INTERFACE

SOCIETY FOR TECHNOLOGY IN ANESTHESIA

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Cardiac Monitors: The Next Generation

New Cardiac Monitors and Old Problems

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Few argue the importance of blood pressure and ECG monitoring even for our healthiest patients having office based or other ambulatory procedures. In fact, strict guidelines for office based practice have rapidly emerged. What is striking is that our elderly patients, those with the highest incidence of co-morbid disease and undergoing more extensive surgical procedures, are often provided the same level of cardiovascular monitoring as the 25 year old having arthroscopy in an office OR. Yet instead of addressing this generation gap, we have come to rely on a "one size fits all" solution for patient monitoring that fits poorly those patients on the extremes.

The limited use of more sophisticated monitors of cardiovascular well-being in these at-risk patients appears surprising. Anesthesiologists have led the field of medicine in patient safety issues. From the technological perspective, we are widely recognized for the early implementation of capnography and pulse oximetry into our practices. The ability of these monitors to detect physician procedural misadventures, such as malpositioned endotracheal tubes and interruption of ventilatory support, led to widespread adoption. But as we made great strides in detecting mishaps of our own design (i.e. "human errors"), we were not nearly as successful in developing monitors to address the challenges our patient's bring to the O.R. table. Perioperative disorders such as ventricular dysfunction and altered fluid status are becoming increasingly commonplace as the population matures.

That elderly patients are at greater risk for cardiac related complications has always been part of common sense clinical practice and is now well established from outcome data. The prevalence of co-morbid diseases rises steadily with increasing age. By the age of age 75, patients presenting with colon cancer were found to average 5 co-morbid disorders in addition to their primary cancer. This data is concerning enough in the context that the number of associated illnesses is strongly linked to peri-operative complication rates. But even more ominous for the elderly patient is that increasing age has a multiplier effect on the relationship of co-morbid disease and operative complications. The presence of two preoperative co-morbidities elevates the elderly patient's complication rate over 3 fold, with greater than 2 co-morbidities the complication rate rises by 6 fold. These patients lack the physiological reserve to compensate for what in many of us would be considered modest insults.

The continuing expansion in the number of persons reaching old age creates the imperative for development of new anesthetic technologies and practices to meet their needs. Over the short time period from 1980 to 1996 the percentage of surgical procedures in which the patient was over age 65 nearly doubled from 19% to 36%. And over the next two decades the U.S. population over age 65 will increase by over 50%, from 30 million to 47 million. Even greater increases will occur in the group of patients greater than 80 years of age. These demographics create the driving force of innovation, but what type of monitors will be useful to manage these patients? The OR poses both sudden and subtle threats to cardiovascular balance. These insults range from preoperative fasting and bowel preparations, to anesthetic vasodilators, to surgical trauma and hemorrhage. In combination they result in substantial perturbations of intravascular fluid volume and composition. At many hospital facilities, two thirds of the administered blood is appropriated to surgical patients. On a per patient basis, a similar usage pattern is seen for the crystalloid and colloid solutions. At these levels of blood and fluid administration it is easily appreciated that the anesthesiologist, armed with only blood pressure and pulse monitors, remains challenged to keep the heart and vasculature in equilibrium. The first appreciation of a miscalculation may be a dramatic drop in arterial pressure, or all too often, the problem occurs more distantly (and less perceptively) in the post-operative period. To aid appropriate therapeutic interventions, top priority should be placed on providing an on-line assessment of the relationship between

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$NICO_2$ – Fick Partial CO_2 Rebreathing Noninvasive Cardiac Output

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FICK METHOD FOR MEASUREMENT OF CARDIAC OUTPUT:

The first known technique for measuring cardiac output in humans is based on the theoretical principle enunciated by Adolf Fick in 1870, who never actually made the measurement himself. The Fick principle states that over a given time period, the quantity of a gas such as O_2 or CO_2 entering or leaving the lungs is equal to the quantity of the gas taken up or expelled by the blood flowing in the pulmonary capillaries. The Fick technique for measurement of cardiac output has long been a standard by which other methods of determining cardiac output have been compared. However, the practical application of the Fick technique in a clinical setting is limited due to technical issues involved in accurate metabolic gas measurements and the need for invasive arterial and mixed venous blood gas measurements. To eliminate the need for invasive blood gas samples, indirect Fick methods known as rebreathing techniques have been developed[1,2,3]. Total rebreathing techniques use estimates of arterial and mixed venous CO_2 contents obtained from measurements of end-tidal CO_2 partial pressure ($ETCO_2$) made at the mouth during normal breathing and rebreathing maneuvers[4]. With total rebreathing, the patient inhales his or her own exhaled gas from a bag attached at the mouth. During the total rebreathing maneuver, no CO_2 is eliminated from the lungs and the concentration of exhaled CO_2 approaches the mixed venous concentration, allowing it to be estimated non-invasively from respiratory gas measurements. $ETCO_2$ is used as a non-invasive estimate of the arterial CO_2 concentration. Even though the total CO_2 rebreathing technique allows noninvasive cardiac output estimation based on routinely obtained respiratory gas measurements, the compliant rebreathing bag and the need for patient co-operation makes it impractical for use in mechanically ventilated patients.

$NICO_2$ – FICK PARTIAL CO_2 REBREATHING NONINVASIVE CARDIAC OUPUT

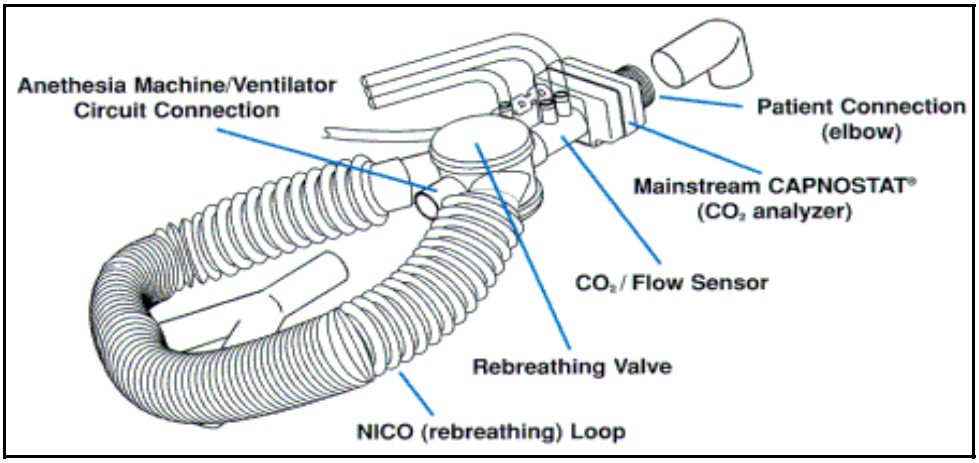

FIGURE 1. $NICO_2$ Sensor assembly consists of a mainstream CO_2 sensor, differential pressure flow sensor, and a rebreathing loop connected to the pneumatic rebreathing valve.

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The partial rebreathing technique, which is used by the $NICO_2$ monitor, employs a differential form of the Fick method for non-invasive measurement of cardiac output. This technique was first described by Gedeon et. al.[5] and later expanded upon by Capek and Roy[6]. With partial rebreathing, a change in VCO_2 (exhaled volumetric CO_2) and an associated change in $ETCO_2$, in response to a change in ventilation, is used in the Fick calculation. $NICO_2$ accomplishes the required change in ventilation by using the rebreathing valve and $NICO_2$ rebreathing loop illustrated in Figure 1 as part of the $NICO_2$ sensor. By temporarily adding a rebreathing volume to the breathing circuit, the patient inhales only a portion of the exhaled gases. The resulting changes in VCO_2 and $ETCO_2$ are used to calculate cardiac output. The $NICO_2$ monitor uses Novametrix proprietary sensors for mainstream CO_2 and respi-

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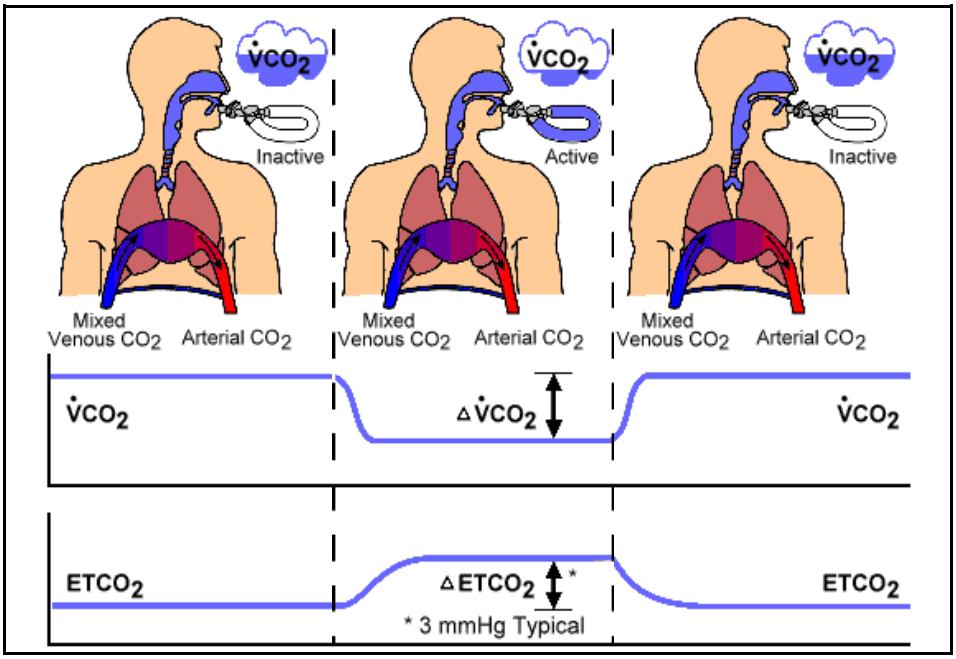

FIGURE 2. NICO Timing Diagram (3 minute cycle)

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ratory flow monitoring capabilities. VCO_2 is calculated as the product of the integrated flow and CO_2 signals.

Every three minutes (see Figure 2), the patient's inhaled and exhaled gases are diverted through the $NICO_2$ loop for 50 seconds by the rebreathing valve, preventing normal volumes of CO_2 from being eliminated. As a result, the CO_2 elimination decreases and the concentration of CO_2 in the pulmonary artery ($CaCO_2$) increases.

The equation for differential Fick partial rebreathing cardiac output is:

$$C.O. = \frac{[\ \dot{V}CO_{2N} - \dot{V}CO_{2R}\ ]}{[\ CaCO_{2R} - CaCO_{2N}\ ]}$$

Where VCO_{2N} and VCO_{2R} are the volumetric CO_2 elimination during normal and rebreathing periods, respectively, and $CaCO_{2N}$ and $CaCO_{2R}$ are the arterial CO_2 concentrations during normal and rebreathing periods, respectively. The preceding equation can also be written as:

$$C.O. = \frac{[\ \Delta\dot{V}CO_2\ ]}{[\ \Delta CaCO_2\ ]}$$

Where delta-VCO_2 and delta-$CaCO_2$ represent the changes in VCO_2 and $CaCO_2$ between normal and rebreathing periods. The change in $CaCO_2$ is reflected in and measured by the change in $ETCO_2$. See http://www.nico2.com/library/techreview/tr_fullmath2.htm for a more detailed mathematical explanation.

It has been shown that mixed venous CO_2 concentration does not change significantly throughout the 50 second rebreathing period[6], thus the terms associated with mixed venous CO_2 concentration cancel out and are not shown in the above equation. This permits cardiac output calculations based entirely on non-invasively monitored physiologic signals. The NI-CO_2 implementation of the partial rebreathing method is automated, providing cardiac output determinations on a real-time and continual basis.[7,8]

When CO_2 concentration is measured indirectly via the breath as $NICO_2$ does, the Fick method considers only that portion of the cardiac output that participates in gas exchange, or the pulmonary capillary blood flow. By estimating the amount of blood flow bypassing the lung (shunt flow) and adding that amount to the equation above, the indirect Fick method accurately reflects the total cardiac output.[8] The $NICO_2$ monitor corrects for shunt using oxygen saturation derived from pulse oximetry and a user entered value for inspired O_2 concentration.

CLINICAL VALIDATION

When evaluating newer methods of cardiac output monitoring, bolus thermodilution cardiac output measurements are routinely used as the comparison standard. The limited reproducibility of thermodilution hampers evaluation of new cardiac output devices.[9,10] Recently, in a multimodality cardiac output study using ultrasonic flow probe placed on the ascending aorta of cardiac surgery patients researchers at the University of Florida, Gainesville have shown that the precision of NI-CO_2 (1 SD = 0.81 L/min) is better when

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compared with bolus thermodilution (1 SD = 0.96 L/min) and Continuous Cardiac Output (1 SD = 1.55 L/min)[11]. The accuracy and precision of $NICO_2$ has also been demonstrated in a number of other clinical studies to be within acceptable clinical limits over a wide range of cardiac outputs.[12-16]

DISCUSSION

The partial rebreathing technique for measurement of cardiac output is non-invasive, easy to use, automated and continual, not technique dependent and is based on the accepted Fick principle. It can be easily implemented and integrated with standard respiratory gas monitoring already available in most patients in the critical care environment. The small increase in end-tidal CO_2 associated with partial rebreathing is not harmful and can be easily tolerated by the patient. $NICO_2$ is not indicated for use in patients with severe lung pathology. $NICO_2$ in its present implementation can be used on patients who are mechanically ventilated (can be total mechanical ventilation or mixed breathing with spontaneous breaths). Future firmware upgrades will allow the user to use $NICO_2$ with a facemask or mouthpiece in spontaneously breathing patients. The per patient cost of the $NICO_2$ sensor and set-up time are much less than that associated with the use of a PA catheter. We expect that this technique may allow cardiac output monitoring in all patients in the OR and ICU, not only in which PA catheterization is not indicated (required or worth the risk), thus allowing a wide patient population to benefit from improved hemodynamic (cardiac) monitoring and management. The simplicity of use and the additional respiratory parameters available with $NICO_2$ offers advantages over other noninvasive cardiac output techniques.

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Call for Abstracts

Annual Medical Simulation Meeting
January 12-14, 2001
Scottsdale, Arizona

Rolling review up to December 1, 2000

The Annual Medical Simulation Meeting will be held on January 12-14, 2001 at the Paradise Valley Doubletree Hotel in Scottsdale, Arizona. This simulation dedicated meeting is being held in cooperation with the Annual Society for Technology in Anesthesia meeting that will be held at the same location on January 11-13, 2001.

This meeting will provide a forum for the discussion and advancement of the application of simulators in clinical medicine and other health sciences. Although the meeting is being held cooperatively with STA, the meeting is by no means limited to anesthesia applications. Abstracts from the allied health specialties, emergency medicine, surgery, radiology, medicine, and others are highly encouraged. The Medical Simulation Meeting will be of interest to those individuals working in the scientific development of simulation technology, as well as

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TruCCOMS™ - by AorTech

The TruCCOMS™ "True Continuous Cardiac Output Monitoring System" is based on an innovative application of thermodynamic heat transfer principles and state-of-the-art signal-processing techniques. It vastly outperforms the other continuous and intermittent methods available on the market that rely on thermal dilution principles.

The TruCCOMS™ represents a major breakthrough in invasive CO measurement and monitoring. Virtually all other invasive CO systems rely on some indicator technique either for measurement, calibration or both. Indicators include heat, cold, dye and Lithium dioxide. An inherent limitation of these indicator-based techniques is that they cannot be real time and must be either intermittent or averaged over long periods since they must wait for the dilution to occur and analyze the dilution curve.

A new paradigm for Cardiac Output measurement

A Heat Transfer Device (HTD) is located on an otherwise standard PA catheter (PAC). The location of the HTD is 7.5 cm from the tip of the PAC. This placement is such that when the PAC is placed in the normal position for obtaining wedge measurements, the HTD is located in the middle of the main PA. The amount of energy required to maintain this HTD at a small temperature differential to the ambient blood temperature, is related to the mass of blood coming in contact with the HTD and therefore a direct, instantaneous measure of flow. The system utilizes the fact that the blood flow in the main PA is turbulent due to both the proximity of the pulmonary valve and the nearby bifurcation of the PA.

The TruCCOM™ system offers significant clinical advantages over current technologies.

Key Advantages and Benefits

- Fast Response - Beat to beat Continuous Cardiac Output (CCO): Provides real-time, continuous, accurate, and reliable cardiac output measurements. This feature is of particular interest during "Beating-Heart" and "Off-pump" CABG operations where the impact on CO of cardiac manipulations are immediately detected and reported.
- Low Cost - Eliminates the need for clinical staff to inject fluids for Cardiac Output Measurement
- Easy to use – Fast arm-up and no calibration required
- User technique independent
- Low power - Less than 1 watt transferred to the patient

New Technology

Using a patented application of the Mass Heat Transfer principle in a turbulent system, the CCO measured by AorTech is fundamentally different from all other CO and CCO measurements. Using a thermistor in a small heating coil, the system measures the energy required to maintain the coil surface at a ~1°C differential above the blood temperature. The Cardiac Output is directly related to this energy, which can be measured continuously.

Clearly better than continuous TD devices

TruCCOMS CCO is truly continuous and can update on every beat if desired. Other "Continuous-TD" devices use intermittent heat pulses to create several TD curve segments and then reconstruct the data to form a dilution curve and determine the CO. This is updated only every 20-30 seconds. Response time of these systems is range from about 6 to 9 minutes depending on averaging employed to in crease the s/n ratio.

Rather than heat the blood with enough energy to create a detectable temperature change, TruCCOMS measures the amount of energy required to maintain a small temperature differential. TruCCOMS uses much less heat as shown in the table below. This lower power that the temperature rise in the patients blood is almost undetectable which means

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it is much safer for the patient and can continue to work safely even in septic patient with elevated temperature. Less heat means less damage to blood cells and a faster response time. As a side benefit the instrumentation is much smaller and less expensive.

Other Features Include

- Provides both continuous and intermittent modes for clinical comparison purposes
- Saves all patient data and provides a PC interface for automated data collection and remote data analysis as well as interface to other monitoring systems.
- With Cardiac Output measured continuously, the clinician can immediately see the effect of both mechanical and drug therapies.
- Haemodynamic changes in unstable patients such as those undergoing cardiac surgery are immediately apparent.
- Keeps a history of patient data

How it Works

Continuous Cardiac Output Monitoring is accomplished through a series of thermodynamic measurements utilising a Pulmonary Artery catheter. A precisely controlled Heat Transfer Devise (HTD coil) is located 7.5 cm from the tip of the catheter. Flow is measured as follows: A temperature-measuring element within the catheter (T2, about 10 cm from the tip) is located upstream from the coil and measures ambient blood temperature. A second temperature-measuring element (T1) is located directly under the coil. By measuring the difference in temperature and knowing the power delivered to the coil, mass flow volume can be calculated by a thermodynamic mathematical formula.

The placement of the HTD at 7.5 cm from the tip of the catheter locates the HTD in the main PA when the catheter is deployed in the normal wedge position. In this position the HTD resides in an area where the blood flow is very turbulent due to the proximity of the pulmonary valve on one side and the pulmonary artery bifurcation on the other. It is precisely this turbulence, which allows the HTD to detect the mass of blood passing through this area. The turbulent flow carries away heat from the HTD and the amount of energy required to replace the heat and maintain the temperature differential is proportional to the flow.

Basic idea

The basic idea involves maintaining a constant temperature gradient of 2.5 degrees centigrade between T1 and T2 by varying the power feeding to the HTD coil. The blood flowing over the HTD coil will carry away heat energy from the coil lowering the surface temperature and therefore T1 thermistor temperature. Lowering the temperature T1 will cause more power to be feed to the coil if a constant temperature gradient between T1 and T2 is to be maintained. The more flow that is passed over the coil, the more the power is needed for the coil to maintain constant temperature difference. At this point it is important to note two key points,

1. The power from the HTD is <u>not</u> used to heat the blood as in thermal indicator methods, and
2. The temperature at the surface of the coil is typically about 1 °C above the ambient blood temperature at about 5-l/min. flow. At zero flow the surface of the HTD will be at a maximum 2.5 °C above ambient blood temperature.

The power supplied by the coil power circuitry to the HTD is controlled in such a manner as to maintain the small temperature differential of about 1 C to about 3 C between the first thermistor and the second thermistor. Determining the actual rate of blood flow can be accomplished by first providing a calibration of known rates of blood flow vs. power and then directly correlating the measured values with the calibration.

As mentioned above, by providing microprocessor control of the process of the TruCCOMS, very small changes in temperature between the first and second thermistor will immediately signal the power servo control loop to change the rate of power flow to the heat transfer element in order to maintain the desired temperature differential. The microprocessor can

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then immediately translate this required decrease or increase in power to a quantitative expression of blood flow rate from a previously determined calibration. The microprocessor then provides an output signal indicating accurate cardiac output in terms of blood flow rate.

The TruCCOMS catheter can be used in the same patient population as the standard PA/TD or oximetry catheters and maintains accuracy and repeatability irrespective of serious patient conditions such as low cardiac output. The described TruCCOMS and process for monitoring cardiac output has been incorporated within a PA catheter but could also be used in other medical devices where flow measurement is indicated.

Because any response to catastrophic events, which may occur, can be more accurately and timely detected, the use of the TruCCOMS additionally increases the effectiveness of any medical intervention, which may be required. Moreover, the likelihood of infection is substantially reduced because the process of the CCOMS does not require injectates such as cold and hot solutions or dyes. Additionally, this measurement can be practiced without the need for high cost equipment and the constant attention of highly trained personnel.

System Specifications

The TruCCOMS™ (True Continuous Cardiac Output Monitoring System) consists of two components, a monitor called TruCCOM™ and a catheter called TruCATH™.

Monitor Specifications

TruCCOMS™: Provides both continuous and injectate modes for monitoring cardiac output. The system includes a fully integrated free-standing monitor, which can be pole mounted. The large flat panel display is easy to read and incorporated the labeling for the soft keys, which operate the software. Automatic input of Injectate Temperature for TD measurements is incorporated. A 3-meter Patient Cable connects to the TruCATH™ Catheter.

The Response Time to detect a change in CO is less than 10 seconds (0-10%, 10-90% in less than 35 sec.). Blood Temperature Range 25 - 45 °C and works well even for unstable patient temperatures and on beating heart bypass patients. The monitor is small in size (approximate 20-cm x 19-cm x 17-cm) and light-weight (less than 3 kg.). It has a system interface RS-232, an analog output and an analog input.

	Heat Req'd/Temp. Rise at Coil	
Cardiac Output	**Continuous TD systems**	**TruCCOMS**
2 liters/minute	5 Watts/4°C	0.45 Watts/1.5°C
15 min/min	7.5 Watts/5°C	0.8 Watts /0.8°C

TruCATH™ Catheter

Usable Length (cm)	110
Catheter Body	7F
Introducer Size	8.5F

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those oriented toward clinical teaching and research applications.

The intent of this meeting is to be as inclusive as possible, with basic scientists, clinicians, and allied health professionals finding it beneficial. Authors should consider their submissions to be for a diverse audience, though all having an interest in the applications of simulator technology. All abstracts will be published in the proceedings and authors will be asked to provide a poster presentation or demonstration at the meeting.

We are particularly interested in posters and demonstrations of the following:

- Applications of simulator technology in teaching health sciences curricula (medicine, nursing, dental, physician assistant)
- Crisis resource management training
- Use of simulation for testing and evaluation
- Use of simulation in medical device user interface design
- Advances in simulator hardware and models

Abstracts should be brief, typically less than 250 words, but may be any of the following:

1. ASCII text
2. MS Word document
3. HTML 3.2
4. A URL to the abstract. This abstract should be viewable with standard browsers (e.g. Netscape or IE 4.x Macintosh, Windows, Unix, with no unusual plugins), and be viewable in less than 2 minutes with a 56K-dialup connection.

DEADLINE: Abstracts will be reviewed on a rolling basis up to December 1, 2000

Submissions should be directed via email to Beverlee Anderson.

VOLUME MANAGEMENT AND NON-INVASIVE HEMODYNAMIC MONITORING WITH THE HEMOSONIC™

Jean-Luc G. Boulnois, Ph.D. Arrow International, 9 Plymouth Street, Everett, MA 02149

Optimal monitoring providing on-line or continuous information is often required in anesthesia or with critically ill patients. Measurement of the Cardiac Output ("CO") together with routine monitoring of heart rate, arterial pressures, electrocardiography, and pulsed oxymetry is very useful in many clinical situations. Until recently, clinically acceptable methods for determining CO have been reserved for cardiac surgery patients or patients with severe hemodynamic instability because the standard flow measurement thermodilution technique ("TD") requires right heart pulmonary artery catheterization with its associated risks, morbidity, and costs [1].

HemoSonic™ (www.arrowintl.com) is a non-invasive monitor that uses proprietary ultrasound technology to accurately measure CO on a beat-by-beat. HemoSonic™ is based on an esophageal probe of great operating simplicity developed by INSERM (U281) in France [2]. HemoSonic™ continuously provides a real-time measurement of the Stroke Volume ("SV") and enables the physician to assess Preload, Contractility, and Afterload: it displays a beat-by-beat hemodynamic profile used to monitor left ventricular ("LV") performance and optimize fluid management under various physiologic and pharmacological conditions.

CARDIAC OUTPUT MEASUREMENT WITH HEMOSONIC™: PRINCIPLE

The HemoSonic™ principle of operation is based on the simultaneous, real-time, independent ultrasound measurements of aortic cross-sectional area ("CSA") and blood velocity to determine the instantaneous volumetric descending Aortic Blood Flow ("ABF") [3]. The externally orientable flowmeter uses a probe equipped with two (2) ultrasonic transducers inserted into the patient's esophagus at the same anatomic level facing the descending thoracic aorta. One transducer measures CSA, whereas the other measures blood velocity, the physiologic parameter reflecting the heart's performance as a pulsatile pump as modified by vascular tone.

Instantaneous aortic CSA measurement is warranted for accuracy and reliability [3-5]. Between the T5 and T6 thoracic vertebrae, the aorta is a quasi-circular cylindrical vessel, thus real-time pulsatile CSA determination only requires an accurate diameter measurement. Other esophageal Doppler systems rely on a built-in nomogram in relation to the patient's height, weight, age and gender to estimate the aortic diameter [6, 7]. As a result, the estimated diameter is not patient-specific and has been shown to exhibit unsatisfactory reliability by comparison to computerized axial tomography [8]. HemoSonic™ uses transesophageal M-Mode echography with a highly collimated 10MHz beam directed toward the thoracic aorta. Upon rotating the probe, the thin M-mode beam transversely scans the aorta and can be centrally directed, resulting in the simultaneous display of two separate echo signals, respectively representing the proximal and distal aortic wall echoes. Display of both aortic wall images unambiguously indicates that the transesophageal probe is optimally positioned. Additionally, through a time of flight technique, the M-mode provides an accurate, real-time measurement of the internal aortic diameter required for a patient-specific CSA determination. To test the HemoSonic™ measurement accuracy, an *in-vivo* comparison between M-mode and bidimensional TEE was made on 20 patients: agreement between both diameter measurement methods was found to be very strong, with bias and precision at 1.1 and 1.4 mm, respectively [9].

A second acoustic transducer generates 5MHz pulsed Doppler emissions for blood flow velocity measurement. The Doppler beam is spatially centered on the M-mode bisecting line: it interrogates the entire aortic CSA uniformly and measures the Doppler-shifted frequency produced by the moving blood cells in the thoracic aorta, following left ventricular ejection. It thus provides a precise measurement of the spatially averaged blood velocity over the entire aortic cross-section. The Doppler velocimeter also takes advantage of the "range gating" property of pulsed wave systems. This effectively eliminates any spurious velocity contribution and background noise that could originate from blood motion in any vessel outside the aorta [10].

HemoSonic™ continuously measures ABF, a hemodynamic parameter closely related to CO [9]. In an animal study, the *in-vivo* accuracy of HemoSonic™ has been compared against an electromagnetic flowmeter inserted around the pulmonary artery, yielding an accuracy of about 95% [11]. Moreover, the reliability

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of ABF monitoring for tracking CO variations has been carefully investigated in critically ill patients: a strong correlation was found between CO-TD and ABF measured with the HemoSonic™ over a wide range of flow conditions [9, 12]. The clinical validity of the ABF-CO relationship was further confirmed in a retrospective multicenter meta-analysis conducted on 90 patients with 311 paired ABF-CO measurements covering a wide domain of flow rates (ABF range: 0.5 to 12.3 l/min) corresponding to a variety of clinical situations [3]. On average, ABF was 4.2 l/min and CO was 5.9 l/min with a 73% ratio: a high positive correlation was found (R^2 =0.79), with a highly significant ($p<0.0001$) linear association. A Bland-Altman analysis further demonstrated the agreement between the two cardiac output measurement methods. As a result, HemoSonic™ relies on this correlation to continuously estimate and display CO and SV from the real-time measurement of ABF and heart rate ("HR").

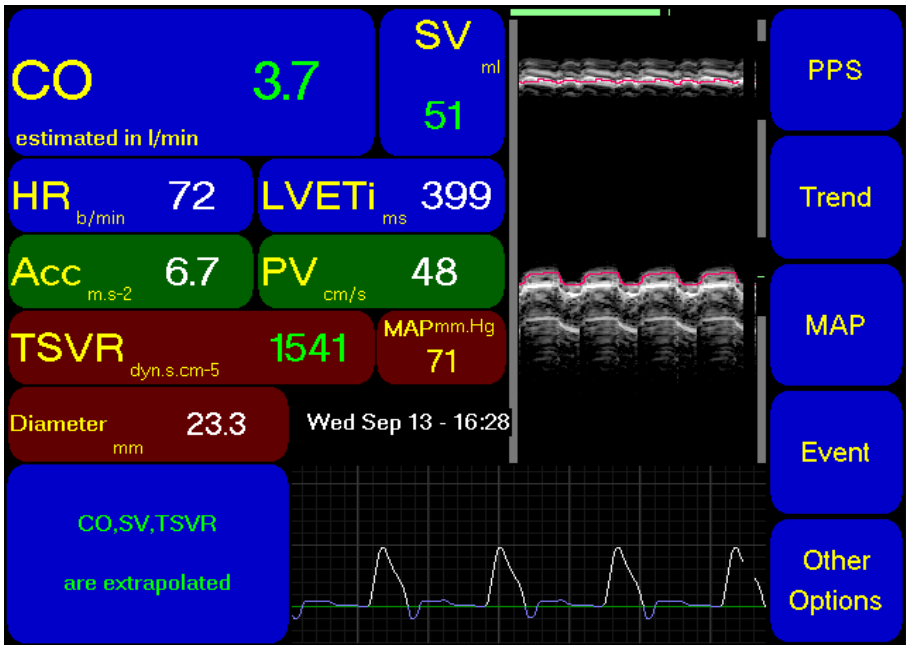
HEMODYNAMIC MONITORING WITH HEMOSONIC™

HemoSonic™ consists of a compact console housing the electrical hardware and a data-recording unit with a color display screen, a transesophageal probe, and a disposable sheath. A fast processor and proprietary software control the flowmeter functions, ultrasound signal processing and the patient composite hemodynamic profile computation and display. Through the Doppler display, the user finds the aorta, verifies probe insertion depth, and optimizes the velocity waveform, while simultaneously achieving optimal probe orientation by manually rotating the probe handle until the two appropriate M-mode traces are obtained.

The 20F-transesophageal probe includes a flexible shaft, a dual sensor sub-assembly located 5 cm from the probe distal end, and a rotatable handle located at the proximal end. The design provides a high degree of torsional rigidity for directional control, yet is sufficiently flexible to be reasonably tolerated by the sedated patient. A biocompatible, sterile, single use, sheath filled with a gel that ensures ultrasound transmission is mounted on the probe. The probe-sheath assembly can be used with a naso-gastric tube inserted *in-situ*.

The patient is monitored with the composite hemodynamic profile shown on Figure 1. Each cardiac cycle is represented in real-time through its corresponding velocity trace. Flow and volume can thus be assessed in real-time by analyzing instantaneous values of CO, HR, and SV. HemoSonic™ also displays trends of all hemodynamic parameters for selected periods of time.

Maximum Acceleration ("ACC"), i.e. the instantaneous rate of change of velocity measured at the onset of systolic flow, was established as a sensitive, clinically significant indicator of global LV performance and myocardial contractility [13-15]. ACC was found to correlate well with ejection fraction and to be less affected by variations of afterload than other contractility indices. By measuring the slope of the velocity curve at the onset of systole, HemoSonic™ provides a real-time determination of this index in a very simple fashion. As a result, a comparison of ACC with SV provides a useful indication of preload: for example, a small SV and a normal ACC are indicative of a good LV performance, albeit in a hypovolemic situation. Measurement and monitoring of ACC together with complementary contractility indices such as Peak Velocity ("PV") and Left Ventricle Ejection Time ("LVET") amplify the understanding of altered contractile events that accompany left ventricle decompensation, and provide an extremely sensitive measure of the effects of pharmacological agents on the heart.



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Finally, monitoring systemic vascular resistance in conjunction with stroke volume SV provides a useful assessment of afterload. HemoSonic™ estimates the Total Systemic Vascular Resistance ("TSVR") from the instantaneous CO and a mean arterial pressure ("MAP") entered manually.

VOLUME MANAGEMENT WITH HEMOSONIC™

HemoSonic™ is intended for managing of volume and optimizing fluid therapy. Clinical indications target patients "at risk". In the OR, this includes patients with a perceived risk related to the type of surgery (e.g., orthopedics, vascular, transplants), a history of cardiovascular deficiencies or risks (e.g., hypertension). In the ICU, indications are for patients with doubts about their hemodynamic status (e.g., instability, pulmonary congestion, shock, etc.), or patients difficult to treat with PAC (e.g., burn). Contraindications are the same as those of TEE. Limitations include thoracic aortic aneurysms, aortic stents, and severe aortic regurgitation.

In the following case, a 60yrs, 6'2", 220-lb. male patient has been in ICU for 5 days for severe ARDS symptoms including non-cardiogenic pulmonary edema, tachycardia and serious peripheral edema. The mechanically ventilated patient is stable, with HR = 112, BP = 110/65, and MAP = 80 mm-Hg, and has received high doses of diuretics. HemoSonic™ transesophageal insertion is easily achieved but produces faint distal wall M-mode echoes perhaps due to tissular water absorption. The baseline (T0) HemoSonic™ data is respectively: SV = 45 cm^3, ACC = 11.2 m/s^2, CO = 5.0 l/min, and TSVR = 1270.

Baseline SV is significantly below normal values, yet the 5-l/min CO is in the normal range because of the patient's tachycardia. Due to the large flow acceleration (ACC = 11.2 m/s^2), LV contractility is thus assessed as being high, indicating good LV performance with a presumed good ejection fraction. Resistance is found to be in the normal range because of normal MAP and CO values. Hence, an excessive afterload does most likely not cause the SV condition. As a result of the poor SV, the patient is diagnosed with insufficient preload and hypovolemia.

After an uneventful 20-min observation period (T1), a series of fluid challenges including colloids (500cc) is undertaken. Twenty minutes into treatment, SV starts to exhibit an increase of about 1.5 cc per 10-minute interval. Over the next hour, a gradual restoration of SV is achieved with no significant change in HR, and a resulting parallel increase in CO. Meanwhile, MAP remains in the normal range (~80 mm-Hg), thus resistance is slowly decreasing.

At T2 = 80 min, ACC is found to have decreased by 20% to 8.9 m/s^2, indicating a minor drop in cardiac contractility and an inotrope is administered to the patient (dobutamine ~ 5mg/kg-min). At T3 = 120 min, a marked improvement of LV contractility is registered with ACC returning to 10.5 m/s^2, associated with a continuing increase in SV which is restored to normal values (~65 cm^3), as seen on Figure 2. With no significant change in HR and arterial pressure, CO keeps increasing with an associated fall in resistance.

This simple case highlights the value of hemodynamic monitoring with HemoSonic™, since the data enabled to successfully guide volume and inotrope therapy in real-time.

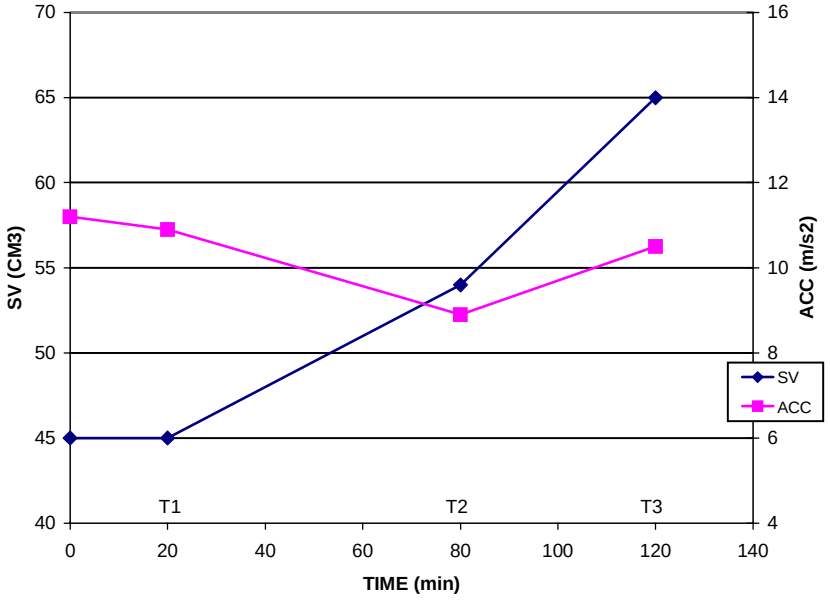

Figure 2.

Stroke Volume (SV) and Maximum Acceleration (ACC) at baseline (T0), onset of fluid challenge (T1), and onset of inotrope injection (T2).

SUMMARY

The operating principles and methods for the non-invasive, real-time, continuous cardiac output and volume determination with the HemoSonic™ system were reviewed. The system uses a novel transesophageal ultrasonic Echo-Doppler probe to simultaneously measure aortic cross-section and blood flow velocity at the same anatomic level. The physician to optimize therapy and fluid management uses a beat-by-beat composite hemodynamic profile consisting of flow/volume data, contractility data, and afterload data.

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Sabbah HN, Khaja F, Brymer JF, McFarland TM, Albert DE, Snyder JE, Goldstein S, Stein PD. Non-invasive evaluation of left ventricular performance based on peak aortic blood acceleration measured with continuous-wave Doppler velocity meter. *Circulation* 1986; 74: 323-329. Figure 1: HemoSonicTM monitoring screen.

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fluid status and cardiac performance. The merits of this model of cardiac performance is well established from decades of application and study since the pioneering work of Starling and Otto. Yet this most fundamental understanding of cardiovascular well being remains beyond our current monitors' grasp.

Attempts to provide more sophisticated cardiac monitoring have been either of limited success or outright failures. Pulmonary arterial (PA) catheters have achieved the greatest acceptance. But with the experience gained from 30 years of PA catheters in anesthetic practice, physicians have become increasingly wary of this approach. The invasive nature of the technique and its inherent complications restrict its use to the most critically ill. Its intermittent and imprecise measurement of cardiac output as well as the vagaries of converting pressure measurements into assessments of ventricular filling are further shortcomings that have led to its disfavor amongst clinicians. In fact, based on interpretations of data showing worse outcomes for the cohorts of patients in whom PA catheters were employed, some have called for an outright ban on the use of PA catheters. One author went as far as to describe the PA catheter monitoring community as a "cult".

Reforms in intraoperative cardiovascular monitoring requires fresh thinking from both practitioners and device manufactures. Encouragingly, several innovations hold promise. Many of these offer automatic, continuous monitoring and are non-invasive. But not unlike recent efforts directed at reforming our political system, money and trust become stumbling blocks to success. How will anesthesiologists be reimbursed for expenses and efforts related to newer technologies? And after witnessing the history of monitoring "black boxes" promising much but delivering little, how can physician skepticism of the performance these newer modalities be overcome? To get a closer look at the future of cardiac monitoring, this issue of ***Interface*** features the perspectives of three promising companies pursuing the next generation of cardiac monitors.

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Meetings Minder

2000

6th Congress of Anesthesiology and Intensive Medicine
September 28—October 1, 2000
Kallithea-Halkidiki, Northern Greece
http://users.otenet.gr/~fkanak/foten5.htm

SIVA 9th Annual Meeting
October 13, 2000
San Francisco, CA
(614) 293-5188

ASA Annual Meeting
October 14-18, 2000
San Francisco, CA
Http://www.asahq.org

NYSSA 54th PGA
December 9-13, 2000
New York, NY
Http://www.nyssa-pga.org

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