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The role of biodegradable stents in the management of benign and malignant oesophageal strictures: A cohort study

Stephen McCain [a,*], *Scott McCain* [a], *Barry Quinn* [b], *Ronan Gray* [a,c], *Joan Morton* [b], *Paul Rice* [b]

[a] *Departments of General Surgery, Craigavon Area Hospital, Craigavon, Northern Ireland, UK*
[b] *Departments of Radiology, Craigavon Area Hospital, Craigavon, Northern Ireland, UK*
[c] *Cancer Epidemiology and Health Services Research Group, Centre for Public Health, Queen's University Belfast, Northern Ireland, UK*

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ABSTRACT

Background: Oesophageal strictures can be caused by benign or malignant processes. Up to 10% of patients with a benign stricture are refractory to pneumatic dilatation and may benefit from biodegradable stent (BD) insertion. Biodegradable stents also have a role in malignant oesophageal strictures to facilitate enteral nutrition while staging or neo-adjuvant treatment is completed. The aim of this study was to review the safety and efficacy of BD stents in the management of benign or malignant oesophageal strictures.
Methods: A single centre retrospective cohort study was performed. Dysphagia was graded before and after stenting using a validated score. All patients were followed up for at least 30 days and all adverse events were recorded.
Results: Twenty eight stents were inserted in 20 patients; 11 for malignant and 17 for benign disease. One further attempted stenting was impossible due to a high benign stricture. There were no perforations and the 30-day mortality rate was zero. Mean dysphagia scores improved from 2.65 to 1.00 (p value <0.001) in benign disease and from 3.27 to 1.36 (p value <0.001) in patients with malignant disease. Surgical resection was not compromised following stent insertion in the malignant group.
Conclusions: Biodegradable stent insertion is a safe and efficacious adjunct in the treatment of benign and malignant oesophageal strictures. In malignant disease, BD stent insertion can maintain enteral nutrition while staging or neo-adjuvant therapy is completed without adversely impacting on surgical resection.

* *Corresponding author*. 8 Crevenagh Way, Omagh, Northern Ireland, BT79 OJE. Tel.: +353 447731856393.
E-mail address: smccain02@qub.ac.uk (S. McCain).
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Introduction

Oesophageal strictures commonly present with symptoms of progressive dysphagia, regurgitation and vomiting. As a result of the obstructive process there may be associated malnutrition and weight loss. Patients with these symptoms require prompt investigation with upper GI endoscopy or barium studies. Strictures can be caused by benign or malignant processes and have an overall incidence of 1.1 per 10 000 within the UK.[1–3]

Benign strictures are most commonly caused by long-standing oesophageal reflux. Other causes include external beam radiation, oesophageal sclerotherapy, caustic ingestions, surgical anastomosis, and rare dermatologic diseases. Routine management of benign strictures involves oesophageal dilatation, often in combination with acid suppression therapy.[4] Up to 10% of all patients will not respond to this treatment and are deemed to have refractory disease.[5] In these cases, self expanding metal stents (SEMS) and self expanding plastic stents (SEPS) have been used to alleviate symptoms. However, the limited symptomatic relief achieved and the high rate of adverse incidents encountered has led to the use of biodegradable (BD) stents, which have been in use since 2008.[6]

Biodegradable stents also have a role in the management of oesophageal malignancy. Palliative patients are managed successfully with SEMS for symptom control. However, many patients with oesophageal cancer present with severe dysphagia and malnutrition prior to the completion of staging investigations or experience worsening symptoms during neo-adjuvant treatment. For these patients, BD stent insertion as "a bridge to surgery" can improve symptoms and allow enteral nutrition while staging or neo-adjuvant treatment is completed.[7,8]

The aim of this study was to review the safety and efficacy of BD stents in the management of benign or malignant oesophageal strictures in our unit.

Methods

A retrospective review was performed between 30th March 2011 and 30th November 2013 in a single district general hospital (Craigavon Area Hospital) within the Northern Ireland Southern Health and Social Care Trust. All patients who underwent BD oesophageal stent insertion during the study period were included. Cases were identified using the radiology Picture Achieving and Communication System (PACS) database while relevant demographic and clinical information was obtained by retrospective chart review using a standardised data collection pro forma.

Patients were followed up until 31st December 2013 through review of outpatient clinic attendances or readmissions to hospital with all patients being reviewed for a minimum of 30 days. The clinical data collated included symptoms, indication for stent insertion, complications, validated pre- and post-stent insertion dysphagia scores, and method of nutrition pre- and post-stent insertion. Dysphagia was graded using the score described by O'Rourke et al. (0 = normal swallow, 1 = able to swallow some solids, 2 = able to swallow semi-solids, 3 = able to swallow liquids only, 4 = unable to swallow liquids).[9] Pathological data and BD stent insertion details were also recorded.

Stent materials and insertion technique

A single experienced gastrointestinal interventional radiologist inserted all stents. Although use of BD stents in oesophageal malignancy does not fall within the current licence, patients were discussed at an upper gastrointestinal multidisciplinary meeting and direct consultant-to-consultant referral was made.

The ELLA stent was inserted in all cases. This is a biodegradable stent made from polydioxanone absorbable surgical suture (Fig. 1). The stent degrades by random hydrolysis and this is accelerated by a low pH. Stent integrity and radial force of the stent is maintained for 6–8 weeks following implantation and stent disintegration occurs at 11–12 weeks from implantation. The stent is radio-transparent and has radiopaque markers at both the proximal and distal ends. The diameter of the stent is 25 mm and there are four available lengths ranging from 60 mm to 135 mm. The stent gradually expands upon release. Contraindications to stent insertion include inability to pass the 9.4 mm (28F) delivery system through the stricture, the presence of a benign stricture at the upper part of the oesophagus in close proximity to the cricopharyngeus muscle and patients who have benign strictures due to previous laryngectomy.[3]

All BD stents were inserted in the Endoscopy Unit under conscious sedation using a titrated dose of intravenous midazolam and opioid analgesia. Direct visualization was performed using a paediatric gastroscope (Olympus GIF-XP260). Under fluoroscopic guidance proximal and distal boundaries of the oesophageal stricture were marked externally using metallic skin markers. The BD stents were then inserted over a guidewire, ensuring overlap of the radio-opaque markers within the stent delivery system and skin markers before deployment. Post procedure, patients were fasted for two hours and then allowed clear fluids. If tolerated, oral intake was then increased to allow solid foods as guided by a dietician.

Statistical analysis

Age has been expressed as a median and inter-quartile range. Time to re-intervention and lifespan post stenting have been

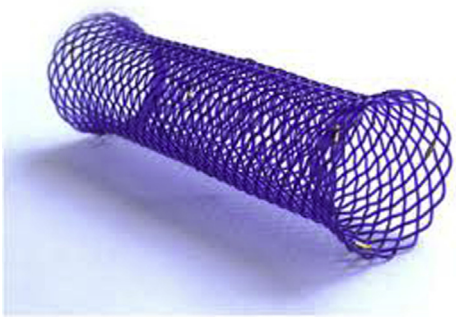

Fig. 1 – ELLA-biodegradable stent made from polydioxanone absorbable material.