The Accuracy of Alternatives to Mercury Sphygmomanometers

OCTOBER 2009

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EXECUTIVE SUMMARY

The mercury sphygmomanometer was first introduced over 100 years ago and has not changed much since then. Due to the move towards removal of mercury from health care settings, alternatives to the mercury sphygmomanometer are in common use in many hospitals and clinics. Concern has been voiced regarding the accuracy of these alternative devices. This monograph comprises a review of the medical literature that evaluates the accuracy of mercury, aneroid, and oscillometric blood pressure devices. Articles published between 1995 and 2009 were included. Seventeen articles met the inclusion criteria.

Mercury sphygmomanometers were not as unfailingly accurate as often expected. Failure rates using various validation, calibration and inspection protocols ranged from 1% to 28%. Aneroid sphygmomanometer accuracy also varied widely, failing calibration tests between 4 and 61% of the time in this literature. Both the mercury and aneroid sphygmomanometers evaluated in the studies had not undergone the recommended regular maintenance and calibration. As to potential substitution of aneroid for mercury devices, recent articles reported that when aneroid devices were calibrated and maintained appropriately, they performed equally or better than mercury devices.

Oscillometric devices were understudied and their performance was variable. Proprietary algorithms to calculate systolic and diastolic pressure from the mean arterial pressure confound the assessment of these devices. However, validated oscillometric devices with digital displays have been demonstrated to be accurate and provide the possibility of removing inter-observer differences in blood pressure measurement. While early data is promising, as yet these devices have not been validated for all clinical conditions.

Although most professional organizations still require mercury for validation protocols, electronic pressure gauges offer superior accuracy and should be substituted for mercury manometers for calibration and validation. Organizations that publish validation and calibration protocols should immediately re-evaluate their recommendations regarding the use of mercury devices.

I. INTRODUCTION

The accurate measurement and control of blood pressure are key elements in the prevention of cardiovascular disease and stroke. Mercury sphygmomanometers, first developed over 100 years ago and largely unchanged since, are used in both hospital and ambulatory settings. They have been considered the 'gold standard' blood pressure measuring devices from which treatment guidelines are developed (O'Brien et al. 2003a, Pickering et al. 2005).

A typical mercury sphygmomanometer

However, mercury has been found to be a potent human neurotoxin. Environmental mercury pollution, mainly from industrial sources such as coal-fired power plants and trash incineration, enters waterways via industrial run-off or settling of airborne particulate matter. It is metabolized by microorganisms into methyl mercury, which then accumulates in fish. In the United States, this has contaminated 30% of U.S. lakes and wetlands, causing 44 states to issue fish advisories recommending limits on the ingestion of locally caught fish by pregnant and nursing women and children. (USEPA 2009) As health care facilities contribute to mercury pollution via breaks and spills and the burning of medical waste, an international effort has developed over the last several years to eliminate the most common health care sources of mercury – the thermometer and sphygmomanometer.

The first indirect blood pressure device utilizing a mercury manometer was developed by Italian physician Scipione Riva-Rocci in 1896 (Roguin 2006). In 1905, Nikolai Korotkoff introduced the auscultory technique, which replaced arterial palpation and established the presence of the diastolic pressure. Indirect blood pressure monitoring has not changed much since that time. Mercury sphygmomanometers are of relatively simple design, consisting of a column of mercury connected by rubber tubing to a manually inflated cuff. Blood pressure is read using the auscultatory technique, using Korotkoff sounds I and V to identify systolic and diastolic pressure readings.

A typical aneroid sphygmomanometer

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. This movement is amplified by a series of gears and transmitted to the dial where the blood pressure is read. As with mercury devices, the cuff is inflated and deflated manually and the traditional auscultatory technique is used 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 is inflated and deflated electronically. The pressure wave generated by the brachial arterial wall is sensed by a transducer in the device. As the cuff pressure is released the pressure wave amplitude increases and peaks at the mean intra-arterial pressure (MAP), then decreases again. The point of maximum amplitude (the MAP) is detected by the oscillometric device. There are no obvious SBP and DBP points on the pressure wave, so the systolic and diastolic pressures are calculated electronically using an algorithm. For example, systolic blood pressure might be calculated as the point of 50% MAP and the diastolic at 80%, or the ratios might be 40% for SBP and 5% for DBP (Jilek and Fukushima 2005). The results are then displayed on the digital readout. There are hundreds of devices on the market manufactured by different companies whose algorithms for translating the mean arterial pressure into diastolic and systolic pressures are proprietary. Information regarding specific algorithms used with specific devices is not available.

There are also "semi-automated" or hybrid devices that combine aspects of both the auscultatory and automatic devices. An electronic pressure gauge reads the pressure in the deflating cuff. The observer identifies the systolic and diastolic pressure via the Korotkoff sounds and reads the digital display (Pickering 2001).

In 2003, the World Health Organization (WHO) established guidelines for devices for use in low-resource settings (Parati et al. 2005). Electronic, automatic devices are preferred to avoid human error with the auscultatory technique. Power should be solar- charged to avoid the need for batteries or a power source. Manual inflation is preferred to save on power. A commercial device meeting the WHO specification for use in low-resource settings has been developed and validated (de Greef et al. 2008).

A typical oscillometric sphygmomanometer

The Seventh Report of the Joint National Commission on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII) (NHBLI 2004) confirmed a long-standing concern over the accuracy of mercury-free 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 (O'Brien et al 2001). Under these protocols, blood pressure is measured in patients representing a range from low to high. The blood pressure is taken sequentially (30-60 seconds apart) with a standard mercury sphygmomanometer and with the test device by a trained observer. The difference in pressure reading between the mercury standard and the test device is calculated for each reading. The validation result is then reported as the number of readings within an acceptable mean range of error.

The BHS protocol includes five stages in its validation process (O'Brien et al 1993). First, the test device calibration is assessed by connecting it to a calibrated mercury sphygmomanometer via a Y-connector. The cuff is then placed around a rigid cylinder, inflated, and the pressure readings are compared between the test device and the mercury standard over the range 0-300 mmHg. At least 28/30 comparisons must be within 3 mmHg. If the device passes, it then goes on to the static validation. Blood pressure readings taken in 85 subjects are compared. The BHS protocol uses a grading scheme from A to D. Devices are considered validated if they receive a grade of A or B, meaning 50% of systolic and diastolic readings fall within 5mmHg of the mercury standard, 75% are within 10 mmHg, and 90% are within 15mmHg of the mercury standard.

Validation under the US AAMI is similar in that it also requires comparison of blood pressure readings in 85 patients using a standard mercury manometer and the test device. Readings with the two devices are taken simultaneously instead of sequentially. To "pass" the validation test, the mean difference in readings between the test device and the mercury standard must not be >5mmHg or have a standard deviation > 8mmHg for diastolic and systolic readings separately (Sun and Jones 1999, ANSI 2008).

A simpler protocol requiring fewer subjects and fewer readings has been developed recently by the European Society of Hypertension (O'Brien et al. 2002), but it has been questioned due to a reduction in the statistical power to determine accuracy (Friedman et al. 2008). This protocol, called the International Protocol, requires 33 subjects, each of whom undergo nine sequential blood pressure measurements. Devices are eliminated in stages. The first stage uses only 15 subjects. Devices fail if less than 25 of 45 comparisons (between the mercury standard and the test device) fall within 5mmHg of each other *or* less than 35 comparisons are more than 10 mmHg different *or* 40 comparisons are >15 mmHg different. All 33 subjects are used in the next two stages, and similar but more stringent criteria are applied.

A field validation protocol has been suggested by Naschitz et al called READ: Rapid Evaluation of Automatic Devices (Naschitz et al.1999, 2000). This method is similar to standard validation techniques, but uses fewer subjects and employs a tilt test to gain a wider range of blood pressures in each subject with which to validate the device. The Japanese Standards Organization (ISO-WG) has proposed an alternative to the sequential and simultaneous arm measurements traditionally used in validation protocols (Shirasaki et al. 2007). Four simultaneous readings are taken in both arms of the subject, switching arms each time. This allows for fewer measurements in each subject and compensates for the blood pressure difference between the right and left arms.

Annual or bi-annual calibration of mechanical instruments has been recommended by device manufacturers, the European Society of Hypertension (O'Brien et al. 2003), and the American Heart Association (Jones et al. 2001). The calibration procedure involves checking pressure readings between a standard pressure meter, either a digital pressure gauge or a mercury sphygmomanometer and the test device, using a Y-connector to the cuff which is wrapped around a rigid cylinder. The BHS recommends devices measure within 4 mmHg of the standard mercury manometer device, while the British Standards Institute recommends mean reading be within 3 mmHg of all calibration points (Knight et al. 2001). The AAMI recommends devices be calibrated to within 3 mmHg of the standard test device (Sun and Jones 1999). The American Heart Association recommends that readings should be within 4 mmHg at 100 and 200 mm Hg inflation levels (Pickering et al. 2005). The WHO recommends device calibration every 6 months (WHO 2005a).

This paper evaluates the current literature on the accuracy of sphygmomanometers. The three main blood pressure measurement devices, the mercury sphygmomanometer, the aneroid manometer, and the oscillometric device, are reviewed. Because technological advances in the construction of aneroid and oscillometric devices over time may have improved their accuracy, only articles published after 1994 are included. Articles and commentaries on sphygmomanometer validation and calibration technique, and device accuracy, are subsequently discussed.

II. METHODS

The PubMed access service at the US National Library of Medicine (NLM), located at the US National Institutes of Health (NIH) was used for the literature search. The ISI Web of Knowledge/Web of Science search engine was used for follow-up searches. A search for articles published after 1994 was performed on PubMed using the search term "sphygmomanometer accuracy." Articles published before 1994 were not considered since sphygmomanometer technology has advanced in the past 15 years and studies using earlier models might not reflect current device performance.

Eighty-seven abstracts were reviewed for appropriateness. Articles were included if they evaluated the accuracy of mercury, aneroid, or oscillometric sphygmomanometers. Studies evaluating specific brands of devices were excluded, 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.

For each article included in the final literature review, the "Related Articles" link from the PubMed results webpage was accessed in order to identify additional articles that may not have been listed in the original search. Subsequently, the bibliographies of all articles included in the literature review were reviewed, and any additional articles not already included were obtained.

ISI Web of Knowledge/Web of Science was then searched with the terms "sphygmomanometer accuracy" and "blood pressure monitor" + "accuracy" to identify articles not listed in the PubMed search. Among articles in the final group for inclusion in this review, several were found to be inappropriate because they evaluated specific brands of devices or did not report results by device type. A total of 17 peer-reviewed articles remained for analysis. Editorials, position papers, and review articles were not considered in this weight of evidence review, but a selection of commentaries are included below.

III.

RESULTS

Studies assessing device accuracy used two types of assessment methods. "Instrument testing" is when the device to be tested is connected to a standard manometer and the difference in readings over several set points is calculated. "Performance testing" is used to compare blood pressure device readings by evaluating results in a sample of patients.

Studies comparing mercury with aneroid devices

A British hospital survey of blood pressure devices currently in use in their facility (n=36 mercury devices, 39 aneroid devices) found that 67 devices appeared to be in good working order (no leaks, mercury column at 0, cuff intact) (Waugh et al. 2002). Those that were found to be in good working order were connected via a three-way tubing system to an inflation device and two recently calibrated mercury columns. Five predetermined test points were identified during deflation, and two observers, blinded to each other's readings, recorded the readings from one of the calibrated mercury devices and the test device, respectively. Twenty-two percent of readings from mercury sphygmomanometers were >= 4mmHg different than the calibrated mercury standard. Forty-two percent of aneroid readings were >= 4 mmHg different than the calibrated mercury standard, and 19% of the aneroid devices had average errors greater than >5mmHg (vs. 3% of mercury devices, p <0·05). Authors recommended that all equipment used for blood pressure measurement be checked for accuracy on a regular basis.

Private practices and one hospital were included in a Brazilian survey of blood pressure devices (Mion and Pierin 1998). A total of 320 mercury sphygmomanometers were evaluated by visual inspection (meniscus at 0, legibility of the gauge, bouncing of the column of mercury during inflation and deflation, and permeability of the filter at the top of the column of mercury). When compared to a calibrated mercury manometer connected to it with a Y-connector and to a rubber pump, 21% failed. (Devices were considered calibrated if the error was <= 3 mmHg.) Fifty-eight percent (n=204) of aneroid devices failed calibration testing. Authors noted that both aneroid and mercury sphygmomanometers showed a high incidence of inaccuracy and reinforce that devices must be checked regularly.

Knight et al surveyed 86 outpatient practices in England and evaluated devices according to a protocol of quality checks that included visual inspection of the manometer tube, rubber hose, and bulb looking for condition of the fittings, discoloration, and legibility (Knight et al. 2001). Zero pressure and gauge accuracy were also recorded by connecting the devices to a comparison standard. The comparison standard was not described, presumed to be a calibrated mercury manometer. Pressures were considered accurate if the mean error was <= 3mmHg at all 7 pressure test points. None of the test mercury sphygmomanometers (n=356 devices) met all standards. Thirty-nine percent met less than half of the standards, and 28% failed to meet study protocol standards for accuracy. Sixty-one percent 61% (n=116 devices) of the aneroid devices were found to be inaccurate. Authors concluded that "the recognized inaccuracy of aneroid instruments does not recommend them as mercury substitutes." They observed, though, that "There exists, …, in the case of mercury sphygmomanometers, risk to the health and safety of observers and patients" and therefore urged further work in this area.

Ashworth et al conducted a survey of one primary care practice group in south London consisting of 32 general practice groups (Ashworth et al. 2001). A Y-connector was used to connect the test devices to a new mercury sphygmomanometer. Readings were compared over a range of five test pressure points. Devices were considered inaccurate if they were in error by 4 mmHg or more at any test point. Two percent of the mercury devices (n=130) and 15% of the aneroid devices (n=61) were found to be inaccurate. The proportion of failing aneroid devices compared to mercury devices was statistically significant. Authors recommend adoption of regular calibration as a performance indicator in primary care.

A survey of 15 primary practices in Birmingham, UK (n=139 devices) defined device inaccuracy as sphygmomanometers with readings greater than 2 mmHg different than the calibrated mercury standard (Ali and Rouse 2002). The study found that 10% of aneroid vs. 1% of mercury sphygmomanometers displayed errors > 10mmHg from the calibrated mercury device. The study does not describe the procedure used to check for accuracy and did not report failure rate (<= 2 mmHg error) by device type. Authors noted that their findings suggest primary care services are less than optimal because practices fail to calibrate their instruments, and practitioners may even be legally at risk for missing diagnoses of hypertension.

A study of 60 general practices in Australia (n=404 devices) evaluated mercury and aneroid sphygmomanometers used in practice (Shah et al. 2004). Devices were tested against a new mercury device by connecting the test device to the mercury standard using a Y-connector leading to the cuff, which was placed on a rigid cylinder. A nurse recorded the pressure on both devices over a range of pressures between 0 and 160mm Hg. For all pressure levels, mercury devices were more accurate than aneroid (p <0·01). The weaknesses of this study include using only one observer, measuring the pressure only once at each designated pressure reading points, and using a smaller range of pressure test points than that recommended by the standard validation protocols described above. Despite these weaknesses, the authors concluded that over 95% of the devices overall were within 5 mmHg of the standard device.

Aneroid device accuracy was assessed in specialty outpatient clinics in Connecticut by connecting an inflation bulb to the aneroid device and a mercury sphygmomanometer using a Y-shaped connector (Moore et al. 2008). Aneroid devices were considered accurate if they agreed with the mercury device within 3 mmHg over a range of six test pressure points (n=282 devices). Thirty-three percent failed at least one test pressure point. The difference in failure rates between wall mounted units and portable devices was significant, with portable units faring worse than wall mounted devices. Authors concluded that vigilance is necessary to maintain the calibration of aneroid devices and that portable devices should be calibrated more often then wall-mounted devices.

A study of an internal medicine practice in North Carolina compared blood pressure measurements taken from hypertensive patients in the clinic with blood pressures taken up to 90 minutes later with a calibrated mercury device (n=100 patients) (Kim et al. 2005). The mean difference was 8·3 mmHg for SBP and 7·1 mmHg for DBP. Both oscillometric and aneroid devices were used in the clinic, but the study did not report results by device type. Weaknesses include the length of time between readings, which might affect the 'white coat' effect.

Studies comparing digital pressure gauges with mercury and aneroid devices

In a survey of primary care clinics in London, sphygmomanometers (n=279 devices) were connected via a Y-connector to an electronic pressure gauge and the cuff was wrapped around a rigid cylinder (Coleman et al. 2005). Pressures were compared at six points throughout the pressure scale. Thirteen percent of mercury sphygmomanometers were found to have errors > 3mmHg, 53% of aneroid devices were off by >3mmHg and 29% were off by >5mmHg. The authors recommend that a simple reference device be made available for routine checks of pressure scale errors.

A study conducted at the University of Michigan used a Biometer to check the calibration of 136 aneroid devices used in their health system (Yarows and Qian 2001). The Biometer was connected to the aneroid device by a Y-connector. Four percent of the aneroid sphygmomanometers failed the calibration protocol (readings within 3mmHg of the standard). The average difference of all readings from the Biometer was 0·2mmHg. The average age of the sphygmomanometers was 5·1 years. No other studies reported the ages of the aneroid devices. Authors conclude that aneroid devices may be used as a replacement for mercury sphygmomanometers if they undergo yearly calibration.

Studies of calibrated aneroid devices

Most of the aneroid sphygmomanometers evaluated in the studies above had not undergone regular maintenance and calibration as recommended by the American Heart Association (Pickering et al. 2005), the European Society of Hypertension (O'Brien et al. 2003), and the JNC VII guidelines.(NHLBI 2004).

Only one study was found that evaluated the accuracy of aneroid sphygmomanometers undergoing regular maintenance. 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 (Canzanello et al 2001). Devices that appeared damaged, did not read zero, or differed from the reference device by > 4mmHg were to be removed and replaced with new devices. The digital pressure gauge used in this protocol was checked twice yearly for accuracy against a mercury manometer and was checked by the manufacturer yearly. A survey of 283 devices was conducted in 1999, five years after implementation of the maintenance protocol. For the assessment of accuracy, the digital pressure gauge was connected to the aneroid device and inflation bulb using a Y-connector. One device failed the protocol and was replaced. Values from the aneroid devices underestimated true values by a mean of 0·5mmHg, but 100% were within 4mmHg of the digital pressure gauge. Authors concluded that "a carefully maintained aneroid sphygmomanometer is an accurate and clinically useful means of blood pressure measurement."

One study by investigators in a diabetes clinical trial evaluated the project's aneroid devices due to concern that the change from mercury to aneroid sphygmomanometers would affect the analysis of their longitudinal outcomes (Ma et al. 2008). All aneroid devices were calibrated at the beginning of the comparative study using a digital pressure gauge. Sequential blood pressure measurements taken 30 seconds apart with a mercury standard and the aneroid test device on 997 randomized participants did not show a clinically significant difference in the mean readings between the mercury and aneroid devices. The mean difference in diastolic readings was 0.8mmHg (p<0·0001) and 0·1 mmHg for systolic readings (p=0·37). Based on these results, the clinical trial changed to aneroid devices.

Study of mercury devices

In a study focused on mercury devices, Markandu et al. performed a survey of blood pressure devices used 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 (Markandu et al. 2000). Thirty-eight percent (n=469 devices) were found to have dirty mercury columns. On 21% of those, the markings were difficult to read due to oxidation of the mercury. Eighteen percent had either an obscured mercury column or faded markings, and three devices were found to have leaking mercury. Of note are the results of cuff inspection: 8% 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. The authors conclude that mercury sphygmomanometers "have outlived their usefulness" and "should be dispensed with now." They recommend replacement with semi-automatic electronic sphygmomanometers.

In contrast, it now appears that an electronic pressure gauge provides considerably more reliability than a mercury manometer in repetitive measurements of pressure. In the survey of primary care clinics in London, the electronic pressure device used in the study was designed to produce a digitation error of +/- 0·005 mmHg while the automatic devices being tested were designed for errors of 0·05 mmHg. It was calibrated at a lab before and after the study and was found to have a drift of less then 0·5%.

The Biometer used in the University of Michigan study is specified to be accurate within +/- 1% of the reading. After the study, it was calibrated by three methods using a water column, mercury sphygmomanometer, and another electronic device. It measured the mercury device exactly, over-read the electronic device by 0·38 mmHg, and the water column by 0·18 mmHg. In the Mayo clinic maintenance protocol, the electronic pressure gauge was checked biannually against a mercury sphygmomanometer and by the manufacturer yearly. When evaluated for the study, it underestimated the mercury devices by 0·12 mmHg.

These electronic gauges cost from a few hundred dollars to several thousand. Electronic pressure transducers use two metallic diaphragms to create a variable capacitor. An electronic signal is created when the diaphragms flex with pressure. The electronic signal is converted into an analog scale which is read on the digital display. The precision of these gauges is superior to all three types of blood pressure devices, including the mercury manometer.

Studies of oscillometric devices

Oscillometric devices measure the mean arterial pressure and calculate the systolic and diastolic pressures from a computerized algorithm. Since these algorithms are proprietary, it is likely that each manufacturer uses a different one. This raises a legitimate concern about the validity of these devices, but also makes research on their calibration difficult, since results must be reported by identifying each brand separately. For this reason, oscillometric devices have been excluded from most accuracy studies.

Sims et al. evaluated automated models available on the European market by surveying manufacturers and reporting characteristics of the available models, including the percentage that had been clinically validated (Sims et al. 2005). One hundred sixteen different models were identified. Clinical validation studies had been conducted on only 12 of the arm devices and 11 of the wrist devices.

Studies of oscillometric devices compared with mercury and aneroid devices

Coleman's survey of primary care clinics in London described above (Coleman et al. 2005) evaluated 134 automated devices by overriding the electronic inflation and deflation sequence. Compared to the mercury and aneroid sphygmomanometers, oscillometric devices were found to have the most accurate pressure scales, with only 4·5% of the automated devices giving errors > 3mmHg. The two oldest models were compared to the newer ones, which were manufactured after 1999. The older models gave a wider range of pressure errors, suggesting deterioration in performance with age.

A study conducted in an urban area of Brazil measured the blood pressure on 400 randomly selected adults in their homes will all three types of devices (Gill et al. 2004). In this study, the "gold standard" was the oscillometric device. Compared to the automatic device, the aneroid significantly under-read and the mercury device significantly over-read the blood pressure. However, the prevalence of hypertension diagnosed with the mercury device was the same as with the electronic device. With the aneroid device, hypertension was 2% less prevalent. The authors conclude that aneroid devices are slightly less efficient but are simpler and safer than the other two types and can be recommended for use in resource-poor settings.

Jones et al. performed a comparison study between mercury sphygmomanometers and electronic devices in a hospital triage area in North Carolina (Jones et al. 1996). The electronic devices used in that hospital underwent calibration by the hospital's medical engineers every six months. Sequential blood pressure measurements were taken 1 minute apart. A difference of 9 mmHg on any readings between the two devices was considered clinically significant. The mean difference in measurements (n=100 patients) was 4·3 mmHg for systolic and 1·3 mmHg for diastolic measurements. Thirty-seven percent of the systolic differences and 26% of the diastolic differences exceeded 9 mmHg. The authors concluded that the diagnosis of hypertension should be made with caution when using an automated device.

The Dinamap oscillometric model was evaluated in an Australian study by comparing sequential blood pressure readings on a convenience sample of 63 hospitalized patients using a calibrated mercury device and a calibrated Dinamap 8100 (Heinemann et al. 2008). Pressures measured with the automated device were significantly lower than those taken with the mercury sphygmomanometer; mean difference was 3·13 mmHg systolic, 5·22 mmHg diastolic. The authors conclude that the Dinamap model can be used with confidence for systolic blood pressure, but with less confidence for diastolic readings.

McManus et al. evaluated blood pressure readings from a general practice clinical database before and after the introduction of electronic devices (McManus et al. 2003). Four general practices were included (n=1,521 patients). No statistically significant changes in systolic and diastolic pressures were found after the phase-out of mercury devices. However, the readings with the two types of devices were separated by several months instead of the usual 30 seconds used in validation protocols.

Additional studies and independent evaluations of specific products

Dozens of other studies have been performed on individual models of oscillometric devices, and their results are not included here. The Working Group on Blood Pressure Monitoring of the European Society of Hypertension has published summaries of peer-reviewed validation studies for all three types of sphygmomanometers (O'Brien et al. 2001). A device is recommended if it fulfills both the AAMI and BHS criteria. Also, 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 (O'Brien 2003b). 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 Society of Hypertension and the British Hypertension Society also publish tables of validated devices on their websites (Reims and Mancia 2005, BHS 2009).

IV. DISCUSSION

Uncalibrated mercury sphygmomanometers

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. Overall, studies reporting the accuracy of mercury devices have not included the ages of the devices tested, but two did report on the condition of the column, tubing, and cuff, noting significant wear and tear on some and their exclusion from the analysis (Waugh et al. 2002, Mion and Pierin 2008). Clearly, to assure accuracy, mercury sphygmomanometers must undergo regular maintenance and calibration checks frequently lacking in clinical practice.

Uncalibrated aneroid sphygmomanometers

In comparison with these uncalibrated mercury devices, uncalibrated 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%. The average age of the devices in that study was less than 5 years. The ages of the devices included in the other validation studies were not included. It has been hypothesized that aneroid devices are susceptible to damage with time due to their multiple small, moving parts. Studies evaluating aneroid devices stratified by device age are needed to explore this further.

Calibrated aneroid and mercury sphygmomanometers

In the two studies that calibrated the aneroid devices before the comparison evaluation (Ma et al. 2008, Canzanello et al. 2001), aneroid devices performed well. Mean differences from the comparison devices were all <1mmHg. In one study the devices were calibrated at the start of the study, and in the other study devices were included in annual maintenance/validation checks. These studies show that aneroid devices undergoing regular calibration are likely to be accurate. Similar to the Mayo Clinic experience, maintenance protocols can be incorporated into regularly scheduled inspections of all medical devices. More research to solidify the evidence that regular maintenance leads to acceptable performance of aneroid sphygmomanometers is needed.

Oscillometric sphygmomanometers

Oscillometric devices do not require a trained observer and are therefore popular for home use. 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 (Heinemann et al. 2008). Since the algorithms used to calculate the systolic and diastolic pressure from the measured mean are proprietary, each model/brand must be validated separately. Because there are dozens of models on the market and therefore dozens of validation studies, the availability of 'clearinghouse' websites and publications are helpful as central repositories of information and device recommendations. These devices will continue to be used and their use will likely increase as more treating physicians come to rely on the ambulatory blood pressure

or intermittent home monitoring for treatment decisions. The questions surrounding their accuracy when used in diabetics, the elderly, pregnant women as well as those with arrhythmias must be resolved (Pickering et al. 2005).

Several articles have addressed the issue of validation and calibration of oscillometric devices. Jilek and Fukushima call for a public database of oscillometric waveforms based on physiologic data for use in research, development, and testing of devices (Jilek and Fukushima 2005). Such a database could also be used to develop a generic algorithm for calculating the systolic and diastolic pressure from the MAP that could be used by device manufacturers. It could also be used for performance testing of individual oscillometric devices. Amoore et al and van Montfrans both introduce a blood pressure simulator that uses a database of 243 oscillometric waveforms from 124 patients to be used in the validation of oscillometric devices (Amoore et al. 2007, van Montfrans 2001).

Sphygmomanometer independent reviews and recommendations

Several national and international organizations have addressed the controversy over the replacement of mercury sphygmomanometers with alternative devices. The American Heart Association (AHA) issued an Advisory Statement in 2001 (Jones et al. 2001) encouraging mercury sphygmomanometers for general use and for calibration of aneroid or electronic instruments "if mercury instruments cannot be reintroduced for regular use." In 2003, the AHA again weighed in on the issue after a meeting convened with the US National Heart, Lung, and Blood Institute (Jones et al. 2003). They concluded that mercury manometers remain the gold standard for blood pressure measurement, that blood pressure measured with a "well calibrated" aneroid device will give the same results as a mercury manometer, and that results with an oscillometric device may be inaccurate.

Other commentaries cover a range of opinions. An editorial in the Journal of the Royal Society of Medicine in 2005 recognizes that mercury sphygmomanometers are disappearing from practice and urges the use of automatic devices for home monitoring (Varughese and Lip 2005). Thomas Pickering cautions against blanket endorsements of aneroid or oscillometric devices because of questions regarding their accuracy (Pickering 2003). Eoin O'Brien predicts that the mercury sphygmomanometer is "destined for the museum shelves" (O'Brien 2003c). He suggests that the millimeter of mercury as a pressure unit will also disappear, as well as the auscultatory technique.

Mercury sphygmomanometers have been banned in Sweden since 1992. A 2005 report summarizes the results of a survey of physicians in which heads of hospital departments in that country were asked whether the phase-out of mercury devices had caused any increased risks for patients (Swedish Chemicals Inspectorate 2005). No negative experiences were found. There were no problems diagnosing hypertension, even in the presence of arrythmias and preeclampsia.

Clinical considerations and observer inaccuracy

The accuracy of blood pressure measurements taken with manual devices, including both mercury and aneroid sphygmomanometers, suffers from the reliance on the human observer. 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 pressure. Studies of terminal digit preference show that observers favor rounding off to the nearest 10mmHg, 5 mmHg, and even vs. odd numbers (Ali and Rouse 2002). 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 with a mercury sphygmomanometer and oscillometric device by an observer, followed by five more readings taken by the oscillometric device without any health professional in the room (Myers et al. 2008). No significant difference was found between readings on the two devices taken by the observer. However, 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 readings and 10 mmHg diastolic.

Oscillometric devices

Despite the potential inaccuracies noted above, because they eliminate terminal digit preference and observer bias, and minimize white coat hypertension, oscillometric devices may continue to increase in popularity. Further testing and more transparency with respect to algorithms for calculating the systolic and diastolic pressure from the MAP may improve the instrument accuracy of these devices.

V. CONCLUSIONS

Mercury is converted to an environmental neurotoxic hazard 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 (WHO 2005b). Several countries have completely replaced mercury sphygmomanometers with alternative devices that soon will become the norm worldwide (HCWH 2008). Yet, *are mercury sphygmomanometers necessary for calibration, validation, or measurement of blood pressure in clinical or research settings?* Based on this review of alternative devices, their mechanisms and accuracy, and current validation protocols, we conclude that:

1. Properly calibrated and maintained aneroid sphygmomanometers are likely to be equally or more accurate than mercury devices. While calibration should be more frequent than with mercury devices, the obstacles are minor and add little to the cost of use at the institutional level.

2. Validated oscillometric devices with digital displays have been demonstrated to be accurate and provide the possibility of removing inter-observer differences in blood pressure measurement. While early data is promising, as yet these devices have not been validated for certain clinical conditions including arrhythmias.

3. A number of aneroid and oscillometric devices on the market have not been validated by their manufacturers and others do not perform as manufacturers claim. Consumers of these devices should review compliance of particular devices with available independent validation protocols.

4. Routine calibration of mercury and aneroid devices should occur on an annual basis and consideration should be given to checking portable devices, which are more prone to bumping and dropping, on a bi-annual schedule.

5. The Emergency Care Research Institute (ECRI) recommends calibration with a digital pressure gauge as the most accurate manometric device (ECRI 2003). This organization also makes specific recommendations for pressure gauge type/brand. The American Heart Association recommends that the calibration standard be a either a mercury sphygmomanometer or an electronic pressure gauge (Pickering et al. 2005). Despite the apparent 10-fold improvement in accuracy when the pressure gauge is used, the British Hypertension Society to this point recommends using a mercury sphygmomanometer as the comparison standard for calibration. Moreover, WHO's 2005 position paper on Mercury in Health Care (WHO 2005) provides that in the short term, "Before final replacement has taken place, and to ensure that new devices conform to recommended validation protocols, health-care facilities will need to keep mercury as the 'gold' standard to ensure proper calibration of mercury sphygmomanometers."

However, it now appears that an electronic pressure gauge provides considerably more reliability than a mercury manometer in repetitive measurements of pressure for purposes of device calibration. The precision of these gauges is superior to all three types of pressure-recording gauges for blood pressure measurement, including the glass mercury manometer as a stand-alone display. This device therefore should be substituted for the mercury manometer for calibration and validation purposes. At this point it appears that the most accurate calibrating protocol utilizes a digital pressure gauge which should be adapted for use by validating organizations.

In sum, mercury sphygmomanometers are not scientifically necessary for calibration, validation, or measurement of blood pressure in clinical or research settings. Alternative devices are either equally or more accurate when maintained properly and are likely to have far less occupational or environmental toxicity.

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