Comparative data analysis to a balloon expandable valve system – MORENA results

Prof. Dr. Christian Hengstenberg
Deutsches Herzzentrum
München, Germany

Potential conflicts of interest

Speaker's name: Christian Hengstenberg

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

proctor: Edwards Lifesciences, Symetis

Balloon-expandable vs. self-expanding THV

	Balloon-exp. THV	Self-expanding THV
Frame height/coronary access	++	+
Radial force	+++	++
Level of valvular function - Intrannular - Supravalvular	+ -	+ ++
Deployment/Positioning - One shot - Stepwise	+	 +
Retrievability/Resheatability	-	(+)

CHOICE Trial

- RCT
- Earlier generation devices
- balloon-expandable (SAPIEN XT) vs. self-expanding valve (CoreValve)

	Balloon-exp. (n= 121)	Self-expanding (n= 120)	p-value
EuroSCORE I	21.5 (12.9)	22.1 (14.7)	-
Device success	116 (95.9)	93 (77.5)	<0.001
New PPI	19 (17.3)	38 (37.6)	0.001
30-day mortality	5 (4.1)	6 (5.1)	0.77
Combined safety endpoint*	22 (18.2)	27 (23.1)	0.42

** Defined as composite of all-cause mortality, major stroke, life-threatening or disabling bleeding, acute kidney injury stage 3, periprocedural mycardial infarction, major vascular complication, repeat procedure for valve-related dysfunction*

M. Abdel-Wahab et. al. JAMA.2014

„Next Generation“ THV
Registry data

	Symetis ACURATE neo	Edwards SAPIEN 3
	N=994	N=1661
EuroSCORE II	6.6%	5.3-8.7%
30-day mortality	1.3%	1.5%
Stroke	1.9%	2%
Life-threatening bleeding	1.5%	3%
Major vascular complications	3.8%	5.8%
New PPI	8.2%	11.2%
PVL II+	4%	3.7%
Reference	*H. Möllmann EuroPCR 2016*	*S. Kodali EHJ 2016*

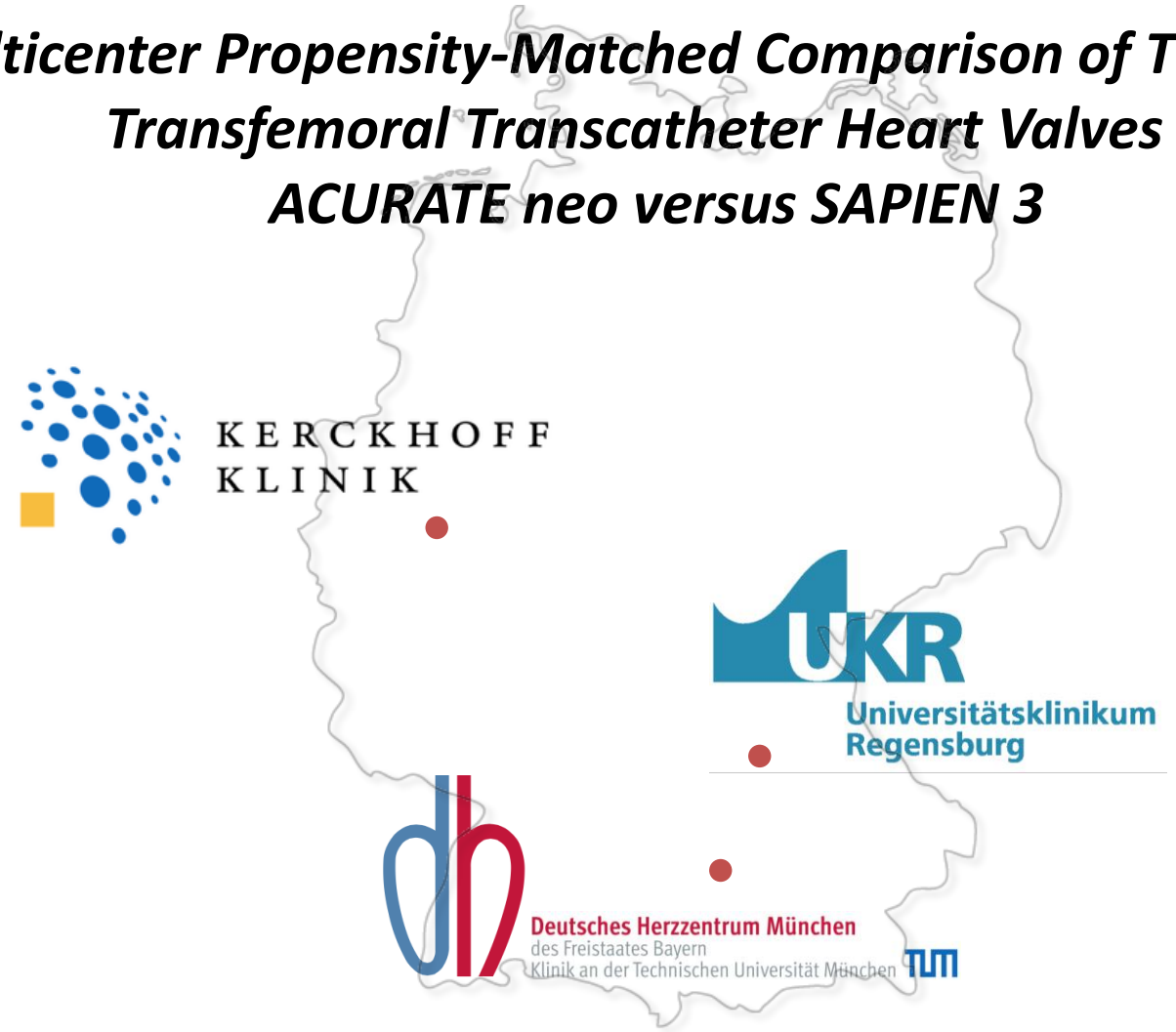
NO COMPARATIVE DATA OF

ACURATE NEO VS. SAPIEN 3 EXIST...

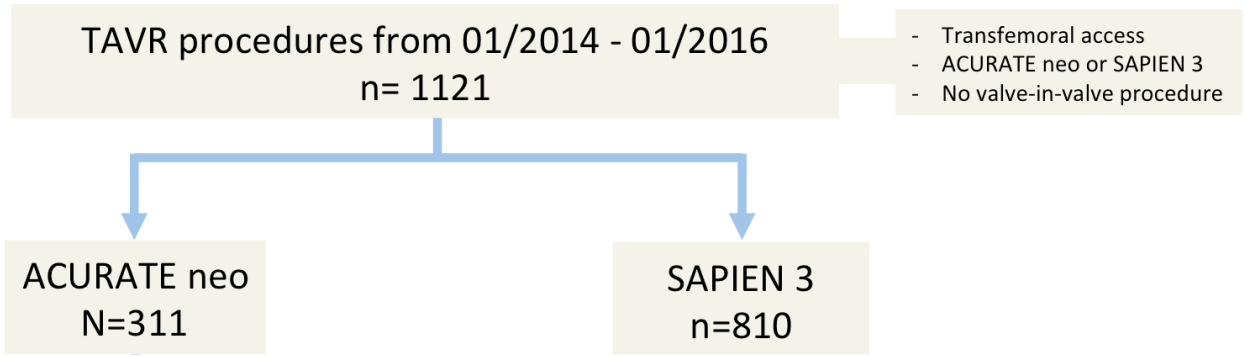
MORENA

München – **RE**gensburg – Bad **NA**uheim

Multicenter Propensity-Matched Comparison of Two Novel Transfemoral Transcatheter Heart Valves – ACURATE neo versus SAPIEN 3



Study Flow



Primary endpoints (VARC-2)

- Device success
  ➔ *Device oriented*
- Early safety composite endpoint (30d)
  ➔ *Patient oriented*

Baseline Characteristics

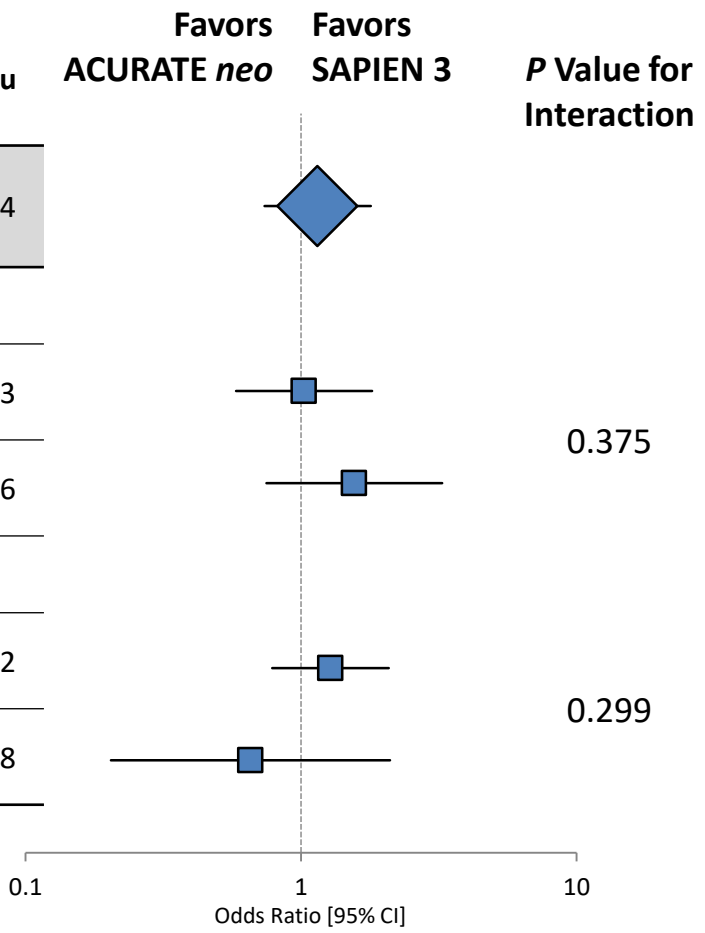
	ACURATE neo (n=311)	SAPIEN 3 (n=622)	p-value
Clinical			
Age (years)	81 ± 6	81 ± 6	0.982
Female gender	189 (61)	344 (55)	0.112
Body mass index (kg/m2)	27 ± 5	27 ± 5	0.660
Logistic EuroSCORE I	18 ± 10	18 ± 12	0.999
NYHA III or IV	256 (82)	489 (79)	0.184
COPD	42 (14)	92 (15)	0.597
Diabetes mellitus	103 (33)	201 (32)	0.805
Glomerular filtration (ml/min)	59 ± 27	57 ± 25	0.205
On dialysis	7 (2)	12 (2)	0.743
Peripheral vascular disease	33 (11)	70 (11)	0.768
Previous stroke major/minor	43 (14)	78 (13)	0.581
Coronary artery disease	190 (61)	390 (63)	0.633
Previous myocardial infarction	31 (10)	63 (10)	0.939
Previous PCI	113 (36)	239 (38)	0.535
Previous CABG	33 (11)	54 (9)	0.339

	ACURATE neo (n=311)	SAPIEN 3 (n=622)	p-value
Echocardiography			
LV ejection fraction < 35%	18 (6)	34 (6)	0.840
Mean transaortic gradient	45 ± 15	44 ± 16	0.590
Mitral regurgitation III+	5 (2)	13 (2)	0.614
Pulmonary hypertension*	24 (8)	60 (10)	0.332
ECG			
Atrial fibrillation	77 (25)	163 (26)	0.634
RBBB	26 (8)	51 (8)	0.933
LBBB	27 (9)	43 (7)	0.334
Previous pacemaker	28 (9)	62 (10)	0.638
MSCT data			
Aortic annular area (cm^2)	4.4 ± 0.6	4.5 ± 0.8	0.003
Eccentricity index of ao annulus	0.2	0.2	0.089
Severe aortic cusp calcification	69 (22)	164 (26)	0.164
Bicuspid valve	10 (3)	21 (3)	0.897

RESULTS

Device Failure

Subgroup	ACURATE *neo*	SAPIEN 3	Odds Ratio [95% CI]	*P* Value	*P* Value for Interaction
Matched population	11% (34/311)	10% (60/622)	1.15 [0.74-1.79]	0.54	
Aortic Cusp Calcification					
Mild/moderate	8% (20/242)	8% (37/458)	1.03 [0.58-1.81]	0.93	0.375
Severe	20% (14/69)	14% (23/164)	1.56 [0.75-3.25]	0.26	
Aortic Annulus Eccentricity Index					
≤0.25	12% (30/253)	10% (47/494)	1.28 [0.78-2.08]	0.32	0.299
>0.25	7% (4/58)	10% (13/128)	0.66 [0.20-2.10]	0.48	



Device Failure

	ACURATE *neo* (n=311)	SAPIEN 3 (n=622)	p-value
Device failure	**34 (11)**	**60 (10)**	**0.539**
Procedural mortality	3 (1)	2 (0.3)	0.340
Correct position	308 (99)	616 (99)	0.999
Intended performance*	280 (90)	564 (91)	0.753
Aortic regurgitation II+	15 (5)	11 (2)	0.008
Elevated gradient (>20mm Hg)	10 (3)	43 (7)	0.021
Multiple valves	7 (2)	7 (1)	0.251
Conversion	5 (2)	4 (1)	0.170

*No prosthesis mismatch, mean aortic valve gradient <20 mmHg or peak velocity <3 m/s, without moderate or severe prosthetic valve aortic regurgitation of the first implanted prosthesis

Procedural Data

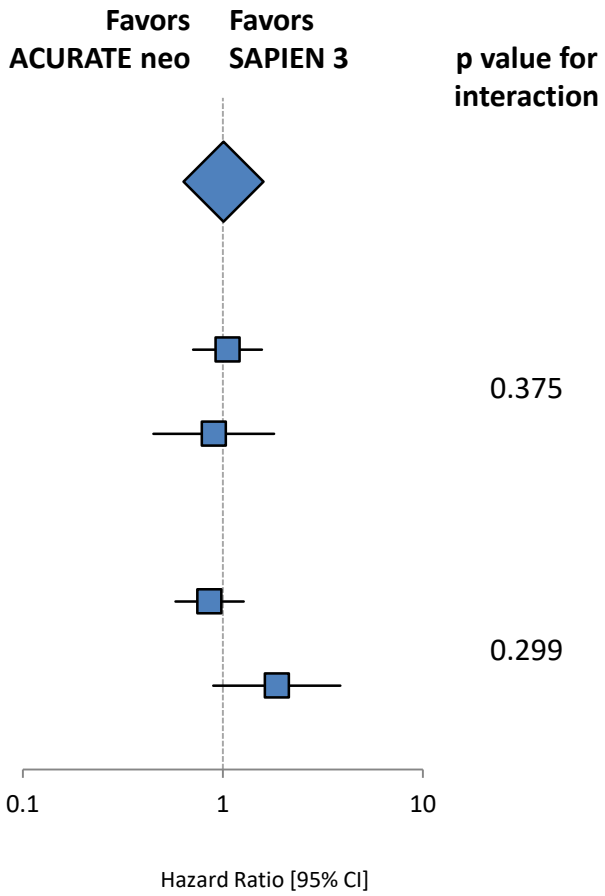
	ACURATE *neo* (n=311)	SAPIEN 3 (n=622)	p-value
Procedural data			
Conscious sedation	147 (47)	286 (46)	0.710
Pre-dilatation	298 (96)	462 (74)	<0.001
Post-dilatation	131 (42)	148 (24)	<0.001
Procedural time (min)	55 ± 30	54 ± 24	0.540
Contrast (ml)	115 ± 54	104 ± 53	0.004
Fluoroscopy time (min)	10 [6-14]	11 [7-15]	0.032

In-hospital outcome

	ACURATE *neo* (n=311)	SAPIEN 3 (n=622)	p-value
In-hospital complications			
All stroke	6 (2)	15 (2)	0.640
Disabling	5 (1.6)	10 (2.4)	0.999
Non-disabling	1 (0.3)	5 (0.8)	0.357
Major vascular complication	32 (10)	53 (9)	0.376
Life-threatening bleeding	13 (4)	23 (4)	0.718
Renal failure (AKIN 2/3, including dialysis)	10 (3)	17 (3)	0.679
Coronary artery obstruction w/ PCI	2 (1)	0 (0)	0.036
Myocardial infarction	0 (0)	0 (0)	-
New pacemaker*	28 (10)	87 (16)	0.024
Days in hospital	8 [6-11]	6 [5-10]	<0.001
Days on Intensive Care Unit	1 [1-2]	1 [1-2]	0.336
In-hospital mortality	5 (2)	7 (1)	0.545

Early Safety
Composite Endpoint at 30 Days

Subgroup	ACURATE neo	SAPIEN 3	Hazard Ratio [95% CI]	*P* Value
Matched population	16% (49/311)	16% (97/622)	1.01 [0.72-1.43]	0.953
Aortic Cusp Calcification				
Mild/moderate	16% (38/242)	15% (68/458)	1.05 [0.71-1.57]	0.783
Severe	16% (11/69)	18% (29/164)	0.90 [0.45-1.81]	0.774
Aortic Annulus Eccentricity Index				
≤0.25	14% (36/253)	16% (81/494)	0.86 [0.58-1.27]	0.450
>0.25	22% (13/58)	13% (16/128)	1.86 [0.89-3.87]	0.095



Early Safety Composite Endpoint at 30 Days

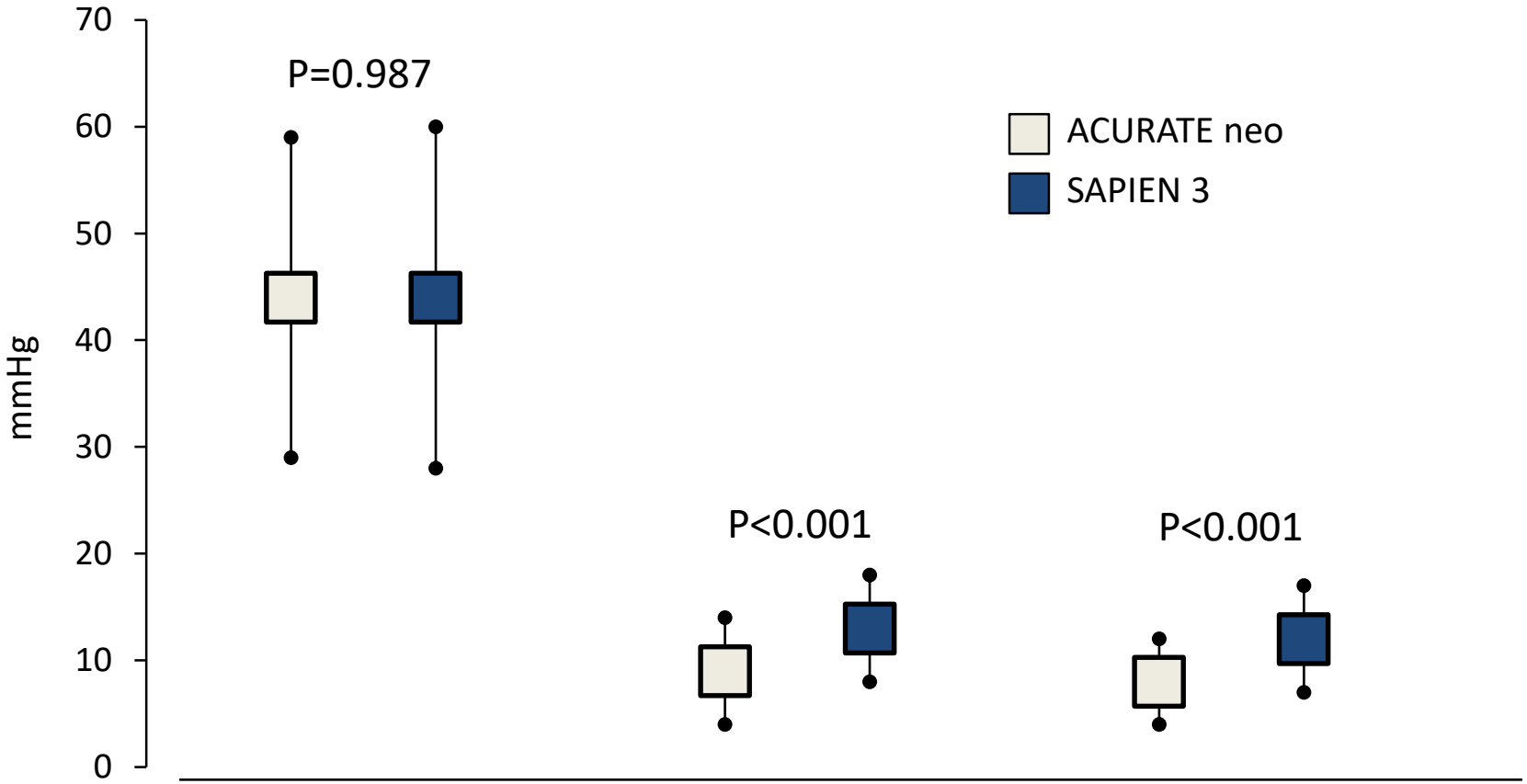
	ACURATE *neo* (n=311)*	SAPIEN 3 (n=622)*	p-value
Early safety composite endpoint 30 Days#	**49 (16)**	**97 (16)**	**0.941**
All-cause mortality 30 days	7 (2)	12 (2)	0.742
Stroke (disabling and non disabling)	7 (2)	19 (3)	0.484
Coronary artery obstruction requiring intervention	2 (1)	0 (0)	0.046
Major vascular complication	32 (10)	53 (9)	0.710
Life-threatening bleeding	13 (4)	27 (4)	0.910
Acute kidney injury (RIFLE 2/3, including dialysis)	10 (3)	17 (3)	0.669
Valve-related dysfunction with BAV, TAVI or SAVR	1 (0.3)	0 (0)	0.159
New permanent pacemaker implantation+	**29 (10.2)**	**92 (16.4)**	**0.018**

*Follow-up at 30 days was available for: ACURATE neo: 310/311 (99.7%); SAPIEN 3 matched population: 614/622 (98.7%)

+ excluding patients with pacemaker at baseline

#Multiple events possible; counting only first event

Mean transvalvular gradients – baseline, discharge and 30 days



	Baseline	Discharge	30 days
SAPIEN 3	44±16 mmHg	13±5 mmHg	12±5 mmHg
ACURATE neo	44±15 mmHg	9±5 mmHg	8±4 mmHg

Limitations and Strenghts

- **Limitations**
  - Observational study
  - No center-independent event adjudication
  - No core-lab analysis for PVL

- **Strengths**
  - 1000+ patients from three high-volume TAVI centers
  - propensity-matching to account for selection bias

Summary- ACURATE neo vs. SAPIEN 3

	ACURATE neo compared to SAPIEN 3
Device failure	11% vs. 10%
Early safety composite endpoint at 30 days	16% vs. 16%
Paravalvular leakage (II+)	5% vs. 2%
Elevated gradients (PG_{mean} >20 mmHg)	3% vs. 7%
New permanent pacemaker	10% vs. 16%

→ Prospective randomized comparison is warranted (SCOPE-I trial)

Thank you very much for your attention!

O. Husser, W-K. Kim, C. Pellegrini, A. Holzamer, T. Walther, N.P. Mayr, M. Joner, AM. Kasel, J. Michel, T. Trenkwalder, T. Rheude, A. Kastrati, H. Schunkert, C. Burgdorf, M. Hilker, H. Möllmann, C. Hengstenberg

Prof. Dr. Christian Hengstenberg
Tel: +49-89-1218-4025
christian.hengstenberg@gmail.com