The Thunderbeat and Other Energy Devices in Laparoscopic Colorectal Resections: Analysis of Outcomes and Costs

Allaix Marco Ettore, Arezzo Alberto, Giraudo Giuseppe, Arolfo Simone, Mistrangelo Massimiliano, and Morino Mario.

The Thunderbeat and Other Energy Devices in Laparoscopic Colorectal Resections: Analysis of Outcomes and Costs

Journal of Laparoendoscopic & Advanced Surgical Techniques

27(12): 1225-1229, 2017,

DOI: 10.1089/lap.2016.0317

The Thunderbeat and Other Energy Devices in Laparoscopic Colorectal Resections: Analysis of Outcomes and Costs

Allaix Marco Ettore, Arezzo Alberto, Giraudo Giuseppe, Arolfo Simone, Mistrangelo Massimiliano, and Morino Mario.

Department of Surgical Sciences, University of Torino, Torino, Italy.

ABSTRACT

Background: The THUNDERBEAT™ (TB) is a recently developed energy-based device. To date, there are no clinical studies comparing TB and other energy sources, such as standard electrosurgery (ES), ultrasonic coagulating shears (US) and electrothermal bipolar vessel sealers (EBVS) in patients undergoing laparoscopic colorectal resection (LCR). The aim of this study was to compare outcomes and costs in patients undergoing LCR with TB, US, EBVS, or ES for both benign and malignant colorectal diseases.

Methods: This study is a retrospective analysis of a prospective database of patients undergoing LCR. Unselected consecutive patients who had the laparoscopic dissection conducted by using TB were compared with consecutive patients undergoing LCR with US, EBVS, or ES.

Results: Mean operative time did not significantly differ between the groups ($P = .947$). Estimated blood loss was significantly higher in the ES group ($P < .001$). Device-related complications occurred in 2.5% of ES patients, in 2.5% of US patients, and in 5% of EBVS patients, while no complications occurred in TB patients ($P = .768$). No significant differences were observed in postoperative complication rates between the groups. Mean postoperative hospital stay was similar in the groups. Cost analysis showed no significant differences between US (1519.1 ± 303 €), EBVS (1474.4 ± 372.8 €), and TB (1474.3 ± 176.3 €) ($P = .737$).

***Conclusion*:** This is the first clinical study comparing TB and other energy-based devices in LCR. They all appear to be equally safe and effective. Costs of surgery are very similar. Further large randomized controlled trials are needed to confirm these data.

Introduction

The last two decades have witnessed a significant increase in the use of the laparoscopic approach for the treatment of colorectal benign diseases and cancer, mainly on the basis of the evidence from several randomized controlled trials (RCTs) showing better short-term outcomes[1–4] and similar survival rates[5–10] when compared with the open approach.

The diffusion of laparoscopic colorectal resection (LCR) has resulted in the development of several disposable multifunctional tools aiming to provide safe dissection and hemostasis without the limitations inherent to conventional electrosurgery (ES), including the risk of collateral thermal injuries, smoke production, and the need for additional instruments such as clips and vascular staplers. Ultrasonic coagulating shears (US) and electrothermal bipolar vessel sealers (EBVS) are the most popular instruments. The THUNDERBEAT™ (TB; Olympus Medical Systems Corp.) is a more recently developed device that integrates both ultrasonic and advanced bipolar energy in a unique tool, thus allowing tissue dissection with ultrasonic energy and reliable sealing of vessels up to 7 mm in diameter with bipolar energy. Even though some RCTs and non-RCTs have compared

ES, US, and EBVS in LCR,[11] very few of them have performed a cost analysis.[12–14] In addition, there are no comparative studies assessing the value of TB in patients undergoing LCR.

To date, it is unclear if these multifunctional tools lead to reduced operative times when compared with conventional ES, and their impact on hospital expenses is under debate. The aim of this study was to compare outcomes and costs in patients undergoing LCR with TB, US, EBVS, or ES for both benign and malignant colorectal diseases.

Materials and Methods

This study is a retrospective analysis of a prospective database of patients undergoing LCR at our Institution between March 2012 and March 2016. Unselected consecutive patients who had the laparoscopic dissection conducted by using TB were compared with consecutive patients undergoing LCR with US, EBVS, or ES.

The same anesthesia, antibiotic prophylaxis, deep venous thrombosis prophylaxis, and postoperative pain control protocols were used in all patients. Preoperative mechanical bowel preparation was used only in patients undergoing low anterior resection.

One surgeon (M.M.) with extensive experience in colorectal and laparoscopic advanced surgery performed all LCRs. Mobilization of the right and transverse colon and dissection of the right mesocolon during laparoscopic right hemicolectomy, transection of the gastrocolic ligament, mobilization of the left colon and rectum, and dissection of the descending mesocolon during left hemicolectomy or anterior resection were obtained by using ES, US, EBVS, or TB. Central vascular ligation of ileocolic vessels during right hemicolectomy and inferior mesenteric vessels during left-sided colorectal resection was achieved in all patients by applying endoscopic clips.

Conversion to open surgery was defined as an unplanned incision or an incision made longer or earlier than planned.

Outcome measurements

Recorded outcomes were operative time, intraoperative blood losses, overall and device-related intraoperative complications (bleeding, thermal injury to intraabdominal organs), device failure, conversion to open surgery, need for blood transfusion, length of postoperative hospital stay, and 30 days of postoperative morbidity and mortality.

Cost analysis

Cost analysis was performed in Euros (€), considering costs of the energy device (US: 658.80 €; EBVS: 624.64 €; TB: 628.30 €), costs of additional energy tools used to achieve hemostasis or tissue dissection, and costs of the operating room (450 € per hour). Costs are hospital expenses and reflect actual costs for the year 2016.

Statistical analysis

Quantitative data are given as mean ± standard deviation and categorical data are expressed as percentages. Statistical analysis among the groups was performed using χ^2 test or one-way ANOVA as appropriate. All *P*-values were two-sided. A level of 5% was set as the criterion for statistical significance. Data were collected in an Excel spreadsheet. The statistical analysis was performed using SPSS version 19 (Copyright © SPSS, Inc., 2000).

Results

A total of 160 patients were included in the study: 40 patients undergoing LCR with TB (TB group) were compared with 40 patients undergoing LCR with ES (ES group), 40 patients undergoing LCR with US (US group) and 40 patients undergoing LCR with EBVS (EBVS group).

Table 1 summarizes the preoperative patients' characteristics.

Table 1. Baseline Patients' Characteristics

	ES (*N = *40)	***US (*N = *40)***	***EBVS (*N = *40)***	***TB (*N = *40)***	**P**
Age (years)[a]	66.4 ± 5.2	68.1 ± 4.5	68.9 ± 5.1	67.4 ± 4.8	.137
Sex (males), *N* (%)	25 (62.5)	23 (57.5)	24 (60)	25 (62.5)	1
BMI (Kg/m^2)[a]	25.6 ± 3.2	26.1 ± 3.6	26.4 ± 3.1	25.9 ± 2.8	.720
ASA score, *N* (%)					.897
I	17 (42.5)	16 (40)	15 (37.5)	16 (40)	
II	15 (37.5)	18 (45)	19 (47.5)	20 (50)	
III	8 (20)	6 (15)	6 (15)	4 (10)	
Indications, *N* (%)					.942
Cancer	32 (80)	33 (82.5)	31 (77.5)	35 (87.5)	
Diverticulitis	8 (20)	7 (17.5)	9 (22.5)	5 (12.5)	
Surgical procedure, *N* (%)					.930
Right hemicolectomy	14 (35)	13 (32.5)	13 (32.5)	15 (37.5)	
Left hemicolectomy	14 (35)	17 (42.5)	19 (47.5)	16 (40)	
Anterior resection	12 (30)	10 (25)	8 (20)	9 (22.5)	

[a]Values are given as mean ± standard deviation unless indicated otherwise.

ASA score, American Society of Anesthesiologists score; BMI, body mass index; EBVS, electrothermal bipolar vessel sealers; ES, Conventional electrosurgery; TB, THUNDERBEAT; US, ultrasonic coagulating shears.

Table 1. Baseline Patients' Characteristics

Intraoperative outcomes

Intraoperative outcomes are reported in Table 2. Mean operative time did not significantly differ between the groups ($P = .947$). Estimated blood loss was significantly higher in the ES group ($P < .001$); no significant differences were observed between the TB, US, and EBVS groups ($P = .772$). No patient required intraoperative blood transfusions.

Table 2. Intraoperative Outcomes

	ES* (N = *40)	***US* (N = *40)***	***EBVS* (N = *40)***	***TB* (N = *40)***	**P**
Operative time (minutes)[a]	117.4 ± 30.5	114.7 ± 40.4	113.3 ± 49.7	112.8 ± 23.5	.947
Blood loss (mL)[a]	131.5 ± 29.2	106.5 ± 31.2	110.4 ± 39.2	105.4 ± 26.2	<.001
Device failure, *N* (%)	0	1 (2.5)	0	0	.527
Device-related complications, *N* (%)	1 (2.5)	1 (2.5)	2 (5)	0	.768
Bleeding	1	1	1		
Injury to organs			1		
Conversion to open surgery, *N* (%)	3 (7.5)	2 (5)	2 (5)	0	.567
Locally advanced cancer	3	1	1		
Adhesions		1			
Pelvic abscess			1		

[a]Values are given as mean ± standard deviation unless indicated otherwise.

EBVS, electrothermal bipolar vessel sealers; ES, Conventional electrosurgery; TB, THUNDERBEAT; US, ultrasonic coagulating shears.

Table 2. Intraoperative Outcomes

Failure of the disposable instrument occurred only in 1 (2.5%) patient in the US group: the surgical procedure was completed by using ES.

Device-related complications occurred in 2.5% of ES patients, in 2.5% of US patients, and in 5% of EBVS patients, whereas no complications occurred in TB patients ($P = .768$).

The rate of conversion to open surgery was 7.5% in the ES group, 5% in the US group, 5% in the EBVS group, and 0% in the TB group ($P = .567$).

Postoperative outcomes

No statistically significant differences were observed when assessing postoperative complications between the groups: 7.5% for ES, 7.5% for US, 7.5% for EBVS, and 2.5% for TB group ($P = 1$). There was no mortality. Mean postoperative hospital stay was similar in the groups ($P = .860$) (Table 3).

Table 3. Postoperative Outcomes

	*ES (*N = *40) US (*N = *40) EBVS (*N = *40) TB (*N = *40)*				**P**
Morbidity, *N* (%)	3 (7.5)	3 (7.5)	3 (7.5)	1 (2.5)	1
Pneumonia			1	1	
Prolonged postoperative ileus	2	1	1		
Anastomotic leak	1	2	1		
Mortality, *N* (%)	0	0	0	0	
Length of hospital stay (days)[a]	7.1 ± 3.1	7.3 ± 4.3	6.8 ± 3.4	6.7 ± 2.9	.860

[a]Values are given as mean ± standard deviation unless indicated otherwise.

EBVS, electrothermal bipolar vessel sealers; ES, Conventional electrosurgery; TB, THUNDERBEAT; US, ultrasonic coagulating shears.

Table 3. Postoperative Outcomes

Cost analysis

Overall, the use of TB or EBVS reduced the mean costs of surgery by 45€. Cost analysis showed no significant differences between US (1519.1 ± 303 €), EBVS (1474.4 ± 372.8 €), and TB (1474.3 ± 176.3 €) (*P* = .737).

Discussion

During the last 15 years, many efforts have been done to improve tissue dissection and vessel control during LCR. Different surgical energy devices using high-frequency ultrasound energy (US) or high current and low voltage energy (EBVS) have been developed aiming to overcome the technical limitations of conventional ES. Current evidence from RCTs comparing ES, US, and EBVS shows intraoperative advantages, including lower intraoperative blood loss and shorter operative time, in patients undergoing LCR with US or EBVS than ES. However, these benefits do not lead to lower rates of postoperative complications or shorter hospital stay.[11,15]

More recently, a new multifunctional laparoscopic device that delivers both ultrasonic and electrically generated bipolar energy, the TB, has become available. Some experimental studies have been conducted to assess safety and efficacy of TB in comparison with commercially available US and EBVS devices.[16–19] For instance, Milsom et al.[16] tested in an experimental study the TB device, Harmonic® ACE (Ethicon Endo-Surgery), LigaSure™ V (Covidien), and EnSeal® (Ethicon) on 10 female Yorkshire pigs. While the four devices were similar in bursting pressure and thermal spread, versatility, defined as the performance of the device in terms of hemostasis, histological sealing, cutting, dissection, and tissue manipulation, was higher and dissection time was shorter with TB compared with the other three tools. Seehofer et al.[17] performed a preclinical *in vivo* comparison of TB with conventional US (Harmonic ACE) and EBVS (LigaSure) devices in terms of sealing capability, cutting speed, thermal profile, and histological damage in 8 German Landrace pigs. Burst pressure measured after using TB in 5 to7-mm vessels was significantly higher than that using the US device and slightly higher than that using the EBVS device. No differences were

observed between the three tools in sealing smaller vessels. The time needed for sealing and cutting arteries or the mesentery was significantly shorter using the TB than US or EBVS device. The evaluation of the thermal profile showed that the EBVS had a significantly lower maximum temperature during and after activation and shorter time to decline to 60°C than TB and US that were comparable. There was no lateral thermal damage to small bowel specimen after division of the mesentery 5 mm from the bowel wall.

Even though the results of these experimental studies show that TB might be a safe and effective alternative to US and EBVS devices and should reduce operative time, the clinical impact of the TB technology is unclear. To date, only a small RCT[20] and a prospective pilot study[21] have been published, confirming safety and effectiveness of TB in humans. Fagotti et al.[20] published in 2014 the results of an RCT comparing the outcomes in 25 women assigned to TB and 25 women assigned to conventional ES during laparoscopic radical hysterectomy and pelvic lymphadenectomy for cervical or endometrial cancer. The median operative time was shorter in the TB group (85 minutes versus 115 minutes, $P = .001$). Endometrial cancer and the use of TB were the only predictors of shorter operative time. Morbidity rates did not significantly differ between the two groups. Milsom et al.[21] reported in 2014 the early outcomes in 30 colon cancer patients undergoing LCR with TB: 12 right and 18 left laparoscopic hemicolectomies. The mean surgical procedure time was 163 ± 86 minutes. No intraoperative or postoperative TB-related complications (bleeding or thermal injuries to intraabdominal organs) occurred. The authors concluded that TB technology is effective in achieving adequate tissue dissection and vessel control in both right and left laparoscopic hemicolectomies. However, a comparative study with other energy devices was claimed to assess the real benefits of TB in LCR.

This is the first clinical study that compares TB with other devices in patients undergoing LCR for cancer or sigmoid diverticulitis. Even though intraoperative blood loss was significantly higher in patients who underwent LCR with ES than US, EBVS, or TB, there was no need for blood transfusions during and after the operation in any patients, and postoperative morbidity did not differ between the groups. No significant differences were observed in operative time, conversion to open surgery rates, and incidence of device-related injury to intraabdominal organs between the four devices. Noteworthy, no thermal injuries occurred in the TB group, confirming the safety profile of this tool.

Limited evidence is available with regard to cost effectiveness of US and EBVS devices used for dissection and vessel control during LCR, and there are no data about costs associated with the use of TB. Costs of surgery depend mostly on operative time and instrument expenses. The analysis that we performed in this comparative study showed that the use of TB or EBVS (that were equally expensive) reduced the mean costs of surgery by 45€ compared with US; however, this difference did not reach a statistical significance. These results are consistent with those reported by Hubner et al.[13] who randomly assigned 20 patients to ES, 20 patients to US, and 21 patients to EBVS. The analysis of costs of the operating room, costs of the allocated energy tool, and for additional instruments used to achieve dissection and vessel control showed no significant differences between the US and EBVS device (1213 ± 259.1 versus 1209 ± 265.8, respectively). The authors speculated that dissection during LCR with these multifunctional and disposable tools becomes cost-effective compared with ES only in high-volume centers (with an annual workload greater than 100 operations), whereas no significant differences might be observed in low-volume centers.

Conclusions

This is the first clinical study comparing TB and other energy-based devices in LCR. They all appear to be equally safe and effective. Costs of surgery are very similar. Therefore, the choice of

one of them should be mainly based on the surgeon's preference. Further large RCTs will be needed to confirm these data.

References

1. AM Lacy, JC García-Valdecasas, S Delgado, A Castells, P Taurá, JM Piqué, J Visa. Laparoscopy-assisted colectomy versus open colectomy for treatment of non-metastatic colon cancer: A randomised trial. Lancet 2002;359:2224–2229.
2. Clinical Outcomes of Surgical Therapy Study Group. A comparison of laparoscopically assisted and open colectomy for colon cancer. N Engl J Med 2004;350:2050–2059.
3. PJ Guillou, P Quirke, H Thorpe, J Walker, DG Jayne, AM Smith, RM Heath, JM Brown. MRC CLASICC trial group. Short-term endpoints of conventional versus laparoscopic-assisted surgery in patients with colorectal cancer (MRC CLASICC trial): Multicentre, randomised controlled trial. Lancet 2005;365:1718–1726.
4. R Veldkamp, E Kuhry, WC Hop, J Jeekel, G Kazemier, HJ Bonjer, E Haglind, L Påhlman, MA Cuesta, S Msika, M Morino, AM Lacy; COlon cancer Laparoscopic or Open Resection Study Group (COLOR). Laparoscopic surgery versus open surgery for colon cancer: Short-term outcomes of a randomised trial. Lancet Oncol 2005;6:477–484.
5. J Fleshman, DJ Sargent, E Green, M Anvari, SJ Stryker, RW Beart Jr, M Hellinger, R Flanagan Jr, W Peters, H Nelson; Clinical Outcomes of Surgical Therapy Study Group. Laparoscopic colectomy for cancer is not inferior to open surgery based on 5-year data from the COST Study Group trial. Ann Surg 2007;246:655–662; discussion 662–664.
6. M Buunen, R Veldkamp, WC Hop, E Kuhry, J Jeekel, E Haglind, L Påhlman, MA Cuesta, S Msika, M Morino, A Lacy, HJ Bonjer. Survival after laparoscopic surgery versus open surgery for colon cancer: Long-term outcome of a randomized clinical trial. Lancet Oncol 2009;10:44–52.
7. DG Jayne, HC Thorpe, J Copeland, P Quirke, JM Brown, PJ Guillou. Five-year follow-up of the Medical Research Council CLASICC trial of laparoscopically assisted versus open surgery for colorectal cancer. Br J Surg 2010;97:1638–1645.
8. AM Lacy, S Delgado, A Castells, HA Prins, V Arroyo, A Ibarzabal, JM Pique. The long-term results of a randomized clinical trial of laparoscopy-assisted versus open surgery for colon cancer. Ann Surg 2008;248:1–7.
9. BL Green, HC Marshall, F Collinson, P Quirke, P Guillou, DG Jayne, JM Brown. Long-term follow-up of the Medical Research Council CLASICC trial of conventional versus laparoscopically assisted resection in colorectal cancer. Br J Surg 2013;100:75–82.
10. E Kuhry, W Schwenk, R Gaupset, U Romild, J Bonjer. Longterm outcome of laparoscopic surgery for colorectal cancer: A cochrane systematic review of randomised controlled trials. Cancer Treat Rev 2008;34:498–504.
11. S Tou, AI Malik, SD Wexner, RL Nelson. Energy source instruments for laparoscopic colectomy. Cochrane Database Syst Rev 2011;(5):CD007886.
12. EM Targarona, C Balague, J Marin, RB Neto, C Martinez, J Garriga, M Trias. Energy sources for laparoscopic colectomy: A prospective randomized comparison of conventional electrosurgery, bipolar computer-controlled electrosurgery, and ultrasonic dissection: Operative outcomes and costs analysis. Surg Innov 2005;12:339–344.
13. M Hubner, N Demartines, S Muller, D Dindo, PA Clavien, D Hahnloser. Prospective randomized study of monopolar scissors, bipolar vessel sealer and ultrasonic shears in laparoscopic colorectal surgery. Br J Surg 2008;95:1098–1104.
14. M Adamina, BJ Champagne, L Hoffman, et al. Randomized clinical trial comparing the cost and effectiveness of bipolar vessel sealers *versus* clips and vascular staplers for laparoscopic colorectal resection. Br J Surg 2011;98:1703–1712.

15. ME Allaix, EJB Furnée, A Arezzo, et al. Energy sources for laparoscopic colorectal surgery: Is one better than the others? J Laparoendosc Adv Surg Tech A 2016;26:264–269.
16. J Milsom, K Trencheva, S Monette, R Pavoor, P Shukla, J Ma, T Sonoda. Evaluation of the safety, efficacy, and versatility of a new surgical energy device (THUNDERBEAT) in comparison with Harmonic ACE, LigaSure V, and EnSeal devices in a porcine model. J Laparoendosc Adv Surg Tech A 2012;22:378–386.
17. D Seehofer, M Mogl, S Boas-Knoop, J Unger, A Schirmeier, S Chopra, D Eurich. Safety and efficacy of new integrated bipolar and ultrasonic scissors compared to conventional laparoscopic 5-mm sealing and cutting instruments. Surg Endosc 2012;26:2541–2549.
18. R Tanaka, M Gitelis, D Meiselman, et al. Evaluation of vessel sealing performance among ultrasonic devices in a porcine model. Surg Innov 2015;22:338–343.
19. M Liberman, M Khereba, E Goudie, et al. Pilot study of pulmonary arterial branch sealing using energy devices in an ex vivo model. J Thorac Cardiovasc Surg 2014;148:3219–3223.
20. A Fagotti, G Vizzielli, F Fanfani, et al. Randomized study comparing use of THUNDERBEAT technology vs standard electrosurgery during laparoscopic radical hysterectomy and pelvic lymphadenectomy for gynecologic cancer. J Minim Invasive Gynecol 2014;21:447–453.
21. JW Milsom, K Trencheva, T Sonoda, G Nandakumar, PJ Shukla, S Lee. A prospective trial evaluating the clinical performance of a novel surgical energy device in laparoscopic colon surgery. Surg Endosc 2015;29:1161–1166.