Original Article

Evaluation of the Omron 705-CP Blood Pressure Measuring Device for Use in Adolescents and Young Adults

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Objective

To assess the Omron 705-CP monitor for measuring blood pressure in adolescents and young adults.

Methods

According to the protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation, we performed validation of the device in 60 adolescents. The Omron monitor was connected in Y to a mercury column. Four consecutive and simultaneous measurements were taken with the mercury column sphygmomanometer and the test device, were independently analyzed, and the mean differences between the blood pressure measurements and the standard deviations of those differences were calculated. The results were analyzed according to the grading system of the protocol used.

Results

Two hundred and forty measurements were evaluated. The mean age of the patients was 16.3 years. When the measurement performed with the mercury column sphygmomanometer was compared with that taken with the device, a difference ≤15 mmHg was observed in 97.9% of the systolic and 98.8% of the diastolic blood pressure measurements; a difference ≤10 mmHg was observed in 86.3% of the systolic and 90.4% of the diastolic blood pressure measurements, which was classified as grade A; a difference ≤5 mmHg was observed in 59.1% of the systolic and 67% of the diastolic blood pressure measurements, and was classified as grade A/B. The mean difference and the standard deviation of that difference for the systolic blood pressure was 2.91±6.42 mmHg, and, for the diastolic blood pressure, it was 1.16±5.79 mmHg.

Conclusion

The Omron 705-CP monitor proved to be useful for measuring blood pressure in adolescents according to the protocol used.

Key words

Omron 705-CP, home blood pressure measurement, adolescents

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Blood pressure can be measured through the direct method by introducing a catheter coupled with a transducer in an artery, or through the indirect method by using the auscultatory or oscillometric technique. In clinical practice, we use the casual blood pressure measurement with the auscultatory technique. Blood pressure is measured in the arm with the aneroid or mercury column sphygmomanometer. However, that method has disadvantages, such as the possibility of error inherent to the indirect method with the auscultatory technique, subjectivity in blood pressure auscultation, rounding off of the measurements, in addition to mercury toxicity to the environment [1].

Currently, an increasing number of semi-automated or automated electronic devices are available at affordable prices. This equipment should be evaluated according to the validation norms required by international entities, such as the British Hypertension Society (BHS)[2] and the Association for Advancement of Medical Instrumentation (AAMI)[3], because adequacy to norms guarantees reliability.

Although the models are manufactured in series and tested by the manufacturer, their validation should also be performed in special groups, such as pregnant women, the elderly, adolescents, and children. The protocol used recommends that the validation criteria of the devices in special groups be the same as those already established for the adult population, and that the equipment used had already been validated by the BHS [4] in the general population.

The present study aimed at validating the automated oscillometric device for blood pressure measurement (Omron 705-CP), which has already been validated for clinical use in the adult population [5], according to the protocol adopted [2] and recommendations for adolescents [3].

Methods

The Omron 705-CP is an electronic digital device for measuring blood pressure in the arm. It has automated air inflation and deflation, and the detection of blood pressure and pulse wave occurs through a pressure transducer of the capacitance type. The measuring method is the oscillometric one, with pressure variation from 0 to 280 mmHg, and heart rate variation from 40 to 200 bpm. The cuff size was approximately 140 mm X 480mm.

We selected individuals of both sexes who were being followed up in the outpatient care clinic of the adolescent unit of the institution, and whose arm circumferences ranged from 26 to 32 cm. Patients with arrhythmias, atrial fibrillation, sound auscultation

down to zero, and auscultatory hiatus were excluded from the sample. Blood pressure measurement was taken after the individuals received instructions about the study and signed a written informed consent.

The casual measurement of blood pressure was performed by using the auscultatory technique, and recording blood pressure in the arm by using a mercury column sphygmomanometer. After that measurement, the Omron 705-CP device was connected in Y with the mercury column device and the inflation mechanism of the device was activated. Four consecutive and simultaneous measurements were taken with the device and the mercury column at 2-minute intervals.

The measurements were independently analyzed, and the mean differences between the systolic and diastolic measurements were calculated, as were the standard deviations of those differences. The classification of the device was performed considering the differences of readings between the mercury column and the automated device, according to the BHS [2] and AAMI [3] protocols. According to the BHS protocol [2], the devices should achieve at least grade B for arterial systolic and diastolic blood pressure so that they could be cataloged as recommended. Grade A corresponds to a greater concordance between the blood pressure measurements obtained with the mercury sphygmomanometer and the device, and grade D corresponds to a lower concordance (chart I).

The criterion established by the AAMI protocol recommends that the differences between the measurements taken with the test device and those with the mercury column sphygmomanometer should not exceed 5 mmHg, or that the standard deviation of the measurements obtained with the mercury sphygmomanometer should be ≤8 mmHg.

Results

Sixty individuals, 38 men and 22 women, were studied. Their mean age was 16.3 (12-21.5) years, their mean weight was 66.7 kg, and their mean height was 166.8 cm. Their mean arm circumference was 28.4 cm (range, 26 to 32 cm). The initial systolic blood pressure, measured with the mercury sphygmomanometer ranged from 82 to 132 (mean, 107.4) mmHg, and the diastolic blood pressure ranged from 46 to 96 (mean, 64.8) mmHg (tab. I).

Comparison between the test device and the mercury column sphygmomanometer was performed by taking 240 simultaneous systolic and diastolic blood pressure measurements. The base of comparison was the magnitude of the differences between the sequential measurements taken in the same individual with the test device and the mercury column sphygmomanometer.

The mean systolic and diastolic blood pressures measured with the mercury column sphygmomanometer were 104.35 and 60.65 mmHg, respectively. The mean systolic and diastolic blood pressures measured with the Omron 705-CP were 101.44 and 59.50 mmHg, respectively.

The mean difference between the systolic blood pressure measurements taken with the test device and the mercury column sphygmomanometer was 2.91 mmHg (95% confidence interval: 2.09 to 3.73) and the standard deviation was 6.42; the mean difference between the diastolic blood pressure measured with the test device and the mercury column sphygmomanometer was 1.16 mmHg (confidence interval: 0.42 to 1.19), and the standard deviation was 5.79.

Figures 1 and 2 show the mean differences observed between the systolic and diastolic blood pressure measurements taken with the mercury column sphygmomanometer and the Omron 705-CP device. The difference between the measurements taken with the electronic device and the mercury column sphygmomanometer was = 15 mmHg in 97.9% of the systolic blood pressure measurements and 98.8% of the diastolic blood pressure measurements, which, according to the BHS classification, is grade A. The difference between the measurements taken with the electronic device and the mercury column sphygmomanometer was ≤10 mmHg in 86.3% of the systolic blood pressure measurements and 90.4% of the diastolic blood pressure measurements, which is grade A, according to the BHS classification. The difference between the measurements taken with the electronic device and the mercury column sphygmomanometer was ≤5 mmHg in 59.1% of the systolic blood pressure measurements and 67% of the diastolic blood pressure measurements, which is grade A/B (tab. II).

Discussion

Most of the existing validation studies of blood pressure devices were performed in the general adult population, and their validation in special groups is important.

Chart I - Criteria used by the British Society of Hypertension. Differences between the automated device and the mercury column sphygmomanometer

Classification	≤5 mmHg	≤10 mmHg	≤15 mmHg
A	60%	85%	95%
B	50%	75%	90%
C	40%	65%	85%
D	worse than C		

The grades represent the accumulated percentage of measures between 5, 10, and 15 mmHg on the mercury sphygmomanometer [6].

Table I - Characteristics of the individuals assessed

Characteristics	Mean (SD)	Variation
Age (years)	16.3 (2.5)	12-21.5
Height (cm)	166.8 (9.3)	144.5-185
Weight (kg)	66.79 (11.8)	43.5-92.9
Arm circumference (cm)	28.4 (2.0)	26-32
SBP (mmHg)	107.4 (11.7)	82-132
DBP (mmHg)	64.8 (11.1)	46-96

SBP - systolic blood pressure; DBP - diastolic blood pressure; SD - standard deviation.

Table II – Comparison between Omron HEM 705-CP and mercury column sphygmomanometer

	N	≤ 5	≤ 10	≤ 15	mean difference ± SD (95% confidence interval)
SBP	240	59.1%	86.3%	97.9%	2.91± 6.42 (2.09 a 3.75)
DBP	240	67%	90.4%	98.8%	1.16±5.79 (0.42 a 1.19)

SBP - systolic blood pressure; DBP - diastolic blood pressure; SD - standard deviation of the difference.

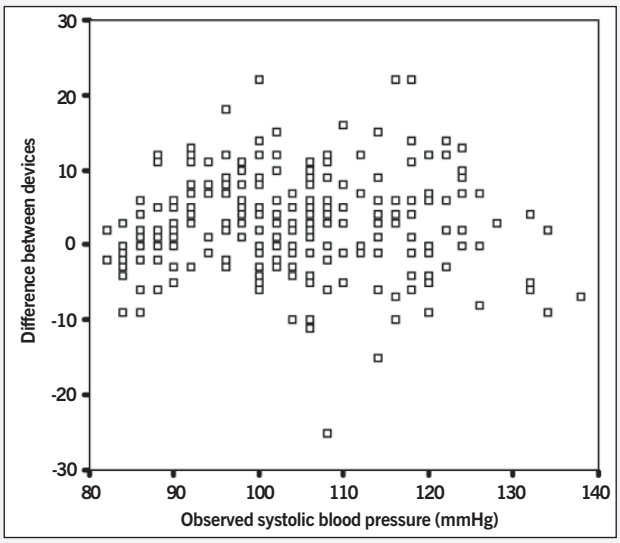

Fig. 1 - Difference of systolic blood pressure x observed systolic blood pressure (n=240).

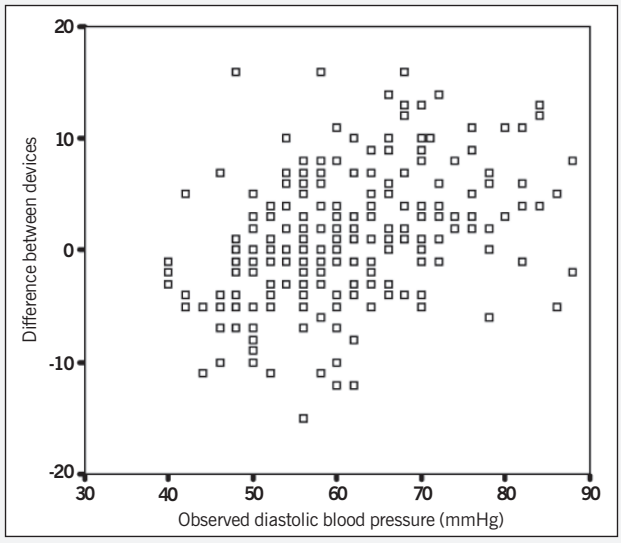

Fig. 2 - Difference of diastolic blood pressure x observed diastolic blood pressure (n = 240).

In adolescents and children, the need for adjusting the cuff size to the arm circumference often leads to technical modifications of the equipment [7], which makes that validation even more necessary. The reliability of those devices according to international norms of validation in special groups is extremely important to the recommendation of its use in clinical practice, mainly aiming at its use for home control of blood pressure.

The Omron HEM 705-CP device has already been validated according to the BHS protocol [2], initially assessed by O'Brien et al [5], when it obtained grade A for both systolic and diastolic blood pressures [5]. That device functions with automated inflation and deflation and has adequate weight and size, and those are important factors for greater adhesion to home control of blood pressure in hypertensive individuals. In our study, that device was classified as grade A/B according to the same criteria for both systolic and diastolic blood pressures, and it achieved the criterion established by the AAMI [3].

The BHS protocol [2] for validation of blood pressure devices recommends that different levels of blood pressure be evaluated, from 100 to 240 mmHg for systolic blood pressure, and from 60 to 120 mmHg for diastolic blood pressure. The AAMI criterion [3] does not recommend that evaluation by blood pressure levels. In our study, the variations in systolic and diastolic blood pressure were 82 to 132 mmHg and 46 to 96 mmHg, respectively, and systolic levels greater than 140 mmHg and diastolic levels greater than 100 mmHg could not be assessed. The few studies available about validation of devices in adolescents have also assessed individuals neither with systolic blood pressure levels greater than 140 mmHg nor diastolic blood pressure greater than 90 mmHg [8,9]. This difficulty to assess higher blood pressure levels in the adolescent population is explained by the lower prevalence of hypertension in that age group as compared with that of adults, and by the smaller chance of finding younger patients with extremely high blood pressure levels. This has led us to suggest that the recommendation of the BHS to use in special groups the same criteria of validation already established for the general adult population should not be applied, mainly to adolescents and children.

In conclusion, we recommend the Omron HEM 705-CP device for blood pressure measurement in adolescents, because it meets the AAMI criterion [3] and was classified as grade A/B, according to the BHS protocol [2] for systolic and diastolic blood pressure measurement.

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