Assessment of the DIXTAL DX-2710 Automated Oscillometric Device for Blood Pressure Measurement with the Validation Protocols of the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI)

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Objective *- To assess the Dixtal DX2710 automated oscillometric device used for blood pressure measurement according to the protocols of the BHS and the AAMI.*

Methods *- Three blood pressure measurements were taken in 94 patients (53 females 15 to 80 years). The measurements were taken randomly by 2 observers trained to measure blood pressure with a mercury column device connected with an automated device. The device was classified according to the protocols of the BHS and AAMI.*

Results *- The mean of blood pressure levels obtained by the observers was 148±38/93±25 mmHg and that obtained with the device was 148±37/89±26 mmHg. Considering the differences between the measurements obtained by the observer and those obtained with the automated device according to the criteria of the BHS, the following classification was adopted: "A" for systolic pressure (69% of the differences < 5; 90% < 10; and 97% < 15 mmHg); and "B" for diastolic pressure (63% of the differences < 5; 83% < 10; and 93% < 15 mmHg). The mean and standard deviation of the differences were 0±6.27 mmHg for systolic pressure and 3.82±6.21 mmHg for diastolic pressure.*

Conclusion *- The Dixtal DX2710 device was approved according to the international recommendations.*

Keywords: validation, automated, oscillometric blood pressure measuring device

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Conventional sphygmomanometry began more than 1 century ago with the Riva-Rocci sphygmomanometer, and auscultation of the Korotkoff sounds still remains the most used method for blood pressure measurement, not only in clinical practice, but also in research conditions. However, the accuracy of the method can be compromised by factors relating to the observer and the equipment, among others. In regard to the observer, the possibility of the white coat effect or hypertension stands out, situations in which more elevated blood pressure values are observed in the measurements taken at the medical office as compared with those obtained with ambulatory blood pressure monitoring or obtained by the patient at his home [1]. The observer may also be a source of error in regard to the technique used for blood pressure measurement and the preference to record blood pressure with values ending in 0 or 5 [2,3].

To ensure the effectiveness of use, manometers should be in perfect condition, mainly in regard to calibration. Some studies have shown unsatisfactory calibration conditions, mainly of the aneroid devices. A study carried out in our country showed that 60% of the aneroid devices and 21% of the mercury column sphygmomanometers were not calibrated [4]. In addition, the use of the mercury column sphygmomanometer has been questioned. The arguments in favor of banishing the mercury sphygmomanometer relate to the environment, due to the toxicity of mercury, and the possibility of error inherent in the indirect method with the auscultatory technique. In addition, replacement of the measuring unit, millimeters of mercury, by the pressure unit, the kilopascal, has been considered. In Europe, this movement is strong and exemplified by other countries, such as the Netherlands and Sweden, which abolished mercury from the hospital environment [5,6]. Considering the possibility of change in the use of the sphygmomanometry in the

new century, automated devices may play an important role. These devices, in addition to being useful for patients to measure their own blood pressure levels at home, may replace the aneroid and mercury column sphygmomanometers at the hospital environment, where their use is still limited.

For automated or semiautomated blood pressure measuring devices to be used, they should abide by the guidelines established to ensure the effectiveness of their use. Two international entities, the British Hypertension Society [7] (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI) [8] have established criteria for allowing the validation of these devices. The assessment provided by the 2 protocols ranges from the description of the procedure to the criteria that allow the validation of the device. The BHS presented its first version in 1990, and 3 years later revised it [9]. On the other hand, the AAMI published its first recommendation in 1987 [10], which underwent modifications in 1992.

The major point in the recommendations refers to acceptance criteria. The BHS considers the proposal by AAMI very comprehensive in regard to the differences between the means of the measurements obtained with the device being analyzed and those obtained with the standard method of up to 5 mmHg for the systolic and diastolic pressures and of up to 8 mmHg for the standard deviation. Considering this, the BHS proposed the analysis of the differences establishing limits and classifying the device in different levels. Table I compares the major points of the recommendations of the BHS and the AAMI.

A significant number of automated and semiautomated devices available in the market have failed to fulfill the requirements of the 2 international entities. O'Brien et al [11] reported that of 14 different devices, 9 were not approved by the AAMI protocol and 7 were not approved by the BHS protocol, and the BHS guidelines could not be applied to 2 devices.

Considering this issue and the use of the Dixtal DX2710 automated oscillometric device by the Hypertension Group of the Hospital das Clínicas of the University of São Paulo, School of Medicine for assistance and research, this study aimed at being the first validation study of the automated oscillometric blood pressure measuring device manufactured in Brazil according to the BHS protocol and the AAMI recommendations.

Methods

All the different stages of the device's validation process comprising the methodology of the study are then described.

Two graduate students in the nursing school of the University of São Paulo, who were also monitors of the Group Hypertension of the Hospital das Clínicas of the University of São Paulo, School of Medicine, were trained by a specialist in blood pressure measurement. The training consisted of the following phases: a) watching a specific movie on blood pressure measurement; b) blood pressure measurement to identify the Korotkoff sounds; c) discussion with the specialist to clarify doubts; and d) assessment of the accuracy test with the specialist and interobserver, according to the criteria of accuracy. Five measurements were performed per observer in 5 individuals with the double stethoscope. Their acceptance into the project required meeting the following criteria: a) on the simultaneous measurement with the specialist, 90% of differences < 5 mmHg and 98% of differences < 10 mmHg; and b) on the interobserver measurement, 85% of differences < 5 mmHg and 95% of differences < 10 mmHg.

For the validation process, 3 Dixtal DX2710 automated oscillometric devices were used. The devices were being used for at least 6 months. To assess calibration, the devices were tested against a mercury column sphygmomanometer using a Y connection, observing the differences in the points assessed (0, 50, 100, 150, 200, 250 mmHg). A difference ≥ 4 mmHg was considered a lack of calibration, which did not occur. For assessment, the facilities and difficulties in handling were considered. The personnel who used to handle the device emphasized these items in a verbal assessment. The assessment was satisfactory.

After these steps, the validation process itself started. At the time of each patient's measurement, the devices were randomly chosen using a table. The project of the study was approved by the committee on ethics of the institution. Blood pressure was measured after the patient agreed and signed the written informed consent.

Ninety-four individuals took part in the study, including hypertensive and nonhypertensive individuals of both sexes and whose ages ranged from 15 to 80 years. To meet

Chart I - Comparison of the BHS and AAMI protocols for assessing automated and semiautomated blood pressure measuring devices

Protocol	AAMI	BHS (1990)	BHS (1993)
Blood pressure measurement	Simultaneous or sequential in the same arm	Simultaneous or sequential in the same arm	Sequential in the same arm
Nº of observers	2	2	3
Nº of patients	85	85	85
Blood pressure limits	10% < 100, 10% > 160	110-240	10% < 90, 10% > 180
Nº of measurements	9	3 ou 9*	3 ou 9*
Patient's position	Sitting/standing/lying down	Sitting	Sitting/standing/lying down*
Nº of devices tested	3	3	3
Criteria of acceptance	Mean of the differences of ± 5 mm Hg and standard deviation of ± 8 mmHg	65% of the differences < 5 mmHg	50% of the differences < 5 mmHg

BHS- British Hypertension Society; AAMI- Association for the Advancement of Medical Instrumentation; * for devices of ambulatory blood pressure monitoring, 3 measurements in each position were taken in 30 additional patients.

Chart II – Classification of the device according to the BHS protocol considering the percentage of the differences between the device being tested and the standard method

	Differences		
Classification	≤5mmHg	≤10mmHg	≤15mmHg
A	80%	90%	95%
B	65%	85%	95%
C	45%	75%	90%
D	<45%	<75%	<90%

BHS- British Hypertension Society.

the criteria of blood pressure distribution, at least 15% of the measurements for systolic pressure and 20% of the measurements for diastolic pressure should be in the following different ranges of pressure: a) systolic pressure: 100-140 mmHg, 140-180 mmHg, 180-220 mmHg, and 220-240 mmHg; and b) diastolic pressure: 60-80 mmHg, 80-100 mmHg, and 100-120 mmHg.

Individuals with arrhythmias, atrial fibrillation, sound auscultation until zero, auscultatory gap, and positive Osler maneuvers were excluded from the study.

Blood pressure measurements were taken by the observers in an isolated environment and in an alternate manner, each observer measuring the blood pressure of 47 individuals, who had been resting for 5 minutes and were sitting with their arms at the level of the heart. A cuff adequate for the size of the patient's arm was used. The device to be tested was connected via a Y connection with the mercury column sphygmomanometer, and the inflation mechanism of the device was activated for 3 consecutive blood pressure measurements at 2-minute intervals. At the end of each measurement, the observer recorded the systolic and diastolic values identified in the mercury column, without knowing the values of the measurements recorded in the automated device.

A total of 282 measurements were taken, and the independent measurements and not the means were used for analysis. The device was classified according to the following: a) the BHS protocol (chart II), considering the percentage of the differences between the readings in the mercury column sphygmomanometer, performed by the observers, and those in the automated device; and b) the criterion of the AAMI using the mean of the differences between the readings obtained with the device being tested and those obtained with the device used by the observers of ±5 mmHg and standard deviation of ±8 mmHg.

The differences between the measurements taken with the automated device and those taken by the observers were plotted against the mean of the observer's pressure values, followed by the specification of the mean of the differences and ±1 standard deviation (fig. 1).

Results

Analyzing the characteristics of the 94 individuals who underwent blood pressure measurement for assessment of the Dixtal DX 2710 automated device, we observed that the recommendations were followed, because an almost equitable distribution was observed in regard to sex, age ranging from 15 to 80 years. Of the 282 blood pressure measurements taken, at least 20% for diastolic pressure and 15% for systolic pressure were within the recommended range, except for the systolic pressure range of 220-240 mmHg, in which 7% of the measurements were obtained. Comparing the means of the measurements taken by the observers and those obtained with the device being tested, agreement for the systolic pressure occurred, but the diastolic value obtained with the device was significantly lower (tab. I).

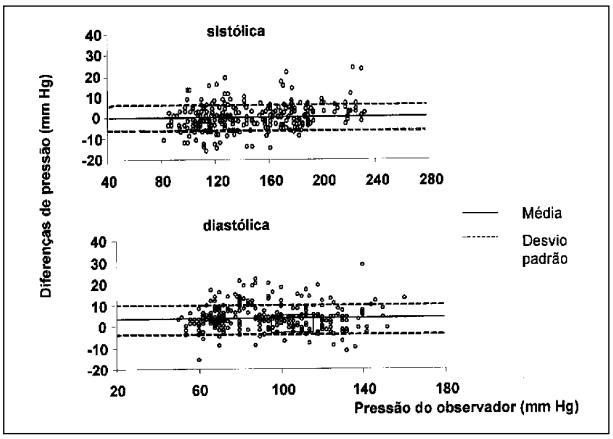

Fig. 1 - Differences between the blood pressure values (obtained by the observer and with the Dixtal DX 2710 device) and those of the observer.

The classification of the Dixtal DX 2710 device according to the guidelines of the BHS, which consider the percentage differences at the intervals ≤ 5 mmHg, ≤ 10 mmHg, and ≤ 15 mmHg between the device being tested and the mercury column sphygmomanometer, was as follows: classification A for the systolic pressure and classification B for the diastolic pressure. The means of the differences and respective standard deviations between the 2 methods were 0±6.27 mmHg for the systolic pressure and 3.82±6.21 mmHg for the diastolic pressure (tab. II and III).

Analyzing the difference between the measurements taken with the device and those taken by the observer plotted against the observer's pressure (fig. 1), tendencies towards concentration of points did not occur, but a relatively uniform dispersion did.

Discussion

The data obtained showed that the Dixtal DX 2710 automated oscillometric blood pressure measuring device was approved for use according to the guidelines of international entities, BHS and AAMI, and, therefore, can be used in clinical practice. One of the major advantages of adopting automated devices relates to the possibility of reducing the observer's influence on blood pressure measurement, which may cause errors when the indirect method or the auscultatory technique is used. The most common sources of errors are as follows: inability or deficit in auscultating

Table I – Characteristics of the patients

Characteristics	Nº	%
Sex (female/male)	53/49	56/44
Age (years)		
15 to 30	21	22
31 to 45	21	22
46 to 60	27	29
61 to 80	25	27
Systolic pressure range (mmHg)		
90-139	139	49
140-179	68	24
180-219	56	20
220-240	19	7
Diastolic pressure range (mmHg)		
50-79	99	35
80-99	68	24
100-140	115	41
Circumference of the arm (mean ± standard deviation, cm)	29.3 ± 4.6	
Systolic/diastolic pressure (mean ± standard deviation, mmHg)		
Observer (average of 3 measurements)	148 ± 38/93 ± 25 *	
Device (average of 3 measurements)	148 ± 37/89 ± 26	
Observer of measurement 1	149 ± 37/94 ± 26	
Observer of measurement 2	149 ± 38/93 ± 25	
Observer of measurement 3	148 ± 39/91 ± 25	
Device of measurement 1	151 ± 36/92 ± 26	
Device of measurement 2	148 ± 37/89 ± 26	
Device of measurement 3	146 ± 37/86 ± 26	

* p<0.05, mean of the 3 measurements of the diastolic pressure, observer versus device.

Table II – Assessment of the Dixtal DX 2710 automated blood pressure measuring device according to the BHS protocol considering the cumulative percentage of the measurements

Measurements (%)	≤5 mmHg	≤10 mmHg	≤15 mmHg	Classification	Approval
Systolic pressure	69%	90%	97%	A	Yes
Diastolic pressure	63%	83%	93%	B	Yes

BHS- British Hypertension Society.

Table III - Assessment of the Dixtal DX 2710 automated blood pressure measuring device according to the AAMI protocol considering the means and standard deviations of the differences between the values obtained with the device being tested and those obtained by the observer

	Mean	Standard deviation	Approval
Systolic pressure (mm Hg)	0	6.27	Yes
Diastolic pressure (mmHg)	3.82	6.21	Yes

AAMI- Association for the Advancement of Medical Instrumentation.

the first sound, which determines the systolic pressure and whose disappearance determines the diastolic pressure; incorrect position of the eyes to read the manometer scale; excessive pressure of the stethoscope, deforming the artery; excessive cuff inflation causing pain; high velocity of deflation, leading to alteration in blood pressure values; reevaluation of the systolic pressure before finishing cuff deflation; rounding the pressure values to figures ending in zero or 5; and interaction with the patient, which may increase blood pressure [2,3]. In addition to the observer's presence, the environment in the medical office or the hospital may also have an influence on blood pressure, resulting in more elevated levels as compared with those taken at the patient's home or with ambulatory blood pressure monitoring (the white coat effect or hypertension).

For the automated devices to be safely used, they should be properly validated according to the international guidelines and periodically calibrated. Despite the multiplicity of the automated devices available in the market, not all fulfill the requirements [11], which may result in diagnostic errors in the clinical practice and nonreliable findings in research.

The use of automated devices has increased, mainly because it allows blood pressure measuring at home. Significant studies carried out in the last 2 decades, such as the PAMELA [12], the SMART [13], the Tecumseh [14], and the Ohasama [15] studies, used that type of device. More recently, in the HOT study [16], blood pressure measurement was taken with the semiautomated oscillometric device (Visomat OZ D2 International) to avoid interobserver variability. For this, the device was tested according to the BHS protocol, and the results showed that the device tended to record lower levels than those recorded in the standard method for systolic and diastolic pressures. In our study, however, this only happened for the diastolic pressure; for the systolic pressure, the values almost coincided. Still considering the device used in the HOT study, the means of the differences of the systolic and diastolic pressure values recorded in the device being tested and in the standard device were, res-

pectively, 6.4 mmHg and 0.9 mmHg, which exceeded the recommended limit of 5 mmHg. According to the BHS protocol, the device used in the HOT study would be classified as level A for the systolic pressure, and between levels C and D for the diastolic pressure. Despite these findings, the authors concluded that the device met the expectations, because the error caused by the observer's measurement could be greater.

Analyzing the means of the differences between the values obtained by the observer and those obtained with the device being tested in different studies of validation, a tendency towards the obtainment of positive [17] and negative [18-20] results has been observed, although all were within the 5-mmHg range. No explanation for this has been found in the literature. Fowler et al [21] reported that, despite the good accuracy, oscillometric devices may overestimate systolic pressure values. In our study, this did not happen, because the means of the differences were zero and 3.8 mmHg for the systolic and diastolic pressures, respectively, and the standard deviations were 6.27 and 6.21 mmHg, below the limit of 8 mmHg imposed by the guidelines of the AAMI. It is worth noting that greater differences concentrated in the more elevated systolic levels, mainly above 180 mmHg; in the 180-219 range, the mean of the differences was 4.1 mmHg; and in the 220-240 range, the mean of the differences was 5.7 mmHg. One of the limitations was that, in the 220-240 mmHg range, the percentage of measurements recommended by the BHS (15%) was not reached; however, in the immediately preceding range, the percentage of measurements was 20%, exceeding the minimum indicated, and approximately half of the measurements were above 200 mmHg.

The oscillometric method for blood pressure measurement was used for the first time at the end of the 19th century with the device designed by E J Marey. It was replaced by the method with the auscultatory technique of Korotkoff. From the 1970s onwards, the devices began to be commercialized. Currently, the great majority of the automated and semiautomated devices is of the oscillometric type. In a publication about this subject with 15 automated and semiautomated devices, only 2 used the auscultatory technique [22].

In the last decade, an increasing use of the automated and semiautomated devices has been observed, caused by the technological advancement of the electronic industry. These devices tend to replace the mercury column and aneroid devices, facilitating the work of the health care professional and eliminating the possibilities of error by the observer. It is worth emphasizing, however, that these devices will only be ready for use after being approved by the current guidelines.

In conclusion, the results of our study showed that the Dixtal DX2710 device is safe for clinical use, because it fulfilled the international recommendations of the BHS and the AAMI [23].

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