

Validation of the TONOPORT V ambulatory blood pressure monitor according to the European Society of Hypertension International Protocol for Validation of Blood Pressure Measuring Devices in Adults

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Background It is now accepted that blood pressure measuring devices should be subjected to an independent evaluation of their accuracy before they are marketed for clinical use. The results of validation of the TONOPORT V blood pressure monitor for the measurement of ambulatory blood pressure according to the European Society of Hypertension International Protocol for Validation of Blood Pressure Measuring Devices in Adults are presented in this paper.

Population Thirty-three subjects were recruited from among staff and patients at Beaumont Hospital, Dublin, Ireland.

Methods The TONOPORT V monitor was connected to the Sphygmocorder, an audiovisual system for validation, which records blood pressure on tape and video for later analysis. Nine sequential same-arm measurements between the device and a standard mercury sphygmomanometer were recorded using the Sphygmocorder.

Results In phase 1, the TONOPORT V monitor produced 28 measurements within 5 mmHg, 37 within 10 mmHg and 40 within 15 mmHg for systolic blood pressure (SBP), and 26 within 5 mmHg, 38 within 10 mmHg and 44 within 15 mmHg for diastolic blood pressure (DBP). The mean differences were -2.2 (8.6) [mean (SD)] mmHg for SBP and $+0.5$ (7.2) mmHg for DBP. The TONOPORT V monitor passed all the criteria for both SBP and DBP. In phase 2.1, the TONOPORT V monitor had 56 measurements within 5 mmHg, 78 within 10 mmHg and 88 within 15 mmHg for SBP, and 60 measurements within 5 mmHg, 83 within

10 mmHg and 97 within 15 mmHg for DBP. The mean differences were -1.4 (8.7) mmHg for SBP and -0.2 (6.8) mmHg for DBP. The TONOPORT V monitor passed the criteria for DBP but failed to meet any of the criteria for SBP. In phase 2.2, 19 subjects had at least two of the differences within 5 mmHg and six subjects had no differences within 5 mmHg for SBP, and 22 subjects had at least two of the differences within 5 mmHg and six subjects no differences within 5 mmHg for DBP. The TONOPORT V monitor failed to meet the criteria for SBP and for DBP.

Conclusions The TONOPORT V monitor cannot be recommended for clinical use in an adult population because it records SBP inaccurately and because it records DBP inaccurately in an unacceptably high proportion of people. *Blood Press Monit* 8:255–260 © 2003 Lippincott Williams & Wilkins.

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Introduction

With the increasing marketing of automated and semi-automated devices for the measurement of blood pressure, there is a need for potential purchasers to be able to satisfy themselves that such devices have been evaluated according to agreed criteria [1]. With this need in mind, the Association for the Advancement of Medical Instrumentation (AAMI) published a standard for electronic or aneroid sphygmomanometers in 1987 [2], which included a protocol for the evaluation of the accuracy of devices; this was followed in 1990 by the protocol of the

British Hypertension Society [3]. Both protocols were revised in 1993 [4,5]. These protocols, which differed in detail, had a common objective, namely the standardization of validation procedures to establish minimum standards of accuracy and performance, and to facilitate the comparison of one device with another [6].

A number of blood pressure measuring devices have been evaluated according to one or both protocols. Experience has, however, demonstrated that the conditions demanded by the protocols are difficult to fulfil. This is

especially so because of the large number of subjects that have to be recruited and the ranges of blood pressure required. The time required to complete a validation study is such that it is difficult to recruit trained staff for the duration of a study. These factors have made validation studies difficult to perform and very costly, with the result that fewer centres are prepared to undertake them. This is particularly unfortunate as more devices are in need of independent validation than ever before.

Aware of these problems, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension has published a simplified protocol – the International Protocol – to facilitate the evaluation process, with the expectation that manufacturers will be more likely to submit their products for validation in order to obtain the minimum approval necessary for a device to be used in clinical practice [7]. The International Protocol, which is applicable to the majority of blood pressure measuring devices on the market, is confined to adults over the age of 30 years (as these will constitute the majority of subjects with hypertension), and it does not make recommendations for special groups, such as children, pregnant women and the elderly, or for special circumstances, such as during exercise.

The TONOPORT V, manufactured by General Electric (GE Medical Systems, Freiburg, Germany), is designed for measuring ambulatory blood pressure using the oscillometric technique.

Methods

Blood pressure measurement technique

A standard mercury sphygmomanometer, the components of which were checked carefully before the study, was used as a reference standard. All blood pressures were recorded to the nearest 2 mmHg. Blood pressure was measured with the arm supported at heart level, with the manometer at eye level and within 1 m of the observer. Device validation was performed at room temperature and disturbing influences, such as telephones and beeps, were silenced. A Littman stethoscope was used for all manual measurements.

The circumference of the arms was measured to ensure that the bladder being used was adequate for the subject.

Measurements made with the TONOPORT V monitor used the appropriate bladder according to the manufacturer's instructions. The same cuff/bladder was used for the standard mercury manometer measurements.

The validation team were instructed in the use of the TONOPORT V monitor and used the device in practice to detect any technical peculiarities that might have influenced the validation procedure. The TONOPORT V is straightforward to use, and no operational difficulties were encountered during familiarization and throughout the study.

Subject selection

Thirty-three subjects (15 for phase 1 and a further 18 for phase 2) with a wide range of blood pressure were selected (Tables 1 and 2). Subjects could be taking antihypertensive medication, but subjects in atrial fibrillation or with any sustained arrhythmia were excluded. Characteristics were as follows:

- *Numbers:* Phase 1 – 15 subjects; phase 2 – 33 subjects.
- *Sex:* Phase 1 – at least five male and five female subjects were required; phase 2 – at least 10 male and 10 female subjects were required.
- *Age range:* All subjects were at least 30 years of age.
- *Arm circumference:* Distribution by chance.
- *Blood pressure range:* There were three ranges for systolic blood pressure (SBP) and three for diastolic blood pressure (DBP), with 11 subjects in each range to provide 99 pairs of measurements (Table 3). The blood pressure used to determine the range was the entry blood pressure at the time of the validation procedure (BPA), and not that measured at the time of recruitment for validation.

Observer measurement

Measurements were recorded using the Sphygmocorder, an audiovisual system for validation [7,8]. Two observers assessed the recordings separately. Where they differed, the recording was reassessed until agreement was reached. Further references to 'observer measurement' refer to the agreed measurement using the Sphygmocorder. At least 30 s were allowed between each measurement to avoid venous congestion, but not more than 60 s, so that variability would be minimized. In some cases,

Table 1 Demographics and entry criteria

		Sex	Age (years)		Arm circumference (cm)		Recruitment blood pressure (mmHg)	
		Male:female	Range	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)
Phase 1	SBP	10:5	30:72	52 (11)	22:37	30 (3)	100:178	145 (24)
	DBP	10:5	30:68	54 (12)	22:37	30 (3)	50:116	90 (17)
Phase 2	SBP	16:17	30:77	54 (11)	22:37	30 (3)	92:180	144 (26)
	DBP	19:14	30:74	55 (11)	22:37	30 (3)	50:122	91 (19)

SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 2 Validation results

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean	SD
Required	One of	25	35	40			
Achieved	SBP	28	37	40	Continue	-2.2 mmHg	8.6 mmHg
	DBP	26	38	44	Continue	0.5 mmHg	7.2 mmHg
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade	Mean	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	56	78	88	Fail	-1.4 mmHg	8.7 mmHg
	DBP	60	83	97	Pass	-0.2 mmHg	6.8 mmHg
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade			
Required		≥ 22	≤ 3				
Achieved	SBP	19	6	Fail			
	DBP	22	6	Fail			

SBP, systolic blood pressure; DBP, diastolic blood pressure.

Table 3 Blood pressure recruitment range requirements

	Low	Medium	High
SBP	90–129	130–160	161–180
	11	11	11
DBP	40–79	80–100	101–130
	11	11	11

SBP, systolic blood pressure; DBP, diastolic blood pressure.

observer measurements were repeated if the supervisor had reason to believe that there might be interference with recorded sounds. Reasons included patient movement and loud external noises. To avoid bias, the repeated measurement was used in all cases regardless of the quality of the first reading.

Procedure

First, the subject was introduced to the observer and the procedure explained. Arm circumference, sex, date of birth and current date were noted. The subject was allowed to relax for 10–15 min to minimize anxiety and any white-coat effect.

Nine sequential same-arm measurements between the test instrument and a standard mercury sphygmomanometer were then recorded as follows:

- **BPA:** Entry blood pressure recorded on the Sphygmocorder with the mercury standard. This value was used to categorize the subject into the low, medium or high range separately for SBP and DBP (Table 1).
- **BPB:** Device detection blood pressure, observer 3. This blood pressure was measured to permit the TONOPORT V monitor to determine the blood pressure characteristics of the subject; this measurement was not included in the analysis.
- **BP1:** Recorded on the Sphygmocorder with the mercury standard.
- **BP2:** Supervisor with the TONOPORT V monitor.

- **BP3:** Recorded on the Sphygmocorder with the mercury standard.
- **BP4:** Supervisor with the TONOPORT V monitor.
- **BP5:** Recorded on the Sphygmocorder with the mercury standard.
- **BP6:** Supervisor with the TONOPORT V monitor.
- **BP7:** Recorded on the Sphygmocorder with the mercury standard.

Documentation was provided for data omitted for legitimate technical reasons; once a subject had been included, the data for that subject were not excluded from the study if blood pressure values were obtainable.

Analysis

The data were analysed using a specially written software program.

Accuracy criteria

Differences were calculated by subtracting the observer measurement from the device measurement. When comparing and categorizing differences, their absolute values were used. A difference was categorized into one of four bands according to its rounded absolute value for SBP and DBP:

- **0–5 mmHg:** These represent measurements considered to be 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 was based on how values in these bands fell cumulatively 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.

Subject measurements

The observer measurements BP1 to BP7 were used to assess accuracy. Each TONOPORT V monitor measurement was flanked by two of these observer measurements, one of which was selected as the comparative measurement.

From these, further measurements were derived as follows:

1. The differences BP2–BP1, BP2–BP3, BP4–BP3, BP4–BP5, BP6–BP5 and BP6–BP7 were calculated.
2. The absolute values of these differences (i.e. without the signs) were derived.
3. The absolute values were paired according to the device reading.
4. Where the values in a pair were unequal, the observer measurement corresponding to the smaller difference was used.
5. Where the values in a pair were equal then the first of the two observer measurements was used.

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 had to be recruited in the order they presented, subjects recruited in the later part of the study might have been suitable for SBP or DBP but not necessarily for both.

Results

Phase 1

Subject characteristics

There were 10 male and five female subjects for both SBP and DBP (12 subjects providing both SBP and DBP measurements). Mean recruitment pressures were 145 (24) [mean (SD)] mmHg for SBP and 90 (17) mmHg for DBP. Ages ranged from 30 to 72 years for SBP and 30 to 68 years for DBP. Arm circumferences ranged from 22 to 37 cm for both SBP and DBP (Table 1).

Validation criteria

To pass phase 1, a device had to have at least 25 of the 45 measurements within 5 mmHg, 35 within 10 mmHg or 40 within 15 mmHg of the comparative observer measurements (Table 2). The TONOPORT V monitor had 28 measurements lying within 5 mmHg, 37 within 10 mmHg and 40 within 15 mmHg for SBP, and 26 within 5 mmHg, 38 within 10 mmHg and 44 within 15 mmHg for DBP. The mean differences were -2.2 (8.6) mmHg for SBP

and $+0.5$ (7.2) mmHg for DBP. The TONOPORT V monitor passed all of the criteria for both SBP and DBP (Table 2).

Phase 2

Subject characteristics

There were 16 male and 17 female subjects for SBP, and 19 male and 14 female subjects for both DBP (24 subjects providing both SBP and DBP measurements). Mean recruitment pressures were 144 (26) mmHg for SBP and 91 (19) mmHg for DBP. Ages ranged from 30 to 77 years for SBP and from 30 to 74 years for SBP and DBP. Arm circumferences ranged from 22 to 37 cm for both SBP and DBP (Table 1).

Validation criteria

Phase 2.1: To pass phase 2.1, a device had to have at least 60 of the 99 measurements within 5 mmHg, 75 within 10 mmHg and 90 within 15 mmHg of the comparative observer measurements, and in addition had also to have either 65 within 5 mmHg and 80 within 10 mmHg, 65 within 5 mmHg and 95 within 15 mmHg, or 80 within 10 mmHg and 95 within 15 mmHg. The TONOPORT V monitor had 56 measurements within 5 mmHg, 78 within 10 mmHg and 88 within 15 mmHg for SBP, and 60 measurements within 5 mmHg, 83 within 10 mmHg and 97 within 15 mmHg for DBP. The mean differences were -1.4 (8.7) mmHg for SBP and -0.2 (6.8) mmHg for DBP. The TONOPORT V monitor passed the criteria for DBP but failed to meet any of the criteria for SBP (Table 2 and Figure 1a).

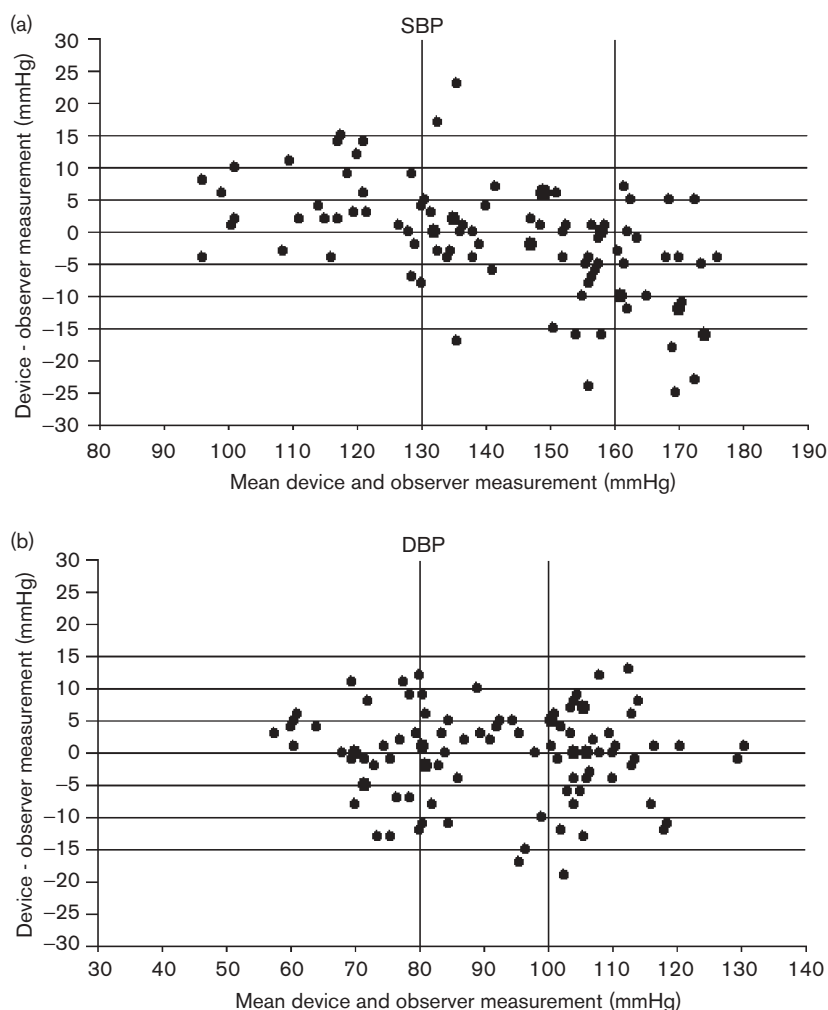
Phase 2.2: To pass phase 2.2, at least 22 of the 33 subjects had to have at least two of their three device measurements within 5 mmHg of the standard, and no more than three subjects could have none of the three measurements within 5 mmHg of the standard. For the TONOPORT V monitor, 19 subjects had at least two of the differences within 5 mmHg and six subjects had no differences within 5 mmHg for SBP, and 22 subjects had at least two of the differences within 5 mmHg and six subjects had no differences within 5 mmHg for DBP. The TONOPORT V monitor failed to meet the criteria for both SBP and DBP (see Table 2 and Figure 1b).

Discussion

Although the TONOPORT V monitor passed all the criteria for phase 1, the passes were relatively marginal. This was particularly so for the 'within 5 mmHg' band. This performance was reflected in both phase 2.1 and phase 2.2.

The TONOPORT V just passed phase 2.1 for DBP, the 'within 5 mmHg' criteria being just met. It also just achieved the criterion in phase 2.2 for the number of subjects on whom it was regarded as accurate – that is,

Fig. 1



(a) Scatterplot showing the systolic blood pressure (SBP) differences between the TONOPORT V monitor and observer readings in 33 subjects. The slightly larger points indicate superimposed points. The vertical lines mark the Low, Medium and High pressure ranges. (b) Scatterplot showing the diastolic blood pressure (DBP) differences between the TONOPORT V monitor and observer readings in 33 subjects. The slightly larger points indicate two superimposed points. The vertical lines mark the Low, Medium and High pressure ranges.

with at least two of the three measurements lying within 5 mmHg of the standard. However, on six patients, almost one in five, it failed to produce an accurate DBP. This means that 18 of the 39 inaccurate (error over 5 mmHg) DBP measurements, that is almost half, were on these six subjects. This indicates a subject-based element in the ability of this device to detect DBP.

The TONOPORT V performed poorly with respect to SBP. In phase 2.1, not a single target in the 'at least two' set was reached, and only one in the 'all three' set was reached. The device failed to reach any target in phase 2.2. This was reflected in the standard deviation of the errors, which, at almost 9 mmHg, fell outside recommendations set by the AAMI [2].

The TONOPORT V monitor cannot be recommended for clinical use because it records SBP inaccurately and because it records DBP inaccurately in an unacceptably high proportion of people.

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