

Rupture of the Spleen With the Harmonic Scalpel: Case Report of an Unexplained Complication

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ABSTRACT

A 69-year-old female patient underwent a standard laparoscopic Nissen fundoplication for repair of a hiatal hernia and correction of reflux. A Harmonic scalpel was used as the only energy source intraoperatively. The operation was uneventful until the middle of the procedure when a significant amount of blood was noted in the left upper quadrant. After aspiration and careful inspection, a 5-cm irregular vertical laceration was found on the posterior and lateral aspect of the spleen, far away from the operative field and any previous instrumentation. Control of bleeding from the spleen was unsuccessful, so a laparoscopic splenectomy was performed, and the procedure was finished without further incident. Histologic examination revealed a normal spleen with no pathologic alterations accounting for the laceration. After comprehensive evaluation of this case to assess a potential cause of the complication, the question arose as to whether the energy produced by the Harmonic scalpel could have caused this splenic laceration.

Key Words: Laparoscopy, Harmonic scalpel, Complication, Nissen fundoplication, Splenectomy, Energy source.

INTRODUCTION

For intraabdominal dissection of tissue, the Harmonic scalpel (Ethicon Endo Surgery, Cincinnati, OH, USA) has been increasingly used worldwide during laparoscopic procedures over the past several years as an alternative to electrical energy sources, such as monopolar or bipolar dissection; or other vessel coagulation techniques; or even classical surgical techniques, such as suturing and sharp scissor dissection. Within the last decade in operative medicine worldwide, the Harmonic scalpel has optimized operative procedures by improving dissection techniques and thereby shortening OR time and reducing the risk for potentially delayed postoperative bleeding. The device has undoubtedly been used for operative tissue dissection in multiple procedures in different specialties and in uncountable procedures around the planet for the benefit of the patients. This is also reflected and confirmed in a large number of scientific publications. As of March 8, 2007, there have been 352 scientific papers listed in the MEDLINE database with the key word "Harmonic scalpel" in the title or abstract.

The function of the Harmonic scalpel is based on an ultrasonic technique and is indicated in general and endoscopic surgery for cutting and coagulating soft tissue when hemostasis is desired with minimal risk of burns, or electrical injury. An ultrasonically activated scalpel controls bleeding by protein denaturation, in contrast with electrosurgery and lasers that destroy tissues by burning, through localized intense heat. The blade tip vibrates longitudinally about 55000 times/second over an excursion of 50 μm to 100 μm and uses ultrasonic energy to denature tissue protein to seal blood vessels up to 5 mm in diameter without tissue desiccation or charring.¹ Functional aspects including pros and cons of the ultrasonic energy source have been previously described^{2,3} According to the published literature, the device seems to work reliably and safely, and few complications have been documented.

In the following case report, we discuss an unexplained complication that occurred while using the Harmonic scalpel in a laparoscopic Nissen fundoplication with suggestions of the possible cause of such an incident.

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CASE REPORT

A 69-year-old Caucasian woman, height 5'8" and weight 195 lbs (88.6 kg), having previously had an open cholecystectomy, hysterectomy, and lumbar spine operations, presented with symptoms of hiatal hernia, and persistent gastroesophageal reflux disease (GERD), nonresponsive to medical management and worsening in severity over several years. She complained of regurgitation with nocturnal aspiration, and an upper GI endoscopy demonstrated a large sliding type hiatal hernia, so surgical intervention was recommended and a laparoscopic Nissen fundoplication was performed at Fayette Medical Center, Fayette, Alabama, USA.

For dissection and preparation of tissue necessary for the Nissen procedure, Harmonic scalpel has proven useful, and it is applied at our institution on a routine basis. We use an UltraCision generator (GEN01), model G110 with 115VAC, 60Hz, 230Watts, serial no. 74151, MFG option 1.35, with foot and switch cable (GEN03) and Luke hand piece (HP05X). All are reusable items except the disposable 5-mm curved active blade device (LCS-C5) used for intraabdominal laparoscopic procedures (all: Ethicon Endo Surgery, Cincinnati, OH, USA). The entire unit was at the time of the incident about 8 years old and had passed all routine safety checks that are performed regularly according to the manufacturer's recommendations. The generator energy level setting is always on Level 2 (1=minimum power level and 5=maximum power level).

Preoperative preparation proceeded in the usual fashion, with induction of general endotracheal anesthesia, and insertion of an oral gastric tube without difficulty. The open Hasson technique was performed superior and lateral to the umbilicus with a blunt 12-mm trocar. Pneumoperitoneum was initially established with 8 mm Hg, and later increased to 10 mm Hg or a maximum of 12 mm Hg if needed. The optic was inserted through the Hasson port, and the patient was placed in a reverse Trendelenburg position with a right lateral decubitus tilt. Two secondary 5-mm ports were inserted both under direct visual control, one below the xiphoid in the midline and one in the left subcostal margin. Several adhesions secondary to the previous cholecystectomy were noted in the right upper quadrant and were taken down with the Harmonic scalpel. Two additional 5-mm ports were placed in RUQ under direct visual control. The left lateral liver lobe was retracted anteriorly by using self-retaining ratcheted forceps placed on the diaphragm. The lesser omentum was divided using the Harmonic scalpel, exposing the right crus of the diaphragm. The peritoneum was incised over

the right crus of the diaphragm, and the esophagus was dissected from the hiatus by using the Harmonic scalpel. The short gastric vessels were divided along the greater curve of the stomach by using the Harmonic scalpel, mobilizing the stomach medially away from the hilus of the spleen. Peritoneal attachments to the left crus of the diaphragm were then taken down with the Harmonic scalpel. The dissection of short gastric vessels from the hilus of the spleen was unremarkable without any adhesions noted or excess retraction necessary. A small window was created on the posterior inferior aspect of the distal esophagus at the gastroesophageal junction, and a Penrose drain was placed around the esophagus and secured with a 0 PDS Endoloop and used for traction. The esophagus was then further dissected from the hiatus by using the Harmonic scalpel until an adequate length of the esophagus was noted in the abdominal cavity. Until this point, the procedure was a normal uneventful laparoscopic Nissen fundoplication.

Before performing the wrap, on inspection of the left upper quadrant, a significant amount of blood was noted. Inspection of the hilus of the spleen, and greater curvature of the stomach and diaphragmatic hiatus failed to reveal any significant abnormality or obvious source of bleeding. The majority of the blood appeared to be originating from the lateral aspect of the splenic body. As the blood was aspirated, inspection of the most lateral aspect of the splenic body revealed an approximately 5-cm long vertical jagged laceration reaching deep into the pulp of the spleen that was bleeding significantly. There were no adhesions present, and the laceration was not at the splenophrenic ligament as a potential source of traction laceration. No prior instrumentation had been performed in this area either. Attempted control of the bleeding by suture of the splenic body was unsuccessful; therefore, it was decided to proceed with a laparoscopic splenectomy. The inferior aspect of the pole of the spleen was dissected with the Harmonic scalpel, the left lateral trocar replaced with a 12-mm port through which a linear stapler was inserted, fired at the base and the hilus of the spleen transecting the vessels. The remainders of the attachments of the superior aspect of the pole were divided, and its lateral attachments divided also completely freeing the spleen. The spleen was placed in a retrieval sac, volume reduced, and removed from the abdomen through the Hasson port and sent to pathology for histological examination. The splenic bed was then reinspected, revealing good hemostasis and showing no other source of bleeding. The Nissen procedure was continued and finished uneventfully. The estimated intraoperative blood loss was

500mL. After an uneventful recovery, the patient was discharged on postoperative day 2 with a follow-up at 10 weeks with no adverse effects. The histologic examination revealed a normal 148-gram, 5x1.7-cm spleen. A reason for the splenic laceration was not found.

DISCUSSION

A wide variety and increasing number of laparoendoscopic procedures are being performed in the Department of Surgery at Fayette Medical Center (FMC). A highly trained general surgeon with comprehensive experience of 5000+ laparoscopies, among them 500+ Nissen funduplications, and a qualified OR team have been performing advanced laparoscopy on a routine base for over 15 years. This complication of a splenic laceration of unknown cause is the first adverse event seen in combination with the Harmonic scalpel at our institution. Although the intraoperative situation was solved with an immediate emergency splenectomy⁴ the event could have had severe consequences if not immediately discovered and treated.

The Harmonic scalpel is explicitly recommended for a laparoscopic Nissen fundoplication by its manufacturer Ethicon Endo-Surgery, Inc. on the instruments website,⁵ and the entire unit at FMC has been shown to work without any problems noted previously or after this procedure. All instruments used in this operation were introduced into the abdomen by the single surgeon, and all instrument tips were always under visual control. Intraoperative damage by instruments towards the spleen could be excluded as a cause for the retrosplenic laceration because all manipulation of tissue was performed by the surgeon and monitored at all times. No intraoperative instrument use was even close to the site of the spleen laceration. Also no other source of energy, eg monopolar or bipolar cautery, was used during this procedure. So the possible injury by stray electric current could be ruled out.

A comprehensive search in the MEDLINE database as of August 6, 2006, listed 24 papers for the combined key words "harmonic scalpel" and "complication," but none of the papers describe a similar adverse event with a splenic rupture parallel to the use of a Harmonic scalpel. Complications published so far mention intraoperative intestinal damage⁶ as well as lateral thermal damage⁷ and proximity injury⁸ in animal models. To avoid thermal damage, a safety margin of 3mm to sensitive structures is recommended,⁹ and limited and careful use of power level 4 and very limited use of power level 5 is suggested. Temperatures can reach up to 294 degrees Celsius at the blade of the instrument when power level 5 is used.¹⁰

After a comprehensive evaluation, the exact cause of the described intraoperative splenic laceration remains unclear at the present time. After exclusion of all other routine causes of splenic injury including adhesions and instrument movement, the hypothesis arose of whether cavitation produced by the Harmonic scalpel can contribute to this type of injury. Cavitation is a routinely observed phenomenon where tissue planes are separated by pressure produced by the energy generated by using the Harmonic scalpel. The intraoperative example seen in **Figure 1** resulted in an area of tissue plane dissection 2 cm to 3 cm in diameter at only a power setting of level 2. Can this phenomenon increase the intraorgan pressure of an encapsulated organ like the spleen, thereby causing an instrument-distant rupture of its capsule and resultant bleeding? It would be of interest if this suggested hypothetical mechanism can be reproduced under controlled conditions or even verified in an appropriate animal model.

A search of the MAUDE (Manufacturer and User Facility Device Experience) database¹¹ from 1992 to March 30, 2006, revealed at least 3 cases of severe complications parallel to using a Harmonic scalpel (Event Keys: #121551, #27984, and #508074). In all 3 cases a Harmonic scalpel was used for a Nissen fundoplication or a hiatal hernia operation. In one case (#27984), the patient had postoperative bleeding that required reoperation on postoperative day 2; however, the patient died on postoperative day 3. The second case report (#508074) was of a patient who had a postoperative perforation of the stomach and died.

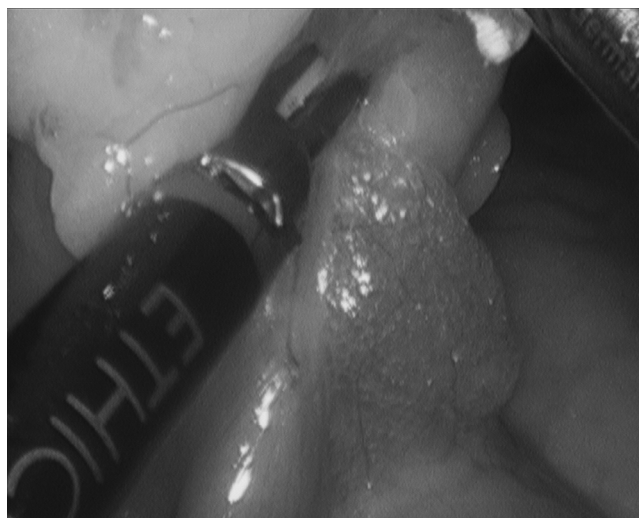


Figure 1. Cavitation phenomenon inside the tissue several centimeters from intraabdominal use of the Harmonic scalpel with tissue expansion.

The third case (#121551) was intraoperative bleeding of unknown origin when the surgeon took down the short gastric vessels. The patient received blood transfusions, and the bleeding stopped without further reoperation. Although information from these 3 reports is very limited and the Harmonic scalpel might not have been related to these incidents, case #1 and #3 especially show similarities with our case report.

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CALENDAR OF EVENTS

September 5-8, 2007, San Francisco, California, USA. **16th SLS Annual Meeting and Endo Expo 2007**, presented by the Society of Laparoendoscopic Surgeons. LOCATION: Hyatt Regency San Francisco. DIRECTORS: Harrith M. Hasson, MD, William E. Kelley, Jr. MD; GENERAL CHAIR: Paul Alan Wetter, MD; SCIENTIFIC CHAIRS: Raymond J. Lanzafame, MD, MBA, Carl J. Levinson, MD.

February 6-9, 2008, Honolulu, Hawaii, USA. **AsianAmerican MultiSpecialty Summit III Laparoscopy and Minimally Invasive Surgery** presented by the Society of Laparoendoscopic Surgeons. LOCATION: Hilton Hawaiian Village Beach Resort & Spa.

September 17-20, 2008, Chicago, Illinois, USA. **17th SLS Annual Meeting and Endo Expo 2008**, presented by the Society of Laparoendoscopic Surgeons. LOCATION: Hyatt Regency McCormick Place.

February 11-14, 2009, Orlando Florida, USA. **EuroAmerican MultiSpecialty Summit III Laparoscopy and Minimally Invasive Surgery** presented by the Society of Laparoendoscopic Surgeons. LOCATION: Disney's Contemporary Resort.

September 9-12, 2009, Boston, Massachusetts, USA. **18th SLS Annual Meeting and Endo Expo 2009**, presented by the Society of Laparoendoscopic Surgeons. LOCATION: Westin Copley Place.

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