all measurements for all patients. These were used to assess the validation criteria in three ways. First the mean and standard deviation of the differences in systolic and diastolic blood pressure were calculated and compared to the validation criterion based on a continuous measure. Secondly, each difference was classified as ≤ 5 mmHg, ≤ 10 mmHg, and ≤ 15 mmHg, and tabulated to assess the validation based on nominal measures. Finally, the inter-observer variability was assessed by comparing the differences between the two raters and classifying them as ≤ 5 mmHg and ≤ 10 mmHg.

All analyses were carried out using SAS, v 9.3 (The SAS Institute, Cary, NC, USA).

Results

A total of 157 subjects were recruited. Of these, 43 subjects did not complete the study as qualifying BP readings were outside the range needed to complete the desired cohorts. In addition, the ABPM device failed to read BP in one subject due to persistent movement. One final subject was excluded due to an inability for the observers to consistently hear Korotkoff sounds. Demographic data for the remaining 112 children who successfully completed the protocol are shown in Table 1. Recruitment goals for varying age, cuff size, and BP range were met for all cohorts except for the low DBP group for which only 10.7% of subjects were classified (goal 16.7%). Inter-observer variability differed by ≤5 mmHg in 82.7% of readings and ≤10 mmHg in 97.2% of readings satisfying requirements of the BHS for a valid study (>80% and >95% required respectively).

The cumulative percentage of readings between the two devices which differed by less than or equal to 5, 10, and 15 mmHg for the overall cohort and by age group is shown in Table 2. Overall, the monitor fell within the grade range of “A” for SBP and “B” for DBP according to BHS criteria. The monitor performed better in the younger age group earning an “A/A” for SBP and DBP respectively than compared to the adolescent age group in which the monitor earned an “A/B” rating.

The mean of the difference between the Spacelabs 90217 and auscultatory readings was (-)2.49 ± 7.090 mmHg for SBP and 4.77 ± 11.060 mmHg for DBP fulfilling AAMI recommendations in all categories except DBP standard deviation. The difference in the younger cohort was (-)1.25 ± 6.74 mmHg and 5.78 ± 8.01 mmHg for SBP and DBP respectively while the difference in the older cohort was (-)3.68 ± 7.24 mmHg for SBP and 3.80 ± 13.39 mmHg for DBP.

Discussion

We conclude that the Spacelabs 90217 ABPM accurately measures BP across a diverse pediatric population. The previous Spacelabs model 90207 received a grade of “C” for SBP and “D” for DBP in an independent validation study[2]. This is considerably worse than the results of our study suggesting that the 90217 model is a better choice for pediatricians performing ambulatory monitoring. However, there is still some concern regarding DBP measurement in children, as the monitor did not completely fulfill AAMI criteria regarding diastolic variability. In an effort to standardize criteria for DBP, the fifth Korotkoff sound was used to determine DBP for all subjects. This resulted in a small number of subjects having an auscultatory DBP < 10 mmHg when the fourth Korotkoff sound may have been more appropriate clinically. The authors speculate that this is the reason for the larger than acceptable difference in the standard deviation between the measures.

While multiple ambulatory monitors are commercially available, few have been independently validated in children. Jones et al[3] validated the AM5600 in 7-18 year olds with a history of elevated BP or first degree relative with HTN. The Tibia Medical Ambulo 2400 ABPM has also been validated using International Standards Organization guidelines which are used to validate monitors in populations that include both children and adults[4]. Unfortunately, other devices which have been validated in children are no longer commercially available.

The most comprehensive recommendations for validating BP measuring devices specifically in children remain the revised BHS protocol published in 1992. These guidelines call for the inclusion of 30 subjects, aged 5-15 years, of random sex with a specified range in baseline SBP, DBP and arm circumference. Given the heterogeneity of BP in children and the vascular changes that occur during puberty, the authors believe these recommendations limit the ability to effectively validate a BP device across this age span. Thus, we increased our enrollment size with a goal of being able to evaluate the monitor independently in two different age groups.

Additionally, entry criteria for this study were aimed at recruiting a range of cuff sizes rather than the population based range of mid-arm circumference suggested by the BHS. Normal values for mid-arm circumference are dated and with the recent obesity epidemic are unlikely to represent the intent of the validation protocol which is to measure BP across a wide range of expected arm sizes. Only one subject in our study required the “extra large” cuff, thus the validity of the monitor for the extremely obese remains unknown.

Recommendations also call for validation of new devices against a mercury manometer. Environmental concerns and subsequent governmental regulations have decreased the availability of mercury manometers, so aneroid devices were utilized in this study. To minimize the potential variability associated with aneroid devices, new devices dedicated solely to this project were purchased and were centrally calibrated prior to starting the protocol. Enrollment was completed in <6 months, so the monitors were not recalibrated. Inter-observer variability did not change throughout the study suggesting that no significant drift occurred with the aneroid devices.

Lastly, recruitment into the “DBP < 1 s.d. below the mean” cohort was challenging. It is suspected that a drift in mean BP has occurred over time with the rising rate of obesity in our country[8] making this already small group even harder to identify. Overall, 12 subjects fell into this low DBP group (5 and 7 subjects in the younger and older age cohorts respectively). An additional 43 subjects were screened in an effort to complete this cohort. Original BHS criteria require 5 subjects out of 30 to fall into this range. Thus, while the study failed to recruit the goal percentage of children with a low DBP we did identify over twice as many children as the original protocol dictates.

Despite these limitations, the study population represents children with a wide range in age, baseline BP, and arm size. Additionally, the study was successfully performed at multiple sites demonstrating the monitor's ease of use in multiple settings by multiple personnel. As the successor to the ambulatory monitor from which the most widely used pediatric normal values were generated[9], the Spacelabs 90217 has been used frequently for both clinical and research applications despite having never undergone a rigorous, independent validation. This study supports the continued use of this monitor in the pediatric population and endorses a wealth of published data demonstrating the superiority of ABPM over casual BP measurements in evaluating children with elevated BP.

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4) The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or any other supporting agency.

Abbreviations (in order of appearance)

HTN Hypertension

ABPM	Ambulatory Blood Pressure Monitor
BP	Blood Pressure
BHS	British Hypertension Society
SBP	Systolic Blood Pressure
s.d.	Standard Deviation
DBP	Diastolic Blood Pressure
AHA	American Heart Association

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Table 1

Characteristics of Subjects

Characteristics of Subjects (n=112)	
Age	11.6 years (6-17 years)
Gender (%)	
Female	53.6%
Male	46.4%
Race	
African American	12.6%
Asian	0.9%
Caucasian	84.7%
Other	1.8%
Ethnicity	
Hispanic	3.8%
Non-Hispanic	96.2%
Entry SBP*	
Low	17.9%
Normal	56.3%
High	25.9%
Entry DBP*	
Low	10.7%
Normal	67.9%
High	21.4%
Cuff Size (%)	
Child (12-20 cm)	8.9%
Small Adult (17-26 cm)	41.1%
Adult (24-32 cm)	38.4%
Large Adult (32-42 cm)	10.7%
X-Large Adult (38-50 cm)	0.9%

SBP, systolic blood pressure; DBP, diastolic blood pressure

* Based on the mean of two observers' auscultatory values; Low - < 1 standard deviation below mean; Normal >1 standard deviation below the mean but < 1 standard deviation above the mean; High - > 1 standard deviation about the mean.

Table 2

Auscultatory readings versus Spacelabs 90217 readings (mmHg)

Difference between Auscultatory readings and Spacelabs monitor			
	≤ 5 mmHg	**≤ 10 mmHg**	**≤ 15 mmHg**
Overall			
SBP	248 (73.8%)	304 (90.7%)	324 (96.4%)
DBP	204 (60.7%)	278 (82.7%)	319 (94.9%)
Children (6 - 12 yrs)			
SBP	138 (79.3%)	135 (94.8%)	170 (97.7%)
DBP	115 (66.1%)	152 (87.4%)	171 (98.3%)
Adolescents (13 - <18 yrs)			
SBP	110 (67.9%)	140 (86.4%)	154 (95.1%)
DBP	89 (54.9%)	126(77.8%)	153 (94.4%)

SBP, systolic blood pressure; DBP, diastolic blood pressure