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Comparison of zone 3 Resuscitative Endovascular Balloon Occlusion of the Aorta and the Abdominal Aortic and Junctional Tourniquet in a model of junctional hemorrhage in swine

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ABSTRACT

Background: Traumatic injuries to the pelvis and high junctional injuries are difficult to treat in the field; however, Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) and the Abdominal Aortic and Junctional Tourniquet (AAJT) constitute two promising treatment modalities. The aim of this study is to use a large animal model of pelvic hemorrhage to compare the survival, hemostatic, hemodynamic, and metabolic profile of both techniques.

Methods: Yorkshire swine ($n = 10$, 70-90 kg) underwent general anesthesia, instrumentation, and surgical isolation of the femoral artery. Uncontrolled hemorrhage was initiated by an arteriotomy. Animals were randomly allocated to either REBOA or AAJT. Following completion of device application, both groups received a 500 mL Hextend bolus. After 1 hour, the injured femoral artery was ligated to simulate definitive hemostasis followed by a second Hextend bolus and device removal. Animals were observed for two more hours. Physiological data were collected throughout the experiments and compared between groups.

Results: Both techniques achieved 100% hemostasis, and all animals survived the entire experiment except one in the REBOA group. During the hour treatment phase, the AAJT group had a higher mean arterial pressure than the REBOA group (59.9 ± 16.1 *versus* 44.6 ± 9.8 mm Hg, respectively; $P < 0.05$). The AAJT-treated group had higher lactate levels than the REBOA-treated group (4.5 ± 2.0 *versus* 3.2 ± 1.3 mg/dL, respectively; $P < 0.05$).

Conclusions: Despite their mechanistic differences, both techniques achieved a similar hemostatic, hemodynamic, and metabolic profile. Some differences do exist including lactate levels and blood pressure.

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Introduction

The ability to effectively and rapidly control prehospital pelvic and junctional hemorrhage remains a challenge in both civilian and military trauma care.[1-3] The source of hemorrhage can vary widely depending on the mechanism and injury pattern, but hemodynamic instability is associated with major venous and arterial injury. While management is multimodal, such as the use of pelvic binders and damage control resuscitation, control of pelvic and junctional arterial inflow is critical.[4-7]

Arterial control has traditionally been performed in hospital by operative or endovascular means, but such an approach has neglected patients who exsanguinate in the prehospital setting. Several techniques have been developed which can be deployed in such an environment.[8-11] The Abdominal Aortic and Junctional Tourniquet (AAJT) is a method of extrinsic control which consists of a pneumatic bladder, which when inflated, compresses the aorta and pelvic vasculature.[12-15] Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) provides intrinsic aortic control via a balloon catheter inserted in the femoral artery and is inflated in the infrarenal aorta (zone 3).[16-18]

Both techniques have demonstrated a promise in experimental and clinical studies, but each suffer from limitations which pertain to physiological sequelae, provider training burden, and the integration with the in-hospital phase of care. While AAJT requires only minimal training for medical providers, the reperfusion injury has been associated with respiratory depression in spontaneously ventilating subjects and causes discomfort in conscious patients.[11,19] Conversely, REBOA requires a practitioner skilled in arterial access to insert the device, but once inserted, there is the option of zone 1 (thoracic aorta) placement, should abdominal hemorrhage be encountered.

The aim of the present study is to compare the hemostatic ability of the AAJT and REBOA using a large animal model of uncontrolled hemorrhage. The hemodynamic, metabolic, and pathologic effects will also be examined in an effort to identify evidence of superiority between techniques.

Materials and methods

This study was a randomized, prospective trial with allocation concealment. Male, Yorkshire-Landrace swine weighing 70-90 kg were housed according to the regulation at an Association for Assessment and Accreditation of Lab Animal Care (AAALAC)-accredited facility and entered into the experimental protocol. The study was approved by the United States Air Force 59th Medical Wing's Institutional Animal Care and Use Committee. All subjects were treated according to "The Guide for the Care and Use of Laboratory Animals."[20] An overview of the experimental procedures is given in Figure 1.

Animal preparation

Each animal was housed on-site for at least 7 d to allow for acclimation and was fasted overnight with free access to water before surgery. Sedation was performed by intramuscular injection of 4.4 mg/kg tiletamine-zolazepam and 2.2 mg/kg ketamine. Buprenorphine was then given for alleviation of pain at 0.01 mg/kg IM. Anesthesia was induced via mask with 2%-4% isoflurane in an air or oxygen mixture of 40%-60%. Following intubation, isoflurane was adjusted to maintain a minimum alveolar concentration of 1.2 or greater throughout the experiment. Ventilation was delivered using a volume-controlled setting at 6 mL/kg.

Vascular access was obtained using the modified Seldinger technique. The left external jugular vein was accessed for resuscitation fluid administration, whereas the right external jugular vein was utilized for insertion of a pulmonary artery catheter (Edwards Lifesciences, Irvine, CA). The right carotid was used for blood collection and for invasive blood pressure. The left femoral artery was cannulated with an 8 Fr access sheath in preparation for REBOA deployment. The AAJT (Compression Works, Birmingham, AL) was placed in position under the animal, but not buckled. FiO_2 was adjusted to 0.21 to replicate atmospheric FiO_2 and was maintained until the end of experimental procedures.

Injury and intervention

The right femoral artery was isolated by cut-down as previously described for arterial injury.[21,22] A 10-cm incision was made above the femoral artery. The underlying adductor muscle was excised to provide unrestricted access to the artery. Adventitia was removed, and any small branches were either cauterized or ligated. Following a 10-min incubation in 20 mL of 2% lidocaine to reduce vasospasm, a 6.0 mm arteriotomy was performed while atraumatic bulldog clamps were placed proximally and distally of the injury site. The start of injury (t = 0) was initiated by release of the bulldog clamps permitting uncontrolled hemorrhage for 90 s. Free bleeding was allowed to continue past the 90 s until the mean arterial pressure (MAP) reached below 25 mm Hg.

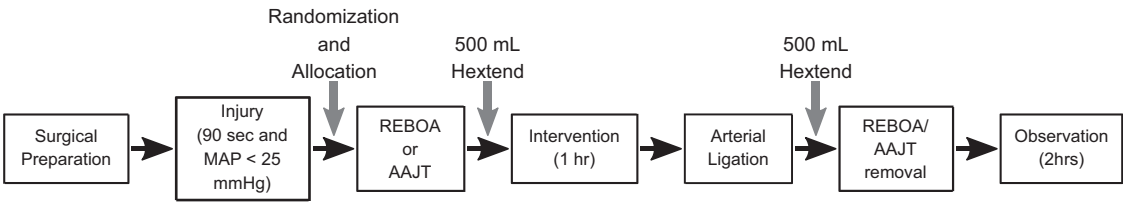

Fig. 1 – Flow diagram of experimental procedures. Each group consisted of 10 animals randomly allocated to intervention.