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**An experimental study**



*Ann. Ital. Chir.*, 2020 91, 2: 201-206  
pii: S0003469X20031747

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**Evaluation of different stapler line strengthening techniques with burst pressures in patients undergoing sleeve gastrectomy. An experimental study**

**AIM:** Obesity is a leading cause of preventable death worldwide and is increasing in both adults and children. Bariatric surgery is the most effective treatment for this condition and its related comorbidities. We aimed to evaluate the effectiveness of different staple line reinforcement techniques on staple line reinforcement through bursting pressures.

**METHODS:** Different stapler line strengthening techniques were performed on resected stomach patterns of 48 patients. The patients were enrolled prospectively into 4 groups according to surgeons preferred type of staple line reinforcement. Data concerning patient demographic variables, surgical parameters, postoperative complications, postoperative readmissions, burst pressure and burst point were collected. None of the obese patients were excluded from this study.

**RESULTS:** There were no statistically significant differences in the characteristics of the groups. The number of staple cartridges fired and the linearity of the staple line were similar in all groups, ( $p$  0.524-0.265). However, there were significant differences in the burst pressure measurements in groups I, II, III and IV ( $p$  .001). In all groups, the burst point on the staple line of resected stomach was most commonly in the fundus section.

**CONCLUSIONS:** We believe that the burst pressure in Fibrin sealant group is significantly higher and that fibrin glue can be effective in preventing stapler line leakage. We believe that more advanced studies are needed.

**KEY WORDS:** Fibrin Sealant, Leakage, Reinforcement

## Introduction

Obesity is a leading cause of preventable death worldwide and is increasing in both adults and children. Obesity is associated with higher rates of death driven by comorbidities such as hypertension, type 2 diabetes mellitus

(T2DM), obstructive sleep apnea (OSA), dyslipidemia, steatohepatitis, gastroesophageal reflux, certain types of cancer, arthritis, polycystic ovary syndrome (PCOs), and infertility<sup>1,2</sup>. Bariatric surgery is the most effective treatment for this condition and its related comorbidities. Among different techniques, laparoscopic sleeve gastrectomy (LSG) has become one of the most frequently performed bariatric procedures worldwide in the last several years<sup>3</sup>. Laparoscopic sleeve gastrectomy (LSG) is a restrictive bariatric surgical procedure requiring resection of the stomach to restrict volume, resulting in weight loss and improved glucose homeostasis. Using a surgical stapler to transect tissue along the greater curvature of the stomach, volume is reduced by approximately 80%, leaving a “sleeve” that connects the esophagus to the small intestine<sup>4</sup>. In comparison with other procedures, it has numerous advantages such as: preservation of gastrointestinal tract continuity, the fact that it is a

*Pervenuto in Redazione Novembre 2019. Accettato per la pubblicazione Dicembre 2019*

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restrictive technique and does not cause malabsorption, and it can be converted to other operations. Although the most critical acute complications are bleeding and leaks, chronic complications such as gastroesophageal reflux disease, stricture, gastric tube dilatation, and insufficient weight loss can also be observed<sup>5</sup>. Therefore, some surgeons use various materials, such as Peri-Strips Dry with Veritas, Seamguard, fibrin sealant and/ or gelatin matrix agents, sutures and clips, to achieve better hemostasis and decrease the incidence of early complications, such as staple-line leaks<sup>6-8</sup>. Fibrin sealant has been approved by the Food and Drug Administration (FDA), and it is the only agent that provides hemostasis, sealing and adhesion<sup>9</sup>. As already known, burst pressure has been used in many studies, particularly to evaluate the resistance of anastomosis<sup>10,11</sup>. In this study, we aimed to evaluate the effectiveness of different staple line reinforcement techniques on staple line reinforcement through bursting pressures.

## Material and Methods

This experimental study was approved by the Institutional Review Board for Kocatepe University Faculty of Medicine (2011-KAEK-2). Informed consent was obtained from all individual participants included in the study. We utilized resected stomachs of patients undergoing laparoscopic sleeve gastrectomy. All selected patients met the National Institutes of Health criteria for bariatric surgery<sup>14</sup> either a BMI greater than 40 kg/m<sup>2</sup> or a BMI greater than 35 kg/m<sup>2</sup> with at least one comorbidity. All patients underwent preoperative evaluation and education with an interdisciplinary group in addition to typical workup including psychology, nutritional, and internal medicine evaluation. Upper GI endoscopy with biopsy was done selectively as indicated for any suspected gastric problems.

Fibrin Sealant (FS) (Tissell; Baxter International, Deerfield, Illinois) was applied to all patients to strengthen the stapler line during the operation. Different stapler line strengthening techniques were performed on resected stomach patterns of 48 patients. The patients were enrolled prospectively into 4 groups according to surgeons preferred type of staple line reinforcement: group I: 12 patients, no reinforcement (NoR); group II: 12 patients suture reinforcement with 3-0 poliglactin sutures (Lembert), group III: 12 patients, suture reinforcement with 3-0 poliglactin sutures (Oversewing); and group IV: 12 patients, fibrin sealant (FS) (Tissell; Baxter International, Deerfield, Illinois).

Data concerning patient demographic variables [age, gender, body mass index (BMI, kg/m<sup>2</sup>)], surgical parameters, postoperative complications, postoperative readmissions, burst pressure and burst point were collected. None of the obese patients were excluded from this study.

## BURST PRESSURE MEASUREMENTS

The resected stomach specimen was removed from the abdomen after the wound caused by the left midclavicular 12-mm working trocar was enlarged. The resected stomach specimens in group II-III (Lembert-Oversewing) were sutured with the 3-0 poliglactin as that used along the staple line. (Figs. 1-2) The staple lines of the specimens in group IV were sprayed with fibrin sealant. The veress needle was inserted by the antrum of the resected fresh stomach. The inflator was attached to the catheter and to a manometer through a 3-way stopcock. The specimen was kept under water and inflated with constant air flow. (Fig. 3) The pressure level of the manometer was recorded as the burst pressure when the first air bubble leak was detected in the staple line. The locations of the leaks along the staple line were also recorded. For this reason, the staple line was subdivided into 3 areas, and leaks were categorized as proximal (fundus), middle (from body to fundus), or distal (from the first staple applied to the body).

## STATISTICAL ANALYSIS

SPSS (Statistical Package for the Social Sciences) 22.0 program was used for statistical analysis. In the comparisons of quantitative data and descriptive statistical data (mean, standard deviation, median, frequency, and ratio), 1-way ANOVA was used for the intergroup comparisons of parameters with normal distribution. The Kruskal-



Fig. 1: Suture reinforcement with 3-0 poliglactin sutures (Lembert)

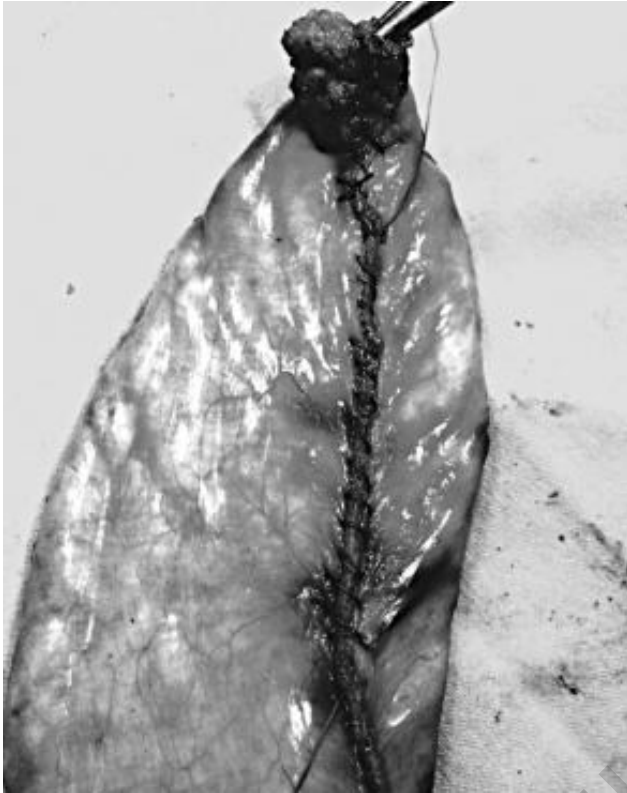


Fig. 2: Suture reinforcement with 3-0 poliglactin sutures (Oversewing)



Fig. 3: Burst pressure Measurement

Wallis test was used for the intergroup comparisons of parameters without normal distribution, and the Mann-Whitney U-test was used to determine the significance of differences between 2 groups. The Fisher-Free-

man Halton test and Fisher's exact test were used for the comparison of qualitative data. The results are presented with 95% confidence intervals and at a significance level of  $P < 0.05$ .

## Results

Table I shows the baseline characteristics of the remaining 48 patients. There were no statistically significant differences in the characteristics of the groups. The number of staple cartridges fired and the linearity of the staple line were similar in all groups, ( $p$  0.524-0.265) (Table II). However, there were significant differences in the burst pressure measurements in groups I, II, III and IV ( $p$  0.001; Table III). In all groups, the burst point on the staple line of resected stomach was most commonly in the fundus section.

## Discussion

Sleeve gastrectomy is more popular in recent years as more data is released on its durable effect for weight loss and resolution of comorbidities. In some centers, SG is the most prominent procedure performed. That is becoming more popular as a "single stage" operation<sup>12,13</sup>. Although the procedure is less invasive and less complex than gastric bypass, leak from stapler line is a challenging complication of this procedure. Many studies have been performed in order to delineate the mechanism of leak and the best techniques to lower the risk of this complication. Among these studies, several have evaluated burst pressure in stapled stomach<sup>14</sup>.

An endoscopic stapler is an indispensable instrument in bariatric surgery. New-generation staplers are designed to have three rows of staples for both sides of the tissue. However, most surgeons continue to use support materials to increase staple-line reinforcement. Ideally, these support materials enhance the anastomosis strength and reduce complications arising from staple-line failure. Many surgeons use different techniques, but a standard technique has not yet been established. One of the early gastric leak etiologies is believed to emanate from high intraluminal pressures, which tend to split the staple line<sup>15</sup>.

The use of smaller bougies to augment weight loss and close stapler approximation around the incisura angularis produced functional obstruction, in addition to the natural physiologic obstructive mechanism of the pylorus. Creating a long, tight sleeve leads to increased intraluminal pressure, which may overcome staple line strength and cause leaks<sup>16,17</sup>. To avoid leaks, most surgeons prefer to reinforce the staple line during LSG, mostly by suturing or using buttressing materials, whereas some surgeons leave the staple line untouched<sup>17,18</sup>. However, the long staple line used in LSG has created particular concerns about the risk of leaks, which has

TABLE I - Patient characteristics.

Characteristic	Group I (NoR) (n = 12)	Group II (L) (n = 12)	Group III(O) (n = 12)	Group IV (T) (n = 12)	P
Age	38.24 ± 10.52	36.08 ± 10.44	35.79 ± 9.69	33.00 ± 8.51	0.465a
Body mass index (BMI)	47.48 ± 6.33	45.5 ± 5.15	46.58 ± 6.21	48.43 ± 6.88	0.356a
Gender					
Female, n	10	9	8	10	0.469b
Male, n	2	3	4	2	
Leaks, n	0	1	0	0	0.453b

TABLE II - Surgical Parameters.

Group	n	Number of Cartridges		SD	Median	Staple Line Uniformity	
		Min-Max	Mean			Uniform	Not Uniform
I (NoR)	12	4-8	5.09	1.442	5.00	10 (83,3)	2 (16,7)
II (FG)	12	4-7	4.61	0.926	5.00	11 (90,9)	1 (9,1)
III (S)	12	4-6	4.83	0.634	5.00	10 (83,3)	2 (16,7)
IV (PS)	12	4-7	5.02	0.873	5.00	11 (90,9)	1 (9,1)
P		0.524 <sup>a</sup>				0.265 <sup>b</sup>	

Table III - Burst Pressure Differences Between the Groups- Burst Point in the Staple Line of the Resected Stomach.

Group	n	Burst Pressure			P	Burst Point in the Staple Line of the Resected Stomach		
		Min-Max (mm Hg)	Mean (mm Hg)	SD (mm Hg)		Proximal 1/3 (Fundus)	Middle 1/3 (Corpus)	Distal 1/3 (Antrum)
I (NoR)	12	120-210	153.33	68.53	0.001 <sup>a</sup>	9 (68%)	2 (24%)	1 (8%)
II (L)	12	80-160	121.25	43.30		8 (53.8%)	3 (38.4%)	1 (7.8%)
III (O)	12	60-130	90.42	54.18		9 (63.6%)	2 (22.7%)	1 (14%)
IV (T)	12	150-260	199.17	59.62		9 (57.2%)	3 (42.8%)	0 (0%)

been reported to range from 0.7% to 5.7%<sup>16,18</sup>. The leak rate in our study was 2.1% (1 leaks in 48 patients). Our leak rate is consistent with the literature.

Fibrin sealant has been approved by the Food and Drug Administration (FDA)<sup>19</sup>. Fibrin sealant has been safely used in a wide variety of surgical procedures, such as cardiovascular surgery, spleen and liver trauma, the closure of colostomies, and repair of bronchial fistulas and dural tear. In many patients, fibrin sealant has been reported to be used safely in laparoscopic surgery<sup>20,21</sup>. In many studies, the use of sutures is one of the most effective methods to strengthen the stapler line. The meta-analysis study of Shikora et al. demonstrated that the staple-line oversewing was the most commonly used reinforced technique with a lower leakage rate than the buttressing material usage, and bovine pericardium was the most effective<sup>22</sup>.

Recent studies make no recommendations about the use of suture.<sup>23</sup> A study by Nimeri et al.<sup>23</sup> that included 310 patients assessed the routine use of oversewing sutures to reinforce the staple line during LSG. Stenosis was detected on intraoperative endoscopy in 10 patients

(3.2%), and all cases were treated after removing the over-sewing sutures. Other major disadvantages of this method is that it is time-consuming and it occasionally causes bleeding and ischemia. The stomach must remain larger for the sero-serosal sutures, and there is no standardization. Rogula *et al.* compared reinforcement techniques using suture on the staple line in sleeve gastrectomy. Their results suggested that continuous Lembert sutures may reduce the risk of staple-line leakage better than through-and-through sutures<sup>14</sup>. This suggests the importance of suturing technique. But most of leaks at through-and-through suture lines were from the suture puncture sites and not from the actual staple-line. In fact, passage of needle through all layers of stomach may create a potential microperforation that may leak when the stomach is distended<sup>14</sup>. In our study, the bursting pressure of group II (Lembert) was significantly higher than group III (oversewing) and was consistent with the literature.

Silecchia et al.<sup>24</sup> reported that fibrin sealant (Tisseel) use could be beneficial for leak prevention. Karakoyun et al.<sup>15</sup> there was no significant difference between the fibrin sea-

lant (Tisseel) group and the control group. However, burst pressure was higher in the group with continuous serosal suture compared with the fibrin sealant (Tisseel) and control groups.

In our study, the highest bursting pressure developed in tisseel (group IV). The second burst pressure was in the control group (group I). Pressures were lower in the suture groups (groups II and III). In our study, the bursting pressure in the tisseel group was significantly higher than the control group. Fibrin Sealant has been shown to increase the stability of the stapler line against increased intragastric pressure after sleeve gastrectomy and also prevent microvessels that cannot be detected in leak tests<sup>25</sup>. In group IV, this is why the bursting pressure is significantly higher than in group I.

Mechanism of leak in SG is not just mechanical bursting due to increased intragastric pressure. Like any other anastomotic leak in gastrointestinal surgery, ischemia, tissue trauma, distal obstruction, hematoma at staple-line, and individual patient factors may contribute to leak from the staple-line. In addition, artificially high bursting pressure in ex vivo studies may be beyond physiologic, real-life, and even pathologic situations. Mean burst pressure in our series was 200 mmHg for fibrin sealant, and about 90 mmHg for oversewing reinforcement. These pressures are much higher than normal intragastric, pylorus, and lower esophageal sphincter (LES) pressures. Yehoshua et al. performed an in vivo study and measured intragastric pressure in a sleeved stomach with a mean basal pressure of 18 mmHg (6-28 mmHg) and maximum pressure of 43 (32-58) mmHg when filled with saline<sup>26</sup>. Therefore even if we assume a sleeved stomach with distal obstruction, intragastric contents should theoretically regurgitate into esophagus when intragastric pressure increases.

As compared to the use of fibrin sealant, although the use of reinforcement sutures may appear to offer certain cost benefits, it should be remembered that it is also associated with longer surgery as well as prolonged occupation of the surgery room and the team. In a study by Bransen et al., the average cost of leak per patient has been estimated to be in the order of €9283 including the costs associated with intensive care, prolonged hospital stay, and use of medications and medical consumables<sup>27</sup>. Although high acquisition costs of fibrin sealant seem to be increasing the overall cost of surgery, the advantages of the prevention of the leak should also be borne in mind.

Although this is a prospective randomized study, the limitation of our study is that there is no in vivo study involving actual intragastric pressure measurements.

## Conclusion

Despite the limitations of our study, we believe that the burst pressure in Fibrin sealant group is significantly

higher and that fibrin glue can be effective in preventing stapler line leakage. We believe that more advanced studies are needed.

## Riassunto

Nell'ambito della chirurgia bariatrica abbiamo valutato l'efficacia delle diverse tecniche di rinforzo della linea di sutura meccanica a fronte della pressioni di scoppio, utilizzando come modello sezioni di stomaco resecato.

A questo scopo sono state eseguite diverse tecniche di rafforzamento della linea di sutura meccanica su modelli di stomaco resecati di 48 pazienti. I pazienti sono stati arruolati in modo prospettico in 4 gruppi in base al tipo di rinforzo della linea di base preferito dai chirurghi. Sono stati raccolti dati riguardanti variabili demografiche del paziente, parametri chirurgici, complicanze postoperatorie, riammissioni postoperatorie, pressione di scoppio e punto di scoppio. Nessuno dei pazienti obesi è stato escluso da questo studio.

RISULTATI: non ci sono state differenze statisticamente significative nelle caratteristiche dei gruppi. Il numero di cartucce di punti metallici sparati e la linearità della linea di punti metallici erano simili in tutti i gruppi (p 0,524-0,265). Tuttavia, c'erano differenze significative nelle misurazioni della pressione di scoppio nei gruppi I, II, III e IV (p. 001). In tutti i gruppi, il punto di scoppio sulla linea di base dello stomaco resecato era più comunemente nella sezione del fondo.

In conclusione riteniamo che la pressione di scoppio nel gruppo dei campioni di stomaco sigillati con colla di fibrina sia significativamente più elevata e dunque che la colla di fibrina possa essere efficace nel contribuire a prevenire il cedimento della linea di sutura con stapler. Riteniamo che siano comunque necessari ulteriori studi sul tema.

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