

(predilation balloon size > minimum annulus diameter) (n=108; 20% groups (Table 1).

RESULTS The need for balloon postdilation post TAVR was lower in the aggressive (23.1%) and conservative predilation (32.9%) groups compared with the no predilation group (37.2%), although the association was not statistically significant after adjusting for covariates (adjusted Odds Ratio [aOR]: 0.95, 95% Confidence Interval [CI]: 0.52 - 1.74 for conservative vs. none; aOR 0.53, 95% CI: 0.25 - 1.16 for aggressive vs. none). Paravalvular leak (PVL) was lowest in the aggressive predilation group (38.5%) compared with conservative (44.0%) and no predilation (42.3%) groups. Compared with no predilation, after adjusting for covariates, conservative predilation was significantly more likely to be associated with PVL (aOR: 1.83, 95% CI: 1.03 - 3.24), while there was no significant association with aggressive predilation (aOR: 1.27, 95% CI: 0.63 - 2.54). Pacemaker implantation was higher with predilation (22.2% in aggressive; 20.5% in conservative groups) compared with no predilation group (18.2%) (aOR 1.82, 95% CI: 0.71 - 4.68 for aggressive vs. none; aOR 2.48, 95% CI: 1.09 - 5.67 for conservative vs. none). There were no differences in 30-day or 1-year rates of stroke and death between the 3 groups.

CONCLUSION Conservative predilation was associated with more PVL and permanent pacemaker requirement rates at discharge. Stroke and death rates at 30 days and 1 year weren't different between the 3 groups after adjusting for covariates.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-304

Impact of predilation before TAVI with five leading new-generation TAVI devices: early results from the RISPEVA Study



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BACKGROUND Transcatheter aortic valve implantation (TAVI) has become a mainstay in the management of significant aortic stenosis in patients at high or intermediate surgical risk. Predilation is often performed to facilitate TAVI implantation, but may be associated with embolization or rupture. It is uncertain whether predilation is needed also in the new-generation TAVI device era.

METHODS We queried the data collected in the prospective multicenter RISPEVA Study, comparing patients with vs without predilation receiving Acurate neo, Evolut R, Lotus, Portico, Sapien3, or devices. Baseline, procedural features and early (within 1 month) clinical and echocardiographic results were compared with unadjusted bivariate analysis and adjusted inverse-probability-of-treatment weighting analysis obtained from propensity scores.

RESULTS A total of 1409 subjects were included, 1055 (74.9%) receiving predilation, and 354 (25.1%) undergoing direct TAVI. Patients undergoing predilation had a higher baseline prevalence of pure aortic stenosis, lower prevalence of prior cardiac surgery, lower EuroSCORE II, higher aortic gradients and lower prevalence of aortic regurgitation 2+ (all $p < 0.05$). Other significant differences between subjects undergoing predilation vs no predilation included general anesthesia, hemostasis device, and device type, with predilation being more proportionally frequent in those receiving Acurate neo, Portico, and Sapien3 (all $p < 0.05$). In-hospital clinical outcomes were similar in the 2 groups, as were the 1-month rates of death (11 [3.1%] vs 15 [4.3%] in those who had undergone direct TAVI, $p = 0.276$), stroke (6 [1.7%] vs 16 [4.6%], $p = 0.947$), myocardial infarction (1 [0.3%] vs 3 [0.8%], $p = 0.315$), major bleeding (9 [2.5%] vs 10 [2.8%], $p = 0.967$), major vascular complication (18 [5.1%] vs 30 [8.5%], $p = 0.096$), and pacemaker implantation (56 [15.8%] vs 160 [46.7%],

$p = 0.018$). One-month echocardiographic follow-up showed similar results for ejection fraction (53.4 ± 8.8 vs 51.9 ± 10.9 in those who had undergone direct TAVI, $p = 0.559$), peak aortic gradient (17.1 ± 11.4 vs 18.3 ± 9.7 mm Hg, $p = 0.214$), mean aortic gradient (9.0 ± 5.2 vs 9.7 ± 5.6 , $p = 0.151$), and aortic regurgitation 2+ (61 [7.9%] vs 33 [9.4%], $p = 0.384$), whereas aortic valve area appeared greater in patients who had received predilation (1.54 ± 0.65 vs 1.48 ± 0.48 cm², $p = 0.036$).

CONCLUSION Direct TAVI is associated with similar clinical results to TAVI after predilation with new-generation devices. Whether predilation can improve long-term echocardiographic results awaits longer follow-up of the RISPEVA study and others.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-305

Importance of Contrast Aortography with Lotus transcatheter aortic valve replacement – a post hoc analysis from the RESPOND Post-market Study

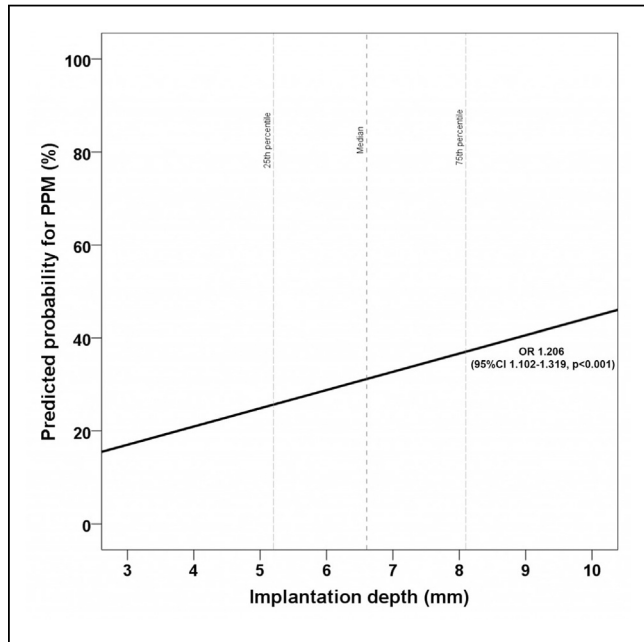


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BACKGROUND Contrast aortography allows for the assessment of implantation depth, relationship to the coronary ostia and paravalvular leak (PVL) during and after transcatheter aortic valve replacement (TAVR). Previous reports suggested an association between final device position and rates of permanent pacemaker implantation (PPI) and PVL. The aim of this post-hoc analysis from the RESPOND post-market study was to assess the final implantation depth on the contrast aortogram after Lotus (Boston Scientific Corporation, Marlborough, Massachusetts, USA) TAVR and to correlate with PPI and PVL.

METHODS RESPOND was a prospective, open-label, single-arm study in 41 centers evaluating outcomes after Lotus TAVR in routine clinical practice. Aortograms were collected at the Erasmus Medical Center and analyzed by researchers who were blinded to clinical outcomes. The primary analysis correlated implantation depth with PPI and PVL and required aortograms in a coaxial projection. The relation between implantation depth and need for PPI was assessed by multivariate logistic regression, adjusting for pre-defined confounders. A secondary analysis compared PVL analysis by contrast aortography with TTE performed by the independent core laboratory.

RESULTS A total of 724 angiographic studies were included in this analysis. Mean Lotus implantation depth was 6.67 ± 2.19 mm. The overall PPI rate was 35%. PPI rate was lower with shallow implants (< 6.5 mm: 21% vs. ≥ 6.5 mm: 41%, $p < 0.001$). Deeper implantation depth was associated with PPI by univariate analysis (Odds ratio (OR) 1.206, 95% confidence interval (CI) 1.102-1.319) per mm increment, $p < 0.001$ (Figure). After adjustment for confounders, implantation depth still independently predicted need for PPI (OR 1.2 per mm increment in depth (95% confidence interval 1.091-1.319, $p = 0.002$). More than trivial PVL was present in 23% by contrast aortography and in 8% by TTE. Implantation depth was not correlated with PVL by contrast aortography or TTE ($p = 0.342$ and $p = 0.149$, respectively). PVL grading by contrast aortography and TTE were concordant in 77%.



BACKGROUND The largest recommended annular area for TAVR with 29mm Sapien3 (S3) valve is 683 mm². We report the first multicenter experience of S3 TAVR in extremely large annuli greater than 683 mm².

METHODS From 6/2013 to 6/2017, 69 patients across 14 centers with annular area >683mm² (mean 723 +/-42 mm², range 684-882 mm²) by computed tomography (CT) underwent S3 TAVR for symptomatic severe aortic stenosis (Figure). Transfemoral approach was used in 93% and 32% were under conscious sedation. Patient, anatomic and procedural characteristics were retrospectively analyzed. VARC-2 outcomes were reported.

TAVR in Extremely Large Annuli Beyond 683 mm ² Using Edwards Sapien 3 Valve		
PATIENT CHARACTERISTICS (N=69)	PROCEDURAL CHARACTERISTICS (N=69)	OUTCOMES (N=69)
Age (years) 77.6 ± 10.4	Staging by CT	In-hospital outcomes
Female 3 (4%)	Annular Dimensions by CT	ICU stay (days) 55.9 ± 84.5
STS score (%) 5.8 ± 3.2	Mean diameter (mm) 28.7 ± 5.3	Median ± IQR (days) 27.4 ± 20.2
EuroSCORE II (%) 7.23 ± 6.75	Area (mm ²) 723.4 ± 42.1	No ICU stay 17 (24%)
Coronary artery disease 33 (48%)	Ellipticity (%) 65.5 (50.2)	Revascularization 4.4 ± 4.9
Type 2 aortic valve 41 (59%)	Paravalvular leak	None/Trace 48 (69%)
Prior TIA/Stroke 8 (12%)	None/Trace 22 (32%)	Moderate 3 (4%)
Cardiovascular disease	Major 2 (3%)	Severe 1 (1%)
Peripheral vascular disease 16 (23%)	Over-sizing by annular area (%) 151.1 ± 14.8	New permanent pacemaker 8 (12%)
Moderate / Severe COPD 18 (26%)	LVOT Dimensions by CT	In-hospital mortality 2 (3%)
Atrial fibrillation 21 (30%)	Mean diameter (mm) 11.1 ± 1.5	None 17 (25%)
Chronic renal insufficiency 19 (28%)	Area (mm ²) 548.5 (508.3)	Moderate 4 (6%)
Pulmonary hypertension (PASP >60mmHg) 8 (12%)	Paravalvular leak	None 3 (4%)
Prior pericardial surgery 20 (29%)	None/Trace 22 (32%)	Moderate 3 (4%)
Prior PCI 22 (32%)	Major 2 (3%)	Severe 1 (1%)
Bioprosthetic aortic valve 8 (12%)	Over-sizing by LVOT area (%) 48.9 ± 11.9	30 DAY OUTCOMES
NYHA III/IV 62 (77%)	Underfilled 25 (37%)	Mortality 14 (20%)
LVOT <20% 15 (22%)	Unfilled 1 (2%)	Stroke 1 (1.5%)
Aortic valve area (cm ²) 0.77 ± 0.22	Overfilled 30 (43%)	Major vascular complication 1 (1.4%)
Mean gradient (mmHg) 40 ± 12	Subtotal post-dilation	None 29 (42%)
Peak gradient (mmHg) 58 ± 19	Final valve balloon volume	Small 7 (10%)
	Unfilled 7 (10%)	Moderate 3 (4%)
	Overfilled 27 (39%)	Severe 0 (0%)
	Implant depth by fluoroscopy	
	% centered by MDCI (%) 25 ± 13	
	Range (%) 5 - 60	
	% centered by LCC (%) 24.6 ± 50	
	Range (%) 3 - 48	

**All Variables expressed as n (%) or Mean ± SD*

CONCLUSION In this post-hoc analysis of the RESPOND study PPI was highly correlated with implantation depth, while PVL was not. Higher Lotus implantation may reduce need for PPI.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-306

Transcatheter Aortic Valve Replacement with Extremely Large Annuli Greater Than 683 mm² Using Edwards Sapien 3 Valve - A Multicenter Experience



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RESULTS Procedural success and 30-day mortality were 100% and 4.3% respectively, with 1 stroke and 1 major vascular complication at 30 days. Post dilatation occurred in 23% with balloon overfilling (1-3cc extra) in 59% of patients. Implant depth by angiography averaged 25 +/-13% (range 5-60%) by non-coronary cusp and 22 +/-10% (range 3-48%) by left coronary cusp. New left bundle branch block occurred in 17% and 12% required new permanent pacemaker. Pre-discharge echocardiography showed excellent valve hemodynamics with mild paravalvular leak (PVL) in 25%, 4% moderate and none severe. There was no annular rupture or coronary obstruction.

CONCLUSION TAVR with 29mm S3 valve beyond recommended range is safe, with acceptable PVL and pacemaker rates. Overexpansion of the S3 frame can be achieved by adding balloon volume before valve deployment or post dilatation with additional volume. Post-TAVR CT may further determine the theoretical annular limit of safe implantation of 29mm S3 valve.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-307

Rapid Ventricular Pacing is Associated With Worse Outcomes After Trans-Catheter Aortic Valve Replacement



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BACKGROUND Rapid ventricular pacing (RVP) is used during transcatheter aortic valve replacement (TAVR) to temporarily reduce the cardiac output and allow valve implantation without the risk of movement. The aim of the present study was to assess the clinical impact of RVP on immediate and long-term clinical outcomes in a large cohort of non-selected TAVR patients.

METHODS 412 consecutive patients with symptomatic severe aortic stenosis who underwent trans-femoral TAVR. Patients were divided according to the number of RVP episodes during the TAVR procedure (0, 1-2, and 3+).

RESULTS Thirteen per cent of patients were not paced during the TAVR implantation, while 60% underwent 1-2 RVP episodes and 27% underwent 3+ pacing episodes. Baseline characteristics of patients were similar. Severe acute kidney injury (AKI) was significantly greater in patients undergoing 3+ pacing episodes compared with those who were not paced or were paced with 1-2 pacing episodes (8% versus 0.5% and 2% respectively, p=0.001), as was incidence of new atrial fibrillation (15% versus 7.3% and 5.6% respectively). One-year mortality was