International Journal of Gastrointestinal Intervention

journal homepage: www.ijgii.org

Original Article

Safety and efficacy of esophageal stents for esophageal anastomotic strictures: A 10-year single-center experience

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A B S T R A C T

Background: The aim of this study was to determine whether esophageal stent placement in recurrent and refractory post-esophagectomy anastomotic strictures improves clinical outcomes and prolongs the intervals between re-interventions.
Methods: This retrospective, observational, single-center study analyzed data from all patients who underwent esophageal stent placement for symptomatic benign post-esophagectomy anastomotic strictures from 2009 to 2019. The primary outcome was technical and clinical success. The secondary outcomes were stent-related complications and re-intervention duration and rates.
Results: Twenty-eight patients underwent esophageal stent placement for post-esophagectomy benign anastomotic strictures. The technical success rate was 96.4%. The clinical success rates at 4 weeks, 12 weeks, and 1 year were 100%, 69.23%, and 72.72%, respectively. Serious stent-related complications occurred in two patients (7.1%), while minor adverse events were noted in 11 patients (39.28%). The rate of stricture recurrence with a mean dysphagia-free interval of 17 weeks after stent placement was 64.28%. The rate of luminal patency with a stent was 73.33% at 12 months.
Conclusion: Stent insertion is an effective and safe treatment modality for anastomotic esophageal strictures. Long-term remission of the stricture, more luminal patency, and an improved dysphagia score were observed, but the findings need to be confirmed through multivariate analysis.

Keywords: Benign strictures; Esophageal anastomotic strictures; Esophageal stents; Post-esophagectomy strictures; Refractory anastomotic strictures

Introduction

Benign esophageal strictures are a well-known complication following esophagectomy, with an incidence reaching 30%.[1,2] The management of these anastomotic strictures is both complex and controversial owing to their recurrent nature.[3,4] Endoscopic balloon or bougie dilatation is considered a standard first-line treatment,[1,3,5–8] although studies have reported various success rates, ranging from 40% to 80%.[9,10] However, clinical success is short-lived, and recurrence is common.[1,2,4–8,10,11] To achieve a sustained benefit, three to nine dilatations are required on average.[12] Dysphagia recurs in around 30%–40% of patients within the first 12 months of the first dilatation,[13] and almost 10% develop refractory strictures, posing a difficult challenge to the endoscopist.[4,8,14] Since repeated endoscopic dilatations place both a physical and a financial burden on the patient, better feasible alternatives need to be explored.[4] When repeated dilatations fail, steroid injection, incisional therapy, and temporary stenting are often considered as second-line options for recurrent and refractory anastomotic strictures.[4,15] Although stenting has a well-established place in the palliative management of malignant strictures,[4,15] its use in benign strictures is limited to refractory or recurrent cases.[6,16,17]

Some studies have reported promising results regarding the use of temporary stents in the management of recurrent and refractory anastomotic strictures.[12,13,18,19] A meta-analysis showed that 40% of patients exhibited complete resolution of symptoms following temporary stent placement and required no additional therapy.[13] Another study reported that stent placement after a single session of dilatation was cost-effective and associated with improved quality of life and prolonged dysphagia-free periods.[17] In this study, we share our 10-year experience of using temporary stents for the management of anastomotic strictures. Our objectives were to evaluate the technical and clinical success of esophageal stent insertion for benign anastomotic strictures and

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Received May 17, 2021; Revised December 20, 2021; Accepted January 27, 2022
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pISSN 2636-0004 eISSN 2636-0012 https://doi.org/10.18528/ijgii210029

to assess the safety and need for re-intervention following stent placement.

Methods

This retrospective study was conducted at Shaukat Khanum Memorial Cancer Hospital & Research Centre, Lahore, Pakistan. The medical records of patients undergoing esophageal stent placement for post-esophagectomy anastomotic strictures from 2009 to 2019 were retrieved. Institutional review board exemption was formally granted, in view of the retrospective nature of the study.

Inclusion and exclusion criteria

The inclusion criteria were patients with 1) an age of 18 years or above, 2) post-esophagectomy benign anastomotic strictures evaluated endoscopically, 3) a dysphagia score of 2 or higher or the inability to pass a standard gastroscope through the stricture, and 4) recurrent and refractory strictures. The exclusion criteria were 1) non-anastomotic benign strictures and 2) histologically confirmed malignant strictures.

Types of stents and stent placement procedure

A fully covered self-expandable metallic stent (FCSEMS) is a silicone-coated nitinol-braided stent available in different sizes. A lumen-apposing metallic stent is a nitinol-braided, silicone-covered metallic stent with a wagon-wheel configuration that helps anchor both ends of the stent. It is particularly associated with low migration rates.[20] Biodegradable (BD) stents are made of a woven polydioxanone monofilament that biodegrades at a low pH. Both ends of this stent have radiopaque markers.[14]

Initially, upper gastrointestinal endoscopy was performed to visualize the cause and site of obstruction and to rule out any signs of tumor recurrence at the anastomotic site. Using a catheter, a guidewire was passed through the stricture, and contrast was injected to confirm the luminal narrowing and extent of the stricture using fluoroscopy. A few extremely narrow strictures required an initial balloon or bougie dilatation. Then, one of the three aforementioned types of stents was used. The stent was deployed over the guidewire under direct vision and fluoroscopic guidance. After placement, fluoroscopic dye was injected to radiologically confirm the stent's patency.

Definitions of variables

Efficacy included both technical and clinical success. Technical success was defined as successful stent deployment confirmed both endoscopically and fluoroscopically.[10] Clinical success was defined as symptom improvement with dysphagia score of 2 or less. A dysphagia score of 0 indicated no symptoms, 1 indicated an ability to eat a solid diet with some difficulty, 2 indicated an ability to eat a semisolid diet, 3 indicated an ability to consume a liquid diet, and 4 represented absolute dysphagia.[10]

The safety of the stents was assessed by evaluating complications associated with stent placement.[10] Complications were characterized as immediate (at the time of stent placement), early (within 1 week of stent placement), and delayed (more than 1 week after stent placement). Re-intervention was defined as any repeat endoscopic procedure after stent placement except for planned stent removal.[10] Recurrent anastomotic strictures were defined as those requiring two balloon/bougie dilatation sessions.[5] Refractory anastomotic strictures were considered those requiring three or more balloon/bougie dilatations prior to stent placement.[6,21] Stent migration was defined as displacement of the stent from the stricture confirmed either radiologically or endoscopically.[22] Early stenting referred to stenting of a recurrent anastomotic stricture, while late stenting referred to stenting of a refractory anastomotic stricture.

Follow-up

Patients were retrospectively followed up by reviewing their electronic notes and examination results, such as radiology scans and endoscopic reports. The patients were followed up for 1 year after stent removal for removable stents and for the same duration for BD stents following placement.

Data collection

The hospital's electronic medical records were used to review patients' baseline characteristics, including demographic characteristics, medical record numbers, body mass index (BMI), comorbidities, smoking habits, previous treatments, type of surgery, site and type of esophageal anastomosis, time from surgery to symptom development, dysphagia score at symptom onset, number and type of procedures prior to stent placement, the type and size of stents, time of complication development (immediate, early, or delayed), dysphagia score after 4–9 weeks following stent removal, refractory and non-refractory cases prior to stent placement, recurrence after stent removal for FCSEMSs and stent placement for BD stents, the number and type of subsequent procedures, further stents, and 1-year outcomes.

Statistical analysis

Statistical analysis was performed using IBM SPSS version 20.0 (IBM Corp., Armonk, NY, USA). We reported the mean and standard deviation (SD) for continuous variables and frequencies and percentages for categorical variables. Categorical variables were compared using the chi-square test. All tests were two-tailed, and P-values < 0.05 were considered to indicate statistical significance.

Ethics approval and consent to participate

The institutional review board of Shaukat Khanam Memorial Cancer Hospital and Research Centre, Lahore approved and exempted the study and also granted a waiver of informed written consent. IRB approval number: EX-21-04-20-03. This study bases its work on principles that have their origin in the Declaration of Helsinki.

Results

Patients' characteristics

A total of 28 patients were reviewed, in whom 46 esophageal stents were placed endoscopically. Five (17.9%) patients were active smokers, and 23 (82.1%) were nonsmokers. The patients' BMI ranged from 15 to 31 kg/m^2 (mean $\pm$ SD = 22.6 $\pm$ 3.91 kg/m^2) at the time of presentation with clinical symptoms of esophageal obstruction. Half of the patients (50.0%) underwent Ivor-Lewis esophagectomy, and the other half underwent McKeown esophagectomy. End-to-end and end-to-side anastomoses were

Table 1 Patients' Demographic and Clinical Characteristics

Variable	Value
Sex	
Male	12 (42.9)
Female	16 (57.1)
Mean age (yr)	53.6 ± 9.9
Comorbidities	
None	25 (89.3)
Hypertension	2 (7.1)
Diabetes mellitus	1 (3.6)
Body mass index at the time of initial dysphagia	
Underweight	5 (17.85)
Normal weight	13 (46.42)
Overweight	10 (35.71)
Previous treatment	
Chemotherapy	7 (25.0)
Chemoradiotherapy	19 (67.9)
None	2 (7.1)
Time from esophagectomy to dysphagia development (wk)	12.5 (4–28)
Number of procedures prior to stenting	2 (1–4)
Recurrent strictures	21 (75.0)
Refractory strictures	7 (25.0)

Values are presented as number (%), mean ± standard deviation, or median (range).

performed in 13 (46.4%) patients each. For the remaining two (7.1%) patients, the type of anastomosis was not specified. All anastomoses were hand-sewn. Proximal anastomosis (less than 25 cm but more than 18 cm from the incisors) was seen in 27 (96.4%) patients, whereas distal anastomosis (more than 30 cm from the incisors) was present only in one (3.6%) patient.

The time from esophagectomy to dysphagia development was 4–28 weeks (Table 1).

Efficacy

Table 2 shows the distribution of the three types of esophageal stents used. The technical success rate was 96.4%. Migration of one of the BD stents immediately upon deployment occurred in one (3.6%) patient. For removable stents, the median time from insertion to removal was 4 weeks, with a range of 1–6 weeks.

The rates of dysphagia score improvement at 4 and 12 weeks of stent placement compared to the baseline scores were 100% and 69.23%, respectively. However, the clinical success rate 1 year after stent removal was 72.72%. Overall, the dysphagia scores improved significantly at all time points compared to the scores prior to stenting (all $P < 0.05$; Table 3).

Safety

The immediate complication rate was 3.6%, as only one patient had instant migration of one of the BD stents at the time of deployment. An early adverse event was seen in one (3.6%) patient who received an FCSEMS and subsequently developed stridor warranting immediate removal. The delayed complication rate was 39.1%, including two serious complications involving fistula formation (7.1%), and nine minor events of stent migration (32.1%). The complications and their distributions are displayed in Table 4.

Table 2 Distribution of the Types of Esophageal Stents Used

Stent type	Number (%)
Fully covered self-expandable metallic stent	20 (71.42)
Lumen-apposing metallic stent	3 (10.71)
Biodegradable stent	5 (17.85)

Table 3 Comparison of Dysphagia Scores Before and After Stent Placement

Follow-up	Before treatment	After treatment	*P*-value
Four weeks (n = 28)	3.29	1.14	< 0.05
Twelve weeks (n = 26)	3.31	1.88	< 0.05
One year (n = 22)	3.32	1.18	< 0.05

Table 4 Distribution of Post-Stenting Complications

Complication	Number (%)
Stridor	1 (3.57)
Stent migration	10 (35.71)
Fistula	2 (7.1)
None	15 (53.57)

Re-intervention/recurrence

The dysphagia recurrence rate was 64.28%. All cases required endoscopic re-intervention. The mean number of pretreatment dilatations in all patients was 1.9. The mean duration from stent removal to dysphagia recurrence was 17.05 ± 12.91 weeks. Seven patients did not experience any recurrence. Three patients were lost to 12-week follow-up and were thus excluded from the clinical success rate calculation.

Recurrent versus refractory strictures

Of the 28 cases, seven (25.0%) were refractory strictures and 21 (75.0%) were recurrent strictures. The clinical success rate for both groups at 4 weeks after stent placement was 100%. However, the dysphagia score showed improvement at 1 year in 80% of the patients in the refractory group and in 66.66% of those in the non-refractory group, with a *P*-value of 0.7 (not statistically significant). The mean dysphagia scores at 4 and 12 weeks and 1 year were better in the recurrent strictures (early stenting) than in the refractory (late stenting) group, but the difference was not statistically significant. A comparison of dysphagia scores between the recurrent and refractory stricture groups is shown in Table 5.

There was no significant difference in the number of procedures between the recurrent and refractory groups, but the mean time to stricture recurrence was longer in patients with recurrent anastomotic strictures than in those with refractory strictures. However, this difference was not statistically significant because of the small sample size (Table 6).

Table 5 Comparison of Dysphagia Scores Between Patients Undergoing Stenting in Recurrent and Refractory Strictures

Follow-up	Mean dysphagia score		*P*-value
	Stenting in recurrent strictures	Stenting in refractory strictures	
Four weeks	1.05	1.43	0.59
Twelve weeks	1.86	2	0.24
One year	1.12	1.40	0.84

Table 6 Comparison of the Mean Numbers of Procedures and time to Recurrence Between Patients undergoing Stenting in Recurrent and Refractory Stricture

Variable	Recurrent stricture	Refractory stricture	*P*-value
Mean number of procedures	4.6	6.2	0.28
Time to recurrence (wk)	18.1	11.6	0.64

Discussion

Stents have a well-established place in the management of malignant esophageal strictures, fistulas, and perforations.[23] For benign strictures, balloon/bougie dilatation is considered a standard first-line therapy, whereas FCSEMSs are reserved for refractory strictures, which are not amenable to repeated dilatations.[21,24] Benign esophagogastric strictures are common after esophagectomy, developing on average 24 weeks postoperatively.[5] The primary aims of treatment are to relieve the symptoms of dysphagia and prevent recurrence, while minimizing procedure-related complications.

Balloon/bougie dilatation is considered the best option in treatment algorithms due to the ease and simplicity of the procedure and its low complication rates. However, esophageal stents are associated with a longer period of remission.[2] The technical success rate of stent placement is as high as 93%,[25] which is comparable to that in our study (96.4%). This makes it a technically feasible procedure. In a recent randomized controlled trial, Kappelle et al[6] reported a mean of 2.4 pretreatment dilatations in a balloon dilatation group and a mean of two dilatations in a stent group. These results are comparable to those in our study, where a stent was inserted in patients with a mean of 1.9 pretreatment dilatations. However, Kappelle et al[6] reported a shorter mean dysphagia-free time after dilatation in the dilatation group—just 33 days. In comparison, the mean time from stent removal to dysphagia recurrence in our stented patients was 18 weeks. Furthermore, Kappelle et al[6] reported a 92% re-intervention rate in the balloon dilatation group, compared to 64.28% for the stent patients in our study. Similarly, Kappelle et al[6] reported higher quality of life scores in the stent group. Another randomized controlled trial found that patients receiving stents had lower re-intervention rates and longer dysphagia-free periods at 12 weeks than patients undergoing balloon dilatation. The same study reported a high mortality rate (20%) in the balloon dilatation group.[26] The aforementioned trials examined the cost-effectiveness of neither modality for refractory strictures.[6,26] Martin et al[18] found that the early use of stents for post-esophagostomy strictures, preferably in a second intervention, improved dysphagia scores and prevented re-interventions, suggesting that stents are more economical than frequent dilatations.

A previous study assessing the usefulness of the endoscopic radial incision and cutting method reported a 93.8% improvement in dysphagia scores at 4 weeks.[9] This is comparable to our rate (100%) over the same period. Another study comparing stents versus endoscopic incisions in refractory anastomotic strictures showed luminal patency of 70% and 20% of patients at 12 months, respectively, whereas the rate was 80% in our patients.[2] Thus, the findings of both studies suggest that stenting leads to longer-lasting dysphagia improvement.

The most serious complication of balloon dilatation is esophageal perforation, with an incidence ranging between 3% and 9%[5,12,26] and an associated mortality rate of 20%.[6] No perforation was seen in our study; however, fistula formation was observed in two patients. The most common complication associated with stent placement is stent migration, with a reported incidence of 35.6%.[25] This is comparable to the rate in our study (35.71%).

The largest multicenter study to date found that FCSEMSs had the lowest migration rate (17%) when deployed for benign strictures.[27] Recent evidence suggests that migration can be reduced to below 17% after endoscopic fixation.[12] FCSEMSs have been approved for benign anastomotic strictures by the US Food and Drug Administration, and more research is being conducted to assess the efficacy and safety of various other types of stents for this purpose. A prospective multicenter study found that FCSEMSs and BD stents are more effective for benign refractory esophageal strictures than self-expandable plastic stents, which are a less favorable choice due to their high migration rate.[10] Another prospective study on BD stents reported promising results in terms of dysphagia improvement in post-esophagectomy strictures.[19]

In this study, we found that stent placement before the anastomotic stricture became refractory produced satisfactory results. The dysphagia scores improved at 4 and 12 weeks and 1 year. Moreover, the time to dysphagia recurrence was prolonged, necessitating fewer re-interventions. Recent studies have advocated for the early use of esophageal stents based on benign stricture etiology and the fact that stenting reduces the treatment cost incurred by repeated dilatations.[12,13,18,19]

Our study was limited by the fact that we did not have a comparison group with other treatment modalities. Moreover, this was a single-center, retrospective study with a small sample size. Therefore, we suggest randomized controlled trials with larger samples for statistical validation of our findings.

Our study demonstrate that anastomotic strictures frequently recur even after stent placement, but with stents, the interval until re-intervention increases and the long-term dysphagia score improves. These findings should be validated in prospective studies with large samples in the future.

Funding

None.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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