60th Medical Group (AMC), Travis AFB, CA
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20160026A
DATE: 4 May 2017

PROTOCOL TITLE: The Effect of Infrarenal Aortic Balloon Occlusion on Weaning from Suprarenal Aortic Balloon Occlusion in a Porcine Model (Sus scrofa) of Hemorrhagic Shock.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Capt Emily Tibbits

DEPARTMENT: SGSE
PHONE #: 937-901-6095

INITIAL APPROVAL DATE: 25 August 2016
LAST TRIENNIAL REVISION DATE: N/A

FUNDING SOURCE: SG

1. RECORD OF ANIMAL USAGE:

<table>
<thead>
<tr>
<th>Animal Species:</th>
<th>Total # Approved</th>
<th># Used this FY</th>
<th>Total # Used to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sus scrofa</td>
<td>23</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in EACH column)

  - Training: Live Animal
  - Medical Readiness
  - Prolonged Restraint
  - Training: non-Live Animal
  - Health Promotion
  - Multiple Survival Surgery
  - Research: Survival (chronic)
  - Prevention
  - Behavioral Study
  - X Research: non-Survival (acute)
  - Utilization Mgt.
  - Adjuvant Use
  - Other ( )
  - Other (Treatment )
  - Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable)  C  X  D  E

4. PROTOCOL STATUS:

  *Request Protocol Closure:
  
  - Inactive, protocol never initiated
  - Inactive, protocol initiated but has not/will not be completed
  - Completed, all approved procedures/animal uses have been completed

5. Previous Amendments:
List all amendments made to the protocol. IF none occurred, state NONE. Do not use N/A.

For the Entire Study Chronologically

<table>
<thead>
<tr>
<th>Amendment Number</th>
<th>Date of Approval</th>
<th>Summary of the Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>19 Sept 16</td>
<td>Procedures, Anesthetic/Analgesic/Antibiotic, Biosample</td>
</tr>
<tr>
<td>2</td>
<td>28 Sept 16</td>
<td>Procedures, Anesthetic/Analgesic/Antibiotic, Biosample</td>
</tr>
<tr>
<td>3</td>
<td>9 Nov 16</td>
<td>Procedures, animal care, biosamples, protocol</td>
</tr>
</tbody>
</table>
6. **FUNDING STATUS:** Funding allocated: $43,372 Funds remaining: $0

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/Al/TC/Instructor) since the last IACUC approval of protocol, or annual review? 

_X_ Yes ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

**ADDITIONS:** (Include Name, Protocol function - PI/CI/Al/TC/Instructor, IACUC approval - Yes/No)

Maj Robert Faulconer (Al) Yes, Col Jeremy Cannon (Al), Yes, Mr. Steven Chu (Al) Yes

**DELETIONS:** (Include Name, Protocol function - PI/CI/Al/TC/Instructor, Effective date of deletion)

None

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

We had to exclude three animals from our study due to technical errors on the part of the investigators. These events were reported to the IACUC.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

**REPLACEMENT (ALTERNATIVES):** Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

**REFINEMENT:** Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentence been identified as potential study/training models in this protocol?

No.

**REDUCTION:** Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

The first or two abstracts for this protocol was submitted to Excelsior for presentation. The second is in progress and will be submitted for presentation at EAST. Both manuscripts are in progress and will be submitted for publication following presentation of the corresponding abstracts.

11. Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?

Yes, the protocol objectives were met. While data analysis is still underway, the results from this study will make a significant contribution to the REBOA literature and address important questions regarding applicability of REBOA in different positions for different therapeutic goals. This will, in turn, help to guide the practice of those providing resuscitative care to our critically injured service members.
12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

**Objectives:** One limitation of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is hemodynamic instability upon balloon deflation due to distal hyperemia and washout of ischemic metabolites. We sought to determine whether stepwise reperfusion after supraretiliac (Zone-1) REBOA by transitioning to infrarenal (Zone-3) occlusion would mitigate the physiologic consequences of balloon deflation and decrease hemodynamic instability.

**Methods:** Twelve anesthetized swine underwent controlled hemorrhage of 25% blood volume, 45 minutes of Zone-1 REBOA, then resuscitation with shed blood. Standardized critical care began with deflation of the Zone-1 balloon in all animals, and continued for six hours. Half of the animals were randomly assigned to Zone-3 REBOA for an additional 45 minutes following Zone-1 balloon deflation.

**Results:** There were no differences in physiology at baseline, during the initial 30 minutes of hypotension, or during the 45 minutes of Zone-1 occlusion. After Zone-1 balloon deflation, there was no difference in proximal mean arterial pressure (pMAP) with or without Zone-3 occlusion, or percentage of critical care time spent within the target pMAP range between 65 and 75 mm Hg. There were also no significant differences in peak lactate concentration or resuscitation requirements.

**Conclusions:** In an animal model of hemorrhagic shock and Zone-1 REBOA, subsequent Zone-3 aortic occlusion did not add significant ischemic burden, but it also did not provide significant hemodynamic support. The effect of this strategy on functional outcomes warrants further study. Continued investigation is necessary to determine optimal resuscitative support strategies during reperfusion following Zone-1 REBOA.

\[X\]

Capt Emily Tibbits
Primary Investigator

**Attachments:**
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission *(Mandatory)*
Objective: We sought to determine whether stepwise reperfusion after suprarenal (Zone-1) REBOA by transitioning to infrarenal (Zone-3) occlusion would mitigate the physiologic consequences of balloon deflation and decrease hemodynamic instability.

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Conclusion: In an animal model of hemorrhagic shock and Zone-1 REBOA, subsequent Zone-3 aortic occlusion did not add significant ischemic burden, but it also did not provide significant hemodynamic support. Continued investigation is necessary to determine optimal resuscitative support strategies during reperfusion following Zone-1 REBOA.

Grant Number: _____________________
From: ______________________________

**If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.