The Michigan Trauma Quality Improvement Program

Ypsilanti, MI
February 13, 2018

Disclosures

- Salary Support for MTQIP from BCBSM/BCN
  - Mark Hemmila
  - Judy Mikhail
  - Jill Jakubus
  - Anne Cain-Nielsen

Evaluations

- Link will be emailed to you following meeting
- You have up to 7 days to submit
- Please answer the evaluation questions
- Physicians/Nurses/Advanced Practitioners:
  - E-mail certificate for 4.0 Category 1 CME

Introductions

- Bryant W. Oliphant, MD MBA
  - Clinical Assistant Professor, Michigan Medicine
  - Orthopedic Trauma Surgery

Introductions

- Todd E. Rasmussen, MD
  - Colonel, United State Air Force
  - Walter Reed National Military Medical Center, Bethesda Maryland
  - Harris B Shumacker Jr, Professor of Surgery at the Uniformed Services University

Introductions

- Lena M. Napolitano, MD
  - Massey Foundation Professor of Surgery, Michigan Medicine
- Jonathan L. Eliason, MD
  - S. Martin Lindenauer Collegiate Professor of
  - Veteran USAF
- Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS)

New MTQIP Trauma Centers

- Beaumont Troy
  - Kerry Kole, DO, TMD
  - Kayela Voss, TPM
- Henry Ford Allegiance
  - Lawrence Narkiewicz, MD, TMD
  - Madonna Walters, TPM
- Mercy Health Muskegon
  - Gregory Myers, MD, TMD
  - Heather Ruffin, TPM

Data Submission

- Data submitted February 2, 2018
  - Every 2 months
  - 3 week turnaround
- Additional NTDS data elements
- Level 3 trauma centers
  - CDM, Imagetrend
  - Assistance
- Next data submission
  - April 6, 2018

Future Meetings

- Spring (MCOT)
  - Wednesday May 16, 2018
  - Traverse City, Grand Traverse Resort
- Spring (Registrars and MCR's)
  - Tuesday June 5, 2018
  - Ann Arbor, Holiday Inn Ann Arbor

MTQIP/MANS Neurosurgery Meeting

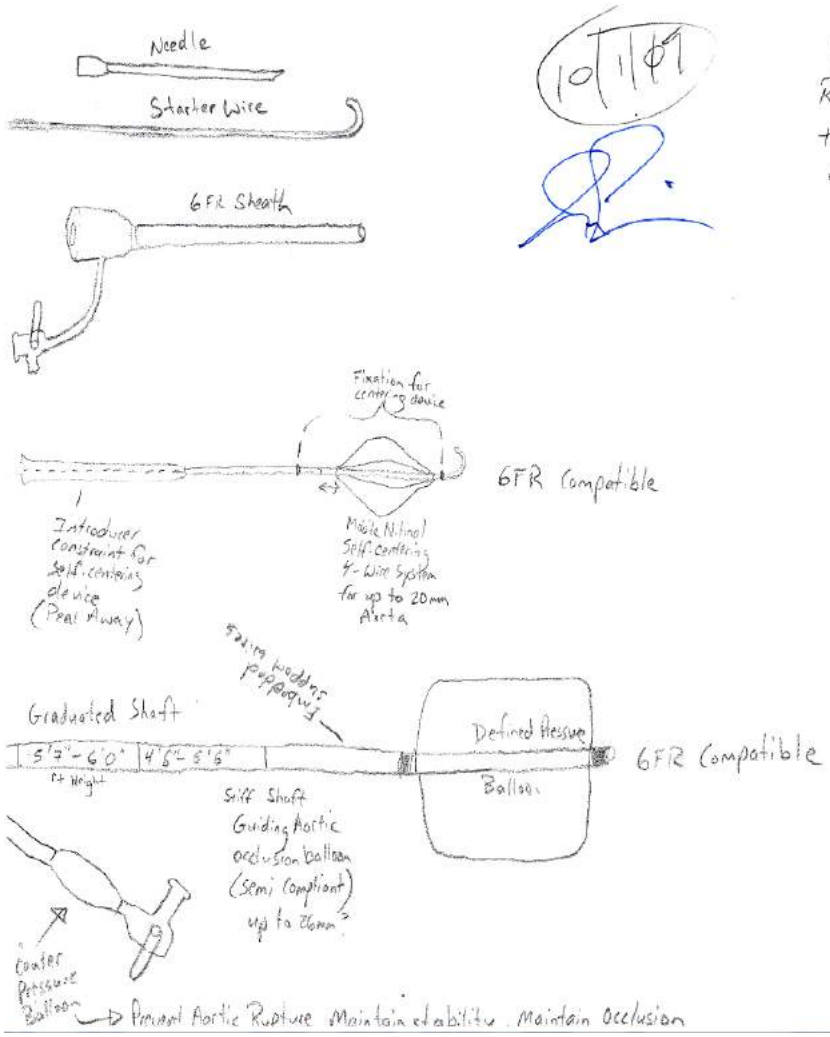
- Spring 2018
  - Friday June 8, 2018
  - Crystal Mountain, MI
  - 12n to 4:30p
- Suggestions
  - Topics
  - Planning

MTQIP/Orthopedic Surgery Meeting

- Fall 2018
  - Thursday October 11, 2018
  - Ypsilanti, EMU Marriott
  - 10a to 3p
- Suggestions
  - Topics
  - Planning

Complex Pelvic Fractures

Bryant W. Oliphant, MD



10/1/09

10/1/09

Prelim. Drawings

Rapidly Deployable

thoracic Aortic

occlusion balloon

HEALTH

Inspired by War Zones, Balloon Device May Save Civilians From Fatal Blood Loss

By DENISE GRADY JUNE 19, 2007

Nanetta Hall, who had been run over by a pickup truck, was the first patient in the city to be treated with the ER-Rebec. Sue Ogrocki for The New York Times

REBOA

Todd E. Rasmussen, MD

Development & Implantation of REBOA within the Military Learning Health System

February 8th, 2018

Todd E. Rasmussen, MD, FACS
Colonel, USAF MC
Associate Dean for Research
Shumacker Professor of Surgery
F. Edward Hébert School of Medicine at the Uniformed Services University, Bethesda, MD

Disclosures

- **Viewpoints are those of the presenter and are not official positions of the DoD or the US Government**

- **Co-inventor of REBOA & vascular shunt technologies, the patents for which are assigned to the US government and the University of Michigan**

- **No consulting, travel, advisory board, or speakers fees, and no stocks or other forms of equity in, or royalties from, any industry entity (past or present)**

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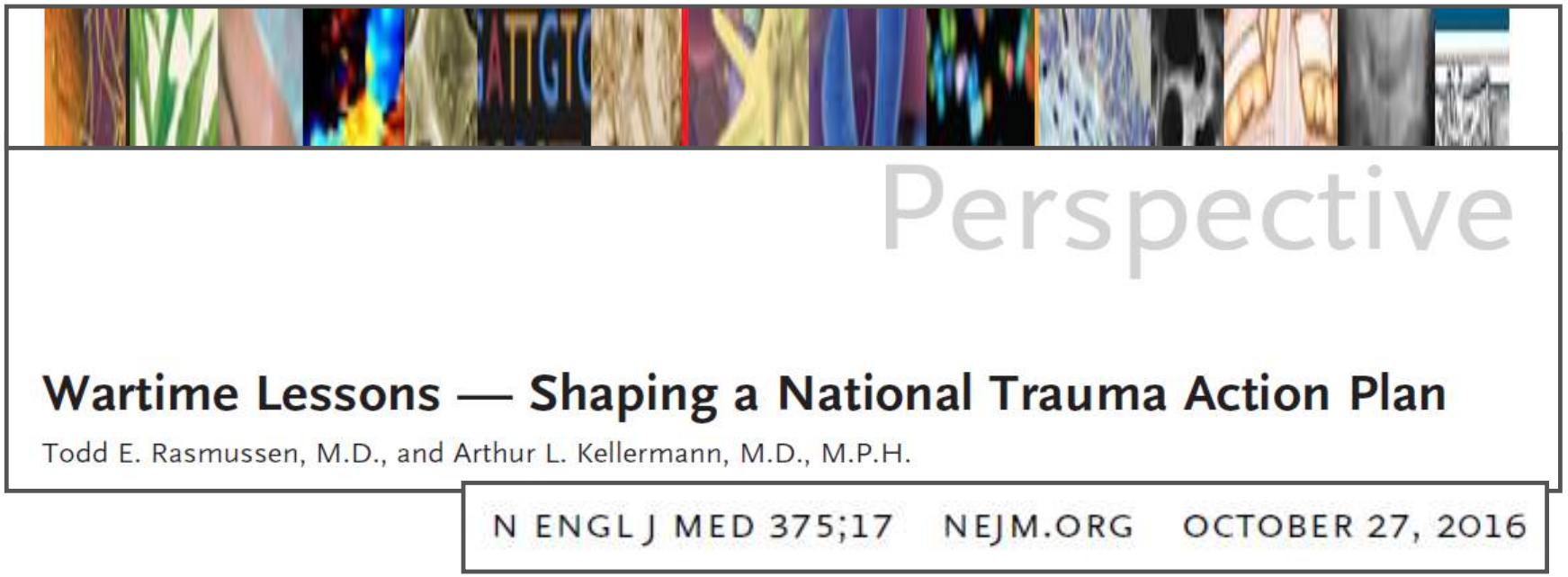
Military-Civilian Partnership to Tackle Challenge



- **In many ways Michigan TQIP and other statewide efforts to have a trauma system (data gathering, guideline-based delivery of care, coordination of care & common training and PI venues) represents a model for the nation as it considers a National Trauma System**

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Reset on REBOA Innovation Effort

CURRENT OPINION

Military-civilian partnership in device innovation: Development, commercialization and application of resuscitative endovascular balloon occlusion of the aorta

Todd E. Rasmussen, MD *and* **Jonathan L. Eliason, MD**, *Bethesda, Maryland*

***J Trauma & Acute Care Surg* 2017;83(4):729-32**

- **Eight factors contributing to origins, development and commercialization of REBOA and ER-REBOA™ catheter (enablers & barriers)**
- **Call for informed and balanced discussion and assessment of device utility (real-world use registries, PI venues, multi-center studies)**

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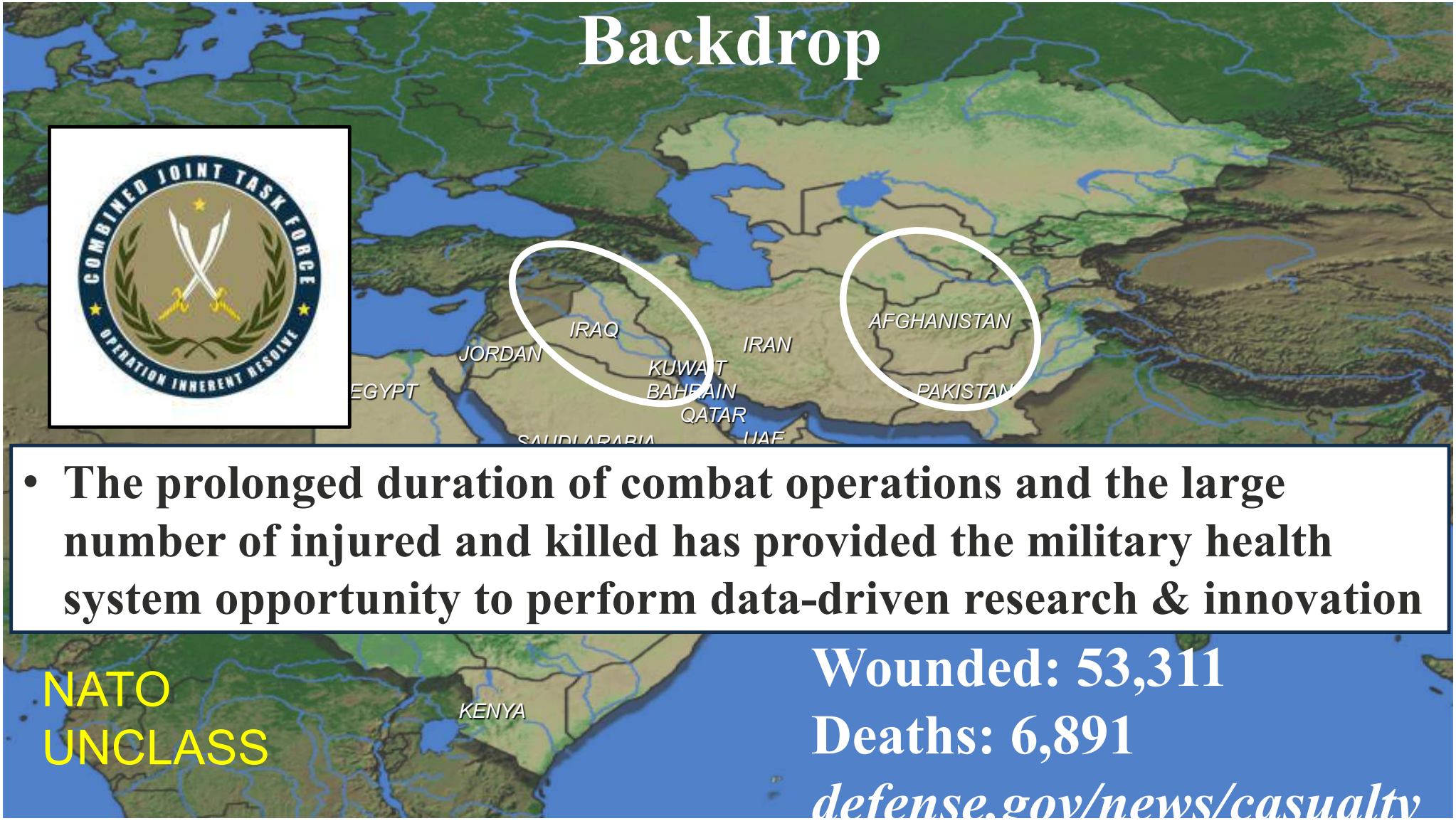
Backdrop



- **The prolonged duration of combat operations and the large number of injured and killed has provided the military health system opportunity to perform data-driven research & innovation**

NATO
UNCLASS

Wounded: 53,311
Deaths: 6,891
defense.gov/news/casualty

Wilford Hall USAF Medical Center

Fall of 2004

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Data Informing Research & Development

Causes of Death in U.S. Special Operations Forces in the Global War on Terrorism

2001–2004

John B. Holcomb, MD, Neil R. McMullin, MD,* Lisa Pearse, MD,† Jim Caruso, MD,†*
Charles E. Wade, PhD, Lynne Oetjen-Gerdes, MA,† Howard R. Champion, FRCS,‡*
Mimi Lawnick, RN, Warner Farr, MD,§ Sam Rodriguez, BS,§ and Frank K. Butler, MD‖*

***Annals of Surgery* 2007;245:986-91**

"…majority of deaths on battlefield are non-survivable. Improved methods of intracavitary, noncompressible hemostasis may increase survival.."

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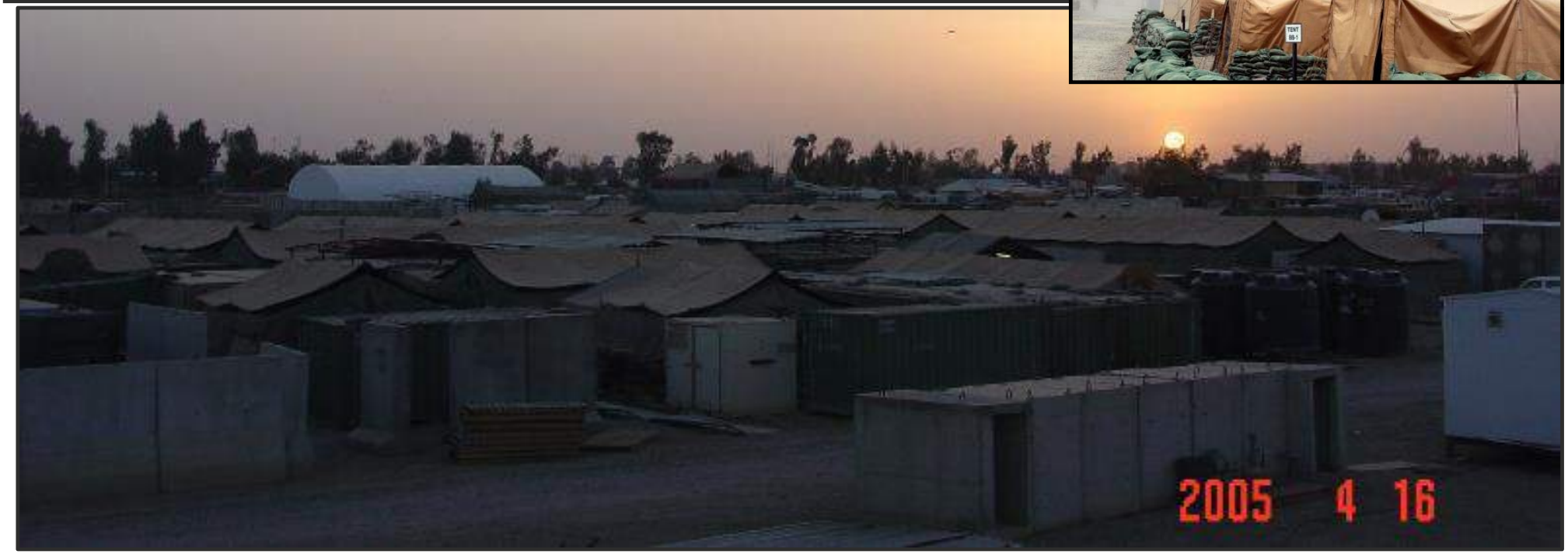
Teams of Military Clinicians & Innovators

Development and Implementation of Endovascular Capabilities in Wartime

Lt. Col. Todd E. Rasmussen, MD, Lt. Col. W. Darrin Clouse, MD, Maj. Michael A. Peck, MD, Lt. Col. Andrew N. Bowser, MD, Maj. Jonathan L. Eliason, MD, Maj. Mitchell W. Cox, MD, Maj. E. Baylor Woodward, MD, Lt. Col. W. Tracey Jones, MD, and Col. Donald H. Jenkins, MD



Development & Implementation of Endovascular

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Data Continued to Inform Research & Innovation

Injury Severity and Causes of Death From Operation Iraqi Freedom and Operation Enduring Freedom: 2003–2004 Versus 2006

Joseph F. Kelly, MD, Amber E. Ritenour, MD, Daniel F. McLaughlin, MD, Karen A. Bagg, MS, Amy N. Apodaca, MS, Craig T. Mallak, MD, Lisa Pearse, MD, Mary M. Lawnick, RN, BSN, Howard R. Champion, MD, Charles E. Wade, PhD, and COL John B. Holcomb, MC

***Journal of Trauma* 2008;64:S21-S27**

Extremity and compressible hemorrhage (axilla, neck, or groin) are two of the three types of hemorrhage evaluated. Controlling these types of hemorrhages is addressed by effective commercial tourniquets and topical hemostatic agents like the widely available hemostatic dressings.[4,24] Continued training and use with these products is warranted. The third type of hemorrhage, and the most challenging type in our study, was noncompressible or torso hemorrhage. There needs to be continued research and clinical practice focusing on intravenous hemostatic adjuncts and damage control resuscitation.[2]

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REBOA is a Data-Driven R&D Effort

ORIGINAL ARTICLE

Death on the battlefield (2001–2011): Implications for the future of combat casualty care

Brian J. Eastridge, MD, Robert L. Mabry, MD, Peter Seguin, MD, Joyce Cantrell, MD, Terrill Tops, MD, Paul Uribe, MD, Olga Mallett, Tamara Zubko, Lynne Oetjen-Gerdes, Todd E. Rasmussen, MD, Frank K. Butler, MD, Russell S. Kotwal, MD, John B. Holcomb, MD, Charles Wade, PhD, Howard Champion, MD, Mimi Lawnick, Leon Moores, MD, *and* Lorne H. Blackbourne, MD

J Trauma Acute Care Surg **2012;73(Suppl1):S431-S437**

- **Of 4,596 wartime casualties, 87% were pre-hospital; of those, 76% non-survivable but 24% (N=976) were potentially survivable - what would you have the military do??**

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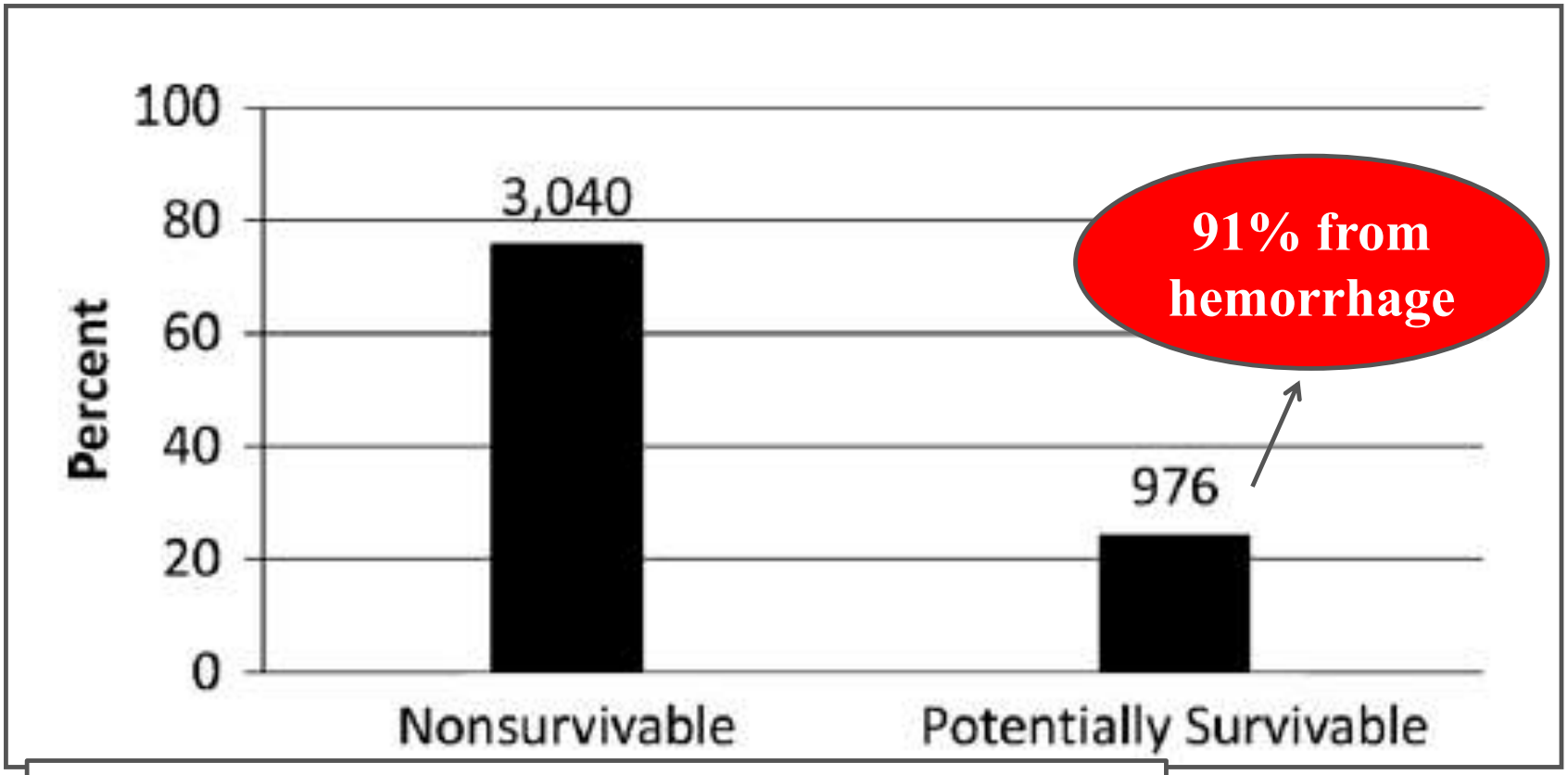
Data Informing Research & Development



J Trauma Acute Care Surg 2012;73(Suppl1):S431-S437

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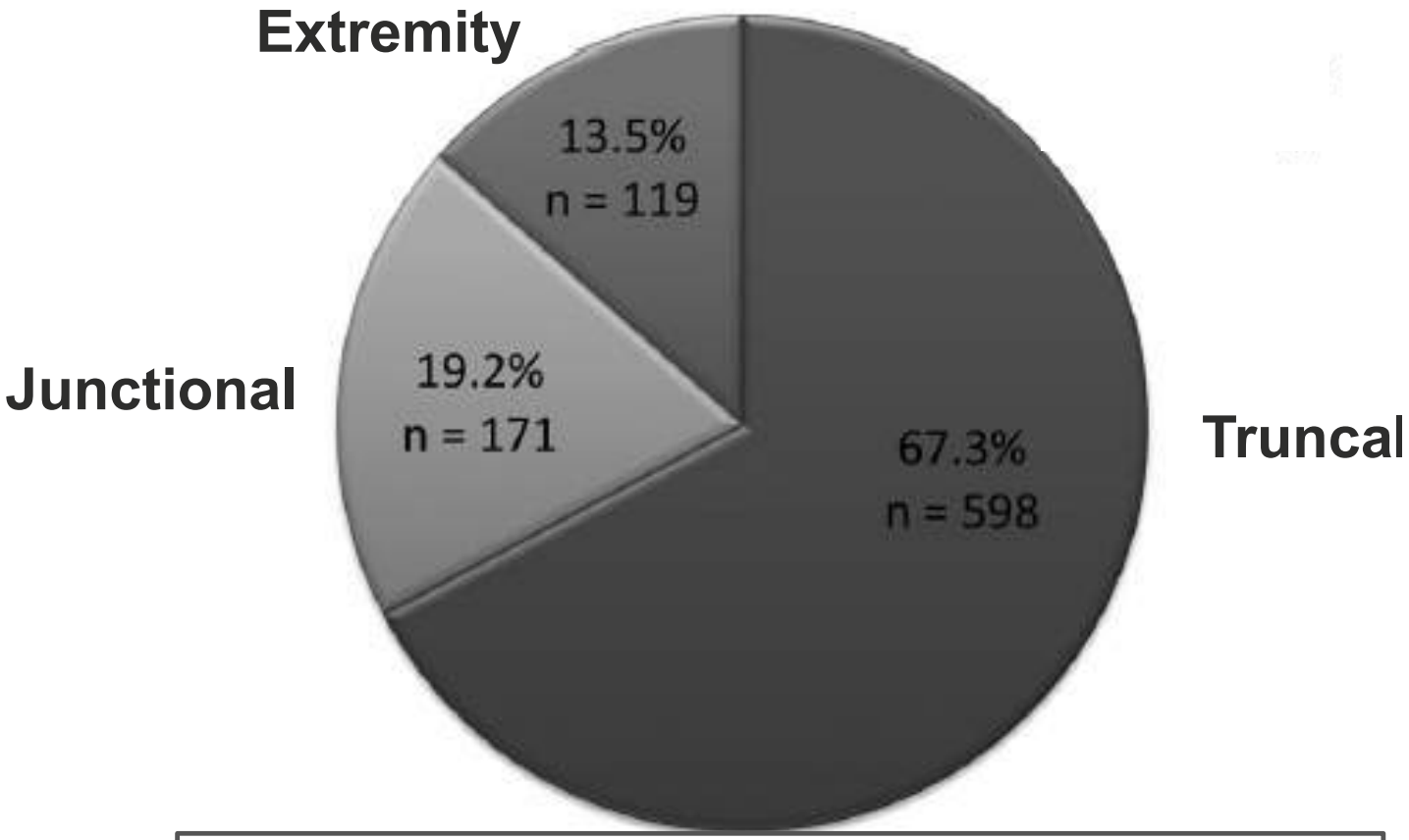
Data Informing Research & Development



J Trauma Acute Care Surg 2012;73(Suppl1):S431-S437

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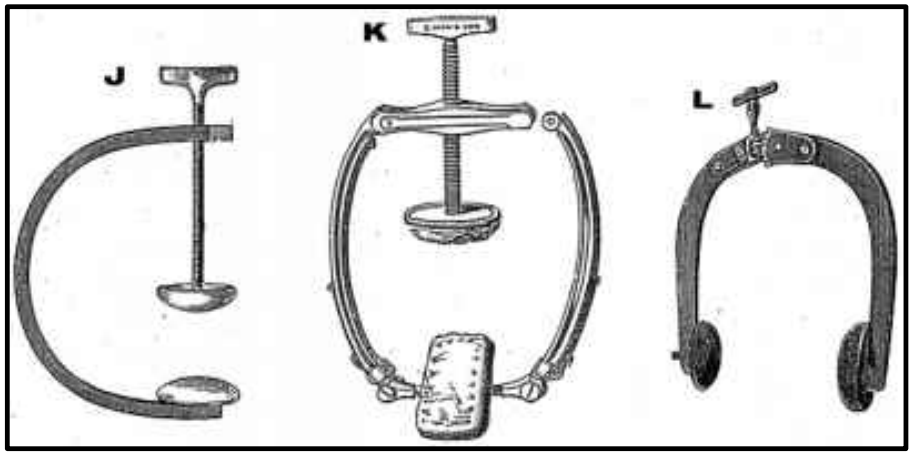
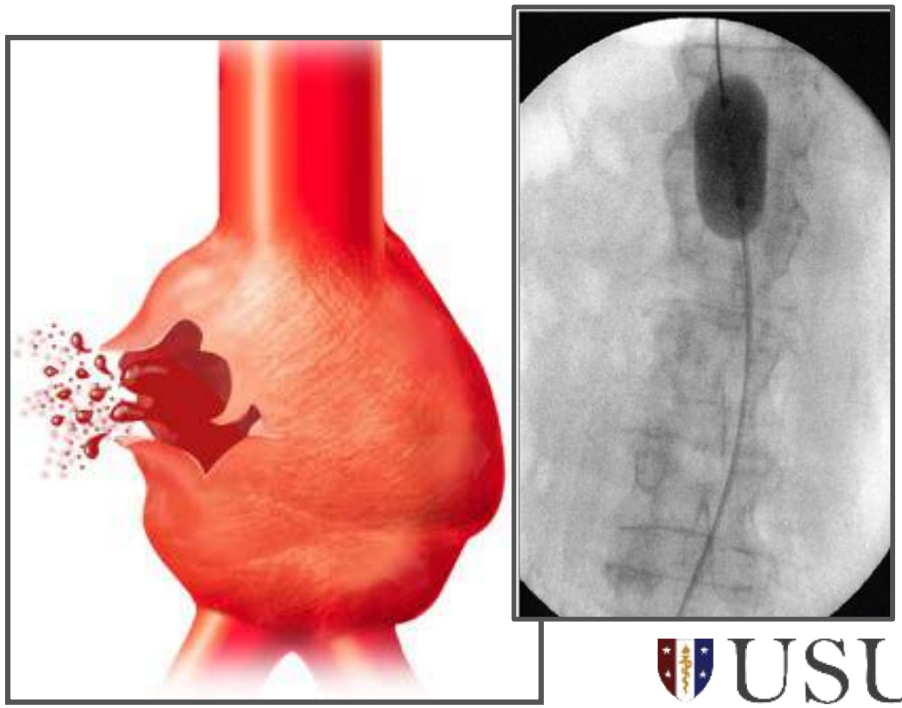
Different Innovation Paths for Bleeding & Shock

- A large portion of traditional surgical & medic communities pursued animal models of hemorrhage, topical hemostatics and variations of the Lister tourniquet



- Others recognized ruptured AAA as a good model & pursued endovascular innovation



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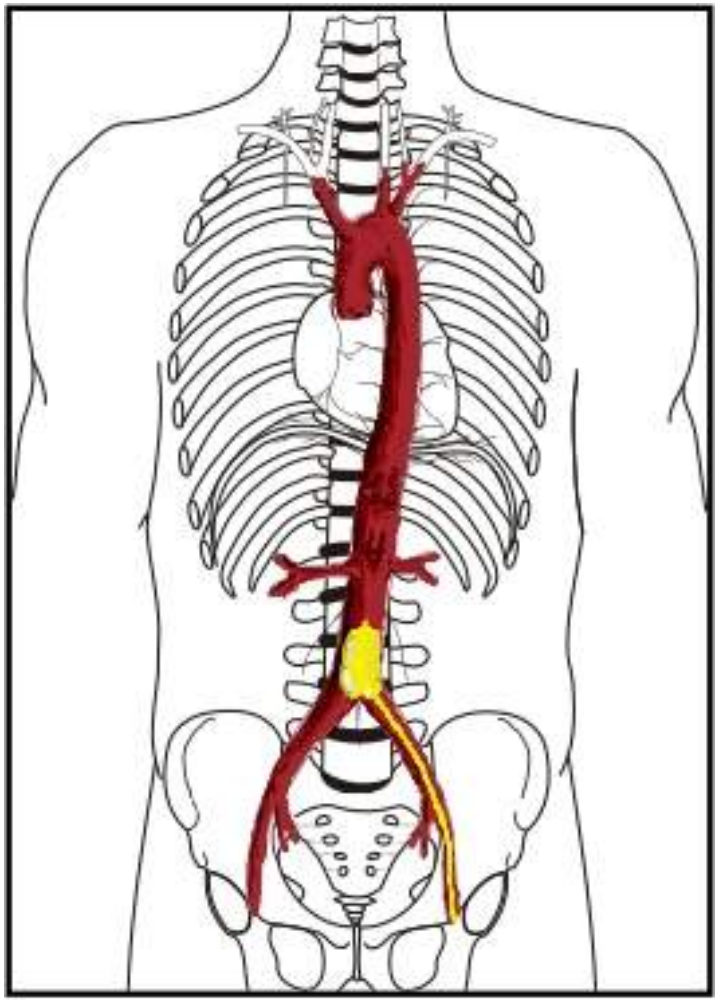
What is REBOA?



- **Resuscitative Endovascular Balloon Occlusion of the Aorta or placement & inflation of a compliant balloon from a remote location into the aorta for the purposes of occlusion**

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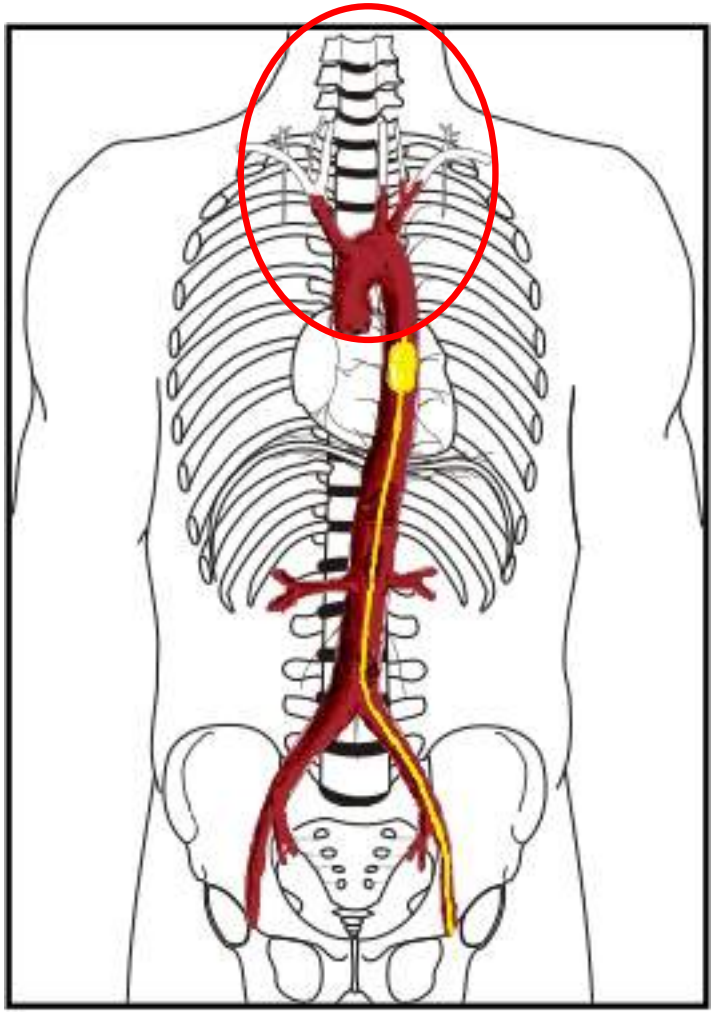
What is REBOA?



- **Performed to provide circulatory support proximal to balloon and inflow (bleeding) control distal or below the balloon**

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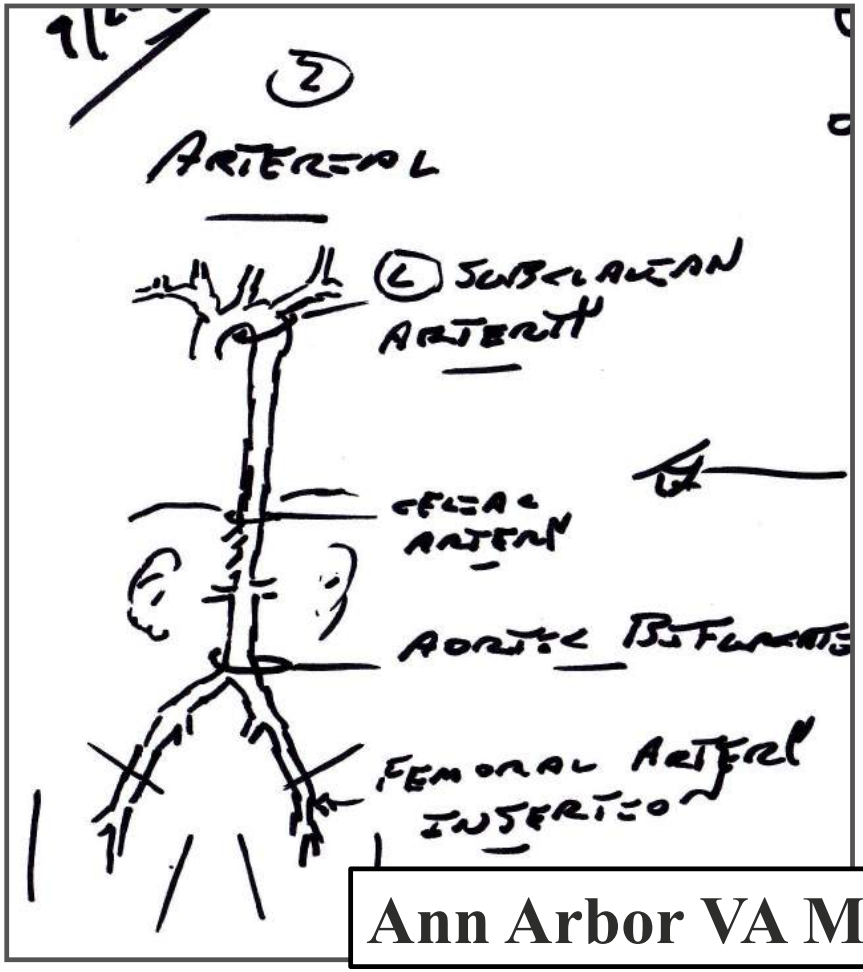
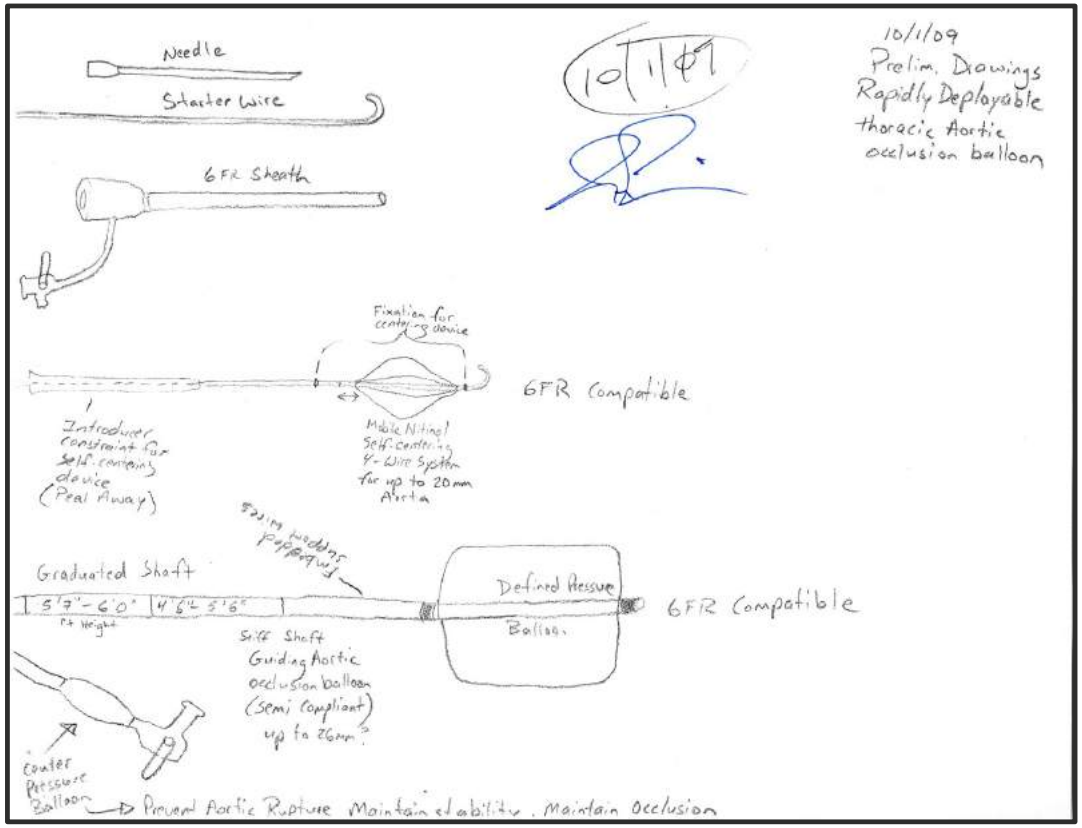
But How to Make Endo- Amenable for Trauma?





Ann Arbor VA Medical Center, October 2009

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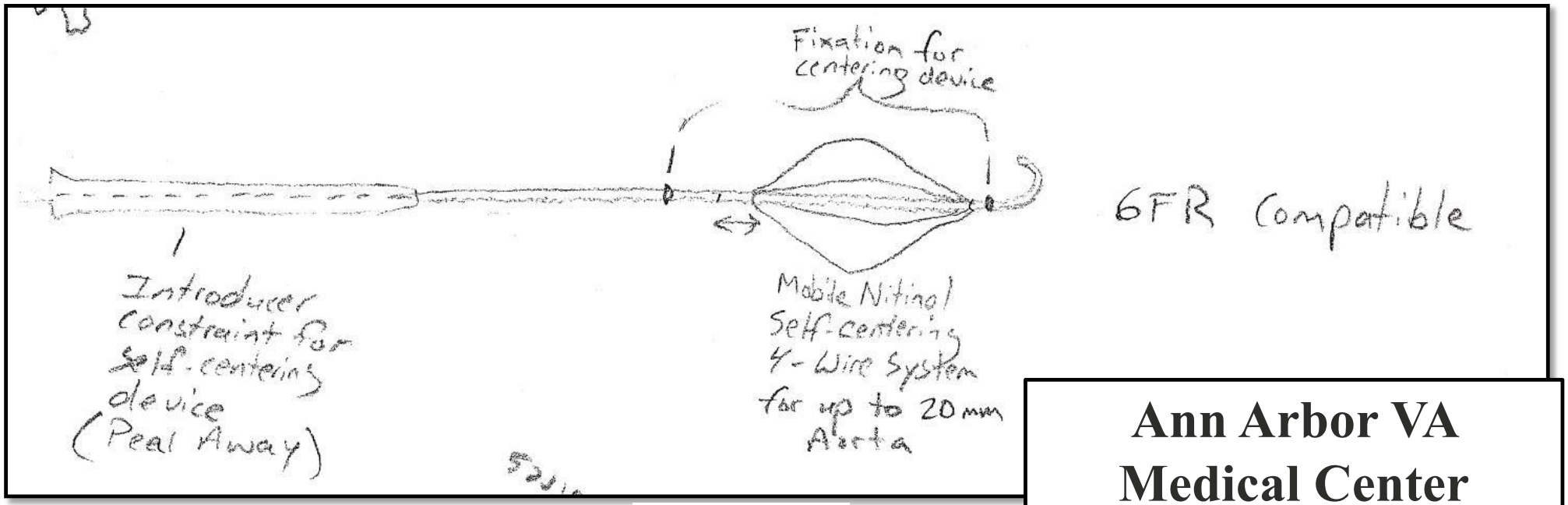
But How to Make Endo- Amenable for Trauma?



Ann Arbor VA Medical Center October 2009

Researcher's six-pack

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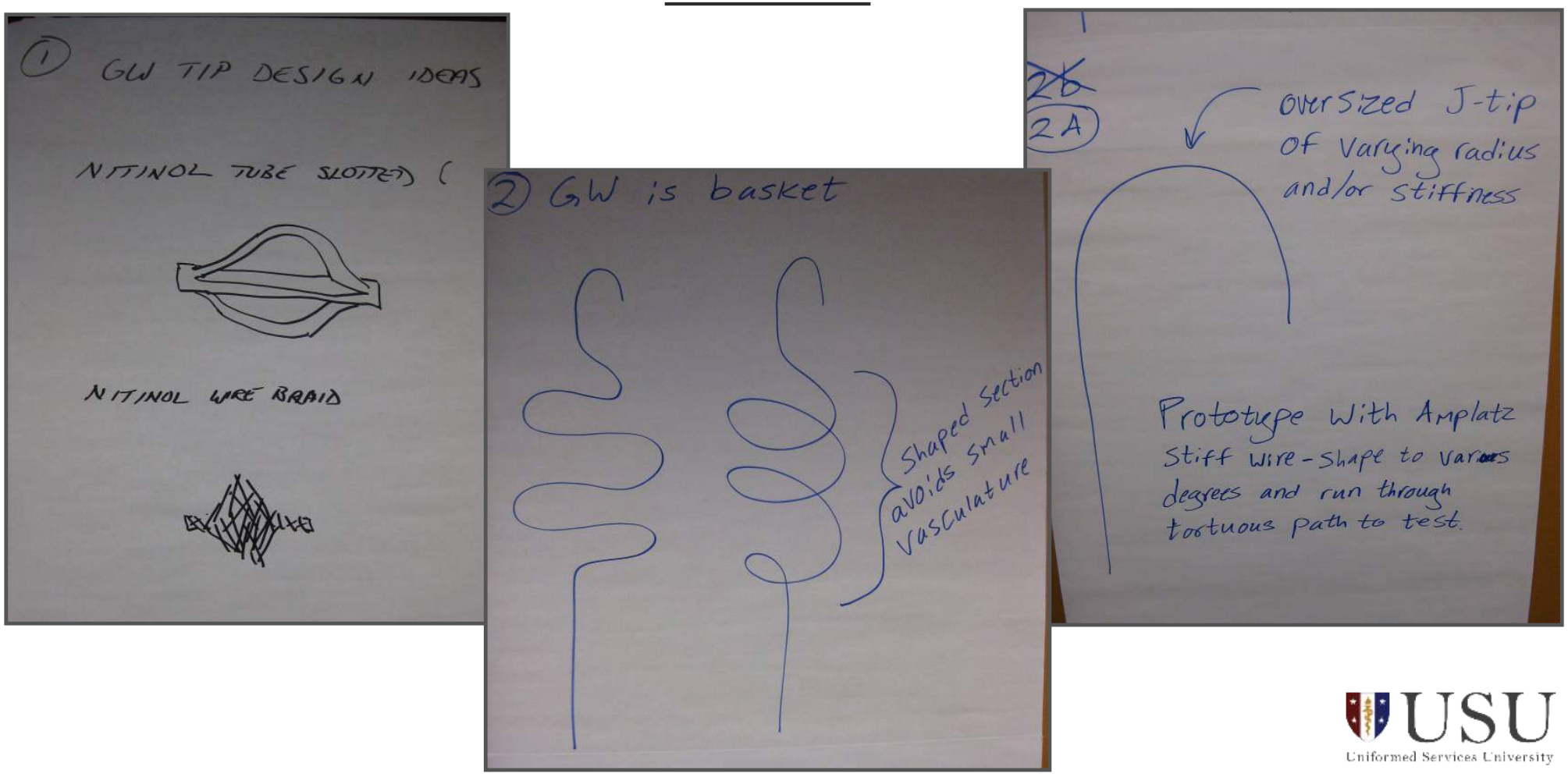
But How to Make Endo- Amenable for Trauma?



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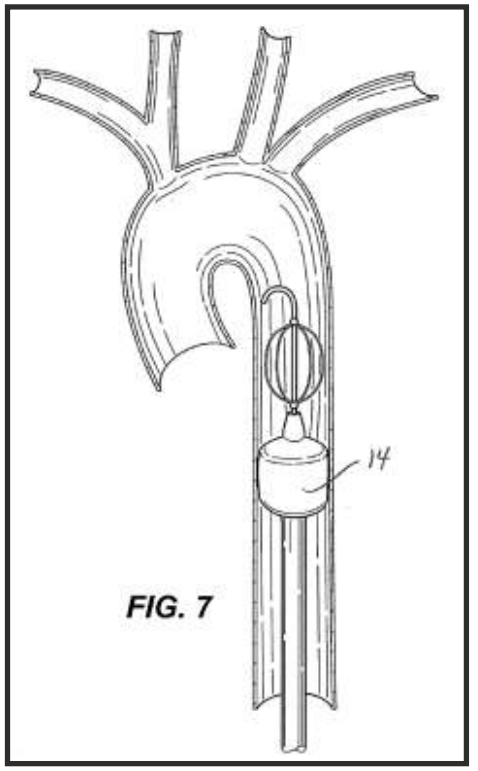
Innovate New Approach for Balloon Occlusion

- **Military-specific IP for new balloon catheter designed to be used in emergency scenarios (public university partnership)**



- **Goals for new balloon catheter technology:**
  - **Reduce the catheter size (7Fr or smaller)**
  - **Obviate need for radiographic imaging**
  - **Obviate need for "over the wire" placement**
  - **Implement arterial monitoring capability**

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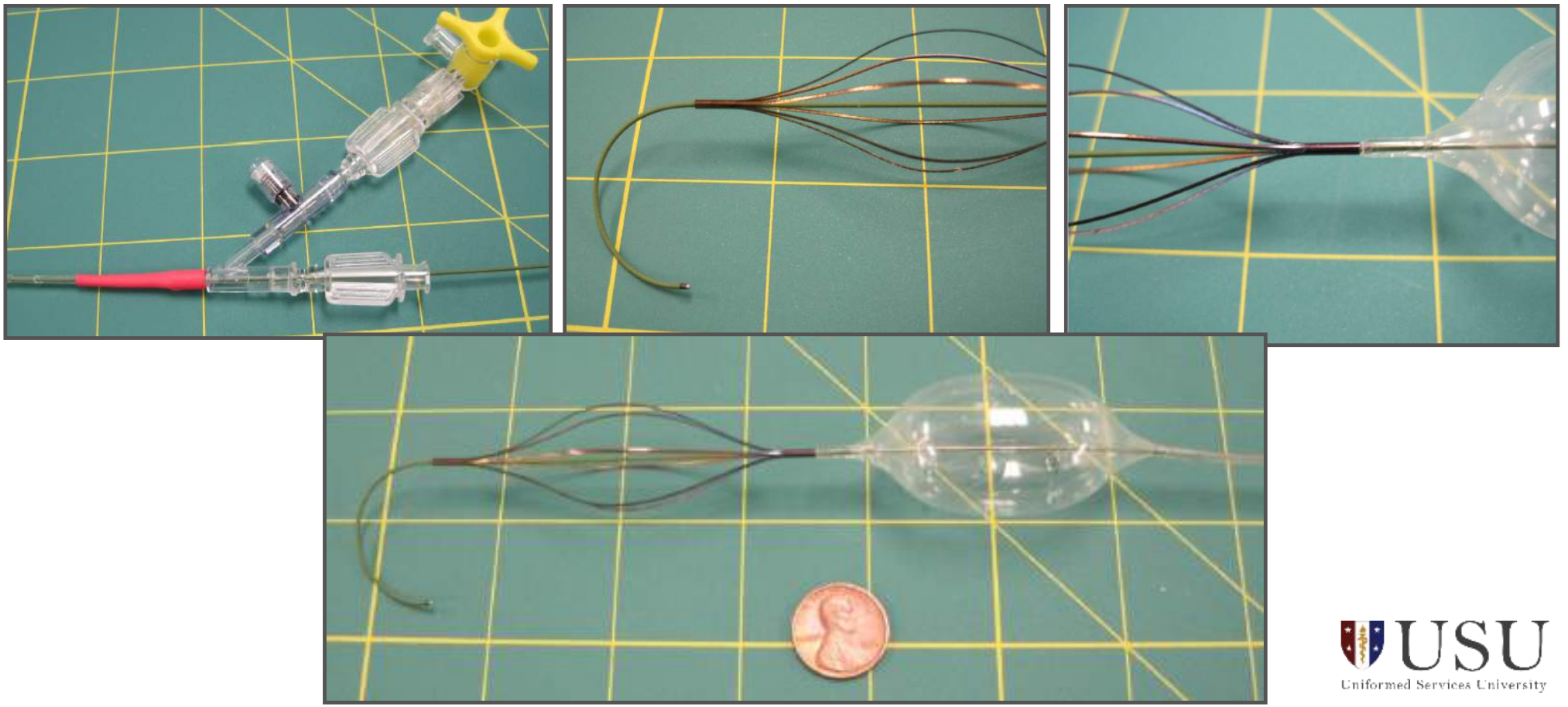
Initial Prototype Funded by University of Michigan and Created by TDC Medical



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Define REBOA for Clinical & Scientific Sectors

PROCEDURES & TECHNIQUES

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an Adjunct for Hemorrhagic Shock

Adam Stannard, MRCS, Jonathan L. Eliason, MD, and Todd E. Rasmussen, MD

Temporary occlusion of the aorta as an operative method to increase proximal or central perfusion to the heart and brain in the setting of shock is not new.[1] Resuscitative aortic occlusion with a balloon was reported as early as the Korean War and has been described in more recent publications.[2–5] Despite potential advantages over thoracotomy with aortic clamping, resuscitative endovascular balloon occlusion of the aorta (REBOA) for trauma has not been widely adopted. Broader application of this procedure may have lagged because of latent technology, a poorly understood skill set, or anticipated ineffectiveness of the technique. However, the recent evolution of endovascular technology and its clear benefit in managing vascular disease such as ruptured abdominal aortic aneurysm suggest that a reappraisal of this technique for trauma is needed. The objective of this report is to provide a technical description of REBOA.

To simplify, this maneuver can be considered in the following five steps each with specific procedural considerations (Table 1):

1. Arterial access
2. Balloon selection and positioning
3. Balloon inflation
4. Balloon deflation
5. Sheath removal

STEP 1: ARTERIAL ACCESS AND POSITIONING OF INITIAL SHEATH

Establishing Arterial Access

At this time, access to the arterial circulation for REBOA for trauma should be obtained through the femoral artery. At the completion of this initial step, a 10- to 15-cm-long sheath will be positioned in the femoral and external iliac artery. Access to the femoral artery can be obtained using one of three techniques: percutaneous, open exposure (i.e., cut down), or exchange over a guidewire from an existing femoral arterial line. Percutaneous access is now commonly accomplished under ultrasound guidance using the same probe applied for the focused abdominal sonography for trauma or focused assessment with sonography for trauma examination. In this scenario, a straight or linear array transducer is superior to a curvilinear transducer. Ultrasound or direct surgical identification of the femoral artery lateral to the vein is especially important in the hypotensive patient without a palpable pulse. Once identified, the artery should be entered at a 45-degree angle with a hollow 18-gauge needle through which a 0.035-inch wire can be passed. After the wire has been passed into the artery, the needle is removed and a small incision made at the interface of the wire and the skin. Next the sheath is placed over the wire into the artery. It is important that any time a sheath is passed over a wire into the arterial system, the sheath's internal dilator is firmly in place to allow a smooth reverse taper from the wire to the diameter of the sheath. Once the dilator and sheath have been advanced over the wire through the skin into the artery, the dilator is removed leaving the sheath as a working port through which other maneuvers can be accomplished. To avoid bleeding from the side port of the sheath after the dilator is removed, it is important that the operator assure that the stopcock is in the "off" position to the patient.

Selection and Positioning of Initial Sheath

Sheaths are measured as French (Fr) (1Fr = 0.333 mm) and are sized based on their internal diameter. Common initial sheaths are 5 Fr to 8 Fr and come in lengths from 8 cm to 15 cm. As long as the operator is confident that the femoral artery has been accessed and the 0.035-inch starter wire passes without resistance, placement of this short sheath can be accomplished without fluoroscopic guidance. As noted, while maintaining arterial access. After a larger opening is created at the wire/skin interface, the short working sheath with its internal dilator in position can be inserted over this wire as previously described.

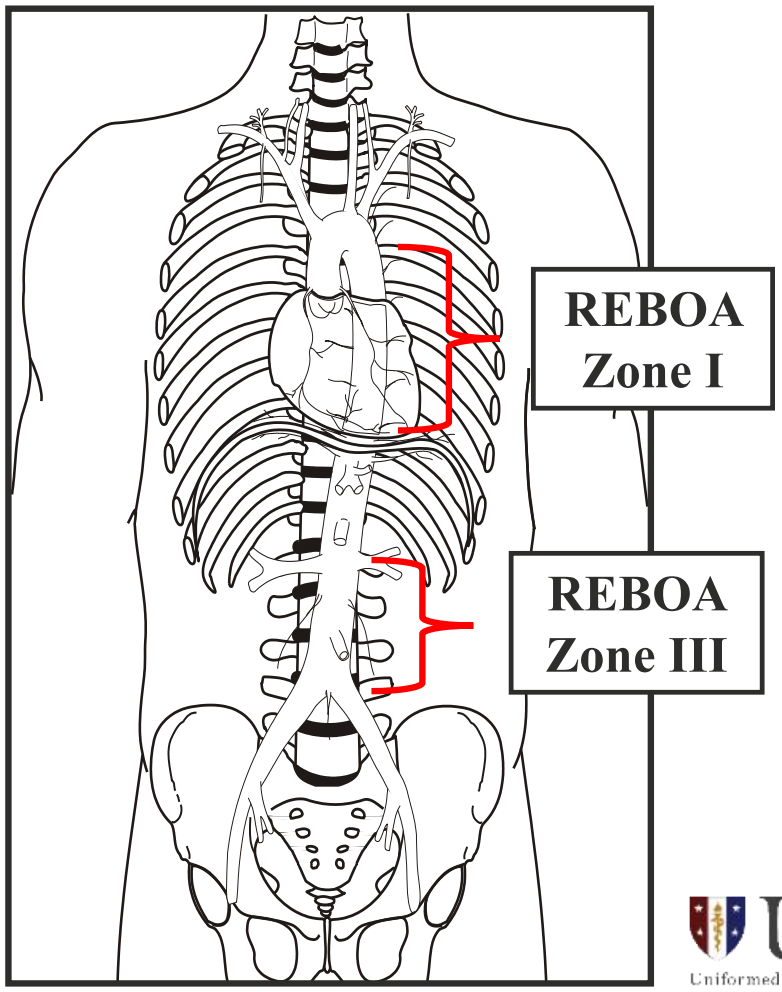
Submitted for publication: October 31, 2011.
Accepted for publication: November 1, 2011.

From the US Army Institute of Surgical Research (A.S., J.L.E., T.E.R.), Fort Sam Houston, San Antonio, Texas; Academic Department of Military Surgery and Trauma

Address for reprints: Todd E. Rasmussen, MD, FACS, US Army Institute of Surgical Research, 3400 Rawley E. Chambers/Suite B, Fort Sam Houston, TX 78234; email: todd.rasmussen@amedd.army.mil.

DOI: 10.1097/TA.0b013e318235fe90c

***J Trauma* 2011;71(6):1869-72**



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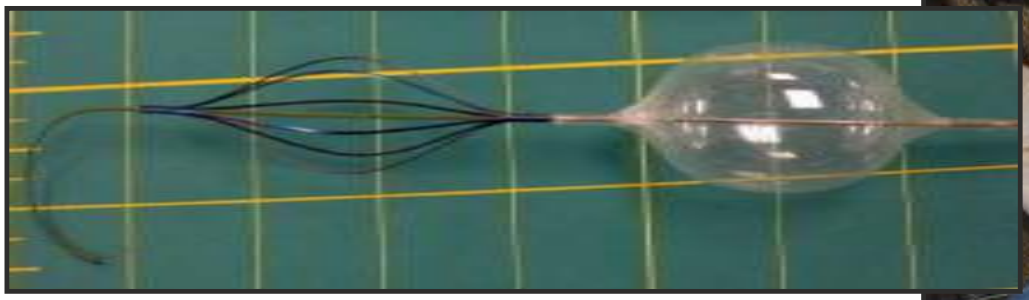
Concept to Prototype Demonstrates Potential

EAST 2013 Poster Paper

A novel fluoroscopy-free, resuscitative endovascular aortic balloon occlusion system in a model of hemorrhagic shock

Daniel J. Scott, MD, Jonathan L. Eliason, MD, Carole Villamaria, MD, Jonathan J. Morrison, MRCS, Robert Houston, IV, MD, Jerry R. Spencer, BS, *and* **Todd E. Rasmussen, MD,** *Ann Arbor, Michigan*

***J Trauma Acute Care Surg* 2013;75:122**



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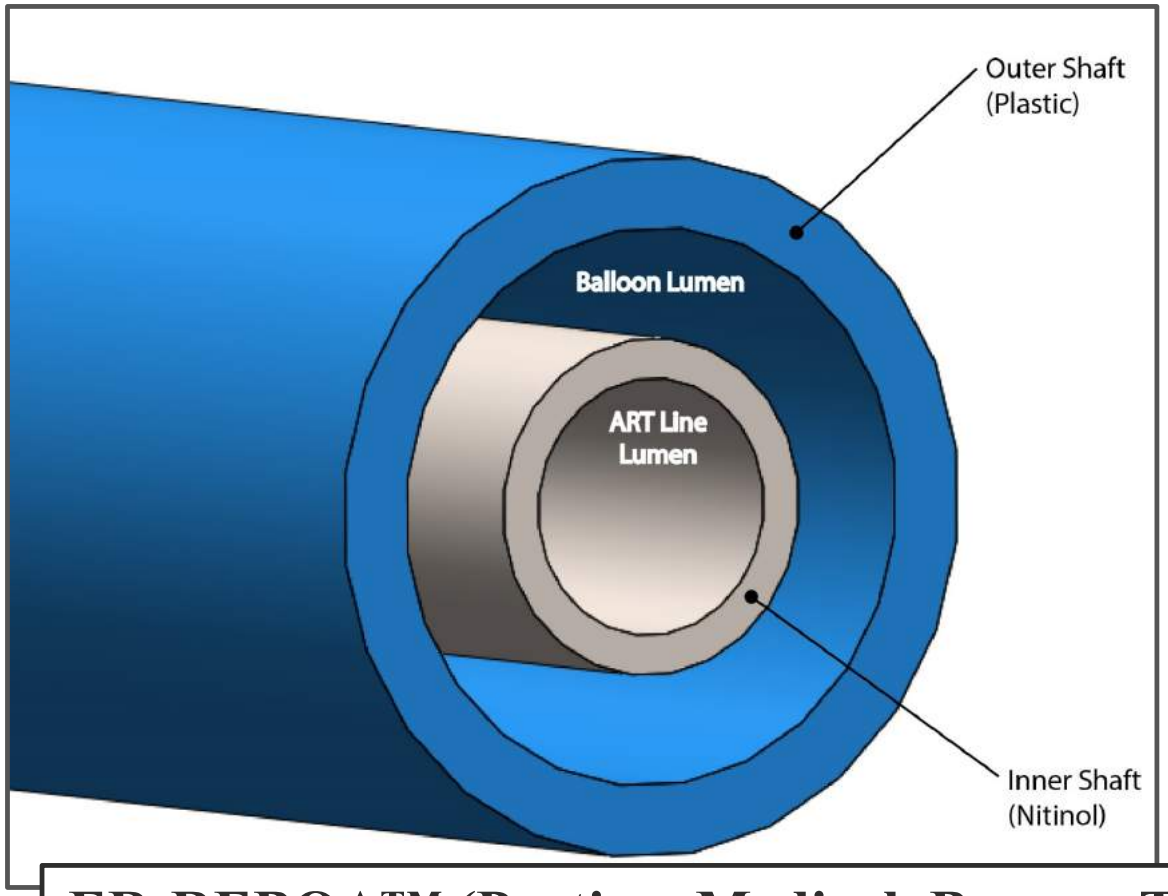
Prototype to Clearance & Commercialization



ER-REBOA™ (Prytime Medical, Boerne, TX)

- **Dual lumen, 6Fr shaft utilizes a "tube in tube" design with an inner, superelastic nitinol tube & a concentric, outer plastic tube**
- **Together, the design & materials create a catheter stiffness obviating the need for traditional "over the wire" insertion**

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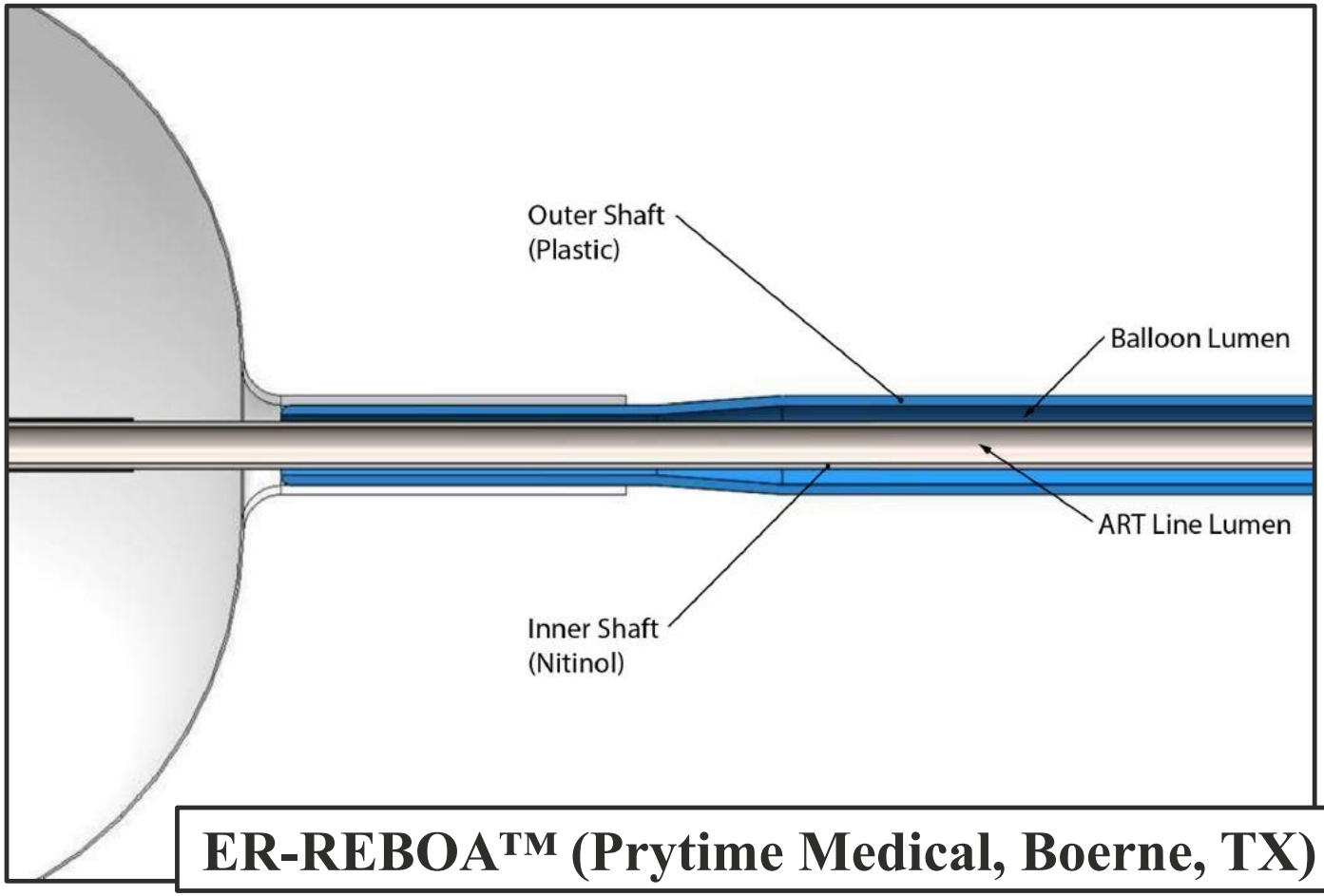
Prototype to Clearance & Commercialization



ER-REBOA™ (Prytime Medical, Boerne, TX)

- **Outer lumen for balloon inflation, inner nitinol lumen for arterial pressure monitor**
- **"P" tip sized to resist side branch entry – catheter shaft has 1cm demarcations**

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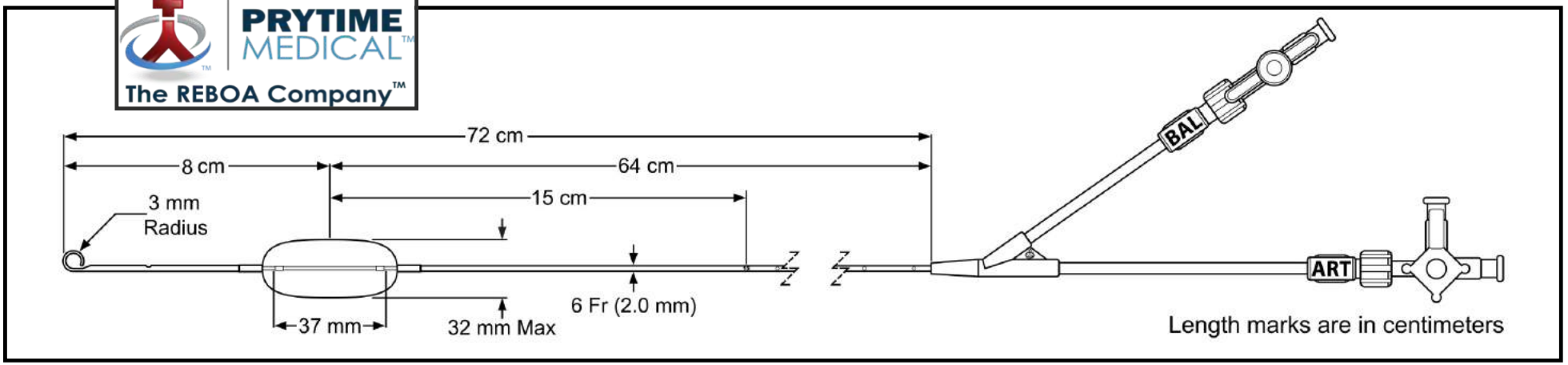
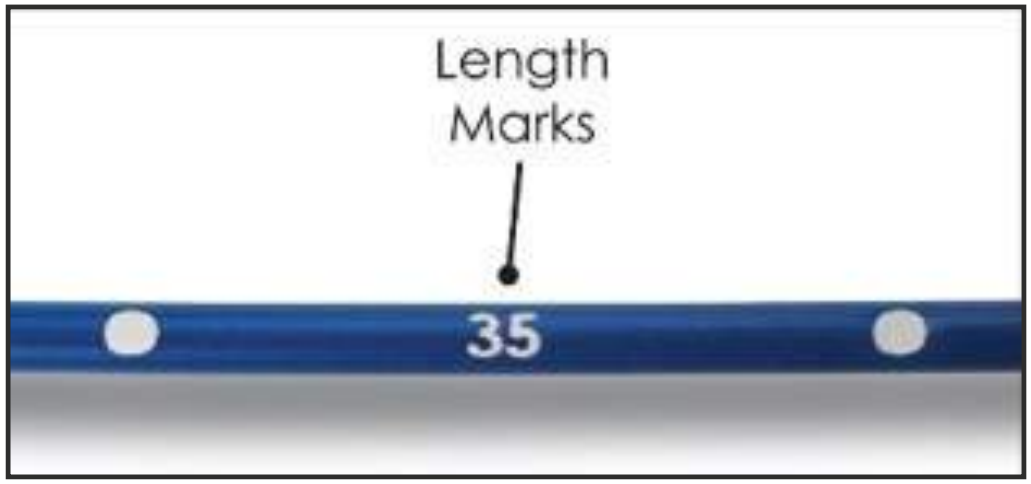
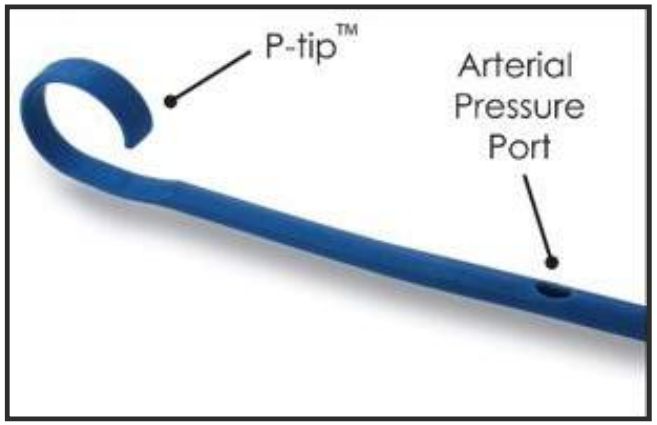
Prototype to Clearance & Commercialization







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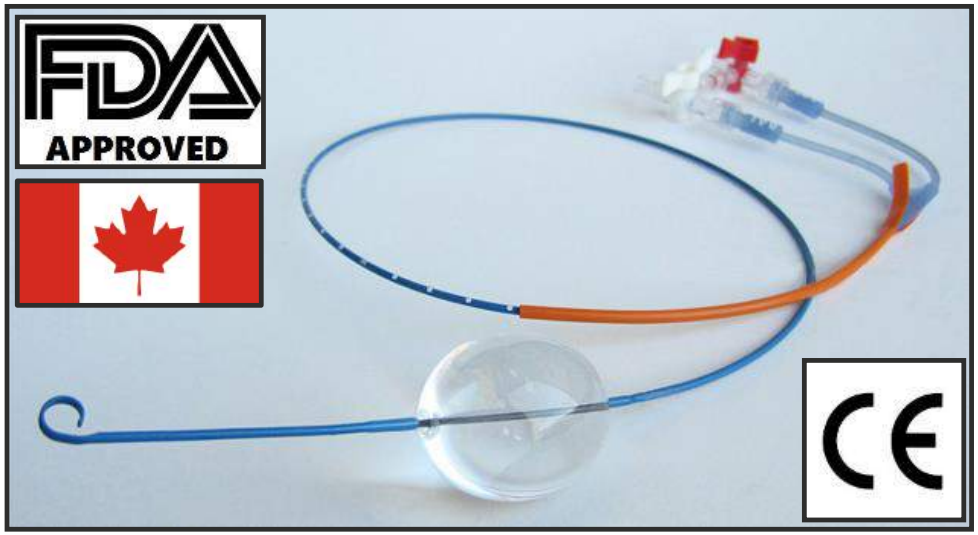
Concept to Prototype to Commercialized Device

Surgical Innovation

Resuscitative Endovascular Balloon Occlusion of the Aorta for Hemorrhagic Shock

JAMA Surg 2017; Published online Sept 20 2017

Todd E. Rasmussen, MD; Curtis J. Franklin, BS; Jonathan L. Eliason, MD



- **Initial experience in medical centers (205 US hospitals & 2000 uses in 24 months since FDA approval)**
- **With increasing familiarity, study & training there is likely to be expanded use, including by non-surgeon & possibly non-physician providers**

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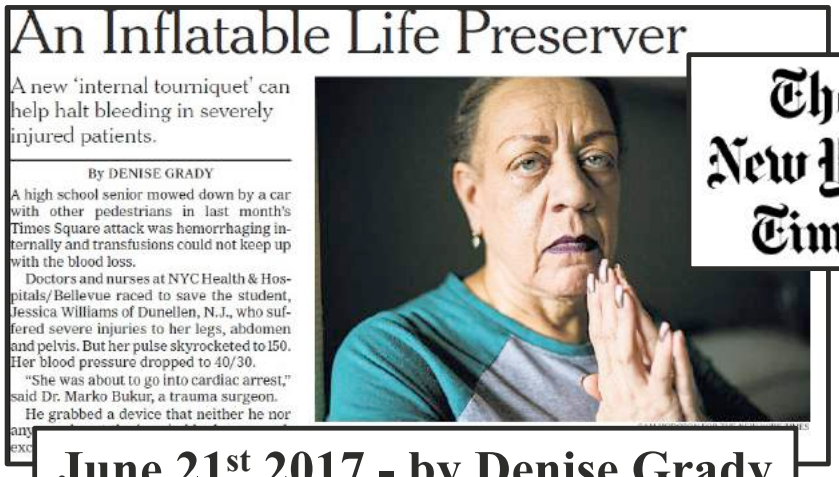
Growing Experience in Civilian Sector

Implementation of resuscitative endovascular balloon occlusion of the aorta as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage

Laura J. Moore, MD, Megan Brenner, MD, Rosemary A. Kozar, MD, PhD, Jason Pasley, DO, Charles E. Wade, PhD, Mary S. Baraniuk, PhD, Thomas Scalea, MD, *and* John B. Holcomb, MD, *Houston, Texas*

***J Trauma Acute Care Surg* 2015;79(4):524-32**



An Inflatable Life Preserver

A new 'internal tourniquet' can help halt bleeding in severely injured patients.

By DENISE GRADY

A high school senior mowed down by a car with other pedestrians in last month's Times Square attack was hemorrhaging internally and transfusions could not keep up with the blood loss.

Doctors and nurses at NYC Health & Hospitals/Bellevue raced to save the student, Jessica Williams of Dunellen, N.J., who suffered severe injuries to her legs, abdomen and pelvis. But her pulse skyrocketed to 150. Her blood pressure dropped to 40/30.

"She was about to go into cardiac arrest," said Dr. Marko Bukur, a trauma surgeon.

He grabbed a device that neither he nor

The New York Times

June 21st 2017 - by Denise Grady

- **Observational, registry-based studies confirming feasibility & empiric benefit**
- **Reports of "saves" related to use in civilian & military settings**

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Thank you from America's Medical School at the Uniformed Services University

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What's Possible

- **Automated, miniaturized vascular access and acute endovascular mediation of perfusion (i.e. new paradigm of automated hemorrhage mitigation and regional perfusion optimization)**

- **Endovascular manipulation of temperature & delivery of drugs & cell-based therapy to stabilize deranged physiology – bridge to ECLS or definitive hemostasis, resuscitation & reparative surgery**

- **Applications for a range of conditions - including cardiogenic shock (cardiac arrest), post-partum hemorrhage, GI and other forms of bleeding and shock**

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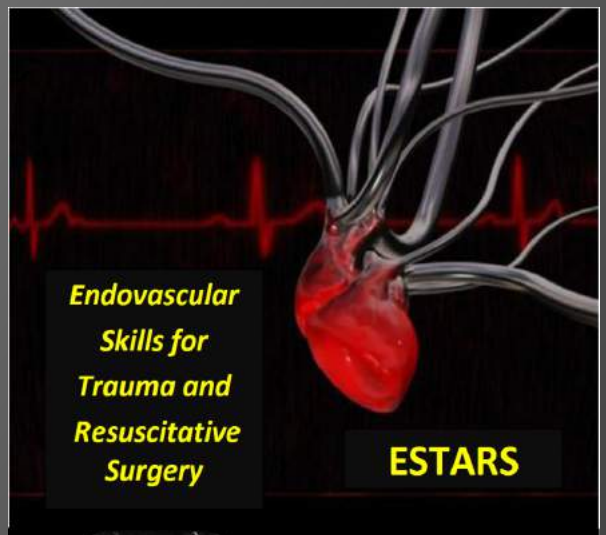
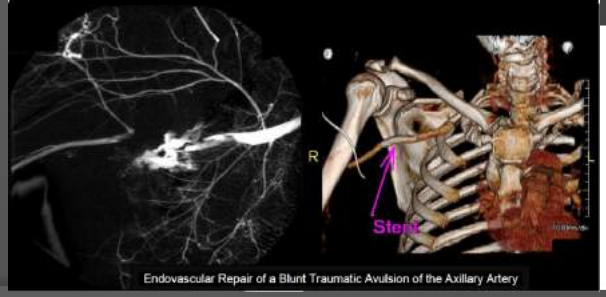
REBOA - Real World

Lena M. Napolitano, MD

REBOA:
ESSENTIAL!!!!!





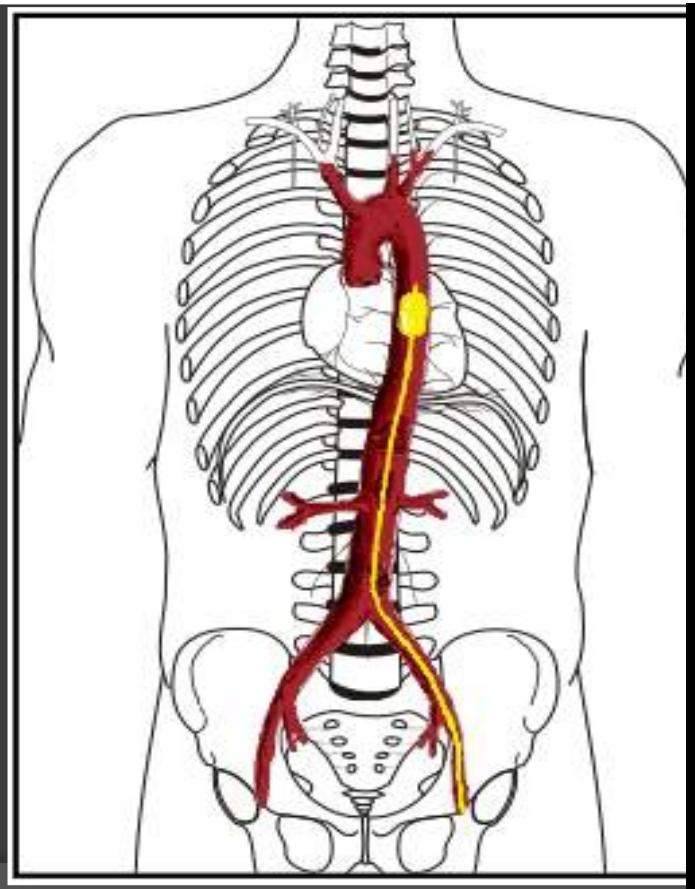
Endovascular Skills for Trauma and Resuscitative Surgery

Lena M. Napolitano MD, FACS
Massey Foundation Professor of Surgery
Acute Care Surgery
[Trauma, Burn, Critical Care, Emergency Surgery]
University of Michigan
Ann Arbor, MI

management of vascular trauma

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an Adjunct for Hemorrhagic Shock

Adam Stannard, MRCS, Jonathan L. Eliason, MD, and Todd E. Rasmussen, MD



- **REBOA: ESSENTIAL !**
- REBOA is an adjunct to provide early hemorrhage control
- REBOA provides early aortic occlusion to transiently stabilize patients to undergo definitive hemorrhage control

Journal of Trauma. 2011 Dec;71(6):1869–72.

REBOA: ESSENTIAL !

- **Need for the technique – patient population**
- Established technique already in use
- National/International & Military guidelines
- National Protocols
- Institutional Protocols
- Already adopted in clinical use

Hemorrhagic Shock

Major cause of trauma mortality (40% civilian/military)

Leading cause of potentially preventable death in trauma

87% due to Noncompressible Torso Hemorrhage

Injury Severity and Causes of Death From Operation Iraqi Freedom and Operation Enduring Freedom: 2003–2004 Versus 2006

Joseph F. Kelly, MD, Amber E. Ritenour, MD, Daniel F. McLaughlin, MD, Karen A. Bagg, MS, Amy N. Apodaca, MS, Craig T. Mallak, MD, Lisa Pearse, MD, Mary M. Lawnick, RN, BSN, Howard R. Champion, MD, Charles E. Wade, PhD, and COL John B. Holcomb, MC

Journal of Trauma. 2008;64(2Suppl):S21–6.

Impact of Hemorrhage on Trauma Outcome: An Overview of Epidemiology, Clinical Presentations, and Therapeutic Considerations

David S. Kauvar, MD, Rolf Lefering, PhD, and Charles E. Wade, PhD

Journal of Trauma. 2006;60(6 Suppl):S3–11.

REBOA: ESSENTIAL !

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- National Protocols
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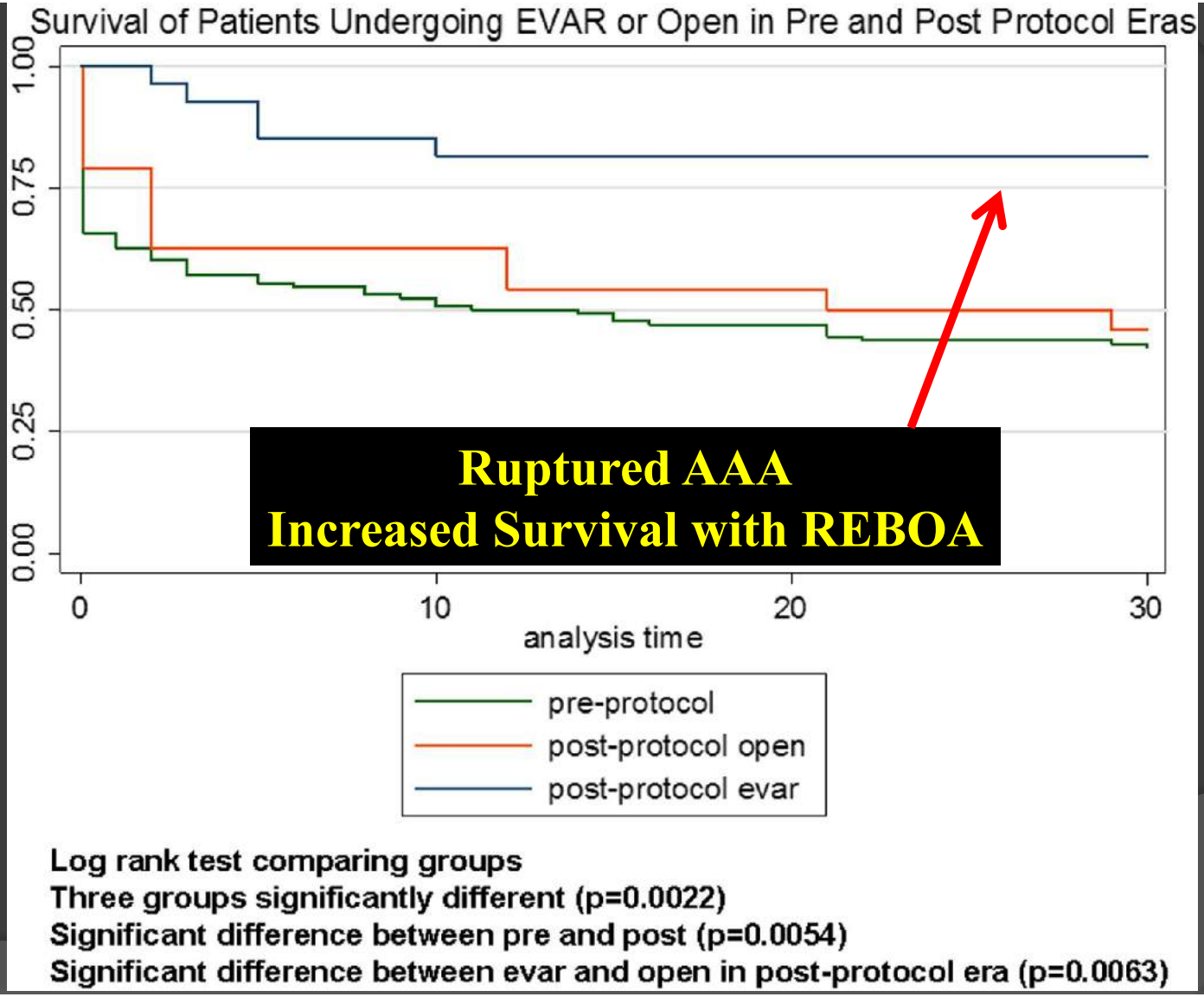
Survival of Patients Undergoing EVAR or Open in Pre and Post Protocol Eras
1.00
0.75
0.50
0.25
0.00
0
10
20
30
analysis time
Ruptured AAA
Increased Survival with REBOA
pre-protocol
post-protocol open
post-protocol evar
Log rank test comparing groups
Three groups significantly different (p=0.0022)
Significant difference between pre and post (p=0.0054)
Significant difference between evar and open in post-protocol era (p=0.0063)

REBOA: ESSENTIAL !

- Need for the technique – patient population
- Established technique already in use
- **National/International & Military guidelines**
- National Protocols
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- Already adopted in clinical use

Joint Theater Trauma System Clinical Practice Guideline

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock

Original Release/Approval		16 Jun 2014	Note: This CPG requires an annual review.
Reviewed:	05 May 2014	Approved:	16 Jun 2014
Supersedes:	**This is a new CPG and must be reviewed in its entirety.**		
☐ Minor Changes *(or)*	☒ **Changes are substantial and require a thorough reading of this CPG (or)**		
☐ Significant Changes			

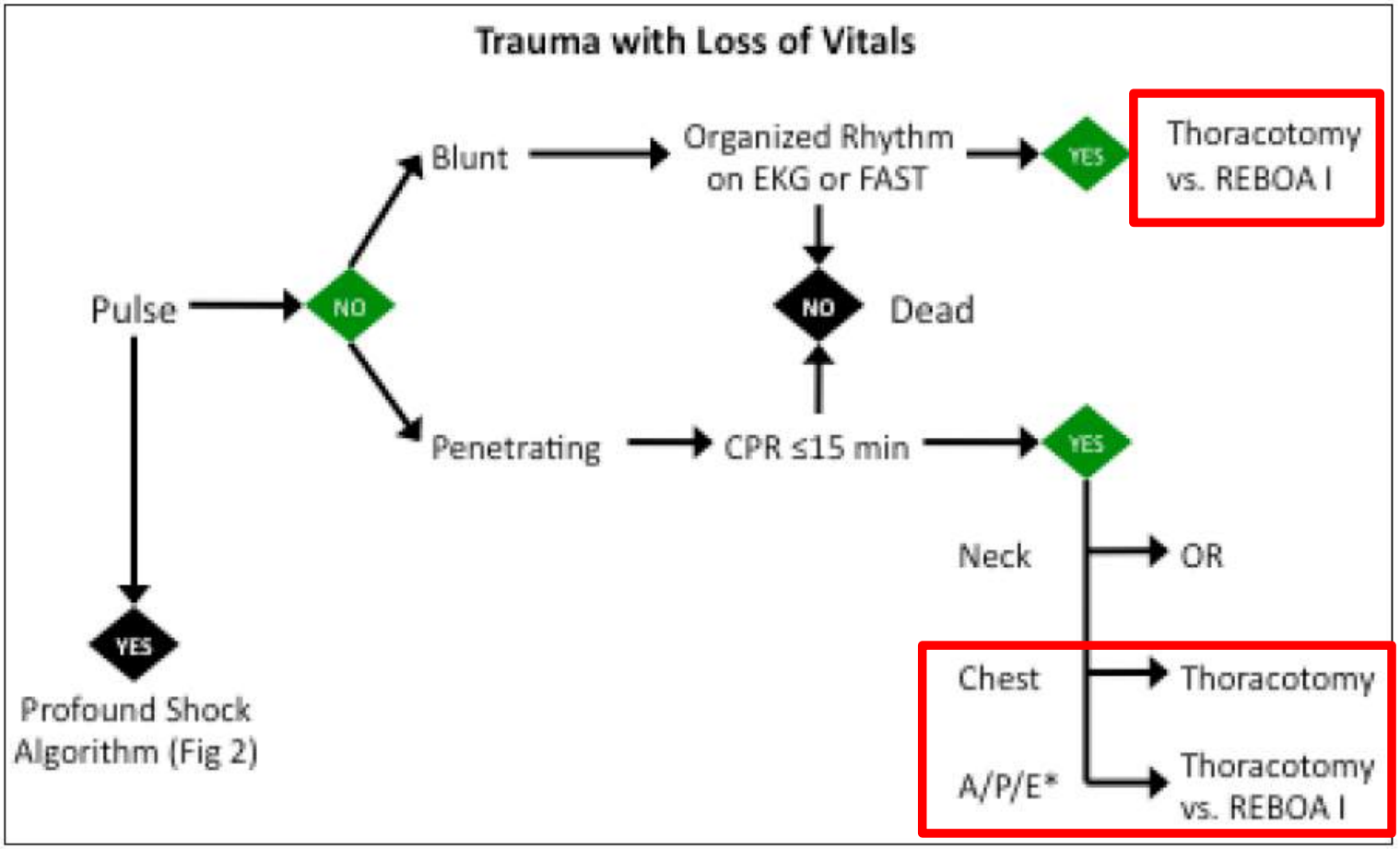
Approved June 2014

1. **Goal**. Review background, explain rationale, establish indications, itemize resources, and describe technique for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as an interventional capability for control of hemorrhagic shock in the setting of uncontrolled truncal and extremity bleeding in surgically capable theater facilities. This Clinical Practice Guideline has been substantially adapted from the Stannard, Eliason, and Rasmussen 2011 publication in the Journal of Trauma.[1]

2. **Background**. Truncal hemorrhage is the leading cause of preventable death on the battlefield. Balloon occlusion as a resuscitative adjunct is not a new or novel intervention.

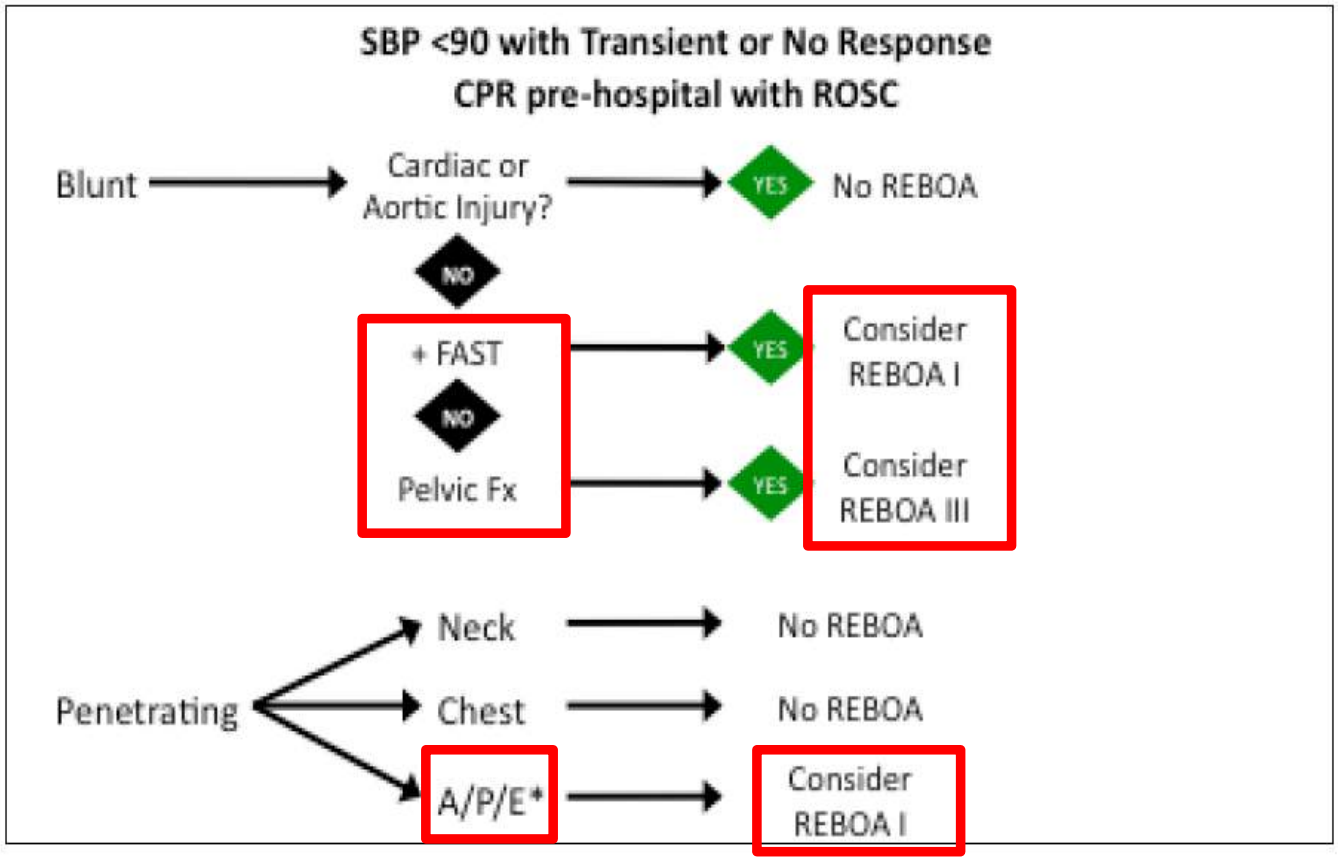
http://www.usaisr.amedd.army.mil/assets/cpgs/REBOA_for_Hemorrhagic_Shock_16Jun2014.pdf

TRAUMATIC ARREST ALGORITHM



*Abdomen/Pelvis/Extremity; REBOA I=Placement of aortic balloon in the thoracic aorta (2-8 cm above the xyphoid)

ALGORITHM FOR THE MANAGEMENT OF PROFOUND SHOCK



*Abdomen/Pelvis/Extremity; ROSC, Return of Spontaneous Circulation; REBOA I Placement of aortic balloon in the thoracic aorta (2-8 cm above the xyphoid); REBOA III Placement of aortic balloon directly above the aortic bifurcation (1-2 cm above the umbilicus)

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock (CPG ID: 38)

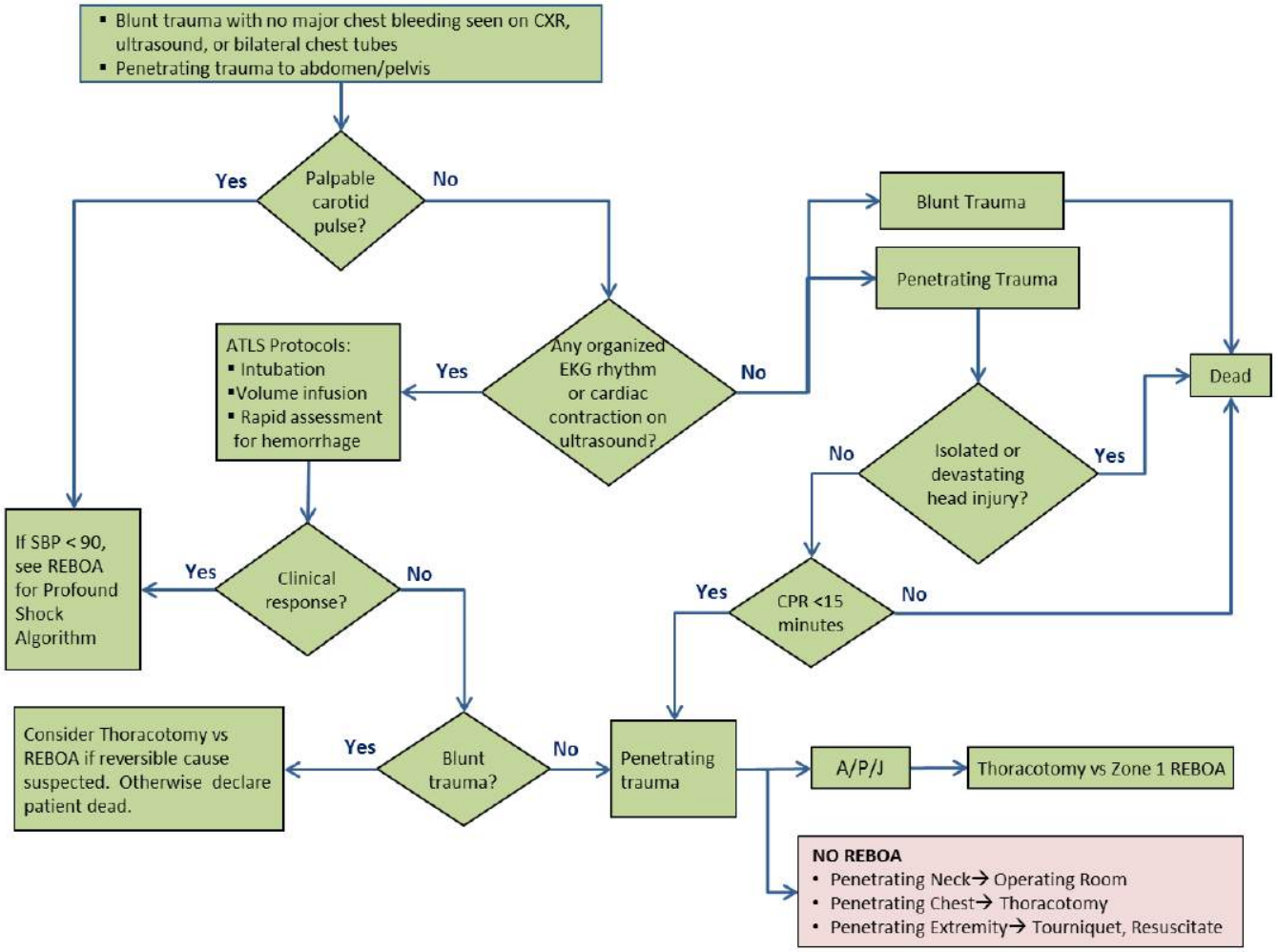
Reviews the range of accepted management approaches to profound shock and post-traumatic cardiac arrest and establishes indications for considering REBOA as a hemorrhage control adjunct.

Contributors

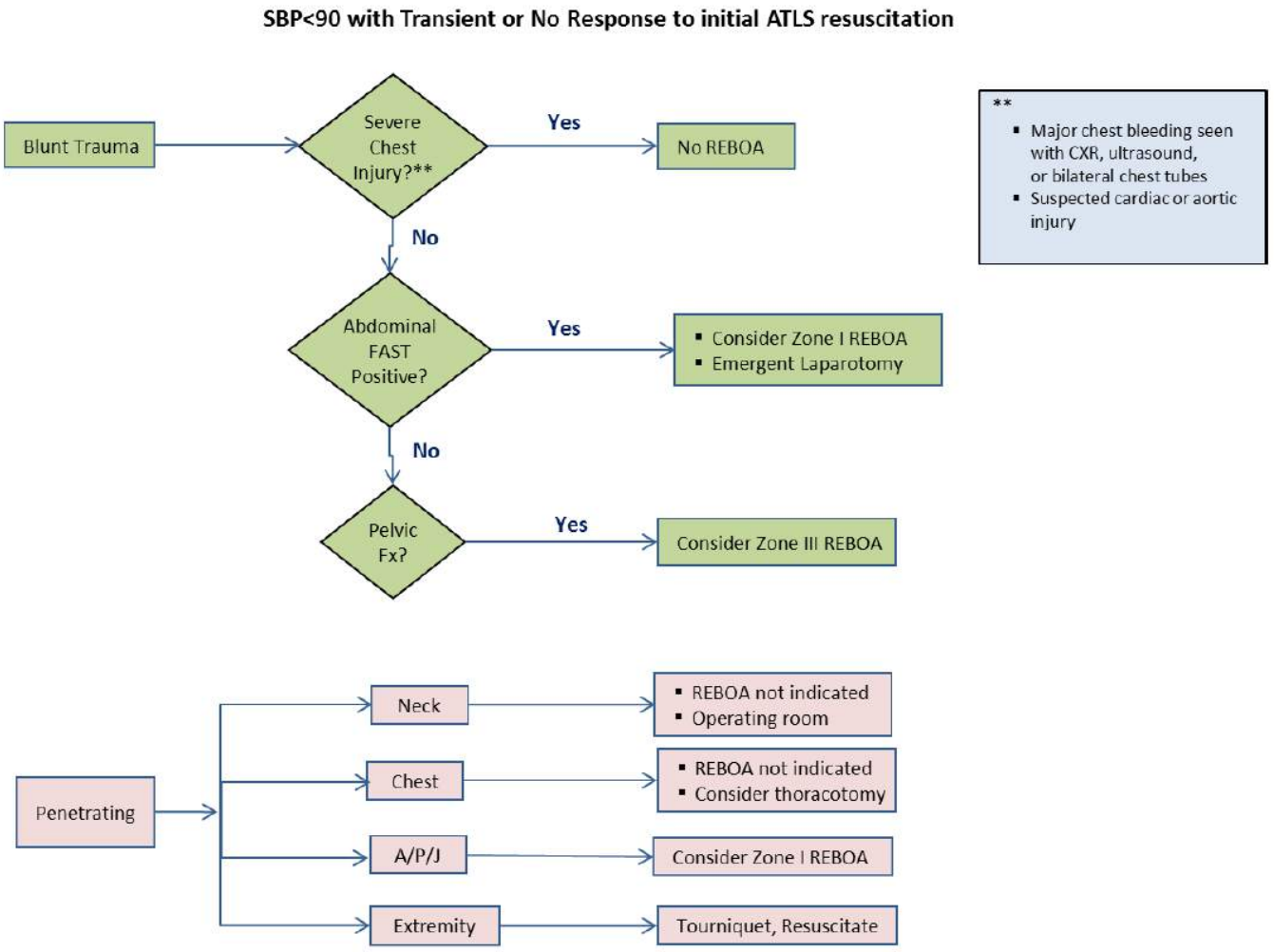
Maj Jason Pasley, USAF, MC
Lt Col Jeremy Cannon, USAF, MC
CDR Jacob Glaser, MC, USN
CDR Travis Polk, MC, USN
MAJ Jonathan Morrison, RAMC
Maj Jason Brocker, USAF, MC
Lt Col Benjamin Mitchell, USAF, MC
Maj Justin Manley, USAF, MC
LTC Tyson Becker, MC, USA
Lt Col Joseph Dubose, USAF, MC
Col Todd Rasmussen, USAF, MC
Col Stacy Shackelford, USAF, MC
CAPT Zsolt Stockinger, MC, USN

First Publication Date: 16 Jun 2014 | Publication Date: 09 June 2017 | Supersedes CPG dated 16 Jun 2014

APPENDIX A: TRAUMATIC ARREST ALGORITHM FOR REBOA



APPENDIX B: ALGORITHM FOR THE USE OF REBOA FOR PROFOUND SHOCK



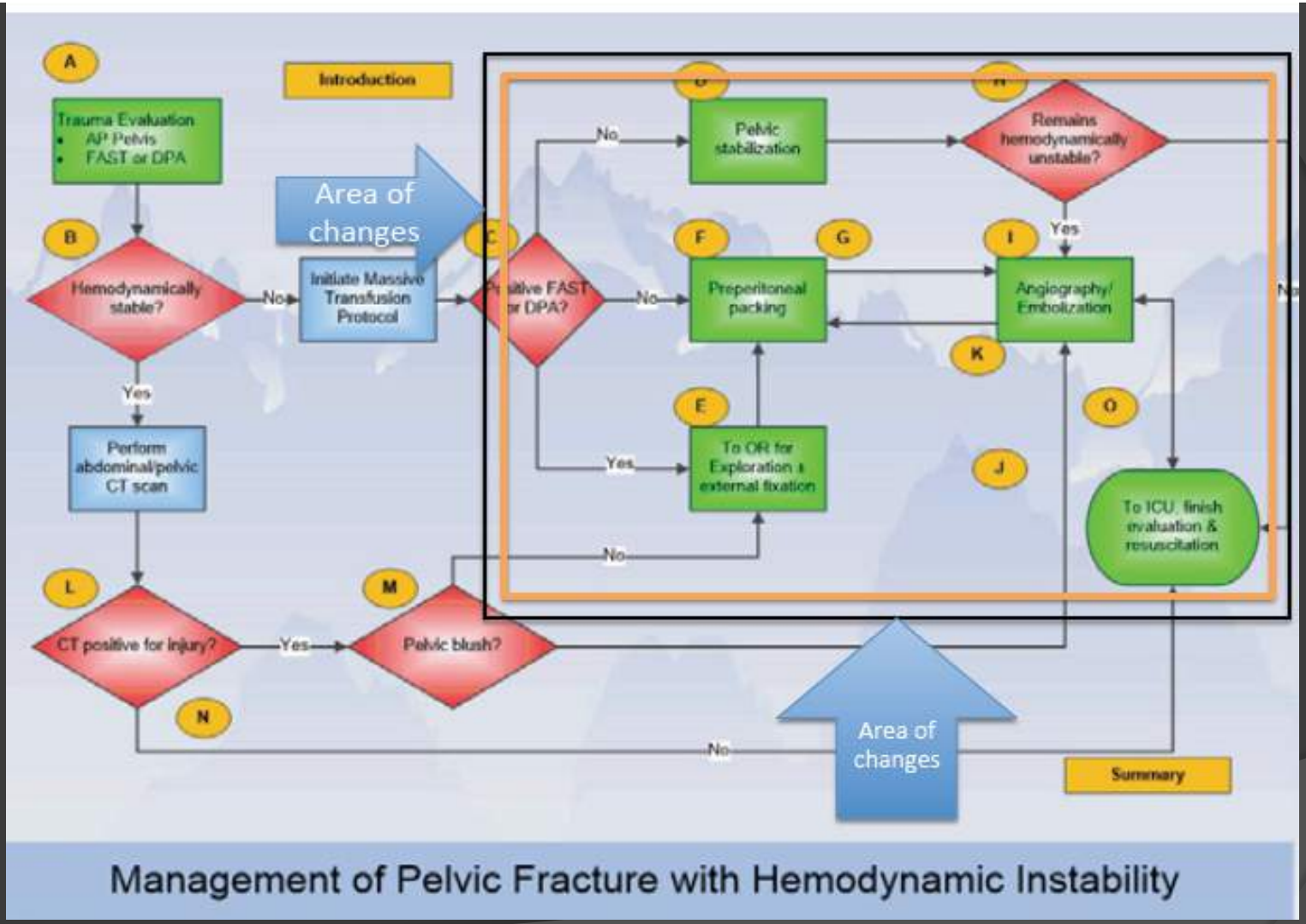
The European guideline on management of major bleeding and coagulopathy following trauma: 4th Edition

- REBOA has been used in patients in end-stage shock following blunt and penetrating trauma together with embolisation of the vascular bed in the pelvis. Descriptions of REBOA are few and there are no published trials. Some combined approaches are reported and the technology is evolving [331]. These techniques can be combined with a consecutive laparotomy if deemed necessary [337].
- REBOA may decrease the high mortality rate observed in patients with major pelvic injuries who have undergone laparotomy as the primary intervention, however non-therapeutic laparotomy should be avoided [341]. Time to pelvic embolisation for haemodynamically unstable pelvic fractures may affect survival [331, 342].

Rossaint R et al. Critical Care 2016;**20**:100

REBOA: ESSENTIAL !

- Need for the technique – patient population
- Established technique already in use
- National/International & Military guidelines
- **National Protocols**
- Institutional Protocols
- Already adopted in clinical use



Management of Pelvic Fracture with Hemodynamic Instability

Pelvic Fx Hemorrhage

- Mean 9.4 u PRBCs
- Median time to angio 286 min
- **Median time to hemostasis with embolization was 344 min**
- In a trauma center with robust resources

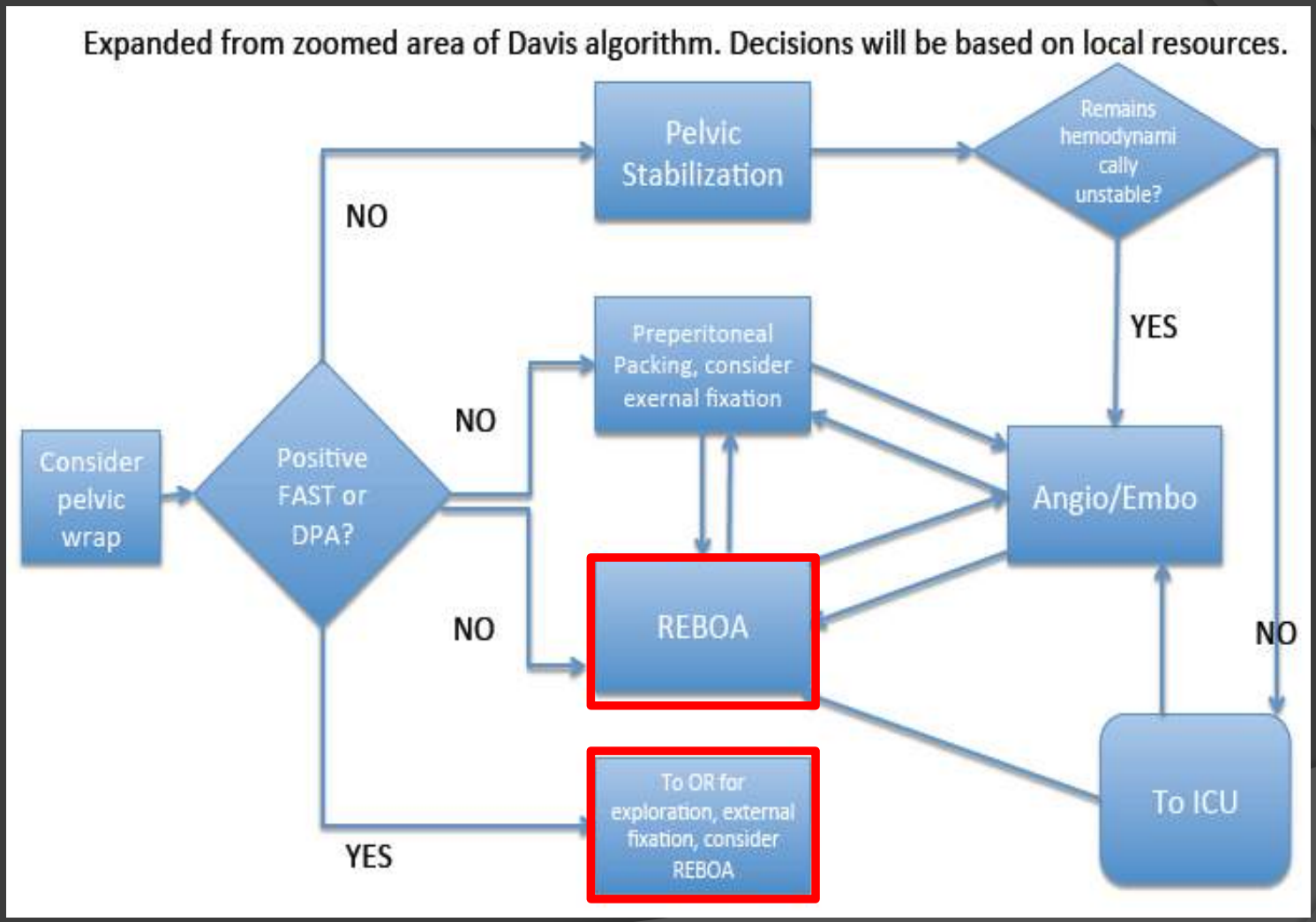
Session: VII: Shock Transfusion Papers 14-17
Paper 16: 10:40-11:00

ANGIOGRAPHIC EMBOLIZATION FOR HEMORRHAGE FOLLOWING PELVIC FRACTURE: IS IT "TIME" FOR A PARADIGM SHIFT?

Ronald Tesoriero MD, Brandon Bruns MD, Mayur Narayan MD, MPH, MBA, Joseph Dubose* MD, Sundeep Guliani MD, Megan Brenner MD, Deborah Stein* MD, MPH, Thomas Scalea* MD, R Adams Cowley Shock Trauma Center

Invited Discussant: John Holomb, MD

Introduction: Major pelvic disruption with hemorrhage has a high rate of lethality. Angiographic embolization is the mainstay of treatment. Time spent awaiting mobilization of the resources needed to perform angiography allows ongoing hemorrhage. Alternative techniques, such as pre-peritoneal pelvic packing and aortic balloon occlusion (REBOA), now exist. We hypothesized that time to angiography and hemostasis using standard therapy would be vastly longer than anticipated.
Methods: A retrospective review was performed of all patients with pelvic fracture who underwent pelvic angiography at a level one trauma center over a 10 year period. The trauma registry was queried for age, sex, injury severity score (ISS), hemodynamic instability (HI) on presentation (SBP $\leq$ 90, HR $\geq$ 120), and transfusion requirements within 24hrs. Charts were reviewed for indications for, and time to, angiography, time to hemostasis by embolization, and mortality.
Results: 4712 patients were admitted with pelvic fractures during the study period. 344 (0.07%) underwent pelvic angiography. 71% were male. Mean age was 46 years. Mean ISS was 32. Mean 24 hour transfusion requirements were 9.4 units of RBC's and 11 units of FFP. 151 (43.9%) presented with HI and 104 (30%) received massive transfusion (MT). 212 (62%) had embolization. Median time to angiography was 286 min (interquartile range [IQR] 210-378) and time to hemostasis with embolization was 344 min (IQR 262-433). Median procedure time for embolization was 51 minutes (IQR 37-83). Times were significantly shorter when stratified for HI (HI 264 vs stable 309 min; p=0.03), and MT (MT 230 vs non-MT 317min; $p < 0.01$). However, time from admission to angiography still took nearly 4 hours. Overall mortality was 18%. Hemorrhage (16%) and sepsis/multiple organ failure (43.5%) accounted for most deaths.
Conclusion: Pelvic fracture hemorrhage remains a management challenge. In our trauma center, with robust resources, the median time to hemostasis was over 5 hours. Nearly 60% of deaths could be directly attributed to, or as a complication of, early uncontrolled hemorrhage. Earlier intervention by Acute Care Surgeons with techniques such as pre-peritoneal pelvic packing, REBOA, and utilization of hybrid operative suites with surgeon performed embolization may improve outcomes.


Expanded from zoomed area of Davis algorithm. Decisions will be based on local resources.
Consider pelvic wrap
Positive FAST or DPA?
NO
Pelvic Stabilization
Remains hemodynamically unstable?
YES
NO
Preperitoneal Packing, consider exernal fixation
NO
REBOA
YES
To OR for exploration, external fixation, consider REBOA
Angio/Embo
NO
To ICU

Western Trauma Association Critical Decisions in Trauma: Management of pelvic fracture with hemodynamic instability—2016 updates

Thai Lan N. Tran, MD, Karen J. Brasel, MD, PhD, Riyad Karmy-Jones, MD, Susan Rowell, MD, Martin A. Schreiber, MD, David V. Shatz, MD, Roxie M. Albrecht, MD, Mitchell J. Cohen, MD, Marc A. DeMoya, MD, Walter L. Biffl, MD, Ernest E. Moore, MD, *and* **Nicholas Namias, MD**, *Miami, Florida*

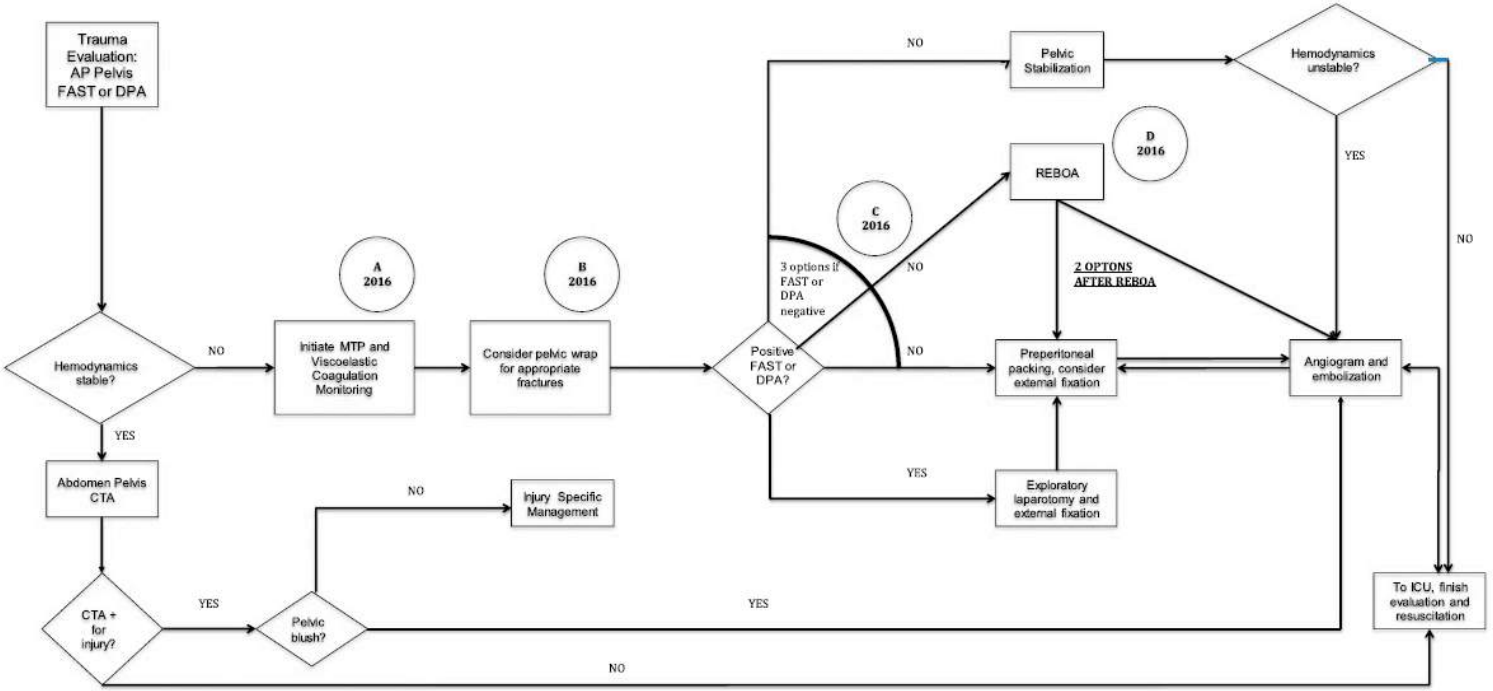
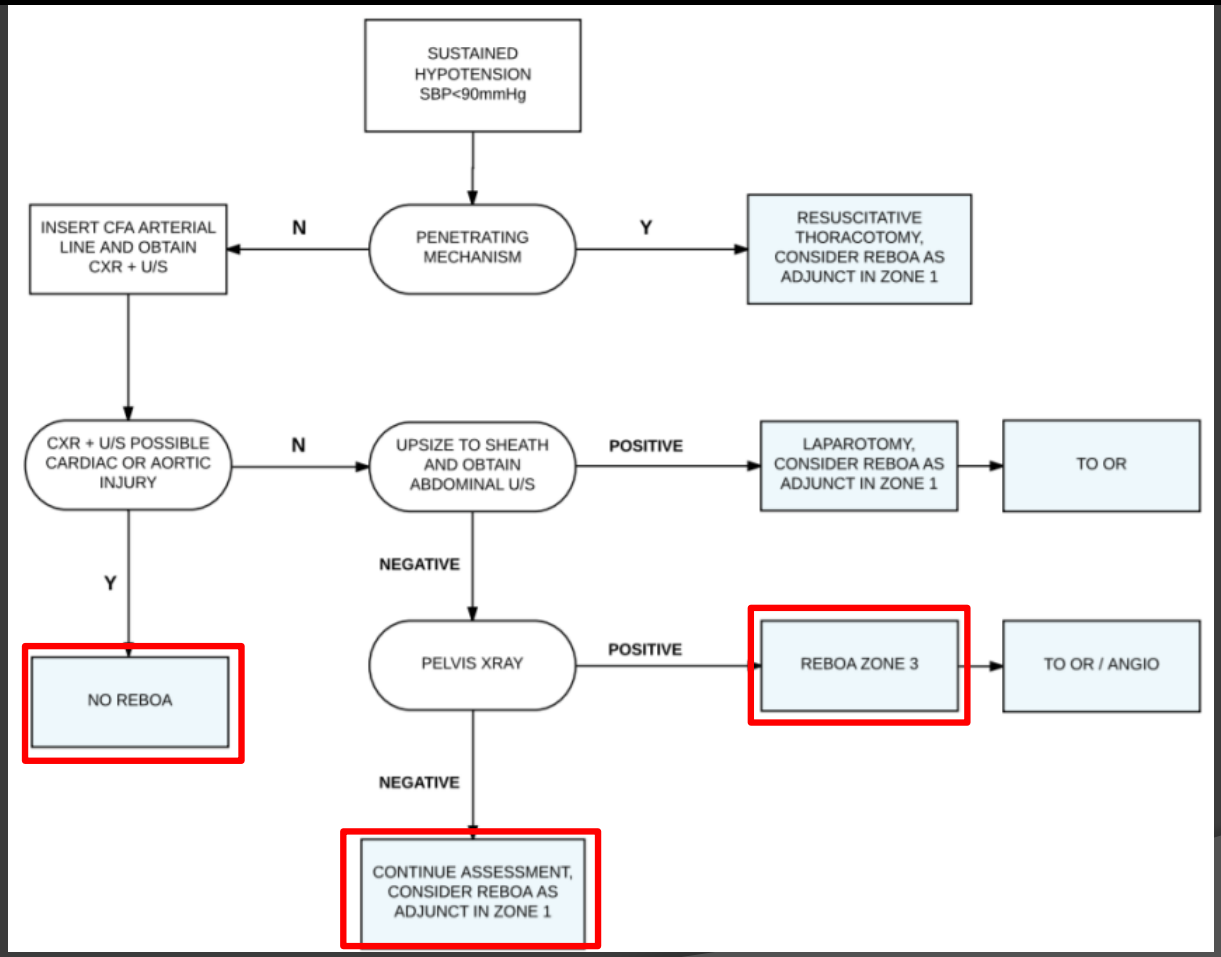


Figure 1. Management of pelvic fracture with hemodynamic instability.

Western Trauma Association (WTA) Algorithm

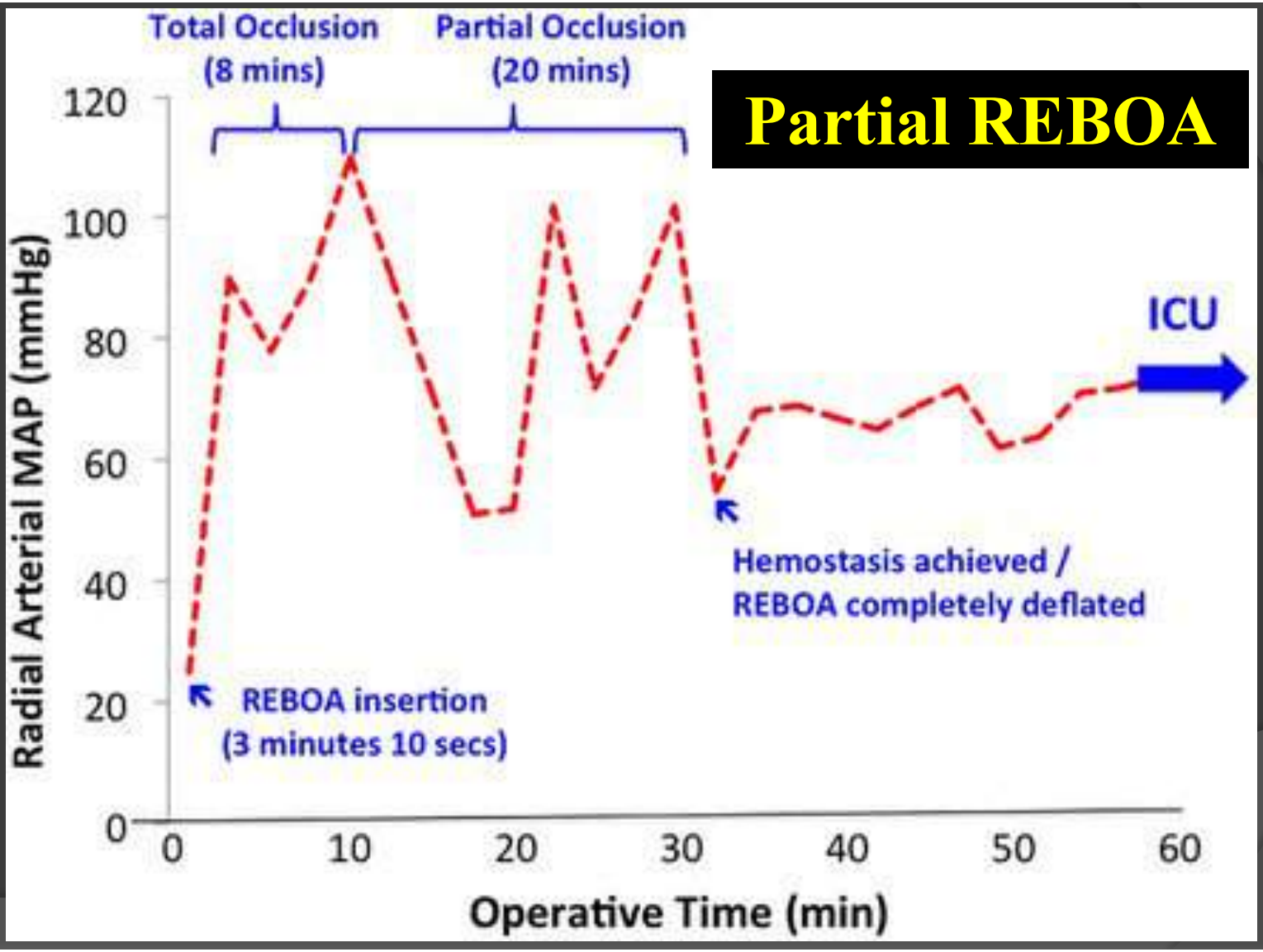


- Inaba K. ALGORITHM 2 – REBOA. Western Trauma Association 47th Annual Meeting. 2017.
- http://westerntrauma.org/documents/meeting/2017/AlgorithmDrafts/2017-WTA-ALGORITHM-REBOA.pdf

For exsanguinating pelvic hemorrhage from blunt trauma:

- **REBOA** (Zone III, above aortic bifurcation) is less invasive than resuscitative thoracotomy
- **REBOA** is more effective at aortic control than thoracotomy with aortic compression
- **REBOA** is quicker to perform than resuscitative thoracotomy
- **REBOA** is easier to control, i.e. intermittent balloon deflation to provide perfusion

Partial REBOA



REBOA: ESSENTIAL !

- Need for the technique – patient population
- Established technique already in use
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- National Protocols
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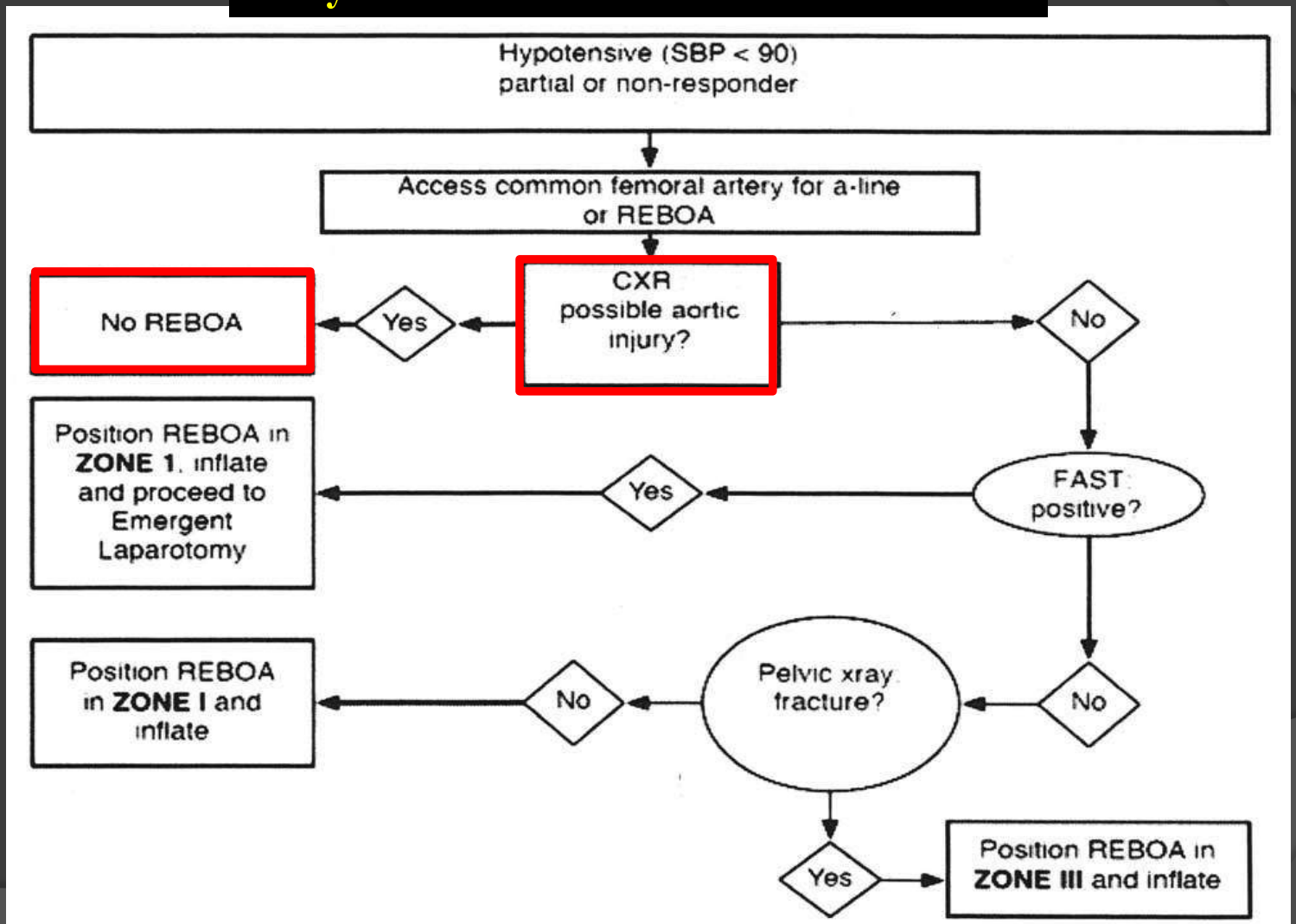
- Already adopted in clinical use

Maryland Shock Trauma Center Protocol



REBOA

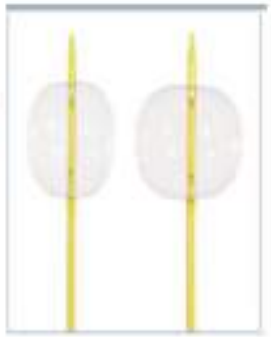
- Must have a protocol
- REBOA kit
- ED & OR
- Educate

University of Michigan
Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Hemorrhagic Shock

Similar to resuscitative thoracotomy with aortic clamping for traumatic arrest due to hemorrhage, REBOA is used for temporary aortic occlusion. REBOA supports proximal aortic pressure and minimizes hemorrhage until hemorrhage control and hemostasis are obtained. REBOA can be used instead of resuscitative thoracotomy in hemorrhagic shock.

REBOA Steps:

1. **Arterial access and Sheath Placement**
   a. Ultrasound-guided femoral arterial access with Micropuncture kit (21 gauge needle, 4 or 5 French catheter and dilator, 0.018 inch guidewire)
   b. Or Femoral arterial cut-down, proximal/distal control for direct puncture
   c. Upsize to 14-French Introducer Sheath using Amplatz guidewire (0.035 in)
   d. Confirm Amplatz guidewire position in proximal aorta – digital radiography
2. **Balloon selection and positioning**
   a. Cook Medical CODA Balloon 14 Fr (32-40mm diameter, 120cm length)
   b. Compliant, low-atmosphere, high volume balloons
3. **Balloon inflation**
   a. Use the minimal pressure to gain wall apposition, to prevent aortic injury.
   b. 30-60cc syringe – fill with NS or ½ NS/Contrast for visualization
   c. All attempts should be made to minimize the time of balloon inflation
4. **Balloon deflation**
   a. Intermittent deflation of REBOA can be used to optimize visceral perfusion, goal SBP > 90 mm Hg
5. **Sheath removal – Primary arterial repair needed after 14Fr sheath removal**



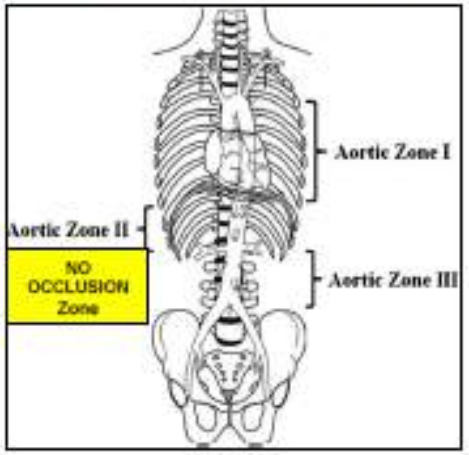
REBOA INTRA-AORTIC PLACEMENT

The placement of the balloon is determined by the location of the injury and ongoing hemorrhage:

Zone 1 Descending Thoracic Aorta (origin of left subclavian artery to celiac artery) is used for truncal hemorrhage control

Zone 2 Para-visceral Aorta (celiac artery to lowest renal artery): **NO-OCCLUSION ZONE**

Zone 3 Infra-renal Aorta (lowest renal artery to aortic bifurcation) for pelvic hemorrhage and junctional bleeding.

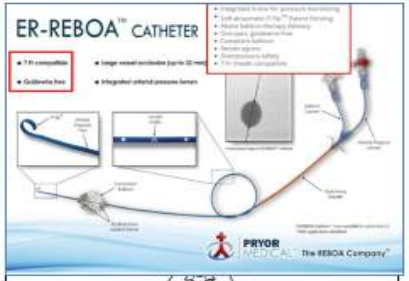


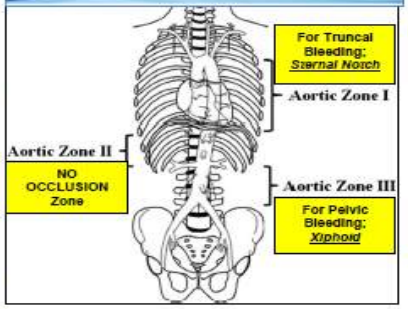
REBOA

- Must have a protocol
- REBOA kit
- Readily available
- ED & OR
- Educate

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Hemorrhagic Shock

REBOA is used for temporary aortic occlusion in traumatic hemorrhagic shock. REBOA supports proximal aortic pressure and minimizes hemorrhage until hemorrhage control and definitive hemostasis are obtained.





REBOA Steps:

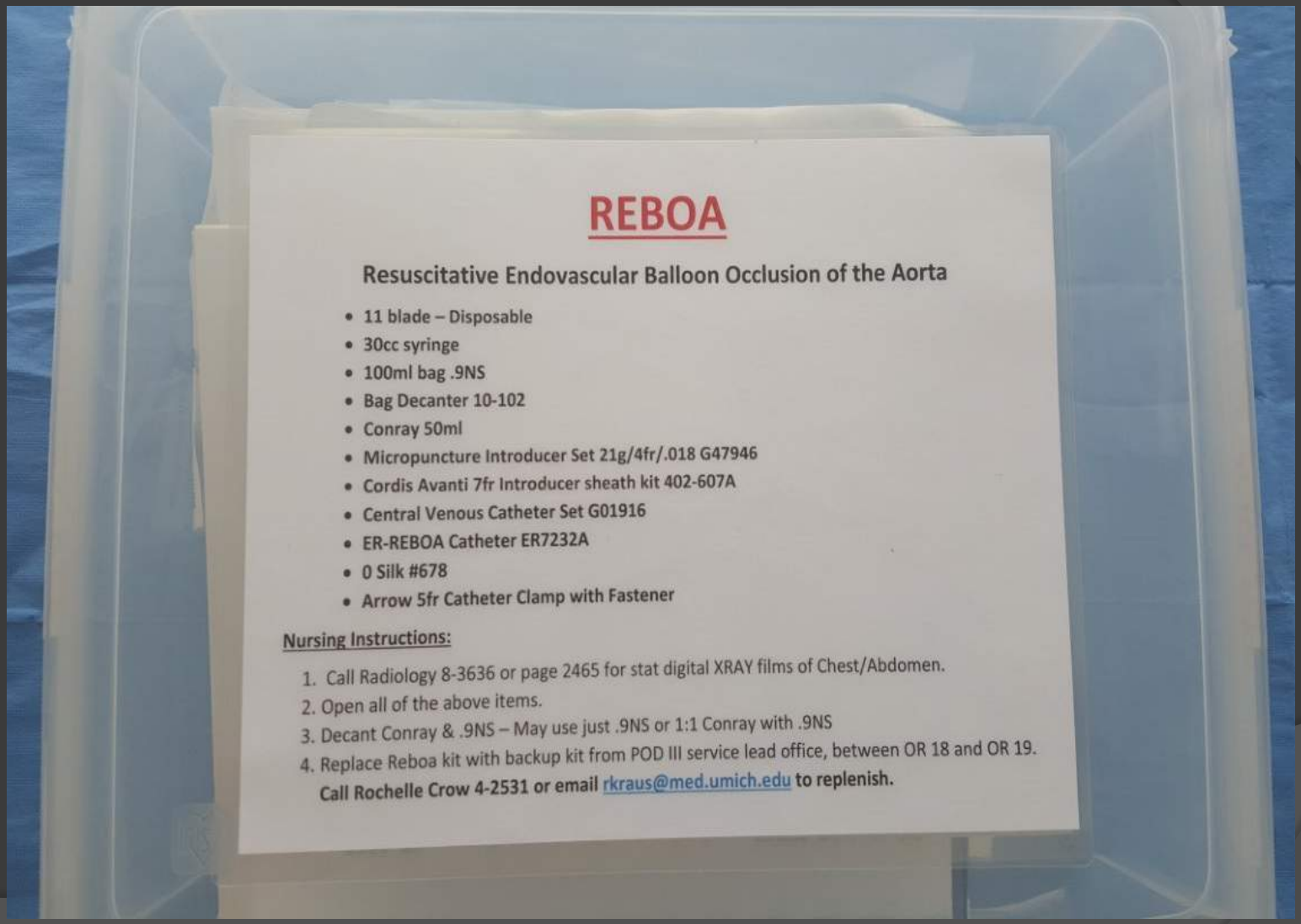
1. **Arterial access and Sheath Placement**
   a. Ulltrasound-guided common femoral arterial access with Micropuncture kit (21 gauge needle, 4 or 5 French catheter and dilator, 0.018 inch guidewire)
   b. Or Cook single lumen arterial line; or Femoral artery cut-down, proximal/distal control for direct puncture
   c. Insert 7-French Sheath (can upsize arterial line)
2. **Balloon selection and positioning**
   a. ER-REBOA catheter (32mm max balloon diameter)
   b. Flush ER-REBOA catheter with saline; connect arterial line to transduce while inserting
   c. Measure sheath to P-tip distance in cm REBOA: **Zone 1 approx 46 cm; Zone 3 approx 27cm**
   d. **Zone 1 P-tip sternal notch, balloon mid-sternum; Zone 3 P-tip xiphoid, balloon at umbilicus**
   e. Insert ER-REBOA to pre-measured distance
   f. Digital Xray to confirm REBOA balloon location
3. **Balloon inflation**
   a. Inflate balloon, tactile feedback
   b. **Zone 1 8cc; Zone 3 2cc "2 or 8, don't overinflate"**
   c. 30cc syringe; NS or ½ NS/Contrast; Max 24cc
   d. **Mark Inflation time**; Minimize balloon inflation time
   e. Suture catheter and sheath; transduce arterial line
   f. **Go to OR or IR for definitive hemorrhage control**
4. **Balloon deflation – Partial REBOA**
   a. Intermittent deflation of REBOA (Partial-REBOA) can be used to optimize visceral perfusion, goal SBP > 90 mm Hg
5. **Femoral Artery Sheath removal**
   a. HD stable, normal coagulation, withdraw balloon saline w/ 30cc empty syringe
   b. 30 min digital pressure at sheath site, keep patient supine for 6 hrs, no hip flexion
   c. Femoral arterial duplex at 24-72 hrs to evaluate patency of femoral artery

REBOA Intra-Aortic Balloon Placement for Hemorrhagic Shock

Balloon placement determined by injury/hemorrhage location:
Zone 1 Descending Thoracic Aorta (origin of left subclavian to celiac) for truncal hemorrhage
Zone 2 Para-visceral Aorta (celiac artery to lowest renal artery): **NO-OCCLUSION ZONE**
Zone 3 Infra-renal Aorta (lowest renal artery to aortic bifurcation) for pelvic/junctional bleeding.

References:
1. Stannard A, Eliason JL, Rasmussen TE. REBOA as an adjunct for hemorrhagic shock. J Trauma. 2011 Dec;71(6):1869-72
2. Brenner ML, Moore LJ, Dubose JJ, Tyson GH, et al. A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation. J Trauma Acute Care Surg. 2013 Sep;75(3):506-511.
3. Villamaria CY, Eliason JL, Napolitano LM, Stansfield B, Spencer JR, Rasmussen TE. An Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS™) Course: Curriculum Development, Content Validation and Program Assessment. American Association for the Surgery of Trauma; J Trauma Acute Care Surg 2014 Apr;76(4):929-35.
4. Dubose JJ, Scalea TM, Brenner M, et al. AAST AORTA Registry: Utilization/outcomes of REBOA. J Trauma 2016 Sep;81(3):409
5. Johnson MA, Neff LP, Williams TK, DuBose JJ, et al. P-REBOA: Clinical technique & rationale. J Trauma 2016 Nov;92:S133.

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN



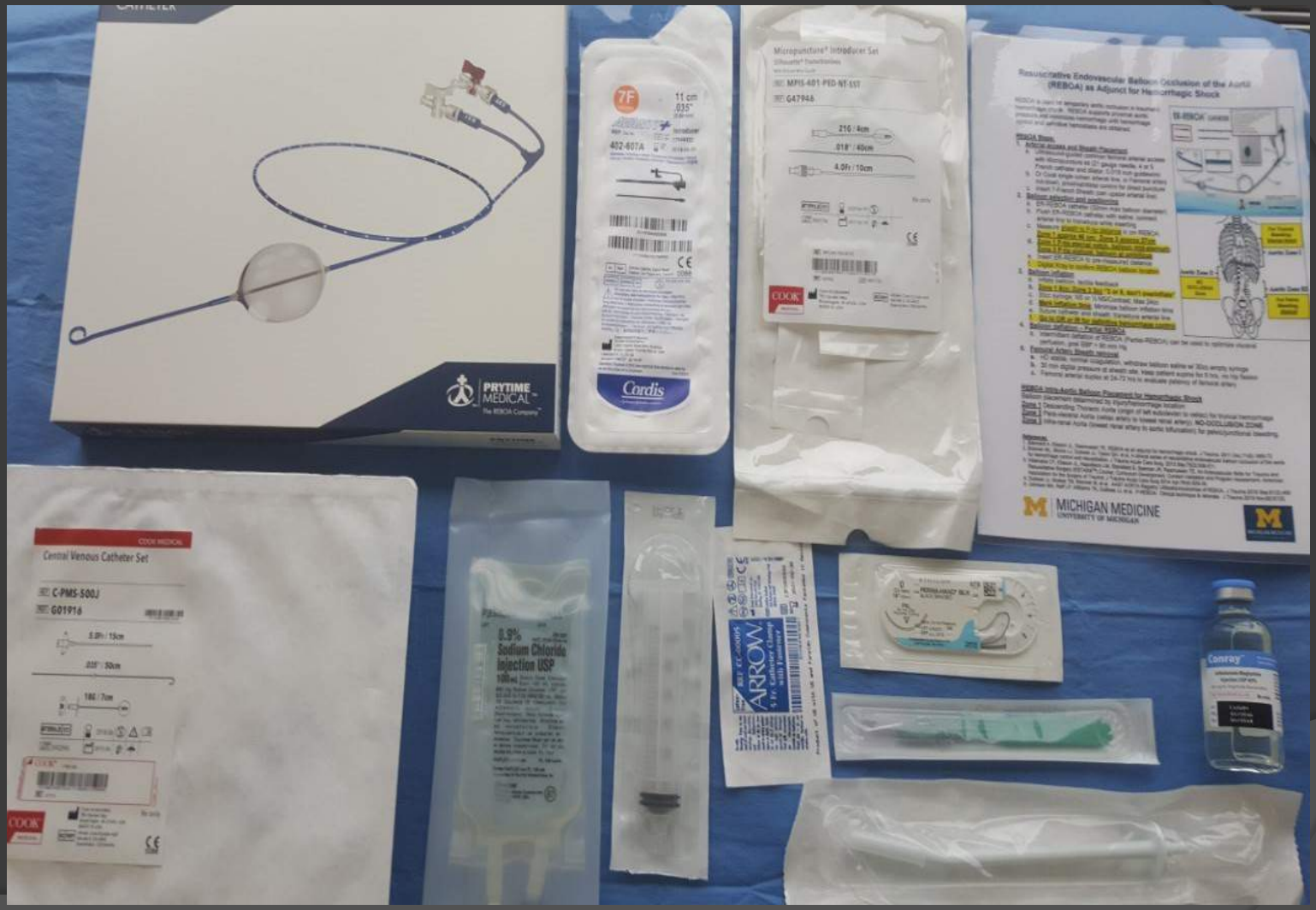
REBOA

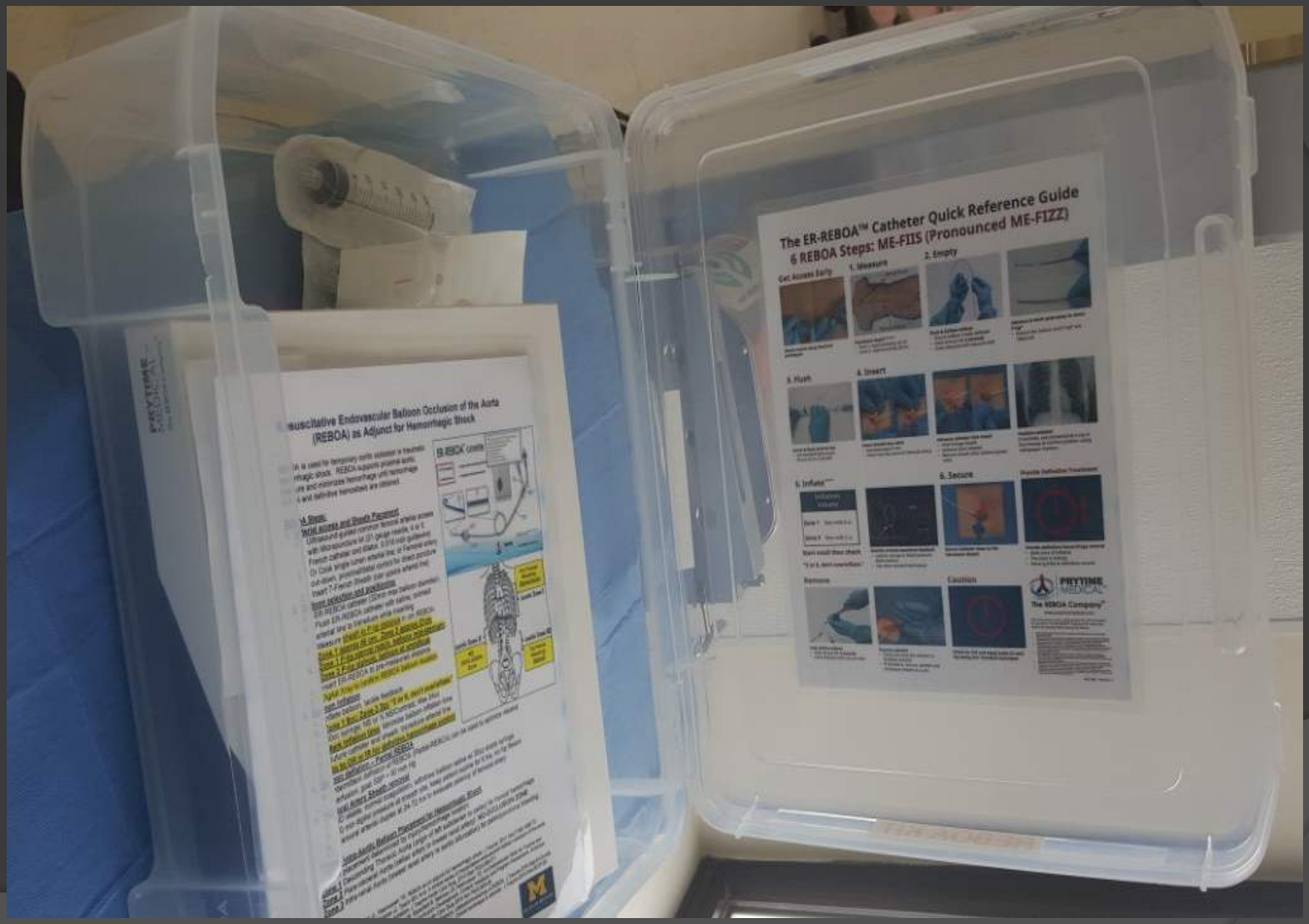
Resuscitative Endovascular Balloon Occlusion of the Aorta

- 11 blade – Disposable
- 30cc syringe
- 100ml bag .9NS
- Bag Decanter 10-102
- Conray 50ml
- Micropuncture Introducer Set 21g/4fr/.018 G47946
- Cordis Avanti 7fr Introducer sheath kit 402-607A
- Central Venous Catheter Set G01916
- ER-REBOA Catheter ER7232A
- 0 Silk #678
- Arrow 5fr Catheter Clamp with Fastener

Nursing Instructions:

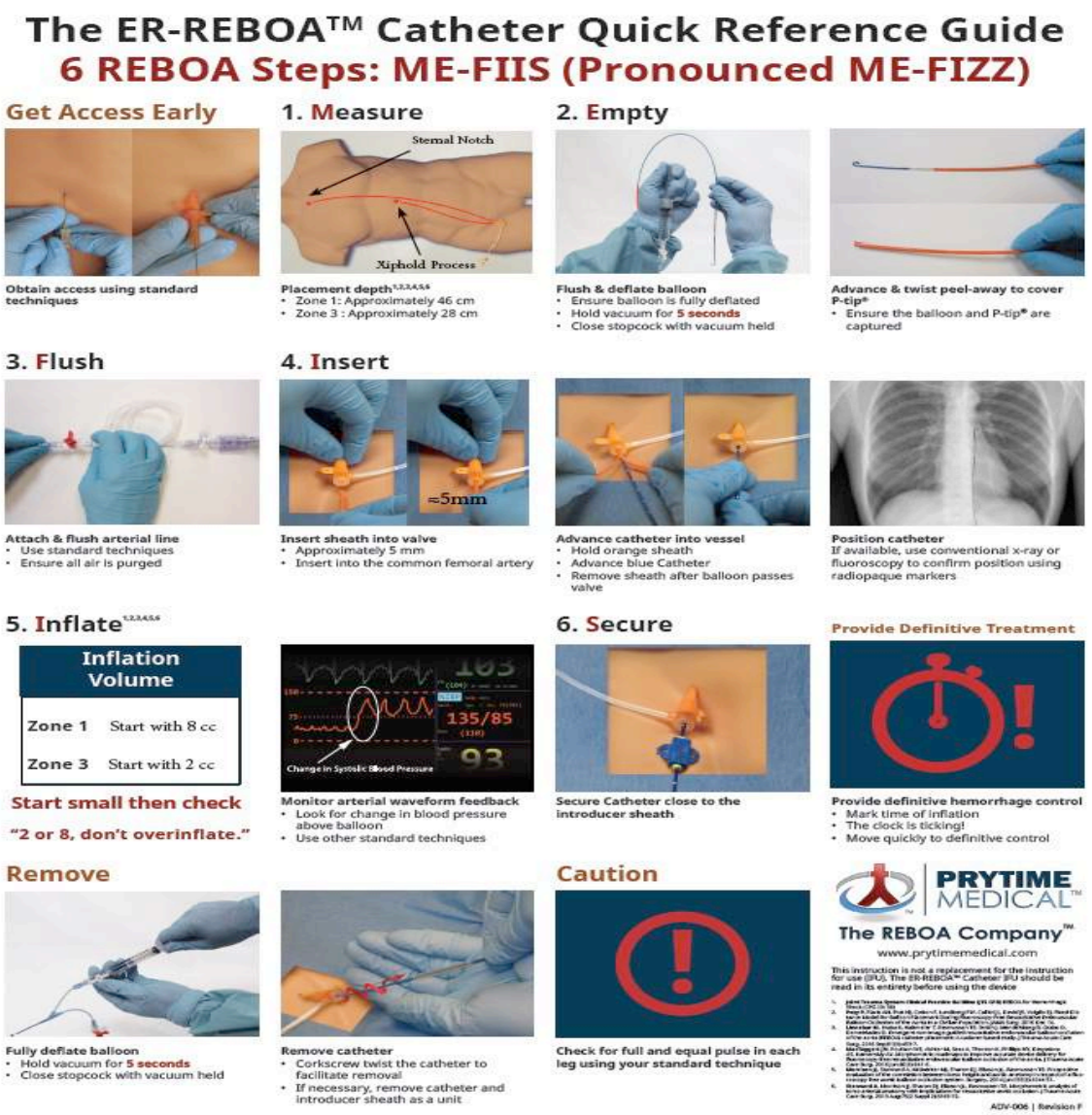
1. Call Radiology 8-3636 or page 2465 for stat digital XRAY films of Chest/Abdomen.
2. Open all of the above items.
3. Decant Conray & .9NS – May use just .9NS or 1:1 Conray with .9NS
4. Replace Reboa kit with backup kit from POD III service lead office, between OR 18 and OR 19.
   Call Rochelle Crow 4-2531 or email rkraus@med.umich.edu to replenish.


PRYTIME MEDICAL
Cordis
Micropuncture® Introducer Set
Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) as Adjunct for Hemorrhagic Shock
MICHIGAN MEDICINE
Central Venous Catheter Set
C-PMS-500J
G01916
0.9% Sodium Chloride Injection USP
ARROW
Conray


The ER-REBOA™ Catheter Quick Reference Guide
6 REBOA Steps: ME-FIIS (Pronounced ME-FIZZ)
Get Access Early
1. Measure
2. Empty
3. Flush
4. Insert
5. Inflate
6. Secure
Caution
PRYTIME MEDICAL
The REBOA Company
Resuscitative Endovascular Balloon Occlusion of the Aorta
(REBOA) as Adjunct for Hemorrhagic Shock

REBOA

- Consider inclusion of quick insertion guide in your REBOA kit



REBOA

- Royal London Hospital

Endovascular Skills for Trauma and Resuscitative Surgery

management of vascular trauma

ENDOVASCULAR SKILLS FOR TRAUMA AND RESUSCITATIVE SURGERY (ESTARS™) COURSE: Curriculum Development, Content Validation, and Program Assessment

Funding through Contract No FA8052-11C-0035 under BAA 11-01-HPW heading: Aerospace Medicine, Clinical Research, Human Performance Research, and Expeditionary Medicine

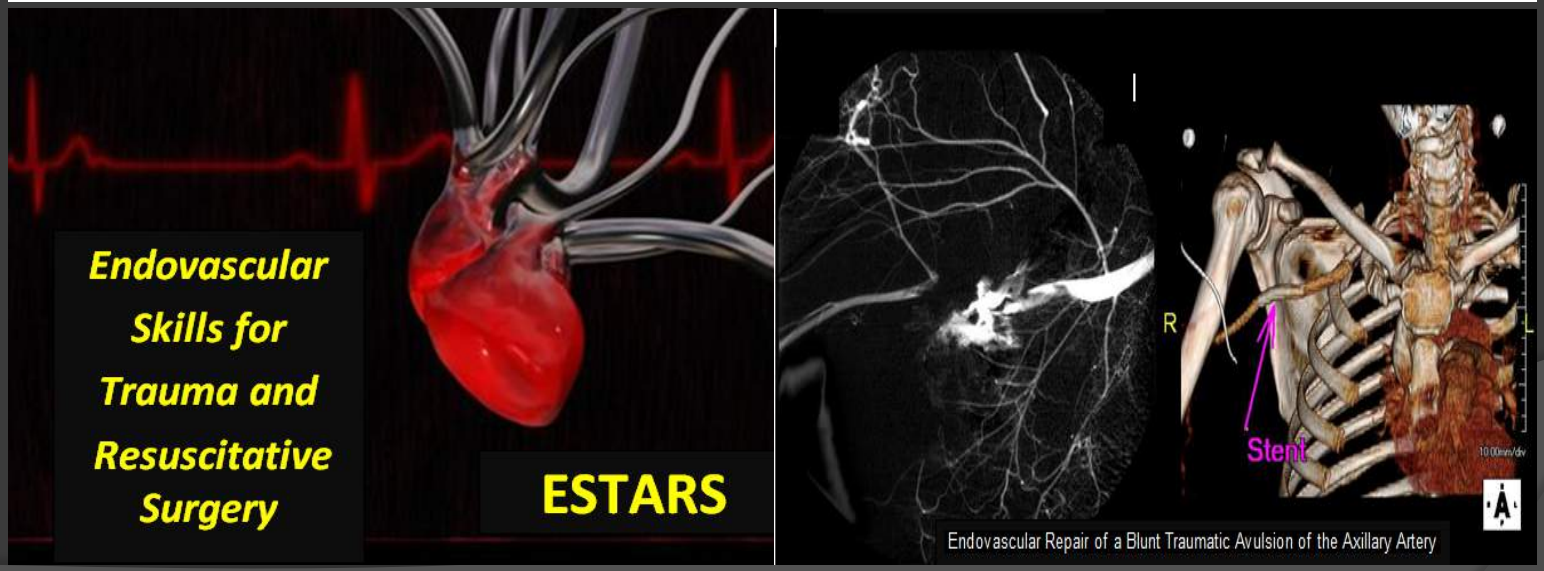
Jonathan L. Eliason MD, Lena M. Napolitano MD, Brent Stansfield PhD, Todd E. Rasmussen MD

Clinical Research Division, Lackland Airforce Base, San Antonio, TX

ORIGINAL ARTICLE

Endovascular Skills for Trauma and Resuscitative Surgery course: Curriculum development, content validation, and program assessment

Carole Y. Villamaria, MD, Jonathan L. Eliason, MD, Lena M. Napolitano, MD, R. Brent Stansfield, PhD, Jerry R. Spencer, BS, *and* **Todd E. Rasmussen, MD,** *Ann Arbor, Michigan*



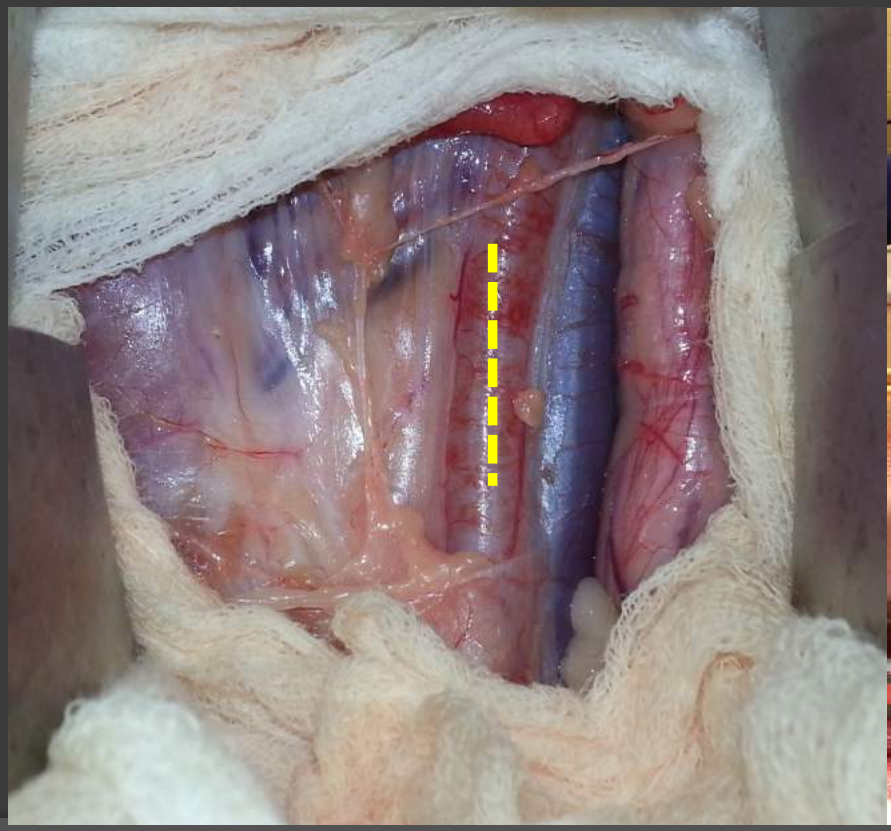
J Trauma Acute Care Surg. 2014 Apr;76(4):929-35.

ESTARS

Aortography

ESTARS

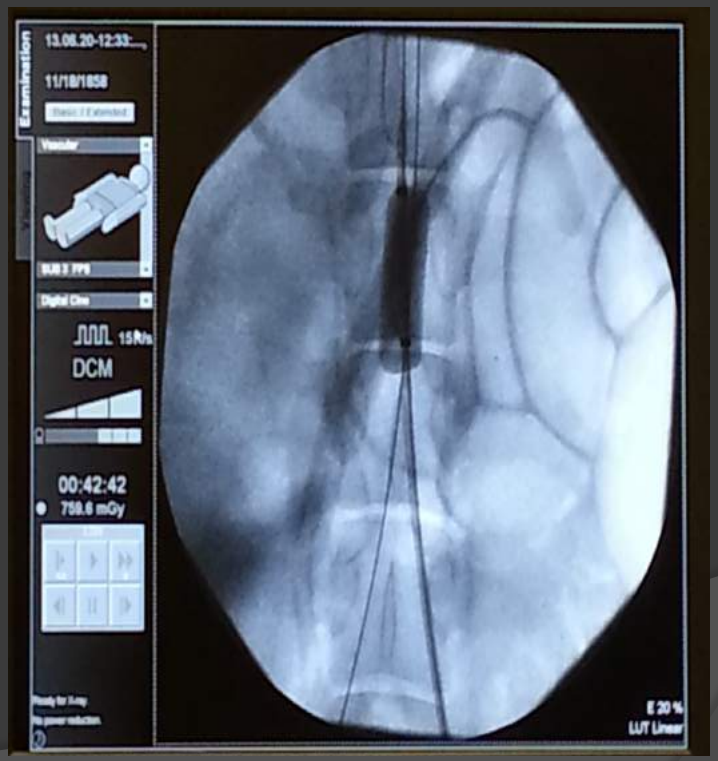
Injury of Iliac artery



Arterial hemorrhage

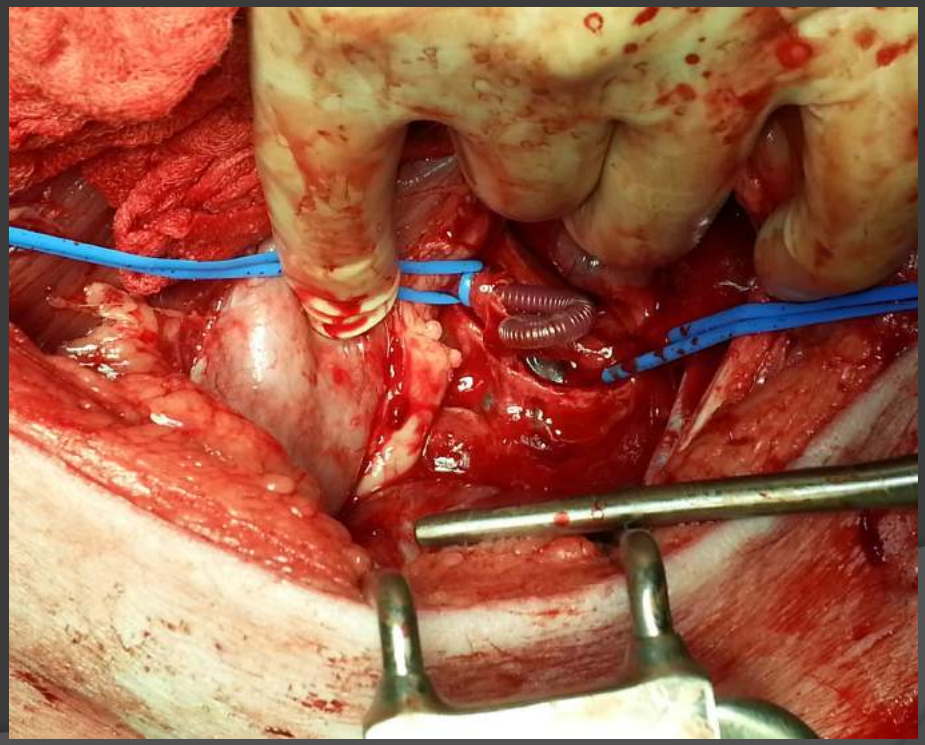
ESTARS

REBOA Balloon Occlusion for Hemorrhage Control

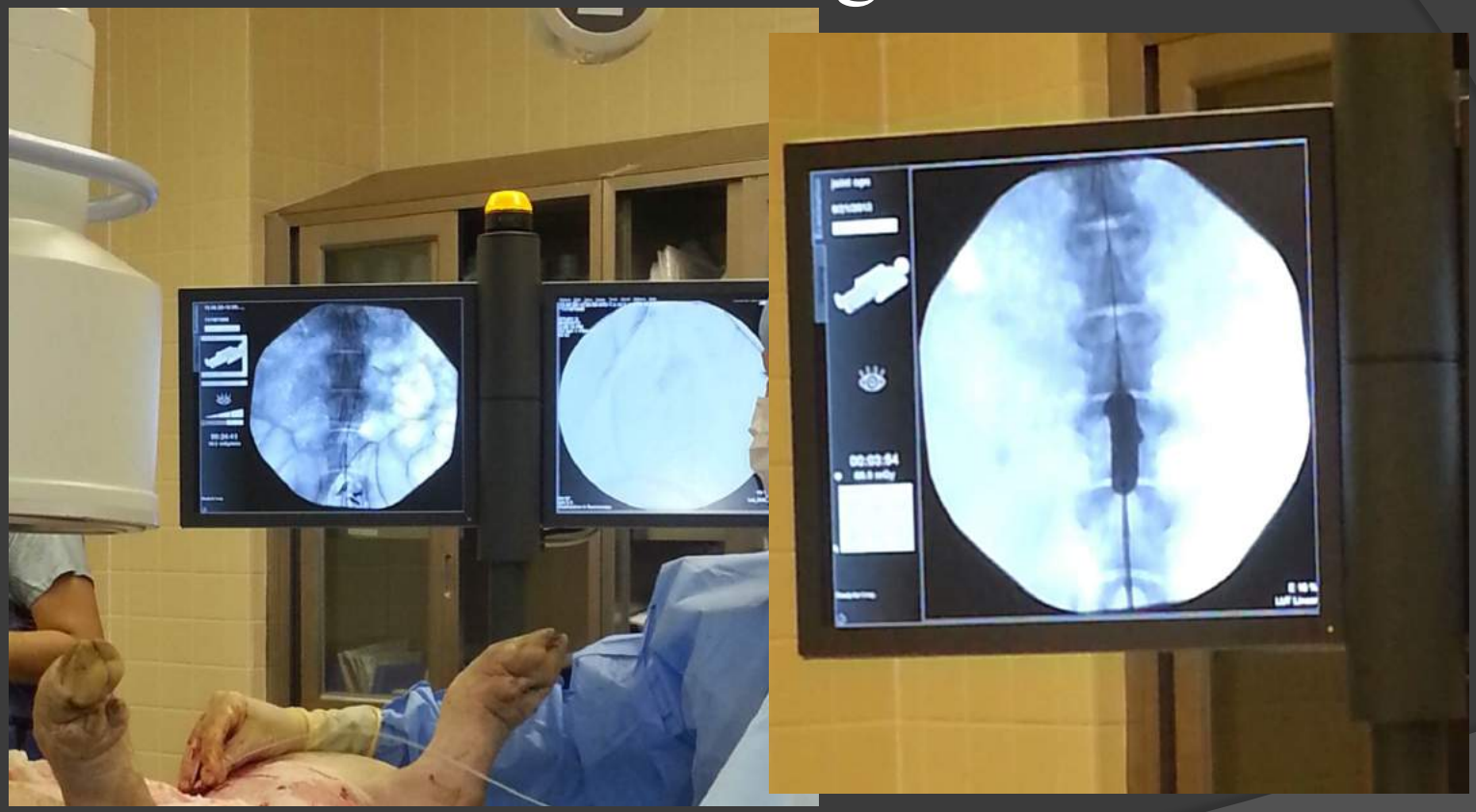


ESTARS

Iliac artery temporary vascular shunt placement
After proximal control of hemorrhage by REBOA



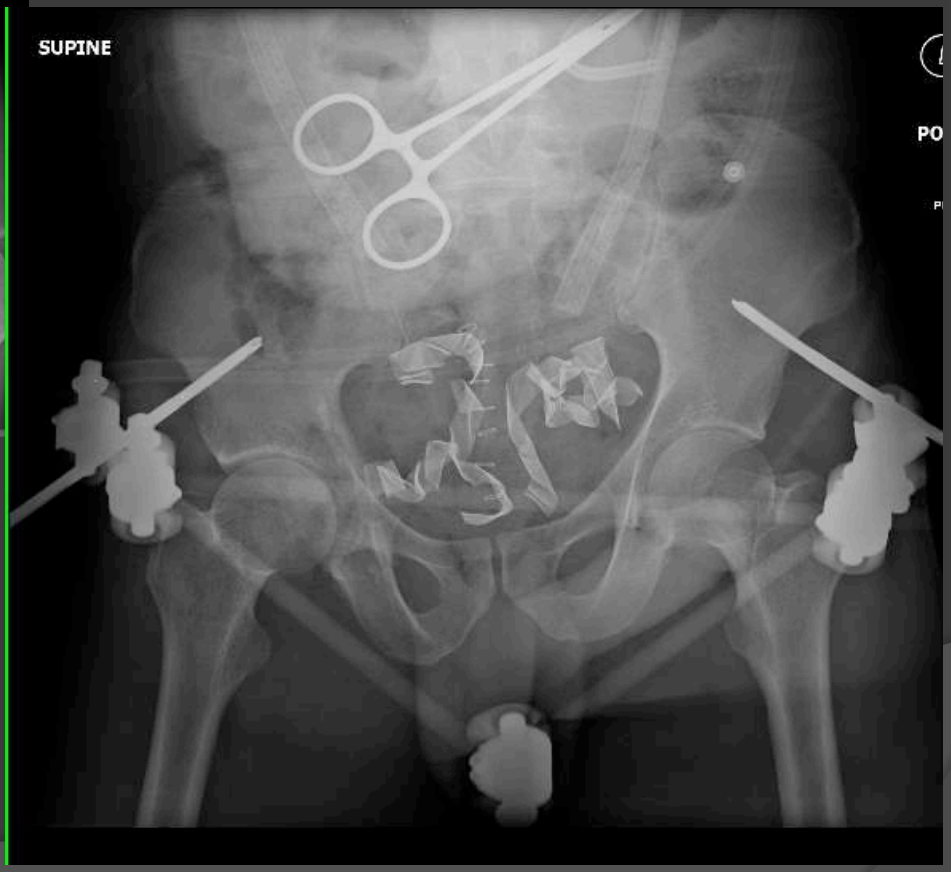
ESTARS Training: REBOA



Students were able to achieve first 3 steps of REBOA in 2 minutes (vascular access, balloon positioning, inflation)

Complex Pelvic Fractures

Complex Pelvic Fractures

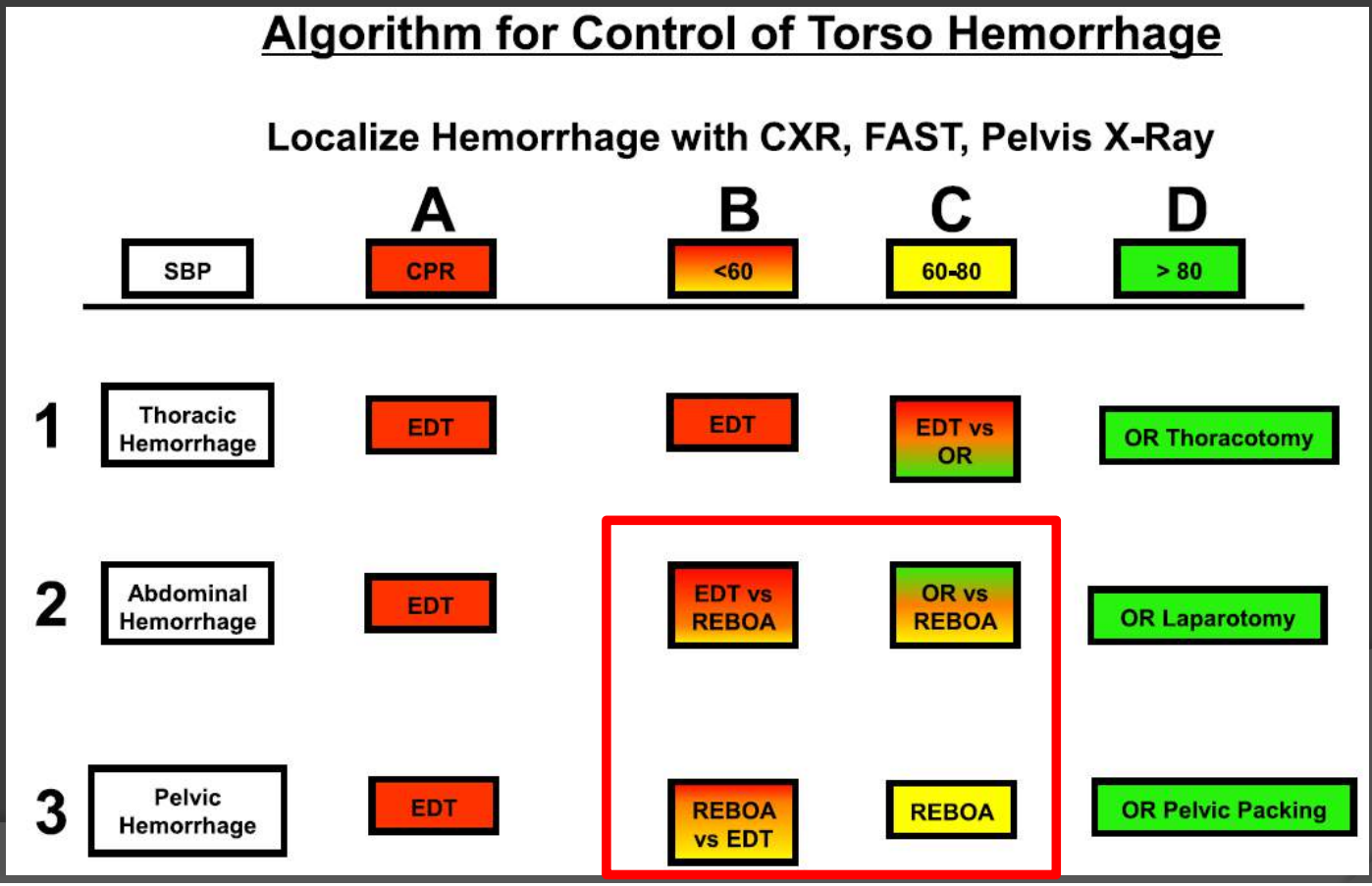


The role of REBOA in the control of exsanguinating torso hemorrhage

Walter L. Biffl, MD, Charles J. Fox, MD, *and* Ernest E. Moore, MD, *Denver, Colorado*

Algorithm for Control of Torso Hemorrhage

Localize Hemorrhage with CXR, FAST, Pelvis X-Ray



DHMC Algorithm: Management of Patient with Unstable Pelvic Fractures and Severe Hemorrhagic Shock

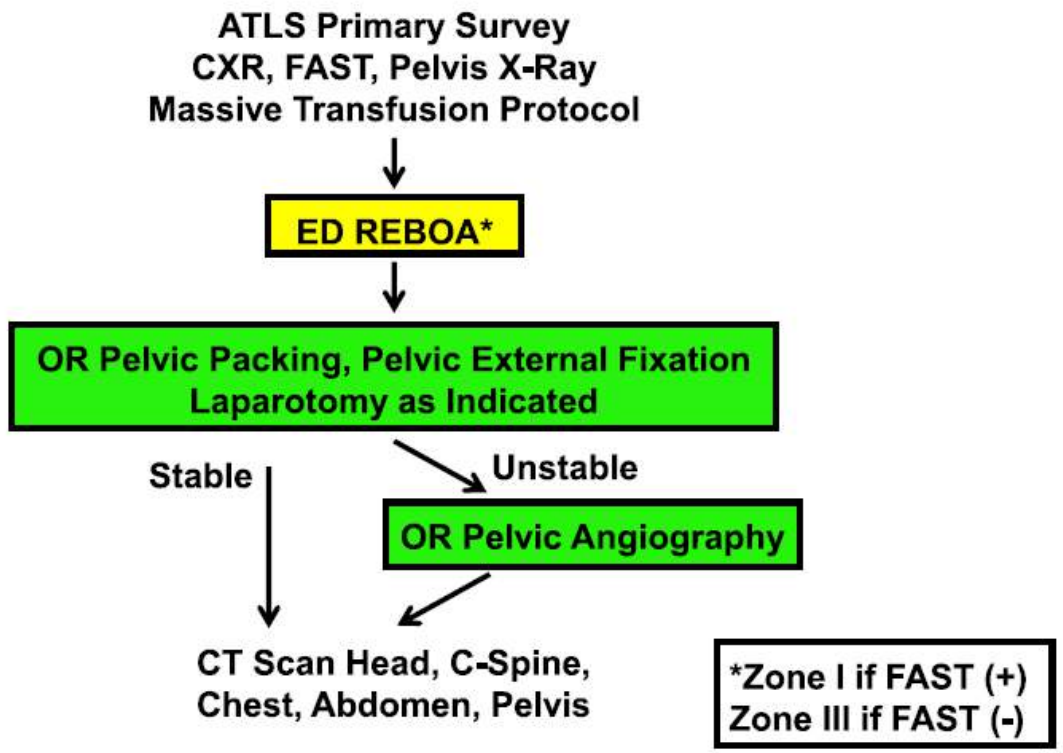


Figure 3. Revised Denver Health Medical Center (DHMC) algorithm for the management of hemodynamically unstable patients with mechanically unstable pelvic fractures. ATLS, advanced trauma life support.

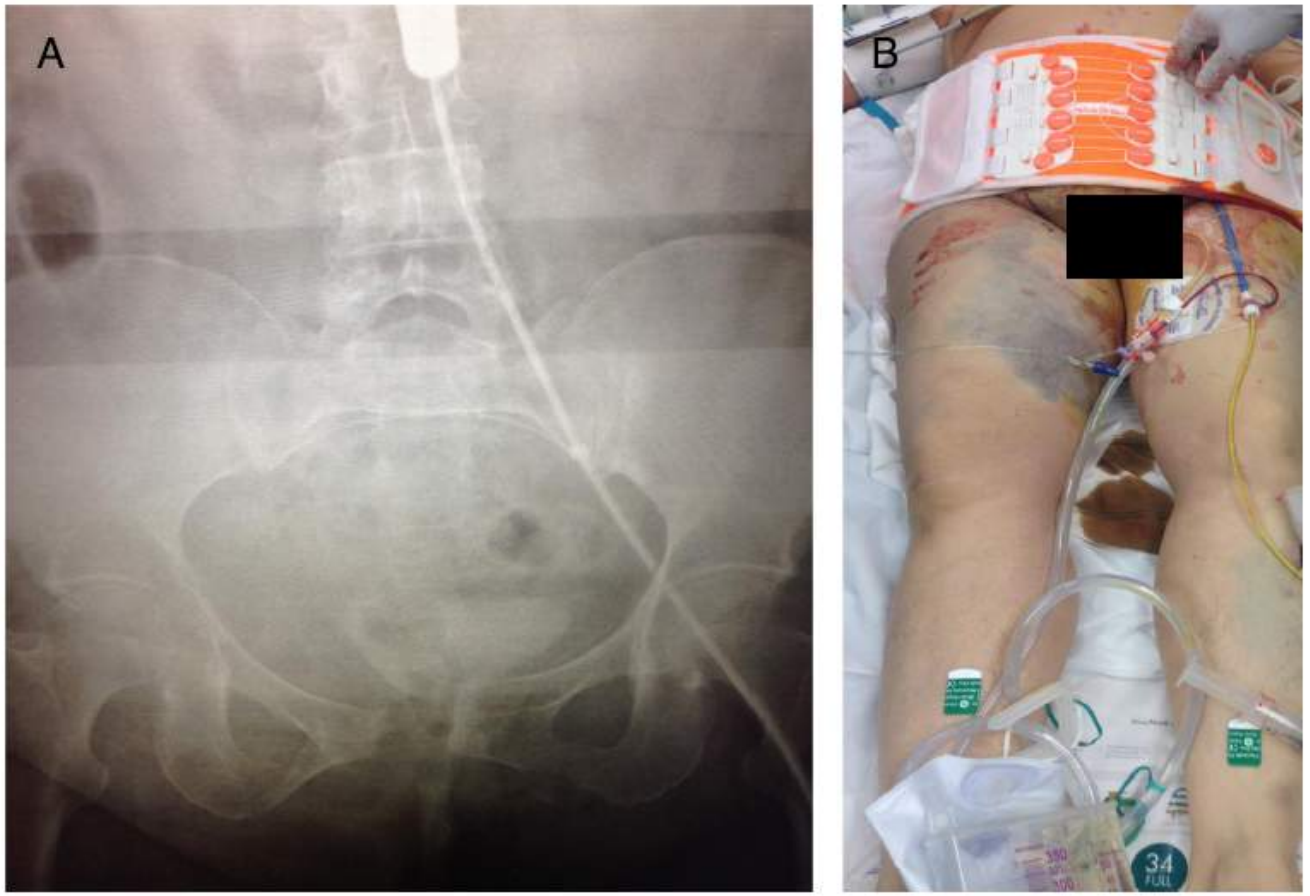


Figure 4. (*A*) Plain x-ray in ED demonstrating REBOA balloon inflated in REBOA Zone III. (*B*) Patient with pelvic binding device secured and REBOA catheter in place in left common femoral artery.

- 60 yo F
- MVC
- Unstable pelvic fx
- CT with traumatic lumbar hernia, right CFA injury
- Tx to Level I
- SBP 50mm
- REBOA Left CFA
- OR for pelvic packing and ExFix Pelvis, pelvic arteriography in OR, vascular repair

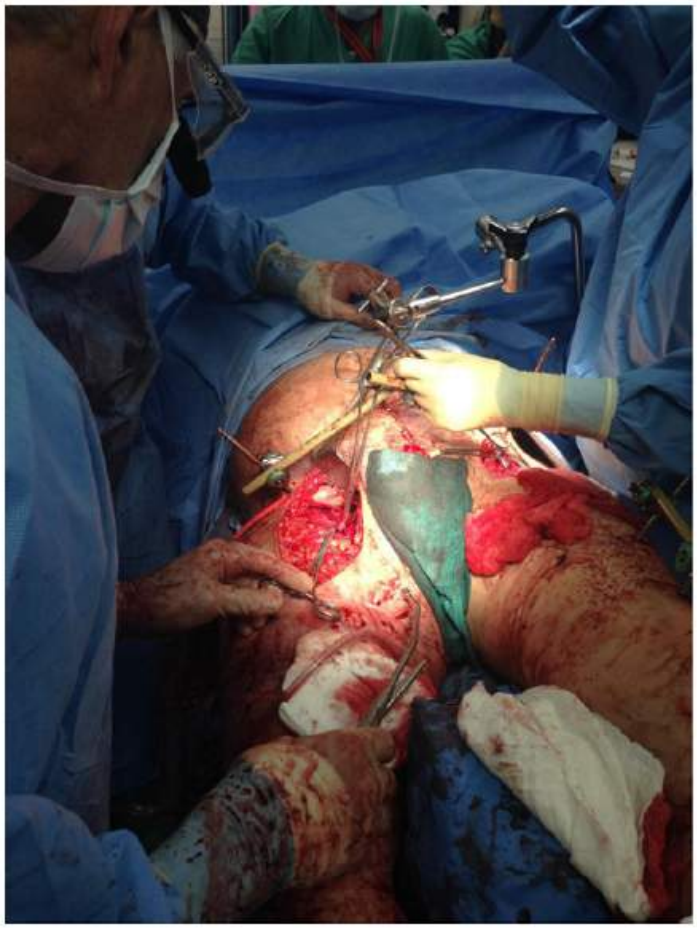


Figure 6. Repair of right common femoral artery. Anterior external fixation device is in place, REBOA has been removed, and the left common femoral artery has been repaired.

Exsanguinating pelvis: Occlude the aorta

Attachments... Police.ppt (2 MB) [Open as Web Page]

From: Moore, Ernest MD [Ernest.Moore@dhha.org]
Sent: Friday, December 11, 2015 5:26 PM
To: Napolitano, Lena (Lena)
Subject:

Your education in San Antonio saved this officers life; 44 mag x 7, no BP on arrival
Best regards

The Denver Health email system has made the following annotations
----------CONFIDENTIALITY NOTICE - T


Revolutionary surgical procedure saves life of Denver police officer
Doctors at Denver Health use new method for Officer Tony Lopez Jr.
DENVER
ONLY ON FOX31
DR. CHARLES FOX
DENVER HEALTH MEDICAL CENTER, CHIEF OF VASCULAR SURGERY

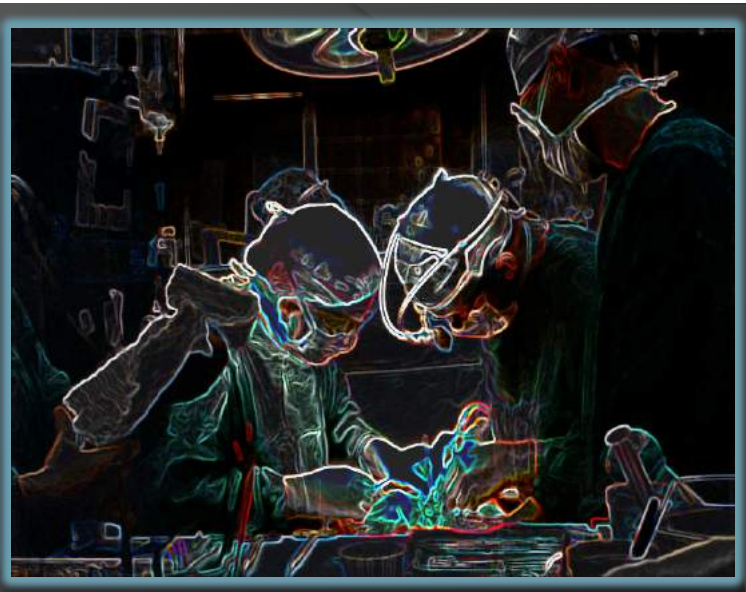
Denver Police officer Tony Lopez Jr. takes first steps after traffic stop shooting

BY: TheDenverChannel.com Team
POSTED: 7:45 PM, Dec 16, 2015
UPDATED: 10:09 PM, Dec 16, 2015
TAG: denver police | officer involved shooting | tony lopez jr.

Shot Denver Police officer Tony Lopez, Jr., released from Denver Health

BY: TheDenverChannel.com Team
POSTED: 1:48 PM, Dec 31, 2015
UPDATED: 10:48 PM, Dec 31, 2015
TAG: denver police | officer shot | tony lopez jr

- **12/11 Admit**
- **12/31 D/C**



CASE #1

Case #1

- 20 yo male
- Motorcycle crash at high speed
- GCS 15, neurologically intact
- SBP 90/60, HR 120
- Arterial oxygan saturation 99%
- Pelvis unstable by physical exam

- FAST exam negative

Case #1

- Hemostatic resuscitation initiated
- Initially transient responder
- Placed femoral arterial line - micropuncture
- **Non-responder**
- **BP 75/60, HR 130**
- **REBOA deployed in ED**
- **To IR for Pelvic angioembolization**
- Arterial oxygen saturation 90%
- Endotracheal intubation AFTER Reboa

University of Michigan Health System

Case #2
Prehospital / Trauma Bay

- 31 yo M, found in middle of a road after being hit by a car at 55mph, ped struck
- At scene, hypotensive, tachycardic, GCS 4
- BMV, O_2 sat 100%, intubated
- Access: IO x 1, IV x 1, MTP 1:1:1
- HR 120, palpable femoral pulse, sat 100%
- Femoral arterial line, femoral venous cordis
- pH 6.9, lac 7.9, HCO3 11

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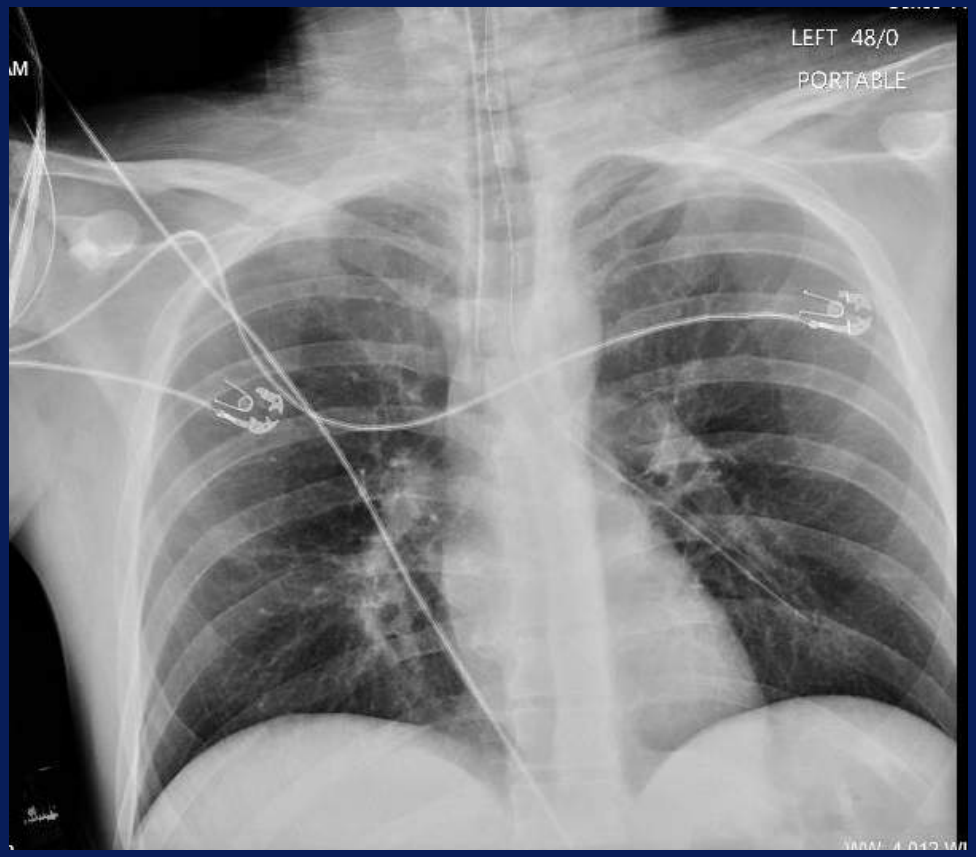
Resuscitation Bay



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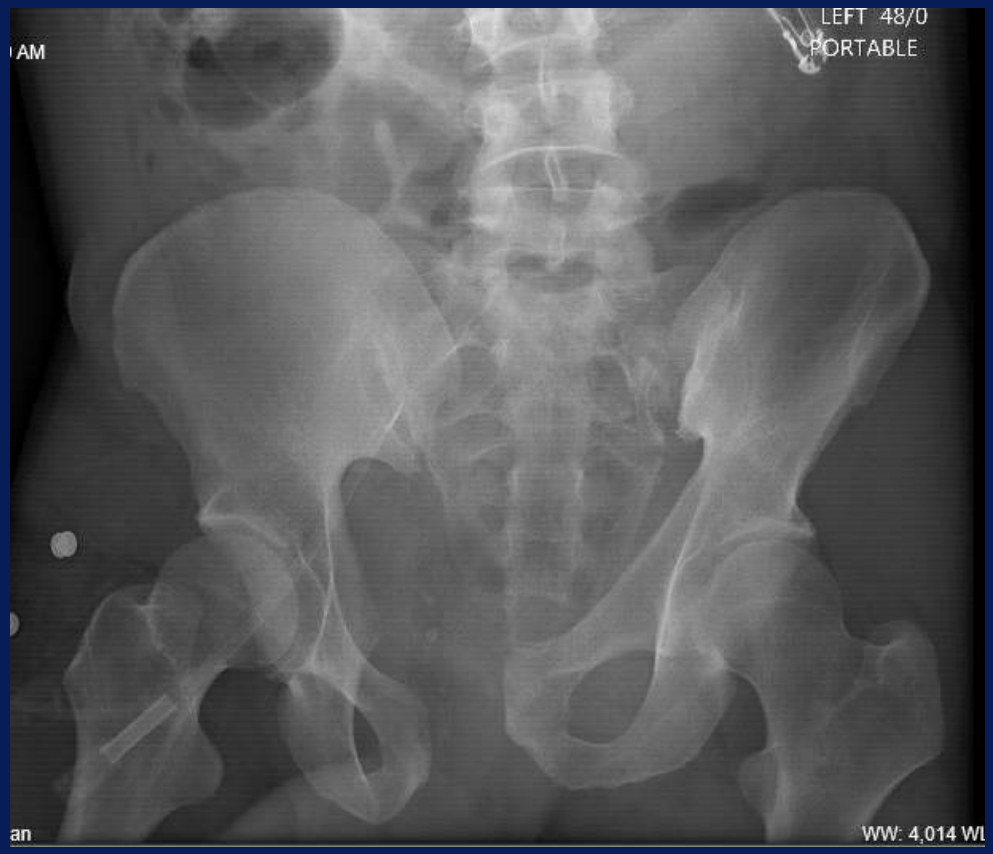
Resuscitation Bay



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Resuscitation Bay

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To OR for Ex-lap

- After transfer to OR bed, sudden loss of BP, ACLS 30 seconds
- **REBOA inflated Zone 1**
- **SBP 70 increased to SBP 110**
- Ex-lap
  - No solid organ injury
  - Mesenteric arterial hemorrhage, vascular ligation
- **REBOA moved to Zone 3 for pelvic bleeding**
- **Pelvic Preperitoneal packing (IR not ready)**

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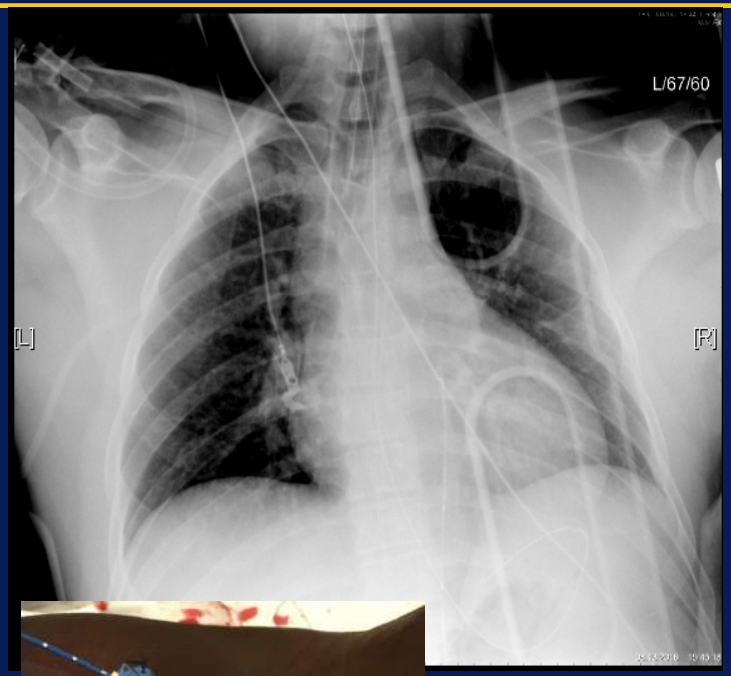
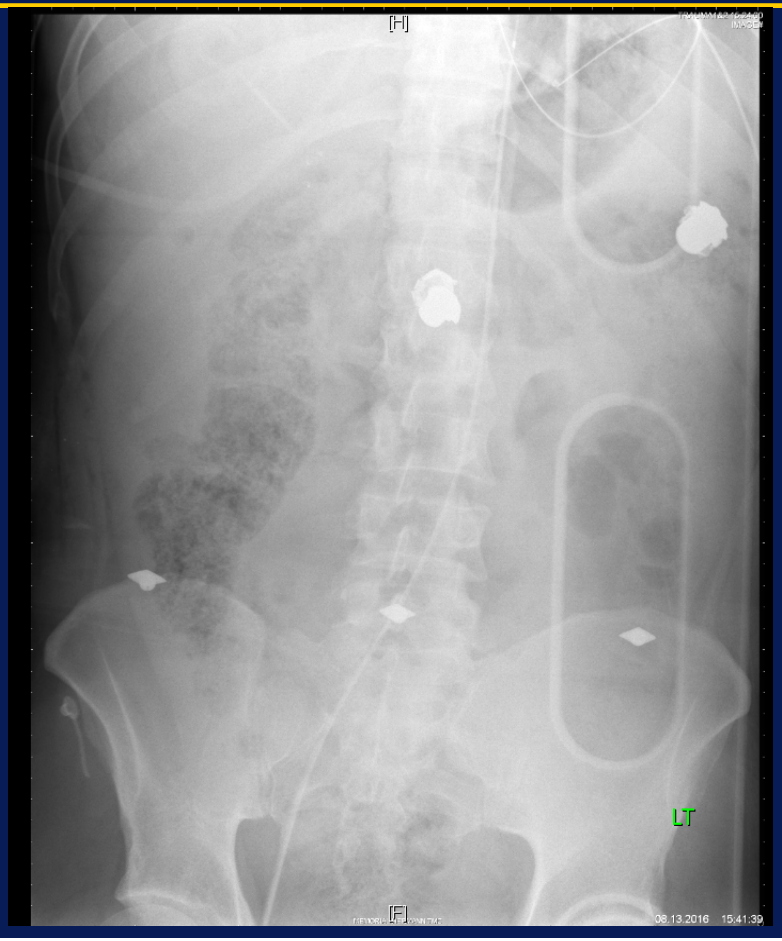
ER–REBOA – ZONE 1





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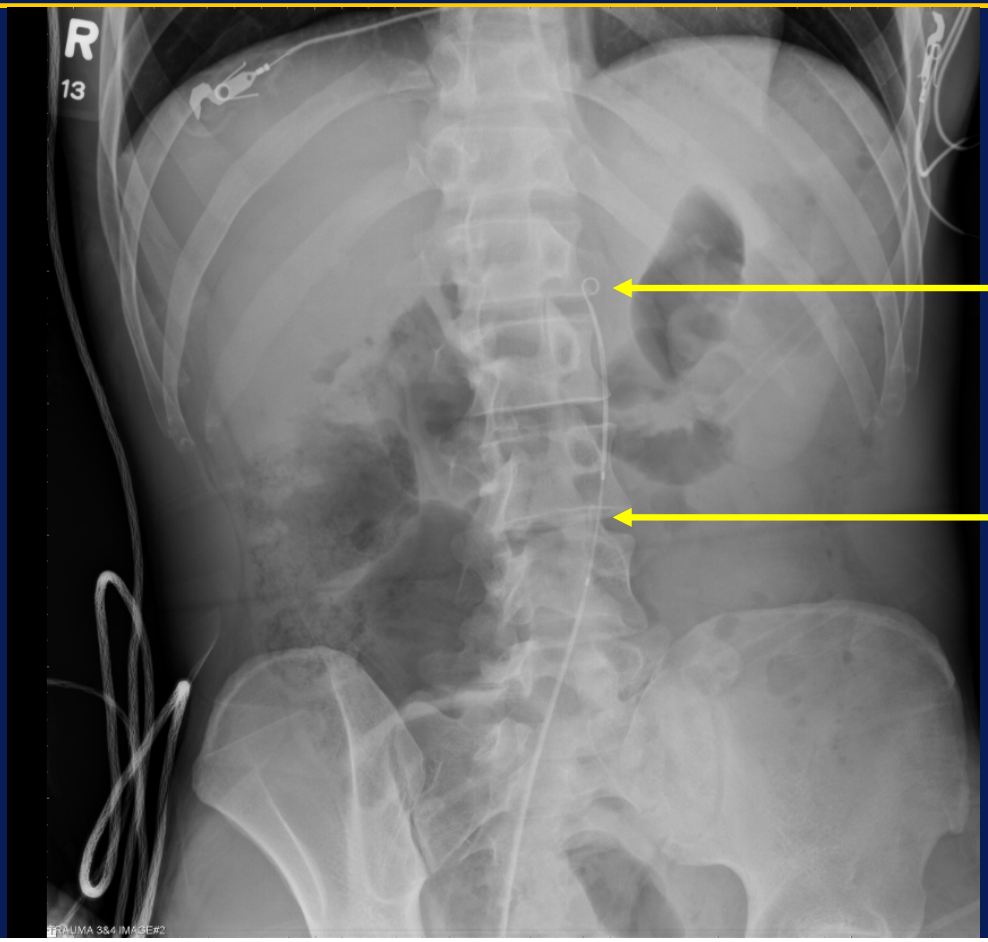
ER-REBOA – ZONE 3



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B/L internal iliac artery embolization

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ICU – Critical REBOA Adjuncts

- Continued **<u>hemostatic resuscitation</u>**
  - –Hypothermia: 33°C -> 37°C
  - –Acidosis: pH 6.9 -> 7.4, HCO_3 11->24
  - –1:1:1 blood products, minimal crystalloid
  - –Coagulopathy
    - TXA
    - Rotem
    - Calcium

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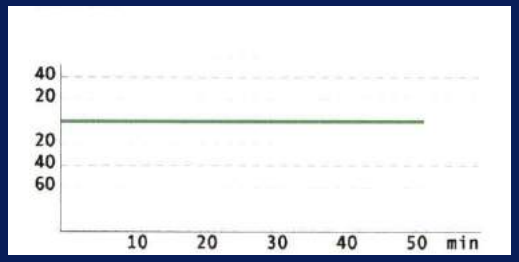
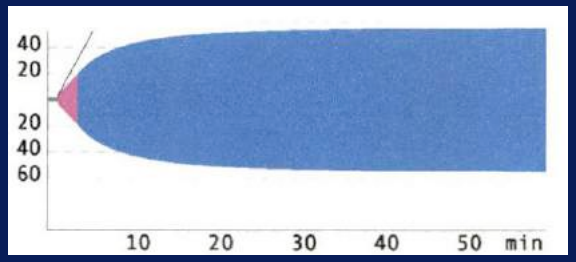
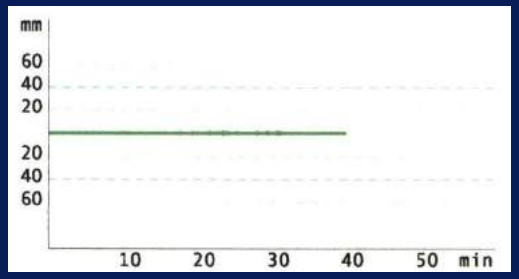
ROTEM

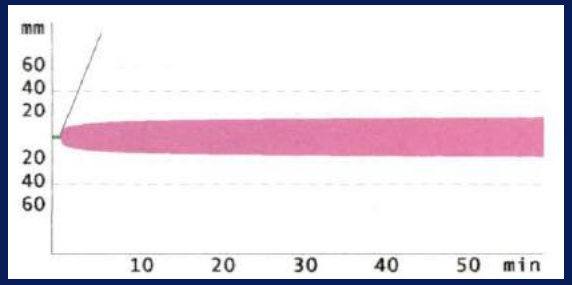
Extem



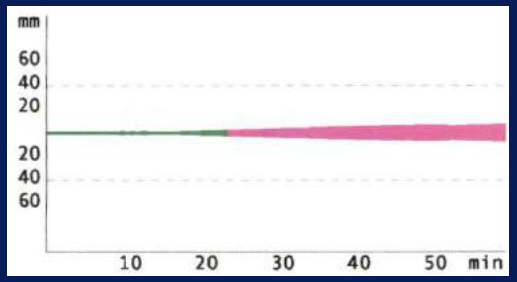


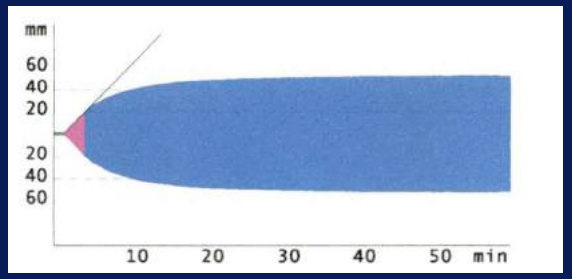
Fibtem





Aptem





Arrival

Post-IR

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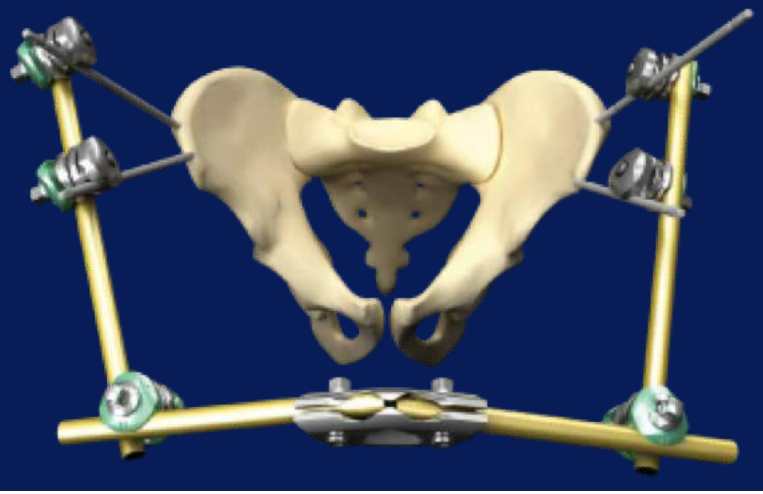
Ex-lap #2

- 2L intraperitoneal blood evacuated
- Bleeding from mesenteric defect controlled
- Packs removed, no ongoing bleeding
- Pelvic ex-fix (Ortho)
- Abthera Abc VAC



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Head CT

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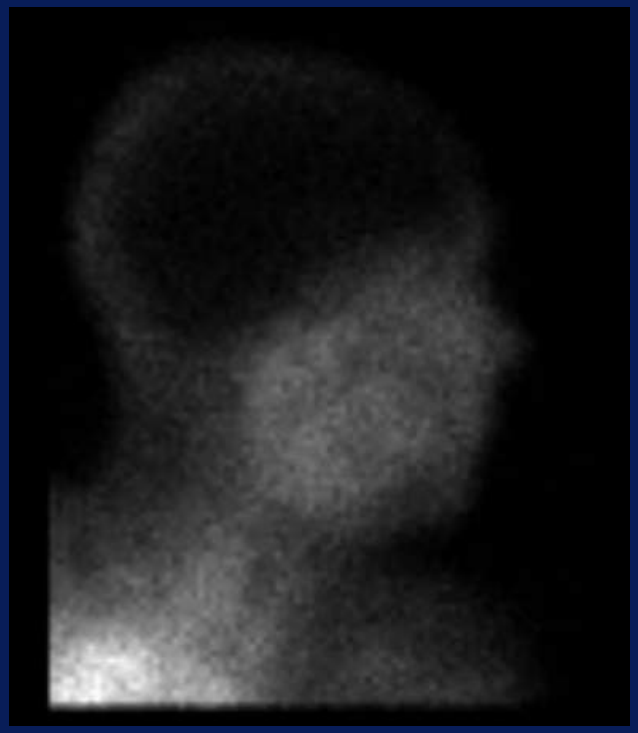
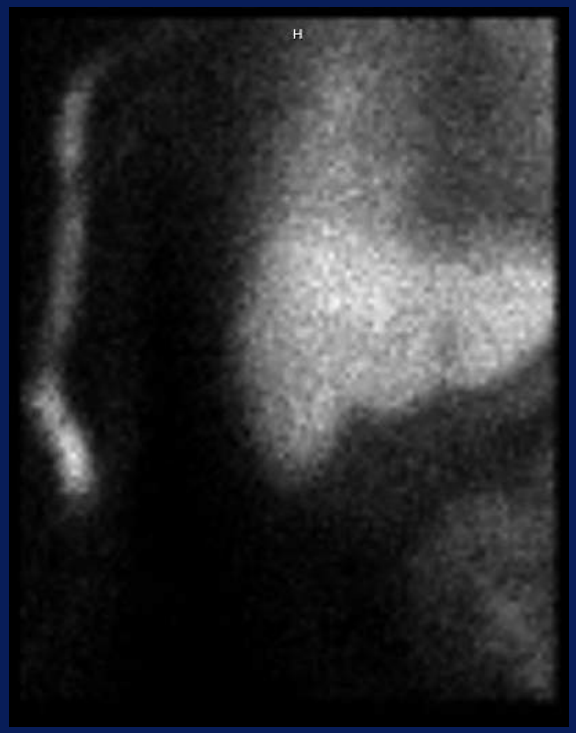
Brain Scan / Gift of Life





Donated heart and liver to in-house recipients

Prehospital REBOA

- London's Air Ambulance Crew
- 1st used in UK by Royal London Hospital
- 2 yrs later…
- Modified technique for prehospital use

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16 June 2014 Last updated at 22:11 ET

Share

Balloon surgery stops fatal bleeding at roadside

By Smitha Mundasad
Health reporter, BBC News

London's Air Ambulance aim to bring the emergency department to the roadside

London's Air Ambulance crew have become the first team in the world to use a balloon device to control catastrophic bleeding at the roadside.

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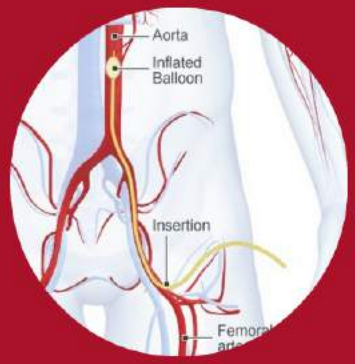
World's first pre-hospital REBOA performed

Monday 16th June 2014



- World's first pre-hospital REBOA carried out by London's Air Ambulance
- Pioneering new technique to prevent trauma patients bleeding to death
- Control of severe pelvic haemorrhage, an injury most commonly associated with cycling incidents and falls from height
- 2 years of development with The Royal London Hospital
- Boris, "stunning advances in medical care are helping people survive serious injury in London"

We have performed the world's first roadside balloon surgery to control internal bleeding. Use of pre-hospital Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA), a technique used first in the UK at The Royal London Hospital, to control haemorrhage in trauma patients is a ground breaking move by London's Air Ambulance.

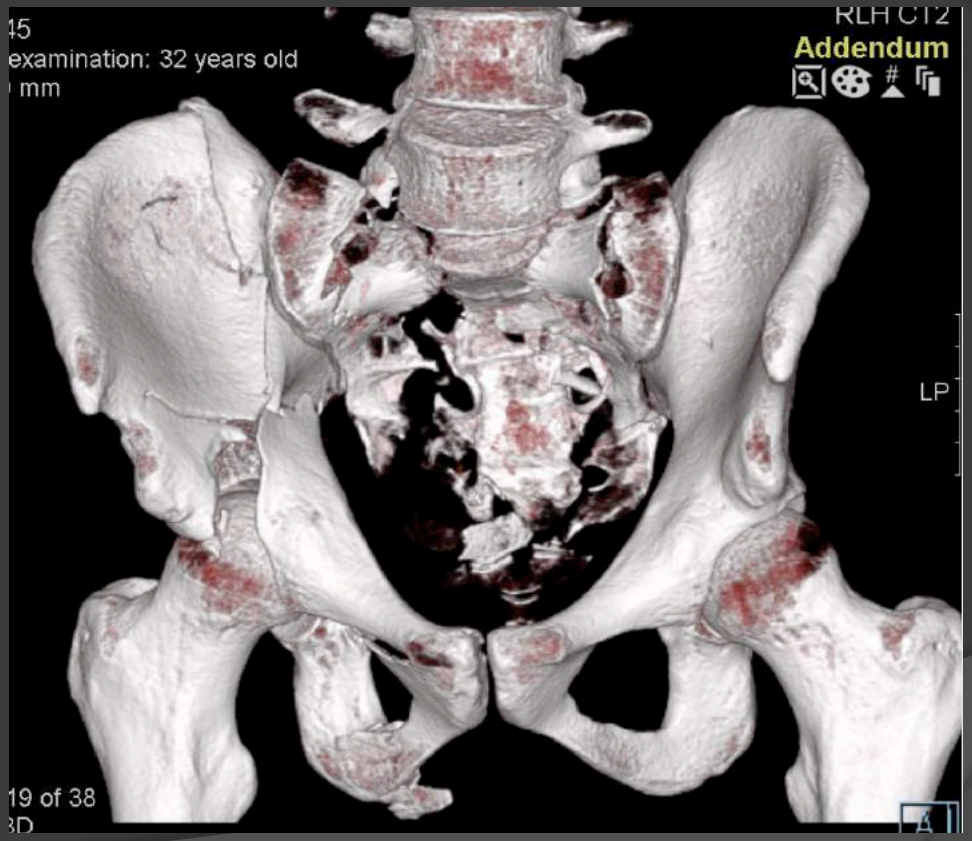
Prehospital REBOA

- 32yo M fell 15 meters on concrete, catastrophic internal hemorrhage due to pelvic fractures.
- He was treated by the Physician-Paramedic team with insertion of a REBOA balloon catheter at the scene to control likely fatal exsanguination.
- He survived transfer to hospital, emergency angioembolization and subsequent surgery.
- He was discharged neurologically normal after 52 days and went on to make a full recovery.

Sadek S. et al. Resuscitative endovascular balloon occlusion of the aorta (REBOA) in the pre-hospital setting: An additional resuscitation option for uncontrolled catastrophic haemorrhage. Resuscitation. 2016 Jul 1. [Epub ahead of print]

Prehospital REBOA

- Team arrived 34 min after injury
- **No BP, HR 130**
- Intubation
- Resuscitation
- 6u PRBCs
- TXA, splint pelvis
- Closest trauma ctr 30 minutes
- **REBOA 7 Fr**



Balloon catheter with guide-wire in situ

REBOA balloon at terminal aorta

Field REBOA

EMCrit Blog

A Discussion of the Practice of ED Critical Care

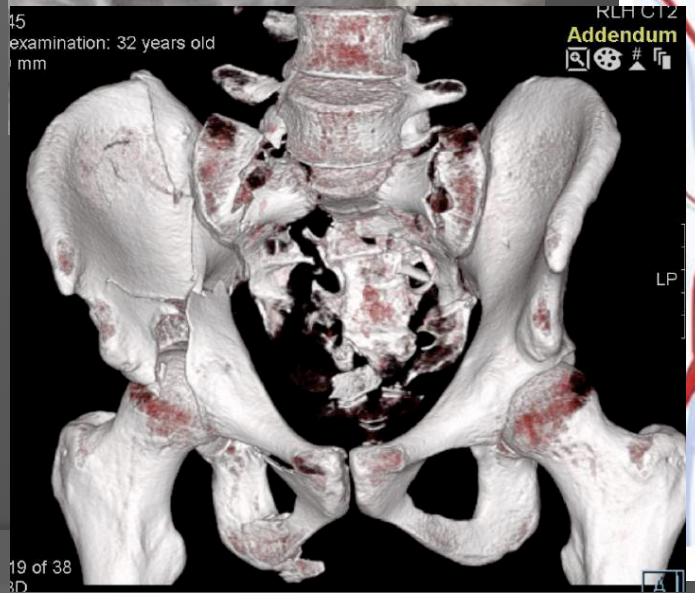
Resuscitative Endovascular Balloon Occlusion of Aorta

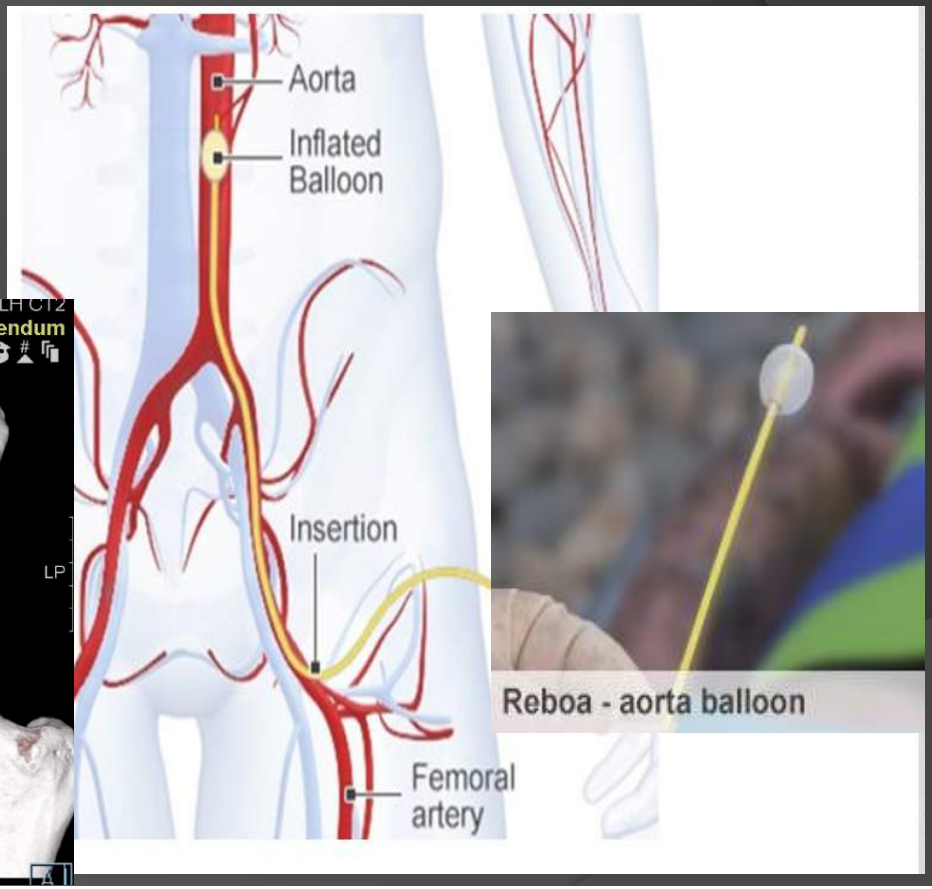
EMCrit Podcast 121 – REBOA

Exsanguinating Torso Hemorrhage

- The most appropriate means of prompt torso hemorrhage control must be tailored to the clinical situation
- Trauma surgeons should have expertise with all approaches:
  - **Resuscitative thoracotomy**
  - **Trauma laparotomy**
  - ***REBOA***

REBOA: ESSENTIAL!





Resuscitative Endovascular Balloon Occlusion of the Aorta: Indications, Outcomes, and Training

Lena M. Napolitano, MD, FCCP, MCCM

KEYWORDS

- Resuscitative endovascular balloon occlusion of aorta • Hemorrhagic shock
- Aortic occlusion • Aortic balloon • Noncompressible torso hemorrhage
- Resuscitative thoracotomy

KEY POINTS

- Resuscitative endovascular balloon occlusion of aorta (REBOA) is an adjunct to trauma hemorrhage control; it provides early aortic occlusion to improve blood pressure and sta-

Critical Care Clinics 2017

Endovascular Skills for Trauma and Resuscitative Surgery

management of vascular trauma

- **<u>Endovascular / REBOA Trauma Education:</u>**

- National Standardized education and training
- <u>Competency-based</u> education
- Take a Course!

- ***<u>REBOA Implementation:</u>***
- Get examples of REBOA protocols / kits from others

- REBOA Module to be added to ASSET and ATOM ACS Courses soon

GUIDELINES

Current opinion on catheter-based hemorrhage control in trauma patients

John B. Holcomb, MD, Erin E. Fox, PhD, Thomas M. Scalea, MD, Lena M. Napolitano, MD, Rondel Albarado, MD, Brijesh Gill, MD, Brian J. Dunkin, MD, Andrew W. Kirkpatrick, MD, Bryan A. Cotton, MD, Kenji Inaba, MD, Joseph J. DuBose, MD, Alan M. Cohen, MD, Ali Azizzadeh, MD, Megan Brenner, MD, Mitchell J. Cohen, MD, Charles E. Wade, PhD, Alan B. Lumsden, MD, Richard Andrassy, MD, Peter M. Rhee, MD, MPH, Barbara L. Bass, MD, Kenneth L. Mattox, MD, L.D. Britt, MD, A. Brent Eastman, MD, David B. Hoyt, MD, Todd E. Rasmussen, MD, *and* the Catheter-Based Hemorrhage Control Study Group, *Houston, Texas*

COMPETENCY AND CREDENTIALING IN CATHETER-BASED HEMORRHAGE CONTROL

At present, no common standard for competency/credentialing exists for endovascular interventions for catheter-based hemorrhage control, but we must work toward this goal for the future, being certain to include the trauma and acute care surgeons in the provider group.

J Trauma Acute Care Surg. 2014 Mar;76(3):888-93

First Endovascular Hemorrhage Control Course at American College of Surgeons Clinical Congress 2015

SSC08 | Endovascular Skills for Hemorrhage Control

Track: VAS
6 Hours, Verification Level III
Monday, October 5, 2015 | 10:00 am–5:15 pm

Chair: Lena M. Napolitano, MD, FACS, FCCP, FCCM, Ann Arbor, MI

Co-Chair: Jonathan L. Eliason, MD, FACS, Ann Arbor, MI

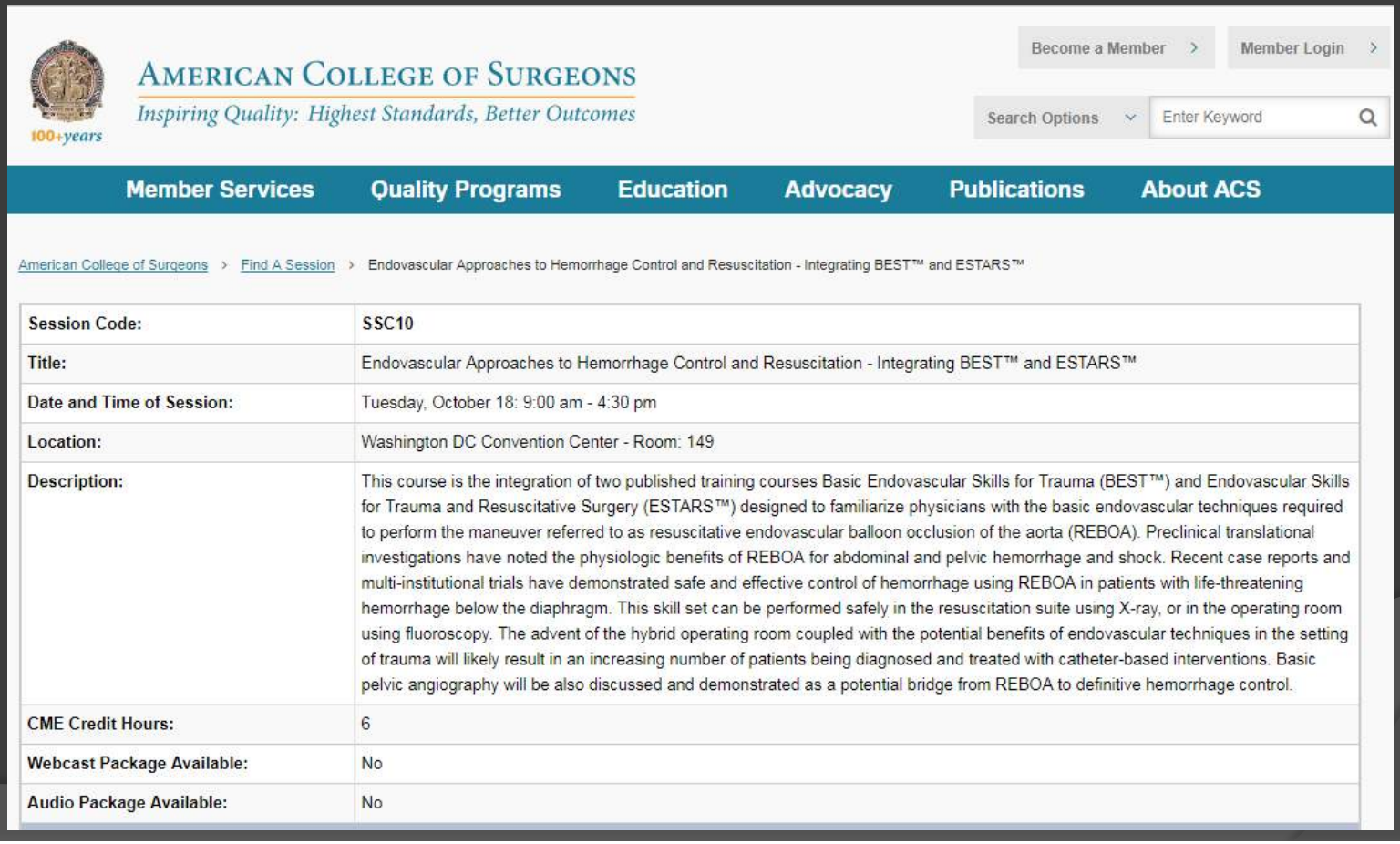
There is an ever-evolving role of endovascular techniques for traumatic vascular injuries. These techniques should be incorporated into the early treatment algorithm of trauma patients, particularly for those requiring difficult operative exposure. This course will provide both lecture and hands-on skills in the use of the Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) and the necessary tools used in the procedure. This course is for vascular and non-vascular surgeons. Note: Live fluoroscopy will be used during the surgical skills lab portion of the course.

Sponsored by: Committee on Surgical Skills Training for Practicing Surgeons

Fee: FELLOW $1,000 | NON-FELLOW $1,275
RAS $500 | NON-RAS $575

SSC10 Endovascular Approaches to Hemorrhage Control and Resuscitation: Integrating BEST™ and ESTARS™

Fellow $995 | Non-Fellow $1,150 | RAS $500 | Non-RAS $580 (2016)



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American College of Surgeons › Find A Session › Endovascular Approaches to Hemorrhage Control and Resuscitation - Integrating BEST™ and ESTARS™

Session Code:	**SSC10**
Title:	Endovascular Approaches to Hemorrhage Control and Resuscitation - Integrating BEST™ and ESTARS™
Date and Time of Session:	Tuesday, October 18: 9:00 am - 4:30 pm
Location:	Washington DC Convention Center - Room: 149
Description:	This course is the integration of two published training courses Basic Endovascular Skills for Trauma (BEST™) and Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS™) designed to familiarize physicians with the basic endovascular techniques required to perform the maneuver referred to as resuscitative endovascular balloon occlusion of the aorta (REBOA). Preclinical translational investigations have noted the physiologic benefits of REBOA for abdominal and pelvic hemorrhage and shock. Recent case reports and multi-institutional trials have demonstrated safe and effective control of hemorrhage using REBOA in patients with life-threatening hemorrhage below the diaphragm. This skill set can be performed safely in the resuscitation suite using X-ray, or in the operating room using fluoroscopy. The advent of the hybrid operating room coupled with the potential benefits of endovascular techniques in the setting of trauma will likely result in an increasing number of patients being diagnosed and treated with catheter-based interventions. Basic pelvic angiography will be also discussed and demonstrated as a potential bridge from REBOA to definitive hemorrhage control.
CME Credit Hours:	6
Webcast Package Available:	No
Audio Package Available:	No

SC10 | Basic Endovascular Skills for Trauma (BEST™) Workshop

4 credits, Verification Level III
Tuesday, October 24; 1:00–5:15 pm
Chair: Megan L. Brenner, MD, FACS, Baltimore, MD
Co-Chair: Joseph J. DuBose, MD, FACS, Davis, CA
Fellow $425 | Non-Fellow $500 | RAS $225 | Non-RAS $300 (2017)

Session Code:	**SC10**
Title:	Basic Endovascular Skills for Trauma (BEST™) Workshop
Date and Time of Session:	Tuesday, October 24: 1:00 pm - 5:15 pm
Location:	San Diego Convention Center - Room: 18
Description:	The utilization of endovascular techniques for vascular control in the bleeding injured patient requires an understanding of indications and contraindications of the procedure as well as a hands-on experience utilizing the required devices. Recent case reports have demonstrated safe and effective temporary control of hemorrhage using Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in trauma patients with life-threatening hemorrhage below the diaphragm. The BEST™ Workshop uses simulation models and is intended to serve as an introduction to REBOA and lays the foundation for more in-depth training at the BEST™ Course.
CME Credit Hours:	4
Webcast Package Available:	No
Audio Package Available:	No

BEST™

BASIC ENDOVASCULAR SKILLS FOR TRAUMA

THE COMMITTEE ON TRAUMA

Target Audience

This course is designed for practitioners seeking to develop or improve their understanding and skills for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

Course Objectives

- To demonstrate indications for REBOA
- To demonstrate access and closure of the common femoral artery
- To demonstrate tools required for REBOA
- To demonstrate technique of REBOA

Course Agenda

*Welcome/Registration and Pre-Test

Introduction, History of REBOA, and Translational Research

Indications for REBOA, Clinical Applications

Technique of REBOA: CODA and ER-REBOA

Simulator Lab

Cadaver Lab

Post-Test, Wrap-up Discussion

CONTINUING MEDICAL EDUCATION CREDIT INFORMATION

Accreditation

The American College of Surgeons is accredited by the ACCME to provide continuing medical education (CME) for physicians.

AMA PRA Category 1 Credit(s)™

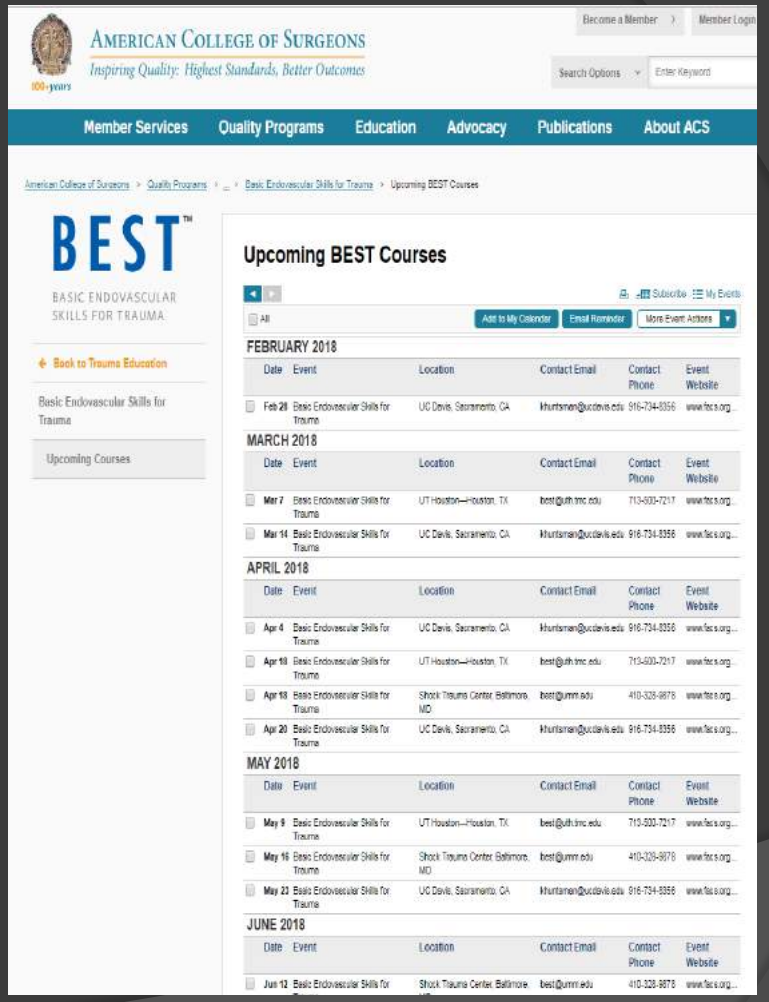
The American College of Surgeons designates this live activity for a maximum of 4 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Of the AMA PRA Category 1 Credit(s)™ listed above, a maximum of 4 credits meet the requirements for Self-Assessment.

Of the AMA PRA Category 1 Credit(s)™ listed above, a maximum of 4 credits meet the requirements for Trauma.

Of the AMA PRA Category 1 Credit(s)™ listed above, a maximum of 4 credits meet the requirements for Surgical Critical Care.

AMERICAN COLLEGE OF SURGEONS DIVISION OF EDUCATION



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FEBRUARY 2018

Date	Event	Location	Contact Email	Contact Phone	Event Website
Feb 28	Basic Endovascular Skills for Trauma	UC Davis, Sacramento, CA	khuntsman@ucdavis.edu	916-734-8356	www.facs.org...

MARCH 2018

Date	Event	Location	Contact Email	Contact Phone	Event Website
Mar 7	Basic Endovascular Skills for Trauma	UT Houston—Houston, TX	best@uth.tmc.edu	713-500-7217	www.facs.org...
Mar 14	Basic Endovascular Skills for Trauma	UC Davis, Sacramento, CA	khuntsman@ucdavis.edu	916-734-8356	www.facs.org...

APRIL 2018

Date	Event	Location	Contact Email	Contact Phone	Event Website
Apr 4	Basic Endovascular Skills for Trauma	UC Davis, Sacramento, CA	khuntsman@ucdavis.edu	916-734-8356	www.facs.org...
Apr 18	Basic Endovascular Skills for Trauma	UT Houston—Houston, TX	best@uth.tmc.edu	713-500-7217	www.facs.org...
Apr 18	Basic Endovascular Skills for Trauma	Shock Trauma Center, Baltimore, MD	best@umm.edu	410-328-9878	www.facs.org...
Apr 20	Basic Endovascular Skills for Trauma	UC Davis, Sacramento, CA	khuntsman@ucdavis.edu	916-734-8356	www.facs.org...

MAY 2018

Date	Event	Location	Contact Email	Contact Phone	Event Website
May 9	Basic Endovascular Skills for Trauma	UT Houston—Houston, TX	best@uth.tmc.edu	713-500-7217	www.facs.org...
May 16	Basic Endovascular Skills for Trauma	Shock Trauma Center, Baltimore, MD	best@umm.edu	410-328-9878	www.facs.org...
May 23	Basic Endovascular Skills for Trauma	UC Davis, Sacramento, CA	khuntsman@ucdavis.edu	916-734-8356	www.facs.org...

JUNE 2018

Date	Event	Location	Contact Email	Contact Phone	Event Website
Jun 13	Basic Endovascular Skills for Trauma	Shock Trauma Center, Baltimore, MD	best@umm.edu	410-328-9878	www.facs.org...

REBOA - Trials and Registries

Jon L. Eliason, MD

University of Michigan
Cardiovascular Center

REBOA – Clinical Trials and Registries

2018

Jonathan L. Eliason, MD
S. Martin Lindenauer Professor of Vascular Surgery
Section of Vascular Surgery

University of Michigan
Cardiovascular Center

Disclosures

- Consultant for Theorem Medical: clinical event committee member for 2 clinical trials related to endovascular devices (neither in today's presentation)
- Consultant for Prytime Medical Devices, Inc.: medical advisory board member, stock options

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Value of Clinical Registries

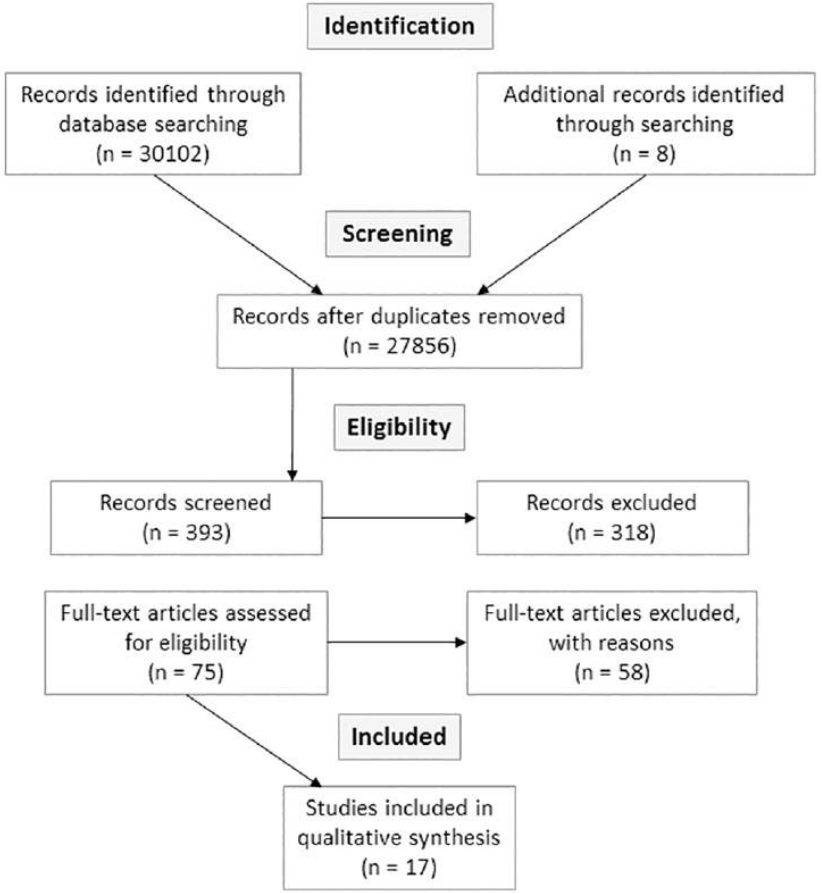

Fig 1. Results of search strategy following PRISMA flow diagram.

Citation: Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM (2017) Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PLoS ONE 12(9): e0183667. https://doi.org/10.1371/journal.pone.0183667

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Value of Clinical Registries

Conclusions

Despite the large number of published articles using data derived from clinical registries, few have rigorously evaluated the impact of the registry as an intervention on improving health outcomes; those that have evaluated this impact have mostly found that registries have improved healthcare processes and outcomes. No studies have evaluated the economic impact of registries as an intervention.

Citation: Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM (2017) Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PLoS ONE 12(9): e0183667. https://doi.org/10.1371/journal.pone.0183667

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REBOA Trials and Registries

- AAST AORTA registry
- EVTM / ABOTrauma registry
- Prytime Emergent Truncal Hemorrhage Observational Study
- NHS United Kingdom REBOA Clinical Trial
- DoDTR Registry

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AAST AORTA registry

- J Am Coll Surg. 2018:S1072-7515 [Epub ahead of print]
- The Prospective Observational Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) study was approved by the American Association for the Surgery of Trauma (AAST) Multicenter Trials Committee
- Adult trauma and acute care surgery (age ≥ 18) patients undergoing aortic occlusion (AO) in the acute phases after injury were enrolled.

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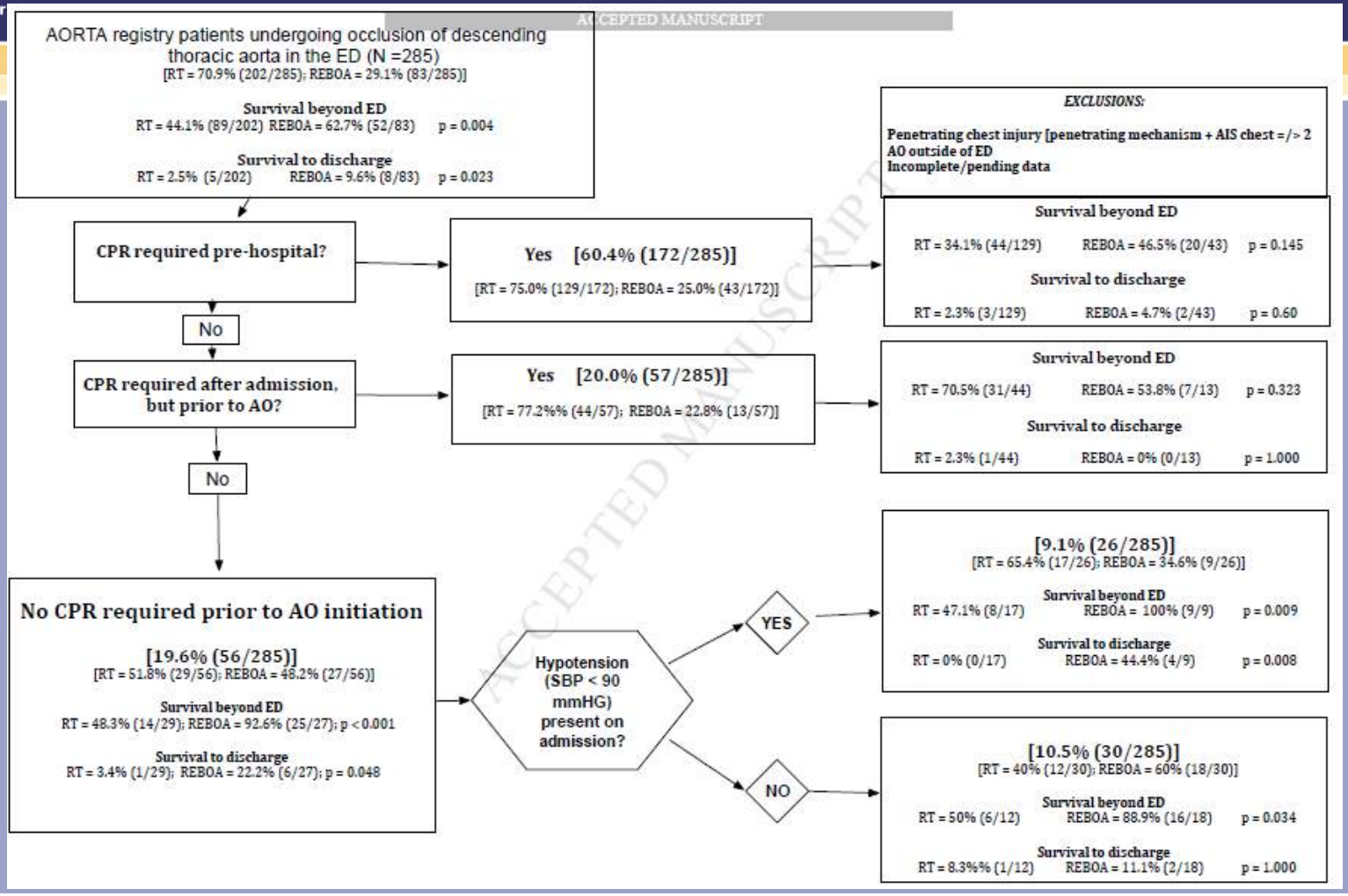
AAST AORTA registry



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AAST AORTA registry

- Conclusions:
  - REBOA may confer a survival benefit over Resuscitative Thoracotomy (RT)
  - This is most evident in patients not requiring CPR
  - Significant further study is required to definitively recommend REBOA for specific subsets of injured patients

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EVTM / ABOTrauma registry

- EndoVascular hybrid Trauma and bleeding Management (EVTM)
- International meeting originated through the department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Sweden
- Organized by Dr. Tal Hörer
- Registry for:
  - New Cases (prospective)
  - Retrospective data collection (former cases)

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  - Retrospective data collection (former cases)

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EVTM / ABOTrauma registry

EndoVascular and Hybrid Trauma and bleeding management (EVTM18) Symposium

Main **round table** Topics:

***EVTM concept**, multidisciplinary approach*
Trauma and non-trauma- PPH, iatrogenic, spontaneous bleeders

***REBOA issues** (Basic and advanced)*
"What do we know" updates. Debates. New data

Vascular trauma/bleeding access Issues

***Pre Hospital** and **Military** REBOA/EVTM reports*

*Technical Aspects for Endo and **hybrid solutions***

***Training** Aspects and debates; Who, When, Where?*

***Complications**, problems and solutions. ICU aspects*

*Animal **research** issues/updates; New endo technologies*
Embolization, endografts and other bleeding solutions.

Upcoming developments in endo and hybrid treatments

Örebro, Sweden

7-8-9th June 2018

In cooperation with the Dept. Of Cardiothoracic and Vascular Surgery & Dept. of Surgery & Dept. of *Anesthesia*/ICU Örebro University Hospital & University, Sweden

www.jevtm.com

Symposium chairs:
Tal Hörer (SE)
Joseph Dubose (US)
Junichi Matsumoto (JP)
Jonny Morrison (UK)
Viktor Reva (RU)
Boris Kessel (IL)
Lauri Handolin (FI)
George Oosthuizen (ZA)
Todd Rasmussen (US)
Megan Brenner (US)
Joe Love (US)

Invited speakers/panelists:
TBA

Supported by
TBA

Region Örebro County
Örebro University Hospital

University of Michigan Cardiovascular Center

EVTM / ABOTrauma registry

- ICD-10-PCS
- Coding Tips
  - To code Zone I
  - W3DJ
  - To code Zone II-III
  - O3DJ

02L

Section	0	Medical and Surgical
Body System	2	Heart and Great Vessels
Operation	L	Occlusion: Completely closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
7 Atrium, Left	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	K Left Atrial Appendage
H Pulmonary Valve P Pulmonary Trunk Q Pulmonary Artery, Right S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier
R Pulmonary Artery, Left	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	T Ductus Arteriosus Z No Qualifier
W Thoracic Aorta, Descending	3 Percutaneous	D Intraluminal Device	J Temporary

Section	0	Medical and Surgical
Body System	4	Lower Arteries
Operation	L	Occlusion: Completely closing an orifice or the lumen of a tubular body part

Body Part	*Approach*	*Device*	*Qualifier*
0 Abdominal Aorta	0 Open 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier
0 Abdominal Aorta	3 Percutaneous	C Extraluminal Device Z No Device	Z No Qualifier
0 Abdominal Aorta	3 Percutaneous	D Intraluminal Device	J Temporary Z No Qualifier
1 Celiac Artery 2 Gastric Artery 3 Hepatic Artery 4 Splenic Artery 5 Superior Mesenteric Artery 6 Colic Artery, Right 7 Colic Artery, Left 8 Colic Artery, Middle 9 Renal Artery, Right A Renal Artery, Left B Inferior Mesenteric Artery C Common Iliac Artery, Right D Common Iliac Artery, Left H External Iliac Artery, Right J External Iliac Artery, Left K Femoral Artery, Right L Femoral Artery, Left M Popliteal Artery, Right N Popliteal Artery, Left P Anterior Tibial Artery, Right Q Anterior Tibial Artery, Left R Posterior Tibial Artery, Right S Posterior Tibial Artery, Left T Peroneal Artery, Right U Peroneal Artery, Left V Foot Artery, Right W Foot Artery, Left Y Lower Artery	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier

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EVTM / ABOTrauma registry

- Eur J Trauma Emerg Surg 2017;1-11
- 96 cases from 6 different countries were reported between 2011 and 2016
- Mean age 52 with 88% blunt trauma
- Median ISS of 41
- Median SBP 60 mmHg → 100 mmHg
- Continuous occlusion 52%; 48% non-continuous occlusion

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EVTM / ABOTrauma registry

	Continuous REBOA	Non-continuous REBOA	*P*
Pre-hospital data			
GCS < 8/*n* (%) (total = 75)	13 (41%)	15 (35%)	0.611
CPR/*n* (%) (total = 91)	11 (23%)	7 (16%)	0.370
Systolic blood pressure			
ED Admission < 80 mmHg/*n* (%) (total = 65)	22 (67%)	21 (66%)	0.929
SBP mm Hg before inflation/median (IQR) (total = 88)	50 (0–70)	68 (43–88)	0.026
SBP mmHg after inflation/median (IQR) (total = 89)	95 (69–120)	110 (90–135)	0.022

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EVTM / ABOTrauma registry

- 30-day mortality
  - Continuous REBOA 64%
  - Non-continuous REBOA 48%

- Extremity compartment syndrome
  - Continuous REBOA n=3 (11%)
  - Non-continuous REBOA n=0

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Prytime Emergent Truncal Hemorrhage Observational Study

- ER-REBOA use and FDA Post Market Surveillance Data (Jan 2016 – Jan 2018)
- Hospitals using device (worldwide): 232
- Number of uses: 2,577

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NHS United Kingdom REBOA Clinical Trial

- Funded by the UK National Institute for Health Research (NIHR – the NHS funding body)
- Funding = 1.3 million pounds
- A pragmatic Bayesian, randomized and sequential block design trial comparing the standard of care versus the standard of care plus REBOA in the management of abdomino/pelvic hemorrhage

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NHS United Kingdom REBOA Clinical Trial

- Does not specify what form “standard of care” is, or what REBOA technique/balloon/zone, so it is a pragmatic (both a strength and weakness)
- Phase one is powered for failure. If REBOA causes harm, should be detected with the first 40 patients
- Phase two is powered for success where the benefit is >10%
- Phase III is full trial N of 140 patients overall, which is powered to tell detect >5% difference in outcome

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NHS United Kingdom REBOA Clinical Trial

- Trial went live October, 2017
- 7 sites enrolling – Pilot sites for phase 1
- Total of 15 centers for full trial
- Based upon English trauma network, fully integrated national system consisting of 25 major trauma centers

- End-point is 90-day mortality

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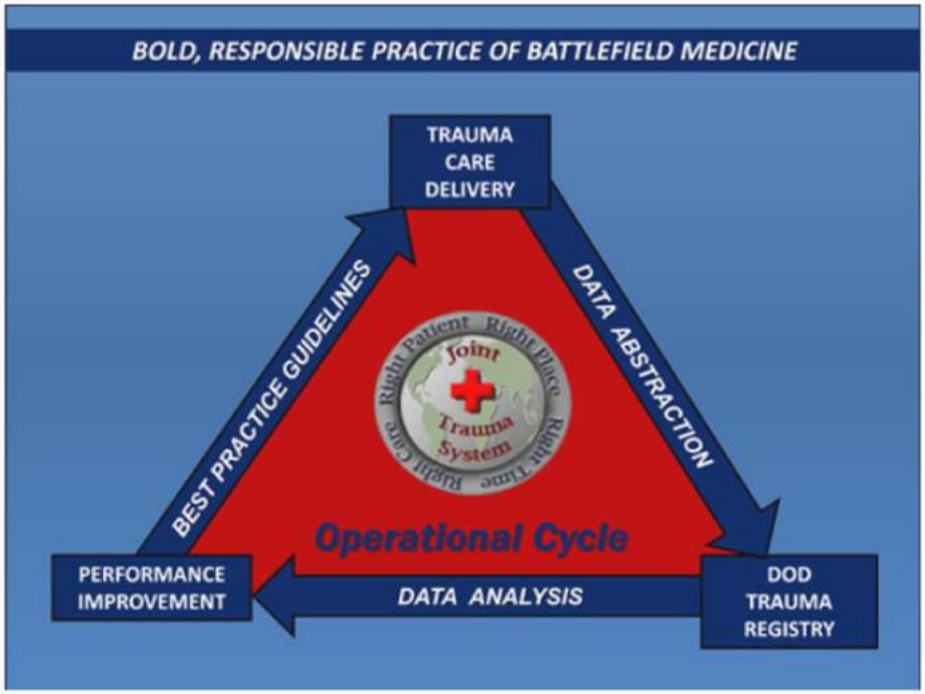
DoDTR Trauma Registry

Joint Trauma System

The Department of Defense Center of Excellence for Trauma



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DoDTR Trauma Registry

- JTS efforts are supported by the concurrent collection and analysis of data maintained in the Department of Defense Trauma Registry (DoDTR), formerly Joint Theater Trauma Registry (JTTR).
- The DoDTR is the data repository for DoD trauma-related injuries
- The goal of this registry is to document, in electronic format, information about the demographics, injury-producing incident, diagnosis and treatment, and outcome of injuries sustained by US/Non-US military and US/Non-US civilian personnel in wartime and peacetime from the point of wounding to final disposition.

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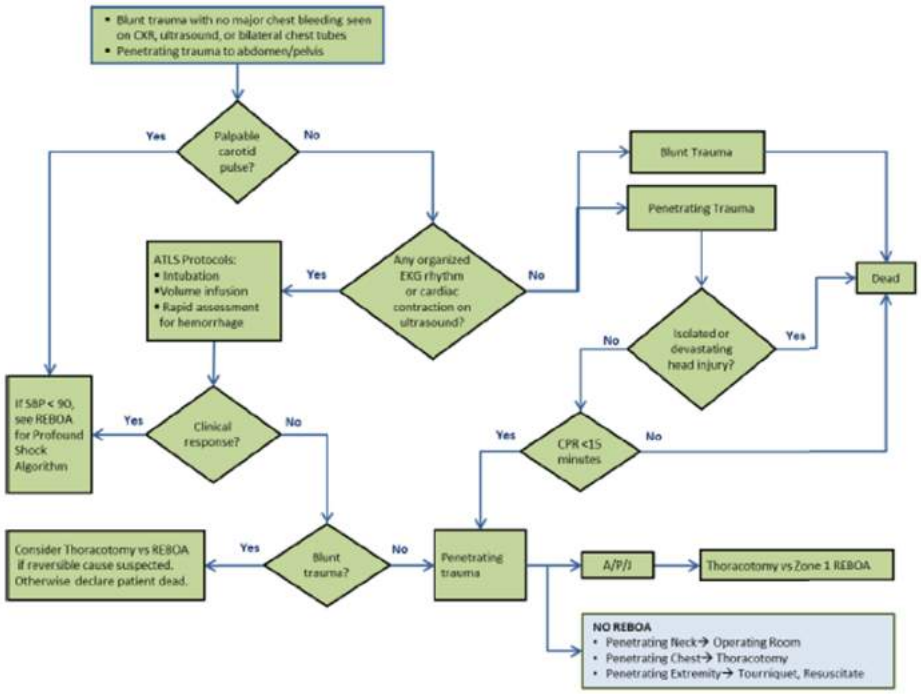
DoDTR Trauma Registry

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Hemorrhagic Shock *CPG ID: 38*

APPENDIX A: TRAUMATIC ARREST ALGORITHM FOR REBOA



REBOA: Resuscitative Endovascular Balloon Occlusion of the Aorta; CXR: Chest X-Ray; EFAST: Extended Focused Assessment with Sonography for Trauma; ATLS: Advanced Trauma Life Support; EKG: Electrocardiogram; SBP: Systolic Blood Pressure; CPR: Cardiopulmonary Resuscitation; A/P/J: Abdomen/Pelvis/ Junctional Lower Extremity.

Zone I REBOA: placement of aortic balloon in the thoracic aorta (insert catheter to 46 cm or measure the balloon to mid sternum/P-tip to sternal notch)

Zone III REBOA: placement of aortic balloon directly above the aortic bifurcation (insert catheter to 27 cm or measure the balloon to the umbilicus).

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DoDTR Trauma Registry

J Spec Oper Med. Spring 2017;17(1):1-8.

A Modern Case Series of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in an Out-of-Hospital, Combat Casualty Care Setting.

Manley JD, Mitchell BJ, DuBose JJ, Rasmussen TE.

Abstract

BACKGROUND: Resuscitative endovascular balloon occlusion of the aorta (REBOA) is used to mitigate bleeding and sustain central aortic pressure in the setting of shock. The ER-REBOA™ catheter is a new REBOA technology, previously reported only in the setting of civilian trauma and injury care. The use of REBOA in an out-of-hospital setting has not been reported, to our knowledge.

METHODS: We present a case series of wartime injured patients cared for by a US Air Force Special Operations Surgical Team at an austere location fewer than 3km (5-10 minutes' transport) from point of injury and 2 hours from the next highest environment of care-a Role 2 equivalent.

RESULTS: In a 2-month period, four patients presented with torso gunshot or fragmentation wounds, hemoperitoneum, and class IV shock. Hand-held ultrasound was used to diagnose hemoperitoneum and facilitate 7Fr femoral sheath access. ER-REBOA balloons were positioned and inflated in the aorta (zone 1 [n = 3] and zone 3 [n = 1]) without radiography. In all cases, REBOA resulted in immediate normalization of blood pressure and allowed induction of anesthesia, initiation of whole-blood transfusion, damage control laparotomy, and attainment of surgical hemostasis (range of inflation time, 18-65 minutes). There were no access- or REBOArelated complications and all patients survived to achieve transport to the next echelon of care in stable condition.

CONCLUSION: To our knowledge, this is the first series to demonstrate the feasibility and effectiveness of REBOA in modern combat casualty care and the first to describe use of the ER-REBOA catheter. Use of this device by nonsurgeons and surgeons not specially trained in vascular surgery in the out-of-hospital setting is useful as a stabilizing and damage control adjunct, allowing time for resuscitation, laparotomy, and surgical hemostasis.

2017.

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Thank You

Questions?

REBOA Simulation Session

Lunch

Back at 1:00p

BCBSM - VBR

Marc Cohen
Manager,
CQI Administration – Value Partnerships

Program Manager

Judy Mikhail, PhD

2017 Performance Index Results

- Mean 90.4
- Range 72.1 to 100

	2014	2015	2016	2017
Mean	85.3	86.4	91	90.4

<u>Performance Measure (Means)</u>

1. Timely VTE (60.7%)
2. LMWH Use (44.5%)
3. MTP Ratio (7.7 pts)
4. S. Complications (8.1 pts)
5. Mortality Rate (7.1 pts)
6. IVC Filter (10 pts)
7. PI Project (8.3 pts)

2018 Performance Index Changes

- Retired
  - IVC Filter
  - PI Project
- New
  - Open fx antibiotic documentation (type, date, time)
  - TBI pts on anticoagulation Head CT documentation (date, time)

2018 MTQIP/BCBSM Statement of Work (SOW) Measures

VTE Rate

Year	Performance	# Centers	Target
Baseline	2.46%	23	1.5%
2011	1.84%	23	1.5%
2012	1.62%	23	1.5%
2013	1.48%	23	1.5%
2014	1.18%	27	1.5%
2015	1.33%	27	1.5%
2016	1.32%	29	1.5%
2017	1.30%	29	1.3%
2018		32	1.1%

VTE Prophylaxis Timeliness

Year	Performance	# Centers	Target
Baseline	38%	23	50%
2013	43%	23	50%
2014	45%	27	50%
2015	53%	27	50%
2016	58%	29	50%
2017	60%	29	50%
2018		32	75%

LMWH Use

Year	Performance	# Centers	Target
Baseline	27%	23	40%
2013	29%	23	40%
2014	31%	27	40%
2015	35%	27	40%
2016	42%	29	50%
2017	43%	29	50%
2018		32	50%

IVC Filter Use

Year	Performance	# Centers	Target
Baseline	3.2%	23	2.0
2013	2.7%	23	2.0
2014	1.6%	27	2.0
2015	1.0%	27	1.5
2016	0.4%	29	1.5
2017	0.5%	29	1.2
2018		32	$\leq$ 0.5

MTP Blood Ratio's

Year	Performance	# Of Centers	Target
Baseline	27.0%	23	80%
2012	52.2%	23	80%
2013	64.9%	23	80%
2014	61.8%	27	80%
2015	75.3%	27	80%
2016	84.0%	29	80%
2017	77.0%	29	80%
2018		32	80%

Serious Complications (Z Score)

Year	Performance	# Centers
Baseline	9.5%	29
2017	8.5%	29
2018		32

- Less than -1, 10 points: 11 centers
- Between -1 and 1, 7 points: 14 centers
- Greater than 1, 5 points: 4 centers

Mortality Rate (Z Score)

Year	Performance	# Centers
Baseline	5.3%	29
2017	4.8%	29
2018		32

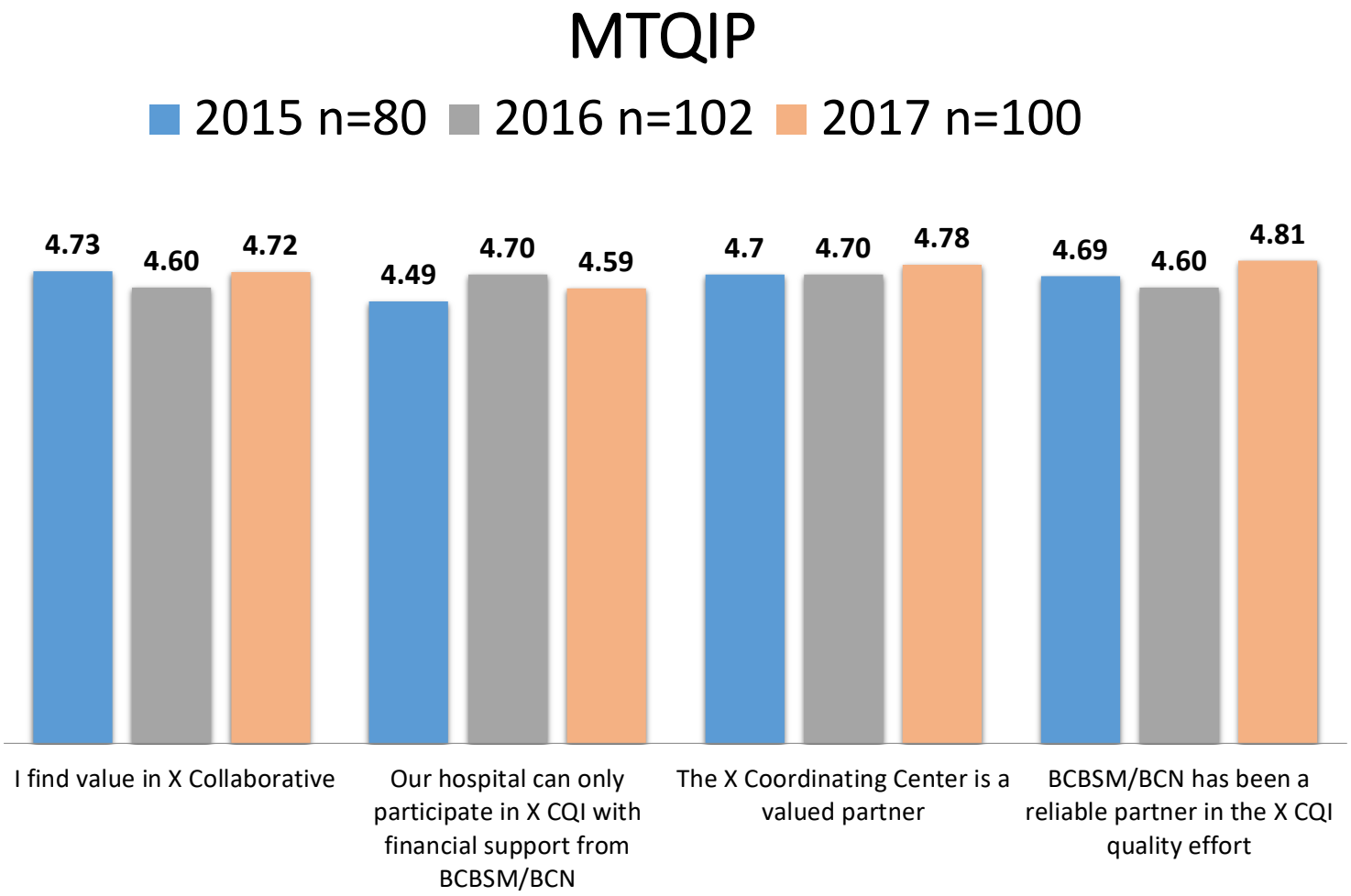
- Less than -1, 10 points: 6 centers
- Between -1 and 1, 7 points: 19 centers
- Greater than 1, 5 points: 4 centers

VALUEPartnerships
Better Care. Better Outcomes. Better Value.

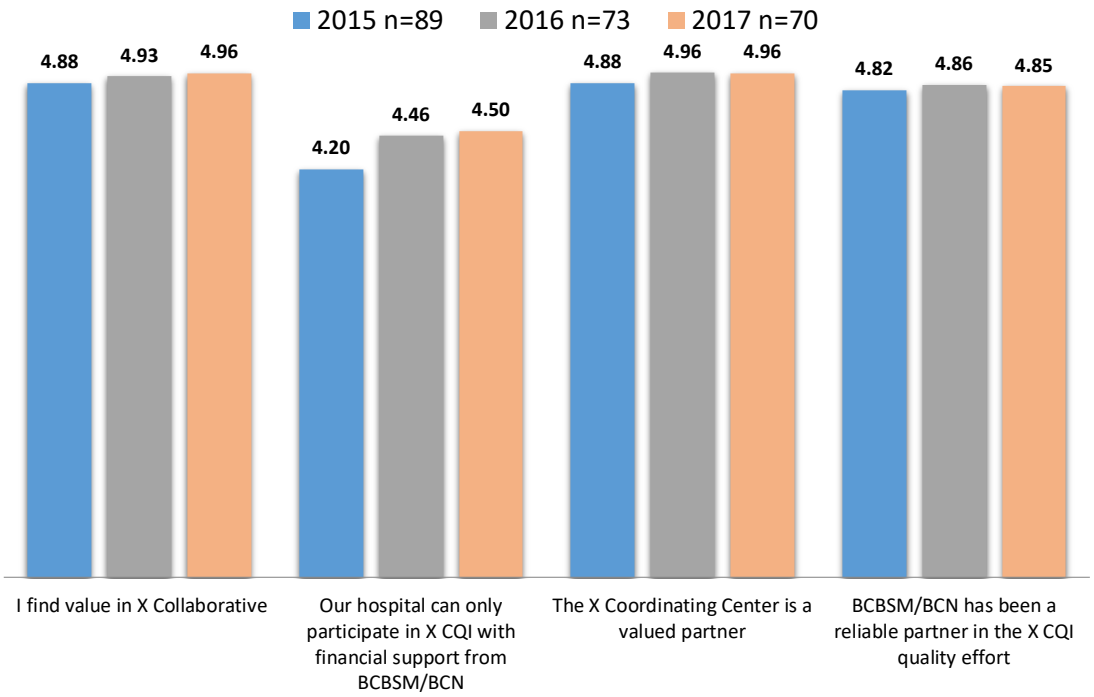
Blue Cross Blue Shield of Michigan

BCBSM CQI Participation Value Survey 4-Question Surveys Conducted 2015-2017 Year over Year Comparison 2/1/2018

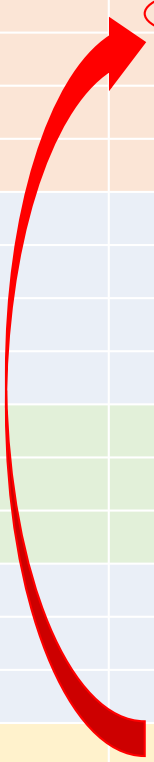
Jackie Rau, MHSA, CQI Project Lead, Value Partnerships
Blue Cross Blue Shield of Michigan

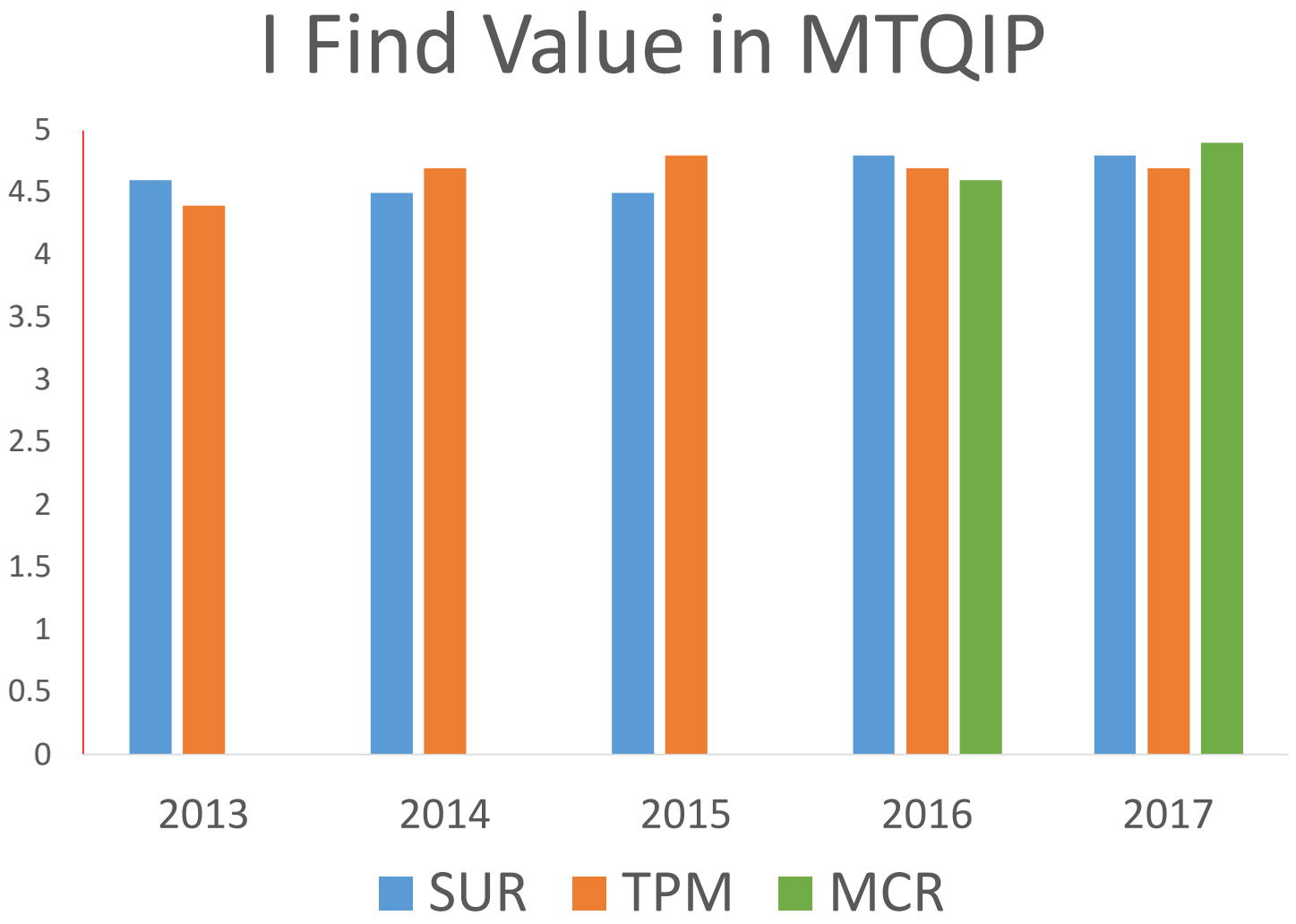

MTQIP
2015 n=80
2016 n=102
2017 n=100
4.73
4.60
4.72
4.49
4.70
4.59
4.7
4.70
4.78
4.69
4.60
4.81
I find value in X Collaborative
Our hospital can only participate in X CQI with financial support from BCBSM/BCN
The X Coordinating Center is a valued partner
BCBSM/BCN has been a reliable partner in the X CQI quality effort

MSTCVS


2015 n=89
2016 n=73
2017 n=70
4.88
4.93
4.96
4.20
4.46
4.50
4.88
4.96
4.96
4.82
4.86
4.85
I find value in X Collaborative
Our hospital can only participate in X CQI with financial support from BCBSM/BCN
The X Coordinating Center is a valued partner
BCBSM/BCN has been a reliable partner in the X CQI quality effort

5 point scale Means	**Role**	**Question #1** I find value in MTQIP	**Question #2** Hospital can only participate with support	**Question #3** MTQIP coord center valued partner	**Question #4** BCBSM reliable partner
2017	SUR	4.8	4.7	4.9	4.9
	TPM	4.7	4.7	4.7	4.7
	MCR	4.9	4.5	4.9	4.9
	Total	4.6	4.7	4.7	4.6
2016	SUR	5.0	5.0	5.0	5.0
	TPM	4.7	4.2	4.5	4.6
	MCR	4.6	4.5	4.7	4.7
	Total	4.6	4.7	4.7	4.6
2015	SUR	4.5	4.5	4.6	4.5
	TPM	4.8	4.5	4.7	4.7
	Total	4.7	4.5	4.7	4.7
2014	SUR	4.5	4.1	4.5	4.1
	TPM	4.7	4.7	4.7	4.7
	Total	4.7	4.4	4.8	4.4
2013	SUR	4.6	4.1	4.6	4.1
	TPM	4.4	4.5	4.2	4.4
	Total	4.5	4.3	4.5	4.3




I Find Value in MTQIP
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
2013
2014
2015
2016
2017
SUR
TPM
MCR


WE NEED
YOU

MTQIP Data

Mark Hemmila, MD

State of Michigan

- Status
  - Level 1 and 2
    - Data submission - Active
    - Reporting: Center, State, Region - Active
    - Education - June
  - Level 3
    - Data submission - First Submission Feb 2
    - Report development, provision 2x/year - Pending
    - Education - June

State of Michigan

- Revised DUA needed
  - Henry Ford Macomb
  - Hurley
  - St. Marys Livonia
  - McLaren Macomb
  - McLaren Oakland
  - MidMichigan Midland
  - Munson
  - Spectrum
  - St. Marys Mercy Grand Rapids

State of Michigan

- Reporting
- Descriptive statistics (volume, means, types)

State of Michigan

- Education
  - Annual meeting
  - Coordinate MTQIP and SOM
  - June

Metrics

Metrics for MTQIP

- Hospital = CQI Scoring Index
  - 10 Measures
  - End result: Hospital P4P
- Surgeon = VBR
  - 3 Measures (VTE Timing, VTE Type, PRBC to Plasma ratio)
  - Scoring as a group practice
  - End result: Surgeon VBR in 2019
- Collaborative = Reporting to BCBSM
  - 11 Measures
  - Targets or Maintain

Collaborative

- VTE rate 1.3 → 1.1%
- LMWH use > 50% collaborative
- VTE prophylaxis timely
  - ≥ 55% within 48 hrs (hospital)
  - 75% of hospitals (24/32), current 21/29
- PRBC to plasma ratio ≤ 2.0 in 80% of patients
- Serious complication rate, improvement
- Mortality rate, improvement
- IVC filter rate, maintain ≤ 0.5%
- TBI intervention in eligible patients ≥ 75%
- TBI intervention timeliness ≥ 80%
- Open Fracture, TBI and anticoagulation baseline

New CQI Index Data

#9 Open Fracture Antibiotic Usage

- Type of antibiotic administered along with date and time for open fracture of femur or tibia
- Presence of acute open femur or tibia fracture based on AIS or ICD10 codes (See list)
- Cohort = Cohort 1 (All)
- Exclude direct admissions
- No Signs of Life = Exclude DOAs
- Transfers Out = Include Transfers Out
- Time Period = 7/1/17 to 6/30/18

#9 Open Fracture Antibiotic Usage

- Measure = % of patients with antibiotic type, date, time recorded
- ACS-COT
  - Administration within 60 minutes

#9 Open Fracture Antibiotic Usage

Trauma C	N	Data OK	< 60	61 to 120	> 120	% OK	% < 60	% 61-120	% > 120
14	15	14	6	4	4	93	40	27	27
8	4	4	4	0	0	100	100	0	0
22	6	6	4	1	1	100	67	17	17
3	2	2	2	0	0	100	100	0	0
5	6	5	2	2	1	83	33	33	17
1	19	10	4	3	3	53	21	16	16
12	1	1	0	1	0	100	0	100	0
18	13	11	8	0	3	85	62	0	23
2	1	0	0	0	0	0	0	0	0
13	6	6	5	0	1	100	83	0	17
26	6	3	2	0	1	50	33	0	17
16	3	3	3	0	0	100	100	0	0
15	10	10	8	0	2	100	80	0	20
19	13	10	7	2	1	77	54	15	8
7	6	6	5	1	0	100	83	17	0
27	4	4	2	0	2	100	50	0	50
	115	95	62	14	19	82.6%	53.9%	12.2%	16.5%

#9 Open Fracture Antibiotic Usage

Trauma C	N	Data OK	< 60	61 to 120	> 120	% OK	% < 60	% 61-120	% > 120
14	15	14	6	4	4	93	40	27	27
8	4	4	4	0	0	100	100	0	0
22	6	6	4	1	1	100	67	17	17
3	2	2	2	0	0	100	100	0	0
5	6	5	2	2	1	83	33	33	17
1	19	10	4	3	3	53	21	16	16
12	1	1	0	1	0	100	0	100	0
18	13	11	8	0	3	85	62	0	23
2	1	0	0	0	0	0	0	0	0
13	6	6	5	0	1	100	83	0	17
26	6	3	2	0	1	50	33	0	17
16	3	3	3	0	0	100	100	0	0
15	10	10	8	0	2	100	80	0	20
19	13	10	7	2	1	77	54	15	8
7	6	6	5	1	0	100	83	17	0
27	4	4	2	0	2	100	50	0	50
	115	95	62	14	19	82.6%	53.9%	12.2%	16.5%

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8	4	4	4	0	0	100	100	0	0
22	6	6	4	1	1	100	67	17	17
3	2	2	2	0	0	100	100	0	0
5	6	5	2	2	1	83	33	33	17
1	19	10	4	3	3	53	21	16	16
12	1	1	0	1	0	100	0	100	0
18	13	11	8	0	3	85	62	0	23
2	1	0	0	0	0	0	0	0	0
13	6	6	5	0	1	100	83	0	17
26	6	3	2	0	1	50	33	0	17
16	3	3	3	0	0	100	100	0	0
15	10	10	8	0	2	100	80	0	20
19	13	10	7	2	1	77	54	15	8
7	6	6	5	1	0	100	83	17	0
27	4	4	2	0	2	100	50	0	50
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3	2	2	2	0	0	100	100	0	0
5	6	5	2	2	1	83	33	33	17
1	14	7	3	2	2	50	21	14	14
12	1	1	0	1	0	100	0	100	0
18	13	11	8	0	3	85	62	0	23
13	5	5	4	0	1	100	80	0	20
26	6	3	2	0	1	50	33	0	17
16	3	3	3	0	0	100	100	0	0
15	10	10	8	0	2	100	80	0	20
19	12	9	6	2	1	75	50	17	8
7	6	6	5	1	0	100	83	17	0
27	2	2	1	0	1	100	50	0	50
	105	88	58	13	17	83.8%	55.2%	12.4%	16.2%

Transfers in excluded

#10 Head CT Scan in ED on patient taking anticoagulation medication with TBI

- Head CT date and time from procedures
- Presence of prehospital anticoagulation or anti-platelet use
- TBI (AIS Head and AIS≥2)
- Cohort1, Blunt mechanism
- Exclude direct admissions and transfer in
- No Signs of Life = Exclude DOAs
- Transfers Out = Include Transfers Out
- Time Period = 7/1/17 to 6/30/18

#10 Head CT

- Measure = % of patients with Head CT, date, and time
- Timing
- Treatment
  - 2018 Data

#10 Head CT

Trauma C	N	Head CT	Time OK	Time < 4	% OK	% No HCT	% OK CT	% OK Time	% < 4 hrs
14	6	5	5	4	83	17%	83	83	67
8	22	21	21	21	95	5%	95	95	95
22	11	11	11	10	100	0%	100	100	91
3	2	2	2	2	100	0%	100	100	100
5	7	7	3	3	43	0%	100	43	43
1	6	6	6	5	100	0%	100	100	83
12	7	7	7	7	100	0%	100	100	100
18	4	4	4	4	100	0%	100	100	100
13	11	10	10	9	91	9%	91	91	82
26	4	4	4	4	100	0%	100	100	100
16	10	8	8	7	80	20%	80	80	70
15	3	3	3	3	100	0%	100	100	100
19	16	16	16	16	100	0%	100	100	100
7	12	12	9	9	75	0%	100	75	75
27	3	3	3	2	100	0%	100	100	67
	124	119	112	106	90%	4%	96%	90%	85%

#10 Head CT

Trauma C	N	Head CT	Time OK	Time < 4	% OK	% No HCT	% OK CT	% OK Time	% < 4 hrs
14	6	5	5	4	83	17%	83	83	67
8	22	21	21	21	95	5%	95	95	95
22	11	11	11	10	100	0%	100	100	91
3	2	2	2	2	100	0%	100	100	100
5	7	7	3	3	43	0%	100	43	43
1	6	6	6	5	100	0%	100	100	83
12	7	7	7	7	100	0%	100	100	100
18	4	4	4	4	100	0%	100	100	100
13	11	10	10	9	91	9%	91	91	82
26	4	4	4	4	100	0%	100	100	100
16	10	8	8	7	80	20%	80	80	70
15	3	3	3	3	100	0%	100	100	100
19	16	16	16	16	100	0%	100	100	100
7	12	12	9	9	75	0%	100	75	75
27	3	3	3	2	100	0%	100	100	67
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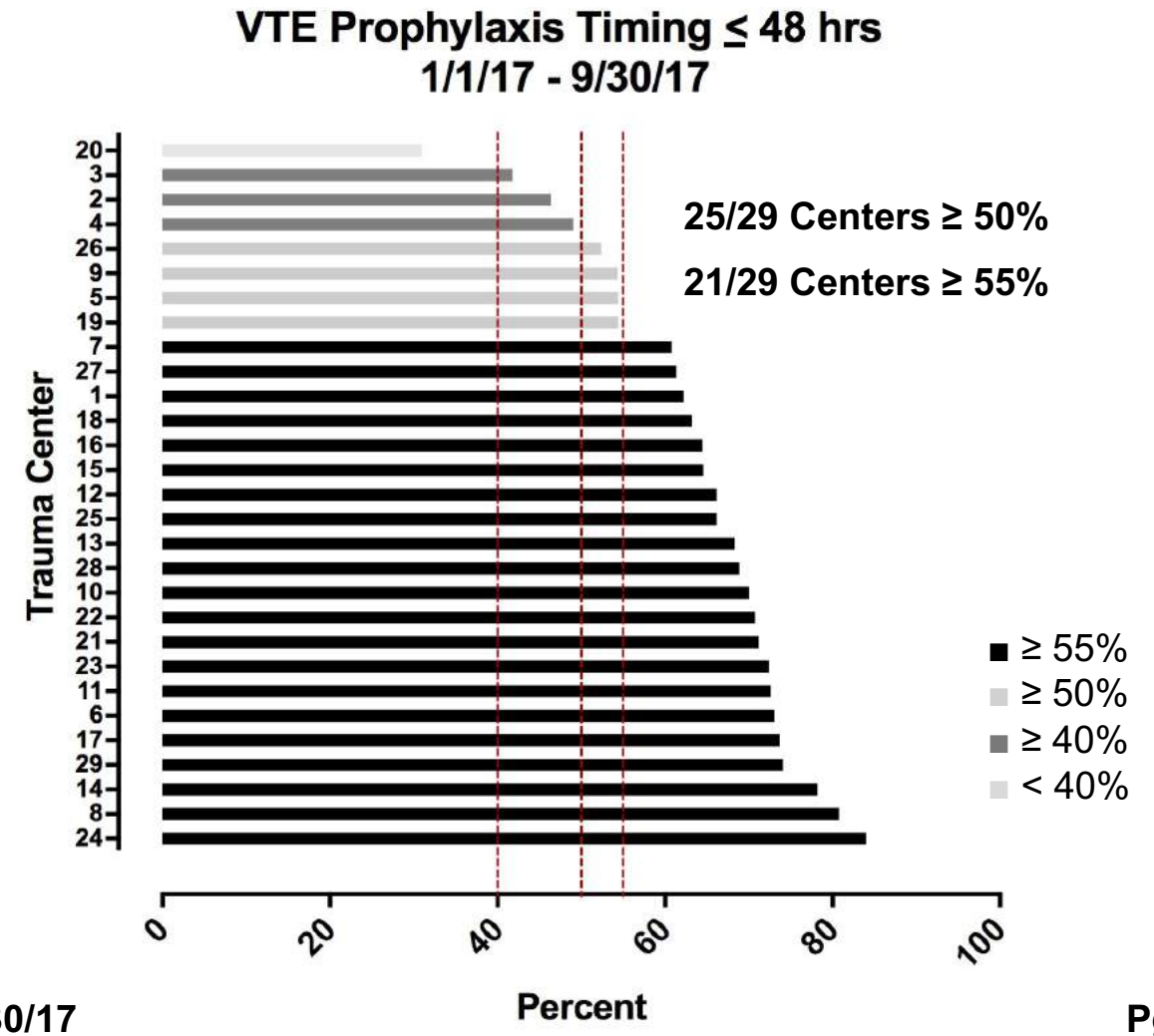
8	22	21	21	21	95	5%	95	95	95
22	11	11	11	10	100	0%	100	100	91
3	2	2	2	2	100	0%	100	100	100
5	7	7	3	3	43	0%	100	43	43
1	6	6	6	5	100	0%	100	100	83
12	7	7	7	7	100	0%	100	100	100
18	4	4	4	4	100	0%	100	100	100
13	11	10	10	9	91	9%	91	91	82
26	4	4	4	4	100	0%	100	100	100
16	10	8	8	7	80	20%	80	80	70
15	3	3	3	3	100	0%	100	100	100
19	16	16	16	16	100	0%	100	100	100
7	12	12	9	9	75	0%	100	75	75
27	3	3	3	2	100	0%	100	100	67
	124	119	112	106	90%	4%	96%	90%	85%

2018 CQI Index Data

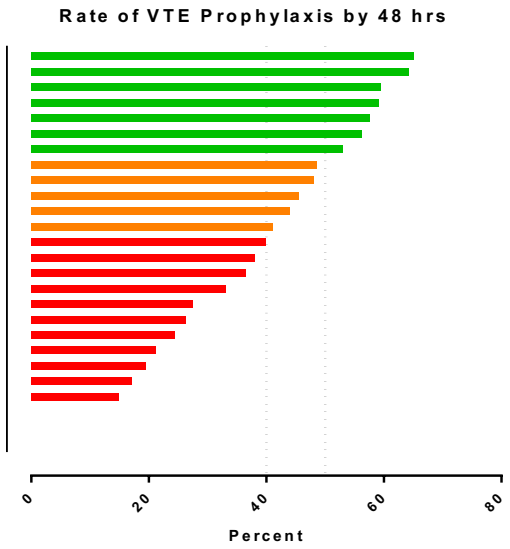
#4 VTE Prophylaxis Initiated ≤ 48 hrs

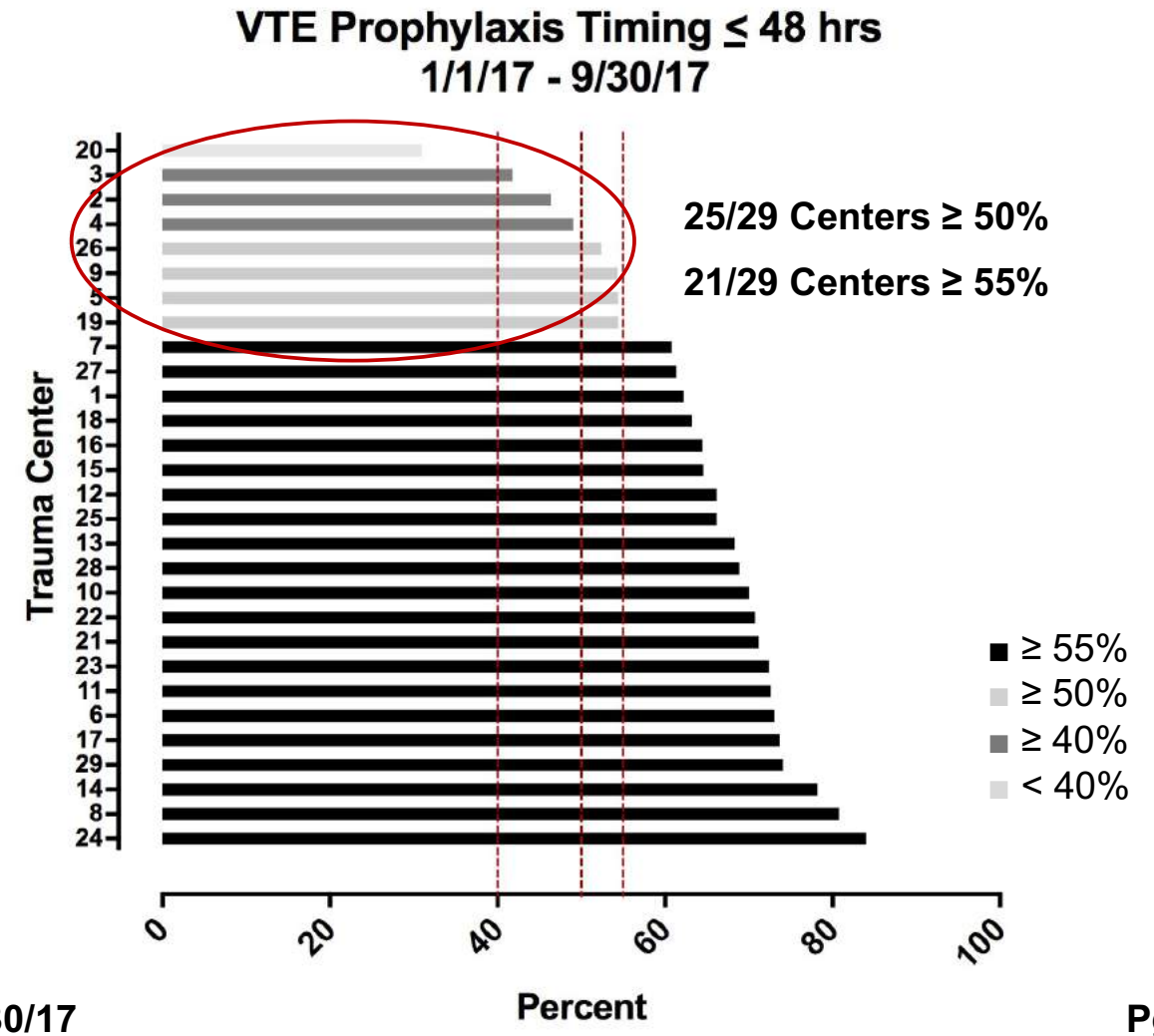
- Website
  - Practices > VTE Prophylaxis Metric
  - Cohort = Cohort 2 (admit to Trauma)
  - No Signs of Life = Exclude DOAs
  - Transfers Out = Exclude Transfers Out
  - Default Period = Set for CQI Index time period
- Heparin, LMWH <= 48 Hours
  - Hospital - Unadj %

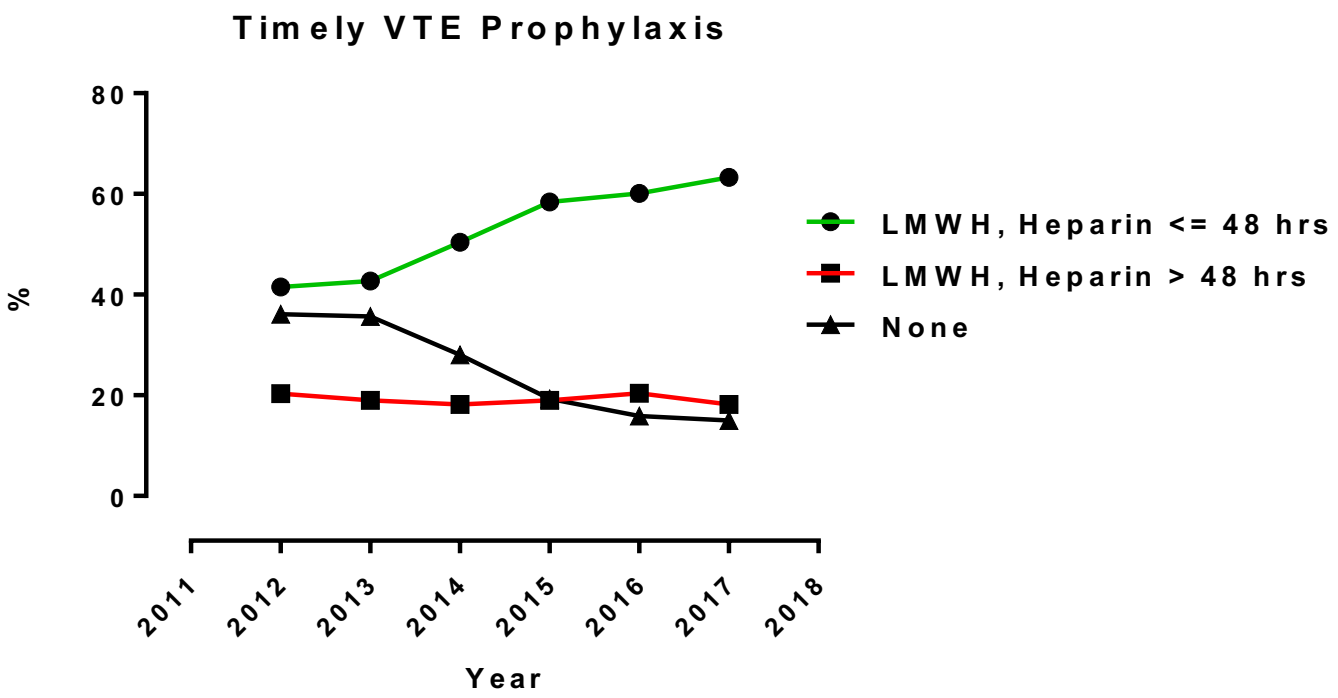

VTE Prophylaxis Timing ≤ 48 hrs
1/1/17 - 9/30/17
25/29 Centers ≥ 50%
21/29 Centers ≥ 55%
Trauma Center
20
3
2
4
26
9
5
19
7
27
1
18
16
15
12
25
13
28
10
22
21
23
11
6
17
29
14
8
24
0
20
40
60
80
100
Percent
≥ 55%
≥ 50%
≥ 40%
< 40%

#4 VTE Prophylaxis Initiated ≤ 48 hrs

- Hospital Target ≥ 55% = 10 points
- CQI Target 75% of hospitals ≥ 55%
  - 24/32 hospital
  - Current is 21 hospitals
  - May 2014: 7 > 50%



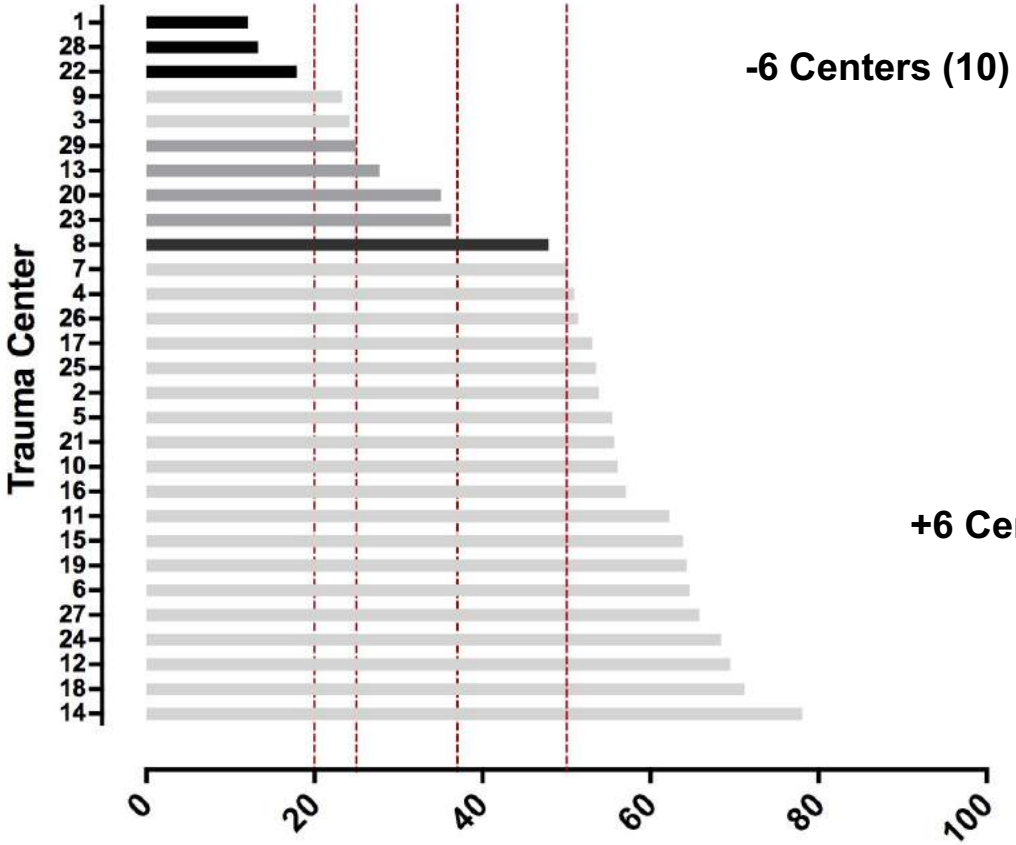

VTE Prophylaxis Timing ≤ 48 hrs
1/1/17 - 9/30/17
25/29 Centers ≥ 50%
21/29 Centers ≥ 55%
Trauma Center
20
3
2
4
26
9
5
19
7
27
1
18
16
15
12
25
13
28
10
22
21
23
11
6
17
29
14
8
24
0
20
40
60
80
100
Percent
≥ 55%
≥ 50%
≥ 40%
< 40%


Timely VTE Prophylaxis
80
60
40
20
0
%
2011
2012
2013
2014
2015
2016
2017
2018
Year
LMWH, Heparin <= 48 hrs
LMWH, Heparin > 48 hrs
None

#5 VTE Prophylaxis with LMWH

- Website
  - Practices > VTE Prophylaxis Type
  - Cohort = Cohort 2 (admit to Trauma)
  - No Signs of Life = Exclude DOAs
  - Transfers Out = Exclude Transfers Out
  - Default Period = Set for CQI Index time period
- LMWH (Type)
  - Hospital - Unadj %

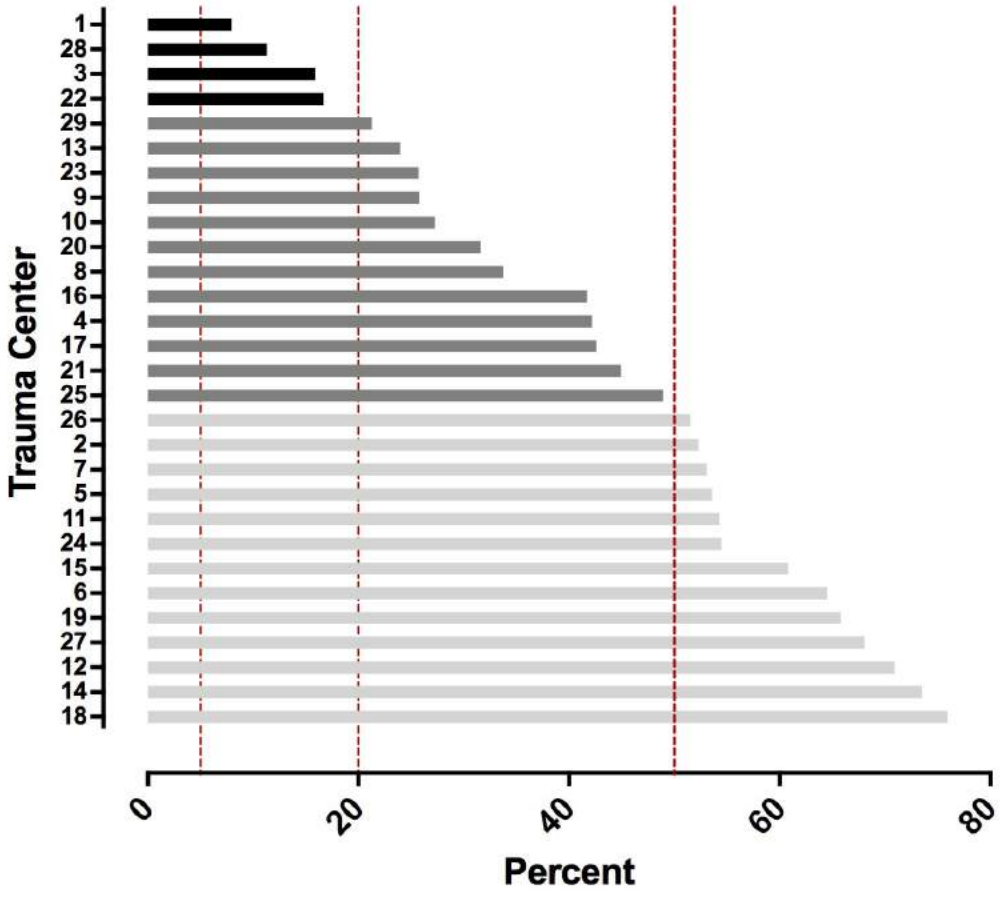
VTE Prophylaxis Type - LMWH
1/1/17 - 9/30/17

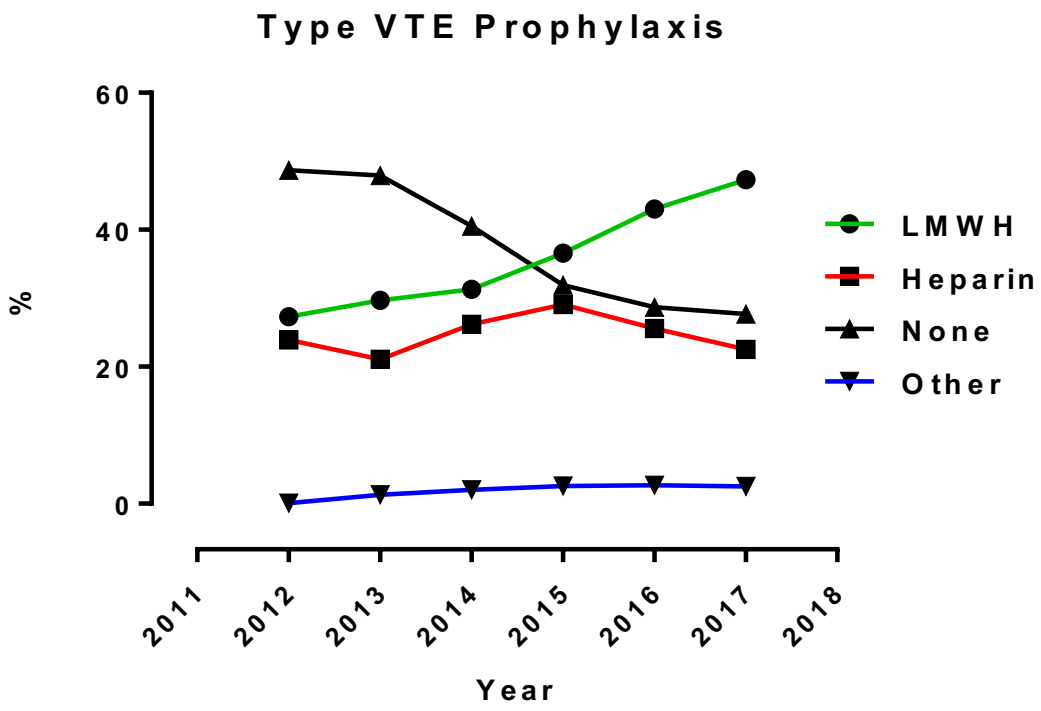


-6 Centers (10)

+6 Centers (19)

1st Dose VTE Prophylaxis Type - LMWH
1/1/16 - 5/31/17




Type VTE Prophylaxis
60
40
20
0
%
2011
2012
2013
2014
2015
2016
2017
2018
Year
LMWH
Heparin
None
Other

Outliers

- Repeated reports
- Present
  - What is your take ?
    - Literature
    - Collaborative data
  - What have you tried ?
  - Barriers ?
  - What do you need help on ?

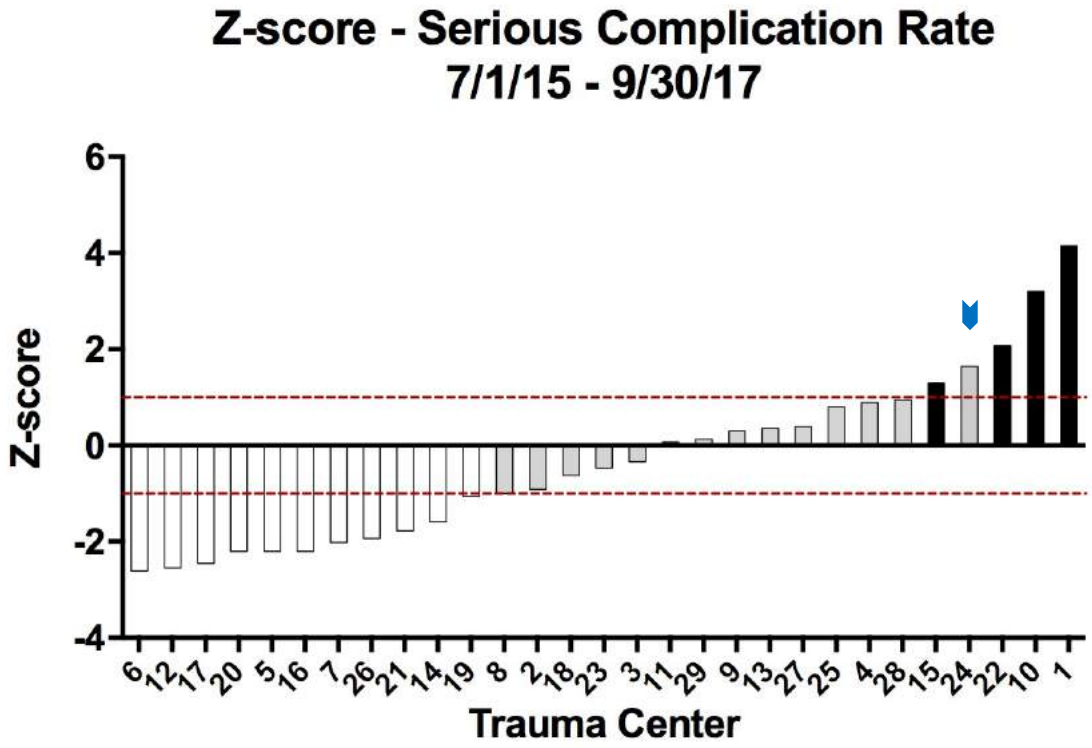
Z-score

- Measure of trend in outcome over time
- Hospital specific
  - Compared to yourself
- Standard deviation
- > 1 getting worse
- 1 to -1 flat
- < -1 getting better

Z-score

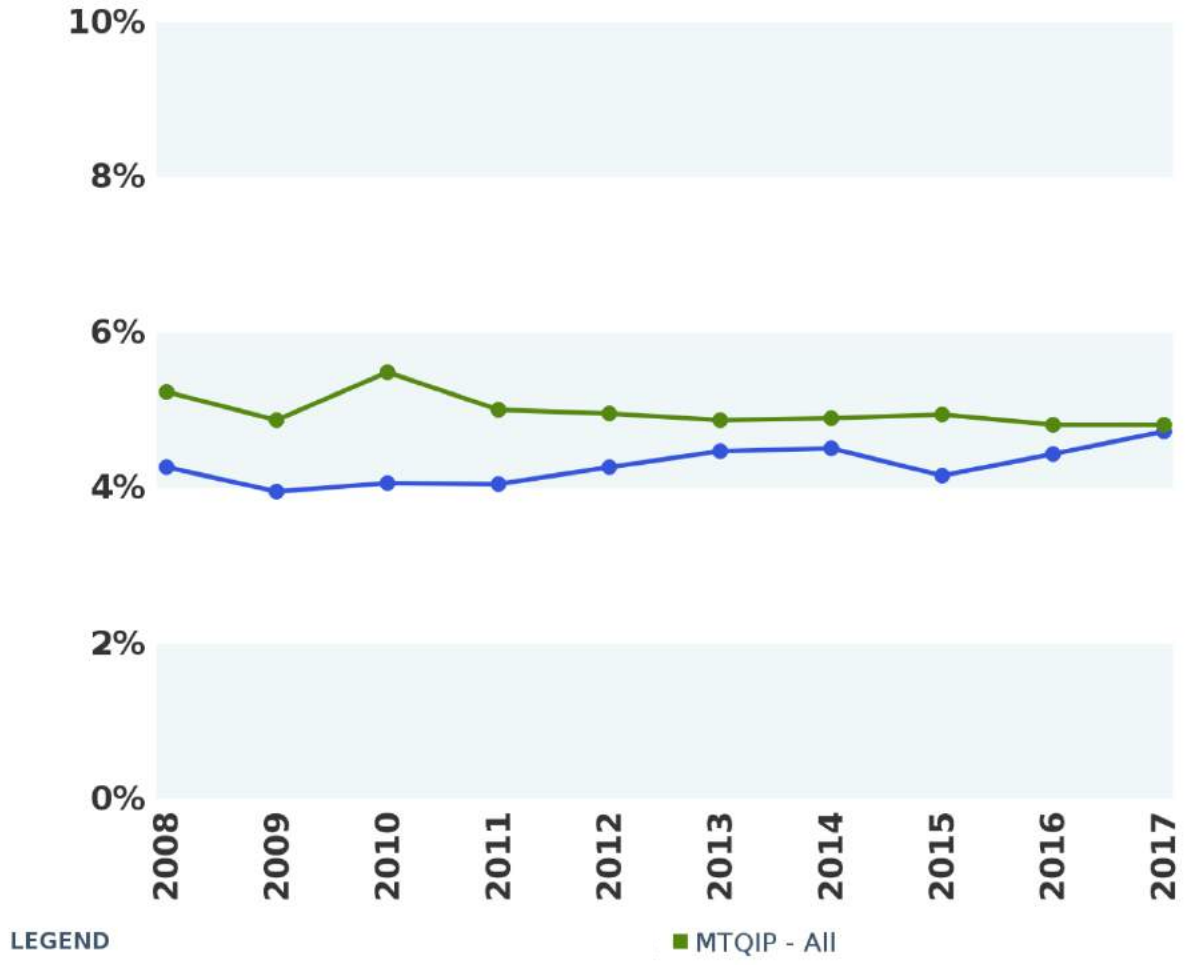
- Time: 7/1/2015 to 9/30/17
- Cohort 2
- Exclude if no signs of life
- Exclude transfers out

#7 Serious Complication Rate (Z-score)

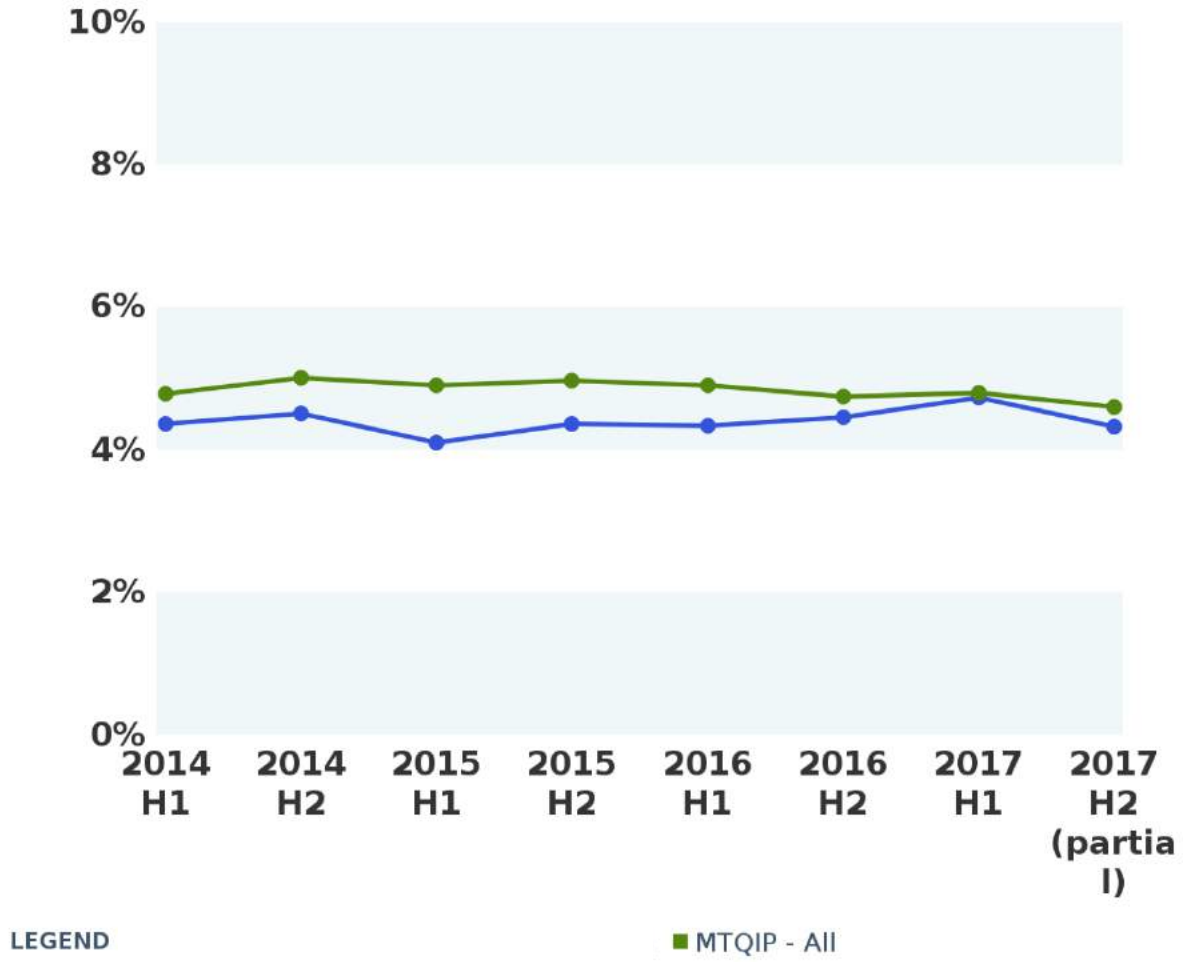


8 Mortality Rate (Z-score)

Outcomes Overview - Dead
Cohort 2 (Admit to Trauma Service), Exclude DOAs, Exclude Transfers Out



Outcomes Overview - Dead
Cohort 2 (Admit to Trauma Service), Exclude DOAs, Exclude Transfers Out



Hip Fractures

JAMA | Original Investigation

Association Between Wait Time and 30-Day Mortality in Adults Undergoing Hip Fracture Surgery

Daniel Pincus, MD; Bheeshma Ravi, MD, PhD; David Wasserstein, MD, MSc; Anjie Huang, MSc; J. Michael Paterson, MSc; Avery B. Nathens, MD, MPH, PhD; Hans J. Kreder, MD, MPH; Richard J. Jenkinson, MD, MSc; Walter P. Wodchis, PhD

IMPORTANCE Although wait times for hip fracture surgery have been linked to mortality and are being used as quality-of-care indicators worldwide, controversy exists about the duration of the wait that leads to complications.

OBJECTIVE To use population-based wait-time data to identify the optimal time window in which to conduct hip fracture surgery before the risk of complications increases.

DESIGN, SETTING, AND PARTICIPANTS Population-based, retrospective cohort study of adults undergoing hip fracture surgery between April 1, 2009, and March 31, 2014, at 72 hospitals in Ontario, Canada. Risk-adjusted restricted cubic splines modeled the probability of each complication according to wait-time. The inflection point (in hours) when complications began to increase was used to define early and delayed surgery. To evaluate the robustness of this definition, outcomes among propensity-score matched early and delayed surgical patients were compared using percent absolute risk differences (RDs, with 95% CIs).

EXPOSURE Time elapsed from hospital arrival to surgery (in hours).

MAIN OUTCOMES AND MEASURES Mortality within 30 days. Secondary outcomes included a composite of mortality or other medical complications (myocardial infarction, deep vein thrombosis, pulmonary embolism, and pneumonia).

RESULTS Among 42 230 patients with hip fracture (mean [SD] age, 80.1 years [10.7], 70.5% women) who met study entry criteria, overall mortality at 30 days was 7.0%. The risk of complications increased when wait times were greater than 24 hours, irrespective of the complication considered. Compared with 13 731 propensity-score matched patients who received surgery earlier, 13 731 patients who received surgery after 24 hours had a significantly higher risk of 30-day mortality (898 [6.5%] vs 790 [5.8%]; % absolute RD, 0.79; 95% CI, 0.23-1.35) and the composite outcome (1680 [12.2%]) vs 1383 [10.1%]; % absolute RD, 2.16; 95% CI, 1.43-2.89).

CONCLUSIONS AND RELEVANCE Among adults undergoing hip fracture surgery, increased wait time was associated with a greater risk of 30-day mortality and other complications. A wait time of 24 hours may represent a threshold defining higher risk.

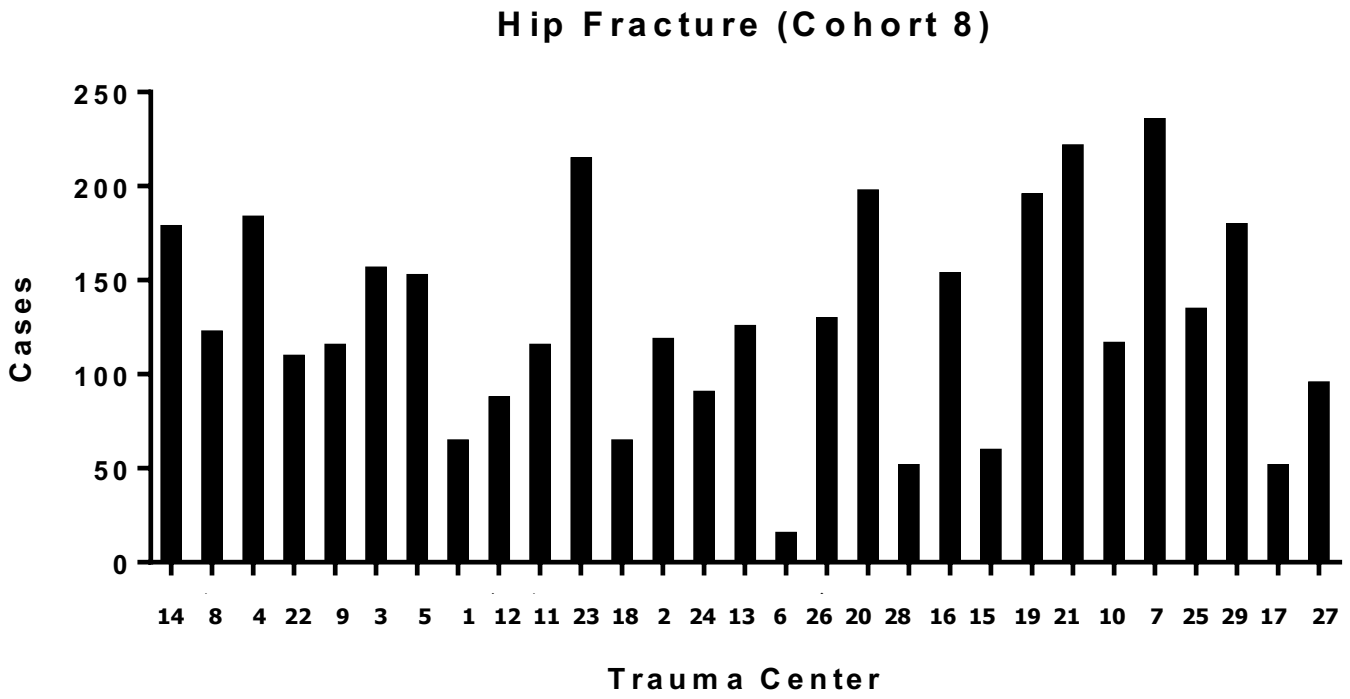
Editorial page 1981

Supplemental content

Author Affiliations: Department of Surgery, University of Toronto, Toronto, Ontario, Canada (Pincus, Ravi, Wasserstein, Nathens, Kreder, Jenkinson); Institute for Clinical Evaluative Sciences, Toronto, Ontario, Canada (Pincus, Ravi, Paterson, Nathens, Kreder, Wodchis); Institute of Health Policy, Management and

Hip Fractures

- Cohort 8
- We have information
  - Patient
  - Timing of OR
  - Discharge dispositions
- Could get
  - Anesthesia
  - Longer term followup ?
  - Morphomics ?



2016
Mortality or Hospice: Unadjusted 0-11.7%, Adjusted 3.4-6.1%

Hip Fractures

- Cohort 8
  - Fall
  - Hip Fracture AIS code
  - AIS Head/Neck, Face, Chest, Abdomen all < 1
- Discussion

Push Reporting
Hi-Low Outliers
Publication Pilot
Rationale for Data Elements

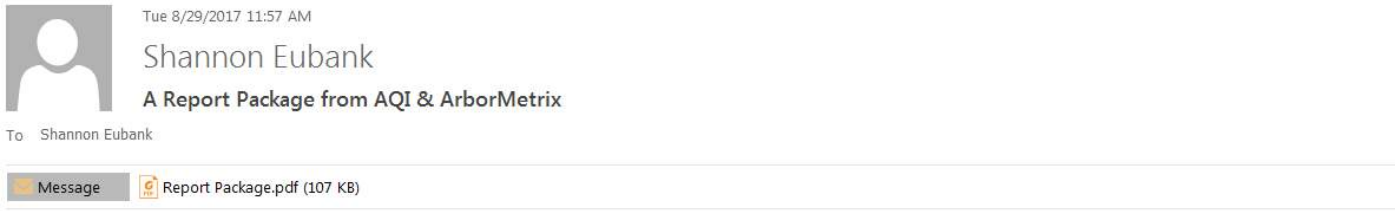
Jill Jakubus, PA-C

Push Reporting

- **Aggregated reporting sent via email**
- **No platform log in requirements**
- **Interval progress reporting feedback**

Target Release: March 2018

Push Reporting



Tue 8/29/2017 11:57 AM

Shannon Eubank

A Report Package from AQI & ArborMetrix

To Shannon Eubank

Message | Report Package.pdf (107 KB)

Hello Dr. Eubank,

Attached you will find a set of reports that detail the outcomes of your individual and hospital performance.

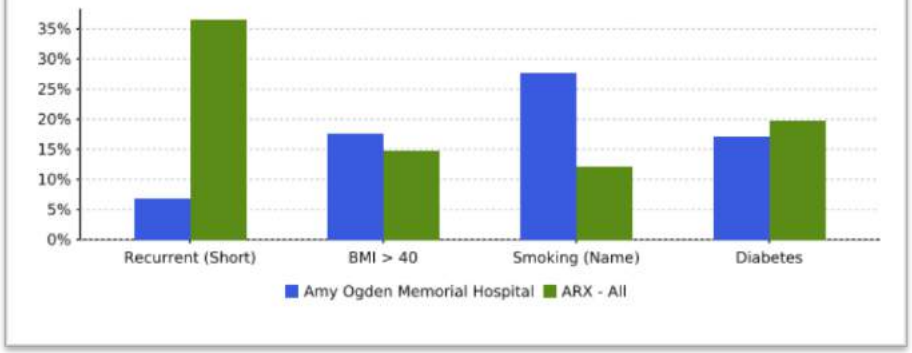
If you would like to know more, please log on to the AQI Registry at www.AQI.arbormetrix.com. These reports, and many others, are available for interaction and investigation.

Target Release: March 2018

Push Reporting

Pushed Paired Bar - Risk Factors - Unadj with Rank

Provider *	Observed	Ranking - Unadj	NUM	DEN
Recurrent (Short)				
Amy Ogden Memorial Hospital	6.9	23 out of 65	2	29
ARX - All	36.4		1304	3579
BMI > 40				
Amy Ogden Memorial Hospital	17.6	50 out of 65	6	34
ARX - All	14.6		531	3635
Smoking (Name)				
Amy Ogden Memorial Hospital	27.6	62 out of 65	8	29
ARX - All	12		430	3579
Diabetes				
Amy Ogden Memorial Hospital	17.2	42 out of 65	5	29
ARX - All	19.8		708	3579

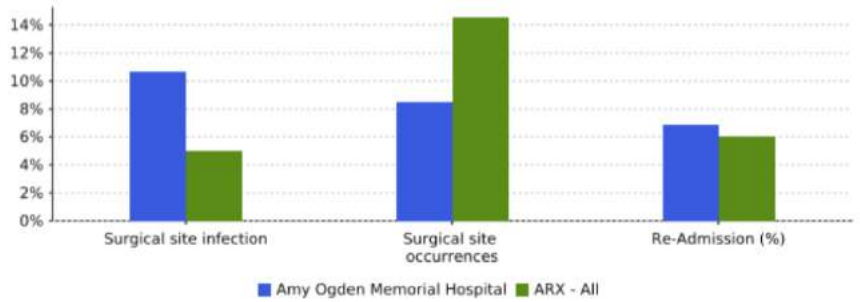


Target Release: March 2018

Push Reporting

Pushed Paired Bar - 30 Day Post-Op complication: Adjusted with percentile & CI

Provider *	Adjusted	Observed	Expected	O/E Ratio	Percentile	Percentile - Unadj	Confidence Interval - High	Confidence Interval - Low	NUM	DEN
Surgical site infection										
Amy Ogden Memorial Hospital	10.6	6.9	3.68	1.88	86%	83%	18.4	2.83	2	29
ARX - All	4.98	4.98	5.66	0.88			5.77	4.19	146	2931
Surgical site occurrences										
Amy Ogden Memorial Hospital	8.45	6.9	14.7	0.47	50%	50%	21.1	0	2	29
ARX - All	14.5	14.5	18	0.81			15.8	13.3	426	2931
Re-Admission (%)										
Amy Ogden Memorial Hospital		6.90%				71%	15.4%	0%	2	29
ARX - All		6.04%					6.90%	5.18%	177	2931



Target Release: March 2018

Push Reporting - Discussion

- **Proposal frequency and content**
- **Feedback**
- **Recipients**

Target Release: March 2018

High/Low Outliers

- **Visual signaling similar to dashboards**
- **User toggle to activate**

Target Release: March 2018

High/Low Outliers

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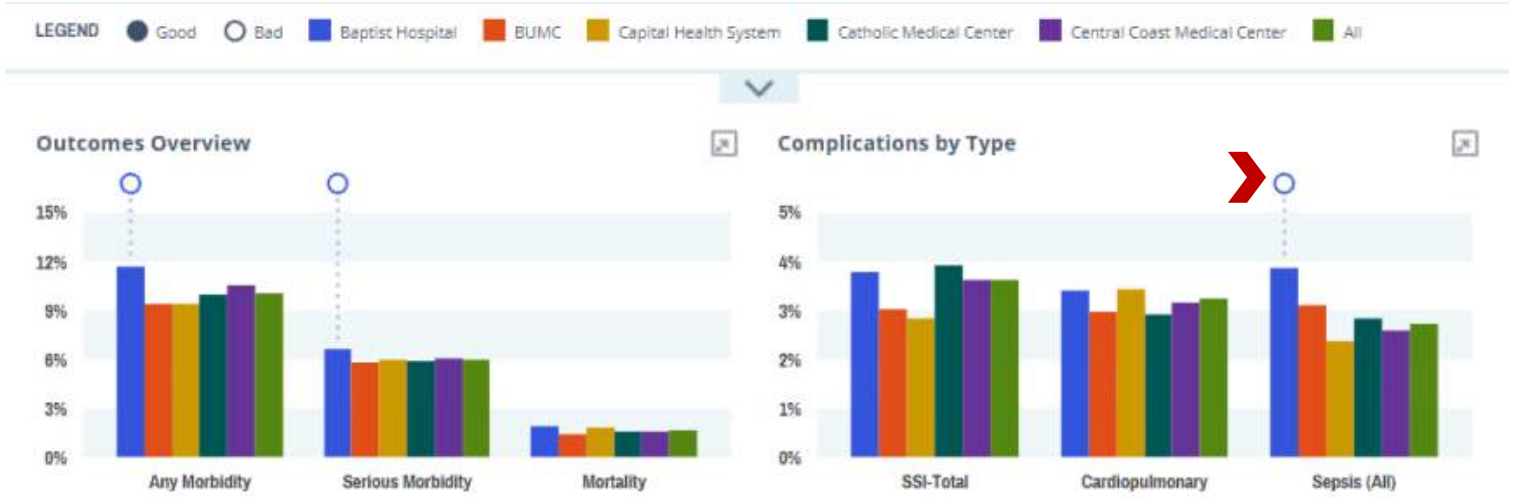
High/Low Outliers



Target Release: March 2018

Publication Pilot - DUA Signed

- **Peter Lopez, MD**
- **Gaby Iskander, MD**
- **Wendy Wahl, MD**
- **Support team**

- **Met Jan 9, 2018**
- **Aggregating plan for MTQIP Publication's Committee**

Data Element Rationale

Change Type – Content	
Rational – NTDS update	
2017	2018
CATHETER-ASSOCIATED URINARY TRACT INFECTION (Consistent with the January 2016 CDC defined CAUTI. Always use the most recent definition provided by the CDC.)	**CATHETER-ASSOCIATED URINARY TRACT INFECTION** (Consistent with the January 2016 CDC defined CAUTI. ~~Always use the most recent definition provided by the CDC.)~~

Data Element Rationale

Change Type – Content	
Rational – Validation variability noted. Clarification at member request.	
2017	2018
ED DISCHARGE DISPOSITION The disposition of the patient at the time of discharge from the ED. • The null value "Not Applicable" is used if the patient is directly admitted to the hospital. • If ED Discharge Disposition is 4, 5, 6, 9, 10, 11, then Hospital Discharge Date, Time, and Disposition should be "Not Applicable". (1) Floor bed (general admission, non-specialty unit bed) (2) Observation unit (unit that provides < 24 hour stays) (3) Telemetry/step-down unit (less acuity than ICU) (4) Home with services (5) Died/Expired (6) Other (jail, institutional care, mental health, etc.) (7) Oper om (8) Inten e Unit (ICU) (9) Home without services	**ED DISCHARGE DISPOSITION** The disposition of the patient at the time of discharge from the ED. • The null value "Not Applicable" is used if the patient is directly admitted to the hospital. • If ED Discharge Disposition is 4, 5, 6, 9, 10, 11, then Hospital Discharge Date, Time, and Disposition should be "Not Applicable". • For patients who require Interventional Radiology in the radiology procedure suite, capture the patient's disposition location following this procedure. • Capture should indicate the actual care being delivered to the patient. • Example 1: The ICU provides floor, step-down, and ICU care. The patient is admitted to the ICU and the documentation indicates the patient is provided floor care. Capture as floor. • Example 2: Floor beds can provide telemetry if patient need exists. The documentation indicates the patient receives telemetry monitoring on the floor. Capture as telemetry.

Conclusion

- Evaluations
  - Fill out and turn in
- Questions?
- See you in May