60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

PROTOCOL #: FDG20170027A **DATE:** 29 July 2018

PROTOCOL TITLE: A Pilot Study of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in a Pediatric Swine (*Sus scrofa*) Model.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Capt Andrew Wishy

DEPARTMENT: SGSE **PHONE #:** 816-729-2673

INITIAL APPROVAL DATE: 17 August 2017 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: SG

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	18	18	18

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 ( )	X__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

_X_ 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

Amendment Number	Date of Approval	Summary of the Change
1	8 Mar 18	Animal use, procedures, biosample, protocol/title/objective/design

6. **FUNDING STATUS:** Funding allocated: $28,350.00 Funds remaining: $ 0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval ofprotocol, or annual review? ___Yes _X_ 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/AI/TC/Instructor, IACUC approval - Yes/No)

None

DELETIONS: (Include Name, Protocol function - PI/CI/AI/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.

1. p2013 was excluded from the study after necropsy found to have bacterial pericarditis and pleuritis. This animal was replaced in the study. IACUC was notified, and replacement was approved.

2. p2122 was excluded from the study after necropsy found to have congenital ventricular septal defect, bilateral hyperplastic adrenal glands, and hypoplasia of the spleen. This animal was replaced in the study. IACUC was notified, and replacement was approved.

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 sentience 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).

None. Planned submission for MSHRS 2019.

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

The protocol objectives were met. We were able to successfully perform REBOA on pediatric pigs, and demonstrated that these animals lost less blood and survived longer than control animals.

This protocol provided valuable insights into the management of pediatric trauma patients and afforded a valuable training opportunity for research residents.

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.)

See below.

ANDREW M. WISHY, Capt, USAF, MC

29Jul2018
(Date)

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1

Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives:

We hypothesized that Resuscitative Balloon Occlusion of the Aorta (REBOA) would be possible in pediatric animals and that those that underwent REBOA would have decreased blood loss and longer survival times than control animals.

Methods:

Anesthetized and instrumented pediatric swine received either complete zone 1 REBOA (n=6) using a 5F Fogarty *embolectomy* balloon for 30 minutes, or no treatment (n=5) following liver injury and 5 minutes of free bleeding. Physiologic data were collected until the end of the experiment and tissues were examined.

Results:

REBOA pigs lost significantly less blood than control pigs (33.0±1.75 vs 61.3±2.5 mL/kg, respectively, $P<0.01$) and had higher hematocrits at the end of the study (28±2% vs.17±4% p=0.02). However, REBOA pigs required more blood infusions (36±1 vs.19±8 mL/kg, p=0.03) than controls to maintain target blood pressure. REBOA pigs survived longer than control pigs, although the difference was not statistically significant (193±22 vs. 140±46 minutes, p=0.29). There were no differences in histologic injury scores between groups for any tissues examined.

Conclusion:

REBOA is possible in pediatric animals and may prove a useful technique in pediatric patients with severe non-compressible torso hemorrhage.

Grant Number:_____

From:___AFMSA/SG5

$50,000