Twenty-four-hour ambulatory blood pressure monitoring: a review of validation data

Eoin O'Brien and Kevin O'Malley

As the clinical applications for 24-h ambulatory blood pressure monitoring expand, market demands increase, and there are now at least 13 manufacturers producing elaborate and expensive systems for recording 24-h ambulatory pressures. It is often difficult to assess the accuracy and performance characteristics of these devices and failure to standardize validation makes it difficult to compare one system with another. The standard of the Association for the Advancement of Medical Instrumentation (AAMI) and the recently published protocol of the British Hypertension Society (BHS) provide standardized validation procedures which allow comparisons to be made between ambulatory devices. Thirty-three published reports on 18 ambulatory systems are listed. Five of these systems have been validated according to the AAMI standard; of these, the SpaceLabs 90202 and the Medilog have satisfied the standard, and the Pressurometer IV, the Accutracker II and the Takeda TM-2420 did not satisfy the AAMI standard. The results of recent validations of the SpaceLabs 90207, the Diasys 200, the Takeda TM-2420 and the Pressurometer IV according to the BHS protocol are awaited and should provide further data that will allow comparisons of the performance and the accuracy of different ambulatory systems.

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Introduction

The clinical management of hypertension and the greater part of clinical research on hypertension is based on a rather frail foundation, the measurement technique used for determining the level of blood pressure. Korotkoff first introduced the auscultatory technique for measurement of blood pressure in 1910 [1] and this has remained the standard technique in clinical practice. Following the early pioneering studies of Brown [2], it soon became apparent that occasional measurements of blood pressure, the so-called 'casual' measurement, might give an unrepresentative estimate of true blood pressure behaviour [3] and other techniques, such as basal blood pressure measurement [4] and home-recording of blood pressure [5], were developed to gain more insight into the influence of different stimuli on blood pressure variability. However, it was not until direct intra-arterial measurement of 24-h blood pressure was introduced [6] that it became possible to detect circadian rhythms and the response to environmental influences. The development of the Remler M2000 system in the early seventies [7], a device capable of measuring daytime ambulatory blood pressure non-invasively, may now be recognized as a major advance in the clinical management of hypertension. With the advent of ambulatory recorders capable of measuring blood pressure non-invasively over 24 h [8] it became possible to study many aspects of blood pressure behaviour relevant to the clinical management of hypertension [9,10]. The assessment of antihypertensive drugs over the 24-h period became feasible [11], and ambulatory monitoring showed promise in assessing prognosis [12] and also provided data on the physiology of blood pressure behaviour [13].

By providing an assessment of blood pressure behaviour over time in the patient's normal environment, ambulatory blood pressure is likely to lead to a reappraisal of the clinical management of hypertension which is presently based on conventional measurement techniques [14]. It is now evident that ambulatory measurement gives a very different assessment of blood pressure from conventional 'office' measurement [15] and it seems likely that the main role of conventional measurement with a mercury sphygmomanometer in the future will be as a screening procedure to differentiate those subjects with normal office blood pressures, who may be deemed normotensive at that time, from those with borderline or definitely elevated office blood pressure, who should undergo 24-h ambulatory measurement to assess more

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fully the level of blood pressure and its behaviour by day and by night. This realization has opened up a market with enormous potential for manufacturers of ambulatory measurement devices [16]; whereas ambulatory measurement might be seen initially as a costly procedure there are substantial hidden savings. For example, in the United States it has been estimated that ambulatory blood pressure monitoring may save as much as $5 billion annually, mainly by reducing drug prescribing [17].

Thirteen ambulatory systems are at present commercially available or are in the later stages of development (Table 1). These systems are expensive, costing over US $10 000 for one recorder and decoding system. It is important, therefore, that the medical profession ensure that ambulatory devices are accurate and reliable. This aspiration is not easily attained. A manufacturer of 24-h measuring devices has to meet national standards of production in countries which have these standards but is not obliged to validate devices for accuracy in clinical situations. This task has been traditionally undertaken by centres with an interest in device validation, but however well intentioned these studies may have been, many centres have failed on methodological or statistical grounds to evaluate devices satisfactorily. The task is all the more daunting as manufacturers often produce an up-dated model every 3–4 years, making it difficult for doctors to keep validation abreast of production. Because both clinical practice and medical research depend on measurement techniques, until validation before marketing becomes obligatory for manufacturers, it is imperative that a comprehensive validation of new devices is undertaken as soon as possible after their manufacture.

The validation of blood pressure measuring devices is a complex and labour-intensive procedure and this is particularly so with ambulatory devices. The American Association for the Advancement of Medical Instrumentation (AAMI) [18] has made recommendations for the validation of electronic and automated sphygmomanometers. The British Hypertension Society (BHS) Working Party on Blood Pressure Measurement has recently examined the issues involved in the evaluation of devices for ambulatory blood pressure measurement. The BHS maintains that evaluation of ambulatory systems must be standardized for the following reasons. (1) Continued uncontrolled marketing will inevitably result in the manufacture and sale of inaccurate devices. This has clear implications for clinical practice, the most important of which is inappropriate diagnostic and management decisions. (2) Without a standardized approach to evaluation, no comparison of results between laboratories is possible and work may have to be repeated with the consequent waste of scarce resources. The BHS working party, having reviewed the possible approaches to the problem, concluded that while the AAMI standard is the most comprehensive recommendation on validation available, it has a number of deficiencies; it does not cover all aspects of evaluation, e.g. interdevice variability, ambulatory assessment and patient acceptability are not included and there are deficiencies in the statistical methodology; it is obtainable only from the AAMI offices on payment of a fee, and is not, therefore, as accessible as a journal publication; and it contains detailed recommendations for manufacturers of ambulatory devices which, though necessary in a standard, are not a requirement of an evaluation protocol. The working party decided, therefore, to prepare a protocol that would serve as a standardized procedure for the evaluation of ambulatory blood pressure measuring devices and to make recommendations for the adoption of this standard procedure [19,20]. Though the working party's brief was to prepare a protocol for ambulatory devices the principles of the procedure adopted can be applied to any automated or semi-automated blood pressure measuring device [21].

The purpose of the present review is to summarize the criteria for validation which the BHS working party considers appropriate and to list the ambulatory systems available at present, indicating which ones have satisfied the AAMI Standard or are being evaluated by the BHS protocol. A list of manufacturers' addresses is also given (Appendix 1) as these can be difficult to obtain.

Table 1. Available ambulatory systems.

Manufacturer	Current model	Method	Cost (US $)
SpaceLabs Inc.	Model 90207	Oscillometric	5500
Del Mar Avionics	Pressurometer IV	K sound/R wave	4000
Suntech Inc.	Accutracker II	K sound/R wave	4000
Oxford Medical	Medilog ABP	K sound/R wave	7480
Takeda (A & D Instruments)	Model TM-2420	K sound	3600
Novacor	Diasys 200	K sound/R wave	9430
Colin Medical	Model ABPM 630	K sound	?
Kardiotec	Physioport	K sound/R wave	7800
Sandoz	Sandoz PS	K sound	?
Clinical Data	Model PB-24	K sound	?
Instromedix	Barograf 24	K sound	?
Finapres	Portapres	Plethysmographic	?
M.E. Commercial Co.	BP 100	Volume oscillometric	?

Principles of validation

The BHS protocol for evaluation of ambulatory systems consists of six phases: phase I, Observer training and assessment; phase II, Before-use interdevice variability; phase III, In-use assessment; phase IV, After-use interdevice variability; phase V, Device validation; and phase VI, Preparation of the report. A device must complete each phase successively before it can proceed to the next phase. The programme is designed to avoid unnecessary testing.

Phase I: Observer training and assessment
Observers should be trained with the use of films, e.g. the BHS video film *Blood Pressure Measurement* [22], and a period of expert training during which the trainee observers are instructed in the different stages of blood pressure measurement as recommended by the BHS [23]. Difficult aspects of interpretation, such as the auscultatory gap and bias, should be discussed and illustrated by example, using a multi-aural stethoscope.

Following training the observers are tested for accuracy against each other and an expert observer by measuring blood pressure in normotensive and hypertensive subjects. Ninety per cent of systolic and diastolic differences between the trainees and the expert must not be greater than 5 mmHg and 98% not greater than 10 mmHg, and 85% of systolic and diastolic differences between each trainee should not be greater than 5 mmHg and 95% not greater than 10 mmHg.

Because devices for ambulatory blood pressure measurement are complex, observers should be instructed in the use of the devices to be tested and practice measurements should be made on a number of subjects before validation commences.

Each ambulatory system should be calibrated according to the instructions of each manufacturer against a mercury sphygmomanometer. All devices must meet the manufacturer's stipulations for calibration.

Phase II: Before-use interdevice variability assessment
Three devices of each type should be assessed in subjects with a representative range of blood pressure. This test is designed to detect variance between models. An analysis of variance should not demonstrate any interdevice variability.

Phase III: In-use assessment
The three devices used for the interdevice assessment are next used to test the performance of the device during and after 24-h ambulatory monitoring in subjects with a wide range of pressure to give a large number of measurements. The editing criteria for each system are left in operation for this phase.

The measurements obtained over each 24-h period are classified according to the number of inflations, valid readings, rejected readings, aborted readings and the ratio of day to night readings. Each subject is asked to comment on the performance of each device.

Phase IV: After-use interdevice variability
At the end of a month of ambulatory assessment the three devices are retested for interdevice variability as in the Before-use interdevice variability test (phase III) to determine whether there has been any change in interdevice agreement after use.

Phase V: Device validation
One device is arbitrarily selected from the three devices for the main validation test. Eighty-six subjects, aged from 15 to 80 years, with a representative range of blood pressures, are selected. Simultaneous measurement of blood pressure between a mercury sphygmomanometer and the ambulatory device is recommended as the validation test of choice. However, in practice this is not possible with many ambulatory systems because of rapid deflation, and sequential same-arm measurements between the test device and a standard mercury sphygmomanometer are then performed.

The percentage of test device measurements differing from the mercury standard by 5, 10 and 15 mmHg or less form a basis for grading the test system according to the criteria in Table 2.

Table 2. Grading criteria based on cumulative percentage of readings, and grades obtained by four devices.

	Difference between standard and test device (mmHg)		
Grade	≤5	≤10	≤15
A	80	90	95
B	65	85	95
C	45	75	90
D	Worse than C	Worse than C	Worse than C

Phase VI: Preparation of the report
Recommendations for the analysis and presentation of data are made in the protocol. Detailed information for the system under test must be provided, such as the cost of the device and its components, compliance with standards, previous validation studies, the adequacy of instructions for use and care and maintenance, the available service facilities, methods of artefact editing and the compatibility of the system with existing computer systems.

Ambulatory systems available

The ambulatory systems available and the validation studies performed to date have been determined from a review of the literature, and manufacturers were also asked to submit a list of validation work conducted on their own devices. Many manufacturers have produced a number of different versions of a particular device over the

years, each being a modification of the basic model. In the present review only the current and penultimate models have been considered. It is our opinion that despite reassurances from manufacturers that the latest model is operationally no different from its predecessor and, therefore, as accurate, all newly marketed models must be fully validated. However, in reaching a decision on which ambulatory system is most suited to each physician's needs it can be helpful to review the validation data on the earlier model and these papers are, therefore listed. Data from abstracts of meeting proceedings have been included only when no other published work is yet available. Thirty-three published reports are listed for 18 ambulatory devices (Table 2) [24–56].

Two ambulatory devices, the SpaceLabs 90202 [30] and the Medilog [44], have fulfilled the criteria for the AAMI standard for both systolic and diastolic pressures, whereas the Pressurometer IV [36] failed to provide measurements of diastolic pressure according to the AAMI standard and the Accutracker II [43] failed for both systolic and diastolic pressures; only one of four Takeda TM-2420 recorders tested fulfilled the AAMI criteria [47]. Therefore, the only systems that can be recommended at present for 24-h ambulatory measurement of blood pressure are the SpaceLabs 90202 and the Medilog. Four other ambulatory systems, the SpaceLabs 90207, the Diasys 200, the Pressurometer IV and the Takeda TM 2420, have been evaluated according to the BHS protocol (Table 2) and the results should be available shortly (E. O'Brien *et al.*, papers submitted for publication).

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Appendix 1: List of manufacturers available

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