

RESEARCH LETTER

Validation of the Stabil-O-Graph blood pressure self-measurement device

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The present work describes the validation of the Stabil-O-Graph, an automated blood pressure device, according to the criteria of the British Hypertension Society (BHS) and the European Society of Hypertension (ESH). In the BHS, validation procedure leads to a final grade A/A for systolic and diastolic blood pressure. In the ESH procedure, the test device passed all phases and the device's measurements were considered to be 'very accurate and with no error of clinical relevance'. Thus, the device met the accuracy requirements of both the BHS and the ESH standard and can be recommended for clinical use.

There is an increasing number of commercially available automated devices for self measurement of blood pressure. Most of these devices have not been validated by a recognized protocol yet. The Stabil-O-Graph (Stolberg, Germany) is a new automated self-measurement blood pressure monitoring device. The range of measurement is 70–260 mm Hg for systolic blood pressure, 45–180 mm Hg for diastolic blood pressure and 40–240 min⁻¹ for heart rate. To improve handling for elderly subjects, it has been designed as a one-button-operated device with large LCD screen. Ninety-nine blood pressure measurements are memorized. To date, the device has not been tested for accuracy. In the present work, the Stabil-O-Graph is validated according to the criteria of the British Hypertension Society (BHS) and the European Society of Hypertension (ESH).^{1–3}

The first part of the validation procedure corresponded to the BHS protocol.^{1,2} A total of 255 measurements were performed in 85 non-preselected subjects. Another 99 measurements were performed in 33 subjects in correspondence with the ESH protocol.³ Informed consent was obtained from all the probands. Cardiac arrhythmia was an exclusion criterion. All the measurements were performed by physicians, registered nurses or pharmacists. All the members of the team were trained according to the tutorial of the BHS website. Agreement of readings of observers and expert was demonstrated to assure validity of measurement results. The manufacturer was asked to loan three devices with differently sized cuffs (small, medium and large). A mercury sphygmomanometer (Erkometer 3000, Erka, Bad Tölz, Germany) was used as reference. Arm circumferences were measured and

recorded to allow correct choice of cuff size. The measurements took place in a quiet room with an ambient temperature of 20–22 °C. Subjects had to rest seated for at least 5 min before the measurement procedure was initiated. The two observers were blinded to each other. Mercury readings were taken by one mercury column and a two-person stethoscope with a Y-connector. Measurement and analysis procedures of the validation process were in strict accordance with the BHS and ESH protocols.

In all, 112 subjects were screened to achieve 85 subjects with the required proportion of subjects in each blood pressure category of the BHS protocol. The device passed phases 1–3 of the BHS protocol. In phase 1, two devices had 28 readings with a difference ≤ 3 mm Hg and one device had 30 readings with a difference ≤ 3 mm Hg. In phase 2, the devices were used in clinical environment and more than 500 measurements were performed. In phase 3, calibration was repeated (one device 29 readings with difference ≤ 3 mm Hg and two devices 28 readings with difference ≤ 3 mm Hg). In phase 4, static device validation was conducted in 85 subjects (39 men, 46 women; mean age 50.6 ± 17.4 years). Mean arm circumference was 29.8 ± 5.2 cm. Table 1a presents the results of the validation procedure including assignment to the predefined grades of the BHS protocol. Observer 1's readings led to a mean systolic blood pressure of 137.2 ± 0.2 mm Hg and a mean diastolic blood pressure of 83.9 ± 16.2 mm Hg. Observer 2's values had a systolic mean of 137.2 ± 30.2 mm Hg and a diastolic mean of 84.0 ± 6.5 mm Hg. The device–observer differences were -1.9 ± 6.6 (systolic) and 0.1 ± 5.8 mm Hg (diastolic) for observer 1 and -1.9 ± 6.6 mm Hg (systolic) and 0.0 ± 5.8 mm Hg (diastolic) for observer 2. Observer 1 was the 'better observer'. Supplementary Figure 1 presents Tukey mean-difference plots of the differences of observer 1 and the device. The device achieved grade A for systolic and diastolic blood pressure for observer 1 and B/A for observer 2 leading to a final grade A/A.

In the second part of the study (ESH validation), 33 participants (18 men, 15 women) were included. A total of 41 subjects had to be screened to reach the required number of 33 subjects that filled the three recruitment blood pressure categories of the ESH protocol. Mean age was 50.0 ± 14.4 years (range: 30–85 years). Mean arm circumference was 30.0 ± 3.7 cm. Mean systolic blood pressure was 140.0 ± 25.6 mm Hg and mean diastolic blood pressure was 87.0 ± 14.9 mm Hg. Mean recruitment blood

Table 1a Results of the BHS validation procedure, $n = 85$ subjects

	Grade	≤5	≤10	≤15	≤30	Mean ± s.d. (mm Hg)	Mean ± s.d. of differences (mm Hg)
<i>Observer 1</i>							
SBP (1 vs 2, 3 vs 4, 5 vs 6)	B	61%	88%	94%	100%	138.4 ± 30.6	-3.1 ± 7.2
DBP (1 vs 2, 3 vs 4, 5 vs 6)	A	67%	94%	98%	100%	83.9 ± 16.2	0.1 ± 5.8
SBP (2 vs 3, 4 vs 5, 6 vs 7)	A	66%	89%	96%	100%	137.2 ± 30.2	-1.9 ± 6.6
DBP (2 vs 3, 4 vs 5, 6 vs 7)	A	67%	95%	99%	100%	83.5 ± 16.2	0.5 ± 5.6
<i>Observer 2</i>							
SBP (1 vs 2, 3 vs 4, 5 vs 6)	B	61%	88%	93%	100%	138.5 ± 30.7	-3.2 ± 7.3
DBP (1 vs 2, 3 vs 4, 5 vs 6)	A	65%	94%	98%	100%	84.0 ± 16.5	0.0 ± 5.8
SBP (2 vs 3, 4 vs 5, 6 vs 7)	B	66%	87%	94%	100%	137.2 ± 30.2	-1.9 ± 6.6
DBP (2 vs 3, 4 vs 5, 6 vs 7)	A	64%	96%	99%	100%	83.5 ± 16.4	0.5 ± 5.8
<i>Final grading</i>							
SBP	A	66%	89%	96%	100%	137.2 ± 30.2	-1.9 ± 6.6
DBP	A	65%	94%	98%	100%	84.0 ± 16.5	0.0 ± 5.8

Abbreviations: BHS, British Hypertension Society; DBP, diastolic blood pressure; SBP, systolic blood pressure. Numbers in column 1 correspond to number of measurements in the BHS protocol (device measurements vs preceding and succeeding observer measurements).

pressure (BPA) was 140.1 ± 25.7 mm Hg (systolic) and 87.1 ± 14.9 mm Hg (diastolic). Mean device-observer differences were 0.0 ± 5.6 mm Hg (systolic) and 1.0 ± 5.7 mm Hg (diastolic). In total, 45 measurements were available from phase 1 and an additional 54 from phase 2. In phase 1, the number of measurements differing from the mercury standard by 5, 10 and 15 mm Hg or less are shown in Table 1b. The number of subjects exceeded the required ones in each of the three error categories. The device passed phase 1 and fulfilled the requirements for phase 2.1. Tukey mean-difference plots of the data is presented in Supplementary Figure 2. Agreement was sufficient for both systolic and diastolic values. In phase 2.2, at least two of three device-observer differences were less than 5 mm Hg in 25 (systolic) and 27 patients (diastolic) and the number of patients in which none of the three values were less than 5 mm Hg was 3 and 1, respectively. The device fulfilled the criteria for phase 2.2.

In both BHS and ESH validation procedure, several subjects showed a decrease of systolic and diastolic blood pressure after the initial measurement (BPA). Since the accuracy of the device was slightly higher in the ESH sample than in the BHS sample, we wanted to exclude a recruitment bias. We extracted the first 33 subjects of the BHS population that fulfilled the categorization criteria of the ESH protocol and performed an additional ESH validation. In phase 2.1, 79 systolic blood pressure readings were in the 5 mm Hg difference range, 92 in the 10 mm Hg and 95 in the 15 mm Hg difference range. For diastolic blood pressure, 74 readings were in the 5 mm Hg range, 92 in the 10 mm Hg range and 98 in the 15 mm Hg difference range. Regarding phase 2.2, at least two of three device-observer differences were less than 5 mm Hg in 28 (systolic) and 25 patients (diastolic) and the number of patients in which

Table 1b Number of measurements required and achieved for systolic (SBP) and diastolic (DBP) blood pressure falling in specified error categories according to phase 1 (number of subjects, $n = 15$, number of measurements, $n = 45$) and phase 2.1 of the ESH protocol (number of subjects, $n = 33$, number of measurements, $n = 99$)

		Error category		
		<5 mm Hg	<10 mm Hg	<15 mm Hg
<i>Phase 1</i>				
Required	One of	≥25	≥35	≥40
Achieved	SBP	32	42	45
	DBP	34	39	43
<i>Phase 2</i>				
Required	Two of	≥65	≥80	≥95
	All of	≥60	≥75	≥80
Achieved	SBP	72	92	99
	DBP	75	90	97

none of the three values were less than 5 mm Hg was 2 and 3, respectively. The device successfully passed phases 2.1 and 2.2 in this study population as well.

The Stabil-O-Graph automated blood pressure monitor proved a high validity in the present BHS validation procedure. The device achieved the highest possible grade A for both systolic and diastolic blood pressure. It may be discussed, however, whether the BHS protocol might be insufficient for the percentage of measurements lying in the 5 mm Hg category (60% for grade A, 50% for grade B) as calculated by the mean device-observer difference of the three readings. The present work additionally provides a separate validation according to the criteria of the ESH protocol, in which the Stabil-O-Graph was considered to be 'very accurate and with no error of clinical relevance'. The Stabil-O-Graph can be recommended for clinical use.

What is known about the topic

- Many patients use self-assessment blood pressure devices to control blood pressure.
- Self-assessment of blood pressure is of great importance to control effective treatment.
- Many self-assessment blood pressure devices on the market have not been validated by approved protocols.

What this study adds

- The Stabil-O-Graph automated blood pressure monitor proved a high validity in the BHS protocol.
 - The Stabil-O-Graph also passed the ESH protocol with a high accuracy.
 - The Stabil-O-Graph can be recommended for clinical use.
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Supplementary Information accompanies the paper on the Journal of Human Hypertension website (<http://www.nature.com/jhh>)