# FloTrac® Monitoring System: What Are Its Uses in Critically Ill Medical Patients?

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**Abstract:** The FloTrac®/Vigileo device uses arterial pressure waveform analysis to calculate stroke volume and cardiac output; it does not require calibration against an independent measurement of cardiac output. Consequently, it provides a method to determine hemodynamic status, changes in the clinical course and responses to therapeutic interventions in patients who have arterial catheters in place. These devices perform relatively well in stable patients undergoing surgery and having an acceptable percentage error in differences between the FloTrac® device and invasive monitoring using pulmonary catheters. However, in patients with septic shock and other clinical states associated with low systemic vascular resistances, such as cirrhosis, the FloTrac® does not provided acceptable correlation with independent measurements with pulmonary artery catheters. FloTrac® measurements often underestimate the cardiac output and have unacceptably high percent error, which ranges from 30% to 60%. There is a moderate correlation with changes in cardiac output after fluid administration, but a poor correlation with changes in cardiac output after increases or decreases in norepinephrine administration. The bias between measurements increases as the systemic vascular resistance decreases. Consequently, cardiac output measurements using the FloTrac® device are not accurate enough for use in patients with septic shock, advanced liver disease and other medical conditions associated with decreased vascular tone.

**Key Indexing Terms:** Arterial pressure waveform analysis; Cardiac output; Stroke volume variation; Systemic vascular resistance; Sepsis; ICU. **[Am J Med Sci 2015;349(4):352–356.]**

Bedside monitoring of vital signs provides important information about clinical status and response to treatment. Cardiac output measurements provide an integrative assessment of cardiac preload, afterload, contractility and heart rate. These measurements usually require invasive monitoring with right-heart catheters. However, the risks associated with these catheters and the uncertain benefits have significantly reduced overall utilization and stimulated research into alternative methods of measuring cardiac output (CO), including arterial pressure waveform analysis, pulsed Doppler's cardiac output, $CO_2$ partial rebreathing and bioimpedance. Arterial pressure waveform analysis represents a potential use of intravascular arterial pressure measurements to determine cardiac output, and this methodology is reviewed in this article with a focus on its use in medical intensive care unit patients.

## THE BASICS FOR WAVEFORM ANALYSIS

Consider a cylinder made of compliant walls holding a volume of fluid. If more fluid is added to the cylinder, the pressure changes in the cylinder. The compliance (C) of the cylinder is defined by Equation 1.

$$C = dV/dP, \quad (1)$$

where V is volume and P is pressure.

If compliance were known for all volumes, the stroke volume (SV) could be calculated from the pulse pressure. The slope of the decay of the pressure waveform from systolic to diastolic values could also be used to calculate the drainage rate out of the cylinder (cardiac output) using the same compliance. The problem becomes one of determining compliance, and the following factors seem important in this discussion. Proprietary methods have been used to relate the mean and standard deviation (SD) in pulse pressure to compliance. Since they are proprietary, we cannot evaluate their merits on theory. Compliance can be determined from test subjects or cadaver blood vessels, and one can assume that compliance measured in test subjects will apply to patients. The problem here is variation between patients and the variation within a single patient due to variables affecting vascular tone. Even if compliance is not known and is not constant for all volumes, but is constant for each volume over all pulses, then arterial pressure waveform analysis can reliably determine whether CO is increasing or decreasing after interventions. The problem with this assumption is that drugs and sepsis almost certainly change compliance over time. Regardless of how the manufacturer determines SV and CO, one can compare these results to other methods, and manufacturers and investigators have done studies comparing the use of the mean and SD to determine CO to the generally accepted Fick and thermodilution methods.

## THE FloTrac® SYSTEM

The FloTrac® system (Edwards Lifesciences Corp, Irvine, CA), first introduced in 2005, includes a pressure sensor and the Vigileo monitor.[1,2] The FloTrac® sensor is connected to an arterial catheter and is used to obtain hemodynamic values based on arterial pressure waveform analysis. These values include CO, cardiac index (CI), SV, SV variation and SV index. If a central venous catheter is introduced, systemic vascular resistance can be calculated, and central venous oxygenation can also be measured depending on the catheter. These values are used to manage cardiovascular resuscitation. The FloTrac® sensor calculates the SV from the arterial pressure waveform, and from this value, the CO and other values are determined. The sensor was initially validated against Fick and/or thermodilution methods in patients undergoing cardiothoracic surgery, and the minimal interventions needed to obtain the hemodynamic values made it promising for the management of patients undergoing surgery or with trauma or sepsis. In addition, it might reduce costs involved with more invasive monitoring.

The FloTrac® system differs from other arterial pressure waveform analysis devices since it does not require calibration (Table 1). Other devices use a transpulmonary dilution catheter to estimate CO and calibrate measurements based on the pulse

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TABLE 1. Devices that estimate hemodynamic variables from arterial pressure waveform analysis

| LiDCO Plus—PiCCO | FloTrac®/Vigileo |
|---|---|
| Estimation of CO with transpulmonary dilution measure | Not calibrated by any "external" measures of CO |
| Require calibration and must be frequently repeated | Arterial compliance calibrated from biometric data |
| Require a specific dilution technique: Thermodilution—Lithium dilution | Continuous "complex" APW analysis |
| | Estimation validated from a human database |

LiDCO Plus, Ltd., Cambridge, United Kingdom (Lithium dilution). PiCCO Pulsion Medical System, Munich, Germany (Thermodilution).

waveform to a certain CO measurement. Unlike other commercial devices, the FloTrac® estimates compliance from the waveform. The calculations from the FloTrac® sensor are based on a proprietary algorithm that estimates SV from the product of the blood pressure SD, referred to as pulsatility, and a factor $k$ that accounts for vascular compliance and resistance measured as milliliters per beats/mm Hg (Equation 2).

$$\text{P (SD)} \; k = \text{SV} \tag{2}$$

Pulsatility measured by the FloTrac® sensor depends on the arterial pressure waveform analysis. This is done by measuring waveforms every 20 seconds with data points within the curves gathered by the device at a frequency of 100 Hz. These multiple data sets are then used to calculate the blood pressure SD every 20 seconds.[3] Factor $k$ is the result of the patient's gender, age, height and weight and dynamic changes in the arterial pressure waveform. The calculations needed to obtain these measurements are based on studies of human vasculature, which take into account arterial wall dynamic elasticity as a result of pressure changes.[4,5] The arterial pressure waveform characteristics used are skewness and kurtosis.[2] Thus, factor $k$ depends on predetermined system data and is recalculated every minute. More recent software recognizes conditions associated with vasodilatation or vasoplegia and provides more accurate measurements in patients with these conditions. The manufacturer does not disclose the specific information and calculations used with these data, and most discussions on this subject are superficial with emphasis on the underlying concepts.

With SV measurements, it is also possible to calculate SV variation. The concept of SV variation as a hemodynamic variable originates from the changes seen in systolic pressure variation in decreased preload situations with mechanical ventilation. Systolic pressure variation is defined as the difference between the lowest systolic blood pressure and end respiratory systolic blood pressure in 1 respiratory cycle.[6] An increase in this difference has been found to indicate fluid responsiveness in ventilated patients with reduced preloads.[7,8] SV variation, much like systolic pressure variation, represents the variability in SV in a respiratory cycle, and it is calculated by dividing the difference of maximum and minimum SV by the mean SV.[9] If this variability is more than 10%, it suggests the patient is hypovolemic, which makes it a useful indicator of preload responsiveness.

## FloTrac® SENSOR IN THE HEMODYNAMICALLY UNSTABLE MEDICAL PATIENT

Most studies to date have evaluated the FloTrac® sensors performance in measuring CO and SV variation in comparison with other devices. These comparisons have mostly been made in surgical patients with a limited number of comparisons performed in nonsurgical patients. The FloTrac® sensor has also been used in fluid management and CO monitoring in medical conditions such as sepsis. Based on the previous assumptions, one of the main concerns is whether the performance of the FloTrac® sensor is the same in vasoplegic states as in patients, such as postoperative patients, with normal systemic vascular resistances.

Patients with sepsis often have vasodilation and a hyperdynamic circulation. In these patients, CO measured by FloTrac® has been compared with thermodilution techniques using pulmonary artery catheters (PACs). This has been done with serial updates of the FloTrac® system software. The first-generation software was developed from a limited pool of information, and the results were disappointing in vasoplegic states. This suggested poor reliability because of changes in arterial compliance and consequently limited usefulness in septic shock patients. The latest generation FloTrac® software (version 3.02) has proved more accurate than previous software and less influenced by total systemic vascular resistance (TSVR) than previous software versions (Table 2).[10–14] This recent software was improved by increasing the number of patients in the

TABLE 2. Studies that compare hemodynamic variables with different FloTrac® software versions in sepsis

| Author | FT version | Baseline TD mean CI/CO (range) | Baseline FT mean CI/CO (range) | TSVR $\text{dyne}\cdot\text{s}^{-1}\cdot\text{cm}^{-5}$ (SD) | Bias, L/min (SD) | PE (%) | $r/r^2$ ($P$) |
|---|---|---|---|---|---|---|---|
| Marque et al,[10] $\text{L}\cdot\text{min}^{-1}\cdot\text{m}^{-2}$ | 3.02 | 3.2 (0.8–6.8) | 3.1 (0.8–6.2) | 905 (367) | −0.1 (2.1) | 64 | 0.47/0.22 |
| Slagt et al,[11] L/min | 3.02 | 8.6 ± 2.7 | 6.8 ± 2.0 | 586 (169) | 1.7 (2.4) | 53 | 0.53/NA |
| De Backer et al,[12] L/min | 1.14 | 7.5 ± 2.0 | 6.5 ± 1.5 | 875 (283) | −0.8 (−1.1 to −0.4)[a] | 29 | NA |
| | 3.02 | 7.5 ± 2.0 | 7.3 ± 2.1 | 875 (283) | 0 (−0.3 to 0.3)[a] | 30 | NA |
| Slagt et al,[13] L/min | 1.07 | 3.6–10.4 | 3.6–7.1 | NA | −1.6 (1.60) | 48 | 0.32/NA |
| | 1.10 | 2.9–12.6 | 3.3–10.8 | NA | −1.2 (1.10) | 32 | 0.9/NA |
| Sakka et al,[14] L/min | 1.07 | 6.6 ± 1.8 | 5.8 ± 2.0 | 551 (106) | 0.5 (2.3) | NA | NA/0.26 |

During most of the comparisons, the patients were on vasopressor therapy.
[a] Limits of agreement.
FT, FloTrac®; TD, thermodilution; PE, percentage error; NA, not assessed.

database with vasoplegic states, but this software still has a 30% error in measurement. The mean bias in CO measurement (the difference between FloTrac® and PAC) decreased from −0.8 L/min (95% CI: −1.1 to −0.4) (previous version) to 0 L/min (95% CI: −0.3 to 0.3) (version 3.02).[12] During these comparisons, the effect of TSVR on CO measurements was also evaluated. The differences or bias between CO measurements increased as TSVR decreased, and CO measurements by arterial pressure waveform analysis underestimated the measurements by PAC. In addition, it was noted that the percentage error was greater when the arterial pressure waveform analysis was performed with a radial catheter instead of a femoral catheter. One plausible explanation for this difference is that the femoral catheter is more "central" than radial catheter. These measurements were made in patients on vasopressors as part of their current treatment. A similar study was later performed comparing system software 3.02 and bolus thermodilution, and these results suggested that CO was underestimated by the FloTrac® system with TSVR below 700 dyne·s$^{-1}$·cm$^{-5}$.[11]

Marque et al compared CI values in septic shock patients measured by FloTrac® software version 3.02 with PAC thermodilution and calculated a percentage error of measurements of 64% with a low correlation ($r^2 = 0.22$). This study also found that a 14% change in CI during fluid challenge was needed to predict fluid responsiveness with a sensitivity of 0.67 and specificity of 0.73. These authors concluded that this software version is still too inaccurate to measure CI in septic patients.[10] Other studies have evaluated the FloTrac® system and its ability to track changes induced by fluid challenges and vasopressor dose adjustments. Mannel measured the concordance rates of changes FloTrac® CO measurements during volume expansion and norepinephrine dose adjustments in septic patients. The concordance rates were 73% and 60%, respectively, and the FloTrac® was considered moderately reliable to detect the effects of fluid administration.[15] A study that used Doppler's echocardiography as a reference method also suggested that the FloTrac® system was not reliable in tracking changes induced by norepinephrine (Table 3).[16]

In addition to CO and CI, SV variation measured by the FloTrac® has been compared with pulse pressure variation in patients with septic shock. To the best of our knowledge, only 1 study determined the predictive value of SV variation with this device in septic patients. SV variation measured by FloTrac® version 3.01 had comparable results with pulse pressure variation measured by IntelliVue MP monitor (Philips Medical Systems, Boeblingen, Germany) in septic patients receiving positive pressure ventilation with a tidal volume of at least 8 mL/kg.[17] An SV variation of 10% measured by FloTrac® had 0.92 sensitivity and a 0.83 specificity to identify fluid responders defined by an increase in SV index of at least 15% with 500 mL of 6% hydroxyethyl starch volume loading. During the study, the patients received a constant infusion of vasopressors, and before volume expansion, the systemic vascular resistance index was 1,428.2 ± 421.2 dyne·s$^{-1}$·cm$^{-5}$·m$^{-2}$.

A comparison between FloTrac® and bolus thermodilution of CO has also been done in patients with intracranial hemorrhage. In these patients, hemodynamic instability occurs after central nervous system injury and is often associated with decreased vascular resistance. Like studies with sepsis, CO measured by the FloTrac® underestimated the thermodilution CO.[18] The mean CO by thermodilution was 7.6 L/min; arterial pressure waveform analysis calculated a mean CO of 6.0 L/min with a percentage error of 58%. Although there is no mention of the baseline mean TSVR in this patient group, the differences between CO values by both techniques were found to be inversely proportional to TSVR.

The FloTrac® has been tested in patients with liver cirrhosis, but these studies have largely determined hemodynamic variables in this subset of patients during perioperative periods during liver transplantation. Some measurements were obtained before and after the surgery, but the statistical analysis mixed the data obtained throughout the surgery. Despite the specialized clinical status of these patients, the information does provide information about software performance. One initial study using the FloTrac® to measure CO found that values had an increased bias compared with PAC-measured CO by thermodilution in patients with Child Pugh Class B and C cirrhosis and low TSVRs.[19] More recent comparisons between CO measured by a PAC and FloTrac® software version 3.02 continue to find a percentage error above 30% with the bias between measurements inversely related to the TSVR index.[20] When this software was compared with an older generation software, some improvement in CI trending in patients with low TSVR was found, but the percentage error is still high.[21] A TSVR below 1000 dyne·s$^{-1}$·cm$^{-5}$ seems to identify a hemodynamic profile in which a significant difference between CO measured by a PAC and FloTrac® software version 3.02 arterial pressure waveform analyses occurs. More supportive data that compare CO measured by these devices and SV variation measured by FloTrac® compared with transthoracic echocardiography show good tracking capabilities of arterial pressure waveform analysis in patients who respond to fluid administration with a median TVSR of 970 dyne·s$^{-1}$·cm$^{-5}$.[22] Also, an inverse relationship was found between SV variation and right ventricular end diastolic volume index measured by a PAC, but this study did not assess TSVR in patients with liver disease.[23] In summary, although patients with advanced cirrhosis undergoing liver transplantation represent a unique group of patients, study outcomes are similar to those in patients with sepsis. The CO difference

TABLE 3. Studies that use FloTrac® software version 3.02 to track fluid challenges and vasopressor dose adjustments

| Author | Challenge method | TSVR, dyne·s$^{-1}$·cm$^{-5}$ (SD) | r/r$^2$ (*P*) | AUC for fluid challenge | Concordance rates, fluid/NE (%) |
|---|---|---|---|---|---|
| Marque[10] | Fluid | 905 (367) | NA | 0.72 | NA |
| Monnet[15] | Fluid/NE | 938 | $r^2 = 0.26$ (0.02)[a], $r^2 = 0.11$ (0.04) | 0.5 | 73/60 |
| Mahjoub[16],[b] | NE | NA | r = 0.59 | NA | NA |

[a] *P*-value for correlation.
[b] Used Doppler's echocardiography as a comparison method.
FT, FloTrac®; TD, thermodilution; NE, norepinephrine; AUC, area under the curve; NA, not assessed.

between that calculated by the FloTrac® and the gold standard thermodilution increases as TSVR decreases. SV variation seems to provide useful data when TSVR is near normal, and liver disease is not as advanced.

Haenggi compared FloTrac® and PAC-measured CO in postcardiac arrest patients who underwent therapeutic hypothermia.[24] This is an important subset of patients in a medical intensive care unit, yet there is limited information about arterial pressure waveform analysis CO by the FloTrac®. The sample size in this study was small; the FloTrac® CO (software version 1.07) measurements tended to have a higher percentage error in hypothermic patients than normothermic patients. It is important to note that the precipitating causes for cardiac arrest were not reported in this study, and the patients involved may be quite heterogenous.

There are no randomized controlled trials that evaluated outcomes only in septic patients or medical patients with reduced TSVR. Studies that have determined into outcome predominantly include in surgical patients who are not vasoplegic and a combination of patients with different medical conditions in the intensive care.[25] Although results from CO and CI measurement with the FloTrac® could lead to questions about its clinical utility, SV variation as a predictor of fluid response and fluid management seems to provide more reliable information.

## CONCLUSIONS

The FloTrac® monitoring system provides a method to measure SV and CO using arterial pressure waveform analysis calculations. Increases in SV variation may identify patients who are fluid responsive. This method correlates relatively well with measurements made by PAC in stable patients who have had surgery or trauma. Patients in the medical intensive care unit could benefit from monitoring with the FloTrac® system. However, this method is much less accurate in patients with sepsis, serious liver disease and patients with reduced systemic vascular resistances. Other limitations include arrhythmias, and possibly the arterial catheter insertion site. Thus, TSVR and the patient's clinical condition (septic or not) should be taken into account when using hemodynamic variables, such as CO/CI, measured by the FloTrac® system. FloTrac® monitoring in patients with severe gastrointestinal bleeding who require intubation and resuscitation may be useful, provided there is no clear evidence of liver disease and a low TSVR. However, more studies are needed to evaluate its usefulness in medical patients, especially in those with sepsis and with different levels of TSVR.

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