Validation requirements for ambulatory blood pressure measuring systems

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The increasing application of ambulatory blood pressure measurement in clinical practice has stimulated the manufacture of a large number of ambulatory systems which must be independently validated. The British Hypertension Society protocol for the evaluation of blood pressure measuring devices has now been used to evaluate eight ambulatory systems. Based on this experience recommendations are made for improving validation techniques for the evaluation of ambulatory devices.

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Introduction

There are at least 15 systems available for the measurement of ambulatory blood pressure and many more are in the developmental stages [1,2]. The accuracy of automated devices for self-measurement of blood pressure has previously been entrusted to manufacturers whose record in this regard has not been good [3]. A similar situation cannot be permitted to develop with ambulatory systems which, quite apart from their expense, may be expected to have a considerable influence on the management of hypertension.

The Association for the Advancement of Medical Instrumentation (AAMI) published an American National Standard in 1987 which contained a validation procedure for ambulatory systems [4]. This validation procedure had, however, a number of deficiencies and its statistical evaluation of accuracy was too liberal [2]. The British Hypertension Society (BHS), therefore, published a comprehensive validation protocol for ambulatory systems in 1990 [5] which has been used to validate seven home devices [3], the Hawksley random zero sphygmomanometer [6], the SpaceLabs 90207 [7], Novacor DIASYS 200 [8], Avionics Pressurometer IV [9], Takeda TM-2420 [10], and the SpaceLabs 90202 [11]. We have just completed an evaluation of the Ch-Druck and Profilomat ambulatory systems and the SpaceLabs 90207 at a 4-mmHg deflation rate according to the BHS protocol (unpublished results, 1991). This paper draws on our experience with the BHS protocol to highlight aspects of validation that might be improved upon in future validation procedures.

Validation of ambulatory systems

Validation phasings

In an effort to minimize unnecessary testing, the BHS protocol has been designed so that the test device passes through phases of evaluation, entry to each test phase being dependent on the successful completion of the preceding phase [5]. This phased approach has proved valuable in that if a device fails one of the initial phases the arduous main validation test need not be undertaken.

The reference standards

The basis of device evaluation is the comparison of blood pressure measurements taken by the device being tested with simultaneous measurements made by a trained observer using a mercury sphygmomanometer. This remains the most accurate standard to date.

Observer training

It is difficult to bring observers to the level of agreement demanded in the BHS protocol, though this is possible using instruction videos, such as the BHS video film *Blood Pressure Measurement* [12,13]. However, our experience suggests that a more reasonable level of accuracy is that 85% of systolic and diastolic differences between each trainee and between the trainees and the expert should not differ by more than 5 mmHg and 95% by not more than 10 mmHg.

Agreement between devices

Inter-device variability should be assessed before beginning the validation test proper, as substantial dif-

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ferences between devices of the same model would render validation impracticable. This occurrence is unlikely with expensive devices such as ambulatory systems before they have been used, though it has occurred with other devices [3]. It is possible that use may affect the accuracy of the manometric system, and the after-use interdevice validation assessment identifies this occurrence and avoids the need for an expensive validation test, the results of which would be worthless.

In-use assessment

The accuracy of a device after use is of more relevance than its accuracy immediately after purchase, before it has been subjected to the wear and tear stresses of daily use that might alter accuracy. In the BHS protocol the main validation test is postponed, therefore, until the device has been in use for a period of 1 month. The in-use phase also provides useful information on the performance of the system, and the comments from subjects aid the overall assessment and may assist manufacturers to make their product more comfortable.

Validation procedure

The BHS protocol recommends using two trained observers in the main validation test, each of whom measures blood pressure in approximately half the subjects. We believe it adds to the strength of the validation to use two observers throughout the validation procedure, as recommended in the AAMI standard [4].

The two most important findings that have emerged from our experience with the BHS protocol in relation to the validation procedure are the necessity of recruiting patients with a wide range of pressures and the difficulty of performing simultaneous same-arm comparisons between the test device and the mercury standard, because of the peculiarities of the deflation mechanisms of most ambulatory systems. The ideal test, simultaneous measurement with the test device and the mercury standard in the same arm, cannot be performed with devices that deflate at rates greater than 4 mmHg/s because faster rates do not permit accurate measurement by an auscultating observer. At fast deflation rates, an auscultating observer will tend to underestimate systolic and overestimate diastolic pressure, by recording the first definite pressure phase at which Korotoff sounds are audible as the systolic value and the last definite phase of audible sounds as the diastolic. A number of other factors also preclude simultaneous same-arm testing with most ambulatory systems [1,4].

The alternatives to simultaneous measurements in the same arm are either simultaneous measurements in opposite arms or sequential measurements in the same arm. We favour the latter approach, because if simultaneous measurements are to be taken in opposite arms it is first necessary to determine that interarm differences are small enough to preclude the introduction of error; however, this would require performing simultaneous measurements in both arms in all 85 subjects, a major undertaking in itself. Furthermore, sequential same-arm measurements are closer to simultaneous same-arm measurements than opposite-arm measurements [14,15].

Device grading

The grading system of the BHS protocol has worked well in practice and provides a more sensitive estimate of accuracy than the AAMI standard which only allows for a pass or fail [4]. The BHS grading system also allows ready comparison between systems [7–11].

The critical assessment of manual information demanded in the BHS protocol should lead manufacturers to produce clearer and more concise documents in future.

Device modifications

Validations of the Takeda TM-2420 by a number of laboratories [9,14,15] have given conflicting results because the manufacturer provided the laboratories with different versions of the device without explaining what modifications had been made. This emphasizes the importance of the stipulation in the BHS protocol that each modification of an ambulatory system must be fully evaluated even if the manufacturer claims that the modification is minor and unlikely to affect accuracy or performance.

Future

The BHS protocol has proved to be an effective validation procedure which permits useful comparisons to be made between ambulatory systems. The development of an automated device to replace observers is expected and would greatly reduce the labour of the validation procedure. Until this device is developed meticulous observer training is mandatory. The use of a bionic arm in the validation of oscillometric devices as a means of supplementing subject measurements, particularly in the high-pressure ranges for which it is often difficult to find subjects, is presently being evaluated and will further lessen the complexity of validation.

Though the BHS protocol provides an assessment of performance during ambulatory use it does not validate accuracy during movement and exercise, nor does it test the device in the variety of positions in which ambulatory measurements may be taken. Consideration must now be given to devising validation procedures under these circumstances.

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