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Newly designed OTS Clip for preventing fully-covered self-expandable metal stent migration in the gastrointestinal tract

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ABSTRACT

Background and study aims Fully-covered self-expandable metal stents (FCSEMS) are frequently used for endoscopic management of gastrointestinal lesions. However, stent migration occurs in up to one-third of patients. Different tools are used to anchor stents to prevent migration. A specifically designed over-the-scope device (Stentfix OTS Clip system) was recently introduced to prevent fully covered SEMS migration in the gastrointestinal tract. The study aimed to evaluate technical success and stent migration rates with the Stentfix device.

Patients and methods Data were collected from consecutive patients at four participating centers who were at high risk of FCSEMS migration and in whom the anchoring system was used to prevent migration.

Results A total of 31 patients were enrolled. Technically successful clip placement was achieved in all cases. At follow-up, the distal part of the device dislocated from the duodenum into the antrum at 3 days in one patient, accounting for a 3.2 % (95 % CI = 0–9.4) rate of stent migration. The underlying lesion being treated healed in all patients, but 10 patients died before stent removal due to neoplastic progression.

Conclusions A dedicated over-the-scope stent fixation device appears to be safe and effective in preventing fully-covered SEMS migration through the gastrointestinal tract.

Introduction

Fully-covered self-expandable metal stents (FCSEMS) are frequently used in clinical practice for treatment of both malignant and benign conditions along the gastrointestinal tract [1]. Although effective, FCSEMS tend to migrate when they fail to imbed in the gastrointestinal wall. Indeed, migration of FCSEMS has been reported in up to 35 % of cases [2, 3]. Consequently, different approaches for anchoring FCSEMS have been

used, including through-the-scope (TTS) and over-the-scope (OTS) clips, as well as endoscopic full-thickness suturing, with variable success [4–6]. A specifically designed over-the-scope fixation device (Stentfix OTS Clip System, AG-Tuebingen Germany) to prevent stent migration has recently been introduced. It consists of a nitinol clip preloaded on an applicator cap to clip the flared end of FCSEMS to the intestinal wall. To our knowledge, only scant data are available on the use of such a device [7, 8]. We report a multicenter experience.

Patients and methods

Patients

The study enrolled consecutive patients treated with FCSEMS for different diseases in the gastrointestinal tract, and the novel OTS Clip device was used to anchor SEMS to the intestinal wall. These included patients with benign diseases at increased risk of migration or with malignant diseases in whom an oncologic (chemotherapy or radiotherapy) therapy was planned. Technical success was defined as successful positioning of the fixation device. 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 an esophageal stent, a proton pump inhibitor was administered orally. Opioid analgesic drugs were administered for 24 hours to manage pain or discomfort. Patients were followed to assess success and delayed adverse events (AEs). Stent migration was documented at X-ray or endoscopy. All patients provided a signed consent for the procedure, and to anonymously use their data for scientific purposes.

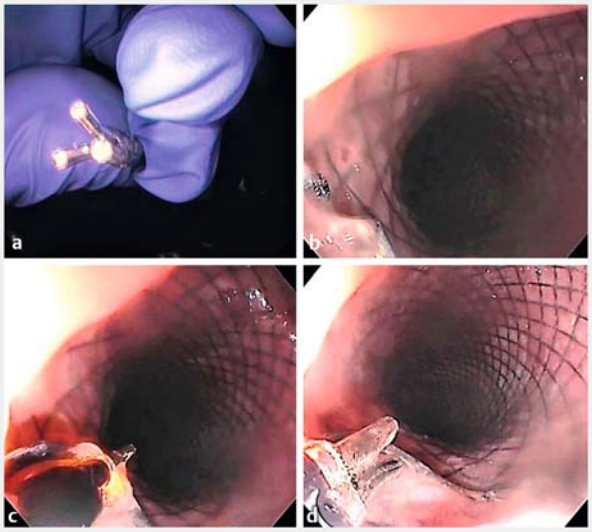
Procedure

All procedures were performed by experienced endoscopists using deep sedation with propofol or general anaesthesia administered by an anesthesiologist. FCSEMS diameters and lengths were selected according to characteristics of strictures, fistulae or perforations. Correct stent placement was verified by fluoroscopic examination. The endoscope was withdrawn and the stent fixation clip device was mounted onto the tip of the endoscope. The proximal edge of the stent was visualized and the clip tooth rows were aligned parallel to the stent opening so that the luminal tissue and stent mesh were evenly captured. The clip was released and a second fluoroscopic examination was performed to reconfirm stent position. For patients who underwent esophageal stent placement, esophagography was obtained the following day to verify position and degree of expansion. Additional esophagrams were scheduled 1 week later and then monthly thereafter. In patients with SEMS placed transrectally, follow-up endoscopy was performed at 24 hours and 7 days following placement.

Device

The Stentfix OTS Clip System (AG-Tuebingen Germany) is a clip mounted in a cap positioned on the tip of endoscope and deployed as other OTS Clip devices (▶ **Fig. 1**). It was specifically designed (fish mouth shape) for anchoring to the gastrointestinal wall 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 using suction at the stent flange, fixing approximately 5 to 6 mm of both stent and bowel wall. The compact design of the device also allows passage through a stent lumen of at least 16-mm diameter. Thus, stent fixation is possible proximally, distally, or both (▶ **Fig. 2**). Clip removal can be achieved using a dedicated system (remOVE DC cutter, OVESCO), which allows the use of direct current (DC) impulse bipolar generator pulse. This DC pulse is applied to the OTS clip via the DC Cutter instrument introduced through the working channel of the endoscope, allowing 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 the first cut. Extraction of the fixation device is performed using grasping forceps, in

▶ **Fig. 1** Stentfix OTS Clip System (AG-Tuebingen Germany). The clip OTS Clip preloaded on the applicator cap in an open state.



▶ **Fig. 2** **a** The device. **b** Positioning of the remOVE DC cutter on the clip bow. **c** Application of the current impulse to cut the clip. **d** The cut clip.

combination with a special cap (remOVESecureCap, OVESCO). Images of this device are shown in ▶ **Fig. 3**.

Results

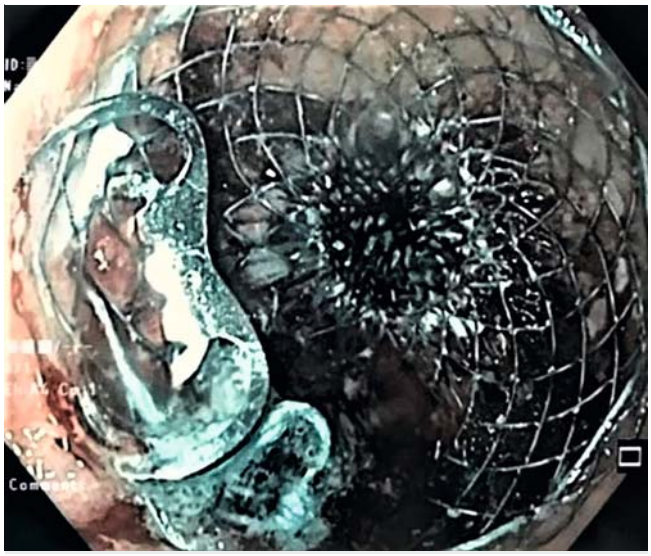
The clinical and demographic characteristics of the 31 treated patients are shown in ▶ **Table 1**. Data were collected from patients treated between December 2019 and April 2021 who consented to undergo the procedure and to publication of their anonymized information. The number of patients enrolled in the four participating centers ranged from five to 12 cases. The stent was positioned in the esophagus (cervical: 7; medium: 7; distal: 5), esophago-gastric (N = 2) and esophago-jejunal (N = 4) anastomosis, antro-duodenal (N = 1), duodenum (N = 2), and across a rectal anastomosis (N = 3). The fixation device was positioned at the index stent placement in 21 patients, and after previous stent migration in the remaining 10. The stent was fixed at the proximal end in 26 patients, at the distal side in four patients with cervical esophagus placement, and both proximal and distal ends in one case in the colon (▶ **Fig. 3**).

Placement of the fixation device was technically successful in all cases (100 %). No AEs were observed. The one migration occurred 3 days after placement in the patient with an antro-duodenal stent, which was fixed at the proximal side, accounting for a 3.2 % (95 %CI 0–9.4) rate of stent migration. This occurred in a patient with abundant ascites due to peritoneal carcinomatosis and the high pressure likely contributed to increase peristalsis. The FCSEMS was removed at various intervals, depending on the underling disease and the general condition of patient (nutritional status, expected prognosis). In detail, it was removed at 16 weeks (1 patient), 12 weeks (10 patients), 8 weeks (5 patients), 6 weeks (1 patient), and 4 weeks (2 patients). Ten patients died before removal, and one case is still being followed up. No late adverse events were observed.

Discussion

SEMS positioning along the gastrointestinal tract is widely performed to endoscopically treat patients with fistula, perforation or stenosis [1–8]. SEMS placement is both technically and clinically successful in a high percentage of cases. Unfortunately, FCSEMS tend to migrate due to lack of embedment, combined with peristalsis. The majority of stent migrations occur within the first month after placement [9], which is generally earlier than necessary to allow healing of underlying lesions. To prevent migration, partially-covered stents can be used as the bare ends anchor the stent by embedding into the tissue. However, their removal can be difficult. Traditional through-the-scope (TTS) clips have been used to anchor FCSEMS. While technically easy to place, the force exerted by these clips is low and they tend to detach quickly and are not effective in preventing migration [4–6]. Endoscopic suture systems have been used, although they are technically more difficult to place and expensive [9].

The OTS stent fixation device is novel and specifically designed for anchoring SEMS to the gastrointestinal wall, although data on its use are scarce [7, 8]. Unlike classical OTS Clip, this device has two grooves in the circumference, which allow a better adherence between the stent and bowel wall, resulting in correct capture of both edges with the clip [7]. We previously reported on the stent fixation device for anchoring FCSEMSs in patients at increased risk of stent migration, due to either position or a prior migration [7]. A high technical success rate was seen in both upper and lower gastrointestinal tracts. This finding was confirmed in the present, large study in which stent migration was observed in only one case (3.2 %). Of note, a recent study found SEMS migration in two of 24 patients (8.3 %) treated with the same fixing device [3]. This compares to the 13 % reported with stent fixation using TTS clips [2], and 6.7 % in a pilot study of naïve patients [10] or 15 % in patients who experienced previous stent migration after use



▶ **Fig. 3** Endoscopic image of Stentfix OTS Clip clipping stent mesh proximally and tissue to anchor a stent to treat an esophago-jejunal anastomotic leak.

▶ **Table 1** Clinical characteristics of patients.

Characteristic	Finding
Male/female	26/5
Mean age ± SD; years	68.6 ± 10.7
Gastrointestinal site	
▪ Upper	28
▪ Lower	3
Indication	
▪ Stricture	14
▪ Fistula	10
▪ Anastomotic leakage	5
▪ Perforation	2

SD, standard deviation.

of a standard OTS Clip [5]. Moreover, a 16 % stent migration rate was observed following endoscopic suturing [6], and in as many as 35 % of cases without any fixing procedure [2, 3]. Data from a small cases series showed that stent fixing was successfully performed in patients with esophageal neoplastic stenosis by using classical OTS Clip for anchoring the SEMSs [11]. However, in as many as 11 patients either partially-covered or long covered SEMS were anchored, while a fully-covered stent was fixed in only one patient. Anchoring a fully-covered stent – as we used in our case series – with classical OTS Clip might be more difficult than using the novel device. Of note, data from an experimental study showed that OTS Clip compression was significantly stronger as compared with either TTS clip and suturing system [12].

The main limitation of our study was the lack of a comparator group. However, when considering the very low migration rate observed by using this system, we believe there is an advantage over other fixation devices.

Conclusions

In conclusion, this novel stent fixation device seems to be a safe and effective endoscopic tool for anchoring FCSEMS.

Competing interests

The authors declare that they have no conflict of interest.

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