Validation of the Microlife WatchBP Home device for self home blood pressure measurement according to the International Protocol

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Objective **Current guidelines recommend that self monitoring of blood pressure at home should only be performed using validated devices. This study assessed the accuracy of the Microlife WatchBP Home device for self home blood pressure measurement according to the European Society of Hypertension International Protocol.**

Methods **Thirty-three participants were included (15 in phase 1 and an additional 18 in phase 2). Simultaneous blood pressure measurements were taken by two observers (Y-tube-connected mercury sphygmomanometers) four times sequentially, with three measurements taken using the tested device. Absolute differences between observer and device measurements were classified into three zones (within 5, 10 and 15 mmHg). The number of measurements with a difference within 5 mmHg was calculated for each individual.**

Results **In phase 1, the device produced 38, 43 and 43 measurements within 5, 10 and 15 mmHg, respectively, for systolic blood pressure and 35, 45 and 45 for diastolic blood pressure. In phase 2.1, the device produced 75, 91 and 97 measurements within 5, 10 and 15 mmHg for systolic, and 74, 93 and 99 for diastolic blood pressure. In phase 2.2, 30 participants had at least two of their differences within 5 mmHg and two participants had no differences within 5 mmHg for systolic blood pressure, whereas for diastolic blood pressure the number of participants were 27 and three, respectively. Mean difference for systolic blood pressure was −0.3 ± 5.6 mmHg and for diastolic −2.4 ± 4.8 mmHg.**

Conclusions **The Microlife WatchBP Home device for self home blood pressure measurement fulfills all the validation criteria of the International Protocol and can, therefore, be recommended for clinical use in the adult population. *Blood Press Monit* 12:185–188 © 2007 Lippincott Williams & Wilkins.**

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Introduction

Self-monitoring of blood pressure (BP) is regarded as a useful adjunct to conventional office BP measurements [1] and several hypertension societies recommend its application in clinical practice for the diagnosis and the long-term follow-up of hypertensive patients [2–5]. Although the accuracy of the devices used for BP measurement is an important prerequisite, few electronic devices for self home BP measurement available on the market have been proved accurate on the basis of independent validation studies [6].

In 2002, the European Society of Hypertension Working Group on Blood Pressure Monitoring developed the International Protocol [7], which, compared with the earlier protocols by the Association for the Advancement of Medical Instrumentation (AAMI) [8] and the British Hypertension Society [9], has been simplified in terms of the sample size required and the entry BP range.

This paper presents the results of a validation study of the Microlife WatchBP Home oscillometric device for self home measurement of BP according to the European Society of Hypertension International Protocol for Validation of Blood Pressure Measuring Devices in Adults [7].

Methods

Tested device

The Microlife WatchBP Home (Microlife, Heerbrugg, Switzerland) is an oscillometric device for self home BP measurement on the upper arm. It measures BP at rest ranging between 30 and 280 mmHg and pulse rate between 40 and 200 beats/min. Inflation is performed

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by an automatic electric pumping system and deflation by an automatic pressure-release valve. The device has a large liquid crystal digital display that simultaneously displays the systolic and diastolic BP and the heart rate. It is powered by four 1.5 V batteries or an AC adaptor and has a personal computer link capacity and memory for 250 measurements. Three cuffs are available for use with the device: small cuff (for arm circumference 17–22 cm), standard (22–32 cm) and large cuff (32–42 cm). Three devices were obtained from the manufacturer for the purpose of the study, together with a written declaration that they were standard production models. To familiarize themselves with the tested device, the investigators took several BP measurements using all the three devices and one of them was randomly selected for the validation procedure.

Blood pressure measurements

One supervisor and two trained observers experienced in the methodology of BP measurement were involved in this validation study. Before the study initiation, the observers were retested for agreement in BP measurement according to the British Hypertension Society protocol [9]. Two standard mercury sphygmomanometers (Riester, diplomat-presameter, Rud. Riester GmbH Co. KG, Jungingen, Germany), the components of which had been carefully checked before the study, and a teaching Littman stethoscope were used for simultaneous (Y-tube) observer-taken reference BP measurements. The supervisor measured BP with the tested device and also checked the agreement of BP measurements taken by the two observers, who were blinded to each other's readings and to those obtained by the device. Observer readings with a difference greater than 4 mmHg were repeated until closer agreement was reached. Two cuffs of the tested device were used for measurements taken with the tested and the mercury device according to the manufacturers' instructions to fit the arm circumference of each individual. All measurements were taken on the left arm, which was supported at heart level. The protocol was approved by the hospital scientific committee.

Participants

According to the International Protocol, in phase 1, a total of 15 treated or untreated participants are included who fulfill the age, sex and entry BP-range requirements (age 30 years or older, at least five men and five women, five participants with entry BP within each of the ranges 90–129, 130–160 and 161–180 mmHg for systolic and 40–79, 80–100 and 101–130 mmHg for diastolic BP). If analysis of these data is successful, additional participants are recruited until a total of 33 participants fulfill the age, sex and entry BP-range requirements for phase 2 (age 30 years or older, at least 10 men and 10 women, 11 participants with entry BP within each of the above-mentioned BP ranges for systolic and diastolic BP). Participants with sustained arrhythmia or irregular pulse during the validation procedure were excluded. Informed consent was obtained from all participants who took part in the study.

Procedure

The validation study was conducted in an isolated room where disturbing noise was avoided. Age, sex and arm circumference of each participant were recorded, together with the cuff size used and the date and time of the validation procedure. After 10–15 min of sitting rest, BP was measured by the two observers (entry BP). This measurement was used to classify participants into the low, medium and high ranges, separately for systolic and diastolic BP, as described above. Device detection measurement by the supervisor followed, to ensure that the device was able to measure the BP of each individual. The two observers took readings BP1, BP3, BP5 and BP7 using the double-headed stethoscope and the mercury sphygmomanometers. The supervisor took readings BP2, BP4 and BP6 using the test device. The validation analysis was based on the last seven measurements (BP1 to BP7).

Analysis

Each pair of observer measurements was averaged and was then subtracted from the device measurement. The absolute differences between BP2 – BP1, BP2 – BP3, BP4 – BP3, BP4 – BP5, BP6 – BP5 and BP6 – BP7 were calculated and paired according to the device reading. For each pair, the one with the smaller difference was used in the analysis. These BP differences were classified into three zones (within 5, 10 and 15 mmHg), separately for systolic and diastolic BP, for 15 participants in phase 1 and for all the 33 in phase 2.1. For each individual participant, the number of readings with a difference within 5 mmHg was also calculated (phase 2.2). Statistical analysis was performed using the MINITAB INC Statistical Software (release 13.31) (Stage College, Pennsylvania, PA, USA).

Results

Study participants

A total of 38 participants were recruited from an Outpatients Blood Pressure Clinic and from patients and staff of a University Department of Medicine. To facilitate the recruitment procedure, emphasis was placed on the recruitment of participants with high diastolic and low systolic BPs first, and those with high systolic and low diastolic BPs next, as recommended by the International Protocol [7]. Four participants were initially excluded because their entry BP was outside the range required for study inclusion. Two of these were included in the study later, after treatment modification. One participant, initially excluded because of Korotkoff sound V persisting down to 0, was later successfully included in the study. A total of 36 participants successfully completed the validation procedure. No participant was excluded because of arrhythmia. In three

BP readings, there was a difference between the observers' measurements greater than 4 mmHg. These were repeated to reach closer agreement.

The first 15 participants (45 BP readings) who fulfilled the International Protocol criteria regarding sex and entry systolic and diastolic BP ranges were included in the analysis of phase 1. Analysis of phase 2.1 and phase 2.2 was based on the first 33 participants (99 BP readings), who fulfilled the study inclusion criteria regarding sex and entry BP. The characteristics of participants in study phases 1 and 2 are presented in Table 1. The standard cuff was used in 23 of the 33 participants and the large one in the other 10.

Validation criteria

The use of the tested device was straightforward and there were no operational problems during the study. There was only one failure of the device to record BP throughout the study. A successful reading was obtained on repeated measurement. The requirements of the International Protocol for phases 1, 2.1 and 2.2 and the results of the validation analysis are presented in Table 2. The differences in BP between the tested device and the observer readings (99 readings) for systolic and diastolic BP are presented in Fig. 1.

In phase 1, the tested device passed all the three criteria (one required), for both systolic and diastolic BP (Table 2). The mean differences between the tested device and the reference method were -0.3 ± 5.6 mmHg for systolic and -1.1 ± 4.5 mmHg for diastolic BP. In phase 2.1, the device comfortably satisfied all the six criteria (five required), for both systolic and diastolic BP (Table 2). The mean differences between the device and the reference method in all the 33 participants were -0.3 ± 5.6 mmHg for systolic and -2.4 ± 4.8 mmHg for diastolic BP. In phase 2.2, the device also passed all the protocol criteria for systolic and diastolic BP.

Discussion

This study provides information on the accuracy of the Microlife WatchBP Home device for self home BP measurement. It showed that this new oscillometric BP monitor comfortably fulfilled the validation requirements of the International Protocol [7] for both systolic and diastolic BP and could, therefore, be recommended for clinical use in the adult population. The algorithm of this device is identical to that of the Microlife BPA100 Plus device, which has recently been validated using the International Protocol and has been shown to be accurate [10]. As significant changes have been made to the WatchBP Home, compared with the BPA100 Plus device, regarding both the hardware and the software, a new validation study was deemed necessary.

The tested device also satisfied the validation criterion of the AAMI protocol, given that the mean difference in BP between the device and the observer measurement was lower than 5 mmHg with a standard deviation lower than 8 mmHg [8] (Table 2). It should be mentioned, however, that, according to the International Protocol, this study included fewer patients than was required by the AAMI protocol.

Table 1 Characteristics of participants in study phases 1 and 2

	Participants (men/women)	Mean age ± SD years (range)	Mean arm circ. ± SD cm (range)	Entry SBP ± SD mmHg (range)	Entry DBP ± SD mmHg (range)
Phase 1	15 (9/6)	50.1 ± 12.6 (31–66)	29.5 ± 3.8 (22–36)	141.2 ± 25.0 (104–178)	86.3 ± 19.6 (50–115)
Phase 2	33 (19/14)	49.1 ± 15.2 (30–82)	29.6 ± 3.5 (22–36)	142.2 ± 23.2 (104–178)	88.5 ± 17.4 (50–120)

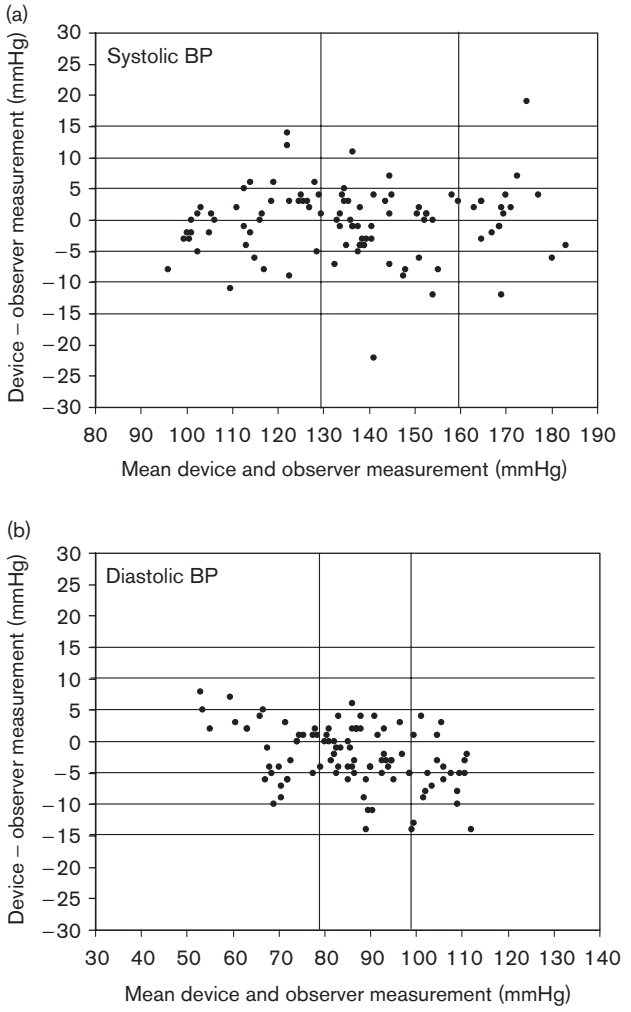
arm circ, arm circumference; DBP, diastolic blood pressure; SBP, systolic blood pressure .

Table 2 Results of the validation analysis

Phase 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommended	Mean difference	SD
Required	One of	25	35	40			
Achieved	SBP	38	43	43	Continue	−0.3	5.6
	DBP	35	45	45	Continue	−1.1	4.5
Phase 2.1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Recommended	Mean difference	SD
Required	Two of	65	80	95			
	All of	60	75	90			
Achieved	SBP	75	91	97	Pass	−0.3	5.6
	DBP	74	93	99	Pass	−2.4	4.8
Phase 2.2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Recommended		
Required		≥ 22	≤ 3				
Achieved	SBP	30	2		Pass		
	DBP	27	3		Pass		

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

Fig. 1



Scatterplots presenting differences in blood pressure between the tested device and the observer readings (99 readings). Recruitment limits regarding entry blood pressure ranges (low, medium and high) are indicated by the vertical lines. BP, blood pressure.

Despite the increasing use of home BP monitoring in clinical practice and its support by hypertension societies [1–5], the vast majority of the devices available on the market have not been subjected to independent validation using the established protocols [6]. One reason for this was the difficulty in conducting validation studies using the earlier cumbersome protocols [8,9]. The application of the International Protocol has significantly facilitated the procedure for the assessment of the accuracy of BP monitors and several validation studies using this protocol have been published [6]. There is an urgent need for more devices available on the market to be properly validated.

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