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Bhattacharya, Sayantan
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Carta Editor

Are bio-degradable stents an option in peptic oesophageal stricture?

Sayantan Bhattacharya sayan.bhattacharya@whh.nhs.uk
Warrington Hospital., Reino Unido

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Treating resistant peptic oesophageal strictures still poses significant challenge to gastroenterologists and GI surgeons around the globe. Although traditional treatment is repeated endoscopic dilatation, there is no clear evidence regarding their indicated frequency or degree of stretching, required for achieving best results. Patients are mostly in their extremis and malnourished, prone to complications from factors both related and unrelated to interventions. Hence, any possible alternative which reduces number of invasive interventions or increases their intervals are worth exploring. In quest for this, use of steroid injection with endoscopic stretching and stents of different varieties have been investigated. Endoscopic steroid injection to the stricture site was reported initially as a better option over endoscopic dilatation alone, however, in absence of a specified dose of injection, set regime and added risk of delayed perforation is still under review. [1] After several initial reports of complications and low success rates in benign setting with metal and plastic stents (embedding, migration and need for re-intervention), biodegradable stents (BDS) emerged as a more viable alternative. However, studies failed to show success rates of more than 55% with BDS. Most of these studies were prospective or retrospective models, with small cohort size. [2,3,4,5] Most studies used heterogeneous cohorts comprising of strictures from several aetiologies, thus introducing selection bias, as a recent meta-analysis found association between aetiology and treatment outcome in benign strictures. [6] Different follow-up periods were used to define clinical success in most studies. Hence, inferences drawn regarding success rates were comparable between reports with difficulty. A randomised trial reported inferior performance of BDS with respect to mean number of adverse outcomes, post intervention dysphagia-score at 6 and 12 months as compared to endoscopic dilatation alone, in benign setting (Table 1). [7] This was also in clear contradiction to reports from non-randomised studies claiming superiority of BDS in providing greater dysphasia free intervals. [8] The meta-analysis, after analysing results from 444 patients and 18 studies, reported no significant difference between results from plastic or metal stents and BDS in benign strictures. [6] The authors, however, warned

about high levels of heterogeneity in participant studies, especially those involving plastic and metal stents. There was also the obvious risk of amplification of bias from several participant studies which were largely non-randomised.

Lastly, stents are liable to cause more strictures at its ends for reasons not entirely clear to us. [9] Probably by keeping the gastro-oesophageal junction open at all times, stents promote continued reflux which is the likely contributory factor. This may also be a reason for shorter dysphagia free intervals with sequential stenting in recurrent stricture. [10]

Hence, prior to advocating its routine use in benign conditions and replacing current treatment with regular endoscopic dilatations with stents, further targeted studies with larger, non-heterogeneous cohorts, longer follow-up periods and more robust evidence base is required.

Year	Type of study	Aims	Results	Definition of clinical success and follow up
2007	Retrospective	Poly-lactic acid knitted BDS in benign non-peptic strictures (n = 13).	1. Clinical success 23%. 2. Migration rate 76%.	Not clearly defined but follow-up was from 7 months - 2 years.
2010	Prospective	Assess efficacy and safety of (n = 21; 33% had peptic strictures).	1. Clinical Success 33% in peptic sub-group & 45% in entire cohort. 2. Significant improvement in post stenting dysphagia score ($p < 0.01$). 3. Migration 16.7% in peptic group and 10% in entire cohort.	No recurrence of dysphagia at the end of at least 6 months follow-up (median 53 weeks for entire cohort).
2011	Prospective	Compared effects of BDS (n = 18) versus temporary SEPS (n = 20) 33% and 5% had peptic strictures respectively.	1. Clinical success in BDS versus SEPS was 33% and 30% respectively ($p = 0.83$). 2. Migration rates were 22.2% and 25% respectively ($p = 0.30$).	No recurrence of dysphagia at the end of follow-up. For BDS, median was 166 days (range 21 - 559 days). For SEPS, median was 385 days (range: 77 - 924).
2012	Prospective	Assess efficacy of BDS in benign (n = 7, none with true benign peptic strictures) and malignant strictures.	1. 45% success in entire cohort (median follow-up 20). 2. Re-intervention rates high after stent dissolves.	Dysphagia free till end of follow-up, median follow up was 20 weeks (range: 13 - 111).
2012	Prospective Multi-centre	Compare SEPS, BDS and fully covered SEMS (n = 10 in each arm) in benign strictures, peptic strictures were in 1, 3 and 3 patients (total 23.3%) respectively.	1. Overall success 26.7% (very low). 2. No difference in dysphagia-free Periods ($p = 0.67$), re-intervention ($p = 0.24$, clinical success ($p = 0.24$) and complication rates ($p = 0.38$). 3. Migration of stents in 36.7% cases (n = 6, 2 and 3 respectively; $p = 0.16$).	Dysphagia free till end of long follow-up. Median follow up was 23.4 months (range: 8 - 66).
2012	Prospective	Assess effects of single and sequential bio-degradable stents in 28 patients (59 stents), peptic strictures in 9 patients (32%), Clinical success defined as dysphagia free period for 6 months.	1. Median dysphagia free periods after 1st, 2nd and 3rd stents (90, 55 and 106 days). 2. Clinical success rate after first stent was 25%. 3. Clinical success rate after second stent was reduced to 15%. 4. Clinical success rate after third stentwas 0%.	Dysphagia free for at least 6 months.
2014	Multi-centre Randomised Trial	Compare BDS (n = 9) versus repeated endoscopic dilatation with CRE balloon (n = 6), 46.7% with peptic stricture (n = 3 and 4 patients respectively).	1. Significantly higher post intervention dysphagia score in stent group after both 6 months and 12 months ($p = 0.029$ and $p = 0.05$ respectively). 2. Mean adverse outcome higher in stents ($p = 0.024$). 3. Results of BDS inferior to repeated dilatation.	Follow up in 6 and 12 months.
2016	Retrospective	Assess results of BDS in benign and malignant strictures of esophagus, 17 stents inserted in 10 patients with benign (80% peptic) stricture.	1. Interval between BDS insertion and 1st post-stenting intervention was significantly longer than pre-stenting dilatation intervals ($p < 0.05$). 2. 80% cases needed multiple dilatation. 3. Quoted 20% (2 out of 10) success but both these patients died before presenting with recurrent symptoms.	Dysphagia free till end of follow-up from March 2011 till July 2015 or till death. Median follow-up was for 171.5 weeks for benign group.
2016	Retrospective	Efficacy and safety of BDS in benign (n = 9% of peptic strictures not specified) and malignant (n = 11) strictures.	1. Significant improvement in dysphagia scores in benign sub-group ($p < 0.001$). 2. 55.6% patients in benign group were symptom free at follow up success). 3. Migration rate was 0%.	Not clearly defined.
2016	Meta-analysis	Compared SEMS (n = 227) versus SEPS (n = 140) versus BDS (n = 77) in 444 patients from 18 studies (17.8% with peptic stricture).	1. Overall Clinical Success 40.5% with stents. Higher heterogeneity in studies involving SEMS and SEPS. 2. BDS had lower success rate (32.9%) as compared to SEMS and SEPS (40.1%, and 31.5% respectively, difference was statistically not significant). 3. Overall migration rate was 28.6% BDS had lower migration rates (15.3%) as compared to SEMS and SEPS (46.2% and 33.3% respectively, difference was statistically not significant). 4. Overall adverse events 20.6%, no significant difference between 3 stents. 5. Strictures due to anastomosis (post surgical) and radio-therapy induced may be more sensitive to stents than other types.	1. Clinical success defined as dysphagia free till end of follow-up. 2. Clinical heterogeneity with regards to length of follow-up noted. 3. Follow-up for entire cohort was from 86 - 1281 days (median follow-up 455 days) in different studies.

Table 1.

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Author notes

sayan.bhattacharya@whh.nhs.uk

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