

Validation of TM-2655 oscillometric device for blood pressure measurement

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Objective To perform validation for an arm-type oscillometric TM-2655 device (A&D Company Ltd, Tokyo, Japan) for blood pressure measurement according to the British Hypertension Society protocol.

Methods Eighty-five study participants (33 men and 52 women) were included in the study. Mean age was 52.9 ± 15.0 years, systolic blood pressure range was 84–208 mmHg and diastolic blood pressure range was 48–120 mmHg. For each participant, three readings of TM-2655 were compared with sequential auscultatory measurements by two trained independent observers. The observers used a calibrated mercury sphygmomanometer and dual stethoscope. The results were graded according to the British Hypertension Society protocol 1993.

Results The average difference between mercury sphygmomanometer and TM-2655 readings for systolic blood pressure was -1.0 ± 5.2 mmHg (mean \pm SD) and for diastolic blood pressure -0.9 ± 4.7 mmHg. The proportions of values agreeing to within 5, 10 and 15 mmHg were 72.5, 93.7 and 99.6% for systolic blood pressure and 78.8, 96.9

and 100% for diastolic blood pressure between the observers and the device (A/A British Hypertension Society grade).

Conclusions The TM-2655 device achieved British Hypertension Society grade A/A and therefore can be recommended for blood pressure measurement in an adult population. *Blood Press Monit* 11:87–90 © 2006 Lippincott Williams & Wilkins.

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Introduction

Relatively new types of devices for stationary use have become available recently. They can be installed in pharmacies, shopping malls, sports centers, etc. These devices are equipped with an automatically adjustable cuff. They are 'one-touch button' operated, labeled with 'how-to-use' instructions so blood pressure (BP) measurement can be taken by participants without healthcare professionals. Thus, at least four types of information on BP level may be obtained: (1) BP level free of 'white-coat effect' caused either by a nurse or by a doctor (e.g. during visit to a medical center), (2) random BP level during usual life activities (e.g. visiting supermarket) may be useful in treated hypertensive patients or in participants with a wide range of symptoms (sudden dizziness, weakness, etc.) or in healthy participants just because of their desire to know their BP, (3) screening BP in any population and (4) before and after sport training for self-assessment of exercise effect on the BP level.

The prognostic significance of randomly assessed BP has not been established but it may provide potentially useful information about the BP level in a wide range of participants [1–4].

In this article, we report the results of a validation procedure of TM-2655 automatic arm-type device (A&D Company Ltd, Tokyo, Japan) according to the revised British Hypertension Society (BHS) protocol [5].

Study participants and methods

Participants

Eighty-five participants (33 men, 52 women) were recruited for the validation procedure. Mean age was 52.9 ± 15.0 years, mean systolic blood pressure (SBP) 143.2 ± 31.8 mmHg (range 84–208 mmHg) and mean diastolic blood pressure (DBP) 84.4 ± 18.8 mmHg (range 48–120 mmHg) (Table 1). All participants were informed about the purpose of the investigation and procedure. The study protocol was approved by the local ethics committee. The patients' distribution, according to BP level, was as required by the BHS validation protocol (Table 2).

Methods

The TM-2655 device was purchased at a medical equipment store and tested according to the BHS revised protocol. Measurements were performed in a quiet room; ambient temperature was continuously controlled during

Table 1 Characteristics of the study population (n=85)

	Mean ± SD	Range
Age (years)	52.9 ± 15.0	19–80
Arm circumference (cm)	28.2 ± 3.4	22–37
Systolic blood pressure (mmHg)	143.2 ± 31.8	84–208
Diastolic blood pressure (mmHg)	84.4 ± 18.8	48–120

Table 2 Patients distribution according to blood pressure level

Systolic blood pressure		Diastolic blood pressure	
Range (mm Hg)	Number of patients	Range (mm Hg)	Number of patients
<90	8	<60	9
90–129	24	60–79	21
130–159	22	80–99	26
160–179	20	100–109	20
>180	11	>110	9

the study. The mid-upper arm circumference was measured before the first BP evaluation.

The BP measurements were taken with the participants in the seated position. The results of the BP measurement obtained with the TM-2655 device were compared with those obtained by two trained observers. The observers underwent the compact disc validation training course. The measurements were started by the observers.

The sequential measurements approach was used as there was no technical opportunity to perform simultaneous readings. The readings were taken on the same arm. The interval between observers and device readings was not more than 1 min.

The observers used the calibrated mercury sphygmomanometer (Spirit CK 403; A&D) and dual stethoscope. SBP was determined by the phase I, DBP – by phase V Korotkoff sound. The mercury column was placed at eye level to minimize reading errors. The observers were blinded to each other’s readings and to those taken by the device.

Data analysis

BP values obtained by the observers and with the TM-2655 device were documented and then processed as specified in the revised 1993 BHS protocol [5].

Results

The total number of pairs of readings available for analysis was 255.

Agreement of observers

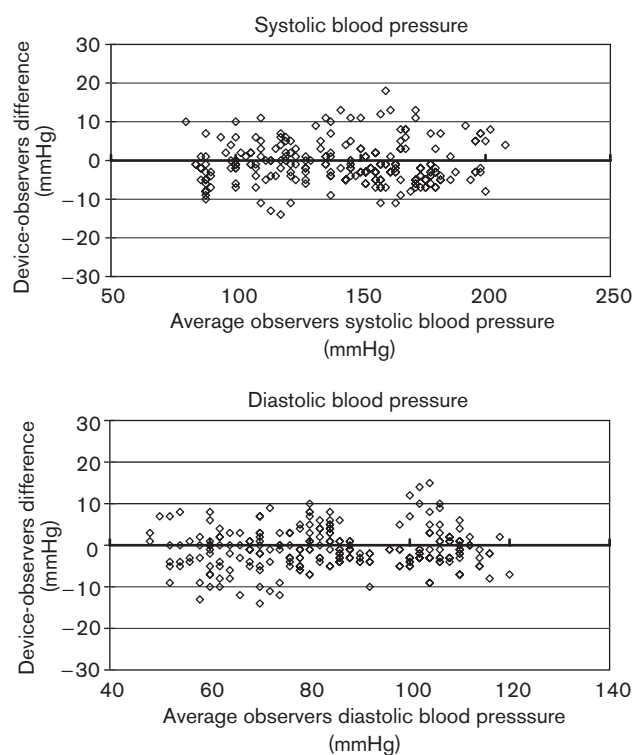
Individual readings by the two observers were compared. All observer differences for SBP and 99% for DBP were within 5 mmHg. For both SBP and DBP, interobserver differences were within 10 mmHg.

Device/observers’ agreement

The difference between the TM-2655 device and mean of the two observers is shown in Fig. 1. The device/observers’ disagreement in the overall group for SBP was -1.0 ± 5.2 mmHg (mean ± SD) and for DBP -0.9 ± 4.7 mmHg. So the device fulfilled AAMI criteria for electronic devices.

The proportions of values agreeing within 5, 10 and 15 mmHg were 72.5, 93.7 and 99.6% for SBP and 78.8, 96.9 and 100% for DBP (Table 3), respectively. So the TM-2655/2655P device fulfilled A/A BHS criteria.

Fig. 1



Differences between the results of device and averaged observers’ readings for systolic and diastolic blood pressure (Bland–Altman plots).

Table 3 Grading for the A&D TM-2655 device according to the 1993 British Hypertension Society (BHS) Protocol

	n	Difference ‘device minus observers’ (mmHg)			BHS grade
		5	10	15	
All measurements					
Systolic blood pressure	255	72.5%	93.7%	99.6%	A
Diastolic blood pressure	255	78.8%	96.9%	100.0%	A

Table 4 The device minus observer difference in low, medium and high blood pressure ranges for the TM-2655 device

	n	Difference 'device minus observers' (mmHg)		
		5	10	15
Low pressure range (<130/<80 mmHg)				
Systolic BP	87 ^a	70%	94%	100%
Diastolic BP		70%	94%	100%
Medium pressure range (130–160/80–100 mmHg)				
Systolic BP	55 ^a	79%	96%	100%
Diastolic BP		81%	98%	100%
High pressure range (>160/>100 mmHg)				
Systolic BP	53 ^a	67%	93%	100%
Diastolic BP		78%	96%	100%

^aThe number of reading satisfying both systolic and diastolic blood pressure criteria. BP, blood pressure.

In all SBP and DBP ranges (low, medium and high), the percentage of readings agreeing within 5 mmHg exceeded 60% (Table 4).

Discussion

TM-2655 is designed for stationary use. Devices of such type are intended for use in medical centers, sports clubs and public places (pharmacies, supermarkets, fitness clubs, etc.). The size of the device is 245 mm × 325 mm × 390 mm (Fig. 2). It is AC/DC powered. The cuff diameter is automatically adjusted from 55 to 115 mm, which corresponds to the arm circumference range of 17–36 cm. Taking into account that according to the BP measurement procedure the cuff bladder should cover at least 80% of arm circumference, the device allows BP measurement in participants with arm circumference from 17 to 45 cm.

As the device may also be used for screening BP evaluation, appropriate cuff size is very important to provide an accurate BP measurement. TM-2655 is equipped with an automatically adjusting cuff. Previous studies demonstrated an increasing proportion of patients with large arms, especially in populations with a high prevalence of overweight and obesity [6]. In such patients, using too small a cuff relative to arm circumference leads to a significant overestimation of BP. Beginning at an arm circumference > 29 cm and with increasing inaccuracy as arm circumference increases, the standard cuff increasingly overestimates the BP [7]. Using too large a cuff, however, may underestimate BP. The use of inappropriate cuff size in screening BP measurement would place the patients at risk of being incorrectly labeled as hypertensive and, if truly hypertensive, for under or overestimation of BP control. Among the patients recruited, 16 (18.8%) had a small arm circumference (26 cm) and 13 (15.3%) a large one (> 32 cm).

The BP measurement can be performed on both the left and the right arm. The upper panel of the device has the information on how to take a BP measurement, so a

Fig. 2

TM-2655 device (TM-2655P modification).

patient can use it without a doctor's or nurse's assistance. The device is also equipped with a 'stop' button, allowing one to interrupt measurement if it is painful or uncomfortable.

The results of BP and pulse measurement are shown on the device display. The TM-2655P modification is available from the same manufacturer. It has the same measuring block and is equipped with a printer (Fig. 2). The printout of BP measurement can be made in four formats including a graph of oscillometric pulsation. The latter provides the opportunity to determine reading artifacts. The printout also includes the date and time of measurement.

To be recommended for wide use, electronic devices must be validated according to accepted protocols or standards. The 1993 BHS protocol has been widely used for validation procedure. For being considered grade A, the difference between observers and test device for less than 5 mmHg should include at least 60% of measure-

ments. The TM-2655 fulfilled A/A BHS criteria with more than 70% of values agreeing to within 5 mmHg (72.5% for SBP and 78.8%, for DBP).

The device also fulfilled AAMI/American National Standard Institution (ANSI) criteria as observers–device disagreement in the overall group for SBP was $-1.0 + 5.2$ mmHg and for DBP $-0.9 + 4.7$ mmHg (AAMI/ANSI requirements are mean differences < 5 mmHg and SD < 8 mmHg).

Thus, the TM-2655 device can be recommended for BP measurement in an adult population.

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