

Clinical Outcomes After Self-Expanding Plastic Stent Placement for Refractory Benign Esophageal Strictures

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Received: 22 October 2009 / Accepted: 17 January 2010 / Published online: 13 February 2010
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Abstract

Background Refractory benign esophageal strictures (RBES) are defined as those that persist structurally and symptomatically after repeated dilation sessions. Small series have reported favorable outcomes after placement and subsequent removal of Polyflex™ self-expanding plastic stents (SEPS).

Aims To characterize the outcomes after Polyflex™ stent placement in patients with RBES.

Methods Outcomes of consecutive patients who underwent Polyflex™ stent placement for RBES between April 15, 2005 and November 20, 2006 were analyzed retrospectively. The etiology of the stricture, number of dilations prior to initial SEPS placement, size of stent placed, stricture resolution after SEPS removal, cases of stent migration, duration of SEPS placement, time to repeat dilation and/or SEPS replacement after stent removal, and complications were assessed.

Results Twenty-three Polyflex™ stents were placed in 13 patients suitable for analysis. The majority of stenoses

(11/13) were attributable to anastomotic strictures after curative esophagogastrectomy for esophageal neoplasms. All 11 patients in this group had satisfactory relief of dysphagia to solids determined clinically with indwelling SEPS placement. SEPS migration occurred in seven instances (30% of SEPS placed). Dysphagia remediation after subsequent SEPS removal was observed in only three patients (23%). Placement of a partially covered metal stent within a Polyflex™ stent was necessary in one case due to epithelial hyperplasia. The mean time for repeat dilation and/or SEPS reinsertion due to recurrent dysphagia after stent removal was 37 days (range 6–120 days).

Conclusions Polyflex™ stents provided satisfactory palliation of dysphagia for RBES while in place. However, unplanned SEPS migration and dysphagia recurrence after stent removal were common.

Keywords Stent · Esophageal stenosis · Endoscopy · Dysphagia

Introduction

The majority of benign esophageal strictures are effectively treated with endoscopic dilation [1]. Esophageal strictures that cannot be dilated to an adequate diameter for relief of dysphagia despite repeated dilation sessions or that require multiple dilations due to recurrence of dysphagia can be generally considered as refractory benign esophageal strictures (RBES) [2, 3]. The use of intralesional corticosteroid injections, electrocautery incisions, and endoscopic scissors for RBES has been reported and may reduce the rate of RBES recurrence [4–8].

Another proposed treatment of RBES is the placement of removable, covered self-expanding plastic stent (SEPS),

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such as the Polyflex™ esophageal stent (Willy Rüschi GmbH/Boston Scientific Corporation, Natick, MA). This stent is composed of a polyester mesh with a silicone covering and has the theoretical advantages compared with self-expanding metallic stents of being removable and decreased tissue ingrowth [9]. Two small studies from 2004 reported dysphagia improvement in over 70% of patients after Polyflex™ stent placement and removal [10, 11]. However, stent migration is not uncommon and higher failure rates have been reported more recently [12–17].

The aim of this study was to characterize treatment outcomes after Polyflex™ stent placement for management of recurrent dysphagia in a cohort of consecutive patients with RBES at our institution.

Methods

This was a retrospective cohort analysis. Outcomes of patients who underwent Polyflex™ stent placement for RBES between April 2005 and November 2006 at the Hospital of the University of Pennsylvania were analyzed. RBES was defined in this series as benign strictures that did not resolve clinically after three or more dilation sessions. Cases in which SEPS were placed for management of fistulas, leaks, or malignant stenoses were excluded.

Dilations and stent placements were performed by three experienced endoscopists. All procedures were performed using either conscious sedation (midazolam, fentanyl) or propofol when necessary. Both Savary-Guilliard dilators (Cook Medical, Bloomington, IN) and CRE (Boston Scientific Corporation, Natick, MA) balloons were used for dilation up to 18–20 mm in diameter for esophageal dilations performed prior to consideration of SEPS placement. At time of SEPS placement, esophageal dilation was performed to 12–14 mm when necessary to allow passage of the Polyflex™ stent delivery device over a stiff guidewire. The SEPS were then deployed under fluoroscopic and endoscopic guidance. Placement was verified endoscopically and fluoroscopically after deployment and modified as indicated (Fig. 1). Stent removal was performed using Olympus FG-47L-1 grasping forceps (Olympus America Incorporated, Center Valley, PA).

In the absence of stent migration or inability to remove the SEPS, the first stent was removed after approximately 6 weeks. If restenosis occurred after SEPS removal, subsequent stents were left in place for approximately 3 months followed by a maximum of approximately 6 months.

Relevant clinical information was obtained from patient charts as well as a computerized endoscopic database. For each patient, the stricture etiology, number of dilations prior to initial SEPS placement, size of stent(s) placed, stricture resolution after SEPS removal, stent migration, duration of

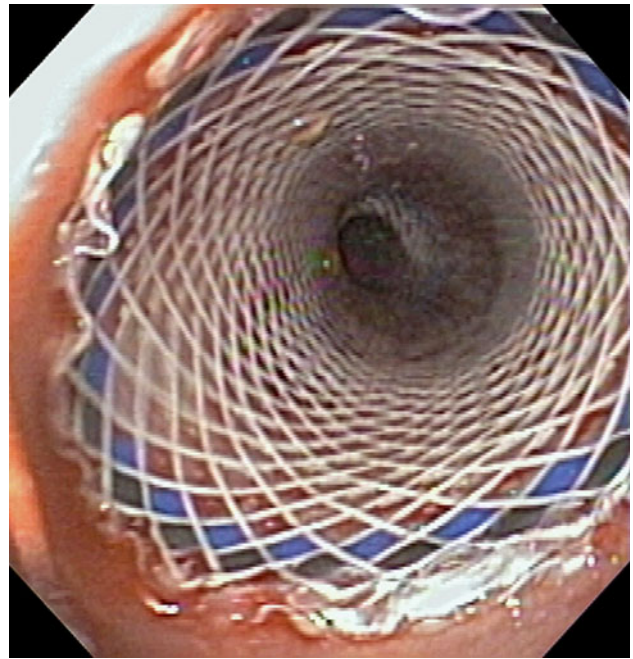


Fig. 1 Polyflex™ stent in proper position that was placed for a RBES due to an anastomotic stricture after curative esophagectomy

SEPS placement, time to repeat dilation and/or SEPS replacement after stent removal, and complications were entered into a spreadsheet (Microsoft Excel, Microsoft Corporation, Redmond, WA) and analyzed. RBES resolution after SEPS placement and removal was defined as the patient reporting no recurrent symptoms of dysphagia and not requiring additional dilation or stent replacement.

For the entire cohort, the mean number of initial dilations, repeat dilations, as well as time to repeat dilation or stent replacement were calculated using the “average” function in Microsoft Excel.

This study was approved by the University of Pennsylvania Institutional Review Board.

Results

Thirteen patients met the study inclusion criteria, in whom a total of 23 SEPS were placed. A summary of stricture characteristics, interventions performed, and outcomes for each patient is outlined in Table 1.

Eleven of the 13 patients were male, and the mean age of this cohort was 66 years (range 47–82 years). Eleven of the 13 patients had RBES due to anastomotic strictures after curative esophagogastrectomy for esophageal cancer. Six of these 11 patients had received neoadjuvant chemoradiotherapy. All 11 patients in this group had satisfactory relief of dysphagia with the SEPS in place, as determined by patient self-reporting. Of the remaining two RBES, one

Table 1 Stricture characteristics, therapy, and outcomes

Patient	Etiology	SEPS used (cm)	Duration of SEPS placement (days)	Outcome
1	Radiation post laryngectomy	21/25	42	Recurrent dysphagia after SEPS removal
2	Anastomotic	21/25	257	Epithelial hyperplasia requiring Ultraflex™ esophageal stent
3	Anastomotic	4 18/23	31, 96, 129	Recurrent dysphagia after SEPS removal
4	Anastomotic	2 18/23	154	Recurrent dysphagia after SEPS removal
5	Anastomotic	18/23, 21/25	Not applicable (migration)	SEPS migration, resolution
6	Anastomotic	18/23	Not applicable (migration)	SEPS migration, recurrent dysphagia after SEPS removal
7	Anastomotic	18/23	86	Resolution
8	Anastomotic	2 18/23	84, 182	Recurrent dysphagia after SEPS removal
9	Anastomotic	18/23	Not available	Lost to follow-up with SEPS in place
10	Anastomotic	2 18/23	85, 95	Recurrent dysphagia after SEPS removal
11	Nasogastric tube	2 18/23, 21/25	Not applicable (migration)	SEPS migration, resolution
12	Anastomotic	18/23	30	SEPS migration with subsequent repositioning, recurrent dysphagia after SEPS removal
13	Anastomotic	2 18/23	39	Recurrent dysphagia after SEPS removal

was attributed to prolonged nasogastric tube placement during intensive care unit admission and the other was due to radiation therapy post laryngectomy for laryngeal carcinoma. There was suboptimal relief of dysphagia in the latter patient with indwelling SEPS placement.

The mean and median number of dilations prior to initial SEPS insertion was eight and seven, respectively (range 3–14). The 9-cm-long 18/23-mm-diameter Polyflex™ stent was used in most cases (19/23), and the 12-cm-long 21/25-mm-diameter Polyflex™ stent was used in the remaining four cases. Of the four cases in which the larger-diameter SEPS was used, two were placed after migration of the smaller-diameter SEPS. The number of SEPS placed per patient ranged from one to four.

Unplanned SEPS migration occurred in seven instances, specifically in 26% (5/19) and 50% (2/4) of the 9-cm 18/23-mm and 12-cm 21/25-mm stents placed, respectively (Fig. 2). In all cases, the migrated stent was successfully removed with grasping forceps. Stricture resolution as determined endoscopically was observed in one out of the seven cases of SEPS migration and occurred after placement of the larger-diameter Polyflex™ stent. A new SEPS was placed in four cases and the old stent was repositioned in two cases; esophageal dilation was required for five of these cases. The migrated SEPS™ was removed without placement of a new stent in one case. For patients in whom stent migration was not observed or who were not lost to follow-up, the mean duration of SEPS insertion was 101 days (range 30–257 days).

In one case, a partially covered Ultraflex™ esophageal stent (Boston Scientific Corporation, Natick, MA) was placed within the Polyflex™ stent to palliate epithelial

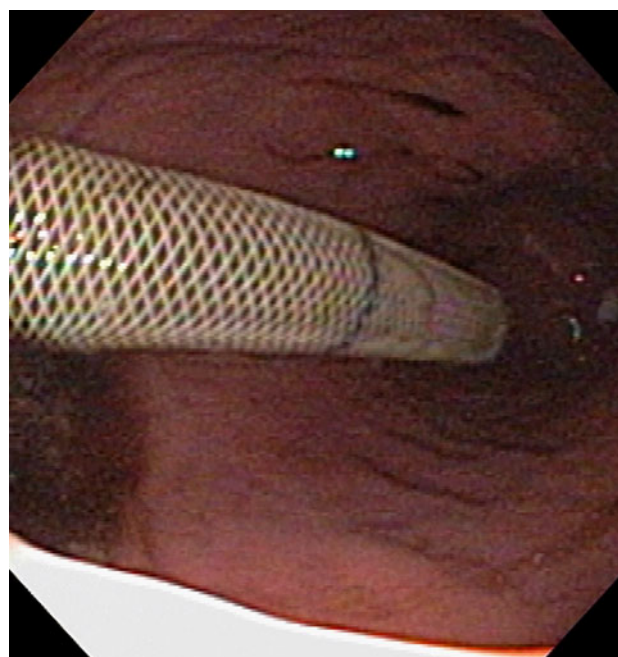


Fig. 2 Polyflex™ stent migration into the gastric remnant. This stent was successfully retrieved with grasping forceps

hyperplasia resulting from an indwelling 12-cm 21/25-mm Polyflex™ stent that had been in place for approximately 10 weeks.

Eventual stricture resolution after subsequent SEPS removal, determined clinically by resolution of dysphagia, was observed in only three patients (23%). Two patients whose dysphagia resolved had a 12-cm 21/25-mm Polyflex™ stent placed prior to removal, although stent migration occurred in both cases. Two of these patients

required multiple SEPS prior to RBES resolution. Of the six patients who had received prior radiation therapy, one patient had resolution of RBES determined clinically. The relationship between stricture resolution and duration of stent insertion could not be analyzed because stent migration commonly occurred. The mean time for repeat dilation and/or SEPS reinsertion due to recurrent dysphagia after stent removal was 37 days (range 6–120 days).

Discussion

Initial studies of SEPS for the treatment of RBES reported encouraging results in terms of resolution of dysphagia with the SEPS in place as well as after subsequent removal [10, 11]. While most patients in our series experienced adequate relief of dysphagia while the SEPS was in place, over 75% of the patients did not have sustained relief of dysphagia once the SEPS was removed. One possible explanation is that the case selection in our series represented a more refractory cohort of benign esophageal strictures compared with those considered in prior studies. Another possibility is that the smaller-diameter (18/23 mm) Polyflex™ stent, placed more commonly in our patients, was less effective in achieving the tissue remodeling needed to promote durable stricture resolution after SEPS removal versus the larger-diameter (21/25 mm) Polyflex™ stent. However, the small numbers of patients treated with each precludes making any definitive association between the two. The small sample size was also inadequate to discern whether prior radiation therapy, which can result in fibrosis of submucosa and muscularis, was associated with failure of RBES to resolve after SEPS placement.

Similar suboptimal results after Polyflex™ stent removal in patients with RBES have been reported by Dua et al., who used inability to maintain luminal diameter of 14 mm despite dilation every 2–4 weeks as an entry criteria [14]. In this series, 40% of patients remained dysphagia free after stent removal and a stent migration rate of 22% was observed. RBES resolution rates as low as 12.5% after stent removal have been reported previously [16]. However, direct comparisons with previously published studies are potentially limited by the different definitions of RBES used. A recently published series from the Mayo Clinic also reported a low rate of long-term improvement of symptoms after SEPS removal in patients with benign esophageal strictures and a high rate of stent migration; however, the patients in this series were not noted to necessarily have RBES [15].

Stent migration occurred in approximately 30% of the patients in this series; all migrated stents were successfully recovered endoscopically. The significance of a higher

percentage of larger-diameter Polyflex™ stents migrating compared with the smaller-diameter stents is unclear given the small number of larger-diameter Polyflex™ stents placed. Prior studies in patients with RBES have reported stent migration rates ranging from 7% to 85% of SEPS placed [10–12, 14, 16]. While no significant adverse sequelae have been reported due to SEPS migration, the possibility of bowel obstruction and perforation potentially exists. Asymptomatic Polyflex™ stent migration per rectum has been reported [13].

Significant epithelial hyperplasia occurred in one patient at the distal end of the Polyflex™ stent. This was surprising in that there was hope that the smooth covered surfaces of this stent would be apt to recruit a lesser degree of reactive epithelial hyperplasia. This phenomenon associated with Polyflex™ stent placement has been similarly reported by others [10, 12, 14, 15].

We did not observe significant complications in our series. However, perforation, tracheal compression, and aortoenteric fistula have been reported in the literature [11, 12, 14, 17–19].

In this cohort of patients with RBES, SEPS provided satisfactory palliation of dysphagia for a majority of patients while in place. However, unplanned stent migration, even with the larger-diameter stent, and stricture recurrence after stent removal commonly occurred. Clinically significant reactive epithelial hyperplasia was also observed. Exclusive use of larger-diameter (21/25 mm) Polyflex™ stents may yield more favorable results for durable RBES resolution. Standardizing entry criteria for patients undergoing endoprosthesis placement would potentially lead to more definitive conclusions in this regard [2].

An effective durable therapy for patients with RBES remains elusive. A discussion raising the consideration of long-term and potentially lifelong endoprosthesis placement may be necessary in some patients, since all esophageal strictures are not equally likely to respond [14, 20]. Further studies will be necessary to determine the optimal application of SEPS placement for the management of RBES in terms of stricture etiology, stent length and diameter, and duration of stent placement.

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