



Man In The Arena

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Surgery
UNIVERSITY OF TORONTO

Disclosures

- Site PI for PROMPT pREBOA Trial Trial
- Received Prytime funding for travel to present at Mattox Las Vegas Course in 2022
- Member of Canadian Forces
- No other relevant disclosures

Why REBOA Matters To Me



JOURNAL ARTICLE

Advanced Non-compressible Torso Hemorrhage Management is Combat Casualty Care's Moon Shot

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Asad Naveed, MBChB, MPH, David Gomez, MD, PhD, Joao Rezende-Neto, MD, PhD, Najma Ahmed, MD, PhD, Andrew Beckett, MD, MSc

Military Medicine, Volume 189, Issue 3-4, March/April 2024, Pages 59–61,

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Non-compressible torso hemorrhage (NCTH) is the leading cause of preventable deaths on the battlefield. Several large studies of British, Canadian, and U.S. combat casualties report a case fatality rate of up to 85.5% because of NCTH.

RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA: A GAP ANALYSIS OF SEVERELY INJURED UK COMBAT CASUALTIES

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ABSTRACT—The control of torso and junctional zone bleeding in combat casualties is particularly challenging because of its noncompressible nature. Resuscitative endovascular balloon occlusion of the aorta (REBOA) has demonstrated promise in translational large animal and early clinical series as an effective resuscitation and hemorrhage control adjunct. However, it is unknown what proportion of combat casualties has an injury pattern and clinical course that is amenable to REBOA deployment. The prospective UK Joint Theatre Trauma Registry was used to retrospectively identify all UK military personnel who has sustained a severe combat injury, defined as an Abbreviated Injury Scale of three or greater, in the course of 10 years. Patients were then divided into three groups based on Abbreviated Injury Scale injury pattern: no indications for REBOA, contraindications (mediastinal, cervical, and axillary hemorrhage), and indications (torso and pelvic hemorrhage). From a total of 1,317 patients, 925 (70.2%) had no indication, 148 (11.2%) had a contraindication, and 244 (18.5%) had an indication for REBOA. Within the group with indications for REBOA, there were 174 deaths: 79 at the point of wounding, 66 en route to hospital, and 29 in-hospital deaths. The median (interquartile range) time to death in patients dying en route was 75 (42–109) min, and the median prehospital time for casualties admitted to hospital was 61 (34–89) min. One-in-five severely injured UK combat casualties have a focus of hemorrhage in the abdomen or pelvic junctional region potentially amenable to REBOA deployment. The UK military should explore REBOA as a potential en route hemorrhage control and resuscitation adjunct.

KEYWORDS—Hemorrhage control, trauma, military surgery, REBOA, Resuscitative endovascular balloon occlusion of the aorta, resuscitation



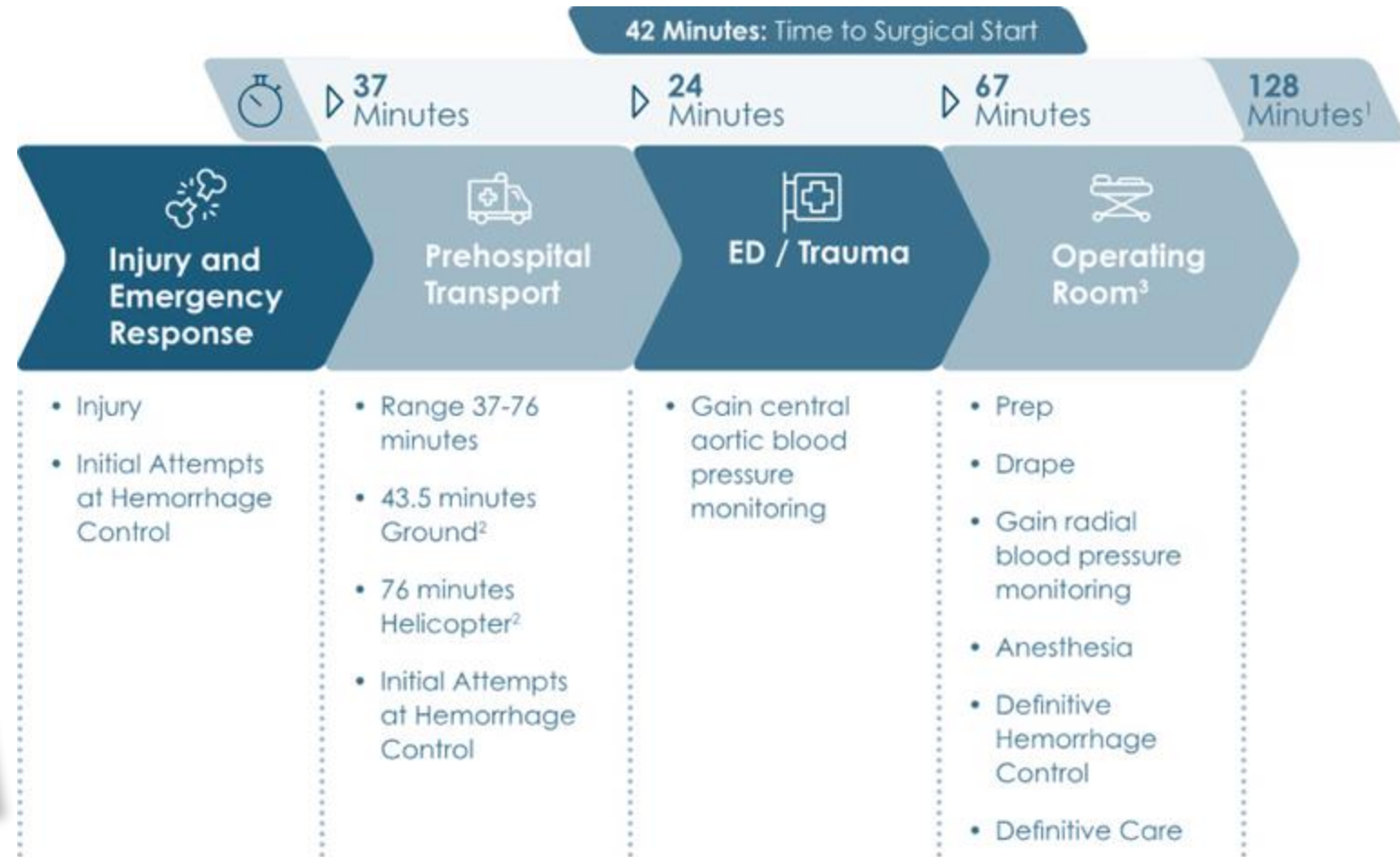
A Modern Case Series of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in an Out-of-Hospital, Combat Casualty Care Setting Spring 2017

Manley JD, Mitchell BJ, DuBoise JJ, Rasmussen TE. 17(1). 1 - 8. (Case Reports)

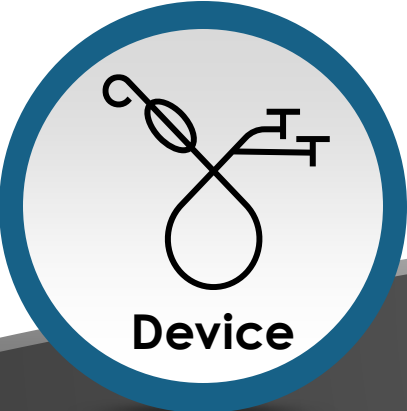
Abstract

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 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-

The Issue At Hand: Time of Injury to Definitive Hemorrhage Control



Driving Innovation Forward

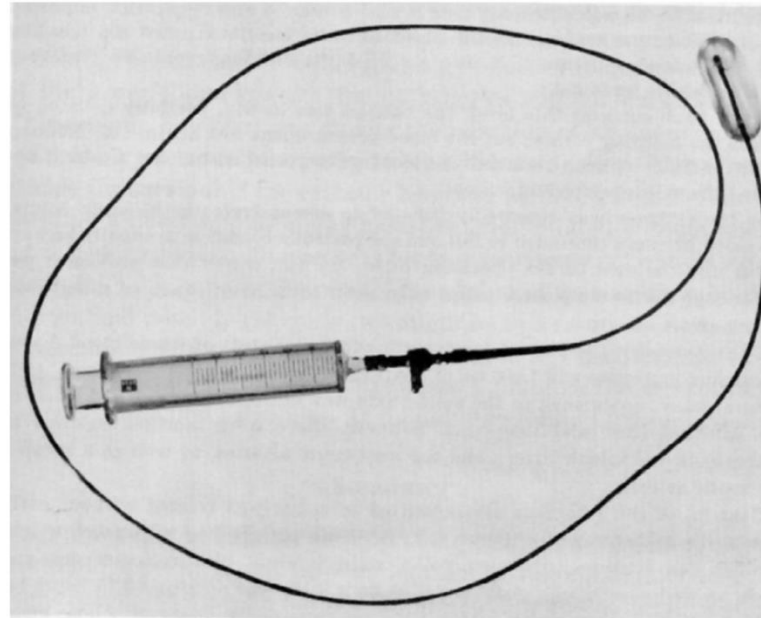


MILITARY SURGICAL HERITAGE
DEPARTMENT OF SURGERY, USUHS

Carl W. Hughes



LTC BOSS MASH, Chof Wan Valley, Korea 1953



The outcomes were terrible, as befits "*moribund cases with evidence of intra-abdominal bleeding*". There was the barest glimmer of a silver lining: "*Although both patients expired, the catheter was effective in temporarily restoring the blood pressure in one case*".

REVIEW ARTICLE*

The arterial tourniquet

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Professor of Anaesthesia
University Hospital of South Manchester

HISTORICAL VIGNETTES IN VASCULAR SURG

Norman M. Rich, MD, Section Editor

A brief history of the tourniquet

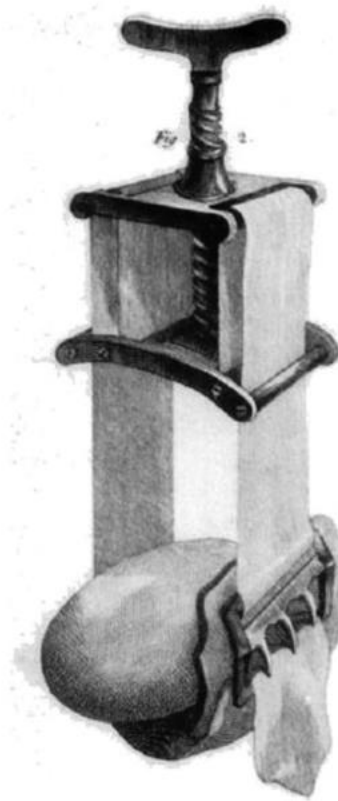
David R. Welling, MD,^a Patricia L. McKay, MD,^a Todd E. Rasmussen, MD,^{a,b} and
Norman M. Rich, MD,^a Bethesda, Md; and Fort Sam Houston, Tex

The tourniquet is a device first used in antiquity; it has been praised or vilified throughout the ages, as it has been at times life-saving and at other times limb-threatening.¹ It

Chauliac was known for wrapping a tight band above the site of amputation to reduce the pressure down on hemorrhage. Botallo taught that a

ATLS 8th Ed

An acutely avascular extremity must be recognized promptly and treated emergently. Although controversial, the use of a tourniquet may occasionally be lifesaving and/or limb-saving in the presence of ongoing hemorrhage uncontrolled by direct pressure.



REVIEW ARTICLE

Open Access

Dealing with complications in interventional radiology

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Abstract

It is widely accepted that most misadventures, which lead to harm have not occurred because but rather due to a failure of process that results in healthcare workers making mistakes. This failure and the pervasiveness of adverse events is just as prevalent in Interventional Radiology (IR) as in Surgery. The true prevalence and prevailing aetiology of complications in IR are not exactly known of investigative literature into this area; especially when compared with other more established as Surgery. Some IR procedures have a higher risk profile than others. However, published data adverse events in IR are preventable (55–84%) and frequently involve a device related complication usage or malfunction. This article aims to discuss factors that contribute to complications in IR and strategies for dealing with them to achieve optimal patient outcomes.

Original Article

Vascular Access Complications in Patients Undergoing Veno-Arterial ECMO and Their Impact on Survival in Patients With Refractory Cardiogenic Shock: A Retrospective 8-Year Study

Vikrampal Singh, Gurmeet Singh, Rajesh Chand Arya¹, Samir Kapoor, Arun Garg, Sarju Ralhan², Vivek K. Gupta¹, Bishav Mohan³, Gurpreet Singh Wander³, Rajiv K. Gupta

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Review Article 9

Endovascular Treatment versus Open Repair for Abdominal Aortic Aneurysms: The Influence of Fitness in Decision Making

Konstantinos G. Moulakakis, MD, PhD, MSc, FEBVS¹ Ilias Dalainas, MD, PhD¹
John Kakisis, MD, PhD, FEBVS¹ Spyridon Mylonas, MD¹ Christos D. Liapis, MD, PhD, FACS, FEBVS¹

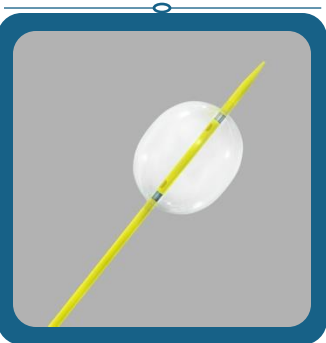
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Int J Angiol 2013;22:9–12.

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According to the available data, there is emerging evidence that patients at high medical risk for open repair may benefit from EVAR while in low-risk patients with suitable anatomy for EVAR, both techniques have similar effects.

Device Evolution



2011
Cook Coda



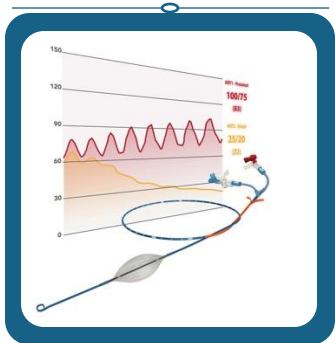
2016
ER-REBOA



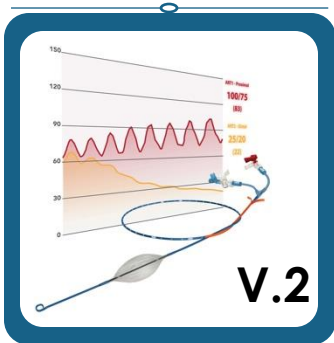
2019
ER-REBOA-PLUS



2021
Frontline Cobra



2021
pREBOA-PRO



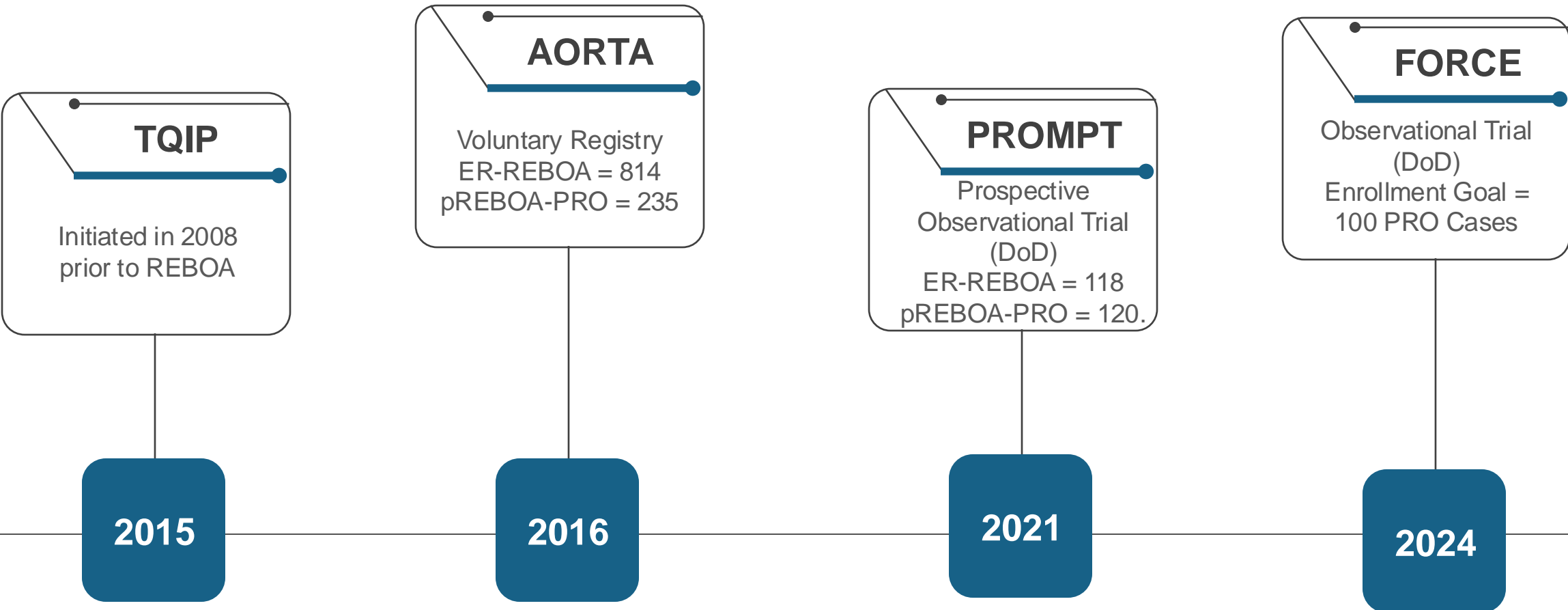
2024
pREBOA-PRO V2

30 Minutes

2-4 Hours



Evolution of Quality Data



From anecdote to data: Learnings from 700+ pREBOA-PRO™ uses



BUYS TIME

- Partial occlusion^{1, 11}
- Extended safe occlusion time^{2, 5, 6, 13}
- More Zone 1⁴



EXPANDS TREATMENT OPTIONS

- CT scans⁹
- Endovascular-only procedures^{6, 9}
- OR procedures⁹
- PRBCs, platelets, cryoprecipitate and crystalloids^{6, 10}



NO INCREASED COMPLICATIONS WITH PROLONGED USE

- AKI^{3,4,7, 8,12}

1. Polcz et al., (2022) J Surg Res. Based on preclinical data. Clinical results in humans are unknown.
2. Necsoiu et al., (2021) Shock. Based on preclinical data. Clinical results in humans are unknown.
3. Russo et al., (2020) J Trauma Acute Care Surg.
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6. Data on file.
7. Ronaldi et al., (2021) Shock. Based on preclinical data. Clinical results in humans are unknown.

8. Madurska et al., (2021) Eur J Trauma Emerg Surg.
9. Meyer, C. et al. (2023) AAST poster presentation.
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11. Edwards et al., (2022) J Am Coll Surg.
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13. Ho et al., (2023) J Trauma Acute Care Surg. Based on preclinical data. Clinical results in humans are unknown.



pREBOA-PRO™ PROGRAM IMPLEMENTATION: THE EMERGING LEARNING CURVE BASED ON THE FIRST 600 PATIENTS IN A MULTICENTER COLLABORATIVE

Moore EE, Raley J, Spalding MC, Radomski M, Beckett A, Smith AA, Mukherjee K, Rezende J, Vassy M, Nguyen J, Dennis BM

Introduction

REBOA is an adjunct for resuscitation of hemorrhagic shock however indications remain controversial

pREBOA-PRO™ is the newest generation device designed to provide titratable partial occlusion and break the 30 min barrier in Zone 1 (supradiaphragmatic). It became available in 2021 to 16 Level 1 Trauma Centers deemed Centers of Excellence (COEs) who received regular training on the new device

The COE quality improvement effort provides an opportunity to collect information on technical challenges, device benefits and QI data, through monthly case debriefs. This data was utilized to develop both institutional and individual learning curve graphs

Hypothesis: Both institutional and individual experience will reduce technical challenges during the implementation of a partial REBOA program

Methods

March 2021-April 2024, 600 pREBOA-PROs were deployed in COEs, and technical challenges were recorded including access, removal, and sheath management

A regression model identified the best fitting curve for institutional and individual challenges

Results

Among the 600 cases 373 underwent formal debriefing showing a progressive increase in zone 1 placement from 2022 at 63% to 2023 at 80%

Cases were grouped in increments of 5 starting from 0 and compared using the Kruskal-Wallis test

The best fitting regression was a cubic model for both institutional and individual learning curves (see graphs for equation and R-square).

A difference between incremental groups for the individual learning curve ($X^2_{(5)}=16.2$, $p<0.006$) was identified. The first group (Cases: 0-5) had more technical challenges than all others ($*=p<0.03$). The institutional learning curve also showed significant difference between groups ($X^2_{(5)}=23.3$, $p<0.04$)

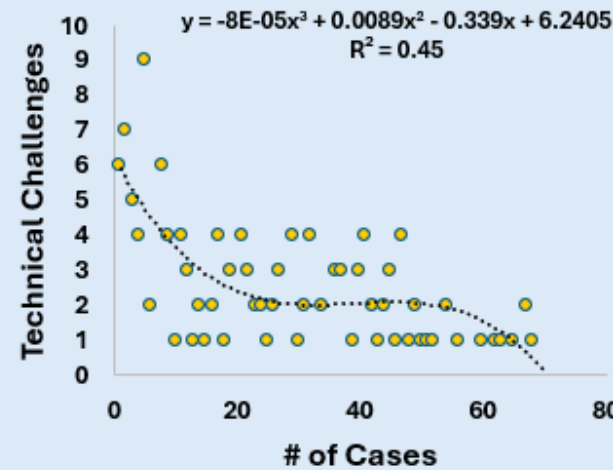
Conclusions

A multicenter collaborative of trauma centers implementing the new device indicates that both institutional case experience (>30) and individual case experience (>5) substantially reduce technical challenges

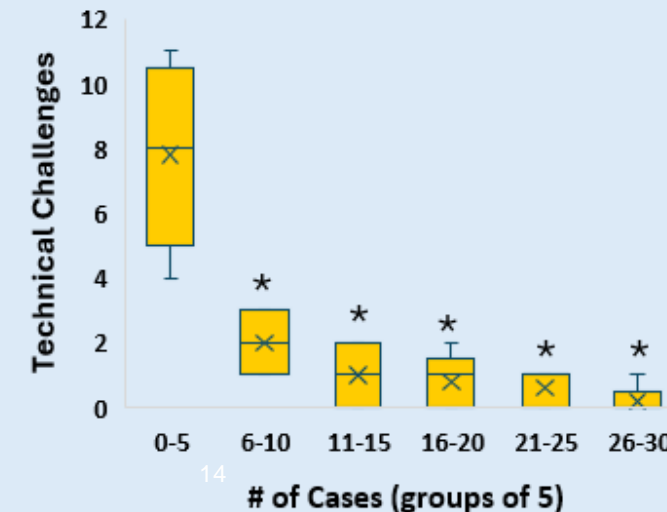
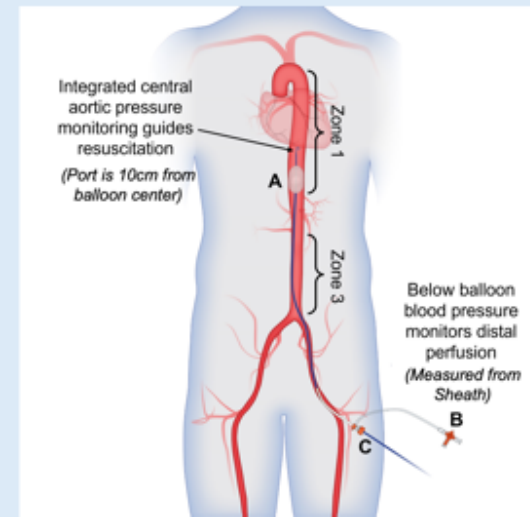
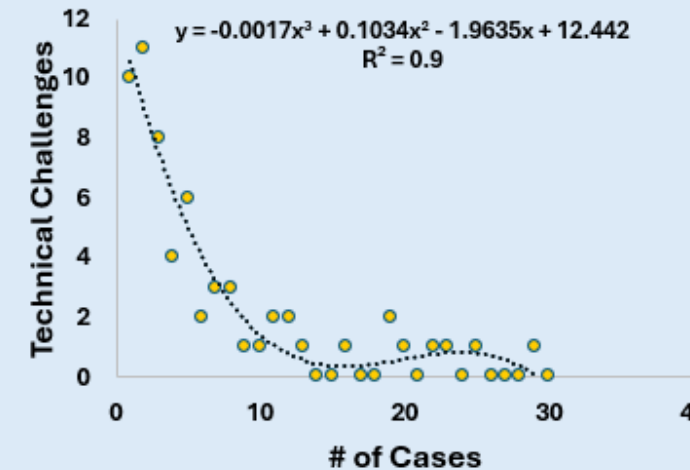
Analysis of the learning curve data is consistent with users of other advanced techniques that require both institutional commitment and individual practice

Findings may explain the UK REBOA study's failure to demonstrate clinical benefit with 19 balloon inflations done among 16 centers over 5 years with one initial training

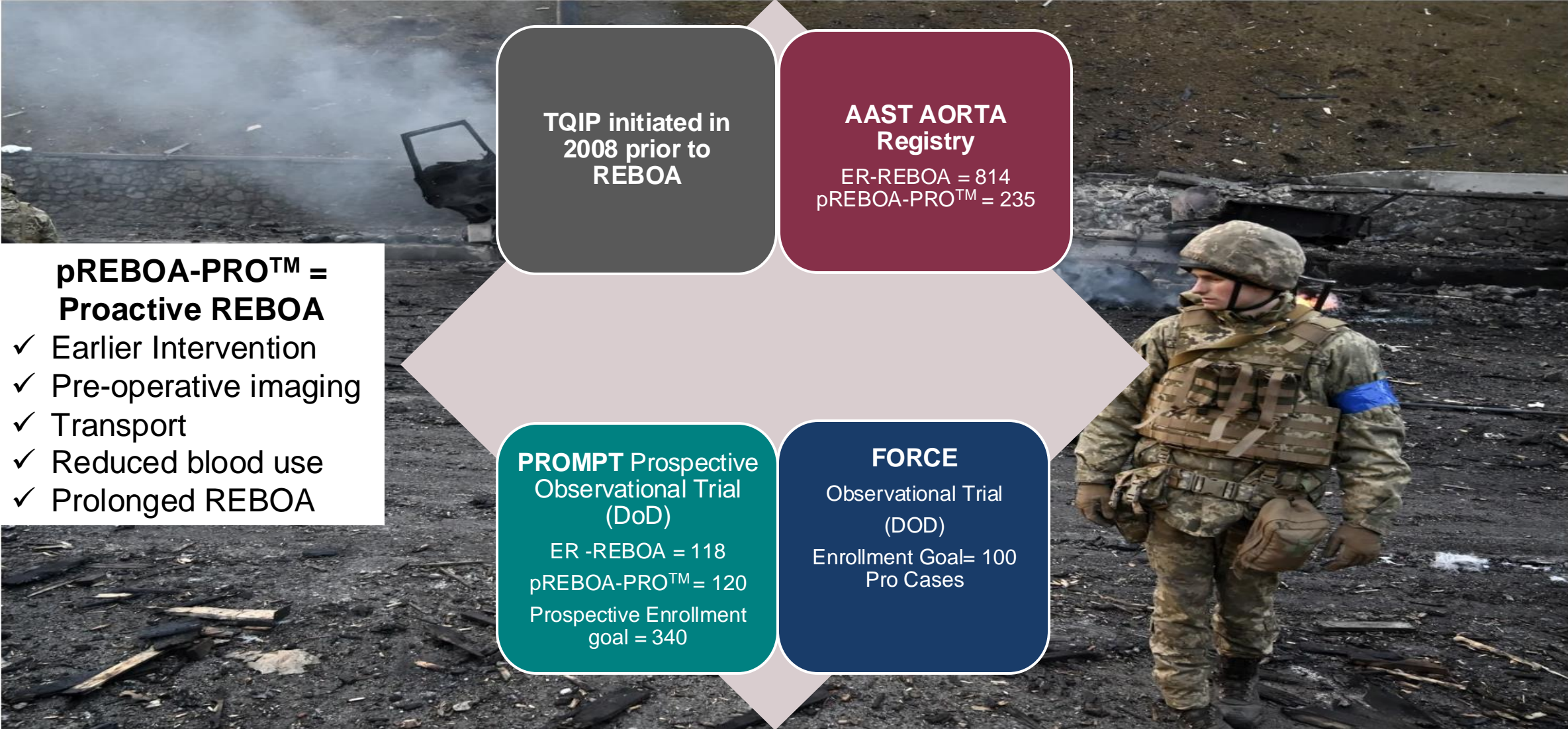
Institutional Learning Curve



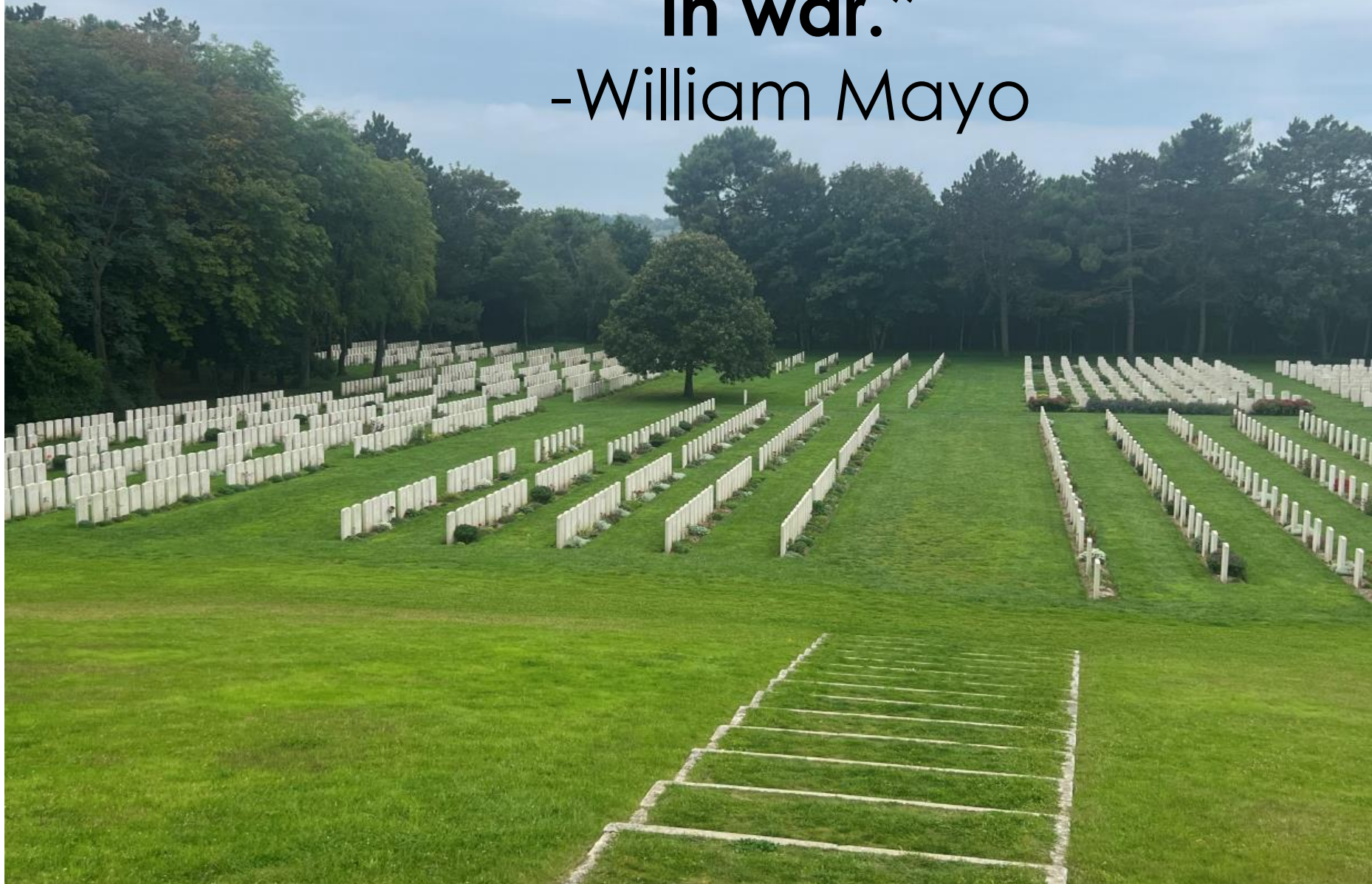
Individual Learning Curve



Evolution of Data for REBOA – Similar to Tourniquets?



**“Medicine is the only victor
in war.”
-William Mayo**



“It is not the critic who counts: not the man who points out how the strong man stumbles or where the doer of deeds could have done better. The credit belongs to the man who is actually in the arena, whose face is marred by dust and sweat and blood, who strives valiantly, who errs and comes up short again and again, because there is no effort without error or shortcoming, but who knows the great enthusiasms, the great devotions, who spends himself in a worthy cause; who, at the best, knows, in the end, the triumph of high achievement, and who, at the worst, if he fails, at least he fails while daring greatly, so that his place shall never be with those cold and timid souls who knew neither victory nor defeat.”

—Theodore Roosevelt



Outline

- Theme: Man in the arena (there is work to be done) – add quote
- Start: Why do I care about this? Use military service as a reason that it is important to him, something he sees in injured service men and women as resuscitative tool
- Talk about Martin (his military service give him respect 3 tours..... I would assume he has a similar mission passion/caring for injured warriors
- Disclosures:
- I agree with everything Marty just said except there is still a problem that needs to be solved
 - Bellal paper- highlight no consensus argument (I agree with you)
- What is the problem- if you show up to trauma center with low BP you have high likelihood of death
- Time of injury to definitive hemorrhage control (slide) takes too long to get
- Many tools we have but the problem persists
- Agree, what has been done with old REBOA is a lot of bad
- How many have done a REBOA case? How many have done 5.....done 10?
- There is relentless ongoing innovation
 - Device, Data, & Learning
- Device
 - 2011 Cook Coda, 2016 ER-REBOA, 2019 ER-REBOA-PLUS, 2021 Cobra = only 30 mins
 - 2021 pREBOA-PRO, 2024 pREBOA-PRO V2 = 2-4hrs
- Data
 - 2015 TQIP = poor (data fields defined before REBOA and not updated)
 - 2016 AORTA = somewhat better (voluntary registry)
 - 2021 PROMPT = better (independent observational)
 - 2024 FORCE = far forward (independent observational)
 - Nguyen, Vassy and other pubs- don't base your opinion on old REBOA
- Learning
 - Learning curve data- learning is still happening
 - 5 cases = practitioner 10 cases = expert
- Complications happen but they are manageable
- UK REBOA trial (very few people got REBOA) proved don't delay hemorrhage control
- Challenges ahead where we are going- still something worthwhile to investigate
- Man in the arena quote