TRANSPLANT INTERNATIONAL

Transplant International ISSN 0934-0874

LETTER TO THE EDITORS

Biodegradable stents after lung transplantation

doi:10.1111/tri.12095

Sirs,

Airway complications (AC) are a major obstacle after lung transplantation (LTx) [1,2]. Metallic stents represent the mainstay treatment, but stent-related complications are frequent [3]. In attempting to address some of these drawbacks, biodegradable stents (BDS) have been developed as a temporary alternative in managing benign lesions and represent a novel alternative for obstructive AC in LTx recipients [4–7]. BD stents are based on Polydioxanone (PD), which is the same material used to suture bronchial anastomoses during lung transplantation. These BDS showed to be well tolerated by the tracheal mucosa, maintain biomechanical strength for 6 weeks, and dissolve completely after 3–4 months [8]. A retrospective small case series on BDS in patients after LTx was recently published [9].

A prospective open-label phase I study was performed in a single center. Inclusion criteria were airway complications after LTx with a target lesion in central airways, except the trachea or main carina. The self-expandable BD stents were custom manufactured from PD in appropriate sizes (Ella-Cs, Ltd., Hradec Kralove, Czech Republic). PD is a semicrystalline biodegradable polymer belonging to the polyester family. It degrades by hydrolysis. Prior to enrollment, the project underwent approval by the Institutional Review Board and was registered at clinicaltrials.gov (NCT00929942).

Eleven BDS were inserted in 10 patients (4 female, age 26–64 years, 3–30 months after transplantation) between July 2009 and October 2010 (Table 1). All patients showed a relief of the clinical symptoms and improvement of pulmonary function test (FEV1 $\Delta 344 \pm 217$ ml/s, FVC $\Delta 160 \pm 92$ ml/s 6-MWT $\Delta 122 \pm 61$ ml/s) after insertion. Patency of target lesion was achieved in 9/11 lesions after 1 year of follow-up. One stent required removal 4 days after insertion as a result of mucosal bleeding. Four patients developed in stent-stenosis after 36–116 days, which was successfully treated with a metallic stent ($n = 1$), argon therapy, and/or balloon dilatation ($n = 3$). Nine Patients were treated with topical mitomycin as a result of granulation tissue during follow-up.

Complete degradation was observed after median 141 days. All patients remained free from further airway intervention after 6 months. In one patient, new airway colonization was observed (Table 1); five had prior colonization. Overall survival was 100%, with no graft loss.

Polydioxanone has proven to be biologically safe and has been used previously in a variety of medical materials, including suture material and bone nails [10]. The principal feature of BD stents is their transient biomechanical benefit and subsequent reabsorption [3]. Besides several case series, our own experience involving 61 lung transplant recipients with metal stents, a re-stenosis rate of 52% was observed [3,11–14]. Re-stenosis free and freedom from intervention-free at 6 months seems to be favorable with BD stents.

An established complication following the insertion of endobronchial prostheses is the increased risk of airway colonization. In our previous study involving 61 lung transplant recipients with metal stents, 77% of patients subsequently demonstrated bacterial colonization [3]. Noppen reported an 80% incidence of new bacterial colonization (mainly Staphylococcus aureus) following the insertion of silicone stents in a nontransplant cohort [15]. New colonization follow metals stent insertion was studied by Burns, demonstrating that 56% of BAL samples turned positive [13]. In this small series, only one patient (10%) subsequently developed a new lower respiratory tract colonization, compared with 40% in our previous metal stent group. This possibly results from matrix removal, thereby preventing biofilm formation following stent degradation.

In some centers, temporary stent insertion remains the preferred management strategy for LTx patients [16], but subsequent removal of stents remains technically challenging and potentially hazardous for the patient, especially in metals stents [17]. There has been limited uptake of silicone stents in LTx cohorts as a result of technical issues regarding their limited suitability when dealing with anatomically complex lesions, their small lumen, and the lack of transmural ventilation for over-stented collateral bronchi. Initial studies also suggested a migration rate of 30–40% with associated complications [18]. Any type pf stent provides at best a mediocre solution to obstructive airway complications following lung transplantation as a result of their significant individual drawbacks. BDS may solve some of these issues by retaining luminal patency and crucially

Table 1. Patient characteristics and adverse events.

No.	Gender	Age (years)	Diagnosis	Months postoperative	Endoscopic intervention previous	Target lesion	Stent Size	Days until degradation	Adverse and serious adverse events
1	M	64	Emphysema	7	×5	Left upper lobe	8 × 26 mm	110	Re-stenting of stenosis
2	F	50	Emphysema	30	×20	Intermediate bronchus	10 × 22 mm	159	Coughing, re-stenosis with intervention
3	F	58	Emphysema	25	×11	Intermediate bronchus	10 × 22 mm	141	Stenotrophomonas maltophilia detection, Re-Stenosis with intervention
4	F	36	CF	4	×3/×4	Left upper lobe	8 × 13 mm	133/105	Re-Stenosis with intervention
5	F	41	PH	5	×6	Intermediate bronchus & right lower lobe	10 × 45 mm	188	Mucosal bleeding with prolonged hospitalization
6	M	61	IPF	7	×5	Left upper lobe	10 × 22 mm	105	
7	M	58	Emphysema	5	×7	Left upper lobe	10 × 22 mm	211	
8	M	26	CF	4	×10	Intermediate bronchus	10 × 22 mm	145	Aspergillus detection
9	M	30	CF	7	×5	Intermediate bronchus	10 × 22 mm	141	Re-stenosis with intervention
10	M	60	IPF	3	×4	Intermediate bronchus	10 × 22 mm	136	

CF, cystic fibrosis; PH, pulmonary hypertension; IPF, idiopathic pulmonary fibrosis.

avoid both permanency avoiding the long-term risks including colonization and the need for extraction.

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Conflict of interest

There is no conflict of interest.

Funding

This study was supported by a grant from the German Federal Ministry of Education and Research/reference number: 01EO0802); the contents of this article are the sole responsibility of the authors.

Acknowledgements

The authors thank Jan Fuge, Department of Respiratory Medicine, Hannover Medical School, for data acquisition and video editing.

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