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Hemostasis with the Ultrasonic Scalpel

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ABSTRACT

Background and Objectives: The ultrasonically activated scalpel is a surgical instrument that is used in minimally invasive surgery to safely cut and seal vessels. This study reported the experimental observations of the use of a laparoscopic ultrasonic scalpel, including its safety and feasibility. in sealing vessels of different diameters in an in vivo animal model during both physiological and supraphysiological blood pressure (BP) conditions.

Methods: One healthy female swine was used. We performed resections of the omentum, biopsies in different regions of the liver, and a hysterectomy. Vessels with diameters ranging from 2 to 10 mm were sealed with the ultrasonic scalpel under regular hemodynamic conditions and during pharmacologically induced arterial hypertension (BP challenge).

Results: For 10 random cuts made in the omentum and during the hysterectomy, the ultrasonic scalpel was effective and fast, with no immediate or delayed bleeding. Bipolar energy, sutures, and hemoclips were not required to control bleeding. No bleeding was observed in sealed vessels up to 8 mm, even during BP challenges sustained for longer than 5 minutes. When testing vessels of 10 mm, bleeding occurred in 1 common iliac vein before 10 minutes of waiting (the point of bleeding was easily identified) and bleeding occurred in 1 of the common iliac arteries during the BP challenge.

Conclusion: Our findings corroborate that the ultrasonic scalpel can safely seal arteries up to 8 mm in diameter to prevent or control bleeding during laparoscopic procedures, even when BP exceeds normal levels.

Key Words: Ultrasonic scalpel, Laparoscopic procedures, Surgical instrument, Minimally invasive surgery.

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INTRODUCTION

The growing use of ultrasonic energy in laparoscopic surgeries reflects the advantages enumerated here and its record as one of the safest energies.[1] The ultrasonically activated scalpel – also known as the ultrasonic scalpel – works by generating the high-frequency harmonic motion of a metallic rod, which denatures proteins. These vibrations can simultaneously cut tissues and coagulate. Cutting is very effective with less bleeding and less thermal damage to the surrounding tissues and, hence, less smoke. There is no transmission of electricity to the patient and no neuromuscular stimulation.[1–4]

Multiple studies have demonstrated the superiority of the ultrasonic scalpel in comparison with conventional energy systems in several surgical subspecialties. The most valued benefits reported are shorter surgical times and less intraoperative bleeding.[5–9]

This study reports the experimental observations of the textural cutting and hemostatic effect of a laparoscopic ultrasonic scalpel device, including its safety and feasibility, for sealing arteries and veins of different diameters in an animal (porcine) model under both physiological and supraphysiological blood pressure (BP) conditions.

MATERIALS AND METHODS

This study was carried out through a partnership between Crispi Institute for Minimally Invasive Surgery and the Faculty of Medical Sciences and Health of Juiz de Fora (SUPREMA). The experimental surgery was conducted in the SUPREMA Surgical Training Center (Juiz de Fora, Minas Gerais, Brazil) with the approval of the Institutional Animal Care and Use Committee (CEUA-SUPREMA Number 004/2017) in accordance with the "Guide for the Care and Use of Laboratory Animals" of the National Research Ethics Commission of the Brazilian Ministry of Health. The animal used in this study had a health certificate issued by a veterinarian, which was provided by the supplier. In addition, the animal was evaluated clinically by the veterinarian responsible for the study (F.L.F.M.) before and during the experimental surgery.

In this experimental surgery, we used a CS3605H model ultrasonic scalpel (Reach Surgical Inc., Tianjin, China), with a 5-mm laparoscopic curved tip shear and a 36-cm pistol (ANVISA Reg. No. 80047300623), attached to the Sound Reach® model CSUS6000 generator (ANVISA Reg. No. 80047300637). The device is composed of an ultrasonic blade that oscillates at 55 $\pm$ 1 KHz, which was configured at a power level of 3 (75% of the maximum power) or 5 (full power), following the manufacturer's operating instructions. Regarding the time for sealing vessels, the device was allowed to reach full transection, and the respective time durations (in seconds) were measured through video analysis.

One healthy female swine (Crossbreed Large White; age 6 months; weight 28 kg) that had fasted for 12 hours was premedicated with intramuscular midazolam (0.5 mg/kg) plus atropine (0.04 mg/kg) plus ketamine (2 mg/kg) plus acepromazine (0.1 mg/kg). General anesthesia was induced with intravenous propofol (4 mg/kg) and maintained with isoflurane (1.5 to 2.5 vol%) in oxygen after oral intubation (flow rate 2 L/min). Monitoring during anesthesia was provided with continuous electrocardiography, pulse oximetry, rectal thermometer, and sphygmomanometer. The ambient temperature of the operating suite was maintained between 21° and 23°C.

During laparoscopy, the animal was placed in dorsal recumbency and the CO_2 pneumoperitoneum was set at 10 mm Hg. Intravenous epinephrine (total dose 1 mg) was used to increase blood pressure above the physiologic range, in order to simulate intraoperative arterial hypertension. The animals were euthanized by deep anesthesia followed by potassium chloride 19.1% (10 mL) intravenous injection.

This experimental surgery was performed by a multidisciplinary team, which included 2 surgeons (1 gynecologist [C.P.C.] and 1 proctologist [P.S.S.R.J.]) with extensive experience with complex laparoscopic procedures and 2 very experienced veterinary anesthesiologists (F.L.F.M. and M.M.F.). All the intraoperative decisions were shared with another experienced group (1 experienced anesthesiologist [M.F.F.] and 1 experienced surgeon [C.P.C.J.]) who worked as external experimental observers in order to obtain consensual conclusions and minimize biases.

Briefly, the study was carried out in 2 phases. In the first phase, the ultrasonic scalpel was used in resections in several porcine organ systems with 2 different power levels (3 and 5). These included resections of the mesosigmoid and of the omentum and performance of a total hysterectomy with resection of the ovaries, uterine ligaments, and horns. Also, although not designed for this purpose, the ultrasonic scalpel was applied in different sites of the liver (at the lower power level) in order to simulate liver biopsies, where bleeding is a paramount concern. Following the manufacturer's instructions, cuts were made using the distal two-thirds of the active portion of ultrasonic scalpel.

The second phase evaluated how well the ultrasonic scalpel (at the lower power level) cut different blood vessels (arteries and veins) and the hemostatic effect that is, the sealing of these blood vessels (**Figure 1** and **Figure 2**). After skeletonization (dissection to isolate the blood vessels), the diameter of each artery was estimated by visual inspection to compare the diameter of the vessel with the known benchmarks of the scalpel (5 and 10 mm) as shown in Figure 2A, inset. The vessels were thus classified as 2 to 3 mm, 4 to 5 mm, 7 to 8 mm, and 10 mm in diameter. Even though it is uncommon to seal vessels larger than 5 mm with an energy device, we purposely exceeded this caliber to investigate if the ultrasonic scalpel was also effective in sealing larger vessels up to 10 mm in diameter. The hemostatic effect of the ultrasonic scalpel was evaluated systematically at 2 time points: immediately after cutting the vessels and up to 10 minutes after cutting. These assessments were made during normal hemodynamic conditions and after pharmacologically induced extreme arterial hypertension (blood pressure challenge).

RESULTS

The physiological parameters during surgery were cardiac frequency 85 to 140 bpm, systolic blood pressure 90 to 130 mm Hg, diastolic blood pressure 50 to 80 mm Hg, and rectal temperature 35° to 37°C. At the end of the surgery,

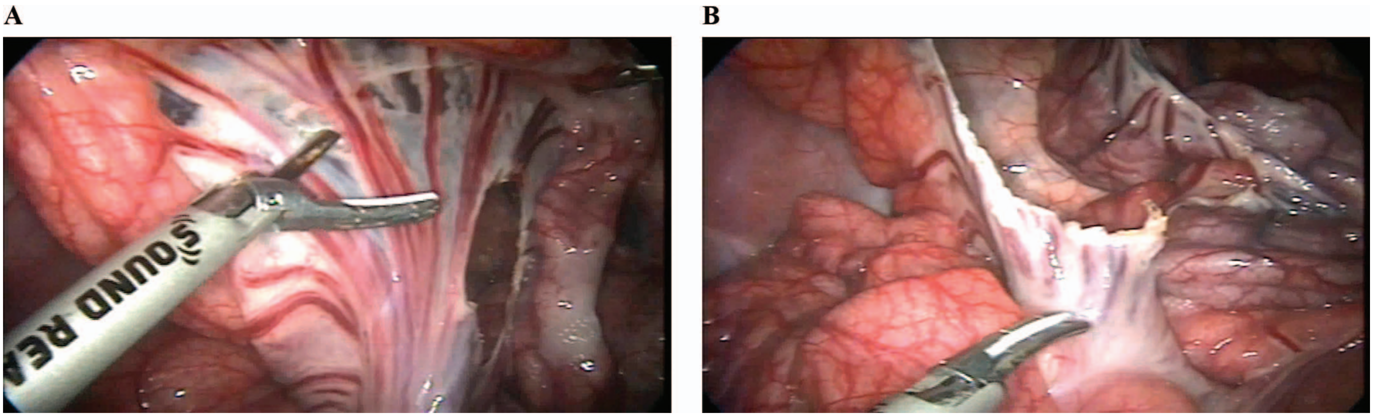

Figure 1. Mesenteric blood vessels. **A.** The 4- to 5-mm mesenteric vessels prior to cutting and sealing. **B.** Immediately after sealing, with no sign of bleeding.

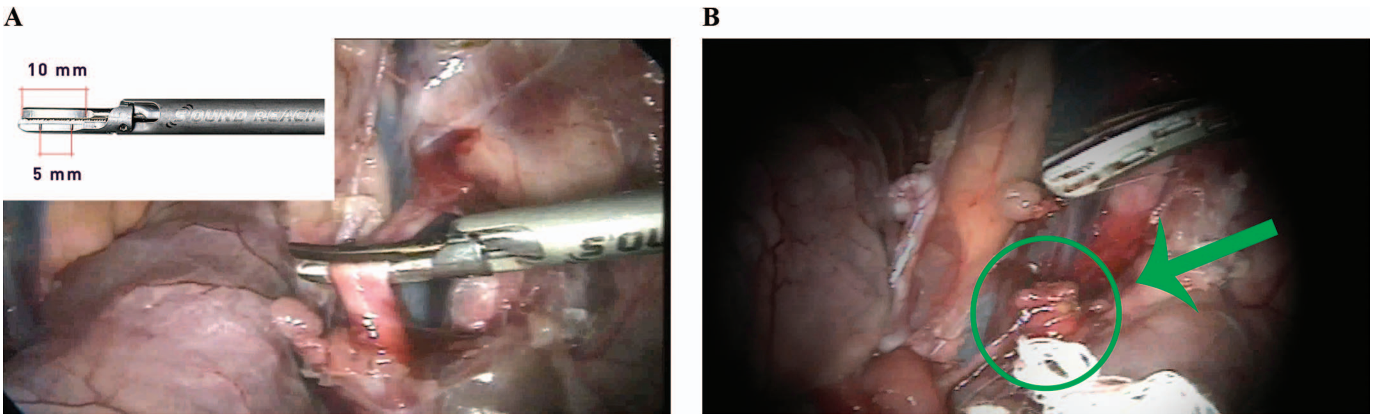

Figure 2. Branch of the iliac artery. **A.** Preparation for sealing after skeletonization of a 7- to 8-mm vessel (benchmarks of the scalpel shown in the inset image). **B.** Shortly after the sealing, without any signs of bleeding.

when an extreme arterial hypertension was purposely obtained with intravenous epinephrine administration (blood pressure challenge), the systolic blood pressure reached values ranging from 220 to 240 mm Hg and the heart rate reached values ranging from 226 to 230 bpm.

Evaluation of Cutting Speeds

Initially, 10 random cuts were made in the omentum using the higher power, which results in a faster cutting speed. All cuts were fast and safe; no blood was observed at the surface of the sectioned vessel.

During the hysterectomy, all surgical steps were successfully performed in tissues of different thicknesses, vascularization, and resistance. The power level used (3 or 5) was at the discretion of the surgeon. Here again, the ultrasonic scalpel was very effective and fast, with no bleeding. No bipolar energy, sutures, or hemoclips were needed to control bleeding.

Finally, despite knowing this equipment had not been designed for this purpose, we tested the ultrasonic scalpel on hepatic tissue, always using the lower power. For the peripheral portions of the liver, in which the scalpel aperture was able to grasp the tissue without difficulty (ie, where the thickness was less than 6 to 8 mm), the cut was completely normal and without bleeding on the surface; this was repeated in 5 randomly selected areas. However, the deeper the cut into the hepatic tissue and, thus, the thicker the tissue, the poorer was the hemostasis. Although the cut remained effective, the sealing quality diminished inversely with the thickness of the hepatic tissue. When the tissue was thicker than 10 mm, it was difficult for the scalpel aperture to grasp the volume of tissue, and the surface of the cut area tended to continue bleeding.

Evaluation of Hemostasis (Vessel Sealing)

The vessels were selected to be cut at power level 3, as recommended by the manufacturer.

Initially, 12 mesosigmoid and omentum blood vessels between 2 and 3 mm were randomly selected to be cut. Sealing was effective; no surface blood was visible immediately after the cutting or 10 minutes later. Eight mesenteric vessels, all 4 to 5 mm in diameter, were sectioned. Again, no bleeding was observed at the sectioned surface immediately after cutting or 10 minutes later (Figure 1).

To test the ultrasonic scalpel on vessels with calibers exceeding 5 mm, we initially used 6 branches of the common iliac arteries, all with a 7- to 8-mm diameter. Results were identical to those obtained with smaller -caliber vessels (Figure 2). There was no bleeding in sealed vessels even on blood pressure challenge.

When the ultrasonic scalpel was tested on vessels of 10-mm diameter, some differences were observed depending on whether the vessel was venous or arterial. We tested the 2 common iliac veins and the 2 common iliac arteries. When the ultrasonic scalpel was tested on the common iliac veins, there was bleeding in one of them before 10 minutes of waiting (at exactly 3 minutes and 5 seconds); the bleeding point being easily identified. There was no bleeding in the contralateral vein even on blood pressure challenge. In the arteries, the sealing power was promising at the initial time. However, there was bleeding in 1 of the common iliac arteries on blood pressure challenge that is, when systolic blood pressure was raised pharmacologically and reached values from 220 to 240 mm Hg for longer than 5 minutes. There was no bleeding in the contralateral artery even on blood pressure challenge.

The time durations to reach full transectionand the evaluation of the bleeding are summarized in **Table 1**.

DISCUSSION

Our experimental observations corroborate previous studies in which the seals obtained with ultrasonic technology in 5- to 7-mm-diameter vessels were reliable.10 The experimental surgery was performed satisfactorily and no complications were observed. The animal was maintained anesthetized through the study procedures.

Ultrasonic energy is nothing new. Indeed, the use of harmonic instruments is already well established in some hospitals and medical teams. It is particularly advantageous in surgeries in which delicate dissection and the avoidance of tissue damage from lateral heat damage are required. With a single instrument able to both cut and coagulate effectively, numerous instrument exchanges – between scalpel and cautery – are eliminated.

Table 1.
Evaluation of the Ultrasonic Scalpel for Sealing Vessels With Diameters Ranging From 2 to 10 mm

Vessels	Time to Reach Full Transection (seconds)	Immediately After Sealing	Bleeding	Upon Blood Pressure Challenge
			Up to 10 min After Sealing	
2 to 3 mm: mesosigmoid (n = 7)	2.5 [2.1–3.1]	No	No	No
2 to 3 mm: omentum (n = 5)	2.5 [2.2–3.2]	No	No	No
4 to 5 mm: mesenteric (n = 8)	3.4 [3.0–4.3]	No	No	No
7 to 8 mm: branches of iliac arteries (n = 6)	6.6 [6.3–8.0]	No	No	No
10 mm: left common iliac artery	13.6	No	No	No
10 mm: left iliac common vein	10.0	No	Yes	—
10 mm: right common iliac artery	14.6	No	No	Yes
10 mm: right common iliac vein	9.1	No	No	—

Time to reach full transection: median [max–min]. The vessels were selected to be cut at power level 3, as recommended by the manufacturer. During blood pressure challenge, extreme arterial hypertension was purposely obtained with intravenous epinephrine administration (systolic blood pressure 220 to 240 mm Hg and heart rate 226 to 230 bpm for 5 min).

Our study has several limitations, which may limit the generalizability of our conclusions. One limitation is the fact that the multiple tests of the sealing efficacy of the ultrasonic scalpel were performed on a single animal. We followed the guiding principles for the most ethical use of animals in testing. Federal laws, regulations, and Institutional policies require us to adhere to the principles of the 3 Rs (replacement, reduction, and refinement) in all animal research. These principles encourage researchers to use methods that enable them to obtain comparable levels of information using the fewest animals possible. Yet, our surgeons are highly experienced in laparoscopic pelvic surgery. The results of this study may not be replicated by less experienced surgeons, that is, those with little experience in complex surgical resections performed laparoscopically.

CONCLUSION

When a healthy young swine was used as the animal model, the ultrasonic scalpel effectively cut and sealed vessels up to 7 to 8 mm in diameter, even when the vessels were subjected to supraphysiological blood pressure levels and tachycardia. These findings reinforce the indication of the harmonic scalpel as a safe and functional surgical instrument as long as the manufacturer's recommendations are followed.

References:

1. Sista F, Abruzzese V, Schietroma M, Cecilia EM, Mattei A, Amicucci G. New harmonic scalpel versus conventional hemostasis in right colon surgery: a prospective randomized controlled clinical trial. *Dig Surg.* 2013;30:355–361.

2. Irfan M, Aliyu YA, Baharudin A, Shahid H. Harmonic scalpel for a bloodless partial glossectomy: a case report. *Med J Malaysia.* 2011;66:148–149.

3. Hodgson WJ, Poddar PK, Mencer EJ, Williams J, Drew M, McElhinney AJ. Evaluation of ultrasonically powered instrument in the laboratory and in the clinical setting. *Am J Gastroenterol* 1979;72:133–140.

4. Roye GD, Monchik JM, Amaral JF. Endoscopic adrenalectomy using ultrasonic cutting and coagulating. *Surg Technol.* 2000;IX:129–138.

5. Lee YJ, Kim HY, Han HH, Moon SH, Byeon JH, Rhie JW, Ahn ST, Oh DY. Comparison of dissection with harmonic scalpel and conventional bipolar electrocautery in deep inferior epigastric perforator flap surgery: a consecutive cohort study. *J Plast Reconstr Aesthet Surg.* 2017;70:222–228.

6. Lim DR, Cho DH, Lee JH, Moon JH. Comparison of a hemorrhoidectomy with ultrasonic scalpel versus a conventional hemorrhoidectomy. *Ann Coloproctol.* 2016;32:111–116.

7. Aoki T, Murakami M, Koizumi T, Enami Y, Koike R, Fujimori A, Kusano T, Matsuda K, Yamada K, Nogaki K, Watanabe M, Otsuka K, Gareer H, Kato T. Skeletonization and isolation of the glissonean and venous branches in liver surgery with an ultrasonic scalpel technology. *Int Surg.* 2015;100:1048–1053.

8. Lang BH, Ng SH, Lau LL, Cowling BJ, Wong KP. A systematic review and meta-analysis comparing the efficacy and surgical outcomes of total thyroidectomy between harmonic scalpel versus Ligasure. *Ann Surg Oncol.* 2013;20:1918–1926.

9. Fitz-Gerald AL, Tan J, Chan KW, Polyakov A, Edwards GN, Najjar H, Tsaltas J, Vollenhoven B. Comparison of ultrasonic shears and traditional suture ligature for vaginal hysterectomy: randomized controlled trial. *J Minim Invasive Gynecol.* 2013;20:853–857.

10. Timm RW, Asher RM, Tellio KR, Welling AL, Clymer JW, Amaral JF. Sealing vessels up to 7 mm in diameter solely with ultrasonic technology. *Med Devices (Auckl).* 2014;7:263–271.