Endoscopic placement of self-expanding metallic stent without fluoroscopy in palliative treatment of esophageal cancer – is it safe and feasible? A multicenter experience

Mohamed Abdelshafy[a], Mahmoud Abdelhameid[a], Murad A. Jabir[b], Adel M. Ismail[c], Mostafa M. Sayed[d], Ahmad A. Maklad[e], Mohammed Tag-Adeen[f], Mohammed M. Wahman[g], Abdallah M. Taha[a]

Departments of, [a]General Surgery Department, [g]Clinical Oncology, Faculty of Medicine, [f]Internal Medicine, South Valley University, Qena, [b]Department of Surgical Oncology, South Egypt Cancer Institute, [d]Department of General Surgery, Faculty of Medicine, Assiut University, Assiut, Egypt, [c]Department of Surgical Oncology, Ismailia Teaching Oncology Hospital, Ismailia, [e]Department of General Surgery, Faculty of Medicine, Suez University, Suez, Egypt

Correspondence to Abdallah M. Taha, MD, Department of General Surgery, Faculty of Medicine, South Valley University, Qena 83523, Egypt
Tel: +20 101 171 6497;
Fax: +2 0965226432;
e-mail: abdallahsurgery@med.svu.edu.eg

Received: 10 June 2022
Revised: 23 June 2022
Accepted: 05 July 2022
Published: 05 April 2023

The Egyptian Journal of Surgery 2023, 41:995–1001

Background
Self-expanding metallic stent (SEMS) is considered nowadays as the gold standard in the palliative management of malignant dysphagia. Esophageal stenting is usually performed under both endoscopic and fluoroscopic guidance. However, placement of SEMS without fluoroscopy is still a common practice in our country owing to limited resources and long waiting list.

Aim
To evaluate the safety and feasibility of SEMS placement under endoscopic guidance only without fluoroscopy.

Patients and methods
A prospective interventional study was conducted on patients with inoperable esophageal cancer who presented to five tertiary hospitals for palliative esophageal stenting during the period from June 2019 to June 2022. Demographic, pathological, periprocedural, and the outcome data were collected, tabulated, and analyzed.

Results
A total of 195 patients were included in the current study. SEMS placement under endoscopic guidance only was done in all patients. No technical problem was encountered during placement of the SEMS. Before SEMS placement, dilatation of stricture was needed in 168 (95.38%) patients. Statistically and clinically significant improvement was seen in the dysphagia score after stenting in all patients (4.15 ± 1 before stenting vs. 1.15 ± 0.5 after stenting, P<0.001).
No major complications were encountered during or immediately after the procedure. Minor complications like retrosternal pain (that relieved by opioid analgesia) occurred in 30 (15.38%) patients. Hiccup occurred in nine (4.61%) patients, and it was stopped within 48 h with adequate treatment. Six (3.076%) stent migrations were encountered 1 week after SEMS placement during follow-up upper endoscopy and managed by restenting.

Conclusion
Placement of SEMS under endoscopic guidance only without fluoroscopy for palliating patients with inoperable malignant dysphagia is safe and feasible in selected patients. It could be adopted when fluoroscopy is not available, in centers with low resources, in low-income to middle-income countries, or in institutions that have restricted access to fluoroscopic guidance.

Keywords:
dysphagia, esophageal carcinoma, fluoroscopy, self-expanding metallic stent

Egyptian J Surgery 2023, 41:995–1001

1110-1121

Introduction

Esophageal cancer is the ninth most common cancer universally, the third common gastrointestinal malignancy, and the sixth leading cause of cancer-related deaths worldwide [1–3]. There are more than 450 000 new cases diagnosed each year worldwide [4], and its incidence is increasing faster than that of any cancer, where the number of cases is expected to increase by ~140% by 2025 [5]. In Egypt, according to the results of the National Population-Based Cancer Registry Program (NCRP) published in 2014, esophageal cancer represents 0.7–4.01% of all malignancies and is considered the 12th most common cancer in Egypt [6].

The esophageal wall is distensible, and most of the patients do not complain of any symptoms until more

than 50% of lumen is obstructed; therefore, esophageal cancer is usually associated with late presentation and poor prognosis, and more than 50% of patients are inoperable at the time of presentation [4]. Life expectancy for patients with esophageal carcinoma is extremely poor, and overall 5-year survival rates approach 10–15% [7].

Dysphagia is the commonest and the main symptom of esophageal cancer and usually indicates advanced stage. It is often associated with severe weight loss, cachexia, and malnutrition. Approximately 90% of these patients require palliative management [8–10].

The primary aim of treatment in these patients is to relieve dysphagia with minimal morbidity and mortality and to improve their quality of life [11]. A myriad of treatment options are available to manage dysphagia, including Nd: YAG laser therapy, photodynamic therapy, argon laser, systemic chemotherapy, external beam radiation therapy, endoscopic tumor ablation with bipolar electrocoagulation, brachytherapy, combined chemoradiation therapy, and esophageal dilatation and stenting. Each of these modalities has its advantages and disadvantages, and the choice of modality depends on its availability, local expertise, clinical situation, the cost, and patient preference. One or a more of these options can be used in combination for the relief of dysphagia [12].

In recent times, placement of a self-expanding metal stent (SEMS) has become the standard option for the palliation of malignant dysphagia. SEMSs relieve dysphagia rapidly, improve the nutritional status of the patient, and improve quality of life [13,14]. Disadvantages of SEMSs include excessive cost; common early and late complications, including chest pain, regurgitation, cough, and foreign body sensation; stent migration; perforation; bleeding; tumor ingrowth; tumor overgrowth; and stent occlusion [15].

Multiple randomized trials revealed that SEMS insertion is a safe and effective procedure in palliative treatment of esophageal cancer dysphagia. In the United Kingdom, SEMSs are the most commonly used method for palliating esophageal obstruction [16–18].

Nonavailability of fluoroscopy in the institution, or difficult access to the service in low-income to middle-income countries, Egypt as an example, might result in postponement of the procedures, delayed patient care, and prolongation of the waiting list, with subsequent deterioration of the general condition of such frail patients. In situations where other modalities for palliating dysphagia are out of hand, and the patient is unfit for any palliative surgical maneuvers, SEMS placement could be tried in the absence of fluoroscopy after proper patient and family consultation and accepting the possible risks and complications.

The current study was designed to evaluate the safety and feasibility of SEMS placement under endoscopic guidance alone without fluoroscopy in patients presented with inoperable malignant dysphagia.

Patients and methods

This prospective interventional study was conducted on 195 patients diagnosed with esophageal cancer, and the MDT decision was to get stenting to palliate their malignant dysphagia. Patients were admitted to general surgery, surgical oncology, and internal medicine departments in five tertiary hospitals. The procedures were performed in endoscopy units, during the period from June 2019 to June 2022.

Inclusion criteria were patients with inoperable malignant dysphagia, owing to either advanced disease or unfitness for surgery, patients with proximal location of tumor, 15–16 cm from incisor teeth, where placement of SEMS was not possible, and patients who did not accept the intervention were excluded. Approval of institutional ethics committee were obtained.

All patients were thoroughly assessed by history taking, clinical examination, proper staging including contrast-enhanced radiological examination of esophagus, and endoscopic examination and tissue biopsy and MDT discussion.

Informed consent was obtained from all patients included in this study after explanations of the nature of the disease and the treatment options, including dilation with stenting and complications of the procedure.

Technique

Preparation was done for all needed equipment and any anesthetic medications or equipment, for any unexpected event during the procedure. WallFlex uncovered esophageal stent (Boston Scientific, Boston, Massachusetts, USA) or Evolution uncovered stent esophageal (Cook Medical Endoscopy, Bloomington, Indiana, USA), and Savary dilators (Savary-Gilliard semi-flexible thermoplastic bougies 5.0–14 mm) were used in our study.

Under conscious sedation using midazolam and fentanyl, the endoscope was passed into the esophagus and the guide wire was placed through the stricture gently, enabling Savary–Gilliard dilatation up to 12 mm.

After adequate dilatation, a gastroscope (8.9 mm in diameter) was gently passed through the esophagus to examine the stomach and any gastroesophageal junction tumor involvement. Then, the scope was pulled back slowly, to estimate length of the tumor and its proximal and distal extension. After estimation of the esophageal stricture, the propitiate SEMS length was selected, at least 4 cm longer than the stricture (of 2 cm on either side of the lesion) and was loaded onto the guide wire and passed through the esophagus.

Endoscopic guidance under direct vision was used during stent deployment, to accurately place it in optimal position, by keeping the proximal white marker of the stent at 2 cm distance just above the proximal tumor edge.

At the end of the procedure, guide wire was removed and gastroscope was introduced through the stent up to the stomach, to confirm stent position and to detect any complications.

Follow-up upper endoscopy was done 1 week after the procedure to confirm proper stent placement and to detect any complications.

Follow-up

The patients were followed up after 1 week and then once a month on an outpatient basis. Any issues related to swallowing, food intake, or procedure-related complications were recorded. Further chemotherapy, radiotherapy, chemoradiation, nutritional management, and pain management were decided and provided when required by clinical oncologist according to histopathology, tumor stage, and patient performance status.

Upper endoscopy, water-soluble gastrografin study, or computed tomography was done when required.

Data collection and analysis

Scoring of dysphagia before and after stenting was graded according to Mellow–Pinkas Dysphagia Score, from grade 0 to grade 4 (Table 1) [19].

Demographic, pathological, and periprocedural data were collected, tabulated, and analyzed by SPSS version 26 (Statistical Package for the Social Sciences; SPSS Inc., Chicago, Illinois, USA).

Qualitative data regarding tumor histopathology and complications are presented as frequencies and percentages. Numerical parameters, that is, age in years, duration of dysphagia, and dysphagia score were expressed as arithmetic mean±SD. Wilcoxon signed-rank test was used to compare dysphagia scores before and after stent insertion. *P* value less than 0.05 was considered as statistically significant.

Table 1 Mellow–Pinkas dysphagia scoring system [19]

Grades	Criteria
0	Able to eat normal diet/no dysphagia
1	Able to swallow some solid foods
2	Able to swallow only semi solid foods
3	Able to swallow liquids only
4	Unable to swallow anything/total dysphagia

Result

A total of 195 patients were included in the study. The mean age was 59.25 ± 15.33 (range, 45–85) years. The majority of patients were males (92.30%). The mean duration of dysphagia was 2.5 ± 0.9 months. Overall, 150 (76.64%) patients were heavy smokers (Table 2).

Most of the tumors were found in the middle third of the esophagus [108 (55.38%)]. Squamous cell carcinoma was the commonest histopathology, seen in 156 (80%) patients (Table 3).

SEMS placement under endoscopic control was successful in all patients. No technical problems were encountered during placement of the SEMS. Dilatation of the stricture before deployment of the stent was needed in 186 (95.38%) patients. The patient dysphagia score was much improved after stenting. Prestenting mean score was 4.15 ± 1 versus 1.15 ± 0.5 after stenting (P<0.001).

Table 2 Demographic and clinical variables of patients

Variables	Results [*n* (%)]
Age (years)	
Age groups	
<45	6 (3.08)
45–55	15 (7.69)
55–65	141 (72.30)
65–75	24 (12.31)
>75	9 (4.61)
Mean±SD	59.25 + 15.33
Range	45–85
Sex	
Male	180 (92.3)
Female	15 (7.7)
Duration of dysphagia (months) (meanM±SD)	2.5 ± 0.9
Dysphagia score (mean±SD)	
Prestenting	4.15 ± 1
Poststenting	1.15 ± 0.5
Smoking	
Heavy smoker	150 (76.64)
Nonsmoker	45 (32.07)

Table 3 Pathological characters of the tumors in the studied group

Variables	Result
Tumor length in cm (mean±SD)	4.67 ± 3.39
Location of tumor [*n* (%)]	
Upper-third	21 (10.77)
Mid-third	108 (55.38)
Lower-third	60 (46.15)
Lower third and extend to cardia	6 (3.07)
Tumor histopathology [*n* (%)]	
Well differentiated squamous cell carcinoma	33 (16.92)
Moderately differentiated squamous cell carcinoma	84 (43.07)
Poorly differentiated squamous cell carcinoma	39 (20)
Well differentiated adenocarcinoma	9 (4.61)
Moderately differentiated adenocarcinoma	24 (12.30)
Poorly differentiated adenocarcinoma	6 (3.076)

Regarding complications, no significant major complications were encountered during stent placement and 24 h after the procedure in any patient. Only nine (7.69%) patients developed minor upper gastrointestinal bleeding and they were treated conservatively. No major complications such as perforation, esophageal respiratory fistula, tracheal compression, or death occurred during or immediately after the procedure. Minor complications like retrosternal pain (relieved by opioid analgesia) occurred in 30 (15.38%) patients, and hiccup occurred in nine (4.61%) patients, which was treated and relieved within 48 h. Six stent migrations occurred 1 week after placement and treated by restenting successfully (Table 4 and Figs 1–3).

Discussion

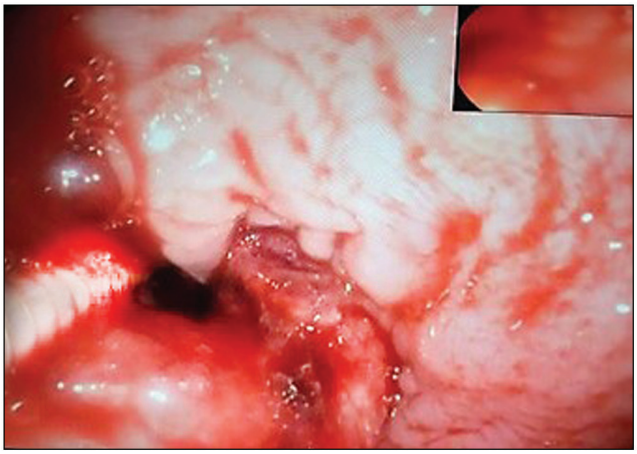
Esophageal cancer is considered the sixth most common cause of cancer death, which leads to more than 450 000 deaths worldwide. More than 80% of the esophageal cancer cases occur in developing countries. In the United States, 16 980 people are diagnosed with esophageal cancer each year and 14 710 die of the disease [30].

Esophageal cancer is a leading global health problem, especially in low-income and middle-income countries. In Egypt, it represents 0.7–4.1% of all malignancies. The esophageal cancers are classified histologically as squamous cell carcinoma (64.7%) or adenocarcinoma (13.7%), which differ in pathology, tumor location, and prognosis. Other histological subtypes including carcinoma not otherwise specified (5.9%), undifferentiated carcinoma (3.9%), mucinous adenocarcinoma (3.9%), Signet ring cell carcinoma (3.9%), and unclassified tumors (3.9%) were reported. Approximately 79.3% of the esophageal tumors are found in the lower third of the esophagus, 6.9% in the

Table 4 Comparison between our study and similar studies

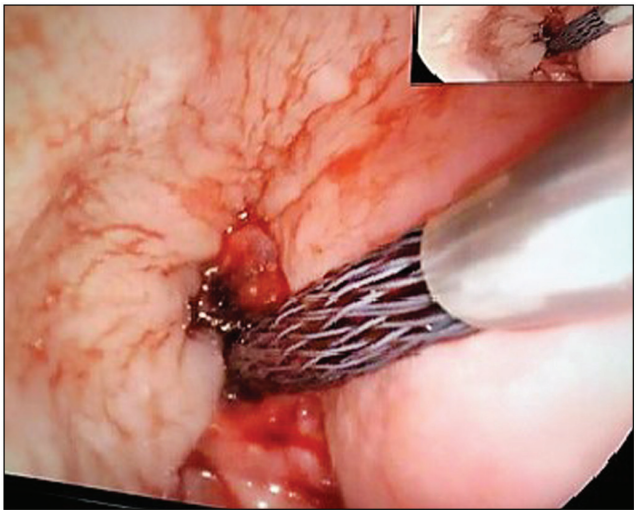
References	Number of patients	Success rate	Complication incidence
White *et al.* [20]	70	100%	2 perforations
			2 tumor in-growth
			1 tumor overgrowth
Austin *et al.* [21]	30	77%	No complication
Ben Soussan *et al.* [22]	33	90%	1 death (pulmonary embolism)
			2 severe retrosternal pain
			1 GERD
			1 food impaction
			5 stent obstruction
			1 esophagorespiratory fistula
Wilkes *et al*. [23]	98	92%	5 stent obstruction
			2 severe retrosternal pain
			1 death (pulmonary embolism)
			1 GERD
			1 food impaction
			1 esophagorespiratory fistula
Siddiqui *et al.* [24]	80	93.75	30 retrosternal pain
			4 upper GI bleeding
			4 aspiration
Dobrucali and Caglar [25]	90	Not available	4 migration
			0 perforation
			0 mortality
Christie *et al*.[26]	100	Not available	8 migrations
			1 perforation
			0 mortality
Cwikiel *et al.* [27]	100	Not Available	1 perforation
			0 mortality
Govender *et al*. [28]	453	100	3 migration
			0 perforation
			0 mortality
Stewart *et al*. [29]	138	Not available	50 chest pain
			17 tumor overgrowth
			10 food bolus obstruction
			3 stent migration
			3 tracheoesophageal fistula
			1 perforation
Our study (2022)	195	100%	30 retrosternal pain (15.83%)
			9 minor bleeding (4.61%)
			9 hiccough (4.61%)
			6 stent migration (3.08%)
			0 aspiration
			0 perforation
			0 tracheal compression
			0 major upper GI bleeding
			0 death due to procedure
			0 respiratory arrest

Figure 1



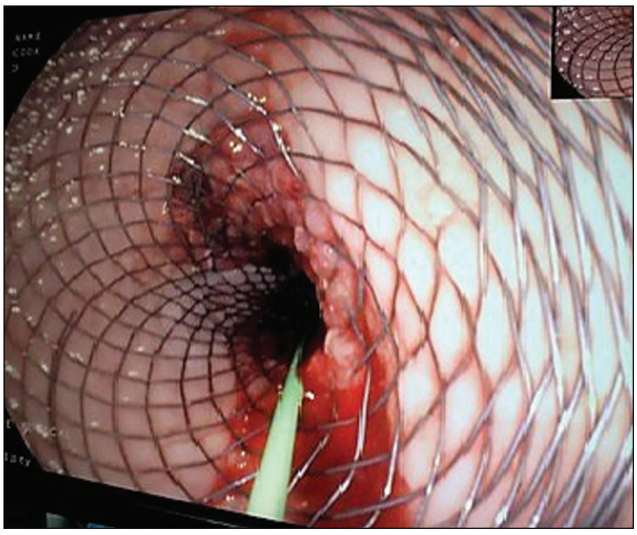
Dilatation of the obstructing mass.

Figure 2



Stent deployment under endoscopic guidance.

Figure 3



Stent in place at the end of the procedure, before removal of guide wire.

cervical esophagus, 10.3%% in the upper esophagus, and 3.4% were overlapping lesions [6].

During the 1960s, in the United States, SCCs accounted for more than 90% of all esophageal cancers, and esophageal adenocarcinomas were considered so uncommon. For the past two decades, however, the incidence of esophageal adenocarcinomas has increased dramatically in Western countries, such that both these tumors now occur with almost equal frequency [31,32].

The prognosis of esophageal cancer is extremely poor as most esophageal cancers are diagnosed at a late stage, with a 5-year survival rate of less than 20% owing to the presence of locally advanced disease and undetected metastatic disease at the time of diagnosis [33].

Dysphagia is the main and late symptom in more than 70% of patients with advanced inoperable esophageal cancer and frequently detected in an advanced stage [34].

More than half of the patients with esophageal cancer need palliative therapy at the time of diagnosis. The ideal palliative therapy must be safe, should not be expensive, should be effective, should provide rapid and permanent relief, and should be easy to perform [35].

Many types of palliative therapies, or combination of therapies, have emerged in recent years such as endoscopic metallic stent, external beam radiation, brachytherapy, chemotherapy, chemoradiotherapy, laser treatment, and photodynamic therapy.

SEMSs are used for the palliation of malignant dysphagia and provide an appropriate quality of life during a short survival period of patients. SEMS is an accepted therapeutic approach in the palliative treatment of dysphagia owing to malignant esophageal stricture. It is simple, more reliable, and better tolerated than other methods. It has low mortality and morbidity rates and allows for swallowing ability to reach an acceptable level rapidly after the procedure, and usually, after a single procedure. It has been shown that SEMSs were superior to plastic stent [36–38].

The use of endoscopic stenting for malignant dysphagia is increasing, because it offers a quick, safe, and easier treatment option. The main advantage of stenting over other treatment options is a noticeable relief of dysphagia immediately after the procedure [39,40]. Moreover, SEMS could be considered as a viable choice for palliative management of patients with extrinsic esophageal compression. Nowadays, esophageal stenting using SEMSs is considered as

the golden standard in the palliative management of malignant dysphagia [8].

In our study, SEMS placement under endoscopic guidance only without fluoroscopy was successful in all studied cases. This might be attributed to the small sample size relative to participating hospitals and long period of the study. Along 3 years of the study period in five tertiary hospitals, one or two cases only were selected and performed in each month in each hospital. A multidisciplinary team (medical oncologist, radiologist, surgeon, internist, and anesthesiologist) selected only the cases that might have a better chance for smooth and rapid procedure under endoscopic guidance only. Moreover, we did not jeopardized patients' rights to use full capacity of available facility services to provide safest possible procedures, as fluoroscopy was used routinely whenever accessible, and these fluoroscopy-guided cases were not included in the study.

Regarding dysphagia, in our study, there was a highly significant improvement in the dysphagia score after stenting. Prestenting mean score was 4.15 ± 1 versus 1.15 ± 0.5 after stenting ($P<0.001$). This agrees with similar studied detailed in Table 4.

Regarding complications, no early major complications (within 24 h) occurred in any patient. Only 15 (7.69%) patients developed minor upper gastrointestinal bleeding that occurred within 3–6 h of stent placement and were treated conservatively. No major complications like perforation, severe bleeding, esophageal-respiratory fistula, tracheal compression, or death during or immediately after the procedure.

Minor complications like retrosternal pain needing opioid analgesia occurred in 30 (15.38%) patients. Hiccup occurred in nine (4.61%) patients, who were treated and relieved within 48 h.

Stent migration distally was encountered in six patients 1 week after SEMS placement, and they were treated by restenting successfully. These results are comparable to similar studies done by White *et al.* [20], Austin *et al.* [21], Ben Soussan *et al.* [22], Wilkes *et al*. [23], Siddiqui *et al.* [24], Dobrucali and Caglar [25], Christie *et al.* [26], Cwikiel *et al.* [27], Govender *et al*. [28], and Stewart *et al.* [29]. The number of patients, success rate, and incidence of complications in these studies are detailed in Table 4.

The results of the current study and similar studies reveal that malignant dysphagia can be palliated by SEMS under endoscopic control only, without considering the absence of fluoroscopy as an obstacle that necessitates procedure cancellation or patient referral. This issue has a good effect on facility services and patient care in the form of earlier intervention, decreasing waiting list and time, and simpler procedure complexity, and burden on both the medical staff and such frail patient.

Conclusion

Placement of SEMS under endoscopic guidance only without fluoroscopy for palliating patients with inoperable malignant dysphagia is safe and is feasible to be performed in selected patients. It could be adopted when fluoroscopy is not available, in centers with low resources, in low-income to middle-income countries, or in institutions have restricted access to fluoroscopic guidance.

Acknowledgements

Authors contributions: all authors participated in the concept and design of the study, selecting patients in MDT, performing the procedures, following up of the studied cases, and collection of data. Mohammed M. Wahman guided the MDT in selection of cases suitable for palliative esophageal stenting and followed up patients in clinical oncology clinic for further oncological and supportive management. Mohamed Abdelshafy performed the statistical analysis and wrote the primary draft of the study manuscript. Abdallah M. Taha refined and edited the manuscript to its final form and is the corresponding author.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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