Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) with a new low profile, not over-the-wire balloon catheter: How it works & potential value in military & civilian injuries

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Epidemiologic Research

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

Brian J. Easteridge, MB, Robert L. Mahal, MD, Peter Septimus, MD, Joyce Carroll, MD, Terrill Tope, MD, Paul Cote, MD, Oyapa Makoli, Yamine Zakeh, Lyman D. Trimble, Todd E. Rasmussen, MD, Frank K. Butler, MD, Hensel S. Kewal, MD, John R. Holcomb, MD, Charles Wade, PhD, Howard C. Champion, MD, Mindy Levenths, lone marosi, MD, and Laura H. Rockerson, MD

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Epidemiologic Research

• In unprecedented burden of injury hemorrhage defined as leading cause of mortality; equated to urgency of effort

Endo for Wartime Injury

Development and Implementation of Endovascular

Endovascular Treatment of a Blunt Aortic Injury in Iraq: Extension of Innovative Endovascular Capabilities to the Modern Battlefield

Brandon W. Propper, Capt, MD; Ethan R. Allen, Maj, MC; Shawn M. Gifford, Capt, MC; Greifeld E. Berkmann, Capt, MC; and Todd E. Rasmussen, Maj, MC

Ann Vasc Surg 2009;23:687

• Potential for endovascular technologies for wartime trauma; 1st presented @ 2006 VEITH

Disclosures

• Co-holder of US patent for REBOA catheter(s) design

• No financial or corporate consulting conflicts of interest

Adapt or Perish; Inexorable Imperative

From the Society for Vascular Surgery

Presidential address: Charles Darwin and vascular surgery

Chicago - June 1996

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Reappraisal of Broader Approach & Technologies

• Reappraisal: “assessment again of the worth or value of a thing or activity....”

• “to view something through a different lens at a different time” (i.e. with new information.)
Reappraisal

- During the early phases of the war, the only procedural adjunct to accomplish this had not changed in decades
- Need for a procedural adjunct to sustain central aortic pressure and mitigate hemorrhage after severe injury

Translation of Knowledge

Management of ruptured abdominal aortic aneurysm in the endovascular era
Benjamin W. Starnes, MD, Ellen Quiroga, MD, Carolyn Hutter, MD, PhD, Nam T. Tran, MD, Thomas Hasekoom, MD, Mark Motto, MD, Kate Tran, MD, and Ted Kohler, MD, Anatomic Path.
J Vasc Surg 2010;51:9-18

Ruptured Abdominal Aortic Aneurysms: Remote Aortic Occlusion for the General Surgeon
CPT Zachary M. Ashburn, MD*, CPT Vance Y. Sohn, MD, Benjamin W. Starnes, MD, FACS*
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**Division of Cardiothoracic Surgery, Psychiatry, and General Medical Center

REBOA

- Military IP (disclosure Oct 2009) - new balloon catheter for emergency scenarios

- Goals:
  - Reduce catheter Fr size (7Fr or less)
  - Obviate need for “over-the-wire” step
  - Obviate need for fluoroscopy/x-ray

First Introduction of REBOA

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

1. Low profile balloon catheter
2. One-pass/not “over-the-wire”
3. Pressure regulated inflation & resists egress

Proactive aortic access, monitoring & control

Licensing/ Commercialization

FDA Cleared November 2015

Pryor Medical Devices Receives FDA 510(k) Clearance for Distribution of its ER-REBOA Catheter

New catheter provides a minimally invasive solution for temporary occlusion of large vessels and arterial pressure monitoring
San Antonio, TX – Oct 26, 2015 – Pryor Medical Devices (The REBOA Company®), today announced it has received FDA 510(k) clearance for the sale and distribution of its ER-REBOA™ catheter. REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta) is a minimally invasive technique used by the Trauma, Critical Care and Emergency Medicine community to temporarily occlude large vessels using a balloon.
### Potential Benefit

- Provides a path to less invasive, proactive monitoring & control for those most immediate to the hemorrhaging – or at risk - patient

### Conclusion

- REBOA arose from military’s experience with unprecedented burden of injury
- REBOA represents adaptation of catheter-based approach to age related disease; reappraisal
- Case study of DoD-led medical research – with urgency - providing materiel solution; efficiency in leverage of academic & private partnership
- Life sustaining or saving benefit of now FDA cleared device to be determined in future study

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### Potential Benefit

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

Laura J. Moore, MB, Megan Bronner, MD, Rosemary A. Keane, MD, PhD, Jason Peake, DO, Charles E. Wade, PhD, Mary S. Baranski, PhD, Thomas Scales, MD, and John B. Holcomb, MD, Shriners Hospitals for Children

J Trauma Acute Care Surg 2015;79:523-32

Conclusion: REBOA feasible & controls truncal hemorrhage in trauma patients in shock. Patients undergoing REBOA have improved survival & fewer earlier deaths compared to those undergoing open resuscitative thoracotomy