Finding the right balance: Partial resuscitative endovascular balloon occlusion (pREBOA) of the aorta in a swine model of uncontrolled vascular injury

Ho, Jessie W[1], Shafik Dawood, Zaiba[1], Nguyen, Jessica[2], Diaz-Perez, Dariel A[1], Taylor, Meredith E[1], Chtraklin, Kiril[1], Jin, Guang[1], Ukachukwu, Crystal[1], Liu, Baoling[1], Alam, Hasan B[1]

[1]Department of Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL, [2] Department of Pathology, Northwestern University, Feinberg School of Medicine, Chicago, IL

Background

- Non-compressible torso hemorrhage (NCTH) is the leading cause of preventable deaths
- Resuscitative endovascular balloon occlusion of the aorta (REBOA) is a promising strategy for control of NCTH
- pREBOA-PRO provides partial aortic occlusion to mitigate downstream ischemia (Figure 1)
- Thoracic aorta can be occluded for 2-4 hours with pREBOA-PRO in swine models
- The optimal inflation strategy for balance between proximal hemorrhage control and distal ischemia is unknown

Objective

Evaluate the hemostatic efficacy of the pREBOA-PRO in a model of uncontrolled vascular injury

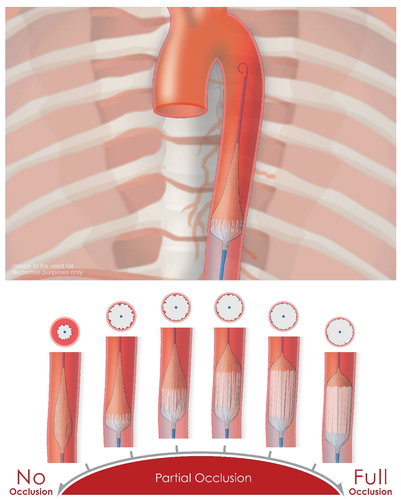

Figure 1. pREBOA-PRO device in various stages of partial aortic occlusion and in the zone 1 aorta. The pREBOA-PRO is a semi-compliant balloon with ridges creating channels along the balloon. With full inflation, the balloon causes a complete occlusion. The variable balloon shape during partial occlusion allows for a gradual change in flow as the balloon is inflated and deflated. Copyright 2023, Prytime Medical Devices, Inc. All Rights Reserved. Reprinted with Permission.[1]

Methods

- Yorkshire swine, 40-45kg (n=5/group)
- Anesthetized and instrumented
- Through-and-through common iliac artery injury (Figure 3)
- Experimental groups:
  1. pREBOA-PRO
  2. Control (no treatment)
- pREBOA inflated at 3 min post-injury
- Inflation target distal mean arterial pressure (MAP): 30mmHg
- No balloon titration after target MAP achieved for 15 minutes
- Rapid normal saline infusion for hypotension
- End organs H&E stained, and reviewed by pathologist
- **End point-** 2 hours survival following balloon deflation
- **Primary Outcome- Post-inflation blood loss**

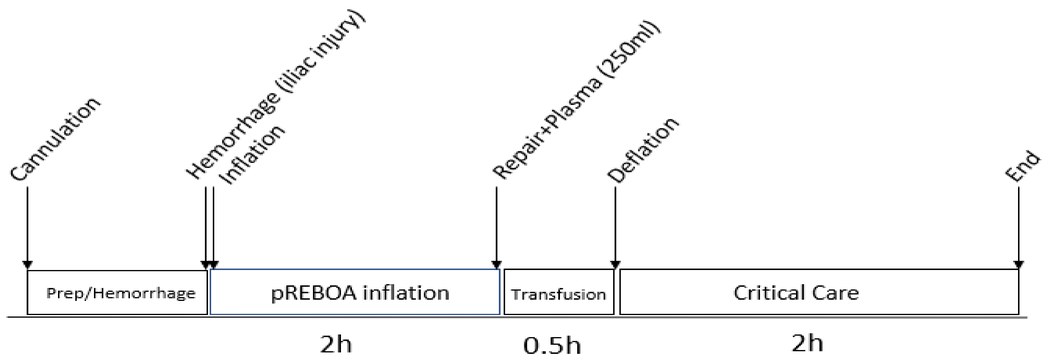

Figure 2. Experimental timeline. The vessels are cannulated. Animals randomized. Common iliac artery injury created. Hemorrhage uncontrolled for 3 min prior to NS resuscitation vs pREBOA inflation. pREBOA inflated for 2 hours. Vessel injury was primarily repaired, 250cc of fresh frozen plasma administered. The balloon was deflated at 0.5cc every 2 minutes given potential for reperfusion injury. 2L of normal saline was administered for resuscitation and norepinephrine for mean arterial pressure <55mmHg during 2 hour critical care time. At the endpoint, animals were euthanized. NS-normal saline, h-hour, ml-milliliters

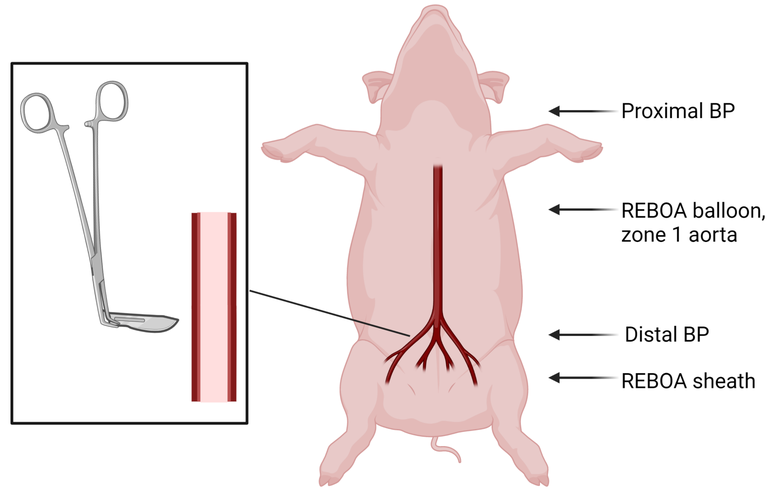

Figure 3. Experimental set up and iliac injury. Proximal blood pressure (BP) was monitored at left common carotid. The 7F REBOA sheath was placed in left femoral artery, 5F arterial sheath placed in left external iliac artery. Lateral through-and-through right common iliac artery injury was made using a 15 blade.

Results

- All pREBOA animals survived to the endpoint
- Control animals had a mean survival time of 35 minutes ($p<0.05$)
- No significant differences in pre-balloon blood loss (813.2±252.4 vs 730±192.7)
- pREBOA group had significantly less post balloon inflation blood loss (93.8±115.3 vs 1980±368.5ml, **Figure 4**). 40% required brief vasopressor support following reperfusion
- Lactate clearance was appropriate (mean peak lactate 6.8, end lactate 4.2mmol/L)
- Pathologic scores had mild to moderate ischemia for kidney, liver, small bowel, and hindlimb

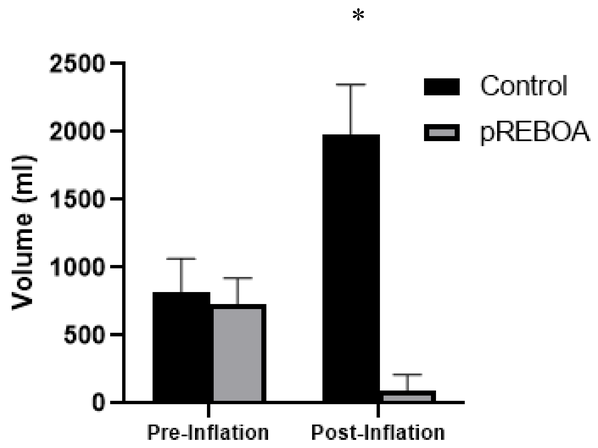

Figure 4. Pre- and post-balloon blood loss *p<0.05, data presented as group mean±standard deviation

Conclusions

Partial aortic occlusion with the pREBOA-PRO can achieve the desired balance between effective hemorrhage control and adequate distal flow, without a need for balloon titration.

Reference

Ho JW, Jin G, Nguyen J, Keeney-Bonthrone TP, Diaz-Perez DA, Dawood ZS, Kemp MT, Alam JS, Gauger MA, Shaikh A, Chtraklin K, Liu B, Alam HB. Prolonging the zone 1 aortic occlusion time to 4 hours using a partial resuscitative endovascular balloon in a swine model. J Trauma Acute Care Surg. 2023 May 15. doi: 10.1097/TA.0000000000004053. Epub ahead of print. PMID: 37184494.

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