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Evaluating Traumagel in a Porcine Compressible Junctional Hemorrhage Model

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Introduction

Compressible hemorrhage is an ongoing risk occurring in both civilian and combat prehospital settings. Between 30 to 40% of world-wide trauma mortality is a result of hemorrhage with 33 to 56% of these deaths occurring in the prehospital setting [1]. During the United States' Global War on Terror, between 2001-2011, 11.6% of potentially survivable combat fatalities were associated with junctional hemorrhages in the axillary and inguinal area [2]. For compressible external hemorrhages not amendable to limb tourniquets, the Committee on Tactical Combat Casualty Care (CoTCCC) clinical practice guidelines (CPG) recommends the use of Combat Gauze or alternatively, Celox Gauze, Chito Gauze or XSTAT for these types of injuries [3]. Because the prehospital setting is always changing, there is a need for continued development and innovations in hemorrhage control. Traumagel® is a hemostatic gel-based device containing sodium alginate and chitosan (poly N-acetyl-D-glucosamine, D-glucosamine) and is FDA approved for temporary external use for controlling moderate to severe bleeding. In this study, we compared the hemorrhage control efficacy of Traumagel to Combat Gauze and XSTAT (n=7 per group) in a porcine junctional hemorrhage model relevant to a point of injury (POI) tactical combat casualty care (TCCC) setting.

Objective

1. Evaluate treatment effect of Traumagel on survival, and post-treatment blood loss in a porcine compressible junctional hemorrhage model.
2. Identify ideal treatment for a porcine compressible junctional hemorrhage model.
3. Discuss Traumagel application in a combat casualty care setting

Methods

Female Yorkshire cross-bred swine were randomized into 3 groups (n=7/group): Traumagel, Combat Gauze, and XSTAT.

1. Prior to injury, swine were given buprenorphine SR and anesthetized with isoflurane and monitored by trained veterinary staff, and anesthesia was maintained until completion.
2. Uncontrolled hemorrhage was induced through a 6-mm femoral arteriotomy to simulate a junctional wound, which was allowed to bleed for 45 seconds before hemostatic treatment application.
3. Hemostatic treatments were applied following the manufacturers' respective instructions for use.
4. Each wound received one treatment, and a laparotomy sponge was packed on top to fill the wound cavity. Manual pressure was applied for 3 minutes directly over the packed wound.
5. After manual pressure was complete, the leg with packed wound was wrapped in a figure 8 cross-pattern.
6. If the packed wound bled during the first 15 minutes following the elastic bandage wrap, one additional manual compression was applied over the packed wound and elastic bandage for 3 minutes.
7. Once completed, hemostasis and animal vitals were monitored for up to 4 hours while in the supine position.
8. Animals were monitored for up to 4 hours or until the animals' MAP fell below 15 mmHg or end tidal CO_2 fell below 10 mmHg for a period of at least 1 minute.
9. The animals were euthanized with sodium pentobarbital injections after completion of the four-hour observation period or one of the terminal endpoints were reached.

Methods (continued)

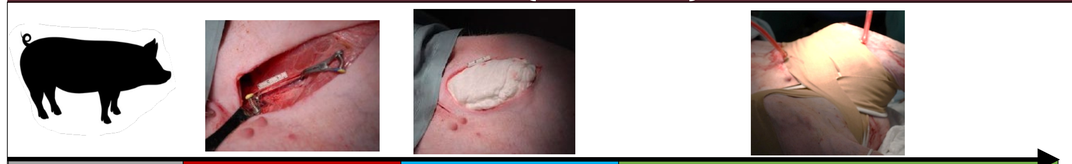

Figure 1. Swine Junctional Hemorrhage Model Timeline. Following line placement, hemorrhage was induced by a 6-mm femoral arteriotomy followed by 45 seconds of free-bleed and hemostatic dressing or device was subsequently applied. Manual compression was then applied directly over the packed wound for 3 minutes. Following compression, the packed wound was wrapped with an elastic adhesive bandage. Survival, hemostasis, blood loss and hemodynamic values were monitored for up to 4 hours post-injury treatment.

Results

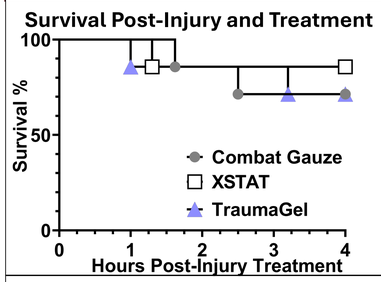

Figure 2. Survival percentage post treatment of junctional hemorrhage in a porcine femoral artery injury model. (n=7/group). XSTAT group had the highest survival rate and mean (SD) duration at 85.7% (6/7) and 3.6 (0.38) hours respectively. Both Combat Gauze and Traumagel treatment groups had survival rates of 71.4% (5/7) with survival durations at 3.4 (0.37) hours and 3.5 (0.43) hours, respectively. No significant differences in survival among the three treatment groups (p=0.8099). Kaplan-Meier survival analysis was performed with significance determined by log-rank (Mantel-Cox) test.

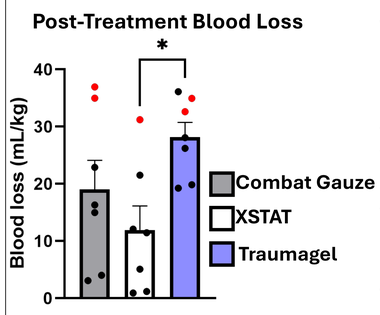

Figure 3. Traumagel treated group had the highest mean post-treatment blood loss. Post-treatment blood loss (ml) includes shed blood from treated and wrapped wounds. Mean (SD) blood loss was normalized to the animal's weight (ml/kg). The XSTAT treatment group exhibited the lowest posttreatment blood-loss at 11.92 (4.22) mL/kg, followed by the Combat Gauze treatment group at 19.02 (5.11) mL/kg. The Traumagel treated group exhibited the highest post-treatment blood-loss at 28.15 (2.59) mL/kg and was significantly higher than the XSTAT treatment group (p=0.0307). Black and red circles represent animals that respectively survived and did not survive the 4-hour observation period post injury and treatment. Mean post-treatment blood loss normality was confirmed by Shaprio-Wilk test and statistically analyzed by one-way ANOVA with Tukey's multiple comparison test. *p<0.05

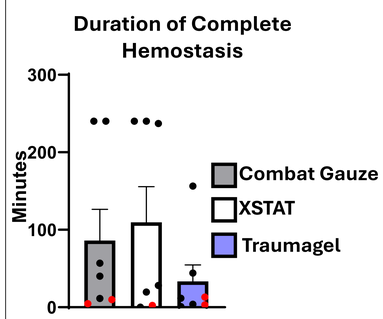

Figure 4. Traumagel group had the lowest mean complete hemostasis duration. Hemostasis was determined as absence of visible bleeding from the wrapped and packed wounds. After the first compression, no bleeding occurred from the packed wounds. In both the Combat gauze and XSTAT groups, 1 of the 7 animals bled from the packed wounds during the leg wrap. In the Traumagel group, 4 of the 7 animals bled from the packed wounds during the leg wrap. Two animals from the Combat Gauze group and 3 animals from the XSTAT group achieved 4 hours of hemostasis. The XSTAT group achieved the longest mean complete hemostasis duration at 109.6 (45.89) minutes followed by Combat Gauze at 86.14 (40.34) minutes then Traumagel at 33.27 (21.26) minutes. Black and red circles represent animals that respectively survived and did not survive the 4-hour observation period post-injury and treatment.

Conclusion

- Following treatment and 3-minute compression, all animals in each treatment group maintained hemostasis prior to applying the elastic bandage wrap. However, during the leg wrap, more Traumagel treated animals began rebleeding from the packed wounds than both Combat Gauze and XSTAT treated animals [4].
- Despite a second 3-minute compression, 6 of the 7 Traumagel treated animals continued to bleed from the packed wounds at a near free-flowing rate whereas, 2 of the 7 Combat Gauze and XSTAT treated animals continued to bleed at a free-flowing rate [4].
- Leg wraps may have negatively impacted Traumagel ability to control the bleeding, the leg wrap is required prior to MEDEVAC as per CoTCCC CPG [3].
- The delivery of Traumagel is faster and seemingly simpler than both Combat Gauze and XSTAT which requires unfolding or unrolling of gauze; or assembling the plunger and applicator prior to administration.
- Overall, our results suggest Traumagel would not be an ideal replacement for Combat Gauze and XSTAT as part of TCCC CPG particularly due to the increased post-treatment blood loss and lower hemostasis duration.

References

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Statements

- Research was conducted in compliance with 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
- This work was funded by a Cooperative Research and Development Agreement (CRADA) between the United States Army Institute of Surgical Research and Cresilon Inc.
- The Traumagel hemostatic devices were provided by Cresilon Inc. under the provisions of a CRADA.

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