

## Original Research Article

# Stapling technology with triple-row and enhanced staple configurations evaluated in a series of 124 consecutive laparoscopic vertical gastrectomies

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## ABSTRACT

**Background:** Laparoscopic sleeve gastrectomy (LSG) is a procedure frequently used to treat morbid obesity, due to its simplicity compared to other bariatric techniques. However, LSG can lead to serious complications, such as gastric leakage and bleeding from the staple line. To reduce these complications, seroserosal reinforcement of the mechanical suture line after gastrectomy is generally recommended. In recent decades, studies have focused on the safety of anastomosis with staples, especially compared to manual sewing techniques. Since studies on the improvement of stapling technology are limited, this study arises to compare the clinical results of staple line oversewing versus stapling technology with triple-row and enhanced staple configurations in laparoscopic sleeve gastrectomy.

**Methods:** A retrospective review from a prospectively maintained database of 124 laparoscopic vertical gastrectomies performed at single centre between March 2010 and December 2016. Patients were divided into two groups, with comparable anthropometric parameters and inclusion criteria. Seroserosal reinforcement was used in the first group, and stapling technology with triple-row and enhanced staple configurations in the second. Rates of anastomotic leakage, bleeding, reoperation, and 30-day mortality were compared.

**Results:** In Group 1 the average surgical time was 125 min, whereas in Group 2 it was 87 min. No differences were found between the two groups regarding leakage or bleeding of the staple line.

**Conclusions:** The use of triple-row stapling devices during laparoscopic vertical gastrectomy enables surgical time to be reduced. Further high-quality studies to evaluate the efficacy and effectiveness of stapling technology with triple-row and enhanced staple configurations are needed.

**Keywords:** Sleeve gastrectomy, Stapler, Staple lines, Staple line bleed, Staple line leak, Staple line oversewing

## INTRODUCTION

The introduction of new technologies in medicine and surgery has helped to achieve great advances that have enabled procedures to become less aggressive, safer, and even faster. Since the introduction of mechanical staplers pioneered by a Hungarian surgeon Humor Hultl known as

the "father of surgical stapling", their use in modern medicine has evolved to this day.<sup>1,2</sup> The latest significant advance in recent years is the arrival in the present market of the possibility of using staplers with Tri-Staple technology. Their effectiveness and qualities have been described in different kinds of surgery, including bariatric surgery.<sup>3-5</sup> Laparoscopic sleeve gastrectomy (LSG) was described as the first-step approach for a Roux-en-Y

gastric bypass or biliopancreatic diversion with duodenal switch.<sup>6</sup> At the beginning of the 2000s it began to be used as a standalone procedure for morbidly obese patients. LSG has lower operative risks and a simpler methodology than other well-established procedures.<sup>7</sup> The main complications of LSG in the early postoperative course are staple line bleeding and leakage. Bleeding from the staple line is the most common complication and exists in approximately 1% to 6% of cases.<sup>8,9</sup> To prevent these complications, different solutions have been described.<sup>10</sup> This study aimed to compare the clinical outcomes of staple line oversewing versus triple-row stapling devices and enhanced staple configurations in laparoscopic sleeve gastrectomy.

## METHODS

All patients who underwent elective laparoscopic sleeve gastrectomy in Hospital Universitario Son Espases between the period of March 1, 2010, and December 31, 2016, were included in the study and clinical information was retrieved from a prospectively maintained database. Ethical approval was obtained from the institutional review board. The vertical laparoscopic gastrectomy was performed in a standardized manner, using 5 trocars (three of 12 mm and two of 5 mm). Gastrotomy of the greater gastric curvature was performed four centimetres from the pylorus. The subsequent gastric section was tutored with a 50 Fr orogastric probe (Fouchet). In the first group of patients, gastric section was performed by mechanical linear suture completed by a seroserosal oversewing reinforcement with interrupted silk sutures. In the second group of patients, gastric section was performed by reinforced linear suture Endo GIA™ Reinforced Reload with Tri-Staple™ MedtronicR technology, without staple line oversewing. In all cases, a nasogastric tube was left in place.

Demographic data, operative data, and postoperative outcomes of patients were analysed. Primary end points were anastomotic complications, namely anastomotic leakage and anastomotic bleeding. Anastomotic leakage was defined according to the well-accepted guidelines of the 1991 United Kingdom Surgical Infection Study Group, as “leak of luminal content from a surgical join between two hollow viscera”.<sup>11</sup> Secondary end points were reoperation rate, 30-day mortality rate, and length of hospital stay.

Statistical analysis was performed with SPSS version 24 (IBM, USA). Categorical variables were compared with either the  $\chi^2$  test or Fisher’s exact test, where appropriate. Continuous variables were checked with the Shapiro–Wilk test for normal distribution. The Mann–Whitney U test was used to compare continuous variables that did not follow a normal distribution. A univariate analysis was performed for the unmatched group, with anastomotic leakage as the dependent variable. Variables with significant univariate associations were included in the multivariate analysis with a forward stepwise logistic

regression model. All comparisons were two-sided, and a p-value of <0.05 was considered statistically significant.

## RESULTS

During the study period, 124 patients underwent laparoscopic sleeve gastrectomies. After gastric section with mechanical linear suture, a seroserosal oversewing reinforcement with interrupted silk sutures was performed in 44 patients. The remaining 80 patients had a sleeve gastrectomy with a reinforced triple-row stapling device. The first group of patients underwent operation between 2010 and 2014, while those in the triple-row stapler group underwent operation between 2014 and 2016. Both groups were homogeneous; there were 33 men and 91 women with an average follow-up period of 29 months (range 14–70 months). Demographic characteristics of patients are described in Table 1.

**Table 1: Demographic characteristics of patients.**

Characteristics	Group I (n=44)	Group II (n=80)	P value
<b>Age</b>	43 (32–61)	46 (26–62)	0.71
<b>Female</b>	32 (72.7%)	59 (73.7%)	0.91
<b>BMI (kg/m<sup>2</sup>)</b>	45.7 (43.4– 51.1)	44.2 (43.4– 54.5)	0.56
<b>Comorbidities</b>			
<b>HTA</b>	30.2%	25.2%	0.27
<b>DMT2</b>	17%	23%	0.65
<b>Dyslipidaemia</b>	28.2%	18.2%	0.42
<b>SAOS</b>	24%	20%	0.55
<b>Arthropathy due to overweight</b>	32%	22%	1.00

In both groups, the female gender was the prevalent one. Body mass index was around 45 kg/m<sup>2</sup> in both groups and the most prevalent comorbidity was hypertension. In the first group, 17% of patients had diabetes, whereas it was 25.2% in Group 2, but with no statistically significant difference.

Characteristics related to surgery are described in Table 2. Upon analysing the variables under study, a statistically significant difference was found in surgical time, which was lower in Group 2. In Group 1, the average time in minutes was 125 compared to 87 in Group 2. The rest of the variables studied did not show significant differences. Blood loss was similar in both groups. In one case, a patient had to be reoperated due to an early fistula located in the oesophagogastric junction. Reoperation rate was 2.5% (2 patients) in Group 2. In one case, reoperation was necessary due to a stenosis, and in the second case due to an oesophagogastric junction leak. Comparison between the two groups did not detect a significant difference. The series did not show mortality

at 30 days after surgery. In Group 2 a late reoperation was necessary in one patient with stenosis at the level of the angularis incisura, requiring reconversion to gastric bypass (1.25%). Bleeding of the staple line occurred in two patients in the first group. In both cases the bleeding was controlled by interrupted continuous silk suture. Mean hospital stay was 3.4 days in the first group, and 2.8 days in the second group without presenting any statistically significant differences.

**Table 2: Characteristics related to surgery.**

	Group I (n=44)	Group II (n=80)	P value
<b>Average surgical time (min.)</b>	125 (110-150)	87 (80-110)	0.04
<b>Estimated blood loss (ml)</b>	45 (0-300)	50 (0-400)	0.82
<b>Early Reoperation (%)</b>	1 (2.27%)	2 (2.5%)	1.00
<b>Late Reoperation (%)</b>	0 (0%)	1 (1.25%)	0.49
<b>Anastomotic leakage (%)</b>	1 (2.27)	1 (1.25%)	0.28
<b>Anastomotic bleeding (%)</b>	2 (4.54%)	0 (0%)	0.09
<b>Median length of stay (days)</b>	3.4 (1.5-7)	2.8 (1.3-5.6)	0.072

## DISCUSSION

LSG is a definitive technique in bariatric surgery that has gained popularity due to it being simpler than other bariatric techniques, and because of its satisfactory results in the medium term with regard to weight loss and comorbidity resolution.<sup>12</sup> It is a restrictive technique that does not present gastrointestinal anastomoses and, in case of failure, enables a potential conversion to other malabsorptive bariatric procedures.<sup>13</sup> Despite this, some worrisome complications associated with LSG have been described.<sup>14</sup> Staple line bleeding and leakage after sleeve gastrectomy are the most important and serious complications in this regard. Incidence of staple line bleeding ranges from 1% to 6%. Bleeding can be intraluminal causing hematemesis and/or melena; or extraluminal causing hemoperitoneum.<sup>15</sup> These complications can range from minor sequelae to extremely serious, life-threatening events. It has been described that the reduction of postoperative bleeding and leakage could prevent serious events such as peritonitis and septic shock.<sup>16,17</sup> To reduce these adverse events, the concept of staple line reinforcement was introduced. Many different reinforcement options have been described but there exists no clear consensus regarding the benefits of these techniques, and standardisation is still lacking. Out of all of these, oversewing of gastrointestinal staple lines is probably the most commonly performed method for reinforcing the staple line.<sup>18</sup> The meta-analysis study of Shikora et al.

demonstrated that staple line oversewing was the most frequently used reinforcing technique with a lower leakage rate than buttressing material usage, while bovine pericardium was the most effective.<sup>10</sup> However, Gagner and Buchwald showed that buttressing material was superior to oversewing of the staple line.<sup>19</sup> The approach to this unresolved situation could change with the arrival on the market of the new type of tri-staple technology. This study arises to evaluate the effectiveness of the new Tri-Staple in preventing both bleeding and fistula of the staple line with respect to staple line reinforcement through oversewing. In a homogeneous group of morbidly obese patients, the same surgical team successively performed 124 sleeve gastrectomies. Patients were divided into two homogeneous groups: in the first group, staple line reinforcement through oversewing was performed. In the second, the new tri-staple technology without oversewing was used. No statistically significant difference was found with respect to intraoperative blood loss, early reoperation, or late reoperation. Neither were any statistically significant differences even found in incidence of anastomotic leakage or in anastomotic bleeding. No difference was detected in leakage, with one episode of early fistula obtained in each group. A decrease in staple line bleeding was observed, although without statistically significant differences. In the meta-analysis published by Wang et al. there was no significant difference in the frequency of staple line bleeding, leakage, or overall complications between the oversewn and not oversewn groups.<sup>14</sup> D'Ugo et al. conducted a multicentre retrospective trial in which 476 out of 1,162 patients underwent staple line oversewing. Bleeding and leakage rates were 1.4% and 3.0% respectively, lower than for the not oversewn group.<sup>20,21</sup> Introduction of the new tri-staple technology could achieve a better stapling line and could reduce all the associated complications. The results of the study published by Fegelman et al. showed that the use of the Gripping Surface Technology stapling system reduced the need for staple line interventions during LSG.<sup>5</sup> A decrease in the number of procedures performed on the staple line could enable a reduction in surgical time. In the analysis of our series, a statistically significant reduction in surgical time was observed in the group in which the tri-staple was used. Taha et al suggested that staple-line reinforcement by hand-sewing may require additional operating time and that average surgical time is significantly shorter in patients who underwent LSG without oversewing of the staple line.<sup>22</sup> This aspect is also highlighted in the meta-analysis of Wang et al.<sup>14</sup> The shorter surgical time detected in our series may be due to the fact that the introduction of the reinforced lines occurred when the learning curve of the surgical team had already been completed, adding enough experience to be able to decrease surgical time. Studies by Aggrwal et al. and Sroka et al. suggest that the diminished bleeding rate after oversewn LSG may be attributed to the learning curve effect and not only the efficacy and effectiveness of the method of reinforcing the stapling line.<sup>23,24</sup> Greater surgical experience and higher quality laparoscopic

staplers would help reduce complications related to LSG. This improvement has probably enabled the great diffusion of this technique for treatment of morbid obesity. Its introduction into the market has made it easier for many groups that previously did not perform bariatric procedures to have vertical gastrectomy as a surgical option in the treatment of morbid obesity.

Some limitations of this study should be addressed. First, the data were derived from a single low-volume bariatric centre. Furthermore, the study does not compare the gastrointestinal quality of life between both groups. Another limitation is that only two ways of reinforcing the staple line were compared, without considering other techniques described in the literature.

## CONCLUSION

In conclusion, laparoscopic vertical gastrectomy may be performed with optimal results using triple-row stapling technology, which allows safety in the technique and reduction of surgical time. No difference was seen between the two groups in staple line bleeding and leakage. A lower complication rate was observed in the anastomoses created by triple-row stapling devices, although the difference was not significant. What was detected is that surgical time was significantly decreased. In view of this, further high-quality studies to evaluate the efficacy and effectiveness of stapling technology with triple-row and enhanced staple configurations are needed.

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