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Iatrogenic esophageal perforation

Endoscopic negative pressure therapy with new approved polyurethane foam drains and negative pressure pump

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Introduction

Iatrogenic perforation rarely occurs during diagnostic esophagogastroduodenoscopy (EGD). The incidence of this severe complication is 0.03%; the mortality rate is high if mediastinitis develops and is around 50%. The predilection site for the injury is located at the pharyngoesophageal junction [1].

In recent years, endoscopic negative pressure therapy (ENPT) has become established as an innovative procedure with a high success rate for treating esophageal defects (anastomotic leaks, perforations) [2–4].

For several months new polyurethane foam drains approved for ENPT and the first negative pressure pump developed exclusively for this method have been available.

Using a case study we report on the successful use of these new materials on a perforation located in the cervical esophagus, which occurred during a diagnostic EGD.

Case study

An EGD needed to be performed on an 88-year-old female patient as part of an anemia work-up. While the diagnostic gastroscope was being introduced a severe coughing fit occurred, resulting in perforation with the distal end of the endoscope at the typical site at the level of the oral sphincter, approximately 15 cm from the incisors. The endoscope was inserted approximately 10 cm into the mediastinum. There was no bleeding. Due to the defect being located directly at the sphincter, endoscopic inspection was difficult. The consensus of an interdisciplinary team was that immediate initiation of intraluminal ENPT for luminal sealing of the defect was indicated.

Material and methods

The method of ENPT in the esophagus was used for the first time in 2006 by our working group for an anastomotic leak. Since then, the method has been continuously refined and has become a firmly established part of surgical complication management.

The therapy in our case study was performed using the intraluminal and intracavitary variants of ENPT. For the intraluminal ENPT, the negative pressure drain was placed in the esophageal lumen covering the defect by the open-pore foammaterial. For the intracavitary therapy, it was placed through the defect into the wound cavity [5, 6].

For this we used for the first time, two newly approved polyurethane foam (PUF) drains (Suprasorb® CNP endo Oral and Oral N, Lohmann & Rauscher International GmbH & Co. KG, Rengsdorf, Germany) and a negative pressure pump designed for ENPT (Suprasorb® CNP endo therapy unit, Lohmann & Rauscher International).

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Table 1 Overview of the different types of the CNP endo Kit and the components

Suprasorb CNP endo Kit Oral	Suprasorb CNP endo Kit Oral N	Suprasorb CNP endo Kit Rectal	Suprasorb CNP endo AddOn
Foam drain	Foam drain with movable feeding tube (9 F)	Foam drain	Foam drain
Overtube	Overtube	Proctoscope	–
Nasal tube	Nasal tube	–	Y-connector
Tube clamp	Tube clamp	Tube clamp	-
Retention dressing, nasal	Retention dressing, nasal	Retention dressing, rectal	Retention dressing, rectal

The two drain kits are part of a comprehensive therapy system for ENPT and are intended for treatment in the upper gastrointestinal (GI) tract. The two kits differ in that the Suprasorb® CNP endo Kit Oral-N is additionally equipped with a movable feeding tube (9 F) integrated into the PUF, thereby facilitating simultaneous feeding during intraluminal ENPT (**Table 1**).

This table provides an overview of the features of the 4 drains used in the CNP endo total system. All of the foam drains have a length of 10 cm and a diameter of 1.9 cm. The polyurethane foam body is attached to the 120 cm long drainage tube by a suture and has a grip loop at its distal end. The foam drain in the CNP endo Kit Oral N is equipped with a channel in which the movable feeding tube (N) with a 9 F diameter and a length of 125 cm is located. The spiral reinforced overtube in the CNP endo Oral and Oral N kits is equipped with a grip tab and has a length of 28 cm (**Fig. 1**).

The PUF drains have a foam body that is approximately 10 cm long and 1.9 cm in diameter which is attached by a suture to the distal end of a drainage tube. At the distal end, the foam body is equipped with a loop that can be grasped by endoscopic forceps for the insertion maneuver. For intraluminal ENPT, the entire length of the 10 cm long foam body is placed intraluminally in the esophageal lumen at the level of the defect, covering the defect. For intracavitary ENPT, shorter foam bodies are often required. For this purpose, the foam body can be shortened to the desired length by the examiner. At the distal end, it is once again secured with a suture to the drainage tube.

Placement of the PUF drains occurs under endoscopic view through an approximately 30 cm long overtube (OT). This serves as both a protective and an insertion aid in the esophagus. The OT is advanced along the endoscope, which is inserted into the esophagus, into the esophageal lumen beyond the oral sphincter, so that the entire oropharyngeal space and proximal esophageal inlet are bridged. This way, the OT ensures oroesophageal access and simplifies the insertion of the PUF drain into the esophagus.

For cervical defects and intracavitary ENPT, the OT can also be used for direct placement of the drain into the wound cavity. In this case, the distal end of the OT is advanced through the transmural defect into the extraluminal wound cavity.

For the actual insertion maneuver for the PUF drain, the loop at the distal end of the PUF is grasped with a pair of forceps. The lumen of the OT and the PUF are coated with lubricant. First, the PUF is fully inserted into the OT with the forceps. Then, it is advanced with the endoscope into the 28 cm long OT until its distal end is reached (cm marking on the endoscope to the upper edge of the OT: approx. 20 cm). By retracting the OT on the endoscope, the PUF is released into the lumen of the esophagus. The OT is parked on the endoscope. Under endoscopic view, the PUF drain is then placed at the desired site.

After oral placement the drainage tube is turned nasally, routed through one nostril and secured here with a dressing, suture or bridle.

Using the electronic therapy unit a continuous negative pressure of –125 mm Hg is applied to the drainage tube coming out of the nose. This negative pressure pump (**Fig. 2**), which is specifically designed for ENPT, is characterized by a very rapidly regulated suction build-up. This results in rapid suction of the PUF on the tissue with defect sealing and drainage.

The PUF drain is removed at intervals of several days (after 3 days), the course of wound healing is monitored endoscopically, and the treatment is adjusted according to the findings.

Results and course of treatment

Immediately after the iatrogenic perforation, we initiated intraluminal ENPT [5, 6] with a CNP endo Kit Oral as an emergency measure to seal the perforation defect and to prevent contamination. This emergency measure could be performed by continuing the propofol sedation for the EGD without any problems and was completed after 15 min. The nonintubated patient was transferred to the monitoring unit and an antibiotic therapy was initiated.

On the following day the clinical development of supraclavicular subcutaneous emphysema with increased signs of inflammation was noted. During the night, the patient exhibited a brief respiratory depression, which prompted the on-duty physician to provide respiratory support using a breathing bag. Pronounced mediastinal emphysema was seen on a computed tomography (CT) scan (**Fig. 3**).

The patient was intubated and an endoscopic follow-up examination was performed. While there were suction patterns in the esophagus caused by the PUF, the 2 cm diameter perforation defect and the wound in the deep tubular cavity did not exhibit adhesion. Perfusion was not impaired (**Fig. 4**).

A switch was made to the intracavitary variant of ENPT [5, 6] with a CNP endo Kit Oral N. The entire sponge body could be placed into the cavity. The feeding tube integrated into the PUF drain had previously been removed from the sponge and then placed as a regular gastric feeding tube.

Abbreviations

dOFD	Double-lumen open-pore film drain
EGD	Esophagogastroduodenoscopy
ENPT	Endoscopic negative pressure therapy
OT	Overtube
PUF	Polyurethane foam

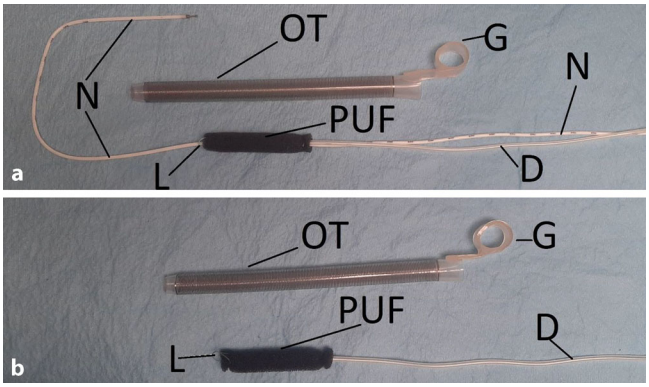

Fig. 1 ▲ The polyurethane foam (PUF) drains used for ENPT. **a** Suprasorb® CNP endo Oral N, **b** Suprasorb® CNP endo Oral; 28 cm long overtube (*OT*) with grip tab (*G*) drainage tube (*D*), polyurethane foam body (*PUF*) 10 cm long and 1.9 cm in diameter, loop for grasping the drain (L), integrated feeding tube (N)

Fig. 2 ▲ Photograph of the Suprasorb® CNP endo therapy unit, the negative pressure pump developed for ENPT

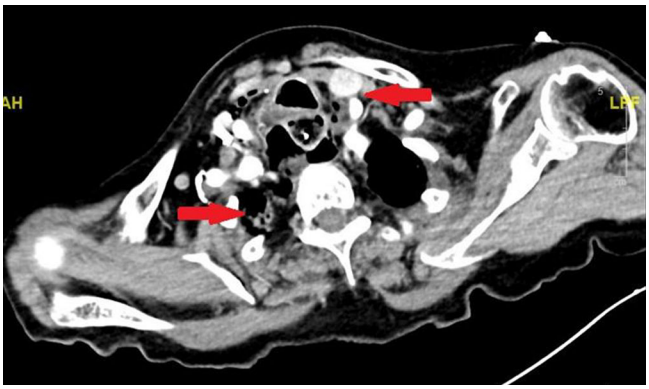

Fig. 3 ◀ Computed tomography (CT) scan in the transverse plane of the thoracic region of the patient showing the mediastinal emphysema with air inclusions (*arrows*), 1 day after perforation

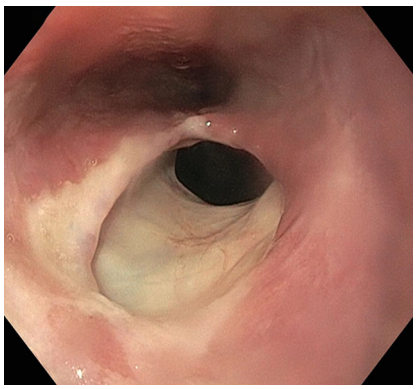

Fig. 4 ▲ Photograph of the endoscopic view in the esophagus showing the perforation defect of the esophagus 1 day after perforation

Ventilation therapy was required for a total of 6 days. The patient was given enteral nutrition via the feeding tube simulaneously with ENPT. The subcutaneous emphysema and the signs of inflammation rapidly regressed under this therapy.

The ENPT with regular drain changes and endoscopic wound monitoring could be continued after 6 days with the patient under analgosedation without interrupting of the negative pressure therapy. The extraluminal wound cavity cleaned itself, shrank and developed the typical erosive granulating wound bed (◘ **Fig. 5**). The intracavitary PUF was able to be incrementally shortened and the wound cavity became continuously smaller. The last cycle of ENPT was once again undertaken with the intraluminal placement of the sponge body for a CNP endo Kit Oral N. The defect healed completely with a small scar without stenosis. The return to a normal diet was entirely problem-free after the completion of ENPT.

Summary of the course of treatment

The total duration of ENPT was 25 days with 9 insertions or changes of a PUF drain. Initial emergency treatment with intraluminal ENPT, then switched to intracavitary ENPT, final cycle with intraluminal ENPT; ventilation for 6 days; enteral nutrition via feeding tube, no surgery, complete scar healing of the perforation defect without stenosis.

Discussion

This case study of iatrogenic perforation at the level of the upper esophageal sphincter as a complication of a diagnostic EGD demonstrates how treatment using endoscopic negative pressure therapy can be successfully performed.

The PUF drains and a pump developed for ENPT of the Suprasorb® CNP endo complete system were used for the first time. These materials are approved for treatment of the upper and lower GI tract supplement the previously commercially available equipment for ENPT (Eso/Endo-Sponge®; formerly B. Braun Melsungen AG, Melsungen, Germany now Boston Sientific, US and VacStentGI™; Microtech, Düsseldorf, Germany) [3].

The Suprasorb® CNP endo drains are open-pore drains made of PUF, a material which has been proven many times during use in ENPT. At a length of 10 cm, they are configured to be longer than the previous drains. In the past, longer drains, which are needed for intraluminal therapy in par-

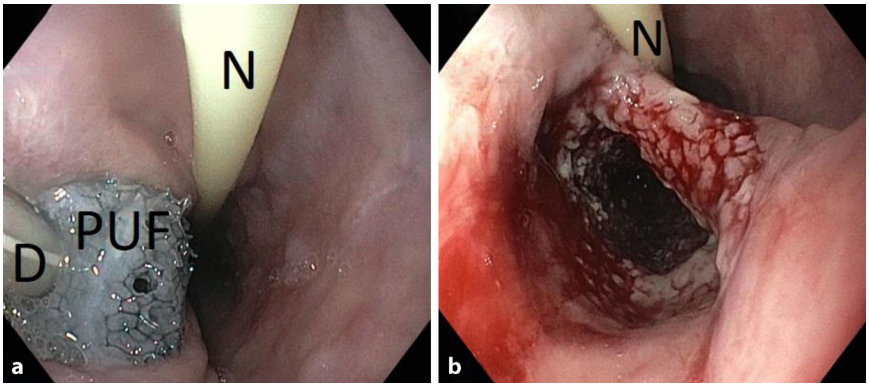

Fig. 5 ▲ Native endoscopic views of the intracavitary ENPT on day 20; **a** The polyurethane foam drain (*PUF*) is placed in the defect which is sealed off. **b** After the drain has been removed the shrunken wound cavity and the defect opening lined with granulation tissue can be seen. *N* feeding tube, *D* drainage tube

ticular, had to be made by the examiners themselves [7, 8]. At a length of 10 cm, the intraluminal variant should ensure safe defect coverage with an adequate safety margin in the oral and aboral directions [5, 6].

The insertion technique is performed using a short OT which is intended to ensure safe oroesophageal access. This safety consideration is especially of interest in ventilated patients in whom the spatial relationships in the oropharynx are constricted and the insertion of voluminous and long PUF drains can be challenging [6]. The actual placement maneuver for the Suprasorb® CNP endo drains is performed under continuous visual control with the endoscope without the need to remove and reinsert the endoscope beforehand. The equipment in the Suprasorb® CNP endo Kit Oral N with the integrated feeding tube facilitates enteral nutrition at the same time as intraluminal therapy. This is an important criterion for healing, especially if long-term treatment is required.

It was shown that the Suprasorb® CNP endo Kit Oral can be used intraluminally as an immediate emergency measure within just a few minutes. Starting treatment without delay is an important criterion for a successful outcome [9]. All equipment for ENPT are found in endoscopy rooms. All staff members are trained in proper handling on a model. The placement maneuver is simple; however, as it differs in some steps from the usual practice it is recommended that this be learned on appropriate training models before the first clinical use [10]. Then even less experienced individuals will be able to perform intraluminal placement of the Suprasorb® CNP endo drain as a first emergency measure.

As an alternative endoscopic treatment option, direct closure of the defect immediately after perforation using a clipping technique could have also been considered. In our case, after perforation had occurred the subsequent endoscopic adjustment of the defect was very difficult and unstable due to its location at the level of the upper esophageal sphincter. Intubation may have provided better examination conditions, although the swallowing movements occurring in this area would still be unfavorable. Stenting could also have been considered. The extremely proximal location of the defect is not without problems in this respect.

Our clinic has a high level of expertise using ENPT to treat defects in an extremely proximal location and extending into the pharynx [11, 12]. Compared to other closure techniques for acute perforations, the significant advantage of ENPT, especially in the esophagus, is the treatment and prevention of mediastinitis [13].

Despite the immediate initiation of ENPT after perforation a total treatment duration of 25 days seems to be long. In 2015, we published the first patient series on ENPT for iatrogenic perforations. We reported a median treatment duration of only 5 days [14]. The cause of the long treatment duration can be attributed to the respiratory support provided via the breathing bag a few hours after the perforation in the nonintubated patient and the hereby exacerbated extraluminal infection. Stathopoulos et al. were able to show in a series of esophageal perforations that patients with an infected mediastinum and delayed start of ENPT resulted in the longest duration of therapy [15]. Even with optimal placement of the PUF drain over the defect, sufficient adhesion to the defect with ENPT may not have occurred within a period of just a few hours, which would have prevented the pumping in of additional air. This resulted in pronounced emphysema and consecutive mediastinitis in our patient. The severity of the complication of iatrogenic perforation should have been an indication to initiate temporary intubation and ventilation of the patient. We suspect that using this procedure would have resulted in a more optimal sealing of the defect and a significantly shorter course of treatment.

Conclusion

The use of ENPT is a suitable procedure for the treatment of iatrogenic cervical esophageal perforations. The newly approved types of polyurethane foam drains and the first ever negative pressure therapy unit approved for ENPT are suitable for ENPT of the upper GI tract.

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Declarations

Conflict of interest. V. Betz, W. Schulze, O. Gobrecht, B. Hornburg and M. Reeh declare that there is no conflict of interest. G. Loske is a consultant for Lohmann & Rauscher GmbH & Co. KG. His patents for negative pressure therapy have been transferred to Lohmann & Rauscher GmbH & Co. KG. There is a conflict of interest due to financial participation in several negative pressure therapy products that are currently being brought onto the market.

This article does not contain any studies with human participants or animals performed by any of the authors. All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from the patient included in the study.

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