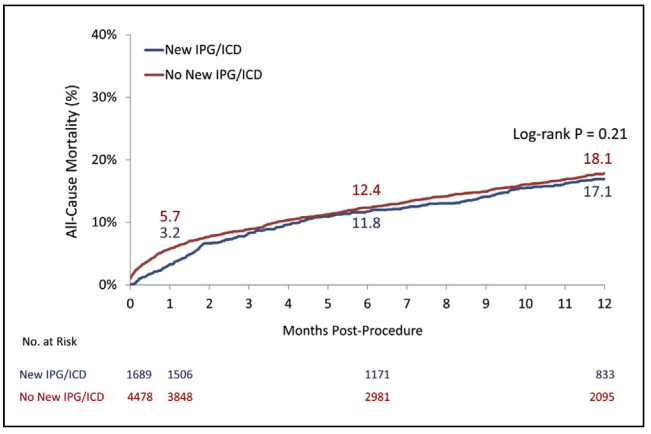
CONCLUSION Permanent pacemaker implantation after TAVR with the self-expanding CoreValve bioprosthesis was not associated with an increased risk for mortality at 1 year. This observation is consistent with published reports for the self-expanding valve in large scale investigational studies.



CRT-800.12

Effect Of Transcatheter Aortic Valve Size And Position On Valve-in-valve Hemodynamics: An In-vitro Study

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OBJECTIVE Transcatheter heart valve implantation in failed aortic bioprostheses (valve-in-valve,ViV) is an increasingly used therapeutic option for high-risk patients. However, high post-procedural gradients are a significant limitation of aortic ViV. Our Objective was to evaluate Medtronic CoreValve® Evolut® R ViV hemodynamics in relation to the degree of device oversizing and depth of implantation.

METHODS 23mm and 26mm Evolut R devices were implanted within 21, 23, and 25mm Hancock® II bioprostheses. Small and gradual changes in implantation depth were attempted. Hemodynamic testing was performed in a pulse duplicator under ISO-5840 standard.

RESULTS A total of 47 bench-testing experiments were performed. The mean gradient of the 26mm Evolut R in 23mm and 25mm Hancock II was lower than 23mm Evolut R ($p<0.001$). However, mean gradient of 26mm Evolut R in 21mm Hancock II bioprostheses R (ranging from 21.30±0.23 to 24.30±0.22mm-Hg) was worse than 23mm Evolut R (ranging from 15.94±0.18 to 20.35±0.16mm-Hg, $p<0.001$). Furthermore, our results suggest that supra-annular implantation of 23mm and 26mm Evolut R devices within the bioprostheses can lead to lower gradient and improved leaflet coaptation. Regardless of implantation depth, superior transvalvular gradient is expected with 26mm Evolut R than 23mm Evolut R in a non-stenotic Hancock II with a true internal diameter > 17.5mm.

CONCLUSION The current comprehensive bench testing assessment demonstrates the importance of both transcatheter heart valve size and device position for the attainment of optimal hemodynamics during ViV procedures. Additional in vitro testing may be required to develop hemodynamics-based guidelines for device sizing in ViV procedure in degenerated surgical bioprostheses.

CRT-800.13

Contemporary Transcatheter Aortic Valve Replacement Experience With Third-generation Balloon-expandable Versus Self-expanding Devices

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INTRODUCTION Two competing TAVR technologies are approved for commercial use in the US: the balloon-expandable Sapien 3 (S3) (Edwards, Irvine, CA) and the self-expanding Evolut R (Medtronic, Minneapolis, MN).

METHODS A total of 257 consecutive patients treated with S3 or Evolut R were included. Baseline demographic, procedural, echocardiographic and CT imaging, and follow-up data were prospectively collected at a tertiary referral hospital in the US where both devices are routinely used.

RESULTS Patients selected for Evolut R were more likely to be female and have lower body surface area (BSA) and smaller iliofemoral vessels (Table 1). There was no difference in the severity of aortic stenosis (valve area 0.70±0.17 vs 0.68±0.13, $p=0.27$ for S3 vs Evolut R). Balloon valvuloplasty was performed more frequently in the S3 group (65.4% vs 36.7%. $p<0.001$). Four patients suffered periprocedure ischemic stroke with S3 compared with 1 with Evolut R. Pacemaker implantation rate was higher in the Evolut R group. The major vascular complication rate was similar in both groups (4.8% vs 4.5%, $p=1.0$, for S3 vs Evolut R) as was the rate of life-threatening and major bleeding (3.5% vs 2.9%, $p=1.0$, respectively). Dimensionless index was significantly higher in the Evolut R group, but the incidence of >mild paravalvular leak was also numerically higher. There was no difference in 30-day mortality.

CONCLUSION In our contemporary experience, both technologies had advantages and disadvantages. These data highlight the importance of individualized decision making, with the choice of TAVR device tailored to each patient. Although there was no difference in 30-day mortality, it will be important to evaluate longer-term prosthesis hemodynamics and clinical outcomes going forward.

	Sapien3 (n=183)	Evolut R (n=74)	p value
Female	46.4%	60.8%	0.037*
Body surface area, mean ± SD (m^2)	1.9 ± 0.3	1.8 ± 0.3	0.048*
Minimal rightiliofemoral diameter, mean ± SD (mm)	6.8 ± 1.5	5.9 ± 1.5	<0.001*
Minimal left iliofemoral diameter, mean ± SD (mm)	6.9 ± 1.4	5.9 ± 1.4	<0.001*
Successful valve deployment	96.4%	98.4%	0.72
Pacemaker implantation	4.7%	12.7%	0.049*
Prosthetic valve dimensionlessindex, mean ± SD	0.50 ± 0.10	0.57 ± 0.12	<0.001%
Paravalvular leak >mild in severity	4.1%	8.2%	0.31
30-day mortality	1.6%	1.4%	1.00

(* denotes statistical significance). SD: standard deviation.

CRT-800.14

Percutaneous Coronary Intervention Prior to Transcatheter Aortic Valve Replacement: A Matched Cohort Analysis

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BACKGROUND A significant proportion of patients with severe aortic stenosis (AS) have coexisting significant coronary artery disease (CAD). There is limited data regarding outcomes of percutaneous coronary intervention (PCI) prior to transcatheter aortic valve replacement (TAVR) in patients with severe AS and significant CAD. We sought to assess clinical outcomes in patients with severe AS who underwent PCI within 30 days prior to TAVR.

METHODS 286 consecutive patients were identified who underwent TAVR from 5/31/2011 to 2/4/2016. Of these, 29 patients underwent PCI for CAD within 30 days prior to TAVR (PCI+TAVR group). We matched these patients in a 1:1 fashion (based on age, gender, prior myocardial infarction and left ventricular ejection fraction) with 29 consecutive non-AS patients who underwent PCI for CAD (PCI group) during the same time period. Primary end-point was a composite outcome of major adverse cardiovascular events (including myocardial infarction and stroke), all-cause mortality and readmissions, all within 30 days. Continuous variables were analyzed using t-test and categorical variables were analyzed using Fisher's exact test.

RESULTS The study population consisted of 58 patients or 29 pairs (69% male, mean age 77±11 years) who were well matched for baseline clinical characteristics. At 30 days, 7/29 patients in each group met the primary end-point (p=1.0). The PCI+TAVR and PCI-alone group had no statistically significant difference in the primary end-point at 30 days.

CONCLUSION PCI prior to TAVR in patients with severe AS and significant CAD appears to be feasible and safe. At 30 days follow-up, no significant differences were seen in mortality, major adverse cardiovascular events or readmissions in patients with severe AS and significant CAD who underwent PCI within 30 days prior to TAVR compared to non-AS patients with CAD who underwent PCI alone. Further population-based studies are needed to assess the safety of PCI prior to TAVR.

CRT-800.15

TAVR in Low Risk Surgical Patients: A Cohort Study With a Mean Follow Up Of 2 Years

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BACKGROUND The Partner 2 Trial results made the case for extending the indications for TAVR into the intermediate risk group with a mean STS score of 5.8. Here, we present our results of TAVR in a low risk group with mean STS score of 2.9 and mean follow up of 2 years.

METHODS This is a prospective cohort study of 46 consecutive patients from our institution who underwent TAVR between 2012 and 2016. All patients were referred to our center with severe symptomatic AS. They underwent a comprehensive assessment by the heart team. Age, functional status, coronary disease, co-morbid conditions were assessed. Imaging parameters included ejection fraction (EF), aortic valve morphology, gradient, annulus, and concomitant valvular disease. Patients who were deemed poor surgical candidates by the heart team were referred for TAVR. Immediate procedural success, mean gradient and paravalvular leak (PVL) were measured. Patients were followed clinically and echocardiographically with a range of 1-4 years.

RESULTS 46 patients were included in this study, 28 men and 17 women with a mean age of 75 years. Twelve had coronary artery disease (5 prior PCI and 5 prior CABG). The mean EF was 56%, mean MG of 51 mmHg and mean PG of 87 mmHg. All valves were trileaflet aortic valves. None had significant coexistent valvular pathology. The mean STS score was 2.9. Forty-two underwent a transfemoral and 4 a transaortic TAVR. Twenty five received the Sapien XT valve while 21 were treated with a Sapien 3 valve (thirty three 23 mm, twelve 26 mm, and one 29 mm valve). All 46 valves were implanted successfully. There was no valve embolization, annular rupture or need for a second valve. One patient had moderate PVL. Postprocdeure mean MG was 11 mmHg. There was one procedure related stroke. Three patients required a permanent pacemaker. 30-Day mortality was 2 out of 46 (4.3%). Follow up ranged from 1-4 years with a mean of 25.5 months. The mean MG at 2 years was 12 mmHg. Those with any degree of PVL, no increase was noted. Those with trace and mild PVL tended to resolve. Late mortality occurred in 5 patients all non-cardiac.

CONCLUSION TAVR in this low risk group of patients was successful with excellent valve performance and no late cardiac mortality. This data supports a randomized trial to determine the validity of TAVR in low risk individuals. Although the STS score clearly identifies intermediate and high risk patients suitable for TAVR, it does not take into account the overall frailty and limited mobility of many elderly patients placing them at a higher surgical risk despite their low STS scores.

CRT-800.16

Utility Of Dobutamine and Pressure Wire Use in Assessing Low Flow Low Gradient Aortic Stenosis With Reduced EF

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BACKGROUND Current guidelines discourage aortic stenosis (AS) evaluation by direct pressure measurement if echocardiography (echo) is adequate. However several studies show sizable differences between echo and catheterization (cath) lab measurements. Dobutamine Challenge is recommended for evaluation of Low flow/low gradient (LF/LG) severe aortic stenosis (AS) with reduced EF.

Using pressure wire for aortic stenosis assessment with dobutamine challenge may offer a safe and higher quality technique to assess the severity of AS in LF/LG and NF/LG AS with reduced Ejection Fraction (EF).

METHODS 42 sequential patients with EF < 50%, AVA <1 cm ^{2} and SVI<35 ml $/m^2$ on echocardiography underwent right and left heart cath with pressure gradients via left ventricular (St. Jude) pressure wire and ascending aorta catheter. Cath derived values were based on simultaneous pressure wire recording of left ventricular pressure and fluid filled pressure catheter recording of aortic pressure measured > 5 cm above the valve at baseline and at maximum dose of Dobutamine. Cardiac output was calculated by thermodilution.

RESULTS Of these 42 patients, Dobutamine challenge resulted in confirming the presence of true AS in 32 patient (76%) , while Pseudo AS was confirmed in the rest 24%. No significant arrhythmias or profound hypotension was observed during or after the procedure. No clinical strokes or TIA were observed in the 30 days after procedure in any of the patients.

CONCLUSION Invasive hemodynamic assessment of AS using a pressure wire and Dobutamine challenge may provide a safe and beneficial tool in identifying true severe in patients with LF/LG AS with Reduced EF.

CRT-800.17

National Estimate of 30-Day Readmission Rate and Associated Cost: A Comparison of Transcatheter Versus Surgical Aortic Valve Replacement in the United States

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BACKGROUND In Medicare population, transcatheter aortic valve replacement (TAVR) was associated with higher cost and lower short-term readmissions compared to surgical aortic valve replacement (SAVR). However, these differences have not been evaluated in a national sample, including all payer sources.

METHODS We used Healthcare Cost and Utilization Project's National Readmission Database to identify TAVR and SAVR cases who survived index hospitalization from January through November, 2013. Weighted national estimates of 30-day readmission and associated cost were calculated. Propensity score matching was used to 1:1 match 2,448 TAVR patients with SAVR patients on discharge weights, demographics and comorbidities including Charlson's comorbidity score. Hierarchal multivariable regression models were used to examine adjusted differences in the matched groups.

RESULTS In the US, an estimated 12,196 TAVR and 68,578 SAVR procedures were performed among patients with mean age of 82 (SE:0.21) and 69 (SE: 0.20) years respectively. Compared to SAVR, TAVR was associated with higher 30-day readmission rate (18.8% vs. 15.8%; P <0.001); higher 30-day mortality (1.26% vs. 0.58; P <0.001); and higher cumulative mean cost over 30-day follow up ($61,216 vs. $56,832; P <0.001).

TAVR cohort had higher rates of readmission due to heart failure (21% vs. 14%; P <0.001), septicemia/pneumonia (11% vs. 8%; P = 0.003), bleeding complications (6% vs. 4%; P = 0.014) and cerebrovascular events (4% vs. 2%; P = 0.004); whereas, SAVR cohort had higher rate of surgical or implant related complications (17% vs. 12%; P <0.001), and cardiac arrhythmia (13% vs. 7%; P <0.001) including atrial fibrillation (8% vs. 3%; P <0.001).

In multivariable analyses, compared to SAVR, TAVR was associated with 14.2% higher mean cost of index hospitalization (β: 0.142; 95% CI 0.123-0.161; P <0.001); and 13.5% higher 30-day cumulative cost (including cost for readmissions) (β: 0.135; 90% CI 0.115-0.155). However, no differences were found in likelihood of 30-day readmission (HR: 1.01; 95% CI 0.933-1.089; P = 0.863) and cost associated with re-hospitalization within 30 days (β: -0.009; 95% CI -0.137-0.118; P = 0.885).