

# Laparoscopic sleeve gastrectomy. Do we need to oversee the staple line?



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## Laparoscopic sleeve gastrectomy. Do we need to oversee the staple line?

**AIM:** *The aim of this study is to compare the material effectiveness of oversewing the staple line following laparoscopic sleeve gastrectomy.*

**MATERIAL OF STUDY:** *A prospective randomized trial has been performed on 100 consecutive patients who underwent laparoscopic sleeve gastrectomy. Just before the intervention patients were randomized to receive (Group A) or not receive (Group B) a polypropylene 3-0 running oversewing suture of the staple line.*

**Results:** *By evaluating preoperative general demographics features and co-morbidities between group A and group B no statistical difference was observed. Main complications evaluated were fistol, bleeding and stenosis and there were no significant difference in fistulas occurrence ( $p = 0.55$ ) and bleeding ( $p = 0,65$ ) while on the other hand it has to be remarked how sleeve stenosis has been significantly higher when oversew is performed ( $p=0.04$ ).*

**DISCUSSION:** *Staple line leakage is a worrisome complication of laparoscopic sleeve gastrectomy (LSG). Despite some reports describe oversewing of the staple line as the solution to prevent such problem; other authors have demonstrated the incidence of leaks being the same in oversewed and not oversewed patients.*

**CONCLUSION:** *This randomized trial has so far shown oversew of LSG to be significantly useless to prevent fistulas formation in patients selected according to our study design.*

**KEY WORDS:** Bariatric surgery, Obesity, Oversew, Sleeve gastrectomy.

## Introduction

Staging of bariatric surgery helps to decrease operative risks especially in super (body mass index  $>50$  Kg/m<sup>2</sup>) obesity<sup>1</sup>. From this, laparoscopic sleeve gastrectomy (LSG), showing major advantages if compared with

other procedures<sup>2</sup>, has been introduced as a first step approach followed by either laparoscopic Roux-en-Y gastric bypass (LRYGBP)<sup>3</sup> or biliopancreatic diversion with duodenal switch (BPD-DS)<sup>4,5</sup>. Afterwards, the encouraging results obtained in some series<sup>6-8</sup>, have led many authors to avoid a second surgical intervention, especially if the excess weight loss percentage (EWL%) of operated patients reached and maintained satisfactory levels. According to these data, an increasing number of authors appears to consider LSG as a definitive procedure to treat morbid obesity<sup>9-11</sup>. Nevertheless, regardless from the correct indications to perform a LSG, some issues about this new, promising intervention, remain controversial although two International consensus summit have tried to define them<sup>12,13</sup>.

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Staple line leakage is a worrisome complication of LSG<sup>12-14</sup>, it is described in several reports, ranging from 0 to 7%<sup>14</sup>. It is a life threatening complication especially if located at the gastroesophageal junction and regardless from the treatment chosen<sup>13</sup>, in some cases a total gastrectomy is needed<sup>15</sup>. Despite some reports describe oversewing of the staple line as the solution to prevent such problem, other authors have demonstrated the incidence of leaks being the same in oversewed and not oversewed patients<sup>16-17</sup>. The aim of this study is to compare the material effectiveness of oversewing the staple line following LSG.

## Materials and methods

We have performed 112 LSG at our institution between February 2007 and September 2010. A prospective randomized trial has been performed on 100 consecutive patients. Informed consent was obtained from the patients and approval was obtained from designated review board of our institution. Before surgery, the patients were randomized into two groups according to the admission protocol number. In a group patients were randomized to receive (Group A) a polypropylene 3-0 running oversewing suture of the staple line, in another group patients were randomized to not receive (Group B) a polypropylene 3-0 running oversewing suture of the staple line. The patients were included following the Italian society for bariatric surgery (SICOB) guidelines<sup>18</sup>. The criteria of exclusion from the study were ASA 4, steroids or FANS assumption, previous sovramesocolic surgery and cancer patients at any stage. Our follow-up was maintained for at least 1 year. The patients were examined with a standard physical examination after 1 week, 1 month, and every 3 months thereafter for 1 year.

The aim of this study was to compare the material effectiveness of oversewing the staple line following laparoscopic sleeve gastrectomy: The sample size was established to elaborate an equivalence study with a beta error of 0,20. Statistical analysis was performed with S.P.S.S. 14,0. The Yates corrected  $\chi^2$  test was used as a means of evaluating differences in categorical variables, and the Mann-Whitney U test was used for continuous variables. Statistical significance was accepted when the *p* value was lesser than 0.05.

The gastric sleeve was prepared using a 60mm stapler (Echelon 60®, Ethicon Endo-Surgery, Johnson & Johnson®, Somerville NJ, USA) following the edge a 38F calibrating oro-gastric tube. A “gold” cartridge was used three times starting 7cm proximal the duodenum followed by a “blue” one until the gastroesophageal junction was reached. Between the closure of the stapler and its firing, a 20 seconds interval has been observed in any case. Buttressing material or fibrin glue or sealant have never been used. Methylene blu was injected into the

stomach in order to evaluate the staple line tightness. In all patient a naso-gastric tube and a drainage tube to evacuate potential leaks along all the staple line, were left in place. An upper GI series with Gastrographin® was performed on third postoperative day, if negative, the nasogastric tube was then removed and the patient started with liquid diet assumption.

## Results

By evaluating preoperative general demographics features and co-morbidities between group A and group B no statistical difference was observed (Table I, II). The average operative time was 80±4 minutes for group B while it was 89±4 minutes for group A (*p*<0.001) (Table III). No intra- or peri-operative deaths occurred. Main complications evaluated were fistula, bleeding and stenosis (Table III). No significant difference was observed in fistulas occurrence (*p*=0.55). The two fistula showed in group B developed on the second postoperative day. They were well drained by the tube and were managed by parenteral nutrition and fasting. The fistula in group A developed on fifth postoperative day, it was treated conservatively as well. No bleeding in both groups required

TABLE I - Characteristics of both groups

	Group A	Group B	Statistical significance
Sex			
Men	15 (37,5%)	22 (55%)	P = 0.8
Women	25 (62,5%)	18 (45%)	
Age	33,9 ± 10,4	33,3 ± 10,1	P = 0.8
BMI	49,6 ± 2,9	48,9 ± 3,1	P = 0.
ASA			
ASA 2	19 (47,5%)	13 (32,5%)	P = 0.3
ASA 3	21 (52,5%)	27 (67,5%)	

TABLE II - Comorbidity in both groups

	Group A	Group B	Statistical significance
Hypertension	23 (57.5%)	27 (67.5%)	P = 0.3
Diabetes II	13 (32.5%)	10 (25%)	P = 0.4
Dyslipidemia	5 (12.5%)	6 (15%)	P = 0.7
Orthopaedic impairment	7 ( 17.5%)	5 (12.5%)	P = 0.5
Sat O <sub>2</sub>	91.1 ± 1.5	90.9 ± 1.4	P = 0.6
Sleep apnea	9 (22.5%)	6 (15%)	P = 0.4

TABLE III - Results

	Group A	Group B	Statistical significance
Fistulas	1 (2.5%)	2 (5%)	P = 0.55
Bleeding	4 (10%)	2 (5%)	P = 0.15
Stenosis	4 (10%)	0	P = 0.0
Operative time	89 ± 4 min	80 ± 4 min	P = 0.001

revisional surgery. They all presented within the first 6 hours from surgery and were managed by transfusion of one blood red cell unit. Haemorrhages in group B were not significantly lower than in group A. By comparing strictures a significant difference was observed by comparing the two groups. All four strictures in group A were accompanied by vomiting and gastric pain. They were all treated by endoscopic dilation and semiliquid diet two months following the surgery.

## Discussion

Laparoscopic sleeve gastrectomy, although it is still considered experimental, as a definitive procedure, by the American Society for Metabolic and Bariatric Surgery<sup>19</sup>, is gaining worldwide popularity as a single step procedure in the treatment of morbidly obese patient. It is usually considered a restrictive procedure even though some other advantages have been observed when compared to other interventions.

They are:

1. The hormonal effect produced by the ghrelin and the glucagon-like peptide 1 (GLP-1) decrease<sup>9,29</sup>. The circulating levels of ghrelin are influenced by the gastric fundus resection. Removing this area which is directly involved in the secretion of this orexigenic hormone results in a decreased feeling of hunger. By comparing adjustable gastric banding to LSG21 or LRYGB to LSG22, the fall of ghrelin blood levels after the intervention has been significantly greater in the LSG group.
2. The accelerated gastric emptying<sup>15,23</sup>.
3. The absence of implanted material.
4. The persistence of normal gastrointestinal continuity.
5. The preservation of gastric antrum in order to allow sufficient production of intrinsic factor<sup>24</sup>.
6. The avoidance of malabsorption.
7. The opportunity to convert LSG into both a LRYGBP or a BPD-DS<sup>12-13,17</sup>.

According to these points we agree with Melissas<sup>15</sup> in considering LSG as a "food limiting" intervention instead of a simple restrictive bariatric procedure.

Although reported to range from 0 to 7%<sup>14,17</sup>, the staple line leak after LSG remains a major problem.

Several studies have described and analyzed different features related to this intervention, but the tools or the techniques used to prevent leaks remain sometimes unclear. If we consider the largest published series about LSG<sup>5,6,24-28</sup>, the percentage of fistulas detected goes from 0.6 to 2.5%, but in these papers it is not defined whether any reinforcement of the suture line has been used or not. On the other hand it has to be considered that although several authors appear to agree in performing a seromuscular running suture of the staple line<sup>7,11,15,29-30</sup> a clear reason to do that has been never given. Moreover if it is usually accepted that a reinforcement of the staple line can prevent fistula<sup>31</sup>, it has to be considered that oversewing may lead to strictures of the gastric sleeve<sup>5</sup>, especially when a too small bougie size is used<sup>13</sup>, or even to both leaks from tears induced by the sutures<sup>17</sup> or intracorporeal bleeding of the staple line<sup>10</sup>. This latter might determine a fistula on ischemic basis<sup>17</sup>. Finally it is interesting to observe the attitude of some experts in bariatric surgery regarding the prevention of the staple line leaks after LSG<sup>13</sup>. The conclusion has been that a total of 65.1% of surgeons reinforce the staple line. Of these, 42.1% use a buttress whereas 50.9% oversew the staple line. If we compare these data with those obtained by Chen<sup>17</sup> in a recent review, whose conclusion has been that there is no reason to believe that reduction of leaks occurs because a reinforcement is used, it is evident we need some answers.

In our opinion it is thus important to determine if it is useful to keep a habit probably coming from open surgery or, by evaluating new technologies and dated article<sup>32,33</sup>, to consider oversewing of the staple line useless or even potentially dangerous. These studies<sup>32,33</sup> led us to consider two factors likely more important than the reinforcement of the staple line. They are first the right choice of the stapler cartridge, and second the interval in seconds that the surgeon has to wait after the closure of the stapler before firing it. In this perspective the use of different cartridges starting with a stronger one (firing staples with longer legs and wider diameter) close to pylorus followed by a thinner one as described in the methods section, appears to meet the different thickness typical of the gastric wall<sup>32,34</sup>, allowing the creation of a strong staple line and avoiding both intra or extra-luminal bleeding. However the outstanding point is probably the demonstration that the awaiting of 20-25 seconds after the stapler closure and before its firing, determines a correct tissue dehydration ideal to obtain an adequate elongation of both anterior and posterior gastric walls while not producing tensile stress in excess. This seems to be of pivotal importance to prepare the stomach to be correctly stapled<sup>33,35</sup>. Our series seem to confirm these concepts. The number of leaks has not presented significant differences between Group A (oversewed) and Group B (not oversewed). On the other hand it has to be

remarked how sleeve stenosis has been significantly higher in the oversewed group ( $p=0.04$ ). Finally one last consideration must be done. Although before starting with laparoscopic bariatric surgery our group have experienced more than fifteen years of general advanced laparoscopic surgery, it always tooks a significantly longer operative time to oversee, requiring an extra operative period in group A patients ( $p=0,001$ ). In this perspective it has to be reminded that saving an obese or super obese patient from extra operative time remains an important issue <sup>1,2,5,12-1</sup>.

## Conclusion

In conclusion, although larger numbers of patients are required, this randomized trial has so far shown oversewing of laparoscopic sleeve gastrectomy to be significantly useless to prevent fistulas formation in patients selected according to our study design.

## Riassunto

La fistola gastrica è una grave complicanza della laparoscopic sleeve gastrectomy (LSG), descritta in letteratura con percentuali che variano da 0 a 7%. Tale complicanza può determinare, seppur raramente, exitus, specialmente quando localizzata al livello della giunzione esofago-gastrica. Inoltre, in determinate circostanze, è necessaria una gastrectomia totale.

Sebbene alcuni autori sostengono l'ipotesi che il confezionare un soprappiglio sulla linea di sutura meccanica possa prevenire tale complicanza, altri autori hanno dimostrato che l'incidenza della filtrazione gastrica è sovrapponibile sia in presenza che in assenza di soprappiglio.

Abbiamo quindi elaborato uno studio prospettico, randomizzato e controllato su 100 pazienti sottoposti a LSG per valutare la reale efficacia del soprappiglio nella riduzione dell'incidenza di fistole gastriche dopo LSG. Il disegno dello studio prevedeva la realizzazione di due gruppi di controllo differenti esclusivamente per l'effettuazione o meno di un soprappiglio dalla linea di sutura. I risultati così ottenuti dimostrano che l'incidenza di fistole non è significativamente maggiore quando non si esegue il soprappiglio ( $p = 0,55$ ). Inoltre l'incidenza del sanguinamento è maggiore, pur in assenza di rilevanza statistica ( $p = 0,65$ ), quando si esegue il soprappiglio, e l'incidenza di stenosi è statisticamente maggiore quando si esegue il soprappiglio ( $p=0,004$ ).

Sebbene la numerosità campionaria è il limite del nostro studio e successive e più numerose valutazioni saranno necessarie, possiamo affermare con criteri scientifici precisi e ripetibili che il soprappiglio può essere ritenuto superfluo, se non dannoso, nella prevenzione delle fistole gastriche dopo laparoscopic sleeve gastrectomy.

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