Background: A Silastic ring has been used to prevent dilation of the gastrojejunostomy in Roux-en-Y gastric bypass (RYGBP). The use of a bio-membrane may prevent dilation of the anastomosis without the risks associated with prostheses. The aim of this study was to evaluate the feasibility and safety of applying such a bio-membrane around the gastrojejunostomy in Laparoscopic RYGBP (LRYGBP).

Methods: We used a new bio-membrane, that is derived from porcine small intestinal submucosa (SIS) and acts as a scaffolding for the ingrowth of connective tissue. Over a 4-month period, 14 LRYGBP patients had their proximal anastomosis wrapped with 10 x 2.5 cm SIS by a single surgeon. We compared these patients to a control group of LRYGBP patients matched for BMI.

Results: The average age of the patients was 35.0 years (control group: 45.1 years). The patients had a mean initial BMI of 44.7 kg/m² (±5.9) standard error, and the control subjects had a mean initial BMI of 46.7 kg/m² (±6.5). SIS application took a mean time of 11 (±3) minutes without any intraoperative complication. The median hospital stay was 3.5 days in the experimental group and 3.7 days in controls. Three patients developed a symptomatic stenosis at the gastrojejunostomy following surgery. In the control group there were two stenoses. At an average follow-up of 87 days (controls: 95 days), the mean reduction in BMI was 7.8 (± 0.8) kg/m² [controls 8.6 kg/m² (±1.5)].

Conclusion: Application of SIS around the gastrojejunostomy in patients undergoing LRYGBP is feasible and safe. Further follow-up is required, however, to evaluate the effectiveness in preventing dilation of the anastomosis.

Key words: Morbid obesity, Roux-en-Y gastric bypass, laparoscopy, small intestinal submucosa, gastrojejunostomy.

Introduction

Among the various bariatric operations, RYGBP is considered by many as the gold standard in the United States. RYGBP is now routinely performed laparoscopically by many surgeons, with low morbidity and mortality. LRYGBP is an effective treatment for morbid obesity. However, some patients experience weight gain that may be attributed to dilation of the proximal stoma.

Linner, in 1985, introduced the concept of stoma reinforcement for the RYGBP. Different methods have been employed to reinforce the stoma in a RYGBP, including prosthetic materials and rectus fascia. However, these techniques have their limitations. Prosthetic materials are associated with a high complication rate, and fascia is not readily
available in a laparoscopic procedure since there are no large incisions. We therefore used a porcine small intestinal submucosa (SIS) membrane (Surgisis ES\textsuperscript{TM}, Cook, Bloomington, IN, USA) to reinforce the gastrojejunostomy. The aim of this study was to evaluate the feasibility and safety of using this bio-membrane.

Material and Methods

A prospective study was performed on 14 patients, at the Mount Sinai Medical Center, New York, NY between July 2000 and November 2000. The control group comprised 14 patients who were matched for their BMI and who underwent LRYGBP without the application of SIS, during the same period of time. Patients who were having revisional surgery were excluded. A dedicated team of physicians, nutritionists, psychiatrists and psychologists evaluated morbidly obese patients who satisfied the NIH criteria before they were considered for surgery.\textsuperscript{4} Specialist consultations were obtained as indicated.

Patient preparation consisted of a detailed explanation of the laparoscopic and open alternatives, including their relative risks and benefits, and short-term and long-term complications.

The technique of LRYGBP was as follows. A 20 ml proximal gastric pouch was created using an endoGIA stapler. The jejunum was divided 50-100 cm beyond the ligament of Treitz; if the BMI was <50, then the distance from Treitz’ ligament was 50 cm, and if the BMI was >50, the distance was 100 cm. A 100-150 cm Roux limb was then created, which was anastomosed to the gastric pouch using a 25-mm EEA stapler; if the BMI was <50, then the Roux limb was 100 cm, and if the BMI was >50, the Roux limb was 150 cm.

A 10 x 2.5 cm strip of SIS of 0.42 mm thickness (Figure 1) was immersed in sterile saline for a period of 10 minutes to allow rehydration. The sheet of SIS was then introduced into the abdomen and was wrapped around the gastrojejunostomy (Figure 2). The two ends of the SIS strip were sutured to each other around the anastomosis with 2 interrupted polyglactin sutures using an intracorporeal knot tying technique (Figure 3). The proximal and distal suture incorporated a small portion of the gastric pouch and jejunum respectively, to prevent migration of the membrane.

A side-to-side anastomosis connected the lower end of the jejunum to the point 100-150 cm from the gastrojejunostomy on the lower segment of the Roux limb. This was done using an endoGIA stapler.

A water-soluble upper gastrointestinal contrast study was routinely performed on the first postoperative day to rule out a leak. Following a normal contrast study, a liquid diet was commenced. If tolerated, this was advanced to a pureed diet on the second postoperative day and to a mechanical soft diet before discharge on the third postoperative day.

The patients were followed-up at 3 weeks, 3 months and 6 months.

Standard error of the mean was used for the data. An unpaired Student’s t-test and Fisher’s exact test were used to compare the variables of the study and control groups.

Results

There were 14 patients who underwent LRYGBP with application of SIS. Eleven of the 14 patients were female, whereas the control group comprised of 10 females and 4 males. The average age was 35.0 ± 11.8 years in the study group. The control group had an average age of 45.1 ± 13.7 years. The 14 patients had a mean initial BMI of 44.7 ± 5.9 kg/m\textsuperscript{2} compared to 47.3 ± 6.5 kg/m\textsuperscript{2} in the control group. SIS application took a mean time of 11 minutes (range 9-14 minutes) without any intraoperative complication. The median hospital stay was 3.5 days (controls: 3.7 days). There was a transient rise in the white cell count which lasted 1 day in 4 patients (7 of the controls had a similar transient rise in white cell count, p=NS). The mean peak WBC count in the study group and controls was 10.7 ± 3.6 and 12.9 ± 3.1 respectively (p=NS). There was no fever lasting more than 1 day. Five patients (3 in the study group and 2 in the control group) developed a symptomatic stenosis at the gastrojejunostomy and were effectively treated with endoscopic dilation, p=NS. There were no