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Large-Vessel Sealing in Laparoscopic Colectomy with an Ultrasonic Device

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ABSTRACT

Background and Objective: The Harmonic ACE+7 Shears with Advanced Hemostasis Mode (Ethicon, Somerville, NJ, USA) is an ultrasonic device designed to transect and seal vessels up to 7 mm in diameter. The device applies an algorithm that optimizes ultrasonic energy delivery combined with a longer sealing cycle. The purpose of this study was to assess the initial clinical experience with the Harmonic device by evaluating large-vessel sealing during laparoscopic colectomy in consecutive cases.

Methods: This prospective, multicenter, observational series involved 40 adult patients who were to undergo elective laparoscopic colectomy where dissection and transection of the inferior mesenteric artery was indicated. The primary study endpoint was first-pass hemostasis, defined as a single activation of the Advanced Hemostasis Mode to transect and seal the inferior mesenteric artery. The use of any additional energy device or hemostatic product to establish or maintain hemostasis was noted. Patients were observed after surgery for ~4 weeks for adverse events that were considered to be related to the study procedure or study device. Descriptive statistical analyses were performed for study endpoints.

Results: Forty patients underwent the laparoscopic colectomy procedure. First-pass hemostasis of the inferior mesenteric artery was achieved and maintained in all 40 patients, with no required additional hemostatic measures. Exposure of the vessel was reported as skeletonized in 22 of 40 (55%) patients. Mean transection time was 21.9 ± 7.4 s. One adverse event (postoperative anemia) was considered possibly related to the study device.

Conclusion: In this initial clinical consecutive series, the device demonstrated successful transection and sealing of the large mesenteric vessels during laparoscopic colorectal surgery.

Key Words: Colectomy, Colorectal surgery, Hemostasis, Inferior mesenteric artery.

INTRODUCTION

Laparoscopy is widely used in colorectal surgery as a treatment modality for benign and malignant bowel disease.[1] Short-term benefits of laparoscopic colorectal surgery over open surgery include less pain, lower morbidity, improved quality of life, and reduced hospital stay.[2–6] Among the challenges in laparoscopic colectomy are safe resection of tissues with minimal collateral damage and secure division and sealing of the mesenteric vessels. Advanced energy devices have been developed to address the technical and hemostatic challenges associated with conventional surgical techniques in an effort to improve patient outcomes.

Ultrasonic coagulating shears are multifunctional devices that transect and seal soft tissue without electrical current passing through the patient. The ultrasonic Harmonic technology uses coaptive coagulation, whereby a vibrating blade cuts soft tissue and denatures the protein to form a coagulum that seals vessels. Several studies have demonstrated the technical and clinical advantages of ultrasonic dissection over electrocautery in different surgical areas.[7–11] Ultrasonic coagulating shears provide efficient transection, minimum thermal damage, reliable vessel sealing, and low visual obstruction from mist or smoke.

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Both ultrasonic and bipolar vessel sealing technologies are indicated for sealing vessels up to 5 mm in diameter. Historically, only bipolar electrosurgical technologies have been effective for sealing vessels 5 to 7 mm in diameter,[12,13] presenting a limitation for the use of ultrasonic technology during procedures that require dissection, mobilization, and sealing of vessels at these larger diameters. In 2013, Ethicon Endo-Surgery, Inc. developed the Harmonic ACE+ Shears with Adaptive Tissue Technology, a set of algorithms that actively monitor the instrument during use and enable the system to sense and respond appropriately to changes in tissue conditions. The Harmonic ACE+7 Shears leverage Adaptive Tissue Technology with the addition of predictive analytics that modulate energy delivery during the sealing cycle. In the Advanced Hemostasis Mode, the device is designed to seal larger vessels up to 7 mm in size by applying an algorithm that optimizes ultrasonic energy delivery combined with reduced cutting speed and a longer sealing cycle to maximize hemostasis.

The purpose of this study was to assess the initial clinical experience with this new ultrasonic device by evaluating its capability for large-vessel sealing during laparoscopic colectomy.

MATERIALS AND METHODS

This was a prospective, multicenter, observational clinical study for evaluation of vessel sealing with the Harmonic ACE+7 device during laparoscopic colectomy in consecutive cases. The study was sponsored by the manufacturer of the device; conducted in the United States, United Kingdom, and Belgium under a single protocol; and approved by an affiliated Institutional Review Board/Ethics Committee before implementation. Three colorectal laparoscopic surgeons at 3 centers (Ziekenhuis Oost-Limburg, Genk, Belgium; Jackson Hospital, Miami, Florida, USA; and The Royal Surrey County Hospital, Guildford, Surrey, UK) participated in the study.

Patient Selection

Before enrolling patients in the study, investigators were required to complete at least 2 laparoscopic colorectal surgeries with the study device, to reduce learning curve bias. The surgeons were also experienced with the use of previous versions of the Harmonic scalpel, including division of the principal colonic vessels. Eligible patients were adults (≥18 years) who were to undergo elective laparoscopic colectomy, in which dissection and transection of the inferior mesenteric artery (IMA) was indicated. Patients with any known or suspected uncontrolled bleeding disorder were excluded. They could also be excluded during surgery, if, before transection of the IMA, the surgeon concluded that isolation and transection of the IMA with exclusive use of the study device could not be safely performed, or where other intraoperative findings precluded conduct of the study procedure.

Study Procedures

All patients who potentially met eligibility criteria were approached for study participation as colectomies were scheduled with the study surgeons. The patients subsequently gave their informed consent for participation in the study. The type of colectomy procedure was not controlled by the study protocol, as long as the IMA was indicated for dissection, isolation, and transection. Laparoscopic colectomy procedures were performed according to each surgeon's own technique and surgical approach. A laparoscopic video recording was taken of the sealing of each named vessel.

For each vessel transection, seal location, time of application, vessel transection time, and tissue sticking (on a 4-point Likert scale) were assessed. The number of additional touch-ups (defined as additional activations) with the study device and use of any other energy device or hemostatic product to achieve hemostasis were noted. For the entire colectomy procedure, tissue sticking and tissue dissection were graded on 4- and 3-point Likert scales, respectively. The type of colectomy performed, operating room time, surgery time, intraoperative and postoperative blood transfusions, and length of hospital stay were recorded.

After the colectomy procedure, the surgeon completed the National Aeronautics and Space Administration–Task Load Index (NASA-TLX) and Surgeon Technique Insights Form. The NASA-TLX was used to assess the surgeon's workload in dissecting and transecting with the study device throughout the colectomy procedure. The NASA-TLX is a fixed-format, self-administered, multidimensional tool that measures workload across 6 dimensions: mental demand, physical demand, temporal demand, performance, effort, and frustration.[14] The 6 subscales are rated for the task within a 100-point range with 5-point steps ranging from low to high. These ratings are then combined to provide the task load index.

Patients were followed up after surgery for ~4 weeks (or according to the standard of care) for adverse events considered either related to the study device or the study procedure. Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) and anticoagulant medications including aspirin were recorded from 24 h before surgery through to

study completion. Any reoperations related to the original colectomy procedure were documented at the final study follow-up visit.

Endpoints

The primary endpoint for analysis was the occurrence of first-pass hemostasis at the IMA, defined as a single activation of the device's Advanced Hemostasis Mode to transect and seal the vessel. Secondary endpoints included the incidence of first-pass hemostasis at the inferior mesenteric vein (IMV), the requirement for use of additional energy devices or products to obtain hemostasis at the IMA and/or IMV, and the use of additional treatment after first-pass hemostasis was achieved (including additional use or touchups with the study device).

Statistical Analysis

This was an observational study and was not intended to test any formal hypothesis. Descriptive statistics were summarized for all study endpoints. Summary statistics included counts and percentages for categorical variables and the number of patients, number of named vessels/pedicles, mean, standard deviation, median, and minimum and maximum for continuous variables. The sample size (N = 40) for this clinical study was considered to be adequate to gather observational data regarding the use of the device to seal larger vessels in laparoscopic colectomy procedures. All available data on the enrolled patients were analyzed for evaluation of the effectiveness and safety endpoints.

Device Description

The Harmonic ACE+7 ultrasonic device combines the precision of the previous Harmonic device with large-vessel sealing capabilities. The instrument allows for the coagulation of vessels up to 7 mm in diameter, using the Advanced Hemostasis hand control button. It is enabled by an advancement in Adaptive Tissue Technology. An advanced ultrasonic algorithm actively monitors the condition of the tissue within the jaws of the device and allows the system to intelligently sense and respond to changes in patient tissue conditions. The system modulates energy delivery based on tissue thickness and tissue type to optimize vessel sealing and provide for secure and reliable large-vessel sealing.

RESULTS

From September 2014 through February 2015, 40 patients were enrolled in the study and underwent a laparoscopic colectomy study procedure. Three of 43 screened patients were excluded during surgery by the surgeon, due to findings that precluded the conduct of the study procedure. Forty patients completed the study and were included in the analysis. The types of colectomy procedure performed were sigmoid colectomy (n = 22), low anterior resection (n = 9), left hemicolectomy (n = 3), and other colorectal surgeries (n = 6) (**Table 1**). The median length of hospital stay was 3.5 nights (range, 1–30 nights).

Table 1.
Study Sample Characteristics ($N = 40$)

Characteristic	Data
Gender, n (%)	
Female	24 (60)
Male	16 (40)
Age (years)	
Mean (SD)	59.8 (13.3)
Median	63.0
Range	28.0–83.0
Body mass index (kg/m^2)	
Mean (SD)	26.1 (5.0)
Median	26.0
Range	17.4–37.7
Primary indication for surgery, n (%)	
Neoplasm	25 (62.5)
Diverticular disease	12 (30.0)
Endometriosis with recto-vaginal nodules	2 (5.0)
Colonic polyp	1 (2.5)
Type of colectomy, n (%)	
Sigmoid colectomy	22 (55.0)
Low anterior resection	9 (22.5)
Left colectomy	3 (7.5)
Abdominoperineal resection	3 (7.5)
High anterior resection	2 (5.0)
Anterior resection (not specified as high or low)	1 (2.5)

All participants were white.

Hemostasis of the IMA and IMV

Hemostasis of the IMA was achieved with a single activation (first pass) of the Advanced Hemostasis Mode in all 40 patients (**Table 2**). Moreover, no reapplications of the study device, use of other energy device, or additional

Table 2.
Vessel Assessments

Surgical Parameters and Events	IMA	IMV
Vessel exposure, n (%)		
Skeletonized	22 (55.0)	19 (47.5)
Not completely skeletonized	18 (45.0)	21 (52.5)
Seal location, n (%)		
Proximal to left colic artery	26 (65.0)	
Distal to left colic artery	14 (35.0)	
First-pass hemostasis, n (%)		
Yes	40 (100.0)	39 (97.5)
No	0	1 (2.5)
Number of Harmonic touchups, n (%)		
0	40 (100.0)	39 (97.5)
1	0	0
2	0	1 (2.5)
Use of other energy device, n (%)		
No	40 (100.0)	39 (97.5)
Yes	0	1 (2.5)
Use of other hemostatic product, n (%)		
No	40 (100.0)	40 (100.0)
Yes	0	0
Vessel transection time (s)		
Mean (SD)	21.9 (7.4)	18.5 (7.1)
Median	20.0	18.5
Range	11.0, 52.0	8.0, 52.0
Tissue sticking, n (%)		
No sticking	39 (97.5)	39 (97.5)
Slight sticking	1 (2.5)	1 (2.5)

IMA, inferior mesenteric artery; IMV, inferior mesenteric vein.

Table 3.
Summary of Adverse Events

Event Term	Patients (N = 40)	Events (n)
Nausea	9 (22.5%)	9
Pain	7 (17.5%)	7
Procedural pain	4 (10.0%)	4
Vomiting	4 (10.0%)	4
Postoperative ileus	2 (5.0%)	2
Small intestinal obstruction	2 (5.0%)	2
Wound infection	2 (5.0%)	2

The events shown occurred in 2 or more patients. The following adverse events were experienced by 1 patient each: anemia, bronchopneumonia, constipation, dehydration, gastrointestinal anastomotic leak, gastrointestinal stoma complication, genital erosion, hematuria, hypotension, ileus, procedural hemorrhage, procedural nausea, pyrexia, splenic hematoma, syncope, and urinary tract infection.

hemostatic product were necessary to maintain hemostasis. The location of the seal did not affect hemostasis, as divisions were performed both proximal (high ligation, n = 26) and distal (low ligation, n = 14) to the origin of the left colic artery. Vessel exposure was characterized as completely skeletonized in 22 patients. The average IMA transection time was 21.9 s. Mean surgery duration was 113.7 min (range, 47.0–265.0 min).

Similarly, for the IMV, first-pass hemostasis was attained in 39 of 40 transections. For the single case in which hemostasis was not realized with a single activation of the device, 2 Harmonic touchups were attempted, followed by use of a monopolar instrument. No further hemostatic products or additional device firings were required. The IMV was skeletonized in 19 patients. The vessel that required additional hemostatic measures was not skeletonized. The average IMV transection time was 18.5 s.

Slight tissue sticking was reported twice in 1 patient during dissection of both the IMV and IMA. In both instances, the study device was activated to release the tissue.

For the entire colectomy procedure, tissue dissection using the study device was rated as exceptional or satisfactory in all 40 cases. The surgeons rated the colectomy procedure as medium to high in complexity for 28 (70.0%) patients.

Adverse Events and Complications

During the postoperative follow-up period, 21 (52.5%) patients had a total of 46 adverse events that were considered definitely or possibly related to the study device or study procedure (**Table 3**). The most common procedure-related adverse events were nausea and pain. Five (12.5%) patients had 8 serious adverse events, including postoperative ileus in 1 patient, postoperative ileus and small intestinal obstruction in 1 patient, gastrointestinal anastomotic leak and procedural hemorrhage in 1 patient, splenic hematoma and small intestinal obstruction in 1 patient, and postoperative anemia in 1 patient.

One adverse event (postoperative anemia) was considered by the surgeon to be potentially related to usage of the study device (and to the study procedure). This patient underwent abdominal perineal resection. The study de-

vice was used during the procedure in a standard manner only on the IMA and IMV. The anemia was diagnosed after surgery on the same day as surgery on standard biochemistry evaluation. The patient was given a blood transfusion (2 U), and the anemia resolved 11 d later without any other action taken. No further investigations were conducted. The investigator considered the anemia to be serious, as it was an important medical event in his opinion and prolonged the postsurgical hospital stay. He considered the event possibly related to the study device, as he could not exclude the possibility of postoperative bleeding from the IMA or IMV site.

Two additional patients required postoperative blood transfusions. One patient experienced postoperative bleeding from a colotomy site in the right colon where a synchronous benign polyp had been removed. The bleeding was controlled by endoscopically placed clips, but there was subsequent leakage from the colotomy site requiring further surgery from which the patient recovered uneventfully. Another patient received 9 U of blood for a ruptured splenic hematoma diagnosed by computed tomography and during laparoscopy. The splenic injury was a delayed event and was thought to be consequent to a fall in the hospital. This same patient underwent laparotomy, adhesiolysis, and peritoneal washout to treat a small bowel obstruction, which resolved after the procedures. Neither the colotomy site bleeding nor splenic hematoma was related to usage of the study device.

In addition to these 2 patients who had reoperations, 1 patient required a reoperation to provide vascular access for adjuvant chemotherapy. Two patients had a nasogastric tube placed for decompression to alleviate symptoms of a postoperative ileus.

One laparoscopic colectomy was converted to an open procedure, as the preoperative localization of the lesion did not correspond with intraoperative findings. Instead of a low sigmoidal lesion, it was discovered during the surgical procedure to be a splenic flexure lesion that was not within the scope of an oncologically sound resection; as such, a conversion to open left hemicolectomy was necessary. This conversion was not considered to be related to the study device.

NASA Task Load Survey

The NASA-TLX overall index, which comprises 6 subscales, yielded an unweighted mean of 8.3 (based on a 100-point scale), indicating that surgeons perceived the task of transecting and sealing the IMA to have a low workload. Analysis of the dimensional scores suggests that mental and physical demands, frustration level, and required effort were viewed as low (**Table 4**). However, mean temporal demand (64.9), the amount of time pressure on the surgeon to complete the task, was relatively high. The surgeons' mean performance level (5.5) indicates a high degree of satisfaction and success in performing the task.

Table 4.
Summary of the NASA-TLX Survey

Survey Items	Score
NASA-TLX index (unweighted)	
Mean (SD)	8.3 (7.8)
Median	3.3
Range	0.0–26.7
Mental demand	
Mean (SD)	2.6 (3.9)
Median	0.0
Range	0.0–15.0
Physical demand	
Mean (SD)	1.1 (2.4)
Median	0.0
Range	0.0–10.0
Temporal demand	
Mean (SD)	64.9 (30.6)
Median	85.0
Range	10.0–100.0
Performance	
Mean (SD)	5.5 (8.5)
Median	0.0
Range	0.0–40.0
Effort	
Mean (SD)	3.0 (5.0)
Median	0.0
Range	0.0–20.0
Frustration	
Mean (SD)	2.4 (3.4)
Median	0.0
Range	0.0–10.0

DISCUSSION

In this clinical study, the study device was successfully used to divide and seal the IMA and IMV in a variety of laparoscopic left-side colorectal operations, including sig-

moid colectomy, anterior resection, left hemicolectomy, and abdominal perineal resection. A single activation of the device (first pass) was sufficient to provide and maintain adequate hemostasis of the IMA in all 40 patients. First-pass hemostasis of the IMV was achieved in 39 of 40 patients. In the single exception, 2 reapplications of the study device were followed by the use of a monopolar electrosurgical instrument.

Several factors related to safe and effective division of the mesenteric vessels have fueled debate among surgeons regarding the utility of energy devices during left-side colectomy procedures. For example, the anatomy of the IMA and IMV varies substantially between individuals.[15] This variation creates difficulty for the surgeon to predict the vessel diameter at the point of transection during a laparoscopic surgery.[16] According to the study protocol, the surgeon activated the Advanced Hemostasis Mode in transecting and sealing the IMA, regardless of the estimated vessel diameter. Even though the IMA is likely to be smaller in diameter than 7 mm, the ability of the device to seal 7-mm vessels provides surgeons with confidence, safety margin, and control. Transection of the IMA was proximal to the left colic artery in 26 patients and distal in 14.

We hypothesized that the degree of skeletonization of the IMA might affect the quality of transection, sealing, and subsequent hemostasis. Although the extent of exposure (incomplete or complete skeletonization) of the mesenteric vessels varied among patients and procedures, it did not appear to be a critical factor in vessel sealing. The surgeons in this study do, however, recommend at least partial skeletonization of the vessels when using the device.

The surgeons commented on the ability of the device to mobilize, skeletonize, seal, and transect larger vessels. The availability of such a multifunctional device may be of particular value in complex laparoscopic procedures, such as colorectal resection. The Harmonic device provides surgeons with flexibility and efficiency by reducing the number of devices necessary to achieve secure and reliable hemostasis. The avoidance of using multiple instruments should result in a cost savings for the overall procedure.

Results from the NASA-TLX survey indicated a high degree of satisfaction with the performance of the device and low perceived mental and physical demand. The only dimension of the task load survey that received a moderately high score was temporal demand, which measures the temporal pressure associated with performing a task. The average time to transect and seal the IMA in these 40 procedures was 21.9 s (range, 11–52 s). Preclinical studies have demonstrated the importance of sealing time on the security of vessel seals.[17–19] The device creates strong and durable vessel seals by modulating the delivery of energy and extending the sealing cycle.[20]

To optimize performance of the device, the surgeons suggest standardization of the methodology to include dissection of the vessel at the site of proposed division to ensure that the vessel is of an appropriate size and fits completely within the jaws of the device. They recommend actively releasing tension off the vessel during sealing and allowing completion of the sealing cycle before opening the jaws. The device provides audible feedback to the surgeon.

This study confirmed the safety profile of the total laparoscopic colectomy, specifically when using Harmonic technology. No collateral damage secondary to advanced energy use was reported, and no blood transfusions were required during the colorectal procedure. Three patients required a postoperative blood transfusion (for postoperative anemia, for a splenic hematoma, and for colotomy site bleeding). The postoperative adverse events were consistent with those reported in other studies describing this technique. Only 1 adverse event (postoperative anemia) was considered by the investigator to have a possible association with the use of the study device.

The strengths of this study are its prospective design as a clinical consecutive series to reduce bias in patient enrollment and the participation of high-volume surgeons who have experience using laparoscopic energy devices during their surgeries. That it involved multiple surgeons adhering to their own technique yields some external validity to the findings. The use of the larger vessels (IMA and IMV) as the endpoints in this study successfully demonstrates the effectiveness of the Advanced Hemostasis Mode of the device in a real-world setting. Limitations of the study are the small sample size and lack of a comparison group to further help the clinician decide which advanced energy device to use in the total laparoscopic colectomy procedure.

CONCLUSION

In this initial clinical series, the Harmonic ACE+7 Shears with Advanced Hemostasis demonstrated successful transection and sealing of the large mesenteric vessels during laparoscopic colorectal surgery. The device can be safely

used in this surgical approach to sealing major mesenteric vessels.

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