Surg Endosc (1999) 13: 763–768

Surgical Endoscopy
Ultrasound and
Interventional Techniques

Prospective, randomized trial of bipolar electrosurgery vs ultrasonic coagulation for division of short gastric vessels during laparoscopic Nissen fundoplication

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Received: 15 May 1998/Accepted: 3 March 1999

Abstract
Background: Division of the short gastric vessels (SGV) during laparoscopic Nissen fundoplication (LNF) may improve outcome. Several techniques are available for SGV division. The aim of this study was to compare in a prospective randomized trial bipolar electrocautery with cutting blade versus ultrasonic coagulation of the SGV during LNF.
Methods: In all, 86 consecutive patients undergoing LNF were prospectively randomized into two similar groups that underwent division of the SGV, respectively, using bipolar cutting forceps (BPCF) or harmonic coagulating shears (HCS). Operative time, bleeding episodes, complications, equipment problems, and surgeon's subjective scoring of satisfaction and ease of use were assessed.
Results: Mean (±SD) time for fundic mobilization and division of the SGV was not significantly different between the two groups (BPCF = 20 ± 12 min vs. HCS = 22 ± 12 min). Bleeding events, estimated blood loss, surgeon satisfaction, and subjective ease of use were similar, and no transfusions were required. Complications in the BPCF group included a delayed gastric perforation requiring reoperation and two gastric serosal burns repaired intraoperatively. There was one splenic capsular tear using the HCS and one splenic capsular tear using the BPCF, both of which were controlled intraoperatively. The number of functional equipment problems were few and statistically similar. In the authors' institution, the per case total costs with capital expenditures amortized over 100 cases indicate savings of approximately $202/case with use of the BPCF versus the HCS. Regression analysis demonstrated a significant correlation between body mass index (BMI) and total case length and time for division of the SGVs.
Conclusions: The BPCF and HCS appear to be equally efficacious for SGV division during LNF. Judicious application of both energy forms and heightened vigilance for gastric serosal injury are required with use of both the BPCF and HCS in cases of tight gastrosplenic adhesions or short SGVs. The BPCF carries a potential cost advantage over the HCS in the authors' institution. The BMI directly correlates with time required to divide SGVs and total length of LNF.

Key words: Bipolar cutting forceps — Bipolar electrocautery — Gastroesophageal reflux disease — Harmonic coagulating shears — Laparoscopic surgery — Nissen fundoplication — Short gastric vessels

First described in 1956 by Dr. Rudolph Nissen [31], the Nissen fundoplication, with various modifications of the original procedure, has long been the preferred surgical alternative to medical therapy for the treatment of refractory gastroesophageal reflux disease (GERD) [9–11, 34, 42]. Since its introduction in 1991 [8, 15], laparoscopic performance of this procedure has been gaining acceptance as an equally efficacious therapy for GERD [3, 5, 6, 19, 39, 45, 46], and may well become the "gold standard" for GERD therapy [47]. The rapid increase in the use and popularity of the laparoscopic Nissen fundoplication (LNF) has been noted in both the academic and community surgical arenas [26, 33].

Although somewhat controversial [4, 13, 18, 21, 37, 47], division of the short gastric vessels (SGV) is commonly performed to achieve a loose and tension-free Nissen fundoplication [7, 13, 17, 20, 24, 28, 35, 36, 44, 45, 47]. Previous studies have compared clipping with sharp division and ultrasonic coagulating shears for SGV division [25, 41]. An additional method that has gained popularity for laparoscopic use is the bipolar electrocautery [12, 27, 30]. The

Presented at the annual meeting of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), Seattle, Washington, USA, 3 April 1998

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Fig. 1. **A** BiCOAG® bipolar cutting forceps (BPCF), (Everest Medical Laboratory, Minneapolis, MN, and Valleylab Force 2™ electrosurgical generator, Valleylab, Inc., Boulder, Colorado, USA). **B** intraoperative view of short gastric vessel division using the BPCF.

Fig. 2. **A** LCS® harmonic coagulating shears (HCS) and ultrasonic generator (Ethicon Endo-Surgery, Cincinnati, Ohio, USA). **B** intraoperative view of short gastric vessel division using the HCS.

objective of this prospective, randomized human study was to compare the performance of bipolar cutting forceps (BPCF) with that of harmonic coagulation shears (HCS) for division of the SGV during LNF.

Materials and methods

A total of 86 individuals undergoing LNF in a single institution by one primary surgeon between August 1996 and March 1998 were prospectively randomized to undergo division of the SGV, respectively, using BPCF (BiCOAG®, Everest Medical Laboratory, Minneapolis, MN, USA), (Fig. 1), or HCS (LCS®, Ethicon Endo-Surgery, Cincinnati, OH, USA), (Fig. 2). During this period, 22 other patients were excluded (not randomized): 12 that underwent alternative fundoplication (i.e., Toupet), six performed by an alternative attending surgeon learning the technique of LNF, and four in which additional procedures were required or alternative equipment was being evaluated.

The BPCF was powered by a Valleylab Force 2™ electrosurgical generator (Valleylab, Inc., Surgical Products Division, Boulder, CO, USA) at a power setting of 60 W for all cases. The HCS was set at level 4 for all cases. Power settings for both devices were empirically established as the most appropriate and effective levels by the study surgeon in consultation with the manufacture's representatives. Both instruments have a 10-mm outside shaft diameter.

Data collection

Randomization was performed at the time of operation using a random numbers table. Demographic data including age, gender, height, and weight (for calculation of body mass index [BMI]) [14, 22] were recorded prospectively.

Intraoperatively, specific procedure times were recorded including start and completion of fundic mobilization and SGV division, and total operative time. Blood loss (EBL) was estimated by the operating surgeon and recorded along with the number of bleeding episodes from any source during SGV division and the number of bleeding episodes from the SGVs at any time following SGV division. After the procedure, the operating surgeon recorded all complications and equipment problems, and scored subjective ease of use and satisfaction for the device using 10-cm visual analog scales.

Statistical analysis

The Student's *t*-test or Fisher's exact test for parametric data, and chi-square or Wilcoxon's rank test for nonparametric data were used for sta-

Table 1. Patient demographics[a]

	Bipolar cutting forceps	Harmonic coagulating shears
No. of patients ($n = 86$)	46	40
Age[b]	44.7 (±10.6)	47.2 (±12.5)
Gender	21 M/25 F	19 M/21 F
Body mass index (kg/m^2)[b]	29.9 (±6.18)	31.0 (±1.2)

[a] $p \geq 0.05$ in all cases
[b] mean ± SD

tistical analysis as appropriate. Linear regression modeling was used to establish correlation between BMI and other study parameters. Statistical significance was defined at $p \leq 0.05$. Summary data are expressed as mean ± standard deviation (SD).

Results

In the entire series, 46 patients were randomized to BPCF and 40 to HCS. There was one crossover from HCS to BPCF secondary to uncontrolled bleeding with the HCS caused by presumed equipment malfunction. Statistically, similar groups based on age, gender, and BMI were achieved (Table 1). Mean time for fundic mobilization and division of the SGVs was not significantly different between the two groups (BPCF = 20 ± 12 min vs. HCS = 22 ± 12 min) (Table 2).

Complications

Bleeding events and estimated blood loss were similar between the two groups, and no transfusions were required. The BPCF group included one patient with a postoperative delayed gastric perforation requiring reoperation on postoperative day 6, and two patients with intraoperative gastric serosal burns, which were oversewn intraoperatively. The gastric perforation was a 1.2-mm diameter full-thickness defect along the greater curve adjacent to a SGV and consistent with either thermal or mechanical injury. The serosal burns appeared as serosal blanching (a distinct visual change of the serosa from translucent to opaque white) at the base of a SGV. There was one splenic capsular tear using the HCS, which required use of the argon beam coagulator for hemostasis, and one splenic capsular tear using the BPCF, which was controlled with Surgicel® (Johnson & Johnson Medical, Inc., Arlington, TX, USA) (Table 2).

There was no significant difference in the number of equipment problems. Also, surgeon satisfaction and subjective ease of use were similar for both devices (Table 2).

Linear regression analyses demonstrated a significant direct correlation between BMI and total operating time in the combined (total) patient group and BPCF group, as well as between BMI and time for SGV division in the total patient, BPCF, and HCS groups (Table 3).

Cost data in the authors' institution indicate a cost of $199 for each BiCOAG® disposable unit and $325 for each LCS® disposable unit. Purchase price for the Valleylab Force 2™ electrosurgical generator is approximately $7,950, and for the LCS® generator approximately $15,500.

Table 2. Comparison of bipolar cutting forceps and harmonic coagulating shears for division of the short gastric vessels[a]

	Bipolar cutting forceps[a] (±SD)	Harmonic coagulating shears[a] (±SD)
SGV division (min)	19.9 (±11.5)	22.1 (±11.8)
Length of case (min)	113 (±22)	10 (±26)
No. of bleeding episodes:		
During SGV division	1.2 (±1.3)	1.1 (±1.4)
After SGV division	0.2 (±0.5)	0.5 (±0.8)
EBL (ml)	43.3 (±30.5)	88.1 (±169.0)
Transfusions	none	none
Satisfaction (0–10)	8.2 (±1.2)	8.5 (±1.4)
Ease of use (0–10)	8.5 (±1.0)	8.9 (±0.9)
Equipment problems	2	4
No. of complications	4	1

[a] $p \geq 0.05$ in all cases

Discussion

Although controversial, division of the SGV during LNF is commonly performed and may improve outcome [13, 47]. Previous clinical studies evaluated SGV division using endoscopic clips with sharp division versus the ultrasonic coagulating shears [25, 41]. These studies showed significant advantages to performing SGV division with the HCS device. Although two recent publications have compared bipolar electrosurgery to ultrasonic coagulation for various laparoscopic applications in animal models [2, 40], to the authors' knowledge, this is the first prospective, randomized human study to compare the technology of bipolar electrocoagulation to ultrasonic coagulation in the division of the SGV during LNF. Admittedly, a prospective survey of a single surgeon's experience is open to concerns of observer bias, but this study was undertaken at a time when the study surgeon was introduced initially to each of these technologies for division of the SGV.

Previous studies have demonstrated that use of ultrasonic technology may decrease operative times by eliminating the need for multiple other conventional single-function laparoscopic instruments and the obligatory port exchanges required for their use [16]. Furthermore, other investigators have noted increased efficiency and ease of use with the HCS [16, 40], primarily because of its synchronous coaptation and cutting ability. However, with the advent of the BPCF, bipolar coagulation technology now is available in a similar multiuse format, and the ability to coagulate and cut synchronously is available with both types of device. The operative handpieces for the devices (Figs. 1 and 2) are similar in size and function (pistol grip), and both offer a similar limited ability for alternative functions, specifically grasping and dissecting. In the current study, the operative time for SGV division was similar whether the HCS® or the BPCF® was used.

Although functionally similar, the BPCF and HCS achieve their coagulation and cut ability via technologically distinct methods. The HCS uses the mechanical energy of a blunt blade oscillating at approximately 55 kHz over an excursion of 50 to 100 μm to denature and solubilize tissue collagen and coapt vessel walls in a tissue-welding technique [1], which produces no smoke and only minimal amounts of vapor. The BPCF uses electromagnetic

Table 3. Correlation of body mass index with outcome variables

Independent variable	Total patient group ($R/R^2/p$)	Bipolar cutting forceps ($R/R^2/p$)	Harmonic coagulating shears ($R/R^2/p$)
Length of case	0.25/0.06/0.02[a]	0.42/0.18/0.003[a]	0.05/0.002/0.77
SGV division time	0.31/0.10/0.003[a]	0.29/0.09/0.05[a]	0.33/0.11/0.04[a]
Surgeon's assessment			
Ease of use	−0.06/0.003/0.58	−0.07/0.005/0.65	−0.09/0.01/0.58
Satisfaction	−0.07/0.01/0.51	−0.16/0.03/0.27	−0.01/0.0001/0.94

[a] Statistically significant correlation
SGV, short gastric vessel

energy to produce coagulation and a second, separate mechanical blade function to cut the coagulated tissue. Local tissue temperatures between and around the blades are significantly higher than required for collagen denaturation, increasing the risk of local thermal injury [2]. Smoke production can be significant with the BPCF, limiting endoscopic vision for short periods of time. Although thermal injury from bipolar diathermy probes is a concern, Ramsay et al. [32] have demonstrated that actual tissue heat transfer produces temperatures well below the injurious level less than 2 mm from the device tip, whereas the monopolar diathermy units produce injurious local tissue temperatures as far as 4 mm from the device tip [32].

The BPCF power setting of 60 W used in the current study was determined empirically in consultation with the manufacturer's representative to be the lowest effective setting for division of the gastrosplenic attachments and SGVs. The authors' experience with this phenomenon in the current study has heightened their level of vigilance for gastric serosal injuries, which may be partially ameliorated by judicious use of lower power settings when the BPCF is used to divide short SGVs and tight gastrosplenic adhesions in close proximity to the greater curve of the stomach. Alternatively, although no HCS-related gastric serosal injuries occurred in the current study, it should be noted that inadvertent grasping and application of ultrasonic energy to the gastric serosa along the greater curve are also of concern. HCS serosal injury can occur as the surgeon proceeds through the gastrosplenic attachments without specifically identifying each individual SGV and may create a type of delayed perforation complication similar to that seen with electrosurgical lateral thermal transfer injuries. Overall, serosal injury during division of the SGV, whether electrosurgically or ultrasonically induced, should be avoidable with a modicum of operator education and training.

In a recent publication, Spivak et al. [40] demonstrated no statistically significant difference in the hemostatic capability among vascular clips, bipolar electrocautery, and harmonic coagulating shears when small and medium-size vessels ($\leq$3.5 mm) are divided in a porcine model. Likewise, no difference in hemostasis during SGV division using either the HCS or the BPCF was demonstrated in the current study.

The complications in the current study were few and statistically similar between the two groups. Use of the BPCF did demonstrate a trend toward lateral thermal-related injuries, which may have been precipitated by use of the BPCF for division of very tight gastrosplenic adhesions or very short SGVs. As mentioned, this type of complication may be ameliorated partially by selection of lower electrosurgical power settings for work in these more difficult and treacherous situations.

The splenic capsule tears in each group were attributable to operator error and appeared to have no distinct device-related etiology. The one case of uncontrolled SGV bleeding requiring crossover from use of the HCS to the BPCF occurred early in the series, and it is thought that this complication was related to a faulty ultrasonic generator or misassembly of the HCS® equipment. Likewise, the number of equipment problems were few and statistically similar between the groups, occurring early in the series and learning curve of the surgeon and operating room staff.

Price data from the authors' institution indicate a cost of $199 for each BiCOAG® disposable unit and $325 for each LCS® disposable unit. Calculation of the approximate total cost per case including capital expenditure for the LCS® generator (~$15,500) and the electrosurgical generator (~$7,950) amortized over 100 cases reveals a total cost savings per case of approximately $202 with use of the BiCOAG® versus the LCS® in the authors' institution. It should be noted that the BPCF device can be used with most existing electrosurgical generators, which may translate to even greater cost effectiveness with the BiCOAG®. Precise cost effectiveness is difficult to assess in comparisons of technologies that are fundamentally different, and true cost effectiveness should be calculated individually at each institution contemplating the acquisition of these competing technologies. Also, since initiation of this study, alternative devices with smaller diameters and subtle differences in design have been marketed, giving the surgeon a broader selection of functions from which to choose and tailor to specific practice needs.

The BMI has been used for many years as a simple, effective, accurate, and quantifiable anthropometric correlate to obesity [14, 22, 23]. Anecdotally, many surgeons feel that obesity increases laparoscopic procedure times. Retrospectively, obesity has been correlated with increased operative times for laparoscopic cholecystectomy [38]. Previous prospective data for laparoscopic cholecystectomy has not demonstrated a significant correlation between laparoscopic operative times and obesity [29], but has shown obesity to be a risk factor for biliary injury [43]. To the authors' knowledge, this is the first prospective series to demonstrate a direct correlation between BMI and laparoscopic operative times.

Conclusions

Bipolar electrocautery and ultrasonic coagulation are equally viable alternatives for short gastric vessel division

during laparoscopic Nissen fundoplication. Relatively few and a statistically similar number of equipment functional problems, bleeding episodes, or other intraoperative complications were associated with the use of either the HCS or the BPCF. In addition, there were no statistically significant differences in surgeon satisfaction or ease of use scores between these devices. Single institution cost data indicate a potential disposable and total cost benefit with use of the BPCF as compared with the HCS. Finally, BMI has a direct statistical correlation with total length of LNF cases and time for SGV division, but does not affect surgeon subjective ease of use or satisfaction with either the BPCF or HCS.

Acknowledgment. The Washington University Institute for Minimally Invasive Surgery is supported by an educational grant from Ethicon Endo-Surgery Inc., Cincinnati, OH, USA.

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