

MP2-14

First Evidence in Humans of Neointimal Regeneration after Stenting of Native Right Outflow Tract: an intracardiac Ultrasound Study.

*Gagliardi M.G., Pilati M., Chinali M., Pongiglione G.
Pediatric Hospital Bambino Gesù, Rome, Italy*

Background: Percutaneous pulmonary valve implantation (PPVI) is a challenge in pts treated with outflow patch. After an adequate selection by echocardiography, cardiac MRI and CT, pts with favorable anatomy are selected for this procedure but a PPVI is considered feasible if a stable percutaneous conduit is built. Aim of our study is to demonstrate neointimal proliferation growth by ICUS in implanted stents in the right native outflow tract. At date, only animal models or aortic samples have been used to report neointimal stent proliferation in aortic position and IVUS studies have been performed only in adult patients with coronary stents.

Methods: We prospectively analyzed 7 children, previously surgically corrected for tetralogy of Fallot by outflow patch, with severe pulmonary regurgitation defining the indication to PPVI. All patients underwent a "two step" procedure for PPVI. At first stage an hybrid stent was implanted in the outflow patch. At the same time, an ICUS study was performed using an Ultrasound Catheter. After 2-8 months a second ICUS study was performed to demonstrate presence and entity of neointimal stent proliferation, preceding covered stenting and PPVI. Neointimal stent proliferation quantification was performed by two independent reviewers, blinded to clinical data. Spearman rho analysis was performed to analyze interobserver variability.

Results: All 7 patients were boys (age 12.6 ± 2.7 years, weight 48 ± 15 Kg). At baseline no neointimal thickness stent was visible in any of the patients. At second procedure (4.5 ± 2.3 months after stent implant) the ICUS study showed presence of endothelization in all children, with a mean neointimal proliferation thickness of 1.3 ± 0.2 mm (range 1.0-1.6 mm), with low interobserver variability (Spearman's $\rho = 0.81$; $p = 0.027$). Interestingly, endothelization thickness was mildly positively correlated to time from implant ($r = 0.53$). At second procedure, all patients underwent successful PPVI.

Conclusions: Our preliminary study is the first evidence in literature of a stent neointimal regeneration in humans with native right outflow patch. Our study demonstrated that neointimal proliferation occurs in all patients in which a stent is implanted and that this phenomenon can be accurately assessed by ICUS. Evidence of neointimal proliferation supports the proposed approach of a "two step" PPVI procedure.