access routes were transmural (n=164), transapical (n=54), axillary (n=5), or transaortic (n=4). A CoreValve prosthesis was implanted in 174 patients, and a Sapien prosthesis in 53 patients. Clinical and echocardiographic investigation was performed at 6 months, one and two years.

Results: Survival was 88.5% at 30 days, 75.9% at six months, 74.5% at 1 year, and 64.4% at 2 years. Patients improved significantly in NYHA class after 6 months (from 2.5±0.7 to 1.7±0.7) and up to two years (1.9±0.7). Cumulative incidence of myocardial infarction, stroke, life-threatening or major bleeding were 2.7%, 6.2%, and 16.2% at two years. The postprocedural mean transprosthetic gradient was 12±4 mmHg for all valves and did not change up to 2 years, the effective orifice area was 1.5±0.8 cm² without limitation by more than 2 years of FII. Moderate or severe prosthetic regurgitation was present in 8% of patients at two years. In 6% of patients, the paravalvular or valvar regurgitation grade increased significantly over time.

Conclusion: With excellent functional recovery of the patients, good systolic valve function and overall low morbidity at two years, we conclude that the CoreValve TAVI can be considered the treatment of choice for aortic valve stenosis in the elderly patient with an increased risk for surgery with heart-lung-machine.

TCT-787
Australian and New Zealand Source Registry: Edwards Sapien Transcatheter Aortic Valve Replacement- 30 Day Outcomes

Darren Walters¹, Ajay Sinha², David Barron¹, Sanjeevan Pasupati¹, Suka Thambari³, Nigel Jepson⁴, Gerald Yong⁵, Alan James⁶, Hugh Woffenden⁷, Adam Gateman³, Peter Brady³, Paul Janze³, Ravi Bhindi⁴, Robert Larbalestier⁴, Andrew Clarke⁴, James Bemetti⁴, Derek Chew⁴
¹Cardiology, The Prince Charles Hospital, Chermside, Australia; ²Royal North Shore Hospital, Sydney, Australia; ³Prince of Wales Hospital, Sydney, Australia; ⁴John Hunter Hospital, Newcastle, Australia, ⁵Wakitek Hospital, Hamilton, New Zealand; ⁶St. Vincent’s Hospital, Sydney, Australia; ⁷Roxulde Perth Hospital, Perth, Australia; ³Flinders Medical Centre, Adelaide, Australia

Background: Transcatheter aortic valve implantation (TAVI) may be considered for those with severe aortic stenosis who are considered inoperable or at high risk for surgical replacement. We report the 30 day outcomes of the Edwards Sapien Source Registry in Australia and New Zealand.

Methods: This study enrolled 133 subjects at eight centres since December 2008. Inclusion criteria included severe symptomatic aortic valve disease, symptomatic degenerative aortic stenosis (AVA ≤0.8sm²), logistic EuroSCORE >20% or STS >10%, agreement between surgeon and cardiologist that the patient not suitable for open surgery due to high risk.

Results: A total of 133 were enrolled with complete data for 99 patients consisting of 53 transfemoral (TF) and 46 transapical (TA) implants. The mean age 82.6 yr (TA), female 32.1% (TF) 56.5% (TA), logistic Euroscore 27.6% (TF) 30.7% (TA), 53 transfemoral (TF) and 46 transapical (TA) implants. The mean age 82.6 yr (TF) and 83.6 yr (TA), female 32.1% (TF) 56.5% (TA), logistic Euroscore 27.6% (TF) 30.7% (TA) with procedural success (successful implant without conversion to surgery or death) of 92.3% (TF) 87% (TA) (p=0.384). Thirty day outcomes were not significantly different between TF and TA implants. These included mortality of 3.8% (TF) 8.7% (TA) (p=0.283), stroke 1.8% (TF) 3.1% (p=0.674), and V ARC major complications of 6.5% (TF) 7.5% (TA) (p=0.859).

Conclusion: TAVR with the Edwards Sapien device is safe and effective therapy by TF or TA route. A high procedural success rate was achieved with an acceptable risk.

TCT-788
Late Occurrence of Bradyarrhythmias After TAVI with the CoreValve® Aortic Bioprosthesis

Emmanuel Chorianopoulos, Ulrike Krumsdorf, Sven T Plegier, Hugo A Katsa, Raffi Bekerejian
Department of Cardiology, Angiology and Pulmology, Heidelberg University Hospital, Heidelberg, Germany

Background: Transcatheter aortic valve replacement (TAVI) has become an alternative therapy in patients with high surgical risk. Among the major drawbacks of this procedure is the potential need for postprocedural permanent pacemaker implantation (PPI) due to bradyarrhythmias.

Methods: We performed a retrospective single center analysis in 130 consecutive patients with successful transfemoral CoreVale implanted pre-procedure. Clinical and echocardiographic investigation was performed post-procedure.

Results: Postprocedural bradyarrhythmias occurred in 47 patients (36.2%) post-TAVI. PPM was performed in 46 patients. One patient died due to asystole. Compared to those without postinterventional bradyarrhythmias, these patients had longer procedural PR-intervals (P=0.012), broader QRS-complexes (P=0.001) and prolonged QTc-intervals (P=0.001). Moreover, patients with postinterventional bradyarrhythmias had a higher logistic EuroSCORE (29.4±18.6) and the medication group (46.2±24.3) (p<0.001) and high of functional class (NYHA II) were as follows: TAVI 91%, SAVR, 79%, BV, 38%, medicina, 16% (p<0.001). One-year mortality rate was dramatically lower in the TAVI group (8.5%) than in the other groups (SAVR 29.8%, BV 39.6%, medicina 38.7%; p<0.001). Multivariable adjustment analysis identified renal failure (GFR<60cc/min, HR: 4.5, p<0.001) and pulmonary pressure (1mmHg, HR: 1.02, p=0.002) as independent correlates for 1-year mortality in the total group; STS score (1%, HR: 1.1, p=0.001) in the AVR group and peripheral vascular disease and in the BV group (HR 6.9, p<0.015).

This prospective clinical evaluation suggests that among the treatment options for high-risk patients with severe AS, TAVI is associated with an excellent prognosis in carefully selected patients. Patients excluded from TAVI have worse outcomes, regardless of the elected mode of treatment, including SAVR.

TCT-789
Clinical Profile and Outcome Correlates in Patients with Severe Aortic Stenosis at High Surgical Risk: Prospective Evaluation According to Treatment Assignment

Rabin Medical Center, Petah-Tikva, Israel

Background: Transcatheter aortic valve implantation (TAVI) is a therapeutic alternative to surgical aortic-valve replacement (SAVR) in high-risk patients with severe aortic stenosis (AS). Patients ineligible for both SAVR and TAVI are treated with medication, or with balloon valvuloplasty (BV). There are very few data on the outcome of these patients according to the treatment assigned in the current TAVI era.

Methods: The study included 403 high-risk patients (55.8% female, age 81±4.7 years) with severe AS referred to a dedicated “TAVI clinic” with meticulous screening and multidisciplinary evaluation. Technical and procedural success (V ARC definitions) and outcome were assessed during median follow-up of 292 days (IQR 138-522).

Results: Of the 343 patients assigned treatment, 100 (29.2%) underwent TAVI (56 CoreValve, 44 Edwards-SAPIEN), 61 (17.8%) SAVR, and 27 (7.9%) BV; 155 patients (45.2%) were given medication only. The BV group had more comorbidities than the other groups, represented by a higher logistic EuroSCORE (30.2±21.6 vs 22.9±14.3, p<0.001) and STS score (14.1±6.7 vs 10.8±5.3, p<0.001). One-month mortality rate was higher in the BV group (18.5%) than in each of the other groups (TAVI 3%, SAVR 11.6%, medication 3.2%, p<0.001). At one-year, patients after TAVI and SAVR had lower mean valve gradients (8.4±6mmHg and 13±5.2, respectively) than the BV group (29.4±18.6) and the medication group (46.2±24.3) (p<0.001). Rates of high functional class (NYHA II) were as follows: TAVI 91%, SAVR, 79%, BV, 38%, medicina, 16%. One-year mortality rate was dramatically lower in the TAVI group (8.5%) than in the other groups (SAVR 29.8%, BV 39.6%, medicina 38.7%; p<0.001). Multivariable adjustment analysis identified renal failure (GFR<60cc/min, HR: 4.5, p<0.001) and pulmonary pressure (1mmHg, HR: 1.02, p=0.002) as independent correlates for 1-year mortality in the total group; STS score (1%, HR: 1.1, p<0.001) in the AVR group and peripheral vascular disease and in the BV group (HR 6.9, p<0.015).

This prospective clinical evaluation suggests that among the treatment options for high-risk patients with severe AS, TAVI is associated with an excellent prognosis in carefully selected patients. Patients excluded from TAVI had worse outcomes, regardless of the elected mode of treatment, including SAVR.