JAMA Internal Medicine | Original Investigation

Effects of Cuff Size on the Accuracy of Blood Pressure Readings
The Cuff(SZ) Randomized Crossover Trial

Junichi Ishigami, MD, MPH; Jeanne Charleston, RN; Edgar R. Miller III, MD, PhD; Kunihiro Matsushita, MD, PhD; Lawrence J. Appel, MD, MPH; Tammy M. Brady, MD, PhD

Invited Commentary

Supplemental content

IMPORTANCE Clinical practice guidelines recommend selecting an appropriately sized cuff based on mid-arm circumference prior to measuring blood pressure (BP). To our knowledge, the effect of miscuffing on BP measurement when using an automated BP device has not been quantified.

OBJECTIVE To determine the effect of using a regular BP cuff vs an appropriately sized BP cuff on automated BP readings.

DESIGN, SETTING, AND PARTICIPANTS This randomized crossover trial of community-dwelling adults with a wide range of mid-arm circumferences took place between March 16 and October 25, 2021, in Baltimore, Maryland. Participants were recruited via BP screening events at a public food market and a senior housing facility, targeted mailings to prior research participants, placement of study brochures in hypertension clinics at Johns Hopkins University, and referrals from physicians providing hypertension care to adults.

INTERVENTIONS Participants underwent 4 sets of triplicate BP measurements, with the initial 3 sets using an appropriate, too-small, or too-large BP cuff in random order; the fourth set of triplicate measurements was always completed with an appropriate BP cuff.

MAIN OUTCOMES AND MEASURES The primary outcome was the difference in mean BP when measured with a regular BP cuff compared with an appropriate BP cuff. The secondary outcome was the difference in BP when using too-small or too-large BP cuffs vs an appropriate BP cuff across all cuff sizes. Results were also stratified by systolic BP (≥130 mm Hg vs <130 mm Hg) and body mass index (calculated as weight in kilograms divided by height in meters squared; ≥30 vs <30).

RESULTS A total of 195 adults (mean [SD] age, 54 [16] years; 67 [34%] male; 132 [68%] Black; 100 [51%] with hypertension) were randomized for inclusion. Among individuals requiring a small BP cuff, use of a regular BP cuff resulted in a statistically significant lower BP reading (mean systolic BP difference, −3.6 [95% CI, −5.6 to −1.7] mm Hg). In contrast, among individuals requiring a large or extra-large BP cuff, use of a regular BP cuff resulted in a statistically significant higher BP reading (mean systolic BP difference, 4.8 [95% CI, 3.0-6.6] mm Hg and 19.5 [95% CI, 16.1-22.9] mm Hg, respectively). For the secondary outcome, BP differences with overcuffing and undercuffing by 1 and 2 cuff sizes were greater among those requiring larger BP cuffs. The results were consistent in stratified analyses by systolic BP and body mass index.

CONCLUSIONS AND RELEVANCE In this randomized crossover trial, miscuffing resulted in strikingly inaccurate BP measurements. This is particularly concerning for settings where 1 regular BP cuff size is routinely used in all individuals, regardless of arm size. A renewed emphasis on individualized BP cuff selection is warranted.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT04610775

JAMA Intern Med. doi:10.1001/jamainternmed.2023.3264
Published online August 7, 2023.

Author Affiliations: Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (Ishigami, Charleston, Miller, Matsushita, Appel); Johns Hopkins University School of Medicine, Baltimore, Maryland (Miller, Matsushita, Appel, Brady).

Corresponding Author: Tammy M. Brady, MD, PhD, Johns Hopkins University School of Medicine, 200 N Wolfe St, The David M. Rubenstein Child Health Building, Room 3062, Baltimore, MD 21287 (tbrady8@jhmi.edu).

Hypertension is the leading cause of cardiovascular disease worldwide.[1] Accurate measurement of blood pressure (BP) is used to screen for hypertension and to diagnose and treat hypertension. Although there are several preparatory and positioning steps required for accurate BP measurement,[2,3] individualized selection of appropriate cuff size is often overlooked, despite clinical practice guidelines. Barriers to adherence to this recommendation often relate to time and resource constraints and include insufficient staff and training, time pressures, and lack of cuffs with different sizes.[4] Accordingly, a regular adult BP cuff is often used routinely for all individuals. While higher or lower BP readings with too-small or too-large BP cuffs have been described in previous studies using BP devices that rely on auscultation,[5-12] this issue has not been rigorously studied with automated oscillometric BP devices, which estimate BP by a fundamentally different technique than auscultatory devices. The few studies that examined the influence of miscuffing when using an automated oscillometric BP device have been limited by their observational study design and selected settings (intensive care unit,[13] home[14,15]). Currently, automated oscillometric BP devices are strongly recommended in clinical guidelines across the globe, including the 2017 adult hypertension guideline.[16,17]

In this context, we conducted a randomized crossover trial to determine the effects of using a regular adult BP cuff vs a BP cuff that is appropriately sized for an individual's measured mid-arm circumference on automated BP readings. We also aimed to more broadly describe the effect of overcuffing and undercuffing on BP readings across multiple BP cuff sizes. We hypothesized that, compared with BP measurements obtained using an appropriately sized BP cuff, using a too-large BP cuff (overcuffing) would result in lower BP readings and using a too-small BP cuff (undercuffing) would result in higher BP readings.

Key Points

Question What is the effect of using a regular size blood pressure (BP) cuff regardless of an individual's mid-upper arm circumference on BP readings when using an automated device?

Findings In this randomized crossover trial of 195 community-dwelling adults with a wide range of mid-arm circumferences, use of a regular BP cuff resulted in a 3.6–mm Hg lower systolic BP reading among individuals requiring a small BP cuff. In contrast, among individuals requiring a large or extra-large BP cuff, use of a regular BP cuff resulted in 4.8–mm Hg and 19.5–mm Hg higher systolic BP readings, respectively.

Meaning Using a regular BP cuff size for all individuals regardless of arm size resulted in strikingly inaccurate BP readings with an automated device; a renewed emphasis on individualized BP cuff selection is warranted, particularly in individuals with larger arm sizes.

Methods

Study Overview

We conducted a randomized crossover trial of community-dwelling adults who were 18 years and older in Baltimore, Maryland. Between March 16 and October 25, 2021, we recruited participants via (1) BP screening events at a public food market frequented by community members and at a senior housing facility, both located in close proximity to Johns Hopkins University School of Medicine; (2) targeted mailings to prior research participants at the ProHealth Research Center located in Woodlawn, Maryland; (3) placement of study brochures in hypertension clinics at Johns Hopkins University; and (4) referrals from physicians providing hypertension care to adults. A research goal was set to enroll at least 35 participants into each of 4 appropriate cuff sizes: small, regular, large, or extra large. A second goal was to enrich the number of participants with hypertensive blood pressure, initially defined as a systolic blood pressure (SBP) of 140 mm Hg or higher but later updated to 130 mm Hg or higher to be in line with prevailing US hypertension guidelines. Exclusion criteria were the presence of any of the following conditions: rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, or arteriovenous shunts on both arms; lacking capacity to consent; pregnancy; and arm circumference exceeding 55 cm.

The study was approved by the institutional review board at Johns Hopkins School of Medicine, and the protocol is available in Supplement 1. All participants provided written informed consent. This study was reported according to the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

Randomization Procedure

Using the REDCap randomization module (https://www.project-redcap.org/), participants were randomized to the order of BP cuff application (appropriate, too small, too large), with randomization stratified based on appropriate cuff size (eTable 1 in Supplement 2). Participants underwent a total of 4 sets of triplicate BP measurements, with the initial 3 sets in random order and the fourth set always a repeat of measurements obtained using an appropriately sized BP cuff. The fourth set of BP measurements was used in sensitivity analyses to determine the reproducibility of the reference measurement using an appropriate BP cuff for each participant. All participants had at least 1 set of BP measurements with the regular cuff, which could have been too small, appropriate, or too large, according to their arm circumference.

Individualized BP Cuff Size Determination

Each participant had their mid-upper arm circumference measured in a standard fashion by research staff who were trained and certified in this measurement procedure. The distance from the acromion to the olecranon was determined with measuring tape while the participant held their arm at a 90° angle. This distance was divided in half to determine the midpoint, where the circumference was then measured using Gulick tape. The appropriate BP cuff was determined based on this measurement according to the manufacturer instructions and available BP cuff sizes for adults in the US market: (1) small BP cuff (20-25 cm), (2) regular BP cuff (25.1-32 cm), (3) large BP cuff (32.1-40 cm), or (4) extra-large BP cuff (40.1-55 cm).

BP Measurement Procedure

All BP measurements were obtained by 2 research staff members who underwent standardized training and successfully completed measurement certification testing by the same individual (J.C.) prior to trial start. The BP measurements were obtained between 9 AM and 6 PM using an automated, validated, oscillometric device (ProBP 2000 Digital Blood Pressure Device [Welch Allyn]). For uniformity, the right arm was selected for all measurements unless there was a compelling reason to use the left arm (eg, open sore). After consent was obtained, participants were asked to empty their bladder. Prior to each set of BP measurements, participants walked for 2 minutes until arriving at the BP measurement station; the 2-minute walk replicated a common clinical setting in which BP is measured. After ensuring proper cuff placement, 3 sequential BP measurements, 30 seconds apart (1 set), were obtained after a rest period of 5 minutes. During this time, participants were seated with their back, feet, and arm supported with arm positioned to ensure that the middle of the cuff was at heart level. At the completion of the 3 sequential measurements, the BP cuff was removed, and the participant walked for 2 minutes until returning to the BP measurement station for a second set of triplicate BP measurements after 5 minutes of rest in the same manner. This was repeated until each participant completed 4 sets of triplicate BP measurements (total of 12 BP measurements). Research staff were present for all measurements, which were obtained in a quiet, private room. Participants were asked not to speak to the research staff or use a smartphone during the measurements or for any of the preceding 5-minute rest periods.

Outcomes

The primary outcome was the difference in the mean SBP and diastolic BP (DBP) obtained with a regular BP cuff compared with an appropriate BP cuff. The secondary outcome was the difference in the mean SBP and DBP using too-small or too-large BP cuffs compared with an appropriate BP cuff across all cuff sizes.

Demographics, Clinical History, and Anthropometry

Research staff obtained self-reported age, sex, race and ethnicity, and medical history (ie, prior diagnosis of hypertension, diabetes, chronic kidney disease, or myocardial infarction and antihypertensive medication use) from all participants. Self-reported body weight in kilograms divided by self-reported height in meters squared was used to estimate body mass index (BMI).

Statistical Analysis

For the primary analysis, we calculated the difference in SBP and DBP by subtracting the mean triplicate BP measurements obtained using an appropriate BP cuff from the mean triplicate BP measurements obtained using a regular BP cuff. As for the secondary analysis, for each cuff size combination, we calculated the difference in SBP and DBP by subtracting the mean triplicate BP measurements obtained using an appropriate BP cuff from the mean triplicate BP measurements obtained using a too-small or too-large BP cuff. The 95% CIs were estimated using the standard errors of the BPs from the appropriate BP cuff and too-small or too-large BP cuff. For these analyses, the first set of triplicate measurements obtained using an appropriately sized cuff were used as the reference measurement.

Several sensitivity analyses were performed. First, we repeated the analyses in strata defined by SBP (≥130 mm Hg vs <130 mm Hg) and BMI (≥30 vs <30). Second, recognizing the inherent variability in BP, we determined how the difference in BP between 2 sets of BPs measured with an appropriate cuff (appropriate cuff BP No. 2 [the mean of the fourth set of triplicate BP measurements] minus appropriate cuff BP No. 1) was different from the difference in BP between the too-large or too-small cuff BP measurement and the reference BP (too-large or too-small BP cuff minus appropriate cuff BP No. 1). Finally, we repeated the analysis using just the first BP reading, instead of the mean triplicate BP readings, because BP is often measured only once during a clinic visit.

A 2-sided $P < .05$ was considered statistically significant. All analyses were performed using Stata, version 15 (StataCorp).

Results

Patient Demographics

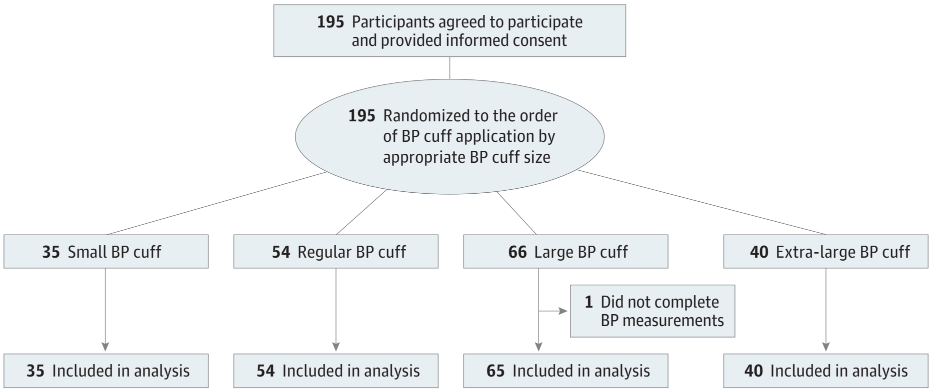
A total of 195 eligible participants were randomized (**Figure 1**). Their mean (SD) age was 54 (16) years, 67 (34%) were male, 132 (68%) were Black, 100 (51%) had hypertension, 39 (20%) had diabetes, and the mean (SD) BMI was 28.8 (8.1) (**Table 1**). Based on measured mid-arm circumference, a small BP cuff (20-25 cm) was appropriate for 35 participants, a regular BP cuff (25.1-32 cm) was appropriate for 54 participants, a large BP cuff (32.1-40 cm) was appropriate for 66 participants, and an extra-large BP cuff (40.1-55 cm) was appropriate for 40 participants. At baseline, stratified by appropriate BP cuff size, mean SBPs were 119.6 mm Hg for participants with small arm circumference, 120.9 mm Hg for those with regular arm circumference, 122.7 mm Hg for those with large arm circumference, and 124.5 mm Hg for those with extra-large arm circumference; the corresponding mean DBPs were 71.5, 72.8, 75.7, and 79.3 mm Hg, respectively (**Table 2**).

Primary Outcome: BP Differences Using a Regular Adult BP Cuff Regardless of Appropriate BP Cuff Size

Figure 2 and Table 2 show the differences in BP obtained with a regular BP cuff compared with an appropriate BP cuff. When a small BP cuff was appropriate, regular BP cuff (1 size too large) measurements resulted in lower SBP with a mean SBP difference (regular minus appropriate) of −3.6 (95% CI, −5.6 to −1.7) mm Hg (Figure 2A). In contrast, when a large BP cuff was appropriate, regular BP cuff (1 size too small) measurements resulted in higher SBP with a mean difference of 4.8 (95% CI, 3.0-6.6) mm Hg. When an appropriate BP cuff was extra large, regular cuff (2 sizes too small) measurements resulted in higher SBP with a mean SBP difference of 19.5 (95% CI, 16.1-22.9) mm Hg (Table 2).

These findings were consistent, albeit to a lesser degree, for DBP: the DBP differences were −1.3 (95% CI, −2.4 to −0.2),

Figure 1. CONSORT Diagram



Participants were randomized to the order of blood pressure (BP) cuff application (appropriate, too small, too large), with randomization stratified based on appropriate cuff size (eTable 1 in Supplement 2).

Table 1. Participant Characteristics (N = 195)

Characteristic	No. (%)
Age, mean (SD), y	54 (16)
Sex	
Female	128 (66)
Male	67 (34)
Race and ethnicity	
Black	132 (68)
Hispanic	5 (3)
White	58 (30)
Medical history	
Hypertension	100 (51)
Antihypertensive medication use	95 (49)
Diabetes	39 (20)
Chronic kidney disease	4 (2)
Myocardial infarction	4 (2)
BMI, mean (SD)[a]	28.8 (8.1)
Arm circumference, mean (SD), cm	34 (7.2)
Appropriate BP cuff size	
Small	35 (18)
Regular	54 (28)
Large	66 (34)
Extra large	40 (21)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); BP, blood pressure.

[a] Based on self-reported weight and height.

1.8 (95% CI, 1.1-2.6), and 7.4 (95% CI, 5.7-9.1) mm Hg when a regular BP cuff was 1 size too large, 1 size too small, and 2 sizes too small, respectively (Figure 2B and Table 2). These findings were consistent when the first BP reading was used instead of the average of triplicate BP measurements (eTable 2 in Supplement 2), when participants were stratified by SBP and DBP (eTable 3 in Supplement 2) or BMI (eTable 4 in Supplement 2), and when intrameasurement BP variability was accounted for using the second set of readings with the appropriate BP cuff (eTable 5 in Supplement 2).

Secondary Outcome: BP Differences Using Too-Small or Too-Large BP Cuffs Across Cuff Sizes

Next, the difference in BP obtained with too-small or too-large BP cuffs was quantified compared with an appropriately BP cuff (**Figure 3** and eTable 6 in Supplement 2). Among those requiring a small BP cuff or an extra-large BP cuff, the magnitude of BP difference was greater when the BP cuff was 2 sizes different compared with 1 size different. For example, for those requiring an extra-large BP cuff, the SBP difference was 9.6 (95% CI, 7.3-11.9) mm Hg when a large BP cuff was used (1 size too small) and 19.5 (95% CI, 16.1-22.9) mm Hg when a regular BP was used (2 sizes too small) (Figure 3A).

The magnitude of these BP differences increased incrementally as the appropriate cuff size progressed from the regular BP cuff to the extra-large BP cuff. For example, a 1-size-too-small cuff resulted in higher SBP by 3.0 (95% CI, 0.9-5.2) mm Hg when the regular BP cuff was appropriate (ie, a small BP cuff was used when the regular BP cuff was appropriate) and by 9.6 (95% CI, 7.3-11.9) mm Hg when an extra-large BP cuff was appropriate (ie, a large BP cuff was used when the extra-large cuff was appropriate) (Figure 3A). These findings were consistent for (1) DBP (Figure 3B); (2) when the first BP reading was compared instead of the average of triplicate BP measurements (eTable 7 in Supplement 2); (3) when participants were stratified by SBP (eTable 8 in Supplement 2) or BMI (eTable 9 in Supplement 2), although sample sizes were limited for those with hypertensive SBP or those with obesity in the small BP cuff group; and (4) when intraindividual BP measurement variability was accounted for (eTable 10 in Supplement 2).

Discussion

In this randomized crossover trial of community-dwelling adults using an automated BP device, BP readings obtained with a regular BP cuff instead of an appropriately sized cuff resulted in strikingly inaccurate BP measurements. Specifically, measurements obtained when the regular BP cuff was too large or too small resulted in clinically and statistically significant lower and higher BP readings, respectively. This effect was consistent across other appropriate cuff sizes, with

Table 2. Mean Difference in BP When a Regular BP Cuff Was Used Regardless of Appropriate BP Cuff Size

Cuff size	Mean (SD), mm Hg[a]		BP cuff size used relative to appropriate BP cuff size	BP difference (95% CI), mm Hg	*P* value for difference
	BP with appropriate BP cuff	BP with regular BP cuff			
Systolic BP					
Small (n = 35)	119.6 (23.5)	116.0 (23.4)	1 Size too large	−3.6 (−5.6 to −1.7)	<.001
Regular (n = 54)	120.9 (21.4)	120.9 (21.4)	Correct cuff size	0 [Reference]	NA
Large (n = 65)	122.7 (14.7)	127.5 (14.9)	1 Size too small	4.8 (3.0 to 6.6)	<.001
Extra large (n = 40)	124.5 (21.8)	144.0 (22.4)	2 Sizes too small	19.5 (16.1 to 22.9)	<.001
Diastolic BP					
Small (n = 35)	71.5 (10.4)	70.2 (10.5)	1 Size too large	−1.3 (−2.4 to −0.2)	.02
Regular (n = 54)	72.8 (11.5)	72.8 (11.5)	Correct cuff size	0 [Reference]	NA
Large (n = 65)	75.7 (7.0)	77.6 (7.7)	1 Size too small	1.8 (1.1 to 2.6)	<.001
Extra large (n = 40)	79.3 (12.2)	86.7 (14.2)	2 Sizes too small	7.4 (5.7 to 9.1)	<.001

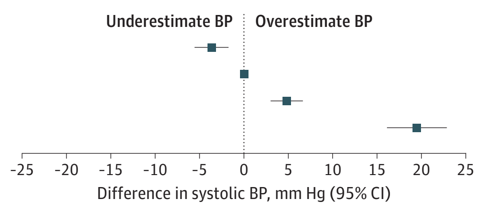
Abbreviations: BP, blood pressure; NA, not applicable.

[a] BPs were based on the average of triplicate BP readings.

Figure 2. Mean BP Difference When an Appropriately Sized BP Cuff Was Used vs a Regular BP Cuff Size

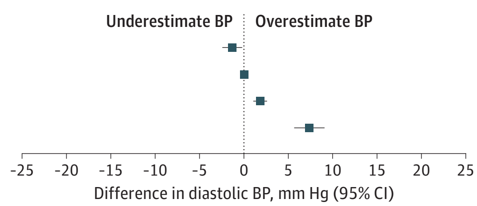
A Systolic BP differences

BP cuff	Difference in systolic BP, mm Hg (95% CI)
Regular cuff 1 size too large	-3.6 (-5.6 to -1.7)
Regular cuff appropriately sized	0 [Reference]
Regular cuff 1 size too small	4.8 (3.0 to 6.6)
Regular cuff 2 sizes too small	19.5 (16.1 to 22.9)



B Diastolic BP differences

BP cuff	Difference in diastolic BP, mm Hg (95% CI)
Regular cuff 1 size too large	-1.3 (-2.4 to -0.2)
Regular cuff appropriately sized	0 [Reference]
Regular cuff 1 size too small	1.8 (1.1 to 2.6)
Regular cuff 2 sizes too small	7.4 (5.7 to 9.1)



Blood pressures (BPs) were based on the average of triplicate BP readings.

the magnitude of difference greater when larger BP cuff sizes were appropriate for participants' mid-arm circumference. This effect was seen even when using a typical approach of using the first BP measurement obtained instead of the average of triplicate measurements, or when accounting for intraindividual BP measurement variability.

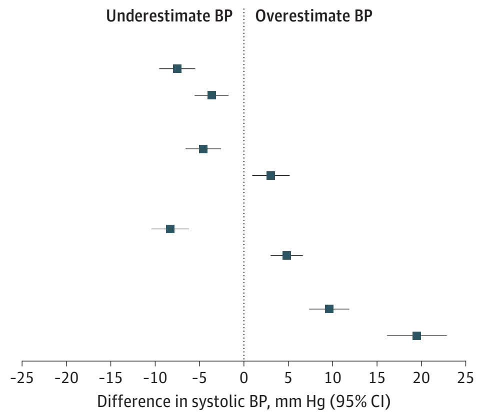
The 2017 adult hypertension guideline recommendations endorse automated BP measurements for hypertension screening, diagnosis, and management.[16,17] Accordingly, automated BP devices are predominantly used in most clinics and for home BP monitoring. Nonetheless, the rationale for a recommendation of using appropriate BP cuff size in these guidelines was based on studies using auscultatory BP measurements[5-12]: Fonseca-Reyes et al reported that among those who required a large or extra-large BP cuff, a regular BP cuff overestimated SBP by 2 to 5 mm Hg with every 5-cm increase in arm circumference.[11] Little data exist as to the effect of miscuffing when using an automated oscillometric BP device with the exception of a few studies, all nonclinical trials, that assessed BPs during an intensive care unit stay[13] or with home BP monitoring.[14,15] The type of BP device studied is an important consideration. The oscillometric technique that the majority of automated devices use for BP estimation is not dependent on the same cuff proportions required for auscultation; thus, one cannot extrapolate the effect of cuff size on automated BP measurement from studies using manual auscultation.

Published studies have demonstrated that individualized cuff selection does not commonly occur in clinic settings. Observation of BP measurement by medical students revealed that only 74% chose the appropriate cuff for measurements.[18] Observation of medical staff at an academic health science center showed that no encounter included measurement of the mid-arm circumference to determine

Figure 3. Mean Difference in BP When a Too-Small or Too-Large BP Cuff Was Used vs an Appropriately Sized BP Cuff, Stratified by Appropriate BP Cuff Size

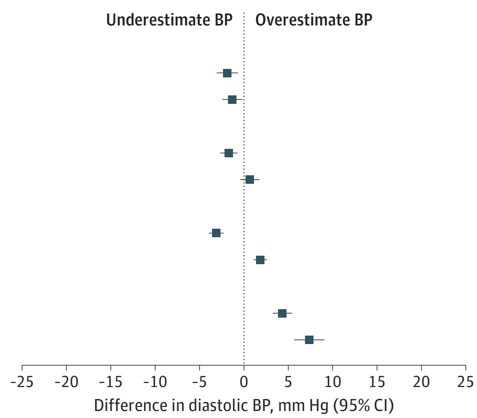
A Systolic BP differences

Appropriate BP cuff size	Difference in systolic BP, mm Hg (95% CI)
Small size	
Large used	-7.5 (-9.6 to -5.5)
Regular used	-3.6 (-5.6 to -1.7)
Regular size	
Large used	-4.6 (-6.6 to -2.6)
Small used	3.0 (0.9 to 5.2)
Large size	
Extra large used	-8.3 (-10.4 to -6.2)
Regular used	4.8 (3.0 to 6.6)
Extra-large size	
Large used	9.6 (7.3 to 11.9)
Regular used	19.5 (16.1 to 22.9)



B Diastolic BP differences

Appropriate BP cuff size	Difference in diastolic BP, mm Hg (95% CI)
Small size	
Large used	-1.9 (-3.1 to -0.7)
Regular used	-1.3 (-2.4 to -0.2)
Regular size	
Large used	-1.7 (-2.7 to -0.7)
Small used	0.7 (-0.4 to 1.7)
Large size	
Extra large used	-3.1 (-3.9 to -2.3)
Regular used	1.8 (1.1 to 2.6)
Extra-large size	
Large used	4.3 (3.3 to 5.4)
Regular used	7.4 (5.7 to 9.1)



This analysis determined the effect of using too-small or too-large blood pressure (BP) cuffs across multiple BP cuff sizes on readings. Blood pressures were based on the average of triplicate BP readings.

cuff size.[19] Observations of a medical clinic in Tanzania and in Brazil revealed that only 1 cuff size was available for use in all patients.[20,21] While the BP device companies may help to limit this problem by having arm circumference range indicators on individual cuffs to guide appropriate cuff size selection for individual measurements, it is not known how often these are used by clinicians or patients. Knowing this, we designed the present trial to not just determine the overall effect of miscuffing on BP readings, but to also determine the effect of using 1 cuff size—a regular adult cuff—for all participants.

Interestingly, the magnitude of measurement error increased with increasing cuff size. For example, BP was approximately 3 mm Hg higher when a small BP cuff was used for those requiring a regular BP cuff but was approximately 10 mm Hg higher when a large BP cuff was used for those requiring an extra-large BP cuff. Underlying reasons are uncertain but may be related to the algorithms used to estimate BP from brachial arterial oscillations. It could also be related to cuff fit, with many individuals who require an extra-large BP cuff having arms with a conicotruncal shape.[22] Regardless of cause, the potential clinical effect among those requiring larger cuff sizes includes overdiagnosis of not just hypertension, but also stage 2 hypertension. The mean BP in those requiring an extra-large cuff based on measured mid-arm circumference was 144/87 mm Hg when a regular BP cuff was used, which is in the stage 2 hypertension range in the US, whereas the mean BP when using an appropriately sized cuff was 125/79 mm Hg, a reading in the elevated BP range. With misdiagnosis to this degree comes additional, likely unnecessary, clinical testing (laboratory and imaging) and treatment, leading to increased cost, psychosocial harm, and risk for adverse events.[23]

Strengths and Limitations

This study has limitations. First, the subgroup analyses had insufficient sample size in some cuff groups, such as individuals with hypertensive BP or obesity in the small BP cuff group, although such scenarios are extremely rare. Also, whether these findings hold true across the range of BMI should be confirmed in future studies, since BMI was self-reported. For example, previous studies have suggested greater intraindividual BP variabilities in individuals with lower BMI.[24,25] Second, the magnitude and direction of BP differences were heterogeneous across individuals, even though we reported statistically significant average BP differences. The application of these findings to respective individuals needs to be made with caution. For example, a simple calibration would not solve the problem for everyone. Third, BPs were measured by trained research staff according to a rigorous protocol, thus the degree of bias due to miscuffing may be even larger in a real-world setting, such as community-based hypertension screening sites. Finally, these findings should be interpreted with caution for those with extreme arm circumferences (eg, <20 cm or >55 cm), although such cases are rare.

This trial also has several strengths. First, the randomized crossover design eliminated the influence of order effect bias (ie, systemic difference in BP by order of BP measurements) and had embedded activity to wash out the rest time between measurements. Second, we evaluated 2 clinically meaningful scenarios, where (1) a regular BP cuff was used regardless of appropriate BP cuff size and (2) too-small or too-large BP cuffs were used across multiple BP cuff sizes. Finally, we repeated the BP measurement with an appropriate cuff size for every participant as the fourth set of BP measurement to address intrinsic BP variability.

This study warrants a renewed emphasis on individualized BP cuff selection, an issue that is relevant for BP measured in health care facilities and at home. Although there are a number of sources of error for BP measurement (eg, crossed legs, unsupported arm, cold exposure), use of appropriate BP cuff has a particularly important public implication because a recent analysis of the National Health and Nutrition Examination Survey revealed that a regular BP cuff was suitable for only 51% (125 million) of US adults, whereas 40% (98 million) would require a large BP cuff.[26] Most BP monitoring devices sold in the US come with 1 BP cuff that is typically the regular BP cuff size. In this context, 40% or more US consumers would obtain BP readings overestimated by almost 5 mm Hg when conducting home BP monitoring. On a global scale, an error in SBP measurement of 5 mm Hg could lead to the misclassification of 84 million people to either undertreatment or overtreatment of hypertension.[27] The undertreatment will result in the occurrence of preventable cardiovascular and kidney complications of hypertension, and the overtreatment will cause unnecessary adverse effects of medical treatment and increase expenditure for medicines.

The current hypertension guidelines recommend confirmation of high BP readings for diagnosis of hypertension and titration of BP-lowering medication.[16,17] Ensuring that BP is measured with an appropriately sized cuff in the initial office setting is essential to ensure that additional measurements are only requested and obtained in those with truly elevated BP (and not in those with artificially elevated BP due to miscuffing). As with clinical measurements, appropriate cuff size is also integral to the accuracy of out-of-office measurements obtained to confirm BP elevation and is critically important to avoid overdiagnosis and underdiagnosis of hypertension. Expanded efforts to encourage assessment of arm size prior to measurement in the clinic and at home is warranted, such as through training clinic personnel and educating patients. Improved BP cuff markings, enhanced device packaging, and manufacturer marketing could also make it easier for clinicians and patients to recognize the importance of cuff fit and ensure that the cuff used for BP measurements is appropriate for an individual's arm size.

Conclusions

In this randomized crossover trial, using a regular BP cuff size for all individuals regardless of arm size resulted in strikingly inaccurate BP readings. A renewed emphasis on individualized BP cuff selection is warranted, particularly in individuals with larger arm sizes.

ARTICLE INFORMATION

Accepted for Publication: May 7, 2023.

Published Online: August 7, 2023. doi:10.1001/jamainternmed.2023.3264

Author Contributions: Drs Ishigami and Brady had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: All authors.
Acquisition, analysis, or interpretation of data: Ishigami, Miller, Matsushita, Appel, Brady.
Drafting of the manuscript: Ishigami, Matsushita, Brady.
Critical revision of the manuscript for important intellectual content: Charleston, Miller, Matsushita, Appel.
Statistical analysis: Ishigami.
Obtained funding: Appel.
Administrative, technical, or material support: Charleston, Appel, Brady.
Supervision: Matsushita, Appel, Brady.

Conflict of Interest Disclosures: Dr Matsushita reported personal fees from Kowa, Fukuda Denshi, and the American Medical Group Association outside the submitted work. No other disclosures were reported.

Funding/Support: This study was supported by Resolve to Save Lives. Resolve to Save Lives is funded by Bloomberg Philanthropies, the Bill & Melinda Gates Foundation, and Gates Philanthropy Partners, which is funded with support from the Chan Zuckerberg Foundation.

Role of the Funder/Sponsor: Resolve to Save Lives had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Data Sharing Statement: See Supplement 3.

Additional Contributions: We thank the participants who volunteered their time and the staff who conducted the study. They were not compensated.

REFERENCES

1. Hypertension. World Health Organization. Accessed June 29, 2023. https://www.who.int/news-room/fact-sheets/detail/hypertension

2. Muntner P, Shimbo D, Carey RM, et al. Measurement of blood pressure in humans: a scientific statement from the American Heart Association. *Hypertension*. 2019;73(5):e35-e66. doi:10.1161/HYP.0000000000000087

3. Jin J. Checking blood pressure at home. *JAMA*. 2017;318(3):310. doi:10.1001/jama.2017.6670

4. Kallioinen N, Hill A, Horswill MS, Ward HE, Watson MO. Sources of inaccuracy in the measurement of adult patients' resting blood pressure in clinical settings: a systematic review. *J Hypertens*. 2017;35(3):421-441. doi:10.1097/HJH.0000000000001197

5. Maxwell MH, Waks AU, Schroth PC, Karam M, Dornfeld LP. Error in blood-pressure measurement due to incorrect cuff size in obese patients. *Lancet*. 1982;2(8288):33-36. doi:10.1016/S0140-6736(82)91163-1

6. Linfors EW, Feussner JR, Blessing CL, Starmer CF, Neelon FA, McKee PA. Spurious hypertension in the obese patient: effect of sphygmomanometer cuff size on prevalence of hypertension. *Arch Intern Med*. 1984;144(7): 1482-1485. doi:10.1001/archinte.1984.00350190188032

7. Gómez-Marín O, Prineas RJ, Råstam L. Cuff bladder width and blood pressure measurement in children and adolescents. *J Hypertens*. 1992;10(10):1235-1241. doi:10.1097/00004872-199210000-00018

8. Bovet P, Hungerbuhler P, Quilindo J, Grettve ML, Waeber B, Burnand B. Systematic difference between blood pressure readings caused by cuff type. *Hypertension*. 1994;24(6):786-792. doi:10.1161/01.HYP.24.6.786

9. Guagnano MT, Palitti VP, Murri R, Marchione L, Merlitti D, Sensi S. Many factors can affect the prevalence of hypertension in obese patients: role of cuff size and type of obesity. *Panminerva Med*. 1998;40(1):22-27.

10. Bakx C, Oerlemans G, van den Hoogen H, van Weel C, Thien T. The influence of cuff size on blood pressure measurement. *J Hum Hypertens*. 1997;11(7):439-445. doi:10.1038/sj.jhh.1000470

11. Fonseca-Reyes S, de Alba-García JG, Parra-Carrillo JZ, Paczka-Zapata JA. Effect of standard cuff on blood pressure readings in patients with obese arms: how frequent are arms of a 'large circumference'? *Blood Press Monit*. 2003; 8(3):101-106. doi:10.1097/00126097-200306000-00002

12. Andrews JC, Dewitt B, Czerwien TE, Bijelic M, Latman NS. Inaccuracies introduced by single width blood pressure cuffs. *Hypertens Res*. 2011;34(2): 209-211. doi:10.1038/hr.2010.210

13. Bur A, Hirschl MM, Herkner H, et al. Accuracy of oscillometric blood pressure measurement according to the relation between cuff size and upper-arm circumference in critically ill patients. *Crit Care Med*. 2000;28(2):371-376. doi:10.1097/00003246-200002000-00014

14. Mourad JJ, Lopez-Sublet M, Aoun-Bahous S, et al. Impact of miscuffing during home blood pressure measurement on the prevalence of masked hypertension. *Am J Hypertens*. 2013;26 (10):1205-1209. doi:10.1093/ajh/hpt084

15. Aylett M, Marples G, Jones K, Rhodes D. Evaluation of normal and large sphygmomanometer cuffs using the Omron 705CP. *J Hum Hypertens*. 2001;15(2):131-134. doi:10.1038/sj.jhh.1001133

16. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension*. 2018;71(6):1269-1324. doi:10.1161/HYP.0000000000000066

17. Williams B, Mancia G, Spiering W, et al; Authors/Task Force Members. 2018 ESC/ESH Guidelines for the management of arterial hypertension: the task force for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension: the task force for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension. *J Hypertens*. 2018;36(10):1953-2041. doi:10.1097/HJH.0000000000001940

18. Rakotz MK, Townsend RR, Yang J, et al. Medical students and measuring blood pressure: results from the American Medical Association Blood Pressure Check Challenge. *J Clin Hypertens (Greenwich)*. 2017;19(6):614-619. doi:10.1111/jch.13018

19. Minor DS, Butler KR Jr, Artman KL, et al. Evaluation of blood pressure measurement and agreement in an academic health sciences center. *J Clin Hypertens (Greenwich)*. 2012;14(4):222-227. doi:10.1111/j.1751-7176.2012.00599.x

20. Edward A, Hoffmann L, Manase F, et al. An exploratory study on the quality of patient screening and counseling for hypertension management in Tanzania. *PLoS One*. 2020;15(1): e0227439. doi:10.1371/journal.pone.0227439

21. Veiga EV, Arcuri EA, Cloutier L, Santos JL. Blood pressure measurement: arm circumference and cuff size availability. *Rev Lat Am Enfermagem*. 2009;17(4):455-461. doi:10.1590/S0104-11692009000400004

22. Palatini P. Blood pressure measurement in the obese: still a challenging problem. European Society of Cardiology. August 15, 2018. Accessed November 8, 2022. https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-16/Blood-pressure-measurement-in-the-obese-still-a-challenging-problem

23. Bell K, Doust J, McGeechan K, et al. The potential for overdiagnosis and underdiagnosis because of blood pressure variability: a comparison of the 2017 ACC/AHA, 2018 ESC/ESH and 2019 NICE hypertension guidelines. *J Hypertens*. 2021;39 (2):236-242. doi:10.1097/HJH.0000000000002614

24. Johansson JK, Niiranen TJ, Puukka PJ, Jula AM. Factors affecting the variability of home-measured blood pressure and heart rate: the Finn-Home Study. *J Hypertens*. 2010;28(9):1836-1845. doi:10.1097/HJH.0b013e32833b6c8a

25. Kuwabara J, Kuwahara K, Kuwabara Y, et al. Cross-sectional study of the association between day-to-day home blood pressure variability and visceral fat area measured using the dual impedance method. *PLoS One*. 2018;13(11): e0206945. doi:10.1371/journal.pone.0206945

26. Jackson SL, Gillespie C, Shimbo D, Rakotz M, Wall HK. Blood pressure cuff sizes for adults in the United States: National Health and Nutrition Examination Survey, 2015-2020. *Am J Hypertens*. 2022;35(11):923-928. doi:10.1093/ajh/hpac104

27. Padwal R, Campbell NRC, Schutte AE, et al. Optimizing observer performance of clinic blood pressure measurement: a position statement from the Lancet Commission on Hypertension Group. *J Hypertens*. 2019;37(9):1737-1745. doi:10.1097/HJH.0000000000002112