One year follow-up of the PREMIER multicenter registry for the Edwards SAPIEN pulmonic transcatheter heart valve


German Heart Centre, Munich, Germany (1); King Faisal Specialist Hospital, Riyadh, Saudi Arabia (2); Institute of Cardiology, Warsaw, Poland (3); Children’s Hospital, Rome, Italy (4); Heart and Diabetes Centre North-Rhine Westphalia, Bad Oeynhausen, Germany (5); Royal Brompton Hospital, London, UK (6); German Heart Centre, Berlin, Germany (7); Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Education & Research Hospital, Istanbul, Turkey (8); Children’s Medical Center of Israel, Petah Tikva, Israel (9); Edwards Lifesciences, Irvine, USA (10); University Hospital Gasthuisberg, Leuven, Belgium (11).

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. A minimum of 100 consecutive patients treated at 10 sites or more have to be included in order to complete the enrollment. One year follow-up has been completed for the first 39 patients and an interim analysis was carried out.

Methods: Edwards SAPIEN™ Pulmonic 23 mm and 26 mm valves were implanted in the pulmonary position in patients with a dysfunctional RVOT. Prospective clinical and echocardiographic data are being collected annually throughout 5 years. If valves were implanted before the registry initiation, data are recorded retrospectively starting with the first commercial implant at the site.

Results: The mean patient age was 27.5 ± 12.4 years, and 38.5% (n=15) of patients were female. A total of 22 patients (56.4%) underwent prior conduit implantation, 5 patients (12.8%) underwent the Ross procedure, 11 patients (28.2%) underwent prior pulmonary valve repair. NYHA functional class was ≥ II in 67.6% of patients, and pulmonary regurgitation was grade 3+ or 4+ in 68.6% of patients. The procedural success rate was 100%. The mean procedure and fluoroscopy time was 185.9 ± 63.6 min and 44.2 ± 29.0 min, respectively. The freedom from all cause mortality at 1 year was 100%. Of the 11 adverse events that have been reported, only one was considered serious (i.e., vascular – stenosis). No valve stent fractures have been observed. There were no re-interventions or reoperations. At 1-year, most subjects with complete echocardiographic evaluation (16/26 or 61.5%) did not have any pulmonary regurgitation and the remaining subjects (10/26 or 38.5%) had trace or mild pulmonary regurgitation.

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