Original Article

Alternatives to the mercury sphygmomanometer

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Abstract The mercury sphygmomanometer was introduced over 100 years ago. Mercury, however, is a potent human neurotoxin. An international effort has developed to eliminate health-care sources of mercury – the thermometer and sphygmomanometer – and replace them with less toxic alternatives. There is concern regarding the accuracy of these alternative devices. We conducted a literature review of articles published between 1995 and 2009 evaluating the accuracy of mercury, aneroid, and oscillometric blood pressure devices. Mercury sphygmomanometers fared the best although they do not always perform as expected, failing calibration tests between 1 and 28 per cent of the time. Up to 61 per cent of aneroid sphygmomanometers failed. Recently calibrated aneroid devices performed well. Oscillometric devices were less studied and their performance was variable. All three devices showed variable performance. They should be validated before purchase and calibrated on a regular basis.
Journal of Public Health Policy advance online publication, 25 November 2010; doi:10.1057/jphp.2010.38

Keywords: sphygmomanometer; blood pressure measurement; mercury pollution

Introduction

Mercury is one of the world's most ubiquitous heavy metal neurotoxins and a persistent environmental pollutant. From the human health disaster at Japan's Minamata Bay, in which hundreds

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of children were born with severe birth defects and developmental delays due to their mothers' ingestion of mercury-laden fish, to the more subtle effects on the developing nervous system found in children exposed to mercury from subsistence marine diets, the health effects of mercury exposure are significant. The United Nations Environmental Programme and World Health Organization have identified the adverse effects of mercury pollution as a serious global environmental and human health problem.[1]

The majority of environmental mercury contamination is due to emissions from industrial sources, including fossil fuels and waste combustion.[2] When released to the air, mercury is moved by global transport processes and deposited in waterways, where it accumulates in lake bottom sediments and is transformed into methyl mercury, which builds up in fish tissue.[3] In the United States, 30 per cent of lakes and wetlands are contaminated with mercury, causing 44 states to issue fish advisories recommending limits on the ingestion of locally caught fish by pregnant and nursing women and children.[4] Health-care facilities contribute to mercury pollution via breaks and spills of mercury-containing devices and via the burning of medical waste. In 1997, a United States Environmental Protection Agency study found that medical waste incinerators accounted for 10 per cent of anthropogenic mercury emissions to the US environment.[2]

Mercury sphygmomanometers, first developed over 100 years ago and largely unchanged since, are used in both hospital and ambulatory settings for the measurement of blood pressure. They are considered the 'gold standard' blood pressure measuring device from which treatment guidelines are developed.[5,6] Because of its prevalence – almost one-third of the American adult population has hypertension and another one-fourth exhibits pre-hypertension[5] – the measurement and control of blood pressure are key elements in the prevention of the devastating cardiovascular and neurovascular effects of chronic hypertension. Blood pressure readings are also used in the hospital setting to represent the cardiovascular and volume status of critically ill patients and those undergoing surgical procedures. Therefore, accurate readings are essential to quality patient care.

To address health-care facilities' contribution to global mercury contamination, international organizations have initiated efforts,

over the last several years, to eliminate the most common health-care sources of mercury – the thermometer and sphygmomanometer. Several countries, including Argentina, the Philippines, and Sweden, have banned or are phasing-out mercury blood pressure devices. The European Union is considering a ban. In 1998 the American Hospital Association agreed to eliminate all hospital uses of mercury by 2005.[7] This has led to the replacement of mercury sphygmomanometers by mercury-free blood pressure devices in many health-care settings in the United States.

The Seventh Report of the Joint National Commission on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[8] raised a long-standing concern over the accuracy of replacement blood pressure devices. In response to this concern, the US Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS) developed validation protocols for blood pressure devices.[9] Device manufacturers, the European Society of Hypertension, and the American Heart Association recommend bi-annual calibration of mechanical sphygmomanometers.[6,10] Nevertheless, uncertainty surrounding the accuracy of alternative blood pressure devices has led to reluctance on the part of health-care providers to replace mercury sphygmomanometers with alternatives less likely to contribute to environmental mercury pollution.

We address the issues surrounding the replacement of mercury-containing sphygmomanometers in the health-care setting. We review the types of alternative blood pressure devices, evaluate the current literature regarding their accuracy, and make recommendations on how to move forward to remove this potential pollutant from health-care practice while maintaining high-quality patient care.

Alternative blood pressure devices

The two commonly used alternatives to mercury sphygmomanometers are the aneroid and oscillometric devices. Aneroid (meaning 'without fluid') sphygmomanometers use mechanical parts to transmit the pressure in the cuff to a dial. As the cuff pressure rises, a thin brass corrugated bellows expands, triggering movement of a pin resting on the bellows. A series of gears amplifies this movement and transmits it to the dial where the blood pressure is read. As with

mercury devices, the observer inflates and deflates the cuff manually, then uses the traditional auscultatory technique to identify systolic and diastolic pressures.

Oscillometric devices, often referred to as automatic devices, do not require observer participation beyond placing the cuff on the arm and noting the digital blood pressure readout. The cuff inflates and deflates electronically. A transducer in the device senses the pressure wave generated by the brachial arterial wall and detects the point of maximum amplitude (the MAP) electronically. There are no obvious systolic and diastolic points on the pressure wave, therefore the device calculates the systolic and diastolic pressures electronically using an algorithm. There are dozens of devices on the market manufactured by different companies whose algorithms for translating the MAP into diastolic and systolic pressures are proprietary.

Literature Review Methods

To address the issue of mercury-free alternative blood pressure device performance, we evaluated the current literature on the accuracy of sphygmomanometers. We reviewed and compared the three types of blood pressure measurement devices: the mercury sphygmomanometer, the aneroid manometer, and the oscillometric device. We used the PubMed access service at the US National Library of Medicine, located at the US National Institutes of Health to search for articles published after 1994 using the search term 'sphygmomanometer accuracy' and accessing the 'Related links' from the results webpage. We then used the ISI Web of Knowledge/Web of Science search engine for follow-up searches with the terms 'sphygmomanometer accuracy' and 'blood pressure monitor' + 'accuracy' to identify articles not listed in the PubMed search. We did not consider articles published before 1994, because sphygmomanometer technology has advanced in the past 15 years and studies using earlier models might not reflect current device performance.

We included articles if they evaluated the accuracy of mercury, aneroid, or oscillometric sphygmomanometers. We excluded studies evaluating specific brands of devices, as well as those that did not report results by device type. Blood pressure devices used for ambulatory monitoring and those specifically for home use were not

included. Seventeen peer-reviewed articles remained for analysis. We did not consider editorials, position papers, or review articles in our 'weight of evidence' review.

Results of literature review

Table 1 shows studies that compare mercury devices to aneroid devices. Most of the authors tested the devices by connecting the tested device (mercury or aneroid) to a standardized mercury manometer via a Y-connector tube or by taking sequential blood pressure measurements, alternating the tested device with a calibrated mercury device.

Because the mercury sphygmomanometer is considered the 'gold standard' used to determine treatment recommendations, many assume that these devices are always accurate. Results in Table 1 show that while aneroid devices often performed poorly and always worse than the mercury devices to which they were compared, mercury devices also gave unacceptable results, failing up to 28 per cent of the time.

Table 2 includes studies that evaluated oscillometric devices not limited to one brand or model. The literature is scant and methods are not robust. Because oscillometric devices calculate the systolic and diastolic pressures from a proprietary computerized algorithm, research on their accuracy is difficult. One study did compare blood pressure readings to a standard by over-riding the electronic inflation and deflation sequence.[19] The oscillometric device performed adequately. Dozens of other studies have been performed on individual models of oscillometric devices, and their results are not included here. This literature review of device comparisons shows that none of the three types of devices is consistently accurate.

Device maintenance (assessment of wear and tear), validity and calibration, and observer bias all affect device accuracy. Regarding device wear and tear, Markandu *et al* performed a survey of blood pressure devices in a large teaching hospital in London, inspecting mercury sphygmomanometers for visibility of the mercury meniscus, appropriate zeroing, clarity of the markings, and whether the mercury column contained debris.[23] They found that 38 per cent of mercury devices had dirty mercury columns, 8 per cent of cuffs were 'worn out', damaged, or had splits, 35 per cent of Velcro cuffs

Table 1: Comparison of mercury devices with aneroid devices

Citation	*Setting*	*Devices tested*	*Outcome*
Waugh *et al*[11]	British hospitals	*n*=36 mercury, 39 aneroid	22 per cent mercury, 42 per cent aneroid readings were $\geqslant$4 mmHg from calibrated mercury standard
Mion and Pierin[12]	Brazilian hospitals, clinics	*n*=320 mercury, 204 aneroid	21 per cent mercury devices were uncalibrated (mercury meniscus did not rest at 0), 58 per cent aneroid $>$3 mmHg from calibrated mercury standard
Knight *et al*[13]	English clinics	*n*=356 mercury, 116 aneroid	28 per cent mercury, 61 per cent aneroid devices failed to meet study protocol standards for accuracy
Ashworth *et al*[14]	London clinics	*n*=130 mercury, 61 aneroid	2 per cent mercury, 15 per cent aneroid devices were $\geqslant$4 mmHg from new mercury device
Ali and Rouse[15]	Birmingham, England clinics	*N*=139 devices	1 per cent mercury, 10 per cent aneroid $>$10 mmHg from the calibrated mercury device
Shah *et al*[16]	Australian clinics	*N*=404 devices	Over a range of 7 pressures, mercury devices were more accurate than aneroid ($P<0.01$) when compared to a new mercury device
Moore *et al*[17]	Connecticut clinics	*N*=280 aneroid	33 per cent aneroids $>$3 mmHg different from the standard mercury manometer
Kim *et al*[18]	North Carolina clinic	*N*=100 hypertensive patients	Measurements were taken with either an oscillometric or aneroid device then with a calibrated mercury device up to 90 min later. The mean difference was 8.3 mmHg for SBP and 7.1 mmHg for DBP
Coleman *et al*[19]	London clinics	*N*=279 devices	13 per cent mercury, 53 per cent aneroid $>$3 mmHg different than electronic pressure gauge

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Table 2: Studies evaluating oscillometric devices

Citation	*Setting*	*Devices tested*	*Outcome*
Coleman *et al*[19]	London clinics	*N*=279 devices	4.5 per cent >3 mmHg different than electronic pressure gauge
Gill *et al* [20]	Urban Brazil	400 patients	Oscillometric device was 'gold standard', aneroid significantly under-read BP, mercury device significantly over-read BP
Jones *et al*[21]	North Carolina Emergency Department	*N*=100 patients	The mean difference between mercury and oscillometric devices was 4.3 mmHg for SBP, 1.3 mmHg for DBP
McManus *et al*[22]	General Practices, England	*N*=1521 patients	No statistically significant changes in systolic and diastolic pressures before versus after the phase-out of mercury devices

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did not stick well enough to resist bursting apart on inflation above 180 mmHg, and seven cuffs contained the wrong size bladder for the cuff. In a different type of study where the authors evaluated newer aneroid devices compared to an electronic pressure gauge, only 4 percent of the aneroid sphygmomanometers failed the calibration protocol (readings within 3 mmHg of the standard).[24] The average difference of all readings from the electronic pressure gauge was 0.2 mmHg. The mean age of the devices in the study was 5 years, perhaps indicating that 'newer' devices can perform adequately.

The sphygmomanometers evaluated in the studies shown in Table 1 had not undergone regular calibration as recommended by the American Heart Association,[5] the European Society of Hypertension,[6] and the JNC VII guidelines.[8] We found two studies that evaluated the accuracy of aneroid sphygmomanometers undergoing regular maintenance and calibration. The Mayo Clinic instituted a four-point maintenance protocol in 1993 that included annual visual inspection of devices for damage, assessment of the position of the needle at zero, and an evaluation of accuracy over a range of 10 readings compared to a digital pressure gauge.[25] In a survey conducted 5 years after implementation of the maintenance protocol, all readings were within 4 mmHg of the digital pressure gauge. In another study of calibrated aneroid devices, investigators of a large diabetes clinical trial evaluated their aneroid devices owing to the concern that the change from mercury to aneroid sphygmomanometers would affect the analysis of their longitudinal outcomes.[26] All aneroid devices were calibrated at the beginning of the comparative evaluation using a digital pressure gauge. Sequential blood pressure measurements taken with a mercury standard and the aneroid test device did not show a clinically significant difference in the mean readings between the two devices.

Oscillometric devices are not required to undergo validation before entering the marketplace; Sims *et al* surveyed device manufacturers of automated models available on the European market and found that out of 116 models identified, only 12 had undergone clinical validation.[27] The lack of validation data has led to uncertainty about the accuracy of these devices. To address this concern, summaries of peer-reviewed validation studies for sphygmomanometers have been published by the Working Group on Blood Pressure Monitoring of the European Society of Hypertension.[9]

A device is *recommended* if it fulfills both the AAMI and BHS criteria. In addition, an on-line resource has been developed by the dabl Education Trust to serve as a 'clearing house' for information on validated devices, at www.dableducational.org.[28] The site includes tables of recommended models and a library of articles and manuscripts on device validation. Currently, eight manual models (mercury, aneroid, and electronic) and 10 oscillometric models are recommended. The European Hypertension Society (EHS) and the BHS also publish tables of validated devices on their websites.[29,30]

Any evaluation of the accuracy of blood pressure devices must take into consideration observer inaccuracy. Blood pressure measurements taken with manual devices (mercury and aneroid sphygmomanometers) are dependent on the person who makes the measurement. Random digit preference, observer bias, and 'white coat hypertension' may lead to blood pressure readings that are not an accurate reflection of a patient's daily blood pressure. Studies of terminal digit preference show that observers favor rounding off to the nearest 10 mmHg, 5 mmHg, and even versus odd numbers.[15] Myers *et al* elegantly illustrated the effect of white coat hypertension in a study of 50 patients from a hypertension clinic who had blood pressure readings taken by a health-care provider followed by five more readings taken by an oscillometric device without any health professional in the room.[31] Mean readings taken with the automated device while the patient was alone in the exam room were significantly lower ($P < 0.001$), up to 20 mmHg for systolic and 10 mmHg for diastolic readings compared to the measurements taken by the provider. This illuminates the advantages of oscillometric devices: they can remove the effect of white coat hypertension while removing observer bias, including digit preference.

Discussion

Because of the simple construction of the mercury sphygmomanometer and the straightforward physical properties of mercury, there is little dispute that a new or calibrated mercury sphygmomanometer is very likely to accurately reflect the true pressure. As such, historically, it is the recommended 'gold standard' used in the validation and calibration of mercury free alternatives. However, this review of the recent literature on sphygmomanometer accuracy

includes several studies that show that mercury devices can be significantly inaccurate, up to 28 per cent in one survey. Clearly, to assure accuracy, mercury sphygmomanometers must undergo regular maintenance and calibration checks that are frequently lacking in clinical practice.

In comparison with uncalibrated mercury devices, uncalibrated aneroid sphygmomanometers resulted in even higher percentages of inaccurate readings. Even though the calibration criteria varied, most studies showed that many aneroid devices fail to meet currently accepted standards. Only one study showed aneroid device error rates less than 5 per cent. Over time aneroid devices may be susceptible to damage owing to their multiple small, moving parts. In studies that tested recently calibrated or newer aneroid devices,[24–26] they performed well. Mean differences from the comparison devices were all <1 mmHg., showing that aneroid devices undergoing regular calibration are likely to be accurate. More research to solidify the evidence that regular maintenance leads to acceptable performance of aneroid sphygmomanometers is needed.

Oscillometric devices do not require a trained observer and are therefore popular for home use. They may also remove the effects of white coat hypertension and terminal digit preference. They will likely continue to increase in popularity. But the majority of oscillometric devices are marketed and sold without undergoing rigorous validation, raising suspicion about these devices among many practitioners.[32] The availability of 'clearinghouse' websites and publications are helpful as central repositories of device information and recommendations. More transparency with respect to algorithms for calculating the systolic and diastolic pressure from the MAP would allow for validation studies that might improve their accuracy. Questions surrounding their accuracy when used in diabetics, the elderly, pregnant women, and in those with arrhythmias[5] should be addressed.

Must mercury manometers be used for validation and calibration of non-mercury devices? It appears that an electronic pressure gauge provides considerably more reliability than a mercury manometer. The Emergency Care Research Institute recommends calibration with a digital pressure gauge as the most accurate manometric device.[33] The American Heart Association also recommends that the calibration standard be a either a mercury sphygmomanometer or an

electronic pressure gauge.[5] Therefore, for health-care systems aiming to completely eliminate mercury, electronic pressure gauges are an acceptable alternative to the mercury manometer.

Conclusions

Environmental mercury is converted to a neurotoxin that can cause health effects at extremely low levels, and therefore mercury use is discouraged where possible. The World Health Organization and other international bodies are committed to removing mercury-containing devices from health-care settings to avoid the potential for environmental pollution.[34] Several countries have completely replaced mercury sphygmomanometers with alternative devices.[35] In this article we reviewed the accuracy of mercury-free blood pressure devices and we conclude the following:

Instrument validation: a new or recently calibrated mercury or aneroid sphygmomanometer is very likely to be valid. Health-care providers should not assume older devices to be so. Manufacturers should validate and certify aneroid devices. The accuracy of these devices may diminish with wear and tear, therefore health-care organizations should replace poorly performing devices or return them to the manufacturer for repair.

Most oscillometric devices on the market have not been validated by their manufacturers. Manufacturers should be required to conduct adequate validation of their instruments, and consumers should be made aware of the quality difference between validated and non-validated models. Patients and providers should purchase only validated devices. Several resources exist for updated information on validated models. Concerns about use of oscillometric devices in the elderly, during pregnancy, or in those with arrhythmias need to be resolved.

Instrument calibration: According to the current literature, few of the three types of blood pressure devices are being calibrated on a regular basis.[13,14,36,37] Properly calibrated and maintained aneroid sphygmomanometers are likely to be equally or more accurate than mercury devices. Health-care organizations should perform routine calibration of mercury and aneroid devices on an annual basis, and they should consider checking portable devices, which are more prone to bumping and dropping, on a bi-annual schedule.

In summary, mercury sphygmomanometers are not scientifically necessary for calibration, validation, or measurement of blood pressure. Alternative devices are either equally or more accurate when maintained properly and are likely to be far less toxic to workers and the environment. All health-care institutions should implement routine calibration and maintenance checks of all blood pressure devices to guarantee that critical health-care decisions are made based on accurate readings, and they should consider removing all mercury-containing manometers, including those used for calibration and validation.

Acknowledgement

Health Care Without Harm funded this work via a grant from the Robert Wood Johnson Foundation.

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