REBOA: An Overview and Update

Gerald Richard Fortuna, Jr. MD, FACS

Assistant Professor of Surgery
Washington University in St. Louis
Sections of Vascular and Trauma/Acute Care Surgery

Col USAF MC SFS
Director
St Louis Center for the Sustainment of Trauma and Readiness Skills
Disclosures

• Speakers Bureau for Prytime
• The views presented today do not represent those of the US Government or those of the US Air Force
Resuscitative Endovascular Occlusion of the Aorta (REBOA)
Epidemiology & Lethality of Torso Hemorrhage

The epidemiology of noncompressible torso hemorrhage in the wars in Iraq and Afghanistan

Adam Stannard, MRCS, Jonathan J. Morrison, MRCS, Daniel J. Scott, MD, Rebecca A. Ivatury, RN, James D. Ross, PhD, and Todd E. Rasmussen, MD, San Antonio, Texas

J Trauma Acute Care Surg 2013;74:830-34

• 18% of wounded US service personnel have injury pattern susceptible to non-compressible hemorrhage
Development and Implementation of Endovascular Capabilities in Wartime


**Background:** Endovascular techniques are widespread in the management of civilian trauma and provide standard treatment for select injuries. Despite the commonality of this less invasive technology, there have been no reports on its use in wartime. The objective of this study was to describe the implementation of endovascular capability at a level III surgical facility in Iraq and illustrate the effectiveness of catheter-based techniques.

**Methods:** From September 1, 2004 through April 30, 2007, injuries at the Air Force Theater Hospital, Balad, Iraq, were registered in a database and reviewed. Patients in whom endovascular procedures were performed comprise the study group (N = 139).

**Results:** During this period, 150 catheter-based procedures were performed, including placement of 39 vena cava filters. The 111 nonfilter procedures were performed in the setting of extremity (N = 72), cervical (N = 19), and torso (N = 20) injuries. Of the diagnostic procedures, an abnormal finding was present in 67 (61%) cases, and 47 of these underwent either open surgical repair (N = 30) or endovascular treatment (N = 17). Endovascular therapies fell into three categories: embolization (N = 10), covered stent placement (N = 5), or miscellaneous (N = 2). The technical success rate of endovascular treatments was 100%, and procedure-related complications were uncommon (N = 4; 3%).

**Conclusion:** This report is the first to demonstrate the effectiveness of diagnostic and therapeutic endovascular capability in the management of acute wartime injury. Implementation of this capability has unique requirements related to imaging and a trauma-specific endovascular inventory. Once established, however, endovascular capability markedly expands the injury management armamentarium and, in certain cases, provides the preferred treatment.

**Key Words:** Vascular injury, Endovascular therapy, Wartime.
Concept of REBOA is Introduced in 2011

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. Resuscitative aortic occlusion with a balloon was reported as early as the Korean War and has been described in more recent publications. 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

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

- Introduced as new strategy for torso hemorrhage
Call For Innovation

• Military-specific IP for new balloon catheter (designed for emergency scenarios)

• Goals:
  – Reduce catheter Fr size
  – Obviate need for “over the wire” placement
  – Obviate need for fluoroscopy/x-ray

Technology Opportunity

Controlling Non-compressible Torso Bleeding

The University of Michigan and the U.S. Air Force seek to commercialize through patent licensing an aortic occlusion system for controlling non-compressible torso hemorrhaging.
Initial REBOA Prototype (patent - circa 2009)

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

Daniel J. Scott, MD, Jonathan L. Eliaason, 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; 75:122-28
Basic Concept

- Preservation perfusion to brain / heart
- Occlusion of arterial flow above bleeding source
Death on the Battlefield
Implications for Prevention, Training, and Medical Care

US Army Institute of Surgical Research
and
Armed Forces Medical Examiner Service

Brian Eastridge
COL, MC, USA
Trauma Consultant
US Army Surgeon General
Battlefield Acute Lethality
Potentially Survivable n=1,075
Potentially survivable combat deaths due to hemorrhage (n=984)
It’s a civilian problem as well....

NTDB Study:

Mortality from hemorrhage at non-compressible sites = 44.6%
Resuscitative Thoracotomy for Trauma

• The only hope for a patient in / nearing extremis despite resuscitation after NCTH?

• Indications?

• Threshold for use?
Survival after Emergency Department Thoracotomy: Review of Published Data from the Past 25 Years

Peter M. Rhee, MD, MSc, FACS, Jose Aguiniga, MD, FACS, Amy R. Ridgeway, MD, FACS, Dennis Wang, MD, FACS, Marlon Jordan, MD, FACS, Norman Rich, MD, FACS

Background: Emergency department thoracotomy (EDT) has become standard of care for patients who suddenly arrest after injury. Patient selection is vital to achieve survival outcomes without mortal harm. The purpose of this study is to analyze the major factors that most influence survival after EDT.

Study Design: Twenty-four articles that included 4,620 cases from institutions that reported EDT for both blunt and penetrating trauma over the past 25 years were reviewed. The primary outcome analyzed were in-hospital survival rates.

Results: EDT led to an overall survival rate of 7.4%. Normal hemodynamic outcomes were seen in 92.4% of surviving patients. Factors reported to influencing outcomes were the mechanism of injury (MOI), location of thoracic injury (DOI), and signs of life (SOL). Injured patients with MOI score of 6 or higher for penetrating injuries and 4 or higher for blunt injuries when prehospital injuries were further separated, the survival rates were 14.8% (n=57) and 10.8% (p=0.005, beta=3.2) for gunshot wounds and 6.3% (n=40) and 2.8% (p=0.017, beta=3.5) for stab wounds in the abdominal region, and 8.3% (n=27) and 9.7% for multiple injuries. When the DOI was the thorax, the survival rate was the highest at 11.5%. The third factor influencing outcome was SOL. If SOL were present on arrival in the hospital, survival rate was 15.5% in contrast to 2.4% if none were present. SOL present during thoracotomy was associated with 2.9% survival, while SOL absent was associated with 2.2% survival.

Conclusion: The most critical factors are signs of life, survival rate, and mechanism of injury. The overall survival rate is 7.4%.

Mechanism: Location major injury

Signs of life

Survival rate = 7.4%

• 25 years of EDT
• 4,620 cases
Survival after EDT

<table>
<thead>
<tr>
<th>Condition</th>
<th>Survival Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shock</td>
<td>25</td>
</tr>
<tr>
<td>No Vital Signs</td>
<td>8</td>
</tr>
<tr>
<td>No Signs of Life</td>
<td>3</td>
</tr>
<tr>
<td>Cardiac Penetrating</td>
<td>1</td>
</tr>
<tr>
<td>Blunt</td>
<td>0</td>
</tr>
</tbody>
</table>

SHOCK NO VITAL SIGNS
NO SIGNS OF LIFE
BLUNT
CARDIAC PENETRATING
An evidence-based approach to patient selection for emergency department thoracotomy: A practice management guideline from the Eastern Association for the Surgery of Trauma

Mark J. Seamon, MD, Elliott R. Haut, MD, PhD, Kyle Van Arendonk, MD, Ronald R. Barbosa, MD, William C. Chiu, MD, Christopher J. Dente, MD, Nicole Fox, MD, Randeep S. Jawa, MD, Kosar Khwaja, MD, J. Kayle Lee, MD, Louis J. Magnotti, MD, Julie A. Mayglothling, MD, Amy A. McDonald, MD, Susan Rowell, MD, MCR, Kathleen B. To, MD, Yngve Falek-Ytter, MD, and Peter Rhee, MD, MPH, Philadelphia, Pennsylvania

Presented: EAST 26th Annual Scientific Assembly – Scottsdale Arizona, January 2013
Published: J Trauma Acute Care Surg. 2015;79(1):159-173.
<table>
<thead>
<tr>
<th>Question</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PICO #1</td>
<td>In patients who present pulseless to the Emergency Department with signs of life after penetrating thoracic injury, we strongly recommend resuscitative Emergency Department thoracotomy. <strong>Strong Recommendation</strong></td>
</tr>
<tr>
<td>PICO #2</td>
<td>In patients who present pulseless to the Emergency Department without signs of life after penetrating thoracic injury, we conditionally recommend resuscitative Emergency Department thoracotomy. <strong>Conditional Recommendation</strong></td>
</tr>
<tr>
<td>PICO #3</td>
<td>In patients who present pulseless to the Emergency Department with signs of life after penetrating extra-thoracic injury, we conditionally recommend resuscitative Emergency Department thoracotomy. <strong>Conditional Recommendation</strong></td>
</tr>
<tr>
<td>PICO #4</td>
<td>In patients who present pulseless to the Emergency Department without signs of life after penetrating extra-thoracic injury, we conditionally recommend resuscitative Emergency Department thoracotomy. <strong>Conditional Recommendation</strong></td>
</tr>
<tr>
<td>PICO #5</td>
<td>In patients who present pulseless to the Emergency Department with signs of life after blunt injury, we conditionally recommend resuscitative Emergency Department thoracotomy. <strong>Conditional Recommendation</strong></td>
</tr>
<tr>
<td>PICO #6</td>
<td>In patients who present pulseless to the Emergency Department without signs of life after blunt injury, we conditionally recommend against resuscitative Emergency Department thoracotomy. <strong>Conditional Recommendation</strong></td>
</tr>
</tbody>
</table>
AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry

• Initiated in November 2013

• Patients (Age ≥ 18) undergoing aortic occlusion after trauma
  • Thoracotomy; Supra-celiac; REBOA

• As of Sept 2017
  • 763 patients ; 28 Level 1 / 2 centers
AORTA ERT Outcomes

• In hospital mortality = 94.8% (294/310)
  • ED 56.1%, OR 30.0%, ICU 13.5%
• Survival > 24 hours = 12.3% (38/310)
• Survival to discharge = 5.2% (16/310)
• Neurologically intact (GCS = 15) discharge = 4.5% (14/310)
### Hospital Survival Comparison
#### AORTA vs. Pooled EAST CPG

<table>
<thead>
<tr>
<th></th>
<th>AORTA (N = 310)</th>
<th>EAST CPG (N = 10,238)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penetrating thoracic WITH admission SOL</td>
<td>14.9% (4/47)</td>
<td>21.3% (182/853)</td>
<td>0.38</td>
</tr>
<tr>
<td>Penetrating thoracic W/O admission SOL</td>
<td>1.9% (1/54)</td>
<td>8.3% (76/920)</td>
<td>0.11</td>
</tr>
<tr>
<td>Penetrating extra-thoracic WITH admission SOL</td>
<td>12.5% (4/32)</td>
<td>15.6% (25/160)</td>
<td>0.70</td>
</tr>
<tr>
<td>Penetrating extra-thoracic W/O admission SOL</td>
<td>1.6% (1/64)</td>
<td>2.9% (4/139)</td>
<td>0.58</td>
</tr>
<tr>
<td>Blunt WITH admission SOL</td>
<td>4.4% (3/68)</td>
<td>4.6% (21/454)</td>
<td>0.94</td>
</tr>
<tr>
<td>Blunt W/O admission SOL</td>
<td>0% (0/45)</td>
<td>0.7% (7/995)</td>
<td>0.57</td>
</tr>
</tbody>
</table>
Conclusions

• Practices and outcomes for EDT have not changed compared to historical controls dating back > 40 years

• **14.5%** (45/310) of EDT performed in the contemporary era are for blunt injuries **WITHOUT SOL** on arrival
  • Compared to **9.7%** for historical controls (995/10,238)

• Considerations
  • Training
  • The human element
## Training?

Provider categories – “Primary performer of procedure”

<table>
<thead>
<tr>
<th></th>
<th>Surgical Trainee</th>
<th>Surgical Attending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penetrating thoracic WITH admission SOL</td>
<td>38.3% (18)</td>
<td>59.6% (28)</td>
</tr>
<tr>
<td>Penetrating thoracic W/O admission SOL</td>
<td>42.6% (23)</td>
<td>53.7% (29)</td>
</tr>
<tr>
<td>Penetrating extra-thoracic WITH admission SOL</td>
<td>28.1% (9)</td>
<td>71.9% (23)</td>
</tr>
<tr>
<td>Penetrating extra-thoracic W/O admission SOL</td>
<td>40.6% (16)</td>
<td>56.3% (36)</td>
</tr>
<tr>
<td>Blunt WITH admission SOL</td>
<td>39.7% (27)</td>
<td>60.3% (41)</td>
</tr>
<tr>
<td>Blunt W/O admission SOL</td>
<td>46.7% (21)</td>
<td>48.9% (22)</td>
</tr>
</tbody>
</table>
Innovations in EDT – last 40 years
What can we translate from modern approach to ruptured abdominal aortic aneurysms?
10 Years of Emergency Endovascular Aneurysm Repair for Ruptured Abdominal Aortoiliac Aneurysms: Lessons Learned

Dieter Mayer, MD,* Thomas Pfammatter, MD,† Zoran Rancic, PhD,* Lukas Hechelhammer, MD,† Markus Wilhelm, MD,* Frank J. Veith, MD,‡ and Mario Lachat, MD*

Conclusion: In this 102 patient contemporary series of eCVAR for RAAA, endografting proved to be safe with 30-day mortality of 13%. Key components of this favorable outcome result were adequate preoperative diagnostic imaging, hypotensive hemostasis, selective transfemoral suprarenal aortic balloon occlusion, predominantly local anesthesia, detection and treatment of ACS, and attention to logistics. Widespread adoption of these treatment components is recommended.

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) for Trauma - History

REBOA in the pre-endovascular era


- 13% survival in 15 trauma patients after REBOA


- 35% survival in 20 trauma patients after REBOA
Endovascular balloon occlusion of the aorta is superior to resuscitative thoracotomy with aortic clamping in a porcine model of hemorrhagic shock.


Use of resuscitative endovascular balloon occlusion of the aorta in a highly lethal model of non-compressible torso hemorrhage

Case Reports for Non-Traumatic Hemorrhage


- ER
- +/-IR
- sheaths left in place
- Zone 1 regardless of injury pattern
- devices different
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 patients
Technique for REBOA

- Hypotensive (SBP < 90)
  - partial or non-responder

  - Access common femoral artery for a-line or REBOA

  - No REBOA

    - CXR: possible aortic injury?
      - Yes
        - Position REBOA in ZONE 1, inflate and proceed to emergent laparotomy
      - No
        - FAST: positive?
          - Yes
            - Position REBOA in ZONE 1 and inflate
          - No
            - POCUS x-ray: fracture?
              - Yes
                - Position REBOA in ZONE III and inflate
              - No

- Position REBOA in ZONE II

  - Aortic Zone I
    - Zone 1 = Origin of left subclavian artery to the celiac artery
  - Aortic Zone III
    - Zone 3 = Lowest renal artery to aortic bifurcation
BJH REBOA ALGORITHM

Hypotensive SBP < 90

Place Common Femoral Artery A-line

REBOA Not indicated
Proceed with indicated procedure

REBOA indicated

CXR Thoracic Injury possible source of hypotension?

YES
REBOA Not indicated
Proceed with indicated procedure

NO

Transient Non Responder (SBP < 90 after 2 units PRBCs)

YES
Upsize to 7 Fr introducer and Position REBOA balloon in Zone 1

NO
Proceed with work up

PROCEDURE TO OR FOR EMERGENT LAPEROTOMY

FAST Positive?

YES
Proceed to OR for Emergent Laparotomy

NO

Pelvic X-Ray Fracture likely cause of hypotension?

YES
Reposition REBOA into Zone 3

CT vs. Angio vs. OR

NO
Proceed to CT/OR
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
The AAST prospective Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry: Data on contemporary utilization and outcomes of aortic occlusion and resuscitative balloon occlusion of the aorta (REBOA)

- 8 centers, 114 patients
- 46 REBOA from 5 centers, 68 RT
- Prospective observational study, voluntary
AAST Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) Registry

• Prospective observational registry
  • AO utilization patients age ≥ 18

• Captured data:
  • Demographics
  • Admission physiology / laboratory values
  • Required procedures
  • Resuscitation requirements
  • Timing, type and conduct of AO
  • Physiologic response, labs and outcomes
Comparison AO techniques

• REBOA (5 centers) – 40.4% (46/114)
  • Zone I = 78.6%
  • Zone II – 2.4%
  • Zone III – 19.0%

• Open – 59.6% (68/114)
  • Anteriolateral thoracotomy (43)
  • Clamshell thoracotomy (18)
  • Laparotomy (7)
Differences in technique populations
Open AO patients:

• Male
  • 88.2%; vs. 69.6%, $p = 0.013$

• Penetrating
  • 47.1% vs. 23.9%, $p = 0.013$

• Admission hypotension (SBP < 90 mm Hg)
  • 69.1% vs. 47.7%, $p = 0.024$

• Lower median admission SBP
  • 0 mm Hg vs. 23 mm Hg, $p = 0.017$

• CPR ongoing during initial AO attempt
  • 72.1% vs. 45.7%, $p = 0.008$
Time durations

- No difference in time FROM ADMISSION to:
  - AO start or completion
  - Definitive hemorrhage control
  - Hemodynamic stability

- Initiation of procedure to successful AO
  - REBOA 6.6 mins, Open 7.2 mins; $p = 0.842$
Open vs. REBOA - No difference

• Resuscitation requirements
• Laboratory values at 24 hours
• Organ system complications
Approach Specific Complications

• REBOA
  • Pseudoaneurysm (1) – 2.2%
  • Distal embolism (2) – 4.4%
  • Balloon migration (2) – 4.4%
  • No limb threatening ischemia, bypass or amputation

• Open
  • Retained hemothorax >> evacuation (1) - 1.4%
  • Local wound infection requiring surgery (2) - 2.9%
REBOA specific practices

• Access - open cut down = 50%

• Imaging utilized
  • Plain film = 52.2%
  • Fluoroscopy = 13.0%
  • No imaging – external landmarks only = 26.1%
Examined REBOA / RT use in broad categories of trauma patients

- Included penetrating thoracic injury
- All anatomic locations of AO
- All locations of procedure (ED, OR) in arrest and hypotensive
- All physiologic states

Findings

- No difference in survival, time to AO, discharge GCS
- Complications REBOA (6.5%) and RT (4.4%)
REBOA – AORTA Registry continued growth

- Adoption (start Nov 2013)

- Feb 2015: 46 patients from 5 centers

- Sept 2017: 234 from 16 centers

- Over 30 months, there has been a 15X patient enrollment increase and a 5X institution enrollment increase
AORTA 2017 Study Design

• Objective
  • Examine REBOA / RT use in a defined population of AORTA patients

• Inclusion Criteria
  • Patients who received AO at aortic Zone 1 (descending thoracic aorta)

• Exclusion criteria
  • Penetrating thoracic injury, chest AIS > 2
  • AO outside the Emergency Department
  • Incomplete survival or outcome data
**Results**

Survival beyond ED

RT = 44.1% (89/202), REBOA = 62.7% (52/83)  \( p = 0.004 \)

Survival to discharge

RT = 2.5% (5/202), REBOA = 9.6% (8/83)  \( p = 0.023 \)
Prognostic value of CPR need and hypotension
## Pre-hospital CPR required?
### Overall = 60.4% (172/285)

<table>
<thead>
<tr>
<th></th>
<th>Resuscitative Thoracotomy 75% (129/172)</th>
<th>REBOA 25.0% (43/172)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival beyond ED</td>
<td>34.1% (44/129)</td>
<td>46.5% (20/43)</td>
<td>p = 0.145</td>
</tr>
<tr>
<td>Survival to discharge</td>
<td>2.3 % (3/129)</td>
<td>4.7% (2/43)</td>
<td>p = 0.60</td>
</tr>
</tbody>
</table>
CPR required AFTER admission, but PRIOR TO AO
Overall = 20.0% (57/285)

<table>
<thead>
<tr>
<th></th>
<th>Resuscitative Thoracotomy 77.2% (44/57)</th>
<th>REBOA 22.8% (13/57)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival beyond ED</td>
<td>70.0% (31/44)</td>
<td>53.8% (7/13)</td>
<td>p = 0.323</td>
</tr>
<tr>
<td>Survival to discharge</td>
<td>2.3 % (1/44)</td>
<td>0% (0/13)</td>
<td>p = 1.000</td>
</tr>
</tbody>
</table>
NO CPR required prior to AO
Overall = 19.6% (56/285)

<table>
<thead>
<tr>
<th></th>
<th>Resuscitative Thoracotomy</th>
<th>REBOA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival beyond ED</td>
<td>48.3% (14/29)</td>
<td>92.6% (25/27)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Survival to discharge</td>
<td>3.4 % (1/29)</td>
<td>22.2% (6/27)</td>
<td>0.048</td>
</tr>
</tbody>
</table>
### Physiology at time of AO

**NON-CPR patients**

(n=56)

<table>
<thead>
<tr>
<th>Aortic occlusion initiation physiology</th>
<th>Total (n = 56)</th>
<th>REBOA (n = 27)</th>
<th>RT (n = 29)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic blood pressure (mm Hg); Median (IQR); n/N</td>
<td>40(66);49/56</td>
<td>64(29);23/27</td>
<td>0(0);26/29</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Aortic Occlusion Physiologic Response**

<table>
<thead>
<tr>
<th>Post occlusion SBP (mm Hg); Mean (± SD); n/N</th>
<th>75 (63); 48/56</th>
<th>120 (34); 23/27</th>
<th>34 (54); 25/29</th>
<th>&lt;0.001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of aortic occlusion (minutes); Median (IQR); n/N</td>
<td>39.0 (48); 34/56</td>
<td>60.0 (99); 15/27</td>
<td>20.0 (21); 19/29</td>
<td>0.008</td>
</tr>
</tbody>
</table>
Summary – AORTA 2

• Among partial and non-responders who have not yet required CPR, REBOA appears superior in survival

  • After CPR started = survival outcomes equivalent

• In clinical utilization, REBOA and RT patient populations are different

  • Higher % of blunt mechanisms

  • More likely to have some measurable blood pressure at time of REBOA
Put another way...

- Providers appear more willing to utilize less invasive REBOA earlier in decompensation course

- Earlier REBOA use in partial and non-responders may mitigate the risk for RT need

- More data needed
Other AORTA Registry findings

• REBOA being performed almost overwhelmingly by Acute Care Surgeons (93.4%)

• Access
  • 47% of patients continue to require open cut down

• Imaging use
  • Balloon position confirmed by bedside x-ray = 57%
  • No imaging utilized = 31%
REBOA complications among survivors

• Procedural complications
  • Balloon migration = 3.6%

• Post-procedural complications
  • Distal embolism = 4.8%
  • Amputation = 1.2%
The pitfalls of resuscitative endovascular balloon occlusion of the aorta: Risk factors and mitigation strategies

Anders J. Davidson, MD, MAS, Rachel M. Russo, MD, MAS, Viktor A. Reva, MD, Megan L. Brenner, MD, Laura J. Moore, MD, Chad Ball, MD, Eileen Bulger, MD, Charles J. Fox, MD, Joseph J. DuBose, MD, Ernest E. Moore, MD, Todd E. Rasmussen, MD, and the BEST Study Group, Sacramento, California
REBOA Complications - Access

• Reality = 50% open cut down requirement

• Access has real consequences
  • SFA or bifurcation stick
  • Inadvertent CFV placement
    • Color of blood not helpful in arrest

• Ultrasound should be utilized whenever possible!!!
REBOA Complications - Imaging limitations

• Imaging availability limited in ED
  • 65% utilization in AORTA registry

• Ideally, digital film obtained once the catheter (or wire) is in place

• Confounders = Arrest / Time
  • If ROSC occurs - > GET AN X-RAY
Balloons – The good
Balloons – The bad
Balloons – The ugly
REBOA Complications – Balloon Inflation

- Migration

- Atherosclerotic disease

- Volume required dictated by aortic diameter
  - Zone 1 vs 3
  - Age / Gender influenced

Image courtesy of Firetime Medical Devices, Inc.
REBOA In-Services

• BJH: 24
• SLU: 21
• Combined events: 2

• Covered Trauma Staff, General Surgery Staff, Residents, ED Staff, Anesthesia Staff, IR staff, OR nurses, ED nurses, ICU nurses

• This is not a one time event! Commitment to continually train as turn over is constant
All staff were required to go through a nationally recognized course for certification or a BEST like course put on by already trained SME’s at each site.

Training consisted of 4 hours of hands on training and didactics.

No measure of proficiency, no tests, no validation.

Ancillary staff and residents were trained to familiarization only.
The ER-REBOA™ Catheter Quick Reference Guide

1. Obtain access
   Using standard techniques

2. Estimated placement
   Zone I Placement: Xiphoid process & right mainstem bronchus
   Zone II Placement: Sternal notch & left mainstem bronchus
   Recommended use of continuous imaging techniques

3. Advance & twist peel-away to P-tip
   Ensure the balloon and P-tip are captured

4. Attach & flush arterial line
   Leaking standard techniques
   Ensure all air is purged from arterial line

5. Insert peel-away sheath into vessel
   Ensure peel-away trocar has entered parent artery
   Introducer sheath valve approximately 5mm

6. Fill syringe with appropriate volume
   For zone I: approximate vessel diameter 25mm
   For zone II: approximate vessel diameter 15mm
   Use appropriate volume:
   - 15mm: 5cc
   - 20mm: 8cc
   - 25mm: 13cc
   - 30mm: 20cc
   - 32mm: MAX 24cc

7. Monitor arterial waveform feedback
   Look for the change in systolic blood pressure

8. Position catheter
   If available, use of balloon angiography fluoroscopy is recommended to confirm position using
   balloon inflation marker

9. Fully Deflate balloon
   Ensure balloon is fully deflated & hold vacuum for 5 seconds
   Close stopcock with vacuum held

10. Remove catheter
    Corkscrew twist the catheter to facilitate removal
    Close stopcock with vacuum held

The REBOA Company

Prytime Medical™

*This instruction is not a replacement for the instructions for use (IFU). The ER-REBOA™ Catheter IFU should be read in its entirety before using the device.
18 gauge (not 20)= compatible with 7Fr Sheath Guidewire
ER-REBOA® CATHETER INTRODUCER KIT
KT1835C
650-014

STERILE CONTENTS
1. NEEDLE, 16 GA, X 3.75 IN. (Sterile, Package)
2. PACKAGING, NEEDLE
3. 1 FR MP 25’’ SHORT GLOVEWARE, STERILE
4. STERILE, 60ML, 6ML STERILE
5. DRAINS, MP, STERILE
6. KEG, 5ML, STERILE
7. SUTURE, NYLON, 3/0, 28, REVERSE CUTTING, STERILE

NON-Sterile CONTENTS
1. PACKAGING, WRAP
2. PACKAGING, TRAY
3. PACKAGING, BUBBLE WRAP
4. INSERT, SUTURE
5. INSERT, CLAMP

Note: ER-REBOA® Catheter Introducer Kit is provided as a non-sterile convenience kit containing individually wrapped, identified components.

LOT 17039129988 2018-05-01
(17039128988 11/17039128988 17/17039128988 17/17039128988 17/17039128988 17)

SINGLE USE ONLY
DO NOT USE IF DAMAGED OR OPENED

MANUFACTURED BY:
PRYTIME MEDICAL
259 North Main Street
Spring, TX 77380
www.prytimemedical.com
Current Sheaths
## REBOA Data Collection Form

### Inflation Parameters

<table>
<thead>
<tr>
<th>Balloon Diameter</th>
<th>Inflation Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 mm</td>
<td>5 cc</td>
</tr>
<tr>
<td>20 mm</td>
<td>8 cc</td>
</tr>
<tr>
<td>25 mm</td>
<td>13 cc</td>
</tr>
<tr>
<td>30 mm</td>
<td>20 cc</td>
</tr>
<tr>
<td>32 mm (MAX)</td>
<td>25 cc (MAX)</td>
</tr>
</tbody>
</table>

### Physician

Date: __________________________  

MOI: __________________________

Injuries:

Admit BP:  
HR:  
Admit GCS:  
Arms: Yes □ No □

Placed Location: ED □ OR □  
A-Line access: Size: _______Fr  
Guided by Ultrasound □

Gain Access: Right □ Left □  
Percutaneous □ Cut-Down □

Target Landing: Zone 1 □ Zone 2 □ Zone 3 □  
Target Confirmation: X-Ray □ Ultrasound □

Arterial Waveform: Yes □ No □  
Arterial Waveform Monitored via REBOA: Yes □ No □

### Catheter Documentation

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>TIME</th>
<th>POSITION CM</th>
<th>BALLOON CC</th>
<th>REBOA BP</th>
<th>DETAL BP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion A-line</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insertion REBOA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Version 5**  

NOT FOR PATIENT RECORD — DATA COLLECTION ONLY
Experience

- 19 REBOAs at Wash U
- 14 REBOAs at SLU
- 14/33 Survival rate (43%)
- 3 access site complications (9%)
- 6 cutdowns (18%)
- 16 placed in patients with cardiac arrest (48%)
- 5 placed in OR (15%)

Early lessons learned:
- Steep learning curve
- Balloon times

Participating in the AAST sponsored AORTIC Registry
- PI every insertion
REBOA Complications – Deflation

- Communication!!!

- Patience is key when deflating

- Reperfusion
SHEATH management complications

• Ideal set up for issues
  • No heparin
  • Active FFP/TXA use

• Use angiography and embolectomy with prudence

• SHEATH mismanagement
Routine Angio = Prudent
REBOA = Not a benign procedure

• Most complications can be avoided through training and protocolized practices

• MULTIDISCIPLINARY!!! REBOA IS A TEAM SPORT!!!

• Sheath mismanagement responsible for most extremity complications
Key questions for REBOA trauma utilization

• Replace Resuscitative Thoracotomy?

• Who should be doing this?

• Procedural Innovations
  • Balloon confirmation
  • Devices
  • Balloon occlusion approaches
Resuscitative thoracotomy and REBOA
The spectrum of decompensation

- REBOA
- Resuscitative Thoracotomy
Who should be doing REBOA?

• Vascular / IR providers have endovascular skillsets
  • But are not at bedside when trauma patient arrives
• Acute care surgeons have demonstrated capability
• Training is paramount to success
Joint statement from the American College of Surgeons Committee on Trauma (ACS COT) and the American College of Emergency Physicians (ACEP) regarding the clinical use of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

GUIDELINES FOR REBOA USE AND IMPLEMENTATION

▶ REBOA should be performed by an acute care surgeon or an interventionalist (vascular surgeon or interventional radiologist) trained in REBOA.

▶ Emergency medicine (EM) physicians with added certification in critical care (EMCC) trained in REBOA, may train and perform REBOA in conjunction with an acute care surgeon or vascular surgeon trained in REBOA, as long as the surgeon(s) is/are immediately available to definitively control the focused source of bleeding.

▶ EMCC-certified physicians trained in REBOA must not perform REBOA unless a surgeon is immediately available.

▶ EM physicians without critical care training should not perform REBOA.
REBOA TRAINING

- Formal, basic training consists of completion of the ACS COT BEST Course®.
- Proficiency in ultrasound-guided and open, cut-down cannulation of the CFA is a critical skill required for REBOA.
GUIDELINES FOR REBOA USE AND IMPLEMENTATION

SPECIAL CIRCUMSTANCES: DEPLOYED MILITARY SETTINGS

- Military surgeons who act as general or trauma surgeons during deployment should complete a formal training course (Basic Endovascular Skills for Trauma (BEST Course®)) and include REBOA in their skill set.
- Military EM physicians who work on a team with acute care surgeons during deployment must complete formal training (BEST Course®) and may include REBOA in their skill set. REBOA must be performed in conjunction with an acute care surgeon. 
- The ability to analyze which patient may benefit from a REBOA is more difficult in austere environments, and careful attention must be paid to patient selection and immediate availability of operative resources.
Basic Endovascular Skills for Trauma

Course Objectives

• Demonstrate indications for REBOA

• Demonstrate access and closure of common femoral artery

• Demonstrate tools required for REBOA

• Demonstrate technique of REBOA
Future Considerations

• Guidelines from national bodies still pending
• Need to expand training to include more specific US guided access procedures and mandatory demonstration of open exposure technique
  • Access is consistently the rate limiting step
• Currency training to demonstrate continued proficiency in a low volume high acuity procedure
  • Re-hack should be annual
• Resource intensive effort
• Sheath ownership and management is critical
• Continue to refine appropriate patient selection for each institution
• Participation in some sort of registry should be mandatory!
• How to tackle pre-hospital implementation
Questions???
Balloon surgery stops fatal bleeding at roadside

By Smitha Mundasad
Health reporter, BBC News

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.
Evolution of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) to a Wartime, Pre-Hospital Hemorrhage Control & Resuscitation Adjunct

Justin D. Manley, MD, Benjamin J. Mitchell, Joseph J. DuBose, MD
Todd E. Rasmussen, MD

Air Force Special Operations Command; University of Alabama Birmingham Medical Center, Birmingham, Alabama

David Grant Medical Center, Travis, AFB; University of California – Davis, California

DoD Combat Casualty Care Research Program, Fort Detrick, Maryland

Uniformed Services University - Walter Reed Department of Surgery
Bethesda, Maryland
Breakthrough in Pre-Hospital Combat Casualty Care

• Case series of resuscitative endovascular balloon occlusion of the aorta (REBOA) in a pre-hospital, combat casualty care setting in Operation Inherent Resolve
Care Setting

- Resuscitation room 3km (10-15 minutes) from point of injury & 2 hours from next higher echelon of care which is level II equivalent
Special Operations Surgical Team (SOST)

- Six member, surgical & resuscitation team
  - General surgeon (MD)
  - Emergency medicine (MD)
  - Anesthesia provider (CRNA)
  - Respiratory therapist (CRT)
  - Registered nurse (CCRN)
  - Registered nurse (CCRN)

- Team composition may vary depending on operational scenario but is not dependent on sub-specialty trained surgeon
Ultrasound Guided Percutaneous Access

- Vscan ultrasound device (GE Healthcare, Inc.)
Intraoperative Bleeding Control & Blood Pressure

- **ER-REBOA™** catheter secured in femoral artery sheath & inflated during damage control laparotomy
Patients & Course of Resuscitation

- There were no ER-REBOA catheter-related complications and all patients survived through their transport to and arrival at the next higher echelon of care

- 50% placed by EM providers
- 50% placed by general surgeons
REBOA 2018 – Procedural Innovations

• Lower profile devices
  • Minimize device-related complications
  • Facilitate full percutaneous access
  • Decrease threshold to utilize
  • Prophylactic placement

• Device capabilities
  • Arterial monitoring port
  • Infusion capabilities?
  • Proximal arterial offloading?
REBOA 2018:
The ER-REBOA Catheter

- FDA-approved
- 7 French
- Arterial Pressure Monitoring
  - Prophylactic
- No Guide wire
- No Fluoroscopy*
Large (11-12F) vs. low (7F) profile outcomes

• AORTA registry; Nov ‘13 – Dec ‘17

• 123 7F; 118 11-12F REBOAs

• Group comparisons

  • No difference in demographics, physiology, presentation

  • Higher ISS with 7F (Mean 39.2 vs. 34.1, p = 0.028)
Low profile (7F) device benefits observed:

• Improvement in access / utilization
  • Lower cut-down utilization (29.0% vs. 23.7%, p = 0.049)
  • Earlier occlusion (Median 25.0 mins vs. 30 mins, p = 0.010)

• Decreased resuscitation requirements
  • Lower median PRBC requirements (10.0 units vs. 15.5 units, p = 0.006)
  • Lower median FFP requirements (7.5 units vs. 14.0 units, p = 0.005)
Low profile (7F) device benefits observed:

• Improved outcomes
  • Higher survival at 24 hrs (58.1% vs. 42.4%, p = 0.015)
  • Lower in-hospital mortality (57.3% vs. 75.4%, p = 0.003)

• Decreased procedural complications
  • Approx. 4X lower rate of distal extremity embolism
    • 5.6% vs. 20.0%, p = 0.014
Partial Resuscitative Balloon Occlusion of the AORTA (P-REBOA): Clinical Technique and Rationale

M. Austin Johnson, MD, PhD¹, Lucas P. Neff, MD,²,³,⁴, Timothy K. Williams, MD⁵, Joseph J. DuBose, MD²,³,⁴,⁵, and The EVAC Study Group

Affiliations:
¹Department of Emergency Medicine, University of California Davis Medical Center, 2315 Stockton Blvd, Sacramento, CA 95917
²Department of General Surgery, David Grant USAF Medical Center, Travis Air Force Base, California 94535
³UC Davis Medical Center, Sacramento, California 94535
⁴Department of Surgery, Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Bethesda, Maryland 20814
⁵Department of Vascular and Endovascular Surgery, David Grant USAF Medical Center, Travis Air Force Base, California 94533
The Next Generation: Early Partial REBOA (P-REBOA)

- **Preservation perfusion to brain / heart**
- **Avoidance of overpressure**
  - Heart Failure
  - Worsening of TBI
- **Initial total occlusion**
  - Permits resuscitation initiation
  - Clot formation
- **Partial balloon occlusion**
  - Minimizes total ischemic time
  - Mitigates re-perfusion injury risk
  - Extends duration of intervention when needed
P-REBOA: Clinical Application

1. Approximately 10-20 minutes of complete aortic balloon occlusion

2. Establish distal arterial pressure monitor

3. Deflate balloon until pulsatile distal waveform achieved

4. Stepwise balloon insufflation with pressure monitoring

5. Re-occlude if proximal pressure does not tolerate
Metabolic Burden Over Time

Lactate Concentration (mmol/L) vs. Time (min)

- Complete
- Partial
- Control
How I do it: Partial resuscitative endovascular balloon occlusion of the aorta (P-REBOA)

Joseph J. DuBose, MD, Travis AFB, California

“How I Do it” Youtube:
- Part 1: https://www.youtube.com/watch?v=-U7MkU3eA7E
- Part 2: https://www.youtube.com/watch?v=DZ5LCEt7PBk
Future near horizons...

• EM training for REBOA

• Improved understanding of optimal patient selection
  • Trauma – C-A-B methodology; prior to intubation
  • Obstetrical complex cases
  • Medical arrest?!?

• Device innovations
  • Devices specifically designed to facilitate p-REBOA
Thank you