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IN THE EXPERT'S FOCUS

Use of OTSC Device System for Closure of Fistulas in the Alimentary Tract - A Case Series ☆☆

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Colovaginal closure;
Leak;
Bear claw;
Video

Abstract

Objective: We report our experience - a case series with the Over the Scope Clip (OTSC), Bear claw, a novel and new tool for the endoscopic entrapment of tissue for closure of fistula and perforations.

Design: Single-center.

Setting: Tertiary referral academic gastroenterology unit and center for advanced therapeutic endoscopy.

Patient:

Case I - referred for endoscopic treatment for the closure of gastrocutaneous fistula (GC).
Case II - referred for endoscopic treatment for the closure of colo-vaginal fistula.
Case III - referred for endoscopic treatment for the closure of GC fistula.

Intervention: The OTSC system was mounted on the tip of the scope and passed down to the level of the fistula. The targeted site of the fistula was grasped with the tissue anchoring tripod and pulled into the cap with concomitant scope channel suction. Once the tissue was trapped in the cap, the Bear claw was deployed.

Main outcome measurements: NA.

Results: All patients recovered. No complication or recurrence noted. Case I showed successful results with closure of the fistula. Case II fistula was not closed due to the cavity beneath the fistula probably abscess formation - which prevented the healing of the fistula site

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despite of the closure with OTSC. Case III fistula did not close successfully due to the larger diameter of the fistula which was greater than 1 cm.
Conclusion: With several new devices being introduced, it is difficult to judge the implementation of one tool over the others. This device has shown promising results for fistula closure if used knowing the limitation of the product.

Video related to this article

Video related to this article can be found online at http://dx.doi.org/10.1016/j.vjgien.2013.04.002.

1. Background

- The mainstay of therapy for GC fistulas has been surgical intervention [1]. However a conservative endoscopic approach has recently been preferred with the advantages of negligible morbidity and mortality, a short hospital stay, and the possibility of prompt resumption of an oral diet [2].
- Routine endoscopic methods to close GI fistulas include stents, injectables, stitch devices and endo-clips, however, endo-clips are currently used for management of perforations and fistula but are limited by their ability to entrap and hold the tissue.
- The Over the Scope Clip-OTSC system (OTSC(R); Ovesco AG, Tübingen, Germany) is a new tool for the endoscopic entrapment of tissue. Indications for its use are hemostasis, compression of large vessels, and closure of leaks/fistulas of the GI tract.
- Preclinical work has shown the device to be feasible and safe for closure of gastric, duodenal, and colonic perforations up to 20 mm in diameter [1,2].

2. Materials

- Over the Scope Clip (OTSC(R); Ovesco AG, Tübingen, Germany).
- GIF-H180J (Standard Gastroscope) (Olympus, Tokyo, Japan).
- EG-450WR5 (Standard Gastroscope) (Fujinon, Tokyo, Japan).
- PCF-H180AL (Pediatric Colonoscope) (Olympus, Tokyo, Japan).

3. Endoscopic procedure

3.1. Procedure technique

- The OTSC system is composed of an application cap, which is mounted onto the distal tip of the endoscope and a connected releasing mechanism, installed on the handle of the scope.
- There are two proprietary devices to draw the tissue into the cap; a dual arm forceps and a tissue anchoring tripod.
- The clip is deployed by a string release fixed to a rotating wheel attached to the accessory channel.

3.2. Case 1

- 80 year old female with complaints of dysphagia. H/O of aortic valve regurgitation, underwent TEE, had esophageal perforation. S/P Surgery, had repair with feeding jejunostomy and venting gastrostomy. Healing of the perforation resulted in gastrocutaneous fistula which persisted for 9 months despite of PPI therapy. The single channel Olympus endoscope was introduced through the mouth and advanced down to the level of a hiatal hernia sac. The greater curvature revealed a retracted mucosal surface in continuity with the gastrostomy site. A savory guide wire was advanced through the skin opening of the abdominal wall and into the stomach. The OTSC system was mounted on the tip of the scope and passed down into the stomach to the level of the fistula. The targeted site of the fistula was grasped with the tissue anchoring tripod and pulled into the cap with concomitant scope channel suction. Once the tissue was trapped in the cap, the Bear claw was deployed.
- Repeat endoscopy was performed after 3 months and the fistula site was successfully healed.

3.3. Case 2

- 37 year old female with past medical history of diverticulosis presents with passage of feculent material from her vaginal canal and recurrent urinary tract infections.
- CT scan demonstrated a fistula between the sigmoid colon and vagina.
- Subsequently an OTSC Bear claw was considered for the closure of the fistula. Careful examination up to the splenic flexure was performed with cap fitted gastroscope. Despite of careful withdrawal, no fistula could be identified. With prior cervical exam, it was evident that the fistula had an opening in the posterior fornix.
- Second gastroscope was introduced towards posterior cervix. A wire guide was introduced into the posterior fornix followed by catheter. The gastroscope with fitted cap was reintroduced into the sigmoid colon and methylene blue dye was injected through the vaginal catheter. After several injections, a small area where the dye was coming from was isolated. The area was marked with an India ink tattoo and just above the area a biopsy was taken also to mark the spot. An atraumatic Bear claw clip on a 17.5 mm cap was attached to the scope and the scope advanced to the marked site. The tissue was then aspirated into the cap without a retracting device and the Bear claw deployed with good entrapment of the identified area.

3.4. Case 3

- 41 year old female s/p colonic interposition for lye ingestion and PEG tube placement.
- After 2 months, patient was able to tolerate PO intake. The PEG tube was removed but the gastrostomy tract persisted for several months. Conventional methods of closure were unsuccessful. Gastroscopy was carried. The foley catheter was aspirated to collapse the retention balloon and the catheter removed. The fistulous tract had some exudate at the gastric orifice. The OTSC Bear claw adapter and clip were advanced to the fistula. The tissue anchor was inserted three times into the tract to attempt to draw the margins of the tract into the cap along with suction. The Bear claw was released when maximum tissue was pulled into the cap.

4. Discussion

In case II, patient was symptom free for few weeks but with recurrent complaints, she was sent for surgery. She was found to have abscess communicating with the colovaginal fistula leading to inability to fistula repair after Bear claw placement.

In case III, the patient started having secretions from the gastrostomy site after few weeks. The theory for the failure of this gastrocutaneous fistula was hypothesized to the size of the fistula diameter which was approximately greater than 1 cm.

Location of the fistula especially trachea-esophageal fistula makes the deployment of the OTSC device difficult due to less space area.

5. Tips and tricks

- Closure of a fistula is dependent on the location in the alimentary tract.
- Fistula in the stomach less than 1 cm and in the colon less than 2 cm is ideal for closure with the aid of OTSC system (Bear claw).
- It is very important to determine the underlying cause of fistula for the outcome. In this case, due to the abscess formed beneath the fistulous tract, healing of the tract was prevented.
- The advantage of OTSC system is the tissue to be grasped can be pulled in with the help of tripod (if used). There is no need for red out of the tissue before deploying the Bear claw – this gives an adequate view of the tissue before deployment allowing proper delivery under vision.

6. Scripted voiceover

Voiceover Text

Traditionally, the mainstay for closure of fistula has been surgical intervention

The current approach for closure of fistula has been divided into 3 categories – Mechanical devices which include clips, loop, and sutures. The 2nd category consists of various types of stents like polyflex stents, partial or fully covered stents. The 3rd category consists of injectables like cyanoacrylate; fibrin glue and fistula plug system. Though endoclips are currently used for management of fistula, perforation but are limited by their capacity to entrap and hold the tissue.

The goal of this presentation is to illustrate the technique for closure of the fistulas with the aid of bear claw – also known as Over the Scope Clip (OTSC)

The OTSC system is composed of an application cap with a nitinol bear claw clip mounted outside the system.

Three variants of clips – traumatic, atraumatic and gastric fistula closure clips are known.

The application system is mounted onto the distal tip of the endoscope and a connected releasing mechanism, installed on the handle of the scope.

In contrast to common endoscopic clips, the OTSC is able to compress larger quantities of tissue. There are two proprietary devices to draw the tissue into the cap; a dual arm forceps and a tissue anchoring tripod. The clip is deployed by a string release fixed to a rotating wheel attached to the accessory channel.

This clip demonstrates the loading of the applicator cap on the endoscope in the same fashion like the band ligation kit.

Once the applicator cap is mounted, the scope is passed to reach the desired area and the lesion is targeted. The dual arm forceps or tripod is aligned with the OTSC applicator and the tissue is grasped into the applicator cap. Once enough tissue is grasped into the cap, the bear claw is deployed.

Case 1

80 year old female with complaints of dysphagia. H/O of aortic valve regurgitation, underwent TEE, had esophageal perforation. S/P Surgery, had repair with feeding jejunostomy and venting gastrostomy. Healing of the perforation resulted in gastrocutaneous fistula which persisted for 9 months despite of PPI therapy.

The single channel Olympus endoscope was introduced through the mouth and advanced down to the level of a hiatal hernia sac. The greater curvature revealed
a retracted mucosal surface in continuity with the gastrostomy site. A savary guide wire was advanced through the skin opening of the abdominal wall and into the stomach. The OTSC system was mounted on the tip of the scope and passed down into the stomach to the level of the fistula. The targeted site of the fistula was grasped with the tissue anchoring tripod and pulled into the cap with concomitant scope channel suction. Once the tissue was trapped in the cap, the Bear claw was deployed.

Repeat endoscopy was performed after 3 months and the fistula site was successfully healed.

Case 2

37 year old female with past medical history of diverticulosis presents with passage of feculent material from her vaginal canal and recurrent urinary tract infections.

CT scan demonstrated a fistula between the sigmoid colon and vagina

Sunsequently an OTSC bear claw was considered for the closure of the fistula. CT imaging of pelvis demonstrate a

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sigmoid colon fistula communicating with the vagina. Careful examination upto the splenic flexure was performed with cap fitted gastroscope. Despite of careful withdrawal, no fistula could be identified.

With prior cervical exam, it was evident that the fistula had an opening in the posterior fornix.

Second gastroscope was introduced towards posterior cervix. A wire guide was introduced into the posterior fornix followed by catheter.

The gastroscope with fitted cap was reintroduced into the sigmoid colon and methylene blue dye was injected through the vaginal catheter.

After several injections, a small area where the dye was coming from was isolated. .

This slide demonstate the fluoroscopic image of the concurrent sigmoidoscopy and colposcopy with the guide wire in the fistula.

The area was marked with an India ink tattoo and just above the area a biopsy was taken also to mark the spot.

An atraumatic bear claw clip on a 17.5 mm cap was attached to the scope and the scope advanced to the marked site.

The tissue was then aspirated into the cap without a retracting device and the bear claw deployed with good entrapment of the identified area.

Patient was symptom free was few weeks but with recurrent complaints, she was sent for surgery. She was found to have abscess communicating with the colovaginal fistula leading to inability to fistula repair after bear claw placement.

Case 3

41 year old female s/p colonic interposition for lye ingestion and PEG tube placement. After 2 months, patient was able to tolerate PO intake. The PEG tube was removed but the gastrostomy tract persisted for several months. Conventional methods of closure were unsuccessful.

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Gastroscopy was carried. The foley catheter was aspirated to collapse the retention balloon and the catheter removed. The fistulous tract had some exudate at the gastric orifice. The OTSC bear claw adapter and clip were advanced to the fistula. The tissue anchor was inserted three times into the tract to attempt to draw the margins of the tract into the cap along with suction. The Bear claw was released when maximum tissue was pulled into the cap.

The patient started having secretions from the gastrostomy site after few weeks. The theory for the failure of this gastrocutaneous fistula was hypothesized to the size of the fistula diameter which was approximately greater than 1 cm.

Conclusion These videos clearly demonstrate the technique of using the over the scope clip for closure of various fistulas. The size of the fistula greater than 1 cm in diameter might not result in the healing of the fistula due to the inability to hold the tissue for entrapment.

Conflict of interest

Truptesh H. Kothari has no conflict of interest and Dr. Gregory Haber is a consultant for Ovesco.

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