The Accuracy of Electronic Wrist Blood Pressure Monitoring Devices

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Abstract

Background: Assessment of blood pressure is the most common diagnostic procedure performed in the outpatient clinic. The purpose of this study was to compare the accuracy of the wrist-cuff electronic oscillometric device with the universally-accepted gold standard measurement made with Korotkoff sound technique mercury sphygmomanometer.

Materials and Methods: This was a randomized, crossover study with a total of 60 subjects. All subjects were at least 30 years of age. Three blood pressure readings were recorded for each subject, two with a wrist-cuff device and one with a mercury sphygmomanometer by the secondary investigator. The order of the 3 readings were determined by chance.

Results: Patients (32 women, 28 men) aged 30-94 (mean age = 55, SD =16) years were included in the study. Based on the paired-sample t-test, the data provided strong evidence that there was no statistically significant difference in systolic or diastolic blood pressure readings between the wrist-cuff electronic oscillometric device and mercury sphygmomanometer.

Conclusions: The evaluation of blood pressure remains a basic diagnostic step in every clinical practice as it positively imparts the clinical well-being of the patient. It is, therefore, important to maintain a good degree of accuracy and reliability in the blood pressure monitoring device.

Key words: Blood pressure, electronic monitoring device, mercury sphygmomanometer

Introduction

Assessment of blood pressure is the most common diagnostic procedure performed in the outpatient clinic.[1] The equipment used to measure blood pressure is as critical as patient preparation and proper technique in obtaining accurate blood pressure readings.[2-6] The most common sphygmomanometers used in outpatient clinics are the mercury and aneroid sphygmomanometers.[7,8] Electronic devices are generally used by patients for home monitoring, but are occasionally used in dental clinics.[7]

All measurements are contaminated by errors that may be divided into two types: random errors and systematic errors.[9, 10] Random errors are different on every occasion and can be reduced by averaging a number of measurements. Random errors are caused by the inherent variability of blood pressure, and the tendency for blood pressure to increase in the presence of a physician (the so-called “white coat effect”). Systematic errors have approximately the same value on every occasion and are not reduced by averaging.[9] Inadequate sphygmomanometer maintenance and calibration is a common cause of systematic error in blood pressure measurements.

Systematic errors are difficult to detect and correct. The only way to reduce systematic errors is to use the correct measurement technique and well-maintained and calibrated instruments. The detection of hypertension is extremely sensitive to systematic errors in blood pressure measurements. A consistent 5mmHg error can more than double or halve the number of patients diagnosed with diastolic hypertension. A consistent 5mmHg error in systolic pressure can result in systolic hypertension being under diagnosed by 30% or over diagnosed by 43%.[10]

For clinical practice, the "gold standard" is a measurements made with the Korotkoff sound technique using a mercury sphygmomanometer, but there is increasing evidence that this may lead to the misclassification of a large number of individuals as hypertensive. In addition, mercury is being banned in many countries, and there is still uncertainty as to what will replace it.[9] The standard location for blood pressure measurement is the brachial artery, although there are several other sites where it can be done. Monitors that measure pressure at wrist and fingers have become popular, but it is important to realize that systolic and diastolic pressures vary substantially in different parts of the arterial tree. In general, the systolic pressure increases in more distal arteries, whereas the diastolic pressure decreases. [9] There is a growing tendency in the United States to replace mercury devices; the unresolved issue is what should replace mercury. Currently, the two alternatives are aneroid and electronic (oscillometric) devices, but neither is regarded as satisfactory.[9]

Electronic devices that will take blood pressure from the upper arm, wrist, or finger are now available. Wrist monitors have the advantage of being smaller than the arm devices and can be used in obese people, as the wrist diameter is little affected by obesity. A potential problem with wrist monitors is the systematic error introduced by the hydrostatic effect of differences in the position of the wrist relative to the heart.[12] Finger monitors are convenient but have so far been found to be inaccurate. The pressure waveform in the finger is different from the brachial artery trace because of the effects of wave reflection. Thus, the systolic peak is shorter and higher, and, hence, finger monitors would be expected to overestimate the brachial artery systolic pressure by about 4mmHg.[13] It has been reported[14] that self-measured blood pressure are better predictors for prognosis of hypertension than office blood pressure and provide a more accurate evaluation of the effect of treatment. Many of the electronic, self-measurement devices have shown poor records of accuracy when validated[15, 16].

The wrist-cuff devices provide a wide range of distribution of differences. Several reasons have been advanced for these differences and one of these is incomplete occlusion of wrist arteries. Insufficient occlusion of wrist arteries depends on the subjects and frequently on the angle of the wrist joint. The arteriosclerotic vascular changes in radial and ulnar arteries might be the remaining possible mechanism for the large difference between auscultation and the wrist-cuff device[17]. Furthermore, the relationship between cuff and thickness of wrist and fitness of cuff still seems to be a factor affecting blood pressure levels measured by wrist-cuff devices. Such factors, in addition to the position of the wrist in relation to the heart, can induce a large standard deviation of the differences between auscultation and wrist-cuff devices[18].

The University of Nebraska-College of Dentistry (UNMC-COD) has a clinic policy to check vital signs. Vital signs provide objective baseline data. The blood pressure (BP) and pulse rate (HR) are recorded on the medical history form. Each patient needs to have a minimum of two blood pressure and heart rate readings and this is complied to routinely especially if a patient is medically compromised. The UNMC-COD guidelines for treating patients with hypertension requires that a patient with blood pressure greater than 180 systolic and 105 diastolic pressures is referred for immediate consultation with his physician and no further dental treatments are provided. Blood pressure monitoring is a critical step in the clinic policy of the UNMC-COD.

The aim of this study, therefore, was to compare the accuracy of the wrist-cuff electronic oscillometric devices with the universally accepted "gold standard" measurement made with the Korotkoff sound technique using a mercury sphygmomanometer.

Methods

This randomized, crossover study was conducted at the clinics of the College of Dentistry of the University of Nebaska in Lincoln, Nebraska, USA. We wanted to detect a 5mmHg difference in mean BP readings between wrist-cuff and mercury sphygmomanometer ($\delta = 5$). A total of 60 subjects was randomly enrolled after consenting to the study. There were no restrictions based on gender, and only subjects between ages 30 and 95 were included.

Ethics Committee Approval

The study was conducted in human participants with the approval of the Office of Regulatory Affairs, Institutional Review Board, IRB #370-09-EP, of the University of Nebraska Medical Center.

Validation measurements

The most difficult component for the validation of blood pressure monitoring devices is the human observer. In this study, the secondary investigator [BOB] was calibrated by the primary investigator [BJB] using the mercury sphygmomanometer. To guarantee the accuracy of the mercury sphygmomanometer reading, agreement of the two observers' values obtained from auscultation was estimated as the mean difference and standard deviation (SD) between the two observers' readings. The validation measurements consisted of a series of practice measurements on volunteers.

Blood Pressure Measuring Techniques

A standard mercury sphygmomanometer, the components of which had been carefully checked before the study, was used as a reference standard. All blood pressure readings were recorded to the nearest 2mmHg. Standard mercury sphygmomanometer measurements were taken with bladder of sufficient length to encircle 80% of the arm circumference.[22]

Blood pressure was measured with the arm supported at heart level, at eye level and within 1m of the observer. A well-maintained, high quality stethoscope was used for all the readings.

Devices for measuring blood pressure at the wrist

There are very few articles regarding the accuracy of devices for the wrist measurement and most studies have shown these devices to be inaccurate. Measurements of blood pressure at the wrist using oscillometric devices generally overestimate blood pressure compared with conventional sphygmomanometers on the upper arm, and the difference can be substantial. [24-26] The device may be inaccurate if the instruction to have the wrist at heart level during measurement is not strictly followed. The blood pressure ranges for entry of blood pressure at the UNMC-College of Dentistry is illustrated in Table 1.

Table 1: Blood pressure ranges for entry of Blood Pressure

	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)
Low	90 - 129	40 - 79
Medium	130 - 160	80 - 100
High	161 - 180	101 - 130

All the wrist cuffs used in the study were stored under well-controlled conditions at the Central Dispensing area of the College, and were checked out as needed.

Observer Measurement

Blood pressure readings were taken thrice on each subject by the attending student and the secondary investigator. The attending student took the initial reading using the wrist-cuff. Two additional readings were taken by the secondary investigator - one with a mercury sphygmomanometer, and the other with the same wrist-cuff used by the attending student. The order of the 3 readings was determined by chance.

Procedure

1. The subject was introduced to the secondary investigator, and the procedure was explained. Sex, date of birth, and current date and time noted. The subject was then asked to relax for 10-15 minutes (in order to minimize anxiety and any white-coat effect, which could increase variability).
2. The student attending to the patient took the initial blood pressure reading using the wrist-cuff device. He or she recorded the reading in the subject's chart and this was kept from the secondary investigator.
3. The secondary investigator took two additional blood pressure readings using both the mercury sphygmomanometer and the wrist-cuff device.
4. All the three readings were then entered into the information abstraction form created for the subject.
5. The three blood pressure readings were done at 5 minutes interval so as to prevent fatigue.

An Overview of Statistical Methods

Descriptive statistics were computed. A paired-sample t-test was used to determine whether there was a significant difference in blood pressure measurement between two types of monitoring

devices (i.e. the electronic sphygmomanometers vs. mercury sphygmomanometers) and the same procedure was used to detect whether the difference existed between the two reading within each blood pressure reading device that were made by the investigators. The Shapiro-Wilks' test was applied to verify the assumption of normality when parametric statistical procedures were carried out.

A significance level of 0.05 was set for all tests, and SAS for Windows (v9.3, SAS Institute Inc, Cary, NC, USA) was used for the data analyses.

Results

Blood pressure readings were classified as low, medium or high. Table 1 provides details of systolic and diastolic blood pressure classification. Sixty patients (32 women and 48 men) aged 30 to 94 (mean age = 55, SD = 16) years were included in the study. Of the 60 subjects, 16 (26.7%) were on anti-hypertensive pills and 23 (38.3%) had medium to high blood pressure readings. Simple descriptive statistics of age, gender and presence of anti-hypertensive medications were provided in Table 2.

Table 2: Characteristics of Respondents

Characteristic	Frequency	Percentage
Age group (years) of Respondents		
30 - 39	13	21.6
40 - 49	12	20.0
50 - 59	10	16.7
60 - 69	15	25.0
70 - 79	6	10.0
80 and above	4	6.7
Gender of Respondents		
Male	28	46.7
Female	32	53.3
Whether on anti-hypertensive medications or not		
Yes	16	26.7
No	44	73.3

The mean diastolic pressure readings of mercury sphygmomanometer (arm readings) of 76.67 (±10.67) was compared with the mean diastolic pressure readings of wrist –cuff electronic oscillometric device (77.3 ±12.43) at 95% confidence interval. This analysis showed no significant difference existed between the two readings (p = 0.59). Table 3. Moreover, the comparison of mean systolic blood pressure readings of mercury sphygmomanometer and wrist-cuff electronic device was conducted. The result indicated no significant difference between the two devices, p = 0.43 (Table 3)

Table 3: Difference in Wrist and Arm Blood Pressure Measurements within each blood pressure reading device

Blood pressure (BP) Reading, mmHg	Arm Readings mean ± SD	Wrist Readings mean ± SD	Student T - test	95% Confidence Interval of the difference	P - value
Diastolic BP	76.67 ± 10.67	77. 3 ± 12.43	-0. 54	(-2.98,1.72)	0.59
Systolic BP	130.13 ± 18.68	131. 36 ± 22.21	-0.80	(-4.28,1.83)	0.43

The majority of subjects on anti-hypertensive medications were taking Lisinopril (n=10). Table 4 and Table 5 provide a list of manufacturers of the electronic wrist-cuff devices included in the study.

Based on the paired-sample t-test, the data provided strong evidence that there was no statistically significant difference in systolic or diastolic blood pressure readings I and II for the electronic sphygmomanometer and mercury sphygmomanometer ($p > 0.05$ for all instances).

Table 4: Types of blood pressure medications subjects were taking

Type of Blood Pressure Medications	Frequency (n)
Lisinopril	10
Diovan CT, Fosamax	1
Benazapril, Hytrin Natuperol	1
Toperol	1
Secctell	1
Enapril	1
Bystolic	1

Table 5: Manufacturer Names of Wrist Cuff Devices used in the Study

Manufacturer Name of Wrist Cuff Device	Frequency (n)
Healthy Living® DBPM Samsung America Inc	22
No Medics BPW - 200	2
No Medics 518728	1
OMRON DWBPM Omron Healthcare Inc	15
ADC American Diagnostic Corporation	13
Homedics	1
Walgreens	1
Sunmark	1
Sunmark OMRON Healthcare Inc	1
Equaline Albertson Inc	3

Discussion

Blood pressure measurement is critical to the diagnosis of hypertension and the detection of hypertension is very sensitive to systematic errors in BP measurements[10]. Therefore, the BP measuring devices need to be calibrated, recalibrated regularly and maintained. Inadequate sphygmomanometer maintenance is a common cause of systematic error in BP measurements.

Automatic oscillometric sphygmomanometers measure cuff pressure by analyzing pulsations in the cuff pressure through the use of proprietary algorithms[10, 20, 28, 29]. The American Heart Association[27] recommends that oscillometric sphygmomanometers should be validated once in each patient to exclude the possibility of clinically significant systematic measurement error before being used to detect or manage hypertension in that patient. This validation is done by comparing a few BP measurements made not less than one minute apart on the same arm of the patient[10, 28]. Our study did not detect any statistically significant difference between the Mercury Sphygmomanometer and the electronic oscillometric BP device. Approximately 82% of the electronic oscillometric devices at the UNMC-COD were from only three manufacturers. This large stock from a narrow range of manufacturers is one possible explanation of the result. It is also possible that the

devices were properly calibrated and validated before being put to use in the clinics. Furthermore, the UNMC-COD has a unique culture of paying close attention to maintenance and proper storage of these devices. Each device is invariably kept in a safe plastic container and dispensed upon request. Another possibility is that the BP measurements were done with the wrist at the level of the heart. The participants in our study were a matured population and blood vessels become less elastic with age and an increase in blood pressure may persist slightly higher than average even after treatment. The result of our study is at variance with similar studies[11, 15].

The protocol for clinical validation of electronic oscillometric BP device adopted in our study is similar to protocols in other studies[19, 20, 30, 31]. This population-based protocol involves BP measurement with the device under test and a reference device (gold standard) sequentially in order to determine the accuracy of the test device. Even though regulatory authorities and professional organizations have varied protocol requirements for non-invasive BP devices, there is no unified protocol or standard as of yet[28].

Whereas the UNMC-COD guidelines for treating patients with hypertension requires that a patient with blood pressure greater than 180mmHg systolic and 105mmHg diastolic is referred for further treatment by the attending physician and the blood pressure reading is classified as low, medium and high; the Joint National Committee[32] at the eighth meeting, JNC 8, made recommendations on treatment thresholds. The JNC-8 classified patients into adults 60 years and older and adults younger than 60 years. Systolic pressure of 150mmHg or higher and diastolic pressure of 90mmHg or higher are thresholds for pharmacologic management of hypertension in patients 60 years and older. For the patients younger than 60 years of age, pharmacologic treatment is commenced at systolic of 140mmHg or higher and diastolic of 90mmHg or higher.[32] While the UNMC-COD classification of blood pressure does not break down the classes along threshold treatment and pharmacologic management, it provides the dentist a quick way of assessing patients and making decisions to refer patients to physicians who will further examine the cardiac status of the individuals.

The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure[33] classified prehypertension and hypertension. The committee classified hypertension as: Normal ($\leq$ 119/79), Prehypertension (120-139/80-89), Stage 1 Hypertension (140-159/90-99) and Stage 2 Hypertension ($\geq$160/100).

In dental practice, the overall health of the patient is important to the dentist as much as the oral health. Therefore, the blood pressure reading is routinely checked in the clinic. While the dentist is not expected to prescribe anti-hypertensive medications, a working knowledge of evidence-based practice in the diagnosis and classification of hypertension is necessary for the good health of the patient. Checking blood pressure is routine and there is need to be conversant with the blood pressure monitoring devices.

Conclusion

The evaluation of blood pressure remains a basic diagnostic step in every clinical practice as it positively imparts the clinical well-being of the patient. It is, therefore, important to maintain a good degree of accuracy and reliability in the blood pressure monitoring device.

Our study showed no difference in blood pressure readings between the electronic wrist-cuff device and mercury sphygmomanometer.

Limitation of study

Our study was done using electronic wrist-cuff devices from different manufacturers. This is a limitation in our study design because of the introduction of confounders into the study.

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