The perfect tool for endoscopic necrosectomy: Miracle or a mirage?

Acute pancreatitis is one of the most common GI emergencies requiring hospitalization, with steadily increasing incidence across the globe. Approximately 20% to 25% of the patients experience necrotizing pancreatitis requiring multiple interventions in the form of percutaneous, endoscopic, or surgical drainage.[1] The endoscopic "step-up" approach has become a standard of care in current times, especially for centrally located collections.[2] After the introduction of the single-step cautery-enhanced lumen-apposing metal stent (LAMS), the procedure now has a steep learning curve with the feasibility of a wider dissemination and decentralization of the technology. Hence, performing a direct endoscopic necrosectomy (DEN) remains the "Achilles heel" for clinical success in patients with walled-off necrosis (WON) with a significant necrosum.[3] Because a pancreatic necrosum is dead tissue with a sticky and cheesy consistency, performing necrosectomy in limited space is a challenge for the majority of endoscopists. In the absence of a dedicated device, endoscopists usually use the snare, forceps, net, and Dormia basket as necrosectomy tools, with limited success rates in a single endoscopy session. As none of these tools are truly dedicated to, the majority of DEN procedures require more than 1 device and multiple sessions, prolonging patients' hospitalization as well as adding financial burden.[3] Recently, 2 dedicated devices have been developed to perform DEN. The OTSG Xcavator (Ovesco Endoscopy AG, Tübingen, Germany) is an over-the-scope grasper attached to the tip of the standard endoscope with an external diameter of 14.7 mm (28.4 mm diameter with opened jaws). Brand et al[4] published their experience with this device in 31 patients with WON. Technical success was 97%. The mean number of DENs required was 4.5 (range, 1-13). In 19 patients, the endoscope had to be removed for cleaning, and in 8 patients, other conventional accessories had to be used for completion of the necrosectomy. Moreover, the problem of grasping a pancreatic necrosum and shifting it to the gastric lumen remains a repeated cumbersome process similar to the use of the above-mentioned conventional accessories.

EndoRotor (Interscope Medical, Inc, Worcester, Mass, USA) is a novel automated endoscopic system designed to perform tissue resection and suction simultaneously, thus obviating the problems of grasping the necrosum and repeated exchange of the catheter or endoscope.[5] The system has a console with a motor unit, peristaltic pump, vacuum regulation unit, foot pedal (for cutting and suction), motorized catheter, and specimen collection trap. The EndoRotor catheter can be advanced through the working channel of an endoscope into the WON cavity through the previously established transmural track. The catheter has a 360° rotatable distal aperture; hence, the necrosectomy field can be visualized and safe dissection is ensured. The rotating catheter rotates at either 1000 or 1700 revolutions per minute, and the necrotic tissue is sucked into the catheter under negative pressure at either 350 to 500 or >500 mm Hg pressure.[6] Both the cutting tool and the suction are controlled by the endoscopist using 2 separate foot pedals (blue and orange, respectively). The device was approved by the U.S. Food and Drug Administration for removing dead pancreatic tissue in December 2020.[5] Initially, the device had a 3.1-mm outer diameter catheter with limited resection (4.4-mm^2 cutting chamber) and suction capacity (1.2-mm suction channel). Remarkably, a systemic meta-analysis has shown its safety and efficacy, with clinical success in 96% of patients and an adverse event rate of approximately 8%. The mean number of necrosectomy sessions required with the use of a 3.1-mm catheter was 2.2 (range. 1-7), which was lower than the necrosectomy sessions required by the performance of DEN with conventional devices (mean number of sessions, 4.09; range, 1-15).[3,7] Recently, a newer NecroMax 6.0 catheter with an outer channel diameter of 5.1 mm has been introduced. It has a 4 times larger cutting chamber (18 mm^2) and double suction capacity, which translates into an 8 times increase in tissue removal (volume/time) capacity.[8] A few case series have shown

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the clinical feasibility of performing DEN with this novel device; however, larger data remain sparse.[9,10]

In this issue of *Gastrointestinal Endoscopy*, Shinn et al[6] share their experience with this newly designed 5.1-mm EndoRotor-powered debridement catheter for performing DEN. The authors did a retrospective analysis of patients who underwent DEN with the use of this newer catheter across 8 institutions in the United States. The study included 41 patients who underwent DEN (64 procedures) with the use of this catheter. Of those, 19 patients underwent DEN (34 procedures) solely with novel catheters, and in the remaining patients, other conventional devices were also used. The primary outcome was the number of DEN sessions required to achieve a WON resolution. Secondary outcomes were the decrease in the percentage of solid WON debris and WON area on cross-sectional imaging after a single DEN session, cumulative time required for WON resolution, and adverse events. Technical success was 100% in all 64 procedures, and all procedures were performed with a 6-mm working channel therapeutic gastroscope (GIF-XTQ160, Olympus, Center Valley, Pa, USA). In the majority of patients (82.9%), a 20-mm LAMS was used for the initial drainage, and the stomach was the access site in 77% of patients. No patient underwent DEN during the index drainage procedure. The majority of patients underwent the procedure with the use of the high-speed (1750 rpm; 87.8%) and high-suction (>500 mm Hg; 75.6%) settings of the catheter. The average duration of EndoRotor therapy per session was 56.6 minutes (range. 12.5-160). An average of 1.6 DEN sessions was required in the study cohort for the WON resolution. For patients in whom a 5.1-mm catheter was used as the sole device for DEN, the average percentage reduction of debris was 85% ± 23% per session, and an average reduction in area of WON was from $97.6^2 \pm 72.0$ cm^2 to $27.1^2 \pm 35.5$ cm^2 ($P < .001$). Overall, 2 intraprocedural migrations, 3 perforations, and 7 bleeding episodes were reported in the study cohort. Although the authors reported that none of the adverse events was catheter related, the overall rates of adverse events were still higher compared with published data.[7]

The authors should be commended on their work in evaluating the safety and efficacy of a newly designed 5.1-mm catheter for performing DEN in patients with WON. These results add a new instrument to the array of endoscopic devices used for necrosectomy. However, certain issues remain to be addressed. Although the authors comment on the reduction of the solid necrosum of the cavity, there were no defined criteria across different centers for calculating the necrosis content of the WON. Moreover, the authors did not report the preprocedural necrosis content within the WON, and the criteria for repeating the DEN procedure were also not clear. Moreover, 18 patients required conventional instruments apart from the 5.1-mm catheter for DEN. The reasons for using these devices apart from the EndoRotor system were also not discussed. The larger diameter of the catheter and the use of a therapeutic endoscope may lead to suboptimal maneuverability inside the cavity, resulting in a requirement of other devices for the completion of DEN. Moreover, there is limited availability of a therapeutic gastroscope with a dedicated 6-mm-channel diameter, which may be a hindrance to its adoption in routine clinical use. Approximately 11% of DEN sessions had to be terminated by the operators because of completion of the functional life of the catheter, which increased the procedure numbers. In an earlier case series by Olsen et al,[9] approximately 20% of procedures had to be terminated because of either catheter/console malfunction (n = 4) or clogging of the catheter by solid debris (n = 2). These issues question the longevity and durability of the catheter. Perhaps it is time for an adequately powered randomized trial comparing a strategy that uses EndoRotor with the current standards to clarify whether EndoRotor will be a new standard of care for the management of WON.

In summary, this study explores the 5.1-mm EndoRotor catheter for DEN retrospectively. It has a wider cutting chamber with a better suction capacity, which hopefully results in fewer DEN sessions required for clinical success and WON resolution. However, the performance of the catheter in real-life scenarios, the technical difficulties associated with wider diameter of the catheter, and the cost implications of this dedicated device in comparison with conventional tools are yet to be explored in future clinical trials.

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Abbreviations: DEN, direct endoscopic necrosectomy; LAMS, lumen-apposing metal stent; WON, walled-off necrosis.

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