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ORIGINAL ARTICLE

Biodegradable Stents for Caustic Esophageal Strictures: Do They Work?

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Abstract Biodegradable (BD) stents have been used for the management of various esophageal strictures (ES) but the experience of its use in caustic strictures is limited. The present study, aimed at evaluating efficacy of BD stents for the treatment of refractory caustic-induced ES, was a retrospective multi-center study conducted at three tertiary care centers in India wherein adult patients with refractory caustic induced strictures underwent placement of a BD stent. Patients were followed up for immediate complications and long term outcome. All 13 patients (39.3 ± 15.1 years) underwent successful BD stent placement. Retrosternal chest pain occurred in 2 patients and stent migration in 1 (7.6%) patient. At 3 months, restenosis with recurrence of dysphagia was seen in nine (69.2%) patients, at 6 months, 10 (77%) patients had dysphagia of whom three underwent surgery and the remaining seven patients required dilatations. At 1 year, one patient remained asymptomatic while nine had dysphagia. The requirement for dilatation was once in 3 months in seven patients & once in a month in two patients. At 2 years, the requirement of dilatations was further reduced to once in 4–6 months in all patients. Over a 3 year follow up three (23%) patients had undergone surgery, one was free of symptoms while nine patients continued to be on periodic dilatation although the requirement had reduced to once in 4–6 months. Efficacy of BD stents in patients with caustic-induced ES is limited and the short term radial force applied by the currently available BD stents is inadequate to provide long term relief in such patients.

Keywords Dysphagia · Deglutition disorder · Esophageal strictures · Biodegradable stents · Caustic strictures · Refractory esophageal strictures · Dilatation

Introduction

Deglutition disorder or dysphagia secondary to esophageal stricture formation is commonly encountered in day-to-day gastroenterology practice. Dilatation by bougies or balloons has been the standard management of benign esophageal strictures (ES). Common etiologies of benign ES include peptic esophagitis and caustic ingestion. Caustic-induced strictures are often long, multiple, and refractory in nature [1]. Although early dilatation initiation has better results [2], a majority of the caustic-induced strictures present late and have frequent recurrences [3]. In fact, long-term success has been to be only 14–16% [3, 4]. The mean number of dilatation sessions needed to attain an adequate dilatation is also higher [5] and so are the complication rates compared to peptic strictures [6]. Various agents have been used to augment endoscopic dilatation such as intralesional triamcinolone [7] and mitomycin C [8] with variable results. Another form of treatment of BES is esophageal stents, which can provide a prolonged radial force to establish sustained luminal patency, an effect akin to repeated dilatation. With an added advantage of elective successful removal after a defined period, self-expandable metallic stents (SEMS) and self-expanding plastic stents (SEPS) have been increasingly used for the management of

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refractory strictures. Two recent studies have shown an overall efficacy of below 50% with SEMS being better than SEPS [9, 10]. Besides migration, stent-induced tissue hyperplasia is a major complication of indwelling stents [11]. To overcome the drawbacks of SEMS and SEPS, biodegradable (BD) stents were devised. The first material to be used was polylactide in 1997 [12]. The largest series was by Saito et al. [13], where 13 patients were treated with Tanaka Marui stent (Marui Textile Machinery, Osaka, Japan). In 2008, a new BD stent became available (SX-Ella-BD stent, Ella- CS, Hradec Kralove, Czech Republic), which is woven in a standard construction from a monofilament of polydioxanone (PDS), a surgical suture material. Since then, most series have reported the use of the same BD stents for mixed etiologies of ES with only a small fraction being caustic strictures [14–16].

The present study was aimed at evaluating efficacy of biodegradable expandable stent (SX-ELLA Biodegradable Esophageal Stent BD, ELLA-CS Ltd, Hradec Kralove, Czech Republic) for the treatment of refractory caustic-induced esophageal strictures.

Materials and Methods

This was a retrospective review of multi-center study conducted at three tertiary care centers in India (Postgraduate Institute of Medical Education and Research, Chandigarh; Sanjay Gandhi Postgraduate Institute, Lucknow; and Asian Institute of Gastroenterology, Hyderabad) from July 2010 to July 2011. Informed consent was obtained from patients before inclusion in the study. The study protocol was approved by Institutional ethics committee of all three centers.

Adult patients (age >18 years) presenting with deglutition disorder secondary to caustic esophageal strictures, which were refractory or recurrent to endoscopic dilatation were included. A stricture was defined as refractory when there was a persisting dysphagia score of two or more, as a result of inability to successfully achieve a diameter of 14 mm over five sessions at 2 week intervals [17]. Recurrent strictures were defined when there was inability to maintain a satisfactory luminal diameter for 4 weeks once the target diameter of 14 mm had been achieved as assessed by the inability to pass a standard gastroscope (diameter 9.8 mm) [17]. Exclusion criteria were strictures that could not be dilated to an adequate diameter allowing the 9.4 mm BD stent delivery system to pass through or if the upper esophageal sphincter was <1.5 cm above the upper margin of the stricture.

Dysphagia severity was graded according to a five-point scale (Table 1) [18].

Procedure

A biodegradable uncovered self-expandable stent was used (SX- ELLA-CS Ltd, Hradec Kralove, Czech Republic) in all the patients. The biodegradable stents are provided with a pull-back delivery system which automatically detaches as the stent starts deploying. It has a 9.4 mm (28 Fr) delivery system which is available in a standard length of 75 cm. A barium swallow examination was carried out in each patient to delineate the site and length of the stricture. The stent length was chosen according to length of stricture. The available stent lengths are shown in Table 2. Patients were prepared in the same manner as for a standard gastroscopic examination. All the procedures were performed with the patients under midazolam sedation. The stricture was dilated before stent placement to a diameter of 11 mm using a bougie or a balloon diameter. A stainless steel-stiff guide wire (Wilson Cook, USA) was introduced through the endoscope and passed through the stenosis under direct vision. Subsequently, the applicator with loaded stent was advanced over the guidewire and stent was released under fluoroscopic guidance by withdrawing the external sleeve while holding the internal pusher stationary (Fig. 1). Endoscopy was performed immediately after stent placement to confirm the positioning and stent expansion.

Follow-up

After stent implantation, patients were observed for 4 h for development of chest pain, respiratory distress, or stridor and bleeding. They were allowed to take liquids after 12 h and if there was no difficulty in swallowing, they were discharged. The patients were maintained on a liquid diet for 48 h and thereafter on semi-solid diet for 7–10 days. Patients were questioned about relief of dysphagia, pain, heartburn, or any other symptoms potentially related to the stent weekly for the first month, monthly for 3 months and then every 3 months. Follow-up gastroduodenoscopy was performed at 1 and 3 months to evaluate stent degradation and the esophageal narrowing. Recurrent dysphagia was defined as difficulty in deglutition, at least, solid food (grade ≥2) and when a standard gastroscope (diameter 9.8 mm) could not be negotiated. Stent migration was defined as either endoscopic or radiographic evidence that the stent had migrated into the stomach or had moved significantly (>3 cm) from its original position. Patients were followed for 3 years. Patients with recurrence of dysphagia were offered periodic dilatation or surgery (Fig. 2).

The following demographic and clinical characteristics of the patients were retrieved: baseline characteristics, technical and clinical success, time to recurrence of dysphagia, treatment needed, complications, and final

Table 1 Dysphagia grading

Dysphagia score	Description
0	No dysphagia: able to eat normal diet
1	Moderate passage: able to eat some solid foods
2	Poor passage: able to eat semi-solid foods
3	Very poor passage: able to swallow liquids only
4	No passage: unable to swallow anything

Table 2 BD stents specifications

Stent body diameter (mm)	Stent flare diameter (mm)	Stent length (cm)
18	23	60/80/100
20	25	60/80/100
23	28	60/80/100
25	31	60/80/100

outcome. Technical success was defined as successful deployment of stent, while clinical success was defined as resolution of dysphagia at the end of the follow-up period (Fig. 3).

Results

A total of 13 patients [mean age 39.3 ± 15.1 years, range 18–72 years, (8 males)] underwent BD stent placement at three centers. All the patients had been on periodic dilatations for over 6 months with median number of dilations received being 13 ± 4.3 (range 9–25). Strictures were located in the upper 1/3rd of esophagus in 1(7.6%) patient, middle 1/3rd in 9 (69.2%) patients, and lower 1/3rd in 3(23%) patients. The mean length of stricture was 4.0 cm (range 2–5 cm). The median dysphagia score at the time of inclusion into study was 3 (range 3–4).

BD stents were placed successfully in all the 13 patients (100% technical success) (Figs. 3, 4). The length of the stent was 80 mm in 12 patients and 115 mm in one patient

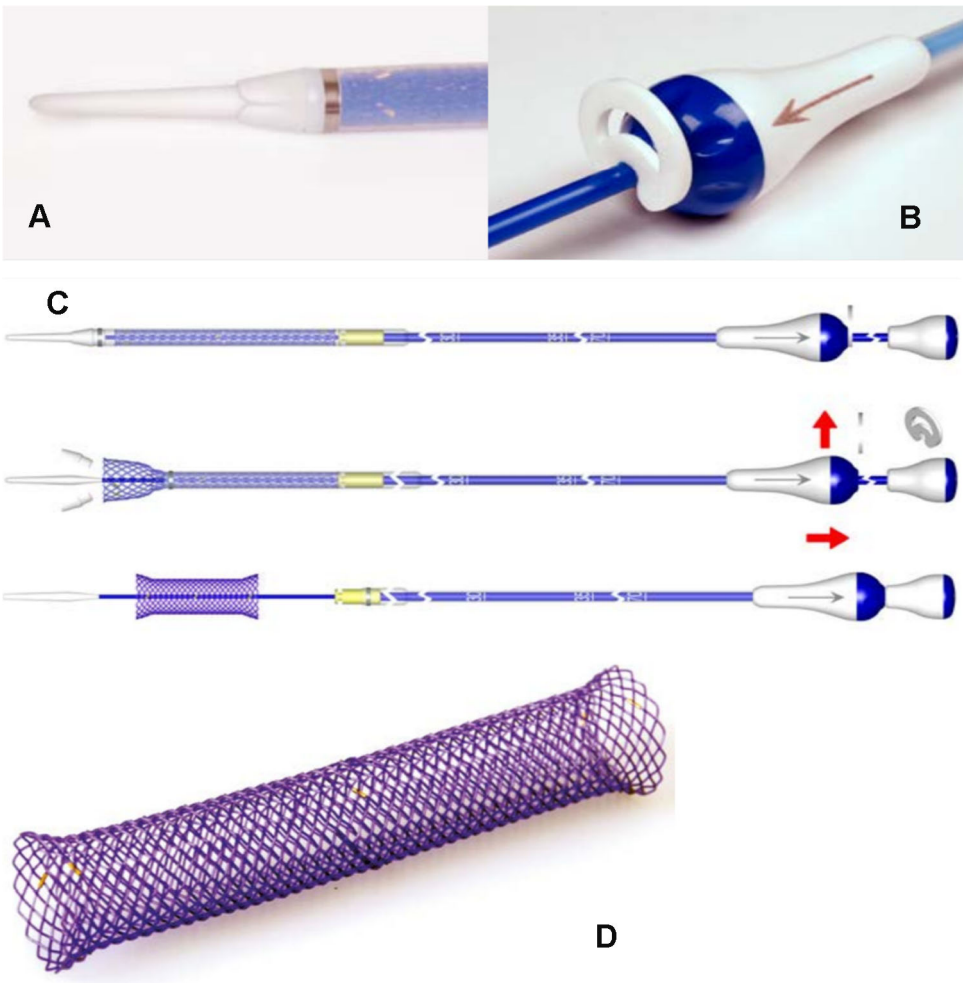

Fig. 1 Stent Delivery system: **a** olive tip/sheath, **b** sheath handle, **c** stent deploying technique, **d** stent when fully deployed (Image courtesy: ELLA-CS, Czech Republic; www.ellacs.eu)

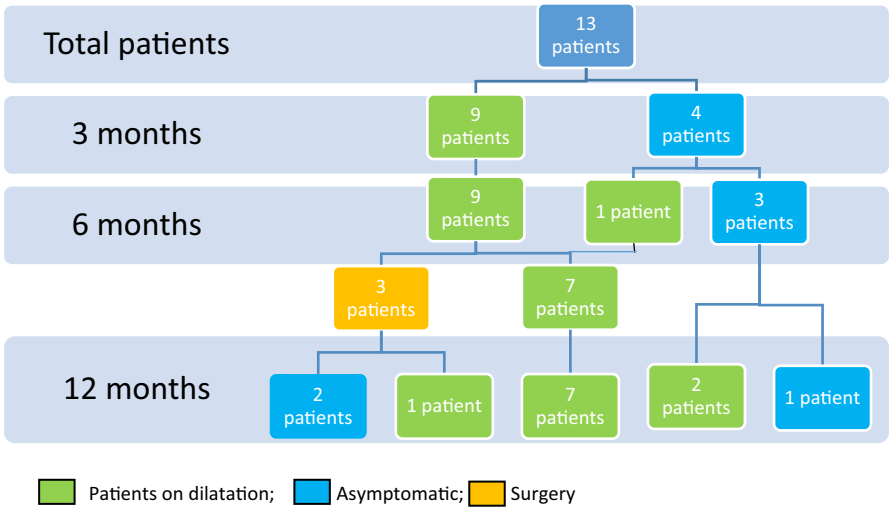

Fig. 2 Flowchart showing patient outcome and follow-up

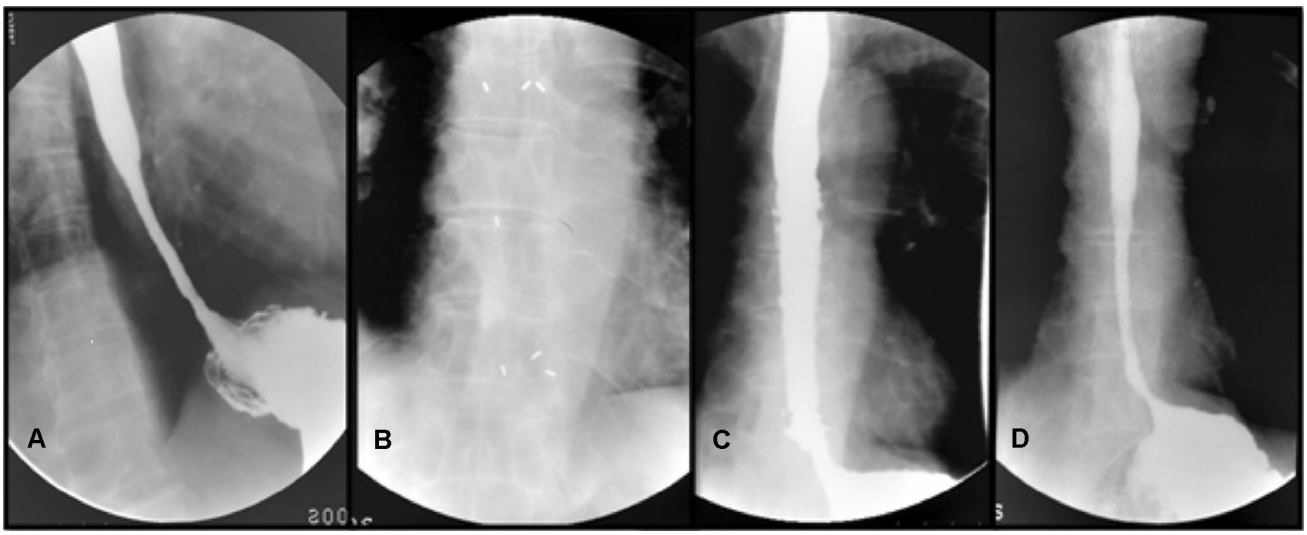

Fig. 3 Serial barium swallow films of a patient undergoing BD stenting. **a** Pre-stenting imaging showing the stricture site and length. **b** Plain X- ray film showing the radiopaque markers of the stent in situ. **c** Imaging after stenting showing the stent in situ. **d** Follow-up imaging after stent degradation (6 months post-stenting)

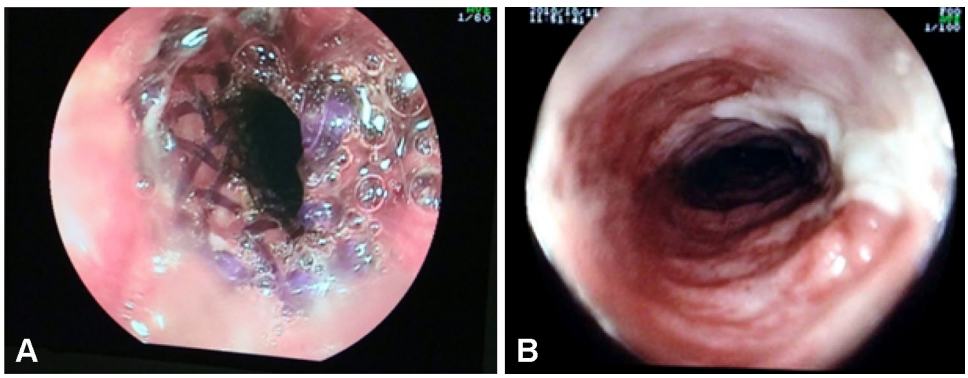

Fig. 4 Endoscopic image of a patient; **a** with stent in situ, **b** follow-up endoscopy after stent degradation (3 months post-stenting)

and the diameter was 23 mm in all. No immediate procedure-related complications were noted. One patient had retention of olive of the stent in the stomach, which was removed endoscopically successfully the same day. Retrosternal chest pain occurred in all 13 patients after BD stent placement, which persisted for 1 week in 10(77%)

Table 3 Stricture sites and outcome of individual patients

Case No	Age/sex	Site of structure	Previous dilatations	Dysphagia score at inclusion	Pain at 1 week	Tissue hyperplasia	Restenosis		
							3 months	6 months	12 months
1	32/M	Lower	12	3	+	+	−	−	−
2	52/F	Middle	9	3	+	+	+	+	+
3	18/F	Lower	12	4	+	−	+	+	+
4	31/M	Middle	11	3	+	−	+	+	+
5	47/M	Middle	15	3	+	+	−	−	+
6	32/M	Middle	20	3	−	−	+	−	+
7	47/M	Middle	25	3	−	−	+	+	+
8	51/M	Lower	11	3	+	+	+	+	+
9	72/F	Middle	13	3	−	−	+	+	+
10	18/F	Upper	12	3	+	−	−	+	+
11	29/M	Middle	15	3	+	+	+	+	+
12	35/M	Middle	18	3	+	−	+	+	+
13	47/F	Middle	16	3	+	−	−	+	+

patients, for 2 weeks in 6(46%) patients, and for 8 weeks in 2(15.3%) patients. 1(7.6%) patient had stent migration into stomach at 4 weeks. Tissue hyperplasia was noted in 6(46%) patients at the proximal end of the stent at 4 weeks. BD stents had disintegrated completely in all the 12 patients at 3 month follow-up endoscopy with no stent seen in situ (Table 3).

All patients were followed for a total period of 3 years. At 3 months, restenosis with recurrence of dysphagia was seen in nine (69.2%) patients. At 6 months, 10 (77%) patients had dysphagia of which three patients underwent surgery and the remaining seven patients required dilatations. At 1 year, one patient remained asymptomatic, while nine had dysphagia. Of the three patients subjected to transhiatal esophagectomy and esophagocolonic anastomosis, one had anastomotic stricture requiring dilatations for 3 months, while the other two remained free of dysphagia. However, the requirement for dilatations was once in 3 months in seven patients and once in a month in two patients. At 2 years, the requirement of dilatations was further reduced to once in 4–6 months in all patients. At 3 year follow-up, the dysphagia scores were 1–2 in all patients requiring dilatations once in 4–6 months. Overall, out of 13 patients who underwent BD stent placement, three (23%) had restenosis requiring surgery and one was free of symptoms while nine patients continued to be on periodic dilatation, though the requirement of dilatation was significantly reduced to once in 4–6 months.

Discussion

We have described outcome of 13 patients with caustic-induced strictures leading to deglutition disorder, who were treated with BD stent placement after having failed to respond to periodic dilatation. The stents could be placed successfully in all 13 patients and over a 3 year follow-up, one patient was free of symptoms, nine required periodic dilatations, and three were subjected to surgery.BD stents disintegrated completely in all the 12 patients at 3 month follow-up endoscopy with no stent seen in situ.

The technical success of 100% is similar to that in other studies. We achieved clinical success of 15.4% at 1 year and 7.7% at 3 years. Different studies have reported clinical success of 14.3–60% in strictures of varied etiologies (Table 4) with a follow-up of 5.5–18.5 months. The varied results of different studies could be due to the differences in etiology, inclusion criteria, and follow-up period. Among the individual published studies, the number of caustic-induced strictures has been only 0–7 with a total of 16 patients in all the studies put together. Caustic-induced strictures are known to be more difficult to treat than other etiologies, requiring more sessions of dilatations, and having more recurrences [5]. Because of this fact, they are candidates for augmentation of dilatation with intralesional steroids [22] or topical mitomycin or for esophageal stents. However, in our study, none of the patients had received intralesional steroids or topical mitomycin.

Table 4 Comparative data of the various major studies using SX-ELLA BD (PDS) stent for benign esophageal strictures

Study (ref)	No. of patients (corrosive strictures)	Technical success (%)	Stricture length (mean)	Pain after stent (%)	Stent migration (%)	Tissue hyperplasia (%)	Follow-up period (median)	Clinical success[β] (%)
Repici et al. [14], BEST study, 2010	21 [4 (19%)]	100	3 cm	3 (14)	2 (9.5)	1 (5)	53 weeks	42.9
Van Boeckel et al. [15],2011	18 [2 (11%)]	85	4 cm	2 (11)	4 (22)	2 (11)	166 days	33
Van Hooft et al. [16] (ESBIO) 2011	10[≠] [0 (0%)]	100	1 cm	–	0	6 (60)	6 months	60
Canena et al. [19], 2012	10 [1 (10%)]	100	2.9 cm	1 (10)	2 (20)	3 (30)	18.5 months	30
Hirdes et al. [20], 2012	28[α] [2 (7%)]	100	–	–	1 no.: 11 2 no: 8 3 no.: 0	0	6 months	After stent first stent: 25 second stent: 15 third stent: 0
Karakan et al. [21] 2013	7 [7 (100%)]	100	5 cm	57	0	3 (43)	60 weeks	14.3
Our study	13 [13 (100%)]	100	4 cm	100	1 (7.6)	6 (46)	3 years	1 yr: 15.4 3 yr: 7.7

[≠] Only patients with anastomotic strictures

[α] Sequential stent placement done

[β] Clinical success defined as clinical remission without the need for further endoscopic dilatation or surgery after stent removal or migration

Our data have shown that a single-time BD stent placement does not provide long-term relief to patients with refractory caustic-induced benign ES. While three patients required surgery, nine were continued on dilatation, though the frequency of dilatation decreased over the follow-up period. In the absence of a control arm in our study, it is not possible to assess whether the natural history of caustic-induced benign ES can be altered by BD stents. A study from Delhi [5] had shown that requirement of dilatation decreased after the first year in such patients. A randomized study with a control arm would be needed to answer this question.

Severe pain after stent placement was observed in 10–14% of patients in various studies. In our study, all patients had complained of mild-to-moderate degree retrosternal pain, while Karakan et al. [21] had reported pain in 57% of patients. This difference could be due to the smaller diameter of BD stents (20 mm) used by Karakan et al. as compared to the 23 mm stent used in our study. None of the patients had post procedural bleed in the current study as compared to significant bleed in one patient in the BEST study [14] and two patients in the study by van Boeckel et al. [15]. Karakan et al. [21] had not reported any stent migration, while we had one stent migration (7.6%), lower than the reported rates of 9.5–22% in various studies [14, 15, 19, 20]. Tissue hyperplasia was seen in six patients (46%) similar to that seen in the other studies (5–60%) [14–16, 19–21]. Stent dissolution was complete at 3 months in the current study, comparable to complete degradation seen at around 3–6 months in various studies [14, 16, 21]. The nature of complete biodegradability of these stents had been demonstrated in one of our previous reports (case no. 5) who had undergone transhiatal esophagectomy. His endoscopy at 3 months had shown complete degradation and the surgical specimen of the esophagus obtained at 6 months after stent placement revealed no evidence of stent material histologically [23]. Our study had excluded patients with strictures within 1.5 cm of the esophageal inlet. While on one hand these upper esophageal strictures are difficult to treat, placement of stents at the upper end is not easy and can lead to foreign body sensation and stridor if respiratory passage is compromised. These problems are likely to be worse with a larger diameter stent like BD sent.

BD stents give only a temporary relief of dysphagia due to the short period of sustained radial force after which they start disintegrating. Hirdes et al. [20] had studied the effect of sequential BD stent placement in ES, wherein after the first, second, and third stent placement, the clinical success rates were 25, 15, and 0%, respectively. Although the sequential stent placement outcome was not very promising, it definitely gives an option of avoiding serial dilatations.

Despite self-expanding stents being in use for more than two decades, an ideal stent has not yet been developed. While fully covered SEMS (FCSEMS) have high migration

rates [10], partially covered SEMS have tissue hyperplasia in a significant number of patients. SEPS also have high migration rates (27%) [10]. BD stents were devised to overcome the deficiencies of metal and plastic stents, but then their efficacy falls short of the expectation. A study comparing SEPS and BD stents in refractory benign ES reported comparable clinical success, with BD stents requiring significantly less number of re-interventions [15]. Another study compared SEPS, BD stents, and FCSEMS in refractory benign ES and found SEPS to be less preferable as compared to BD stents or FCSEMS in terms of higher migration rates (60 vs. 20–30%), greater need for re-interventions and lesser long-term improvement rates (10 vs. 30–40%). In fact, FCSEMS had a higher efficacy and similar migration rates compared to BD stents [19]. BD stents have the advantage of less tissue hyperplasia and infrequent local complications. However, the durability of response is limited by the disintegration of the current stent by around 3 months. Comparatively, FCSEMS, while being removable with less tissue regrowth, provide more therapeutic radial force to the stricture segment. The number of strictures, the length of the stricture, the interval between the stricture formation and placement of stent, the number of dilatations prior to stent placement, and the prior use of agents such as steroids are some of the factors which may modify the outcome of BD stents and need to be studied prospectively.

Limitations of our study are that it is a retrospective study with a small sample size. Larger, multi-center, randomized, prospectively designed studies would be able to answer the definite role of BD stents in caustic-induced or other refractory strictures causing deglutition disorder. Another limitation is that the data regarding the duration for which the patients had esophageal strictures before being enrolled in our study was not available. This is important as the evolution of the stricture is time-dependent. We also did not have data on the number of patients excluded based on the exclusion criteria. Thus, our results cannot reflect response on intention-to-treat based. We had only one patient with a stricture in the upper third of esophagus. Such patients are more difficult to treat with dilatation. Stent placement in patients with strictures close to the upper esophageal sphincter may be associated with foreign body feeling or stridor if the respiratory passage is compressed especially with a large diameter stent such as the BD stent. For this reason, we had excluded patients with strictures within 1.5 cm of the upper sphincter. Attempts to design better BD stents with a slower disintegration rates are warranted since the concept of a self-disintegrating stent is very attractive.

To conclude, the efficacy of BD stents in patients with caustic-induced ES is limited. We believe that the short-term radial force applied by the currently available BD stents is inadequate to provide long-term relief of dysphagia in such patients.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest.

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