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Endoscopic removal of over-the-scope clips: Clinical experience with a bipolar cutting device

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Abstract

Background: Over-the-scope clips (OTSCs) are increasingly used for the closure of perforations/fistulae, hemostasis and endoscopic full-thickness resection (FTRD system). When OTSC-associated complications occur or re-therapy at the OTSC site is needed, OTSC removal may be indicated. An experimental study in an animal model and a case series have shown good results for OTSC removal with a bipolar cutting device. We present a larger clinical study using this device.

Methods: Data of all consecutive patients with indication for OTSC removal were collected and analyzed retrospectively. OTSCs were cut at two opposing sites using a bipolar grasping device to apply short direct current impulses. OTSC fragments were extracted with a standard forceps and a cap at the tip of the endoscope to avoid tissue damage.

Results: Between December 2012 and February 2016 a total of 42 OTSC removals in the upper ($n = 25$) and lower ($n = 17$) gastrointestinal tract have been performed at our department. Overall technical success, defined as cutting the OTSC at two opposing sites and extraction of both fragments, was achieved in 92.9% (39/42) of all cases. Successful fragmentation of the OTSC was achieved in 97.6% (41/42). Minor bleedings were rare and could be managed endoscopically in all cases. There were no perforations and no major or delayed bleedings.

Conclusion: Endoscopic OTSC removal with a bipolar cutting device is feasible, effective and safe. This technique can be applied in the upper and lower gastrointestinal tract.

Keywords

Endoscopic removal, over-the-scope clip, OTSC, remOVE system, bipolar cutting device

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Introduction

Over-the-scope clips (OTSCs) are increasingly used for hemostasis, closure of perforations/fistulae and full-thickness resection in the upper and lower gastrointestinal (GI) tract.[1–7] Although OTSCs are designed as durable implants, removal of an OTSC can be indicated when OTSC-associated complications (e.g. local inflammation, ulceration, luminal obstruction) occur, when the clip was misplaced, re-therapy after incomplete full-thickness resection is needed or an OTSC-fixed stent has to be removed. The feasibility of OTSC cutting and consecutive removal using a prototype bipolar cutting device has been reported in an experimental study[8] and a smaller case series.[9] The device has recently been Conformité Européene (CE) approved in Europe and is now commercially available. We present a retrospective study to investigate the efficacy and safety of OTSC removal in a larger patient cohort.

Methods

OTSCs were cut with a bipolar direct current (DC) grasping device (remOVE system, Ovesco, Tuebingen, Germany) (Figure 1). The device gained the Conformité Européenne (CE) mark in September 2015. The electric DC impulses are delivered by a special electric generator connected to the grasping device. The bipolar grasper can be advanced through a 2.8 mm endoscope working channel. Its tip consists of three electrodes that are brought in contact with the thinnest parts of the nitinol clip. Application of DC impulses

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Figure 1. The remOVE system grasping the frame of an over-the-scope clip (with permission from Ovesco Endoscopy, Tuebingen, Germany).

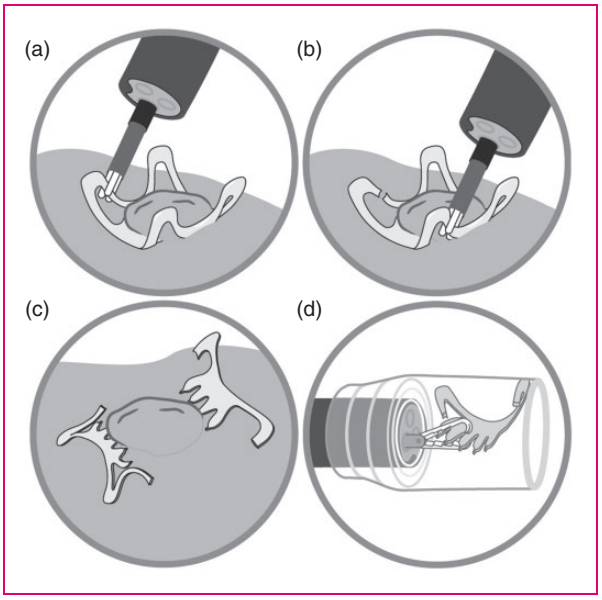

Figure 2. Schematic illustration of an over-the-scope clip (OTSC) removal. (a) The grasper of the bipolar cutting device getting hold of the OTSC nitinol frame. (b) After having cut one side, the OTSC has to be cut on the opposing side. (c) Both fragments can be retracted from the tissue. (d) A plastic cap is used to safely extract the fragments.

then selectively heat up and melt the nitinol. As soon as the clip is cut or the contact to the nitinol is lost during the cutting process, an integrated safety feature automatically stops the current flow. The OTSCs are cut at two opposing sites (Figure 2). In the next step the OTSC fragments are extracted from the tissue with a standard forceps. For extraction of the fragments out of the patient, a cap at the tip of the endoscope was used to avoid tissue damage (Figure 3).

After approval of our institutional review board (IRB approval number 2016-0617, ethics committee of Regionale Kliniken Holding (RKH)), data were collected and analyzed retrospectively. The primary endpoint was overall success defined as successful OTSC fragmentation (cutting at two opposing sites) and extraction of both fragments. As secondary endpoints complications and procedure time were analyzed. Procedure time was defined as the time span between start and end of propofol administration as indicated in the sedation protocols.

Results

Between December 2012 and February 2016 a total of 42 OTSC removals in the upper ($n = 25$) and lower ($n = 17$) GI tract have been performed at our department. Patient characteristics and indications are shown in Table 1.

Successful fragmentation of the OTSC was achieved in 97.6% (41/42). Overall technical success, defined as cutting the OTSC at two opposing sites and extraction of both fragments, was achieved in 92.9% (39/42) of all cases. The mean procedure time was 47 minutes (range 25–100 minutes) in the upper GI tract and 58 minutes (range 40–75 minutes) in the lower GI tract.

In five cases the OTSC had been completely or partially overgrown by hyperplastic tissue (Figure 4). Mean time of OTSC in situ did not significantly differ in those cases compared to all other cases (104 days vs. 99 days). Localization was duodenum in two cases, coecum, ascending colon and sigmoid colon. Nevertheless complete removal of the OTSC was managed in two of five cases after removal of hyperplastic tissue with a standard snare (ascending colon and sigmoid colon). Cutting current was applied for resection. Complications did not occur in those cases. In the other three cases, removal of the OTSC was not successful. In one case, it was possible to cut the clip in the coecum at two opposite sides; however, the fragments could not be mobilized because of deep ingrowth into the colonic wall. In this case removal of the clip had been planned to inspect the resection site and take biopsies after full-thickness resection of an adenoma at the base of the appendix with the FTRD system (Ovesco Endoscopy). Biopsies taken from adjacent tissue did not show recurrence of the adenoma, so no further therapy was scheduled. In a case of an OTSC causing duodenal stenosis the clip was successfully cut, but only one fragment could be extracted. Duodenal passage was restored by resection of granulation tissue with a standard snare. A second duodenal OTSC, which had been placed to close a perforation after endoscopic mucosal resection (EMR) of a duodenal adenoma, could be cut on only one side, so mobilization was not possible and biopsies had to be taken from the surrounding tissue. Since biopsies revealed recurrence of the adenoma, pancreas-sparing duodenectomy was performed.

After OTSC removal immediate minor bleeding at the former OTSC site occurred in four cases (4/42, 9.5%). Hemostasis was endoscopically achieved by application of hemoclips and injection of diluted

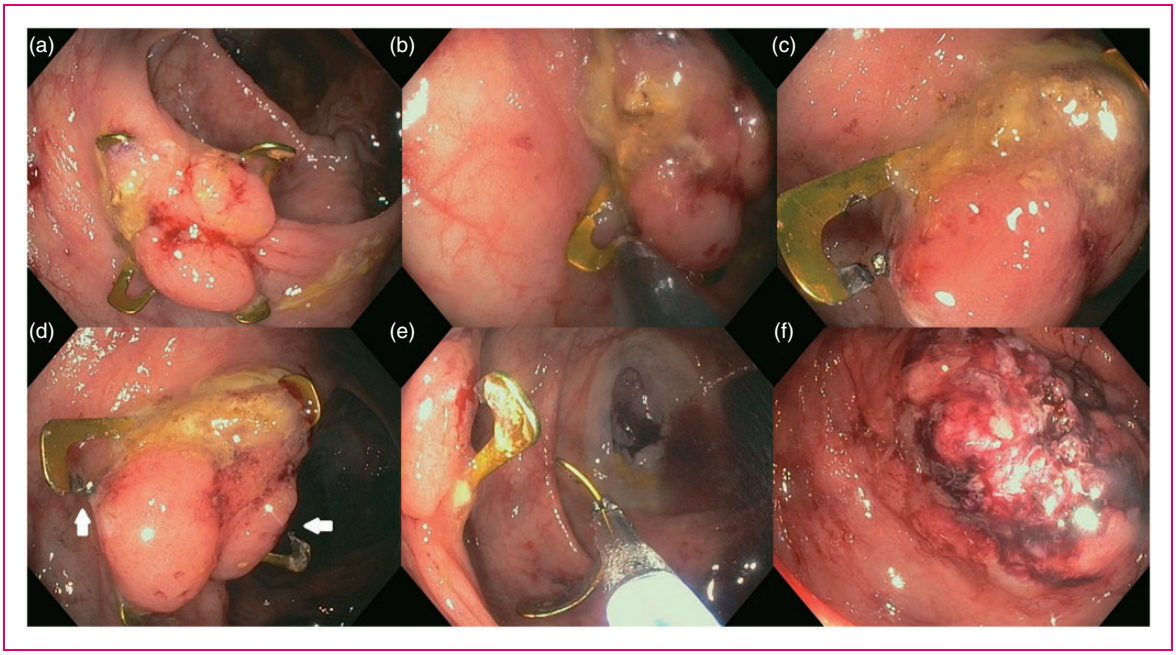

Figure 3. Removal of an OTSC. (a) OTSC in the ascending colon. (b) The grasper has been brought in contact with the nitinol frame of the OTSC. (c) The nitinol frame has been cut on one side. (d) The OTSC frame has been cut on two opposing sides. (e) Extraction of the first fragment. (f) Local inspection after extraction of both fragments. OTSC: over-the-scope clip.

Table 1. Patient characteristics and indications for OTSC removal.

Patients	
Number of patients, *n*	42
Male, *n*	28
Female, *n*	14
Age, mean (range), years	65 (35–89)
OTSC site	
Upper GI tract	25
Esophagus	6
Gastric antrum	5
Pylorus	3
Duodenum	11
Lower GI-tract	17
Coecum	10
Ascending colon	3
Sigmoid colon	2
Rectum	2
Indication for OTSC removal	
Re-biopsy/-therapy after full-thickness resection	22
Dysphagia/stenosis (only upper GI tract)	9
Abdominal pain	4
Misplaced clip	4
Clip-associated local ulceration	2
Removal of OTSC-fixed esophageal stent	1
Time of OTSC in situ, mean (range), days	99 (1–469)

OTSC: over-the-scope clip; GI: gastrointestinal.

suprarenine in all cases. There was no delayed and no major bleeding. There were no perforations. During electrocardiogram monitoring no cardiac arrhythmia during clip cutting was observed. Outcome and complication data are summarized in Table 2.

Discussion

OTSC removal using a special grasping device with DC impulses has been shown to be feasible in a small case series.[9] Our data obtained from a larger cohort further confirm that this method is effective and safe with an overall technical success of 92.9% (39/42) and minor adverse events in 9.5% (4/42).

Although there are no data on natural history of OTSCs, more than 70% of all FTRD clips spontaneously detach from the colonic wall within three months after full-thickness resection (WALL RESECT Study, presentation, Digestive Disease Week (DDW) 2016[10]). Time to OTSC dislodgement may depend on the amount of tissue grasped and the clip location. In some cases OTSCs may durably remain in situ. The removal of an OTSC may be necessary when clip-associated complications occur (e.g. localized ulceration, inflammation, luminal obstruction). Furthermore, the removal of an OTSC is indicated after incomplete full-thickness resection for further endoscopic therapy or surveillance. In case of misplaced clips or planned extraction of stents fixed

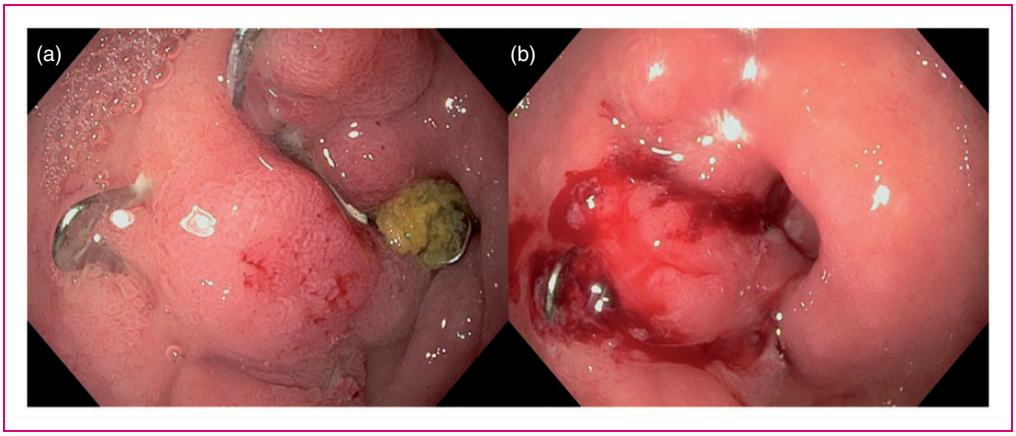

Figure 4. (a) Example of an OTSC in the duodenum partially overgrown by hyperplastic tissue. (b) It was possible to cut the nitinol frame of the OTSC on two opposing sides, but only one fragment could be mobilized. OTSC: over-the-scope clip.

Table 2. Outcome and complications.

Success rates	
Cutting of OTSC at two opposing sites	41/42 (97.6%)
Extraction of all OTSC fragments	39/42 (92.9%)
Overall success	39/42 (92.9%)
Complications	
Minor bleedings	4/42 (9.5%)
Major bleedings	0/42 (0%)
Delayed bleedings	0/42 (0%)
Perforations	0/42 (0%)

OTSC: over-the-scope clip.

by an OTSC, clip removal is also indicated.[9,11] Because of the upcoming widespread use of the FTRD device (Ovesco, Germany) and growing use of OTSCs in various indications, there may be an increase in the number of cases requiring OTSC removal in the future.

Difficulties in clip removal may occur in the following situations. Compared to other OTSCs the nitinol structure of the modified OTSC used with the FTRD system is somewhat thicker. Consequently it may take more time to melt FTRD clips. However, in our study the times for FTRD removal compared to OTSC removal in this study were comparable (54 minutes vs. 49 minutes). Possibly the aspects described below have more influence on difficulty than the thickness of the nitinol structure. There are no further data available comparing OTSC and FTRD clip removal.

OTSC removal may also be complicated by partial or complete ingrowth into the GI wall. Removal of granulation tissue may be needed prior to clip cutting in those cases. Theoretically, ingrowth or overgrowth of the clips may depend on the length of time the OTSC is in place. However, in our study the mean time of the OTSC being in place did not differ between overgrown OTSCs and all other OTSCs.

Furthermore, difficulties may occur when OTSCs are located at sites that limit mobility of the endoscope and the grasper such as the upper and lower duodenal knee and the colonic flexures. In this study the longest time (100 minutes) was needed for the removal of an OTSC in the descending duodenum. It was difficult to grasp and cut one OTSC site because of the localization near the upper duodenal knee. After successful removal of both clip fragments, a minor bleeding had to be stopped.

It has to be mentioned that procedure time had to be defined as the time span between the start and end of propofol administration because of the retrospective design of this study. The points of time when the cutting device was introduced into the GI tract and when the fragments had been successfully extracted could not be determined in many cases retrospectively. This may result in an overestimation of procedure time in some cases since additional proceedings such as re-biopsies or re-therapies could not be distinguished from the process of cutting and extracting the OTSC. This study is limited by its retrospective and monocentric design. Although the number of cases presented is restricted by the novelty of the technique, it still exceeds by far the number of cases published for the alternative techniques described below.

Several techniques for OTSC removal have been proposed. Neumann and colleagues published a technique based on guidewire cannulation of the small oval hole in the jaw of the OTSC.[12] After cannulation, they removed the clip by pulling on the wire. In this ex vivo animal study, the overall success rate to remove the clips was as low as 53.3% because the oval hole could not be cannulated in four out of 12 cases. In all cases with successful cannulation the removal of the clip was

also successful. Given this low success rate, this technique may be feasible only in selected cases with visibility of the oval hole. Another concern may be that the clip is removed in a closed position, which may result in tissue damage, bleeding or even perforation. Arezzo and colleagues suggested cooling down the OTSC to lower the mechanical resistance of the nitinol frame prior to its extraction by a standard grasping forceps.[13] This was achieved by flushing the nitinol with ice-cold normal saline for one minute and gently pulling the OTSC out of the wall as soon as it is deformable. Although this is a very interesting and potentially safe approach, there are currently no larger series confirming efficacy of this method. One major concern could be that the surrounding tissue may quickly warm up the nitinol again, which would lead to a rapid change to its stiff state again. In contrast, when a cutting technique is used, the endoscopist has enough time to grasp and remove the clip from the tissue once the nitinol is successfully cut.

Another proposal was the removal of the OTSC by dissection of the tissue at the base of the clip in EMR or endoscopic submucosal dissection (ESD) technique.[14] This was successful in two cases. In a case series investigating OTSC-fixed esophageal stents, OTSC was removed in six cases after creating a fluid cushion underneath its base by submucosal injection, followed by dissection or EMR.[15] OTSC removal was feasible without any complications in both case series, but available data are limited to a few patients. Both EMR and ESD are limited to superficially placed clips and may harbor a higher risk of bleeding or even perforation as both methods are more invasive than the use of the bipolar cutting device.

Similar to the technique described in this case series, the use of an argon plasma beamer or Nd:YAG laser to cut an OTSC is based on heating up and melting the nitinol of the OTSC.[11] The Nd:YAG laser was effective and safe in three cases of OTSC removal. However, there may be a risk of thermal damage in case of accidental approach of the surrounding tissue. In contrast to the Nd:YAG laser and the argon plasma beamer, the generator of the bipolar cutting device is provided with an auto-stop function that immediately stops current flow after losing contact with the nitinol structure. This may reduce the probability of local complications. Moreover, the necessary instrumentation may not be widely available, whereas the Ovesco remOVE system was exclusively developed for this indication and is commercially available.

Compared to those techniques, the use of the bipolar cutting device for OTSC removal has been demonstrated to be effective with a high success rate of 92.9% and to be safe in a larger number of cases. Furthermore, it is now widely available in Europe.

In conclusion OTSC fragmentation and removal with the novel bipolar cutting device is effective and safe in the upper and lower GI tract.

Declaration of conflicting interests

None declared.

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