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Comparison of pulmonary artery catheter, echocardiography, and arterial waveform analysis monitoring in predicting the hemodynamic state during and after cardiac surgery

Paul Power¹, Allison Bone¹, Nicholas Simpson¹², Cheng-Hon Yap³⁴, Simon Gower⁵, Michael Bailey⁶

ABSTRACT

Objective: The aim of this trial was to determine whether Flotrac Vigileo™ (FV™) provides a reliable representation of the hemodynamic state of a cardiac surgical patient population when compared to pulmonary artery catheter (PAC) and echocardiography in the peri-operative period.

Design: This was a prospective observational trial comparing perioperative hemodynamic states using transesophageal echocardiography (TEE), transthoracic echocardiography (TTE), FV™ and PAC during and post cardiothoracic surgery.

Setting: Tertiary regional hospital Intensive Care Unit (ICU).

Participants: 50 consecutive adult cardiothoracic patients with written consent provided.

Intervention: Comparison of the perioperative hemodynamic states using echocardiography, FV™ and PAC was performed. Evaluation of the hemodynamic state (HDS) was performed using TEE, TTE, PAC and FV™ during and after cardiac surgery. Data were compared between the three hemodynamic assessment modalities.

Main Outcome Measure: Predicted hemodynamic state.

Results: FV™ and PAC were shown to correlate poorly with TEE/TTE assessment of the hemodynamic state. Both PAC and FV™ showed significant discordance with echocardiographic assessment of the hemodynamic state.

Conclusions: In this trial, FV™ and PAC were shown to agree poorly with TTE/TEE assessment of the HDS in an adult cardiothoracic population. Agreement between the FV™ and PAC was also poor. Caution is recommended in interpreting isolated hemodynamic monitoring data. All hemodynamic monitoring devices have inherent sources of error. Caution is advised in interpreting any single device or measurement as a gold standard. We suggest that hemodynamic measuring devices such as FV™/PAC may act as triggers for a global hemodynamic assessment including consideration of TTE/TEE.

Key Words: Anesthesia, cardiothoracic, hemodynamic monitoring, intensive care

INTRODUCTION

Invasive hemodynamic monitoring is commonly utilized in the perioperative care of cardiac surgery patients, and...
is an essential component of decision-making in relation to the hemodynamic state (HDS). The pulmonary artery catheter (PAC) is used to measure cardiac output (CO) and systemic vascular resistance (SVR) to evaluate the hemodynamic status of a patient. PACs have been in use for 30 years, despite equivocal evidence as to their utility in an intensive care environment. PACs are associated with adverse events, including increased incidence of arrhythmias, providing false readings under certain conditions, and pulmonary artery rupture and death. Noninvasive CO monitoring devices have some desirable properties but have been found to be variably reliable. Several recent trials have evaluated the efficacy of arterial waveform analysis monitoring using the FloTrac/Vigileo™ (FV™) (Edwards Lifesciences, Irvine, CA, USA) monitoring system. FV™ data are extrapolated from the arterial pressure waveform after correction for body height and weight, age, and gender. Several iterations of FV™ software have made the device increasingly reliable. The majority of trials have sought to validate the measurements of the FV™ compared to a gold standard (e.g., PAC, transthoracic echocardiography [TTE]). To safely manage patients during and after cardiac surgery, it is important to have reliable and regular assessments of the HDS. The aim of this study was to determine whether FV™ provides a reliable representation of the patients’ HDS when compared to PAC and echocardiography in the intra- and post-operative period.

METHODS

Patients and setting
University Hospital Geelong is a tertiary regional hospital with a level 3 Intensive Care Unit (ICU), and performs over 400 cardiac surgeries each year. The current method of hemodynamic monitoring during and after surgery includes a PAC in combination with perioperative transesophageal echocardiography (TEE).

Methods
After the Local Human Research Ethics Committee approval and obtaining prior written informed consent, fifty adult patients scheduled for elective or semi-urgent coronary artery bypass grafting (CABG) and or valve replacement/repair with cardiopulmonary bypass were included in the trial. Exclusion criteria were the presence of atrial fibrillation at the time of consent, planned intra-aortic balloon pump placement, and severe valvular dysfunction. FV™ monitors were loaned by Edwards Lifesciences for the duration of the trial; however, consumables were funded independently. Edwards Lifesciences were not involved in trial design or the trial itself, including data analysis or write-up.

Routine intra- and post-operative management
Anesthetic and postoperative management followed institutional clinical guidelines for intra- and post-operative care. After induction and intubation, a PAC (7.5 F, Edwards, Irvine, CA, USA) was placed through the internal jugular vein and correct positioning confirmed by pulmonary artery pressure waveform analysis. The PAC was then connected to an Edwards Vigilance II™ monitor for continuous CO monitoring. FV™ 3rd generation software was utilized. After radial artery cannulation, the arterial pressure waveform was confirmed as accurate and the pressure monitoring set and FV™ monitor were connected. Patients’ height and weight were entered into the Vigilance II™ and FV™ monitors. All pressure transducers were referenced to the mid-axillary line and zeroed before recording of hemodynamic parameters.

Measurement of transthoracic echocardiography/
transesophageal echocardiography hemodynamic parameters
The initial two TEE studies were performed in the operating theater as the part of routine cardiac assessment during surgery. An initial TEE was performed prebypass (TEE 1) and a 2nd postbypass (TEE 2). At these time points central venous pressure (CVP), cardiac index (CI) and SVR index (SVRI) from the PAC and FV™ were documented by an anesthetist. Postoperative TTE/TEE was performed after transfer to the ICU, when the patient was hemodynamically stable and able to be positioned on their left side. At the time of the TTE/TEE, CVP, CI and SVRI from the PAC and FV™ were documented by a registered nurse. In addition, after admission to ICU, CI, and SVRI from the FV™ were documented as part of the trial until the PAC was removed. CVP was used in preference to pulmonary artery wedge pressure (PAWP) as PAWP is potentially hazardous and not routinely recorded in this cardiothoracic center. Hemodynamic parameters were collected and documented by an anesthetist or registered nurse with a specialty postgraduate qualification. TTE/TEE was performed by cardiac anesthetists/intensivists holding a qualification in critical care echocardiography (PTEeXAM/H.A.R.T.scan®/Postgraduate Diploma in Clinical Ultrasound [PGDipCU]). Echocardiographic views and measurements were based on standard practice and commonly measured criteria during rapid assessment scanning protocols. Echocardiograms were classified into one of four HDSs using an algorithm based on modified H.A.R.T.scan® criteria [Appendix 1]. Criteria included measurements of ventricular volume, systolic function, and intratral and interatrial septal motion. Left ventricular (LV) function was based on the measurement of fractional shortening (FS) or area change while the filling state was assessed using the LV end-diastolic diameter or area (depending on TTE or TEE). A vasodilated state was denoted by the echocardiographic findings of a hyperdynamic state (FS>44%) in the absence of criteria for “empty.” Using proprietary instructions on monitoring interpretation, measurements from the PAC (including CVP) and FV™ were used to determine one of these four hemodynamic states for
each device. Where HDSs were overlapping, the cardiac state was deemed to be the primary state (e.g., primary systolic failure [PSF] vs. vasodilated). All TTE/TEE studies were reviewed independently for agreement by a cardiac anesthetist and intensivist holding echocardiography qualifications (PTEeXAM®/PGDipCU).

**Blinding**

Vigilance II™ and Vigileo™ monitor screens were obscured at the time the anesthetist/intensivist was performing the TTE/TEE. Hemodynamic parameters were documented at the time the TTE/TEE was performed or immediately after.

**Data**

Each patient was allocated a number and patient identifiers were removed. Baseline data was collected for each patient. This included age, gender, procedure performed, length of ICU stay, APACHE II score, and duration of mechanical ventilation. TTE/TEE and corresponding hemodynamic data for the time points described above were entered into the patient database.

**Statistical analysis**

Continuous normally distributed variables were presented as means (standard deviation), whereas nonnormally distributed variables were reported as medians (interquartile range). Comparison was performed between multiple devices (TTE/TEE/PAC/FV™) for 4 HDSs, with agreement reported using kappa concordance.

**RESULTS**

**Demographics**

Table 1 demonstrates patient characteristics. The cohort was predominantly male (86%), with the most frequent procedure CABG (58%) then aortic valve replacement (24%) surgery. The mean age was 68.5 years.

**Hemodynamic states**

Table 2 describes the HDS indicated by echocardiography. The majority of patients were classified as having an empty or normal HDS at the first echocardiogram (TEE), with an increased number of abnormal HDSs occurring peri- and immediately post-operatively.

**Pulmonary artery catheter and transthoracic echocardiography/transesophageal echocardiography**

The strength of the relationship between PAC HDSs and TTE/TEE assessment was poor [Table 3]. PAC empty states only correctly predicted TTE/TEE empty state in 17/33 (51.5%) measurements, while a normal TTE state correlated with a PAC normal state on 29/80 (36.3%) measurements. Where echocardiography was normal, the PAC suggested an empty state in 39/58 (67.2%) measurements. A normal PAC state coincided with an empty TTE/TEE state in 10/33 (30.3%) measurements.

The kappa correlation between echocardiography and PAC HDSs was 0.06.

**FloTrac/Vigileo™ and transthoracic echocardiography/transesophageal echocardiography**

The strength of the relationship between FV™ and echocardiographic states was also poor [Table 4]. The overall kappa concordance was 0.14. FV™ predicted the normal HDS in 56/83 (67.5%) TTE/TEE measurements.
but only predicted empty in 12/30 (40%) measurements and PSF in 2/19 (10.5%) measurements when compared to echocardiography.

**FloTrac/Vigileo™ and pulmonary artery catheter**

There was little relationship between HDSs when comparing FV™ and PAC [Table 5]. In particular, in this group, there was little correlation in the state of PSF between devices.

**Primary systolic failure**

Both PAC and FV™ tended to over-report the HDS of PSF when compared to echocardiography [Tables 6 and 7]. When the HDS was determined as PSF by PAC this was confirmed by echocardiography in 2/19 (10.5%) measurements and in 3/22 (13.6%) measurements when determined by FV™.

**Comparison and the “normal” state**

Appendix 2 describes the HDSs when compared between the 3 devices. PAC and FV™ were comparably more reliable in their correlation with PSF states as determined by echocardiography (PAC = 3/9, FV™ = 2/7); although, numbers in this group were small. Both FV™ and PAC tended to over-record abnormal states when compared to echocardiography. When compared with TTE, FV™ predicted “normal” states in 56/83 (67.4%) while for PAC the rate was 29/90 (32%). The PAC recorded CI <2.2 in 6/90 (6.7%) readings simultaneously with “normal” TTE’s while FV™ recorded 1/90 (1.1%) of these instances. FV™ predicted the “normal” HDS in 56 of 83 “normal” patients as determined by echocardiography (67%), PAC predicted the “normal” HDS in 29 of 90 “normal” patients as determined by echocardiography (32%). At T1, for the same patient cohort, 37 abnormal HDSs were suggested by PAC (vs. 25 for FV™ and 15 for TEE/TTE).

**DISCUSSION**

This trial was designed to compare the HDS based on information from FV™, echocardiography, and PAC in a cardiothoracic surgical population. While overall correlation was poor, our data suggest that both FV™ and PAC may be useful in acting as triggers for assessment of the HDS.

To date, literature on FV™ has reported variable results. FV™ has been extensively studied in a number of settings. Many of these studies involve earlier software iterations,[10,21] or were used in discrete clinical contexts such as sepsis[12] or volume expansion.[22] There are few studies that are based in the intensive care setting, with a percentage error between compared devices of 33% and 40% suggesting that the use of FV™ in this setting may be less reliable.[23] More recent literature is mixed. A study of 40 cardiac surgery patients demonstrated percentage error rates of up to 61.5%[24] while an error rate of 66.5% was demonstrated when comparing FV™ with PAC bolus thermodilution in a cohort of 25 cardiac surgery patients.[10]

Recent research using FV™ has focused on absolute values rather than the overall HDS[15] and seldom using TTE/TEE for comparison.[13] The evidence for the accuracy of FV™ data in a variety of clinical settings is mixed, although the correlation with invasive monitors appears to be improving through software iterations.[12,21] Questions still remain over the accuracy of FV™ in the setting of tachyarrhythmias and valvular heart disease,[15] although, FV™ has been compared more favorably with TTE derived CO measurements when these patients groups have been excluded from the study.[13]

**Sources of error from previous studies**

The accuracy of FV™ in measuring CO under certain conditions has been questioned. Suehiro et al. stratified three groups according to SVR and demonstrated a lower concordance with lower SVR states.[24] This finding was reproduced by Sotomi et al. in a cardiac surgery population,[25] McLean et al. reported that in critically ill
patients, after the exclusion of patients with irregular heart rhythms and aortic stenosis, that FV™ was clinically comparable to TTE in CO measurements in critically ill patients, and also made the point that multiple paired values (from the same patients) used in other studies may increase bias. No studies to date have sought to compare TTE evaluation of the HDS, or the potential clinical decision made, with FV™, or PAC.

The case for hemodynamic assessment
While rates of error may be variable with noninvasive monitoring devices, this may not affect the hemodynamic decision that is made. We chose to compare HDS rather than absolute variables for a number of reasons. Management of a patient’s HDS is rarely based on a single parameter, but on an overall assessment of the cardiovascular system. While in many cases, clear parameters do not exist for treatment decisions, a combination of variables is frequently used to interpret and act on the HDS. We have taken a pragmatic view of this decision-making in tandem with proprietary suggestions regarding monitoring values, and Australasian practice. TTE is performed regularly on patients who have acute hemodynamic disturbance and algorithms exist for emergent interpretation of the HDS (e.g., RACE, H.A.R.T.scan®). A difference in variables has less clinical significance or impact if it does not alter treatment. It has been suggested that the use of PACs does not alter outcomes in large critical care populations, and that the introduction of FV™ has not been associated with increased mortality. Data supporting the safety of FV™ come from Kirton et al., who demonstrated no significant change in mortality over 5 years period of change from PAC to FV™ monitoring in a surgical intensive care population. Therefore, we designed the trial to assess the clinically relevant endpoint of HDS, rather than performing further measurements. Our trial examined hemodynamic data which may represent decision points in the postoperative setting (e.g., empty = fluid therapy, vasodilated = vasopressor, and PSF = inotrope).

Potential for decreased intervention
Our data is consistent with previous studies, with a poor absolute correlation between devices, and a tendency for noninvasive monitors to over-record abnormal HDSs when compared to PAC/echocardiography. An important role of any monitoring device is to guide the clinician as to when no intervention is required. Monitoring devices may promote active management if staff react to abnormal parameters. This trial showed a large potential difference in active intervention between the 3 hemodynamic assessment modalities and that a less interventional style of management may be enhanced by the use of TTE.

Strengths
Our trial was a pragmatic design, and was the first to utilize algorithmic echocardiography to determine the HDS in comparison to two monitoring devices (PAC and FV™). Efforts were made to ensure a standardized system of measurement (modified H.A.R.T.scan® criteria, practice-based monitoring parameters) and standardization (all TTE/TEE practitioners had completed PTEeXAM®/H.A.R.T.scan®/PGDipCU).

All TEE/TEEs performed were independently evaluated by practitioners who were blinded to the monitoring data. “Normal” values for FV™ and PAC can be disputed; however, proprietary guidelines were used where possible, in tandem with unit practice. Several studies have shown a lack of correlation between PAC and FV™. This trial allowed a third hemodynamic assessment modality to be applied in order to assess which device is more representative of the HDS.

We targeted the main HDSs which lead to intervention perioperatively in the cardiothoracic patient population, with measures of preload, afterload, and contractility. We used simple, reproducible, echocardiographic definitions with parameters which have been studied in critical care.

Limitations
This was a small, observational trial, which contained a small number of patients with abnormal HDSs. Patients with poor ejection fractions (<20%) were not evaluated as a separate patient population.

Although blinding was maintained at the time of data collection, the timing of the devices is not uniform. FV™ updates the CO approximately every 20 s while a Vigilance IT® monitor averages readings over a longer time duration, and average values can be delayed by several minutes. Limited TTE/TEE may take several minutes to perform. These circumstances are similar to the real practice of intensive care, which frequently evolves the performance of a TTE/TEE several minutes after being triggered by a PAC/FV™ reading. Measurements in the trial were taken, as far as reasonably possible, simultaneously.

While the algorithm for HDSs was constructed to mirror local practice and evidence base as closely as possible [Appendix 1] this may not reflect practice in all sites. Many sites do not consider CVP in assessment of the HDS, and there is no broad consensus as to interpretation of this variable. In addition, no assessment of right heart function was undertaken. Right heart function may influence both CVP and cardiac performance. CVP remains a commonly measured and utilized measurement in the perioperative care of the cardiac surgery patient, in a manner that is reflective in the pragmatic design of this trial.

While efforts were made to standardize TTE/TEE performance and measurement, different techniques, patient habitus, and echo windows introduce variability, which is reflected
in the actual practice of critical care echocardiography. A number of TTEs were technically difficult, which mirrors the cardiothoracic postoperative population.

CONCLUSIONS

In this trial, FVTM™ and PAC were shown to agree poorly with TTE/TEE assessment of the HDS in an adult cardiothoracic population. Agreement between the FVTM™ and PAC was also poor. Caution is recommended in interpreting isolated hemodynamic monitoring data. All hemodynamic monitoring devices have inherent sources of error. Caution is advised in interpreting any single device or measurement as a gold standard. We suggest that hemodynamic measuring devices such as FVTM™/PAC may act as triggers for a global hemodynamic assessment including consideration of TTE/TEE.

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FVTM™ monitors were loaned by Edwards Lifesciences for the duration of this trial.

Financial support and sponsorship

FVTM™ monitors were loaned by Edwards Lifesciences for the duration of the trial however consumables were funded by the hospital. Edwards Lifesciences were not involved in trial design, or the trial itself including data analysis and write-up.

Conflicts of interest

There are no conflicts of interest.

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Appendix 1: Hemodynamic states for echocardiography, pulmonary artery catheter, and FloTrac/Vigileo™

| Echocardiography | PAC | FV™ |
|------------------|-----|-----|
| Normal           |     |     |
| FS: 28%-44%      | CVP ≥12 mmHg | SVV ≤13% |
| FAC: 50%-65%     | CI > 2.2 L/min/m² | CI > 2.2 L/min/m² |
| LVEDD: 3-5.6 cm  | SVRI > 1970 dynes.s.cm⁻¹ | SVRI > 1970 dynes.s.cm⁻¹ |
| LVEDA: 8-14 cm   |     |     |
| Empty            |     |     |
| IAS mid systolic buckle/LVEDD < 3 cm/LVEDA < 8 cm² | CVP < 12 mmHg | SVV ≥13% |
| PSF              |     |     |
| FS < 28%         | CI < 2.2 L/min/m² | CI < 2.2 L/min/m² |
| FAC < 50%        | SVRI > 1970 dynes.s.cm⁻¹ | SVRI > 1970 dynes.s.cm⁻¹ |
| Vasodilated      |     |     |
| FS > 44% (FAC > 65%) + normal LAP | SVRI < 1970 dynes.s.cm⁻¹ | SVRI < 1970 dynes.s.cm⁻¹ |

SVV: Stroke volume variation, IAS: Intra atrial septum, LVEDD: Left ventricular end diastolic diameter, LVEDA: Left ventricular end diastolic area, FS: Fractional shortening, FAC: Fractional area change, LAP: Left atrial pressure, CI: Cardiac index, PSF: Primary systolic failure, SVRI: Systemic vascular resistance index, CVP: Central venous pressure, FV™: FloTrac/Vigileo™, PAC: Pulmonary artery catheter

Appendix 2: Hemodynamic state data

| Patient number | EHDS #1 | PACHDS #1 | FV™ HDS #1 | EHDS #2 | PACHDS #2 | FV™ HDS #2 | EHDS #3 | PACHDS #3 | FV™ HDS #3 |
|----------------|--------|-----------|------------|--------|-----------|------------|--------|-----------|------------|
| 1              | N      | E         | N          | N      | E         | N          | N      | E         | N          |
| 2              | N      | PSF       | E          | E      | E         | E          | E      | N         | N          |
| 3              | N      | N         | N          | N      | N         | N          | E      | N         | N          |
| 4              | N      | PSF       | E          | N      | E         | N          | N      | E         | N          |
| 5              | N      | E         | PSF        | PSF    | E         | N          | E      | N         | E          |
| 6              | PSF    | N         | PSF        | N      | N         | E          | E      | N         | N          |
| 7              | N      | N         | N          | N      | N         | N          | N      | E         | N          |
| 8              | E      | N         | E          | E      | PSF       | N          | N      | PSF       | N          |
| 9              | N      | E         | PSF        | V      | N          | N          | E      | N         | E          |
| 10             | N      | E         | N          | E      | N          | N          | E      | V         | V          |
| 11             | N      | PSF       | N          | N      | N          | N          | N      | N         | N          |
| 12             | N      | PSF       | E          | N      | E         | N          | E      | N         | N          |
| 13             | PSF    | PSF       | PSF        | V      | N          | N          | E      | E         | N          |
| 14             | N      | N         | N          | N      | E         | N          | E      | N         | N          |
| 15             | N      | E         | N          | E      | N          | E          | E      | N         | N          |
| 16             | PSF    | PSF       | PSF        | E      | PSF       | PSF        | E      | N         | N          |
| 17             | V      | V         | N          | E      | N          | E          | N      | E         | N          |
| 18             | E      | E         | PSF        | E      | E          | N          | E      | N         | N          |
| 19             | N      | PSF       | PSF        | V      | N          | N          | E      | E         | N          |
| 20             | E      | PSF       | PSF        | N      | E          | N          | N      | E         | N          |
| 21             | PSF    | N         | N          | N      | N          | N          | N      | N         | N          |
| 22             | N      | E         | PSF        | E      | E          | E          | N      | E         | N          |
| 23             | N      | E         | N          | PSF    | N          | N          | E      | N         | N          |
| 24             | N      | E         | N          | PSF    | N          | PSF        | PSF    | E         | N          |
| 25             | N      | E         | PSF        | N      | E          | N          | N      | N         | E          |
| 26             | E      | E         | N          | E      | PSF       | N          | E      | PSF       | N          |
| 27             | E      | E         | N          | E      | N          | N          | N      | E         | N          |
| 28             | N      | E         | V          | V      | N          | N          | N      | N         | N          |
| 29             | N      | E         | N          | E      | E          | N          | N      | E         | N          |
| 30             | N      | E         | N          | E      | N          | N          | E      | N         | N          |
| 31             | N      | E         | E          | E      | PSF       | N          | N      | N         | N          |
| 32             | N      | PSF       | E          | E      | N          | E          | N      | N         | N          |
| 33             | E      | E         | PSF        | E      | E          | N          | N      | N         | N          |
| 34             | N      | E         | N          | V      | PSF        | N          | N      | E         | N          |
| 35             | N      | N         | V          | N      | E          | N          | N      | E         | N          |
| 36             | PSF    | N         | E          | N      | N          | E          | N      | N         | N          |
| 37             | N      | E         | N          | V      | E          | N          | N      | N         | N          |
| 38             | N      | E         | N          | N      | E          | N          | N      | E         | N          |
| 39             | N      | PSF       | E          | N      | PSF       | N          | N      | N         | N          |
| 40             | N      | N         | N          | E      | N          | E          | N      | N         | N          |
| 41             | N      | PSF       | E          | N      | PSF       | N          | N      | E         | N          |
| 42             | N      | N         | PSF        | N      | N          | PSF        | N      | N         | PSF        |
| 43             | N      | N         | E          | E      | PSF       | N          | N      | E         | N          |
| 44             | E      | PSF       | E          | E      | N          | E          | N      | E         | PSF        |
| 45             | E      | E         | E          | N      | N          | N          | N      | N         | PSF        |
| 46             | E      | E         | E          | N      | N          | N          | N      | N         | PSF        |
| 47             | N      | PSF       | N          | N      | N          | N          | N      | N         | N          |
| 48             | E      | E         | E          | E      | N          | N          | E      | N         | N          |
| 49             | E      | E         | E          | PSF    | E          | N          | E      | N         | E          |
| 50             | E      | E         | E          | N      | N          | N          | N      | E         | N          |

EHDS: Echocardiography hemodynamic state, PAHDS: Pulmonary artery catheter hemodynamic state, FV™HDS: FloTrac/Vigileo™ hemodynamic state, E: Empty, N: Normal, V: Vasodilated
