

Reliability of the Automatic Blood Pressure Monitor for Measuring the Blood Pressure in Children

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Abstract

Background: The mercury sphygmomanometer has been the gold standard used for obtaining blood pressure (BP). However, due to environmental concerns and more use of automated BP devices, an alternative to using the standard mercury sphygmomanometer to measure BP. **Aim:** The aim of this study is to determine the reliability of Automatic Blood Pressure Monitor (ABPM) for measuring the blood pressure in children. **Methods:** One thousand children were enrolled in this study. Those who were critically ill and those who did not give consent were excluded. The accuracy of Omron HEM-7121 BP readings was compared with that of mercury BP device readings. All children rested for 5 min prior to the first BP reading. Each children had four BP measurements recorded sequentially i.e. two valid systolic readings, and two valid diastolic readings by both methods. **Results:** BP taken with the automated (OMRAN) device was systolic 104.71 ± 6.75 and diastolic was 67.90 ± 6.89 . Compared to systolic 107.82 ± 7.49 , and mean diastolic of 69.61 ± 7.21 measured by manual mercury sphygmomanometer BP readings ($P < 0.001$). The comparison of the manual versus the automated readings showed a high coefficient of correlation (r^2) for systolic BP ($r^2 = 0.86$) and diastolic BP ($r^2 = 0.89$) readings. Comparison of mean differences between automated and manual measures showed the automated machine consistently under-read both systolic and diastolic blood pressures. Linear regression analysis showed that the automated systolic BP and is a significant predictor ($\hat{\alpha} = 0.864$, $P < 0.001$) of manual systolic BP. Similarly, automated diastolic BP was also a significant predictor ($\hat{\alpha} = 0.806$, $P < 0.001$) of manual diastolic BP. **Conclusions:** This study concludes that the automated blood pressure device is reliable and accurate for measuring the BP in children. So, Conventional manual BP readings can be replaced by readings taken using a validated, automated BP recorder in population surveys.

Keywords: Mercury Sphygmomanometer; Automatic Blood Pressure Monitor; Systolic Readings; Diastolic Readings.

Introduction

Blood pressure (BP), also referred to as arterial blood pressure, is the pressure exerted by circulating blood upon the walls of blood vessels, and is one of the principal vital signs.¹ An accurate assessment of blood pressure is very important for the diagnosis

and treatment of hypertension.²⁻³ The importance of attaining the diagnosis of high blood pressure and its continuous monitoring are well known. The blood pressure profiles in childhood varies with age, sex, weight, height, body mass index (obesity), family history of hypertension, socio-economic status and dietary habits⁴⁻⁵. Studies have concluded that both systolic and diastolic blood pressure have an direct

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correlation with weight and with height (independent of age)⁶⁻¹⁰. Although digital monitors are much easier to use when compared to the mercury sphygmomanometers, it is essential to establish their reliability and validity. Traditionally, blood pressures have been measured using a manual mercury sphygmomanometer, but in recent years the use of automated blood pressure machines such as the Dinamap and Omron have been the trend in most hospitals.¹¹ It is predicted that it is only matter of time when alternatives to 100 year old mercury sphygmomanometer will be completely replaced. There is some evidence in the literature that digital monitors are reliable and accurate when compared with other devices, such as the aneroid or mercury devices.¹²⁻¹⁵ It seems that this type of equipment can replace the others in some contexts, such as at home or in epidemiological studies within the community. The level of agreement between automated and manual blood pressure measurements can vary for systolic and diastolic readings, and in relation to type of machine and patient population. However, most studies were done only on adults, and therefore, the reliability of automated blood pressure machines among children's is unclear¹⁶⁻¹⁷. This study was done to determine the reliability of automatic BP machine for measuring the Blood pressure in children.

Material and Methods

Study Design

Diagnostic study.

Setting

The AVBRH, Sawing is the rural medical college located in Maharashtra. This study was conducted over a period of 2 years, beginning from August 2013 to July 2015.

Participants

1. Inclusion criteria: Children were age 5-15 years and no known history of serious illness.
2. Exclusion criteria: 1) Ill children 2) Those who did not give consent

Data Collection

The study was commenced after obtaining clearance from the Institutional Ethics committee (Ref. No. DMIMS(DU)/IEC/2013-14/162). Children were explained about study in their local language. A semi-

structured pre-tested proforma was filled. Parents were asked to provide written informed consent for this study and those who were not willing were excluded from the study.

Method of Collection of Data

BP measurements were taken by postgraduate student in pediatrics.

Equipment

- ❖ The manual device which was used is a standard mercury sphygmomanometer (M) with an appropriate cuff and Littman Classic II stethoscope.
- ❖ The automated device (A) which was used is the OMRON machine with different size of cuffs [HEM-CS24 17-22cm(7-9inch) & HEM-CR24 22-32cm(9-13inch)].
- ❖ All machines which were used in the study were calibrated and checked for compliance to machine standards by the Biomedical Engineering Department of the Hospital.

Measurement of Blood Pressure

The research was approved by an Institutional Ethics Committee (IEC) and informed consent was obtained from the parents. Children were positioned supine, with arms straight and legs uncrossed. Appropriate size of the cuff was selected by measuring mid arm circumference at the halfway point between shoulder tip and elbow tip. After that, we fitted the cuff to the patient's arm.

By Mercury sphygmomanometer(M)

Firstly, we determined a 'systolic estimate' of the children BP by inflating the cuff until the radial pulse can no longer be palpated. Then, again inflate the cuff a further 30mmHg and release the valve at 2mmHg per second until the radial pulse reappears. We recorded this reading as the systolic BP estimate.

Again we inflated the cuff to 30mmHg higher than the 'systolic estimate' and then slowly deflated the cuff at 2mmHg per second and, using a stethoscope, record measures corresponding to the 1st and 5th Korotkoff sounds. 1st Korotkoff sound was considered as systolic BP and 5th Korotkoff sound was considered as diastolic BP. If Korotkoff sounds persist, the measurement was repeated with less pressure on the stethoscope head. If the sounds persist at low

intensity, then K4 (muffling of sounds) was recorded as the diastolic pressure.

By Automatic blood pressure machine (A)

The Omron HEM-7121 automatic measurements are based on smart “inflate” technology (IntelliSense), where inflation is driven by a pumping system, and deflation is driven by an electromagnetic control valve that allows rapid air release. We pressed ‘start’ button on machine to commence BP measurement. Record was digitally displayed as systolic and diastolic BP.

Frequency of BP Measurement

For each person, the average of the 2 measurements were calculated from the two devices, which leads to four readings per subject denoted as systolic manual, systolic automated, diastolic manual, and diastolic automated. Half of the BP was measured first with the digital and subsequently with the mercury one, whereas the remaining half was evaluated in the opposite order. Heart rate was also obtained. There was a 2-min break between automatic and manual BP readings.

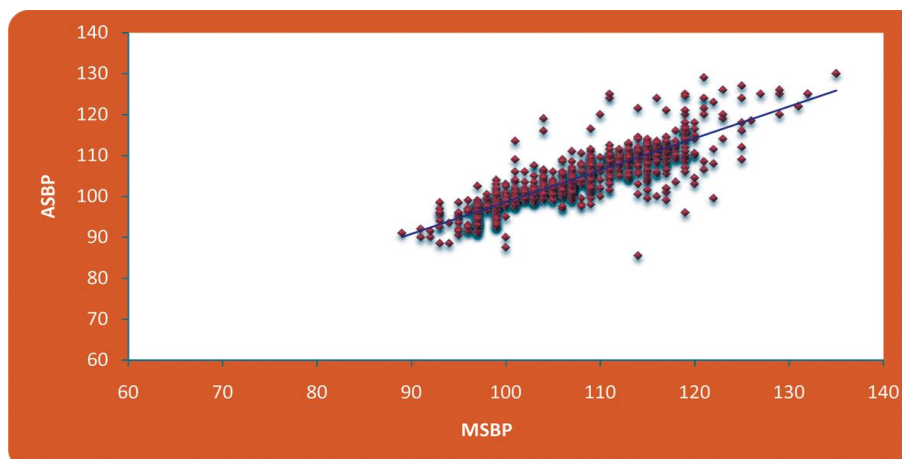
Statistical Analysis

All the data collected by means of questionnaire was entered in the Microsoft Office Excel software version 2007. Each of the variables associated with Blood pressure were studied and analyzed. The analysis was done using SPSS 17 software. Means and standard deviations of manual and automated systolic and diastolic BP values were calculated. A p value of <0.05 was considered to be statistically significant and p value of <0.001 as highly significant. A paired t-test was used to assess the differences

between the manual BP and automated BP readings. Pearson’s correlation coefficient was used to determine the relationship between BP’s measured by manual and automated BP device. Bland-Altman plots were used to show the distribution of the differences between the methods at all pressures and the mean and standard deviation of the differences. A linear regression analysis was performed to examine the relationship between the automated and manual BP readings with the automated systolic and diastolic BPs as the independent variables.

Results

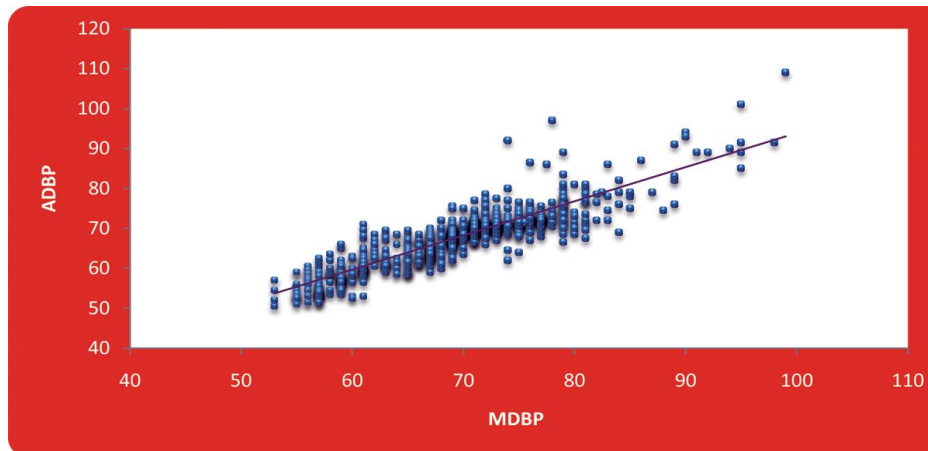
We included 1000 children of 5-15 years studied, maximum children were in the age 14 years (154) followed by 5 years (130) and with mean age being 9.74. Out of total 1000 children, 54% were males and 46% were females with a ratio of M: F =1.17:1. we found that SBP and DBP was more in females compared to males by both Mercury sphygmomanometer and Automated device but difference was not statistically significant and also as the age increases systolic and diastolic blood pressure values by both Mercury sphygmomanometer and Automated device also increases significantly. Mean SBP was 107.82 ± 7.49 and mean DBP was 69.61 ± 7.21 by Mercury sphygmomanometer and by Automated device SBP was 104.71 ± 6.75 and DBP was 67.90 ± 6.89 . ($P < 0.001$). The comparison of the manual versus the automated readings showed a high coefficient of correlation (r^2) for systolic BP ($r^2 = 0.86$) and diastolic BP ($r^2 = 0.89$) readings. *Linear regression analysis* showed that the automated systolic BP is a significant predictor ($\beta = 0.864$, $P < 0.001$) of manual systolic BP with a regression equation (systolic BP = $20.70 + 0.779 * ASBP$).



Graph 1: Scatter plot of Omron and mercury systolic blood pressure values overlaid by regression and unity lines

Linear regression analysis showed that the automated diastolic BP was also a significant predictor ($\beta = 0.806, P < 0.001$) of manual diastolic BP with a

regression equation (Diastolic BP = $8.39 + 0.855 \times$ automated diastolic).



Graph 2: Scatter plot of Omron and mercury diastolic blood pressure values overlaid by regression and unity lines

Coefficient of correlation was calculated to assess the relation between BP and anthropometric variables

By using Pearson’s Correlation Coefficient significant positive correlation was found between height and SBP($r=0.755$), weight and SBP($r=0.748$), BMI and SBP($r=0.606$ and midarm circumference and SBP($r=0.587$) and also significant positive correlation was found between height and DBP($r=0.642$), weight and DBP($r=0.634$), BMI and DBP($r=0.508$) and midarm circumference and DBP($r=0.545$). This reveals that as Anthropometric parameters increases SBP and DBP mmHg also increased significantly by Mercury sphygmomanometer and for automated device by using Pearson’s Correlation Coefficient significant positive correlation was found between height and SBP($r=0.659$), weight and SBP($r=0.665$), BMI and SBP($r=0.569$) and

midarm circumference and SBP($r=0.497$) and also significant positive correlation was found between height and DBP($r=0.557$), weight and DBP($r=0.542$), BMI and DBP($r=0.435$) and midarm circumference and DBP($r=0.474$). This reveals that as Anthropometric parameters increases SBP and DBP mmHg also increased significantly by Automated device.

Bland–Altman plot (Fig. 3 and 4) demonstrates the mean difference between systolic and diastolic blood pressure measured by Mercury Sphygmomanometer & automated BP device (OMRON). Black line is the mean of the differences; dotted lines are both lower and upper 95% confidence interval. If the differences within mean ± 1.96 SD are not clinically important, the two methods may be used interchangeably.

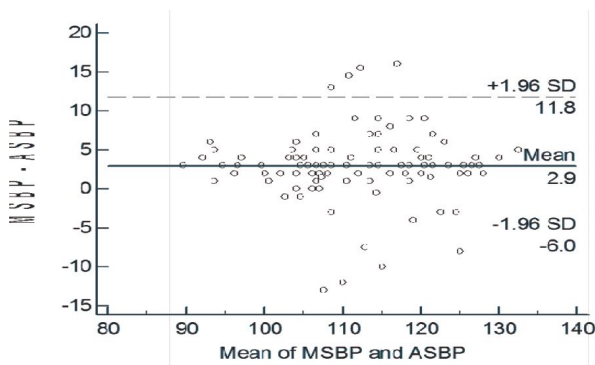


Fig. 3: Bland and Altman plot showing difference of systolic BP (SBP) between mercury sphygmomanometer and automated device.

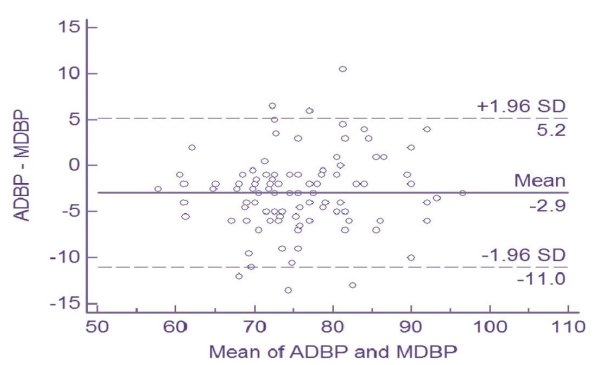


Fig. 4: Bland and Altman plot showing difference of diastolic BP (DBP) between mercury sphygmo-manometer and automated device

In our study we made percentile graphs and plotted systolic and diastolic blood pressure values of both

mercury and automated against 5th, 10th, 15th, 25th, 50th, 75th, 90th, and 95th percentiles.(fig 5 and fig 6)

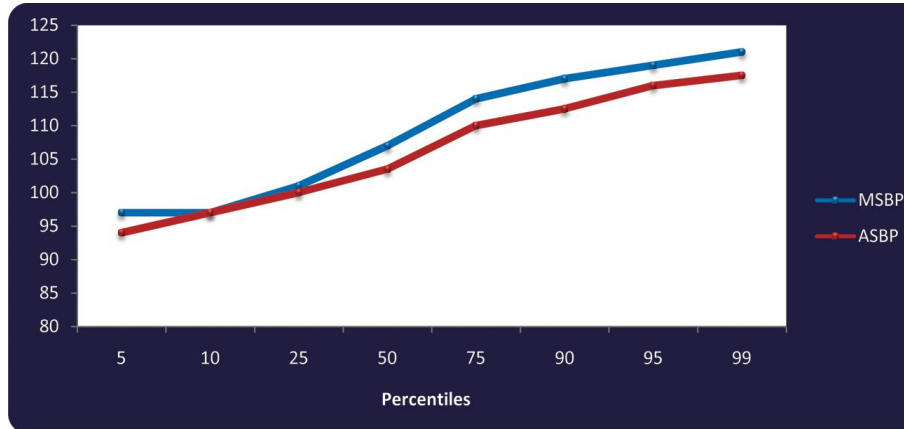


Fig. 5: Systolic Bp Percentile Graph

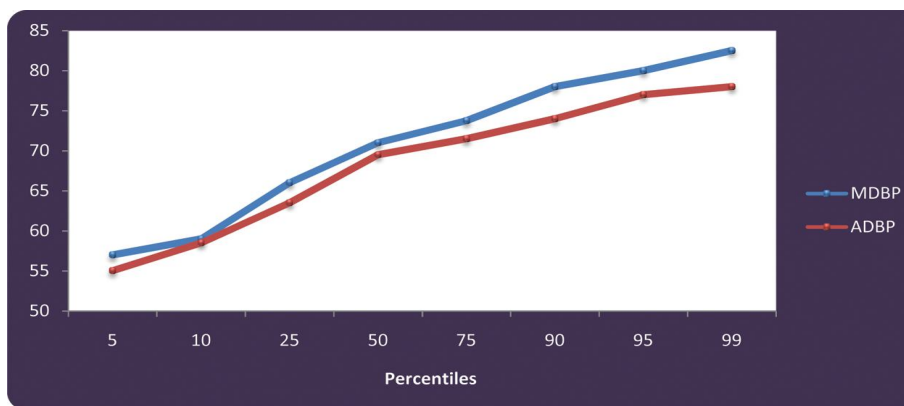


Fig. 6: Diastolic BP Percentile Graph

Discussion

Blood pressure (BP), also referred to as arterial blood pressure, is the pressure exerted by circulating blood upon the walls of blood vessels, and is one of the principal vital signs. An accurate assessment of blood pressure is very important for the diagnosis and treatment of hypertension. The importance of attaining the diagnosis of high blood pressure and its continuous monitoring are well known. The blood pressure profiles in childhood varies with age, sex, weight, height, body mass index (obesity), family history of hypertension, socio-economic status and dietary habits. In recent years the use of automated blood pressure machines has become the norm in most hospitals. Reasons for this trend are that automated machines are easier to use, allow continuous or intermittent blood pressure monitoring, provide printouts of readings, and for some machines, allow pulse rate and oxygen saturation levels to be taken concurrently. However, blood pressure monitoring has been challenging, because aneroid and mercury manometers are expensive and require a trained health professional to use them. As an

alternative, digital devices have received growing attention, and well-known health associations are recommending their use. The replacement of manual recorders such as the mercury sphygmomanometer with Automatic Blood Pressure Monitor is relatively inexpensive, requires minimal training, and will make accurate BP measurement much less dependent on the expertise and training of the person recording the BP.

Regardless of the recommendations, the validity of digital monitors needs to be confirmed prior to their widespread utilization.

The study done by *Sigurdsson JA et al*¹⁸ found that the agreement between the automatic BP and the conventional mercury sphygmomanometer in adult is unsatisfactory for clinical purposes and therefore the methods are not interchangeable. *Shibata K et al*¹⁹ concluded that the reproducibility of BP measured with mercury sphygmomanometer was less than 4%, with each Digital sphygmomanometer less than 9%. In another study, *Rotch AL et al*²⁰ reported that compared with the mercury sphygmomanometer, the automatic monitor was the most accurate in measuring. *Eliasdottir SB et al*²¹ found a significant

correlation between the difference in systolic BP obtained by the two methods and BMI ($r = 0.077$, $P = .013$), while the correlation with BMI percentile, height, and weight did not reach statistical significance. The difference in diastolic BP obtained using the two methods correlated significantly with height ($r = 0.10$, $P = .001$) but not with weight, BMI, or BMI percentile. In our study we found positive correlation of blood pressure values by both the methods. *Menezes AM et al*²² reported the digital device showed a high level of agreement with the mercury manometer when measuring systolic BP. The level of agreement was lower for diastolic BP. In our study, we found high level of agreement between BP measured by manual mercury sphygmomanometer and automated devices which was similar to our study. *Wong WC et al*²³ showed that the average absolute difference between measurements with the patient's BP Automated device and the mercury sphygmomanometer for systolic BP (SBP) was 9.5 mmHg ($P = 0.40$) and for diastolic BP (DBP) 9.4 mmHg ($P = 0.08$). The agreement between the mercury sphygmomanometer and the automated devices was poor, with average differences of 9.5 mmHg for systolic and 9.4 mmHg for diastolic and no clear advantage for either site of measurement. *Mohamed A et al*²⁴ showed that the Omron M-51 and the Omron 705IT devices pass the validation recommendations of the international protocol. And can be used interchangeable with mercury sphygmomanometer. Bland-Altman plot were plotted to showed the positive correlation. *Bern L et al*²⁵ found a statistically significant difference in BP obtained with an automated BP method as compared to the manual BP method. Bland-Altman graphing techniques showed a wide variation in differences between systolic and diastolic BP by both the devices. Previous studies (13-16) comparing the Omron (automated) device with mercury consistently showed lower readings of Omron (automated) for both systolic and diastolic BP (7-10). *The Ostchega Y et al*¹² reported that the Omron (automated) and mercury device measurements were correlated ($r = 0.92$ for systolic BP and $r = 0.79$ for diastolic BP), same finding was found in our study also. A high coefficient of correlation (r^2) was found for systolic BP ($r^2 = 0.86$) and diastolic BP ($r^2 = 0.89$). A study conducted by *Menezes A MB et al*²², he gave Descriptive data on BP measurement in adolescents and he plotted values in percentiles 5th, 10th, 25th, 50th, 75th, 90th, 95th percentile of systolic and diastolic BP by both mercury manometer and Digital manometer. 5th percentile systolic BP for boys, MSBP was 93.0 ASBP was 95.8 and for girls MSBP was 88.5 and ASBP was 82.3, and diastolic BP for boys, MDBP was 47.5, ADBP was

54.5 and for girls, MDBP was 42.5 and ADBP was 52.8. 95th percentile systolic BP for boys, MSBP was 139.5, ASBP was 142.3 and for girls MSBP was 122.0 and ASBP was 122.0, and diastolic BP for boys, MDBP was 81.0, ADBP was 86.8 and for girls, MDBP was 76.5, and ADBP was 79.8. In our study, BP measurement in children were plotted in percentiles across 5th, 10th, 25th, 50th, 75th, 90th, 95th percentile. 5th percentile value for MSBP was 97, MDBP was 57, ASBP was 94 and ADBP was 55.02 and 50th percentile for MSBP was 107, MDBP was 71, ASBP was 103.50 and ADBP was 69.50, and 90th percentile for MSBP was 117, MDBP was 78, ASBP was 112.50 and ADBP was 74.

Conclusion

This study concludes that the automated blood pressure device is reliable and accurate for measuring the BP in children. Also, we can use this device in the pediatric OPD as there is no risk of mercury leakage and also reduces individual differences in measurement methods (human error).

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