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Validation of the Omron HEM-7201 upper arm blood pressure monitor, for self-measurement in a high altitude environment, according to the European Society of Hypertension International Protocol revision 2010

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Abstract

Few studies have been conducted on blood pressure monitors and their use at high altitude. This study is the first to evaluate an automated blood pressure device at high altitude following a standard validation protocol. The Omron HEM-7201 upper arm automatic blood pressure monitor was tested for accuracy in Lhasa, Tibet, China (3650 m above sea level) according to the European Society of Hypertension International Protocol revision 2010 (ESH-IP2). Thirty-three participants received 9–10 sequential blood pressure measurements alternating from a mercury sphygmomanometer and the device. The mean device-observer measurement difference was 1.0 ± 5.9 mmHg for systolic blood pressure (SBP) and −3.1 ± 4.6 mmHg for diastolic blood pressure (DBP). Of the 99 measurement pairs analyzed, 72, 90, and 97 device readings were within 5, 10, and 15 mmHg, respectively, of the observer measurements for SBP, and 68, 92, and 99 readings for DBP. The number of participants with at least two out of three measurements within 5mmHg was 27 for SBP and 25 for DBP. Three participants had no measurements within 5 mmHg for SBP or DBP. The Omron HEM-7201 passes the ESH-IP2 validation criteria and can therefore be recommended for use in adults in this setting.

Keywords

blood pressure; high altitude; International Protocol; Tibet; validation studies

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Conflict of interest The authors declare no conflict of interest.

Introduction

The accurate measurement of blood pressure is a fundamental component of any health-care practice to informing clinical care, especially in patients with hypertension and cardiovascular disease. Since its introduction, manual measurement using the auscultatory method with a mercury sphygmomanometer has been considered the accepted gold standard for indirect blood pressure measurement. However, the automatic digital blood pressure monitor has come to steadily replace the mercury sphygmomanometer for blood pressure measurement in clinics and hospitals around the world. Along with addressing the environmental concerns associated with mercury-containing instruments, automated blood pressure monitors minimize or circumvent issues such as poor observer technique, digit preference, observer bias and the `white coat effect'. (1–5) There is also growing evidence for the use of automated measuring in clinical trials and registration studies. (6,7) At the same time, the devices' widespread availability and ease of use have allowed patients to monitor their own blood pressures at home. (8)

With the introduction of automatic blood pressure monitors for clinical use and self-measurement, the Association for the Advancement of Medical Instrumentation (AAMI), (9) the British Hypertension Society (10), and the European Society of Hypertension (11,12) established protocols to evaluate the accuracy of blood pressure measuring devices against manual blood pressure measurement using the auscultatory method. Following these guidelines, many automatic devices have been validated as being acceptable alternatives to the mercury sphygmomanometer, while others have failed to meet the minimum standards for accuracy. (13–18) Efforts by manufacturers to comply with these standards have led to a trend in devices that are more accurate and are validated by one or more protocols. (19) However, most, if not all, of these validations have taken place in areas of normal altitude, leaving an informational gap on their use in high altitude areas.

High altitude is considered to be an altitude greater than 2438 m above sea level. High altitude areas are home to over 140 million people around the world, including the peoples of the Peruvian Andes, Tibetan plateau, and Ethiopian highlands. (20) Up to now, only two prior reports have assessed blood pressure monitoring at high altitude. The first study evaluated the accuracy of a portable aneroid device among residents living in Cerro de Pasco situated in the Peruvian Andes (4370 m), while the second study tested the accuracy of an automatic blood pressure monitor in Dangxiong County, Tibet (4300 m). (21,22) Both studies, however, did not firmly follow an accepted validation protocol for their investigations. Further evaluation is still needed to assess the functionality and suitability of blood pressure measuring devices, particularly automated devices, in these parts of the world.

The aim of this study was to evaluate the accuracy of an automatic blood pressure monitor at high altitude in Tibet, China using an internationally accepted protocol for blood pressure device validation in adults.

Methods

Device

The Omron HEM-7201 automatic blood pressure monitor (Omron Healthcare, Kyoto, Japan) is an upper arm, oscillometric measuring device designed for blood pressure self-measurement and has been previously validated by the AAMI protocol at normal altitude (Figure 1). Cuff inflation and deflation is automated while the device's cuff self-check feature can alert users to improper cuffing. The model comes with a standard sized cuff applicable to arm circumferences ranging from 22 to 32 cm. A large cuff is also available for arm circumferences ranging from 32 to 42 cm. Three units were purchased from the local market for this study.

Recruitment

The study was conducted in Tibet, China at the administrative capital, Lhasa, which has an average altitude of 3650 m above sea level. Hypertensive and normotensive participants were recruited from those attending a general outpatient clinic at a local hospital in Chengguan District in central Lhasa and from the county hall of Linzhou County in northeast Lhasa. Only participants at or older than 25 years old and in sinus rhythm were allowed to participate in the study. Participants were screened to determine their eligibility with qualified participants continuing with the study and without appointment. All participants gave written informed consent. The study was approved by the Institutional Review Boards at Peking University Health Science Center, China and Duke University, USA.

Procedure

A familiarization period of about one week took place at our office where over 40 test measurements were taken with the automated device without issue. The validation team included two trained observers, a physician and a medical student experienced in blood pressure measurement, and one supervisor. Both observers had adequate hearing and sight and completed the BHS blood pressure measurement training on digital versatile disc.

The European Society of Hypertension International Protocol revision 2010 (ESH-IP2) (12) for the validation of blood pressure devices in adults was followed precisely. Each eligible participant received 9 to 10 sequential blood pressure measurements alternating between the mercury sphygmomanometer and the automated device. A rest period of 30–60 seconds was allowed between each blood pressure measurement to prevent venous congestion and increased blood pressure variability between measurements. Overseen by an independent supervisor, the manual mercury measurements were recorded by the two observers blinded from both each other's readings and from the device readings. The manual measurements were taken simultaneously by the two observers using two mercury sphygmomanometers connected by a Y-tube and a double headed teaching stethoscope. Observer 1 controlled the inflation and deflation of the blood pressure cuff, maintaining a deflation rate of about 2 mmHg/s. Any simultaneous measurements recorded by the two observers that differed more than 4 mmHg was repeated, with any participant having such a discrepancy occur twice

being excluded from the study. The device used to obtain the automated blood pressure measurements was operated by the supervisor.

Results

A total of 61 adults were screened to recruit the 33 participants needed to achieve the necessary distribution of recruitment blood pressure values in the low, medium, and high blood pressure range categories for systolic blood pressure (SBP) and diastolic blood pressure (DBP) (Table 1). Of the 33 participants, 12 were men, meeting the minimum of 10 needed for each gender. All participants were older than 25 years old, and one participant, with an arm circumference of 32.5 cm, required the use of a large cuff (Table 2).

The manual blood pressure measurements obtained from the 33 participants used in the validation analysis satisfied the blood pressure range category distribution requirements with the exception of the need for one recorded DBP measurement of 50 mmHg or less (Table 3). Eleven measurements were repeated due to observer disagreement with all final measurements having an inter-observer difference at or within 4 mmHg (Table 4).

Using the two-part validation criteria of the ESH-IP2, the Omron HEM-7201 satisfies all the conditions for both SBP and DBP measurements (Table 5). As a measure of the device's overall accuracy, part 1, a sufficient number of blood pressure measurements made by the Omron HEM-7201 was within 15 mmHg, 10 mmHg, and 5 mmHg of the corresponding manual blood pressure measurements for both SBP and DBP. On reviewing the validation criteria examining intra-participant variability in blood pressure measurements, part 2, it was found that the minimum of 24 participants requiring at least two of their three device readings to be within 5 mmHg of their corresponding manual readings was achieved for both SBP and DBP. One participant had all three SBP device readings outside 5 mmHg when compared to the corresponding manual readings, while there were two participants with that outcome for DBP. The mean difference between the device and mercury sphygmomanometer was 1.0 ± 5.9 mmHg for SBP and −3.1 ± 4.6 mmHg for DBP. Mean-difference plots representing the difference between the device measurements and their corresponding manual observer measurements against the mean of the device and observer measurements are shown in Figure 2 (for SBP) and Figure 3 (for DBP).

Discussion

The Omron HEM-7201 automatic digital blood pressure monitor was able to meet all of the ESH-IP2 validation criteria at 3650 m above sea level in Lhasa, Tibet, passing validation for both SBP and DBP. The mean-difference plots for SBP and DBP both show the wide range of blood pressures measured, but reveal fewer points in the high range denoting the difficulty with recruiting participants in this blood pressure category. The appropriate number of measurements was still obtained from each recruitment range to ensure a representative group for the study.

This validation is the first to follow an internationally accepted validation protocol to investigate the accuracy of an automatic blood pressure monitor specifically in a high altitude environment. In assessing the Omron HEM-7201 in Lhasa, all the necessary

recruitment requirements were fulfilled with the exception of having at least one participant with a measured DBP of 50 mmHg or less during the validation measurements section of the study. The lowest DBP obtained was 56 mmHg, but this range omission should not have an appreciable effect on the final pass decision. The mean-difference plot for DBP shows limited point variability across the three blood pressure ranges, with strong agreement as one goes below 70 mmHg. Even considering a worst-case measurement difference at or below 50 mmHg, the device would still be able to satisfy all validation criteria to receive a pass result.

Information on automatic digital blood pressure monitors currently do not address their suitability for use in high-altitude areas. Most manufacturers either do not provide guidelines on optimal storage and operating pressures or disclose a pressure range that is below pressures seen in communities living in high altitude. For example, the atmospheric pressure in Lhasa (3650m) equates to around 630 hPa, a pressure that falls well outside the Omron HEM-7201 specified operating pressure range of 700 hPa ~ 1060 hPa. It is unclear as to what effect a lower atmospheric pressure can have on the accuracy of automatic blood pressure monitors, but this study suggests little to no obvious effect of altitude on at least one model of an automated blood pressure measuring device.

Currently, only one other study by Li *et al*. (22) has examined the accuracy of an automatic blood pressure monitor at high altitude. In Li's study, the group tested the Omron HEM-759P upper arm automatic blood pressure monitor in Dangxiong County, Tibet, China (4300 m) using an internally devised protocol and concluded that the device could provide an accurate measurement of DBP (0.4 ± 3.9 mmHg difference), but required a simple calibration for SBP (5.8 ± 4.7 mmHg difference). All 129 participants in the study received three consecutive blood pressure measurements which were taken using a mercury sphygmomanometer connected to the automatic blood pressure device by a Y-tube to provide simultaneous measuring. The use of simultaneous measuring with blood pressure cuff inflation and deflation controlled by the automatic device can influence the accuracy of the manual readings if cuff deflation is quicker than recommended. Furthermore, although the study encompassed a large sample size, the use of a convenience sampling scheme raises concern about the generalizability of the findings given the wide range of blood pressures that a blood pressure measuring device is intended to handle. Therefore, it may be difficult to interpret the practical value of the study's results, let alone compare the tested device to other automated devices tested at high altitude.

Our study follows the ESH-IP2 for validation of the Omron HEM-7201 and provides new evidence on the use of an automatic blood pressure monitor at high altitude. However, as previous ESH-IP2 validation studies have mentioned, the small number of participants needed to carry out the validation protocol limits the study's statistical power. (14,15,23) One must also keep in mind that inherent to the current protocols for evaluating blood pressure monitors, a certain amount of variability is allowed among devices that `pass' or receive grade `A' ratings; for example, device measurements may deviate greater than 15 mmHg up to 6% of the time based on the ESH-IP2.

Conclusion

To the best of our knowledge, this study is the first to evaluate the accuracy of an automatic digital blood pressure monitor in high altitude according to an internationally accepted protocol. Based on the ESH-IP2, the Omron HEM-7201 can be recommended for self-measurement in adults at high altitude. This automatic blood pressure monitor can serve as a simple and accurate alternative to traditional auscultatory monitoring in these areas. However, continued evaluation should be considered to support these findings and better inform the accuracy of such automated devices at high altitude in practice.

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figure 1. Omron HEM-7201 automatic digital blood pressure monitor

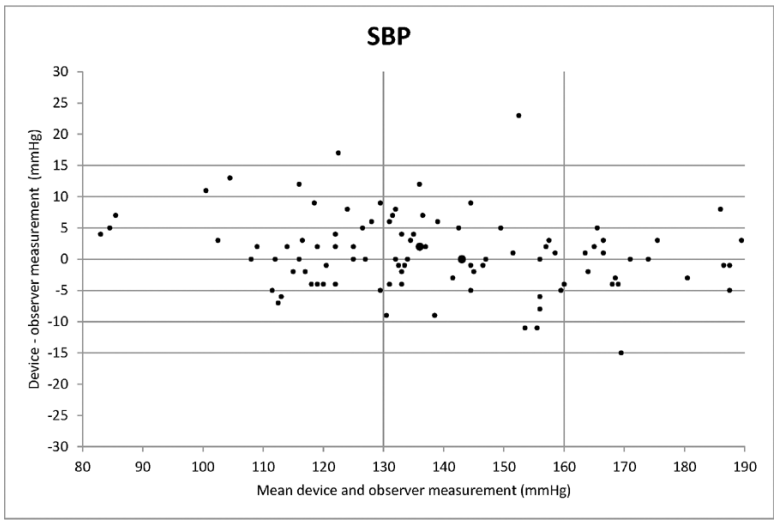

figure 2. Systolic blood pressure (SBP) differences between the device and manual observer readings against the average of the two readings (large dots represent two superimposed points)

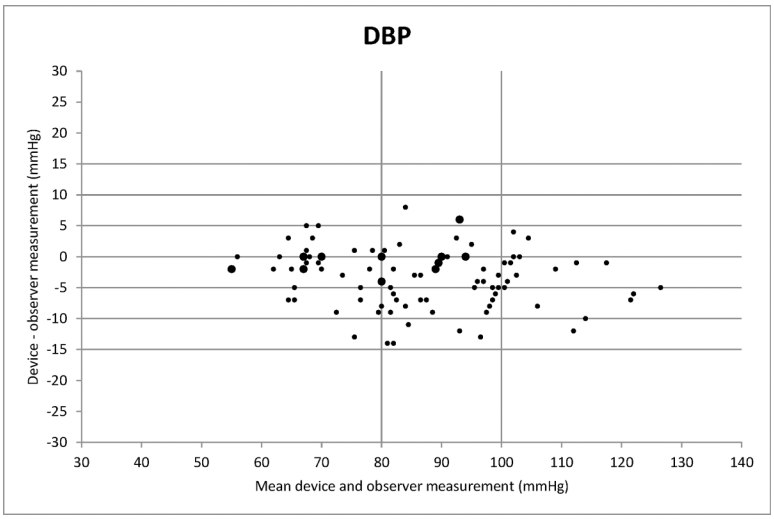

figure 3. Diastolic blood pressure (DBP) differences between the device and manual observer readings against the average of the two readings (large dots represent two superimposed points)

Table 1

Screening and recruitment details

Screening and Recruitment		Recruitment ranges				
Total screened	61	*BP range*		*mmHg*	All	On Rx[2]
Total excluded	28		*Low*	*<90*	1	2
Ranges complete	14			*90–129*	11	
Range adjustment	2	*SBP*	*Medium*	*130–160*	11	9
Arrhythmias	0		*High*	*161–180*	7	8
Device failure	0			*>180*	3	
Poor quality sounds	2					
Cuff size unavailable	0		*Low*	*<40*	0	4
Observer disagreement	5			*40–79*	11	
Distribution	3	*DBP*	*Medium*	*80–100*	11	7
Other reasons[1]	2		*High*	*101–130*	11	8
Total recruited	33			*>130*	0	

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure

[1]Two participants had to leave for personal reasons before completing the sequence

[2]On antihypertensive medication

Table 2

Participant details

Sex		
Male: Female	12 : 21	
Age (years)		
Range (Min:Max)	26 : 82	
Mean (SD)	55.2 (14.7)	
Arm circumference (cm)		
Range (Min:Max)	22 : 32.5	
Mean (SD)	27.4 (2.9)	
Cuff for test device		
Standard (22–32 cm)	32	
Large (32–42 cm)	1	
Recruitment BP (mmHg)	*Systolic*	*Diastolic*
Range (Min:Max)	76 : 201	48 : 128
Mean (SD)	142.2 (27.7)	87.9 (16.6)

Abbreviations: SD, standard deviation; BP, blood pressure

Table 3

Observer measurements in each recruitment range

SBP (mmHg)		**DBP (mmHg)**	
Overall range (Low:High)	81 : 190	Overall range (Low:High)	56 : 129
Low (<130)	38	Low (<80)	30
Medium (130–160)	39	Medium (80–100)	44
High (>160)	22	High (>100)	25
Maximum difference	17	Maximum difference	19

Abbreviations: SBP, systolic blood pressure; DBP, diastolic blood pressure

Table 4

Observer differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low:High)	−4 : +4	−4 : +4	
Mean (SD)	−0.6 (1.6)	−0.4 (1.6)	11

Abbreviations: SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure

Table 5

Validation results

Part 1	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass Requirement						
Two of	*73*	*87*	*96*			
All of	*65*	*81*	*93*			
Achieved						
SBP	72	90	97	Pass	1.0	5.9
DBP	68	92	99	Pass	−3.1	4.6

Part 2	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade 2	Grade 3
Pass Requirement	*≥ 24*	*≤ 3*		
Achieved				
SBP	27	1	Pass	Pass
DBP	25	2	Pass	Pass

Abbreviations: SD, standard deviation; SBP, systolic blood pressure; DBP, diastolic blood pressure