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Clinical Feasibility and Safety of Endoscopic Self-Expandable Metal Stent Placement for Upper Gastrointestinal Pathologies

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We aimed to review our experiences to evaluate the practicality, safety, and effectiveness of endoscopic stent placement for the palliation of malignant obstructions of the upper gastrointestinal system (GIS) and the treatment of postoperative complications such as failure of anastomoses and fistulae. Endoscopic stent placement is increasingly used in the upper GIS for the management of both high grade malignancies causing obstruction and benign pathologies such as anastomosis failures, gastrointestinal fistulae, and strictures. Hospital records, clinical data, and endoscopy reports of 61 patients who had undergone endoscopic stenting between the years 2012 and 2015 were analyzed retrospectively. For all patients, self-expandable metal covered stents were used. Data involving technical and clinical success rates, complication, morbidity, and mortality rates of the endoscopic stenting procedure was collected and simple statistical analyses were made. Endoscopic stenting was successful in 60 of 61 patients (98.3%). Overall technical success rate was found to be 98.3%; clinical success rate, 86.6%; complication rate, 4.9%. No stent related mortality was observed in our series. Endoscopic stents can be effectively and safely used in the treatment of various lesions of the upper GIS.

Key words: Endoscopic stent – Gastrointestinal malignancy – Anastomotic leakage

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Endoscopic stent placement is increasingly used in the upper gastrointestinal system (GIS) for the management of both high grade malignancies causing obstruction and benign pathologies such as anastomosis failures, gastrointestinal fistulae, and strictures.

Upper GIS obstruction as a late complication of advanced esophagus, stomach, or duodenum malignancies is a problematic situation that might result in malnutrition and thus worsen the quality of life.[1] For such patients with limited life expectancy, the purpose of surgery is only to provide passage through the GIS to allow feeding. However, procedures such as feeding gastrostomy / jejunostomy or palliative surgical interventions such as bypass surgery are reported to be associated with high rates of mortality and morbidity.[2,3] Numerous studies recommend endoscopic stent placement as a viable alternative to surgery in such patients not suitable for definitive surgery.[2–5] After any upper GIS surgery, detachment at the anastomosis or suture line, or fistulae are life-threatening complications with high rates of mortality and morbidity.[6] Early diagnosis and appropriate treatment are crucial for prevention from fulminant mediastinitis or intraabdominal sepsis. Among classical approaches are primary repair, resection, and drainage combined with esophageal exclusion. Though surgical intervention in the first 24 hours is considered to improve survival, reported mortality rates are still high.[7] Surgical mortality is comparable to conservative treatment, especially in the elderly and debilitated patients.[8] Recently, closure of the segment containing the leaking anastomosis or the fistula tract with an endoscopic stent has been practiced as an effective treatment method.[9,10]

In this article, we aimed to review our experiences and reported a wide variety of indications for endoscopic upper GIS stent placement, including malignant obstructions of the upper GIS, benign esophageal strictures due to peptic ulcer disease, leaks after sleeve gastrectomies, and anastomotic strictures.

Materials and Method

Hospital records, clinical data, and endoscopy reports of 61 patients who have received endoscopic stents in the General Surgery Clinic, Endoscopy Units of Sisli Etfal Training and Research Hospital and Istanbul Training and Research Hospital, Istanbul between the years 2012 and 2015 were retrospectively analyzed. Demographic data, indications for stent placement, anatomic localization of the current pathology, technical and clinical success of the procedure, complications, follow-up duration, morbidity, and mortality rates were recorded. In this study, pathologies related to tumor were referred to as malignant lesions, while benign lesions expressed as pathologies related to postoperative anastomotic line or peptic/inflammatory strictures.

For all patients, self-expandable metal covered stents were used (Hanarostent Duodenum/Pylorus Lasso – NCN, MI Tech Co, Seoul, South Korea). While those used for patients with benign strictures were fully covered, others were partially covered. For patients with malignancy or strictures, the procedure was performed under fluoroscopy to ascertain the length of the stricture and to determine the size of the stent to be used. All patients were given oral nutrition 24 hours after stent placement. Postprocedural pain in patients with esophageal stents was controlled by nonsteroidal anti-inflammatory drugs. The follow-up and treatment of patients stented for detachment of anastomosis and fistulae continued in the hospital setting until the fistulae were closed and the clinical signs were normal. Patients stented for stricture of anastomosis, fistulae, and benign strictures had the stent moved 3 to 4 weeks after the initial procedure to ensure easier removal of the stent.

Technical success stands for the endoscopic stenting procedure to be performed without any complications; clinical success for clinical symptoms to disappear and not recur after stenting with no need for repeat procedures; complication for pathologic events associated with the stent; and mortality for death associated with the stent.

Data involving technical and clinical success rates, complication, morbidity; and mortality rates of the endoscopic stenting procedure was collected and simple statistical analyses were made.

Results

The mean age of the patients was 60.4 (23–97) years. Of the 61 patients, 29 had a tumor at the esophagus, 11 at the esophagogastric junction and 6 had pyloric obstruction due to a tumor at the distal stomach. For 2 patients, stents were placed because of a tracheoesophageal fistula due to an esophageal tumor and pleura-esophageal fistula formation secondary to lung cancer. Table 1 lists the pathologies of the patients undergoing endoscopic stent placement.

Table 1 Pathologies of patients undergoing endoscopic stent placement

Pathological characteristics	n = 60 (%)
Malignant pathologies	
Esophageal cancer	29 (48.3)
Esophago-gastric junction cancer	11 (18.3)
Gastroduodenal cancer	5 (8.3)
Benign pathologies	
Anastomotic leakage/fistulae	7 (11.6)
Anastomotic stricture	3 (5)
Esophageal peptic/inflammatory stricture	5 (8.3)

Endoscopic stenting was successful in 60 of 61 patients (98.3%). In 1 patient with obstruction due to a tumor at the gastric outlet the procedure was not successful as the guide wire could not be passed beyond the stricture. Surgical gastrojejunostomy was performed for this patient.

Of the 60 patients successfully stented, 4 had complications related to the stent (4.9%).

One patient with sleeve gastrectomy performed for obesity and postoperative fistula from the anastomosis had nausea and vomiting 3 days after the procedure. In the endoscopic examination performed on the fourth day, the stent was seen as migrated proximally. The stent was removed and a new stent was placed. No early or late complications were observed after the second procedure.

Another patient with cardia tumor stent migrated 3 days after. The stent was removed and a new stent has been placed.

Another patient with total gastrectomy performed for gastric tumor developed a fistula on postoperative day 5. In the endoscopic examination, the anastomosis line was observed as 50% detached from the anterior. The site of leakage was closed by placing a full covered stent. With the fistula controlled, the patient was discharged with cure 1 week after the stenting procedure. Twenty days after stenting, the patient presented with hematemesis and was allowed to the inpatient clinic. In the upper GIS endoscopy, the stent was in place and there was recent coagulum in the lumen, but no source of hemorrhage was observed. The stent could not be removed due to risk of hemorrhage. During follow-up, the patient became hemodynamically unstable because of sudden onset massive hematochezia and hematemesis. The emergency coeliac angiography revealed a pseudoaneurysm in the splenic artery in contact with the lower end of the stent and active bleeding from this site (Fig. 1). The hemorrhage was controlled by coil-embolization from the origin of the splenic artery (Fig. 2). On the 12th day after

Fig. 1 Celiac angiography shows a pseudoaneurysm in the splenic artery in contact with the lower end of the stent.

embolization the patient was discharged with cure. Twenty-eight days after embolization, removal of the stent was attempted but failed. Despite completion of adjuvant chemotherapy, the patient died on the postoperative 8th month due to progression of disease. The cause of mortality was not associated with the stent.

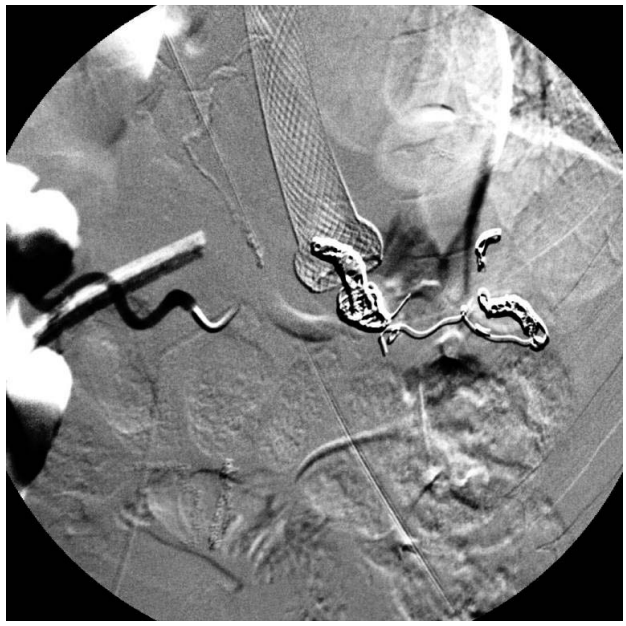

Fig. 2 Coil-embolization of total splenic artery from the origin to the splenic hilus.

Table 2 Approaches to complications and clinical failure, and patients' outcomes

Complications and clinical failures	Managements	Outcomes	N = 60 (%)
Migration	Stent removal: Restenting Dilations of stricture	Recovery Clinical failure	3 (5)
Stent obstruction	Stent in stent placement	88-day survival	2 (3.3)
Hemorrhage	Angiographic embolization	Hemodynamic stability	1 (1.6)
Stricture recurrence	Dilations of stricture	Observation	2 (3.3)

Treatment of patients stented for detachment at the anastomosis and fistulae continued in the hospital until clinical recovery. Mean duration of hospital stay in this group was 10 (4–36) days. In 2 patients who had a stent placed for malignancy related esophageal obstruction, the stent lumen was found to be occluded due to tumor growth 29 and 62 days after stenting. The passage was provided by placing another stent through the existing stent.

Five patients with strictures due to inflammation and benign ulcers in the esophagus were treated with an average of 4 (2–6) sessions of balloon dilatation and 3 patients with strictures at the hypopharyngeal anastomosis after esophagectomy with an average of 3.6 (3–4) sessions of rigid dilatation using Savary–Gilliard dilatators (No. 7, 9, 11, 12.8: in order). For these 5 cases where the dilatation procedure failed, stenosis was overcome by placing fully covered self-expandable metallic stents. One patient had stent migration 28 days after the procedure. The stent was removed and dilatation procedure was restarted for this patient. Other patients' stents were removed with no complications after an average of 5 (4–6) weeks. Two of these cases had recurrent stricture after 4 (3–5) weeks average. Consequently dilatation with Savary–Gilliard dilatators was performed once again. Three cases with anastomosis strictures whose stenosis resolved and dysphagia regressed are still being followed.

Of the 60 patients stented, 49 were stented for obstruction and fistulae related to tumors. Seven of these patients have left clinical follow-up. Among those under surveillance, a total of 17 patients (7 with esophageal tumors, 7 with esophagogastric junction tumors, 1 with tumor related tracheoesophageal fistula, and 2 with tumors at the distal stomach causing pyloric obstruction) have died during follow-up because of disease progression. Neoadjuvant therapy was planned for the 3 patients with pyloric obstruction due to tumor at the distal stomach and 12 patients with tumor related obstruction at the esophagus. Endoscopic stents were applied to these patients to allow feeding during neoadjuvant therapy.

In this group, mean survival after stent placement was 51 (12–165) days. No stent obstruction or any other complications were observed throughout the survival of other patients with malignancies.

All 5 patients stented for fistulae at the suture line after bariatric surgery had their stents removed after an average of 7 (6–8) weeks. All patients stented for fistulae had their stents removed with no complications after the 6th week. No complications or mortality occurred for any of the patients. Approaches to clinical failure and complications, as well as the outcomes, are summarized in Table 2.

According to this data, overall technical success rate was found to be 98.3%; clinical success rate, 86.6%; complication rate, 4.9 %. For malignancies only, technical success rate was 97.8%; clinical success rate, 95.5%; and complication rate, 2.3%. No stent related mortality was observed in our series. For benign lesions, technical success rate was 100%; clinical success rate, 60%, and complication rate, 13.3% (Table 3).

Table 3 Success rates and complication rates according to the etiologic cause

	Malignant pathologies, n = 46 (%)	Benign pathologies, n = 15 (%)	Overall pathologies, n = 61 (%)
Technical success	45 (97.8)	15 (100)	60 (98.3)
Clinical success	43 (95.5)	9 (60)	52 (86.6)
Complication	1 (2.3)	2 (13.3)	3 (4.9)
Mortality	-	-	-

Discussion

Despite the advances in surgical techniques, palliation might be the only option in high grade malignancies of the GIS. The main goals of palliation are controlling symptoms, eliminating dysphagia, allowing oral nutrition intake, and preventing aspiration. Also, gastrointestinal surgery might have serious complications even when performed for

benign reasons. This last situation results in long hospitalization, need for reoperation, increase in mortality rates, and increased costs. Therapeutic endoscopy might play an important role in such problems of the upper GIS.[10] Self-expandable metallic stent procedures have been widely accepted as an effective treatment option.[11,12] On the other hand, complications such as bleeding, perforation, stent obstruction due to tumor growth, or migration related to endoscopic stenting for malignant obstructions of the upper GIS can be observed. However, no statistically significant difference has been shown between the rates of the aforementioned complications and those of standard palliative surgical interventions.[13] Besides, delayed oral nutrition after surgery and longer hospitalization can be considered as disadvantages of surgery.[14] In this study, the majority of the cases involving placed endoscopic stents were patients with malignant obstruction. Malignant obstruction of the upper GIS is a common complication of high grade tumors. More than 50% of esophageal tumors are inoperable at the time of diagnosis. For these patients, palliative chemotherapy has not been proven superior to supportive treatment in terms of survival.[15] The classical procedure for palliative treatment of inoperable upper GIS tumors is surgically opening feeding gastrostomies / jejunostomies or bypass procedures. In recent years, noninvasive procedures have been increasingly preferred. These procedures, each of which has different rates of success and risks of complication, are thermal ablation, photodynamic therapy, radiotherapy, chemotherapy, chemical injection, electrocoagulation, and stenting procedures. Endoscopic stent placement procedure is increasingly preferred over other methods because it resolves the obstruction faster and for a longer duration than other methods, has lower morbidity rates, shorter hospital stay, and lower costs. For obstructive esophageal tumors, technical success rate of stenting as reported as 85%–100%; clinical success rate, 80%–90%; complication rate, 30%.[16–19] Another complication of esophageal tumors is tracheoesophageal fistulae caused by the infiltration of cancer to the respiratory tract. Many case series report successful closure of the fistulae by endoscopic stenting. These series report technical success rates of 70%–100% and complication rates of 10%–30%.[20–22]

Technical success rates of the endoscopic stent placement procedure for palliation of malignancies causing obstruction at the gastric outlet is not different from that of esophageal stent placement. However, clinical success rates of the stenting procedures for gastric outlet obstruction are reported to be lower. The reasons for this finding can be listed as incomplete opening of the stent, acute angulation of the stent and insufficient stent length for long segment lesions, among others.[23]

In our series, the majority of the patients stented for malignancy related symptoms had esophagus or esophagogastric junction tumors, and to a lesser extent, distal stomach malignancies causing pyloric obstruction. Our results for cases with upper GIS malignancies are consistent with previous studies; technical success rate being 97.8% and clinical success rate being 95.5%.

Rate of recurrence of symptoms and stent obstruction requiring repeat intervention due to tumor growth is 13%–18%. Stent obstruction is directly related to the length of survival.[24] In our series, only 2 patients with esophageal tumor stented for malignant obstruction had stent obstruction due to tumor growth. Compared to the literature, a complication rate of 2.3% is extremely low. The time it has taken from the placement of the stent to its obstruction (29 and 68 days), however, is longer than the average survival (51 days). As one of the complications following upper GIS surgery for both malignant and benign pathologies, failure of anastomoses causing leakage and fistulae has significant morbidity and mortality (50% and 10%, respectively).[25] The management options of this complication are surgical interventions and conservative treatment consisting of restricting oral intake, antibiotic treatment, and drainage procedures. Because of the high mortality of surgical interventions, such cases of anastomosis failure are currently treated by closing with self-expandable metallic stents. Endoscopic stent placement procedure for anastomosis failure is suitable for detachments smaller than 50%–70% of the circular perimeter of the anastomosis. In the existence of longer anastomosis detachments, peritonitis or mediastinitis, or persistent severe sepsis, surgical treatment is recommended.[26,27] On the other hand, Donnie *et al* have reported a case of complete anastomosis failure treated by endoscopic stenting.[28] Still, evidence from randomized controlled trials in a well-defined population is needed. Even though there are no randomized controlled trials about endoscopic stenting for fistulae and leakages, the rate of success is reported to be 80%–85% in systematic reviews.[29]

Possible complications after the treatment of fistulae and leakages by stenting are stent migration, perforation, and hemorrhage. In a meta-analysis by

Van Beckel *et al* stent migration rate is reported as 9%–26%. Rate of migration is reported to be especially higher in fully covered stents than partially covered stents.[29]

Hemorrhage, one of the major complications, is rare (<5%).[30] Although the mechanisms of hemorrhage after stenting are not defined in the literature in detail, case reports usually report such incidents weeks after the stenting procedure. One possible mechanism is sharp edges of the metal stent causing ulcer formation and hemorrhage by eroding the mucosa. Most of such cases of hemorrhage are controlled with conservative treatment.[31] On the other hand, a case of massive hemorrhage after stenting resulting in death has been reported by Due *et al*.[32] In our series, 1 case that was applied a self-expandable metallic stent because of 50% detachment at the esophagojejunostomy and had massive gastrointestinal hemorrhage 20 days after the procedure was revealed by angiography to be resulting from the lower end of the metal stent causing erosion at the splenic artery. The hemorrhage was controlled by angiographic splenic artery coil embolization. Twenty-eight days after angiography removal of the stent was attempted, but failed. Despite adjuvant chemotherapy, carcinomatosis peritonei developed and the patient died due to disease progression on 8th month postoperatively. Even though this patient had cancer, the stented lesion is a benign leakage developing postoperatively. Thus, mortality of this case was not related to the stent but rather considered to be the result of malignancy.

The incidence of stricture at the anastomosis line following upper gastrointestinal surgery is between 5% and 46% and varies greatly.[33,34] Postoperative anastomosis failure, fistulae, or ischemic injury are complications contributing to the development of strictures at the anastomosis line.[35] Recently, stent placement procedure is increasingly used for anastomosis strictures. Even though fully covered self-expandable metallic stents are approved by the FDA only for use in malignancies, they are ideal for use in benign esophageal strictures. The purpose here is to resolve the stricture by applying extended radial force on the stenosis.[36,37] Most of the data on the use of self-expandable metallic stents for esophageal strictures is derived from case series or case reports.[38–40] According to the management algorithm from the review by Manta *et al* for anastomosis strictures; first, 4 to 6 sessions of dilatation; if the stricture does not resolve, 1 to 2 times radial incision with or without dilatation; if still not successful, surgery; or for patients not suitable for surgery, stent dilatations is recommended.[10] Self-expandable metallic stent procedures for benign esophageal strictures might cause serious complications such as migration, bleeding, fistulae, perforation, and recurrence of stricture.[41,42] Five cases in our series were applied self-expandable metallic stents for esophageal strictures persisting even after repeated dilatations.

Although our technical success rate regarding stent placement for benign esophageal strictures appears to be 100%, compared to patients with malignant obstructions, our clinical success rate in this group is lower (95.5% versus 60%) and stent related complication rate higher (2.3% versus 13.3%).

Many studies have concluded that long term success in metallic stenting is related to the etiology and short length of the stricture. Clinical success rate in radiotherapy induced strictures is higher than that in benign peptic strictures or anastomotic strictures.[43,44] It has also been reported that using small sized stents might decrease new stricture formation.[39] Thus, Jee *et al* do not recommend routine use of self-expandable metallic stents for benign esophageal strictures. Until long term data is available from controlled clinical trials, self-expandable metallic stents are only recommended for selected patients.[23] Stenting procedure for benign strictures has disappointing results; rate of the stricture resolving and symptoms disappearing in the long term is reported as 6%–30% and rate of migration, the most common complication, 22%–64%.[45] In our series, for patients with benign strictures, despite a clinical success rate (60%) that was higher than that reported in the literature and a similar complication rate (13.3%), complications during follow-up after stenting was one of the factors causing a low total success rate.

Our study has weak points such as being retrospective, nonrandomized, and not making a comparison with other stent types as only covered metal stents were used. However, it contributes to data supporting endoscopic stenting as an effective and safe strategy in upper gastrointestinal system lesions.

Conclusions

Endoscopic stents can be effectively and safely used in the treatment of various lesions of the upper GIS. In addition to its palliative use in high grade malignant upper GIS obstructions, endoscopic stent placement is a valuable treatment modality to allow feeding during treatment for patients with malignant obstruction with a neoadjuvant therapy plan. Clinical results are similar to palliative surgical

procedures such as feeding gastrostomy / jejunostomy or bypass surgery while avoiding the morbidity and mortality of surgery.

Because of disappointing clinical results, the routine use of self-expandable metallic stents in benign esophageal lesions such as anastomosis failure, fistulae, and strictures is limited. It is recommended for selected patients.

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