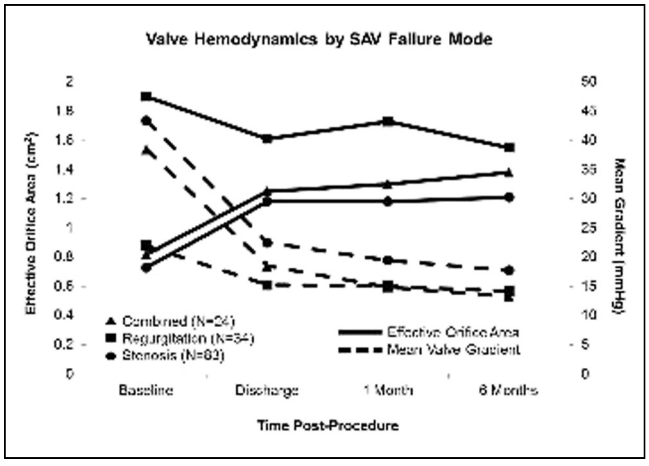
AV stenosis unsuitable for surgery. We are reporting 6 month outcomes in TAVR pts with a failed surgical bioprosthesis who were unsuitable for open surgery.

METHODS The CoreValve US Expanded Use Study is a prospective, nonrandomized, single arm study that evaluates safety and effectiveness of TAVR in complex subsets of extreme risk pts including those who are symptomatic with failed surgical bioprosthesis. Baseline echocardiographic data were reported by the sites, while an independent core lab evaluated all follow-up findings. The primary endpoint was a composite of all-cause mortality or major stroke rate at 1 year.

RESULTS From Mar 2013 - Oct 2014, 143 pts had an attempted implant. Surgical failure mode was stenosis 59%, regurgitation 24%, combined 17%. 141/143 (98.6%) pts had successful TAVR implantation with 2 aborted procedures. Pts were elderly 77 ± 11 years, 66% were men, STS PROM 9.4 ± 6% and severely symptomatic (NYHA III/IV 87%). All-cause mortality or major stroke at 6 mo was 10.7% (mortality 9%, major stroke 1.8%). 6mo Mod/Sev PVL 1.2% & NYHA III/IV 3.4%. Permanent pacemaker rate was 8.3%.



CONCLUSIONS CoreValve TAVR in pts with failed surgical bioprosthesis at extreme risk for surgery was associated with a low 6 mo mortality and stroke rate, significant reduction in aortic valve gradients, and a low incidence of moderate/severe PVL and NYHA III/IV failure.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, TAVR, Transcatheter aortic valve replacement

TCT-97

Transcatheter Aortic Valve Replacement Using the Self-Expanding Bioprosthesis: First Report from the Transcatheter Valve Therapies Registry

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BACKGROUND Transcatheter aortic valve replacement has become the default treatment for patients with severe aortic stenosis at extreme or high risk for surgery. Extrapolation of the safety and efficacy established in the CoreValve US Pivotal trials has not been confirmed after regulatory approval. The objective of this study was to report the 30-day clinical outcome of patients treated with the CoreValve self-expanding bioprostheses in commercial practice.

METHODS A total of 4913 patients with severe aortic stenosis implanted with the self-expanding CoreValve at 186 US centers between January 2014 and March 2015 were included in the Transcatheter Valve Therapies (TVT) Registry (extreme risk (ER), 41.5%; high risk (HR), 53.3%; intermediate risk, 3.6%; other; 1.6%). Patients were followed for at least 30 days for Valve Academic Research Consortium criteria for mortality and major complications.

RESULTS The 30-day results of the TVT Registry are found in the Table. A transfemoral approach was used in 89.4% of patients. CoreValve sizing recommended by CTA included: 23 mm, 4.3%; 26 mm, 22.4%; 29 mm, 38.8%; 31 mm, 34.5%. For discussion, the combined results of the CoreValve US Pivotal Extreme Risk and High Risk Trials are provided (Popma JACC 2014, Adams, NEJM 2014) (Table). No statistical comparisons were performed with the TVT Registry due to the differing patient populations, data collection and enrollment periods.

CONCLUSIONS This first report of the TVT Registry provides assurance of the early safety and effectiveness of the CoreValve self-expanding bioprosthesis in clinical practice. Longer-term follow-up is needed to establish the extended benefit in these patients.

Table

Variable	TVT Registry N=4,913	ER/HR Pivotal Study N=1,030
Baseline		
Age, years / STS PROM, %	81.1 / 8.8	83.0 / 9.2
Diabetes, % / Prior CABG, %	38.4 / 30.1	37.9 / 35.8
CAD, % / Prior Pacemaker, %	70.1 / 21.8	79.1 / 24.9
Mean AV gradient Pre / Post, mmHg	43.3 / 8.4	48.0 / 9.7
30-Day Events		
All-cause Mortality, % / Any Stroke, %	5.3 / 2.8	6.9 / 5.0
Major Vascular, % / New PPM, %	1.1 / 22.3	7.5 / 20.2
Device Thrombosis, % / Fracture, %	0 / 0	0 / 0
PVL*, % / Valve-in-Valve, %	9.8 / 3.2	10.5 / 2.6
Device Implanted Successfully, %	98.0	98.9

CABG = coronary artery bypass surgery; CAD = coronary artery disease; STS PROM= STS Predicted Risk of Mortality; *Moderate or severe.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Transcatheter aortic valve implantation, Transcatheter aortic valve replacement

TCT-98

Clinical Outcomes at 1 Year with a Repositionable Self-Expanding Transcatheter Aortic Valve

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BACKGROUND The repositionable CoreValve Evolut R transcatheter aortic valve (TAV) was designed to permit optimal valve placement at the desired plane of the native aortic valve and depth of implant. The Evolut R TAV (26, 29 mm) obtained CE marking after demonstrating safety and efficacy at 30 days in patients with symptomatic aortic stenosis and heart-team assessed risk of operative mortality. Outcomes at 1 year will be available at the time of the meeting.

METHODS The Evolut R CE Study included 60 patients implanted at 6 sites in Australia, New Zealand and the United Kingdom and included the first use of the valve for all operators. An independent echocardiographic core laboratory was employed, and Clinical Events Committee adjudicated major adverse events according to Valve Academic Research Consortium-2 criteria. Major adverse events, functional improvement, and valve performance were assessed early post-procedure, at 30 days, 6 months, and 1 year.

RESULTS A total of 60 patients were enrolled and all received the Evolut R TAV; mean age was 82.8± 6.1 years; 66.7% were women, 68.3% had New York Heart Association (NYHA) III/IV symptoms, and the mean STS-PROM was 7.0%±3.7%. The majority of patients (68.3%) were considered frail. The repositioning feature of the Evolut R was successfully used 22 times in 15 patients. There were no deaths at 30 days and all-cause mortality at 6 months was 5.0%. One disabling stroke occurred between 30-day and 6-month follow-up. There were no valve embolization, migration, endocarditis or thrombosis events, and no coronary obstruction. The Evolut R TAV effectively treated the

aortic stenosis with a mean AV effective orifice area of 1.9±0.5 cm2 and 1.9±0.4 cm2; and gradient of 8.1±3.3 mmHg and 7.6±3.1 mmHg, at 30 days and 6 months, respectively. Compared with baseline, 76.3% of patients experienced improvement in NYHA class at 30 days, and 84.9% at 6 months. Permanent pacemaker rates were 11.7% at 30 days, and 13.4% at 6 months.

CONCLUSIONS The Evolut R TAV is associated with exceptional safety at 30 days, which continued at 6 months. We plan to report 1-year outcomes at the time of the meeting.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Outcomes, TAVI

TAVR II

Tuesday, October, 13, 2015, 2:00 PM-4:00 PM

Abstract nos: 99 - 106

TCT-99

Valve thrombosis after transcatheter aortic valve replacement: incidence, characteristics and outcomes

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BACKGROUND Data on transcatheter aortic valve replacement (TAVR) failure is limited. The study objective was to determine the incidence, timing, clinical characteristics and treatment outcomes of patients diagnosed with TAVR failure attributed to transcatheter heart valve (THV) thrombosis.

METHODS A retrospective analysis of prospectively raised data included in a single center TAVR registry. Patients in this 100% follow-up registry have a predefined echocardiographic and clinical follow-up schedule (1 month, 6 months,1 year and yearly thereafter or earlier if symptomatic). THV thrombosis was defined as (1) valve dysfunction (mean transvalvular gradient >20 mmHg, reduction of the aortic valve area to <1.2 cm2 or new onset more than mild transvalvular regurgitation) secondary to thrombosis diagnosed based on response to anticoagulation therapy or typical findings on imaging modality (Echo/CT) or (2)mobile mass suspicious of thrombus detected on the valve, irrespective of dysfunction, and in the absence of infection. The primary study endpoint was the incidence of THV thrombosis.

RESULTS During the study period (September 2007-March 2015), 588 patients underwent TAVR (CoreValve-305, Sapien XT-124,Sapien 3-117,Lotus-40,others-2). THV thrombosis was diagnosed in 12(2%) patients: Sapien XT-9, Sapien3-1 and Lotus-2. Thrombosis was not observed in any of the CoreValve patients. The mean age was 79±8years and the majority were females (n=10, 83.3%). The median time to thrombosis detection was 180 days(interquartile range, IQR 23-472). 3 patients were diagnosed early (within 1 month) after TAVR, of which 2 had a Lotus valve. In another 3 patients, thrombosis was diagnosed late (>1 year after TAVR). Half of the patients had no worsening symptoms at the time of diagnosis. In symptomatic subjects, exertional dyspnea with change in NYHA class was the most common mode of presentation (n=5). 1 patient presented with stroke. Treatment at the time of detection of thrombosis was dual antiplatelet therapy in 11 and aspirin monotherapy in 1. No cases of THV thrombosis were seen in patients discharged on oral anticoagulation. Mean aortic valve pressure gradient was elevated in 10(83%) of thrombosis patients; mean transvalvular gradient for all subjects being 36±16mmHg. Other echocardiographic findings included thrombotic mass on the leaflets (n=7, 58.3%) and thickening of leaflets with reduced mobility. Median serum NT-proBNP level was 1318 pg/ml (IQR 1123-1605). After treatment with anticoagulants, mean aortic gradient and NT-proBNP levels reduced significantly. There were no deaths related to valve thrombosis.

CONCLUSIONS THV thrombosis is a rare but an important cause of TAVR failure, most frequently detected at a median of 180 days after the procedure. Patients may present with exertional dyspnoea and/or increased transvalvular gradients. Anticoagulation is effective in improving gradients and clinical status. Optimal antithrombotic therapies after TAVR need to be defined, and randomized controlled trials are needed.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS TAVI, Thrombosis, Transcatheter aortic valve replacement

TCT-100

Transcatheter Aortic Valve Replacement in Patients With End-Stage Renal Disease: One Year Outcomes from the CoreValve US Expanded Use Study

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BACKGROUND End stage renal disease (ESRD) poses unique challenges in the treatment of patients with severe aortic stenosis. While surgical valve replacement in patients with ESRD has been associated with an increase in the risk of morbidity and mortality, the results from transcatheter valve replacement have not been clearly defined.

METHODS The CoreValve US Expanded Use Study is a prospective, nonrandomized trial of transcatheter aortic valve replacement (TAVR) in extreme risk (ER) patients with ESRD or other specific comorbidities excluding them from the Pivotal Trial. Patients with ESRD who were deemed to be ER by two surgeons, had symptoms attributable to aortic stenosis, had an aortic valve area of ≤0.8 cm2 (or aortic valve area index ≤ 0.5 cm2), and either a mean gradient ≥40 mmHg or peak velocity ≥ 4.0 m/s with one year of follow up are included in this report. The primary endpoint for the study was all-cause mortality or major stroke at 12 months. One year outcomes are compared with patients enrolled in the CoreValve ER US Pivotal Trial and an objective performance goal (OPG) pre-specified for the ER US Pivotal Trial.

RESULTS Fifty-four patients with ESRD underwent TAVR with CoreValve as part of the US Expanded Use Study and have reached one year follow up. Mean STS-PROM was 17.1 ± 8.4 in ESRD patients versus 10.3 ± 5.5 in ER US Pivotal patients. The rate of all-cause mortality or major stroke at 12 months was 26% in the ER US Pivotal Trial, 35% in the ESRD Expanded Use Study, and compared with 43% which is the ER US Pivotal Objective Performance Goal. Initial 30 day all-cause mortality was 7.4% (8.4 % in US Pivotal) and 1 year was 35.2% in ESRD patients. Any stroke or TIA at 1 year was 1.9%, major vascular injury was 3.7% and new permanent pacemaker rate was 22.9%. Valve performance at one year was comparable to post-procedure in effective orifice area (1.82 cm2 post-procedure v. 1.81 cm2 1 year) and mean gradient (9.8 mmHg post-procedure v. 9.2mmHg 1 year).

CONCLUSIONS Early mortality in patients with ESRD is comparable to ER patients without ESRD but one year data suggest a higher mortality likely due to comorbid conditions. Stroke and major vascular injury were infrequent and valve durability is maintained at one year.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic valve stenosis, Renal failure, end-stage, Transcatheter aortic valve replacement

TCT-101

Experience with cerebral protection during transcatheter aortic valve replacement: the ALSTER registry

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BACKGROUND A peri-procedural stroke rate of 2-7% remains a major complication after transcatheter aortic valve replacement (TAVR) and