Article published online: 2021-04-30

Esophageal stenting for benign and malignant disease: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2021



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published online 30.4.2021

Bibliography

Endoscopy 2021; 53: 751–762

DOI 10.1055/a-1475-0063

ISSN 0013-726X

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This article is published by Thieme.
Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Tables 1s–6s
Supplementary material is available under
https://doi.org/10.1055/a-1475-0063

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MAIN RECOMMENDATIONS

Malignant disease

1 ESGE recommends placement of partially or fully covered self-expandable metal stents (SEMSs) for palliation of malignant dysphagia over laser therapy, photodynamic therapy, and esophageal bypass.
Strong recommendation, high quality evidence.

2 ESGE recommends brachytherapy as a valid alternative, alone or in addition to stenting, in esophageal cancer patients with malignant dysphagia and expected longer life expectancy.
Strong recommendation, high quality evidence.

3 ESGE recommends esophageal SEMS placement for sealing malignant tracheoesophageal or bronchoesophageal fistulas.
Strong recommendation, low quality evidence.

4 ESGE does not recommend SEMS placement as a bridge to surgery or before preoperative chemoradiotherapy because it is associated with a high incidence of adverse events. Other options such as feeding tube placement are preferable.
Strong recommendation, low quality evidence.

Benign disease

5 ESGE recommends against the use of SEMSs as first-line therapy for the management of benign esophageal strictures because of the potential for adverse events, the availability of alternative therapies, and their cost.
Strong recommendation, low quality evidence.

6 ESGE suggests consideration of temporary placement of self-expandable stents for refractory benign esophageal strictures.
Weak recommendation, moderate quality evidence.

7 ESGE suggests that fully covered SEMSs be preferred over partially covered SEMSs for the treatment of refractory benign esophageal strictures because of their very low risk of embedment and ease of removability.
Weak recommendation, low quality evidence.

8 ESGE recommends the stent-in-stent technique to remove partially covered SEMSs that are embedded in the esophageal wall.
Strong recommendation, low quality evidence.

9 ESGE recommends that temporary stent placement can be considered for the treatment of leaks, fistulas, and perforations. No specific type of stent can be recommended, and the duration of stenting should be individualized.
Strong recommendation, low quality of evidence.

10 ESGE recommends considering placement of a fully covered large-diameter SEMS for the treatment of esophageal variceal bleeding refractory to medical, endoscopic, and/or radiological therapy, or as initial therapy for patients with massive bleeding.
Strong recommendation, moderate quality evidence.

SOURCE AND SCOPE

This Guideline is an official statement of the European Society of Gastrointestinal Endoscopy (ESGE). It provides guidance on the use of esophageal stents for both malignant and benign conditions. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system was adopted to define the strength of recommendations and the quality of evidence.

1 Introduction

Esophageal cancer is the seventh most common cancer type worldwide, with a global incidence of 604 100 new cases in 2020 [1–3]. The main symptoms of esophageal cancer include dysphagia, with concomitant weight loss and odynophagia [4]. Because patients with esophageal cancer are usually asymptomatic in the early stages, more than half of patients are diagnosed at an advanced stage of the disease and are not eligible for treatment with curative intent [5].

One of the main goals of palliative treatment is to relieve dysphagia and improve nutritional intake. A variety of therapeutic options are available, including external beam radiation therapy (EBRT), brachytherapy, and esophageal stent placement. Esophageal stent placement is preferable in patients with an expected short-term survival because of its rapid relief of dysphagia symptoms [6]. Different stent designs are available, varying in stent material (plastic, metal), covering, diameter, and antimigration features. Partially covered self-expandable metal stents (PCSEMSs) and fully covered self-expandable metal stents (FCSEMSs) are most often used in current practice.

In addition to their use for the palliation of dysphagia, esophageal stents can be used for the treatment of benign esophageal diseases. Stents are usually removed after several weeks as this timeframe allows for the resolution of disease and safe stent removal. FCSEMSs have been mostly used for the treatment of benign disorders. In recent years, biodegradable stents (BDSs) have gained increasing attention for obviating the need for stent removal.

This is an update of the clinical guideline on the use of esophageal stents for benign and malignant disease issued in

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ABBREVIATIONS

BDS	biodegradable stent
CI	confidence interval
CRP	C-reactive protein
EBRT	external beam radiation therapy
ECOG	Eastern Cooperative Oncology Group
ESGE	European Society of Gastrointestinal Endoscopy
ESPEN	European Society of Parenteral and Enteral Nutrition
FCSEMS	fully covered self-expandable metal stent
GRADE	Grading of Recommendations Assessment, Development and Evaluation
LAMS	lumen-apposing metal stent
OD	odds ratio
PCSEMS	partially covered self-expandable metal stent
RBES	refractory benign esophageal stricture
RCT	randomized controlled trial
SEMS	self-expandable metal stent
SEPS	self-expandable plastic stent
TIPS	transjugular intrahepatic portosystemic shunting

2016 by the European Society of Gastrointestinal Endoscopy (ESGE) [7]. In this guideline update, the current evidence will be discussed and recommendations on the use of esophageal stents will be provided.

2 Methods

The ESGE Guidelines Committee (chair, J.v.H.) commissioned this guideline update and appointed a Guideline leader (M.S.). Key questions (**Table 1s**, see online-only Supplementary Material) were prepared by a coordinating team (M.S., R.v.d.B., L.F., T.B., J.v.H.) and were approved by all guideline participants. Each guideline participant was assigned to a research question in one of two areas: malignant disease (taskforce leader, L.F.) and benign disease (taskforce leader, T.B.).

A literature search of MEDLINE and the Cochrane library was conducted in August 2020 using the PICO structure (where P stands for population/patient, I for intervention/indicator, C for comparator/control, and O for outcome). The quality of collected studies was graded according to the Grading Recommendations Assessment, Development and Evaluation (GRADE) system and retrieved study outcomes were translated into evidence tables. Evidence tables and proposed guideline recommendations were collected by the Guideline leader and circulated 2 weeks before the digital face-to-face meeting held on 22 October 2020. During the digital face-to-face meeting, outcomes of the PICOs were discussed and consensus was reached on guideline recommendations.

In November 2020, a draft was prepared by M.S. and R.v.d.B. and sent to the guideline team. The revised draft was reviewed by two independent experts. After adjustment and final approval by the guideline team, the manuscript was submitted for publication by *Endoscopy*.

This Guideline was issued in 2021 and will again be considered for updating in 2025.

3 Malignant disorders

3.1 Efficacy

RECOMMENDATION

ESGE recommends placement of partially or fully covered self-expandable metal stents (SEMSs) for palliation of malignant dysphagia over laser therapy, photodynamic therapy, and esophageal bypass.

Strong recommendation, high quality evidence.

RECOMMENDATION

ESGE recommends brachytherapy as a valid alternative, alone or in addition to stenting, in esophageal cancer patients with malignant dysphagia and expected longer life expectancy.

Strong recommendation, high quality evidence.

RECOMMENDATION

ESGE recommends patient characteristics be taken into account when selecting patients for esophageal stent placement as a palliative method.

Strong recommendation, low quality evidence.

RECOMMENDATION

ESGE recommends against the placement of nonexpandable and expandable plastic stents for the palliation of malignant esophageal strictures.

Strong recommendation, high quality evidence.

Several randomized controlled trials (RCTs) have compared the outcomes of esophageal stent placement with other treatment strategies for the palliation of malignant dysphagia due to esophageal cancer (**Table 2s**). Laser therapy, photodynamic therapy, and esophageal bypass surgery have shown comparable outcomes to esophageal stent placement [8–13].

Based on two RCTs comparing the outcomes of self-expandable metal stent (SEMS) placement versus brachytherapy, brachytherapy may be considered over SEMS placement in patients with expected long-term survival [14, 15]. Even though SEMS placement leads to a more rapid relief of dysphagia, brachytherapy is preferable in these patients for its durable relief of symptoms [15, 16]. Furthermore, the use of brachytherapy is associated with a lower risk of serious adverse events and favorable quality of life outcomes [14, 15]. Despite these benefits, the availability of brachytherapy in daily practice is restricted by the need for local expertise and dedicated logistics

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[17]. A short course of EBRT may be a valid alternative to brachytherapy [18]. In patients with a good performance status, chemoradiotherapy can be considered to prolong dysphagia-free survival, but is associated with an increased toxicity compared with radiotherapy alone [19].

Esophageal stent placement is indicated in patients with an expected short-term survival (i.e. less than 3 months) for its rapid relief of symptoms, usually within 1–2 days after stent placement [6]. Several prognostic tools may aid the selection of esophageal stent candidates, but these lack external validation [20–22]. The presence of metastases and poor performance status have repeatedly been shown to be associated with poor survival [21–24]. When esophageal stent placement is considered, SEMSs are recommended over self-expandable plastic stents (SEPSs) owing to a lower rate of symptom recurrence and serious adverse events [6]. To date, there have been no differences shown in the outcomes of FCSEMS and PCSEMS placement, or the placement of SEMSs with or without an anti-reflux mechanism [25–28].

3.2 Safety

In the previous ESGE guideline, a meta-analysis of the available evidence was performed for the occurrence of stent-related adverse events [7]. The major adverse event rate was reported to be 21 % for FCSEMSs and 18 % for PCSEMSs. The most frequent early adverse events were reflux (9.3 %), severe pain (8.7 %), and bleeding (7.6 %). The most frequent late adverse events were reflux (15 %), severe pain (15 %), and ingrowth/overgrowth (14 %).

In recent years, an increase in stent-related adverse events has been reported, which has been attributed to the increased use of chemotherapy and/or radiotherapy before SEMS placement [29]. Other patient characteristics that appear to be associated with an increased risk of adverse events include female sex and dilation before SEMS placement [28, 29].

3.3 Fistula

RECOMMENDATION

ESGE recommends esophageal SEMS placement for sealing malignant tracheoesophageal or bronchoesophageal fistulas.

Strong recommendation, low quality evidence.

RECOMMENDATION

ESGE recommends the application of double stenting (esophagus and airway) when fistula occlusion is not achieved by esophageal or airway prosthesis placement alone.

Strong recommendation, low quality evidence.

The incidence of esophageal fistulas has increased markedly as a result of advances in palliative therapies for esophageal cancer [30, 31]. Esophageal fistulas usually occur in the context of advanced esophageal cancer, but may also result from other malignancies or prior (palliative) therapy [30–34]. The symptoms of an esophageal fistula include cough, fever, and pneumonia [35]. Because the development of an esophageal fistula is considered to be an indicator of poor survival (weeks to months), treatment strategies should aim to rapidly relieve symptoms and improve the patient's remaining quality of life.

The clinical success rate of SEMS placement for malignant fistulas ranges between 56 % and 100 % [35–44]. Factors associated with treatment failure include proximal fistula location, fistula orifice size >1 cm, and Eastern Cooperative Oncology Group (ECOG) performance status of 3–4 [42, 43]. After the fistula has been successfully sealed, reopening occurs in 0–39 % of patients [39–42]. In most cases, reopening can be managed endoscopically by repositioning the SEMS or by placement of an additional SEMS [41, 42]. Airway stenting may be considered in addition to esophageal SEMS placement to improve the success rate and prevent airway obstruction [44–47].

The outcomes of SEMS placement have been compared with other treatment strategies in two retrospective studies [37, 38]. Chen et al. reported on the outcomes of SEMS placement (n = 30) versus feeding gastrostomy/jejunostomy (n = 35) and found SEMS placement to be associated with an improved overall survival [37]. In a study by Hu et al., the outcomes of SEMS placement (n = 17) were compared with gastrostomy (n = 9) and best supportive care (n = 9) [38]. The median survival was comparable among the treatment arms. Patients who underwent SEMS placement had favorable quality of life outcomes on several subscales, including eating and respiratory problems.

3.4 Bridge to surgery

RECOMMENDATION

ESGE does not recommend SEMS placement as a bridge to surgery or before preoperative chemoradiotherapy because it is associated with a high incidence of adverse events. Other options such as feeding tube placement are preferable.

Strong recommendation, low quality evidence.

Neoadjuvant therapy followed by surgery is the current clinical standard for treatment with curative intent for esophageal cancer [48, 49]. Malnutrition and cachexia – common in esophageal cancer patients – are known risk factors for treatment-related adverse events and poor survival [50–52]. From this perspective, the European Society of Parenteral and Enteral Nutrition (ESPEN) recommends regular assessment of a patient's nutritional status [53]. Initial screening can be performed by assessment of nutritional intake, weight change, and body mass index. Nutritional support is strongly recommended for patients at severe nutritional risk, defined as more than 10 %–15 % weight loss in the previous 6 months [54, 55].

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Esophageal stents have been used to improve nutritional status before neoadjuvant therapy and surgery. In a meta-analysis of nine studies (5 SEPS, 3 SEMS, 1 SEPS + SEMS), the outcomes of 180 patients undergoing stent placement prior to or during neoadjuvant therapy were pooled [56]. Stent placement was technically successful in 95 % of patients, with a statistically significant improvement in dysphagia symptoms, but without improvement in weight or serum albumin levels. Stent migration and chest discomfort occurred in 32 % and 51 % of patients, respectively. The relatively high rate of stent migration in this setting has been attributed to neoadjuvant therapy-induced tumor shrinkage, as most of these patients do not require repeated intervention [56, 57]. To overcome the substantial risk of adverse events, van den Berg et al. investigated the outcomes of BDS placement in 10 patients scheduled to undergo neoadjuvant chemoradiotherapy [58]. A statistically significant decrease in dysphagia symptoms occurred without any major adverse events. Nevertheless, 7 of 10 patients required additional nutritional support and median weight loss before surgery was 5.4 kg.

In the past, SEMS placement before surgery has been reported to be associated with a worse oncologic outcome with a lower rate of R0 resections, a higher rate of major adverse events, and decreased overall survival [59, 60]. Contrarily, recent studies have reported no difference in R0 resection rate, overall survival, and postoperative complications [61–63].

Alternatives to esophageal stent placement include oral nutritional supplements, nasogastric tube placement, percutaneous feeding tube placement, and parenteral nutrition. In general, the use of percutaneous feeding tube placement (i. e. percutaneous endoscopic gastrostomy or endoscopic jejunostomy) is recommended when enteral feeding is expected to be continued for at least 4 weeks [64–66]. In surgical candidates, percutaneous endoscopic gastrostomy is considered by some surgical teams to be a contraindication as it may compromise the construction of a gastric conduit created during distal esophageal/proximal stomach reconstruction.

3.5 Combined approach

RECOMMENDATION
ESGE does not recommend the concurrent use of radiotherapy if an esophageal stent is present.
Strong recommendation, low quality evidence.

RECOMMENDATION
ESGE suggests that SEMS placement with concurrent single-dose brachytherapy is safe and effective for relief of dysphagia.
Weak recommendation, low quality evidence.

To improve the outcome of stent placement, the use of radiotherapy in addition to SEMS placement has been investigated. This combined approach may potentially lead to prolonged dysphagia relief and improved overall survival [67–70]. Nevertheless, a high risk of major adverse events has been reported for the combination of EBRT and stent placement, suggesting stent placement is better reserved for patients who have failed prior radiotherapy [71].

In contrast to EBRT, the combination of single-dose brachytherapy and SEMS placement is safe and effective [67]. The use of irradiated SEMSs has been a topic of interest that potentially provides an advantage of combining the benefits of SEMS placement and brachytherapy. Based on a meta-analysis of six RCTs, the use of irradiated SEMSs led to an increased dysphagia-free time compared with traditional SEMSs, without affecting the rate of adverse events [72]. To date, however, all of these studies have been performed in Chinese populations, thereby warranting (prospective) evaluation in Western populations.

Only one study has investigated the outcomes of single-dose brachytherapy in addition to BDS placement [68]. Although satisfactory relief of symptoms was achieved, an unacceptably high rate of major adverse events was observed, which necessitated premature study termination.

3.6 Prior palliative therapy

In patients with recurrent dysphagia after first-line palliative radiotherapy, SEMS placement is considered the main treatment [73]. However, the association between prior palliative therapy and stent-related adverse events remains controversial. Several studies have reported that prior chemotherapy and/or radiotherapy increase the risk of life-threatening adverse events after SEMS placement, whereas other studies have shown the risk of adverse events to be unaffected [29, 34, 74–82]. Pneumonia, fistula formation, and stent-related pain may be increased in patients with prior therapy who receive stents [29, 34, 80–82].

The increased risk of adverse events has been explained by pulmonary toxicity and radiation-induced changes, which increase the susceptibility to pressure necrosis [29, 79, 81–85]. The potential role of radiotherapy-induced changes is supported by the increase in the rate of adverse events with a corresponding increase in radiation dosage [82, 83]. Regardless, the increased adverse event rate may also be partially explained by advanced disease stage, which is known to be related to an increased risk of life-threatening bleeding and fistula formation [34, 79].

4 Benign disease

4.1 Refractory benign esophageal strictures

RECOMMENDATION
ESGE recommends against the use of SEMSs as first-line therapy for the management of benign esophageal strictures because of the potential for adverse events, the availability of alternative therapies, and their cost.
Strong recommendation, low quality evidence.

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RECOMMENDATION
ESGE suggests consideration of temporary placement of self-expandable stents for refractory benign esophageal strictures.
Weak recommendation, moderate quality evidence.

RECOMMENDATION
ESGE suggests that fully covered SEMS fixation by endoscopic suturing or over-the-scope clips be considered in patients with previous stent migration.
Weak recommendation, low quality evidence.

The use of esophageal stents for the treatment of benign esophageal strictures has mainly been investigated in the context of refractory or recurrent benign esophageal strictures (RBESs; **Table 3s**). As defined by Kochman et al., these patients either fail to reach a target diameter of 14 mm after biweekly dilations over 5 weeks or fail to maintain the target diameter up to 4 weeks after the last dilation [86]. Esophageal stent placement has a potential benefit because of its continuous expansion force, which may lead to stricture remodeling. Although stent placement has not been compared with dilation in treatment-naïve patients, it is generally accepted that esophageal stent placement should only be considered as a second-line approach owing to its relatively high rate of adverse events and its cost.

In a recent meta-analysis, the outcomes of 18 studies with a total of 444 patients were pooled [87]. The clinical success rate after stent placement was 40.5 % (95 % confidence interval [CI] 31.5 %–49.5 %). Stent migration was the most common stent-related adverse event, occurring in 28.6 % (95 %CI 21.9 %–37.1 %). Other adverse events occurred in 20.6 % (95 %CI 15.3 %–28.1 %). Treatment outcomes did not differ among the SEMS, SEPS, and BDS groups.

To reduce the risk of SEMS migration, endoscopic stent fixation by endoscopic suturing or over-the-stent clips has been investigated (**Table 4s**). In general, endoscopic stent fixation is highly successful (96.7 %; 95 %CI 92.3 %–98.6 %) and safe (procedure-related adverse events, 3.7 %; 95 %CI 1.6 %–8.2 %) [88]. In the largest study of RBES patients, endoscopic suturing of the FCSEMS led to a reduction in stent migration rate compared with no suturing (9.4 % vs. 39.5 %; $P = 0.01$) [89]. It remains unclear if there is a benefit of routine stent fixation, and it may be considered in patients with prior stent migration.

Another method to reduce the risk of stent migration is the use of lumen-apposing metal stents (LAMSs). It is believed that the typical wide flanges and short lengths of LAMSs may prevent stent migration. To date, LAMSs have only been investigated in mixed study populations restricted by small sample sizes [90–94]. More studies are needed to evaluate their potential benefit in RBES patients.

4.1.1 Factors predicting successful treatment

RECOMMENDATION
ESGE does not recommend permanent stent placement for refractory benign esophageal stricture; stents should usually be removed at a maximum of 3 months following insertion.
Strong recommendation, low quality evidence.

RECOMMENDATION
ESGE suggests that fully covered SEMSs be preferred over partially covered SEMSs for the treatment of refractory benign esophageal strictures because of their very low risk of embedment and ease of removability.
Weak recommendation, low quality evidence.

RECOMMENDATION
ESGE does not recommend the use of biodegradable stents over SEMSs in the treatment of benign esophageal strictures.
Strong recommendation, low quality evidence.

RECOMMENDATION
ESGE recommends the stent-in-stent technique to remove partially covered SEMSs that are embedded in the esophageal wall.
Strong recommendation, low quality evidence.

The current literature provides some evidence that patient characteristics affect outcomes following stent placement in RBES patients. The previously mentioned meta-analysis showed a tendency toward a higher clinical success rate in studies that included a larger proportion of patients with radiotherapy-induced strictures and anastomotic strictures [87]. A similar trend was observed for the risk of stent-related adverse events, with the risk seeming to be lower in anastomotic strictures compared with other etiologies. In addition to stricture etiology, cervical stricture location and increasing stricture length have been reported to be associated with lower clinical success rates [95–97]. Because most studies do not take into account patient characteristics when reporting study outcomes, their specific impact remains unclear.

The optimal stent duration for the management of RBES patients has not been formally tested. It is recommended that stents remain in place for at least 6–8 weeks, but not longer than 10–12 weeks after stent placement. It is believed that this stent duration provides sufficient time to induce stricture remodeling and at the same time prevents stent embedment. One retrospective study investigated the influence of stent duration on the safety of stent removal but found no such association [98]. Stent design was the only independent predictor

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of complicated stent removal. Adverse events were more common with PCSEMSs (odds ratio [OR] 8.83; 95 %CI 3.29–23.70) and SEPSs (OR 4.71; 95 %CI 1.39–15.97) when compared with FCSEMSs. The use of BDSs has been suggested to obviate stent removal, but compelling evidence for BDSs over other stent types is lacking [96, 99].

Different methods for endoscopic removal of an embedded PCSEMS have been described [100–106]. Most studies have reported on the use of the stent-in-stent technique, which relies on the placement of an additional FCSEMS fully overlapping the location of the embedded PCSEMS. To induce pressure necrosis, the stent diameter of the additional FCSEMS should be at least that of the embedded PCSEMS. In >90 % of patients, both SEMSs can be safely removed 10–14 days after placement of the additional FCSEMS [100, 101]. If removal of the embedded PCSEMS is unsuccessful, the stent-in-stent technique can be reattempted.

4.1.2 Combined approach

RECOMMENDATION

ESGE suggests that a combined approach of stent placement with additional techniques (e. g. corticosteroid injection, chemotherapeutic topical application) should not be undertaken in an attempt to improve the long-term benefit of temporary stenting.

Weak recommendation, very low quality evidence.

Concurrent endoscopic incisional therapy, corticosteroid injection, and mitomycin-C application are reported to enhance treatment outcomes of endoscopic dilation therapy. Data on the use of these endoscopic interventions in combination with esophageal stent placement are scarce. Only one study has reported on the outcomes of corticosteroid injection in combination with FCSEMS placement but no clear benefit was found [107].

4.1.3 Options after stent failure

RECOMMENDATION

ESGE suggests alternative treatment strategies such as self-dilation or surgical treatment for patients with refractory benign esophageal strictures that have not satisfactorily improved after two separate treatments with temporary stenting.

Weak recommendation, low quality evidence.

RECOMMENDATION

In poor surgical candidates, ESGE recommends self-dilation with rigid dilators.

Strong recommendation, low quality evidence.

In patients with recurrent dysphagia after stent placement, repeated esophageal stent placement may be considered, but has not been shown to have significant incremental benefit [108, 109]. When repeat esophageal stent placement does not lead to satisfactory results, alternative treatment strategies should be considered. Surgical treatment represents a valid option in selected patients, depending on the stricture location and patient performance status. Furthermore, self-dilation is safe and effective in the majority of patients [110–112]. Treatment success with self-dilation relies on patient compliance, restricting its use to self-motivated patients and poor surgical candidates.

4.2 Leaks, fistulas, and perforations

RECOMMENDATION

ESGE recommends that temporary stent placement can be considered for the treatment of leaks, fistulas, and perforations. No specific type of stent can be recommended, and the duration of stenting should be individualized.

Strong recommendation, low quality of evidence.

RECOMMENDATION

ESGE recommends esophageal stents be placed as early as possible for the treatment of leaks, fistulas, and perforations.

Strong recommendation, moderate quality evidence.

RECOMMENDATION

ESGE recommends including stent placement in a multimodality treatment protocol for leaks, fistulas, and perforations to optimize the healing success rate and minimize the risk of adverse events.

Strong recommendation, low quality evidence.

Esophageal stents are increasingly used in the management of esophageal perforations [113]. Based on three systematic reviews on the use of PCSEMSs, FCSEMSs, and SEPSs in anastomotic leaks and perforations, the clinical success rate of esophageal stent placement is 81 %–87 %, with no difference among the stent types [114–116]. Even though the clinical success rates are comparable, SEMSs are reported to perform better than SEPSs in leaks and perforations, with higher technical success (95 % vs. 91 %; P =0.03), and reduced risk of migration (16 % vs. 24 %; P=0.001) and stent repositioning (3 % vs. 11 %; P<0.001), as well as a reduced risk of perforation when considering anastomotic leaks only (0 % vs. 2 %; P=0.01) [116]. Data on the use of BDSs in these patients are restricted to a few small retrospective studies (**Table 5s**) [117–119].

To identify patients who may benefit from esophageal stent placement, van Halsema et al. developed a clinical prediction

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rule based on four clinical parameters: etiology (leak, fistula, perforation), location, orifice size, and C-reactive protein (CRP) level [120]. In the validation cohort, the sensitivity and specificity for a 70 % predicted probability of clinical success were 33 % and 89 %, respectively. Multivariable logistic regression showed fistulas and orifice size of >2 cm to be associated with a lower rate of clinical success. The observed difference between anastomotic leaks and fistulas emphasizes that leaks, fistulas, and perforations are different entities and may require an individual approach. For instance, in fistula patients, SEMS placement is usually performed in combination with other therapies and a longer stent duration may be needed in anastomotic leaks compared with perforations [121, 122]. Nevertheless, the current literature provides insufficient data to formulate separate recommendations.

No study has investigated the optimal stent duration. Stents are usually removed 6–8 weeks after insertion and repeated stent placement is needed in 11 % of patients [114–116]. In patients who are endoscopically treated for benign esophageal perforations, early diagnosis (<24 hours) has been shown to be associated with a lower need for re-intervention and intensive care admission, and a shorter hospital stay [123].

Recently, the outcomes of SEMS placement have been compared with endoscopic vacuum therapy for the treatment of post-surgical leaks [124]. The use of endoscopic vacuum therapy was associated with a higher leak closure rate, more endoscopic device changes, shorter duration of treatment, and lower in-hospital mortality. Because the management of these patients may be challenging and often requires a multimodality approach, esophageal stent placement may still be considered in addition to other endoscopic techniques to optimize treatment outcomes [119].

4.2.1 Safety

Stent migration is the most common stent-related adverse event and tends to be higher when FCSEMSs (26 %) and SEPSs are used (31 %) compared with PCSEMSs (12 %) [114]. The use of large-diameter SEMSs has been suggested to reduce the risk of stent migration in anastomotic leaks [119]. Furthermore, suturing of FCSEMSs may render migration rates similar to those of PCSEMSs, without the difficulties associated with the removal of PCSEMSs and with a lower risk of adverse events [125]. Other stent-related adverse events include the development of a stricture, stent erosion, perforation, and bleeding [114–116]. Repeated endoscopic intervention is needed in 17 %–25 % of patients and 7 %–13 % require surgical intervention [114–116].

4.3 Acute variceal bleeding

RECOMMENDATION

ESGE recommends considering placement of a fully covered large-diameter SEMS for the treatment of esophageal variceal bleeding refractory to medical, endoscopic, and/or radiological therapy, or as initial therapy for patients with massive bleeding.

Strong recommendation, moderate quality evidence.

Esophageal stent placement for acute variceal bleeding has mainly been investigated in small retrospective studies using a dedicated stent design (SX-ELLA stent DANIS) for the treatment of refractory bleeding (**Table 6s**). Stent duration is reported to range from 1–30 days [126]. Pooled data analysis shows that SEMS placement leads to control of bleeding in >80 % of patients, without severe stent-related adverse events [126, 127]. In 21 % of patients, bleeding reoccurs within 6 weeks after SEMS placement [128]. Only one RCT has performed a direct comparison of SEMSs and balloon tamponade [129]. In this study of 28 patients, SEMS placement led to a higher rate of control of bleeding during the first 15 days (85 % vs. 47 %; P = 0.04) and a lower rate of adverse events (31 % vs. 73 %; P = 0.02).

Despite its effectiveness, the 30-day mortality rate after SEMS placement may be as high as 36 %, also reflecting the severity of the underlying condition [127]. Accordingly, SEMSs have been proposed as a bridge to transjugular intrahepatic portosystemic shunting (TIPS) or liver transplantation.

Disclaimer

The legal disclaimer for ESGE guidelines [130] applies to this Guideline.

Acknowledgments

The authors are grateful to Dr. Cesare Hassan, Nuovo Regina Margherita Hospital, Rome, Italy, and Professor Konstantinos Triantafyllou, National and Kapodistrian University of Athens, Athens, Greece, for their review of this manuscript; and for comments received from Dr. David Karsenti on behalf of the French Society of Digestive Endoscopy (SFED), Dr. Tony C. K. Tham on behalf of the Irish Society of Gastroenterology (ISG), and Dr. Endrit Shahini, University of Bari Aldo Moro, Bari, Italy.

Competing interests

T.H. Baron has been a speaker and consultant for Boston Scientific and Cook Endoscopy (2014 to present). A. Repici has been on the advisory board and provided consultancy to Boston Scientific and Medtronic, and provided consultancy to ERBE (all 2017 to present). P.D. Siersema receives research support from Pentax, The eNose company, Norgine, Motus GI, and MicroTech; he is Editor-in-Chief of Endoscopy. M.C.W. Spaander has received research support from Boston Scientific (2013 to present). J.E. van Hooft has provided consultancy to Boston Scientific (2014 to 2017) and Olympus (2021), has received lecture fees from Medtronics (2014, 2015, and 2019) and Cook Medical (2019); her department has received research grants from Cook Medical (2014 to 2019) and Abbott (2014 to 2017). D. Albers, D. Blero, M. Conio, L. Czakó, A. de Ceglie, S. Everett, L. Fuccio, J.-C. Garcia-Pagán, A. Ginès, M. Jovani, E. Rodrigues-Pinto, R.D. van der Bogt declare that they have no conflict of interest.

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