

Real-time Monitoring for Risk of Acute Kidney Injury

Kai Kuck, Ph.D.

History of Innovation



Raman Gas Monitor
1986

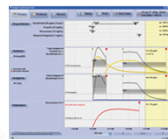


Flow Sensor

NMB Monitor
1992



NICO Monitor
1998



Drug Display

QED
2002



Aneclear
2004



Vapor-Clean
2008

2010

Safe Sedation Training (SST)
2012

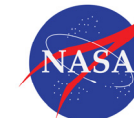
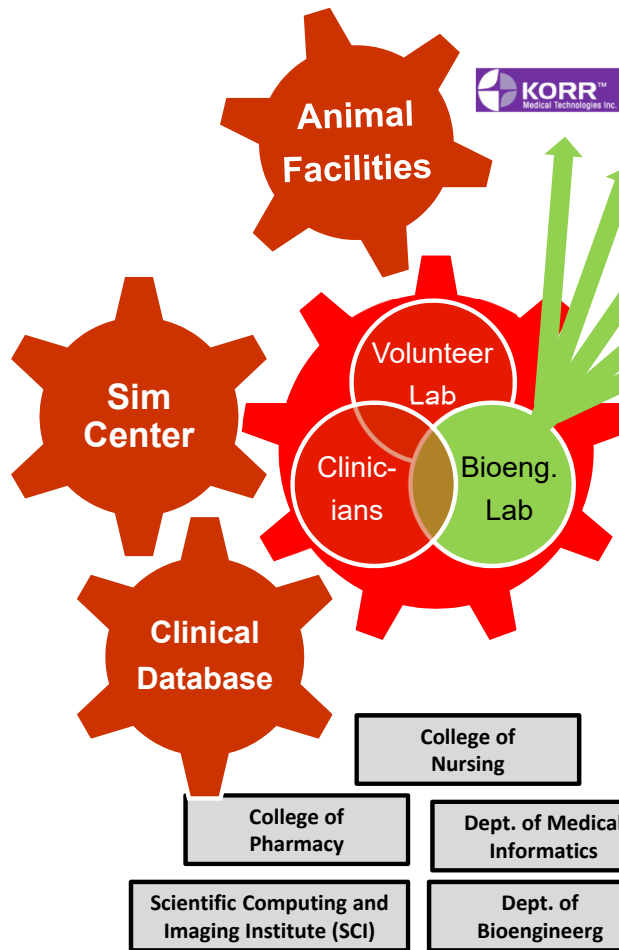


SST-Deep
2014



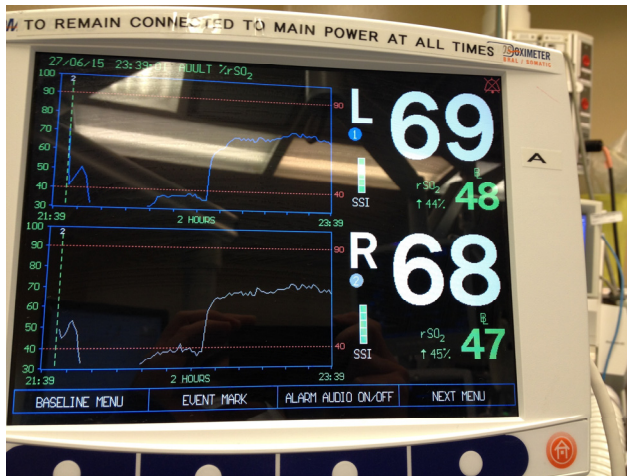
- Blood Loss Estimation
- Acute Kidney Injury Risk Monitor
- Respiratory Depression Detection
- Virtual Reality Pediatric Distraction

Deeply Embedded in Clinical Department

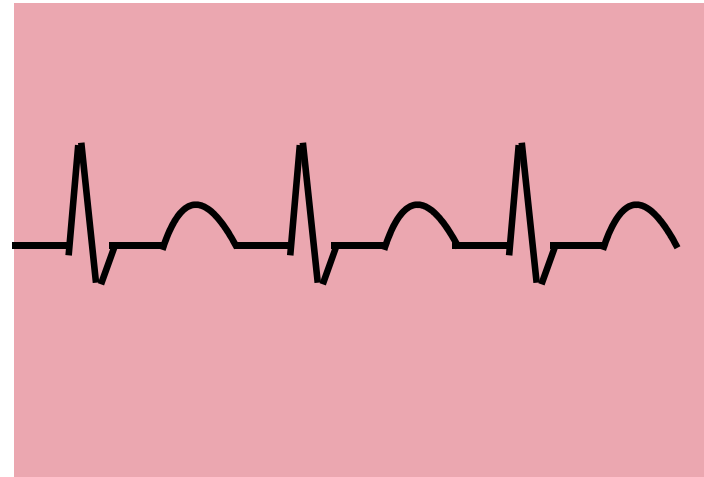


Important Unanswered Question in Anesthesia & Critical Care

**Ideal BP
for
Adequate Kidney Perfusion?**



Cerebral
Oxymetry



EKG Changes

Assumption

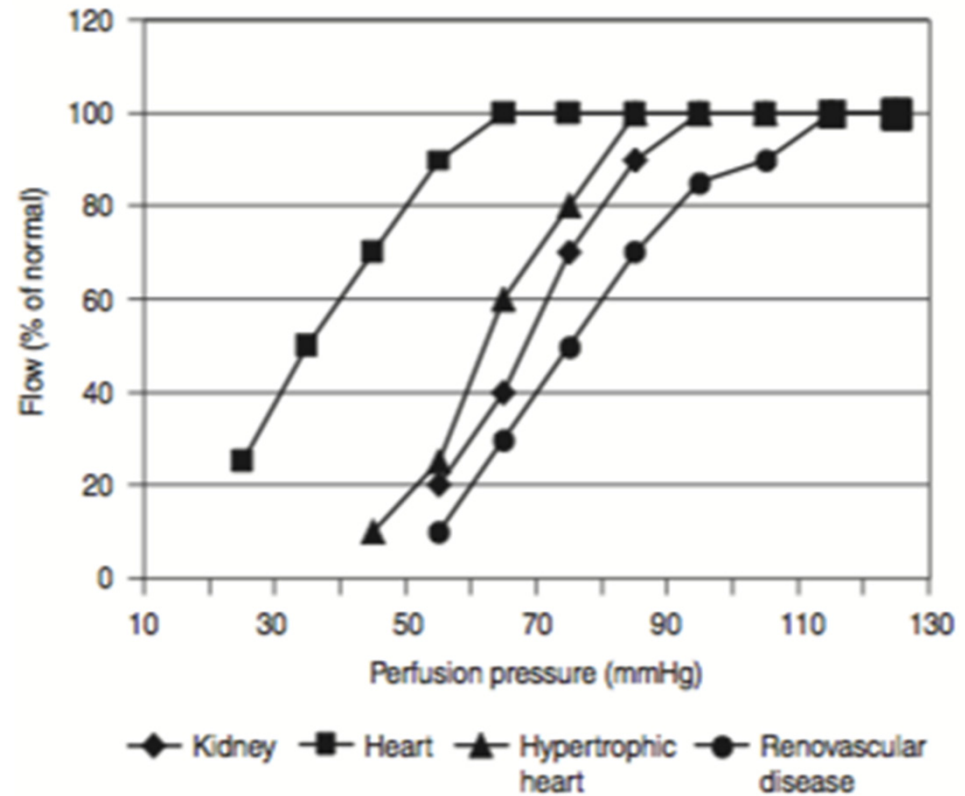


The Brain & Heart: Sensitive
Monitors For Hypoperfusion

But....

Adequate Brain & Heart...

...Poor Renal Perfusion



Acute Kidney Injury (AKI) is Multifactorial

Nephrotoxins

Emboli

Anemia

Hypoxemia

Blood Transfusion

Hypoperfusion

AKI Associated with Cardiac Surgery

Robert H. Thiele, James M. Isbell,[†] and Mitchell H. Rosner[‡]*

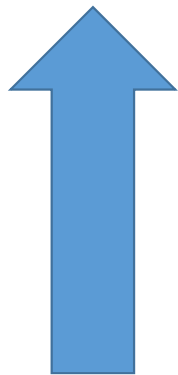
Clin J Am Soc Nephrol. 2015 Mar 6;10(3):500-14.

Renal Injury ~ Up to 50%

AKI Incidence ~ 20-30%

Need for RRT ~ 2-6%

Acute Kidney Injury



Mortality
ICU Length of Stay
Hospital Length of Stay

The Problem

Traditional Diagnosis

- Prolonged Oliguria (6-12 hrs)
- Rise in Creatinine

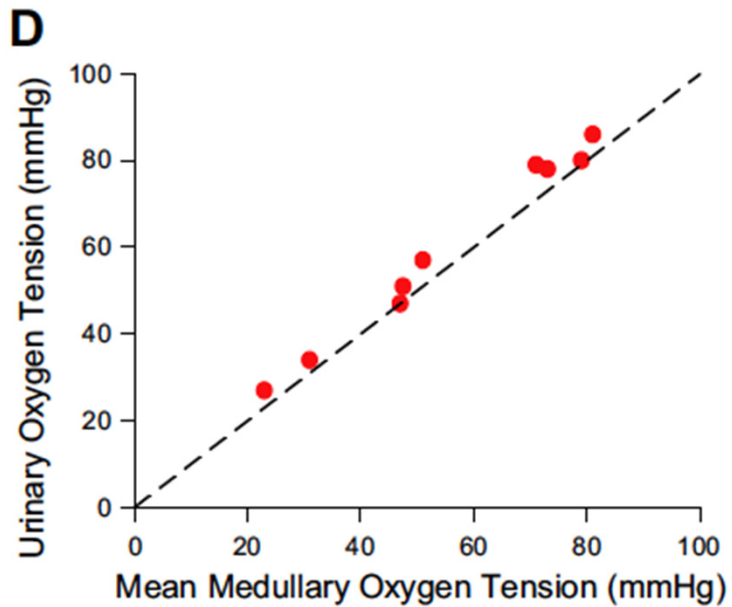
Biomarkers

- NAG, NGAL, TIMP-2, IGFBP-7, KIM-1
- Still only predictive 3-4 hrs after injury.

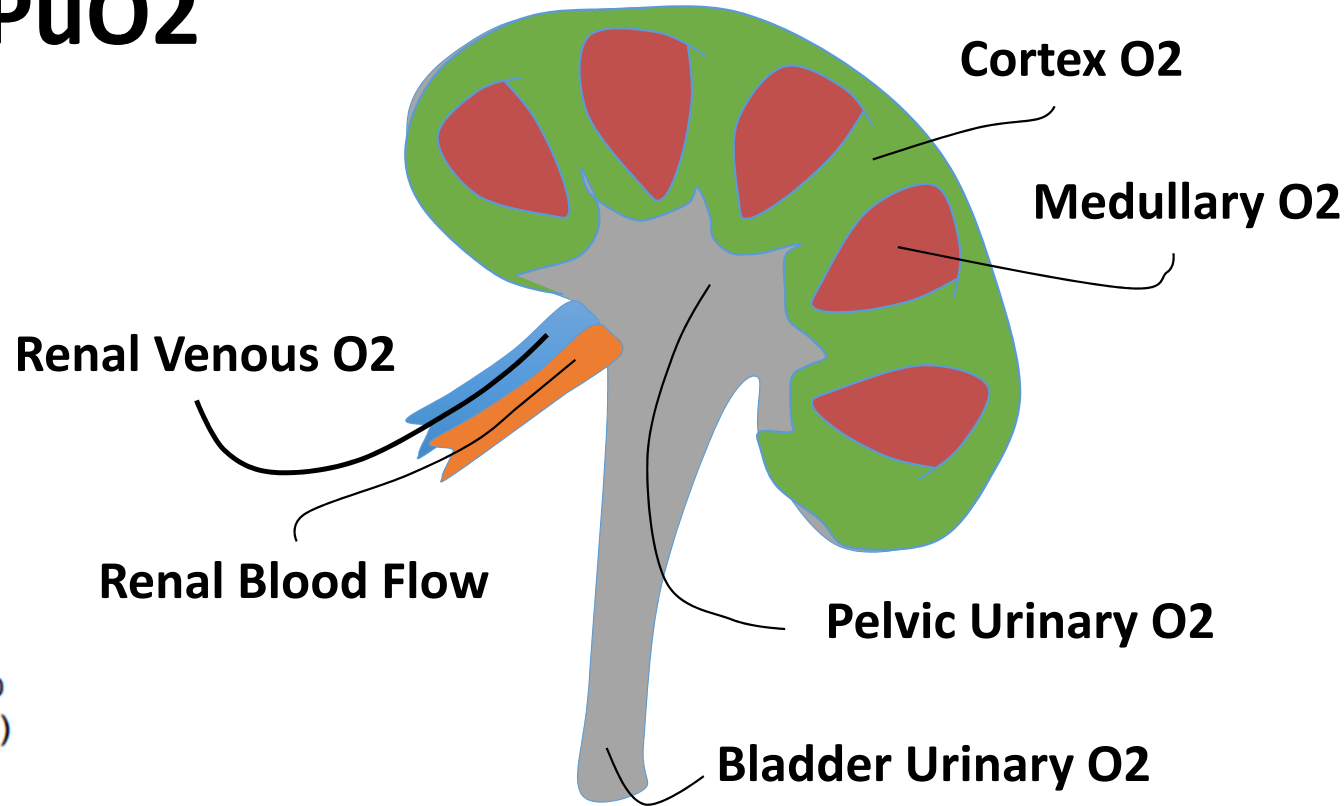
It takes hours to diagnose AKI

Late diagnosis precludes prevention.

Animal Studies: PuO₂



Evans et al 2013



In Humans

PuO₂ that remained below
baseline after CPB



Predicted AKI after Cardiac
Surgery

Kainuma et al 1996



Device
Develop-
ment



Bench
Valid-
ation



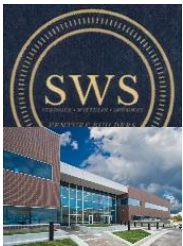
Natalie Silverton, MD, Assistant Professor of Anesthesiology

- Fellowships in Cardiac Anesthesia, Thoracic Anesthesia, and Echocardiography. Double boarded in Emergency Medicine.
- Day to day clinical experience in hemodynamic management and the care of patients with multi-organ disease.
- Research in comparative physiology, cardiac anesthesia, echocardiography, and the detection of acute kidney injury



Kai Kuck, PhD, Professor of Anesthesiology

- Bioengineering, Innovation Management, Research Director
- Former Head of Research at major global med device co.
- Research: Pharmacokinetic/dynamic visualization, signal processing, hemodynamic monitoring, intelligent systems



SWS Medical Ventures

- experienced Utah research company with know-how in developing clinical fiber optic based sensors
- ISO 13485 quality systems, regulatory expertise will help in subsequent transitioning towards an FDA 510(k) and CE (Europe) cleared medical product.



U S T A R

Subj #58 out of 100

Clinical Studies

(Cardiac Surgery,
Sepsis, Renal
Transplant)

**Device
Develop-
ment**

**Bench
Valid-
ation**

Basic Science

(Autoregulation,
Vasopressors, Fluid
Managment)

**Development and
Validation of a
Protocol for Renal
Hypoxia**

QUESTIONS FOR THE PANEL

- **how far should we drive the maturity of this technology ?**
 - proof of principle / feasibility
 - 510(k)
 - manufacturing
 - regional/national/global sales

- **what is the best option for exiting / developing our business**
 - sublicensing to vs partnering with established players in the market ?
 - begin our own (or contract) manufacturing ?
 - beginning our own distribution/sales ?

- what do we need to pay attention to with respect to **reimbursement aspects ?**

- **is it sufficient to get IP protection in the US ?** (which other countries ?)

- **\$\$\$**
 - how much can we expect to need ?
 - options for raising those funds