

Similarity between blood pressure values assessed by auscultatory method with mercury sphygmomanometer and automated oscillometric digital device

Similaridade entre os valores da pressão arterial aferida pelo método auscultatório com aparelho de coluna de mercúrio e o método oscilométrico automático com aparelho digital

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ABSTRACT

Introduction: One of the biggest challenges in the management of hypertension is adequate blood pressure (BP) control. To achieve this goal, home blood pressure measurement (HBPM) with automated devices has been encouraged. However, part of the medical community still disputes its validity, believing that HBPM may lead to incorrect readings. **Objective:** To evaluate the correspondence between the simultaneous measurements of BP with the auscultatory method and an oscillometric digital method, commonly used in HBPM. **Methods:** BP was determined simultaneously in 423 individuals (normotensive and hypertensive) with a validated automated digital device (ONROM 705IT) and with the auscultatory method with a mercury sphygmomanometer. Both devices were connected through a Y-shaped connection to a cuff whose size was adjusted to the arm circumference. **Results:** The values represent mean \pm SD (minimum-maximum values): age 40.8 ± 16.3 years (18–92), arm circumference 28.2 ± 3.7 cm (19–42), systolic BP (SBP) auscultatory 127.6 ± 22.8 mmHg (69–223), SBP automated 129.5 ± 23.0 mmHg (56–226), diastolic BP (DBP) auscultatory 79.5 ± 12.6 mmHg (49–135) DBP automated 79.0 ± 12.6 mmHg (48–123). The mean difference in SBP between the two methods was 1.9 mmHg (-15 to +19) and 0.5 mmHg for DBP (-19 to +13). The Bland-Altman analysis showed clinically acceptable agreement between the methods. **Conclusion:** BP measured with the automated method closely mirrors that determined with the conventional auscultatory method

RESUMO

Introdução: Um dos maiores desafios no manejo da hipertensão arterial é o adequado controle pressórico. Para se alcançar esse objetivo tem se difundido a medida residencial da pressão arterial (MRPA) com aparelhos automáticos. Entretanto, parte da comunidade médico-científica ainda discute sua validade, acreditando que as medidas pressóricas domiciliares podem ser incorretas. **Objetivo:** Avaliar a correspondência entre as medidas simultâneas da pressão arterial (PA) pelo método auscultatório convencional e método digital automático, habitualmente utilizado na MRPA. **Métodos:** Através de uma conexão em “Y” acoplamos um manguito a um aparelho digital automático validado (ONROM 705IT) e a um esfigmomanômetro de coluna de mercúrio, permitindo aferir simultaneamente a PA pelos dois métodos. Determinamos a PA em 423 indivíduos (normotensos e hipertensos), adequando o tamanho do manguito à circunferência braquial. **Resultados:** Os valores representam média \pm desvio padrão (DP) (valores mínimo-máximo): Idade $40,8 \pm 16,3$ anos (18–92), circunferência braquial $28,2 \pm 3,7$ cm (19–42), PA sistólica (PAS) auscultatório $127,6 \pm 22,8$ mmHg (69–223), PAS automático $129,5 \pm 23,0$ mmHg (56–226), PA diastólica (PAD) auscultatório $79,5 \pm 12,6$ mmHg (49–135), PAD automático $79,0 \pm 12,6$ mmHg (48–123). A diferença média da PAS entre os dois métodos foi de 1,9 mmHg (-15 a +19) e a diferença da PAD de 0,5 mmHg (-19 a +13). Os índices de correlação de Pearson entre os métodos são para a PAS ($r = 0,97$), e PAD ($r = 0,91$). A análise de Bland-Altman mostrou concordância clinicamente aceitável entre os métodos. **Conclusão:** A PA

and should be used to improve the diagnosis and control of hypertension.

Keywords: Blood Pressure. Blood Pressure Determination. Blood Pressure Monitors. Hypertension.

INTRODUCTION

Hypertension is the most prevalent disease of the adult, its impact on the cardiovascular and renal systems, sometimes devastating, being proportional to blood pressure (BP) levels.^{1,2} Most complications are due to inadequate BP control, something observed even in countries with high development indices.³ Auscultatory measurement with the sphygmomanometer is the most widespread method for indirect BP determination, having a high concordance level with the direct intra-arterial method.⁴ Yet, procedure standardization must be observed if BP values are to be valid.^{5,6} Guidelines include: 5-10 minute patient's rest before measurement; cuff-size adequate to the patient's arm circumference and positioned 2-3 cm above the antecubital fossa; positioning of the central portion of the rubber bladder on the brachial artery; positioning of the upper limb at the heart's level; focusing of the examiner's eyes on the mercury column level; positioning of the Bell of the stethoscope on the brachial artery and; 1-2 minute interval between measurements. Training is then necessary before reliable BP measurements are obtained with the auscultatory method. The use of aneroid sphygmomanometers, which are easily decalibrated, is a common source of error with the auscultatory method.^{7,8}

Oscillometric BP determination with automated digital devices has become more frequent. In spite of its limitations, the method has increasingly substituted for the traditional auscultatory one, chiefly when the patient or a family member is responsible for home blood pressure measurement (HBPM).⁹

Besides being promoted as an instrument to help reach adequate BP control, HBPM is an excellent warning strategy, helping with patient education and guiding the adjustment of therapeutic regimens. Several studies have demonstrated the benefits of HBPM compared with casual ambulatory BP measurements, making the diagnosis of hypertension more precise and favoring BP control, with consequent lower disease-related morbidity and

aferida pelo método digital automático apresenta boa concordância com o método auscultatório convencional, devendo ser usada no auxílio do diagnóstico e controle da hipertensão arterial (HA).

Palavras-chave: Pressão Arterial. Determinação da Pressão Arterial. Monitores de Pressão Arterial. Hipertensão.

mortality.^{10,11} In spite of great technological advances and the high acceptability of automated digital devices, some researchers still dispute HBPM validity, believing that values obtained outside a medical environment are prone to error.¹²⁻¹⁴

Because of controversy surrounding the precision and effectiveness of the automated oscillometric method, the purpose of this study was to compare measurements simultaneously obtained, through use of the same cuff, with the mercury sphygmomanometer auscultatory method and the automated digital method.

MATERIAL AND METHODS

SAMPLE SELECTION

The individuals who composed the sample were adults of all ages, deliberately selected and matched for sex: normotensives, hypertensives and those with comorbidities known to alter BP, such as chronic renal disease and atherosclerosis. They were extracted from the population (and their caregivers) being followed up at facilities with mentorship provided by clinicians-educators: basic health units, specialty ambulatories and dialysis units. The final sample, with the whole range of BP levels, was thought to better represent the general population.

BLOOD PRESSURE DETERMINATION

BP was measured in the non-dominant upper limb of the sitting patient, after a 5-minute rest. The arm circumference was measured for adequacy of the cuff size. Two BP measurements were obtained with 1-minute interval between them, with recording of the systolic blood pressure (SBP) and diastolic blood pressure (DBP) with both methods. The values shown correspond to the means of the two measurements, which were obtained according to the VI Arterial Hypertension Brazilian Guidelines.⁶

SBP and DBP were simultaneously measured with the auscultatory and oscillometric (automated digital) methods. For this purpose, we designed a system through which an automated digital

device (OMRON 705IT, validated by the British Hypertension Society)¹⁵ and a newly-calibrated mercury sphygmomanometer were jointly connected to a single cuff, through a Y-shaped connection. The cuff insufflation and deflation rates were determined by the automated device, deflation happening at an approximately 2mmHg/s rate.

The procedure was performed by two independent observers. While one measured the BP according to the auscultatory method, recording the values obtained, the other observer recorded the values shown by the automated device, so that bias was avoided. Age, arm circumference, abdominal circumference and the presence of associated diseases were also recorded. All observers (MAP, GES, HAK, KMN and NDMN) were trained by the main researcher and study organizer (FAA) for BP determination by the auscultatory method and methodology adequacy, during several training sessions that preceded the start of the study.

ETHICAL AND STATISTICAL FEATURES

The study protocol and the informed consent form were approved by the Committee of Research Ethics of the *Faculdade de Ciências Médicas e da Saúde* of the PUC/SP. Before undergoing any procedure, the participants were informed on the study's general characteristics, main objectives and method.

Sample size was based on a pilot study of 138 individuals, considering an α error of 5% and a β error of 20% for an estimate of a clinically relevant difference of 4 mmHg between the methods. Minimum sample size was estimated to include 403 individuals.

Student's *t* test was used to assess whether there were significant differences between the SBP and DBP values obtained with the two methods. Pearson's coefficient was used to assess correlation between SBP and DBP measurements obtained with the two methods and between the SBP and DBP and other measurable continuous variables. The Bland-Altman method was used to assess agreement between the SBP and DBP values obtained with the two methods in relation to the difference between the two methods.¹⁶ The Z test was used for proportion comparison. Minimum significance for the null hypothesis (α error) was set at 5%.

RESULTS

Data were obtained from 423 individuals whose characteristics allowed their inclusion in the

study. Table 1 shows the means, standard deviation (SD) and maximal and minimum values for age, arm circumference, abdominal circumference and SBP and DBP as measured with the two methods. SBP values with the automated method were significantly higher than those obtained with the auscultatory method, being 129.5 ± 23.0 mmHg and 127.6 ± 2.8 mmHg, respectively ($p < 0.01$). Conversely, DBP values were significantly lower with the automated method, in comparison with the auscultatory one, being 79.0 ± 12.0 mmHg and 79.5 ± 12.5 mmHg, respectively ($p < 0.05$).

Figure 1 shows SBP (Figure 1A) and DBP (Figure 1B) in graphs of frequency distribution, comparing the values obtained with the auscultatory and automated values. It is noteworthy that there was a Gaussian distribution of the results in both methods.

The means of the differences of SBP and DBP between the automated and auscultatory methods were calculated. The mean of the differences and the minimum and maximal values of the differences between the two methods, for SBP and DBP were 1.9 mmHg (-15 to +19) and -0,6 mmHg (-19 to +13), respectively. Therefore, in the 423 study individuals, the two methods of BP determination did not reach the clinically relevant 4 mmHg minimum difference, as defined on the decision on the sample size.

Pearson's correlation coefficients between the values determined by the auscultatory and automated digital methods for SBP and DBP were 0.97 and 0.91, respectively ($p < 0.001$).

Figure 2 shows a dispersion graph with the correspondence between BP levels determined by the two methods, highlighting the proximity of the points to the identity line, thus depicting a visual representation of the correspondence of the values obtained with the two methods.

Table 1 CHARACTERISTICS OF THE INDIVIDUALS

Variable	Mean \pm SD
	(minimum value – maximal value) (n = 423)
Age	40.8 \pm 16.3 years (18–92)
Arm circumference	28.2 \pm 3.7 cm (19–42)
Waist circumference	89.4 \pm 13.2 cm (59–133)
Auscultatory SBP	127.6 \pm 22.8 mmHg (69–223)
Automated SBP	129.5 \pm 23.0 mmHg (56–226)**
Auscultatory DBP	79.5 \pm 12.5 mmHg (49–135)
Automated DBP	79.0 \pm 12.0 mmHg (58–123)*

SD: standard deviation; SBP: systolic blood pressure; DBP: diastolic blood pressure. * $p < 0.05$; ** $p < 0.01$.

Figure 1. Distribution of systolic blood pressure (A) and diastolic blood pressure (B) of individuals assessed with the auscultatory method (gray bars) and automated method (black bars). Notice the wide range of blood pressure values, whose distribution is Gaussian for both methods.

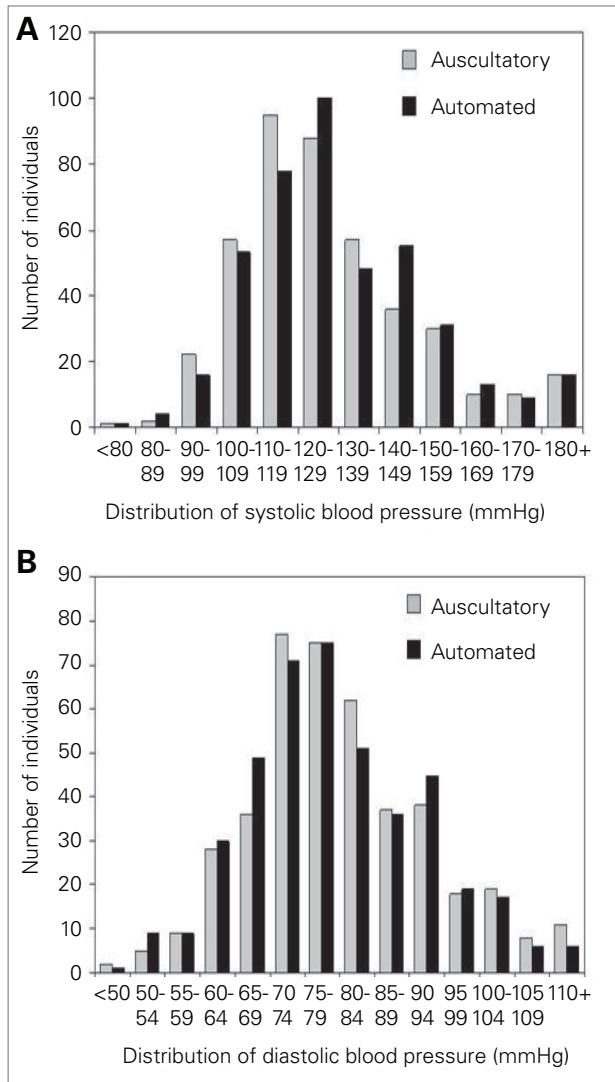
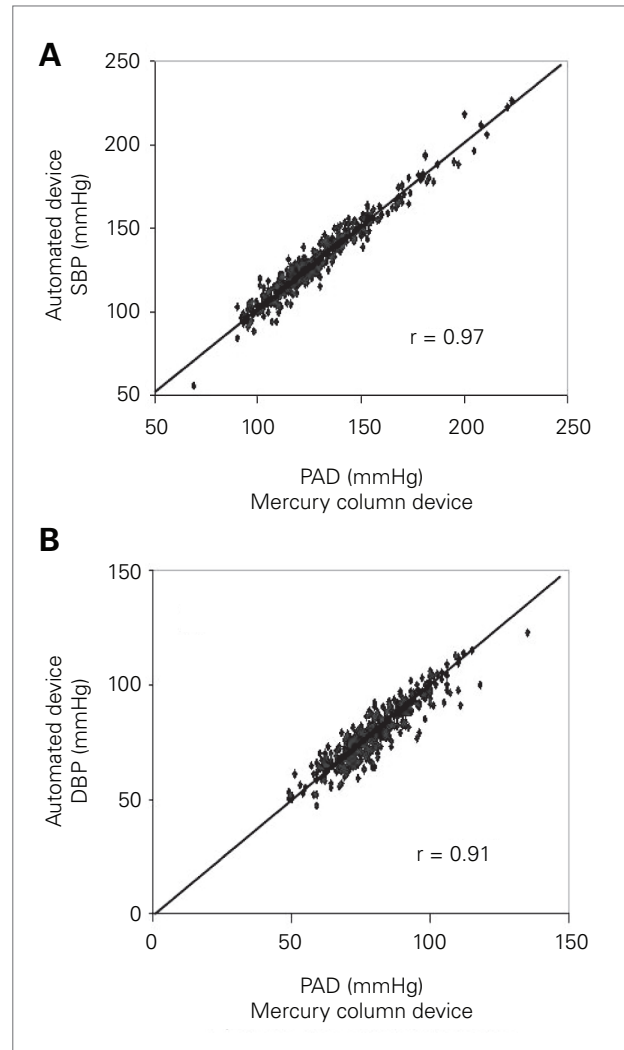


Figure 2. Correspondence between systolic blood pressure (A) and diastolic blood pressure (B) measured with the mercury sphygmomanometer auscultatory method and oscillometric automated method. Notice how the values are close to the identity line, SBP=systolic blood pressure; DBP = diastolic blood pressure.



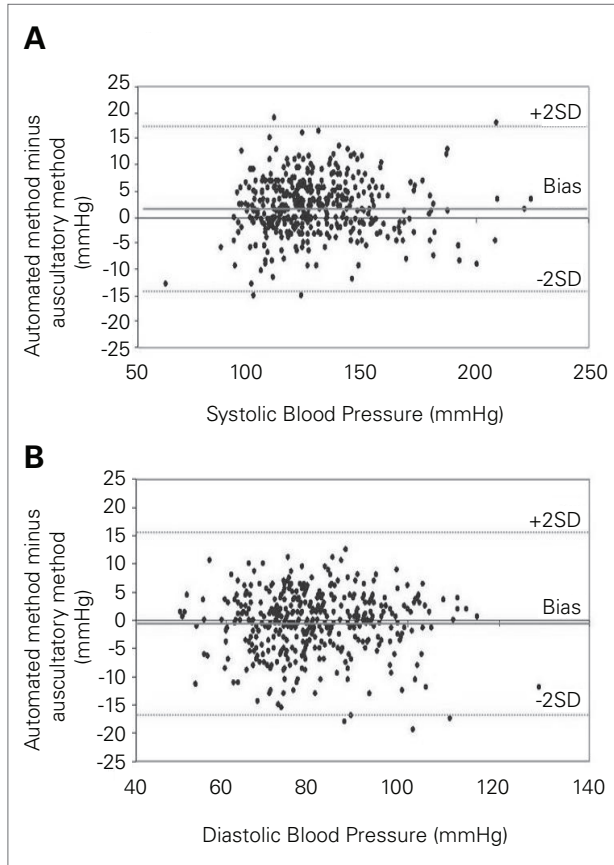
SBP: systolic blood pressure; DBP: diastolic blood pressure

The Bland-Altman method was used to analyze the agreement between the BP values determined with the two methods (Figure 3). As can be seen, when plotting the mean differences between the BP values obtained with the automated method minus the ones obtained with the auscultatory method against the mean SBP or DBP values determined with the two methods, less than 1% of the points fall beyond the limit of two standard-deviations above and below bias, whose value is also close to zero. For SBP (Figure 3A) bias was +1.9 mmHg, with an upper limit of +16.9 mmHg (95% CI; +16.3 to +17.6 mmHg) and lower limit of -13.1 mmHg

(95% CI; -12.4 to -13.7 mmHg). For DBP (Figure 3B) bias was -0.6 mmHg, with an upper limit of +14.9 mmHg (95% CI; +14.2 to +15.5 mmHg) and lower limit of -16.0 mmHg (95% CI; -15,3 to -16,6 mmHg). It should also be noted that the differences did not increase or decrease at extreme SBP or DBP values.

Although positive correlation indices were found between abdominal circumference and SBP ($r = 0.32$, $p < 0.01$); between abdominal circumference and DBP ($r = 0.26$, $p < 0.01$); between age and SBP ($r = 0.44$, $p < 0.01$) and between age and DBP ($r = 0.23$, $p < 0.01$), we did not detect significant BP differences between

Figure 3. Bland-Altman analysis of concordance between systolic blood pressure (SBP) (A) and diastolic blood pressure (DBP) (B) obtained with the two methods.



In the vertical axis, the values obtained with the automated method minus the values obtained with the auscultatory method. In the horizontal axis, the means of the SBP (A) and DBP (B) obtained with the two methods. For SBP (A) bias was +1.9 mmHg with an upper limit of 2 standard deviations (SD) of +16.9 mmHg (95% CI; +16.3 to +17.6 mmHg) and lower limit of -13.1 mmHg (95% CI; -12.4 to -13.7 mmHg). For DBP (B) bias was -0.6 mmHg, with upper limit of +14.9 mmHg (95% CI; +14.2 to +15.5 mmHg) and lower limit of -16.0 mmHg (95% CI; -15.3 to -16.6 mmHg). Less than 1% of the values fall beyond the ± 2 SD limit.

the two methods, either for male/female comparison or concerning the arm circumference or the age of the participants.

As for the possibility of diagnosing hypertension (SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg) with each one of the two methods, based on two consecutive BP measurements as performed in this study, hypertension would be diagnosed in 128 individuals (30.3% of the sample) with the auscultatory method and in 122 individuals (28.8% of the sample) with the automated method, with diagnostic disagreement in only 8 individuals (1.9%), which was not statistically significant.

DISCUSSION

This study showed that BP values obtained with the automated digital method agreed with the values obtained with the conventional mercury sphygmomanometer auscultatory method, strengthening the safety, reliability and usefulness of the former for hypertension diagnosis and treatment adequacy. Although our data agree with national and international HBPM guidelines,^{5,6,10,11} they differ from those of a study which used a similar method to assess a predominantly elderly population followed up at a cardiology outpatient facility.¹⁴ The authors of the latter valued the statistically significant difference of +2.1 to +2.3 mmHg between the automated method and the auscultatory one, with larger differences in individuals aged 65 years or above.¹⁴ We also observed statistically significant differences of +1.9 mmHg for SBP and -0.6 mmHg for DBP. However, taking into account all the clinical benefits of HBPM (see discussion below), we chose to deem these statistically significant differences clinically irrelevant. Likewise, even with occasional differences of up to 19 mmHg between the methods, it is statistically known that as the number of measurements increases (and repeated measurements are advised for HBPM) the values (differences) tend to show a regression to the mean.

Validated automated machines for BP reading in the arm, with memory capacity, are the most widely recommended devices for HBP monitoring, as they are easy to handle and reliable.^{10,11} Although there is still reluctance on the part of the medical community to indicate HBPM, its use has become more common, the strategy being now an important source of information on BP levels.^{9,17,18} Furthermore, HBPM has high acceptability by the patients.¹⁹ The increasing use of HBPM may improve the quality of hypertension diagnosis and control, a desirable scenario for a disease that is silent and has high rates of cardiovascular and renal complications.^{10,11,17} There is extensive evidence for the role of emotional, hormonal and environmental factors in the important oscillations BP values may experiment. A classical example is the white coat hypertension and the white coat phenomenon, present in 10–20% of the individuals, which may confound diagnosis and treatment adequacy.^{17,20,21} Because it allows several measurements, HBPM minimizes BP variability, helping to more safely confirm or exclude hypertension, being highly indicated for the diagnosis of white coat hypertension.^{10,11,18,20,21} Furthermore, recent data have indicated that the use of automated machines for BP determination in the

physician's office also reduces the rates of the white coat phenomenon.²²

Small differences in the BP greatly impact on the development of hypertension complications, mainly as this is a highly prevalent public health hazard.^{2,23} A systematic review, followed by a recent meta-analysis, has shown that HBPM counters clinical inertia, leading the physician to more strictly seek the therapeutic goal, resulting in better BP control.²⁴ Another meta-analysis of 18 randomized, controlled trials observed that in hypertensive patients followed up at health units, the use of HBPM, compared with casual BP measurements, resulted in better BP control and higher likelihood of reaching adequate BP targets, strengthening the applicability of the method to the management of hypertension.²³

Prospective studies have shown that HBPM values were better correlated to cardiovascular and renal complications when compared to ambulatory measurements.²⁶⁻³¹

In conclusion, we observed that BP values obtained with the automated digital method have good agreement with those obtained with the conventional auscultatory method. The results indicate that HBPM with validated digital devices should be encouraged as a strategy to help with BP control and increase the treatment compliance of hypertensive patients. We thus hope that this simple and practical method for HBPM can better control hypertension, thus reducing the devastating scale of its complications.

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