Evaluation of the Validity of Three MABIS Blood Pressure Monitors

To the Editor:
Elevated blood pressure (BP) is positively correlated with age, stroke, coronary heart disease, end-stage renal disease, and heart failure. Hypertension is, usually, diagnosed by the measurement of systolic or diastolic BP. Achievement of normalization of BP is often considered the goal of hypertension management. Therefore, a valid, accurate, and reliable method is essential for the diagnosis and management of hypertension.

Although accurate and practical noninvasive BP monitoring has been available since the early 1900s, a number of difficulties are associated with these methods. In a brief review of the literature, Latman et al identified compliance “as a major problem in the treatment of hypertension.” They concluded that patient compliance and outcome can depend on BP monitors that were accurate and easy to use. Historically, the standard for noninvasive BP measurements has been a mercury or aneroid sphygmomanometer combined with a variation of the Riva-Rocci brachial compression cuff. Detection of systolic and diastolic BP has relied on auscultation of the Korotkoff sounds.

Although the manual auscultatory methods of the early 1900s could produce accurate systolic and diastolic BP measurements, they had several limitations. They were very user-skill dependent. As self-monitoring of BP became more common, the ease or lack of ease-of-use of the instruments gained in significance. Before the early 1900s, attempts to improve noninvasive BP monitor were mainly concerned with improving accuracy and reliability. Since that time attempts to improve noninvasive monitors have involved improving the ease-of-use as a way of reducing user-skill-related errors, reducing the time required to acquire a BP, and increasing compliance. Regardless of the improvements in ease-of-use, the instruments must exhibit an acceptable accuracy.

The purpose of this study was to evaluate three new electronic, digital blood pressure monitors for accuracy. These instruments are designed to increase the ease-of-use by reducing the limitations of many previous and currently available instruments. Typically, in noninvasive BP instruments, the compression cuff pressure is increased above the purported systolic pressure, and the BP is measured as the cuff is deflated. Two of the test instruments use this traditional method. One is unique by measuring BP as the compression cuff pressure increases, theoretically reducing the time required to measure BP.

This study evaluated the accuracy of three electronic, digital BP monitors currently on the market. The test instruments were the MABIS Semi-Automatic (model 04-263-001), MABIS SmartRead (model 04-310-001), and the MABIS SmartSpeed Plus (model 04-320-001) (MABIS Healthcare, Inc., Waukegan, IL). (Support for research: the test instruments were provided by MABIS HealthCare, Inc.) Each monitor exhibits different design characteristics. The Semi-Automatic model requires the compression cuff to be manually inflated with automatic deflation and pressure determinations. The SmartRead model is fully automatic. The SmartSpeed Plus model is fully automatic and determines BP as the compression cuff is inflated. The SmartSpeed Plus, therefore, theoretically should reduce the time required to obtain a BP measurement.

Blood pressure from the three test instruments were compared with sequentially recorded BPs determined by auscultation of the brachial artery using an aneroid sphygmomanometer. The end of Korotkoff phase 4 sound and beginning of phase 5 were used to determine diastolic pressures. The accuracy of all aneroid sphygmomanometers were validated against a mercury sphygmomanometer immediately before the evaluations and again after all data were collected. The auscultatory procedure was performed according to the guidelines in the ANSI/AAMI SP10: 2003 standard. Each test instrument was operated according to the manufacturer’s instructions that accompanied the instrument.

Data collection consisted of four phases: 1) relaxation of subject—the subject was seated for several minutes and demographic data were collected; 2) determination of palpatory systolic BP; 3) determination of manual auscultatory systolic and diastolic BP; and 4) determination of BP by each of the three test instruments. The order of the three test instruments as well as the manual auscultatory BP was alternated randomly to prevent any possible effect of order on the results. At least 1 or 2 min were allowed between steps 2, 3, and 4. Measurements were, therefore, determined sequentially using the same arm of each subject for all measurements.

Accuracy was expressed by the mean difference and standard deviation (SD) of the individual paired (auscultatory/test instrument) observations. Accuracy was determined in accordance with section B, 4.4.5.1.1.B, method 1 of the ANSI/AAMI SP10: 2003 standard. This standard requires that a mean difference of the individual paired measurements of the test instrument and the auscultatory reference method “shall be ±5 mm Hg or less, with a standard deviation of 8 mm Hg or less.” All other guidelines and recommendations of the standard were followed or exceeded. All test instruments were evaluated on the same group of subjects.

This project, the experimental protocol, and the process for obtaining informed consent were approved by the Institutional Review Board of West Texas A&M University. Data analyses were performed with the Excel computer program on a Windows platform.

The sample of subjects consisted of 284 individual paired BP measurements from 206 different subjects. Repeat paired
observations were performed on 78 individuals. The sample was composed of 47% men and 53% women. Subjects ranged in age from 18 to 81 years. Systolic BP ranged from 88 to 204 mm Hg and diastolic ranged from 50 to 110 mm Hg. The heart rate ranged from 49 to 108 beats/min.

As required by the ANSI/AAMI SP10: 2003 standard, 10% of the subjects used in the evaluation exhibit hypertension (>160 mm Hg systolic or >100 mm Hg diastolic) and 10% exhibited hypotension (<100 mm Hg systolic or < 60 mm Hg diastolic). Rather than the minimum 10% of the subjects required by the standard to exhibit large arm circumference (>35 cm) and 10% to exhibit small (<25 cm), the sample exceeded those minima and exhibited 15% with large and 12% with small arm circumference. The sample of subjects was, therefore, sufficiently diverse to meet or exceed the standard.

The mean difference of individual paired BP measurements and their SD between each test instrument and the auscultatory reference method is shown in Table 1. In every case, each test instrument exhibited a mean difference less than ±5 mm Hg and a SD less than 8 mm Hg for both the systolic and diastolic pressures as required by the ANSI/AAMI SP10:2003 standard for accuracy.

The evaluations were done in compliance with the ANSI/AAMI SP10: 2003 standard for manual, electronic, or automated sphygmomanometers. A widely varied sample of subjects were used in this evaluation. This sample satisfies section 5.4.5.1.1.B of the standard.

According to section 4.4.5.1.1.B, method 1, the mean difference of the individual paired measurements of the test instruments and the auscultatory reference method “shall be ±5 mm Hg or less, with a standard deviation of 8 mm Hg or less.” The systolic and diastolic pressures are required to be analyzed separately. As can be seen from Table 1, the MABIS Semi-Automatic, MABIS SmartRead, and MABIS SmartSpeed Plus satisfy this section of the standard.

It appears, therefore, that a variety of configurations of the MABIS BP monitors designed to provide an improvement in ease-of-use, reduction in user skill-dependent error, and increase compliance can satisfy this accuracy standard. From this evaluation, it appears that these three test instruments can satisfy this standard over a wide range of individuals.

In conclusion, all three instruments evaluated in this study, MABIS Semi-Automatic, MABIS SmartRead, and MABIS SmartSpeed Plus, appear to be in compliance with the requirements of the accuracy standards of ANSI/AAMI SP10: 2003. Therefore, according to that standard (section 4.1.3), “Blood pressure measurements determined with this [these] device[s] are equivalent to those by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, ‘Manual, electronic, or automated sphygmomanometers.’”

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