

# Safety of bipolar sealing device in gastric staple-line hemostasis during laparoscopic one-anastomosis gastric bypass

Ahmed M. Hassan, Hany A. Balamoun, Sameh Mikhail, Mohamed Y. Ibrahim

Department of General Surgery, Faculty of Medicine, Cairo University, Cairo, Egypt

Correspondence to Sameh Mikhail, MBBCh, MD, FRCS, 8 Marguil Street Zamalek, Cairo, Post Code: 11211, Egypt.  
Tel: 00201270048278;  
e-mail: samehmikhail@kasralainy.edu.eg

**Received:** 1 June 2021

**Accepted:** 10 July 2021

**Published:** xx Month 2021

**The Egyptian Journal of Surgery** 2021, 40:1157–1161

## Objective

Despite the rarity, the consequences of bleeding and leaks after bariatric procedures can be drastic and potentially fatal, mandating the search for preventive maneuvers. In this study, we investigated the safety and efficacy of the staple-line hemostasis using LigaSure patients subjected to one-anastomosis gastric bypass (OAGB).

## Patients and methods

This prospective study involved 92 patients scheduled for OAGB. Patients were followed up during the next 2 weeks after the operation. Hemostasis of the stomach's stapler line was done using bipolar diathermy (LigaSure) to stop the bleeding sites if present. Postoperatively, the patients were monitored regularly for clinical signs of bleeding and leakage.

## Results

Operative time did not exceed 120 min. All patients during the operation suffered from bleeding from the staple line and underwent hemostasis by using LigaSure. LigaSure secured complete hemostasis within 10 min and did not cause any intraoperative or postoperative complications in the form of electrothermal injury to the surrounding structures. Two patients suffered from postoperative intraluminal bleeding from the staple line and required blood transfusion. No case of leakage was recorded. Most of the study cohort ( $n=90$ , 97.8%) stayed only 1 day after surgery.

## Conclusion

The bipolar diathermy device LigaSure is a promising technique for staple-line hemostasis in patients undergoing OAGB. It was not associated with increased leakage or other postoperative complications.

Egyptian J Surgery 40:1157–1161  
© 2021 The Egyptian Journal of Surgery  
1110-1121

## Introduction

The one-anastomosis gastric bypass (OAGB) is gaining popularity as a prevalent bariatric procedure since 2011 [1]. International Federation for the Surgery of Obesity and Metabolic Disorders now approves OAGB as a standard treatment procedure [2]. Recently, it is increasingly accepted as a more simple and safe alternative to Roux-en-Y gastric bypass (RYGB) [3,4]. Compared with RYGB, OAGB was found to reduce the technical difficulty and early and late complications [5,6]. Early complication rates range from 3.5 to 7.5% [5,7,8]. The most frequent postoperative complications after bariatric surgery are bleeding, leaks, and stenosis of the anastomosis [9]. Staple-line bleeding is the most reported complication. In 0.3–0.6% of these cases, reoperation or endoscopic interventions are mandatory [10,11]. Also, leak is a common complication of this procedure (0.1–1.9%) [5,8].

Although the incidence of bleeding and leaks is relatively small, the consequences can be drastic and potentially fatal. Therefore, preventive maneuvers to

reduce the probability of these complications are warranted. In this study, we investigated the safety and efficacy of the staple-line hemostasis using LigaSure patients subjected to OAGB surgery.

## Patients and methods

This prospective study was carried out at the General Surgery Department—Cairo University Hospitals, from April 2019 to April 2020. The study involved all patients scheduled for OAGB. Patients were followed up during the next 2 weeks after the operation. The operator was not the same in all cases. The study implemented the principles of the Declaration of Helsinki (1964) and its following revisions and was approved by the Review Board of the General Surgery Department—Cairo University. The patients were informed about the surgical

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

procedure and use of LigaSure for hemostasis of the staple line, explaining the risks and benefits and ensuring that their treatment plan will not be affected if they quit the study at any time. All patients provided written informed consent to participate.

Inclusion criteria were BMI more than 40 kg/m<sup>2</sup> or more than 35 kg/m<sup>2</sup> with an obesity-associated comorbidity in patients 16–65 years old who are motivated and accepting surgical risks. Patients should have tried and failed to lose weight using diet, exercise, and/or medication for at least 6 months. Pregnant or breastfeeding women, those with endocrinal causes of obesity, significant heart/lung disease, or other severe systemic diseases, and those who refused to take part in the study were excluded.

Preoperatively, all patients were subjected to thorough clinical examination and routine investigations. Low-molecular-weight heparin at the night of surgery was administered in a prophylactic dose (40 mg Enoxaparin).

#### Surgical technique

- (1) The patient is lying in the supine reverse Trendelenburg position securing the position before draping. A Veress needle was introduced to inflate the abdomen using CO<sub>2</sub> gas to 15 mmHg. Five ports were introduced as follows:
  - (a) Camera port: 10 mm in the midline approximately two handbreadths below the xiphisternum (ignoring the location of the umbilicus).
  - (b) 15-mm port (the surgeon's left hand working port) between the right midclavicular and anterior axillary line, two to three fingerbreadths below the right costal margin.
  - (c) 15-mm midline port (the liver retractor port), —two to three fingerbreadths below the xiphisternum. We use either a 5- or a 10-mm blunt stainless-steel rod to retract the left lobe of the liver.
  - (d) 12-mm port in the left midclavicular line two to three fingerbreadths below the patient's left costal margin is the surgeon's right-hand working port
  - (e) 5-mm assistant port in the left anterior axillary line, two to three fingerbreadths below the left costal margin.

The gastric tube was constructed using green and blue staplers (Endo GIA™, Covidien, Mansfield, MA, USA), keeping it long enough to retain the bile away from the gastro-esophageal junction. The gastro-jejunal anastomosis was constructed distal to the duodenojejunal junction by 200 cm using a blue

reload (45 mm). Endo-GIA (Covidien) and Echelon Flex™ (Ethicon Inc., Somerville, NJ, USA) (J&J) staplers were both used. The enterotomy of the anastomosis was closed using V-loc (2/0) two layers. Hemostasis of the stomach's stapler line was done using bipolar diathermy (LigaSure™, Covidien, Mansfield, MA, USA) to stop the bleeding sites if present. LigaSure (5 mm–37 cm blunt-tip hand piece) was applied to the most distal part of the stapler line, not reaching the serosa of the stomach. The blades of the bipolar were only approximated, not closed against each other. The electrothermal current duration did not exceed 2 s to avoid thermal injury to the surrounding structures. In some cases, this was repeated till hemostasis was achieved. Drains were not routinely used.

Postoperatively, the patients were monitored regularly for clinical signs of bleeding and leakage. Anticoagulant therapy was given within hours after surgery. All patients were discharged on medical treatment in the form of proton-pump inhibitors, analgesics, antibiotics, multivitamins, and low-molecular-weight heparin for 2 weeks. All patients were instructed to follow a particular diet regimen. The patients were followed up 2 weeks after the operation for vital signs and pain.

Data were collected, tabulated, and analyzed. Numerical variables were presented as median and interquartile range. Categorical data were presented as numbers and percentages.

#### Results

The study recruited 92 patients subjected to OAGB. Their clinical characteristics are shown in Table 1.

Operative time did not exceed 120 min. All patients during the operation suffered from bleeding from the staple line and underwent hemostasis by using LigaSure. In all cases, the bleeding stopped without any complications. Two patients suffered from

**Table 1** Baseline and clinical characteristics of the study cohort

	Value
Age (years)	39 (20–62)
Sex (male/female)	24/68
BMI (kg/m <sup>2</sup> )	40 (36–45)
Comorbidities	
Hypertension	20 (21.7)
Diabetes mellitus	40 (43.5)

Data are presented as median (interquartile range), or *n* (%).

**Table 2 Operative details of the study cohort**

	Value
Duration of operation (min)	90 (60–120)
Duration to hemostasis (min)	10 (8–12)
Complications	
Bleeding	2 (2.2)
Blood transfusion	2 (2.2)
Hospital stay (days)	1 (1–2)

Data are presented as median (interquartile range), or *n* (%).

postoperative intraluminal bleeding from the staple line, and the two patients required a blood transfusion. No case of leakage was recorded. Most of the study cohort (*n*=90, 97.8%) stayed only 1 day after surgery (Table 2).

One of the two patients who suffered bleeding was known to be hypertensive. He presented postoperatively by tachycardia with no hemoglobin drop. Supportive measures were done, then the patient developed attacks of melena. Upper-gastrointestinal (GI) endoscopy was done on day 1 postoperatively and revealed anastomotic site bleeding, which was controlled. The second patient presented 1 week postoperatively with tachycardia and hypotension. She gave a history of two attacks of melena. On the second day of presentation, upper GI endoscopy revealed an anastomotic site bleeding that was controlled by adrenaline injection.

## Discussion

This study demonstrated the effectiveness of LigaSure in staple-line hemostasis in patients undergoing OAGB. Two patients out of 92 (2.2%) suffered postoperative bleeding that was intraluminal. LigaSure secured complete hemostasis within 10 min and did not cause any intraoperative or postoperative complications in the form of electrothermal injury to the surrounding structures. Using LigaSure was not associated with any change regarding surgical technique. None of the patients in the current study had staple-line leakage. Using bipolar diathermy was not associated with increased leakage. It was believed that reinforcing interventions may reduce the staple-line integrity, leading to increased risk for a postoperative leak. Inadequate blood supply and oxygenation can impede healing and therefore increase the risk of leaks [12].

Bleeding following gastric bypass procedures is a relatively uncommon incident, but it can be a life-threatening complication. Hospital stay is prolonged in any case with a bleeding complication. Besides, serious

morbidities are frequently encountered, including sepsis, respiratory difficulties, and organ failure [13]. In a large series of 4466 patients who underwent gastric bypass, early postoperative bleeding was reported in 0.68% of them. Staple line was the source of bleeding in one-third of these cases [13]. Postoperative bleeding occurred in 1.5% of a large series of 43 280 patients subjected to LRYGB patients [14]. Bleeding after OAGB is the most commonly reported complication ranging from 0.2 to 3.5% [9]. The considerable frequency (28.6%) reported by Copăescu *et al.* [15] is probably an indication of a small sample investigated in the initial experience of their center with OAGB. Bleeding in this procedure may arise from staple lines of the long gastric pouch, the eliminated stomach, and the gastro-jejunal anastomosis. In the current study, staple-line bleeding occurred in 2.2% of cases.

The commonly used methods to prevent bleeding after bariatric procedures such as RYGBP and sleeve gastrectomy include adequate staplers and hemostatic control and using hemostatic devices. Electrocautery is usually preferred as an accessible and cost-effective tool. But, compared with bipolar or ultrasonic energy devices, it is less efficient and produces more lateral thermal damage to the peripheral tissues [16]. Many researchers have investigated methods for preventing postoperative bleeding after bariatric procedures. Silecchia and Iossa [9] recommended staple-line buttress or glue application to staple lines to minimize postoperative bleeding in cases of LRGYB. Other studies have shown that the buttressing reduced intraoperative and postoperative staple-line bleeding [17,18]. Also, Dick *et al.* [19] proposed staple-line reinforcement devices to prevent early postoperative GI bleeding. Available literature lacks well-powered studies investigating the appropriate prophylactic method to prevent bleeding after OAGB. Probably, the current study would be the first to address this issue.

In this study, we tested the safety and effectiveness of LigaSure to prevent staple-line bleeding following OAGB. LigaSure is a radiofrequency-driven bipolar electro-surgical device that delivers high current and very low voltage. LigaSure uses combined pressure and continuous bipolar energy to produce vessel fusion while monitoring and adjusting energy delivery to the tissue. Collagen and elastin fibers of the vessel wall are denatured, creating a new solid fence of collagen and elastin tissue [20]. Electro-surgical devices inevitably produce varying degrees of thermal spread in laparoscopy [21,22]. Monitoring via a tissue-based feedback program regulates the administered

dose of energy. This enables the device to provide greater tissue sealing with limited heat created in the target tissue [23]. These features are probably the cause of low collateral thermal damage associated with LigaSure [24]. In addition to hemostasis, LigaSure can be used for gastric pouch preparation, dividing the intestinal mesentery, gastrostomy, enterotomy, and dividing the greater omentum [25].

The use of the LigaSure device has increased in many aspects of surgery, including bariatric procedures. In patients undergoing LRYGB, Kirmizi *et al.* [25] compared harmonic scalpel and LigaSure. The two methods were comparable in procedure duration and the total amount of blood loss. Tsamis *et al.* [26] compared LigaSure and Harmonic Ace in laparoscopic sleeve gastrectomy. The authors reported no difference in operative time and perioperative complications. Similar results were reported by Velotti *et al.* [27], who retrospectively compared LigaSure and Harmonic scalpel in 422 patients undergoing laparoscopic sleeve gastrectomy.

In colorectal surgery, LigaSure was associated with less bleeding than the harmonic scalpel in one study [18], but both techniques were similar with one another [28]. Grieco *et al.* [29] assessed the safety and effectiveness of LigaSure for major vessel sealing during laparoscopic colorectal cancer surgery in a series of 759 patients. LigaSure was effective in vessel dissection and sealing in all cases without any intraoperative or postoperative bleeding. In patients subjected to pancreaticoduodenectomy, Eng *et al.* [30] found LigaSure usage to be safe and effective. Only 1.8% of patients developed thermal injury. LigaSure safety and efficacy were compared with traditional electrical cauterization in 756 patients undergoing laparoscopic myomectomy. The authors found no difference in blood loss between groups. They confirmed the efficiency of LigaSure for large myomas [31]. LigaSure successfully reduced blood loss, transfusions, and intraoperative complications during emergency peripartum hysterectomy [32].

A systematic review of seven RCTs, including 554 patients reported, showed LigaSure effectiveness compared with other electrothermal or ultrasonic devices in abdominal surgery. LigaSure was superior in two studies concerning less blood loss and shorter operating time and was comparable in the other studies [33].

The main limitation of our study is the absence of a comparative group to confirm the superiority of

LigaSure to other hemostatic techniques. The study's prospective nature, single-surgeon supervision, different surgeons' cooperation, participation, and 100% patient compliance are points of strength in this study. The study also emphasized the new, cheap, easy, and effective method for the hemostasis of staple-line bleeding.

In conclusion, using the bipolar diathermy device LigaSure for hemostasis of the gastric staple line has shown promising results in controlling the bleeding points of the staple line with no postoperative complications.

#### Acknowledgements

The authors thank Dr Mina K. Girgis for his help in data collection.

#### Financial support and sponsorship

Nil.

#### Conflicts of interest

There are no conflicts of interest.

#### References

- Buchwald H, Oien DM. Metabolic/bariatric surgery worldwide 2011. *Obes Surg* 2013; 23:427–436.
- De Luca M, Tie T, Ooi G, Higa K, Himpens J, Carbajo M-A, *et al.* Mini gastric bypass-one anastomosis gastric bypass (MGB-OAGB)-IFSO position statement. *Obes Surg* 2018; 28:1188–1206.
- Lee WJ, Almalki OM, Ser KH, Chen JC, Lee YC. Randomized controlled trial of one anastomosis gastric bypass versus Roux-En-Y gastric bypass for obesity: comparison of the YOMEGA and Taiwan studies. *Obes Surg* 2019; 29:3047–3053.
- Robert M, Espalieu P, Pelascini E, Caiazzo R, Sterkers A, Khamphommala L, *et al.* Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity (YOMEGA): a multicentre, randomised, open-label, non-inferiority trial. *Lancet* 2019; 393:1299–1309.
- Carbajo MA, Luque-de-León E, Jiménez JM, Ortiz-de-Solórzano J, Pérez-Miranda M, Castro-Aljija MJ. Laparoscopic one-anastomosis gastric bypass: technique, results, and long-term follow-up in 1200 patients. *Obes Surg* 2017; 27:1153–1167.
- Poublon N, Chidi I, Bethlehem M, Kuipers E, Gadiot R, Emous M, *et al.* One anastomosis gastric bypass vs. Roux-en-Y gastric bypass, remedy for insufficient weight loss and weight regain after failed restrictive bariatric surgery. *Obes Surg* 2020; 30:3287–3294.
- Mahawar KK, Jennings N, Brown J, Gupta A, Balupuri S, Small PK. 'Mini' gastric bypass: systematic review of a controversial procedure. *Obes Surg* 2013; 23:1890–1898.
- Parikh M, Eisenberg D, Johnson J, El-Chaar M, American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery review of the literature on one-anastomosis gastric bypass. *Surg Obes Relat Dis* 2018; 14:1088–1092.
- Silecchia G, Iossa A. Complications of staple line and anastomoses following laparoscopic bariatric surgery. *Ann Gastroenterol* 2018; 31:56–64.
- Victorzon M. Single-anastomosis gastric bypass: better, faster, and safer? *Scand J Surg* 2015; 104:48–53.
- Georgiadou D, Sergentanis TN, Nixon A, Diamantis T, Tsigris C, Psaltopoulou T. Efficacy and safety of laparoscopic mini gastric bypass. A systematic review. *Surg Obes Relat Dis* 2014; 10:984–991.
- Al Hajj GN, Haddad J. Preventing staple-line leak in sleeve gastrectomy: reinforcement with bovine pericardium vs oversewing. *Obes Surg* 2013; 23:1915–1921.

- 13 Heneghan HM, Meron-Eldar S, Yenumula P, Rogula T, Brethauer SA, Schauer PR. Incidence and management of bleeding complications after gastric bypass surgery in the morbidly obese. *Surg Obes Relat Dis* 2012; 8:729–735.
- 14 Zafar SN, Miller K, Felton J, Wise ES, Kligman M. Postoperative bleeding after laparoscopic Roux en Y gastric bypass: predictors and consequences. *Surg Endosc* 2019; 33:272–280.
- 15 Copăescu C, Munteanu R, Prala N, Turcu FM, Dragomirescu C. Laparoscopic mini gastric bypass for the treatment of morbid obesity. Initial experience. *Chirurgia (Bucur)* 2004; 99:529–539.
- 16 Diamantis T, Kontos M, Arvelakis A, Syroukis S, Koronarchis D, Papalois A, *et al.* Comparison of monopolar electrocoagulation, bipolar electrocoagulation, Ultracision, and Ligasure. *Surg Today* 2006; 36:908–913.
- 17 Wong JB, Henninger DD, Clymer JW, Ricketts CD, Fryrear RS. A novel, easy-to-use staple line reinforcement for surgical staplers. *Med Devices (Auckl)* 2020; 13:23–29.
- 18 Daskalakis M, Berdan Y, Theodoridou S, Weigand G, Weiner RA. Impact of surgeon experience and buttress material on postoperative complications after laparoscopic sleeve gastrectomy. *Surg Endosc* 2011; 25:88–97.
- 19 Dick A, Byrne TK, Baker M, Budak A, Morgan K. Gastrointestinal bleeding after gastric bypass surgery: nuisance or catastrophe? *Surg Obes Relat Dis* 2010; 6:643–647.
- 20 Karande VC. LigaSure™ 5-mm blunt tip laparoscopic instrument. *J Obstet Gynaecol India* 2015; 65:350–352.
- 21 Hefermehl LJ, Largo RA, Hermanns T, Poyet C, Sulser T, Eberli D. Lateral temperature spread of monopolar, bipolar and ultrasonic instruments for robot-assisted laparoscopic surgery. *BJU Int* 2014; 114:245–252.
- 22 Vilos GA, Rajakumar C. Electrosurgical generators and monopolar and bipolar electrosurgery. *J Minim Invasive Gynecol* 2013; 20:279–287.
- 23 Mathonnet O. LigaSure Atias™ instrument. *Minim Invasive Ther Allied Technol* 2002; 11:237–242.
- 24 Heniford BT, Matthews BD, Sing RF, Backus C, Pratt B, Greene FL. Initial results with an electrothermal bipolar vessel sealer. *Surg Endosc* 2001; 15:799–801.
- 25 Kirmizi S, Kayaalp C, Karagul S, Tardu A, Ertugrul I, Sumer F, *et al.* Comparison of Harmonic scalpel and Ligasure devices in laparoscopic Roux-en-Y gastric bypass. *Wideochir Inne Tech Maloinwazyjne* 2017; 12:28–31.
- 26 Tsamis D, Natoudi M, Arapaki A, Flessas I, Papailiou I, Bramis K, *et al.* Using Ligasure™ or Harmonic Ace® in laparoscopic sleeve gastrectomies? A prospective randomized study. *Obes Surg* 2015; 25:1454–1457.
- 27 Velotti N, Manigrasso M, Di Lauro K, Vitiello A, Berardi G, Manzillo D, *et al.* Comparison between LigaSure™ and Harmonic® in laparoscopic sleeve gastrectomy: a single-center experience on 422 patients. *J Obes* 2019; 2019:3402137.
- 28 Rimonda R, Arezzo A, Garrone C, Allaix ME, Giraud G, Morino M. Electrothermal bipolar vessel sealing system vs. harmonic scalpel in colorectal laparoscopic surgery: a prospective, randomized study. *Dis Colon Rectum* 2009; 52:657–661.
- 29 Grieco M, Apa D, Spoletini D, Grattarola E, Carlini M. Major vessel sealing in laparoscopic surgery for colorectal cancer: a single-center experience with 759 patients. *World J Surg Oncol* 2018; 16:101.
- 30 Eng OS, Goswami J, Moore D, Chen C, Brumbaugh J, Gannon CJ, *et al.* Safety and efficacy of LigaSure usage in pancreaticoduodenectomy. *HPB* 2013; 15:747–752.
- 31 Li YC, Chao A, Yang LY, Huang HY, Huang YT, Kuo HH, *et al.* Electrothermal bipolar vessel sealing device (LigaSure™) versus conventional diathermy in laparoscopic myomectomy: a propensity-matched analysis. *PLoS One* 2018; 13:e0193611.
- 32 Lauroy A, Verhaeghe C, Vidal F, Parant O, Legendre G, Guerby P. Perioperative outcomes using LigaSure compared with conventional technique in peripartum hysterectomy. *Arch Gynecol Obstet* 2020; 301:229–234.
- 33 Janssen PF, Brölmann HAM, Huirne JAF. Effectiveness of electrothermal bipolar vessel-sealing devices versus other electrothermal and ultrasonic devices for abdominal surgical hemostasis: a systematic review. *Surg Endosc* 2012; 26:2892–2901.