Accuracy of Digital Arm and Wrist Manometers: Clinical Implications for the Dental Hygienist

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Abstract

Purpose: Utilization of digital manometers chairside is fast becoming a standard of care in dental hygiene education. It is imperative to ensure accurate blood pressure measurements regardless of modality to avoid medical emergencies in the dental chair. This study sought to determine the accuracy of the automated digital arm and wrist cuffs utilized by students in the University of Maine at Augusta, Bangor Campus Dental Health Programs' dental hygiene clinic.

Methods: After institutional review board approval, 121 subjects were recruited, with 21 excluded for a total of 100 subjects. Subjects were randomly assigned to different test modalities upon check-in. Initial blood pressure measurements were taken with a calibrated aneroid control device by a principal investigator. A second measurement was taken with the randomized arm or wrist manometer 5 minutes later. Investigators were blinded to the modality of test manometer and measurements obtained from the second reading. All readings were taken according to manufacturers' instructions to ensure technique consistency.

Results: Data indicated lower readings for each modality from the control for both systolic and diastolic measurements. The differences in the systolic and diastolic readings for the wrist modality were significantly lower than the control with ($p=0.000$) and ($p=0.000$), respectively.

Conclusion: Automated digital manometers should be used with caution as a screening tool in the dental setting, particularly when administration of pharmacological agents such as local anesthesia may be used during the course of treatment. These automated modalities should not be used for patients with cardiac or hypertensive conditions.

Keywords: blood pressure, dental hygiene, manometer, accuracy

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Introduction

Thorough patient assessment is the first step to successful treatment planning and risk management in the dental hygiene process of care. Data that indicates the physical health status of a patient must be gathered and analyzed. A key piece of determining a patient's current health status is obtaining accurate vital signs, particularly blood pressure. In addition to contributing to the picture of the patient's overall health status, the assessment of vital signs is imperative in avoiding immediate medical emergencies in the dental chair, such as myocardial infarction or cerebrovascular accident. This is especially important for a wide array of patients, such as the growing geriatric population with concomitant medical conditions, those with multiple prescribed medications, and those with uncontrolled hypertension. The risk for a medical emergency is then further compounded by the use of pharmacologic agents, such as local anesthesia or anxiety provoking procedures.

The mercury manometer is an instrument that requires skill to use.[1,2] However, the mercury manometer is now gradually being phased out due to a heightened awareness of mercury safety and its impact on the environment.[3-5] Practitioners may have the perception of this modality requiring more time and being more technique sensitive than alternative methods. In light of this, many institutions are transitioning to automated digital or aneroid manometers. In addition to being mercury-free, these devices are thought to be quick and less technique sensitive.[6] Observation of the investigators indicates dental hygiene education programs and dental offices appear to be following this trend. Whether it is to save time and frustration, or whether programs feel students will get more accurate readings than with an auscultatory device is not clear.

Most automated devices detect oscillation in the arterial wall as opposed to the sound of blood moving through the artery.[6-8] The American Association of Medical Instrumentation (AAMI) and the British

Hypertension Society (BHS) have protocols in place to validate such devices. However, not all devices on the market have been validated. Bern et al noted there is no standard algorithm in the manufacture of automated devices to identify systolic and diastolic measurements; each manufacturer uses their own unique algorithm.[6] The purpose of this study was to determine whether or not these modalities are a valid option for use in the dental hygiene practice setting.

A review of the literature has revealed several points relevant to this study. Accuracy in non-invasive blood pressure monitoring devices appears questionable regardless of modality. Even if a device has been validated, it does not mean that it will perform accurately in clinical use. The validation, accuracy, required techniques and special considerations for the use of non-invasive blood pressure monitoring devices will be reviewed with emphasis on automated blood pressure monitoring devices.

Incidence

Obtaining vital signs, including blood pressure readings, are essential to appropriate patient care in dentistry as well as medicine. Nelson et al noted, "obtaining [blood pressure] has been identified as one of the most important measurements in clinical medicine."[5] The American Dental Hygienists' Association (ADHA) defined the collection of vital signs as a standard of clinical hygiene practice.[5,9] Therefore, it is imperative that the devices utilized in blood pressure measurement be accurate.

The most accurate means of measuring blood pressure is via a catheter placed directly in an artery.[6] This is not a feasible method for everyday measurement. For more than a century, practitioners have relied on mercury sphygmomanometers in order to obtain blood pressure readings. This modality requires the use of a stethoscope to listen to the movement of blood through the artery. The auscultatory piece of the mercury modality adds the disadvantage of relying on the hearing of the operator.[5,10] Hearing is variable amongst each operator, introducing or increasing the chance for inaccuracy. Furthermore, the recognition of the toxic nature of mercury and its accompanying environmental hazards is leading to the replacement of this modality with aneroid and automated digital modalities.[3-5]

Automated digital manometers have multiple benefits. There is no need for a stethoscope, as measurements are taken by detecting the movement of the arterial wall.[6-8] These devices are operated by the simple push of a button, leaving the clinician free to attend to other matters. Many devices will give a pulse reading in addition to the blood pressure measurement.

The popularity of automated blood pressure devices has led to an explosion of manufacturing, with numerous varying devices being produced all over the world. A wide array of inexpensive, automated options can be conveniently purchased at drug and grocery stores. One study reported that in the UK alone there were 40 manufacturers offering nearly 100 different automated devices.[4] In an effort to help clinicians and institutions select devices to fit their needs, organizations such as the AAMI and the BHS have instituted protocols and standards to validate automated devices, while also testing many devices and publishing the results. When choosing a device it is recommended that selection be based on validation by the AAMI or BHS. However, these devices may be cost prohibitive in the dental hygiene educational and clinical practice settings.

Considerations in Practice

Wan et al noted that a blood pressure measurement device that has received validation by the AAMI or the BHS does not necessarily guarantee clinical accuracy.[1] They further noted that validated devices are not necessarily more accurate than those that failed protocol validation. Calibration of the automated device is key to accurate blood pressure measurements, as well as patient safety. Uncalibrated devices increase the chances of patients being misdiagnosed as hypertensive or within healthy limits.[4] The clinician must also be aware that automated blood pressure devices wear out much more quickly.[4,11]

Several studies have noted that the technique guidelines published by the American Heart Association (AHA) should be used when obtaining automated blood pressure measurements in order to increase accuracy.[1,10,11] In addition, the clinician must also be aware that the automated device is not appropriate for blood pressure measurement of all patients. The use of the automated blood pressure device is contraindicated in patients with several cardiac related conditions, such as atherosclerosis, hypertension, hypotension and dysrhythmias.[1-3,6,8,10,12]

Clearly, ease of use does not equal accuracy. Although automated, these devices require as much attention to technique as an auscultatory method. It is critical that practitioners follow manufacturer directions for the use of automated devices. Stergiou et al noted that inappropriate cuff size can lead to overestimation and underestimation of blood pressure measurement as well.[13] Accurate blood

pressure measurement is important for the overall treatment and wellbeing of the patient. Although automated devices take readings at the push of a button, the clinician must give great consideration to technique, patient selection, equipment maintenance and equipment longevity.

Methods and Materials

For this study, 121 subjects aged 18 and over were recruited from the University of Maine at Augusta Dental Health Programs' Dental Hygiene clinic patient pool at appointment check-in. Exclusion criteria included: cardiac arrhythmia, arterial stiffness, having a full bladder, trouble breathing, tobacco use, pain, arm circumference larger than 16 inches, myocardial infarction within the last 6 months, current cancer therapy and the inability to present a bare arm. A total of 21 subjects were excluded for a final sample size of 100. The sample size of 100 was determined to be a suitable size for the study by the biostatistician. Eighteen senior dental hygiene students worked with the principal investigators (PIs) on this project and were trained on how to operate each of the test modalities, and 2 dental hygiene faculty members with experience in conducting clinical research studies served as the PIs. Subject blood pressure would be obtained first with the control unit by 1 of the PIs, followed by another reading taken by a student with 1 of the test modalities. The study received approval from the University of Maine at Augusta Institutional Review Board.

An aneroid manometer (American Diagnostic Corporation® E-Sphyg2™, Hauppauge, NY) was used as the control modality for this study. Investigators took the control unit to the local medical center's biomedical engineer for calibration both before and after the study. The control unit measured at ±2 mm Hg at both calibrations, which was well within the AAMI and BHS ranges for validity. Senior dental hygiene students were given a training session and were taught to utilize both variable modalities according to strict adherence to manufacturer instructions and study protocols and to record the necessary data.

In addition, both PIs completed a calibration exercise for inter-rater reliability. Investigators each took the blood pressure of 8 volunteers before commencing the study. These readings were taken with the control unit, strictly adhering to manufacturer's instructions and using the patient qualifying criteria. The "r" value for this reliability study was 0.898, which was deemed appropriate for this type of study and were confident to move forward enrolling subjects. The PIs conducted this exercise to determine the degree to which the investigators would be able to obtain reliable results when using the control unit on the intended subject population. It also offered a formal protocol training session for both PIs prior to the initiation of study subject enrollment.

Assignment

Upon obtaining consent, subjects were randomized into modality A (arm) or B (wrist) sequentially by reception staff. Data collection sheets were inserted into subject charts, indicating to students the randomized modality to be used. Investigators determined subject eligibility or exclusion once subjects were seated and medical history obtained. Once the subject was determined eligible, a PI acquired a baseline blood pressure reading with the control unit, recorded the reading and exited the operatory. The student operator would then return to the operatory, and acquire another blood pressure reading with the randomized modality after 5 minutes.

All units used in the experiment came from the manufacturer programmed for use on the left arm and wrist; all subjects had their blood pressure taken on the left arm. All readings were taken with the subject seated in an upright position, with both feet flat on the floor. Subjects were instructed to remain still, and not to speak during measurement, as this could affect the reading. All other manufacturer instructions were followed for each of the modalities.

Analysis and Statistics

Pearson Chi-square was done to determine if randomization produced balanced groups in each of the test modalities. Differences between control measurements and variable modality measurements were tested using 2 sample t-tests. For a comparison of inter-rater reliability, the following tests were run: paired t-test, comparison of variances, Pearson correlation and concordance correlation coefficient.

Results

Nominal variables for demographics such as age ($p=0.151$), gender ($p=0.433$) and randomization to each PI ($p=0.356$) showed no differences in distribution. Average measurements for control systolic and diastolic blood pressure compared to age showed no difference between the two randomized groups.

Comparison of randomized group means of systolic and diastolic blood pressure to control measurements displayed mixed results. Although measurements were lower for modality A compared to the control, the values were not statistically signifi-

cant. Readings fell within the AAMI and BHS guidelines with comparative means for the systolic of 129.1 mm Hg for the control, and 127.3 mm Hg for modality A (p=0.274). Results show measurements for group B were significantly lower for both systolic (p=0.000) and diastolic readings (p=0.000) compared to the control measurements. Regression models show test modalities tended to be more accurate for those with lower blood pressures.

The results for inter-rater reliability showed no significant difference between the measurements of the PIs. The p-values for the paired t-test were 0.822 (systolic) and 0.803 (diastolic). For the tests of equal variances the p-values were 0.469 (systolic) and 0.201 (diastolic). The Pearson correlations were 0.898 (systolic) and 0.730 (diastolic), with the concordance correlation coefficients were 0.897 (systolic) and 0.691 (diastolic). With a 95% confidence interval for the concordance correlations, results show a concordance for both systolic (0.811, 0.945) and diastolic measurements (0.527, 0.805).

Discussion

This study demonstrated that the automated digital modalities record lower readings than the aneroid manometer, whether arm or wrist type. These findings are consistent with the evidence discussed in the literature.[7,8,10] The wrist modality demonstrated lower readings well beyond accepted limits and should therefore not be considered for use in the assessment of dental hygiene patients at this time. However, these findings are based on only 2 measurements per patient. Future studies may want to include a third measurement, to follow the protocol set forth by the AAMI and BHS.[14-16] While the literature is conflicting in regards to the accuracy of aneroid manometers,[3-5] the aneroid unit utilized as the control in this study was found to be well within the range of validity both pre and post study.

The tendency to measure lower readings suggests the opportunity for misdiagnosis of the hypertensive patient. Lower measurements introduce more risk to dental treatment, increasing chances of a medical emergency in the dental chair. This may lead to a patient who should be dismissed for having a blood pressure measurement outside of treatment guidelines remaining in the chair for procedures. The risk for medical emergency may be particularly compounded when administering local anesthetic agents and nitrous oxide and oxygen sedation.

The reasons for the lower readings are not clear, but some conclusions can be drawn. The risk for operator error is always inherent. It is of note that even when using new units and following strict adherence to manufacturer instructions, the test modalities still vary. However, the AHA guidelines for obtaining blood pressure measurements were not used in this study - manufacturer instructions were followed.[1,10,11] Dental hygiene clinics that choose to include automated arm or wrist modalities to be included in student kits should consider developing a protocol for obtaining blood pressure measurements. The protocol should combine the AHA guidelines with manufacturer's instructions. Contraindications for the use of these modalities, such as hypertension or hypotension and dysrhythmias should also be included in any protocol. Anyone utilizing these types of manometers should be aware that they come calibrated for use on a specific arm, and that acquiring a reading from the opposite arm, or following the manufacturer's directions on switching the machine to the opposite arm can introduce variance of measurements. In addition, these modalities should be stored in a way that minimizes wear and tear, as these manometers are already prone to quicker deterioration, which leads to inaccuracy. Although the literature does not suggest a time frame or number of measurements as a turning point in these manometers' lifespan, consideration should be given to replacing the units within a set time based on the patient load. Consideration should also be given to purchasing validated aneroid manometers that can be calibrated regularly.

This study may be limited by the fact that hypertensive patients were not excluded, as results showed both modalities to perform more accurately on lower blood pressure readings. These modalities are not meant for baseline assessments in the clinical setting. Although hypertension is contraindicated for the use of these modalities, other literature clearly delineates use of these manometers at home as means for hypertensive patients to monitor the control of their condition for their primary care provider. These findings indicate that their use in the clinical environment should be limited.

Conclusion

Although both convenient in use and low in cost, automated digital arm and wrist modalities are not intended for the clinical assessment of vital signs, and therefore do not offer the clinical accuracy needed by the dental hygiene practitioner. Strict protocols should be developed for obtaining blood pressure measurements that include: AHA guidelines, manufacturer instructions and literature supported contraindications for use. Dental hygiene education programs should consider integrating an established protocol into their preclinical and clinical curriculum to ensure patient safety. Considering

the number of people in the U.S. with some form of hypertension, use of these modalities is not recommended for routine dental hygiene assessment. The purchase of aneroid or other reliable manometers that can be calibrated and serviced on a regular basis, together with strict measurement protocols can offer the safety and efficacy needed for clinical dental hygiene treatment.

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