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Reliability and validity of blood pressure measurement in the Secondary Prevention of Small Subcortical Strokes study

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Abstract

Rationale—The Secondary Prevention of Small Subcortical Strokes study is a multicenter, international trial funded by the National Institutes of Health testing the role of lowering systolic blood pressure to < 130 mmHg in the prevention of stroke recurrence and cognitive decline in patients with recent symptomatic small subcortical stroke. Reliable and unbiased blood pressure measurement is critical to successful completion of the trial.

Methods—We looked at the reliability and validity of both the device used for blood pressure measurement and observer performance during measurement to assess the quality of blood pressure determination in the study. The Colin 8800C blood pressure device was tested for performance to Association for the Advancement of Medical Instrumentation standards and for presence of skipped digits. Observer performance was tested by examining adherence to the Secondary Prevention of Small Subcortical Strokes protocol.

Results—The mean difference (in mmHg) between the Colin device and the average of the two observers was 3.9 (SD 6.7) and − 2.1 (SD 6.1) for systolic and diastolic pressures respectively, thereby meeting Association for the Advancement of Medical Instrumentation requirements. No skipped digits were found between 82–230 and 40–120 mmHg for systolic and diastolic pressures, respectively. Observer performance was excellent with greater than 90% of patients having blood pressure measured consistently according to the protocol.

Conclusions—Device and observer performance in Secondary Prevention of Small Subcortical Strokes is excellent. Interpretation of the Secondary Prevention of Small Subcortical Strokes data for the effect of lowering systolic blood pressure on patient outcomes will not likely be adversely affected by these factors. Accuracy will be monitored throughout the remainder of the trial to ensure that this high quality is maintained.

Keywords

accuracy in blood pressure measurement; clinical trials; device assessment; quality control; stroke

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Background

The Secondary Prevention of Small Subcortical Strokes (SPS3) study is an ongoing multicenter international trial funded by National Institutes of Health with the objective of defining efficacious therapies for prevention of stroke recurrence and cognitive decline in patients with recent symptomatic small subcortical stroke [1] (www.SPS3.org). The trial is testing the hypothesis that control of systolic blood pressure (SBP) to a target of < 130 mmHg (intensive group) will result in fewer recurrent strokes, less cognitive decline, and a decrease in other major vascular events with no adverse impact on quality of life compared with a target of 130–149 mmHg (usual group). Drawing on best published evidence, investigators with training and expertise in the treatment of hypertension are managing participants' blood pressure to the randomly assigned target SBP ranges. Additionally, the trial is testing the effectiveness of aspirin compared with aspirin plus clopidogrel on these outcomes. A recruitment goal of 2500 participants, followed for an average of 3.5 years, with a mean difference of 10 mmHg between the two groups, is required to have sufficient power to answer these questions.

As the blood pressure arm of the SPS3 study is unblinded, several strategies for reducing bias have been employed. The prospective, randomized, open-label, blinded-endpoint study design [2] is being used. This design has been employed in several blood pressure trials [3-5] and its advantages are that it preserves the benefits of randomization and reduces bias in ascertainment of outcomes through blinded end-point detection. An additional strategy for reducing bias in the SPS3 study is ensuring accurate blood pressure measurements through the use of an automated oscillometric electronic device for the measurement of blood pressure and standardized teaching of the observers who use the automated device. These devices have the potential to minimize bias introduced by human error, particularly digit preference for zero, the most common form of observer error [6,7]. Given the two target SBP groups (< 130 and ≥ 130 to < 149), digit preference for zero could overestimate or underestimate blood pressure prompting changes in blood pressure regimens in an effort to reach the participant's assigned targets. Erroneous blood pressure values could result in over or under treatment of blood pressure with resultant reduction in the ability to detect the true impact of the difference in SBP control between the two treatment arms. Electronic blood pressure devices are the most reliable method of removing digit preference for zero [8].

Although the use of electronic monitors in clinical practice is becoming quite common [9], not all automated oscillometric blood pressure measurement devices have passed any of the accepted validation studies [10-12] leading to ongoing concerns regarding their accuracy. How oscillometric devices work has been well described [13], but manufacturers do not share proprietary information about how their devices calculate blood pressure leading to the surprising finding that a commonly used device (DINAMAP GE Healthcare, Amersha Bucks, UK) skipped certain values for SBP and diastolic blood pressure [14].

Each SPS3 clinical site uses the Colin 8800C (Colin Medical Instruments, an Onrom Company, San Antonio, Texas, USA) to measure blood pressure. Although the Colin 8800C has passed the US Association for the Advancement of Medical Instrumentation (AAMI) standards [15], validity is not determined by one study alone but is a matter of cumulative evidence and further independent validation of this device is recommended [16].

Accuracy in blood pressure measurement requires not only a valid measuring device but also reliability in its measurement. The impact of observer error on accurate blood pressure measurement is well described [17-19] leading to guidelines by several organizations to enhance accuracy and reliability in measurement [20-22]. Despite these guidelines, observer errors remain common in clinical practice and hypertension trials [23-26]. The SPS3

observer protocol for quality blood pressure measurement incorporates the elements from the American Heart Association blood pressure measurement guidelines and The JNC 7 Report [21,22] (Table 1). Given the importance of accurate blood pressure measurement to this trial, this paper presents the analyses undertaken, as part of an ongoing process, to enhance the quality of blood pressure measurement in the SPS3 study. The specific research objectives were (i) to examine the accuracy of the Colin 8800C electronic device compared with manual auscultation of blood pressure, (ii) to test the Colin 8800C algorithm for the presence of skipped digits, and (iii) to assess observer adherence to the SPS3 blood pressure measurement protocol.

Methods

Accuracy of the Colin 8800C electronic device

Validation of the Colin electronic device was undertaken following the AAMI protocol. This study was approved by the Institutional Review Board of the University of Texas Health Sciences Center at San Antonio. Adult healthy volunteers and patients from outpatient clinics (Neurology, Nephrology, Internal Medicine, Family Medicine, and General Surgery) were recruited. Participants were chosen to reflect the population of the SPS3 study, meet the requirements of the AAMI validation protocol, and to provide a distribution of ages, in particular ensuring that participants older than 60 years were represented in the sample. As specified in the AAMI protocol (see Table 2), participants were selected to represent all values of blood pressure and arm size (circumference). Consenting participants had a minimum of three sets of blood pressure measurements taken in a quiet room over a period of 6–15 min. The appropriate-sized blood pressure cuff was wrapped snugly on the bare upper arm over the brachial artery.

The AAMI protocol calls for two trained observers to independently measure SBP and diastolic blood pressures (three consecutive measurements) on at least 85 adult participants which will provide 255 data points. The AAMI protocol bases its sample size on being able to detect a difference between the standard and the automatic device of 5 ± 8 mmHg at a significance level of 0.05 and a power of 0.90.

The Colin 8800C monitor was calibrated and checked at the beginning of each session for proper operation. A mercury manometer was connected to the oscillometric blood pressure monitor using a T-tube connection to allow simultaneous measurements by the oscillometric and the auscultatory methods. A research assistant recorded the SBP, diastolic, and mean blood pressure reading at the time of deflation from the monitor's display screen. Two observers, trained in blood pressure measurement, made simultaneous blood pressure readings on each participant using a W.A. Baum dual head stethoscope and an automated mercury sphygmomanometer and recorded the pressures. Each was blinded to the other's recording and to the reading obtained by the Colin device. The first and fifth Korotkoff sounds were used for measurement of SBP and diastolic blood pressures, respectively. To meet AAMI standards, 100% of the measurements from the two observers had to agree within 10 mmHg and at least 90% within 5 mmHg. An independent assistant examined the measurements made by the two observers; those that fell outside these requirements were discarded and additional pressures taken.

Examining the validity of the Colin device is a form of concurrent validity where the test device (Colin 8800C) is compared to a 'gold standard' (the manual measurements). The extent to which the Colin 8800C device and the manual pressures produce the same blood pressure values was examined in several ways. The mean difference in the measurements obtained from the Colin 8800C device and the blood pressures from the auscultatory method was calculated. On the basis of the AAMI criteria, an automatic blood pressure measurement

device is designated as a ‘pass’ and is acceptable for clinical practice when the mean difference between the test instrument and the mean auscultatory measurements is 5 mmHg or less with a standard deviation of 8 mmHg or less. The percentage of the Colin device readings that fell within 5, 10, and 15 mmHg of the mean of the auscultatory readings was also calculated. Finally, Bland–Altman plots were created to provide a graphical representation of both the degree of correspondence as well as the extent of the agreement.

Testing the Colin 8800 algorithm

The Colin 8800C algorithm was examined for the presence of skipped digits. At each SPS3 visit blood pressure is measured three times in the seated position and one time standing. Although the average of the three sitting readings is used for clinical decision making, all SBP and diastolic blood pressure readings (not just the average of the three readings) available in the SPS3 study were used for this analysis. Frequency distributions were generated for SBP and diastolic blood pressure measurements and these were visually inspected for the occurrence of skipped digits.

Secondary Prevention of Small Subcortical Strokes procedures for blood pressure measurement

Before initiating the trial, study coordinators, the majority of whom are registered nurses, attend a training program that includes information on blood pressure measurement techniques, training with the Colin 8800C electronic device, and instruction on the SPS3 protocol for managing participants into their assigned targets. To increase reliability in blood pressure measurement in SPS3, all sites follow carefully documented procedures. Assessing blood pressure with a calibrated electronic device will increase interrater (and also intrarater) reliability [8] and requires less training than auscultation with a manual mercury sphygomomanometer [23,27]. This was an important consideration given the challenges associated with standardizing measurement procedures for multiple investigators across more than 60 sites spanning more than six countries. Review programs are held on an annual basis or more often when changes in personnel occur. The protocol for blood pressure measurement emphasizes use of the appropriate sized cuff, a defined resting period before measuring the blood pressure, obtaining three blood pressure measurements, and using the average of these three measurements for clinical decision making. As noted above, sitting blood pressure is measured three times with each measurement 2 min apart. Blood pressure is then measured once after standing for 2 min. At the initial visit, blood pressure is measured in both arms. Subsequent pressures are taken in the right arm unless the blood pressure in the left arm is at least 10 mmHg higher; the arm revealing the highest blood pressure is then used for all subsequent measurements. Table 1 provides further information on the protocol for blood pressure measurement. Moreover, and as part of this protocol, the Colin 8800 device undergoes annual calibration.

Key aspects of the SPS3 measurement protocol were examined for adherence by the observers. These included using the Colin 8800 device for blood pressure measurement instead of other devices, use of the appropriate size of blood pressure cuff, measurement of blood pressure in both arms to choose the ‘selected arm’, use of the ‘selected arm’ for subsequent measurements, measuring blood pressure three times at each visit, and frequency with which blood pressure readings were taken at least 3 h after the intake of antihypertensive medications.

Results

Colin 8800C validation study

To satisfy the AAMI criteria for blood pressure distribution, 96 participants from the clinics at University of Texas Health Science Center, San Antonio were recruited. The majority were men (63%), the mean age of participants was 49 years (20% at least 60 years of age), 60% had a history of hypertension, and one-third were diabetic. As seen in Table 2, the AAMI recommended distribution of blood pressures and arm circumferences was achieved. The mean blood pressure of the group was 134/76. Excellent agreement was observed between the two observers for the 96 adult participants (288 data points), with 98% of the systolic and diastolic readings of the two observers agreeing within 5 mmHg. The mean difference between the two observers was less than 1 mmHg for both the SBP and the diastolic blood pressures. Given this close agreement, the AAMI standards recommend using the average of the two observers for comparison with the electronic device.

The mean difference (in mmHg) expressed as the Colin device minus the average of the two observers (electronic minus manual) was 3.9 (SD 6.7) for systolic pressure and −2.1 (SD 6.1) for diastolic pressure (Table 2) thereby meeting AAMI requirements for a difference of 5 mmHg or less with a standard deviation of 8 mmHg or less. Good agreement was seen between the manual readings and the Colin device with at least 85% of the readings agreeing within 10 mmHg and at least 95% agreement within 15 mmHg for both the systolic and the diastolic pressures. Scatter plots that incorporate both correspondence and agreement (Bland–Altman plots) can be seen in Figs 1 and 2 for the SBP and the diastolic blood pressures. Over 95% of both the systolic and the diastolic measurements were within two standard deviations from the mean. From these scatter plots, the difference between the electronic measurements and manual measurements does not seem to be a function of blood pressure although there may be slightly more variability with higher SBP values.

Examination of the Colin 8800C algorithm

To examine for the presence of skipped digits, we used 26 506 blood pressure measurements currently in the SPS3 study using the Colin 8800C device. Of these, 7018 were obtained at a baseline visit, 9549 were obtained at a quarterly follow-up visit, and 9939 were obtained at blood pressure check visits. No skipped digits were observed over the ranges of 82–230 mmHg for SBP and 40–120 mmHg for diastolic blood pressure. This finding was consistent when examined within the limited number of sites that have at least 500 blood pressure measurements.

Adherence to the blood pressure measurement protocol

To date, there have been 6840 follow-up visits (mean of 8.8 per patient with a range of 1–31 visits) and of these, the high majority (85%) show adherence to the blood pressure protocol. Most importantly, there are no differences by blood pressure treatment group. Approximately 94% of patients have had their baseline blood pressure measurements taken according to the SPS3 blood pressure protocol. A small number of deviations from the protocol (Table 3) exist including not using the Colin device for measurement (4%) and not measuring the blood pressure in both arms to determine the arm with the highest measurement for subsequent measurement (2%). The main protocol deviation relates to the timing of ingestion of antihypertensive medications and the blood pressure measurement. The protocol requires measurement of blood pressure at least 3 h after the last ingestion of antihypertensive medications (holding a dose if necessary). For about 11% of the blood pressure measurements, the elapsed time between taking medications and measurement was less than 3 h. For a small percentage of follow-up visits (4%), a device (electronic or manual) other than the Colin 8800C was used for blood pressure measurement. In a small

number of cases the choice of arm changed in the course of the trial (1%). For almost all follow-up visits (99%), blood pressure was measured three times and averaged to provide the decision value for SBP.

Discussion

The diagnosis and treatment of hypertension is predicated on accurate blood pressure measurement. The importance of accurate blood pressure measurement in the SPS3 study necessitates ongoing quality control activities to ensure quality measurements. The blood pressure arm needs to demonstrate a 10 mmHg difference in SBP between the two treatment groups, making accurate blood pressure measurement critical. Our review of the quality of blood pressure measurement focuses on two areas, performance of the Colin 8800C and the effectiveness of the training of the nurse observers who measure blood pressure in the trial. The Colin 8800C would reduce digit bias for zero, a common observer error [6,7] and one that is most important in SPS3 owing to target ranges of < 130 and 130–149 mmHg. An overrepresentation of zero could obliterate the true difference in SBP between the two groups, making the trial a failure. Our results demonstrated that the Colin 8800C passed the AAMI guidelines, consistent with the findings by Ling *et al*. [15]. The British Hypertension Society protocol [11] specifies a more detailed distribution of blood pressure values, which was not satisfied by the participants recruited for this study. We did, however, apply their standards to these data and found that the percentage of differences between the Colin 8800C device and the observers that fell within 5, 10, and 15 mmHg yielded a ‘B’ rating for systolic pressures and an ‘A’ rating for diastolic pressures. Instruments that meet at least a ‘B’ rating are considered to have passed the British Hypertension Society criteria [11].

Despite passing a validation study [13], it was not known whether other flaws in measurement such as skipped digits would occur with the Colin device. The analysis examining the Colin 8800C for the presence of skipped digits found that all possible values for SBP and diastolic blood pressures were represented within the range of blood pressures studied, further lending support to the accuracy of the Colin 8800C device. Skipped digits have been reported for other automatic devices used in population-based studies [14]. For example, the DINA-MAP automated oscillometric blood pressure device has been reported to skip multiple values of SBP including 130, 140, and 150 mmHg [14]. Given the goal of managing participants into specific target groups by SBP, the implications of skipped digits for SPS3 could lead to an under or overestimation of those participants falling within their assigned target group and could impact their subsequent treatment. Thus, results from these initial investigations undertaken here to examine blood pressure measurement in the SPS3 study support the validity of our measurement tool.

The second concern was the impact of the training program for the observers on reduction in the observer-related errors that may occur in blood pressure measurement. Observer errors applicable to our protocol include incorrect cuff selection and positioning, use of a nonoscillometric device, inadequate rest period, and lack of repeat measurements [17-19,28]. These errors are made by both nurses and physicians [24,29-31] and may introduce sufficient bias to damage the study’s ability to detect whether intensive blood pressure control is valuable postlacunar stroke. Reliability of measurement has been found to be improved when the observers receive proper training and the measurements are obtained using a standardized protocol [32,33].

As part of our ongoing oversight of quality in SPS3, we wanted to identify how adherent the SPS3 observers are to their blood pressure measurement training standards seen in Table 1. Our analyses indicate a high level of performance by the SPS3 observers in measuring blood pressure in the study. For the high majority of participants, blood pressure is always

measured with the Colin device. Although all blood pressures should be measured with the Colin device, in the first 3 months of the SPS3 study multiple clinic visits are often required to adjust antihypertensive therapy to achieve the assigned target. This can be burdensome for some participants who are recovering from their stroke, so the protocol permits study coordinators to make home visits on these patients if required to obtain blood pressures to use for therapy titration. In these occasions, other devices (sphygmomanometer or other oscillometric devices) have been used for blood pressure measurements. These 490 measurements (< 2% of total blood pressure determinations) were analyzed for digit preference for zero and none was found (results not shown) providing further evidence of the positive impact of the SPS3 training on reduction in observer error. For 99% of patients, three sitting blood pressure measurements were averaged to determine if the participant is within their assigned target group and to dictate their management. Evidence exists that measurement variability is reduced when two or more measurements are averaged [34]. The timing of ingestion of medications may affect the observed measurement. Although study coordinators ask patients to hold medications before blood pressure measurement, in about 10% of the follow-up visits, patients had taken their medications within 3 h of having their blood pressure measured. Faced with the choices of sending the patient home without having their blood pressure measured and asking them to return for another follow-up visit or having them sit in clinic until 3 h has passed since taking medications, coordinators frequently elect to proceed with blood pressure measurement. Wingfield *et al.* [26] showed in the Syst-Eur trial that feedback on observer performance can improve the quality of blood pressure measurement in a hypertension treatment trial. Feedback on observer performance in the SPS3 study is presented to the study centers at the annual meeting along with formal retraining on blood pressure measurement.

A limitation of our analyses of adherence to the protocol is that it is based only on data available in our entry system. Other aspects of the protocol are not captured through our data entry system and may be important determinants of quality. To ensure continued high performance in all aspects of measurement, retraining in the blood pressure protocol is undertaken at the annual meetings and site visits are conducted frequently to observe blood pressure measurement procedures and to provide feedback to the sites.

Accuracy in blood pressure measurement requires not only a valid measuring device but also reliability in its measurement. Validity concerns the extent to which an instrument measures what it intends to measure whereas reliability can be defined as the extent to which a measurement is consistent and free from error [32]. In summary, accurate measurement of blood pressure is critical both to the execution of the SPS3 study and to the conclusions that can be drawn from the results that could affect clinical practice. These analyses support the validity of the Colin 8800C oscillometric device for blood pressure measurement in the SPS3 study. Observer training in SPS3 has been successful in reducing measurable observer errors that can be identified in our data entry system that might lead to errors in blood pressure measurement. Ongoing analysis of observer performance with feedback to all centers will continue for the duration of the trial.

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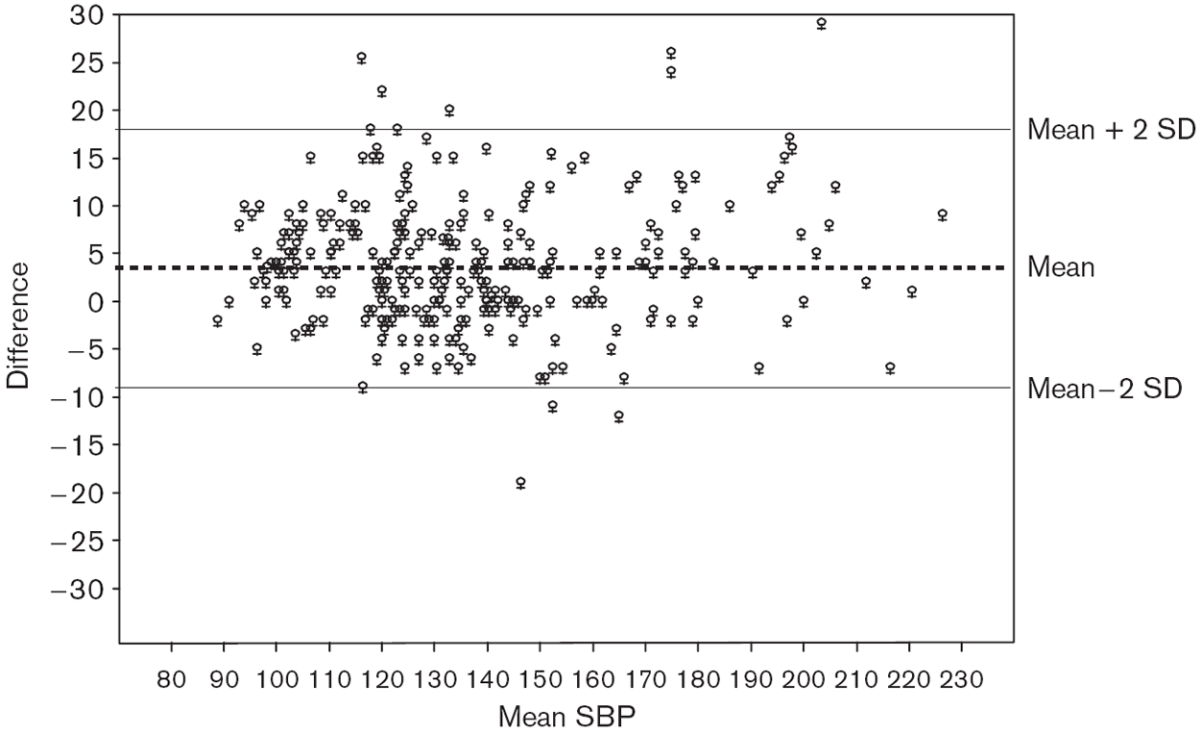

Fig. 1.

Mean systolic blood pressure (SBP) versus Colin/manual difference. Scatter plot of the difference between the Colin 8800 and the average of the two observers for the SBPs. The *x*-axis represents the mean of the Colin 8800 and the observer measurements. The *y*-axis represents the difference between the Colin 8800 and the observer measurements.

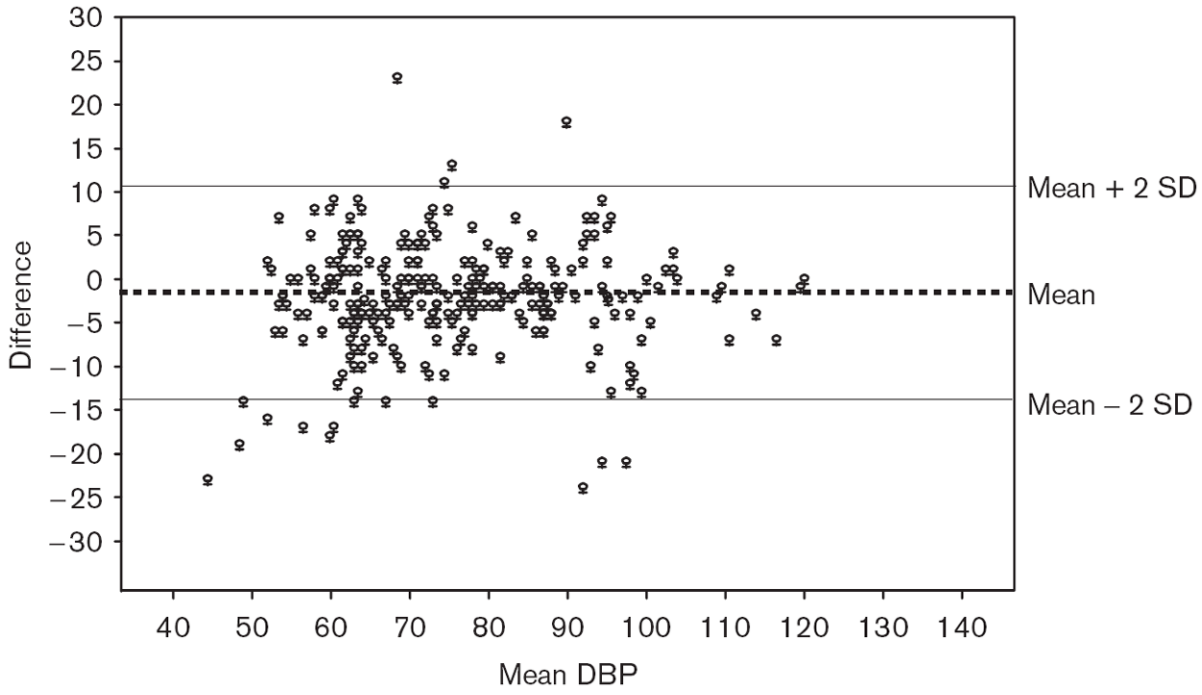

Fig. 2.

Mean diastolic blood pressure (DBP) versus Colin/manual difference. Scatter plot of the difference between the Colin 8800 and the average of the two observers for the diastolic blood pressures. The *x*-axis represents the mean of the Colin 8800 and the observer measurements. The *y*-axis represents the difference between the Colin 8800 and the observer measurements.

Table 1

SPS3 protocol for BP measurement

(adapted from JNC-VII recommendations and American Heart Association BP measurement guidelines [21,22])

1	Measure BP in the morning with morning BP medications held or at least 3 h after taking BP medications
2	No caffeine or tobacco within prior to BP measurement 60 min
3	Sitting position: ‘selected’ arm relaxed and supported at level of the heart after 15 min of sitting quietly
4	Record the reading using the Colin electronic device
5	Bladder of the cuff length > 80% of upper arm circumference; width 40% of the circumference. Proper cuff size is recorded for future use
6	Minimize physical contact during measurement
7	Three readings separated by > 2 min taken in the seated position
8	Orthostatic (standing) measurements obtained after sitting BP readings are measured
9	If the measured BP is unexpectedly high or low, recheck with a recently calibrated (preferably mercury) sphygmomanometer

BP, blood pressure; JNC, Joint National Committee.

Table 2

Colin 8800 validation study sample compared with AAMI requirements

	AAMI SP10: 2002 standards	Colin 8800C validation study	
Sample size	***n*** **≥ 85 (255 data points)**	***n*** **= 96 (288 data points)**	
Blood pressure			
< 100 mmHg systolic	At least 10% of sample	10%	
> 160 mmHg systolic	At least 10% of sample	18%	
< 60 mmHg diastolic	At least 10% of sample	10%	
> 100 mmHg diastolic	At least 10% of sample	10%	
Mean SBP (SD)		134 (28)	
Mean DBP (SD)		76 (15)	
Range for SBP		89–222	
Range for DBP		50–120	
Arm sizes			
< 25 cm	At least 10% of sample	11%	
> 35 cm	At least 10% of sample	16%	
Observer agreement			
Within ± 10 mmHg	100% of sample	100%	
Within ± 5 mmHg	At least 90% of sample	98%	
Mean (SD) of differences between	5 mmHg ± 8 mmHg[a]	SBP 3.9 (6.7)	
Electronic device and average of the observers		DBP – 2.1 (6.1)	
Percentage of differences[b]	≤ 5	≤ 10	≤ 15
SBP	58	85	95
DBP	71	91	96

AAMI, Association for the Advancement of Medical Instrumentation; BHS, British Hypertension Society; DBP, diastolic blood pressure; SBP, systolic blood pressure.

[a] Required to rate as a ‘pass’ by AAMI standards.

[b] For an ‘A’ rating for the BHS standards, 60% of differences between electronic device and manual must fall within 5 mmHg, 85% within 10 mmHg, and 95% within 15 mmHg; for a ‘B’ rating, 50% of differences between the electronic device and the manual must fall within 5 mmHg, 75% within 10 mmHg, and 90% within 15 mmHg.

Table 3

Adherence to the BP measurement protocol

Baseline measurement	**'Usual' BP group (*n* = 394)**	**'Intensive' BP group (*n* = 415)**	**All (*N* = 809)**
BP measured with Colin device	383 (97%)	393 (95%)	776 (96%)
BP measured in both arms at initial reading to choose 'selected arm'	388 (98%)	406 (98%)	794 (98%)
BP measurement according to protocol at baseline visits	375 (95%)	384 (93%)	759 (94%)
Follow-up measurement	'Usual' BP group (*n* = 3283)	'Intensive' BP group (*n* = 3557)	All (*N* = 6840)
Measurement made beyond 3 h of intake of antihypertensive medications	2908 (89%)	3150 (89%)	5804 (89%)
BP measured with Colin device	3182 (97%)	3415 (96%)	6597 (96%)
'Selected arm' used for measurement	3262 (99%)	3543 (99%)	6805 (99%)
BP measured three times and averaged	3270 (99%)	3537 (99%)	6807 (99%)
BP measurement according to protocol at follow-up visits	2795 (85%)	3009 (85%)	5804 (85%)

BP, blood pressure.