Accuracy of Automated Blood Pressure Measurement in Children

Evidence, Issues, and Perspectives

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There is a general consensus in the European[1] and American[2] guidelines for pediatric hypertension that children from 3 years of age and older who are seen in a medical setting should have their blood pressure (BP) measured. This is because hypertension in children and adolescents has become an emerging public health issue, with increasing prevalence mainly driven by the obesity epidemic in this population.[1,2] Because hypertension is almost always asymptomatic until there is severe organ damage or it evolves into a malignant phase, the only method for early detection and intervention aiming to prevent its complications is the measurement of BP.

The accurate measurement of BP is a prerequisite in the adults and in children for the reliable diagnosis of hypertension and the avoidance of misdiagnosis and over- or undertreatment.[1,2] The main methods for noninvasive measurement of BP are the auscultatory method using conventional mercury or aneroid devices and the automated method using electronic, mostly oscillometric, devices.[3] This article aims to discuss the evidence and the issues of automated BP measurement in children (age 3–12 years).

Auscultatory BP Measurement in Children

Current guidelines for pediatric hypertension in Europe[1] and the United States[2] recommend the auscultatory BP measurement method for the diagnosis of hypertension in children. If elevated BP in children is detected by an electronic (oscillometric) BP monitor, it should be confirmed by auscultatory BP measurement.[1,2] This is mainly because in children, the available reference values for defining the threshold for hypertension diagnosis have been obtained by the auscultatory method and the fact that auscultatory and automated electronic BP measurements are not necessarily interchangeable.[1]

In children, the auscultatory BP measurement encounters several obstacles, mainly because of anatomic and physiological characteristics of the young individuals. These include small arm dimensions, small and elastic arteries, small waveforms, large differences between peripheral (brachial) and central (aortic) BP, occasional need to use Korotkov sound K4 for defining diastolic BP because Korotkov sounds might be audible when the cuff is fully deflated, and difficulties in defining K4 (sounds of low amplitude and often difficult to hear).[1,4,5] In addition, as it is the case also in the adults, the auscultatory BP measurement even when applied in a medical setting is subject to observer error, prejudice and bias, and terminal digit preference.[3]

Automated (Oscillometric) BP Measurement in Children

Ambulatory BP Monitoring

In children, the phenomena of white-coat and masked hypertension are particularly common as in the adults.[1,6] Therefore, out-of-office BP evaluation with 24-hour ambulatory BP monitoring is recommended by European[1] and American[6] guidelines for confirming hypertension in children before starting antihypertensive drug treatment. This is in line with the guidelines by major scientific organizations recommending ambulatory BP monitoring for confirming the diagnosis of hypertension in adults before proceeding to any investigation or treatment.[7–9]

Ambulatory BP monitoring is by definition automated, and almost all the monitors available on the market are oscillometric.[10] Furthermore, the recommended reference values for defining ambulatory hypertension in children have been derived using an oscillometric device.[1,6]

Home BP Monitoring

Surveys in the United States, Canada, and Germany showed that >70% of the pediatric nephrologists use home BP monitoring in children with hypertension or renal disease, and 64% of them consider these measurements as more important than the office measurements.[11,12] Home BP monitoring in children has been less well studied than ambulatory monitoring[1,13,14] and shown to be useful in the detection of white-coat and masked hypertension.[15] As ambulatory BP monitoring cannot be easily performed frequently, home BP monitoring is recommended for regular follow-up of treated hypertension in children, aiming to improve the assessment of BP control.[1]

For home BP monitoring in adults, electronic devices are recommended because they avoid the observer bias and error and require less training than the auscultatory devices.[16] In children, because the available evidence on the clinical application of home BP monitoring,[1,13] as well as its reference values,[1,17] have been obtained using electronic devices, such devices should be preferred in clinical practice.

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Office BP Measurement

For professional office or clinic BP measurement in children, the auscultatory method using a standard mercury sphygmomanometer is regarded as the standard.[1,2] However, because of environmental issues with mercury toxicity and issues related to service for devices' maintenance and potential mercury spillage in the medical setting, mercury sphygmomanometers are being progressively banned from medical use and are being replaced mainly by professional aneroid or electronic (oscillometric) devices.[18] Aneroid devices are widely available and commonly used, but require the auscultatory method and, thus, are subject to the abovementioned observer-related drawbacks.[18] Also, they may lose accuracy in long-term use and require regular maintenance and calibration. Electronic oscillometric devices have gained ground over the other standard methods during the last years. However, as mentioned earlier, it is currently recommended that elevated BP in children detected using an electronic BP monitor requires confirmation by auscultatory measurement.[1,2] Thus, the auscultatory method remains the gold standard for office BP measurement in children.

Independent from the measurement method, in adults,[7–9] as well as in children,[1,6] it is widely recognized that office BP measurement alone can be insufficient for the reliable diagnosis of hypertension and the decision for long-term drug treatment, mainly because of the white-coat and masked hypertension phenomena.

In conclusion, current guidelines for pediatric hypertension recommend the wide use of out-of-office BP monitoring for the initial diagnosis (mainly ambulatory BP monitoring)[1,6] and also for the long-term follow-up (mainly home BP monitoring).[1] Because out-of-office BP monitoring is based almost exclusively on automated BP measurements and reference values are derived from such measurements,[1,6] the wide use of automated BP monitors is often needed in clinical practice for confirming hypertension out of the office.

Methodology for the Validation of BP Monitors in Children

The accuracy of the device is fundamental to any method of BP measurement.[3] It is acknowledged that the accuracy of electronic BP monitors should be tested in independent validation studies, and relevant protocols have been developed.[19–21] The validation of a BP monitor in children faces several challenges, which are because of their special structural and functional characteristics, including small arms but with wide variation requiring several cuff sizes, relatively low BP levels, and difficulties in the accurate assessment of diastolic BP because of the abovementioned issues in defining Korotkov sounds K4 and K5 in children.[4,5] Thus, the validation protocols developed for adults are not fully applicable in children, and several adaptations are needed. More importantly, there are data suggesting that an electronic BP monitor that has been successfully validated in adults might be inaccurate in children.[19–22] Thus, children are regarded as a special population for BP monitors validation, requiring separate validation studies.[19–21]

Table 1. Key Features of Current Protocols for the Validation of Blood Pressure Monitors in Children

Requirements	BHS[19]	ESH-IP[21]	ANSI/AAMI/ISO[20]
Number of children	30, if the device has been successfully validated in general population	33 for narrow age range (otherwise to be adjusted)	Device for children/adults or with pediatric mode: 35; device only for children: 85
Age range	5–15 y (younger subjects in separate study)	NS	3–12 y (additional requirements for younger subjects)
Age distribution	Even distribution	NS	NS
Sex	Distribution by chance	≥10 (30%) male, ≥10 (30%) female	≥30% male, ≥30% female
BP range	5 with SBP >mean+1 SD for population; 5 with DBP <mean−1 SD for population	NS	NS
Arm circumference	5 subjects >70th and 5<30th centile for weight	NS	Single cuff: 40% of subjects' circumference within upper half of range; 40% within lower half; 20% of subjects' circumference within upper quarter of range; 20% within lower quarter. N cuffs, test each in ≥1/(2×n) subjects
Reference BP measurement	Mercury sphygmomanometer	Mercury sphygmomanometer	Mercury sphygmomanometer, or nonmercury auscultatory device with max permissible error±1 mm Hg
Reference diastolic BP	Korotkov K5	NS	Korotkov K4
Pass criteria	Mean difference and SD for test vs reference BP differences to be reported. No pass threshold is provided.	Part 1: number of device-observer BP differences ≤5, 10, 15 mm Hg. Part 2: number of subjects with 0, 2, or 3 of absolute BP differences ≤5 mm Hg	Criterion 1: mean±SD for test vs reference BP differences ≤5±8 mm Hg. Criterion 2: intersubject SD of BP differences within threshold dependent on mean of criterion 1

AAMI indicates Association for the Advancement of Medical Instrumentation; ANSI, American National Standards Institute; BHS, British Hypertension Society; BP, blood pressure; DBP, diastolic blood pressure; ESH-IP, European Society of Hypertension International Protocol; ISO, International Organization for Standardization; NS, not specified; SBP, systolic blood pressure; and SD, standard deviation.

The British Hypertension Society (BHS) validation protocol is the oldest one still in use and requires a device to be tested in 30 children aged 5 to 15 years, after a successful study in general population has been completed (Table 1).[19] The BHS protocol has specific inclusion criteria for children, in regard to their age, sex, and entry BP distribution. The mean BP difference between test device and reference measurements and its standard deviation need to be reported, yet there are no fixed pass criteria as for general population studies (Table 1).

The American National Standards Institute (ANSI)—Association for the Advancement of Medical Instrumentation (AAMI)—International Organization for Standardization (ISO; ANSI/AAMI/ISO) protocol currently is the most comprehensive protocol for the validation of BP monitors in children (Table 1).[20] For devices intended for use in children and adults, 35 children aged 3 to 12 years are required together with 50 older subjects. If a device has a specific mode for children, then additional testing in this mode is needed in 35 children. For devices intended only for use in children (no previous study in general population), an 85-child study is required. The protocol has criteria for sex distribution and cuff sizes, but not for age distribution and entry BP levels. For reference diastolic BP, Korotkov sound K4 is recommended, which is in contrast with current guidelines for hypertension diagnosis in children, recommending the K5.[1,2] More importantly, this protocol allows 35 children to be studied together with 50 subjects (any age >12 years) and analyzed altogether, which might miss an inferior level of accuracy in children or in older subjects. Both the 85-child and the 85-mixed population studies should meet the 2 ANSI/AAMI/ISO criteria for BP differences of individual readings and of individual subjects (Table 1).[20]

The European Society of Hypertension International Protocol has been developed specifically for adults (Table 1).[21] Thus, no specific recommendations for special groups such as children are provided. It is stated, however, that a 33-subject study is appropriate only if a narrow age range of children is included.

Validation Studies of Electronic BP Monitors in Children

Although a plethora of electronic BP monitors are currently available in the market, a successful validation study has been reported in <15%.[10] This issue is also crucial in children, in whom there is evidence that few devices have been properly and successfully validated using an established protocol.[10,19–21] A systematic review of validation studies of electronic BP monitors in children was performed. Medline and EMBASE databases were searched via Dialog ProQuest. Eligible studies were full-text articles in English published from January 1, 1987, to November 23, 2016, that presented validation data from children alone or together with other age groups and followed an established validation protocol. The following search terms were applied: *(children OR adolescents OR pediatric) AND (blood pressure) AND (monitor OR device OR oscillometric OR validation OR accuracy).* Results were narrowed by applying the following subject terms: *child*, *blood pressure*, *adolescent*, *blood pressure measurement*, *device*, *oscillometry*, *blood pressure determination*, *pediatrics*, *sphygmomanometer*, *validation study*, *blood pressure monitor*, *measurement accuracy*. Data sources were also identified through manual search of references of articles. The study selection and data extraction were performed independently by 2 investigators (A. Kollias and N. Boubouchairopoulou). Disagreements were resolved by consensus with a senior author (G. Stergiou).

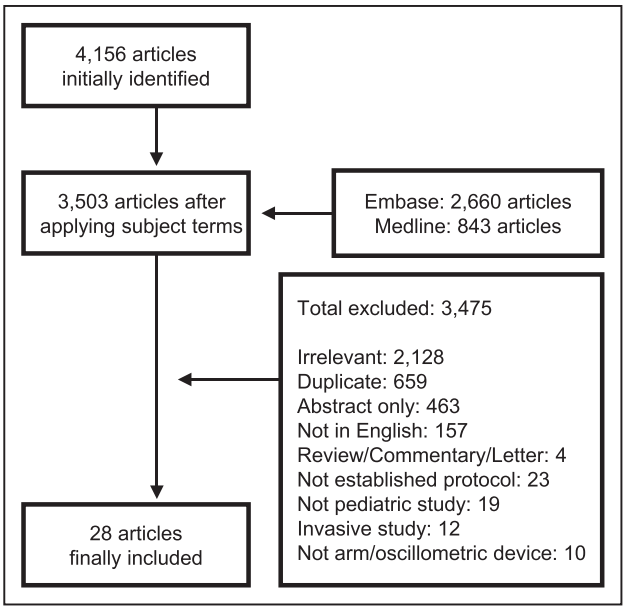

Figure. Flowchart of process for selecting validation studies of blood pressure monitors in children.

The initial literature search retrieved 4156 articles. The flow diagram of the selection procedure of articles is presented in Figure. Finally, 28 articles were included, which reported 31 validation studies of 29 devices.[23–50] Details on the device type, sample size, age range, number of children, validation protocol, and main results of each study are presented in Table 2. Evaluation of these data in children leads to the following conclusions:

1. Thirty-one validation studies of electronic BP monitors performed in children in the last 20 years were identified and 13 (42%) were published a decade ago or longer.
2. A total of 3067 subjects were included of whom 1450 (47%) were children aged 3 to 12 years (for 11 studies that included children and older subjects and did not report the number of children, the minimum protocol requirement of N=35 was assumed). Sixteen studies (52%) included also adolescents and 5 (16%) also adults.
3. A total of 29 devices have been validated, 16 (55%) designed for professional office BP measurement, 7 (24%) for ambulatory BP monitoring, and 6 (21%) for home monitoring.
4. Fourteen studies (45%) applied validation criteria of >1 protocols. The AAMI or ISO protocol was used in 20 studies (65%), the BHS in 18 (58%), and the European Society of Hypertension International Protocol in 6 studies (19%).
5. Korotkov K5 was used for reference diastolic BP in 14 studies, K4 in 1 study, and 4 studies used K4 or K5 depending on the subject (not reported in 12 studies).
6. Twenty-two studies passed the validation protocol requirements (71%) and 9 (29%) failed (6 for systolic and diastolic BP and 3 for diastolic only). Two devices passed 1 protocol criteria and failed another.[33,45]

Table 2. Validation Studies of Automated BP Measuring Devices That Included Children

Study	Device	Use	Total N	≤12 y, N	Age Range, y	DBP Definition	Validation Protocol	Result (SBP/DBP)
Ling et al[23]	Colin BP8800MS	O	85	NR	1–16	K5	AAMI	P/P
Alpert[24]	CAS 9010	O	88	NR	4–78	NR	AAMI	P/P
Barker et al[25]	Dinamap 8100	O	55	55	5–10	NR	BHS	F/F*
Mattu et al[26]	BpTru	O	36	28	3–18	K5	AAMI, BHS	P/P
Wong et al[27]	Dinamap Procare-120	O	44	29	5–15	K5	ESH-IP	P/F
Wong et al[27]	Datascope Accutorr Plus	O	44	32	5–15	K5	ESH-IP	P/P
Wong et al[27]	Welch-Allyn Vital Signs	O	44	29	5–15	K5	ESH-IP	F/F
Alpert[28]	Welch-Allyn Spot Vital Signs	O	88	NR	5–77	K5	AAMI, BHS	P/P
Alpert and Blakely[29]	Fukuda Denshi DS-7000/NIBP-701, normal deflation	O	101	15	3-NR	NR	AAMI, BHS	P/P
	Fukuda Denshi DS-7000/NIBP-701, quick deflation							P/P
Chiolero et al[30]	Dinamap XL CR9340	O	30	30	8–10	K5	ESH-IP	F/F*
Alpert[31]	Welch Allyn SureBP, inflation algorithm	O	86	15	NR	K5	AAMI, BHS	P/P
	Welch Allyn StepBP, deflation algorithm							P/P
Alpert[32]	Welch Allyn ProBP 3400	O	92	14	NR	K5	AAMI, BHS	P/P
Lee et al[33]	Dinamap ProCare 200	O	45	NR	7–18	NR	AAMI, ESH-IP	P/P, P/F
Alpert[34]	Nihon Kohden PVM-2701/Impluse-1	O	110	41	NR	K4 or K5	AAMI; ISO	P/P
Chahine et al[35]	Omron M3500, normal mode	O	135	35	4–93	NR	AAMI/ISO	P/P
	Omron M3500, high speed mode							P/P
Meng et al[36]	Omron HBP-1300	O	85	35	4–72	K4	AAMI/ISO	P/P
White et al[37]	QuietTrak	A	122	NR	4–89	NR	AAMI	P/P
Modesti et al[38]	QuietTrak	A	33	33	3–8	K5	BHS	P/P*
Belsha et al[39]	Spacelabs 90207	A	85	49	6–18	K5 or K4	BHS, AAMI	F/F, P/F
O'Sullivan et al[40]	Takeda 2421, Korotkov method, sitting	A	529	292	7–15	K4 and K5	BHS	P/P
	Takeda 2421, Korotkov method, standing							P/F
	Takeda 2421, Oscillometric method, sitting							F/F
	Takeda 2421, Oscillometric method, standing							F/F
Jones et al[41]	AM5600	A	111	NR	7–18	K5	AAMI, BHS	P/P
Alpert[42]	Ambulo 2400	A	85	35	NR	NR	ISO, BHS	P/P
Yip et al[43]	A&D TM-2430	A	61	NR	5–15	NR	BHS	P/P
Ledyaev et al[44]	BPLab	A	30	20	5–15	K5	BHS	P/P
Redwine et al[45]	Spacelabs 90207	A	112	NR	6–17	K5	BHS, AAMI	P/P, P/F
Barker et al[25]	Omron M1	H	47	47	5–10	NR	BHS	F/F*
Stergiou et al[46]	Omron 705IT	H	197	144	6–16	K5	ESH-IP, AAMI	P/P
Narogan et al[47]	A&D UA-778	H	85	NR	4–15	NR	AAMI, BHS	P/P
Christofaro et al[48]	Omron MX3 Plus (HEM742-E)	H	165	NR	10–15	NR	BHS, AAMI	P/P
Christofaro et al[49]	Omron HEM742	H	150	NR	10–16	NR	BHS	P/P
Dong et al[50]	Raycome RBP-1200	H	87	87	3–12	K4 and K5	AAMI	P/P*

A indicates ambulatory blood pressure; AAMI, Association for the Advancement of Medical Instrumentation; BHS, British Hypertension Society; DBP, diastolic blood pressure; ESH-IP, European Society of Hypertension International Protocol; F, fail; H, home blood pressure; ISO, International Organization for Standardization; NR, not reported; O, office blood pressure; P, pass; and SBP, systolic blood pressure.

*Data from children analyzed separately (not together with adolescents and adults).

7. Results from children were reported together with those of older subjects (adolescents or adolescents and adults) in 26 studies (84%).

Taken together, these data suggest that the published evidence for the accuracy of electronic BP monitors in children is limited and with considerable heterogeneity among studies

regarding the population included, the validation protocol and criteria used, the reference method for defining diastolic BP, and the approach for analysis and reporting. Because most of the studies reported results for children together with older subjects, it might be argued that the results for children might have been different in the 2 groups if analyzed separately. An issue is that several studies did not fulfill all the requirements of the validation protocols, and misreporting of crucial data was not uncommon, which is a recognized issue also for such studies in adults.[51–53] Moreover, several negative validations are probably not published because the manufacturers prefer to further develop their devices and then retest them (publication bias).

Because electronic BP monitors are currently used in children in clinical practice and are supported by pediatric hypertension guidelines[1,6] particularly for ambulatory and home BP monitoring, the existing evidence on their accuracy has major implications for clinical practice and research. In an individual child, the BP difference between the 90th and 95th centile (which define normotension, high-normal BP, and hypertension) is only 3 to 4 mm Hg,[1] which demonstrates the major practical risks of inaccurate BP measurement. Moreover, it is scientifically problematic that the normalcy tables currently recommended[1,6] for the evaluation of ambulatory BP in children are based on a single study[54] that used a BP monitor, which has not been successfully validated in children[39,45] (Table 2).

Optimizing the Validation Procedure for BP Monitors in Children

From the validation protocols currently used in children (Table 1), the BHS, although it requires specific evaluation of devices in children, does not provide pass criteria because it is an old protocol with the last revision in 1993.[19] On the other hand, the European Society of Hypertension International Protocol, which is the most widely used protocol in adults,[51] did not specifically address the issue of pediatric validations.[21] Thus, the ANSI/AAMI/ISO[20] currently is the best available protocol for the validation of BP monitors in children. However, further development is still necessary specifically for children, and a universal protocol needs to be agreed and applied globally.

In regard to the sample size required for a validation study in children, there is consensus among the validation protocols that a minimum of N=30 to 35 is needed and that this should be performed after a successful general population study.[19–21] However, the ANSI/AAMI/ISO protocol allows a general population study to include 35 children (3–12 years) and 50 older subjects[20] and the analysis to include all the 85 subjects together. It might be argued that an automated device might be easier to pass a validation study in children that have smaller arms and lower BP levels. On the other hand, by analyzing data in children together with those in adults, it is possible that a device is inaccurate in children, yet this finding might be diluted by good results in the adults. Among 5 validation studies that provided separate analysis in children (age 3–12 years), only 2 reported a pass result.[25,30,38,50] The Spacelabs 90207 ambulatory BP monitor has passed the BHS and the AAMI protocol criteria in adults[10] but failed in 2 studies that used the same protocols in children.[39,45] The Welch Allyn Vital Signs professional office BP monitor has been successfully validated in adults[10] but failed in children.[27] Because children constitute a rather heterogeneous population, it is important that the pediatric data are analyzed separately from those in older subjects. Moreover, inclusion criteria for age distribution are needed in pediatric validations to ensure that the entire 3- to 12-year age range is well represented.

Both the European and the American guidelines for pediatric hypertension recommend the use of Korotkov sound K5 for the diagnosis of hypertension in children.[1,2] Thus, it is an important scientific inconsistency that the ANSI/AAMI/ISO standard recommends K4 for the determination of reference diastolic BP in children.[20] It is certainly inappropriate to use K4 for the validation of BP monitors and recommend K5 for diagnosing hypertension in clinical practice. The European and American guidelines base their recommendation on population data in children and risk-associated epidemiological data in adults,[1,2] whereas the ANSI/AAMI/ISO standard[20] cites a single and old invasive study in children showing K4 to be a better estimate of aortic BP.[55] Interestingly, there has been a consistent preference for using K5 in pediatric clinical research, even in validation studies (Table 2).[56] This is probably because the between-observers agreement is closer for K5 because the sounds disappearance is easier to define.[5,57] This is acknowledged by the ANSI/AAMI/ISO standard, which states that K4 seems to be more difficult to determine and most healthcare personnel are trained to recognize K5.[20] However, in cases of children with Korotkov sounds audible at complete deflation or at unphysiologically low levels, K4 should be recorded and reported.

The validation procedure is a demanding task and often too difficult for young children. It requires at least 9 sequential BP measurements, which might last longer than 20 minutes, while the child should remain seated without moving or talking.[19–21] Thus, a quality check of validation sessions is necessary in children, assessing movement, talking, and other interference that might increase the BP variability.

Perspectives

Although automated electronic devices are currently recommended and widely used for ambulatory, home, and office BP measurement in children, the published evidence on their accuracy in this population is limited. In most studies, the results in children are uncertain because they were analyzed together with those in older subjects. The current validation protocols do not adequately address all the specific requirements of BP monitors validation in children. There is need for (1) more automated devices to be tested in children; (2) a universal protocol that meets the specific issues of children to be developed, and (3) the review process for publishing validation studies to follow a detailed checklist.

Disclosures

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