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Esophageal strictures, tumors, and fistulae: alternative techniques for palliating primary esophageal cancer

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Of all nonstent modalities available for palliating esophageal cancer, brachytherapy with or without external beam radiation therapy is the best modality, providing a survival benefit with a better quality of life in the long-term compared with stent placement. Both stent placement and brachytherapy provide comparable palliation to endoscopic chemical ablative therapy but are preferable because of the reduced requirement for reintervention. Other available modalities, such as laser therapy, photodynamic therapy, or chemical ablation, are not recommended for palliation of dysphagia because of a high incidence of complications and recurrent dysphagia.

The incidence of esophageal cancer has risen markedly over the past 3 decades in the Western world because of a marked increase in the incidence of adenocarcinoma.[1,2] The prognosis of esophageal cancer is poor, with a 5-year survival rate of 10% (United States) and 16% (Europe).[3] Surgical resection with or without neoadjuvant chemotherapy or chemoradiation is currently the primary treatment for esophageal cancer if the patient is fit enough to undergo surgery and the tumor is considered resectable without evidence of distant metastases.[4]

Because the tumor is often asymptomatic in the early stages, more than 50% of patients are diagnosed at an advanced stage, involving locally unresectable disease or distant metastases. A subgroup of patients includes patients with locally unresectable tumors (T4N0-1M0-Ia), who are in a good general condition, or patients who refuse surgery. For these patients, a definitive treatment schedule of chemotherapy or chemoradiation may be beneficial.[5]

Unfortunately, most patients with inoperable disease have metastases or a poor medical condition. Median survival of these patients is approximately 5-6 months, and in most, a palliative treatment is warranted to restore or maintain the ability to eat. There is a wide range of palliative treatment modalities available to relieve dysphagia in patients with inoperable esophageal cancer (Table 1). These include mechanical measures, such as dilation, stent placement, and surgery, and antineoplastic methods, such as radiation therapy (external beam radiation therapy [EBRT], intraluminal radiotherapy [brachytherapy], or combined), laser therapy, photodynamic therapy (PDT), chemical ablation using injection of alcohol or chemotherapeutic agents, and nutritional support.

The optimal treatment for dysphagia caused by advanced primary esophageal cancer is not established, although continued progress is ongoing to achieve this goal. Worldwide, most patients are palliated with stents. In this review, we will report the efficacy of nonstent, palliative modalities (Table 1) that are used for the palliation of dysphagia in patients with primary esophageal cancer.

Nonstent palliative modalities

Dilation

Pros

- Easy to perform
- Cheap, especially when bougies are used

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Table 1 Palliative treatment modalities for treating dysphagia from esophageal cancer

Modality	
Mechanical methods	Antineoplastic methods
Dilation	Radiation therapy
Stent placement	external beam radiotherapy (EBRT)
Surgery	intraluminal radiotherapy (brachytherapy)
	Combined EBRT + brachytherapy
	Nd:YAG laser therapy
	Photodynamic therapy
	Chemical ablation with alcohol or chemotherapeutic agents
	Nutritional support
	Nasoenteral feeding tube
	Percutaneous endoscopic gastrostomy (PEG)

Cons

- Repeat treatment sessions are necessary within 2-4 weeks
- Risk of perforation

Dilation can relieve dysphagia temporarily, but it often provides palliation for only a few days and up to 4 weeks.[6] It is sometimes used to allow access through the tumor for different forms of palliative treatments such as stent placement. Dilation is a simple and cheap method, but complications, including perforation and hemorrhage, occur and are reported in up to 10% of patients.

Some authors advocate systematically increasing dilation of a malignant stricture over several sessions; however, scientific evidence for this is lacking. The most commonly used dilators are polyvinyl wire-guided bougies, the most common of which are Savary–Gilliard dilators (Figure 1) and through-the-scope hydrostatic balloons. There is no study comparing these dilators in patients with malignant strictures and demonstrating a benefit of either method.

Because dilation as a sole therapy must be repeated at frequent (1- to 4-week) intervals, it should only be performed in patients with a very short life span in whom stent placement may not be considered cost-effective.

Brachytherapy

Pros

- Long-term effectiveness
- Relatively low complication rate

Cons

- Up to 15% persistent dysphagia after treatment
- Long-term effectiveness (ie, improvement of dysphagia) in approximately 50% of patients in single-arm retrospective series
- No short-term (<1 month) benefit

In 1980, brachytherapy was introduced as a boost after EBRT for the treatment of esophageal squamous cell carcinoma. Five years later, brachytherapy as a single treatment was reported to be effective for the palliation of dysphagia from inoperable esophageal cancer.[7] The most commonly used radioactive source is iridium (^{192}Ir). Brachytherapy is increasingly being delivered at a high dose rate with a dose of 12 Gy or more per hour. This regimen substantially reduces treatment time compared with previous schedules and can be performed as an outpatient procedure. Several studies have used brachytherapy as a single treatment using a dose of 7.5-20 Gy in 1-3 fractions.[8]

Dysphagia improvement has been reported in 50% of patients. The complication rate after single-dose brachytherapy is low (20%) and mainly consists of fistula formation, mild retrosternal pain, and radiation esophagitis. Persistent/recurrent dysphagia following single-dose brachytherapy is most commonly caused by tumor persistence (15%), tumor recurrence (35%), and benign stricture formation (5%).[9]

Proven effective brachytherapy strategies are 12 Gy given in 1 fraction, 16 Gy given in 2 fractions, or 21 Gy given in 3 fractions, although future studies are warranted to optimize the treatment strategy.[8]

Neodymium yttrium–aluminum–garnet (Nd:YAG) laser therapy

Pros

- Low complication rate (only in experienced hands!)
- Preferable for exophytic tumors

Cons

- Technically difficult to perform
- Expensive

Figure 1 Increasing sizes (top to down) of Savary–Gilliard dilators that can be used to dilate a malignant or benign esophageal stricture. These dilators are usually advanced over a stiff guidewire (0.038 inch). (Color version of figure is available online at www.techgiendoscopy.com).

- Repeated treatment sessions necessary every 4-6 weeks
- Risk of perforation in submucosal tumors, tumors with extrinsic compression, and angulated tumors

Treatment of obstructing esophageal cancer with the high-power Nd:YAG laser is another relatively safe but often temporary palliation of dysphagia. Tumors that are relatively short (<6 cm), exophytic, and located in the mid-esophagus are most amenable to laser ablation. Laser treatment is unsafe for submucosal tumors, tumors causing extrinsic compression, and angulated tumors, whereas circumferential tumors are vulnerable to stricture formation. It is less effective for cancer of the proximal esophagus or gastroesophageal junction.[6,10]

Dysphagia improvement is significant (ie, 35%-80% of patients are able to eat solids starting a few days after the procedure). However, many patients (70%-95%) require more than 1 treatment session. Therefore, patients are usually reassessed at 4- to 6-week intervals. Complications include perforation and to a lesser extent fistula formation, hemorrhage, and sepsis in 5%-10% of patients. The complication rate increases in nonexperienced hands.[10] Moreover, laser equipment is expensive and the equipment is usually large.

Photodynamic therapy

Pros

- Technically easier and less operator dependent than Nd:YAG laser

Cons

- Expensive
- Skin photosensitivity for a prolonged period
- Repeated treatment session necessary after 8 weeks

PDT involves the local destruction of tumor tissue using the light of a specific wavelength activating a previously administered photosensitizer, which is retained in malignant tissue. Porphyrin compounds, such as porfimer sodium (Photofrin), have been the most commonly used photosensitizers for the palliation of malignant dysphagia. Clinical experience with PDT for palliation of malignant dysphagia is limited to a few centers in western Europe, Canada, and the United States. One or two treatment sessions are usually required for an adequate tumor response. The most frequent complication is prolonged skin photosensitivity. Patients must avoid direct sunlight for a period of 4 to 6 weeks after treatment.[6,11]

Dysphagia improvement is seen in 40%-70% of patients; however, because of recurrent tumor growth, treatment must be repeated every 6-8 weeks. Major complications, including perforation, fistula formation, and (benign) strictures, have been reported in up to 30% of patients. Other side effects include fever, chest pain, and pleural effusion, probably secondary to a transient, local inflammation, but the latter adverse effects are usually mild.[11]

The costs of PDT are high because of the high costs of a special laser unit and those of Photofrin.

Chemical injection therapy

Pros

- Easy to perform
- Cheap, depending on injection fluid used

Cons

- Treatment effect is unpredictable and depends on local factors, such as tumor characteristics (firm/fibrotic vs loose) and spreading of injection fluid into the surrounding tissue
- Repeated treatment session necessary at 4- to 6-week intervals

Chemical injection therapy for the treatment of malignant dysphagia is an inexpensive alternative requiring no special equipment. Ethanol or polidocanol in aliquots of 0.5-1 mL is injected into the tumor, leading to tumor necrosis within several days after therapy. Some anecdotal experience has reported the use of chemotherapeutic agents.[6] Exophytic tumors are most amenable to injection therapy, whereas firm and fibrotic tumors (after radiotherapy) prove difficult to inject.

Dysphagia improvement is seen in 80%-90% of patients. Complications are rare but only a few studies have been reported, with fistula formation (n = 2), perforation (n = 1), and mediastinitis (n = 1) as the major ones.[6] In general, 2 sessions were necessary to obtain a maximum effect and retreatment was necessary at 4- to 6-week intervals. The main disadvantage is that the treatment effect cannot be predicted, for example, in chemical injection therapy, where there is a risk of unwanted complications, such as perforation and fistula formation.[6]

Nutritional support

Pros

- Escape treatment when other palliative treatments fail or are technically not possible and survival of patients is at most 4-6 weeks

Cons

- Difficult to decide when to stop nutritional support in end-stage esophageal cancer

When different palliative therapies fail (stent placement has no effect) or when other palliative modalities are technically not possible, nutritional support to maintain adequate calorie intake can be considered. The overall condition and the prognosis of the patient should be considered before nutritional support is offered to a patient. Furthermore, tumor-induced cachexia may not respond to forced nutritional intake. Placement of a nasoenteral feeding tube is the easiest and least invasive feeding method. Maintaining the position of an endoscopically placed nasoenteral feeding tube beyond the pylorus is often problematic because of retrograde migration. Fixation of a feeding tube to the small intestinal wall with an Endoclip may prevent this (Figure 2).[12] For some patients with a longer life expectancy, placement of a

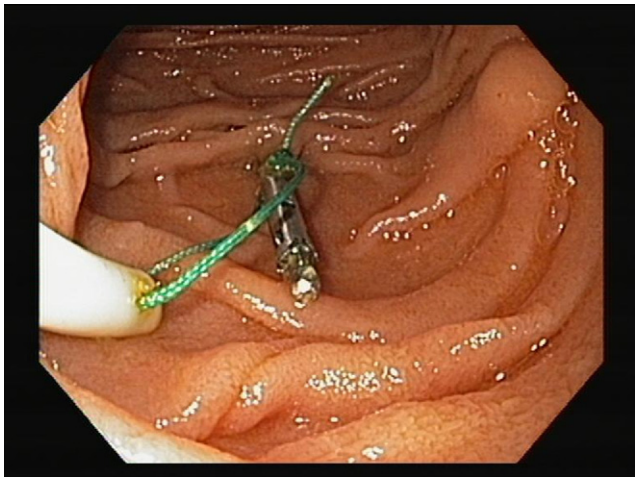

Figure 2 Fixation of a nasoenteral feeding tube to the wall of the duodenum with an Endoclip in an effort to prevent retrograde migration of the tube. (Color version of figure is available online at www.techgiendoscopy.com).

percutaneous endoscopic gastrostomy/jejunostomy (PEG/PEJ) is the preferred strategy. Only rarely, central venous alimentation is indicated for maintaining or restoring adequate nutritional status. It can be difficult to decide when to stop nutritional support in end-stage esophageal cancer patients, particularly when quality of life (QoL) is no longer positively affected.[6]

Placement of a PEG using the classic "pull" method through a preexisting esophageal stent or in the presence of a malignancy can be problematic. In these cases, PEG placement without endoscopy using a direct percutaneous catheter insertion technique ("push" method) is indicated.

Comparative studies

Based on the results of various treatment modalities used for the palliation of dysphagia in esophageal cancer, it is difficult to decide what the most optimal treatment is. A physician's experience with a particular palliative method and patient characteristics, such as expected survival, will likely influence treatment choice. In patients with an expected survival <2 weeks, an easy-to-apply treatment, such as dilation, is worthwhile to consider because the relatively high risk of recurrent stenosis is less important in this group. By contrast, in patients with an expected survival >3 months, a prolonged treatment effect, such as that caused by radiation therapy, is important to consider.

In the following, we will summarize some of the published randomized controlled trials (RCTs) related to palliation of malignant dysphagia in which at least 1 nonstent modality was included for comparison. A summary of all published RCTs can be found in a recently published Cochrane review.[13]

Stents versus brachytherapy

Two studies randomized 274 patients to Ultraflex stent (Boston Scientific, Natick, MA) or brachytherapy.[14,15] In the largest of the 2 studies (n = 209), 1 dose (12 Gy) of brachytherapy was delivered,[14] whereas in the other study 3 doses (3 × 7 Gy) in 2-4 weeks were delivered.[15] Both studies included patients with esophageal adenocarcinoma and squamous cell carcinoma.

In the study by Homs et al,[14] dysphagia improved more rapidly after stent placement than after brachytherapy, but long-term relief of dysphagia was better after brachytherapy (Figure 3). Stent placement had more complications than

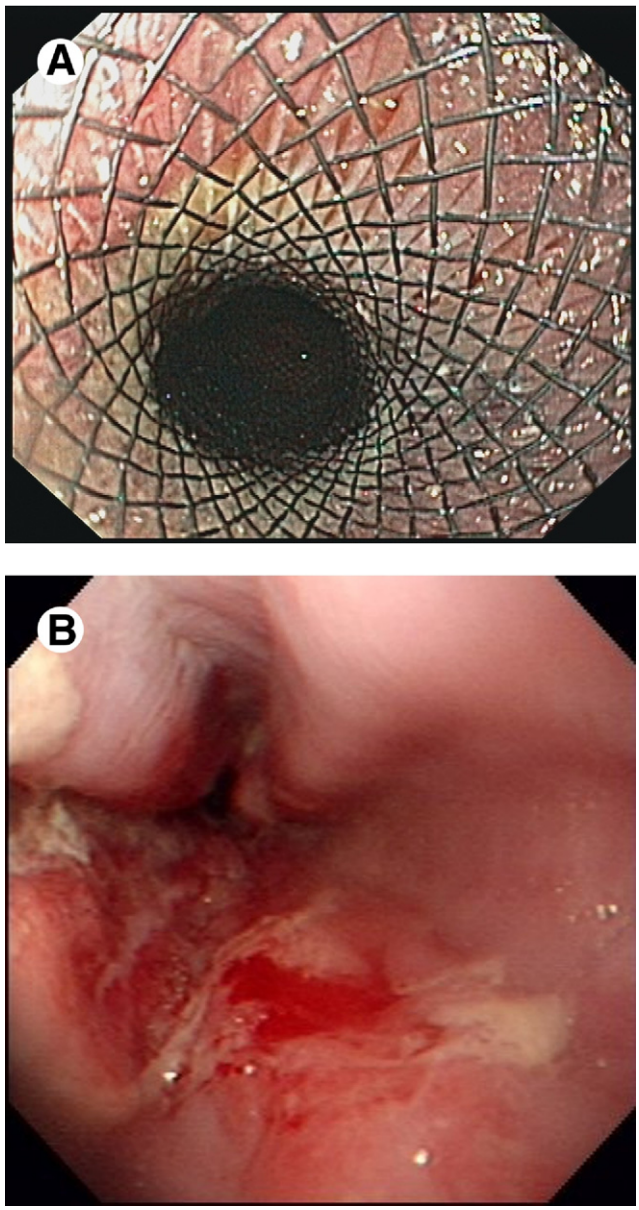

Figure 3 (A) Immediate relief of dysphagia after stent placement. (B) The effect of brachytherapy (as seen here 5 days after treatment) on dysphagia relief takes usually 2-4 weeks. (Color version of figure is available online at www.techgiendoscopy.com).

brachytherapy (36/108 [33%] vs 21/101 [21%]; $P = 0.02$), which was mainly caused by an increased incidence of late bleeding (14 [13%] vs 5 [5%]; $P = 0.05$). The treatments did not differ in persistent or recurrent dysphagia or median survival. QoL after 3 months was in favor of brachytherapy compared with stent placement. Total medical costs were similar for stent placement ($10,348) and brachytherapy ($10,247). In the Bergquist et al study,[15] QoL was the primary endpoint, which was reported in detail. The authors concluded (like Homs et al[14]) that long-term QoL remained more stable in patients treated with brachytherapy compared with those treated with stent placement.

In summary, despite slow improvement, single-dose brachytherapy gives better long-term relief of dysphagia and better QoL, with fewer complications than stent placement.

The Dutch group used their results to develop a prognostic model that could help guiding treatment (ie, stent placement or brachytherapy) in individual patients who had dysphagia from esophageal cancer.[16] A simple score was developed, which included age (increasing age has a worse prognosis), gender (men have a worse prognosis), tumor length (increasing length is associated with a worse prognosis), World Health Organization (WHO) performance score, and presence of metastases (Table 2). A total score based on these factors was used to differentiate among patients with a relatively poor, intermediate, or good prognosis. In the intermediate and good prognostic groups, brachytherapy resulted in better dysphagia-adjusted survival. Alternatively, in the poor prognosis group, the difference in dysphagia-adjusted survival was 23 days in favor of stent placement compared with brachytherapy (77 days vs 54 days). Based on this model, it was recommended that stents should be used in patients with a calculated life expectancy of ≤3 months and that brachytherapy should be reserved for patients with a life expectancy >3 months. Stent placement should also be reserved for patients with persistent or recurrent tumor after brachytherapy.

Table 2 Results of brachytherapy versus stent placement by prognostic risk group

Prognostic group	Brachytherapy	Stent	*P* value
Good (score < 3.5*)			
Median survival (days)	218	189	0.13
Dysphagia-adjusted survival (days)	138	104	0.17
Intermediate (score 3.5-5*)			
Median survival (days)	147	132	0.35
Dysphagia-adjusted survival (days)	98	68	0.09
Poor (score > 5*)			
Median survival (days)	75	90	0.47
Dysphagia-adjusted survival (days)	54	77	0.16

*Score chart for survival with total score of items (a)-(e) determining total score: (a) gender, female, 0; male, 1; (b) age: 40 years, −1; 50 years, −0.5; 60 years, 0; 70 years, 0.5; 80 years, 1; (c) tumor length: >10 cm, 2; (d) metastases: 2; and (e) World Health Organization performance score: score 1, 1; score 2, 2; score 3, 3.

Stents versus laser therapy

Two studies randomized 125 patients.[17,18] Both studies used uncovered Strecker or Ultraflex stents and covered Wallstents of similar diameter. In the Dallal et al study[18] (n = 65), not all patients were treated with Nd:YAG laser therapy; some patients (n = 9) were treated with argon plasma coagulation instead.[18]

Stent placement was successful in all patients; whereas laser therapy was not possible for technical reasons in 7/52 (13.5%) patients (pooled odds ratio [OR] 12.2, 95% confidence interval [CI] 1.40-106.2). Dysphagia improvement was not different between patients treated with a stent or laser therapy (pooled analysis was not possible). Twenty-eight of 73 (38.4%) stented patients and 10/52 (19.2%) patients treated with laser had complications (pooled OR 2.26, 95% CI 0.96-5.33) such as perforation, fistula, bleeding, bolus obstruction, tumor regrowth, and tumor overgrowth. Perforation and fistula formation were only observed in the laser group and bleeding and migration only in the stent group. Persistent or recurrent dysphagia occurred in 18/70 (25.7%) patients with a stent and in 16/52 (30.8%) patients treated with laser therapy (pooled OR 0.67, 95% CI 0.30-1.54) in favor of stent placement. Twenty-five of 73 (34.2%) patients required a reintervention in the stent group and 31/52 (59.6%) patients in the laser group (pooled OR 0.27, 95% CI 0.12–0.60 in favor of stent placement). This was caused by the fact that Adam et al[17] considered all subsequent laser therapies as reinterventions. Repeated laser treatment is required to provide adequate palliation. Dallal et al found a significant increase in median survival for laser therapy (125 days) compared with stent placement (68 days).[18] In that study, QoL at 1 month also indicated that physical function, physical health, pain and emotional health, and cancer-specific questionnaires were significantly worse in patients with a stent compared with those treated with laser.

In summary, improvement of dysphagia and complications and recurrent dysphagia did not differ between stent placement and laser therapy. However, it is evident that some complications are specific for each group. Finally, it is uncertain whether the results regarding overall survival and QoL (in favor of laser therapy) and those regarding technical success and reintervention (in favor of stent placement) can be extrapolated to routine clinical practice.

Other studies comparing stents with other modalities

Six RCTs compared stent placement with various other modalities.[19-24] Comparisons included stent versus esophageal bypass surgery,[19] stent versus stent *plus* laser

therapy versus laser *plus* radiotherapy,[20] stent versus PDT,[21] stent versus EBRT,[22] stent versus stent followed by chemotherapy or chemoradiation,[23] and stent versus rigid plastic tube placement versus nonstent therapy (including EBRT, brachytherapy, thermal ablation therapy, and ethanol tumor necrosis, which were left to the discretion of the treating physicians).[24]

In summary, stent placement is effective and safe and provides rapid relief in the palliation of dysphagia compared with other modalities; importantly, it avoids delays in effectively treating these patients. However, this analysis also demonstrates that other modalities, including brachytherapy and EBRT, may provide a survival advantage and possibly better QoL compared with stent treatment.

Other studies comparing laser therapy with other modalities

Six RCTs compared laser therapy with radiation therapy or laser therapy with laser therapy augmented by radiotherapy.[25-30] Comparisons included laser versus brachytherapy,[25] laser versus laser augmented by EBRT,[26] and laser versus laser augmented by brachytherapy.[27-30]

In addition, laser therapy was also compared with other nonstent modalities (ie, laser vs PDT,[31,32] laser vs rigid plastic tube placement,[33-35] and laser vs chemical ablation).[36,37]

In summary, laser treatment and brachytherapy are comparable in palliating dysphagia in patients with primary esophageal cancer. This analysis provides evidence to support the augmenting effect of EBRT and brachytherapy to laser treatment to improve dysphagia-free interval and reduce recurrent dysphagia. There is equivocal evidence that addition of brachytherapy to laser treatment reduces the need for reintervention. Adding brachytherapy to laser therapy does not improve overall survival and QoL or reduce complications.

Conclusions

The currently available stent and nonstent modalities for the palliation of malignant dysphagia are not yet optimal in achieving fast and sustained dysphagia relief with minimal morbidity and mortality. Of all methods, brachytherapy may be the safest modality given the results on improvement of dysphagia and QoL in the longer term. This is particularly true for patients with a relatively good prognosis.

In the future, combination treatments will likely be increasingly used, especially in patients with a "good" prognosis. In this regard, a combination of a dysphagia-relieving treatment (stent or brachytherapy) with a treatment modality that has an effect on the tumor mass, both local and systemic, such as chemotherapy, EBRT, or, preferably, chemoradiation, is most attractive. These new combinations should be studied in well-designed RCTs that focus on not only dysphagia relief, complications, QoL, and costs, but also survival.

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