Feasibility, safety, and efficacy of iron bioresorbable scaffold in neonates with duct-dependent pulmonary circulation

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ABSTRACT

Introduction : **Bioresorbable stent has the theoretical advantage in the pediatric age group; however, experience in the literature is very limited.**

Objectives : **This pilot study sought to evaluate the feasibility, safety, and performance of iron bioresorbable scaffold (IBS Angel™) as short-term palliation in lesions with noncomplex patent ductus arteriosus (PDA).**

Materials and Methods : **Nine neonates with duct dependent but dual-source pulmonary blood flow (PBF) were included. Major stent-related complications, in-hospital course, stent patency up to 6 months, and unplanned re-interventions were studied, as well the percentage of stent material resorbed in patients in whom the stents were explanted at the surgery.**

Results : **IBS Angel™ was successfully implanted in all nine patients (mean weight range 3.4 ± 0.4 kg). Six were pulmonary atresia with an intact ventricular septum and 1 critical pulmonary stenosis patients where PDA stenting was done together or after balloon dilation. The mean procedure and fluoroscopy times were 89 ± 39 min and 16.3 ± 6.9 min, respectively. There were no major complications such as stent thrombosis or embolization and there were no in-hospital deaths. Post procedure overshunting and prolonged ventilatory support was a prominent feature. The median ventilation days was 3 (1–11 days). One patient died after 1 month due to respiratory syncytial virus pneumonia at the referring hospital. At 6 months follow-up, four had patent stents and four had blocked or restrictive stent flow. One patient received re-stenting at 4 months for restrictive stent flow. In three patients where microcomputed tomography of explanted stent was available, resorption of iron was 15% at 6 months and >65% at 16 months.**

Conclusions : **Ductal stenting with IBS Angel™ is feasible and safe in selected patients. Because of early luminal loss, its use may be recommended for lesions with dual-source PBF with noncomplex PDA morphology that requires a short duration of palliation.**

Keywords : Ductal morphology, ductal stenting, iron bioresorbable scaffold

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INTRODUCTION

Ductal stenting (DS) using coronary stents in neonates with duct-dependent complex cyanotic heart disease is gaining wider acceptance as a temporary palliation before surgical repair.[1-4] Subsequent surgical repair also incorporates stent removal and often reconstruction of branch pulmonary arteries 6–12 months post stenting. Conventional bare metal stent – when embedded in dense fibrous tissues – may pose specific challenges at surgical repair and impact outcomes.[5] Bioresorbable stent has theoretical appeal in the pediatric setting. Once stent material has been resorbed, obstacles to surgical reconstruction are diminished or large stents may be implanted in keeping with somatic growth. Magnesium (BIOTRONIK SE and CO. KG. Berlin, Germany) and poly-L-lactic acid (Abbot Laboratories, Chicago, Illinois, USA)-based coronary scaffolds have been implanted on neonates, but these were limited to case reports.[6,7]

Iron bioresorbable scaffold (IBS Angel™, Biotyx Medical [Shenzhen] Co., Ltd., which spins off from Lifetech Scientific [Shenzhen] Co., Ltd.), is a new iron-based resorbable scaffold which has shown promising results in early human trials and proceeding animal studies.[8] Unlike stent implantation in other lesions, DS serves as temporary palliation following which the stent is left to auto-occlude when RV growth is achieved after balloon dilation in pulmonary atresia intact ventricular septum (PAIVS), or as in the majority of cases of congenital heart disease (CHD), the stented PDA is removed at the time of surgical repair later in infancy.

The objective of this prospective pilot study was to evaluate the feasibility, safety, and early outcome of IBS Angel™ in DS in CHD with noncomplex PDA morphology. The study was approved by the institutional review board and parental consent was obtained for all patients.

MATERIALS AND METHODS

From September 2018 to August 2019, consecutive neonates with duct-dependent CHD were recruited into the study if the following criteria were met:

i. Weight >2.5 kg,
ii. Presence of dual-source pulmonary blood flow (PBF), i.e., antegrade flow to the pulmonary arterial bed as well as from the stented PDA at the end of the procedure, and
iii. Noncomplex PDA morphology, i.e., those that were relatively straight and arising from the descending aorta as typically represented in PAIVS, critical pulmonary stenosis (PS), and tricuspid atresia (TA).

Preterm neonates, metabolic disorders and those with syndromes were excluded.

The primary endpoints were: stent patency up to 6 months, in-hospital mortality and unplanned re-intervention for cyanosis. Stent-related major complications were recorded (cardiac tamponade, acute stent thrombosis, and stent embolization).

The IBS Angel™, Biotyx Medical (Shenzhen) Co., Ltd.,

IBS Angel™ is made of pure iron tube, the strut thickness is ~70 μm incorporated with nitrogen of ~0.05% of its weight, the iron strut was coated with a pure zinc buffer layer of 600-nm thickness, and then, poly-D, L-lactic acid (amorphous, PDLLA) was sprayed. The compound layer design can ensure IBS Angel™ is intact in the first 3 months after implantation. A gold radiopaque marker is located at each end of the stent to enhance the X-ray visibility. The IBS Angel™ characteristics are comparable to an equivalent cobalt-chromium (Co-Cr)-based stent such as Xience™ (Abbott Laboratories, Chicago, Illinois USA). For a 3-mm diameter, stent the crossing profile is 1 mm, and has a radial strength of 120 kPa. The scaffolds are expected to lose integrity and scaffolding force at about 4 months and 9 months, respectively, and totally corroded in about 1–1.5 years.[9,10]

In the ongoing coronary artery trial, the stent is sirolimus coated, but for this study, nondrug eluting IBS Angel™ was used. The available stent diameters were 3.0 and 4.0 mm, and lengths 12 mm, 15 mm, and 18 mm.

Stent implantation procedure

The stent implantation procedure was as described in our previous paper.[11] All implantations were via the femoral artery route using 25 cm 4F sheath (Terumo Corporation, Tokyo, Japan). In PAIVS and critical PS patients, this was done either electively at the time of balloon dilation of the pulmonary valve as the right ventricle (RV) was obviously small or semi-emergently within the same admission in those with borderline RV who developed significant severe cyanosis (SaO2 <75%) following balloon dilation when the PDA started closing.

The data recorded were procedure and fluoroscopy time, duration of ventilation, intensive care unit (ICU) and hospital stay, SaO_2 in the first 48 h and signs of overshunting. We defined overshunting as oxygen saturation of more than 90%, failure to extubate within 48 h and signs of organ hypoperfusion depicted by gut ischemia, renal impairment, or ICU stay more than 1 week due to heart failure.

Follow-up and subsequent procedures

Post procedure, all patients were followed up first at 1 month and thereafter three monthly. The stent patency and efficacy of palliation were assessed by echocardiography and clinical findings, i.e., murmur and oxygen saturation. Stent visibility and integrity were assessed using chest X-ray and fluoroscopy when

necessary. Similarly, iron study was sent at baseline and at follow-up. The stent or remnants explanted during planned surgery were sent for histopathology and microcomputed tomography scan (CT) (Advanced Medical Services, CV Path Institute, Gaithesburg, MD, USA).

Any procedure like Blalock Taussig shunt (BTS), ductus restenting or RV overhaul and right ventricular outflow tract (RVOT) reconstruction before the 6 months, due to total blockage of PDA stent or due to restrictive flow across the stent, were considered as unplanned reintervention due to cyanosis. The stent was considered to have served its purpose if it remained patent until 6 months, the stented PDA was deemed not necessary in PAIVS and critical PS patients who have achieved adequate antegrade flow and RV growth.

Statistical analysis

Statistical analysis was performed using SPSS version 26.0 (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp). Results are expressed as mean with standard deviation and median with interquartile range.

RESULTS

Patient data

During the study period, nine patients underwent DS using IBS Angel™. By diagnosis, six were PAIVS, one patient critical PS, the remaining two were TA with severe PS. The mean age at the time of DS was 20 ± 6 days and the mean weight was 3.4 ± 0.4 kg.

Procedure outcome

Femoral artery route was used in all patients. Balloon dilation and DS were done at the same setting in three PAIVS patients. In the remaining three PAIVS and one critical PS patients, balloon dilation was done initially and DS was performed semi-emergently when the forward flow needed to be augmented by additional source of PBF. In the two univentricular patients (TA) DS was the only procedure done.

The mean total procedure time was 89 ± 38 min, including the three patients who underwent balloon dilation and DS as one procedure. The mean fluoroscopy time was 16.3 ± 6.9 min. The stent visibility was subjectively scored at 50% of the Co-Cr stent. In regard to stent diameter, 4 mm stent was used in all cases except one where 3-mm diameter stent was used. The length of the stents used were 12 mm, 15 mm, and 18 mm. There was neither procedural mortality nor major complications of cardiac tamponade, acute stent thrombosis, or stent migration.

Postprocedure care and morbidities

Post-DS median ICU stay was 7 days (2–21 days) and median ventilator days were 3 days (1–11 days). Three patients had no significant signs of overshunting and were extubated within 24 h. Two patients needed ventilatory support more than 1 week (8 days and 11 days) due to overshunting/heart failure. One of these two patients developed Grade III necrotizing enterocolitis requiring laparotomy. Three patients developed mild acute kidney injury due to overshunting and were managed conservatively. Mean arterial saturation during the first 48 h was 88%. There was no case of stent blockage during the hospital stay and no patient required restenting or surgical procedure after DS during the same admission. The median vasoactive inotropic score was 18 (interquartile range 10–31).

Follow-up

The median follow-up was 16 months (10–20 months). One patient died of confirmed respiratory syncytial virus (RSV) pneumonia at the referring hospital 1-month post balloon dilation and DS for PAIVS. The stent was widely patent at the time of death. The serum iron level remained normal during follow-up. The stent flow steadily decreased over the follow-up period but remained visible on X-ray. Four patients had blocked/severely restrictive stent flow (2 PAIVS, 1 Critical PS, 1 TA), whereas four other patients remained well palliated. Of the former, 1 PAIVS patient underwent RV overhaul and RVOT reconstruction. The other PAIVS and critical PS patients had good RV growth and unobstructed antegrade flow with full oxygen saturation. The PDA stent was deemed no longer required. One TA patient underwent re-stenting with a Co-Cr stent 4 months post owing to severe in-stent stenosis (unplanned re-intervention) [Figure 1].

Of those in whom the stents were patent beyond 6 months, three were PAIVS patients. Two underwent RV overhaul with RVOT reconstruction and 1 underwent subvalve resection of RVOT muscle bundle. The remaining – the other patient with TA – was confirmed to have severe pulmonary vein stenosis and was managed conservatively [Figure 2].

In 2 PAIVS patients, there was an overhang of stent in the main pulmonary artery. The overhanging segment of the stent with the gold marker was suspected to have fractured and migrated to a distal RPA branch from the X-ray and fluoroscopy. There was no obstruction of contrast flow at angiography [Figure 3]. All four patients who reached surgery without intervening unplanned re-intervention had PAIVS as the diagnosis. No major difficulties were encountered during surgery and there was no major evidence of fibrosis involving the pulmonary arteries. All the patients had no major residual lesions at the latest follow-up.

Three explanted stent material was sent for histopathology and microCT. The report showed that stent lost weight

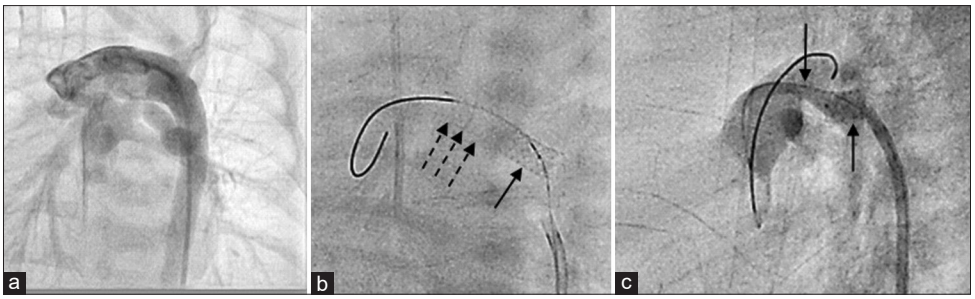

Figure 1: Angiographic images of ductal stenting in a single ventricle patient with tricuspid atresia. (a) Aortic angiogram showing ductus with acute curve at aortic end. (b) Angiogram showing the aortic end stented with Co-Cr stent (solid arrow) and rest of the ductus with IBS Angel™ (broken arrows), the visibility difference can be seen clearly. (c) In-stent restenosis at 4 months mainly affecting the IBS Angel™ (downward arrow) while sparing Co-Cr stent (upward arrow). CO-Cr: Cobalt-Chromium, IBS Angel™: Iron bioresorbable scaffold

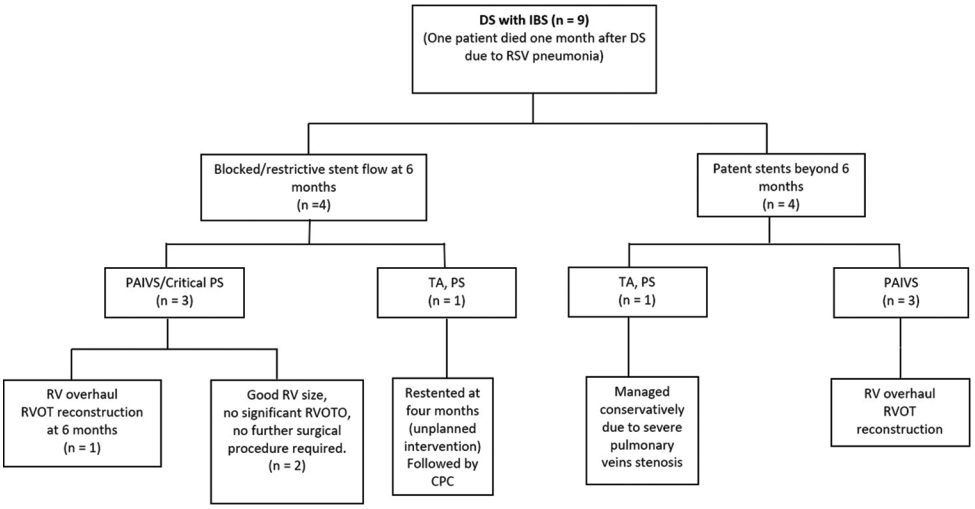

Figure 2: Flow chart showing the status of patients following ductal stenting. CPC: Cavopulmonary connection, DS: Ductal stenting, PAIVS: Pulmonary atresia with intact ventricular septum, PS: Pulmonary stenosis, RSV: Respiratory syncytial virus, RV: Right ventricle, RVOT: Right ventricular outflow tract, RVOTO: Right ventricular outflow tract obstruction, TA: Tricuspid atresia

of <10% after 6 months (one patient) while the weight loss was at least 65% after 16 months (two patients). After 6 months implantation, a few inflammatory cells and many macrophages with a lot of hemosiderin phagocytized in cells were found around the stent struts. With increasing time of stent being *in situ*, there is evidence of increasing proliferation of smooth muscle cells (SMC) and collagen fiber in the stent struts [Figure 4].

DISCUSSION

DS has evolved as an alternative in the palliation of patients with duct-dependent cyanotic CHDs.[3] However, a peculiar feature of these congenital lesions is the variable complex morphology of the PDA. Often, they arise from the undersurface of the aortic arch and tend to be elongated with kinks or curves before connecting to the pulmonary artery.[11] Of significance, the PDA has a tendency to connect to the LPA (in the left aortic arch). Ductal tissues tend to infiltrate the pulmonary arterial walls, and with constriction (and eventual closure) this often leads to branch pulmonary artery stenosis.[12] It is for this reason that DS in this type of PDA morphology has remained controversial, as fibrotic reaction to stent material (Co-Cr) may aggravate pulmonary branch stenosis.[13] This may pose additional challenges at the time of surgical repair, namely stent removal and pulmonary artery reconstruction. This has been borne out in a small series by Vida *et al.* although they concluded that surgical repair post DS is not particularly daunting.[5] Our own experience of surgery post DS reflects the findings of Vida *et al.*[5]

Of interest, many of duct-dependent cyanotic heart disease patients require surgical correction and reoperations and intervention in the course of their life-long management, such that stents constructed from bioresorbable materials would be conceptually desirable if such a stent could be developed that have the ideal characteristics of good radial strength, does not result in aggressive neointimal proliferation that would limit its duration of palliation, and the stent material would have been largely resorbed at the time of surgical repair and PA reconstruction.

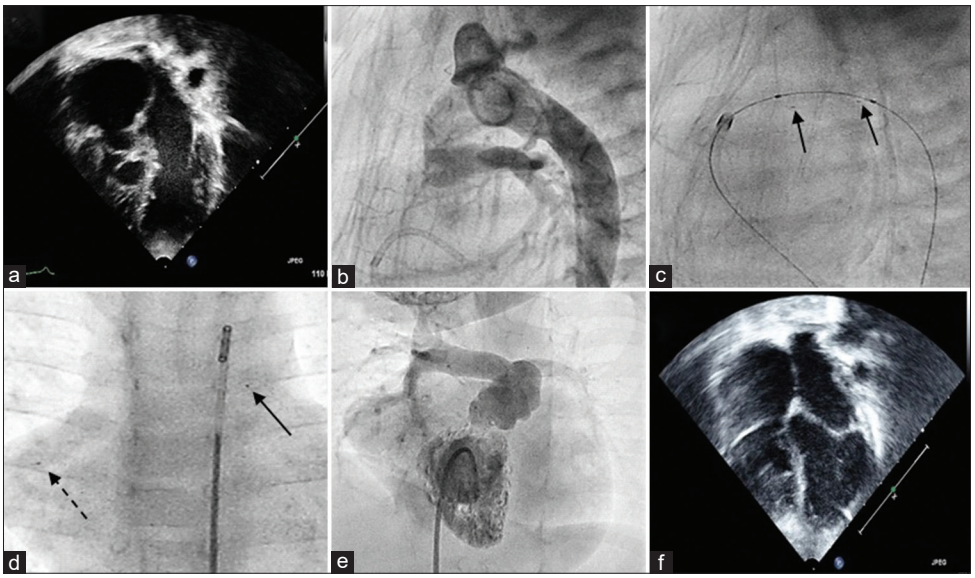

Figure 3: (a) PAIVS patient with small RV, (TV/MR ratio 0.65). (b) Aortic angiogram showing short ductus inserted into main pulmonary artery. (c) Post balloon dilation of pulmonary valve and DS at same setting, IBS Angel™ is implanted, the stent visibility can be rated 50% as compared to Co-Cr stent, the gold markers are prominent (arrows). (d) Four months after DS noted stent material with gold marker embolized to RPA, fluoroscopy showing stent material in RPA (broken arrow), solid arrow is pointing toward original stent. (e) RV angiogram showing small RV with subvalvular stenosis. Also showing the flow to the segment is not compromised where the stent material embolized. (f) Post-RV overhaul, RVOT reconstruction and CPC. The RA is not enlarged and there is no more septal bulge toward LA. CPC: Cavopulmonary connection, DS: Ductal stenting, IBS Angel™: Iron bioresorbable scaffold, LA: Left atrium, MV: Mitral valve, PAIVS: Pulmonary atresia intact ventricular septum, PTBV: Percutaneous transluminal balloon valvuloplasty, RA: Right atrium, RPA: Right pulmonary artery, RV: Right ventricle, RVOT: Right ventricular outflow tract, TV: Tricuspid valve

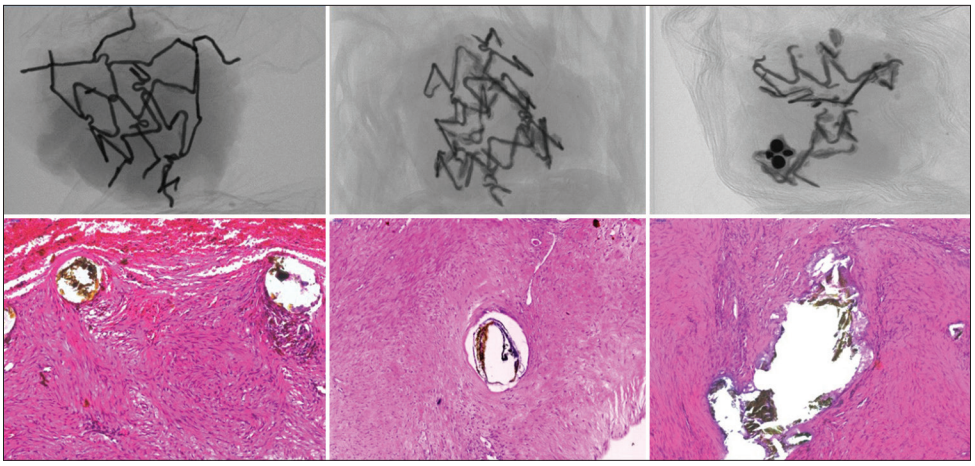

Figure 4: Upper panels showing micro-CT scan and lower panels showing H and E images of the stent material and tissue explanted from three patients. After IBS AngelTM implanted in human body, the weight loss was <10% in 6 months (upper left panel) while the weight loss was no <65% in 16 months (upper middle and right panels). After 6 months implantation, a few inflammatory cells and many macrophages with a lot of hemosiderin phagocytized in cells were found around the stent strut (lower left panel). For the other follow-up time points, no inflammatory cells or foreign body giant cells was found in any samples, and neovascularization was observed in the neointima. With the implantation time increasing, the proliferation of smooth muscle cell and collagenous fiber on the stent strut was increased. After implantation of 16 months, the tissue repair was finished without necrocytosis. (lower middle and right panels). CT: Computed tomography, H and E: Hematoxylin and Eosin, SMC: Smooth muscle cell

We conducted this pilot study to evaluate if the IBS Angel™'s performance is comparable to conventional Co-Cr stent as initial palliation in PDAs of simple morphology before considering it to lesions with branch PA stenosis as part of a complex PDA morphology– lesions where bioresorbable stents is conceptually more advantageous in the longer term.

IBS Angel™ implantation was successful in all 9 cases with no major complications. The X-ray visibility at implantation was 50% of the Co-Cr stent [Figure 1b]. Although X-ray visibility was lower, the gold marker was well visualized on fluoroscopy and made it easy to implant the stent. The ease of implantation, as depicted by procedure and fluoroscopy time, was comparable

to Co-Cr stents. There was no 30 days mortality, but the early postprocedure course was characterized by longer ventilation and ICU days due to excessive PBF compared to recent data from a multicenter UK study.[15] We suspect that the cause of necrotizing enterocolitis in one patient who required laparotomy was due to extreme overshunting. The mortality in our series was attributed to confirmed RSV pneumonia, but the patient had a longer hospital stay due to overshunting which may have predisposed this.

While most studies reported early survival advantages with DS, unplanned re-intervention before second-stage surgery is known to be higher in DS compared to BTS as reported in the UK multicenter study above.[15] Glatz *et al.*, however, in a multicenter US study reported superior outcomes with DS as compared to BTS, unplanned reintervention for causes other than cyanosis were more in DS group.[16] In our series, one patient with single ventricle physiology required unplanned re-stenting due to rapid neointimal proliferation into the stent. The long PDA in this patient had an acute curve at the aortic end, this part was stented with Co-Cr stent, while rest of the PDA was stented using IBS Angel™ to avoid overhang of the latter into the aorta. It was of interest that the intimal growth was mainly at the IBS Angel™ region [Figure 1c]. However, it is too early to draw a conclusion on this aspect from this small pilot study.

By 6 months post implantation, stents were blocked/severely restrictive in four patients. Three of them were PAIVS patients where palliation was no longer needed because improved RV physiology had been achieved or the patients were ready for staged RV reconstruction surgery.,[17,18] Based on our small number of patients, overshunting was a significant finding early in the course, but the long-term durability of palliation appeared limited by early in-stent stenosis as compared to Co-Cr stents. Nevertheless, in current surgical practice, repair/palliation of patients with either single-ventricle or two-ventricle physiology is often done as early as 6 months.

The main observation in this study was the shorter duration of palliation afforded by IBS Angel™ due to rapid neointimal hyperplasia despite early overshunting compared to Co-Cr stents although generally sufficient to take the patient through to the next stage of treatment (or achieve adequate RV growth in PAIVS). As the iron started losing its protective layer, the inflammatory cells accumulated to absorb the iron, as seen at 6 months. Subsequently, there was increase SMC and collagen deposition which caused the occlusion of the lumen. From the favorable early experience of sirolimus-eluting bioresorbable coronary scaffold (IBS) in adult coronary intervention, drug coating may mitigate the issue of durability of palliation in DS.

Because of difficulty in matching exact lengths of stent required, in two patients the stent was overhanging into the pulmonary artery. This subsequently fractured and a small segment embolized to a distal pulmonary artery branch [Figure 3]. We speculated that as the stent was corroded and lost integrity, the segment that overhung eventually fractured, broke off with the cardiac pulsations and migrated distally. However, there was no obstruction to the blood flow distal to embolized fragments on follow-up angiogram. It would be advisable to take care that bioresorbable stent should not protrude into the aorta (>1–2 mm), as similar occurrence on the systemic side may not be as benign. For the same reason, use of bioresorbable stent at the systemic side, for example, in coarctation of the aorta or pulmonary vein stenosis would not be recommended at this stage. In a long PDA with an acute curve near the aortic origin, a second shorter stent made of Co-Cr may be deployed to prevent this occurrence on the systemic side. IBS Angel™ may be safely used in right-sided lesions, i.e., branch pulmonary artery stenosis and superior vena cava obstruction.

Limitations

This is a small nonrandomized prospective pilot study from a single center. Although the PDA morphology was of relatively straight type, the pathologies were varied, some destined for biventricular pathway and some for the univentricular pathway.

CONCLUSIONS

Deployment of IBS Angel™ was feasible in all patients with noncomplex relatively straight neonatal ducts. In view of relatively rapid neointimal proliferation with IBS Angel™ within a few months of implantation, it can be recommended in neonates with dual pulmonary blood supply rather than those with exclusive duct dependent flow, typically represented by PAIVS and critical PS following balloon dilation. Further refinement to the design and perhaps incorporating an antiproliferative drug to the scaffold would need to be considered before studies for wider usage of IBS Angel™.

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Nil.

Conflicts of interest

Deyuan Zhang works at National and Local Joint Engineering Laboratory of Interventional Medical Biotechnology and System, Lifetech Scientific (Shenzhen) Co., Ltd., Shenzhen, China.

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