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TOPIC HIGHLIGHT

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Biodegradable stents in gastrointestinal endoscopy

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Abstract

Biodegradable stents (BDSs) are an attractive option to avoid ongoing dilation or surgery in patients with benign stenoses of the small and large intestines. The experience with the currently the only BDS for endoscopic placement, made of Poly-dioxanone, have shown promising results. However some aspects should be improved as are the fact that BDSs lose their radial force over time due to the degradable material, and that can cause stent-induced mucosal or parenchymal injury. This complication rate and modest clinical efficacy has to be carefully considered in individual patients prior to placement of BDSs. Otherwise, the price of these stents therefore it is nowadays an important limitation.

Key words: Biodegradable stents; Strictures; Endoscopy; Endoscopic placement; Stenoses

Core tip: The experience with the currently the only biodegradable stents (BDSs) for endoscopic placement, made of poly-dioxanone, have shown promising results. However some aspects should be improved as are the fact that BDSs lose their radial force over time due to the degradable material, and that can cause stent-induced mucosal or parenchymal injury. This complication rate and modest clinical efficacy has to be carefully considered in individual patients prior to placement of BDSs. Otherwise, the price of these stents therefore it is nowadays an important limitation.

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INTRODUCTION

Metal and plastic stents are an effective treatment to manage both benign and malignant strictures throughout the gastrointestinal (GI) tract; however, the use of these stents is associated with several common problems including migration, tissue ingrowths and repetitive endoscopic procedures. During the last two decades, significant advances have been made in the development of biocompatible and biodegradable materials for medical applications, and to overcome those shortcomings, stents made of biodegradable materials have been developed. The cardiovascular stent market is the dominant driving force for research and development of biodegradable stents (BDSs)[1]. In the GI tract much less is currently known about the clinical utility and the experience with these stents.

BIOMATERIALS

Biomaterial is a non-living material used in a medical

device and designed to interact with biological systems. Biomaterial can be (1) inert, do not trigger any reaction in the host; (2) bioactive, ensure a more stable performance in a long time or for the period you want; or (3) biodegradable, it can be chemically degraded or decomposed by natural effectors as bacteria. The mean features of these materials for medical applications are absence of carcinogenicity, immunogenicity, teratogenicity and toxicity.

More used biomaterials are magnesium alloys based and synthetic polymers: poly-lactic acid (PLA), polyglycolic acid (PGA), poly-caprolactone (PCL), polydioxanone (PDX) and poly-lactide-co-glycolide.

Main advantages of magnesium alloys based are high biocompatibility and property to be dissolved into human body during the degradation process; however, due to this high corrosion rate, degradation occurs before the end of healing process.

Polymers degrade slower than magnesium alloys. Most polymers used in medical devices allow the spread of water within molecular structure and can therefore result in processes hydrolysis. The ideal polymer should be: (1) sufficiently strong until surrounding tissue has healed; (2) does not invoke inflammatory or toxic response; (3) to be metabolized in the body after fulfilling its purpose; (4) leaving no trace to be easily processable into the final product form; (5) must demonstrates acceptable shelf life; and (6) to be easily sterilized. With these characteristics; the main advantages of synthetic polymers are: (1) good biocompatibility; (2) possibility of changing in composition and in physical-mechanical properties; (3) low coefficients of friction; (4) easy processing and workability; (5) ability to change surface chemically and physically; and (6) ability to immobilize cells or biomolecules within them or on the surface (Drug Eluting Stent). Biodegradable polymers used for drug release represent the next technological modification and preliminary results are favorable in vascular system and clinical efficacy as first-generation drug eluting stent, but gastrointestinal application has not been reported yet[2].

According to these features, BDS can be made of different synthetic polymers (PLA, PGA) or their copolymers (PDX). Their degradation is hydrolytic and the speed of biodegradation is dependent not only on the size and structure, but also influenced by temperature, pH and type of body tissue/fluid[3,4].

CLINICAL EXPERIENCE

The first report was published in 1993[5] in an experimental model of urethral stenosis with rabbits treated with a stent made of PLA. In gastrointestinal endoscopy, BDSs made of PLA were developed by Goldin *et al*[6], who reported their experience with five patients with benign esophageal strictures. These authors described that this prototype did not maintain significantly radial force over a 3-wk period, and disintegrated 6 wk later and obstructed the esophageal lumen, data that was confirmed by another group[7].

BDSs made of PDX have improved the results because stent integrity and radial force can be maintained for 6-8 wk after implantation[8]. In this pilot study with three patients with benign tight small and large intestinal stenoses, the authors confirmed that stent degradation and fragmentation occurs 11-12 wk after its insertion; otherwise, the speed of degradation is pH-dependent (faster in lower pH).

The prolonged dilatory effect before stent absorption and the progressive stent degradation could represent a more favorable solution for patients with benign strictures refractory to standard dilation therapy compared with self-expandable metal and plastic stents. These newly stents allow for constant radial dilation, similar to date achieved by a metallic stent, but with the advantage that they do not have to be removed. To date, PDX-BDSs could be an alternative for benign refractory strictures in the GI tract.

Esophagus

Placement of BDS is an emerging and promising treatment alternative for benign esophageal strictures and achalasia. These strictures are often caused by esophageal reflux, the ingestion of caustic substances, esophageal surgery and radiation therapy[9]. Endoscopic dilation using bougies or balloons has been established as a standard therapy, and it is associated with an immediate 80%-90% success rate of relieving dysphagia[10]. However, 30%-60% of benign strictures will recur during long-term follow-up; thus, an alternative treatment strategy should be considered[11].

BDSs have recently been developed. Initially, these stents were made of PLA, with a configuration and mechanical radial force similar to those commercially available esophageal stents[12]. Saito *et al*[13,14] reported results from two series of patients who received this type of PLA esophageal stents, but the majority (77%) of stents had migrated out of the esophagus within 10-21 d of insertion, although clinical success was observed in all cases within the follow-up period of 7 mo to 2 years.

Another novel stent (Ella esophageal stent) composed of the biodegradable polymer PDX has become to be used from 2007 (and currently the only). This stent is assembled onto a 9.4-mm (28 F) delivery system, and comes in several sizes, with stent body diameters ranging from 18 to 25 mm and fully deployed lengths of 60-135 mm. Integrity and radial force are completely maintained for approximately 6 wk following implantation. From 7-9 wk is 2/3 of the initial, after the 9 wk is 1/3, and the average time to complete degradation of the stent is reported to be 11-12 wk[8]. Acid-suppressing therapy is recommended, because more rapid degradation occurs with acid exposure.

Published experience has been reported with the SX-ELLA-BD stent for treatment of refractory benign esophageal strictures (RBES)[9,15-29] as well as achalasia[30] (Table 1). Technical success, clinical responses and out-

Table 1 Cases series evaluating the outcomes of biodegradable stents with polydioxanone for refractory benign esophageal strictures

Ref.	Year	Type of study	*n*	Follow-up (mo)	Technical success	Complications	Clinical success
Dhar *et al*[23]	2009	CS	4	4	100%	Chest pain, 25%	50%
Vandenplas *et al*[15]	2009	CR	1	4	100%	0%	100%
Orive-Calzada *et al*[16]	2009	CR	1	3	100%	T. hyperplasia, 100%	0%
Stivaros *et al*[27]	2010	CS	2	7	100%	Chest pain, 50% Stent migration, 50%	50%
Bychkova *et al*[24]	2009	CR	1	4	100%	0%	100%
Hair *et al*[30]	2010	CR	1	8	100%	T. hyperplasia, 100%	0%
van Hooft *et al*[17]	2011	CS	10	6	100%	Chest pain, 20%	60%
Repici *et al*[29]	2010	CS	21	13.2	100%	Chest pain, 14% Hemorrhage, 5% Stent migration, 9%	45%
Nogales Rincon *et al*[21]	2011	CR	1	2	100%	Stent collapse, 100%	0%
Martín Cano *et al*[25]	2012	CS	3	4	100%	0%	100%
Griffiths *et al*[28]	2012	CS	7	4	96%	0%	76%
Canena *et al*[9]	2012	RCT	10	12	100%	Chest pain, 10% Hemorrhage, 10% Stent migration, 20 T. hyperplasia, 30%	30%
Fischer *et al*[19]	2012	CS	2	12	100%	T. hyperplasia, 50%	50%
Dumoulin *et al*[20]	2012	CR	1	18	100%	T. hyperplasia, 100%	0%
Hirdes *et al*[22]	2012	CS	28	10	100%	Chest pain, 22% Hemorrhage, 8%	25%
Basha *et al*[18]	2013	CR	1	4	100%	0%	0%
Karakan *et al*[26]	2013	CS	7	15	100%	T. hyperplasia, 57%	43%

CR: Case report; CS: Case series; RCT: Randomized clinical trial; T. hyperplasia: Tissue hyperplasia.

comes were varied. Stent implantation is not a problem, but clinical success ranged from 0 to 100, with a mean of 39.4%. The largest long-term follow-up series of BDSs placement in 28 patients with RBES were reported by Hirdes *et al*[22], with a clinical success rate after the first BDS placement of 25%.

To avoid complications of partially covered/uncovered stents, temporary placement of 3 different types of expandable stents have been used for the treatment of RBES: self-expanding plastic stents (SEPSs), BDSs and fully covered self-expandable metal stents (FC-SEMSs). To date there is only one published study that compares the efficacy of these three types of stent for the treatment of RBES[9]. These authors showed that temporary placement of BDSs or FC-SEMSs have similar utility in the treatment of RBES, with a long-term dysphagia-free period in 30% and 40% of patients, respectively. The use of SEPSs were associated with the worst clinical success rate (10%) as well as with a higher number of migrations and reinterventions. A long stricture was the only significant fact associated with a higher recurrence rate after stent placement. Migration rate was higher with FC-SEMSs (30%) than with BDSs (20%). The implementation of balloon dilatation of the BDS stent after deployment did decrease migration rated compared to before balloon dilation.

Thoracic pain is the most frequent complication reported in the literature. Hyperplasic tissue reaction occurs in conjunction with stent degradation and the severity of the tissue response and the time to complete degradation, both important factors when considering patients for placement of a BDS, are still well not understood. Cases of severe tissue hyperplasia resulting in recurrent dysphagia have been described[16,19,20,26,30]. To alleviate symptoms in this type of stent, endoscopic balloon dilation[26,30], or argon plasma coagulation have been reported[20], but there are no recommendations to guide what endoscopic approach is best. Other potential complications of BDS that have been addressed are collapse of the biodegradable stent mesh inside the esophageal lumen[21] and tracheoesophageal fistula[31]. Finally, fully covered BDSs could be useful in the treatment of esophageal perforations and anastomotic leaks[32].

Small intestine and colon

BDSs are a promising therapeutic option for benign intestinal and colonic strictures. Strictures following colorectal surgery are the most frequent, and occur in 1.5%-8% of patients[33]. Published information is limited to patients with anastomotic colorectal strictures following resection for colon cancer[34-37], postsurgical colonic fistulas[35], and stricturing Crohn's disease[38,39] (Table 2). Intestinal insertion is technically possible and relatively simple, except for proximal stenoses and in patients with considerable deformity and angulations. The standard delivery system of PDX-BDS has an active length of 75 cm that limitates proximal stent insertion, and in most cases it may not be possible to place the stent at more than 30 cm from the anus[35]. Technical difficulties for more proximal stenoses are pre-empted due to the necessity of a special introduction system for stent insertion through a balloon overtube[38]. Early stent migration is an important drawback and is the main reason of clinical failure, but can be solved using cyanoacrylate, with a

Table 2 Cases series evaluating the outcomes of biodegradable stents with polydioxanone for benign intestinal and colonic strictures

Ref.	Year	Type of study	Indication	*n*	Follow-up (mo)	Technical success	Complications	Clinical success
Janík *et al*[37]	2011	CS	PS	3	5	100%	0%	66%
Rejchrt *et al*[8]	2009	CS	Stricturing CD	11	14	91%	Stent migration, 27%	64%
Toth *et al*[36]	2011	CR	PS	1	5	100%	0%	100%
Pérez Roldán *et al*[35]	2012	CS	PS and fistula	10	13	90%	Stent migration, 10%	50%
Repici *et al*[34]	2013	CS	PS	11	3	100%	Stent migration, 36%	45%
Rodrigues *et al*[39]	2013	CR	Stricturing CD	1	16	100%	0%	100%

CR: Case report; CS: Case series; RCT: Randomized clinical trial; CD: Crohn's disease; PS: Postsurgical strictures.

clip placement in the upper flare or by improvements in stent design. Mucosal hyperplasic reaction after insertion of BDS has been documented in esophageal strictures but not in intestinal strictures.

Pancreatobiliary tract

Endoscopic therapy of benign biliary strictures (BBSs) is now first-line therapy. The paper of BDSs in clinical practice is unknown, and is one the main targets in endoscopic research. The causes of BBSs are diverse, with the 2 most common causes being postsurgical strictures and chronic pancreatitis[40]. Commercially available plastic and metal stents for the bile duct and pancreatic duct have many limitations. Endoscopic placement of BDSs have demonstrated feasibility of implantation, relatively safety, and potential efficacy in the biliary and pancreatic ducts in animal models[41,42]. The use of a novel, self-expanding, radiopaque PLA-barium sulphate BDS and a polyethylene stent was investigated in 12 pigs with cystic-duct leakage, showing that the total external output of bile was significantly smaller with BDS compared with the plastic stent group[42]. This group of authors investigated the degradation, patency, and toxicity of this PLA-BDS stent placed into the pancreatic duct of pigs, and after six months no histological or anatomical changes were observed[41].

Recently, other group of authors have developed other self-expandable BDS made from a poliglecaprone, an absorbable surgical suture. This stent was successfully endoscopically inserted in the pancreatic and bile ducts in 4 pigs[43]. However, future animal studies are needed to evaluate the short-term patency, tissue reactivity and degradation of this stent.

There is no published clinical experience with endoscopic placement of BDSs. However, percutaneously placement of BDSs have been addressed recently[44,45]. In this two pilot studies a total of 12 patients with refractory postsurgical BBSs have been treated with BDSs-PDX in the biliary tree, with clinical success with up to 2-years of follow-up.

CONCLUSION

BDSs are an attractive option to avoid ongoing dilation or surgery in patients with benign stenoses of the small and large intestines. The experience with the currently the only BDS for endoscopic placement, made of PDX, have shown promising results. However some aspects should be improved as are the fact that BDSs lose their radial force over time due to the degradable material, and that can cause stent-induced mucosal or parenchymal injury. This complication rate and modest clinical efficacy has to be carefully considered in individual patients prior to placement of BDSs. Otherwise, the price of these stents therefore it is nowadays an important limitation.

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