Ambulatory blood pressure measurement is indispensable to good clinical practice

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The traditional technique of blood pressure measurement is being phased out in most countries and is being replaced by automated measurement. The era of automated blood pressure measurement brings its own problems, not least being the need to evaluate blood pressure measuring devices independently for accuracy. Towards this end, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension has published an international protocol with the aim of having all devices assessed for basic accuracy before being put on the market. The main thrust of this review is that if ambulatory blood pressure measurement has become indispensable to the management of patients with hypertension, it then becomes imperative to encourage the use of ambulatory blood pressure measurement (ABPM) in general practice rather than restricting its

availability to specialist hospital centres. However, if ABPM is to be widely used in general practice, there is a need to establish appropriate educational processes and to improve the methods of presenting and analysing ABPM data. J Hypertens 21 (suppl 2):S11-S18 © 2003 Lippincott Williams & Wilkins.

Journal of Hypertension2003, 21 (suppl 2):S11-S18

Keywords: ambulatory blood pressure measurement, blood pressure, apparatus, hypertension, quidelines

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Why do we tolerate inaccurate blood pressure measurement?

The technique for measuring blood pressure was introduced into clinical medicine in 1896 and it has survived largely unchanged for over a century, despite being an inherently inaccurate technique [1,2]. The future of conventional sphygmomanometry is, however, now under serious threat, not because of its many shortcomings, but rather because of a growing environmental move to ban mercury from clinical use [3].

Why, we might ask, have we connived for so long in perpetuating inaccurate measurement in both clinical practice and hypertension research? The technique has had problems from the outset. Within a few years of its introduction, Heinrich von Recklinghausen showed that the cuff used by Riva-Rocci, being only 5 cm in diameter, was causing serious errors and the cuff controversy has raged ever since [4,5]. In 1904, Theodore Janeway, in an authoritative monograph, warned against relying on casual blood pressure readings [4]. His message went largely unheeded until it was taken up again by Sir George Pickering in the 1960s, who showed the remarkable variability of blood pressure and cautioned against making our patients miserable by prescribing unneeded drugs [4]. The identification of white-coat hypertension (WCH) and the realization that many patients are being treated needlessly with blood pressure-lowering drugs is the latest factor in the growing case against the traditional technique of blood pressure measurement [6].

Whatever mitigating circumstances may be invoked to excuse the many doctors and nurses measuring blood pressure in busy clinical practice accepting inaccurate blood pressure readings, the failure of research scientists to address this issue is debasing to the ethic of scientific enquiry. Not only have specialists in hypertension accepted the inaccuracy of the technique - systematic error, terminal-digit preference and observer prejudice, as clearly enunciated by Geoffrey Rose in 1964 [7], they have, in addition, been prepared to use instruments that have been damned for their inaccuracy [8]. As if this were not enough, editors of prestigious journals, by ignoring their own standards, have perpetuated what can best be called a scientific lottery, but alas, one on which decisions of considerable global, social and economic importance are based. In 1980, after reviewing this issue, we wrote: '...in the interests of scientific accuracy and comparability editors and referees must apply to blood pressure measurement reporting the same critical standards given to other measurement methods' [9]. A decade later, a survey of papers on hypertension in leading medical journals showed that one-third of the papers surveyed failed to provide necessary detail on the technique of measurement and less than 5% of papers made reference to the accuracy of the device used to measure blood pressure [10], 'Why,' we asked, 'do editors of prestigious scientific medical journals demand (quite correctly) the exact methodology of a hormonal assay technique but disregard the detail of methodology of blood pressure measurement on which may depend, for example, the acceptance (or rejection) of an antihypertensive drug in clinical practice?'

Against this litany of collective irresponsibility, some progress can be claimed in one area at least, namely, reducing the error introduced to blood pressure measurement by inaccurate devices. In 1987, the Association for the Advancement of Medical Instrumentation (AAMI) published a standard for electronic or aneroid sphygmomanometers, which included a protocol for the evaluation of the accuracy of devices, and this was followed in 1990 by the protocol of the British Hypertension Society (BHS). Both protocols were revised in 1993 [11,12]. These protocols, which differed in detail, had a common objective, namely the standardization of validation procedures to establish minimum standards of accuracy and performance, and to facilitate comparison of one device with another.

A large number of blood pressure measuring devices have now been evaluated according to one or both protocols [13]. However, experience has demonstrated that the conditions demanded by the protocols are extremely difficult to fulfil because of the large number of subjects with extreme levels of blood pressure that have to be recruited. These factors have made validation studies difficult 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 [14].

Aware of this problem, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension set itself the task of drafting a much simplified protocol that would not sacrifice the integrity of the earlier protocols. This International Protocol has been published recently [14], and it is hoped that it will encourage manufacturers to submit their products for validation so as to obtain the minimum approval necessary for a device to be used in clinical medicine, and that, in time, most devices on the market will be assessed for basic accuracy according to this protocol.

Conventional auscultatory blood pressure measurement

The auscultatory technique is being replaced by automated techniques and its place in medicine may soon be of historical rather than practical interest [1,15,16]. The technique is fraught with inaccuracies, the majority of which arise from the observer [7].

Mercury and aneroid sphygmomanometers

The mercury sphygmomanometer is a simple and accurate device, which can be easily serviced, but, rightly, there are concerns about the toxicity of mercury for individuals using mercury sphygmomanometers, and for those who have to service them. All too often its continuing efficiency has

been taken for granted, whereas the aneroid manometer, which is not generally as accurate, is often assumed to be as reliable. These devices have certain features in common: each has an inflation/deflation system and an occluding bladder encased in a cuff, and both devices measure blood pressure by auscultation using a stethoscope [1,161. The mercury sphygmomanometer is a simple and accurate device, which can be easily serviced, but there are, quite rightly, concerns about the toxicity of mercury for individuals using mercury sphygmomanometers, and for those who have to service them. Users should therefore be alert to the hazards associated with handling mercury. However, the greatest concern about mercury is its toxic effects on the environment. The mercury thermometer has been replaced in many countries, and the use of mercury is no longer permitted in hospitals in Sweden and the Netherlands. However, in other European countries, including the UK and Ireland, the move to ban mercury from hospital use has not been received with enthusiasm on the grounds that there is no accurate alternative device to the mercury sphygmomanometer. None the less, the fear of mercury toxicity is making it difficult to get mercury sphygmomanometers serviced, and the precautions recommended for dealing with a mercury spill are influencing purchasing decisions. Indeed, this is what central governmental policy in many countries would favour - the gradual disappearance of mercury from clinical use rather than imposing a ban [2,3,17–19]. Banning mercury from the wards raises another issue, which may be of even greater importance for clinical medicine. If the millimetre of mercury is no longer the unit of measurement for blood pressure, there can be no scientific argument against its replacement with the Système International (SI) unit, the kilopascal, which is the accepted unit of pressure measurement in science [20].

Aneroid sphygmomanometers register pressure through a bellows-and-lever system, which is mechanically more intricate than the mercury reservoir and column [1]. The jolts and bumps of everyday use result in loss of accuracy over time; usually leading to falsely low readings with the consequent underestimation of blood pressure [21,22]. Moreover, aneroid sphygmomanometry is prone to all the problems of the auscultatory technique, namely observer bias and terminal-digit preference.

Automated sphygmomanometers

An accurate automated sphygmomanometer capable of providing printouts of systolic, diastolic and mean blood pressure measurements together with heart rate and the time and date of measurement would eliminate errors of interpretation and abolish the observer bias and terminaldigit preference present in the traditional auscultatory technique. The advent of accurate automated devices, however welcome, is not without problems [17,231. First, automated devices have been notorious for their inaccuracy, though accurate devices are now appearing on the

market. Second, most of the available automated devices were designed for self-measurement of blood pressure, and it should not be assumed that they will be suitable for clinical use or that they will remain accurate with use, though some are being used successfully in hospital practice and a number of major hypertension studies. Thirdly, oscillometric techniques cannot measure blood pressure in all situations, particularly in patients with arrhythmias, such as rapid atrial fibrillation, and there are also individuals in whom these devices cannot measure blood pressure for reasons that are not always apparent. Fourthly, doctors are uneasy about trusting algorithmic methods, which are zealously guarded by manufacturers [17].

Self blood pressure measurement

It has been recognized for over 50 years that blood pressure recorded by self-measurement in the home is lower than that recorded by a doctor [4]. The discrepancy between pressures recorded in the home and the clinic has been confirmed repeatedly, and is present regardless of whether patients or their relatives or friends measure blood pressure [24].

Self blood pressure measurement (SBPM) has not received widespread acceptance in medical practice, though its popularity with patients is considerable. However, the advent of accurate inexpensive automated devices that can provide a printout of blood pressure measurement with the time and date of measurement, or which allow storage of data for later analysis, plotting and/or electronic transmission of data, has removed many of the drawbacks referred to above, and there is now a renewed interest in SBPM. This revival of interest in an old methodology was recognized when experts from around the world gathered at the First International Consensus Conference on Self Blood Pressure Measurement in Versailles in 1999 to discuss the evidence for and against the technique and to establish guidelines for its use in clinical medicine [25]. One of the recurring themes of the conference was the need for further research to determine the precise role of SBPM in practice.

Devices and validation

The automated devices available for self-measurement all use the oscillometric technique. There are three categories available - devices that measure blood pressure on the upper arm, at the wrist and at the finger [13,26]. Devices that measure blood pressure at the finger are not recommended because of the inaccuracies that occur because of measurement distortion with peripheral vasoconstriction, the alteration in blood pressure the more distal the site of recording, and the effect of limb position on blood pressure [26]. Devices that measure blood pressure at the wrist are subject to the latter two problems and, though they are more accurate than finger measur-

ing devices, there are strong reservations about the correct use of these devices, especially with regard to the correct placement of the occluding cuff at heart level [26]. Devices that measure blood pressure on the upper arm are the most accurate devices at present but recommendations that apply to blood pressure measurement in general are applicable to these automated devices.

Clinical indications

The clinical applications of SBPM are only beginning to become apparent as the technique becomes more widely used and scientific data are gathered; as evidence becomes available, the indications may prove to be similar to those for ABPM.

Ambulatory blood pressure measurement

Ambulatory blood pressure measurement (ABPM) has now become indispensable to good clinical practice and should be available to all patients diagnosed as having hypertension [27–31]. In recognition of this, a number of national societies have published recommendations for the use and interpretation of ABPM in clinical practice [32–35], and the European Society of Hypertension has published recommendations on blood pressure measuring devices, including devices for ABPM [13].

Why is ABPM superior to conventional blood pressure measurement?

The evidence that ABPM gives information over and above conventional blood pressure measurement (CBPM) has been growing steadily over the past 25 years [27]. Evidence is now available from longitudinal studies that ABPM is a much stronger predictor of cardiovascular morbidity and mortality than CBPM [30,31], and in the USA, the Centers for Medicare and Medicaid Services have recently approved ABPM for reimbursement [36]. It would seem, therefore, that there is now international acceptance that ABPM is an indispensable investigation in patients with established and suspected hypertension and that it should be available to all hypertensive patients.

ABPM devices

The first step in adopting the technique of ABPM is selecting a device, and the first consideration is to ensure the device selected is accurate. A number of ABPM devices have been evaluated according to the AAMI or BHS protocols [13] (Table 1).

ABPM software

Though the BHS protocol does make certain recommendations in relation to the software programs in ABPM devices, too little consideration has been given to this important aspect of the technique. All ABPM devices are sold with individual software packages, which present data in a variety of ways, and in some instances the software programs are neither 'user friendly' nor inexpensive.

A&D TM-2420 Model 6 Meditech ABPM-04 A&D TM-2420 Model 7 Profilomat I A&D TM-2421 Quiet-Trak A&D TM-2430 Save 33 Model 2 CH-Druck Schiller BR-102 Daypress 500 Spacelabs 90202 **DIASYS** Integra Spacelabs 90207 ES H-531 Spacelabs 90217

It is important, therefore, to be sure that the software program with the ABPM device selected is suitable for the use for which the device has been chosen. For example, in a busy general practice, perhaps basic data giving average day- and night-time values and a visual plot are all that will be required, whereas for research purposes, statistical detail on the windows of the 24-h profile and indices, such as pulse pressure, blood pressure load, coefficient of variation, etc., may be required.

The use of ABPM in clinical practice could be greatly facilitated by two developments. First, if the graphic presentation of ABPM data were standardized, much as is the case for electrocardiograph (ECG) recordings, the presentation of data would be independent of the type of ABPM monitor used and the user would not have to become familiar with a variety of programs. Moreover, standardization would facilitate the interchange of ABPM recordings between databases, such as a hospital and primary-care practice. Second, if ABPM software programs could provide a printed report of the ABPM data, as is possible with ECG recordings, doctors and nurses unfamiliar with the technique would be assisted in learning the variety of patterns generated by ABPM and, importantly, the time needed for a physician to report on each ABPM would be greatly reduced, thereby reducing the cost of the technique [31] (Fig. 1).

Clinical indications for ABPM

ABPM provides a large number of blood pressure measurements over a period of time – usually the 24-h period – which can be plotted to give a profile of blood pressure behaviour. Though in practice the average blood pressures are used to govern decisions, the clinical use of ABPM has allowed for a number of phenomena in hypertension to be more clearly identified than is possible with other methods of blood pressure measurement [37,38] (Fig. 1). If one had to single out one clinical indication over and above all others in which the technique is so valuable as to be indispensable, that would have to be the identification of white-coat hypertension (WCH).

Patients with suspected white-coat hypertension

The importance of WCH rests on a curious haemodynamic phenomenon, which has quite profound clinical relevance: patients – let us call them people, because they may not be ill – who appear to have hypertension when their blood pressure is measured by the traditional Riva-Rocci/Korotkoff method, have normal blood pressures when ABPM is used to record their blood pressures away from the medical environment [39]. Put another way, conventional blood pressure measurement is misleading in people with WCH and if decisions are based on these measurements, inappropriate diagnosis and treatment may result.

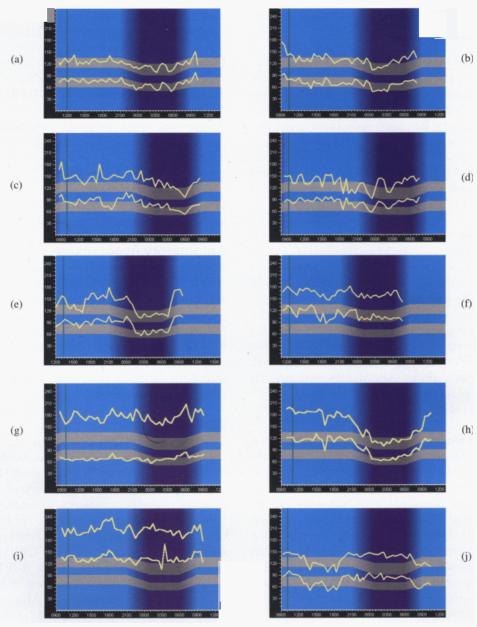
The most popular definition of WCH requires a blood pressure measured by conventional techniques in the office, clinic or surgery to be above 140/90 mmHg, with normal ABPM measurements throughout the 24-h period, except perhaps during the first hour of the 24-h recording when the patient is under the pressor influence of the medical environment while having the monitor fitted [37].

Although WCH is common, its prevalence depends, of course, on how the condition is defined. The prevalence of WCH has been variably described as comprising 10–35% of clinic referrals for ABPM, with the prevalence in the population probably being around 10% [6,30,31].

The clinical importance of WCH centres on the argument as to whether or not it carries an entirely benign prognosis. If WCH carries little or no risk, then establishing the diagnosis has significant implications, not just for those newly referred subjects in whom the diagnosis is suspected, and who can be reassured, but also for a large proportion of patients who have been labelled as 'hypertensive' with conventional measurement, and from whom the burden of unnecessary drug therapy may often be lifted, at least temporarily. The clinical significance of WCH has become clearer from a growing mass of data, including some event-based cohort studies [39-44], which suggest that subjects with elevated office/clinic blood pressure who have normal average daytime pressures on ABPM have a risk of major cardiovascular events comparable with that of clinically normotensive subjects and less than that of subjects with elevated daytime pressures. On the other hand, some studies have suggested that patients with WCH may be at increased risk, albeit a smaller risk than patients with sustained hypertension [37,45]. Evidence to date does not therefore permit a conclusive statement on this issue, but clearly if patients with WCH are at risk, the risk is very much smaller than for patients with sustained hypertension.

White-coat effect

White-coat hypertension must be distinguished from white-coat effect, which is the term used to describe the rise in pressure that occurs in the medical environment regardless of the daytime ABPM level. In other words,



Standardized common patterns in ambulatory blood pressure measurement (ABPM) and reports generated by the dab/8-ABPM program (ECF Medical Ltd., Blackrock, Co. Dublin, Ireland; www.ecfmedical.com). (a) Normal ABPM pattern. The ABPM suggests* normal 24-h systofic and diastolic blood pressure (128/78 mmHg daytime, 110/62 mmHg night-time). (b) White-coat hypertension. The ABPM suggests* white-coat hypertension (175/95 mmHg) with otherwise normal 24-h systolic and diastolic blood pressure (133/71 mmHg daytime, 119/59 mmHg nighttime). (c) White-coat effect. The ABPM suggests* mild daytime systolic hypertension (149 mmHg), borderline daytime diastolic hypertension (87 mmHg), borderline night-time systolic hypertension (121 mmHg) and normal night-time diastolic blood pressure (67 mmHg) with white-coat effect (187/104 mmHg). (d) Borderline systo-diastolic hypertension. The ABPM suggests* borderline daytime systolic and diastolic hypertension. (135/87 mmHg) and mild night-time systolic and diastolic hypertension (132/81 mmHg). (e) Moderate systo-diastolic hypertension. The ABPM suggests* mild daytime systolic and diastolic hypertension (147/93 mmHg) and normal night-time systolic and diastolic blood pressure (111/66 mmHg). (f) Severe systo-diastolic hypertension. The ABPM suggests* moderate daytime systolic and diastolic hypertension (164/112 mmHg), severe night-time systolic hypertension (157 mmHg) and moderate night-time diastolic hypertension (101 mmHg) with whitecoat effect (181/134 mmHg). (g) Isolated systolic hypertension. The ABPM suggests* severe 24-h isolated systolic hypertension (176/68 mmHg daytime, 169/70 mmHg night-time). (h) Hypertensive dipper. The ABPM suggests* severe daytime systolic hypertension (181 mmHg), moderate daytime diastolic hypertension (117 mmHg) and normal night-time systolic and diastolic blood pressure (111/68 mmHg). (i) Hypertensive nondipper. The ABPM suggests* severe 24-h systolic and diastolic hypertension (210/134 mmHg daytime, 205/130 mmHg night-time). (j) Autonomic failure. The ABPM suggests* normal daytime systolic and diastolic blood pressure (125/72 mmHg), moderate night-time systolic hypertension (140 mmHg) and mild night-time diastolic hypertension (84 mmHg) with mild white-coat effect (148/91 mmHg). *Common to all reports: On the basis of the data recorded and the available literature, the ABPM suggests etc. Common to all plots: vertical axis, blood pressure level; horizontal axis, 24-h clock times; horizontal bands, normal levels for 24-h systolic and diastolic blood pressures; shaded vertical area, night-time. Modified with permission from Lippincott Williams & Wilkins [31].

the term indicates the phenomenon found in most hypertensive patients whereby CBPM is usually higher than the average daytime ABPM, which is none the less elevated above normal.

Masked hypertension (reverse white-coat hypertension)

Recently, a group of patients have been identified in whom CBPM levels of pressure are normal but ABPM levels are elevated [46,47]. This phenomenon, which is more common in the elderly, has previously been given the awkward titles of 'reverse white-coat hypertension' or 'white coat normotension', and now Pickering and his colleagues have proposed the more sensible term 'masked hypertension', to denote blood pressure elevation that is hidden until ABPM is performed [47].

Systolic and diastolic hypertension

Combined systolic and diastolic hypertension is the commonest form of hypertension, and ABPM allows for a more detailed assessment of the severity of elevation of systolic and diastolic pressures as well as the duration of elevation throughout the 24-h period. Moreover, the degree of white-coat effect can be quantified. In patients with resistant hypertension, defined as a CBPM consistently above 150/90 mmHg in spite of treatment with three antihypertensive drugs, ABPM may indicate that the apparent lack of response is in fact due to the whitecoat phenomenon [31].

Elderly patients in whom treatment is being considered

A number of ABPM patterns may be found in elderly subjects. The results of the ABPM sub-study of the Systolic Hypertension in Europe (Syst-Eur) Trial show that systolic blood pressure measured conventionally in the elderly may average 20 mmHg higher than daytime ABPM [48], thereby leading to inevitable overestimation of isolated systolic hypertension in the elderly and probable excessive treatment of the condition. Moreover, results from this study also show that ambulatory systolic blood pressure was a significant predictor of cardiovascular risk over and above conventional systolic blood pressure. A number of ambulatory patterns are found in the elderly, among which are a variety of hypotensive states due to baroreceptor or autonomic failure. As the elderly can be particularly susceptible to the adverse effects of blood pressure-lowering drugs, identification of hypotension becomes particularly important [49], though its management may present a considerable therapeutic challenge.

Suspected nocturnal hypertension

ABPM is the only non-invasive blood pressure measuring technique that permits measurement of blood pressure during sleep. The relevance of nocturnal hypertension has been controversial, but recent evidence has shown that a non-'dipping' nocturnal pattern is a strong independent risk factor for cardiovascular mortality [50-54]. It has also been shown that absence of nocturnal

'dipping' of blood pressure to lower levels than during the day is associated with target organ involvement, and may be a useful (though non-specific) clue to the presence of secondary hypertension [31].

Pregnancy

As in the non-pregnant state, the main use for ABPM in pregnancy is the identification of WCH, which may occur in nearly 30% of pregnant women [31,35]. Its recognition is important so that pregnant women are not admitted to hospital or given antihypertensive drugs unnecessarily or excessively. Moreover, women with WCH tend to have more Caesarean sections than normotensive women, suggesting that if ABPM was used to measure blood pressure rather than the conventional technique, caesarean delivery might be avoided [55].

Ambulatory hypotension

Reference has already been made to the clinical use of ABPM in identifying hypotensive episodes in the elderly, but it may also be used in young patients in whom hypotension is suspected as a cause of symptoms [49]. ABPM may also demonstrate drug-induced drops in blood pressure in treated hypertensive patients, which may have untoward effects in patients with a compromised arterial circulation, such as those with coronary and cerebrovascular disease [56].

ABPM and drug treatment

The role of ABPM in guiding drug treatment is currently the subject of much research, and its place in this regard has not yet been fully established. However, recent reviews have highlighted the potential of 24-h ABPM in guiding antihypertensive medication [57–59]. Furthermore, in a well-controlled study by Staessen and co-workers [60], adjustment of antihypertensive treatment based on either ABPM or CBPM resulted in less intensive drug treatment in the ABPM group despite comparable blood pressure control in both groups, and, importantly, patients in the ABPM group, who received less drug treatment, were not disadvantaged as judged by left ventricular mass on echocardiography. Quite apart from this attribute, ABPM gives the prescribing doctor an assessment of the response to treatment that conventional measurement cannot provide: the efficacy of treatment without the white-coat effect can be ascertained, excessive drug effect and the occurrence of symptoms can be determined, and the duration of drug effect over the 24-h period can be demonstrated.

Conclusion

After a long gestational period in research, ABPM has now become an indispensable technique in the management of hypertension. This being so, there is a need to encourage the use of ABPM in general practice rather than restricting its availability to specialist hospital centres as has tended to be the case until now. However,

diagnostic and management decisions based on the interpretation of ABPM patterns are more complex than has been the case with conventional measurement of blood pressure and suitable educational processes must also be initiated. Standardization of data handling and presentation, the display of normal bands, the delineation of the windows of the 24-h profile and computer-generated reports as physician assistance, are steps that should make the technique easier to use and interpret so that its manifest advantages can be utilized to improve the management of hypertension, which remains so abysmally poor.

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