Experience with the Cook Formula balloon expandable stent in congenital heart disease

Quandt D., Ramchandani B., Penford G., Bhole V., Mehta C., Dhillon R., Stumper O.
Birmingham Children's Hospital, Birmingham, UK

Introduction: Balloon expandable stents are an integral part in the catheter treatment of congenital heart disease. In the growing child, stents require dilatation to greater diameters over time. The Cook Formula stent is a recent 316 stainless steel open-cell design licensed for peripheral vascular work.

Methods: Following extensive ex-vivo studies, 95 stents were implanted in 84 children [median age 3.7 (0.02 – 16.6) years; median weight 13.4(2.4-62.8) kg] over a two year period.

Results: Bench testing revealed that there was no stent shortening for dilatation to nominal diameter and beyond. The 5 mm stents could be dilated up to 10 mm, and the 10mm stents to 20mm. Stents were implanted through 4 – 7F sheaths or guidecaths over appropriate wires. Stent tracking and delivery was excellent.

Twenty-two stents were implanted in the right ventricular outflow tract in Fallot-type lesions, 47 for branch pulmonary artery stenosis (17 post cavopulmonary shunt/Fontan), 10 conduit stenosis, 8 Fontan fenestrationss, 3 PDA in hybrid stage 1 Norwood, 4 in coarctation and 1 for SVC obstruction. 51 stents (54%) were overdilated. There were no stent fractures. Radial strength was very good, whereas stent conformability was limited.

Conclusion: The Cook Formula stent is a versatile pre-mounted balloon-expandable stent that can be significantly overdilated with virtually no shortening allowing for precise placement and minimal protrusion into adjacent vessels. This stent design is a great addition to the range of stents for use in the catheter treatment of complex congenital heart disease in children.