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Blood pressure cuff comparability study

Yechiam Ostchega[a], **Tatiana Nwankwo**[a], **Guangyu Zhang**[b], **Michele Chiappa**[c]

[a]Operations Branch, NHANES Program, Hyattsville, Maryland, USA

[b]Divison of Research and Methodology, NCHS, CDC, Hyattsville, Maryland, USA

[c]Harris Corporation, Hyattsville, Maryland, USA

Abstract

Background—Manufacturer-supplied blood pressure (BP) cuffs are part of the automatic oscillometric BP devices algorithm.

Materials and methods—This study assessed the differences in BP values using the Omron HEM 907-XL (Omron) device with two types of cuffs: the Baum cuff (BC) and the supplied Omron cuff (OC). A sample of 102 adults participated in the study, 34 per cuff size (adult, large, and extra-large). After a 5-min resting period, three pairs of BP determinations (systolic and diastolic) were taken simultaneously on both arms. One arm was cuffed with a BC and the other arm was cuffed with an OC. The cuffs were switched to opposite arms after 5 min of rest. The order was decided randomly as to which cuff was applied to which arm first.

Results—The BP readings were highly correlated between the cuffs (systolic BP, $r = 0.98$; diastolic BP, $r = 0.98$). The overall mean differences (BC − OC) were 2.66 mmHg (SD = 3.9 mmHg) for systolic BP ($P < 0.05$) and 0.33 mmHg (SD = 2.03 mmHg) for diastolic BP ($P > 0.05$). Increased cuff size corresponded to increased differences in systolic BP values (adult: 1.51 mmHg; large: 2.56 mmHg; and extra-large: 3.9 mmHg; $P < 0.05$). For diastolic BP values, a statistically significant difference was observed only for adult cuff size (difference = 1.31 mmHg, SD = 1.34 mmHg, $P < 0.05$).

Conclusion—Using a BC with the Omron could result in higher systolic BP readings and higher diastolic BP readings with the adult cuff size.

Keywords

automatic oscillometric blood pressure device; blood pressure cuffs; comparison

Introduction

Because of environmental concerns and an increased use of automated oscillometric BP devices in medical offices [1], the National Health and Nutrition Examination Survey

Correspondence to Yechiam Ostchega, PhD, RN, Operations Branch, NHANES Program, NCHS, CDC, 3311 Toledo Road, Room 4319, Hyattsville, MD 20782, USA, Tel: + 1 301 458 4408; fax: + 1 301 458 4813; yxo1@cdc.gov.

Conflicts of interest

There are no conflicts of interest.

(NHANES) is investigating alternative methods in blood pressure (BP) collection that could replace the mercury devices used in the NHANES mobile examination centers. In the 2009–2010 NHANES cycle, a study was carried out comparing the Omron HEM 907-XL oscillometric automatic BP device with the mercury sphygmomanometer device used in NHANES as the 'gold standard.' The study, however, used only one brand of cuff, the Baum cuff (BC), to perform all BP measurements with both the mercury sphygmomanometer and the Omron HEM 907-XL. No cuffs were changed between device readings and the Omron device was adapted to accept the BCs. The major reason for not changing the cuffs was the fact that as NHANES III, BP determinations (systolic/diastolic) have been performed 30 s apart, and this 30 s window did not allow adequate time to remove the BC cuff and correctly fit an Omron cuff (OC). For more information on the study, see National Health Statistic Report no.59 [1].

It is important, however, to compare the manufacturer-supplied cuff for the Omron 907-XL (i.e. OC) with the one used in the previous study (i.e. BC) because there is very little information on whether BP accessories, in particular, cuffs from different manufacturers, are interchangeable. There are some physical differences between the standard BC and the manufacturer-supplied OC. The BC size dimensions are different from the OC size dimensions and the suggested arm circumference to be cuffed by each is also different (Table 1). The dimensions and architecture of the BP cuffs are part of the oscillometric BP device's manufacturer internal algorithm for calculating systolic and diastolic BP and are unique to each device [2]. To date, to the best of our knowledge, apart from one study comparing manufacturer-supplied cuffs versus replacement cuffs attached to the same device, no other study assessed the impact of cuff replacement [3]. The current study was carried out to examine the impact on systolic and diastolic BP readings when using the BC compared with those when using the manufacturer-provided OC with the Omron HEM 907-XL.

Materials and methods

Sample

One hundred and two volunteers aged 18 years and older participated in the study, with 34 participants for each cuff size (adult, large adult, and extra-large adult). These volunteers were not part of NHANES, but were selected specifically to participate in this study.

Sample size and power were calculated to take into account the ability to test a difference of 1 mmHg (BC − OC) with a SD of 2 mmHg. With 34 participants per cuff size, there was 80% power within each cuff size and 99% power across all cuff sizes to test the aforementioned difference. The α-level for a significance test was set at P value less than 0.05.

Equipment

The Omron HEM 907-XL (Omron USA, Lake Forest, Illinois, USA) is a digital upper-arm electronic BP monitor designed to be used in clinical settings. According to the manufacturer's information, the HEM 907-XL is an updated version of the HEM 907, which was specifically upgraded to enable inflation of an extra-large adult cuff size. The algorithm was modified to accept the measurements for a larger arm circumference. The Omron HEM 907-XL automatic measurements are based on smart 'inflate' technology (IntelliSense), where inflation is driven by a pumping system and deflation is driven by an electromagnetic control valve that allows rapid air release. The measurement scale ranges from 0 to 280 mmHg. A special function, 'hide' mode, concealed BP values from the participant's view, which helped to reduce participant anxiety.

Two Omron HEM 907-XL devices were used in the study. Both devices' tubing was slightly altered to accept the BC.

Study design

The study was carried out at the ProHealth Facility in Baltimore, Maryland, an affiliate of Johns Hopkins University, over a 3-month period. A convenience sample was recruited from a pool of volunteers whose upper mid-arm circumference ranged from 22 to 50 cm. Pregnant women and participants who could not use both arms were excluded from the study. BP was measured simultaneously on both the right and the left arms by two trained NHANES observers: one arm with an OC and the other arm with a BC. To control for the effect of inter-arm physiological differences (the right arm measuring BP higher than the left arm) and to cancel its effect, two sets of measurements were obtained [4–6]. Each set consisted of three systolic and three diastolic BP determinations for each cuff for a total of six systolic and six diastolic individual measurements for both cuffs. After the first set of measurements, the two cuffs were switched to the opposite arms to obtain the second set of measurements. A randomization schedule was developed before the start of the study to determine which cuff (OC or BC) would be applied to which arm first.

The participants were blinded to the BP values and the values were recorded separately by two observers using a specially created paper form, which was later compared for accuracy before data entry was performed. A 100% audit trail was performed by a third observer matching the paper forms and the keyed-in data.

Procedure

Appropriate BP cuff size was selected according to the participant's mid-arm circumference following the NHANES protocol for collecting the mid-arm circumference measurement during the anthropometry (body measures) exam in the NHANES mobile examination centers. Briefly, the participant's right arm circumference was measured by a trained observer at the midpoint of the upper arm. The observer made a mark on the posterior surface of the arm indicating the mid-point where the measurement was taken, to the nearest 1 cm, using a steel measuring tape. The measuring tape had to fit snugly against the skin without indenting the skin [7].

The BC dimensions (adult, large adult, and extra-large adult) were used as the standard for cuffing. As Table 1 indicates, arm circumference cuffing parameters were not equal between BC and OC cuff sizes. For example, participants with a mid-arm circumference of 39 cm were cuffed with an extra-large BC and extra-large OC, although they should have been cuffed with a large OC. This difference in designated cuff sizes led to 17 study participants being assigned to a BC extra-large cuff rather than the OC designated large cuff and seven participants being assigned to a BC large cuff rather than an OC adult cuff.

Two additional points need to be brought up on mid-arm circumference cuffing dimensions. First, although we used the OC manufacturer-marked dimensions for mid-arm circumference to be cuffed in this study, this was not the case for the BC specifically. Since NHANES survey year 1999, the mid-arm circumference cuffing dimensions for the BC are calculated on the basis of the ~ 40% ratio of bladder width dimension to mid-arm circumference dimension in cm, as it was recommended by the AHA 1993 guidelines [8,9]. Second, a more recent study by Marks and Groch [10] suggested that a ratio of 46.4% of bladder width to mid-arm circumference is more appropriate for accurate systolic BP readings. As for accurate diastolic BP readings, the ratio needs to be wider than 55%, which is untenable [11].

After randomization, the cuffs were applied to both arms and two sets of BP measurements were obtained per participant. Performing the BP readings required participants to be seated in a chair with back support, both feet resting comfortably on the floor, and both forearms supported on a leveled surface at the heart level. Each set was separated by 5 min of rest and there was a 30 s rest interval between each measurement of systolic and diastolic BP.

Statistical analysis

All statistical analyses were carried out for systolic and diastolic BP separately using SAS software (SAS 9.3; SAS Institute Inc., Cary, North Carolina, USA). Statistical significance was set at P value less than 0.05.

Cuff-to-cuff comparison

Pearson correlation coefficients were calculated to examine the correlation between the BC and the OC readings for systolic BP and diastolic BP, respectively. Scatter plots overlaid by an identity line and a regression line were provided to assess the above correlation. In addition, BP values for each cuff by selected percentiles (1, 10, 25, 50, 75, 90, 95, and 99%) were compared.

Between-cuff differences

The average of six measurements using the BC and the average of six measurements using the OC were calculated for each participant. The difference (D) between the two cuffs was calculated as the BC reading minus the OC reading. A one-sample t-test was used to check whether there was a significant difference between the two cuffs, for example, the null hypothesis: $D = 0$.

In addition, Bland–Altman graphs (a graphical display of the differences of two-cuff readings (BC − OC) against the means of the two-cuff readings [(BC + OC)/2] were used to check whether there were any systematic differences between the two cuffs for both systolic and diastolic BP.

Results

The mean age of the study participants was 52 years (SD 17.7 years, range 18–82 years). Two-thirds of the sample were women. No statistically significant differences were found in the means of age and mid-arm circumference between the randomized groups (BC on the right arm first or BC on the left arm first). In addition, the percentage of men and women was the same between the randomized groups.

Cuff-to-cuff comparison results

Figures 1 and 2 show the scatter plots between the BC and the OC readings for systolic and diastolic BP, respectively, overlaid by an identity line and a regression line. The regression line was below the identity line for systolic BP, suggesting that BC overestimated the systolic BP compared with those obtained by OC. As for diastolic BP, besides four data points above 90 mmHg, there were no divergences between the identity and the regression lines. Finally, the correlations between the two cuffs were 0.98 for both systolic and diastolic BP ($P < 0.001$).

Table 2 describes the mean and SD of cuff bladder width to mid-arm circumference ratios for the entire sample by BC and OCs. For both cuffs, the ratios were within the acceptable parameters of 40–46.4% [9,10]. Overall, the mean between-cuff ratio difference (Baum – Omron ratio) was small, but significant. Similarly, there were significant differences in ratios for large adult and extra-large adult cuff categories.

Table 3 compares selected percentile values by cuff type. For systolic BP, the BC readings at the specified percentiles were higher than the OC readings, with the majority of the differences greater than 1 mmHg, except for the 50th percentile, which was 0.83 mmHg. For diastolic BP, the BC readings were close to the OC readings, with the majority of differences between the two cuffs less than 1 mmHg, except for the 10th and 99th percentiles, which were 1.83 and 3.5 mmHg, respectively.

Between-cuff differences

Table 4 compares the between-cuff differences (BC − OC). On average, the between-cuff difference was 2.66 mmHg (SD = 3.96 mmHg) for systolic BP ($P < 0.05$) and 0.33 mmHg (SD = 2.03 mmHg) for diastolic BP ($P > 0.05$). The between-cuff differences for systolic BP increased with cuff sizes [adult cuff: difference = 1.51 mmHg (SD = 4.26 mmHg); large adult cuff: difference = 2.56 mmHg (SD = 3.42 mmHg); and extra-large adult cuff: difference = 3.9 mmHg (SD = 3.89 mmHg); $P < 0.05$ for all]. As for diastolic BP, the between-cuff difference was statistically significant for adult cuff size [difference = 1.31 mmHg (SD = 1.34 mmHg)], but not for large adult and extra-large adult cuff sizes.

Figures 3 and 4 show graphic displays of the differences of the two-cuff readings (BC − OC) against the corresponding averages of the two-cuff readings [(BC + OC)/2] for systolic and diastolic measurements separately (Bland–Altman graphs). Both figures show some extreme values beyond 2 SDs, but no discernible linear relationship could be ascertained, suggesting that the between-cuff differences were not linearly related to the BP values. The Spearman correlation between the absolute difference and the mean was 0.1 for systolic BP and 0.06 for diastolic BP; both correlations were not statistically significant.

Finally, further analysis of the between-cuff difference showed that in 24 (24%) of the cases, there was a cuff mismatch because of cuff specific mid-arm circumference cut points. Seventy-eight individuals (76%) were correctly matched; the correctly matched cuff sizes' overall mean difference for systolic was 2.15 mmHg, SD = 4.0 ($P < 0.05$), and for diastolic 0.53 mmHg, SD = 2.0 (see Table 5 for more details).

Discussion

The BC and OC measurements were significantly correlated ($r = 0.98$ for both systolic and diastolic). Notwithstanding the high correlation, the results of the study suggest that the Omron HEM 907-XL machine using a cuff not supplied with the device may affect systolic and diastolic BP readings. Specifically, there were significant increases in systolic BP, which increased with larger cuff sizes. It appears that the greatest impact of using non-manufacturer-supplied cuffs on systolic BP occurs when using extra-large adult cuffs (mean difference = 3.9, SD = 3.89). During NHANES survey years 2007–2010, ~ 52.7% of all adult individuals aged 20 years required an adult cuff size; 42.9% required a large adult cuff size and 1.9% required an extra-large cuff size [12]. As for diastolic BP, significant differences were only observed when using an adult cuff size (mean difference = 1.31, SD = 1.34). Finally, Table 2 shows some significant differences in width/mid-arm circumference ratios between BC and OCs (overall, large adults, and extra-large adult cuffs). Accordingly, to rule out the assumption that the cuff-ratio differences accounted for between-cuff systolic and diastolic BP differences, we used regression analysis. The models included between-cuff differences for systolic and diastolic as outcome variables, the Baum minus Omron ratio differences as regressors, and cuff categories as a covariate. Adjusting for cuff categories, there was no significant association between-cuff ratio differences and between-cuff systolic and diastolic BP values (data not shown).

The implications of our findings may have a clinical impact. Indeed, a number of recent studies suggested that sphygmomanometer cuffs can transmit infectious pathogens among patients in a hospital/clinic setting [3,13]. For example, Zargaran *et al.* [13] swabbed 120 BP cuffs used in hospital and outpatient settings; 102 or 85% were positive for bacteria (mostly coagulase-negative species). Consequently, to reduce bacterial spread, numerous hospitals use non-manufacturer-provided disposable BP cuffs that may or may not conform to the device algorithm [14]. Finally, our study results suggest that this practice may result in erroneous systolic BP readings; however, it is not clear what the clinical implications of our results are as yet. Another implication for our finding is BP survey related. As automatic BP devices change and there is a need for continuation with legacy data, the impact of cuff differences should be considered in calibrating from the old to the new BP device.

This study is subject to a number of limitations. We focused on the impact of two specific cuffs (BC and OC) fitted on one specific device (Omron HEM 907-XL). It is unclear whether the same phenomenon would be observed with other manufacturer cuffs or models. Second, it is not clear if we re-did the study using the same design but with OC for both arms, what the results would be. In other words, the assumption is that the study design overcame the physiological phenomenon and results are related to different cuffs used; this may not be the case [4–6]. Also, we measured the mid-arm circumference of the right arm. There is a chance that the left mid-arm circumference may be larger or smaller than the right mid-arm circumference and may contribute toward the cuff difference. Third, as much as we attempted to apply the cuffs in a standardized manner, upper arm anatomy is not the same for every individual. It is sometimes short, cylinder shaped, or conical shaped, just to name a few anatomical differences. Fourth, the majority of the sample were women; although equally distributed between the two randomization groups, the effect on generalizability is not clear. However, a previous study suggested that after adjusting for all covariates, only BMI was significantly associated with BP cuff sizes [8]. Fifth, the study design resulted in 24% mismatched cuffs, overall, and 50% mismatched with the extra-large cuffs. Ideally, the study should have been powered for between specific cuff comparisons. Nonetheless, 78 individuals were correctly matched and the correctly matched cuff sizes' overall mean difference was 2.15 mmHg, SD = 4.0 ($P < 0.05$) for systolic and 0.53 mmHg, SD =2.0 for diastolic.

Conclusion

This study examined a simple question: what happens when a 'different' cuff rather than a manufacturer-suggested cuff is used? This study used a convenience sample. Therefore, the results of this study should not be used to adjust the results of the aforementioned 2009–2010 NHANES methodology study, which was a population-based study selected in accordance with the NHANES criteria.

The results of our limited study indicate that the BCs were not interchangeable with the OCs, especially for extra-large cuff, when measuring systolic BP. BP cuffs as related to the Omron HEM 907-XL are an integral part of the device. More studies are needed to examine other devices.

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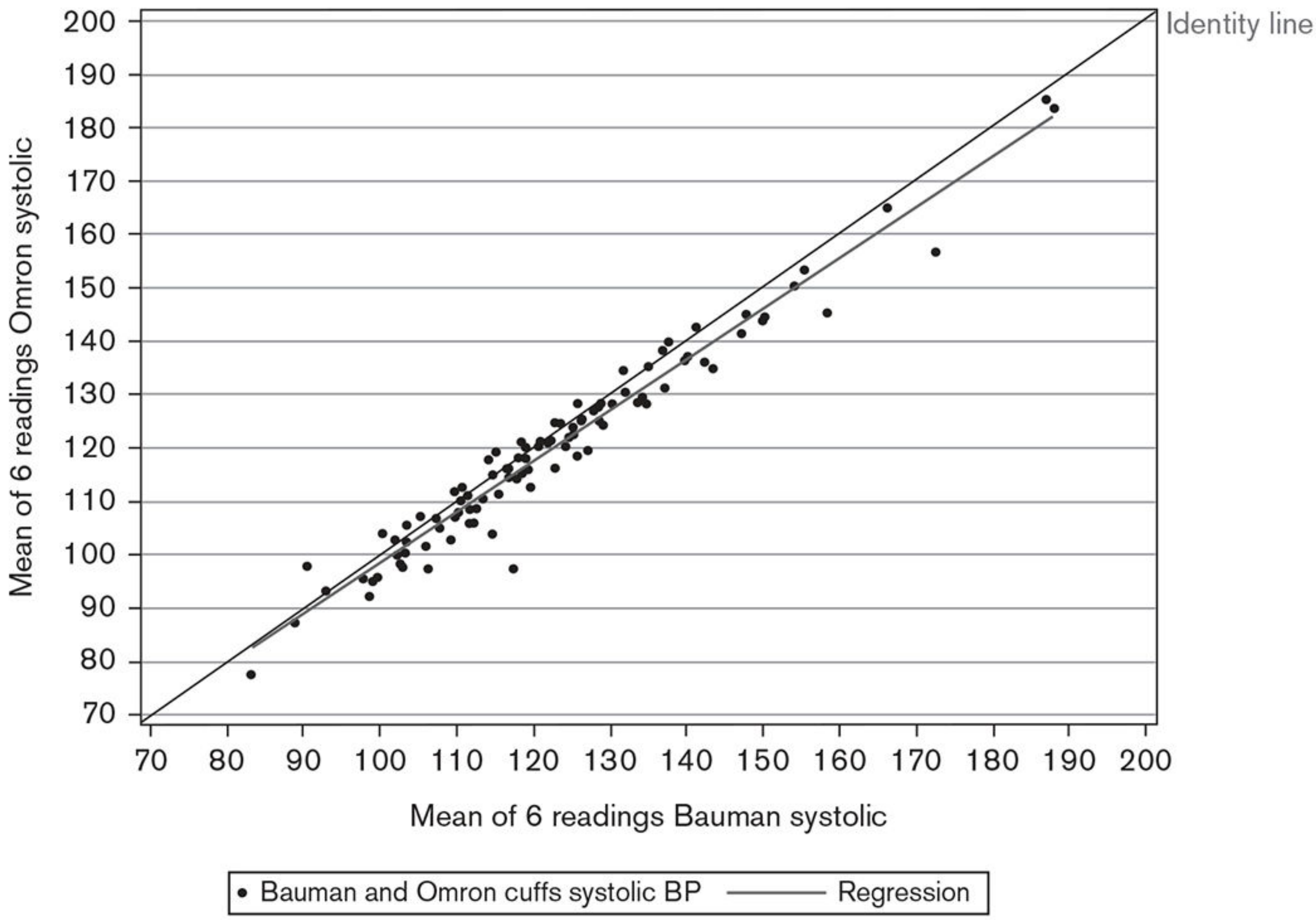

Fig. 1.
Between cuffs correlation scatter plot overlaid with an identity line and a regression line (systolic). BP, blood pressure.

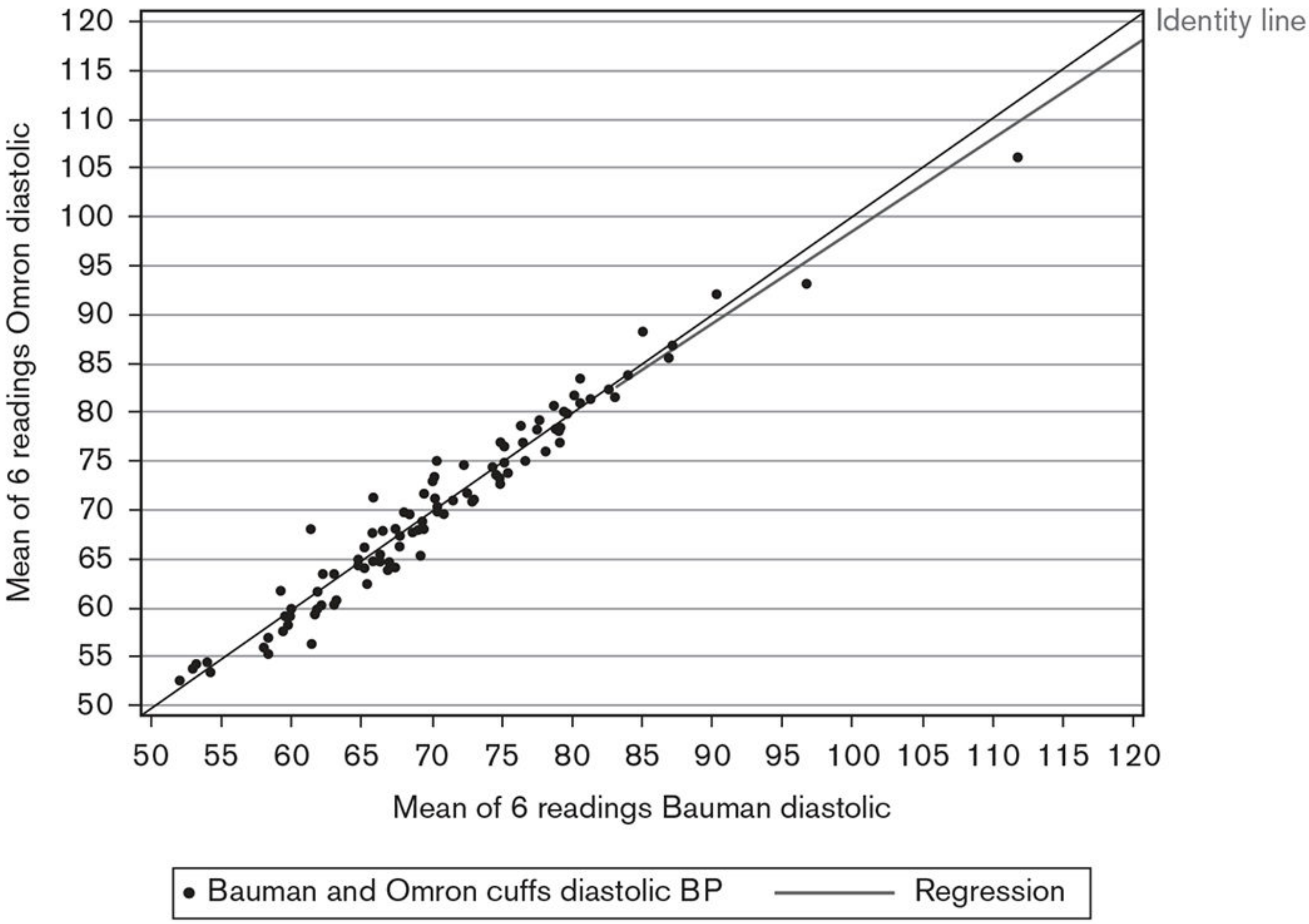

Fig. 2.

Between cuffs correlation scatter plot overlaid with an identity line and a regression line (diastolic). BP, blood pressure.

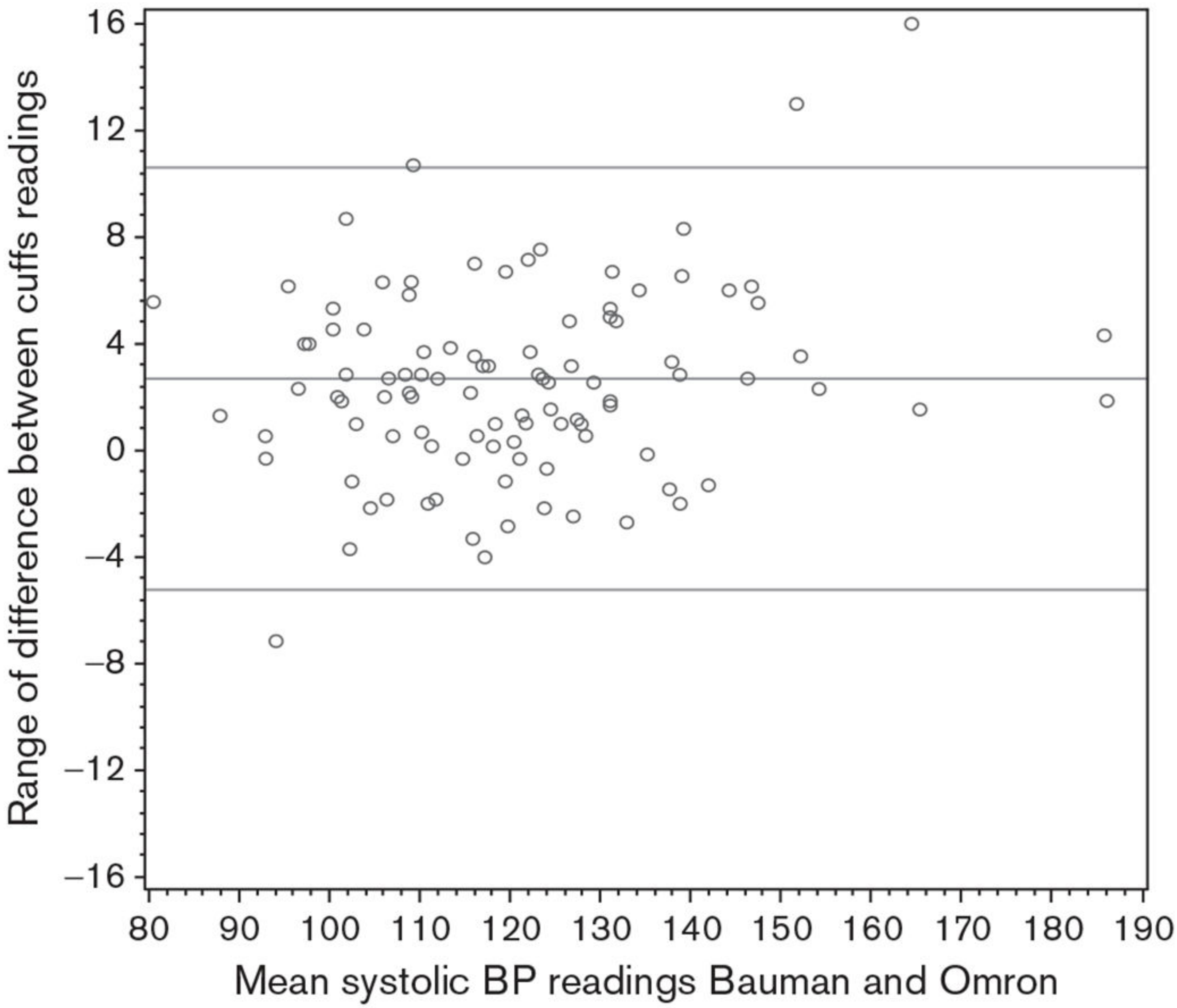

Fig. 3.
Bland–Altman graph Bauman versus Omron cuffs (systolic). BP, blood pressure.

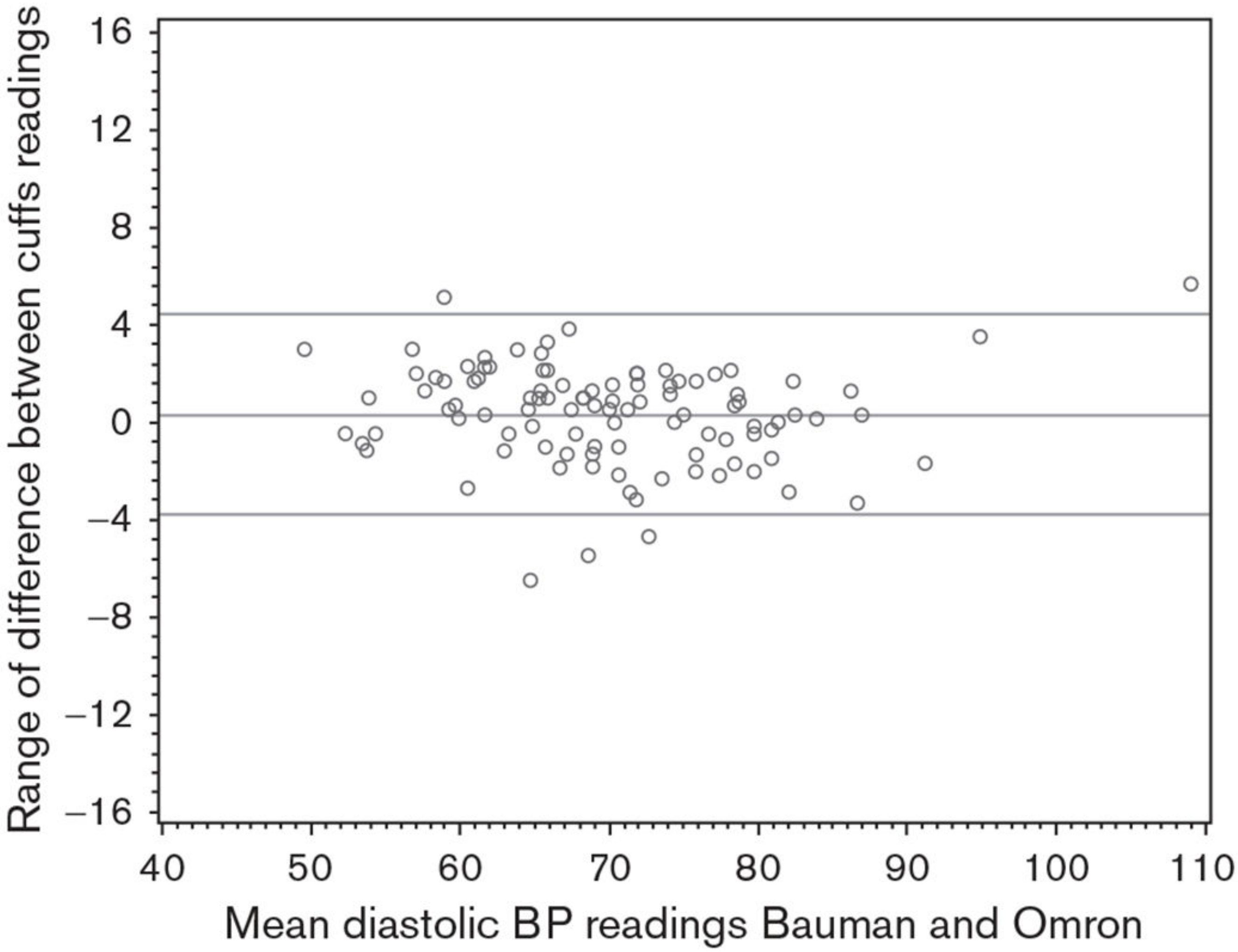

Fig. 4.

Bland–Altman graph Bauman versus Omron cuffs (diastolic). BP, blood pressure.

Table 1

Bauman and Omron 907 cuff dimensions and arm circumference parameters by cuff size

	Arm circumference parameters (cm)		Bladder width by length (cm)	
Cuff sizes	**Baum cuffs**	**Omron cuffs**	**Baum cuffs**	**Omron cuffs**
Adult	22.0–30.0	22.0–32.0	12 × 23	12.5 × 23.5
Large adult	30.0–38.0	32.0–42.0	15 × 33	15 × 31
Extra-large adult	38.0–48.0	42.0–50.0	18 × 36	18 × 38

Table 2

Mean and SD for cuff width to mid-arm circumference ratios in percentages and by cuff type

	Sample	Baum cuff [mean (SD)]	Omron cuff [mean (SD)]	Baum – Omron [difference (SD)]
Overall	102	0.44 (0.03)	0.42 (0.04)	0.02 (0.04)[†]
Cuff size				
Adult	34	0.44 (0.03)	0.44 (0.03)	0
Large adult	34	0.45 (0.03)	0.43 (0.03)	0.02 (0.04)[†]
Extra-large adult	34	0.43 (0.03)	0.39 (0.02)	0.04 (0.04)[†]

[†] $P < 0.05$.

Table 3

Mean BP values across selected percentiles by cuff type and the differences of the BP values at the corresponding percentiles

	Mean	1%	5%	10%	25%	50%	75%	90%	95%	99%
Systolic										
Bauman	121.97	88.66	97.83	101.83	109.83	119.08	132.00	147.33	155.33	187.00
Omron	119.31	87.33	95.16	97.66	105.83	118.25	128.50	142.66	150.50	183.66
Difference	2.66	1.33	2.67	4.17	4.00	0.83	3.50	4.67	4.83	3.34
Diastolic										
Bauman	70.17	52.00	54.33	59.33	63.17	69.25	76.33	80.66	85.00	96.66
Omron	69.83	52.50	54.50	57.50	63.50	69.50	76.50	81.50	85.50	93.16
Difference	0.34	−0.50	−0.17	1.83	−0.33	−0.25	−0.17	−0.84	−0.50	3.50

BP, blood pressure.

Table 4

Means and SD of between cuffs differences (Bauman cuffs – Omron cuffs)

	n	Systolic BP [difference (SD)] (mmHg)	Diastolic BP [difference (SD)] (mmHg)
Overall	102	2.66 (3.96)[†]	0.33 (2.03)
By cuff sizes			
Adult	34	1.51 (4.26)[†]	1.31 (1.34)[†]
Large adult	34	2.56 (3.42)[†]	0.14 (1.47)
Extra-large adult	34	3.9 (3.89)[†]	−0.46 (2.65)

BP, blood pressure.

[†] $P < 0.05$.

Table 5

Means and SD of between cuffs differences (Bauman cuffs – Omron cuffs) when correctly matched cuffs sizes

	n	Systolic BP [difference (SD)] (mmHg)	Diastolic BP [difference (SD)] (mmHg)
Overall	78	2.15 (4.0)[†]	0.53 (2.0)
Cuff sizes			
Adult	34	1.52 (4.26)[†]	1.32 (1.35)[†]
Large adult	27	2.8 (3.6)[†]	0.18 (1.55)
Extra-large adult	17	2.4 (4.34)[†]	−0.50 (2.91)

BP, blood pressure.

[†] $P < 0.05$.