

Has conventional sphygmomanometry ended with the banning of mercury?

Eoin O'Brien

The banning of mercury from clinical practice will lead to the inevitable demise of traditional clinical sphygmomanometry. There are differences in approach to this important issue between European countries on the one hand, which generally have accepted that the mercury sphygmomanometer must be replaced with alternative devices, and the U.S. on the other, where the view is that the mercury sphygmomanometer should remain as the mainstay of blood pressure measurement. The availability of alternative devices for the mercury sphygmomanometer is improving but the problem of independent validation is a serious issue, which is being addressed by the European Society of Hypertension Working Party on Blood Pressure Monitoring, which has drafted an International Protocol for validating blood pressure measuring devices. The removal of the mercury sphygmomanometer from clinical practice has other implications, which merit careful consideration; the advent of automated devices must lead inevitably to the disappearance of the traditional clinical auscultatory technique of blood pressure measurement, and with the disappearance of mercury it will be argued that the *Système International* (SI) unit of measurement – the kilopascal – should replace the millimetre of mercury. *Blood Pressure Monit* 7:37–40 © 2002 Lippincott Williams & Wilkins.

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Blood Pressure Unit and ADAPT Centre, Beaumont Hospital, Dublin 9, Ireland,

Correspondence and requests for reprints to Professor E. O'Brien, Blood Pressure Unit and ADAPT Centre, Beaumont Hospital, Dublin 9, Ireland.
E-mail: eobrien@iol.ie

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Introduction

There are a number of issues related to the growing move to ban mercury from the environment, which will affect the measurement of blood pressure in clinical practice. It is important, therefore, to anticipate these issues so as to prevent changes in measurement adversely affecting the management of patients with hypertension. The major issues for consideration are: (i) removal of mercury from clinical practice and disappearance of the mercury sphygmomanometer; (ii) availability of accurate alternative devices; (iii) demise of the traditional auscultatory technique of blood pressure measurement; and (iv) replacement of the millimetre of mercury with the kilopascal.

Removal of mercury and disappearance of the mercury sphygmomanometer

It is interesting to contrast the American and European views on the issue of mercury toxicity. In a recent editorial in *Hypertension* entitled "Mercury Sphygmomanometers Should Not be Abandoned" [1], which was written by the Council for High Blood Pressure Research of the American Heart Association, the view was expressed that because there have been few reported cases of mercury toxicity in clinical practice "mercury instruments are approved and are legal devices in this country, and we believe they should remain so" [1]. In Europe concern with mercury toxicity is focused not on health care workers, with whom instances of mercury toxicity are indeed rare, but rather on the disposal of mercury, which is a major threat to the environment [2–5]. Mercury is a toxic substance, and there is mounting pressure from environmentalists to have it banned from use in hospitals. In Scandinavian countries and The Netherlands the use of mercury is no longer permitted. In the rest of Europe the move to ban mercury from clinical use has been resisted on the grounds that the once common alternative, the aneroid sphygmomanometer, becomes inaccurate with use and should not, therefore, be substituted for the mercury instrument [2]. However, the reluctance of servicing personnel to handle mercury because of the danger of toxicity, is forcing the pace of change with the unsatisfactory consequence of mercury sphygmomanometers being replaced without due consideration being given to the accuracy and performance of the alternative device.

Europe is preparing, therefore, for changes in clinical sphygmomanometry. A number of EU countries have banned mercury, and even those which will not resort to

an outright ban, such as the UK, are advocating a policy of removing mercury sphygmomanometers from clinical medicine [6]. The Medical Device Agency has stated: "Although at present no ban has been imposed on the use of medical devices containing mercury in the UK, it is recommended that consideration is given to the selection of mercury-free devices where appropriate" [7]. The ESH Working Group must clarify its stance as to whether or not it supports the removal of mercury from clinical practice in the interests of patient and environmental safety.

Availability of accurate alternative devices

The Working Group has been urging manufacturers to develop suitable automated devices for clinical use [8]. Slow though manufacturers have been in responding to an obvious market, there are now three automated devices [9–12] that have fulfilled the criteria of the protocols of the British Hypertension Society [13] and the Association for the Advancement of Medical Instrumentation [14], and others are in the pipe-line. Two of these devices, the A & D UA-767 [11] and the Omron HEM-705CP [9,10], which were designed for self-measurement of blood pressure have been adapted for hospital use, and the Omron HEM-705CP is being used in the large multicentre Anglo-Scandinavian Cardiac Outcome Trial (ASCOT) [15].

However having an accurate automated alternative to the mercury sphygmomanometer begs another question. Does automated sphygmomanometry have the potential to give more accurate blood pressure measurements than the conventional auscultatory technique? Again, it is interesting to compare the American [1] versus the European [2] answer to this question. The European answer would be in the affirmative simply because conventional measurement is an inaccurate technique, which as the American statement acknowledges, requires training and re-training. Moreover, the European view acknowledges that automated devices can remove observer error and terminal digit preference, while also providing printouts of the measurement with the date and time of the measurement, and digital output that can be stored and plotted [2]. In fact it might be argued that the sooner we rid ourselves of the inaccurate conventional technique, on which we base so many important decisions of management, the better [2,16]. The American recommendation would appear to be contrary: "the general use of mercury manometers as the instrument of choice" is encouraged, but only "until other instruments are better validated" [1]. The two opinions are not irreconcilable – the European view is that at long last we may now have validated alternatives to the mercury sphygmomanometer [2,16], whereas the American view is that this stance is premature [1].

Leaving aside the issue of accuracy of automated devices, there are other factors which merit consideration. The

American statement rightly draws attention to the fact that electronic sphygmomanometers have not been subjected to use in the variety of clinical circumstances that pertain to busy hospitals [1]. The European view cautions that "the advent of accurate automated devices, however welcome, is not without problems... Oscillometric techniques cannot measure blood pressure in all situations, particularly in patients with arrhythmias, such as rapid atrial fibrillation, but there are also individuals in whom these devices cannot measure blood pressure for reasons that are not always apparent" [2]. There is also considerable concern about trusting algorithmic methods, which are so "zealously guarded by manufacturers" that they refuse to divulge how individual algorithms function [2].

The medical and nursing professions, which constitute the clinical market for blood pressure measuring devices, must insist that manufacturers provide us with accurate devices designed to our specifications, rather than accepting, as we have in the past, devices in which these considerations are secondary to the commercial success of the product. However, the Working Group has a role in this process. Firstly, it can facilitate manufacturers to have blood pressure devices independently validated for accuracy according to a rational protocol – towards this end, the Working Group is drafting an *International Protocol* [17]. There is then the problem of keeping track of devices being manufactured, and importantly, identifying those which have been validated and of keeping a record of the results of such validations. The Working Group published a 'state-of-the-market' paper in the *British Medical Journal* in 2000 [8], but this is already out-of-date. At the meeting of the Working Group in Milan in June 2001, it was agreed that an application would be submitted to the ESH seeking funding for a secretariat to perform this function on the ESH website, as this seems the only rational way of keeping abreast of a rapidly growing market.

Demise of the traditional auscultatory technique of blood pressure measurement

If we accept that automated devices will in time replace the traditional mercury or aneroid sphygmomanometers and the stethoscope, all of which are necessary for measuring blood pressure according to the Riva-Rocci/Korotkoff method, then we must also prepare for the disappearance of the clinical technique to which we are so accustomed. Indeed, the influence of automated devices on this long-serving measurement technique in clinical medicine is already apparent in the new generation of nurses and medical students. But might there not be more to the conventional auscultatory technique than meets the eye? The Riva-Rocci/Korotkoff technique may possess "that mystique peculiar to the clinical relationship, which is sensed by doctors and nurses and appreciated by patients" [2]. Could it be this feature which makes

clinicians so unhappy at having to relinquish the acquired skill inherent in the auscultatory technique, which for all its inaccuracies may possess subtle virtues "important in establishing the rapport from which a successful clinical relationship between doctor and patient may develop" [2]. This may or may not be the case, but it would seem reasonable to ask manufacturers of blood pressure measuring equipment to provide an electronic equivalent to the mercury column, so that the conventional auscultatory technique can live on. Indeed three such devices have been developed, though none has, as yet, been subjected to independent validation (Accusphyg, Accosan, and TNO, personal communications 2001) [6].

Replacement of the millimetre of mercury with the kilopascal

The inevitable disappearance of mercury raises a polemical issue, namely, replacing of the millimetre of mercury as the unit of measurement with the kilopascal. This issue will have profound international implications, and is therefore worthy of deliberation [18]. If in the course of some short time the mercury sphygmomanometer disappears, the mainstay of the medical argument for retaining the millimetre of mercury as a unit of measurement, namely that we measure what we see, will also disappear. There is then no scientific (as distinct from a clinical) argument against its replacement with the kilopascal. This issue, which remains high on the scientific agenda, will come to the fore when the mercury sphygmomanometer goes. In fact the debate might be said to have begun with MacGregor suggesting (with tongue in cheek, I suspect) that we should do away with both the millimetre of mercury and the kilopascal and return to the unitage used by the Reverend Stephen Hales over 250 years ago – inches (or centimetres) of blood [19]. The American response to this issue has been as follows: "We are concerned that this transition may create confusion in the minds of clinicians and their patients if implemented now. For the present, we suggest we focus our educational efforts on the important issue of systolic blood pressure control and focus our research efforts on validation of blood pressure instruments" [20]. Perhaps the Working Group should support this stance, but in doing so it would be wise to look back 20 years or so when the *Système International* (SI) units were introduced [18]. When it was proposed that the kilopascal should become the measure of pressure in medicine there was an indignant outcry from doctors, who claimed that the confusion resulting from such a change of unitage would be unacceptable. They won the day, but on the understanding that the moratorium would last only until such time as a suitable replacement could be found for the mercury sphygmomanometer (21,22).

How then should the medical profession react? It could fight for the retention of mercury for medical use but the

weight of argument from the environmentalists would overturn this tactic. It could then be argued that even if the mercury sphygmomanometer has to go, the introduction of the kilopascal into clinical practice would also be unacceptable because of the resulting chaos. However, the same line of reasoning was used unsuccessfully against the introduction of SI units into the biochemistry of medicine and, so again, is unlikely to succeed.

An alternative approach would be to anticipate and welcome the necessity for change. We could take the scientific view that a common unitage for pressure measurement is desirable and that in scientific terms there can be little justification for retaining the archaic millimetre of mercury, especially as it would no longer exist. Indeed one of the major sources of bias in blood pressure measurement is that the mercury unitage lends itself to tidy rounding which results in a huge digit preference for zero, which is to say the least, most unscientific. The kilopascal (kPa) does not lend itself as readily to such behaviour. For example, 90 mmHg is equivalent to 12.00 kPa, 100 mmHg to 13.33 kPa, 150 mmHg to 20.00 kPa, 160 mmHg to 21.33 kPa, 200 mmHg to 26.66 kPa, and so on. Indeed, if we take the scientific argument further, we would acknowledge that there is a remarkable lack of agreement internationally as to what constitutes hypertension and at which levels of blood pressure treatment should, or should not, be instigated (18). This being so, we could use the introduction of a new unit of measurement as an opportunity to prepare internationally agreed definitions of normotension and hypertension. Put another way, the opportunity for radical change would allow us to put our clinical house in order once and for all, and thereby serve the mainstay of our existence as clinicians – the patient. Perhaps the Working Group should encourage manufacturers to utilize to the full the capabilities of contemporary technology by having automated devices provide blood pressures in both millimetres of mercury and kilopascals so that users become familiar with the latter units.

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