Original Article

Evaluation of the conditions of use of sphygmomanometers in hospital services*

Avaliação das condições de uso de esfigmomanômetros em serviços hospitalares

Evaluación de las condiciones de uso de esfigmomanómetros en servicios hospitalarios

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ABSTRACT

Objective: To evaluate the conditions of sphygmomanometers in use at public and private hospitals. **Methods:** A descriptive study using a quantitative approach, undertaken in four major hospitals in the State of São Paulo, in the period between 2009 and 2010. The aneroid manometers were tested against a calibrated mercury manometer. They were considered out of calibration when the differences were ≥ 4 mmHg. **Results:** We assessed 162 sphygmomanometers (78 in a public hospital and 84 from philanthropic and private institutions) and 98.1% were of the aneroid type. It was verified that 56.2% of the manometers were not calibrated (48.6% of private hospitals and 63.1% of public hospitals). Analyzing the mean differences of negative decalibration, there was a significant difference between the manometers of the private hospital and the public hospitals (-6.14 ± 2.66 mmHg vs. -8.97 ± 6.74 mmHg, respectively, p <0.05). It was also observed that in 70.2% there was no periodic evaluation made, 26.7% had aged rubber extension, 20.5% presented leaking valves, and 27% of the manometers did not rest with the pointer on the zero mark. **Conclusion:** The decalibration of the aneroid sphygmomanometers was significant and may lead to incorrect evaluation of blood pressure.

Keywords: Sphygmomanometers; Blood pressure determination/instrumentation; Equipment failure; Evaluation studies as topic; Hospital services

RESUMO

Objetivo: Avaliar as condições de uso dos esfigmomanômetros em hospitais públicos e privados. **Métodos:** Estudo descritivo de abordagem quantitativa realizado em quatro hospitais de grande porte do Estado de São Paulo, no período entre 2009 e 2010. Os manômetros aneroides foram testados contra manômetro de mercúrio calibrado. Foram considerados descalibrados quando as diferenças foram ≥ a 4 mmHg. **Resultados:** Foram avaliados 162 esfigmomanômetros, (78 de um hospital público e 84 de instituições filantrópicas e privada) e 98,1% eram do tipo aneróide. Verificou-se que 56,2% dos manômetros estavam descalibrados (48,6% do hospital privado e 63,1% dos hospitais públicos). Analisando-se as médias das diferenças negativas da descalibração, houve diferença significativa entre os manômetros do hospital privado e os dos hospitais públicos (-6,14±2,66 mmHg *vs* -8,97±6,74 mmHg, respectivamente, p<0,05). Observou-se ainda que em 70,2% não era feita avaliação periódica; 26,7% tinham extensão de borracha envelhecida; 20,5% das válvulas apresentaram vazamento; e 27% dos manômetros não estavam com o ponteiro na marca zero. **Conclusão** A descalibração dos esfigmomanômetros aneróides foi expressiva e pode acarretar avaliação incorreta da pressão arterial.

Descritores: Esfigmomanômetros; Determinação da pressão arterial/instrumentação; Falha de equipamento; Estudos de avaliação como assunto; Serviços hospitalares

RESUMEN

Objetivo: Evaluar las condiciones de uso de los esfigmomanómetros en hospitales públicos y privados. **Métodos:** Estudio descriptivo de abordaje cuantitativo realizado en cuatro hospitales de gran porte del Estado de Sao Paulo, en el período entre 2009 y 2010. Los manómetros aneroides fueron probados contra manómetro de mercurio calibrado. Se consideraron descalibrados cuando las diferencias fueron ≥ a 4 mmHg. **Resultados:** Fueron evaluados 162 esfigmomanómetros, (78 de un hospital público y 84 de instituciones filantrópicas y privadas) y el 98,1% eran del tipo aneroide. Se verificó que el 56,2% de los manómetros estaban descalibrados (48,6% del hospital privado y 63,1% de los hospitales públicos). Analizándose las medias de las diferencias negativas de la descalibración, hubo diferencia significativa entre los manómetros del hospital privado y los de los hospitales públicos (-6,14±2,66 mmHg *vs* -8,97±6,74 mmHg, respectivamente, p<0,05). Se observó aun que en el 70,2% no se realiza la evaluación periódica; 26,7% tenían extensión de jebe envejecido; el 20,5% de las válvulas presentaron derramamiento; y el 27% de los manómetros no estaban con el puntero en la marca cero. **Conclusión:** La descalibración de los esfigmomanómetros aneroides fue expresiva y puede acarrear evaluación incorrecta de la presión arterial.

Descriptores: Esfigmomanómetros; Determinación de la presión arterial/instrumentación; Falha de equipamento; Estudios de evaluación como asunto; Servicios hospitalarios

** Study conducted in four large hospitals in the State of São Paulo: one private hospital, two Santas Casas, and one public hospital.*

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INTRODUCTION

Several factors can affect blood pressure measurement, with emphasis on conditions of sphygmomanometers, especially their calibration. Measurement of blood pressure determines diagnosis and leads the treatment of hypertension. Therefore, it must be performed correctly to avoid misdiagnosis. Diagnosis of normotension in a hypertensive subject will deprive him/her of a proper treatment. On the other hand diagnosis of hypertension in a normotensive subject will submit him/her to an unnecessary treatment. Thus, accurate sphygmomanometers that work properly are essential for accurate measurement of blood pressure. The type of healthcare institution is another factor that can directly affect the equipment condition. It is known that public or philanthropic institutions depend on either funds from the Unified Health System or donations. As a consequence, they may be unfavored, experiencing more difficulty in both acquiring quality equipment and performing their maintenance. In contrast, private institutions are less exposed to such difficulties.

In the hospitals studied herein, indirect measurement of blood pressure was usually performed using mercury and aneroid sphygmomanometers. However, use of mercury in hospitals was banned by the Ministry of Labor (NR 15 125.001-9/I4)[1] thus limiting the use of mercury sphygmomanometers. Since then, aneroid sphygmomanometers have been the only type of device used in measuring blood pressure in many institutions.

However, national and international studies have shown that calibration of aneroid gauges has been inadequate[2-6]. Given the simple structure of mercury sphygmomanometers, miscalibration is rarely observed. Their calibration can be assessed instantly by observing the level of the mercury meniscus, which must be always in the zero point of the measuring scale. This is not true in aneroid sphygmomanometers, since permanence of the pointer on the zero point does not mean they are calibrated. For more than a century, the mercury sphygmomanometer was considered the gold standard in the measurement of blood pressure. Its replacement with new equipment has been recommended by reasons including mercury toxicity, auscultatory method-related human error, variability in blood pressure, and tendency of blood pressure to increase in the presence of a health professional[7]. However, accidental exposure to mercury from sphygmomanometers is rare[8].

It is recommended that aneroid or mercury sphygmomanometers are evaluated at least every 6 months. In addition, the National Institute for Weights and Measures (INPM) established that all aneroid gauges must have a warranty seal (issued by the INPM) to be sold, and must be periodically tested since they are in use[9].

Furthermore, studies[2-4] assessing the state of sphygmomanometers showed poor conservation as well as high level of miscalibration, especially in public hospitals. In view of the features mentioned above, the purpose of authors in the present study was to assess the conditions in which equipment for measurement of blood pressure are used in public and private hospitals.

METHODS

A descriptive study, with quantitative analysis, was performed in the State of São Paulo in the period 2009-2010. Four large hospitals (one private hospital, two Santas Casas, and one public hospital) were randomly selected. For analytical purposes, the two Santas Casas and the public hospital were combined into "Public Hospitals". Both permission to carry out the study and signature of the Free and Informed Consent were requested to the institutions. After this stage, the nurses in charge of the hospital units were asked to answer a questionnaire, and the sphygmomanometers were tested. All aneroid and mercury sphygmomanometers in use in different units of the hospitals were tested. These data were collected by undergraduate and graduate students of the School of Nursing, University of São Paulo (USP).

A questionnaire, with open and closed questions, was used for collecting information, which was filled by the students when the sphygmomanometers were inspected. The following features of the devices were evaluated: conservation status of the cuff, integrity of rubber tubing and inflating bulb, functionality of the release valve, presence of leakage, and calibration of pressure gauge.

In order to assess calibration of the aneroid sphygmomanometer, a test was performed against a reference mercury one, using a Y-shaped connector according to the following procedure:

1) connect each of rubber tubes of the aneroid (to be tested) and mercury pressure gauges to the upper ends of the "Y", and the inflating bulb to the lower end of the "Y" ;

2) slowly inflate the system up to 300 mm Hg;

3) slowly open the release valve of the inflating bulb to reduce pressure;

4) during inflation and deflation of the system, check correspondence between the values in both gauges every 10 mm Hg, and

5) record the difference (in mm Hg) between the values for each of the levels tested.

Aneroid sphygmomanometers were considered miscalibrated when the difference between the two scales were greater than or equal to 4 mm Hg, for any of the levels tested. According to the National Institute of Me-

trology, Quality and Technology (INMETRO; Portaria no. 153/2005), differences of up to 3 mm Hg (1% of full scale pressure gauge) were considered acceptable.

The research project was approved by the local Ethics Committee (Index number: 644/2007CEP-EEUSP).

Data are shown in four tables and one figure with absolute and percent values. For devices found to be miscalibrated, differences from the standard (mercury) device are shown as mean ± standard deviation. [Data from] devices used in public hospitals were gathered (n=84) and compared with those of the private hospital (n=78). *P* values <.05 were considered significant. The *Mann-Whitney* test was used for comparing differences between mean values of pressure read in the sphygmomanometers.

RESULTS

A total of 162 sphygmomanometers were tested. Almost all of them (159; 98.1%) were of the aneroid type, and only 3 (1.9%) were of the mercury type. Regarding conditions of the cuffs, dirtiness or blood were found in 13.0% of sphygmomanometers, and tears were identified in only 2.5% of them. Rubber parts were aged in about one third of inflating bulbs and tubing, and the release valve was leaking in less than one third of sphygmomanometers (Table 1).

Table 1 – Characteristics of sphygmomanometers in four large hospitals in São Paulo (SP), Brazil (2009-2010)

Variables		n	(%)
Types			
aneroid		159	98.1
mercury column		3	1.9
Condition of			
Cuffs:	clean	138	85.7
	with dirtiness or blood	21	13.0
	with tears	4	2.5
Inflation bulb:	with intact rubber	110	69.6
	with aged rubber	46	29.1
Rubber tubing			
intact		118	73.3
aged		43	26.7
with dirtiness or blood		3	1.9
Release valve			
in good closing conditions		124	77.0
with leakage		33	20.5

Examination of cuffs revealed that in most sphygmomanometers (81.4%), the type of closure with metal rods, was prevalent and part of them was damaged or was not complete (15.3%). Adherence of the Velcro cuffs was impaired in 20.0% of sphygmomanometers. Regarding dimension of the cuffs, most of them had neither a larger cuff for obese people (88.9%) nor a smaller one for those with thin arms (76.4%). However, about half of the professionals surveyed reported using the appropriate cuff for measurement of blood pressure in obese people, whereas 38.3% of them used the standard cuff. As for measurement in people with thin arms, a significant number of them (56.2%) reported using the standard cuff (Table 2).

Table 2 – Characteristics of the cuff in sphygmomanometers in four large hospitals in São Paulo (SP), Brazil (2009-2010)

Variables	n	(%)
Types of closure of the cuff		
velcro	30	18.6
metal	131	81.4
Condition of :		
Metal		
intact	111	84.7
crushed/bent	16	12.2
incomplete	4	3.1
Velcro:		
clean	28	93.3
with dirtiness or blood	2	6.7
adherent	24	80.0
Does the device have a cuff for obese individuals?		
yes	18	11.1
no	144	88.9
What is made to assist an obese individual?		
the measurement is not made	2	1.2
the standard cuff is used	62	38.3
the measurement is made in the forearm	10	6.2
an appropriate cuff is used	82	50.6
other	6	3.7
Does the device have a cuff for thin arm?		
yes	38	23.6
no	123	76.4
What is made to assist an individual with thin arm?		
the measurement is not made	9	5.6
the standard cuff is used	91	56.2
an appropriate cuff is used	57	35.2
other	5	3.1

Inspection of gauges indicated that the pointer did not read zero (27.0%). Alternatively, the pointer was above (15.1%) or below (11.9%) the zero point. As to the conditions of the pressure gauges, 5.8% of them had cracked glass, although most of them (89.7%) had their outside in good condition. The seal of approval required by the INMETRO was not present in more than a quarter of devices (27.8%) and calibration was regularly assessed in only about one third of the units. However, most respondents (76.6%) could not answer how often calibration was performed. Almost all devices lacked the date of the last inspection (96.3%) and only 3.1% of them were tested in the last three months (Table 3).

Table 3 – Assessment of calibration of sphygmomanometers in four large hospitals in São Paulo (SP), (2009-2010)

Variables	n	(%)
Pointer of the aneroid sphygmomanometer		
reading zero	116	73.0
reading above zero	24	15.1
reading below zero	19	11.9
Conditions		
cracked glass	9	5.8
outside in good condition	139	89.7
Seal of the INMETRO*		
yes	117	72.2
no	45	27.8
Calibration regularly assessed		
yes	47	29.2
Frequency		
3 months	3	6.4
6 months	3	6.4
ignored	36	76.6
other	5	10.6
no	114	70.8
Date of the last inspection		
without information	156	96.3
last 3 months	5	3.1

* INMETRO: National Institute for Metrology, Quality and Technology (former National Institute for Metrology, Standardization and Industrial Quality).

Assessment of calibration of aneroid sphygmomanometers (tested against the mercury one) revealed that 56.2% of all devices were miscalibrated, 48.7% in private hospitals and 63.1% in public hospitals (Figure 1).

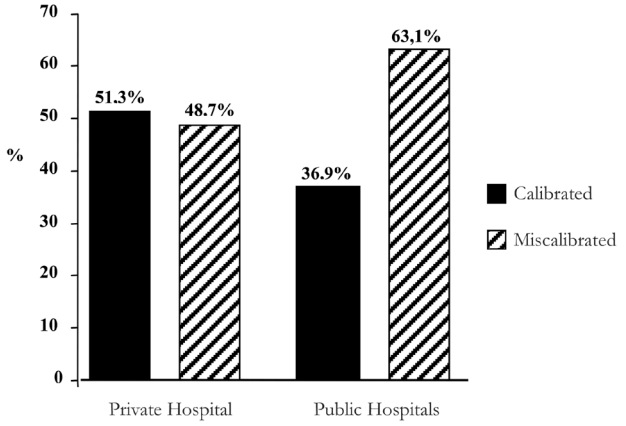

Figure 1 – Calibration of gauges on public and private institutions in São Paulo (SP), Brazil (2009-2010).

Evaluation of aneroid sphygmomanometers tested against the mercury one (standard used in this study), revealed that the differences observed between devices in private and public hospitals were, respectively, 41.0 and 45.2% (4-9 mm Hg), 3.8 and 05.09% (10-14 mm Hg), 3.8 and 8.3% (> 14 mm Hg). In Table 4, the mean differences show positive and negative values. When comparing differences between the public and private institutions, statistically significant difference was observed in the negative values (-8.97 ± 6.74 *vs.* -6.14 ± 2.66 mm Hg), ie, the values indicated in aneroid sphygmomanometers were higher than those indicated in the mercury one, and the same was observed with the total difference (7.72 ± 5.81 *vs.* 6.32 ± 4.14).

Table 4 – Values (mm Hg) for differences observed in the calibration of aneroid sphygmomanometers in private hospitals (1) public and (4) in São Paulo (SP), Brazil (2009-2010).

Variables	Mean ± SD	Min	Max	P
Private hospital				
Negative diferences	-6.14 ± 2.66	-10	-4	<0.001
Positive diferences	6.38 ± 4.44	4	30	0.097
Total diference	6.32 ± 4.14	4	30	<0.001
Public hospitals				
Negative diferences	-8.97 ± 6.74	-38	-4	
Positive diferences	5.60 ± 2.58	4	22	
Total diference	7.72 ± 5.81	4	38	

Max: Maximum values; **Min**: Minimum values; **SD**: standard deviation.

DISCUSSION

The information that "more than half (56.2%) of aneroid gauges tested was shown to be miscalibrated" is a significant and disturbing finding, since these devices are in use in hospitals where the study was conducted. The miscalibration found in this sample reminds the finding of the first study of its kind held in São Paulo. In 1998, it was shown that 204 aneroid sphygmomanometers and 320 mercury sphygmomanometers (in a total of 524 devices inspected), ie, 58% of the aneroid sphygmomanometers and 21% of mercury sphygmomanometers were miscalibrated[2]. Based on that study, INMETRO started a study on this issue, which resulted in a specific legislation for the use of aneroid sphygmomanometers.

The present study showed that nearly all sphygmomanometers used in the sample hospitals (98.1%) are of the aneroid type. However, it is known that such devices are easily damaged and miscalibrated by falls and everyday shocks. There is evidence from several studies that miscalibration in aneroid sphygmomanometers is more frequent than in the mercury ones[3-6,10]. Brazilian studies published before the recommendation to eliminate mercury from hospitals already showed a preference (59.6-67.8%) for equipment of the aneroid type[11,12].

Mercury sphygmomanometers are no longer used in many countries, mainly in Europe, where they have been replaced with automated and non-aneroid devices, which is very uncommon in Sao Paulo. Recently, the World Health Organization[13] published a handbook with recommendations for replacement of mercury thermometers and sphygmomanometers, especially in view of the potential damage of mercury toxicity to the environment. In that document, the importance of proper conditions of new sphygmomanometers mainly their calibration, is emphasized. Since there an inverse relationship between quality and cost, it can be inferred that quality frequently is not given priority when new equipment is purchased. This leads to the purchase of aneroid sphygmomanometers, which are of unsatisfactory quality, further facilitating the lack of calibration of the equipment. This evidence could explain the difference between the sample public and private institutions in the calibration of their equipment. It was observed that sphygmomanometers of the private institution were in better condition, ie, less frequently miscalibrated (48.7%) than those of public institutions (63.1%). Private institutions do not depend on public funds and thus may have conditions to acquire good quality devices. Despite the difference, it is noteworthy that the rate of miscalibration (48.7%) is still much lower than that required. It is important to emphasize that frequent inspection of these sphygmomanometers (at least every six months) is necessary. Testing of the aneroid sphygmomanometer against the mercury one (suitably calibrated) can be easily performed using a Y-shaped connector. Each device is adapted to one the two upper ends, and the rubber tube to the inflating bulb at the lower portion of the connector. In this way, the readings on the two sphygmomanometers can be compared when the system is inflated and deflated. This is a homemade way of assessment that would be ideally performed by a suitably calibrated electronic device for pressure generation, which has a higher accuracy.

The use of automatic or semiautomatic devices for measurement of blood pressure is an increasingly growing reality in clinic practice and research, since they minimize observer-related errors, including preference for "zero" and "five" terminal digits, inadequate auscultation of sounds produced by systolic and diastolic pressure, and inadequate interaction with the patient (causing the white-coat effect). However, cost of devices that are suitable for use in hospitals is higher than those of many aneroid devices. They are suitable for use only if they are submitted and approved by validation studies, according to protocols such as those recommended by organizations such as the *British Hypertension Society*[14], *Association for the Advancement of Medical Instrumentation*[15], and *European Society of Hypertension*[16]. Consulting the websites of *dabl Educational* (http://www.dableducational.org/sphygmomanometers/devices_2_sbpm.html) and *British Hypertension Society* (http://www.bhsoc.org/bp_monitors/automatic.stm) is a reliable way to identify whether the device was validated. In addition to provide data on the validation of equipment, these sites also include their prices. It should be stressed that approved automatic and semiautomatic devices for measurement of blood pressure also require periodic inspection, which is usually performed by the manufacturer or an authorized agent.

The magnitude of miscalibration of sphygmomanometers in public hospitals (as assessed by mean differences), higher than that of those in the private hospital, is another finding that deserves attention. This means that reliability of blood pressure measurements may be compromised in those hospitals. Among public hospitals, a sphygmomanometer with a negative difference of up to 38 mm Hg was found. Reading in a device with a negative difference can lead health professionals to fail in diagnosing arterial hypertension, depriving patients from the benefits of antihypertensive treatment and subjecting them to a possible damage in a target organ. About a decade ago, predominance of negative differences was also found in a study conducted in São Paulo[17]. In another study, in which measurement of blood pressure with miscalibrated sphygmomanometers was

simulated, the authors showed that such devices would not diagnose 20.0% of cases of systolic hypertension and 28.0% of cases of diastolic hypertension after three medical consultations, accounting for misdiagnosis of hypertension in 15.0% of cases of systolic pressure and 31.0% of cases of diastolic pressure[18].

Furthermore, it should be added that such improper calibration of aneroid sphygmomanometers is related to the fact that 70.0% of respondents reported that the devices were not evaluated frequently. Most of those who answered "yes" could not tell how often assessments were performed. Surprisingly, they commented that they considered the device was calibrated even when they saw the pointer reading out of zero. Similar data were found in a survey[12] with physicians, in which only one third of respondents reported assessing calibration of sphygmomanometers with intervals smaller than one year. On the other hand, a similar study, which was conducted a few years later, revealed quite different data, in which 72.9% of physicians referred assessing calibration of the device at intervals shorter than one year[11].

The present study also showed that most of services lacked an appropriate cuff for larger arms, like those of obese people, and thinner ones (88.9 and 76.4%, respectively). In such situations, usually the standard-size cuff was used, which could result in misreading of blood pressure, hyper- or underestimating the value for blood pressure of the patient. Another study showed that the right cuff decreased hyperestimates of diastolic records[19], and provided pressure values closer to those obtained with photopletismographic equipment[20], considered the gold standard in the indirect measurement of blood pressure.

An appropriate relationship between size of the arm and width of the rubber cuff is that it must correspond to 40.0% of the arm circumference as measured between the midpoint of the bony acromion and olecranon prominences[9]. A study carried out among health professionals about their knowledge on blood pressure measurement, particularly cuff size, revealed that they did not know cuffs with different size[21].

In addition to ensure that the sphygmomanometer is calibrated, the condition of other parts of the device also should deserve attention of health personnel. Bad condition of the inflating bulb and rubber tubing can contribute to erroneous assessment of blood pressure. Although most cuffs were clean, with intact tubing and inflating bulbs and without leakage, it is important to stress that leakage problem in the release valve makes inflation of the rubber bag hard, with difficulty to control the rate of deflation, causing reading errors, with a false decrease in systolic pressure and elevation in diastolic pressure.

Data from the present study confirmed important and disturbing findings that should justify action in public and private health institutions, determining periodic verification of sphygmomanometers and replacement of those in inadequate conditions of use, to improve the quality and reliability of equipment used in those institutions.

CONCLUSION

Sphygmomanometers showed significant miscalibration both in public hospitals and in the private one, although miscalibration has been worse in public institutions. In addition, the devices lacked adequate cuffs for measurement in obese people and lean adults, and they were not subjected to a regular assessment of their calibration. This set of deficiencies may lead to incorrect assessment of blood pressure in many other hospitals. The importance of health professionals, especially nurses, in guiding their team and being able to identify the need to reassess sphygmomanometer calibration is extremely important for a correct assessment of blood pressure, thus ensuring the accompaniment of a correct therapy.

As measurement of blood pressure is the most frequent procedure carried out in healthcare, blood pressure measurement should be performed in any examination, regardless of specialty, in all age groups, and should be mandatory in children aged three years old on. Therefore, search for a suitable condition for sphygmomanometers is a responsibility of all health professionals who use them. In Brazil, nursing professionals have much of this responsibility that starts in the appraisal and indication of the best type of equipment to obtain reliable values for blood pressure.

Since a sphygmomanometer is in use, its periodic evaluation must be established as a routine, as recommended by the Brazilian Guidelines of Arterial Hypertension, to allow the earliest possible identification of any change that would impair obtaining correct values of blood pressure.

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