Early Concerning Outcomes for the Edwards Inspiris Resilia Bioprosthesis in the Pulmonary Position: Should the Implantation Technique be Modified?

OBJECTIVE: Inspiris Resilia (IR) bioprosthesis has gained widespread use in the aortic position due to its good hemodynamics, anti-calcium binding properties and the ease of future valve-in-valve therapy. The use of this prosthesis, however, is relatively new for the pulmonary position with very limited data.

METHODS: We reviewed our outcomes for the IR bioprosthesis in the pulmonary position between Aug 2019 and June 2021 in both pediatric and adult pts.

RESULTS: A total of 25 pts (15 females, 60%) (mean age 21.7 ± 15.8 yrs), underwent pulmonary valve (PV) replacement (PVR) with IR bioprosthesis. The majority of pts had free pulmonary regurgitation (PR) prior to surgery (21 pts, 84%), while four pts (16%) had calcified pulmonary conduits with mixed regurgitation and stenosis. The most common original pathology was tetralogy of Fallot (TOF) with pulmonary stenosis (12 pts, 48%), followed by isolated congenital PV stenosis (7 pts, 28%), and pulmonary atresia with or without TOF (4 pts, 16%), while truncus arteriosus and TOF with absent PV syndrome were present in one pt., each. Four patients (16%) had transcatheter interventions on the PV with no previous surgery. The indication for surgical PVR were related to right ventricular enlargement (mean RVEDVI =164.2 ± 46.1 ml/m2) and/or symptoms (14 pts, 56%). Sternotomy or repeat sternotomy was the most common approach for PVR (19 pts, 76%), while the remaining 6 pts (24%) underwent minimally invasive left anterior minithoracotomy. Standard technique for PVR using running suture with anterior pericardial patch augmentation was the most common technique used (23 pts, 92%), while the IR prosthesis was implanted as a conduit in the remaining three pts (12%). The most common concomitant procedure was residual shunt closure (7 pts, 28%). Antiplatelet therapy was used in all pts at time of discharge. The mean prosthetic peak gradient at discharge was 13.8 ± 5.9 mmHg) with trivial to mild prosthetic regurgitation in 6 pts (24%). There was no early mortality. Follow-up was complete in all patients (mean 13 ± 5.9 months). No late mortality or late reoperations. New prosthetic regurgitation (PR) developed in 13 pts (52%), all of them underwent replacement with standard surgical technique. No regurgitation occurred in the conduit cases. This progressed to moderate PR in 8 pts (32%) and was severe in one (0.2%). One pt. underwent transcatheter valve-in-valve 9 months after his surgical PVR. Symptoms and RVEDVI improved during follow-up.

CONCLUSIONS:
Despite the excellent hemodynamic profile for the IR bioprosthesis and its satisfactory outcome in the aortic position, the early data regarding its use in the pulmonary position is concerning. There were no structural deteriorations for the prosthesis, but the development and progression of prosthetic regurgitation may require modifying the implantation technique.

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