

Complications of endoscopic esophageal stent implantation

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Abstract

Endoscopic esophageal stent implantation is an effective method for dysphagia management in malignant esophageal stricture. However, this technology is associated with the risk of many complications, including those fatal to life. These include bleeding, restenosis, stent fragmentation and destruction, stent migration, pneumomediastinum, the formation of esophageal fistulas, perforations, clogging of the stent with food, retrosternal pain, gastroesophageal reflux changes, airway compression, aspiration pneumonia, and fever. The overall complication rate is 36–40%. Mortality rates associated with stenting is between 3.9 and 27.2%. Nevertheless, today there are ways to minimize the incidence of complications due to the constant progress of endoscopic technologies and improvements in the design of modern stents. In addition, most endoscopic interventions can manage the vast majority of complications effectively after stent implantation subject to their early detection. Optimal selection of an esophageal stent and careful selection of patients with a low risk of complications associated with stent implantation are important problems in the prevention of complications to achieve high efficiency of stenting. Evaluation of risk factors for possible complications, the design of stents and their characteristics, as well as using modern methods of effective management of possible complications improves the quality and duration of life in incurable patients with esophageal cancer. The review reflects all possible complications of stenting in esophageal and gastroesophageal junction, factors affecting the occurrence of complications, as well as modern and effective methods of their correction and prevention.

Keywords: endoscopic stenting, self-expandable metallic stents, dysphagia, esophageal anastomosis, stent complications.

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Implantation of esophageal stents can quickly and effectively eliminate dysphagia in patients with esophageal cancer. Several randomized controlled trials demonstrated that stenting can resolve dysphagia in incurable patients better than photodynamic and laser therapy. In most cases, stent implantation in malignant stenosis can reduce the severity of dysphagia by 2 points within 1–2 days [1,2].

However, stenting bears a risk of serious complications, including hemorrhage, restenosis, fragmentation, migration, and destruction of the stent, pneumomediastinum, esophageal fistulas, perforations, stent obstruction with food masses, retrosternal pain, gastroesophageal reflux changes, airway compression, aspiration pneumonia, and fever [3–5]. The overall complication rate is 36%–40% [6].

Complications associated with stenting are divided into early and late ones. Early complications, such as pain, fever, bleeding, gastroesophageal reflux, perforation, and stent migration, occur during stent implantation or within 2 weeks after the procedure [7,8]. Compared with early complications, late complications, such as dysphagia relapse, stent migration, stent overgrowth with granulation tissues, stent obstruction with food masses, and esophageal fistulas, are more common and occur 2 weeks or even months after the stent placement [9]. Meanwhile, the incidence of early complications decreases significantly because of the gradual progress of stent designs and delivery systems; late complications still occur with an incidence of up to 65% of the total number of complications, with the

incidence of endoscopic re-intervention reaching 50% [5].

Complications after stenting can also be classified as more serious (perforation, fistulas, hemorrhage) and minor (migration, esophagus overgrowth with granulations, stent obstruction with food) ones [5]. Serious complications, such as hemorrhage, perforation, esophageal fistula, and aspiration pneumonia, occur in 22% of all complications [6]. The mortality rates associated with stenting range from 3.9% to 27.2% [1, 10, 11]. In some cases, death soon after stent placement is often closely related to the development of respiratory complications [6].

In this regard, prevention of complications and careful selection of patients with a low risk of complications associated with stent implantation are extremely important. Endoscopic reinterventions could be performed to cope effectively with the vast majority of complications [12], provided they are detected early [13].

Stent migration. Stent migration is the most common among early and late complications, with a wide frequency range of 7%–75% [14]. Stenting is still accompanied with a high rate of stent migration, regardless of the improvement in the design of self-expandable metallic stents (SEMS) [15, 16]. In a meta-analysis of 18 studies with 444 patients, stent migration was registered in 29% of patients with benign strictures [17]. Stent migration in malignant esophageal stenosis occurs with a frequency of 23%–31% [7, 18]. In some clinical situations, stent migration may reflect the positive effect of the treatment, such as resolution of benign stenosis or regression of malignant stricture during chemoradiotherapy [18]. In all other situations, migration is considered a failure of stenting [19].

Partially covered self-expandable metallic stents (PSEMS) are associated with a low migration rate of 9%–31% [20, 21]. By contrast, the migration rate of full covered self-expandable metallic stents (FSEMS) reaches 26%–36% [22, 23]. These results are consistent with a randomized study by H. Lee, who found statistically significant differences in the frequency of stent migration between PSEMS and FSEMS in malignant esophageal stenosis (7.1% versus 37.8%) [24].

Stent reimplantation is an effective way to resolve stent migration [13]. Stent repositioning is also an effective alternative to stent reimplantation because of its economic component and relative simplicity [13]. Stent replacement is indicated in cases of the degree of its migration and the peculiarities of clinical symptoms (relapse of dysphagia, pain syndrome), which do not allow the stent to perform its primary function [19].

In general, most stents do not migrate beyond the stomach, thereby preventing serious complications. However, the small intestine can be perforated in rare situations. Previous studies described six cases of this complication resulting from the migration of an esophageal stent [25–27].

According to international authors, stent migration has risk factors. One of them is the anatomical area of stenting [28]. Stenting of carcinoma of the esophagogastric junction has its special characteristics and a high incidence of complications. Stent migration is the most common complication in such cases. This situation is due to the fact that the stent can be retained only in the lower third of the esophagus, while its distal part is freely located in the lumen of the stomach [29, 30]. However, some authors did not reveal statistical significance in such conclusions in their studies [31].

Another factor contributing to the migration of esophageal stents is the achieved clinical effect of chemoradiation therapy [31, 32].

The risk of migration may also be associated with specific models and characteristics of implantable stents [33]. Recent studies have shown promising results with the use of special stents with anti-migration double covers and wide proximal flanges [16]. However, these results have not been equally successful in other studies [34, 35].

The proximal stent diameter may be significant in preventing migration [29]. In a randomized trial, P.D. Siersma et al. noted that 12 out of 13 migrations were associated with a small stent diameter, and only 1 migration occurred in a stent with a wide diameter [36]. However, a wide stent diameter increases the incidence of perforation and hemorrhage [36, 37]. Thus, information on the effect of the diameter and anti-migration properties of the stent is currently limited to a small sample of reports and requires further evaluation.

A common misconception is that SEMS migration rarely occurs in the presence of stenotic esophageal disease due to malignant neoplasms. In patients with malignant stenosis, which allows passage of a standard gastroscop, the risk of stent migration is significantly high [15].

However, neither the size and location of the tumor, the type of stent, nor the occurrence of complications is a predictor of short life expectancy in malignant esophageal and gastroesophageal junction stenosis. However, this thesis is also limited by the small size of the study sample [29].

In an attempt to prevent FSEMS migration, various methods have been developed, such as stent fixation with endoscopic clips and endoscopic suturing using a special Overstitch suturing device [15]. In such situations, clips are placed on

the proximal end of the stent and fixed behind the esophagus wall. However, retrospective analysis of cases continues to show high migration rates in the range of 13%–17% [38–40]. The use of stent fixation using the Overstitch device provides a significantly higher migration resistance compared with clipping and placement of the stent without fixation [41].

The claimed technical success of endoscopic suturing of the stent beyond the proximal margin is 92.3%–100% with an average stent fixation time of 12.5 min [42–45]. In addition, endoscopic suturing is effective in patients with a history of stent migration, with a success rate of 95% [46].

Thus, stent fixation should be considered on an individual basis in patients with malignant dysphagia, in whom an endoscope with a standard diameter is advanced through the esophageal lumen, patients who have received or are receiving chemotherapy and/or radiation therapy, and in patients with benign diseases of the esophagus (perforation, leakage of the esophageal anastomoses, esophageal fistulas, and refractory esophageal strictures) [15,47].

Recurrence of dysphagia. Recurrent dysphagia occurs in 31% of patients as a result of stent migration (11%), tumor or granulation tissue growth (14%), or food obstruction of the stent (6%) [48].

In such cases, side effects from radiation therapy and chemotherapy can compromise oral nutrition. Thus, in patients with malignant dysphagia in the presence of esophageal cancer, a persistent deterioration in nutritional status can persist even after successful stent implantation [49]. In addition, dysphagia may persist in a subgroup of patients with disseminated tumor lesions in esophageal cancer due to peritoneal metastases, causing mechanical obstruction of the gastrointestinal tract at different levels [29].

With the widespread use of FCSEMS, tumor growth through a stent is very rare but can occur if the esophageal protector coating is degraded or fragmented from the stent [50].

In contrast to continued growth of the tumor, overgrowth of granulation tissue remains a common late complication, occurring in about 5% of patients after FSEMS placement [50].

The overgrowth and ingrowth of granulation tissue either through the stent or at either end of the PSEMS leads to dysphagia recurrence and subsequent technically more difficult stent removal [51]. This situation results from the traumatic effect of the stent on the healthy wall of the esophagus, which causes excessive growth of granulation tissues and fibrotic changes, leading to the formation of a new stricture at the uncoated end of the stent [46]. Granulation tissue growth increases with

time, and stent overgrowth is possible within 10–15 days after its implantation [52]. In general, such a complication occurs within 2 months after stenting [34,53,54].

However, the causes of excessive granulation growth are not fully understood [31]. The degree of granulation tissue growth depends on a combination of factors, such as the type and diameter of the stent, radial and axial force, and the duration of stent presence in the esophageal lumen (> 2 weeks) [55].

The degree of granulation tissue growth is pronounced in PSEMS. Such a complication occurs in 41%–53% of cases after implantation of these stents [20,21]. The growth of granulation tissue is less pronounced in stents with a diameter of 18 mm [37]. However, this finding is not supported by other studies that used stents with a diameter of 23 mm [56,57].

In addition, no association was found between the degree of granulation response and previous chemotherapy and/or radiation therapy [52]. The stent material and radial force are significant in this complication [52]. Previous studies have reported that recurrent dysphagias are more likely to occur with Ultraflex metal stents (Boston Scientific) than with Polyflex plastic stents (Boston Scientific) or Niti-S stents (Taewoong Medical). However, Polyflex stents have been associated with a high rate of stent migration [34,58]. In this regard, the placement of Polyflex plastic stents is not recommended nowadays [59,60].

Secondary stricture requires additional endoscopic intervention with recanalization or repeated stenting [46]. However, stent extraction in the case of stent overgrowth with granulation or tumor tissues can be a technically complicated task and is associated with possible ruptures of the mucous membrane and the esophageal wall, as well as the development of bleeding from the mucous membrane [55]. Serious complications, such as esophageal perforation, avulsion, and fistula, occur after PSEMS removal [61,62].

Given the complications described, the advisability of using PSEMS in benign esophageal diseases is controversial. Despite all these disadvantages, some experts still recommend these stents to prevent migration in conditions such as refractory benign strictures, esophageal anastomoses leakage, esophageal fistulas, and perforations, especially in patients with a history of FSEMS migration or a high risk of poor stenting outcome during stent migration [22,63].

The stent-to-stent method is an effective method for removing esophageal protectors. In this case, the radial force of the second stent placed in the first stent leads under pressure to ischemia and

necrosis of granulation tissue, contributing to successful mobilization followed by removal of both stents [64,65]. With this approach, both stents are removed after 10–14 days [63,64].

Another method of rather effective resolution of granulation stenosis is argon plasma destruction [66]. However, it requires long-term procedures, is technically difficult, and is associated with serious complications [67,68].

Recurrence of dysphagia is also possible as a result of stent migration. Stent fracture is another rare and late complication, which can lead to poor food passability. In this situation, implantation of a second stent using the stent-to-stent technique is a safe and effective method. Endoscopic removal of a fragmented stent is also possible [69].

Dysphagia caused by food occlusion of the stent usually occurs because of lack of patient awareness and failure to follow dietary guidelines. Verbal and written dietary instructions should be given to patients and family members and/or carers [70]. Endoscopic removal of food lumps in stent obstruction by using special instruments is a highly effective and safe method of extracting foreign bodies.

Pain syndrome. After stenting, mild, moderate, or severe pain syndrome occurs in 12–30% of cases. In 14.1% of them, mild pains are registered, but 3.6% of patients report severe retrosternal pains [71,72]. As a rule, pain syndrome weakens on average 10 days after the prescription of analgesics and proton pump inhibitors without the need to remove the stent. According to the authors, pain syndrome is caused by increased pain sensitivity in the upper esophagus and ulceration of the esophageal mucosa resulting from gastroesophageal reflux [73,74].

Nevertheless, many studies reported a high incidence of pain syndrome. A.N.Rejim et al. reported severe retrosternal pain during the first 2 weeks after stent placement in 2/3 of patients with malignant dysphagia [75]. In another study, 60% of patients immediately after SEMS implantation had severe retrosternal pain, and 25% of patients reported persistent pain syndrome despite analgesic therapy [76].

However, pain is a common symptom in patients with cancer. Its intensity increases with the progression of the disease and metastases with a frequency of 64% [77,78]. For this reason, this fact may compromise studies with a high incidence of pain syndrome after implantation of esophageal stents. However, pain is a significant symptom because of its negative impact on the quality of life [76]. Therefore, patients should be informed about this common side effect of stent implantation.

Pain syndrome is common during stenting of the cervical esophagus [50]. For this reason, spe-

cial small-diameter cervical stents have been developed. The frequency and intensity of pain after implantation of different SEMS models varies depending on the type, dilation force, and flexibility of the stent [71,79]. SEMS with high axial dilation force are thought to be more probable to cause retrosternal pain because of high pressure and subsequent damage to the esophageal wall. This assumption is highlighted in two studies, where stents with significant axial dilation force were used [71,80].

The radial forces of dilation of stents can be divided into two pressure profiles. Group 1 of stents is characterized by a relatively low initial radial force with a gradual decrease during stent dilation, whereas group 2 exhibits an initial high radial force, followed by a rapid decrease during dilation. Aspects of group 2 can implicitly cause pain syndrome because of immediate forced dilation in the stricture zone [81]. However, A.N. Rejim et al. could not identify a significant relationship between these characteristics of stents. In addition, this work did not reveal the effect of previous chemotherapy and/or radiation therapy on pain syndrome after stenting [75]. Nevertheless, the authors of the study still recommend interpreting these findings with caution, given the limitations of the study groups.

Thus, at present [13], a reliable prognostic method in determining the probability of pain syndrome in the chest after stent implantation remains lacking [75,82].

Gastroesophageal reflux complications. Strictures of the abdominal esophagus represent a serious problem because placement of a stent in the gastroesophageal junction can lead to severe gastroesophageal reflux disease and aspiration syndrome [83]. Implantation of SEMS in the gastroesophageal junction leads to the forced position of the distal part of the stent in the stomach and the disappearance of the physiological barrier. Stenting at this location does not diminish the stent efficiency in resolving dysphagia but promotes gastroesophageal reflux through the stent [84].

A recent study by J.Włodarczyk et al. has found that 30%–45% of patients had severe reflux after stent implantation [31]. In addition, A.Sarper et al. found that perforation, stent fracture, and hemorrhage are common complications of stent implantation into the gastroesophageal junction [85].

Stents with an integrated antireflux system have been proposed to avoid such complications [83]. However, none of them has demonstrated real clinical benefit in terms of reflux prevention [86]. In addition, some stents with an integrated antireflux system showed a higher migration rate [87].

Complications of stenting the proximal esophagus. Traditionally, strictures near the upper esophageal sphincter are difficult to treat. Stent implantation in this location is associated with pain syndrome and foreign body sensation, as well as complications such as perforation, proximal stent migration, aspiration pneumonia, and the risk of airway compression [88,89].

E.M. Verschuur et al. implanted esophageal stents in 104 patients with malignant strictures and malignant fistulas within 8 cm from the upper esophageal sphincter. Technical success was achieved in 96% of patients with an average improvement in dysphagia scores of 2 points. The fistula was sealed in 79% of cases. Complications included pain (15%), foreign body sensation (8%), aspiration pneumonia (8%), perforation (2%), and stent migration (3%). Multivariate analysis revealed no difference in complication rates depending on the distance between the stricture and the upper esophageal sphincter [90]. However, we recommend interpreting these findings with caution because of very rare cases in clinical practice.

Lethal outcomes have been associated with compression of the trachea from the esophagus and the development of acute respiratory failure after stenting of the proximal esophagus [6]. This complication is due to the close anatomical relationship between the esophagus and the bronchial tree (trachea and main bronchi). Patients diagnosed with regional cancer after stenting are also at risk of developing esophageal fistulas. In such situations, bronchoscopy is advisable, especially when the neoplastic infiltration is located within 25 cm of the anterior incisors. Moreover, these patients may require bronchial tree stenting [29]. In such situations, esophageal stenting requires a team trained in simultaneous stenting of the esophagus and the bronchial tree [91]. Airway stenting should be performed as the first step [29].

Many authors recommend the use of ultrathin and flexible esophageal stents (Niti S Taewoong Medical) in such situations to reduce the risk of compression of the membranous trachea and prevent respiratory complications. However, the improvement in the degree of dysphagia with such stents in their study was assessed as 1.33, which is significantly lower than that when stents of a standard diameter were used [82].

Hemorrhage. Hemorrhage after stenting is another life-threatening complication and occurs in 2%–28% of cases [72,92,93]. However, the incidence of minor hemorrhage at the time of SEMS implantation or 1–2 days after it is 5%. Serious massive hemorrhage requiring surgery occurs in less than 1% of patients [50].

Hemorrhage has several possible causes. First, esophageal stents injure the mucous membrane and tumor tissue. Second, if a tumor has invaded the wall of a large artery, such as the aorta, pressure from the stent on the esophageal wall can rupture the artery and cause fatal bleeding.

The stent exerts constant pressure on the esophageal wall and tumor tissue, and this circumstance may increase the risk of local necrosis, an inflammatory reaction with increased tissue hypertrophy and fibrosis, and degeneration of the muscle layer of the esophagus [94]. Such changes in the wall of the esophagus and tumors can cause hemorrhage and perforation, and may be associated with the properties of certain stent models. However, these complications can be the result of natural progression of the disease or trauma from the sharp end of the stent in case of its fragmentation [95,96].

Location of the stent in the gastroesophageal junction area can also contribute to hemorrhage. This phenomenon is due to the fact that the free segment of the stent takes a forced position with the possibility of traumatizing the greater curvature of the stomach, which leads to ulceration and hemorrhage [29].

Perforations and fistulas of the esophagus. Esophageal perforation is the most serious complication in patients with malignant dysphagia. Perioperative mortality in esophageal perforation after stenting is 0.5%–7.0%, and 30-day mortality is in the range of 7% to 18% [5,53,92]. Several studies reported that perforation during or shortly after SEMS implantation occurs in less than 1% of patients [14,50].

Some authors reported that esophageal perforation is more common in patients who have previously received chemotherapy and/or radiation therapy [97]. It can also be associated with the use of wide-diameter stents. On the one hand, stents with high axial and radial dilation forces and wide diameters are more effective in relieving dysphagia than their counterparts [6]. On the other hand, stents with large diameters may be associated with a high incidence of perforation, fistula formation, and hemorrhage [37].

Fistulas of the bronchial tree can be late, life-threatening complications. Stent-associated esophageal fistula usually occurs several months after implantation. A recent retrospective study has found that stent-associated esophagobronchial fistulas develop in 4% of patients after esophageal stenting. Additional FSEMS implantation is an effective treatment method in this case [3,98].

Conclusion. Thus, despite its efficiency in resolving dysphagia, esophageal stenting is associa-

ted with a high frequency of various complications. Nevertheless, the overwhelming majority of them are minor and are easily resolved by endoscopic interventions, provided they are timely identified. Risk factors for complications should be considered before installation individually for each patient. The choice of the stent model is also important to minimize adverse consequences.

However, with regard to risk factors for stenting, various studies found no unambiguous relationship between the frequency of complications and their possible causes, and many studies found conflicting results.

Further study and analysis of the results of stenting with various stent models and risk factors are required to minimize early and late complications.

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