

## Analysis of Mercury Sphygmomanometers in A Hospital School-Analysis of Mercury Sphygmomanometers

Priscila Cristina Silva, Rodolfo Souza de Faria, Adriano Gonçalves Sallum, Luiz Vinicius de Alcantara Sousa, Vitor E. Valenti, Paulo José Oliveira Cortez

Priscila Cristina Silva, Rodolfo Souza de Faria, Paulo José Oliveira Cortez, Faculty of Medicine of Itajubá (IMF), Minas Gerais General, Brazil.

Rodolfo Souza de Faria, Laboratory of Human Physiology, Faculty of Medicine of Itajubá.

Adriano Gonçalves Sallum, Laboratory of Clinical Engineering and Technical Maintenance of the School Hospital of the Faculty of Medicine from Itajubá.

Luiz Vinicius de Alcantara Sousa, Laboratory of Epidemiology and Data analysis. Faculty of Medicine of ABC - FMABC, Santo Andre, SP, Brazil.

Vitor E. Valenti, Post-graduation Program in Physical Therapy, UNESP, Presidente Prudente, SP, Brazil.

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**Correspondence to:** Luiz Vinicius de Alcantara Sousa, Faculty of Medicine of ABC - FMABC, Santo Andre, SP, Av. Lauro Gomes, 2000, Santo André, Brazil.

Email: [luiz.sousa@fmabc.br](mailto:luiz.sousa@fmabc.br)  
Telephone: +55-11-4993-5400

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### ABSTRACT

**AIM:** This work focus is analysis of the physical and calibration

conditions of the sphygmomanometers used at the Itajubá school hospital.

**METHOD:** A quantitative, observational, cross-sectional study was performed with data collection of all aneroid and mercury sphygmomanometers from the institution, excluding those that were not in use or not belonging to the School Hospital. The analyzed variables were: Identification, Gauge, Clamp, Pear, Deflation valve, Air exhaust, Measured pressure measurements and Calibration. **RESULTS:** Of the final sample of 76 sphygmomanometers, were unbalanced 76 sphygmomanometers, of which 56 (73, 7%) were of the aneroid type, 12 (15.8%) of the wall, 6 (7.9%) of the mobile column and 2 (2.6%) of mercury column, of the marks was predominant sphygmomanometers of the mark 1, with 30 (41.7%). Most of the analyzed sphygmomanometers had a serial number of 98.7% and a number of Inmetro 75%. A clamp-type relationship with calibration prevalence was found, with velcro clamps being 6 times more likely to be calibrated than clamp-type.

**CONCLUSION:** The analysis was satisfactory in relation to the quality, calibration and general state of the apparatus, with new analyzes necessary for other variable variables to obtain a good blood pressure measurement.

**Key words:** Calibration; Sphygmomanometer; Blood Pressure

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### INTRODUCTION

Instruments present in the hospital environment have the role of assisting and promoting diagnoses and treatments more accurately. The general conditions of the equipment used as well as its handling are of great importance for good prognostics<sup>[1]</sup>. The device for the measurement of blood pressure called sphygmomanometer, which

is part of the day-to-day life of health professionals, is among those biomedical equipments.

The sphygmomanometer is a measuring instrument<sup>[2,3]</sup> with an appropriate cuff to the patient (recommendations of the *AHA-American Heart Association*)<sup>[4]</sup>, air outlet control valve, pear, unidirectional air pump valve and manometer. In order for this device to measure a person's blood pressure, minimizing measurement errors, some specific care is required. In this sense, sphygmomanometers should be evaluated as a measuring instrument with authentication, regulation, calibration, good conditions for use and handling as established by measurement organs (Institutes of Weights and State Measures) and the Brazilian Network of Legal Metrology and Quality - RBMLQ besides Inmetro<sup>[5]</sup> that describes the law n° 8,078, which specifies the calibration of sphygmomanometers<sup>[6]</sup>.

Any action that promotes disturbances or errors in this procedure can generate problems in the diagnosis and treatment of serious diseases such as systemic arterial hypertension<sup>[7,8]</sup> (> 140/90 mm Hg) that is present in 22.3% to 43.9% of the Brazilian population in some cities.

In view of the above consideration, we aimed to perform an analysis of the physical and calibration conditions of the sphygmomanometers used in a Hospital School, in order to generate data that can be used by the institution in search of better diagnostic conditions and consequently of therapeutic institution to patients attended.

## METHODS

The Hospital school (HS) of the Medical School of Itajubá, maintained by the Association of Social Integration of Itajubá, composes the group of "Reference Hospitals" in the south of the state macro region of Minas Gerais in hospital procedures of average and high complexity, with direct regulation by the SUS Easy. The HS is a reference to 15 cities in the micro-region of Itajubá and is currently classified as general teaching hospital. It has hospital admission services in the areas of Medical, Surgical, Maternity, Pediatrics, Adult and Infantile Intensive Care Units and Units. Currently, it has high complexity services, being a secondary and tertiary reference in the region in elective and emergency services, being inserted in the Program of the State Health Secretariat of Minas Gerais, PRO-HOSP.

An observational cross-sectional study was carried out in the clinical engineering laboratory of the School Hospital of the Medical School of Itajubá, Minas Gerais, Brazil, in 2016 and 2017.

The study analyzed sphygmomanometer devices in use, with the exception of digital manometers, which resulted in a definitive sample of 76 devices ( $N = 76$ ). We excluded devices that were not in use, with parts incomplete or not belonging to the School Hospital.

For the data collection the variables were divided into: Identification, Manometer, Clamp, Pear, Deflation valve, Air exhaust, Measured pressure measurements and Calibration. The conditions of use, enumeration by label and which sector was the apparatus were collected with purpose of orientation for the researcher. The variables were collected according to the Inmetro Ordinance n° 153, de 12 of August 2005, which specifies and characterizes factors for sphygmomanometer analysis, and NIE-DIMEL-006, which describes the calibration method<sup>[9-11]</sup>.

Data collection was performed through a MS Office Excel 2010 Windows® worksheet, under the authorization of the Engineer responsible for the Laboratory of Clinical Engineering and Nurse responsible for the hospital sectors, from September 2016 to March

2017.

In the identification of the apparatus we collected and analyzed the presence of initial identification of Inmetro<sup>[10,11]</sup>, serial number, identification of the manufacturer brand and what type of appliance. The types found during the research were aneroid mechanical sphygmomanometer, mobile column sphygmomanometer, wall sphygmomanometer and mercury column sphygmomanometer.

The analysis of the manometer was made by the visible scale, quality of the manometer, quality of the indicating device, indicating device in the zero mark without insufflating the cuff and quality of the glass / plastic protector. The analysis of the quality of the gauge items is intended to indicate cracks, cracks or any other changes that could compromise the operation of the pressure gauge.

In the clamp the evaluated items were the quality of the cuff, type of cuff being these of Velcro or clamp, indicative markings and quality of the cuff. It was evidenced that there were alterations that would compromise the measurement of pressure such as cuts in the cuff, erroneous markings, absent or faded. The pear evaluation process aimed at its physical quality, observing whether the pear contained cracks, dried portions or defects in inflation valve.

The deflation valve was analyzed for its quality as valve opening/closing difficulty, inadequate size for the pear or hose, it was also analyzed the presence of continuous leakage with minimum pressures.

Air leakage analysis was then performed. This procedure consists in analyzing if the decrease of the pressure of the apparatus is acceptable, the accepted variation is of 20mmHg in 5 minutes. The procedure for determining air leakage consists of a sphygmomanometer<sup>[9]</sup>, In a pneumatic system, subjected to a pressure of 280 mmHg, waiting for up to 1 minute for the air to enter thermodynamic equilibrium in the system, then waiting for 5 minutes without adjusting the indication of the instrument is read if this manometer indicates Less than 260 mmHg, should reject because it does not fit the admissible frame, since its variation was superior to 20 mmHg.

The variables measured pressure measurements and calibration are complementary to each other, since the measured measures allow to classify the sphygmomanometer as calibrated or not. In order to carry out the measured pressure measurements, a pneumatic system was created in the laboratory, which consists of wrapping the sphygmomanometer cuff in a vertical rigid metal cylinder. In order to have as comparative, a calibrated mercury column sphygmomanometer was established as the working standard. By connecting the pneumatic system to the working standard by means of a hose and Y-connector (Figure 2), a system for comparing pressure measurements was formed, allowing verification of the calibration.

Using the comparison system for calibration, 4 measurements were established to verify calibration, each with a variation of 40 mmHg between them, the measurements were: 60 mmHg, 100 mmHg, 140 mmHg and 180 mmHg. The comparison was made four times in a growing cycle and four times in a decreasing cycle, the variation of 4mmHg was accepted or decreasing admissible values. Thus, values greater or less than the allowable value were characterized unbalanced devices, regardless of the cycle that this episode occurred. Therefore, the calibration characterization was performed by analyzing the 8 measured pressure measurements.

For data analysis, descriptive statistics were performed through the MS Excel 2013 program, generating the tables. The software Bioestat 5.0 was used in two tests, the first one was the Logistic Regression analysis in order to evaluate the possible correlation

between the variables and the calibration. A second test, the chi-square test, was applied to the table to test if there is one type of apparatus with better performance in the calibration.

## RESULTS

A total of 76 sphygmomanometers were analyzed, among which 56 (73.7%) were of the aneroid type, 12 (15.8%) of the wall, 6 (7.9%) of the mobile column and 2 (2.6%) of the Mercury, brand 1 sphygmomanometers predominated with 30 (41.7%). Most of the analyzed sphygmomanometers had a serial number (98.7%) and Inmetro numbering (75%), Table 1.

Table 2 shows the identification of the sphygmomanometers considering the brand and type of each device.

Among the 76 instruments analyzed, 30 (39.5%) had an out-of-zero indication of manometer, although variables such as visible scale (0%) and Indicator device (5.4%) were shown to perform well in relation to manometer characterization.

The ratio of amounts of clamps by type 54 (71.1%) were velcro type while 22 (28.9%) were stapled. Of these, 73.7% presented good quality in general. The pears were in good quality 60 (78.9%).

Of the 76 of the analyzed devices, only 13 (17.6%) were not calibrated, although air leakage was present in 35 (47.9%), Table 5. According to the Logistic Regression tests it was verified that the only factor that Influenced the calibration of the apparatus was the type of clamp, where the type of it increases in approximately 6 times the chance of being calibrated the device, where it was found that the best type is Velcro where in this type the device has a 95% chance of Be calibrated while the staple type drops to 65% chance of it remaining calibrated.

According to the Chi-square test applied to the table, the value  $p = 0.3666$  was obtained, which means that there was no significant difference in the calibration in relation to the types analyzed, ie, the calibration is not influenced by the type of apparatus.

## DISCUSSION

The process of blood pressure measurement using manual sphygmomanometers has several variables including errors of the observer and the device used<sup>[12-14]</sup>, which makes measurement error a problem and a generator of discussion in the midst of the health community. Discussions like the correct method, most common errors, sizes and proportions of the cuff and cuff<sup>[13]</sup> are constant in the search for a more reliable gauge that demonstrates the patient's actual blood pressure.

In order to elucidate the conditions of use of the sphygmomanometers with the calibration of the devices from the applied tests, it was observed that of the 76 (100%) evaluated apparatus 13 (17.6%) were de-calibrated. Through analysis of the relationship between the calibration and the type of device, we reached  $p = 0.3664$ , which cancels out the relation between the type of sphygmomanometer and the calibration; differently from what is found in other articles that describe the prevalence of calibrated aneroid-type devices stand out from other types<sup>[15,16]</sup>.

In the present study, the type of cuff was shown to be highly related to calibration. Velcro-type clamps increase the chance of the device being calibrated by approximately six times. This issue can be approached as a factor of the efficiency and ease of Velcro in keeping in the patient's arm, unlike the clamp that has points predetermined to be fixed, generating spaces and possible gaps which can generate problems in the measurement of blood pressure that can be compared to the use of arm rests of inadequate arm circumference<sup>[17,18]</sup>.

**Table 1** Identification of the devices as to the serial number and number of the Inmetro.

	N° Inmetro	N° Series
Gift	57 (75)	75 (98.7)
Absent	12 (15.8)	1 (1.3)
Ineligible	7 (9.2)	0 (0)

**Table 2** Identification of the devices for the brand and type.

Brand	Frequency (%)	Type	Frequency (%)
Brand 1	30 (41.7)	Aneroid	56 (73.7)
Brand 2	17 (23.6)	Mobile Column	6 (7.9)
Brand 3	12 (16.7)	Wall	12 (15.8)
Brand 4	7 (9.7)	Column of Mercury	2 (2.6)
Brand 5	6 (8.3)		

**Table 3** Manometer analysis related to scale, indicating device, zeroed indication, protection glass and quality of the physical condition of the apparatus (N / %).

	Visible Scale	Indicator Device	Quality	Indicates 0	Glass
Accordinging	76 (100)	70 (94.6)	60 (78.9)	46 (60.5)	60 (78.9)
Not Conform	0 (0)	4 (5.4)	16 (21.1)	30 (39.5)	16 (21.1)

**Table 4** Clamp and analyzed variables, cuff quality, marking, clamp type and clamp quality per se (N / %).

	Cuff	Markings	Quality	Type	Type quantity
Accordinging	61 (80.3)	64 (84.2)	56 (73.7)	Clip	22 (28.9)
Not Conform	15 (19.7)	12 (15.8)	20 (26.3)	Velcro	54 (71.1)

**Table 5** Pear quality description and air leakage verification.

	Pear	Air Leakage	
	Quality (%)		Amount (%)
Satisfactory	60 (78.9)	Suitable	38 (52.1)
Not satisfactory	16 (21.1)	Inappropriate	35 (47.9)

**Table 6** Evaluation of the Deflation Valve and presence of leakage of this component.

	Quality (%)	Leakage (%)	
Satisfactory	55 (75.3)	Absent	47 (65.3)
Not satisfactory	18 (24.7)	Gift	25 (34.7)

**Table 7** Description of Calibration in the analyzed Sphygmomanometers.

	Amount (%)
Yes	61 (82.4)
No	13 (17.6)

**Table 8** Logistic Regression Analysis.

	p value
Calibration x Model/Type	0.229
Calibration x Manometer	0.009
Calibration x Clamp	0.118
Calibration x type of Clamp	0.024
Calibration x Deflation valve	0.528
Calibration x Pear	0.383
Calibration x Air exhaust	0.663

**Table 9** Analysis of the type of apparatus in relation to the quantity of calibrated. apparatus.

	Aneroid (%)	Column (%)	Wall (%)
Calibrated	41 (80.4)	6 (100)	10 (90.9)
Uncalibrated	10 (19.6)	0 (0.0)	1 (9.1)

However, there are no previous studies demonstrating the relationship of devices with clamp type clamps to be more unbalanced than devices with Velcro clamps. A previous study discussed the efficiency of BP measurement from the use of a cuff recommended by the American Hypertension Association, raising discussions of situations such as hyper estimation of values when the cuffs are narrower and hypo estimation when the cuffs are too broad and the arms thin, which may lead to complications. The treatment of hypertension, treating unnecessarily normotensive and not treating hypo estimates but hypertensive<sup>[19]</sup>.

The need for more attention to the quality of the sphygmomanometers is evidenced by the number of devices with air leakage 30 (39.5%) and outside the zero marking 35 (47.9%) present in the study. Even if these have not been correlated with the calibration recommendations of the device evaluation body, Inmetro<sup>[13]</sup>, on these two items evaluated during the qualification of the device demonstrate that present alterations can generate, as well as the clamp, hyper factors or hypo estimations of BP values.

We suggest the continuity of the study seeking to correlate the remaining variables with the calibration of the device and a follow-up of the apparatuses of the school hospital of the Medical School of Itajubá evidencing if there was any future improvement in relation to the present study and if there is preservation of the correlation of the type of Clamp with calibration.

## CONCLUSION

The analysis of the sphygmomanometers of the Hospital School of the Medical School of Itajubá shows a satisfactory relation of the quality and calibration of the devices as well as their general state, however, new analyzes are necessary to show other factors such as leakage of valves, non-zero indicators that can be deterministic for a significant change in blood pressure measurement.

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