

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 #: FDG20140037A

DATE: 25 June 2015

PROTOCOL TITLE: A pilot study of chest tube versus pigtail catheter drainage of acute hemothorax in Swine (*Sus scrofa*).

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Maj Scott Zakaluzny/Capt R. Russo

DEPARTMENT: General Surgery

PHONE #: (707)423-5224

INITIAL APPROVAL DATE: 28 August 2014

LAST TRIENNIAL REVISION DATE: N/A

FUNDING SOURCE: USAF Surgeon General's Office.

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
<i>Sus scrofa</i>	15	12	12

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
☒ Research: non-Survival (acute)	☐ Utilization Mgt.	☐ Adjuvant Use
☐ Other ()	☐ Other (Treatment)	☐ 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

Amendment Number	Date of Approval	Summary of the Change
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6. **FUNDING STATUS:** Funding allocated: \$ Funds remaining: \$

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, 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)

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

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

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

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol? No

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: A pilot study of chest tube versus pigtail catheter drainage of acute hemothorax in Swine (*Sus scrofa*). Western Trauma Association 45th Annual Meeting. 1 March 2015. Telluride, CO

Oral presentation: A pilot study of chest tube versus pigtail catheter drainage of acute hemothorax in Swine (*Sus scrofa*). UC Davis Resident Research Day. 27 April 2015, Sacramento, CA

Poster Presentation: A pilot study of chest tube versus pigtail catheter drainage of acute hemothorax in Swine (*Sus scrofa*). DGMC research day. 15 June, 2015 Travis, AFB, CA

Upcoming Poster Presentation: A pilot study of chest tube versus pigtail catheter drainage of acute hemothorax in Swine (*Sus scrofa*). MHSRS (date TBD). Orlando, FL

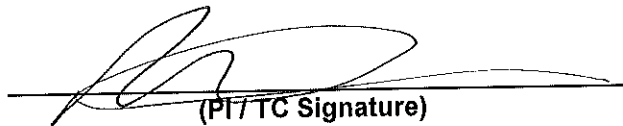
Publication: Russo, RM. Et. Al. A pilot study of chest tube versus pigtail catheter drainage of acute hemothorax in swine. Journal of Trauma and Acute Care Surgery. In press.

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

The objectives were partially met. The first protocol hypotheses was that there is no significant difference in the rate of blood drainage from the chest between pigtail catheters and standard tubes in an in vivo pig model. This objective was met. The second hypothesis was that this drainage rate will not be significantly altered with the patient on positive pressure ventilation as compared to spontaneously breathing. The volume of hemothorax necessary for this study produced high mortality and low information yield in the spontaneously ventilating group during model development so the decision was made to limit the experiment to mechanically ventilated pigs. This pilot study will serve as the basis for future translational studies on the use of less invasive catheters for the treatment of traumatic hemothorax to speed patient recovery, decrease complication rates associated with current treatment, reduce patient pain, and decrease the weight/size of combat medical packs.

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 attachment


(PI/TC Signature)

(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.

Background: Management of traumatic hemothorax (HTx) with pigtail catheters has not been widely adopted due to concerns about blood evacuation rates. We compared pigtail catheters with standard chest tubes for the drainage of acute HTx in a swine model.

Methods: Seven hundred-fifty milliliters of blood was withdrawn from each femoral artery and instilled into each pleural space in mechanically ventilated swine. A 32F chest tube was placed in one randomly assigned hemithorax; a 14F pigtail catheter was placed in the other. Output from each drain was measured every minute for 5 minutes, then every 5 minutes for 40 minutes.

Results: Blood drainage was more rapid from the chest tube during the first three minutes compared to the pigtail catheter (348 ± 109 mL/min vs. 176 ± 53 mL/min) but this difference was not statistically significant ($p=0.19$). Thereafter, the rates of drainage between the two tubes were not substantially different. The chest tube drained a higher total percentage of the blood from the chest (87.3% vs 70.3%), but this difference did not reach statistical significance ($p=0.21$).

Conclusion: We found no statistically significant difference in the volume of blood drained by a 14F pigtail catheter compared to a 32F chest tube.

Grant Number: _____

From: _____

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