ischemic complications (HR, 0.93; 95% CI, 0.43 to 2.05; $P = .87$) and major bleeding (HR, 1.35; 95% CI, 0.64 to 2.84; $P = .44$).

Parsing out the secondary end point data did reveal a significant difference in MI (6-week, n = 6 [2.0%]; 6-month, n = 0; $P = .029$). Bleeding Academic Research Consortium (BARC)-defined bleeding overall did not differ significantly between the groups (6-week, 37.6%; 6-month, 40.2%; HR, 0.94; 95% CI, 0.73 to 1.21; $P = .63$). But, comparison of BARC-defined bleeding prior to randomization with that occurring at 9 months was significant (6-week, 20.5%; 6-month, 27.9%; HR, 0.68; 95% CI, 0.47 to 0.98; $P = .04$).

Prof Sarafoff concluded that shortening clopidogrel therapy from 6 months to 6 weeks after DES implantation in patients who are also receiving aspirin and oral anticoagulation is not superior in terms of net clinical outcomes.

TAVR Suitable Procedure for High-Risk AS Patients: 5-Year Results From the PARTNER Trial

Written by Maria Vinall

Transcatheter aortic valve replacement (TAVR) is the recommended treatment for "inoperable" patients with severe aortic stenosis (AS). One-, 2-, and 3-year data from the Placement of Aortic Transcatheter Valves study [PARTNER; NCT00530894] showed significant reductions in all-cause mortality, cardiac mortality, and rehospitalization [Kapadia SR et al. *Circulation*. 2014; Makkar RR et al. *N Engl J Med*. 2012; Leon MB et al. *N Engl J Med*. 2010]. Samir R. Kapadia, MD, Cleveland Clinic Foundation, Cleveland, Ohio, USA, reported the 5-year outcomes for the PARTNER trial. Benefits as to all-cause and cardiovascular (CV) mortality, repeat hospitalization, and functional status were sustained in the TAVR-treated patients compared with those given standard therapy. Valve durability was demonstrated with no increase in transvalvular gradient or attrition of valve area.

The PARTNER trial included patients (n = 358) with severe symptomatic AS with aortic value area < 0.8 cm^2 (effective orifice area index < 0.5 cm^2/m^2), and mean gradient > 40 mm Hg or jet velocity > 4.0 m/second. Patients deemed "inoperable" (defined as risk of death or serious irreversible morbidity of AVR exceeding 50%) were assessed by a cardiologist and 2 surgeons. Participants were randomly assigned (1:1) to TAVR or standard therapy. After 3 years, 20 patients crossed over to TAVR from standard therapy.

The study's primary end point of all-cause mortality was evaluated when all patients reached 1-year follow-up. Key end points for the 5-year analysis included all-cause and cardiac mortality, rehospitalization, stroke, NYHA functional class, and echo-derived valve areas, transvalvular gradients, and paravalvular leak. Mortality outcomes were stratified by Society of Thoracic Surgeons (STS) risk score, paravalvular leak, and age.

At baseline, subjects were mean age 83 years with mean STS scores between 11.2 and 12.1. Most (> 90%) were NYHA III or IV and about 70% had coronary artery disease; 46% were men. Creatinine values > 2 mg/dL were present in 5.6% of TAVR patients and 9.6% receiving standard therapy. Frailty was 18.1% for TAVR and 28% for standard therapy. A porcelain aorta was present in 19% of TAVR subjects and 11.2% of patients receiving standard therapy ($P = .05$). The incidence of chronic obstructive pulmonary disease was significantly higher in the standard therapy group (52.5% vs 41.3% in the TAVR group; $P = .04$). Average chest wall radiation was 8.6%.

At 5 years, all-cause mortality in the intention to treat (ITT) population was 93.6% for standard therapy and 71.8% for TAVR (HR, 0.50; 95% CI, 0.39 to 0.65; $P < .0001$). Other key end point events are shown in Table 1.

The mortality benefit was similar in elderly (> 85 years) patients compared with those ≤ 85 years. A CV mortality

Table 1. Events at 5 Years in ITT Population

Event	TAVR	Standard Rx	Log-rank *P* Value
All-cause mortality, %	71.8	93.6	< .0001
STS < 5	55.9	100	.0012
STS 5-15	75.2	93.4	.0002
STS > 15	73.7	93.3	.0749
Median survival, mo	29.7	11.1	< .0001
Cardiovascular mortality, %	57.3	85.9	< .0001
STS < 5	41.1	100	< .0001
STS 5-15	61.6	82.4	< .0001
STS > 15	57.8	91.8	.0098
Repeat hospitalization, %	47.6	87.3	< .0001
NYHA Class III and IV, %	14.3	40.0	ns
Incidence of stroke, %	14.6	5.7	ns

STS, Society of Thoracic Surgeons risk score; TAVR, transcatheter aortic valve replacement.

and all-cause mortality benefit was seen even in patients with high STS scores. Beyond early procedural risk of stroke in TAVR-treated patients, there was no persistent risk over 5 years of follow-up. Echocardiography showed a sustained increase in aortic valve area and decrease in transvalvular gradient after TAVR. Moderate and severe paravalvular leak was associated with a higher CV mortality particularly in patients with less comorbidity.

Despite an increase risk of major stroke, TAVR is a beneficial treatment for patients with severe AS who are not suitable candidates for surgery.

ABSORB II: Comparable Clinical Outcomes Noted With ABSORB Scaffold and XIENCE Stents

Written by Maria Vinall

Results from ABSORB II [Serruys PW et al. *Lancet.* 2014], the first study to compare an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent, demonstrated similar 1-year clinical outcomes in patients with coronary artery disease. Data were presented by Patrick W. Serruys, MD, Imperial College, London, United Kingdom.

ABSORB II is an ongoing, randomized, single-blind, multicenter clinical investigation comparing clinical and procedural outcomes between the ABSORB everolimus-eluting bioresorbable vascular scaffold system and the everolimus-eluting coronary stent (XIENCE). The coprimary end points are vasomotion (change in mean lumen diameter before and after nitrate administration at 3 years) and the difference between minimum lumen diameter (after nitrate administration) after the index procedure and at 3 years. Prof Serruys presented the secondary clinical and procedural outcomes; a composite clinical end point of death, myocardial infarction (MI), and coronary revascularization; device and procedural success; and angina status.

ABSORB-II included patients (n = 501) aged 18 to 85 years with evidence of myocardial ischemia and up to 2 de novo native lesions in different epicardial vessels randomized to either the ABSORB scaffold (n = 335) or XIENCE stent (n = 166). Procedural performance was assessed by quantitative angiography and intravascular ultrasound (IVUS). Device and procedural success were presented in percentage. Angina status was assessed by the Seattle Angina Questionnaire (SAQ). Exercise testing occurred at 6 and 12 months. Post hoc adverse event (AE) reporting was used to determine cumulative angina rate.

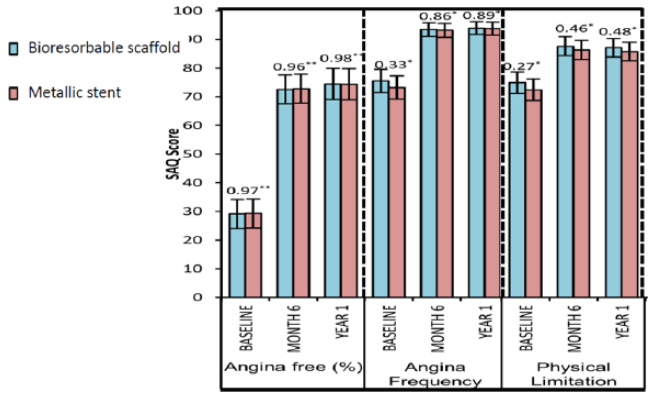
Approximately 84% of patients had single vessel disease, of which the majority (98%) was class B1/B2 lesions. There were no differences in procedural details per lesion except for nominal diameter of last balloon used (ABSORB 3.08 mm vs XIENCE 3.16 mm; $P = .02$) and maximum last balloon pressure used (ABSORB 14.23 atm vs XIENCE 15.03 atm; $P = .01$).

Clinical device and procedural success rates for both devices were > 95%. There was no difference in the cumulative incidence of the composite clinical outcome of death, MI, or revascularization (7% and 9% ABSORB and XIENCE arms, respectively; $P = .47$). Acute lumen gain whether by angiography (ABSORB 1.15 mm vs XIENCE 1.46 mm) or IVUS (Absorb 2.85 mm^2, XIENCE 3.60 mm^2) was significantly (both $P < .001$) lower in the ABSORB arm compared with the XIENCE arm. The investigators suggested this may be attributable to the greater pressure and larger size of balloon used during the postimplantation dilatation with XIENCE.

One definite acute, 1 definite subacute, and 1 probable late incidence of scaffold thrombosis was documented in the ABSORB arm and none in the XIENCE arm. The per-protocol periprocedural MI rates were 4% and 1% in the ABSORB and XIENCE arms ($P = .16$), respectively. There were 17 (5%) major cardiac AEs with ABSORB compared with 5 (3%) events in the XIENCE arm. The most common AEs were MI and target-lesion revascularization. Myocardial biomarkers (troponin, creatine kinase, creatine kinase-MB) did not indicate a substantial difference in myonecrosis between the 2 devices.

Exercise performance and angina status as assessed by SAQ were comparable (Figure 1). Cumulative rates

Figure 1. SAQ Exercise Performance and Angina Status



*P value from post hoc t test; **†P value from post hoc χ^2 test.

SAQ, Seattle Angina Questionnaire.

Reproduced from Serruys PW et al. A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomized controlled trial. *Lancet*. 14 Sept 2014; In Press, Corrected Proof. Copyright 2014, with permission from Elsevier.