Task Force I: Methodological aspects of blood pressure measurement

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Objective To reach a consensus on important methodological aspects of blood pressure measurement.

Methods A Task Force on the methodological aspects of blood pressure measurement wrote this review after the Eighth International Consensus Conference on Ambulatory Blood Pressure Monitoring, in Sendai, Japan (28–31 October 2001). This consensus paper is based on the papers presented by Task Force I and on the discussion sessions, and is therefore representative of a broad spectrum of expert opinion.

Points of consensus Consensus was reached on the following five issues: (1) there is an urgent need for a simplified protocol for the validation of blood pressure measuring devices; (2) there is a need for a means of updating the "state of the market" for validated devices so that users can have easy access to this information; (3) new devices must be validated independently, and existing devices that have not been validated must be reappraised; (4) manufacturers should confirm when new models use algorithms which have been validated previously; (5) the Food and Drug Administration now accepts that when ambulatory blood pressure measurement is used in clinical short-term trials in which side-effects are not being assessed, a placebo arm is not required. *Blood Press Monit* 6:313–315 © 2001 Lippincott Williams & Wilkins.

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Introduction

Four Working Groups were constituted for the Eighth International Consensus Conference on Blood Pressure Monitoring. Before the conference, each Task Force member was asked to review a specific topic. After the meeting, these review articles were amended to include opinions aired at the conference and to reflect the consensus reached in the discussions. Task Force I focussed on the methodological aspects of blood pressure measurement, and this report summarises the areas of consensus.

Consensus I: Need for validation of blood pressure measuring devices [1]

Only a fraction of the blood pressure measuring devices currently on the market have been independently validated for accuracy. The procedures for validation in the most commonly used protocols (the standard of the Association for the Advancement of Medical Instrumentation [AAMI] and the protocol of the British Hypertension Society [BHS]) are difficult and time-consuming to perform, especially because of the large number of subjects who have to be recruited and the ranges of blood pressure required. These factors have made validation studies tedious to perform and very costly, with the result that fewer centres are prepared to undertake them. This is particularly unfortunate as more devices are in need of independent validation than ever before.

The Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) has produced a simplified protocol – the International Protocol – based on data from 19 validation studies performed according to the AAMI and BHS protocols at the Blood Pressure Unit in Dublin, Ireland. It is anticipated that the relative ease of performance of the International Protocol will encourage manufacturers to submit blood pressure measuring devices for validation in order to obtain the minimum approval necessary for a device to be used in clinical medicine. It is anticipated that more devices on the market will be assessed for accuracy according to this simplified protocol.

Consensus recommendation

The Task Force acknowledged the need for a validation procedure that would be easier to follow than the existing AAMI and BHS protocols without sacrificing the integrity of these protocols.

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Consensus II: Updating validation status of blood pressure measuring devices [2]

The Working Group on Blood Pressure Monitoring of the ESH published its recommendations on blood pressure measuring devices in the *British Medical Journal* in 2001 to guide the would-be purchaser through a complex market. The Task Force pointed out that the *British Medical Journal* review, helpful though it had been, was now out of date as it had reviewed validated instruments only up to December 1999. There is an urgent need, therefore, for some authoritative body to take responsibility for updating information on the state of the market. The Task Force agreed that the most effective way of doing this was via a website, preferably that of the ESH.

Consensus recommendation

The Task Force urged the ESH to establish a secretariat that could oversee the updating of a website dedicated to informing users of blood pressure monitoring devices as to their accuracy in accordance with current validation standards.

Consensus III: Need for critical appraisal of new techniques and reappraisal of established techniques [3–5]

Blood pressure measuring devices are increasingly using the oscillometric technique to record blood pressure. Although a number of devices have now passed both the AAMI and BHS criteria, the technique must continue to be evaluated critically. The advent of simulators to facilitate validation is to be welcomed [3].

Although several studies have shown that ambulatory blood pressure is more reproducible than clinic blood pressure, large differences may occur when ambulatory blood pressure monitoring (ABPM) is repeated, and although such differences might be caused by true biological variability, it is probable that differences in the methodology between one ABPM measurement and the next might account for much of the variability. It is important, therefore, to standardize the technique in order to minimize the variation between ABPM recordings [4].

New techniques for measuring blood pressure, such as recording the normalized blood pressure using a double-cuff sphygmotonometer, will provide alternative devices that do not use the conventional techniques, but all such techniques must be critically evaluated [5].

Consensus recommendation

The Task Force agreed that the Working Group on Blood Pressure Monitoring should proceed with drawing up guidelines for blood pressure measurement, which would encompass conventional, self- and ambulatory blood pressure measurement techniques.

Consensus IV: Need to be able to confirm the integrity of algorithms [6–8]

Because so many important decisions are based on the results of blood pressure measurement, the manufacturers of blood pressure measuring devices have an obligation to ensure that measurement is accurate [6,7]. Because blood pressure self-measurement is becoming so popular, the Japan Home-health Apparatus Industrial Association has been established to promote and improve techniques of self-measurement [8]. This body ensures that all applications to national agencies in the many countries to which Japanese devices are exported include concise details on the pressure circuit, algorithm flow charts, materials and construction, all of which can influence the accuracy of blood pressure measurement. Notification is also provided for any modifications affecting the circuit, parts, cuffs and algorithms and on how these might affect accuracy. When distributors ignore these stipulations, notification is made to the appropriate national certification body.

The blood pressure levels generated by blood measuring devices are derived by algorithms, but the users of such devices are denied information on the methodology of the algorithms. There are examples of the serious consequences that may arise if manufacturers alter algorithms without notification. It was considered unlikely that manufacturers would disclose their algorithms for general access, but it was agreed that disclosure to certain responsible bodies, such as the Food and Drug Administration (FDA), which would respect their confidentiality, was a possible compromise. It was also agreed that the verification of algorithms by independent agencies should be undertaken by manufacturers.

Consensus recommendation

The Task Force recommended that manufacturers should clearly announce changes in algorithms. When a new model is being introduced with an existing algorithm, the manufacturer should provide independent evidence that the algorithm has not been altered.

Consensus V: Ambulatory monitoring removes the need for a placebo arm in drug studies in which side-effects are not being assessed [9,10]

Regulatory authorities differ in their recommendations for evaluating the blood pressure-lowering effect of antihypertensive drugs, but before a new antihyperten-

sive drug receives regulatory approval, it must demonstrate a significant blood pressure-lowering effect over its entire dosing interval. The FDA in the USA and the Committee for Proprietary Medicinal Products in Europe differ in their approaches for demonstrating a drug's antihypertensive activity [9].

On the basis of the analysis of a large number of studies submitted to the Division of Cardio-renal Drug Products of the FDA in which ABPM had been used in addition to conventional measurement, there was a negligible placebo effect in short-term studies [10].

Consensus recommendation

The Task Force welcomed the FDA statement that a placebo is not required in short-term drug studies using ABPM in which side-effects are not being assessed.

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