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DISEASES OF THE ESOPHAGUS

Case report

Biodegradable stents for caustic esophageal strictures: a new therapeutic approach

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SUMMARY. **The treatment of caustic esophageal strictures is a challenging topic. Although traditional therapies have limited efficacy, most of these patients eventually require surgery. Biodegradable (BD) stents are newly designed stents for benign conditions. This is a retrospective case series of seven patients with caustic esophageal stricture. BD esophageal stents were inserted for palliation of dysphagia. The position of the stent was checked at 1, 4, 8, 12 16, 20, and 24 weeks and at the end of follow-up period. The follow-up period was 60 ± 23 (36–102) weeks. Complete dissolution of the stent occurred at 16 ± 4 (12–20) weeks. Three patients had partial/complete relief of dysphagia. The remaining four patients experienced tissue hyperplasia at the edges of the stent and required serial dilations. At the end of follow-up, all patients had partial or complete relief of dysphagia. Although BD stents have some efficiency, tissue hyperplasia is the main limiting factor. Further randomized trials are needed to determine efficiency of BD stents for caustic damage.**

INTRODUCTION

Caustic ingestion compromises a large spectrum of gastrointestinal damage, including oropharyngeal, esophageal, gastric, and even duodenal burns. Esophagus is the most common site for patient morbidity, causing severe fibrosis and resultant stricture. Today, there is no optimal standardized therapeutic approach. Strictures typically develop during the phase of proliferation of esophageal fibroblasts with deposition of collagen. This usually occurs 1–3 months after the injury, but it may not develop until 1 year later. Apart from dilation therapies, temporary stenting for severe strictures was performed by some centers.[1] Recently, a new type of stent, biodegradable (BD) self-expandable stent is introduced. The Ella stent (ELLA-CS, s.r.o., Hradec Kralove, Czech Republic) is a BD stent that is manufactured from commercially available polydioxanone absorbable surgical suture. We report our experience with BD stent in caustic esophageal strictures.

CASE SERIES

Between January 2009 and June 2011, we have performed BD stent on seven patients (mean age 30 ± 12, range 5–48, six males, one female). All patients (or parents of patients) had accepted and signed informed consent. The timing of stent placement was 15 (9–22) months after caustic ingestion. The follow-up period was 60 ± 23 (36–102) weeks. The etiology of strictures was caustic ingestion in all patients. The mean stricture length was 5 ± 2 cm.

The dysphagia symptom was measures according to standard criteria, which was described by Knyrim *et al.*:[2] 0 = able to eat normal diet/no dysphagia; 1 = able to swallow some solid foods; 2 = able to swallow only semi solid foods; 3 = able to swallow liquids only; and 4 = unable to swallow anything/total dysphagia.

The median presenting dysphagia score was 3 (range 3–4). Three patients were taking nill per os, and they were on parenteral nutrition. The mean

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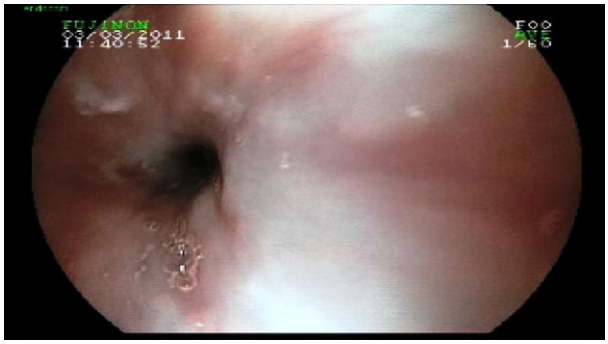

Fig. 1 Caustic esophageal stricture at the mid-esophageal location.

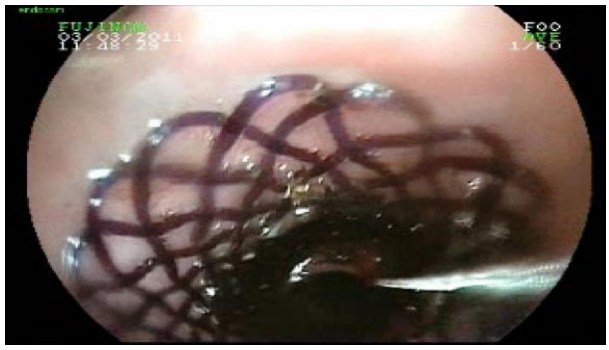

Fig. 2 Insertion of biodegradable stent.

number of dilation sessions before stenting was 4.6 ± 1.5 per month (range 2–5). Total number of dilations before stenting was 11.3 ± 3.8 (6–12). The criteria used for stent decision was more than five dilations in a relatively short period of time and/or patients' preference of a possible permanent treatment (stent insertion).

Strictures were located in the distal esophagus in two patients (28.5%) and in the mid-esophagus in five patients (71.5%). The stent had a body diameter of 20 mm and a length of 80 or 100 mm, according to the length of the stricture. Technical insertion of the stent was successful in all of the patients. In four patients, the stricture was dilated with 12 mm through the scope (TTS) balloon to insert the stent. The median procedure time was 30 minutes (range 22–48 minutes). A 8-cm stent was used in two patients (28.5%), and a 10-cm stent was used in the remaining patients. All of the procedures were performed with the patients under sedation with midazolam or propofol. Before insertion, the proximal margin of the stricture was marked by lipiodol injection. Savary dilation over a guidewire under fluoroscopic guidance was then performed to facilitate the introduction of the stent applicator. Subsequently, the applicator with the uploaded stent was advanced over the guidewire and positioned with the proximal radiopaque marker approximately 2 cm proximal to injection site. No intraprocedural complications occurred. All patients started proton pump inhibitors (lansoprazole 30 mg/day). Immediately after stent placement, severe thoracic pain requiring medical treatment with analgesics, including meperidine, developed in four patients (57%). Three patients had nausea for the first 24 hours, responsive to metaclopramide. One patient had severe headache starting hours after stent insertion. There were no signs of superior vena cava syndrome or neurological abnormalities. Cranial magnetic resonance imaging was in normal limits. Although severity of headache diminished over weeks, a mild pain insisted for at least 4 weeks. We were unable to determine the cause of headache for that patient.

After stent insertion, all of the patients were able to feed via oral route without any further parenteral nutrition requirement. However, some patients had recurrence of dysphagia due to stent-induced mucosal hypertrophy, and these patients had a short-term cessation of oral feeding until dilation therapy. However, none of the patients required parenteral support during follow-up period.

The position of the stent was checked at 1, 4, 8, 12 16, 20, and 24 weeks and at the end of follow-up period. Stent dissolution started at 12 ± 4 (8–16) weeks (Figs 1–3). Complete dissolution of the stent occurred at 16 ± 4 (12–20) weeks. First three patients experienced severe tissue overgrowth at 6 weeks. These patients had dysphagia score of 3 and required immediate dilation (with 12 mm TTS esophageal balloon). Although dysphagia improved in all three patients, they had consecutive dilations on a monthly basis. Total number of dilations at the end of the follow-up period was 6 ± 2 (5–9). The remaining four patients had complete resolution of dysphagia until 20 weeks; however, two of them required two (for each patient) additional dilations. At the end of the follow-up period, all of the patients had relief of their dysphagia symptom (only three patients had some complaints about solid foods). There were no stent migrations observed.

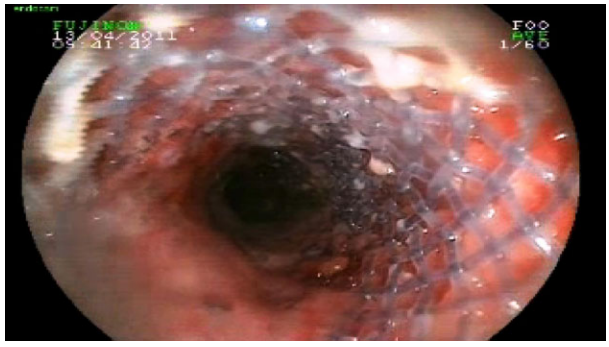

Fig. 3 Six weeks after stent insertion. Note that the stent has been partially degraded.

DISCUSSION

Management of benign refractory esophageal strictures is still a challenging issue. Although self-expandable metal stents (SEMS) are used for benign strictures, there are many obstacles limiting its efficacy, such as embedded tissue at the edges of bare ends, and traumatic retraction process of the stent.[1] Fully covered SEMS might be another option; however, there is a disturbing migration problem that occurs approximately 25–30% of patients.[3,4] Based on available data, SEMS are not approved by Food and Drug Administration for benign esophageal conditions.[1] Another option is self-expandable plastic (or silicon) stents (SEPS). However, SEPS placement for benign esophageal disorders reported a high rate of migration (62%) and a low rate of clinical success (17%).[5] Another study reported a clinical success (patients free of severe dysphagia score) of 30% at the end of 1-year follow-up.[6]

BD stents are encouraging in the field of benign esophageal strictures. There is only one recent study investigating the efficacy and safety of BD stents for benign refractory stenosis, the Best Study (Biodegradable Esophageal Stent).[7] This study was a prospective multicenter trial including 21 patients. Stent migration occurred in two patients (9.5%). The median pre- and post-stenting dysphagia scores were 3 (range 3–4) and 1 (range 0–2), respectively, with a median follow-up of 53 weeks (range 25–88 weeks). Nine of 20 patients (45%) were dysphagia free at the end of the follow-up. No major complications occurred. However, this study included only two patients with caustic strictures.[8]

Van Hooft *et al*. investigated the role of BD stents in benign anastomotic esophagogastric strictures in 10 patients.[8] In six patients, placement of the BD stent proved an effective 1-step treatment for their stenoses without the need for reintervention during 6 months of follow-up. The remaining patients required additional dilations, and finally all of the patients were free of dysphagia at the end of follow-up period.

Vandenplas *et al*. reported a child with caustic esophageal stricture who was treated with BD stent.[9] The patient was a 10-year-old boy with severe caustic injury, and a 25 mm, 8-cm long BD stent was introduced. Although the patient remained symptom-free during 4 months, he developed a severe distal esophageal stenosis more than 4 cm about 10 months after initial ingestion and 6 months after the stent placement. We have also noted severe tissue hyperplasia at proximal and distal ends of the stent in one of our adult and two pediatric patients (Table 1). Probably, tissue hyperplasia was a reaction to trauma applied by the stent, since the stent diameter was 25 mm. and it might be oversized for pediatric patients. There is another report of severe epithelial hyperplasia in the literature.[10]

Although the exact timing of stent placement after caustic injury remains unclear, we speculate that earlier stent placement (after mucosal healing) might prevent tissue remodeling and resistant fibrotic strictures. However, due to small sample size, we are not able to reach a conclusion on this matter.

The main question from our study is the efficacy of BD stents over removable SEMS. It has clearly shown that fully covered SEMS have a high rate of distal migration (approximately 30%). Our institutional experience is in parallel to these data, which are 10 of 28 patients with distal migration (35.7%) (unpublished data). In patients with a benign disorder such as caustic stricture, BD stents seem to be more durable and do not require extraction.

We have presented the largest series of caustic esophageal stricture treatment with BD stents. Main conclusions from this case series are: BD stents are safe therapeutic options for this indication; and tissue hyperplasia is the main limiting factor for relief of dysphagia (although responsive to dilation therapies).

Table 1 Clinical and demographic features of patients

Patient number	Gender	Age	Months after caustic ingestion	Stricture site†	Follow-up (weeks)	Number of post-stent dilations	Dysphagia score‡	Complications
1	M	5	22	1/3	102	12	0	Early: Chest pain, nausea vomiting, Late: Tissue hyperplasia
2	M	14	15	2/3	98	10	2	Early: Chest pain, nausea vomiting, Late: Tissue hyperplasia
3	M	39	21	3/3	56	3	0	Tissue hyperplasia
4	M	48	9	3/3	42	2	1	Minor-transient
5	F	42	12	2/3	52	2	1	Late dissolution of stent (20 weeks)
6	M	37	14	2/3	36	1	0	Minor-transient
7	M	25	12	2/3	39	0	0	Minor-transient

†1/3:upper third, 2/3; middle, 3/3; lower third. ‡Dysphagia score at the end of F/U. F/U, follow-up. F, female, M, male,

Further studies investigating host- and stent-related factors for occurrence of tissue hyperplasia are needed.

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