Alternatives to the mercury sphygmomanometer

Buchanan, Orris, Karliner

Introduction

Mercury is one of the world's most ubiquitous heavy metal neurotoxicants and is considered a persistent environmental pollutant. From the human health disaster at Japan's Minamata Bay, in which hundreds 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 Environment Programme (UNEP) 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% of U.S. 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 (EPA) study found that medical waste incinerators accounted for 10% 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] Since 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. In addition, blood pressure readings are 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 also 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.

However, 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) have developed validation protocols for blood pressure devices.[9] In addition, 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 that are less likely to contribute to environmental mercury pollution.

The purpose of this paper is to 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, so 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

In order to address the issue of the performance of mercury-free alternative blood pressure devices, we evaluated the current literature on the accuracy of sphygmomanometers. We reviewed and compared the three main 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 (NLM), located at the US National Institutes of Health (NIH) 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 since 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. A total of 17 peer-reviewed articles remained for analysis. We did not consider editorials, position papers, and review articles in this ‘weight of evidence’ review.

Results of literature review

Table 1 shows studies which 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. Since the mercury sphygmomanometer is considered the “gold standard” used to determine treatment recommendations, many assume that these devices are always accurate. But the 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% 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. Since oscillometric devices calculate the systolic and diastolic pressures from a computerized algorithm that is proprietary, research on their accuracy is difficult. Only one study compared 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.

The issues of 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] Authors found that 38% of mercury devices had dirty mercury columns, 8% of cuffs were “worn out”, damaged, or had splits, 35% of Velcro cuffs did not stick well enough to resist bursting apart on inflation above 180 mmHg, and seven cuffs contained the wrong size bladder for the size of the cuff. In a different type of study where the authors evaluated newer aneroid devices compared to an electronic pressure gauge, only four percent of the aneroid sphygmomanometers failed the calibration protocol (readings

within 3mmHg of the standard).[24] The average difference of all readings from the electronic pressure gauge was 0.2mmHg. 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 five years after implementation of the maintenance protocol, one hundred percent of the readings were within 4mmHg of the digital pressure gauge. In another study of calibrated aneroid devices, investigators of a large diabetes clinical trial evaluated their aneroid devices due to 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.[24] The lack of validation data has led to uncertainty regarding 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 d*abl* 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 ten oscillometric models are recommended. The 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 the manual devices (mercury and aneroid sphygmomanometers) are dependent on the human element. 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 10mmHg, 5 mmHg, and even vs. 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 ($p<.001$), 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 also 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% 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 these uncalibrated mercury devices, uncalibrated aneroid sphygmomanometers resulted in even higher percentages of inaccurate readings. Even though the calibration criteria varied, the majority of studies showed that many aneroid devices fail to meet currently accepted standards. Only one study showed aneroid device error rates less than 5%. It has been hypothesized that aneroid devices are susceptible to damage with time due to their multiple small, moving parts. In the studies that tested

recently calibrated or newer aneroid devices,[24,25,26] aneroid devices performed well. Mean differences from the comparison devices were all <1mmHg. These studies show 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 also may remove the effect of white coat hypertension and terminal digit preference. As such they will likely continue to increase in popularity. However, the majority of oscillometric devices are marketed and sold without undergoing rigorous validation. This has led to a suspicion of these devices among many health care 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 would improve their accuracy. Some have raised questions surrounding their accuracy when used in diabetics, the elderly, pregnant women as well as those with arrhythmias,[5] and these issues should be addressed.

Regarding the use of mercury manometers 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 (ECRI) recommends calibration with a digital pressure gauge as the most accurate manometric device.[33] Also, the American Heart Association recommends that the calibration standard

be a either a mercury sphygmomanometer or an electronic pressure gauge.[5] Therefore, for those healthcare 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 its 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 that soon will become the norm worldwide.[35] In this paper 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. Healthcare 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, so healthcare organizations should replace poorly performing devices or return them to the manufacture 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 alike should purchase only validated devices, and there are several resources for updated information on validated models. There is some concern regarding use of oscillometric devices in the elderly, during pregnancy, or in those with arrhythmias, and more research is needed to address this.

Instrument Calibration: According to the current literature, few to none 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. Healthcare 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 have far less occupational or environmental toxicity. All health care institutions should implement routine calibration and maintenance checks of all blood pressure devices to guarantee that critical health care decisions are being made based on accurate readings, and they should consider removing all mercury-containing manometers, including those used for calibration and validation.

References

1. United Nations Environmental Programme, *Global Mercury Assessment*, UNEP Chemicals, Geneva, December 2002.

2. United States Environmental Protection Agency. Mercury Study Report to Congress. Volume II:An Inventory of Anthropogenic Mercury Emissions in the United States. EPA-452/R-97004, Table ES-3, December 1997.

3. Health Canada 2009. Mercury. Your Health and the Environment. Available at http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/q47-q56_e.html. Accessed 10/20/09.

4. United States Environmental Protection Agency. Environmental Effects: Fate and Transport and Ecological Effects of Mercury. 2009. Available at http://www.epa.gov/mercury/eco.htm. Accessed 4/20/09.

5. Pickering TG, Hall JE, Appel LJ, Falkner B,Graves J, Hill M et al. Recommendations for blood pressure measurement in humans and experimental animals, part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. Hypertension 2005;45:142-161.

6. O'Brien E, Asmar R, Beilin L, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. J Hypertens. 2003;21(5):821-848.

7. Hospitals for a Healthy Environment.2009. Regulated Medical Waste Reduction.http://www.h2e-online.org/. Accessed 2/3/09.

8. National Heart, Blood and Lung Institute. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure: US Department of Health and Human Services; August 2004. http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf. Accessed 2/18/09.

9. O'Brien E , Waeber B; Parati G, Staessen J, Myers MG. Blood pressure measuring devices: recommendations of the European Society of Hypertension. Brit Med J. 2001;322:531-536.

10. Jones D, Frohlich E, Grim C, Grim C, Taubert K. Mercury sphygmomanometers Should not be abandoned: an advisory statement from the Council for High Blood Pressure Research, American Heart Association. Hypertension 2001;37:185-186.

11. Waugh J, Gupta M, Rushbrook J, Halligan A, Shennan AH. Hidden errors of aneroid sphygmomanometers. Blood Press Monit. 2002;7(6):309-312.

12. Mion D, Pierin AMG. How accurate are sphygmomanometers? J Hum Hypertens. 1998;12:245-248.

13. Knight T, Leech F, Jones A, et al. Sphygmomanometers in use in general practice: an overlooked aspect of quality in patient care. J Hum Hypertens. 2001;15:681-684.

14. Ashworth M, Gordon K; Baker G, Deshmukh A. Sphygmomanometer calibration: a survey of one inner-city primary care group. J Hum Hypertens. 2001;15:259-262.

15. Ali S and Rouse A. Practice audits: reliability of sphygmomanometers and blood pressure recording bias. J Hum Hypertens. 2002;16:359-361.

16. Shah N, Sibbritt D, Heaney S, Sharples J. Sphygmomanometers. An audit in general practice. Aust Fam Phys 2004;33:952-954.

17. Moore T, Sorokin A, Hirst C, Thornton-Thompson S, Thompson P. The accuracy of aneroid sphygmomanometers in the ambulatory setting. Prev Cardiol Spring 2008:90-94.

18. Kim J, Bosworth H, Voils C, Olsen M, Dudley T, Gribbin M et al. How well do clinic based blood pressure measurements agree with the mercury standard? J Gen Intern Med 2005;20:647-649.

19. Coleman AJ, Steel DS, Ashworth M, Vowler SL, Shennan A. Accuracy of the

Pressure scale of sphygmomanometers in clinical use within primary care. Blood Press Monit. 2005;10(4):181-188.

20. Gill G, Ala L, Gurgel R, Cuevas L. Accuracy of aneroid sphygmomanometer blood pressure recording compared with digital and mercury measurements in Brazil. Trop Doct 2004;34:26-27.

21. Jones D, Engelke M, Brown S, Swanson M. A comparison of two noninvasive methods of blood pressure measurement in the triage area. J Emerg Nurs 1996;22:111-5.

22. McManus R, Mant F, Hull M, Gobbs F. Does changing from mercury to electronic blood pressure measurement influence recorded blood pressure? An observational study. J Gen Pract 2003;53:953-956.

23. Markandu ND, Whitcher F, Arnold A, Carney C. The mercury sphygmomanometer should be abandoned before it is proscribed. J Hum Hypertens. 2000;14:31-36.

24. Yarows SA, Qian K. Accuracy of aneroid sphygmomanometers in clinical usage: University of Michigan experience. Blood Press Monit. 2001;6(2):101-106.

25. Canzanello VJ, Jensen PL, Schwartz GL. Are aneroid sphygmomanometers accurate In hospital and clinical settings? Arch Intern Med. 2001;161:729-731.

26. Ma Y, Temprosa M, Fowler S, Prineas RJ, Montez MG, Brown-Friday J, Carrion Petersen ML, Whittington T. Evaluating the accuracy of an aneroid sphygmomanometer in a clinical trial setting. Am J Hypertens. 2008:1-4.

27. Sims AJ, Menes JA, Bousfield DR, Reay CA, Murray A. Automated non-invasive Blood pressure devices: are they suitable for use? Blood Press Monit. 2005;10:275-281.

28. O'Brien E. A website for blood pressure monitoring devices: dableeducational.com. Blood Press Monit. 2003b;8:177.

29.Reims HM KS, Mancia G. Home blood pressure monitoring. European Society of Hypertension Scientific Newsletter: Update on hypertension management. Vol 6; 2005.

30. British Hypertension Society. Validated Blood Pressure Monitor List. www.bhsoc.org/blood_pressure_list.stm. Accessed 3/4/09.

31. Myers MG, McInnis NH, Fodor GJ, Leenen FHH. Comparison between and Automated and manual sphygmomanometer in a population survey. Am J Hypertens. March 2008;21(3):280-283.

32. Heinemann M, Sellick K, Rickard C, Reynolds P, McGrail M. Automated versus Manual blood pressure measurement: A randomized crossover trial. Int J Nurs Pract. 2008;14:296-302.

33. Emergency Care Research Institute. Replacing Mercury-Column Sphygmomanometers. Health Devices 2003;32:109-117.

34. World Health Organization. Department of Protection of the Human Environment Water, Sanitation and Health. Mercury in Health Care. August 2005.

35. Health Care Without Harm. End Of An Era. The phase-out of mercury-based blood pressure measurement devices in the United States and its implications for Europe and the rest of the world. 2008. http://www.noharm.org/details.cfm?type=document&ID=2030. Accessed on 4/3/09.

36. Carney SG, AHB; Green, SL; Paterson, O; Taylor, MS; Smith, AJ. Hospital blood pressure measurement: Staff and device assessment. *Qual Clin Practice.* 1999;19:95-98.

37. Rouse AM, T. The extent and implications of sphygmomanometer calibration error in primary care. *J Hum Hypertens.* 2001;15:587-591.