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Case Report Open Access

Failure of the Flotrac™/Vigileo™ (3.01) to Track Rapid Hemodynamic Changes in an Unstable Cardiac Surgical Patient

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Introduction

Pulmonary artery catheters have long been the gold standard for tracking hemodynamic variability in high-risk surgical patients and this despite lack of outcome benefit, and the potential for serious complications [1]. Recently, less invasive continuous cardiac output (CO) monitors have evolved. The Flotrac™/Vigileo™ (Edwards Lifesciences) relies on the arterial blood pressure waveform to calculate stroke volume. This task is done via a proprietary algorithm that represents interplay of patient demographics, compliance of the arterial vasculature, and the rapidly changing nature of vasomotor tone. The Flotrac™/Vigileo™ monitor is also capable of continuously measuring stroke volume variation as an essential index of preload responsiveness, systemic vascular resistance as a clinical indicator of the cardiac afterload, and central venous hemoglobin saturation as a surrogate of global tissue oxygen consumption. The Flotrac™/Vigileo™ have been regarded as a user-friendly monitor of cardiac output as it does not require an external system for calibration. However, several concerns have been raised regarding the ability of the earlier generations of this device to respond in a timely and accurate manner to rapid changes in afterload during high-risk surgical procedures [2]. We hereby describe our experience with a new generation Flotrac™/Vigileo™ (3.01) under rapidly varying hemodynamic conditions occurring in the immediate postoperative period in a cardiac surgical patient.

Case Report

A 53 year old morbidly obese (BMI=43 kg/m^2) male was scheduled to undergo mechanical prosthetic aortic valve replacement for severe aortic stenosis. Medical history was significant for essential hypertension controlled with atenolol. His preoperative transthoracic echocardiography (TTE) was pertinent for severe aortic stenosis (Aortic Valve Area=0.8 cm^2, mean and peak pressure gradients across the aortic valve of 60 mm Hg and 106 mm Hg, respectively), and preserved left ventricular ejection fraction (>60%). After uneventful induction of general anesthesia with etomidate (12 mg), cisatracurium (12 mg) and fentanyl (250 mcg), the trachea was intubated with an 8.0 mm endotracheal tube and general anesthesia was maintained with isoflurane in 100% FiO_2, and boluses of fentanyl, and cisatracurium. The patient was monitored using standard American Society of Anesthesiologists (ASA) monitors in combination with a left radial arterial line catheter, a central venous catheter, and transesophageal echocardiography (TEE) (Siemens Acuson CV70). TEE confirmed a relatively small aortic annulus (1.9 cm) to Body Surface Area (BSA) (2.35 m^2), normal right ventricular function and size, mild tricuspid regurgitation, and mild diastolic dysfunction. While technically difficult, a mechanical aortic prosthesis (St. Jude size #21) was successfully implanted in the aortic position. Intraoperative TEE demonstrated a well-seated valve and normal left ventricular function after uneventful weaning from cardiopulmonary bypass. The mean pressure gradient across the aortic prosthesis was 20 mmHg.

Following intraoperative management, the patient was transferred to the cardiac surgical ICU on a dexmedetomidine infusion in preparation for fast-track extubation. The patient was supported on a low dose norepinephrine infusion (0.03 mcg/kg/min). Upon arrival to the ICU, the Flotrac™ / Vigileo™ (3.01) monitor was applied (Note: the device was not used in the operating room). Ninety minutes after arrival to the ICU, a spontaneous breathing trial (Continuous Positive Airway Pressure–CPAP of 5 cm H_2O) was initiated in preparation for extubation. Readings on the Flotrac™/Vigileo™ denoted normal cardiac function throughout the spontaneous breathing trial. Despite of the normal readings on the Flotrac™/Vigileo™, arterial blood pressure recordings showed a gradual decline in the systolic, diastolic and mean arterial pressures (Figures 1 and 2). Approximately one hour later (14:00), and while still intubated and breathing spontaneously, the patient was noted to be unresponsive and developed pulseless ventricular tachycardia. Cardiopulmonary resuscitation according to the Advanced Cardiac Life Support (ACLS) protocol was employed intermittently for approximately 1 hour (a total of intravenous boluses of epinephrine 1 mg, amiodarone 300 mg were administered combined with chest compressions). Following this period, an electrocardiogram revealed new ST- segment elevations in the right precordial leads indicative of acute right ventricular infarction (Figure 3). Concomitant TEE revealed right ventricular dilatation, global right ventricular wall akinesis, mild tricuspid regurgitation and leftward bowing of the interventricular septum. Physiologic data points for cardiac output per the Flotrac™/Vigileo™ were reported as normal limits throughout the episode of cardiac arrest (Figures 1 and 2).

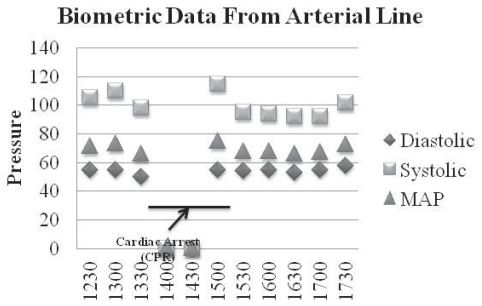

Figure 1: Schematic representation of arterial blood pressure before, during, and after the episode of cardiac arrest. Data are depicted at every half an hour intervals. MAP; mean arterial pressure. CPR; cardiopulmonary resuscitation.

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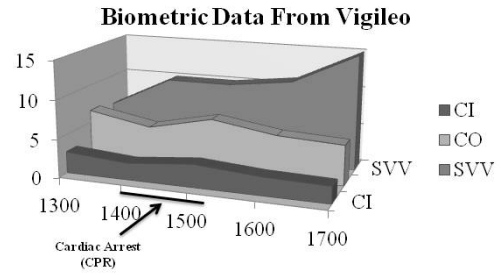

Figure 2: Schematic representation of the FlotracTM/VigileoTM readings before, during and after the episode of cardiac arrest. Data are depicted at every half an hour intervals. SVV; stroke volume variation, CI; cardiac index, CO: cardiac output, CPR; cardiopulmonary resuscitation.

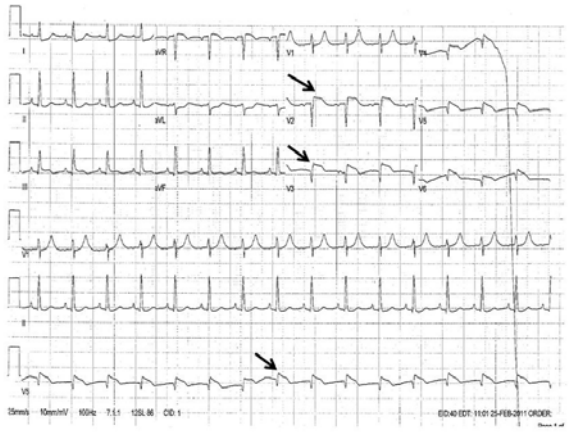

Figure 3: EKG of the patient after CPR showing acute ST segment elevation in right precordial leads significant of right ventricular infarction (precordial leads placed on right chest during this tracing). EKG; electrocardiogram, CPR; cardiopulmonary resuscitation.

The patient was rushed into the cardiac angiography suite and found to have total right coronary artery occlusion not amenable to stenting. The patient was subsequently taken back to the operating room for emergent right coronary bypass grafting. Ensuing severe global right ventricular akinesis and recalcitrant hemodynamic instability required use of the TandemHeart™ Right Ventricular Assist Device (RVAD). The patient was transferred to the cardiac ICU in critical-severe condition. His postoperative course was complicated by persistent cardiogenic shock unresponsive to high doses of ionotropic agents. He was not amenable to weaning from RVAD, and rapidly developed multi-organ failure requiring the institution of continuous venovenous hemodiafiltration (CVVHDF). Four days later his care was deemed futile and the family elected to withdraw life support.

Discussion

This case report presents a situation in which the Flotrac™/Vigileo™ (3.01) failed to respond to rapid hemodynamic changes occurring in the immediate postoperative period in a patient who developed acute total right ventricular infarction. In such a scenario, the cardiac index and stroke volume are expected to abruptly and sharply fall. However, the readings on the Flotrac™/Vigileo™ (3.01) consistently showed a CO between 5 and 6, l/min and failed to follow changes in arterial pressures both prior to and during cardiac arrest (Figure 1, Figure 2). These readings were obtained in the presence of a fully functional radial arterial line.

While similar observations were reported with earlier generations of the device [3], recent reports on newer software generations Flotrac™/Vigileo™ (3.01) have reported more accurate measurements of cardiac output and stroke volume in patients with sepsis [4]. Our patient differs from this cohort in several ways. First, the hemodynamic profile of acute cardiogenic failure is inherently different from a septic patient. Second, our patient underwent mechanical aortic valve replacement and thus experienced altered rheology across the artificial valve and through the aorta (it is unknown whether altered flow dynamics through prosthetic aortic valves alter the accuracy of Flotrac™/Vigileo™ (3.01)-interpreted radial arterial line readings). Third, our patient was morbidly obese (It is unknown whether large deviations from normal weights affect the accuracy of the newer device). Fourth, the large variability in temperature fluctuations secondary to active rewarming in the immediate post cardiopulmonary bypass period may have caused inaccurate physiologic data from the radial artery. This may have reflected an underestimation of actual hemodynamics derived from more central locations (femoral and brachial arteries) [5]. Mayer et al. [6], have emphasized the lack of agreement between the Flotrac™/Vigileo™ algorithm and intermittent thermodilution techniques (ITD) in the immediate post cardiopulmonary bypass period secondary to thermal changes that occur during this period.

The Flotrac™/Vigileo™ system suffers many inherent limitations which may help explain the scenario. First, the algorithm used by the device to self–adjust to rapid changes in the vascular tone is speculative and limited. It describes only 2 deviations (horizontal and vertical) of an arterial waveform tracing (http://www.edwards.com/products/mininvasive/Pages/flotracalgorithm.aspx?Vigileo=1). In this algorithm, horizontal deviation or skewness is attributed to changes in vascular resistance, while vertical deviations (kurtosis) are attributed to changes in the compliance of large vessels. Although mathematical modeling and resulting algorithms must be derived from somewhere, ascribing only two possibilities for deviations to a rapidly changing dynamic waveform seems to be an oversimplification. Obviously, a near-infinite number of deviations can occur at any one moment in time.

Furthermore, this algorithm has no reported adjustments for changes in the dynamic properties of the tubing system used in transmitting the arterial line waveform. Therefore, the resonance frequency and damping coefficient can be highly variable between systems. It is unknown whether changes in the arterial waveform from patient movement are represented in this algorithm.

Moreover, increases in the pulse pressure may not always reflect an increase in stroke volume. In fact, to the contrary, it may actually reflect an underlying decrease in the stroke volume–as can be seen with utilization of vasopressors [7]. These phenomena have been inaccurately delineated per the Flotrac™/Vigileo™ as Meng et al. [8], demonstrated through the comparison of phenylephrine and ephedrine administration with total body tilting using the Esophageal Doppler as the reference method. Such inaccuracies were also demonstrated with increasing doses of norepinephrine in patients undergoing orthotropic liver transplantation [9].

Another limitation is that the device does not account for differences in the pulse pressure readings recorded from different arterial cannulation sites. According to the phenomenon of distal pulse amplification, as the arterial pressure waveform travels peripherally, pulse pressures widen due to an increase in the systolic upstroke and a decrease in diastolic pressure. Failure to account for these differences

was a major limitation of the second generation of the Flotrac™/Vigileo™ [10]. Despite reports of better correlation among different arterial cannulation sites with the third generation of this device [11], these data were derived from inadequately powered studies conducted under stable hemodynamic conditions.

Moreover, arrhythmogenic states are difficult to trend in the best of conditions. While this device is insensitive to rhythms other than sinus, the reported physiologic data was likely inaccurate during the episode of ventricular tachycardia. Thus, as a whole, the Flotrac™/Vigileo™ (3.01) device continues to suffer technological imitations that affect its accuracy in the tracking of rapid hemodynamic changes. With that said, the authors acknowledge that the trending of dynamic waveforms in conditions of health (yet alone disease) is a challenging task for any arterial waveform-based monitoring device.

Moving beyond the critique of the proprietary algorithm; the Flotrac™/Vigileo™ has been clinically compared to thermodilution pulmonary artery catheters using the Bland-Altrman statistical analysis [12]. While this statistical method is used to compare new devices with a standard device, it has inherent limitations. A major limitation is that the Bland-Altman analysis assumes that data points are unrelated and are derived from separate subjects and experiments. However, in studies that assess trending, repeated measurements from the same subject should be used. As such, the Bland-Altman analysis may not be the most ideal statistical method to analyze continuous cardiac output trending [13]. The lack of an agreed upon gold standard is also problematic. As such, thermo-dilution continuous cardiac output data derived via pulmonary artery catheter may not be the best comparison for the Flotrac™/Vigileo™ [14].

In summary, we describe our experience with the Flotrac™/Vigileo™ (3.01) in a clinical setting in which the device completely failed to recognize acute heart failure and cardiac arrest. In fact, not only did it fail to respond to the clinical reality, it continuously revealed normal physiologic data. We hold firm that this specific device has serious inherent technological flaws that, in its current form, make it an unreliable instrument for tracking rapidly evolving hemodynamics in the immediate post-cardiopulmonary bypass period. While reliable monitors of cardiac output should continue to be applied as indicated, clinical judgment remains paramount.

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