SURGERY

Original Research

Laparoscopic sealing devices on animal models: searching the least harmful for the surrounding tissue

Bogdan Petrut[1,2], Cristina Eliza Bujoreanu[2], Vasile Vlad Hardo[3], Cristian Vasile Maris[3], Adrian Grivei[3], Bogdan Fetica[4]

1) Department of Urology, Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania

2) Department of Urology, Transilvania Hospital, Cluj-Napoca, Romania

3) Department of Urology, "Prof. Dr. I. Chiricuta" Institute of Oncology, Cluj-Napoca, Romania

4) Department of Pathomorphology, "Prof. Dr. I. Chiricuta" Institute of Oncology, Cluj-Napoca, Romania

Abstract

Background and aims. Sealing devices can produce mechanical and thermal damage to collateral tissue, with few studies analyzing these effects. However, the least harmful device for the surrounding tissue will achieve optimal functional results.

Methods. We compared the tissue damage made by different laparoscopic electro-cauterization instruments while using them as hemostatic means on the stomach and epiploon of Wistar rats, respectively on the diaphragm and urinary bladder of a porcine model. Five devices were used based on either radio frequency diathermy or ultrasound energy, with one coagulation cycle for the automatic hemostasis. Infrared thermography tracked thermal injury on the collateral tissue made by each device on the porcine model.

Results. We analyzed the collateral tissue with irreversible thermal damage caused by each sealing device with infrared thermography with ANOVA statistical test. Based on histopathological examination, we calculated the mean value of the area with edema and coagulation necrosis caused by these maneuvers of hemostasis as a pattern of tissue damage around the sealing mark of every hemostatic device.

Conclusions. Compared with bipolar sealing devices, ultrasound-based devices offered better collateral tissue preservation, with the smallest damaging temperature spread, on animal models. Further research on ultrasound vs. bipolar sealing devices used as hemostatic tools could more accurately assess their impact on functional outcomes in real life surgery setting.

Keywords: sealing devices, animal model, thermography, tissue damage, laparoscopic devices

DOI: 10.15386/mpr-2768

Manuscript received: 11.07.2024
Received in revised form: 12.09.2024
Accepted: 03.10.2024

Address for correspondence:
Cristina Eliza Bujoreanu
bujoreanucristina@yahoo.com

Background and aims

A perfect sealing device for laparoscopic electro-cauterization would be one that it is comfortable to handle and offers excellent hemostasis with minimal thermal damage, a high burst pressure, reduced risk of nerve damage through mechanical compression, and the lowest quantity of mist or smoke for the best visualization. Nevertheless, the reality of surgery comes with challenges such as tissue sticking, the effect of blood coagulum, multiple firing and repetitive use of the sealing device in the same location, difficult perpendicular placement of the devices on the tissue, and thermal damage. Different studies approached sealing devices searching for the best one regarding comfortable technical use, safety, and reliability without affecting oncologic and functional results. With different sealing devices available nowadays, the damage to the surrounding tissue during coagulation is diminished, and the surgeon obtains control, precision and multifunctionality while operating [1].

In our tertiary healthcare center, the predominant surgical treatment for uro-oncologic pathologies is minimally invasive. Because of routinely utilizing different devices for sealing and transecting blood vessels instead of laparoscopic suture ligation, we are interested how these sealing devices harm the surrounding tissues. The objective of the present paper is to discover which is the least harmful device for surrounding tissues, offering better tissue preservation by minimizing cell lysis and tissue destruction outside the jaws of the sealing device.

Methods

Sealing devices

The devices were categorized depending on the energy used for sealing or hemostasis, no references were made regarding the company that produced them or the name of the sealing device. Therefore, the following sealing devices were used: B1-5: radio frequency diathermy (first device), 5 mm; B1-10: radio frequency diathermy (first device), 10 mm; B2: radio frequency diathermy (second device); BU: radio frequency diathermy and ultrasound energy; U: ultrasound energy. The same compression force was used on the tissues with each sealing device.

Scientific purpose of using an animal model

The first step of our experiment consisted in using the devices (B1-10, B2, BU, U) on the stomach and epiploon of 6 female Wistar rats weighing 300 grams. The second step consisted in choosing a bigger animal model (porcine), as the D muscle and the urinary bladder (UB) harvested from a pig weighing 30 kg offer us a tissue that is very close to human tissue due to its histologic properties. A bigger tissue sample and different types of tissue were preferable for thermography and histopathological examination. This was helpful as we could determine the gentlest sealing device to be used as a hemostatic tool during laparoscopic surgical treatment in cases of nerve sparing procedures.

Experimental protocol

First step - Wistar rats

The experiment was performed on 6 female Wistar rats weighing 300 grams that were kept under anesthesia during the surgical intervention. Four different devices (B1-10, B2, BU, U) were used as hemostatic tools on the stomach and epiploon of the animal model with one coagulation cycle for the automatic hemostasis. The Wistar rats were kept alive for 2 more hours after the surgical intervention before being sacrificed, observing the ethical guidelines for the use of animals in research. The tissue samples were drawn and analyzed by a histopathologist to determine the degree of cell lysis and tissue damage. The external margin of the wound made by the mechanical compression of the tissue was considered a reference point for the measurements. A mean value was calculated for each series of samples, respectively for each of the 4 devices that were used.

Second step - Porcine model

The second step of the experiment consisted in using one pig weighing 30 kg that was euthanized under anesthesia, observing the ethical guidelines for the use of animals in research. Within the next 30 minutes, the D muscle and the UB were harvested. We have chosen the D and the UB because of their histology consisting in muscle, connective tissue, vessels, and nerves. Each organ was portioned into 5 samples of tissue strips. The five different sealing devices mentioned above were used on one tissue sample twice for each harvested organ, with one coagulation cycle for the automatic hemostasis.

Infrared thermography was used with an infrared camera (Testo thermal imaging camera) assessing the maximum temperature (°C) during the process of sealing and immediately after the sealing device was removed from the tissue. Also, the mean value of the extent of collateral tissue with irreversible thermal damage caused by each sealing device was measured (Calipers measuring software-units), focusing on the tissue area with temperature above 42°C (included).

The tissue samples were drawn and placed in 10% formaldehyde solution and a histologic analysis was performed by a histopathologist to determine the degree of cell lysis and tissue damage. Each series of tissue samples was coded by the coordinator of the team, so that the histopathologist was not aware of which of the five devices was used on it. The external margin of the wound made by the mechanical compression of the tissue was considered a reference point for the measurements, presenting indentations in the tissue. The tissue that suffered thermal injury had cells presenting large vacuoles, lack of striation with disrupted muscle fibers and shrunken nuclei. We measured the distance from the external margins of the wound and the area with normal muscle tissue presenting normal cell volume, striation and intact nuclei. A mean value was calculated for each series of samples, respectively for each of the 5 devices we used, both for the D muscle and the UB.

* Regarding electrosurgical generator power used, data are available upon request, but the most important aspect has been added - it was the same power for all specimens and we used one coagulation cycle for the automatic hemostasis. This signifies that the device stopped coagulation through its automated feedback from tissue impedance. The tissue was approached perpendicularly each time to ensure homogeneity in the experiment.

Ethical statements

The present animal model study was managed respecting the Helsinki ethical guidelines for the use of animals in research, according to local and national ethical and regulatory principles and local licensing arrangements. The study has been approved by the Institutional Ethics Committee – Animal care and use - "Prof. Dr. I. Chiricuta" Oncology Institute in Cluj-Napoca, Romania- no. 3076/28.03.2018.

Data analysis

The information was stored in an Excel document and the sealing devices were compared grouped as: group 1: B1-10, B2 and group 2: BU, U. ANOVA analysis was performed for thermography data- between groups B10, B2 and BU, U. Therefore, the focus remained the energy used for the tissue sealing or hemostasis, not the device itself or the producing company. Data regarding the exact sealing devices that were used are available upon request.

Results

The results from the histopathological examination of the 12 samples from the Wistar rat model, regarding the mean values of the microscopic extent of collateral tissue with irreversible cellular damage can be observed in figure 1. When grouped, (group 1: B1-10, B2 and group 2: BU, U), group 1 presented 758 μm vs. 482 μm in group 2 (microscopic extent of collateral tissue with irreversible cellular damage).

Regarding the second step of the experiment performed on the porcine model, the infrared thermography images are exemplified in figure 2, along with the assessment of the temperature peak (°C), the highest temperature is color-coded with white) during the process of sealing (first row- D). Also, the assessment of the extent of collateral tissue with irreversible thermal damage caused by each sealing device (Calipers measuring software- units), (this time the tissue area with temperature above 42°C, included, is color coded with white), immediately after the sealing device was removed from the tissue (second row- UB).

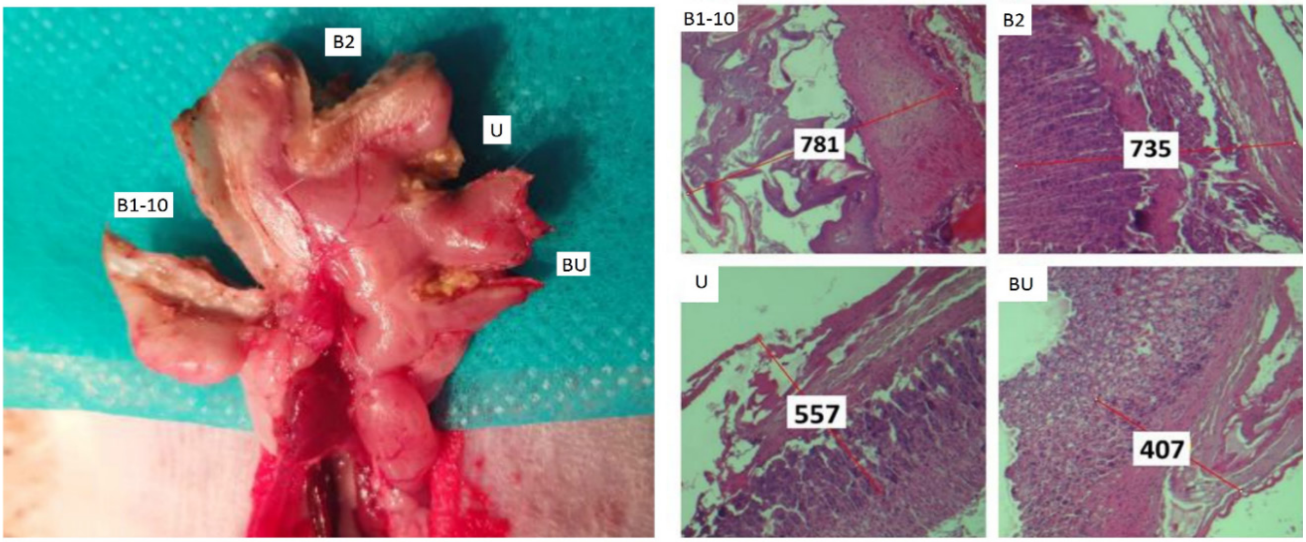

Figure 1. Macroscopic and microscopic examination (mean values of collateral tissue damage made by each sealing device- μm, microscopy 10X), after the usage of B1-10, B2, U and BU on the stomach and epiploon of a Wistar rat female weighing 300 grams.

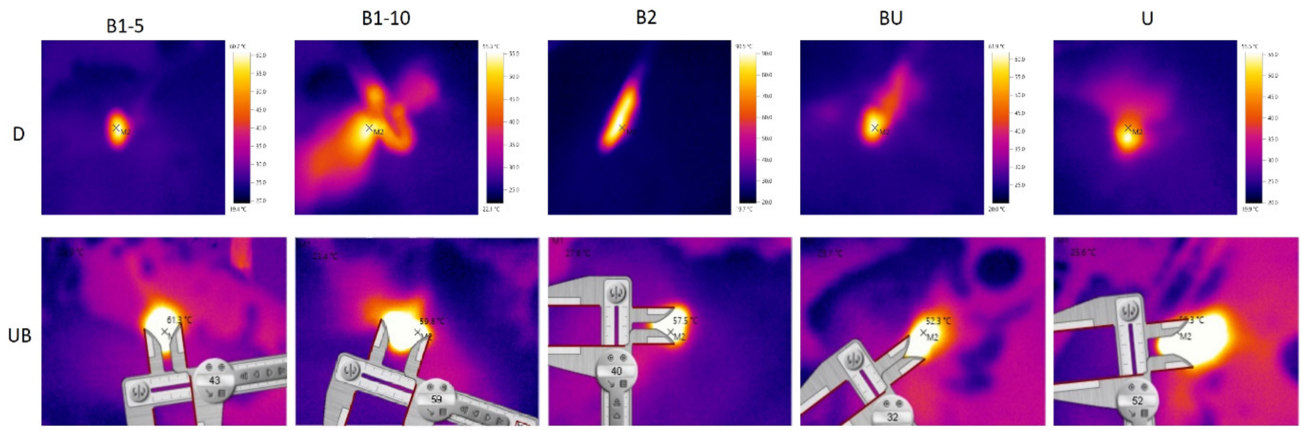

Figure 2. Infrared thermography images using Testo thermal imaging camera: assessment of the temperature peak (°C, the highest temperature is color coded with white) during the process of sealing (first row- D); assessment of the extent of collateral tissue with irreversible thermal damage caused by each sealing device (Calipers measuring software- units), (this time the tissue area with temperature above 42 °C, included, is color coded with white), immediately after the sealing device was removed from the tissue (second row- UB).

The measurements of 20 tissue samples with the mean values of the highest temperatures (°C) during and right after the sealing occurred, along with the area of irreversible tissue damage caused by each sealing device (units) are found in table I (diaphragm), and table II (urinary bladder). The sealing devices, classified from the gentlest one to the most damaging one, are represented in table III.

Table I. Mean values of the highest temperatures (°C) during and right after the sealing occurred, along with the area of irreversible tissue damage (Calipers measuring software- units) caused by each sealing device on the D.

D			
Device	**T during (°C)**	**T after (°C)**	**Damage (units)**
B1-5	58.4	59.3	31.25
B1-10	50.8	64.3	58.6
B2	93.8	60.3	30.25
BU	76	56.45	38.25
U	129.15	56.2	36.25

Table II. Mean values of the highest temperatures (°C) during and right after the sealing occurred, along with the area of irreversible tissue damage (Calipers measuring software- units) caused by each sealing device on the UB.

UB			
Device	**T during (°C)**	**T after (°C)**	**Damage (units)**
B1-5	64.65	58.6	42.5
B1-10	63.65	60.1	51
B2	88.05	59.75	34.75
BU	63.75	51.2	36
U	73.75	68.7	52.5

The dimension of the sealing device plays a role in collateral tissue damage (B1-5 vs. B1-10). When grouped (group 1: B1-10, B2 and group 2: BU, U), the results showed that ultrasound sealing devices were the least aggressive with surrounding tissue, when used on the D and the UB of a porcine model (40.75 units vs. 43.6 units). They offered the minimum collateral spread of a temperature that would irreversibly destroy it.

Table III. The sealing devices, classified from the gentlest one to the most damaging one, depending on the highest temperature (°C) during and right after the sealing occurred, along with the area of irreversible tissue damage (Calipers measuring software- units) caused by each sealing device on the UB.

D			UB		
T during (°C)	**T after (°C)**	**Damage (units)**	**T during (°C)**	**T after (°C)**	**Damage (units)**
B1-10	U	B2	B1-10	BU	B2
B1-5	BU	B1-5	BU	B1-5	BU
BU	B1-5	U	B1-5	B2	B1-5
B2	B2	BU	U	B1-10	B1-10
U	B1-10	B1-10	B2	U	U

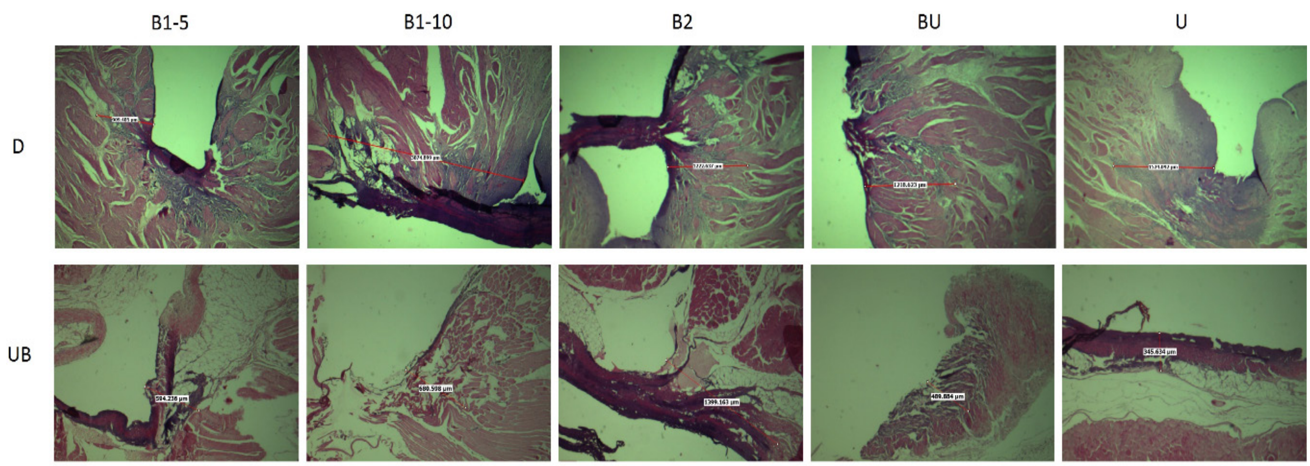

Figure 3. Samples from the histopathological examination of the D (first row) and UB (second row) sealed by each of the 5 devices (columns) and the degree of cell lysis and tissue damage (the tissue that suffered thermal injury had cells presenting large vacuoles, lack of striation with disrupted muscle fibers and shrunken nuclei) expressed as the distance (µm) from the external margins of the wound presenting indentations and the area with normal muscle tissue presenting normal cell volume, striation and intact nuclei.

ANOVA analysis was performed for thermography data- between group 1 (B1-10, B2) and group 2 (BU, U). Ultrasound based devices in group 2 (BU,U) presented statistically significantly less harm on surrounding tissue compared to diathermy based instruments in group 1 (B1-10, B2)- bladder of the porcine model (p=0.038) and diaphragm of the porcine model (p=0.026).

The histopathologic exam of the UB (Figure 3, first row) confirmed the results, as group 1 presented 2148.76 µm vs. 1371.35 µm in group 2 (microscopic extent of collateral tissue with irreversible cellular damage). The histopathologic exam of the D muscle (Figure 3, second row) confirmed the results, as group 1 presented 964.5 µm vs. 452 µm in group 2 (microscopic extent of collateral tissue with irreversible cellular damage).

We also report a lateral flame effect when using the sealing devices (exemplified in figure 2 when B1-10 device was used on the D).

Discussion

The feasibility of the initial experiment performed on Wistar rats led to the second step in which infrared thermography analysis was added comparing more sealing devices on a bigger animal model. A study showed that at 1 mm lateral distance from the bipolar vascular sealing device, the tissue temperature is usually above 45° C, which is considered critical temperature for neural damage. Also, if the instrument is used twice in the same area, even at 2 mm lateral distance the temperature from the bipolar instrument still produces neural damage. Therefore, the strategic placement of surgical instruments such as a rectangular clamp next to the sealing device can reduce the thermal spread as a heat sink, obtaining a temperature below 45°C at 1.2 mm lateral distance from the bipolar hemostatic device [2]. Also, many times the tissue cannot be approached perpendicularly, so advanced bipolar devices are designed for compression uniformity, which improves the delivery of energy and heat offering consistent sealing [3]. The present study does not analyze the time exposure of the tissues at different temperatures and does not take into account the use of the sealing device repetitively in nearby areas along with the intra-abdominal temperature. Even so, the histopathological results clearly show the effect of the sealing devices, with ultrasound devices being the gentlest ones with surrounding tissue. An interesting fact is that BU device surpassed U device in our experiment. An important aspect may be the lateral flame effect that we observed in the present study when using the sealing devices, which was not correlated only with one type of device or tissue.

Ultrasonic devices are known for their adaptive tissue technology, producing less tissue damage as a result of different factors such as: blade temperature, transection time, tissue properties and the vascularity of the transected tissue [4] and multiple studies have shown they are superior to bipolar devices. This is not only for vessels up to 5 mm in diameter, but also in vitro for larger vessels up to 7 mm with reliable and durable sealing, offering better burst pressure than devices with sealing cycles [5]. There are fewer studies on the effect of these devices on tissues and this study is important as it can guide the surgeon's choice of surgical instruments. Even if the inflammatory response that occurs within hours after an injury could not be evaluated as the experiment was performed minutes after the tissues were harvested, the diaphragm allowed the use of sealing devices on tissue samples from the same pig, with the same size and consistency. However, the dimensions and shape of the sealing device and time exposure to different temperatures may be important factors for tissue damage during laparoscopy, with further investigations being required. Attention has been brought on the subject in the urological community regarding the effect of cautery instruments on collateral tissue during nerve sparing radical prostatectomy. A study showed that bipolar cautery may not be safer than monopolar because of a greater temperature rise of surrounding tissues within 1 cm of its use, with a rise of more than 55° C in tissues being implicated in irreversible tissue damage. The authors measured the intra operatory temperature in real time with a needle electrode placed in the peritoneal cavity during robotic nerve sparing radical prostatectomy [6]. The adjacent collateral neural tissue suffering from irreversible thermal injury could imply a negative impact on sexual function recovery post operatively. Another study showed that application of ice cold irrigation during vascular pedicle control of robot-assisted radical prostatectomy reduces the collateral tissue damage [7]. The importance of the subject remains as nerve sparing techniques have implications in functional outcomes regarding continence and sexual function, influencing the life quality of patients treated for prostatic adenocarcinoma [8].

Our study represents an important set of samples analyzing the feasibility of future research. In real-life surgery, depending on the dissection angle and surgeon's technique, the approach of the tissue is subjective, and different for different surgeries/ surgical steps, especially in laparoscopy with no 360-degree movement of the instruments (compared with robotics). With this animal model data, we can only speculate the comparison with human tissue and real live surgery implications, in the context of academic publications. How these findings could be applied in real-world surgical practices can be the subject of a new research paper.

Conclusions

The studied sealing devices on a porcine model offered different peaks and levels of temperature spread on collateral tissue with ultrasound devices having the smallest collateral area with a damaging temperature spread and being the least aggressive with surrounding tissues. This study is valuable because choosing ultrasound instead of bipolar devices when performing laparoscopic procedures raises possible implications in tissue damage correlated with preserving the neurovascular bundles and in offering better functional outcomes. Further research is advisable, regarding ultrasound vs. bipolar sealing devices used as hemostatic tools and their impact on functional outcomes in real-life surgery settings. However, the dimensions and shape of the sealing device, the lateral flame effect, and time exposure to different temperatures, dissection angle, and surgical technique may be important factors for tissue damage. Further investigations are being required, along with attentive analysis of bias elements for an intra-operatory setting study design.

References

1. Tremp M, Hefermehl L, Largo R, Knönagel H, Sulser T, Eberli D. Electrosurgery in urology: recent advances. Expert Rev Med Devices. 2011;8:597-605.
2. Eberli D, Hefermehl LJ, Müller A, Sulser T, Knönagel H. Thermal spread of vessel-sealing devices evaluated in a clinically relevant in vitro model. Urol Int. 2011;86:476-482.
3. Chekan EG, Davison MA, Singleton DW, Mennone JZ, Hinoul P. Consistency and sealing of advanced bipolar tissue sealers. Med Devices (Auckl). 2015;8:193-199.
4. Phillips CK, Hruby GW, Durak E, Lehman DS, Humphrey PA, Mansukhani MM, et al. Tissue response to surgical energy devices. Urology. 2008;71:744-748.
5. 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.
6. Mandhani A, Dorsey PJ Jr, Ramanathan R, Salamanca JI, Rao S, Leung R, et al. Real time monitoring of temperature changes in neurovascular bundles during robotic radical prostatectomy: thermal map for nerve-sparing radical prostatectomy. J Endourol. 2008;22:2313–2317.
7. Zorn KC, Bhojani N, Gautam G, Shikanov S, Gofrit ON, Jayram G, et al. Application of ice cold irrigation during vascular pedicle control of robot-assisted radical prostatectomy: EnSeal instrument cooling to reduce collateral thermal tissue damage. J Endourol. 2010;24:1991–1996.
8. Gralnek D, Wessells H, Cui H, Dalkin BL. Differences in sexual function and quality of life after nerve sparing and nonnerve sparing radical retropubic prostatectomy. J Urol. 2000;163:1166–1169; discussion 1169-1170.