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Accuracy of Automated Blood Pressure Monitors

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Purpose. *The purpose of this study is to determine if automated and aneroid manometers are as accurate a means of determining blood pressure as the mercury manometer. Obtaining vital signs for patients is considered standard of care, yet many dental offices do not routinely perform this health service because of technique inconsistencies and time constraints. The use of automatic blood pressure monitors addresses both concerns. The mercury column manometer, the control in this study, has long been considered the most accurate and preferred instrument for obtaining blood pressure measurements.*

Methods. *During this study, 94 participants (19 years of age and older) consented to having blood pressure taken by each of 4 different monitors. These included the mercury column manometer and stethoscope, the aneroid manometer and stethoscope, the automatic arm blood pressure monitor, and the automatic wrist blood pressure monitor. Each of 3 investigators was assigned to and calibrated for a specific monitoring device. All measurements were taken from the left arm with 5 minutes allowed between measurements. Identical stethoscopes were used with the manual monitors. Strict adherence to the manufacturers' directions and patient preparation was followed for all monitors. Investigators were not aware of readings obtained by other investigators during testing. Eighty-three subjects completed all tests.*

Results. *Review and analysis of data indicates little difference for pulse readings between the automated and digital methods. Systolic readings by automated wrist manometers were the most unreliable. Automated arm monitors tended to provide higher measures than the mercury standard on average, and demonstrated significantly different diastolic readings in one age group compared to the control. All monitors exhibited low reliability for participants over age 50 compared to the control.*

Conclusion. *This study demonstrates there is inaccuracy in the use of automated blood pressure monitors and traditional aneroid manometers when compared to the gold standard mercury column manometer for subjects of all ages and blood pressure ranges.*

Keywords: hypertension, accuracy, automated, monitor, validation

Introduction

The purpose of this study is to assess the accuracy of analogue and automated arm and wrist blood pressure (BP) monitors when compared to the mercury manometer on a large number of individuals of varying ages. This study matches the Health

Promotion/Disease Prevention category identified in the American Dental Hygienists' Association's National Dental Hygiene Research Agenda, 2007. The agenda identifies the need to "Validate and test assessment instruments/strategies/mechanisms that increase health promotion and disease prevention among diverse populations"¹. Recording patients' vital signs has long been considered a standard of care in dentistry. In the 2007 draft of the American Dental Hygienists' Association Standards of Clinical Dental Hygiene Practice, the taking and recording of patient BP is identified as a standard component of patient assessment.² Most commonly, BP, pulse rate, and respiration rate are recorded. This health care standard serves as a screening tool, alerts the provider to alter planned treatment when abnormal readings are found, and provides a baseline in emergency situations. Obtaining BP has been identified as one of the most important measurements in clinical medicine.³ Traditionally, the patient's BP has been found with an aneroid or mercury column manometer and stethoscope using the auscultatory method, requiring the operator to listen for Korotkoff sounds. This technique, which has been used for nearly 100 years, has experienced few changes.⁴ Current concern regarding the safety of mercury has resulted in the banning of this sphygmomanometer within Veterans Administration hospitals, other locations in this country, and other countries as well.⁵ This safety concern, plus the required attention to detail and the time involved in obtaining BP with auscultatory methods, has resulted in an increased use of electronic units and development of alternative nonmercurial manometers. In fact, the primary reason 55% of dental hygienists in one 2006 study did not take BP on patients was lack of time during the appointment.⁶ Electronic units record BP at the wrist, upper arm, or finger with the oscillometric technique. Utilizing automated BP measuring devices that give inaccurate results defeats the purpose of taking BP measurements, when those readings can indicate potential cardiovascular incidents.

Review of the Literature

There are accuracy issues with all types of BP monitoring devices. Observer bias and hearing acuity are major disadvantages of both traditional mercury and aneroid devices, as is mechanic wear of the aneroid unit.⁷ Mercury manometers tend to maintain function and accuracy for years, while aneroid units need frequent calibration to ensure accuracy.⁸ Inaccuracies with oscillometric units at specific BP levels appear to be related to equipment algorithm insufficiencies rather than patient individuality.⁹ Another study found decreased performance of automated devices over time.⁸ In addition, automated arm units are difficult to calibrate and are not suitable for those with arrhythmias.^{3,7} The same holds true for wrist and finger units, with the additional indication that wrist devices are extremely sensitive to heart level positioning, and finger devices cause erroneous readings in individuals with cold or slender fingers.⁷

Yarows and Brook (2000) found little difference between BPs taken by 12 automated devices on 2 normo-tensive subjects when compared with those of mercury or aneroid and validated automated manometers. Also found were similar ranges of deviation between traditional and automated methods of measurement, indicating operator interpretation during traditional methods are as variable as output by automated devices with digital displays.¹⁰ Terra et al (2004) found consistency, yet inaccuracy, in healthy participants when BPs were measured with an automated arm device and a mercury manometer; systolic BPs consistently measured 3-5 mmHg higher by automated units than by the control, while diastolic BP measures consistently measured 3-5 mmHg lower than the control.¹¹

In a study by Stryker et al (2004), hypertensive individuals without arrhythmias, who owned automated BP units, participated in a study to determine accuracy of self-measurement. Results found well-trained, at-home users of newer automated monitors could take accurate BP measurements. Inaccuracy levels of monitors used in the study were: arm units (14%) and wrist and finger monitors (33% and 33%, respectively).¹² Newer monitors are more likely to be accurate than earlier versions.¹² In another study, researchers concluded that BP measured by wrist devices was unreliable.¹³

Due to continued inconsistencies in study data, use of only validated automated arm units is recommended, while no general recommendations for wrist and finger devices have been made at this time.^{4,14}

O'Brien et al (1996), strictly followed British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) protocol in evaluating 3 automated BP devices. Only one manometer passed criteria of both agencies for normal range BP, although it was inaccurate at high blood pressure (HBP) ranges. Failure of the other 2 devices was primarily due to inaccurate systolic readings.¹⁵

Positioning of the patient is vital to obtaining proper BP results. In 2005, Mourad et al found that currently recommended arm positioning may lead to inaccurate outcomes in many studies of wrist-cuff automated manometers. Placing the arm midsternally, in opposition to American Heart Association guidelines and those of some manufactures, produced more consistent readings between the wrist cuff and the arm cuff.¹⁶

The need to rely on experienced and reliable testing agencies to provide validation outcomes for BP monitoring devices on the market is indicated by the many conflicting study outcomes. Until arm and wrist positioning is standardized by device manufacturers and national and international guidelines, it will continue to be difficult for researchers and clinicians to be assured they are obtaining accurate results.

Need for Vital Signs Review in Dental Offices

BP is defined as the amount of pressure exerted by the blood circulating in the arteries. It is measured in mmHg and recorded as a fraction, ie, 110/70. Readings are more accurate when the patient is rested and in a sitting position, which allows the upper arm to be at heart level. Operators should be aware that right and left arm BPs vary, and using incorrectly-sized cuffs can lead to inaccurate readings. The upper number of a BP measurement, known as the systolic pressure (SP), is obtained when the heart is in systole or is contracting. The second number of the fraction is known as the diastolic pressure (DP) and is the arterial pressure during dilation of the heart. On any given day, a person's BP may be affected by muscle tension and/or anxiety, respiration, exercise, meals, pain, temperature, bladder distension, arm position, background noise, talking during the procedure, alcohol or nicotine consumption, or stimulants.¹⁷ A diagnosis of HBP or hypertension is not made with just one higher reading but with consistently higher readings.

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure in 2003 defined normal BP for an adult (18 years and older) at levels below 120 mmHg systolic and 80 mmHg diastolic pressure.¹⁹ Prehypertension, a new classification defined in this same publication, is a reading of 120-139/ 80-89; levels previously considered within normal range.¹⁹ Individuals with prehypertension are more likely to develop HBP and are encouraged to make diet and lifestyle modifications to bring levels into normal range. Approximately one-fourth of the adults in this country have BP measurements in this category.²⁰ The 2003 report estimates 30% of the United States population is unaware they have HBP.²⁰ It is estimated that 65 million or 1/3 of the adults in the United States have been diagnosed with HBP (readings \leq 140/90 mmHg) or take antihypertensive medication.^{1,2} In addition, the risks of developing high blood pressure increase with age; individuals over 50 years of age have a 90% chance of developing HBP.^{19,21} These statistics show the importance of obtaining BP as a screening tool in the dental setting.

Most medical emergencies in the dental office can be avoided when adequate information is obtained from the patient prior to treatment. Historically, this information has included the patient's medical and dental history. To be complete, it must also include the patient's BP, pulse rate, and respiration rate. A higher than normal BP measurement increases the risk of a stress-related emergency. Patients with hypertension present with a greater risk for stroke, heart failure, myocardial infarction, and kidney dysfunction.²⁰ A normal pulse rate for the adult patient is 60-100 beats per minute (bpm). An irregular pulse at 120 bpm or greater for unknown reasons should alert the operator to a potential emergency situation, and a fast, irregular pulse is the most common precursor to cardiac arrest²⁰. Further, elective dental treatment should be postponed when the BP level is \geq 180/110.²¹

The American Society of Anesthesiologists (ASA) risk classification was developed to estimate the risks to a patient during procedures using anesthesia. The ASA classification is also used to determine treatment risks when anesthesia is not used.²²

Patients are classified into ASA categories depending on current or past medical conditions, age, anxiety level, and BP measurements. A healthy patient with no current or past systemic disease and no medications is considered an ASA I. The same patient presenting with a BP of 140/90 is moved to ASA II, indicating the operator should perform treatment with caution.²² When the BP reaches 160-199/95-114, the patient becomes an ASA III, while a level of $\geq 200/115$ categorizes the patient as an ASA IV with elective care not recommended as associated risks are too great and pain and infection management should be palliative.²²

BP measurements should be taken every 6-12 months for patients with levels within normal range and no history of hypertension or related medications. When the BP is higher than normal and/or the patient is taking antihypertensive medication, or has a history of diabetes, hyperthyroidism, kidney disease, and/or heart disease, this vital sign should be checked at every dental appointment. If local anesthetics with vasoconstrictors or nitrous oxide/oxygen sedation are to be used, a baseline BP measurement is imperative.^{22,23}

Monitoring Device Components

Components of BP monitoring devices include the cuff, manometer, and stethoscope or digital monitor. Arm cuffs are available in child, adult, large arm, and extra large (thigh) sizes. Cuff width is significant; an erroneously high reading results when using a cuff that is too small; likewise, using a cuff that is too large will result in mistakenly low readings.^{3,4,24} Studies indicate that when cuff width is accurate, the length of the cuff is also correct.²⁴

Types of Monitors

Mercury Manometers

Mercury column sphygmomanometers consist of a portable or wall-mounted unit containing a glass column where mercury resides in a bowl at the base of the column. Using the auscultatory method, the bulb is pumped to inflate the cuff, causing the mercury to rise in the glass column that is demarcated in millimeters of mercury (mmHg). Mercury manometers retain their accuracy because of their nonmechanical design (Figure 1). Mercury are considered the gold standard in accuracy and their use is critical when determining the accuracy of all other BP devices.^{3,4}



Figure 1.

Aneroid Manometers

Aneroid manometers (Aneroid) consist of a portable or wall-mounted unit that contains springs and other mechanical parts. The manometer needle should always be located at zero prior to inflating the cuff. The auscultatory method is used to take BP. One disadvantage of aneroid units is that the mechanical parts tend to dysfunction over time and when handled roughly (Figure 2).^{3,4} Wall mounted units are less susceptible to trauma and therefore, more accurate.²⁵



Figure 2.

Automated Arm Manometers

Automated arm BP devices (Arm) consist of a portable or wall-mounted unit that uses oscillometrics to determine BP taken from the upper arm. Patient positioning and cuff placement are the same as for the mercury and aneroid methods. Automated units use algorithms to determine BP in a digital display. The automated devices provide a large digital display of BP and pulse readings that is easily read by the operator, patient, and home user. Most units store results in memory. A major disadvantage of many automated units is lack of validation for accuracy. Automated devices are not recommended for persons with arrhythmias or arterial stiffness, which affects many middle-aged and older adults.

Automated Wrist Manometers

Automated wrist BP devices consist of a portable unit that uses oscillometrics to determine BP taken from the wrist, unlike the mercury, aneroid, and automated arm manometers. Like the automated arm units, the visual display of BP and pulse is a positive feature. However, algorithms and mechanics involved in the production of BP readings and accuracy is problematic, as is use of these devices on persons with arrhythmias or arterial stiffness.

Proper Patient Positioning

According to Jones, et al (2003), under or overestimating BP by 5 mmHg would affect the treatment, or lack of, for 48 million people.²⁶ Regardless of the type of monitoring device used to test BP, it is important to understand and use proper technique and procedure when taking vital signs. The patient is seated with their elbow resting on a table or chair arm, positioning the upper arm at heart level. If the upper arm is placed above heart level, an inaccurate lower BP reading will result; if positioned below heart level, an inaccurately higher reading will result.^{3,4} Both systolic and diastolic readings will be 2-3 mm higher with the patient seated as compared to positioning supinely.^{3,4} Patients should be sitting with their

legs uncrossed and their back and arm supported. The BP device is placed according to manufacturer's directions (see specific instructions under type of monitor).

For the mercury, aneroid, and arm monitors, the patient should be asked to roll up his/her sleeve so the cuff can be placed directly on the skin, with the bottom of the cuff one inch above the antecubital fossa (the inside crease of the patient's elbow). The cuff should be placed snugly, allowing 2 fingers to fit between the cuff and patient's arm (picture). Most cuffs have an arrow that indicates placement of the cuff over an artery. For the wrist monitor, the cuff is placed snugly over bare skin at the wrist, with the digital display located on the distal surface of the wrist.

BP may vary as much as 10 mmHg from an individual's right to left arm,¹⁸ making it necessary to indicate which arm or wrist is used for measurement. Also, BP measurements tend to drop if taken sequentially; recommendations vary regarding resting periods between readings, with most experts recommending at least 30 seconds and up to 5 minutes rest between readings.^{18-20,27}

For manual units, the cuff is inflated until the radial pulse can no longer be felt; the cuff is then inflated 20-30 mm higher.^{18,19,27} Neither the patient nor operator should talk during the procedure. The transducer or diaphragm is placed in the antecubital fossa without contacting the cuff. As the cuff is deflated at a rate of 2-3 mm per second, the first Korotkoff sound should be heard close to the point where the radial pulse ceased. This first sound is the systolic reading and the last Korotkoff sound is the diastolic pressure. To assure there are no additional sounds, continue to slowly release the gauge for another 10 mm before complete deflation. When reading mercury column or aneroid manometers, operators tend to error by recording a zero as the last digit in the systolic and diastolic reading rather than the nearest 2 mmHg; for example, 116 becomes 120 or 74 is recorded as 70.3

Automated or digital BP monitors are easy to use. Once the patient and cuff are positioned properly, the operator needs only to press a button on the unit to begin measuring BP with the oscillometric technique. No stethoscope is needed and BP and pulse readings are displayed on the unit's screen (Figures 3 & 4). Oscillations of pressure are recorded during the slow deflation of the cuff. Since the oscillations begin much higher than the systolic pressure and continue well below the diastolic, each unit has an empirical algorithm to estimate systolic and diastolic pressures.^{3,4} Algorithms are specific to individual units/manufacturers and are not public record.^{26,28} Using the correct cuff size is crucial, a requirement often overlooked as automated units are generally packaged with a standard adult-sized cuff. Alternative cuffs may be available for an additional cost. With proper training on the specific unit and close attention to positioning, fewer operator errors occur. In a study by Stryker et al (2004), 80 subjects were observed taking their own BP with their personal automated units, and then were given training and observed again.¹² After the 10-minute training on proper technique, a significant improvement in the accuracy of readings was evident.¹²



Figure 3.



Figure 3.

Studies show patients fabricate or fail to record digital readings more often than not.^{3,4} An advantage of some automated units is the capability to print the measurements and/or store them in memory, eliminating operator bias. Outside noise is not a concern as with the auscultatory technique. Home use may eliminate higher readings for the 20-35% of individuals who experience the white coat effect of upwards of 30 mmHg higher BP reading when taken by a health care worker.^{4,19} In addition, frequent BP testing at home allows patients and health care providers to monitor how lifestyle and/or medications affect cardiovascular health; self-monitoring with memory or printouts is more reflective of actual pressures than intermittent readings in a medical setting.^{3,19} To date, finger monitors and finger cuff methods of obtaining BP are considered inaccurate and not recommended.^{3,29}

Ambulatory BP measurements (ABPM), taken over a 24-hour period in a home environment during normal activities and sleep, have been shown to more accurately reflect BP than readings recorded in medical settings.³⁰ Obtaining the mean level of these measurements can help identify patients with white coat effect, thereby preventing unnecessary medicating.^{28,30} In this country, APBM has been approved for reimbursement by Medicare and Medicaid.^{4,19} Studies show ambulatory pressures are a better predictor of cardiovascular risk than measurements obtained in a medical setting.^{4,19}

Validation

The Association for the Advancement of Medical Instrumentation (AAMI), the British Hypertension Society (BHS), and the European Hypertension Society (EHS) have developed protocols for the validation of BP devices. The AAMI validation protocol was most recently revised in 2002, with the latest BHS revision in 1993.³ The International Protocol of the EHS is a recent development as a replacement for the more cumbersome aforementioned protocols.³ Both AAMI and BHS protocols involve 85 participants having BP recorded at 3 separate instances with the mean expected to fall within 5 mmHg and a SD of 8 mmHg.³¹ Needing such a large number of subjects for obtaining validation is difficult, therefore many units are not independently evaluated.^{3,32} The BHS system grades performance using letter grades A, B, C, and D; grades A and B indicate accuracy.³³ An easier method of validation, the International Protocol, requires BP comparisons on 33 subjects by 2 trained observers, plus a supervisor and a medical doctor. Subjects must be 30 years or older, represent both genders, and have BP readings distributed among 6 categories based on high, medium, and low levels of both systolic and diastolic readings.³² Units with measurements within 5 mm are considered very accurate; within 6-10 mm are slightly inaccurate; and within 11-15 mm are moderately inaccurate; and those with greater than 15 mm differences are very inaccurate.

Validation is awarded when one-half of the systolic and diastolic readings are within 5 mm of each other.³² Manufacturers are not required to meet either AAMI or BHS standards before units are sold in the United States.³ There are several online source lists of validated BP monitoring devices, including the BHS website³⁴ and the dabl Educational Trust website.³⁵

The first mercury-free, nonautomated BP device to pass the international protocol for accuracy is the Accoson Greenlight 300.³⁶ BP is taken in the traditional manner, listening for Korotkoff sounds, but the readings are displayed digitally. Another, the hybrid monitoring device, uses the auscultatory technique but replaces the mercury component with an electronic pressure gauge.^{3,28}

Calibration

According to the BHS, aneroid units should be calibrated with a mercury manometer biannually using Y-tubing (See Figure 5). To be considered accurate, the aneroid unit should test within 4 mm of the mercury at both 100 and 200 mm inflation levels.^{3,4} Aneroid and automated units calibrated against the mercury manometer and found to be inaccurate should be returned to the manufacturer.²⁶ As reported by Dr. Grim at the National High Blood Pressure Education Program, National Heart Lung and Blood Institute, and American Heart Association Working Meeting on BP Measurement (2002), 35% of aneroids are inaccurate by at least 6 mmHg.³¹ In a study by Coelman et al (2005), 18% of BP units used in 45 London medical practices were inaccurate; aneroid devices being most affected.⁸ Additionally, the study found that promotional devices provided by pharmaceutical or other companies were the most inaccurate.²⁸ Inaccuracy rates of 1-44% have been found for aneroids in hospital settings.^{3,4}



Figure 5.

Methods & Materials

In this study, investigators used the Omron 711A with Intellisense Automatic BP Monitor, the Omron HEM-608 Portable Wrist BP Monitor, and a Prestige Medical CEO120 traditional certified analogue unit. The control was an Omron 12-605 mercury sphygmomanometer. The automated units were selected because they could be purchased locally. None of the units were validated against the mercury manometer prior to use in the study, as lack of validation of purchased units and resultant inaccuracy was the focus of this study. The Omron wrist unit and the Omron arm unit both were used by one investigator because they automatically outputted BP and pulse readings. A second investigator took BP readings using the standard analogue unit and took pulse measurement manually by finger pressure on the radial artery. The third investigator used the Omron mercury monitor to test BPs and took pulse measurements manually, also. All 3 investigators have expertise in obtaining BP and pulse rates as they teach dental hygiene students how to perform vital signs procedures for all patients. In addition, they familiarized themselves with the machines and the manufacturers' use protocols, plus calibrated their results on at least 5 volunteers before beginning the study. Calibration consisted of following proper manufacturer's recommendations for each manometer and taking BP at least twice on each of 5 volunteers using the same technique and device to assure that results were consistent per device. No statistical calibration was done.

The pool of 94 volunteer participants, ranging in age from 19-92, was recruited from the University of South Dakota Department of Dental Hygiene and from an apartment residence for older adults. University of South Dakota Institutional Review Board clearance was obtained prior to beginning the study. Participants read and signed a consent form, and were given separate identification numbers. Only the ages and names of the participants were collected on the consent forms. The ID number and age of each participant was placed on a card that the participant carried to each investigator, maintaining confidentiality while allowing the investigators to verify that a particular method of BP was completed. This helped reduce confusion among the participants and allowed for a more efficient use of time. Investigators sat at a single round table and participants randomly sat at one of the testing stations, depending on availability. After each testing, the participant walked about 3-5 feet to the next station and rested prior to additional testing. There was neither consistent sequence nor purposeful randomization to the testing order. Using the same arm per participant, BP was taken by all 4 methods; a 5-minute rest was allowed between measurements. Manufacturers' recommendations were followed for proper positioning of the participants and proper use of the machines. At each of the 4 BP monitoring stations, the investigators recorded which arm was used for testing, the ID number of the participant, and the obtained BP and pulse values. These same values were recorded on similar forms at each station. Once all 4 methods of testing BP were completed for each participant, the validation card was kept by the investigators.

Results

A total of 94 subjects participated, with an average age of 37.21 (SD = 21.81, range 19 to 92; 1 subject did not report age). Subjects for whom we were unable to obtain a blood pressure measurement were eliminated from the study; the most common reasons for inability to obtain measurements were too large of arm for the standard cuff, digital error messages, and inability to hear Korotkoff sounds. Due to these eliminations, analyses were conducted on a final sample of 83 subjects (mean age = 36.52, SD = 21.73, range 19 to 92; one subject did not report age).

Descriptive statistics

Table 1 contains the 95% confidence interval for all BP devices and measurements. Systolic BPs by mercury sphygmomanometer ranged from 84-158 mmHg, while diastolic pressures ranged from 56-100 mmHg. Pulse rates ranged from 50-108 bpm.

Table 1: Descriptive Statistics for all Blood Pressure Devices

Variable	Mean	SD	Minimum	Maximum	95% confidence interval	
					Upper	Lower
Mercury	116.67	16.68	84	160	113.03	120.32
Aneroid	116.70	13.51	96	168	113.75	119.65
Wrist	118.57	18.43	91	169	114.54	122.59
Arm	125.78	22.34	95	192	120.91	130.66
Mercury	74.24	9.65	56	100	72.13	76.35
Aneroid	72.98	9.66	58	108	70.87	75.08
Wrist	76.04	17.28	56	195	72.26	79.81
Arm	76.69	10.93	58	107	74.30	79.07
Mercury	75.25	9.97	50	96	73.08	77.43
Wrist	77.71	13.76	55	131	74.71	80.72
Arm	76.88	11.13	54	110	74.45	79.31

Note: The 95% confidence interval about the mean represents the range within which we would be 95% confident that the true population mean would fall.

Differences in pressure and pulse measurements by type of monitor and by age

The measurements were analyzed via mixed model ANOVA with monitor type as a within-subjects variable and age as a between-subjects variable. Tests of each effect (age, monitor type, and interaction) control for the other effects. For example, when interpreting the effects of monitor type, be aware that it controls for age (ie, the analysis statistically factors out differences due to age so that the differences due to type of monitor can be isolated).

Systolic

Systolic pressure significantly increased with age, $F_{1, 80} = 80.96$, $MSE = 508.35$, $P < .0001$. While systolic pressure did not significantly differ by monitor, $F_{3,240} = 1.98$, $MSE = 66.40$, $P = .12$, the interaction of monitor and age was significant, $F_{3,240} = 14.48$, $P < .0001$. Thus, the differences among monitors changed with age (Table 2).

Table 2. Mean differences in systolic pressure measurements by each monitor and the mercury by age (monitor-mercury)

Age	Monitor	n	Mean Difference	SD	Cohen's <i>d</i> Effect Size
<=21	Aneroid	27	1.85	8.54	0.22
	Wrist	27	3.41	13.41	0.25
	Arm	27	5.70**	10.06	0.57 ^M
21- 24.5	Aneroid	18	0.78	9.05	0.09
	Wrist	18	0.22	10.32	0.02
	Arm	18	8.33***	6.59	1.26 ^L
24.5 - 50	Aneroid	16	0.88	8.97	0.10
	Wrist	16	-1.63	8.44	-0.19
	Arm	16	6.94*	9.62	0.72 ^L
> 50	Aneroid	22	-3.45	12.50	-0.28
	Wrist	22	3.95	15.82	0.25
	Arm	22	15.50**	17.95	0.86 ^L

Note: * $P < .05$, ** $P < .01$, *** $P < .001$; ^Mmedium effect size, ^Llarge effect size. All other effects are small.

To better understand the interaction of monitor by age, subjects were divided into 4 groups based on age. To form groups, subjects were divided into fourths by age with roughly 25% of subjects per group. Results are reported in Table 2. The groups included those aged less than 21 ($n = 27$), 21-24.5 ($n = 18$), 24.5-50 ($n = 16$), and greater than 50 ($n = 22$). The number of measurements in each fourth is not exactly equal to 25% because there were several individuals with ages exactly at the cut-off values (ie, 21, 14.5, 50). The difference between measurements of each monitor and those of the mercury monitor was averaged for each age group (monitor-mercury) and tested via dependent t-tests. For all age groups, the arm measurement was significantly higher than the mercury device ($P < .05$). However, this difference changed as a function of age. The difference was largest for those aged 21-24.5 (Cohen's $d = 1.26$, a large effect, see discussion of effect size below), followed by those aged 24.5 to 50 ($d = .72$, a large effect), and those less than 21 years old ($d = .57$, a medium effect). The measurements from the arm monitor were consistently higher than from the mercury monitor for those aged less than 50 years old. However, the differences between arm and mercury measures were highly variable for those over 50. For some individuals, the arm measures were much higher and for others they were lower than the mercury measures. This indicates poor reliability of the arm monitor, especially for those over 50 years old. The measurements from the other monitors did not significantly differ from the mercury at any age.

In addition to statistical significance tests, measures of effect size (Cohen's d) were also provided. Cohen's d is a measure of the difference in readings (monitor-mercury) divided by standard deviation. With smaller sample sizes, as we see when we divide the data into age groups, power is lower. This results in a lower probability of correctly rejecting the null hypothesis. The benefit of effect size is that it provides a standardized measure of the strength of the effect removing the potential influence from sample size. As such, it allows one to compare effects across analyses to determine which are the strongest and weakest effects. Effect size measures can be classified as large, medium, or small.³⁷ A large effect is one that could typically be discerned by lay people in real-world settings. A medium effect could be detected by trained professionals. A small effect, while still possible meaningful, is not likely to be easily noticed even by trained professionals in real-world settings.

We also explored the variability of the differences between alternate and mercury monitors across individuals. The consistency with which the alternate monitor varies from the mercury is a measure of reliability. It should be noted that the variability of the differences (monitor-mercury) was highest for wrist measurements in all age groups, except for participants aged 24.5-50. This indicates lower reliability for the wrist measurements relative to the other measures. There appeared to be greater variability in differences with increased age. To test this, variances in difference scores

(monitor-mercury) across age were statistically tested with F tests of variances, using $P < 0/5$ for all tests of variance. Results indicate that theaArm monitor was significantly more variable among those aged over 50 than at any other age. The Aneroid monitor was significantly more variable among those aged over 50 than for those 21 or younger, and the wrist monitor was significantly more variable for those over age 50 than for those 21-24.5 and from 24.5 to 50 years of age.

In sum, the measurements of each monitor were compared to the mercury standard. The aneroid and wrist measures did not significantly differ from mercury measures at any age. However, it was found that the arm measures, on average, provided measures greater than the mercury standard, $P < .05$. For individuals over 50 years of age, the differences between arm and mercury measures were less consistent. In some cases, the arm measurement was higher than the mercury measures and lower in others, indicating especially low reliability for the arm measurement for those aged 50 years old. Similarly, the wrist measurements, as compared to mercury, were also more variable for those over 50 than at other ages.

Diastolic

Diastolic pressure significantly increased with age, $F_{1, 80} = 20.72$, $MSE = 314.74$, $P < .0001$. Diastolic pressure did not significantly differ by monitor, $F_{3, 240} = 1.92$, $MSE = 67.34$, $P = .13$, but the interaction of monitor and age was significant, $F_{3, 240} = 3.80$, $P < .05$ (Table 3), indicating that the increase in diastolic pressure across age is different across types of monitors.

Table 3. Mean differences in diastolic pressure measurements by each monitor and the Mercury by age.

Age	Monitor	n	Mean Difference	SD	Cohen's <i>d</i> Effect Size
<=21	Aneroid	27	-1.70 [†]	4.95	-0.34
	Wrist	27	1.56	9.96	0.16
	Arm	27	0.93	6.37	0.15
21- 24.5	Aneroid	18	-2.00	7.82	-0.26
	Wrist	18	-0.39	5.40	-0.07
	Arm	18	3.39 [*]	5.67	0.60 ^M
24.5 - 50	Aneroid	16	0.75	5.11	0.15
	Wrist	16	-2.06	6.26	-0.33
	Arm	16	3.13	7.90	0.40 ^{S-M}
> 50	Aneroid	22	-1.59	6.08	-0.26
	Wrist	22	6.68	25.37	0.26
	Arm	22	3.05	11.26	0.27

Note: [†] $P < .10$, ^{*} $P < .05$, ^{**} $P < .01$, ^{***} $P < .001$; ^{S-M}small to medium effect size, ^Mmedium effect size. All other effects are small.

To further explore the interaction, the difference between measurements of each monitor and those of the mercury (monitor-mercury) was averaged for each age group, divided into fourths, and tested via dependent t-tests. For those less than 21, the aneroid monitor was significantly lower than the mercury measurement ($P = .086$, Cohen's $d = .34$, a small effect) and the arm measurement was significantly greater than the mercury for those 21 to 24.5 ($d = .60$, a medium effect).

The variability of the differences between these measurements and the mercury was highest for participants over age 50, with the exception of the aneroid. Further, the variability of the difference between wrist and mercury measures was significantly higher than other monitors for participants over age 50. Thus, the reliability of the wrist and arm measures is lowest for participants over age 50. This is especially true of the wrist monitor.

In sum, the differences between measurements from alternate monitors and the mercury monitor were small, for the most part. The only exception was that the arm measurement tended to be somewhat higher than mercury for those aged 21-24.5.

Differences between alternate measures and mercury tended to be most variable for those over 50, indicating lower reliability for those in the older category.

Pulse

Pulse did not change significantly with age, $F_{1,80} = 0.03$, $MSE = 310.24$, $P = .86$. Further, pulse did not significantly differ by monitor, $F(2, 160) = 2.33$, $MSE = 45.33$, $P = .10$; the interaction of monitor and age was also not significant, $F_{2,160} = 0.63$, $P = .53$ (Table 4).

Table 4. Mean differences in pulse between measurement by each monitor and the Mercury by age

Age	Variable	N	Mean Difference	SD	Cohen's <i>d</i> Effect Size
<=21	Wrist	27	4.07 [†]	11.33	0.36
	Arm	27	1.56	8.97	0.17
21- 24.5	Wrist	18	0.83	10.17	0.08
	Arm	18	3.11	9.68	0.32
24.5 - 50	Wrist	16	5.56	15.84	0.35
	Arm	16	2.94 [†]	5.95	0.49 ^M
> 50	Wrist	22	-0.45	6.36	-0.07
	Arm	22	-0.45	6.22	-0.07

Note: [†] $P < .10$; ^Mmedium effect size. All other effects are small.

Even though the interaction was not statistically significant, we examined the effect sizes (Cohen's *d*). The effect size for the difference between arm measure and mercury for those aged 24.5-50 was of medium size ($d = .49$), but only marginally statistically significant ($P = .07$). The discrepancy between lack of statistical significance and effect size is due to low power for the significance test. This evidence would not support a claim that the arm measurements do not deviate from the mercury measurement.

For pulse measurements, the pattern of variances was different from that of the systolic and diastolic pressures. The biggest difference in variability was seen for participants in the 24.5-50 years of age category, where the differences from the wrist monitor were significantly more variable than those from the arm monitor (Table 4).

In sum, pulse measurements from alternate monitors were not significantly different from mercury measurements at any age group. This does not mean that the difference in measurements was small for all individuals. In fact, for those 24.5 to 50, the wrist monitor yielded significantly more variable results than at any other age and other monitors. Thus, pulse measures are likely to be more reliable than either systolic or diastolic BP measures, at all ages. However, there is reason to further explore the differences seen with the wrist monitors for those aged 24.5 to 50.

Overall, measures from alternate monitors deviated somewhat from mercury measures. Further, the differences between alternate monitor and the mercury monitor varied by age. The biggest mean differences from mercury standard were seen for systolic pressure, especially from the arm monitor. The arm monitor consistently yielded measurements higher than the mercury monitor. Measures of diastolic pressure from alternate measures differed from the mercury to a lesser extent. Although, the arm monitors still tended to yield measures greater than the mercury. It is interesting that the difference was greater for those in middle adulthood (aged 24.5 to 50) than those over 50 and less than 21 years old. Pulse measures from alternate monitors did not significantly differ from the mercury.

If given grades for accuracy, based on BHS standards, no monitor was rated acceptable for all measurements (ie, systolic, diastolic, and pulse). All monitors of systolic pressure and pulse would be given grades of lower than C. With regard to diastolic pressure, the wrist measure would be graded lower than C, but the arm and aneroid measures would receive B grades.

In addition to exploring the mean difference between the alternate and the mercury monitors, we also compared the variability of these differences. The consistency with which the alternate monitor varies from the mercury is a measure of reliability. That is, can we count on the pattern of results being similar from person to person and reading to reading? Systolic and diastolic measures from alternate monitors, especially arm monitors, were least reliable for those over 50 years of age. For these individuals, alternate monitors yielded a wide range of results, sometimes higher and sometimes lower than the mercury, with little consistency. Interestingly, the reliability of pulse measurements, though, was lowest for those aged 24.5 to 50 years than for those less than 21 or greater than 50.

Analysis of data indicates little difference for pulse readings between automated and digital methods. We can conclude, with regard to systolic pressure, that the automated arm and wrist measures are least reliable, and the automated arm monitors tended to provide higher measures than the mercury standard, on average. All monitors exhibited low reliability for those over age 50 compared to the control. For diastolic pressure, the only significant difference between monitor measure and the mercury standard was for the automated arm measurements of those aged 21-24.5. Again, the differences between each monitor's reading and the mercury readings were most variable for participants over age 50. This suggests a pattern in which these alternate BP monitors are least reliable for those older than 50 years. In direct contrast, pulse measures using the wrist monitors were variable for all age groups, but most consistent for those in the over 50 age group.

Discussion

This study had an adequate number of subjects in the convenience sample, although including similar numbers of subjects at each age range would have been beneficial. Some of the limitations of this study include the lack of statistical analysis of investigator calibration, the limited number of participants with low and high BP, the limited number of BP measuring devices used, and the limited number of participants in some age groups (middle and old). The limitations are similar to those of other studies of BP monitoring devices. In fact, validation protocols for BP devices have recently been changed because of the difficulty of obtaining large enough subject pools to ensure adequate representation at all ranges of age and BP.³²

It has been the personal experience of the authors, and supported by the literature, that automated wrist and arm manometers are being used in health care settings and by many individuals in their homes. In addition to not consistently following proper technique for taking BP, health care personnel record readings from automated manometers in the permanent patient record, which may erroneously be used in diagnosis and treatment. This study and others demonstrate the inaccuracy of automated BP monitors and traditional aneroid manometers when compared to the gold standard mercury column manometer, especially for different age groups.^{3,4,7-9,11-13, 15} In particular, the low reliability of measurements taken by nonmercury monitors on individuals older than 50 years of age is a major source of concern. Using nonvalidated devices can negatively impact dental care, in particular for patients over age 50, since false results limit identification of patients at risk of cardiovascular incidents associated with the use of vasoconstrictors or during times of stress or anxiety during a clinical appointment.

The authors recommend the exclusive use of validated BP monitoring devices for use at home and in health care settings. It is also essential to recognize the need for frequent calibration of aneroid units with the mercury column manometer.

Continued research and validation of the mercury-replacing BP devices is necessary, particularly automated manometers, as their popularity is sure to increase. With new products continually entering the market, the need to validate accuracy and reliability of the products must occur. Of particular interest for study are the wrists and finger cuff models.

Education of health care personnel and home users regarding validation of devices and proper technique is vital. The best technique will not make up for an inaccurate device, nor will poor technique allow an accurate device to provide precise data. The need for a properly fitted arm cuff cannot be over emphasized.

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Conclusions and Recommendations

As in other studies and reports,^{7,9,12,15} our study found that the automated arm and wrist units and the aneroid sphygmomanometer used in the study did not pass standards set forth by the BHS and AAMI due to variability of systolic and diastolic BPs in mmHg when compared to the control. Whether the inaccuracies are due to arm positioning at heart level, as observed in the study by Mourad et al (2005), or due to inadequate algorithms, as indicated in the study by Dieterle et al (2005), there is evidence that more study is needed before mercury manometers are formally replaced by other devices.^{9,16} BP measurement should be an exact science since it is used in diagnosis and treatment, yet many studies indicate there are far too many variables, such as operator variability and training,^{7,10,12} arm positioning,¹⁶ and software⁹ or mechanical functioning.⁸

Dental hygienists routinely assess patient oral and general health. The standard of care for clinical dental hygiene includes the taking and recording of patient blood pressure. The results of our study indicate that dental hygienists should follow these recommendations in order to be assured their results are accurate:

Use only validated BP measuring devices. Check validity by using BHS or dabl Educational Trust websites prior to purchasing such units.

Use mercury and calibrated aneroid-style monitors since they are the most accurate means of taking BP. Limitations of these devices are typically due to operator error in rounding off readings, in hearing Korotkoff sounds, and in ensuring the gauge is set to zero at pre- and post-measurement.

Limit use of automated BP monitors to those that are independently validated and biannually calibrated. These units are quick and easy to use and provide a large digital display that gives a distinct reading. Limitations of these devices include standard-only cuff sizes and inaccurate readings for patients with arrhythmias and hardening of the arteries.

Calibrate BP manometers (aneroid and automatic) twice each year against a mercury manometer, and/or return to manufacturer for calibration and repair.

Place patients in an upright position with the arm supported at heart level. Let the patient rest at least one minute prior to or between BP readings. Discourage movement or talking during the procedure to improve accuracy.

Educate the dental team and other health care providers regarding accuracy of BP monitoring devices, and review proper patient and equipment positioning annually.

Notes

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