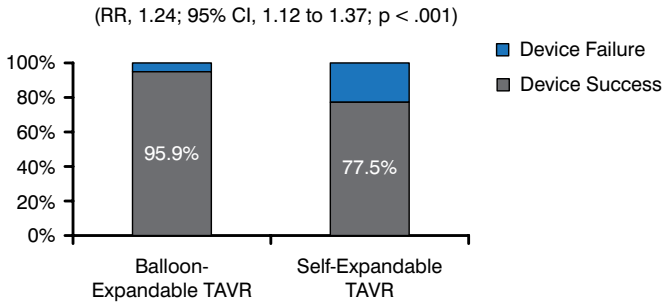
Figure 2. Device Success With Balloon-Expandable TAVR Better Than With Self-Expandable TAVR



RR=relative risk; TAVR=transcatheter aortic valve replacement.

Reproduced from Popma JJ et al. Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery. *J Am Coll Cardiol*. 2014;63(19)1972–1981. With permission from Elsevier.

clear incremental benefits (all-cause mortality at 1 year and valve hemodynamics) compared with AVR.

CHOICE

The CHOICE randomized clinical trial compared transcatheter deployment of aortic valves using either a balloon-expandable (SAPIEN XT; n = 121) or self-expandable (CoreValve; n = 120) system [Abdel-Wahab M et al. *JAMA* 2014]. The study was also performed in patients with severe AS at high surgical risk. The primary end point was device success (successful vascular access and deployment of the device and retrieval of the delivery system, correct position of the device, and intended performance of the heart valve without moderate or severe regurgitation).

Device success occurred in 95.9% of patients in the balloon-expandable valve group and 77.5% patients in the self-expandable valve group ($p < .001$; Figure 2), which the investigators attributed to the need for more multiple-valve implantations and a higher frequency of paravalvular regurgitation in the self-expanding group.

Major clinical outcomes (death, stroke, and myocardial infarction vascular complications) at 30 days were similar between the 2 groups. There was improved valve hemodynamics but increased paravalvular aortic regurgitation with the self-expandable system. This was a small and somewhat controversial study with a questionable primary end point that may exaggerate the clinically meaningful difference between the 2 systems.

Conclusions

TAVR has become the preferred therapy for high-risk AS patients, transcending the usual bounds of a new interventional therapy while transforming the pathways for managing patients with complex cardiovascular disease.

Successful Stent Implantation and Lower MACE Rates With OAS

Written by Toni Rizzo

Calcified coronary lesions are difficult to treat for several reasons. They are prone to dissection of the arterial wall and can prevent adequate stent expansion. They are also difficult to dilate completely [Cavusoglu E et al. *Catheter Cardiovasc Interv* 2004] and can preclude stent delivery to the desired location [Gilutz H et al. *Catheter Cardiovasc Interv* 2000]. These factors result in poor clinical outcomes, including higher major adverse cardiac events (MACEs) and angiographic complications.

Researchers of the Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions trial [ORBIT II; NCT01092416], presented by Jeffrey Chambers, MD, Mercy Hospital, Minneapolis, Minnesota, USA, examined the safety and efficacy of the coronary Orbital Atherectomy System (OAS) to prepare de novo, severely calcified coronary lesions for enabling stent placement.

This prospective multicenter single-arm trial comprised 443 patients at 49 US sites. Inclusion criteria included fluoroscopic or intravascular ultrasound evidence of severe calcification in the target lesion, a target vessel reference diameter ≥2.5 mm and ≤4.0 mm, and target lesion length ≤40 mm. Almost 65% of the patients were male, and the mean age was 71.4 years. The efficacy end point was successful facilitation of stent deployment in severely calcified coronary lesions. Safety end points included cardiac death, target vessel revascularization, myocardial infarction, and MACE. The patients were followed for 1 year.

Stent implantation was successful in 97.7% of patients, with < 50% residual stenosis in 98.6% of patients. Low safety end point rates at 30 days and 1 year showed that the OAS was safe for treating de novo, severely calcified coronary lesions.

Univariate analysis showed that only a history of coronary artery bypass graft was associated with an increased risk of MACE at 1 year (odds ratio, 1.89; 95% CI, 1.10 to 3.26; $p = .0214$). Safety comparisons with the ROTAXUS trial [Abdel-Wahab M et al. *JACC Cardiovasc Interv* 2013] and the ACUITY and HORIZONS trials [Genereux P et al. *J Am Coll Cardiol* 2013] revealed lower rates of MACE, all-cause mortality, and target lesion revascularization in the ORBIT II trial [Chambers J, data on file at Cardiovascular Systems, Inc].

Based on both inpatient and outpatient procedures, mean costs were $3198 lower in ORBIT II patients compared with Medicare stent patients with calcified lesions ($p = .003$).

The Diamondback Coronary OAS is the first Food and Drug Administration–approved novel technology for

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).

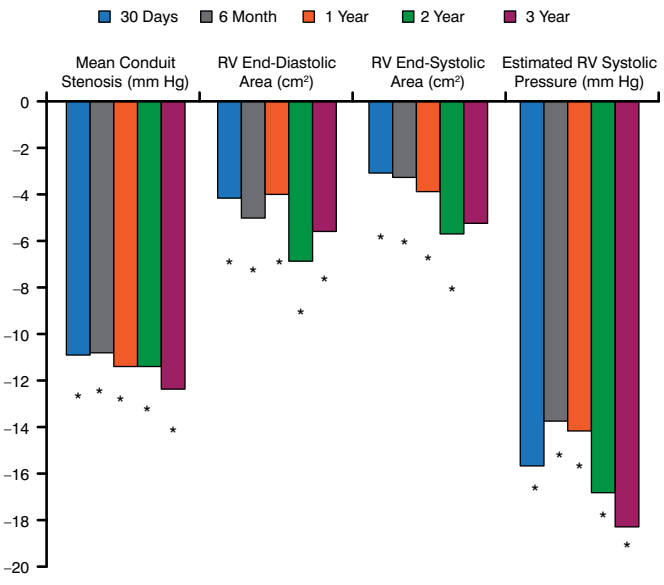
Similarly, good clinical results were seen in the ongoing European study, the Pulmonic Valve Replacement Multidiscipline EMEA Registry [PREMIER; NCT01356108]. This retrospective-prospective, single-arm, multicenter registry is evaluating the safety and efficacy of the Edwards

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.
Reproduced with permission from D Kenny, MB, MD.

Figure 1. Echocardiographic Changes From Baseline: First 50 Patients in the COMPASSION Trial



*p<.05; RV=right ventricular.
Reproduced with permission from D Kenny, MB, MD.