J Gastrointest Surg (2016) 20:1760–1768
DOI 10.1007/s11605-016-3217-9

ORIGINAL ARTICLE

Efficacy and Safety of Combined Ultrasonic and Bipolar Energy Source in Laparoscopic Surgery

Daniel C. Steinemann[1,2] · **Sebastian H. Lamm**[1] · **Andreas Zerz**[1,3]

Received: 16 May 2016 / Accepted: 13 July 2016 / Published online: 25 July 2016

Abstract
Aim Energy devices represent an alternative to clips and staplers for vessel sealing. Outcome data of patients undergoing laparoscopic surgery with use of a novel combined ultrasonic and bipolar energy device (TB, Thunderbeat™) was gathered.
Methods Consecutive patients undergoing laparoscopic surgery using TB were prospectively included between November 2011 and January 2016. Large vessels were dissected using the energy device without additional clips or staplers. The type of procedure, operative time, length of stay, complications, blood transfusions, number and type of vessels being dissected, and need for additional clips were noted.
Results Six hundred eighty-three patients underwent 758 procedures with dissection of 1310 large vessels. No additional hemoclips or vascular staplers were used. There were 0.7 % (5/758) intraoperative and 2.6 % (20/758) postoperative bleeding complications. Eleven bleeding occurred at the stapler line of anastomosis, leaving 1.8 % (14/758) bleeding that were potentially related to inadequate hemostasis. Failure of large vessel dissection occurred in two cases (0.15 %, 2/1310) and device-related complications in 1.1 % (8/758). Two of 42 conversions (5.5 %) were bleeding-related.
Conclusion TB provides a reliable and effective hemostasis. However, ligation failure may occur. As with any kind of electrosurgery, the hot tip of the instruments bears the risk of potentially fatal thermal injuries.

Keywords Energy source · Laparoscopy · Ultrasonic · Bipolar

Introduction

Given the lack of direct access, the importance of effective and reliable hemostasis is magnified in laparoscopy compared to open surgery.[1,2] In case of bleeding, the field of exposure is rapidly lost and reactive conversion to open surgery may be necessary.[3,4] Monopolar electrocautery scissors (MES) enables fast and effective hemostasis. However, MES has some disadvantages, including the potential for burns and the spread of current to surrounding tissue.[5] Furthermore, hemostasis can be inadequate for larger vessels, leading to the additional requirement for sutures or clips.[6]

A number of multifunctional devices using more sophisticated energy sources have been developed. Ultrasonic coagulation shears (UCS) uses a high vibration frequency that generates friction and heat in tissue. These ultrasonic energy devices enable cutting of tissue with a lateral thermal spread limited to 2–3 mm, and vessel sealing up to 5 mm is allowed. On the other hand, advanced electrothermal bipolar vessel systems (EBVS) provide an even more reliable vessel sealing (up to 7 mm) and a lateral thermal spread of less than 1 mm. However, this comes at the cost of reduced cutting speed and a lower level of handling ergonomics as coagulation and cutting in a single step is impossible.[7]

Clinical Trials Register: NCT01999296

✉ Daniel C. Steinemann
daniel.steinemann@gmx.ch

[1] Department of Surgery, Kantonsspital Baselland, CH-4101 Bruderholz, Switzerland

[2] Department of Surgery, St. Claraspital AG, CH-4058 Basel, Switzerland

[3] Clinic Stephanshorn, Brauerstrasse 97, CH-9016 St. Gallen, Switzerland

In 2010, a novel energy device integrating both ultrasonic and bipolar energy in a single instrument became available (TB, Thunderbeat™, Olympus, Japan). In its seal and cut mode, both types of energy are applied at the same time. It is assumed that tissue dissection is faster than with bipolar devices and more reliable than with a pure UCS.[7] In a case series of 30 laparoscopic colorectal resections for neoplasms, it has been shown that the instrument is effective and that sealing of large vessels (up to 7 mm in diameter) was successful.[8] In a randomized, controlled trial of laparoscopic hysterectomy, the median operating time was significantly faster with TB relative to MES.[9]

Although it is known that electrocautery devices may lead to complications due to inadvert thermal injury, data on such complications is very scarce in the literature. While overall complications are listed in several clinical trials, they do not discuss whether these were device-related.[6,10,11] In a register analysis, it has been demonstrated that with an increasing number of novel devices and a rapid innovation cycle, the equipment problems increase.[12] Thus, it is important to monitor the safe use of novel devices after their introduction.

TB was introduced in the surgical and gynecological department of our hospital in 2011 for all laparoscopic procedures. It replaced all formerly used UCS and EBVS as well as vessel ligation by clips and staplers. Data on all laparoscopic procedures performed using TB at our institution have been gathered in a prospective registry. The aim of the present study was to evaluate its efficacy and possible adverse events.

Material and Methods

Prospective Database

Consecutive patients undergoing laparoscopic surgery using TB were prospectively included in this cohort study between November 2011 and January 2016. Ethical approval was obtained and all patients gave written informed consent. The study was registered on the ClinicalTrials.gov website as NCT01999296.

It was at the discretion of the surgeon to use TB for a specific procedure. However, during the study period, no other energy device was available for use. If TB was not used, dissection was performed by means of MES. The postoperative complication rates and the bleeding rates were compared retrospectively to the rates of the 2 years preceding the introduction of TB (January 2010 to October 2011) at our institution. Before introduction of TB, MES, UCS, or EBVS was used for hemostasis at discretion of the surgeon.

Variables

Details of the type of procedure, the operative time, length of stay, intraoperative and postoperative complications classified according the Clavien-Dindo classification,[13] requirement for blood transfusion, need for additional clips or devices for hemostasis, and vessel sealing were noted. For intraoperative and postoperative complications, it was assessed whether those were device-related or not. Complications suspected to be device-related were bleeding complications and thermal injuries. For these complications, the detailed case files were studied. The number and type of large vessels were defined for each procedure (Tables 1, 2, 3, and 4). Vessels with a known diameter of more than 2 mm were considered large. In order to obviate an underestimate of the rate of failure to seal, only vessels that were sealed in a routine manner in the respective procedures were counted.

Details for the procedures were grouped in to colorectal, upper gastrointestinal, gynecological, and general surgery.

Surgical Technique

Large vessels were sealed and dissected using the energy device without additional clips or vascular staplers. Vessels were grasped with TB after they were freed from adjacent tissue. Tension on the vessel was released and the vessels were dissected in a single step using the seal and cut modes.

All colorectal resections were performed using an oncologic technique with a high tie of the vascular pedicle regardless of the underlying diagnosis. Liver resections consisted of non-anatomic wedge resections.

Data Management and Statistical Analysis

At the time of unpacking, a TB device in the operating room patients were labeled for the register. A data sheet was compiled and inserted in the patient file. Surgeons filled in the intraoperative variables, the responsible residents on the ward the postoperative variables in a real-time manner. Morbidity was documented as clear text. After discharge of the patients, the data sheet was transferred to a dedicated and trained data typist. The data typist entered the variables in an electronic case reporting form. Furthermore, after discharge of the patient, the operative report, the anesthesia report, and the medical discharge report were cross-checked for missing information in the data sheet. The data was stored in a web-based electronic data capture system (secutrial®, interActive Systems GmbH, Berlin, Germany). Also at the time of the patient's discharge, the authors performed classification of complications according to Clavien-Dindo as well as the interpretation if complications were suspicious to be caused by the device.

Table 1 Number, ligated vessels, and details of laparoscopic colorectal procedures and their complications in patients when using a TB device

	N	Ligated vessels	Operation time, mean ± SD	Length of stay, mean ± SD	Conversions to laparotomy % (*n*)	Intraoperative complications, % (*n*)	Postoperative complications, % (*n*)	Transfusions, % of patients (*n*); mean units ± SD
Left colonic resection	149	IMA, IMV	163 ± 52	7.8 ± 4.8	5.4 % (8)	1.3 % (2)	19.5 % (29)	3.4 % (5); 2.3 ± 2.1
Low anterior resections	26	IMA, IMV	192 ± 62	12.4 ± 7.6	11.5 % (3)	0	34.6 % (9)	11.5 % (3); 2.3 ± 1.5
Right hemicolectomy	40	ICA, ICV	111 ± 57	8.1 ± 3.7	7.5 % (3)	2.5 % (1)	27.5 % (11)	10 % (4); 2 ± 1.4
Transverse colon resection	6	MCA, MCV	130 ± 43	7.5 ± 2.6	33.3 % (2)	0	16.7 % (1)	16.6 % (1); 2 ± 0
Colorectal resections	221							
Rectopexy	6		85 ± 45	13.8 ± 13.6	16.6 % (1)	0	16.7 % (1)	0
Hartmann conversion	19		192 ± 71	9.5 ± 4.2	0	0	15.8 % (3)	10.5 % (2); 2.5 ± 0.7
TEM	6		80 ± 68	6.8 ± 2.7	0	0	33.3 % (2)	0
Stoma	14		88 ± 54	10.7 ± 9.6	0	0	7.1 % (1)	0
Small bowel resection	4		75 ± 64	9 ± 4.7	25 % (1)	0	25 % (1)	0
Other procedures	49							
Colorectal procedures	270			8.8 ± 6.1	7.5 % (18)	1.1 % (3)	21.5 % (58)	5.6 % (15)

IMA inferior mesenteric artery, *IMV* inferior mesenteric vein, *ICA* ileocolic artery, *ICV* ileocolic vein, *MCA* middle colic artery, *MCV* middle colic vein

For statistical analysis, SPSS Standard version 23 (IBM Corp., Armonk, USA) was used. Mean values with standard deviations were calculated for all numerical data according to the type of surgery. Proportions between groups were compared using a two-tailed Mann-Whitney test assuming a nonparametric distribution. Categorical variables were compared using a two-sided Fisher exact test. A two-sided p value ≤ 0.05 was considered to be statistically significant.

Table 2 Number, ligated vessels, and details of laparoscopic upper gastrointestinal procedures and their complications in patients when using a TB device

	N	Ligated vessels	Operation time, mean ± SD	Length of stay, mean ± SD	Conversions to laparotomy, % (*n*)	Intraoperative complications, % (*n*)	Postoperative complications, % (*n*)	Transfusions, % of patients (*n*); mean units ± SD
Cholecystectomy	34	CA	107 ± 78	8.5 ± 5.2	8.8 % (3)		23.5 % (8)	0
Antireflux surgery	36		98 ± 45	6.2 ± 3.8	0	2.8 % (1)	11.1 % (4)	0
Gastrectomy	10	RGEA, RGEV, LGEA, LGEV, RGA, LGA	141 ± 78	9.8 ± 4.3	0		20 % (2)	10 % (1); 1 ± 0
Bariatric surgery	52		118 ± 35	6.3 ± 9.9	0		9.6 % (5)	5.8 % (3); 2 ± 0
Liver surgery	10		83 ± 45	9.5 ± 5.8	20 % (2)		20 % (2)	20 % (2); 1.6 ± 0.5
Left pancreatic resection	2	SA, SV	172 ± 152	6 ± 4.2	0		50 % (1)	100 % (2); 2 ± 0
Splenectomy	4	SA, SV	94 ± 26	13.2 ± 6.9	25 % (1)		50 % (2)	0
Upper gastrointestinal procedures	148			7.4 ± 7.1	4.1 % (6)	0.7 % (1)	16.2 % (24)	5.4 % (8)

CA cystic artery, *RGEA* right gastroepiploic artery, *RGEV* right gastroepiploic vein, *LGEA* left gastroepiploic artery, *LGEV* left gastroepiploic vein, *RGA* right gastric artery, *LGA* left gastric artery, *SA* splenic artery, *SV* splenic vein

Table 3 Number, ligated vessels, and details of laparoscopic gynecologic procedures and their complications in patients when using a TB device

	N	Ligated vessels	Operation time, mean ± SD	Length of stay, mean ± SD	Conversions to laparotomy, % (*n*)	Intraoperative complications, % (*n*)	Postoperative complications, % (*n*)	Transfusions, % of patients (*n*); mean units ± SD
Adnexectomy	92	OA, OV	99 ± 65	4.9 ± 4.6	5.45 %(5)	1.1 % (1)	12 % (11)	2.2 % (2); 2 ± 0
Resection of Endometriosis	9		131 ± 60	4.2 ± 1.7	0	11.1 % (1)	11.1 % (1)	0
Hysterectomy	144	RUA, RUV, LUA, LUV	123 ± 62	4.3 ± 1.9	6.3 % (9)	3.5 % (5)	13.9 % (20)	1.4 % (2); 2.5 ± 0.7
Omentectomy	4		136 ± 114	6.5 ± 5.7	25 % (1)	25 % (1)	25 % (1)	0
Colposacropexy	56		136 ± 83	5.6 ± 5.2	3.6 % (2)	3.6 % (2)	10.7 % (6)	3.6 % (2); 3.5 ± 0.7
Gynecologic procedures	305			4.8 ± 3.7	5.6 % (17)	3.3 % (10)	12.8 % (39)	2.0 % (6)

OA ovarian artery, *OA* ovarian vein, *RUA* right uterine artery, *RUV* right uterine vein, *LUA* left uterine artery, *LUV* left uterine vein

Results

In the study period, a total of 3339 laparoscopic procedures were performed. Of those, 683 patients undergoing 758 procedures were included. In 474 procedures, TB dissected a total of 1310 large vessels. No additional hemoclips or vascular staplers were used.

In the 2581 procedures that did not involve the use of TB, dissection was performed by means of MES. This concerns 728 cholecystectomies, 612 appendectomies, 218 adhesiolysis, 765 groin hernia repairs, and 258 incisional hernia repairs.

Colorectal

In 254 patients with a mean age of 62.2 ± 14.4 years, 270 colorectal procedures were performed. The type of procedure, dissected vessels, operative time, length of hospital stay, intraoperative and postoperative complications as well as transfusions are depicted in Table 1. The postoperative complication rate was 21.5 % (58/270) compared to 39.3 % (44/112) prior to the use of TB ($p = 0.0006$).

Intraoperative complications of left colonic resections consisted of one patient with a primary anastomotic leak with need to overstitch and a failed sealing of the inferior mesenteric artery with subsequent massive bleeding and reactive conversion to laparotomy. The patient was transfused with an uneventful recovery. A thermal bowel lesion needed to be sutured in one patient.

There were 5.4 % (13/270) bleeding complications compared to 8.9 % (10/112) prior to TB use ($p = 0.16$). In TB, this included the abovementioned severe intraoperative bleeding. This includes 10 cases (3.7 %) of perianal bleeding after colorectal resections from the anastomosis: 5 received transfusions and resolved, 2 needed endoscopic intervention, and 2 developed anastomotic bleeding which were stopped by rectoscopic hemostasis under general anesthesia. Additional relaparoscopy did not reveal intraabdominal bleeding. Two patients experienced major blood loss during laparoscopic abdominoperineal resection and laparoscopic transverse colon resection. Both were admitted to the intensive care unit and

Table 4 Number, ligated vessels, and details of laparoscopic general surgery procedures and their complications in patients when using a TB device

	N	Ligated vessels	Operation time, mean ± SD	Length of stay, mean ± SD	Conversions to laparotomy, % (*n*)	Intraoperative complications, % (*n*)	Postoperative complications, % (*n*)	Transfusions, % of patients (*n*); mean units ± SD
Adhäsiolyse	18		127 ± 87	5.5 ± 4.8	0	0	25 % (2)	0
Appendectomy	6		115 ± 59	8.3 ± 3.6	16.6 % (1)	0	16.6 % (1)	0
Hernioplasty	8		132 ± 71	6.5 ± 2.1	0	0	12.5 % (1)	12.5 % (1), 2 ± 0
Sympathectomy	2		65 ± 2	11.5 ± 0.7	0	0	0	0
Adrenalectomy	1	SRA, SRV	65 ± 0	4 ± 0	0	0	0	0
General surgery procedures	35			6.5 ± 4.1	2.9 % (1)	0 % (0)	11.4 % (4)	2.9 % (1)

SRA suprarenal artery, *SRV* suprarenal vein

received transfusions. In one patient, relaparoscopy for bleeding after sigmoidectomy revealed intraabdominal blood but no active bleeding.

Two of the intraoperative complications (sealing failure and thermal small bowel injury) and a colonic perforation due to thermal lesion proximal to the anastomosis after sigmoidectomy were considered device-related (1.1 %, 3/270). In the latter case, relaparoscopy and suture of the lesion were performed at the day of initial surgery.

Upper Gastrointestinal Surgery

In 111 patients with a mean age of 55.3 ± 19.6 years, 148 upper gastrointestinal procedures were performed (Table 2). The postoperative complication rate was 16.2 % (24/148) compared to 10.2 % (20/116) before the use of TB ($p = 0.87$). One intraoperative complication occurred in a patient undergoing mesh-augmented hiatoplasty. Epistaxis after nasotracheal intubation was treated by tamponade. After laparoscopic gastric bypass, bleeding at the upper anastomosis from the stapler line occurred and was treated by relaparoscopy. This corresponds to a bleeding complication rate of 0.7 % (1/148) compared to 1.0 % (2/116) before introduction of TB ($p = 0.58$).

There was one patient with a postoperative colonic fistula in the left flexure after left pancreatectomy and splenectomy. This injury is suspicious for thermal injury by the energy device that led to a delayed perforation of the colon. Device-related complication rate was 0.7 % (1/148).

Gynecology

In 291 patients with a mean age of 55.3 ± 14.6 years, 305 procedures were performed (Table 3). The postoperative complication rate was 12.8 % (39/305) compared to 15.9 % (20/126) before use of TB ($p = 0.44$). Intraoperative complications included four bladder injuries that occurred during adhesiolysis, one uterine perforation, two thermal lesions to the small bowel and four bleeding events. Intraoperative bleeding occurred during adhesiolysis before colposacropexy, during ligation of the uterine artery in hysterectomy and during myomectomy. TB controlled bleeding in a second attempt. In laparoscopy for tubar gravidity, massive bleeding after rupture of the tube led to conversion to open surgery and adnexectomy (Table 6).

Among the postoperative complications (Table 5), there were five patients necessitating transfusions. One of those patients was admitted to the intensive care unit for surveillance. Another patient underwent relaparoscopy for bleeding from the mesentery of the small bowel after small bowel resection for intraoperative thermal lesion during hysterectomy. The rate of intraoperative and postoperative bleeding complications was 3.3 % (10/305) compared to 6.4 % (8/126) before the use of TB ($p = 0.18$).

In one patient, a rectal perforation occurred 3 days after colposacropexy that might be related to a thermal injury. Laparotomy with open sigmoidectomy was necessary. This complication as well as the two intraoperative thermal bowel injuries and the failure to seal a uterine artery were considered device-related (1.3 %, 4/305).

General Surgery

In 27 patients with a mean age of 59.7 ± 17.4 years, 35 procedures were performed (Table 4). The complication rate was 11.4 % (4/35) compared to 14.3 % (16/112) before TB use ($p = 0.78$). No intraoperative complication occurred and none of the postoperative complications was suspicious for being device-related. There was one postoperative transfusion (2.9 %, 1/35) compared to 3.6 % (2/112) before TB introduction ($p = 1.0$).

Synopsis

In total, there were 0.7 % (5/758) intraoperative and 2.6 % (20/758) postoperative bleeding complications (Table 5). The overall bleeding rate was 3.3 % (25/758) compared to 4.4 % (24/546) before introduction of TB ($p = 0.31$). In 11 of those cases, the bleeding occurred at the stapler line of an anastomosis, leaving 1.8 % (14/758) bleeding events that may be related to inadequate hemostasis. The rate of bleeding complication in the four subgroups was not different ($p = 0.16$). In 3.9 % of procedures (20/508) including large vessel dissection and in 4 % of procedures (10/250) without large vessel dissection, transfusions were given ($p = 1.0$). Failure of large vessel dissection using the energy device occurred in two cases, corresponding to a failure rate of 0.15 % (2/1310 sealed vessels).

There were five intraoperative and three postoperative adverse events possibly related to TB. This corresponds to a device-related complication rate of 1.1 % (8/758). Device-related complications were equally frequent in procedures performed by experienced surgeons (6/507) and in teaching procedures (2/251, $p = 1.0$).

The overall conversion rate to open surgery was 5.5 % (42/758). The reasons of conversion are shown in Table 6. Two of the conversions were bleeding-related and are described in details before.

Discussion

In this prospective registry on 758 consecutive patients undergoing laparoscopic surgery in different subspecialties, TB showed a high level of efficacy. Two failures to seal a vessel

Table 5 Postoperative morbidity and mortality in colorectal, upper gastrointestinal, gynecologic, and general surgery classified according Clavien-Dindo[1]

	Colorectal ($n = 270$)			Upper gastrointestinal ($n = 148$)			Gynecology ($n = 305$)			General ($n = 35$)		
	%	*n*	Type	%	*n*	Type	%	*n*	Type	%	*n*	Type
I	1.5	1	Hypopotassemia	0.7		Epiglottic edema	2.6	4	Prolonged pain			
		1	Stoma related skin problem					1	Wound infection			
		2	Wound infection					1	Labia edema			
								1	Petechiae			
								1	*Hematoma*			
II	9.3	6	Pneumonia	10.8	2	Lung embolism	6.9	6	Intestinal paralysis	11		Intestinal
		5	Intestinal paralysis		6	Pneumonia		1	Lung embolism	4	2	paralysis
		1	Addison crisis		3	Delirium		5	Urinary infection		1	Arrhythmia
		2	Allergic reaction		1	Intestinal paralysis		2	Delirium		1	*Anemia, transfusion*
		4	Arrhythmia		1	Agranulozytosis		2	Cardial decompensation			
		1	Goat, prednisone		1	Allergic reaction		4	*Anemia, transfusion*			
		1	Pancreatitis		1	Renal insufficiency		1	Arrhythmia			
		5	*Peranal bleeding, transfusion*		1	Arrhythmia						
III a	4.1	6	Urinary retention				2	6	Urinary retention			
		3	*Peranal bleeding, endoscopy*									
		2	Abscess, drainage									
b	5.3	1	***Colon perforation, relaparoscopy***	2	1	*Bleeding, relaparoscopy*	0.7	1	*Bleeding, relaparoscopy*			
		2	Anastomotic leak, laparotomy		1	Anastomotic leak		1	***Rectal perforation, laparotomy***			
		4	Pelvic infection, relaparoscopy		1	***Colon perforation, laparotomy***						
		1	Dehiscence of colpotomy									
		2	*Bleeding, relaparoscopy*									
		1	Wound infection, revision									
		2	Colonic ischemia, laparotomy									
IV a	1.9	1	Anastomotic leak, laparotomy	2	1	Myocardial infarction	0.3	1	*Bleeding, transfusion*			
		2	*Bleeding*		1	Cardial decompensation						
		1	Myocardial infarction		1	Pulmonal insufficiency						
		1	Pneumonia									
b												
V	0.4		Anastomotic leak	0.7	1	Aspiration						

Italic bleeding-related complications, ***bold italic*** device-related complications

(0.15 %) with subsequent bleeding and a need for reactive conversion in one of these cases were found. There was an overall rate of 3.3 % for bleeding complications, whereas the rate of bleeding that is possibly related to inadequate sealing was 1.4 %. Furthermore, 1.1 % of device-related adverse events were identified. While the complication and bleeding rate did not change due to introduction of the novel energy device, TB allowed omission of vascular clips and staplers in laparoscopic surgery at our institution.

In contrast to the current study, in a series of 30 patients undergoing colorectal resection with TB, no failure of major vessel ligation and no adverse events were found.[8] In a randomized controlled trial comparing TB or MES for hysterectomy in 50 patients, no difference in complication was found while the operative time in TB was shorter.[14] Failure to seal a vascular pedicle by TB was found in 0.15 % in this registry. Marcello et al. reported a failure rate of 3 % for EBVS and 9.2 % for stapler and clips in laparoscopic colectomy. However, only in one EBVS case a major blood loss was associated with ligation failure whereas there was no relevant bleeding in the stapler and clip group.[10] Compared to MES, the Cochrane review demonstrated a reduced blood loss for UCS whereas the

Table 6 Conversion rates to open surgery in colorectal, upper gastrointestinal, gynecologic and general surgery in patients undergoing laparoscopy using a TB device

Type of surgery	Conversions, % (*n*)	Reason (*n*)
Colorectal (*n* = 270)	18 (6.7 %)	Infiltration of tumor in adjacent organs (4)
		Inflammatory conglomerate (3)
		Insufficient exposure (3)
		Severe adhesions (7)
		Massive bleeding (1)
Upper gastrointestinal tract (*n* = 148)	6 (4.1 %)	Severe Adhesions (3)
		Biliary peritonitis (1)
		Infiltration of tumor in adjacent organs (2)
Gynecology (*n* = 305)	17 (5.6 %)	Insufficient exposure (6)
		Severe adhesions (3)
		Large uterine myoma (5)
		Massive bleeding (1)
General (*n* = 35)	1 (2.9 %)	Inflammatory conglomerate (1)
Total (*n* = 758)	42 (5.5 %)	

Italic bleeding-related conversions

difference did not reach significances for EBVS.[15] However, there is only one study comparing blood loss in EBVS against MES.[6]

Previous clinical trials on energy devices in laparoscopic surgery reported infrequently device-related thermal injuries for EBVS such as ureter injury,[16] small bowel perforation,[6,17] colonic perforation,[18] and vascular injury.[18] However, none of the existing studies with sample sizes between 30 and 146 patients is powered for safety analysis. Only Rimonda et al. report 2.8 % of intraoperative device-related complications for both UCS and EBVS.[18] In the current study, six thermal injuries related to the TB were identified. While in three cases, thermal small bowel injury was identified as intraoperative and treated by oversewing the lesions in the remaining three patients, re-operation for colon or rectal perforation was necessary. It is important to bear in mind that TB includes an ultrasonic component that is responsible for considerable heat production during dissection. The heat production during single activation while dividing mesenteric tissue reaches 85 °C for EBVS, 209 °C for UCS, and 229 °C for TB.[7] Until the tip of the TB cools down, it takes a considerable amount of time. To avoid potential fatal injuries, extreme caution is warranted while handling the device within the abdominal cavity but also outside of the patient. To avoid skin burns, the device should not be placed on the drapes and the patient.

In the current study, all vessels were ligated by TB only. While preceding studies using EBVS also avoided additional use of clips or staplers,[6,10,16] in UCS, clips or a vascular stapler invariably controlled the vascular pedicle.[18–20] In a randomized controlled trial in the left colectomy, a median of nine clips was used in MES, 3 in UCS and none in EBVS.[6] A shorter operative time for EBVS[6,16,20,21] and UCS[6,20] in comparison to MES was found. However, one trial comparing UCS and MES for colorectal resection failed to show a difference in operative time.[19] Operative time for UCS versus EBVS was demonstrated to be not different for colorectal resections.[18] Costs were reduced if EBVS is used without additional clips for pedicle ligation in colorectal surgery.[6,16]

Unlike for drug approval, a novel surgical device might be approved and become commercially available without rigorous comparative studies demonstrating its efficacy and safety.[22] This underlines the importance of postmarket evaluation. Postmarket evaluation may be performed at two different levels. First, adverse events possibly related to a medical device are to be reported to authorities like the Food and Drug Administration (FDA). These reports are collected, i.e., in the Manufacturer and User Facility Device Experience Database (MAUDE). Secondly, clinical trials evaluating the efficacy and safety of devices and, thirdly, voluntary registries are encouraged by the FDA. Such registries, as the current one, can effectively elucidate device-related events and identify safety signals that are not addressed by the existing literature.[23]

Complications due to energy devices in MAUDE may be allocated in four categories: thermal burn, hemorrhage, failure to seal, and fire.[24] For TB, MAUDE lists for the event type "injury" and "death" include 19 hemorrhages, 15 thermal burns, and 3 failures to seal (search date 03-07-2016). It is likely that MAUDE does not give an accurate picture of complications related to the device. In contrast to MAUDE, the current registry puts events into a relation to the number of applications of the device.

A prerequisite of a voluntary register is the acquisition of a complete record of procedures and complications. It has been shown that acquisition of data by residents, as practiced in most registries, is afflicted with a high number of missed events.[25] In this registry, a dedicated and trained data typist gathered data. A further strength of this study is that TB was used as the only energy device without any restriction on the

type of laparoscopic procedure in a consecutive large series of patients. The decision to use TB or to perform a procedure with MES only was at the discretion of the surgeons. However, the findings are limited by the missing of a prospective comparative group and no conclusions on advantages or disadvantages of TB compared to other energy source may be drawn. The comparisons made with a historic series of patients that underwent laparoscopic surgery in the 2 years preceding the introduction of TB may be confounded by its retrospective nature and a possible inhomogeneity of performed procedures. It is worth bearing in mind that fast-paced changes in the market for surgical tools as well as the high costs of patient randomization make it difficult to conduct randomized controlled trials powered for efficacy and safety assessment.

Conclusion

In conclusion, TB provides a reliable and effective hemostasis. However, the surgeon should cut vessels with caution and avoid any tension on the vessel during dissection to allow the device enough time for safe coagulation. In any doubt, additional clips should be used at a low threshold. As the tip of the TB reaches high temperature during and after activation, caution is warranted while handling the device to avoid potentially fatal thermal injuries.

Author Contributions DCS, SHL, and AZ designed the study; DCS analyzed and interpreted the data; DCS and SHL drafted the article; AZ performed a critical revision. All authors gave their final approval of the current version to be published. All authors agree that they are accountable for all aspects of the work.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest. The authors declare to have no affiliations with the producer of Thunderbeat™ Olympus K.K.

References

1. Lyons SD, Law KS (2013) Laparoscopic vessel sealing technologies. Journal of minimally invasive gynecology 20:301–307
2. Smith R, Pasic R (2008) The role of vessel sealing technologies in laparoscopic surgery. Surgical technology international 17:208–212
3. Sandberg EM, Cohen SL, Jansen FW, Einarsson JI (2016) Analysis of Risk Factors for Intraoperative Conversion of Laparoscopic Myomectomy. Journal of minimally invasive gynecology 23:352–357
4. Sultan AM, El Nakeeb A, Elshehawy T, Elhemmaly M, Elhanafy E, Atef E (2013) Risk factors for conversion during laparoscopic cholecystectomy: retrospective analysis of ten years' experience at a single tertiary referral centre. Digestive surgery 30:51–55
5. Sankaranarayanan G, Resapu RR, Jones DB, Schwaitzberg S, De S (2013) Common uses and cited complications of energy in surgery. Surgical endoscopy 27:3056–3072
6. Hubner M, Demartines N, Muller S, Dindo D, Clavien PA, Hahnloser D (2008) Prospective randomized study of monopolar scissors, bipolar vessel sealer and ultrasonic shears in laparoscopic colorectal surgery. The British journal of surgery 95:1098–1104
7. Seehofer D, Mogl M, Boas-Knoop S, Unger J, Schirmeier A, Chopra S, Eurich D (2012) Safety and efficacy of new integrated bipolar and ultrasonic scissors compared to conventional laparoscopic 5-mm sealing and cutting instruments. Surgical endoscopy 26:2541–2549
8. Milsom JW, Trencheva K, Sonoda T, Nandakumar G, Shukla PJ, Lee S (2015) A prospective trial evaluating the clinical performance of a novel surgical energy device in laparoscopic colon surgery. Surgical endoscopy 29:1161–1166
9. Fagotti A, Vizzielli G, Fanfani F, Gallotta V, Rossitto C, Costantini B, Gueli-Alletti S, Avenia N, Iodice R, Scambia G (2013) A randomized study comparing the use of Thunderbeat technology vs. standard electrosurgery during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecological cancer. Journal of minimally invasive gynecology
10. Marcello PW, Roberts PL, Rusin LC, Holubkov R, Schoetz DJ (2006) Vascular pedicle ligation techniques during laparoscopic colectomy. A prospective randomized trial. Surgical endoscopy 20:263–269
11. Di Lorenzo N, Franceschilli L, Allaix ME, Asimakopoulos AD, Sileri P, Gaspari AL (2012) Radiofrequency versus ultrasonic energy in laparoscopic colorectal surgery: a metaanalysis of operative time and blood loss. Surgical endoscopy 26:2917–2924
12. Kambakamba P, Dindo D, Nocito A, Clavien PA, Seifert B, Schafer M, Hahnloser D (2014) Intraoperative adverse events during laparoscopic colorectal resection–better laparoscopic treatment but unchanged incidence. Lessons learnt from a Swiss multi-institutional analysis of 3,928 patients. Langenbeck's archives of surgery / Deutsche Gesellschaft fur Chirurgie 399:297–305
13. Dindo D, Demartines N, Clavien PA (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Annals of surgery 240:205–213
14. Fagotti A, Vizzielli G, Fanfani F, Gallotta V, Rossitto C, Costantini B, Gueli-Alletti S, Avenia N, Iodice R, Scambia G (2014) Randomized study comparing use of THUNDERBEAT technology vs standard electrosurgery during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecologic cancer. Journal of minimally invasive gynecology 21:447–453
15. Tou S, Malik AI, Wexner SD, Nelson RL (2011) Energy source instruments for laparoscopic colectomy. The Cochrane database of systematic reviews:CD007886
16. Adamina M, Champagne BJ, Hoffman L, Ermlich MB, Delaney CP (2011) Randomized clinical trial comparing the cost and effectiveness of bipolar vessel sealers versus clips and vascular staplers for laparoscopic colorectal resection. The British journal of surgery 98:1703–1712
17. Hubner M, Hahnloser D, Hetzer F, Muller MK, Clavien PA, Demartines N (2007) A prospective randomized comparison of two instruments for dissection and vessel sealing in laparoscopic colorectal surgery. Surgical endoscopy 21:592–594
18. Rimonda R, Arezzo A, Garrone C, Allaix ME, Giraudo G, Morino M (2009) Electrothermal bipolar vessel sealing system vs. harmonic scalpel in colorectal laparoscopic surgery: a prospective, randomized study. Diseases of the colon and rectum 52:657–661
19. Morino M, Rimonda R, Allaix ME, Giraudo G, Garrone C (2005) Ultrasonic versus standard electric dissection in laparoscopic colorectal surgery: a prospective randomized clinical trial. Annals of surgery 242:897–901, discussion 901
20. Targarona EM, Balague C, Marin J, Neto RB, Martinez C, Garriga J, Trias M (2005) Energy sources for laparoscopic colectomy: a prospective randomized comparison of conventional

electrosurgery, bipolar computer-controlled electrosurgery and ultrasonic dissection. Operative outcome and costs analysis. Surgical innovation 12:339–344
21. Trilling B, Riboud R, Abba J, Girard E, Faucheron JL (2016) Energy vessel sealing systems versus mechanical ligature of the inferior mesenteric artery in laparoscopic sigmoidectomy. International journal of colorectal disease
22. Waetjen LE, Parvataneni R, Varon S, Saberi NS, Jacoby VL, University of California Fibroid N (2015) Obstacles to Studying Emerging Technologies. Obstetrics and gynecology 126:391–395
23. Rajan PV, Kramer DB, Kesselheim AS (2015) Medical device postapproval safety monitoring: where does the United States stand? Circulation Cardiovascular quality and outcomes 8:124–131
24. Overbey DM, Townsend NT, Chapman BC, Bennett DT, Foley LS, Rau AS, Yi JA, Jones EL, Stiegmann GV, Robinson TN (2015) Surgical Energy-Based Device Injuries and Fatalities Reported to the Food and Drug Administration. Journal of the American College of Surgeons 221:197–205 e191
25. Dindo D, Hahnloser D, Clavien PA (2010) Quality assessment in surgery: riding a lame horse. Annals of surgery 251:766–771