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Original research

# Totally hand-sewn anastomosis using barbed suture device during laparoscopic gastric bypass in obese. A feasibility study and preliminary results

Silvia Palmisano<sup>a,\*</sup>, Michela Giuricin<sup>a</sup>, Petra Makovac<sup>a</sup>, Biagio Casagranda<sup>a</sup>, Giuseppe Piccinni<sup>b</sup>, Nicolò de Manzini<sup>a</sup>

<sup>a</sup> Department of Medical, Surgical and Health Sciences, General Surgery Clinic, University Hospital of Trieste, Strada di Fiume, 447, Trieste, Italy <sup>b</sup> Unit of Endocrine, Digestive and Emergency Surgery, Department of Biomedical Sciences and Human Oncology, Section of General and Oncologic Surgery, University Medical School of Bari "Aldo Moro", Bari, Italy

## HIGHLIGHTS

• Laparoscopic intracorporeal hand sewn anastomosis is a technical demanding procedure.

- A knotless barbed suture device makes the intracorporeal sutures easier.
- We proposed the use of the barbed suture device for intestinal anastomosis.
- Few studies in literature propose its use for intestinal anastomosis.

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## ABSTRACT

Introduction: Barbed sutures are routinely used for laparotomy, peritoneal and mesenteric closure, but few studies have reported their use for intestinal anastomosis. We proposed their use for totally handsewn anastomosis during laparoscopic gastric bypass secured at the end of the suture with an absorbable clip. Materials and Method: Two totally hand-sewn single-layer extramucosal running sutures were performed for side-to-side gastrojejunal and jejuno-jejunal anastomosis during laparoscopic gastric bypass. Each run (anterior and posterior layer) was locked at the end by an absorbable poly-p-dioxanone suture clip. Results: A total of 96 hand-sewn anastomoses were performed. A total of two leaks occurred originating from the jejunaljejunal anastomosis. No cases of leakage from gastrojejunostomy were recorded. Two stenoses of the gastrojejunal anastomosis were recorded. They were successfully treated with three sessions of endoscopic balloon dilatation. No bleeding occurred. Conclusion: In our experience, the suture-related complication rate is comparable with the data reported in the literature. Further studies are needed to address the safety and efficacy of the self-maintained suture in digestive surgery. © 2014 Surgical Associates Ltd. Published by Elsevier Ltd. All rights reserved.

anastomosis.

suture

requires the longest learning curve [5]. Laparoscopic intracorporeal suturing and knot tying for anastomosis are technically demanding

tasks even for well-trained laparoscopic surgeons due to the need

to maintain the correct tension of the thread along the run of

used to close the mesenteric defects, to create a totally gastro-

jejunal and jejuno-jejunal hand-sewn anastomosis, or to close the

intestinal opening, if the mechanical anastomosis was performed. The manual anastomotic technique required running sutures for each anastomosis, while the closure of the intestinal opening left after the mechanical anastomosis required a single extramucosal

In the bariatric field, laparoscopic intracorporeal suture can be

## 1. Introduction

Laparoscopic gastric bypass (LGB) is the most effective bariatric surgery in reducing weight and improving quality of life and obesity related diseases such as diabetes and hypertension [1-3].

Although several different types of anastomotic technique are available (hand-sewn, linear stapled and circular stapled anastomosis), the ideal one has yet to be identified [4]. Certainly handsewn anastomosis is the most difficult one to perform and

Corresponding author.

E-mail address: spalmisano@units.it (S. Palmisano).

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Over time, several types of suture have been proposed and used, resorbable and not absorbable, both requiring the thread to be kept constantly in tension.

A knotless barbed suture device has been proposed to make the intracorporeal sutures easier, but there are only few studies in the literature that propose its use for intestinal anastomosis [6-9].

The aim of this retrospective study was to understand whether or not this new suture with an absorbable clip secured at the end of the suture is capable of obtaining a safe totally hand-sewn anastomosis during laparoscopic gastric bypass (primary outcome), thus saving surgical time and money (secondary outcomes). We evaluated the incidence rate of anastomosis-related complication as early, leakage and bleeding, and late (stenosis) occurring during the follow-up program.

### 2. Methods

A retrospective study of patients undergoing elective LGB between August 2011 and April 2013 was performed in our department. All consecutive consenting patients were included in the study in accordance with the international guidelines: age 18-65 years, a body mass index (BMI) of 40 kg/m<sup>2</sup> or between 35 and 40 kg/m<sup>2</sup> with obesity-related co-morbidities, well-informed and motivated patients with acceptable operative risks, failure of nonsurgical treatments, declared compliance to follow lifelong medical surveillance [10]. The preoperative workup included psychiatric and nutritional appraisal, upper gastrointestinal endoscopy with gastric biopsy to seek Helicobacter pylori bacteria, respiratory and cardiac evaluation and a complete blood test. Before surgery all patients were well informed about the surgical technique and the surgical risks. The surgeon ensured that the patient understood the information received and the patient signed a full informed consent for the operation. The use of the device was already documented in the literature, therefore we asked the approval of the department ethical board committee.

All the procedures were performed by one senior surgeon expert in laparoscopic surgery and two trained but not experienced surgeons and the standardized surgical technique did not differ for any patient during the study.

The side-to-side gastro-jejunal and jejuno-jejunal anastomosis were created using the V-loc 90 (Covidien, Mansfield, MA, USA) 3/ 0 absorbable monofilament suture. Two totally hand-sewn single-layer extramucosal running sutures were performed for both anastomoses. Each suture (anterior and posterior layer) was then locked by an absorbable suture clip made of poly-p-dioxanone (Lapra-TY II, Ethicon Endo-Devices, Cincinnati, OH, USA) (Fig. 1).

During the postoperative hospital stay, a standardized postoperative management program is applied to all patients before the discharge, in order to recognise early clinical symptoms and signs of serious complications. The patient's pulse and blood pressure, respiration and oxygen saturation, fever and pain were recorded every 3 h in first postoperative day (POD) and than every 6 h. The content of the abdominal drains are measured every 3 h in first POD and than daily. The blood tests were required in first POD and just before the discharge and the contrast swallow study was performed on POD 3. Drains were removed after the radiological control and than food oral intake was allowed.

Before discharge, the patients were advised to avoid fast sugars and invited to take multivitamin supplements, calcium, iron, folate and vitamin B12. An oral intake protocol and dates for medical visit were given to all patients. They were enrolled in a follow-up program including medical visit and clinical examination every 3 months plus extensive blood tests every 6 months during the first post-operative year; during the second and third post-operative years the clinical examination and blood tests are carried out every 6 months, and once a year thereafter.

Data including age, sex, BMI, co-morbidities, previous failed bariatric surgery, length of hospital stay, early (within 30 days after surgery) and late complications, re-interventions and follow-up time were recorded.

We compared the operation time needed to perform manual anastomosis during LGB using the barbed suture and other non absorbable monofilament suture used in our surgical equipe prior to introducing V-loc in a comparable group of patients.

The statistical analysis was performed using Microsoft Excel 2007 (Microsoft Excel 2007, Redmond, WA, USA) and continuous variables are expressed as mean  $\pm$  standard deviation.

#### 2.1. Surgical technique

Patients were placed in the supine position with both arms extended and both legs abducted, the operating table was positioned in gentle reverse Trendelenburg position. All patients were given 2 g of cefazolin intravenously in the operating room, after general anaesthesia induction, as antibiotics prophylaxis.

After the creation of pneumoperitoneum by Veress needle in the left hypochondrium [11], five abdominal trocars were inserted. A T1 optical trocar was inserted in the midline 15 cm under the xiphoid process; two operator's trocars were positioned: T2 in the left lumbar region along the left mid-clavicular line and T3 5 cm under the costal margin in the right mid-clavicular line. Two retraction trocars were placed in the epigastric position (T5) and in the left anterior axillary line close to the costal margin (T4) respectively.

A liver retractor was used to move the left lobe laterally and visualize the hiatus and the lesser curve. A 34-French orogastric tube was inserted by the anaesthesiologist to calibrate the future gastric pouch. The dissection began between the first and second vascular arcades on the lesser curvature and a laparoscopic linear



Fig. 1. Absorbable clip at the end of the barbed suture. A: gastrojejunal anastomosis; B: jejunaljejunal anastomosis.



Fig. 2. Posterior layer (A) and Anterior layer (B) of the gastro-jejunostomy.

stapler was fired. The first suture line was horizontal, the second line ran parallel to the oesophagus towards the angle of His. During this process, exposure of the left crus was extremely important to divide the remainder of the stomach. An additional linear stapler was often necessary.

Once the gastric pouch was completely separated from the bypassed stomach, the omentum and the transverse mesocolon were lifted upwards and the ligament of Treitz was identified. The biliary limb was measured 100 cm distal to the ligament of Treitz and the alimentary limb was measured up to 120 cm. Two handsewn running sutures were performed for each anastomosis (Fig. 2). Manual single-layer gastrojejunostomy was performed between the gastric pouch and the alimentary limb; manual sideto-side single-layer jejunojejunostomy was performed between the alimentary and biliary limbs. The first 2 cm of the suture is without barbs, so the beginning of each suture started over the top of the visceral openings; in this way the barbs were available for the closure. At the end of each manual running suture an absorbable suture clip was used to lock them.

An intraoperative test with coloured water irrigation through a naso-gastric tube was routinely performed to verify gastro-jejunal anastomosis integrity. Two abdominal drainages were placed close to both anastomoses.

## 3. Results

During the study period, 48 patients underwent LGB using a totally hand-sewn anastomosis. Among the 48 consecutive patients enrolled in our study, 41 (85.4%) underwent primary procedure and 7 (14.6%) had revisional procedures. The latter included previously failed laparoscopic adjustable gastric banding to bypass in all cases. The epidemiologic data are summarized in Table 1.

A total of 96 hand-sewn anastomoses were performed and no "conversion" to usual sutures were recorded.

A total of two leaks occurred originating from the jejuno-jejunal anastomosis. The diagnosis of anastomotic leakages was clinical in both of cases. The leakages were suspected based on the presence of biliary content in the abdominal drainage. All leaks were treated by surgical re-interventions on the first postoperative day (POD). A laparoscopic approach was performed in both cases and a localized peritonitis was found. Extensive washing with lukewarm physiologic serum was performed and a revision of the anastomosis was carried out. No cases of leakage from gastro-jejunostomy were recorded.

The mean operation time using the V-loc device was  $132.4 \pm 4.3$  min. The duration of operation was  $164.7 \pm 2.1$  min using other no barbed suture device, therefore there is a time savings of approximately half an hour (32 min).

The mean post-operative hospital stay was  $5.3 \pm 3.1$  days. In the present study, this time was useful to complete the postoperative controls (the contrast swallow study, the first nutritional visit, the first solid meal and the blood tests) before the discharge.

The mean follow-up time was  $10.1 \pm 5.2$  months and two stenosis of the gastro-jejunal anastomosis were recorded: 15 days and 2 months after surgery respectively. Both of the strictures were successfully treated with three sessions of endoscopic balloon dilatation. No cases of post-operative bleeding were recorded.

In summary, there were 3 complications within 30days of surgery (two anastomotic leakages and one stricture), and one later complication consisting of the stricture of the gastrojejunal anastomosis (Table 2).

For totally gastro-jejunal and jejuno-jejunal hand-sewn anastomosis we used 4 V-loc 90 (Covidien, Mansfield, MA, USA) 3/ 0 absorbable monofilament suture and 4 absorbable clips: two layers (anterior and posterior) for each anastomosis The cost of one V-loc 90 (Covidien, Mansfield, MA, USA) 3/0 absorbable monofilament suture was  $\in$  37.80 and the cost of the single pocket of absorbable suture clips within 2 pieces was  $\in$  62.00. The total cost was  $\in$  275.20.

For mechanical technique 2 linear staplers, 2 V-loc 90 (Covidien, Mansfield, MA, USA) 3/0 absorbable monofilament suture and 2

The epic	lemio	logic	data.
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Data	No of patients
Sex	
Females	32
Males	16
Mean BMI (Kg/m <sup>2</sup> ) $\pm$ standard deviation	$42.9 \pm 4.8$
Females	$43.2 \pm 4.7$
Males	$42.9 \pm 4.9$
Mean age (years) $\pm$ standard deviation	$44.7 \pm 11.6$
Comorbidities	
Diabetes	21
Insulin Therapy	9
Oral antidiabetic drug	12
Hypertension	22
OSAS	6
Arthropathy	4
Dyslipidemia	10
Cardiac failure	8
Class I <sup>a</sup>	6
Class II <sup>a</sup>	2
Chronic obstructive pulmonary disease	4
Smoking status	5
ASA <sup>b</sup>	
ASA 3	42
ASA 4	6
Previous failed laparoscopic gastric banding	7

<sup>a</sup> The New York Heart Association (NYHA) classification.

<sup>b</sup> The American Society of Anaesthesiologist (ASA) Physical Status classification.

Table 2	
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Surgical complications and postoperative data.

Data	No of patients
Anastomotic leakage	
Gastrojejunal anastomosis	0
Jejunaljejunal anastomosis	2
Bleeding	0
Strictures	2
Reinterventions	2
Length of hospital stay (mean $\pm$ standard deviation)	$7.2 \pm 3.24$ days
Follow-up time (mean $\pm$ standard deviation)	$10.1 \pm 5.2$ months

absorbable suture clips could be used to close the intestinal opening. The cost of 2 endocutters blue cartridges could be  $\in$  536.80, the cost of 2 barbed sutures could be  $\in$  75.60 and the cost of the single pocket of absorbable suture clips within 2 pieces was  $\in$  62.00. The total cost could be  $\in$  674.40. Mechanical anastomosis is 2.4 times more expensive than the manual one.

#### 4. Discussion

Bariatric surgery results in greater and durable weight loss than conventional treatment in moderate and severe obesity [12,13].

The type of anastomosis that are during LGB are hand-sewn, linear stapled and circular stapled ones. No difference in terms of complication rate was reported using the three commonly performed techniques and at the moment there is no data to identify a better anastomotic technique. Bendewald and co-workers report no statistical differences in terms of early anastomotic complications between the three types of techniques, underlining that the manual anastomosis is likely to be less expensive than the mechanical one [4].

The surgeon's decision to adopt the hand-sewn technique to perform both anastomosis is affected by the personal surgical training and experience, but manual intestinal anastomosis is a technically demanding procedure even for experienced laparoscopic surgeons [5], this is because of intrinsic technical difficulties like maintaining a correct tension of the thread during intracorporeal sutures and knot tying. Moreover, considering a teaching purpose, manual anastomosis is a surgical act that allows skills and proficiency in laparoscopic surgery to be improved, especially for the in-training surgeons.

The knotless barbed suture has been introduced in practice to make laparoscopic intracorporeal sutures easier. The device has a looped end that allows one end of the suture to be tethered without a knot; additionally the first 2 cm of the suture is without barbs to facilitate readjustment of the throws before the barbs are engaged. The tension is self-maintained during the running suture with no need for permanent traction and once pulled tight, the suture does not slip.

Although many advantages have been described for this device, few studies with small samples are reported in literature. The feasibility of using the barbed suture on the bowel has been demonstrated in porcine and canine models. Stomach, jejunum and colon enterotomies were closed using the barbed suture and burst-strength tested [14,15].

On human subject, the efficacy and safety of these types of suture were tested in gynaecologic [16-18], plastic [19,20], urologic [21-24] and orthopaedic surgery [25] without any differences respected to conventional monofilament sutures.

In digestive surgery, the barbed sutures are routinely used for laparotomy, peritoneal and mesenteric closure, but few studies report their use for intestinal anastomosis. Moreover only a small sample of patients, in these studies, underwent a totally hand-sewn intestinal anastomosis using the barbed suture [6,8]. On the contrary a larger experience has been described in the closure of intestinal openings after using the mechanical stapler [6-9,26,27].

The findings of these studies encouraged us to use the barbed suture devices to create a totally hand-sewn anastomosis during LGB, both for the gastro-jejunostomy and the jejeuno-jejunostomy. We found two properties of paramount importance: the barb and the looped end. The barbs allow a self-maintained suture to be performed without requiring permanent traction. This characteristic makes the tissue approximation easier and less tiring to perform. The looped end obviates the need of tying knots and makes the beginning of each suture more standardized and predictable. In our opinion, both of these properties are time saving and speed up the learning curve of the training surgeons.

Driven by greater caution, we decided to secure the end of the suture with an absorbable clip. This choice was justified because little data with a short follow-up period had been previously published supporting the use of the barbed suture on human subjects for totally hand-sewn intestinal anastomosis. We believe that in this preliminary experience it would be more prudent to use a "safety" clip.

In addition, during the study, we noted that the absorbable clip could be a valid option to secure the sutures even when there is an insufficient length of the free tail (<1.5 cm) outside the bowel.

We achieved zero mortality rate and a low rate of early (3.1%) and late (1.04%) suture-related complications, comparable with the data reported in literature [28–30]. The two jejuno-jejunostomy leakages had an early onset and required a re-intervention in first POD; the two strictures were successfully resolved with endoscopic treatment.

In conclusion, in this initial experience limited as retrospective and with a small sample size, the barbed suture seems to be a valid device for the creation of totally hand-sewn gastrointestinal anastomosis during laparoscopic gastric bypass. With the above mentioned limits, it is our opinion that the use of the barbed suture had an excellent short-term safety profile and was also a costeffective method. It was time saving respect to other types of intracorporeal suture requiring both permanent traction during the running suture and the creation of the initial knot. This device is a self-maintaining suture with a terminal loop that allows one end of the suture to be tethered without a knot. These characteristics allow skills and proficiency in laparoscopic surgery to be improved, especially for the in-training surgeons. The use of an absorbable clip at the end of the suture is an additional cost but appears to be safe and feasible and it is not time consuming. Further studies are needed to address the safety and efficacy of the self-maintained suture without any kind of secured end device like a comparative study with a traditional monofilament suture and, at the end, with a mechanical anastomosis.

## **Ethical approval**

None declared.

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None.

#### Author contribution

Silvia Palmisano: study design, data analysis, writing. Michela Giuricin: data collections, writing. Petra Makovac: data collections. Biagio Casagranda: data collections. Giuseppe Piccinni: data analysis, writing. Nicolò de Manzini: study design, writing.

## **Conflicts of interest**

None.

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