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ORIGINAL ARTICLE

Validation of TONOPORT V blood-pressure measuring monitor in adults

A Haensel[1,3], K Utech[1] and W Langewitz[2]
[1]*Outpatient Clinic, Department of Internal Medicine, University Hospital Basel, Basel, Switzerland;*
[2]*Department of Psychosomatic Medicine, University Hospital Basel, Basel, Switzerland*

A new automatic blood-pressure (BP) measuring device TONOPORT V was evaluated according to the International Protocol for Validation of Blood Pressure Measuring Devices in adults by the European Society of Hypertension. BP values measured by the TONOPORT V were compared to BP readings from two independent observers. A total of 33 patients (20 males, 13 females) provided systolic and diastolic BP readings in the normotensive, borderline hypertensive, and hypertensive range. Their age varied between 30 and 83 years, and their arm circumference between 23 and 36 cm. The device showed a mean (±s.d.) deviation from observer measurements of −0.7 (4.6) mmHg for systolic and −0.8 (4.4) mmHg for diastolic BP. The accuracy of the device did not vary according to BP values or other patient characteristics. The device passed all phases of the protocol and can be recommended following the regulation rules of the European Society of Hypertension.
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Introduction

Automated and semiautomatic devices for the measurement of blood pressure (BP) are increasingly used in the diagnosis of patients with borderline hypertensive blood pressure and for the evaluation of antihypertensive medication.[1] Therefore, there is a need for potential purchasers to choose among the available devices on the basis of reliable validation data.[2] In 1990, the British Hypertension Society (BHS) published an evaluation protocol for the assessment of the accuracy of automated and semiautomated devices,[3] which was revised in 1993.[4] These protocols provide standards for the validation procedures that allow for the comparison of different devices with one another. In 2002, the working group on BP monitoring of the European Society of Hypertension published the International Protocol, which describes a less complex procedure for the evaluation of BP measuring devices.[5] This protocol will be applied in the current investigation on the accuracy of TONOPORT V, a new oscillometric device offered by PAR Medizintechnik, Berlin, Germany.

Methods

BP measuring technique

A standard mercury sphygmomanometer was used as a reference standard. It had been calibrated by official authorities 4 months before measurements took place and was carefully checked before the study. Blood pressures were recorded to the nearest even number, measured with the arms supported at heart level, with the manometer at eye level, and within 60 cm of the observer. Measurements were taken in a room shielded from ambient noise; telephones and beepers were silenced, room temperature was kept constant. A Littman stethoscope was used for the auscultation of the brachial artery. In every subject, the circumference of both arms was measured and the size of the bladder and the cuff was adjusted according to the manufacturer's instructions so that at least two-thirds of the arm circumference were covered by the bladder.

Before starting the validation procedure, the validation team practised with the TONOPORT V device to exclude measurement errors due to unexpected technical problems with the device.

Correspondence: Professor W Langewitz, Department of Psychosomatic Medicine, Internal Medicine, Hebelstrasse 2, CH-4031, Basel, Switzerland.
E-mail: wlangewitz@uhbs.ch
[3]I declare that the information given in this paper is original, is not under consideration and has not been previously published elsewhere and its contents has not been anticipated by any previous publication, to my knowledge.
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Observer measurement

Two observers took measurements independently with a time interval between two observations varying between 30 and 60 s. This interval was chosen in order to allow for venous decongestion of the arm and to avoid large variations in blood pressure by extending the intermeasurement interval. When observers differed, recordings were repeated until agreement was reached. The observers are experienced clinicians or researchers in psychophysiology familiar with BP measurements. Their accuracy was checked before the experiment by taking BP readings under supervision of a third clinician (WL). The observers were blinded in relation to the automatic readings. These were read out from the device memory after having obtained all readings in a subject. Furthermore, they were unaware of the other observer's readings.

Ethical approval for the study was not obtained from the Ethical Committee of the University Hospital Basle, because most subjects were clinic employees. Subjects gave their written informed consent and were offered the amount of CHF 50 for their participation.

Procedure

(1) After introducing the subject to the observers and explaining the procedure, subjects were seated, the cuff was attached, and arm circumference, gender, and age were noted. The subjects were then left alone for 10 min and told to relax as best as they could.
(2) Table 1 lists nine sequential measurements taken on the same arm between TONOPORT V and the standard mercury sphygmomanometer per subject for the subjects in Phase 2. They were recorded as follows:

Clinical BP reading (cBP)

- The mean of two observer BP measurements recorded with mercury standard sphygmomanometer was calculated. This value was used to divide subjects into BP ranges for both systolic blood pressure (SBP) and diastolic blood pressure (DBP).

Start blood pressure device (dBP)

- Initial BP taken by TONOPORT V, which allowed for the internal calibration of the device. This BP reading is not used for further analysis.

obBP1 — Mean of two observer BP readings
deBP1 — TONOPORT V monitor
obBP2 — Mean of two observer BP readings
deBP2 — TONOPORT V monitor
obBP3 — Mean of two observer BP readings
deBP3 — TONOPORT V monitor
obBP4 — Mean of two observer BP readings

(3) If either of the two observers did not agree on an entry BP (cBP; nonagreement: either an SBP or a DBP value, which differed by $\geqslant 5$ mmHg) or if the device was unable to record a measurement within three attempts, these measurements were omitted from further analysis; subjects were excused and sent home. When initial BP readings by the observers and by the TONOPORT V yielded valid data, the subject's BP readings were included into the analysis. Patients included in Phase 1 were evenly distributed among the three BP ranges (90–129/130–160/161–180 mmHg for SBP and 40–79/80–100/101–130 mmHg for DBP readings).

Data processing

Data analysis was performed by using a software programme which incorporates the requirements for the validation procedure as outlined in.[5]

Accuracy criteria
Differences were calculated by subtracting the observer measurement from the device measurement. When comparing and categorising differences, their absolute values have been used. A difference is categorised into one of four bands according to its rounded absolute value for SBP and DBP:

0–5 mmHg: These represent measurements considered very accurate (no error of clinical relevance).

6–10 mmHg: These represent measurements considered to be slightly inaccurate.

11–15 mmHg: These represent measurements considered to be moderately inaccurate.

>15 mmHg: These represent measurements considered to be very inaccurate.

The analysis has been based on the distribution of values among these bands, dividing differences into three zones:

Within 5 mmHg: This zone represents all values falling in the 0–5 mmHg band.

Within 10 mmHg: This zone represents all values falling in the 0–5 and 6–10 mmHg bands.

Within 15 mmHg: This zone represents all values falling in the 0–5, 6–10, and 11–15 mmHg bands.

The required number of readings falling into these ranges is listed in the results section.

Subject measurements
For accuracy assessment, the observer measurements obBP1, obBP2, obBP3, and obBP4 were used. Each TONOPORT V monitor measurement (deBP1, deBP2, deBP3) is thus flanked by two of these observer measurements and one of these is selected as the comparative measurement.

Comparing adjacent measurements yields the following observations:

The differences deBP1−obBP1, deBP1−obBP2, deBP2−obBP2, deBP2−obBP3, deBP3−obBP3, and deBP3−obBP4 were arrived at.

The absolute values of these differences were paired according to the device reading. When values in a pair were unequal the observer measurement corresponding to the smaller difference was used. When the values in a pair were equal the first of the two observer measurements was used. In order to reduce the number of subjects necessary for the investigation, individuals provide data on SBP and DBP readings separately. For example, an individual with hypertensive DBP readings and intermediate SBP readings may be listed with his/her DBP readings only when the intermediate SBP cell was filled already. For each subject there were three device readings for SBP and three for DBP. Each of these six readings now had a single corresponding observer measurement, a difference between the two and a band for that difference as described above. Owing to the requirement that subjects must be recruited in the order they present, subjects recruited in the later part of the study might have been suitable for SBP or DBP but not necessarily for both.

Results

Subjects were investigated between December 2003 and March 2004.

Phase 1

Subject characteristics
There were eight male and seven female subjects for both SBP and DBP (14 subjects provided *both* SBP and DBP measurements, and one provided either SBP *or* DBP readings only). Mean recruitment pressures were 148 (28) mmHg for SBP and 88 (13) mmHg for DBP. Ages ranged from 34 to 83 years for both SBP and DBP. Arm circumferences ranged from 23 to 36 cm for both SBP and DBP (Table 2).

Validation criteria
To pass Phase 1a, the device must have at least 25 of the 45 measurements within 5 mmHg or 35 within 10 mmHg or 40 within 15 mmHg of the comparative observer measurements (Table 2). The TONOPORT V monitor had 38 measurements within 5 mmHg, 42 within 10 mmHg and 45 within 15 mmHg for SBP, and 39 within 5 mmHg, 45 within 10 mmHg and 45 within 15 mmHg for DBP. The mean differences were −1.2 (4.3) mmHg for SBP and +0.2 (3.7) mmHg for DBP. The TONOPORT V monitor passed all of the criteria for both SBP and DBP (Table 3) (Figures 1 and 2).

Phase 2

Subject characteristics
There were 20 male and 13 female subjects who provided SBP values and 19 male and 14 female subjects whose values were registered for DBP (31 subjects provided both SBP and DBP measurements). Mean recruitment pressures were 147 (24) mmHg for SBP and 88 (13) mmHg for DBP. Ages ranged from 30 to 83 years for both SBP and DBP. Arm circumferences ranged from 23 to 36 cm for both SBP and DBP (Table 2).

Validation criteria: Phase 2.1
To pass Phase 2.1 a device must have at least 60 of the 99 measurements within 5 mmHg and 75 within 10 mmHg and 90 within 15 mmHg of the compara-

Table 1 Mean values ± s.d. for SBP and DBP readings ($N = 33$)

	CBP Observer	*dBP Device*	*obBP 1 Observer*	*deBP 1 Device*	*obBP 2 Observer*	*deBP 2 Device*	*obBP 3 Observer*	*deBP 3 Device*	*obBP 4 Observer*
SBP (mmHg)	146.70	143.12	141.61	141.48	141.36	139.27	141.45	140.06	140.06
SD SBP	24.36	23.62	23.58	23.70	23.28	23.20	23.89	23.65	22.74
DBP (mmHg)	88.12	88.21	88.17	87.33	87.00	87.17	87.30	85.21	86.26
SD DBP	13.19	13.61	13.11	13.11	13.05	14.05	13.54	14.91	12.32

Table 2 Demographics and entry criteria

	Sex	*Age (years)*		*Arm circumference (cm)*		*Recruitment BP (mmHg)*	
	Male:Female	*Range*	*Median (s.d.)*	*Range*	*Mean (s.d.)*	*Range*	*Mean (s.d.)*
Phase1							
SBP	8:7	34–83	57 (16)	23–36	28 (4)	108–210	148 (28)
DBP	8:7	34–83	57 (15)	23–36	28 (4)	68–106	88 (13)
Phase2							
SBP	20:13	30–83	45 (16)	23–36	28 (3)	108–210	147 (24)
DBP	19:14	30–83	43 (16)	23–36	28 (3)	67–107	88 (13)

Table 3 Validation results

(a) Absolute number of required and actual measurements fulfilling quality criteria (*at least: 25/45 comparisons with a difference ⩽5 mmHg, or 35/45⩽10 mmHg, or 40/45⩽15 mmHg) based upon a total of 45 comparisons during Phase 1

Phase 1 (N = 45 comparisons)	*⩽5 mmHg*	*⩽10 mmHg*	*⩽15 mmHg*	*Result*	*Mean (Tonoport−observer)*	*s.d.*
Required (*) at least one of	25	35	40			
Achieved						
SBP	38	42	45	Continue	−1.2 mmHg	4.3 mmHg
DBP	39	45	45	Continue	0.2 mmHg	3.7 mmHg

(b) Absolute number of required and actual measurements fulfilling quality criteria (* at least: 60/99 comparisons with a difference ⩽5 mmHg, and 75/99⩽10 mmHg, and 90/99⩽15 mmHg and in addition either 65/99 within 5 mmHg and 80/99 within 10 mmHg, or 65/99 within 5 mmHg and 95/99 within 15 mmHg, or 80/99 within 10 mmHg and 95/99 within 15 mmHg) based upon a total of 99 comparisons during Phase 2.1

Phase 2.1 (N = 99 comparisons)	*⩽5 mmHg*	*⩽10 mmHg*	*⩽15 mmHg*	*Result*	*Mean (Tonoport−Observer)*	*s.d.*
Required (*) all of	60	75	90			
and at least two of	65	80	95			
Achieved						
SBP	83	93	98	*Pass*	−0.7 mmHg	4.6 mmHg
DBP	80	96	97	*Pass*	−0.8 mmHg	4.4 mmHg

(c) Absolute number of required and actual subjects in whom measurements fulfil the following quality criteria: two out of three comparisons ⩽5 mmHg in at least 22/33 subjects and at most three subjects in whom no comparison showed a difference ⩽5 mmHg), based upon 33 subjects and 99 comparisons

Phase 2.2 (N = 33 subjects)	*2/3⩽5 mmHg*	*0/3⩽5 mmHg*	*Result*
Required	⩾22	⩽3	
Achieved			
SBP	30	2	Pass
DBP	29	1	Pass

tive observer measurements, and in addition it must also have either 65 within 5 mmHg and 80 within 10 mmHg, or 65 within 5 mmHg and 95 within 15 mmHg, or 80 within 10 mmHg and 95 within 15 mmHg. The TONOPORT V monitor had 83 measurements within 5 mmHg, 93 within 10 mmHg and 98 within 15 mmHg for SBP, and 80 measurements within 5 mmHg, 96 within 10 mmHg and 97 within 15 mmHg for DBP. The mean differences were −0.7 (4.6) mmHg for SBP and −0.8 (4.4) mmHg for DBP. The TONOPORT V monitor passed all of the criteria for both SBP and DBP (Table 3).

Validation criteria: Phase 2.2
To pass Phase 2.2, at least 22 of the 33 subjects must have at least two of their three device measurements within 5 mmHg of the standard, and no more than three subjects can have any of the three measurements within 5 mmHg of the standard. For the TONOPORT V monitor, 30 subjects had at least two of the differences within 5 mmHg and two subjects had no differences within 5 mmHg for SBP, and 29 subjects had at least two of the differences within 5 mmHg and one subject had no differences within 5 mmHg for DBP. The TONOPORT V monitor has therefore passed the criteria for SBP and for DBP (Tables 3 and 4).

Discussion

The TONOPORT V monitor passed all validation criteria during Phase 1, Phase 2.1, and Phase 2.2 (Table 3). This is in contrast to results by O'Brien *et al*[6] that were published in 2003. He had reported inaccurate measurements especially with respect to SBP readings. We can only speculate why our results differ from those obtained by O'Brien and coworkers. The problem is that neither O'Brien's nor our publication provides individual data which, however, is in accordance with the ESH protocol. However, these data would be necessary to discuss the observed discrepancy. Concerning the validation protocol the crucial issue is that it is based upon the comparison of *sequential* BP readings. The Achilles' heel of such a protocol is the stability of individual BP values during the series of measurements. If there is a substantial amount of baseline shift during the measurement period the device cannot be assessed correctly. Therefore, every care must be taken to ensure stable experimental conditions such that BP readings fluctuate within a physiological range only and as little as possible in response to external factors as ambient noise. Asking for a 5 min premeasurement rest period as the protocol does, may not be sufficient to fulfill this require-

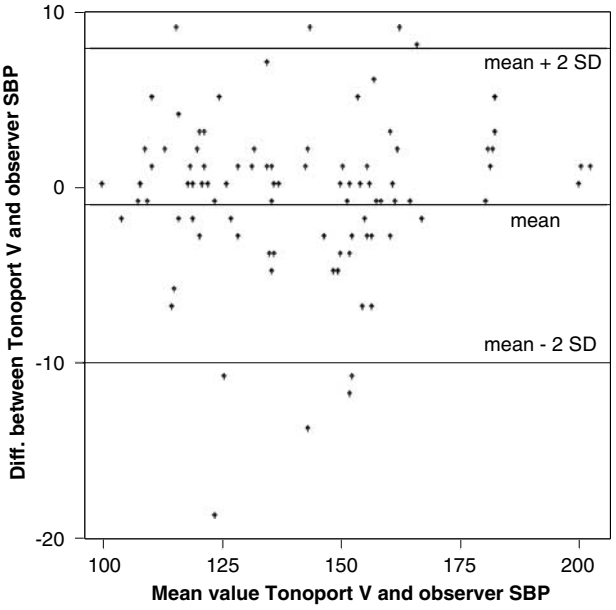

Figure 1 Bland–Altmann plot showing SBP differences between the TONOPORT V monitor and observer readings in 33 subjects, each yielding three comparisons. Horizontal lines indicate mean $\pm$ 2 s.d.s.

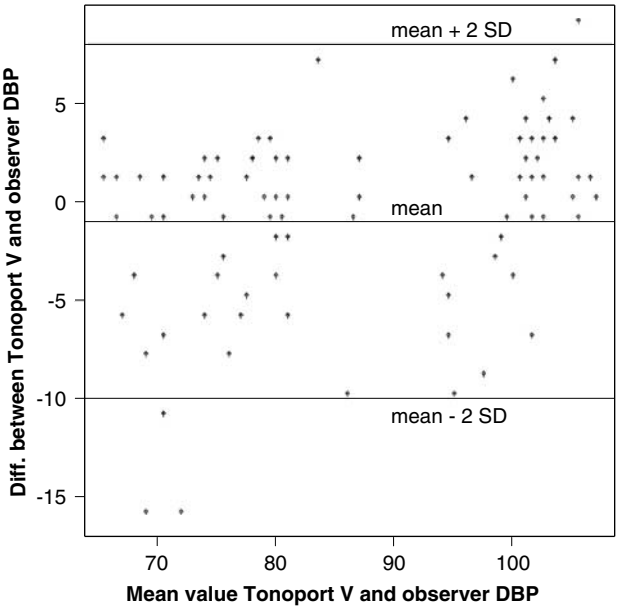

Figure 2 Bland–Altmann plot showing DBP differences between the TONOPORT V monitor and observer readings in 33 subjects, each yielding three comparisons. Horizontal lines indicate mean $\pm$ 2 s.d.s.

ment. In O'Brien's sample it appears that the environmental conditions were not sufficiently under control because he mentions that some readings had to be omitted because there was too much ambient noise to identify Korotkov sounds. In our view this points to less than perfect measurement conditions during which not only the observers but also probably subjects were irritated by distracting noise.

Table 4 Distribution of subjects according to BP ranges

	Low	*Medium*	*High*
SBP	90–129 mmHg 11 subjects	130–160 mmHg 11 subjects	161–180 mmHg 11 subjects
DBP	10–79 mmHg 11 subjects	80–100 mmHg 11 subjects	101–130 mmHg 11 subjects

Number of subjects in respective blood pressure ranges defined by cBP.

Furthermore, the literature shows that the fact that different evaluation groups yield validation data of different quality is not the exception but the rule (see: British Hypertension Society, Information Service at http://www.bhsoc.org/Blood_pressure_Publications.htm). According to this list provided by the British Hypertension Society in most devices there have been positive and negative reports indicating that probably characteristics of participants and external factors during the assessment play a major role in the performance of the devices under investigation.

We conclude that in our hands TONOPORT V yields reliable results that are in accordance with the validation criteria of the International Protocol,[5] and that therefore TONOPORT V can be recommended by the European Society of Hypertension.

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