Customized Expandable Polyurethane Stent Valve, implanted by catheter. Strategies for Pulmonary Artery approach.

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Summary

Background: Patients with tetralogy of Fallot, undergoing Right Ventricular Remodeling, in childhood, with or without pulmonary valve reconstruction, evolve, in the late follow-up, with pulmonary insufficiency and Right Ventricular dysfunction, requiring the implantation of a pulmonary prosthesis.

The anatomical variations of the pulmonary artery, associated with the presence of calcifications, dilations, or stenosis as a result of surgeries performed, require adequate planning in the surgical approach for Transcatheter Pulmonary Valve Replacement - TPVR.

Material: A new Expandable Polyurethane Stent Valve, implanted by catheter, in pulmonary position has been developed and approved in Biocompatibility, Physical, Hydrodynamic, Fatigue, Experimental, and Ultrastructure Study of explanted sheep prostheses after 24 months of follow-up, analysis, following ISO 5840-3, 2015 [1]

Method. In a group of 43 adult patients, in the late follow-up of surgical correction of Tetralogy of Fallot, with late follow-up, at São Paulo Federal University, with an indication for TPVR, they were classified into 6 groups according to the anatomical aspects of the pulmonary artery, analyzed by CT Angiography:

Type.1: Pulmonary valve insufficiency (PVI) (7 pat.); Type.2: PVI + pulmonary trunk stenosis (8 pat.); Type.3: PVI + pulmonary trunk aneurysmal dilation (15 pat.); Type.4: PVI + PT + RPA + LPA – stenosis (6 pat.); Type.5: Pulmonary prosthesis dysfunction (5 pat.); Type.6: RV-PA Conduit disfunction (4 pat.)

Result: Through post-processing images by CT Angiography, it was possible to enlarge them to their natural size, followed by 3D printing, in elastic and transparent plastic mass, keeping the interior of the hollow cardiac cavities.

Custom prosthesis manufacturing: 3 transverse diameters (TD) are measured: TD1: At the level of the Pulmonary Ring; TD2: In the middle third of the TP and TD3: At the level of the origin of the pulmonary arteries. Also, a longitudinal measure (LM), allows for knowing the length of the prosthesis: The distance between the Pulmonary ring and the origin of the pulmonary arteries.

Patients older than 7 years are treated with interventional hemodynamic procedures: G1: TPVR procedure. G2, G3, and G6: Double Sent Valve Technique, is performed. After implanting in the same surgical procedure, a cylindrical stent is firstly implanted to correct the lesions in the pulmonary trunk and then the valve stent is implanted inside the cylindrical stent. In G4, as well as in patients under 7 years of age, valve stent implantation is performed by surgical approach; the correction of defects is made with synthetic material, such as a Polytetrafluoroethylene (PTFE) prosthesis or Polyurethane membrane, followed by implantation of a cylindrical stent. G5: Valve in valve procedure is indicated.

Conclusions: Programmed expansion of stent valves with PU leaflets, calcification resistance, and resistant to fatigue tests, is expected to reduce the number of reoperations in pediatric patients.

References:

Miguel Maluf et al. Expandable Polyurethane Stent Valve, implanted by catheter. Results of Physical, Hydrodynamic, animal, and structural studies. ***International Journal Innovation Science and Research Technology, March 2021,*** **6 (3): 354-9**

Summary of CV

Miguel Maluf, MD, PhD, Full Professor in the Cardiovascular Division, Federal University of São Paulo and Founder of Synthetic Heart Technology Company.



I received training at GOSH with Mr. Mark De Leval and Brompton Hospital with Mr. Christopher Lincoln. Knowing the results of cardiac prostheses implanted in children:

Early calcification and mismatch, require reoperation, in 70 to 80% of patients, with 9 years of follow-up, for this reason, we have oriented our research to the area of valvular heart disease in children.

Synthetic Heart Technology, in collaboration with Companies in the USA and Germany, developed a Synthetic Stent Valve (polyurethane), with 2 models: - Model 1: Expandable Prosthesis, For Children: Stent valve manufactured by laser cutting and application of PU by dip coating and Model 2: Customized Prosthesis, for Adults: Stent valve manufactured with 3D printing technology and application of PU, injection technique.

We developed a Synthetic Endoprosthesis: **Expandable Polyurethane Valve Stent - EPSV**, (**Patent: BR 10 2021 020737 0**), implanted by catheter, in pediatric and adult patients.

We performed all the tests required by the FDA: ISO 5840-3, 2015, all of which were approved, such as:

Physical tests: Study of PU leaflets surface scanner. There was no alteration of the structure after 30 min of prosthesis crimping.

Hydrodynamic tests: Gradients of 5 mmHg, using systemic pressure: 120 x 80 mmHg and HR of 100 b x min.

International Clinical Trial will be programmed, in 2022-2023