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The use of fibrin sealant to prevent major complications following laparoscopic gastric bypass: results of a multicenter, randomized trial

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Abstract
Background Published interim results have shown that fibrin sealant (Tissucol®/Tisseel® Baxter AG, Vienna, Austria) may be effective in preventing anastomotic leaks and internal hernias following laparoscopic Roux-en-Y gastric bypass (LRYGBP). We report the final results of a multicenter, randomized clinical trial evaluating the use of fibrin sealant in LRYGBP.
Methods Between January 2004 and December 2005, 340 patients aged 21–65 years with a body mass index (BMI) of 40–59 kg/m^2 undergoing LRYGBP were randomized (1:1) to two treatment groups: fibrin sealant group (applied to gastrojejunal and jejunojejunal anastomoses and over mesenteric openings), and control group (no fibrin sealant; suture of the mesenteric openings). Operative time, early and late complications, reinterventions, time to oral diet initiation, and length of stay were assessed.
Results Overall, 320 patients were included into the study: 160 in the control group and 160 in the fibrin sealant group. All patients completed follow-up assessments at 6 and 12 months, and 60.9% completed assessments at 24 months. There were no significant differences between groups with respect to demographics, operative time, oral diet initiation, hospital stay, and BMI reduction at 6, 12, and 24 months. The incidence of anastomotic leak was numerically, but not significantly, greater in the control group. The overall reintervention rate for specific early complications (<30 days) was significantly higher in the control group ($p = 0.016$). No deaths or conversions to open laparotomy occurred.
Conclusion The use of fibrin sealant in laparoscopic RYGBP may be beneficial in reducing the reintervention rate for major perioperative (<30 days) complications. Larger studies are needed.

Keywords Laparoscopic Roux-en-Y gastric bypass · Bariatric surgery · Fibrin sealant · Tissucol®

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Introduction

During the last 30 years, the use of biological fibrin sealants has gained great popularity for an increasing number of indications throughout all surgical fields [1, 2]. These sealants are primarily used to achieve hemostasis, but their use in wound healing and as biological sealants in various situations (bile, air, gastrointestinal or lymphatic leaks) has been widely reported [1–6]. Their role in tissue engineering is currently under investigation [7].

Fibrin sealants are currently approved (Food and Drug Administration FDA, USA and European Union EU) for use in cardiovascular surgery, spleen trauma and for the closure of

colostomies, although the precise indications differ between the USA and Europe [2]. Off-label indications include hemostasis following trauma, closure of various gastric or rectovaginal fistulae, coverage of the bile duct, tracheal anastomoses and bronchial stump reinforcement [7–9]. Also, the widespread use of fibrin sealants has been reported in urology [8] and in many laparoscopic procedures [5, 9, 10–17]. In Europe, several types of fibrin sealants are currently available (Tissucol®/Tisseel® [Baxter AG, Vienna, Austria], Quixil™ [Omrix], Beriplast® [Behring]) [1, 2, 5, 7, 9].

Biological fibrin sealants typically contain two basic components (human fibrinogen and human thrombin), together with a fibrinolysis inhibitor to prevent fibrin degradation during storage. The differences between the various sealants are largely dependent on the quality and quantity of the two basic components, as well as the nature of the fibrinolysis inhibitor [2, 7, 18]. For this study, Tissucol®/Tisseel® fibrin sealant was chosen due to its favorable safety profile (no side effects, no transmitted infectious diseases and no embolization or coagulopathy reported [2, 7, 8, 19, 20]), wide-scale use, long clinical history, reported use in laparoscopic procedures [21–23] and easy-to-use laparoscopic delivery devices.

In order to reduce the incidence of postoperative major complications following laparoscopic Roux-en-Y gastric bypass (LRYGBP), technical modifications and reinforcement products have been developed and utilized over the years. A prospective, multicenter, risk-adjusted cohort study of 1356 gastric bypass cases has shown that LRYGBP has a better safety profile than open gastric bypass with respect to early (<30 days) postoperative complications [24]. However, there is also evidence to suggest that LRYGBP has a higher risk of late bowel obstruction [25–27].

Also, recent studies have reported the use of fibrin sealants to prevent anastomotic leaks following open gastric bypass [9, 20], and laparoscopic bariatric surgery [21–23]. These nonrandomized clinical trials suggested that the use of fibrin sealant following surgery in high-risk morbidly obese patients may help reduce early complications, and may prove a useful tool during the learning curve for these complex procedures.

Interim results of the present study suggested that major complications may be reduced by the use of fibrin sealant [28]. Here we report the final results of the first prospective, multicenter, randomized clinical trial to evaluate the use of biological fibrin sealant in the prevention of major complications following LRYGBP.

Materials and methods

This was a prospective, multicenter, randomized clinical trial designed to assess the safety and efficacy of human fibrin sealant (Tissucol®/Tisseel®, Baxter AG, Vienna, Austria) in the prevention of specific major complications following laparoscopic Roux-en-Y antecolic antegastric gastric bypass (LRYGBP) for the treatment of morbid obesity.

Morbidly obese patients [29] were enrolled from six specialized centers (five in Italy, one in France), and randomized (1:1) to two treatment groups: fibrin sealant and control (no fibrin sealant). Computerized randomization was performed on the same day as surgery by the coordinating center. Patients included men and women aged 21–65 years with a body mass index (BMI) of 40–59 kg/m^2, undergoing LRYGBP. Exclusion criteria included previous bariatric surgery, concomitant surgical procedures (except for cholecystectomy), and conversion to open laparotomy. In the case of a preoperative ultrasound diagnosis of gallstones, cholecystectomy was performed concomitantly with the LRYGBP. Written informed consent was obtained for each patient prior to inclusion. There was no blinding of the randomized treatment to any participant at any stage. Informed consensus to surgery was obtained in every participant.

Surgical technique

The surgical procedure consisted of the creation, using linear staplers, of an isolated gastric pouch (estimated volume 15–25 mL), and has been described in detail in a previous publication [28]. Three different surgical techniques were used for the gastro-jejunostomy, depending on the surgeon's personal experience: circular stapling using the 25-mm CEEA Plus (US Surgical Corporation, Norwalk, CT, USA) with the stapler's anvil placed transorally (Gagner technique), linear stapling, or using two layers of handsewn sutures. All gastrojejunal anastomoses were tested intraoperatively by injecting methylene-blue through a nasogastric tube. A 50-cm biliary limb and a 75–150 cm alimentary limb were created. The jejunojejunostomy consisted of a side-to-side stapled anastomosis (45 × 25 mm cartridge, six rows), together with handsewn suturing of the enterotomies.

This study employed the Tissucol®/Tisseel® fibrin sealant kit (Baxter AG, Vienna, Austria). The sealant was stored in frozen syringes and thawed at 33–37°C on the morning of the surgery. During the surgical procedure, fibrin sealant was applied to both the gastrojejunal and jejunojejunal anastomoses, covering both anterior and posterior lines. The sealant was not applied over the stapled lines of the isolated gastric pouch or the distal remnant stomach. Application was carried out using a laparoscopic double-syringe dispensing unit, prepared with a 2- or 5-mL kit, depending on the surgeon's preference.

In the control group, closure of the mesentery defects and the Petersen space was carried out using stitches

(the type of suture used was dependent on the personal preference of the surgeon). In the study group these were carried out using laparoscopic application of fibrin sealant over the section-damaged mesenteric tissues without suture.

Drainage was left in place at the surgeon's discretion, and a postoperative contrast X-ray (Gastrographin) was carried out in all patients before commencing the oral diet.

Outcome measures

Data were collected regarding the patients' demographics, operation (technique, time, conversion, methylene-blue test, fibrin sealant usage, and time to oral diet initiation), postoperative gastrointestinal contrast X-ray, hospital stay, and complications (early and late). Postoperative follow-up data were collected at 6, 12, and 24 months, with additional updates as required.

The primary efficacy endpoint was the proportion of complication-free patients in each treatment group. Primary safety endpoints were the occurrence of early complications (anastomotic leak, anastomotic bleeding, internal hernia), late complications (bowel obstruction), and adverse effects directly related to fibrin sealant application.

Secondary endpoints were the time to postoperative oral diet, length of hospital stay, occurrence of anastomotic stenosis, and weight loss.

Statistical analysis

A sample size of 160 subjects per study arm (without dropouts) was required in order to have a statistical power of 80% ($\alpha = 0.05$) for the detection of a decrease in the rate of LRYGBP complications from 5% to 2%. Comparisons between the two study arms were based on the Chi-square test for homogeneity (or Fisher's exact test if the cell frequencies were small).

The safety population was defined as all randomized patients who underwent surgery. The intent-to-treat (ITT) population was defined as all randomized patients who underwent surgery and received at least one post-baseline follow-up.

Results

The first patient was randomized in January 2004, and the last patient treated in December 2005. A total of 340 patients were randomized but only 320 were included in the analyses. Sixteen patients were excluded because they did not meet the inclusion criteria, while four patients were excluded due to incomplete follow-up data. Both the control group (mean age 39.8 ± 11.3 years, mean BMI 46.9 ± 7.6 kg/m^2), and the fibrin sealant group (mean age 41.6 ± 10.9, mean BMI 47.2 ± 6.5) consisted of 160 patients. Baseline characteristics (sex, age, and BMI) were similar for both treatment groups, and are summarized in Table 1. Patients ($n = 320$) completed a minimum follow-up of 18 months, up to a maximum of 42 months, with 60.9% of patients ($n = 195$) completing follow-up assessments at 24 months. A total of 98.1% of patients provided BMI data at 6 months and 95.6% provided data at 12 months. At 24 months, postoperative complications and BMI data were reported for 64.6% ($n = 104$) and 63.7% ($n = 102$) of patients, respectively.

There were no significant differences between treatment groups with respect to operative time, postoperative hospital stay, time to oral diet (Table 2) and excess weight loss at 6, 12, and 24 months postoperatively (Fig. 1). No local (anastomoses, mesenteric openings) or general (adhesions, transmitted infections) adverse events directly related to the use of the fibrin sealant were reported at a mean of 29.6 ± 6.5 months follow-up (range 18–42 months).

There was no significant difference between treatment groups in the number of patients receiving each type of gastrojejunostomy techniques during LRYGBP: circular stapling (48 versus 56 for fibrin sealant and control groups, respectively); linear stapling (42 versus 37); or handsewn (69 versus 67). The 2 mL Tissucol®/Tisseel® kit was used

Table 1 Characteristics of patients undergoing laparoscopic Roux-en-Y gastric bypass surgery, by randomized treatment group (fibrin sealant versus control)

	Fibrin sealant ($n = 160$)	Control ($n = 160$)
Age (years)	41.6 ± 10.9	39.8 ± 11.3
Body Mass Index (kg/m^2)	47.2 ± 6.5	46.9 ± 7.6
Gender (female:male, %)	79:21	75:25

No significant differences were observed between treatment groups. All values quoted are mean ± standard deviation (SD), unless otherwise stated

Table 2 Secondary efficacy measures in patients undergoing laparoscopic Roux-en-Y gastric bypass surgery, by randomized treatment group (fibrin sealant versus control)

	Fibrin sealant ($n = 160$)	Control ($n = 160$)
Operative time (min)	149.4 ± 36.5	142.7 ± 34.1
Patients requiring drainage (n, %)	91 (56.8%)	85 (53.1%)
Time to oral diet (days)	3.5 ± 1.8	3.8 ± 1.5
Postoperative hospital stay (days)	7.1 ± 4.2	6.7 ± 1.8

No significant differences were observed between treatment groups. All values quoted are mean ± standard deviation (SD), unless otherwise stated

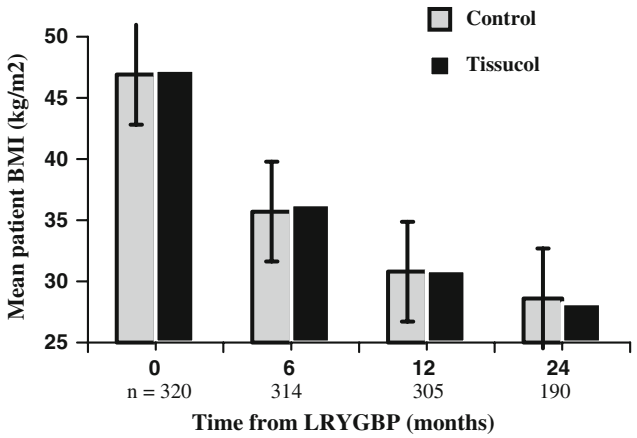

Fig. 1 Mean patient BMI, by treatment group, at 6, 12, and 24 months postoperatively (n = number of patients)

in 53 patients (32.9%) and the 5-mL kit in 68 (42.2%), while in 40 patients (24.8%) two kits of 2 mL were used (mean = 3.7 mL, $n = 160$).

Table 3 shows early complications requiring reintervention; Table 4 shows late complications. One anastomotic leak and one late internal hernia occurred in the fibrin sealant group. The leak was identified at the postoperative contrast X-ray and laparoscopic reoperation (suture of the leak site) was carried out on the third postoperative day. The late internal hernia at the mesenteric opening occurred 16 months postoperatively, and was successfully treated using a laparoscopic approach.

Two gastric remnant leaks occurred in the fibrin sealant group: one early leak that was resolved using conservative treatment (total parenteral nutrition for 55 days), and one late leak that was diagnosed 5 months postoperatively, and that developed a further gastro-gastric fistula that required laparoscopic resection 11 months postoperatively. Gastric remnant leak was not considered a primary endpoint of our study (fibrin glue was not applied over the gastric remnant stapler line).

Three gastrojejunal leaks and three internal hernias occurred in the control group. All anastomotic leaks occurred in the early postoperative course and required reoperation: closure of the fistula was achieved in one patient by handsewn stitches (open surgery); in one patient by laparoscopic sutures; and one patient required open gastric pouch resection and esophagojejunal anastomosis, which was further complicated by anastomotic stricture. Two early small-bowel occlusions due to internal hernia occurred in the control group and required open enteral resection. The late internal hernia was treated by laparotomy (suturing of the mesenteric defects). In the control group two occurrences of bleeding from the gastrojejunal anastomosis required reoperation.

Other complications not related to the use of fibrin-glue that required reintervention occurred in the control group. One early gastric remnant leak required open staple-line suture (not a primary endpoint). One small-bowel occlusion (no internal hernia) due to intestinal kinking was followed by reintervention on the 7th postoperative day. One iatrogenic spleen lesion (fibrin sealant group) required open splenectomy after nine postoperative days; there was one laparoscopic reoperation on the third day postoperative due to incidental jejunal microperforations (control group).

There were no deaths or conversions to open laparotomy in either treatment group.

Overall, fewer reports of early complications (primary safety endpoints) occurred in the fibrin sealant group versus the control group; however these differences did not reach statistical significance (Table 3). However, the overall reoperation rate for specific early complications (<30 days) was significantly greater for the control group ($p = 0.016$). The incidence of major late complications (follow-up range 18–42 months), including gastrojejunal anastomotic stenosis, was similar for both treatment groups (Table 4).

Table 3 Specific early complications (<30 days) leading to reoperation following laparoscopic Roux-en-Y gastric bypass surgery, by randomized treatment group (fibrin sealant versus control)

Early complication leading to reoperation	Treatment group		p-value
	Sealant ($n = 160$)	Control ($n = 160$)	
Total primary safety endpoints	1	7	0.016
Gastrojejunal anastomotic leak	1	3	ns
Internal hernia	0	2	ns
Gastrojejunal anastomotic bleeding	0	2	ns

ns = nonsignificant

Table 4 Major late complications in patients following laparoscopic Roux-en-Y gastric bypass surgery, by randomized treatment group (fibrin sealant versus control) during 29.6 months mean follow-up

Late complication	Fibrin sealant ($n = 160$)	Control ($n = 160$)
Internal hernia[a]	1[b]	1[b]
Gastric remnant fistula	1[b]	0
Gastro-jejunostomy stenosis	6	6
Anastomotic ulcer	2	2
Total	10	9

[a] Primary safety endpoint

[b] Required reoperation

Discussion

Anastomotic leak and pulmonary embolus are the two most common life-threatening complications of LRYGBP, and

many efforts have been made to reduce the risk to the patient. However, even with modern laparoscopic techniques, anastomotic leak occurs in 1–3% of patients in experienced clinical centers [20, 21, 27]. This complication is followed by reoperation in a large percentage of cases, and accounts for a high proportion of postoperative mortality [27, 30, 31].

The use of fibrin sealant in bariatric surgery and as a treatment for postoperative anastomotic leak has been previously reported [19–22], and represents an ideal alternative method for the closure of fistulae [32–34]. Typical causes for reoperations following LRYGBP include gastro-gastric fistula, leaking of the stomach remnant, and bleeding from the anastomoses stapler line. The two gastric remnant leaks that occurred in the fibrin study group, even if not considered as primary endpoint, support the use of reinforcement material at the stapler lines.

In our study, although individual endpoints did not show any significant difference between treatment groups, fewer anastomotic leaks were reported for the fibrin sealant treatment group versus the control group. Furthermore, the overall reoperation rate for early complications such as anastomotic leaking, anastomotic bleeding, and internal hernia following LRYGBP was significantly reduced in the fibrin sealant group versus the control group ($p = 0.016$).

Estimates of the incidence of anastomotic bleeding after gastric bypass range from 0.8% to 4.4% of cases, with a higher rate reported for laparoscopic procedures (1.9% versus 0.6% for open gastric bypass, $p = 0.008$) [31]. In our study, bleeding from gastrojejunal anastomoses occurred in both groups, but reintervention for anastomotic bleeding occurred only in the control group (two cases, $p =$ ns). The haemostatic, sealing, and "filling" properties of the fibrin glue should be helpful in preventing the submucosal bleeding that can occur after a laparoscopic gastrojejunal anastomosis. The fibrin glue not only covers and reinforces the suture line, but can also fill the interface at the anastomotic verge to help prevent or reduce subsequent intraluminal bleeding.

Anastomotic stricture is one of the most common late complications following LRYGBP, and the "wound repair" properties of fibrin sealants suggest that they could potentially increase the risk of stricture, due to a peri-anastomotic scar reaction which may be induced by the fibrin glue. In our study the incidence of clinically relevant gastrojejunal stenosis was similar in both treatment groups, and all patients were successfully treated by repeated sessions of endoscopy or interventional radiological dilatation. Similar results for both treatment groups were observed for all other secondary endpoints, including operative time, hospital stay, and postoperative weight loss, and the incidence of late complications.

In a previous study [20], two cases of small-bowel obstruction, ostensibly related to the site of sealant application, were reported in 738 open gastric bypass procedures. In our study, no adverse effects related to the fibrin sealant, such as bowel adhesion at the application site, scar reaction stimulus or transmitted infections, were reported during follow-up (mean 29.6 ± 6.5 months, range 18–42 months).

Limitations of our study include the small sample size, with too few complications reported to allow any firm conclusions to be reached. Another limitation was the patient loss to follow-up at 24 months. Complications such as internal hernia may develop at any time during the postoperative course [25], and so a longer follow-up should be carried out. No data on cost-effectiveness was collected.

In practical terms, the surgeons in our study reported that the use of human fibrin sealant in LRYGBP was not time consuming, required only a small quantity of sealant to cover both the anastomoses and the mesenteric openings, and the devices were easily handled. One potential disadvantage of fibrin sealant noted was that it must be frozen for adequate storage, and carefully thawed prior to use. However, once thawed it may be used for up to 36 h.

In conclusion, the use of fibrin sealant during LRYGBP suggests a possible benefit in reducing the rate of reoperation due to early complications (<30 days). No significant between-group differences were noted for operative time, hospital stay, time to postoperative diet, incidence of major late complications, or postoperative weight loss at 24 months follow-up. The present data do not support the routine use of fibrin glue in primary laparoscopic RYGBP.

Further studies should be carried out to compare the safety and efficacy of various fibrin sealants, to evaluate the cost-effectiveness of their use in bariatric surgery, and to identify potential subsets of patients (i.e., revisional surgery, super-obese etc.) who may benefit more or less from this form of treatment.

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