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Title: OSCAR 2 Blood Pressure Monitor graded A for both Systolic and Diastolic Blood Pressure when assessed according to the British Hypertension Society protocol

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Body: As mercury sphygmomanometers are phased out there is an increasing need for accurate alternatives which have been validated against well recognised criteria. The OSCAR 2 is a new small and light weight ambulatory blood pressure monitor designed for clinic and home use. We undertook an assessment of the OSCAR 2 according to the British Hypertension Society (BHS) protocol. Having passed the initial phases of the protocol, relating to before and after use calibration and a field assessment, a static device validation was undertaken by three observers who, after a period of appropriate training, achieved a high level of agreement in paired measurement of both systolic and diastolic blood pressure. Blood pressure measurements undertaken by the trained observers were compared to those taken by a third observer using the OSCAR 2. To ensure that 85 subjects stratified for both systolic and diastolic blood pressure were included, a total of 114 adults were studied. 56 subjects were included in both analyses. The subjects had the following characteristics: male sex 47.6%, mean age 54.3 (range 18 - 88) years, mean arm circumference 29.2 (range 21 - 49) cm. There was very close agreement between the trained observers and the OSCAR 2, 0 mmHg for systolic and -1 mmHg for diastolic blood pressure. All readings taken by the trained observers were within 5 mmHg. As > 60% of the OSCAR 2 readings were within 5 mmHg, > 85% were within 10 mmHg and > 95% were within 15 mmHg, the final grade for the static device validation as defined by the BHS

protocol was A for both SBP and DBP. As a result the OSCAR 2 can be recommended for clinical use in adults. The OSCAR 2 is the first instrument to be receive an A grading for both systolic and diastolic blood pressure using the BHS protocol and to have achieved a pass under the international protocol.

Grading criteria for OSCAR 2 - static validation

	Grade	Differences (mmHg)			Mean BP	Mean difference
		≤5	≤10	≤15	mmHg ± SD	mmHg ± SD
Observer 1						
SBP	B	62	84	96	131 ± 29	1 ± 7
DBP	A	70	92	98	83 ± 19	-1 ± 6
Observer 2						
SBP	A	62	87	95	132 ± 29	0 ± 7
DBP	A	67	91	98	83 ± 19	-1 ± 6
Final Grade						
SBP	A	62	87	95	132 ± 29	0 ± 7
DBP	A	70	92	98	83 ± 19	-1 ± 6

Differences are between standard and OSCAR 2

Disclosure:

I HAVE FINANCIAL INTEREST/ARRANGEMENT OR AFFILIATION WITH ONE OR MORE ORGANIZATIONS THAT COULD BE PERCEIVED AS REAL OR APPARENT CONFLICT OF INTEREST IN THE CONTEXT OF THE SUBJECT OF THIS PRESENTATION.

Affiliation/Financial Interest

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Consultant

Speakers' Bureau

Major Stock Shareholder

Other Financial or Material Support

Name of Organization

SunTech Medical, Inc

Signature of Presenting Author:

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Validation of the OSCAR 2 oscillometric 24-hour ambulatory blood pressure monitor according to the International Protocol for the validation of blood pressure measuring devices

Stephen C. Jones¹, Mary Bilous¹, Sue Winship¹, Paul Finn²
and James Goodwin²

Objectives The accuracy of blood pressure measuring devices is of prime importance and should be validated before devices are used clinically. We carried out an independent evaluation of the OSCAR 2 oscillometric ambulatory blood pressure monitor (SunTech Medical model 222) according to the European Society of Hypertension International Protocol.

Methods Adult subjects were recruited from patients and staff at The James Cook University Hospital, Middlesbrough, UK. Nine sequential same-arm blood pressure measurements were taken alternating between simultaneous readings by two independent, trained observers using mercury sphygmomanometers and the device operated by a third observer. In phase one, 15 subjects participated (five in each of the low, medium and high blood pressure ranges) with 18 subjects participating in phase two. Data from 33 subjects (11 in each of the three blood pressure ranges) were analysed for systolic (19 male, 14 female, mean age 56.0 years) and for diastolic (17 male, 16 female, mean age 51.1 years) blood pressure.

Results The OSCAR 2 passed the first phase of the validation process. In phase 2.1, the OSCAR 2 monitor had 71 readings within 5 mmHg, 86 within 10 mmHg and 94 within 15 mmHg for systolic blood pressure (SBP) and 72

readings within 5 mmHg, 88 within 10 mmHg and 96 within 15 mmHg for diastolic blood pressure (DBP). Mean (\pm SD) differences between observers and device were 0.9 ± 2.3 mmHg for SBP and -0.5 ± 2.3 mmHg for DBP. In phase 2, 24 subjects had at least two of the differences within 5 mmHg and three subjects had no differences within 5 mmHg for SBP while for DBP 25 subjects had at least two of the differences within 5 mmHg and two subjects had no differences within 5 mmHg.

Conclusions The OSCAR 2 passes all requirements for validation by the International Protocol and can be recommended for clinical use in an adult population. *Blood Press Monit* 9:219–223 © 2004 Lippincott Williams & Wilkins.

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Keywords: Blood pressure, oscillometric, European Society of Hypertension, International Protocol for the validation of blood pressure

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Introduction

As mercury sphygmomanometers are phased out the need for alternatives to accurately record blood pressure is rising. We tested the OSCAR 2 oscillometric 24-h ambulatory blood pressure (ABP) monitor—a small lightweight upper arm device designed for office and home use—according to the International Protocol for the validation of blood pressure measuring devices. This method represents a very rigorous assessment of a blood pressure measuring device and was described by O'Brien *et al.*, on behalf of the European Society of Hypertension [1]. The International Protocol is itself a modification of the protocol described by the British Hypertension Society (BHS) [2]. The European Society for Hypertension defined the International Protocol recognising that

other protocols such as that defined by the British Hypertension Society are costly and difficult to undertake. Particular emphasis is placed on the need to maintain the integrity of the previous protocols whilst simplifying the process and reducing the numbers of subjects that are studied. To our knowledge there are no previous reports of a validation of the OSCAR 2 monitor using the International Protocol.

Methods

Subjects

The subjects of this study were recruited from the adult patients and staff of a large teaching hospital in the UK. Ethical approval was obtained from the local ethical committee before the study began and informed consent

was obtained from all subjects who took part. Only adult subjects were approached to take part in the study. The following subjects were excluded: (1) subjects with atrial fibrillation or sustained arrhythmia and (2) those in whom it was not possible to identify clearly all Korotkoff sounds during auscultation.

Blood pressure measurement technique

Blood pressure was measured according to the method described in the International Protocol. Briefly two mercury sphygmomanometers (Baumanometer, WA Baum Co Inc, New York, USA) were calibrated and represented the reference standard. All components of the manometers were carefully checked for serviceability. Blood pressure was checked after at least 10 min rest, with the arm supported at heart level using an appropriately sized cuff and bladder, which would encircle at least 80% of the arm circumference.

Observer training

Three observers were trained according to the standards defined in the International Protocol using the training CD-ROM produced by the BHS. To monitor and minimise inter-observer differences, three 'drift' or interim checks were carried out at the beginning, middle and towards the end of the validation exercise. These checks involved 10 randomly sampled blood pressure readings on each of five patients who were not involved in the main study, giving 50 measurements in total, as detailed in the BHS protocol [2]. Initial training and subsequent drift checks were carried out under the supervision of an expert observer and were satisfactory at all stages of the study. The additional drift checks are not a requirement of the International Protocol but were carried out to ensure that the quality of data obtained was of a consistently high standard.

Familiarisation session

Having successfully completed initial training the observers went through a process of familiarisation using the OSCAR 2 device. Three machines were obtained from the manufacturer, who gave a written declaration that they were standard production models. The familiarisation session enabled the observers to gain experience in using the OSCAR 2 device and to confirm that all three devices were performing well and without idiosyncratic problems. Each observer used the monitor to carry out a minimum of two 24-h ambulatory data collections as part of the familiarisation process. No problems were identified at this stage and one of the machines was selected at random for the formal validation exercise.

Subject selection

Subjects were selected according to the criteria defined in the International Protocol. Subjects were stratified according to their blood pressure described in Table 1 below. Entry blood pressure was defined in three groups:

low, medium and high for both systolic (SBP) and diastolic blood pressure (DBP). Of the 33 subjects required for the systolic and diastolic validation, 15 participated in phase one and 18 in phase two, with 11 out of the 33 subjects falling in each of the three blood pressure bands (as in Table 1). Subjects were not stratified according to arm circumference or age.

Observer measurement

The two observers, under supervision, made measurements simultaneously. Observers were blinded from each other's readings and those recorded by the device. Readings were made using simultaneous same-arm measurement, each observer using a dual head binaural stethoscope and a calibrated mercury sphygmomanometer. Data were recorded independently, to the nearest 2 mmHg and were checked by the supervisor who also operated the device. Observer readings that were more than 4 mmHg apart were repeated until agreement was reached, as required by the International Protocol. At least 30 seconds but no more than 60 seconds was allowed between readings.

Procedure

Having given consent each subject was introduced to the observers. Arm circumference, gender and age were recorded plus the date and time of the session. Care was taken to ensure that the environmental conditions were constant, including the exclusion of extraneous noise. The subject was allowed to relax, in the seated position for a minimum of 10 min in order to reduce arousal levels or any 'white-coat' effect. Subjects with a history of atrial fibrillation or who were found to have an

Table 1 Blood pressure ranges for entry blood pressure

	Systolic blood pressure	Diastolic blood pressure
Low	90–129	40–79
Medium	130–160	80–100
High	160–180	100–130

Systolic and diastolic blood pressure stratification for patients entering the International Protocol.

Table 2 Summary of subject clinical characteristics

	Systolic blood pressure (n=33)	Diastolic blood pressure (n=33)
Sex (M/F)	19/14	17/16
Age (years)		
Mean \pm SD	56.0 \pm 12.1	51.1 \pm 12.9
Range	31–86	22–78
Arm circumference (cm)		
Mean \pm SD	30.9 \pm 4.6	30.4
Range	25.0–49.0	21.0–49.0

Clinical characteristics of subjects taking part in the International Protocol validation of the OSCAR 2 oscillometric 24-h ambulatory blood pressure monitor.

irregular pulse were excluded before blood pressure measurements were undertaken. Nine sequential same-arm readings were taken using standard mercury sphygmomanometers and the device, alternating between the two. The mean of the first readings, taken by the observers using sphygmomanometers, was used as the entry blood pressure. This classified the subject into the low, medium or high range separately for SBP and DBP (Table 1). The first readings taken by the observers and device were not used in the validation. Thus seven readings, four manual readings taken by blinded observers and three readings taken by the device and recorded by the supervisor, were used in the analysis.

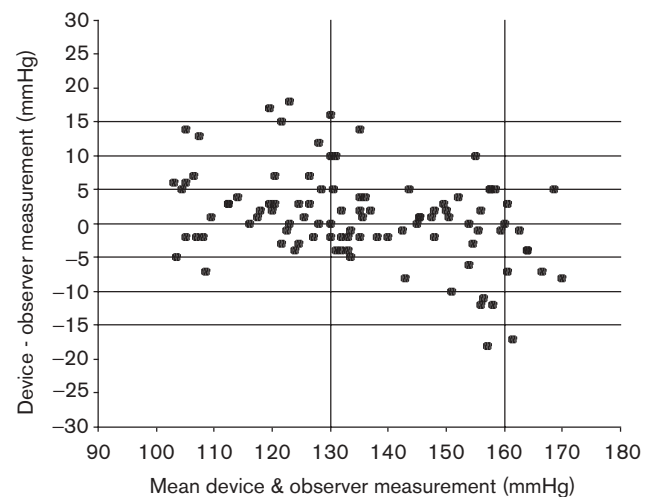
Analysis

Data were analysed and presented according to the method described in the International Protocol. For phase one, subject recruitment was stopped as soon as there were five subjects in each of the three blood pressure ranges (high, medium and low; see Table 1). The data were analysed to determine whether the instrument met the requirements to proceed to phase two. The criteria required to pass this initial phase of the assessment are described in Table 3. Briefly the differences between test readings taken by the device and sphygmomanometer standard readings are classified according to whether they lie within 5 mmHg, 10 mmHg, and 15 mmHg. The grading is based in the number of differences falling into these categories. Phase two of the analysis was then carried out. Phase 2.1 of the analysis compared all of the readings obtained by observers and the device. Phase 2.2 of the analysis considered the readings obtained for individual subjects. To pass the latter part of the analysis no more than three subjects can have all of the blood pressures readings recorded by the device more than 5 mmHg different from that recorded by the observers.

Results

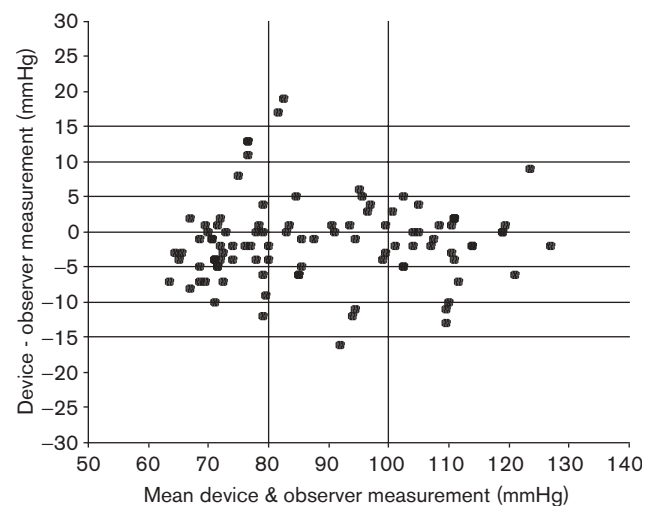
A total of 104 subjects were approached, gave informed consent and underwent at least one initial blood pressure measurement. Forty-six subjects were excluded, as their entry blood pressures did not fit within the ranges needed. Six subjects were excluded because of atrial fibrillation. Three subjects were excluded as a result of difficulties in hearing Korotkoff sounds, and one subject was excluded as the systolic blood pressure readings recorded by the observers varied by more than 20 mmHg according to the protocol variation described by Cuckson *et al.*, [3]. Thus a total of 48 subjects were included in the data collection, their blood pressure ranging from 96 to 180 mmHg for SBP and 63 to 125 mmHg for DBP, respectively. Data on 18 subjects were included in both the systolic and diastolic analyses. The clinical characteristics of the two groups are described in Table 2.

Fig. 1



Scatter plot of systolic blood pressure readings in all subjects ($n=99$). Plot of the mean of device and observer readings on the X-axis against device minus observer readings on the Y-axis for systolic blood pressure.

Fig. 2



Scatter plot of diastolic blood pressure readings in all subjects ($n=99$). Plot of the mean of device and observer readings on the X-axis against device minus observer readings on the Y-axis for diastolic blood pressure.

Observer-device agreement

The blood pressure data are expressed graphically in Figures 1 and 2 below in which the mean of readings taken by the device and the observers is plotted against the difference between the observers and the device. The mean differences between observers and device

Table 3 Device validation phase 1

		Within 5 mmHg	Within 10 mmHg	Within 15 mmHg
Required	At least one of	25	35	40
Achieved	SBP	33	40	44
	DBP	34	41	44

Recommendation: instrument meets requirements to proceed to phase two

Table 4 Device validation phase 2

		Within 5 mmHg	Within 10 mmHg	Within 15 mmHg
Required	Two of	65	80	95
	All of	60	75	90
Achieved	SBP	71	86	94
	DBP	72	88	96

Data (99 comparisons) are analysed to compare the number of comparisons falling within the 5, 10 and 15 mmHg error bands. To pass there must be a minimum of 60, 70 and 90 comparisons falling within 5, 10 and 15 mmHg, respectively. In addition to pass there must be a minimum of either 65 comparisons within 5 mmHg and 80 comparisons within 10 mmHg, or 65 comparisons within 5 mmHg and 95 comparisons within 15 mmHg, or 80 comparisons within 10 mmHg and 95 comparisons within 15 mmHg.

Recommendations for phase 2.1: SBP: Pass DBP: Pass.

Table 5 Device validation phase 2.2

		2/3 within 5 mmHg	0/3 within 5 mmHg
Required		At least 22	At most 3
Achieved	SBP	24	3
	DBP	25	2

Analysis by subject to determine the number of comparisons per subject falling within 5 mmHg. At least 22 of the 33 subjects must have at least two of their three comparisons lying within 5 mmHg. At most three of the 33 subjects can have all of their comparisons over 5 mmHg apart.

Recommendations for phase 2.2: SBP: Pass DBP: Pass.

were 0.9 ± 2.3 mmHg and -0.5 ± 2.2 mmHg for systolic and diastolic blood pressure respectively.

The results of the phase one analysis (15 subjects) are shown in Table 3. For both systolic and diastolic blood pressure the OSCAR 2 passed the first phase of the International Protocol as more than 25, 35 and 40 of the 45 comparisons fell within 5, 10 and 15 mmHg respectively. The data for phase 2.1 are shown in Table 4. For systolic blood pressure the measurements within the three categories were 71, 86 and 94 respectively and for diastolic blood pressure, 72, 88 and 96. Thus both are well within the criteria defined in the protocol. In addition for both systolic and diastolic blood pressure more than 65 comparisons were within 5 mmHg and more than 80 within 10 mmHg fulfilling the second part of phase 2.1 of the analysis.

Data were then analysed with respect to the phase 2.2 of the protocol. The data are presented in Table 5. This final stage of the validation analyses the data per subject.

The OSCAR 2 passed this stage of the International Protocol for both diastolic and systolic blood pressure as at least 22 subjects were within 5 mmHg for two out of the three comparisons. In addition no more than three subjects in each group had all of their readings more than 5 mmHg apart. Thus for systolic blood pressure at least two of the three comparisons were within 5 mmHg for 24 individuals. Only three individuals had all three comparisons more than 5 mmHg apart. For diastolic blood pressure at least two of the three comparisons were within 5 mmHg for 25 individuals and all three comparisons were more than 5 mmHg apart in only two subjects. Thus the OSCAR 2 passed phases 1, 2.1 and 2.2 of the International Protocol for the validation of blood pressure measuring devices.

Discussion

The device was validated across a range of blood pressures from low to severe hypertension. The main difficulty encountered in this study was in identifying patients with low systolic and high diastolic blood pressures who were well enough and able to consent to take part in the study. To complete the analysis of diastolic blood pressures two subjects under the age of 30 with high diastolic blood pressure were included. Although the International Protocol suggests that patients should be aged over 30 we do not believe that the inclusion of the two patients in their twenties is of clinical or physiological significance. Each of these patients was hypertensive, which is the inclusion principle on which the age criterion of 30 appears to be based. One additional subject was excluded as a result of very variable blood pressure values, which varied by more than 20 mmHg between readings, according to the modification described by Cuckson *et al.*, [3].

Subjects in whom high values were recorded in the clinical setting were often found to have much lower blood pressures when studied in the optimal conditions defined by the International Protocol. This explains why a large number of subjects were recruited to complete the diastolic and systolic arms of the International Protocol. This discrepancy between screening measurements in the clinical setting emphasises the need not only for devices that are accurate and precise but also the need to adhere to guidelines for the process of blood pressure measurement in the clinical setting.

The OSCAR 2 oscillometric 24-h ambulatory blood pressure monitor passed the International Protocol for the validation of blood pressure measuring devices for both systolic and diastolic blood pressure. To our knowledge this is the first report of the successful validation of an ambulatory blood pressure device using the International Protocol. As a result the OSCAR 2 can be recommended for use in the adult population.

Acknowledgements

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Blood Pressure Monitoring. 9(4):219-223, August 2004.

Jones, Stephen C. 1; Bilous, Mary 1; Winship, Sue 1; Finn, Paul 2; Goodwin, James 2

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