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 #: FDG20150002A
DATE: 10 September 2015

PROTOCOL TITLE: "Partial Resuscitative Endovascular Balloon Occlusion of the Aorta (P-REBOA) in a pig model (Sus scrofa)."

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Maj Lucas Neff

DEPARTMENT: General Surgery
PHONE #: 423-5179

INITIAL APPROVAL DATE: 20 November 2014
LAST TRIENNIAL REVISION DATE: N/A

FUNDING SOURCE: Internal O&M funding

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>18</td>
<td>18</td>
<td>18</td>
</tr>
</tbody>
</table>

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

  ____ Training: Live Animal
  ____ Training: non-Live Animal
  ____ Research: Survival (chronic)
  ____ Research: non-Survival (acute)
  ____ Other ( )

  ____ Medical Readiness
  ____ Health Promotion
  ____ Prevention
  ____ Utilization Mgt.
  ____ Other (Treatment )

  ____ Prolonged Restraint
  ____ Multiple Survival Surgery
  ____ Behavioral Study
  ____ Adjuvant Use
  ____ Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable)  ____ C  ____ 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>18 Dec 14</td>
<td>Procedures, Biosample(s), Protocol title/objective/design</td>
</tr>
<tr>
<td>2</td>
<td>19 Feb 15</td>
<td>Procedures, Biosample(s), Protocol title/objective/design</td>
</tr>
<tr>
<td>3</td>
<td>21 May 15</td>
<td>Personnel</td>
</tr>
</tbody>
</table>
6. **FUNDING STATUS:** Funding allocated: $ Funds remaining: $

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)

Dr. Sarah Ashley Ferencz – 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.

None

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).

Oral Presentation at the 2015 Annual Meeting of the American Association for the Surgery of Trauma and Clinical Congress of Acute Care Surgery in Las Vegas, NV.

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

Yes, this study represents a foundation for future combat casualty care project and therapies.

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.)

---

(PI / TC Signature)  

13 Nov 2015  

(Date)
Background: Partial REBOA (P-REBOA) may permit longer periods of occlusion by allowing some degree of distal perfusion. However, the ability of this procedure to limit exsanguination is unclear. We evaluated the impact of P-REBOA on immediate survival in a highly lethal swine liver injury model.

Methods: Fifteen Yorkshire-cross swine were anesthetized, instrumented, splenectomized, and subjected to 30% liver amputation. Coagulopathy was created through hemodilution. Randomized swine received no intervention (control), P-REBOA, or complete REBOA (C-REBOA). Central mean arterial pressure (cMAP), carotid blood flow, and blood loss were recorded. Balloons remained inflated in the P-REBOA and C-REBOA groups for 90m followed by graded deflation. The study ended at 180m from onset of hemorrhage or death of the animal. Survival analysis was performed.

Results: Survival times in the control, P-REBOA, and C-REBOA groups were, 25±21, 86±40, and 163±20m, respectively (p<0.001). There was no difference in blood loss among the groups. P-REBOA maintained near-baseline carotid blood flow and cMAP, while C-REBOA generated extreme cMAP and prolonged supraphysiologic carotid blood flow. Both experimental groups experienced profound decreases in cMAP following deflation.

Conclusions: With severe ongoing hemorrhage, P-REBOA increased survival time while maintaining cMAP and carotid flow at physiologic levels.