



Stapling Versus Hand Suture for Gastroenteric Anastomosis in Roux-en-Y Gastric Bypass: a Randomized Clinical Trial

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Abstract

Background Different anastomotic techniques have been evaluated during a laparoscopic Roux-en-Y gastric bypass (RYGB); however, no techniques have proven to be better than any other regarding complications and the percentage of weight loss (excess weight loss (%EWL)), and there are few controlled prospective studies to compare them.

Methods A randomized, prospective study was conducted in 238 patients undergoing RYGB for morbid obesity between July 2008 and September 2012 to compare the early and late postoperative complications between the two surgical techniques: gastrojejunal hand-sutured anastomosis (HSA) and circular-stapled anastomosis (CSA). Minimum follow-up was 24 months.

Results The two groups of patients were similar for demographic data and preoperative comorbidities. There were no significant differences between the surgical techniques regarding %EWL at 3, 12, and 24 months. The patients with CSA had a greater frequency of postoperative gastrointestinal bleeding (GIB) (4.2 vs. 0 %, $p=0.024$) and surgical wound infection (11.1 vs. 3.4 %, $p=0.025$) than the patients with HSA, with no significant differences in the other early complications. There were no significant differences in either group for late complications (gastrojejunal anastomosis (GJA) stricture, marginal ulcer, GJA perforation, bowel obstruction, and eventration). No significant differences were observed in operative time, rate of reoperation and postoperative length of hospital stay.

Conclusions HSA and CSA were techniques with similar safety and effectiveness in our study. HSA had a lower rate

of bleeding complications and surgical wound infection, although it does require greater experience in laparoscopic hand suturing.

Keywords Roux en Y gastric bypass · Gastrojejunal anastomosis · Hand sewn anastomosis · Circular stapled anastomosis · Total weight lost

Introduction

Laparoscopic Roux-en-Y gastric bypass is considered the gold standard surgical treatment for obesity, with percentages of excess weight loss (%EWL) of 70–80 % [1]. One of the stages of RYGB is the gastrojejunal anastomosis (GJA), which depends on the experience of the surgeon and is a source of complications, some of them serious: anastomotic leak, stricture, bleeding, and development of a marginal ulcer. Different techniques have been described for performing the GJA. The three most commonly used techniques are hand-sutured anastomosis (HSA), lineal-stapled anastomosis (LSA), and circular-stapled anastomosis (CSA) [2–4]. In 2008, a review showed that American bariatric surgeons performed 43 % CSA, 41 % LSA, and 21 % HSA [5]. There is currently no consensus on the technique of choice, as most of the series published [6, 7] conclude that all three techniques are safe for performing GJA in RYGB and there are no significant differences regarding the number of complications. However, these studies are limited by the fact that most centers specialized in bariatric surgery use just one type of GJA. Moreover, the studies comparing different GJA techniques are retrospective, with a disparate number of patients in each group and, in most cases, limited follow-up.

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Following the principles of evidence-based medicine, we conducted a randomized prospective study to compare the early and late complications and the %EWL between two types of GJA (HSA and CSA) during RYGB.

Patient and Methods

Study Design

Between July 2008 and September 2012, 238 patients underwent RYGB to treat morbid obesity in the bariatric and metabolic Surgery Department of the Virgen de la Arrixaca University Hospital (Murcia, Spain). Two groups of patients were compared: HSA was performed in one and CSA in the other. The primary endpoint of the study was to analyze the rate of postoperative complications (early and late) with both types of anastomoses (HSA vs CSA). The secondary endpoints were %EWL, surgical time, rate of conversion to open surgery, and intraoperative complications.

The study protocol was approved by the hospital's ethical committee and registered in ClinicalTrials.gov under number NCT02077517. The patients were informed of the aim of the study in their native language, and their participation was voluntary, after they had signed their informed consent. Included in the study were patients aged over 18 years with a body mass index (BMI) of >35 kg/m² and associated comorbidities or morbid obesity with a BMI of >40 kg/m². The criteria for exclusion were a history of cirrhosis or alterations in coagulation, pregnancy, inability to sign informed consent, or history of bariatric surgery. Prior to surgery, all patients were studied by a polydisciplinary team, including members of the departments of endocrinology, surgery, psychiatry, and anesthesia. All operations were performed by the same surgical team with experience in laparoscopic bariatric surgery.

Randomization

Randomization was done using a computer-generated sequence (Statistical software EPIDAT 4.0). The randomization sequence was not concealed.

The sample size was calculated based on a retrospective analysis of the early and late postoperative complications reported for CSA and HSA, 17 and 6 % respectively [2, 8]. Utilizing a power of 0.80 and α of 0.05 in a two-tailed model and estimated losses of 10 %, we obtained a sample size of 238 patients (119 for each technique).

Surgical Procedure

All patients included in the study received the same preoperative protocol: antibiotic prophylaxis with intravenous amoxicillin-clavulanic (2 g) or intravenous metronidazole

(500 mg) and gentamicin (160 mg) for allergic patients, intravenous ranitidine (50 mg), and intravenous metoclopramide (10 mg) and compression stockings. A gastric pouch of approximately 20–30 ml was created with an alimentary loop of 150 cm left in obese patients and 200 cm in superobese patients (BMI >50 kg/m²) and a biliopancreatic loop of 100 cm. A side-to-side jejuno-jejunal anastomosis was performed at the base of the loop. The GJA was done, according to the group to which the patient belonged, using the following techniques:

HSA Technique

The Roux limb was brought up to the gastric pouch, close to the gastric division line, using 3/0 continuous absorbable sutures. A gastrotomy was performed in the gastric pouch and an enterotomy in the jejunum using monopolar coagulation. The posterior side of the anastomosis was done with 3/0 continuous absorbable suture. A 34-Fr catheter was pushed through the anastomosis from the stomach to the jejunal loop to ensure that the caliber of the anastomosis is correct. A double anterior layer was then performed with 3/0 double-layer continuous absorbable suture.

CSA Technique

Prior to completion of the gastric pouch, a gastrotomy is performed in the distal part of the stomach. The anvil of the circular stapler is inserted through the 12-mm port site in the left upper quadrant and then through the gastrotomy. The 21-mm circular stapler is inserted through the opening of the 12-mm laparoscopic port in the left upper quadrant (any wound protection was used at the site of the circular stapler placement) and then into the Roux limb through the enterotomy. The end of the stapler is pushed through the antimesenteric margin of the Roux limb, and when the anvil and stapler have been coupled, the anastomosis is performed. The stapler is removed and the enterotomy of the Roux limb closed using a linear endostapler. Reinforcement sutures are then placed on the anterior and lateral side of the staple line using 2/0 absorbable material.

The anastomosis in both techniques was antecolic-antegastric, and once it was completed, their absence of leak was evaluated with the application of methylene blue via a nasogastric tube. The mesenteric defect was closed with 2/0 continuous absorbable suture to prevent development of internal hernias.

Postoperative Care and Follow-up

After the first 24 h, the patients were permitted oral liquids, and following tolerance and absence of complications, the patients were discharged. The criteria for hospital discharge

were tolerance to a liquid diet, absence of postoperative ileus, ambulation, and absence of fever and uncontrolled pain. At discharge, all the patients were prescribed a daily proton pump inhibitor and subcutaneous heparin. Early complications were defined as those occurring within the first 30 days of the surgery and late complications after this time.

All the patients in the study had a minimum follow-up of 24 months. Outpatient assessment was done 7 days after discharge, monthly for the first 3 months, then quarterly during the first year, and half-yearly thereafter. The patient would be asked about food tolerance, weight loss, stool frequency and characteristics, state of the surgical wound, and postoperative pain. Regular blood tests (ferritin; iron; hemoglobin; zinc; vitamins E, C, A, D₃, B₁, and B₁₂; folic acid; total proteins; albumin; and calcium) were conducted to evaluate any nutritional deficiencies in these patients. Any symptoms suggesting stricture (dysphagia, inability to go from a liquid to solid diet, nausea, vomiting, and/or abdominal pain) were investigated by upper gastrointestinal (UGI) endoscopy. Stricture of the GJA was defined when it was impossible to insert the 10-mm endoscope in the presence of the above symptoms.

Data Analysis and Statistical Methods

The data were analyzed using the SPSS 19.0 statistical package for Windows (SPSS, Chicago, IL). In order to compare

quantitative variables in independent samples, we used a combination of Student's *t* test or Behrens-Fisher test depending on whether there was variance or homogeneity between the two groups. To study the relationship between the qualitative variables and to compare the ratios for the independent samples, we conducted an analysis of contingency tables using Pearson's "chi-square" test.

Results

Between July 2008 and September 2012, 238 Caucasian patients participated in the study (22 patients were excluded prior to randomization: 21 patients for a prior history of bariatric surgery and one patient due to a coagulation issue). Two hundred and thirty-eight patients were randomized (119 patients in the HSA group and 119 patients in the CSA group). The HSA group had three patients lost to follow-up and the CSA group lost two (Fig. 1). There were no significant differences in demographic data or comorbidities (Table 1). None of the patients were converted to open surgery.

The rate of *early complications* (<30 days) was 8.6 % (10 patients) in the CSA group and 18.8 % (22 patients) in the HSA group ($p=0.024$). The patients with CSA had a greater frequency of postoperative gastrointestinal bleeding (GIB) (4.2 vs. 0 %, $p=0.024$) and surgical wound infection (11.1

Fig. 1 CONSORT diagram showing the flow of participants through the trial

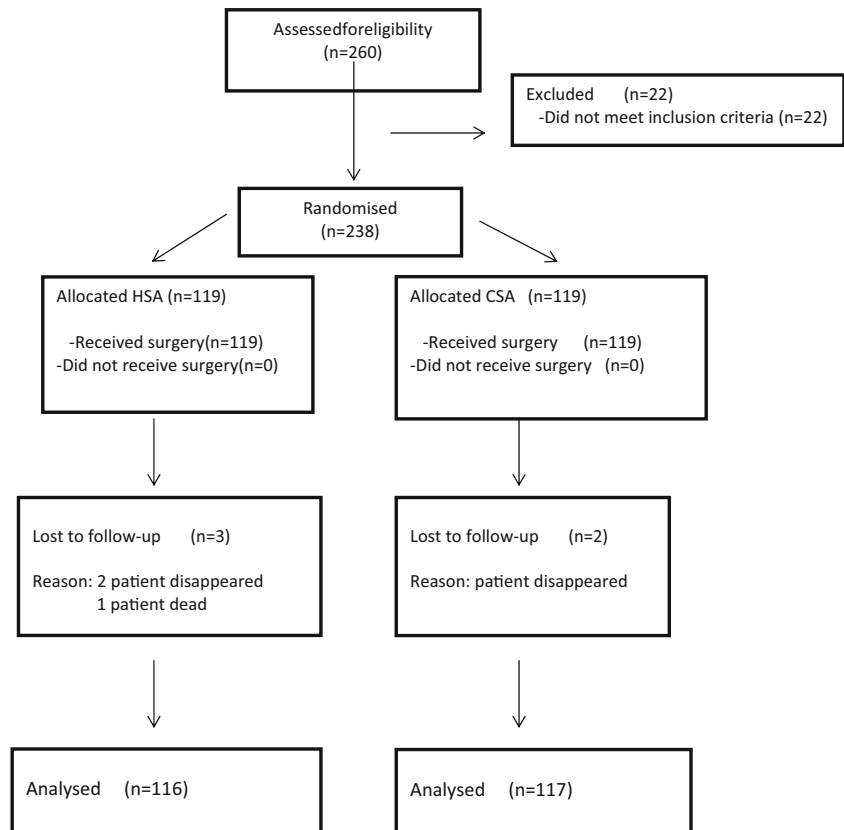


Table 1 Demographic data and comorbidities in the two groups

Variable	HSA	CSA	<i>p</i> value
Patient (<i>N</i>)	116	117	–
Age (years)	41.1±11.1	42.4±12.2	0.35
Sex (F/M)	72/44	81/36	0.26
BMI	47.7±8.1	46.8±5.8	0.31
Comorbidities			
AHT (<i>n</i> /%)	48 (41.4 %)	45 (38.5 %)	0.29
DM (<i>n</i> /%)	33 (28.4 %)	29 (24.8 %)	0.53
OSAS (<i>n</i> /%)	23 (19.8 %)	14 (11.9 %)	0.10
Hyperlipidemia	39 (33.6 %)	41 (35.1 %)	0.82

BMI body mass index, AHT arterial hypertension, DM diabetes mellitus, OSAS obstructive sleep apnea syndrome

vs. 3.4 %, *p*=0.025) than the patients with HSA. There were no significant differences for the other early complications. Of the five patients with postoperative GIB (one upper GIB and four melena), two required a transfusion for symptoms of anemia with hemodynamic consequences (hypotension, tachycardia, and hemoglobin <8 mg/dl (Table 2).

The rate of late complications (≥30 days) was 8.6 % (10 patients) in the HSA group and 12.8 % (15 patients) in the CSA group (*p*=0.30). Analysis of GJA stricture, anastomotic marginal ulcer, GJA perforation, bowel obstruction, and incidence of port site hernia revealed no significant differences between the two groups (Table 2). The patients presenting with stricture of the GJA required endoscopic dilatation, but no reoperations were necessary. There were no significant

Table 2 Comparison of the early and late postoperative complications for both groups of patients (HSA and CSA)

Type of complication (<i>n</i> /%)	HSA (<i>n</i> =116)	CSA (<i>n</i> =117)	<i>p</i> value
Early complications			
Postoperative gastrointestinal bleeding	0	5 (4.2 %)	0.024
Intraabdominal bleeding	4 (3.4 %)	2 (1.7 %)	0.40
Strangulated hernia	0	1 (0.8 %)	0.31
Gastrojejunostomy leak	1 (0.8 %)	0	0.31
Acute pancreatitis	1 (0.8 %)	0	0.31
Surgical wound infection	4 (3.4 %)	13 (11.1 %)	0.025
Total	10 (8.6%)	22 (18.8%)	0.024
Late complications			
Gastrojejunostomy stricture	3 (2.6 %)	5 (4.3 %)	0.47
Marginal ulcer of anastomosis	1 (0.8 %)	0	0.31
Gastrojejunostomy perforation	1 (0.8 %)	3 (2.6 %)	0.31
Eventration	3 (2.6 %)	6 (5.1 %)	0.30
Bowel obstruction	2 (1.7 %)	1 (0.8 %)	0.55
Total	10 (8.6%)	15 (12.8%)	0.30

Bold type means it is a statistically significant value

differences for reoperation rates between the groups (five HSA patients and six CSA patients; *p*=0.81) (Table 3). There were no significant differences for %EWL at 3, 12, and 24 months between the two surgical techniques (Fig. 2).

Mean operative time was 112.9±23.4 min in the HSA group and 107.5±22.1 min in the CSA group (*p*=0.055). The mean length of postoperative hospital stay was 1.9±1.1 days in the HSA group and 2.2±3.4 days in the CSA group (*p*=0.454). There was no mortality in the group of patients with a CSA anastomosis, and there was one in the HSA group (0.86 %) secondary to sepsis due to dehiscence of the GJA.

Discussion

RYGB is one of the most commonly used techniques in the treatment of morbid obesity, accounting for approximately 60 %. The rate of overall early complications in our study was 13.4 % (due mainly to infection of the surgical wound), and late complications represented 10.5 %. One of the most important challenges for a surgeon performing a laparoscopic RYGB is the GJA, which can be done by hand or mechanically with a circular or linear stapler. The most common GJA-related complications are anastomotic leak (0.8–6.6 %), anastomotic bleeding (1.7–8.1 %), peri-anastomotic ulcer (1.2–2.8 %), and stricture (1.1–33.3 %) [9]. There is great variability in the rate of complications published in the literature possibly due to the need for more randomized studies, the increasing existence of bariatric surgery units with their learning curve, and difficulty to measure some complications such as stricture or intestinal bleeding. Although there are several studies in the literature comparing the different types of GJA, they are mostly retrospective; no prospective controlled study has been found to compare the results between mechanical and manual anastomoses, which is the justification for the present study.

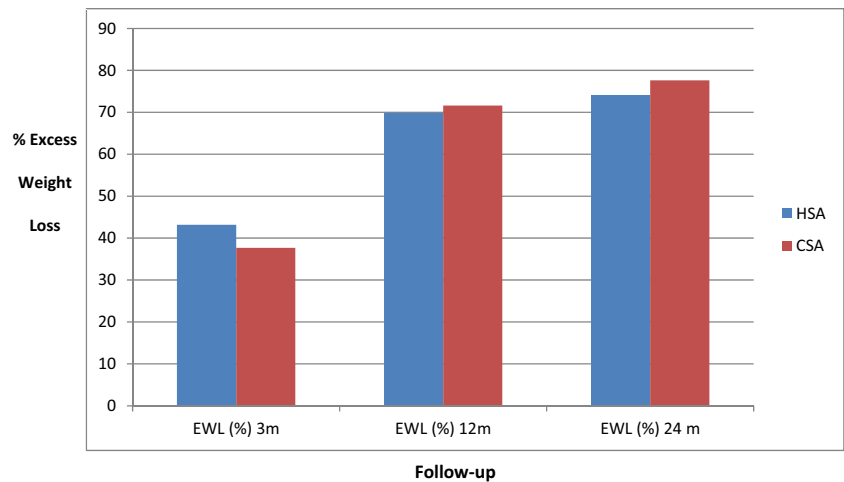
Among the early complications, incidence of surgical wound infection (11.47 vs 3.44 %) predominates in the

Table 3 Rate of surgical reoperation and justification in both groups of patients

Cause of reoperation	HSA (116)	CSA (117)
GJA perforation	1 (0.8 %)	3 (2.5 %)
Bowel obstruction	2 (1.7 %)	1 (0.8 %)
Incarcerated eventration	–	1 (0.8 %)
Early dehiscence of GJA	1 (0.8 %)	–
Postoperative hemoperitoneum	1 (0.8 %)	1 (0.8 %)
TOTAL	5 (4.3 %)	6 (5.1 %)

GJA gastrojejunal anastomosis
p=0.81 (ns)

Fig. 2 Comparison of percentage of weight loss (%EWL) between the two techniques for the different follow-up periods



patients with CSA. These results coincide with those published by González et al. [3] and Shope et al. [10]. In the case of CSA, the circular stapler is inserted through the abdominal wall without protection, which may cause contamination of the subcutaneous cell tissue when it is removed together with the resected bowel segment in the performance of the anastomosis.

Another of the most frequent early complications in the group of patients with CSA was GIB (4.1 %). As in our study, the articles published on HSA by Ahmed [11] and Ruiz de Adana [2] report a GIB incidence of 0.4 %. However, mechanical anastomosis presents a rate of GIB ranging from 1.7 to 8.1 % [9, 12]. A meta-analysis on more than 9000 patients shows greater postoperative GIB for CSA than for LSA ($p < 0.0001$). The greater incidence of postoperative GIB in mechanical anastomoses might be explained by the bleeding at the staple line on the inside of the anastomosis or by bleeding at the line of gastric pouch division; various techniques, such as continuous reinforcement suture or the use of hemostatic material-like SEAMGUARD®, have demonstrated a reduction in the rates of postoperative GIB. In cases that are not self-limited, UGI endoscopy is the cornerstone in the diagnosis and treatment of this complication [13]. GJA leakage is an uncommon complication following RYGB, although it is associated with high morbidity and mortality rates. The incidence of GJA leakage ranges from 0 to 6.6 % in the various studies published [3, 7, 14]. In our study, there was only one case of anastomotic leakage (0.86 %), in the HSA group, which was resolved with suture of the dehiscence and placement of drainage. The meta-analysis published by Penna et al. [12] shows no differences in the incidence of leakage between CSA and LSA. The incidence of anastomotic leakage in the study published by Kravetz et al. [15] is 0.9 % (with no significant differences between HSA and CSA). These studies suggest that anastomotic leakage is not related to the type of GJA and the more important factors for its prevention are the correct vascularization and absence of GJA tension.

Among late complications, different retrospective studies analyzed the stricture rate with different GJA techniques, with controversial results. Bandewald et al. [6] demonstrated no statistically significant differences in stricture rate between CSA (4.3 %) and HSA (6.1 %). Abdel-Galil et al. [7] report a greater incidence of stenosis in HSA (33.3 %) than in CSA (16.7 %). However, the interpretation of this study is limited, because the authors do not mention the size of the circular stapler and also because the stricture rates reported in their study are much higher than those reported in the literature. Gonzalez et al. [3] show that the stricture rate is significantly higher in CSA (30.7 %) than in HSA (3.5 %) using a 21-mm circular stapler. Creating the HSA using a monofilament suture has been shown to reduce the stricture rate when compared to a multifilament suture [16]. According to the size of the CSA stapler, a higher incidence of stenosis has been observed with 21-mm staplers than with 25 mm, with no differences in the weight loss [17, 18]. In the present study, we used a 21-mm circular stapler and monofilament suture to create the HSA and observed no significant differences in the rate of strictures between the two groups.

The incidence of marginal ulcer (MU) varies greatly by publication (2.3–3 % for CSA and 1.2–1.3 % for HSA) [18]. We only had one case of MU in the group of patients with HSA (0.86 %) and none in the patients with CSA. The use of absorbable sutures in creating the anastomosis, as in our study, has been shown to reduce the rates of MU compared to permanent suture [19]. Another factor discussed in the prevention of MU is the type of prophylaxis used after surgery. D'Hondt et al. [20] find statistical significance in the incidence of MU with proton pump inhibitor therapy in patients positive for *Helicobacter pylori*. One of the possible consequences of uncontrolled MU might be perforation in the region of the GJA. Our study shows a greater incidence of GJA perforation in the CSA group, but with no significant differences (2.4 vs 0.8 %). This serious complication may occur several years after

surgery, which highlights the importance of a long-term follow-up in patients undergoing RYGB [21].

Most studies published in the literature [3, 4, 6, 7] find no significant differences between type of GJA and %EWL, which seems logical, as weight loss is influenced by different factors such as demographic characteristics, size of the gastric pouch, length of the bowel loops, and multiple hormonal factors that are currently under study.

Surgical time in the present study was longer in the patients with HSA, although without significant differences. Most publications report a longer operative time for performing HSA [15]. It is fundamental, in order to be able to compare the two surgical techniques, for surgical teams to have wide experience in performing HSA, as they involve a greater surgical complexity and require a correct learning curve. Every surgeon should perform the technique that he or she is comfortable with. Our surgical team had ample previous experience in performing both HSA and CSA, for which reason, the learning curve was overcome prior to the study.

In this study, no endoscopy was performed to confirm the source of GIB; the limitation is being unable to draw conclusions about the source of bleeding. This trial does not include the lineal stapling between the compared techniques, what is a weakness in the study.

Conclusion

HSA and CSA are techniques with similar safety and effectiveness. HSA involves a lower rate of bleeding complications and surgical wound infection but requires greater experience in laparoscopic hand suture.

Conflict of Interest The authors declare that there are no conflicts of interest

Author Contribution Israel Abellán and Victor López: study design, data acquisition, and manuscript drafting; J. Abrisqueta, MD, Frutos, and Q. Hernández: data acquisition and manuscript drafting; Juan Luján: data acquisition, manuscript drafting, and statistical analysis; and P. Parrilla: data acquisition, manuscript drafting, and revision.

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