Evaluation of a novel sphygmomanometer, which estimates central aortic blood pressure from analysis of brachial artery suprasystolic pressure waves

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Background: Central arterial pressure is a better predictor of adverse cardiovascular outcomes than brachial blood pressure, but noninvasive measurement by applanation tonometry is technically demanding.

Method: Pulsecor R6.5 is a novel device adapted from a standard sphygmomanometer which estimates the central aortic pressure from analysis of low-frequency suprasystolic waveforms at the occluded brachial artery. A physics-based model, which simulates the arterial system using elastic, thin-walled tube elements and Navier–Stokes equations, is used to calculate arterial pressure and flow propagation. To determine the reliability of the device, we compared 94 central systolic pressures estimated by Pulsecor to the simultaneous directly measured central aortic pressures at the time of coronary angiography in 37 individuals.

Results: There was good correlation in central SBP between catheter measurements and Pulsecor estimates by either invasive or noninvasive calibration methods ($r = 0.99$, $P < 0.0001$ and $r = 0.95$, $P < 0.0001$, respectively). The mean difference in central systolic pressure was 2.78 (SD 3.90) mmHg and coefficient of variation was 0.03 when the invasive calibration method was used. When the noninvasive calibration method was used, the mean difference in central systolic pressure was 0.25 (SD 6.31) mmHg and coefficient of variation was 0.05.

Conclusion: We concluded that Pulsecor R6.5 provides a simple and easy method to noninvasively estimate central SBP, which has highly acceptable accuracy.

Keywords: central systolic pressure, Pulsecor, suprasystolic pressure waveform

Abbreviations: AAMI, Association for the Advancement of Medical Instrumentation; cDBP, central DBP; cMAP, central mean arterial pressure; cSBP, central SBP

INTRODUCTION

There is increasing evidence that central arterial pressure predicts cardiovascular outcomes more reliably than peripherally measured brachial pressures\cite{1-4}. Brachial blood pressures do not accurately reflect central blood pressures as a result of peripheral amplification, and there is a considerable variation in central blood pressure even between individuals with similar brachial blood pressure\cite{5,6}. Cardiovascular outcomes also differ between different classes of antihypertensive medication despite similar reductions in peripheral blood pressure. These differences may be explained by different effects on central arterial pressure\cite{7-10}. Central pressures are pathophysiologically more relevant because they more directly determine cardiac loading and myocardial perfusion\cite{11,12} and the arterial pressure waveform conveys useful information regarding systemic vascular compliance\cite{13}. Knowledge of the central arterial characteristics may, therefore, provide an advance in monitoring and titration of interventions in various cardiovascular diseases.

A simple noninvasive method to estimate central aortic pressure wave is needed for research and general clinical application. To date, the most widely used method is applanation tonometry, which uses an externally applied micromanometer-tipped probe to record peripheral pulse waveforms\cite{14,15}. A generalized transfer function is then applied to correct for pressure wave amplification in the upper limb\cite{16,17}. However, this method has limitations. Although estimated central SBPs correlate with invasive central measurements\cite{18,19}, the generalized nature of the transfer function assumes that the properties of the upper limb arteries are identical among all the individuals\cite{20}. In addition, applanation tonometry is technically demanding and, therefore, only suited to research settings with measurements made by trained technicians.

Pulsecor is a novel device which estimates central pressures in the ascending aorta from an oscillometric pressure cuff on the upper arm. A physics-based model is applied to...
Study protocol

The study involved the acquisition of invasive arterial waveforms and pressures directly measured from the ascending aorta (at the sinotubular junction) or aortic arch (at the left subclavian bifurcation) by Judkins Right catheter or pigtail catheter in patients undergoing diagnostic left heart catheterization, and noninvasive central pressure estimates were obtained simultaneously by Pulsecor R6.5 device.

Invasive calibration involves using invasively measured central mean arterial pressure and central DBP to calibrate suprasystolic brachial waveform to estimate central SBP (cSBP). This methodology has been recommended to remove the confounding influence of the less accurate brachial oscillometric recordings. Noninvasive calibration involves using oscillometric SBP, DBP, MAP and the normalized suprasystolic brachial waveform obtained by Pulsecor to calibrate the suprasystolic brachial waveform using a method that is specific to the proprietary oscillometric algorithm used in the device. This calibrated waveform is then used to estimate the central pressure waveform, including cSBP and cDBP.

Noninvasive central pressure estimates

Once in the catheter laboratory, the participant’s left arm was placed on an arm board with the cuff of the Pulsecor R6.5 device wrapped around the left upper arm. The Pulsecor R6.5 device first inflated and deflated to identify oscillometric brachial SBP and DBP and then inflated again to 30 mmHg above oscillometric brachial systolic pressure for 10 s during which the suprasystolic signals were recorded. During this period of suprasystolic inflation, 10 s of invasive arterial waveforms were simultaneously recorded from the catheter with an ECG to facilitate timing of pulse waveforms.

Invasive central pressure measurements

Participants were prepared according to standard cardiac catheterization laboratory protocols, including administration of sedatives, intravenous fluids and oxygen, as required. Either a femoral or radial arterial access was used to introduce a 6 F Judkins Right 4 or pigtail catheter under local anaesthesia employing the Seldinger technique. Invasive measurements were collected either towards the start or end of the diagnostic coronary investigation, or both. The catheters were 100 cm long (110 cm for pigtail catheter) with an internal diameter of 1.8 mm. The catheters were connected by semirigid fluid-filled tubing to a disposable pressure transducer (TrueWave; Edwards Lifesciences, Saint-Prex, Switzerland). At each fluoroscopically confirmed position in the vascular tree, the catheter was attached to a pressure line and 10 s were allowed for the trace to stabilize. Catheter position was adjusted to avoid damping. Transducers were factory calibrated and exceeded Association for the Advancement of Medical Instrumentation (AAMI) standards for performance interchangeability. Calibration of the transducer was verified using the True-Cal system to be within 1 mmHg of the calibrated noninvasive pressure sensor before each study. The transducers were of a precision, solid-state type and

Pulsecor device

Pulsecor R6.5 (Pulsecor Ltd, Auckland, New Zealand) estimates the central pressures from the brachial cuff pressure fluctuations. First, the device uses oscillometry to determine brachial systolic and diastolic pressures during deflation of the cuff. The device then inflates again and holds cuff pressure approximately 30 mmHg above the brachial systolic pressure (i.e. suprasystolic measurement) for approximately 10 s. Intra-arterial pressure waves impinging on artery occlusion, caused by the suprasystolic cuff, transfer part of their energy to the surrounding upper arm tissue and then into the cuff. The small cuff pressure fluctuations recorded during this period can then be directly related to the intra-arterial pressure oscillations. The intra-arterial pressures in the brachial artery at the cuff measurement site are then used to estimate the pressures in the aorta by applying a physics-based model of the left subclavian-to-brachial branch. The model involves establishing a time-domain representation of pressure wave reflection within a uniform closed tube. Pressure waves enter this tube from the aorta and are transmitted towards the cuff occlusion, where they are reflected back towards the aorta and further reflected within the tube. Total pressure at the aorta and under the cuff are modelled as the superposition of the reflected waves. By estimating the reflection characteristics at the ends of the tube and transmission time for pressure wave propagation down the tube, the model allows estimation of the pressure waveform at the open end of the tube (i.e. the aorta) from the closed end (i.e. under the cuff) [21].

METHODS

Study population

The study was conducted at the Cardiac Investigations Unit, Auckland City Hospital between January 2010 and December 2010, and was approved by the regional research ethics committee. Eligible patients were identified from those scheduled to undergo diagnostic coronary angiography. Written informed consent was given by all individuals.

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Evaluation of a novel sphygmomanometer

RESULTS

The study population was 37 individuals (mean age 64±12 years, range 32–78 years, 12 women, 25 men) undergoing diagnostic coronary angiography via either a femoral (n = 15) or radial (n = 22) approach. Ninety-four simultaneous invasive and noninvasive central aortic pressure readings were obtained. Table 1 provides a summary of clinical characteristics of the patients.

Figure 1 demonstrates typical features of synthesized aortic pressure waveform by Pulsecor R6.5 device and simultaneously measured invasive aortic pressure waveform in four example patients at steady state. Synthesized aortic pressure waveforms display good concordance to those directly recorded by invasive catheter method in both pulse amplitude and contour. The waveforms display agreement with minimal distortion.

Directly recorded values of cSBP and values estimated using invasive calibration method showed a strong correlation (Pearson’s r = 0.99, P < 0.0001) with no statistically significant differences between absolute values, and a strong agreement between direct measurements and estimated values is also observed (Table 2; Fig. 2). The coefficient of variation was 0.03, signifying small dispersion of the estimated cSBP values relative to the recorded values. When heart rate is divided into tertiles of less than 57, 57–74 and 75 beats per minute or greater, the differences in SBP between the tertiles were similar and not statistically significant (Table 2). Agreement between the directly measured SBP and the estimated value using invasive calibration was similar for individuals with a heart rate above and below the median.

Table 3 displays the mean values and SDs of cSBP and cDBP, recorded by catheter and those estimated by Pulsecor R6.5 using a noninvasive calibration method. The

### TABLE 1. Clinical characteristics of the study patients

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>64±12</td>
</tr>
<tr>
<td>M/F (n)</td>
<td>25/12</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.7±0.1</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>82.3±14.0</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.11±4.22</td>
</tr>
<tr>
<td>History of CAD, n (%)</td>
<td>11 (30)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>25 (68)</td>
</tr>
<tr>
<td>β-blockers</td>
<td>23 (62)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>15 (41)</td>
</tr>
<tr>
<td>Angiotensin receptor blockers</td>
<td>5 (14)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>14 (38)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>7 (19)</td>
</tr>
<tr>
<td>Smoking history, n (%)</td>
<td>4 (11)</td>
</tr>
<tr>
<td>Current smoker</td>
<td></td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>19 (51)</td>
</tr>
<tr>
<td>Dyslipidaemia, n (%)</td>
<td>28 (76)</td>
</tr>
<tr>
<td>HMG-CoA reductase inhibitor use, n (%)</td>
<td>28 (76)</td>
</tr>
<tr>
<td>Type 2 diabetes mellitus, n (%)</td>
<td>6 (16)</td>
</tr>
</tbody>
</table>

Severe lesion(s) on diagnostic angiogram necessitating revascularization procedure
- PCI and/or stent insertion, n (%) | 11 (30) |
- Coronary artery bypass graft, n (%) | 3 (8) |

Values are mean ± SD or numbers (%). ACE, angiotensin-converting enzyme; CAD, coronary artery disease; HMG Co-A, 3-hydroxy-3-methyl-glutaryl-CoA; PCI, percutaneous coronary intervention.
differences between absolute values observed were not statistically significant. There is a strong correlation between directly recorded cSBP and cDBP and the values estimated by Pulsecor using noninvasive calibration (Pearson’s $r = 0.95$, $P < 0.0001$ and $0.81$, $P < 0.0001$, respectively) and a strong agreement between direct measurements and estimated values is also seen (Figs 3 and 4). Again, the coefficient of variation for cSBP and cDBP were 0.05 and 0.07, respectively, signifying small dispersion relative to the corresponding recorded central pressure values.

When noninvasively calibrated cSBP and cDBP estimates are plotted according to the ANSI/AAMI SP10 criteria using the fifth to 95th percentile of invasive recorded values as the range, accuracy of the readings can be observed to fall well within the SP10-recommended standard (Fig. 5).

When cSBP recorded by catheter were compared to the corresponding brachial oscillometric readings obtained by Pulsecor, a systematic error was observed, particularly at the higher end of pressure readings (Fig. 6). A larger coefficient of variation of 0.11 indicates a greater dispersion of brachial pressure readings relative to the corresponding invasive central pressure readings. A similar observation may be noted when comparing cDBP recorded by catheter to brachial oscillometric readings.

**DISCUSSION**

The cSBP and pulse pressure both predict future cardiovascular events independently of blood pressure measured at the brachial artery [23]. However, the difference between central and brachial pressure predominantly relates to differences in SBP, whereas central and peripheral diastolic pressures are similar [6]. The accuracy of the Pulsecor device for estimating central systolic pressure was the primary outcome measure in this study.

To measure central pressures in large populations, an accurate and noninvasive device that is easy to operate is needed. In this study, we demonstrated that central pressure waveforms derived by the Pulsecor R6.5 device correlated closely with those obtained invasively from a catheter. We have shown that the contour and changes in the estimated aortic waveform were similar to the invasively measured aortic pulse and the technique provided clinically acceptable estimates of central systolic pressures in patients with different age, sex, height, heart rate and disease state. In addition to the benefits of being noninvasive, Pulsecor R6.5 is much less operator dependent than applanation tonometry and the results are likely to be more consistent. The physics-based model used by Pulsecor theoretically presents some advantages over radial tonometry as a basis for generalized transfer functions: the measurement site is more proximal, resulting in less variance in arterial geometry (and avoiding the radial–ulnar bifurcation); the cuff occlusion removes effects from the downstream circulation and provides a standardized end-impedance; and it becomes hypothetically possible to tailor the model parameters to an individual participant, rather than a potentially unrepresentative sample of the population. However, such tailoring has not been applied in this study and its potential impact on accuracy is a subject of future work.

We reported results derived using both invasive and entirely noninvasive methods of calibration. In previous studies when noninvasive waveforms were calibrated using invasive diastolic and mean pressures, estimation of central systolic pressures had good agreement with the invasive measurements [18,19,24]. This method of calibration removes the confounding influence of the less accurate brachial cuff recordings [25]. However, invasive calibration
is not possible when only noninvasive measurements are made. In this situation, the diastolic and mean pressures used to calibrate the waveform come from a noninvasive blood pressure measurement system and scaling relies on a sufficiently accurate difference between mean and diastolic pressures and the absence of any unknown systematic bias in the oscillometric measurement system. For example, it is not required by the oscillometric method that a peripheral artery waveform scaled between reported systolic and diastolic pressures will have the same mean (by integration) pressure as the mean pressure reported by oscillometry. Possibly for reasons such as these, when the noninvasive waveforms were calibrated using oscillometric brachial blood pressures, more substantial discrepancies between central pressure estimates and invasive measurements are usually reported [26–28]. In our study, the noninvasive calibration method compensated for specific and known characteristics of the proprietary oscillometric algorithm integrated into the measurement system using information available in the normalized suprasystolic waveform. Our study showed that although a larger range of differences were observed using noninvasive over invasive calibration, the agreement between invasive cSBP and those derived from oscillometric pressures using Pulsecor R6.5 device remains well within the AAMI SP10 recommendations [29].

The ANSI/AAMI SP10 standard establishes safety and performance requirements for all sphygmomanometers which use an occluding cuff for the indirect determination of arterial blood pressure. Typically, the standard is used to compare accuracy of peripheral blood pressures from oscillometric devices with measurement by auscultation. However, the standard also includes recommendations for accuracy when compared to invasive reference pressures. SP10 Annex C: Verification of overall system efficacy by comparison with intra-arterial measurements suggests comparing the output of the device under test to the highest and lowest intra-arterial pressures during the time period the noninvasive device is measuring. This recommendation is applicable to most oscillometric blood pressure devices, which determine mean, systolic and diastolic pressures using the shape of the oscillometric envelope acquired over the entire period of the measurement. The measurement is, therefore, sensitive to fluctuations in intra-arterial blood pressure, such as those caused by natural respiratory pressure fluctuations. In this study, we applied a reference range between the fifth to 95th percentiles to reduce oversensitivity from transient haemodynamic changes.

The AAMI SP10 criteria specify that agreement should not exceed a mean difference of 5 mmHg with a SD of the difference of 8 mmHg in an appropriately large number of measurements (25 or more for invasive comparisons). Using both invasive and noninvasive calibration methods, estimates of cSBPs by Pulsecor R6.5 were well within this range. Although the mean difference for noninvasive calibration (0.25 mmHg) has been found in this study to be closer to invasive values than the mean difference for invasive calibration (2.78 mmHg), the limits of agreement using noninvasive calibration are 60% wider, as would be expected due to the added variability introduced by the noninvasive diastolic pressures. A calculation of the 95% confidence intervals on the mean difference for the two methods shows that they overlap. The Bland-Altman plots and the correlation plots drawn have also demonstrated strong agreement and correlation between invasive and noninvasive methods.

### TABLE 2. Comparison between central systolic pressure recorded by catheter and values estimated by Pulsecor R6.5 using invasive calibration methods

<table>
<thead>
<tr>
<th>Central SBP</th>
<th>N</th>
<th>Heart rate, Median (interquartile range)</th>
<th>Catheter measurement, mean (SD)</th>
<th>Pulsecor measurement, mean (SD)</th>
<th>Absolute difference, mean (SD)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>All participants</td>
<td>64 (55–76)</td>
<td>121.92 (23.87)</td>
<td>124.71 (24.95)</td>
<td>2.78 (3.90)</td>
<td>0.52</td>
<td></td>
</tr>
<tr>
<td>Heart rate &lt;57</td>
<td>33</td>
<td>134.96 (29.11)</td>
<td>138.21 (30.59)</td>
<td>3.24 (5.29)</td>
<td>0.59</td>
<td></td>
</tr>
<tr>
<td>Heart rate 57–74</td>
<td>29</td>
<td>114.81 (21.56)</td>
<td>117.96 (22.60)</td>
<td>3.15 (3.18)</td>
<td>0.68</td>
<td></td>
</tr>
<tr>
<td>Heart rate ≥75</td>
<td>32</td>
<td>114.92 (21.88)</td>
<td>116.83 (13.18)</td>
<td>1.92 (2.82)</td>
<td>0.66</td>
<td></td>
</tr>
</tbody>
</table>

Results are also given by heart rate divided into tertiles.
noninvasive values. Even when compared to median invasive pressures, the accuracy of noninvasive estimates was still within the AAMI SP10 standard. This finding is in contrast to previous validation studies of SphymoCor system which underestimated cSBP by 1.5–13.3 mmHg and overestimated cDBP by 10.4–12.2 mmHg [27,28,30].

**Study limitations**

The values of estimated central systolic pressures depend on the validity and applicability of the physics-based model of the left subclavian-to-brachial branch used to generate the central aortic waveforms. This study was relatively small. Data from a larger and more varied patient population is needed to provide a more comprehensive evaluation of the reliability and accuracy of this device in a broader range of clinical settings. Fluid-filled manometer tubing was used for the invasive measurement of intraarterial pressure. Measurement error due to damping was minimized by adjusting the catheter position before invasive recordings were taken. Although fluid-filled manometer tubing may introduce high-frequency distortion to the pressure signals, it is generally agreed that central blood pressures are not dependent on these higher frequency components [31]. Also, we did not screen patients for the presence of proximal upper extremity obstructive atherosclerosis and cannot exclude this as a possible confounding variable. A potential weakness of this technology is that the calibration of central aortic pressures depends on the accuracy of the brachial pressure measurements. Tailoring of the model to an individual has not been applied in this study, and its potential impact on accuracy is a subject of future work.

In conclusion, Pulsecor R6.5 is an easy to use, sphygmomanometer-based device which can also accurately

### TABLE 3. Comparison between central blood pressures recorded by catheter and values estimated by Pulsecor R6.5 using noninvasive calibration method

<table>
<thead>
<tr>
<th>Central Pressure</th>
<th>Catheter measurement, mean (SD)</th>
<th>Pulsecor measurement, mean (SD)</th>
<th>Difference, mean (SD)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP (mmHg)</td>
<td>121.92 (23.87)</td>
<td>122.18 (22.41)</td>
<td>0.25 (6.31)</td>
<td>0.95</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>68.64 (8.40)</td>
<td>68.71 (5.71)</td>
<td>0.07 (4.65)</td>
<td>0.83</td>
</tr>
</tbody>
</table>

Data are means ± SD.
Evaluation of a novel sphygmomanometer

estimate central aortic blood pressure from analysis of the suprasystolic brachial artery pressure waves. Pulsecor R6.5 may have broad research and clinical applications wherein knowledge of central aortic pressure is useful, including the optimization of antihypertensive therapy.

ACKNOWLEDGEMENTS

Conflicts of interest

A.L. is an employee and minor shareholder in Pulsecor Limited. The remaining authors have no conflicts of interest to declare.

REFERENCES


Reviewer’s Summary Evaluations

Reviewer 1

There is increasing interest in extending noninvasive estimation of central aortic pressure using tonometric techniques from peripheral pulse wave detection to brachial cuff-based detection of the pulse wave. This paper describes the use of a conventional brachial cuff for measurement of arterial pressure using supersystolic cuff pulse wave to estimate central aortic pressure. This technique gives reproducible results when compared to invasive catheter recordings. Although the algorithm estimates the waveform, this study reports only values of systolic and diastolic pressure with no indices based on waveform features. There is also a systematic error increasing with pressure, but in general measurements are within accepted limits.

Reviewer 2

The study of Lin et al. evaluates Pulsecor, a novel device for noninvasive estimation of central pressures. The strength of this study is that the noninvasive Pulsecor-derived central systolic pressure is validated with the directly (invasively) measured aortic systolic pressure, confirming a satisfactory agreement between these measurements. The findings of the study have potential clinical implications, as accumulating evidence suggests that central pressures are predictors of cardiovascular outcomes. However, in the light of recent data showing a superiority of the clinical relevance of central pulse pressure compared to central systolic pressure, the performance of Pulsecor in estimating central pulse pressure needs to be evaluated.