

REBOA - Trials and Registries

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REBOA – Clinical Trials and Registries

2018

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Disclosures

- 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

Value of Clinical Registries

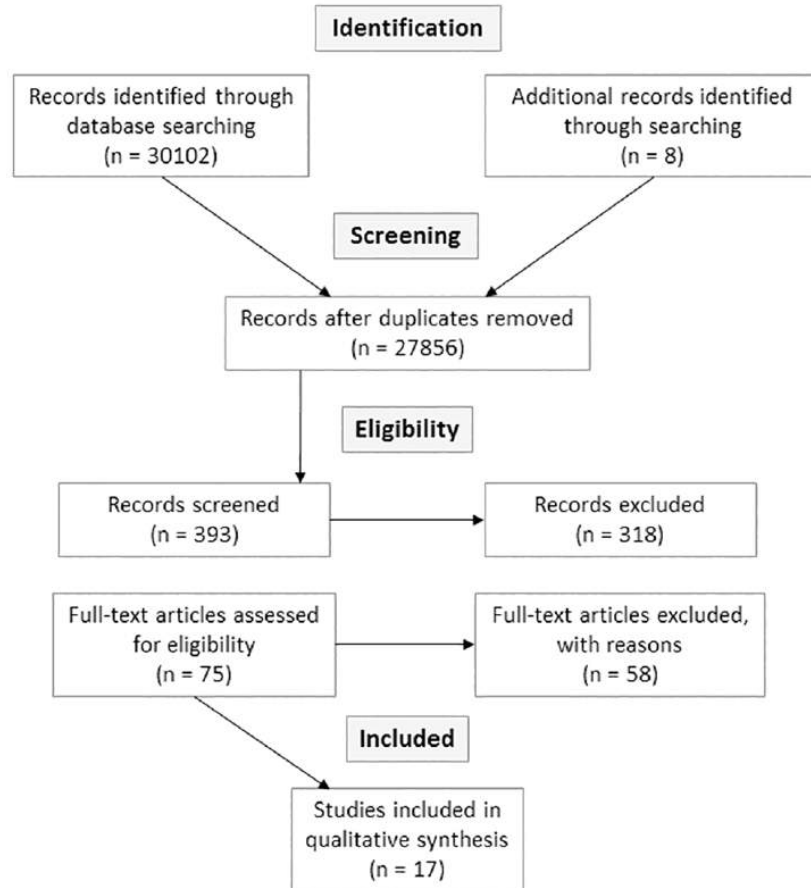


Fig 1. Results of search strategy following PRISMA flow diagram.

Citation: Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM (2017) Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PLoS ONE 12(9): e0183667. <https://doi.org/10.1371/journal.pone.0183667>

Value of Clinical Registries

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.

Citation: Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM (2017) Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PLoS ONE 12(9): e0183667. <https://doi.org/10.1371/journal.pone.0183667>

REBOA Trials and Registries

- AAST AORTA registry
- EVTm / ABOTrauma registry
- Prytime Emergent Truncal Hemorrhage Observational Study
- NHS United Kingdom REBOA Clinical Trial
- DoDTR Registry

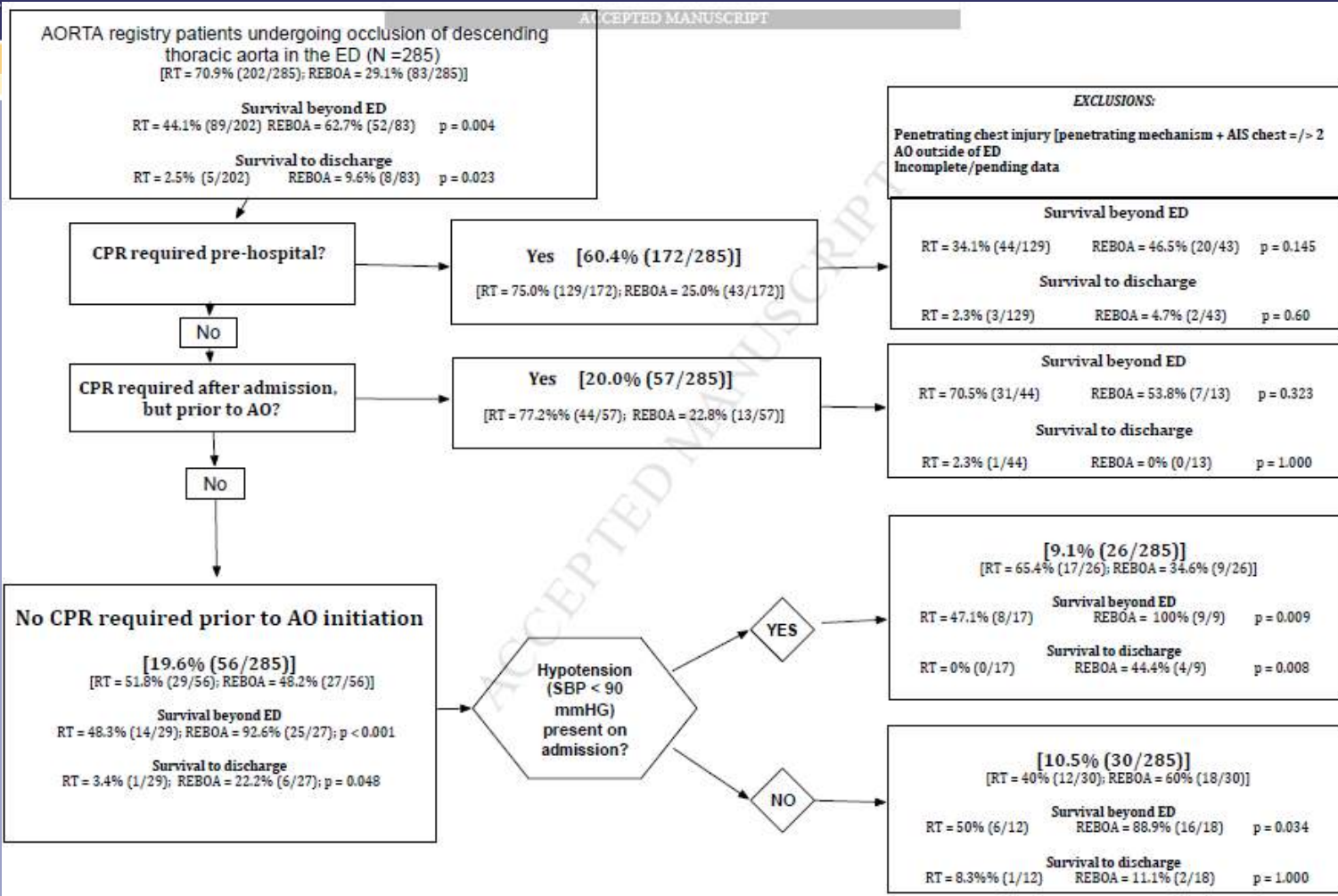
AAST AORTA registry

- 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.



AAST AORTA registry

ACCEPTED MANUSCRIPT



- 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

Main round table Topics:

EVTM concept, multidisciplinary approach

Trauma and non-trauma- PPH, 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

Örebro, Sweden

7-8-9th June 2018

In cooperation with the Dept. Of Cardiothoracic and Vascular Surgery & Dept. of Surgery & Dept. of Anesthesia/ICU Örebro University Hospital & University, Sweden



Save the date!

www.jevtm.com

Symposium chairs:

Tal Hörer (SE)

Joseph Dubose (US)

Junichi Matsumoto (JP)

Jonny Morrison (UK)

Viktor Reva (RU)

Boris Kessel (IL)

Lauri Handolin (FI)

George Oosthuizen (ZA)

Todd Rasmussen (US)

Megan Brenner (US)

Joe Love (US)

Invited speakers/panelists:

TBA

Supported by

TBA

EVTM / ABOTrauma registry

- ICD-10-PCS
- Coding Tips
 - To code Zone I
 - W3DJ

02L

Section	0	Medical and Surgical		
Body System	2	Heart and Great Vessels		
Operation	L	Occlusion: Completely closing an orifice or the lumen of a tubular body part		
Body Part	Approach	Device	Qualifier	
7 Atrium, Left	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	K Left Atrial Appendage	
H Pulmonary Valve P Pulmonary Trunk Q Pulmonary Artery, Right S Pulmonary Vein, Right T Pulmonary Vein, Left V Superior Vena Cava	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier	
R Pulmonary Artery, Left	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	T Ductus Arteriosus Z No Qualifier	
W Thoracic Aorta, Descending	3 Percutaneous	D Intraluminal Device	J Temporary	

Section	0	Medical and Surgical		
Body System	4	Lower Arteries		
Operation	L	Occlusion: Completely closing an orifice or the lumen of a tubular body part		
Body Part	Approach	Device	Qualifier	
0 Abdominal Aorta	0 Open 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier	
0 Abdominal Aorta	3 Percutaneous	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier	
0 Abdominal Aorta	3 Percutaneous	D Intraluminal Device	J Temporary Z No Qualifier	
1 Celiac Artery 2 Gastric Artery 3 Hepatic Artery 4 Splenic Artery 5 Superior Mesenteric Artery 6 Colic Artery, Right 7 Colic Artery, Left 8 Colic Artery, Middle 9 Renal Artery, Right A Renal Artery, Left B Inferior Mesenteric Artery C Common Iliac Artery, Right D Common Iliac Artery, Left H External Iliac Artery, Right J External Iliac Artery, Left K Femoral Artery, Right L Femoral Artery, Left M Popliteal Artery, Right N Popliteal Artery, Left P Anterior Tibial Artery, Right Q Anterior Tibial Artery, Left R Posterior Tibial Artery, Right S Posterior Tibial Artery, Left T Peroneal Artery, Right U Peroneal Artery, Left V Foot Artery, Right W Foot Artery, Left Y Lower Artery	0 Open 3 Percutaneous 4 Percutaneous Endoscopic	C Extraluminal Device D Intraluminal Device Z No Device	Z No Qualifier	

- To code Zone II-III
- O3DJ

EVTM / ABOTrauma registry

- 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

EVTM / ABOTrauma registry

	Continuous REBOA	Non-continuous REBOA	<i>P</i>
Pre-hospital data			
GCS < 8/ <i>n</i> (%) (total = 75)	13 (41%)	15 (35%)	0.611
CPR/ <i>n</i> (%) (total = 91)	11 (23%)	7 (16%)	0.370
Systolic blood pressure			
ED Admission < 80 mmHg/ <i>n</i> (%) (total = 65)	22 (67%)	21 (66%)	0.929
SBP mm Hg before inflation/median (IQR) (total = 88)	50 (0–70)	68 (43–88)	0.026
SBP mmHg after inflation/median (IQR) (total = 89)	95 (69–120)	110 (90–135)	0.022

EVTM / ABOTrauma registry

- 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

NHS United Kingdom REBOA Clinical Trial

- 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

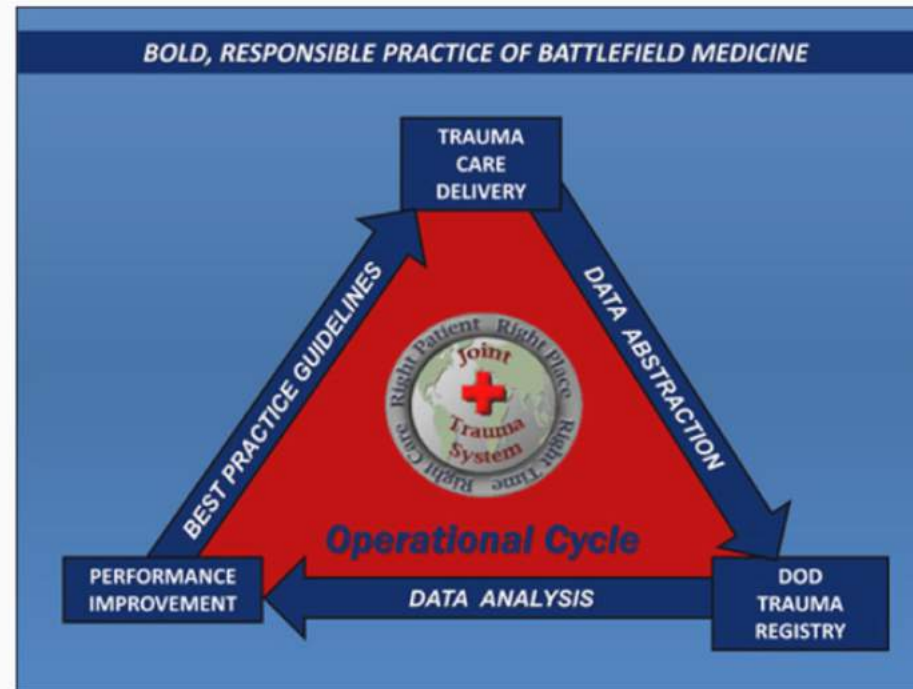
- Trial went live October, 2017
- 7 sites enrolling – Pilot sites for phase 1
- Total of 15 centers for full trial
- Based upon English trauma network, fully integrated national system consisting of 25 major trauma centers
- End-point is 90-day mortality

DoDTR Trauma Registry



Joint Trauma System

The Department of Defense Center of Excellence for Trauma

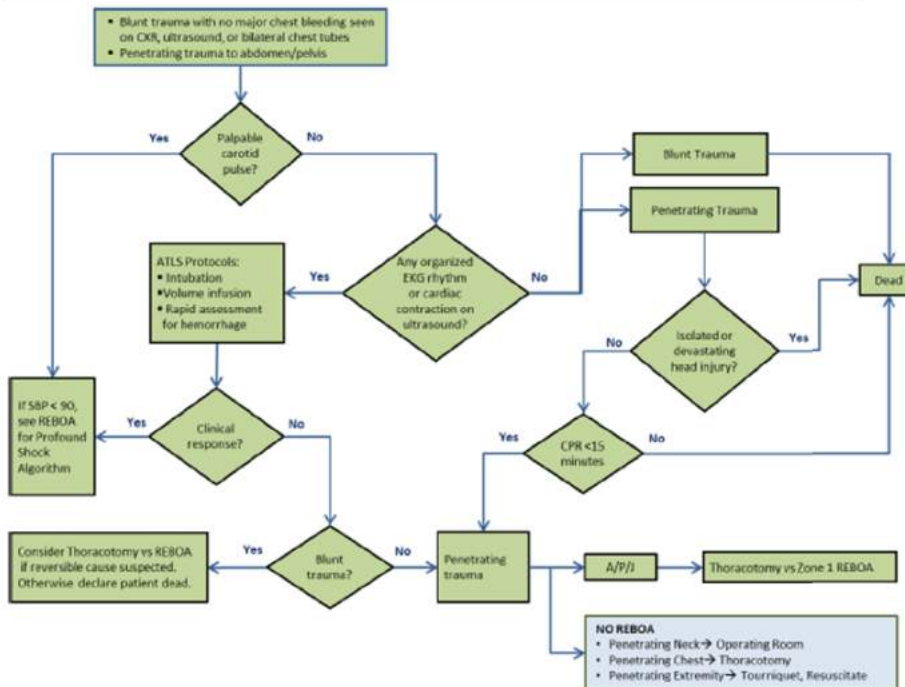


DoDTR Trauma Registry

- 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.



APPENDIX A: TRAUMATIC ARREST ALGORITHM FOR REBOA



REBOA: Resuscitative Endovascular Balloon Occlusion of the Aorta; CXR: Chest X-Ray; EFAST: Extended Focused Assessment with Sonography for Trauma; ATLS: Advanced Trauma Life Support; EKG: Electrocardiogram; SBP: Systolic Blood Pressure; CPR: Cardiopulmonary Resuscitation; A/P/J: Abdomen/Pelvis/ Junctional Lower Extremity

Zone I REBOA: placement of aortic balloon in the thoracic aorta (insert catheter to 46 cm or measure the balloon to mid sternum/P-tip to sternal notch)

Zone III REBOA: placement of aortic balloon directly above the aortic bifurcation (insert catheter to 27 cm or measure the balloon to the umbilicus).



J Spec Oper Med. Spring 2017;17(1):1-8.

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, DuBose JJ, 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 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-hospital setting is useful as a stabilizing and damage control adjunct, allowing time for resuscitation, laparotomy, and surgical hemostasis.

2017.



Thank You



Questions?