Surgical Endoscopy (2022) 36:2290–2299
https://doi.org/10.1007/s00464-021-08504-z

A new designed self-expandable metal stent for the management of benign radiotherapy-induced hypopharyngeal or cervical esophageal strictures

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Received: 29 August 2020 / Accepted: 7 April 2021 / Published online: 26 April 2021

Abstract

Background and aims The management of patients with hypopharyngeal or cervical esophageal refractory benign strictures (RBS) after surgery and radiotherapy ± chemotherapy for laryngeal cancer is challenging. We aimed to assess the long-term efficacy and safety of a new designed fully covered SEMS in these patients.

Methods We reviewed the results of a prospectively collected database of 40 consecutive patients with dysphagia due to RBS of the cervical esophagus or hypopharynx after surgery and radiotherapy with or without chemotherapy for laryngeal cancer, unfit for surgery, referred in two tertiary-care endoscopic centers from June 2005 to December 2018. All of them were treated with placement of a Niti-S Conio cervical stent.

Results After placement of the first stent, dysphagia improved in all patients. The total number of adverse events was 35 out of a total of 299 procedures (11.7%): 25 (8.4%) stent migrations, 6 (2%) tumor overgrowth, 3 severe pain and 1 pharyngo-cutaneous fistula. Stents were periodically changed. In only one patient with a cervical esophageal stricture the stent was definitively removed after 7 sessions of stent placement because of stricture resolution. Patients were followed-up for a median of 11.6 months and a significant improvement in dysphagia was reported in all patients ($p < 0.001$).

Conclusions The use of this conformable, small caliber new designed Niti-S stent, exchanged periodically, appeared safe and permitted durable oral intake in patients with difficult-to-treat hypopharyngeal or cervical esophagus strictures, avoiding the need for periodic dilations.

Keywords Hypopharynx · Esophagus · Refractory benign strictures · Cervical stent

Pharyngo-esophageal strictures are common in patients having undergone surgery combined with radiation therapy (RT) with or without chemotherapy (CT), for advanced laryngeal cancers. Up to a quarter of these patients develop strictures causing severe dysphagia with inability to swallow saliva, compromising nutritional status and quality of life [1–3]. Generally, these are complex strictures (longer than 2 cm, angulated, irregular and severely narrowed) becoming refractory to repeated endoscopic dilations.

Several therapeutic options are available for refractory benign esophageal strictures (RBES), but none of them are able to reverse the underlying pathologic process, characterized by extensive fibrosis, involving the submucosa and sometimes even the muscularis propria [4]. Surgical procedures for these strictures could be potentially curative but carry high rates of morbidity/mortality. Moreover, patients with RT-induced RBES are often poor surgical candidates and therefore repeated sessions of balloon or bougie

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dilations are still the gold standard for the management of RBES [5].

Theoretically, temporary placement of a self-expandable metal stent (SEMS) would permit a longer-lasting dilation effect, maintaining luminal patency and simultaneously stretching the stricture, but with the disadvantage of high recurrence rates after stent removal, particularly in patients with cervical stricture longer than 2 cm [6–8]. The long-term clinical success rate of stent placement for RBES therefore remains disappointing, with conflicting data from individual studies, systematic reviews and meta-analyses [9–12].

The European Society of Gastrointestinal Endoscopy (ESGE) clinical guidelines do not recommend long-term SEMS placement for RBES, and if so, suggest its removal after a maximum of 3 months. Alternative treatment strategies such as self-dilation or surgical treatment can be considered if strictures have not satisfactorily improved after two separate treatments with temporary stenting. However, these recommendations are only supported by low-quality evidence from studies in which results were not stratified according to stricture etiology [13].

The aim of this study was to assess the long-term efficacy and safety of a new designed fully covered SEMS in patients with hypopharyngeal or cervical RBES after surgery and RT with or without CT for laryngeal cancer.

Material and methods

We reviewed the results of a prospectively collected database of all consecutive patients referred in two tertiary-care endoscopic centers in the period from June 2005 to December 2018. In total, 40 patients with refractory benign strictures of the cervical esophagus or hypopharynx after surgery and RT, with or without CT, for laryngeal cancer were treated with placement of a new designed fully covered SEMS (FCSEMS). Before stent placement all patients underwent CT scan of the neck and chest in order to exclude the presence of neoplastic disease. When a small caliber endoscope could not be passed thought the stricture, brushing cytology was performed before procedure.

All patients were considered to be poor candidates for surgery after discussion in the multidisciplinary tumor board (MDTB).

The cervical esophagus was defined as the segment between C6 at the pharyngo-esophageal junction (12 cm from the dental arch) and the thoracic inlet of T1 (20 cm from the dental arch). Refractory strictures were defined as those that could not be remediated to a diameter of 14 mm over 5 dilatation sessions at 2 week intervals [14].

Inclusion criteria were age ≥ 18 years; dysphagia score of at least 2 (Appendix A); refractory benign stricture (RBS) of the cervical esophagus or hypopharynx after surgery and RT with or without CT for laryngeal cancer; patients who had received at least 5 dilatation sessions (bougies or balloon-assisted) with dilation up to a maximum diameter of 14 mm; patient capable to provide written informed consent.

Exclusion criteria included dysphagia caused by hypopharyngeal or cervical esophageal cancer or extrinsic compression on the esophageal lumen due to malignancy; severe co-morbidity precluding stent placement.

Written informed consent was obtained from all enrolled patients. The study was approved by the Ethics Committees and was conducted in accordance with the Helsinki declaration. The stent manufacturer did not provide any support to the study.

Device information

The stent used was the Niti-S Conio Esophageal stent (Taewoong Medical Co Ltd/Korea). The stent consists of a body and an upper flared end. The entire surface is composed of two monofilaments of braided nitinol hooks, covered with silicone. The type of weave makes the stent particularly self-conformable to the tortuosity of the lumen. Radiopaque markers are placed at both stent ends and in the middle (Fig. 1). The body diameters of the stents used in the present study were 12, 14, and 16 mm, with

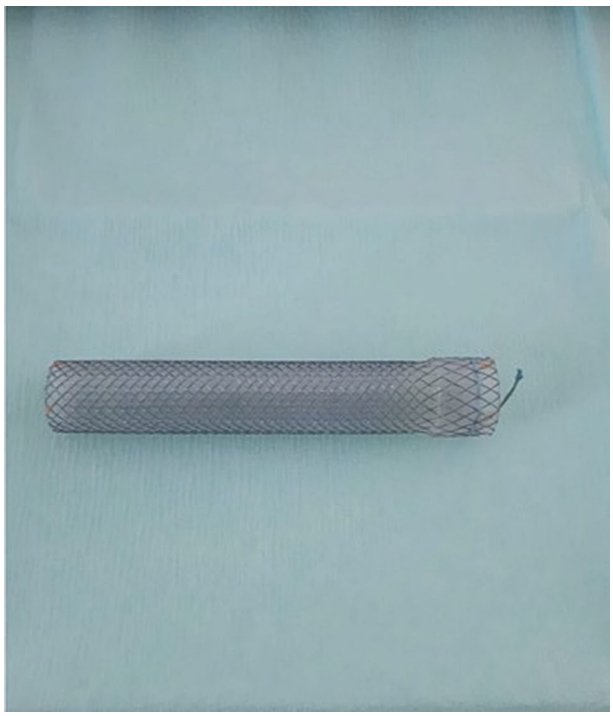

Fig. 1 Niti-S conio esophageal stent

a proximal flare end of 14, 16 and 18 mm, respectively. Total stent lengths were 80, 100, 120 mm. The length of the upper flared end was 10 mm.

Stent insertion

Endoscopic procedures were performed under deep sedation with propofol administered by an anesthesiologist.

Over the Wire (OTW) stents with distal release introducer were used in all patients. Stent diameters and lengths were selected according to the characteristics of the stricture. The length of the stent was determined by the stricture length plus a minimum of 15 mm at each end, except in patients with hypopharyngeal strictures in whom the proximal end was 10 mm longer than the stricture. No dilation was performed at the time of stent placement and the technique of slightly oversizing the stent diameter relative to that of the stricture was used to prevent early migration.

A small caliber (5.9 mm and more recently 5.4 mm) forward-viewing video-endoscope (Olympus Optical Co, Tokyo, Japan) was used and a 0.035-inch hydrophilic guidewire (Tracer Metro Direct-Cook Medical, Winston Salem, NC) was advanced across the stricture.

When the endoscope could not be passed through the stricture, the guidewire was advanced under fluoroscopic guidance. The location of the stricture was defined using the distance from the incisors to the upper margin of the stenosis and subdivided into hypopharynx or cervical esophagus. When feasible, the distal end of the stricture was marked by submucosal injection (Disposable Varices Injector—Cook Medical) of radio-opaque contrast agent into the esophageal wall; when the small caliber endoscope could not be inserted, meglumine diatrizoate (Gastrografin; Bayer Health Care Pakistan (Pvt), Ltd) was injected through the operative channel in order to visualize the distal end of the stricture.

The stent was advanced over the guidewire until it passed the distal end of the stricture, followed by deploying the stent under fluoroscopic and endoscopic guidance to avoid close contact with the upper esophageal sphincter. A "rat-toothed" forceps (Olympus Optical Co) was used, if needed, to reposition or remove the stent. After placement of the stent, contrast fluoroscopy was used to confirm proper stent position. All patients underwent esophagography within 24 h after stent placement to verify position and the degree of expansion of the stent (Fig. 2).

Ingestion of liquid was permitted on the first day. After 24 h, patients were invited to progressively resume a semi-liquid diet. Antibiotics were not administrated before or after the procedure. Opioid analgesic drugs were administered for 24 h when severe pain or foreign body sensation occurred.

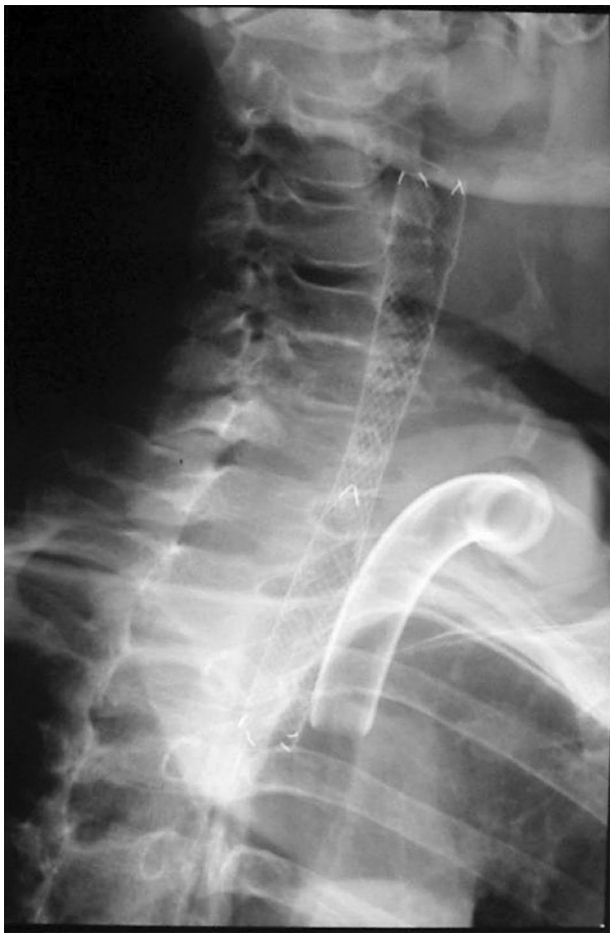

Fig. 2 Niti-S conio esophageal stent released in a patient with benign hypopharyngeal stricture

Definition of events

Technical success was defined as deployment of the stent across the stricture with patency visualized both endoscopically and fluoroscopically.

Clinical success was defined as dysphagia improvement of at least 1 point on the Ogilvie and Atkinson score [14]. Dysphagia scores were assessed before stent placement and at 1, 4 and 8 weeks after stent placement. Stent dysfunction was defined as stent occlusion and stent migration, causing recurrent dysphagia, with stent migration objectified by fluoroscopy and/or endoscopy. Persistent improvement was defined as no stricture recurrence during follow-up.

Adverse events (AEs) were classified as immediate (< 24 h), early (within 7 days) or delayed (after 7 days) following stent placement. Severe AEs (SAEs) were defined as those resulting in hospital stay (≥ 1 day) or requiring an endoscopic and/or surgical procedure and included perforation, hemorrhage, and fistula formation [15].

Immediate and early SAEs included bleeding, perforations, pain, foreign body sensation, recurrence of dysphagia due to stent malposition/migration, while late SAEs were bleeding, perforation, fistula formation, dysphagia due to stent migration or overgrowth, pain, foreign body sensation. Pain was measured by an objective visual analogue pain scale and analgesic use [16].

Follow-up

Patients were evaluated clinically after 1, 4 and 8 weeks following stent placement. Dysphagia, pain, foreign body sensation or any other symptom potentially related to the stent were assessed and ECOG scores (Appendix B) were calculated [17].

Elective endoscopic removal of the stent was scheduled at 8 weeks after placement and it was considered whether additional stent placement with similar or larger diameters was indicated. Each time, stent with different length from the previous one was placed to avoid that its end was placed in the same site of previous stent end, so avoiding hyperplastic epithelium growth. If dysphagia recurred before 8 weeks endoscopy was performed.

Patients with severe underlying diseases, and inability to return to the hospital were similarly evaluated by monthly telephone calls until death. Loss to follow-up was considered when patient contact could not be obtained within 3 months after stent placement.

Outcomes and data collection

The primary outcome was the efficacy of stent placement in improvement of dysphagia. Secondary outcomes were stent safety, measured as stent-related AEs (for details see above) and recurrent dysphagia due to stent dysfunction (stent migration and stent occlusion). Data collection is summarized in Appendix C.

Statistical analysis

Data were summarized as median (range) for continuous variables and number (%) for categorical variables. Difference in dysphagia score at different times was compared by means of Wilcoxon test for related samples. The Kaplan Meier method was used to estimate overall survival (OS) defined as the time in months until death from any cause and or last follow-up. Patients still alive were censored at the date of last follow-up or date last known to be alive.

Statistical calculations were performed using the SPSS statistical package version 23. A two sided p value of < 0.05 was considered as statistically significant.

Results

General characteristics

Eight patients (20%) underwent percutaneous endoscopic gastrostomy (PEG) placement 1 to 13 months before stenting (median 6.1 months) and 4 patients had a nasogastric feeding tube (10%). Before stent placement, patients underwent periodic dilation sessions: 37 patients (92.5%) with bougie dilator (7 of them were also treated with balloon dilations) and 3 patients with balloon dilations only. The median number of dilations was 6 dilations (range 5–8) performed every two weeks. Median dilator diameter was 12.8 mm (range 9–14 mm) as in the majority of patients the severely narrowed stenosis prevented to reach a diameter of 14 mm.

At the time of SEMS placement, dysphagia was graded as grade 3 and 4 in 17 (42.5%) and 23 (57.5%) patients, respectively.

In Table 1 the patients' characteristics are summarized.

Stent insertion and complications

Passage of a small caliber endoscope through the stricture was possible in 18 patients (45%); in the other cases the guidewire was advanced under fluoroscopic guidance.

Location of the stenosis was the esophageal cervical segment in 25 cases and hypopharynx in 15 cases. Median stricture length was 4 cm (range, 3–5 cm). RT or RT ± CT

Table 1 Characteristics of patients at stent placement

	N (%)
Total	40
Sex	
Male	31 (77.5)
Female	9 (22.5)
Age, median (range)	68.5 (43–86)
Tumor location	
Cervical segment	25 (62.5)
Hypopharynx	15 (37.5)
Presence of trachea-esophageal fistula	2 (5.0)
Dysphagia score at enrollment	
3	17 (42.5)
4	23 (57.50)
Length of stricture, median (range), cm	4 (3–5)
Cause of stenosis	
Laryngectomy + RT ± CT	40 (100.0)
PEG	8 (20)
Naso-gastric feeding tube	4 (10)
Total number of stents	291
Number of stents per patient, median (range)	4 (2–46)

Table 2 Stents inserted during the follow-up and complications

Stents	Patients (*N*)	Time from previous stent, days median (range)	Stent characteristics, mm median (range)	Adverse effect (*N* patients)
2nd	40 (100%)	62.5 (3–102)	Diameter 14 (12–16) Length 100 (80–120) Proximal diameter 16 (12–18)	Migration: 5 overgrowth: 2
3rd	38 (95%)	63 (12–428)	Diameter 14 (12–16) Length 80 (80–120) Proximal diameter 16 (14–18)	–
4th	28 (70%)	63 (54–232)	Diameter 14 (12–16) Length 100 (80–120) Proximal diameter 16 (12–18)	Overgrowth: 1 (no dysphagia)
5th	15 (37%)	63 (27–603)	Diameter 16 (12–16) Length 100 (80–120) Proximal diameter 18 (14–18)	Migration: 2 (one with total dysphagia*) overgrowth: 2
> 6th	9 (22%)	6 to 46 stents positioned every 8 weeks	Diameter 16 (12–16) Length 100 (80–120) Proximal diameter 18 (14–18)	Migration: 3 ** pharyngo-cutaneous fistula: 1***

*Patient with concomitant tracheo-esophageal fistula and hypopharyngeal stricture

**In one of these patients, having a trachea-esophageal fistula following Ella stent placement, migration of two stents occurred within a week after each stent placement

He was treated with a Montgomery® Salivary Bypass Tube placement in hypopharynx

***The patient was treated with a Montgomery® Salivary Bypass Tube placement in hypopharynx

was performed 2.13 to 80.2 months before occurrence of dysphagia (median time 6.9 months). All patients had previous laryngectomy; two patients also had pharyngectomy or semi-pharyngectomy, respectively.

The RBES was associated with a tracheoesophageal fistula in two patients: the first patient had a hypopharyngeal stricture one year after pharyngolaryngectomy with fasciocutaneous free-flap repair and adjuvant radiotherapy for locally advanced pharyngeal squamous cell carcinoma. The fistula occurred after multiple mechanical and pneumatic dilation sessions (maximum diameter of dilation: 14 mm) and was treated with the placement of 16 × 100 × 18mm FCSEMS. The second patient had a refractory hypopharyngeal stricture following surgery and radiotherapy for laryngeal cancer, previously treated with placement of a 23 mm biodegradable (BD) Ella stent (SX-ELLA; Ella-CS, Hradec Králové, Czech Republic). The fistula occurred 2 weeks later, with protrusion of the distal end of stent into the trachea.

Median length and body diameter of inserted stents were 80 mm (range 80–120 mm) and 12 mm (range 12–16 mm), respectively. The patient with tracheo-esophageal fistula following BD stent placement was treated by placing two stents: a 16 × 18 × 100mm FC Conio Cervical Stent to cover the fistula and restoring the esophageal lumen, and a second similar stent, with its proximal end in the hypopharynx, where there was a 30 mm stricture. The stent occluding the tracheo-esophageal fistula was exchanged every 12 months due to the disruption of the covering; the hypopharyngeal stent was scheduled to be changed every 2 months.

Stent insertion was successful during the first endoscopic session in all patients (100%). Severe, immediate pain occurred in 3 patients (7.5%, all with cervical strictures) controlled in two patients by opioid analgesia and in one patient with stent removal and placement of a new, smaller diameter stent placed 21 days later.

Barium swallow within 24 h showed a 2 cm distally migrated stent in one patient and proximal migration in another patient: both stents were repositioned with proximal and distal traction using *rat-toothed* forceps, respectively.

Early stent migration occurred in 3 patients (7.5%; 2 with hypopharyngeal stenosis): in one the stent was repositioned with proximal traction after 24 h; in 2 other patients (both having a tracheoesophageal fistula), the stents were replaced after 3 and 5 days with 2 mm larger diameter stents. Late migration was observed after a median of 47 days (range 21–60) in 10 patients (25%), eight with hypopharyngeal strictures; in two dysphagia recurred 2 days before the scheduled procedure. Hyperplastic overgrowth at the proximal end of the stent was found in one patient who did not report worsening of dysphagia.

In Table 2 the number of stents inserted during the follow-up and complications are reported.

Overall, the number of stents placed ranged from 2 to 46 (median of 4 stents), with a median of 5 procedures (stent placement and/or traction) performed in each patient (range 2–46) in a time frame of 5 to 95 months.

The total number of AEs was 35 of a total of 299 procedures (11.7%); 25 (8.4%) stent migrations, 6 (2%) tumor overgrowth, 3 severe pain and 1 pharyngo-cutaneous fistula (Table 3).

Stents were periodically changed with a maximum of 46 stents placed in one patient. In only one patient with a cervical esophageal stricture the stent was definitively removed after 7 sessions of stent placement because of stricture resolution.

Patients with fistula

In detail, the patient with the concomitant tracheo-esophageal fistula after multiple dilations had total dysphagia two weeks after placement of the fifth hypopharyngeal stent, due to migration. Endoscopy detected a tight hypopharyngeal stricture after stent migration. A 5.4 mm caliber gastroscope was introduced through the tracheostomy and confirmed the tracheo-esophageal fistula (Fig. 3A) and the distally migrated stent. Another 16 mm FCSEMS was placed to cover the fistula and restore the esophageal lumen. To prevent migration, two over-the-scope clips (Stentfix OTSC® System, AG-Tuebingen, Germany) were placed (one proximal, one distal) to secure both flared ends of the stent to the esophageal wall. A second similar stent was placed to treat the hypopharyngeal stenosis, proximal to the previous stent (Fig. 3B). Contrast fluoroscopy confirmed fistula sealing. Esophagogram performed 24 h, 1 week, and 1 month later showed no stent migration. The proximal stent was changed 8 weeks later to avoid hyperplastic tissue at the proximal end of the stent. The stent overlapping the fistula was still in place when the patient died five months later due to tumor progression.After the sixth stent placement, distal migration of two stents occurred within a week after each stent placement (two attempts) in the patient with a trachea-esophageal fistula following Ella stent placement, as the distal part of the FCSEMS at hypopharynx was inside the previously placed covered stent. The proximal stent was removed, and a 14 mm Montgomery® Salivary Bypass Tube (Boston Medical Products Inc.) was placed. It was well tolerated as the diameter of the proximal end conformed to the anatomy.

Another Montgomery type stent was placed in a patient previously treated by multiple dilations who developed a pharyngo-cutaneous fistula after the sixth stent placement.

Table 3 Outcome in patients included in the study

	N (%)
Patients with adverse event with 1th stent	
Immediate (< 24 h)	5 (12.5)
Migration	2 (5.0)
Severe Pain	3 (7.5)
Early (≤ 7 days)	3 (7.5)
Migration	3 (7.5)
Late (> 7 days)	11 (27.5)
Migration	10 (25.0)
Overgrowth	1 (2.5)
Patients with migrations after the 2nd stent	8 (20%)
Adverse events/total patients	35/40 (87.5%)
Migration	25/40 (62.5%)
Pain	3/40 (7.5%)
Overgrowth	6/40 (15.0%)
Pharyngo-cutaneous fistula	1/40 (2.5%)
Patients with adverse events/total patients	24/40 (60.0)
Migration	19/40 (47.5)
Pain	3/40 (7.5)
Overgrowth	6/40 (15.0)
Pharyngo-cutaneous fistula	1/40 (2.5)
Adverse events/total procedures	35/299 (11.7%)
Adverse events/total stents	35/291 (12.2%)
Migration	25/291 (8.5%)
Pain	3/291 (1.0%)
Overgrowth	6/291 (2.0%)
Pharyngo-cutaneous fistula	1/291 (0.3%)
Total migrations/total procedures	25/299 (8.4%)
Total follow-up, median months (range)	11.6 (1.2–112.1)
Dysphagia score at the end of follow-up	
Median (range)	2 (0–4)
0	2 (5.0)
1	14 (35.0)
2	23 (57.5)
4	1 (2.5)
Survival, months (median, 95%CI)	11.2 (8.7–13.8)
Dead	37 (92.5)
Cause of death	
Tumor progression (metastatic disease)	3 (7.5)
Comorbidities	34 (85.0)

Outcome and survival

Patients were followed-up for a median of 11.6 months (4.2 to 112.1 months). At the end of follow-up median dysphagia score was 2 (range 0–4). Persistent improvement of stenosis was observed in one patient (2.5%) and a significant

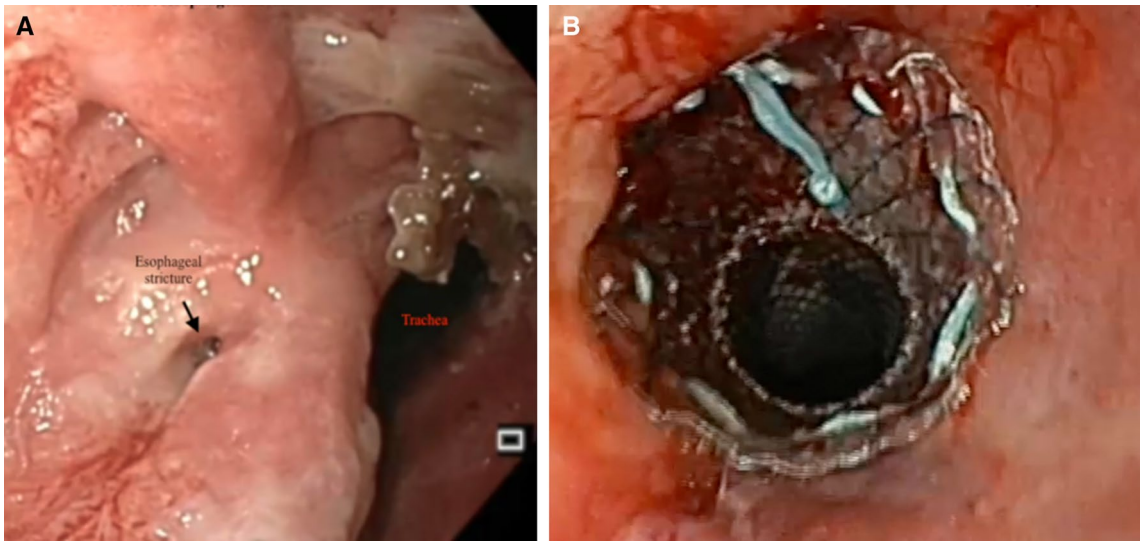

Fig. 3 **A** Endoscopic image of tracheo-esophageal fistula and benign hypopharyngeal stenosis. **B** Endoscopic image of Niti-S conio esophageal stent after its release

Table 4 Dysphagia scores at follow-up according to score before treatment with esophageal stents (baseline)

Score at baseline	Score at the end of follow-up *N* of patients				Total
	0	1	2	4	
3	2	7	8	0	17
4	–	7	15	1	23

improvement in dysphagia was reported in all patients ($p < 0.001$). Table 4 shows the dysphagia scores before treatment (baseline) and at the end of follow-up.

During follow-up, no pain or foreign body sensation or food impaction was reported. At the end of follow-up, median ECOG performance status was 3. Weight and albumin serum level improved in all patients.

Thirty-seven patients (92.5%) died from metastatic disease (8%) or comorbidities (92%). Median survival was 11.2 months (95%CI: 8.7–13.8 months).

Discussion

The management of patients with hypopharyngeal or cervical RBS after surgery and RT with or without CT for laryngeal cancer is challenging. Long-term outcomes of endoscopic treatment in these patients are poor, with no patients achieving complete resolution of dysphagia but requiring continuous endoscopic treatments.

Repici et al. reported lower odds of clinical resolution of dysphagia in patients with cervical strictures treated with dilations or with dilations plus stent placement when compared with middle or lower esophagus stenosis [18].

In our study, a significant long-term improvement of dysphagia was obtained in all patients, although stricture improvement was not observed in almost all patients (97.5%) during follow-up. AEs were reported in 11.7% of cases, when the total number of endoscopic procedures were considered. Migration was the most frequently SAE observed, and occurred in 47.5% of patients; however, when the total number of stents placed was considered, migration occurred in 8.5% of cases.

Few experiences in a small number of patients (ranging from 1 to 17) treated with self-expandable plastic stent (SEPS) or SEMS for pharyngoesophageal strictures after surgery and RT with or without CT for laryngeal cancer have been reported [19–23]. We previously published a case series including 7 different patients with hypopharyngeal strictures treated with the same Niti-S Conio Cervical stent, with dysphagia score improvement from 4 to 2, avoiding the need for feeding tubes and periodic bougienage [23]. In the present study, we considered only patients with complex esophageal strictures (37.5% involving the hypopharynx) following surgery and RT for laryngeal cancer, in whom it was possible to obtain a long-lasting dysphagia improvement using small caliber FCSEMS, with periodically changing stents to minimize risks of AEs.

These stents are unique because of their small diameters and proximal flare 2 mm larger than the body allowing complete expansion in the hypopharynx. In addition, their main feature is conformability that allowed better adaptation to the morphology of the stenosis without reducing either the length or the radial expansion force.

The stent cover prevents growth of granulation tissue and allows periodic safe stent removal. The choice of stent is essential because standard available stents have a relatively large diameter being designed for malignant esophageal strictures, leading to incomplete expansion in the hypopharynx and resulting in foreign body sensation and increasing the risk of adverse events. In particular, in patients with cervical RT-induced strictures, stent pressure against the esophageal wall affected by previous RT may result in perforation and esophago-respiratory fistula, especially when relatively large-sized stents exerting a high radial force are used [24]. Moreover, in patients with laryngectomy, the pressure of a large diameter stent against the endotracheal cannula could increase the risk of fistula formation [25].

Better results with small diameter stents, have also been described by Pang et al. who reported tolerance and improvement of dysphagia when fully covered biliary (10 mm in diameter) SEMS or narrow diameter (14, 16, 18 mm in diameter) esophageal SEMS were used in proximal esophageal lesions located within 18 cm of the incisors and 18–22 cm from incisors, respectively, when optimal stent-to-mucosal apposition was achieved [26].

Bechtler et al. reported a high clinical success rate and good tolerability using 10 mm biliary metal stents in upper esophagus in 10 patients [27]. However, when SEMS having a diameter $\leq$ 10 mm, a downside is the ability to intake only liquid diet.

In our study, the smallest body size used was 12 mm, and all patients were able to resume a semiliquid diet.

The maximum body stent size was 16 mm; the smaller diameter and shape of these stents explains the different results compared to those reported by Poincloux et al. who used a stent with an 18 mm body, 26 mm flare length with a 15 mm flare length and a shorter proximal head (5 mm height vs 15 mm of other stents). The stents were well tolerated in malignant and benign diseases, however, a five-fold increased risk of major complications was observed in the benign stenosis group.

Although the risk of migration is theoretically high when small size FCSEMS are used, their better adaptability to the morphology of complex strictures might explain why FCSEMS were more likely to result in clinically relevant migration when large diameters and/or length > 100 mm stents were used [28].

We observed an 8.5% rate of migration *vs* a 28% overall stent migration rate reported by Fuccio et al. [12] and 18% reported by Thomas et al. [19] for proximal esophagus stent placement. This low rate of migrations was probably also seen because the stent was exchanged every 8 weeks. In two patients, stent migration occurred more than once and all in presence of hypopharyngeal stenosis.

A modified Montgomery stent was used as temporary treatment in one patient in which migration repeatedly occurred even when a 2 mm larger diameter stent was placed into the hypopharynx and in another patient affected by a pharyngo-cutaneous fistula following dilation.

Optimal stent dwell times are still unknown. Generally, FCSEMS and SEPS should not to remain in place for more than 12 weeks to avoid stent embedment; however, in a multicenter study considering a total of 329 stent extractions in 214 patients, adverse events caused by stent removal were not time dependent [29].

In our experience, an 8 week period was adequate to avoid hyperplastic epithelium growth at the stent ends, which could limit ease of stent removal, whereas the presence of the silicone covering prevents ingrowth of granulation tissue.

In conclusion, in our opinion, the use of conformable, small caliber stents exchanged periodically appears safe and permits durable oral intake in patients with refractory hypopharyngeal or cervical esophageal strictures, avoiding the need for frequent dilations that are associated with an increased risk of perforation and fistula formation.

Appendix A

The ogilvie & atkinson dysphagia score

Grade 0	No dysphagia, able to eat normally
Grade 1	Able to swallow some solid foods
Grade 2	Able to swallow only semisolid foods
Grade 3	Able to swallow liquids only
Grade 4	Aphagia

Mellow LH et al. Arch Intern Med 1985; 145: 1443–6

Appendix B

ECOG performance status

Grade

0 Fully active, able to carry on all pre-disease activities without restriction. (KarnofskY 90–100)

1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work. (Karnofsky 70–80)
2 Ambulatory and capable of all self-care, but unable to carry out any work activities. Up and about more than 50 percent of waking hours. (Karnofsky 50–60)
3 Capable of only limited self-care, confined to bed or chair 50 percent or more of waking hours. (Karnofsky 30–40)
4 Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. (Karnofsky 10–20)
5 Dead

Appendix C

The following data were collected: age, sex, stricture site, prior laryngectomy, date of last radiotherapy with and without chemotherapy, presence of esophago-respiratory or esophago-cutaneous fistula; number of dilation sessions prior stent placement and maximum reached diameter of dilation, presence of feeding tube, percutaneous endoscopic gastrostomy presence, dysphagia score before and after stent placement, weight and albumin serum level at the beginning and at the end of the follow up, length of stenosis, date of stent placement, length and diameter of stent, dilation at the time of stent placement, immediate, early and late AEs, position and degree of expansion of the stent at the esophagography within 24 h after stent placement; date and number of following stent placement, persistent improvement of dysphagia, persisting improvement of stricture, other associated treatment after stent release, Montgomery stent placement, status of patient, and cause of death.

Declarations

Disclosure Drs Massino Conio, Rosa Angela Filiberti, Peter D Siersema, Raffaele Manta, Sabrina Blanchi e Antonella De Ceglie, have no conflict of interest or financial ties to disclosure.

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