The Effects of Blood Pressure on Rebleeding When BleedArrest™ is Used in a Porcine Model of Lethal Femoral Injury

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This study was funded by a grant from Hemostasis, LLC

Significance

- Mabry, et al. (2000) Uncontrolled bleeding is the leading cause of death in trauma
- Alam, et al. (2003) Effective techniques for early control of hemorrhage: the application of a tourniquet or the application of a hemostatic agent
- Ward, et al. (2007) Hemostatic agents better suited for areas where bleeding cannot be controlled by a tourniquet
- Alam, et al. (2005) No ideal hemostatic agent yet exists and re-bleeding is one of the major limitations of current hemostatic agents

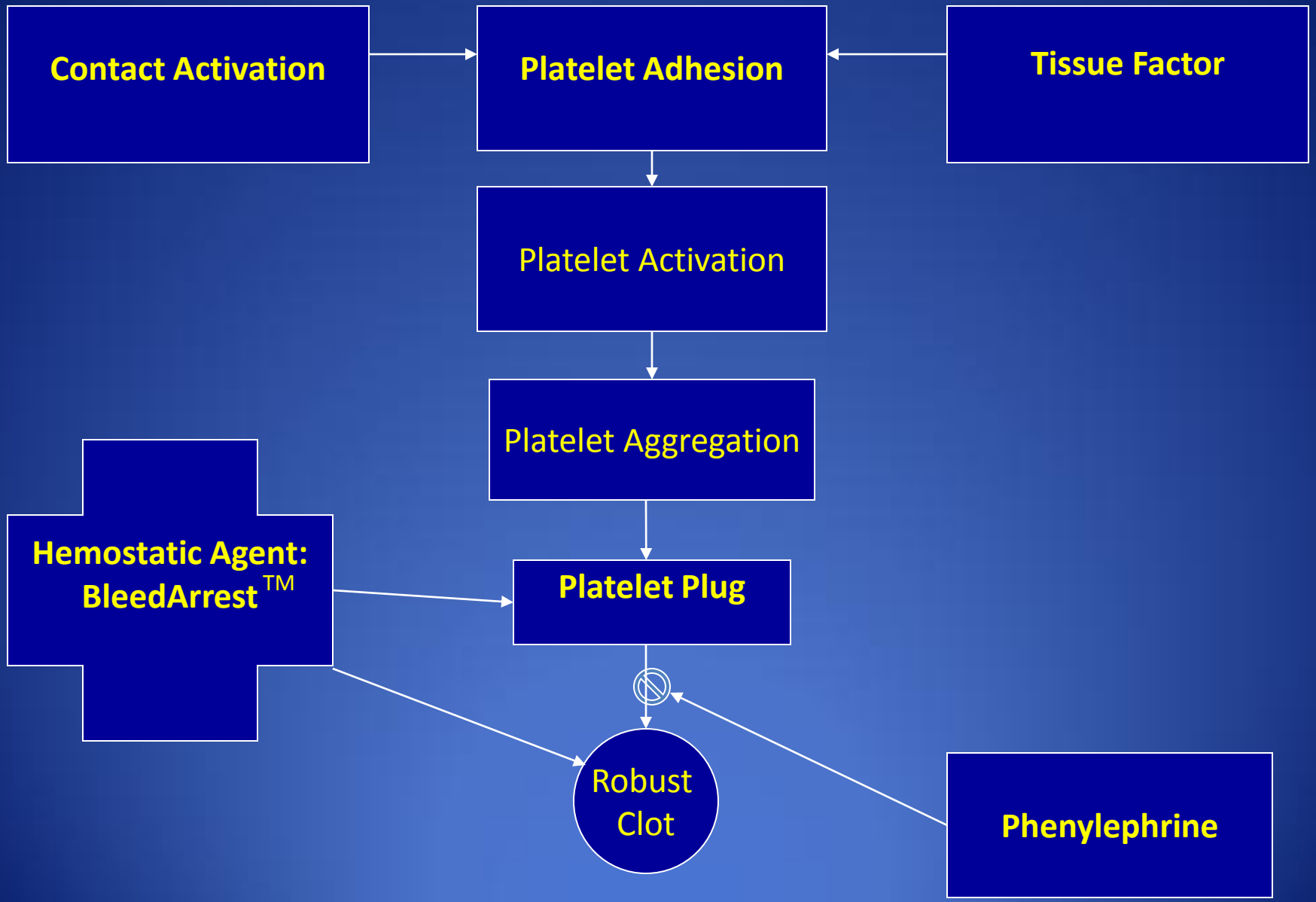
Problem Statement

- It is unknown at what blood pressure rebleeding will occur when BleedArrest™ is used in a lethal femoral injury

Research Question

- Are there statistically significant differences in arterial blood pressures at which rebleeding occurs between the BleedArrest™ and control groups?

Theoretical Framework



Mechanism of Action BleedArrest™

Literature Review

- Mabry, et al. (2000) Uncontrolled bleeding is the leading cause of death in trauma
- Alam, et al. (2003) Effective techniques for early control of hemorrhage: the application of a tourniquet or the application of a hemostatic agent
- Alam, et al. (2004) No ideal hemostatic agent yet exists and rebleeding is one of the major limitations of current hemostatic agents
- Sondeen, et al. (2002) There is a reproducible BP at which rebleeding occurs in a model of uncontrolled hemorrhage
- Burgert, et al. (2009) Found that hemostatic agents are effective in raising the threshold for rebleeding over standard dressing, with Celox™ being more effective than Traumadex™

Research Design

- Prospective
- Between Subjects
- Experimental Design
  - Randomized to treatment
  - Two groups
    - Control group
    - Bleed Arrest™ group

Data Collection Procedures

Hemorrhage Phase I	Hemostasis and Blood Loss Phase II	Phenylephrine Administration Phase III
1. Femoral artery and vein transected 2. Hemorrhage 60 seconds 3. Blood collection 4. Control or BleedArrest 5. Manual pressure for 5 minutes 6. Pressure dressing for 30 minutes 7. Hextend administered	1. Dressings removed 2. Blood (if any) collected for 60 seconds 3. Blood loss calculated 4. Hemostasis observed and defined as ≤ 2% over 5 minute period	1. Phenylephrine infusion started and titrated in increments of 10 mm/Hg 2. Each BP manipulation maintained for 3 minutes 3. Hemostasis observed 4. Rebleeding will be measured and defined as > 2% over 5 minute period

Instruments

- Marquette Solar 800 Medical System (precise within 1mmHg ; accurate within 2mmHg)
- TIF Scale (precise within 0.01 Gm; accurate within 0.5 Gm)
- Stopwatch from Radio Shack (precise within 0.01 second; accurate within 0.1 second)

Power Analysis

- Effect size = 0.6
- Power = 0.8
- Alpha = 0.05
- Five animals per group (Using G-Power 3.00)
- Two groups

Statistical Analysis

- ANOVA for baseline data
- MANOVA for outcome data
- Tukey post-hoc test

What questions do you have?

Operational Definitions

- Transection-complete severing of the femoral artery and vein
- Firm Pressure-25 pounds of hand-held pressure as measured by the pressure scale under to the litter.
- Bleeding-the amount of blood from the injury site
- Rebleeding-any volume greater than 2% of blood volume in a five minute period