ACUTE, EARLY AND INTERMEDIATE EFFECTS OF A NOVEL 8 MM DIAMETER DOUBLE OPPOSED HELICAL BIODEGRADABLE STENT IN PORCINE ARTERIES

Poster Contributions
Hall C
Saturday, March 29, 2014, 3:45 p.m.-4:30 p.m.

Session Title: Pediatric Interventional Cardiology
Abstract Category: 10. Congenital Heart Disease: Pediatric
Presentation Number: 1153-271

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Background: Double opposed helical (DH) biodegradable stents (BDS) enable manufacturing to diameters applicable to congenital heart disease. The primary objective is to evaluate delivery and deployment of 6 and 8mm diameter DH BDS in a porcine animal model. Secondary objectives are to evaluate patency, thrombosis, and inflammation at 1-week, 1 and 9-months.

Methods: 6 and 8mm diameter DH BDS were manufactured with poly-L-lactic acid fiber and delivered in the external iliac artery (EIA) and distal descending aorta (DAO) of Sinclair minipigs. Patency and thrombosis was assessed at 1-week, 1 and 9-months with angiography and intravascular ultrasound. Histopathology was performed at each time interval.

Results: 14 stents were placed in 9 animals: 8mm (8) and 6mm (1) were delivered in the DAO and 6mm (5) in the EIA. The 8mm diameter stent required a 9Fr delivery sheath. 8mm stents were frequently too small for this model with embolization of 4/9 stents requiring recapturing and redilation. All stents remained patent with no thrombosis. There was mild neointimal proliferation (NIP) at 1 week and 1 month and moderate NIP at 9-months follow-up. Neoendothelialization was complete at 1 month.

Conclusions: DH BDS designed to 8mm diameter have been manufactured and implanted. A sustained, significant inflammatory response with moderate NIP was seen at 9 months. Further improvements in fiber properties, investigation of anti-inflammatory drug coatings and miniaturization for ease of delivery are needed.

IVUS 1x H&E 20x H&E

1 mo

9 mo

IVUS and H&E staining of 8 mm PLLA stent in DAO at 1 and 9 months
* = stent strut; NI = neointima