Continuous Non-Invasive Hemodynamic Monitoring: The Time is Now!

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Speaker Disclosures

I receive research support from Masimo Corp and Consult for Pfizer
Advances in Surgery

• Anesthesia and Intensive Care
• Infection Control
The Future for Non-invasive Monitoring is Now!

• MAJOR ADVANCES IN TECHNOLOGY
• FEWER COMPLICATIONS
• LESS ACCURACY BUT GOOD PRECISION
• LESS COST – MOSTLY
• BETTER PORTABILITY
• EASE OF USE – PLUG AND PLAY
“You Can’t Manage What You Don’t Measure”

Moermann A, Absalom AR

J. Clin Monit Comput 2016;30:253-4
The Goal of Monitoring

• Maintain or restore tissue perfusion and oxygenation.
• Most monitors focus on macro-hemodynamic targets: Blood Pressure and Cardiac Output
• The focus needs to be on the microcirculation which ultimately determines tissue perfusion
Flow Monitoring

“It is a source of regret that the measurement of flow is so much more difficult than the measurement of pressure. This has led to an undue interest in the blood pressure manometer. Most organs, however, require flow rather than pressure...”

Jarisch, 1928
“Found Dead in Bed”

• No patient in our hospital should be found dead in bed
• Our hospitals should be the safest place in the world to be when you are sick
• Every patient should have a noninvasive monitor wirelessly connected to the smart phone of the nurse
• Many of you have a monitor on you right now:
  – Apple watch
  – Fitbit
  – Samsung Fitband
Dead in Bed

Dr. Ramsay,
Please forgive me for being so bold. I found your name in a news report on the local news. My husband died following a successful laminectomy. After one hour in a PACU he was placed on a low risk medical surgical floor. He was on IV pca dilaudid. He was not monitored. He was not checked on after his initial admission until pain management came to adjust his medication nearly 2 hours later. He was dead. They coded him for 3 hours in attempt to resuscitate him. The cause of death was listed as respiratory depression less than 3 hours, bradycardia less than 3 hours and hypotension less than 3 hours.

I am telling you my story in hopes you can head me in the right direction. I have an attorney who tells me it is not the standard of care so there is no one who will stand with me and be Toms voice. He should not be dead. I learned from this report that you are a patient safety advocate. My hope is that the local hospitals take the risk of respiratory depression with the use of opioids drugs seriously I know this is out of the ordinary but I would be appreciative for any advice.

Sincerely,
MONITORS

• Must Know:
  – Accuracy, Precision, Validity, Stability and Reliability

• Trade Off:
  – More invasive High Accuracy Good Precision
  – Non-Invasive Less Accuracy, Good Precision

• Accuracy:
  – Less accuracy but good trend may be acceptable if less risk and less cost.

Accuracy and Precision

ACCURACY = TRUTH

PRECISION = REPEATABILITY
or TRENDS
Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. Martin Makary and Michael Daniel assess its contribution to mortality and call for better reporting.

Martin A Makary professor, Michael Daniel research fellow

Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, MD 21287, USA

Based on our estimate, medical error is the 3rd most common cause of death in the US

Cancer: 585k
Medical error: 251k
Heart disease: 611k
COPD: 149k
Motor vehicles: 34k
Suicide: 41k
Firearms: 34k

All causes: 2,597k

However, we’re not even counting this - medical error is not recorded on US death certificates

Data source:
http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf

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2004 – 2012 Types of Sentinel Event

- Wrong-patient, wrong-site, wrong-procedure: 928
- Ventilator Death: 44
- Utility System Failure: 19
- Unintended Retention of a Foreign Body: 116
- Transfusion Error: 117
- Transfer-Related Event: 24
- Suicide: 773
- Severe Neonatal Hyperbilirubinemia: 55
- Self-Inflicted Injury: 117
- Restriction related Event: 30
- Radiation Overdose: 30
- Perinatal Death/Injury: 695
- Other Unanticipated Event: 239
- Op/Post-op Complication: 425
- Medication Error: 747
- Med Equipment-related: 747
- Maternal Death: 378
- Inpatient Drug Overdose: 193
- Infection-Related Event: 163
- Infant Discharge to wrong Family: 747
- Infant Abduction: 26
- Fire: 98
- Fall: 538
- Elopement: 79
- Dialysis-Related Event: 790
- Delay in Treatment: 790
- Criminal Event: 256
- Anesthesia-related Event: 94

(The Joint Commission 2012)
Stories of preventable medical errors

Nancy Conrad
(wife of astronaut Charles "Pete" Conrad)

While motorcycling with friends in Ojai, California, Pete ran off the road and crashed. At the emergency room, staff first thought the 69-year-old's injuries were minor, but he died from internal bleeding about five hours later. He was buried with full honors at Arlington National Cemetery. Following the death of her husband, Nancy co-founded the Community Emergency Healthcare Initiative, designed to measurably affect preventable injury and death now occurring in emergency departments.
Stories of Preventable Medical Errors

Lenore Alexander
(mother of Leah Coufal)

Ten years ago, Lenore Alexander’s healthy, 11-year-old daughter, Leah Coufal, underwent elective surgery to correct pectus carinatum at a prestigious Southern California hospital. Though the surgery went well, Lenore awoke at 2 a.m. on the second post-operative night to find Leah “dead in bed,” a victim of undetected respiratory arrest, caused by the narcotics that were intended to ease her pain. If Leah had been monitored continuously after the surgery, staff would have been alerted and Leah would probably have been rescued. But ten years later, knowing that the standard of care remains unchanged, Lenore works to make continuous postoperative monitoring the law (Leah’s Law) to help prevent other children suffering the same fate as Leah.
Continuous Postoperative Electronic Monitoring and the Will to Require It.

RK Stoelting Anesth Analg 2015;121:579-81

“A monitor would have saved my child’s life. All that stands between us and universal postoperative monitoring, is the will to use it”

-Lenore Alexander
APSF Recommends:

“Electronic monitoring of all hospitalized adult patients receiving postoperative opioids for pain management”

“Patients should be monitored with continuous pulse oximetry with data transmitted wirelessly to a qualified health care professional”

“Incorporation of a monitor of ventilation if supplemental oxygen is needed to maintain an acceptable SpO$_2$”
What should we monitor?

Who should we monitor?
Noninvasive Monitoring in the 1960’s

• **Finger on the pulse:**
  - Measure strength, volume and character of pulse
  - Continual; BP at least 70 mmhg if you can feel the superficial temporal pulse
  - Assessment of temperature and diaphoresis

• **Monoaural Stethoscope:**
  - Breath sounds and respiratory rate
  - Respiratory pattern
  - Continual

• **Sphigmomonitor:**
  - Stethoscope under cuff

• **Pupils:**
  - Size and reactivity
  - Depth of anesthesia
  - Equality
Perioperative cardiovascular monitoring of high-risk patients: a consensus of 12

Jean-Louis Vincent¹, Paolo Pelosi², Rupert Pearse³, Didier Payen⁴, Azriel Perel⁵, Andreas Hoeft⁶, Stefano Romagnoli⁷, V Marco Ranieri⁸, Carole Ichai⁹, Patrice Forget¹⁰, Giorgio Della Rocca¹¹ and Andrew Rhodes¹²

Abstract

A significant number of surgical patients are at risk of intra- or post-operative complications or both, which are associated with increased lengths of stay, costs, and mortality. Reducing these risks is important for the individual patient but also for health-care planners and managers. Insufficient tissue perfusion and cellular oxygenation due to hypovolemia, heart dysfunction or both is one of the leading causes of perioperative complications. Adequate perioperative management guided by effective and timely hemodynamic...
A Consensus of 12

- Insufficient tissue perfusion and cellular oxygenation due to hypovolemia, heart dysfunction or both is one of the leading causes of perioperative complications. Adequate perioperative management guided by effective and timely hemodynamic monitoring can help reduce the risk of complications and improve outcomes.
Table 1 What hemodynamic monitoring do you routinely use for the management of high-risk surgery patients? (Please mark all that apply)

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<th>ESA respondents (n = 195)</th>
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<td>Response percentage</td>
<td>Response percentage</td>
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<td>Non-invasive arterial pressure</td>
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<td>Global end-diastolic volume</td>
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From [19]. ASA, American Society of Anesthesiology; ESA, European Society of Anaesthesiology.
The Pulmonary Artery Catheter

- Invasive
- Infection Risk
- Accuracy??

- A series of large prospective, multicentered, randomized controlled trials failed to show a mortality benefit when PACs were utilized in critically ill patients.

Non-Invasive Monitoring Cardiac Output

• Transesophageal Echocardiography
  – Assess ventricular function – Ejection Fraction
  – Volume status
  – Fluid responsiveness

• Non-invasive Pulse Contour Analysis

• Esophageal Doppler

• Bioimpedance and bioreactance

• Inert Gas Rebreathing
Importance of Oxygen in the Body

- Oxygen has a critical role in cell metabolism to convert nutrients into energy\(^1\)

- Deprivation of adequate oxygen in the body can cause several complications, which may be deadly\(^2\)

- The components that are involved in transporting oxygen throughout the body and to the tissues are thus extremely important to proper life function\(^2\)
Oxygen Delivery ($\text{DO}_2$)

$$\text{DO}_2 = \text{CO} \times \text{CaO}_2$$

**DO$_2$** is the amount of oxygen (in ml) that is delivered from the heart to the tissues per minute.

**Cardiac Output** is the amount of blood that is ejected from the heart per minute. Monitoring the components of CO in patients is important to ensure that there is sufficient volume in the body to transport oxygen.

- **SV** Stroke Volume
- **HR** Heart Rate
1974 First Pulse Oximeter

Figure 1. Takuo Aoyagi, John Severinghaus, and Yoshiyuki Honda, 1987.
Now Pulse Oximeters can Measure More

Oxygenated Hgb and reduced Hgb absorb different amounts of Red (RD) and Infrared (IR) Light.
CONSENSUS STATEMENT

Perioperative fluid management: Consensus statement from the enhanced recovery partnership

Monty G Mythen¹*, Michael Swart², Nigel Acheson³, Robin Crawford⁴, Kerri Jones⁵, Martin Kuper⁶, John S McGrath⁷ and Alan Horgan⁸
Perioperative Goal Directed Fluid Therapy

- Fluid and inotrope therapy guided by minimally invasive cardiac output or stroke volume optimization.
- Increase in global oxygen delivery
- Goal is increase in microcirculation
- Results in less overall fluid infused peri-operatively
Minto G, Scott MJ, Miller TE. Monitoring needs and goal-directed fluid therapy within an enhanced recovery program. Anesthesiol Clin
COMPICATIONS

Hypovolemia
- Altered tissue perfusion
- Renal failure
- Anastomotic breakdown
- Confusion
- CVA
- Splanchnic ischemia
- MOF

Hypervolemia
- Edema
- Intra-abdominal hypertension
- Respiratory failure
- Impaired healing
- Altered mobilization
- MOF

VOLUME STATUS
Fluid administration is one of the most common interventions to increase CO. However, fluid administration has to be carefully titrated since both hypovolemia and hypervolemia can be associated with negative outcomes.

- Too little fluid can lead to inadequate CO.
- Too much fluid can lead to edema.

**References**

Fluid responsiveness is defined as the response of CO to an increase in preload (circulating volume), generally with the administration of fluid.

A patient whose CO increases post fluid administration is considered a “Responder” and a patient whose CO does not increase is considered a “Non-Responder.”
Fluid responsiveness can also be assessed by the response of SV to a mechanical breath. Under positive-pressure ventilation, there is a transient reduction in venous return and thereby a reduction in preload.
Multiple dynamic parameters have been shown to help clinicians assess fluid responsiveness.

- Pulse pressure variation (PPV) and stroke volume variation (SVV) utilize the arterial waveform from an indwelling (invasive) arterial cannula.
- Some also require a dedicated sensor and/or dedicated software, which may become costly.

Dynamic parameters are meant to be used in mechanically ventilated adults, who do not have an open chest or severe arrhythmia, and will be most accurate at tidal volumes of 7-8 ml/kg.
Pleth Variability Index
Noninvasive > Continuous

PVI Calculation: How It Works

Perfusion Index (PI) is the ratio of nonpulsatile to pulsatile blood flow through the peripheral capillary bed. PVI is an automatic measure of the dynamic change in PI that occurs during the respiratory cycle.

$$PVI = \frac{PI_{MAX} - PI_{MIN}}{PI_{MAX}} \times 100$$

The greater the PVI, the more likely the patient will respond to fluid administration.
Several peer-reviewed clinical studies have evaluated the utility of PVi as a fluid responsiveness indicator in mechanically ventilated patients.¹⁻³ For example:

> **Operating Room:** In a study of patients undergoing major abdominal surgery, researchers found that PVi can serve as a valid indicator of fluid responsiveness¹.

> **Intensive Care Unit:** In a study of patients with circulatory insufficiency, researchers found that PVi can predict fluid responsiveness noninvasively under mechanical ventilation².

In a study of patients undergoing major abdominal surgery, researchers found that PVi-based goal-directed fluid management reduced the volume of intraoperative fluid infused and reduced intraoperative and postoperative lactate levels.\(^1\)

In a study of patients undergoing colorectal surgery, researchers found that the implementation of an enhanced recovery protocol which included PVi led to improved patient satisfaction and substantial reductions in lengths of stay, complication rates, and costs for patients.\(^2\)
Benefits of PVi Monitoring

Compared to other dynamic parameters, PVi has the following benefits:

- Noninvasive
- Continuous*
- Real-Time*
- Available where Pulse Oximetry is used
- Has been used frequently in procedures where an arterial line was not applied\(^1\)

\(^{*}\)PPV and SVV are also continuous and real-time

Value of SpHb and PVi Monitoring

When used together, SpHb and PVi can provide additional insight.
Enhanced Recovery Program for Colorectal Surgery

• **Reduced opioids**: Tap Blocks; Non-opioid analgesia

• **Goal Directed Fluids**: Leads to reduced IV Fluids

• **Out of Bed in PACU**:
  • Mean length of stay reduced to 2 days from 5-7 days

• **Cost savings in first year**: $500,000
Cerebral oxygenation during changes in vascular resistance and flow in patients on cardiopulmonary bypass – a physiological proof of concept study

N. H. Sperna Weiland,1 D. Brevoord,1 D. A. Jöbsis,1 E. M. F. H. de Beaumont,2 V. Evers,2 B. Preckel,3 M. W. Hollmann,3 S. van Dieren,1 B. A. J. M. de Mol4 and R. V. Imming2,5

1 Resident, 2 Staff member, 3 Professor, Department of Anaesthesiology, 4 Professor, Department of Cardiothoracic Surgery, 5 Laboratory for Clinical Cardiovascular Physiology, Department of Anatomy and Embryology, Academic Medical Center, Amsterdam, The Netherlands

Summary

Despite a rise in blood pressure, cerebral oxygenation decreases following phenylephrine administration, and we hypothesised that phenylephrine reduces cerebral oxygenation by activating cerebral α1 receptors. We studied patients on cardiopulmonary bypass during constant flow. Phenylephrine raised mean arterial pressure (α1-mediated) from mean (SD) 69 (8) mmHg to 79 (8) mmHg; p = 0.001, and vasopressin raised mean arterial pressure (V1 mediated) from 69 (8) mmHg to 83 (6) mmHg; p = 0.001. Both drugs elicited a comparable decrease in cerebral oxygenation from 61 (7)% to 60 (7)%; p = 0.023 and 61 (8)% to 59 (8)%; p = 0.022, respectively. This implies that after phenylephrine or vasopressin administration, cerebral oxygenation declines as a result of cerebral vasoconstriction, due to either both cerebral α1 and V1 receptors being equipotentially activated or to an intrinsic myogenic mechanism of cerebral vasculature in reaction to blood pressure elevation.
Figure 1 The effects of phenylephrine (circles), vasopressin (triangles) and an increase in cardiopulmonary bypass flow (diamonds) on mean arterial blood pressure (MAP; upper panel) and cerebral oxygenation ($rS_{O_2}$; lower panel). Values are mean, SD every 60 s (as error bars).
Perioperative goal-directed haemodynamic therapy based on flow parameters: a concept in evolution

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Abstract

Haemodynamic management incorporating direct or surrogate stroke volume monitoring has experienced a rapid evolution, because of emergence of the “goal-directed therapy” concept and technological developments aimed at providing a parameter leading to the goal. Nonetheless, consensus on both definitions of the ideal “goal” and strategies for achieving it remain elusive. For this review, we first consider basic physiological and patient monitoring factors relevant to the concept of “fluid responsiveness”, and then focus upon randomized controlled trials and meta-analyses involving goal-directed haemodynamic therapy based on various flow parameters. Finally, we discuss the current status of noninvasive methods for monitoring fluid responsiveness.

Key words: blood pressure; fluid therapy; haemodynamics; monitoring; stroke volume
Review of splanchnic oximetry in clinical medicine

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New York University School of Medicine, Division of Neonatology, Department of Pediatrics, 462 First Avenue 8S15, New York, New York 10016, United States

Abstract. Global tissue perfusion and oxygenation are important indicators of physiologic function in humans. The monitoring of splanchnic oximetry through the use of near-infrared spectroscopy (NIRS) is an emerging method used to assess tissue oxygenation status. Splanchnic tissue oxygenation ($\text{SrSO}_2$) is thought to be potentially of high value in critically ill patients because gastrointestinal organs can often be the first to suffer ischemic injury. During conditions of hypovolemia, cardiac dysfunction, or decreased oxygen-carrying capacity, blood flow is diverted toward vital organs, such as the brain and the heart at the expense of the splanchnic circulation. While monitoring $\text{SrSO}_2$ has great potential benefit, there are limitations to the technology and techniques. $\text{SrSO}_2$ has been found to have a relatively high degree of variability that can potentially make it difficult to interpret. In addition, because splanchnic organs only lie near the skin surface in children and infants, and energy from currently available sensors only penetrates a few centimeters deep, it can be difficult to use clinically in a noninvasive manner in adults. Research thus far is showing that splanchnic oximetry holds great promise in the ability to monitor patient oxygenation status and detect disease states in humans, especially in pediatric populations.

© 2016 Society of Photo-Optical Instrumentation Engineers (SPIE) [DOI: 10.1117/1.JBO.21.9.091306]

Keywords: splanchnic oximetry; near-infrared spectroscopy; regional tissue oxygenation; gut perfusion.

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Smartphone-enabled pulse rate variability: An alternative methodology for the collection of heart rate variability in psychophysiological research

James A.J. Heathers
Fig 1 Examples of non-invasive haemodynamic monitoring techniques. (A) Bioimpedance tracheal tube (ECOM, San Juan Capistrano, CA, USA), (B) bioreactance electrodes (Cheetah, Newton Center, MA, USA), (C) miniaturized single-use transoesophageal echocardiography probe (Imacor, Garden City, NY, USA), (D, E) volume clamp finger cuff systems (CNSystems, Graz, Austria and Edwards, Irvine, CA, USA) and (F) applanation tonometry wrist device (Tensys, San Diego, CA, USA).
Fig. 5 Wearable and wireless sensors. Examples of FDA cleared sensors designed to monitor heart rate, heart rate variability, respiratory frequency and/or thoracic fluid content.
A sneak peek into digital innovations and wearable sensors for cardiac monitoring

Frederic Michard¹

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Fig. 1 The digital and wireless cardiac patient. Apps digital applications, SMS text message, HR heart rate, HRV heart rate variability, RR respiratory rate, PAP pulmonary artery pressure, PWTT pulse wave transit time, iBP intermittent blood pressure, cBP continuous blood pressure, $SpO_2$ arterial oxygen saturation.

- Track & share physiologic signals & numbers
- Record ECG 1 lead
- Receive SMS to lose weight, stop smoking, increase physical activity, & take medications

Bioimpedance necklace
- HR, HRV
- RR
- Thoracic fluid content

Implantable sensor
- PAP
- Chest patch
- Wireless brachial cuff
- iBP

Wrist sensor
- HR, HRV
- ECG (1 lead)
- $SpO_2$
- cBP
- Activity tracker
Fig. 2 Digital stethoscope. On this prototype, the membrane is part of a phone case. Sound is directed to the microphone, amplified, digitized, and saved. As a result, heart murmurs can be visualized, as they were in the past with phonocardiograms, and valve diseases more easily identified by non-cardiologists.
Fig. 6 Tiny and wireless blood pressure sensor prototypes able to monitor continuously radial (left) or carotid (right) arterial pressure. From [34] with permission.
Connectivity Between Monitors

- STATEMENT ON THE INTEROPERABILITY OF MEDICAL DEVICES
- Committee of Origin: Equipment and Facilities
- (Approved by the ASA House of Delegates on October 22, 2008 and reaffirmed on October 16, 2013)
- ASA believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. ASA also recognizes that, as in all technological advances, interoperability poses safety and medico legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit.
The Current Clinical Environment

- Multiple Data Sources
- Multiple Monitors (with asynchronous data)
- Multiple Stakeholders
- Multiple Opportunities for Suboptimal Decision Making
Integrated display: Cockpit
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<th>RRa</th>
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Additional data includes: %SpO2, BPM, RRa, Halo, and other health-related metrics.
The automotive industry saved thousands of lives annually by adding warning buzzers to use seat belts.

Healthcare settings need automated alerts for clinicians to prevent harm to patients.
Better Safer Care is Most Cost Effective!

Our goal is to monitor every patient. No one should be “Found Dead in Bed” Our hospitals should be the safest place for a patient to be NOT the most dangerous!
Thanks for your attention