Comparison of the Complior Analyse device with Sphygmocor and Complior SP for pulse wave velocity and central pressure assessment

Francesco Stea\textsuperscript{a,b}, Erwan Bozec\textsuperscript{c}, Sandrine Millasseau\textsuperscript{d}, Hakim Khettab\textsuperscript{c}, Pierre Boutouyrie\textsuperscript{e}, and Stéphane Laurent\textsuperscript{f}

Background: The Complior device (Alam Medical, France) was used in epidemiological studies which established pulse wave velocity (PWV) as a cardiovascular risk marker. Central pressure is related, but complementary to PWV and also associated to cardiovascular outcomes. The new Complior Analyse measures both PWV and central blood pressure during the same acquisition. The aim of this study was to compare PWV values from Complior Analyse with the previous Complior SP (PWVcs) and with Sphygmocor (PWVscr; AtCor, Australia), and to compare central systolic pressure from Complior Analyse and Sphygmocor.

Method: Peripheral and central pressures and PWV were measured with the three devices in 112 patients. PWV measurements from Complior Analyse were analysed using two foot-detection algorithms (PWVca\_it and PWVca\_cs). Both radial (ao-SBPscr) and carotid (car-SBPscr) approaches from Sphygmocor were compared to carotid Complior Analyse measurements (car-SBPca). The same distance and same calibrating pressures were used for all devices.

Results: PWVca\_it was strongly correlated to PWVscr ($R^2 = 0.93$, $P < 0.001$) with a difference of $0.0 \pm 0.7$ m/s. PWVca\_cs was also correlated to PWVcs ($R^2 = 0.90$, $P < 0.001$) with a difference of $0.1 \pm 0.7$ m/s. Central systolic pressures were strongly correlated. The difference between car-SBPca and ao-SBPscr was $3.1 \pm 4.2$ mmHg ($P < 0.001$), statistically equivalent to the difference between car-SBPca and ao-SBPscr ($3.9 \pm 5.8$ mmHg, $P < 0.001$), whilst the difference between car-SBPca and car-SBPca was negligible ($-0.7 \pm 5.6$ mmHg, $P = \text{NS}$).

Conclusion: The new Complior Analyse device provides equivalent results for PWV and central pressure values to the Sphygmocor and Complior SP. It reaches Association for the Advancement of Medical Instrumentation standard for central blood pressure and grades as excellent for PWV on the Artery Society criteria. It can be interchanged with existing devices.

Keywords: arterial stiffness, central pressure, Complior, pulse wave velocity, validation

Abbreviations: ao-SBPscr, aortic SBP from transformed radial pressure with Sphygmocor; BP, blood pressure; car-SBPca, central SBP from Complior Analyse; car-SBPscr, carotid SBP from Sphygmocor; cBP, central blood pressure; PWV, pulse wave velocity; PWVca, pulse wave velocity measured with the Complior Analyse; PWVca\_cs, pulse wave velocity from Complior Analyse with the Complior SP algorithm; PWVca\_it, pulse wave velocity from Complior Analyse with the intersecting tangent algorithm; PWVcs, pulse wave velocity measured with the Complior SP; PWVscr, pulse wave velocity measured with the Sphygmocor; scr, Sphygmocor device

INTRODUCTION

Aortic stiffness measured by carotid-femoral pulse wave velocity (PWV) has proven its clinical importance as an independent marker of cardiovascular risk and mortality in the general population [1–7] and in a variety of disease conditions including renal failure [8–14], diabetes [15], stroke [16–18] and hypertension [19–21]. Most of these epidemiological studies have been performed with the Complior device (Alam Medical, France) [1,4,5,9,12,14,18–20] as it provides rapid and reproducible assessment of PWV [22,23]. Complior uses simultaneous carotid and femoral measurements and is advised by the Artery Society [24]. Although widely used for PWV measurement, sensors used in the previous version were not sufficiently responsive for performing pressure wave analysis. In its latest evolution, Complior Analyse is equipped with high-quality pressure sensors which have been shown to record invasive signals accurately [25]. It is therefore now possible during standard PWV measurement to assess central pressure directly from carotid waveforms. Carotid pressure waveforms have been shown to be relatively similar to aortic pressure waves [26,27]. Three out of six studies showing that central pressure predicts cardiovascular mortality better than peripheral pressure have been performed from carotidograms [26–30].
two from invasive aortic waveforms [31,32] and only one from estimated aortic waveforms [33].

The previous version of Complior has been validated for PWV values [22,34,35]. Since then, the Artery Society has produced guidelines and a protocol to validate noninvasive PWV devices [24]. However, to date, no standardized protocol exists to validate measurement of central pressure. As sensors and the algorithm to detect the foot of the waveform have changed, the first aim of the present study was to estimate the ability of the Complior Analyse device to measure PWV following the protocol from the Artery Society. The second objective was to compare central systolic pressure values measured with Complior Analyse with noninvasive assessments of central pressure with the Sphygmocor CVMS device (AtCor, Australia).

**METHODS**

One hundred and twelve patients were recruited subsequently from the Artery Research Laboratory in European Hospital of George Pompidou. Measurements were performed as part of clinical research studies or part of a routine arterial screening procedure including among other things, central pressure, carotid-femoral PWV, carotid intima–media thickness and carotid wall characterization. All patients gave written informed consent.

**Pulse wave velocity study**

After 10 min of supine rest, peripheral blood pressure was measured every 3 min to check haemodynamic stability. Carotid femoral PWV was then measured alternatively by trained operators (F.S. and E.B.) in triplicate with the previous Complior SP device (PWVcs), with the Sphygmocor (PWVscr) and with the new Complior Analyse device (PWVca). Single recordings were deemed acceptable if the SD of PWV recording was below 0.5 m/s. Distance was assessed as 0.8 times the direct surface measurement between the carotid and femoral arterial sites as now recommended [36]. The same distance was used for the three devices.

Both Complior SP and Sphygmocor were used as comparison devices. Indeed, Complior SP was used in numerous epidemiological studies [1,4,5,9,12,14,18–20]. It measured simultaneous distension waveforms sampled at 4 kHz on 12 bits and qualified as the recommended noninvasive reference for the Artery Society protocol [24]. However, the foot of the waveforms is detected with a validated proprietary algorithm based on the second derivative and auto-correlation [22]. This algorithm has been found to differ from the now recommend intersecting tangent algorithm, especially for higher values of PWV [37].

The Sphygmocor system (v8.2; AtCor, Australia) uses ECG-gated tonometric measurement sampled at 128 Hz on 12 bits and the intersecting tangent algorithm. As such, it only qualified as ‘secondary reference’ in the Artery Society guidelines [24].

The new Complior Analyse system uses simultaneous pressure signals sampled at 1 kHz on 16 bits and allows both algorithms to be used. Complior Analyse PWV values with SP algorithm (PWVca_cs) were hence compared to Complior SP PWV values (PWVcs), whereas values from the Complior Analyse with the intersecting tangent algorithm (PWVca) were compared to Sphygmocor PWV values (PWVscr).

**Central pressure study**

Radial and carotid tonometry with Sphygmocor was performed to assess central pressure. Radial tonometry waveforms were calibrated to brachial cuff systolic and diastolic pressures performed immediately before testing and used to estimate aortic systolic pressure with the Sphygmocor’s generalized transfer function (ao-SBPscr). Carotid waveforms were calibrated to cuff diastolic pressure and mean pressure assessed from the area under the radial curve [38]. No transfer function was applied on the carotid waveforms, and carotid systolic pressure was obtained from direct calibration of the carotid waveform (car-SBPscr) using mean and DBP. Carotid systolic pressure from Complior Analyse (car-SBPca) was obtained from carotid traces acquired during the PWV assessment. It has to be highlighted that ao-SBPscr is an estimation of the aortic arch systolic pressure, whereas car-SBPscr and car-SBPca are direct measures at the carotid level. While carotid and aortic pressures are usually both referred to as central pressure, it is important to note that they are actually from different anatomical sites. In order to compare accuracy of signal recordings, Complior Analyse and Carotid Sphygmocor traces were calibrated using the same brachial cuff diastolic and integrated mean radial pressures. All measures were done in triplicate.

**Statistics**

For each patient, the average of the three recordings taken with each device was calculated. The coefficient of variation was calculated as averaged patient mean SD divided by the patient mean value and expressed as a percentage. Scatter plot and Pearson’s correlation coefficient were used to check correlation between variables. A Bland Altman plot was used to assess the amplitude of the difference and check the absence of trend across the value range. The accuracy criteria for PWV were taken from the Artery Society guidelines document [24].

Pulse wave velocity measurements were classified as ‘excellent’ if the mean difference is below 0.5 m/s and the SD of the difference 0.8 m/s, and as ‘acceptable’ if the mean difference is below 1.0 m/s and SD 1.5 m/s or less. The standard requirements for the noninvasive brachial BP monitors from the Association for the Advancement of Medical Instrumentation (AAMI) [39] were used to evaluate the accuracy of agreement between central systolic pressure values: mean difference below 5 mmHg and SD below 8 mmHg.

**RESULTS**

**Pulse wave velocity validation**

Three patients were discarded for PWV analysis for failing to obtain in triplicate with one of the three devices good quality carotid recordings which prevent correct foot detection (one per device). Two were further discarded because both blood pressure and heart rate, or either of the two, varied by more than 10 mmHg or 5 b.p.m. between devices.
Characteristics of the remaining 107 patients are shown on Table 1.

Coefficient of variation values were 5.25% for PWVscr, 4% for PWVcs, 3.4% for PWVca with the intersecting tangent algorithm and 3.0% for PWVca with the 2nd derivative algorithm.

As expected from the literature [37,40], PWVscr and PWVcs were strongly correlated (\( R^2 = 0.87 \), \( P < 0.001 \)), but they were different, especially for higher value of PWV, with Complior SP underestimating PWV compared to Sphygmocor as shown on Fig. 1 (overall mean difference = 0.3 ± 0.9 m/s, \( P = \text{NS} \)). The accuracy between these two devices reached ‘acceptable’ on the Artery Society guidelines [24].

Pulse wave velocity measured with the Complior Analyse with the intersecting tangent algorithm was strongly correlated with PWVscr (\( R^2 = 0.93 \), \( P < 0.001 \)) with very little difference (error = 0.0 ± 0.7 m/s, \( P = \text{NS} \)) and no trend across the PWV range (see Fig. 2). This rated ‘excellent’ on the accuracy criteria from the Artery Society [24].

Pulse wave velocity measured with the Complior Analyse with the SP algorithm was also strongly correlated with PWVcs (\( R^2 = 0.90 \), \( P < 0.001 \)). The difference and its SD between the previous and the latest version of Complior were 0.1 ± 0.8 m/s (\( P = \text{NS} \)) reaching the ‘excellent’ grade (Fig. 3).

Central pressure comparison

Fourteen patients were discarded due to inability to get good-quality carotid recordings in triplicate with stable peripheral blood pressure: nine with the Sphygmocor device, six with the Complior Analyse device, including two on both devices.

Characteristics of the remaining 98 patients are shown on Table 1. Measurements of central systolic pressures from direct carotid traces with Sphygmocor (car-SBPscr) and Complior Analyse (car-SBPca) showed very strong correlation (\( R^2 = 0.94 \), \( P < 0.001 \); Fig. 4). The difference and its SD was small and fulfilled the AAMI criteria (0.7 ± 5.6 mmHg, \( P = \text{NS} \)).

TABLE 1. Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD</th>
<th>Range</th>
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<tbody>
<tr>
<td>PWV validation (n = 107) (55 men and 52 women)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>47.2 ± 15.7</td>
<td>16–83</td>
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<tr>
<td>BMI (kg/m(^2))</td>
<td>24.5 ± 4.2</td>
<td>17.4–35.4</td>
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<td>SBP (mmHg)</td>
<td>128 ± 51</td>
<td>91–224</td>
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<tr>
<td>DBP (mmHg)</td>
<td>70 ± 11</td>
<td>46–108</td>
</tr>
<tr>
<td>HR (bpm.)</td>
<td>66 ± 10</td>
<td>45–95</td>
</tr>
<tr>
<td>PWV Sphygmocor</td>
<td>8.6 ± 2.5</td>
<td>5.1–19.9</td>
</tr>
<tr>
<td>PWV Complior SP</td>
<td>8.2 ± 2.1</td>
<td>4.9–17.6</td>
</tr>
<tr>
<td>PWV Complior Analyse intersecting tangents algorithm</td>
<td>8.6 ± 2.6</td>
<td>5.3–19.4</td>
</tr>
<tr>
<td>PWV Complior Analyse peak of second derivative algorithm</td>
<td>8.3 ± 2.4</td>
<td>5.2–18.3</td>
</tr>
<tr>
<td>Central pressure validation (n = 98) (49 men and 49 women)</td>
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<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>47.4 ± 15.4</td>
<td>18–83</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>24.6 ± 4.2</td>
<td>17.6–35.4</td>
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<tr>
<td>Peripheral SBP (mmHg)</td>
<td>131 ± 20</td>
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<td>Peripheral DBP (mmHg)</td>
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<td>Peripheral MBP (mmHg)</td>
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<tr>
<td>HR (bpm.)</td>
<td>66 ± 10</td>
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<td>Aortic SBP (Sphygmocor, transfer function)</td>
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<td>84–220</td>
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<td>Carotid SBP (Sphygmocor)</td>
<td>121 ± 24</td>
<td>83–246</td>
</tr>
<tr>
<td>Carotid SBP (Complior Analyse)</td>
<td>120 ± 22</td>
<td>88–232</td>
</tr>
</tbody>
</table>

HR, heart rate; MBP, mean blood pressure; PWV, pulse wave velocity.

FIGURE 1 Comparison of pulse wave velocity values from Sphygmocor device (PWVscr) and the Complior SP device (PWVcs). Left: scatter plot with regression line (solid line). The dotted line represents the identity line. Right: Bland–Altman plot of the difference.
When compared to aortic pressure estimated from radial waveforms with Sphygmocor (ao-SBPscr), car-SBPca was also strongly correlated ($R^2 = 0.96$, $P < 0.001$; Fig. 5), but the Bland-Altman analysis showed a small significant difference between the two anatomically different sites (error = $3.1 \pm 4.2$ mmHg, $P < 0.001$; Fig. 5). This difference was of the same magnitude as the one observed between carotid and estimated aortic from Sphygmocor ($R^2 = 0.96$, $P < 0.001$, error = $3.7 \pm 5.5$, $P < 0.001$; Fig. 6). However, they both still fulfilled the AAMI criteria.

**DISCUSSION**

The study showed that the new Complior Analyse device provides similar PWV results to the Sphygmocor CVMS device or to the previous Complior SP device when a matching algorithm is used. Central pressure measurement from the carotid with Complior Analyse was also comparable to noninvasive Sphygmocor estimates.

The Complior SP device was used in most epidemiological studies [1,4,5,9,12,14,18–20]. It has been validated in the past when the recommended foot detection algorithm was not the intersecting tangent [22,34,35]. Our results confirm that the new Complior Analyse system is substitutable to older versions of Complior SP when using the same algorithm.

Pulse wave velocity can be assessed with simultaneous measurement, as with Complior, or alternatively, successive ECG-gated acquisitions can be performed. These two approaches have been found equivalent when haemodynamic state is stable [41]. However, our results showed that the coefficient of variation for repeated measures was slightly higher with ECG-gated measurements (5.25% for PWVscr) than with simultaneous measurements (3.4% for PWVca with intersecting tangent algorithm) even in highly controlled conditions where blood pressure and heart rate were very stable.

Several algorithms have been proposed to detect the foot of the waveform [22,42,43]. They are unfortunately not equivalent, especially regarding higher values of PWV [37,43,44]. However, as it is less sensitive to measurements artefact and shows the least variability [42], the Artery Society [24] and the Expert consensus on arterial stiffness [36] recommend the use of ‘intersecting tangent’ algorithm. This algorithm is now implemented in the latest version of the Complior system and shows quasi perfect agreement with the Sphygmocor v8.2 device with no trend across PWV range (right panel, Fig. 2). A recent publication [45]
comparing carotid to leg cuff approach to Sphygmocor CVMS showed an overall small difference, but with a much higher discrepancy for higher value of PWV, therefore questioning its applicability in higher-risk patients.

After foot-detection algorithm, the second parameter largely influencing PWV is the arterial distance. Because our aim was to compare techniques, we chose to use the same distance for each device. Indeed, when comparing two techniques, the use of the correct distance is less important than using identical distance values for the three devices. Using a different distance methodology (calliper instead of tape measure, for example) would only have modified absolute values of PWV. Similar results are obtained by comparing directly transit time. It would not change our conclusion that Complior Analyse PWV measure reaches ‘excellent’ on the Artery Society criteria.

As recommended, our study population had a large range of age and blood pressure; however, only 25% of the study group had an elevated PWV value (>10 m/s). Hence, our results might not be generalized to a population of patients with very stiff arteries.

With its new pressure sensors, Complior Analyse now records carotid pressure waveforms during the standard PWV measurement.

The accuracy to correctly monitor invasive pressure traces has been published elsewhere with good agreement between harmonics content of invasive and Complior Analyse waveform [25]. Sphygmocor tonometer also showed similar frequency content to invasive waveforms [46]. The quality of central pressure assessment relies on the fidelity of recording of the pressure wave, coupled with adequate calibration. Because of increased capacity of analog to digital converters, Complior Analyse, compared to SphygmoCor, allows an 8x increase in time resolution and improved dynamics by 10 dB, which might contribute to the good performance of this device. Both Complior Analyse and SphygmoCor devices use applanation tonometry, which provide uncalibrated waveforms whose amplitude and offset depends on the applied pressure, on the underlying tissue characteristics and on intra-arterial pressure. Our results here show that provided with a similar calibration, Complior Analyse gives similar central systolic pressure to Sphygmocor. The Sphygmocor device has been extensively validated and shows good agreement with invasive pressure when invasively calibrated [47].

We have shown that there is an excellent agreement between SphygmoCor and Complior Analysis devices in terms of waveform analysis and we obtained values of

![Figure 4](image_url)

**FIGURE 4** Comparison of central systolic pressure measured from Sphygmocor carotid traces (car-SBPscr) and Complior Analyse carotid traces (car-SBPca). Left: scatter plot with regression line (solid line). Right: Bland–Altman plot of the difference.

![Figure 5](image_url)

**FIGURE 5** Comparison of central systolic pressure estimated from Sphygmocor radial traces (ao-SBPscr) and Complior Analyse carotid traces (car-SBPca). Left: scatter plot with regression line (solid line). Right: Bland–Altman plot of the difference.
central pressure that are practically similar. Thus, both devices are interchangeable.

Our results also highlight the presence of a small difference between aortic and carotid systolic pressure which is expected on physiological grounds. Whereas carotid and ascending arteries are geographically and functionally very close, the 10–15 cm difference between the two sites might explain the obtained amplification of 3 mmHg between carotid and aortic pressures. Invasive studies comparing carotid and aortic waveforms did not focus on central systolic pressure [20,27]; however, Salvi et al. [41] reported a difference of 2.5 mmHg between the two sites, which is comparable to our results. In their study comparing invasive pressures with carotid distension waveforms, Van Bortel et al. [38] also found similar difference (3.8 mmHg). This difference is small and falls well within the AAMI criteria. It does not invalidate studies showing that central pressure is a stronger predictor of cardiovascular events and mortality than peripheral pressure [28–30]. Despite that the carotid approach is the one the most used in mortality studies, it has been mentioned that good-quality carotid waveforms can be difficult to obtain with tonometry. Indeed, the absence of underlying bony structure, the presence of the soft tissues and the proximity of the trachea can make the measurement difficult as shown by the fact we had to discard 10% (14 out of our 112) of the patients due to inability to perform triplicate measurements with both devices. Here we were able to use the ‘real’ mean blood pressure by integrating radial blood pressure. Because there are small but quantifiable differences between brachial and radial pressure waveforms form factors, and because application of radial artery may not be routinely performed with Complior Analyse, the use of calculated mean arterial pressure might induce larger discrepancies with alternative methods.

The new Complior Analyse system is equivalent to Complior SP or SphygmoCor devices when the appropriate algorithm is used and it grades ‘excellent’ on the Artery Society criteria. Carotid-femoral PWV is a recommended parameter to assess organ damage and cardiovascular risk in the management of arterial hypertension [48]. Our results show that the medical device industry is actively working to provide accurate and reliable systems to the market. This will surely contribute to the expansion of the measurement of arterial stiffness in routine patient risk assessment.

Complior Analyse new pressure sensor with appropriate calibration allows accurate measurement of central systolic pressure directly from the carotid with no assumption or mathematical modelling. It could hence be used in research studies and clinical routine, especially in patients when the application of a transfer function is questionable such as children or patients with upper arm arterial calcification.

ACKNOWLEDGEMENTS

Conflicts of interest

S.M. works as a freelance specialist on pulse wave analysis and receives revenues from several medical devices companies including Alam Medical and AtCor Medical whose devices have been used in this work.

REFERENCES

Validation of the Complior Analyse device

Reviewer’s Summary Evaluation

Reviewer 1
A strength of this comparison of carotid-femoral PWV and estimated central BP assessed in the same individual at the same session using the Complior (original and new versions) and SphygmoCor devices is that it employed the same transit distances and BP readings in all devices; as such it is probably as close to a valid comparison as possible. It provides useful information to those choosing a particular device, but also raises general issues related to noninvasive assessment. In particular, whether a different device can be used to compare previous results obtained in an individual using another device. While SphygmoCor and the original Complior have been available for a long time none of the available devices truly provide a result any more valid than others.