Successful off-label implantation of the ‘aortic’ Edwards SAPIEN XT valve (29 mm) in right heart valvular lesions

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Introduction: Percutaneous implantation of the ‘Melody’ valve (Medtronic Inc., Minneapolis, MN, USA) and the Edwards valve (Edwards Lifesciences, Irvine, CA, USA) in pulmonary position has become a routine procedure in congenital heart diseases (CHD). The utilization of these valves is restricted to a maximum native valve diameter of 22 mm in the Melody valve and to 23 and 26 mm in the Edwards valves. Therefore their application in wider right ventricular outflow tracts as well as in alternative positions, such as the tricuspid ring, is substantially limited. To overcome this limitation, we describe the successful ‘off-label’ implantation of the new 29 mm ‘aortic’ Edwards SAPIEN XT transcatheter heart valve (Edwards Lifesciences) in pulmonary and tricuspid position.

Methods: Three patients (age 24-34 years) underwent a percutaneous valve procedure: 2 patients with valvular stenosis and insufficiency following tricuspid valve replacement by stented bioprosthesis (C-E 33 mm) received the Edwards SAPIEN XT valve (29 mm) in tricuspid position as a valve-in-valve procedure. In the third patient, who had pulmonary valve stenosis and insufficiency (s/p RVOT patch augmentation), the Edwards SAPIEN XT valve (29 mm) was implanted in pulmonary position after prestenting. All the implantations were performed using the Edwards Novaflex+ transfemoral system (20 F) with ‘reverse’ mounting of the valve.

Results: The transfemoral Edwards SAPIEN XT valve (29 mm) implantation was successful in all cases without any peri- or postprocedural complications. The implanted valves showed excellent functional and clinical results in all 3 cases, resulting in clinical and hemodynamic improvement in all patients during acute and short-term follow-up of a median of 1.2 months (0.7 – 4.2 months).

Conclusions: Off-label use of the ‘aortic’ transfemoral Edwards SAPIEN XT valve (29 mm) extends the application range of the percutaneous valve implantation technique in CHD patients beyond currently approved indications and is technically feasible and safe. It offers a good alternative to surgical valve repair in CHD patients with larger sized target regions up to a maximum diameter of 29 mm in either pulmonary or tricuspid position. These findings need to be confirmed by further cases and longer follow-up data.