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NEW CONCEPT

Stapler-Less Robotic Partial Gastrectomy: a Safety and Feasibility Experimental Study

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Abstract

Background No true preliminary work has been performed and published on the use of the bipolar cautery devices for transection of the stomach when performed as a part of the sleeve gastrectomy or gastric wedge resection. The objective of this study was to investigate the feasibility and safety of substitution of linear surgical stapling devices for use of a bipolar electrosurgical sealing instrument in the performance of a totally robotic partial gastrectomy (TRPG).

Methods Ten female pigs were assigned to an intervention or control group. Intervention included TRPG with a robotic bipolar tissue coagulation device. In the control group, TRPG was performed using the staplers. Assessed outcomes included presence of the intraoperative and postoperative bleeding or leak and features of the sections from the stapled line or sutured line.

Results Mean operating time was (130 ± 31 min) and (87 ± 23 min) in the study and control groups ($p = 0.03$). Intraoperative gastroscopy revealed slow bleeding associated with the staple line in 3/5 control pigs; oozing was not appreciated in any of the study pigs (0/5). No leak was detected during intraoperative gastroscopy. No major complications were suspected postoperatively or identified at postmortem exam in either group. Mean injury width was (1.12 ± 0.93 mm) in the control group with greater mean injury width (7.88 ± 3.73 mm) in the study group ($p = 0.001$). Mean depth of ulceration was (0.99 ± 0.94 mm) in the control group, with greater mean ulceration depth (2.25 ± 0.84 mm) in the study group ($p = 0.002$).

Conclusion The study showed the technical feasibility of performing stapler-less gastric wedge resection. The electrocautery alone failed to demonstrate the technical feasibility which was obtained with the concomitant use of a tissue clamp and a suture.

Keywords Stapler-less totally robotic sleeve gastrectomy · Partial gastrectomy · Wedge gastric resection · Animal model · Experimental surgery

Background

In 2009, the American Society of Metabolic and Bariatric Surgeons (ASMBS) reclassified the laparoscopic sleeve gastrectomy (LSG) from an experimental procedure to an acceptable procedure for the primary surgical treatment of morbid obesity ("Updated Position Statement on SG") [1]. Some studies have shown that in the short and mid-term, LSG has been effective in terms of weight loss [2–4]. Evidence also suggests that LSG is effective in improving glycemic control in patients with type II diabetes, independent of weight loss [2–5]. Sleeve gastrectomy may be performed as a staging operation before gastric bypass or duodenal switch or as a standalone procedure for weight loss [6]. In 2013, the ASMBS estimated that LSG overtook Roux-en-Y gastric bypass (RYGB) as the most commonly performed bariatric procedure, comprising 42% of 192,000 weight loss procedures performed in 2013 [7]. Furthermore, in 2014, LSG constituted 51% of all bariatric procedures as part of an ongoing trend that started a decade earlier [8].

Sleeve gastrectomy may be performed by open, laparoscopic, and robotic methods by firing of a linear cutting stapler

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starting at about 2–6 cm proximal to the pylorus and proceeding toward the angle of His to form a tubularized stomach. Controversy exists over the utilization of the robot for bariatric surgery. Widely reported disadvantages of utilization of the robotic platform for bariatric surgery include increased operating time, higher costs, and a paucity of reported outcomes [9–11]. Recently, several authors have reported similar and decreased rates of perioperative and short-term complications after robot-assisted sleeve gastrectomy when compared to conventional LSG [12–14]. Robotic surgery has resulted in reduced blood loss and transfusion rates when compared to open or minimally invasive operations [10]. It also provides the advantage of endowristed instruments for 360° manipulation of the robotic instruments, allowing for precise operation [12]. Surgeons who use the robot for LSG report ease of oversewing the staple line as the primary reason for doing so [12].

Stapling technology, despite significant improvements, still has some limitations. Stapler line bleeding and fistulas are the most important complications of sleeve gastrectomy, which may be related to inappropriate stapling [4, 12]. Long-term complications such as ulcer formation and chronic abdominal pain may be a result of remaining foreign bodies such as staples [15]. Complication rates after LSG have been reported between those of the adjustable gastric band and the RYGB [16]. Using buttressing materials or oversewing is intended to improve the outcomes, but there is little data on the actual benefits [17].

There is a single report which detailed the case of a patient with a documented metal allergy where staples use was contraindicated and necessitated the creation of a gastric tube using a two-layered suture closure of the gastric body [17]. No true preliminary work has been performed and published on the use of the bipolar cautery devices for transection of the stomach when performed as a part of the sleeve gastrectomy.

Objective

The objective of this study was to investigate the feasibility and safety of substitution of linear surgical stapling devices for use of a bipolar electrosurgical sealing instrument in the performance of a totally robotic partial gastrectomy (TRPG).

Methods

The Institutional Animal Care and Use Committee (IACUC) approved the study protocol (2015-1377).

Design

This is an experimental study to evaluate the feasibly of substituting the linear stapler with a robotic bipolar tissue coagulation device (Vessel Sealer™, Intuitive Surgical, Sunnyvale, CA) for division of the gastric body during performance of partial gastrectomy. Ten female pigs were assigned to an intervention or control group. Intervention included TRPG with a robotic bipolar tissue coagulation device (TRPG—without stapler). In the control group, TRPG was performed in standard fashion—using the staplers. Assessed outcomes included presence of the intraoperative and postoperative bleeding or leak and features of the sections from the stapled line or sutured line.

Preoperative Protocol

The pigs were placed on a liquid diet starting at midnight the day of surgery. Animals were assigned to control or treatment procedure at the time of surgery. All animals underwent standard general anesthesia with endotracheal intubation. An orogastric tube was inserted for evacuation of the stomach after anesthesia induction.

Surgical Technique

Pneumoperitoneum was established by insufflation by Veress needle technique in the left upper quadrant, followed by robotic trocar placement. The peritoneal cavity was accessed with a standard laparoscopic technique and the initial evaluation was completed. The robot (Da Vinci Si, Surgical Intuitive, CA, USA) was then docked for use in the remainder of the operation. Four additional trocars were placed in the supraumbilical, right para-medial, right superior midaxillary lines, and the left upper quadrant under direct laparoscopic visualization. The robotic arms were placed through the right superior midaxillary and left upper quadrant trocars, while the camera was inserted through the supraumbilical trocar. Right para-medial trocar was used as an axillary port to deliver laparoscopic staplers and additional instruments for assistance (Fig. 1). After identification of the landmarks on the stomach, the short gastric vessels and gastro-splenic attachments were taken down with bipolar cautery. The experimental procedure was adapted in accordance with animal welfare guidelines [18]. Guidelines for the welfare of animals used in research stipulate that suffering must be kept to a minimum have been followed. Rapid weight loss can be one of many indicators of animal pain and distress and should be avoided when possible [18]. To minimize the weight loss effect and associated stress, a minimal (wedge) resection was carried out along the greater curvature of the stomach, starting 10–15 cm proximally from the pylorus and ending at the proximal fundus, away from the gastroesophageal junction and the lesser curvature in order to maintain near-normal capacity of the stomach.

Fig. 1 Robotic arms and trocars setup

Study Group—TRPG Without Stapler

The gastrectomy started at the lowest point of the mobilized greater curvature of the stomach by application of a non-crushing tissue clamp to immobilize the anterior and posterior wall in good apposition to facilitate transection with the robotic controlled bipolar electrocautery (EndoWrist Vessel Sealer, Intuitive Surgical, Sunnyvale, CA, USA) allowing a temporary seal for approximation and sutured approximation of the anterior and posterior walls of the gastric lumen by continuous robotically sewn 2-0 absorbable stitch. The non-crushing clamp was advanced along the stomach, and transection with the bipolar cautery was repeated in a sequential fashion until the desired section of the greater curve was removed (Fig. 2). The oversewn edge was closely inspected for its integrity. Next, imbrication of the suture line with duplication of the anterior and posterior gastric wall was completed robotically with 2-0 absorbable stitch in running fashion traveling 1–1.5 cm between needle applications in the seromuscular layer, using 8-mm robotic needle drivers.

Control Group—TRPG with Staplers

In the control group, the gastrectomy started at the lowest point of the mobilized greater curve of the stomach by application of the stapler to fire 60-mm linear cutting stapler cartridges (Endo GIA™ 60 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology, Medtronic, Minneapolis, USA) across the greater curve. The stapler was applied laparoscopically via an accessory port by an assistant. Interrupted figure-eight stitches were used to oversew the cut-edge if there was arterial pulsatile bleeding. The transected stapler line was closely inspected for its integrity and oversewn using the Lembert technique. Oversewing was completed robotically with 2-0 absorbable stitch in running fashion traveling 1–1.5 cm between needle applications in the seromuscular layer, using 8-mm robotic needle drivers.

Gastroscopy

Intraoperative gastroscopy was performed after transection and closure to check for intraluminal bleeding and to perform leak testing by insufflation of the stomach to confirm its integrity and a widely patent lumen. The stomach was submerged using saline irrigation and the gastroscope was used to insufflate the stomach while observed for air bubbles. On postoperative day (POD) 14, gastroscopy was performed again on all subjects, under moderate sedation, to evaluate sleeve for signs of bleeding, leak, or fistula formation.

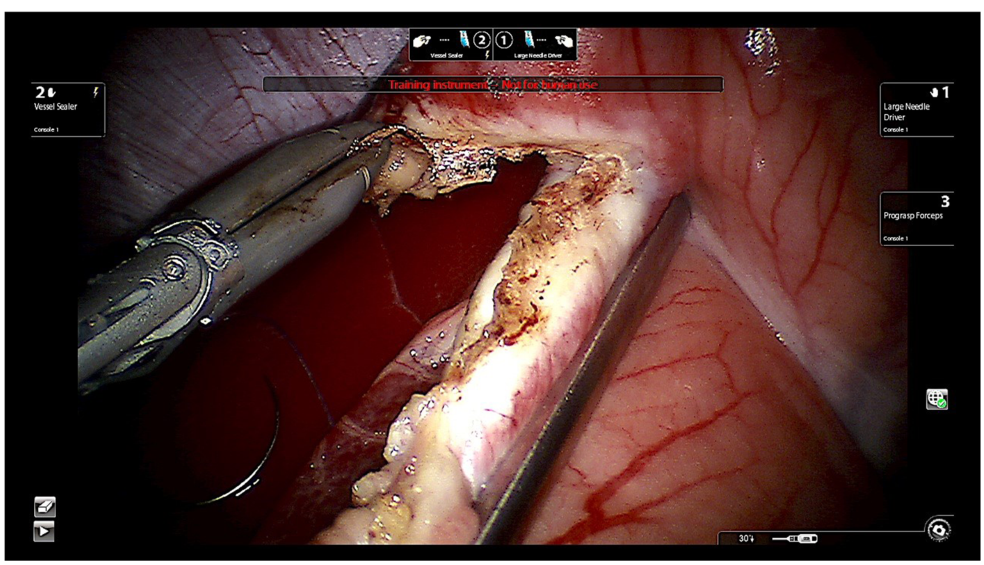

Fig. 2 Gastric wall immobilized with a non-crashing clamp and sealed with robotically controlled bipolar coagulation

Postoperative Protocol

After surgery, animals recovered under supervision of the veterinarian and the surgeon. Animals were kept alive for 2 weeks in cages under direct supervision of the veterinarian and a designated research fellow. The observers were blinded to the control or study status. During the first 72 h postoperatively, the animals were fed with a mostly liquid and very soft diet ad lib then advanced to soft mechanical diet. A regular solid diet was introduced POD 8.

Ex Vivo Testing

Immediately following gastroscopy on POD 14, animals were sacrificed. Laparotomy was performed in order to do ex vivo leak testing. The extracorporealized stomachs were filled with methylene blue-colored aqueous solution. A small incision was made at one corner of the gastric specimen and a non-compliant plastic tube was connected to an electronic pressure gauge. A second tube was inserted and secured at the opposite corner of the gastric specimen to infuse water colored with methylene blue at a constant rate. Filling was stopped when either a leak was visualized or the measured pressure reached 760 mmHg (Torr) pressure (Fig. 3).

Histology Review

After in situ intraabdominal examination upon autopsy, the stomach was removed, collected, and sent to pathology. Sections from the stapled line or sutured line were taken, fixed in 10% neutral buffered formalin. The tissue was subjected to routine process in histology lab and then paraffin embedded. Sections of 4 μm thickness were taken and stained with eosin and hematoxylin (H&E).

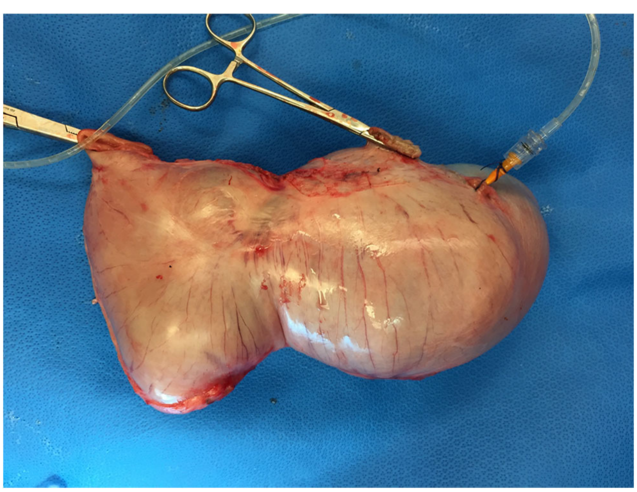

Fig. 3 Ex vivo examination of the stomach under pressure to assess integrity and leaks

A Board-Certified Pathologist who was blinded to the treatment groups reported on width of injury (in mm), depth of ulceration (in mm), level of ulceration (mucosa, submucosa, muscularis propria, or subserosa/serosa), inflammation (using a scale of 1–4 with 1 being minimal, 2 mild, 3 moderate, and 4 severe), fibrosis (using a scale of 1–3 with 1 being minimal, 2 mild, 3 significant), fat necrosis (present or absent), wound symmetry (yes or no), calcification (present or absent), suture granuloma (present or absent), and other features such as focal arterial thrombosis, fistula tract, mural abscess, or diverticulosis. Cases with no mucosal lesion but only subserosal/serosal/omental changes were deemed not applicable for ulceration (depth and level), inflammation, and fibrosis evaluation. Cases with no mucosal lesion or only partial mucosal lesion sampled were deemed not applicable for symmetry of injury evaluation. The mean and standard deviation for injury width, depth of ulceration, inflammation, and fibrosis were calculated using MS Excel ver. 15 (Microsoft Corp., Redmond, CA). The t value and p value was calculated at the 95% confidence interval (CI) for each variable using the Student's two-tailed t test for comparison of two independent means.

Results

Intraoperative

Mean operating time was (130 ± 31 min) and (87 ± 23 min) in the study and control groups respectively ($p = 0.03$). Arterial pulsatile bleeding was seen with use of the linear stapler following transection of the gastric body in all of the control pigs. In the study group, no intraoperative bleeding was seen with transection of the stomach using bipolar cautery. The initial seal was complete in all control specimens with firing of the stapler while the stomach was not completely sealed when using the bipolar cautery. During the operation in the first study pig, an incomplete seal resulted in spillage of luminal contents into the peritoneal cavity. This spillage was prevented in subsequent operations by utilization of a long non-crushing clamp to stabilize the stomach during application of the bipolar cautery. Intraoperative gastroscopy revealed slow bleeding associated with the staple line in 3/5 control pigs whereas oozing was not appreciated in any of the study pigs (0/5). No leak was detected during intraoperative gastroscopy.

Perioperative

No complications during the study period, including postoperative bleeding, leak, fistula, or intraabdominal abscess, were suspected postoperatively or identified at postmortem exam in either group. In the control group, there were no postoperative complications. In the study group, apathy (1/5), vomiting

(1/5), and lethargy (2/5) were observed. Final gastroscopy prior to euthanasia on POD 14 revealed intact line of gastrectomy both in study and control groups. In the study group, a mild erythema and edema (3/5) was found. Similar but less common erythema was seen in the control group (2/5).

Post-euthanasia

At autopsy, the subjects were examined for intraabdominal abscess formation and gross evidence of gastric leak. In examining the connection lines of the control group, staples were visible in 1/5 pigs, dislocated in 3/5 pigs, and opened in 1/5 pigs (Fig. 4a). In the study group, stitches were visible in 4/5 pigs, dislocated in 1/5 pigs, and loose in 3/5 pigs (Fig. 4b). All of the specimens from both groups were filled with methylene blue-colored aqueous solution to a recorded pressure of 760 mmHg, and none of the specimens from either control group or study group leaked. Summary of clinical outcomes is presented in Table 1.

Pathology

Mean injury width, depth of ulceration, inflammation, and fibrosis were compared between groups. Mean injury width was (1.12 ± 0.93 mm) in the control group with greater mean injury width (7.88 ± 3.73 mm) in the study group ($p = 0.001$). Mean depth of ulceration was (0.99 ± 0.94 mm) in the control group, with greater mean ulceration depth (2.25 ± 0.84 mm) in the study group ($p = 0.002$). Fat necrosis was present in all samples in both study and control groups that contained fat. Despite a significant difference in mean injury width, depth of ulceration, inflammation, and fibrosis, these did not contribute to a clinical difference in outcomes. There was not a correlation between microscopic findings and other results (Table 2).

Discussion

The current study is the first comparative, in vivo study in an animal model to show the feasibility of performing partial gastrectomy without staples. A well-designed, experimental study compared the mechanical durability of two techniques, utilizing linear surgical stapler and LigaSure™ (Medtronic, Minneapolis, MN) for closure of in vitro gastric remnants following sleeve gastrectomy [4].

Recent advancements in stapling technologies and extensive experience lead to significant decrease of complication after sleeve gastrectomy. Stapler allergies are very rare and may not justify replacement of conventional stapling. Sleeve gastrectomy has become the most common procedure for weight loss, yet bleeding and staple line leaks are two issues that arise from this procedure. We tried to develop a contemporary method that does not utilize the stapler and uses diathermy to eliminate bleeding. The use of the bipolar coagulation was intended to facilitate a temporary seal that would allow for two-layered closure of anterior and posterior gastric walls. There were no postoperative complications including fistulas, leaks, sepsis, bowel obstruction, or hemorrhage requiring blood transfusion in either group. All operations were performed by the same surgeon. Because of the long resection line, application of the bipolar cautery device did not result in complete closure of the gastric sleeve. The initial study procedure was performed without a long non-crushing clamp, which resulted in difficulty handling the tissue and intraoperative spillage of luminal contents into the field. Subsequent performance with a non-crushing clamp resulted in better handling and approximation of tissue. Although application of the bipolar cautery device did not result in perfect seal each firing, the advantage was the bloodless division of the anterior and posterior gastric walls.

A prior extensive experience with robotic bariatric surgery was helpful in this study [19]. Bipolar diathermy was designed to divide and coagulate tissues such the omentum or

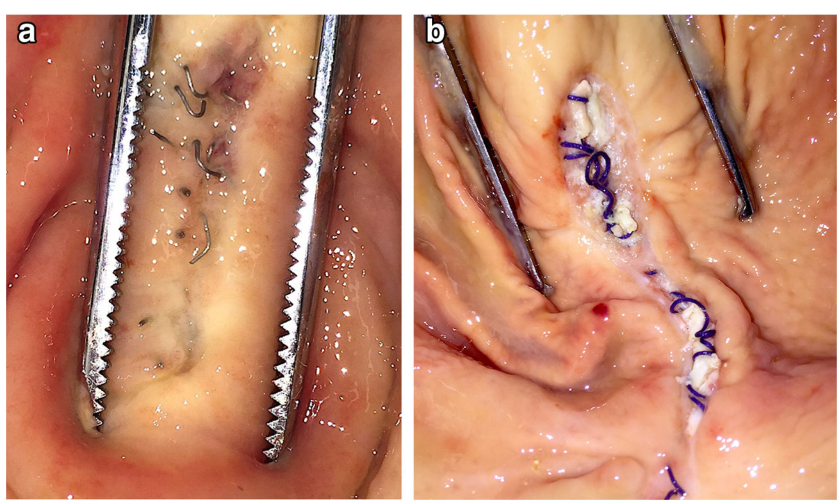

Fig. 4 Dislocation of staplers in the control group (**a**) and stitches in the study group (**b**)

Table 1 Clinical outcomes

		Control	Study
Intraoperative			
Operation time mean (minutes)		66	117
Bleeding	Profuse	2	0
	Large pumping	2	0
	Pumping	0	0
	Oozing	1	0
	No bleeding	0	5
Initial seal	Not sealed at all	0	1
	25% sealed	0	2
	50% sealed	0	2
	75% sealed	0	1
	Completely sealed	5	0
Intraoperative EGD	Leak	0	0
	Blood oozing	3	0
Postoperative day 14 EGD	Leak	0	0
	Erythema/edema	2	3
Post-euthanasia			
Intraluminal	Staple line visible	1	N/A
	Staplers dislocated	3	N/A
	Staplers open	1	N/A
	Sutures visible	N/A	4
	Sutures dislocated	N/A	1
	Sutures loose	N/A	3
Extraluminal	Intraabdominal abscess	0	0
	Fistula	0	0
	Leak during pressure test	0	0
	Hemorrhage	0	0

mesentery. Since the gastric wall consists of different tissues, one cannot conclude it provides similar results. Advantages of the robotic surgical platform include improved dexterity of the needle driver that may eliminate the need for an assistant and allow improved approximation of the seromuscular layers.

Cost Savings

A formal cost analysis was not performed; however, there is renewed attention to spending allocation, with a shift away a fee-for-service reimbursement model toward reimbursement around episodes of care. Affordable Care Organizations (ACOs) are evaluating strategies to reduce expenses associated with the provision of healthcare services to consumers. Lopez et al. pointed out that non-reusable stapler technology contributes to significant costs for every LSG. When five stapler cartridges are required, the cost of the operation was increased. For example in the USA, cost of staplers averages over $2000 per sleeve performed in the standard technique [4]. Other investigators reported the cost reduction after adoption of a stapler-less RYGB [20]. The actual costs may be different depending on a location and health system economy. Despite high costs, surgeons continue to use surgical staplers for resection and closure of the gastric tube in the performance of LSG. The robotic technique increases overall expenses associated with the robot, robotic instrumentation, and increased operating room (OR) time. There is not enough data to support these costs are compensated by elimination of staplers.

Table 2 Histological findings

	Control	Study	*p*
Mean injury width (mm)	1.12 ± 0.93	7.88 ± 3.73	0.001
Mean depth of ulceration (mm)	0.99 ± 0.94	2.25 ± 0.84	0.002

Electrocoagulation

Historically, surgeons performed gastrectomies and hand-sewn anastomoses without use of staplers with similar outcomes to current stapling techniques. Hemostasis was achieved with or without energy devices. Recently, a number of electrocoagulation devices have been developed allowing more secure division of tissue bundles along with coagulation of vascular structures. These tools aim to decrease blood loss and improve operation times of minimally invasive procedures. In addition to their original purpose of sealing vessels, they have been used for bloodless dissection of the liver, pancreas, adrenals, and other solid organs [4, 21]. Himpens and Ettinger described the RYGB performed without staples using the LigaSure Atlas™ (LSA) as the initial seal, allowing for closure of the gastric lumen and preventing spillage of gastric contents. The authors reported healing of the gastric wall was not only impaired but also stressed the importance of invagination of any devascularized tissue at the time of closure [20, 22]. An ex vivo study reported on the four different methods for closure of gastric specimens after sleeve gastrectomy as well as the results of pressurized leak tests. Pressure at which leaks were documented varied widely in range from 30 to 110 mmHg and was related to the method of specimen closure used [20, 22]. In one group, bipolar cautery was reinforced with a running suture and resulted in similar strength as the combination of linear stapler and suture reinforcement of the staple line. A major limitation of that study is that it was performed using postmortem avascular tissue, which is incapable of healing or restoration of integrity. The results we present from this in vivo pig study permitted 14 days of healing and tissue restoration to more accurately assess integrity after healing was well underway. Extensive use of energy devices, such as a robotically controlled bipolar diathermy, may result in ischemia, ulceration, inflammation, and fibrosis and lead to major complications exceeding potential benefits of stapler-less gastrectomy.

Limitations

We did not perform a formal robotic or laparoscopic sleeve gastrectomy. We are unable to answer the question as to whether this could be used as a suitable weight loss procedure. The intent was to compare the sealing method and evaluate early healing. The greater curve of the stomach was resected in similar as needed to perform sleeve gastrectomy; however, because animal welfare was taken into consideration during the study design, a true sleeve gastrectomy was not created. The sample size is small and the results are limited to a 14-day follow-up period. Although no complications were noted, the short study period is not sufficient to evaluate medium- or long-term complications associated with the proposed procedure, but should be sufficient to evaluate complications that would result from technical error. True sleeve gastrectomy was not done and the remnant stomach after wedge resection may have different bio- and mechanical characteristics; therefore, no conclusion on the complications rate after true sleeve gastrectomy can be drawn. The porcine stomach is a thicker and more muscular organ compared to the human stomach. In recent years, several thermal coagulation devices have become available, but the present study reports on the results of a particular device and results may differ with the use of alternate energy devices.

Conclusions

The study shows the technical feasibility of performing stapler-less TRPG; however, further studies are necessary to evaluate long-term outcomes. In this study, the use of bipolar cautery instrumentation as a substitute for stapler in TRPG resulted in a decrease of intraoperative blood loss and reduced utilization of single-use stapler cartridges. Although no complications were noted in the study group that consists of wedge resection, no conclusion on the complications rate after true sleeve gastrectomy can be drawn.

The electrocautery alone failed to demonstrate the technical feasibility which was obtained with the concomitant use of a tissue clamp and a suture. The study design does not allow to differentiate between the impact of electrocautery and the impact of the clamp with sutures in gastric resection. As a result of this clinical experiment, we demonstrated that histologic differences in the gastric seal between control and study groups did not affect the outcomes. As a result of our observations, we suggest further development of surgical instruments.

Compliance with Ethical Standards

Ethical Approval Statement All applicable institutional and/or national guidelines for the care and use of animals were followed. The Cleveland Clinic's Institutional Animal Care and Use Committee approved the study protocol (2015-1377).

Informed Consent Statement Does not apply.

Disclosures The study was supported by Intuitive Surgical, Sunnyvale, CA, USA (2015 Clinical Robotic Research Grant) to help offset the costs associated with acquisition and perioperative care of the animals.

The study was carried out at the Cleveland Clinic Animal Facility which is fully accredited by AAALAC International.

Conflict of Interest Tomasz Rogula reports grants and non-financial support from Intuitive Surgical, during the conduct of the study.

David Leifer has nothing to disclose.

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Valerie Zeer has nothing to disclose.

Piotr Fiedorczuk has nothing to disclose.

Jan Baczek has nothing to disclose.

Philip Schauer has nothing to disclose.

Abbreviations ACA, Affordable Care Act; ACO, Accountable Care Organization; ASMBS, American Society of Metabolic and Bariatric Surgeons; CI, Confidence interval; LAR, Laboratory animal research; LRYGB, Laparoscopic Roux-en-Y gastric bypass; LSG, Laparoscopic sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; TRSG, Totally robotic sleeve gastrectomy; USD, US dollar

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