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Feasibility and Safety of Through-the-scope versus Over-the-wire Stents for the Palliation of Malignant Dysphagia. A Cohort Real-Life Study

Javier Tejedor-Tejada, Benito Hermida, Maria Pipa-Muñiz, Covadonga Garcia-Suarez, Zhuraida Salman, Cesar Gomez, Aranzazu Alvarez-Alvarez, Jose Perez-Pariente

Department of Gastroenterology, Hospital Universitario de Cabueñes, Gijón, Asturias. Spain

Address for correspondence:
Javier Tejedor-Tejada
Institution: Department of Gastroenterology, Hospital Universitario de Cabueñes, st Los Prados, 395, 33394. Gijón, Asturias. Spain.
jtejedor1991@gmail.com

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ABSTRACT

Background & Aims: In the presence of malignant dysphagia in non-surgical candidates, a self-expanding metal stent (SEMS) represents a safe and effective approach. Recently, a through-the-scope (TTS) SEMS was launched. The aim of our study was to assess the feasibility and safety of the TTS versus over-the-wire (OTW) SEMS in patients with malignant dysphagia.

Methods: This single-center retrospective cohort study included patients with malignant dysphagia undergoing esophageal TTS and OTW-SEMS from 2012 to May-2022. The primary outcomes were the technical and the clinical success of the SEMS placement. Secondary outcomes included adverse events, patency, and survival. Patients were prospectively followed until death or loss of follow-up.

Results: A total of 98 patients were enrolled, including 34 patients in the TTS group and 64 patients in the OTW group. TTS and OTW SEMS placement were feasible in 33 (97.1%) and 64 (100%) procedures , respectively (p=0.118). Overall, 32 patients (94.1%) in the TTS group and 62 patients (96.9%) in the OTW group showed an improvement in Ogilvie score (p=0.432). Recurrent dysphagia occurred in 30 patients, 12 in TTS group and 18 in OTW group, due to migration (4 vs. 5), stent deformation (1 vs. 1), tissue ingrowth (5 vs. 5) and overgrowth (2 vs. 7). No patient died from a stent-related cause. Median survival was 123 days (IQR: 59-209) in TTS group and 113 days (IQR: 73-271) in OTW group (p=0.349).

Conclusions: Placement of esophageal TTS and OTW stents resulted in similar technical and clinical outcomes, stent patency and survival in patients with malignant dysphagia.

Key words: dysphagia – esophageal cancer – esophageal stent – endoscopy –gastroenterology.

Abbreviations: AE: adverse event; fcSEMS: fully covered self-expanding metal stent; IQR: interquartile range; NRS: numeric rating scale; OTW: over-the-wire; pcSEMS: partial covered self-expanding metal stent; SD: standard deviation; SEMS: self-expanding metal stent; TTS: through-the-scope; ucSEMS: uncovered self-expanding metal stent.

INTRODUCTION

Esophageal cancer is the seventh most common cancer worldwide with a global incidence of 604,100 (3.1%) new cases in 2020 [1-3]. Moreover, esophageal cancer is often diagnosed in an advanced stage and supportive care is recommended. The most frequent symptom is dysphagia associated with weight loss [4]. Therefore, esophageal stenting plays a key role in relieving malignant dysphagia [5].

Self-expanding metal stent (SEMS) insertion is safer, more effective and a quicker approach to palliate dysphagia compared with other modalities in patients with esophageal cancer and poor prognosis [4-6].

Several reports have been published demonstrating better clinical results and lower rates of tumor ingrowth with fully covered SEMS (fcSEMS) or partially covered SEMS (pcSEMS) than conventional uncovered SEMS (ucSEMS) in reliving malignant dysphagia. However, the preferred technique for esophageal SEMS has not been reported [7, 8]. There are no differences between fcSEMS and pcSEMS to relieve malignant dysphagia [6, 8, 9].

There are two methods for stent placement, a through-the-scope (TTS) delivery system under endoscopic guidance and over-the-wire (OTW) delivery system under fluoroscopic

guidance [10-14]. A simplified and practical OTW technique under endoscopic control without fluoroscopy has been described by gastroenterologists [15]. The TTS esophageal SEMS delivery makes the procedure shorter and easier than OTW technique.

The aim of our study was to assess the feasibility, clinical success and safety of the TTS versus OTW esophageal stent in a retrospective and real-life cohort study of patients with malignant dysphagia.

METHODS

Between 2012 and May 2022, consecutive patients with malignant dysphagia undergoing esophageal stent placement in an academic center were registered. Patients were included when they had severe malignant dysphagia (grade ≥ 2 according to Ogilvie et al. [16]) caused by inoperable esophageal cancer, esophagogastric junction cancer or ab-extrinsic esophageal compression. Exclusion criteria were previous esophageal stent placement, upper gastrointestinal surgery or radiation-induced esophageal stricture.

The study was performed according to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement [17] and received the approval from the Medical Ethics Committee and Institutional Review Board. Medical records and patient images were retrospectively reviewed.

Malignant dysphagia in all patients was diagnosed by endoscopy. Tumor margins were determined by a computed tomography (CT) scan study.

The type of the stent was selected depending on the estimated survival (ucSEMS if estimated survival was less than 3 months and pcSEMS or fcSEMS if it was more than 3 months to prevent tissue ingrowth). The diameters of SEMS were 18, 20, 22 and 23 mm. The stent was available in six lengths: 6, 8, 9, 10, 12 and 15 cm. Through-the-scope stent placement was performed using Hanaro (M.I Tech Co Ltd, Seoul, Korea) or Alagile (Boston scientific, Natick, MA) stents (Fig. 1). On the other hand, OTW stent placement was performed using Ultraflex or Wallflex (Boston Scientific, Natick, MA) stents (Fig. 2). In our simplified technique, a 0.035-inch guide wire with a soft and straight tip (Jagwire – Boston Scientific, Natick, MA) was advanced into the gastric cavity and SEMS was deployed by a proximal or distal-release delivery system under endoscopic guidance. The stent must be long to bridge the stricture. Therefore, the stent should extend 2 cm beyond the ends of the stricture to minimize the chance of tumor overgrowth. All procedures were conducted under deep sedation by an anesthesiologist or endoscopist.

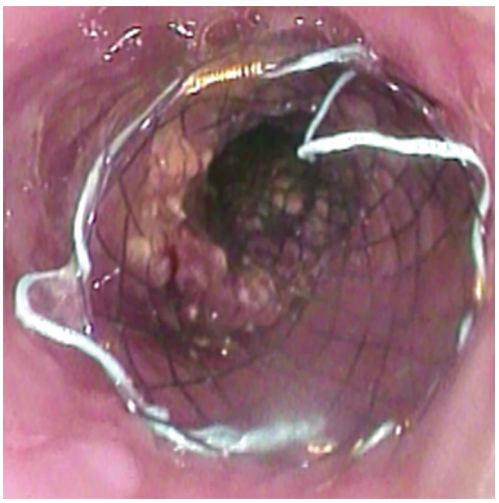

Fig. 1. Placement of esophageal TTS-stent with endoscopic control.

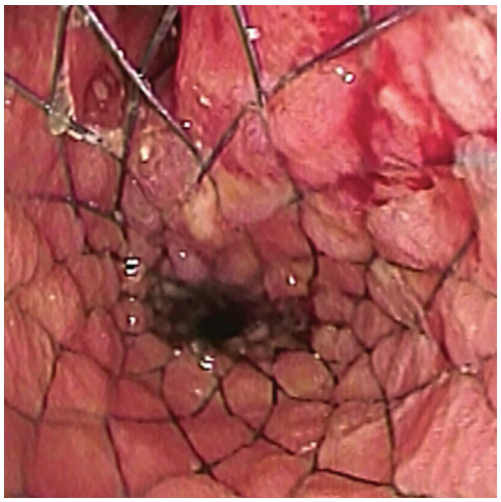

Fig. 2. Placement of esophageal OTW-stent with endoscopic control.

Demographics and clinical data (such as age, gender, comorbidities according to Charlson index [18]) were reported; previous therapy, tumor characteristics, technical data, complications, stent patency and survival were also registered.

The technical success was defined as the ability to accurately place and expand the stent at the desired level under endoscopic control. The clinical outcome was defined as an improvement of at least two grades in the Ogilvie classification [16]; this was evaluated at the time of procedure and after two weeks. Stent patency was defined as the period from the initial stent placement to the recurrence of obstructive symptoms due to stent dysfunction.

The experience of endoscopists in esophageal SEMS placement were classified as expert (if performed more than 10 procedures in the last year) or non-expert (if performed less than 10 procedures) endoscopists [19].

Patients were prospectively followed at day 14 and 30, and subsequently every three months after stent placement until death. The adverse events (AEs) evaluated were dysphagia, bleeding, aspiration, perforation, nausea, vomiting and chest pain at 24 hours (defined as early AEs) and after 24 hours (defined as delayed AEs).

Chest pain was assessed using a numeric rating scale (NRS). If significant pain was present, acetaminophen and/or non-steroidal anti-inflammatory drugs were prescribed. A repeat endoscopy was performed when patients reported recurrent dysphagia, bleeding, severe nausea or vomiting. Finally, patients' survival after esophageal SEMS was evaluated.

Descriptive statistics were used to report characteristics of patients. Continuous variables were shown as mean ([± standard deviation (SD)], and median [± interquartile range

(IQR)] whenever appropriate. Categorical variables were presented as frequencies and percentages. The differences in mean procedure time were analyzed with the independent t-test. Univariate analysis was performed to assess differences in baseline characteristics and AEs of patients undergoing TTS and OTW stent placement. The Chi-square test for dichotomous variables and the Student t-test for continuous variables.

Kaplan-Meier analysis and the log-rank test were used for comparing the survival between patients of TTS-SEMS group and OTW-SEMS group after stent placement. Statistical analyses were performed using IBM SPSS Statistic for Windows (Version 24.0. IBM Corp, NY, USA). For all analyses, a p-value <0.05 was considered statistically significant.

RESULTS

A total of 134 patients were eligible for our study of whom 98 patients were finally included. The remaining 36 patients were excluded in accordance with our exclusion criteria (previous esophageal stent placement n=30, upper gastrointestinal surgery n=2 and radiation-induced esophageal stricture n=4). Ninety-eight patients underwent palliative esophageal SEMS placement using either a TTS method (n=34) or an OTW method (n=64). Malignant dysphagia was caused by esophageal squamous cell carcinoma (n=36) or adenocarcinoma (n=48), malignant extrinsic compression (lung cancer, n=10) or other (undifferentiated cancer, n=2; and neuroendocrine tumor, n=1). Baseline characteristics of both groups of patients are described in Table I. No statistically significant differences between the TTS group and the OTW group with regard to demographics were observed.

Technical Outcome

Table II shows the technical outcome of both groups. Most of patients received a pcSEMS (n=59). Through-the-scope stent placement was feasible in 33 procedures (97.1%); technical unsuccessful was due to proximal misplacement, so another stent was successfully placed in the same session by stent-in-stent technique. Over-the-wire stent placement was technically successful in 68 patients (100%). The technical success rate was similar in the TTS and OTW groups (97.1% vs 100%, p=0.118), by the use of a guidewire [n=2 (5.9%) vs n=59 (92.2%), p<0.01]. Moreover, the technical success rate was similar in TTS and OTW groups among non-expert (90.9% vs 100%) and expert (100% vs 100%) endoscopists. The mean TTS procedure time was 11 minutes (SD ± 4) with a 7-minute mean increase in time when OTW stent was placed (18 minutes, SD ± 5).

Clinical Outcome

In total, 122 stents were placed in 98 patients. At the time of procedure, 96 patients had severe dysphagia (Ogilvie score of 3 or 4). Overall, 32 of 34 patients (94.1%) in the TTS group and 62 of 64 patients (96.9%) in the OTW group showed an improvement in Ogilvie score but the clinical success rate did not differ significantly between both groups (p=0.432). Cessation of stent patency occurred in 12 (35.3%) patients in the TTS group and in 18 (28.1%) patients in the OTW group

Table I. Baseline characteristics of all patients treated for palliation of malignant dysphagia

	TTS-SEMS group N= 34 patients	OTW-SEMS group N= 64 patients	p
Male, n (%)	26 (76.4%)	46 (71.9%)	0.406
Age, mean (SD)	77.3 (8.8)	75.9 (11.1)	0.497
Charlson comorbidity index, mean (SD)	6.2 (1.4)	6.58 (1.4)	0.150
Neoplasia	16	20	0.452
Squamous cell carcinoma	14	34	
Adenocarcinoma	3	7	
Extrinsic compression - lung cancer	- 3	- 7	
Neuroendocrine tumors	1	3	
Undifferentiated cancer	- 1	- 2	
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Dysphagia score, n (%)			0.420
Grade 2	0 (0)	2 (3.1)	
Grade 3	15 (44.1)	28 (43.8)	
Grade 4	19 (55.9)	34 (53.1)	
Stricture length, cm, mean (SD)	5.2 (1.6)	5.6 (1.8)	0.239
Stricture location			0.474
Proximal	1	1	
Medium	14	23	
Distal	19	40	
Previous therapy, n (%)			0.343
Chemotherapy	2 (5.9)	5 (7.8)	
Radiation	5 (14.7)	8 (12.5)	
Combination	7 (20.6)	11 (17.2)	
None	20 (58.8)	39 (60.1)	
Experience of endoscopist, n (%)			0.142
Non-expert endoscopists	11 (32.4)	13 (20.3)	
Expert endoscopists	23 (67.6)	51 (79.7)	

OTW: over-the-wire; SD: standard deviation; SEMS: self-expanding metal stent; TTS: through-the-scope.

Table II. Technical and clinical outcomes of stent placement for palliation of malignant dysphagia

	TTS-SEMS group N= 34 patients	OTW-SEMS group N= 64 patients	p
Type of stent			0.04
ucSEMS	7	26	
pcSEMS	25	34	
fcSEMS	2	4 f	
Stent length			0.05
60-90 mm	24	15	
100-120 mm	4	46	
> 120 mm	6	3	
Stent diameter			0.07
18 mm	5	13	
20 mm	19	1	
22 mm	5	9	
23 mm	5	41	
Overall procedure time (minutes), mean (SD)	11 (4)	18 (5)	0.037
Guidewire, n (%)	2 (5.9)	59 (92.2)	< 0.01
Technical success, n (%)	33 (97.1)	64 (100)	0.118
Non-expert vs expert endoscopists	10/11 vs 23/23	13/13 vs 51/51	
Clinical success, n (%)	32 (94.1)	62 (96.9)	0.432
Non-expert vs expert endoscopists	10/11 vs 22/23	13/13 vs 49/51	

fcSEMS: fully covered self-expanding metal stent; pcSEMS: partial covered self-expanding metal stent; ucSEMS: uncovered self-expanding metal stent. For other abbreviations see Table I.

(p=0.106) (Table III). Median dysphagia-free time after SEMS placement in the TTS and OTW groups were 85 days (IQR: 64-107 days) and 103 days (IQR: 38-212 days) respectively, with no significant difference between the two groups (p=0.106).

A total of 96 patients were followed until death and 2 patients were still alive after 16.6 months of follow-up. The median survival after stent placement in TTS and OTW groups were 113 days (IQR: 73-271) and 123 days (IQR: 59-205), respectively (Fig. 3). A total of 84 (87.5%) patients died because of tumor progression and 12 (12.5%) from infection. No patient died from a stent-related causes.

Table III shows all AEs reported during follow-up. Thirteen (38.2%) patients in the TTS group experienced complications occurring between 5-266 days. In comparison, 22 (34.4%) patients in the OTW group experienced complications occurring between 7-305 days (p=0.106). The most frequent AE was recurrent dysphagia. A total of 30 (30.6%) patients experienced recurrent dysphagia: 12 (35.3%) patients in the TTS group and 18 (28.1%) patients in the OTW group (p=0.106) because of stent migration (4 in TTS group vs 5 in OTW group, p=0.108), stent deformation (1 in TTS group vs 1 in OTW group, p=0.156), tissue ingrowth (5 in TTS group vs 5 in OTW group, p=0.108) and tissue overgrowth (2 in TTS group vs 7 in OTW group, p=0.335). All the patients with tumor ingrowth or overgrowth underwent second SEMS placement by stent-in-stent technique. In the rest of the patients the deformed or migrated stent was treated by a replacement with a different SEMS or endoscopic reposition of the stent.

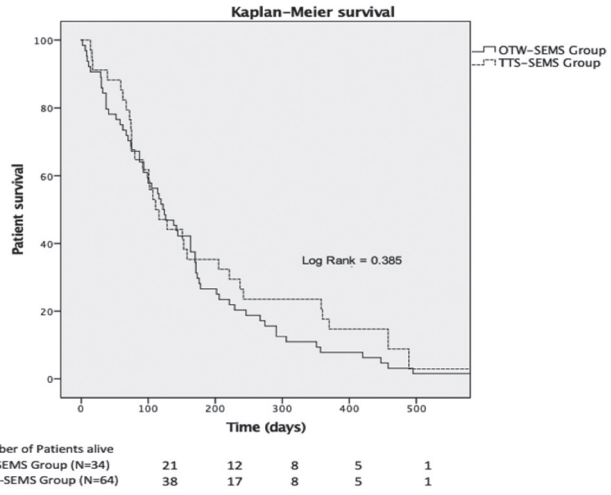

Fig. 3. Kaplan-Meier analysis of overall patient survival in the through-the-scope (TTS) and over-the-wire (OTW) groups.

Furthermore, two patients experienced early AEs. On the day after SEMS placement, 1 patient reported self-limited chest pain in the TTS group (2.9%) and 1 patient reported nausea and vomiting in the OTW group (3.1%). During the follow-up, two patients experienced delayed AEs in the OTW group (3.1%), 1 patient reported chest pain and 1 patient reported self-limited bleeding that did not require transfusion. No delayed AEs were observed in the TTS group. All AEs were mild (grade I-II) according the AGREE classification [20].

DISCUSSION

This feasibility study demonstrates that TTS and OTW esophageal SEMS placement can be performed in patients with malignant dysphagia, showing similar results for relieving of dysphagia. Moreover, the technical and clinical success rate were similar between non-expert and expert endoscopists in both groups.

The study also demonstrated that TTS SEMS placement was effective, with a technical success rate of 97.1%. The clinical success (94.1% vs 96.9%, p=0.432) and dysphagia-free time (median time, 85 vs 103 days, p=0.106) after SEMS

Table III. Survival and adverse events during follow-up after treatment with through-the-scope or over-the-wire stent for palliation of malignant dysphagia

	TTS-SEMS group N= 34 patients	OTW-SEMS group N= 64 patients	p
Early AE (< 24 hours), n (%)	1 (2.9)	2 (3.1)	0.725
Chest pain (NRS >5)	1	1	
Nausea and vomiting	0	1	
Aspiration	0	0	
Perforation	0	0	
Upper gastrointestinal bleeding	0	0	
Procedure-related mortality	0	0	
Delayed AEs (> 24 hours), n (%)	0 (0)	2 (3.1)	0.424
Chest pain (NRS >5)	0	1	
Bleeding	0	1	
Recurrent dysphagia caused by	12 (35.3)	18 (28.1)	0,106
Stent deformation	1	1	0.478
Stent migration	4	5	0.108
Tissue ingrowth	5	5	0.156
Tissue overgrowth	2	7	0.335
Stent migration			0.401
ucSEMS	1	2	
pcSEMS	3	2	
fcSEMS	0	1	
Time migration occurrence (days), mean (SD)	55.8 (34.6)	84.8 (124.3)	0.567
Time from diagnosis of stent migration and stent replacement (hours), mean (SD)	2.6 (0.8)	11.5 (0.6)	0.734
Tissue ingrowth			0.007
ucSEMS	5	5	
pcSEMS	0	0	
fcSEMS	0	0	
Time ingrowth occurrence (days), mean (SD)	175.8 (114.6)	73 (37.7)	0.098
Tissue overgrowth			0.784
ucSEMS	1	3	
pcSEMS	1	4	
fcSEMS	0	0	
Time overgrowth occurrence (days), mean (SD)	222 (183.8)	144.7 (85.2)	0.390
Follow-up (days), median (IQR)	122 (73.8-223.1)	111 (67-199.8)	0.349

AE: adverse event; NRS: numeric rating scale; IQR: interquartile range. For the other abbreviations see Tables I and II.

placement trended to be higher in the OTW group. There was a statistical difference in the procedure time with a mean time of 11 minutes in TTS group and 18 minutes in OTW group (p=0.037). Several authors have presented case-series [10, 11] and observational studies [21] demonstrating that TTS SEMS placement can be safe and less time consuming with outcomes being comparable to those published about OTW method [22, 23]. Thus, short-term outcomes in patients with malignant dysphagia are similar in the TTS and OTW groups; therefore, the choice of fluoroscopic or endoscopic SEMS placement remains unclear and should depend on the X-Ray availability and local expertise.

Comparing our results to a recent study of ASGE standard of practice [24], we observed a lower rate of complications in our study. We found no significant increase in AEs that could be related to the TTS method. There were mild AEs (grade I and II) according the AGREE classification [20]. During the first day after SEMS placement, chest pain and nausea/vomiting were the most frequent AEs in both groups. The incidence of AEs during the follow-up was higher in the OTW than TTS group (p=0.424). Moreover, AEs were reported predominantly during the first week of follow-up [11]. We found that recurrent dysphagia was not significantly lower in the OTW than TTS approach (28.1% vs 35.3%, p=0.106). The underlying mechanisms leading to stent dysfunction were stent deformation or migration and tumor ingrowth or overgrowth. Our findings suggest that stent dysfunction may be due to two reasons. First, the difference in the type of stent. Second, 38.8% (38/98) of patients underwent chemotherapy and/or radiation therapy before stent placement as Reijm et al. [25] demonstrated. No patient died from a stent-related cause.

There are some limitations of our study. The retrospective and non-randomized design and its performance at a single medical centre represent the major limitations of our study. The retrospective nature of this study limits our data recording to the available medical records and documentation. Despite the database being thoroughly screened, we cannot exclude some degree of underreporting due to inherent limitations of non-standardized clinical documentations. Fewer patients underwent TTS than OTW SEMS placement. Partially covered SEMS was the most frequent type of stent. However, one-third of patients underwent an ucSEMS for palliation of malignant dysphagia in the OTW group because some of these procedures were performed before the recommendation of the ESGE

in 2016 [6]. In addition, two different types and designs of TTS (Hanaro or Alagile stent) and OTW SEMS (Ultraflex or Wallflex stent) were used.

CONCLUSIONS

This study demonstrated the feasibility of TTS was similar to the OTW placement of an esophageal stent in patients with malignant dysphagia. Moreover, outcomes of TTS SEMS did not differ with respect to OTW method, including clinical success rate, adverse events, stent patency and survival during the follow-up. Therefore, TTS SEMS seems to be a faster, effective and safe approach in the absence of fluoroscopy for the relief of malignant dysphagia due to an inoperable tumor.

Conflicts of interest: None to declare.

Authors' contribution: J.T.-T. and A.A.-A. conceived and designed the study. J.T.-T., M.P.-M., C.G.-S., Z.S., and C.G. collected the data. J.T.-T., and A.A.-A. analyzed the data and interpreted the results. J.T.-T., B.H., M.P.-M., C.G.-S., Z.S., C.G. and J.P.P. drafted the manuscript. All the authors revised the paper, read and approved the final version of the manuscript.

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