Vol 19 No 1 February 2014

ISSN 1359-5237

Blood Pressure Monitoring

Wolters Kluwer Health | Lippincott Williams & Wilkins

www.bpmonitoring.com

Validation of the A&D BP UA-651 device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010

Elisabetta Benetti, Claudio Fania and Paolo Palatini

The objective of this study was to determine the accuracy of the A&D BP UA-651 device for home blood pressure (BP) measurement according to the International Protocol of the European Society of Hypertension. Device evaluation was carried out in 33 patients. The mean age of the patients was 48.3±15.5 years, the mean systolic BP was 138.3±24.9 mmHg (range 90–180), the mean diastolic BP was 88.3±13.8 mmHg (range 60–108), and the mean arm circumference was 28.6±3.4 cm (range 23–36). The protocol requirements were followed precisely. The device passed all requirements, fulfilling the standards of the protocol. On average, the device underestimated the systolic BP by 0.4±4.4 mmHg and diastolic BP by 1.3±3.5 mmHg. The device–observer discrepancies were unrelated to patients' clinical characteristics. These data show that the A&D BP UA-651 device fulfilled the requirements for validation by the International Protocol and can be recommended for clinical use in the adult population. *Blood Press Monit* **19:50–53 © 2014 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

Blood Pressure Monitoring 2014, 19:50–53

Keywords: device, home blood pressure, self-measurement, validation

Department of Medicine, University of Padova, Padua, Italy

Correspondence to Paolo Palatini, MD, Department of Medicine, University of Padova, via Giustiniani, 2-35128 Padua, Italy
Tel: +39 049 8212278; fax: +39 049 8754179; e-mail: palatini@unipd.it

Received 25 September 2013 Revised 18 November 2013
Accepted 19 November 2013

Introduction

Self-blood pressure (BP) monitoring presents several advantages compared with office BP measurement as it provides multiple readings under standardized conditions and avoids the white-coat effect [1–3]. Oscillometric devices are becoming increasingly popular, especially for self-measurement of BP at home. The accuracy of BP measuring devices is of prime importance and all of them should be validated according to agreed criteria [2,4]. The aim of the present study was to verify the accuracy of the UA-651 (Fig. 1) (UA-611 without AC adapter), an oscillometric device developed by the A&D Company for self-BP measurement at the upper arm, according to the International Protocol revision 2010 of the European Society of Hypertension (ESH) [5].

Materials and methods

Device

The UA-651 device is a compact and fully automated monitor developed by the A&D Company (Tokyo, Japan), which measures BP at the upper arm using the oscillometric technique. Systolic BP, diastolic BP, and heart rate are displayed on a liquid crystal digital display. The device detects BP values during the deflation period. Power supply is provided by four batteries or through an AC adapter. The same device without AC adapter is marketed under the name UA-611. There are three cuffs provided by the manufacturer that are suitable for upper arm circumferences ranging between 22 and 32 cm (standard adult cuff), between 23 and 37 cm (semilarge cuff), and between 31 and 45 cm (large cuff).

Familiarization

Forty test measurements were carried out. No problems were encountered. The observer agreement was evaluated according to the ESH protocol [5] and was −1.0±2.0 mmHg for systolic BP and −0.8±2.2 mmHg for diastolic BP.

Protocol

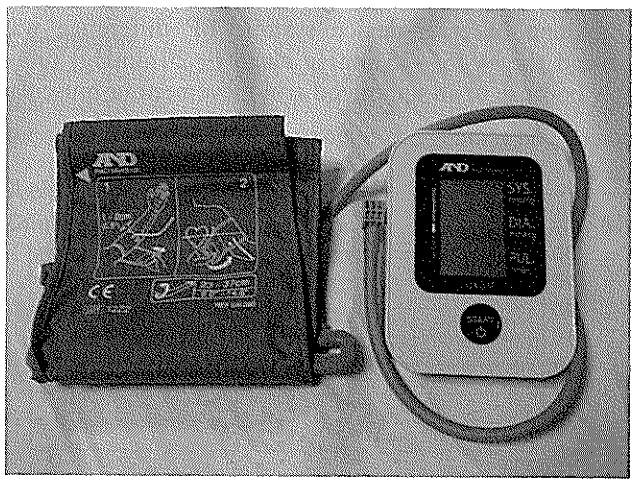
The International Protocol revision 2010 of the ESH requires the enrollment of 33 patients who are divided into three groups according to their BP range [5]. The number of observer test measurements in each pressure range must be between 22 and 44. The difference between the range with the highest count and that with the lowest count cannot exceed 19. Ideally, the recruitment BPs should be in the range 90–180 mmHg for systolic BP and 40–130 mmHg for diastolic BP. However, if patients with BPs beyond these ranges are available, they may be included but only to a maximum of four such pressures. The discrepancy between the reading provided by the sphygmomanometer and the mean of the observer's measurements is allocated to four zones of accuracy, which is determined by the number of differences in these ranges.

Participants and recruitment

The UA-651 device was evaluated in 42 adult individuals (20 men) with BPs within the ranges required by the protocol. The participants were recruited from the outpatient clinics, wards, and from among the medical staff at the Department of Medicine, University

DOI: 10.1097/MBP.0000000000000020

Fig. 1



Digital image of the A&D BP UA-651 device for upper arm self-blood pressure measurement used in the study.

of Padova, Padua, Italy. Nine participants (seven men) were excluded because their BP was within the BP ranges already completed, leaving an overall number of 33 participants (13 men and 20 women). Recruitment details and participant characteristics are reported in Tables 1–3. There was some difficulty in recruiting patients with BP in the high ranges, but apart from this, there was no problem. The study was approved by the Ethics Committee of the University of Padova, and written informed consent was provided by the participants.

Procedure

The validation team included three individuals (two observers and one supervisor). The two observers involved in the validation (C.F. and E.B.) had received adequate training by an expert in BP measurement. The BP was measured in a quiet room at a comfortable temperature, without any noise that could interfere with the auscultation of BP. During the test, the participants were evaluated in the sitting position, and sequential same arm measurements were taken. The two observers were blinded to the measurements obtained by each other and to the device readings. BP measurements were taken with a mercury sphygmomanometer at the upper arm, using an adult cuff with a bladder that was at least 80% of the arm circumference and had a width that was at least 40% of the same. The mean value of the first observer's measurement was used to categorize the participant into a low, medium, or high BP range, separately for systolic BP and diastolic BP (Table 3). Four sequential readings were taken by observers 1 and 2 using a double-headed stethoscope and a mercury sphygmomanometer (BP1, BP3, BP5, and BP7), whereas

Table 1 Participant details

Sex		
Male : female	13 : 20	
Age (years)		
Range (low : high)	25 : 79	
Mean±SD	48.3±15.4	
Arm circumference (cm)		
Range (low : high)	23 : 36	
Mean±SD	28.6±3.4	
Cuff for the test device		
Standard size (22–32 cm)	0	
Large size (31–45 cm)	0	
Semilarge (23–37 cm)	33	
Recruitment BP (mmHg)	SBP	DBP
Range (low : high)	90 : 180	60 : 108
Mean±SD	138.3±24.9	88.3±13.8

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

Table 2 Screening details

Screening and recruitment	
Total screened	42
Total excluded	9
Range complete	9
Range adjustment	0
Arrhythmias	0
Device failure	0
Poor-quality sounds	0
Cuff size unavailable	0
Observer disagreement	0
Distribution	0
Other reason	0
Total recruited	33

Table 3 Recruitment ranges

	mmHg	All	On Rx
SBP	<90	0	
Low	90–129	12	5
Medium	130–160	11	5
High	161–180	10	6
	>180	0	
DBP	<40	0	
Low	40–79	11	4
Medium	80–100	11	8
High	101–130	11	7
	>130	0	

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

three BP readings were taken by the supervisor using the test instrument (BP2, BP4, and BP6). At least 60 s were allowed between two measurements. The differences between the readings provided by the device and the mean observer measurements were calculated. Therefore, each device measurement was compared with the previous and the next mean observer measurement. Correlations between device–observer differences and other clinical variables were calculated using Pearson's test with Bonferroni adjustment for multiple tests. Between-sex comparisons were evaluated using an unpaired *t*-test adjusting for age and arm circumference. A *P*-value of less than 0.05 was considered statistically significant. For analyses, the Systat, version 11 statistical package (SPAA Inc., Evanston, Illinois, USA) was used.

Results

The results of the study are presented in Tables 4–6. The observer measurements showed a good agreement. The device–observer disagreement was -0.4 ± 4.4 mmHg for systolic BP and -1.3 ± 3.5 for diastolic BP. The validation results fulfilled all the 2010 ESH revision Protocol criteria for the general population and passed all validation grades. No correlation was found between the systolic or diastolic BP discrepancies and age, body weight and height, arm circumference, and mean device and observer BP level (all $P > 0.10$). The BP discrepancies did not vary according to sex ($P > 0.11$).

Discussion

The present study showed that the A&D UA-651 BP monitor fulfilled the recently proposed ESH standards for use in the general adult population because it passed all phases of the 2010 ESH revised Protocol. The recruitment of individuals in the high BP range proved to be difficult and accounted for the extra number of screened participants. The UA-651 BP device proved to be accurate across the entire range of age, BP level, body size, and arm circumference, and its performance did not vary according to sex. Visual inspection of the device–observer discrepancies (Fig. 2) confirmed that the error was unrelated to patient BP levels and that the discrepancies were not higher at the extremes of BP. Only one observer–device systolic BP difference was beyond the $+15/-15$ mmHg range (+20 mmHg) probably because of an unnoticed arm movement or muscular

Table 4 Observer measurements in each recruitment range

SBP (mmHg)		DBP (mmHg)	
Overall range (low : high)	90 : 179	Overall range (low : high)	58 : 110
Low (<130)	41	Low (<80)	35
Medium (130–160)	34	Medium (80–100)	41
High (>160)	24	High (>100)	23
Maximum difference	17	Maximum difference	18

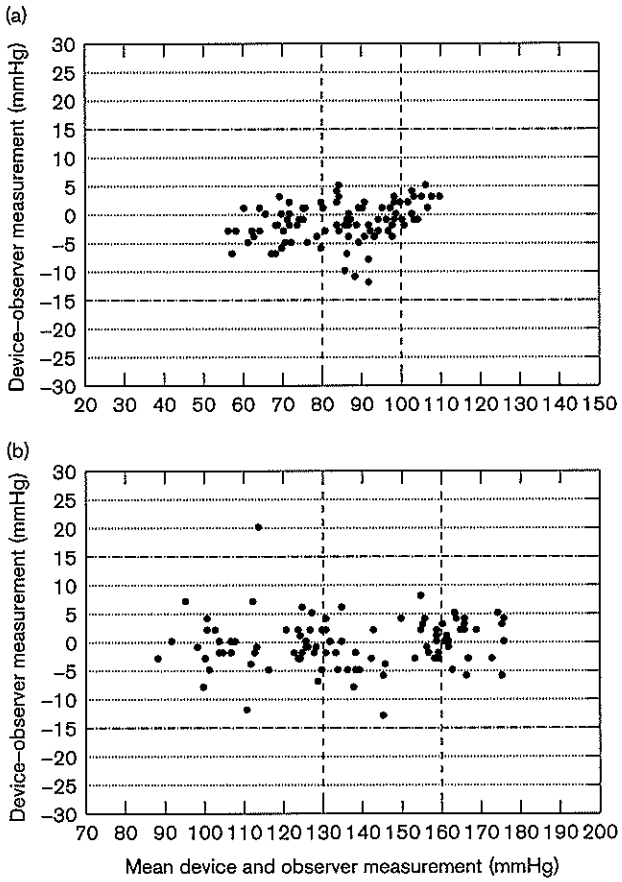
DBP, diastolic blood pressure; SBP, systolic blood pressure.

Table 5 Observer differences

	SBP	DBP	Repeated measurements
Observer 2 – observer 1			
Range (low : high)	−4 : 4	−4 : 4	–
Mean (SD)	−0.6 (2.5)	−0.8 (2.6)	0

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

Fig. 2



Plots of the (a) diastolic and (b) systolic device–observer blood pressure differences in the 33 participants enrolled in the study. The *x*-axis represents the mean of the device and observer measurements in mmHg. The *y*-axis represents the difference between the device and observer measurements in mmHg. A positive value indicates that the device measurement is greater than the observer's measurement.

Table 6 Validation results

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass requirement						
Two	73	87	96			
All	65	81	93			
Achieved						
SBP	84	96	98	Pass	−0.4	4.4
DBP	88	97	99	Pass	−1.3	3.5
Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade 2		Grade 3
Pass requirement	≥ 24	≤ 3				Pass
Achieved						Pass
SBP	31	0		Pass		Result
DBP	31	0		Pass		Pass

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

contraction during the deflation phase that may have affected the accuracy of measurement.

Conclusion

As the UA-651 device (UA-611 without AC adapter) has reached the required ESH standards, it can be recommended for self-BP monitoring in the general population.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

References

1 Ohkubo T, Imai Y, Tsuji I, Nagai K, Kato J, Kikuchi N, *et al.* Home blood pressure measurement has a stronger predictive power for mortality than does screening blood pressure measurement: a population-based observation in Osama, Japan. *J Hypertens* 1998; 16:971–975.

2 Parati G, Stergiou GS, Asmar R, Bilo G, de Leeuw P, Imai Y, *et al.* European Society of Hypertension practice guidelines for home blood pressure monitoring. *J Hum Hypertens* 2010; 24:779–785.

3 Mancia G, Fagard R, Narkiewicz K, Redón J, Zanchetti A, Böhm M, *et al.* 2013 ESH/ESC Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). *J Hypertens* 2013; 31:1281–1357.

4 Palatini P, Frick GN. Techniques for self-measurement of blood pressure: limitations and needs for future research. *J Clin Hypertens* 2012; 14: 139–143.

5 O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, *et al.* Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Press Monit* 2010; 15:23–38.