Why Cardiac Output? "Flow-Directed Goal-Directed Therapy"

Summary

Traditional monitoring, using vital signs alone, has been shown to be inadequate in some clinical instances. While HR, SBP, CVP and MAP are useful indicators, relying solely on these can lead to unfavorable therapy, including over resuscitation or inappropriate resuscitation. Evidence suggests that early application of these indicators in conjunction with flow parameters in a goal-directed protocol can lead to significant clinical and economic benefits, including:

- **Reduced mortality**
- **Fewer complications and reduced morbidity**
- **Shorter length of hospital stay**
- **Lower costs to hospitals**

Minimally invasive Cardiac Output monitoring technologies, such as the FloTrac sensor and the Vigileo monitor, benefit the clinician by providing key flow parameters to help guide the treatment of critically ill and high-risk patients. The FloTrac system sets up rapidly, is easy to use and requires no manual calibration. This ease of application may lead to earlier initiation of flow-directed goal-directed therapy, which has been shown to improve patient outcomes. When coupled with goal-directed therapy (such as a Rivers EGDT protocol), it enables clinicians and nurses to manage patients' oxygen delivery more precisely than traditional vital sign monitoring alone.

Why Flow-Directed?

Clinical therapy has traditionally centered on monitoring various vital signs. A growing body of literature, however, suggests that goal-directed therapy focusing on maximizing effective blood flow, in conjunction with vital sign monitoring, bears the potential for considerable improvement to the outcome of both critically ill and high-risk surgical patients. Bennett has suggested that traditional vital sign monitoring that stresses blood pressure, Heart Rate (HR), respiratory rate and temperature may not be sufficient as a predictive indicator and should be monitored in combination with flow parameters.[1]

Traditional vital signs and monitoring parameters may include ECG, non-invasive and/or intra-arterial blood pressure, SpO_2, and Central Venous Pressure (CVP). However, in some instances, vital signs can be of limited use or lead to unfavorable therapy:

- **Baroreceptor-mediated vascular compensation by increasing vascular tone can sustain a constant blood pressure in a patient losing as much as 18% of blood volume before being associated with a drop in Mean Arterial Pressure (MAP).**[1]
- **MAP monitoring can be a poor predictive indicator because "…systemic hypoperfusion usually precedes hypotension, especially in patients with hemorrhage and sepsis."**[2]
- **Evidence suggests that no solid link exists between oxygen delivery and Systolic Blood Pressure (SBP) in hemorrhaging trauma patients.**[3]
- **HR, respiratory rate and SBP may be poor predictors of critically ill patients.**[4]
- **Monitoring of HR and SBP alone may not adequately reveal hypovolemia or may "cloak" hypoperfusion.**[1,5]
- **SBP, CVP and HR show considerable lack of sensitivity and specificity as predictors of fluid responsiveness in neurosurgery compared to stroke volume variation (SVV).**[6] **Incorrect measurement and/or interpretation based on traditional vital signs alone can lead to imprecise interventions such as over or under resuscitation and inappropriate resuscitation. Instead, the clinician may consider the use of flowdirected parameters to help guide and give confidence in the direction of therapy.**

Edwards

Evidence for Flow-Directed Goal-Directed Therapy

Protocolized therapy based on flow-directed parameters can lead to considerable advantages in treatment of critically ill patients. Such flow parameters include Cardiac Output (CO) and Cardiac Index (CI), Stroke Volume (SV) and Stroke Volume Index (SVI), and Oxygen Delivery (DO_2). Mixed Venous Oximetry (SvO_2) can be used as an indirect marker of Oxygen Delivery by determining the "adequacy of Oxygen Delivery" against Oxygen Consumption (VO_2).[4,7] Central Venous Oximetry ($ScvO_2$) can also be used in determining the adequacy of oxygen delivery with the understanding that it usually differs ±7% higher than SvO_2 and this difference can widen greatly in shock states. However, $ScvO_2$ trends with SvO_2 90% of the time.[8] Flow-directed, goal-directed optimization using the above parameters in a rigorous and well designed treatment protocol has been effective in the treatment of a variety of patients, including those undergoing major elective and high-risk surgery, cardiac surgery, in the emergency department and those suffering from hypovolemia or organ failure.

Reduced Mortality

INVESTIGATOR	FLOW PARAMETER	CONTROL	PROTOCOL	PATIENT TYPE
Wilson	CI, DO_2	17%	3% (p=0.007)	Major Elective Surgery
Boyd	DO_2	22.2%	5.7% (p=0.015)	High Risk Surgery
Shoemaker	CI, DO_2	35%	12.5% (p<0.02)	Critical Postoperative
Shoemaker	CI, DO_2	33%	4% (p<0.01)	High Risk Surgery

Fewer Complications / Reduced Morbidity

INVESTIGATOR	FLOW PARAMETER	CONTROL	PROTOCOL	PATIENT TYPE
MORBIDITY		% DIFFERENCE	% DIFFERENCE	
Pearse	CO	68%	44% (p=0.003)	High Risk Surgery
Venn	SV, CO	28%	7% (p<.05)	Hip Fracture Repair
COMPLICATIONS		COMPLICATIONS PER PATIENT	COMPLICATIONS PER PATIENT	
Boyd	DO_2	1.35	0.68 (p=0.008)	High Risk Surgery
Shoemaker	CI, DO_2	1.34	0.76 (p<0.05)	Critical Postoperative
Shoemaker	CI, DO_2	1.30	0.39 (p<0.01)	High Risk Surgery

Shorter Length of Stay – Hospital Days

INVESTIGATOR	FLOW PARAMETER	CONTROL	PROTOCOL	PATIENT TYPE
Pearse	CO	14	11	High Risk Surgery
Gan	CO, SV	7±3	5±3	Major Surgery
Wilson	CI, DO_2	22	13	Major Elective Surgery
Shoemaker	CI, DO_2	25.2±3.4	19.3±2.4	High Risk Surgery
McKendry	CI, DO_2	14	11	High Risk Surgery
Sinclair	CO, Max SV	20	12	Hip Fracture Repair

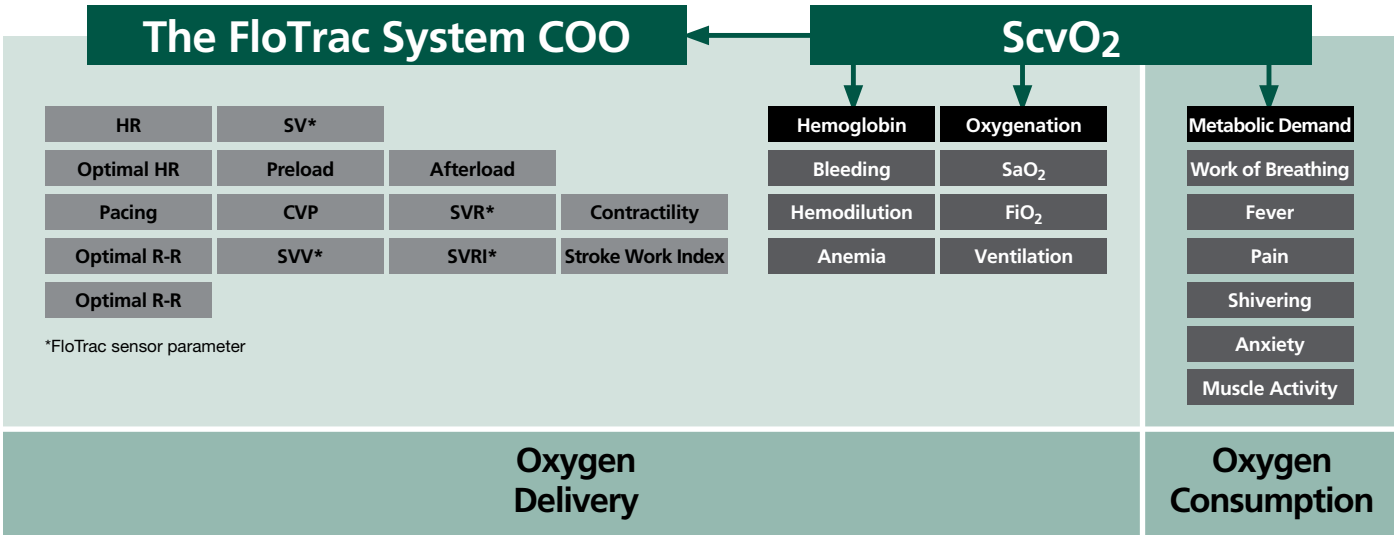
Reduced Mortality

INVESTIGATOR	FLOW PARAMETER	PROTOCOL
Fenwick	CI, DO_2	Mean cost of pre-optimized patients was 33% less than control group
Guest	CI, DO_2	Cost of obtaining a survivor in protocol group was 31% less than control group
Shoemaker	CI, DO_2	Hospital charge of protocol group was 26% less than control

Various studies suggest that significant benefits are realized from protocol-driven perioperative flow-directed therapy.[9-17] Furthermore, optimization of flow-directed therapy using specific treatment protocols can lead to significant benefits in prevention of organ failure stemming from hypovolemia, particularly in cases of renal failure.[1,19] While hypovolemia is poorly predicted by traditional vital sign monitoring, it can be predicted and prevented by monitoring and optimizing SV and CO.[5,15,20] This can reduce the chances of a critically ill patient acquiring End-Stage Renal Failure (ESRF), a condition which can cost a hospital more than $51,000/patient/year.[19-21]

Solution

A minimally invasive hemodynamic monitoring technology has been developed which can be used to monitor and optimize critically ill patients using various flow parameters. The FloTrac sensor and the Vigileo monitor use an existing peripheral arterial line to monitor CO, SV and SVV in realtime. $ScvO_2$ is also available when the Vigileo monitor is used in conjunction with the PreSep central venous oximetry catheter. The FloTrac system can be set up in just a few minutes and is easy to use for both the nurse and the physician. The technology requires no manual calibration since the FloTrac algorithm automatically compensates for the continuously changing effects of vascular tone. The FloTrac sensor has been proven accurate and reliable in monitoring CO in clinical studies when compared against Continuous Cardiac Output (CCO), Intermittent Cardiac Output (ICO).[22] The benefits seen in the previously mentioned studies using flow-directed goal-directed therapy should be equally realized with the FloTrac system. In addition, this ease of use and application can result in earlier initiation of flow-directed goal-directed therapy, which in itself has been shown to provide better patient outcomes.



For further information on the Flotrac sensor and the Vigileo monitor, please visit www.edwards.com/flotrac.

References:

1. Bennett D. Arterial Pressure: A Personal View. Functional Hemodynamic Monitoring. *Berlin: Springer-Verlag,* 2005. ISBN: 3-540-22349-5.
2. Rackow EC. Pathophysiology and treatment of septic shock. JAMA 1991, 548-554.
3. Dutton RP. Hypotensive Resuscitation during Active Hemorrhage: Impact on In-Hospital Mortality. *J Trauma 2002*, 1141-1146.
4. Rady MY. Resuscitation of the Critically Ill in the ED: Responses of Blood Pressure, Heart Rate, Shock Index, Central Venous Oxygen Saturation, and Lactate. *Am J Emerg Med* 1996, 218-225.
5. Hamilton-Davies C. Comparison of commonly used clinical indicators of hypovolaemia with gastrointestinal tonometry. *Intensive Care Med* 1997, 276-281.
6. Berkenstadt H. Stroke Volume Variation as a Predictor of Fluid Responsiveness in Patients Undergoing Brain Surgery. *Anesth Analg* 2001, 984-989.
7. Pinsky MR. Hemodynamic monitoring in the intensive care unit. *Clin Chest Med 2003*, 549-560.
8. Reinhart K. Continuous central venous and pulmonary artery oxygen saturation monitoring in the critically ill. *Intensive Care Med.* 2004,1572-8.
9. Wilson J. Reducing the risk of major elective surgery. *BMJ* 199,1099-1103.
10. Boyd O. A Randomized Clinical Trial of the Effect of Deliberate Perioperative Increase of Oxygen Delivery on Mortality in High-Risk Surgical Patients. *JAMA* 1993, 2699-2707.
11. Shoemaker WC. Use of Physiological Monitoring to Predict Outcome And to Assist in Clinical Decisions in Critically Ill Postoperative Patients. *AM J Surg* 1983, 43-50.
12. Shoemaker WC. Prospective Trial of Supranormal Values of Survivors as Therapeutic Goals in High-Risk Surgical Patients. *Chest* 1988, 1176-1186.
13. Pearse R. Early goal-directed therapy after major surgery reduces complications and duration of hospital stay. *Critical Care* 2005, R687-693.
14. Venn R. Randomized controlled trial to investigate influence of the fluid challenge on duration of hospital stay and perioperative morbidity in patients with hip fractures. *Brit J Anaest* 2002, 65-71.
15. Gan TJ. Goal-directed Intraoperative Fluid Administration Reduces Length of Hospital Stay after Major Surgery. *Anesthesiology* 2002, 820-826.
16. McKendry M. Randomised controlled trial assessing the impact of a nurse delivered, flow monitored protocol for optimization of circulatory status after cardiac surgery. *BMJ*, doi:10.1136/bmj.38156.767118.7C
17. Sinclair S. Intraoperative intravascular volume optimisation and length of hospital stay after repair of proximal femoral fracture. *BMJ* 1997, 909-912.
18. Fenwick E. Pre-operative optimisation employing dopexamine or adrenaline for patients undergoing major elective surgery *Int Care Med* 2002, 599-608.
19. Kellum JA. Primary prevention of acute renal failure in the critically ill. *Curr Opin Crit Care* 2005, 537-541.
20. O'Leary MJ. Preventing renal failure in the critically ill. *BMJ* 2001, 1437-1439.
21. Chikotas N. Uremic syndrome and end-stage renal disease. *JAANP* 2006 195-202.
22. Manecke G. Poster, SCCM 2005. McGee W. Poster, ISICEM 2005.

Any quotes used in this material are taken from independent third-party publications and are not intended to imply that such third party reviewed or endorsed any of the products of Edwards Lifesciences.

For professional use. CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards Lifesciences | edwards.com
One Edwards Way | Irvine, California 92614 USA
Switzerland | Japan | China | Brazil | Australia | India

Edwards