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ORIGINAL CONTRIBUTIONS

Endoscopic Management of Bariatric Surgery Complications According to a Standardized Algorithm

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Abstract

Background and Aims Endoscopy is effective in management of bariatric surgery (BS) adverse events (AEs) but a comprehensive evaluation of long-term results is lacking. Our aim is to assess the effectiveness of a standardized algorithm for the treatment of BS-AE.

Patients and Methods We retrospectively analyzed 1020 consecutive patients treated in our center from 2012 to 2020, collecting data on demographics, type of BS, complications, and endoscopic treatment. Clinical success (CS) was evaluated considering referral delay, healing time, surgery, and complications type. Logistic regression was performed to identify variables of CS.

Results In the study period, we treated 339 fistulae (33.2%), 324 leaks (31.8%), 198 post-sleeve gastrectomy twist/stenosis (19.4%), 95 post-RYGB stenosis (9.3 %), 37 collections (3.6%), 15 LAGB migrations (1.5%), 7 weight regains (0.7%), and 2 hemorrhages (0.2%). Main endoscopic treatments were as follows: pigtail-stent positioning under endoscopic view for both leaks (CS 86.1%) and fistulas (CS 77.2%), or under EUS-guidance for collections (CS 88.2%); dilations and/or stent positioning for sleeve twist/stenosis (CS 80.6%) and bypass stenosis (CS 81.5%). After a median (IQR) follow-up of 18.5 months (4.29–38.68), complications rate was 1.9%. We found a 1% increased risk of redo-surgery every 10 days of delay to the first endoscopic treatment. Endoscopically treated patients had a more frequent regular diet compared to re-operated patients.

Conclusions Endoscopic treatment of BS-AEs following a standardized algorithm is safe and effective. Early endoscopic treatment is associated with an increased CS rate.

Keywords Endoscopy · Sleeve gastrectomy · Gastric by-pass · Adverse events · Leak · Fistula · Stenosis · Stricture · Twist · Endoscopic internal drainage · Bariatric surgery · Lap band · SEMS · Double pigtail · LAMS

Key Points

-Endoscopy is effective in management of bariatric surgery adverse events.

-Application of a standardized algorithm allowed a high clinical success rate.

-Early endoscopic treatment is associated with increased endoscopic clinical success.

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Introduction/Purpose

Bariatric surgery (BS) is the most effective and durable treatment for morbid obesity and its comorbidities [1–4]. Despite the gradual increase in surgical safety, adverse events (AE) still occur in 0.4 to 25% of patients and often require revision [5–7]. Endoscopic management has shown to be effective, has a lower morbidity compared to revisional surgery, and can be adopted both as definitive treatment or as bridge to surgery [8, 9].

Several studies have described different endoscopic approaches to the AE [10–12]; however, a comprehensive evaluation of long-term results and the definition of a standardized management are still lacking.

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The aim of this study is to assess the effectiveness and long-term outcomes of a standardized treatment algorithm for BS-AEs in an interventional endoscopy tertiary referral center.

Materials and Methods

From December 2012 to February 2020, all patients addressed to our endoscopic center for suspected AE after BS were enrolled in a prospective database. Data were then retrospectively analyzed.

The Institutional Review Board of Ramsay France approved the study for Human Research. Informed consent for retrospective analysis of anonymized data was obtained from all participants. All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration.

All procedures were performed by 5 expert endoscopists (>300 advanced therapeutic procedures) in an interventional endoscopic suite equipped with fluoroscopy under general anesthesia. The patients were referred to our hospital from a network of 218 bariatric surgeons comprising more than 30 hospitals throughout northern France. All treatments were preoperatively discussed with the referring surgeon and with our anesthesiological equipe.

In our center, during the whole study period, a systematic algorithm for the diagnosis, treatment, and outcome assessment of BS-AEs has been developed and is used.

This algorithm was developed in accordance with our previous experience in the management of bariatric surgery AE with other endoscopic approaches, and it was shared and discussed with referring bariatric surgeons.

Detailed algorithm is available in Fig. 1. We systematically defined the type of AE, its corresponding endoscopic treatment, and the outcomes for clinical success. Detailed definitions of all AEs and treatments are available in Appendix.

Study Outcomes and Definitions

Primary outcome of the study was to evaluate clinical success (CS) and long-term follow-up of endoscopic management according to the specific type of AE and to the definitions provided. Secondary outcomes include evaluation of timespan between index surgery and first endoscopic session, previous bariatric/foregut surgeries (PS), emergency interventions before endoscopy, number of endoscopic sessions, length of treatment, patients' alimentation during and after treatment, and complication rates related to each endoscopic approach.

Some patients presented concomitant AEs requiring a combination of different techniques. However, for statistical analysis only the first major AE was considered.

According to Rosenthal classification, AEs were classified in acute (7days), early (8 days–6 weeks), late (6 weeks–3 months), and chronic (≥ 3months) [13].

Statistical Analysis

Data were recorded in a computerized spreadsheet (Microsoft Excel 2016; Microsoft Corporation, Redmond; WA) and analyzed with statistical software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY).

The distribution of continuous variables was assessed with Shapiro-Wilk tests. Results are reported as means–standard deviation (SD) or medians–interquartile range (IQR). Differences in means/medians were evaluated with Student *T*-test and Mann-Whitney test, respectively. Differences in proportions were analyzed using chi-square test. Logistic regression was used to provide odds ratio for individual variables.

Results

Patient Characteristics

In 7 years, 1020 consecutive patients with AEs after BS were treated by five highly experienced interventional endoscopists performing respectively 572 (56.1%), 245 (24.0%), 56 (5.5%), 59 (5.8%), and 88 (8.6%) procedures.

Patients (850 females, 83.3%) had a mean (SD) age of 44.2(±11.9) years and had a mean BMI of 41.5(±7.6) kg/m^2 at index BS. Index bariatric surgeries causing the complication (BSCC) were as follows: sleeve gastrectomy (SG) (796/1020, 78%), Roux-en-Y gastric bypass (RYGB) (137/1020, 13.4%), one-anastomosis gastric bypass (OAGB) (69/1020, 6.8%), and laparoscopic adjustable gastric banding (LAGB) (18/1020, 1.8%).

Regarding previous surgical treatments, 799 patients (78.3%) were referred after index surgery only (BSCC), 190 (18.6%) had one PS (1 PS+BSCC), and 31 (3.0%) had two PS (2 PS+BSCC).

Regarding previous AE treatments, 667 patients (65.4%) were referred to our unit directly after BSCC whereas 151 (14.8%) had undergone percutaneous drainage and 202 (19.8%) emergency surgery before endoscopy.

The most common referred AEs were as follows: fistula (339—33.2%), leak (324—31.8%), sleeve twist/stenosis (198—15.9%), bypass stenosis (95—7.7%), and collection (37—3.6%). All AEs are available in Table 1.

Endoscopic Treatment Characteristics

The full description of the performed endoscopic procedures is summarized in Table 2.

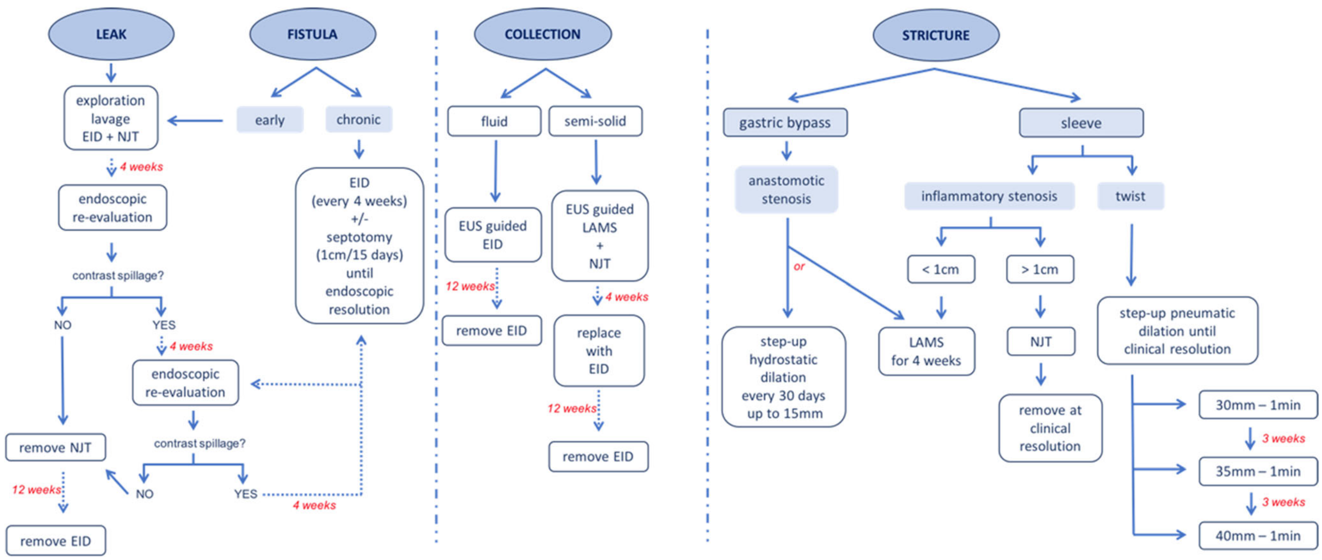

Fig. 1 Endoscopic treatment of bariatric surgery adverse events: our algorithm

Out of 1020, 135 patients (13.2%) had normal endoscopic and fluoroscopic findings requiring only NJT deployment to allow proper enteral feeding.

The mean number of endoscopic sessions was 2.96 (SD 2.37).

Clinical Success

Endoscopic outcome was evaluated at a median follow-up of 18.53 months (IQR 4.29–38.68). One hundred patients were excluded because lost at follow-up (67) or still under treatment (33).

Overall long-term CS was achieved in 751 patients (81.6%), 160 subjects (17.4%) needed a redo-surgery and 9 (1.0%) died (5 under treatment and 4 after endoscopic healing). Clinical success varied according to different AEs treated: leak (86.1%), fistula (77.2%), collection (88.2%), sleeve twist/stenosis (80.6%), bypass stenosis (81.5%), LAGB migration (86.7%), weight regain (100%), hemorrhage (100%). Details on outcome according to the type of AE and the timespan between BSCC and endoscopic treatment are reported in Table 3.

Adverse Events of the Endoscopic Management

A total of 19 (1.9%) adverse events occurred due to endoscopic management:

- 7 perforations (4 during pigtail positioning, 3 during pneumatic dilation). Two cases required emergency surgery;
- 5 bleedings (1 hematoma after lap-band removal and 4 due to pigtail stent deployment or erosion of vascular structures). Two cases of splenic artery erosion required embolization and one needed splenectomy;
- 3 pigtail stent migrations;
- 1 myocardial infarction;
- 1 massive gas embolism;
- 1 massive pneumoperitoneum;
- 1 necrotizing pancreatitis that required endoscopic necrosectomy.

Two patients died (myocardial infarction and gas embolism) and 3 subjects required emergency surgery whereas the remaining 14 cases were treated conservatively.

Variables Associated with Endoscopic Treatment Outcomes

The presence of PS was associated with a significant reduction in the endoscopic CS rate, decreasing from 75.1% (600/799) to 69.5% (132/190) and 61.3% (19/31) for no, one, and two previous surgeries, respectively. Correspondingly, the need for redo-surgery increased respectively from 13.4% (107/799) to 23.2% (44/190) and 29.0% (9/31) (Table 4).

The univariate analysis showed a 1.8 times increased risk of redo-surgery in case of a previous bariatric surgery (1PS+BSCC) (95% CI 1.25–2.78, p 0.002) and of 2.6 times in case of two previous surgeries (2 PS+BSCC) (95% CI 1.17–6.02, p 0.019).

When analyzing the influence of previous percutaneous/surgical drainage, no significant differences in CS were found between patients that had undergone a previous treatment as compared to those that had not (p 0.226).

In order to better analyze our results, we divided all AEs in two subgroups sharing similar characteristics: one including leak, fistula, and collection and the other including stenosis

Table 1 Descriptive data, overall and divided per type of complications. Unreported data in the table were recorded as "other"

Variable		**Overall** *n=1020**	**Type of complication**							
			LAGB migration *n=15*	**Leak** *n=324*	**Fistula** *n=339*	**Collection** *n=37*	**Sleeve twist/ stenosis** *n=198*	**Bypass stenosis** *n=95*	**Weight regain** *n=7*	**Hemorrhage** *n=2*
Sex	*Female*	**850 (83.3%)**	11 (73.3%)	264 (81.5%)	279 (82.3%)	29 (78.4%)	174 (87.9%)	81 (85.3%)	7 (100%)	2 (100%)
	Male	**170 (16.7%)**	4 (26.7%)	60 (18.5%)	60 (17.7%)	8 (21.6%)	24 (12.1%)	14 (14.7%)	0	0
Age *years – mean (SD)*		**44.2 (11.9)**	48.4 (15.1)	43.8 (12.1)	44.6 (11.4)	42.3 (11.4)	43.4 (12.7)	46.8 (11.9)	41.5 (6.8)	39.5 (12.0)
BMI at bariatric surgery causing complication kg/m^2 – *mean (SD)*		**41.5 (7.6)**	36.4 (17.3)	41.9 (6.8)	41.6 (7.1)	41.3 (4.8)	41.8 (6.0)	40.0 (11.8)	40.7 (9.8)	49.5 (3.7)
Current status	*Deceased*	**9 (0.9%)**	0	3 (0.9%)	4 (1.2%)	1 (2.7%)	0	1 (1.1%)	0	0
	Cured	**751 (73.6%)**	13 (86.7%)	253 (78.1%)	227 (67.0%)	30 (81.1%)	145 (73.2%)	75 (78.9%)	6 (85.7%)	2 (100%)
	Under treatment	**100 (9.8%)**	2 (13.3%)	30 (9.3%)	45 (13.3%)	3 (8.1%)	18 (9.1%)	3 (3.2%)	1 (14.3%)	0
	Re-operated	**160 (15.7%)**	0	38 (11.7%)	63 (18.6%)	3 (8.1%)	35 (17.7%)	16 (16.8%)	0	0
Bariatric surgery causing complication	*LAGB*	**18 (1.8%)**	15 (100%)	1 (0.3%)	2 (0.6%)	0	0	0	0	0
	Sleeve	**796 (78.0%)**	0	286 (88.3%)	279 (82.3%)	30 (81.1%)	198 (100%)	0	0	1 (50.0%)
	RYGB	**137 (13.4%)**	0	25 (7.7%)	39 (11.5%)	5 (13.5%)	0	62 (65.3%)	5 (71.4%)	1 (50.0%)
	OAGB	**69 (6.8%)**	0	12 (3.7%)	19 (5.6%)	2 (5.4%)	0	33 (34.7%)	2 (28.6%)	0
Emergency intervention	*Surgery*	**202 (19.8%)**	1 (6.7%)	2 (0.6%)	182 (53.7%)	3 (8.1%)	6 (3.0%)	8 (8.4%)	0	0
	Percutaneous drainage	**151 (14.8%)**	0	1 (0.3%)	147 (43.4%)	2 (5.4%)	1 (0.5%)	0	0	0
	No	**667 (65.4%)**	14 (93.3%)	321 (99.1%)	10 (2.9%)	32 (86.5%)	191 (96.5%)	87 (91.6%)	7 (100%)	2 (100%)

[*] 3/1020 patients were recorded as "other" and not reported

Table 2 Endoscopic treatment per type of complications. Unreported data in the table were recorded as "other"

		Overall *n=1020**	LAGB migration *n=15*	Leak *n=324*	Fistula *n=339*	Collection *n=37*	Sleeve twist/ stenosis *n=198*	Bypass stenosis *n=95*	Weight regain *n=7*	Hemorrhage *n=2*
Endoscopic treatment	*LAGB removal*	**15 (1.5%)**	15 (100%)	0	0	0	0	0	0	0
	Pigtail stent	**591 (57.9%)**	0	276 (85.2%)	308 (90.9%)	1 (2.7%)	6 (3.0%)	0	0	0
	Pneumatic dilation	**110 (10.8%)**	0	0	1 (0.3%)	0	106 (53.5%)	4 (4.2%)	0	0
	hydrostatic dilation	**38 (3.7%)**	0	0	0	0	3 (1.5%)	34 (35.8%)	0	0
	LAMS	**71 (7.0%)**	0	0	2 (0.6%)	0	39 (19.7%)	30 (31.6%)	0	0
	SEMS	**2 (0.2%)**	0	0	0	0	2 (1.0%)	0	0	0
	EUS-guided pigtail stent	**37 (3.6%)**	0	3 (0.9%)	1 (0.3%)	33 (89.2%)	0	0	0	0
	APC	**6 (0.6%)**	0	0	0	0	0	0	6 (85.7%)	0
	EGD simple	**135 (13.2%)**	0	44 (13.6%)	21 (6.2%)	3 (8.1%)	40 (20.2%)	24 (25.3%)	1 (14.3%)	1 (50.0%)

* 3/1020 patients were recorded as "other" and not reported

Table 3 Clinical outcome according to the type of adverse event and the timespan between index surgery and endoscopic treatment

Presentation (days)	LAGB migration *n 15*	Leak *n 294*	Fistula *n 294*	Collection *n 34*	Sleeve twist/stenosis *n 180*	Bypass stenosis *n 92*	Weight regain *n 6*	Hemorrhage *n 2*
Endoscopic success								
Tot	***13 (86.7%)***	***253 (86.1%)***	***227 (77.2%)***	***30 (88.2%)***	***145 (80.6%)***	***75 (81.5%)***	***6 (100%)***	***2 (100%)***
0–7 days	0	47 (16.0%)	26 (8.9%)	2 (5.9%)	4 (2.2%)	1 (1.1%)	0	1 (50.0%)
8–42 days	0	171 (58.2%)	172 (58.5%)	16 (47.0%)	51 (28.3%)	15 (16.3%)	0	1 (50.0%)
43–90 days	0	16 (5.4%)	18 (6.1%)	4 (11.8%)	28 (15.6%)	10 (10.9%)	0	0
> 90 days	13 (86.7%)	19 (6.5%)	11 (3.7%)	8 (23.5%)	62 (34.5%)	49 (53.3%)	6 (100%)	0
Endoscopic failure								
Tot	***2 (13.3%)***	***41 (13.9%)***	***67 (22.8%)***	***4 (11.8%)***	***35 (19.4%)***	***17 (18.5%)***	***0***	***0***
0–7 days	0	5 (1.7%)	3 (1.0%)	0	1 (0.6%)	0	0	0
8–42 days	0	19 (6.5%)	43 (14.6%)	3 (8.9%)	8 (4.4%)	3 (3.3%)	0	0
43–90 days	0	8 (2.7%)	3 (1.0%)	1 (2.9%)	8 (4.4%)	4 (4.3%)	0	0
> 90 days	2 (13.3%)	9 (3.0%)	18 (6.2%)	0	18 (10.0%)	10 (10.9%)	0	0

Abbreviations: *LAGB* laparoscopic adjustable gastric banding, *Tot* total

Three missing cases were classified as “other” in the database and so not considered

Table 4 Endoscopic outcome divided per number of previous bariatric surgeries

Patient status	Pre-endoscopic treatment surgeries		
	Only BSCC *n=799*	1PS + BSCC *n=190*	2PS + BSCC *n=31*
Deceased	7 (0.9%)	2 (1.1%)	0
Under treatment	85 (10.6%)	12 (6.3%)	3 (9.7%)
Cured	600 (75.1%)	132 (69.5%)	19 (61.3%)
Re-operated	107 (13.4%)	44 (23.2%)	9 (29.0%)

Abbreviations: *BSCC* bariatric surgery causing complication, *1PS* one previous surgery, *2PS* two previous surgeries

and sleeve twist. In the first group, there was an increase of 1% in the need of redo-surgery every 10 days of delay between BSCC and endoscopic treatment (OR 1.001, 95% CI 1.001–1.002, p<0.001). No significant difference was found in the second group (n 293, p 0.443).

When analyzing patient alimentation both during the endoscopic treatment (nutrition) and after the end of the treatment (diet), we considered the same aforementioned subgroups. Nutrition in the leak/fistula/collection group was mainly through NJ tube (80.9%, 566/700), while in the stenosis/sleeve twist group it was mainly a regular or liquid per os feeding (84.6%, 248/293) (Table 5). Furthermore, the leak/fistula/collection subgroup has a significant difference between patients treated endoscopically from those requiring redo-surgery with, respectively, 84.2% on regular diet and 69.6% on fractional diet versus 15.8% and 30.4% (p 0.011). No significant difference was highlighted in the other subgroup (p 0.357) (Table 6).

Discussion

A well-defined algorithm was applied according to clinical presentation, type of AE, BSCC, and delay of endoscopic treatment. We strictly adopted the algorithm for all cases, combining more than one of its strategies, if necessary. In our opinion, the high number of procedures coupled with a standardized approach to each pathology is the keystone to successful treatment. The in-depth analysis of each technique is beyond the goal of this study and requires different studies.

A great variety of endoscopic approaches were developed and adopted according to the type of bariatric surgery complication.

Most cases of leak and fistula were treated with pigtail stent deployment. The choice of pigtail stents over other available devices (i.e., Self-Expandable-Metal-Stents) [14] is due to the authors' assumption that pigtail approach has higher efficacy and safety [15,16] and lower costs [17]. This data is in line with studies with significant sample sizes [8,18]. Nonetheless, previous studies reported the outcome of EID for the management of acute/early leaks; the results of this study acquire an important value considering our outcomes in persistent/late leaks and fistula, usually burdened by a higher rate of failures [19]. Specifically designed endoluminal vacuum systems may represent, in the future, an effective approach as well. Similarly to EID it induces trans-luminal drainage promoting healing and sepsis control [20].

Post-surgical collections were treated with EUS-guided pigtail stent deployment, following a strict strategy in the wide range of possibilities described in the literature (i.e., percutaneous drainage, both surgical or radiological, and endoscopic drainage) [21].

Our 88.2% CS rate represents a rare data considering the lack of results focused on collections without active leak after BS in the literature.

Pneumatic dilation was the most common procedure in case of sleeve twist/stenosis whereas bypass stenosis was treated mostly with hydrostatic dilation or LAMS deployment, respectively in 35.8% (34/95) and 31.6% (30/95) of cases. The high rate of LAMS deployment in case of RYGB could be related to late referral with subsequent higher prevalence of cicatricial stenosis that are less susceptible than membranous ones to single-session endoscopic dilation [22]. In a similar scenario, potential advantages of LAMS are lower risk of perforation and lack of multiple repeated interventions [23].

After excluding the 135/1020 cases of simple EGD which had a single session, the mean number of endoscopic sessions

Table 5 Type of nutrition during endoscopic treatment

Type of nutrition	Leak/fistula/collection *n 700*	Stenosis/sleeve twist *n 293*
CVC/PICCLINE	12 (1.7%)	1 (0.3%)
NJ tube	566 (80.9%)	22 (7.5%)
Jejunostomy	8 (1.1%)	0
Per os regular/liquid diet	97 (13.9%)	248 (84.6%)
ND	17 (2.4%)	22 (7.5%)

Abbreviations: *CVC* central venous catheter, *PICCLINE* peripheral inserted central catheter, *NJ tube* naso jejunal tube, *ND* not defined

Table 6 Diet after endoscopic treatment vs diet after endoscopic treatment + redo surgery

		Fractional diet	Regular diet	*p*
Leak/fistula/collection	*Cured*	32/46 (69.6%)	478/568 (84.2%)	***0.011***
	Re-operated	14/46 (30.4%)	90/568 (15.8%)	
Stenosis/twist	*Cured*	28/37 (75.7%)	192/234 (82.1%)	*0.357*
	Re-operated	9/37 (24.3%)	42/234 (17.9%)	

Pearson Chi-square test

was 2.96. This data is in line with current literature, confirming the efficacy of endoscopic management without the need of long-lasting and expensive treatment [9,17].

After excluding patients still under treatment, 751 patients (81.6%) were cured after the endoscopic management whereas 160 patients (17.4%) needed a redo-surgery. These results are consistent with available literature [24]. Considering leaks management, we had a slightly superior result (86.1%) compared to a recent systematic review which reported an 83.4% success rate [18]; this discrepancy should take into consideration that the review referred to 385 patients from 11 different studies thus increasing the risk of heterogeneous managements. Moreover, our 294 patients presented a longer delay between index surgery and endoscopic management. The median delay from BSCC to endoscopy, for overall patients with leak, fistula, and collection, was of 17 days (IQR 10–33) (range 0–2464).

A similar difference was observed for sleeve twist/stenosis; our success rate of 80.6% (*n* 180) is slightly superior to the 76% reported in a recent meta-analysis of 18 studies comprising 426 patients [25], with an overall median delay of 88 days (IQR 35.5–346.5) (range 3–6999).

Our study highlighted some interesting issues on how different variables influenced CS.

First, time between BSCC and endoscopic management is paramount for the management of leak, fistula, and collections. In this subgroup, there was a 1% increase in the risk of redo-surgery every 10 days of delay between index surgery and first endoscopic session. This result is consistent with previous studies demonstrating that a short delay between diagnosis and start of endoscopic treatment is an independent predictive factor for healing [26]. According to Rosenthal classification [13], we found that among endoscopically healed patients, the vast majority were referred in the early period (8–42 days). Early transfer to an experienced center can prevent patient deterioration, improve clinical outcome, and ultimately reduce overall costs [17]. A similar correlation was highlighted neither for SG twist nor for RYGB stenosis.

Second, we found that previous surgical procedures negatively influence endoscopic outcomes. We showed that success rate progressively decreased with the increase of previous surgical procedures and, collaterally, the need for redo-surgery grew. From our analysis, the risk of redo-surgery increased by 1.8 times in case of 1PS+BSCC and by 2.6 times in the case of 2PS+BSCC.

Third, emergency surgical or radiological procedures prior to endoscopic treatment seemed not to influence the endoscopic final outcome. In our population, 667/1020 (65.4%) were referred directly to our unit while 151/1020 (14.8%) presented a percutaneous drainage and 202/1020 (19.8%) had undergone an emergency surgery. Nonetheless, no differences were highlighted in clinical outcome among these three groups.

Finally, adequate nutrition during the treatment is fundamental for CS. The favored nutritional intake should be a high-calorie, high-protein enteral support. Experimental evidence shows that early enteral nutrition maintains the intestinal mucosal barrier, improves blood flow, improves healing, and results in lower infectious complications [27]. According to a recent systematic review [18], our algorithm supports the enteral nutrition through a NJT in case of leak/fistula/collection and the oral diet in case of stenosis.

Furthermore, our evaluation of diet regimen after the end of the treatment highlighted that endoscopically treated patients have more regular diet compared to patients who underwent redo-surgery and need more often a fractional diet, showing that endoscopy has probably less sequelae on gastric physiology.

We experienced a small percentage of endoscopy-related adverse events, of which the vast majority was treated conservatively, 3 required emergency surgery, and 2 resulted in death. The 2 deaths were related to myocardial infarction and gas embolism. Endoscopic management showed to be safer than revisional surgery with a much lower mortality and morbidity rate [28]. Our complication rate was considerably lower than previous studies. A similar result could be explained by the large volume of procedures, by the expertise of the endoscopist, and by treatment standardization.

This is the largest series to date published on this topic and has the unique strength of a systematized algorithm that was used throughout the whole study period. Furthermore, the solidity of the algorithm is shown by the uniformity in treatment choices and outcomes, performed by 5 different operators, confirming the reproducibility of our results.

This study also has some limitations. First, its retrospective design over a long-time span may introduce a quota of selection bias. However, the inclusion of all consecutive patients referred to our center reduces this risk. Second, the diverse assortment of bariatric complications treated may introduce heterogeneity in the results, although our systematized approach and substantial uniformity in clinical outcomes suggests that this possibility was limited. Finally, our algorithm is not validated; however, it has been elaborated based on the large volume of cases in our center.

In conclusion, our study confirms that endoscopy is the gold standard treatment for the management of AE after BS in case of stable patients, and that early endoscopic management is a predictive factor of clinical success for the most common BS-AEs. When applying a standardized treatment algorithm, clinical success is high across multiple operators. In case of leaks and fistulae, surgery should be adopted for unstable patients with general peritonitis or after failure of endoscopic treatments.

Appendix. Adverse events standardized definition and treatment

Leak

Definition Any disruption of the staple line or dehiscence of anastomosis with spillage of fluid, with or without a concomitant collection.

Treatment Leak treatment consists in the insertion of one/multiple double pigtail stents (DPS) and simultaneous positioning of a naso-jejunal feeding tube (NJT) for the first 4 weeks. The aim is to achieve an endoscopic internal drainage (EID) safeguarding the enteral feeding. This promotes granulation tissue with progressive collapse of the abscess cavity. Whenever possible, endoscopic exploration of the abscess cavity allows to perform lavage and/or necrosectomy. The first endoscopic follow-up is scheduled after 4 weeks. Per protocol, at first follow-up, DPS are left in place whereas the NJT is removed and the patient is allowed to restart the oral diet. Second endoscopic follow-up is scheduled 3 months later to remove the DPS or, if the abscess cavity persists, to perform their replacement and continue treatment for three more months.

Success Criteria Absence of contrast agent extravasation with normal C-reactive protein and white blood cells, no need for antibiotic therapy, normal oral intake and no chronic pain.

Fistula

Definition Any communication between two epithelialized structures — i.e., gastro-bronchial, gastro-jejunal, gastro-colic, or gastro-cutaneous (all cases with surgical or radiological drainage were considered presenting an iatrogenic gastro-cutaneous fistula).

Treatment For acute fistula with percutaneous drainage still in place, EID with DPS is performed in order to reverse liquid flow into the stomach, thus allowing firstly to retract and then to remove the percutaneous drainage to avoid the development of a chronic fistula.

In case of a persistent chronic fistula, a septotomy is done during repeated endoscopic sessions. Argon plasma coagulation (APC-Forced Effect 2, Watt 60) is performed coupled with clipping at the base of the endoscopic incision in order to facilitate emptying of the associated collection within the GI lumen, similarly to Zenker diverticula treatment [29].

Success Criteria As for leaks.

Collection

Definition Any well delimited fluid or semi-solid collection, adjacent to the foregut tract and with no direct communication with it, reachable by endoscopic ultrasound (EUS).

Treatment EUS-guided 19-gauge needle puncture is first performed. Then, the entry site is enlarged with a cystotome and hydrostatic dilation. Multiple DPS or a lumen-apposing metal stent (LAMS) is deployed into the cavity. DPS are kept in place for 3 months while LAMS is exchanged after 1 month with DPS; the patient has a normal oral diet.

Success Criteria As for leaks.

Stenosis

Definition A clinically significant narrowing of the upper GI tract related to previous surgery. Depending on the type of surgical procedure, the following stenosis may occur:

-Anastomotic stricture following gastric by-pass (GBP);

-Early stricture following SG, which typically occurs as a consequence of inflammation during the first weeks after surgery being related to hematoma, edema, or erroneous calibration of the gastric tube;

-Functional stenosis (helix stricture/twist), defined as a clockwise rotation of the gastric sleeve altering the regular gastric flow.

Treatment

-Anastomotic stricture after GBP needs multiple endoscopic sessions using hydrostatic dilation up to 15 mm of diameter every 30 days, or deploying a 16×30 mm LAMS for 4 weeks.

-Early inflammatory stricture following SG (< 1 month) is treated conservatively with steroids, coupled, in a minority of cases, with NJT or gastric calibration by LAMS deployment.

-Helix stricture following SG (> 1 month) needs pneumatic dilation up to 30-35-40 mm of diameter in multiple consecutive sessions, 1 min every 3 weeks. For tight or persistent stenosis, a fully covered self-expandable metal stent (FCSEMS) or LAMS can be deployed for 21 days [30].

Success Criteria Regular oral intake without vomiting, associated with a normal swallowing study or an easy exploration with a 9.8-mm gastroscope.

Lap-Band Migration After Erosion

Definition Lap-band migration is diagnosed when erosion of more than 30% of the gastric circumference occurs.

Treatment Cutting of the silicone ring and the connection tube (if port was not removed before) with a 450-cm guide wire and a standard extracorporeal lithotripsy system, followed by its removal with a polypectomy snare [31].

Success Criteria Complete removal of the lap-band with no AE, namely leak/perforation and bleeding/sepsis.

Weight Regain

Definition Any weight increase after RYGB.

Treatment Multiple endoscopic sessions of APC (forced coagulation, 60 watt) at the level of the gastro-jejunal anastomosis are performed in order to induce fibrosis and reduce the diameter of the anastomosis [32].

Success Criteria Interruption of weight regain or recovery of weight loss.

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Declarations

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare no competing interests.

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