Vigileo™/FloTrac™ System: Stroke Volume Variation and Hemodynamic Trends are Beneficial for Acute Care Management of Perioperative Patients.

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Citation

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Abstract

Background: Hemodynamic monitoring is a necessary priority in the perioperative setting. Invasive and noninvasive monitoring technologies have been used to improve patient care. Literature pertaining to a new hemodynamic monitoring system, the Vigileo™/FloTrac™ system, was explored to ascertain the 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 patients' 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.

INTRODUCTION

Hemodynamic monitoring has been utilized for over four 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 render the PAC inconsequential.

The Vigileo™/FloTrac™ system is unique because it does not require central venous access or placement of a PAC to obtain hemodynamic data. This particular 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).[5] 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.[5-7]

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.[8-11] SV is calculated by 3 different variables: arterial pulsatility, resistance, and compliance.[8,10] Arterial pulsatility is the standard deviation of the pulse pressure and is multiplied by the constant Khi (□) to obtain the SV.[12] Khi is used to represent compliance and vascular resistance and originated from a multivariate

model.[12] Khi is derived from Langewouter's aortic compliance, mean arterial pressure (MAP), variance, skewness, and kurtosis of the arterial pressure curve.[9] A study produced by Langewouter determined that there is a correlation with aortic compliance and age, gender, and MAP.[13] An equation was then developed and was able to determine the aortic compliance with the utilization of the other factors.[13] Khi arises from the patient specific information that is input into the monitoring system.[9] 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.[14] 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.[8,10] SVV is then measured by the variation of the SV from the mean of the arterial waveform with every beat of the heart.[15]

Calibration is not necessary with this system which is unique to the Vigileo™/FloTrac™. 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 was collected which allows the monitoring system to associate pressure calculations with SV values.[8] This permits the system to operate without invasive calibration.[8] The benefits of a noncalibrated system include ease of use, decreased risk with less invasiveness, , a quick setup, and the ability to use the Vigileo™/FloTrac™ monitor in many different clinical settings.[11]

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.[16] The Vigileo™/FloTrac™ 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 patient's need and response to fluid.

There also exists a Vigileo™/FloTrac™ monitoring system volume responsive algorithm (decision tree)[17] (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.

A systematic review to identify if the Vigileo™/FloTrac™ monitoring system derived values are reliable and accurate was conducted.

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 or critically ill patients. 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 no new articles were found. Additionally, cross referencing was completed between the FirstSearch: 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. All 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.

Figure 1

Level I	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
Level II	Evidence obtained from at least one well-designed RCT
Level III	Evidence obtained from well-designed controlled trials without randomization
Level IV	Evidence from well-designed case-control and cohort studies
Level V	Evidence from systematic reviews of descriptive and qualitative studies
Level VI	Evidence from single descriptive or qualitative study
Level VII	Evidence from the opinion of authorities and/or reports of expert committees

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 noninvasive and invasive monitoring as deemed appropriate for each individual patient and their clinical condition.[18] 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 which obtain similar results.[19] 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 two different types of measurements that are comparing the same type of variables, eg CO.[20] 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 ≤30% is a reference point to accept the new technology being studied when compared to current technology.[21] This signifies that the accuracy and precision of the new device is relatively equal and acceptable to the reference, ie PAC.[21] 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.[21] 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 critically ill patients and 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™ system accuracy of SVV in the prone position.[22] This experimental and comparative study analyzed a group of 30 subjects that were undergoing scoliosis surgery. Initial data points were recorded with the patients in the supine position. Subsequent recordings were with the patients positioned prone. Three subjects were excluded due to cardiac arrhythmias. The Vigileo™/FloTrac™ system was utilized for data collection. A small sample size was used, which posed a weakness for this study. The Vigileo™/FloTrac™ system 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™ system accurately predicted which patients would respond to fluid based on SVV.

Biais and colleagues studied a group of 20 hemodynamically stable patients over a two year period that had acute lung injury or acute respiratory distress syndrome within 72 hours following a liver transplant.[9] The goal of this prospective study was to compare the hemodynamic data obtained from a PAC and Vigileo™/FloTrac™ system 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. A drawback of this study is the small population sample used and the specificity of the type of patients that were studied. The use of such a select group of patients may make it difficult to apply the results to a larger population of patients. Another

problem was the limit of 6-7ml/kg of tidal volume (Vt). The manufacturer of this system recommends a Vt of at least ≥8ml/kg.[17] 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™ system with mechanically ventilated patients, with the addition of PEEP, to predict a decrease in SV.

Biais carried out additional research in 2009 that included a prospective observational study of 30 patients undergoing liver transplant surgery that required the use of vasopressor agents.[6] 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. , Like many others, this study 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.[23] 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 the need for 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.[24] 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 characteristics similar 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.[25] The PiCCO system is an invasive hemodynamic monitoring system that requires an arterial catheter (radial, axillary, femoral, or brachial), a CVC, and calibration.[25] Data analysis was performed by paired-samples t-test, Pearson's correlation coefficient, and Bland-Altman analysis.[24] 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 which led to an abrupt increase in vascular tone. Before the patient was placed on CPB and while the chest was open, the monitor did not correlate with the other two 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. Overall, this study supports the use of the Vigileo™/FloTrac™ monitoring system after CPB and in the ICU.

Hofer performed a comparative study of 40 patients undergoing an elective CABG.[16] 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 analyses were completed using 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 hemodynamic data points at a predetermined time for comparison of the two systems. The study determined that there was a clinically acceptable agreement and a strong correlation between the Vigileo™/FloTrac™ system 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™ system to CVP values from an internal jugular CVC.[26] 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.[24] 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 surgery.[27] Data were collected at several different time points during hemodilution and volume replacement. The comparison method in this study was a transesophageal echocardiogram (TEE) 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™ system 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™ system 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.[28] The group was divided into a control group with routine anesthetic care and the other group utilized a Vigileo™/FloTrac™ system 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, the 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), a decreased number of hypotensive episodes (P=0.0001), and the reception of a greater amount of colloid infusions. (=0.0028) throughout surgery. The control group had a decreased hospital stay and morbidity was decreased; however, there was no reduction in mortality or decrease in ICU stay. 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.[29] 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 is 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.[30] The patients were placed into two groups: a control group and an enhanced goal-directed hemodynamic monitoring group (GDT group). The control group's 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 as well as decrease the amount of fluids administered and the need for additional medication support perioperatively. The study provided neither 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.[7] This study recorded data points after the induction of anesthesia and at 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 of 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.[31] A heterogeneous population was studied and consisted of four different groups: 20 patients without valvular stenosis or insufficiency, 10 patients with significant aortic stenosis, 10 patients with severe aortic insufficiency, and 12 patients who 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 four groups and statistically analyzed by a paired t-test, linear regression analysis, and Pearson's 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 two 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 measured with the PAC 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 along 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.[32] These patients were postoperative 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 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.[33] The Vigileo™/FloTrac™ system was compared to two other methods of hemodynamic measurements: PAC-CCO and the NICCOM™ system. The NICCOM™ system is a completely noninvasive system that utilizes bioimpedance with four 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 four different criteria set forth by the group and the relationship between the three 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.[34] The Vigileo™/FloTrac™ system was compared to the PAC-ICO method. The hemodynamic data were collected at eight 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;[40] 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 the previous 10 minutes to 60 seconds. Significant improvement was seen from the previous study[41] and performance of the Vigileo™/FloTrac™ monitoring system related to the values obtained from the PAC-ICO.

The work of McGee studied 84 patients, 69 of which were surgical patients that required a PAC for their clinical care.[35] 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 two 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.[36] 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 one and three hours after surgery and on postoperative day one. Statistical analysis showed an acceptable limit of agreement with Bland-Altman analysis.

Senn conducted an observational study of 50 patients undergoing elective cardiac surgery.[37] 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.[38] The comparison method of the Vigileo™/FloTrac™ system was PAC-ICO for a total of 192 data pairs. Data were recorded at seven 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.[39] The patients were either undergoing elective CABG and/or valve surgery. Bland-Altman analysis and paired t-tests were 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 three 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 three types of measurement for CO were statistically comparable.

Mayer conducted an observational study of 40 patients undergoing a CAGB or valve repair.[40] 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 following 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 two 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.[41] CO values were obtained from four different methods: Vigileo™/FloTrac™, 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™/FloTrac™ 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 four separate interventions: an increase in Vt, an addition of 10cm H_20 of PEEP, passive leg raising, and the head up position. Bland-Altman analysis was used for statistical analysis. CO changes between the three comparison methods with the PAC were statistically significant ($p<0.001$). An overestimation with the Vigileo™/FloTrac™ system 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™/FloTrac™ system produces CO values comparable to the PAC with a trend towards overestimation.

Prasser conducted an observational study of 20 critically ill patients.[42] 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 three 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.[43] Data were compared with the PiCCO plus system, thermodilution technique, and the Vigileo™/FloTrac™ 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 most likely are not applicable 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.[9] An experimental study was completed using the Vigileo™/FloTrac™ system 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. One strength of this study is its comparison of methods PAC, Vigileo™/FloTrac™ system, and TTE before and after volume expansion. 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™ system ($P<0.005$). CO also showed a statistically significant increase after VE between the three 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™ system 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.[44] 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 and the large number of data points. Also, this study measured both CO and SVV which are important values obtained by the Vigileo™/FloTrac™ system. 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 obtainment of CI values.[5] Two strengths of this study are the large number of data points used for comparison (290), and the purpose to investigate if the Vigileo™/FloTrac™ system 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. The data points were collected in the operating room at five different time intervals and data were also collected in the ICU at 5 different time intervals. 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 set collected in the ICU included patients able to breathe spontaneously; this inclusion may have affected the results of data. The manufacturer of this system does not support the use of the Vigileo™/FloTrac™ system on spontaneously breathing patients.[17] 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™ system, shows trending to be similar. Indeed there is a discrepancy between the value of the PAC and Vigileo™/FloTrac™ system in which the Vigileo™/FloTrac™ system consistently underestimates the CI value. The main problem with this study, as identified by the authors, is failure of the software to calculate accurate hemodynamic values with a low SVR state. However, with the introduction of new software and improved technology, the Vigileo™/FloTrac™ system may better compensate for changes in vascular tone.[17]

Lahner completed a prospective study with 20 patients undergoing major abdominal surgery.[45] 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™ system 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.[46] 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_{SM}).[12] The ICO_{SM} is similar to the thermodilution method; however the ICO_{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 five stages of data measurements: after anesthesia induction, after portal clamping, after the hepatectomy, after reperfusion, and in the ICU. A large percentage error of 43% was recorded in this study. The ICO_{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_{SM}; however, the ICO_{SM} may not be accurate itself with the type of patient population studied. Unfortunately vasodilation may have produce skewed results on the Vigileo™/FloTrac™ system in liver transplant patients where the SVR is low and CO is high. This patient population represents a group of patients that have extreme variations in hemodynamics. The Vigileo™/FloTrac™ 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™/FloTrac™ system to TEE for comparison of CO measurements in 10 patients.[46] 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, therefore 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 which is, an operator dependent system.

Compton conducted a comparative study of 25 heterogenous hemodynamically unstable patients in the medical ICU.[48] 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 three 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™ system 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, but 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.[49] The study compared an esophageal Doppler to the first and second generation Vigileo™/FloTrac™ system software to determine the accuracy of monitoring for SV and SVV. A large number of data points were collected and this was the first study to compare the Vigileo™/FloTrac™ system 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 that each operator of the esophageal Doppler was an experienced clinician with at least 10 years experience and each clinician was 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.[21] 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.

{image:2}

CONCLUSION

The key finding that emerged from the literature is that the Vigileo™/FloTrac™ system can be utilized for perioperative hemodynamic monitoring. The Vigileo™ system can be a viable option for assisting anesthesia providers in guiding appropriate care based on hemodynamic data obtained from the system. The majority of articles obtained for this review supported the use of the Vigileo™ system. The Vigileo™/FloTrac™ system has the possibility to increase patient safety in relation to perioperative hemodynamic monitoring while providing accurate and reliable data for hemodynamic monitoring and fluid management.

Strength of this systematic review is the extensive research that was utilized. A review of the literature was completed on numerous occasions and cross referenced with an additional database for exhaustion of the literature. A limitation presented in this literature review is the first and second generation software studies were included. The improvement of software appears to be in a transitional stage and a third generation software has been introduced by the manufacturer. Edwards Life Sciences claims that large changes in vascular tone is better accounted for with software upgrades.[17] Hemodynamic instability with large changes in SVR currently pose a problem with accuracy and this monitoring system. The inclusion of research studies that investigated the new software may or may not have improved the strength of this literature review. To date there are currently very few studies on the new software. The Vigileo™/FloTrac™ system can be an important tool for anesthesia providers to assist in making decisions to improve patient outcomes.

FUTURE DIRECTIONS/RECOMMENDATIONS

The introduction of the third generation software may improve upon the accuracy of the Vigileo™/FloTrac™ system.[16,50,51-53] 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 clincial situations in which the Vigileo™/FloTrac™ system are not 100% accurate due to large variations in vascular tone.

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 hemodynamically monitored before. Prior to minimally invasive monitoring, the risks of the PAC may have prevented monitoring in patients that could have benefited from collection of hemodynamic data. 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™ system. The hemodynamic data obtained from this system could become the basis for therapeutic decisions in the operating room.

The use of this system can be an asset to intraoperative monitoring. This minimally invasive monitoring system can be used in the operating room with an appreciation of the systems strengths and limitations. As more studies become available on the third generation software, the system needs to continue to be stideid for accuracy with spontaneously breating patients and patients with wide swings in hemodynamics.

{image:3}

Volume Response algorithm. Reprinted with permission McGee WT.

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