Vigileo™/FloTrac™ Stroke Volume Variation and Hemodynamic Trends are Reliable for Acute Care Management of Perioperative Patients

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Capstone Project

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Abstract

**Background:** Hemodynamic monitoring is a necessary priority in the perioperative setting. Invasive and non-invasive monitoring technologies have been used to improve patient care. Literature pertaining to a new hemodynamic monitoring system, the Vigileo™/FloTrac™, was explored to ascertain the accuracy and reliability of data obtained from patients in the perioperative setting. The objective was to assess cardiac output (CO), stroke volume variation (SVV), and data trends over time for reliability in perioperative hemodynamic management.

**Methods:** A systematic review was conducted that focused on the reliability of hemodynamic data obtained from the Vigileo™/FloTrac™ system. Google Scholar and FirstSearch: Medline database were utilized for this review.

**Results:** The Vigileo™/FloTrac™ system provides reliable SVV and data trends that may guide hemodynamic management of perioperative patients.

**Conclusion:** The Vigileo™/FloTrac™ system provides reliable data that may be used to manage perioperative patient hemodynamics. The system reliably trends CO values for estimation of patient hemodynamics. Also, the monitoring system produces reliable SVV which is practical for assessing patients need and responsiveness to fluid. SVV contributes data that the anesthesia provider can incorporate for hemodynamic management decision making.
PART ONE

Introduction

Hemodynamic monitoring has been utilized for over 4 decades to help healthcare providers optimize patient outcomes and provide quality care. However, until recently the only hemodynamic monitoring tool that provided extensive and detailed data was the pulmonary artery catheter (PAC). Unfortunately controversy surrounds the use of the PAC due to concerns related to morbidity and mortality risks. Some researchers have suggested that the PAC does not improve outcomes.\(^1\) Randomized controlled trials (RCT) appear to support this premise.\(^2,3\) Conversely, a meta-analysis showed a significant reduction in morbidity and mortality with the use of a PAC.\(^4\) A less invasive monitor that provides similar hemodynamic data as the PAC would be ideal and possibly negate the PAC controversy.

Since the introduction of the PAC in the 1970’s, practitioners have used this device in many clinical settings, especially the operating room and intensive care unit (ICU).\(^5\) This highly specialized device is a tool utilized for obtaining hemodynamic parameters of heart and lung function. It helps guide practitioners in the diagnosis and treatment of critically ill patients. The healthcare community assumed the PAC to be a device that provided clinically important information, readily available at the bedside, that led to improved outcomes in patient morbidity and mortality.\(^6\) However, due to a lack of supportive evidence regarding PAC’s safety and efficacy, a meta-analysis of RCT’s was performed. Shah, Hasselblad, and Stevenson stated that PAC’s “neither increased overall mortality or days in hospital nor conferred benefit.”\(^7\) This RCT outcome and results suggested no benefits from the use of a PAC for hemodynamic management.\(^8\)
If there is no improvement of mortality or benefit with the utilization of a PAC, then the risks of insertion and infection of a central venous catheter (CVC) take greater precedence. Approximately 5 million CVC’s are inserted each year with a 3% to 8% incidence in infection coinciding with a 12% to 25% mortality rate. The use of a PAC is valuable in obtaining hemodynamic data but carries this risk. The Vigileo™/Flotrac™ monitoring system has the capability of providing similar hemodynamic data without the associated CVC risks. This may afford the anesthesia provider with the opportunity for an additional tool for perioperative hemodynamic management.

The use of the minimally invasive Vigileo™/FloTrac™ system would forgo the risks of insertion of a CVC, particularly the PAC. This particular system is unique because it does not require central venous access or placement of a PAC to obtain hemodynamic data. The Vigileo™/FloTrac™ system utilizes an existing radial or femoral arterial line that is attached to its monitoring unit. The system obtains comprehensive hemodynamic data including cardiac output (CO), cardiac index (CI), systemic vascular resistance (SVR), stroke volume (SV), stroke volume index (SVI), and stoke volume variation (SVV). This monitoring system derives hemodynamic values from a mathematical algorithm that analyzes the arterial waveform. The device incorporates individual patient demographic values that include height, weight, age, and gender for patient specific data.

The algorithm uses basic hemodynamic principles for the determination of SV from the arterial waveform and includes heart rate (HR) to calculate CO (CO=SV x HR). The system analyzes the arterial pressure waveform 100 times per second every 20 seconds for a total of 2000 data points for use in its algorithm. Heart rate is determined based on the peaks of the arterial waveform. SV is calculated by 3 different variables: arterial pulsatility, resistance,
Arterial pulsatility is the standard deviation of the pulse pressure and is multiplied by the constant $K_{hi}$ ($K$) to obtain the SV. $^{17}$ $K_{hi}$ is used to represent compliance and vascular resistance and originated from a multivariate model. $^{17}$ $K_{hi}$ is derived from Langewouter’s aortic compliance, mean arterial pressure (MAP), variance, skewness, and kurtosis of the arterial pressure curve. $^{14}$ A study produced by Langewouter determined that there is a correlation with aortic compliance and age, gender, and MAP. $^{18}$ An equation was then developed and was able to determine the aortic compliance with the utilization of the other factors. $^{18}$ $K_{hi}$ arises from the patient specific information that is input into the monitoring system. $^{14}$ By employing and including variables such as compliance and vascular resistance, the monitoring system is able to account for changes in vascular tone by the internal waveform analysis. $^{19}$ The patient specific information is employed to account for larger vessel compliance.

Pulse pressure is the difference between the systolic and diastolic blood pressure and is comparative to flow. Pulse pressure (arterial pressure) and SV are proportional. Therefore, pulse pressure is incorporated in the algorithm to derive hemodynamic data. $^{13,15}$ SVV is then measured by the variation of the SV from the mean of the arterial waveform with every beat of the heart. $^{20}$

A simple equation is used for calculation of the SVV value. The maximum SV value is subtracted from the minimum SV value over a specified period of time and then divided by the mean. $^{15}$ (Figure 1) SVV is an expected occurrence in which the arterial waveform fluctuates 5-10mmHg with spontaneous breathing due to the changes in intrathoracic pressure. A greater variation of 10mmHg is known as pulsus paradoxus. Controlled mechanical ventilation produces the same variation but in a reverse manner. The arterial waveform rises during inspiration and falls during expiration. The waveform is reversed due to the positive pressure
introduced with mechanical ventilation versus negative pressure with spontaneous breathing.\textsuperscript{20} The assessment of SVV is intended to predict fluid responsiveness.

The FloTrac\textsuperscript{TM} sensor is a key component for operation of the monitoring system. The sensor replaces the traditional arterial line transducer and provides two pressure cable connections. One pressure cable connection allows for conventional arterial waveform monitoring and the other connects directly to the Vigileo\textsuperscript{TM} monitoring unit. The Vigileo\textsuperscript{TM} monitor is the processing and display unit of the system.

Calibration is not necessary with this system and is unique to the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM}. Other noninvasive systems must be calibrated with a CVC, which negates the usefulness of a “noninvasive” system. During the development of the algorithm for this system, a large amount of data were collected which allows the monitoring system to associate pressure calculations with SV values.\textsuperscript{13} This permits the system to operate without invasive calibration.\textsuperscript{13} The benefits of a noncalibrated system include ease of use, less invasiveness with decreased risk, a quick setup, and the ability to use the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} monitor in many different clinical settings.\textsuperscript{16}

The traditional hemodynamic variables that have been employed on critically ill patients to assess volume status are central venous pressure (CVP), pulmonary artery occlusion pressure (PAOP), HR, and MAP. However, these static collected variables may not accurately predict a patient’s fluid status or response to fluid therapy accurately.\textsuperscript{21} The Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} monitoring system has been validated to provide hemodynamic data, such as CO and CI, comparable to the PAC along with the additional values of SVV that may be more useful at predicting the patients need and response to fluid.
There also exists a Vigileo™/FloTrac™ monitoring system volume responsive algorithm (decision tree)\textsuperscript{22} (Figure 1) that assists the anesthesia provider in making clinically relevant decisions for treating the perioperative patient based on the obtained values. SVV is the main focus of the algorithm in guiding preload and/or volume responsiveness. The algorithm guides and assists the anesthesia provider through a series of decisions to obtain fluid optimization versus the need for other interventions, such as vasopresser support, inotropic support, or diuretic therapy.

We undertook a systematic review to identify if the Vigileo™/FloTrac™ monitoring system derived values are reliable and accurate.
Overview

Methodology

Data Collection

An initial review of the literature was conducted using Google Scholar. Google Scholar originally returned 371 articles with the term “Vigileo monitor.” Three additional terms, “accuracy,” “cardiac output,” and “stroke volume variation,” were included in the criteria which provided a more focused search return of 94 articles. The inclusion time period was set after the year 2000 which further reduced the search return to 83 articles. All 83 article abstracts were reviewed and articles that addressed CO and SVV measurements were identified. Particular focus was placed on studies that compared hemodynamic monitoring between the Vigileo™/FloTrac™ system and other hemodynamic monitoring modalities. The criteria for retrieval of the full articles included the English language and patients undergoing surgery. Exclusion criteria included all editorials, opinion articles, and articles regarding pediatric subjects. A total of 28 articles for use in this review were obtained. Using Google Scholar, the search was conducted over the course of 12 months from January 2010 until January 2011. The search was repeated every other month until consistent duplication of results was achieved. Additional cross referencing was completed between the First Search: Medline database and Google Scholar. The initial FirstSearch review was conducted with the search term “Vigileo” and returned 76 articles. The term “accuracy” was then included with a return of 18 articles. Each of the articles were examined and the same inclusion and exclusion criteria were applied. Google Scholar email notifications were also established with the 4 key terms to acquire any new retrievable articles. An additional 5 articles were added to the literature synthesis over the 12
month period using this notification tool. The 33 articles used in this synthesis are critiqued below.

Levels of Evidence

The Joanna Briggs Institute recommendation for levels of evidence was utilized. An explanation of this level of evidence taxonomy can be found in Appendix 1.

Institutional Review Board

Project approval was requested and approved from the Texas Christian University Institutional Review Board (IRB) during Fall 2010. (Appendix 2)
PART 2

Literature

Background

The American Association of Nurse Anesthetists holds each nurse anesthetist to a scope of practice and standards. All nurse anesthetists must select, apply, insert, and interpret non-invasive and invasive monitoring as deemed appropriate for each individual patient and their clinical condition. The indications for monitoring must be based on each anesthesia provider’s expertise and clinical knowledge. The current accepted gold standard of hemodynamic monitoring is the PAC; however, there are other viable options that are available to substitute for the PAC and obtain similar results. This review was conducted to determine if the Vigileo™/FloTrac™ monitoring system is a reliable means of obtaining hemodynamic data.

Review and Literature Synthesis

A recurrent statistical analysis utilized in the studies for this review was Bland-Altman analysis. Bland-Altman analysis is a method of measurement to quantify 2 different types of measurements that are comparing the same type of variables, ie CO. This particular type of statistical methodology is often used when studying the Vigileo™/FloTrac™ monitoring system because the system is frequently compared to the PAC. A meta-analysis conducted by Critchley and Critchley comparing CO measurement techniques using bias and precision statistics concluded that a percentage error $\leq 30\%$ is a reference point to accept the new technology being studied when compared to current technology. This signifies that the accuracy and precision of the new device is relatively equal and acceptable to the reference, ie PAC. A large number of
studies regarding the Vigileo™/FloTrac™ system used the acceptable limit agreement of ≤30% to determine if the Vigileo™/FloTrac™ system could be used accurately according to the work published by Critchley and Critchley. Critchley and Critchley’s suggestion for a percentage error of ≤30% was utilized in many studies published for acceptance of the Vigileo™/FloTrac™ system. This statistical analysis can lend objective quantifiable analysis to determine the appropriateness and reliability of the Vigileo™/FloTrac™ system compared to PACs.

A majority of the articles analyzed for this literature review supported the use of the Vigileo™/FloTrac™ monitoring system on patients undergoing a wide variety of surgeries. Some of the reviewed studies focused solely on SVV, while others studied CO.

Support SVV

Biais studied the Vigileo™/FloTrac™ accuracy of SVV in the prone position. This experimental and comparative study analyzed a group of 30 subjects that were undergoing scoliosis surgery. The data points were initially recorded in supine position and then after the patient was positioned prone. Three subjects were excluded due to cardiac arrhythmias. The Vigileo™/FloTrac™ monitor was utilized for data collection. A small sample size was used, which posed a weakness for this study. The Vigileo™/FloTrac™ has not previously been studied in the prone position, which may have affected the results of measurements. When compared to results recorded for the supine position, the SVV value increased more in the prone position, as expected. The Vigileo™/FloTrac™ monitor accurately predicted patients that would respond to fluid based on SVV.
Biai and colleagues studied a group of 20 hemodynamically stable patients over a 2 year period that had acute lung injury or acute respiratory distress syndrome within 72 hours following a liver transplant. The goal of this prospective study was to compare the hemodynamic data obtained from a PAC and Vigileo™/FloTrac™ monitor, with the application of positive end expiratory pressure (PEEP). This study concluded that the SVV values from the Vigileo™/FloTrac™ system can accurately predict a decrease in SV, with the addition of PEEP, on this group of patients. A drawback of this study is the small population sample used and the specificity of the type of patients that were studied. A very select group of patients was utilized and, therefore, may make it difficult to disseminate the results to a larger population of patients. Another problem was the limits of 6-7ml/kg of tidal volume (Vt). The manufacturer of this system recommends a Vt of at least ≥8ml/kg. Regardless, this is a minor difference, and this study supports the accuracy and usefulness of this system. Overall, the study presented statistically significant (P<0.001) evidence for the use of the Vigileo™/FloTrac™ with mechanically ventilated patients with the addition of PEEP to predict a decrease in SV.

Biais carried out additional research in 2009 that was a prospective observational study of 30 patients undergoing liver transplant surgery that required the use of vasopressor agents. The goal of this study was to compare the Vigileo™/FloTrac™ system to a transthoracic echocardiogram (TTE) to assess SVV. This particular study utilized Bland-Altman analysis and showed correlation of the values of SVV obtained from the Vigileo™/FloTrac™ and TTE with the Mann-Whitney test. The study considered SVV before volume expansion (VE) with 4% Albumin and after VE. Unfortunately, this study only utilized the TTE to compare the Vigileo™/FloTrac™ system and not an additional method or the PAC. This study, like many others, analyzed a small, specific sample set. This study concluded that the Vigileo™/FloTrac™
system can accurately predict fluid responsiveness to SVV with rapidly changing SV in patients undergoing liver transplant surgery.

Cannesson evaluated 25 patients undergoing coronary artery bypass grafting (CABG) in a comparative and experimental study. The goal of the authors was to research if the Vigileo™/FloTrac™ system accurately predicted fluid responsiveness with SVV. The population size may appear small, as in many other studies completed on this same subject; however, the authors completed a power analysis. The power analysis determined that 25 patients were needed to identify a statistically significant relationship. Statistical analysis was assessed with a nonparametric Mann-Whitney U-test or Wilcoxon’s ranked sum test and Bland-Altman analysis. The study excluded patients with known cardiac arrhythmias. A potential problem with the monitor was identified in this study because an arrhythmia was observed and a SVV number was still displayed. This is not a reason to discontinue use of the system; however, the problem should be noted. Another notable conclusion of this study is that there needs to be at least one minute of hemodynamic stability upon initiation of the monitoring system to determine that the SVV value presented is accurate. Overall, based on the statistical analysis of the hemodynamic data recorded, this study supports the use of the Vigileo™/FloTrac™ system to predict fluid responsiveness by utilizing SVV.

de Waal conducted a prospective clinical study to compare the accuracy of the Vigileo™/FloTrac™ system to a transpulmonary thermodilution (TPCO) and pulse contour cardiac output (PiCCO) for 22 patients undergoing CABG. The PiCCO system utilizes TPCO and obtains hemodynamic data by detecting temperature changes after cold saline is injected into a CVC. The PiCCO system has similar characteristics to the Vigileo™/FloTrac™ system
because it is a pulse contour device, but the PiCCO requires calibration and a CVC. Recalibration may be needed as often as every hour. The PiCCO system is an invasive hemodynamic monitoring system that requires an arterial catheter (radial, axillary, femoral, or brachial), a CVC, and calibration. Data analysis was performed by paired-samples t-test, Pearson’s correlation coefficient and Bland-Altman analysis. A power analysis was completed to obtain the adequate number of patients needed for the sample size. A large number of data points were recorded for a total of 184 sets of CO measurements. The best correlation of data between the Vigileo™/FloTrac™ system and TPCO method was seen after weaning the patient off cardiopulmonary bypass (CPB) and in the postoperative period while the patient was in the ICU. The worst correlation was seen before the patient was put on CPB and after a dose of vasopressors was given. This led to an abrupt increase in vascular tone. Overall, this study supports the use of the Vigileo™/FloTrac™ monitoring system after CPB and in the ICU. Before the patient was placed on CPB and while the chest was open, the monitor did not correlate with the other 2 methods. While the TPCO and PiCCO methods have been supported in literature, the study did not use the PAC for comparison. The Vigileo™/FloTrac™ monitoring system is precise for calculating hemodynamic data after CABG surgery and in the ICU.

Hofer performed a comparative study of 40 patients undergoing an elective CABG. The comparison method to the Vigileo™/FloTrac™ system was the PiCCO system attached to a femoral arterial catheter. The manufacturer guidelines were followed for calibration. The aim of this study was to determine if the Vigileo/FloTrac™ system correlated with the PiCCO system predicting fluid responsiveness by using SVV during a change in body position. Hemodynamic data were recorded and compared at a 30 degree head-up position and 30 degree head-down
position. Data analysis were completed by Student’s t-test, Pearson’s correlation, and Bland-Altman analysis. Statistically significant variables (P<0.001) were seen in all hemodynamic data with the exception of HR and SVR. A strength of this study design is the use of a large number of many hemodynamic data at a predetermined time for comparison of the 2 systems. The study determined that there was clinically acceptable agreement and a strong correlation between the Vigileo™ and PiCCO systems for a predictor of fluid responsiveness by using SVV. A weakness of this study is presented with the change in position. The patients’ fluid status changes were forced by a change in position verses the need for fluid for improved hemodynamic stability. When compared to the PiCCO system, the Vigileo™/FloTrac™ system can be utilized as a noninvasive monitor for predicting fluid responsiveness with SVV.

Kobayashi performed a retrospective study of 18 patients that had an esophagectomy and compared SVV obtained from the Vigileo™/FloTrac™ to CVP values from an internal jugular CVC. The goal of this study was to assess if the SVV and CVP values could adequately predict fluid responsiveness. Statistical analysis was completed with a chi squared test, linear regression, and Pearson’s correlation. SVV and CVP were also compared to CO; SVV had a statistically significant value when compared against a change in CO (P=0.049), where as CVP did not. There appeared to be many data points recorded for each patient; however, there is not a clear delineation of the total amount of data points obtained. A graphical representation of SVV, CO, and CVP are available but it is difficult to determine how many points were recorded. Another weakness of this study is the comparison method of a CVP because CVP may be an inadequate predictor of fluid volume status. However, the Vigileo™/FloTrac™ system was shown to accurately predict the need for fluid with a SVV value >13%. The
Vigileo™/FloTrac™ system is accurate for assessing fluid responsiveness and is also useful for assessing the appropriateness of fluid replacement therapy.

Kungys studied a group of 25 patients undergoing an elective open prostatectomy, cystectomy, cystoprostatectomy or anterior/posterior spinal fusion procedures in which each of the patients underwent acute normovolemic hemodilution prior to the surgery. Data were collected at several different time points during hemodilution and volume replacement. The comparison method in this study was a TEE (transesophageal echocardiogram) that was supervised by a board certified operator. Pearson’s correlation was utilized for statistical analysis. During the study, as the normovolemic hemodilution process began, the SVV increased and as the volume was replaced, the value on the Vigileo™/FloTrac™ monitor decreased close to baseline. SVV changes were statistically significant (P<0.05). A weakness identified in this study was the comparison method of TEE and not a PAC with thermodilution. The study group used a certified operator of the TEE probe but the operator was not blinded to the Vigileo™/FloTrac™ results. Overall, this study proved that the Vigileo™/FloTrac™ system can be utilized for fluid volume replacement to guide intraoperative fluid management.

Benes conducted a prospective, randomized study evaluating 120 patients undergoing elective intraabdominal surgery. The group was divided into a control group with routine anesthetic care and the other group utilized a Vigileo™/FloTrac™ to guide intraoperative care. The goal of this study was to utilize SVV to determine if patients with fluid optimization guided by the Vigileo™/FloTrac™ had better outcomes. Statistical analysis was completed by t-tests, Mann-Whitney U test, and the Wilcoxon rank-sum test. A strength of this study was the size of the sample population. A limitation of this study resides in the location of the study. This was a
single-center study and a larger multi-center study would be beneficial to help support the data from this study. Overall, the Vigileo™/FloTrac™ control group had statistically significant outcomes resulting in fewer complications (P=0.0033), decreased number of hypotensive episodes (P=0.0001), and received a greater amount of colloids (P=0.0028) throughout surgery. The control group had a decreased hospital stay; however, there was no reduction in mortality or decrease in ICU stay but morbidity was decreased. SVV can be a helpful tool intraoperatively for fluid management.

Derichard completed a prospective study on 11 patients undergoing major abdominal and/or vascular surgery.33 A total of 56 fluid challenges were given during times of hemodynamic instability, and fluid administration was guided by SVV. Hemodynamic instability was defined as a 20% decrease in systolic blood pressure and/or a 20% decrease in HR. If this scenario was observed, the patient was volume loaded with a minimum of 200 mL. The Vigileo™/FloTrac™ system was compared to an esophageal Doppler. CI and SVI were obtained from the Doppler system. Statistical analysis was completed using Pearson’s linear correlation coefficient $r$ or Spearman’s rank correlation coefficient $p$. The area under the receiver operating characteristic (ROC) curve was also calculated. The area under the ROC curves are utilized for diagnostic accuracy, and the values obtained from both types of systems were within range. This study utilized actual hemodynamic instability situations and did not obtain data on created situations or scenarios. A limitation of this study is the small sample size and the comparison method via the Doppler. This study concluded that the Vigileo™/FloTrac™ system is as accurate as the esophageal Doppler for predicting fluid responsiveness.

Mayer completed a single-center prospective randomized trial of 60 high risk patients undergoing abdominal surgery.34 The patients were placed into two groups: a control-group and
an enhanced goal-directed hemodynamic monitoring group (GDT-group). The control groups
goals were to keep the MAP between 65-90 mmHg, CVP between 8-12 mmHg, and urine output
>0.5mL/kg/hr. The GDT group’s goal was to keep CI ≥2.5 L/min. This study found that GDT
would decrease hospital stay and secondarily decrease the amount of fluids administered and the
need for additional medication support perioperatively. The study did not provide statistical
information nor comparison to another hemodynamic measurement method; however, that was
not the goal of this study. The generalization of this study supports the use of the
Vigileo™/FloTrac™ for optimizing fluid therapy with SVV for improved patient outcomes with
the use of CI values.
Support CO

Cannesson completed a comparison study of 11 patients undergoing a CABG. This study recorded data points after the induction of anesthesia and many other periods until the patient was discharged from the ICU, for a total of 166 pairs of data. The Vigileo™/FloTrac™ system was compared to the PAC for assessment of CO. The values from both methods correlated well with a statistically significant relationship (P<0.001) analyzed by the paired t-test. Data analysis was also performed with Bland-Altman analysis and the Kolmogorov-Smirnov test. A limitation with this study is the small sample size. The use of CO for assessing interventions for patients perioperatively and for trending is valuable from the data obtained in this study. The statistical relationship is weak but apparent and the Vigileo™/FloTrac™ may be a useful device for hemodynamic monitoring.

Lorsomradee completed a prospective study with 52 patients undergoing elective cardiac surgery. A heterogeneous population was studied and consisted of 4 different groups: 20 patients without valvular stenosis or insufficiency, 10 patients with significant aortic stenosis, 10 patients with severe aortic insufficiency, and 12 patients had an intraaortic balloon pump (IABP) in place. To compare each group, data sets were recorded at identical time intervals for each patient. A baseline was recorded before the skin incision, before CPB, 15 minutes after CPB, and at the end of the surgery. Over 2000 data points were collected between the 4 groups and statistically analyzed by a paired t-test, linear regression analysis, and Pearson correlation coefficient. Continuous cardiac output (CCO) was recorded at each of these data points between the Vigileo™/FloTrac™ system and thermodilution method with the PAC. A major limitation of this study is that 25% of the patients included in data analysis were patients with an IABP in
place. The manufacturer does not recommend the Vigileo™/FloTrac™ system for this population of patients due to the alteration of the arterial waveform secondary to the IABP. The study noted that for more than 10 minutes in 8 of the IABP patients that the Vigileo™/FloTrac™ read “check arterial waveform” or “unusable signal.” The study noted a poor correlation between the 2 CO measurements when data were recorded for the IABP group. The study group with aortic insufficiency showed a poor relationship and a large limit of agreement with a low precision. However, the control group without severe aortic pathology and the aortic stenosis group showed agreement between the CCO and Vigileo™/FloTrac™ system. The Vigileo™/FloTrac™ system can be recommended for use in the OR; however, the monitoring system should be used cautiously in patients with severe aortic pathology and with an IABP because of the unpredictability of the arterial pressure waveform. The variability of the waveform may produce inaccurate readings on the monitor.

Manecke produced a prospective, observational study of 50 patients. These patients were post operative cardiac surgical patients and data were collected for a total of 12 hours. A total of 295 CO measurements were recorded and analyzed by Bland-Altman analysis. The comparison method consisted of intermittent thermodilution (ICO), CCO, and the Vigileo™/FloTrac™ system. All of these patients were hemodynamically stable and did not require a high dose of vasopressor or inotropic therapy. This could be a weakness of this study because there were not any clinical situations in which the arterial pressure waveform analysis may have been changed rapidly. Hemodynamic instability may have added an avenue to the study for comparison in more hemodynamically unstable patients. However, in this group of patients, the Vigileo™/FloTrac™ system correlated well with the other comparison methods and was determined to be a viable option for hemodynamic monitoring.
Marque completed an observational study of 29 patients that were post cardiac surgery. The Vigileo™/FloTrac™ system was compared to 2 other methods of hemodynamic measurements: PAC-CCO and the NICCOM™ system. The NICCOM™ system is a completely non-invasive system that utilizes bioimpedance with 4 double electrodes on the chest. A total of 12,099 data points were collected over 20 hours. Data analysis was performed using a Student’s t-test, Wilcoxon test, and Bland-Altman analysis. The research group defined clinical acceptability by 4 different criteria set forth by the group and the relationship between the 3 devices was determined clinically acceptable. The Vigileo™/FloTrac™ system provided hemodynamic variables to the healthcare provider in a quicker manner than the CCO. The accuracy and usefulness of the Vigileo™/FloTrac™ system was supported for CO monitoring.

Mayer compared 282 data pairs from 40 patients undergoing elective CABG. The Vigileo™/FloTrac™ system was compared to the PAC-ICO method. The hemodynamic data were collected at 8 different time intervals throughout surgery and up until 24 hours after surgery. The data were statistically analyzed using Bland-Altman analysis. The overall percentage error was 24.6%, less than the 30% level of acceptance. This research group completed a similar study in 2007; however, in this study they utilized newer software and refined algorithm of the device. The rate of adjustment for the variable compensating for changes in vascular tone decreased from 10 minutes previously to 60 seconds. Significant improvement was seen from the previous study and performance of the Vigileo™/FloTrac™ monitoring system related to the values obtained from the PAC-ICO.

The work of McGee studied 84 patients, of which 69 were surgical patients that required a PAC for their clinical care. The total number of data points is not stated, and each patient had
a different number of recorded CO values dependent on data collector preference and institution protocol. A strength of this study is the relatively large number of patients enrolled. Similar precision was reported between the 2 methods, but a percentage error was not reported. A hemodynamically unstable group of patients was used which differed from many of the other studies. However, in this patient population, the authors validated the accuracy and usefulness of this system for hemodynamic monitoring.

Breukers conducted a study of 20 patients and measured data for up to 24 hours after cardiac surgery. The comparison method was a PAC-ICO and a total of 56 simultaneous CO measurements were recorded with a percentage error of 30%. A small number of data points were collected 1 and 3 hours after surgery and on postoperative day 1. Statistical analysis showed an acceptable limit of agreement with Bland-Altman analysis.

Senn conducted an observational study of 50 patients undergoing elective cardiac surgery. This study compared an older version of the Vigileo™/FloTrac™ system software (first generation) to a newer version (second generation). The results were then compared to the PiCCO system and both of these data sets were compared to TPCO. This study observed the changes in each measuring method with altering the body position of the patient from supine, to 30 degree head-up, 30 degree head-down, and then back to supine. A total percentage error for the older version of the software was 37.5% whereas the other percentage errors were less than 30%. A weakness of this study is the use of body positioning to change the hemodynamics of the patients. This may not be an accurate depiction of true hemodynamic changes encountered during surgery. Upgraded software improved the accuracy of the monitoring system. A consistent trending of CO is shown with the newer version of the software when compared with the TPCO and PiCCO system.
Zimmerman performed a prospective study of 30 patients undergoing elective CABG. The comparison method of the Vigileo™/FloTrac™ system was PAC-ICO for a total of 192 data pairs. Data were recorded at 7 different time periods, beginning after induction of anesthesia and ending the morning after extubation of the patient in the ICU. About half of the data were recorded from a radial arterial catheter site and the other half was recorded at a femoral cannulation site. Statistical analysis was performed by Bland-Altman analysis. A total of 25% of the data measured was outside of the acceptable 30% range but overall the study supported the use of the Vigileo™/FloTrac™ system for CO monitoring.

Button completed a comparison study with a PAC and PiCCO system of 25 cardiac surgery patients with preserved left ventricular function. The patients were either undergoing elective CABG and/or valve surgery. Bland-Altman analysis and paired t-tests was utilized for statistical analysis. Data points were measured after induction, after sternotomy, at skin closure, and after the patients were transferred to the ICU. Before the patients were placed on CPB the CO measurements were significantly higher (P<0.05) when compared to CCO and ICO. The main strength of this article is the comparison method of 3 different hemodynamic measuring entities. The PAC was utilized for CCO measurements and intermittent measurements. The weakness of this article is the type of patients studied. The patients were hemodynamically stable with minimal changes in hemodynamic parameters. Overall, the Vigileo™/FloTrac™ system showed smaller limits of agreement when compared to the PiCCO system. All 3 types of measurement for CO were statistically comparable.

Mayer conducted an observational study of 40 patients undergoing a CAGB or valve repair. A PAC with CCO was utilized for comparison of the Vigileo™/FloTrac™ system. The
CO/CI data were collected at 8 different time intervals perioperatively and after: after induction, before CPB, after CPB, after sternal closure, on arrival to the ICU, and at 4, 8, and 24 hours after surgery. This allowed for a wide range of collection times and a total of 244 data sets were obtained and analyzed by Bland-Altman analysis. There was only a moderate agreement between the 2 methods with a percentage error of 46%. A limitation of this study was that first generation software was used and improvements have been made to produce more accurate hemodynamic variables. The ability of the monitoring system to trend the output data is accurate. Intraoperatively and postoperatively the CI measurements showed good agreement.

de Wilde conducted a comparison study of 13 postoperative cardiac surgical patients for a total of 104 paired CO values.\textsuperscript{45} CO values were obtained from 4 different methods: Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM}, non-calibrated Modelflow, the ultra-sound HemoSonic system, and the PAC with thermodilution. The Modelflow system is a pulse contour device and is similar to the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} monitoring system. The system can be utilized with or without calibration. The HemoSonic monitor utilizes an ultrasound probe with Doppler transducers. Data were measured before, during, and after 4 separate interventions: an increase in tidal volume, an addition of 10cm H\textsubscript{2}O of PEEP, passive leg raising, and the head up position. Bland-Altman analysis was used for statistical analysis. CO changes between the 3 comparison methods with the PAC were statistically significant (p<0.001). An overestimation with the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} was observed with comparison of the PAC, however, the directional changes and trending of CO were similar. A strength of this study is the number of comparison methods for CO values. Unfortunately, the sample size was small. Overall, the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} system produces CO values comparable to the PAC with a trend towards overestimation.
Prasser conducted an observational study of 20 critically ill patients. The study group consisted of a wide range of patients that had a large subset of disease processes. The group was compared to PAC-ICO for hemodynamic data. A total of 164 measurements were recorded. However, the number of CO values collected for each patient was not similar. The range of measurements could be deemed statistically inappropriate because measurements were as low as 3 for some individuals and as high as 20 for others. A percentage error of 49.3% was obtained from the statistical analysis of the data. This study showed that the Vigileo™/FloTrac™ system underestimates high CO and overestimates low CO but the direction of change and trending was similar.

Sakka conducted an observational study of 24 patients with septic shock. Data were compared with the PiCCO plus system, thermodilution technique, and the Vigileo™/FloTrac™ monitoring system. Statistical analysis was completed with linear regression analysis and the Bland-Altman method. This study showed that the Vigileo™/FloTrac™ system did not correlate well with the other comparison techniques, but the CO from the Vigileo™/FloTrac™ system trended in the same direction with a tendency to underestimate the CO value. Each patient had an equal number of CO values recorded for comparison. The patient population studied had reduced peripheral resistance with wide swings in hemodynamic stability, so the results are probably not able to be generalized to other patient populations. However, this study supports the use of CO values for trending with the notion of underestimation of values.
Support SVV and CO

Biais produced another study that analyzed the monitoring system and recorded data points for both SVV and CO. An experimental study was completed using the Vigileo™/FloTrac™ monitor compared to the PAC and TTE to obtain CO and SVV. The population studied was a total of 40 liver transplant patients, mechanically ventilated, that needed VE. The strengths in this article are the method of comparison between the PAC, Vigileo™/FloTrac™, and TTE before and after VE. Each method was used to obtain hemodynamic variables before and after VE with 4% Albumin administered over 20 minutes. The baseline SVV and decreased SVV seen after the VE statistically correlated between the PAC and Vigileo™/FloTrac™ monitor (P<0.005). CO also showed a statistically significant increase after VE between the 3 methods. Ideally, a larger group of randomized patients should have been studied for a more accurate depiction of the significance of the values. However, the study showed that the Vigileo™/FloTrac™ monitor correlated well with the PAC and TTE for utilizing SVV and CO values to improve hemodynamic management of liver transplant patients.

Liu completed a prospective observational study in 100 cardiac surgery patients. This study measured CCO with thermodilution to the Vigileo™/FloTrac™ monitoring system’s arterial based CO. SVV values were also measured and compared by TEE and PAC to other preload indicators, such as CVP, PAOP, left ventricular end-diastolic area, and left ventricular end-diastolic volume. Statistical analysis was completed with Bland-Altman analysis, Pearson’s correlation, and ANOVA. CCO and CO obtained from the Vigileo™/FloTrac™ system found a high correlation with 480 data points (p=0.0001). SVV when compared to left ventricular end-diastolic area (480 data points) and left ventricular end-diastolic volume (240 data points) also
had a high correlation (P=0.0001). The strengths of this study were found in the large population sample combined with a large number of data points. Also, this study measured both CO and SVV which are important values obtained from the Vigileo™/FloTrac™ system. The main weakness in this study is the type of study conducted. This study was utilized to compare current hemodynamic variable monitoring techniques to the Vigileo™/FloTrac™ system. An outcome study could be used as a follow up to determine if clinical outcomes can be improved from this data. This study concluded that the use of SVV as a preload indicator can help achieve optimal hemodynamic function and CO.
No Support

Biancofiore completed a comparison study of 29 liver transplant patients. The Vigileo™/FloTrac™ system was evaluated alongside a PAC thermodilution method for obtaining CI values. An asset of this study was the large number of data points used for comparison (290), and the goal was to assess if the Vigileo™/FloTrac™ and PAC values were similar. Data analysis was conducted with Bland-Altman, Student’s t-test, Bonferroni test, Pearson’s correlation coefficient, and linear regression. This study failed to find that the Vigileo™/FloTrac™ system can reliably trend CI values in liver transplant patients; however, there were many limitations that could have affected the study. The data points were collected in the operating room at 5 different time intervals and data were also collected in the ICU at 5 different time intervals. The problem with the data set collected in the ICU is the patients were able to breathe spontaneously. The manufacturer of this system does not support the use of the Vigileo™/FloTrac™ on spontaneously breathing patients. The inclusion of patients who could breathe spontaneously may have affected the results of data collection. The study found the CI trend analysis of 145 pairs of the 261 recorded data points. This presents with a 67% concordance which was well below the threshold value of 90-95%. The threshold value assumes trending ability in which the CI values changed in a similar manner. However, the line graph presented in this article, comparing the PAC and Vigileo™/FloTrac™ shows trending to be similar. Indeed there is a discrepancy between the value of the PAC and Vigileo™/FloTrac™ in which the Vigileo™/FloTrac™ consistently underestimates the CI value. The main problem identified by the authors with this study is failure of the software to calculate accurate hemodynamic values with a low SVR state. However, with the introduction of a new software
and improved technology, the Vigileo™/FloTrac™ system may better compensate for changes in vascular tone.\textsuperscript{22}

Lahner completed a prospective study with 20 patients undergoing major abdominal surgery.\textsuperscript{49} The Vigileo™/FloTrac™ system was compared to an esophageal Doppler to determine the accuracy of SVV. The operator of the Doppler was blinded to the Vigileo™/FloTrac™ results. A large number of data sets were collected during 67 fluid boluses and statistically analyzed by a Mann-Whitney U-test. The data were recorded before, during, and after each bolus. The esophageal Doppler may have significant operator variability that may affect the results of the hemodynamic parameters.\textsuperscript{50} This study does not recommend the use of the Vigileo™/FloTrac™ system in clinical practice without further testing. However, the second generation software was utilized and newer software is currently being studied for improvement. Also, comparison to the hemodynamic gold standard was not utilized.

Biais completed a comparison study measuring CO with the Vigileo™/FloTrac™ system and instantaneous CO stat-mode (ICO\textsubscript{SM}).\textsuperscript{17} The ICO\textsubscript{SM} is similar to the thermodilution method except the ICO\textsubscript{SM} obtains hemodynamic data using automatic thermodilution. The study enlisted 20 patients undergoing a liver transplant. Even though a small sample size was used, a large number of data points were recorded. There were 5 stages of data measurements: after anesthesia induction, after portal clamping, after the heptatectomy, after reperfusion, and data were also recorded in the ICU. The ICO\textsubscript{SM} has shown agreement with the PAC in previous studies but the monitoring technique has disadvantages that may not provide accurate results. This system has a time delay (60 seconds) and may fail to detect the rapidly changing hemodynamics with liver transplant patients. The Vigileo™/FloTrac™ system did not show
correlation with the ICO\textsubscript{SM}; however, the ICO\textsubscript{SM} may not be accurate itself with the type of patient population studied. A large percentage error of 43\% was recorded in this study. Unfortunately in patients with liver disease, where the SVR is low and CO is high, the extent of vasodilation may produce skewed results on the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} monitor. This patient population represents a group of patients that have extreme variations in hemodynamics. The Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} system may have short periods of inaccuracy with hemodynamically unstable patients. Conversely, the study did not utilize the PAC thermodilution method.

Concha compared the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} system to TEE for comparison of CO measurements in 10 patients.\textsuperscript{51} These patients were hemodynamically stable and undergoing laparoscopic colorectal surgery. Data collection was performed at several points during the surgery for a total of 88 CO measurements. Limits of agreement were analyzed with Bland-Altman analysis. CO values were recorded after intubation, after placing the patient in the surgical position, after establishing the pneumoperitoneum, every 30 minutes or sooner if the MAP decreased greater than 20\% from baseline, during incision, and at the completion of the surgery after the pneumoperitoneum had been released and the patient was supine. The study was different than many others performed because it utilized stable patients undergoing laparoscopic surgery. Many other studies used liver transplant patients or cardiac surgical patients that have a wide range of hemodynamic changes. Several weaknesses emerged from this study. A small sample size was used and the gold standard for hemodynamic variables, PAC, was not used for comparison. The patient population studied did not need a PAC for their surgery, so the TEE was used. The mean percentage error was 40\% and therefore differences were evident for this type of patient population in laparoscopic colorectal surgery when compared to a TEE, an operator dependent system.
Compton conducted a comparative study of 25 heterogenous hemodynamically unstable patients in the medical ICU.52 A variety of statistical methods were used for analysis, such as nonparametric Mann-Whitney U, Wilcoxon testing, linear regression analysis, and Bland-Altman analysis. This observational study obtained 324 data points over 3 days. However, the data points were not collected at predetermined intervals and each patient had a different number of data points collected. The only requirement for data collection was that it was recorded during routine care, which was not defined, and not during or after a bolus of vasopressor agents. The comparison method used against the Vigileo™/FloTrac™ was the PiCCO system that utilized a femoral arterial catheter. In this study, a radial arterial catheter was used with the Vigileo™/FloTrac™ system. The PiCCO system requires calibration parameters set forth by the manufacturer, and the guidelines were not followed. The calibration was completed less frequently than required. The study did not utilize a PAC for comparison. The statistical analysis of the data had a percentage error of >30% but the limitations found in this study may outweigh the poor statistical correlation for acceptance of the Vigileo™/FloTrac™ system.

Chatti completed a prospective multicenter study of 60 patients.53 The study compared the first generation software to the second generation software version to an esophageal Doppler for accuracy of the Vigileo™/FloTrac™ system for monitoring SV and SVV. A large number of data points were collected and this was the first study to compare the Vigileo™/FloTrac™ software to determine if improvements for obtaining hemodynamic variables had been made with an updated version of the software. Statistical analysis was performed by Bland-Altman. A strength of the study was each operator of the esophageal Doppler was an experienced clinician with at least 10 years experience and each clinician were blinded to other results obtained during the study to eliminate selection bias. A large sample size was used; however, the patients were
separated into groups based on the different versions of the software. The second generation software of the Vigileo™/FloTrac™ system had better agreement and correlation; however, the software version accuracy was above the clinically acceptable range (58%) proposed by Critchley and Critchley.²⁵ A weakness of this study was that it was completed at 4 different hospitals by different operators of the Doppler system and 2 different types of Doppler systems were used. Also, an additional comparison to a PAC would have been beneficial to include in this study. The second generation software version cannot completely be ruled out for evaluation of hemodynamic data but this study does not support replacing the current accepted method of hemodynamic monitoring by the PAC.
Summary

The key findings that emerged from this literature review indicated that the Vigileo™/FloTrac™ system's specific values for CO and CI may not correlate exactly with PAC with 100% accuracy. However, the trends of these Vigileo™/FloTrac™ system derived values are useful to estimate hemodynamic status. Additionally, the SVV values are reliable for gauging vascular fluid status and the adequacy of need for additional intravascular fluid volume. Although the Vigileo™/FloTrac™ monitoring system is a relatively new technology the trending values and SVV have been found to be reliable and useful in current studies (Table 1). A strength of this systematic review is a large literature search exploring the use of SVV for gauging fluid responsiveness and CO during surgery was conducted. A limitation presented in this literature review is that only the first and second generation software studies were available for synthesis. The improvement of software appears to be in a transition stage and third generation software has been introduced by the manufacturer. The technology of this system is centered around an algorithm, and the algorithm has been improved to provide updated information every 20 seconds versus every 10 minutes with the first generation software. Also, Edwards LifeSciences claims that large changes in vascular tone is better accounted for with software upgrades. The third generation software algorithm is comprised of a larger patient database with expansive patient conditions. The software includes patients with hyperdynamic conditions in which there are large adjustments in SVR and vasodilation. The key change in the third generation software is the inclusion of Dynamic Tone Technology, a new software technology that automatically adapts to the significant hemodynamic changes that may currently pose a problem with accuracy of this monitoring system. The inclusion of research studies that investigated the third generation software may or may not have improved the strength of this
literature review; however, there are very few at this time. Currently there is an observational study being conducted with the third generation software on patients with acute circulatory failure to determine if the new software has improved the performance of the Vigileo™/FloTrac™ system. The study is currently recruiting participants and the study completion date was set for February 2011.

The Vigileo™/FloTrac™ system can be an important tool for anesthesia providers to assist in making decisions to improve patient outcomes. There are many situations in which the Vigileo™/FloTrac™ system can be implemented in practice. Specifically for anesthesia providers, the use of the monitoring system in the operating room may have the potential to provide hemodynamic monitoring to patients that may not have been monitored before. Prior to minimally invasive monitoring, the risks of the PAC may have prevented monitoring in patients that could have benefited from observation of hemodynamic data. These patients may have, unfortunately, been under monitored. All patients undergoing surgical procedures that require an arterial line for continual blood pressure monitoring could benefit from the information and guidance of the Vigileo™/FloTrac™. The hemodynamic data obtained from this system could become the basis for therapeutic decisions in the operating room.

Fluid optimization guided by SVV and CO to improve hemodynamics has many benefits for patients, such as decreased length of hospital stay, an earlier return to bowel function after a major operation, and a decrease in postoperative nausea and vomiting. Management of the hemodynamic data obtained from this system is guided by the values identified on the monitor that directly correlate to the volume responsive algorithm (Appendix 1). Hemodynamic stability can be assessed by the SVV and assist the anesthesia provider in determining if the patient is
hypovolemic or in need of a vasopressor agent, inotrope, or diuretic. SVV is a significant and major data point utilized for guiding intravascular fluid status perioperatively. The balance of fluid optimization is critical in patients hemodynamic status because too much or too little fluid may result in devastating consequences perioperatively, such as pulmonary edema, shock, or renal failure. A SVV >13% may indicate the need for volume replacement and can be investigated with a volume challenge. The type of volume required is a choice based on the anesthesia providers’ experience and overall clinical depiction of the patient. If the SVV is <13%, the SVI must be considered. A normal SVI (40-50mmHg) may indicate the need for vasopressor support, a low SVI (<40mmHg) may specify the need for an inotrope, and a high SVI (>50mmHg) may require a diuretic.\textsuperscript{22}

The Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} monitoring system has no absolute contraindications but has limitations that must be taken into account. Currently, the monitoring system is only recommended for patients that are 100% mechanically ventilated and not spontaneously breathing. Arrhythmias can change the arterial pressure waveform and, therefore, alter the SVV and ability to accurately predict fluid responsiveness along with CO. Nonetheless, the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} monitoring system will alert the anesthesia provider to a large amount of pulse rate variability with a yellow heart on the monitor screen known as the SVV filtering indicator. The monitor has the innate ability to filter 2 atypical beats every 20 seconds. Elevated levels of PEEP can erroneously increase SVV and warrant for fluid resuscitation per the monitor but may not actually be needed for the patient. Finally, large changes in vascular tone or vasodilation may also correlate with an increased SVV.\textsuperscript{22}

Cost effectiveness should be a consideration for each anesthesia department when determining which hemodynamic system to use. A cost analysis completed by Manecke in
Southern California estimated that the cost of usage of the Vigileo™/FloTrac™ monitoring system is about $225 with minimal preparation or implementation time. The cost of a PAC is about $75. This article also concludes that operating room time is about $25/minute. The average total cost of a PAC then totals about $125 to $250 when including the minutes required for insertion and preparation of the PAC. The market purchase price of the Vigileo™/FloTrac™ system is approximately $15,000.

The use of this system can be an enormous asset to anesthesia monitoring. However, clinical judgment cannot be substituted for data obtained from the system. This minimally invasive monitoring system can be used in the operating room with an appreciation of the system’s limitations. Even with widely accepted practices in anesthesia, clinical judgment is of utmost importance and should always be utilized. As studies become available on the third generation software, the system needs to continue to be analyzed for accuracy with the changes that have been implemented. SVV can be a respectable tool with guidance of the volume responsiveness algorithm for key decisions during surgery. The use of CO/CI values can also be helpful. While CO/CI values may not always be 100% accurate, the trend of the values are useful perioperatively. Some studies concluded that the Vigileo™/FloTrac™ underestimated CO values while others overestimated CO. More importantly with the application of clinical knowledge and judgment, the CO values obtained from the Vigileo™/FloTrac™ monitoring system can be a valuable and efficacious means of hemodynamic data.

Based on current evidence, the Vigileo™/FloTrac™ system is a viable option for hemodynamic monitoring perioperatively. The monitoring system should be considered for all patients undergoing a surgical procedure in which the need for hemodynamic monitoring may be
beneficial during the course of the operation. Critically ill patients that are expected to have wide variations in hemodynamic status or considered as hyperdynamic, such as high SVR or septic patients, may still benefit from the use of the Vigileo™/FloTrac™. However, caution is advised under these circumstances due to the rapid and large changes of SVR that may affect the hemodynamic data. The use of the Vigileo™/FloTrac™ monitoring system in the operating room will offer hemodynamic monitoring to patients that have not been monitored in the past because of the risks of PAC’s.
PART THREE

Intervention

Implementation Addendum

Upon completion of a thorough and concise review of the literature, one can see that it is apparent there is substantial evidence in support of implementing the Vigileo™/FloTrac™ monitor into practice for hemodynamic monitoring of perioperative patients. In lieu of implementation of this project, the literature review will be submitted to the Critical Care Nursing Journal, Association of Perioperative Registered Nurses Journal, and/or American Association of Nurse Anesthetists Journal for dissemination through peer-reviewed publication. The goal and purpose of this intervention is to educate anesthesia providers by dissemination of this synthesis of the literature. Publication in a peer-reviewed professional journal will allow education of anesthesia providers and other healthcare personnel better utilize this system in their daily practice. Dissemination through publication is an efficacious tool to reach a large audience interested in evidence based practice. A presentation will also be conducted in Fort Worth, Texas to provide an opportunity to educate and inform local anesthesia providers. The guiding framework and model used for the development of this implementation is the Iowa Model of Evidence-Based Practice (EBP).56 (Figure 2)

Below is an example of an implementation plan.

The Vigileo™/FloTrac™ monitor will be implemented as an alternate method for obtaining CO and SVV at Plaza Medical Center in Fort Worth, Texas. There are many key steps that need to be completed for successful implementation and execution of this project.
The first step in implementation is to contact the hospital administrators, operating room manager, head of the anesthesia department, and the Vigileo™/FloTrac™ vendor to notify them of the project and gain support and cooperation needed to implement the Vigileo™/FloTrac™ monitor in the operating room.

The next step is to identify the problem and knowledge focused triggers that are relevant to this facility. Problem focused triggers can be identified by a verbal interview with anesthesia providers who are currently using other methods of hemodynamic monitoring and assessing particular data points: risk management, process improvement, internal/external benchmarking, and financial data. Knowledge focused triggers can be acquired by researching the current practice guidelines recommended by the Joint Commission and seeking the opinions/comments from the facilities standards committee. The facilities standards committee can assist in identifying appropriate knowledge focused triggers.

Next, information collected from the interview process of anesthesia providers, regarding problem and knowledge focused triggers, will determine if this topic is a priority. Data supporting the risks and complications of the PAC will be compiled for presentation to the anesthesia department.

A team will be formed including anesthesia providers who will be using the monitor, the Vigileo™/FloTrac™ vendor, the operating room manager, and the head of the anesthesia department. A team leader will be selected.

A meeting will be conducted with the representative of the Vigileo™/FloTrac™ monitor and purchasing/central services to prepare to order the necessary supplies for initial set up and continued use of the monitor after the pilot period.
• All anesthesia providers will be provided with training and education concerning this system. An in-service will be required for all providers. The Vigileo™/FloTrac™ representative will be available to answer questions following the in-service.

• At this point, the staff will be able to review the current synthesized literature. The synopsis of the literature review will be presented in a succinct, easy to follow PowerPoint presentation with handouts. The information gathered from the synthesis and articles utilized will be available to the team for review. The literature review previously conducted determined there is enough research to support implementation and that the research base is adequate.

• The team will establish relevant outcomes to be achieved. The anesthesia providers will complete a pre-pilot questionnaire and baseline data will be collected from past patient charts.

• The team members will collectively write an evidence-based practice guideline with assistance from the vendor. The vendor has likely implemented this monitor in other facilities and can offer guidance and suggestions.

• Initially, 4 Vigileo™/FloTrac™ monitoring systems will be used for the pilot in conjunction with 4 selected anesthesia providers. These providers will insert a PAC and arterial line in every stable CABG surgery for comparison of the 2 systems.

• Implementation of the pilot will then begin in 4 of the 17 operating rooms.

• During this time, a questionnaire will be completed after each surgery. The questionnaire will have questions that provide information on ease of use, comfort with the monitoring system, familiarity, and overall satisfaction of the monitor.
• During the 2 month pilot period, a notebook will be kept with each monitor for the user to describe any problems, concerns or questions with the monitor during use. Each week, the team leader will check the notebook and immediately address concerns with the anesthesia providers. A phone number will also be available for the Vigileo™/FloTrac™ representative for contact with any immediate problems or concerns.

• After the pilot period of 2 months, a post pilot meeting will be held to compile all the information gained from the pre and post-pilot questionnaires.

• The information from the questionnaires will assist the team in modifying and finalizing the practice guideline.

• The team will decide if the change is appropriate for the facility by these factors: patient safety, ease of use, practitioner preference, and overall satisfaction with the monitoring system.

• Another PowerPoint presentation will be formulated and presented to the anesthesia department regarding information obtained during the pilot study.

• If the project is accepted, the change will be instituted in each operating room suite, including non-cardiac surgeries.

• Data collection that utilizes the previous questionnaire will continue for a period of 6 additional months to monitor and analyze structure, process, and outcome data related to the environment, staff, and cost. Each week, anesthesia providers will complete the questionnaire.

• Internally within the facility, results will be disseminated by presenting the information hospital wide to the board of directors, decision makers of the hospital, and to the
anesthesia department. Externally, the results will be published in an anesthesia journal and presented at a national anesthesia conference.
Implementation Plan and Results

Iowa Model of Evidence-Based Practice

Problem/Knowledge-focused triggers

The Iowa Model of Evidence-Based Practice (Figure 2) will direct the implementation of the Vigileo™/FloTrac™ monitor in the operating room for monitoring hemodynamic data. Identification of problem and knowledge triggers will justify the implementation of this monitor into the operating room. This information will assist the staff in making them aware of the problems relevant to this facility and hemodynamic monitoring. Risk management data can be obtained by analyzing patient charts for previous adverse events and processes that were utilized to improve these problems. Process improvement data will play a key role in improving patient mortality and morbidity by measuring complication rates from the insertion of invasive lines. Internal benchmarking can be achieved when verbally interviewing the anesthesia providers by asking questions that will reveal their opinions and concerns on their current hemodynamic monitoring methods and techniques. The vendor may be able to offer data from another facility that successfully implemented this monitor to provide for an external benchmark. Financially, the cost of the Vigileo™/FloTrac™ system and the PAC with monitoring is approximately the same; yet less insertion risk is involved when using the Vigileo™/FloTrac™ system. While operating costs of the 2 devices are about the same, the risks carried with the PAC may make the PAC much more costly. One blood stream infection obtained from a CVC can cost in excess of $28,000.
Knowledge focused triggers arise from national agencies, such as the Joint Commission, that mandates healthcare providers to “continuously improve the safety and quality of care provided to the public.”\textsuperscript{59} This improvement can be achieved by introducing new technology in the operating room that is safe, effective, and reliable. The hospital internal standards committee can be contacted regarding concerns with invasive monitoring and the facility’s philosophy and mission can be reviewed for guidance. The last knowledge focused trigger is to review new research or other literature. This trigger was identified in the literature review that was previously completed.

\textit{Priority}

The use of the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} monitor provides a safe alternative to the PAC and is a priority for implementation to continue to obtain valuable hemodynamic data with less risk posed to the patient. The risks associated with the insertion of a PAC include arrhythmias, hemorrhage, bacteria introduction, pulmonary artery rupture, thrombosis, and pulmonary valve damage.\textsuperscript{60} This wide spectrum of potential complications makes this monitor a priority for any facility using PACs’. The infection possibilities correlated to CVC insertion also add to the importance of utilizing a less invasive form of hemodynamic monitoring. Approximately 5 million CVCs are inserted each year with a 3\% to 8\% incidence in infection and an occurrence of a 12\% to 25\% mortality rate.\textsuperscript{61}

\textit{Form a Team}

The formation of a team for implementation will include those members previously mentioned. The team leader will be utilized for education, training, and to act as a resource
person. Members of the team should be eager and fully engaged in the project and they will assist in “development, implementation, and evaluation of the EBP.”62(p.503)

Assemble relevant research/literature

Relevant research and literature has been assembled in the literature review presented.

Critique and synthesis of research

A systematic review of relevant literature was completed and the data confirmed the need for a less invasive monitor. In regards to the Iowa model, the inclusion for studies used in the synthesis were based on three specific criteria: “1) the overall scientific merit of the study, 2) the type of subjects enrolled in the study and their similarity to the patient population to which the findings are to be applied, and 3) the clinical relevance of the study.”62, p. 504

Is there a sufficient research base?

The amount of research currently available is supportive for the use of the Vigileo™/FloTrac™ monitoring system in the operating room. There is enough supportive research to begin using the Vigileo™/FloTrac™ monitor in relatively hemodynamically stable patients undergoing non-complicated surgery. The PAC should continue to be available for use in critically ill, unstable patients that are expected to experience a wide range of hemodynamic changes.

Pilot the Change in Practice

Piloting the change in practice will be the next step in determining if this project will ultimately be implemented in this facility. The main outcome to be measured is the improvement
of staff use, comfort with the monitoring system, and familiarity after education. Another outcome to be accomplished is providing the anesthesia staff with a less complicated monitoring system for obtaining hemodynamic variables. Baseline data will be obtained from investigating the number of PACs used in the last year and recording the number of adverse events related to their use. Another piece of baseline data collected will come from the pre-implementation interview of anesthesia providers. Evidence-based practice guidelines will be established and designed to promote up-to-date, superior patient care with the use of the Vigileo™/FloTrac™ monitor. The Vigileo™/FloTrac™ monitor will initially be used on stable patients for training purposes and comparison. The monitor will eventually be disseminated to patients that will benefit from hemodynamic monitoring but do not necessarily need invasive monitoring with the PAC.

The pilot will be implemented as previously stated. The processes and outcomes will be monitored by short questionnaires filled out after each surgery by the 4 anesthesia providers. A post-pilot meeting will be held with the team members to evaluate the process and outcomes as evidenced by the questionnaires. With this information, the guideline will be modified and finalized for ease of use of the system, feasibility of the patient population in the operating room, and reliability of utilization over the entire surgical patient population.

Is Change Appropriate for Adoption in Practice?

Two months after the pilot study implementation, all of the pre and post pilot questionnaires will be compiled and a meeting will be held between the 4 anesthesia providers, the Vigileo™/FloTrac™ representative, the operating room manager, and the head of the anesthesia department. This meeting will be used to determine if the Vigileo™/FloTrac™
The system is appropriate for adoption into practice at this facility. The goals of this meeting will be to assemble a presentation with the information obtained from the questionnaires to present the information to the entire anesthesia department. This meeting will be able to provide feedback for improvements, changes that need to be made, and suggestions for future uses of the system before the full operating room integration. The team will analyze the questionnaires and feedback from the users of the system and discuss the appropriateness of the monitor for their facility. The team will finalize practice guidelines for use of the monitor. If the team decides that the outcomes have not been met and the implementation of this project is not feasible in their facility, then the team will need to continue to evaluate quality of care and seek new knowledge to find alternatives to invasive hemodynamic monitoring.

Monitor and Analyze Structure, Process, and Outcome Data

If the decision is made to implement the Vigileo™/FloTrac™ system facility wide, the system will be placed in each operating room suite and all anesthesia providers will have access to the monitor and equipment needed. After the implementation of the Vigileo™/FloTrac™ monitor, the collection of data will continue and the team will monitor and analyze structure of the new system. A cost benefit analysis will be performed during this time. This will determine if the Vigileo™/FloTrac™ system is cost effective in comparison to the PAC in this facility.

Disseminate Results

The results will be disseminated after the 2 month implementation periods as previously stated in the intervention section.
Outcomes

The following outcome measures will be assessed.

- The percentage of patients who have hemodynamic monitoring before the implementation and 6 months after implementation. An increased percentage is anticipated due to the option of a less invasive monitor with a relatively easy set-up and simple interpretation of hemodynamic data.

- The number of adverse events related to hemodynamic monitoring for a 6 month period before implementation and for a 6 month period following implementation. A decreased percentage is anticipated due to improved monitoring capabilities.

- A final questionnaire will be completed 6 months after implementation to obtain information on the anesthesia providers’ opinions and value of the Vigileo™/FloTrac™ system. A 75% acceptance measure from the anesthesia providers will be expected because of ease of use of the system and improved patient monitoring.
SWOT Analysis

**Strength**
- Unique Product
- Ease of use
- Valuable hemodynamic data
- Possibility of improved patient outcomes

**Weakness**
- Lack of systems available
- Special equipment required
- Continuity of use

**Opportunity**
- Improve algorithm
- Education on system
- Provide information on benefits of use
- Risks of PAC's

**Threat**
- Cost
- Currently using PAC's
- Arterial lines not routinely used
Strength

The uniqueness of the Vigileo™/FloTrac™ lies within the monitor’s ability to provide hemodynamic data without the need for calibration of the system or central venous access. The set up of this system is simple and utilizes an already existing arterial line. The hemodynamic parameters received from this monitor provide valuable information on the patients’ oxygen delivery (CO), fluid status, and the need for supportive agents such as vasopressors or inotropes. A recent study has supported that fluid optimization and improved hemodynamic status can decrease postoperative patient complications and decrease their hospital stay.32

Weakness

This system requires a special purchase of the Vigileo™ monitor and the FloTrac™ sensors for proper usage. The FloTrac™ sensors are connected to the arterial line and replace the current transducing system. This system has the potential to assist anesthesia providers in guiding critical decisions; however, the anesthesia providers must be educated on the benefits and limitations of the system. Continuity of use is imperative and needs to be encouraged for successful implementation and continued usage of the monitoring system.

Opportunity

The manufacturer of the system has continually improved the algorithm to better compensate for hemodynamic changes to improve accuracy and reliability. Educating anesthesia providers that will have the opportunity to use this system will help improve their confidence in the system. Not all anesthesia providers routinely work in an environment where they utilize hemodynamic monitoring tools, but, with the Vigileo™/FloTrac™ system, they will have the
ability to obtain valuable hemodynamic data for assistance in guiding their decisions on patient management. The Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} will provide an unfulfilled need of hemodynamic monitoring that anesthesia providers do not currently have access to outside of the cardiac surgery specialty. An opportunity also lies within the realm of the benefits of the Vigileo\textsuperscript{TM}/FloTrac\textsuperscript{TM} system verses the risks of PAC’s.

**Threat**

The cost of purchasing a new product may be problematic because of growing healthcare costs. Anesthesia providers currently using PAC’s may not feel inclined to switch because of contentment with the current accepted gold standard of hemodynamic monitoring. Also, arterial lines are not routinely used in all surgeries and may pose a problem because arterial lines are mandatory for operation of this monitoring system.
Conclusion

The best measurement of the benefits associated with this project is the reduced number of adverse events and a possible decreased rate of patient mortality and morbidity due to the inclusion of hemodynamic monitoring in their surgery. The implementation of this monitor will allow for hemodynamic monitoring in patients who may not have previously been considered candidates due to risks versus benefits. The Vigileo™/FloTrac™ monitor has the ability to increase patient safety in relation to perioperative hemodynamic monitoring while providing accurate and reliable data for hemodynamic monitoring and fluid management.

- The key number to treat for SVV is >13%. This value will provide information assisting the anesthesia provider if the patient needs intravascular volume, pressor agents, inotropes, or diuretics, based on the volume responsive algorithm.
- CO values from the Vigileo™/FloTrac™ system trend in a similar manner to PAC. CO can be used confidently for trending hemodynamic data.
- Clinical judgment when utilizing this monitoring system is of utmost importance. The entire clinical picture must be analyzed before deciding on interventions that the patient requires.
- Optimization of hemodynamic variables with the assistance of the Vigileo™/FloTrac™ monitoring system may improve patient outcomes. Hemodynamic monitoring of CO, CI, and SVV may now be available to a larger patient population with the utilization of the minimally invasive monitoring system.
Future Directions/Recommendations

The introduction of the third generation software may improve the accuracy of the Vigileo™/FloTrac™ monitoring system suggested by more studies. Future research studies should focus on studying the third generation software due to modifications that are expected to account for extreme changes in vascular tone, such as with septic patients and other hemodynamically unstable patients. The first and second generation software are currently being used in the perioperative setting with confidence, yet there are clinical situations in which the Vigileo™/FloTrac™ monitoring system are not 100% accurate due to large variations in vascular tone.

The cost of each system is an important aspect when approaching implementation of the Vigileo™/FloTrac™ into practice. The actual price of each system may be hospital dependent based on the purchase price exclusive to each hospital. Future research should encompass a cost analysis compared to the PAC when establishing the usefulness and appropriateness of this system in the perioperative period. The current research regarding specific cost of the Vigileo™/FloTrac™ system is limited. A cost analysis produced by future DNP students may provide strong evidence for the use of the Vigileo™/FloTrac™ monitoring system for comparable hemodynamic data at a possible decreased or similar cost to the healthcare system. Healthcare costs are expected to be 4.5 billion in 2019, an increase from 2.6 billion today. It will be imperative that anesthesia providers continue to provide quality healthcare at an economically conscious manner.
References


<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Study Type</th>
<th>Evidence</th>
<th>Strengths</th>
<th>Weakness</th>
<th>Population</th>
<th>Generalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bias et al, 2009</td>
<td>Experimental/Comparison</td>
<td>4</td>
<td>-First to study prone position and position changes</td>
<td>-Small sample size</td>
<td>Scoliosis Surgery</td>
<td>-prone position increased value of PPV and SVV</td>
</tr>
</tbody>
</table>
|                     |                     |           | -Recorded 4 types of data points for comparison (PPV, SVV, CO, static compliance) | -VE given before prone position
- May have affected PPV and CO                                              | n=30                | -Vigileo™/FloTrac™ predicted fluid responsiveness in supine position and similar in prone position |
| Bias et al, 2009    | Prospective         | 4         | -Studied accuracy of SVV with PEEP                                         | -Small sample size                                                          | Liver Transplant   | -Vigileo™/FloTrac™ accurately predicted decreased SV with PEEP                   |
|                     |                     |           |                                                                           | -Did not follow manufacturer guidelines for Vt                             | n=20               |                                                                                 |
| Bias et al, 2009    | Prospective/Observational | 4         | -Statistical analysis showed correlation with Doppler                      | -Compared to TEE only                                                     | Liver Transplant   | -Can accurately predict SVV with rapidly changing SV                              |
|                     |                     |           | -Measured prior to VE                                                     | -Patients hemodynamically stable                                           | n=30               |                                                                                 |
| Canneson et al, 2009 | Comparison         | 4         | -Compared to PAC                                                          | -Need at least 1 minute of hemodynamic stability before recording SVV     | CABG n=25          | -Accurate for SVV                                                                 |

Table 1
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>n</th>
<th>Power Analysis Comment</th>
<th>Group Characteristics</th>
<th>Outcome Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>de Waal et al, 2007&lt;sup&gt;28&lt;/sup&gt;</td>
<td>Prospective</td>
<td>4</td>
<td>-Power analysis completed -Adequate for n</td>
<td>CABG n=22</td>
<td>-Vigileo™/FloTrac™ precise for calculating hemodynamic data after CABG and in ICU</td>
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<tr>
<td>Hofer et al, 2008&lt;sup&gt;21&lt;/sup&gt;</td>
<td>Comparative</td>
<td>4</td>
<td>-Observed and recorded large amount of variables in head up and head down position -Compared to PiCCO, not PAC</td>
<td>Elective CABG n=40</td>
<td>-System accurately predicted fluid responsiveness with SVV</td>
</tr>
<tr>
<td>Kobayashi et al, 2008&lt;sup&gt;30&lt;/sup&gt;</td>
<td>Retrospective</td>
<td>4</td>
<td>-Examined relationship of SVV predicting fluid needs while CVP values showed no change or need for VE -Reliably predicted hypotension from decreased intravascular volume</td>
<td>Esophagectomy n=18</td>
<td>-Acceptable for predicting fluid responsiveness with SVV and appropriateness of timing of fluid</td>
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<tr>
<td>Kungys et al, 2009&lt;sup&gt;31&lt;/sup&gt;</td>
<td>Non-randomized, Observational</td>
<td>4</td>
<td>-Recorded a large number of data points -TEE for comparison -Operator judgment</td>
<td>Elective Surgery n=25</td>
<td>-Weak statistical relationship but support for use of intraoperative fluid management</td>
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<tr>
<td>Benes et al 2010&lt;sup&gt;32&lt;/sup&gt;</td>
<td>Prospective/ Randomized</td>
<td>4</td>
<td>-Large population -Single center study</td>
<td>Elective intraabdominal surgery n=120</td>
<td>-Decreased hospital stay and morbidity -No decrease in mortality -SVV helpful tool in intraoperative fluid management</td>
</tr>
<tr>
<td>Derichard et al 2009&lt;sup&gt;33&lt;/sup&gt;</td>
<td>Prospective</td>
<td>4</td>
<td>-Hemodynamic instability defined per -Small sample size -Esophageal</td>
<td>Major Abdominal Surgery n=11</td>
<td>-Vigileo™/FloTrac™ accuracy is similar to esophageal Doppler for predicting fluid</td>
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<tr>
<td>Study Protocol and Utilization</td>
<td>Doppler Comparison</td>
<td>Responsiveness</td>
<td></td>
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<tr>
<td>Mayer et al, 2010&lt;sup&gt;34&lt;/sup&gt;</td>
<td>Prospective Randomized Trial</td>
<td>2</td>
<td>-Control group versus GDT group</td>
<td>-No comparison method</td>
<td>High Risk Abdominal Surgery n=60</td>
</tr>
</tbody>
</table>

**Support CO**

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<thead>
<tr>
<th>Study Protocol and Utilization</th>
<th>Doppler Comparison</th>
<th>Responsiveness</th>
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<tr>
<td>Canneson et al, 2007&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Comparison</td>
<td>4</td>
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<tr>
<td>Lorsomradee et al, 2007&lt;sup&gt;35&lt;/sup&gt;</td>
<td>Prospective</td>
<td>4</td>
</tr>
<tr>
<td>Manecke et al, 2007&lt;sup&gt;36&lt;/sup&gt;</td>
<td>Prospective/Observational</td>
<td>4</td>
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<tr>
<td>Marque et al, 2008&lt;sup&gt;37&lt;/sup&gt;</td>
<td>Comparative</td>
<td>4</td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Sample Size</td>
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<tr>
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<tr>
<td>Mayer et al, 2008&lt;sup&gt;38&lt;/sup&gt;</td>
<td>Observational</td>
<td>4</td>
</tr>
<tr>
<td>McGee et al, 2007&lt;sup&gt;39&lt;/sup&gt;</td>
<td>Multicenter, Prospective Clinical Trial</td>
<td>4</td>
</tr>
<tr>
<td>Breukers et al, 2007&lt;sup&gt;40&lt;/sup&gt;</td>
<td>Prospective</td>
<td>4</td>
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<tr>
<td>Senn et al, 2009&lt;sup&gt;41&lt;/sup&gt;</td>
<td>Observational</td>
<td>4</td>
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<tr>
<td>Zimmerman et al, 2008&lt;sup&gt;42&lt;/sup&gt;</td>
<td>Prospective</td>
<td>4</td>
</tr>
<tr>
<td>Button et al, 2007&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Comparison</td>
<td>4</td>
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<tr>
<td>Mayer et al, 2007&lt;sup&gt;44&lt;/sup&gt;</td>
<td>Observational</td>
<td>4</td>
</tr>
<tr>
<td>de Wilde et al, 2009&lt;sup&gt;45&lt;/sup&gt;</td>
<td>Comparison</td>
<td>4</td>
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<tr>
<td>Prasser et al, 2007&lt;sup&gt;46&lt;/sup&gt;</td>
<td>Observational</td>
<td>4</td>
</tr>
<tr>
<td>Study</td>
<td>Study Design</td>
<td>Study Type</td>
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<td>-------------------------------</td>
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<tr>
<td>Sakka et al, 2007(^{47})</td>
<td>Observational</td>
<td>4</td>
</tr>
<tr>
<td>Bias et al, 2008(^{15})</td>
<td>Experimental</td>
<td>4</td>
</tr>
<tr>
<td>Liu et al, 2010(^{48})</td>
<td>Prospective, Observational</td>
<td>4</td>
</tr>
<tr>
<td>Biancofiore et al, 2009(^{11})</td>
<td>Comparison</td>
<td>4</td>
</tr>
<tr>
<td>Lahner et al, 2009(^{49})</td>
<td>Prospective</td>
<td>4</td>
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<tr>
<td>-----------------------------------------</td>
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</tr>
<tr>
<td>Concha et al, 2009&lt;sup&gt;51&lt;/sup&gt;</td>
<td>Comparison</td>
<td>Data recorded at many different time intervals, Small sample size, Compared to TEE not PAC, Operator variability</td>
</tr>
<tr>
<td>Compton et al, 2008&lt;sup&gt;52&lt;/sup&gt;</td>
<td>Observational</td>
<td>Data collection inconsistent, PiCCO system not used correctly according to manufacturer's recommendation</td>
</tr>
<tr>
<td>Chatti et al, 2009&lt;sup&gt;53&lt;/sup&gt;</td>
<td>Prospective</td>
<td>Did not use PAC for comparison, Doppler has operator variability, Study completed at 4 different facilities, possible increasing operator error</td>
</tr>
</tbody>
</table>

Abbreviations: CABG, coronary artery bypass graft; CCO, continuous cardiac output; CI, cardiac index; CO, cardiac output; CVP, central venous pressure; GDT, goal directed therapy; ICO, intermittent cardiac output; ICO<sub>SM</sub>, instantaneous cardiac output stat-mode; ICU, intensive care unit; IABP, intraaortic balloon pump; PAC, pulmonary artery catheter; PEEP, positive end expiratory pressure; PiCCO, pulse contour cardiac output; PPV, pulse pressure variation; SV, stroke volume, SVV, stroke volume variation; TEE, transesophageal echocardiogram; VE, volume expansion; Vt, tidal volume
Figure 1

**FloTrac System**

**Volume Responsive Algorithm**

© WT McGee MD 2005

**Volume Responsive SVV > 13%**

- **YES**
  - Volume Challenge
  - SVI Normal (40-50)
  - SVI Low (<40)
  - SVI High (>50)
  - Pressor
  - Inotrope
  - Diuretic
- **NO**

**Stroke Volume Variation**

A sensitive indicator of preload responsiveness
(on control ventilated patients)

\[ \%SVV = \frac{SV_{max} - SV_{min}}{SV_{mean}} \]

Airway Pressure

Arterial Pressure

Expiration

Inspiration

Controlled Ventilation

Controlled Ventilation
### Appendix 1

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>Evidence from a systematic review or meta-analysis of all relevant randomized controlled trials (RCTs), or evidence-based clinical practice guidelines based on systematic reviews of RCTs</td>
</tr>
<tr>
<td>Level II</td>
<td>Evidence obtained from at least one well-designed RCT</td>
</tr>
<tr>
<td>Level III</td>
<td>Evidence obtained from well-designed controlled trials without randomization</td>
</tr>
<tr>
<td>Level IV</td>
<td>Evidence from well-designed case-control and cohort studies</td>
</tr>
<tr>
<td>Level V</td>
<td>Evidence from systematic reviews of descriptive and qualitative studies</td>
</tr>
<tr>
<td>Level VI</td>
<td>Evidence from single descriptive or qualitative study</td>
</tr>
<tr>
<td>Level VII</td>
<td>Evidence from the opinion of authorities and/or reports of expert committees</td>
</tr>
</tbody>
</table>
Ms. Rhonda Walker

Dear Ms. Walker:

RE: Accuracy of the Vigileo™ monitoring system

The proposed study has been reviewed by the TCU Nursing Institutional Review Board (IRB) and was determined to meet the criteria for an exempt review. The proposed study is a literature synthesis and education presentation of the Vigileo monitoring system.

The study is approved for one year from the above date. Another review by the TCU Nursing IRB is required if your study changes in any way and the TCU Nursing IRB must be notified immediately with regard to any adverse events.

If you have any question please do not hesitate in contacting the TCU Nursing IRB.

Sincerely,

Terri S. Jones, CRNA, DNP

TCU Nursing IRB- Chair