treating patients with severely calcified coronary lesions. Dr. Chambers concluded that using the OAS for lesion preparation before stent implantation offers patients with severely calcified coronary lesions a new treatment option with potential cost benefits.

Early Data Show Safety and Efficacy of SAPIEN Pulmonic THV

Written by Mary Beth Nierengarten

Early data on the use of the Edwards SAPIEN transcatheter heart valve (THV) for use in the pulmonary position to treat patients with pulmonic disease show excellent clinical outcomes, as well as the durability of the device without stent fractures or the development of endocarditis.

Damien Kenny, MB, MD, Rush University Medical Center, Chicago, Illinois, USA, presented updated clinical experience on the use of the SAPIEN valve in the pulmonary position from 2 ongoing trials that are underway in the United States and Europe.

He first presented updated results of the first 50 patients enrolled in the Congenital Multicenter Trial of Pulmonic Valve Regurgitation Studying the SAPIEN Interventional THV trial [COMPASSION; NCT00676689]. This is a prospective, nonrandomized, multicenter study to assess the safety and efficacy of the SAPIEN THV for the treatment of patients with dysfunctional right ventricle–pulmonary artery conduits with or without stenosis.

The primary end point of the trial is freedom from the device or procedure-related death and/or reoperation at 1 year. Secondary end points are freedom from a major adverse cardiac or cerebrovascular event at 6 months, and functional improvement (ie, improved valve function, improvement in exercise tolerance, and freedom from recurrent pulmonary stenosis if treated for stenosis).

Current enrollment in the study is 72 patients from 7 sites in the United States. Of these, 63 have received the valve implant with a median follow-up of 2.33 years, and 55 have been followed for 1 year.

Dr. Kenny presented the characteristics and outcomes of the first 50 patients (Table 1).

At a follow-up of 87.9 total patient-years, the study found significant echocardiographic changes from baseline (Figure 1), 100% improvement in pulmonary regurgitation at 1 year (Figure 2), and no patients needing re-intervention (Figure 3).

Similarly, good clinical results were seen in the ongoing European study, the Pulmonic Valve Replacement Multidiscipline EMEA Registry [PREMIER; NCT01356108]. This retrospective-prospective, single-arm, multicenter registry is evaluating the safety and efficacy of the Edwards

Table 1. Characteristics of the First 50 Patients Treated With SAPIEN THV in the COMPASSION Trial

Patients (current)	n = 50
Age	28.7 ± 15.0 years (10–72)
Sex	31 male and 19 female
Weight	72.8 ± 24.5 kg
Diagnosis	
ToF	40%
Ross procedure	36%
Open heart surgeries	2.1 (1–4)
RVOT conduit type	96% homograft
Original RVOT conduit size	24 ± 3 mm (18–29 mm)
Indication	
Mixed	64%
Regurgitation	18%
RVOT pre-stenting	100%

RVOT=right ventricular outflow tract; THV=transcatheter heart valve; ToF=tetralogy of Fallot.
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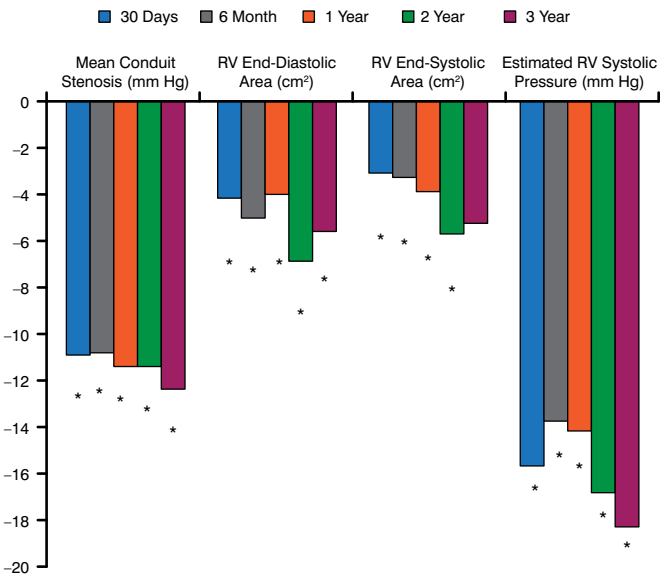
Figure 1. Echocardiographic Changes From Baseline: First 50 Patients in the COMPASSION Trial



*p<.05; RV=right ventricular.
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Figure 2. Pulmonary Regurgitation at 1 Year: 100% Improvement

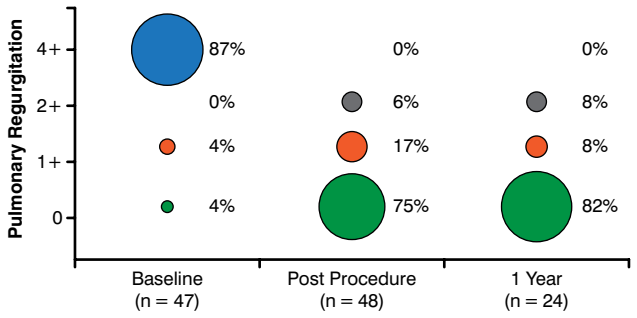

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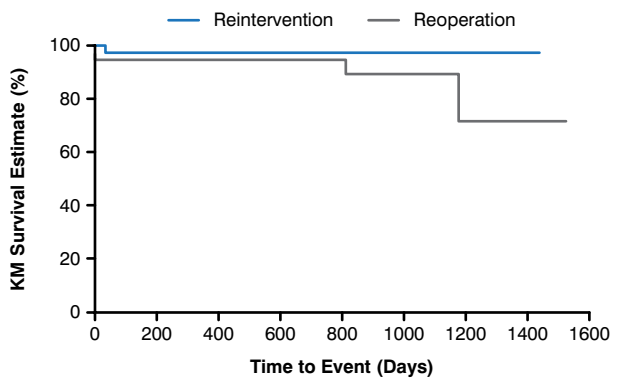
Figure 3. Freedom From Reintervention



KM=Kaplan–Meier.

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Table 2. Clinical Outcomes at 1 Year: PREMIER Registry.

Events (%)	1 Year
Mortality	0%
Reoperation	0%
Reintervention	0%
Arrhythmia or conduction system injury (defect)	3.8%
Bleeding or hemorrhage	2.3%
Infection or respiratory infection	0.8%
Vascular or arteriovenous fistula	1.5%
Device performance	
Valve stent fracture	0%
Device migration/malposition requiring intervention	3.1%
Valve stenosis or restenosis	0.8%

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SAPIEN pulmonic valve for treating patients with conduit failure in the right ventricular outflow tract, or moderate to severe pulmonary regurgitation with or without stenosis. Objectives of the study are to observe the use of the device in routine clinical practice of percutaneous pulmonary valve implantation and to evaluate its efficacy and safety in a real-world situation.

Currently, 131 patients are enrolled in the study, and 130 patients have completed both 6- and 12-month follow-up. Clinical outcomes at 1 year are shown in Table 2.

The study also found significant improvements ($p < .0001$) in pulmonary regurgitation and hemodynamics at both 6 months and 1 year compared to baseline.

Dr. Kenny concluded by stating that in assessing these 2 studies, there is momentum to complete the COMPASSION trial.

Early Data Show Benefits of New Device for Closing Congenital Heart Defects

Written by Mary Beth Nierengarten

A new-generation device used in the treatment of transcatheter closure of congenital heart defects provides easier delivery, better septal apposition, and faster endothelialization than an older version of the device. Early clinical experience showed the device to be efficient and successful in closing both atrial septal defects (ASDs) and patent foramen ovales (PFOs).

Joseph Paolillo, MD, Sanger Heart and Vascular Institute, Levine Children's Hospital, Charlotte, North Carolina, USA, presented information on the GORE Septal Occluder device, early clinical trial data, and experience with using the device for closure of ASDs and PFOs.

Similar to its earlier version—the GORE HELEX Septal Occluder—the design of the GORE Septal Occluder maintains a number of advantages. Both devices are soft and conformable, have a flattened profile, are easily repositioned, and include a retrieval cord concept.

Additional advantages of the new design include an improved delivery system for ease of use and a 5-wire design that provides enhanced disc conformability for rapid closure.

Early clinical data from a number of international trials show a high level of technical success and a high percentage of occlusion rates with the use of the device for closure of both PFO and ASD [Grohmann J et al. *Catheter Cardiovasc Interv* 2014; Smith B et al. *Catheter Cardiovasc Interv* 2014; Nyboe C et al. *Catheter Cardiovasc Interv* 2013].