CLINICAL WHITE PAPER

Comparison of Hemostatic Efficacy of ChitoGauze® and Combat Gauze in a Lethal Femoral Arterial Injury in Swine Model

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Introduction

Uncontrolled hemorrhage is the leading cause of death of soldiers in wartime. **Quickly accessing and stabilizing the wound with effective hemostatic techniques is the key to saving lives on the battlefield.** There exists a need for a hemostat that is efficacious in achieving hemostasis in severe traumatic combat wounds and easy to apply. In this study, we evaluated the hemostatic efficacy of two advanced hemostatic wound dressings: ChitoGauze® (HemCon Medical Technologies Inc., Portland, OR) and QuikClot® Combat Gauze™ (Z-Medica Co., Wallingford, CT), in a swine femoral arterial injury model.

ChitoGauze

Combat Gauze

Methods & Materials

Sixteen male Yorkshire crossbred swine with an average body weight of 40 Kg were randomly assigned into either the Combat Gauze or ChitoGauze group. An arterial injury was created with a 6 mm arterial punch on the left femoral and free bleed of 45 seconds was required prior to application of test dressing. Each hemostatic dressing was applied through a pool of blood with the applicator blinded, followed by three minutes of manual compression. Pressure was released after three minutes and the wound was observed for bleeding. If bleeding occurred within two minutes, a second application of the test dressing was allowed. Fluid resuscitation was administered as necessary to re-establish a mean arterial pressure (MAP) at above 60 mmHg level or continuous infusion in a 3-hour observation period if MAP dropped below 60 mmHg. The primary measured outcomes were immediate hemostasis, 3-hour survival and total blood loss. Secondary endpoints were average number of applications, time to hemostasis, change of mean arterial pressure, resuscitation volume, volume of blood loss during the 45 second prebleed and femoral artery diameter.

Results

Surgical information including body weight, pre-treatment blood loss, vessel size, MAP change and resuscitation volume were similar between the two treatment groups. **Average post treatment blood loss over three hours or survival was less in the ChitoGauze group than the Combat Gauze group (430 mL vs. 1180 mL).** In the ChitoGauze group, seven (87.5%) animals achieved hemostasis and survived without any blood loss or oozing. Only two (25%) animals achieved immediate hemostasis and five (63%, p = 0.04) survived in the three hours observation time in the Combat Gauze group. In the survived animals, five out of seven animals had complete hemostasis in first attempt using the ChitoGauze; two out of five animals achieved hemostasis in first attempt with the Combat Gauze. Number of applications in the ChitoGauze group was less than that in the Combat Gauze group (1.4 ± 0.5 vs. 1.8 ± 0.5). **Average time to achieve complete hemostasis in the survived animals was three minutes with the ChitoGauze and 12 minutes using Combat Gauze.**

Conclusion

Both ChitoGauze and Combat Gauze demonstrate hemostatic effectiveness in this lethal extremity hemorrhage model. Both dressings were easy to apply into the femoral wound geometries. While both bandages performed similarly in this small sample, we did note a trend toward more blood loss among the successful Combat Gauze applications as compared to ChitoGauze. ChitoGauze had greater success in achieving immediate hemorrhage control with less blood loss than Combat Gauze in this model.

TABLE 1. SURGICAL INFORMATION (MEAN ± SD)

	ChitoGauze (n=8)	Combat Gauze (n=8)	P Value
Body Wt (Kg)	41 ± 2	40 ± 3	0.3
Average arterial diameter (mm)	6.1	6.2	0.9
Pre-blood loss (g)	680 ± 160	730 ± 150	0.21
Post-blood loss (g)	430 ± 1100	1180 ± 1370	0.26
Change of MAP (mmHg)	33 ± 6	36 ± 6	0.39
Immediate* hemostasis (%, n/n)	63% (5/8)	25% (2/8)	0.04**
Average time to achieve hemostasis (min)	3 ± 5	12 ± 19	0.21
3-Hour survival (%, n/n)	88% (7/8)	63% (5/8)	0.25**

*Defined as hemostasis on first application out of two possible applications; **Chi-square test; T-test unmarked

FIGURE 1. Hemostatic Efficacy in Femoral Injury Model

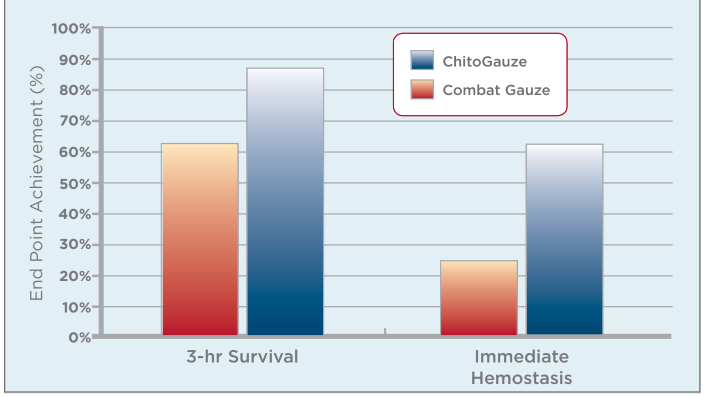

FIGURE 2. Change of Average Mean Arterial Pressure (MAP) in three-hour Observation

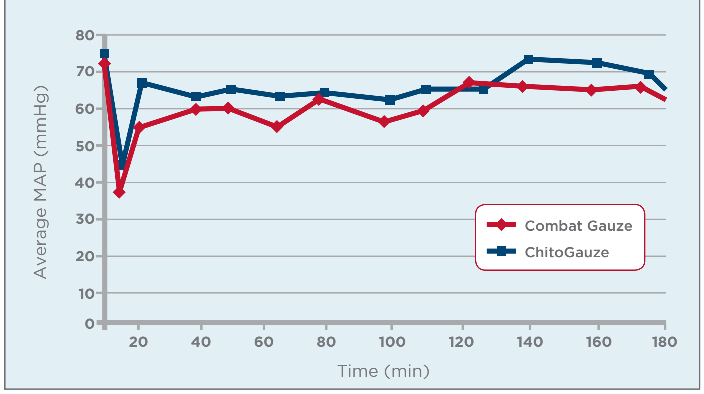

Figure 3: Images show a typical hemostatic effectiveness of ChitoGauze (top) and Combat Gauze (bottom) in the femoral arterial injury model. The ChitoGauze has the capability to achieve immediate hemostasis. The Combat Gauze usually established hemostasis following a gradual reduction of hemorrhaging.