Performance of a minimally invasive cardiac output monitoring system (FloTrac/Vigileo)

Editor—We read with great interest the study by Compton and colleagues comparing minimal invasive measurements of cardiac output obtained with two devices, the PiCCO™ and the FloTrac™/Vigileo™ system. The latter has been introduced into clinical practice in 2005, and early studies comparing this device with established methods to determine cardiac output have shown limited agreement only. As a consequence, the algorithm for calculating stroke volume, heart rate, and hence cardiac output derived from the arterial pressure waveform (pulse contour analysis) has been modified and several software updates have been released. Compton and colleagues claim that they used the new, improved software version named 1.10, which was released in November 2006, and not in spring 2006 as stated. On the other hand, patients were included between July 2006 and May 2007. Thus, the question arises which software version was really used or how many of their 25 patients were studied using the latest software update. This question is of importance as the updated software resulted in an improved percentage error of measurement values compared with standard techniques (Table 1, which updates Table 4 from the original article). One of the software updates refers to the detection of arrhythmias, eliminating one of the study limitations raised by the authors. A second point refers to the data presentation. In the Method section, the authors claim that both the transpulmonary thermodilution-derived cardiac output and the pulse contour-derived continuous cardiac output values of the PiCCO™ system were used for comparison with the new device. However, in the Results section, no comparison between both pulse contour-derived methods is presented. Instead, PiCCO™ data obtained from transpulmonary thermodilution and pulse contour analysis were pooled. It would be interesting to see the agreement between data obtained from transpulmonary thermodilution and pulse contour analysis obtained with the PiCCO™. Finally, we wonder if transpulmonary thermodilution is a good choice for obtaining reference values for cardiac output, particularly in patients with acute lung injury, as the femoral thermodilution curve is likely affected by pulmonary oedema. In the Compton study, 19 of the 25 patients suffered from acute respiratory failure. The authors state that re-calibration of the PiCCO™ device was done at least every 24 h. A recent paper has shown that the accuracy of obtained values exceeds the accepted percentage error of 30% as early as 60 min after re-calibration. Hence, a frequent recalibration of the PiCCO™ device (every 20–30 min) is required to obtain reliable results, particularly in the presence of vasopressor therapy. In their discussion, the authors state that arrhythmia was a ‘limitation’, but provide no information regarding its incidence. In this respect, it is noteworthy that the key feature of the latest software version (v1.10) is the improved performance during arrhythmia.

In conclusion, we challenge the conclusions presented by the authors concerning the (lack of) accuracy of the FloTrac™/Vigileo™ system since they obviously did not consistently use the improved new software version throughout their study as stated. Furthermore, the inappropriate choice and use of the reference method precludes expecting a close agreement between the two techniques.

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Table 1 Clinical evaluation studies on FloTrac™ accuracy of cardiac output measurement. CABG, coronary artery bypass grafting; ICU, intensive care unit; SD, standard deviation; 2SD/mean, percentage error

<table>
<thead>
<tr>
<th>Author Year</th>
<th>Patients Software</th>
<th>2SD/mean</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>deWaal and colleagues 2007</td>
<td>CABG V 1.01</td>
<td>33%</td>
<td>7</td>
</tr>
<tr>
<td>Mayer and colleagues 2007</td>
<td>Cardiac V 1.01</td>
<td>46%</td>
<td>8</td>
</tr>
<tr>
<td>Opdam and colleagues 2006</td>
<td>Cardiac V 1.03</td>
<td>40%</td>
<td>9</td>
</tr>
<tr>
<td>Sander and colleagues 2006</td>
<td>CABG V 1.03</td>
<td>54%</td>
<td>10</td>
</tr>
<tr>
<td>Manecke and Auger 2007</td>
<td>Cardiac V 1.03</td>
<td>33%</td>
<td>11</td>
</tr>
<tr>
<td>Prasser and colleagues 2007</td>
<td>Neuro-ICU V 1.03</td>
<td>49%</td>
<td>12</td>
</tr>
<tr>
<td>McGee and colleagues 2007</td>
<td>Mixed V 1.03</td>
<td>50%</td>
<td>13</td>
</tr>
<tr>
<td>Breakers and colleagues 2007</td>
<td>Cardiac V 1.03</td>
<td>36%</td>
<td>14</td>
</tr>
<tr>
<td>Sakka and colleagues 2007</td>
<td>Septic V 1.07</td>
<td>35%</td>
<td>15</td>
</tr>
<tr>
<td>Lorsomradae and colleagues 2007</td>
<td>Cardiac V 1.07</td>
<td>29–56%</td>
<td>16</td>
</tr>
<tr>
<td>Button and colleagues 2007</td>
<td>Cardiac V 1.07</td>
<td>40%</td>
<td>17</td>
</tr>
<tr>
<td>Cannesson and colleagues 2007</td>
<td>CABG V 1.07</td>
<td>37%</td>
<td>18</td>
</tr>
<tr>
<td>Prasser and colleagues 2007</td>
<td>CABG V 1.10</td>
<td>26.9%</td>
<td>5</td>
</tr>
<tr>
<td>Mayer and colleagues 2008</td>
<td>CABG V 1.10</td>
<td>24.6%</td>
<td>6</td>
</tr>
<tr>
<td>Compton and colleagues 2008</td>
<td>Medical-ICU V 1.07/V 1.10</td>
<td>51.7%</td>
<td>1</td>
</tr>
</tbody>
</table>

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Editor—We would like to thank Drs Scheeren and Wiesenack for their interest in our work. It is correct that two versions of the FloTrac™/Vigileo™ software were used in the study. Despite our timely inquiries, we were only informed after publication that six of our patients were not measured using the latest version (1.10). According to Edwards Lifesciences, the software was updated sometime in August 2006. Omitting those six patients (57 measurement pairs) and recalculating the data, however, yield comparable lack of success, as can be seen below. Our results and thus our conclusions remain unchanged.

Agreement between arterial pressures: MAPem/MAPrad bias 3 mm Hg, limits of agreement (LOA) –12 to 18 mm Hg.

Comparison of radial and femoral artery pressures: systolic arterial pressures $P_2=0.2517$, mean arterial pressures $P<0.001$, and diastolic arterial pressures $P<0.001$.

Agreement between cardiac indexes: reference-CI/AP-CI bias 0.69 litre min$^{-1}$ m$^{-2}$, LOA $-1.22$ to $2.62$ litre min$^{-1}$ m$^{-2}$; TD-CI/AP-CI bias 0.77 litre min$^{-1}$ m$^{-2}$, LOA $-1.11$ to $2.65$ litre min$^{-1}$ m$^{-2}$.

As suggested by Scheeren and Wiesenack, we also calculated agreement between PiCCO pulse contour values only (PC-CI) and the corresponding FloTrac/Vigileo measurements (AP-CI): PC-CI/AP-CI bias 0.72 litre min$^{-1}$ m$^{-2}$, LOA $-1.23$ to $2.66$ litre min$^{-1}$ m$^{-2}$.

Re-analysis of subgroups and $\Delta$CI values did not yield significant changes either.

We regret any confusion concerning the measurements in our study.

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