

BRIEF REPORT

Validation of the Omron HEM-650 wrist blood pressure device using the British Hypertension Society protocol in emergency patients in Hong Kong

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Aims. Automated wrist cuff blood pressure (BP) devices are more compact and easier to use, particularly when access to the upper arm is restricted, for example in emergencies.

Methods. We tested the Omron HEM-650 wrist device using the validation criteria of the British Hypertension Society (BHS) protocol in a major emergency department (ED) in Hong Kong. 85 patients had three measurements each by both the Omron HEM-650 wrist device and the mercury sphygmomanometer. The conventional automated BP with arm cuff was also measured using an oscillometric (Colin BP-88S NXT) device for comparison.

Results. The Omron HEM-650 achieved a grade B for both systolic and diastolic BP and demonstrated acceptable accuracy and reliability in Chinese patients in the emergency setting.

Conclusions. The Omron HEM 650 wrist device can be recommended for use in adult emergency patients. Further research is warranted for its use in pregnant women and critically ill patients.

Keywords: Blood pressure. Wrist device. Validation. Oscillometric. Sphygmomanometer.

Validación del esfigmomanómetro de muñeca Omron HEM-650 utilizando el protocolo de la Sociedad Británica de Hipertensión en pacientes atendidos en un servicio de urgencias de Hong Kong

Objetivos. Los dispositivos automáticos de muñeca para medir la presión arterial (PA) son más compactos y fáciles de usar, sobre todo cuando el acceso a la parte superior del brazo está restringido, por ejemplo, en situaciones de emergencia.

Métodos. Hemos probado el dispositivo de muñeca Omron HEM-650 utilizando los criterios de validación del protocolo de la Sociedad Británica de Hipertensión en un gran servicio de urgencias (ED) de Hong Kong. Se realizaron 3 mediciones en 85 pacientes con el dispositivo Omron HEM-650 y el esfigmomanómetro de mercurio. También se utilizó la medición automatizada convencional de PA con banda para el brazo mediante un dispositivo oscilométrico (Colin BP-88S NXT) para la comparación.

Resultados. El Omron HEM-650 logra una calificación de grado B para las presiones arteriales sistólica y diastólica y demostró una precisión y fiabilidad aceptables en pacientes chinos en el servicio de urgencias.

Conclusiones. El dispositivo de muñeca Omron HEM 650 se recomienda para su uso en pacientes adultos de urgencias. Se necesita más investigación para su uso en mujeres embarazadas y los pacientes en estado crítico.

Palabras clave: Presión arterial. Dispositivo de muñeca. Validación. Oscilométrico. Esfigmomanómetro.

Introduction

The Omron HEM 650 is a wrist oscillometric blood pressure (BP) monitor with a positioning sensor which has met published international standards^{1,2}. The wrist devices do not require appropriate sizes of cuff but manual and automated upper arm devices do, to obtain accurate blood pressure measurement^{3,4}. The obese adults can also be benefited from using the devices, especially in some well developed countries². However, it has never been validated in emergency settings, particularly in a Chinese population. The aim of this study was to validate this device in a university hospital emergency department in Hong Kong.

Method

The study was a validation study of the Omron HEM 650 device carried out from November 2010 to February 2011 in the ED of a university teaching hospital in Hong Kong with an annual census of 150 000. The Omron HEM 650 device is a fully automated, oscillometric wrist blood pressure monitor with advanced positioning sensor. It measures blood pressure range from 0 to 299 mmHg and pulse range from 40 to 180 beats per minute. The advanced positioning sensor of the device detects the level of the heart and only allows measurements to be taken once the position is confirmed. When the sensor alarm emitted signals telling that the wrist was too far away from the heart, the pa-

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Table 1. Distribution of frequencies of the variables related to the aggressor

Comparison		Blood pressure (Mean±SD)	Device-observer (Diff ± SD)	Differences < 5 mmHg %	Differences < 10 mmHg %	Differences < 15 mmHg %	Grade
SBP	Manual	137 (33)	-0.8 (8.0)	74	93	95	B
	Omron (wrist)	136 (34)					
DBP	Manual	83 (17)	0.5 (6.3)	69	92	97	B
	Omron (wrist)	84 (19)					
SBP	Manual	137 (33)	6.1 (11.0)	45	71	81	D
	Colin* (upper arm)	145 (34)					
DBP	Manual	83 (17)	-0.3 (6.40)	67	88	97	B
	Colin* (upper arm)	82 (18)					

*Only two readings per patient was taken for DINAMAP device compared to the three readings for Omron HEM 650 device.

tient changed his/her wrist position according until the position was correct.

We used the British Hypertension Society (BHS) protocol which has been widely used for the validation of BP measuring devices⁵. Grade A (best) to D (worse) represent the cumulative percentage of readings falling within 5, 10 and 15 mmHg of the mercury standard. Patients who were pregnant, younger than 18 or older than 80 years, suffering from upper arm or wrist injuries, or those requiring resuscitation were excluded. The gold standard for BP measurement was manual measurements by our researcher (WYL) using a mercury sphygmomanometer (Baumanometer® Desk Model). Conventional automated BP with arm cuff was also measured twice using an oscillometric (Colin BP-88S NXT) device as part of the routine care. The Omron device was used to obtain three BP readings, and three readings were taken with the mercury sphygmomanometer. Values were independently measured between the different devices. All results were expressed in mmHg by convention.

All data was analyzed by using IBM SPSS version 19.0 for Windows. Pearson correlation coefficients were assessed for comparison between blood pressure by the wrist device and the mercury sphygmomanometer as well as that between the conventional arm cuff device and the mercury sphygmomanometer. The Bland-Altman plots were made by MedCalc Version 10.2.0.0 of Frank Schoonjans. Simple linear regression techniques were used to evaluate the blood pressure measurements. Ethics approval was granted by the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee,

Results

The selection criteria for the BHS protocol were fulfilled. 85 patients were recruited, with at least 13 patients recruited in five systolic BP and diastolic BP categories (<100/60 mmHg to >180/110 mmHg). All participants were Chinese and ranged from 18 to 78 years old. There were 39 (46%) males and the mean wrist circumference was 15.2 ± 1.4 cm (range 13.5-18 cm). The systolic BP ranged from 90-198 mmHg, and the diastolic BP from 50-114 mmHg.

The Pearson correlation between the Omron device and the mercury sphygmomanometer was high for both systolic ($r=0.97$, $P<0.001$) and diastolic ($r=0.94$, $P<0.001$) BP. The device qualified for a B rating under the BHS guidelines (Table 1). Bland-Altman plots (Figure 1a and b) revealed a small linear association between the differences and the mean for diastolic BP ($r=0.32$, $P<0.001$) but failed to give a good estimate for systolic BP ($r=0.45$, $P=0.473$). The Omron HEM 650 tended to underestimate the diastolic BP in low BP ranges, and overestimate the diastolic BP in high BP ranges.

For the arm cuff device, the correlation was also high for both systolic ($r=0.95$, $P<0.001$) and diastolic ($r=0.93$, $P<0.001$) BP, but this only qualified as a grade D for systolic BP and grade B for diastolic BP according to the BHS guidelines (Table 1).

Discussion

Despite many researchers' claims that wrist blood pressure devices might take inaccurate measurements⁶⁻⁸, we found the Omron HEM 650 wrist BP device was qualified and appropriate for use in the ED.

Some practical issues may limit the applicability of the Omron HEM 650 device for patients with critical conditions. Since it is necessary for the device to be at the same level as the heart⁹, the sensor emits a signal when either the position is not correct or that it is too far away from the heart, and the patient has to adjust the wrist position accordingly. This is clearly impractical if the patient is unable to cooperate.

The study has several limitations, particularly including modifications made to the BHS protocol due to administrative and logistical constraints. In our study, only one observer (instead of two) was used to collect data, and only three mercury sphygmomanometer measurements (instead of four) were obtained. Other limitations include the small sample size and the exclusion of critically ill patients as explained above.

Conclusion

In this study, we have demonstrated that the Omron HEM 650 wrist device was reliable and can be re-

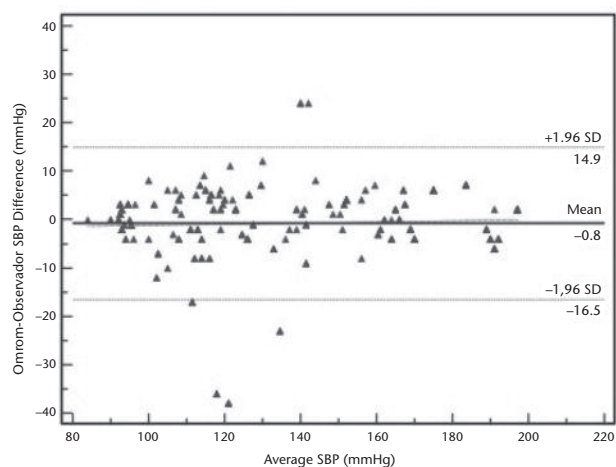


Figure 1. Bland-Altman plot of the difference between the measurements by the Omron HEM 650 device and the mercury sphygmomanometer (device – observer) against the mean of the measurements for systolic BP.

commended for adult emergency patients. Further validation of this and similar devices should be done in specific groups like pregnant women and critically ill patients.

Conflict of interests

The authors declare no conflict of interest related to this article.

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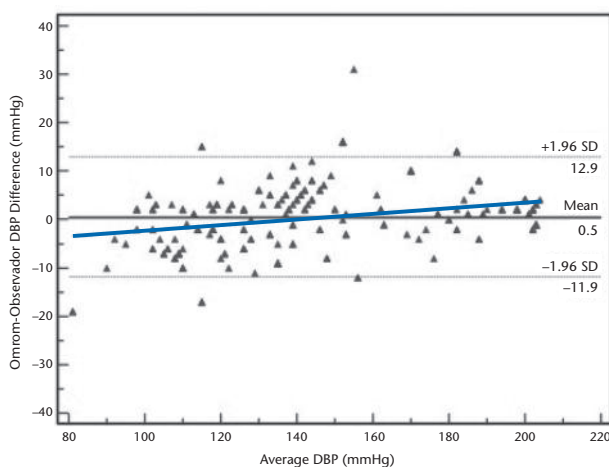


Figure 2. The blue central line represents the mean difference; the upper and lower brown dotted lines represent the 95% limits of agreement (mean \pm 1.96 SD); the pink dotted line is the regression line.

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