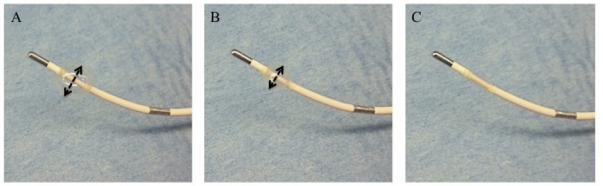
BACKGROUND Cardiac tamponade is one of the important life-threatening complications during transcatheter aortic valve implantation (TAVI). This complication is often due to right ventricular (RV) perforation by the temporary pacing lead. This study sought to assess the safety and efficacy of rapid pacing with an inflated balloon-tip electrode to prevent RV perforation.

METHODS Consecutive 749 patients undergoing TAVI from October 2013 to July 2015 were included in the Optimized transCathEter vAlvular iNtervention (OCEAN-TAVI) registry. All patients received SAPIEN XT valve. Among those, 729 patients who underwent TAVI under the rapid pacing with transvenous balloon-tip lead were the subjects of this study. The cohort was stratified into three groups, according to the state of the balloon located at the tip of the temporary pacing lead used for rapid pacing: full inflation (Figure 1A), when the balloon was inflated to 100% of its total volume (full inflation group: n=100, 13.8%); partial inflation (Figure 1B), when the balloon was inflated to approximately 75% of its total volume (partial inflation group: n=196, 27.0%); and deflation (Figure 1C), when the balloon was completely deflated in the RV (deflation group: n=430, 59.2%). Study endpoints were defined as pacing lead related RV perforation, rapid pacing failure, valve malpositioning due to rapid pacing failure, device success and 30-day mortality, and were compared among the three groups.

Figure 1



RESULTS Pacing lead related RV perforation occurred only in deflated group (full inflation group: 0.0%, partial inflation group: 0.0%, and deflation group: 1.4%, p=0.12). Rapid pacing failure occurred most frequently in full inflation group (4.0%, 0.5%, and 0.5%, respectively p=0.004), although no malpositioning due to pacing failure was observed. Rate of device success (97.0%, 95.9%, and 94.2%, p=0.41) and 30-day mortality (2.0%, 2.0%, and 1.9%, p=0.90) were similar among the three groups.

CONCLUSION Partial inflation of the balloon at the tip of the pacing lead may reduce the risk of RV perforation without increasing the risk of pacing failure or valve malpositioning.

TCTAP A-161

Comparison of Next Generation Transcatheter Heart Valves: Angiographic, Echocardiographic and Hemodynamic Evaluation of an Extended All-comers Study Cohort Using the Dimensionless Aortic Regurgitation Index

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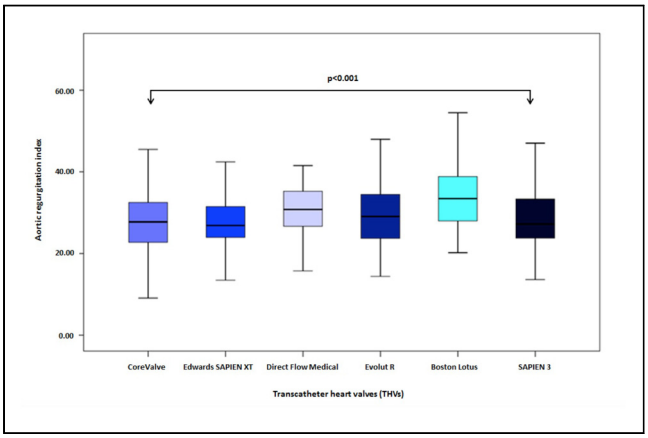
BACKGROUND More than mild paravalvular aortic regurgitation (pAR) negatively impacts prognosis after trans catheter aortic valve implantation (TAVI). Next generation transcatheter heart valves (THVs) promise to improve outcome by reducing the rate of TAVI-related issues such as pAR by specific design features such as paravalvular sealing mechanisms and repositionability/recapturing. The aim of the present study was to evaluate and compare the hemodynamic performance of next generation THVs.

METHODS In 805 patients undergoing TAVI, the degree of pAR was compared using imaging modalities (angiography, echocardiography) and hemodynamics (aortic regurgitation index, diastolic pressure time index). Severity of pAR and outcome were assessed in accordance with the VARC-2 criteria.

RESULTS 805 patients (mean age 80.9 ± 6.3 years, 50.8% male, mean left-ventricular ejection fraction 52.6 ± 14.0%, median STS PROM 5.2 (3.4-8.3)) underwent TAVI with use of the Medtronic Core Valve (n=400), Edwards SAPIEN XT (n=48), Direct Flow Medical (n=38), Medtronic Evolut R (n=114), Boston Lotus (n=104), and Edwards SAPIEN 3 (n=101). 30-day, 1-year and 3-year all-cause mortality were 4.8% (39/805), 19.9% (160/805), and 30.2% (243/805), respectively. Trans thoracic echocardiography post TAVI revealed that 326/805 (40.5%) of the patients had no relevant pAR, 420/805 (52.2%) trace or mild pAR, whereas 59/805 (7.3%) of the patients suffered from moderate/severe pAR.

More than mild pAR occurred significantly less frequently in patients undergoing TAVI with next generation THVs (p<0.001): Medtronic Core Valve (10.8%), Edwards SAPIEN XT (12.5%), Direct Flow Medical (5.3%), Medtronic Evolut R (4.4%), Boston Lotus (0.0%), and Edwards SAPIEN 3 (0.0%). The post-procedural AR index was significantly higher (p<0.001) with use of the Boston Lotus (34.2 ± 8.7), and the Direct Flow Medical (30.8 ± 6.9) THV compared with the Medtronic Core Valve (28.1 ± 8.3), Edwards SAPIEN XT (27.7 ± 7.2), Medtronic Evolut R (29.6 ± 9.2), and Edwards SAPIEN 3 (28.4 ± 6.9). Furthermore, the diastolic pressure time index (DPTI) after TAVI also differed significantly: Core Valve: 23.2 ± 9.2, Edwards SAPIEN XT: 25.1 ± 9.5, Direct Flow Medical: 28.5 ± 10.4, Medtronic Evolut R: 25.1 ± 8.4, Boston Lotus: 32.2 ± 11.3, Edwards SAPIEN 3: 26.7 ± 8.5, p<0.001).



CONCLUSION TAVI with the use of next generation trans catheter heart valves significantly reduces pAR. Improved outcome might also be explained by more beneficial hemodynamics as assessed with the aortic regurgitation index (AR index) and diastolic pressure time index (DPTI).

TCTAP A-162

Late Recoil of Balloon-expandable Transcatheter Aortic Bioprosthesis: Insights from the OCEAN-TAVI Registry

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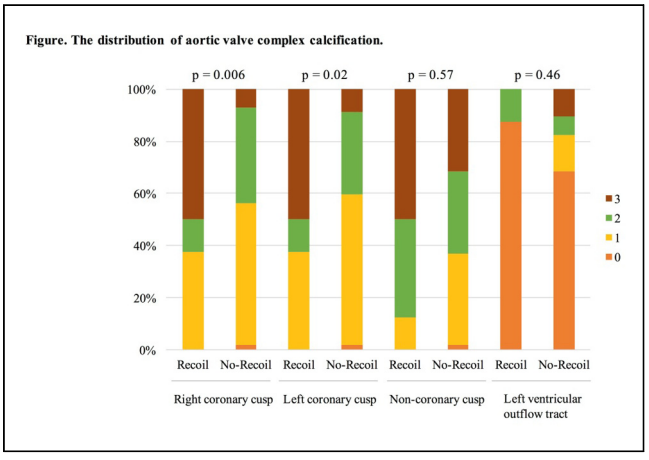
BACKGROUND Transcatheter aortic valve implantation (TAVI) was developed to improve survival and quality of life of patients with severe symptomatic aortic stenosis (AS) who are inoperable or at high risk of surgery. Recently, the mid-term outcomes of TAVI are being studied in intermediate-risk patients. The durability of transcatheter heart valves (THV) should be evaluated properly before expanding the use of TAVI to lower-risk and younger patients.

Previous reports have identified several types of THV failure such as THV thrombosis, prosthetic valve endocarditis, and structural valve failure in the late phase. As is known well in the coronary field, because the THV deployed on a calcified aortic valve must have sufficient radial force to resist elastic recoil, THV recoil may occur and affect valve hemodynamics, especially in a balloon-expandable bioprosthesis. However, even though this could cause failure of the bioprosthesis, relevant data has been obtained only in the acute phase. This study sought to evaluate, in a prospective multicentre registry, the incidence, predictors, and clinical impact of late THV

recoil after TAVI with the balloon-expandable bioprosthesis by using multidetector computed tomography (MDCT).

METHODS We analyzed data from 101 patients undergoing TAVI with balloon-expandable THVs in the Optimized Transcatheter Valvular Intervention (OCEAN-TAVI, Japan) registry, which is an on-going, prospective multicentre registry. We obtained follow-up multidetector computed tomography before discharge and at 6 months along with data on echocardiography and clinical outcomes including death, New York Heart Association (NYHA) class, and aortic regurgitation (AR). Using MDCT, we measured THV area at each follow-up and scored aortic valve complex calcification from 0 to 3 at baseline. Significant late THV recoil was defined as a percent decrease of ≥3% in an area during 6 months. We divided the 101 patients into two groups according to the degree of the interval change in THV area between the time of discharge versus at the 6-month follow-up (the recoil group; patients with significant THV recoil and the no-recoil group; patients without significant THV recoil).Furthermore, we compared the baseline characteristics and clinical outcomes between the groups.

RESULTS Significant late THV recoil was observed in 13 of 101 patients (12.8%; the recoil group). Late absolute and percent recoil was 18.1 mm^2 (interquartile range, 14.5-21.1) and 5.0% (4.1-6.0) with the recoil group; -4.5 mm^2 (-7.6-0.8) and -1.3% (-2.0-0.4) with the no-recoil group, respectively. Patients in the recoil group had greater body mass index (24.4 ± 4.8 kg/m^2 vs. 22.1 ± 3.1 kg/m^2, p=0.02), higher rate of atrial fibrillation (38.4% vs. 19.3%, p=0.02), smaller indexed aortic valve area (0.37 (interquartile range, 0.32-0.43) vs. 0.45 (0.40-0.54) cm^2, p=0.01) and larger annulus area (394 (368-443) vs. 365 (329-412) mm^2, p=0.04). The approach and bioprosthesis size were similar between the groups. No significant differences were observed in the frequency of pre-dilatation, underfilling, and post-dilatation. However, the annular area oversizing rate was lower in the Recoil group (9.2 (3.4-16.8)% and 20.3 (13.0-29.6)%, respectively, p<0.01). Patients in the recoil group had a higher degree of leaflet calcification in right and left coronary cusp (p<0.01 and p=0.02, respectively) (Figure). No significant differences were observed in valve hemodynamics including AR, indexed effective orifice area, and mean aortic gradient and clinical outcomes including death, NYHA class, and AR at 1 year between the groups.



CONCLUSION A certain degree of late THV recoil was shown in patients undergoing TAVI with a balloon-expandable bioprosthesis. Patients with heavily calcified leaflets may have an increased risk for THV recoil in the late phase. However, the condition was subclinical and did not affect valve hemodynamics at 1 year.

TCTAP A-163

Follow-Up Results of Balloon Valvuloplasty in Aortic Stenosis of Rheumatic Etiology

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BACKGROUND To study the long-term results of balloon aortic valvuloplasty (BAV) in a large cohort of patients with rheumatic valvular aortic stenosis. Balloon aortic valvuloplasty is proved as a palliative procedure as a bridge to TAVI and surgical AVR. We do not know the long-term outcomes of BAV in rheumatic etiology. We studied the outcomes of BAV in aortic stenosis of rheumatic origin and immediate and long-term data analyzed. The long term data is prudent as a majority of rheumatic patients are younger in age. We looked at the need for a surgical replacement among patients following BAV in rheumatic AS and survival following BAV.

METHODS Single center retrospective data analysis of immediate and long-term outcomes in patients following BAV from 2000 to 2009. One hundred and forty-four (144) patients with rheumatic aortic stenosis (AS) were studied who underwent BAV. Patients were divided into 3 groups for analysis following BAV. Successful BAV (more than 50% reduction in baseline gradient) (Group A), partially successful BAV (25-50% reduction in baseline gradient) and BAV failed <25% reduction in baseline gradient (Group C).

RESULTS Mean age of patients was 21.7 years (95% CI 14.3-28.9) with a mean follow-up period of 5.7 years (± SD 1.3). 123 (85.9%) subjects were in Group A,12 (8.7%) subjects in Group B and 7 (5.4%) subjects in Group C. Concomitant balloon mitral valvuloplasty was done in 35/144 cases. Mean left ventricular systolic pressure decreased from 165.6 (95% CI 142.7-196.3) to 110.9 mmHg (95% CI 92.1-129.6) and mean aortic valve (AV) gradient from 50.7 (95% CI 35.12-66.22) to 27.2 mmHg (95% CI 25.83-31.23). The mean change in ejection fraction and mean AV gradient were significantly different between success (Groups A and B) and failure groups (P<0.001). Different grades of AR were noted in 50 (34.78%) patients post BAV (severe regurgitation in 2.18%). ANOVA post hoc analysis showed sustained gradient reductions at 1- and 5-year follow-up. 5-year survival in isolated rheumatic AS following successful BAV (N=123) versus and surgical AVR (205) showed similar outcomes (P=0.632).

CONCLUSION BAV is an effective treatment strategy in dominant AS in multivalvular rheumatic disease situations. Combined aortic and mitral valvuloplasty was performed in one-fourth of study patients. The need for surgery was much lower in Group A (2.5%) compared to Group B (50%) and C (100%). Five-year survival in isolated rheumatic AS following successful BAV showed similar outcomes with surgery.

TCTAP A-164

Post-procedure 3D Mitral Valve Geometry Alteration in Transapical Mitral Valve-in-valve Surgery Using Two Different Valve System

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BACKGROUND Alteration of the 3-dimensional (3D) mitral valve (MV) geometry in transapical mitral valve-in-valve (VIV) procedure is not well-defined. We aimed to investigate the 3D post-procedural MV geometry change in patients who received two different types of prosthesis.

METHODS We enrolled 12 patients who had undergone tissue mitral valve surgery (degenerative mitral regurgitation, n=9; rheumatic mitral regurgitation, n=1; rheumatic mitral stenosis, n=1; ischemic mitral regurgitation, n=1) (Figure 1). After the median of 9.5 (IQR: 5.3-13.7) years post-MV replacement, all 12 patients had failed mitral bioprosthesis (2 had mitral stenosis and 10 had mitral regurgitation).

VIV procedure was performed using Edward Sapien XT valve in 6 patients, and Boston Lotus valve in the other 6 patients. 3D transesophageal echocardiography (TEE) was performed before and immediately after the procedure. 2D transthoracic echocardiography (TTE) was also performed before VIV procedure and during the follow-up period (3- and 6-month post-procedure). The severity of mitral regurgitation was graded as no regurgitation (0), mild (1+), moderate (2+), moderately-severe (3+) and severe (4+) on the basis of vena contracta, regurgitant volume, and effective regurgitant orifice area. All analysis of 3D MV geometry was performed using QLAB 10.4 (Philips, Andover, MA).