Endoscopic Surgery for Bariatric Revision After Weight Loss Failure

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I. Study Design

This is a pilot study to examine the feasibility and role of endoscopic suturing for bariatric gastric bypass revision. The University of California, San Francisco (UCSF) is a tertiary referral center for bariatric surgery. Both primary bariatric procedures and revision procedures are offered to morbidly obese patients to assist them in losing weight. The most commonly performed procedures are either laparoscopic Roux-en-Y Gastric Bypass (RYGB) or Sleeve Gastrectomy. Patients can expect to lose 45-80% of their excess weight loss (EWL) after such procedures. However, weight loss can plateau and nearly 20% of patients who undergo RYGB fail to lose substantial weight defined as less than 50% EWL despite dietary and lifestyle alterations. The most common causes are either the gastric pouch is too big or the gastrojejunostomy anastomosis is dilated. Gastrojejunostomy is the connection created by the surgeon to join the small intestine to the gastric pouch. Sometimes the gastrojejunostomy can also be referred to as the GJ-stoma.

Surgical revision is usually required if weight loss stagnates. Sometimes this can be done using minimally invasive laparoscopic techniques depending on the density of intra-abdominal scar tissues. Other times it will require a large midline abdominal incision in order to enter the abdomen. Treatment is resection of the prior GJ anastomosis and creation of a new one. Intestinal bypass lengthening can be done concurrently at the surgeon's discretion.

We propose to explore the possibility of utilizing a new FDA approved endoscopic suturing device, Apollo EndoSurgery OverStitch™, to narrow the GJ anastomosis endoscopically thereby restricting food passage and creating early satiety. This negates having to re-enter the abdomen to resect portions of the gastrointestinal tract.

Case reports have described and reported success with such technique. However, to the best of our knowledge, a case series has never been reported. We would like to initiate a pilot study by recruiting 20 patients who require gastric bypass revision for poor weight loss and implement endoscopic suturing.

Specific Aims

1.) Describe the technique of endoscopic suturing using the Apollo EndoSurgery OverStitch™ device.

2.) Conduct a pilot study on the long-term efficacy for weight loss from endoscopic revision of the gastrojejunostomy anastomosis.

At The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2012 meeting, Dr. Manoel Galvao and colleagues from South America reported their abstract on Endoscopic Revision of RYGB with a Suturing Device. The suturing device was the Apollo EndoSurgery OverStitch™. Fifteen patients underwent revision of the gastrojejunostomy by reducing the size of the anastomosis and all the patients reportedly did well at 12-month follow-up. Unfortunately, the details of this study were never published. We aim to replicate this study and report the 2 year weight loss profile. We have successfully completed 20 procedures with no major complications or deaths. However, due to the learning curve, we didn't perfect our technique until 6th patient. Thus, we would like to recruit another additional 20 patients to see if we can demonstrate a clear benefit in weight loss.

Inclusion Criteria:

All adult patients (>18 years old) who have previously undergone a Roux-en-Y gastric bypass (RYGB) and failed to lose 50% of their excess body weight two years after their RYGB will be considered candidates. Furthermore, patients will need to show no gastrointestinal (GI) abnormalities during the initial endoscopy and upper GI small bowel follow-through series.
We will follow the general criteria for bariatric surgical revision where patients with a gastrojejunostomy stoma > 2 cm in diameter and/or gastric pouch volume > 30 mL will be considered as candidates for this novel endoscopic procedure.
Candidates will need to first undergo counseling by our dedicated bariatric dietician where a diet and lifestyle modification plan will be set forth. The goal of this plan is to allow the patient to lose weight at a rate of 1-2 pounds per week. Patients will need to adhere to this regimen and follow-up with the dietician once a month for weight check. Those who can demonstrate weight loss will continue on this plan. Patients who fail to lose weight for two consecutive months will then proceed to be evaluated for endoscopic intervention.

Exclusion Criteria:

Patients with marginal ulcers at the gastrojejunostomy anastomosis site detected during the endoscopic procedure. The procedure will be aborted and patients will be placed on proton pump inhibitors. Marginal ulcers are usually caused by foreign bodies such as staple lines or retained permanent sutures. Therefore, we will not place sutures in ulcerated tissue fearing that may exacerbate the problem even more.
All patients will require general anesthesia for this procedure and those with contraindications to general anesthesia will be excluded.
Those with severe esophageal disease such as strictures, masses, and/or autoimmune diseases afflicting the esophagus will be excluded as well. These patients may be at a slightly higher risk for endoscopic esophageal perforation.

Procedure:

Patients who underwent prior Roux-en-Y Gastric Bypass (RYGB) or sleeve gastrectomy who fail to lose 50% of their excess body weight after two years or those who regain more than 50% of their excess body weight two years or more after their RYGB will be offered the opportunity for endoscopic revision. These patients would have already exhausted their dietary and lifestyle modifications at weight loss attempt.

Patients will be offered the procedure during their routine clinic follow-up. If they are not meeting their goal weight, the surgeon will discuss this procedure once all other medical or noninterventional options (i.e. dieting) have been exhausted.

Current standard of care for patients with weight re-gain or lack of adequate weight loss after bariatric surgery is nutritional counseling. Patients will be asked to count their calories and undergo an evaluation by a nutritionist. If there is a failure to lose weight despite dieting, an endoscopy will be performed was well as an upper gastrointestinal x-ray series. These studies will determine the following:

1.) The size of the gastric pouch
2.) Look for any abnormal communications between the gastric pouch and gastric remnant

3.) Determine the diameter of the gastrojejunostomy (for gastric bypass patients).

If the diameters are >2 cm and continued failure of weight loss despite maximal medical therapy, then the current standard of care for those who had a Roux-en-Y gastric bypass, then a revision of the gastric bypass by either creating a smaller gastric pouch, lengthening the bypassed intestinal length, or both.

Both of the above procedures are invasive and a lot of times cannot be completed laparoscopically because of intra-abdominal adhesions from prior surgeries. Therefore, these will then be done in standard open fashion through a midline incision. There is higher postoperative morbidity and mortality. Therefore, we are proposing this endoscopic technique where we make the diameter of the food exit site smaller by placing sutures. Preoperatively, patient demographics, weight profile, preexisting co-morbidities, failure of prior medical weight loss treatment, previous surgical details, and metabolic profile labs (cholesterol, diabetes, liver function, and kidney function) will all be recorded.

All patients will undergo preoperative evaluation by UCSF anesthesia-ran PREPARE clinic to determine their anesthesia risks. This is a pre-existing service that all surgical patients have to attend. The procedure would be performed under general anesthesia in the operative suite. An esophageal overtube (US Endoscopy, Mentor, OH) is positioned to grant continuous safe access to the stomach. The pouch and stoma size of the gastrojejunostomy (GJ) anastomosis is measured. The surgeon will then utilize the Apollo EndoSurgery OverStitch™ system to reduce the size of the stoma. The OverStitch™ is a cap-based suturing system that is mounted on a high definition therapeutic dual-channel endoscope (GIF-2T180; Olympus Medical Systems Corporation, Tokyo, Japan.)

The curved needle arm mounts to the tip of the endoscopic. These are re-loadable through the working channels of the endoscope there by negating the need to withdraw and reinsert the endoscope. A GJ stoma or pylorus greater than 2 cm will be considered to be dilated based on previous defined studies in the literature. This will be measured visually. Simple interrupted 2-0 sutures polypropylene (PP) will be placed under direct visualization. We estimate that we will need 2 to 3 sutures to narrow the stoma to a diameter of 0.8 to 1.0 cm. This should create the feeling of early satiety hopefully leading to decreased caloric intake followed by weight loss. Current literature estimates nearly a mean 25% EWL.

Patients will be followed with the current UCSF bariatric protocol. No special follow-up or exams will be required from the usual population. The current protocol entails that patients will be seen 1-2 weeks after discharge and then every 3 months the first year and then every 6 months thereon after. They are specifically instructed to avoid non-steroidal anti-inflammatory drugs to decrease ulcers and bleeding. They will also be discharged on Omeprazole or an equivalent to decrease the acid in their stomach. This will be taken for 3 months to decrease gastrointestinal ulcers and minimize bleeding and/or perforation. Patients will be placed on a thick liquid diet the first two weeks and can advance to pureed food after their first postoperative visit with their surgeon.

Signs and symptoms for post-procedural bleeding or perforation include, but not limited to, the following:

- Hematemesis
- Abdominal pain
- Melena
- Hematochezia

- Fever
- Nausea/Vomiting
-Tachycardia

Data collected will include post-procedural weight profile, resolution of pre-existing comorbidities, and metabolic profile labs (cholesterol, diabetes, liver function, and kidney function) will all be recorded. Patients will be queried on their satisfaction with this novel but expanding endoscopic suturing technique for weight loss.

Time Commitment: The current follow-up for patients who undergo any type of bariatric procedure at the UCSF Bariatric program is for the patient to follow-up every 3 months for the first year and subsequently every 6 months thereafter. These patients are seen in clinic where their weight and estimated daily caloric intake are recorded. Nutritional labs are monitored. Our proposed study will not deviate from this.

All patients will be screened by the bariatric surgeons to see if they would benefit from a gastric bypass revision. They will follow the current NIH guidelines for bariatric surgery. All patients will be given the standard informed consent. HIPPA guidelines will be strictly adhered.

Risks/Benefits:
There may be a slight risk of esophageal or gastric perforation but this risk is very low. We are using the standard Olympus Dual-Channel Endoscope which is similar to the endoscopes used by gastroenterology daily for both diagnostic and therapeutic purposes. The caliber of the endoscope is not bigger than the endoscopes we are already using here at UCSF.

There may be a risk of poor weight loss but this should not be considered uncomfortable or life threatening. There may be a risk of nausea or vomiting from general anesthesia or the gastrojejunostomy or
pylorus revision being too narrow causing obstructive like symptoms. Patients can have the sutures removed endoscopically if they desire. This can be done under conscious sedation instead of general anesthesia.

Data and Safety Monitoring Plan
All patients will be subjected to the same monitoring and safety like current bariatric patients. Our procedure is even less invasive than the current options. There are no other special requirements for patients undergoing endoscopic suturing for weight loss. Current bariatric surgeries are followed every 3 months in clinic during the first year and subsequently every 6 months thereon after. Clinic visits consists of the following:

Weight monitoring

Lab checks (drawn before clinic visit):
CBC
Serum Iron
Serum Folate
Liver Panel – AST, ALT, alk phos, T-bili, Direct bili, Albumin
Vitamin B12
Serum Calcium

Electrolytes
Cholesterol Panel
Fasting Blood Sugar

II. Statistical Analysis

Pre-operative, peri-operative, and postoperative data consisting of patient demographics, preoperative and surveillance laboratory data, operative details, percentage of excess weight loss (% EWL), resolution of co-morbidities, morbidity and mortality will be collected prospectively. Paired t-tests were used to calculate statistical differences between preoperative and postoperative values (Microsoft Excel, Seattle, WA).

III. Background:

The Roux-en-Y gastric bypass (RYGB) is among the most-performed bariatric procedures in the United States. It is currently the gold standard for bariatric surgery in terms of resolution of co-morbidities and percentage excess weight loss (%EWL). However, despite very good results, this procedure has a failure rate of over 20% in maintaining weight loss. Postoperative weight loss failures can be defined in many different ways. One of the most accepted parameters involves the patients' ability to achieve and maintain 50% EWL. If a patient who has undergone RYGB does not achieve 50% or more EWL, a surgical revision procedure may be required.

Surgical revisions after RYGB are, by nature, complex, and associated with significant morbidity and even questionable efficacy. Among possible causes of RYGB procedure failure is dilation of the gastro-jejunostomy (GJ) and/or gastric pouch enlargement. The development of endoluminal therapies and devices for stoma revision can fulfill the need for a less-invasive approach that maintains some of the principles of surgical outlet revision while avoiding intra-abdominal surgery. As the number of bariatric surgeries, including RYGB, increases into the hundreds of thousands annually, it is natural that weight loss failure rates will also increase proportionally. The reported RYGB failure rate varies widely, from less than 10 percent to 50 percent, depending on the assessment parameters.

Patients who have regained weight to a condition of morbid obesity while under multidisciplinary surveillance should consider revision surgery. A revision on an RYGB procedure can be done on its restrictive component (the gastric pouch and the GJ) or at its malabsorptive/metabolic component (bowel limb lengths). Surgical revisions of the RYGB are always a matter of concern due to higher rates of complications and mortality when compared with primary series. This require re-entering a previously operated field, either laparoscopically or open, where the anatomy is distorted and view is obscured from dense intra-abdominal adhesions.

One potential solution is to avoid from having to enter the abdomen all together and perform the revisions endoscopically. Endoscopic suturing to narrow the gastrojejunostomy will increase the transition time for food to pass through resulting in early satiety and decreased caloric absorption. The Apollo EndoSurgery OverStitch™ is the latest endoscopic suturing system approved by the FDA for minimally invasive endoscopic therapies.

This device has a small suturing needle mounted at the end of the endoscope thereby permitting full tissue thickness endoscopic suturing under direct visualization. It has been approved for securing stents, closing fistulas or leaks, and even stopping bleeding vessels. Currently, UCSF has the surgeons and gastroenterologists who are adept at using advanced endoscopes but lacking the equipment to do so. We are choosing the Apollo EndoSurgery OverStitch device since it is the latest endoscopic suturing technology that allows the exchange of the suturing needle without having to remove the entire endoscope. This decreases the need to withdraw and re-insert the endoscope minimizing procedure length and endoscopic trauma.

As aforementioned, the current standard of care for patients who have undergone prior bariatric procedures and developed recidivism despite maximal medical therapy is re-operation. This endoscopic technology will permit us to perform full thickness bites to narrow the gastrojejunostomy orifice thereby delaying the passage of food. The full thickness tissue bites are exactly what this suturing device was designed to for.

IV. Preliminary Studies

There have been very few preliminary studies regarding the efficacy of endoscopic revision of the gastrojejunostomy anastomosis for failed Roux-en-Y Gastric Bypass for weight loss.

Recently, a study from the Cleveland Clinic discussed a trial where patients who underwent prior

gastric bypass and regained weight were randomized to this very technique we described.1 Patient s were selected based on their weight re-gain profile or inadequate weight loss as well as a gastrojejunostomy (GJ) diameter > 2 cm. They were either randomized to endoscopic suturing or a sham procedure where the endoscope was inserted but no suturing was performed. The suturing device they used, however, was the BARD ENDOCINCH suturing system. The goal of endoscopic suturing is to decrease the GJ diameter to 5-6 mm therefore significantly delaying the passage of food resulting in early society. They were able to demonstrate that this maneuver reduces weight regain following gastric bypass.

Thompson,5 also from the Cleveland Clinic in a separate study was able to show that dilation of GJ anastomosis does in fact contribute to inadequate weight loss and suturing led to a better weight loss profile at 1 year compared to those without.

V. **References**:

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If you have a separate bibliography, attach it to the submission with your other study documents.