

# Endorotor-Based Endoscopic Necrosectomy as a Rescue or Primary Treatment of Complicated Walled-off Pancreatic Necrosis. A Case Series

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## ABSTRACT

Direct endoscopic necrosectomy (DEN) is a cumbersome, time-consuming procedure that can be necessary in cases of infected pancreatic walled-off necrosis (WON) not responding to endoscopic ultrasound (EUS)-guided drainage only. Until now, DEN has been performed with non-dedicated devices, thus requiring multiple, long-lasting sessions to achieve adequate clearance of necrotic content. These results in prolonged hospital stay, increased costs and have potential consequences for patients who must undergo multiple endoscopic interventions under sedation. We report four cases of DEN performed in patients with WON after EUS-guided drainage with the Endorotor system, a new morcellator device specifically designed to perform the procedure.

**Key words:** endoscopic necrosectomy – walled-off pancreatic necrosis – acute pancreatitis – Endorotor.

**Abbreviations:** DEN: direct endoscopic necrosectomy; EUS: endoscopic ultrasound; RPM: revolutions per minute; WON: pancreatic walled-off necrosis.

## INTRODUCTION

Pancreatic walled-off necrosis (WON), once drained under endoscopic ultrasound (EUS) guidance, may require direct endoscopic necrosectomy (DEN) as a definitive treatment in case of infection or when the necrotic content is highly prevalent. Indications and timing of DEN after drainage are not well established. Different studies have reported the effectiveness of a step-up approach strategy, which limits DEN to failure cases [1, 2], even though collection size and proportion of necrotic content might predict failure of drainage alone [3, 4].

Until now, DEN has been performed using non-dedicated devices, such as common polypectomy snares, caps, Dormia baskets and retrieval nets [3, 4]. The procedure in this fashion is time-consuming, cumbersome, and multiple

sessions are usually required, possibly leading to prolonged hospitalization and high costs [5]. Moreover, in cases where a fully covered metal stent has been used for drainage, the numerous passages of the endoscope through the previously placed stent may result in an increased risk for stent dislocation. Finally, these devices are blindly advanced into the necrotic content, with the risk of damaging unseen vessels causing major bleeding, which may be lethal in some cases.

A newly developed endoscopic morcellator device, the Endorotor system, has been recently introduced to specifically perform DEN. This device potentially provides the advantage of enabling the procedure to be performed under constant endoscopic visualization. Three patients with WON treated with Endorotor have been reported, two of whom after failure of conventional DEN [6] and another one performed as a primary treatment in a collection with 70% necrotic content [7]. Furthermore, van der Wiel et al. [8] reported their preliminary multicenter experience with Endorotor in 12 patients.

## CASE SERIES

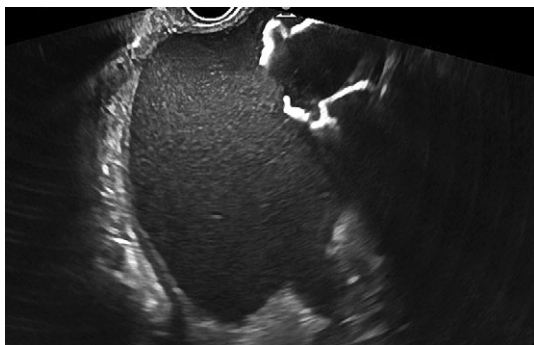
We described four additional patients treated with Endorotor system for either failure of previous DEN attempts or as a primary treatment in cases of high necrotic content.

In all patients, EUS-guided drainage was performed using a therapeutic echoendoscope (EG38-J10UT, Pentax Europe GmbH, Hamburg, Germany) and the electrocautery-enhanced

Received: 10.05.2020

Accepted: 04.08.2020

Axios system with the placement of a 10x15 mm or a 10x20 mm stent (Fig. 1). Dilatation of the central part of the stent was performed using balloon dilatation up to 15-20 mm, when needed. After completion of necrosectomy, a double pig-tail stent was placed through the central part of the previously placed metal stent and both stents were removed 3-4 weeks after the final DEN session using foreign body forceps.



**Fig. 1.** Endoscopic ultrasound view of necrotic pancreatic collection after Axios deployment: distal flange of the metallic stent.

The Endorotor system consists of a console unit that delivers cutting, suction and irrigation via footswitch control through a 3.1 mm diameter flexible catheter, which has an open window at its distal tip and an inner cannula that can rotate at 1,000 or 1,750 revolutions per minute (RPM) (Fig. 2). The system also utilizes a high-performance Medela Dominant Flex vacuum pump, which provides 40-60 liters/min flow rate. Once actuated, the inner cannula of the Endorotor catheter with “teeth” on its edge rotates and debrides necrotic tissue, which is then aspirated through the console and collected in the vacuum canister.



**Fig. 2.** The catheter tip extending from a therapeutic endoscope: the fixed outer cannula and the hollow inner cannula.

The DEN procedure was performed using an Olympus GIF-1TH190 with a 3.7 mm working channel, and the Endorotor high rotation speed setting (1,750 RPM), with progressive increase of suction flowrate up to 60 l/min at -750mmHg in all cases.

Four patients underwent DEN with the Endorotor system. All patients had a WON with at least 30% of necrotic content.

#### CASE 1

A 59-year old male was transferred to our unit for a 20 cm infected WON after an alcohol-related acute pancreatitis. He had a history of liver cirrhosis that decompensated with the

development of spontaneous bacterial peritonitis due to the infected WON. He underwent four sessions of DEN of about 90 minutes each using polypectomy snares and Dormia baskets. Because of persistent infection, DEN was performed using the Endorotor system with complete clearance of all residual necrotic content in a single session of about 50 minutes. Unfortunately, the conditions of his liver cirrhosis deteriorated further, and he died one month later.

#### CASE 2

A 67-year old male with a 15 cm WON secondary to acute biliary pancreatitis with 70% of necrotic content treated with a percutaneous drainage was transferred to our hospital after he developed severe sepsis. Emergent EUS-drainage was performed, and a vessel was seen, which was found to be the superior mesenteric artery (Fig. 3). The patient underwent two sessions (40 and 140 minutes) of DEN using the Endorotor system under careful and constant endoscopic visualization and was sent home few days after completion of DEN. Stents were removed three weeks after and the patient was fine thereafter.



**Fig. 3.** Computed tomography scan: superior mesenteric artery inside the pancreatic collection.

#### CASE 3

A 68-year old male with a 9 cm WON with more than 90% of necrotic content (Fig. 4) secondary to an acute biliary pancreatitis three months before, was sent to our department for a definitive treatment due to persistence of symptoms. Endorotor was scheduled as primary DEN treatment (Fig. 5). A single DEN session of 140 minutes was performed, with complete clearance of the cavity (Fig. 6). The patient went home the day after, while stents were removed three weeks after.

#### CASE 4

A 73-year old female with a post-acute biliary pancreatitis WON with a necrotic content of about 30% underwent EUS drainage. Two days after drainage, she developed persistent high fever with chills not responsive to antibiotic therapy. Direct endoscopic necrosectomy with Endorotor was urgently performed and took about 75 minutes, with nearly complete clearance of the entire cavity. The day after DEN she was completely afebrile and was sent home the day thereafter, with stent removal done three weeks later.



Fig. 4. Axial and coronal CT scans demonstrating necrotic pancreatic collection.

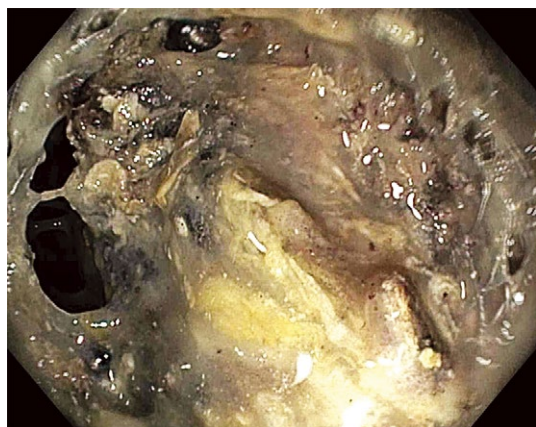


Fig. 5. Cavity of the pancreatic collection through the Axios stent completely filled up with necrotic tissue occupying more than 90% of the lumen.

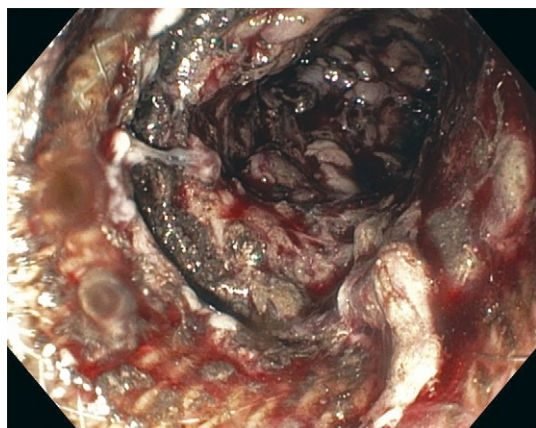


Fig. 6. Complete cleaning of the cavity achieved in a single session of 140 minutes

## DISCUSSION

We described our initial experience utilizing the Endorotor system, a new endoscopic morcellator device specifically developed to perform DEN under direct endoscopic visualization in four patients after failed previous DEN attempts, as a step-up approach after EUS-guided drainage to relieve infection, or as a primary treatment in a case of high necrotic content. Overall, DEN was successfully performed

in all patients in a mean of 1.25 sessions, with a mean time of 74 minutes.

Direct endoscopic necrosectomy is a cumbersome procedure, usually requiring multiple sessions, using non-dedicated devices, such as polypectomy snares, caps, or Dormia baskets. All these accessories are used to cut, grasp and remove necrotic material from the WON cavity by repetitive transits through the metal stent or the newly formed fistulous tract, with possible risk of stent dislodgement. More importantly, DEN is performed using devices that are blindly advanced into the necrotic content, without knowing what lies beneath, potentially increasing the risk of major bleedings.

To overcome some of these limitations, the Endorotor, a specifically designed automated mechanical system for tissue dissection and resection has been developed. The DEN procedure performed using the Endorotor is different from that described for all the other available devices. The catheter is initially positioned at the center of the necrotic aggregate and utilized to create a central channel, which allows progressive excavation into the necrotic tissue, through debridement and necrotic tissue removal under constant endoscopic visualization. The tip of Endorotor catheter can also be used as a sword to cut the necrotic tissue, which is then aspirated and removed from the working field. This is repeated while leaving the catheter inside the collection, thus avoiding multiple passes through the previously placed metal stent, potentially reducing the risk of stent displacement and procedural time. This process is performed until most or all the cavity is free of necrotic material.

In our experience limited to four patients, the understanding of the operation and handling of the Endorotor was very intuitive. The short learning curve rendered the procedures very smooth and deliberate, with only one session needed in all but one patient, and without any adverse events. The patient who required two sessions of DEN represented a special situation, due to the presence of the superior mesenteric artery running through the collection.

The user-friendly and straightforward approach implicit in Endorotor may render the workload of the endoscopist more bearable. Previous to our patients, a total of 15 other successful cases have been described in literature [6-8].

The largest multicenter series on the use of Endorotor published so far is the one by van der Wiel et al. [8], which described 12 patients with symptomatic WON. In most cases



plastic stents were placed (8/12 patients), while in our patients only lumen apposing metal stent were utilized. Furthermore, the authors did not report the amount of necrotic content of the treated WON, which is important to correctly compare their results with those of other studies and to interpret the reported procedural time. Finally, the first 19 procedures (out of 27) were done with a different catheter designed for mucosectomy, while in our series only the Endorotor XT catheter, the one specifically designed for necrosectomy, was used.

## CONCLUSION

The results of our experience are in line with those of previously reported cases and suggests that Endorotor can become a very important tool in the armamentarium of accessories utilized to perform DEN in patients with WON.

Future randomized multicenter controlled studies in patients with different indications to perform DEN are required to really quantify the advantages, if any, of the Endorotor over existing accessories, in terms of procedural time, number of sessions needed, adverse events occurrence, length of hospital stay, and efficacy.

**Conflicts of interests:** None to declare.

**Authors' contribution:** G.R. and A.L. conceived the study. G.R., M.R., M.I. collected the data and drafted the manuscript. A.L., A.G. and G.C. revised it critically for important intellectual content. All authors critically revised the manuscript, approved the final version to be published, and agree to be accountable for all aspects of the work.

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