REBOA - Trials and Registries

Jon L. Eliason, MD
REBOA – Clinical Trials and Registries

2018

Jonathan L. Eliason, MD
S. Martin Lindenauer Professor of Vascular Surgery
Section of Vascular Surgery
• 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
Fig 1. Results of search strategy following PRISMA flow diagram.
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.

• AAST AORTA registry
• EVTM / ABOTrauma registry
• Prytime Emergent Truncal Hemorrhage Observational Study
• NHS United Kingdom REBOA Clinical Trial
• DoDTR 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.
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
• 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)
• EndoVascular hybrid Trauma and bleeding Management (EVTM)
• International meeting originated through the department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Sweden
• Registry for:
  – New Cases (prospective)
  – Retrospective data collection (former cases)
EndoVascular and Hybrid Trauma and bleeding management (EVTM18) Symposium

Örebro, Sweden
7-8-9th June 2018

Main round table Topics:

- **EVTM concept, multidisciplinary approach**
- **Trauma and non-trauma - PPL, 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**

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

Invited speakers/panelists:
- TBA

Supported by
- TBA

www.jevtm.com
• **ICD-10-PCS**
  - **Coding Tips**
    - To code Zone I
      - W3DJ
    - To code Zone II-III
      - O3DJ
• 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
<table>
<thead>
<tr>
<th></th>
<th>Continuous REBOA</th>
<th>Non-continuous REBOA</th>
<th>(P)</th>
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</thead>
<tbody>
<tr>
<td><strong>Pre-hospital data</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>GCS &lt; 8/(n) (%) (total = 75)</td>
<td>13 (41%)</td>
<td>15 (35%)</td>
<td>0.611</td>
</tr>
<tr>
<td>CPR/(n) (%) (total = 91)</td>
<td>11 (23%)</td>
<td>7 (16%)</td>
<td>0.370</td>
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<td><strong>Systolic blood pressure</strong></td>
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<tr>
<td>ED Admission &lt; 80 mmHg/(n) (%) (total = 65)</td>
<td>22 (67%)</td>
<td>21 (66%)</td>
<td>0.929</td>
</tr>
<tr>
<td>SBP mm Hg before inflation/median (IQR) (total = 88)</td>
<td>50 (0–70)</td>
<td>68 (43–88)</td>
<td>0.026</td>
</tr>
<tr>
<td>SBP mmHg after inflation/median (IQR) (total = 89)</td>
<td>95 (69–120)</td>
<td>110 (90–135)</td>
<td>0.022</td>
</tr>
</tbody>
</table>
• 30-day mortality
  - Continuous REBOA 64%
  - Non-continuous REBOA 48%

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

The Department of Defense Center of Excellence for Trauma

Operational Cycle

- Performance Improvement
- Data Analysis
- DoD Trauma Registry
- Data Abstraction
- Best Practice Guidelines
- Trauma Care Delivery

BOLD, RESPONSIBLE PRACTICE OF BATTLEFIELD MEDICINE
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.
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, DuRose JU, 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 Army Special Operations Surgical Team at an austere location fewer than 3km (5-10 minutes’ travel) 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, hemothorax, and class IV shock. Hand-held ultrasound was used to diagnose hemothorax 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 REBOA-related 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.
Thank You

Questions?