Oscillometric estimation of central blood pressure: validation of the Mobil-O-Graph in comparison with the SphygmoCor device

Wolfgang Weiss, Christopher Gohlisch, Christl Harsch-Gladisch, Markus Tölle, Walter Zidek and Markus van der Giet

Background Hypertension is a major risk factor for a wide range of cardiovascular diseases and is typically identified by measuring blood pressure (BP) at the brachial artery. Although such a measurement may accurately determine diastolic BP, systolic BP is not reflected accurately. Current noninvasive techniques for assessing central aortic BP require additional recording of an arterial pressure wave using a high-fidelity applanation tonometer. Within one measurement cycle, the Mobil-O-Graph BP device uses brachial oscillometric BP waves for a noninvasive estimation of central BP. We therefore validated the Mobil-O-Graph against the SphygmoCor device, which is widely known as the commonly used approach for a noninvasive estimation of central BP.

Methods For each individual, we compared three readings of the central BP values obtained by the Mobil-O-Graph and SphygmoCor device consecutively. One hundred individuals (mean age 56.1±15.4 years) were recruited for measurement. Differences between the central BP values of the test device and the SphygmoCor device were calculated for each measurement.

Results The mean difference (95% confidence interval) for the estimated central systolic BP between both devices was –0.6±3.7 mmHg. Comparison of the central BP values measured by the two devices showed a statistically significant linear correlation (R=0.91, P<0.0001). The mean between-method difference was 0.50 mmHg for central systolic BP estimation. The intrarater reproducibility between both the devices was also comparable. Bland and Altman analyses showed that the mean differences (95% confidence interval) between repeated measurements were 1.89 (0.42–3.36) mmHg and 1.36 (–0.16 to 2.83) mmHg for the SphygmoCor and the Mobil-O-Graph device, respectively. Thus, neither of these differences was statistically significantly different from 0. The limits of agreement were –16.34 to 19.73 and –15.23 to 17.17 mmHg for the SphygmoCor and the Mobil-O-Graph device, respectively.

Conclusion Oscillometric noninvasive estimation of central BP with the Mobil-O-Graph BP device is as effective as using the well-established SphygmoCor applanation tonometry device. In comparison, the Mobil-O-Graph combines the widespread benefits of brachial BP measurement and also provides central BP within one measurement.

Keywords: applanation tonometry, augmentation index, central systolic blood pressure, Mobil-O-Graph, oscillometric central blood pressure estimation, SphygmoCor


Introduction There is increasing evidence that central systolic blood pressure (cSBP) may be a better predictor of future cardiovascular events than brachial pressure [1–7]. However, in daily clinical practice, the use of cSBP is currently not common because of the fact that most measurement devices, despite noninvasive techniques, require a trained operator, introducing potential operator dependence. The Mobil-O-Graph is a validated automated self-measurement 24-h BP monitoring device for clinical use that achieved grade A for systolic and diastolic BP measurement according to the requirements of the British Hypertension Society standard [8]. It is also the first automated device that uses brachial oscillometric BP for a noninvasive estimation of the cSBP within one measurement, bringing central pressure a step closer to routine clinical practice. Current noninvasive techniques for assessing central aortic BP require additional recording of an arterial pressure wave using a high-fidelity applanation tonometer. In this study, we therefore validated the Mobil-O-Graph against the SphygmoCor device, which is widely known as a commonly used approach for the noninvasive estimation of central BP. The SphygmoCor uses a radial-to-aortic generalized transfer function. In contrast, the Mobil-O-Graph derives cSBP from oscillometric brachial BP also using a computed transfer function. In addition, the device can also measure the augmentation index by an integrated pulse wave analysis device. This feature is not validated in this study and has been validated previously [8],

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Methods
A total of 100 individuals were included in this study. The protocol was approved by the ethics board and written informed consent was obtained from all the probands. Cardiac arrhythmia (atrial fibrillation, frequent extrasystoles) was an exclusion criterion. All SphygmoCor (Version 8.2; AtCor Medical Pty Ltd, West Ryde, Australia) measurements were performed by a single experienced operator (study nurse C. H.-G.). Participants had fasted and measurements were taken in a seated position after resting for at least 10 min. The measurements took place in a quiet room with an ambient temperature of 20–22°C. The measurements of radial artery tonometry were performed on the left arm of each participant with the SphygmoCor (acquiring 10 s of wave data). The quality of the recordings was maintained by discarding all SphygmoCor measurements with an operator index below 80. The measurements of cSBP and peripheral systolic blood pressure (pSBP) with the Mobil-O-Graph (Stollberg, Germany) were also taken on the left arm following a break of 2 min after SphygmoCor measurements. Arm circumferences were measured and recorded to allow the correct choice of cuff size (two sizes available: 24–34 and 32–42 cm). With a conventional cuff, the determination of the cSBP is on the basis of an oscillometric BP measurement and uses the pulse waves assessed at A. brachialis. After estimation of peripheral BPs, the cuff instantly reinflates and recordings for cSBP are carried out at diastolic pressure levels for ~10 s [8]. For each participant, we compared the three readings of the central BP values obtained from the Mobil-O-Graph and the SphygmoCor device consecutively. Differences between the central BP values of the test device and the SphygmoCor device were calculated for each measurement and presented as mean (SD). The correlation between variables was assessed using Pearson’s correlation coefficients. Differences between cSBP and pSBP estimates were assessed using paired Student’s t-tests. P values lower than 0.05 were considered as statistically significant. Furthermore, data were analyzed using the methods of Bland–Altman [9]. Analyses were performed using GraphPad Prism 5 (GraphPad Software, La Jolla, California, USA).

Results
The basic population characteristics are shown in Table 1. The male/female ratio was 55/45 and 56 of all participants were hypertensive according to the European Society of Hypertension guidelines [10] (prevalence of 56%).

During the estimation of central BP, Mobil-O-Graph and SphygmoCor were used according to the instructions of the manufacturers. Three repeated measurements of all central pressure estimates were conducted consecutively. Mobil-O-Graph BP measurements were completely error free. In five of 100 cases, SphygmoCor measurements must be repeated once because of quality index adherence. cSBP-Mobil-O-Graph and cSBP-SphygmoCor are the cSBP values computed by the Mobil-O-Graph and the SphygmoCor and were 123.7±15.7 and 124.3±16.8 mmHg, respectively. The differences observed between the average values of cSBP are presented in Fig. 1. When using both devices according to the instructions of the manufacturers, the corresponding systolic (r = 0.97, P < 0.0001, Fig. 1a) estimates (cSBP-Mobil-O-Graph and cSBP-SphygmoCor) correlated strongly. For cSBP estimation, the mean between-method difference (95% confidence interval) was 0.50 mmHg (Fig. 1b). According to Bland–Altman analyses, repeated measurements showed 95% limits of agreement from –8.36 to 9.37 mmHg for systolic central BPs. The mean pSBP for Mobil-O-Graph was 133.6 (17.1) mmHg. The mean pSBP and cSBP estimates showed a mean difference of 9.4 mmHg for Mobil-O-Graph and SphygmoCor, respectively (P < 0.001).

The intrarater reproducibility between both the devices was also comparable. The first two repeated measurements of each device were used for analysis. Using Bland–Altman analyses (Fig. 2a), the mean differences (95% confidence interval) for cSBP between repeated measurements were 1.89 (0.42–3.36) mmHg and 1.36 (–0.16 to 2.83) mmHg for the SphygmoCor and the Mobil-O-Graph device, respectively. Thus, neither of these differences was statistically significantly different from 0, so that according to Bland–Altman analyses, repeatability could be assumed. The 95% limits of agreement for cSBP were –16.34 to 19.73 and –15.23 to 17.17 mmHg for the SphygmoCor and the Mobil-O-Graph device, respectively.

Discussion
According to Bland–Altman analyses, the results from this study showed no considerable difference between the central systolic pressure estimates from SphygmoCor and Mobil-O-Graph. When both devices were used according to the instructions of the manufacturers, the mean difference in cSBP for both devices was 1695 (–0.06 to 3.476) mmHg. Differences were not statistically significant and were considerably below the thresholds of ±5 (8 SD) mmHg for mean difference and SD recommended by the association for the Advancement of Medical Instrumentation [12]. It appears that the main reason for the slight difference in cSBP may be attributed to differences between the two measurement techniques using applanation tonometry (SphygmoCor) and oscillometric

<table>
<thead>
<tr>
<th>Table 1 Basic population characteristics</th>
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<tbody>
<tr>
<td>Age (years)</td>
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<tr>
<td>57 (13.9)</td>
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<tr>
<td>Height (cm)</td>
</tr>
<tr>
<td>170 (8.7)</td>
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<tr>
<td>Weight (kg)</td>
</tr>
<tr>
<td>80 (18.1)</td>
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<tr>
<td>BMI (kg/m²)</td>
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<tr>
<td>27 (5.1)</td>
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<tr>
<td>SBP (mmHg)</td>
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<tr>
<td>133.6 (17.1)</td>
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<tr>
<td>DBP (mmHg)</td>
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<tr>
<td>88.2 (12.6)</td>
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<tr>
<td>MAP (mmHg)</td>
</tr>
<tr>
<td>103.4 (12.9)</td>
</tr>
<tr>
<td>HR (beats/min)</td>
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<tr>
<td>69 (14.2)</td>
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DBP, diastolic blood pressure; HR, heart rate; MAP, mean arterial pressure; SBP, systolic blood pressure.
Waveform detection (Mobil-O-Graph) depending on the manufacturer’s calculation algorithm and transfer function, respectively. During repeated measurements, the intrarater reproducibility was also comparable between both the devices and did not differ significantly. In comparison with radial applanation tonometry by the SphygmoCor, the Mobil-O-Graph does not provide any information to the user on which of these oscillometric curves are used for the calculation of the central BP estimates and which are recognized as artifacts and excluded. In contrast, this information is provided by the SphygmoCor software, which marks in red the curves that are inaccurate and have not

Fig. 1

![Graph 1](image)

(cSBP-Mobil-O-Graph and cSBP-SphygmoCor are the central systolic (cSBP) pressures as computed by Mobil-O-Graph and SphygmoCor, respectively when using both devices according to the instructions of the manufacturers: regression (a) and Bland–Altman plot (b). Peripheral systolic blood pressures (pSBP) were obtained using the validated [11] Mobil-O-Graph during each measurement cycle.)

Fig. 2

![Graph 2](image)

Intrarater reproducibility of central systolic blood pressure (cSBP) measurements by the SphygmoCor (a). Intrarater reproducibility of central SBP measurements by the Mobil-O-Graph (b).
been used for analysis. The Mobil-O-Graph software does not provide a warning when data do not satisfy a given quality. This operator index is given by the SphygmoCor. As the Mobil-O-Graph is a validated 24-h BP measurement device [8], it can be easily used for central BP estimation during the first measurement cycle. Thus, it also provides central BP within one measurement. 24-h oscillometric detection of central BP during a 24-h ambulant blood pressure measurement (ABPM) was not conducted in this study, although it is possible according to the manual provided by the manufacturers. Validation of 24-h central BP measurement during 24-h ABPM should be assessed in further studies.

Limitations
The most important limitation of this study is the lack of invasive central systolic pressure values. Although we consider the cSBP used in this study as the best non-invasive estimate for central systolic pressure, comparison of the central pressure estimates of Mobil-O-Graph and SphygmoCor with direct invasive measurements of aortic pressure is still recommended. The technique integrated in the Mobil-O-Graph has been tested in a different device called ARC-Solver (Austrian Institute of Technology, Vienna, Austria) [13]. The technique for measurement of central BP was tested by invasive studies. In contrast, the possibility of a successful estimation of central aortic systolic BP by a multivariate prediction model using an oscillometric BP monitor in comparison with invasive measurements was also shown by Cheng et al. [14]. Furthermore, the Mobil-O-Graph and SphygmoCor were not applied in a randomized order. For practical reasons, each patient was first measured with Mobil-O-Graph and then with SphygmoCor. Although patients were at rest during both measurements, it cannot be established with certainty that BP remained unchanged. First measured brachial BP was used to calibrate the radial waveforms from the SphygmoCor device for all ongoing measurements. Oscillometric-derived waveforms of the Mobil-O-Graph a cSBP estimates could be generated newly during each measurement cycle. Hence, the measurement accuracy of Mobil-O-Graph regards BP changes directly without measurement delay as known by applanation tonometry. Both devices yielding almost identical cSBP predictions, this effect seems negligible under the study conditions, but may be important for example, during 24-h estimation of central BP.

Conclusion
In conclusion, when the SphygmoCor and Mobil-O-Graph were used according to the instructions of the manufacturers, the mean difference in cSBP predicted by both devices was 1695 (– 0.06 to 3.476) mmHg. Thus, oscillometric noninvasive estimation of cSBP with the Mobil-O-Graph BP device is as effective as using the well-established SphygmoCor applanation tonometry device. In comparison, the Mobil-O-Graph combines the widespread benefits of brachial BP measurement and – within one measurement cycle – also provides central BP. There is no measurement delay, which is present in applanation tonometry. The Mobil-O-Graph also provides the possibility to measure central BP during 24-h ABPM, which was not conducted in this study. Further examinations have to be made to validate this prospective feature.

Acknowledgements
Conflicts of interest
There are no conflicts of interest.

References
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5 Weis et al