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.

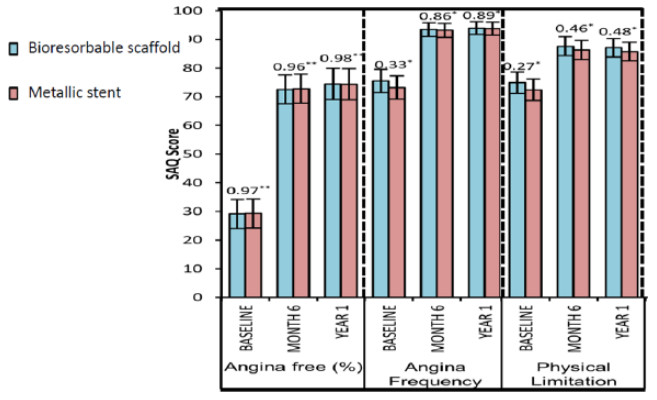
Approximately 84% of patients had single vessel disease, of which the majority (98%) was class B1/B2 lesions. There were no differences in procedural details per lesion except for nominal diameter of last balloon used (ABSORB 3.08 mm vs XIENCE 3.16 mm; $P = .02$) and maximum last balloon pressure used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

of new, recurrent, or worsening angina were lower in the ABSORB (21.8%) group compared with the XIENCE (30.5%) group ($P = .04$). If the first 7 days including hospitalization were excluded, the rates were 16.4% and 25.6% ($P = .02$). This post hoc, hypothesis-generating observation warrants further physiological and clinical investigation.

CLEAN-TAVI: Less Radiological Evidence of Stroke in Patients Treated With TAVR Plus a Cerebral Embolic Filter

Written by Maria Vinall

Stroke is a major complication following transcatheter aortic valve replacement (TAVR) that increases mortality by >3.5 fold [Eggebrecht H et al. *EuroIntervention*. 2012]. About two-thirds of patients undergoing TAVR have evidence of ischemic events following the procedure [Daneault B et al. *J Am Coll Cardiol*. 2011]. The presence of silent brain infarcts increases the risk of major stroke by >3 fold [Vermeer SE et al. *Stroke*. 2003]. They are also associated with several adverse neurological and cognitive consequences. Axel Linke, MD, University of Leipzig, Heart Center, Leipzig, Germany, reported that using an embolic filter with TAVR significantly reduces the number and volume of cerebral infarcts.

The Claret Montage dual-filter Cerebral Protection System was developed to protect the brain from injury caused by embolic debris. The Claret Embolic Protection and Transcatheter Aortic Valve Implantation Trial [CLEAN-TAVI; NCT01833052] evaluated the impact of the use of this filter on the number of cerebral lesions in high-risk, aortic stenosis (AS) patients undergoing TAVR using the Medtronic CoreValve (MCV). The study hypothesis was that use of the Claret Montage filter would reduce the number of cerebral emboli by 50% at 2 days post procedure.

Patients (50 in each group) were randomized (1:1) in a blinded fashion to TAVR with and without the filter. The primary end point was the numerical reduction in positive postprocedure diffusion-weighted MRI (DW-MRI) perfused brain lesions relative to baseline at 2 days in various territories of the brain. Patients with symptomatic and relevant AS with an indication for TAVR using the Medtronic CoreValve were included. Patients with a pacemaker, patients having a stroke within the past 12 months, and patients with >70% stenosis of the carotid artery were excluded.

Table 1. Procedural Outcomes

	Control[a] (n = 50)	Filter (n = 50)	*P* Value
Acute kidney injury, no. (%)	5 (10)	1 (2)	.23
Thoracotomy, no. (%)	0 (0)	3 (6)	.24
New-onset/worsening AF, no. (%)	7 (14)	7 (14)	1.00
Death at 30 days, no. (%)	1 (2)	0 (0)	1.00
Fluoroscopy time, min	14.3 ± 6.5	17.0 ± 9.1	.03
Amount of contrast medium, mL	131 ± 33	125 ± 29	.61
Lesions positive at 2 days, no. (%)	44/45 (98)	47/48 (98)	1.00

AF, atrial fibrillation.

Control = transcatheter aortic valve replacement without the Medtronic CoreValve filter.

Baseline characteristics were similar between the groups with 51% having coronary artery disease, 92% in congestive heart failure, and 34% having prior atrial fibrillation/flutter.

Device success was 96% (48/50) with 2 unsuccessful filter deployments (1 each left coronary cusp tortuosity and stratum corneum tortuosity). Procedural success was 94% with accidental dislocation of a correctly deployed filter in one patient. Table 1 shows the procedural outcomes.

There were significantly fewer lesions at 2 and 7 days in regions of the brain when TAVR was performed with the Claret Montage filter compared with the control group in which TAVR was performed without the filter. In the protected regions, there were 60% fewer lesions using the filter at 2 days ($P = .009$) and 57% fewer lesions at 7 days ($P = .0023$). In all regions, there were 50% less lesions with the filter compared with controls at day 2 ($P = .0023$) and 50% less lesions at day 7 ($P = .0123$).

Similar outcomes were noted for the total volume of lesions. Neurological outcomes were similar at 2, 7, and 30 days between the 2 groups in the intention-to-treat analysis. At 2 days, a neurological deficit was observed in 28% of the control patients when evaluated by a NIHSS-trained specialist. There were significantly ($P < .05$) fewer incidences of ataxia in the filter group (9%) at 2 days compared with the control group (24%) in the per-protocol analysis.

Use of Claret Montage filter during transfemoral TAVR using the MCV in surgically at risk patients with severe AS significantly reduces the number and volume of cerebral lesions as determined by DW-MRI subtraction at 2 and 7 days after procedure. Larger studies are needed to validate the observed beneficial effects of routine cerebral protection during TAVR in improving acute neurological outcome and reducing stroke rate.