Validation of the OMRON HBP-1320 upper arm blood pressure monitor, in oscillometry mode, for clinic use in a general population, according to the European Society of Hypertension International Protocol revision 2010

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Abstract

The OMRON HBP-1320, an upper arm blood pressure monitor, in oscillometry mode, for clinical use, was validated, in a general population, according to the European Society of Hypertension International Protocol revision 2010. The protocol requirements were followed precisely. The device passed all of the requirements and, fulfilling the standards of the protocol, is recommended for clinical use.

Device Details

Brand	OMRON
Model	HBP-1320
Manufacturer	OMRON HEALTHCARE Co., Ltd.
Location	Upper Arm
Method	Oscillometry
Purpose	Clinic Measurement
Operation	Fully Automatic
Arm Cuffs	Small Adult: 17.0 cm to 22.0 cm, Standard Adult: 22.0 cm to 32.0 cm, Large Adult: 32.0 cm to 42.0 cm and other cuffs: 12.0 cm to 50.0 cm
Other Features	The cuff size "Other" refers to either the Extra Small Cuff,12.0cm to 18.0cm, or to the Extra Large cuff, 42.0cm to 50.0cm. There are functions to detect irregular pulse wave and body movement. The function to enable auscultation by an observer.

Methodology

Familiarisation

Numerous test-measurements were carried out. No problem was found.

Recruitment

Hypertensive subjects were recruited from outpatients clinic in the Department of Cardiology in Biwako Central Hospital (Shiga, Japan). Some participated immediately without appointment. Normotensive subjects were recruited from outpatients and volunteers.

Screening and Recruitment Details

Screening and Recruitment		Recruitment Ranges				
Total Screened	64			mmHg	All	On Rx
Total Excluded	31		Low	< 90	1	2
Ranges Complete	0			90 - 129	10	
Ranges Adjustment	0	SBP	Medium	130 - 160	11	2
Arrhythmias	0		High	161 - 180	10	0
Device Failure	0			> 180	1	
Poor Quality Sounds	0					
Cuff Size Unavailable	0		Low	< 40	0	2
Observer Disagreement	0			40 - 79	11	
Distribution	0	DBP	Medium	80 - 100	12	2
Other Reasons	31		High	101 - 130	10	0
Total Recruited	33			> 130	0	

Procedure

The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely.[1] Overseen by an independent supervisor, measurements were recorded by two observers blinded from both each other's readings and from the device readings.

Results

Subject Details

Sex			
Male : Female	10 : 23		
Age (years)			
Range (Low : High)	31 : 73		
Mean (SD)	52.9 (9.5)		
Arm Circumference (cm)			
Range (Low : High)	16.6 : 42.1		
Mean (SD)	28.6 (5.9)		
Cuff for test device			
Small	4	(17.0 - 22.0 cm)	
Standard	19	(22.0 - 32.0 cm)	
Large	8	(32.0 - 42.0 cm)	
Other	2	(12.0 - 50.0 cm)	
	SBP	DBP	
Recruitment BP (mmHg)			
Range (Low : High)	84 : 210	46 : 129	
Mean (SD)	142.3 (31.3)	88.2 (20.0)	

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	92 : 196	Overall Range (Low : High)	47 : 128
Low (< 130)	33	Low (< 80)	32
Medium (130 – 160)	30	Medium (80 – 100)	28
High (> 160)	36	High (> 100)	39
Maximum Difference	6	Maximum Difference	11

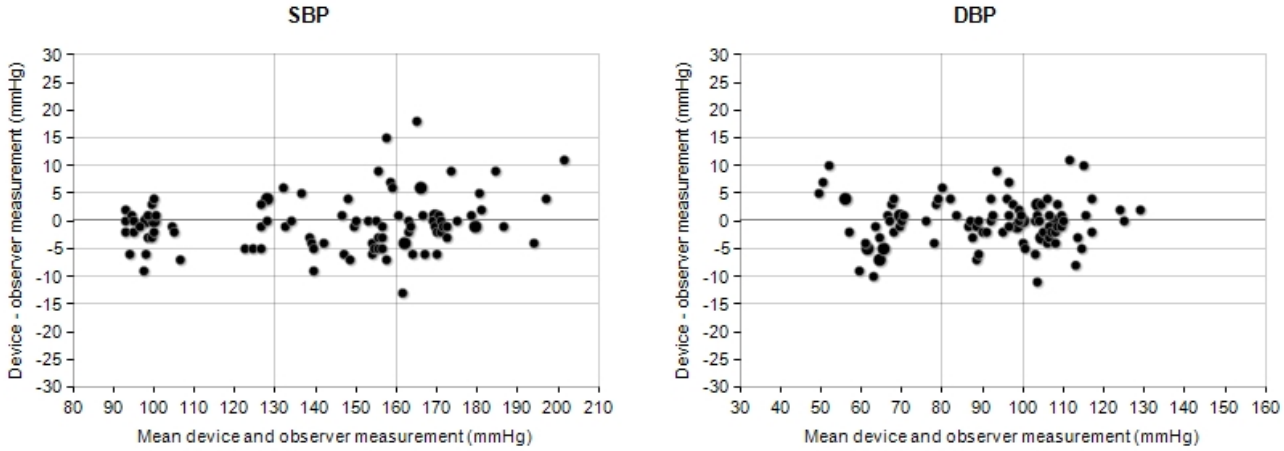
Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	0.1 (1.5)	-0.1 (1.7)	0

Validation Results

Part 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
	Pass Requirements						
	Two of	73	87	96			
	All of	65	81	93			
	Achieved						
	SBP	75	95	98	Pass	-0.4	4.9
	DBP	83	97	99	Pass	-0.2	4.2
Part 2		2/3 ≤ 5 mmHg		0/3 ≤ 5 mmHg	Grade 2		Grade 3
	Pass Requirements	≥ 24		≤ 3			
	Achieved						
	SBP	28		1	Pass		Pass
	DBP	30		0	Pass		Pass
Part 3							Result
							PASS

Plots



Discussion

The study finished without any problems. However, it was hard to recruit patients with high blood pressure levels of 161 to 180mmHg. The agreement between observer and device was similar in the three BP ranges and the magnitude of discrepancies were within 15mmHg.

Conclusion

As the device has reached the required standards, it is recommended for clinical and personal use in a general population.

Acknowledgements and Conflict of Interest

The monitor was supplied for the purposes of the study by the manufacturer OMRON Healthcare CO.,LTD. who also funded the study. The author does not have any association with OMRON Healthcare CO.,LTD. and did not receive any personal benefit from OMRON Healthcare CO.,LTD..

References

1. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; on behalf of the 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.