Video Article

A Saline/Bipolar Radiofrequency Energy Device As an Adjunct for Hemostasis in Solid Organ Injury/Trauma

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Abstract

Solid organ (liver, spleen, and kidney) hemorrhage is often life-threatening and can be difficult to stop in critically ill patients. Traditional techniques for arresting this ongoing bleeding include coagulation by high voltage electrocautery, topical hemostatic application, and the delivery of ignited argon gas. The goal of this study/video was to demonstrate the efficacy of a new energy device for arresting persistent solid organ hemorrhage.A novel instrument utilizing bipolar radiofrequency (RF) energy which acts to ignite/boil dripping saline from a simple handpiece is employed to arrest ongoing bleeding from solid organ injuries in a porcine model. This instrument is extrapolated from experience within elective hepatic resections. An escalating series of injuries to solid organs within a porcine model will be created. This will be followed by arresting hemorrhage with this novel energy device in sequence. A standard suction device will also be employed. This simple saline/RF energy instrument has the potential to arrest ongoing solid organ surface/capsular bleeding, as well as moderate hemorrhage associated with deep lacerations.

Introduction

Uncontrolled hemorrhage due to solid organ injury remains a leading cause of morbidity and mortality in both blunt and penetrating trauma[1]. With the advent of effective damage control resuscitation strategies, the rate of non-operative management for abdominal trauma continues to increase[2]. As a result, patients requiring operative management have increasingly complex injuries and associated physiologic derangement. In these patients, early control of hemorrhage is an essential component of effective damage control resuscitation and desirable outcomes.

The surgical management of solid organ injuries remains a key competency for trauma, acute care, and general surgeons. A wide variety of surgical techniques and hemostatic adjuncts for these injuries have been described[3]. Traditional techniques for treating solid organ bleeding include coagulation by high-voltage electrocautery, application of topical hemostatic agents, sutured repairs, and partial or total organ excision. Argon beam coagulation has also been described[4]. While each of these techniques has a role in achieving hemostasis, none is universally applicable or successful.

Many novel tools and hemostatic therapies have been described in the elective surgical setting. This is especially true in the realm of hepatobiliary surgery[5]. As familiarity with these tools increases, many of them have also shown promise in the surgical management of traumatic injuries. One such device utilizes a combination of ignited saline and bipolar radiofrequency energy to arrest hemorrhage. Additionally, it has the ability to simultaneously seal small- to medium-sized bile ducts within the liver[6]. The positive experience with this tool in the management of solid organ injuries has been described previously[6,7,8].

The goal of this publication is to demonstrate the potential application of this novel device using simulated solid organ injuries in a porcine model.

Protocol

Procedures involving animal subjects have been approved by the Animal Care Committee at the University of Calgary and follow the guidelines set by the Canadian Council of Animal Care. The committee ensures the study is ethical and that the animals are treated humanely.

1. Model Preparation

1. House the 50 kg adult male pig in an animal care facility for 1 week prior to the surgery to acclimatize the animal to the housing conditions and the handlers. Fast the model for a minimum of 6 h prior to the initiation of anesthesia.
2. Anesthetize the model using an intramuscular injection of ketamine (33 mg/kg), atropine (0.04 mg/kg), and buprenorphine (0.05 mg/kg) as well as inhaled isoflurane (5%)[9].
3. Move the model into the supine position and spray the vocal cords with lidocaine (1%) in order to prevent laryngospasm. Perform direct endotracheal intubation using a 6.5 Fr cuffed endotracheal tube. Confirm the correct position of the endotracheal tube using capnography.
4. Insert an 18G IV in the marginal ear vein and begin an infusion of Ringer's lactate at a rate of 200 mL/h. Apply a bland ointment to the model's eyes to prevent dryness while under general anesthesia.

5. Monitor the model's heart rate and oxygen saturation using a pulse oximeter applied to the model's tail. Ventilate the model between 14 - 16 breaths/min using a mechanical ventilator and a tidal volume of 5 - 10 mL/kg. Maintain an adequate anesthesia by targeting a minimal alveolar concentration (MAC) of isoflurane between 2 to 2.5.
6. Prior to the initiation of surgery, confirm the adequate depth of anesthesia by testing pain reflexes with a hind leg toe pinch. Reevaluate pain reflexes at regular intervals throughout the surgery.

2. Device Preparation

1. Prepare the ignited saline/bipolar radiofrequency (SBRF; **Figure 1**) device as per the manufacturer's specifications.
    1. Open the handpiece (6.0 bipolar sealing tip) and connect it to the generator.
    2. Set the saline flow rate setting to **Low**. Use 0.9% saline for a maximal energy conduction.
    3. Set the radiofrequency power setting to 160 W.

3. Surgery: Laparotomy

1. Perform a long open midline laparotomy incision using a #10 scalpel extending from the xiphisternum to the pubis and passing through all layers of the abdominal wall.
2. Establish an adequate exposure of the solid organs of interest (*e.g.*, liver, spleen, kidney), mobilize other structures, and insert a retractor as necessary.
   NOTE: For simplicity, the liver will be referred to as the solid organ of interest for the remainder of this protocol. This protocol will also include creating injuries of similar grade within the kidney and spleen.

4. Surgery: Simulated Solid Organ Injury

NOTE: The injuries described below represent a worsening hierarchy of injuries. The injuries are created by an expert trauma surgeon and hemostasis will be obtained by another surgeon.

1. Using a #10 scalpel blade, apply an abrasive (back and forth) force to the liver capsule in order to induce capsular bleeding. The injury should be superficial (*i.e.*, 1 - 2 mm) and 2 cm^2 in size. The size of the injury can then be increased in increments of 1 cm^2 at the operator's discretion.
2. Create solid organ lacerations of increasing severity using the direct application of a scalpel. The length of the laceration can extend from 5 cm to the entire length of the organ. The depth of the laceration should be 1 cm and then increased in increments of 1 cm at the operator's discretion.
3. Create penetrating injuries with a blunt device such as a Kelly clamp using a stabbing motion. These can be of a partial thickness (*i.e.*, 50% of the organ) or of full thickness (*i.e.*, passing completely through the organ).

5. Hemostasis

1. Depress the handpiece's button, initiating the simultaneous flow of saline and the delivery of bipolar radiofrequency energy. The saline will boil at the site of application.
2. Apply the device's tip directly onto the liver's raw surface, to superficial areas of bleeding, or within defects in the liver itself. Do not stab the organ with the end effector.
3. Apply concurrent suctioning from a standard surgical sucker as needed in order to deliver the heated saline and energy directly to the areas of ongoing hemorrhage. This also helps visualize the precise location of the ongoing hemorrhage.
4. Heat the tissues to approximately 100 °C (thermal coagulation without significant charring) using a gentle back and forth motion. An auditory 'pop' will occur after 3 - 5 s and signifies that the burn is complete. The user may then move the instrument in an organized manner to the next targeted site.
5. If necessary, apply precisely directed high-voltage electrocautery in conjunction with the application of the SBRF and suction devices in order to obtain hemostasis. This may be required for the largest and most vigorous hemorrhage.

6. Sealing Small to Medium Bile Ducts

1. Using the same method as described above, apply the instrument tip across the cut/injured edge of the liver parenchyma to seal small to medium bile ducts.

7. Model Euthanasia

1. At the completion of the experiment, euthanize the anesthetized model via exsanguination according to the institution's Animal Care Guidelines.
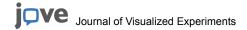
Representative Results

The SBRF device described herein provides effective hemostasis for a variety of solid organ injuries. The efficacy of the SBRF device in a porcine model has been described previously[8]. The results of this study are republished here with permission from the authors.

Using a porcine model, injuries of increasing severity were applied to four separate models. The injuries were described as surface decapsulation, superficial laceration, deep laceration, penetrating 'through and through' missile trajectories, and complete transection. Effective hemostasis was determined by five operating surgeons as well as a careful video review by a separate group of two surgeons. Regardless of the injury severity, the SBRF device was determined to be effective in achieving hemostasis by the operating surgeons in 99% of the injuries, and by the video review surgeons in 97% of the injuries. Additionally, due in large part to the simple design, the operating surgeons involved in the initial study also found the device very easy to use[8].

The depth of the tissue penetration by the SBRF device was also determined in the previous porcine study[8]. The tissue penetration varied by target organ (**Table 1**). Notably, no tissue coagulation was observed when the inferior vena cava was targeted. This is likely due to the heat sink effect from significant blood flow and further supports the safety of the device's use around large vascular structures.

Figure 1: Saline/bipolar radiofrequency (SBRF) energy device. (**A**) This panel shows the SBRF device handpiece with the single-button design. (**B**) This panel shows the SBRF's 6.0 blunt bipolar sealing tip. Please click here to view a larger version of this figure.

Target organ	Depth of tissue penetration (mm)
Liver	2.7
Spleen	2.5
Kidney	3
Abdominal wall	2.4
Lung	1.1
Heart	1.3
Inferior vena cava	0

Table 1: Tissue penetration by target organ. This table has been modified from Ball *et al*[8].

Discussion

The rapid and effective control of hemorrhage is an essential component of modern damage control resuscitation[10]. A variety of operative and adjunctive techniques are available to arrest hemorrhage in a solid organ injury[3]. None of these techniques has proven to be universally applicable or successful in achieving hemostasis. The initial experience with the SBRF device described here has been positive[6,7,8]. This device is a valuable adjunct in achieving rapid and effective hemostasis in complex solid organ injuries.

In the current protocol, a porcine model was employed to simulate traumatic solid organ injuries. In doing so, the characteristics of the study's device are demonstrated in a high-fidelity setting. Porcine models have previously been demonstrated to be an effective model for equivalent human disease processes, particularly in the area of surgical education and simulation[11].

This protocol does have one notable limitation. The simulated injuries are created in a porcine model which is anesthetized under standardized conditions. Although the simulated injuries are relatively realistic, they are created in isolation to the physiologic state of the model. As a result, the model is not necessarily exposed to the acute coagulopathy and other physiological derangements that normally influence outcomes in traumatically injured patients.

Despite this limitation, the human patient experience with the device in solid organ hemorrhage has been extremely encouraging[6,7]. The SBRF device is simple to use and has demonstrated effective hemostasis in a highly selected group of trauma patients with challenging solid organ injuries. The SBRF device also allows simultaneous hemostasis and the sealing of small- and medium-sized bile ducts within the liver.

To our knowledge, there have been no reports of short-term or long-term complications related directly to the use of an SBRF device in trauma patients or during its use in elective surgery. Because the device functions at a relatively low operating temperature (*e.g.*, 100°C), there is less risk of injury to innocent bystander vascular structures in the operative field. For example, there appears to be no or very limited risk to structures such as the inferior vena cava and portal vein due to the strong heat sink created by the high blood flow through these structures. As the use of and the experience with the SBRF device increases, its users will have to remain observant for any potential complications.

Damage control laparotomy is associated with significant potential morbidity and mortality[11,12]. This is particularly true in the management of complex solid organ injuries. Possessing a versatile device for effective primary hemostasis in these complex injuries may lead to a reduction in the need for temporary abdominal closure and its inherent risks. It is also a superb instrument for surgeons who must stop ongoing hemorrhage in these challenging areas, but do not necessarily have comfort in either the intra-organ anatomy or the anatomical region of the injury.

Disclosures

The authors have nothing to disclose.

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