Received: 23 March 2016 | Revised: 28 October 2016 | Accepted: 31 October 2016

DOI 10.1111/jep.12685

WILEY Journal of Evaluation in Clinical Practice
International Journal of Public Health Policy and Health Services Research

ORIGINAL ARTICLE

Surgical glue in laparoscopic sleeve gastrectomy: An initial experience and cost-effectiveness analysis

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Abstract

Rationale, aims, and objectives Laparoscopic sleeve gastrectomy (LSG) is one of the most common bariatric procedures. Gastric leaks and bleeding are the most frequent complications, associated with a high clinical and economic burden. The best method of staple line reinforcement in LSG is debated. Surgical glue is one of the options available. The aim of this study was to assess the safety, efficiency, and relative cost-effectiveness of surgical glue used to perform LSG in morbid obese adults as compared with standard stapling.

Methods A prospective, observational, and comparative before-after study was conducted. All consecutive patients undergoing LSG at Montpellier University Hospital in 2011 and 2012 were included and treated according to 2 groups: standard stapling (n = 99, group 1) and surgical glue reinforcement (n = 94, group 2). Clinical and economic outcomes were measured after 6 months.

Results The duration of intervention was significantly shorter in group 2 (68 vs 82 minutes, P = .001). There was no significant difference regarding complications, but leaks in group 1 were more severe. Group 2 was also associated with a reduced initial length of stay (4.8 vs 5.2 days, P = .01). Six-month readmissions and total length of stay were also shorter in group 2 (5.5 vs 6.1 days, P = .003). Surgical glue use was associated with a significant reduction in the initial inpatient cost (€5488 vs €6152, P = .005) and in the 6-month total inpatient cost, including readmissions (€6006 vs €6754, P = .005). The incremental cost of glue to avoid a severe complication was −€5446.33 (95 confidence interval, −8202.01 to −2690.66).

Conclusions Surgical glue might be a safe and cost-effective intervention in laparoscopic sleeve gastrectomy.

KEYWORDS

bariatric surgery, cost, effectiveness, glue, obesity, sleeve

1 | INTRODUCTION

There is increasing evidence that health of obese persons with different comorbidities, including metabolic control of diabetes and its associated risk factors, can benefit substantially from bariatric surgery.[1,2] Laparoscopic sleeve gastrectomy (LSG) is currently the most common restrictive method in France. Gastric leaks and staple line bleeding are the most frequent short-term complications and have a significant clinical and economic burden.[3]

By means of their adhesive and hemostatic functions, surgical glues may decrease the risk of leaks and hemorrhages after digestive surgery. Furthermore, in the current setting of resource constraint prevailing in most countries, information about the relative costs and effectiveness of interventions is of utmost importance both for hospitals and for third party payers.[4]

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Data regarding direct and prospective evaluation of surgical glue versus standard stapling in LSG as well as its effectiveness in the field are lacking.

The aim of this study was to evaluate the use of surgical glue IFABOND® (Vitalitec, Plymouth, Massachusetts) in LSG in morbid obese adults in terms of safety, efficiency, and reduction of surgical complications and also to assess its relative costs and effectiveness in this setting.

2 | METHODS

2.1 | Setting

The study was conducted at Montpellier University Hospital (CHU de Montpellier), France. Inpatient care is financed through a prospective payment system based on a diagnosis-related group (DRG).[5,6] This system was introduced in France since 2004 and is a standardization of payment rates. All medical devices such as surgical glues are included in DRG tariffs.

2.2 | Study design

A prospective, monocentric, observational, and comparative study was conducted following the STROBE guidelines.[7] This design was chosen to assess the effect of surgical glue IFABOND® in routine clinical management using an observational methodology and to avoid trial-related costs and behavioral changes. All consecutive patients admitted to the bariatric surgery department of Montpellier University Hospital for an LSG have been included in the study.

During the first period (standard stapling phase, from January 2011 to December 2011), LSG was performed according to a standard technique without surgical glue (group 1). A 2-week transitional period was organized between the periods. During the second period (surgical glue phase, from January 2012 to December 2012), LSG was performed with surgical glue application after standard stapling (group 2). No other staple line reinforcement was used for neither of the groups.

Patients were followed up during 6 months after intervention.

We have to emphasize that our team has been performing LSG since 2005, so that no learning period should affect the results of our study.

2.3 | Study population

Because of the absence of published data on the expected effect of surgical glue on costs, we were not able to perform an a priori sample size calculation. Thus, we decided to include all consecutive patients during a 2-year period. Given the observational design of the study, the French law did require neither individual informed consent nor institutional review board approval.

Inclusion criteria:

- Morbid obesity (body mass index [BMI] >40 kg/m^2) or severe obesity (BMI >35 kg/m^2) associated to comorbidities (type 2 diabetes, sleep apnea syndrome, arterial hypertension)
- Indication for LSG after multidisciplinary evaluation
- 18 years and older

Exclusion criteria

- Perioperative complication other than bleeding and leak
- Lost at follow-up

2.4 | Interventions

All operations were performed laparoscopically under general anesthesia using the French position (legs abducted with the surgeon standing between the patient's legs). Each procedure required 5 trocars. Pneumoperitoneum was induced by primary trocar insertion at the ombilicus (Hasson technique) and maintained at a pressure of 15 mm Hg. Dissection began on the greater curvature, 5 cm from the pylorus. The gastrocolic ligament along the greater curvature of the stomach was opened using an impedance coagulator Ultracision® (Ethicon Endo-surgery; Johnson-Johnson Inc. 2010, USA) and was freed as far as the cardio esophageal junction at the root of the left pillar of the hiatus. The short gastric vessels close to the spleen were carefully coagulated separately. A calibration tube 37-F, Midsleeve® (Medical Innovation Development, Dardilly, France) was then inserted transorally into the stomach by the anesthesiologist and was directed toward the antrum, and then 50 mL of saline was inserted in the distal balloon to define the beginning of the staple line. A laparoscopic linear stapler (Echelon®, gold cartridges; Ethicon Endo-surgery, Johnson-Johnson Inc. 2010) was introduced into the peritoneal cavity and was positioned so that it divided the stomach parallel to the orogastric tube along the lesser curvature. The instrument was fired and reloaded, and the maneuver was repeated; a maximum of 7 gold cartridges were used to staple the antrum, the body, and the fundus of the stomach. Active bleeding at the level of the staple line was controlled with bipolar cautery or single suture in both groups, and then 1.5 mL (1 full drop) of glue was added to totally cover the staple line with gastrocolic and gastrosplenic ligament in the group 2, with the intention of preventing postoperative bleeding and leak.

IFABOND® Glue (Vitalitec) is a laparoscopic surgical glue with delivery device. A pure cyanoacrylate is applied using a fully disposable device. It is easy to assemble and is a straight forward application with no learning curve required. This glue will only polymerize when in contact with the tissue, minimizing waste).

2.5 | Outcomes and data sources

Baseline characteristics included age, gender, weight, and BMI. Duration of operation, length of stay, postoperative morbidity (leaks, abscesses, hemorrhages, or hematomas), reoperation during initial stay, and rehospitalization at 6 months were assessed. The severity of gastric leaks was assessed using a CT scan–based classification in 4 stages: type I being the less severe one, with a collection of <5 cm on upper left quadrant on CT scan; type II correspond to a collection >5 cm; type III is a leakage with diffuse abdominal collections; and type IV is the one associated with pleural collections.[8] Weight loss at

6 months was expressed using change in BMI, percentage of excess weight loss (%EWL, with the calculation of ideal body weight as that equivalent to a BMI of 25 kg/m^2), and percentage of total weight loss. Duration of operation was defined as the time between incision and closure. Only rehospitalizations due to postoperative complications were included during the 6-month follow-up period.

Demographic and clinical data were recorded prospectively using a standardized case report form. Complications and reoperations were assessed through a systematic review of patients' electronic medical records and hospital discharge database.

2.6 | Economic analysis

Economic analysis was performed according to French and international reporting guidelines evaluating direct medical costs during 6 months from the initial intervention.[9,10]

Direct medical costs were evaluated from a hospital perspective during 6 months from the initial intervention. Indeed, surgical glue is not expected to have any effect on resource consumption beyond that point. Costs were not discounted given the shortness of the follow-up. All costs are expressed hereafter in 2013 euros.

Resource consumption was assessed prospectively using the standardized case report form, the electronic medical records, and the computerized operating room register, including duration of operation. Outpatient care was not considered because it amounts to less than 1% of the total cost of complicated sleeve gastrectomies.[3] Resource units were then valued using bottom-up microcosting at patient level. Regarding the extra operating room costs, 4 categories of expenses were considered: staff, drugs and medical equipment, laboratory and radiology, and overheads (ie, supplies, taxes, insurance, utilities, and loan interest). The cost of the surgical glue (ie, €100) was included in the "drugs and medical equipment" category. Operating room costs (including staff) were assessed separately. Operating room expenses were assigned proportionally to the actual duration of operation, while extra operating expenses were allocated proportionally to the length of stay. In total, 2 direct medical costs were computed: the cost of the initial stay and the total inpatient cost, which included rehospitalizations.

2.7 | Statistical analysis

Baseline characteristics, clinical outcomes, direct medical costs, and lengths of stay were compared between both periods using standard univariate statistical tests taking into account distributions. An incremental cost-effectiveness ratio (ICER) was calculated using the rate of follow-up without severe complication (leak or abscess) as the efficacy endpoint. This ICER is interpreted as the mean cost to avoid a severe complication. The 95% confidence interval of the ICER was estimated using bootstrap with 5000 replicates. The significance threshold was set at 5% for all statistical tests. The analysis was carried out at the Medical Information Department of Montpellier University Hospital using the SAS software (SAS Institute, Cary, North Carolina).

3 | RESULTS

In total, 193 patients were included in the study: 99 during the standard stapling period (group 1) and 94 during the surgical glue period(group 2). Baseline characteristics were similar across groups (Table 1): 74% women; mean (SD) age, 44 (13) years; and mean (SD) initial BMI, 43 (8) kg/m^2.

All patients were available for the 6-month follow-up, and during this period, 15 patients (7.8%) experienced at least 1 postoperative morbidity (Table 2), including 6 gastric leaks, 4 abscesses, and 7 hematomas. The severity of gastric leaks seems to be lower in group 2: 2 patients experienced a type I leak. By contrast, 1 patient experienced a type I leak and 3 patients experienced a type II leak in group 1. Five patients underwent blood transfusion. Although there were less gastric leaks and more hematomas in group 2, the differences were not statistically significant. The rates of reoperation during initial stay (4% in group 2 vs 3% in group 1, P = .72) and of rehospitalization (5% in group 2 vs 8% in group 1) did not significantly differ across groups. The six-month mean (SD) EWL in groups 2 and 1 were 55% (22%) and 57% (25%), respectively (P = .53).

The duration of intervention was significantly shorter in group 2, as shown in Table 3, mean (SD), 82 (32) vs 68 (28) minutes, P = .001. Taking into account 6-month rehospitalizations, the total length of stay remained shorter in group 2, 6.1 (4.8) vs 5.5 (4.4) days, P = .003. Surgical glue (group 2) was associated with a significant reduction in the initial inpatient cost, €6152 (€1884) vs €5488 (€1559), P = .005, and in the 6-month total inpatient cost, including rehospitalizations, €6754 (€3899) vs €6006 (€3090), P = .005. The reduction in the inpatient initial cost was mainly explained by a reduction in the operating room cost, €2924 (€1096) vs €2407 (€929), P = .001, and in the staff cost, €1644 (€527) vs €1522 (€500), P = .002.

In total, 97% of patients were free of leak and abscess in group 2 as compared with 94% in group 1 (P = .49). The ICER was equal to −€5446.33 per additional patient without any severe complication (bootstrap 95% confidence interval, −8202.01 to −2690.66) (Figure 1).

TABLE 1 Baseline characteristics

	Group 1(n = 99)	Group 2 (n = 94)	*P*
Age, mean (SD), y	42 (13)	46 (13)	.05
Female/male, n (%)	69 (70)/30 (30)	73 (78)/21 (22)	.20
Weight, mean (SD), kg	120 (22)	114 (17)	.11
Excess weight, mean (SD), kg	51 (19)	46 (15)	.10
BMI, mean (SD), kg/m^2	43 (7)	42 (6)	.24

BMI indicates body mass index.

TABLE 2 Comparison of clinical outcomes at 6 months

	Group 1 (n = 99)	Group 2 (n = 94)	*P*
Postoperative morbidity, n (%)[a]	7 (7)	8 (9)	.71
Abscess	3 (3)	1 (1)	.62
Hematoma	2 (2)	5 (5)	.27
Leak	4 (4)	2 (2)	.68
Leak severity			
Type I (less severe)	1	2	
Type II (more severe)	3	0	
Free of leak and abscess, n (%)	93 (94)	91 (97)	.49
Blood transfusion, n (%)	2 (2)	3 (3)	.68
TWL, mean (SD), %	23 (9)	21 (7)	.23
BMI change, mean (SD), kg/m^2	−9.5 (3.9)	−8.8 (2.8)	.20
EWL, mean (SD), %	57 (25)	55 (22)	.53
Reoperation during initial stay, n (%)	3 (3)	4 (4)	.72
Rehospitalization, n (%)	8 (8)	5 (5)	.57

BMI indicates body mass index; TWL, total weight loss; EWL, excess weight loss.

[a]Patients might have several postoperative morbidities.

TABLE 3 Comparison of resource consumption and direct medical costs

	Group 1 (n = 99)	Group 2 (n = 94)	*P*
Duration of operation, mean (SD), min	82 (32)	68 (28)	.001
Initial length of stay, mean (SD), d	5.2 (1.7)	4.8 (1.6)	.005
Total length of stay, mean (SD), d	6.1 (4.8)	5.5 (4.4)	.003
Cost of initial stay, mean (SD), €			
Operating room	2924 (1096)	2407 (929)	.001
Staff	1644 (527)	1522 (500)	.002
Drugs and devices	357 (243)	377 (146)	.002
Lab and radiology	253 (142)	251 (151)	.8
Overheads	974 (325)	931 (276)	.1
Total	6152 (1884)	5488 (1559)	.005
Cost of rehospitalization[a], mean (SD), €	8969 (8435)	8725 (5205)	.41
Total inpatient cost, mean (SD), €	6754 (3899)	6006 (3090)	.005

[a]Average values for 8 rehospitalizations in the standard stapling group and 5 in the surgical glue group.

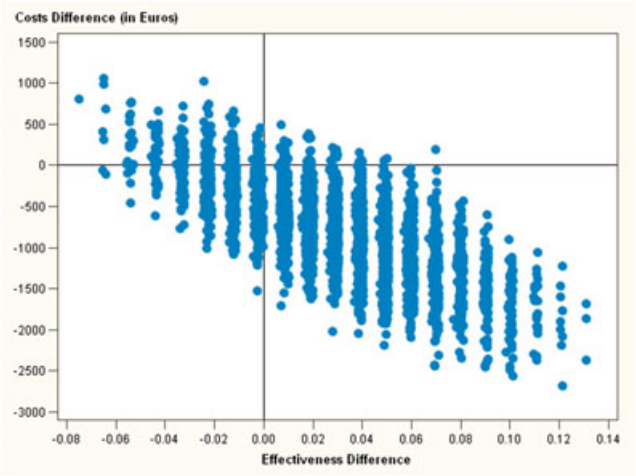

FIGURE 1 Bootstrap replications of the cost and effectiveness differences

4 | DISCUSSION

Staple line reinforcement, especially for bariatric surgery, is a topic of debate and growing interest. Several strategies, including the use of glue, have been used to prevent and decrease complications and also to manage them when they occur.[11–14]

This observational comparative study suggests that using surgical glue during LSG is associated with a reduced duration of operation and a reduced inpatient total cost. The average cost to avoid a severe complication with the glue is significantly negative. The surgical glue is associated with both a lower inpatient cost and a decreased risk of severe complication.

Also statistically significant is the difference in length of stay. Initial and total lengths of stay were lower in the glue group. No significant effect on EWL, postoperative morbidity, rehospitalization, and reoperation has been demonstrated. The reduction in the inpatient

total cost can be explained by 3 factors. First, the lower rate of postoperative leaks in the Ifabond® group might translate into a shorter hospital stay. Second, an easier management of intraoperative bleedings might explain the significantly shorter operating room time in this group. Nevertheless, we were not able to track the amount of operating time related to the management of intraoperative bleedings. Additional research should be conducted on this topic. Finally, the readmission rate tended to be lower in the Ifabond ® group, although not significantly. This might be a consequence of the lower rate of postoperative leaks in this group.

Our technique consists of performing a much narrowed sleeve for a 37-F tube. The overall leak rate of 3.2% is within the 1% to 4% reported rate in the literature.[15] Ifabond® surgical glue might be associated with less severe gastric leaks. Three of the 4 leaks in control group were considered more severe, with an increased diameter of the abscess. These might be a positive and logical effect of the use of surgical glue reducing the severity of gastric leaks by quickly isolating the leak from the abdominal cavity. This might translate into easier postoperative management and to a reduced length of stay.

All the strategies that may decrease the degree of complications of sleeve complications should be considered, despite an apparently initial higher cost. Readmissions and especially prolonged hospital stays in ICU or even in the ward are the most expensive drawbacks in the healing process of sleeve bleedings and fistulas.[3]

Microcosting, bottom-up, and top-down are health economics concepts. The microcosting analysis was used because it is more detailed than the gross costing and includes all relevant costs. The choice of bottom-up was because it is considered to be more accurate and relevant than top-down microcosting regarding labor-intensive services, including surgery, because it accounts for individual variations and not just an average of patients costs.[16,17]

The economic analysis suggests that surgical glue might be an efficient complement in the technique of surgical management of morbid obesity.

4.1 | Limitations

First limitation is sample size that seems not sufficient for the clinical end points. The absence of other significant clinical effect may be due to the number of patients involved. It is known that a huge number of patients is necessary to prove a real benefit in the use of whatever maneuver or biomaterial applied to the staple line to reduce the incidence of fistula.[18,19] However, we were not able to include more patients due to the monocentric design of the study. The nonrandomized study design might be prone to confusing and information bias. For instance, surgeons might have managed patients differently in the second period because they were aware of the ongoing study (performance bias). However, the 2 groups of patients are comparable. Still, there is no obvious reason why these differences might have explained the results. Another shortfall of before-after comparisons is that the observed effect might be explained by organizational or technological changes unrelated to the intervention. However, the short duration of the study (2 years) makes it unlikely. Regarding the economic analysis, we did not look at variation in outpatient costs. However, the cost of outpatient care is likely to be negligible, and surgical glue had no significant effect on postoperative complications. Because the study was monocentric, the generalizability of its results might suffer from different organizational features in other settings. Nevertheless, the stapling technique is widespread and is the current standard of practice worldwide. Lastly, the absence of statistically significant difference regarding the frequency and severity of gastric leaks might be due to a lack of power. A large multicenter study could address this issue.

4.2 | Strengths

This study combines a 6-month clinical follow-up and a comprehensive economic evaluation. The nonexperimental design has several advantages. First, a pragmatic study accurately reflects the management of obese patients in daily practice. Second, it prevents the issue of trial-related costs which might lead to biased cost estimates.[20]

5 | CONCLUSIONS

This study suggests that IFABOND® surgical glue is a safe and effective complement to the technique of LSG. It is also associated to a decrease in total length of stay that economically justifies its routine use.

ACKNOWLEDGMENTS

The authors are grateful to Guillaume Bourel (Department d'Information Médicale, CHU de Montpellier, Montpellier, France) who reviewed the economic analysis.

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How to cite this article: Mercier G, Loureiro M, Georgescu V, Skalli EM, Nedelcu M, Ramadan M, Fabre JM, Lefebvre P, Nocca D. Surgical glue in laparoscopic sleeve gastrectomy: an initial experience and cost-effectiveness analysis. *J Eval Clin Pract*. 2017. https://doi.org/10.1111/jep.12685