Bridging the Gap: Endovascular Techniques and the Acute Care Surgeon

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Associate Professor of Surgery
Division of Trauma/Surgical Critical Care, RA Cowley Shock Trauma Center
Division of Vascular Surgery, University of Maryland School of Medicine
Disclosures

Pryor Medical Inc: Clinical Advisory Board

Patent pending: Central Pressurized Cadaver Model (CPMC) UMB 2014
Outline

• Statement of the Problem
• History
• Translational/Clinical Research
• Product Development
• Future
Statement of the Problem

- Hemorrhage remains a leading cause of death in civilian and wartime trauma.
- Vascular disruption with concomitant hemorrhage is the leading cause of *potentially preventable death*.
- Traditional options for trauma patients with exsanguinating hemorrhage below the diaphragm:
  - EDT with aortic cross clamp in arrest/prior to laparotomy and/or pelvic packing
  - Laparotomy in ED with proximal control

DISMAL OUTCOMES
Methods of aortic occlusion
Is there a better way?

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)
USE OF AN INTRA-AORTIC BALLOON CATHETER TAMPONADE FOR CONTROLLING INTRA-ABDOMINAL HEMORRHAGE IN MAN

Lieutenant Colonel Carl W. Hughes, Medical Corps, United States Army, Washington, D. C.

(From the Division of Surgery, Army Medical Service Graduate School, Walter Reed Army Medical Center)
Early Technology

- 13% survival in 15 trauma patients after REBOA

- 35% survival in 20 trauma patients after REBOA
Endovascular era improves technology and outcomes


Transfemoral balloon aortic occlusion balloon during open CPR improves myocardial and cerebral blood flow. Spence et al 1990


Endovascular balloon occlusion of the aorta is superior to resuscitative thoracotomy with aortic clamping in a porcine model of hemorrhagic shock. White et al 2011

Forty minute Endovascular Aortic Occlusion Increases Survival in an Experimental Model of Uncontrolled Hemorrhagic Shock caused by Abdominal Trauma. Avaro et al 2011
Case Series - Trauma

Intra-Aortic Balloon Occlusion to Salvage Patients With Life-Threatening Hemorrhagic Shocks From Pelvic Fractures

Thomas Martinelli, MD, Frédéric Thony, MD, Philippe Decléty, MD, Christian Sengel, MD, Christophe Broux, MD, Jérôme Tonetti, MD, PhD, Jean-François Payen, MD, PhD, and Gilbert Ferretti, MD, PhD

J Trauma 2010 Apr;68(4):942-8

- 13 patients with pelvic fracture, refractory hypotension
- Aortic occlusion performed by IR – in-house
- 46% survival
Case Reports – Non-Trauma


All performed by Interventionalists
• 13 faculty from the Division of Trauma and Critical Care at the R Adams Cowley Shock Trauma Center
• novice interventionalists
• “off the shelf” technology used for Endovascular
• excluded if they had taken a similar endovascular training course, had additional training in endovascular surgery, or had performed this procedure in the clinical setting
<table>
<thead>
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<th>Min</th>
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<td>Years since residency</td>
<td>7.4</td>
<td>1</td>
<td>17</td>
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<tr>
<td># endovascular cases in residency</td>
<td>28.23</td>
<td>0</td>
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<td># of intra-aortic balloon pumps (IABP) placed in fellowship</td>
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<td># of intra-aortic balloon pumps (IABP) placed since fellowship</td>
<td>0.3</td>
<td>0</td>
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<td># central and arterial lines placed per week</td>
<td>2.69</td>
<td>0</td>
<td>10</td>
<td>2.84</td>
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Conclusion

• Significant improvements in procedural time and knowledge can be achieved regardless of endovascular experience in residency, years since residency, or other parameters.

• Novice interventionalists (acute care surgeons) can add a specific skillset (REBOA) to their existing core competencies.

J Trauma Acute Care Surg. 2014 Aug;77(2):286-91
A clinical series of resuscitative endovascular balloon occlusion of the aorta for hemorrhage control and resuscitation

Megan L. Brenner, MD, Laura J. Moore, MD, Joseph J. DuBose, MD, George H. Tyson, MD, Michelle K. McNutt, MD, Rondel P. Albarado, MD, John B. Holcomb, MD, Thomas M. Scalea, MD, and Todd E. Rasmussen, MD

<table>
<thead>
<tr>
<th>Patient</th>
<th>1</th>
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<td>24</td>
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<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>F</td>
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<td>Mechanism of injury</td>
<td>MVC</td>
<td>GSW</td>
<td>GSW</td>
<td>MVC</td>
<td>MCC</td>
<td>ATV collision</td>
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<td>Injury Severity Score</td>
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<td>50</td>
<td>9</td>
<td>25</td>
<td>48</td>
<td>43</td>
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<td>Systolic Blood Pressure (SBP) prior to REBOA (mm Hg)</td>
<td>70</td>
<td>70</td>
<td>0</td>
<td>60</td>
<td>70</td>
<td>85</td>
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<td>Cardiac arrest prior to REBOA</td>
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<td>no</td>
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<td>no</td>
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<td>SBP after REBOA (mmHg)</td>
<td>135</td>
<td>122</td>
<td>100</td>
<td>110</td>
<td>130</td>
<td>125</td>
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<td>Time to occlusion (mins)</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>6</td>
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<td>Time of occlusion (mins)</td>
<td>12</td>
<td>16</td>
<td>70</td>
<td>60</td>
<td>65</td>
<td>36</td>
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<td>Surgery after REBOA</td>
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<td>yes</td>
<td>yes</td>
<td>yes</td>
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<td>Embolization after REBOA</td>
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<td>yes</td>
<td>no</td>
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<td>Complication of REBOA</td>
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<td>no</td>
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<tr>
<td>Outcome</td>
<td>Alive</td>
<td>Alive</td>
<td>Alive</td>
<td>Alive</td>
<td>Brain death</td>
<td>Death (Care withdrawn)</td>
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</table>
Implementation of REBOA as an alternative to resuscitative thoracotomy for noncompressible truncal hemorrhage


24 REBOA
• STC and UTH
• ACS performing REBOA
• “off the shelf” devices
• No difference in admission physiology

• Survival: EDT=9.75%, REBOA=37.5%, p=0.003
• Died in ER: EDT=69.2%, REBOA=29.7%, p<0.001
• ICU deaths: Early death from hemorrhage EDT 71.4%, REBOA 0%

Conclusion
• May improve survival
• No severe procedure-related complications
• ACS can perform REBOA safely with current technology
Number of RT and REBOA cases

1st Six Months: 29 RT, 0 REBOA
2nd Six Months: 33 RT, 5 REBOA
3rd Six Months: 19 RT, 10 REBOA
Training and Clinical Use

ACS Committee on Trauma Introduces Basic Endovascular Skills for Trauma (BEST) Course

NEWS FROM THE AMERICAN COLLEGE OF SURGEONS | FOR IMMEDIATE RELEASE

CHICAGO (October 7, 2016): The American College of Surgeons Committee on Trauma (ACS COT) has introduced the Basic Endovascular Skills for Trauma© (BEST) course.

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<td>Apr 12</td>
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Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA)

A prospective observational study of the Endovascular Skills in Trauma and Resuscitative Surgery

PI: Dr. J Dubose

http://www.aast.org/Research/MultiInstitutionalStudies.aspx
The AAST Prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry

Dubose et al. JTACS 2016 Sep;81(3):409 19

REBOA n=46
• Groin cutdown 50% of REBOAs
• 65% imaging use
• No difference in AO time (6-7mins) REBOA vs EDT
• 87% REBOAs placed by ACS

Conclusion:
• No severe procedure-related complications
• ACS can perform REBOA safely with current technology

0.035” 260cm guidewire, 12 Fr sheath, CODA 32mm
REBOA – Japan


• Norii et al. Survival of severe blunt trauma patients treated with resuscitative endovascular balloon occlusion of the aorta compared with propensity score-adjusted untreated patients. J Trauma Acute Care Surg. 2015 Apr;78(4):721-8. 452 patients

• Inoue J et al. REBOA MIGHT BE DANGEROUS IN PATIENTS WITH SEVERE TORSO TRAUMA A PROPENSITY SCORE ANALYSIS SAYS. J Trauma Acute Care Surg. 2016 Apr;80(4):559-67. 374 patient

• Teeter et al. Smaller introducer sheaths for REBOA may be associated with fewer complications. J Trauma Acute Care Surg. 2016 May 27. 33 patients
## TABLE 1. Clinical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
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<td>64</td>
<td>69</td>
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<tr>
<td>Mechanism</td>
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<td>ISS</td>
<td>75</td>
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<td>50</td>
<td>25</td>
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<td>Liver injury</td>
<td>Grade II</td>
<td>—</td>
<td>Grade V</td>
<td>Grade IV</td>
<td>—</td>
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<td>Splenic injury</td>
<td>—</td>
<td>Grade IV</td>
<td>—</td>
<td>—</td>
<td>Grade III</td>
<td>Grade IV</td>
<td>Grade III</td>
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<td>FAST scan</td>
<td>Negative</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
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<td>Renal injury</td>
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<td>Grade III</td>
<td>Grade II</td>
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<td>Retropertioneal hemorrhage</td>
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<td>No</td>
<td>No</td>
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<td>Pelvic fracture</td>
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<td>Femoral fracture</td>
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<tr>
<td>SBP before REBOA, mm Hg</td>
<td>80</td>
<td>80</td>
<td>99</td>
<td>74</td>
<td>84</td>
<td>71</td>
<td>78</td>
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<tr>
<td>SBP after REBOA, mm Hg</td>
<td>90</td>
<td>130</td>
<td>139</td>
<td>135</td>
<td>92</td>
<td>190</td>
<td>153</td>
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<td>PRBC within 24 h, mL/U</td>
<td>6,000 mL/50 U</td>
<td>3,600 mL/30 U</td>
<td>2,400 mL/20 U</td>
<td>6,240 mL/52 U</td>
<td>3,600 mL/30 U</td>
<td>2,640 mL/22 U</td>
<td>1,200 mL/10 U</td>
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<tr>
<td>FFP within 24 hours, mL/U</td>
<td>5,400 mL/60 U</td>
<td>6,300 mL/70 U</td>
<td>900 mL/10 U</td>
<td>4,050 mL/45 U</td>
<td>2,700 mL/30 U</td>
<td>2,700 mL/30 U</td>
<td>1,800 mL/20 U</td>
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<tr>
<td>PC within 24 hours, mL/U</td>
<td>1,000 mL/50 U</td>
<td>1,200 mL/60 U</td>
<td>600 mL/30 U</td>
<td>600 mL/30 U</td>
<td>200 mL/10 U</td>
<td>200 mL/10 U</td>
<td>250 mL/15 U</td>
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<td>FFP/PRBC ≥ 1, U</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Total occlusion time, min</td>
<td>No deflation</td>
<td>97</td>
<td>74</td>
<td>85</td>
<td>150</td>
<td>43</td>
<td>33</td>
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<td>REBOA-related complications</td>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<td>Additional operative management</td>
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<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>28-d outcome</td>
<td>Dead</td>
<td>Alive</td>
<td>Alive</td>
<td>Alive</td>
<td>Alive</td>
<td>Alive</td>
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</table>

FFP: fresh frozen plasma; PC: platelet concentrate; PRBC, packed red blood cell; SBP, systolic blood pressure.
REBOA: Japan

- ER
- +/-IR
- sheaths left in place
- Zone 1 regardless of injury pattern
- devices different
Pryor Medical Inc.

- Systemic arterial pressure monitoring
- Large vessel occlusion
- Fluoroscopy free
  - Wire-free
  - 7Fr compatible
  - Catheter markings for insertion
  - 32mm compliant balloon

FDA approved 10/26/2015

www.prytimemmedical.com
Clinical Study of REBOA for Severe Pelvic Fracture and Abdominal Hemorrhage using Continuous Vital Signs and Video Monitoring

March 2015-March 2017
Department of Defense (DOD)

Physiologic Data
Outcomes Data
Clinical Study of REBOA using Continuous Vital Signs and Video Monitoring

- 101 REBOA 02/2013-present
  - 89 Trauma
    - 50 CODA, 39 ER-REBOA
  - 12 Non Trauma
    - 5 CODA, 7 ER-REBOA

STC institutional series

- Patients in arrest from penetrating non-thoracic hemorrhage:
  - 25% survival to hospital discharge
  - 100% neurologically intact
Clinical Study of REBOA using Continuous Vital Signs and Video Monitoring

• AAST 2016
  • Time to aortic occlusion: It's all about access
• ACS 2016
  • Paradigm shift in hemorrhagic traumatic arrest: REBOA is at least as effective as RTACC
  • Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Can Be Performed Rapidly and Safely By Acute Care Surgeons
• ACEP 2016
  • Virtual Reality Simulation can help prepare EM physicians for REBOA
  • Resuscitative Endovascular Balloon Occlusion of the Aorta improves quality of resuscitation versus Thoracotomy in Patients in Traumatic Arrest
Clinical Study of REBOA using Continuous Vital Signs and Video Monitoring

• REBOA as an Alternative to Cross-Clamp for Intra-Operative Proximal Aortic Control
• Duration of aortic occlusion and survival
• Utility of CT in Patients Receiving REBOA
• REBOA in patients with mangled extremities: ischemic burden
• Newly approved ER-REBOA device
Complications

n=89

- 1 interposition graft
- 2 patch angioplasties
- 9 thrombectomies; 6 with 12Fr sheath
- 3 balloon ruptures; 2 over-inflation
- 1 amputation from mismanagement of in-dwelling sheath
REBOA as a tool for resuscitation

- Feb 2013-Sept 2016
- groups
  - REBOACC (n=21)
  - OCCMACC (n=24)
    - All patients in arrest at the time of REBOA/OCC
    - All patients in arrest from penetrating non-thoracic hemorrhage
    - Admission physiology and down-time similar

- EtCO2 pre- and post- AO: initial, peak, final, mean/median
- rate of ROSC
- total cardiac compression fraction

- continuous vital sign monitoring
- time-stamped videography

- location of death
- mortality
# Results: pre-AO EtCO2

<table>
<thead>
<tr>
<th></th>
<th>REBOACCC</th>
<th>OCCMACC</th>
<th>p=</th>
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<tbody>
<tr>
<td>Initial</td>
<td>11.5±11.5</td>
<td>5.1±6.8</td>
<td>0.08</td>
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<tr>
<td>Peak</td>
<td>29.6±17.3</td>
<td>16.2±10.29</td>
<td>0.01</td>
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<tr>
<td>Final</td>
<td>22.2±15.2</td>
<td>9.2±6.4</td>
<td>0.0005</td>
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<tr>
<td>Mean</td>
<td>15.2±10.7</td>
<td>7.5±6.2</td>
<td>0.01</td>
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<tr>
<td>Median</td>
<td>14.5±10.4</td>
<td>7.0±6.6</td>
<td>0.01</td>
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## pre-AO TCCF

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<tr>
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<th>TCCF* (p&lt;0.0001)</th>
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<td>REBOACCC</td>
<td>85.3±12.7%</td>
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<tr>
<td>OCCMACC</td>
<td>35.2±18.6%</td>
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## Results: post-AO EtCO2

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<th>REBOACCC</th>
<th>OCCMACC</th>
<th>p=</th>
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<tbody>
<tr>
<td>Initial</td>
<td>20.7+14.3</td>
<td>10.2+7.3</td>
<td>0.006</td>
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<tr>
<td>Peak</td>
<td>32.8+16.7</td>
<td>24.8+20.9</td>
<td>0.07</td>
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<tr>
<td>Final</td>
<td>21+15.9</td>
<td>11.6+13.5</td>
<td>0.04</td>
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<tr>
<td>Mean</td>
<td>21.8+12.7</td>
<td>12.7+10.1</td>
<td>0.01</td>
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<tr>
<td>Median</td>
<td>21.3+12.6</td>
<td>12.5+11.3</td>
<td>0.01</td>
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## post-AO TCCF

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<td>REBOACCC</td>
<td>88.3+7.8%</td>
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<tr>
<td>OCCMACC</td>
<td>71.9+24.4%</td>
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</table>
Results

- Trend for REBOACCC patient survival to OR (p=0.09)

<table>
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<tr>
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<th>ROSC* (p=0.037)</th>
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<tbody>
<tr>
<td>REBOACCC</td>
<td>57%</td>
</tr>
<tr>
<td>OCCMACC</td>
<td>24%</td>
</tr>
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</table>

- In-hospital mortality 93% (p=0.9)
- Location of death significantly different (p=0.03)
  - 100% OCCMACC in ED or ICU
  - 72% REBOACCC in ED or ICU
  - 3 died in ICU, 3 discharged to home neurologically intact
Conclusions:

Compared to OCCMACC

- REBOACC patients have higher EtCO2 levels before and after aortic occlusion
- REBOACC patients receive a greater percentage of cardiac compressions, have a higher rate of ROSC, and survive more often beyond the resuscitation area
REBOA is Superior to Resuscitative Thoracotomy in Select Patients with Hemorrhagic Shock: Early results from the AAST AORTA Registry

- Survival benefit out of ED and to hospital discharge in select patients in extremis from non-penetrating thoracic injury
REBOA: UK

London's Air Ambulance Performs World's First Prehospital REBOA


Resuscitative endovascular balloon occlusion of the aorta (REBOA) in the pre-hospital setting: An additional resuscitation option for uncontrolled catastrophic haemorrhage.

Sadek S et al. Resuscitation. 2016 Jul 1
Special Operations Surgical Team

- Multi-disciplinary team (surgeon, EM etc)
- Formal training at the BEST™ Course
- Deployed to Role 2 equivalent
- 4 REBOAs performed
- Hand-held ultrasound used to guide femoral artery placement of 7Fr sheath
- ER-REBOA™ catheter positioning without x-ray
- Zone 1 (N= 3)
- Zone 3 (N=1)
- No complications
- Patients survived to next echelon of care
Epidemiology & Lethality of Torso Hemorrhage

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

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Future: Physiology

- Maximal occlusion times Zone 1 and 3
- Flow velocities above and below occlusion
- Cerebral perfusion, TBI
- Cardiac perfusion, afterload
- Inflammatory response to REBOA
- Distal ischemic burden
Partial REBOA

Endovascular Variable Aortic Control (EVAC) Study Group
Travis AF Base/UC Davis, Dr. J. Dubose

- Concern for distal ischemia
- Potential to expand indications and length of use particularly at Zone 1
Future: Technology

- Wire-free devices
- Fluoroscopy free – ultrasound, magnetic field devices
- Combination infusion/resuscitation/occlusion
- Automatic release valve for over inflation
- Pressure regulated balloons for partial occlusion
Future: Applications

• Trauma/Acute Care Surgeons
  – Trauma, arrest and hemorrhagic shock
    • Hemorrhagic shock, neurogenic shock, cardiogenic shock
  – Non-trauma, arrest and hemorrhagic shock

• Pre-hospital/medics
• Military applications
• ER+Critical Care
Future: Applications

- Adrian Kantrowitz, MD; Steinar Tjønneland, MD; Paul S. Freed, MS; et al. Initial Clinical Experience With Intraaortic Balloon Pumping in Cardiogenic Shock. JAMA. 1968;203(2):113-118


- Christopher R. Foerster, Anuar Turgulov. Prehospital endovascular occlusion of the aorta is now a technically feasible strategy for improving haemodynamics in CPR. Resuscitation Volume 93, August 2015, Pages e25
Future: Applications

- Multi-institutional trial for REBOA in medical arrest
  Clinical algorithms, operational hurdles mirror early efforts and rational in trauma
  - Translational research promising
  - EDT>NCTH dismal outcomes
  - as a solitary resuscitative measure
  - as a bridge to ECMO or IABP

- In-hospital: ECMO teams with surgical capability

- Pre-hospital capabilities
Summary

Preliminary clinical research demonstrates:

Compared to EDTCC:

– Higher rate of ROSC, EtCO2
– Survival benefit, out of ED and to hospital discharge

Overall:

– Currently used in select centers by ACS
– Currently used by US military and others abroad in pre-hospital setting
– ACS do not need extensive training to perform REBOA
– Complications exists, almost all non limb or life-threatening
– Paradigm shift in clinical practice
Thank you