International Surgery Journal
Braghetto I et al. Int Surg J. 2025 Jan;12(1):12-19
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: https://dx.doi.org/10.18203/2349-2902.isj20243765

Original Research Article

Evaluation of the safety and effectiveness of easyEndo™ universal stapler compared with easyEndo™ E-lite in patients submitted to gastric surgery: a retrospective/prospective study including a large number of patients

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Received: 05 November 2024
Revised: 29 November 2024
Accepted: 30 November 2024

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ABSTRACT

Background: Staple line complications represent the most dangerous complication after gastric surgery. Better-formed staples could potentially reduce complications postoperatively. The newer motorized generation stapling system would lead to fewer intraoperative staple line complications compared to traditional stapling systems. Purpose was to evaluate the safety and efficacy of these two types of stapler models by determining its intraoperative performance and peri-operative complications.
Methods: It was an observational cohort study including a total of 3613 patients submitted to gastric surgery for benign or malignant disease. The study was conducted within two periods: stage A using easyEndo™ universal (n=2359 patients, from January 2017 to December 2022) and stage B (n=1254 patients, from January 2023 to June 2024) using easyEndo™ E-lite motorized stapler including obese patients (n=3239), benign diseases with indication of surgical treatment (n=268) and patients with gastric cancer (n=106).
Results: Although higher rate of leaks and postoperative complications were observed in patients submitted to sleeve gastrectomy or gastric bypass during stage A compared with stage B (p=0.0025), both type of staplers are safe and effective for performing gastric surgery. In patients submitted to gastric resections, no significates differences were demonstrated in terms of postoperative complications comparing the two groups (p=0.1).
Conclusions: Patients operated on using motorized stapler presented less suture line interventions but no differences regarding postoperative complication. The results confirmed data published in previous reports and meta-analysis, but now including a big number of patients and complex procedures.

Keywords: Laparoscopy, Gastric surgery, Stapler, Complications, Safety, Efficacy

INTRODUCTION

Acute complications associated with laparoscopic gastric surgery including bleeding, abscess, and staple line leaks are the most frequent and risky complications after gastric resection.[1-3] Staple line leaks represent the most dangerous and life-threatening of these complications, the mean leak incidence is almost 3%.[4]

Stapling is particularly important because biological soft tissues contain interstitial fluid that responds to natural or applied pressures, consequently, the type of device and the mechanism of functioning is an important factor.

The newer generation stapling system would lead to fewer intraoperative staple line interventions or complications compared to traditional stapling systems.[5-7]

Primary objectives

Primary objective was to evaluate the safety of easyEndoTM E-lite stapler as compared to the use of easyEndoTM universal (EziSurg Medical Co, Shanghai, China).

Secondary objectives

Secondary objective was to evaluate the performance of easyEndoTM E-lite stapler as compared to the use of easyEndoTM universal in laparoscopic gastric surgery.

Primary endpoint was determination of peri- and postoperative anastomotic leaks and intraluminal/ intraperitoneal bleeding.

Secondary endpoints were determination of peri- and early postoperative complications; assessing technical success, we evaluated conversion to open laparotomy and readmissions after hospital discharge; and also to assess efficacy, we evaluated body mass index (BMI) reduction after bariatric procedures, postoperative complications, improvement of gastroesophageal reflux disease (GERD) and R0 resection for patients with gastric cancer.

METHODS

For this observational cohort study there were 3 institutions involved, University of Chile Hospital, Redsalud Providencia Clinic and Rennat Clinic, including a total of 3613 patients. The diagnosis for patients submitted to surgery is shown in Table 1 and correspond to obese patients (n=3239), patients suffering benign diseases with indication of surgical treatment (n=268) and patients with gastric cancer (n=106). Two main surgeons (IB-GC) performed surgical procedures. The study was conducted within two periods: stage A using easyEndo^{TM} universal (n=2359 patients from January 2017 to December 2022) and stage B (n=1254 patients from January 2023 to June 2024). Retrospective data were obtained from the surgical protocols as well as the clinical postoperative outcomes of patients registered in the informatics Tycares® system for stage A, while during stage B data were prospectively registered in a specific protocol. Table 2 presents the patients' demographic characteristics and describes the baseline characteristics and risk factors, including age, gender, race, BMI, and medical history of cardio metabolic conditions like diabetes, hypertension, and hypercholesterolemia for each group of patients from stage A and stage B.

Inclusion criteria

Subjects were included who had no previous gastrointestinal surgery, no history of chronic steroid use, were ≥18 years of age, underwent a laparoscopic gastric surgery involving the use of the easyEndo E-lite stapler or easyEndo universal, having early or resectable advanced gastric cancer.

Exclusion criteria

Patients submitted to emergency surgery, who showed early postoperative complications, who had a BMI of ≤60 kg/m^2, or who had unresectable gastric cancer type IV were excluded.

Stapler characteristic and functioning

EasyEndo™ Universal stapler is characterized by sequential manual firings. Mechanic staple closing, force and firing speed are variable depending on the operator and therefore variability on the suture line effect.

EasyEndo™ E-lite motorized stapler motorized stapler is characterized by one touch firing mechanism, minimal effort is required to enhance precision by minimizing tissue movement, more constant force and speed, less variability in the firing, more standardized result. The staples in motorized staplers close at different heights

Surgical procedures

The subjects were placed supine in Grassi's French position. Each of the laparoscopic procedures were performed according to techniques published elsewhere.[10-16] The intraoperative outcomes and complications related to the stapler's use were analyzed, that is, required interventional maneuvers (defined as nonprophylactic actions taken to avoid bleeding or other damage along the staple line after tissue transection). Bleeding was defined when a continuous, pulsatile blood jet requiring clip placement. Over sewing if a positive methylene blue test or bleeding was observed after stapling.

Statistical analysis

Descriptive statistics, including number, mean, standard deviation (SD), median, minimum, and maximum, were calculated for all continuous variables; frequency and percentage were tabulated for all categorical variables which were given as mean±SD. The groups were compared using the independent samples t-test. Percentages were compared using a chi-squared test or Fisher's exact test as appropriate; $p<0.05$ was considered statistically significant. with 95% confidence interval; a p value of <0.05 was considered statistically significant.

RESULTS

The diagnosis of included patients is presented in Table 1, many of them with obesity, submitted to bariatric surgery, the most frequent gastric surgery performed in our units in the past decade. Patients with related GERD consequences including long-segment Barrett's esophagus, failed Nissen

fundoplication, or esophagitis after sleeve gastrectomy (SG), they were submitted to distal gastrectomy which is the technique of choice as has been previously published.[12] A group of patients with gastric cancer undergoing gastric resection were also included.

Table 1: Diagnosis of patients submitted to laparoscopy gastric surgery (n=3613).

Diagnosis	Stage A	Stage B
Obese patients (n=3239)	2077	1162
Sleeve gastrectomy	1152	899
Roux Y gastric bypass*	925	263
Bening diseases (n=268)	194	74
Primary Barret´s esophagus (n=141)	110	31
Failed Nissen fundoplication (n=71)**	45	26
GERD after sleeve gastrectomy*(n=56)**	39	17
Gastric cancer (n=106)	88	18
Total (n=3613)	2359	1254

*Resectional gastric bypass (298 stage A, 20 stage B), **conversion to redo fundoplication with distal gastrectomy, ***conversion to resectional gastric bypass

Table 2 describes the demographic characteristic of the included patients. Obese patients with a BMI of ≥35 kg/m^2 were frequently associated with medical morbidities, but low ASA scores, or Charlson's index. Patients with GERD-related disease presenting overweight or obesity type I were frequently observed and patients with gastric cancer were within a normal BMI.

Table 3 shows the results observed after surgery in obese patients, comparing the two stages evaluated. Operative time was more prolonged in the group of patients submitted to bariatric surgery (SG or GBP) during stage A when mechanical stapler was used (p=0.001). No significant differences concerning bleeding were identified. A significantly higher rate of leaks and postoperative complications was observed in patients submitted to SG or Roux-and-Y-gastric bypass during stage A compared to stage B (p=0.0025) probably associated with the use of non-motorized stapler. The use of clips and reinforcement was most frequent necessary in patients undergoing bariatric surgery during stage A (p=0.002) probably as prevention maneuver´s to avoid leaks or bleeding. Regarding complications, no differences were observed.

In patients submitted to partial distal gastrectomy for benign diseases, the results showed no significant difference regarding bleeding or complications, demonstrating the efficacy of both used devices (p=0.50 and p=0.10, respectively). Highly successful results were also observed for the other parameters evaluated. Only one patient undergoing conversion to distal gastrectomy due to esophagitis after sleeve gastrectomy in stage A presented peri gastric collection without a confirmed leak; the patient was discharged at 21 postoperative days, resulting in a more prolonged in hospital stay for this group (Table 4).

Table 5 shows the results observed in patients submitted to partial or total gastrectomy for gastric cancer. We observed more prolonged operative time in stage A for both procedures when using a mechanical stapler, also clip placement was more frequently needed (p=0.001). In this group, no significant differences were demonstrated in terms of bleeding (p=0.62) or leaks or postoperative complications (p=0.10). More prolonged recovery was observed in patients submitted to total gastrectomy during stage A, because the enhanced recovery after surgery (ERAS) management at that time was not routinely indicated in our units.

Conversion to open surgery, and readmission were similar in both groups. Complications after total gastrectomy were more frequent using both types of staplers. R0 resection was obtained in all patients. We had no mortality in the 3,613 patients operated on.

Table 2: Baseline demographic characteristics of patients submitted to laparoscopic gastric surgery for obesity, benign diseases or gastric cancer (n=3613).

Variables	Obesity	Benign diseases			Gastric cancer
	n=3239	Primary Barrett (n=141)	GERD after Filed Nissen (n=71)	GERD after SG (n=56)	n=106
Age (years)					
Mean	38±15	55±18.3	45.9±11.9	42±10.7	66.1±17.3
Range	21-56	25-72	31-62	23-51	25-81
Sex					
Male	1036	49	38	19	73
Female	2203	92	33	37	33
BMI (kg/m^2)	42.5±5.4	33.2±2.9	26.7±4.5	32.6±2.1	24.2±4.9
25-30	-	113	64	-	106
31-35	-	28	7	41	-
36-40	2134	-	-	15	-
41-50	1105	-	-	-	-

Continued.

Variables	Obesity	Benign diseases			Gastric cancer
	n=3239	Primary Barrett (n=141)	GERD after Filed Nissen (n=71)	GERD after SG (n=56)	n=106
51-55	-	-	-	-	-
More 55	-	-	-	-	-
Comorbidities					
Hyperinsulinism	1403	-	-	-	-
Art hipertension	1118	0	0	0	17
Diabetes II	959	0	0	0	9
Dyslipidemia	2812	0	0	37	8
Fatty liver	3239	2	0	1	-
Hypothyroidism	681	0	1	0	-
GERD					
Esophagitis	771	41	41	-	-
Barret	154	141	27	9	-
ASA score					
I	2915	141	71	56	87
II	324	-	-	-	19
III	-	-	-	-	-
Charlson´s comorbidity score					
0	2627	129	71	51	102
1	612	12	-	5	4
2	-	-	-	-	-
+3	-	-	-	-	-

Table 3: Intra and postoperative early outcome of obese patients submitted to SG or GBP using easyEndo™ universal (stage A) versus easyEndo™ E-lite stapler (stage B) (n=3239).

Variables	SG		GBP	
	Stage A (n=1152)	Stage B (n=925)	Stage A (n=899)*	Stage B (n=263)**
Operative time	65.3±12.7	28.34±2.36	105.1±21.5	41.93±2.94
	p<0.001		p<0.001	
Complications stapler related, N (%)	28 (0.24)	5 (0.5)	8 (0.9)	2 (0.7)
Bleeding, N (%)	10 (0.9)	4 (0.4)	3 (0.3)	2 (0.7)
	p=0.15		p=0.31	
Leaks	22	92	33	37
	p=0.0025		p=0.5	
Collections	4 (0.3)	0	1 (0.1)	0
Suture line interventions				
Total clips used	13.0±8.2	10.7±5.4	12.8±8.8	3.7±1.1
	p=0.32		p=0.002	
Reinforcement, N (%)	116 (10.4)	36 (4)	18 (1.6)	1 (0.4)
	p<0.001		p=0.09	
Conversion to open surgery	0	0	0	0
Total postoperative complications, N (%)	58 (5)	10 (1.1)	81 (9)	8 (3)
	p<0.001		p=0.001	
Mortality	0	0	0	0
Readmission	0	0	0	0
In hospital stay (days)	1±0.8	1	2	1.8±0.8
Efficacy (postoperative BMI* **	959	0	0	0
Pre-op	38.8±3.6	39.5±4.4	40.7±3.7	39.7±4.3
Post-op	25.1±2.9	25.3±2.7	27.1±1.8	25.8±2.7
	p=0.66		p=0.52	

*Resectional gastric bypass, **non resectional gastric bypass, *** 6 months after the operation

Table 4: Intra and postoperative early outcome of patients suffering benign diseases submitted to partial distal gastrectomy using easyEndo™ universal (stage A) or easyEndo™ E-lite stapler (stage B) (n=268).

Variables	Primary Barrett (n=141)		GERD after Failed Nissen (n=71)		GERD after SG (n=56)	
	Stage A (n=120)	**Stage B (n=21)**	**Stage A (n=43)**	**Stage B (n=26)**	**Stage A (n=39)**	**Stage B (n=17)**
Operative time	169±17.8	157±22.3	249±55.7	187±19	155±14	147.3±10.2
	p=0.006		p<0.001		p=0.04	
Complications stapler related	1	1	2	0	4	0
Bleeding	1	1	2	0	1	0
	p=0.50					
Leaks	0	0	0	0	1	0
	p=0.10					
Collections	0	0	0	0	2	0
Suture line interventions						
Total clips used	2±1.9	1±1.3	3.0±0,9	2.5±0.2	6.3±4,1	4±0.0
	p=0.02		p=0.006		p=0.02	
Reinforcement (%)	2 (1.6)	0	0	0	1 (2.5)	0
Conversion to open surgery	0	0	0	0	0	0
Total postoperative complications (%)	8 (6.6)	1 (4.7)	9 (20)	5 (19.2)	5 (12.8)	2 (11.8)
Mortality	0	0	0	0	0	0
In hospital stay (days)	3.8±1.9*	2	3.3±7.3	2	9.5±11.1*	2.2±16.6
Improvement after surgery	62% regression of Barrett		93.2% symptoms improvement		96.9% symptoms improvement	

*Perigastric collection

Table 5: Intra and postoperative early outcome of patients suffering gastric cancer submitted to partial distal gastrectomy or total gastrectomy using easyEndo™ universal (stage A) or easyEndo™ E-lite stapler (stage B) (n=106).

Variables	Partial distal gastrectomy		Total gastrectomy	
	Stage A (n=14)	**Stage B (n=7)**	**Stage A (n=74)**	**Stage B (n=11)**
Operative time	185.9±18.5	157.3±10.2	273±195	220±120
	p=0.002		p=0.25	
Complications stapler related, N (%)	2 (18.2)	0	17 (22.9)	1 (9)
Bleeding	2	0	3	1
	p=0.62			
Leaks*	0	0	12*	-
Collections	-	-	2	-
Suture line interventions				
Total clips	2	1	9	4
Total clips	3.40±0.89	1.00±0.63	7.62±1.59	5.00±0.83
	p=0.001		p<0.001	
Reinforcement	2	0	1	-
Conversion to open surgery	0	0	1	0
Total postoperative complications (%)	3 (2.1)	0	24 (32.4)	2 (18.1)
	p=0.1			
Readmission	0	0	0	0
Mortality	0	0	2 (2.7)	0
In hospital stay (days)	7.6±2.3	3.2±1.2	17±20.3* (6-85)	6±1.1
R0 resection (%)	100	100	100	100

*Due to leaks management

DISCUSSION

Currently, many procedures of complex gastric surgery can be performed laparoscopically due to the great progress in the development of instruments that allow safe gastrointestinal anastomoses. Thus, gastric resections for benign diseases or cancer are being done in that way with increasingly good results, as better mechanical sutures are available.[17]

Mechanical sutures have progressively evolved in terms of safety, effectiveness, and fewer complications from their use. Today, new models of staples offer greater security due to their better interaction with tissue without causing tissue damage, and they feature three lines of staples that reduce postoperative complications. These new devices also require less skill from the surgeon. Several different models of motorized stapler which the staples and knife blade are driven by a power source have been used since 2010, and subsequent versions have been introduced to increase stability and enable more precise stapling compared to non-powered (manual) staplers.[7-9,18]

Experimental study comparing the safety of different staples to minimize the risk of leaks after gastric resection have been reported.[19,20] Serhan comparing blue green EndoGIA cartridges (BGCs, Medtronic, Norwalk, CT), versus purple tri-staple cartridges (TSCs, Medtronic) suggested that the compatibility of the cartridge with the tissue thickness play a role in the development of leaks.[20] Intraluminal pressure and volume to induce leak were higher when using the tri-stapler than a standard stapler. New motorized models currently available have demonstrated the superiority of these models.[21-23] Comparing outcomes between the two latest innovations in powered stapling technology, the echelon flex™ gripping surface technology (GST) and the signia™ stapling system (SIG), among patients undergoing sleeve gastrectomy for obesity, echelon flex™ GST system was associated with a lower rate of hemostasis-related complications as compared with the signia™ stapling system. A powered stapler with a GST system has demonstrated safety in gastric surgery, reduces the need for staple line interventions in LSG. But both stapling systems had an acceptable safety profile.[22,23]

Other studies have suggested that the Aeon endo stapler produces a significantly drier staple line than the echelon flex powered stapler and is associated with less interventional control of the staple line.[24,25] Other study comparing a conventional tri-stapler suture with the motorized system presented remarkably similar performance in terms of intra- and postoperative safety; in that research, the main advantage of using a motorized stapler was the total surgical time employed for finishing the procedure.[26] Currently, complication rate after bariatric procedures is very low, Zilberstein reports an occurrence of leakage of 1.93% for SG and 2.18% for GBP as well as an incidence of bleeding of 1.29% in SG and 0.81% in GBP.[27]

Regarding safety after gastric cancer laparoscopic resection, our results are remarkably like those reported in the literature, which describes both low mortality (1.75%) and low major morbidity (3.50%) rates. The results observed after laparoscopic gastrectomy in the present study are like to those described in the literature, complications and mortality after subtotal gastrectomy were 15.7% and 0.0%, respectively. After total gastrectomy, the reported surgical complications range from 7.1 to 41% of cases and mortality from 0.0% to 2.2%, mainly represented by esophagojejunostomy leak (2.4%), and duodenal stump leak (2.1%).[16,28,29]

The readmission rate within 30 days is 4%.[30,31] This low incidence of postoperative complications and mortality revealed the efficacy of the laparoscopic procedure with use of mechanical and motorized staplers.[32]

The use of mechanic staplers in laparoscopic allow to apply ERAS management having very low rates of complications and mortality as well as faster recovery with a shorter postoperative hospital stay than under conventional management among patients undergoing subtotal gastrectomy or total gastrectomy, results comparable with those observed in the present study and confirm efficacy of laparoscopic procedures for the treatment of gastric cancer.[33,35-40]

Limitations

The limitation of this study is because it is not entirely prospective, and the groups are not strictly matched. However, the strengths are because only 2 main surgeons performed the procedures and include a large number of patients very well studied and controlled.

CONCLUSION

Both easyEndo™ E-lite stapler or easyEndo™ universal were safe and effective for performing gastric surgery including a big number of patients and complex procedures that confirmed data published in previous reports and meta-analysis, but further investigations for definitive results are needed.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Braghetto I, Czwiklitzer G, Korn O, Brante P, Salinas M. Evaluation of the safety and effectiveness of easyEndoTM universal stapler compared with easyEndo™ E-lite in patients submitted to gastric surgery: a retrospective/ prospective study including a large number of patients. Int Surg J 2025;12:12-9.