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Introduction:

In infants and small children stent implantation for pulmonary artery (PA) stenosis may be challenging and require re-interventions to match the patient's growth. Until recently, the lack of stents, dilatable to adult sizes, has limited the more widespread application of this therapy in the youngest patients. We evaluated the implantation and mid-term performance of the Valeo stent, which can be dilated up to 20 mm, for the treatment of PA stenosis.

Methods:

A retrospective analysis of Valeo stents implanted for PA stenosis at two large volume paediatric centres was performed. Patient profile, pre- and post-implant catheterization data, follow-up imaging and re-interventions were reviewed.

- 10 month old, 6 kg
- DORV, MA
- S/p Norwood + Sano
- S/p right-sided B-T shunt
- LPA stenosis
- Implantation of 6 x 18 mm Valeo stent
- Neointimal hyperplasia
- Stent redilation with 6 x 20 mm Tyshak balloon



- 4 year old, 12 kg
- TA, TGA, hypoplastic Ao,
- S/p Norwood
- S/p BDG
- LPA stenosis
- Implantation of 6 x 26 mm Valeo stent



| Patients characteristics and previous interventions | N = 51 (%) |
|---|-------------|
| Age (years) | 5.3 ± 3.6 |
| Weight (kg) | 18.1 ± 11.3 |
| BSA (m ²) | 0.7 ± 0.3 |
| Male (%) | 29 (57) |
| SV circulation (%) | 31 (61) |
| BV circulation (%) | 20 (39) |
| Most recent surgery | |
| SV circulation | |
| Blalock-Taussig shunt | 2 (4) |
| Bidirectional Glenn shunt | 20 (39) |
| Extracardiac Fontan operation | 9 (17.5) |
| BV circulation | |
| Total correction | 9 (17.5) |
| RVOT reconstruction with a graft | 10 (20) |
| Unifocalization | 1 (2) |
| Previous trans-catheter intervention | |
| Numer of patients (%) | 23 (45) |
| PA balloon dilation (%) | 13 (27) |
| PA stent implantation (%) | 10 (22) |
| Site of stenosis (54 lesions) | |
| RPA (%) | 13 (24) |
| LPA (%) | 33 (61) |
| Both (%) | 8 (15) |

| | Pre | Post | P |
|---------------------|-------------|-------------|---------|
| All patients (n=51) | | | |
| Min PA diameter | 4.6 ± 1.8 | 8.9 ± 2.2 | <0.0001 |
| Max PA diameter | 9.2 ± 1.9 | 9.5 ± 2.2 | 0.061 |
| SV patients (n=31) | | | |
| Min PA diameter | 4.8 ± 1.8 | 8.8 ± 2.1 | <0.0001 |
| Max PA diameter | 8.8 ± 2.0 | 9.2 ± 2.3 | 0.072 |
| Proximal pressure | 16.5 ± 3.6 | 15.6 ± 4.0 | 0.0068 |
| Distal pressure | 14.8 ± 3.1 | 15.3 ± 2.8 | 0.138 |
| Pressure gradient | 1.6 ± 1.5 | 0.3 ± 0.8 | <0.0001 |
| BV patients (n=20) | | | |
| Min PA diameter | 4.5 ± 1.7 | 8.9 ± 2.4 | <0.0001 |
| Max PA diameter | 9.6 ± 1.6 | 9.9 ± 2.2 | 0.463 |
| Proximal pressure | 54.1 ± 21.8 | 43.6 ± 12.3 | <0.0001 |
| Distal pressure | 20.7 ± 5.0 | 26.9 ± 6.3 | <0.0001 |
| Pressure gradient | 33.5 ± 21.1 | 15.9 ± 11.0 | 0.0003 |
| RV/LV pressure | 0.7 ± 0.2 | 0.6 ± 0.1 | 0.024 |

Results:

Between 11/2012 and 12/2015, 51 patients received 56 Valeo stents.

- The median age was 4.9 years (7 months - 16 years) and median weight was 14.7 kg (5.7 - 53 kg).
- There were 31 patients (61%) with single ventricle physiology and 20 patients (39%) with biventricular circulation.
- Twenty seven patients (53%) weighed less than 15 kg, including 12 patients (23%) weighing less than 10 kg.
- Nine patients (18%) had the stent implanted within 30 days post-surgery.
- In 10 patients (20%) the Valeo stent was implanted in a previously placed stent.
- Improvement in PA diameters and hemodynamic values was achieved across all patient subgroups.
- Complications occurred in 4 patients (8%); including stent embolization (2), stent dislodgment from the balloon during delivery (1) and hemodynamic instability (1).
- In the median follow-up of 17 months (2 - 42) one patient died and one was lost from follow-up.
- Of the remaining 49 patients, 7 (14%) underwent catheter re-intervention after a median of 15.9 months (1 day - 20.7 months) due to significant neointimal proliferation (6) and early stent deformation (1).
- In 25 patients (51%) the stent was visualized either on chest X-ray (23) and/or in fluoroscopy (8).
- Stent distortion was noted in 8 patients (32%).

Conclusions:

Based on our results the Valeo stent provided effective relief of PA stenosis in various clinical settings including low body weight, early post-operative course or stenosis within a previously placed stent. Although stent deformation was commonly observed on follow-up imaging, pronounced neointimal proliferation was the most common indication for re-intervention.