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**The Over-The-Scope-Grasper - A new tool for pancreatic necrosectomy and beyond - first multicenter experience**

Over-The-Scope-Grasper for pancreatic necrosectomy

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## **Abstract**

### **BACKGROUND**

Endoscopic treatment of pancreatic necrosis can be challenging and time consuming because sticky necrotic debris is sometimes difficult to remove. With the Over-The-Scope-Grasper, a new tool has recently become available for this purpose, which might also be useful for other indications. However, clinical data on the efficacy and safety of this new device are lacking.

### **AIM**

The purpose of this retrospective study was to evaluate the technical success and safety of the device in a multicenter setting.

### **METHODS**

The Over-The-Scope-Grasper was used in nine selected endoscopic centers between November 2020 and October 2021 for appropriate indications. Overall, 56 procedures were included in the study. We retrospectively evaluated procedural parameters of all endoscopic interventions using a predefined questionnaire, with special respect to technical success, indication, duration of intervention, type of sedation and complications. In the case of pancreatic necrosectomy, the access route, stent type, number of necrosis pieces removed, and clinical handling were also recorded.

### **RESULTS**

A total of 56 procedures were performed, with an overall technical success rate of 98%. Most of the procedures were endoscopic pancreatic necrosectomies (33 transgastric, 4 transduodenal). In 70% access to the necrotic cavity was established by a lumen apposing metal stent. The technical success of pancreatic necrosectomy was 97%, with a mean of 8 pieces (2-25 pieces) of necrosis removed in a mean procedure time of 59min (15-120min). In addition, the device has been used to remove blood clots ( $n = 6$ ), to clear insufficiency cavities before endoluminal vacuum therapy ( $n = 5$ ), and to remove

foreign bodies from the upper gastrointestinal tract ( $n = 8$ ). In these cases, the technical success rate was 100%. No moderate or severe/fatal complications were reported in any of the 56 procedures.

## CONCLUSION

First multicenter data demonstrate that the Over-The-Scope-Grasper is a promising device for endoscopic pancreatic necrosectomy, that is also appropriate for removing foreign bodies and blood clots, or cleaning insufficiency cavities prior to endoluminal vacuum therapy.

**Key Words:** Over-the-scope-grasper; Endoscopic pancreatic necrosectomy; Grasper; Direct endoscopic necrosectomy; Pancreatic necrosis; Endoscopic tool

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**Core Tip:** The objective of our retrospective multicenter study was to evaluate the efficacy and safety of the Over-The-Scope-Grasper, a new endoscopic grasping tool, originally designed for endoscopic pancreatic necrosectomy. A total of 56 procedures were evaluated, including 37 pancreatic necrosectomies with a technical success of 97%. In the other indications - removal of foreign bodies and blood clots or cleaning of insufficiency cavities before endoluminal vacuum therapy - the technical success rate was 100%. First multicenter data show the Over-The-Scope-Grasper as a promising tool for endoscopic pancreatic necrosectomy and beyond.

## INTRODUCTION

Interventional endoscopy continues to evolve with new techniques, that allow minimally invasive treatment of gastroenterological diseases. The development and improvement of these methods have always been accompanied by the development of new, optimized equipment and tools [1-4].

In the case of endoscopic pancreatic necrosectomy, some new tools for endoscopic ultrasound (EUS) guided access to the necrotic cavity have been developed, such as lumen apposing metals stents (LAMS) [5]. Dedicated instruments for necrosectomy are scarce, although a new motorized device (EndoRotor™) has been tested for this indication, providing encouraging data [6]. Therefore, in addition to suction and irrigation, various snares, baskets, or forceps are usually used to remove the tough and sticky necrotic tissue from the retroperitoneal cavity. Since these instruments are less suitable for this purpose, they often slip off from the necrotic tissue and necrosectomy is cumbersome and time consuming. Incidentally, the same problems occur during removal of larger foreign bodies or blood clots from the gastrointestinal tract.

The Over-the-Scope-Grasper, an extra-large grasper attached to the tip of the endoscope, is a new tool developed to overcome the mentioned limitations, especially to facilitate pancreatic necrosectomy [7]. The aim of this retrospective study was to evaluate the efficacy and safety of the new device in a multicenter setting.

## **MATERIALS AND METHODS**

### ***Description of the device***

The Over-the-Scope-Grasper (OTSG Xcavator™ - Ovesco Endoscopy AG, Tübingen, Germany) is an approved single use extra-large grasper attached to the tip of the endoscope. The device is made of transparent plastic to restrict the endoscopic view as little as possible. With a diameter of 14.7mm (forceps closed), the grasping tool can be well inserted through large caliber LAMS. The diameter of open forceps (28.4mm) allows grasping larger pieces of tissue or necrotic debris. The volume inside the closed grasper is just over 1cm<sup>3</sup>. A central 1.1 mm opening at the tip of the device allows additional guidance and stiffening of the endoscope by a guidewire, if necessary. The

instrument is connected to a semi-rigid spout that is fixed onto the endoscope's tip (**Figure 1**). The 1650 mm flexible shaft of the instrument is fixed to the ring and connected proximally to a standard handgrip for opening and closing the grasping tool. To prevent the mucosa from becoming trapped between the endoscope and the cable, both (system and endoscope) are covered with a transparent plastic sheath.

#### ***Application of the device in pancreatic necrosectomy***

The device was applied as follows: The endoscope with the attached grasping tool was inserted into the necrosis cavity. Inside the cavity, the necrotic tissue was grasped by opening the tool and advancing the endoscope while the tissue was sucked into the grasper. After closing the device, the endoscope was withdrawn into the stomach, the grasper was opened, and the tissue was pushed out of the grasper by irrigation through the working channel (**Figure 2 and 3, Video1**).

#### ***Study design***

In this multicentric retrospective study the Over-the-Scope-Grasper was used in selected centers in the early phase of its market launch and 5 mo beyond (from November 2020 to October 2021). After a dedicated introduction into the system, the device was applied by experienced endoscopists for appropriate indications. Preparation and application of the system took place as previously described [7].

The main study objective was to evaluate the technical success of the device application, defined as the smooth advancement of the grasper into the target region, capturing and removing the foreign body/ necrotic tissue.

Other outcome parameters were indication, duration of intervention, type of sedation and complications. In the case of necrosectomy, the access route, stent type, number of necrosis pieces removed and clinical handling (cleaning, additional instruments, *etc.*) were also considered. Complications were classified according to the American Society for Gastrointestinal Endoscopy Lexicon [8]. The overall procedure time was calculated from the first insertion to the last removal of the endoscope, while the "grasper on time"

corresponds to the time period during which the grasper was attached to the endoscope.

### ***Data acquisition and statistics***

To evaluate procedural parameters in a standardized manner, for each procedure a predefined questionnaire was retrospectively completed by the endoscopist. Data were extracted from the clinical database at each center and submitted in anonymous form to the coordinating center. In the coordinating center, all data were collected centrally and in anonymized form. A complete case analysis was performed for all 56 procedures. Experience of at least 4 procedures was mandatory to have patients included in our prospective registry.

Data analysis was performed using Microsoft Excel (version 16.54). Due to the non-interventional study design, no between-group significance tests were performed, and only descriptive statistics were used (mean and range). Before each endoscopic procedure, the patients gave their written consent to the procedure. Retrospective analysis of clinical data has been approved by the local ethics committee without requiring separate written informed consent from each patient for data analysis (Ethics Committee of the University of Würzburg).

## **RESULTS**

In 9 centers the Over-the-Scope-Grasper was used in 56 procedures (in 50 patients) performed between November 2020 and October 2021. All procedures were on-label uses. Details about the number of patients from each center are shown in the supplementary data (**Suppl. Table 1**).

### ***Primary Outcome***

The overall technical success of the device application was 98% (55 of 56 procedures). In one case (pancreatic necrosectomy with transduodenal access), the device could not be inserted into the necrosis cavity due to an unfavorable angle of entry.

### *Pancreatic necrosectomies*

Most of the procedures (66%,  $n = 37$ ) were pancreatic necrosectomies, with preferred transgastric approach (33 transgastric vs. 4 transduodenal). EUS-guided access to the necrosis cavity was achieved *via* LAMS (70%,  $n = 26$ ) or *via* double pigtail stents (30%,  $n = 11$ ). Three different types of SEMs were used. Almost all LAMS (25/26) had a small diameter (15 or 16mm). In mean the first necrosectomy session was performed 35.7 (14 – 90) days after the beginning the pancreatitis (**Table 1**).

The technical <sup>1</sup> success of necrosectomy was 97%, with a mean of 8 pieces (2-25 pieces) of necrosis removed. The mean overall procedure time was 59min (15-120min), of which the grasper was used for a mean of 32min (10-70min). In 8 cases, an additional snare was used to pull the tissue into the grasping tool. In all cases an irrigation pump was used, to push the necrotic tissue out of the grasper. However, in 51% removal of the endoscope was necessary to clean the device outside the patient. Almost all necrosectomies were performed under sedation. In three patients the procedure was performed under general anesthesia because prolonged ventilation was required due to the severity of the pancreatitis.

### *Other indications*

In addition to endoscopic necrosectomy, the device has been used for other appropriate indications (19 cases, **Table 2**). In 8 patients, the tool was used to remove foreign bodies from the upper gastrointestinal (GI) tract (**Figure 4**). In each case, complete removal of the foreign body was achieved. In 6 cases the device was used to remove large blood clots in case of upper GI bleeding. In addition to pancreatic necrosectomy, the device was also used to clear insufficiency cavities prior to endoluminal vacuum therapy ( $n = 5$ ). In all these cases, the technical success rate was 100%.

### *Safety and complications*



Overall, five mild complications occurred. In three cases, dislocation of the LAMS occurred during endoscopic necrosectomy. None of these cases resulted in further problems (bleeding, *etc.*). In all three cases, pigtail stents were inserted instead to keep access to the necrosis open.

In one case, superficial laceration of the upper esophageal sphincter occurred during insertion of the device. In another case, a minor bleeding occurred during necrosectomy, which could be treated endoscopically (no transfusion required). No moderate or severe/fatal complications were reported in any of the 56 procedures.

## **DISCUSSION**

Direct endoscopic necrosectomy (DEN) of pancreatic necrosis is an important development in interventional endoscopy and has significantly improved the prognosis of these patients [9]. The method is well established and has been further developed in recent years, especially with new, specially shaped LAMS that facilitate EUS-guided access to the necrosis cavity [5]. To our knowledge, new devices, designed for necrosectomy have not yet been developed [10-12]. Therefore, DEN is often performed by a combination of sucking debris through the working channel, removing necrotic material with a removal device, and applying irrigation. This method is often time consuming, as effective suction needs a free working channel, therefore used devices (snare, *etc.*) have to be introduced and removed frequently. The devices used so far also have disadvantages in necrosectomy. Frequently, snares or baskets cannot be fully opened in the narrow retroperitoneal necrosis cavity, thus grabbing of tissue can be difficult. In addition, snares often cut through the soft necrotic tissue rather than capturing it. Therefore, other systems for necrosectomy have been tested recently, such as the EndoRotor™ (Interscope Inc., Northbridge, Massachusetts, USA), a technically complex device originally developed for polypectomy and available only in a few centers [6, 13, 14].

With the Over-the-Scope-Grasper, a simple tool has been developed that can overcome several of the problems mentioned above. Since the grasper is mounted on the tip of the

endoscope, the working channel remains free, allowing the necrotic tissue to be captured and aspirated simultaneously. The new device also cuts through the soft tissue, but the captured material remains in the grasper and can be removed. Furthermore, the grasping tool is easy to open even in tight space and can be even used in half-opened position. However, in foxhole-like branched necrotic cavities, the device is less applicable due to its size. Since the system can be attached to a standard gastroscope, it is quickly and easily ready for use and does not require any special additional equipment.

In our study, the new device was used in 9 centers after a dedicated introduction into the system. No moderate or severe/fatal complications were reported in a total of 56 cases, underlining the ease of use and safety of the system.

Insertion of the device through the pharynx and esophagus but also entry into the necrosis cavity was usually straightforward. However, the transgastric approach to necrosis appears to be more favorable because the device significantly extends the tip of the endoscope, which may hinder manipulation within the duodenum. This should already be considered when creating the EUS access, as an unfavorable access angle (e.g., in the duodenum) can make insertion of the grasping tool impossible.

Removal of necrotic material with new device works well, even in small LAMS diameters (15 to 16mm). However, there is little a risk of stent dislocation, especially if the grasper has captured a lot of tissue. LAMS with a larger diameter (³ 20mm) may be advantageous in this situation. For effective use, a therapeutic gastroscope with a large working channel is recommended. To improve the suction performance, we recommend using a combined suction-irrigation attachment directly at the upper end of the working channel. Irrigation with a pump is also helpful to flush the necrotic pieces out of the grasper. Cleaning the grasper outside the patient is time consuming and frequent passage through the upper esophageal sphincter is an additional burden to the patient. Therefore, we recommend wetting the surface of the device with an Anti-Fog solution, to reduce the necrotic material sticking at the grasper and to improve the visibility through the transparent plastic cover.

Insufficiency cavities after gastrointestinal surgery are often treated by endoluminal vacuum therapy<sup>[15]</sup>. To achieve rapid healing of the insufficiency, the cavity is previously cleansed of pus and necrotic tissue. For this purpose, the new grasping tool can be used in the same way as for pancreatic necrosectomy if the access to the insufficiency cavity is large enough.

With respect to endoscopic removal of foreign bodies from the gastrointestinal tract, examiners experience that in case of extra-large or hard foreign bodies, the grasper may slip off the foreign body. Here, additional use of a snare might be helpful to pull the foreign body firmly into the grasper<sup>[7]</sup>. In case of small foreign bodies, the grasping tool completely encloses the foreign body, preventing it from being lost in the pharynx and eliminating the risk of aspiration. Therefore, the system is particularly suitable for removing button cell batteries and small magnets.

Last not least, the new device appeared to be a helpful tool in the management of upper gastrointestinal bleeding. In addition to quick removal of large blood clots, the transparent plastic scoops of the grasper can be used to compress the bleeding vessel. Thus, after removal of the blood clot the bleeding source can be compressed while an instrument (clip, injection needle, *etc.*) is inserted through the free working channel. After opening the device, the source of bleeding can then be treated directly, making hemostasis potentially easier and faster.

In summary, our data highlights the usefulness of this new device in several indications, but the study has several limitations. Due to the retrospective design, the study may be affected by selection bias in favor of the device. The multicenter study design with heterogeneous patient populations and operator experience may also lead to bias (e.g., referral bias). Since this is a retrospective study a standardized approach to the necrosectomy was not possible. Therefore, only descriptive statistical methods are used and any benefit from the device cannot be quantified or statistically proven.

## **CONCLUSION**

This first multicenter data demonstrate that the Over-the-Scope-Grasper is a promising device for endoscopic pancreatic necrosectomy. Other appropriate indications seem to be cleaning insufficiency cavities prior to endoluminal vacuum therapy and removal of foreign bodies. In the management of upper gastrointestinal bleeding, the grasping tool has been reported to be a useful device beyond the removal of blood clots. However, prospective studies including more patients should be conducted to demonstrate the efficacy and clinical utility of the device and to gather even more information on the safety of the device.

## **ARTICLE HIGHLIGHTS**

### ***Research background***

1

Endoscopic treatment of pancreatic necrosis can be challenging and time consuming because sticky necrotic debris is sometimes difficult to remove. With the Over-The-Scope-Grasper, a new tool has recently become available for this purpose, which might also be useful for other indications.

### ***Research motivation***

To evaluate the technical success and safety of the new Over-The-Scope-Grasper in a multicenter setting.

### ***Research objectives***

We retrospectively evaluated the use of the Over-The-Scope-Grasper in nine selected endoscopic centers and aimed to investigate the technical success and safety of device use.

### ***Research methods***

We retrospectively evaluated 56 procedures performed between November 2020 and October 2021. In addition to technical success and complications, we evaluated procedural parameters such as the indication, duration of the procedure, type of

sedation, and, in the case of pancreatic necrosectomy, the access route, stent type, and number of pieces of necrosis removed.

### ***Research results***

The overall technical success rate was 98%. The technical success of pancreatic necrosectomy (37 cases) was 97%, with a mean of 8 pieces of necrosis removed in mean 59min. <sup>1</sup> In addition, the device has been used to remove blood clots ( $n = 6$ ) to clear insufficiency cavities before endoluminal vacuum therapy ( $n = 5$ ), and to remove foreign bodies from the upper gastrointestinal tract ( $n = 8$ ). In these cases, the technical success rate was 100%. No moderate or severe/fatal complications were reported.

### ***Research conclusions***

The Over-The-Scope-Grasper is a promising device for endoscopic pancreatic necrosectomy, that <sup>1</sup> is also appropriate for removing foreign bodies and blood clots, or cleaning insufficiency cavities prior to endoluminal vacuum therapy.

### ***Research perspectives***

Prospective studies including more patients should be conducted to demonstrate the efficacy and clinical utility of the device.

### **ACKNOWLEDGEMENTS**

Prior to its market launch, the Over-the-Scope-Grasper was provided free of charge to the centers by Ovesco Endoscopy AG, Tübingen, Germany. Data collection was supported by Ovesco Endoscopy AG, Tübingen, Germany (S. Kern). Ovesco Endoscopy AG, Tübingen, Germany was not involved in the design, recruitment, analysis, interpretation, or writing of the manuscript. <sup>4</sup> LS is supported by the Berta-Ottenstein-Programme, Faculty of Medicine, University of Freiburg, Germany.

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