



## ABC of hypertension: Blood pressure measurement

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*ABC of hypertension***Blood pressure measurement***Part IV—Automated sphygmomanometry: self blood pressure measurement*

Eoin O'Brien, Gareth Beevers, Gregory Y H Lip

It has been recognised for over 50 years that blood pressure measured in the home is lower than that recorded by a doctor.<sup>1</sup> 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.<sup>2</sup>

Why then has home measurement of blood pressure failed to achieve the success and popularity of home urinalysis in diabetes? There are a number of explanations: training patients to measure their own blood pressures using the auscultatory technique was troublesome and time consuming and not suitable for many subjects; the technique is subject to bias whereby some patients record pressures of their own making; doctors often perceive the technique as one which induces anxiety or causes the patient to take an obsessional interest in blood pressure; most automated devices available for self measurement had not been validated adequately, or had been shown to be inaccurate; finally, because the technique was little used data have been lacking to provide the evidence needed to assure its place in modern clinical practice.

For these reasons home measurement of blood pressure has not received widespread acceptance in medical practice, although its popularity with patients is considerable. However, the advent of accurate inexpensive automated devices which 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 self blood pressure measurement. This revival of interest in an old methodology was recognised when experts from around the world gathered at the First International Consensus Conference on Self-Blood Pressure Measurement (SBPM) in Versailles in 1999 to discuss the evidence for and

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A selection of automated devices

against the technique and to establish guidelines for its use in clinical medicine.<sup>3-10</sup> One of the recurring themes of the conference was the need for further research to determine the precise role of self measurement in practice.

A number of developments, not least the availability of accurate automated devices, herald the demise of so called classic sphygmomanometry and the dawning of a new era in blood pressure measurement.

**Automated devices: an automated alternative to mercury**

Automated devices, by providing timed printouts of blood pressure, remove many of the sources of error associated with the conventional auscultatory technique, and thereby improve the overall accuracy of measurement, provided, of course, that they themselves are accurate. Although the mercury sphygmomanometer is disappearing from use, unfortunately there are not many alternative devices available to replace it. The automated devices on the market have been designed for self measurement of blood pressure, and although automated devices are being developed specifically for clinical use, the automated devices presently being used in clinical practice have been adapted for a use for which they were not designed.

The advent of accurate automated devices, however welcome, is not without problems. Firstly, automated devices have been notorious for their inaccuracy, although accurate devices are now appearing on the market. Secondly, 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, although 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, zealously guarded by manufacturers. To ensure that new devices conform with recommended validation protocols the mercury sphygmomanometer will have to be retained as a gold standard in designated laboratories.<sup>11</sup>

**Details of ABPM device manufacturers**

Additional information about manufacturers can be found on the *BMJ's* website: [www.bmj.com](http://www.bmj.com). See also O'Brien et al. *BMJ* 2001;322:531-6

## Device accuracy: validation requirements for sphygmomanometers

Manufacturing blood pressure measuring devices is big business. In Germany, for example, 1.2 million wrist devices for self measurement of blood pressure are sold annually.<sup>11</sup> Only a fraction of the many hundreds of models available worldwide have been subjected to independent validation. It therefore follows that the consumers who constitute the large market from which manufacturers may profit are not well served by their suppliers, and this includes medical as well as non-medical consumers. As the professional consumers we have an obligation to ensure that when blood pressure is measured, the readings obtained are accurate and a true reflection of the haemodynamic state. If this basic principle is ignored our patients will be subject to inaccurate diagnosis and inappropriate management, which may involve inadequate drug treatment, on the one hand, or unnecessary drug treatment for life on the other. Hence, in the past decade or so, much attention has been given to validating blood pressure measuring devices for accuracy independently of the sometimes extravagant claims made by manufacturers for their products. There are two published standards for the evaluation of blood pressure measuring devices—the American Association for the Advancement of Medical Instrumentation (AAMI) Standard,<sup>12</sup> which is accepted by the Food and Drug Administration as the national standard in the United States, and the more comprehensive protocol of the British Hypertension Society (BHS).<sup>13</sup> In brief these protocols compare an ABPM device against the traditional auscultatory technique of blood pressure measurement in normotensive and hypertensive subjects with a wide range of blood pressures, and in varying age groups. On the basis of these results, the protocols recommend that only those devices that achieve a high grade of accuracy for both systolic and diastolic blood pressure should be recommended for clinical use.

Manufacturers are not at present obliged to guarantee the accuracy of their product, although most reputable manufacturers welcome the opportunity of having their devices



The Omron HEM 705-CP monitor (top) and the A&D UA-767 device (bottom) for self measurement of blood pressure. Both devices have fulfilled the criteria of the BHS and AAMI protocols

evaluated independently according to a generally accepted protocol. The European Community has drawn up a directive<sup>14-16</sup> for all blood pressure measuring devices, which is legally binding on member states, in which it is recommended (but not obligatory) that devices should be validated independently according to a clinical protocol.

## Devices for self measurement

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, the wrist, and the finger.

### Finger devices

Devices that measure blood pressure at the finger are not recommended because of the inaccuracies caused by measurement distortion with peripheral vasoconstriction, the alteration in blood pressure due to the more distal the site of recording, and the effect of limb position on blood pressure.

### Wrist devices

Devices that measure blood pressure at the wrist are subject to the latter two problems, and although more accurate than finger measuring 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.

### Upper arm devices

The recommendations that apply to blood pressure in general are applicable to these automated devices. Appropriate cuff sizes should be available. It may not be possible to measure blood pressure with automated devices in patients with arrhythmias, and there are some patients in whom automated measurement is not possible but for which there is no obvious reason.

### Devices for SBPM

- Devices for SBPM must have an EU certificate
- Devices for SBPM should be subjected to independent accuracy validation according to the AAMI or BHS protocols
- SBPM devices should provide blood pressures in both millimetres of mercury and kilopascals
- Finger measuring devices are not recommended
- Wrist measuring devices should be used with great care
- Arm measuring devices are the recommended choice
- Manufacturers should be encouraged to produce an “adjustable cuff” applicable to all adult arms
- An annual “state of the market” review listing validated devices for SBPM should be published

SBPM = self blood pressure measurement

## User procedure

The recommendations for self measurement do not vary in principle from those that apply for blood pressure measurement in general, but there are some points in need of emphasis.<sup>7</sup>

### Use in primary care

At present self measurement is performed mostly by patients on their own initiative using devices bought on the free market, without medical control. Self measurement should be seen by primary care physicians as offering a means of gaining further insight into blood pressure control and the effects of management strategies in motivated and informed patients who remain under medical supervision.

### Frequency of measurement

The frequency of self recorded measurements may vary according to the indication and the information that is being sought. Measurements from the first day should be excluded from the statistical analysis because these may represent a period of familiarisation and anxiety with the technique, and often yield measurements that are not representative of the true blood pressure profile.<sup>7</sup>

### Observer prejudice

The unreliability of self measured blood pressures as reported by patients themselves has been demonstrated by comparing the recorded pressures to those recorded secretly by an automatic data storage system.<sup>7</sup> Memory equipped devices have the potential to reduce this observer prejudice.

### Training of patients

Doctors must themselves be conversant with the strengths and limitations of self measurement, and be aware of the accuracy and reliability of the equipment being used by their patients, and be able to advise them on the state of the market for automated devices.<sup>3</sup> Training should focus on equipment, the self measurement procedure, interpretation of results, blood pressure variability, levels of normality and the need of the calibration, and maintenance of the equipment. Towards this end nurses in primary care practices, who are most suited to training patients, may find the available CD Roms and the booklet of the British Hypertension Society useful for demonstration to patients anxious to know more about self measurement.<sup>17</sup>

### Patient requirements

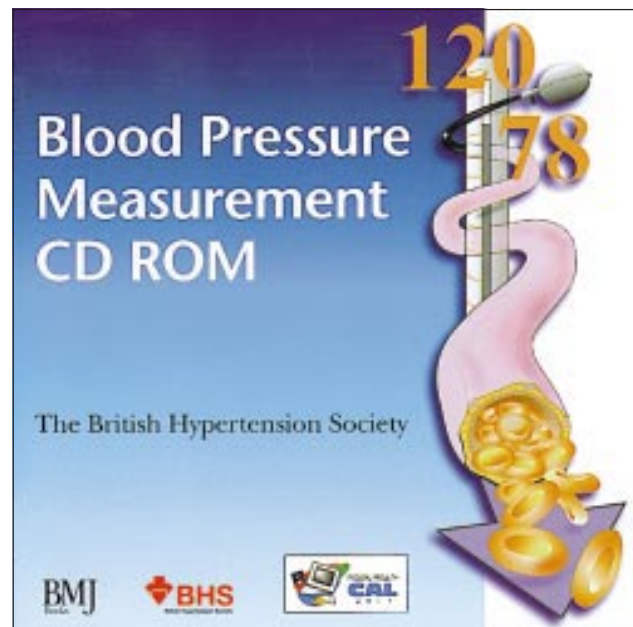
Few patients are unable to perform self blood pressure measurement. The method may be advocated for hypertensive patients who would like to contribute to their own management. Self measurement may be unsuitable for patients with physical problems or mental disabilities.

## Diagnostic thresholds

The association between blood pressure and cardiovascular risk is continuous, without a threshold above which risk suddenly increases. However, clinical decisions must be based on diagnostic or operational thresholds. In this regard, there is an agreement that the thresholds currently applicable for conventional sphygmomanometry cannot be extrapolated to automated measurements. Different methodological approaches may be used for the determination of threshold values, the most satisfactory of which is to be able to relate blood pressure thresholds to cardiovascular outcome. However, as this data is not available for self measurement, the recommended thresholds in the box opposite are derived from

### User procedure

- SBPM should be performed after a period of 5 minutes' rest
- SBPM should be performed with validated fully automated devices
- Use brachial artery occluding devices
- Wrist monitors are unreliable
- Device cuff must be at heart level on the arm with the highest blood pressure
- Measurement frequency
  - Initial phase and the treatment period—1-week SBPM: 2 SBPM morning and evening
  - Long term observation—minimum 1 week per quarter
- Patient diaries are unreliable
- Use printer or memory equipped devices with possibility to store or transmit
- Discard first day readings
- Use all other data to calculate the mean SBPM
- Manual device may be needed when arrhythmias are present
- SBPM should be performed under medical supervision
- Patients should be trained in SBPM and re-evaluated annually
- SBPM suited for patients motivated towards their health management
- Patients with physical or mental disabilities may be unsuited to SBPM



Blood Pressure Measurement CD Rom

### Diagnostic thresholds

- Data from longitudinal studies is lacking
- Reference values are derived from statistical evaluation of databases
- 135/85 mm Hg may be considered as upper limit of normality
- SBPM needs to be further evaluated in prospective outcome studies

statistical considerations in a large population database comprising some 5422 normotensive and untreated hypertensive subjects.<sup>6-9</sup>

## Clinical indications

The clinical applications of self measurement are only beginning to become apparent as the technique becomes more widely used and scientific data is gathered; the potential uses for the technique are summarised in the box and are generally the same as for ABPM (see previous section), though the evidence for SBPM is not as strong as for ABPM.<sup>8</sup>

### Potential clinical uses for SBPM

*These applications are largely tentative and the evidence in support of the use of SBPM in these circumstances must await the outcome of ongoing studies*

- White coat hypertension
- The elderly
- Pregnancy
- Hypertensive patients with diabetes mellitus
- Resistant hypertension
- Improving compliance to treatment
- Predicting prognosis
- As a guide to drug treatment

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### *A memorable patient* The Aga baby

It was the sort of Sunday evening in February for sitting in front of the fire. I was on call for both practices in our small town when, at 10 pm, the telephone rang. The caller, Trisha, a family friend and patient of the neighbouring practice, was concerned about her 20 year old daughter's abdominal pain, which had been increasing since they both went running that morning. "Could it be her gall bladder?"

I reached the isolated farmhouse half way up the fell as snow began to fall. Greeted by a worried Trisha, I entered to find Mary lying on the floor in the middle of a contraction and the perineum beginning to bulge. Despite the clinical findings, between contractions Mary denied that she was pregnant, and my repeated questions as to the date of her last period elicited only the reply "A month ago," so the maturity of the infant was in doubt. Trisha's expression told me that she, too, was unaware of the pregnancy; she had suspected, but Mary had persuaded her otherwise. By a tragic irony, the only person who knew of the pregnancy was Mary's own general practitioner, who had died the previous week in a climbing accident.

As I hadn't brought the midwifery bag, Trisha raided the airing cupboard for towels and blankets and the kitchen for scissors and string, while John, Mary's father, put out the cat and I commandeered the telephone. The district midwife was out at a confinement, the second on call wasn't answering, and the baby's head was just appearing. I summoned an ambulance, requesting an incubator, and despatched John to meet it and guide it back to the house—and the cat, which had re-entered by the window, was

again removed. Meanwhile, Mary was labouring on, and my midwifery "skills," atrophied by long disuse, were hastily resurrected. She was brilliant; I was perspiring freely as I removed the cord from around the baby's neck, and together we delivered a healthy, full term daughter, who was wrapped up and placed in a laundry basket in front of the open Aga oven, displacing the lambs already in residence. Thankfully, I delivered the placenta without difficulty, or ergometrine, and again sent out the cat.

Snow was still falling when the ambulance arrived, with John but without incubator. "Congratulations, Granddad" shook John a bit, but three generations of the fairer sex set off to hospital, while John and I took a little light refreshment from Scotland.

Returning home, I had to deflect my wife's questions, though I was dying to relate the story, and respond to four more calls that had come in. And the questions continued at my colleague's funeral the next day.

But all turned out well. Hannah is now nearly 8 years old and proud of her fame as the "Aga baby," though the lack of incubator had caused her to be cold on arrival at hospital, where she took two days to thaw out. The ball of string that I used to tie the cord has been kept as a memento. But I have to admit that, during the most hectic hour of my professional career, I omitted one vital midwifery task. I didn't put the kettle on.

Robert Hodkinson *general practitioner, Stonebridge Surgery, Longridge, Lancashire*