CMS Feasibility Study: Test the feasibility of using a bivalve chest dressing to treat an open chest wound in an injured, bleeding swine model

Task 1.1: To test the feasibility of using a bivalve chest dressing to treat an open chest wound in an injured, bleeding swine model

ABSTRACT

INTODUCTION

Background

The second leading cause of preventable death on the today's battlefield is undiagnosed tension pnuemothorax injuries. These injuries account for 6 percent of preventable combat deaths. [1]

Current treatment for chest injuries on today's battlefield includes the Asherman Chest Seal and The HALO Chest Seal. Both dressing are not optimal for today's dynamic battlefield. The Asherman has inferior adhesive which is designed for civilian applications where, time from injury to definitive care is minimal. The adhesive on this dressing does not perform well in a combat environment, where evacuation times are extended and significant bleeding can be associated with wounds.

The current replacement for the Asheman, The HALO, has reasonable adhesive properties but the current design does not include a valve, which in the presence of a pnuemothorax can be dangerous. No current dressings have a design which allows fluids to drain from the wound, which can also lead to adhesion failure. There are no optimal solutions that are currently fielded. CMS and Entrotech have created a bivalve chest seal. The bi-valved dressing allows for venting of air and also includes a collection and drainage system for fluids. This experiment will test the valve and collection area function and adhesive properties in presence of bloods on human role models.

Methods

Two commercial Yorkshire swine were used for this experiment. Animal weight was 70-80 kg. This facility is an Association for Assessment and Accreditation of Laboratory Animal Care International accredited facility. The protocol for the experiment in this proposal has already been approved by the OSU Animal Welfare and Use Committee. All animals were fasted 12 hours before the surgical procedure. Anesthesia was maintained with isoflurane (1-2%). Both animals were surgically prepped and the lateral chest wall both left and right side was shaved to remove all excess hair.

[1] SOF cause of death

Injury
A 3cm open chest wound was produced in the lateral chest wall at the 5th intercostal space via a surgical procedure. The injury was produced by incising thru the dermis and fascia with a no 11 surgical scalpel. A curved Kelly hemostat was used to blunt dissect thru the tissue and then into the chest cavity. A rib spreader was used to spread the ribs for access to the lung parchmeal. A 2cm injury was created in thru the parital pleura and into parchmeal pleura using a no.11 scalpel and curved Kelly hemostats to initiate significant hemorrhage, Animal were placed in a semi-recumbent position to allow bleeding to drain out the wound.
The wounds were cleaned and dried with a gauze pad and a bi-valved chest seal were placed over the injury. The dressings were monitored for 30 minutes for function of the bi-valved design, collection area and adhesive adherence.

End Points
Bleeding was rated as minimal <50cc, moderate, 50cc-250cc, heavy >250cc.
Adhesion was determined as Pass/Fail. Pass. Dressing is still 75% adhered at end of 30 minutes. Valves were rated as Pass/Fail. Valves must both function throughout the experiment. Upper valve must continue to vent air and lower valve must continue to drain fluid. Collection area was rated as Pass/Fail. Area must allow blood to collect and not allow adhesive failure throughout experiment.

Results

Patient #	Adhesion	Valve Function	Collection Area	Bleeding
1	Pass	Pass	Pass	Moderate
2	Pass	Pass	Pass	Heavy

Conclusions
The new CMS/Entrotech bi-valved chest seal performed to design specification and is a design that should function well in the extreme environments and situations of combat operations. Further studies are warranted to test effectiveness when compared to other fielded chest dressings.