The Accuracy of the Vigileo/FloTrac System Has Been Improved—Follow-up After a Software Update: A Blinded Comparative Study of 30 Cardiosurgical Patients

To the Editor:

The Vigileo pulse contour cardiac output system (Edwards Lifesciences, Irvine, CA), especially in its first version, was controversial regarding its accuracy.1-12 The authors presented an evaluation of the system in its first software version (1.01).1 Since then, Vigileo has undergone further software development: the algorithm has been improved, and the data sampling rate has been accelerated from 20 minutes to 1 minute. This was reason enough to perform a second validation study of the improved software (version 1.10) with the same method as before in order to evaluate the current status of its accuracy. Only the site of the arterial catheter differs from the previous study, since we found that the results obtained by femoral artery catheters did not differ from those obtained by radial artery catheters. Therefore, we used only radial artery cannulae in this investigation.

After approval by the ethics committee and with written informed consent, 30 patients undergoing coronary artery bypass graft surgery with extracorporeal circulation were studied. The statistical evaluation was performed by using the Bland-Altman13 method of analysis. In addition, a ±20% deviation from the pulmonary artery catheter thermodilution technique was evaluated (20% criteria).14 Synchronized measurements using both methods were made at 7 predefined time points, intra- and postoperatively, producing 210 data pairs. The demographic data of the included patients were found comparable. Thus, the improvements regarding the precision are not influenced by patient characteristics but by the modified properties of the Vigileo system itself.

The recorded data of 6 of the 30 patients had to be excluded because of technical complications (loss of data or incorrect recording because of the complicated handling of the data transfer). Thus, only 138 of the 210 data pairs were available for analysis. A descriptive, cumulative presentation of all data pairs is shown in Figure 1. Thirty-one percent of all measurements at the 7 time points did not meet...
the 20% criteria (former study, 46%), which is graphically shown in Figure 1. The Bland-Altman plots showed similar results. The cumulative presentation of all data in the Bland-Altman diagram is shown in Figure 2. At the low bias between the methods (0.04 L/min), the limits of agreement were ±2.13 L/min (±3.0 L/min in the former study).

In our first evaluation, the system had not met the 20% criteria (ie, 75% of all data pairs were outside the ±20% range). In the new evaluation, this situation has improved; 69% of data pairs were found within the ±20% limits. The results are better, and the values are now very close to the strict limits published by Critchley and Critchley.14

Reflecting the Critchley criteria (20% limits) and the results according to Bland-Altman (1.96σ = ±2.13 L/min), the accuracy of the Vigileo system has improved, although the narrow precision criteria are not yet completely met. Therefore, the authors are of the opinion that the device should not yet be used during and after cardiac surgery because the deviation from the clinical standard method is still out of scale. However, we expect that further development of the system will improve its accuracy. Future validation studies after evolution of the Vigileo system should be considered.

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Acute Cardiovascular Collapse in Total Anomalous Pulmonary Venous Connection

To the Editor:

Obstruction of the pulmonary venous drainage has been recognized as the event that leads to sudden death in total anomalous pulmonary venous connection (TAPVC).1 A 3-month-old infant weighing 4.7 kg presented to the emergency room with cyanosis and respiratory distress. Workup included an echocardiogram that revealed a severely dilated right ventricle with mixed TAPVC with the right upper, right lower, and left lower pulmonary veins draining to the coronary sinus and the left upper pulmonary vein draining to the innominate vein via a vertical vein. Flow was unobstructed. There was a small nonrestrictive atrial septal defect. The patient was scheduled for elective surgical repair.

Preoperative vital signs included a heart rate of 164 beats/min and blood pressure of 90/59 mmHg with a pulse oximeter saturation of 95% breathing room air. In the operating room, anesthesia was induced uneventfully. After tracheal intubation, invasive catheters were sited. Monitoring included near-infrared spectroscopy (NIRS) (INVOS, Somanetics, Inc, Troy, MI) on the forehead (rSO2-C, cerebral) and on the right flank (rSO2-S, somatic). Baseline rSO2-C and rSO2-S values were 60 and 53, respectively. Corresponding systemic saturation was 100%. Transesophageal echocardiography (TEE) was not used. While positioning the patient, a rolled towel was placed under the patient’s shoulders. Acute profound hypotension ensued (systolic blood pressure <40 mmHg). Initial resuscitation included a bolus of 30 mL of normal saline, 50 mg of calcium chloride, and 5 µg of epinephrine intravenously. This resulted in an increase in heart rate but with no effect on blood pressure. The shoulder roll was then removed with immediate return of the vital signs to baseline. Simulation of shoulder roll placement produced an identical response. The patient was repositioned (without a shoulder roll) and underwent surgical correction without complication. Figure 1 shows the NIRS values recorded during the event.

The exact mechanism of obstruction in our patient is unknown. We hypothesize that it was caused by compression of the pulmonary venous confluence against the esophagus and vertebral bodies resulting in an acute loss of cardiac output. It is also possible that the shoulder roll caused a shift in the mediastinal contents that resulted in distortion and restriction of the atrial septal defect.

Obstruction of the pulmonary venous drainage in patients with TAPVC may be due to external compression of the draining veins. TEE has been reported to compress the pulmonary venous confluence in patients with TAPVC2 and is relatively contraindicated in this lesion. Some authors advocate waiting until after median sternotomy before undertaking TEE.3 Hesford and McEwan4 reported acute desaturation in a patient with TAPVC after 15° head down tilt for central catheter placement. They postulated that the desaturation was caused by an increased pressure in the superior vena cava raising pulmonary venous pressure and causing pulmonary edema.

NIRS is being used increasingly in pediatric congenital heart surgery. In a previous report, NIRS detected acute aortic obstruction from a TEE probe.5 Although this technology was not diagnostic in this case, we were able to record the event and subsequent recovery.

REFERENCES
