The Max Harry
Weil Institute
FOR CRITICAL CARE RESEARCH & INNOVATION

REBOA Alternatives for Noncompressible Torso Hemorrhage

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Disclaimers/Conflicts of Interests:

- Patents: University of Michigan
- Technology licensed to Precision Trauma LLC. Equity in Precision Trauma LLC
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- Views Expressed do not necessarily represent those of the US Army or US Department of Defense

Non-compressible Torso Hemorrhage (NCTH)

25-45% of military and civilian deaths from NCTH

Peak time of death from high grade NCTH within 30 min

Time to definitive operative hemostasis: 128 minutes

- 37 minutes Prehospital
- 24 minutes Emergency Department
- 67 minutes Operating Room

Shortening time to OR after ED arrival does not appear to improve survival

Hemorrhage control from first contact: Create Selective Prehospital Advanced Resuscitative Care (SPARC) teams

Transport Time and Preoperating Room Hemostatic Interventions Are Important: Improving Outcomes After Severe Truncal Injury

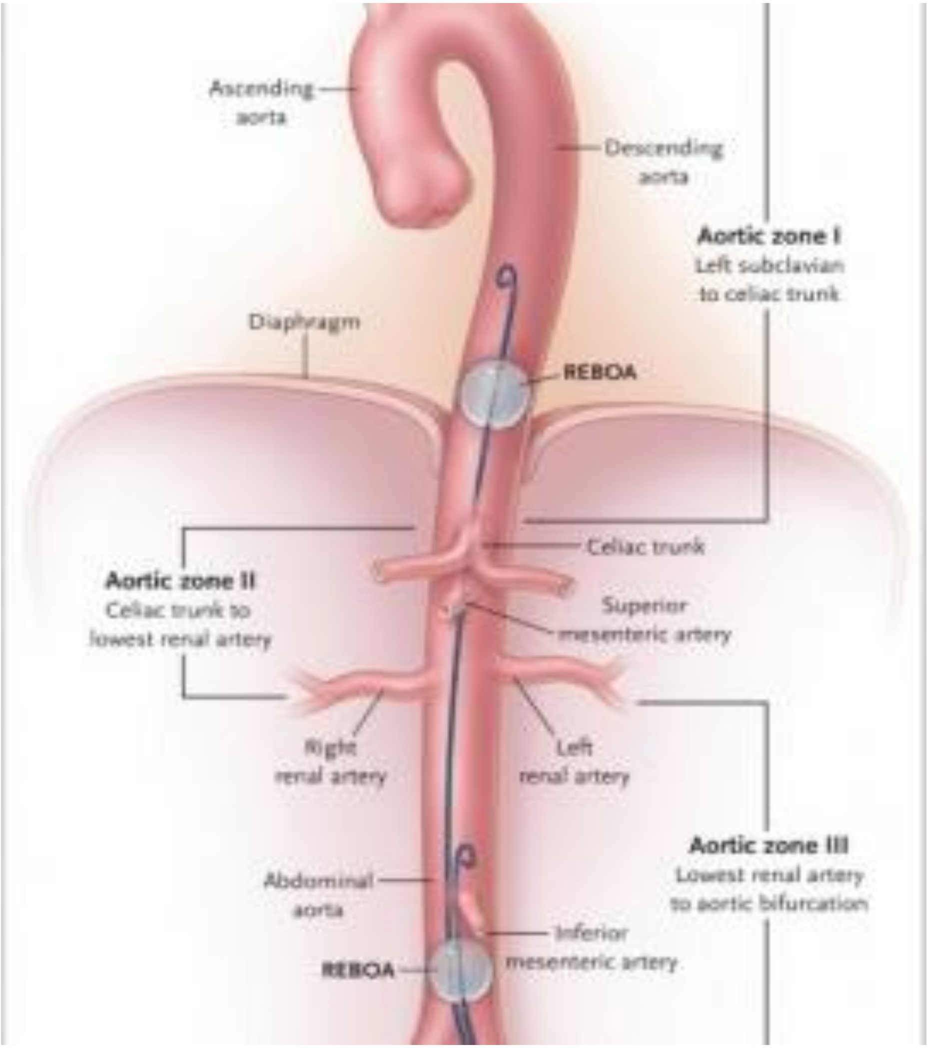
John B. Holcomb, MD, FACS   Critical Care Medicine

Impact of time to surgery on mortality in hypotensive patients with noncompressible torso hemorrhage: An AAST multicenter, prospective study (J Trauma Acute Care Surg. 2022;92: 801–811.

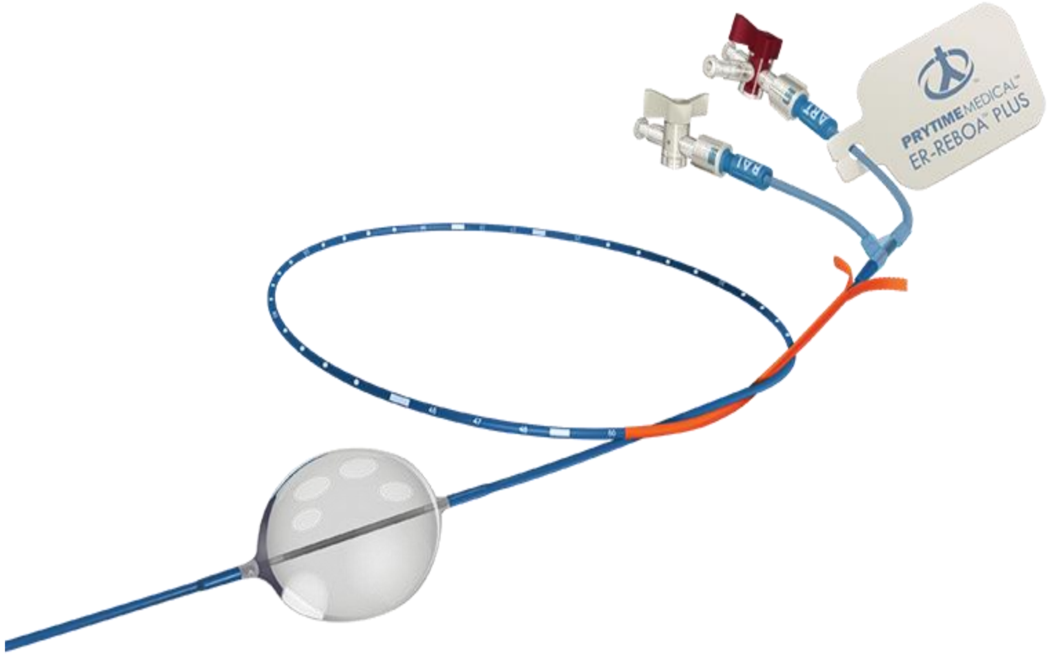
SELECTIVE PREHOSPITAL ADVANCED RESUSCITATIVE CARE – DEVELOPING A STRATEGY TO PREVENT PREHOSPITAL DEATHS FROM NONCOMPRESSIBLE TORSO HEMORRHAGE SHOCK, Vol. 57, No. 1, pp. 7–14, 2022

Resuscitative Endovascular Balloon Occlusion of the Aorta: REBOA

- Procedural times to place REBOA
  - 6-19 minutes
  - Most prehospital reports are with REBOA and CPR
- Placement success rates by trained teams
  - 58-90%
- Time from injury to balloon inflation
  - 34-138 minutes



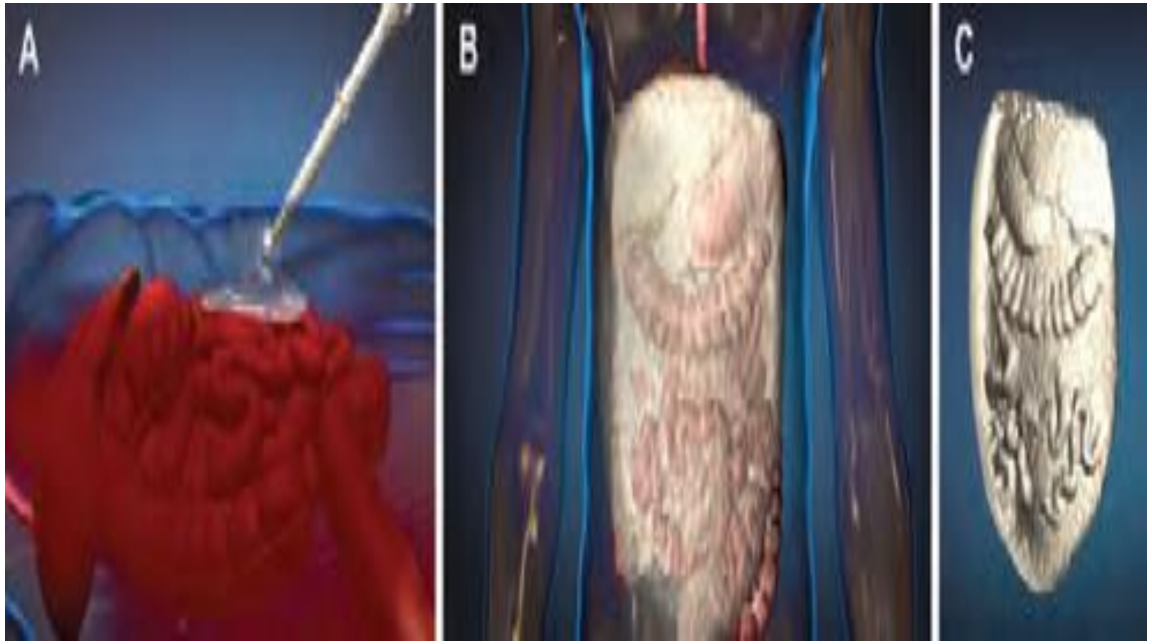
REBOA: Right Tool but Implemented at the Wrong Time?

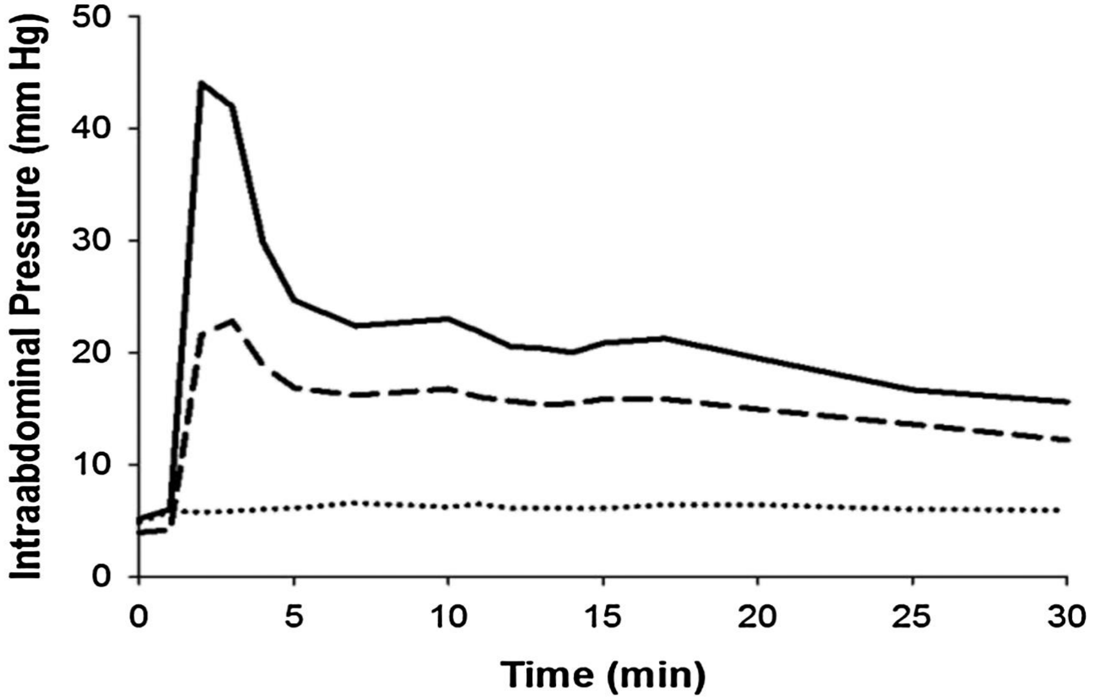


- Rapidly accumulating O2 Debt in severe NCTH
- When applied in the Trauma Center, creates additional large O2 Debt
  - Too much to recover from
  - Partial REBOA could change this
- Need scalable tools/methods that trained first responders can use at scene
- Couple with blood

ResQFoam: Arsenal Medical

- Self expanding polyurethane foam
  - Expands 35 times initial volume
  - Conforms to anatomical structures
  - Not biodegradable
- Mixing 2 liquid phase components
  - Reaction gels material into solid cohesive polyurethane foam
- Shown to improve survival in animals with grade V liver laceration
- Causes transient elevated IAPs
- Uniformly causes intestinal injury requiring imbrication or resection
  - What about diaphragm injuries?
- Not biodegradable: Commitment to surgery for removal
- Has been awaiting clinical trial since 2018

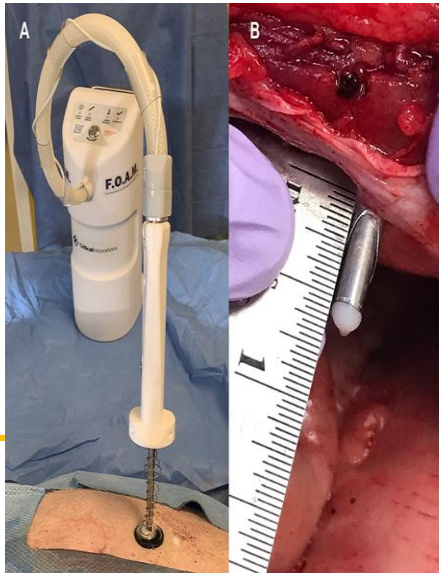


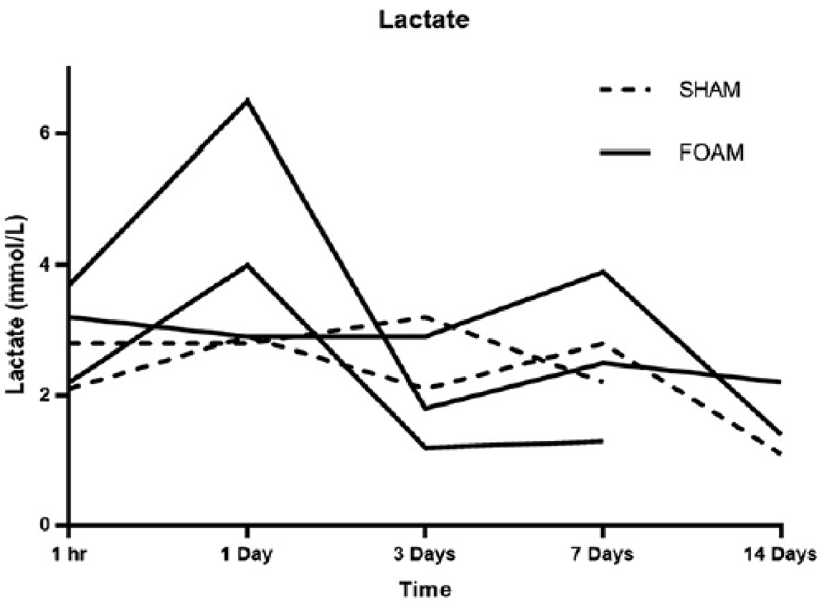


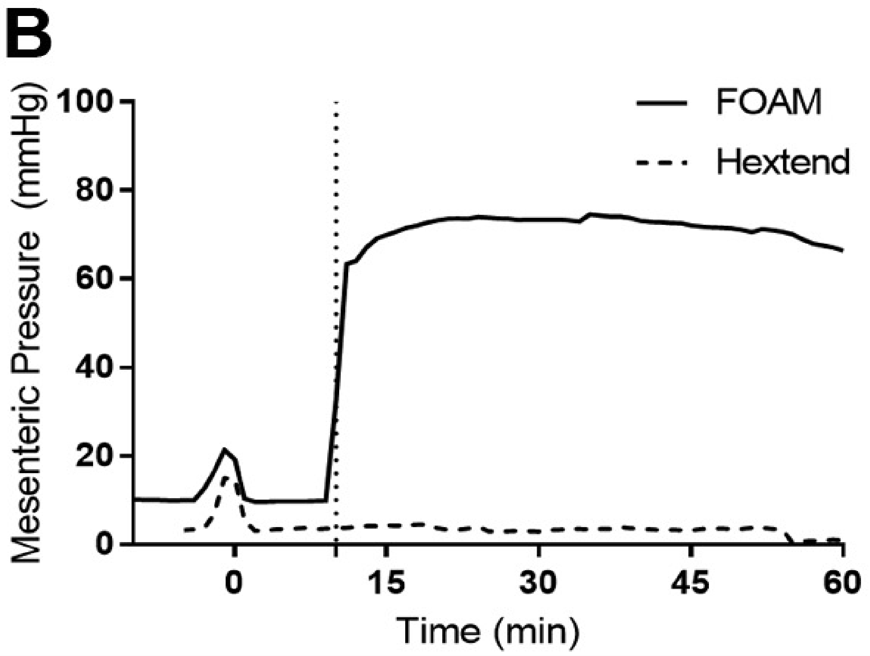
MILITARY MEDICINE, 00, 0/0:1, 2022

Thermoreversible Reverse-Phase-Shift Foam for Treatment of Noncompressible Torso Hemorrhage, a Safety Trial in a Porcine Model

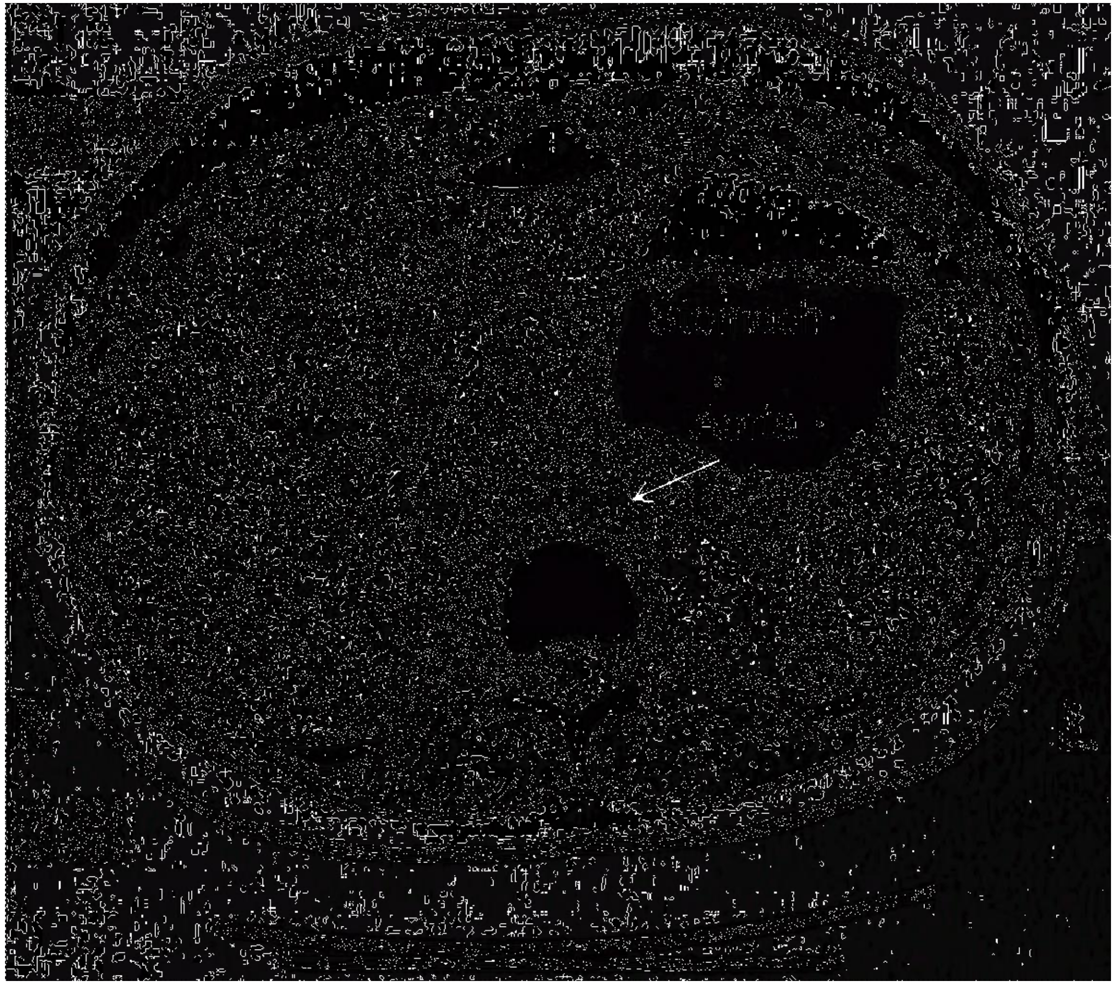
- Fast Onset Abdominal Management (FOAM)
  - Critical Care Innovations LLC
- Thermoresponsive poloxamer solution blended with a hydoflurocarbon gas
- Foaming achieved by expansion of the gas
- Poloxamer solution undergoes reversible sol-gel phase transition in response to temperature. Poloxamer gel is water soluble
- Theoretically can be left in place (biodegradable)
- No statistically significant improved animal outcome studies
- Appears to raise IAP for prolonged period causing lactate elevation (in control animals)

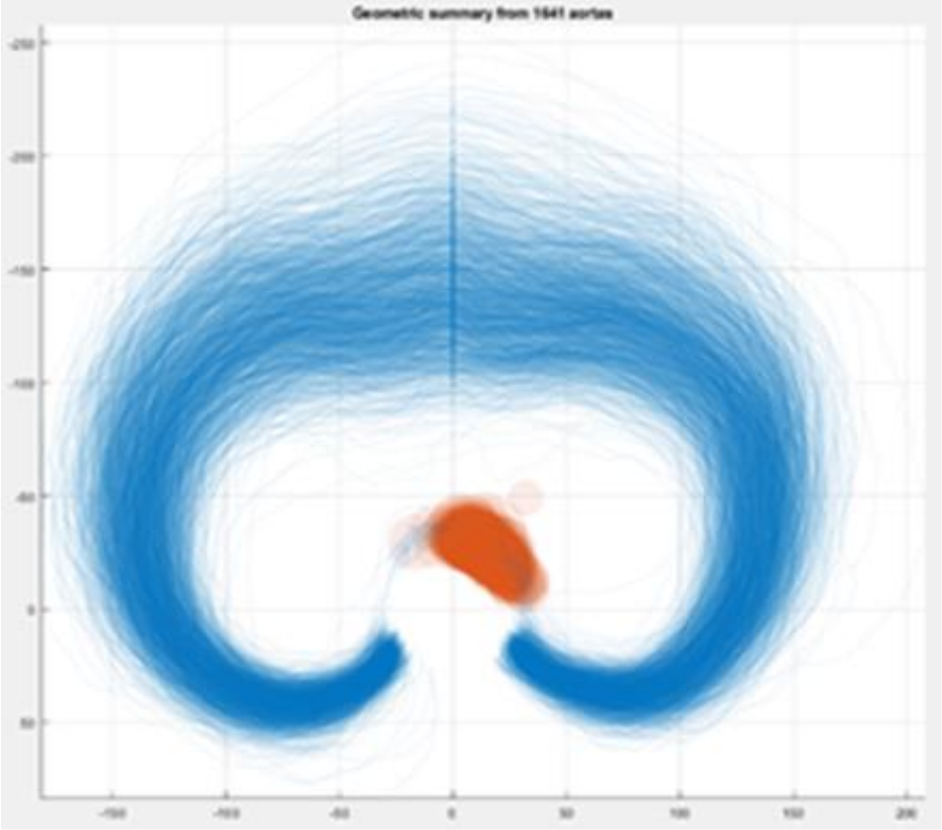






Morphomics Analysis:
Based on 1641 Human Abdominal CTs



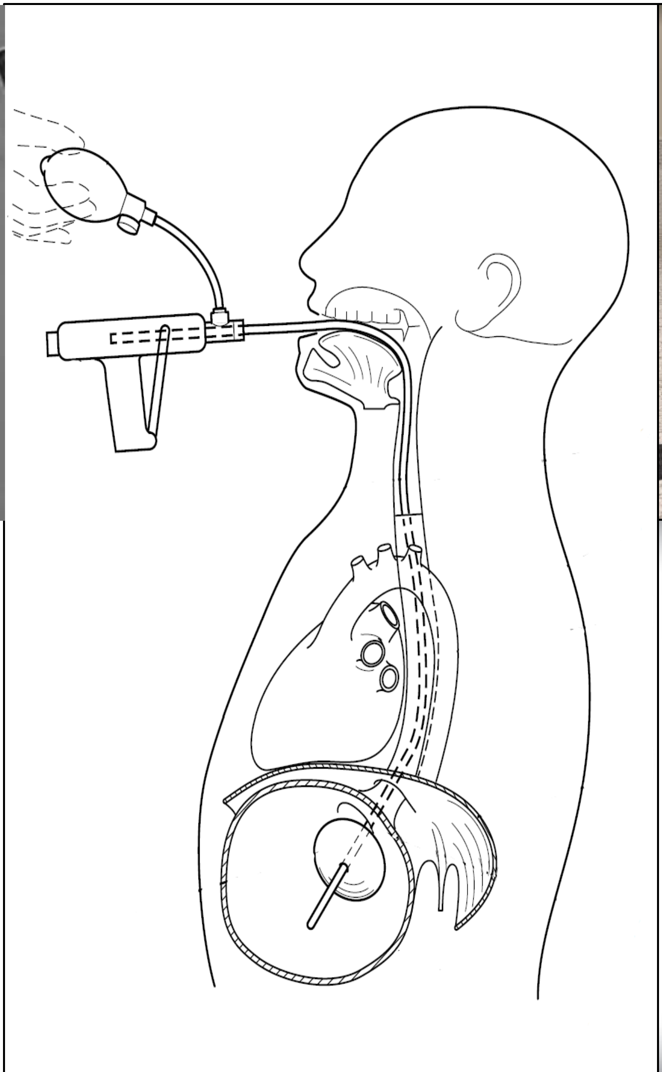


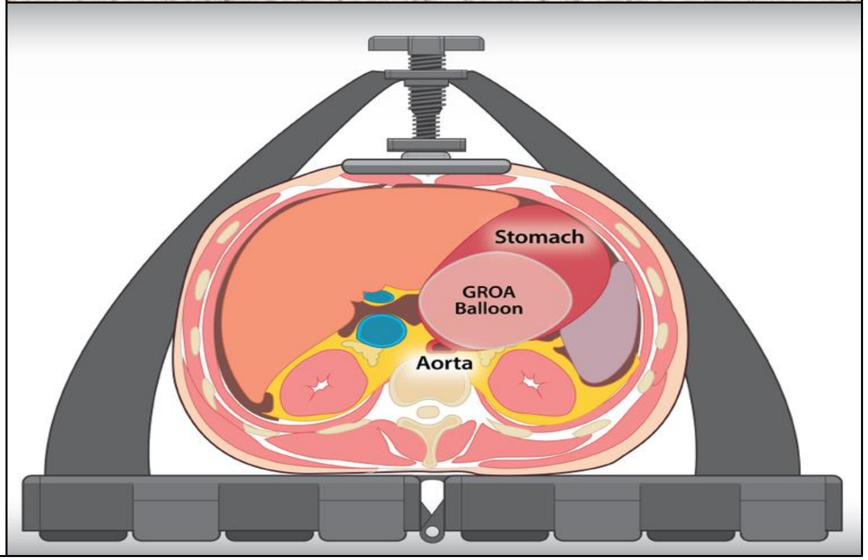
Radial relationship to center of vertebral body

The blue lines represent the outer border of the abdominal cavities. To better visualize the aortas the vertebral bodies have been removed from the image but their position can be easily inferred.

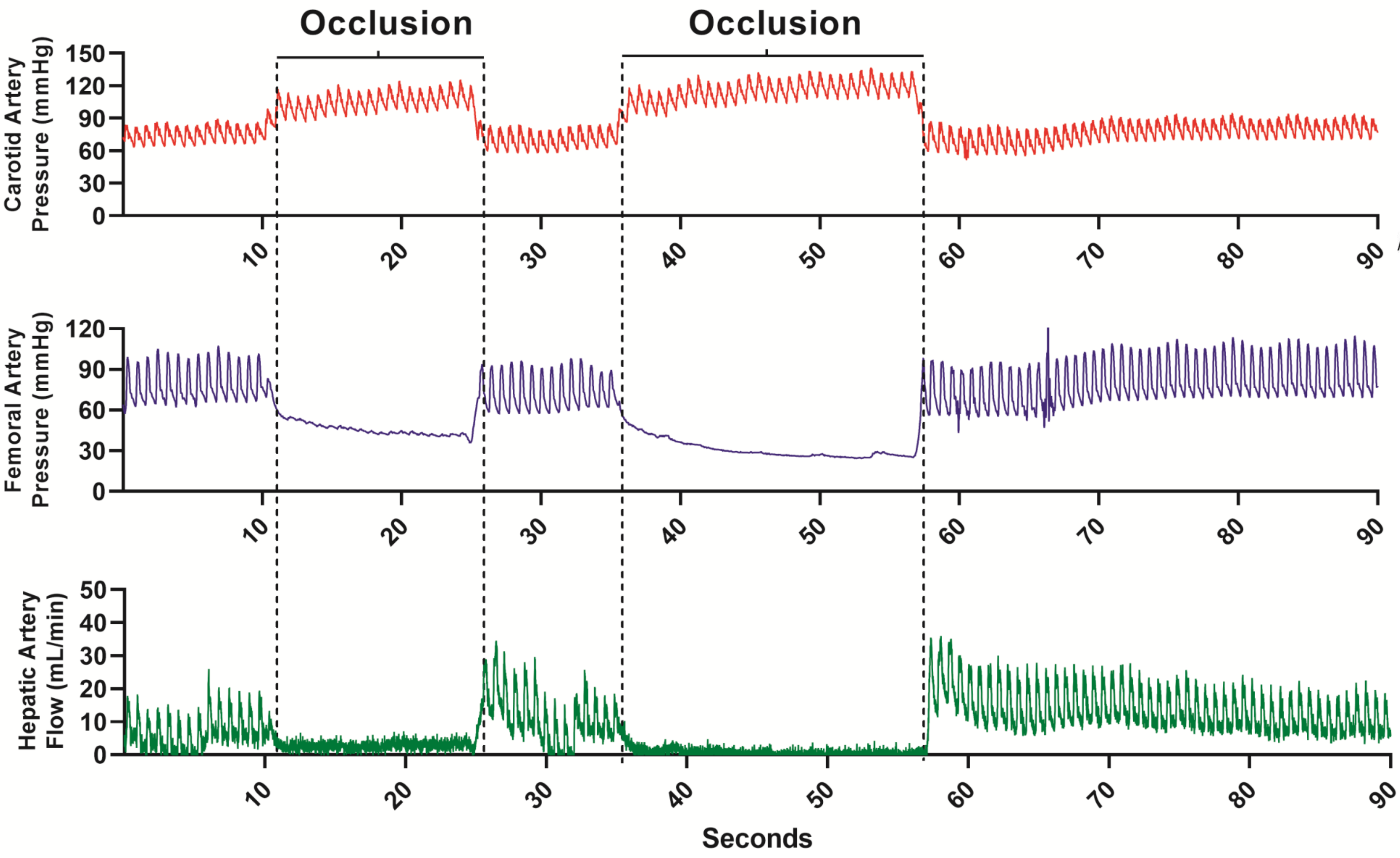
Gastroesophageal Resuscitative Occlusion of the Aorta (GROA)

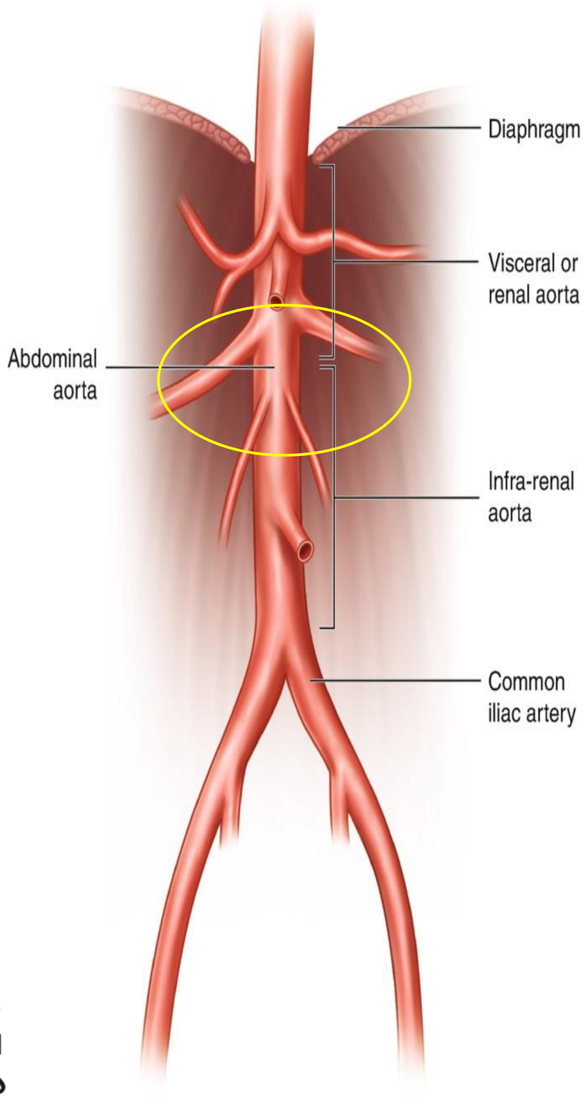
- Gastroesophageal tube, balloon, air gauge and hand pump
- 3 lumens: suction, air vent, inflation
- Inflates in ellipsoid shape
- Max volume 1600 cc
- 17 cm diameter
- Medical grade balloon with special compliance



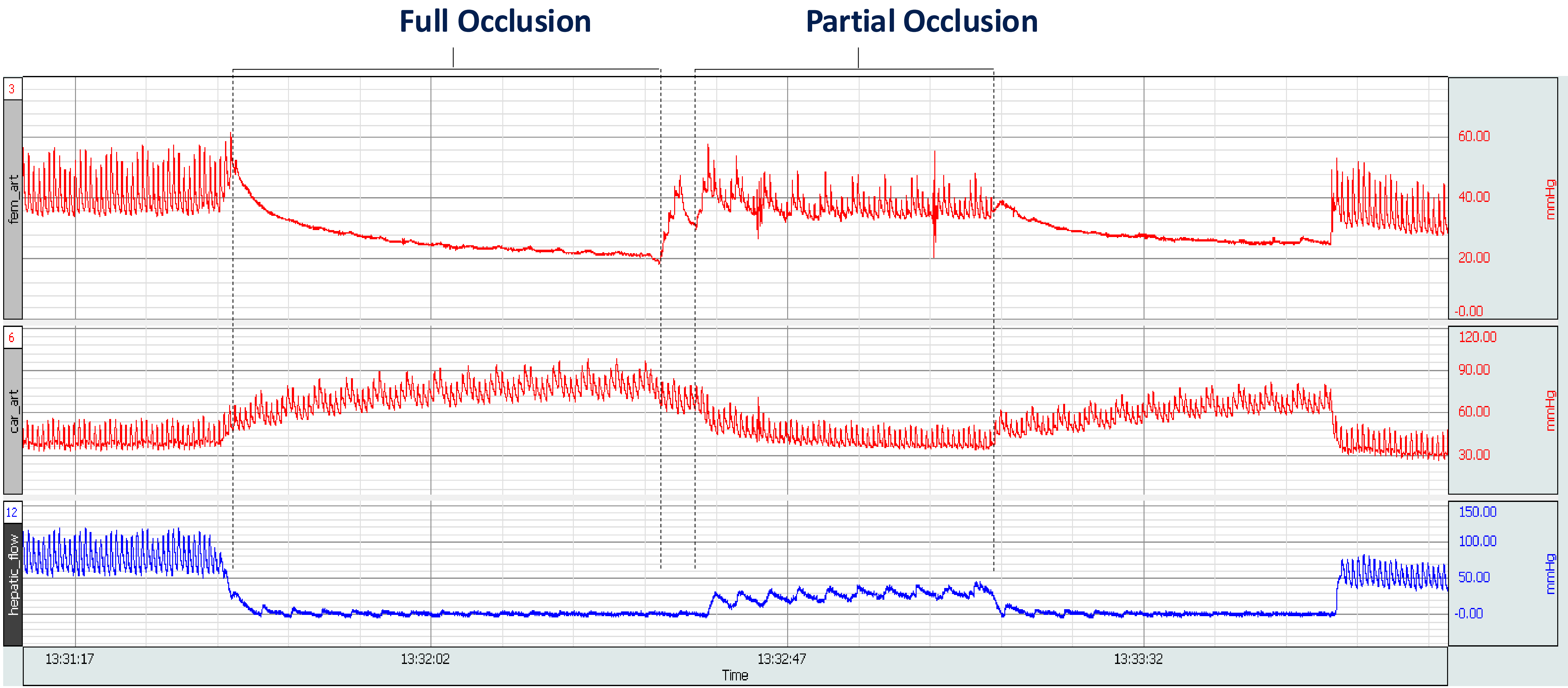


The GROA system creates High Zone II Aortic Occlusion





GROA partial occlusion of the aorta



Published Studies to Date

Gastroesophageal resuscitative occlusion of the aorta: Physiologic tolerance in a swine model of hemorrhagic shock

Journal of Trauma 2020;89: 1114–1123

Gastroesophageal resuscitative occlusion of the aorta prolongs survival in a lethal liver laceration model

(J Trauma Acute Care Surg. 2022;92: 880–889.

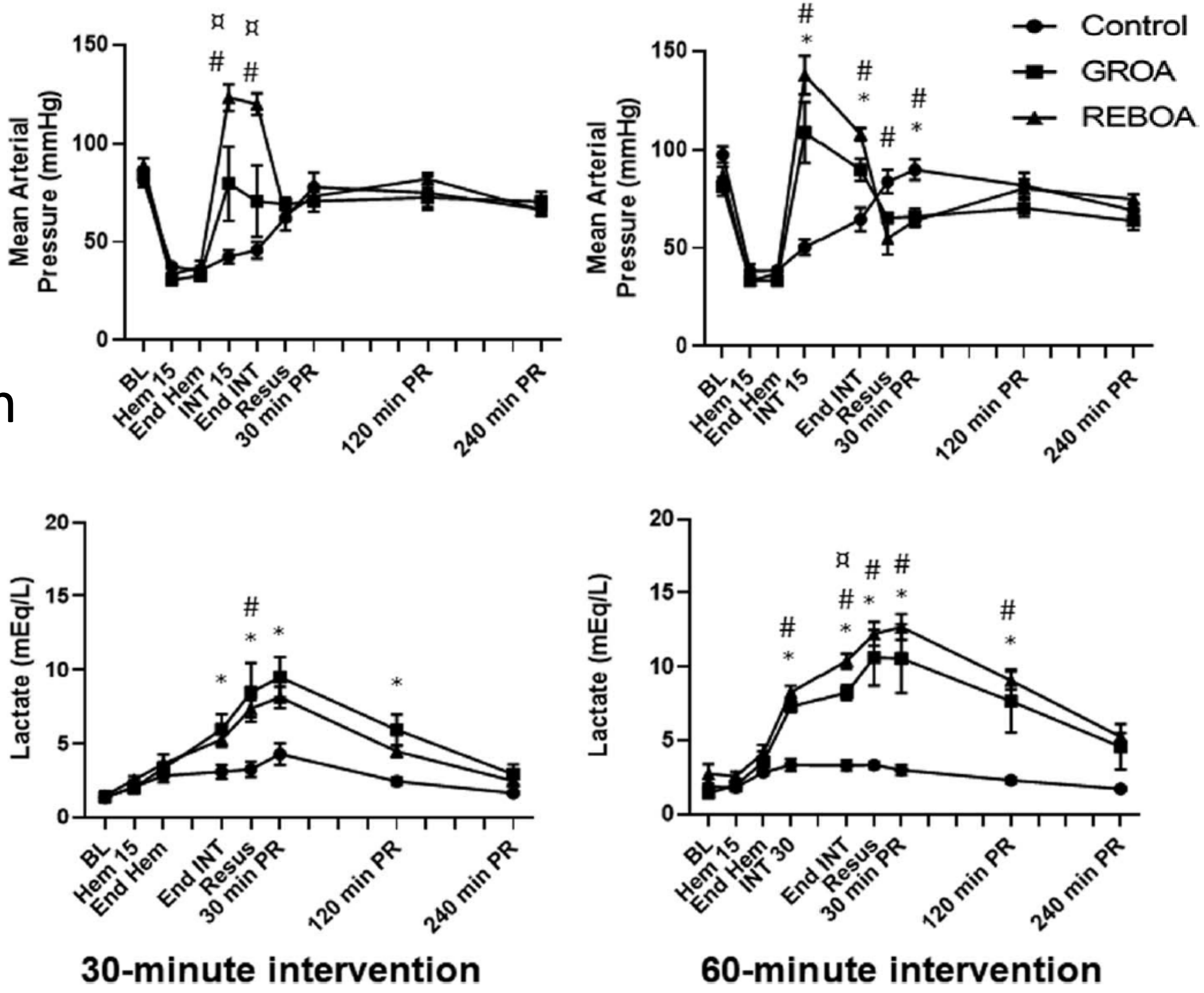
Tandem use of gastroesophageal resuscitative occlusion of the aorta followed by resuscitative endovascular balloon occlusion of the aorta in a lethal liver laceration model

J Trauma Acute Care Surg. 2023;94: 148–155.

Gastroesophageal resuscitative occlusion of the aorta: Physiologic tolerance in a swine model of hemorrhagic shock

Journal of Trauma 2020;89: 1114–1123

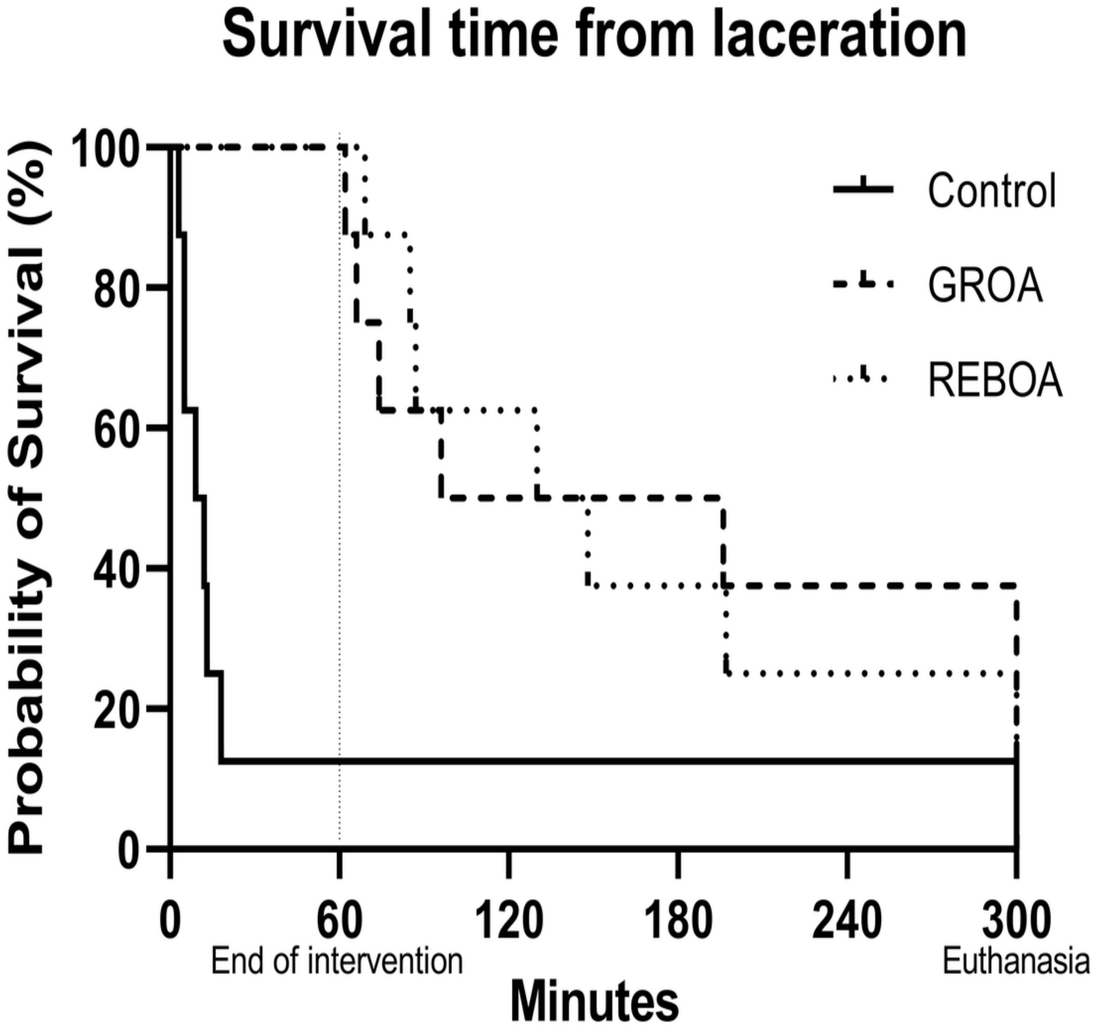
- 35% blood volume removal
- Control, REBOA or GROA
- 30, 60, 90 minutes
- Resuscitation with shed blood
- No clinically significant differences in MAP, SmVO2, Lactate between REBOA and GROA in 30 and 60 min occlusion and resuscitation
- 2 GROA animals survived 90 min occlusion vs 0 REBOA
- Statistically significant increase in airway pressure of GROA group: 20-33 cmH20 during application.



Gastroesophageal resuscitative occlusion of the aorta prolongs survival in a lethal liver laceration model

(J Trauma Acute Care Surg. 2022;92: 880–889.

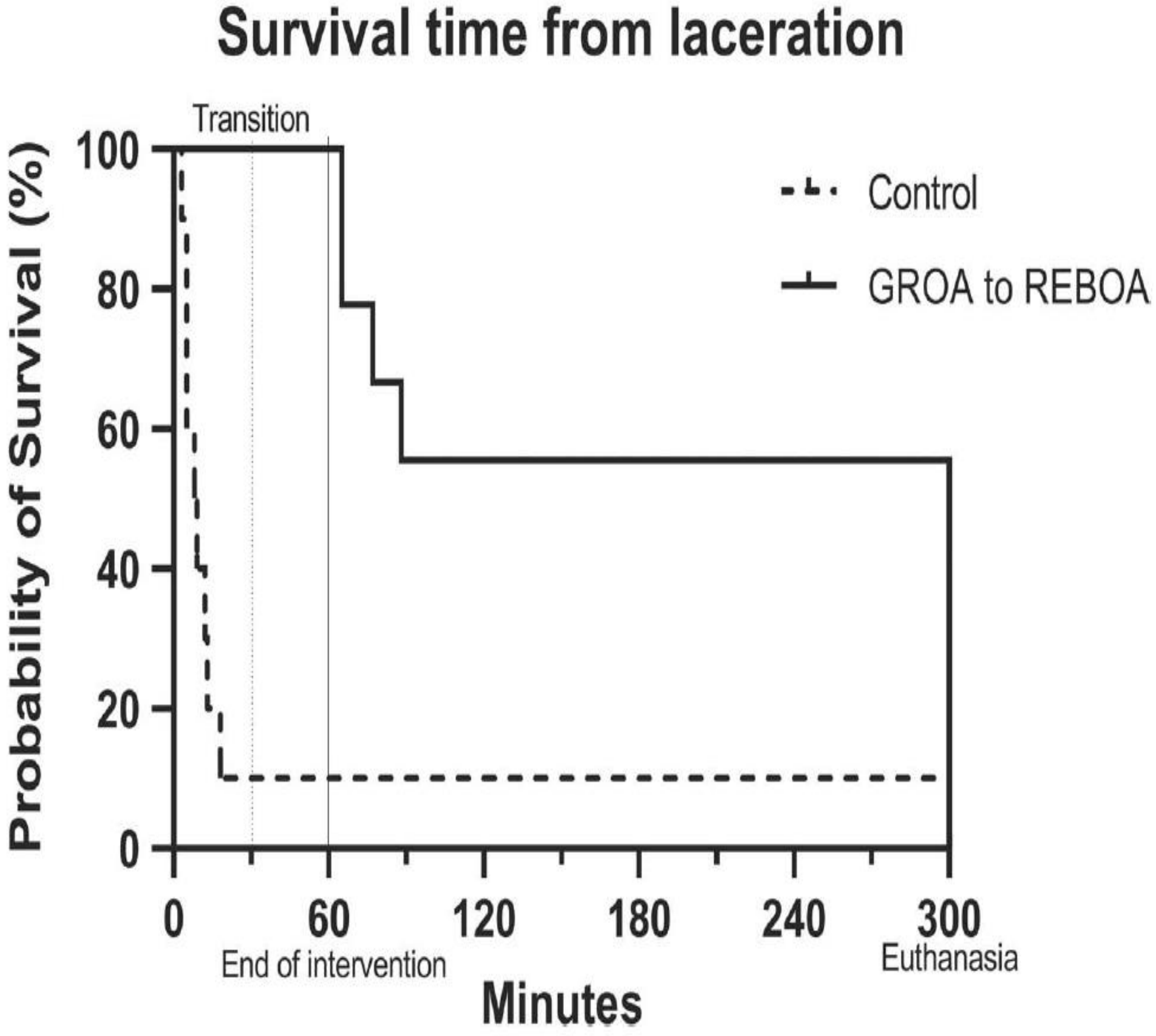
- 30% TBV removed
- Grade V liver laceration
- Control, GROA, or REBOA (preplaced)
- 60-minute occlusion
- At 60 minutes REBOA and GROA deactivation
  - Damage control packing
  - Resuscitation with shed blood
- No significant survival difference between GROA or REBOA in survival
- Except for airway pressure no significant different in:
  - MAP, Lactate, SmVO2, TEGs, or Cytokine profiles



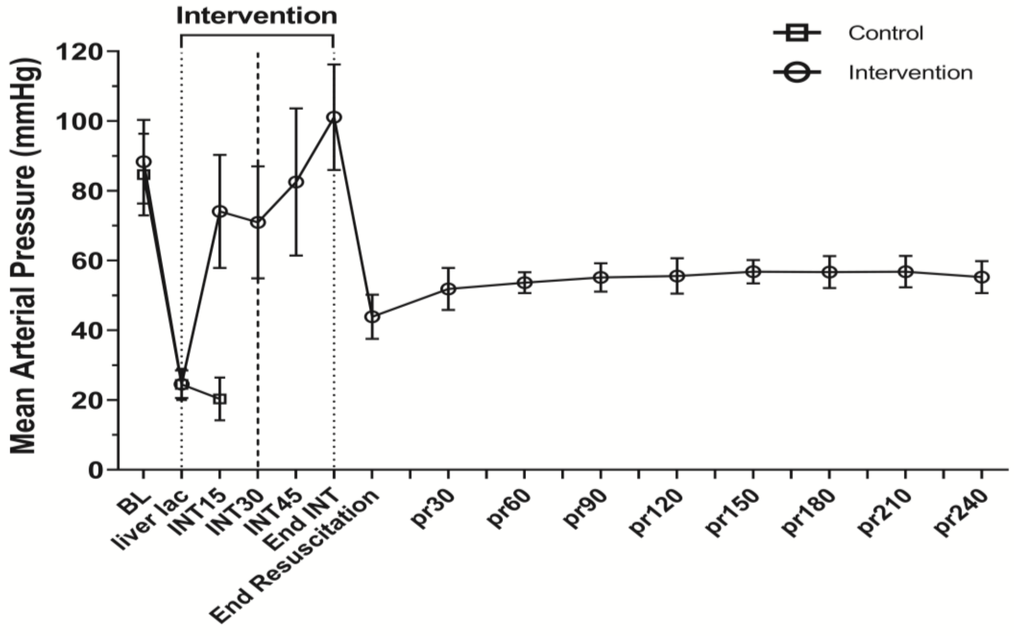
Tandem use of gastroesophageal resuscitative occlusion of the aorta followed by resuscitative endovascular balloon occlusion of the aorta in a lethal liver laceration model

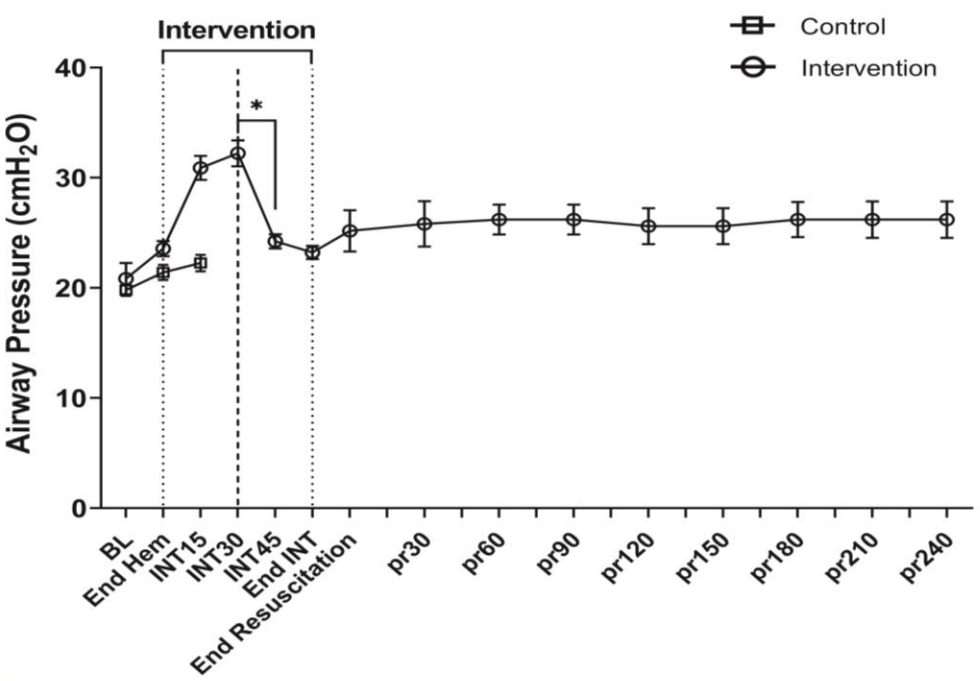
J Trauma Acute Care Surg. 2023;94: 148–155.

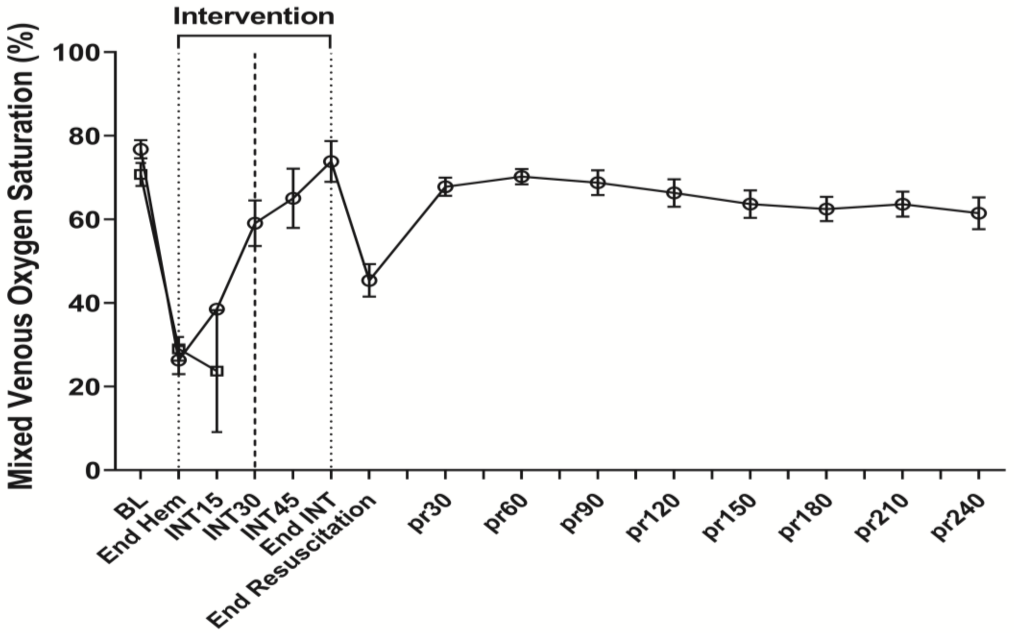
- 30% TBV removed
- Grade V liver laceration
- GROA placed and activated after 2 minutes of liver bleeding vs no treatment (control)
- 30-minute occlusion by GROA
- Transition to REBOA for additional 30 minute
- At 60 minutes REBOA deactivation, damage control packing and transfusion of shed blood
- Significant survival difference between GROA and Control
- 100% success rate in transition

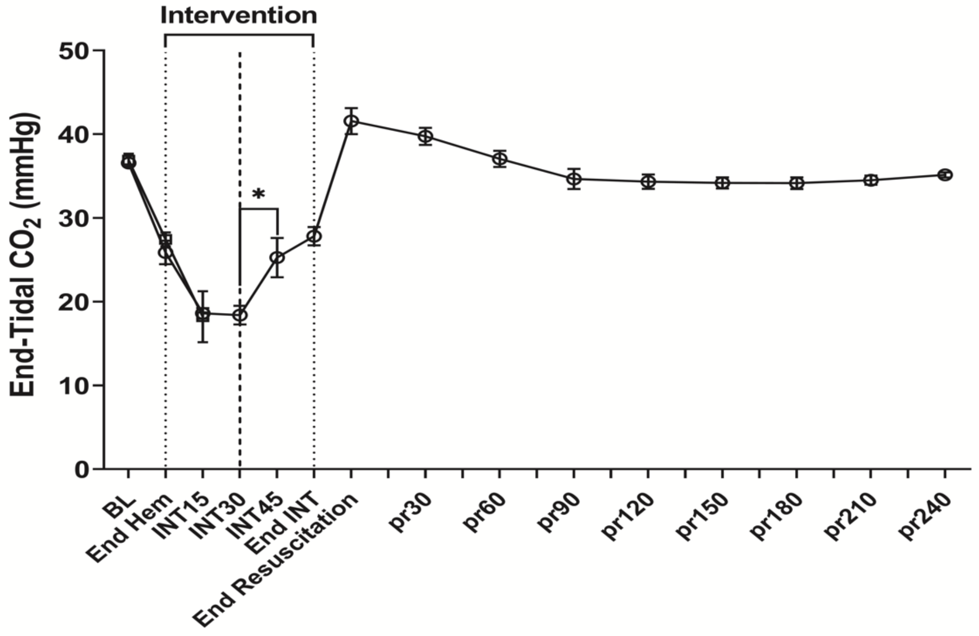


Results: Transition Physiology



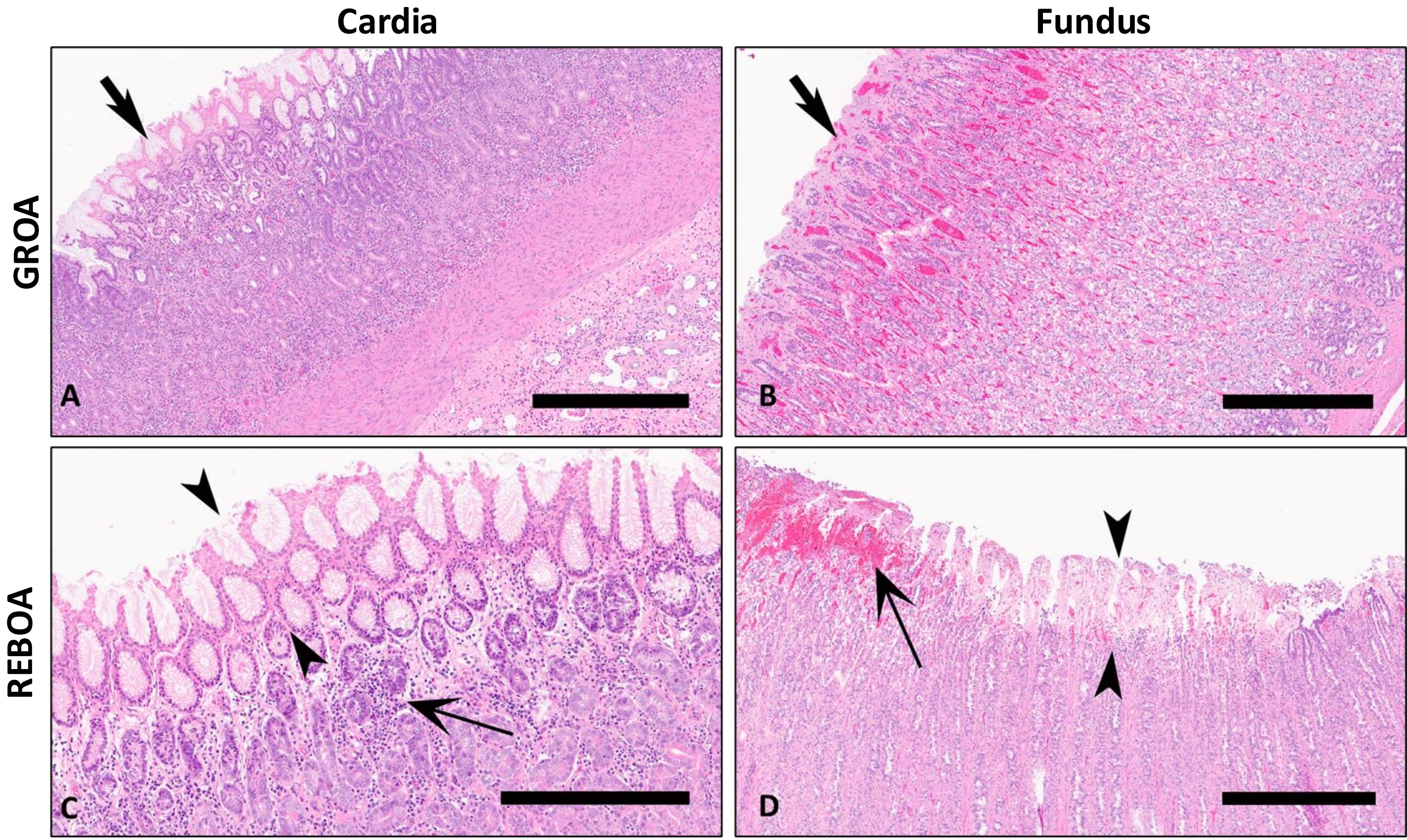






Histopathology

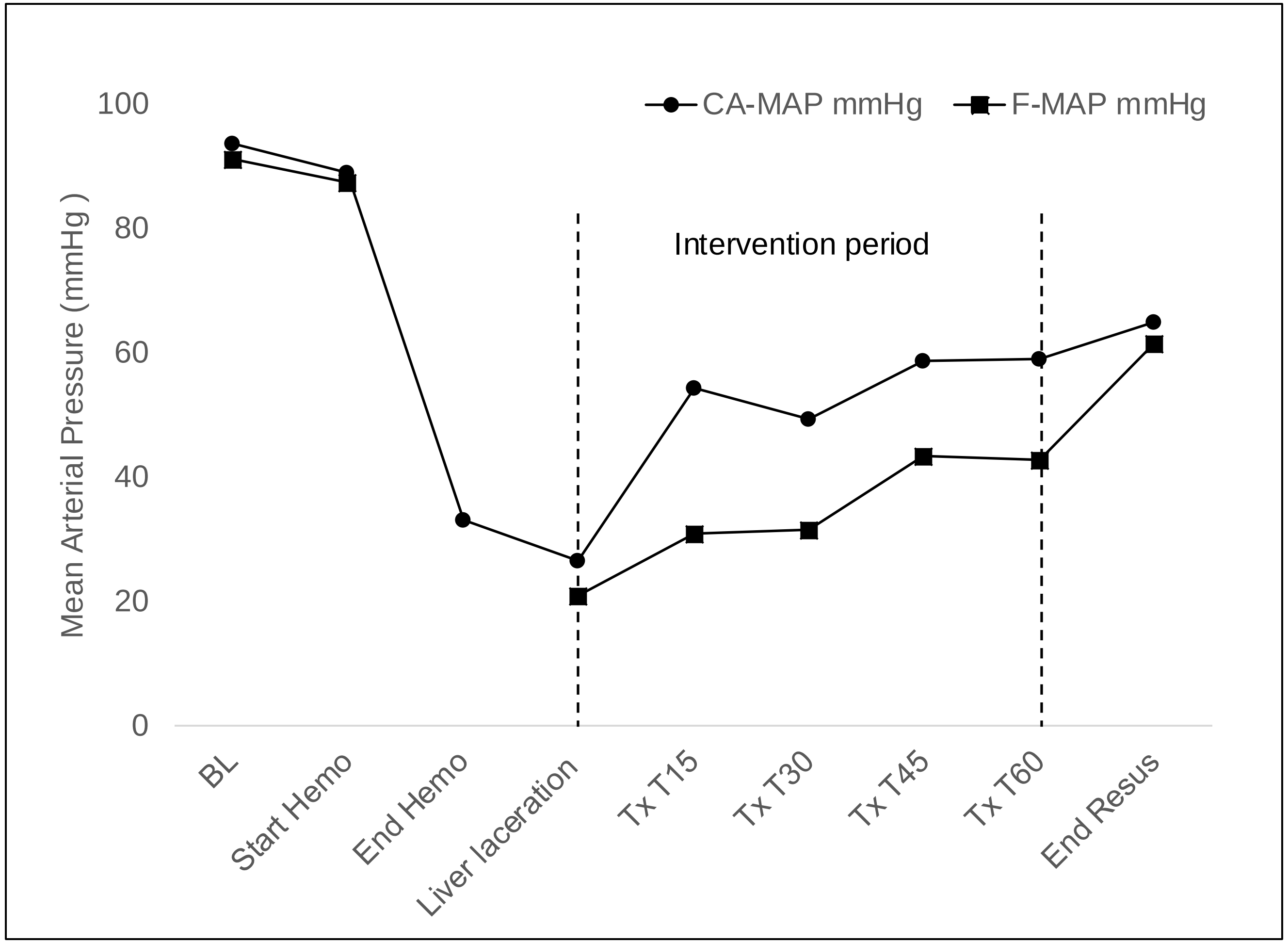
- **No lesions** were noted in the **esophageal mucosa, aorta, celiac trunk** in any animals.
- Evidence of **mild diffuse inflammation** to the **superficial mucosa** was present in **most examined sections** of the stomachs.
- Findings **across all animals** was either **absent or deemed minimal** and consistent with **mild ischemic injury**.
- Some similar findings in animals with REBOA



Representative histological images of the GROA (A & B) and REBOA (C & D) interventional effects on the cardia and fundus. A) GROA: Cardia, bar = 500um, arrow indicates focal superficial mucosal necrosis. B) GROA: Fundus, bar = 600um, arrow indicates superficial mucosal necrosis. C) REBOA: Cardia, bar = 300um, Superficial ischemic change (arrowheads) associated characterized by hypereosinophilia and loss of cellular and nuclear detail, underlain by scattered mixed inflammatory cell infiltrates (arrow). D) REBOA: Fundus, bar = 600um, There is multifocal necrosis of the superficial mucosa (arrowheads) associated with areas of hemorrhage (arrow).

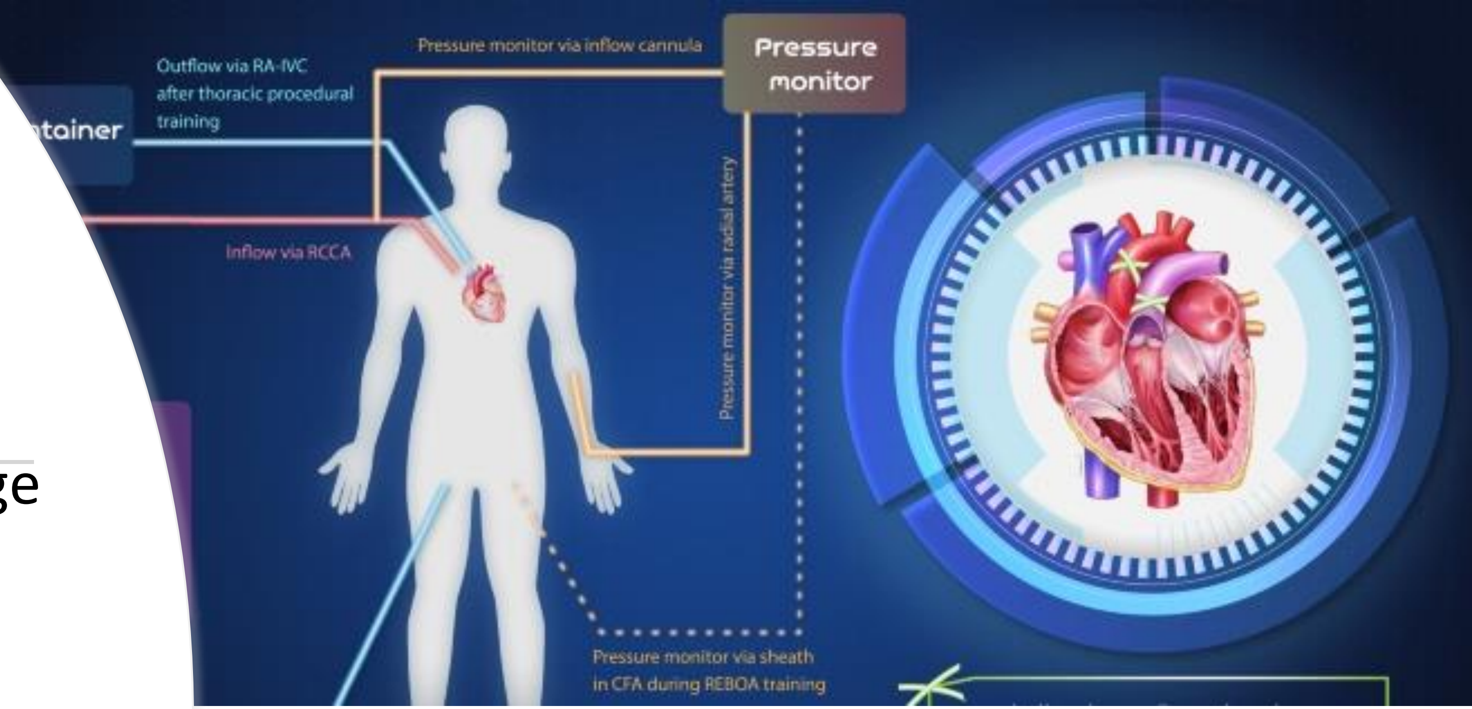
Beginning Partial GROA Studies

- 30% TBV hemorrhage
- Grade V Liver Laceration
- Partial occlusion followed by resuscitation with shed blood
- Attempt above GROA MAP 60 mmHg and below GROA MAP 40-50 mmHg
- Lactate burden appearing to be 33-50% lower.



Next Steps

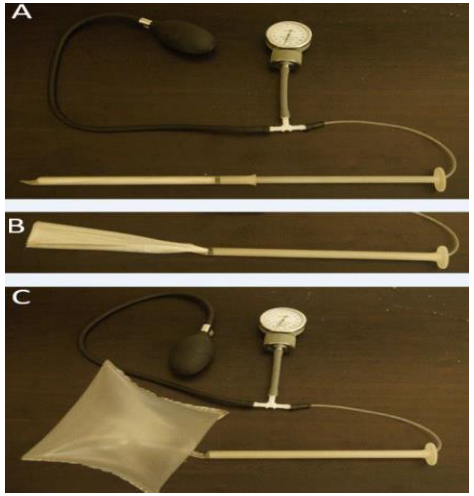
- Refinement of Catheter/Balloon
- 96-hour survival studies of animals undergoing 60 minutes GROA or REBOA to examine end-organ damage
- Perfused cadaver studies in collaboration with Madigan Army Medical Center (including field use)
- Protocols for Airway management and placement without activation
- FDA input
- Studies on partial GROA use
- Better understanding of monitoring options during GROA use to guide full versus partial occlusion

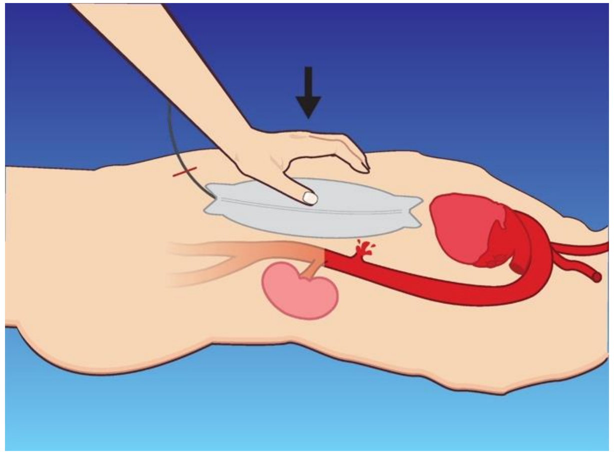


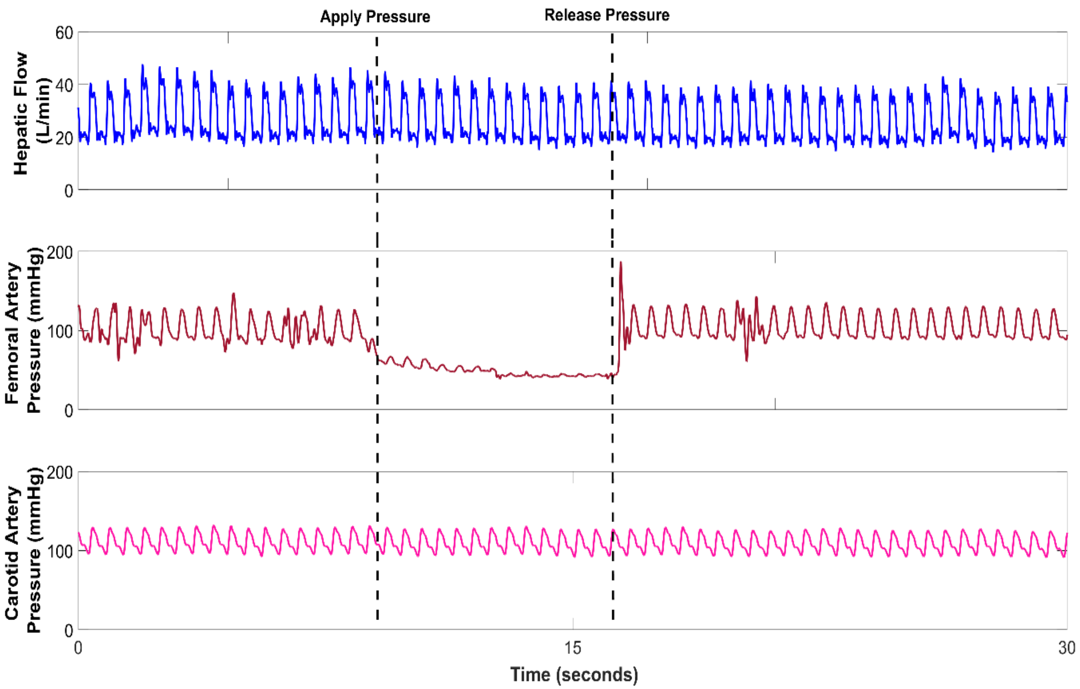
Novel intraperitoneal hemostasis device prolongs survival in a swine model of noncompressible abdominal hemorrhage

J Trauma Acute Care Surg. 2021;90: 838–844.

- Medical grade balloon placed via trocar
  - Balloon 18 x 18 cm square
  - 10 cm anterior-posterior
  - Holds 1650 cc air
- Controls hemorrhage by indirect tamponade
- Balloon pushes nonbleeding tissues into contact with bleeding tissues
- Pressure can be controlled
- Can produce complete aortic occlusion if needed (hand or external pressure titration device)
- Can remove if no surgery needed
- Potential to heat balloon







Liver, Spleen and Kidney Lacerations (injuries at various heights)

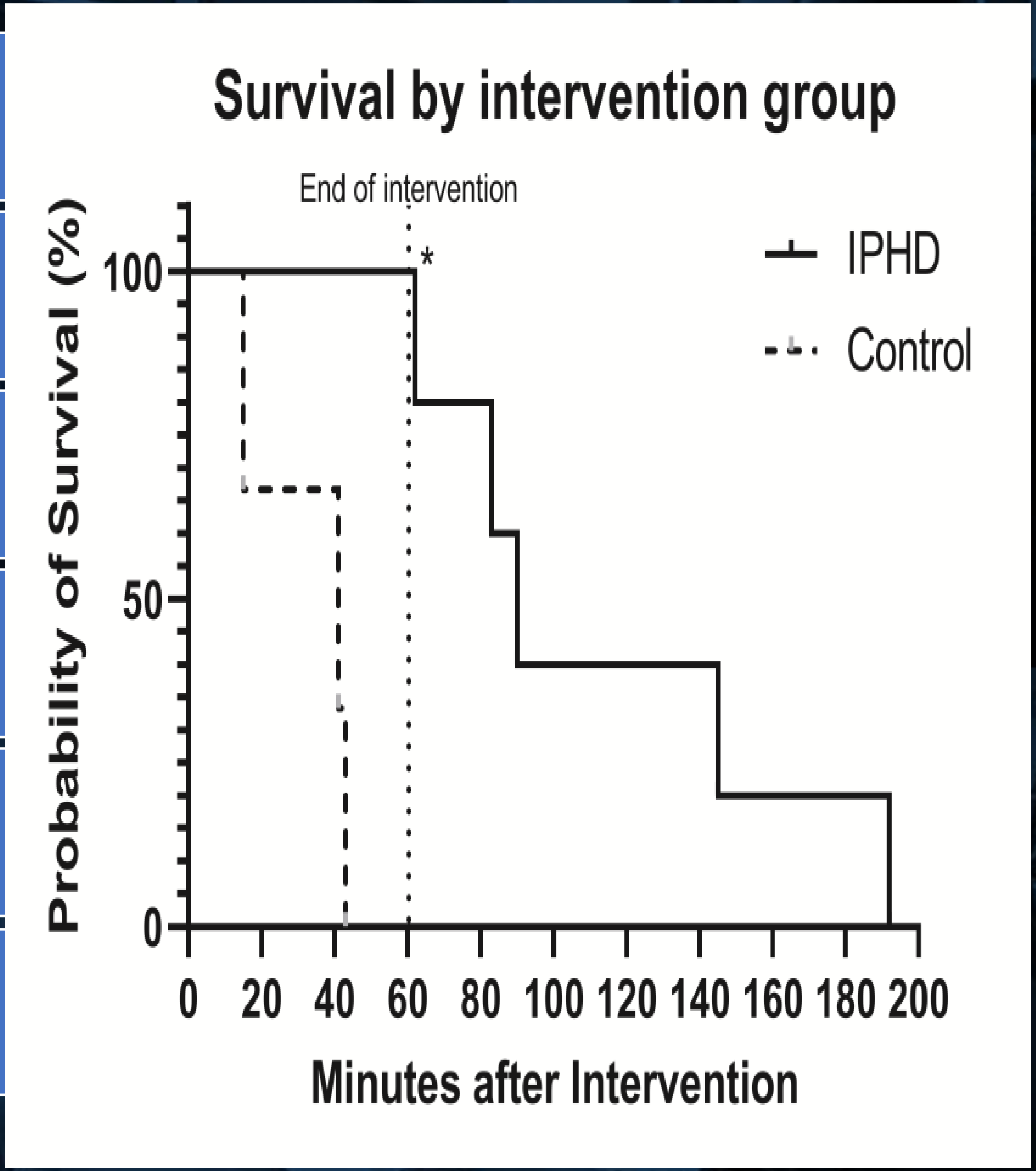
Randomized to receive intraperitoneal balloon or no balloon. Balloon inflated but no external pressure placed

Animals resuscitated with Hetastarch (to produce coagulopathy), whole blood and crystalloid

Balloon removed at 60 minutes

No packing or repair: Animals allowed to rebleed to demonstrate severity of injury

No aortic occlusion required



Summary

- NCHT continues to pose a major challenge for field intervention
- Major gap is providing tools that a well trained first responder (civilian paramedic/SOCM medic) can place quickly at or near point of injury
  - Option to place and use or not use without committing to surgery
- Technology needs to be scalable
- Should have capability to control hepatic and splenic bleeding (Zone 2 and below)
  - Many times we don’t know what’s bleeding.
- Have option to control occlusion pressure to create partial to full occlusion
- Lends itself to easy transition to endovascular control (REBOA)
- Easier means to monitor effects
- Best to use any adjunct with blood