Activating the Neural Tourniquet: Vagus Nerve Stimulation Reduces Blood Loss in a Swine Model of Non-Compressible Trauma

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Disclaimer

- The views expressed in this presentation reflect the results of research conducted by the author and do not necessarily reflect the official policy or position of the Defense Health Agency, Department of War, nor the U.S. Government.
- The experiments reported herein were conducted in compliance with the Animal Welfare Act and per the principles set forth in the "Guide for the Care and Use of Laboratory Animals, Eighth Edition", The National Academies Press, 2011.
- Neither the Defense Health Agency, any other component of the Department of War nor the U.S. government has approved, endorsed or authorized this product. No Federal endorsement of Spark Biomedical or any manufacturer is intended.
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Introduction

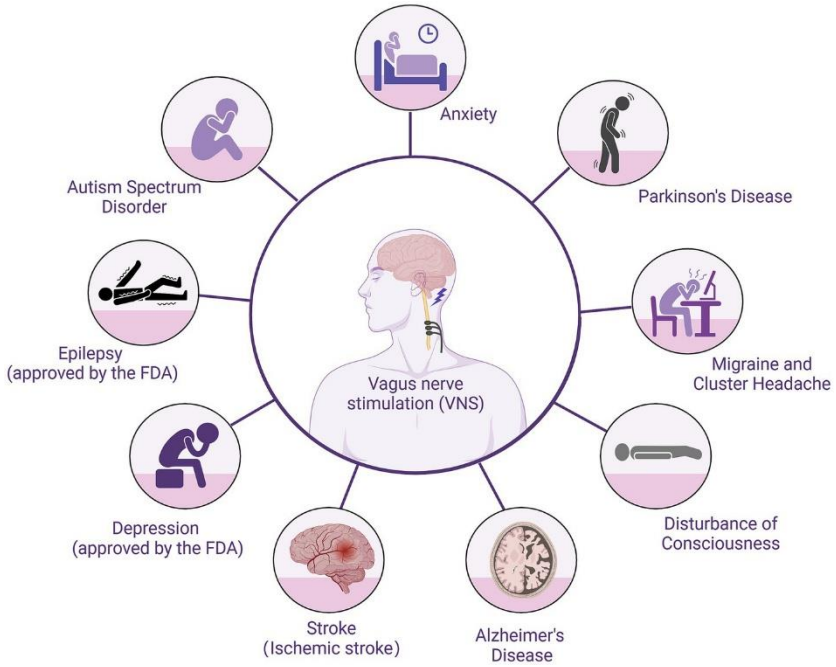
- Uncontrolled hemorrhage remains a leading cause of battlefield mortality
- Existing hemorrhage control products have limitations
  - Wound dressings
  - Tourniquets
  - Fluid resuscitation
  - Blood products
- There is a critical need for a hemorrhage control product without significant logistical constraints that is universally compatible, can be used in prolonged care situations with minimal medical training, and can be used alone or in support of additional products

- Military Medical Industry Day 2021/22

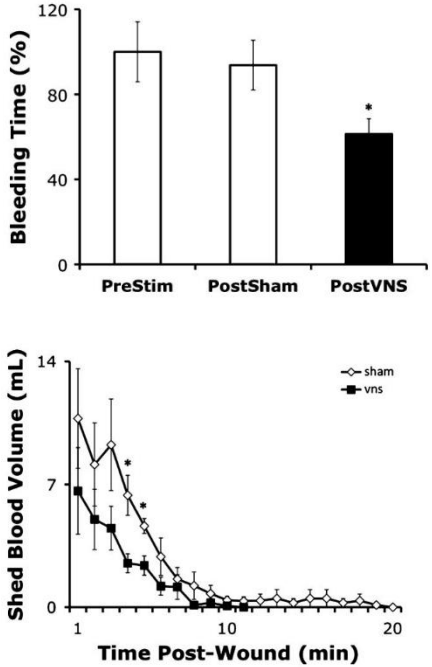
Vagus Nerve Stimulation

- The vagus nerve is a primary component of the parasympathetic nervous system
- “Rest and digest” to counteract the “fight or flight” of the sympathetic system
- Involved in regulating digestion, heart rate and blood pressure, breathing and respiration, inflammatory response, sensory function, mood and mental health

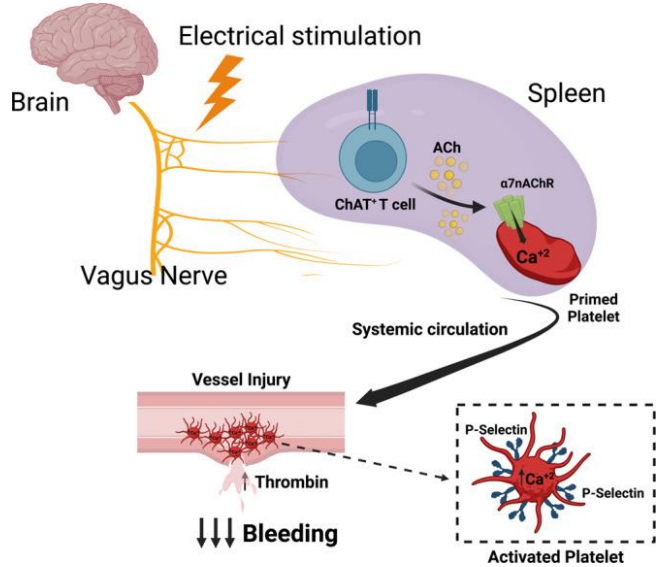
- Electrical stimulation of the vagus nerve is widely studied, with several FDA-approved uses



“Neural Tourniquet” Mechanism



Czura, et al. *Shock*, 2010.



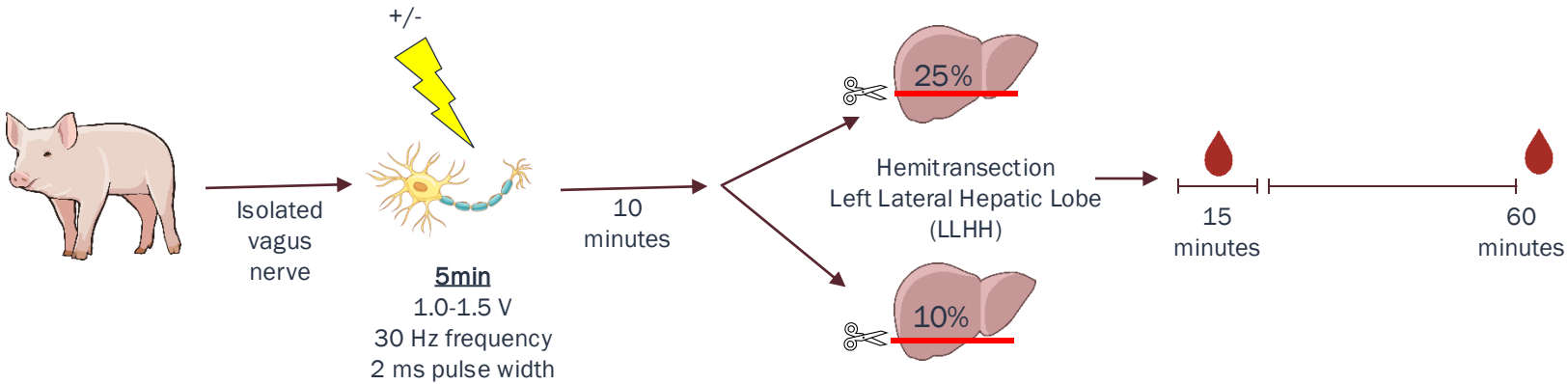
Bravo-Iniguez, et al. *Nat Commun*, 2023

Research Questions

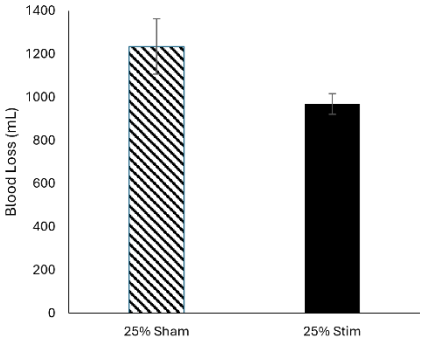
- Can the hemostatic effect of electrical stimulation of the vagus nerve be scaled to a military-relevant level?
- Can we demonstrate activation of the splenic nerve resulting from non-invasive stimulation of the vagus nerve through the auricular branch in the ear?
- Is this non-invasive stimulation sufficient to replicate the effect of direct stimulation?

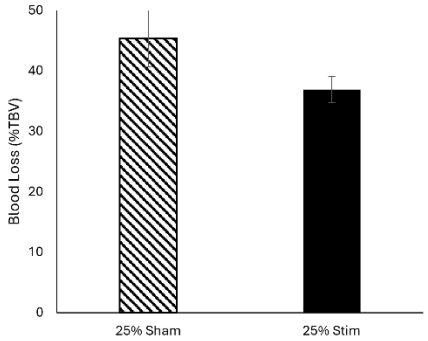
Aim 1, Experimental Design

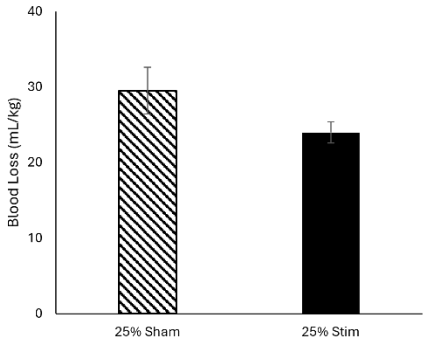
- Can the hemostatic effect of electrical stimulation of the vagus nerve be scaled to a military-relevant level?

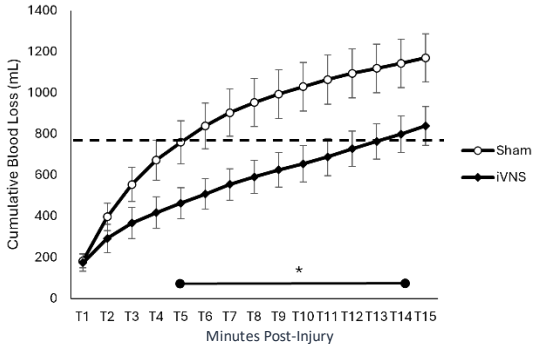


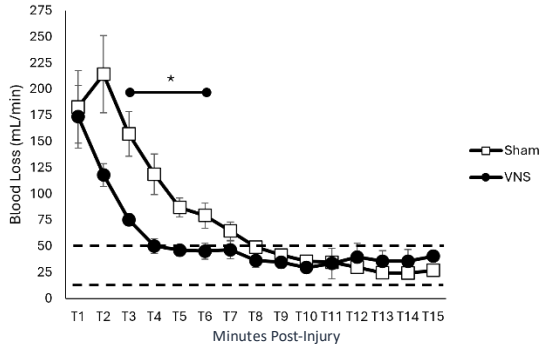
Effects of VNS on blood loss following 25% LLHH











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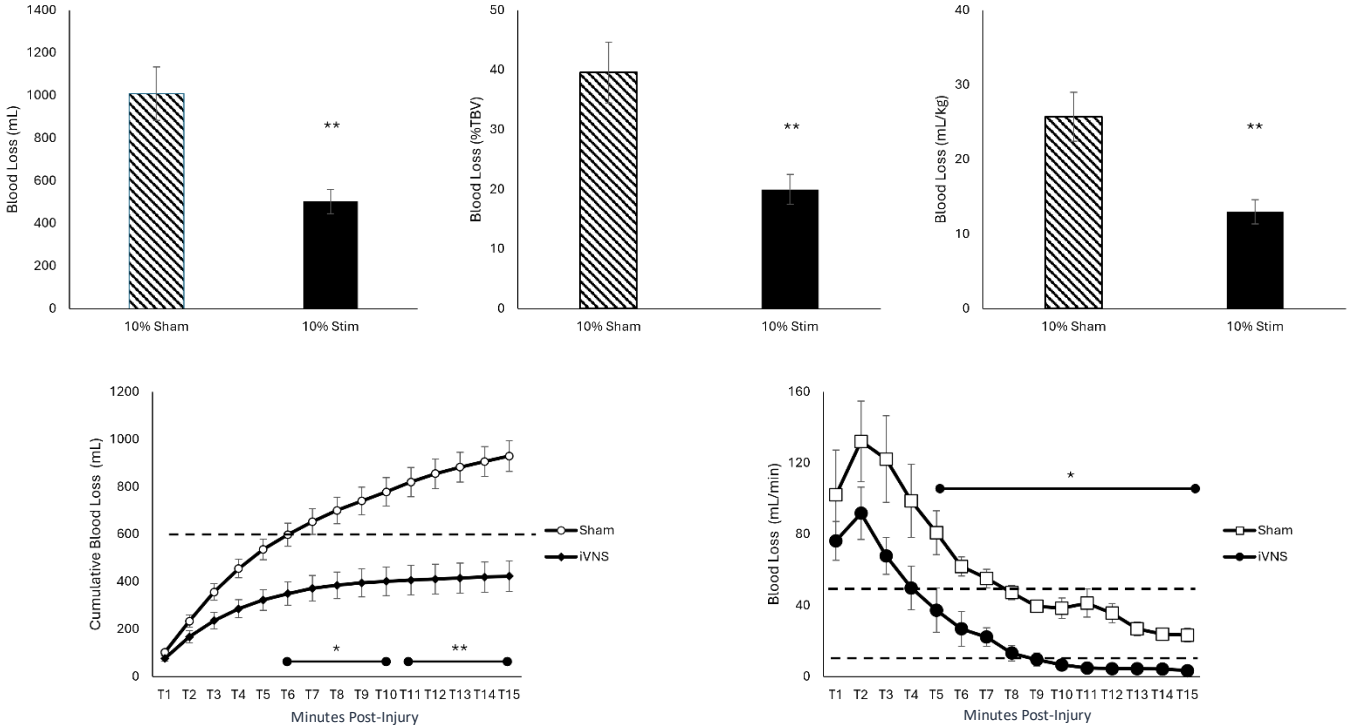
Effects of VNS on blood loss following 10% LLHH



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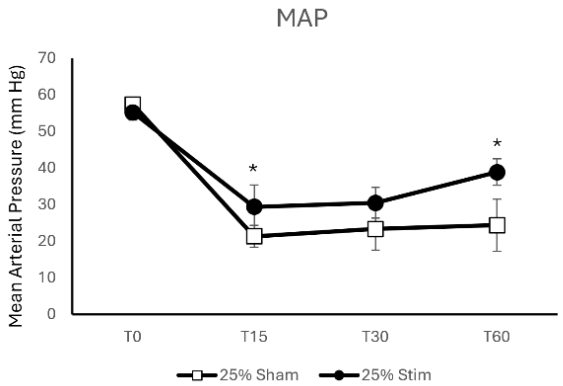
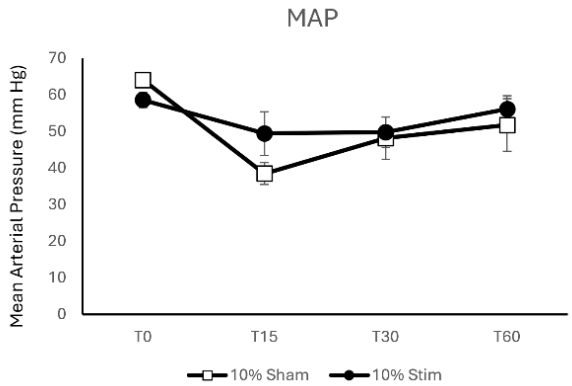
Effects of VNS on Arterial Pressure Following LLHH





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Research Questions

- **Can the hemostatic effect of electrical stimulation of the vagus nerve be scaled to a military-relevant level?**
  - Yes
  - Modest reduction following 25% LLHH with notable improvements in hemorrhage rate.
  - Significant reductions in blood loss and improved hemorrhage rates following 10% LLHH
  - 10% LLHH chosen for further Aims

  - Bonus: VNS stimulation may prevent/delay onset of shock

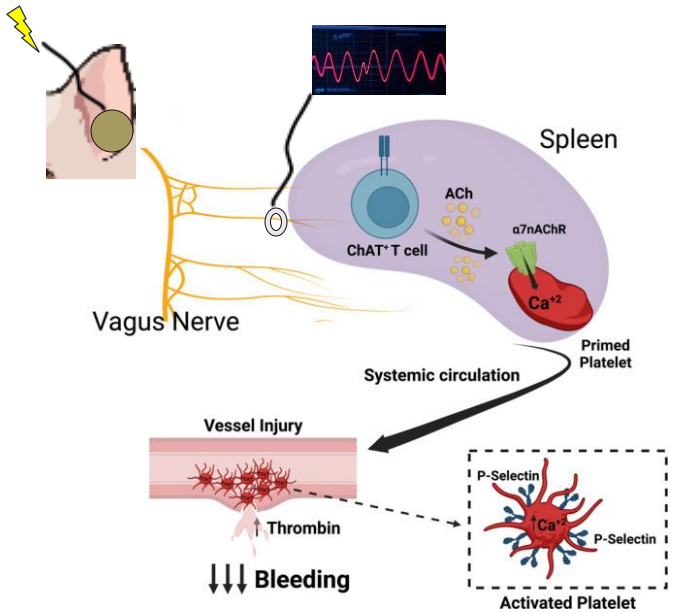
Research Questions

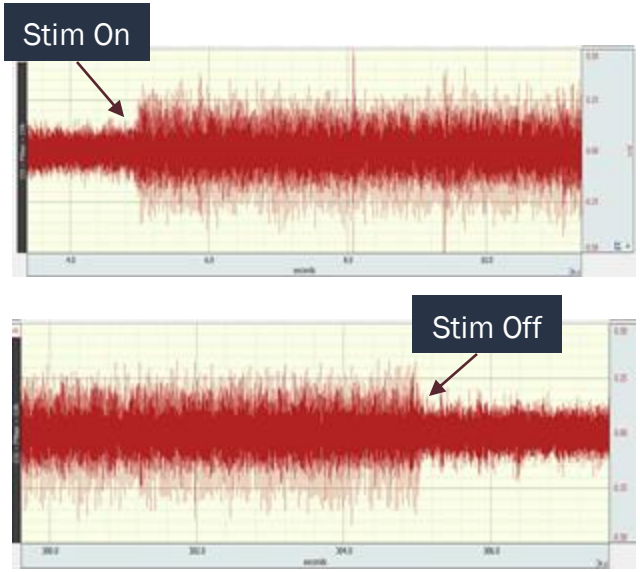
- Can the hemostatic effect of electrical stimulation of the vagus nerve be scaled to a military-relevant level?

- Can we demonstrate activation of the splenic nerve resulting from non-invasive stimulation of the vagus nerve through the auricular branch in the ear?

- Is this non-invasive stimulation sufficient to replicate the effect of direct stimulation?

Indirect Electrical Stimulation of the Splenic Nerve





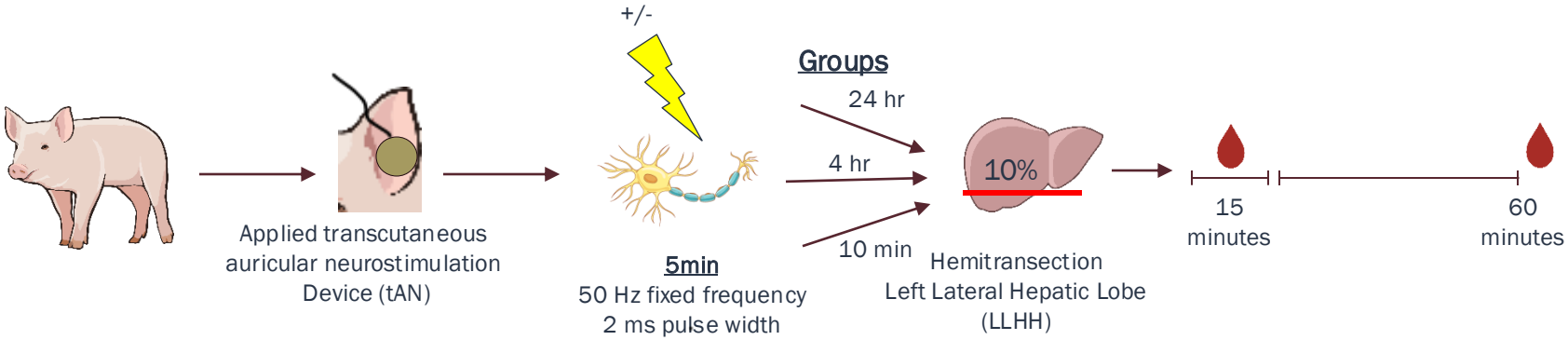
- Can we demonstrate activation of the splenic nerve resulting from non-invasive stimulation of the vagus nerve through the auricular branch in the ear?
  - Yes

Research Questions

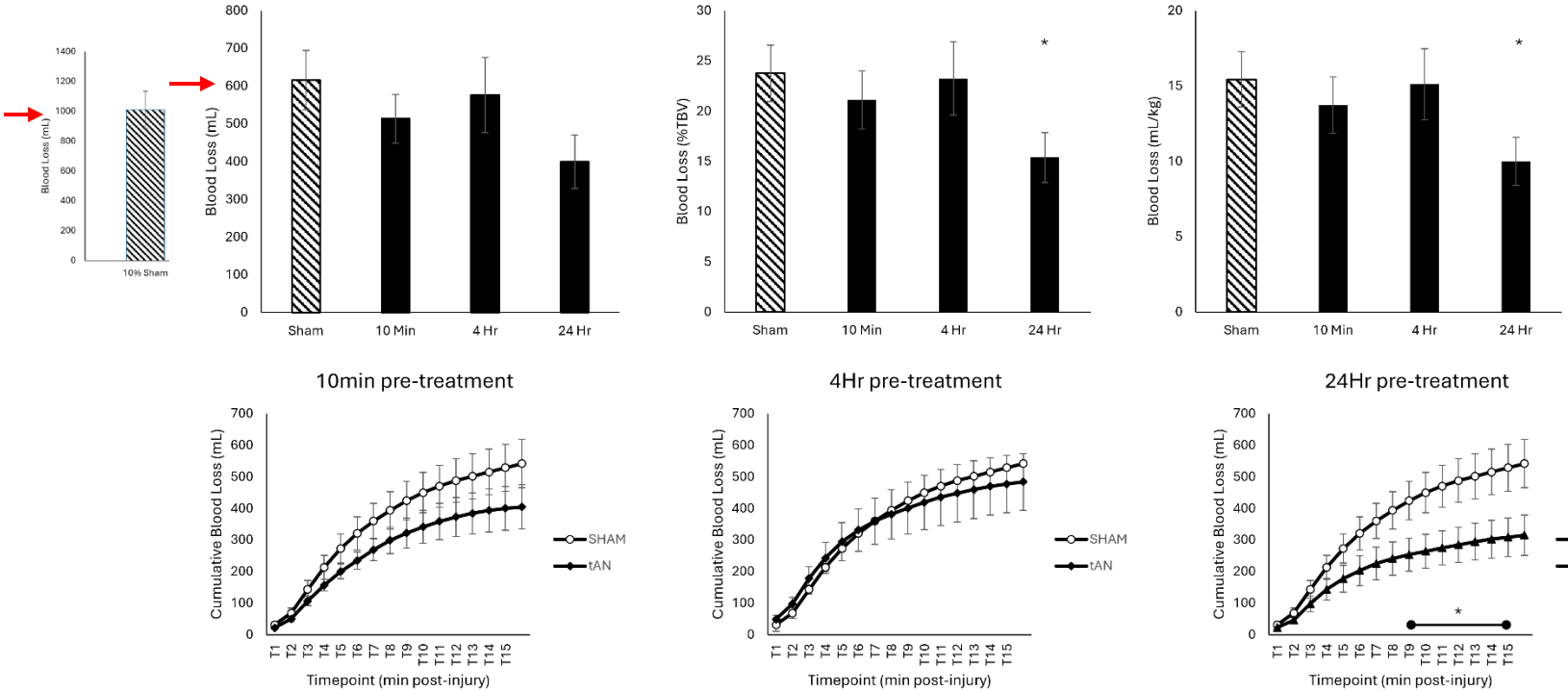
- Can the hemostatic effect of electrical stimulation of the vagus nerve be scaled to a military-relevant level?
- Can we demonstrate activation of the splenic nerve resulting from non-invasive stimulation of the vagus nerve through the auricular branch in the ear?
- Is this non-invasive stimulation sufficient to replicate the effect of direct stimulation?

Aim 2, Experimental Design

- Is this non-invasive stimulation sufficient to replicate the effect of direct stimulation?

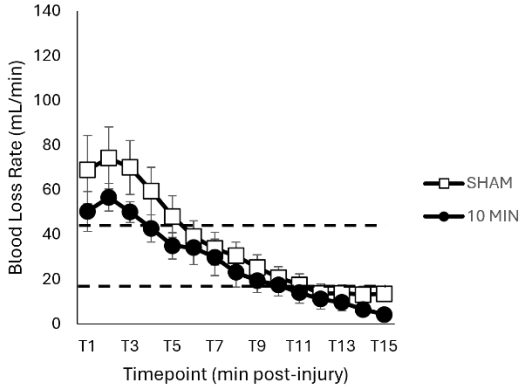


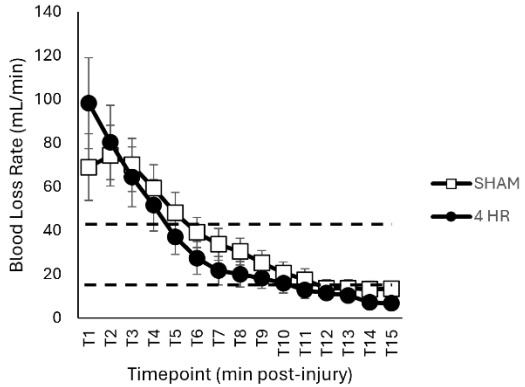
Effects of tAN on blood loss following 10% LLHH

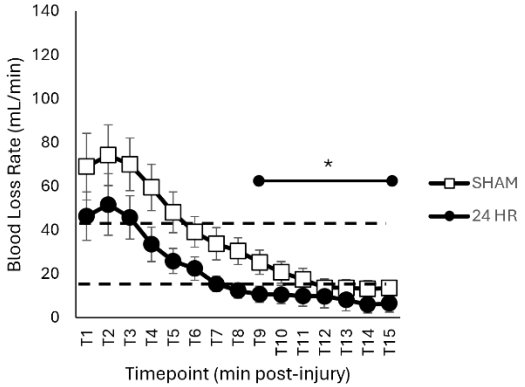


* p<0.05

Effects of tAN on blood loss rate following 10% LLHH







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Research Questions

- Is this non-invasive stimulation sufficient to replicate the effect of direct stimulation?
  - Prophylactic treatment with tAN device trends towards decreased blood loss and improved hemorrhage rates, with 24 hr pre-treatment displaying the most promising performance
  - These findings demonstrate the need to study additional parameters:
    - Stimulation time
    - Stimulation intensity
    - Stimulation post-injury
    - Stimulation further pre-injury

Conclusions

- Stimulation of the vagus nerve in swine activates the “neural tourniquet” mechanism
- Blood loss in our model is reduced by clinically relevant margins
- Indirect stimulation through tAN is capable of triggering the splenic nerve
- Indirect stimulation can provide a measurable impact on blood loss and hemorrhage rate even 24 hours post-stimulation
  - We are encouraged to conduct further investigation to fine tune the stimulation parameters and timing

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