The need for a standardized protocol for validating non-invasive ambulatory blood pressure measuring devices

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Increasing interest in ambulatory blood pressure measurement has resulted in the proliferation of non-invasive measurement systems. This paper discusses the problems associated with validation of these systems. There is an urgent requirement for a standardized protocol for validation of ambulatory systems which is practicable, universally applicable and which is acceptable to investigators, publishing houses and the manufacturing industry.

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Introduction

Ambulatory blood pressure measurement has become an established procedure in the clinical management of hypertension [1], in the assessment of antihypertensive drugs [2,3] and as a means of predicting outcome in hypertension [4]. There is evidence to suggest that ambulatory blood pressure measurement, by providing an assessment of blood pressure behaviour over time in the patient's own environment, may well result in a radical reappraisal of the clinical management of hypertension previously based on conventional measurement techniques [1].

One consequence of the increased interest in ambulatory measurement has been the creation of a large market for ambulatory devices. In less than 5 years, the number of devices available commercially has risen from three to more than 10 with many others in the development phase. However, ambulatory measuring systems are expensive, often costing as much as £4000 sterling, and the additional operational and maintenance costs may be considerable.

At present there is no obligation on manufacturers to comply with a standards recommendation. In fact, there is no standard for automated blood pressure measuring devices in the United Kingdom and Ireland.

In the United States, the Association for the Advancement of Medical Instrumentation (AAMI) has produced a comprehensive standard for semi-automated and automated devices [5]. However, in its present form there are some practical problems. First, it is primarily a standard, and as such contains recommendations for the manufacture of ambulatory devices which, though necessary in a standard, are not a requirement of a validation protocol. Second, it is published as a standard which may be obtained from the Association but is not as widely available as a journal publication. Finally, the AAMI recommendations for device validation, though the most comprehensive available, do not cover all aspects of validation.

This paper outlines the requirements for a validation protocol for ambulatory blood pressure measuring devices. The Working Party on Blood Pressure Measurement of the British Hypertension Society is expanding these requirements into a comprehensive validation protocol, which is likely to be accepted as a standardized approach to the validation of all ambulatory systems.

Basic requirements for a validation protocol

Validation methodology

Validation tests must include tests for observer agreement and to assess interdevice variability, and tests for devices with controllable inflation rates, devices with rapid inflation rates and devices with noise interference. In addition, there must be a test for accuracy after a period of use, and assessments of devices in ambulatory use, of patient/subject acceptibility and of service and maintenance facilities.

Subject selection

A group of about 85 subjects should be selected with systolic blood pressures in the range 100–240 mmHg, and diastolic blood pressures from 60 to 120 mmHg. The age of the subjects should range from 15 to 80 years.

Data analysis

Data analysis should use a variety of statistical tests to assess interdevice variability, and to ensure ambulatory and after-use accuracy, as well as basic laboratory accuracy.

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Accuracy requirement

The overall performance of the ambulatory device must meet the following requirement: the mean difference of the paired measurements of the ambulatory device and the reference system shall be ± 5 mmHg or less, with a standard deviation of ≤8 mmHg [5].

Discussion

The absence of an enforceable standard allows manufacturers to market expensive ambulatory systems without being obliged to provide evidence of their accuracy. Unless academic institutions interested in ambulatory measurement acquire and validate these devices, no independent evaluation is carried out. Although at one time investigators had to purchase ambulatory systems, many manufacturers are now prepared to supply equipment to reputable laboratories for validation. However, the labour-intensive task of validation usually has to be paid for from the laboratory's resources. Perhaps it is not unreasonable to look forward to a relationship between the profession and the manufacturing industry akin to that which exists with the pharmaceutical industry.

Validation studies have been performed on a variety of devices by a number of laboratories, each using its own protocol and statistical criteria for assessment [6–13]. Because of considerable variation in methodology it is not always possible to compare one study with another and to reconcile conflicting validatory results. Recently the AAMI standard has been used for validation in the UK [14] and goes some of the way towards solving this problem.

Another difficulty is the time-lag between manufacture of a device and validation, with publication of the validation results in a reputable journal. In practice the time-lag may be as long as 5 years, by which time the manufacturers are ready to market a modification of the validated device and the results of validation are thereby rendered obsolete.

The development of ambulatory blood pressure measurement has reached an important stage. Recognition of the value of the technique in the management of hypertension, and in particular the likelihood that the threshold for pharmacological intervention may be raised with substantial savings in drug prescription (estimated at approximately $6 billion per annum in the USA [15]), has provided a potent marketing stimulus to manufacturers. While this has the benefit of making improved technology available to medicine, investigators are faced with a large variety of expensive ambulatory devices, few of which have been validated for accuracy. In the non-ambulatory home measuring market, many devices are available but few have been validated and most are probably inaccurate. If we are to prevent a similar situation arising in the ambulatory home-measuring market, stringent guidelines must be set without delay. However, guidelines, and even national standards, may be ineffective in the face of overwhelming market forces.

Manufacturers, investigators and potential purchasers of ambulatory blood pressure measuring systems must have guidelines to ensure the accuracy of these expensive devices.

Only if investigators and all those involved with publishing follow a standard protocol for ambulatory devices are we likely to see the responsible development of a valuable technique.

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