Clinical evaluation of the Welch Allyn SureBP algorithm for automated blood pressure measurement

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Objectives **To clinically evaluate an inflation-based algorithm incorporated into a new automated blood pressure monitor manufactured by Welch Allyn, Inc.**

Methods **Device evaluation was performed according to the Association for the Advancement of Medical Instrumentation standard. An overabundance of patients with hypertension (32) were part of the 110 total participants. The data were also analyzed as described in the British Hypertension Society protocol.**

Results **The mean error and standard deviation for systolic blood pressure were −0.9 mmHg ± 7.2; for diastolic blood pressure −2.2 mmHg ± 6.7. These passed the Association for the Advancement of Medical Instrumentation standard requirements. By British Hypertension Society data analysis, the device achieved an AA grading. Over 90% of the cycles' blood pressure values were obtained during inflation.**

Conclusions **The SureBP inflation-based algorithm successfully passed the Association for the Advancement of Medical Instrumentation standard requirements and achieved an AA rating by British Hypertension Society data analysis. The monitor has great advantages for patient comfort and speed of readings (average 15 s per reading). As the population studied was skewed by including a much larger than needed number of patients with hypertension, clinicians can have added confidence in this new technology.** ***Blood Press Monit*** **12:215–218 © 2007 Lippincott Williams & Wilkins.**

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Introduction

As mercury sphygmomanometers are being phased out of clinical use worldwide, clinicians have become more dependent upon automated blood pressure (BP) devices for the evaluation of patients' BP. Virtually all of the currently manufactured automated devices inflate an arm cuff to a predetermined pressure likely to be greater than the systolic BP (SBP). The device then begins either step-mode or continuous-mode deflation and records either cuff oscillations (oscillometric) or Korotkoff sounds (auscultatory) to estimate SBP and diastolic BP (DBP). Often, the device must reinflate because the level of SBP reads too close to the initial inflation pressure for accurate determinations.

On the other hand, if a device measures BP during inflation, then the maximal inflation pressure necessary to ensure accurate values could be substantially reduced. This would significantly shorten the time needed for each measurement, allowing for more measurements (if needed) during a particular time period. The degree of discomfort that a patient experiences at the highest inflation pressures would also be reduced because the obligatory large overshoot of pressure to trigger a deflation algorithm would not exist.

The Association for the Advancement of Medical Instrumentation (AAMI) has published the American National Standard for the validation of automated sphygmomanometers [1]. The standard describes the test procedures and analysis methods to be used as guidelines for the Food and Drug Administration (FDA) to approve a device for clinical use in the United States. For a noninvasive (auscultatory) standard comparison study, the protocol calls for a minimum of 85 participants. The AAMI standard calls out specific recommendations with respect to age, BP ranges, and cuff sizes. The standard allows the manufacturer to design the validation study for a specific target population, that is, neonates, infants, children, and/or adults.

This SureBP study reports the results of an American National Standards Institute/AAMI SP10: 2002 clinical evaluation study. In addition, the BP data were analyzed using the criteria set by the British Hypertension Society (BHS) [2].

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Methods

Background information

The Welch Allyn SureBP algorithm was incorporated into a device called the Spot Vital Signs LXi (Welch Allyn, Skaneateles Falls, New York, USA). The device displays SBP and DBP, mean BP, and pulse rate. The data are collected during inflation. If acceptable data are recorded during inflation, the device performs a rapid deflation after SBP has been obtained. If the data do not meet certain performance requirements of the algorithm, the device will inflate to 160 mmHg, the factory default target pressure. If signals are detected at 200 mmHg, the device will reinflate once more to 240 mmHg before beginning step deflation. The target maximal cuff inflation is always dependent upon the data collected during inflation rather than an arbitrary goal inflation pressure, which might be too high or low for optimal pressure measurement and patient comfort.

Participant selection

The participants were recruited from three sites: one each in Cooperstown, New York; Endwell, New York, USA; and Hamilton, Ontario, Canada. The appropriate human research committee at each site approved the study. Each participant gave written informed consent before testing. All participants were adults, so no assent was necessary. Participants reported to be healthy and were free of atrial fibrillation or other significant heart rhythm disorders.

Blood pressure measurements

All observers were trained by an expert observer and each achieved expertise in Korotkoff sound BP measurement accuracy. All observers had had a normal audiogram before the start of the study. The study duration was short; no retraining was performed during the study. Drift in agreement between observers was evaluated every 20 participants during enrollment. Ninety percent of intraobserver BP differences were ≤ 5 mmHg; 100% were ≤ 10 mmHg. No trend to these differences related to BP level or patient demographics was seen. The testing was performed in a quiet environment. Each participant was seated and gave needed demographic data (age and relevant medical history). The observers then measured the upper arm circumference and selected a BP cuff of appropriate size [1]. The cuff was snugly applied to the arm and the participant sat quietly, without speaking, for 5 min. The participant was seated in a chair with his/her back supported and feet on the floor with legs uncrossed. The measurement tubing from the cuff was attached by a three-way-stopcock to allow for manual inflation by the observers. Each set of two trained observers utilized a calibrated mercury sphygmomanometer (Baumanometer, W.A. Baum Co., Inc., Copiague, New York, USA) and a double-earpiece stethoscope (allowing simultaneous auscultation by both observers). The observers were blinded to each other during the measurements.

Protocol

The initial cuff inflation/BP measurement was performed manually by the observers. This reading was used for BP classification. At least 1 min separated each subsequent reading. The data used for validation were collected from sequential same-arm readings. The order of the readings was always the observers' reading followed by a device reading followed by the observers' reading until three valid measurement sets had been performed. The device error was calculated as the difference of the device reading subtracted from the average of the two observer readings, which bracketed it before and after. Thus, three error measurements were achieved per participant. The observers were blinded from each other's readings and the device reading during data acquisition.

In each participant, the observers utilized the first and fifth Korotkoff sounds as SBP and DBP, respectively. The data were entered into an Excel spreadsheet (version 2000, Microsoft Inc., Redmond, Washington, USA).

Results

Of the 120 participants screened, 110 completed the study. The child, adult, and large adult cuffs were all utilized. The characteristics of the study population are shown in Table 1.

Blood pressure ranges

The AAMI standard calls for 10% of the required 85 participants to have SBP values < 100 mmHg. Eight of the participants were in this group. The requirement for SBP > 160 mmHg is the same, but in the population studied, 32 participants qualified (3.5 times the minimal number). AAMI requires 10% of DBP < 60 mmHg; nine participants qualified. Nine participants were required at DBP > 100 mmHg; 16 qualified. Thus, the population was extraordinarily over-represented by patients with hypertension, the group for which clinicians demand the most accuracy in BP readings.

Arm circumference

The AAMI standard requires 10% of arm circumference measurements to be either less than 25 cm or more than 35 cm. In the study group, there were 10 in the small arm

Table 1 Characteristics of the study population

	Mean ± SD	Range
Age (years)	55 ± 16	18–86
Male : female	56 : 64	
Height (cm)	169 ± 10	145–191
Weight (kg)	85.1 ± 25.6	44.4–200.0
Pulse (beats/min)	72 ± 12	46–126
Arm circumference (cm)	30.3 ± 4.1	20.0–41.0
Systolic blood pressure (mmHg)	138 ± 29	86–216
Diastolic blood pressure (mmHg)	80 ± 14	48–116

Values are expressed as means ± standard deviation (SD).

group and 15 in the large arm group. Another five participants were present with an arm circumference of 25 cm.

Error statistics

The Excel program was used to calculate the mean ± standard deviation (SD) of the error data for both SBP and DBP. The AAMI Standard Method 1 requires that each BP value be within a mean of 5 mmHg with a SD of ± 8. For SBP, the values were mean −0.9 mmHg with a SD of 7.2. Sixty percent of the errors were within 5 mmHg, 86% within 10 mmHg, and 96% within 15 mmHg. For DBP, the mean error was −2.2 mmHg with a SD of 6.7. Identical percentages of diastolic errors were within 5, 10, and 15 mmHg as for SBP.

Bland–Altman plots of the entire data sets are shown in Figs 1 and 2. For SBP, there was no relationship between BP level and error (Fig. 1). For DBP, there was a relationship (P = NS) showing systematic under/overestimation of BP at the extremes of measurement. Despite this observation, the mean ± SD was well within the requirements of the AAMI standard.

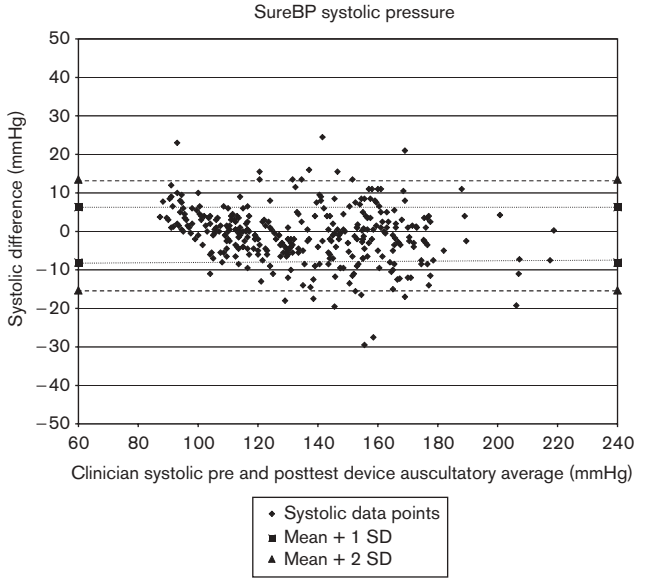
Discussion

The data from the participants studied showed that the SureBP algorithm within the Spot Vital Signs LXi device fulfilled virtually all of the requirements of the AAMI standard. One participant was missing from the SBP < 100 mmHg group to fulfill the minimum of nine participants (8.5, is in fact, the required number). The population was heavily skewed to the hypertensive end of the BP spectrum, the group for which clinicians demand the greatest accuracy because of the implications of misidentifying a patient with hypertension as being a patient with normotension, and vice versa. The weak slope relationship of DBP demonstrated on the Bland–Altman plot (Fig. 2) did not cause the device data to fall outside the required mean ± SD values.

The average time to obtain a valid reading was only 15 s, about 1/3 of the time needed for a typical deflation-based algorithm. More than 90% of the valid readings by the device were derived from inflation-only measurements. Less than 10% of the inflations required over-shoot and step-deflation to obtain valid readings. This feature reduces patient discomfort in clinical applications. The inflation algorithm is also able to tolerate higher levels of motion and extraneous noise and preserve accuracy in patient measurement. The inflation algorithm also reduces maximal inflation pressure significantly because the rapid deflation is initiated as soon as the device determines that it has achieved a correct measurement of SBP. The DBP value has already been determined in almost 100% of the inflations, avoiding a slow step-deflation.

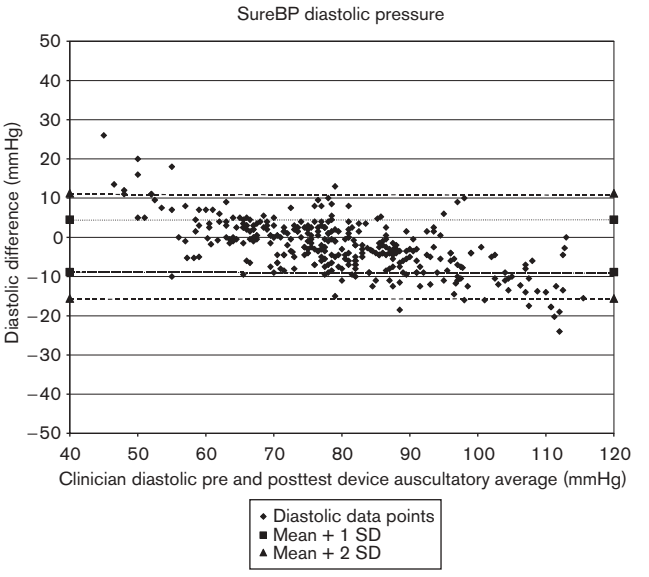
Healthcare facilities in many countries such as the UK and Canada may also require BP devices to obtain a passing grade based on the BHS protocol. The inclusion criteria for the BHS are weighted heavily toward patients with hypertension. The BHS protocol data analysis results in a grading of A, B, C, or D, depending upon the percentages of error data within 5, 10, and 15 mmHg

Fig. 1



Agreement between test and reference method for systolic pressure.

Fig. 2



Agreement between test and reference method for diastolic pressure.

from observer data. The BHS does not use the average of the two blinded observers for each device data point, but allows the manufacturer to choose the observer data point closer to the device reading. Members of the International Standards Organization (ISO) Sphygmomanometer Committee have brought this feature into question (the author is a voting member for the USA on this committee). To achieve the highest grade, A, on the BHS protocol data analysis, at least 60, 85, and 95% of the error readings must be within 5, 10, and 15 mmHg, respectively, from each chosen observer value. The SureBP algorithm resulted in SBP errors within 5, 10, and 15 mmHg in 72, 91, and 98% of the analyzed readings, respectively. For DBP, the comparative percentages were 71, 91, and 97%. Thus, the device tested achieved an A rating for each SBP and DBP by using the BHS protocol data analysis.

The population chosen was heavily overrepresented by patients with hypertension. Thus, the minor deficiency of having 1 (or 0.5) too few individuals with low SBP is of no clinical consequence for an adult population, for whom hypertension is the major clinical concern. SureBP was able to achieve 'passing' grades for both SBP and DBP readings by AAMI analyses and AA grading by BHS analyses.

Inflation-based algorithms reduce patient discomfort and allow more readings in a briefer period of time. Both features are of clinical importance. It was of greatest clinical significance that the SBP accuracy of the device did not degrade in the hypertensive BP range. This should give clinicians added confidence when they are using the devices with SureBP to screen patients for hypertension, by far the most common BP abnormality worldwide.

Acknowledgement

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