

Factors influencing validation of ambulatory blood pressure measuring devices

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With the introduction of 24 h ambulatory blood pressure monitoring into clinical practice a vast market for ambulatory blood pressure monitoring devices has been created. To satisfy this market manufacturers are producing an array of ambulatory blood pressure monitoring devices. There is no obligation on manufacturers to have such devices validated independently, even though two national protocols, one from the British Hypertension Society (BHS) and the other from the Association for the Advancement of Medical Instrumentation (AAMI), call for independent validation and state the means of doing so. However, many factors can influence the validation procedure. They include compliance to the protocol being employed; the accuracy of the standard; establishing precisely the model being validated; the influences of blood pressure level, age and exercise on device accuracy; the provisions necessary for special populations, such as pregnant women, the elderly and children; the influence of oscillometric versus Korotkoff sound detection and electrocardiographic gating on comparative measurements; the assessment of performance as distinct from accuracy; and the relevance of general factors, such as the algorithm being employed and computer compatibility. Forty-three ambulatory blood pressure monitoring devices have been marketed for ambulatory blood pressure measurement and of those only 18 have been validated according to either the BHS or the AAMI protocol. The influence of the factors listed above on the validation studies of those devices will be considered and the relevance of validation procedures to the clinical use of ambulatory blood pressure monitoring devices will be discussed.

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Introduction

When the technique of blood pressure measurement was introduced to clinical medicine in the early years of this century, the importance of accuracy and the limitations of the technique were well recognized [1]. However, the standards called for by the clinicians and scientists who introduced the technique were relaxed as the 20th century progressed. Now, once again, the methodology of blood pressure measurement both in clinical practice and in hypertension research is recognized to be a cause for concern [2]. The first serious approach to device validation must have been that of Halls Dally [3], who in 1926 called in the help of The National

Physics Laboratory to endorse the manufacturer's claim for accuracy of the new Baumanometer. Since the 1930s, various national bodies, such as the British Cardiac Society, the American Heart Association and the World Health Organization have been paying lip service to the importance of device accuracy but none of those organizations have stated how it was to be achieved [4]. Likewise, national standards institutions have expressed the relevance of device accuracy but do not usually have the authority to impose minimal standards of accuracy [4]. The importance of device accuracy has been voiced more strongly in recent years by individuals who are involved in hypertension research, which is evident from the growing number of publications on the subject [5].

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In 1986 the Association for the Advancement of Medical Instrumentation (AAMI) published a standard for automated blood pressure measuring devices which included a protocol for the evaluation of device accuracy [6] and this was succeeded in 1990 by the protocol of the British Hypertension Society (BHS) [7]. Those protocols, which differed in detail, had a common objective, namely the standardization of validation to establish minimum standards of accuracy and performance and to facilitate comparison of one device with another [8,9]. Both protocols have been revised recently [10–13].

Forty-three ambulatory blood pressure monitoring devices from 31 manufacturers have been marketed in recent years. Of them, only 18 have been validated according to the BHS or AAMI protocols, or both, in 22 reported studies [4]. In nine of the studies in which the AAMI protocol alone was used, the protocol was not adhered to and the results are therefore questionable. Of the 14 ambulatory blood pressure monitoring devices which have been evaluated according to the accuracy criteria of both protocols, nine fulfilled their requirements in that they achieved at least B/B grading for systolic and diastolic blood pressures and the mean difference between the ambulatory device and a mercury standard was less than 5 mmHg with a SD < 8 mmHg [4]. It is the purpose of the present review to examine the factors that can influence validation procedures.

Factors affecting validation studies

Which protocol to use

There are many features common to the BHS and AAMI protocols, although there are significant differences that have been discussed in an effort to reconcile the two protocols [14]. It has been recommended that the criteria for both protocols should be fulfilled [15] and the means of doing so have been delineated [14].

The importance of adhering strictly to the protocol that is being employed

The importance of not deviating from the protocol is illustrated by the nine studies [16–23] in which the Hawksley random-zero sphygmomanometer was substituted for the mercury sphygmomanometer recommended both in the AAMI [11] and in the BHS [13] protocol.

Three manufacturers have had their systems validated according to the first AAMI protocol [6]. The devices are the Accutracker, the Medilog and the Takeda (A & D) TM-2420. Nine validation studies have been performed on various models of those devices by reputable centres, but all nine studies failed to adhere strictly to the AAMI protocol recommendations [16–24]. The most serious protocol violation, which occurred in eight

studies, was substitution of the Hawksley random-zero sphygmomanometer for the mercury sphygmomanometer recommended in the protocol [16–23] (Table 1). This was done with the laudable intention of reducing observer bias but the Hawksley device has subsequently been shown to underestimate blood pressure [25] and we have presented previously the consequences of that on validation studies [26]. In a further study we combined a database of paired blood pressure measurements using the Hawksley random-zero sphygmomanometer and a standard mercury sphygmomanometer and a database of paired measurements made on a SpaceLabs 90202 ambulatory recorder and a standard sphygmomanometer to determine how the SpaceLabs 90202 device would have fared had it been assessed against the Hawksley random-zero sphygmomanometer instead of against a standard sphygmomanometer. The effect of replacing the standard instrument with a Hawksley sphygmomanometer was to reverse the direction of the average measurement error found and to demote the SpaceLabs 90202 from BHS grades C and B, for systolic and diastolic blood pressure accuracy respectively, to grade D overall (the lowest rating of accuracy in the BHS grading system [27]). The conclusions of the eight validation studies which substituted the Hawksley device for the standard sphygmomanometer are therefore questionable [16–23] because we do not know how the results of those studies were affected by the Hawksley sphygmomanometer. In one study the numbers recruited were well below the number stipulated in the AAMI protocol and the results of that early study must also be regarded as questionable insofar as they relate to the AAMI accuracy criteria [24].

Table 1. Nine validation studies performed with the AAMI protocol alone.

Device	Study	Accuracy criteria	Comment
TM-2420 ^a	[24]	Passed	Few subjects Protocol violation
	[22]	Passed	RZS Protocol violation
	[22]	Passed	Pregnancy/RZS Protocol violation
	[23]	Passed	Elderly/RZS Protocol violation
	[16]	Passed	RZS Protocol violation
Accutracker ^a	[18]	Failed	RZS Protocol violation
Accutracker II	[17]	Failed	RZS Protocol violation
Medilog ^a	[20]	Passed	RZS Protocol violation
	[19]	Passed	RZS/exercise Protocol violation

^aModel number not specified. RZS, Hawksley random-zero sphygmomanometer.

The importance of establishing precisely the model that is being validated

The original BHS protocol emphasized the importance of manufacturers indicating by a change in model number any modifications made to blood pressure measuring devices [7]. The importance of that stricture is illustrated well by the conflicting reports from a number of laboratories concerning the accuracy of the Takeda TM-2420 device [14,21–24,28–32], many of which employed the AAMI or BHS validation procedures. The results of the individual studies concerning that device, which have been reviewed in detail elsewhere [30], show that apparent differences between laboratories can be accounted for in terms of different models being submitted for validation by the manufacturers without the users being made aware that modifications may have been made to the device. It is to be hoped that that trend has passed and it is perhaps significant that two recent reports on the Takeda device stipulate the version that is being used [31,32].

Another example of device modification affecting accuracy is that reported by Hansen and Orskov [33], who observed apparently inexplicable variations in mean arterial blood pressure in a longitudinal study, which were inconsistent with the observed changes in systolic and diastolic blood pressures. It became apparent that the SpaceLabs 90202 monitors used at the initiation of the study, which had been sent for repair, had had the software programs updated by the manufacturers. Also, new devices supplied by the manufacturers during the course of the study, even though ostensibly the same 90202 model, also contained the updated software. The company readily admitted that it had modified the software program for mean arterial pressure in the interests of greater accuracy and that the modification had resulted in mean arterial pressure being 3–4 mmHg higher with the new program, but they had not disclosed that to the user [33].

The importance of device modification is also illustrated in the evaluation of the Profilmomat ambulatory system [34]. The Profilmomat device was developed for use in general practice by modifying the more expensive and elaborate CH-Druck ambulatory system [35]. During validation it became evident that the Profilmomat device was providing fewer valid measurements during ambulatory use than the parent CH-Druck device, because the facility for repeating measurements in the event of a failed measurement had been removed and when it was replaced the modified recorders comfortably fulfilled the protocol requirements [34].

Therefore, the revised BHS protocol emphasizes that it is incumbent upon manufacturers to indicate clearly all modifications in the technological and software components of automated devices by changing the device number. Furthermore, modified devices must be subjected to renewed validation [13].

The effect of blood pressure level on device accuracy

During the performance of validation of six ambulatory devices in our laboratory, a tendency of accuracy to deteriorate with increasing levels of blood pressure was noted [36]. When the data were analysed according to tertiles of pressure for low-, medium- and high-pressure ranges, all six devices held their overall grading, or improved them slightly in the low- and medium-pressure ranges, but, in the high-pressure range, the devices lost accuracy (Table 2). Therefore, the revised BHS protocol recommends that the validation analysis should be performed not for the overall pressure range alone but also according to tertiles of pressure [13].

Table 2. BHS criteria for six ambulatory blood pressure monitoring devices for overall (90–196/56–136 mmHg), low ($\leq 130/80$ mmHg), medium (130–160/80–100 mmHg) and high ($\geq 160/100$ mmHg) pressures.

Device	Overall SBP/DBP	Low SBP/DBP	Medium SBP/DBP	High SBP/DBP
CH-Druck	A/A	A/A	B/A	C/C
Profilmomat	B/A	A/A	B/A	D/D
SpaceLabs	B/B	B/B	B/B	C/C
Novacor	C/C	C/C	C/C	C/B
Pressurometer	C/D	B/D	C/D	D/D
Takeda	D/D	B/D	C/D	D/D

The effect of age on device accuracy

Miller *et al.* [37] observed that discrepancies between an ambulatory device and a mercury standard were systematically related to characteristics of the participating subjects, such as age, gender and race, with age demonstrating the strongest correlation. Clark *et al.* [23] also noted a tendency for ambulatory systems, especially those using the oscillometric technique, to be less accurate in the elderly. Those results suggest that ambulatory systems for use in the elderly should be evaluated specifically in an aged population and that the effects of age and blood pressure level on accuracy should be examined carefully [38]. Both of the revised protocols acknowledge the influence of age on the accuracy of blood pressure measurement and the BHS protocol has a special group validation procedure for devices that might be used particularly often in the elderly [13].

The effect of exercise on accuracy

White [39,40] showed that ambulatory devices tend to perform poorly during the performance of exercise and that the ambulatory systems operate best when the subject is motionless with the arm in which pressure is being measured held immobile. In fact, ambulatory systems do not measure ambulant blood pressure but rather the blood pressure at rest intermittently over the 24 h period. The BHS protocol stipulates that, if devices are claimed to be accurate during exercise, then separate

validation must be performed to assess their accuracy under exercise conditions [13].

Special populations, pregnancy and the elderly

The revised BHS protocol stipulates that ambulatory systems must be validated in special groups, such as children, the elderly and pregnant women [13]. Three validation studies have been performed with pregnant women; one in normotensive pregnant women using the SpaceLabs 90207 device [41], which fulfilled the BHS and AAMI requirements; one in hypertensive pregnant women using the SpaceLabs 90207 device [42], which again fulfilled the BHS and AAMI requirements. Clark *et al.* evaluated the Takeda TM-2420 device in pregnant women [22] and in the elderly [23] but they did not adhere to the protocol in that they substituted the Hawksley random zero sphygmomanometer for a standard mercury manometer and the results are therefore questionable.

Performance as distinct from accuracy

It has to be realized that the BHS and AAMI protocols primarily test bench accuracy rather than performance, although the revised BHS protocol does assess performance and it recommends a non-invasive assessment during exercise for ambulatory systems that claim accuracy during motion [13]. To overcome the problem of devices losing accuracy under the stress of everyday use, the BHS protocol stipulates that validation should be performed only after the device has had a reasonable period of use [13]. That test serves a number of functions. Firstly, devices may fail to function before the validation phase [43] and it would clearly be wasteful of resources to proceed to the main validation procedure with such a device. Therefore, the test serves as an indicator of the ability of the device to tolerate the stresses of everyday use. The value of the prevalidation phase in highlighting inadequacies in the device, which may be amenable to easy correction by the manufacturers, has been illustrated by the account cited above of the ability of the Profilomat device, which had had the facility for a repeat measurement removed in the interests of reducing the cost of the device [34]. The period of use also permits some expression by the user concerning the acceptability of the device and sometimes useful recommendations can be made to the manufacturer, which result in an improved device.

The revised AAMI protocol recommends comparison in opposite arms using direct intra-arterial measurement either during bicycle exercise using standard intra-arterial techniques or during ambulatory activity using the Oxford system to provide continuous recording [11]. Comparison of blood pressure measuring systems that utilize indirect measurement with direct intra-arterial measurement of blood pressure is not recommended in the BHS protocol, mainly because of ethical considerations; but also because systolic and diastolic blood pressure values obtained by the direct technique are different from the measurements by indirect methods

which have been used so far to establish epidemiological and clinical criteria for the management of patients [13]. Nonetheless, the protocol acknowledges that valuable information may continue to be provided by those few centres with long experience and great expertise with those methods, especially in assessing the accuracy of ambulatory systems throughout the 24 h period when motion and posture may affect accuracy. However, intra-arterial comparison should not be undertaken unless the device has achieved satisfactory grades on the BHS protocol and fulfilled the AAMI criteria [13].

Oscillometric versus Korotkoff sound

An appraisal of the latest ambulatory devices shows a trend towards devices that measure blood pressure by oscillometry and the success of the manufacturers in producing accurate algorithms has encouraged that trend. Several ambulatory systems now provide both oscillometric and auscultatory detection of blood pressure, and such devices require separate evaluation of the auscultatory and oscillometric modes [13]. Clark *et al.* [22,23] have raised the issue of whether oscillometry is as accurate as auscultatory measurement under certain circumstances, such as during pregnancy and in the elderly.

Electrocardiographic gating

Some ambulatory systems, such as the Accutacker II and Novacor DIASYS 200 devices, use electrocardiographic gating, whereby microphonically detected Korotkoff sounds are related in time to the QRS complex of the electrocardiogram [44]. A time-window, or time-gate, is opened after the R-wave of the electrocardiogram has been recorded by electrodes on the chest, and the device admits only those sounds within this window. The rationale of the technique is that the closer the Korotkoff sound is to ventricular systole, as indicated by the QRS complex of the electrocardiogram, the more likely it is to be a true rather than an artefactual sound. The disadvantages of gating mechanisms are the considerable time added to fitting the device on a subject, especially in men with hairy chests, which have to be shaved to ensure electrode placement, and the displacement of electrodes during the period of recording. Moreover, electrocardiographic gating does not always enhance accuracy, especially during exercise [19]. In some systems this facility is optional, being recommended when greater accuracy is required. In this circumstance the device should be evaluated with and without electrocardiographic gating [13].

Appendices of BHS protocol

The BHS protocol has an extensive appendix, which is rarely published with the accuracy validation because of journal space restraints but which should be available on request from the laboratory performing the validation [13]. That appendix contains important information relating to the precise model that is being validated, costs of the device and components, previous validations,

instructions and precautions for use, service facilities, artefact editing and computer compatibility.

Conclusion

Blood pressure measurement has become of such importance in hypertension research in recent years that it merits a section to itself in the indexing process. Advances in technology have opened the market for an array of innovative devices for blood pressure measurement. In anticipation of the market demand for devices for ambulatory blood pressure measuring devices, the British Hypertension Society published a protocol in 1990 [7], one of the aims of which was to put the onus on manufacturers to have their product independently evaluated before marketing it. The Society was at least partially successful in this endeavour and in 1993 it published a revised protocol [13] that is applicable to all blood pressure-measuring devices. Likewise, the Association for the Advancement of Medical Instrumentation published a revised protocol [11] that is applicable to all devices. However, as this review illustrates, those protocols must be adhered to rigorously by centres that validate devices and the protocols themselves need to be examined critically with the intention of improving them. Moreover, advances in technology will lead to innovative methods of blood pressure measurement that will necessitate flexibility in the methodology of the protocols.

It is now imperative for manufacturers to have blood pressure measuring devices validated before they put them on the market and it should no longer be acceptable for manufacturers to market systems that have not been evaluated. Manufacturers should provide prospective purchasers with the results of such validations published in a peer-reviewed journal. We have experience of two pernicious practices to which manufacturers resort and to which attention must be drawn. Firstly, a manufacturer may apply the favourable results of a validation on one model to another, which has not been validated. The BHS protocol clearly states that each model must be subjected to independent validation. Secondly, manufacturers may claim to have satisfied a particular protocol by quoting the results of published work in which the AAMI or BHS criteria are applied to data derived from a validation study that did not adhere to the protocol requirements. Efforts are being made to highlight such occurrences in the correspondence columns of the relevant journals.

The adoption of standards by manufacturers of blood pressure measuring devices may not be easily effected. Manufacturers are not obliged to guarantee the accuracy of their product, although most reputable manufacturers welcome the opportunity of having their devices evaluated independently according to a generally accepted protocol. The European Community has established a

working party (CEN/TC 205/WG 10 Non-invasive sphygmomanometers) to draw up a standard for all blood pressure-measuring devices and a directive will be issued in 1996 that will be legally binding on member states [45].

Manufacturers of blood pressure systems must be encouraged to have their product evaluated independently, according to an approved evaluation procedure. That procedure, which necessarily takes time, has been influenced beneficially by editors of general medical, clinical pharmacology and hypertension journals demanding evidence supporting the accuracy of ambulatory blood pressure systems that are used in research studies. Health authorities and sponsoring organizations should not continue to purchase equipment that has not been evaluated adequately. In some hypertension studies, such as the Syst-Eur Study (Systolic Hypertension in the Elderly) [46], the APTH (Ambulatory Blood Pressure Treatment of Hypertension) Study [47] and the OvA (Office versus Ambulatory Measurement) Study [48], the protocols stipulate that automated systems cannot be used in the study unless they have been evaluated independently according to an accepted protocol.

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