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Endoscopic 'suction room' to treat complex enteral stump leaks after upper gastrointestinal surgery

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ABSTRACT

Leaks/dehiscence of the enteral stump associated with infected peri-enteric collections after upper gastrointestinal surgery are a life-threatening adverse event, not usually endoscopically treatable.

We describe a new endoscopic approach to treat complex entero-cutaneous fistulas (CECF) by creating a "suction room" through placement of multiple stents (enteral, biliary and/or pancreatic) and a large nose-enteral suction tube inside the enteral stent maintained on a continuous negative aspiration suction.

Between January 2016 and December 2019, six consecutive patients referred to our unit with CECF of the enteral stump after failed redo surgeries underwent creation of a "suction room." In five patients, enteral, biliary and pancreatic stents were positioned before a nose-to-stent or nose-to-collection large 18 Fr tube placement. In one patient, a pancreatic stent was not placed. Technical and clinical success were achieved in all patients. Mean and median times of aspiration were 49 and 27 days, respectively, with a mean hospital stay of 56 days after the endoscopic procedure. Stents were successfully removed. Mean post-procedural follow-up was 17.3 months.

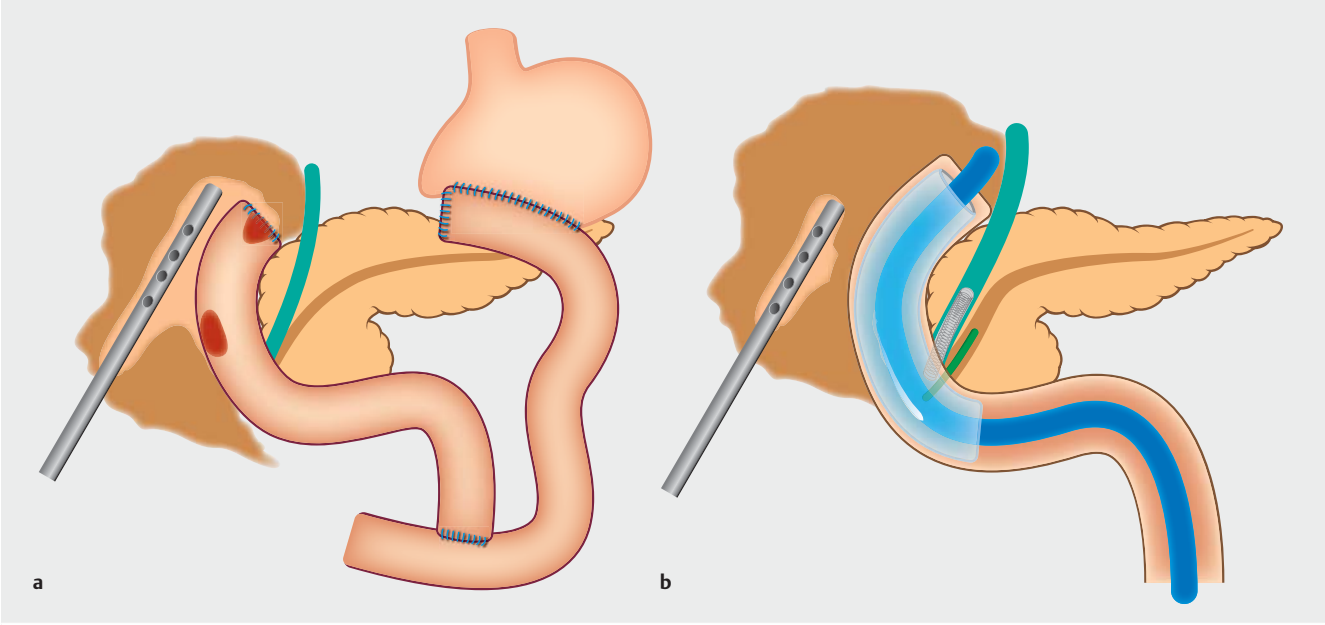
Endoscopic creation of the "suction room" offers the unique possibility of treating complex entero-cutaneous fistulas in surgically altered sites, which are difficult to manage with standard endoscopic methods.

Introduction

Application of negative pressure is increasingly utilized in the management of anastomotic leaks and perforations in both the upper and lower gastrointestinal tract. The rationale for its use is to eliminate from the site of the leak/perforation gastrointestinal secretions and bile and pancreatic juices, reducing the cause of local inflammation and interstitial edema, favoring granulation of the fistula and eventually its closure [1].

Complex entero-cutaneous fistulas (CECF) (▶ **Fig. 1a**) are bowel perforations at the level of the duodenal stump after subtotal gastrectomy or of the jejunal stump after hepaticojejunostomy on Roux-en-Y loop. These perforations can be worsened by an additional dehiscence of the enteral stump due to partial or complete leakage of surgical sutures, with development of an infected peri-perforation collection(s).

Redo surgery is considered the gold standard treatment for CECF [2], but it has high morbidity and mortality rates (20 %–65 %) due to leak recurrence [2]. Moreover, repeated surgical interventions and prolonged conservative management strategies can worsen the septic status [2, 3]. In this clinical scenario, standard endoscopic treatments for defect closure, such as



▶ **Fig. 1** Images showing **a** schematic example of "complex enterocutaneous leak" with a surgical/percutaneous drainage and **b** creation of a "suction room" with enteral, biliary, and pancreatic stents and a suction tube inside the enteral stent.

over-the-scope or through-the-scope (TTS) clips, glues, and sealants do not properly work because of necrotic and/or infected tissues (and eventually fluid collections) around the leak [4, 5]. In addition, presence of chronic and inveterate fistulas results in extremely high failure rates with endoscopic treatment.

In case of CECF, large-bore (>20-mm diameter, over-the-wire) fully-covered self-expandable metal stents (FC-SEMS) to divert bowel contents away from the leak/dehiscence are difficult to place at the level of enteral stapled stumps due to technical limitations of insertion devices. Small-diameter TTS covered enteral stents also fail due to inability to create complete adherence between the intestinal wall and the stent itself. Finally, standard vacuum-assisted intraluminal systems cannot be used in these settings, because of overtube and insertion device length, and dimensions of the vacuum sponge.

We herein describe an innovative endoscopic approach developed to treat CECF by creating a "suction room," in which after placement of combined enteral, biliary and/or pancreatic stents a new vacuum-assisted therapy is placed and used to create a negative pressure curative chamber (▶ **Fig. 1**).

Methods

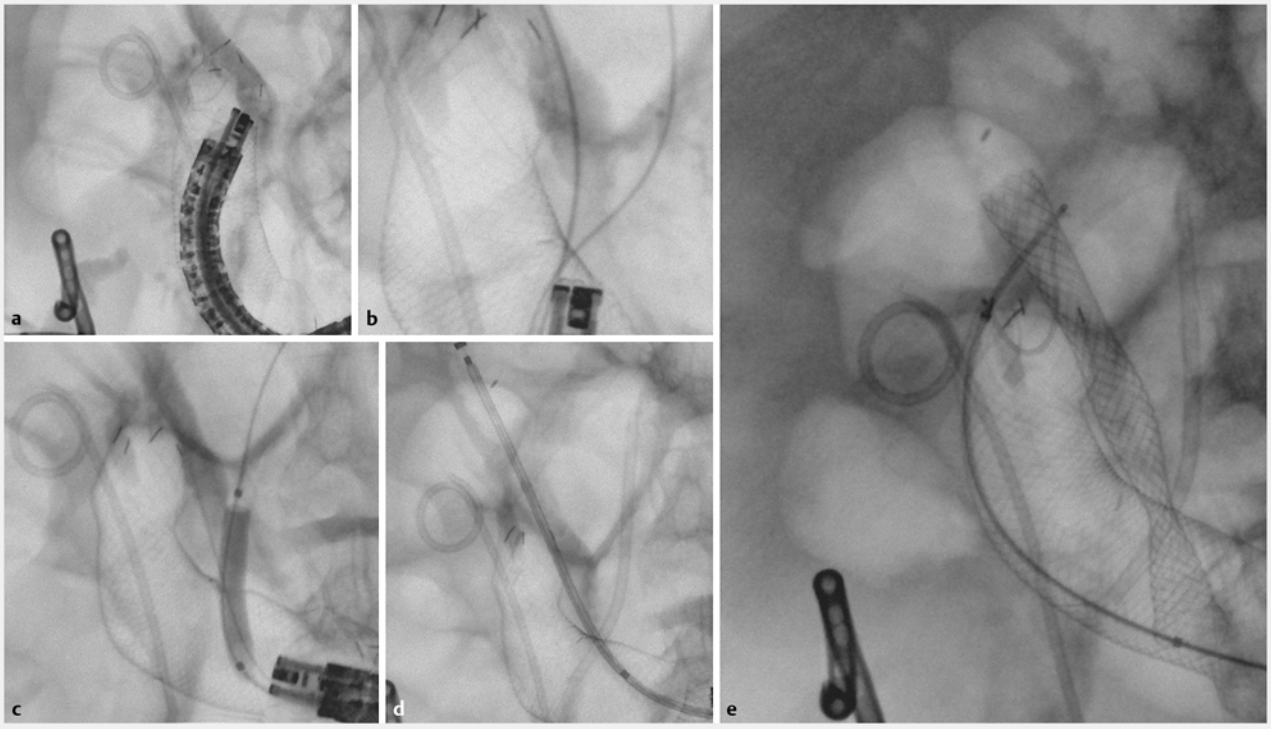
This was a retrospective study of all patients who underwent endoscopic treatment in our hospital between January 2016 and December 2019 with a newly developed approach, which we named a "suction room," for CECF refractory to repeated surgery.

Procedure

All procedures were performed under deep sedation or general anesthesia, preferably in the prone position, under fluoroscopy. For all patients, an informed consent was obtained before the procedure.

Endoscopic retrograde cholangiopancreatography (ERCP) was performed to evaluate biliary and pancreatic anatomy and carry out biliary sphincterotomy to help subsequent cannulation through the mesh of the enteral stent. A pancreatic plastic stent was placed to be used as an endoscopic/radiological landmark.

A pediatric colonoscope (3.8-mm working channel, Pentax Medical) was then used through which an enteral TTS FC-SEMS (20-mm, 8–12 cm, Taewoong Medical) was deployed (▶ **Fig. 2a**) with the distal crown positioned at the level of the enteral surgically stapled cul-de-sac, overlapping the site of the leak by at least 2 cm. If dehiscence of the duodenal/jejunal stapled stump was present, the distal crown of the FC-SEMS was placed 2 cm outside the dehiscent enteral stump, into the peritoneal cavity. Biliary and pancreatic ducts were subsequently cannulated using a standard ERCP cannulotome ball-tip (ERCP-1-HKB, Cook Medical) or double-channel sphincterotome (CCPT-25, Cook Medical) with a hydrophilic guidewire (Delta, Cook Medical, Bloomington, Indiana, United States) by traversing the mesh of the FC-SEMS (▶ **Fig. 2b**). Pneumatic balloon dilation (6 mm, 4 cm, Hurricane Balloon, Boston Scientific) of the mesh was done to simplify subsequent biliary and pancreatic stent placement (▶ **Fig. 2c**), which was performed over the guidewires, through the covering membrane of the enteral stent (▶ **Fig. 2d**). Biliary FC-SEMSs (8–10 mm, 6–8 cm, Wallflex, Boston Scientific) and pancreatic plastic stents (7–8.5 Fr, 7–9 cm, CHBS Cook Medical) were used. In patients after hepaticojeju-



▶ **Fig. 2** Sequential creation of the "suction room." **a** Enteral stent placement. **b** Guidewires in both the common bile and pancreatic ducts through the mesh in the enteral stent. **c** Pneumatic balloon dilation of the mesh in the enteral stent. **d** Pancreatic and biliary stenting. **e** 18 Fr nose-to-stent tube placement through the guidewire.

nostomy to avoid closure by FC-SEMS of the small diameter biliary ducts, two biliary plastic stents (8.5 Fr, 9 cm, CHBS, Cook Medical) were inserted with the distal edges inserted into the enteral stent (▶ **Fig. 2e**).

To guarantee adherence of the enteral stent to the lateral leak and divert bowel secretions from the stump dehiscence, a nose-to-stent or nose-to-collection 18Fr tube (Salem Sump Dual Lumen Stomach Tube, Covidien) was positioned, with the distal tip in the enteral stent or over the stump along the fistula path in the peritoneal cavity and continuous negative aspiration pressure (- 80/-100 mmHg) was maintained. One or two flaps were made in proximity to the distal tip of the tube to anchor it to the site of the leak and reduce risk of dislodgement.

Surgical drains, when present, were pulled 5 to 6 cm away from the leak site and placed under gravity. Continuous aspiration was used 24 hours a day for 10 days in all patients to obtain complete resolution of fluid flow from the abdominal drainage. When surgical drains produced no fluid for at least 2 to 3 days, they were removed. Trans-nasal aspiration was continued for another 15 days. Once the fistula healed, aspiration was stopped and an abdominal computed tomography (CT) scan was performed to exclude residual abdominal collections. Stent removal was scheduled 8 weeks after first placement (▶ **Fig. 3**).

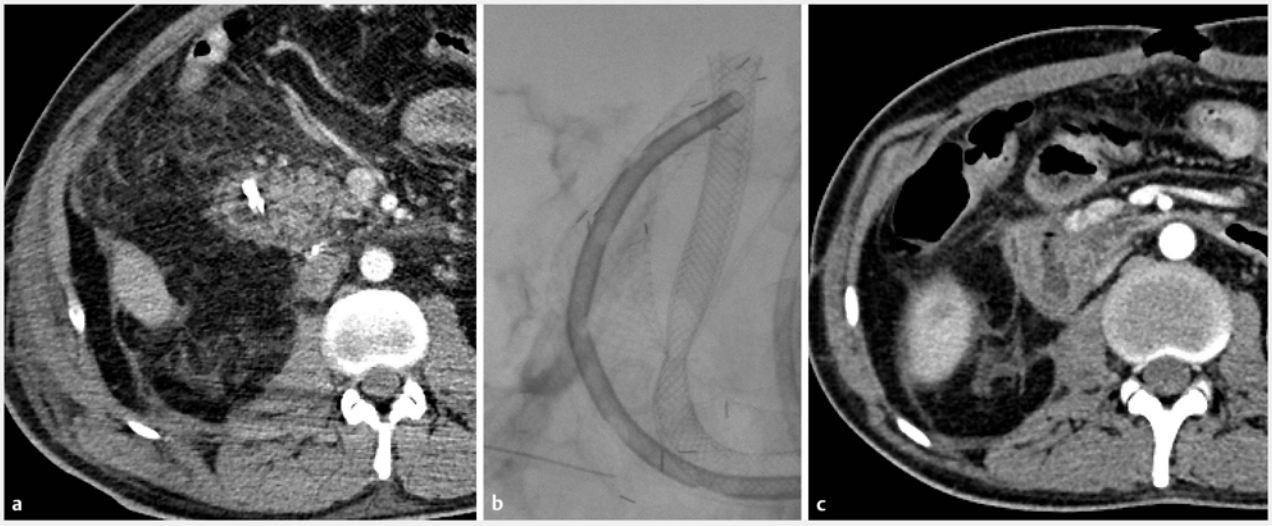
Outcome definition

Technical success of the procedure was defined as successful creation of the "suction room." Clinical success was defined as closure of the fistula without evidence of remnant peri-enteric fluid collection on abdominal CT and the patient was discharged home.

Results

Six consecutive patients (M/F 4/2; mean age 50 ± 11.1 years; mean American Society of Anesthesiologists score: 4) with upper gastrointestinal surgery complicated by refractory CECF who underwent "suction room" creation were retrospectively identified. All patients underwent repeat surgical intervention in our hospital, which is a referral center for these types of complicated leaks/dehiscence. Endoscopic intervention was attempted after a mean hospital stay of 32 ± 9 days, during which no improvement in patient clinical status was observed. Patient characteristics, types and number of previous surgical interventions, and type of leak/dehiscence are shown in ▶ **Table 1**. All patients had abdominal surgical/percutaneous drains placed at the level of the leak/dehiscence at the time of repeat surgery.

All procedures were performed by a single experienced biliopancreatic endoscopist (M.M.). Technical success was achieved in all six cases. In five patients, enteral, biliary, and pancreatic stents all were placed (▶ **Fig. 3**), while in the remaining patient, two biliary plastic stents were positioned through the enteral



▶ **Fig. 3** A complex duodenal leak after subtotal gastrectomy with Roux-en-Y reconstruction. **a** CT scan of the retroperitoneal thickening due to the enteral leak. **b** Fluoroscopic view of the "suction room" in place. **c** Follow-up CT 7 days after stent removal showing the complete resolution of the retroperitoneal edema.

stent (▶ **Fig. 4**). In a who had bariatric gastric by-pass (No. 2 in ▶ **Table 1**) and subsequent subtotal gastrectomy with maintenance of the Roux-en-Y loop, the duodenal stump was reached by creation, under EUS guidance, of a jejunal-jejunal bypass utilizing a 15 mm × 10 mm lumen apposing metal stent (Axios stent mounted on the electrocautery and delivery system; Boston Scientific), as previously described [6].

Clinical success was obtained in all six patients. Abdominal drains became null after a mean of 48 hours (range: 24–72). The "suction room" system was kept in negative pressure for a mean of 49±30 days (range: 24–103). The overall mean hospital stay was 160±113 days (range: 47–273), while mean hospital stay after endoscopic procedure was 76 ± 45.5 days (range: 31–122). Clogging of the tube during aspiration occurred in one patient and required replacement of the tube, which was easily performed under fluoroscopy. Abdominal drains were removed after a mean of 50 ± 25.5 days (range: 16–86) after the procedure. In one patient with duodenum-colon-cutaneous fistula (No. 2 in ▶ **Table 1**), the cutaneous side was completely sealed at the end of treatment, while a minimal duodenum-colonic fistula remained opened, but asymptomatic. This patient also developed a chronic malabsorptive syndrome, which seemed not to be related to the procedure we described, even though persistence of the minimal duodenum-colonic fistula also could have been caused by a permanent colonic bacterial infection.

Finally, stent removal was successfully achieved in five patients after a mean of 10 ± 2 weeks (range: 8–12) after discharge. One patient lost to follow-up experienced stent migration, which caused small bowel obstruction requiring surgical intervention 24 weeks after stent placement. Post-procedural median follow-up for the entire cohort was 17.3 ± 6.7 months (range: 6–26) with no recurrences of the treated leak/dehiscence.

Adverse events (AEs) occurred in two patients. One experienced transient self-limited fever the day after stent removal. The other one is the patient described above who had stent migration that caused bowel obstruction requiring surgery. In this patient, however, AE could be related to the fact that the stent was not removed at the proper time because he did not come back for the procedure.

Discussion

We presented our experience in treating difficult, complex entero-cutaneous fistulas refractory to repeat surgical intervention with a newly developed endoscopic approach that we named a "suction room." This approach included utilization of a large enteral stent positioned as previously described, depending on the presence of a leak or a dehiscence, followed by biliary and/or pancreatic stent placement. To finally seal the area and guarantee adherence of the enteral stent to leak or dehiscence, a 18 Fr tube was placed and maintained under continuous negative aspiration pressure.

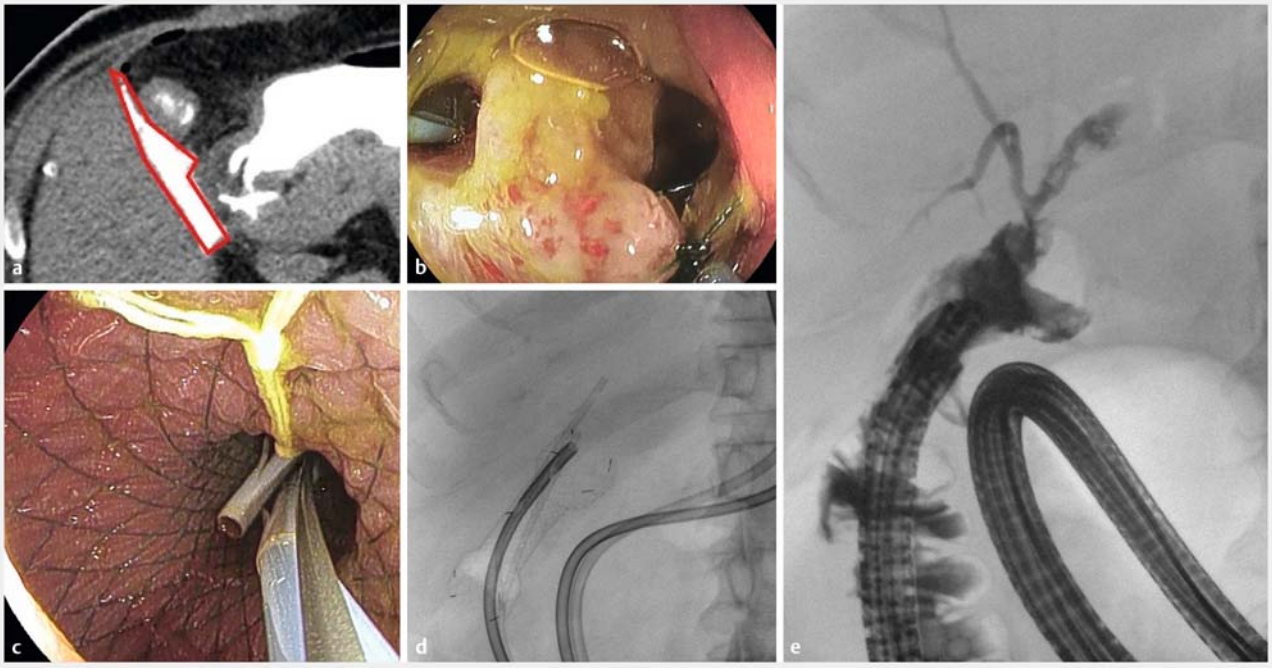
Simple enteral stapled stump dehiscence can be endoscopically treated with suction nose-to-stump tube placement to dry the peri-duodenal collection and gradually heal the fistula on the basis of vacuum-assisted principles [1]. In situations like CECF similar to the ones we have described, nose-to-collection tubes alone are not sufficient to resolve the entire process because the enteral mucosa tends to intussuscept into the tube, constantly counteracting application of aspiration.

The rationale behind the creation of the "suction room" came from two experiences: multiple stent placement and use of transluminal vacuum-assisted devices [1, 7, 8]. Complete iso-

▶ **Table 1** Demographics, details of surgery, type of leak, endoscopic procedure and outcomes of patients who underwent 'suction room' treatment.

Patients (sex, age)	CCI	ASA score	Type of surgical operation	Type of redo surgery	Type of the leak	Fistula output (mL/die)	Endotherapy	Working days of "suction room"	Days to stop outflow	Days to drainage removal	Adverse events	Follow-up (months)
1 (M, 62)	3	4	Subtotal gastrectomy + Billroth-II reconstruction	Direct suture	Duodenal stump + duodenal lateral side	350	Enteral fc-SEMS 20 mm 8 cm + biliary fc-SEMS 10 mm 6 cm + pancreatic plastic stent 7Fr 9 cm + 18 Fr nose-to-collection tube	24	1	43	Bowel occlusion due to stents' spontaneous migration	6
2 (F, 33)	6	5	Gastric bypass + subtotal gastrectomy + Roux-en-Y reconstruction	Total gastrectomy. Direct suture. Re-stapled duodenal stump.	Duodenal stump + colonic leak + duodeno-colo-cutaneous fistula	500	Enteral fc-SEMS 20 mm 10 cm + biliary fc-SEMS 10 mm 8 cm + pancreatic plastic stent 7 Fr 9 cm + 18-Fr nose-to-collection tube [1]	103	3	86	Chronic malabsorptive syndrome. Persistent asymptomatic colon-duodenal fistula.	26
3 (M, 43)	5	3	Hepaticojejunostomy + Roux-en-Y reconstruction	Direct suture + omental patch	Jejunal stump + anastomotic complete leak	500	Enteral fc-SEMS 20 mm 12 cm + two biliary plastic stents 8,5Fr 9 cm + 18 Fr nose-to-collection tube	25	2	31	– (subsequent 6 months stenting to avoid anastomotic stricture)	22
4 (M, 56)	4	4	Subtotal gastrectomy + Roux-en-Y reconstruction	Direct suture	Duodenal stump + duodenal lateral side	400	Enteral fc-SEMS 20 mm 8 cm + biliary fc-SEMS 8 mm 6 cm + pancreatic plastic stent 7 Fr 9 cm + 18 Fr nose-to-collection tube	36	1	16	–	20
5 (F, 45)	5	4	Subtotal gastrectomy + Roux-en-Y reconstruction	Direct suture	Duodenal stump + lateral duodenal side	600	Enteral fc-SEMS 20 mm 8 cm + biliary fc-SEMS 8 mm 6 cm + pancreatic plastic stent 8,5Fr 9 cm + 18 Fr nose-to-collection tube	76	2	81	–	18
6 (M, 64)	3	4	Subtotal gastrectomy + Braun reconstruction	Direct suture	Duodenal lateral side	300	Enteral fc-SEMS 20 mm 8 cm + biliary fc-SEMS 10 mm 6 cm + pancreatic plastic stent 8.5 Fr 9 cm + 18 Fr nose-to-collection tube	29	3	41	Transient self-limited fever after stents' and surgical drain removals	12

fc-SEMS, fully covered self-expandable metal stent; CCI, Charlson Comorbidity Index; ASA, American Society of Anesthesiologists.
[1] through an endoscopic ultrasound-guided endoscopic bypass [6].



▶ **Fig. 4** Complete dehiscence of end-to-end hepaticojejunostomy complicated by jejunal stapled stump necrosis. **a** CT scan of contrast extravasation from the jejunal stump (red line). **b** Endoscopic view of the dehiscence. **c** Endoscopic view of the "suction room" showing enteral stent and two biliary plastic stents before nose-to-stent tube placement. **d** Fluoroscopic view of "suction room" in place. **e** Fluoroscopic examination after stent removal showing no residual leaks.

ation of leak/dehiscence obtained by placement of multiple stents is of paramount importance to avoid repeated damage to tissue by both bile and pancreatic juices, which prevent the healing process from taking place. In parallel, continuous aspiration reduces bacterial load and increases local perfusion, inducing the appearance of healthy granulation tissue [8]. The third stent placed, the enteral stent, prevents collapse of the bowel with consequent closure of the nose-to-collection tube, creating a well-working aspiration chamber. To obtain this result, the enteral stent has to adhere completely to enteral walls, a process that is only possible by applying negative aspiration pressure through the vacuum, which collapses the bowel wall on the stent, mechanically closing the perforation site. This principle also can be applied whenever a discrepancy between an enteral stent and the intestinal wall caliber is present, not only at the level of complex duodenal leaks but also, for example, in esophageal anastomotic dehiscence [9].

Technically our approach was feasible in all patients and the procedure was associated with clinical success in all of them. Despite the lack of a control group, we postulated that the clinical resolution of CECF was related to the utilization of the "suction room," because it was only after this intervention that patients started to recover after being hospitalized for 32 days prior to our endoscopic intervention. Moreover, the success of the technique was well-demonstrated by abdominal drainage annulment after 1 to 3 days. The presence of the surgical drains themselves, especially when held in the same position for a long time, acts against the reparative process because the fistula's path is filled by the drainage and it cannot heal properly. The creation of the "suction room" allows gradual retrieval of the drainage tubes, permitting containment of the fistula's path in the vacuum-packed system and enabling formation of reparative granulation tissue. The long time before abdominal drain removal was mostly related to previous inappropriate management of the system and the surgical drains, mainly related to a lack of communication between surgeons/anesthesiologists and endoscopists.

The major limitations of this study are: (1) its retrospective nature and the small sample size, which did not allow us to draw any definitive conclusions; and (2) the single-center experience with all procedures performed by a single endoscopist. One strength of the study was that all repeat surgeries were performed in our hospital by surgeons highly experienced with this type of lesion, avoiding bias.

Conclusion

In conclusion, the "suction room" method allowed us to successfully treat very difficult CECF cases in a tertiary referral endoscopy center that had significant expertise in management of post-surgical leaks and dehiscence. Future larger studies with standardized patient selection and comparative interventions are needed to fully assess the feasibility, reproducibility, and efficacy of this very attractive endoscopic approach.

Competing interests

The authors declare that they have no conflict of interest.

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CORRECTION

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In the above-mentioned article the institution of Ludovica Venezia was corrected. Correct is: Gastroenterology Unit, Azienda Ospedaliera Santi Antonio e Biagio e Cesare Arrigo, Alessandria, Italy.

This was corrected in the online version on March 19, 2021.