An extended validation of the ScottCare 320 ambulatory blood pressure monitor: recommendations for clinical application

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Objectives **The purpose of this study was to validate the ScottCare 320 ambulatory blood pressure monitor (ABPM) using both group-level and individual-level validation procedures. The group-level validation followed a modified protocol of the European Hypertension Society's validation protocol. The individual-level validation was conducted to ensure that the monitor is valid from both a research and clinical perspective.**

Methods **Participants ($n=41$) had three simultaneous blood pressure (BP) measurements taken by a trained listener using a mercury column sphygmomanometer and the ScottCare ABPM, which was used to validate the monitor at the group-level and the first half of the individual-level validation (i.e. the difference between the ABPM and auscultatory means for each participant <5 mmHg). The second half of the individual-level validation occurred by examining participants' responses on diary questionnaires taken immediately following the BP measurements (i.e. can extreme or deviant BP values be explained by situational factors).**

Results **At the group level, the ABPM passed the criteria laid out by the European Hypertension Society. At the individual level, the difference between the auscultatory and ABPM means was less than 5 mmHg for both systolic and diastolic BP for 36 participants on the initial attempt, and the remaining five on the second attempt. Furthermore, the deviant values were largely attributed to explainable causes, mainly movement.**

Conclusion **The ScottCare ABPM is a highly accurate monitor that can be considered valid at both the group and the individual level, and thus appropriate for both clinical and research use.** ***Blood Press Monit*** **18:151–155 © 2013 Wolters Kluwer Health | Lippincott Williams & Wilkins.**

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Introduction

The first goal of this paper was to validate the ScottCare ABP 320 (Cleveland, OH, USA; previously manufactured as the Mobil-O-Graph; IEM GbmH, Stolberg, Germany [1]) oscillometric ambulatory blood pressure monitor (ABPM), using a modified validation procedure established by the European Society of Hypertension (ESH) [2]. The second goal was to extend the group-level validation procedures for ABPMs by performing individual-level validation in two ways.

First, for the ABPM to be valid, we required that it have an error of no more than 5 mmHg systolic blood pressure (SBP) or diastolic blood pressure (DBP) on a person-by-person basis. Validation criteria, such as the British Hypertension Society's [3] or ESH's [2], somewhat problematically require that the mean disagreement between the ABP and criterion value (usually auscultatory measurement) is no more than 5 mmHg across subjects, and that the mean, across persons, has no greater than a 5 mmHg SD. These group-level validation protocols thus allow individual values (i.e. person mean values) to diverge by up to 10 mmHg for a quarter of patients [4]. Although this amount of error may be acceptable from a research perspective, from a clinical perspective 10 mmHg can be the difference between a diagnosis of hypertension and prescribed medical treatment or not. Therefore, we take the more conservative view that individual-level validation must occur by assuring that the mean disagreement between the ABP and auscultatory measurements are no more than 5 mmHg, systolic or diastolic, for each patient.

Second, we extended our analysis to include whether blood pressure (BP) measurements taken in the field are valid, focusing particularly on what we term 'deviant' values (i.e. a value that is 40 + % higher/lower than the awake mean, excluding the deviant value). The basis for this extended individual-level validation is that ABPM validation protocols are better in assuring reliability for research purposes that focus on group means (where measurement error is more tolerated) than for clinical diagnostic purposes where clinicians tend to focus on the individual patient (where measurement error could lead

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to misdiagnosis). In other words, although the deviant values are considered tolerable 'noise' to researchers and may 'average out' across large numbers of individuals, to the physician it may hold clinical significance. For example, if such a very high measurement occurred while the patient was exercising, it would be of less concern than if the patient reported he or she was relaxing when the BP was taken. (A low deviant value in this example would also be of concern and we examine the data for both low and high deviant values; however, we expect most deviant values to be on the high end.) To address this, in the current study patients gave contextual information using a provided electronic diary immediately following each BP measurement.

Methods

Participants

A community sample of 41 participants was recruited (27 women, 14 men) through advertisements and paid $75 for participation. Participants self-identified as predominantly non-Hispanic Caucasian (92.3%) and were aged 30–77 ($M = 51.54$, $SD = 13.62$). The mean auscultatory BP was 116.91 mmHg, $SD = 13.89$ (SBP); and 74.18 mmHg, $SD = 9.38$ (DBP). Thirteen participants qualified as prehypertensive or hypertensive. Five participants were excluded from the electronic diary validation analyses because of equipment malfunction with the ABPM ($n = 2$) or the electronic diary ($n = 3$).

Procedure

All procedures were approved by, and complied with, The Pennsylvania State University's Institutional Review Board. A modified version of the ESH protocol was used to validate the monitor. Simultaneous BP measurements were taken by a trained listener using a mercury column sphygmomanometer (Baumanometer; W.A. Baum Co. Inc., Copiague, New York, USA), and the ScottCare ABPM. Three simultaneous readings were taken using a t-connector to link the sphygmomanometer and the ABPM and the averages for each device, for each person, were computed when the measurements were completed. The mean of the SBP and DBP taken using the ABPM were subtracted from the corresponding means of the auscultatory measurements and constituted the 'errors'.

Our first level of individual-level validation was accomplished by 'switching out' an ABPM if the mean error, for a given participant, was greater than 5 mmHg for SBP or DBP, and redoing the validation procedures using a second monitor. We allowed a maximum of three attempts at which point the participant would be dismissed and the monitor would be deemed invalid (no more than two attempts were ever required).

Our second level of individual-level validation took place in the field as participants continued to wear the ABPM for 24 h. The device took measurements at 20-min intervals during the participant's awake hours (by self-report) and at 30 min during sleep. Immediately following each BP measurement during the awake period, participants used an electronic diary which recorded situational information that might affect the BP.

Materials

The provided electronic diary (Palm *Z22*; Palm Inc., Sunnyvale, California, USA) recorded the following information: (a) Activity level as either none (sitting down), mild (standing, moving around), moderate (walking, climbing stairs), or heavy (running, breathless). (b) General mood, indicating how sleepy versus active/alert, depressed versus excited, and relaxed versus stressed participants felt at that moment (each measured on a 7-point bipolar scale). (c) How angry they were at that moment (1 = not at all, 7 = very much).

Results

Group-level validation

Across participants, the ScottCare ABPM proved to be highly accurate. ABPM systolic ($M = 117.3$ mmHg, $SD = 14.8$) and diastolic ($M = 74.3$ mmHg, $SD = 10.1$), and auscultatory systolic ($M = 117.2$ mmHg, $SD = 15.6$) and diastolic ($M = 74.7$ mmHg, $SD = 9.8$), indicated only very small differences between the two in both systolic and diastolic means (0.1 and 0.3 mmHg, respectively) and SDs (3.0 and 2.5, respectively).

We then examined whether the observed values obtained would classify the monitor as validated according to the ESH. The criteria state that the difference scores for each reading between the ABPM and the auscultatory method must fall within certain ranges (see Table 2 for specific percentages). Our sample yielded 123 values (three readings for each of 41 participants). As Table 1 demonstrates, the ScottCare ABPM fell well within range of each of these percentages. The ESH also requires that two-thirds of the participants must have at least two of their three ABPM–auscultatory differences fall within 5 mmHg, with no more than 1 out of 11 with all three errors greater than 5 mmHg. For SBP, 92.7% of participants had

Table 1 Comparison of European Society of Hypertension ranges with observed percentages

	Within 5 mmHg (%)	Within 10 mmHg (%)	Within 15 mmHg (%)	Validated
ESH required				
Two of	66	81	96	
All of	61	76	91	
Achieved				
SBP	82.1	96.8	100	Pass
DBP	88.6	99.2	100	Pass

Because of our larger sample size than required for ESH validation, we converted the count data reported from the original paper into percentages. Regarding the ESH requirements, 'two of' refers to the need for two of the three within 5, within 10, or within 15 mmHg (%) ranges to be observed; 'all of' refers to the need for all of the three within 5, within 10, and within 15 mmHg% to be observed.
ESH, European Society of Hypertension.

two comparisons falling within 5 mmHg, with no participants having all three comparisons more than 5 mmHg apart. For DBP, 97.6% of participants had two comparisons falling within 5 mmHg, with no participants having all three comparisons more than 5 mmHg apart. Thus, the ScottCare ABPM can be considered validated according to the criteria laid out by the ESH.

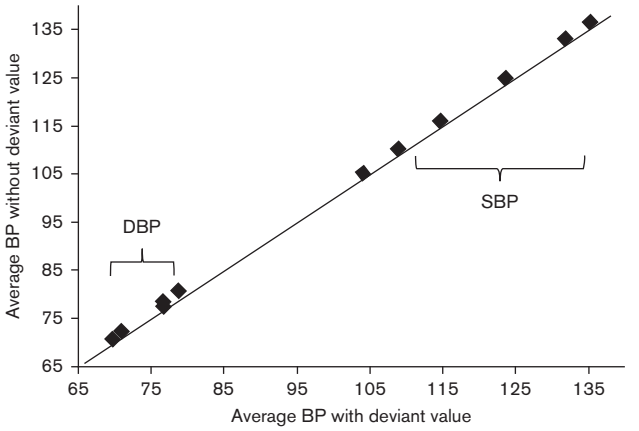
Individual-level validation

The ScottCare monitor also was considered valid based on our first level of individual-level validation. A monitor had to be switched out for only five participants with values being off for SBP for three participants (values ranging from 5.7 to 8.0) and DBP for two participants (values ranging from 5.3 to 6.0). In each case the monitor was successfully validated for each individual on the second attempt (i.e. the difference between the BP and auscultatory means were <5 mmHg for all participants).

The second level of individual-level validation concerned the analysis of deviant values. A measurement was defined as a deviation if it was 40% or greater compared with the mean of that participant's awake measurements, exclusive of the value in question. Note that the selection of 40% is arbitrary. There is no gold standard for this, as the issue has never systematically been addressed. As Berardi *et al.* [5] note in their review of methods of detecting outliers for group-level analyses, extreme values are calculated according to varying rules (e.g. being 3 SDs from the mean; if BP changed by more than 25 mmHg from one reading to the next and heart rate remained constant), resulting in large ranges in the number of outliers detected. For the present purposes, we suggest that the determination of a deviant value is not a theoretical or analytical question, but a clinical one as it is the clinician who may be concerned over a deviant value. It should be noted that the patient's average ABP did not change markedly because of the deviant value. The difference in BP from the whole data series to the series excluding the deviant value ranged from 0.6 to 1.8 (Fig. 1).

Of the 36 participants with usable data, nine (25%) had at least one value that satisfied the criteria for a deviation. Deviant values constituted anywhere from 2 to 5% of an individual's total ABP measurements, and 0.7% of all measurements taken across participants. Table 2 shows the participant's average BP exclusive of the deviant value, the BP values of the deviation and the values that immediately preceded and followed the deviation, the corresponding self-reported situational factors that were reported simultaneously, and the overall means for the self-reported situational factors. Two participants did not have diary data, but subsequent diary and ABPM data indicated that they were likely to be physically active during this time period. Of the remaining seven participants, six of them reported being at least mildly active. Furthermore, all seven participants reported being at least moderately alert and excited (i.e. values >4). Six of seven participants responded that they were experiencing at least some level of stress (i.e. a value >1); however, only one person reported any anger. Furthermore, for all participants, the diary data accompanying the deviant value was generally higher than the mean for that particular value (suggesting moments of physical and/or emotional activation). Overall, movement is a likely explanation for all but two of the participants (6021 and 6040), suggesting that the monitor is valid in its measurement of deviant values.

Fig. 1



Average blood pressure (BP) with and without deviant values. DBP, diastolic blood pressure; SBP, systolic blood pressure.

Discussion

The ScottCare ABP320 was found to be valid both at the group and individual level. At the group level, the difference between the ABP and auscultatory measurements was 0.1 and 0.3 mmHg SBP and DBP, with all the values falling well within range of the prescribed cut-offs of the ESH. At the individual level, the differences between the ABP and auscultatory values were less than 5 mmHg for all participants (with only five participants requiring a second validation attempt to achieve this required level). Finally, the deviant values analysis indicated that it was reasonable to infer that the very high measurement was indeed due to a higher level of activity for seven of nine participants. For the other two participants, the cause of the deviations could not be determined from the diary entries, yet the diary values accompanying the deviant values were higher than the mean values suggesting some (perhaps partially unmeasured) situational factor was likely to be the cause of the deviant value.

It is important to note that although we recruited a community sample, the majority of participants self-identified as non-Hispanic Caucasian. With that said, we

Table 2 Ambulatory blood pressure and electronic diary data for outlier values

	ABP		Diary data				
ID	Time	SBP/DBP (% from mean)	Activity	Alert	Excited	Stressed	Angry
6009	Pre-	114/79	Moderate	5	5	2	1
	Outlier	**148 (42.3)/101 (44.9)**	**Heavy**	6	6	3	1
	Post-	125/71	Mild	6	6	3	1
	Average	104.0/69.7	–	5.00	5.03	1.51	1.00
6010	Pre-	112/86	None	5	4	2	1
	Outlier	140 (18.0)/**112 (46.2)**	**Mild**	4	4	2	1
	Post-	129/71	Mild	4	5	2	1
	Average	118.6/76.6	–	4.78	4.85	1.85	1.04
6012	Pre-	117/77	No diary data. Participant was likely getting ready for bed as self-report indicates participant laid down shortly after BP reading				
	Outlier	**192 (42.0)**/74 (– 4.1)					
	Post-	–					
	Average	135.2/77.2					
6019	Pre-	118/74	Moderate	4	6	4	3
	Outlier	**176 (53.4)/127 (78.9)**	**Moderate**	**6**	5	**5**	3
	[a]Post-	108/66	Mild	6	4	4	3
	Average	114.7/71.0	–	5.18	4.57	2.61	1.35
6021	Pre-	140/80	None	6	4	2	1
	Outlier	**184 (39.5)**/76 (3.8)	None	6	5	2	1
	Post-	143/81	Mild	6	4	2	1
	Average	131.9/73.2	–	5.33	4.58	1.58	1.17
6025	Pre-	168/67	None	7	7	2	1
	Outlier	**174 (40.8)**/67 (– 12.0)	**Moderate**	5	4	**4**	1
	Post-	132/91	None	5	5	3	1
	Average	123.6/76.1	–	4.67	4.89	1.64	1.03
6035	Pre-	121/91	No data, however, this value was followed by three movement errors suggesting that the participant was active				
	Outlier	133 (22.0)/**108 (40.4)**					
	Post-	–					
	Average	109.0/76.9					
6039	Pre-	139/53	None	7	4	1	1
	Outlier	178 (24.6)/**123 (56.1)**	**Mild**	7	4	1	1
	Post-	131/107	Mild	6	4	3	1
	Average	142.8/78.8	–	5.19	4.00	1.77	1.23
6040	Pre-	114/84	Mild	6	6	2	1
	Outlier	**154 (41.4)**/68 (– 0.1)	Mild	6	6	2	1
	Post-	115/77	Mild	6	6	2	1
	Average	108.9/68.1	–	4.88	4.92	1.69	1.08

ABP, ambulatory blood pressure; BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.
[a]Immediate measure after outlier was a movement error. Reported values are for the next time BP was recorded. Items in bold indicate the outlier value, percentage, or likely cause of outlier.

do not have reason to believe that the ScottCare monitor would be less accurate among individuals of varying racial or ethnic identities. Furthermore, we varied the ESH protocol such that only one listener took BP measurements, so as to reduce the time burden placed on participants due to the individual-level validation. It should be emphasized that we used a highly trained listener, and when compared with a second highly trained listener the readings taken by the two listeners were correspondent. About 25% of the sample was classified, according to the auscultatory readings, as prehypertensive or hypertensive. This relatively healthy sample thus limits confidence in generalizing to individuals with very high BP. Finally, although we assessed a range of factors that may explain a deviant value, additional factors, such as one's behaviors (e.g. ingesting caffeine), could have had explanatory power beyond what was reported. Likewise, although the assessment of activity levels was the best indicator of a deviant value, more fine-grained analyses of one's exercise patterns may be better able to explain deviant values. In sum, future research would benefit from exploring a wider array of factors that predict when, or for whom, a deviant value will occur.

On the basis of these results, we suggest that the optimal strategy for the clinician is the following: (a) To select a monitor that has passed one of the validated group-level validation protocols, such as ESH. (b) To ensure that the proper techniques to improve the quality of the measurements, including appropriate arm cuff size and adjustment when the cuff is being fit to the patient's arm, are used. (c) To validate each monitor using the first level of individual-level validation (i.e. ensuring that the ABPM and auscultatory measurements do not differ by more than 5 mmHg for both SBP and DBP). Given the relatively few number of patients on whom the monitor was not valid at the individual level on the initial try (in our study it was $<13\%$), and that this validation procedure is unlikely to add more than 10 min to the procedure, we suggest that having the most accurate monitor for a patient is worth the additional time and effort.

Finally, we recommend that when physicians are concerned with the patient's mean values (e.g. when making a hypertension diagnosis) they can ignore single-point outliers (that we found largely to reflect participant movement/activity). To be clear, by 'ignore' we mean that

the physician does not need to be concerned with adjusting the patient's mean BP due to the deviant value. Before 'ignoring' the value, we do recommend that the physician probe the patient about his or her activities when the deviant value occurred so as to rule out any possible indicators of risk or disease (e.g. the patient reports chest pain at the time of the outlier measurement). We acknowledge this may be seen as a controversial recommendation, but make it based on the following information: Only 25% of participants had a deviant measurement, of which no more than 5% of any participant's total number of measurements were classified as deviant. In most instances this deviant value was easily accounted for by patient activity level. Finally, and perhaps most importantly, as Fig. 1 shows, the patient's average BP with and without the outlier did not differ markedly. If the deviant value is not an isolated (single) reading, however, but rather one of several successive readings, the higher readings should be further evaluated by the clinician (i.e. not assumed to be movement related or other artifacts). Last, when such ambiguity exists, if the clinician feels that it is of sufficient concern, a second ambulatory monitoring can be undertaken. Similarly, the physician would not typically render a diagnosis of hypertension after one clinic visit by the patient, as the data rendered may not be reliable enough to support a strong diagnosis. A second ambulatory monitoring addresses the same issues, and can impart greater confidence in the measurements.

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Conflicts of interest

There are no conflicts of interest.

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