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Endoscopic Management of Pancreatic Necrosis Using the EndoRotor Resection System



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INTRODUCTION

In the USA, the annual incidence of acute pancreatitis ranges from 4.9 to 35 per 100,000 population.¹ Worldwide, the incidence of acute pancreatitis is rising, largely due to rising rates of obesity and gallstones.²

Approximately 20% of patients with acute pancreatitis will develop pancreatic necrosis and one in three of these patients will develop infected pancreatic necrosis, which is associated with high mortality.^{3,4,5} Infected pancreatic necrosis requires interventional treatment. Over recent decades, the treatment of infected pancreatic necrosis has changed dramatically. Early surgery is associated with a very high mortality rate and is largely avoided.⁶

A shift towards minimally invasive techniques has become the standard of care. Minimally invasive techniques such as video-assisted retroperitoneal drainage (VARD) or endoscopic ultrasound (EUS)-guided transluminal drainage, and if necessary, direct endoscopic necrosectomy (DEN), have been shown to improve patient outcomes in regard to

mortality, multi-organ failure, external fistula, and endo- and exocrine insufficiency.^{5,7,8} Several studies have reported on the potential and efficacy of direct endoscopic necrosectomy.^{9,10}

Following EUS-guided transgastric or transduodenal drainage, the pancreatic fluid collection (PFC) cavity can be entered with a standard forward viewing endoscope to perform DEN. This can be achieved by balloon dilation of the transgastric fistula (up to 20mm) when plastic double pigtail stents were placed initially, or directly through the stent opening when a large bore fully covered metal lumen apposing stent was placed. Usually, several sessions are required for complete removal of the necrosis; the mean number of DEN sessions varied from 1 to 15 in a meta-analysis by Puli et al. with a weighted mean of 4.09 procedures.¹¹

One of the main limitations of endoscopic necrosectomy is the lack of dedicated instruments to remove necrotic tissue from within PFCs. For this purpose, various instruments, originally designed for other indications, are widely used. These devices, including lithotripsy baskets, grasping forceps, retrieval nets, and polypectomy snares, are able to grasp and remove necrotic material. Still, endoscopic necrosectomy can be tedious work and these procedures are often time consuming.

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The EndoRotor

The EndoRotor (Interscope Medical, Inc., Worcester, MA, United States) is a novel automated mechanical endoscopic system designed for use in the gastrointestinal tract for tissue dissection and resection with a single device. It comprises of a console that houses the motor drive, peristaltic pump, and vacuum regulation, a foot pedal, a catheter device, and a specimen collection trap. The EndoRotor was approved by the Food and Drug Administration for the removal of dead pancreatic tissue in December, 2020.¹²

The EndoRotor system can be advanced through the working channel of a therapeutic endoscope with a working channel of at least 3.2mm in diameter. The EndoRotor can be used to aspirate, cut, and remove small pieces of tissue through a catheter, consisting of a fixed outer cannula with a hollow inner cannula. A motorized, rotating, cutting tool driven by an electronically controlled foot console and attached to suction performs tissue resection and rotates at either 1000 or 1700 revolutions per minute.¹³

The catheter shaft is flexible and can tolerate endoscope bending or manipulation up to greater than 160 degrees. If greater manipulation is required, a longer catheter can be used to facilitate less torsional stress on the device. The necrotic tissue is sucked into the catheter using negative pressure and cut by the rotating blade from the inner cannula. Tissue is transported to a standard vacuum container. Both the cutting tool and suction are controlled by the endoscopist using two separate foot pedals.

Procedure

Prior to using the EndoRotor, endoscopists need to first perform EUS-guided transgastric drainage by creating a fistula from the stomach or small bowel to the adjacent PFC. The choice of placement of one or more plastic stents or a lumen apposing metal stent (LAMS) is at the discretion of the endoscopist. Endoscopic necrosectomy can then be performed. For this, a therapeutic gastroscope is advanced into the PFC. The EndoRotor is then inserted through the working channel of a therapeutic endoscope and advanced into the PFC collection cavity. Rotation speed of the EndoRotor catheter is recorded as well as changes in settings. Suction is typically

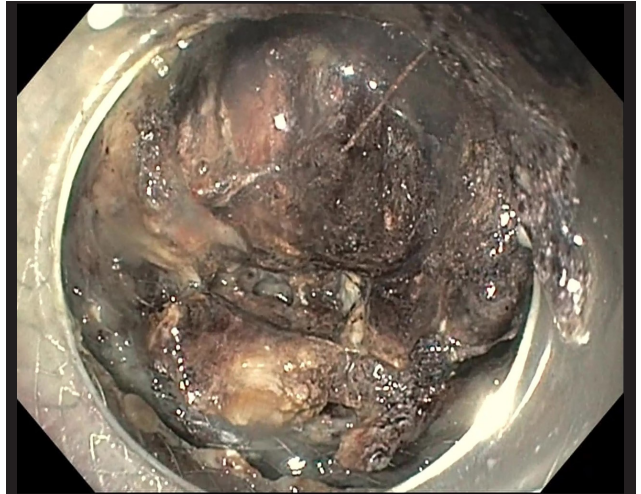


Figure 1a. Endoscopic image of pancreatic necrosis in a pancreatic fluid collection

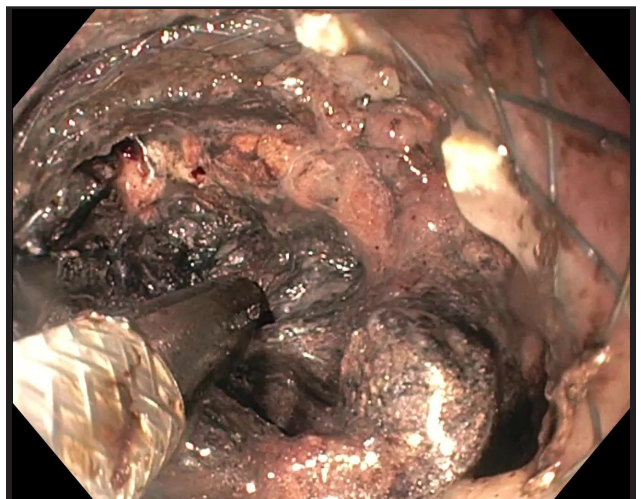


Figure 1b. EndoRotor in use

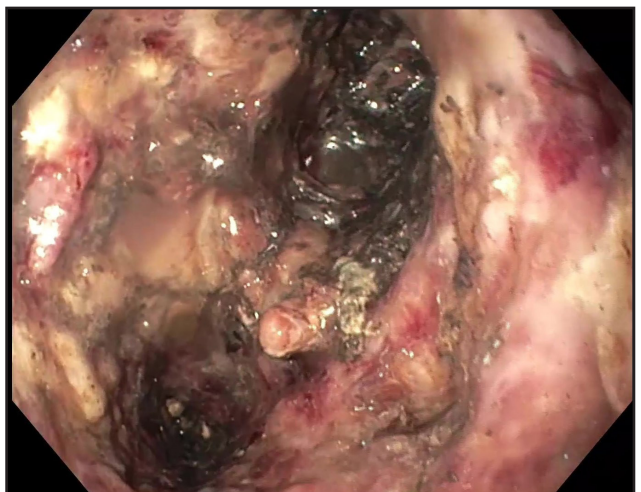


Figure 1c. Pancreatic fluid collection after endoscopic necrosectomy with EndoRotor

set between 500 and 620mmHg, the maximum achievable negative pressure level. (Figure 1)

More recently, EndoRotor was trialed using a percutaneous route. Zuener et al. reported a single case report of percutaneous endoscopic necrosectomy performed using the EndoRotor resection device.¹⁴ The procedure involved percutaneous dilation from 14 to 18mm to allow insertion of the flexible endoscope into the retroperitoneal cavity. Necrosectomy was performed with the EndoRotor device by using high suction (750mmHg) and low cutting speed (1000rpm).

Outcomes

Stassen et al. evaluated the use of the EndoRotor to remove solid debris under direct endoscopic visualization.¹⁵ The prospective trial involved 10 international sites which enrolled 30 patients (mean age 55 years, 60% male) with walled off pancreatic necrosis which ranged in size from 6mm to 22 mm with >30% solid component based on computed tomography (CT). The authors reported that 15/30 (50%) achieved complete debridement in one session, and 21/30 (73%) achieved complete debridement after 2 sessions.

The mean time between LAMS or SEMS placement and debridement was 14 days. A median of 2.1 interventions (range 1-7) was required. Mean EndoRotor procedure time was 71 minutes (SD 37 minutes). Mean overall endoscopic procedure time was 117 (SD 50 minutes). Baseline necrotic debris was 69% (SD 20%) and the mean reduction of solid necrosis of 68% (SD 29%), 54% (SD 34%), 58% (SD 36%) and 34% (SD 29%) was achieved after the first, second, third and fourth procedure, respectively. At the 21-day follow-up, the mean reduction in necrosis volume from baseline was 90% (SD 19%). Average duration from the start of necrosectomy until discharge was 16 days (SD 27 days).

In a case series involving 12 patients (median age 60.6 years), van der Wiel reported outcomes following the use of the EndoRotor.¹⁶ From the study cohort, a total of 27 procedures were performed. Three patients had already undergone unsuccessful endoscopic necrosectomy procedures using conventional tools. The mean size of the walled-off cavities was 117.5 ± 51.9 mm. An

average of two procedures (range 1–7) per patient was required to achieve complete removal of necrotic tissue with the EndoRotor. No procedure-related adverse events occurred.

A questionnaire was sent to endoscopists to rate their experience with the EndoRotor. Endoscopists rated the EndoRotor easy in its use (mean 10-point Likert scale score, 8.3; range, 8 to 9) and an effective tool to remove necrotic tissue (mean 10-point Likert scale score, 8.3; range, 8 to 9). They were satisfied by the ability to manage the removal of necrotic tissue in a controlled manner (mean 10-point Likert scale score, 8.6; range, 8 to 9). The risk of causing complications was estimated to be low (mean 10-point Likert scale score, 1.9; range, 1 to 2). Overall, the device was judged to be of substantial additional value in the management of pancreatic necrosis (mean 10-point Likert scale score, 8.6; range, 8 to 9), and respondents were very willing to use the device in subsequent patients with necrotizing pancreatitis (mean 10-point Likert scale score, 9.3; range, 9 to 10).

Soota et al. performed a small retrospective study involving four patients (mean age 49 years, all male) with greater than 30% cyst wall involvement of necrosis.¹⁷ The study reported complete cyst resolution was observed in ¾ patients (one was currently still being treated) with mean time to resolution of 84 days. Mean length of hospital stay and time to discharge after treatment was 33 and 19 days, respectively. There were no patient-related complications and only one technical complication of the EndoRotor getting caught on the LAMS. This was remedied by removal of the stent and the EndoRotor without any further sequelae. Additionally, the authors noted that no patients required additional surgical or interventional radiology procedures. One patient was managed as an outpatient, and 2 others were able to achieve early discharge.

Adverse Events

Most studies reporting outcomes of the EndoRotor have noted low rates of adverse events. Stassen et al. noted in their study that no EndoRotor-associated adverse events were reported.¹⁵ One patient died during the follow up period due to shock and multi-organ failure, unrelated to the treatment with the EndoRotor. van der Wiel reported no adverse events

occurred during the necrosectomy procedures or within 24 hours.¹⁶ Three patients (27.2%) experienced adverse events within the course of their infected pancreatic necrosis. One patient died eight days after the last endoscopic necrosectomy as a result of ongoing multi-organ failure caused by collections of infected pancreatic necrosis which, despite multiple sessions, could not be completely removed. One patient eventually died three months after discharge due to an underlying pancreatic carcinoma after having undergone two successful endoscopic necrosectomy procedures for infected pancreatic necrosis using the EndoRotor. In one patient, a gastrointestinal bleed occurred two days after the procedure necessitating coiling of the splenic artery. It should be noted that while EndoRotor is designed to help clear necrotic contents from pancreatic fluid collections, data on adverse events associated with the use of this device remain limited.

Other Applications

While there is limited study on the use of EndoRotor for the management of walled-off necrosis (WON), its application is being studied in other realms. Kaul et al. applied EndoRotor for endoscopic resection of flat and polypoid lesions in the colon and foregut.¹⁸ EndoRotor was also used in treating esophageal and gastric lesions, including Barrett's esophagus.^{19,20} Furthermore, Gubatan et al. reported a single case where the EndoRotor device was safely used to clear large blood clots in a patient with upper GI bleeding as an aide to traditional methods.²¹ While these reports highlight possible expanded applications of EndoRotor, outcome data remains very sparse and limited to academic centers.

CONCLUSION

Using direct endoscopic visualization, the EndoRotor device is designed to facilitate removal of dead tissue in patients with walled off pancreatic necrosis. Overall, with the limited data available, the EndoRotor resection system appears to be safe and effective. However, most studies are limited by very small sample size as well as study design (case series, retrospective, etc). Large prospective comparative evaluation of the EndoRotor system is required to confirm these favorable observations and to further evaluate its safety profile and clinical efficacy. ■

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