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Percutaneous pulmonary Melody valve implantation in small conduits: early and long-term results.

Bensemlali M.(1,2), Malekzadeh-Milani S. (1), Mostefa-Kara M. (1,2), Bonnet D. (1,2), Boudjmeline Y. (1,2)
Hôpital Necker Enfants malades, APHP, Centre de référence Malformations Cardiaques Congénitales Complexes - M3C -Paris, France (1)
Université Paris Descartes, Sorbonne Paris Cité, Paris, France (2)

Background: The Melody® transcatheter pulmonary valve received approval for treatment of dysfunctional right ventricular (RV) outflow tract conduit ≥16mm. Limited data are available for the use of the device in small conduits.

Objective: To investigate technical and clinical outcomes of patients who underwent percutaneous pulmonary valve implantation (PPVI) in conduit ≤ 16-mm.

Methods and results: Eleven patients were included between 2009 and 2015. Primary underlying diagnosis was tetralogy of Fallot(n=4), Ross Procedure(n=4) and common arterial trunk(n=3). RV outflow tract characteristics included: heterograft or homograft (n=11, expandable in n=10). Conduit diameter at time of surgical implant range from 12 to 16-mm. Indication of PPVI was stenosis or mixed lesions in 10 and regurgitation in one. All were prestented: 6 during a previous cardiac catheterization (median time between stenting-PPVI, 11-months, range 3 to 86 months) and 7 during the PPVI procedure (3 patients in addition with a previously placed stent). The median largest dilatation balloon diameter/implanted conduit diameter ratio was 1.25. All procedures were successful. Procedural hemodynamics showed a decrease in peak RV to PA gradient (-mmHg) from 45,5 ± 22,6 to 11,7 ± 6,8 ($p<0,001$), in RV systolic pressure (-mmHg) from 67,8 ± 22,8 to 39,8 ± 8 ($p<0,001$), and in the RV/Ao ratio from 0,74 ± 0,22 to 0,44 ± 0,09 ($p<0,001$). No patient had significant pulmonary regurgitation. Early complications occurred in four patients. There were 2 confined conduit tears managed with placement of a covered stent; and 2 local vascular complications requiring prolongation of hospital stay but no transfusion. Mean follow-up after PPVI was 3,6-years (23days to 6,7years). Late complications occurred in 4 patients: 2 endocarditis requiring surgical removal (1 early, 1 late); 2 recurrent stenosis with one requiring surgical conduit replacement, and one a percutaneous Melody re-dilatation. Freedom from valve dysfunction or re-intervention was 64% at last follow up.
Conclusion: PPVI is feasible in small conduit ≤16mm with good procedural and early hemodynamic result postponing the need for surgery. However, rates of reintervention and complications are higher as compared with patients with larger conduits.