

Early outcomes of percutaneous pulmonary valve implantation using the Edwards Sapien 3 transcatheter heart valve system – German experience

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Background:

Percutaneous pulmonary valve implantation (PPVI) is an increasingly practiced treatment option for patients with right ventricular outflow tract dysfunction. After encouraging results with the Edwards Sapien and XT valves in the pulmonary position, Edwards' latest modification, the Sapien 3 valve is available for clinical PPVI trials.

Objectives:

This study aimed to review procedural data and early outcomes for the Sapien 3 valves (Edwards Lifesciences, Irvine, California) for PPVI.

Methods:

We performed a multicenter, retrospective, observational registry analysis of patients who underwent PPVI with the Edwards Sapien 3 transcatheter heart valve between 2015 and 2017 in 5 centers in Germany.

Results:

46 patients could be enrolled (mean weight $56,8 \pm 26,9$ kg, min. 11,8, max. 114 kg). The majority had tetralogy of Fallot as underlying diagnosis (48%), and a Contegra conduit as the most common RVOT configuration pre PPVI (34,8%). However, pulmonary insufficiency or both, insufficiency \geq moderate and stenosis \geq 20 mmHg were the leading indications for PPVI (78,3%). Most procedures were 2-stage procedures (82,6%) with 100% pre-PPVI. Valve sizes were 20 mm (n = 1), 23 mm (n = 15), 26 mm (n = 18), 29 mm (n = 12). Procedural success rate was high (95,6%) with a low frequency of periprocedural complications (4,3%): In 2 patients surgical pulmonary valve implantation had to be performed after balloon rupture during (one-stage) PPVI procedure.

Follow-up data was available up to 24 month post PPVI. NYHA class improved in all patients (93,3% were at NYHA I). The rate of patients with moderate/severe pulmonary regurgitation decreased from 74% at baseline to 0% after PPVI, and the calculated peak systolic gradient for all patients decreased from 24.2 (SD \pm 20.9) mmHg to 7,1 mmHg (SD \pm 5,0). There were no episodes of endocarditis, no thromboses and no stent fractures documented.

Conclusions:

The Edwards Sapien 3 valve is a viable option for PPVI in patients with conduits, native pulmonary valves or transannular patches. Continued data collection is necessary to verify long-term results.