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A Study of Partial REBOA Use on the Battlefield: Enabling Transport of Combat Casualties with NCTH

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Disclaimer & Acknowledgement

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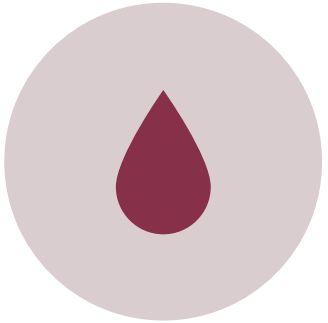
- The views and conclusions contained herein are those of the author(s) and should not be interpreted as representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

Situational Control for Combat Wounded in Ukraine

Drone-saturated airspace in Ukraine creates extreme evacuation delays for wounded soldiers



Non-compressible torso hemorrhage (NCTH) is a leading cause of preventable combat death

pREBOA-PRO facilitates partial aortic occlusion via femoral access to control hemorrhage

Effective deployment requires earlier, far-forward placement. This study addresses that gap

Russo RM et al. Scoping review and recommendation to establish standardized best practices for resuscitative endovascular balloon occlusion of the aorta in combat casualties: A North Atlantic Treaty Organization exploratory team report. J Trauma Acute Care Surg. 2025 Aug 1;99(3S Suppl 1):S164-S169.

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pREBOA-PRO™ Catheter Enables FDA-Defined Partial Aortic Occlusion

Safe partial aortic occlusion for 2 hours in zone 1

Above and below blood pressure monitoring capability

4X increase in permitted occlusion time compared with traditional occlusion catheters

Formal regulatory definition of partial aortic occlusion:

Proximal (above-balloon) SBP > 90–110 mmHg

Distal (below-balloon) SBP > 20 mmHg

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Scientific Overview/Purpose

The goal of this study is to examine how the pREBOA-PRO catheter provides initial situational control and transport options via 2+ hours of safe aortic occlusion, in real NCTH battlefield conditions. Old REBOA stops bleeding but can only be safely used for 30 minutes.

The purpose of this study is to collect observational clinical data from **combat wounded** treated with pREBOA-PRO to **stabilize** patients long enough for transport and **enable** survival in prolonged field care scenarios.

These findings will help shape military clinical guidelines for future **Large-Scale Combat Operations** where surgical care may be delayed.

Main Methodology

- Design: Observational, post market, non-interventional study (device already FDA and CE approved)
- Population: 100 Ukrainian injured military members, age 18+, treated for NCTH with the pREBOA-PRO device

Data Collection:

- Clinicians complete structured case report forms (injury, details, vitals, interventions)
- Virtual debriefs with treating clinicians
- Medical record review for outcomes up to 5 days

Study Timeline

100 pREBOA-PRO devices and kits shipped to Ukraine Oct 2024

Protocol approved by OHRO & Ukraine LEC 3/18/25

Virtual SIVs for sites completed 3/21/25

First subject enrolled 5/24/25

First case debrief 5/29/25

UAT testing began with Clinvigilant 7/29/25

Latest subject enrolled 7/3/26

Latest case debrief 6/11/26

Survivability Concentrated in Patients with Best Presenting Physiology, while Complications Were Notably Absent

A high-acuity REBOA cohort with early deaths driven by pre-intervention instability.

Cohort	Penetrating trauma	Overall mortality	Day 1 mortality
17 patients	94.1%	58.8% (10/17)	41.2% (7/17)

Key mortality pattern

- CPR before REBOA carried **72.7%** overall mortality.
- Shock physiology carried **66.7%** overall mortality.
- Low GCS 8 or less carried **83.3%** overall mortality.

Earlier use of pREBOA-PRO May Improve Survival

- Earlier use of pREBOA-PRO may improve survival before severe physiologic collapse.
- Titratable partial occlusion provides rapid control and supports earlier device use.
- Longest occlusion time: 6.5 hours.

Prolonged Occlusion Demonstrated a Favorable Safety Profile

Despite prolonged occlusion, no device-related or post-procedural complications were observed in this challenging subgroup

5 cases | **Day 1 mortality 0.0%** | **Overall mortality 20.0%** | **Max Total AO 390 min**

Patient	Total AO	CPR	SBP	GCS	Outcome
1	390 min	0	50	9	Died
2	200 min	1	-	6	Survived
3	80 min	0	60	-	Survived
4	80 min	0	60	11	Survived
5	62 min	0	65	15	Survived

Extremely Long Partial AO with pREBOA-PRO is Safe

- No device-related amputation, distal embolism or vascular access difficulty was documented.
- No AKI, MOF, or sepsis was documented in the cohort.
- The only death was the 390-minute case and was due to multi-organ failure, not hemorrhagic shock.

Lessons Learned: Attempted Solutions and Unmet Needs

Lessons Learned

- Structured pre-deployment pREBOA-PRO training is necessary, but not sufficient
- True learning occurs immediately after first use, highlighting the need for near-real-time, peer based, same-language performance feedback
- Difficulty with CFA access
- Earlier intervention with PRO will be facilitated by a safe, field-expedient, non-powered femoral access device

Attempting Various Solutions

- Just-in-Time Training: Use the new ARTI PRO immediately before a case to provide realistic, scenario-based simulation that prepares the user for battlefield conditions and reinforces critical skills when they are most relevant
- Move device closer to point of injury
- Leverage super user Peer-to-Peer Teaching

Needs

- More pREBOA-PRO devices in country
- Funding for access device to allow pREBOA-PRO placement at point of injury
- Funding to provide ARTI PRO mannequins to sites
- No cost extension to continue data collection

Far-Forward Next Generation PRO During Modern War

The pREBOA-PRO catheter closes the evacuation gap delivering early, safe hemorrhage control at the point of injury to increase survival to definitive care.

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