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DOI: 10.17235/reed.2025.11330/2025
Link: PubMed (Epub ahead of print)

Please cite this article as:
Relvas Luís Miguel, Gago Tânia, Barros Sónia, Carvalho Isabel, Portugal Margarida , Velasco Francisco, Caldeira Paulo, Peixe Bruno. Is fluoroscopy necessary for oesophageal SEMS placement? A retrospective cohort study. Rev Esp Enferm Dig 2025. doi: 10.17235/reed.2025.11330/2025.

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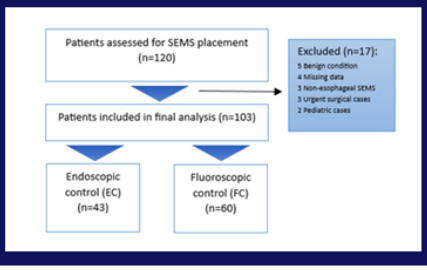
Is Fluoroscopy Necessary for Oesophageal SEMS Placement? A Retrospective Cohort Study

🎯 To **compare the safety and effectiveness** of self-expanding metal stent (SEMS) placement in the esophagus **guided by endoscopy** (EC) and **fluoroscopy** (FC).

Methods

Patients selection:



Outcomes evaluated:

- Technical success;
- Complications;
- Survival.

Results

Main indications: malignant stricture (91.3%); tracheoesophageal fistula (5.8%); malignant extrinsic compression (2.9%)

Early complications: FC 49% versus EC 53% *(p-value = 0.70)*

Late complications: FC 31% versus EC 28% (*p-value = 0.74)*

Common complications: Pain, vomiting, stent migration, bleeding, dysphagia

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Is fluoroscopy necessary for oesophageal SEMS placement? A retrospective cohort study

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Keywords: Oesophageal cancer. Oesophageal stents. Malignant dysphagia. Fluoroscopy control. Endoscopy control.

List of abbreviations:

SEMS - Self-expanding metal stents;

EC group - endoscopic control group;

FC group - Fluoroscopic control group.

Lay summary

The primary treatment for malignant dysphagia is the placement of self-expanding metal stents (SEMS). Currently, stent placement can be performed under either fluoroscopic or endoscopic guidance, but the most effective and safest method has not yet been clearly established. In this study, we reviewed 114 SEMS procedures performed at our hospital between 2011 and 2023. Patients were treated using either fluoroscopic or endoscopic guidance, depending on equipment availability. We evaluated procedural success, complication rates, and patient outcomes over time. We found that both methods were similarly effective and safe. Early and late complications—such as stent movement, pain, or tumor growth into the stent—occurred at comparable rates in both groups. Our findings suggest that either method can be used successfully, depending on clinical circumstances and available resources.

Abstract

Introduction: Self-expanding metal stents (SEMS) are widely used for the palliation of malignant esophageal conditions, including strictures, fistulas, and extrinsic compression. Placement may be guided by fluoroscopy (FC), direct endoscopy (EC), or both. However, few studies have directly compared the outcomes of these techniques.

Objective: To compare the safety and efficacy of SEMS placement under endoscopic versus fluoroscopic control in a real-world clinical setting.

Methods: We conducted a retrospective observational study of adult patients who underwent esophageal SEMS placement between January 2011 and December 2023. Patients were assigned to either the EC or FC group based on fluoroscopy availability. Outcomes included technical success, complication rates (early and late), and overall survival.

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Results: A total of 103 patients were included (mean age 69.4 years; 79% male), with 43 receiving SEMS under EC and 60 under FC. The primary indication was malignant esophageal stricture (91.3%). Technical success was achieved in 97% of EC cases and 100% of FC cases. Early complications occurred in 53% of EC and 49% of FC patients (p = 0.70), including chest pain (40.7%), vomiting (22.3%), and stent migration (5.8%). Late complications occurred in 28% of EC and 31% of FC cases (p = 0.74), most commonly tumor overgrowth (14.6%) and stent migration (10.7%). Thirty-day mortality was 2.3% in the EC group and 0% in the FC group (p = 0.31). Median survival was 102 days (EC) vs. 113 days (FC) (p = 0.44).

Conclusions: SEMS placement under both endoscopic and fluoroscopic control is safe and effective, with no significant differences in complication rates, technical success, or survival. Endoscopic guidance may be a viable alternative to fluoroscopy in experienced hands, particularly in resource-limited settings.

Introduction

Oesophageal cancer is one of the most aggressive malignancies, characterised by a high mortality rate and a rising incidence, particularly in Western countries. Most patients are diagnosed at advanced stages of the disease, making curative treatment often unfeasible. In this context, palliative treatment becomes essential. The primary goal is symptom relief, with dysphagia being one of the most commonly associated symptoms of oesophageal cancer (1, 2).

Oesophageal stents, particulary self-expanding metal stents (SEMS), have emerged as one of the most effective solutions for relieving malignant dysphagia. These stents have been widely used in the treatment of malignant oesophageal strictures, providing rapid, effective, and long-lasting symptomatic relief (3–5). Currently, SEMS are the preferred approach for malignant dysphagia and oesophageal fistulas, with covered stents achieving technical success rates approaching 100%. However, placement may be associated with complications in 20–30% of cases, with stent migration being one of the main challenges (6–8).

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SEMS placement has traditionally been performed under fluoroscopic guidance, which enables visualisation of the stent's position during the procedure and ensures precise placement. However, fluoroscopy involves radiation exposure, may prolong procedure times, and requires specific infrastructure which may not be available in all settings (9). As an alternative, SEMS placement under direct endoscopic visualisation has been explored as a simpler and potentially more effective technique. Several studies suggest that endoscopic stent placement without fluoroscopic assistance may be equally safe and effective (10–13), and more accessible, especially in settings where fluoroscopy is unavailable.

Despite the perceived advantages of direct endoscopic placement, comparative studies between these two approaches (direct endoscopic vs. fluoroscopic guidance) remain limited, and there is no consensus on which technique offers better outcomes in terms of safety, efficacy, and complication rates.

This study aims to assess the safety and efficacy of SEMS placement under endoscopic control without fluoroscopy and to compare its results with the traditional fluoroscopy-guided approach. We evaluated the technical success rate, incidence of complications, and impact on survival.

Methods

Study design and patient cohort

Following approval by the local ethics committee, a retrospective observational study was conducted at a regional hospital. All adult patients (>18 years) who underwent SEMS placement for malignant esophageal obstruction between January 2011 and December 2023 were eligible for inclusion.

Exclusion criteria included: patients <18 years, SEMS placement for benign conditions, insufficient clinical data (e.g., missing records on complications or procedural technique), stents placed in non-esophageal locations (e.g., trachea or biliary tract), or urgent SEMS placement with surgical backup unrelated to cancer palliation. In cases where patients received more than one SEMS, only the first procedure was

considered.

Patients were assigned to one of two groups based on procedural technique: SEMS placement under direct endoscopic control (EC) or fluoroscopic guidance (FC). In most cases, patient allocation was dictated by the availability of fluoroscopy at the time of the procedure, reflecting routine clinical workflow. However, in selected cases—such as those involving altered anatomy, complex strictures, or fistula suspicion—fluoroscopic guidance was intentionally preferred, irrespective of equipment availability, to enhance procedural safety and precision. Informed consent was obtained prior to all interventions.

A flow diagram detailing patient selection and exclusion is presented in Figure 1.

Data collection

Data were retrospectively extracted from medical records and included: age, sex, indication for stent placement, histologic tumor type, tumor location, degree of dysphagia, prior oncologic treatment (chemotherapy and/or radiotherapy), stent characteristics, need for dilation, complications, and survival.

Definitions

Early complications were defined as those occurring within 30 days post-procedure. Late complications were defined as those occurring thereafter.

Complications were classified as major if they were life-threatening or caused significant morbidity, including perforation, bleeding, stent migration or malposition, tumor overgrowth, severe chest pain, and fistula formation (tracheoesophageal or bronchoesophageal). Aspiration events were also classified as major complications, due to their potential association with fistulas or reflux of food/secretions. Minor complications included mild to moderate chest pain, transient vomiting, reflux, or self-limited fever without identifiable infection.

Technical success was defined as accurate placement and full expansion of the SEMS on the first attempt.

Stent characteristics and deployment technique

All SEMS used were covered metal stents (fully or partially). Stent lengths ranged from 80 to 140 mm, and diameters from 18 to 24 mm, with the majority being 20 mm in diameter.

In all cases, stent deployment was performed using a distal release mechanism. In the EC group, this allowed direct endoscopic visualization of the proximal tumor margin during release.

Statistical analysis

Statistical analysis was performed using SPSS for Windows (version 23.0; SPSS Inc., Chicago, IL, USA). Categorical variables are presented as absolute numbers and percentages, while continuous variables are expressed as medians and interquartile ranges (IQR). The chi-square test was used for categorical variables, and the Mann–Whitney test for continuous variables. A significance level of $p < 0.05$ was considered statistically significant.

Missing Data and Ethical Considerations

Cases with missing essential information (e.g., procedural technique, complications) were excluded from analysis. The study adhered to the ethical principles outlined in the Declaration of Helsinki.

Results

A total of 103 patients who underwent oesophageal stent placement were included in the study, with 43 (41.7%) assigned to the endoscopic control group (EC) and 60 (58.3%) to the fluoroscopic control group (FC).

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Patient and tumor characteristics

Most patients were male (n=82, 79.6%), with a median age of 69.4 years (range: 32-90). The most common indication for SEMS placement was malignant stricture (91.3%), with squamous cell carcinoma being the most frequent histological type (63.1%).

The most common site of malignant obstruction was the lower oesophagus/cardia (47.6%), followed by the mid-oesophagus (37.8%) and the upper oesophagus (14.6%). A total of 22 patients (21.3%) had received prior chemotherapy and/or radiotherapy, with no significant difference between groups (30.2% in EC vs. 15% in FC, p = 0.07).

Baseline dysphagia scores were similar between groups (mean: EC 3.2 vs. FC 3.1, p = 0.54). Full clinical and demographic data are summarized in Table 1.

Procedural characteristics

Dilation was required prior to SEMS placement in 12 patients (11.7%), due to inability to pass the stricture with the endoscope. The majority of stents used were fully covered (90%), with lengths ranging from 80 to 140 mm and diameters between 18 and 24 mm, most commonly 20 mm. Stent deployment was performed using a distal-release mechanism, which allowed precise control during positioning.

Technical success was achieved in 42 out of 43 patients (97%) in the EC group and in all FC cases (100%). One case in the EC group required fluoroscopic rescue after failed initial deployment.

Early Complications

Early complications occurred in 53% of EC patients and 49% of FC patients (p = 0.70). The most frequent events were chest pain (40.7%) and vomiting (22.3%). Aspiration

pneumonia occurred in one patient (EC group), and was classified as a major complication.

Rates of perforation (1.9%), hemorrhage (3.9%), and malposition/migration (5.8%) were low and did not differ significantly between groups. All immediate migrations occurred in stents placed near the gastroesophageal junction, and were successfully managed via repositioning or additional stent placement. Detailed complication data are provided in Table 2.

Late Complications and Reintervention

Late complications were observed in 31 patients (30.1%), with no significant difference between EC and FC groups (p = 0.74). The most frequent event was tumor overgrowth (14.6%), with a non-significant trend toward higher incidence in the EC group (20.9% vs. 10%, p = 0.14).

Reintervention was required in 9.7% of EC patients and 7.8% of FC patients (p = 0.69), mostly due to recurrent dysphagia. These were managed with dilation (n=3) or secondary stent placement (n=4).

Impact of Prior Oncologic Treatment

To explore whether neoadjuvant therapy influenced outcomes, we compared complication rates between patients who received prior chemotherapy and/or radiotherapy (n=22) and those who did not. No significant differences were found in early (p=0.34) or late complications (p=0.27).

Thirty-Day Mortality and Survival

Thirty-day mortality was low, with 1 death (2.3%) in the EC group and none in the FC group (p = 0.31). Median overall survival was 102 days [IQR 55–178] for EC and 113 days [IQR 60–186] for FC (p = 0.44), with no significant difference observed.

Kaplan–Meier survival curves (Figure 2) showed similar survival patterns between groups.

Discussion

The placement of self-expanding metal stents (SEMS) remains the treatment of choice for palliation of malignant dysphagia. These stents can be inserted under endoscopic control, with or without fluoroscopic guidance. The conventional approach typically favors fluoroscopy, as it provides real-time imaging of the anatomy, facilitates guidewire placement and dilation, and ensures precise positioning of the stent [15–19]. However, access to fluoroscopic equipment may be limited in certain centers or urgent scenarios, prompting exploration of endoscopic-only techniques [1,10–12,20].

Several studies have reported encouraging outcomes using endoscopic control alone, demonstrating technical feasibility and acceptable complication rates [11,20,21]. In our study, both endoscopic and fluoroscopic techniques showed success and complication rates comparable to those reported in previous observational studies.

In the endoscopic control (EC) group, technical success was achieved in 97% of cases, and complications were similar to those in the fluoroscopic control (FC) group. Importantly, no significant differences were found in early or late complication rates, nor in 30-day mortality or median overall survival. Our findings suggest that endoscopic-only SEMS placement can be safely performed in appropriate candidates, particularly in centers with limited access to fluoroscopy [1,11,20]. These findings may support more flexible procedural planning in palliative care, especially in community or resource-limited hospitals.

Our results are in line with previous studies, including that of Ferreira et al (2015), who retrospectively compared the two approaches in 126 patients and reported no significant differences in complications or outcomes [14]. Like them, we observed a

trend toward higher tumor overgrowth in the EC group, though this did not reach statistical significance.

The endoscopic approach offers several practical advantages: it allows precise visualization of the proximal tumor margin, enables immediate correction of intra-procedural complications such as migration, and avoids radiation exposure for both patient and staff [1,13]. These benefits may improve workflow and reduce procedural time in particularly when performed by operators familiar with non-fluoroscopic techniques.

However, certain clinical scenarios — such as complex anatomy, prior surgery, or suspected fistulas — may still benefit from fluoroscopic guidance. It is important to individualize the technique based on operator expertise, tumor characteristics, and available resources.

Despite these strengths, our study has important limitations. First, this was a retrospective, single-center study, which inherently carries a risk of selection and information bias. Although patient allocation was primarily guided by fluoroscopy availability, in specific clinical scenarios—such as complex strictures or altered anatomy—fluoroscopy was intentionally selected. As a result, some degree of confounding by indication may have occurred. Despite demographic similarities between groups, the possibility of residual bias cannot be fully excluded. Second, we did not perform multivariate analysis, as the relatively small sample size and low event rate would have undermined the robustness of such models. This limits our ability to adjust for potential confounders such as tumor location or prior treatment. Similarly, no formal sample size calculation or power analysis was conducted, so negative findings should be interpreted with caution. Third, a standardized grading system for complication severity (e.g., Clavien-Dindo or CTCAE) was not applied. Instead, complications were categorized as major or minor based on clinical relevance and need for intervention. While this simplified classification is aligned with other SEMS studies [11,14,20], future research should adopt validated grading systems to better characterize adverse events. Lastly, although we attempted to assess clinical outcomes, as post-procedural dysphagia scores were inconsistently recorded, we were

unable to assess clinical improvement following SEMS placement.

Conclusion

In conclusion, SEMS placement under direct endoscopic visualization may represent a safe and effective alternative in selected cases. While complication rates and survival outcomes were comparable in our cohort, the decision to use fluoroscopy or endoscopic guidance should be based on lesion complexity, available expertise, and procedural context. Further prospective, randomized studies with standardized complication grading and functional endpoints are needed to better define the optimal strategy for SEMS deployment in diverse clinical settings.

Key points box

- SEMS are standard treatment for malignant esophageal strictures; fluoroscopic guidance is commonly used but not always available.
- Endoscopic-only SEMS placement is technically feasible, with a 97% success rate and no procedure-related mortality in this study.
- No significant differences in early or late complication rates were found between endoscopic and fluoroscopic approaches.
- Endoscopic guidance enables real-time adjustments, avoids radiation exposure, and may be advantageous in urgent cases or settings where fluoroscopic equipment is unavailable.
- These findings support endoscopic-only SEMS placement as a safe and effective alternative, when performed by experienced endoscopists and in appropriately selected patients.

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Table 1 - Clinical and demographic characteristics of patients undergoing SEMS placement

	Endoscopic control (n= 43)	**Fluoroscopic control (n=60)**	**p-value**
Gender (M/F)	32/11	50/10	0.61
Average age (years)	69.2 (32-90)	68.9 (49-87)	0.84
Indication, n (%)			
Malignant stenosis	38 (88.4%)	56 (93.3%)	0.42
Neoplastic oesophago-bronchial/oesophago-tracheal fistula	3 (6.9%)	3 (5%)	0.68
Extrinsic compression	2 (4.7%)	1 (1.7%)	0.38
Tumour pathology, n (%)			
Scamous cell carcinoma	28 (65.1%)	37 (61.7%)	0.74
Adenocarcinoma	13 (30.2%)	22 (36.7%)	0.48
Tumour localization, n (%)			
Upper oesophagus	4 (9.3%)	11 (18.3%)	0.21
Middle oesophagus	15 (34.9%)	24 (40%)	0.61
Lower oesophagus/cardia	24 (55.8%)	25 (41.6%)	0.16
Previous QRT, n (%)	13 (30.2%)	9 (15%)	0.07
Average dysphagia score	3.2	3.1	0.54

Percentages may not add up to 100% due to rounding.

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Table 2 – Procedure characteristics, complications, and main outcomes

	Endoscopic control (n=43)	**Fluoroscopic control (n=60)**	**p-value**
Previous dilation, n (%)	6 (13,9%)	6 (10%)	0.57
Stent type, n (%)			
Fully covered	38 (88.3%)	54 (91.2%)	0.66
Parcially covered	5 (11.7%)	6 (8.8%)	0.66
Mean stricture length (range, mm)	86 mm (50-110)	89 mm (30-120)	0.39
Early complications, n (%)	23 (53%)	29 (49%)	0.70
Chest pain	19 (44.2%)	23 (38.3%)	0.56
Vomiting	12 (27.9%)	11 (18.3%)	0.26
Dysphagia	2 (4.7%)	3 (5%)	0.95
Haemorrhage	1 (2.3%)	3 (5%)	0.42
Malposition/migration	2 (4%)	4 (6.7%)	0.55
Repositioning	2	3	
New stent	0	1	
Perforation	1 (2.3%)	1 (1,7%)	0.83
Aspiration (pneumonia)	1 (2.3%)	0	0.31
Late complications, n (%)	12 (28%)	19 (31%)	0.74
Tumor ingrowth	1 (2.3%)	3 (5%)	0.48
Tumor overgrowth	9 (20.9%)	6 (10%)	0.14
Dilation	2	1	
Stent in stent	3	1	
Food impaction	0	2 (3.3%)	0.19
Haemorrhage	1 (2.3%)	2 (3.3%)	0.74
Fistula	3 (6.9%)	1 (1.7%)	0.27
Stent migration	5 (11.6%)	6 (10%)	0.78
Reinterventions (%)	9.7%	7.8%	0.69
30-day mortality (%)	2%	0%	0.31
Mean survival (days)	102 (11-372)	113 (44-368)	0.44

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Some patients experienced more than one complication; totals may exceed 100%.

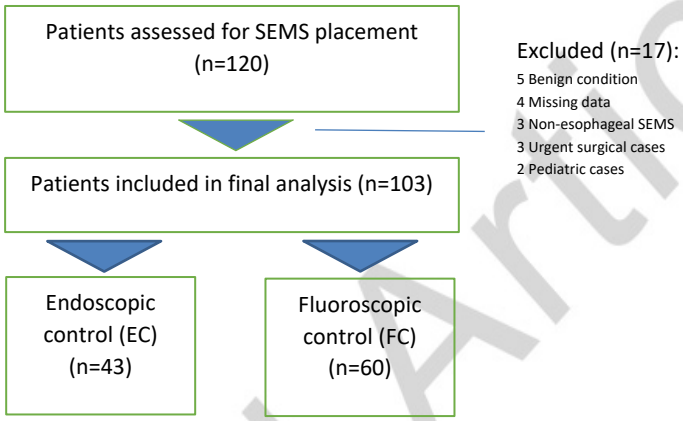

Figure 1 – Study flowchart showing patient selection and exclusion.

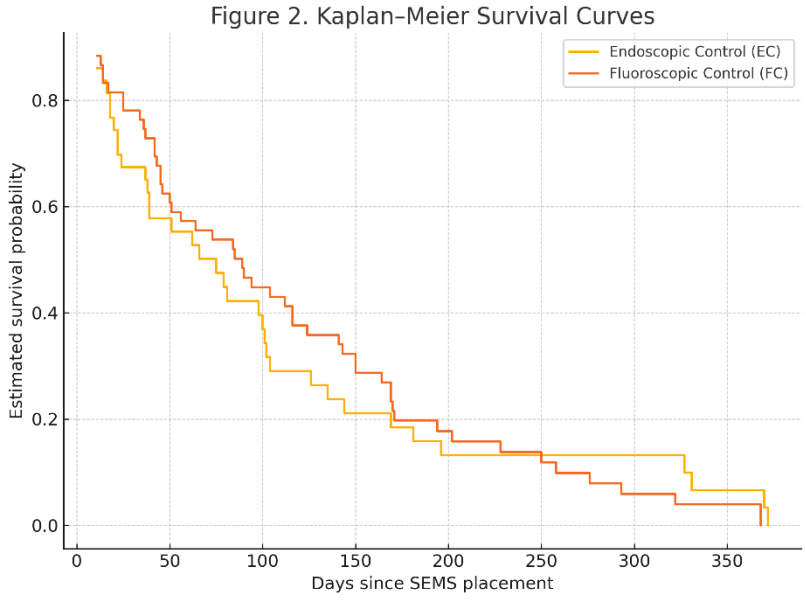

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Figure 2. Kaplan–Meier survival curves for patients undergoing oesophageal SEMS placement under endoscopic (EC) and fluoroscopic (FC) control.