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ORIGINAL ARTICLE

Evaluation of the Profile and Quality of Sphygmomanometers Available at a Health Education Institution in Belo Horizonte

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Abstract

Abstract

Background: Arterial hypertension affects around 30% of the Brazilian adult population, showing a direct and progressive relationship with an increased risk of cardiovascular diseases (CVDs). In this context, adjustments in the calibration and physical constitution of sphygmomanometers are essential conditions for obtaining correct blood pressure (BP) measurements.

Objectives: Analyze the profile and quality of sphygmomanometers used in various sectors of a health education institution in Belo Horizonte, Minas Gerais.

Methods: The present study conducted a cross-sectional, observational, and non-interventional study to assess adherence to various quality parameters of the sphygmomanometers available in the outpatient clinic, emergency department, and ward of an educational institution in the municipality of Belo Horizonte.

Results: We analyzed 78 devices, in which high rates of adherence were identified for velcro/pins, 93.5% (73/78); bulbs/rubbers, 92.1% (70/76); valves, 93.4% (71/76); the seal of the National Institute of Metrology, Quality, and Technology (INMETRO), 97.4% (76/78); and the clock, 92.1% (70/76). However, these parameters showed no statistical significance. Institutions (hospital/outpatient clinic) recorded higher calibration rates, 75% (39/52, $p<0.001$), in accordance with the deadlines stipulated by INMETRO, and the cuff/equipment compatibility showed its highest value (52%) among students (32/61, $p = 0.004$).

Conclusion: Our study showed that 38.4% (30/78) of the devices did not presented some type of inadequacy, with outpatient-owned devices had the highest compliance rate ($p = 0.015$). These findings are worrisome, as they can lead to inaccurate BP measurements.

Keywords: Sphygmomanometers; Hypertension; Cardiovascular Diseases; Equipment Failure.

Introduction

Arterial hypertension is a Noncommunicable Disease (NCD), characterized by a persistent rise of blood pressure (BP), with systolic blood pressure (SBP) equal to or greater than 140 mmHg and/or diastolic blood pressure (DBP) equal to or greater than 90 mmHg. It is a multifactorial condition with both modifiable and non-modifiable risk factors.[1-3] This pathology has a high prevalence in Brazil, affecting approximately 30% of the population.[4,5] Cardiovascular diseases (CVDs) are the leading cause of death globally, representing 32% of all global deaths in 2019.[6,7] There is a direct and progressive relationship among elevated BP, atherosclerotic effects, and other risk factors, contributing to CVD risks.[8] BP measurements are considered routine and straightforward procedures in medical practice and should be taken whenever possible during clinical assessments.[9] Healthcare professionals must ensure several factors, including at least two BP measurements; accurate recording; the use of the correct cuff size for the patient's arm circumference; and proper functioning,

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Central Illustration: Evaluation of the Profile and Quality of Sphygmomanometers Available at a Health Education Institution in Belo Horizonte

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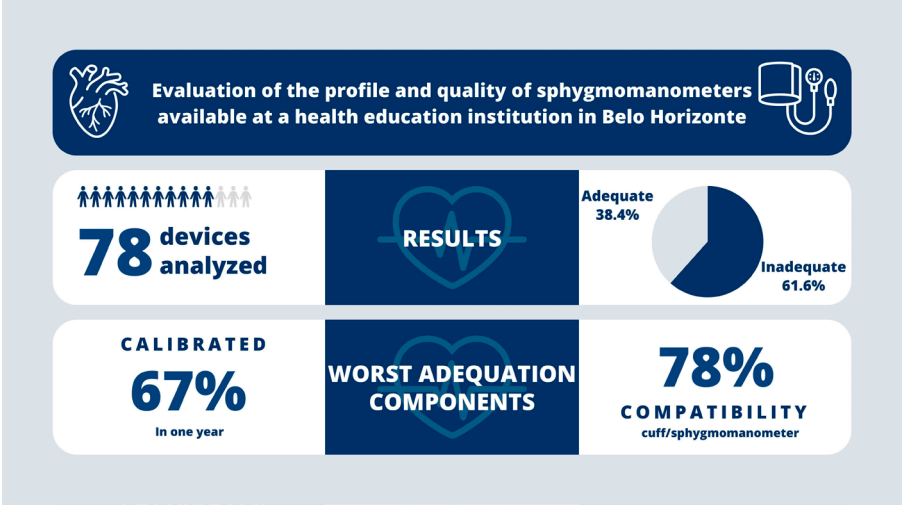

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validation, and calibration of the measuring devices (sphygmomanometers) according to the standards set forth by the National Institute of Metrology, Quality, and Technology (INMETRO).

There are various types of sphygmomanometers used for BP measurement, including aneroid, mercury, and digital models. Aneroid devices, commonly used in clinical practice due to their portability and low cost, require a stethoscope for use. Mercury devices, once considered the gold standard for BP measurement, were prohibited in 2019 by the National Health Surveillance Agency due to their toxic nature.[10] Digital devices are user-friendly, more accurate, and do not require a stethoscope, but they need validation for professional use.

The objective of this study was to analyze the equipment available in the outpatient clinic and university hospital of a health education institution in Belo Horizonte, including those used by students, nurses, and physicians in this environment. The focus was on evaluating elements directly impacting accurate BP measurement, such as INMETRO validation, INMETRO-accredited calibrations, the condition of macroscopic components (bulb, rubber, velcro or pins, manometer, mercury column, valve), availability of different cuff sizes, and correspondence between cuff and sphygmomanometer brands. Additionally, this study sought to analyze collected data regarding sphygmomanometer inadequacies and compare devices available in different healthcare services.

Methods

This is a cross-sectional, observational, and non-interventional study conducted in healthcare services provided by a health education institution in Belo Horizonte, Minas Gerais, Brazil. The study aimed to report on the quality of sphygmomanometers based on metrological specifications provided by INMETRO to ensure their reliability. Data were collected through a questionnaire (Table 1) filled out by researchers based on the analyzed equipment. Before questionnaire administration, participants, sector technical supervisors, and clinical rights authorizations from each institution provided signed informed consent. Multiple searches and evaluations of various devices were conducted, including digital and aneroid sphygmomanometers. No mercury column devices were found in the services.

This study was approved by the Research Ethics Committee of the Faculty of Medical Sciences of Minas Gerais, CAAE: 62581722.4.0000.5134; approval number: 5.633.803, dated 09/09/2022.

INMETRO: National Institute of Metrology, Quality, and Technology.

Table 1 - Questionnaire

Identification (INMETRO number / Property number / Owner's initials):
Was the device inspected? ( ) Yes ( ) No
Owner of the Sphygmomanometer: ( ) Doctor ( ) Nurse ( ) Academic ( ) Institute
Location where the device was inspected: ( ) Hospital ( ) Outpatient Clinic
What type of Sphygmomanometer is being analyzed ( ) Aneroid ( ) Eletronic ( ) Mercury
In case of an eletronic device, is it for: ( ) Wrist ( ) Arm ( ) Not applicable
Does it have the INMETRO symbol? ( ) Yes ( ) No
Is it regularly calibrated (Every year)? ( ) Yes ( ) No
Date of last calibration: __/__/__
Does the sphygmomanometer have cuffs of different sizers? ( ) Yes ( ) No
Are there cuffs of different sizes in the facility? Specify the sizes:
Is there cuff/equipment compatibility? ( ) Yes ( ) No
If not, cuff/equipment brand for later verification:
Condition of bulbs/rubbers: ( ) Adequate ( ) Inadequate
Condition of the gouge/clock: ( ) Adequate ( ) Inadequate
Condition of the valves: ( ) Adequate ( ) Inadequate
Condition of the velcro/straps: ( ) Adequate ( ) Inadequate

Data were collected from February to May 2023, with device inspections conducted by researchers immediately after questionnaire completion. To assess calibration, the inspection date printed on institutional devices was checked. For personally used devices by physicians, students, and nurses, the date of the last calibration was inquired, considering those calibrated within the last year as appropriate. Bulbs and rubber bulbs were deemed suitable for use when they showed no structural damage or manipulation difficulties. Clocks (manometers) were considered adequate when inflation and deflation occurred normally, and markers started and ended at zero, with intact numbers and pointers. Velcro should have good adherence, and pins should be defect-free. Simple handling of valves during inflation and deflation, as well as their integrity, were also considered for adequacy. The presence of the INMETRO seal was also considered in order to evaluate the adequacy of sphygmomanometers.

Inclusion Criteria

Approval of the Educational Institution to participate in the Research.

Healthcare professionals (doctors, nurses) and health sciences students allowing the evaluation of their sphygmomanometers.

Exclusion Criteria

Non-acceptance of the healthcare services of the Institution to participate in the research.

Non-acceptance of healthcare professionals (doctors, nurses) and health sciences students to participate in the research.

Statistical analysis

In this study, the selection of the Fisher exact test as a statistical method was based on the consideration of small sample sizes or cells in contingency tables with limited frequencies. To establish the statistical validity of associations, a confidence level of 0.05 was adopted. Therefore, any result with a p-value less than 0.05 indicates that the relationships between variables are statistically significant, providing robust evidence to reject the null hypothesis of independence.

Initially, a sample characterization was performed using descriptive statistical resources. Additionally, the evaluation of device characteristics (qualitative variables) was presented using absolute and relative frequency. Finally, for further analyses, the sample was stratified by sphygmomanometer owner and cuff sizes.

Results

Sample Characterization

Table 2 provides the sample characterization, presenting simple frequencies and percentage frequencies for the variables of interest.

This study evaluated 78 sphygmomanometers owned by two healthcare facilities (outpatient clinic and hospital) affiliated with a health education institution in Belo Horizonte, MG, as well as those personally owned by students, nurses, and doctors. Among the total sample, 76 devices were aneroid devices (41 from the institutions, 34 from students, 1 from the doctor), and 2 were electronic devices (owned by the nursing staff of the hospital). The devices were distributed as follows between the two locations studied: 45 were in the hospital (22 from the institution, 20 from students, 2 from the nursing team, and 1 from the medical team), while 33 were in the outpatient clinic (19 from the institution and 14 from students). Additionally, the presence of 11 differently sized cuffs was observed in the institution's outpatient clinic. Nonetheless, these devices were not considered in the sample space, as it was not possible to assess their macroscopic aspects. The relationship between the quantity and size of the cuffs is addressed in Table 6.

Examining the macroscopic aspects and quality of parameters, a high rate of adequacy was observed for velcro/pins (94%, 73/78), bulbs/rubbers (92%, 70/76), valves (93%, 71/76), and the clock (92%, 70/76). Electronic devices were excluded from these last three items. When investigating the presence of the INMETRO seal, we obtained an adequacy rate of 97% (76/78). However, the calibration parameter had the lowest adequacy rate of 67% (52/78). The correspondence between cuff and sphygmomanometer brands achieved a percentage of 78% (61/78).

Table 3 presents the cross-referencing of the Sphygmomanometer Owner variable with the main study variables.

For the description and statistical analysis of the presented data, we chose not to correlate the data for the groups of nurses and doctors due to the small number of participants in these categories, which could impact the representativeness of the sample. When comparing the components of institutional-owned sphygmomanometers with those owned by academic individuals, a detailed analysis of various aspects was conducted. Our results indicate that certain components, such as velcro/pins, bulbs/rubbers, clocks, and valves, showed no statistically significant differences between these two groups.

However, when examining the percentages related to calibration parameters and cuff/equipment adequacy, statistically significant associations were identified between these variables and the types of owners (institutional and academic).

Specifically, it was found that institutions presented the best rates of devices calibrated within the one-year timeframe established by INMETRO, reaching 75% (39 out of 52 calibrated devices, $p < 0.001$). By contrast, academic owners demonstrated the highest cuff/equipment compatibility rate, with a value of 52% (32 out of 61 suitable devices, $p = 0.004$).

Table 4 presents a detailed description of the variable "Sphygmomanometer Owner" concerning the sample space considering the devices considered adequate compared to the total number of analyzed devices (n = 78).

In the study, it was found that 38.4% (30/78) of the analyzed devices showed no inadequacy in the observed components. When assessing different institutions, devices owned by outpatient clinics exhibited higher rates of adequacy, reaching 57.8% (11/19). By contrast, devices owned by students demonstrated higher levels of adequacy in the hospital setting, achieving a compliance rate of 50% (10/20). These results are summarized in Table 4.

Table 5 provides a detailed cross-analysis of the "Sphygmomanometer Owner" variable concerning the sample space, considering only the devices that demonstrated total compliance with the analyzed parameters (n=30).

Through the application of the Fisher exact test, with a significance level of 0.05, it was possible to identify the existence of statistically significant associations between the variables "Hospital/Outpatient Clinic" and "Sphygmomanometer Owner." This suggests that the relationship between the type of location analyzed (outpatient clinic) and the ownership of the sphygmomanometer (institution) has statistical relevance ($p = 0.015$).

Regarding the availability of cuffs of various sizes in the service, it was found that only the outpatient clinic had this variety. In total, 11 cuff units of different dimensions were identified, covering a circumference range from 10 to 51 cm, as shown in Table 6.

Table 2 - Sample Characterization

Characteristics	N = 78[1]
Sphygmomanometer Owners	
Hospital	22 (28.1%)
Outpatient	19 (24.3%)
Hospital academic	20 (25.6%)
Outpatient academic	14 (17.9%)
Nurse (Hospital)	2 (2.6%)
Doctor (Hospital)	1 (1.3%)
Location where the device was inspected:	
Hospital	45 (58%)
Outpatient	33 (42%)
What type of Sphygmomanometer is being analyzed?	
Aneroid	76 (97%)
Eletronic	2 (2.6%)
Does it have the INMETRO symbol?	
Yes	76 (97%)
No	2 (2.6%)
Is it regularly calibrated (One year)?	
Yes	52 (67%)
No	26 (33%)
Is there cuff/equipment compatibility?	
Yes	61 (78%)
No	17 (22%)
Condition of bulbs/rubbers:	
Adequate	70 (92%)
Inadequate	6 (7.9%)
Is the clock well maintained?	
Yes	70 (92%)
No	6 (7.9%)
Condition of valves:	
Adequate	71 (93%)
Inadequate	5 (6.6%)
Is the velcro/strap well maintained?	
Yes	73 (94%)
No	5 (6.4%)

[1] *n (%)*
INMETRO: National Institute of Metrology, Quality, and Technology.

Table 3 - Division of Standards Evaluated by Sphygmomanometer Owners

Sphygmomanometer Owners						
Characteristics	**Total, N = 78[1]**	**Academic, N = 34[1]**	**Nurse, N = 2[1]**	**Institution, N = 41[1]**	**Doctor, N = 1[1]**	**P-Value[2]**
What type of Sphygmomanometer is being analyzed?						<0.001
Aneroid	76 (100%)	34 (45%)	0 (0%)	41 (54%)	1 (1.3%)	
Eletronic	2 (100%)	0 (0%)	2 (100%)	0 (0%)	0 (0%)	
Does it have an INMETRO symbol?						0.3
Yes	76 (100%)	32 (42%)	2 (2.6%)	41 (54%)	1 (1.3%)	
No	2 (100%)	2 (100%)	0 (0%)	0 (0%)	0 (0%)	
Is it calibrated regularly? (One year)						<0.001
Yes	52 (100%)	12 (23%)	0 (0%)	39 (75%)	1 (1.9%)	
No	26 (100%)	22 (85%)	2 (7.7%)	2 (7.7%)	0 (0%)	
Is there a cuff/ equipment compatibility?						0.004
Yes	61 (100%)	32 (52%)	2 (3.3%)	26 (43%)	1 (1.6%)	
No	17 (100%)	2 (12%)	0 (0%)	15 (88%)	0 (0%)	
Are the bulbs/rubbers adequate?						0.056
Adequate	70 (100%)	34 (49%)	0 (0%)	35 (50%)	1 (1.4%)	
Inadequate	6 (100%)	0 (0%)	0 (0%)	6 (100%)	0 (0%)	
Is the clock well maintained?						0.3
Yes	70 (100%)	33 (47%)	0 (0%)	36 (51%)	1 (1.4%)	
No	6 (100%)	1 (17%)	0 (0%)	5 (83%)	0 (0%)	
Are the Valves Adequate?						0.12
Adequate	71 (100%)	34 (48%)	0 (0%)	36 (51%)	1 (1.4%)	
Inadequate	5 (100%)	0 (0%)	0 (0%)	5 (100%)	0 (0%)	
Is the velcro/strap well maintained?						0.7
Yes	73 (100%)	31 (42%)	2 (2.7%)	39 (53%)	1 (1.4%)	
No	5 (100%)	3 (60%)	0 (0%)	2 (40%)	0 (0%)	

[1]n (%)
[2]*Fisher's exact test*
INMETRO: National Institute of Metrology, Quality, and Technology.

Table 4 - Devices with No Inadequacy in Evaluated Standards Compared to the Total (n = 78)

	Sphygmomanometer Owners				
Characteristics	**Institution, N = 41[1]**	**Academic, N = 34[1]**	**Nurse, N = 2[1]**	**Doctor, N = 1[1]**	**Total, N = 78[1]**
Location where the device was inspected:					
Hospital	6/22 (27,2%)	10/20 (50%)	0/2 (0%)	1/1 (100%)	17/45 (37,7%)
Outpatient	11/19 (57,8%)	2/14 (14,2%)	-	0 (0%)	13/33 (39,3%)
Total	17/41 (41,4%)	12/34 (35,2%)	0/2 (0%)	1/1 (100%)	30/78 (38,4%)

[1]n (%)

Table 5 - Devices with No Inadequacy in Evaluated Parameters

	Sphygmomanometer Owners				
Characteristics	**Total, N = 30[1]**	**Academic, N = 12[1]**	**Institution, N = 17[1]**	**Doctor, N = 1[1]**	**P-value[2]**
Location where the device was inspected:					0.015
Hospital	17 (100%)	10 (59%)	6 (35%)	1 (5.9%)	
Outpatient	13 (100%)	2 (15%)	11 (85%)	0 (0%)	

[1]n (%)
[2]Fisher's exact test

Table 6 - Cuffs of different available sizes.

Local/Types of cuffs:	Children's (10-13 cm)	Children's (10-18 cm)	Children's (10-23 cm)	Children's (12-19 cm)	Children's (16-20 cm)	Obese (31-39 cm)	Obese (35-51 cm)	Total
Hospital	0	0	0	0	0	0	0	0
Outpatient	1	1	1	1	1	1	5	11
Total	1	1	1	1	1	1	5	11

Discussion

Our study revealed that 61.6% (48/78) of the sphygmomanometers observed in different departments of a health education institution in Belo Horizonte, MG, exhibited some form of inadequacy in one or more assessed parameters. The criterion with the poorest quality assessment was the calibration date, as a total of 33.4% (36/78) of the devices did not comply with the INMETRO guidelines, as they had been calibrated beyond the recommended one-year timeframe. However, sphygmomanometers owned by the institution (both in the hospital and outpatient clinic) achieved excellent results in this parameter, with a total of 75% (39/41) compliance. By contrast, a previous study conducted by Maia et al. (2017) in the same research institution in Belo Horizonte, MG, had already revealed high rates of neglect regarding the annual calibration practice of sphygmomanometers. In that study, 337 BP measuring devices in emergency medical services for the adult population were examined. The results showed

an inadequacy rate of 78.4% (264/337) concerning one or more analyzed components/parameters.[1]

A study by Rabelo et al. assessed 416 sphygmomanometers owned by medical students at a private university in Rio de Janeiro. It was found that 90% of the students (389) had never calibrated their devices.[11] Additionally, the study demonstrated that 61.1% (264) of the students claimed never to have been instructed on the periodicity of verification, with 47.9% of them stating they were unaware of the risks to which they were exposing their patients.Furthermore, a computer simulation conducted by Tuner et al. demonstrated that, after three tests, an uncalibrated device caused 20% systolic and 28% diastolic hypertension in undetected adults. It also falsely identified 15% systolic and 31% diastolic hypertension.[12]

To ensure the accuracy of measurements with these devices, INMETRO set forth ordinance number 46, dated January 22, 2016, defining criteria for sphygmomanometer calibration.[13] This norm dictates that instruments should be calibrated annually, based on standardized procedures, by calibration laboratories accredited by the agency. This aims to ensure that sphygmomanometers are correctly adjusted and provide reliable results. Calibration involves comparing the readings of the tested instrument with a reference standard with well-established metrological traceability. This enables the identification of any deviations and their correction, ensuring accurate and consistent readings over time.[13]

According to the recommendations of the Brazilian Society of Cardiology Guidelines for obtaining the correct BP measurement, the cuff's length, the inflatable chamber of the sphygmomanometer cuff, should cover a minimum of 80% of the arm's circumference.[14,15] Additionally, the width should represent 40% of the arm's length. In this context, our research pointed out that there were only 11 extra cuffs of different arm circumference sizes, which were located in the outpatient clinic's wards of the educational institution. This hindered access and agility in screening/treatment. By contrast, no varied cuff sizes were found in any nursing department or bed in the hospital, which would be essential for accurate BP measurement. Therefore, the lack of size variety remains a challenge for healthcare professionals to improve service quality.[16] Ostchega et al., in their study, assert that among men, 44.8% of the population would require a larger cuff, up to 2 sizes above the standard adult cuff. In women, 13.5% need a smaller cuff, and 28.1% need a larger one than the standard; hence, 86.4% of the population would have their BP incorrectly assessed, considering only the cuff size.[17] The use of an improperly sized cuff in relation to the arm's circumference is the most widely debated factor in inaccurate BP measurement.[16] In another study by MH Maxwell et al., it was observed that 86% (57/63) of all participants with arms larger than 34cm, using the standard adult sphygmomanometer cuff (between 27cm and 34cm), experienced overestimation of SBP, ranging from 4 to 11 mmHg, and DBP), from 3 to 11 mmHg.[18] Therefore, narrow cuffs yield elevated BP values, leading to an increase in the consumption of antihypertensive drugs, while larger cuffs used on lean patients result in incorrect diagnosis and treatment of systemic arterial hypertension.[17,19]

Moreover, 78.3% (61/78) of sphygmomanometer/cuff sets corresponded between brands. Of the 17 devices that showed a mismatch between the set, 11 belonged to the hospital, where there were no indications that the combination used was INMETRO approved.[13] Under this analysis, INMETRO Ordinance No. 46 states, in Section 7, that each cuff or sphygmomanometer purchased separately must be approved and display a verification seal as determined in NIE-Dimel-097.[13,20] The replacement of cuffs in a sphygmomanometer cannot be considered a repair or maintenance of the device.[20,21]

This research has some limitations as an observational study, which does not allow for causal inferences based on the results. However, the data from this study corroborate important and concerning findings that can justify actions in a public health institution to improve the quality and reliability of the sphygmomanometers being used. This can be achieved through periodic equipment verification and replacement of those in inadequate conditions for use.

Conclusion

The evaluated sphygmomanometers showed a lack of annual calibration, especially in academic equipment. Additionally, a deficiency in cuffs sui for obese and slender individuals was observed, with a more critical shortage in the hospital environment, lacking non-conventional size cuffs.

These gaps can lead to inaccurate BP assessments. It is crucial for institutions, healthcare professionals, and students to recognize the need to review the calibration of devices and ensure their maintenance. Adopting these measures is essential in order to ensure accurate readings, thus contributing to correct diagnoses and effective treatment monitoring.

Author Contributions

Conception and design of the research, analysis and interpretation of the data: Costa ME, Moraes SM, Maia KAP; acquisition of data, obtaining financing and writing

of the manuscript: Costa ME, Moraes SM; statistical analysis: Costa ME; critical revision of the manuscript for intellectual content: Costa ME, Maia KAP.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This study is not associated with any thesis or dissertation work.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the Faculdade de Ciências Médicas de Minas Gerais under the protocol number 62581722.4.0000.5134/5.633.803. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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