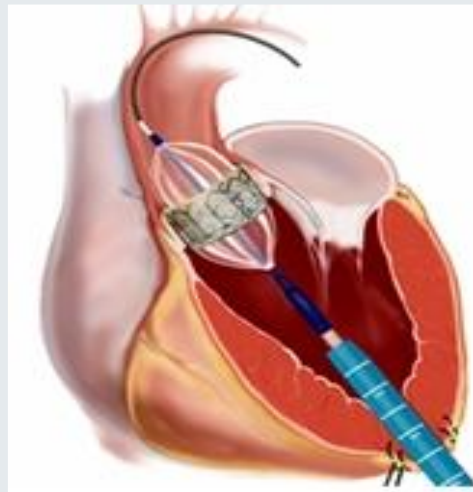


Cardiology Update Davos

# TAVI: Transapical Procedures



UniversitätsSpital  
Zürich

Volkmar Falk, MD  
University Hospital Zürich

# TA-AVI: antegrade, simple, safe



# Transapical TAVI

- Technical advantages of TA approach
- Is transfemoral better than transapical ?
- Results of latest generation TA valves
- New devices for access closure and percutaneous transapical access

# Transapical TAVI

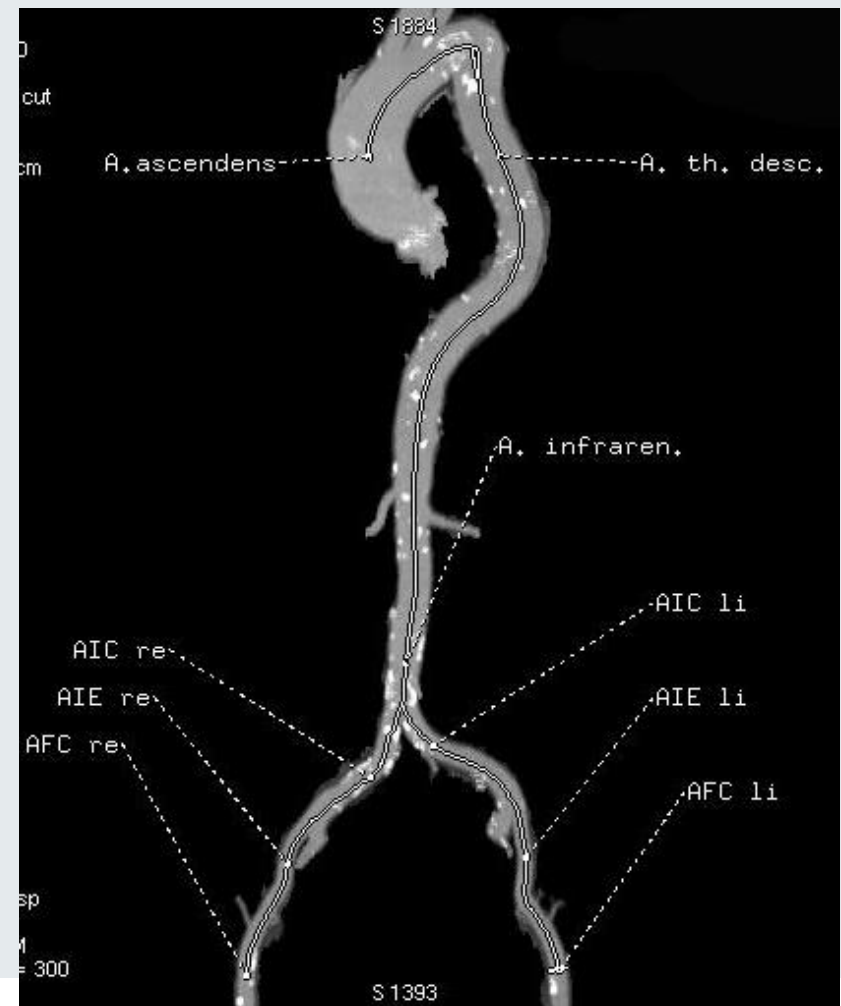
- Technical advantages of TA approach
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- Results of latest generation TA valves
- New devices for access closure and percutaneous transapical access

# Technical Advantages of TA approach

- Only antegrade access
- Short distance to AV, excellent control
- Facilitates coaxial orientation of implant
- Limited aortic manipulation
- Limited radiation exposure
- No limitations for diameter
  - allows for larger, (cuffed) devices



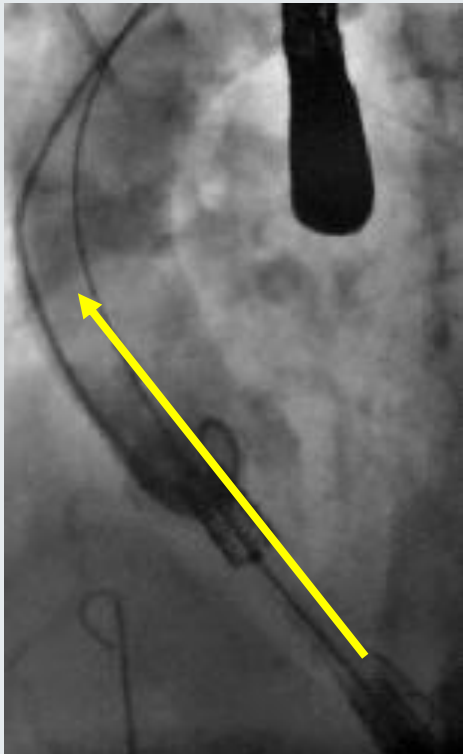
# Direct antegrade vs remote retrograde access



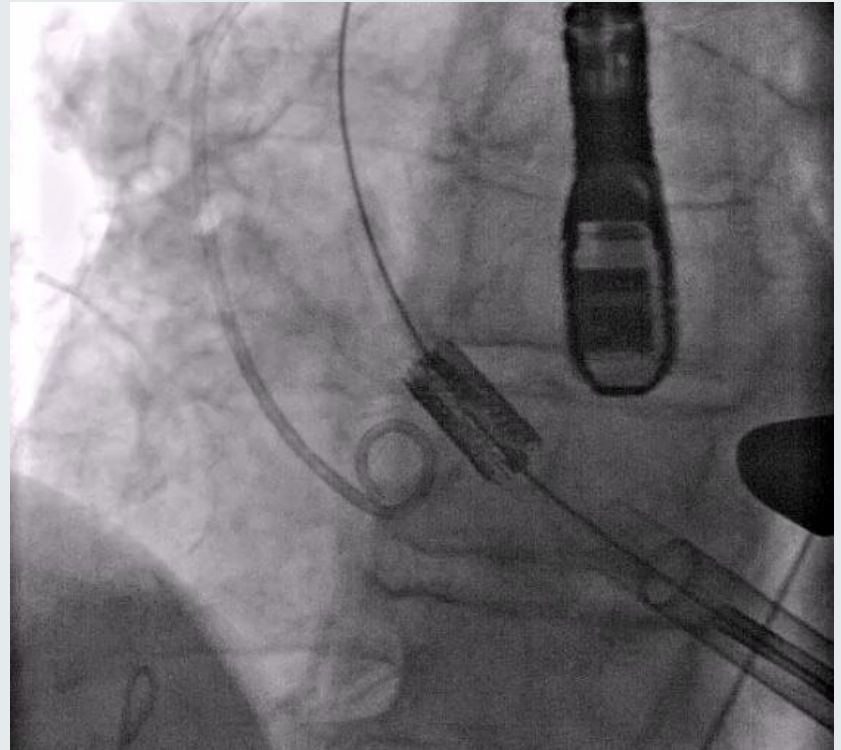


# TA-AVI: Coaxial orientation of implant

antegrade, coaxial  
orientation



easy wire adjustments



# Transapical TAVI

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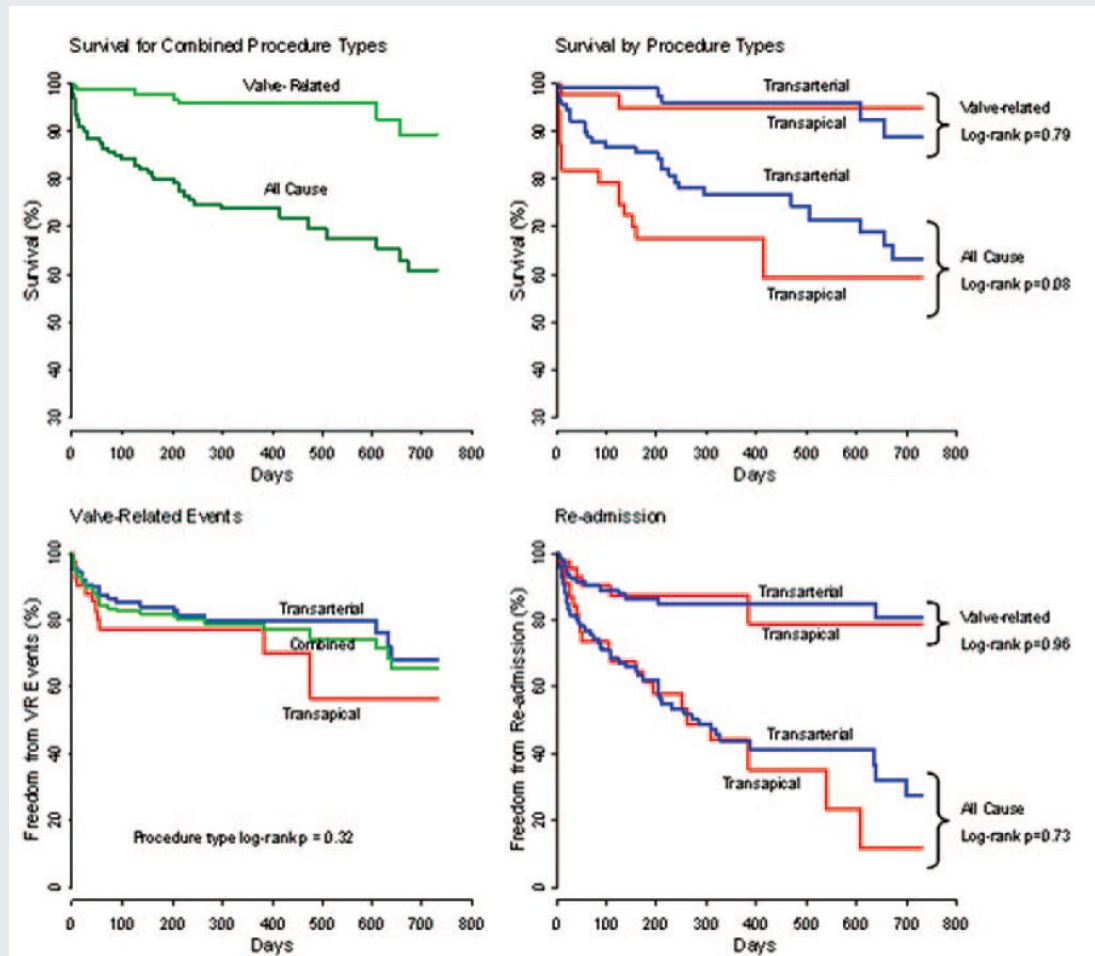


# Transapical TAVI

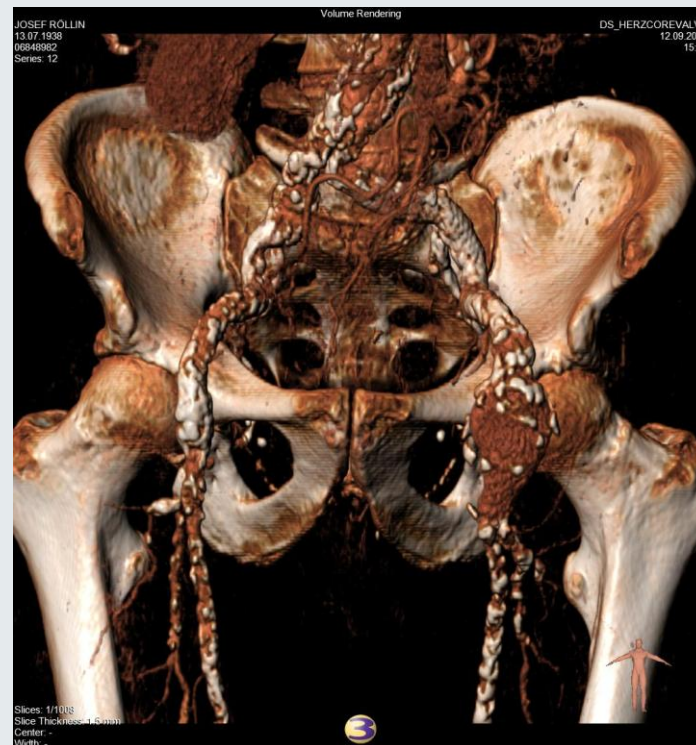
- Technical advantages of TA approach
- Is transfemoral better than transapical ?
  - Mortality
  - Complications

# Canadian experience TF - TA

## No difference in outcomes



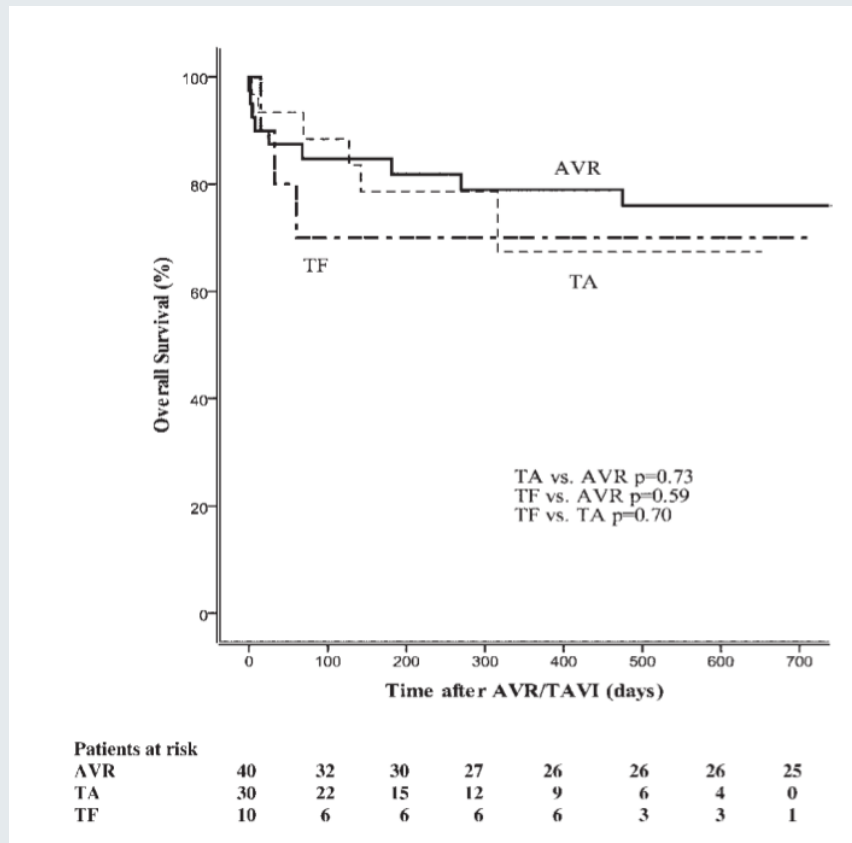
# Transapical AVI only in case of poor vascular access – transfemoral first strategy



# Canadian experience TF - TA

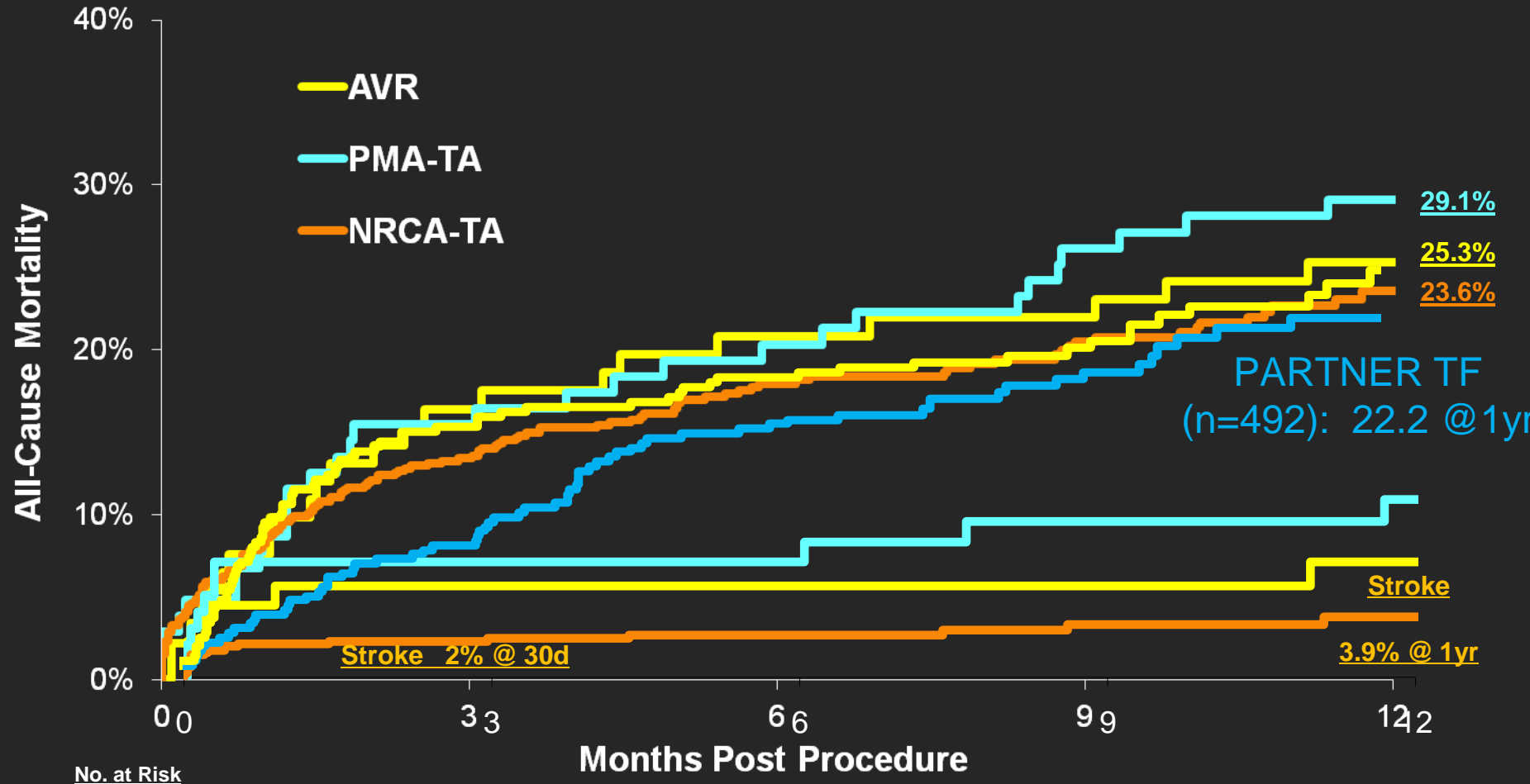
	TF = 162	TA = 177
Peripheral vascular disease	19%	50%
STS Score	9%	10.5%
30-day mortality	9.5%	11.3%
1 year survival	75%	78%
2 year survival	65%	64%

# Transapical Versus Transfemoral Aortic Valve Implantation: A Comparison of Survival and Safety



No difference in survival for TF vs TA in propensity matched groups.

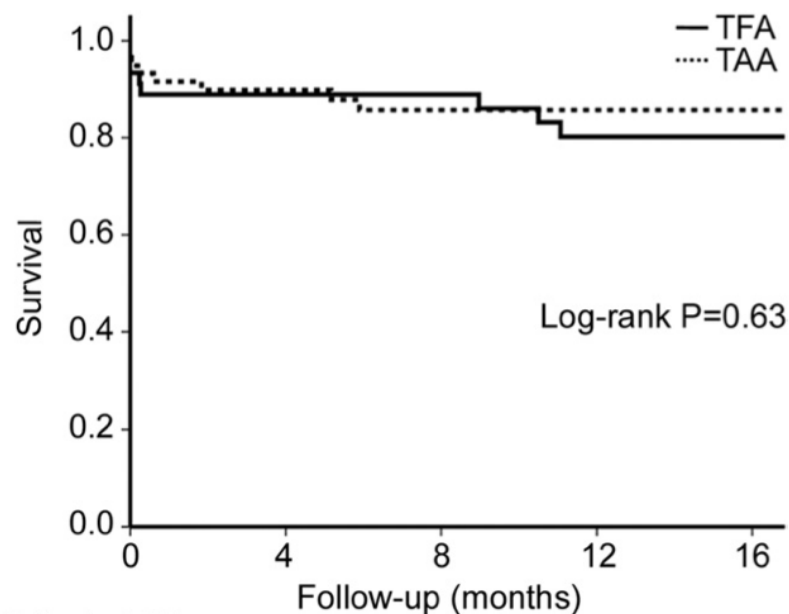
# TA: PARTNER (n=104) versus continued access (n=822)



AVR	92	76	71	70	67
PMA-TA	104	87	82	76	73
NRCA-TA	822	571	370	297	126

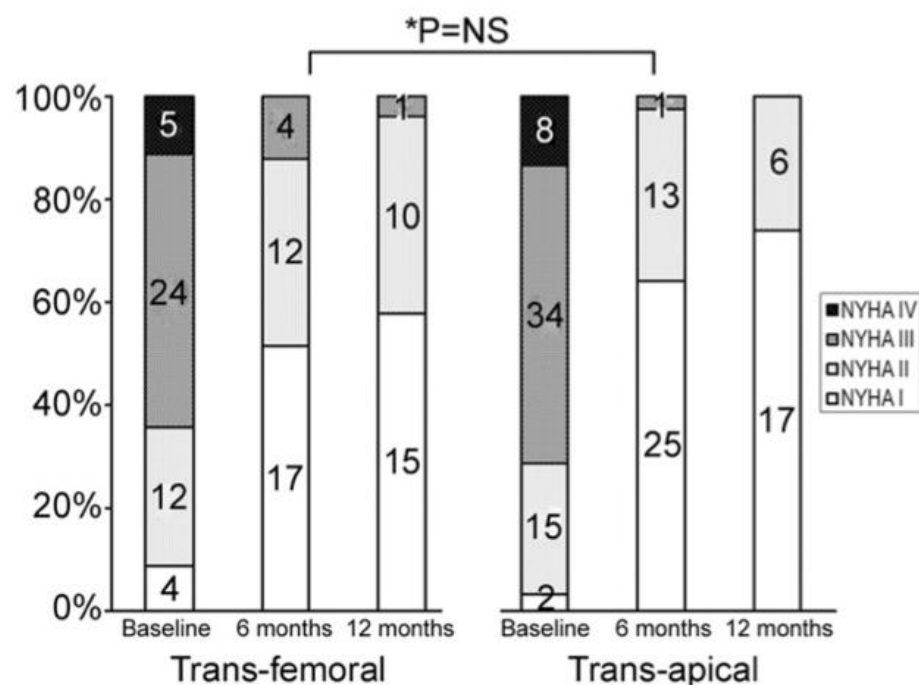


# Outcomes After Transcatheter Aortic Valve Implantation: Transfemoral Versus Transapical Approach



Patients at risk

TFA	45	36	33	26	23
TAA	59	50	36	28	20



*“Early, midterm, clinical, and echocardiographic outcomes were comparable in both approaches.*

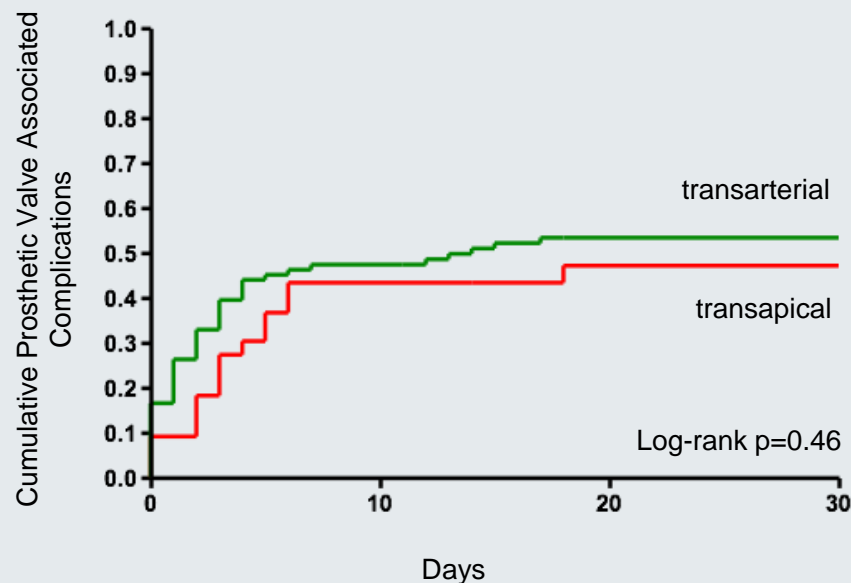
*However, TAA has the additional benefit of **reducing radiation exposure** (5 vs 12 min) **and contrast use** (173 vs 80ml) intraoperatively without prolonging the length of hospital stay.”*

# Transapical TAVI

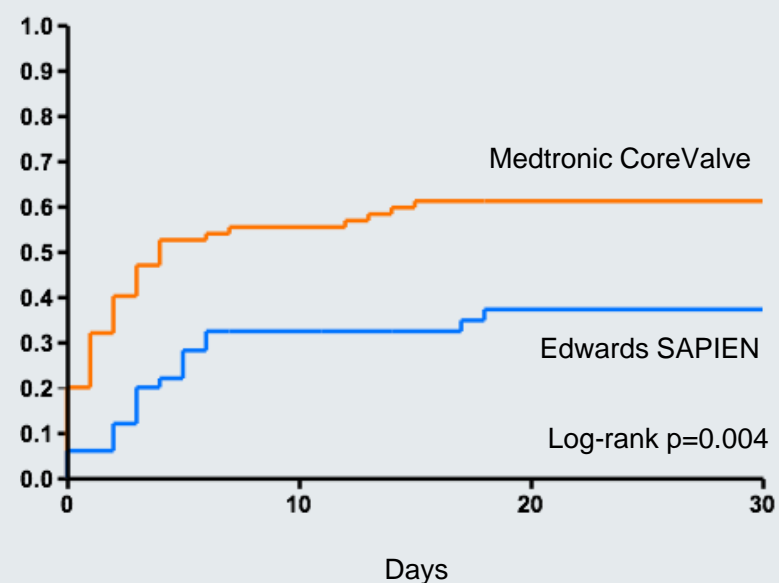
- Technical advantages of TA approach
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  - Complications

# USZ TAVI Experience: VARC Prosthesis Associated Complications

Grouped by procedure



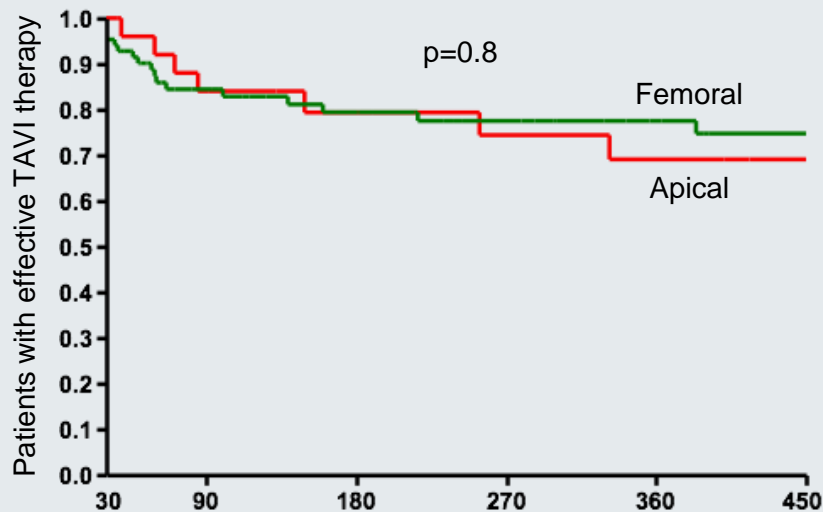
Grouped by prosthesis



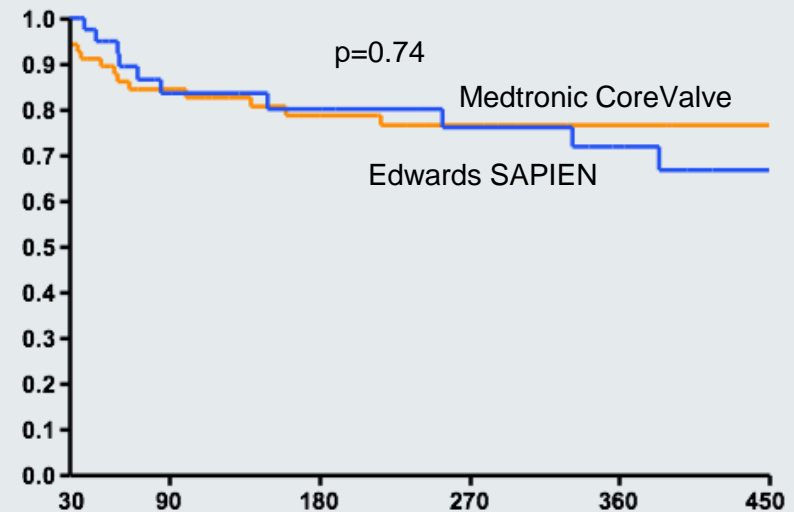
# USZ TAVI Experience: VARC Combined Efficacy Endpoint

Grouped by procedure

Grouped by prosthesis

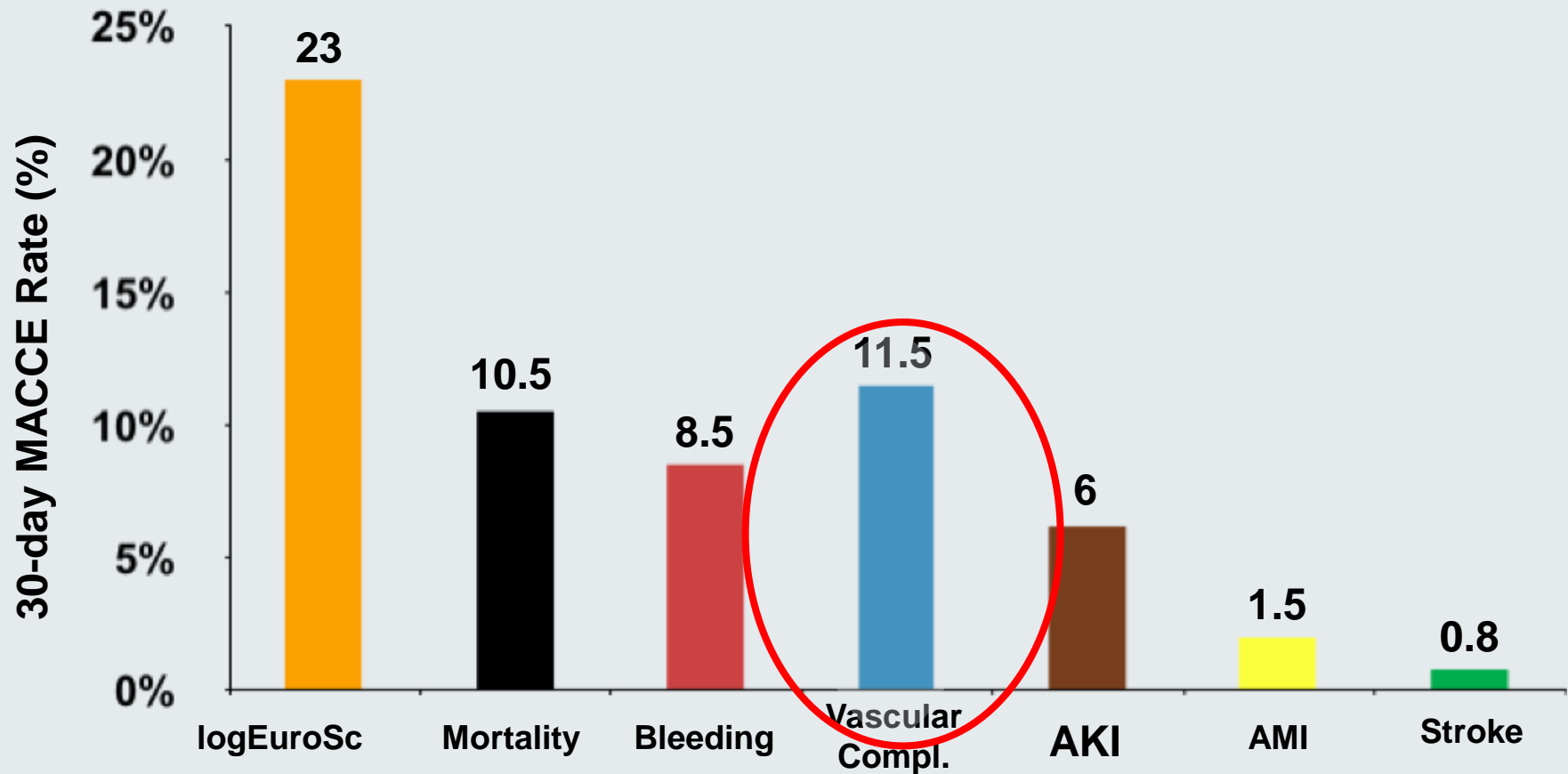


No. at Risk	Days		
	30	180	450
TAP	27	18	14
TF	76	46	30



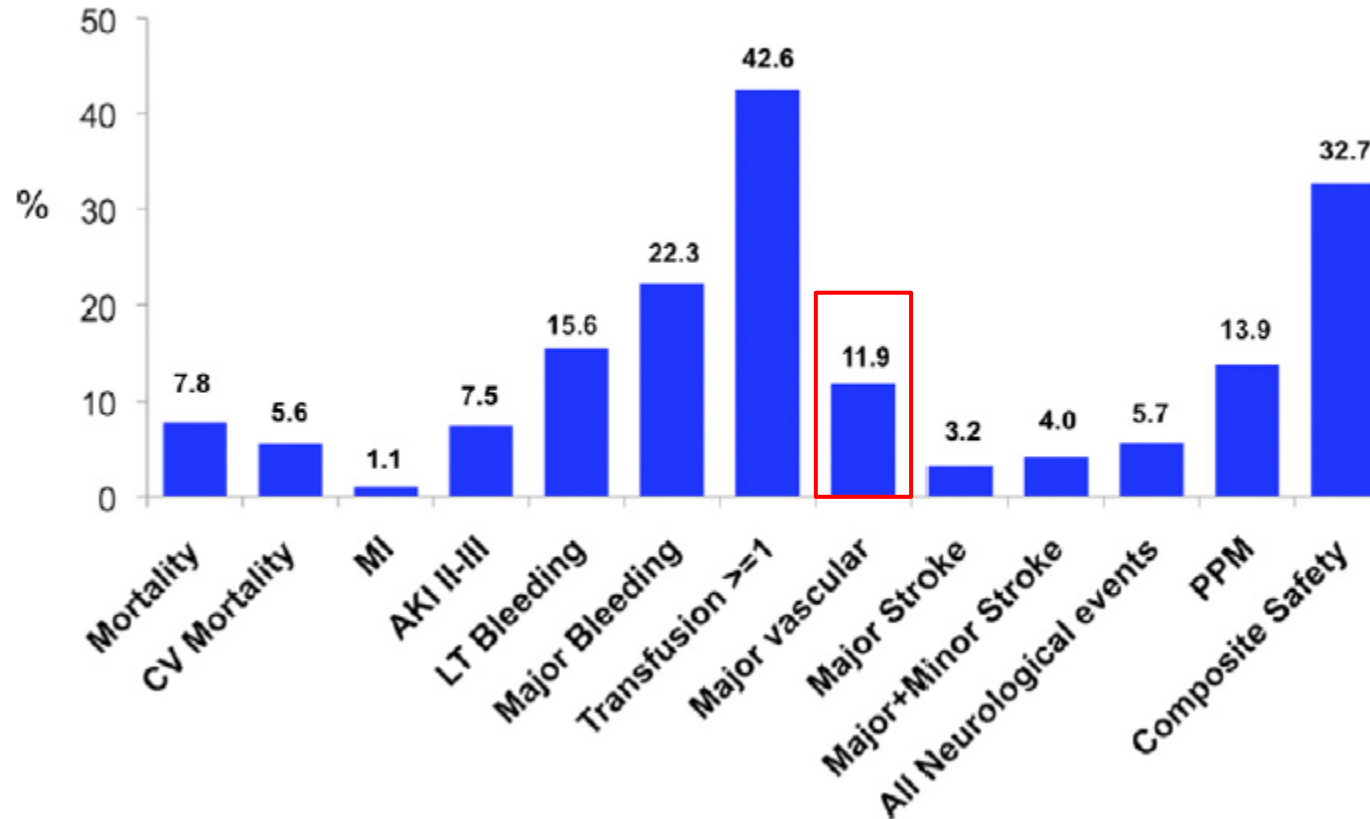
No. at Risk	Days		
	30	180	450
CV	61	40	29
ES	42	24	15

## USZ TAVI Experience: 30-Day (VARC) MACCE Rate





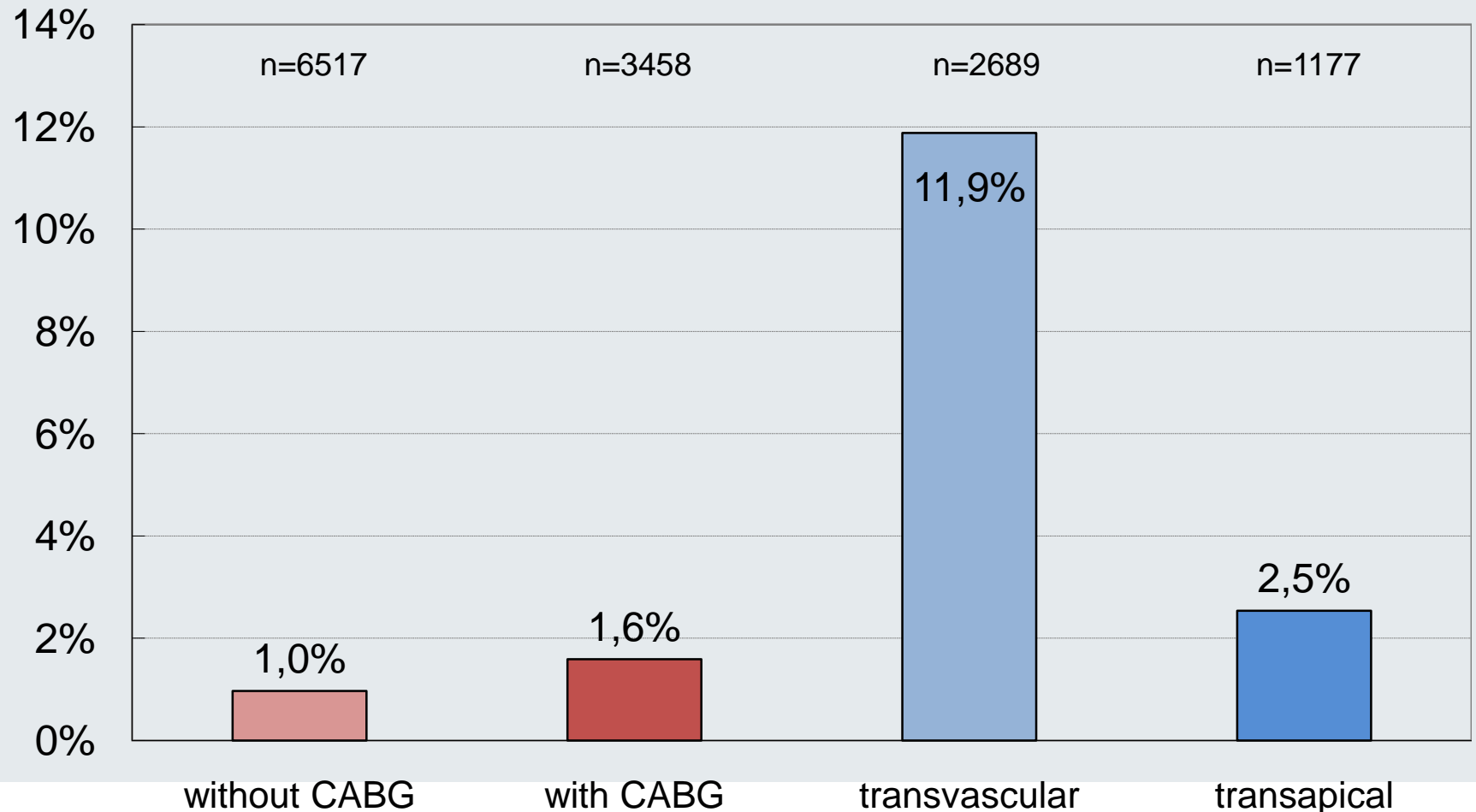
# Vascular complications



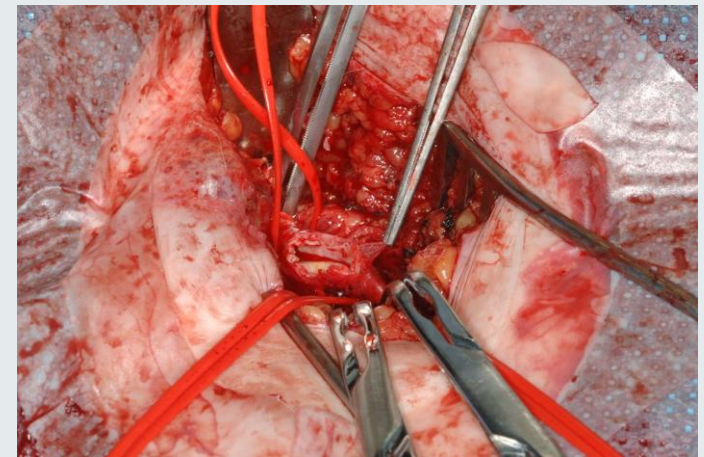
Metaanalysis 3519 patients from 16 studies

# GARY-Registry Results – Procedure

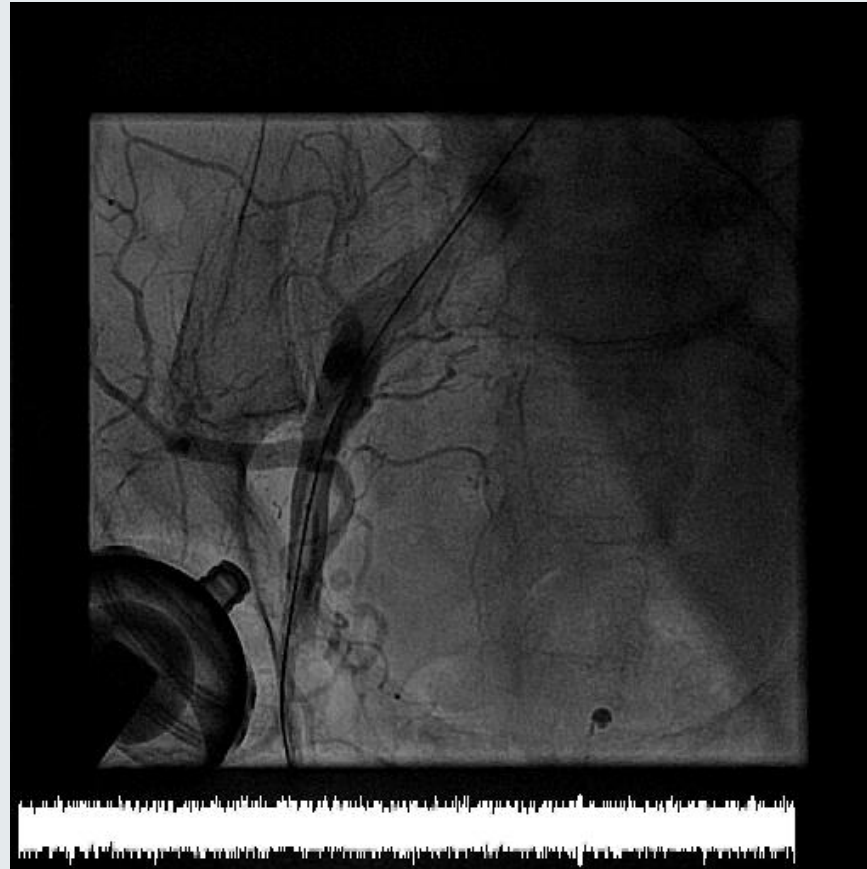
## Vascular complications



# Vascular complications with TF approach: bleeding



# Vascular complications with TF approach: occlusion



# Vascular complications with TF approach: dissection



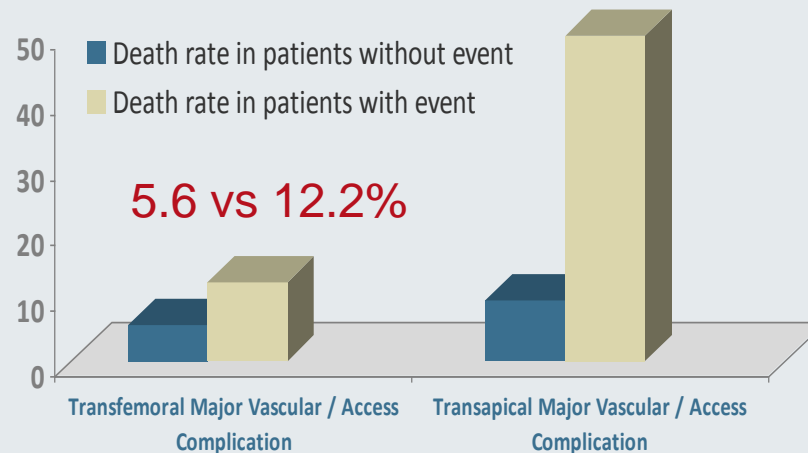
# Vascular complications with TF approach





# Transfemoral (Sapien) : Major Vascular/Access Complications 30 d Source Registry (n=463)

Vascular Complications	# events/pts	% pts with event
Access Related Complications	91/83	17.9%
Aortic Dissections (AD below)	9/9	1.9%
Non-Access Related	6/5	1.1%
All Vascular Complications		
Major (includes aortic dissection)	55/49	10.6%
Minor	51/48	10.4%



# TA access related complication rate

**Source: 0.6%,  
Prevail: 0.7%**

# TAVI- Stroke

Registry	n	ES	30d mortality
German <sup>1</sup>	697	20.5	12.4%
French <sup>2</sup>	244	25.6	12.7%
French 2 <sup>3</sup>	759	22-24	7.8-11.3%
Belgian <sup>4</sup>	328	28	11%

- Stroke 2.8 -7.7%<sup>1-4</sup>
- Permanent pacemaker 9.4 - 39%<sup>1-4</sup>
- Moderate paravalvular AI  
independent predictor of late death<sup>5</sup>

1 EHJ 2011

2 EHJ 2011

3 unpublished data

4 ICTVS 2011

5 Heart 2011

# TA: consistently lower stroke risk

## Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients

Holger Eggebrecht<sup>1</sup>, MD, FESC; Axel Schmermund<sup>1</sup>, MD, FESC; Thomas Voigtländer<sup>1</sup>, MD, FESC; Philipp Kahlert<sup>2</sup>, MD; Raimund Erbel<sup>2</sup>, MD, FESC, FACC, FAHA; Rajendra H. Mehta<sup>3</sup>, MD, MS

*1. Cardiac  
Essen, U*

*Heart Center*

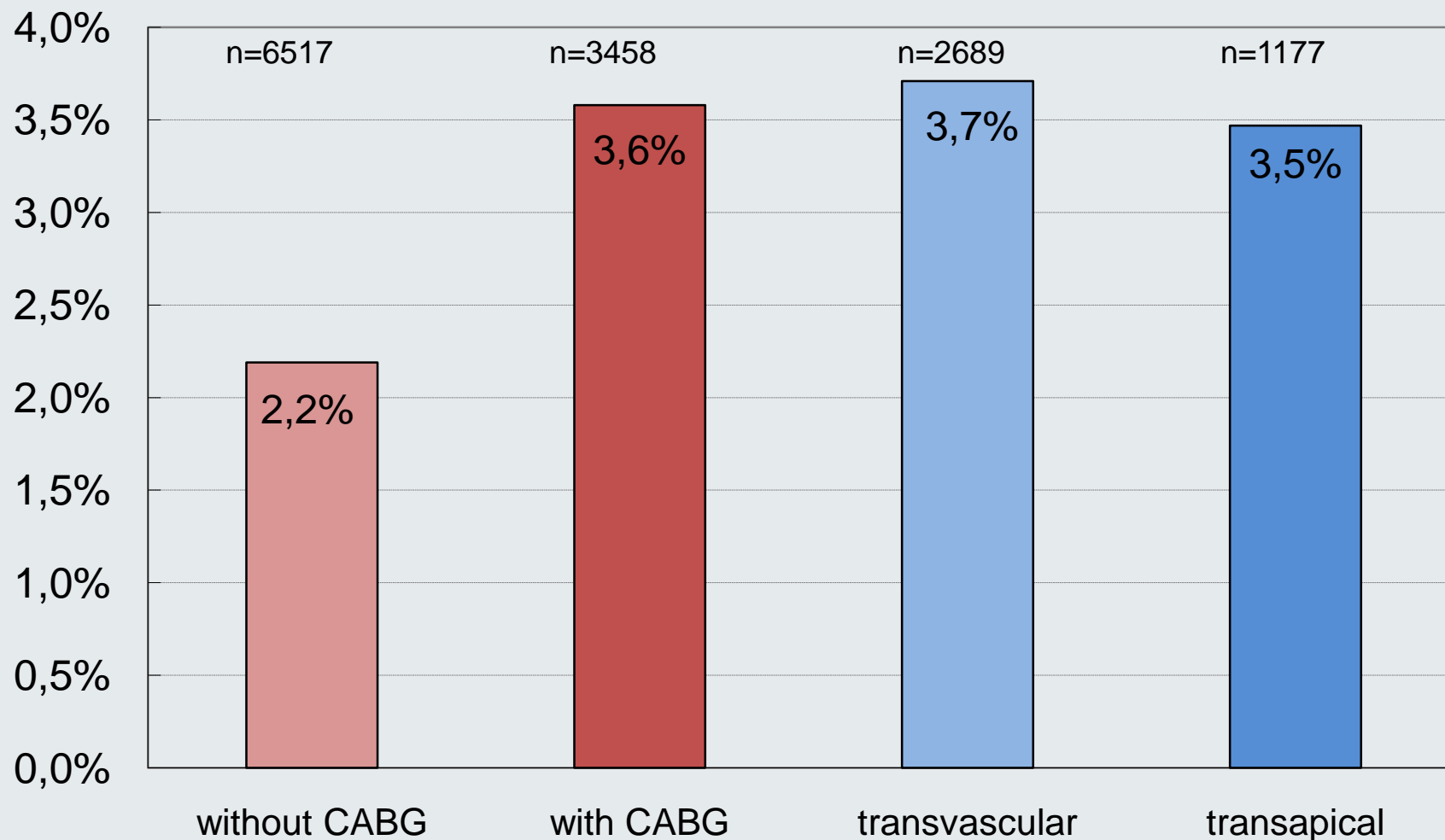
n			Log. EuroScore	Stroke / TIA 30-days
3236	TF	MCV	22 %	3.1 ±2.2 %
1733	TF	ES	26 %	4.2 ±2.2 %
2482	TA	ES	29 %	2.7 ±1.4 %

## Risk of stroke after TAVI: a meta-analysis of 10,037 published patients.

- Fifty-three studies including a total of 10,037 patients
- Procedural stroke (<24 h) occurred in  $1.5 \pm 1.4\%$
- 30-day stroke/TIA was  $3.3 \pm 1.8\%$
- Differences in stroke rates were associated with different approaches and valve prostheses used
- **lowest stroke rates after transapical TAVI ( $2.7 \pm 1.4\%$ )**

# Results – Outcome

## Cerebrovascular Events





# TAVI – permanent pacemaker

Registry	n	ES	30d mortality
German <sup>1</sup>	697	20.5	12.4%
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1 EHJ 2011

2 EHJ 2011

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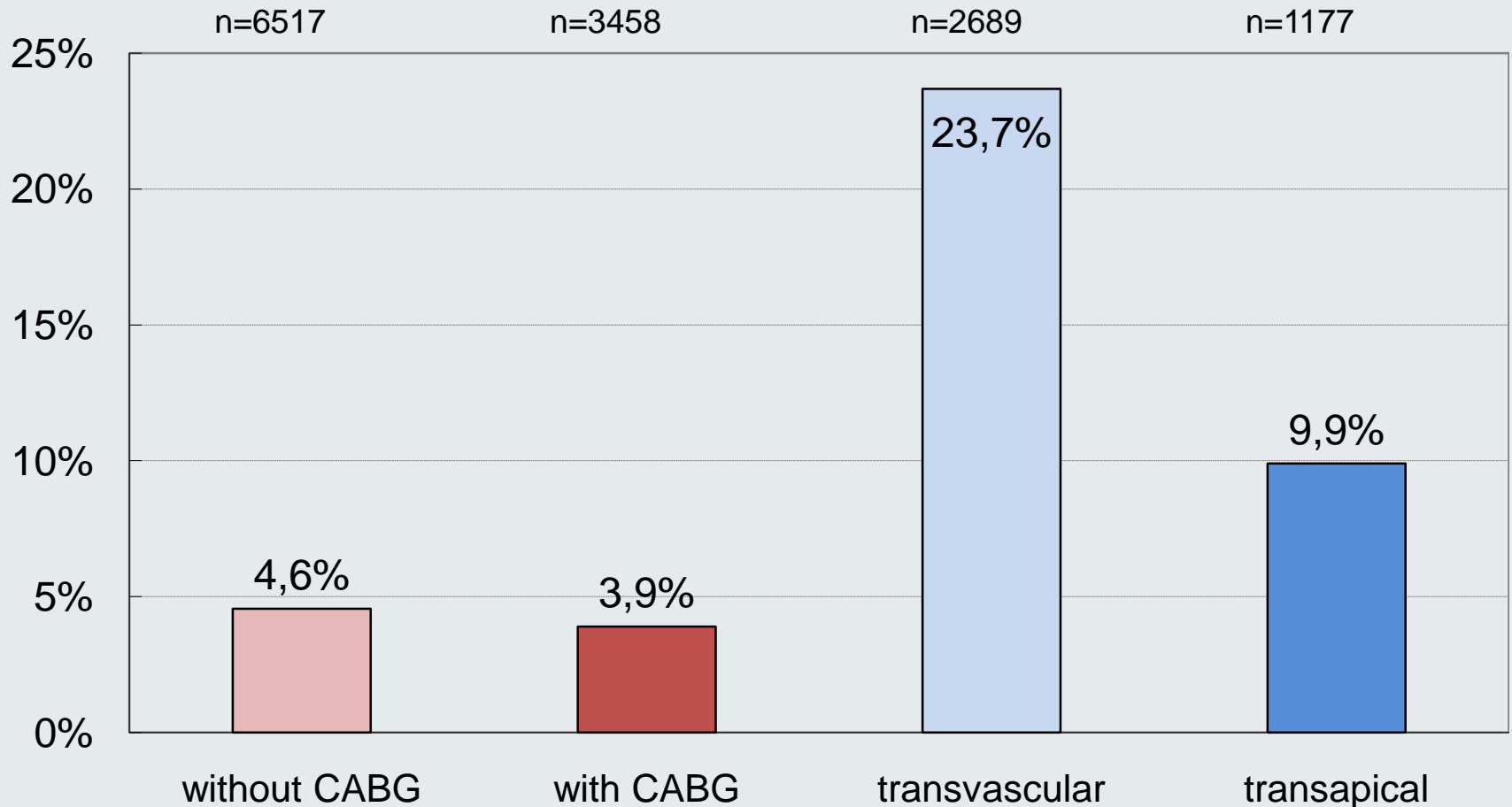
4 ICTVS 2011

5 Heart 2011



# GARY-Registry Results – Procedure

## New Pacemaker



# TAVI – paravalvular leakage

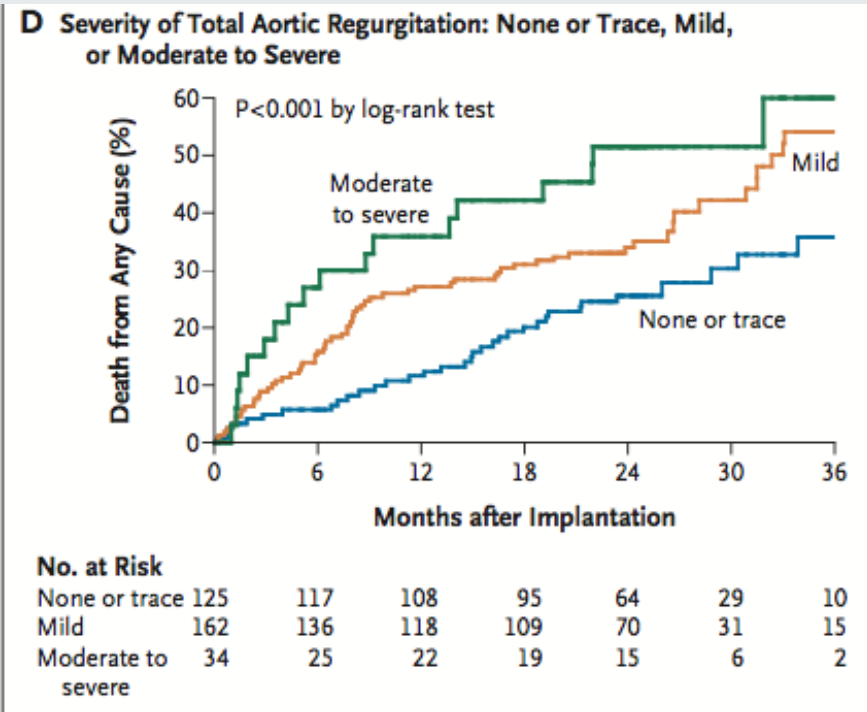
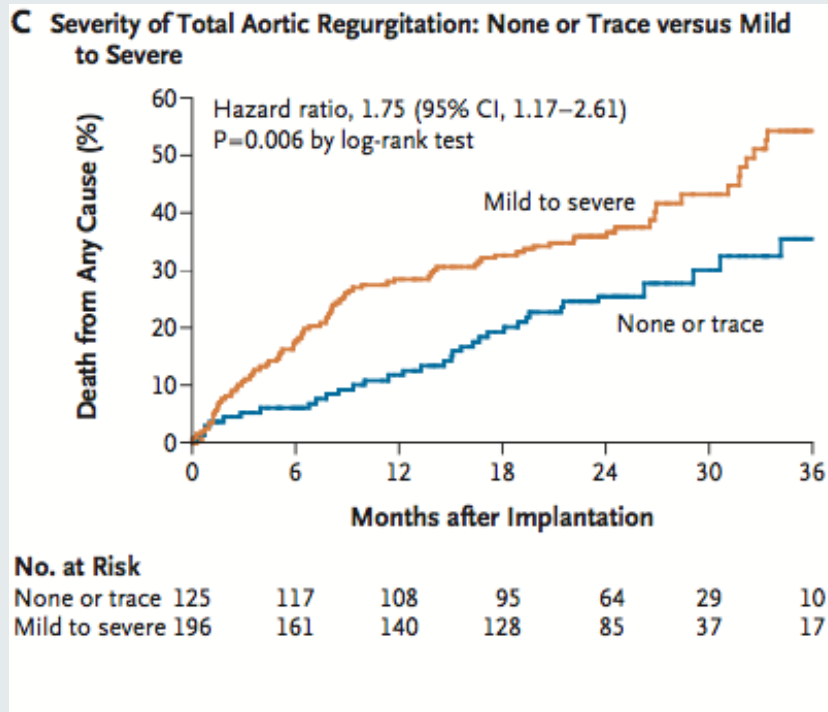
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1 EHJ 2011  
2 EHJ 2011  
3 unpublished data  
4 ICTVS 2011  
5 Heart 2011

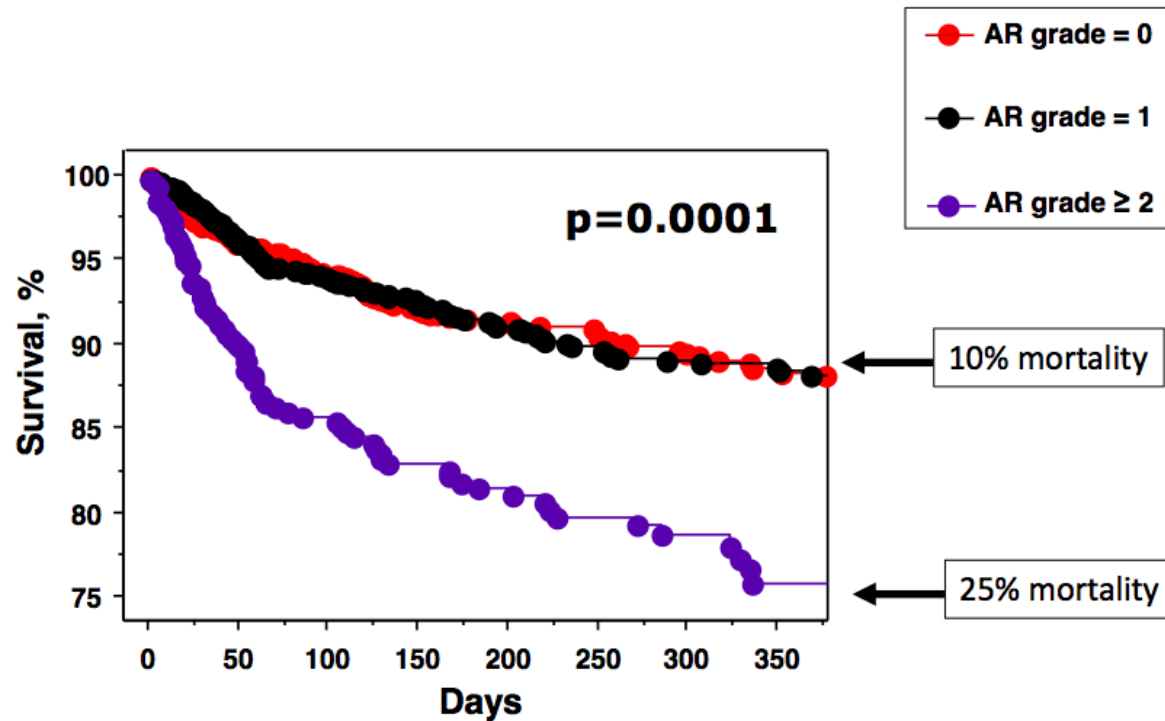
# Effect of paravalvular leakage on survival

## PARTNER 2y FU: TAVI group

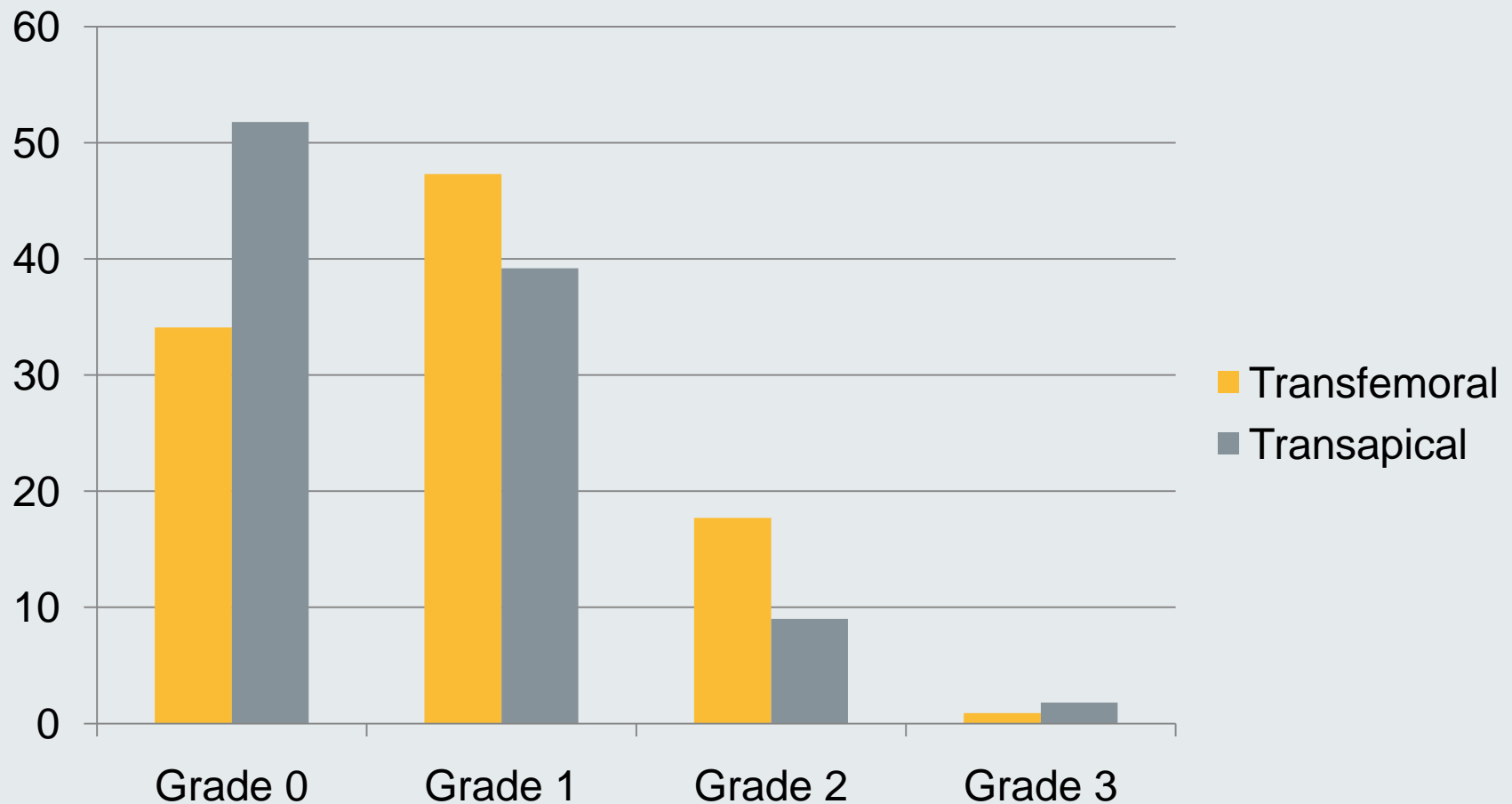


# French II Registry

## 1 year Actuarial mortality according to post-procedural aortic regurgitation



# FRANCE II Registry – rate of PVL



## Conclusion from FRENCH II Registry

- The occurrence of post-procedural perivalvular AR grade  $\geq 2$  was observed in about 15% after a successful TAVI procedure in the FRANCE2 Registry.
- Its occurrence was associated with a 2 fold increase in 1-year mortality rate and was the strongest and independent predictor of 1-year mortality.
- Among procedural parameters, the use of a Self expandable device and of a femoral delivery approach were the 2 major determinants of AR (HR $>2$ ).

# Transapical TAVI

- Technical advantages of TA approach
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JenaValve



Engager



Symetis

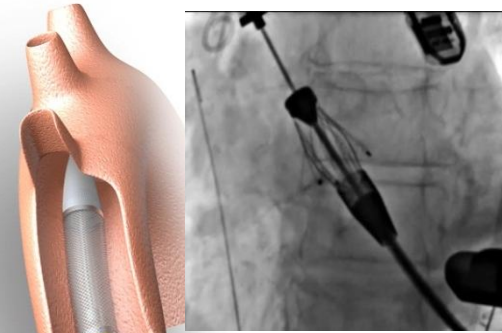
# Jena Valve - Valve Design

- Native porcine aortic valve
- Self-expanding Nitinol stent with flexible stent posts
- “Feeler” for anatomically correct positioning
- Clipping fixation to leaflets
- Sizes 23, 25, 27 mm
- Device retrieval capability



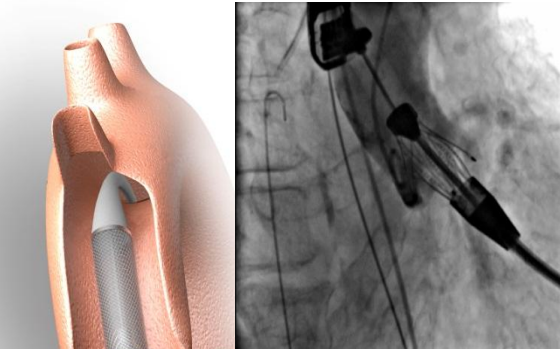
CE mark as of October 2011

# Jena Valve – Three Step Delivery System



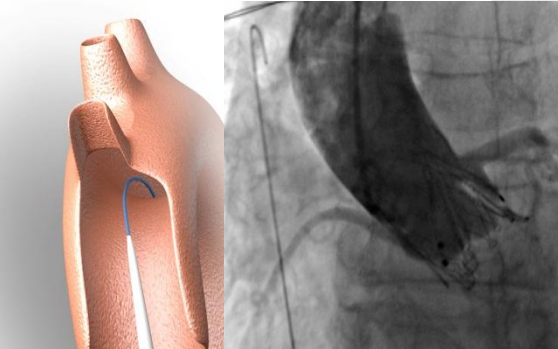
Step 1

- Unsheathing of Feelers
- Orientation of Markers
- Anatomically Correct Positioning



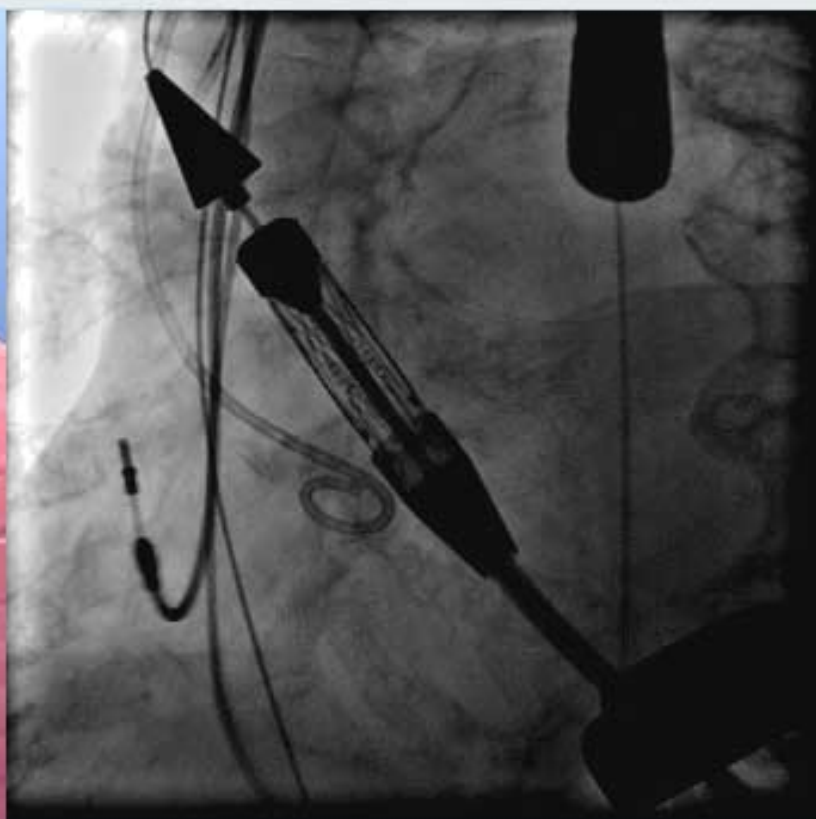
Step 2

- Clipping on native leaflets

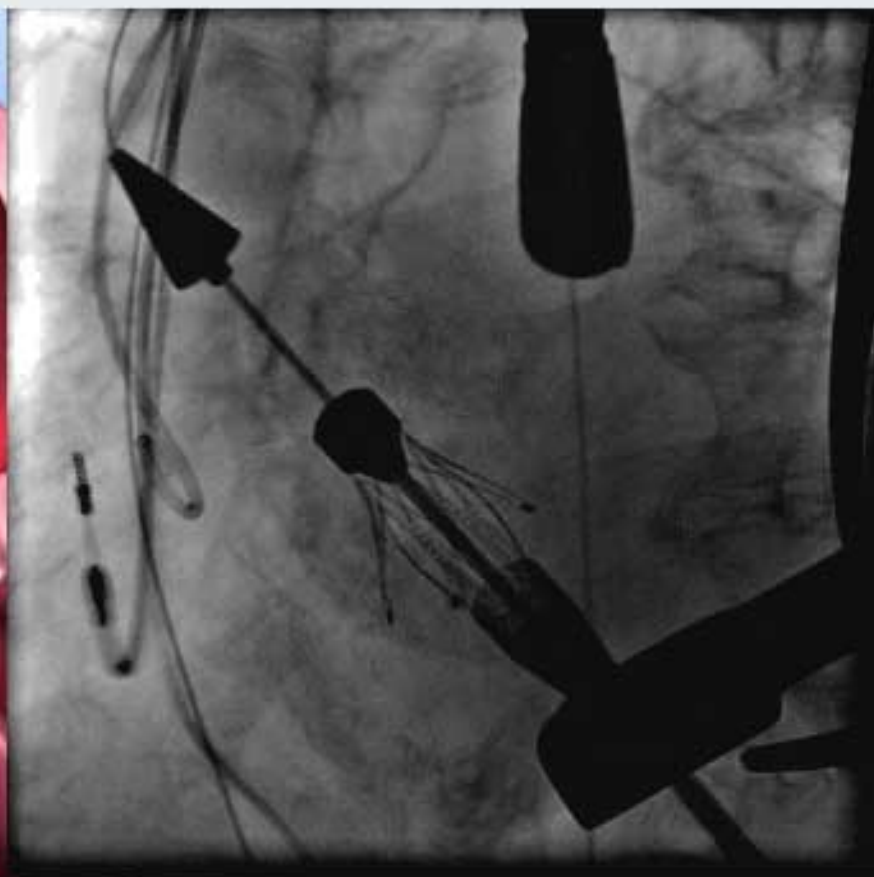


Step 3

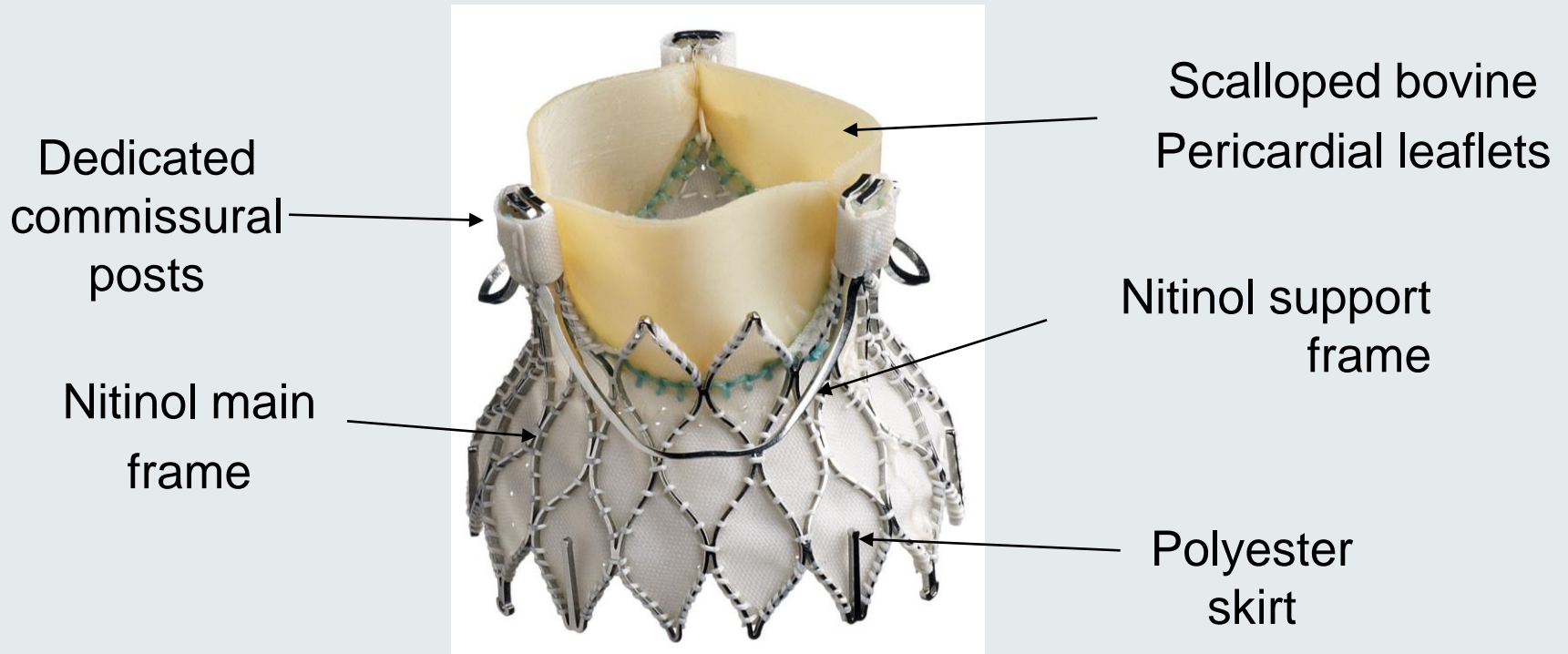
- Final Valve Release
- Correct positioning
- No Rapid Pacing needed







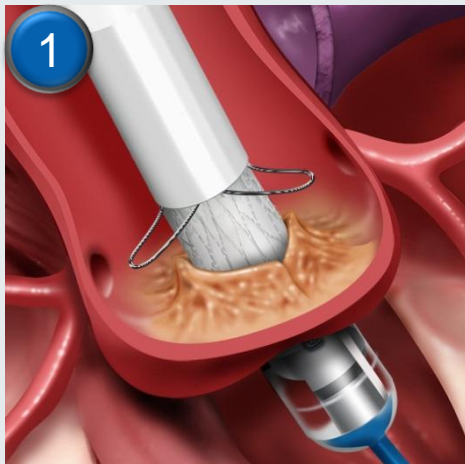
# Medtronic Engager Transcatheter Valve



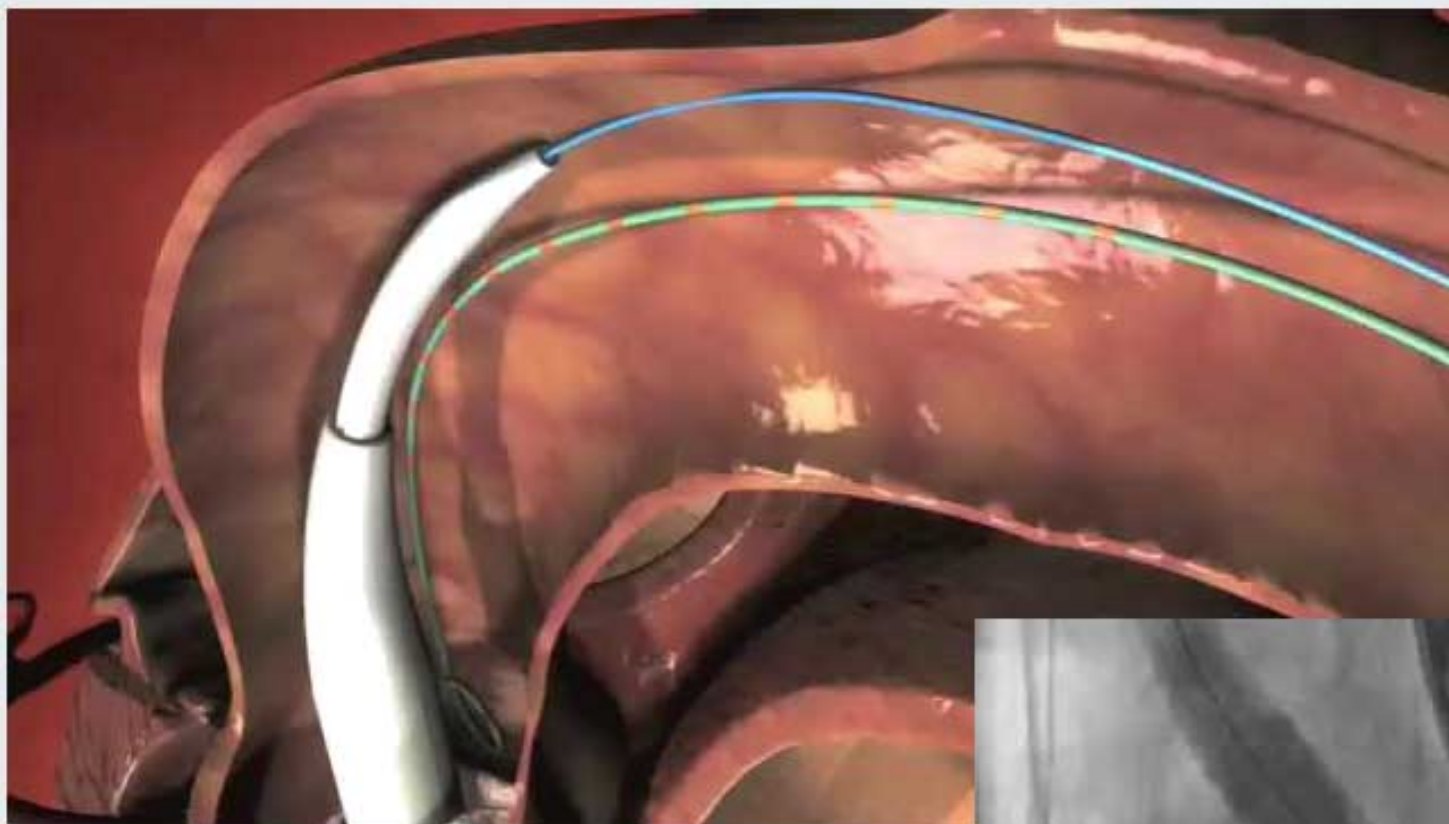
- Self-guided, reproducible, intuitive deployment into an anatomically correct supraannular position
- Relies on axial in addition to radial forces for fixation
- Leaves the coronary ostia unobstructed and accessible

# Engager Control Arm Function

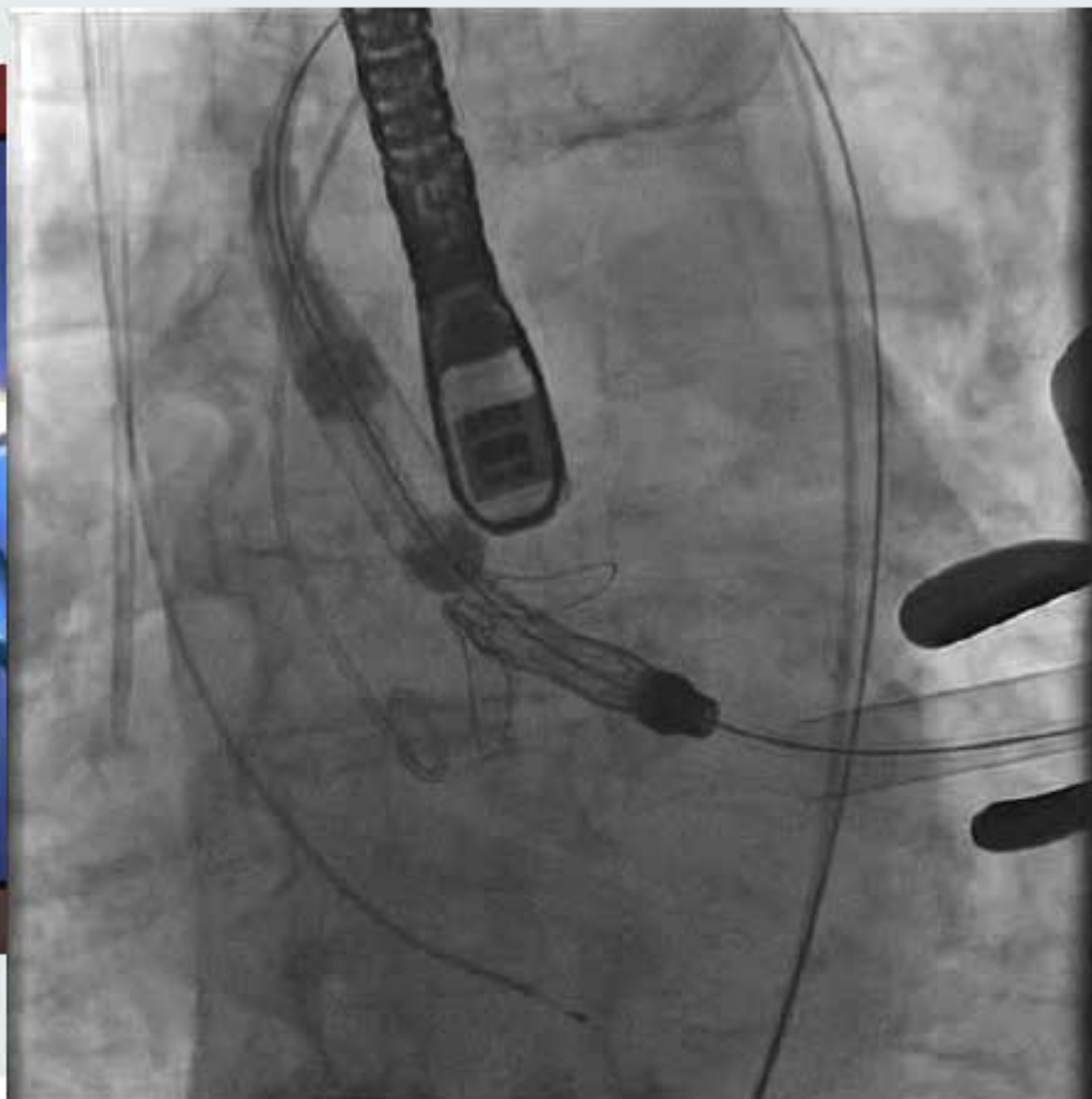
- **Precise Valve Positioning:** Control arms provide tactile feedback and stabilize bioprosthesis during deployment
- **Minimal Paravalvular Leak:** Control arms capture the native leaflets and the self-expanding frame conforms to the annulus



*Control arms are released as the first stage in device deployment and are placed in contact with the native leaflets*



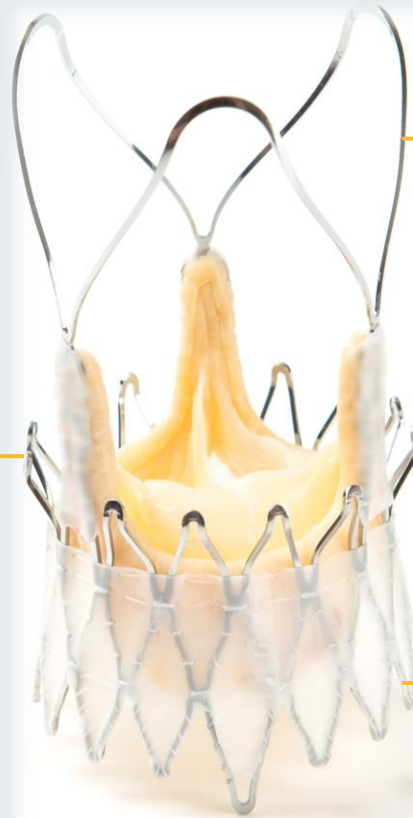






# Symetis AcurateValve (CE 2011)

- porcine aortic valve  
non coronary leaflets
- Self-expanding Nitinol
- Sizes 23, 25, 27 mm



## STABILIZATION ARCHES

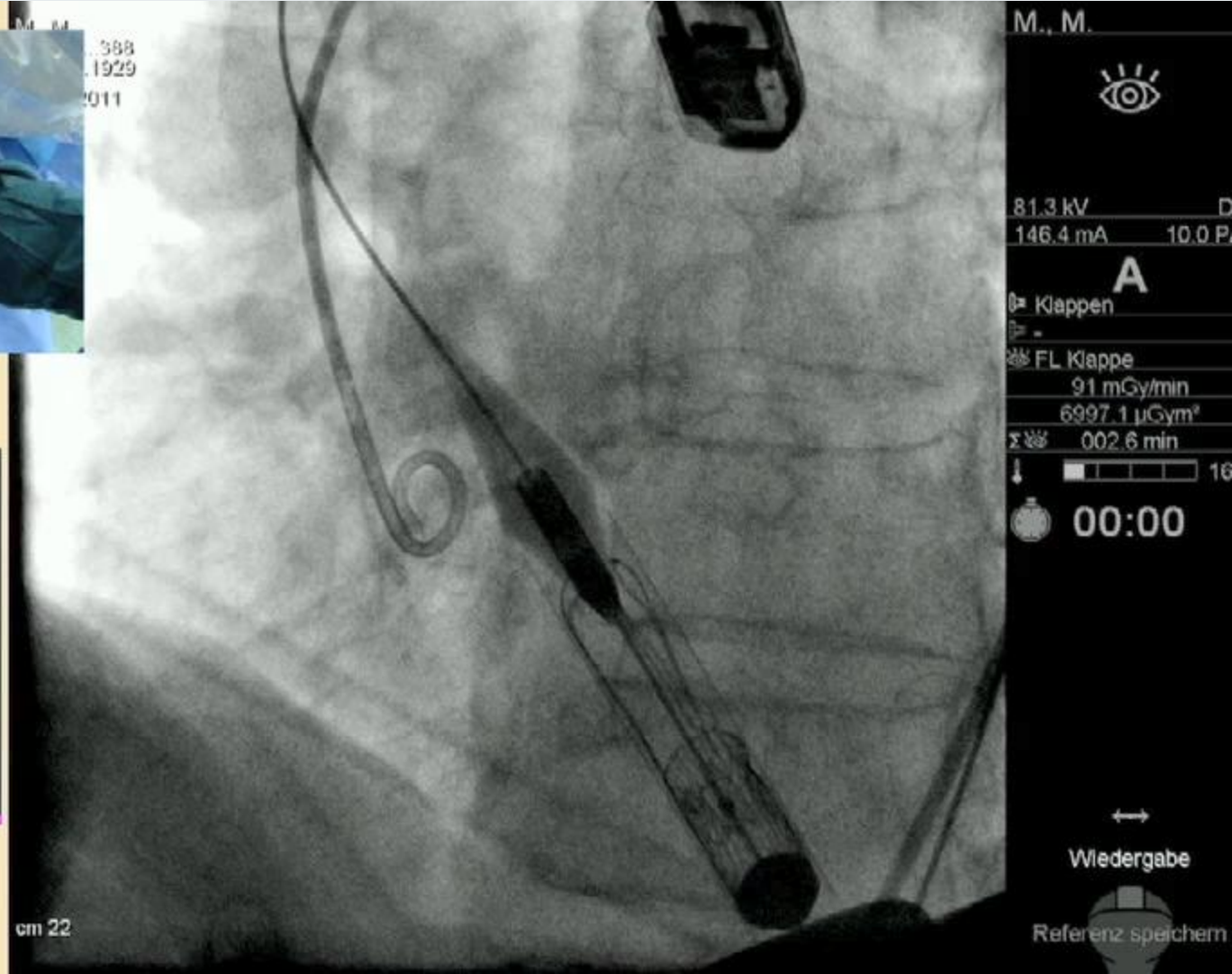
Flexible  
Self-aligning

## UPPER CROWN

Supra-annular anchoring  
Stable positioning  
Easy placement  
Tactile feedback

## LOWER CROWN / PET SKIRT

Minimal stent protrusion into LV  
Seals within the native annulus



# 30 day outcomes

	Log ES	Survival 30d	Stroke 30d	PVL 2+ or >2+	P mean	New PM
Jena (73)	28.4	92.5	3.0	13.6	10.0	10.6
Engager (61)	18.9	90.1	1.8	3.3	11.5	30.2
Symetis (90)	20.2	92.2	3.3	2.9	11.6	11.1
Symetis (250)	22.3	95.2	0.8	3.8*	12.8*	4.8
GARY (1181)	22.4	92.3	3.5	-	-	9.9

\*data from 150 pts.

# Transapical TAVI

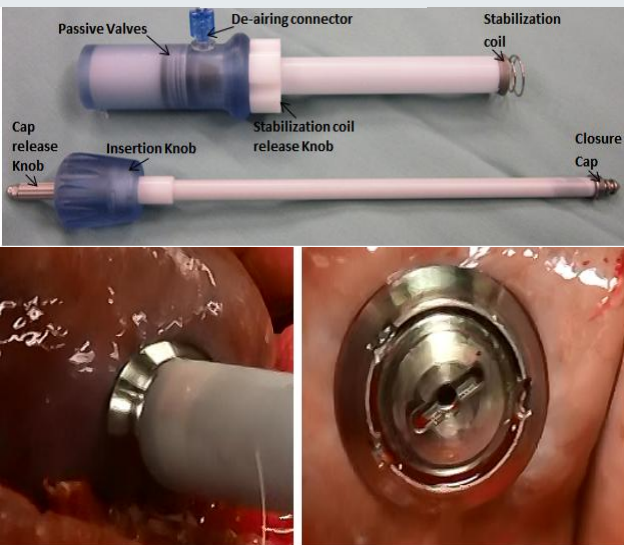
- Technical advantages of TA approach
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# TA: Occlusion devices

## *Outlook on new transapical companion devices*

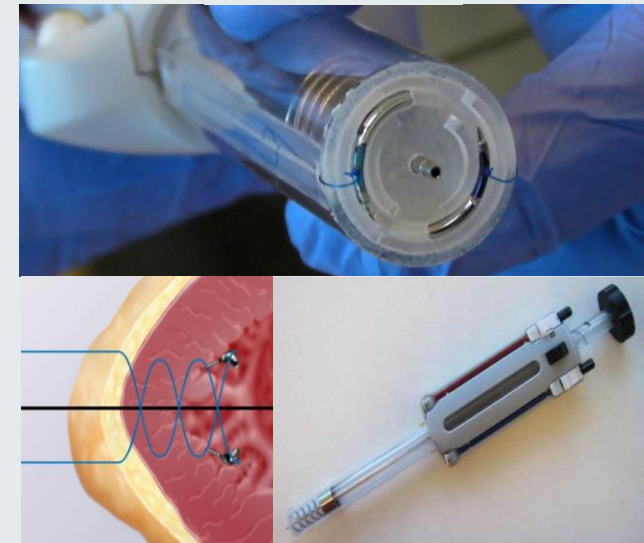
Apica



Permaseal

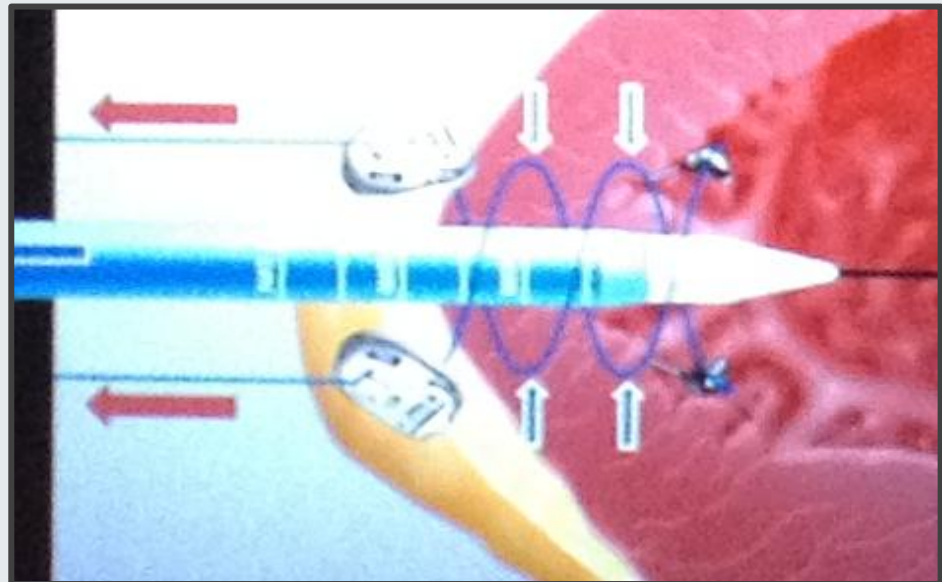


EnTourage



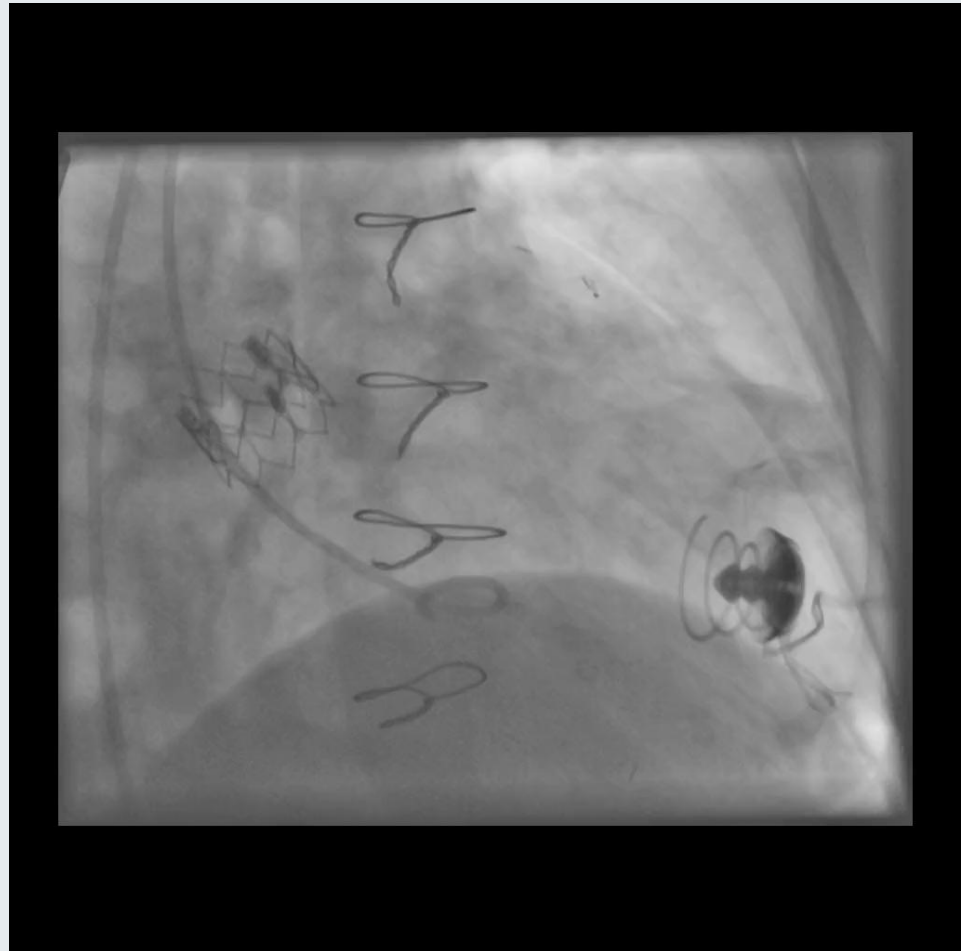
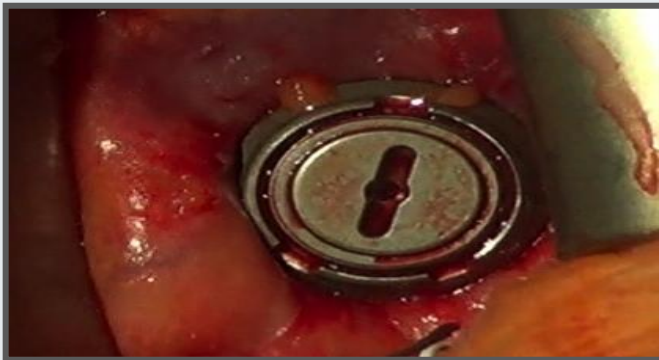
# Cardioclose™ transapical closure system

- Anchored sutures
- Potential for percutaneous access and closure





# FIH „closure device“ – Apica



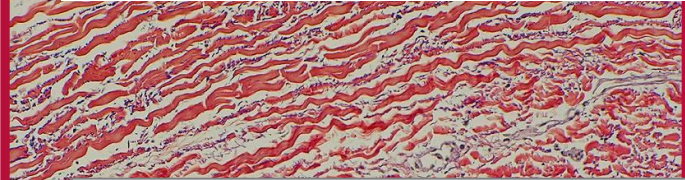


# CARDIAPEX

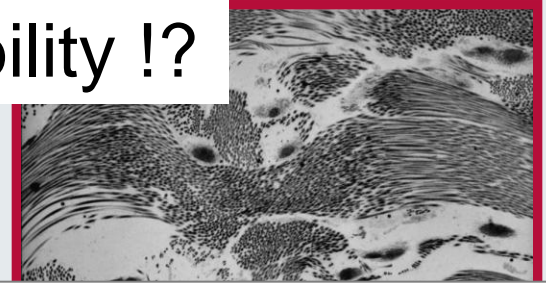
A NEW PORT INTO THE HEART

# TA - larger sheath diameter - advanced prostheses

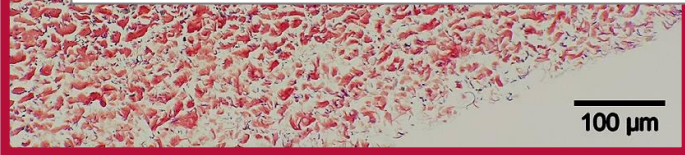
Less crimping => improved durability !?



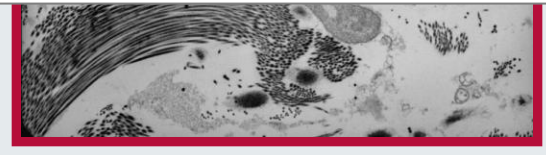
1 day crimped  
=> fragmentation



Crimping / sheath diameter may affect structural integrity



*Kiefer, Walther, et al.:  
Ann Thorac Surg 2011*



## Solutions to reduce PV leak:

- Cloth may better seal off against PV leaks.
- Hydrophilic coatings



# Transapical TAVI

- Safe antegrade approach
- Ease of implantation
- Low complication rate
- Outcomes comparable or better to TF
- No limits with regards to size or design of prosthesis



■ Aortic valve  
 ■ Mitral valve  
 ■ Mechanical Circulatory Assist systems  
 ■ Hybrid procedures  
 ■ ...

- Aortic valve
- Mitral valve
- Mechanical Circulatory Assist systems
- Hybrid procedures
- ...

