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ORIGINAL ARTICLE

Calibration mode influences central blood pressure differences between SphygmoCor and two newer devices, the Arteriograph and Omron HEM-9000

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The objective of this study was to compare central systolic blood pressure (cSBP) and augmentation index (AIx) from two recently introduced devices, Omron HEM-9000 (OM) and Arteriograph (AG), not using a transfer function with those of the widely used SphygmoCor (SC) calibrated on brachial blood pressure like OM. Random-order manufacturer-recommended measurements using SC and OM by radial tonometry and AG were taken on the left arm in 35 men (54 ± 10 years) after 5 min supine rest. Results are means (95% confidence interval) of differences using paired *t*-tests. cSBP by OM was 4.1 (1.0–7.1) mm Hg higher than by AG. Both OM and AG estimated the mean cSBP to be significantly higher than did SC (114.8 mm Hg) by 12.5 (10.3–14.7) and 8.6 (4.9–12.3) mm Hg, respectively, although closely correlating with SC (r=0.9). Calibrating SC with diastolic blood pressure (DBP) and more accurate mean arterial pressure (as DBP+0.4×PP) resulted in significantly higher cSBP statistically not different from AG's cSBP: 0.9 (−1.1 to +2.9)mm Hg, and closer to OM's: 5.1 (3.4–6.8)mm Hg. Radial AIx from SC and OM disagreed by 3 (0.7–5.4)%, and correlated (r=0.8) with AG's brachial AIx. AG's aortic AIx was 7.9 (5.7–10.2)% higher than SC's, but closely correlated (r=0.9). Clinically significant, higher cSBP measured by AG, OM and more accurately calibrated SC adds to previous data suggesting that SC measurements by classic calibration underestimate cSBP. Invasive studies involving all three devices would be more illuminating.
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INTRODUCTION

Central blood pressure (cSBP) and indices of wave reflections have become relevant to cardiovascular risk stratification and hypertension management. The primary organs targeted by hypertensive damage (heart, brain and kidneys) may be exposed more closely to aortic blood pressure (BP) and pulsations rather than that estimated by traditionally measured brachial pressures.[1] Moreover, antihypertensive medications may affect central and peripheral pressures differently[2] which could influence drug efficacy and risk reduction.[3] Our previous data from the CAFE study suggested that one drug class and combination produced greater central but not peripheral BP change based on SphygmoCor (SC).[2]

There are still few large cohort studies comparing the prospective value of central versus peripheral (brachial) pressures, but a number of small to medium size studies have demonstrated the value of invasively measured central systolic and pulsating pressures prospectively.[4] Large trials demand quick non-invasive measurement of central pressures.

In the past decade, the SC device has provided a commercial scale non-invasive method for estimation of central pressures and reflection waves. It uses a generalized transfer function (GTF) to estimate the aortic pressure waveform from the radial pulse waveform recorded by a tonometry probe calibrated against non-invasively measured brachial pressures. The GTF has been derived and tested in several invasive studies using 'invasive' calibration of radial waveform.[5–9] However, there is still controversy over accuracy of the typical outpatient SC measurements using 'non-invasive' calibration with brachial pressures, and in different patient populations.[4,10–14]

Recently, two other non-invasive devices that do not use a transfer function have been introduced for cSBP and wave reflection measurement, the Omron HEM-9000 (OM) (Omron Healthcare, Kyoto, Japan) and Arteriograph (AG) (TensioMed, Budapest, Hungary). The aim of this study was to compare the cSBP and reflection wave indices from the two newly introduced devices with that of SC, and between themselves.

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METHODS

Devices

The SC (AtCor Medical, Sydney, Australia) uses a tonometry probe manually applied by a trained user on the radial artery pulse on the wrist. It records the pulse waveform, which is calibrated against upper arm cuff BPs. A GTF is then applied to the radial waveform to derive that in the aorta and calculate cSBP.

The OM uses an automatic tonometry probe wrapped onto the wrist to record radial waveforms, which are then calibrated against the contralateral brachial BP measured by an arm cuff immediately after tonometry. It then applies an algorithm based on a linear regression model to estimate cSBP from the 'late systolic shoulder' ($pSBP_2$) of the radial pulse waveform, which has been shown to agree closely with cSBP.[15,16] The device uses the maxima of the 'multidimensional derivatives' on the recorded pressure waveforms to detect first and second inflection points corresponding to early and late systolic ($pSBP_2$) pressures.[15,17]

The AG records the brachial pressure waveform using an oscillometric method after occluding the brachial flow by inflating an arm cuff to about 35 mm Hg above the systolic pressure without any calibration. The device estimates cSBP from a commercial algorithm based on the correlation between the $pSBP_2$ on uncalibrated brachial waveforms and aortic systolic pressures derived from the inventors' invasive studies.[18] The AG's algorithm for brachial BP measurement was shown to meet the accuracy criteria from BHS and AAMI.[19]

Each device measures some indices of wave reflection, mainly augmentation index (AIx) peripherally and/or centrally. Peripherally, SC and OM both measure radial AIx (rdAIx) on calibrated radial waveforms while the AG measures brachial AIx (brAIx) from uncalibrated brachial waveform. Centrally, SC estimates aortic AIx (aoAIx) from the values on the aortic waveform derived by its transfer function, but AG calculates aoAIx from its relationship with brAIx by its commercial algorithm. OM does not give central AIx values.

OM and SC both calculate their peripheral AIx as $(P_2-DBP)/(P_1-DBP)$, taking P_1 and P_2 as the first and second inflection points on the radial pulse waveform. However, calculation of aoAIx in both SC and AG and that of the brAIx in AG is performed using $(P_2–P_1)/PP$.

Participants and protocol

The participants were 35 men, 40–80 years of age, who had already been recruited to the European Male Ageing Study in Manchester, UK. The participants were free of active liver and kidney disease or malignancy.

All measurements were done in the morning. Participants were advised to avoid caffeine-containing beverages and tobacco 3 h before their visit, and alcohol from the night before. In accordance with a standard protocol, sitting BP was measured using a standard Omron automatic device on the left upper arm, three times after 5 min of rest in a temperature-controlled room. The values from the last two readings were averaged. Afterward, the three device measurements were performed supine in random order on each participant using computer-generated random allocation. The participants were asked to remain still, relaxed and silent during all measurements.

A trained single observer conducted standard SC radial tonometry on the left wrist, with BP calibrated by average systolic and diastolic BPs from two supine measurements made by an automatic Omron BP measurement device on the left arm immediately before the procedure. Three quality measurements were selected and averaged (SCOR-2000 software, version 7.1, AtCor Medical, Sydney, Australia). The AG cuff was tightly wrapped around the left arm. Only quality measurements were filtered and averaged for each participant (TensioClinic software version 1.10.0.0, TensioMed, Budapest, Hungary). OM measurement was conducted with the tonometry probe fastened on the left wrist and the BP cuff on the right arm in order not to interfere with the tonometer measurements on the same side, as recommended by the manufacturer.

Comparisons and statistical analysis

cSBPs from the three devices were compared two by two. OM's rdAIx and AG's aoAIx were compared with their SC counterparts, respectively. OM's $pSBP_2$ was also compared with cSBP from SC. Comparisons were repeated after cross-calibrating SC by three methods using three sets of brachial BPs from AG and OM. Method 1 used systolic blood pressure (SBP) and diastolic blood pressure (DBP), method 2, DBP and mean arterial pressure (MAP) calculated by the classic formula: DBP + (PP/3), and method 3, DBP and MAP by a newer formula: DBP + (0.4×PP) derived by Bos *et al.*[20] comparing non-invasive and invasive brachial BPs. This has been recommended as a more accurate estimate of brachial MAP.[21,22]

SPSS 16 was used for statistical analysis. Paired *t*-tests were used to obtain mean differences (95% confidence interval), Bland–Altman plots (that is, mean ± 2s.d. of difference) for agreement, with Pearson's *r* for correlation between the device measurements. *P*-values <0.05 were considered significant.

RESULTS

The general characteristics of the participants are shown in Table 1. Three patients used statins, one of whom also took antihypertensive medications. Three subjects had known type 2 diabetes.

cSBP comparisons

Both the new devices estimated cSBP significantly higher than did SC before and after cross-calibration by methods 1 and 2 (Tables 2 and 3). The Bland–Altman plots revealed that cSBP did not agree across the three devices (Figures 1a and b, and 2c), with more discrepancy at higher pressures. OM's $pSBP_2$ agreed with SC's (Figure 2d) but was significantly lower than AG's and OM's cSBP estimations (Table 3).

The calibration methods 1 and 2 did not significantly change the cSBP difference between SC and the two other devices, but narrowed limits of agreement and improved correlations (Tables 2 and 3; Bland–Altman plots in Supplementary Information, Figures A and B). However, calibration method 3 resulted in significantly higher cSBP with SC, statistically no longer different ($P=0.37$) from AG's cSBP (that is, near agreement; SD difference: 6 mm Hg) and closer to OM ($P<0.001$) (Tables 2 and 3, Figures 1c and d). This also increased the $pSBP_2$ difference between SC and Omron (Table 3).

The difference between the two new devices' cSBP and that of SC tended to increase with the average across-device cSBP (Figures 1a and b). In regression models including age, height, heart rate (HR) and MAP, the cSBP difference between original readings of SC and AG was independently associated with HR, MAP and height, and that between SC and Omron, with height and HR. The difference between AG and Omron decreased with average cSBP, and was related to younger age and higher MAP (Supplementary Information, Table A).

No significant differences (mean (95% confidence interval)) were found between the standard arm SBP measurements by the AG and OM (−0.3 (−3.2 to +2.6) mm Hg) or the standard Omron sphygmomanometer used to calibrate SC (0.7 (−2.1 to +3.6) mm Hg). The two Omron devices' SBP difference (1 (−0.8 to +2.8) mm Hg) was also not significant.

AIx comparisons

OM's and SC's rdAIx disagreed (Figure 2a) but were closely correlated (Table 3). AG's aoAIx was significantly lower than but closely

Table 1 General characteristics of the participating men ($n=35$)

	Mean ± s.d.	*Min–max*
Age (years)	54 ± 10	41–76
Weight (kg)	81 ± 11	53–103
Height (cm)	173 ± 6	163–184
BMI ($kg\,m^{-2}$)	27 ± 3	19–34
SBP[a] (mm Hg)	122 ± 17	99–172
DBP (mm Hg)	79 ± 10	64–99
HR (b.p.m.)	61 ± 9	44–83

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; HR, heart rate; SBP, systolic blood pressure.
[a]Measured in sitting position.

Table 2 Mean ± s.d. of the measurements by the three devices and SphygmoCor's estimates after cross calibration by three methods

			SphygmoCor			
				Calibrated by[a]		
mm Hg or %	*Omron HEM-9000*	*Arteriograph*	*Original*	*Method 1*	*Method 2*	*Method 3*
cSBP	127.3 ± 16	123.5 ± 20	114.8 ± 13	115.5 ± 17	115.3 ± 17	122.6 ± 17
$pSBP_2$	112.1 ± 15	NA	NA	NA	NA	NA
SBP	126.2 ± 14	125.9 ± 18	125.2 ± 14[b]	NA	NA	NA
aoAIx (%)	NA	30 ± 13	22 ± 9	22 ± 9	22 ± 9	22 ± 9
rdAIx (%)	73 ± 11	NA	76 ± 13	76 ± 13	76 ± 13	76 ± 13
brAIx (%)	NA	−15 ± 25	NA	NA	NA	NA

Abbreviations: aoAIx, aortic augmentation index; brAIx, brachial augmentation index; cSBP, central systolic blood pressure; NA, not applicable; $pSBP_2$, late systolic shoulder on the radial pulse pressure waveform; rdAIx, radial augmentation index.
[a]Cross calibrated with Arteriograph's brachial blood pressure (BPs). See text for Methods 1–3. Using Omron HEM-9000's brachial BPs gave similar results.
[b]Measured by a standard Omron oscillometric sphygmomanometer.

Table 3 Comparison of central blood pressures and augmentation index between SphygmoCor and Omron HEM-9000 or Arteriograph before/after cross-calibrating 'SphygmoCor' with different sets of brachial pressures from Arteriograph and Omron HEM-9000

			After SC cross-calibration by					
	Original comparisons		*Method (1) SBP/DBP*		*Method (2) MAP*[a]*/DBP*		*Method (3) MAP*[b]*/DBP*	
mm Hg or %	*Mean diff. (CI)*	r	*Mean diff. (CI)*	r	*Mean diff. (CI)*	r	*Mean diff. (CI)*	r
cSBP OM–SC	12.5 (10.3 to 14.7)[c]	0.91	12.4 (11.2 to 13.6)[c]	0.98	12.7 (11.1 to 14.3)[c]	0.96	5.1 (3.4 to 6.8)[c]	0.95
cSBP AG–SC	8.6 (4.9 to 12.3)[c]	0.88	8.0 (6.5 to 9.4)[c]	0.99	8.1 (6.2 to 10.1)[c]	0.98	0.9 (−1.1 to 2.9)	0.97
cSBP OM–AG	4.1 (1.0 to 7.1)[c]	0.91	NA	NA	NA	NA	NA	NA
cSBP SC–$pSBP_2$ OM	2.0 (−0.1 to 4.1)	0.91	2.1 (1.0 to 3.2)[c]	0.98	1.9 (0.5 to 3.3)[c]	0.96	9.4 (7.8 to 11.0)[c]	0.95
rdAIx OM–SC (%)	−3.0 (−5.4 to −0.7)[c]	0.84	−2.5 (−4.9 to −0.03)[c]	0.84	−2.9 (−5.2 to −0.5)[c]	0.85	−2.9 (−5.2 to −0.5)[c]	0.85
aoAIx AG–SC (%)	7.9 (5.7 to 10.2)[c]	0.86	7.9 (5.7 to 10.2)[c]	0.86	7.9 (5.7 to 10.2)[c]	0.86	7.9 (5.7 to 10.2)[c]	0.86

Abbreviations: aoAIx, aortic augmentation index; AG, Arteriograph; cSBP, central systolic blood pressure; mean diff. (CI), mean difference (95% CI); OM, Omron HEM-9000; $pSBP_2$, late systolic shoulder on the radial pulse pressure waveform; rdAIx, radial augmentation index; SC, SphygmoCor.
All Pearson's *r* correlations are significant.
[a]MAP calculated by classic formula: DBP + (PP/3).
[b]MAP calculated by newer formula: DBP + (0.40 × PP).
[c]Significant *P*-values.

correlated with SC's aoAIx (Table 3). The difference between the aoAIx by AG and SC seemed to increase with the average cross-device values (Figure 2b).

The AG's brAIx correlated with SC's rdAIx (r=0.84, $P<0.001$) and OM's rdAIx (r=0.75, $P<0.001$). SC's aoAIx correlated with HEM-9000's rdAIx (r=0.87, $P<0.001$) and AG's brAIx (r=0.86, $P<0.001$).

A unified overview of all AIx values across the three devices using a single AIx calculation formula $(P_2–P_1)/PP$ is illustrated in Figure 3. The values are shown from central to peripheral measurement sites. As expected, an ascending gradient exists with the most negative AIx values at the radial artery, slightly less negative at the brachial artery and positive values estimated for the aorta.

None of the cross-calibration methods above significantly changed AIx differences between SC and the newer devices (Tables 2 and 3).

DISCUSSION

To our knowledge, this is the first study comparing cSBP and augmentation indices by the three devices at one time. None of the published studies comparing SC and AG[23–25] reported a comparison of central pressures. Providing uniformly calculated AIx values across devices, and comparing the results using different calibration approaches with SC are strong points of this study.

cSBP

Both the newer devices estimated cSBP significantly higher than did SC, calibrated by methods 1 and 2. Richardson *et al.* similarly found higher cSBP (12.2 ± 4.6 mm Hg) by OM than SC in younger subjects.[26] The key question is whether SC is underestimating or the new devices are overestimating cSBP. Several invasive studies tested SC's GTF for cSBP estimation from radial pressure waveforms.[5–9] However, they calibrated radial waveforms by 'invasive' central DBP and MAP and not oscillometric arm pressures, which is how SC measurements are done in practice. Later, other invasive studies consistently showed that cSBP estimated by a GTF with 'non-invasively' calibrated radial waveforms significantly underestimated invasively measured cSBP[10–12] with the mean difference being 11–13 mm Hg in two studies,[10,27] 7–8 mm Hg in three[11,28,29] and 1.5–4.2 mm Hg in two reports.[13,14] The s.d. of the difference ranged 7–15 mm Hg in these studies unacceptable by BHS or AAMI criteria.

Two explanations have been suggested for such discrepancies. First, oscillometric brachial cuff methods are prone to error especially for DBP.[13,30] Second, real radial pressures are generally higher than brachial due to the amplification phenomenon.[21,22] Calibrating radial waveforms using brachial BPs is therefore a source of pressure underestimation. Such pressure errors can be 'transferred' by the

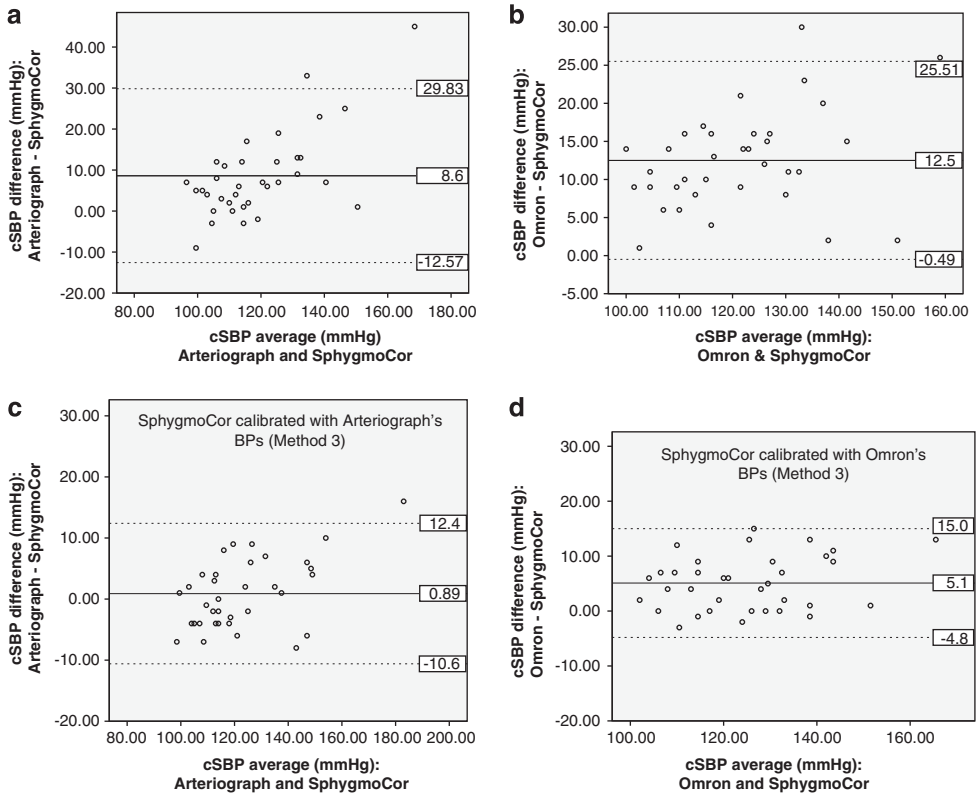

Figure 1 Bland–Altman plots testing cSBP agreement between SphygmoCor and Arteriograph or Omron HEM-9000. (**a**, **b**) Original comparisons. (**c**, **d**) After cross-calibrating by more accurate estimates of brachial BPs (method 3). Dashed lines show limits of agreement. BP, blood pressure; cSBP, central systolic blood pressure.

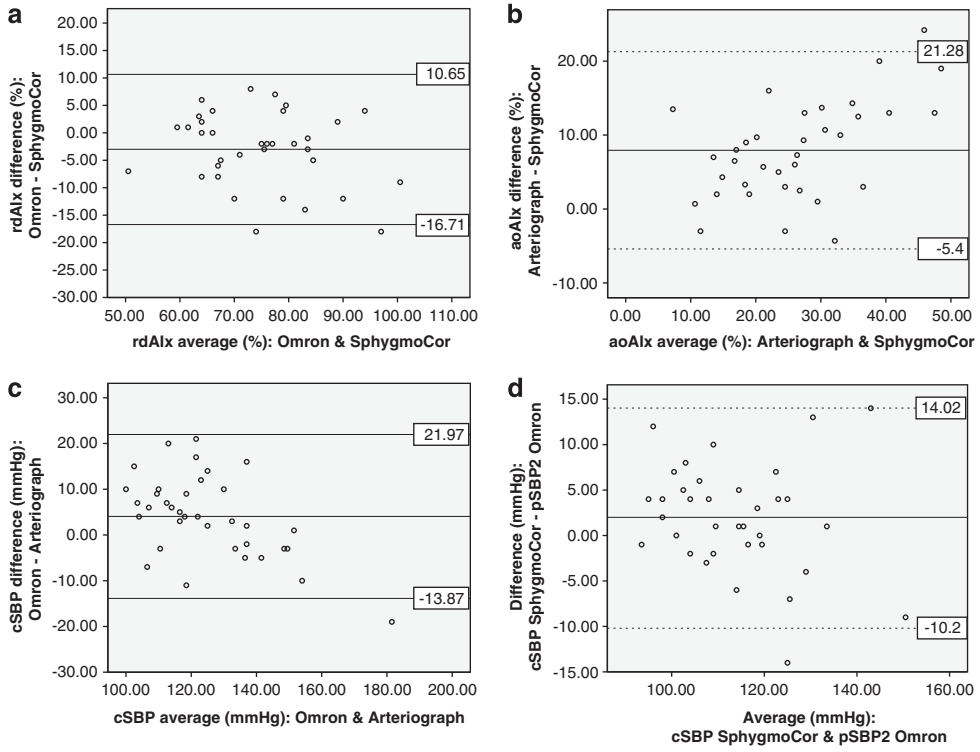

Figure 2 Bland–Altman plots. (**a**) rdAIx: Omron HEM-9000 and SphygmoCor. (**b**) aoAIx: Arteriograph and SphygmoCor. (**c**) cSBP: Arteriograph and HEM-9000. (**d**) SphygmoCor's cSBP and HEM-9000's $pSBP_2$. aoAIx, aortic augmentation index; cSBP, central systolic blood pressure; $pSBP_2$, late systolic shoulder on the radial pulse pressure waveform; rdAIx, radial augmentation index.

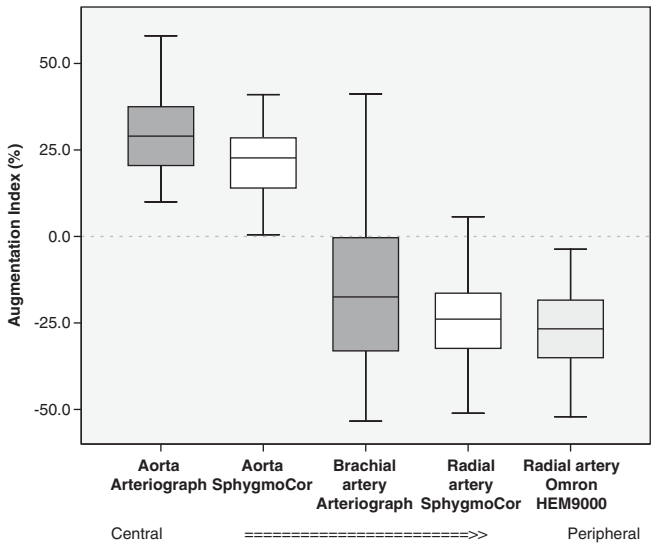

Figure 3 A box-plot comparison of central and peripheral augmentation index (AIx) values measured by Arteriograph (dark gray), SphygmoCor (white) and Omron HEM-9000 (light gray), all calculated by a unified formula (P2–P1/PP). Whiskers are ranges; heavy horizontal line represents the median and box borders are 25th and 75th percentiles.

transfer function to cSBP estimates.[5,31] In line with the first explanation, our results show that when more accurate estimates of peripheral pressures are used to calibrate SC (that is, method 3),[20–22] the cSBP estimates are significantly higher, and less or not different from the two newer devices. Given the evidence on SC's traditional calibration, the relatively higher cSBPs by the two new devices and that from SC calibrated here by method 3 are likely to be closer to real. However, invasive studies simultaneously including all three devices can further elucidate this matter.

There are serious consequences in clinical practice and scientific data of these results. At least three important studies in the Consensus document[1] used SC, and the data here suggest that re-analysis is appropriate of previous SC data recalibrated with recently recommended, more accurate brachial BP estimates.[20–22]

In contrast with SC, initial invasive studies that gave rise to the newer devices and their standard outpatient measurements both estimate cSBP from non-invasively calibrated radial (OM),[15] or uncalibrated brachial (AG)[18] pressure waveforms. Including such errors at the initial development stage could make their measurement less vulnerable, but not immune to oscillometric inaccuracies.

The higher cSBP estimations by the newer devices and the alternatively calibrated SC by method 3 seem closer to peripheral pressures, and so may be questioned considering the concept of central to peripheral pressure 'amplification'.[8,21] In our data, AG cSBP was 2.5 (0.3–4.7) mm Hg lower (P=0.03) than, and OM cSBP statistically not different from, arm SBP (mean difference: 1.14 (−1.1 to 3.3), P=0.31) (Table 2). cSBP not statistically different from arm pressures have been previously reported with OM[26] and two invasive studies.[11,29] In contrast, direct invasive measurements along central–radial arterial path found significant amplification at the peripheral sites.[8,21] Two points need attention. First, less amplification is expected among older subjects with stiffer arteries, usually comprising a majority of cases in device validation/comparison studies (including ours). Second, it may be inappropriate to judge amplification by comparing invasive cSBP and (subtracting from) error-prone oscillometric brachial SBP. Comparing the newer device's cSBP with invasively measured peripheral pressures, or those calibrated by invasive DBP and MAP, may be more valuable.

Other issues merit attention. The occlusion of the brachial artery by the AG will create additional wave reflections. To what extent this could alter the recorded waveforms or central pressures has not been investigated. OM and AG's cSBP estimation algorithms depend on $pSBP_2$, which itself might not be an accurate surrogate of cSBP in lower cSBP ranges.[32]

The 4.1 mm Hg difference between cSBP estimations of the AG and OM may reflect the differences in the invasive studies producing their algorithms (that is, use of peripheral waveforms in different sites) and Omron's dependence on calibration by contralateral brachial BPs compared with AG's direct recording of pressure waveforms.

Augmentation index

Unlike cSBP where absolute values are important, ranking of AIx or its relative change appears more important. In practice, using the new devices for AIx measurement seems as useful and less complex considering high inter-device correlation, which is still not the same as agreement.

Though HR is an important determinant of AIx, we did not use HR-adjusted AIx values from Omron and SC because AG does not adjust for HR. However, average HR was not statistically different across the three devices (mean differences: SC–AG: −0.1 (r=0.94), SC–OM: 0.7 (r=0.96), OM–AG: −0.8 (r=0.95), P=NS for all).

Here, the rdAIx by OM was 3% higher than but closely correlated with SC's rdAIx. Richardson *et al.* found no statistical difference between rdAIx values for the two devices and similar correlations to ours.[26] These suggest that rdAIx by SC and OM might be used interchangeably with care. However, it is unclear what extent of AIx difference would be of clinical or practical significance.

SC's lower aoAIx than AG (by 7.9 ± 6.7%) may be due to the differences in cSBP estimation although previous invasive studies showed that a GTF could underestimate invasively measured aoAIx by 7 ± 9%[5] and 6 ± 20%.[33]

The close correlations between central and peripheral AIx values across devices (for example, SC's aoAIx and AG's brAIx) found here and previously[23,24] suggest that directly measured peripheral AIx values might be preferred over the 'estimated' central one.[15,34]

Uniform calculation of AIx across devices as performed here is recommended for future reports. The AG reports peripheral (brAIx) and central (aoAIx) using P_2–P_1/PP. SC uses the same formula for aoAIx, but not for rdAIx, calculated by (P_2−DBP)/(P_1−DBP), as in the Omron. Uniform calculation is possible using P_2–P_1/PP, as P_1 and P_2 are available in the devices' outputs. The results range from negative values in peripheral to predominantly positive values in central sites (Figure 3).

Limitations of this study include few younger and no female participants. As always, a wider range of other variables (for example, BP, HR, and so on) might have been useful but the ranges used here were similar to usual practice.

Conclusions

When traditionally calibrated by less-accurate brachial BPs, SC estimated cSBP significantly lower than two newer devices. Using more accurate estimates of brachial BPs to calibrate SC removed or significantly reduced the between-machine differences. Invasive studies including all the three devices and over a wide range of blood pressures will further clarify this issue.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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