Accurate blood pressure during patient arm movement: the Welch Allyn Connex Spot Monitor's SureBP algorithm

Bruce S. Alpert^a, David Quinn^b, Matthew Kinsley^b, Tyson Whitaker^b and Thomas T. John^c

Background Current blood pressure (BP) measurement guidelines specify patient requirements, including being still. Some populations of patients cannot comply. A new International Organization for Standards is being developed to test devices that claim tolerance to transport-induced motion artifacts. This study proposes the first protocol to assess BP device accuracy in the presence of patient-induced motion.

Participants and methods Forty healthy volunteers (23 males) participated. The device tested was the Welch Allyn Connex Spot Monitor (CSM) using the SureBP algorithm. A reusable cuff was placed on the left arm. During inflation/deflation cycles the participant performed pronation/supination movements of the left forearm every 5 s. The CSM readings during motion were compared to the average of manual resting auscultatory estimations immediately before and after each motion cycle (bracketing).

Results The CSM recorded a BP reading on the first cycle in 37 participants. It displayed a reading in all 40 participants with one repeat cycle in the other three. The mean $\pm$ SD for the device minus the manual BP values was 0.9 ± 7.3 mmHg for systolic BP and -3.4 ± 7.9 mmHg for diastolic BP.

Conclusion This study represents a proposal for an automated BP device assessment in the presence of patient-induced motion. The CSM device, which uses an inflation-based algorithm, routinely produced BP values that closely matched auscultatory values bracketed immediately before and after the motion-associated cycle. The CSM should be of significant clinical value in populations in whom resting 'still' readings are not usually feasible, such as pediatric and geriatric patients, and patients in pain from injury or illness. *Blood Press Monit* 24:42–44 Copyright © 2018 Wolters Kluwer Health, Inc. All rights reserved.

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^aDepartment of Pediatrics, University of Tennessee Health Science Center, Memphis, Tennessee (Retired), ^bDepartment of Mathematics, Welch Allyn, Skaneateles Falls and ^cDepartment of Mathematics, Syracuse University, Syracuse, New York

Correspondence to Bruce S. Alpert, MD, 1350 Poplar Ridge Dr, Memphis, TN 38120, USA

Tel: +1 901 229 3719; fax +1 901 757 8181; e-mail: bsa2347@gmail.com

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Introduction

The current USA national guidelines for blood pressure (BP) estimation by noninvasive techniques recommend that the participant/patient be at rest for several minutes, seated, with the arm supported at the level of the heart, back supported, with feet flat on the floor [1,2]. This condition may not always be practical, especially in pediatric and geriatric patients. In those populations the patient may be unable to sit still and follow all of the above guidelines. Currently, the Association for the Advancement of Medical Instrumentation (AAMI) and the International Organization for Standards (ISO) sphygmomanometer committees are developing an addition to the current standard [3] that will address validation of automated sphygmomanometers under the condition of vehicle-induced motion during patient transport by road, air, and rotary ambulances. That document will become ANSI/AAMI/ISO 81060-4.

There has been no published attempt to date to develop a validation testing protocol for BP estimation in the

presence of patient-induced motion, that is, either voluntary or involuntary arm movement during the BP cycle.

After evaluation of hundreds of real-world BP cycles, the algorithm-development staff at Welch Allyn recognized that patient movement during the BP cycle in primary care patients was very common. These movements create significant pressure perturbations in the oscillometric waveform. The most common patient movements were separated into four groups: (a) patients tensing and relaxing their hands, presumably due to cuff compression discomfort; (b) patients repositioning their arm, causing significant shifts in baseline cuff pressure, also presumably due to cuff compression discomfort; (c) patients filling out forms during the BP cycle; and (d) patients who were unable to keep their arm still because of tremor or restlessness. The movement in the patient-motion protocol described in this paper was developed to mimic aspects of these four categories with intentional arm movements that can be repeatedly performed by test

participants. This study was designed and implemented by the engineering and research staff at Welch Allyn.

Participants and methods

Participants

Participants were healthy volunteers recruited by the staff of the Welch Allyn simulation center. The study was performed on a total of 40 participants, 23 of whom were male. The mean participant age was 43.9 years, with a SD of 13.3 and a range of 23–63. All BP readings were done on the left arm with the participant seated per clinical guidelines [1,2]. The data were collected from 1 February 2018 to 30 March 2018.

Device specifications

The device used for testing was the Welch Allyn Connex Spot Monitor (CSM) using the SureBP algorithm (Welch Allyn, Skaneateles Falls, New York, USA), which has been validated to the AAMI standard [4]. The cuffs utilized were reusable. The algorithm derives its BP estimate while the cuff is inflating.

Protocol

The motion utilized to test the device's accuracy was serial pronation/supination of the left forearm. There were manual auscultatory readings of both systolic blood pressure (SBP) and diastolic blood pressure (DBP) performed 1 min prior to and 1 min after the forearm motion. These values were averaged (bracketed) around each motion-associated inflation/deflation cycle. At the start of inflation, the participant began to pronate then supinate the left forearm every 5 s during the inflation/deflation cycle of the device. There was no attempt to perform manual auscultation during the pronation/supination motions.

The motion was designed to simulate, in a controlled manner, arm movements observed in clinical practice with automated BP devices. It is possible to simulate many different arm movements. However, Welch Allyn has found that pronating and supinating the forearm causes cuff pressure disturbances with characteristics similar to those observed in the clinic and serves as a representative and repeatable device evaluation procedure.

The specific arm movement utilized was pronating and supinating the left forearm. To perform this motion the clinician had the participant rest his/her forearm on the table perpendicular to the body, with his/her hand on the table palm up and fingers extended. When it was time for the motion the clinician instructed the participant to pronate his/her arm, hold for a second, and then supinate his/her arm. The full motion took ~3 s.

Data analysis

The values obtained during the bracketed manual auscultation were subtracted from the values obtained by the CSM. Thus, if the device values were higher for SBP or DBP than the manual readings the differences would be positive; if lower, the differences would be negative.

Results

The CSM was able to generate a BP value on the first inflation/deflation cycle during motion in 37 of the 40 participants, or 93% of the attempts. The CSM recorded a value in all 40 participants when a second attempt was included. The mean $\pm$ SD for SBP for the differences between CSM versus manual readings was 0.9 ± 7.3 mmHg. For DBP, the values were -3.4 ± 7.9 mmHg. As can be seen on the Bland–Altman plots, 87.5% of the SBP values and 85% of the DBP values taken during motion were within ± 10 mmHg of the manual BP values (Fig. 1a and b).

Discussion

The current USA BP guidelines [1,2] recommend, for the highest level of accuracy, that the patient be still and in a 'basal' state after several minutes of rest. The need for accurate BP estimation in patients who are ill enough to need urgent transport by road or air has led the AAMI/ISO sphygmomanometer committees to develop rigorous testing protocols to ensure that devices that claim motion tolerance produce BP values that accurately reflect clinical status. That document is well into the development stages and will be issued as ISO 81060-4. The performance of devices/algorithms during patient-induced motion has not been evaluated to date. The performance of automated sphygmomanometers in populations in whom motion cannot be eliminated, especially infants, children, and the elderly, must be accurate if healthcare professionals are to be able to make correct diagnostic and therapeutic decisions.

Welch Allyn researchers developed statistical analyses of an algorithm's performance when the participant was performing a representative arm movement. The key statistics are the accuracy of the readings and the percentage of cycles that result in a BP determination. The goal of the device development team was to limit the statistical error induced by the motion while maximizing the accuracy of readings provided to the clinician. This results in clinically relevant readings in the presence of motion, thus eliminating the need to repeat readings, or series of readings, when clearly erroneous readings or error codes result from seemingly insignificant movements by the participant during the BP cycle.

The engineers at Welch Allyn have developed the CSM in association with the SureBP algorithm [4], which has been shown in this study to give excellent results during a series of controlled arm motions. The participant performed the arm movements using the same arm that was fitted with the BP cuff. The current USA national standard [3] requires that in 85 participants, each of whom has three sets of manual versus device differences measured, the mean $\pm$ SD must be less than or equal to 5 ± 8 mmHg (criterion 1) in order to be successful. The mean $\pm$ SD values for the differences between motion and 'still' values in this study were quite favorable to the standard's passing criteria. A weakness of the study was the lack of

Fig. 1

Bland-Altman plots of the automatic device-observer differences for (a) systolic blood pressure and (b) diastolic blood pressure. The x-axis represents the mean of the device and observer measurements and the y-axis shows the discrepancy between the device and observer measurements.

manual BP attempts during motion. It was assumed that the manual resting BP values would not be significantly changed due to the motions being performed. The mean differences between values obtained during motion versus resting confirm this assumption.

Conclusion

The engineers at Welch Allyn have developed a protocol for the assessment of the accuracy of an automated sphygmomanometer, the CSM, during patient-induced motions that occur commonly in the clinic and the hospital. The CSM device, using the inflation-based SureBP algorithm, performed in an excellent manner, with 93% of readings obtained on a first attempt and 100% of readings obtained in only two cycles, demonstrating consistency and reliability of the SureBP algorithm. Low mean $\pm$ SD differences were consistently observed when compared to bracketed manual auscultatory BP values.

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Conflicts of interest

B.S.A. serves as an advisor for Welch Allyn and has received honoraria. T.T.J. helped with the analysis and consults for Welch Allyn. D.Q., M.K., and T.W. are employees of Welch Allyn.

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