

Fibrin Glue as a Sealant for High-Risk Anastomosis in Surgery for Morbid Obesity

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Background: Fibrin sealants promote hemostasis and wound healing. Complex revisional surgery is performed for morbid obesity, and high-risk patients undergo weight loss surgery routinely. Fibrin sealant, Tisseel™, was used by one surgeon on 120 consecutive patients at the gastrojejunal anastomosis in Roux-en-Y gastric bypass (RYGBP). We hypothesized that the application of fibrin sealant would decrease anastomotic leaks.

Methods: One surgeon (Surgeon A) used fibrin sealant for 120 consecutive patients, while two other surgeons (Surgeons B & C) served as controls and did not use fibrin glue for their last 120 patients. Surgeon A did not use fibrin glue in 120 patients to serve as an internal control. All 480 patients underwent a RYGBP. Fibrin glue was applied at the gastrojejunal anastomosis.

Results: The fibrin sealant group did not have any documented leaks on the previous 120 patients, while 5 patients with Surgeon B, 2 patients with Surgeon C and 1 patient with Surgeon A without fibrin sealant experienced enteric leaks requiring re-operation, drainage, or long-term total parenteral nutrition (N=480 total patients).

Conclusions: Fibrin sealant may be useful in preventing leaks and promoting healing of the "high risk" anastomosis during complex gastrointestinal surgery. While the cost of fibrin glue is to be considered, re-operation and management of subsequent enterocutaneous fistulas or anastomotic strictures may be more costly than routine use for high-risk morbidly obese patients.

Key words: Fibrin sealant, gastric bypass, enteric leaks,

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Introduction

Morbid obesity is increasingly being recognized as an epidemic throughout the United States. While obesity continues to rise, weight loss surgery is increasingly being used to help patients lose weight. The Roux-en-Y gastric bypass (RYGBP) is the most commonly performed bariatric procedure in the United States. One of the most feared complications is a gastrojejunal anastomotic leak, causing sepsis or contributing to future strictures or fistulas in morbidly obese patients who have a low threshold to complications.

While the RYGBP continues to be an effective weight loss operation, technological advances continue, with instrumentation allowing more surgeons to perform the procedure with an acceptably low complication rate. One of these advances is the ability to apply bio-materials such as the fibrin sealant, Tisseel™, to accelerate the ability to heal wounds and achieve hemostasis.¹⁻³ Tisseel™ is a product that was initially used by our group to decrease bleeding along staple-lines during the laparoscopic approach to RYGBP. Fibrin sealant was also applied to our open RYGBP procedures to examine whether it is effective in preventing gastrojejunal leaks in the early postoperative period. While the incidence of gastrojejunal leaks can be as low as 1%, some series have reported anastomotic leaks at 20%.⁴ We are reporting our initial experience with the fibrin

sealant applied around the gastrojejunal anastomosis.

Materials and Methods

Patients underwent standard RYGBP involving creation of a proximal gastric pouch of 20-30 cc, measurement of a Roux limb approximating 80-100 cm, and construction of a hand-sewn gastrojejunal anastomosis. Patient ages ranged from 21 to 60 years old, with a predominance of female patients (85%). All three surgeons performed RYGBP within the same time period, spanning October 2000 to February 2002. All patients underwent the RYGBP procedure at a teaching hospital.

All patients undergoing RYGBP by Surgeon A underwent placement of fibrin sealant around the gastrojejunal anastomosis in 120 consecutive patients. Fibrin sealant, Tisseel™ (Baxter, Glendale, CA), was prepared with a 5-ml kit (total volume 10 cc) and was applied intraoperatively with a double syringe dispensing unit provided in the kit. The Tissomat (Baxter, Glendale, CA) nitrogen sprayer was used to apply a thin layer of Tisseel over the gastrojejunal anastomosis, while a 32-F bougie was used to size the anastomosis. A perivisceral fat pad was placed over the anastomosis within 3 minutes of application to the gastrojejunal anastomosis at the antero-lateral aspects. This allowed for the adhesive effects of fibrin sealant to maintain a fat pad over the anterior and lateral aspects of the gastrojejunal anastomosis. All gastrojejunal anastomoses were tested with air insufflation before the placement of Tisseel™. Any remaining fibrin sealant was applied over the proximal pouch and allowed to polymerize for at least 3 minutes before releasing the left lobe of the liver from the retractor. This was performed to prevent adhesions to the left lobe of the liver.

Statistical analysis was performed with STATA software package using analysis of proportions with Chi-square methodology. Statistical significance is considered as $P < 0.05$.

Results

A total of 480 patients underwent RYGBP during the period of analysis. Surgeon A performed 120

patients with fibrin sealant placed around the gastrojejunal anastomosis. Of the 120 patients, 60 patients underwent laparoscopic RYGBP and the remaining patients underwent an open RYGBP. No anastomotic leaks were observed in patients with Tisseel™ placed around the anastomosis. Surgeon A also had 120 patients undergo RYGBP without fibrin sealant. Of the 120 patients in the control arm, 55 patients underwent laparoscopic RYGBP and the remaining underwent open RYGBP. One patient undergoing an open RYGBP had a leak at the gastrojejunal site requiring re-operation and revision of the gastrojejunal anastomosis 7 days after surgery. The patient was re-admitted and re-operated without any long-term complications.

Surgeon B served as a control where all open RYGBP were performed without fibrin sealant. Surgeon B experienced five leaks out of 120 patients during the study period. Two patients had a posterior leak near the esophagus and posterior gastrojejunal anastomosis while undergoing revisional surgery. One of these patients sealed spontaneously within 5 days, and the other patient required re-operation but was left with a controlled fistula through a closed suction drainage tube. An additional three patients had gastrojejunal anastomotic leaks requiring re-operation with no subsequent complications.

Surgeon C also served as a control. Of the 120 patients undergoing open RYGBP without fibrin glue, two patients developed a gastrojejunal leak. One patient was managed conservatively with parenteral nutrition, nil per os, and intravenous antibiotics for 4 weeks and the leak sealed after repeated studies. Another patient was re-operated, but experienced a stricture at the gastrojejunal anastomotic site. No mortalities occurred in any of the leaks with all three surgeons. Table 1 summarizes the leaks experienced by all three surgeons.

The Tisseel group when individually compared with Chi-squared revealed the following P levels: $P < 0.16$ for Surgeon A without Tisseel; $P < 0.013$ for Surgeon B without Tisseel; $P < 0.08$ for Surgeon C without Tisseel. When all three control arms are combined with the treated group, a $P < 0.051$ is achieved.

Table 1. Summary of patients undergoing RYGB with and without Fibrin Sealant

	N	Outcome
Surgeon A (fibrin sealant) (Test Group)	120	No leaks
Surgeon A (no fibrin sealant) (Control A)	120 $P<0.16$	1 Leak, re-operation
Surgeon B (no fibrin sealant) (Control B)	120 $*P<0.013$	2 Leaks in revisional surgery with 1 subsequent fistula 3 Leaks in primary RYGBP, re-operation on all
Surgeon C (no fibrin sealant) (Control C)	120 $P<0.08$	2 Leaks in primary RYGBP with 1 re-operation and 1 subsequent stricture

$P<0.051$ with combined Controls (A+B+C), N=360 by Chi Square.

Discussion

Although leaks are an uncommon event, the morbidity and cost of caring for leaks is enormous. Long-term complications such as gastrojejunal strictures or fistulas can be devastating for patients. We are presenting our early experience with fibrin sealant, Tisseel™, placed around the gastrojejunal anastomosis in RYGBP patients. Initial use was for laparoscopic cases because of staple-line bleeding encountered during the procedure. This usage was adopted to open cases and has been found to be beneficial in both laparoscopic and open RYGBP procedures. The gastrojejunal anastomosis is similar between open and laparoscopic RYGBP. The anatomy of both the open and laparoscopic cases are the same, but early experience with most surgeons reveals a higher incidence of gastrojejunal anastomotic leaks during the “learning curve”.⁴ We have not observed this, and there appears to be a decreased rate of gastrojejunal anastomotic leaks with the laparoscopic approach. The use of fibrin sealant during the learning curve period may be beneficial to surgeons when first starting laparoscopic RYGBP. In addition to laparoscopic patients, open RYGB patients with high risk factors for a gas-

trojejunal leak may also benefit with application of fibrin sealant around the proximal gastric pouch and gastrojejunal anastomosis. These high-risk patients may include super-obese patients with body mass index >50, diabetic patients, males, revisional bariatric surgery, and patients requiring continuous positive airway pressure, CPAP, for treatment of their sleep apnea immediately after surgery.

Our institution's leakage rate had an average of 0.9% in the past 1,650 patients. Most gastrojejunal anastomotic leaks occur somewhere along the anterolateral aspects of the anastomosis, where tension may promote a leak along this suture-line area. Fibrin sealant was applied to prevent early postoperative leaks. The application of this product should not be substituted to make up for poor surgical technique, but it may be helpful in preventing the morbidity encountered with patients who suffer from sepsis as a result of an anastomotic leak.

Fibrin sealants have been used in a wide array of surgical applications, with beneficial effects noted on wound healing in colon surgery,^{5,6} biliary tract,⁷ hernia repair,⁸ urologic surgery,⁹ and thoracic surgery.³ Previous studies have shown that RYGBP has a higher incidence of complications than the vertical banded gastroplasty,¹⁰ with leaks from the anastomoses or from the proximal gastric pouch. The application of fibrin sealants to high-risk anastomoses in colorectal surgery and on the bronchus in thoracic surgery have revealed increased hydroxyproline deposition and fibroblast migration to the wound site. Tisseel's abilities to decrease leaks, increase hemostasis and promote wound healing are all desirable attributes in prevention of anastomotic leaks. The designation of a high-risk anastomosis may be difficult to interpret from institution to institution. The initiation of a laparoscopic RYGBP program may be a good indication to use fibrin sealant until surgical skills are fully matured. Otherwise, most surgeons may want to use fibrin sealants in patients who are on low-dose steroids, poor wound healing from diabetes, men with a long torso who may also have a foreshortened jejunal mesentery, revisional surgery and patients requiring high airway pressure instillation via a CPAP machine.

The data presented in this report details 120 consecutive patients by one surgeon's experience using Tisseel (Case-control, non-randomized). Control data (no fibrin sealant) was gathered from three sur-

geons including the surgeon who used the fibrin sealant. A larger series with randomization of patients in a multi-center study with the fibrin sealant, will delineate the benefits with RYGBP surgery. The groundwork for a randomized prospective study has been presented in this paper, but further studies will need to be performed to determine efficacy in a more objective manner.

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