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Safety and efficacy of the EndoRotor device for the treatment of walled-off pancreatic necrosis after EUS-guided cystenterostomy: A systematic review and meta-analysis

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ABSTRACT

Debridement of infected walled-off pancreatic necrosis is indicated to treat and prevent sepsis-related multiorgan failure. The aim of this study was to evaluate the efficacy and safety of the EndoRotor-powered endoscopic debridement system to remove solid debris under direct endoscopic visualization. Search strategies were developed for PubMed, EMBASE, and Cochrane Library databases from inception to June 2022, in accordance with Preferred Reporting items for Systematic Reviews and Meta-Analyses and Meta-Analysis of Observational Studies in Epidemiology guidelines. Outcomes of interest included technical success defined as successful use of device for debridement, clinical success defined as complete debridement and cyst resolution, and procedure-related adverse events. A random-effects model was used for analysis, and results were expressed as odds ratio along with 95% confidence interval. A total of 7 studies (n = 79 patients) were included. The mean walled-off pancreatic necrosis size was 154.6 ± 34.0 mm, whereas the mean procedure time was 71.4 minutes. The mean number of necrosectomy sessions required was 2.2 (range, 1–7). The pooled rate of clinical success was 96% (95% confidence interval, 91%–100%; I^2 = 0%) with a pooled technical success rate of 96% (91%–100%; I^2 = 0%). The pooled procedure-related adverse event rate was 8% (2%–14%; I^2 = 6%), which included procedure-associated bleeding, pneumoperitoneum, peritonitis, pleural effusion, and dislodgement of lumen-apposing metal stents. Our study shows that the novel EndoRotor device seems to be safe and effective for treating pancreatic necrosis. Patients undergoing endoscopic necrosectomy with the EndoRotor seem to require less debridement sessions when compared with studies using conventional instruments.

Key words: EUS; EUS-guided; LAMS; PFC; WON; Pancreatic necrosis; Necrosectomy; Linear echoendoscope

INTRODUCTION

Approximately 20% of patients with acute pancreatitis will develop pancreatic necrosis, and one-third of these patients will develop infected pancreatic necrosis, which is associated with high rates of morbidity and mortality.[1–4] Infected pancreatic necrosis requires interventional treatment.[5] Over the past 10 years, 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 toward minimally invasive techniques has become the standard of care whereby a step-up approach with endoscopic transluminal drainage by direct endoscopic necrosectomy (DEN) through the lumen-apposing metal stent (LAMS) representing the best therapeutic option for walled-off necrosis (WON).[5,7–10] After EUS–guided transgastric or transduodenal drainage, a pancreatic fluid collection (PFC) cavity can be entered with a standard forward viewing endoscope to perform DEN. 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.[11] with a weighted mean of 4.09 procedures.

One of the main limitations of endoscopic necrosectomy is the lack of dedicated, on-label instruments to remove necrotic tissue from within PFCs. For this purpose, various instruments, originally designed for other indications including those for use in endoscopic retrograde cholangiopancreatography (ERCP) and colonoscopy, among other procedures, are widely used. These devices, including lithotripsy baskets, grasping forceps, retrieval nets, and polypectomy snares, are able to grasp and remove necrotic material. Nonetheless, DEN remains a tedious and time-consuming procedure in cases not responding to EUS-guided drainage only.

The EndoRotor (Interscope Medical, Inc., Worcester, MA) is a novel automated mechanical endoscopic system designed for use

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in the gastrointestinal tract for tissue dissection and resection with a single device. The EndoRotor was approved by the Food and Drug Administration for the removal of dead pancreatic tissue in December 2020.[12] The aim of this study was to evaluate the efficacy and safety of the EndoRotor debridement system to remove solid debris under direct endoscopic visualization by endosonographers and endoscopists.

METHODS

Search strategy

We conducted a comprehensive search of several databases and conference proceedings including PubMed, EMBASE, Web of Science, Google Scholar, and Cochrane Database from inception to June 2022. An experienced medical librarian using inputs from the study authors helped with the literature search. We followed the Preferred Reporting items for Systematic Reviews and Meta-Analyses and Meta-Analysis of Observational Studies in Epidemiology guidelines to identify studies reporting the use of the EndoRotor for treating walled-off pancreatic necrosis (Supplementary Table 1, http://links.lww.com/ENUS/A352).

Key words used in the literature search included a combination of "EndoRotor," "pancreatic debridement," "direct endoscopic necrosectomy," "pancreatic fluid collection," and "walled-off necrosis" (supplementary Table 2, http://links.lww.com/ENUS/A353). The search was restricted to studies performed on human subjects and published in the English language in peer-reviewed journals and conference abstracts. Two authors (D.R., Z.A.) independently reviewed the title and abstract of studies identified in the primary search and excluded studies that did not address the research question, based on prespecified exclusion and inclusion criteria. The full text of the remaining articles was reviewed to determine whether it contained relevant information. Any discrepancy in article selection was resolved by consensus and in discussion with a coauthor. The bibliographic section of the selected articles, as well as systematic and narrative articles on the topic, was manually searched for additional relevant articles.

Study selection

We included studies that evaluated outcomes associated with the EndoRotor used in the treatment and removal of necrotic pancreatic tissue. Studies irrespective of the sample size, inpatient/outpatient setting, and geography were included as long as they provided data needed for the analysis. Inclusion criteria were as follows: (1) patients with pancreatic necrosis and (2) patients undergoing pancreatic debridement using EndoRotor. Exclusion criteria included the following: (1) pediatric (age <18 years) studies, (2) studies not published in the English language, and (3) case reports. In the event of multiple publications from the same cohort and/or overlapping cohorts, data from the most recent and/or most appropriate comprehensive report were retained.

Data abstraction and quality assessment

Study references and citations were collected in EndNote X9 (Thomson Reuters, New York, NY). Covidence systematic review software (Veritas Health Innovation, Melbourne, Australia; https://www.covidence.org/) was used to further screen and extract relevant studies. The full text of each selected article was reviewed to verify that it contained relevant information. Data on study-related outcomes in the individual studies were abstracted by 2 authors (D.R., Z.A.), and 2 authors (S.D., D.M.) did the quality scoring independently. Nonrandomized studies were assessed via the Risk of Bias in Non-randomized Studies—of Interventions [ROBINS-I] tool.[13,14] No further assessment tools were necessary because there were no randomized controlled studies based on our literature search. Using the ROBINS-I tool, each form of bias was awarded either a low, moderate, serious, or critical risk of bias.

Study outcomes

Outcomes of interest included technical success defined as successful use of the EndoRotor, clinical success defined as complete debridement of pancreatic tissue, and procedure-related adverse events. Mortality was also evaluated. Adverse events and their severity were extracted according to the American Society for Gastrointestinal Endoscopy lexicon when possible; otherwise, adverse events were extracted as reported in the original studies.

Statistical analysis

We used meta-analysis techniques to calculate the pooled estimates in each case following the methods suggested by DerSimonian and Laird using the random-effects model.[15–17]

According to the Cochrane handbook, the choice between fixed- and random-effects model should be based on an expectation of whether the intervention effects are truly identical, preferring the fixed-effects model if this is likely and a random-effects model if this is unlikely. Because it is generally considered to be implausible that intervention effects across studies are identical, this leads to the prevalent use (like in this case) of the random-effects model.

We assessed heterogeneity between study-specific estimates by using Cochran Q statistical test for heterogeneity and the I^2 statistics.[13,14,18,19] In this, values of <30%, 30% to 60%, 61% to 75%, and >75% were suggestive of low, moderate, substantial, and considerable heterogeneity, respectively.[20,21]

Publication bias was ascertained, qualitatively, by visual inspection of funnel plot and quantitatively, by the Egger test.[22,23] A P value <0.05 was considered statistically significant for comparison of groups. All statistical analyses were conducted using RevMan 5.3 software (the Cochrane Collaboration, Oxford, UK).

RESULTS

Search results and characteristics

From an initial total of 189 identified articles, 124 titles were screened after removal of duplicates, and 34 full-length articles were reviewed. The final analysis included 7 studies.[24–30]

The schematic diagram of study selection is illustrated in Figure 1. One prior multicenter international study abstract was identified but not included,[31] as an updated series was published.[30] Of included studies, 2 were prospective, 1 was a retrospective cohort, and 4 were case series.

Seventy-nine patients with pancreatic WON were treated using the EndoRotor in the context of DEN. The most common etiology of WON was biliary pancreatitis (30%). Mean WON size was 154.6 ± 34.0 mm, whereas mean procedure time was 71.4 minutes. LAMS were used to create a cystgastrostomy for 73.6% of cases, with the remaining cases relying upon the placement of plastic stents (24.2%) or self-expanding metal stents (2.2%). The mean number of necrosectomy sessions required was 2.2 (range, 1–7). Additional study and population characteristics are described in Table 1.

Study quality

Overall, 1 study was considered high quality. The remaining studies were considered medium quality. There were no low-quality studies. Supplementary Table 3, http://links.lww.com/ENUS/A354, provides a detailed assessment of study quality.

Meta-analysis outcomes

The pooled cumulative rate of clinical success was 96% (95% confidence interval, 91%–100%, I^2 = 0%) with a pooled cumulative technical success rate of 96% (91%–100%, I^2 = 0%). The pooled cumulative procedure-related adverse event rate was 8% (2%–14%, I^2 = 6%) [Figures 2–4]. The subtypes of adverse events were procedure-associated bleeding, pneumoperitoneum, peritonitis, pleural effusion, and LAMS dislodgement or entanglement, and stent perforation. Four patients died of a cause unrelated to the EndoRotor. Adverse events are summarized in Table 2.

Validation of meta-analysis results

Sensitivity analysis

To assess whether any 1 study had a dominant effect on the meta-analysis, we excluded 1 study at a time and analyzed its effect on the main summary estimate. In this analysis, no single study significantly affected the primary outcomes.

Heterogeneity

We assessed dispersion of the calculated rates using I^2 percentage values. I^2 tells us what proportion of the dispersion is true versus chance. Minimal heterogeneity was present in the pooled event rates of technical success, clinical success, and adverse events. Further subgroup analysis and/or meta-regression analysis was not possible because of the limited study sample size.

Publication bias

A publication bias analysis was not done, as the total number of studies included in the final analysis was less than 10.

DISCUSSION

In this meta-analysis, we assessed the technical and clinical outcomes of the EndoRotor device for endoscopic debridement of pancreatic necrosis. We report high pooled rates of technical success (96%) and clinical success (96%), with minimal heterogeneity. To the best of our knowledge, this is the first meta-analysis on this topic.

Traditionally, WON has been treated using a step-up approach, but this paradigm has shifted dramatically in recent years. In the past, interventional percutaneous and invasive surgical approaches were

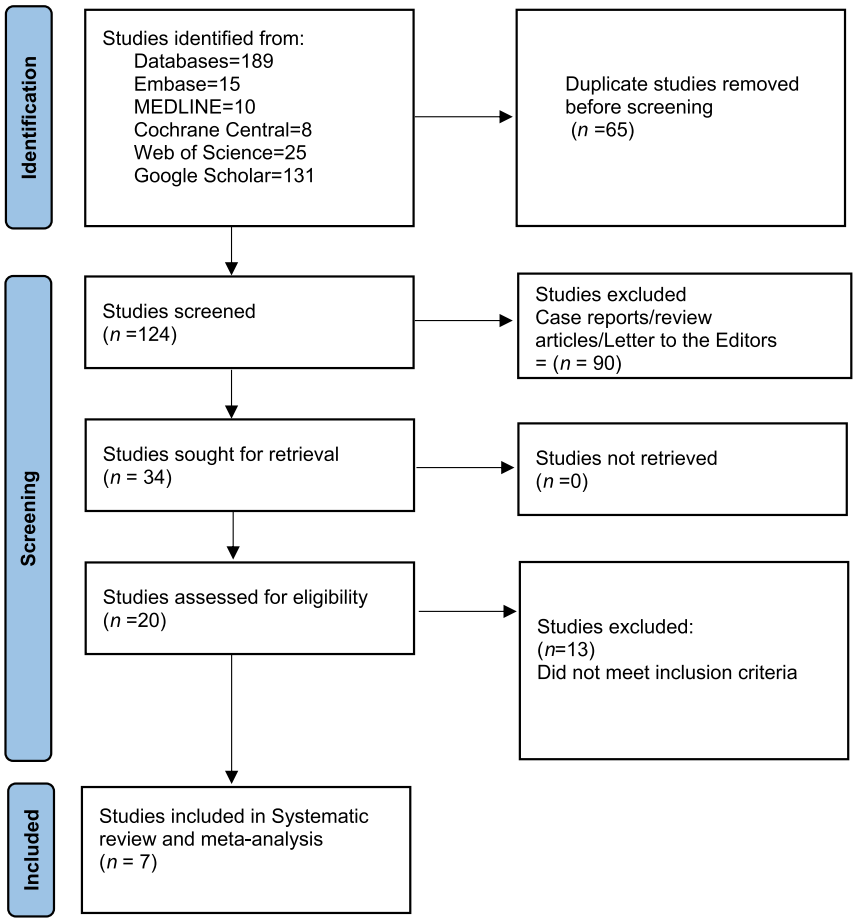

Figure 1. PRISMA flowchart. PRISMA: Preferred Reporting items for Systematic Reviews and Meta-Analyses.

Table 1

Characteristics of studies included for meta-analysis.

Article	Study Design	Location	Patients	Mean Age, y	Percent Male	Technical Success	Clinical Success	Average No. Procedures Per Patient	Average Time, min
Rizzatti et al.[24]	Case series	Italy	4	66.75 ± 5.8	75	4	4	1.25 (1–4)	74
van der Wiel et al.[25]	Case series	Netherlands	12	60.6 ± 11.4	75	12	12	2 (1–7)	46
Stassen et al.[30]	Prospective multicenter	Netherlands, United States, Germany	30	55 ± 15.5	60	29	29	2.1 (1–7)	71
Soota et al.[26]	Retrospective cohort	United States	4	49 (SD NR)	100	4	3	1.25 (1–2)	NR
Morris and Geraghty[27]	Case series	UK	3	52.6 ± 4.2	33	3	3	3.96 (2–7)	NR
Fahmawi et al.[28]	Case series	United States	3	47 ± 16.8	66	3	3	3.3 (2–5)	70
Shinn et al.[29]	Prospective multicenter	United States	23	NR	NR	22	23	2.0	65

used. However, with the introduction of LAMS after about 2014, endoscopic therapy became the de facto first-line therapy.[32,33]

One of the main limitations of endoscopy is the lack of dedicated, on-label instruments to remove necrotic tissue from within PFCs, leaving practitioners to use various endoscopic devices in an off-label manner, to varying degrees of success. The EndoRotor device is the first on label device for the endoscopic debridement of pancreatic necrosis. Traditional endoscopic methods used to treat WON required as many as 3 to 10 sessions for complete debridement of the necrotic cavity.[34] EndoRotor seems to require less number of necrosectomy sessions. However, some endoscopists may choose to use the EndoRotor in combination with other devices. Our meta-analysis showed that patients required an average of 2 sessions for debridement of the necrotic cavity.

Most studies reporting outcomes of the EndoRotor have noted low rates of adverse events. Our meta-analysis showed an overall 7% rate of adverse events, where most were managed conservatively. Furthermore, LAMS was predominantly used in most cases. Bleeding was most commonly reported, followed by LAMS-related problems. Only one case of stent perforation was reported. Compared with traditional methods of endoscopic necrosectomy, complications are usually stent-related such as stent occlusion and stent-induced bleeding and migration.[35] A randomized trial showed that there was no difference in clinical outcomes or adverse events between LAMS and plastic stents.[36] However, a recent meta-analysis showed that LAMS was associated with a marginally lower rate of adverse events compared with plastic stents (LAMS *vs.* plastic stents, 16.0% *vs.* 20.2%; $P = 0.009$; Risk Ratio (RR) = 0.746).[37] Our study was not powered to evaluate outcomes with the EndoRotor according to stent type. However, it should be noted that, although EndoRotor is designed to help clear necrotic contents from PFCs, data on adverse events associated with the use of this device remain limited. Future comparative studies are needed.

The strengths of this review are as follows: systematic literature search with well-defined inclusion criteria, exclusion of redundant studies, inclusion of good quality studies with detailed meticulous extraction of data, rigorous evaluation of study quality, and statistics to establish and/or refute the validity of the results of our meta-analysis. Heterogeneity was zero with the pooled outcomes of technical and clinical success.

There are limitations to this study, most of which are inherent to any meta-analysis. The included studies were not entirely representative of the general population and community practice, with most studies performed in tertiary care referral centers. Our analysis included studies that were retrospective in nature, contributing to selection bias. We were not able to directly compare our results with other endoscopic methods for treating WON because of no available studies in this context. One other knowledge gap is the potential added cost of using the EndoRotor in the debridement of pancreatic WON. To this end, future cost-effective studies are warranted. However, if EndoRotor requires less sessions to achieve complete endoscopic debridement (with minimal adverse events), then it is reasonable to assume that the EndoRotor would not add considerably to the overall cost. Nevertheless, this study is

Table 2

Summary of adverse events.

Article	Bleeding	Pneumoperitoneum	Peritonitis	Pleural Effusions	LAMS Placement Issue	Stent Perforation
Rizzatti et al.[24]	0	0	0	0	0	0
van der Wiel et al.[25]	0	0	0	0	0	0
Stassen et al.[30]	1	1	0	0	1	0
Soota et al.[26]	0	0	0	0	1	0
Morris and Geraghty[27]	0	0	0	0	0	0
Fahmawi et al.[28]	0	0	1	1	0	0
Shinn et al.[29]	6	0	0	0	1	1

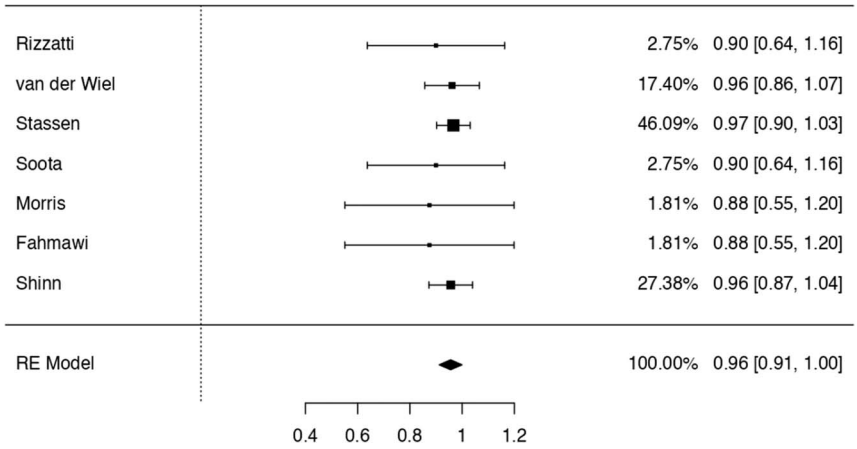

Figure 2. Forrest plot of showing pooled rates of technical success.

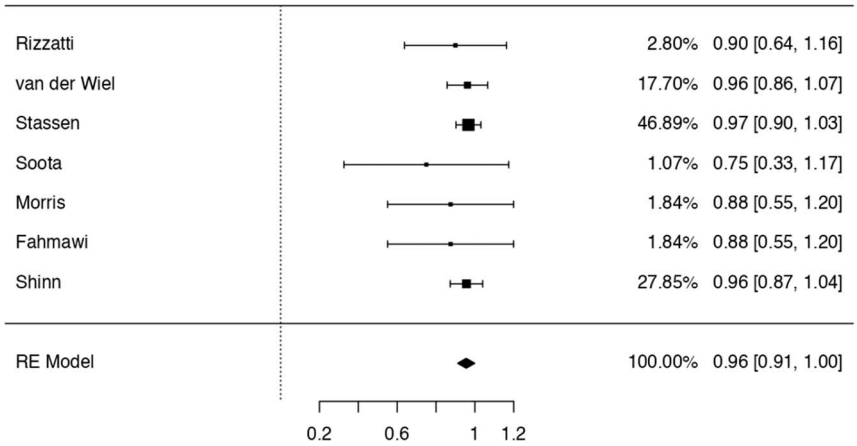

Figure 3. Forrest plot of showing pooled rates of clinical success.

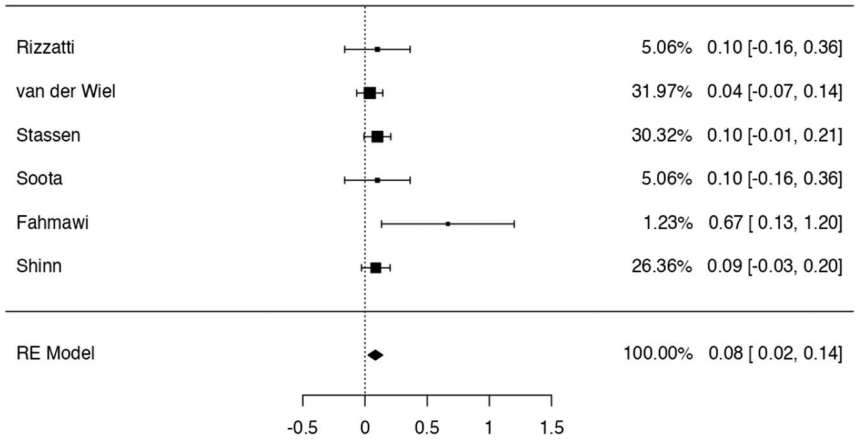

Figure 4. Forrest plot of showing pooled rates of adverse events.

the best available in the literature thus far that summarizes outcomes of EndoRotor for debridement of pancreatic WON.

CONCLUSIONS

The EndoRotor device is designed to facilitate removal of dead tissue in patients with pancreatic WON. This approach may be useful in cases not responding to EUS-guided drainage only. This meta-analysis demonstrates excellent technical and clinical success using the EndoRotor, with minimal heterogeneity. We believe that the use of the EndoRotor adds a dedicated instrument in the armamentarium used for treating WON, filling a large gap for endosonographers and patients with an acceptable safety profile. Future cost-effective studies are warranted.

Conflicts of Interest

Douglas G. Adler is the Co-Editor-in-Chief of the journal. This article was subject to the journal's standard procedures, with peer review handled independently of the editor and his research group.

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None.

Author Contributions

Daryl Ramai conceived the idea for the study. Data collection was performed by Daryl Ramai and Zohaib Ahmed. Data analysis was performed by Daryl Ramai. The first draft of the manuscript was written by Daryl Ramai and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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