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COMPARISON OF TWO INSTRUMENTS
THAT MEASURE PULSE WAVE VELOCITY

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ABSTRACT

Background. Measurements of the carotid-femoral pulse wave velocity (PWVcf) by applanation tonometry as used by the SphygmoCor are used in adults to assess arterial stiffness. In young children, however, this method is difficult to perform. Therefore, techniques are needed that are less dependent on patient compliance. The Vicorder device uses the oscillometric technique to measure the PWVcf. This automatic method is thought to be easier to use, less time consuming and less dependent on operator skills.

Aim. The aim of this study was to compare the PWVcf measured by an extensively used device (SphygmoCor) and the Vicorder.

Methods. 38 healthy volunteers (20 men, mean age 48 ± 13.1 years) participated in this cross-sectional study. The PWVcf was assessed twice by both the SphygmoCor and the Vicorder by a single investigator during one visit. Intra-rater reproducibility of each instrument and comparison between the two instruments were assessed by the Bland-Altman method.

Results. The mean difference [95% Confidence Interval] between repeated measurements was 0.09 [-0.20 – 0.38] m/s and 0.24 [-0.55 – 1.03] m/s, for the SphygmoCor and Vicorder, respectively. The Limits of Agreement were -1.53 – 1.71 m/s and -4.24 – 4.72 m/s, for the SphygmoCor and Vicorder, respectively. The PWVcf measured by the Vicorder was 0.58 [-0.20 – 1.35] m/s higher than the PWVcf measured by the SphygmoCor. The Limits of Agreement between the two instruments were -3.50 – 4.66 m/s.

Conclusions. The Limits of Agreement of the Vicorder PWVcf measurements are considered too wide for using this technique reliably in adults or in children.
INTRODUCTION

Carotid-femoral PWV (PWVcf) is nowadays considered the ‘gold-standard’ indicator of arterial stiffness [1]. PWVcf has been demonstrated to be a strong predictor of cardiovascular mortality in various patient populations, especially in patients with End Stage Renal Disease (ESRD) [2]. In children and young adults with ESRD the mortality is mainly due to cardiovascular disease [3]. Therefore, PWVcf measurement might be a valid indicator of the extent of vascular damage in this patient group and could be used to identify patients at higher risk of cardiovascular disease.

Although measuring the PWV over the carotid-femoral trajectory has been considered the gold standard in a recent guideline [1], there is no consensus about which measurement method is the most valid and reliable [4]. Therefore, various non-invasive techniques have been used like computerized oscillometry [5], tonometry [6], ultrasound [7, 8] and methods using mechanotransducers[9].

The SphygmoCor is an instrument using applanation tonometry that has been extensively used, is easily performed in adults and has a fair reproducibility [10, 11]. However, we noticed that in young children the measurements by the SphygmoCor are often difficult to carry out as they are time consuming and require some degree of patient cooperation. Therefore we searched for a new device that is better applicable in children.

The Vicorder is a new automatic device that was originally used to measure differences in blood pressure like the ankle-brachial index [12]. It has been adapted to measure the PWVcf by adding a neck pad which is placed over the carotid artery. The Vicorder uses the oscillometric technique to measure the PWVcf, through the inflation of this neck pad and a cuff around the thigh. It is presented as a simple and quick non-invasive method which is little dependent on operator skills and experience [13].

Before investigating the clinimetric properties of the Vicorder in children, we decided to test the validity of the instrument in adults. To this purpose, we compared the Vicorder with the SphygmoCor in a group of adults in an ongoing study. The precise aims of the current study are the following:

» to compare the test-retest reproducibility of the PWVcf measurements with the SphygmoCor and the Vicorder; and

» to investigate the comparability of the PWVcf measurements with both instruments.

METHODS

Participants

The HORCIA study is a single centre cohort study to detect late sequelae of radio- and chemotherapy in survivors of Hodgkin lymphoma. To detect preclinical markers of cardiovascular disease, PWVcf measurements with the SphygmoCor are performed in all patients. Forty spouses of the patients were randomly selected and asked to participate as control subjects. These control subjects also underwent PWVcf measurements in order to have reference values for their spouses. These volunteers were invited to participate in the
present cross-sectional study. Ethical approval has been given by the Institutional Review Board of the St. Antonius hospital in Nieuwegein.

**Technique**

All participants were measured twice with both devices during a single visit. The measurements were performed as described in the manual of each device. Prior to the measurements the participants took 10 minutes of rest lying supine in a quiet room. Blood pressure (BP) was measured before each PWVcf measurement. The BP was measured using an automatic oscillometric device (Model MX3 Plus, Omron Matsusaka, Tokyo, Japan). All measurements were done by one researcher in the same room. The order of PWVcf measurements was as follows: Vicorder1, SphygmoCor1, SphygmoCor2 and Vicorder2.

**SphygmoCor**

The SphygmoCor (Model SCOR-Px, Software version, 7.01, AtCor Medical Pvt. Ltd, Sydney, Australia) uses a single high-fidelity tonometric Millar transducer. To determine the PWVcf, the pulse wave is recorded sequentially at the femoral artery and at the carotid artery by the transducer. A simultaneously recorded electrocardiogram (ECG) is used as a reference to calculate wave transit time. Transit time between carotid and femoral pressure waves is calculated using the ‘foot-to-foot’ method. Wave ‘feet’ are identified using intersecting tangent algorithms. Two surface distances are measured by the investigator: between the recording point at the carotid artery and the sternal notch (distance 1) and between the sternal notch and the recording point at the femoral artery (distance 2). The distance travelled by the pulse wave (DPW) is calculated by the SphygmoCor as (distance 2) - (distance 1). The PWVcf is then calculated as $\text{PWVcf} = \frac{\text{DPW (m)}}{\text{transit time (s)}}$.

**Vicorder**

The Vicorder (Skidmore Medical Limited, Bristol, United Kingdom) is a new device that received FDA approval on December 20th 2007 [12]. The Vicorder simultaneously records the pulse wave from the carotid and femoral site by using the oscillometric method. First a neck pad which is only inflatable over several centimetres is placed around patient’s neck. This pressure pad is applied over the right carotid artery to prevent compression of the trachea and compression of both carotid arteries at the same time. Next a cuff is placed around patient’s upper right thigh. Both carotid and femoral cuffs are inflated automatically to 65mmHg and the corresponding oscillometric signal from each cuff is digitally analyzed to extract, in real time, the pulse time delay. After acquiring several steady pulses the investigator “freezes” the recording on the display and the Transit Time in milliseconds is presented. DPW is measured as follows: $\text{DPW} = \text{the distance between the upper edge of the femoral cuff and sternal notch minus the distance between the lower edge of the carotid cuff and sternal notch}$. This value is entered into the computer and the Vicorder software computes the PWVcf.
Statistics
For the intra-rater reproducibility Bland-Altman plots were used [14]. Intraclass Correlation Coefficients (ICC) and Coefficients of Variation (CV) were calculated as well, as previously described by others [15]. The measurement results of the two devices were compared by Bland-Altman plots. In a Bland-Altman plot the differences between two measurements per patient are plotted against the means of two measurements per patient. If differences are associated with mean values, a correction has to be applied. The 95% Confidence Interval of the mean difference should include zero to exclude systematic differences. The Limits of Agreement (LoA) (± two times the Standard Deviation of the differences per patient) indicate the range between successive measurements in a subject without real change. Only changes greater than the LoA can be interpreted as “real” change, not due to measurement error. All analyses were performed using SPSS 16.2. P-values smaller than 0.05 were considered statistically significant.

RESULTS
Of the 40 invited subjects 38 were willing to participate. Two female subjects did not participate for practical reasons not related to the study. Table 1 summarizes the characteristics of the study group.

Useful results of repeated measurements were obtained in a total of 30 subjects. In three subjects the PWVcf values obtained by the SphygmoCor were rejected because of quality control reasons as described elsewhere [11]. One or both Vicorder recordings were missing in five patients for various reasons, mainly because they were not saved properly.

The mean difference [95% Confidence Interval] between repeated measurements was 0.09 [-0.20 – 0.38] m/s and 0.24 [-0.55 – 1.03] m/s, for the SphygmoCor and Vicorder, respectively. This means that neither of these differences was statistically significant different from 0. The LoA were -1.53 – 1.71 m/s and -4.24 – 4.72 m/s, for the SphygmoCor and Vicorder, respectively (Fig.1 and Fig.2). The ICC was 0.76 and 0.54 for the SphygmoCor and the Vicorder, respectively. The CV was 9% and 22% for the SphygmoCor and the Vicorder, respectively.

Table 1. Demographic characteristics of the study group (n=38).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean</th>
<th>SD</th>
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<tr>
<td>Male*</td>
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<tr>
<td>Age (years)</td>
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<td>Weight (kg)</td>
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<td>Height (cm)</td>
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<td>BMI (kg/m²)</td>
<td>25.9</td>
<td>3.3</td>
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<tr>
<td>Heart rate (bpm)</td>
<td>60.2</td>
<td>10.2</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>127.9</td>
<td>16.8</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>76.3</td>
<td>9.3</td>
</tr>
</tbody>
</table>

* Expressed as n and %
The PWVcf measured by the Vicorder was 0.58 [-0.20 – 1.35] m/s higher than the PWVcf measured by the SphygmoCor, i.e. not statistically significant different. The LoA between the two instruments were -3.50 – 4.66 m/s (Fig.3).

**Figure 1.** Intra-rater reproducibility SphygmoCor.

**Figure 2.** Intra-rater reproducibility Vicorder.
The main finding of our study is that the measurement error of both the SphygmoCor and the Vicorder exceeds a value of 1.5 m/s. This measurement error indicates that changes in an individual less than 1.5 m/s cannot be determined reliably. Although there is no consensus about the size of a minimal clinically relevant difference, the size of this measurement error is larger than what we would consider clinically relevant. The LoA for the Vicorder were much wider than for the SphygmoCor, indicating that the reproducibility of the Vicorder is by far inferior.

The LoA we have found for the PWVcf measured by the SphygmoCor are better than those reported by Wilkinson (-2.27–2.41 m/s) in a group of 10 healthy subjects, 8 hypertensive and 6 hypercholesterolemic patients [10]. Also the CV for the PWVcf measured by the SphygmoCor was in line with values found by others [16]: 13% vs 9% in our study.

SphygmoCor uses the systolic upstroke to detect the pressure wave. Oscillometric devices (Vicorder) detect the moment of maximal pressure. The moment of maximal pressure during the pressure wave can differ from site to site. The systolic upstroke is amplified towards the periphery. At peripheral measurement sites as the brachial artery or the femoral artery the maximal pressure excursion will occur early in systole. In central arteries like the aorta and the carotid artery reflected pressure waves may cause the maximal pressure to occur late during systole. Pressure wave reflections vary from person to person and also from moment to moment. The fact that the maximal pressure occurs early during systole at the femoral artery, and at a later moment in the pressure cycle at the carotid artery, theoretically results in the calculation of a higher PWV. This is in agreement with our observation that we derived a PWV with Vicorder which was, on average, higher than

![Figure 3. Comparison Vicorder and SphygmoCor.](image)

**DISCUSSION**

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the PWV calculated with SphygmoCor. The variability in the moment of maximal pressure excursions caused by variations in reflected pressures might in part explain the differences between PWV as calculated with both techniques. A technique which uses the systolic upstroke (SphygmoCor) is not hampered by variations in pressure later during the pressure cycle, and might thus be expected to show a better reproducibility. This is in agreement with our observations.

As far as we know, this is the first study published using the Vicorder with the neck pad. We believe that the wide LoA values are due to the cuff used at the carotid site. The pulse wave recorded at this site was frequently not accurate, with numerous artifacts being recorded, and irregular shapes of the PWVcf. These might have altered the PWVcf calculations by the Vicorder. We think this is the cause of the inaccurate measurements because the pulse waves recorded at the femoral site had in almost all cases the expected regular shape. Unlike the other cuffs used by the Vicorder, the carotid cuff is not inflatable all around the neck, but just for a few centimeters, to be applied over the right carotid artery. It is possible that this adaptation of the carotid cuff is the cause of the inaccurate measurements because only locally inflating the pad to 65 mmHg may not be enough to exclude other oscillating movements by veins, other arteries than the carotid artery, muscles or air from the trachea. These artifacts are being recorded by the cuff and transmitted to the software, giving rise to additional curves besides the carotid artery pulse wave. However, the Vicorder does not provide any information to the user on which of these oscillometric curves are used for calculation of the PWVcf and which are recognized as artifacts and excluded. This information is provided by the SphygmoCor software which marks in red the curves which are inaccurate and have not been used for analysis.

We became aware of this flaw already at the beginning of the recordings and have tried several ways to reduce the amount of artifacts. We instructed the patients to lie absolutely still, to take a deep breath, exhale and hold their breath while the recordings were made; we tried positioning the head in such way that the neck muscles were completely relaxed, but unfortunately none of these adjustments improved the recordings.

The lack of experience or previous descriptions of the use of the Vicorder may have contributed to the results of the current study. However, we have followed the instructions in the Vicorder manual and those provided on site by a representative of the manufacturer [13]. Furthermore, for five patients, one or two Vicorder recordings were not available, most because of faults in saving the data. This probably did not alter the results of the study, because the available recordings of the remaining 33 subjects were consistent in showing multiple artifacts.

We conclude that the Vicorder, although it may be useful for many other applications, is not suited for accurate measurements of the PWVcf adults or probably in children. Before further research can be initiated with this device, we recommend the manufacturer to improve the neck pad and/or provide more detailed user information to solve the problems we encountered.
REFERENCES


