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A newly designed over-the-scope-clip device to prevent fully covered metal stents migration: A pilot study

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ABSTRACT

Background: Fully covered self-expandable metal stents (FCSEMS) have increasingly been used in the endoscopic management of malignant and benign gastrointestinal diseases.
The main limitation of FCSEMS is the risk of migration, occurring in at least one-third of patients.
Different methods have been employed for anchorage of esophageal stent, as external fixation with endoscopic snare and internal fixation using both through-the-scope (TTS) and over-the scope (OTS) clips to fix the upper flared end of the FCSEMS to the esophageal mucosa.
A new designed over-the-scope device called Stentfix OTSC® System (AG-Tuebingen– Germany), has been developed to avoid migration. It consists in a Nitinol clip preloaded on the applicator cap used to clip the flared end of FCSEMS to the gastrointestinal mucosal layer
Aims: To evaluate the clinical outcomes of patients treated with Stentfix device.
Methods: Five consecutive patients (median age: 58 years; males, 80%) were enrolled. All patients had experienced FCSEMS migration. The OTSC device was placed to prevent further stent migration.
Results: Technical and clinical success was achieved in all patients. In one patient with a benign rectal anastomotic stricture long-term luminal patency was achieved after stent placement. One patient died of causes unrelated to endoscopic procedures.
The other patients are still being followed. Dysphagia improvement of at least 1 point was seen in these patients.
Conclusions: The StentfixOTSC® System appears to be a useful and safe device in the preventing FCSEMS migration in a variety of clinical scenarios.

1. Introduction

Fully covered self-expandable metal stents (FCSEMS) have increasingly been used in the endoscopic management of malignant and benign gastrointestinal diseases.

The main limitation of FCSEMS is migration, occurring in at least one-third of patients and requiring endoscopic re-interventions with additional costs, and increased risk of adverse events related to endoscopic procedures [1–4].

Stent migration occurs more often in the absence of luminal obstruction and when stents are placed across the gastroesophageal junction [5].

Different methods have been employed for anchorage of esophageal stents, such as external fixation with an endoscopic snare, which is poorly tolerated. Internal fixation can be achieved using both through-the-scope (TTS) and over-the-scope (OTS) clips to fix the upper flared end of the FCSEMS to the esophageal mucosa [6–8].

A recent systematic review and meta-analysis by Law et al. including14 studies, demonstrated a high rate of technical success (96.7%) with a low rate of serious adverse events (3.7%) when an endoscopic full-thickness suturing device (OverStitch, Apollo Endosurgery, Austin, TX) was used to affix esophageal FCSEMS. However, migration still occurred in 1 out of 6 cases [9].

Abbreviations: FCSEMS, Fully covered self-expandable metal stents; TTS, through-the-scope; OTS, over-the scope; OTSC, over-the-scope clip; FTRD, Full Thickness Resection Device; PEG, percutaneous endoscopic gastrostomy

Conflicts of interest: Todd H Baron is consultant and speaker for BSCI, Cook, ConMed, Olympus and W.L. Gore.
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A newly designed over-the-scope device (StentfixOTSC® System, AG-Tuebingen– Germany), has been specially developed to prevent stent migration. It consists of a Nitinol clip preloaded on an applicator cap to clip the flared end of FCSEMS to the gastrointestinal wall.

We present our experience with this new over-the-scope clip (OTSC) device in the prevention of stent migration.

2. Patients and methods

Between December 2018 and April 2019, 5 consecutive patients (4 males, 80%) were enrolled in this study. All patients had experienced FCSEMS migration. The OTSC device was used to fixate the stent to prevent further migration. All patients were considered unfit for surgery.

The study was approved by the local ethics committees and each patient gave written informed consent before the endoscopic procedure. The device manufacturer did not provide any support to the study.

The characteristics of patients enrolled in this study are summarized in Table.

2.1. Device information

The device is mounted onto the tip of an endoscopic instrument in the same manner as other OTSC devices (eg, OTSC Clip, OVESCO and Full Thickness Resection Device—FTRD; Figure 1) [10,11].

The clip is preloaded on the applicator cap in an open state. The newly designed clip consists of shape-memory nitinol alloy, which returns to its initial shape when released from the applicator, with resultant clip closure. The clip is deployed when a wire attached to the clip on one end and a hand wheel on the other end, which is fixed on the endoscope working channel, is pulled.

The rounded design of the clip (fish mouth shape) adapts to the gastrointestinal anatomy (especially the esophagus) without obstructing food passage.

The cap has a depth of 7 mm and an oval shape. This modified cap shape can easily be positioned parallel to the stent opening so that stent mesh and tissue can be evenly captured.

The compact design of the device also allows passage through the stent lumen (minimal diameter of 16 mm); therefore, fixation is possible proximally or distally, or both. Mobilization of the tissue into the cap is possible by grasping tissue at the stent mesh edges.

Clip removal can be achieved using a dedicated system (remOVE DC) consisting of direct current (DC) impulse bipolar generator pulse. This DC pulse is applied on the OTS clip via the DC Cutter instrument introduced trough the working channel of the endoscope, and results in localized melting and cutting of the clip. The clip is grasped with the DC Cutter instrument preferably at the thinnest parts and repeated at a point on the clip opposite to the first cut. Safe extraction is performed using grasping forceps, in combination with a special cap (remOVESecureCap),

In Europe, the StentfixOTSC System and removal kit have a market price of 300€ respectively, while the remOVE DC is provided free of charge by the manufacturer.

2.2. Intervention and follow-up

All procedures were performed by an experienced endoscopist (MC) using deep sedation with propofol administered by an anesthesiologist. Patients were placed in the left lateral position on a radiological table.

SEMS diameters and lengths were selected according to the characteristics of strictures, fistulas and perforations.

After stent placement, its position was endoscopically confirmed followed by fluoroscopic confirmation using water-soluble contrast instilled through the endoscope working channel. This confirmed

Table
Characteristics of patients and outcome.

Case no., age (y)/sex	Indication	Location	Prior stent placed (body, length, upper flare)	Final stent placed (body, length, upper flare)	Number of stentfix/side	Immediate technical success	Fixation-related AEs	Stent migration	Stent and stentfix dwell time (days)
1, 87/M	Perforation Postdilatation for achalasia	Distal esophagus	FCSEMS Taewoong - Double Type Esophageal stent 22 × 100 × 30 mm	FCSEMS Taewoong - Niti-S Beta™ Esophageal stent 22 × 120 × 30 mm	1 proximal end	Yes	No	No	60
2, 53/M	Tracheoesophageal fistula	Cervical esophagus	FCSEMS Taewoong – Conio™ Esophageal Stent 16 × 100 × 18 mm	FCSEMS Taewoong - Conio™ Esophageal Stent 16 × 100 × 18 mm	2 (1 at proximal end and 1 at distal end)	Yes	No	No	150
3, 58/M	Post RTCHT Broncho-esophageal fistula in advanced lung cancer	Medium esophagus	FCSEMS Taewoong Niti-S Beta™ Esophageal Stent 22 × 120 × 30 mm	FCSEMS Taewoong - Niti-S Beta™ Esophageal Stent 22 × 120 × 30 mm	1 proximal end	Yes	No	No	90
4, 58/M	Stenotic adenocarcinoma	Esophagogastric junction	FCSEMS Taewoong-Niti-S Beta™ Esophageal stent 22 × 80 × 30 mm	FCSEMS Taewoong - Niti S Double type Esophageal stent 20 × 100 × 28 mm	2 proximal end	Yes	No	No	105
5, 77/F	Anastomotic stricture after surgery for rectal cancer	Distal Rectum	FCSEMS Taewoong-Niti-S Beta™ Esophageal stent 22 × 80 × 30 mm	FCSEMS Taewoong - Niti-S Enteral Stent 24 × 100 × 32 mm	1 distal end	Yes	No	No	7

Abbreviations: no, number; M, male; F, female; RT, radiotherapy; RTCHT, radiotherapy/chemotherapy; AEs, adverse events.

Fig. 1. Stentfix OTSC System (AG-Tuebingen– Germany): The clip OTSC preloaded on the applicator cap in an open state.

stent location and fistula/perforation exclusion. The endoscope was withdrawn and the clip device was mounted onto the tip of the endoscope as previously described; clip tooth rows were aligned parallel to the stent opening so that esophageal or rectal mucosae and stent mesh were evenly captured. When distal stent fixation was performed, mobilization of tissue into the cap was performed by grasping below the stent mesh. The clip was released at the proximal or distal edge of the stent (or both) according to placement into the esophagus or rectum, respectively. Optimal adaptation of the clip to the wall was achieved in all patients.

A second contrast fluoroscopic examination was performed immediately after clip placement to verify the absence of perforation or stent dislocation.

In patients who underwent esophageal stent placement, a contrast esophagram was obtained 24 hours later to verify position and degree of expansion; other clinical and radiological studies were scheduled after one week and monthly thereafter. The one patient with a rectal anastomotic stricture underwent endoscopy 24 hours and 1 week later.

A liquid diet was initiated on the first day after stent placement, then progressively advanced as tolerated. Antibiotics were administrated after the procedure in patients with fistulas or leaks. In all patients with esophageal indications a proton pump inhibitor was administered orally (pantoprazole, 40 mg/d).

Opioid analgesic drugs were administered for 24 hours if severe pain or foreign body sensation occurred.

2.3. Definitions

Stent migration was defined as stent misplacement at X-ray or endoscopy.

Clinical success was defined as a dysphagia improvement of at least 1 point on the Ogilvie & Atkinson score [12] for patients in whom esophageal or esophagogastric junction stents were placed, and as the absence of obstructive symptoms in the patient with a rectal anastomotic stricture.

The duration of stent placement was calculated from the time of stent placement to the time of stent removal or migration.

Technical success was the ability to fixate the FCSEMS to the esophageal/rectal wall for at least 1 week.

3. Results

The results are summarized in Table.

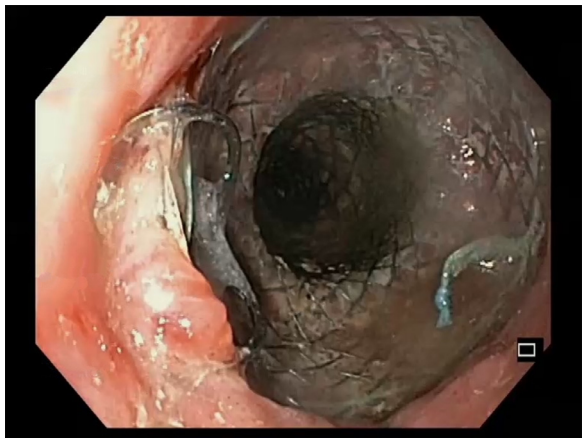

Fig. 2. Endoscopic image of Stentfix OTSC clipping stent mesh and tissue.

3.1. Case 1

An 87-year-old man with type II achalasia experienced an esophageal perforation following 30 mm pneumatic balloon dilation. An OTSC (OVESCO, Ovesco™ Endoscopy AG, Tubingen, Germany) and a 22 × 100 mm FCSEMS were placed to seal the large perforation. The patient underwent drainage of pleural and mediastinal fluid along with continued antibiotic therapy.

Stent migration occurred 6 days later. A second 22 × 120 mm FCSEMS was placed and was fixed to the esophageal wall to prevent stent migration using the new clip device (Figure 2).

Esophagography 24 hours after confirmed complete sealing of the perforation. The patient's clinical course improved and he was discharged home 20 days later. Radiological study 1 month later showed that the stent in good position. The patient was free of dysphagia

He died 2 months later from unrelated causes without clinical signs of stent migration or occlusion.

3.2. Case 2

A 53-year-old man with indwelling percutaneous endoscopic gastrostomy (PEG) and tracheostomy developed severe dysphagia due to a complex hypopharyngeal stricture one year after pharyngolaryngectomy and adjuvant radiotherapy for locally advanced pharyngeal squamous cell carcinoma. A tracheoesophageal fistula occurred after multiple mechanical and balloon dilation sessions. A 16 mm fully covered stent was placed. Two weeks later the patient presented with complete dysphagia.

Endoscopy again showed a tight hypopharyngeal stricture. A small caliber gastroscope was introduced through the tracheostomy and reconfirmed the tracheoesophageal fistula and distally migrated stent.

Another 16 mm FCSEMS was placed to cover the fistula and restore the esophageal lumen. To prevent further migration, 2 Stentfix clips were placed (one proximally approximatively at 15 cm from the dental arch, 3 cm distal to the upper esophageal sphincter, one distally at 25 cm from the dental arch) to secure both flared ends of the stent to the esophageal wall (Video 1).

To treat the hypopharyngeal stenosis, a second similar stent was placed and its distal edge rested on the proximal stentfix clip to prevent migration. Contrast fluoroscopy confirmed sealing of the. Esophagogram performed 24 hours, 1 week, and 1 month later showed that the stent remained in good position. The proximal stent was changed every 8 weeks to avoid hyperplastic tissue at the proximal end of the stent. The stent overlapping the fistula was still in place at the last radiological study after 4 months. The patient died for tumor progression five months later and he was able to swallow semiliquid diet.

3.3. Case 3

A 58-year-old man developed a broncho-esophageal fistula after chemoradiation treatment for advanced lung adenocarcinoma treated with FCSEMS placement.

Esophagography 24 hours later showed the stent migrated 2 cm distally.

A standard foreign body forceps was used to reposition the stent and a clip fixation device was used to anchor the proximal flared end of the stent.

Esophagographies performed 1 day, 1 and 2 months later showed the stent remained in position. The patient tolerated a semisolid diet until death due to tumor progression 3 months later.

3.4. Case 4

A 58-year-old man with locally advanced esophagogastric adenocarcinoma and grade 3 dysphagia underwent placement of a 22 mm FCSEMS with antimigration features. Esophagography performed 24 hours later showed stent migration into the stomach.

The stent was easily removed to avoid the risk of small bowel obstruction. It was replaced with another FCSEMS. After 24 hours, the stent had migrated 2 cm distally; it was repositioned by means of a "*rat-toothed*" forceps and fixed to the esophageal wall by placing 2 OTSC devices at its proximal end.

Esophagrams performed after 24 hours and 1 week later and then monthly, showed good stent position. The patient was discharged after 24 hours and he was able to tolerate a semisolid diet during chemotherapy until death from tumor progression 3.5 months later.

3.5. Case 5

A 77-year-old woman developed intestinal obstruction due to an anastomotic stricture after surgery for rectal cancer.

Multiple balloon dilatations failed to restore luminal patency. Under radiological and endoscopic guidance, an 22 mm esophageal FCSEMS with antimigration features was placed; endoscopy performed after 24 hours showed proximal migration of the stent. It was removed and replaced with a 24 mm enteral FCSEMS. The distal end of the stent was fixed to the rectal mucosa by an OTSC device (Video 2).

The stent and the fixation clip were removed 1 week later because of a bleeding due to ulceration at both the proximal and the distal stent edges; the anastomosis was widely patent. The patient remained without obstructive symptoms or bleeding. Repeat endoscopy 1 and 2 months later showed the anastomosis remained patent.

4. Discussion

In this study, we report our experience with the use of a new clip device to prevent stent migration of FCSEMS in 5 patients unfit for surgery.

Technical success was obtained in all patients; clinical success was related to stent function rather than the fixation procedure per se. Long-term patency of the rectal anastomotic stricture was achieved after stent placement and Stentfix OTSC removal in 1 patient. Two patients died after 1 and 3 months, respectively and in each the stent was remained in good position at time of last follow-up.

The remaining patients are still undergoing follow-up. Dysphagia improved at least 1 point on the Ogilvie & Atkinson score in these patients. Median stent and Stentfix dwell time were 90 days (range 7-150).

The aim of FCSEMS anchoring is to keep the stent in place for at least 1 month. The majority of stent migration occurs within the first month after placement [13].

Data regarding stent fixation for the prevention of FCSEMS migration and improvement in clinical outcome have emerged, though there are no comparative studies on the different fixation techniques [6–8,14–17]. Prior stent migration has been considered to be the main risk factor for migration, occurring even after fixation [14].

In a randomized controlled trial, early stent migration did not occur in patients with malignant esophageal strictures when 2 TTS clips were symmetrically placed at the proximal end of the stent for fixation vs 14.6 of migration rate in the control group [6].

Similarly, in a pilot comparative study of stent fixation using TTS clips by Vanbiervliet et al., the migration rate decreased from 34% to 13% in patients treated with placement of FCSEMS for esophageal malignant or benign strictures, fistulas or perforation. The predictive value of absence of migration after clip placement was 87% [7].

Placement of an OTSC has been demonstrated to be safe and effective to secure FCSEMS [8,18].

In a study by Irani et al., a standard OTSC was used to affix SEMS in patients with benign strictures who previously experienced FCSEMS migration; migration occurred in only 2/13 patients and occurred at a mean of 32 days compared with a mean of 3.5 days for prior migration without OTSC [8]. Although traditional OTSC are technically difficult to remove because of overgrowth of granulation tissue, their removal has been reported [8,18].

In last few years, endoscopic suturing has been used to prevent stent migration [9,15–17]. However, in a systematic review and meta-analysis by Law et al., the estimated rate of stent migration was 15.9% when stents were secured using sutures [9].

In a retrospective study comparing 44 patients who had stents secured with endoscopic suturing with 81 patients without stent fixation, stent migration rate was significantly reduced in the suture group (6% vs 33%, $P = 0.03$) with a higher clinical success (60% vs. 38%, $P = 0.03$) for treating the underlying disease for which the stent was placed [15]. Endoscopic suture fixation prevented migration in the majority of patients in whom prior SEMS placement resulted in migration (33% vs 74% for stent placed without suture in the same patients) [16]. Sharaiha et al. reported an overall clinical success of 91.4% in stent anchorage of FCSEMS. Clinical success was based on the etiology requiring stent placement: 93% for perforations, 80% for fistulas, and only 27% for anastomotic leak closure [17].

It has been suggested that endoscopic suture fixation should be performed in all cases of FCSEMS placement, when technically feasible, although this incurs additional procedural costs [9].

Despite the small number of patients in our preliminary study, the results are encouraging using this new device, which is easy to deploy and removable.

To our knowledge, we describe the first case of anchoring a stent to the rectal wall using FCSEMS. FCSEMS can be used for the management of benign refractory colonic obstruction due to diverticular or anastomotic stenosis [19–22].

In this case, stentfix clip removal was easy and safe although it added about €300 to the procedural cost. However, this device can also be used to remove all available OTSC.

In 2 cases, we repositioned (instead of removing and replacing) the previously migrated stents and affixed them to the gastrointestinal wall, which reduced cost, while preventing additional stent migration. To avoid further endoscopic re-intervention, we also preferred to deploy 2 stentfix clips in patients believed to be at greater risk of stent migration, which are stents positioned in the cervical esophagus and across the esophagogastric junction [5,23,24].

The main limitations of this pilot study are its single and referral-center setting and the heterogeneity of patients, stent locations, and types of stents.

In conclusion, the StentfixOTSC system represents an effective, easy to perform, and safe endoscopic technique for endoluminal fixation of FCSEMS; it can be considered as another evolution of the OTSC system. Further experience is necessary to define the effectiveness of this technique to prevent stent migration.

Author contribution

Massimo Conio: conception and design of the study, analysis of the data, critical revision of the article for important intellectual content and final approval of the article.

Maria Flavia Savarese: acquisition of data, critical revision of the article for important intellectual content and final approval of the article.

Todd H Baron: critical revision of the article for important intellectual content and final approval of the article.

Antonella De Ceglie: analysis and interpretation of the data and drafting the article. Final approval of the article.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.tige.2020.05.004.

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