Surg Endosc (2003) 17: 1228–1230 DOI: 10.1007/s00464-002-8833-7

Springer-Verlag New York Inc. 2003

and Other Interventional Techniques

Comparison of ultrasonic energy, bipolar thermal energy, and vascular clips for the hemostasis of small-, medium-, and large-sized arteries

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Received: 3 October 2002/Accepted: 5 November 2002/Online publication: 13 June 2003

Abstract

Background: Advanced laparoscopic procedures have necessitated the development of new technology for vascular control. Suture ligation can be time-consuming and cumbersome during laparoscopic dissection. Titanium clips have been used for hemostasis, and recently plastic clips and energy sources such as ultrasonic coagulating shears and bipolar thermal energy devices have become popular. The purpose of this study was to compare the bursting pressure of arteries sealed with ultrasonic coagulating shears (UCS), electrothermal bipolar vessel sealer (EBVS), titanium laparoscopic clips (LCs), and plastic laparoscopic clips (PCs). In addition, the spread of thermal injury from the UCS and the EBVS was compared.

Methods: Arteries in three size groups $(2-3, 4-5, 4-7)$ mm) were harvested from freshly euthanized pigs. Each of the four devices was used to seal 16 specimens from each size group for burst testing. A 5-Fr catheter was placed into the open end of the specimen and secured with a purse-string suture. The catheter was connected to a pressure monitor and saline was infused until there was leakage from the sealed end. This defined the bursting pressure in mmHg. The ultrasonic shears and bipolar thermal device were used to seal an additional 8 vessels in each size group, which were sent for histologic examination. These were examined with hematoxylin and eosin stains, and the extent of thermal injury, defined by coagulation necrosis, was measured in millimeters. Analysis of variance was performed and, where appropriate, a Tukey's test was also performed.

Results: The EBVS's mean burst pressure was statistically higher than that of the UCS at 4 or 5 mm (601 vs 205 mmHg) and 6 or 7 mm (442 vs 175 mmHg). EBVS had higher burst pressures for the 4 or 5-mm group (601 mmHg) and 6 or 7-mm group (442 mmHg) compared with its pressure at 2 or 3 mm (128 mmHg) $(p = 0.0001)$. The burst pressures of the UCS and EBVS at 2 or 3 mm were not significantly different. Both clips were statistically stronger than the thermal devices except at 4 or 5 mm, in which case the EBVS was as strong as the LC (601 vs 593 mmHg). The PC and LC were similar except at 4 or 5 mm, where the PC was superior (854 vs 593 mmHg). The PC burst pressure for 4 or 5 mm (854 mmHg) was statistically higher than that for vessels 2 or 3 mm (737 mmHg) but not different from the 6 or 7 mm pressure (767 mmHg). Thermal spread was not statistically different when comparing EBVS and UCS at any size (EBVS mean $= 2.57$ mm vs UCS mean $= 2.18$ mm).

Conclusions: Both the PC and LC secured all vessel sizes to well above physiologic levels. The EBVS can be used confidently in vessels up to 7 mm. There is no difference in the thermal spread of the LigaSure vessel sealer and the UCS.

Key words: Electrosurgery — Bipolar energy — Ultrasonic shears

Electrosurgery has impacted laparoscopy by allowing the secure division and coagulation of vascular structures without the application of clips or the tedium of suture ligation. Currently, bipolar thermal energy devices and ultrasonic devices are routinely employed for the ligation of blood vessels during laparoscopic operations. Despite their popularity, the capability and limitations of these devices to seal vessels of various sizes have been poorly delineated. In addition, a direct measurement of the thermal spread of these instruments is important to protect nearby tissues. The purpose of this study was to compare the bursting pressure of arteries sealed with ultrasonic coagulating shears (UCS) (Laparo-Sonic Coagulation Shears, Ethicon, Cincinnati, OH, USA), electrothermal bipolar vessel sealer (EBVS) Correspondence to: B. T. Heniford (LigaSure, Valleylab, Boulder, CO, USA), titanium

EBVS, electrothermal bipolar vessel sealer; UCS, ultrasonic coagulating shears; PC, plastic clip; LC, laparoscopic titanium clip

Table 2. Mean length of thermal spread (mm) based on vessel size

Device	2 or 3-mm vessel	4 or 5-mm vesse	6 or 7-mm vessel
EBVS	2.0	ر . ب	3.3
UCS	1.0	2.4	2.4
p value	NS	NS	NS

EBVS, electrothermal bipolar vessel sealer; UCS, ultrasonic coagulating shears; NS, not significant

laparoscopic clips (LCs) (Ethicon), and plastic laparoscopic clips (PCs) (Hem-O-Lok, Weck, Raleigh, NC, USA). In addition, the spread of thermal injury from the ultrasonic shears and the bipolar sealer was measured by evaluating the extent of coagulation necrosis of the vessel walls.

Materials and methods

Pigs weighing 20–30 kg were euthanized following a laparoscopic teaching course, and arteries were immediately harvested from the neck and abdomen. The diameter of the vessels was determined using a standard ruler from a surgical marking pen-and-ruler set. The four devices were used to seal 16 vessels, each in three different size groups (2–3, 4–5, and 6–7 mm). Vessels were sealed with the UCS on power level 3 and the EBVS was set at two illuminated bars. Clips were applied in the standard fashion using medium-sized titanium and plastic clips. Burst strength pressure testing consisted of placing a 5-Fr dual-lumen catheter into the cut end of the vessel, which was then occluded with a purse-string suture. One lumen of the catheter was attached to a 12-cc syringe of 0.9% normal saline for injection. The other lumen was attached to a Sorenson Transpac Transducer (Abbott Critical Care Systems). This in turn was attached to a Spacelabs 514 Patient Monitor, which measured pressure changes in mmHg. Saline was injected toward the sealed end until there was leakage of fluid from the end. This was considered the burst pressure. Standard statistical analysis was used to evaluate burst pressures.

An additional 48 specimens were harvested for histology. Eight vessels in each of the three size groups were sealed with the UCS and EBVS. These were stained with hematoxylin and eosin for light microscope examination. Two histologists, blind to the type of instrument used, measured the extent of thermal injury from the cut edge of the vessel, as defined by coagulation necrosis.

Analysis of variance (ANOVA) was performed to determine burst pressure differences between devices at each vessel size. ANOVA was also performed to determine pressure differences based on vessel size for each individual device. Where appropriate, a Tukey's test was performed. Statistical significance was defined as $p < 0.05$.

Results

The EBVS's mean burst pressure was statistically higher than that of the UCS at 4 or 5 mm (601 vs 205 mmHg) and 6 or 7 mm (442 vs 174 mmHg) ($p < 0.0001$) (Table 1). The burst pressures of the UCS and EBVS at 2 or 3 mm were not statistically different. Both clips were statistically stronger than the thermal devices except at 4 or 5 mm, where the EBVS was as strong as the LC (601 vs 593 mmHg). The PC and LC were similar except at 4 or 5-mm, where the PC was superior (854 vs 593 mmHg) $(p < 0.0001)$. The EBVS had higher burst pressures for the 4 or 5-mm group (601 mmHg) and the 6 or 7 mm group (442 mmHg) compared with its pressure at 2 or 3 mm (128 mmHg) ($p \le 0.0001$). The PC burst pressure for 4 or 5-mm (854 mmHg) was statistically higher than its burst for vessels 2 or 3 mm (737 mmHg) ($p = 0.02$) but not different from the pressure at 6 or 7 mm (767 mmHg). The UCS and LC did not have statistically different pressures based on vessel size.

Both the EBVS and UCS showed increasing thermal spread with increasing vessel size (Table 2). However, there was no statistical difference in thermal injury between the devices at any vessel size. The overall mean spread regardless of vessel size was also not statistically different between EBVS and UCS at any size (EBVS mean = 2.57 mm vs UCS mean = 2.18 mm).

Discussion

Due to the cumbersome nature of suture ligation of vascular pedicles during minimally invasive surgery, the use of clips and unique energy sources for hemostasis have become extremely popular. Each method has its limitations. Our aim in this experiment was to better define the operating parameters of these instruments by determining the burst pressures of various-sized vessels after instrument application and delineating the distance of thermal injury imposed by the energy sources.

Titanium clips are a mainstay in open surgery and have been liberally used in minimally invasive procedures. Clips create a seal by mechanical compression and pose little risk to surrounding tissues when accurately applied. Although clips achieve reliable seals, they carry the risk of dislodgment with tissue manipulation. Clips require precise dissection of vessels prior to application, and they can hinder the use of devices such as

surgical staplers because of their bulk. Plastic clips have been designed with a toothed grasping surface and locking device to overcome the problem of clip dislodgment but still have the other disadvantages inherent to clips.

Ultrasonic energy is also employed for vessel coagulation and division. UCS transfer high frequency (55,000 cycles/s Hz) to a vibrating blade that is used to grasp tissue against a nonvibrating pad. The vibration denatures hydrogen bonds in tissue and vessel proteins forming a coagulum. This coagulum seals the vessel lumen [2]. The UCS have the advantage of dividing tissue at the time of coagulation and are available in 5 and 10-mm sizes for laparoscopy. The UCS are Food and Drug Administration (FDA) approved for vessels up to 3 mm in diameter.

The EBVS was developed for laparoscopic and open surgery to ligate vessels and tissue bundles. It is FDA approved for use on vessels up to 7 mm in diameter. This device produces a hemostatic seal by applying high current (4 A) and low voltage $(< 200 \text{ V})$ to the vessel. This energy denatures the collagen and elastin in the vessel wall, and the pressure applied by the instrument apposes the walls to allow the proteins to form as a seal [3]. Histologically, the internal elastic lamina is preserved, and collagen bundles form across the previous lumen. The instrument is available in various sizes for both open and laparoscopic surgery. The laparoscopic versions are either 5 or 10 mm. The 10-mm laparoscopic EBVS has a cutting blade within it for tissue transection.

In this study, titanium clips and plastic clips both created seals resistant to pressures that were statistically higher than those of the electrothermal devices except in the 4 or 5-mm vessel range, where the EBVS performed as well as the titanium clips. Although clips create a dependable seal, they carry the risk of dislodgment and can act as a nidus for adhesion formation. Titanium clips have been shown to be adhesiogenic, but no data exist regarding adhesion formation to the newer plastic clips [4]. Additionally, the ability of the plastic clip locking mechanism to decrease clip slippage needs further study. The EBVS creates seals in the larger vessel sizes that have burst strengths at least three times physiologic normals. The device appears as if it would adequately seal the majority of vessels that a general surgeon would encounter in day-to-day surgery, including mesenteric vessels. The UCS should be limited to use in vessels 3 mm or less in diameter.

The use and development of energy devices for hemostasis and tissue ligation will likely continue to increase. The importance of quantifying the thermal spread of these devices to prevent injury to adjacent structures cannot be overstated. Our study correlates with others that have shown the thermal spread of the EBVS and UCS to be limited to a few millimeters [5, 6]. These measurements reflect the spread along purposefully sealed tissues. Another important issue concerns the situation in which energy devices create injury to surrounding structures, such as the intestine or ureter. Goldstein et al. [1] studied the extent of thermal injury along divided ureters in a porcine model and demonstrated the mean length of spread for the EBVS to be 2.11 mm, which was no different than the surrounding tissue injury induced by the UCS (1.92 mm). This quantification helps to determine the amount of devitalized tissue that would need to be resected in order to perform a safe repair in the event of inadvertent injury. Study of these instruments to delineate their safe parameters of operation with regard to blood vessels and other organs must continue.

Conclusion

Our study demonstrates that the EBVS can be used confidently in vessels up to 7 mm in diameter. In vessels ranging from 4 to 7 mm, it has mean bursting pressures well above physiologic systolic blood pressure. The UCS is effective for vessels in the 2 or 3-mm range only. Both PC and standard LC achieve substantial bursting pressures for all vessel sizes. Thermal sealing devices have very little spread of thermal injury regardless of the size of the vessel they are used to seal.

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