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Original article

Endoscopic internal drainage for the management of leak, fistula, and collection after sleeve gastrectomy: our experience in 617 consecutive patients

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Abstract

Background: Endoscopy plays a pivotal role in the management of adverse events (AE) following bariatric surgery. Leaks, fistulae, and post-operative collection after sleeve gastrectomy (SG) may occur in up to 10% of cases.

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Objectives: To evaluate the efficacy and safety of endoscopic internal drainage (EID) for the management of leak, fistula, and collection following SG.
Setting: Retrospective, observational, single center study on patients referred from several bariatric surgery departments to an endoscopic referral center.
Methods: EID was used as first-line treatment for the management of leaks, fistulae, and collections. Leaks and fistulae were treated with double pigtail stent (DPS) deployment in order to guarantee internal drainage and second intention cavity obliteration. Collections were treated with endoscropic ultrasound (EUS)–guided deployment of DPS or lumen apposing metal stents.
Results: A total of 617 patients (83.3% female; mean age, 43.1 yr) were enrolled in the study for leak (n = 300, 48.6%), fistula (n = 285, 46.2%), and collection (n = 32, 5.2%). Median follow-up was 19.5 months. Overall clinical success was 84.7% whereas 15.3% of cases required revisional surgery after EID failure. Clinical success according to type of AE was 89.5%, 78.5%, and 90% for leak, fistula, and collection, respectively. A total of 10 of 547 (1.8%) presented a recurrence during follow-up. A total of 28 (4.5%) AE related to the endoscopic treatment occurred. At univariate logistic regression predictors of failure were: fistula (OR 2.012), combined endoscopic approach (OR 2.319), need for emergency surgery (OR 1.755), and previous endoscopic treatment (OR 4.818).
Conclusion: Early EID for the management of leak, fistula, and post-operative collection after SG seems a safe and effective first-line approach with good long-term results. (Surg Obes Relat Dis 2021;■:1–8.)

Key words: Double pigtails; Leak; Fistula; Sleeve gastrectomy; LAMS; EUS; Collection; Endoscopic internal drainage

Sleeve gastrectomy (SG) has become the most common surgical procedure for the management of morbid obesity worldwide [1] being a safe and effective primary procedure with good results even at long-term follow-up (FU) [2,3].

Despite surgical technique improvements and standardization [4], SG is still burdened by a morbidity rate up to 10 % [5] mainly related to leaks, fistulae, post-operative collections, and strictures. Leaks occur in .2% to 2.5% of cases [6,7] , with a reported mortality rate that reaches up to .4 % of cases [8]. Leaks represent one of the most feared adverse event (AE) due to their clinically relevant implications on patient's quality of life and on SG-related morbidity. Endoscopy has emerged both as primary and rescue therapy for the management of AE after bariatric surgery (BS). Endoscopic management has shown to be a safe and effective minimally invasive approach [9]. Moreover, it may be helpful as a bridge to stabilize the patient thus increasing the number of deferred surgeries over emergency procedures [10].

Several endoscopic techniques have been proposed, however, a standardized treatment protocol is still lacking. Considering leak and fistula, mainstay treatments consist of 2 opposite endoscopic approaches. On one hand, defect sealing by means of covered self-expandable metal stent (SEMS) deployment, and on the other, draining the cavity with double pigtail stents (DPS) [11].

In this study we report the outcomes of EID as first-line therapy for leak, fistula, and intra-abdominal collection (IAC) after SG according to a large cohort of 617 consecutive patients.

Methods

Study design and patients

This is a retrospective, observational, single center, open-label study. Between February 2012 and August 2020 all patients referred to our unit for endoscopic management of AE after SG were enrolled. All data were inserted in a prospective database and were retrospectively analyzed.

All included patients were 18 years or older, received at least one bariatric surgery with a related AE, were referred to our unit from primary hospitals based on bariatric surgeons' choice to perform EID, and were stable; furthermore, we included patients who received emergency surgery, percutaneous drainage, or previous endoscopy in other centers. Exclusion criteria were critically ill conditions and surgical AE other than leaks, fistulae, and collections.

The Institutional Review Board of Ramsay France approved the study for Human Research. Informed consent 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.

Definitions

Leak was considered as an extravasation of contrast medium due to a defect on the staple line.

Fistula was defined as an abnormal communication between 2 epithelialized structures. All patients with a surgical or radiologic drainage were considered as having a fistula (i.e., iatrogenic gastro-cutaneous fistula).

IAC was defined as a well-organized postsurgical collection with no communication with the gastrointestinal tract demonstrated by oral contrast CT scan and confirmed by endoscopic/fluoroscopic examination before EID

Leaks, fistulae, and IACs were classified as early, acute, late, and chronic according to Rosenthal classification [12].

If more than 1 AE was present in the same subject, a combined endoscopic approach was performed; however, for statistical analysis, only the major AE was considered.

Procedures

All procedures were performed under general anesthesia in an endoscopic suite equipped with fluoroscopy on an inpatient basis. At postoperative day 1, if no endoscopic-related AE occurred, the patients were transferred to the referring hospital.

For leak and fistula, the aim of upper endoscopy coupled with contrast study was to identify the defect within the staple line. Whenever feasible, the gastroscope was pushed across the defect in order to evaluate the associated cavity and eventually perform necrosectomy. One or multiple 10 or 7 French double pigtail stents (DPS) were deployed across the defect according to the size and anatomic structure of the pseudocavity. For acute/early defects, DPS was coupled with naso-jejunal feeding tube for 30 days. Whereas, in case of a late leak, fistula, and IAC, a normal diet was restarted the day after the endoscopic procedure. The first follow-up endoscopy was scheduled at 1 month. In case of pseudocavity obliteration, DPS were left in place and oral diet started; in case of a marked reduction in size, DPS exchange was performed coupled with naso-jejunal tube removal, whereas, in case of a big pseudocavity persistence, DPS exchange was coupled with prolonged enteral feeding. At 3-month follow-up, if we obtained closure of the leak, C reactive protein <5 U/L and normal leukocytosis, DPS were definitely removed [13]. When endoscopic success was obtained, patients' follow-up was based on symptoms.

Management of IAC was as follow: EUS evaluation of IAC location and size in order to decide the proper access route avoiding any intervening vessels; EUS-guided puncture with a 19G needle; guidewire looping within the collection; over-the-wire enlargement of the puncture site; deployment of multiple DPS or lumen-apposing metal stent (LAMS). LAMS size was 16 $\times$ 30 mm in most cases. Per protocol, LAMS were exchanged at 1 month with DPS; instead, primary DPS were kept in place for 90 days.

The time limit of endoscopic treatment was set at 120 days. After this period, in case of treatment failure patients were referred to revisional surgery. This timespan was decided according to our data showing that treatment duration >90 days was associated with a statistically significant higher rate of failure.

All procedure-related AEs occurring early after the endoscopic procedures or during FU were reported.

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 evaluated with Kolmogorov-Smirnov and Shapiro-Wilk tests. Continuous variables were compared by independent sample Mann-Whitney's test, while categoric variables were analyzed using Pearson's Chi-squared test.

Univariate logistic regressions were realized to provide odds ratios (OR) for individual variables, identifying possible predictors of outcome. A stepwise backward multiple logistic regression model was built to identify independent predictors of endoscopic treatment failure and to estimate adjusted OR and 95% confidence interval (CI). Only significant ($P < .05$) variables at univariate analysis were included in the model. Possible association between nominal variables was evaluated with Cramer's V test. A strong correlation was assumed in case of $V > .3$.

A time-to-event analysis was performed according to the Kaplan-Meier method to compare the incidence rates of endoscopic failure depending on the need of a secondary endoscopic treatment. Log-rank test was assessed to evaluate differences among groups.

P values below .05 were considered statistically significant.

Results

Patient characteristics

From December 2012 to August 2020, 1070 subjects were referred to our tertiary center for the management of AEs following bariatric surgery. Overall, 829 of 1070 patients were referred for AEs after SG. In total, 617 AEs were included in the study and comprised: leak (n = 300, 48.6%), fistula (n = 285, 46.2%), and IAC (n = 32, 5.2%).

The vast majority of patients were female (n = 514, 83.3%) with a mean age of 43.1 years (SD 11.7) at index surgery (the bariatric surgery causing complication [BSCC]). Patients were referred to our center for the following clinical manifestations: sepsis (n = 399, 64.7%), fever (n = 84, 13.6%), vomiting (n = 6, 1.0%), dysphagia (n = 5, .8%), or hemorrhage (n = 3,.5%).

Five hundred fifty-seven patients had no previous bariatric surgery before the BSCC whereas 56 patients had a previous bariatric procedure before BSCC: 47 lazp adjustable gastric banding (LAGB), 8 prior SG, and 1 one anastomosis gastric bypass (OAGB). Four patients were referred after 2 bariatric surgeries before BSCC. The first procedure was a LAGB in all 4 cases whereas the second one was a LAGB re-positioning for 2 of them and a SG in the remaining 2.

At a median follow-up of 19.5 months (IQR 5.3–41.8) (range 1–91 mo), 463 subjects were definitely cured by endoscopy, 84 required revisional surgery after endoscopic failure, 38 patients were lost at FU, and 28 subjects are still under treatment. During the study period, 4 patients died (1 intraprocedural myocardial infarction and 3 deaths not related to endoscopy).

Overall, 70 patients (under treatment/lost to FU or died during the study period) were excluded from statistical analysis concerning clinical outcomes.

Overall results

Overall clinical success was achieved in 84.7% of cases whereas revisional surgery was required in 15.3% after the clinical failure of the endoscopic treatment. According to the 3 subgroups (leak, fistula, and collection), clinical success was achieved in 89.5%, 78.5%, and 90%, respectively whereas revisional surgery was required in 10.5%, 21.5%, and 10% (Table 1).

Ten of 547 patients (1.8%) presented a clinical recurrence during the first year of follow-up. All recurrences were successfully managed performing a new EID.

A total of 28 (4.5%) peri-procedural endoscopy-related AEs occurred. Of that 1/28 was fatal due to intraprocedural myocardial infarction. The most frequent AE was bleeding 15/617 (2.4%), requiring in 11 cases interventional radiology embolization and in 4 cases elective surgery with precautionary splenectomy due to splenic artery pseudo-aneurism (surgeon choice). Finally 13 of 28 AEs were managed conservatively and were namely 4 air embolism, 5 pneumo-peritoneum, and 4 migration of DPS in the spleen.

Subgroup analysis

In total, 526 of 617 patients received a single endoscopic treatment, whereas 91 (14.7%) required a combination of 2 different endoscopic approaches.

In the first group (single approach), 443 patients were treated with DPS, 30 with EUS-guided EID (28 by DPS and 2 by LAMS), and 53 underwent a diagnostic EGD only.

In the second group (combined approach), beyond DPS: 65 patients required a second endoscopic approach for the management of a concomitant stricture (n = 29 LAMS, 31.9%; n = 26 pneumatic dilation with achalasia balloon, 28.5%; n = 3 hydrostatic dilation, 3.3%; and n = 7 SEMS, 7.7%), 24 patients underwent septotomy for persistent clinically significant pseudocavity, and 2 patients underwent EUS-guided EID for an associated IAC. A significant difference ($P < .002$) was highlighted between the single and combined-approach groups: of 463 endoscopically healed patients, 406 (87.7%) underwent a single treatment while 57 (12.3%) a combined approach; whereas out of 84 endoscopic failures, 62 (73.8%) underwent a single treatment while 22 (26.2%) a combined one. The subanalysis according to type of AE showed a significant difference in clinical outcome for leaks only (Table 2).

Analyzing the distribution of endoscopic failure over time by means of Kaplan-Meier curve, the combined-approach group presented a higher rate of failure that occurred at an earlier stage in comparison with the single-approach group ($P = .063$) (Fig. 1).

330 patients were referred to our unit directly after the BSCC, 165 underwent previous emergency surgery and 122 received percutaneous drainage.

After excluding patients still under treatment, we evaluated the primary outcome depending on previous emergency treatments.

Considering endoscopically healed patients, 71% were referred directly for endoscopic management while 29% underwent previous emergency surgery. Endoscopic failures were 57.1% and 42.9%, respectively. This difference resulted statistically significant ($P = .034$). On the contrary, no significant difference was found for emergent percutaneous drainage ($P = .161$) (Table 3).

In 34 patients (5.5%) a previous endoscopic treatment was attempted in peripheral hospitals. A statistically significant ($P < .001$) higher clinical success was highlighted for those patients directly referred to our center.

Analyzing the time of referral to our unit according to Rosenthal classification [12], a statistically significant higher failure rate was found hand-in-hand with the delay of endoscopic treatment. Overall and subgroup results are shown in Table 4.

Predictors of failure

At univariate logistic regression the fistula had a double probability of failure (OR 2.012, CI 95% [1.254–3.229], $P = .004$) and the combined endoscopic approach

Table 1
Clinical outcome after the endoscopic treatment: overall and divided per type of adverse event

Clinical outcome	Leak (n = 275)	Fistula (n = 242)	IAC (n = 30)	Overall (n = 547)*
Success	89.5%	78.5%	90%	84.7%
Failure	10.5%	21.5%	10%	15.3%

IAC = intra-abdominal collection.

* Overall, 70 patients (undergoing treatment, lost to follow-up, or died during the study period) were excluded from statistical analysis concerning clinical outcomes.

Table 2
Clinical outcome depending on the use of single or combined endoscopic treatment

Adverse event	Endoscopic treatment	Endoscopic success	Endoscopic failure	*P* value
Leak (n = 275)	Single	220 (89.4%)	20 (69%)	.002
	Combined	26 (10.6%)	9 (31%)	
Fistula (n = 242)	Single	162 (85.2%)	39 (75%)	.128
	Combined	28 (14.8%)	13 (25%)	
Collection (n = 30)	Single	24 (88.9%)	3 (100%)	.525
	Combined	3 (11.1%)	0	

showed a similar trend (OR 2.319 CI 95% [1.339–4.019], $P = .003$). The need for emergency surgery resulted in a failure rate 75% higher (OR 1.755, CI 95% [1.038–2.967], $P = .036$), whereas percutaneous drainage showed a 51% higher failure rate; however, the latter was not statistically significant (OR 1.514, CI 95% [.846–2.710], $P = .163$). A previous endoscopic treatment performed in other hospitals resulted in almost 5 times higher risk of failure (OR 4.818, CI 95% [2.260–10.274], $P < .001$), and an increase of 2% was highlighted every 10 days of delay from BSCC and referral to our center. (OR 1.002, CI 95% [1.001–1.003], $P < .001$)

At multiple logistic regression, all the aforementioned variables were independent predictors of failure for endoscopic management of BS AEs. Type of complication was excluded from this analysis due to its association/correlation with an emergency treatment (Cramer's V test .689).

The predictive ability of this model is 82.9% (Table 5).

The median treatment duration was 80.0 days (IQR 29–128). In particular, it was 66.5 days for leaks (IQR 28–119), 89 days for fistulas (IQR 32–140), and 78.5 days for IAC respectively. (IQR 16.5–128).

Five endoscopists performed respectively 305, 139, 46, 31, and 26 procedures. No statistical differences in clinical outcome were highlighted among each operator ($P = .323$).

Discussion

Bariatric surgery (BS) is the most effective treatment for morbid obesity and its related co-morbidities [14,15].

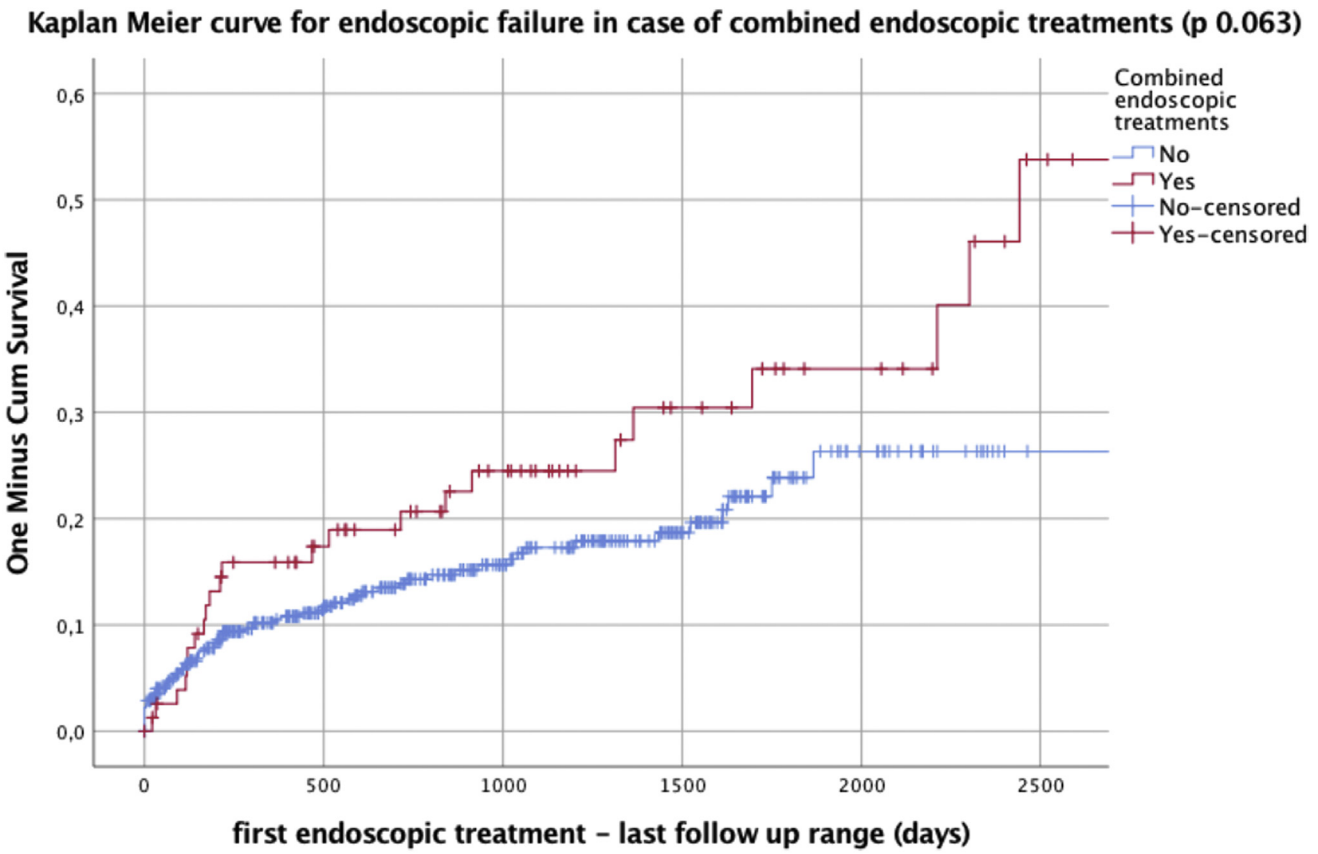

Fig. 1. Time-to-event analysis to compare the incidence rates of endoscopic failure depending on the need of a secondary endoscopic treatment.

Table 3
Clinical outcome of endoscopic treatment in case of prior emergency surgery or percutaneous drainage

Emergency treatment	Endoscopic success, n (%)	Endoscopic failure, n (%)	*P* value
No	267 (71%)	36 (57.1%)	.034
Surgery	109 (29%)	27(42.9%)	
No	267 (75.4%)	36 (63.2%)	.161
Percutaneous drainage	87 (24.6%)	21 (36.8%)	
Surgery	109 (55.6%)	27 (56.3%)	.644
Percutaneous drainage	87 (44.4%)	21 (43.7%)	

Sleeve gastrectomy has become the most frequent bariatric procedure worldwide [16], with favorable long-term results [2]. Unfortunately, up to 3% [17] of patients present BS-related AE. The endoscopic approach has become the treatment of choice for the management of most BS-related AEs. However, a well-defined protocol is still lacking. Several endoscopic techniques have been proposed with mixed results [18]; moreover, due to the limited population size of most studies, a proper comparison of long-term results between the different approaches is difficult. When, why, and on whom to apply one approach over another is still debated among bariatric surgeons and interventional endoscopists. EID with DPS deployment is safe and cost-effective [19,20].

We were among the first to report our results of EID for the treatment of leaks and fistula after BS [21]. We adopted this approach based on our previous experiences and failures with the so-called "sealing" approach [22] (fully covered self-expandable metallic stents [FCSEMS], over-the-scope clip, plugs). The effectiveness of FCSEMS was the subject of 2 recently published systematic reviews [23,24]. They highlighted a success rate and a migration rate of 72%–89 % and 23%–30.5%, respectively. The high rate of FCSEMS-related AE should be considered a major drawback of this approach. In our opinion, EID has some intrinsic advantages over the "sealing" approach: the short drainage route and the favorable pressure gradient allow a proper drainage of surrounding collections. This "third" pathologic space is a virtual pseudocavity that, once drained, tends to collapse and heal for second intention closure; DPS acts as a foreign body promoting granulation tissue thus accelerating pseudocavity obliteration.

In contrast to other authors [25,26] that advise the use of SEMS over EID for defect orifice >20 mm, we adopted EID with multiple DPS deployment in all cases independent of defect size.

In our study, only 91 patients needed an adjunctive endoscopic technique coupled with EID. This combined approach was mainly related to concomitant presence of a stenosis. SG is a restrictive procedure inducing a pressure increase within the gastric remnant that may magnify the risk of leak [27]. Most probably, the primum movens of leaks is relative ischemia at the upper third of the staple line; nonetheless, the presence of a stenosis may further increase intraluminal pressure enduring spillage of fluids in the pseudocavity and thus slowing the healing process. Our analysis showed that the need for such a combined approach was an independent risk factor for treatment failure. This finding, most probably, correlates to the increased complexity and severity of cases requiring 2 simultaneous endoscopic treatments. TAccording to our protocol, enteral feeding was maintained for one month in all cases after EID. We believe this is important for 3 main reasons: firstly, to overcome the transient physiologic inflammatory

Table 4
Clinical outcome according to timespan between index surgery and endoscopic treatment (Rosenthal classification)

Time after presentation	Leak n = 275	Fistula n = 242	Collection n = 30	Total n = 547
Endoscopic success				
Overall	246 (89.5%)	190 (78.5%)	27 (90%)	463 (84.7%)
0–7 d	53 (19.3%)	22 (9.1%)	2 (6.7%)	77 (14.1%)
8–42 d	156 (56.7%)	144 (59.5%)	16 (53.3%)	316 (57.8%)
43–90 d	18 (6.5%)	15 (6.2%)	3 (10%)	36 (6.6%)
>90 d	19 (6.1%)	9 (3.7%)	6 (20%)	34 (6.2%)
Endoscopic failure				
Overall	29 (10.5%)	52 (21.5%)	3 (10.%)	84 (15.3%)
0–7 d	2 (1.5%)	3 (1.2%)	0	5 (.9%)
8–42 d	12 (4.4%)	33 (13.7%)	2 (6.6%)	47 (8.6%)
43–90 d	7 (2.5%)	2 (.8%)	1 (3.3%)	10 (1.8%)
>90 d	8 (3.0%)	14 (5.8%)	0	22 (4%)
P value	.001	<.001	.634	<.001

Table 5
Independent predictors of treatment failure at multiple logistic regression

Variable	Odds ratio	CI (95%)	*P* value
Combined endoscopic treatment	2.076	1.168–3.687	.013
Emergency surgery before endoscopy	1.923	1.113–3.324	.019
Emergency percutaneous drainage before endoscopy	1.427	.772–2.636	.256
Previous endoscopy in other centers	3.564	1.579–8.043	.002
BSCC–Endoscopy interval*	1.001	1.000–1.002	.005

BSCC = bariatric surgery causing complication.
* BSCC–Endoscopy interval is the number of days between bariatric surgery that caused the complication and first endoscopic treatment at our unit.

narrowing after SG; secondly, to guarantee a higher caloric intake; and ultimately, to avoid super-infection of the pseudocavity [12].

Need of emergency surgery for peritoneal lavage before endoscopy was a risk factor for clinical failure (75% higher) whereas percutaneous drainage did not reach a statistically significant difference in clinical success. These data could be explained by the assumption that the need for emergency surgery may reflect more complex cases. However, it is known that revisional surgery is burdened by an increased morbidity [28] and in a delay of endoscopic treatment, thus influencing overall clinical success [25]. EID as first-line treatment is adequate to achieve complete drainage of perigastric pseudocavity collection in case of localized peritonitis. Therefore, in a similar scenario emergency surgery should be reserved only in case of unstable/septic patients or if a therapeutic endoscopist is not readily available. Whenever possible, radiological drainage should be preferred over surgery.

On the contrary, in case of generalized peritonitis, surgical management is mandatory but should be followed by early EID in order to allow early removal of external drainages and achieve internal drainage thus avoiding chronic gastro cutaneous fistula formation [29].

The timing of endoscopy has been shown to have a strong impact on clinical outcome. In stable patients, the sooner EID is performed the better the results are [30]. The study highlighted an increase of 2% in clinical failure every 10 days of delay from BSCC. EID allows sepsis control and collection drainage, thus reducing the need for surgery. Whereas delay in endoscopic management is associated with higher costs due to sepsis persistence and more frequent referral to the intensive care unit [31,32].

Available literature showed a lower success rate for chronic fistula compared with leaks [33]. This evidence was confirmed by our study. Nonetheless, EID may be successful even in complex chronic fistulas (i.e., gastrocutaneous and gastro-bronchial). Previous endoscopic treatment in peripheral hospitals was associated with a lower success rate as well. Possible explanations for this evidence are: delayed referral to high-volume centers, lack of a standardized treatment protocol, and frequent use of a "sealing technique" in low-volume centers. Our study highlighted a 2% increase of failure every 10 days of delay in endoscopic treatment. No differences were highlighted in the overall outcome among different operators as long as the procedures are performed in a referral center and a standardized protocol is applied [31,34].

The rate of endoscopy-related AEs was 4.5% with almost half of the cases managed conservatively. Our complication rate was much lower than the average AE rate reported in literature [20]. Such data could be explained by the fact that all procedures were performed in a tertiary center with high-volume activity with particular focus on interventional endoscopy (>4500 procedures per year).

The most frequent DPS-related AEs are mainly related to injuries of vascular structures close to the cardial region (i.e., splenic vessels) and to persistent sepsis. In this large series, we showed that first-line exclusive management with DPS induced complete healing in 87.3%, 77.4%, and 89.3% in case of leak, fistula, and IAC, respectively. Clinical success rate was higher when compared with data reported in literature [35–37]. Study strong points are the large number of patients treated, the application of a well-defined protocol for DPS independent from type of AE, size of the defect, gastric location, and delay from index surgery. Study limitations include its retrospective nature and the lack of a standardized treatment for comparison; the use of unvalidated protocol, based on experience in large series; the single-center experience, even if mitigated by the presence of several endoscopists sharing a common method; and the population heterogeneity. The study population comprises all consecutive patients subjected to EID since 2012 and it includes data previously published by our group on a smaller number of patients.

Conclusion

In conclusion, first-line early EID for the management of leak, fistula, and IAC after SG seems a safe and effective approach with good long-term results, allowing for reduced need of rescue surgery for clinically stable patients. However, fistula, concomitant stenosis, and previous emergency surgery or endoscopic treatment are independent risk factors

for clinical failure. Surgical management before endoscopy is mandatory for unstable patients.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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