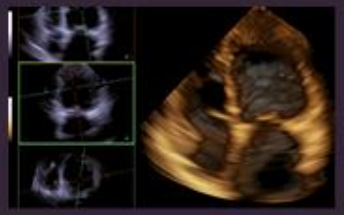

EuroValve
March 10-11, 2016

TAVI minimizing complications : Permanent pacing

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Cliniques universitaires SAINT-LUC UCL BRUXELLES

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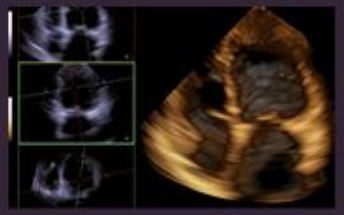


EuroValve
March 10-11, 2016

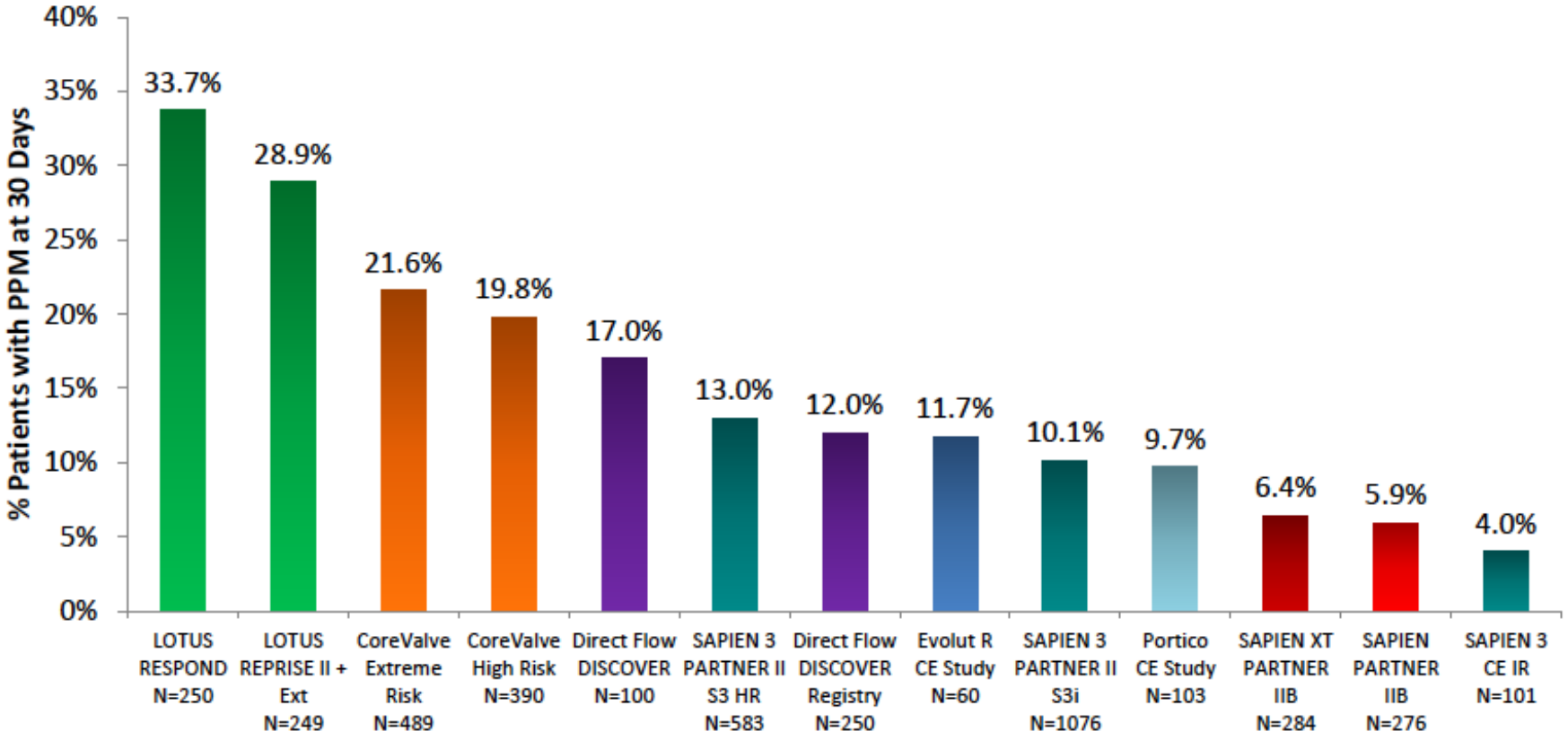
Faculty disclosure

Joelle Kefer

I disclose the following financial relationships:

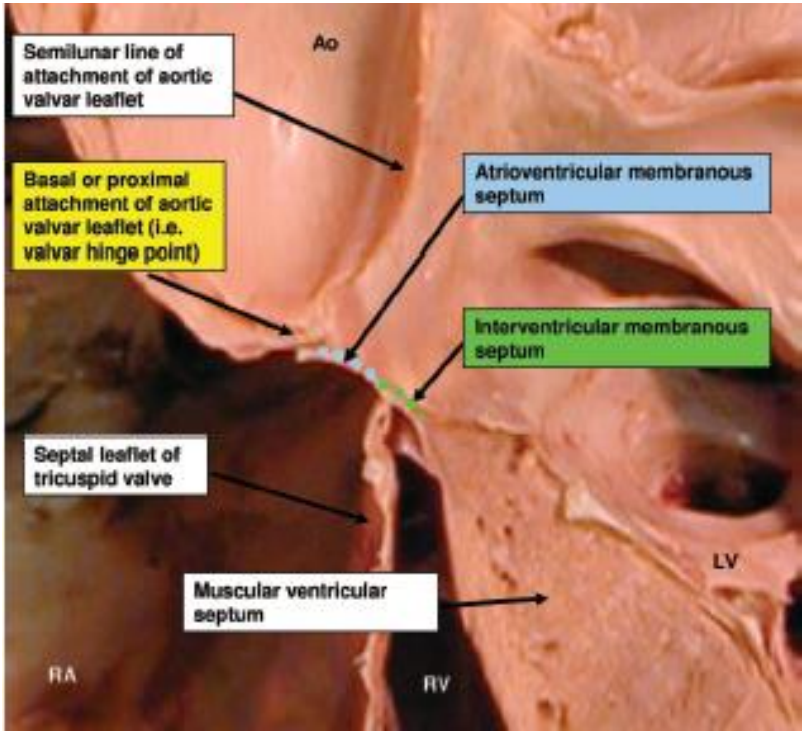
Consultant for StJude Medical
Receive grant/research support from Abbott Vascular

Permanent pacemaker rate after TAVI



[1]Van Mieghem, et al., presented at EuroPCR 2015; [2]Meredith, et al., presented at PCR London Valves 2014; [3]Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; [4]Adams, et al., *N Engl J Med* 2014; 370: 1790-8; [5]Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; [6]Kodali, et al., presented at ACC 2015; [7]Naber, et al., presented at EuroPCR 2015; [8]Meredith, et al., presented at ACC 2015; [9]Kodali, et al., presented at ACC 2015; [10]Manoharan, et al., et. al. presented at TCT 2014; [11]Leon, et. al. presented at ACC 2013; [12]Vahanian, et al., presented at EuroPCR 2015

Aortic valve close spatial proximity to the bundle of His, left bundle branch



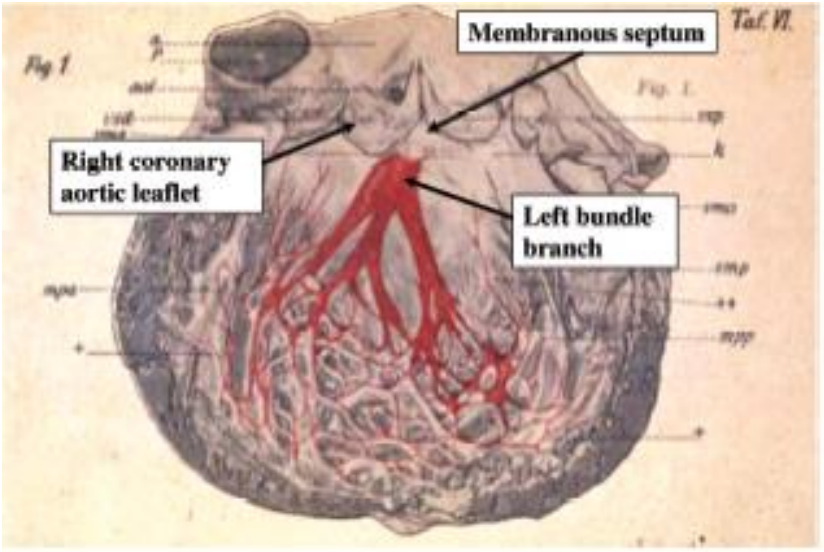
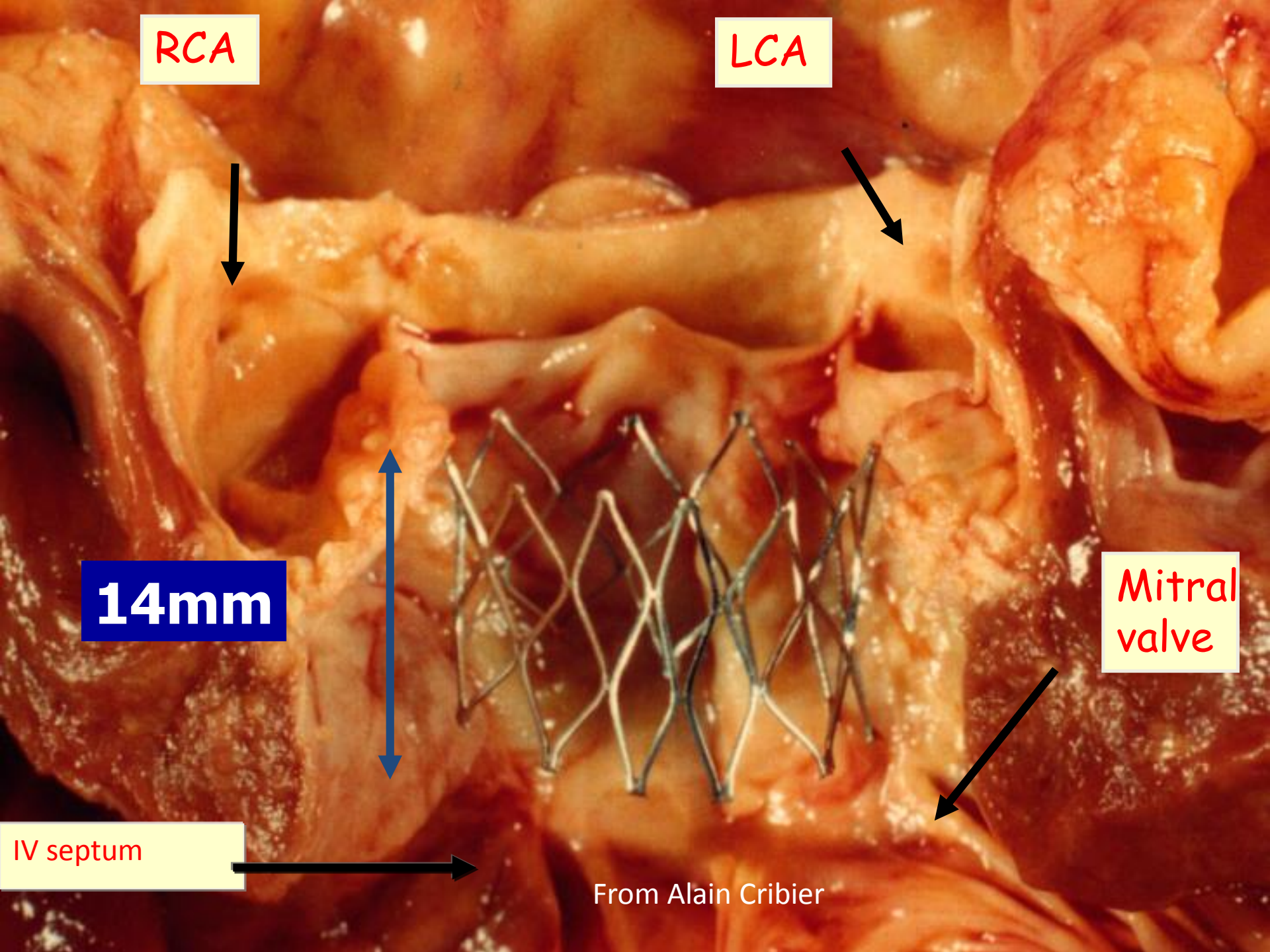


Figure 8. This original monograph from Tawara (1906)[32] shows the left bundle branch exiting below the base of the interleaflet triangle separating the noncoronary and right coronary leaflets of the aortic valve and fanning out to descend along the septal surface of the left ventricular myocardium.

Piazza JACC interv 2008



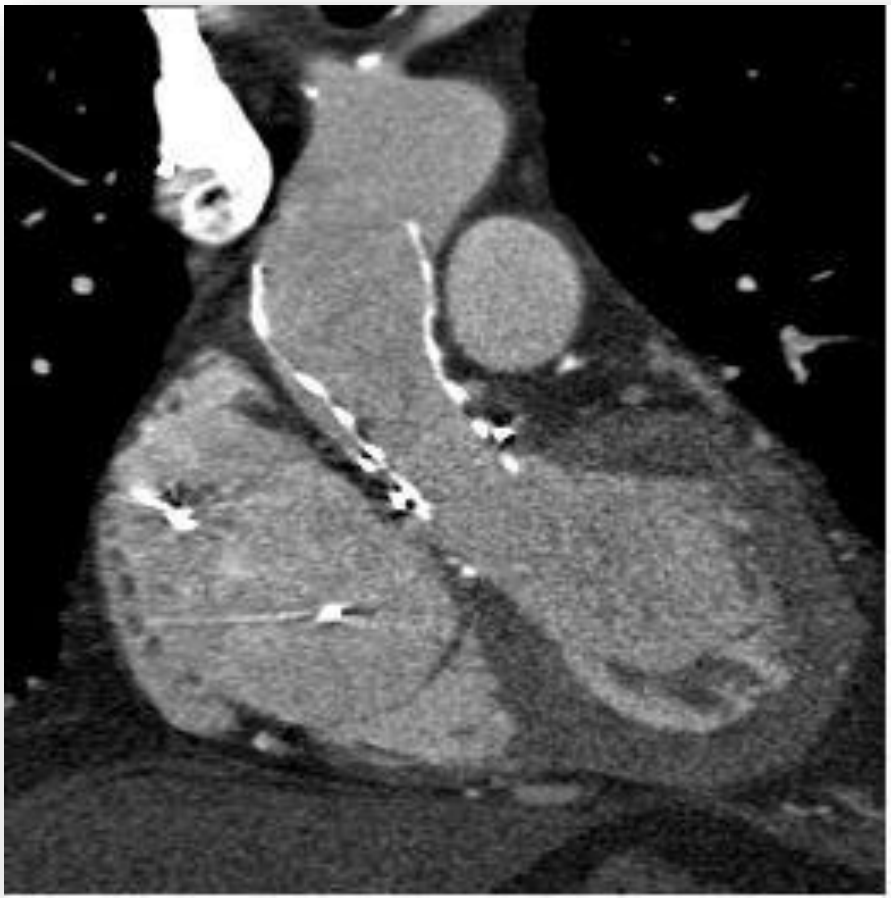
From Alain Cribier

Anatomical interaction :

the stent frame of the TAVI prosthesis may exerce a mechanical stress on the LV wall, septum and conduction system, leading to potential complete AV-block and new LBBB.

Sapien valve

Corevalve



JACC Cardiovasc Interv. 2012 May;5(5):540-51. doi: 10.1016/j.jcin.2012.03.004.

Need for permanent pacemaker as a complication of transcatheter aortic valve implantation and surgical aortic valve replacement in elderly patients with severe aortic stenosis and similar baseline electrocardiographic findings.

Bagur R[1], Rodés-Cabau J, Gurvitch R, Dumont É, Velianou JL, Manazzoni J, Toggweiler S, Cheung A, Ye J, Natarajan MK, Bainey KR, DeLarochellière R, Doyle D, Pibarot P, Voisine P, Côté M, Philippon F, Webb JG.

METHODS: A total of 411 patients with severe aortic stenosis (AS) and no prior pacemaker who underwent **TAVI** with the balloon-expandable Edwards valve (Edwards Lifesciences, Irvine, California) were matched (1:1) with 411 elderly patients with severe AS who underwent isolated SAVR on the basis of baseline ECG findings. The incidence, reasons, and predictive factors for PPI within 30 days **after** the procedure were compared between groups.

RESULTS: Mean age was similar in both groups (p = 0.11), and the **TAVI** group had a higher Society of Thoracic Surgeons score (p < 0.001). The rate of new PPI was higher **after TAVI** (7.3%) compared with SAVR (3.4%), p = 0.014. **Complete** AVB and severe symptomatic bradycardia, respectively, were the reasons for PPI in the **TAVI** (5.6% and 1.7%, respectively) and SAVR (2.7% and 0.7%, respectively) groups (p = 0.039 for **complete** AVB, p = NS for symptomatic bradycardia). The presence of baseline right bundle branch **block** was the only variable associated with PPI in the **TAVI** group (odds ratio: 8.61, 95% confidence interval: 3.14 to 23.67, p < 0.0001), whereas no variable was found in the SAVR group.

CONCLUSIONS: Transcatheter aortic valve implantation was associated with a higher rate of **complete** AVB and PPI compared with SAVR in elderly patients with severe AS and similar baseline ECG findings. The presence of baseline right bundle branch **block** correlated with the need for PPI in the **TAVI** group.

JACC Cardiovasc Interv. 2014 Feb;7(2):128-36. doi: 10.1016/j.jcin.2013.08.015. Epub 2014 Jan 15

OPEN ACCESS

Impact of new-onset persistent left bundle branch block on late clinical outcomes in patients undergoing transcatheter aortic valve implantation with a balloon-expandable valve.

Urena M[1], Webb JG[2], Cheema A[3], Serra V[4], Toggweiler S[2], Barbanti M[2], Cheung A[2], Ye J[2], Dumont E[1], DeLarochellière R[1], Doyle D[1], Al Lawati HA[2], Peterson M[3], Chisholm R[3], Igual A[4], Ribeiro HB[1], Nombela-Franco L[1], Philippon F[1], Garcia del Blanco B[4], Rodés-Cabau J[5].

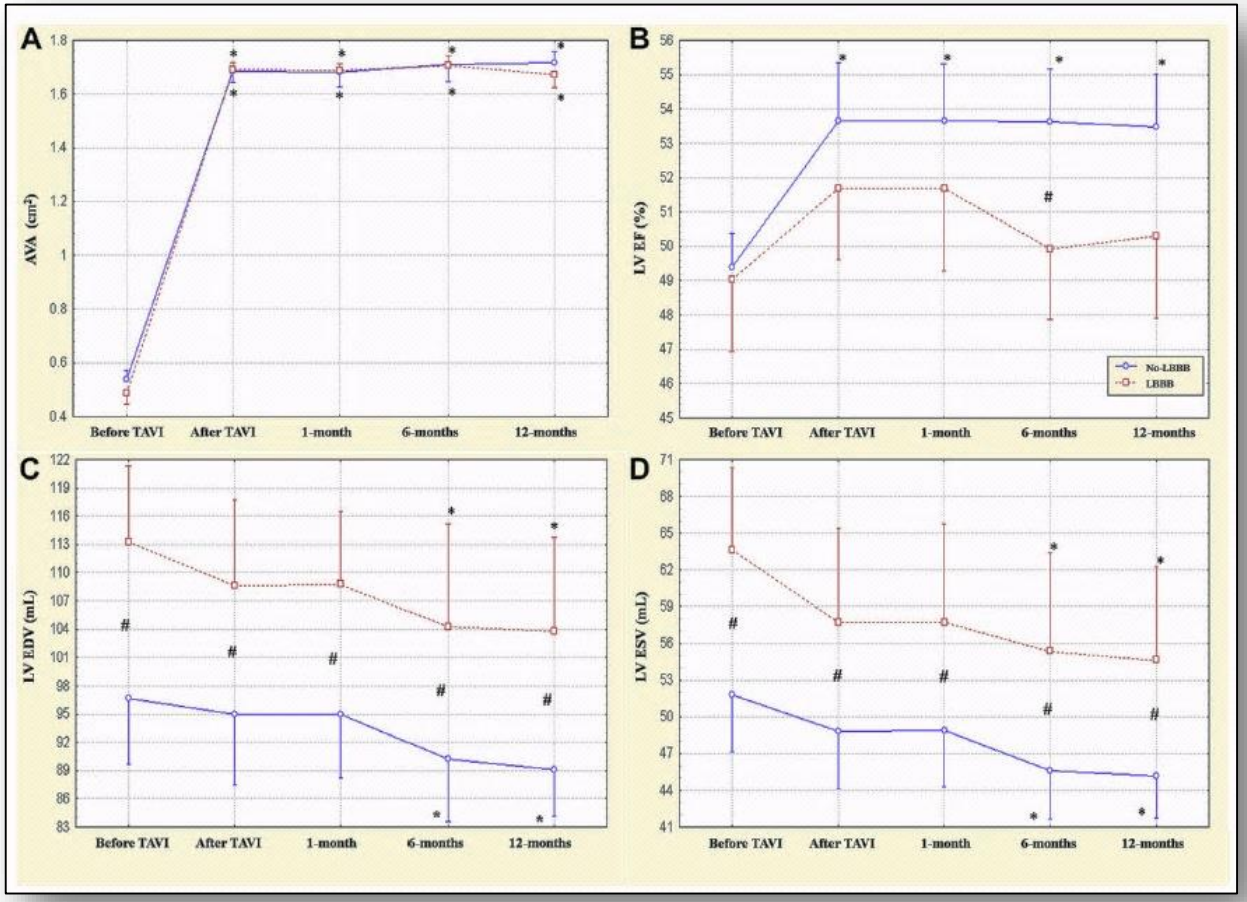
RESULTS: New-onset **LBBB** occurred in 128 patients (19.2%) immediately after **TAVI** and persisted at hospital discharge in 79 patients (11.8%).

CONCLUSIONS: NOP-**LBBB** occurred in ~1 of 10 patients who had undergone **TAVI** with a balloon-expandable valve. NOP-**LBBB** was associated with a higher rate of PPI, a lack of improvement in left ventricular ejection fraction, and a poorer functional status, but did not increase the risk of global or cardiovascular mortality or rehospitalizations at 1-year follow-up.

Impact on Left Ventricular Function and Remodeling and on 1-Year Outcome in Patients With Left Bundle Branch Block After Transcatheter Aortic Valve Implantation

Nazario Carrabba, MD*, Renato Valenti, MD, Angela Migliorini, MD, Marco Marrani, MD, Giulia Cantini, MD, Guido Parodi, MD, PhD, Emilio Vincenzo Dovellini, MD, and David Antoniucci, MD

LBBB : less reverse remodeling, less recovery of LV systolic function, higher rate of PCMK



(Am J Cardiol 2015;116:125–131)

Heart. 2015 Oct;101(20):1665-71. doi: 10.1136/heartjnl-2015-307666. Epub 2015 Aug 10.

Chronic pacing and adverse outcomes after transcatheter aortic valve implantation.

Dizon JM[1], Nazif TM[1], Hess PL[2], Biviano A[1], Garan H[3], Douglas PS[2], Kapadia S[4], Babaliaros V[5], Herrmann HC[6], Szeto WY[6], Jilaihawi H[7], Fearon WF[8], Tuzcu EM[4], Pichard AD[9], Makkar R[7], Williams M[10], Hahn RT[1], Xu K[11], Smith CR[1], Leon MB[1], Kodali SK[1]; PARTNER Publications Office.

Author information

Abstract

OBJECTIVE: Many patients undergoing transcatheter aortic valve implantation (**TAVI**) have a pre-existing, permanent pacemaker (PPM) or receive one as a consequence of the procedure. We hypothesised that chronic **pacing** may have adverse effects on **TAVI** outcomes.

METHODS AND RESULTS: Four groups of patients undergoing **TAVI** in the Placement of Aortic Transcatheter Valves (PARTNER) trial and registries were compared: prior PPM (n=586), new PPM (n=173), no PPM (n=1612), and left bundle branch block (LBBB)/no PPM (n=160). At 1 year, prior PPM, new PPM and LBBB/no PPM had higher all-cause mortality than no PPM (27.4%, 26.3%, 27.7% and 20.0%, p<0.05), and prior PPM or new PPM had higher rehospitalisation or mortality/rehospitalisation (p<0.04). By Cox regression analysis, new PPM (HR 1.38, 1.00 to 1.89, p=0.05) and prior PPM (HR 1.31, 1.08 to 1.60, p=0.006) were independently associated with 1-year mortality. Surviving prior PPM, new PPM and LBBB/no PPM patients had lower LVEF at 1 year relative to no PPM (50.5%, 55.4%, 48.9% and 57.6%, p<0.01). Prior PPM had worsened recovery of LVEF **after TAVI** (Δ=10.0 prior vs 19.7% no PPM for baseline LVEF <35%, p<0.0001; Δ=4.1 prior vs 7.4% no PPM for baseline LVEF 35-50%, p=0.006). Paced ECGs displayed a high prevalence of RV **pacing** (>88%).

CONCLUSIONS: In the PARTNER trial, prior PPM, along with new PPM and chronic LBBB patients, had worsened clinical and echocardiographic outcomes relative to no PPM patients, and the presence of a PPM was independently associated with 1-year mortality. Ventricular dyssynchrony due to chronic RV **pacing** may be mechanistically responsible for these findings.

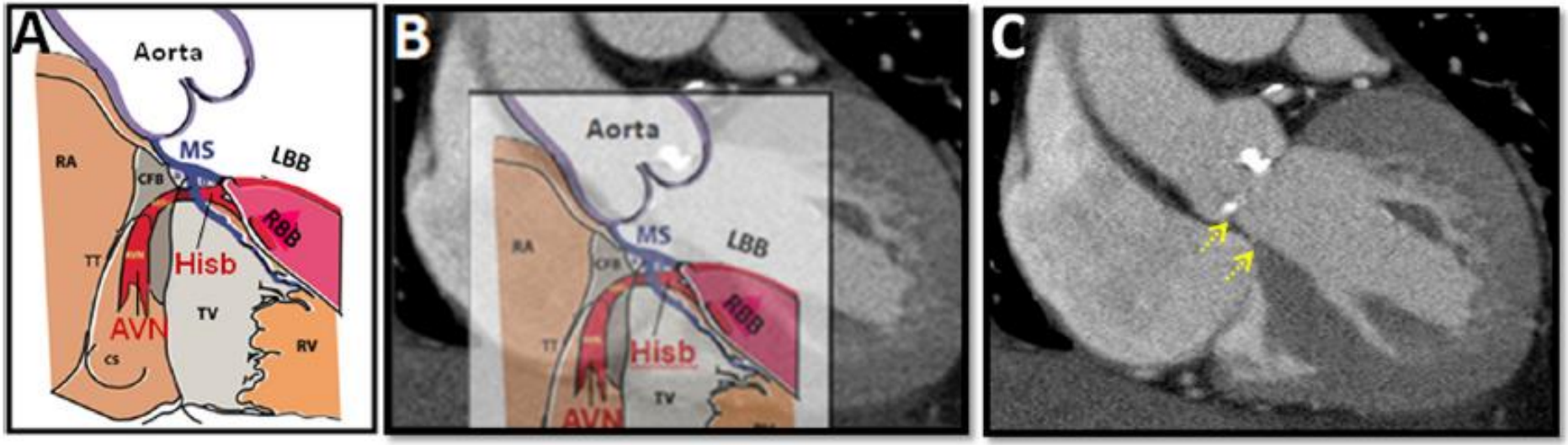
Difference between the lenght of membranous septum and implantation depth is the most powerful predictor of complete AV block after TAVI

TABLE 3 Univariate Analysis of Predictors of Permanent Pacemaker Implantation and Multivariate Logistic Regression in an *Ante-Factum* Prediction Model (Pre-Procedural Predictors) and a *Post-Factum* Prediction Model (Pre-Procedural and Post-Procedural Predictors)

	Univariate Analysis			Multivariate Analysis					
				Pre-Procedural			Pre- and Post-Procedural		
Parameter	Odds Ratio	95% CI	p Value	Odds Ratio	95% CI	p Value	Odds Ratio	95% CI	p Value
Right bundle branch block	3.8	0.8-18.9	0.09	-	-	-	-	-	-
Calcification in basal septum	3.4	1.1-10.8	0.04	-	-	-	4.9	1.2-20.5	0.031
Prosthesis perimeter	1.33	0.97-1.8	0.08	-	-	-	-	-	-
Membranous septum length	1.43	1.1-1.8	0.002	1.43	1.1-1.8	0.002	-	-	-
Implantation depth	1.18	1.0-1.4	0.01	-	-	-	-	-	-
ΔMSID	1.34	1.2-1.6	<0.001	-	-	-	1.39	1.2-1.7	<0.001

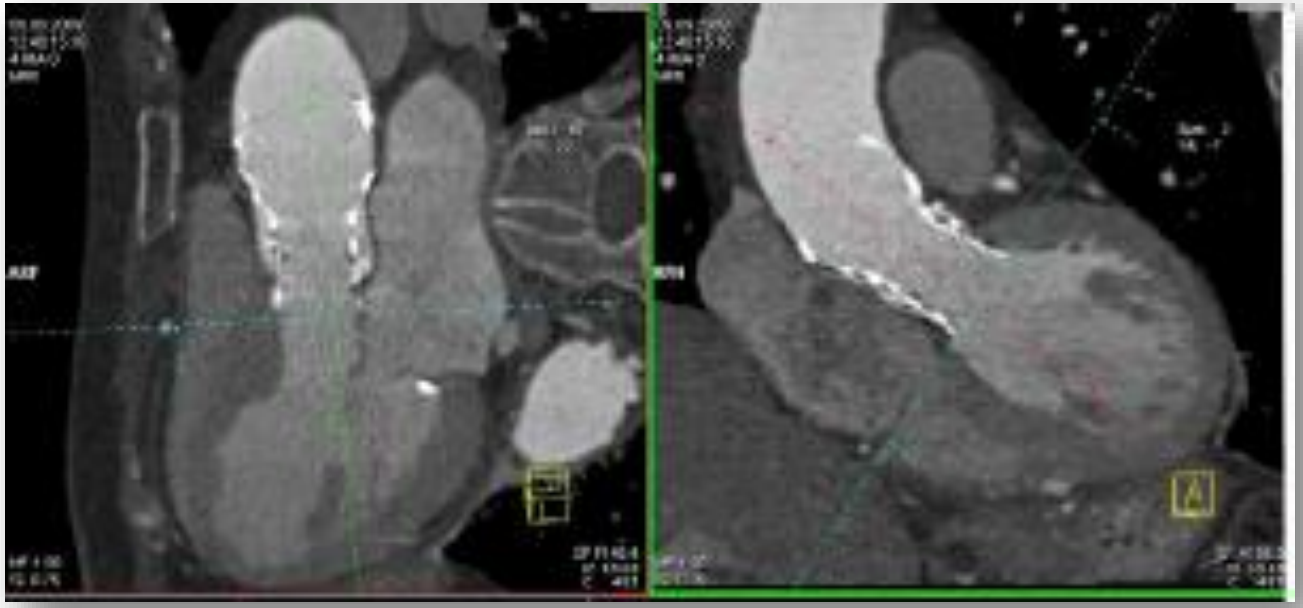
CI = confidence interval; ΔMSID = difference between MS length and implantation depth.

Hamdam A et al, JACC intv 2015;8:1218-28



Implantation depth measured by 64-slice computed tomography is associated with permanent pacemaker requirement following transcatheter aortic valve implantation with the Core Valve® system

Jürgen Kammler (MD)[a,1,*], Hermann Blessberger (MD)[a,1], Franz Fellner (MD)[b], Alexander Kypta (MD)[a], Thomas Lambert (MD)[a], Magdalena Engl (MD)[a], Simon Hönig (MD)[a], Michael Lichtenauer (MD)[c], Michael Grund (MD)[a], Klaus Kerschner (MD)[a], Karim Saleh (MD)[a], Clemens Steinwender (MD)[a]



Journal of Cardiology 2016, Epub

Univariate logistic regression analysis could identify implantation depth of the prosthesis as the only significantly correlated risk factor for PM need in our cohort (OR 1.27, 95% CI: 1.08–1.51, $p = 0.004$). A cut-off value of 6 mm predicted this need with a sensitivity of 89% and specificity of 40%.

Risk factors for new PCMK and LBBB

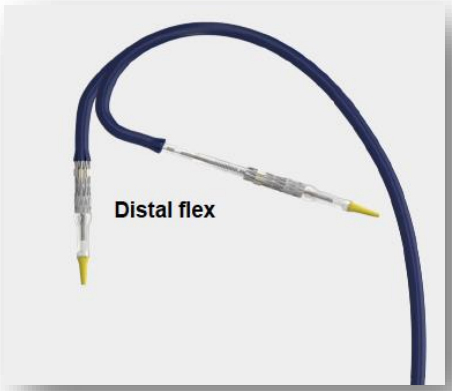
Not modifiable

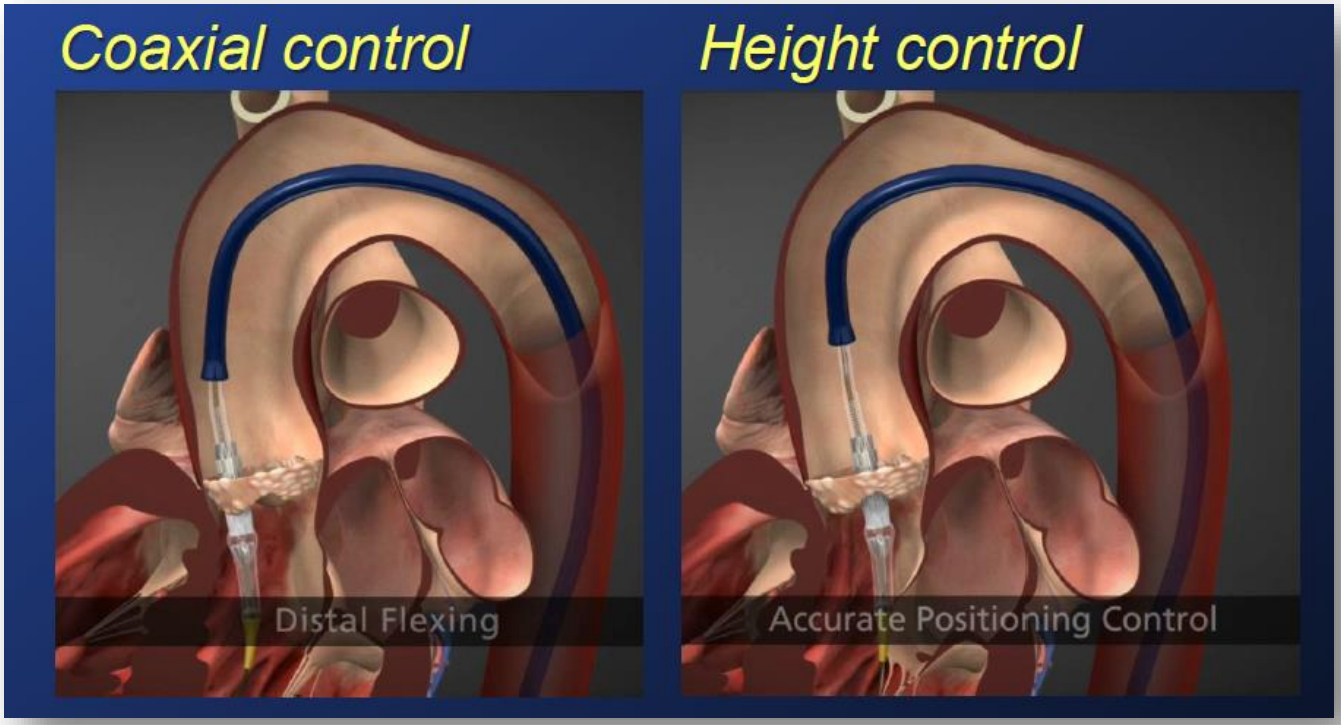
- ✓ Pre-existing long PR
- ✓ Pre-existing wide QRS
- ✓ Pre-existing RBBB
- ✓ No prior valve surgery

Modifiable

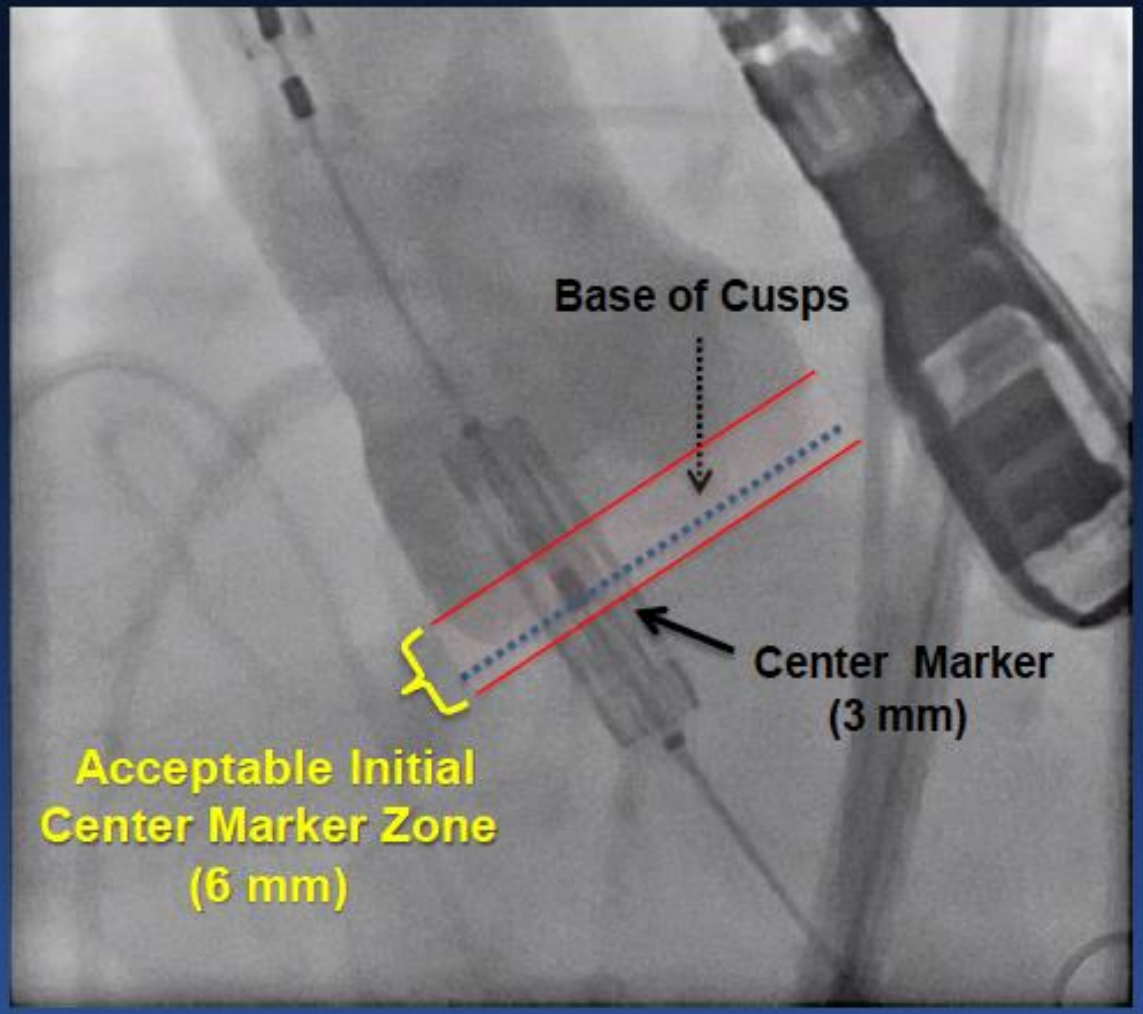
- ✓ Depth of the implant
- ✓ Implementation of the guidelines for PCMK indications

Sapien 3 : accurate positionning, better control





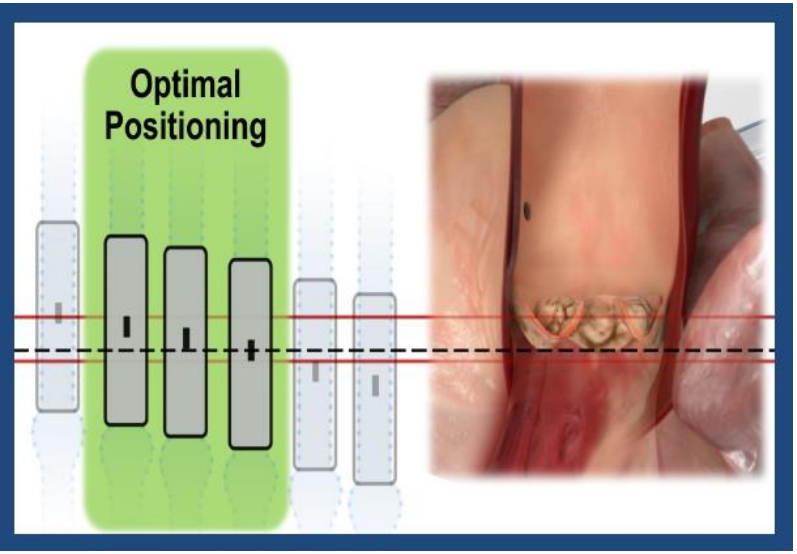
Optimal SAPIEN 3 Positioning Based on Current Analysis

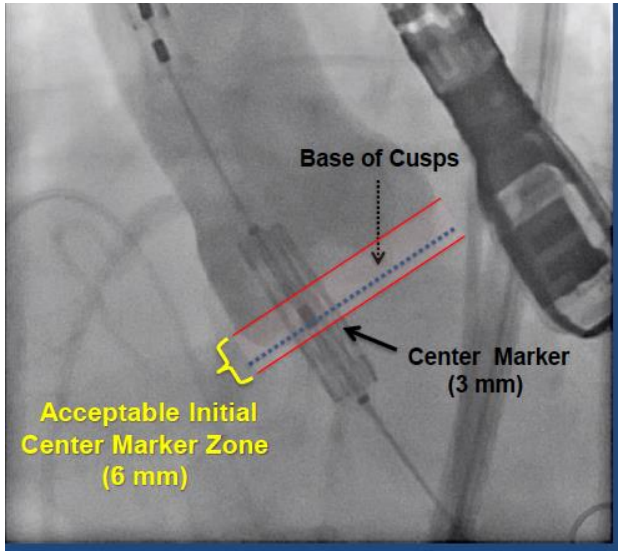


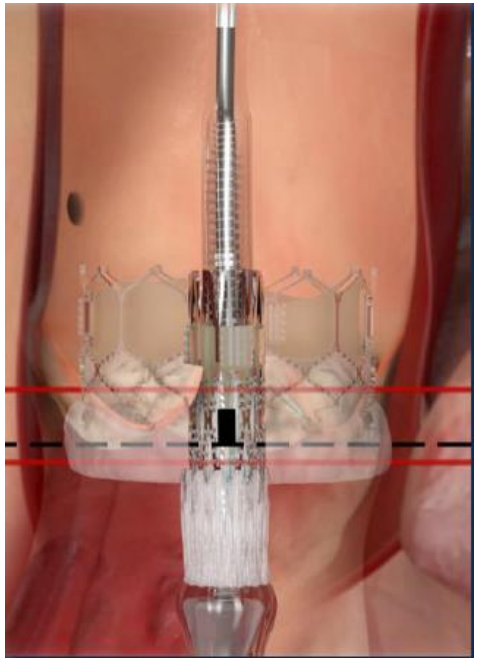
OPTIMAL-S3

Multicenter Assessment of SAPIEN 3 Implantation with Optimization of Clinical Outcomes

D.Dvir, Vancouver, Canada



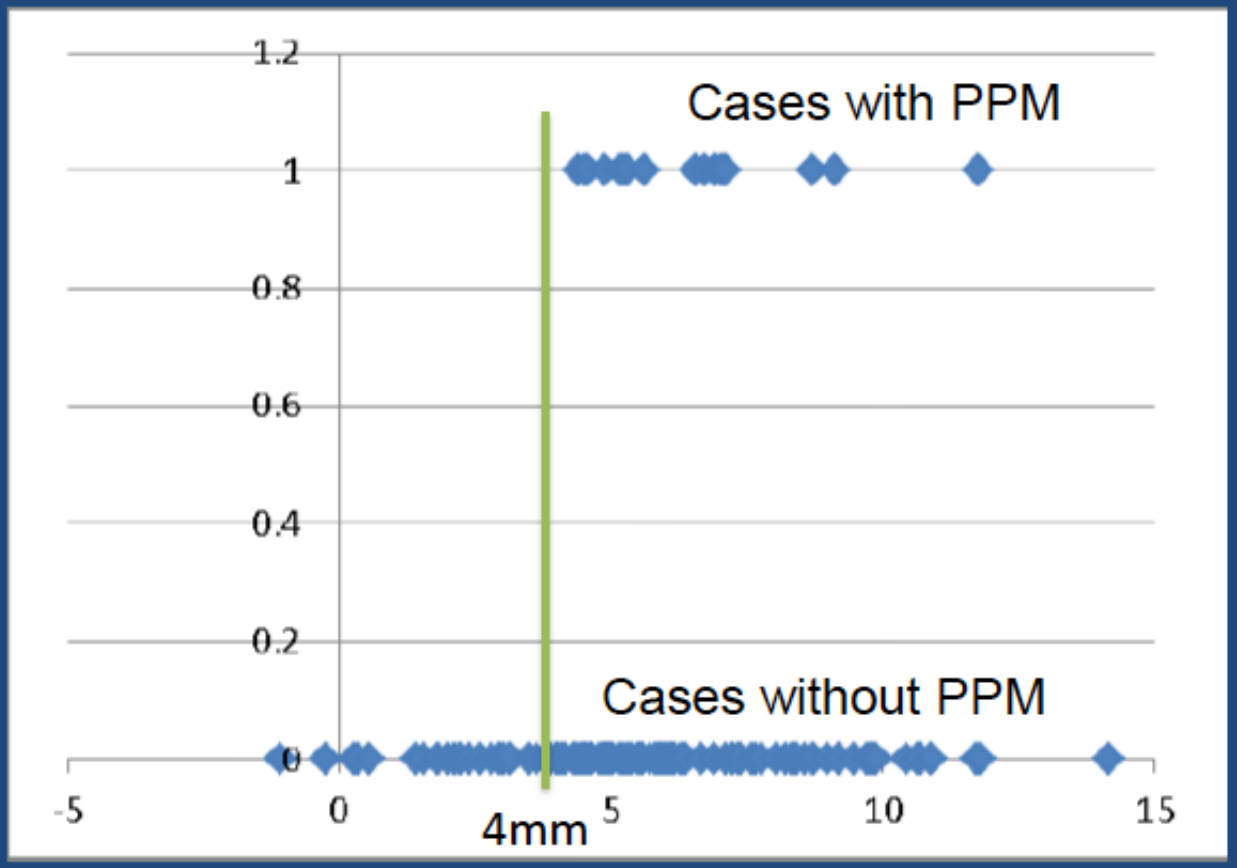




	Optimal Position (n=66)	Non-Optimal Position (n=82)	P-value
S3 size (mm)	25.9 ± 2.2	25.9 ± 2	0.86
S3 crimped height (mm)	27.3 ± 2.3	27.3 ± 2.1	0.90
Non-transfemoral approach	19.7%	23.2%	0.88
Post inflation	0%	7.1%	0.04
Coronary obstruction (%)	0%	0%	NA
PM implant (%)	6.7%	18.2%	0.04
Major stroke (%)	0%	1.9%	0.31
Death (%)	0%	4.9%	0.07
PVL ≥ moderate (%)	1.5%	2.4%	0.87
PVL ≥ mild (%)	13.6%	25.6%	0.05

D.Dvir, TVT 2015

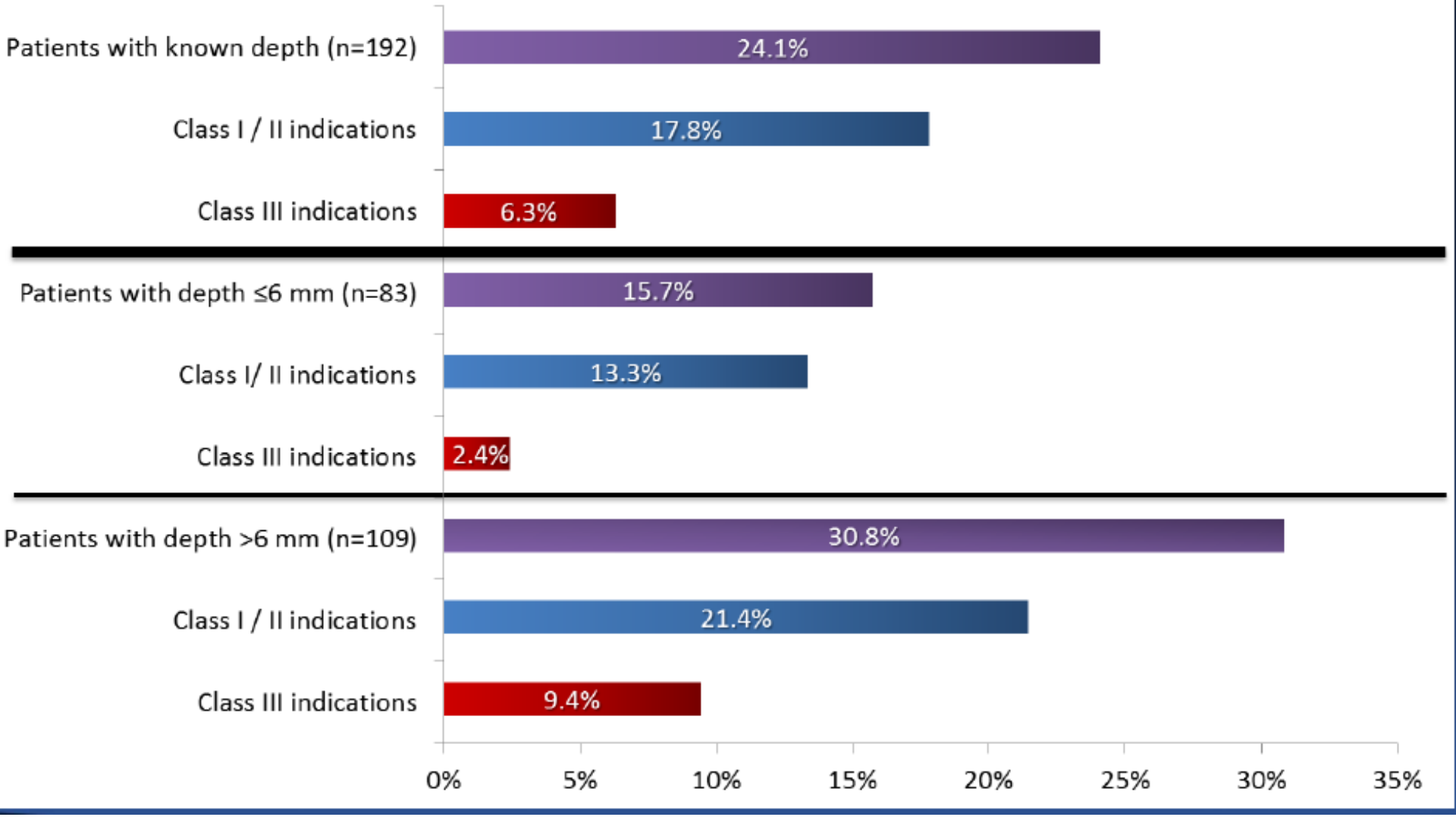
New PPM According to Frame Depth



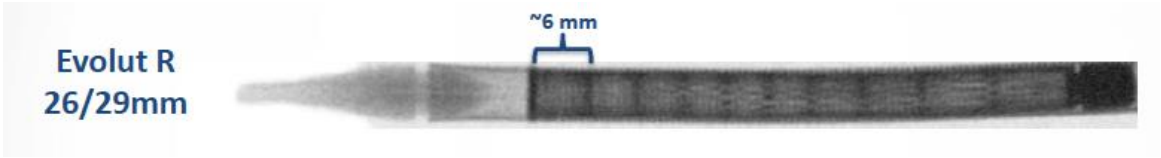
No New PPM when THV frame is <4mm deep into LVOT

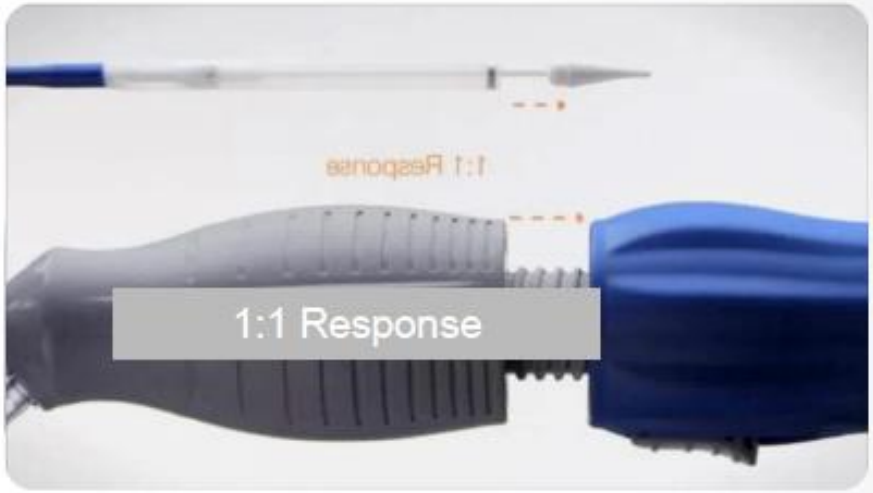
ADVANCE II

New Permanent Pacemaker Rate at 30 Days



Evolut-R : new design, recapturable, repositionable, deployment accuracy with 1:1 response.





CoreValve
31 mm

CoreValve
Evolut
23mm

euro PCR 2015

Evolut CE Mark: Safety

Event, K-M rates (no. of patients)	30 Days N=60	6 Months N=60
All-cause mortality	0.0 (0)	5.0 (3)
Cardiovascular	0.0 (0)	3.3 (2)
All stroke	0.0 (0)	1.7 (1)
Disabling	0.0 (0)	1.7 (1)
Non-disabling	0.0 (0)	0.0 (0)
Major vascular complications	8.3 (5)	8.3 (5)
Life-threatening or disabling bleeding	5.0 (3)	8.4 (5)
Embolization or migration	0.0 (0)	0.0 (0)
Endocarditis	0.0 (0)	0.0 (0)
Coronary obstruction	0.0 (0)	0.0 (0)
Valve thrombosis	0.0 (0)	0.0 (0)
Pacemaker*	11.7 (7)	13.4 (8)

*Patients with a prior pacemaker included in the denominator.

Presented par I Meredith

CoreValve Evolut R CE Study

Implant Depth by Pacemaker Implantation

Mean Implant Depth

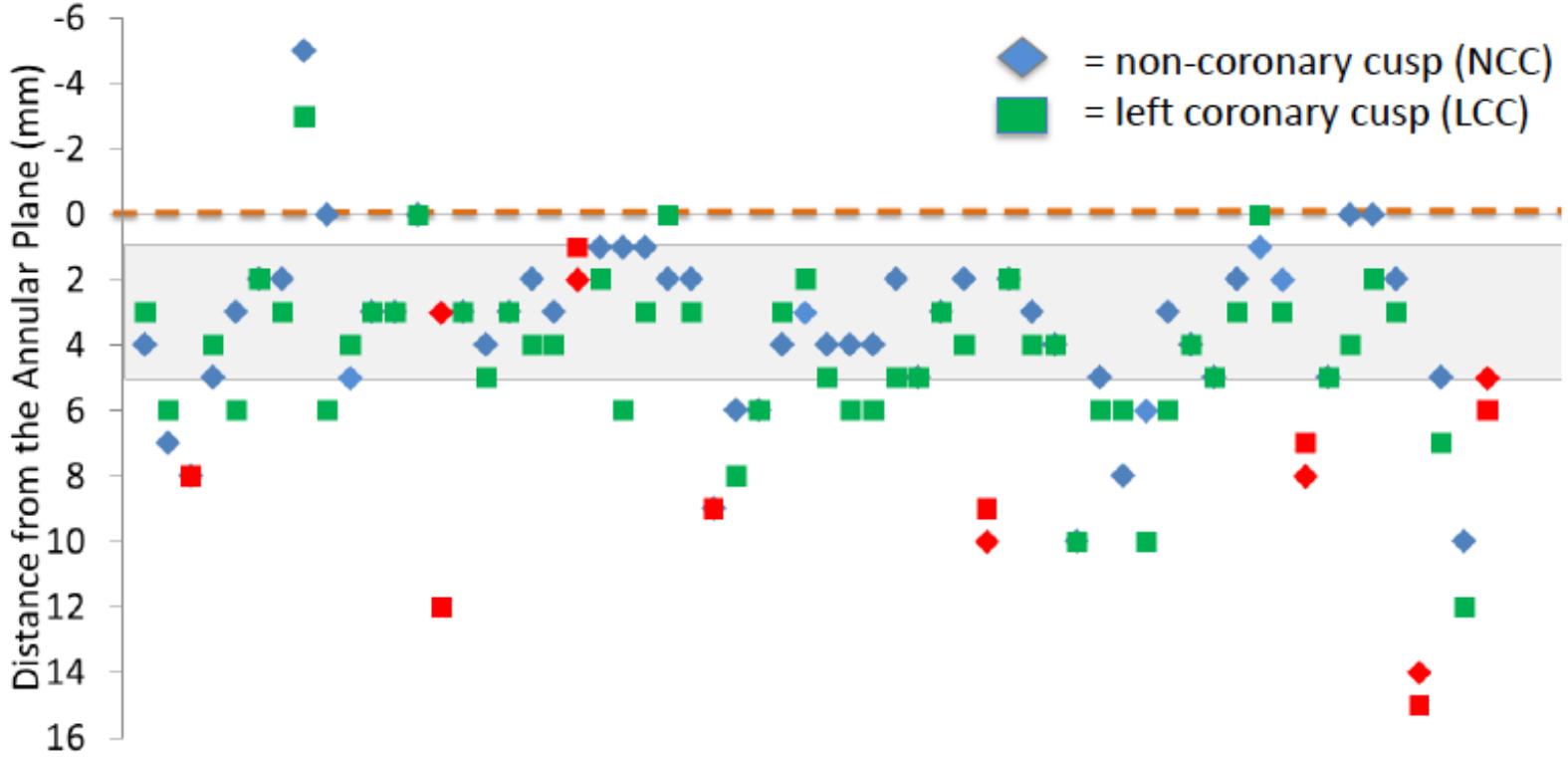
Patients with a pacemaker

- 8.1 ± 3.5 mm (non-coronary cusp)

Patients with NO pacemaker

- 3.3 ± 2.5 mm (non-coronary cusp)

Difference (P<0.001)



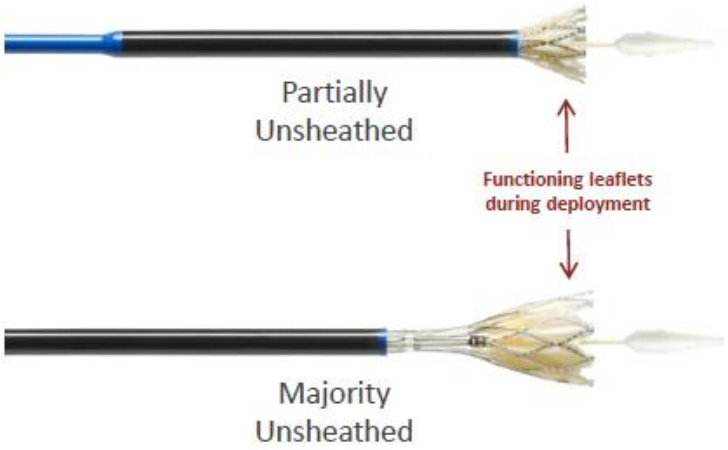
= annular plane Patients with Pacemaker (8)

CoreValve Evolut R CE Study

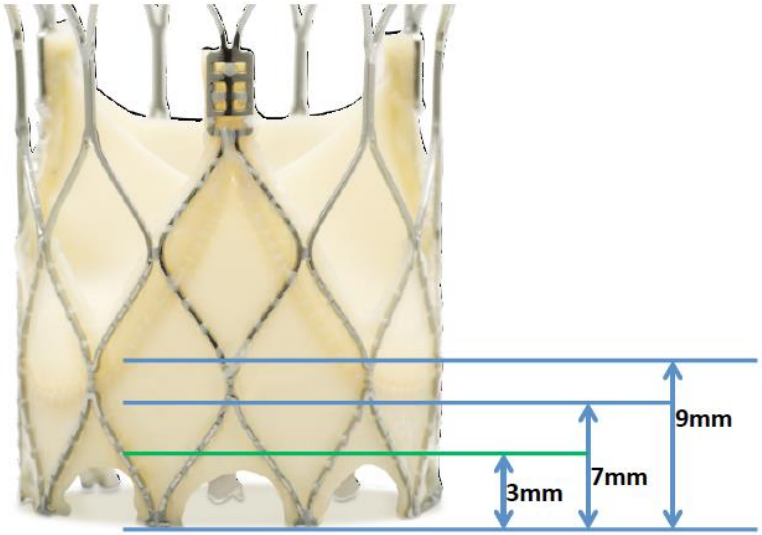
Portico : intraannular placement, recapturable designed to address conduction system interference

Fully Sheathed

Landing zone : 3 mm (range 1-9 mm)



Manoharan G, TVT 2015



Clinical Safety Results:23 /25mm Portico CE Study

All events adjudicated by an independent clinical events committee

Event	30 day Rate (%) n = 103	1 yr overall Rate (%) n = 103
Death ▪ Cardiovascular Death	2.9% 2.9%	8.7% 5.8%
Disabling (Major) stroke Non-disabling (Minor) stroke	2.9% 1.0%	3.9% 1.9%
New pacemaker implantation	9.7%	10.7%
Myocardial infarction	1.9%	1.9%
Acute kidney injury ▪ Stage 3 AKI	7.8% 1.9%	9.7% 2.9%
Major vascular complication Minor vascular complication	5.8% 3.9%	6.8% 3.9%
Life threatening or disabling bleeding	3.9%	3.9%
Coronary Obstruction	0%	0%

TAVI Portico – clinical results from UCL-Saint-Luc Brussels

1° case : december 2012

Cliniques universitaires
SAINT-LUC
UCL BRUXELLES

Baseline characteristics of patients;N=24

Characteristic		
Age	years	85 ± 7
Gender	M/F	5/19
Aortic valve area	cm^2	0.6 ± 0.2
Mean transvalvular gradient	mmHg	48 ± 16
Logistic Euroscore	%	28 ± 17
STS score	%	6.5 ± 4
Sherpa score		4.7 ± 2
Chronic Obstructive Pulmonary Disease	n (%)	4 (17)
Renal Failure	n (%)	14 (58)
Diabetes	n (%)	3 (12)
Previous stroke/TIA	n (%)	6 (25)
Previous pacemaker	n (%)	5 (21)

Results : VARC-2 criteria

Index TAVI hospitalisation

Characteristic		
Device success	n (%)	24 (100)
In-hospital mortality	n (%)	0
Cardiovascular mortality	n (%)	0
Stroke	n (%)	0
Myocardial infarction	n (%)	0
Bleeding	n (%)	2 (8)
Lifethreatening	n (%)	0
Major	n (%)	2 (8)
Minor	n (%)	0
Acute kidney injury	n (%)	1 (4)
Stage 1	n (%)	1
Stage 2	n (%)	0
Stage 3	n (%)	0
Vascular complications	n (%)	2 (8)
Major	n (%)	0
Minor	n (%)	1
Closure device Failure	n (%)	1 (4)
Conduction/Rythm	n (%)	5
New pacemaker	n (%)	1 (4)
New LBB	n (%)	3 (12)
New atrial fibrillation	n (%)	0
Other arrhythmia	n (%)	1 (4)

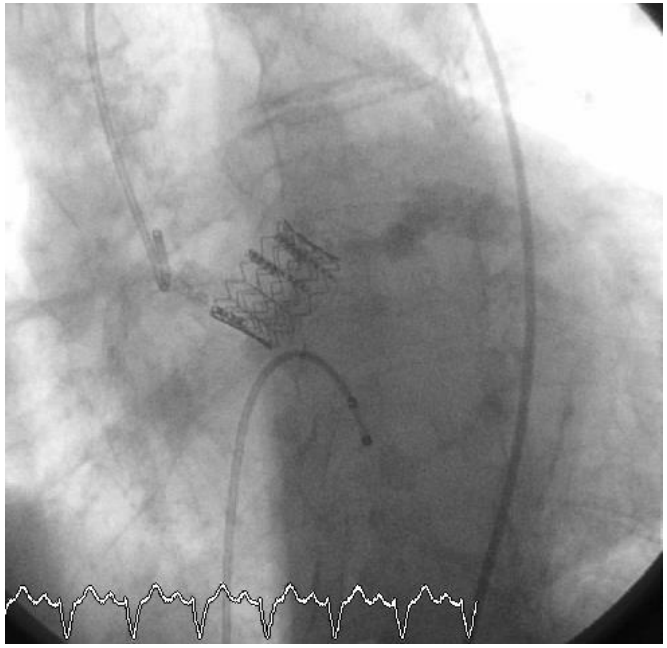
Results : VARC-2 criteria

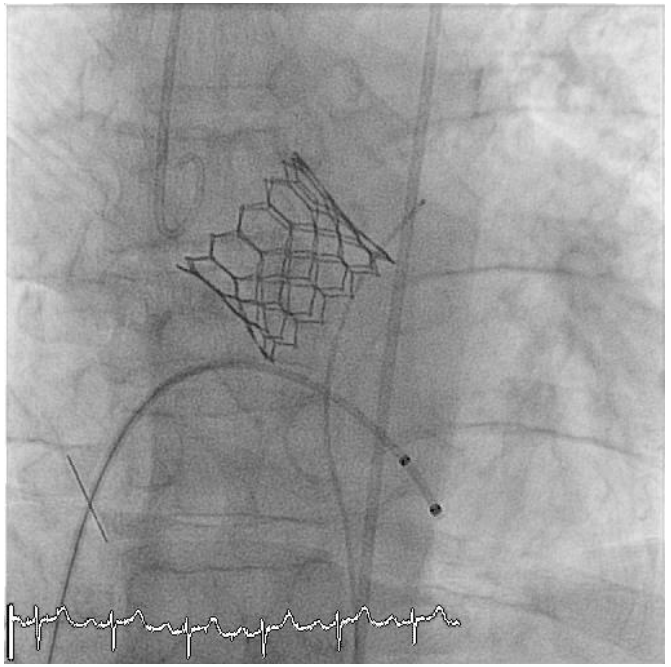
Follow-up (mean : 364 ± 246; IQ range : 84 – 538 days)

Characteristic		
Overall mortality	n (%)	1 (4)
Stroke	n (%)	0
Myocardial infarction	n (%)	0
Bleeding	n (%)	1 (4)
Acute kidney injury	n (%)	0
Vascular complications	n (%)	0
New pacemaker	n (%)	1 (4)
Rehospitalisation for HF	n (%)	1 (4)

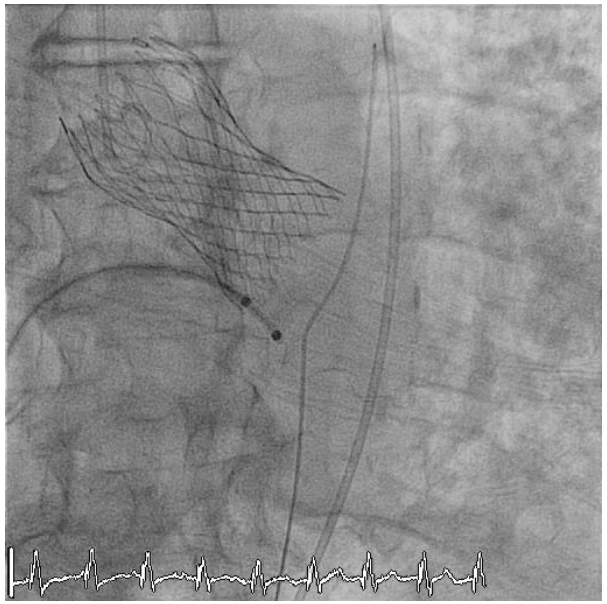
TOTAL NEW PCMK : 8.3%

2007 - Sapien

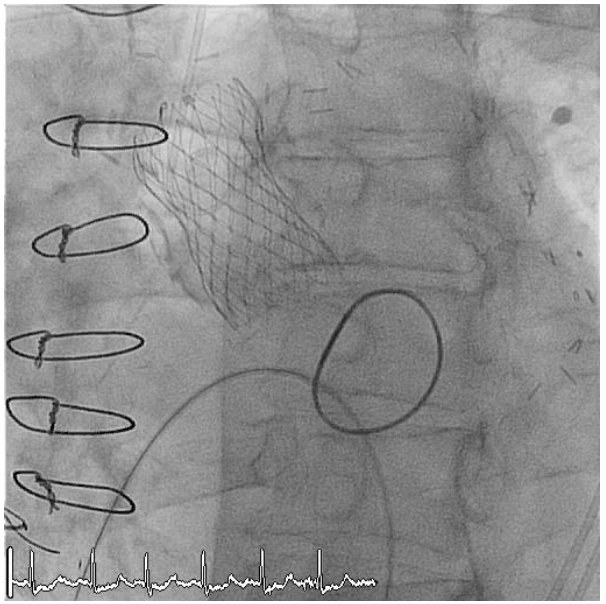




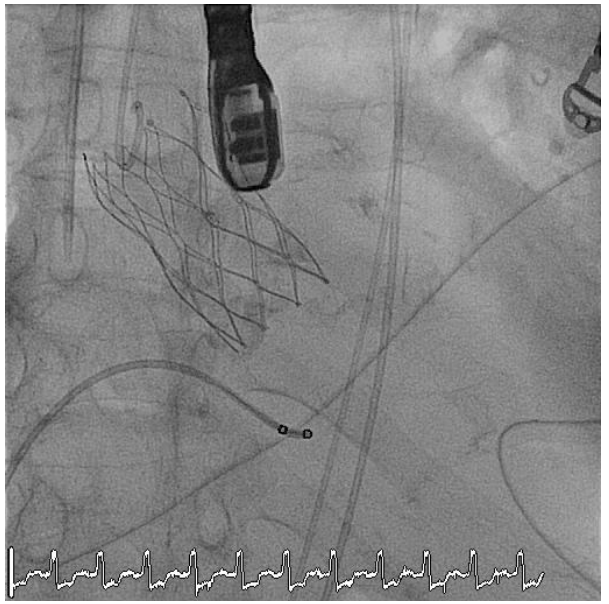
2016 – Sapien 3



2010 – CoreValve



2016 – Evolut R



2016 - Portico

CONCLUSIONS

- ✓ Need for new PCMK and new LBBB are more frequent after TAVI than after SAVR
- ✓ Negative impact on the outcome
- ✓ Depth of impant is crucial
- ✓ Novel technologies usefull, optimal positioning

- ✓ Need for better understanding, EP, CRT ?
- ✓ Ongoing trials : MARE,… algorithm on new LBBB management