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Endoscopic internal drainage using transmural double-pigtail stents in leaks following upper gastrointestinal tract surgery.

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ABSTRACT

Introduction

Different endoscopic procedures have been proposed for the management of surgical leaks. Endoscopic internal drainage using trans-fistulary double-pigtail plastic stents has emerged as an alternative, especially in fistulae presenting after laparoscopic gastric sleeve.

Methods

Retrospective case series conducted at a single tertiary care center including all upper gastrointestinal post-surgical leaks primarily managed with endoscopic trans-fistulary insertion of double-pigtail plastic stents. Clinical success was defined as the absence of extravasation of oral radiographic contrast and radiological resolution of the collection with adequate oral intake.

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Results

Nine patients were included, 6 (66.6%) females, median age: 52.6 years (IQR 47—60). Five cases presented after laparoscopic gastric sleeves, 2 cases after distal esophagectomies, one after a Roux-en-Y gastric bypass and another one after a pancreaticoduodenectomy. Fistulae measured <10 mm in 5 patients (55.6%) and 10-20 mm in 4 patients (44.4%). Six were early leaks. Technical and clinical success was achieved in 9 (100%) and 7 (77.8%) cases, respectively. Seven (77.8%) patients required ≤3 endoscopic procedures. Median hospital stay after the first endoscopic procedure was 12 days (IQR 6.5-17.5 days), while overall median time until leak healing was 118.5 days (IQR 84.5-170). One patient presenting a post-esophagectomy intrathoracic leak developed an esophageal-tracheal fistula 37 days after stent deployment.

Conclusions

Our results support the use of endoscopic internal drainage in postsurgical abdominal leaks, regardless of the type of surgery, although only two patients with intrathoracic dehiscence were included.

Keywords

Double-pigtail stents, endoscopic internal drainage, gastrointestinal surgery complications, leaks.

INTRODUCTION

Anastomotic leaks count among the most severe complications following upper gastrointestinal surgery. Their incidence ranges between 2% after laparoscopic sleeve gastrectomy (1), 5.3% after Roux-en-Y gastric bypass (RYGBP) (2) and 5-30% after esophageal anastomoses (3), with mortality rates of up to 18.9% (3). Clinical presentation of anastomotic leaks includes perianastomotic collections, pneumothorax or pneumoperitoneum, abscess formation and mediastinitis (4).

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Surgery has been the historically preferred management strategy to control the infection and close the dehiscence. Although it is still the preferred management in case of mediastinitis, severe sepsis or a large fistula involving more than 50% of the anastomotic circumference, less invasive endoscopic approaches have been proposed for cases presenting with milder symptoms (4). Reported endoscopic procedures include deploying covered self-expandable metal stents (cSEMS) (5) (6) , fibrin glue(7) , endoscopic suturing(8) , endoluminal vacuum therapy (9) and fistula closure with over-the-scope clips (OVESCO) (10). These techniques have achieved widely variable clinical success rates, ranging from 37 to 86% (1)(3)(6) (7) (8) (9).

Endoscopic internal drainage (EID) has been recently proposed as a promising alternative to treat anastomotic leaks. It consists on deploying double-pigtail stents (DPS) with one end inside the collection and the other in the intestinal lumen. It drains the collection diverting the flow into the empty intestinal lumen, while it also induces the growth of granulation tissue, thus promoting the closure of the fistula. This procedure can be performed with a gastroscope or duodenoscope. Most available studies of EID assess laparoscopic sleeve gastrectomy (LSG) leaks, reaching leak closure rates of 74.6% (11), and up to 85% when employed after other failed endoscopic treatments (12). Studies assessing its results in non-LSG related upper gastrointestinal leaks are scarce: Bouchard et. al reported a case series including 28 LSGs and 5 patients with a Roux-en-Y gastric bypass with an overall clinical success rate of 78.8 % (13) while another case series showed optimal results in 4 anastomotic leaks following upper and lower gastrointestinal surgeries (14) .

Thus, we decided to report our experience treating upper gastrointestinal leaks using EID with DPS insertion, assessing its efficacy and adverse events.

METHODS

The present study is a retrospective case series conducted at a single tertiary care center in Spain. All patients or their next of kin provided informed consent for all procedures performed. The study was approved by the local Institutional Review Board (PI008-20).

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Participants

All patients undergoing endoscopic treatment of postsurgical anastomotic leaks or fistulae after upper gastrointestinal surgeries between May 2017 and June 2019 were included. Patients were identified using a prospective database kept in the endoscopy unit, including all subjects undergoing advanced therapeutic procedures. After identifying all patients undergoing endoscopic management of fistulae, medical records were reviewed to include those with a previous upper gastrointestinal surgery. Since May 2017, in our endoscopic unit we use the EID with transmural DPS as first line treatment of postsurgical anastomotic leaks.

Inclusion criteria

The only inclusion criterion was the endoscopic treatment of upper abdominal abscesses secondary to post-surgical leak or fistulae with trans-fistulary insertion of DPS.

Exclusion criteria

Patients with at least one previous attempt of surgical treatment.

Procedures

All endoscopic procedures were performed under sedation by the interventional endoscopist with propofol +/- midazolam, without oro-tracheal intubation, unless critically ill. Broad-spectrum antibiotic treatment was started at the time of diagnosis. A gastroscope (Olympus GIF 160 Gastroscope) was used to evaluate the leak (figure 1), cannulate the orifice and, after guidewire insertion (Jagwire 0.035in, Boston Scientific), insert one or more 5-7 cm 7 Fr DPS (Advanix, Boston Scientific, Massachusetts or Visio Gflex Europe, Belgium) (figure 2a). The stents were deployed through the leak, placing one end inside the collection and the other inside the gastrointestinal lumen, in order to achieve the drainage. The size of the DPS was chosen at the discretion of the endoscopist. We used the 5 cm DPS for smaller collections and the 7 cm DPS for the larger ones. Also, according to the size of the fistula orifice we chose to insert one or more DPS.

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Systematic endoscopic follow-up was performed to assess the fistula and consider the removal or exchange of the DPS (figure 2b). Timing was decided at the discretion of the attending physician. In case of persistent abscess or collection, further endoscopies were performed until complete resolution of the leak.

Definitions and outcomes

Postsurgical leaks were defined as the extravasation of radiographic contrast in CT scan confirmed by upper gastrointestinal endoscopy. The time until onset and location of the fistula were defined according to the UK surgical infection study group (15). Briefly, time until onset was classified as acute [onset on post-operative day (POD) 1 to 7], early (POD 8 to 48), delayed (POD 49 to 84) and chronic (presenting beyond 12 weeks after surgery). Technical success was defined as the correct trans-fistulary deployment of at least one DPS. Clinical success was defined as the absence of extravasation of oral radiographic contrast accompanied by the radiological resolution of the collection and adequate oral intake. Leak healing was defined as leak closure observed on endoscopy with withdrawal of the DPS with no need for further exchange and absence of collections on CT scan. Treatment failure was defined as the need for surgery, other endoscopic treatments or death. Adverse events were graduated according to ASGE recommendations (16).

Data retrieval

Endoscopic data were retrieved from the advanced endoscopic procedures database, which includes patient's demographics and variables describing the procedure. Other patients' data (demographics, radiological findings, clinical outcomes and adverse events) were retrospectively retrieved from medical electronic records. Clinical management and follow-up were performed according to the attending physician's decisions. Patients' data were collected into a newly created database. In case of unclear or contradictory statements in the medical records, a consensus decision was made.

Statistical analysis

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The statistical analyses were performed using IBM SPSS Statistic version 15.0 (Inc IL. USA). Continuous variables were presented as mean and standard deviation or median with interquartile range, as warranted. Categorical variables are presented as numbers and percentages.

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RESULTS

Participants

Between May 2017 and June 2019, a total of 9 patients presenting post-surgical anastomotic leaks were submitted to our endoscopy unit. Two patients underwent urgent laparotomy after the leak diagnosis without finding its exact location, therefore not receiving surgical treatment. Thus, all patients were included in the final analysis.

Six (66.6%) patients were female and the median age was 52.6 years (IQR 47—60). Most leaks were secondary to LSG (5 cases), but we also included 2 cases after distal esophagectomy and lymphadenectomy with gastric pull-up, one presenting after a RYGBP and another after a pancreaticoduodenectomy (Whipple's procedure) with gastrojejunostomy. The comorbidity assessment through the ASA system were: 5 patients ASA III, 3 patients ASA II and 1 patient ASA IV. One third of patients were in the intensive care unit at the time of the procedure, due to the severe clinical conditions.

Characteristics of leaks and fistulae

The diameter of the fistula was measured as <10 mm in 5 patients (55.6%) and 10-20 mm in 4 patients (44.4%). In the two patients with previous esophagectomy, the location was intra-thoracic in the esophagogastric anastomosis; in the patient with previous Whipple's procedure the locations was the gastrojejunal anastomosis and in the gastric pouch in the patient who underwent a RYGBP. In the remaining LSG, the location was in the proximal gastric staple line.

Anastomotic leaks were identified after a median of 9 days (IQR 3-31) after surgery. Most fistulae (66.6%) were classified as early leaks; the remaining 3 (33.3%) were acute.

The median time between surgery and the first endoscopic procedure was 14 days (IQR 7-34 days). The number of endoscopic procedures per patient was as following: 1 procedure (N= 1), 2 procedures (N= 5), 3 procedures (N=1) and 4 procedures (N= 2).

Endoscopic procedures

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Fluoroscopic control for cannulation and insertion of the guidewire to deploy the DPSs was used in all patients. Most procedures were performed with a gastroscope, but in 2 cases an endoscopic ultrasound was used to deploy the DPS. Seven patients received 2 DPS, the remaining 2 received only one.

In 4 out of 5 patients with a previous LSG, an antral balloon dilation to allow an adequate gastric emptying was performed due to postsurgical distal staple line stenosis.

Further postsurgical collections besides those communicating through the fistulae were observed in 2 cases who required simultaneous percutaneous drainage of synchronous collections not amenable to endoscopic drainage. Both were cases following LSG; the first case was a 50 years-old female presenting a 10 x 7 cm collection and the other case was a 36 years-old female who presented a 4 x 7 cm collection.

Outcomes

Technical and clinical success was achieved in 9 (100%) and 7 (77.8%) cases, respectively. Two patients were deemed to be treatment failures. A 68-years-old female who underwent a Whipple procedure for an ampullary adenocarcinoma and developed a 10 to 20 mm leak in the gastrojejunostomy anastomosis presented an intraperitoneal haemorrhage from a ruptured gastroduodenal aneurysm causing haemorrhagic shock 7 days before the endoscopic procedure. Despite initial clinical improvement, the patient died 38 days after surgery due to multiple organ dysfunction. This adverse event was not considered to be related to the endoscopic procedure, as the aneurysm was not in the vicinity of the collection and it presented before placing the DPS. The second case of treatment failure was due to the development of an esophageal-tracheal fistula (see below).

The median hospital stay after the first endoscopic procedure was 12 days (IQR 6.5-17.5 days). The median time until the first follow-up endoscopy was 87 days (range 21 to 171 days, IQR 40-146 days). Overall median time until leak healing was 118.5 days (IQR 84.5-170), ranging from 71 to 208 days.

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Adverse events related to the endoscopic procedure

Two patients developed stent related adverse events. A patient with a LSG presented a moderate upper gastrointestinal bleeding due to a mucosal erosion by a DPS 128 days after the index endoscopy. Neither endoscopic treatment nor blood transfusions were required. Another patient with a previous esophagectomy and gastric pull up developed a tracheoesophageal fistula. The patient was readmitted 37 days after stent deployment, complaining of fever, cough and chest pain. On endoscopy a persistent fistula was noted, so the DPS was removed, and a SEMS (Wallflex®) was deployed. Despite the endoscopic intervention, the patient persisted with cough and purulent sputum. A bronchoscopy confirmed a 1-cm-size orifice of an esophageal-tracheal fistula 2 cm above the carina (Figure 3). We hypothesize the proximal end of the DPS was responsible of the tracheal perforation. Two attempts of endoscopic suture of the orifice were unsuccessful. Repeated bronchoscopies were performed with instillation of ethanol with endoscopic needle and bioglue (Cryolife Inc, Kennesaw, Georgia). After three months, a complete healing of the fistula was achieved.

DISCUSSION

Our study presents the first single center retrospective case series assessing the outcomes of EID in upper gastrointestinal postsurgical anastomotic leaks or fistulae in Spain. Apart from LSGs we also included other different upper gastrointestinal surgeries. Overall, we attained clinical success in 7 cases (77.8%), although it reached 100% in LSG but dropped to 50% in non-LSG cases.

The endoscopic approach in post-surgical leaks seems to be widely accepted. The deployment of SEMS remains the most popular endoscopic approach, but a poor tolerance and high migration rate of up to 83% have been reported (17). In post-LSG leaks, EID has shown excellent results. A recently published systematic review, including 385 patients with gastric leaks following LSG, reported overall clinical success rates of 83.4% and 84.7% when only first line treatment was included. Also, a low complication rate (13.7%) and good tolerance have been reported (18). Reported adverse events include bleeding, drainage migration, perforation, gastrobronchial fistula, splenic hematoma, stricture, bleeding ulcer, peritonitis and wall incarceration

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(18). Moreover, this rate seems to vary greatly when used as first line or second line treatment. Gonzalez et al reported a 47% overall adverse event rate when used as second line treatment, while it was only 4.7% when only first line treatment were considered (19).

We included 4 patients with surgeries different from LSG, 2 cases after distal esophagectomy and lymphadenectomy with gastric pull-up, one presenting after a RYGBP and another after a Whipple's procedure with gastrojejunostomy. In these patients the clinical success was achieved in only 2 cases. While one failure presented a severe adverse event (esophageal-tracheal fistula requiring various endoscopic treatments and prolonged hospital stay), the second one did not reach clinical success as she died due to complications unrelated to the endoscopic treatment (rupture of a gastroduodenal artery aneurysm which presented 7 days before the endoscopic procedure). Three studies assessing the use of EID with DPS in leaks presenting after surgeries different from LSG have been published. Firstly, Donatelli et al reported 9 cases with previous upper gastrointestinal surgeries other than LSG (3 total gastrectomy, 3 cholecystectomies, tumorectomy of retroperitoneal cancer, distal esophagectomy and esophageal diverticulotomy), although only five cases were anastomotic leaks. The observed only 2 (22.2%) clinical failures, both following total gastrectomy with esophageal-jejunal anastomosis; one presented a perforation on POD 1 and the other a persistent gastric leak (14). Secondly, Bouchard et al, reported 5 cases after GPB with another 28 LSGs, observing a combined clinical success rate of 78.8% (13). Lastly, the largest case series published to date, also by Donatelli et al., includes exclusively patients following RYGB using EID by DPS. Thirty-three patients were included reaching clinical success in 31 (93.9%)(20) .

The median length of stay after the procedure (12 days) and the need for intensive care in 3 patients show the complexity of these patients. The median time until leak healing was prolonged (118.5 days), but patients were attended in the out-patient clinic. This data is similar to the interval to leak healing reported by Giulani et al (118.1 days, Range 55.5-227)(18) .

In supradiaphragmatic postsurgical leaks the paucity of published reports is even higher than in non-LSG procedures. Donatelli et al reported 5 cases (3 leaks in the

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esophagojejunal anastomosis following a total gastrectomy, 1 case in the esophagogastric anastomosis and 1 case in the esophageal staple line) (14). Only 3 (60%) achieved clinical success. In our series, we identified a severe esophago-tracheal fistula and a success rate of 50%. Interestingly, Meunier et al. reported an esophago-pericardial fistula following EID using a DPS in a LSG, requiring surgical treatment (21). Including the 2 cases from our series, DPS has reached clinical success in 4 (57.1%) patients, with 2 (28.6%) severe adverse events among the 7 reported cases. We consider these results raise serious concerns regarding the use of DPS in intrathoracic fistulae.

In our protocol, the endoscopist decided the removal of the DPS. According to our experience it should not be done before 3 months. In our series the median time until the second endoscopist procedure was 87 days. In case of good clinical evolution, no radiological images were required for the removal and if no replacement was needed due to successful leak closure, we did not use any additional endoscopic procedure for the closure of the orifice.

There are several limitations to our study. Firstly, the limited number of patients included does not allow to draw firm conclusions. Secondly, the retrospective design misses interesting data, especially regarding the endoscopic procedure, although the strict clinical follow-up allowed us to adequately retrieve all primary and secondary outcomes. Thirdly, there might be a selection bias, as the decision to refer patients for endoscopic therapy was made by the attending surgeon. Finally, as concluded by other case series and retrospective studies, the lack of prospective multicentre studies precludes the assessment of the role of the expertise of the endoscopist, which could be determinant in the feasibility and use of this technique(13) (18).

In summary, our results support EID with transmural double-pigtail stents in leaks and suture-line dehiscence as a highly effective method for abdominal postsurgical fistulae, regardless of the gastrointestinal surgery involved, although we included only two cases of intrathoracic leaks. .

DISCLOSURES

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Dr. Manuel Perez-Miranda is a consultant for Boston Scientific, Olympus, Medtronic and M.I. -Tech. The remaining authors have no conflict of interest.

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Table 1. Patients' baseline characteristics (n=9)

Patient 9	**Patient 8**	**Patient 7**	**Patient 6**	**Patient 5**	**Patient 4**	**Patient 3**	**Patient 2**	**Patient 1**	
Female, 64	Male, 56	Male, 52	Female, 35	Female, 54	Female, 68	Female, 50	Male, 49	Female, 45	**Sex, Age**
LSG	E	E	LSG	GBP	PD	LSG	LSG	LSG	**Type of Surgery**
9	23	39	2	6	17	3	40	4	**Fistula onset (days)**
10-20 mm	10-20 mm	10-20 mm	<10 mm	10-20 mm	10-20 mm	<10 mm	<10 mm	<10 mm	**Fistula diameter**
Gastric staple line	Esophageal-gastric anastomosis	Esophageal-gastric anastomosis	Gastric staple line	Gastric pouch	Gastro-jejunal anastomosis	Gastric staple line	Gastric staple line	Gastric staple line	**Fistula location**
2	2	4	2	2	1	4	3	2	**Number of endoscopic procedures**
2	2	2	1	2	2	2	1	2	**Number of pigtails**
Balloon dilatation	-	-	Balloon dilatation	US-guided drainage	-	US-guided drainage	Balloon dilatation	Balloon dilatation	**Other procedures**
-	-	Esophageal-tracheal fistula	-	-	Aneurysm rupture. Death	Upper gastrointestinal bleeding	-	-	**Adverse event**

LSG: laparoscopic sleeve gastrectomy. PD: pancreaticoduodenectomy. GBP: Roux-en-Y gastric bypass. E: esophagectomy and lymphadenectomy with gastric pull-up.

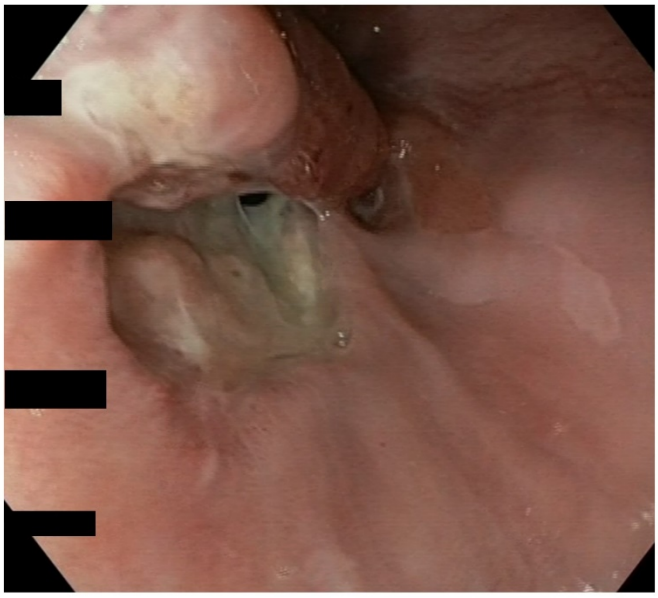

Figure 1: Post-surgical leak following a laparoscopic gastric sleeve in a 45 years-old woman. A suture dehiscence in the proximal staple line in the gastroesophageal junction is seen.

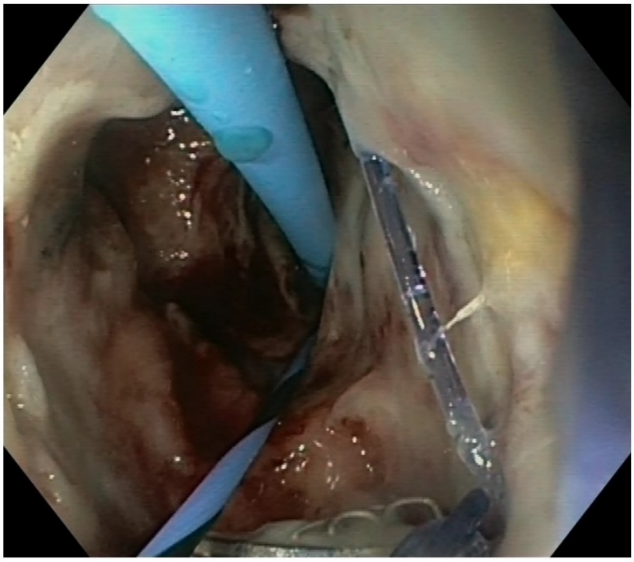

Figure 2a: Endoscopic imagen of a fistula in a laparoscopic gastric sleeve in a 45 years-old woman. A double-pigtail plastic stent can be observed accessing the collection through the fistula, while a guidewire is inserted to deploy a second double-pigtail stent.

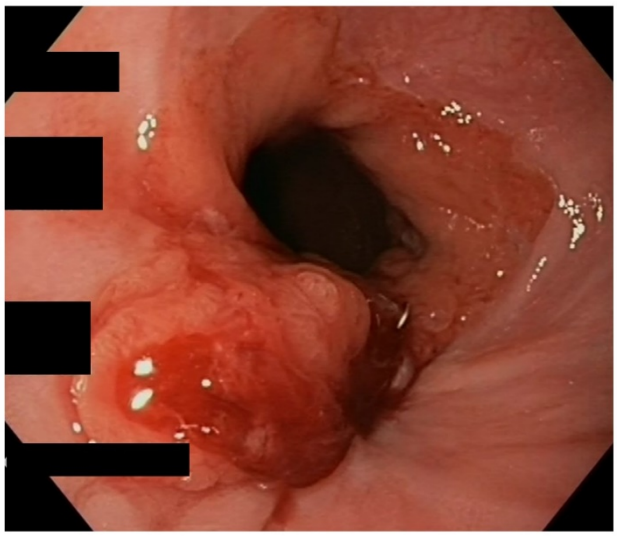

Figure 2b: Endoscopic view of the same patient obtained 95 days after stent placement and just after stent removal, where the fistula is completely closed.

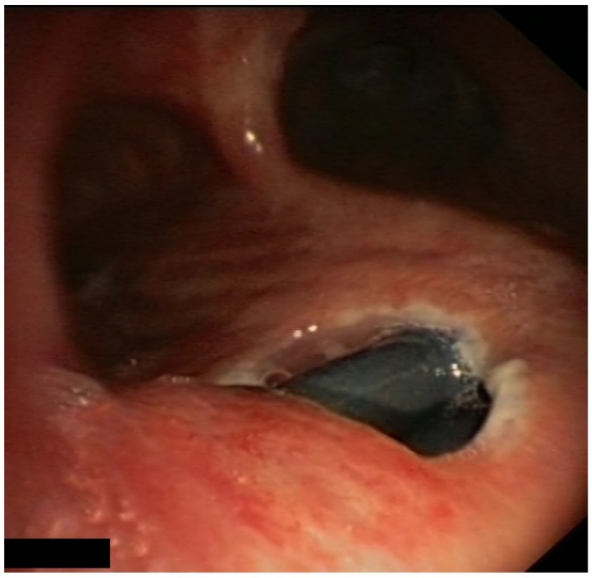

Figure 3: Bronchoscopic view of an esophageal-tracheal fistula secondary to an endoscopic internal drainage of a postsurgical leak in a patient with previous esophagectomy and gastric pull up using double-pigtail stents. The plastic stent can be observed through the fistula.