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Are pitfalls of oscillometric blood pressure measurements preventable in children?

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Abstract While the routine measurement of blood pressure (BP) in children is common practice, there is lack of uniformity in the types of devices used to measure BP in children. Oscillometric devices are replacing conventional sphygmomanometry in many medical centers. However, the BP determined by these two methods is not identical, nor is it systematically different. Moreover, there is paucity of normative data on oscillometric BP measurements in children. Since oscillometric devices may well ultimately replace conventional standard mercury and aneroid manometers, users of these devices need not only to ensure strict adherence to the technique of obtaining BPs as put forth by the National Heart, Lung and Blood Institute, but also to be certain that the specific device being used has been tested for accuracy in children of the target age in accordance with standard guidelines, and that they are regularly maintained and calibrated. Due to limited normative data on BPs using oscillometric devices in children, we feel that further studies are needed before the auscultatory methods can be altogether eliminated.

Keywords Hypertension · Methodology · Sphygmomanometry · Oscillometry

Why are blood pressure measurements important in children?

The need for blood pressure (BP) measurement in children stems from the recognition that both high BP and frank hypertension are pervasive problems in adults [1]. While the epidemiology of childhood hypertension is less well defined, the reported prevalence of pediatric hypertension varies from a low of 0.8% [2] to a high of 5% [3]. Notwithstanding the lower prevalence of hypertension in children, the clinical impact of BP monitoring in children should by no means be considered negligible since childhood BP, to date, remains the strongest identified predictor for adult hypertension [4].

Even if one considers the link between childhood BP and adult hypertension suspect, the adverse effects of severe hypertension on organ function can lead to life-threatening complications such as aortic dissection [5], intra-cranial hemorrhage, heart failure [6], and encephalopathy [7]. Less devastating, but possibly an equally worrisome effect of hypertension, is left ventricular hypertrophy, a major risk factor in adults for morbid cardiac events [8].

Recognizing the importance of BP monitoring, the National Heart, Lung, and Blood Institute and the American Academy of Pediatrics have long advocated the routine monitoring of BP in all children above the age of 3 years on an annual basis [9], or at least at the time of routine examinations. Consequently, BP measurements in children have become commonplace in the medical field. However, at the same time, so has the number of different devices being employed for its measurement, causing confusion and lack of uniformity in the method of BP determination. This raises important questions regarding the validity and accuracy of these devices and also underlies the need for having a standardized means of testing and monitoring their performance to avoid errors in measurement that could have egregious consequences. The purpose of this review is specifically to address oscillometric devices and their use in children. Details pertaining to the process of BP determination in

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children, such as their position, the choice of cuff, etc., are not addressed.

Overview and mechanics of oscillometric devices

Oscillometric devices have all but replaced the mercury manometer in a large number of medical centers, especially in European countries where concern about environmental contamination with mercury has been greater [10]. A recent informal poll of pediatric nephrologists revealed that 47% of the 36 respondents used oscillometric devices for BP measurement most of the time, and an additional 17% used them exclusively (personal communication via the PedNeph List-Serv, April 17, 2002). Development of the first commercial oscillometric device for BP measurement started in the early 1970s and resulted in the 'Dinamap', an acronym for 'device for indirect noninvasive mean arterial pressure' [11]. Since that time, a plethora of oscillometric devices for automated BP measurement has flooded the market, including several new modifications of the original Dinamap Model 825 (Critikon division of Johnson and Johnson, Tampa, Fla., USA). The fundamental concept underlying these devices is the same as that of other cuff-based BP measuring devices, in that compression of the brachial artery by an inflatable cuff allows indirect determination of the intra-arterial vascular pressure. However, the physiological differences among the various devices are potentially sizeable, since the auscultatory method relies on the association between Korotkoff sounds and systolic and diastolic pressure, while oscillometry relies on the association between the amplitude of oscillations of the arterial wall and BP. Another difference is that in oscillometric devices cuff inflation and deflation are always automated and that BP determination is made by a microprocessor using information sent to it from a pressure transducer; this potentially is tremendously advantageous since it should eliminate all observer biases. In brief, the BP cuff gets automatically inflated to between 160 and 180 mmHg (or 70–125 mmHg in the neonatal mode), depending upon the specific device, for the first BP determination and subsequently to between 20 and 35 mmHg above the previously recorded systolic value [11]; in some newer devices, the level of inflation can be selected by the user. After a brief holding period, the cuff pressure is reduced in a discontinuous manner in 5- to 10-mmHg decrements. As the cuff pressure decreases, oscillations of the arterial wall increase in amplitude and reach a maximum when the cuff pressure approaches the mean arterial pressure. With further deflation of the BP cuff, oscillations of the arterial wall diminish and eventually stop altogether. The monitor uses this information to compute and display values for the mean, systolic and diastolic BP. The precise method of BP determination is far more complicated and is determined by a complex algorithm that varies from one device to another; the pressures displayed on the monitor, therefore, may be 'calculated' rather than actually 'measured'. These algorithms

have been considered proprietary information and are therefore kept in confidence, making it impossible for investigators to verify the accuracy of their underlying physiological principals.

Advantages of oscillometric devices

The potential advantage of oscillometric devices over conventional sphygmomanometry is manifold. First and foremost, they are felt to be convenient and easy to use, theoretically eliminating the need for highly trained personnel, although this may not truly be the case [12]. Moreover, by avoiding terminal digit preference and bias related to prior knowledge of recorded BPs, use of these devices, if accurate, may improve measurement precision and substantially lower the sample size required in clinical trials of hypertension. For younger children, neonates, and infants, in whom movements of the arm may make it difficult to use auscultation, oscillometric devices use a more reliable method, albeit not completely so. The success of oscillometric devices in obtaining BPs has been demonstrated in this age group by Park and Menard [13]. The use of such devices also obviates the controversy of whether the Korotkoff 4 or Korotkoff 5 sound, during conventional sphygmomanometry, is a more accurate reflection of diastolic BP [14], since the oscillometric devices correlate very closely with direct intra-arterial diastolic pressures [15].

The greatest advantage of these devices may turn out to be an ecological one. Since oscillometric devices do not use mercury they may eventually supplant all mercury manometers due to the previously mentioned concern about the environmental hazard posed by this element [10]. Alternatively, aneroid manometers, when properly maintained are a less expensive, accurate alternative to mercury [16], but they suffer from the other observer biases encountered with the mercury manometer.

Problems with oscillometric devices

While oscillometric devices, when correctly chosen, can greatly add to the management of patients with hypertension and improve clinical trials, their use is not without problems. Caution must be advised before a particular device is chosen for use, since the accuracy of many newer devices has not been tested in an unbiased manner. In addition, these are expensive pieces of equipment and need continued upkeep and servicing to ensure optimal functioning, all of which adds to their cost. This includes the need for periodic calibration with a frequency ranging from once every 3 months to once every 2–3 years, either against a mercury manometer or non-mercury standards, depending on the specific piece of equipment. Certain drawbacks also exist in the design of these machines. While perhaps not applicable to any great extent in pediatrics, it is noteworthy that the upper limit of systolic pressure that these devices can measure

Table 1 Comparison of the various methodologies for casual blood pressure (BP) measurement

	Advantages	Problems
Conventional sphygmomanometry (CS)	Easy to use Inexpensive Commonly available Pediatric BP normative data based on it	Operation: observer biases Output: affected by technique, environmental, and mechanical factors (e.g., cuff size) Debate over use of K4 vs. K5 as being representative of diastolic BP
Mercury	Perhaps the “gold” standard Minimal maintenance required to maintain calibration	Environmental issues re handling, spills, disposal Often not maintained
Aneroid	Portable; inexpensive Accurate Measures same parameters as mercury	Easily loses calibration Gauge more subject to bias/misread than mercury column? Often not calibrated
Oscillometry	Easy to use No mercury in the instrument Frees user to allow more than one thing to be done at the same time Eliminates observer biases Easier to use in infants and young children compared with CS	Design: expensive and requires periodic maintenance Many devices on the market, few of which have been validated for use in children Output: affected by technique, environmental, and mechanical factors (e.g., cuff size). High initial inflation pressure may cause anxiety and motion artifacts Limited normative data available for children BP reading not equivalent to CS readings

is limited and varies from 240 to 280 mmHg (or about 160–190 mmHg in the neonatal mode) [15]. Difficulties may also arise in BP measurements in children with cardiac arrhythmias and in those children who are uncooperative and cannot hold still, leading to motion artifacts, although this may also be true with conventional sphygmomanometry [11]. Moreover, the rapid rate of inflation of the cuff by the machine may be uncomfortable and disconcerting to children, and may cause them to resist the BP measurement, leading to erroneously high readings. In fact, a ‘first-reading’ effect, in which the first of several BP readings is 3–5 mmHg higher than subsequent readings a few minutes later, has been noted by several investigators using oscillometric as well as auscultatory devices [13, 17]. Therefore, repeat measurements of BP are important in children to avoid overdiagnosis of hypertension. The optimal number of measurements, per patient and per visit, for oscillometric devices, may vary from machine to machine. For one particular device, the Dinamap 845 XT, the reliability was noted to increase quite significantly when the number of BP measurements went from three to four per visit, and the number of visits went from one to two [18]. Lastly, an issue that has irked clinical investigators for long is the knowledge that the algorithms used for determination of BP by oscillometric devices vary from one manufacturing company to another and also between different models of the same device. These algorithms have been considered to be proprietary information, and being confidential, have never been subjected to scientific scrutiny, causing health-care professionals to be somewhat skeptical of their validity [19]. Some important advantages and disadvantages of oscillometric devices compared

with auscultatory methods of BP measurement are shown in Table 1.

Comparability of oscillometric devices with other methods of BP determination

In the PedNeph survey, 67% of the respondents felt that oscillometric devices gave accurate and reliable BP readings for clinical decision making, and as many as 55% perceived the devices to be accurate enough even for purposes of clinical research. Several studies have demonstrated the accuracy of oscillometric devices in measuring BP in children. However, it is important to remember that all oscillometric devices do not report the same results when used simultaneously in the same patient [20], so it is crucial to keep the specific type of device in mind when determining its suitability. Studies have evaluated the correlation of oscillometric readings with BP readings obtained by invasive means. Park and Menard [15] compared the Dinamap model 1846 and a conventional mercury sphygmomanometer with radial artery pressures in a group of infants and children admitted to the intensive care unit. While both the Dinamap 1846 and the conventional mercury sphygmomanometer readings correlated well with intra-arterial BP measurements, the correlation coefficient was better for BP readings obtained using the Dinamap 1846. The difference between the Dinamap 1846 and intra-arterial BP readings was small and ranged from –7 to +7 mmHg, –9 to +10 mmHg, and –10 to +8 mmHg for systolic, diastolic, and mean BP, respectively. Similarly, BP readings obtained in infants using the Dinamap 847 neonatal and

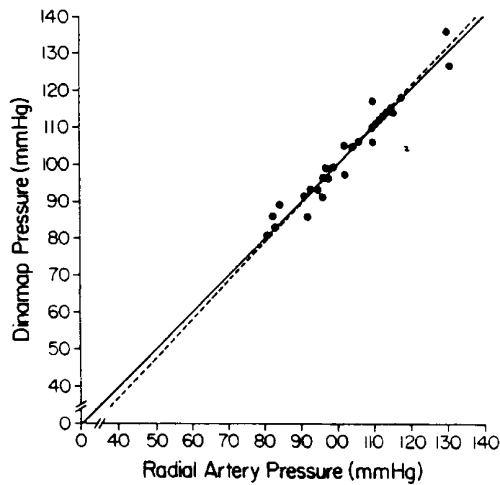


Fig. 1 Relationship between systolic pressure measured by Dinamap and by radial artery catheter. Linear regression equation is $y=1.05x-5.36$ and $r=0.970$, where y =the Dinamap and x =radial artery pressures. *Broken line* is calculated regression line; *solid line* is line of identity. (Reprinted from [15])

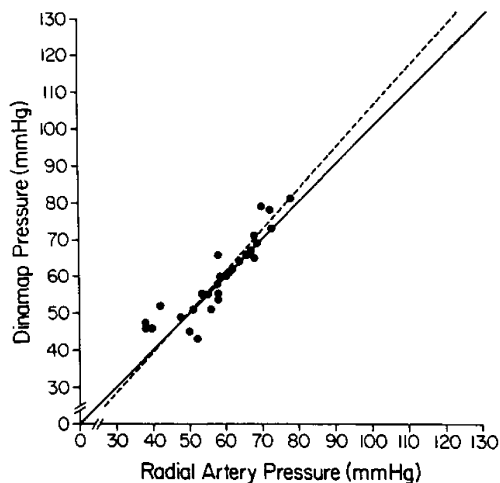


Fig. 2 Relationship between diastolic pressure obtained by Dinamap and by radial artery catheter. Linear regression equation is $y=1.10x-4.65$ and $r=0.903$. *Broken line* is calculated regression line; *solid line* is line of identity. (Reprinted from [15])

Dinamap 845 vital signs monitor were found to correlate well with BP values obtained using a central aortic catheter, with even smaller mean absolute pressure differences than seen in the previous study [21] (Figs. 1, 2).

Recent comparisons between BP readings using a mercury sphygmomanometer and some oscillometric devices, especially the newer models, demonstrate that the two methods are not comparable. A large single-center study evaluating the newer Dinamap model 8100 against the conventional mercury sphygmomanometer in over 7,000 children found that the mean Dinamap 8100 readings were higher for both systolic (by 10 mmHg) and diastolic (by 5 mmHg) values. However, the 95th percentile confidence intervals for differences in systolic and diastolic BPs between the two methods were quite large and

Table 2 Protocols for assessment of the accuracy of BP measuring devices – British Hypertensive Society (BHS) grading criteria

Grade	Difference between test and 'standard' device readings (%)		
	≤5 mmHg	≤10 mmHg	≤15 mmHg
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse	Worse	Worse

Table 3 Protocols for assessment of the accuracy of BP measuring devices – Association for the Advancement of Medical Instrumentation (AAMI) criteria

Grade	Mean difference between devices	Standard deviation
Pass	≤5 mmHg	≤8 mmHg
Fail	>5 mmHg	>8 mmHg

ranged from -4 to $+24$ mmHg and -14 to $+23$ mmHg, respectively, making the 'error' non-systematic and unpredictable [22]. Similarly, in the Bogalusa Heart Study, significant differences were noted in BPs obtained using the Dinamap 8100 and a conventional sphygmomanometer. While the mean systolic pressure with the Dinamap 8100 was higher than that obtained using a conventional sphygmomanometer, similar to the study of Park and Menard [15], the mean diastolic pressure was, in fact, lower with the Dinamap 8100 [17]. Moreover, an age-related difference was noted in the discrepancies between the two devices for diastolic BP. In children under 8 years of age, the Dinamap 8100 diastolic BPs were higher compared with the conventional sphygmomanometer readings, while in children over 8 years, the Dinamap 8100 underestimated diastolic BP (Tables 2 and 3).

Based on the guidelines put forth by the British Hypertensive Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI) for evaluating BP measuring devices for accuracy [23], O'Brien et al. [24] recently reviewed several oscillometric devices available in the market and found that only a few fulfilled accuracy criteria for both protocols. Some of the devices that are recommended in this report for use in children are the CAS Model 9010 (CAS Medical systems, Branford, Conn., USA) for in-hospital use, the Omron HEM-750CP (Omron Health Care, Vernon Hills, Ill., USA) for self-measurement and the Daypress 500 (Neural Instruments, Florence, Italy) for ambulatory BP monitoring, although only at rest. One of the more commonly used oscillometric devices in the United States, the Dinamap model 8100, has yielded varying results when tested for accuracy.

Few pediatric studies have followed the strict guidelines of the AAMI and BHS protocols to evaluate the Dinamap 8100. In a small study in a cohort of pre-pubertal children (8–13 years old), compared with the conven-

tional sphygmomanometer, the Dinamap 8100 was found to overestimate systolic BP and underestimate diastolic BP. These differences, however, were within the range acceptable by both the validation standards [25]. The mean difference (standard deviation) between the BP readings obtained by the Dinamap 8100 and the conventional sphygmomanometer was 4.8 (7.5) mmHg for systolic and -1.9 (7.5) mmHg for diastolic BP, making the device acceptable to the AAMI. Similarly, using the BHS criteria, the Dinamap 8100 achieved a grade of B since more than 50% of its readings were within 5 mmHg and more than 90% were within 15 mmHg of the conventionally obtained measurements. However, other studies have not been as supportive of this device. In a study by O'Brien et al. in 1993 [26], the Dinamap 8100 was evaluated for accuracy in an adult population according to the strict guidelines of the BHS protocol, and found to achieve a grading of D (unacceptable) for diastolic BP and B (acceptable) for systolic BP. Therefore, in the absence of further study in a larger group of children, the use of the Dinamap 8100 cannot be recommended without reservation. Furthermore, it has recently been documented that the Dinamap has been programmed in such a way that it specifically cannot report certain values of BP [27]. When data from three separate studies were pooled together, certain 'skip' patterns were noted for systolic BP using two different models of the Dinamap; several systolic BP values such as 89, 119, 120, and 124 mmHg were never reported by the device. While this 'error' would probably not significantly impact the clinical management of patients, it could affect epidemiological studies, since the direction and extent of the 'error' are unpredictable.

Also, while several oscillometric devices designed for BP determination at the wrist are available and may potentially reduce the error related to cuff size (since there is less variation in cuff and wrist dimensions between ages compared with arm size differences), none of these devices have been validated for use in children [24].

How do we reconcile the concerns with oscillometric devices?

It is unclear as to whether the source of the discrepancy in the readings between oscillometric devices and conventional sphygmomanometry is mechanical and lies in the oscillometric device, or due to observer error while using the conventional sphygmomanometer. Moreover, the lack of perfect concordance between the Korotkoff sounds and arterial wall oscillations further adds to the problem. It is also certainly possible that the 'error' arises from the more accurate determination of BP (especially the diastolic BP) by the oscillometric device. Perhaps oscillometry measures a 'truer' pressure, closer to intra-arterial BP, thereby eliminating the error inherent in the conventional sphygmomanometer, which necessarily has to rely on the Korotkoff sounds as an indirect and approximate indicator of 'true' pressure [28]. It must be

noted that the currently accepted normal values for BP in children [9] are based upon measures that were exclusively obtained by auscultation. What is clear from studies comparing oscillometric devices with conventional sphygmomanometers is that these two methods of BP measurement should not be used interchangeably and that they may be measuring different biological parameters.

However, it is apparent that these devices are beginning to replace auscultation. Users of oscillometric devices must bear in mind several issues to ensure reproducibility and accuracy of BP measurements obtained using these devices.

1. Of greatest importance is the need to use devices that have been validated, using the aforementioned guidelines, in children.
2. All oscillometric devices, no matter how accurate when taken out of the box, are machines subject to mechanical and electrical stress. Calibration and maintenance on a regular basis are critical.
3. Although oscillometric devices eliminate observer bias, they share with the sphygmomanometer the likelihood that BP readings may be affected by environmental (e.g., ambient temperature) and patient factors (e.g., stress and arm size-cuff size discrepancies), towards which meticulous attention must be directed.
4. As mentioned earlier, BPs obtained by conventional sphygmomanometry and using oscillometric devices should not be used interchangeably for study purposes, since even with the most accurate of devices, differences do exist between the two.
5. Lastly, normative data in use at present in children are based on BP measurements obtained by conventional sphygmomanometry. Therefore, using these norms to determine if the BP, measured in a particular child by an oscillometric device, is normal or not, may not be appropriate. Some normative reference data on BPs using an oscillometric device are available for children younger than 5 years of age [13]; the number of children studied, however, was quite small, and limited to a single device that is no longer manufactured. Further studies are certainly needed to establish more accurate normative data on oscillometric BP measurements before a complete substitution can be made from using mercury manometers to oscillometry.

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