International Journal of Cardiovascular Sciences. 2017;30(2):100-108

ORIGINAL ARTICLE

Inadequacies of Sphygmomanometers Used in Emergency Care Services in a Large Capital City in Brazil

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Abstract

Background: Hypertension is the main risk factor for cardiovascular diseases. Technical quality of sphygmomanometers is a prerequisite for the correct measurement of arterial pressure.

Objectives: To evaluate sphygmomanometers available in emergency services in the city of Belo Horizonte, Brazil.

Methods: We performed a cross-sectional, observational, non-interventional study to evaluate characteristics of the sphygmomanometers available in adult emergency services of public and private hospitals in the city of Belo Horizonte, Brazil. We evaluated 337 sphygmomanometers of 25 hospitals – 15 (of 16) public hospitals and 10 (of 12) private hospitals.

Results: Twenty-six percent (88/337) of devices were considered inadequate regarding the INMETRO (National Institute of Metrology, Quality and Technology) standards, 39.2% (132/337) for calibration dates, and 54% (188/337) for the mismatching between cuff's and device's brands. In 13 of 25 hospitals (52%), there were no spare cuffs in different sizes for different arm circumferences. Higher adequacy was found for aneroid and mercury sphygmomanometers used in private hospitals ($p = 0.038$ and $p < 0.001$, respectively) and electronic devices used in public hospitals ($p < 0.001$) compared with others.

Conclusion: Seventy-eight percent of sphygmomanometers available in emergency services had technical inadequacies, and half of these services had no spare cuffs in different sizes available. These findings serve as a warning of the conditions of the equipment used in healthcare services provided to the general population in Brazil. (Int J Cardiovasc Sci. 2017;30(2):100-108)

Keywords: Hypertension; Sphygmomanometers; Emergency Medical Services; Hospitals, Public; Hospitals, Private; Equipment Failure.

Introduction

Systemic arterial hypertension (SAH) is a multifactorial clinical condition diagnosed and characterized by sustained increased arterial pressure (AP) levels.[1] SAH affects nearly 30% of adult population,[2,3] and is considered as the main risk factor for cardiovascular diseases, which in turn are the major cause of deaths in Brazil and in the world.[4] Significant increases in AP is responsible for approximately 3% of emergency room admissions.[5]

Patients are considered hypertensive if they have a hypertensive urgency or emergency at their medical visit.[5] AP measurements should be performed in every clinical assessment by a physician or other healthcare professionals.[1] However, although simple and easy to perform, determination of AP is not always conducted as recommended. A correct measurement of AP, crucial for diagnostic and decision-making processes, is determined by proper functioning of sphygmomanometer and use of appropriate technique,[1] which involves determination of arm circumference and selection of appropriate blood

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DOI: 10.5935/2359-4802.20170028

Manuscript received July 04, 2016, revised manuscript November 30, 2016, accepted December 02, 2016.

pressure cuff size.[1,7] The arm circumference/cuff width ratio must be of 0.40, and bladder length should be of 80-100% of arm circumference.[1,8] Standard bladder should be 12-13 cm wide and 35 cm long, and larger and smaller bladders should be available for large and thin arms, respectively.[9,10] Measurements can be performed either indirectly, by auscultatory method and use of aneroid sphygmomanometer, or by oscillometric technique, using a semi-automated device.[10,11] All devices should be validated and calibrated.[10,12]

The present study was designed to assess the quality of AP measurement devices used at emergency care units in the city of Belo Horizonte, which is the sixth most populated city in Brazil, with more than 2.5 million inhabitants.[13] It aimed to evaluate sphygmomanometers available at adult emergency care services of Belo Horizonte, Minas Gerais state, Brazil. Outcome measures were parameters directly related to the quality of AP measurements – validation by the National Institute of Metrology, Standardization and Industrial Quality (INMETRO), availability of blood pressure cuffs in different sizes, conditions of their components – bulb, hose, hook and loop closures (Velcro and hooks), manometer, mercury column, valve – calibration, and adequacy between sphygmomanometer and cuff brands. Also, the study aimed to compare sphygmomanometers and components available at public and private adult emergency services.

Methods

This was an observational, non-interventional study. After obtaining approval from clinical or technical directors of the institutions, and informed consent from participants, a questionnaire on the outcome measures of this study (Table 1) was administered to physicians, nurses and administrative staff members of emergency care services of public and private hospitals in Belo Horizonte. The study was approved by the Ethics Committee of the School of Medical Sciences of Minas Gerais (certificate of submission: 35484614.9.0000.5134; certificate of approval: 846.017, 10/19/2014).

After the questionnaires were filled out by participants, the investigators evaluated all AP measurement devices available in participating hospitals. A calibration interval of up to one year was considered adequate, based on the date when calibration was last performed (printed on the equipment or informed by the emergency service). Bulb and hose conditions were considered adequate when no damage or difficulty in manipulation was detected. Manometers and mercury columns should have numbers and pointers starting at zero and in perfect conditions during inflation and disinflation. Hook and loop closures should be in good conditions, with Velcros with good stickiness. Valves should be intact and easily manipulated during inflation and disinflation. INMETRO certificate seal should be present in every device. Data were collected from January to August 2015.

Table 1 – Questionnaire

Questionnaire
Do the sphygmomanometers available at the service belong to the institution or to the physicians/nurses? ( ) institution ( ) professionals ( ) both
How many sphygmomanometers are available at the emergency department, considering triage, consultation and observation rooms?
What type of sphygmomanometer is available at the emergency department of this hospital/institution? ( ) aneroid ( ) electronic ( ) mercury Quantity, brands and models:
In addition to standard cuffs, are there different sized cuffs available at the service? ( ) no ( ) yes – available number, brands and sizes
Is there an adequacy between cuff and device? ( ) yes ( ) no
Are the sphygmomanometers regularly calibrated? ( ) yes ( ) no Date of last calibration:

Inclusion criteria

Both public and private hospitals offering emergency care services for the general population.

Exclusion criteria

Hospitals that did not accept to participate in the study, hospitals whose emergency services are not open for the general population, and specialized hospitals (maternity, pediatric, psychiatric hospitals, otolaryngology, ophthalmology and orthopedics emergencies).

Statistical analysis

According to information provided by the Medical Board of Minas Gerais, 16 public hospitals and 12 private hospitals that met the inclusion criteria were identified.

For sample calculation, we used the following equation

$$n = \frac{[(p_1.q_1)N_1 + (p_2.q_2)N_2].(Z_{\alpha/2} + Z_\beta)^2}{(p_1N_1 - p_2N_2)^2}$$

Where:

Variable	Meaning
n	Sample size
a	Probability of type I error
b	Probability of type II error
$z_{a/2}$	(1-a) percentile from the standard normal distribution
p1	Estimate of proportion (of variable of interest) in group 1; if unknown, $p_1 = 0.5$
p2	Estimate of proportion (of variable of interest) in group 2; if unknown, $p_2 = 0.5$
N1	Group 1 population size
N2	Group 2 population size

$$n = \frac{[(p_1.q_1)N_1 + (p_2.q_2)N_2].(Z_{\alpha/2} + Z_\beta)^2}{(p_1N_1 - p_2N_2)} =$$

$$= \frac{[(0.5*0.5*16) + (0.5*0.5*12)](1.96 + 0.84)^2}{(0.5*16 - 0.5*12)} = 14$$

A minimum of 14 (6 private and 8 public, according to proportionality) should be randomly selected. A level of significance of 5% (z = 1.96), estimate of proportion of 0.5 (since p1 and p2 were unknown), and probability of type II (b) error of 20% (z = 0.84) were adopted.

First, descriptive analysis was used to characterize the sample; qualitative variables were described in absolute and relative frequencies. The sample was stratified by type of hospital (public/private). The chi-squared test was used to compare characteristics of sphygmomanometers used in public emergency services with those used in private emergency ones. Statistical significance was set at $p < 0.05$. Analysis was performed using the SPSS (Statistical Package for Social Sciences) software, version 20.0, 2012.

Results

A total of 337 sphygmomanometers used in 25 emergency care services (15 out the 16 public hospitals, and 10 of the 12 private hospitals) in the city of Belo Horizonte, Brazil, were assessed. One hundred and ninety-seven sphygmomanometers (120 from public hospitals and 77 from private hospitals) were of aneroid type, 134 were electronic (98 from public hospitals and 36 from private hospitals), and 6 (1 from a public hospital and 5 from private hospitals) of mercury column type (Table 2). With respect to the quality of device components, high percentage of bulb and hose (96.4%, 325/337), valve (98.8%, 333/337), hook and loop closures (92%, 310/337), and manometers and mercury columns (97.5%, 198/203) were considered adequate. For the last item (manometers and mercury columns, electronic sphygmomanometers were not included in the analysis. INMETRO certificate seal was detected in 74% (49/337) of the instruments, and was more frequently absent in electronic devices compared with manual ones.

A calibration date indicating an interval of less than one year elapsed from the last inspection was found in 60.8% (205/337) of the sphygmomanometers. Adequacy between sphygmomanometer and cuff brands was observed in 45.7% (154/337) of the devices (Table 3). If all quality parameters of the components were simultaneously analyzed, only 21.6% (73/337) of them were in adequate conditions, i.e., 78.4% had one or more quality parameter or component considered as inadequate (Table 4).

Table 2 – Types of sphygmomanometers available at adult emergency care services in Belo Horizonte, Brazil

Devices	Public hospitals	Private hospitals	Total
Aneroid	120 (61%)	77 (39%)	197 (100%)
Electronic	98 (73%)	36 (27%)	134 (100%)
Mercury column	1 (17%)	5 (83%)	6 (100%)
Total	219 (65%)	118 (35%)	337 (100%)

Table 3 – Adequacy of sphygmomanometers' components and quality outcome measures

Components	Adequacy of aneroid devices	Adequacy of electronic devices	Adequacy of mercury devices	Total
Bulb / Hose	185/197 (93.9%)	134/134 (100%)	6/6 (100%)	325/337 (96.4%)
Valve	193/197 (98%)	134/134 (100%)	6/6 (100%)	333/337 (98.8%)
Manometer / Mercury Column	192/197 (97.5%)	-	6/6 (100%)	198/203 (97.5%)
Velcro / Hooks	173/197 (87.8%)	131/134 (97.8%)	6/6 (100%)	310/337 (92%)
INMETRO certificate	188/197 (95.4%)	55/134 (41%)	6/6 (100%)	249/337 (74%)
Calibration	109/197 (55.3%)	91/134 (67.9%)	5/6 (83.3%)	205/337 (60.8%)
Adequacy between cuffs' and devices' brands	86/197 (43.7%)	66/134 (49.3%)	2/6 (33.3%)	154/337 (45.7%)
Sphygmomanometers considered adequate for all components and quality parameters '	44/197 (22.3%)	27/134 (20.1%)	2/6 (33.3%)	73/337 (21.6%)

Table 4 – Sphygmomanometers considered adequate for both components and quality outcome measures

	Public hospital	Private hospital	Total	p-value
Aneroid	19/120 (15.8%)	25/77 (32.5%)	44/197 (22.3%)	0.038
Electronic	27/98 (27.5%)	0/36 (0.0%)	27/134 (20.1%)	< 0.001
Mercury column	0/1 (0.0%)	2/5 (40%)	2/6 (33.3%)	< 0.001
Total	46/219 (21%)	27/118 (23%)	73/337 (21.6%)	0.896

In 52% (13/25) of the hospitals, there were no spare cuffs in different sizes in addition to the standard ones (Table 5). Significant differences were found in comparisons of sphygmomanometers and components available at public emergency services with those of private services. First, there was a better matching of cuffs' with sphygmomanometers' brands in aneroid and mercury devices of private hospitals than those of public institutions (Table 6).

In addition, private hospitals showed better maintenance of aneroid sphygmomanometers in terms of calibration periodicity ($p < 0.01$) (Table 7). INMETRO certificate seal was found in only 41% (55/134) of electronic devices, and yet in a significantly higher frequency in private hospitals than in public ($p = 0.002$) (Table 7). When sphygmomanometer components – bulb, hose, valve, manometer or mercury

column, Velcro and hooks – of aneroid, electronic and mercury devices were grouped, there was no statistically significant difference between public and private hospitals (Table 8). When all outcome measures (related to quality and components) were simultaneously assessed, a high degree of inadequacy was seen in all types of sphygmomanometers (78.4%, 264/337) in both public and private hospitals. However, higher adequacy of aneroid ($p = 0.038$) and mercury ($p < 0.001$) sphygmomanometers was observed in private hospitals, whereas higher adequacy of electronic devices was seen in public hospitals ($p < 0.001$) (Table 4).

Spare cuffs for different arm circumferences were available in 60% (6/10) of private hospitals and 40% (6/15) of public hospitals, with no statistically significant difference ($p = 0.428$) (Table 5). With respect to portability, 84% (165/197) of devices were trolley-mounted, 10% (20/197) were wall-mounted and 6% (12/197) were portable (manual). Regarding electronic equipment, 98.5% (132/135) were integrated into a multi-parameter monitor and used at the patients' bedside, and only 1.5% (2/134) was portable, trolley-mounted devices. Six mercury sphygmomanometers were assessed, 67% (4/6) of them trolley-mounted and 33% (2/6) wall-mounted.

Table 5 – Hospitals with spare cuffs in different sizes in addition to standard cuffs

Spare, different sized cuffs	Yes	No	Total	p-value
Public hospital	6 (40%)	9 (60%)	15	0.428
Private hospital	6 (60%)	4 (40%)	10	
Total	12 (48%)	13 (52%)	25 (100%)	

Table 6 – Adequacy between cuffs' and manometers' brands

	Public hospital	Private hospital	Total	p-value
Aneroid	44/120 (36.7%)	42/77 (54.5%)	86/197 (43.7%)	0.018
Electronic	48/98 (49%)	18/36 (50%)	66/134 (49.3%)	1.00
Mercury column	0/1 (0%)	2/5 (40%)	2/6 (33.3%)	< 0.001

Table 7 – Adequacy of sphygmomanometers for calibration and INMETRO (National Institute of Metrology, Quality and Technology) certificate

	Public hospital	Private hospital	Total	p-value
Calibration of aneroid devices	50/120 (41.7%)	59/77 (76.6%)	109/197 (55.3%)	< 0.001
Calibration of electronic devices	68/98 (69.4%)	23/36 (63.9%)	91/134 (67.9%)	0.540
Calibration of mercury column	0/1 (0%)	5/5 (100%)	5/6 (83.3%)	0.167
Aneroid devices, INMETRO certificate	116/120 (96.7%)	72/77 (93.5%)	188/197 (95.4%)	0.317
Electronic devices, INMETRO certificate	50/98 (51%)	29/36 (80.6%)	55/134 (41%)	0.002
Mercury column, INMETRO certificate	1/1 (100%)	5/5 (100%)	6/6 (100%)	-

Table 8 – Adequacy of the quality of sphygmomanometers' components in public and private hospitals

	Public hospital	Private hospital	Total	p-value
Bulb / Hose – aneroid devices	110/120 (91.7%)	75/77 (97.4%)	185/197 (93.9%)	0.131
Valve – aneroid devices	118/120 (98.3%)	75/77 (97.4%)	193/197 (98%)	0.645
Manometer – aneroid devices	117/120 (97.5%)	75/77 (97.4%)	192/197 (97.5%)	1.00
Velcro / Hooks – aneroid devices	101/120 (84.2%)	72/77 (93.5%)	173/197 (87.8%)	0.073
Bulb / Hose – electronic devices	98/98 (100%)	36/36 (100%)	134/134 (100%)	-
Valve – electronic devices	98/98 (100%)	36/36 (100%)	134/134 (100%)	-
Manometer - electronic devices	-	-	-	-
Velcro / Hooks - electronic devices	97/98 (99%)	34/36 (94.4%)	131/134 (97.8%)	0.176
Bulb / Hose – mercury devices	1/1 (100%)	5/5 (100%)	6/6 (100%)	-
Valve - mercury devices	1/1 (100%)	5/5 (100%)	6/6 (100%)	-
Mercury column - mercury devices	1/1 (100%)	5/5 (100%)	6/6 (100%)	-
Velcro / Hooks - mercury devices	1/1 (100%)	5/5 (100%)	6/6 (100%)	-

Discussion

Our study showed that 78.4% (264/337) of sphygmomanometers used in adult emergency services in Belo Horizonte, Brazil, showed some degree of inadequacy in one or more components/quality parameter evaluated. Besides, there were no spare cuffs available for different arm circumferences in 52% (13/25) of the services. Technical quality of sphygmomanometers is a *sine qua non* for the correct AP measurement. Our study showed that date of last calibration was not updated for more than one year in 39.2% (132/337) of the equipment, which was more common in public hospitals than in private ones. In a computer simulation study, after three blood pressure measurements, uncalibrated sphygmomanometers caused 20% of all undetected systolic hypertension and 28% of all undetected diastolic hypertension. Also, they were responsible for 15 and 31% of falsely detected systolic and diastolic hypertension, respectively.[14] A study by Serafim et al.[15] conducted in Brazilian hospitals showed that 56.2% of the 162 sphygmomanometers examined were uncalibrated. Turner et al.[16] pointed out the necessity of having all sphygmomanometers calibrated annually, and suggested a 6-month calibration interval for aneroid sphygmomanometers to decrease the occurrence of errors in blood pressure measurements. A study[17] conducted in a large British hospital assessed 127 devices (18 mercury, 62 aneroid and 47 automatic), and showed that 25% of them were uncalibrated. The INMETRO's decree number 46, issued on January 22, 2016,[18] states that all sphygmomanometers should be calibrated annually by one of the members of the Brazilian Association of Legal Metrology and Quality. This calibration periodicity is also recommended by the VI Brazilian Guidelines on Hypertension.[1]

In our study, there was a mismatch between device's and cuff's brands in 54.3% (183/337) of the sphygmomanometers, and there was no evidence that the device and cuff combinations used in the service had been approved by INMETRO. This was more frequently observed in public than in private hospitals. In 2013, Shaw et al.[19] demonstrated that replacement of original (manufacturer-supplied) cuffs with others led to underestimation of AP measurements. Although one third of patients had poorly controlled hypertension, they were erroneously considered normotensive after using substitute cuffs. The authors concluded that sphygmomanometer cuffs are not interchangeable between devices of different brands. The INMETRO

approves the use of specific cuffs for specific manometers regarding brands and models, and determines that, if a cuff of electronic devices had been previously used with equipment of different brands, this brand/model combination should be clearly informed.[18,20] There has been a strong recommendation[21] on replacement of mercury column sphygmomanometers with others due to high risk of toxicity and environmental contamination. However, its use is still approved by the Brazilian National Health Surveillance Agency. This type of sphygmomanometer accounted for 1.7% (6/337) of all equipment evaluated in this study.

Furthermore, in our study, nearly half of hospitals, including public and private ones, did not have spare, different size cuffs in the emergency rooms. The importance using correct cuffs for different arm circumferences has been shown by several authors,[22-24] and is an essential prerequisite for proper measurement of AP.[1,6,10] A cuff smaller than the arm circumference overestimates, whereas larger cuffs underestimates AP measurements.[24,25] A study analyzing scientific papers published in Brazilian journals reported that 64% of the studies did not mention the sizes of the cuffs or their adequacies to arm circumferences.[26] A study conducted in a teaching hospital in Sao Paulo state showed that using an arm circumference to cuff width ratio of 0.4, more than 50% of patients required a cuff smaller than 12 cm and 22% a larger one. The study showed that the standard sized cuff was adequate for only 17% of participants.[27] Similarly, Freitas et al.[28] found that only 50% of patients used adequately sized cuffs, since standard cuffs were the only available ones at public health centers. The unavailability of cuffs for different arm circumferences is still a challenge faced by healthcare providers, and this scenario was also found in emergency care units in Belo Horizonte.

The INMETRO also recommends that every cuff, even if not in use, should be inspected once a year, counting from the date of last acquisition.[29] We found that 26% of the cuffs did not have the INMETRO seal, which is required by the technical metrology regulations.[18,20,29] In Europe and the United States, devices are released for use after being submitted and approved by validation studies, according to the standards issued by the British Hypertension Society,[30] the Association for the Advancement of Medical Instrumentation[31] and the European Society of Hypertension,[32] available at *http://www.dableducational.org/sphygmomanometers/devices_2_sbpm.html)* e *http://www.bhsoc.org/bp_monitors/automatic.stm*.

The INMETRO requires that every manufacturer presents a clinical trial on the use of the sphygmomanometer, conducted according to international guidelines, as a prerequisite for approval for use in Brazil.[18,20] On the dableducational.org website, we did not find any review of the models available in our study. Taking into account all components and quality parameters, we found a high percentage of inadequacy (78%) of devices, especially due to lack of regular calibration or INMETRO certificate, and mismatching between cuff's and device's brands.

This study has some limitations. Due to the observational nature of the study, we and could not test and confirm the calibration status or the adequacy between cuffs and sphygmomanometers, which were verified by date of last calibration (or its absence) and the brands of components, respectively. Besides, the small number of mercury sphygmomanometers makes the comparison with other types difficult.

Conclusion

Most of sphygmomanometers available at adult emergency care services of the hospitals included in the study in Belo Horizonte, Brazil, were considered inadequate for use. Their general conditions should be improved, particularly in terms of regular calibration, availability of spare cuffs for different arm circumferences, and compatibility between cuffs and manometers.

Author contributions

Conception and design of the research: Maia KAP, Malachias MVB. Acquisition of data: Maia KAP, Paiva IV, Mariano RM, Paiva RV. Analysis and interpretation of the data: Maia KAP, Malachias MVB. Statistical analysis: Maia KAP. Obtaining financing: Maia KAP. Writing of the manuscript: Maia KAP, Malachias MVB. Critical revision of the manuscript for intellectual content: Maia KAP, Malachias MVB.

Potential Conflict of Interest

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

Sources of Funding

There were no external funding sources for this study.

Study Association

This article is part of the thesis of master submitted by Kleisson Antonio Pontes Maia, from Faculdade de Ciências Médicas de Minas Gerais.

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