Intrathoracic Pressure Regulation for the Treatment Of Hypotension and Elevated Intracranial Pressure

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August 12, 2009

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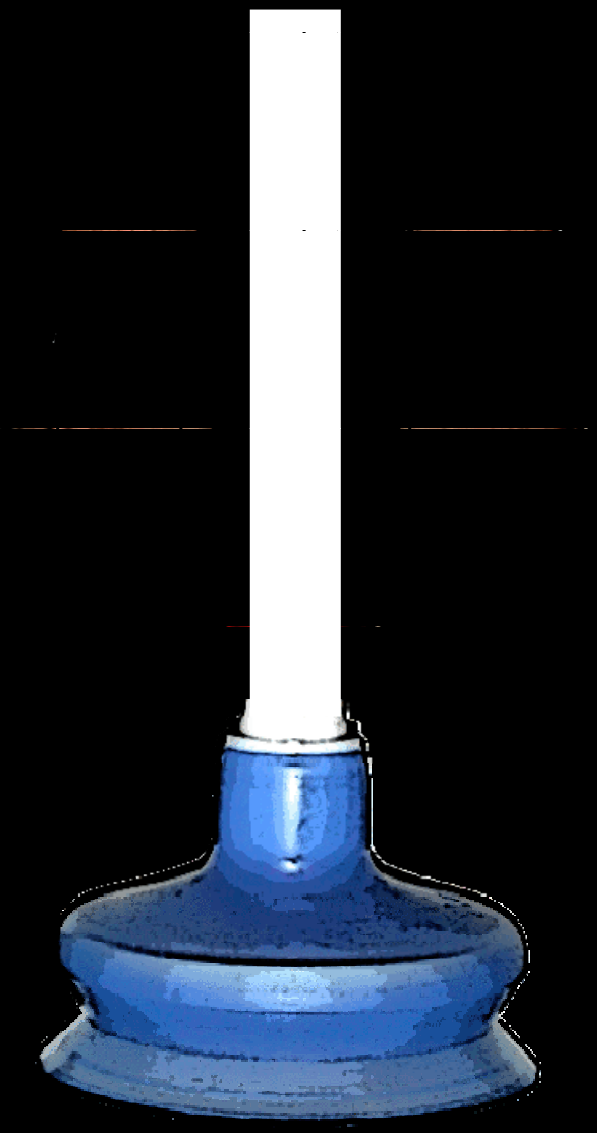
Conflict of Interest Disclosure

Founder and Chief Medical Officer of Advanced Circulatory System, Inc that manufactures the technology discussed in this presentation.

Index Case 1987

"CPR: the P Stands for Plumber's Helper"

Lurie et al
JAMA 1990



CPR, Shock, TBI(?)

Index Case

Cardiac arrest

CPR

ResQPOD®
ResQPump®
LUCAS®

Hypotension

Breathing Pt

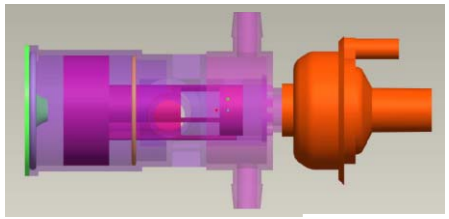
ResQGard®

Hypotension/TBI?

Non-breathing Pt

CirQLator ®

ResQVent ®

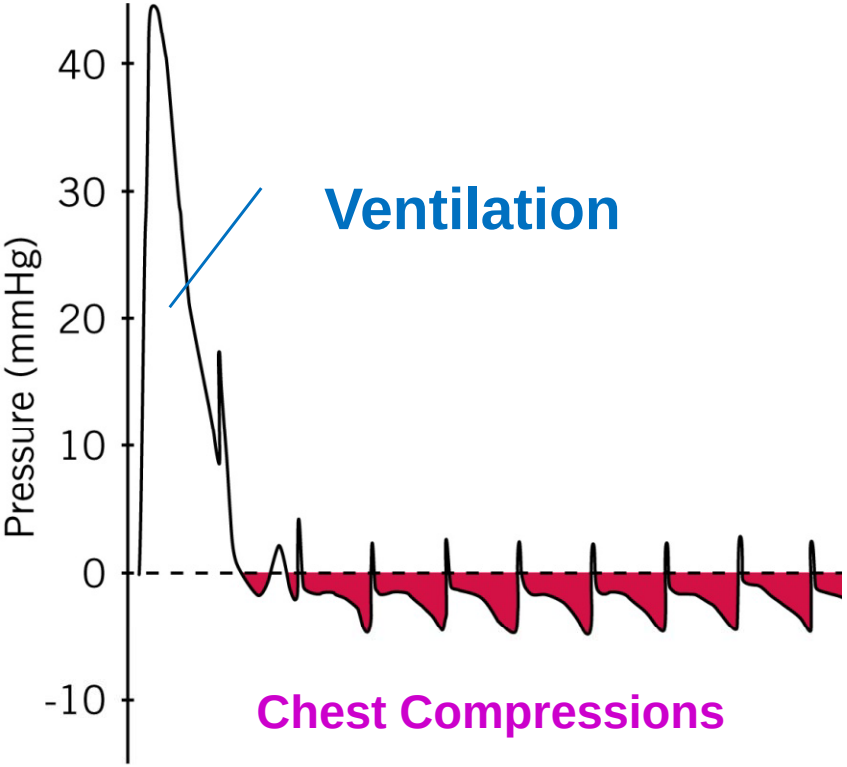


Objectives

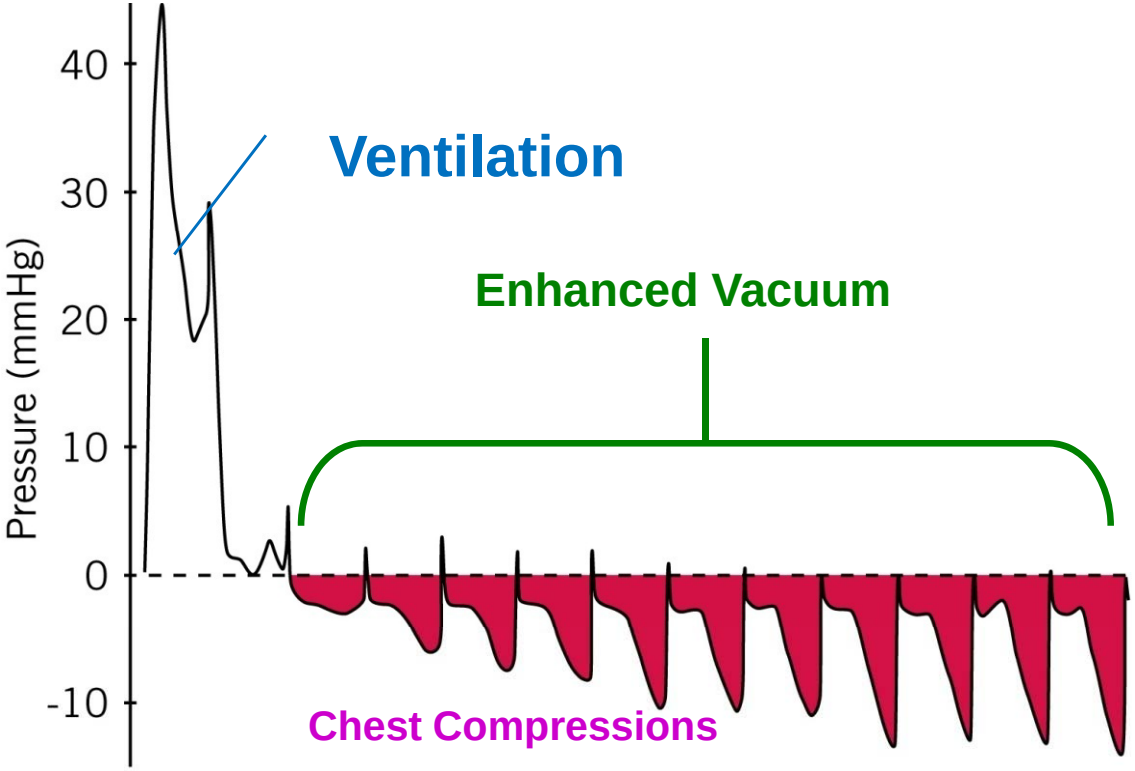
- Describe the impedance threshold device (ITD) for cardiac arrest
- Describe the ITD for spontaneously breathing hypotensive patients
- Describe Intrathoracic Pressure Regulation Therapy for apneic patients

Benefits of Inspiratory Impedance

Conventional CPR



Conventional CPR + ITD

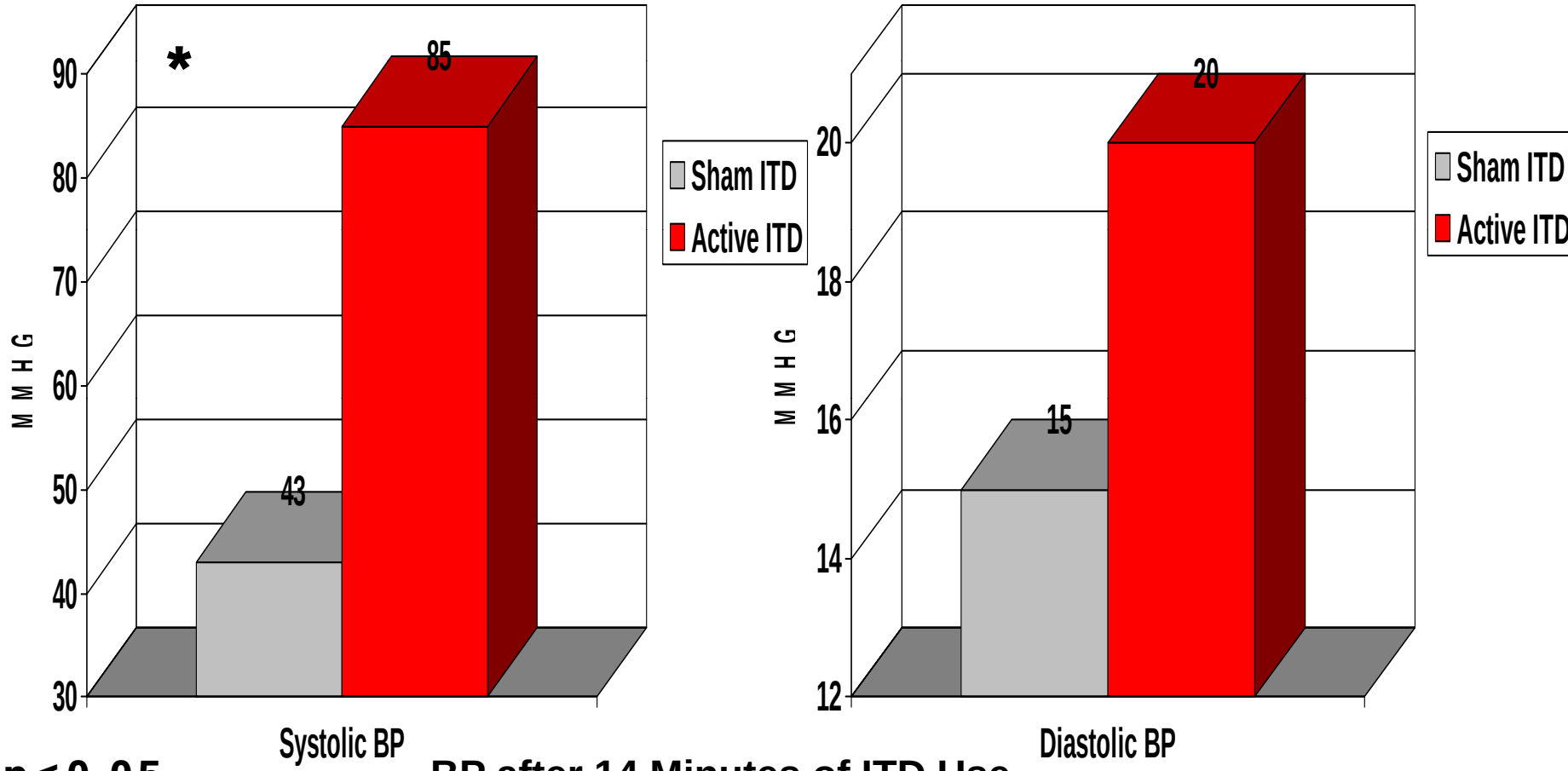


Lower intrathoracic pressures improve refilling after each chest compression and also lowers ICP

Using an ITD

Human Data: Blood Pressure

Milwaukee, WI



*** p < 0.05**

BP after 14 Minutes of ITD Use

n = 22

Pirrallo et al. *Resuscitation* 2005;66:13-20.

A Tale of Six EMS Systems: An Impedance Threshold Device and 'New CPR' Improves Survival Rates after Out-of-hospital Cardiac Arrest

Authors:
Aufderheide TP (Milwaukee), Lick C (Anoka Co), Myers B (Wake Co), Romig L (Pinellas Co), Stothert J (Omaha), Vartanian L (Harris Co).

Presented at the American Heart Association Scientific Sessions
November 2008

Critical Care Medicine 2008

Outcome Results

	Control	Intervention	P-value	Odds Ratio (95% CI)
ROSC	30.4% (535/1757)	34.1% (586/1719)	0.022	1.18 (1.022, 1.366)
Hospital Discharge	9.7% (170/1757)	12.6% (216/1719)	0.007	1.34 (1.078, 1.671)
HD (VF)	19.0% (85/447)	31.1% (128/412)	<0.001	1.91 (1.384, 2.667)
CPC 1 or 2	31.4% (11/35)	55.2% (32/58)	0.033	2.68 (1.027, 7.213)

Aufderheide AHA 2008

Meet Samantha

Take Heart America Save
March 2009

Samantha:
- 18 yrs old
- 16 wks Pregnant
- VF

Bystander CPR

First responders:
- New CPR, ITD, AED

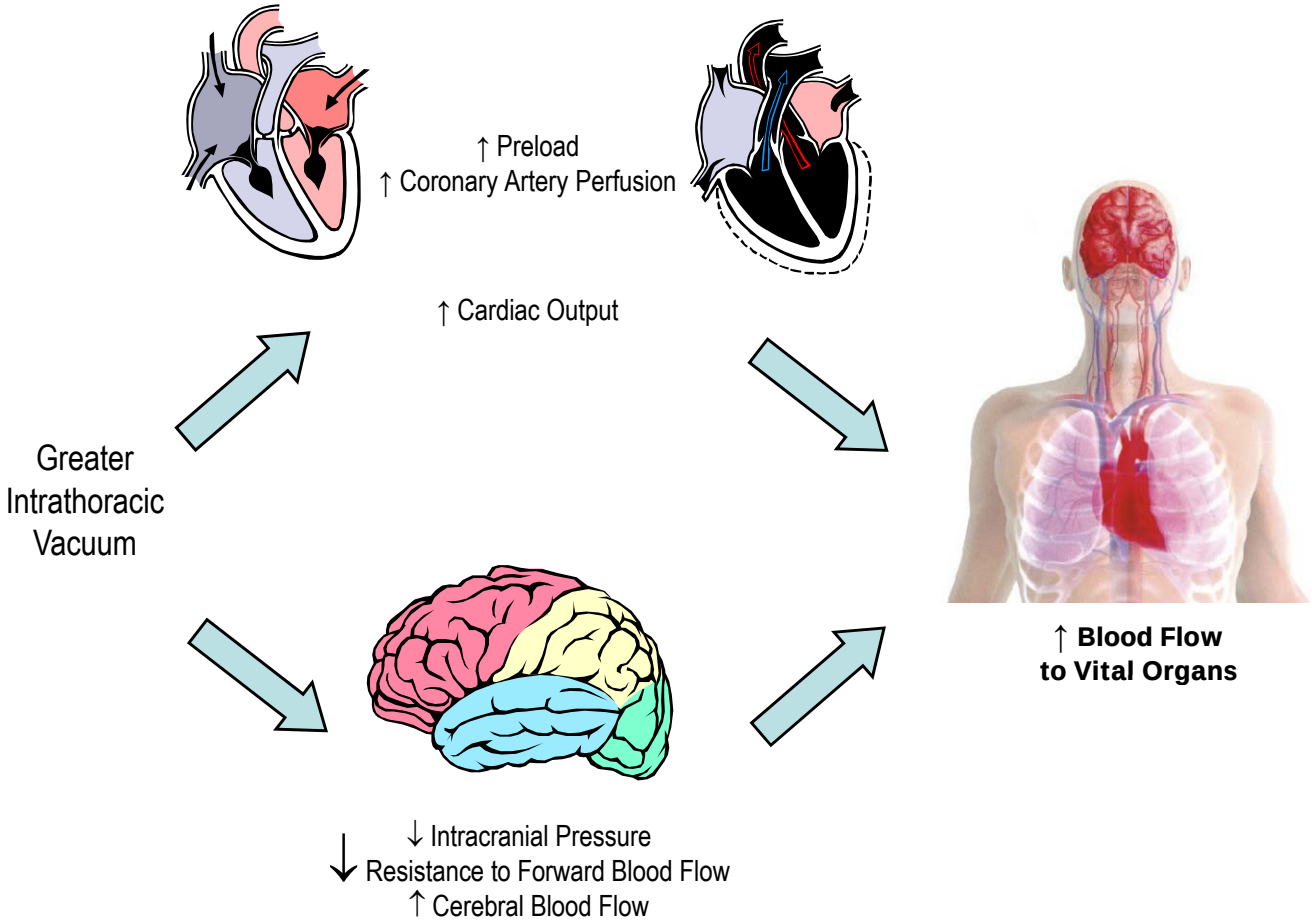
ALS:
- Stabilize, Transport

Resuscitation Center:
- Cooling, ICD

Serenity, Samantha's baby

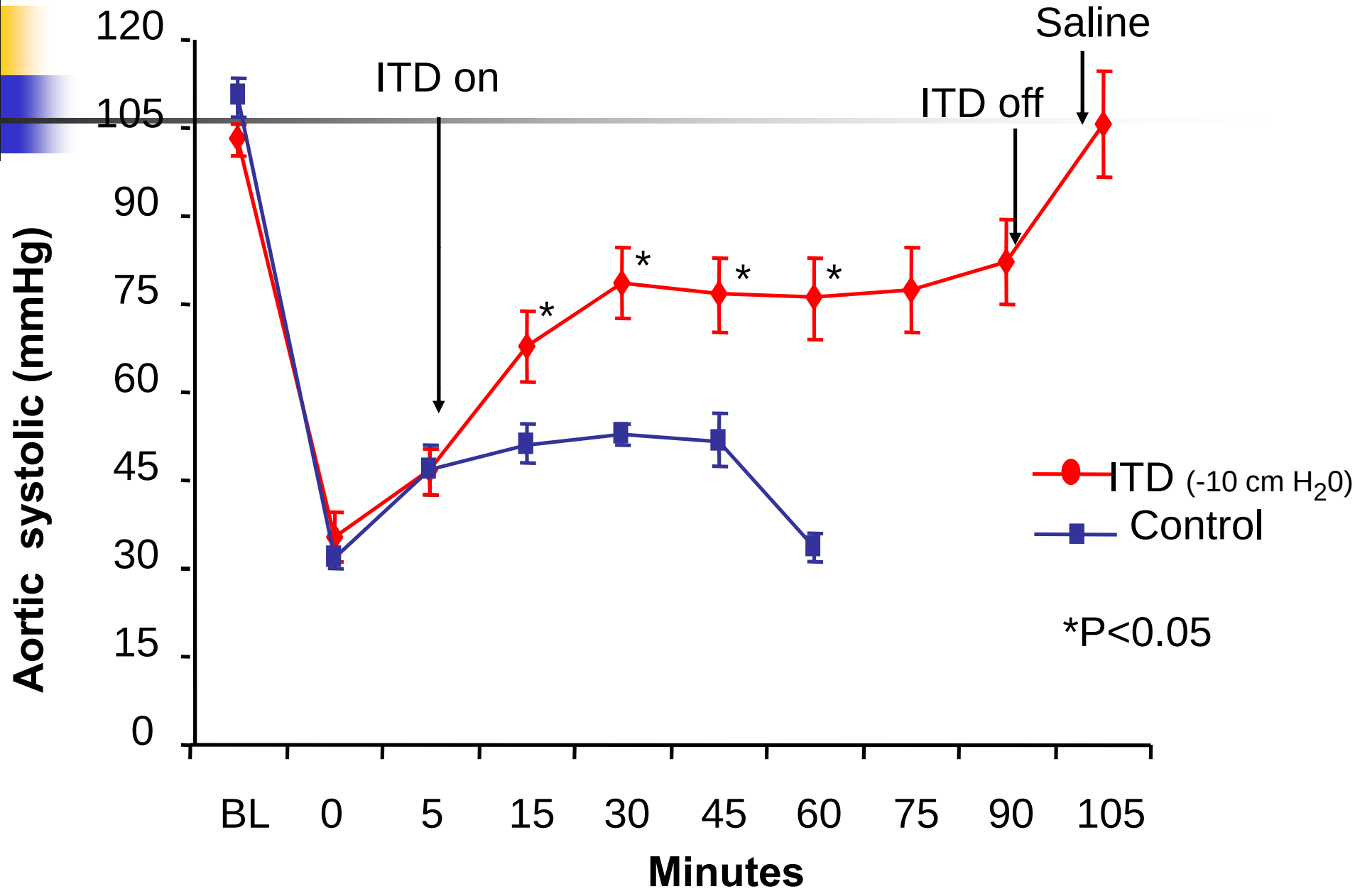
Inspiratory Impedance Effect

Breathing through the ITD



OCTOBER 1999
Swine Model:
Moderate
Hemorrhage

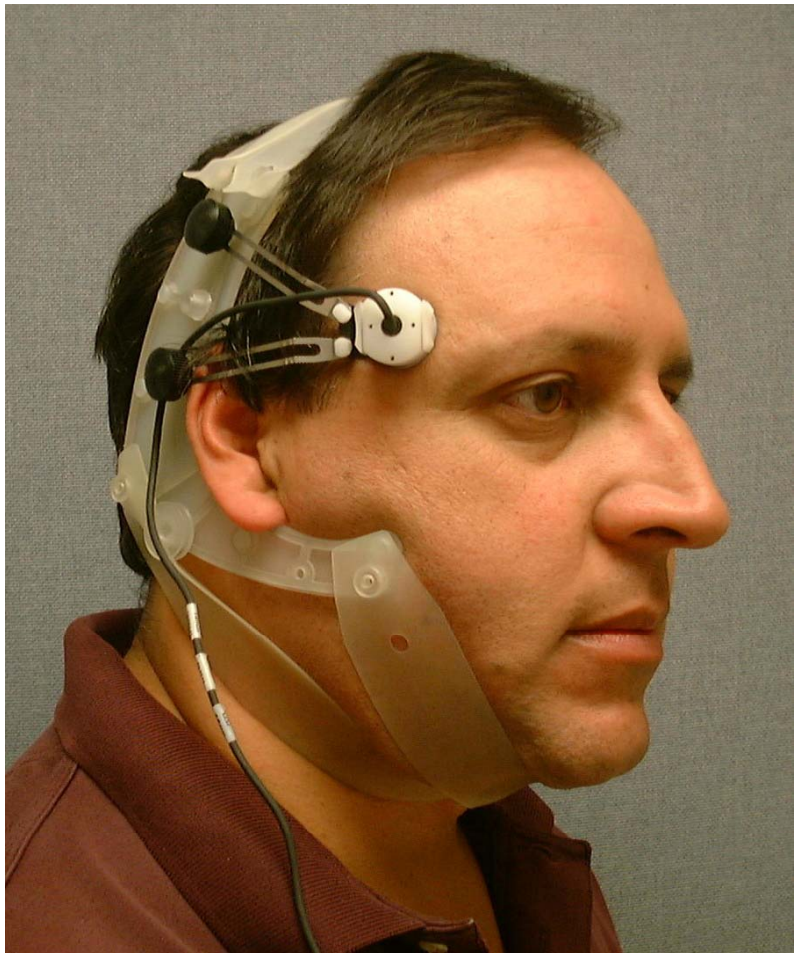
Systolic Blood Pressure in Spontaneously Breathing Swine in Hemorrhagic Shock



Lurie et al, Critical Care Medicine, 2004

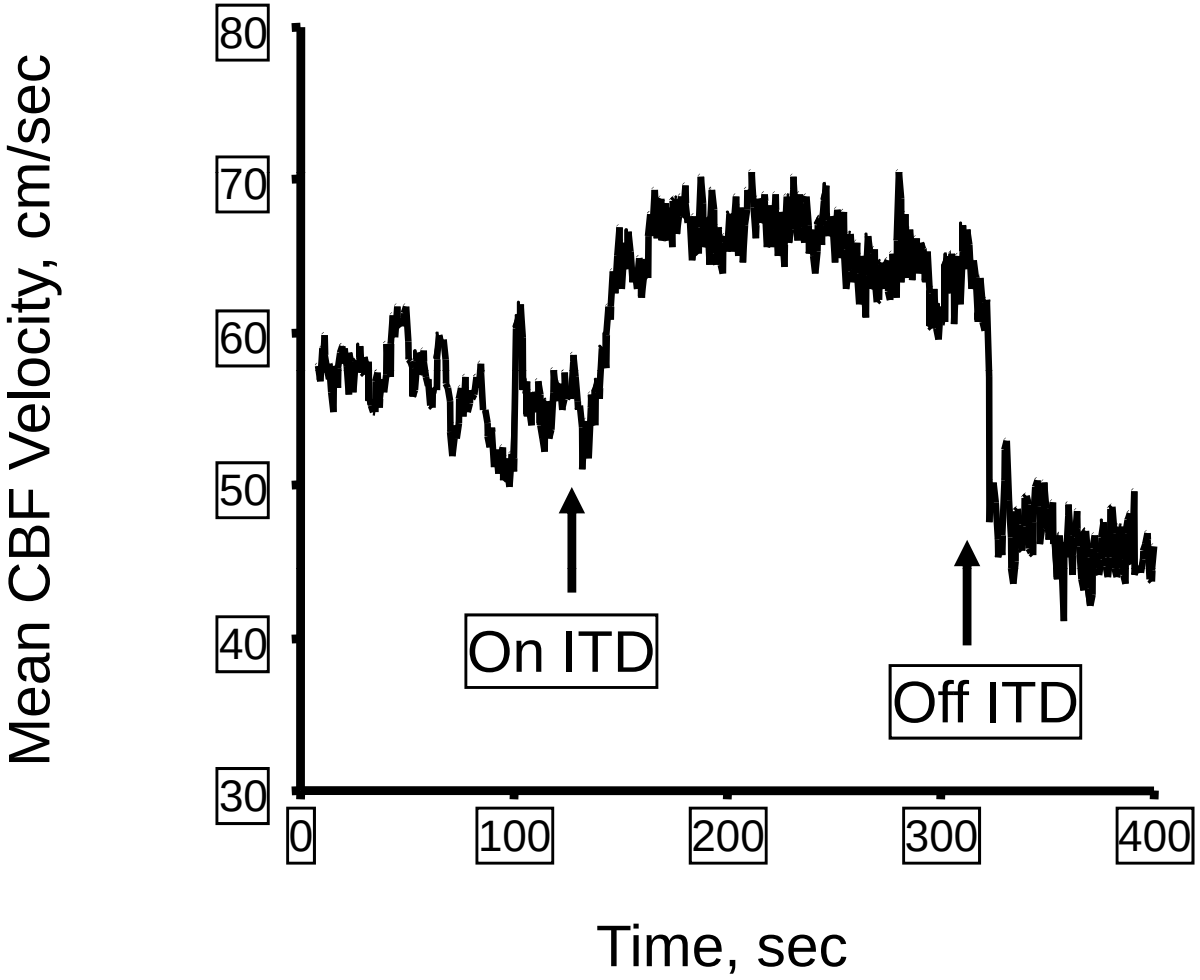
Effect of ITD on Brain Perfusion

Transcranial Doppler



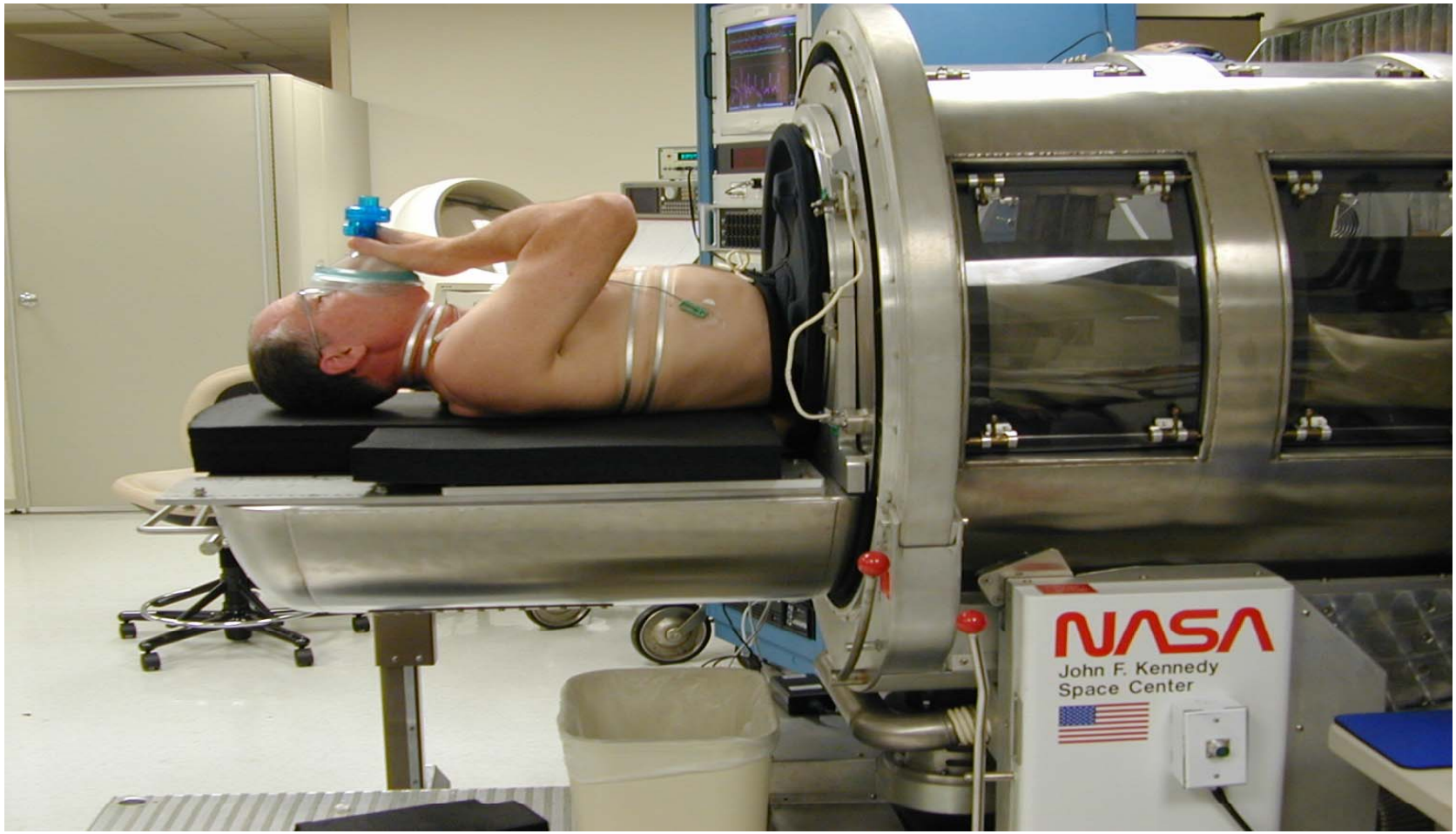
Cerebral Blood Flow

Effects of ITD on Cerebral Blood Flow



Cooke W. et al, 2005

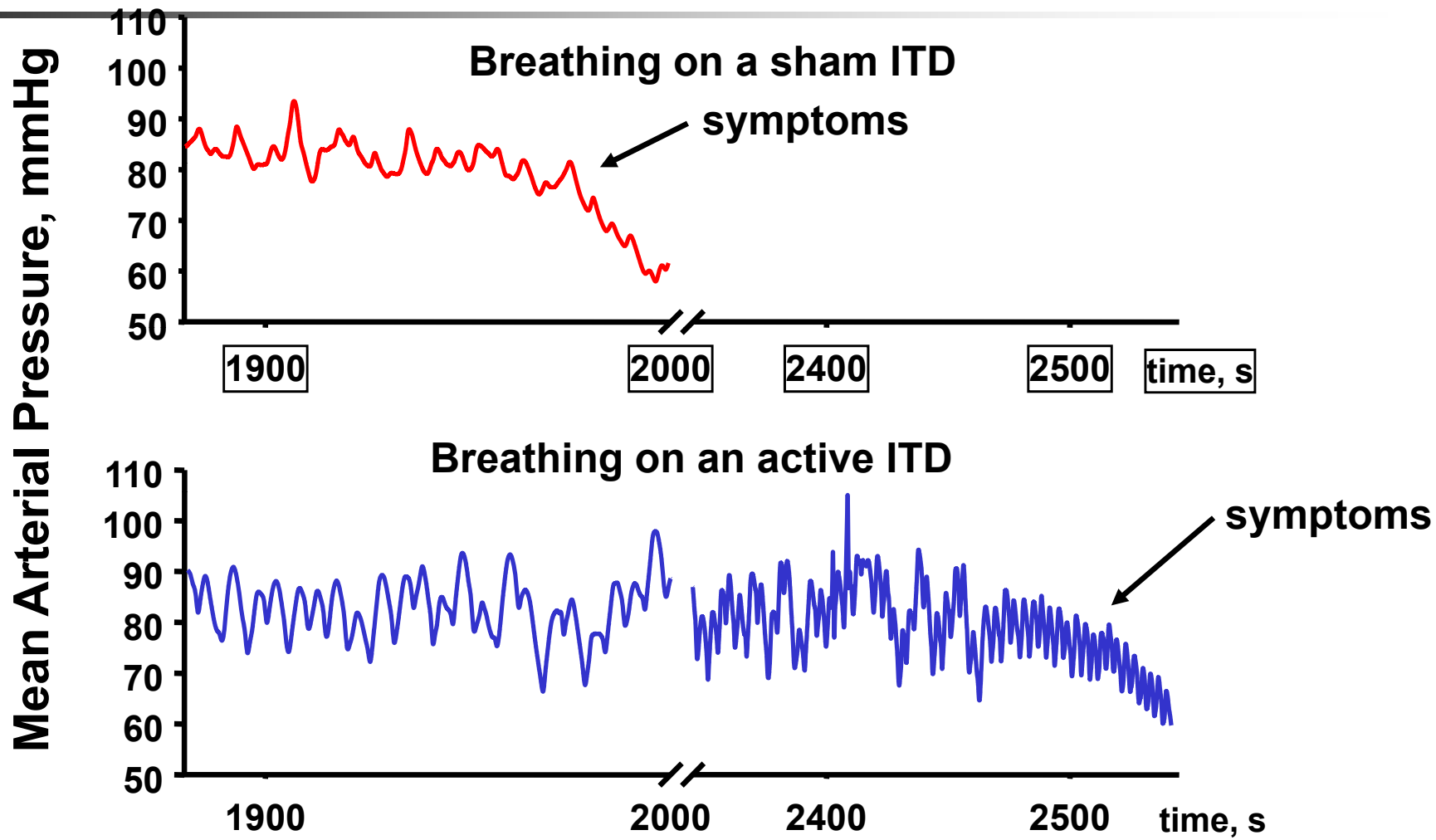
Model of Hemorrhage at USAISR

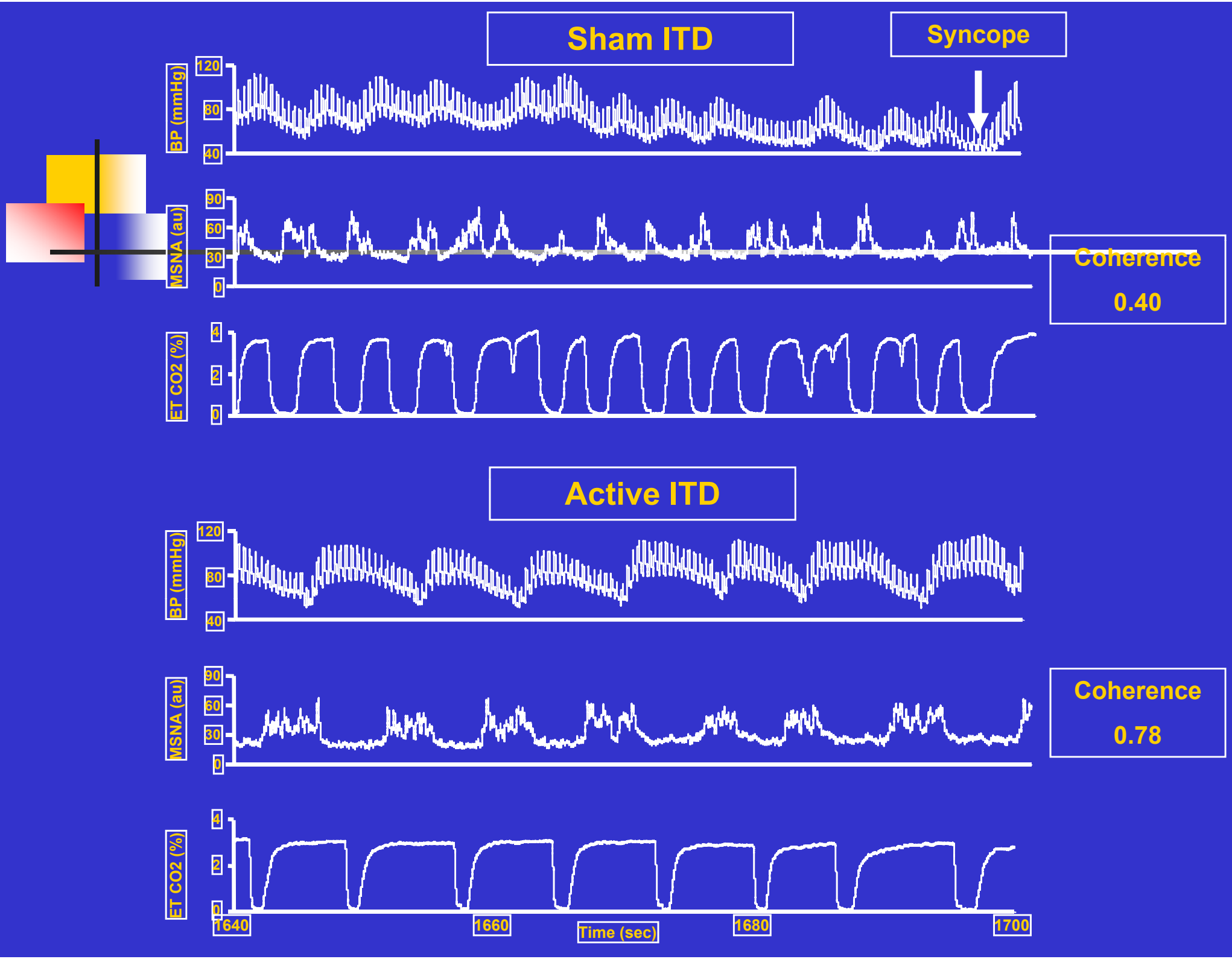


Convertino and Cook, 2005

Inspiratory resistance maintains arterial pressure during central hypovolemia: implications for treatment of patients with severe hemorrhage.

Convertino VA, Ryan KL, Rickards CA, Cooke WH, Idris AH, Metzger A, Holcomb JB, Adams BD, Lurie KG. *Crit Care Med* 2006




Sham ITD
Syncope
BP (mmHg)
120
80
40
MSNA (au)
90
60
30
0
Coherence
0.40
ET CO2 (%)
4
2
0
Active ITD
BP (mmHg)
120
80
40
MSNA (au)
90
60
30
0
Coherence
0.78
ET CO2 (%)
4
2
0
1640
1660
1680
1700
Time (sec)

Clinical Experience with Hypotensive Patients

- Blood Bank
- Orthostatic Hypotension
- Dialysis
- Emergency Room
- EMS
- NASA Astronauts

USE OF AN IMPEDANCE THRESHOLD DEVICE INCREASES BLOOD PRESSURE IN SPONTANEOUSLY BREATHING HYPOTENSIVE PATIENTS

David A Lindstrom, MD, FACEP

Medical Director, Lucas County (OH) EMS

Brent A. Parquette, NREMT-P

Lucas County EMS

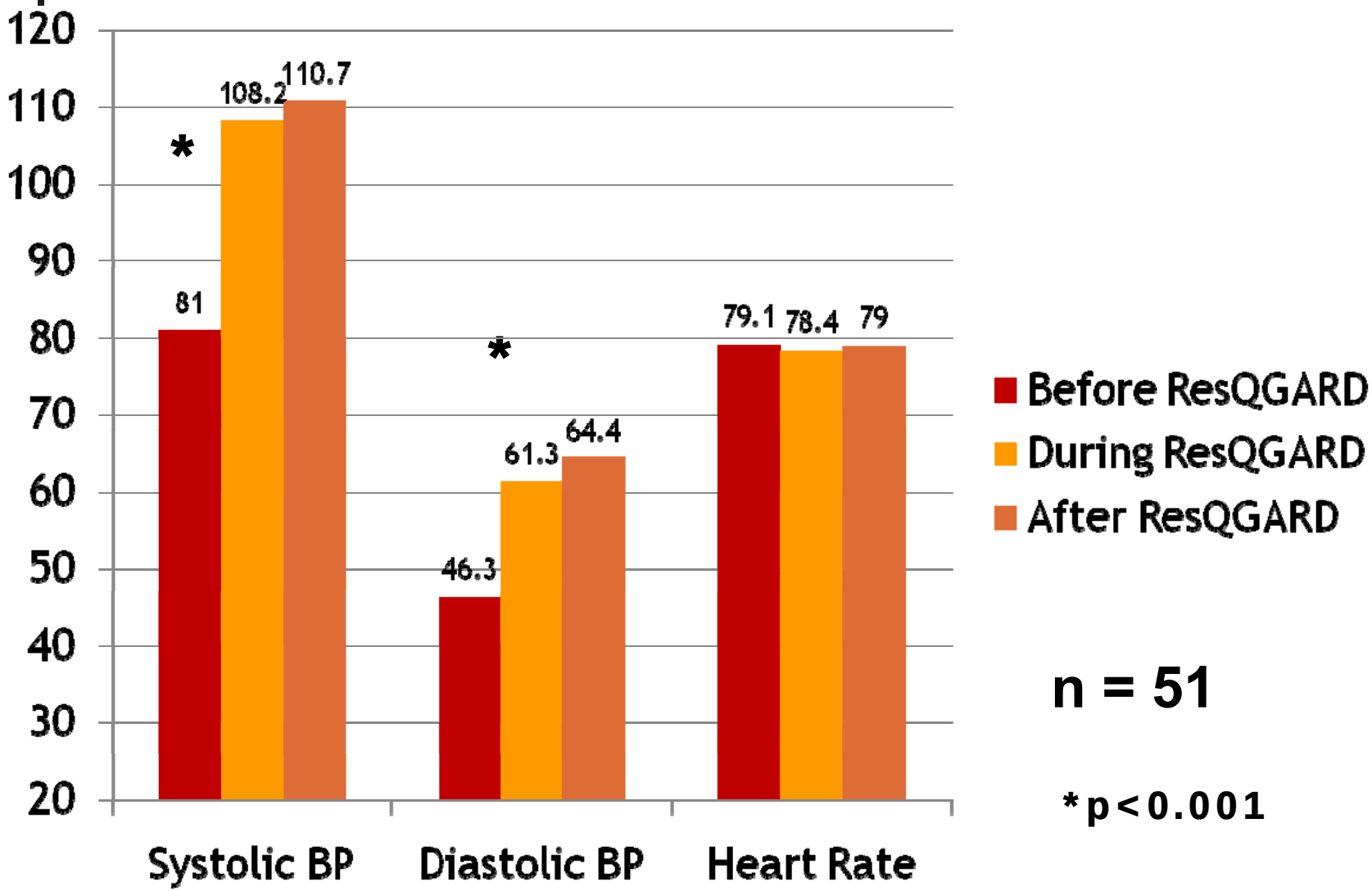
Results

- ITD applied to: 54 pts (24 males)
- Average age: 63 ± 19 yrs; range: 9 – 90 yrs
- Two pts did not tolerate ITD
  - One removed immediately; one wore for 8 min
- Concomitant IV fluids: 47/53 pts
- Vasopressors before/during ITD use: 2 pts
- Facemask used: 46 pts
- Mouthpiece used: 9 pts
- Average duration: 16.5 ± 7 min
- Subsequent results from 51 pts
  - 2 patients who rec'd meds removed from data set

Results - Etiologies

- 19 - Orthostatic intolerance/ syncope
- 9 – Unknown
- 3 – Possible dehydration
- 3 – Post dialysis hypotension
- 3 – Drugs or drug reaction
- 2 – R/O GI bleed
- 2 – R/O post-op bleeding
- 2 – Bleeding from wound
- 2 – Possible vasovagal
- 1 – Weakness/lethargy
- 1 – Post plasma donation
- 1 – R/O sepsis
- 1 – Post exercise
- 1 - Post seizure
- 1 – Abdominal/back pain

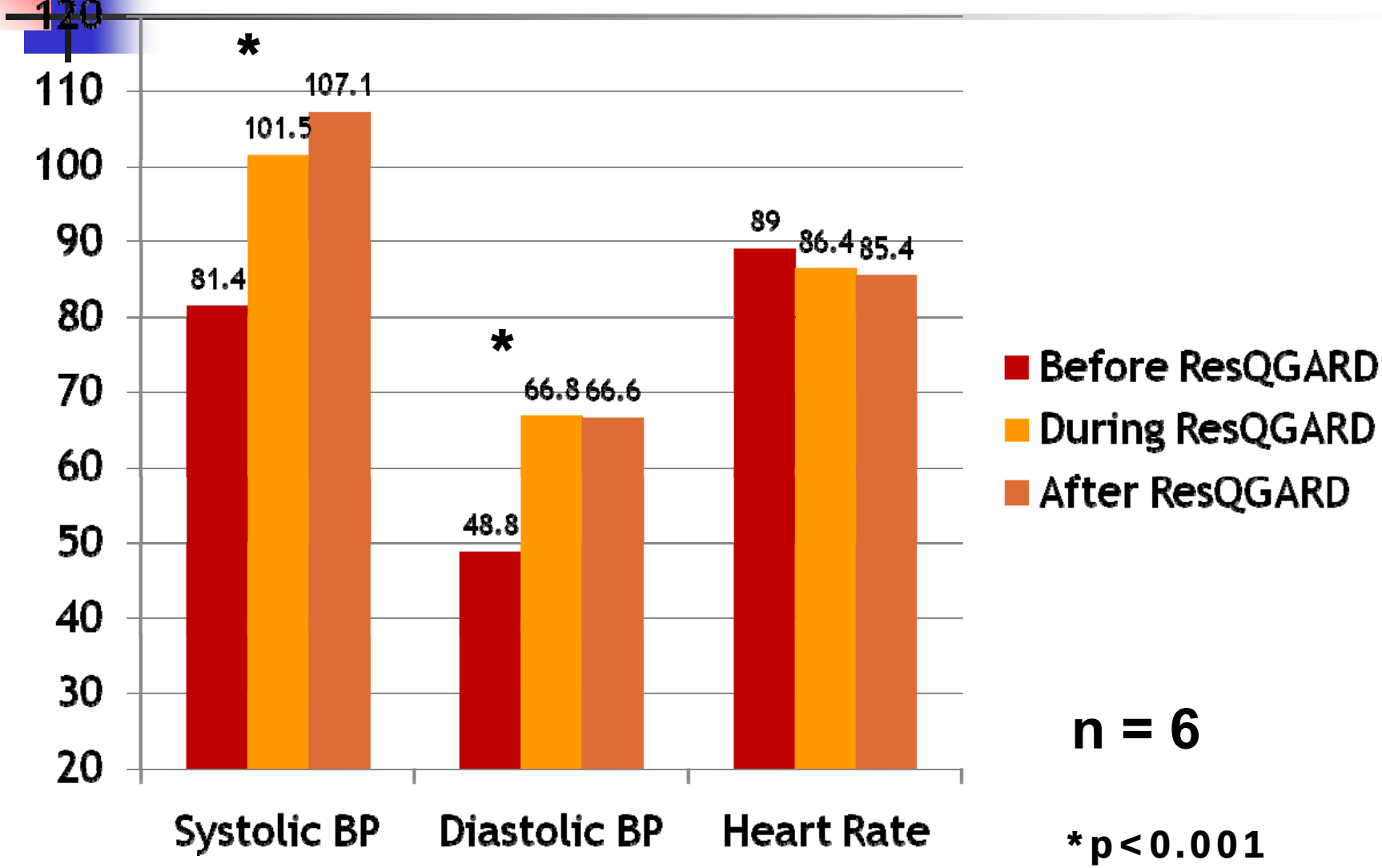
Results: All patients



n = 51

*$p < 0.001$

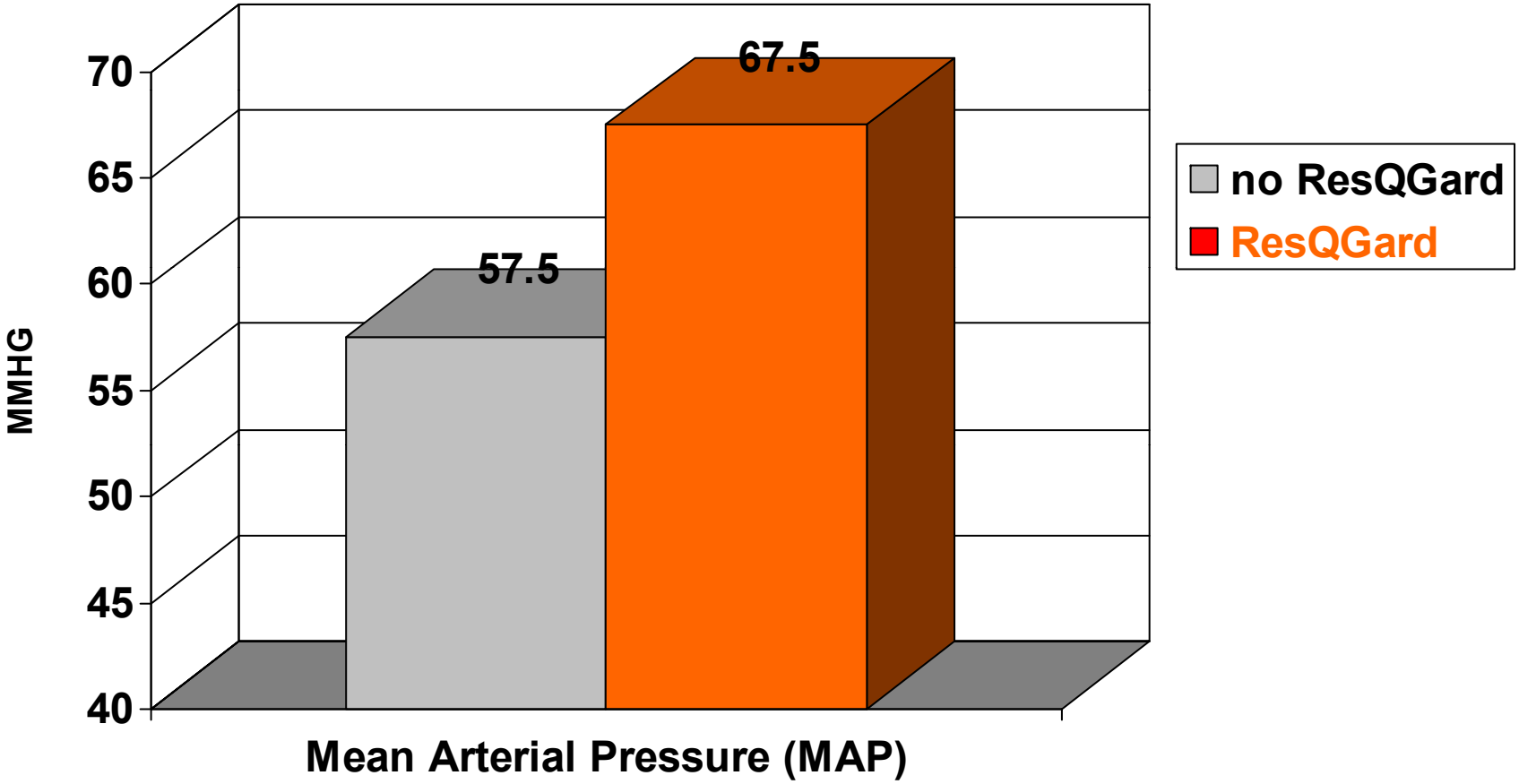
Results: Pts with No IV Fluids



n = 6

*p<0.001

ResQGard Benefit in Hypotensive Patients with No I.V.



N=10 pts (6 from Toledo, 4 from Minneapolis)

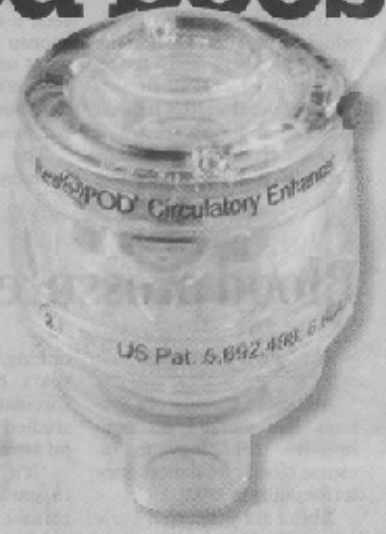
P<0.01

Summary (per Dr. Lindstrom)

- 1st reported use of ITD to treat hypotension in spontaneously breathing patients by EMS
- ITD was well-tolerated by most patients
- SBP rose by 34% in all patients
- SBP rose by 25% in patients not receiving IVs
- Therapy was safe, effective & clinically valuable
- Beneficial therapy for EMS:
  - Non-invasive and fast-acting
  - Could be administered by BLS
  - Great alternative therapy when starting IV is problematic (e.g. entrapment, during transport, poor veins, etc.)
- Beneficial therapy for military, especially in cases of controlled extremity bleeding, dehydration, heat shock and orthostatic intolerance/syncope

Brain-blood booster

The ResQPod helps to increase blood circulation, and it may be used on astronauts today after the Atlantis space shuttle lands. Low blood pressure is a common problem for astronauts after reentry.



The ResQPod is attached to a mouthpiece or face mask to create low chest-cavity pressure so the heart pumps more blood to the brain.

By BRADY AVERILL • baverill@startribune.com

WASHINGTON—A Minnesota-made device may help Minnesota astronaut Heide Stefanyshyn-Piper get back on her feet more easily today.

After the space shuttle Atlantis lands, physicians will have ready a device called the ResQPod, which increases blood flow to the heart and brain, if astronauts develop low blood pressure.

Low blood pressure is a common symptom when astronauts are reintroduced to gravity, according to Advanced Circulatory Systems Inc., maker of the device. They can become lightheaded; in the past, some have fainted.

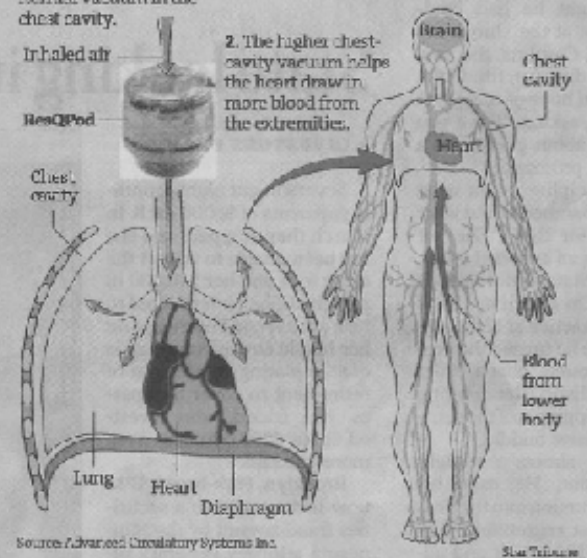
"We just think it would be a nice way for our company to contribute to this program, especially to help a native Minnesotan who is also an astronaut," said Dr. Keith Lurie, creator of the device used by NASA and chief medical officer of Eden Prairie-based Advanced Circulatory Systems.

A mouthpiece would be attached to the golf ball-sized device, into which astronauts can breathe for 30 to 60 seconds to boost blood circulation. The ResQPod typically is used during CPR in ambulances and emergency rooms, connected to a face mask or a breathing tube, said Lurie, who also is a University of Minnesota professor.

ResQPod continues: NASA studied the device for five years. **D2 ►**

MINNESOTA-MADE DEVICE HELPS NASA

The ResQPod device will be available to Atlantis space shuttle astronauts after reentry today. It's common for astronauts to develop low blood pressure when their bodies are reintroduced to gravity. The device helps increase blood flow quickly to the heart and brain.



Source: Advanced Circulatory Systems Inc. Star Tribune

Benefit of Modulating Intrathoracic Pressure during Respiration: Part of the Normal Physiological Response

Function of breathing prior to/during shock

1. Gas exchange
2. Heat exchange
3. Lowers intrathoracic pressure with resultant increased venous return and increased cardiac output
4. Maintains mean arterial pressure (MAP) during stress
5. Modulates autonomic nervous system regulation
6. Reduces intracranial pressure (ICP) and increases cerebral perfusion pressure gradient

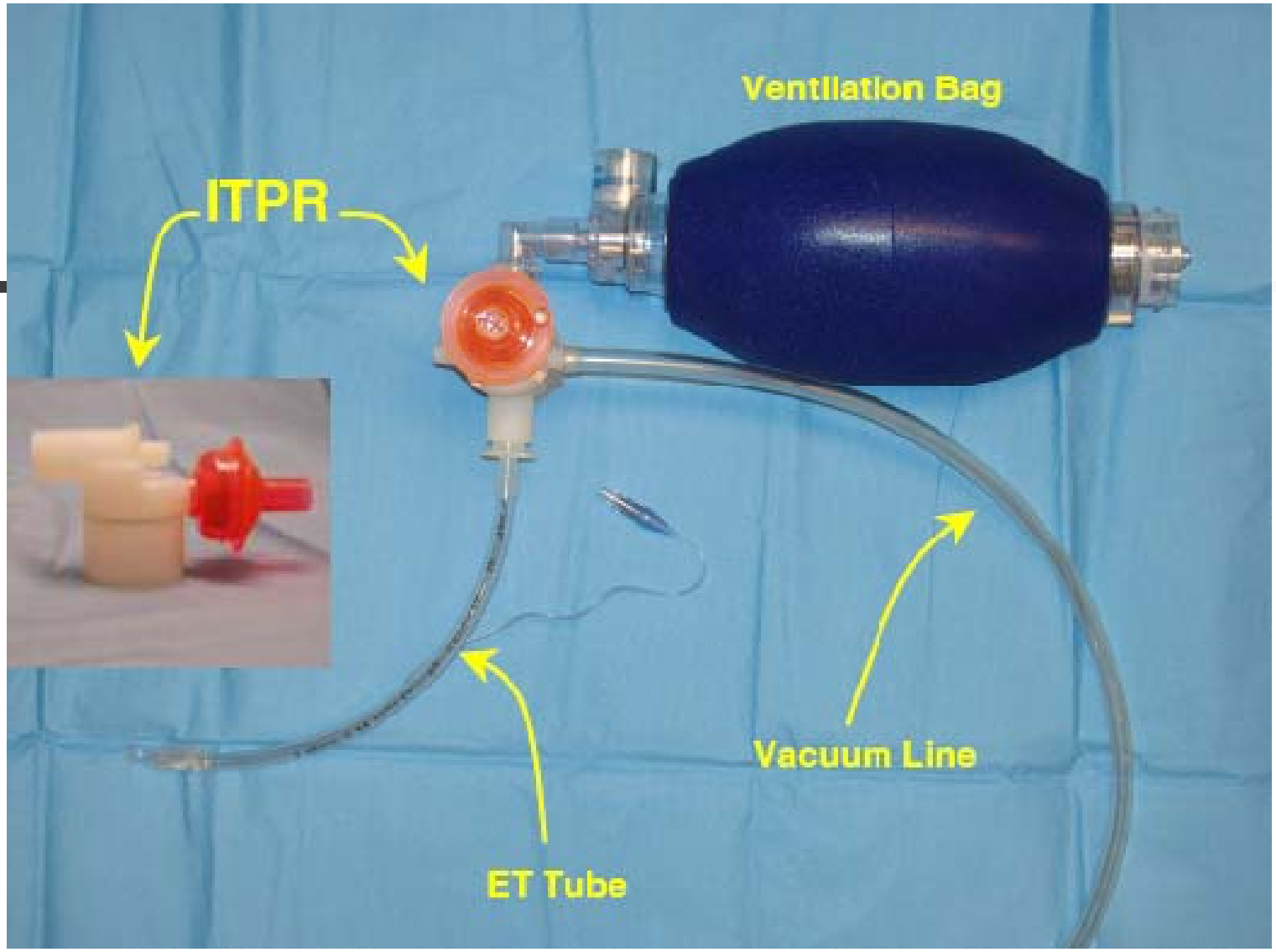
Next Steps

The ultimate technology will be able to optimize the thoracic pump mechanism by modulating intrathoracic pressure to treat intra-operative hypotension, cardiac arrest, sepsis, hemorrhagic shock and TBI

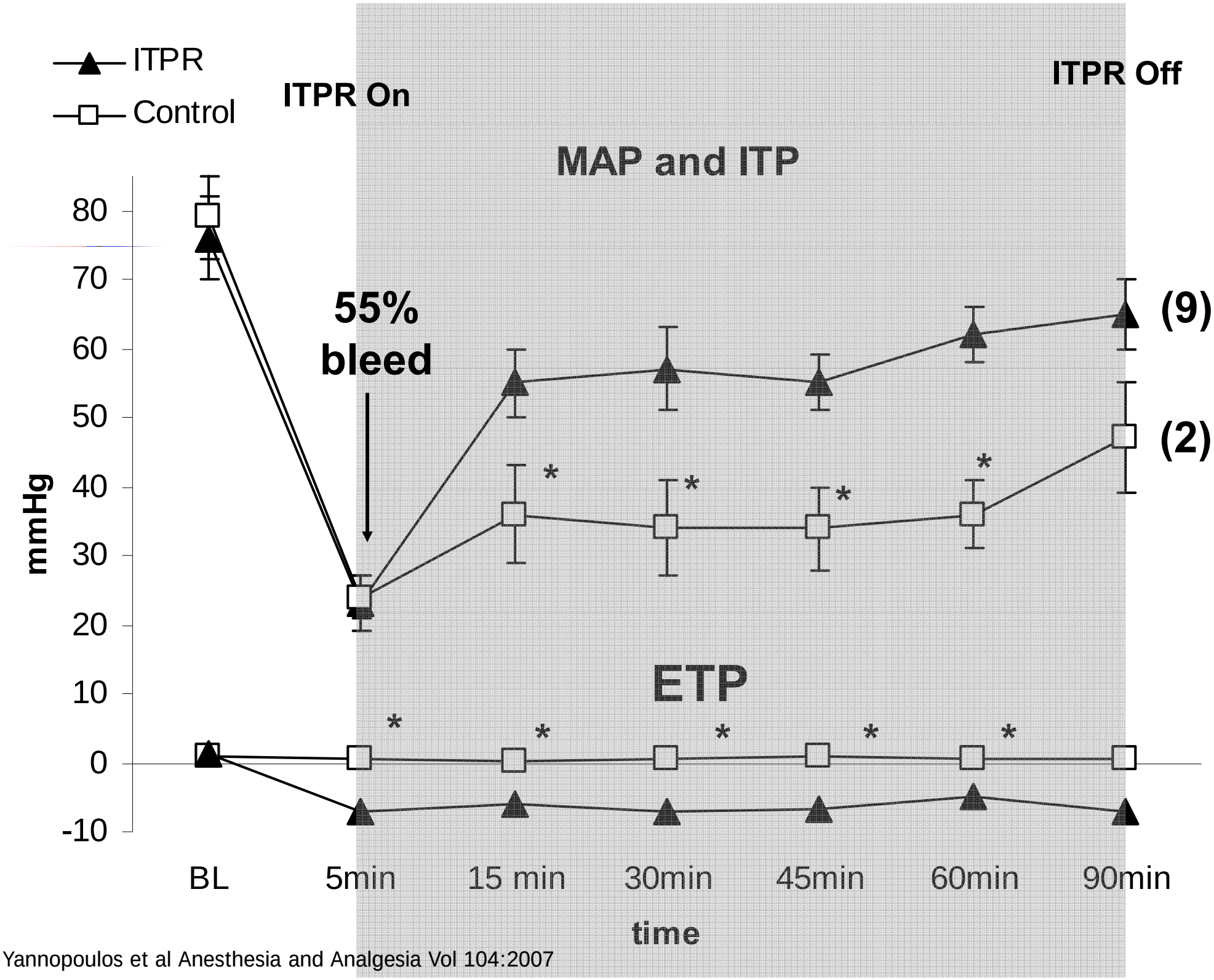
The Intrathoracic Pressure Regulation (IPR) The CirQLator™

Creating an intra-thoracic vacuum in the non-breathing patient will buy time

Intrathoracic Pressure Regulator (ITPR) Lowers Intrathoracic Pressures during Exhalation

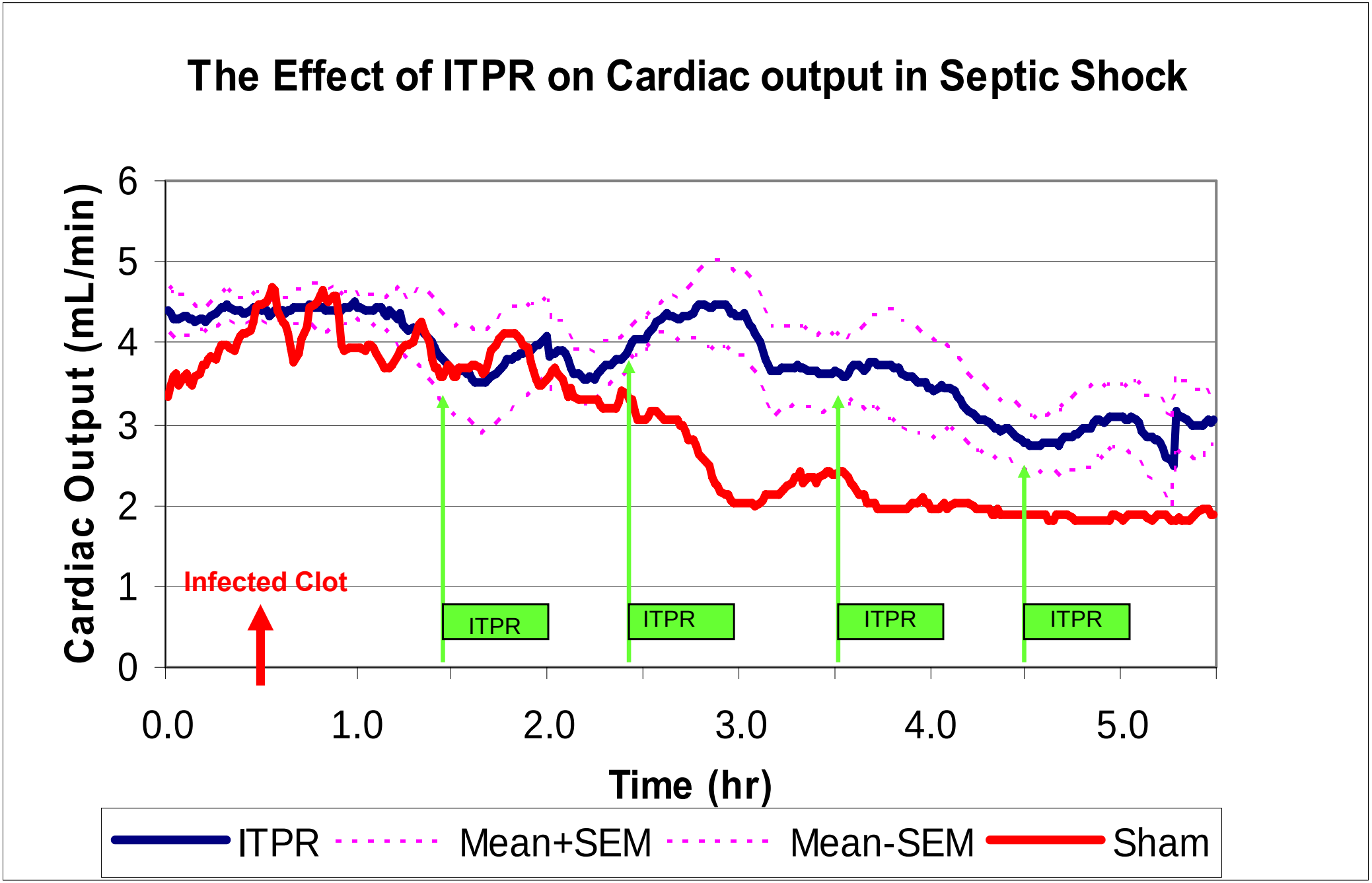


Use in Hemorrhagic Shock



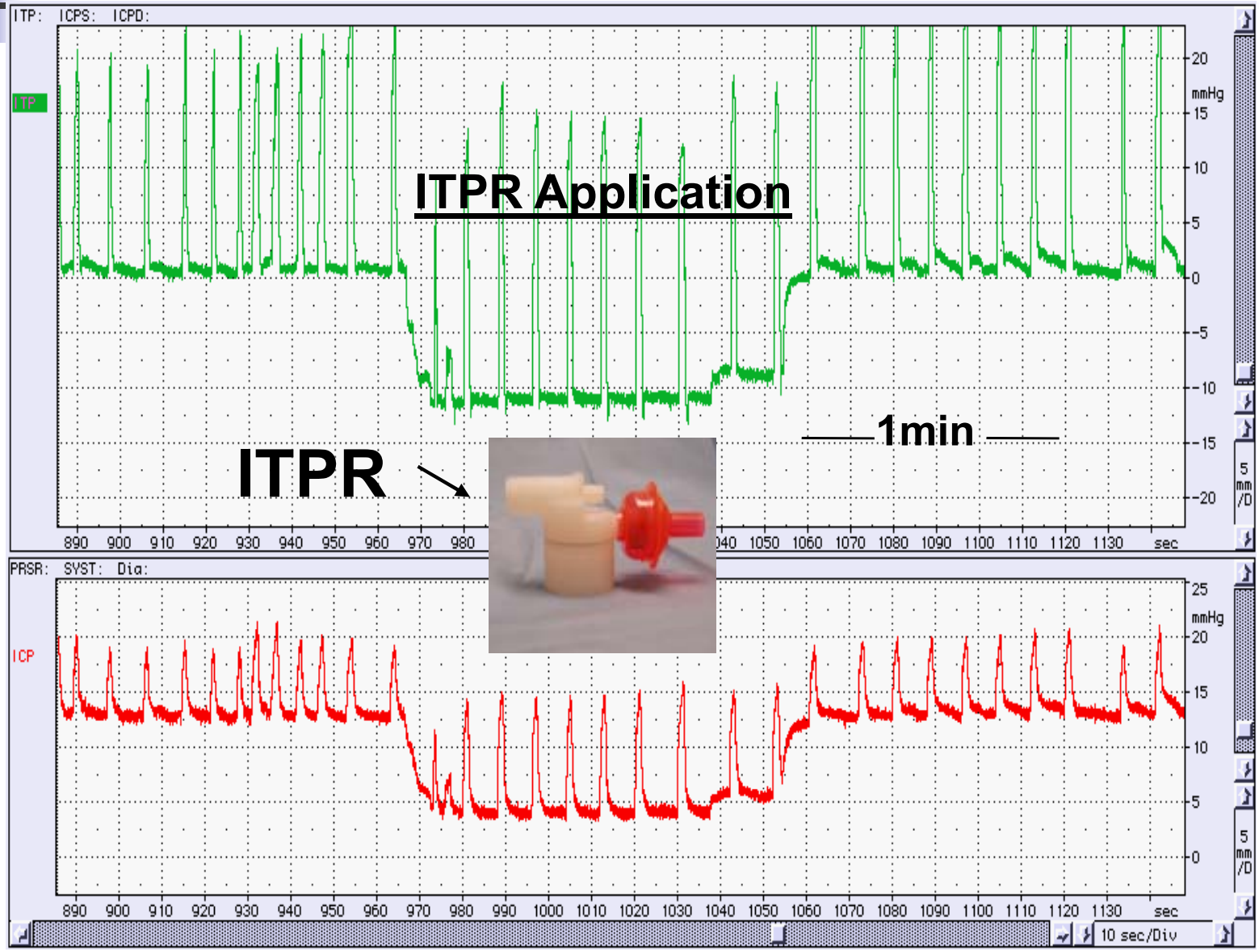
Yannopoulos et al Anesthesia and Analgesia Vol 104:2007

Use in Sepsis in Pigs



Cinel et al Critical Care Medicine Feb 2009

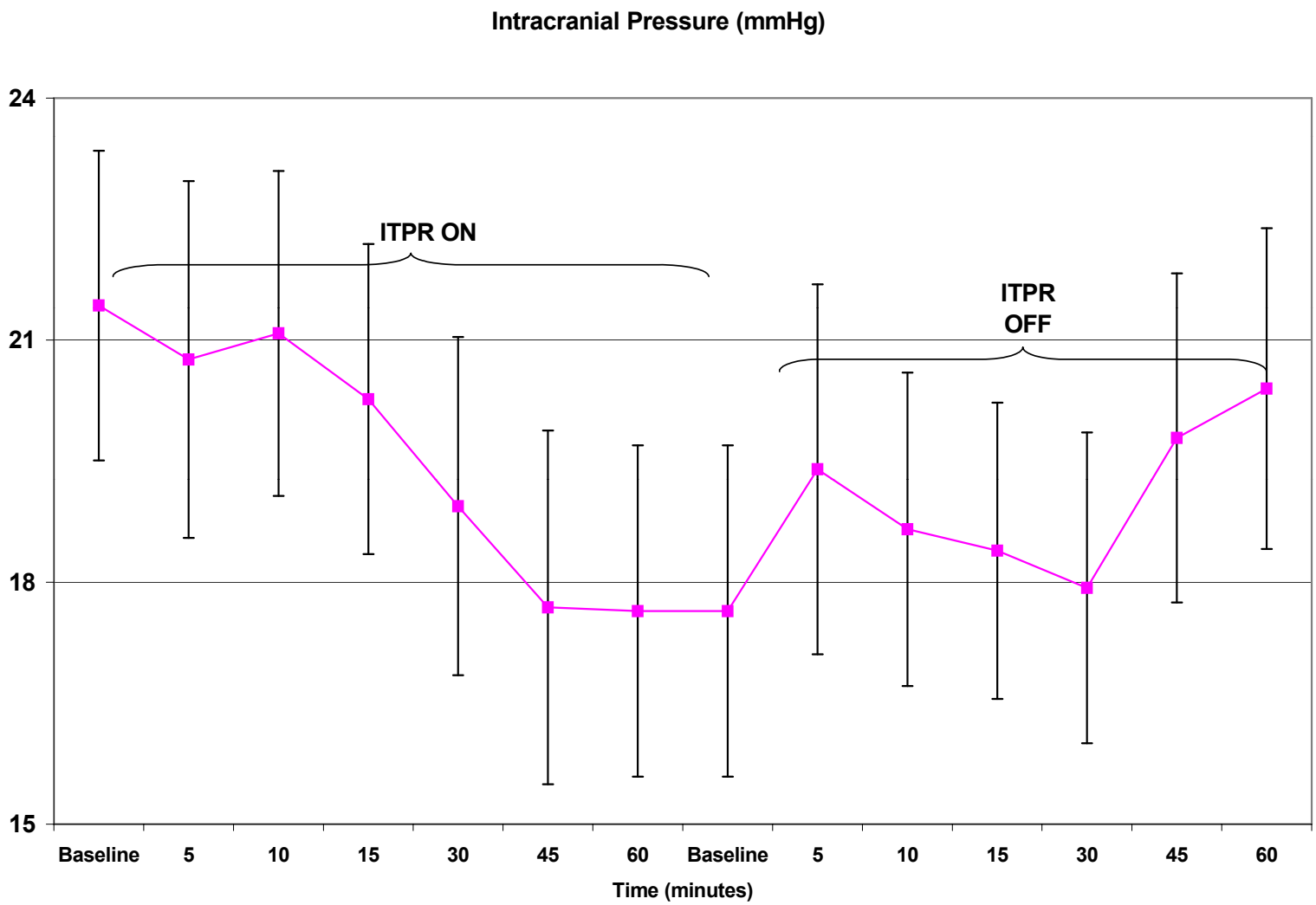
Effect of ITPR on Tracheal Pressure and ICP in Apneic Pigs



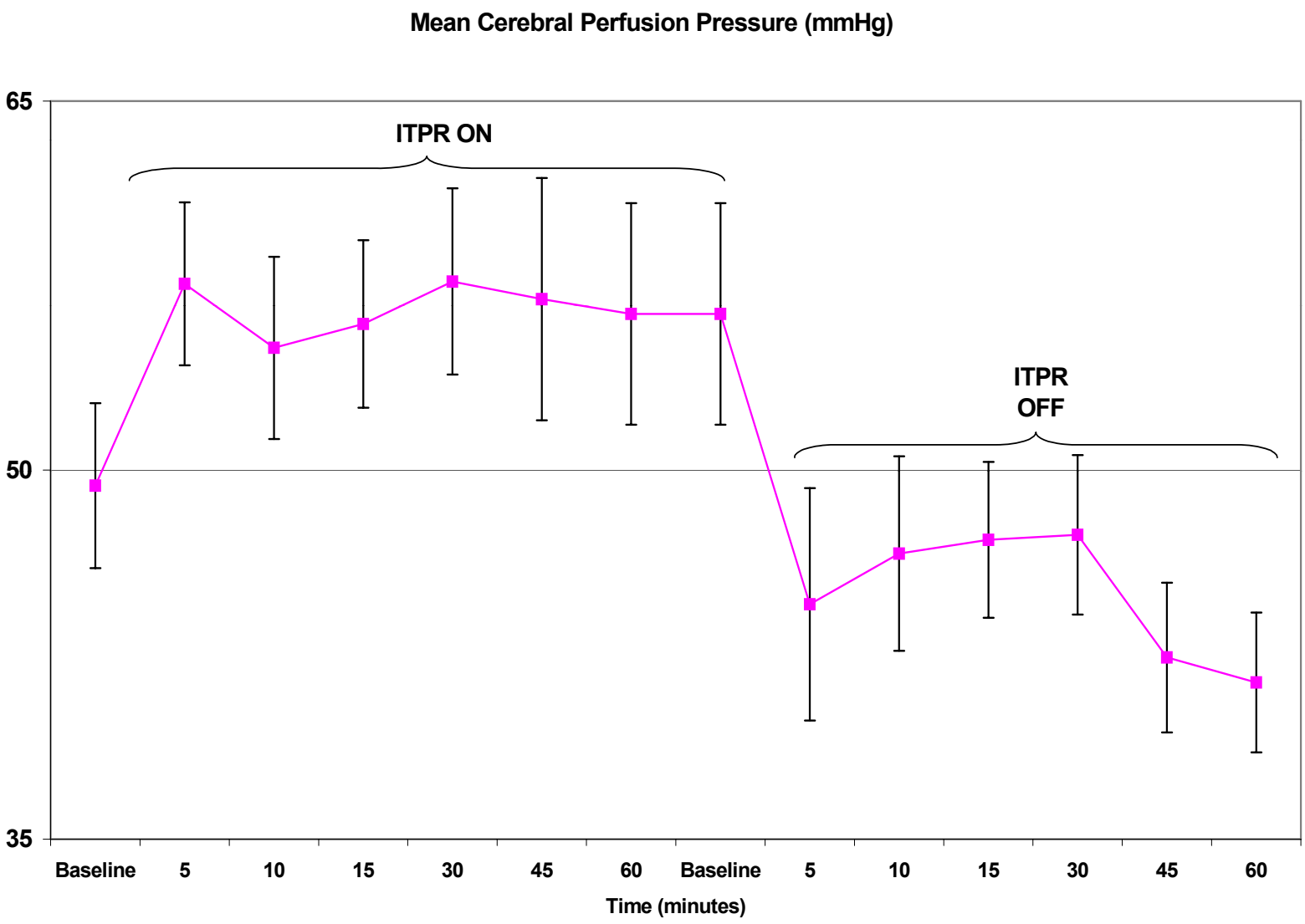
Use in TBI in Pigs

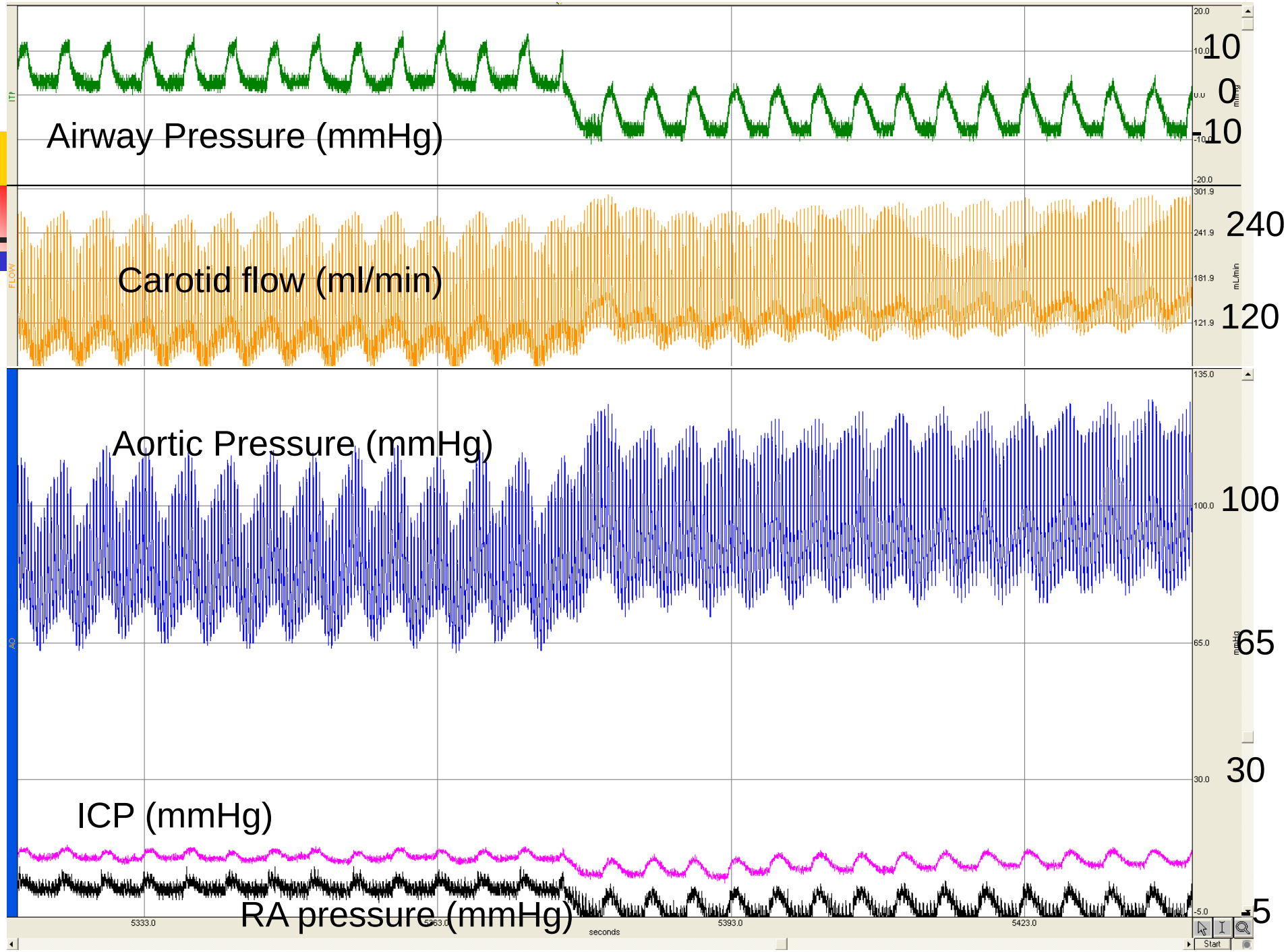
Mass Balloon Model
n=8
Inflated over 3 hours
Applied ITPR to 90 min then removed

Effect on ICP

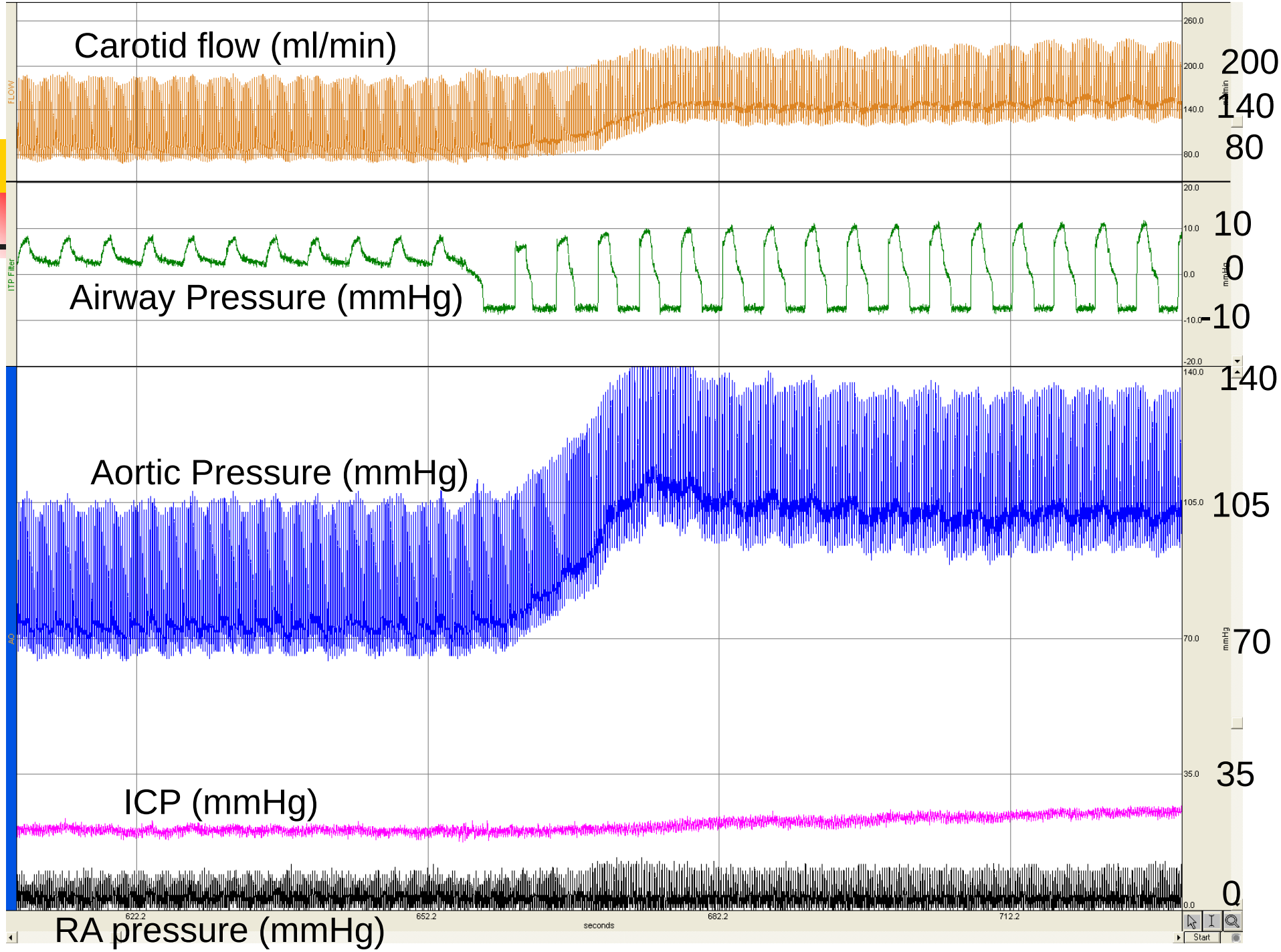


Effect on Cerebral Perfusion Pressure (Ao-ICP)





45% bleed, **Intact Thorax**, Addition of IPR



45% bleed, **Open Thorax**, Addition of IPR

Intrathoracic Pressure Regulator During Continuous-Chest-Compression Advanced Cardiac Resuscitation Improves Vital Organ Perfusion Pressures in a Porcine Model of Cardiac Arrest

Demetris Yannopoulos, MD; Vinay M. Nadkarni, MD;
Scott H. McKnite, BS; Anu Rao, MD; Kurt Kruger, BS; Anja Metzger, PhD;
David G. Benditt, MD; Keith G. Lurie, MD

Background—A novel device, the intrathoracic pressure regulator (ITPR), combines an inspiratory impedance threshold device (ITD) with a vacuum source for the generation of controlled −10 mm Hg vacuum in the trachea during cardiopulmonary resuscitation (CPR) while allowing positive pressure ventilation. Compared with standard (STD) CPR, ITPR-CPR will enhance venous return, systemic arterial pressure, and vital organ perfusion in both porcine models of ventricular fibrillation and hypovolemic cardiac arrest.

Methods and Results—In protocol 1, 20 pigs (weight, 30±0.5 kg) were randomized to STD-CPR or ITPR-CPR. After 8 minutes of untreated ventricular fibrillation, CPR was performed for 6 minutes at 100 compressions per minute and positive pressure ventilation (100% O_2) with a compression-to-ventilation ratio of 15:2. In protocol 2, 6 animals were bled 50% of their blood volume. After 4 minutes of untreated ventricular fibrillation, interventions were performed for 2 minutes with STD-CPR and 2 minutes of ITPR-CPR. This sequence was repeated. In protocol 3, 6 animals after 8 minutes of untreated VF were treated with ITPR-CPR for 15 minutes, and arterial and venous blood gases were collected at baseline and minutes 5, 10, and 15 of CPR. A newer, leak-proof ITPR device was used. Aortic, right atrial, endotracheal pressure, intracranial pressure, and end-tidal CO_2 values were measured (mm Hg); common carotid arterial flow also was measured (mL/min). Coronary perfusion pressure (diastolic; aortic minus right atrial pressure) and cerebral perfusion pressure (mean arterial minus mean intracranial pressure) were calculated. Unpaired Student *t* test and Friedman's repeated-measures ANOVA of ranks were used in protocols 1 and 3. A 2-tailed Wilcoxon signed-rank test was used for analysis in protocol 2. Fischer's exact test was used for survival. Significance was set at $P<0.05$. Vital organ perfusion pressures and end-tidal CO_2 were significantly improved with ITPR-CPR in both protocols. In protocol 1, 1-hour survival was 100% with ITPR-CPR and 10% with STD-CPR ($P=0.001$). Arterial blood pH was significantly lower and Pa_{CO_2} was significantly higher with ITPR- CPR in protocol 1. Arterial oxygen saturation was 100% throughout the study in both protocols. Pa_{CO_2} and Pa_{O_2} remained stable, but metabolic acidosis progressed, as expected, throughout the 15 minutes of CPR in protocol 3.

Conclusions—Compared with STD-CPR, use of ITPR-CPR improved hemodynamics and short-term survival rates after cardiac arrest. (*Circulation*. 2005;112:803-811.)

Key Words: cardiopulmonary resuscitation ■ cerebrovascular circulation ■ circulation ■ perfusion ■ resuscitation

Circulation

Clinical Experience – U of MN

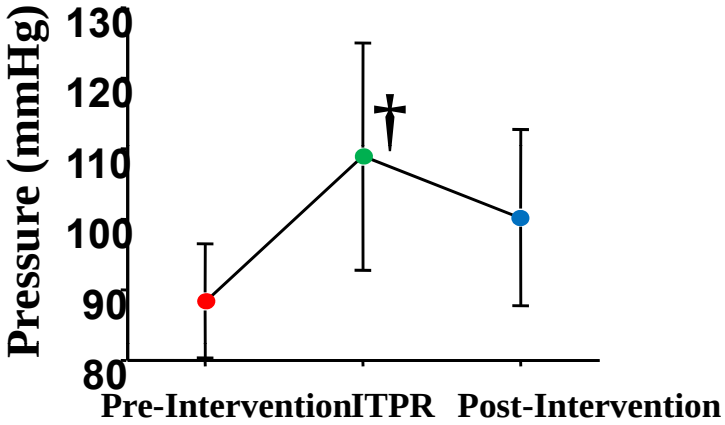
Treatment of Intra-operative Hypotension during Abdominal Surgery

First experience with 6 cases

Increase is SBP within 5 minutes

Systolic Pressure

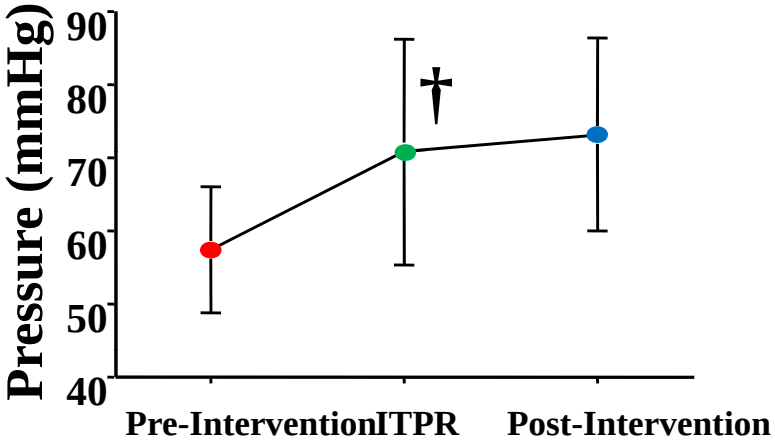
(Mean ± SD)



† p = 0.03
(Pre vs. During)

Diastolic Pressure

(Mean ± SD)



† p = 0.05
(Pre vs. Post)

Clinical Experience – U of Va

Patients undergoing CABG

First 5 patients

Increase in C.O. by 1L/min within 3 min

Thank you

Questions?