

# The Use of Bovine Pericardial Strips on Linear Stapler to Reduce Extraluminal Bleeding during Laparoscopic Gastric Bypass: Prospective Randomized Clinical Trial

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**Background:** A prospective comparison was conducted of extraluminal bleeding following gastric transection with or without staple-line reinforcement by dehydrated bovine pericardium (Peri-Strips Dry® - PSD) during laparoscopic Roux-en-Y gastric bypass (LRYGBP).

**Methods:** From January 2001 to September 2003, 98 consecutive morbidly obese patients underwent LRYGBP. Patients were randomly allocated to 2 groups according to the use (Group A, n= 50) or not (Group B, n= 48) of Peri-Strips Dry®. In both groups, mortality, intra- and postoperative early and late complications, operating-time, number of hemostatic clips used, blood transfusion and any specific event directly related to the prosthetic material were prospectively evaluated. Data were expressed as mean  $\pm$  SD except as otherwise indicated. Statistical analysis was done by means of Student *t*-test and Fisher exact test. *P*-value cut off for statistical significance was set at 0.05.

**Results:** Intra- and postoperative mortality were absent. Intra-operative methylene blue test was positive in 6/48 (12.5%) of Group B patients (*P*<0.001). Overall laparotomic conversion was 3/98 patients (3.1%). One/48 Group B patient was converted because of unsatisfactory exposure and one for linear stapler misfire. One/50 Group A patients was converted for short gastric vessels bleeding during dissection. No patients were re-operated or transfused because of extraluminal bleeding. Mean number of clips used was significantly lower in Group A patients (5 vs 23, *P*<0.001). The operating-time was signifi-

cantly less in Group A patients (120 $\pm$ 60 vs 220 $\pm$ 100 minutes, *P*<0.01).

**Conclusions:** Gastric staple-lines reinforced with Peri-Strips Dry® result in a significant reduction in the number of Endo-clips used and prevent bleeding. A dry operating field was obtained, and operating-time was significantly reduced. No adverse events could be related to the use PSD.

**Key words:** Morbid obesity, gastric bypass, bleeding, linear stapler, laparoscopy, bovine pericardium strips

## Introduction

Roux-en-Y gastric bypass (RYGBP) is currently the most common bariatric operation worldwide, with laparoscopic gastric banding being the preferred operation outside the USA.<sup>1</sup> In North America where RYGBP is the most common bariatric procedure, the number of centers performing it by the laparoscopic approach is still limited because of the complexity of the operation. However, in Europe the appreciation of RYGBP when performed by laparoscopy (LRYGBP) is steadily growing. The procedure is based mainly on the use of the endoscopic linear stapler to transect the stomach and create a small isolated gastric pouch.<sup>2</sup> Gastric transection margins usually bleed. While in open surgery, oversewing the margins can be easily accomplished in a reasonable amount of time, this technical prob-

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lem remains consistent in laparoscopy.<sup>2-4</sup>

In trying to overcome this technical problem, an attempt was made to buttress the linear stapler during LRYGBP by using a non-absorbable biological tissue derived from dehydrated bovine pericardium (Peri-Strips Dry<sup>®</sup> - PSD). This product was originally introduced in 1994 to reduce air-leaks during lung resection, and its benefit has been largely proved in lung volume reduction surgery over the past 10 years.<sup>5,6</sup> Recently, Shikora et al<sup>7</sup> demonstrated the absence of acute leak by the use of Peri-Strips Dry<sup>®</sup> on the gastric staple-lines of 250 non-randomized morbidly obese patients undergoing LRYGBP. This product received CE mark clearance for bariatric indication in 1999 and FDA clearance in 2000. The current study is a prospective comparison of results obtained in extraluminal bleeding following gastric transection with or without staple-line reinforcement by Peri-Strips Dry<sup>®</sup> during LRYGBP.

## Methods

### Patients

From January 2001 to September 2003, 98 consecutive morbidly obese patients were considered for LRYGBP. Patients were randomly allocated into two groups according to the use (Group A, n=50) or not (Group B, n= 48) of dehydrated bovine pericardium. In both groups, mortality, intra-operative and postoperative early and late complications, operating-time, number of hemostatic clips used, blood transfusion and any specific event directly related to the prosthetic material were prospectively evaluated. Intra-operative blood loss was not recorded by blood suction, because of the use of an irrigation system and laparoscopic swabs. Bleeding was defined as any intra-operative event which required attempts or particular manoeuvres to achieve hemostasis.

### Materials

Endo-GIA<sup>®</sup> (35-45-60 mm) blue cartridge (3.5 mm) were manufactured by USSC (Norwalk, CT, USA). The 25 PCEEA was from Tyco. Balloon Bougie<sup>®</sup> was from Inamed (Santa Barbara, CA, USA).

Bovine dehydrated pericardium, Peri-Strips Dry<sup>®</sup>, were manufactured by Synovis Surgical Innovations (St. Paul, MN, USA). Endo-Clip<sup>®</sup> ML and L 10 mm were from USSC (Norwalk, CT, USA). Ligaclip<sup>®</sup> M and L 10 mm and Ultracision<sup>®</sup> 5 mm were from Ethicon Endo-Surgery (Cincinnati, OH, USA). Ultra Shears<sup>®</sup> 5 mm were from USSC Tyco Healthcare (Norwalk, CT, USA). PDS LapraTy<sup>®</sup> and Blake Drains<sup>®</sup> 19-Fr were from Johnson & Johnson (Cincinnati, OH, USA)

## Surgical Technique

Patients were positioned in reverse Trendelenburg lithotomy position. Closed CO<sub>2</sub> pneumoperitoneum was created, and six trocars were inserted. The gastric bougie was trans-orally positioned in the stomach. The balloon was inflated with 30 ml of saline solution, and was retracted backward by the anesthesiologist to reach the cardio-esophageal junction. Dissection was started at the equator of the balloon in the peri-gastric space between the neurovascular bundle of Latarjet and lesser curvature of the stomach using the harmonic scalpel. The retro-gastric space below the bursa omentalis was entered, and gastric transection was performed by multiple linear stapling (reinforced by PSD<sup>®</sup> in Group A patients), fired in sequence up to the angle of His.

In Group A patients, PSD was mounted on the linear stapler by using a film of adhesive hydrogel (PSD gel) to re-hydrate the strips and create a bond between the strips and the jaws of the linear stapler. In both Group A and B patients, bleeding points were controlled with the application of hemoclips, while any malformed staple-lines were over-sewn. In Group B patients, diathermy was also used to achieve hemostasis. The flip-top anvil of a 25-mm circular stapler was advanced trans-orally into and through the proximal gastric pouch, using a modified naso-gastric tube anvil apparatus. The Roux limb was constructed by transecting the small bowel 30 to 50 cm distal to the ligament of Treitz. A service jejunotomy on the alimentary limb was created and the circular stapler was introduced transabdominally, and was advanced into the lumen of the jejunum to create an ante-colic ante-gastric end-to-side gastro-jejunostomy. The service jejunotomy was closed with a PSD-reinforced 60-mm linear stapler in Group A patients.

Gastro-jejunostomy leak was tested by injecting 40-60 cc of methylene blue through the naso-gastric tube previously positioned into the alimentary limb temporarily clamped. Test positivity was considered by the presence of methylene blue extraluminally. Side-to-side jejuno-jejunostomy was performed by a 45-mm linear stapler through the jejunotomy service, 100-150 cm distal to the gastro-jejunostomy. The anastomosis was completed by 2-0 PDS continuous sutures.

## Statistical Analysis

Randomization was performed according to Lison tables.<sup>8</sup> Data were expressed by mean  $\pm$  standard deviation except as otherwise indicated. Student *t*-test and Fisher exact test were used for statistical analysis, and  $P < 0.05$  was considered significant.

## Results

Patient characteristics of both Groups were similar and without significant differences (Table 1). Intra- and postoperative mortality was absent. Intra-operative methylene blue test was positive in 6/48 (12.5%) of Group B patients ( $P < 0.001$ ), and in all but one case 2-0 Vicryl<sup>®</sup> interrupted stitches were inserted to control the leak. Overall laparotomic conversion was 3/98 patients (3.1%). One/50 Group B patient with a posterior leak was converted to a

laparotomy because of unsatisfactory exposure, and one other patient was converted to a laparotomy for linear stapler misfire. Conversion to a laparotomy was also required in 1/50 Group A patients for short gastric vessels bleeding during dissection of the gastric fundus. No patients were re-operated or transfused because of extraluminal bleeding. The mean number of clips used was significantly lower in Group A patients (5 vs 23,  $P < 0.001$ ). The operating-time was significantly less in Group A patients (120 $\pm$ 60 vs 220 $\pm$ 100 minutes,  $P < 0.01$ ). These results are presented in Table 2. No adverse clinical or surgical event could be related to the use of PSD. Late gastrointestinal intra- or extraluminal bleeding was not observed in both groups.

## Discussion

The current endoscopic linear staplers by Ethicon and Tyco evolved from the laparotomic GIA staplers that were introduced into clinical practice at the end of the 1970s. These modern instruments are flexible, rotate 360°, and come in different cartridge lengths (30 mm, 35 mm, 45 mm, 60 mm) and different staple sizes (white 2.5 mm, blue 3.5 mm and green 4.8 mm) according to the thickness of the tissue to be transected. The Ethicon stapler divides the tissue between two lines of staples, while Tyco leaves three lines of staples on each side. Because of their different mechanism of transection with only

**Table 1.** Patient characteristics

|         | Age<br>(mean $\pm$ SD; range) | Sex<br>(M/F) | BMI - kg/m <sup>2</sup><br>(mean $\pm$ SD; range) | % Excess Weight<br>(mean $\pm$ SD; range) |
|---------|-------------------------------|--------------|---|---|
| Group A | 36.1 $\pm$ 11.5; 19-58        | 12/38        | 49.3 $\pm$ 4.9; 37-59                             | 97.6 $\pm$ 15.5; 45.1-150                 |
| Group B | 35.8 $\pm$ 10.8; 20-60        | 10/38        | 50.0 $\pm$ 3.7; 38-58                             | 98.1 $\pm$ 14.7; 45.9-152                 |

**Table 2.** Patient outcome

|         | Clips used<br>(mean $\pm$ SD; range) | Leak<br>(methylene blue test) | Operating-time<br>(mean $\pm$ SD; range) | Laparotomic conversion |
|---------|--------------------------------------|-------------------------------|--|------------------------|
| Group A | 5 $\pm$ 1; 0*-7                      | 0/50                          | 120 $\pm$ 60 #                           | 1/50 (2.0%)+           |
| Group B | 23 $\pm$ 8; 10-33§                   | 7/48 (12.5%)                  | 220 $\pm$ 100                            | 2/48 (4.2%)            |

\* = in five patients; § =  $P < 0.001$ ; # =  $P < 0.01$ ; + =  $P < 0.01$ .

two lines of staples, the Ethicon endocutter 45 flex was used in the authors' experience in only five patients (three with PSD). To avoid study bias, they were not included in the present analysis. The limited case number does not allow us to make an evaluation of this device.

After 20 years of evolution, the modern endoscopic linear staplers share, in common with the old traditional laparotomic instrumentation, the extraluminal bleeding on the transection staple-lines.<sup>4,9-11</sup>

In open surgery, the amount of blood loss secondary to linear-stapler visceral transection is generally minimal; it can be ignored and treated by swab compression which stimulates spontaneous patient self-coagulation. In a number of cases, it is necessary to overstitch the transected staple-line. Ischemia from this manoeuvre in the transection margins remains a potential sequel.

On the contrary, in laparoscopy, a bloodless operating field is mandatory. Bleeding decreases the definition of the image on laparoscopic view. Under these circumstances sharp dissection is difficult due to the continuous loss of exposure of the operative field, and suction, irrigation, and camera cleansing are often required, prolonging operating-time.

Although diathermy and laparoscopic titanium clips are commonly used to control the bleeding of the transected gastric pouch during LRYGBP, their effect on the strength of the staple-lines has not been tested in experimental or clinical studies. Stitching which is used in open surgery would probably represent the method of choice, but is not easy to perform laparoscopically. All these techniques are time-consuming, and potentially lead to postoperative life-threatening leaks and perforation.

In the present study, the mean number of titanium clips used to control extraluminal bleeding ( $23\pm 8$ ) on the gastric pouch in the group of patients without PSD reinforcement (Group B) corresponds nicely with the results reported by Champion and Williams<sup>12</sup> in a prospective study ( $21\pm 7$  EndoGIA and  $30\pm 9$  ETS). The use of PSD in group A patients lowered the mean number of clips to  $5\pm 1$  ( $P < 0.001$ ). Although intra-operative blood loss was not directly measured in this study, the reduced number of clips applied relates directly to the reduced number of bleeding episodes which required additional surgical manoeuvres for hemostasis. Therefore, bleeding was obviously non-existent when using PSD.

The operating-time was also significantly reduced in this group of patients because of the reduced number of surgical manoeuvres to identify and control the bleeding source. Interestingly, in the present study, the intra-operative methylene blue test was positive in 12.5% of group B patients where the anvil of the circular stapler was passed through the staple-line of the gastric pouch according a modified Knight and Griffen anastomotic technique. In the group A patients who had PSDs, the intra-operative positive methylene blue test was 0, because the anvil was never passed through the staple-line, and the anastomosis was performed on the anterior or the posterior wall of the gastric pouch. The knife of the circular stapler is not able to cut safely through the Peri-Strip Dry<sup>®</sup> and the tissue is too thick for the staples.

In conclusion, Peri-Strips Dry<sup>®</sup> can be safely applied to linear staplers for LRYGBP. The benefit of PSD reinforcement of the gastric staple-lines to prevent bleeding was demonstrated by a significant reduction in the number of Endo-clips used. As a consequence of less staple-line bleeding, a dry operating field was obtained. The extra time required to identify a bleeding source and control it was saved, and the total operating-time was significantly reduced.

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