Comparison of two versions of the Vigileo-FloTrac™ system (1.03 and 1.07) for stroke volume estimation: a multicentre, blinded comparison with oesophageal Doppler measurements

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Background. Our aim was to evaluate the validity of stroke volume measurements obtained using the Vigileo-FloTrac™ system in comparison with those obtained using oesophageal Doppler considered as a reference.

Methods. Prospective, multicentre study (four university hospitals), in which investigators were blinded to stroke volume values acquired simultaneously with the other technique. Two different versions of the Vigileo software (1.03 and 1.07) were studied and compared over two consecutive periods of time. Forty critically ill patients (three ICUs) and 20 high-risk surgical patients (one operating theatre) were studied over a 6-month period.

Results. Two hundred and forty paired stroke volume values obtained using the second version of the Vigileo (1.07) yielded better correlation and agreement (R=0.48, P<0.001; bias=4 ml, limits of agreement: ±41 ml) than the 207 paired values obtained using version 1.03 (R=0.12, P=0.1; bias=1 ml, limits of agreement: ±75 ml). However, even with the second version, the percentage error in stroke volume measurement was 58%, a value still above the range considered clinically acceptable (30%).

Conclusions. The precision of stroke volume estimation using Vigileo-FloTrac™ has improved with the second version of the software (1.07), but remains insufficient to allow the replacement of the reference technique in the population studied.

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Stroke volume (SV) is a useful complement to systemic arterial pressure measurement to quantify the effects of intravascular fluids and other cardiovascular treatments on global tissue perfusion in patients. Various techniques have been developed to estimate flow without the need for pulmonary artery catheter placement. Among these techniques, those based on pulse-contour analysis are very attractive because they provide beat-by-beat cardiac output, i.e. SV. However, these techniques usually require frequent calibration to remain accurate over time. Such calibration can be obtained using transpulmonary thermodilution (PiCCO™, Pulsion, Germany) or lithium chloride dilution (PulseCO™, LiDCO, UK), which increases the invasiveness, the cost, and the complexity of the procedure. A new pulse-contour technique has been recently launched which estimates SV without the need for any calibration. This device called ‘Vigileo-FloTrac™’ (Edwards, Irvine, CA, USA) has been compared with
bolus thermodilution as well as transpulmonary thermodilution. Contradiction exists among studies regarding the ability of this technique to provide reliable SV estimation.\textsuperscript{1–17} Three different versions of the Vigileo software have been used by investigators over the past 2 yr. Since no study has compared the different versions, it is unclear whether the software upgrade itself yielded a significant improvement in measurement accuracy.

We designed a multicentre, double-blind study to evaluate the agreement between SV measurements obtained using oesophageal Doppler and the Vigileo-FloTrac\textsuperscript{TM} system. Two versions of the Vigileo software (1.03 and 1.07) were tested over two consecutive periods of time, which provided us with the opportunity to quantify the improvement associated with the implementation of the second version of the software. We choose to use oesophageal Doppler as our reference technique for SV measurement, because this was the technique used routinely at all centres for flow monitoring. On the basis of the work of Critchley and Critchley,\textsuperscript{18} we prospectively decided that the new technique (Vigileo-FlorTrac\textsuperscript{TM}) would be considered suitable to replace oesophageal Doppler if limits of agreement represented <30\% of mean SV value.

**Methods**

Sixty sedated and mechanically ventilated patients from four centres: two surgical intensive care units (29 patients), one medical intensive care unit (11 patients), and one orthopaedic surgery operating theatre (20 patients) were studied prospectively over a 6-month period. All patients had an indwelling arterial catheter for instantaneous pressure monitoring and an oesophageal Doppler for cardiac output monitoring as part of their standard care (critically ill patients, or ‘high-risk’ surgical patients undergoing major orthopaedic surgery). At the time of entry into the study, the physicians in charge of the patient’s care considered them to be eligible for a fluid challenge on the basis of their clinical status. No additional invasive procedure or blood samples were necessary for this study; therefore, our Institutional Review Board waived the need for informed patient consent. Patients were excluded if they were less than 18 yr old, if they had arrhythmia, or severe aortic stenosis, or if they were pregnant. Two centres used CardioQ\textsuperscript{TM} (Deltex medical) and two centres used Hemosonic\textsuperscript{TM} (Arrow Intl.) oesophageal Doppler monitors. Each centre had expert investigators with its own monitor, i.e. more than 10 yr of routine use of the device in clinical practice. All patients had a 4F arterial catheter inserted in a radial artery.

**Measured variables**

Patient characteristics (age, gender, height, and weight), SAPS2 (critically ill patients) or ASA class (surgical patients), use of vasoactive agents, and haemodynamic data, i.e. heart rate, systemic arterial pressure (systolic, diastolic, and mean), were collected. In addition, we measured SV using oesophageal Doppler (SV\textsubscript{OD}) and Vigileo\textsuperscript{TM} (SV\textsubscript{V}).

**Data acquisition**

Two independent investigators were in charge of acquiring simultaneous SV data. One collected oesophageal Doppler data, while the other was in charge of Vigileo- FloTrac\textsuperscript{TM}. Each investigator was blinded to the results obtained by the other. Oesophageal Doppler SV value was calculated by the monitor as the average of five consecutive cardiac cycles, to smooth possible respiratory variability. SV was calculated by the Vigileo\textsuperscript{TM} monitor from the pressure waveform acquired over the past 20-s period. During the time-course of the study, two versions of the Vigileo\textsuperscript{TM} software were tested and compared. The first 29 patients were studied using version 1.03 of the software and the next 31 patients were studied using version 1.07.

**Study protocol**

Patients were considered haemodynamically stable when three consecutive pressure and flow measures obtained at 1-min intervals varied by <10\%. Baseline values were calculated as the mean of these three measurements. After baseline data collection two consecutive challenges of 250 ml of normal saline were infused rapidly. Haemodynamic data were collected at the end of each fluid challenge. Additional data were collected afterwards at the discretion of investigators, when haemodynamic variations occurred either spontaneously or as the result of a therapeutic intervention dictated by patient’s status.

**Statistical analysis**

The agreement between SVs estimated using Vigileo-FloTrac\textsuperscript{TM} and oesophageal Doppler monitors and between the change in SV between two consecutive measurements, estimated using the two monitors was shown using scatter plots and Bland and Altman plots. Bias and limits of agreement were in the presence of repeated measurements in each group of subjects, we used the method described by Bland and Altman\textsuperscript{19} and modified by Myles and Cui\textsuperscript{20} to take account of repeated measures. The method described by Myles and Cui uses a random effects model to estimate the within-subject variance. Analyses were performed separately for each version of the Vigileo\textsuperscript{TM} software. The effect of fluid challenges on haemodynamic data was assessed using one-way repeated measure ANOVA on ranks. We decided, according to Critchley’s recommendations, that the new technique (Vigileo\textsuperscript{TM}) would be considered clinically interchangeable with oesophageal Doppler if
the percentage error was <30% (i.e., limits of agreement did not represent more than 30% of mean SV).

**Results**

A total of 60 patients were enrolled, of whom 29 were studied using version 1.03 of the Vigileo™ and 31 using version 1.07. The CardioQ™ was used in two centres recruiting 36 patients, while Hemosonic™ was used in two other centres that included 24 patients. The patients’ characteristics are shown in Table 1.

Haemodynamic data (HR, MBP, and SV\textsubscript{OD}) were recorded before (baseline) and after each fluid challenge and are presented in Figure 1.

Two hundred and seven paired SV measurements were obtained in the group of patients studied with version 1.03 of the Vigileo™, and 240 in the group studied with version 1.07. SV values measured using oesophageal Doppler ranged from 17 ml to 146 ml in the group studied with version 1.03 [73 (SD 34) ml], while they ranged from 7 ml to 126 ml in the group studied with version 1.07 [70 (27) ml]. Agreement between SV\textsubscript{OD} and SV\textsubscript{VI} for both versions of the Vigileo™ software is presented in Figure 2 (version 1.03) and Figure 3 (version 1.07). Bias and limits of agreement were 1 ml [774 ml; 776 ml] for version 1.03, and 4 ml [237 ml; 45 ml] for version 1.07. The percentage error for SV measurement was 103% using version 1.03, and was reduced to 58% using version 1.07 (P<10\textsuperscript{-4}).

The proportion of SV values obtained using CardioQ™ (70%) and Hemosonic™ (30%) was the same in the subgroups studied with version 1.03 and 1.07.

The changes in cardiac output between two consecutive measurements, as measured with oesophageal Doppler (ΔSV\textsubscript{OD}) and Vigileo™ (ΔSV\textsubscript{VI}), were also compared. Correlation and agreement are presented in Figure 4 (version 1.03) and Figure 5 (version 1.07). Using the earlier version of Vigileo™, 51 out of 134 (38%) variations in cardiac output yielded opposite changes, i.e. negative variation with one technique and positive with the other. These data points are located in the upper left and lower right corners of Figure 4(A). Using version 1.07, 44 out of 165 variations (26%) yielded opposite changes in cardiac output (Fig. 5A). Bias and limits of agreement

**Table 1** Patient characteristics. Age is given as median [range]. Other results are expressed as mean (SD)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>64.5 [19–92]</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>38/22</td>
</tr>
<tr>
<td>Surgical/ICU</td>
<td>20/40</td>
</tr>
<tr>
<td>ASA score (surgical patients, n=20)</td>
<td>I: n=8, II: n=11, III: n=1</td>
</tr>
<tr>
<td>SAPS2 (critically ill patients, n=40)</td>
<td>53 (16)</td>
</tr>
<tr>
<td>Surgical patients receiving catecholamines: n (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Critically ill patients receiving catecholamines: n (%)</td>
<td>29 (73)</td>
</tr>
</tbody>
</table>

**Fig 1** Box plots showing the effect of two consecutive fluid challenges (250 ml of saline each) on heart rate (A), mean arterial pressure (MAP, B), and SV measured using the oesophageal Doppler (C). *P<0.05 vs baseline; †P<0.05 vs 250 ml. The error bars indicate 10th and 90th percentiles, and the open circles indicate values below or beyond the latter limits, respectively.

**Fig 2** Graphs representing agreement between SV values obtained using oesophageal Doppler (SV\textsubscript{OD}) and Vigileo™ (SV\textsubscript{VI}) with version 1.03 (207 paired cardiac output values, 29 patients). Bias value was 1 ml and limits of agreement were ±75 ml.
were, respectively, 0 ml [−47 ml; +47 ml] for version 1.03 and 0 ml [−35 ml; +35 ml] for version 1.07.

**Discussion**

This multicentre study was undertaken to evaluate the agreement between SVs measured using a new pulse contour technique (Vigileo-FlotracTM, Edwards) with values obtained using the oesophageal Doppler. Two successive versions of the VigileoTM software were tested and compared. The second version (1.07) yielded better agreement and correlation than the previous version (1.03) for SV and SV variations over time. However, even with the second version, the percentage error was still above the range considered clinically acceptable.

Oesophageal Doppler is now widely accepted as a reliable method for cardiac output measurement in clinical practice and has been validated in comparison with thermodilution by several studies. Recently, a meta-analysis of all the studies published reinforced this validity. In the four centres participating into this study, this technique has been routinely used for more than 10 yr as a simple, non-invasive alternative to thermodilution. Thus, we decided to use oesophageal Doppler as our reference method for SV measurement. Different oesophageal Doppler monitors are commercially available. All rely on the measurement of instantaneous blood flow velocity in the descending aorta to calculate aortic velocity–time integral (VTI), but they differ in the final algorithm converting this VTI into SV. HemosonicTM (Arrow Intl.) measures
instantaneous diameter of the descending aorta using M-mode echo, while CardioQ™ (Deltex, UK) uses a nomogram based on age, weight, and height to convert descending aortic VTI into systemic SV. Although the CardioQ™ is the most extensively validated and widely used, it has experience of at least 10 probe placements. The Vigileo™ system became available after the beginning of this trial, giving us the opportunity to evaluate the potential improvement between the two versions.

Present findings

The patients responded to the fluid challenges with a 14% increase in SV and a minor (but significant) increase in arterial pressure, while heart rate was slightly reduced. This haemodynamic response indicates that the patients were fluid-responders and that fluid challenges were not harmful. The correlation and agreement between SV measured using oesophageal Doppler and Vigileo™ were shown to be very good (<10% variation) when observers have experience of at least 10 probe placements. The Vigileo™.FloTrac™ system (Edwards, Irvine, CA, USA) is the latest technique for SV estimation based on arterial pulse-contour analysis. Its exact algorithm remains undisclosed by the manufacturer but relies on the assumption that SV is proportional to pulse pressure and to a factor reflecting arterial mechanical properties (mainly: resistance and compliance). Unlike previous pulse-contour techniques (i.e., PiCCO™, Pulsion, Germany; and PulseCO, LiDCO, UK) that require frequent calibration to ensure adequate measurement accuracy, Vigileo™ does not use external calibration. The arterial pressure waveform is sampled at 100 Hz over 20 s, which provides 2000 data points for analysis by the Vigileo™ monitor. The standard deviation of these pressure values is matched with empirical data to estimate SV at any time. A factor reflecting arterial mechanical properties is calculated using patient demographic characteristics (age, weight, and height) and statistical data derived from pressure waveform analysis (mean, skewness, and kurtosis). Initially, with version 1.03 of the Vigileo™ software, this factor was integrated every 10 min. With the second version (1.07) this delay was reduced to 1 min. The version 1.07 of the Vigileo™ software was considered clinically acceptable.

All previous studies aiming at validating Vigileo™.FloTrac™ cardiac output measurements have used the latest version 1.07 of the Vigileo™ software. The limits of agreement for cardiac output variations were also reduced almost by half as well as the number of contradictory variations in SV.

Table 2 Validation studies of the Vigileo monitor. The software version is shown. Bias and limits of agreement were expressed as indexed values (three studies) or as a percentage (one study). We placed a # next to numbers when exact values were not explicitly provided in the results but could only be estimated from Bland and Altman representations. Percentage error was the ratio (expressed as a percentage) of the limits of agreement to the mean cardiac output. Only a limited number of studies specified that investigators acquiring cardiac output values were blinded to results obtained by the other technique. Reference techniques included: bolus thermodilution through a pulmonary artery catheter (PAC-BTD), continuous cardiac output thermodilution through a pulmonary artery catheter (PAC-CCO), and transpulmonary thermodilution using PiCCO™ (PiCCO-TPTD).

<table>
<thead>
<tr>
<th>Vigileo software version</th>
<th>First author, Yr, ref.</th>
<th>Reference technique</th>
<th>Bias</th>
<th>2 SD</th>
<th>Percentage error</th>
<th>Blinded observers</th>
</tr>
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<tr>
<td>1.03</td>
<td>Sander M, 2006, 2</td>
<td>PAC-BTD</td>
<td>0.6 litre min⁻¹</td>
<td>2.8 litre min⁻¹</td>
<td>54</td>
<td>Not specified</td>
</tr>
<tr>
<td>1.03</td>
<td>Opdam H, 2007, 7</td>
<td>PAC-BTD</td>
<td>0.21 litre min⁻¹</td>
<td>1.02 litre min⁻¹</td>
<td>40 #</td>
<td>Not specified</td>
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<td>1.03</td>
<td>Mayer J, 2007, 9</td>
<td>PAC-BTD</td>
<td>0.46 litre min⁻¹</td>
<td>1.2 litre min⁻¹</td>
<td>46</td>
<td>Yes</td>
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<tr>
<td>1.03</td>
<td>Manecke GR, 2007, 5</td>
<td>PAC-BTD</td>
<td>0.55 litre min⁻¹</td>
<td>1.96 litre min⁻¹</td>
<td>36 #</td>
<td>Not specified</td>
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<tr>
<td>1.03</td>
<td>De Waal EC, 2007, 4</td>
<td>PiCCO-TPTD</td>
<td>0 litre min⁻¹</td>
<td>1.74 litre min⁻¹</td>
<td>33</td>
<td>Not specified</td>
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<tr>
<td>1.03</td>
<td>Lorsomnaree S, 2007, 8</td>
<td>PAC-CCO</td>
<td>−1%</td>
<td>50%</td>
<td>56</td>
<td>Not specified</td>
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<tr>
<td>1.03</td>
<td>Zimmermann A, 2008, 12</td>
<td>PAC-BTD</td>
<td>−0.1 litre min⁻¹</td>
<td>2.9 litre min⁻¹</td>
<td>50 #</td>
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<tr>
<td>1.07</td>
<td>Button D, 2007, 11</td>
<td>PAC-BTD</td>
<td>0.5 (#) litre min⁻¹</td>
<td>2 (#) litre min⁻¹</td>
<td>40 #</td>
<td>Not specified</td>
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<tr>
<td>1.07</td>
<td>Cannesson M, 2007, 10</td>
<td>PAC-BTD</td>
<td>−0.26 litre min⁻¹</td>
<td>1.74 litre min⁻¹</td>
<td>35</td>
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<td>1.07</td>
<td>Breakers RM, 2007, 9</td>
<td>PAC-BTD</td>
<td>−0.14 litre min⁻¹</td>
<td>2.0 litre min⁻¹</td>
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<tr>
<td>1.07</td>
<td>Sakkas SG, 2007, 3</td>
<td>PiCCO-TPTD</td>
<td>0.5 litre min⁻¹</td>
<td>2.3 litre min⁻¹</td>
<td>34</td>
<td>Not specified</td>
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<tr>
<td>1.07</td>
<td>Mehta Y, 2008, 16</td>
<td>PAC-BTD</td>
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<td>1.32 litre min⁻¹</td>
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<td>Yes</td>
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<tr>
<td>1.07</td>
<td>Blais M, 2008, 13</td>
<td>PAC-CCO</td>
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<td>2.6 litre min⁻¹</td>
<td>43</td>
<td>Yes</td>
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<td>1.10</td>
<td>Compton FD, 2008, 15</td>
<td>PiCCO-TPTD</td>
<td>0.76 litre min⁻¹</td>
<td>1.75 litre min⁻¹</td>
<td>58</td>
<td>Not specified</td>
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<td>1.10</td>
<td>Mayer J, 2008, 7</td>
<td>PAC-BTD</td>
<td>0.19 litre min⁻¹</td>
<td>1.2 litre min⁻¹</td>
<td>25</td>
<td>Yes</td>
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</table>
between two techniques measuring the same variable, but it does not provide a quantitative way to decide whether the precision observed is acceptable or not, leaving this judgement to the investigator himself. To avoid discordant interpretations of the agreement between various techniques to measure cardiac output, Critchley and Critchley proposed calculating the 'percentage error', i.e. how many per cent of mean cardiac output represent the limits of agreement. They suggest that a new technique can replace the old one when the limits of agreement represent <30% of the mean cardiac output value. Up to now, only three Vigileo™ validation studies out of 15 have reported a percentage error smaller than 30%, while the others reported figures varying from 33% to 58% (Table 2). The poor results reported by Compton and colleagues who used the most recent version of the software (1.10) may be explained in part by the fact that they enrolled patients who were in atrial fibrillation, a well-known limit of pulse-contour methods. The agreement and percentage error between oesophageal Doppler and Vigileo™ version 1.03 observed in the present cohort were even worse than those reported in previous studies. One of the reasons is related to the fact that we used a modified Bland and Altman technique to take into account repeated measurements obtained in each subject. This more rigorous approach increased the limits of agreement by roughly 10% in comparison with the ‘classic’ Bland and Altman representation that was used in previous studies. Another possible explanation is that we kept each investigator blinded to the results obtained using the other technique. In addition, the multiplicity of investigators as a result of the multicentre design of the study also increased the variability in SV measurement and, hence, worsened the agreement. Finally, two different types of oesophageal Doppler monitors were used and their different algorithms may also be a factor of increased variability in reference SV measurement. However, Doppler SV variations are mainly governed by changes in descending aortic velocity–time integral, which is a common measurement to CardioQ™ and Hemosonic™. Supporting this statement, we did observe similar improvements in agreement and percentage error when CardioQ™ and Hemosonic™ were compared separately with Vigileo™ version 1.03 and version 1.07 (data not shown). In other words, results are exactly the same when CardioQ™ or Hemosonic™ data are presented separately or pooled together. The design of the present study precludes any meaningful comparison between the two oesophageal Doppler monitors.

We believe that our results are robust for two main reasons. First, investigators were blinded to each other, a mandatory precaution to rule out selection bias. Second, the multicentre design of the trial better reflects reality than a single-centre study with a limited number of investigators.

In conclusion, the Vigileo™Flowtrac™ system version 1.07 yielded significant improvements in comparison with version 1.03. However, version 1.07 of the software still appears too inaccurate to be considered interchangeable with oesophageal Doppler for SV estimation. Further refinements in the algorithm are required to produce results that will be accurate enough to be used for easy SV estimation from any arterial pressure waveform without calibration. Version 1.10 seems promising according to one of the validation trials, but more data are needed to confirm that clinicians can rely on this new SV measurement technique.

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