Validation Study to Determine the Accuracy of Central Blood Pressure Measurement Using the Sphygmocor Xcel Cuff Device

Martin G. Schultz,* Dean S. Picone,* Matthew K. Armstrong, J. Andrew Black, Nathan Dwyer, Philip Roberts-Thomson, James E. Sharman

Abstract—Numerous devices purport to measure central (aortic) blood pressure (BP) as distinct from conventional brachial BP. This validation study aimed to determine the accuracy of the Sphygmocor Xcel cuff device (AtCor Medical, CardieX, Sydney, Australia) for measuring central BP. 296 patients (mean age 61±12 years) undergoing coronary angiography had simultaneous measurement of invasive central BP and noninvasive cuff-derived central BP using the Xcel cuff device (total n=558 individual comparisons). A subsample (n=151) also had invasive brachial BP measured. Methods were undertaken according to the Artery Society recommendations, and several calibration techniques to derive central systolic BP (SBP) were examined. Minimum acceptable error was ≤5±≤8 mm Hg. Central SBP was significantly underestimated, and with wide variability, when using the default calibration of brachial-cuff SBP and diastolic BP (DBP; mean difference±SD, −7.7±11.0 mm Hg). Similar variability was observed using other calibration methods (cuff 33% form-factor mean arterial pressure and DBP, −4.4±11.5 mm Hg; cuff 40% form-factor mean arterial pressure and DBP, 4.7±11.9 mm Hg; cuff oscillometric mean arterial pressure and DBP, −18.2±12.1 mm Hg). Only calibration with invasive central integrated mean arterial pressure and DBP was within minimal acceptable error (3.3±7.5 mm Hg). The difference between brachial-cuff SBP and invasive central SBP was 3.3±10.7 mm Hg. A subsample analysis to determine the accuracy of central-to-brachial SBP amplification showed this to be overestimated by the Xcel cuff device (mean difference 4.3±9.1 mm Hg, *P*=0.02). Irrespective of cuff calibration technique, the Sphygmocor Xcel cuff device does not meet the Artery Society accuracy criteria for noninvasive measurement of central BP. **(*Hypertension*. 2020;76:244-250. DOI: 10.1161/HYPERTENSIONAHA.120.14916.)** • **Data Supplement**

Key Words: angiography ■ aorta ■ arterial pressure ■ blood pressure ■ hypertension

Blood pressure (BP) is conventionally measured at the upper arm over the brachial artery. However, it is well understood that systolic BP (SBP) undergoes variable amplification from the central aorta to the large arteries of the upper arm, such that brachial SBP may not be the same as aortic SBP.[1] Theoretically, BP assessed at the level of the aorta should hold greater clinical relevance than brachial BP, given its proximity to the vital organs such as the heart, brain, and kidneys. Thus, numerous BP devices have been developed that purport to estimate a central (aortic) BP as distinct from brachial BP.[2,3] Many of these devices are similar in appearance and operation to conventional automated cuff devices but also record the brachial artery waveform. The brachial waveform is then calibrated and transmuted via proprietary algorithms to estimate a central BP waveform.

In past years, the protocols for accuracy testing (validation) of central BP devices have been ad hoc, and with many limitations, including the use of noninvasive central BP devices as the reference comparator. To address this, in 2017, the Artery Society published recommendations on appropriate validation protocols for central BP devices, and this included a requirement for invasive central BP being the reference.[4] The aim of the current study was to determine the accuracy of the Xcel cuff device to estimate central BP following the Artery Society protocol recommendations.

Methods

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Participants

All participants had a clinical indication to undergo coronary angiography at the Royal Hobart Hospital catheterization laboratory. The flow of participants in the study is depicted in Figure S1 in the Data Supplement. Briefly, 388 people were approached for participation, with 6 declining to take part. Individuals were further excluded from analysis based on several factors, including the presence of, or

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From the Menzies Institute for Medical Research, University of Tasmania, Hobart, Australia (M.G.S., D.S.P., M.K.A., J.A.B., N.D., P.R.-T., J.E.S.); and Royal Hobart Hospital, Hobart, Australia (J.A.B., N.D., P.R.-T.).

*These authors contributed equally to this work.

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Correspondence to James E. Sharman, Menzies Institute for Medical Research, College of Health and Medicine, University of Tasmania, Hobart, 7000, Australia. Email james.sharman@utas.edu.au

identified history of atrial fibrillation (n=15) or aortic stenosis (n=5). Others were subsequently excluded due to technical error or equipment failure that led to insufficient data for analysis to take place (n=30) or medical complications or clinical/procedural issues that arose during the angiogram and disallowed the research protocol to proceed (n=17). A subsample of participants had measurements of invasive brachial BP (for calculation of central-to-brachial SBP amplification). For these participants, interarm differences in cuff BP were assessed by simultaneous triplicate measurement of left and right arm BP using identical devices (UA767 A&D Medical, Tokyo, Japan). If the average interarm difference was >5 mm Hg, people were excluded from participation (n=19). Altogether, there were 296 people with data available for analysis. All participants provided informed written consent for participation, and measures were carried out according to the Artery Society protocol recommendations (Table S4).[4] All data is made available on reasonable request to the authors.

Intraarterial (Invasive) BP

Invasive central BP was recorded at the ascending aorta before the clinical angiogram procedure. A fluid-filled catheter (5F or 6F size) was advanced from a right radial artery access site (or via the right femoral artery when radial artery access could not be made) and positioned in the ascending aorta within 3 cm of the aortic valve (positioning confirmed by fluoroscopy). The system manifold was maintained on the catheter table at a height equivalent of the heart, and the system was flushed before continuous acquisition of invasive central BP waveforms. All pressure waveform signals were acquired at a sample rate of 1000 Hz via an analog-to-digital converter (PowerLab ML870; AD Instruments, Bella Vista, Australia) and recorded using LabChart 7 software (AD Instruments). Event markers were inserted at the precise time of brachial-cuff inflation and deflation, and the start and finish of brachial-cuff BP waveform capture (a period of 5 seconds). Those participants with additional measures of invasive brachial BP to determine invasive central-to-brachial SBP amplification, had recordings following the clinical angiogram procedure. For this, the catheter was once again positioned in the ascending aorta to capture invasive central BP waveforms, before being pulled back to the mid-humeral level in the right brachial artery where invasive brachial BP waveforms were recorded. The frequency response and damping coefficient of the catheter system were assessed using pop tests and confirmed to be in the appropriate range (frequency >18 Hz, damping coefficient >0.3) as explained by Gardner.[5] Since all waveform signals were digitally acquired, they were converted from Volts to mm Hg via an offline 2-point calibration procedure that we have previously outlined.[6] The 5 second period of invasive central BP waveforms corresponding directly with the time of Xcel cuff waveform capture were ensemble-averaged for analysis. The SBP was taken as the peak of the ensembled waveform and diastolic BP (DBP) as the nadir. Sensitivity analyses were conducted to determine the influence of increased BP variability. This was defined as per the latest International Standard (ISO 81060-2:2018[E]) as an invasive central SBP range >20 mm Hg or invasive DBP >12 mm Hg over the 5-second BP waveform capture period.

Sphygmocor Xcel Cuff Measurement

Once participants were positioned ready and lying on the catheterization laboratory table, the cuff of the Xcel device (appropriately fitting as per reference range indicators on each cuff) was placed on the participants' left upper arm. BP measurement with the cuff involved an automatic recording of standard oscillometric brachial BP, immediately followed by reinflation of the cuff to a sub-diastolic pressure level. The cuff was held inflated at this sub-diastolic pressure for a period of 5 seconds, during which time volumetric (cuff displacement) waveforms were recorded. These waveforms were then calibrated (with the brachial-cuff measured SBP and DBP by default) before a generalized transfer function (GTF) was applied to estimate a central BP waveform. The peak of this waveform was the estimated central SBP. For all measurements, participants were instructed to keep their arm relaxed at their side and to refrain from any movement during the inflation and waveform measurement periods. Similarly, all catheterization laboratory and research staff were instructed to remain still and silent during all measurements.

Calibration and Comparisons

The measured brachial-cuff BP waveforms required calibration before central BP could be estimated. The default calibration with brachial-cuff SBP and DBP was automatically undertaken by the device software, using the values that were measured on the first inflation of the cuff (immediately before waveform capture). Based on data suggesting that mean arterial pressure (MAP) and DBP calibration will provide superior estimates of central BP,[7] we also rescaled the Xcel cuff waveforms using several recalibration methods as described in Table 1. This included calibration with the device oscillometric MAP and DBP (measured on a separate cuff inflation) in a subsample of 58 participants (representing 112 comparisons). Calibration with the integrated (true) invasive central MAP and DBP was also used to test the SphygmoCor Xcel transfer function (GTF) separate from cuff-derived calibrations. Based on each of these calibration methods, the subsequent estimated central SBP was compared with the simultaneously recorded (reference) invasive central SBP. We also compared the brachial-cuff SBP (without calibration or application of a GTF) with invasive central SBP, and in a subsample of 151 participants, noninvasively estimated central-to-brachial SBP amplification with invasive central-to-brachial SBP amplification.

Central Hypertension

Central hypertension was defined as invasive central SBP ≥130 mm Hg based on the threshold described in the paper of Cheng et al,[8] or as ≥140 mm Hg.

Statistical Analysis

Data were analyzed using SPSS for Windows (Version 24; Chicago, IL). Agreement between estimated central SBP and invasive central SBP was assessed by mean difference and SD of the mean difference. Bland-Altman analysis was used to visualize agreement between estimated central SBP and invasive central SBP. Pearson correlations within Bland-Altman plots were used to determine magnitude and direction of any systematic bias. χ^2 tests were used to assess level of concordance in classification of central hypertension. $P<0.05$ was considered statistically significant.

Results

Participant Characteristics

Clinical characteristics of the study population are outlined in Table 2. Participants were predominantly of middle-to-older age, male, and with comorbidities commensurate with a clinical population undergoing diagnostic coronary angiography.

Estimation of Central SBP With Various Calibration Modes

A summary of all absolute BP values is outlined in Table S1, and the mean difference and SD between invasive central SBP and Xcel cuff–estimated central SBP using various calibration methods depicted in Figure 1. All Xcel cuff estimates of central SBP were correlated with invasive central SBP (Table S2). When the Xcel brachial-cuff waveforms were calibrated with default brachial-cuff SBP and DBP, the central SBP underestimated invasive central SBP, with correlation and Bland-Altman plots indicating evidence of systematic bias (Pearson $r=-0.50$, $P<0.001$) for greater underestimation at higher levels of SBP (Figure 2A and 2B). Recalibration of the Xcel brachial-cuff waveforms with brachial-cuff form-factor derived MAP (both 33 and 40% form-factor) and DBP improved the mean difference between the estimated central SBP and invasive central

Table 1. Rationale for Assessment of Each Calibration Method to Assess Central Blood Pressure, and Other Comparisons

Variable	Calibration Method	Rationale for Calibration	Reference
Estimated central SBP	Brachial-cuff SBP/DBP	Manufacturer default and recommended	Invasive central SBP
	Brachial-cuff 33%FF MAP/DBP	To provide a theoretically more accurate central SBP	
	Brachial-cuff 40%FF MAP/DBP	To provide a theoretically more accurate central SBP	
	Brachial-cuff oscillometric MAP/DBP	To provide a higher and theoretically more accurate estimated central SBP (commensurate with a type 2 central BP device)	
	Invasive aortic MAP/DBP	To test the performance of the generalized transfer function independent from the cuff measured BP	
Brachial-cuff SBP	Nil	N/A	
Estimated central-to-brachial SBP amplification	Brachial-cuff SBP/DBP (for estimated central SBP used to calculate SBP amplification)	N/A	Invasive central-to-brachial SBP amplification

DBP indicates diastolic blood pressure; FF, form factor; MAP, mean arterial pressure; N/A, not applicable; and SBP, systolic blood pressure.

SBP, although variability remained high. In the subsample of participants, brachial-cuff oscillometric MAP and DBP calibration led to a substantial underestimation of invasive central SBP, with the correlation and Bland-Altman plots indicating wide scatter in the mean difference and strong systematic bias (Pearson r=–0.70, P<0.001) towards greater underestimation at higher levels of SBP (Figure 3A and 3B).

Table 2. Clinical Characteristics of the Study Sample (n=296).

Variable	Mean±SD or n(%)
Age, y	61±12
Male sex, n (%)	201 (69)
Height, cm	170±36
Weight, kg	86.5±21.7
Hypertension, n (%)	191 (69)
Type 2 diabetes mellitus, n (%)	72 (26)
Coronary artery disease, n (%)	200 (68)
High total cholesterol, n (%)	125 (68)
Current smoker, n (%)	52 (19)
Creatinine, µmol/L	85±30
Statins, n (%)	165 (63)
Antihypertensive medications, n (%)	204 (78)
Beta-blockers, n (%)	93 (36)
Calcium channel blocker, n (%)	69 (26)
Angiotensin-converting enzyme inhibitors, n (%)	62 (24)
Angiotensin receptor blockers, n (%)	72 (28)
Diuretic, n (%)	52 (20)
Vasodilators, n (%)	65 (25)

Data are mean±SD or n (%). Clinical characteristics were retrieved from patient medical records where available/recorded.

Sensitivity analysis indicated there were only 14 participants (comprising 18 measures in total) with invasive BP variability >20 mm Hg invasive central SBP or >12 mm Hg invasive central DBP. Although the Xcel cuff–estimated central SBP underestimated the invasive central SBP in these cases to a greater extent (mean difference –9.1±12.3 mm Hg), excluding them from analysis did not appreciably change the mean difference from the full complement of measures (post-exclusion –7.6±10.8 mm Hg versus preexclusion –7.7±11.0 mm Hg, respectively).

Additional Comparisons

To test the SphygmoCor GTF, the brachial-cuff waveforms were calibrated with invasive central MAP (integrated) and DBP. This calibration had the smallest mean difference between the estimated central SBP and invasive central SBP of all the calibration methods (Figure 1). Brachial-cuff SBP (without application of a GTF) was also compared to invasive central SBP, and although the mean difference was small, variability was outside the minimal tolerable error (Figure 1). In the subsample, invasive central-to-brachial SBP amplification was highly variable in magnitude (mean 8.0±9.2 mm Hg), whereas the Xcel device estimated central-to-brachial amplification was higher but had less variability (12.3±3.6 mm Hg). This was irrespective of BP level (Figure 4).

Discrimination of Central Hypertension

Data depicting classification of central hypertension is displayed in Table S3. Estimated central SBP calibrated with brachial-cuff SBP and DBP incorrectly classified 23% of measures at the invasive central SBP threshold of 130 mm Hg, and 12% of measures with an invasive central SBP threshold of 140 mm Hg (χ^2 P<0.001 for both). Classification of central hypertension was similar irrespective of cuff calibration mode. Discrimination of central hypertension was

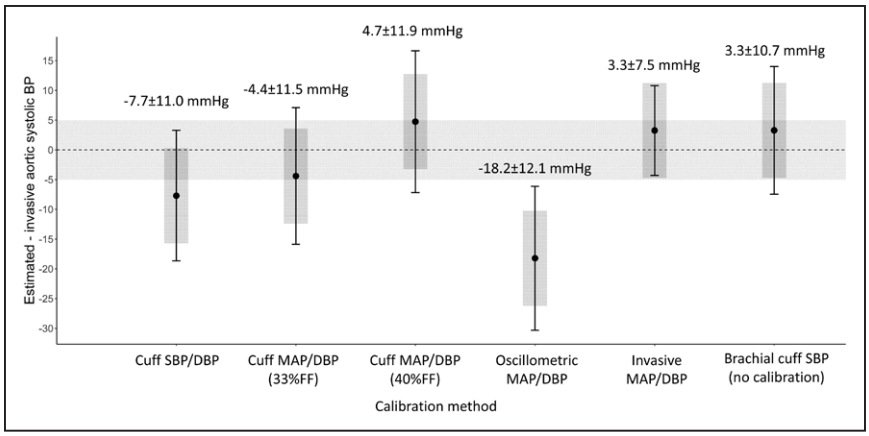

Figure 1. Mean difference (black dots) and SD (error bars) between invasive central systolic blood pressure (SBP) and Xcel cuff–estimated central SBP using various calibration methods (values indicated on figure). The dashed zero line represents 100% agreement. The light gray shaded zone represents the accuracy limits (±5 mm Hg) and dark gray boxes the SD limits (±8 mm Hg) as per Artery Society recommendations. To pass accuracy criteria, the black dots would need to be within the light gray shaded zone and the error bars completely within the dark gray boxes. DBP indicates diastolic blood pressure; FF, form factor; and MAP, mean arterial pressure.

similar, or better, with the uncalibrated brachial-cuff SBP, with 20% of measures incorrectly classified at the invasive central SBP threshold of 130 mm Hg, and only 10% of measures at the invasive central SBP threshold of 140 mm Hg (χ^2 $P<0.001$ for both).

Discussion

This validation study aimed to assess the accuracy of the Xcel cuff device to estimate central BP according to recommendations of the Artery society.[4] When the Xcel brachial-cuff BP waveform was calibrated with manufacturer recommended brachial-cuff SBP and DBP, the estimated central SBP substantially underestimated invasive central SBP. The mean difference and variability exceeded the minimum accepted levels for a central BP device to meet validation criteria. When brachial-cuff BP waveforms were recalibrated with MAP (derived in several ways) and DBP, there were minor improvements to the mean difference between estimated central SBP and invasive central SBP; however, variability remained high and still exceeded accepted standards. Taken altogether, the SphygmoCor Xcel does not meet the accuracy standards for central BP assessment according to the Artery Society.[4]

The original SphygmoCor device (CVMS, Atcor Medical) that operated with radial tonometry and central BP estimation via radial-to-aortic GTF was the first commercially available central BP device to gain United States Food and Drug Administration clearance. This technology gained prominence in the field and was even cited as the noninvasive reference standard.[9] Although there has been a wealth of research data generated using this system,[10,11] clinical uptake has been poor due to such things as having markedly different operating characteristics from standard cuff BP that doctors are used to, as well as relative complexity and operator dependency of acquiring high-quality waveforms. To increase clinical applicability, the same Food and Drug Administration–cleared GTF methodology was adapted to operate within the cuff-based Xcel device that we have assessed in this current study. Studies comparing the radial tonometry method for estimating central SBP with invasive central SBP show a similar level of underestimation (−8.2±10.3 mm Hg) as we report with the Xcel cuff device in the current study.[12] Moreover, several independent studies,[13,14] including one of our own,[15] reported that central SBP estimated by the cuff-based Xcel device was substantially equivalent to tonometry-based SphygmoCor CVMS estimated central SBP. However, in 2017 the Artery Society published a consensus document recommending that devices purporting to measure central BP be tested by comparison to a reference standard of invasive central BP rather than noninvasive methods, such as tonometry.[4]

Two previous validation studies using the Xcel device compared with invasive central BP have been conducted.[16,17] A study by Shoji et al[16] found the Xcel estimated central SBP to underestimate invasive central SBP −4.6±9.9 mm Hg (a similar variability as found in our study). However, study numbers were much lower (n=36) than those stipulated as necessary in the artery recommendations (n=85). The more recent study by Gotzmann et al[17] satisfied requirements regarding the number of study participants but reported a mean difference from invasive SBP of −5.0±7.7 mm Hg, which was within the accepted error margin and the authors concluded

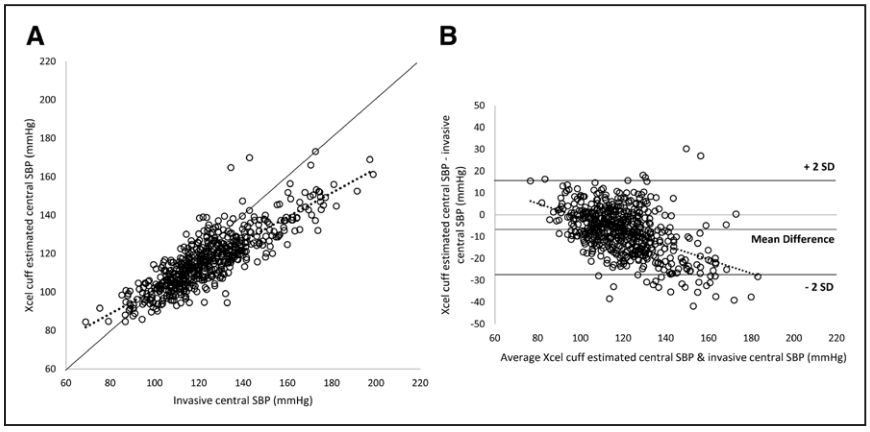

Figure 2. Estimating central blood pressure (BP) with the default calibration. Correlation (**A**) and Bland-Altman (**B**) plots indicating wide scatter and evidence of systematic bias for greater underestimation of central systolic blood pressure (SBP) with increasing level of BP when the Xcel device was calibrated with the default cuff SBP and diastolic BP. Dashed lines are the lines of best fit. Solid line is the line of identity (**A**) and mean difference and ±2 SDs of the difference between estimated and invasive central SBP (**B**).

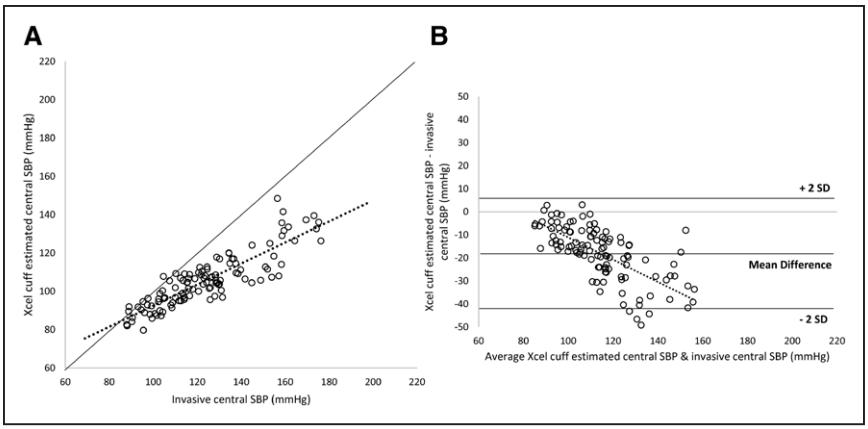

Figure 3. Estimating central blood pressure (BP) using an oscillometric mean arterial pressure for calibration. Correlation (**A**) and Bland-Altman (**B**) plots indicating wide scatter and systematic bias for substantially greater underestimation of central systolic blood pressure (SBP) with increasing level of BP when the Xcel device was calibrated with the device oscillometric mean arterial pressure and diastolic BP in a subsample of participants (n=58, 112 comparisons). Dashed lines are the lines of best fit. Solid line is the line of identity (**A**) and mean difference and ±2 SDs of the difference between estimated and invasive central SBP (**B**).

that the device passed validation testing. This differs from our results and conclusions, which is difficult to reconcile but is something we have sought clarification on.[18] In this study, we adhered to all recommendations of the Artery taskforce and found that when using the default peripheral cuff SBP and DBP calibration, the SphygmoCor Xcel device substantially underestimated invasive central systolic BP (Figure 1 and 2) and was outside the limits for device accuracy.[4] In the default calibration mode, the Xcel device operates as a type I device, which estimates a central BP relative to brachial BP (the latter of which is used to calibrate the peripheral waveform). It is well known that brachial-cuff SBP underestimates the true (intraarterial) brachial SBP but overestimates the true (intraarterial) brachial DBP.[19] These errors lead to inaccurate calibration of the cuff waveform and a consequent transfer of error (underestimation) to the estimated central SBP. Furthermore, intraarterial brachial SBP is underestimated to a greater extent by brachial-cuff SBP at higher SBP levels,[19] which accounts for the strong systematic bias we observed for greater underestimation of central SBP at higher SBP in this study. The systematic underestimation of central SBP may, however, not be unexpected for a type I device because the underlying premise is that such devices will only estimate a central SBP relative to brachial-cuff SBP. However, this cannot be construed as accurate measurement of central SBP.

The Xcel device significantly overestimated SBP amplification. We are unable to explain this result, but it may be because the GTF is constrained in the ability to detect the true interindividual range in the variability of invasive central-to-brachial SBP amplification.[20] It is also important to highlight that brachial-cuff systolic BP had the smallest mean difference compared with invasive central systolic BP (3.3±10.7 mm Hg), which suggests that achieving an accurate estimate of central SBP may be difficult when using the default calibration of the device. Another potential cause of the underestimation of invasive central systolic BP is the noninvasive waveform captured by the brachial cuff. This is recorded at a sub-diastolic pressure in response to volumetric changes in the artery and produces a dampened and relatively featureless waveform, unlike those from invasive BP or, indeed, radial tonometry. Although the waveform quality may have minimal impact when the default calibration is used (calibration to peak/nadir), it may impact the ability to accurately estimate MAP, which, if used for calibration, could lead to further errors in central BP estimation.

It has been shown that to achieve a more accurate,[7,21] and clinically relevant (prognostic),[22–24] estimate of invasive central systolic BP, peripheral BP waveforms should be calibrated with MAP and DBP. In the current study, we trialed MAP and DBP calibrations using a MAP derived by standard form-factor equations (33% and 40% of the PP) as well as the oscillometric MAP provided by the Xcel device. When using the form-factor equations, there were marginal improvements in the mean difference between the estimated central SBP and invasive central SBP by comparison to the standard brachial-cuff SBP and DBP calibration approach. The 40% form-factor derived MAP and DBP calibration even led to a slight overestimation of invasive central SBP, likely owing to the fact that the 40% form factor MAP derived from brachial-cuff SBP and DBP overestimated the true invasive (integrated) aortic MAP in this study (see Table S1 in the Data Supplement). However, variability remained high and still exceeded accepted standards for device variability (SD±8 mm Hg) when using MAP/DBP

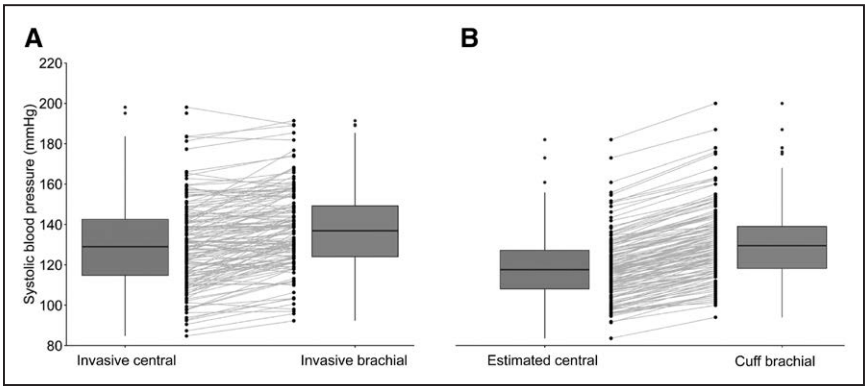

Figure 4. Central to peripheral systolic blood pressure (SBP) amplification. Invasive central-to-brachial SBP amplification (**A**) and cuff-estimated central-to-brachial SBP amplification (**B**). Box plots represent the mean and spread of the data for invasive central and estimated central SBP and invasive brachial and cuff-brachial. The gray lines represent the SBP amplification of each individual in the study sample.

calibrations. This variability, when using form-factor MAP for waveform calibration, is likely in-part related to variable central-to-brachial SBP amplification,[1] which we have found to impact form-factor derived MAP accuracy.[25] Calibration with oscillometric MAP (and DBP) using the Mobil-O-Graph device has been shown to provide estimates of central SBP that are higher and that more closely resemble invasive central BP,[21] commensurate with a type II central BP device.[4] Importantly, our study shows this to be a device-specific phenomenon because when the Xcel device was calibrated with oscillometric MAP and DBP, there was gross underestimation of the invasive central systolic BP with major systematic bias for greater underestimation at higher SBP (Figure 3).

The development of devices to estimate central BP is underpinned by the physiological rationale that central BP is more closely related to clinical outcomes and organ damage than conventional upper-arm brachial BP. Indeed, markers of target organ damage have been shown to be more strongly correlated with central, rather than brachial BP.[26] However, hard outcome data on central BP is less definitive with respect to this assertion, and to our knowledge, there is no outcome data for prediction of clinical events available from SphygmoCor Xcel derived central BP. Nonetheless, clinical cut points have been derived for central BP hypertension at a threshold of ≥130/90 mm Hg.[8] In the present study, the estimated central BP from the default and additional calibration schemes had ≈80% concordance to discriminate a 130 mm Hg invasive central SBP threshold. However, classification of central hypertension was equivalent (slightly better) when simply using the brachial-cuff SBP uncalibrated and with no transfer function applied, again supporting the notion that some brachial-cuff devices provide best approximation of invasive central systolic BP.[27]

Limitations

The study population comprised patients with a clinical indication to undergo coronary angiography; therefore, the results may not be generalizable beyond this population. We used fluid-filled catheters to record invasive central and brachial BP, and if handled incorrectly, could lead to inaccurate measurement of BP. However, in accordance with the Artery taskforce recommendations, we provided a specific description of handling methods, with a standardized and methodical protocol for the measurement of invasive central BP, including removal of bubbles from the arterial line, regular flushing, and confirming the dynamic response to be within the required range. Although all research measures were taken during a hemodynamically stable period of undisturbed rest, clinical directives meant that antihypertensive medication (when taken) was not withheld on the day of the coronary angiogram procedure. Some vasoactive medications were administered locally at the time of gaining intra-arterial access, although research procedures typically took place >5 minutes from this time.

Perspectives

There is well-reasoned rationale behind the justification to measure central BP as distinct from brachial BP. Noninvasive methods to estimate central BP have become popular in research because they allow widespread measurement on people who do not have a clinical indication for an invasive procedure. However, to date, the clinical outcome data to support measurement of central BP, above and beyond conventional brachial-cuff BP, is lacking. This may be due to challenges with measurement accuracy of devices that need to scale peripheral waveforms using potentially inaccurate cuff BP values. Although all noninvasive BP measurement methods remain susceptible to inaccuracy, we have shown that the SphygmoCor Xcel device does not meet minimum accuracy standards irrespective of cuff calibration approach. Further efforts to improve accuracy of this device are needed if it were to become recommended for general clinical use.

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Disclosures

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Novelty and Significance

What Is New?

- Devices that purport to measure central blood pressure (BP) should undergo rigorous testing for accuracy (validation) by comparison to invasive central (aortic) BP. In this study, estimated central BP by the SphygmoCor Xcel cuff–based device was compared to invasive central (aortic BP) using multiple calibration methods.

What Is Relevant?

- Using the default calibration method (brachial-cuff systolic and diastolic BP), the SphygmoCor Xcel cuff underestimated invasive central BP with high variability. Similar variability was observed with all other calibration techniques.

Summary

Irrespective of cuff calibration technique, the SphygmoCor Xcel cuff device does not meet the Artery Society accuracy criteria for non-invasive measurement of central BP. Without further refinement, the device could not be recommended for clinical use to assess central BP.