

**One Year Follow-Up of the PREMIER Multicenter Registry for the Edwards SAPIEN Pulmonic Transcatheter Heart Valve: An Interim Report**

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**Introduction:** PREMIER is a single arm, multi-center registry assessing the safety and efficacy of the commercially available Edwards SAPIEN™ Pulmonic Valve for treatment of patients with conduit failure in the right ventricular outflow tract (RVOT), or moderate to severe pulmonary regurgitation with or without stenosis. One year follow-up has been completed for the first 99 patients and an interim analysis was carried out.

**Methods:** The Edwards SAPIEN™ Pulmonic 23mm and 26mm valves were implanted in the pulmonary position in 131 patients with a dysfunctional RVOT. Enrolment has been completed and patients are being followed up annually throughout 5 years. If valves were implanted before the registry initiation, data were recorded retrospectively starting with the first commercial implant at the site.

**Results:** The mean patient age was 27.3±12.9 years, and 35.9% of patients were female. A total of 46 patients (35.4%) underwent prior conduit implantation, 12 patients (9.2%) underwent the Ross procedure, 41 patients (31.5%) underwent prior pulmonary valve repair. NYHA class was ≥II in 63.0% of patients, pulmonary regurgitation was grade 3+ or 4+ in 75.2% of patients and the mean RVOT gradient was 39.5±22.2mm Hg. The procedural success rate was 92.4%. The mean procedure and fluoroscopy time was 179.0±71.3min and 38.1±26.4min, respectively. The survival at 1 year after the valve implantation was 100%. There were no valve stent fractures, no re-interventions or reoperations. Adverse events occurred in 19.1% of patients. Of the 40 adverse events reported, only 6 were considered serious with right pulmonary artery rupture treated with surgery being the most significant one. At 1-year, 68.9% of subjects with complete echocardiographic evaluation (51/74) had none/trace pulmonary regurgitation, 25.7% had mild and 5.5% (4/74) had moderate (n=3) or severe (n=1) pulmonary regurgitation. At 1-year, follow up the RVOT gradient decreased significantly by 14.9±16.8mmHg (p<0.0001).

**Conclusions:** This interim reports suggests that the Edwards SAPIEN™ valve can be implanted safely in the pulmonary position with very low risk and significantly improve pulmonary regurgitation and RVOT gradient at 1-year. Further evaluation and long term follow-up is in progress to validate the clinical implications of this promising treatment for patients with dysfunctional RVOT.