Novel Analgesic SBS-1000 Does Not Alter Survival or Cardiorespiratory Responses after Traumatic Moderate Hemorrhage in Rats

Carmen Hinojosa-Laborde, PhD, Science Lead
carmen.hinojosa-laborde.civ@health.mil
Miryam M. Pando, PhD, Research Scientist
Miryam.m.pando.ctr@health.mil
US Army Institute of Surgical Research (USAISR)

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Disclaimer

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Non-Disclosure

- Carmen Hinojosa-Laborde, PhD, has no conflicts to report.
- Miryam M. Pando, PhD, has no conflicts to report.

Animal Statement

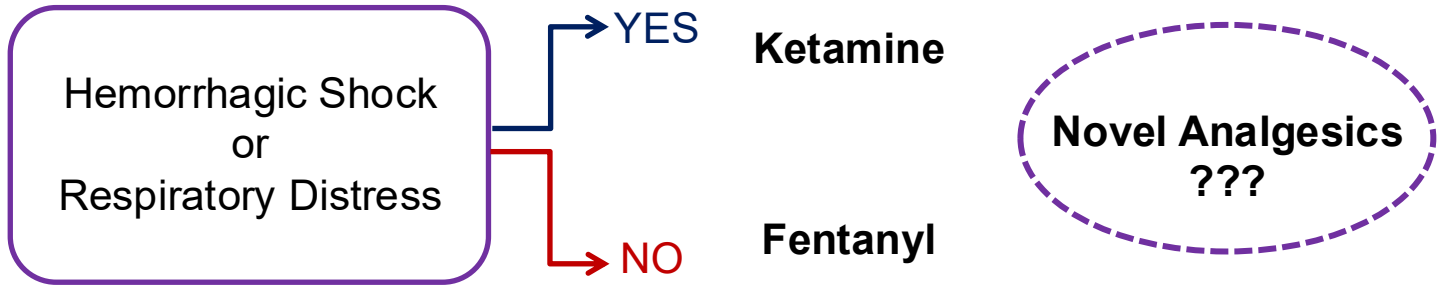
Research was conducted in compliance with the Animal Welfare Act, the implementing Animal Welfare regulations, and the principles of the Guide for the Care and Use of Laboratory Animals. The Institutional Animal Care and Use Committee approved all research conducted in this study. The facility where this research was conducted is fully accredited by the AAALAC International.

All rats were deeply anesthetized and monitored prior to and during the extremity trauma injury.

This presentation has received all required approvals for presenting.

Challenges of Battlefield Pain Management

Current Tactical Combat Casualty Care (TCCC) Guidelines



Knowledge Gap

- Military guidelines for analgesia are based on critical information from clinical outcome studies and provider recommendations
- Only a few laboratory studies have assessed the impact of analgesics on the ability to tolerate and survive hemorrhage
- Effects of analgesic techniques on pathophysiological processes are unknown

Ideal Characteristics for a Battlefield Analgesic

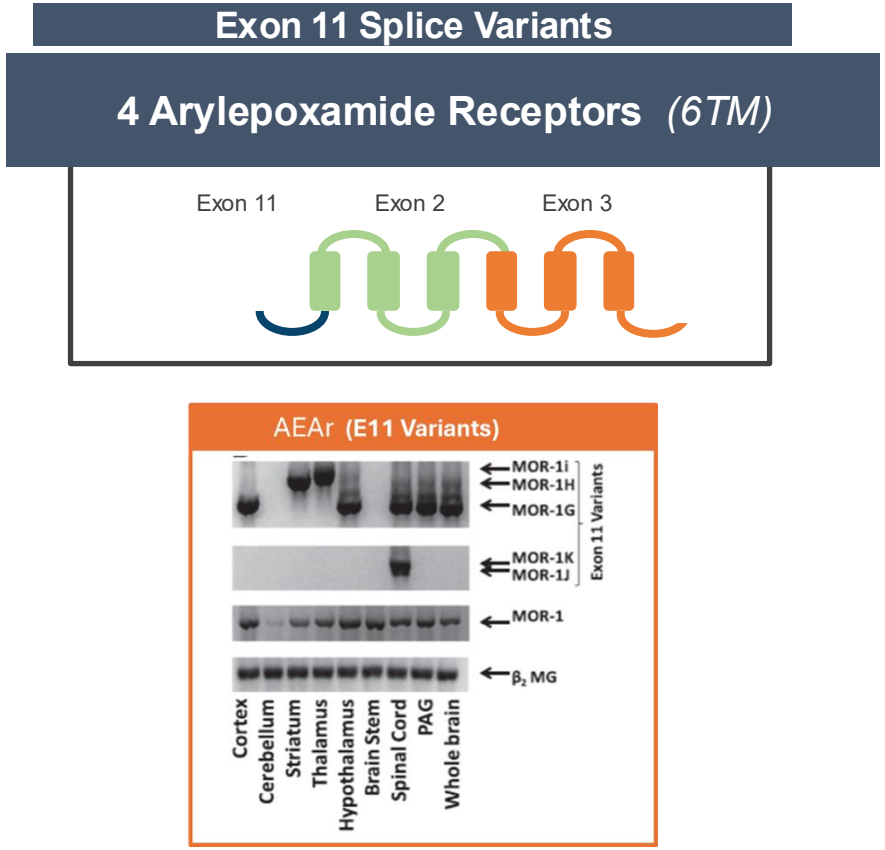
- Effective pain relief
- Maintain cognitive capacity
- Keep fighting capability

- Immobility
- Sedation, loss of consciousness
- Addiction, rewarding properties
- Deleterious effects on compensatory mechanisms after hemorrhage
- Suppressed respiratory rate
- Additional toxicities (e.g., liver, kidney damage)

Arylepoxamide Receptor (AEAr) and SBS-1000

- AEAr is a splice variant of the Opioid Receptor Mu 1 (OPRM1) gene
  - Truncated 6 transmembrane receptor (6TM)
  - Reduced coupling to certain G proteins
  - Potentially different downstream effects
  - Lower side-effect profile, possibly due to lack of expression in the brainstem

- SBS-1000 is a novel AEAr agonist
  - Developed by Sparian Biosciences
  - Analgesic effects in:
    - Burn Pain Model
    - Extremity Trauma (ET) Model



» Sources: Sparian Biosciences, LLC

» Pasternak. Pharmacol Rev. 2013 Oct; 65(4): 1257–1317, October 2013. TM: Transmembrane. EX: Exon.

» Pasternak. Pharmacol Rev. 2013 Oct; 65(4): 1257–1317; 2004. Abbadie et al. IMMUNOHISTOCHEMICAL STUDY OF THE EXPRESSION OF EXON11-CONTAINING OPIOID RECEPTOR VARIANTS IN MOUSE BRAIN.

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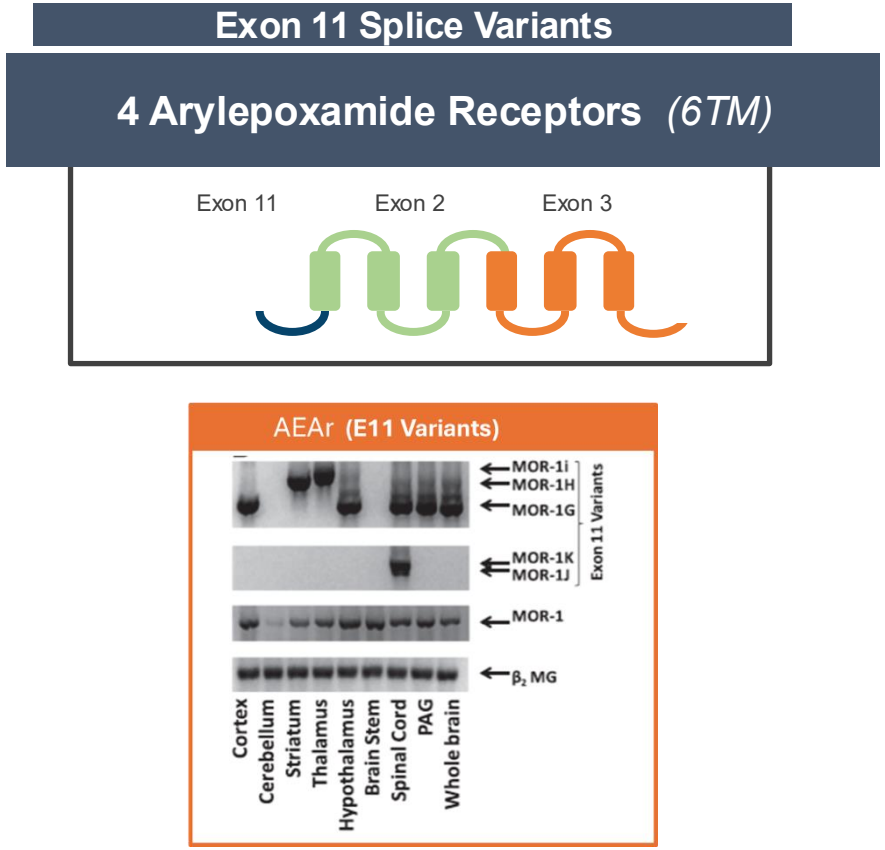

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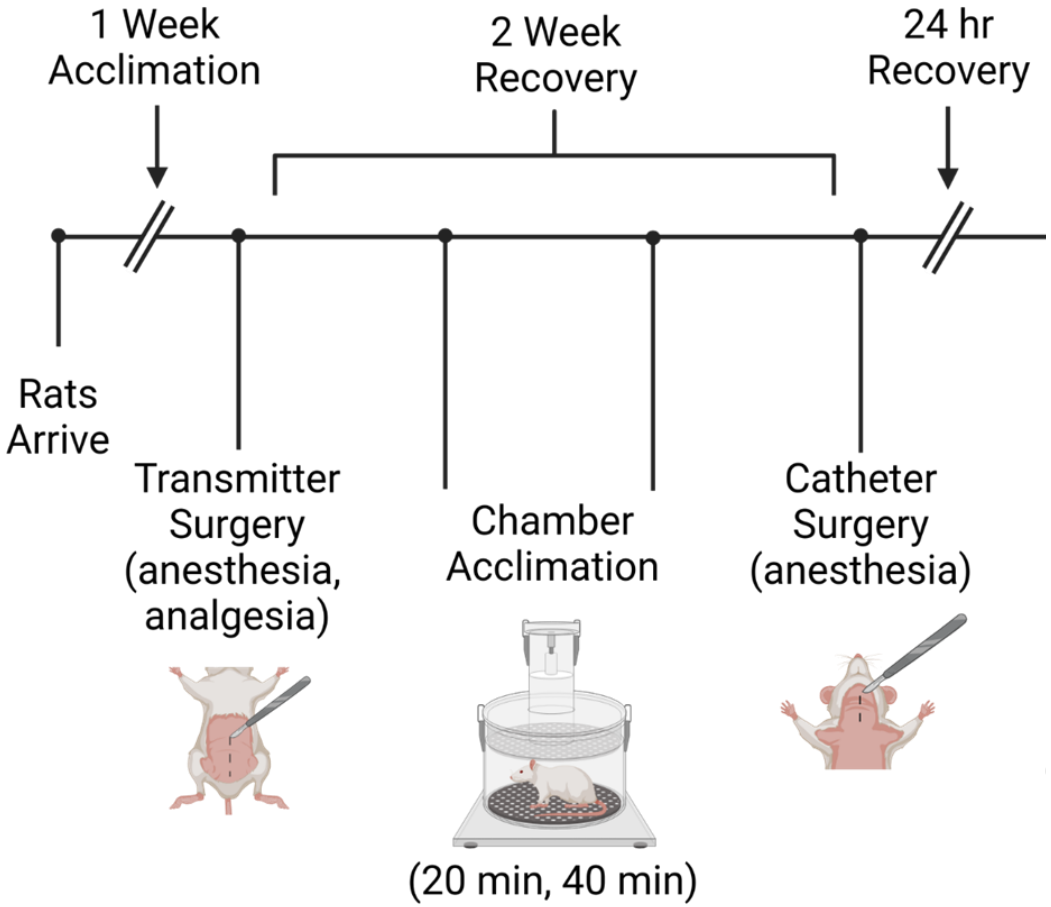
Objective and Hypothesis

The objective of this study was to test effects of an analgesic dose of SBS-1000 on cardiorespiratory responses and survival in an animal model of battlefield extremity trauma (ET) and hemorrhage (HEM).

We hypothesized that, when given after ET and HEM, SBS-1000 will suppress cardiorespiratory responses to HEM by 30% or more and thereby decrease survival.

Experimental Timeline



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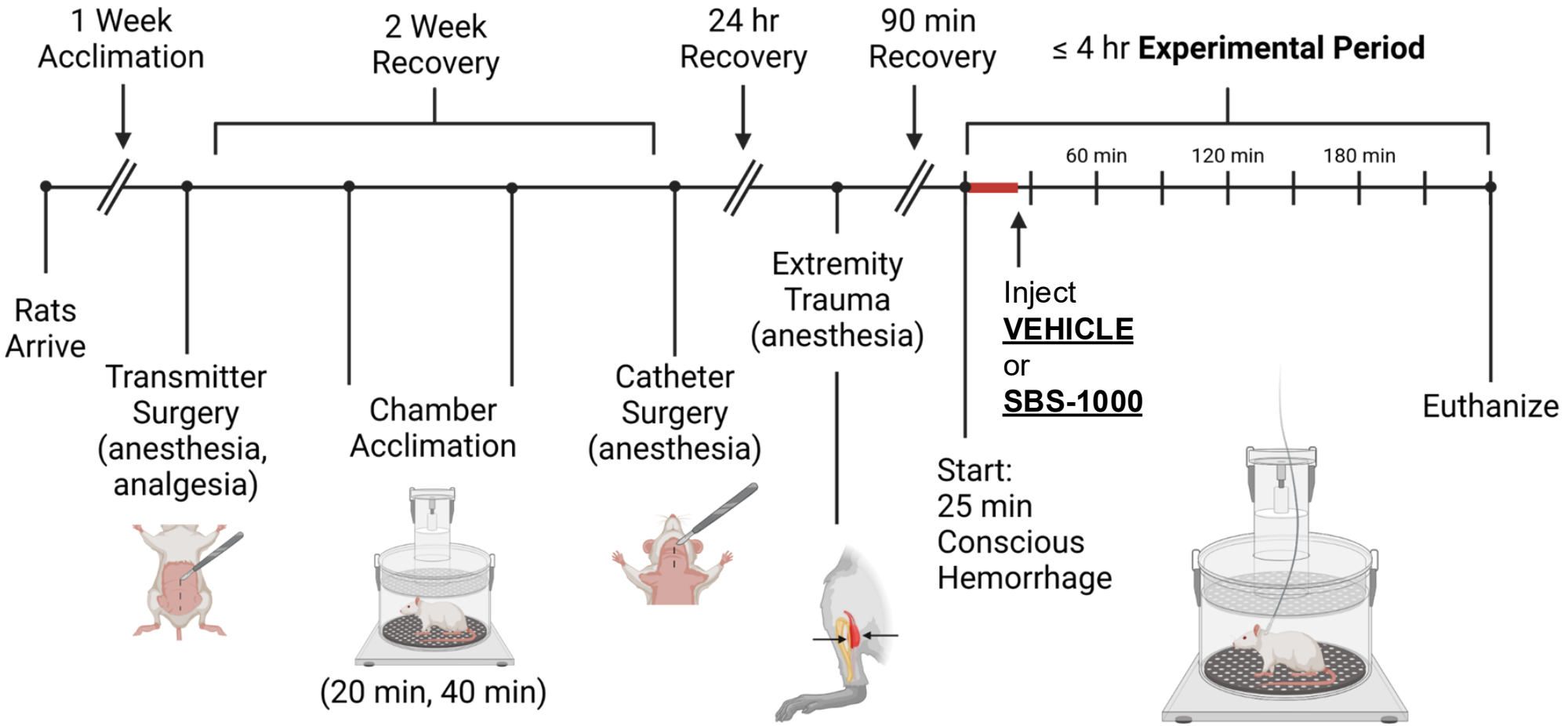
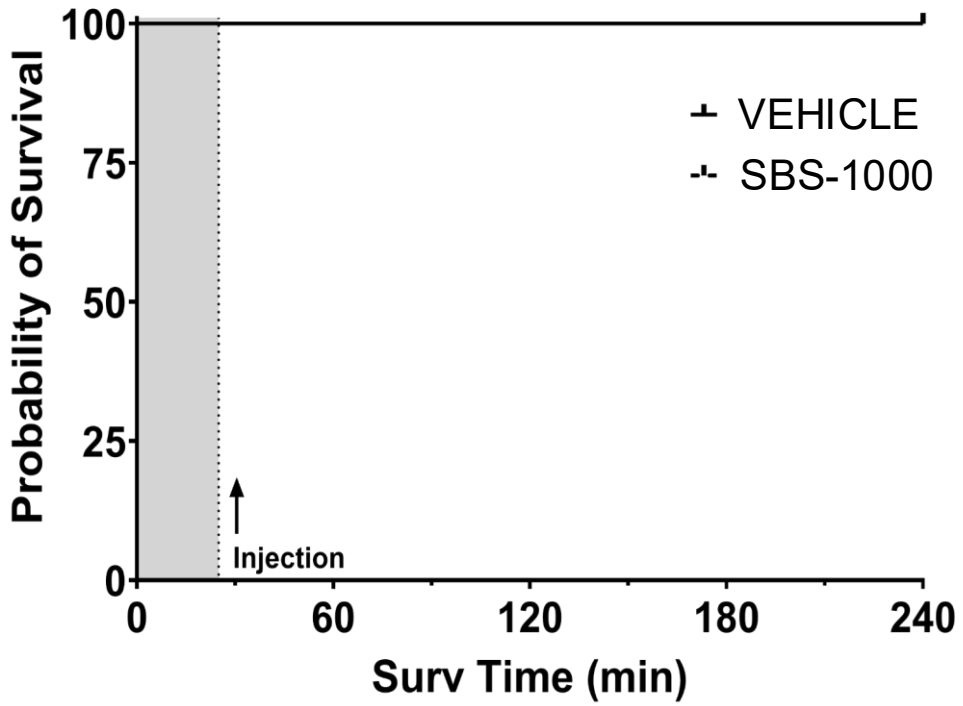


Study Design and Statistics

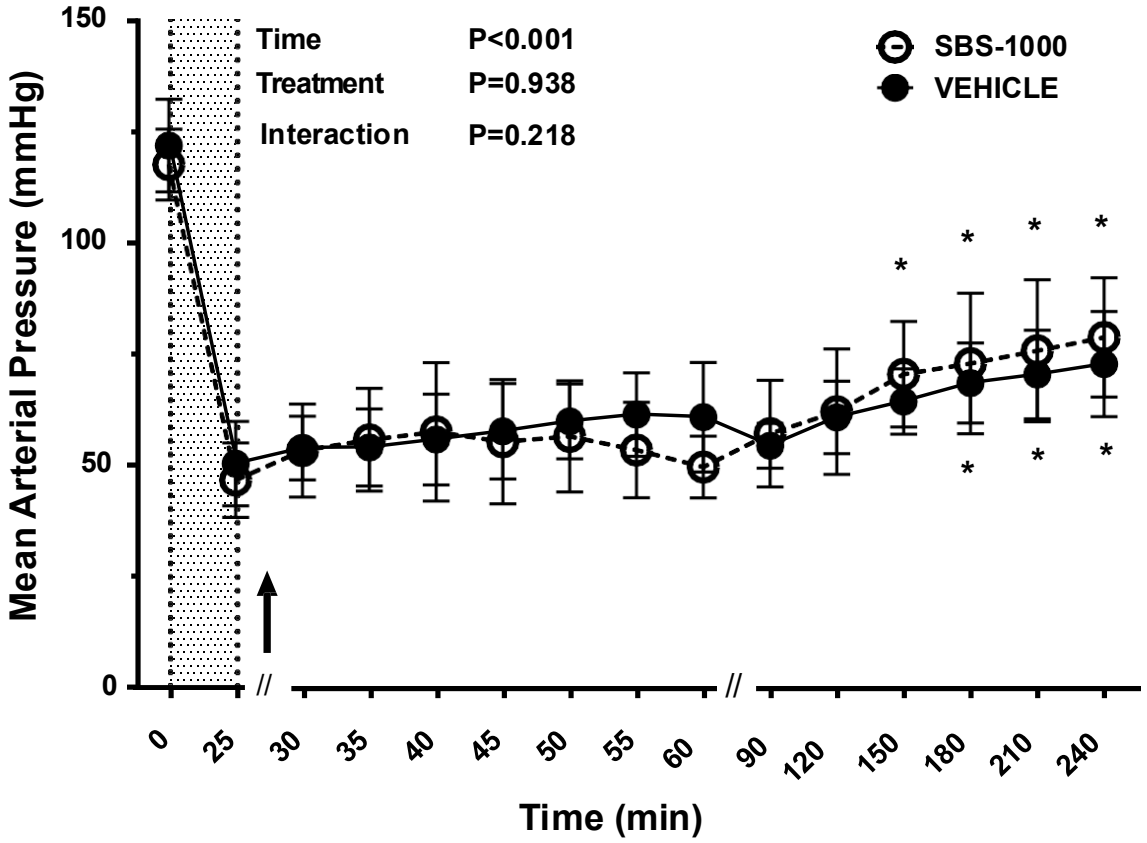
- Groups
  - Moderate Hemorrhage (37%)
    - VEH, N=8
    - SBS-1000 (1 mg/kg), N=9

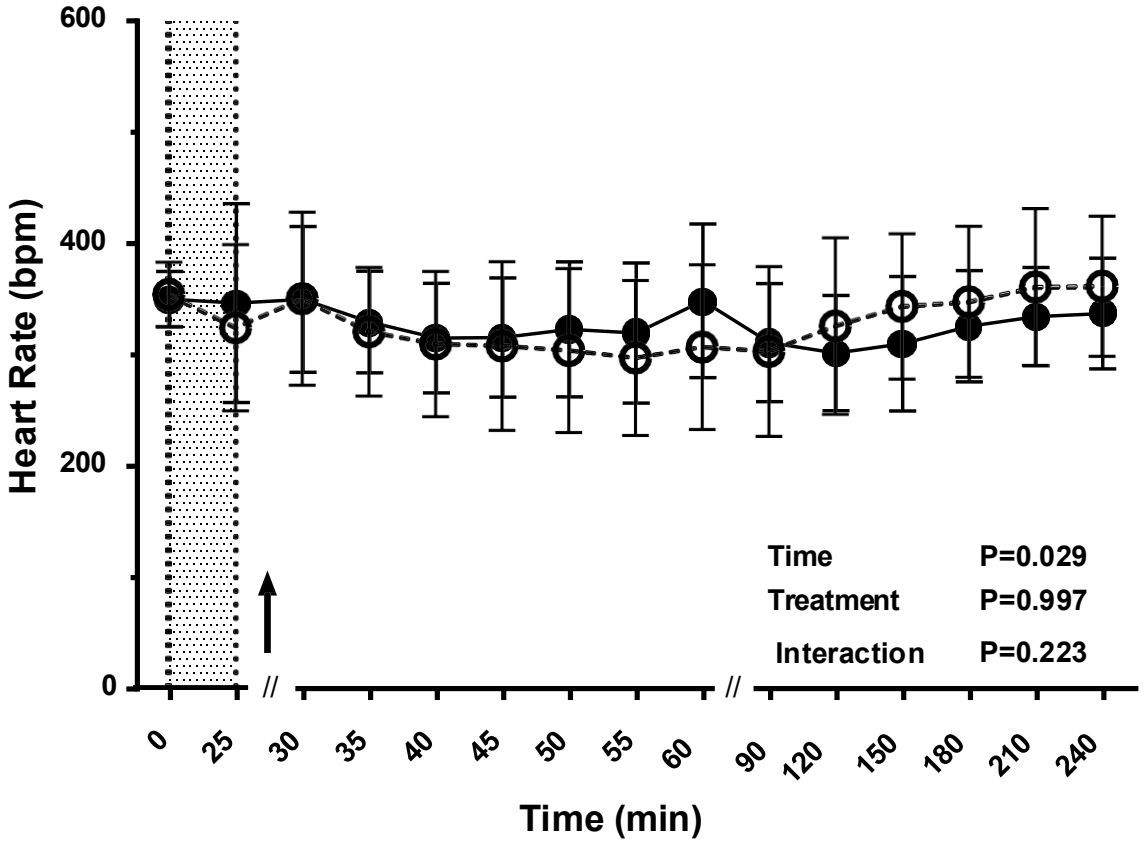
- Statistics
  - **PASS** software used to calculate sample size and power
  - **GraphPad Prism** procedures
  - Survival: Associated Kaplan-Meier procedure and log-rank test.
  - Cardiovascular and Respiratory: Two-way repeated measures ANOVA and the Šidák test was used for multiple means comparisons

SBS-1000 does not alter Survival



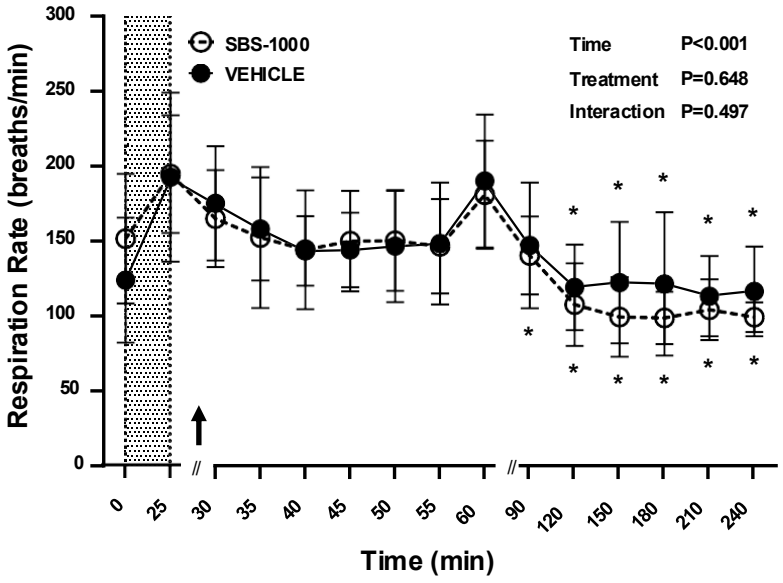
SBS-1000 does not affect cardiovascular parameters

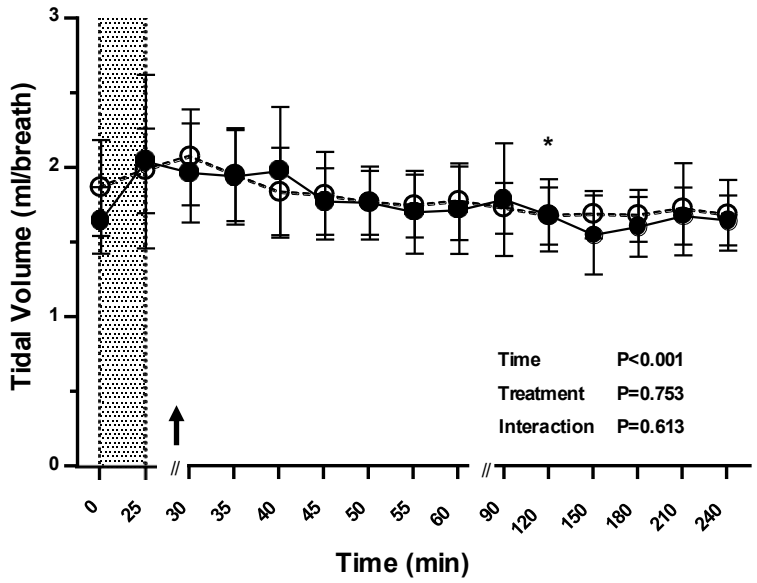


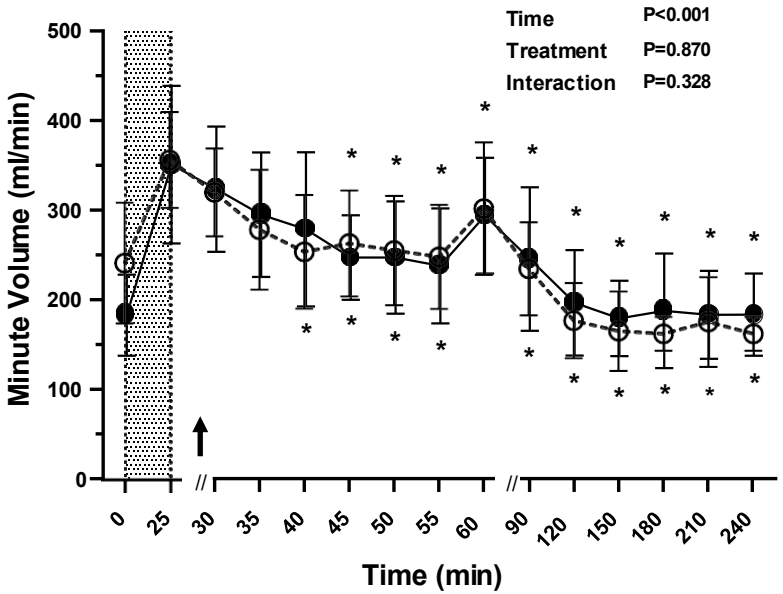


* P<0.05 compared to t=25 min within treatment group

SBS-1000 does not affect respiratory parameters







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Summary and Conclusion

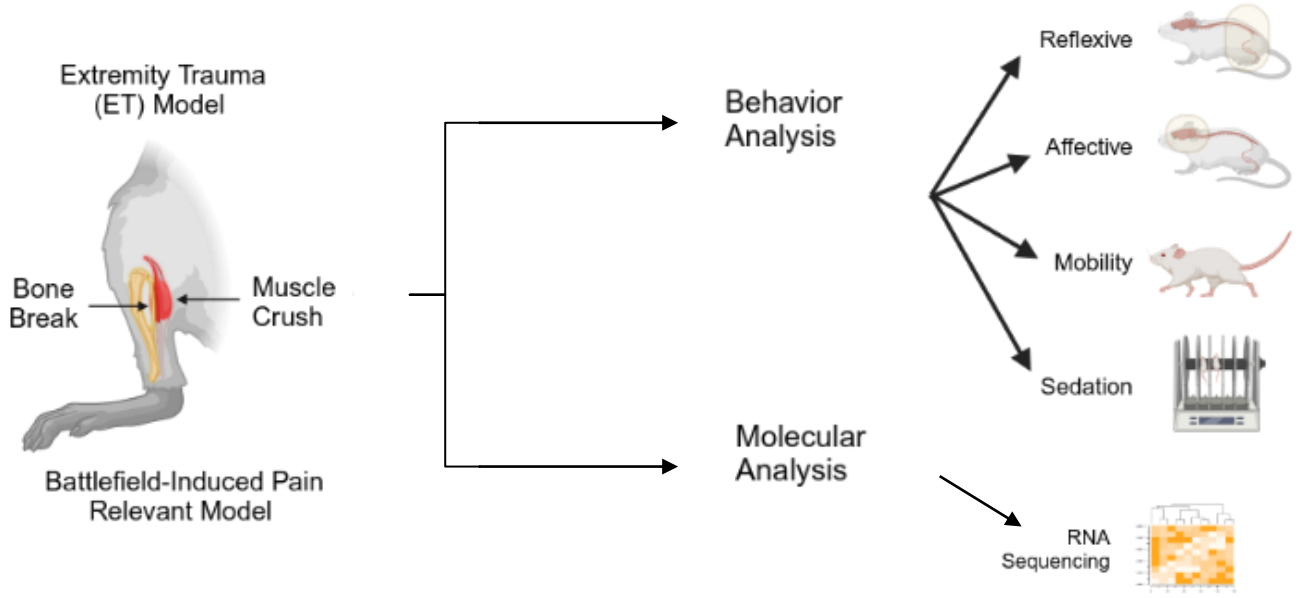
- A single dose of SBS-1000 administered after moderate HEM did not alter survival.

- There were no differences between VEH and SBS-1000 in MAP, HR, RR, TV, MV at either baseline (t = 0 min), end of HEM (t = 25 min), or after VEH/SBS-1000 injection (t = 25-240 min) and 37% HEM.

- Conclusion: SBS-1000, a promising novel analgesic, does not further compromise cardiorespiratory function after moderate traumatic HEM, suggesting that it may be useful in future treatment of trauma patients in both battlefield and civilian sectors.

Future Studies

- Test new formulation of SBS-1000 currently in clinical trials.
  - Analgesia in the ET model
    - Reflexive Testing
    - Affective Testing
  - Changes in miRNA, Biomarkers
  - Effects after **severe** traumatic hemorrhage (50% HEM)



Questions

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- MG Paula C. Lodi, Commanding General, USAMRDC