

# **Low new permanent pacemaker rate with ACURATE *neo***

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**I have the following potential conflicts of interest to report:**

- Honorarium: Edwards Lifesciences, Medtronic Inc, Symetis SA
- Institutional grant/research support: Symetis SA
- Consultant: NVT GmbH, Symetis SA

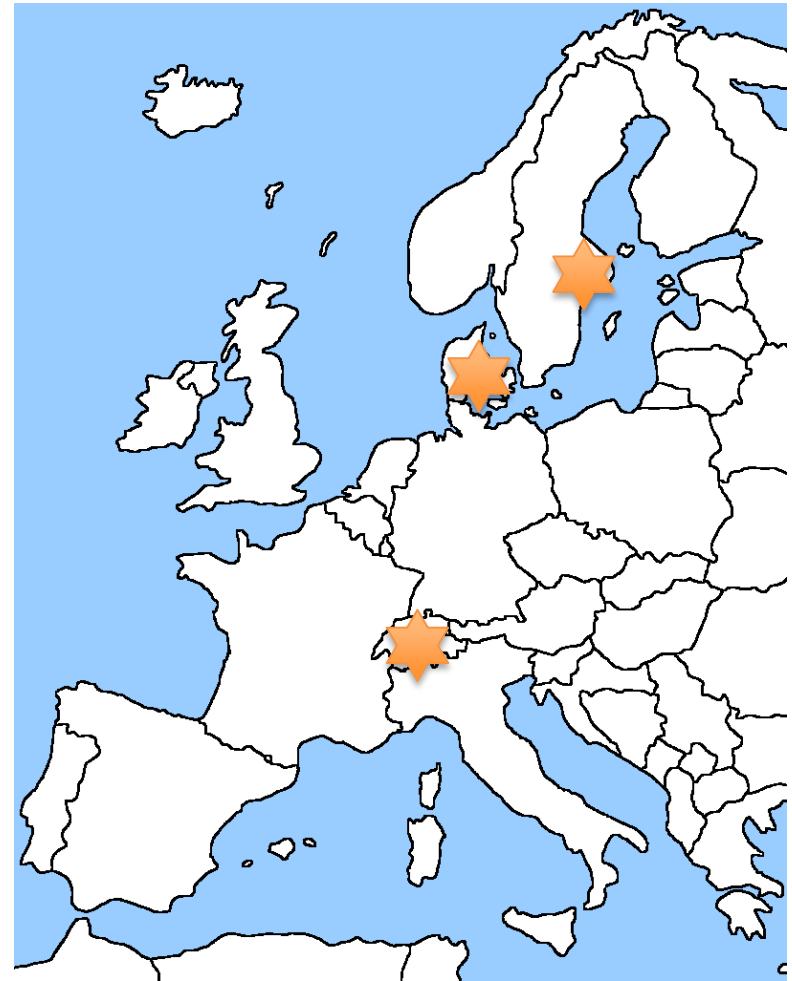
# Background / study aim

- New conduction disorders after TAVI remain a problem and values exceed those of surgical aortic valve replacement
- The self-expanding Symetis ACURATE neo TF system has been associated with low pacemaker rates (8.2% in the SAVI TF 1000 registry, Moellmann EuroPCR 2016 / 2017)
- We aimed to assess if pacemaker can be further reduced by careful selection of pre- and post-dilatation balloons, hence minimizing the trauma to the aortic annulus and LVOT



# Study centres / study design

- 3 centres (Heart Center Lucerne, Switzerland, Karolinska University Hospital, Stockholm, Sweden, and Odense University Hospital, Denmark)
- 175 consecutive patients undergoing TF TAVI with the ACURATE neo THV
- Same strategy for choice of valve and balloon size



# Choice of balloon and valve size

- Predilatation in all patients, balloon 1-3 mm smaller than perimeter derived annular diameter
- Valve according to perimeter derived annular diameter, oversize in borderline cases
- Postdilatation only if relevant paravalvular regurgitation, with a balloon 1-2 mm smaller than perimeter derived annular diameter



# Main results – baseline characteristics

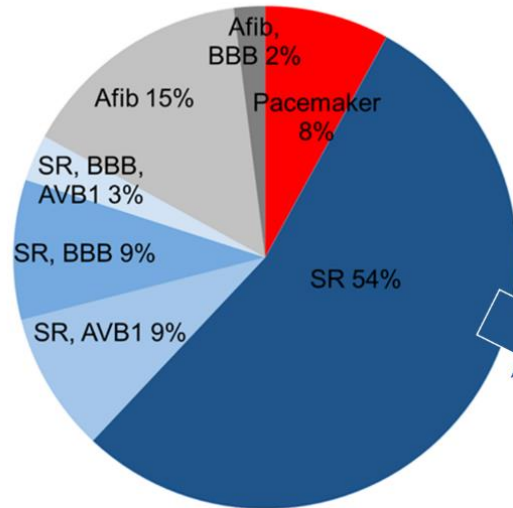
	All patients (n =175)	Patients w/o new conduction disorders (n = 124)*	Patients with new conduction disorders (n = 37)*	p value
Age, years	83 ± 6	83 ± 6	83 ± 4	0.73
Female sex	102 (58%)	79 (64%)	18 (49%)	0.10
Diabetes	35 (20%)	20 (16%)	13 (35%)	0.01
Coronary artery disease	59 (34%)	35 (28%)	15 (41%)	0.16
Betablocker at admission	91 (52%)	57 (46%)	24 (65%)	0.04
Prior pacemaker	14 (8%)	N/A*	N/A*	N/A*
Left bundle branch block	13 (7%)	11 (8%)	0 (0%)	0.07
Right bundle branch block	15 (9%)	11 (9%)	3 (8%)	1.00
STS PROM, %	4.1 ± 2.4	3.8 ± 2.1	5.0 ± 3.1	0.049
Aortic valve area, cm <sup>2</sup>	0.70 ± 0.16	0.69 ± 0.15	0.75 ± 0.18	0.07
Mean gradient, mmHg	48 ± 15	49 ± 15	43 ± 14	0.04
Ejection fraction, %	55 ± 12	56 ± 11	51 ± 13	0.05

# Main results - outcomes

	All patients (n =175)	Patients without new conduction disorders (n = 124)*	Patients with new conduction disorders (n = 37)*	p value
Perimeter derived annular diameter	24.0 ± 1.5	23.9 ± 1.5	24.4 ± 1.2	0.11
Implanted valve size				0.25
- S	31 (18%)	25 (20%)	4 (11%)	
- M	75 (43%)	55 (44%)	15 (41%)	
- L	69 (39%)	44 (36%)	18 (47%)	
Predilatation balloon size, mm	22.2 ± 1.6	22.1 ± 1.6	22.5 ± 1.5	0.15
Need for postdilatation	46 (26%)	37 (30%)	6 (16%)	0.10
Postdilatation balloon size, mm	23.5 ± 1.5	22.9 ± 2.4	24.0 ± 1.1	0.08
Implantation depth, mm	4.2 ± 1.6	4.1 ± 1.5	4.5 ± 1.5	0.34
Aortic valve area, cm <sup>2</sup>	2.0 ± 0.4	2.0 ± 0.4	1.8 ± 0.4	0.06
Mean gradient, mmHg	6.9 ± 3.7	6.8 ± 3.8	6.9 ± 3.4	0.95
Paravalvular regurgitation				0.57
none/trace	66 (38%)	46 (37%)	12 (32%)	
mild	101 (58%)	73 (59%)	22 (59%)	
moderate	8 (5%)	5 (4%)	3 (8%)	
Major vascular complication	12 (7%)	7 (6%)	5 (14%)	0.27
Major or life-threatening bleeding	13 (7%)	7 (6%)	5 (14%)	0.26
Any stroke at 30 days	3 (2%)	3 (2%)	0 (0%)	0.34
Mortality at 30 days	1 (1%)	0 (0%)	1 (3%)	0.07

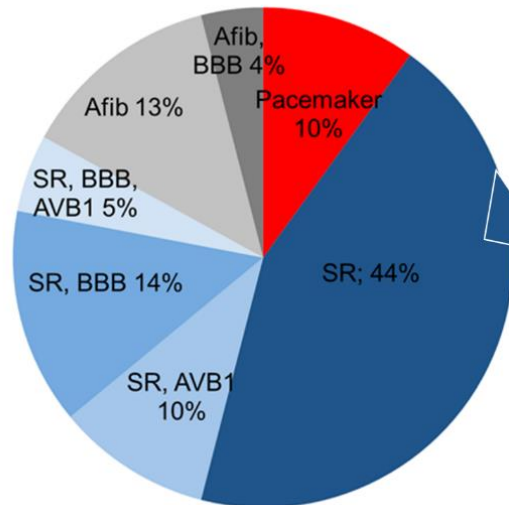
# Results – ECG before and after TAVI

Before TAVI



- ✓ ACURATE neo size selection based on perimeter derived annular diameter
- ✓ Predilatation balloon 1-3 mm smaller than the perimeter derived annular diameter
- ✓ If required postdilatation balloon 1-2 mm smaller than the perimeter derived annular diameter

After TAVI



2.3% new permanent  
pacemaker rate  
10.3% new left bundle  
branch block rate



# Discussion – key findings

- Lowest pacemaker rate (2.3%, 2.5% after excluding patients with a prior pacemaker) after TAVI in a larger series of patients
- Rate of moderate paravalvular regurgitation still  $< 5\%$
- Self-expanding valves usually 10-35% pacemaker rate
- Inflow portion of valve in vicinity to conduction system, but low radial force
  - Balance of radial force
  - Implant depth does not correlate with PM rate

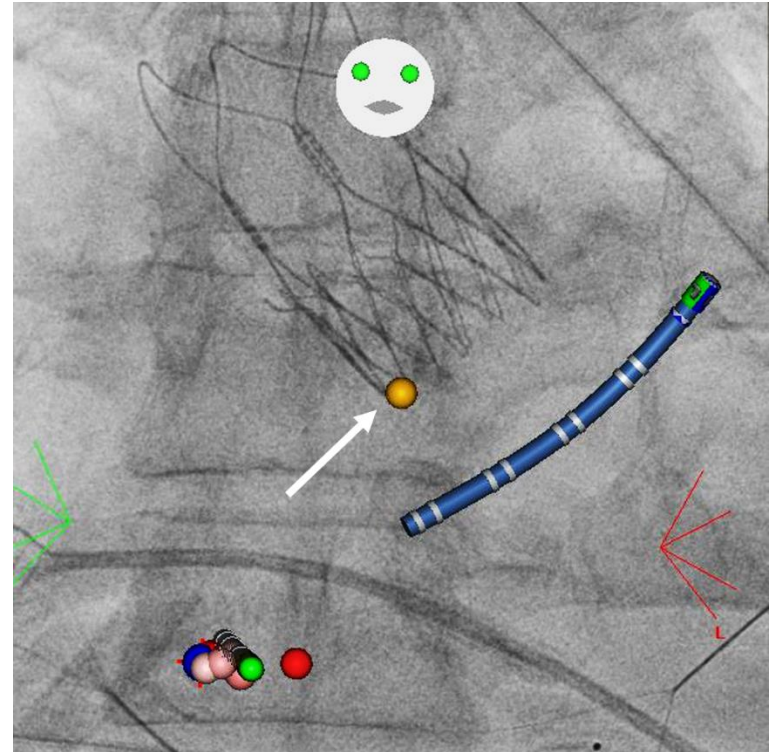


Image taken during radiofrequency ablation of atrial flutter. The yellow dot shows the location of the atrioventricular node

# Comparison to other TAVI devices

**Table 1.** Incidence of LBBB and PM implantation with new-generation transcatheter aortic valve.

Authors, year	N. of patients	Valve type	30-day new-onset LBBB %	30-day PM implantation %
Bax et al, 2014 [22]	4035	Overall	27.1 (4.4–57)	17.1 (2.3–51.1)
Siontis et al, 2014 [23]	11210			
Bax et al, 2014 [22]	4035	Medtronic CoreValve	47.6 (38.0–56.8)	28 (16.4–51.1)
Siontis et al, 2014 [23]	11210			
Bax et al, 2014 [22]	4035	Edwards SAPIEN/SAPIEN XT valve	14.1 (4.4–28.2)	6 (2.3–14.4)
Siontis et al, 2014 [23]	11210			
Kempfert et al, 2013 [24]	40	Symetis ACURATE TA	NA	11.7 (7.5–21.0)
Seiffert et al, 2014 [25]	62			
Mollmann et al, 2014 <sup>a</sup>	250			
Maeda et al, 2015 [26]	15	Symetis AUCURATE neo	NA	7.7 (0–9.0)
Mollmann et al, 2014 <sup>a</sup>	89			
Meredith, 2015 <sup>b</sup>	60	Medtronic Evolut R	NA	11.7
Schofer et al, 2014 [27]	100	Direct Flow Medical Valve System	NA	16.4 (13.6–17.0)
Treede et al, 2010 [28]	22			
Kodali et al, 2014 <sup>c</sup>	1659	Edwards SAPIEN 3 Valve	18.0	11.5 (11.3–13.3)
Webb et al, 2014 [29]	150			
Wendler et al, 2014 <sup>d</sup>	180	JenaValve	NA	12.6 (9.1–14.8)
Treede et al, 2012 [30]	67			
Seiffert et al, 2014 [25]	88			
Meredith et al, 2014 [31]	11	Medtronic Engager	NA	28.7 (26.9–36.4)
Meredith et al, 2014 [32]	120			
Gooley et al, 2015 [33]	50			
Wohrle et al, 2015 [34]	26			
Seiffert et al, 2014 [25]	50	Medtronic Engager	NA	30.0
Manoharan et al, 2015 <sup>e</sup>	102	SJM Portico	22.2	8.9 (0–9.8)
Willson et al, 2012 [35]	10			

**This study**

**175**

**ACURATE neo**

**10.3**

**2.3**

# Comparison to open heart surgery

Studie	N	STS score	New PPM
PARTNER 1	315	11.7%	<b>3.6%</b>
U.S. CoreValve	401	7.5%	<b>7.1%</b>
NOTION	135	3.1%	<b>1.6%</b>
PARTNER 2	1021	5.8%	<b>6.9%</b>
SURTAVI	796	4.5%	<b>6.6%</b>

Smith et al., NEJM 2011

Adams et al., NEJM 2014

Thyregod et al., JACC 2015

Leon et al., NEJM 2016

Reardon et al., NEJM 2017

# Possible benefits of low PPM and LBBB rate

- Pacemaker implantation considered a complication by the patient
- Lower costs
- Improved long-term prognosis (LBBB)
- Normal ECG after TAVI – no need for telemetry
- Shorter duration of hospitalisation

Regueiro et al., Circ Cardiovasc Interv 2016

Urena et al., JACC 2015

Urena et al., JACC Interv 2014

Toggweiler et al., JACC Interv 2016

# Conclusion

- Pre- or (if applicable) postdilatation choosing a balloon size 1-2 mm smaller than the perimeter derived annular diameter was associated with very low conduction disorders and permanent pacemaker rates following transfemoral implantation of the ACURATE neo
- With this technique, it appears that the permanent pacemaker rate may be reduced below the level of surgical aortic valve replacement
- This may lead to a paradigm shift that TAVI does not essentially have to be associated with higher rates of permanent pacemakers
- **Manuscript under revision EuroIntervention Journal**



Thank you



Hospital and Heart Center Lucerne, Switzerland