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Lionel Rebibo MD[1, 2], Meghane Tricot MD[3], Jeanne Dembinski MD[3], Abdennaceur Dhahri MD[3], Franck Brazier MD[4], and Jean-Marc Regimbeau MD, PhD[3, 5].

1. Department of Digestive, Esogastric, and Bariatric Surgery, Bichat Claude Bernard University Hospital, 46 rue Henri Huchard, F-75018 Paris, France
2. Université de Paris, Inserm UMR 1149 F-75018 Paris, France
3. Department of Digestive Surgery, Amiens University Medical Center, 1 Rond-Point du Professeur Christian Cabrol, 80054 Amiens Cedex 1
4. Department of Hepato-Gastroenterology, Amiens University Medical Center, 1 Rond-Point du Professeur Christian Cabrol, 80054 Amiens Cedex 1
5. SSPC (Simplification of Surgical Patient Care) - Clinical Research Unit, University of Picardie Jules Verne, 80054 Amiens Cedex 01, France.

Short Title: Gastric leak after sleeve gastrectomy

Correspondance :

Professor J.-M. Regimbeau

Service de Chirurgie digestive, CHU Amiens-Picardie, Site Sud, 1 Rond-Point du Professeur Christian Cabrol, 80054 Amiens Cedex 1

Phone: +33 322 668 301

Fax: +33 322 668 680

E-mail: regimbeau.jean-marc@chu-amiens.fr

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Abbreviations: sleeve gastrectomy (SG), gastric leak (GL), coated stent (CS), double pigtail stent (DPS), post-operative day (POD), body mass index (BMI)

ABSTRACT

Background. Gastric leak (GL) is the most highly feared early postoperative complication after sleeve gastrectomy (SG), with an incidence of 1 to 2%. This complication may require further surgery/endoscopy, with a risk of management failure that may require additional surgery, including total gastrectomy, leading to a risk of mortality of 0 to 9%.

Objectives. Assess the impact of factors that may lead to a poorer evolution of GL.

Setting. University Hospital, France, public practice.

Methods. This was a retrospective, single-center study of a group of patients managed for GL after SG between November 2004 and January 2019 (n = 166). Forty three patients were excluded. The population study was divided into two groups: patients with easy closing of the GL (n=73) and patients with difficult closing of the GL or failure to heal (n=50). Patients were allocated to one of the two groups depending on the time to heal (median time of 84 days). The study's primary efficacy endpoint was to determine the risk factors for a poorer evolution of GL.

Results. Among 123 patients included in this study, 103 patients had undergone primary SG (83.7%). The mean time to the appearance of GL was 15.1 days (1-156). Seventy-four patients underwent a reoperation (60%). The mean number of endoscopies per patient was 2.7 (2-7). The mean time to healing was 89.5 days (18-386). There were eight cases of healing failure (6.5%). Multivariate analysis identified body mass index (>47kg/m^2), time to referral (>2 days), and serum pre-albumin level (<0.1g/dl) to be independent risk factors for a poorer evolution of GL.

Conclusion. Improvement of the nutritional status prior to SG and early referral for GL could reduce the risk of delayed closure or the need for further surgery.

Key words: sleeve gastrectomy; gastric leak; double pigtail stent; gastric fistula.

INTRODUCTION

Gastric leak (GL) is only one of the major surgical postoperative complications of sleeve gastrectomy (SG), but it is the most feared. The incidence of GL has decreased over time [1] due to improvements in the SG technique and a better knowledge of the mechanisms responsible [2].

GL is a complication that is difficult to manage and may require complex or radical additional surgical procedures for chronic fistula [3, 4]. Following SG, there is also a risk of complicated GL, such as gastrobronchial fistula [5] and pseudoaneurysms [6]. The reported risk of mortality for GL after SG ranges from 0 to 9%, depending on the series [7-9]. The prognosis of GL after SG has gradually improved due to the emergence of new endoscopic techniques, in particular, double pigtail stents (DPSs) [10-12], an implementation algorithm for surgical and endoscopic management, and, especially, better classification of GL, making it possible to propose revisional surgery to reduce the morbidity risk of GL in certain cases [13].

Although many risk factors for GL after SG have been reported [14-16], no risk factors for a poorer evolution of GL have been described. This is probably due to the fact that most published studies of post-SG GL have concerned small (n < 65) groups of patients [17-19], without standardized management of GL. Currently, few studies with large series have analyzed the results of GL management after SG.

We aimed to assess the impact of factors that could lead to a poorer evolution of GL after SG in a large single-center study.

MATERIALS AND METHODS

Population

We performed a retrospective analysis of prospectively gathered data on a group of patients managed for GL after SG (primary and secondary SG) over a 15 year-period (between November 2004 and January 2019). Based on our database, at least seven papers have been published that include at least some of the data of these patients.

Inclusion criteria

Patients included in the study had to meet the following criteria: post-SG GL visualized during an abdominal CT scan, endoscopy, or surgery [13], and a complete set of data during management of the GL.

Exclusion criteria

Patients who underwent bariatric procedures other than SG were excluded from the study. In addition, the first 20 patients of our series were excluded because of the beginning of our experience in managing GL after SG and non-standardized management, as well as patients with GL on a distal part of the SG (because the management of GL in this case is different [**20**]), patients referred to our center for the management of gastrobronchial fistula and/or chronic GL requiring revisional surgery, patients refereed to our center too long after the diagnosis of GL (≥ 50 days from the diagnosis of GL, because such a long time since the diagnosis could have biased the results), and patients who died prematurely without the possibility of performing endoscopic treatment. However, patients with a GL orifice (measuring more than 2 cm in diameter) and/or stenosis associated with GL were not excluded from our study.

Group selection

The population study was divided into two groups: the first group included patients with easy-closing GL, the "easy" GL (eGL) group, and the second, patients with difficult-closing GL or GL that failed to heal (appearance of a gastropulmonary fistula or pseudo aneurysm), the "hard" GL (hGL) group. Patients were allocated to one of the two groups depending on the time it took the GL to heal from its discovery. According to a previous publication, the median time for a GL to heal from its discovery is 84 days [13]. Thus, the eGL group included patients for whom the GL healed before the 85^{th} day after its discovery, whereas the hGL group included patients for whom the GL healed after the 84^{th} day following its discovery, as well as patients for whom the GL did not heal or those with complications related to GL.

Definition of GL

The presentation, time to onset, and staple line site of GL were classified according to the modified UK Surgical Infection Study Group definitions [21, 22]. The patient's clinical presentation was further described in terms of systemic signs of inflammation (tachycardia (> 100 bpm) and hyperthermia (> 38°C)), peritonitis (diffuse abdominal tenderness), pulmonary symptoms (cough and expectoration), and intra-abdominal abscess (localized abdominal tenderness). The time to onset after SG was used to differentiate between early-onset GL (from post-operative day (POD) 1 to 7) and delayed-onset GL (≥ POD 8). The definition for early- vs. delayed-onset GL was decided based on our experience with GL [10]. We used oral-contrast-enhanced abdominal computed tomography (CT) and/or upper gastrointestinal endoscopy to determine the site of leakage along the staple line.

Management of GL

All cases of post-SG GL were discussed in a multidisciplinary staff meeting that included bariatric surgeons, a radiologist, an endoscopist, and an intensive care physician. This allowed us to develop a protocol for the standardized management of post-SG GL (**Figure 1**) based on leak-related data and the patient's clinical status [10, 23].

<u>Management of early-onset or poorly tolerated GLs</u>

Our reoperation procedures for GL have been described in detail elsewhere [23]. For cases of early-onset (≤ POD 7), poorly tolerated GL, open surgery consisted of sample collection for bacteriological and yeast cultures [24], washing of the abdominal cavity, suturing of the orifice of the leak (if possible, and depending on intra-operative local conditions), drainage of the GL (with two drains for post-operative irrigation and drainage), and implementation of a feeding jejunostomy. Laparoscopy was performed for early-onset, well-tolerated GLs.

Management of delayed-onset, well-tolerated GLs and after reoperation

Endoscopy was performed by gastroenterologists with extensive experience in the management of post-operative complications.

For cases of GL requiring an immediate reoperation, an oral-contrast-enhanced abdominal CT scan was performed six days after reoperation (to check that the GL was well drained before endoscopy). Endoscopic treatment was performed seven days after reoperation (the day after oral-contrast-enhanced abdominal CT scan). In cases of delayed (POD > 7), well-tolerated GL (not requiring reoperation), endoscopy was performed on the day that the leak was discovered.

Stents, either a CS (Hanarostent®, Life Partners Europe, Bagnolet, France) or DPS (Zimmon® Biliary Stent, Cook Ireland Ltd, Limerick, Ireland), depending on the case, were implanted with radiological guidance.

During the study period, we changed our endoscopic procedures for GL treatment. Before 2008, we used CSs. From 2008 onwards, we progressively abandoned CSs in favor of DPSs to drain the GL inside the stomach [10]. Based on our increasing experience of managing GL, endoscopic treatment sometimes required combining CS and DPS placement for GL associated with stenosis below the leak orifice and/or large gastric leak orifice (measuring over than 2 cm diameter) [25]. Patients were allowed to drink water after stent implantation and thus wash the GL.

An oral-contrast-enhanced abdominal CT scan was performed three to four weeks after implantation of a CS or six weeks after implantation of a DPS. Endoscopy was performed the day after the abdominal CT scan to remove (if the GL had healed) or change the stent (if the GL had not healed).

Definition of GL healing

In our multidisciplinary staff meeting, healing of a GL was defined as the resumption of oral feeding in the absence of (i) surgical drainage or endoscopic stenting, (ii) flow through a previous surgical drainage path (e.g. a gastrocutaneous fistula), and (iii) collections near the staple line site on an abdominal CT scan (whether contrast-enhanced or not).

Endpoints and data recorded

The primary efficacy endpoint of the study was to determine risk factors for adverse outcomes of GL after SG. Hence, the following data were recorded:

- Patient and preoperative data: age, gender, body mass index (BMI), and comorbidities (diabetes mellitus, hypertension, dyslipidemia, and OSAS).
- Operative data: type of SG performed (history of gastric banding, repeat-SG) and the frequency of SG performed in another institution.
- GL data: time interval between surgery and GL (early-onset GL vs. delayed-onset GL), GL requiring reoperation (at the initial center, at the referral center, or both), time interval between the diagnosis of GL and transfer to the referral center, type of reoperation (laparoscopy and/or laparotomy).
- Endoscopic data: type of GL, type of stent used, alternative used of a different stent, number of endoscopies performed.

- Biological data at the discovery of GL: white blood cell count and C-reactive-protein and serum-creatinine levels.
- Nutrition data: type of nutrition, serum albumin and serum pre-albumin levels at the time of GL diagnosis.
- Hospitalization data: overall length of hospital stay, rate of admission to the intensive care unit (ICU), and length of stay in the ICU.
- Overall management: success rate of GL healing, time to heal, type of GL complication.

Statistical analysis

The patients' baseline characteristics are expressed as the means ± standard deviation (SD) and medians (interquartile range) for continuous data and as numbers (frequency) for categorical data. Intergroup comparisons of quantitative variables were performed using Student's t-test, whereas intergroup comparisons of qualitative variables (including the primary endpoint) were performed using a chi-squared test with Yates' correction, if required. The threshold for statistical significance was set to $p \leq 0.05$.

Risk factors for a poorer evolution of GL after SG were identified using univariate and multivariate analyses with backward stepwise selection. Variables with a p value < 0.15 were included in a multivariable regression model.

All statistical analyses were performed using STATA software (Stata/IC 15.1, TX, USA).

RESULTS

Population of the study

During the study period, 166 patients were managed in our institution for GL after the SG procedure. The first 20 patients from this population were excluded, as well as six because they were referred to our institution more than 50 days after the discovery of GL, four for the management of gastro-bronchial fistula, and four for the surgical management of chronic GL requiring revisional surgery. In addition, four were excluded because of incomplete data, four because the GL was repaired using sutures of the GL only, without the need for further endoscopy, and one because of early death (the day of admission) (**Figure 2**). Finally, our study population included 123 patients, divided between 73 in the eGL group and 50 in the hGL group.

Demographic data (Table 1 & 2)

The mean (range) age of the study population was 37.1 years (19 - 68) and the mean BMI 42.7 kg/m^2 (28.7 – 62.5). There were 94 women (76.5%). Pre-operative comorbidities were diabetes mellitus in 13% of cases (n = 16), hypertension in 22.8% (n =28), dyslipidemia in 18.7% (n = 23), and obstructive sleep apnea in 23.5% (n = 29). Nineteen patients (15.4%) had a BMI $\geq$ 50 kg/m^2. Most (103) patients had undergone primary SG (83.7%), whereas the remainder had undergone revisional SG. The initial surgery was performed in another institution for 65.8% (n = 81). The only significant difference concerning the demographic data between the two groups was the mean BMI, with a lower BMI in the eGL group (42 kg/m^2 vs. 44.4 kg/m^2, p = 0.02) (**Table 1**).

Gastric leak data

The mean time to the appearance of post-SG GL was 15.1 days (1 - 156).

<u>Clinical data</u>

Fifty-three patients had early-onset GL (43%), whereas the others had delayed-onset GL. More patients in the hGL group had early-onset GL (54 vs. 35.6%, p = 0.04). The frequency of hypovolemic shock was 19.5% at admission in our institution, with a higher frequency in the hGL group (30 vs. 12.3%, p = 0.02). The rate of ICU admission was similar between the two groups (**Table 3**).

Biological data

At admission in our institution, the mean white blood cell count was 13,785 (3,900 – 32,400), mean C reactive protein 217 (25 - 472), mean serum creatinine 67.1 (29-158), mean serum pre-albumin 0.1 (0.03 - 0.37), and mean serum albumin 25 (12 - 42.7). Patients in the hGL group had higher mean serum creatinine levels and lower normal serum pre-albumin and albumin levels (**Table 4**).

Surgical management for GL

Seventy-four patients underwent a reoperation (60%), laparoscopic surgery was performed in 46 cases (62.2%), and the fistulous orifice was sutured in 19 (25.6%). Feeding jejunostomy was performed on 63 patients. Eight patients (6.5%) underwent primary radiological drainage as an alternative to surgery. There were significantly fewer reoperations for GL in the eGL group (48 vs. 78%, p < 0.001) and less implementation of feeding jejunostomy as a method for renutrition (41 vs. 66%, p = 0.01) (**Table 5**).

Among patients referred for the management of GL (n = 81), there were more reoperations in the hGL group (62.8 vs. 34.7%, p = 0.01) and the mean time for referral was higher (7.7 vs. 3 days, p = 0.007) (**Table 6**).

Endoscopic management

The mean time interval between the diagnosis of GL and first endoscopy was 10.1 days (0 - 48). The mean number of endoscopies per patient was 2.7 (2 - 7). Most endoscopies showed classical GL (73.2%, n = 90), whereas other endoscopies showed associated gastric stenosis in 5.7% (n = 7) and large GL in 21.1% (n = 26) of patients. Most GLs were treated using a DPS only in 70% of cases (n = 86), whereas the use of a CS only was required in 3.2% of cases and alternative use of CS and DPS in 26.8% of cases (n = 33). The combined use of CS and DPS was required for 18 cases (14.6%).

The mean time interval between the discovery of GL and first endoscopy was longer in the hGL group (14 vs. 7.6 days, $p < 0.001$). The frequency of classical GL was higher in the eGL group (83.5 vs. 58%, $p = 0.002$). Finally, more endoscopies were performed for the hGL group, with less use of a DPS only and a greater need for the use of a DPS and CS (T**able 7**).

Outcomes

The mean duration of hospitalization from the diagnosis of GL was 19.7 days (2 – 86). The mean time for the GL to heal was 89.5 days (18-386). There were eight cases of failure to heal (6.5%), including three patients who developed gastro-bronchial fistula (2.4%), requiring revisional surgery, and five (4.0%) who required revisional surgery for chronic GL. There was no mortality in this study population.

Multivariate analysis

All variables with $p < 0.15$ in the univariate analysis were included in a multivariate analysis. Multivariate logistic regression modeling identified a BMI > 47 kg/m^2 (OR = 0.90; 95% CI, 0.84-0.97; $p = 0.008$), time to referral > 2 days (OR = 0.92; 95% CI, 0.86-0.98; $p = 0.01$), and a serum pre-albumin level < 0.1 g/dl (OR = 1.64; 95% CI, 1.13-2.37; $p = 0.04$) to be independent risk factors for a poorer evolution of GL after SG (**Table 8**).

DISCUSSION

This series provides important information, as it was a single-center study with the largest population yet studied, making it possible to not only to show the results of GL management but also to search for risk factors for a poorer evolution of GL. Our mortality rate in the management of GL after SG is low, with a rate of 0.6% (1 of 166). The mean time to the appearance/diagnosis of post-SG GL was 15.1 days in our population. Faced with GL, most patients underwent a reoperation (60%) and the mean number of endoscopies performed for managing GL was 2.7 per patient. Although our series showed good outcomes, with 93.5% of patients cured without the need for revisional surgery, initial management required a length of hospitalization of nearly 20 days and the mean time to heal was 89.5 days, showing that this complication must be taken seriously. Maybe that some patient undergoing reoperation could have rather a radiological drainage rather than a reoperation [26], but in our experience radiological drainage is difficult to achieve due to location of the GL.

Our mortality rate was zero, due to our exclusion criteria in this study, versus a mortality rate of 1.2% in one of our previous publications [13]. However, despite our good results in terms of mortality rate, it must not be forgotten that GL is a life-threatening complication, with a mortality rate of 9.7% in a recent review of the literature [27], and that some patients require revisional surgery, as in our series, possibly leading to total gastrectomy and/or splenectomy in some cases [3].

Complete healing of GL without the need for revisional surgery was achieved in 93.5% of the cases in our series, with a mean time to heal of 89.5 days (18-386). In their five-year retrospective analysis of 73 cases (2012 to 2017), Bashah et al. [28] reported impressive results, with a mean time to heal of 8.8 weeks and a success rate of endoscopic treatment of 97.1%, with only two patients requiring fistula-jejunostomy. In a previous publication, our mean time to heal was 111 days [13], higher than that for our current series and probably linked to the fact the first series included all patients managed for GL since 2004, whereas we excluded patients managed during our learning curve of managing patients with GL for the current series.

In addition, our management of GL has improved over the years. At the beginning, we used only CSs and then progressively switched to DPSs [10]. This resulted in better results than those for patients managed using CSs only, as well as better tolerance of this type of prosthesis, along with simpler management, ultimately reducing the initial length of the hospital stay. The eGL group had more patients for whom only DPSs were used than the hGL group (**Table 7**), although we failed to show a significant difference in our multivariate analysis. Nonetheless, even with DPSs, our goal of 100% resolution, without the need for revisional surgery, was far from being achieved, probably due to the fact that some cases of GL had associated stenosis (or a twist). Thus, although the DPS has become the gold standard for the endoscopic management of GL, it is not effective in certain cases. We therefore developed an endoscopic treatment algorithm based on endoscopic findings, with the objective to provide "à la carte" treatment [13]. This probably explains the difference between our results and those on other series evaluating DPS, such as the metanalysis of Giuliani et al. [29], showing that the overall success rate of endoscopic closure of GL was 83.4% for 681 patients, with a mean time to heal of 118.1 days.

Our large series allowed us to search for risk factors for the poor evolution of conservative management. Univariate analysis identified many risk factors, such as the type of GL (early vs. delayed), hypovolemic shock (**Table 3**), and certain biological parameters, such as mean serum creatine and lower pre-albumin and albumin levels in the hGL group. This could be explained by the fact that hypovolemic shock required ICU management with increased need for protein. And so, these patients are probably more undernourished than patient without major sepsis explaining lower pre-albumin and albumin levels. Also, most cases of patient with hypovolemic shock concern acute presentation of the GL. These patients had delayed access to endoscopy and thus prolongated abdominal drainage explaining the difficulty of healing a fistula in the process of organization rather than a leak. After multivariate analysis, three statistically significant risk factors for a poorer evolution of GL remained: a BMI > 47 kg/m^2, a time to referral > 2 days, and a serum pre-albumin level < 0.1 g/dl. These findings are important, as two of these three factors are alterable. The serum pre-albumin concentration can be changed by optimizing the pre-operative nutritional status before SG, as many patients are probably malnourished before bariatric surgery [30]. Furthermore, the management of GL requires early refeeding, preferentially via an enteral route (nasojejunal tube or feeding jejunostomy). Our series also further strengthens the argument for centralizing the management of complications, as previously demonstrated by Caiaizzo et al. [31]. Our series showed that delayed referral was associated with a poorer evolution of GL. Thus, early referral to expert centers for the management of post-SG complications is critical to reduce morbidity and mortality.

Our study had several limitations, such as the retrospective design, although all other studies published on this topic were also retrospective. The small number of series described in the literature argues for the creation of a national or international database, as there is still insufficient knowledge on the management of GL and most SG surgery concerns young patients, for whom a zero-mortality rate should be an objective. The size of our study population could be considered to be small, but there have been no single-center studies published with as many patients. This is probably why there have been no previous studies to search for risk factors for a poorer evolution of GL after SG. Also, no endoscopic findings were associated with worth outcomes, in particular the occurrence of gastric stenosis or twist associated with GL. This could be due to the fact that probably diagnosis of stenosis or twist were underestimated as most cases concern last cases of our study. Finally, our results were probably influenced by the algorithm-based management specific to our center, probably different to other center and other definition of type of GL [32]. This is why we decided to exclude patients referred tardively, because the management of such cases in other centers may be different than ours and could have introduced a bias in the interpretation of the results.

CONCLUSION

GL is a difficult complication to manage. We found that a BMI > 47k g/m^2, a time to referral to a specialized center > 2 days, and a serum pre-albumin level < 0.1g/dl were independent risk factors for a poorer evolution. Two of these three factors are modifiable, suggesting that it may be possible to reduce the morbidity and mortality of GL after SG.

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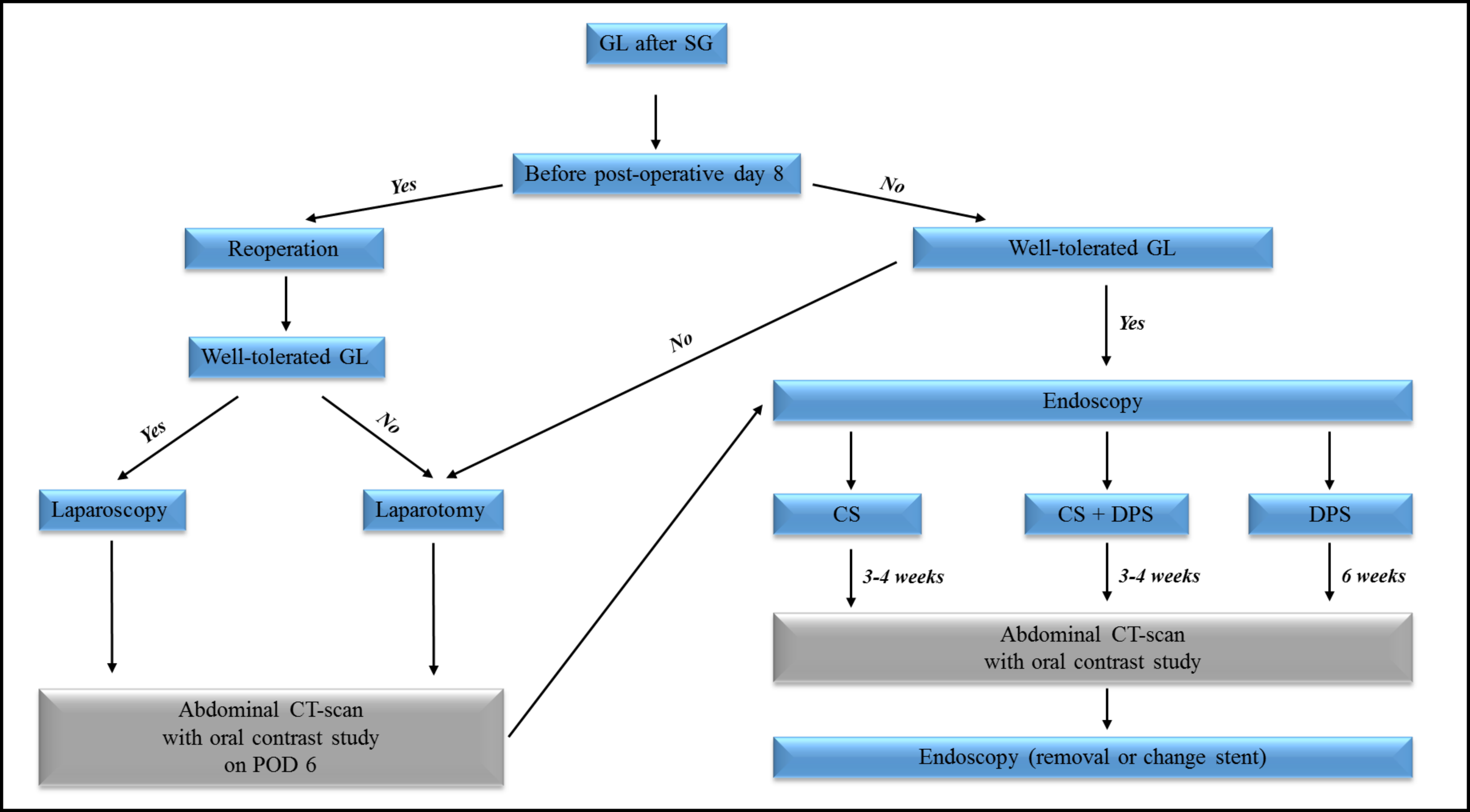
FIGURE LEGENDS

Figure 1. Synopsis of the treatment procedures for post-SG GL.

DPS: double pigtail stent;, CS: coated stent, GL: gastric leak, CT: computed tomography, POD: post-operative day

Figure 2: Study flow chart.

GL: gastric leak


GL after SG
Before post-operative day 8
Yes
No
Reoperation
Well-tolerated GL
Well-tolerated GL
Yes
No
Yes
No
Laparoscopy
Laparotomy
Endoscopy
CS
CS + DPS
DPS
3-4 weeks
3-4 weeks
6 weeks
Abdominal CT-scan with oral contrast study on POD 6
Abdominal CT-scan with oral contrast study
Endoscopy (removal or change stent)

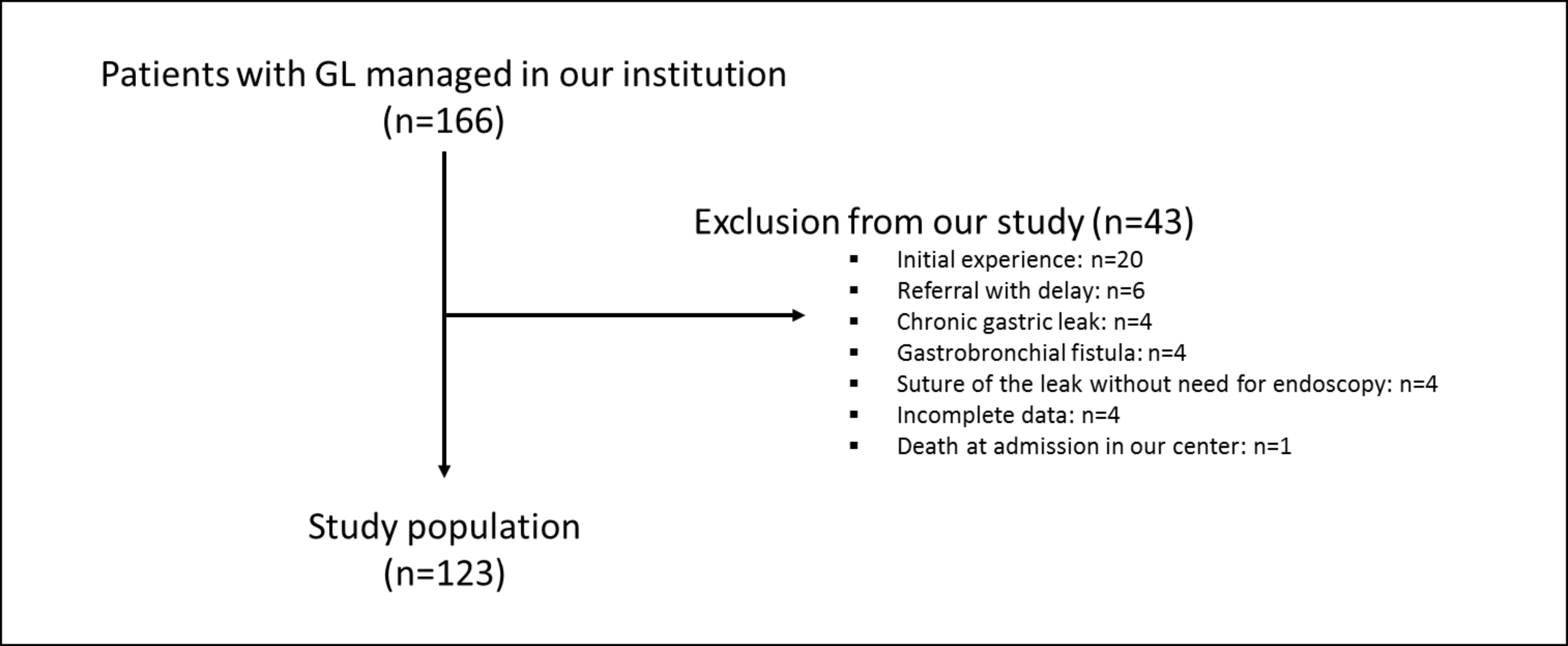

Patients with GL managed in our institution
(n=166)
Exclusion from our study (n=43)
Initial experience: n=20
Referral with delay: n=6
Chronic gastric leak: n=4
Gastrobronchial fistula: n=4
Suture of the leak without need for endoscopy: n=4
Incomplete data: n=4
Death at admission in our center: n=1
Study population
(n=123)

Table 1. Comparison of pre-operative data between the eGL and hGL groups.

	eGL group (n = 73)	hGL group (n = 50)	Total group (n = 123)	*p value*
Male gender (n, %)	21 (28.7)	8 (16)	29 (23.5)	0.17
Mean age (years, range)	36 (19 - 65)	38.8 (21 - 68)	37.1 (19 - 68)	0.19
Age < 30 years (n, %)	25 (34.3)	13 (26)	38 (30.9)	0.33
Age between 30 and 50 years (n, %)	39 (53.4)	25 (50)	64 (52)	0.71
Age ≥ 50 years (n, %)	9 (12.3)	12 (24)	21 (17.1)	0.09
Mean BMI (kg/m^2, range)	42 (28.7 - 62.5)	44.4 (36.3 - 59)	42.7 (28.7 – 62.5)	0.02
BMI ≥ 50 kg/m^2 (n, %)	10 (13.7)	9 (18)	19 (15.4)	0.52
Comorbidities				
Type 2 diabetes (n, %)	10 (13.7)	6 (12)	16 (13)	0.78
Hypertension (n, %)	16 (22)	12 (24)	28 (22.8)	0.79
Dyslipidemia (n, %)	14 (19.1)	9 (18)	23 (18.7)	0.87
OSAS (n, %)	15 (20.5)	14 (28)	29 (23.5)	0.34

BMI: body mass index, OSAS: obstructive sleep apnea syndrome

Table 2. Comparison of the type of surgery and institution that performed the surgery between the eGL and hGL groups.

	eGL group (n = 73)	hGL group (n = 50)	Total group (n = 123)	p value
Type of SG				
Primary SG (n, %)	62 (85)	41 (82)	103 (83.7)	0.67
SG with history of GB (n, %)	5 (6.8)	3 (6)	8 (6.5)	0.85
SG with simultaneous GB removal (n, %)	3 (4.1)	4 (8)	7 (5.7)	0.36
Repeat SG (n, %)	3 (4.1)	2 (4)	5 (4)	0.98
Institution who performed initial surgery				
Other center (n, %)	46 (63)	35 (70)	81 (65.8)	0.42
Referral center (n, %)	27 (37)	15 (30)	42 (34.2)	

SG: sleeve gastrectomy, GL: gastric leak, GB: gastric banding

Table 3. Clinical data at admission in our institution

	eGL group (n = 73)	hGL group (n = 50)	Total group (n = 123)	p value
Type of GL				0.04
Early GL (n, %)	26 (35.6)	27 (54)	53 (43)	
Delayed GL (n, %)	47 (64.4)	23 (46)	70 (57)	
Mean delay of diagnosis (in days, range)	17.3 (1 - 156)	11.8 (1 - 78)	15.1 (1 - 156)	0.06
Hypovolemic shock rate	9 (12.3)	15 (30)	24 (19.5)	0.02
Admission in ICU rate	24 (32.8)	14 (28)	38 (30.9)	0.57

GL: gastric leak

Table 4. Biological data at admission in our institution for GL after SG.

	eGL group (n = 73)	hGL group (n = 50)	Total group (n = 123)	p value
White blood cell count				
Mean	13631 (5 600 - 32 400)	14010 (3 900 - 27 800)	13785 (3 900 - 32 400)	0.35
< 10,000	17 (23.3)	13 (26)	30 (24.4)	0.73
Between 10,000 and 20,000	49 (67.1)	32 (64)	81 (65.9)	0.72
> 20,000	7 (9.6)	5 (10)	12 (9.7)	0.94
C-Reactive protein level				
Mean	212 (51.6 - 434)	224 (25 - 472)	217 (25 - 472)	0.28
< 100	14 (19.2)	6 (12)	20 (16.3)	0.29
Between 100 and 200	20 (27.4)	14 (28)	34 (27.6)	0.94
> 200	39 (53.4)	30 (60)	69 (56.1)	0.47
Serum creatinine				
Mean	62.4 (29 - 125)	73.9 (32 - 158)	67.1 (29-158)	0.01
Serum pre-albumin level				
Mean	0.12 (0.04 - 0.37)	0.09 (0.03 - 0.24)	0.1 (0.03 - 0.37)	0.98
< 0.1 g/dl	40 (54.8)	32 (64)	72 (58.6)	0.31
Between 0.1 and 0.2 g/dl	19 (26)	15 (30)	34 (27.6)	0.63
> 0.2 g/dl	14 (19.2)	3 (6)	17 (13.8)	0.04

Serum albumin level				
Mean	26.3 (13.6 - 42.7)	23.1 (12 - 36)	25 (12 - 42.7)	0.99
< 20 g/dl	15 (20.6)	13 (26)	28 (22.7)	0.48
Between 20 and 34 g/dl	47 (64.4)	36 (72)	83 (67.6)	0.38
> 34 g/dl	11 (15)	1 (2)	12 (9.7)	0.02

Table 5. Reoperation data and type of renutrition of patients with GL after SG.

	eGL group (n = 73)	hGL group (n = 50)	Total group (n = 123)	p value
Reoperation				
Rate of reoperation	35 (48)	39 (78)	74 (60)	< 0.001
Reoperation using laparoscopy	20 of 35 (57.1)	26 of 39 (66.6)	46 of 74 (62.2)	0.37
Reoperation using laparotomy	15 of 35 (42.9)	13 of 39 (33.4)	28 of 74 (37.8)	0.48
Suture of the GL	10 of 35 (28.5)	9 of 39 (23)	19 of 74 (25.6)	0.52
Type of renutrition				0.01
Feeding jejunostomy	30 (41)	33 (66)	63 (51.2)	
Nasojejunal tube	38 (52)	13 (26)	51 (41.4)	
Venous catheter	5 (7)	4 (8)	9 (7.4)	

GL: gastric leak

Table 6. Data on patients undergoing SG in another institution

	eGL group (n = 46)	hGL group (n = 35)	Total group (n = 81)	p value
Surgery for GL in primary institution in case of referral				
Yes	15 (32.6)	15 (42.8)	30 (37)	0.34
Surgery for GL after admission in referral center				
Yes	16 (34.7)	22 (62.8)	38 (46.9)	0.01
Delay for referral				
Mean delay (in days, range)	3 (0 - 28)	7.7 (0 - 40)	5 (0 - 40)	0.007
< 2 days	31	18	49	0.15
Between 2 and 4 days	6	4	10	0.83
> 4 days	9	13	22	0.08

GL: gastric leak

Table 7. Endoscopic data

	eGL group (n = 73)	hGL group (n = 50)	Total group (n = 123)	p value
Number of endoscopies				
Mean number of endoscopies	2.2 (2 - 5)	3.3 (2 - 7)	2.7 (2 - 7)	< 0.001
Between 0 and 2 endoscopies	57 (78.1)	12 (24)	69 (56.1)	< 0.001
Between 3 and 4 endoscopies	15 (20.5)	32 (64)	47 (38.2)	< 0.001
More than 4 endoscopies	1 (1.4)	6 (12)	7 (5.7)	0.01
Endoscopic data				
Classical GL	61 (83.5)	29 (58)	90 (73.2)	0.002
Associated gastric stenosis	3 (4.1)	4 (8)	7 (5.7)	0.36
Large orifice GL	9 (12.4)	17 (34)	26 (21.1)	0.004
Type of prothesis				
DPS only	57 (78.1)	29 (58)	86 (70)	0.02
CS only	3 (4.1)	1 (2)	4 (3.2)	0.52
DPS and CS	13 (17.8)	20 (40)	33 (26.8)	0.006
Simultaneous DPS and CS	8 (11)	10 (20)	18 (14.6)	0.16
Time interval between GL and first endoscopy				
Mean time interval	7.6 (0 - 34)	14 (0 - 48)	10.1 (0 - 48)	< 0.001
≤ 7 days	43 (58.9)	16 (32)	59 (48)	0.004
Between 7 and 15 days	22 (30.1)	18 (36)	40 (32.5)	0.49
≥ 15 days	8 (11)	16 (32)	24 (19.5)	0.004

GL: gastric leak, DPS: double pigtail stent, CS: covered stent

Table 8. Results of the multivariate logistic regression model

Risk factors	Odds ratio	95% confidence interval	p value
BMI	0.90	0.84 - 0.97	0.008
Delay of diagnosis of GL	1.01	0.98 – 1.05	0.46
Delayed GL	1.05	0.29 – 3.79	0.94
Delay for referral	0.92	0.86 - 0.98	0.01
Hypovolemic shock	0.38	0.12 – 1.18	0.09
Serum pre-albumin level	1.64	1.13 - 2.37	0.04

BMI: body mass index