

Cyanoacrylate sealant compared to fibrin glue in staple line reinforcement during laparoscopic sleeve gastrectomy. Pilot prospective observational study

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SUMMARY: Cyanoacrylate sealant compared to fibrin glue in staple line reinforcement during Laparoscopic Sleeve Gastrectomy. Pilot prospective observational study.

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Laparoscopic Sleeve Gastrectomy (LSG) is associated with serious complications, such as staple line leaks and bleeding. This paper presents a novel approach aimed at the successful consolidation of the suture by the use of the cyanoacrylate, here compared to the use of fibrin glue.

Fifty consecutive patients, recruited from October 2015 to March

2016, were submitted to laparoscopic sleeve gastrectomy by standardized surgical technique. The staple line was reinforced with cyanoacrylate or fibrin glue.

There were no post-operative complications and no operative time prolongation. An early removal of the draining and a reduction of the average hospitalization were observed.

The results suggest that staple line reinforcement with cyanoacrylate during laparoscopic sleeve gastrectomy is as easy, safe and cost-saving as with fibrin glue. Furthermore, cyanoacrylate allows a chemical omentoplasty with the result of restoring the anatomy. Therefore, this approach is viable and useful for future trials on the efficacy in preventing surgical post-operative complications.

KEY WORDS: Cyanoacrylate - Fibrin glue - Reinforcement - Sleeve gastrectomy - Staple line.

Highlights

- A staple-line reinforcement with cyanoacrylate is proposed.
- Cyanoacrylate allows a chemical omentoplasty restoring the anatomy.
- Cyanoacrylate could decrease the incidence of postoperative complication in LSG.

Introduction

Laparoscopic sleeve gastrectomy (LSG) is currently unanimously considered a simple, fast and less invasive bariatric procedure than others, such as the gastric bypass (L-RYGB) and biliopancreatic diversion (BPD). The major complications are leaks and bleeding (3.93 and 4.07%) (1) and are related to the long suture line. This

implies an unfavourable impact on clinical outcomes and healthcare costs, therefore most surgeons use a reinforcement of the gastric suture.

Currently the validity of the use of the reinforcement is still debated.

The results of a review in 2009 indicate that the reinforcement does “not necessarily” reduce the development of fistulas, even though it has a positive effect on the incidence of bleeding (2).

The Parikh metanalysis (about 10.000 patients), concludes that the reinforcement with absorbable material does not cause a significant impact on the incidence of fistulas, that, on the contrary, are related to the dimension of the calibration bougie and to the long and narrow gastric remnant (3).

In 2014, a systematic review on 88 studies (about 9.000 patients) highlighted that the *absorbable polymer membrane* (APM) seems to have a preventive effectiveness on the fistulas (with up to 1.1% reductions). APM proved more effective than the other compared options, such as non-absorbable strips in bovine pericardium, continuous reinforcement suture (*oversewing* or *overlock*) and no reinforcement (4).

A prospective randomized study in 2016, comparing various reinforcement techniques to the simple section

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of the stomach without reinforcement, concluded that the reinforcement only prolongs the operative times (5).

On the contrary, a recent study on 1000 patients by Coskun et al. concluded that fibrin sealant is a reliable and useful tool to reinforce the staple line (6).

This paper presents a novel approach aimed at the successful consolidation of the gastric suture using cyanoacrylate (Glubran 2®). This glue performs an adhesive hemostatic and sealing action on the tissues and creates an antiseptic barrier against the most common pathogenic agents. Glubran 2® is already used in surgical and endoscopic procedures to guarantee high bonding strength between biological tissues, and when applied on anastomoses it provides a higher resistance to intraluminal pressures (7).

We reported our experience in reinforcement techniques during LSG with the use of cyanoacrylate sealant compared to the use of fibrin glue, to reinforce the gastric suture line in order to prevent surgical post-operative complications.

Patients and Methods

This pilot prospective observational study included 50 consecutive patients submitted to LSG between October 2015 and March 2016, and classified in two groups: group A (Glubran 2®, cyanoacrylate sealant reinforcement; n 25) and group B (Tisseel®, fibrin glue reinforcement, n 25). Inclusion criteria were a body mass index (BMI) above 40 kg/m². Exclusion criteria were age above 65 years and previous bariatric procedures (Table 1).

LSG was performed by standardized technique. The omentum was dissected from the greater curvature with a vessel-sealing device (advanced bipolar energy or ultrasound energy). The stomach section was performed by linear stapler and using a Fr 38 probe for calibration. A standard leak test was performed with the instillation of methylene blue through the probe. Aerosolized Glubran 2® or Tisseel® were used as a reinforcement of the staple line (Figure 1).

The follow-up was at 1, 3 and 6 months.

TABLE 1 - PATIENT CHARACTERISTICS.

	Group A	Group B	p value
Number	25	25	-----
Sex (F/M)	17/8	20/5	p 0.04
Age (years) ^a	41.2 (18-65)	42.5 (25-65)	p 0.04
BMI (kg/m ²) ^a	45.5 (41-50)	44 (40-49)	p 0.03

^a Mean (range)

^b p value obtained from paired-sample T-Test.



Figure 1 - Reinforcement of the staple line: aerosolized sealant.



Figure 2 - Chemical omentoplasty: adhesion of the greater omentum to the staple line.

TABLE 2 - OPERATION DATA AND HOSPITAL STAY.

	Group A	Group B	p value ^b
Operative time ^a , min	110 (90-140)	104 (100-120)	p 0.02
Glue amount	1 ml	2 ml	-----
Hospital stay ^a , days	5 (4-6)	5 (4-6)	p 0.03

^a Mean (range)

^b p value obtained from paired-sample T-Test.

Results

Both glues, Glubran2® and Tisseel®, were easy to apply, and did not increase the operative times. About 1 ml of Glubran 2® was enough to cover the entire staple line, while for fibrin glue 2 ml were needed. Furthermore,

Glubran 2® rapidly polymerizes in 60-90 seconds and allowed to create a kind of chemical omentoplasty, which is a *bonding* of the section margins of the greater omentum without suture (Figure 2).

The post-operative progress was excellent in all the patients, with no complications for both groups (Table 2).

Discussion

In order to prevent complications after LSG, such as staple line leaks and bleeding, a growing focus has been placed on the reinforcement of the suture line. Every reinforcement, though, is burdened by the fear of making the procedure more difficult and prolonging the

operative time without any certainty of obtaining a reduction of the complications.

Our experience suggests that Glubran 2®, with its triple sealing, hemostatic and bacteriostatic action, applied in its aerosolized formulation along all the staple line in the LSG, can be an efficient, safe and cost-saving option to manage the risk of major complications. The results are identical to the use of fibrin glue, widely described in literature, but Glubran 2® allows a chemical omentoplasty with the final result of restoring the anatomy, thus probably reducing the risk of a leak.

This little variation in the technique with chemical omentoplasty does not imply any technical difficulty nor a significant prolongation of the procedure. We need randomized trials that will confirm its validity in the prevention of post-operative complications.

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