



TCTAP Seoul

TAVI: Incidence and Treatment of Procedural Complications

Eberhard Grube MD, FACC, FSCAI

Hospital Oswaldo Cruz - Dante Pazzanese, São Paulo, Brazil

University Hospital Bonn, Germany

Stanford University, Palo Alto, California, USA



Background

For patients at increased surgical risk and those not suitable candidates for SAVR, transcatheter aortic valve implantation (TAVI) has emerged as a promising less-invasive treatment option, with a growing body of evidence on safety and efficacy in this particular patient population.

TAVI is very feasible with procedural success rates ranging between 90%-99% in latest registries

Some complications have been identified to be of relevance



Complications in TAVI

Mortality

Stroke

Vascular complications

Pacemaker

Paravalvular regurgitation

TAVI versus SAVR

PARTNER A- Safety

	30 Days			1 Year		
	TAVI (N = 348)	AVR (N = 351)	p-value	TAVI (N = 348)	AVR (N = 351)	p-value
All mortality – no. (%)	12 (3.4)	22 (6.5)	0.07	84 (24.2)	89 (26.8)	0.44
Cardiac mortality	11 (3.2)	10 (3.0)	0.9	47 (14.3)	40 (13.0)	0.63
Myocardial infarction	0	2 (0.6)	0.16	1 (0.4)	2 (0.6)	0.69
Acute kidney injury	10 (2.9)	10 (3.0)	0.95	18 (5.4)	20 (6.5)	0.56
Vascular complications						
All	59 (17.0)	13 (3.8)	<0.01	62 (18.0)	16 (4.8)	<0.01
Major	38 (11.0)	11 (3.2)	<0.01	39 (11.3)	12 (3.5)	<0.01
Major bleeding	32 (9.3)	67 (19.5)	<0.01	49 (14.7)	85 (25.7)	<0.01
Endocarditis	0 (0.0)	1 (0.3)	0.32	2 (0.6)	3 (1.0)	0.63
New pacemaker	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68
All Stroke or TIA	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
TIA	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
Major Stroke	13 (3.8)	7 (2.1)	0.2	17 (5.1)	8 (2.4)	0.07
Minor Stroke	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84



Complications in TAVI

Mortality

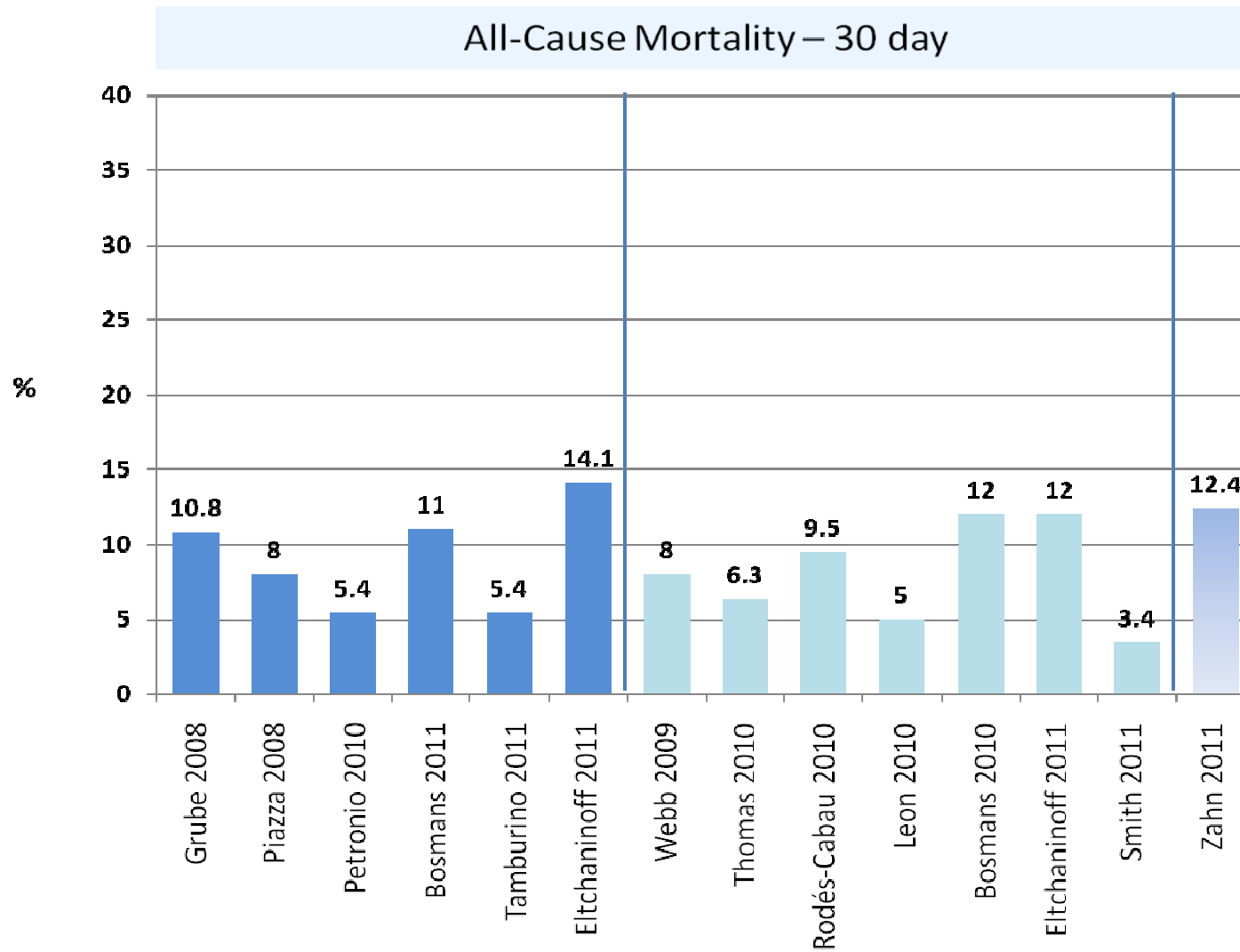
Stroke

Vascular complications

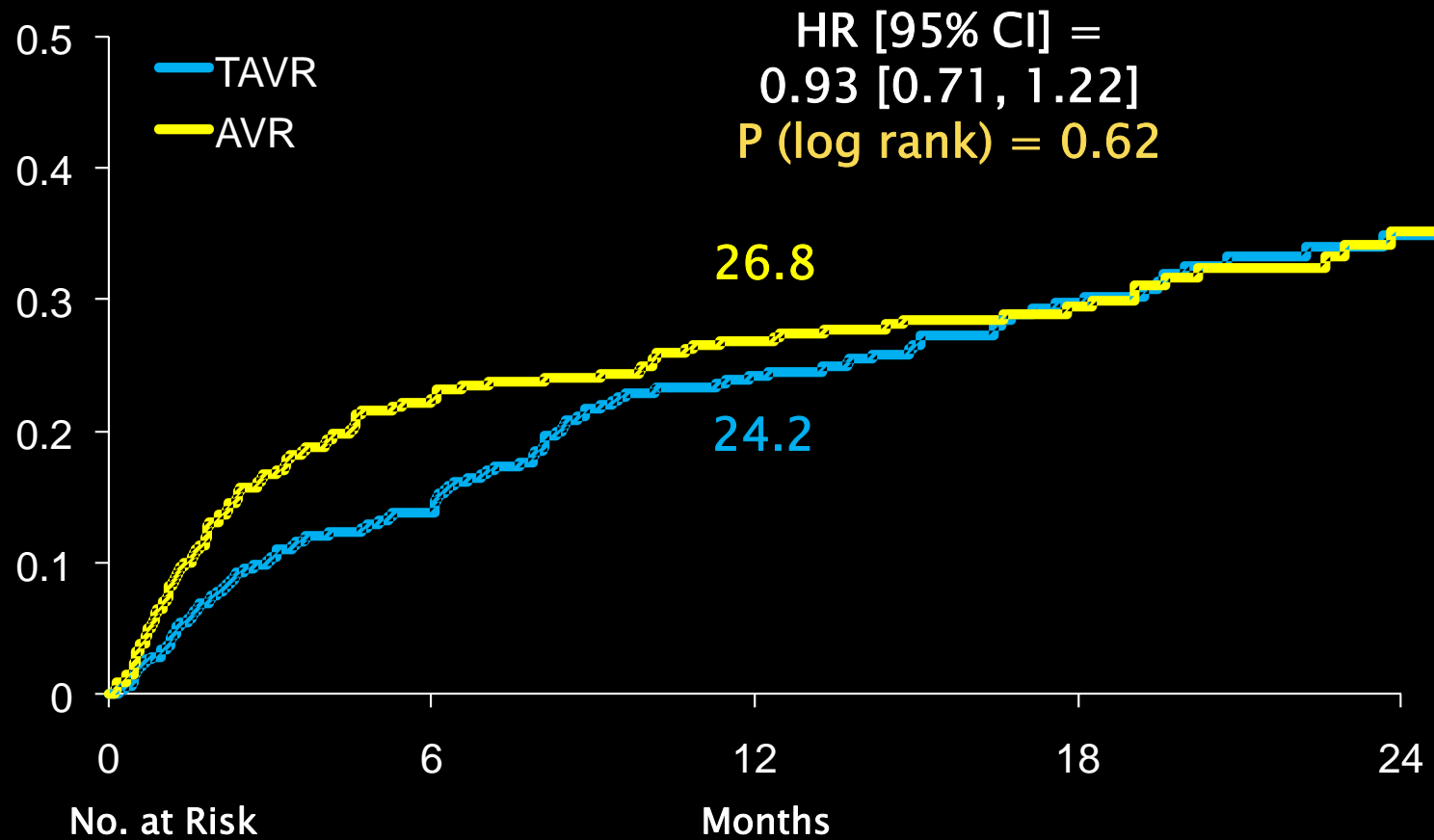
Pacemaker

Paravalvular regurgitation

Complications in TAVI



PARTNER: Mortality at 12 months



No. at Risk

Months

348

TAVR

260

147

67

351

AVR

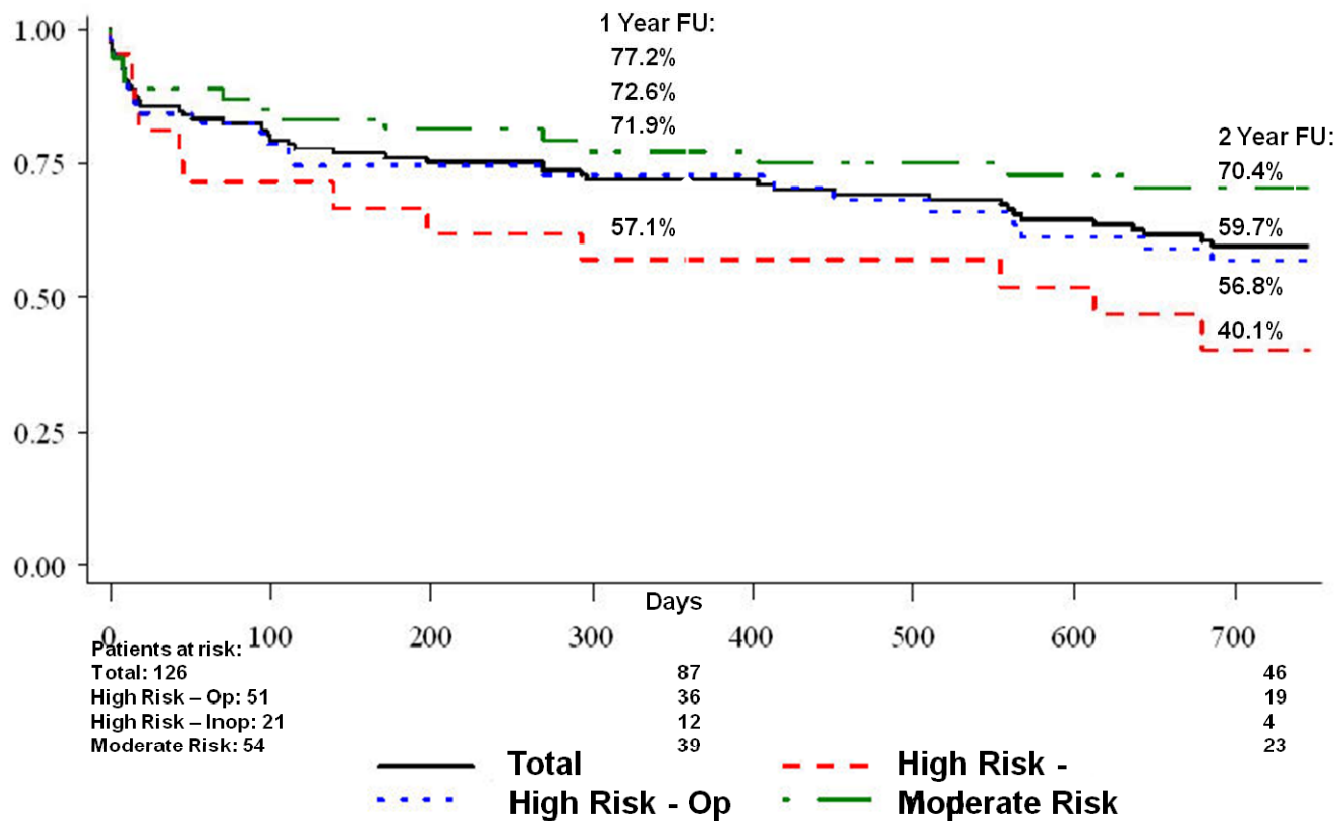
236

139

65

Long-term Outcome of TAVI With CoreValve

Two Year Survival – 18 French Safety and Efficacy Study





Complications in TAVI

Mortality

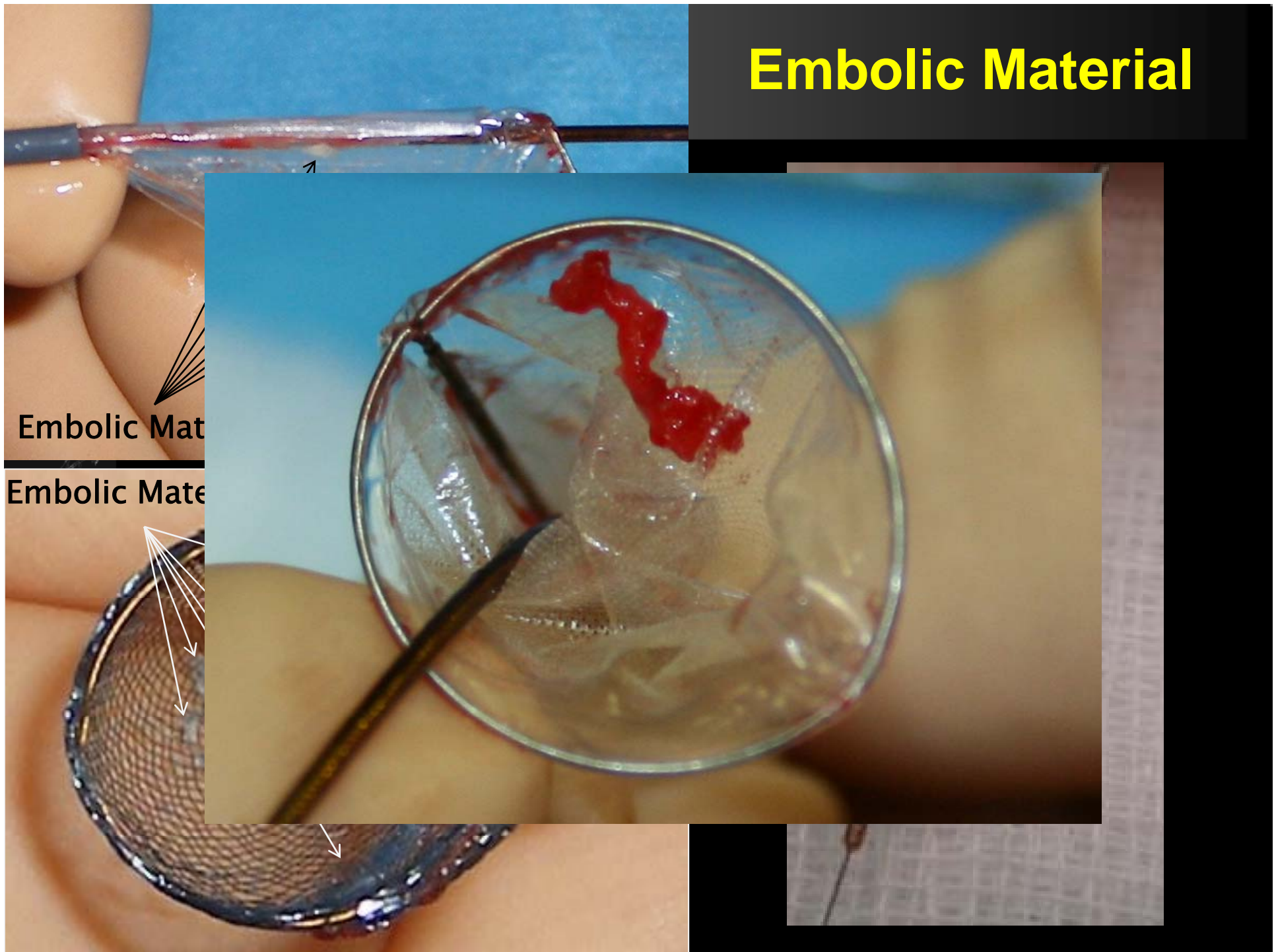
Stroke

Vascular complications

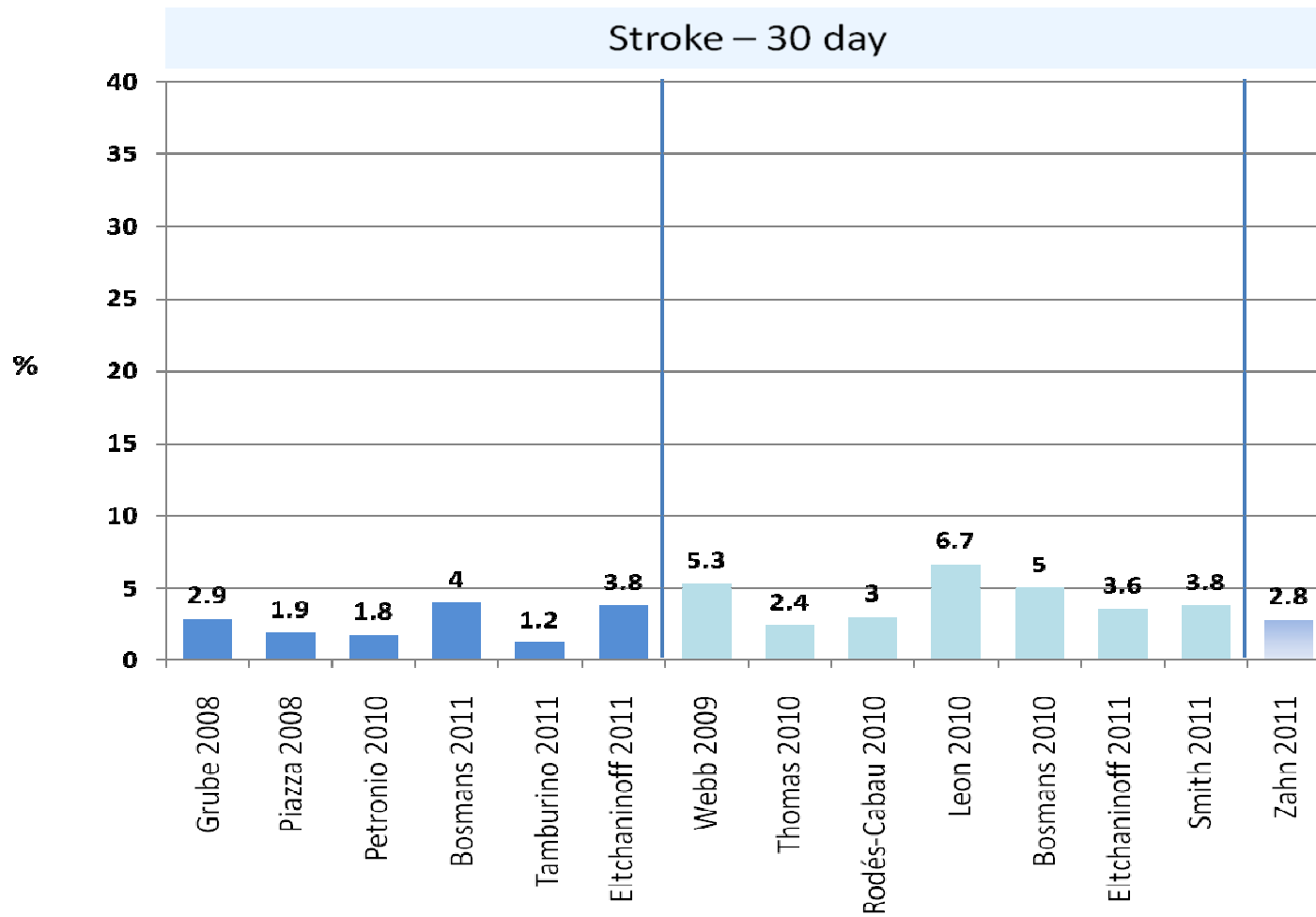
Pacemaker

Paravalvular regurgitation

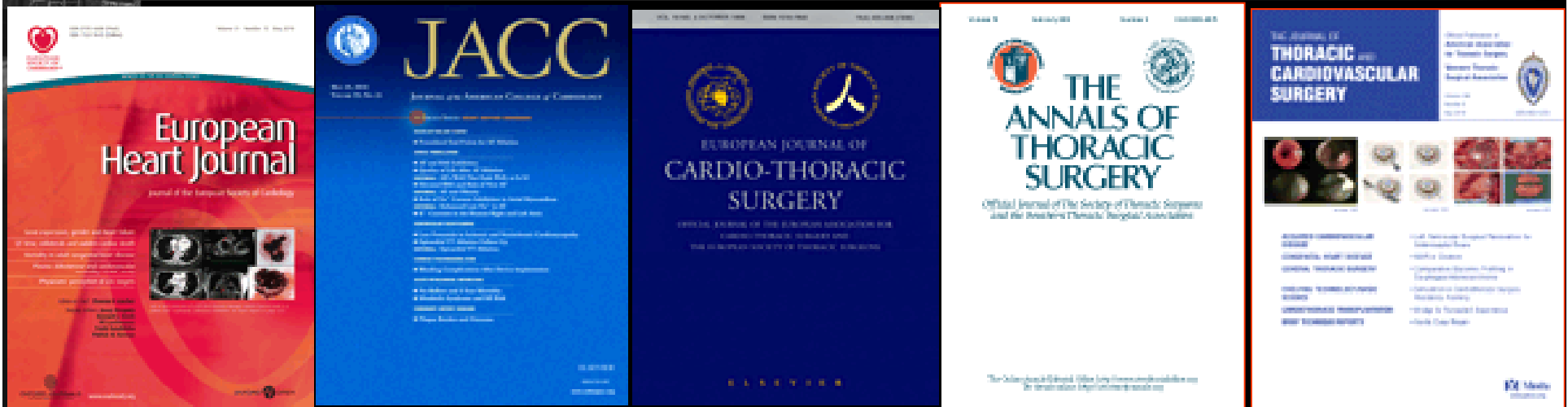
Embolic Material



Complications in TAVI



VARC Endpoint Definitions



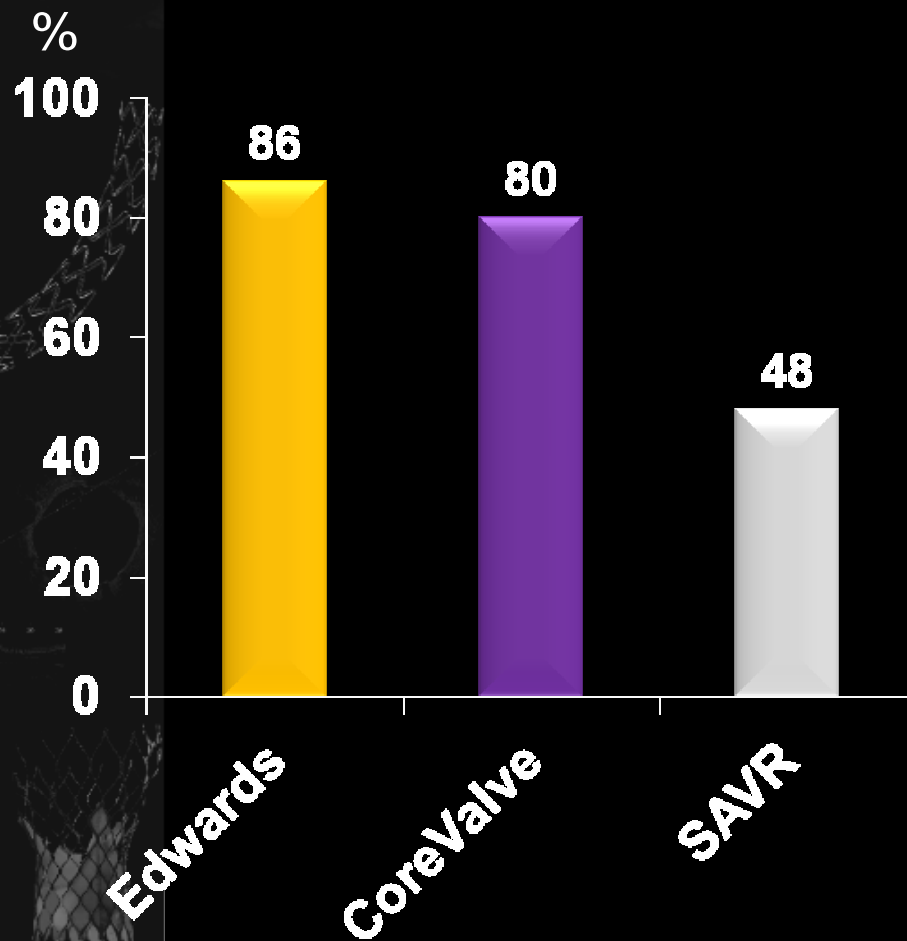
STANDARDIZED ENDPOINT DEFINITIONS FOR TRANSCATHETER AORTIC VALVE IMPLANTATION CLINICAL TRIALS: A CONSENSUS REPORT FROM THE VALVE ACADEMIC RESEARCH CONSORTIUM

Martin B. Leon, Nicolo Piazza, Eugenia Nikolsky, Eugene H. Blackstone, Donald E. Cutlip, A. Pieter Kappetein, Mitchell W. Krucoff, Michael Mack, Roxana Mehran, Craig Miller, Marie-angele Morel, John Petersen, Jeffrey J. Popma, Johanna J. M. Takkenberg, Alec Vahanian, Gerrit-Anne van Es, Pascal Vranckx, John G. Webb, Stephan Windecker, and Patrick W. Serruys

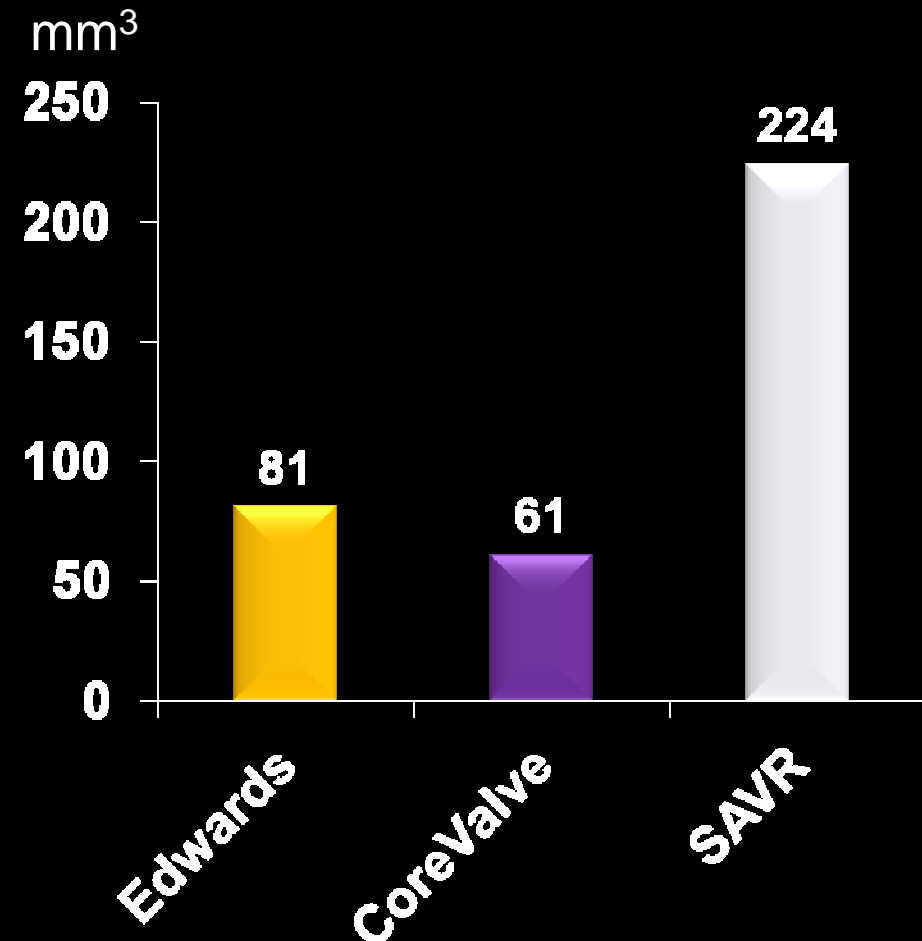
Cerebral Ischemia After TAVI

Kahlert PK et al. *Circulation* 2010;121:870-878

New Lesions



Lesion Volume

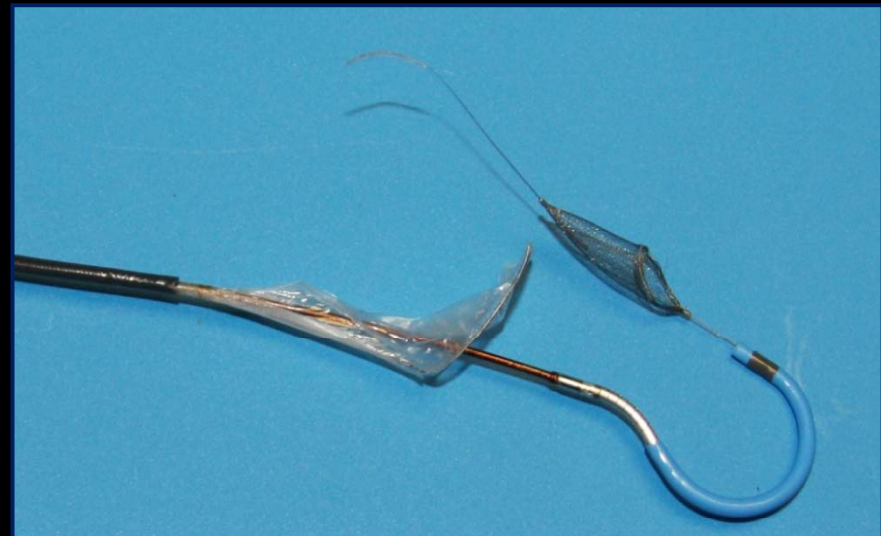


Cerebral Embolic Protection Device

Goal – to improve the safety of the procedure



**Embrella Embolic
Deflector Device**



Claret Dual Filter Device



Complications in TAVI

Mortality

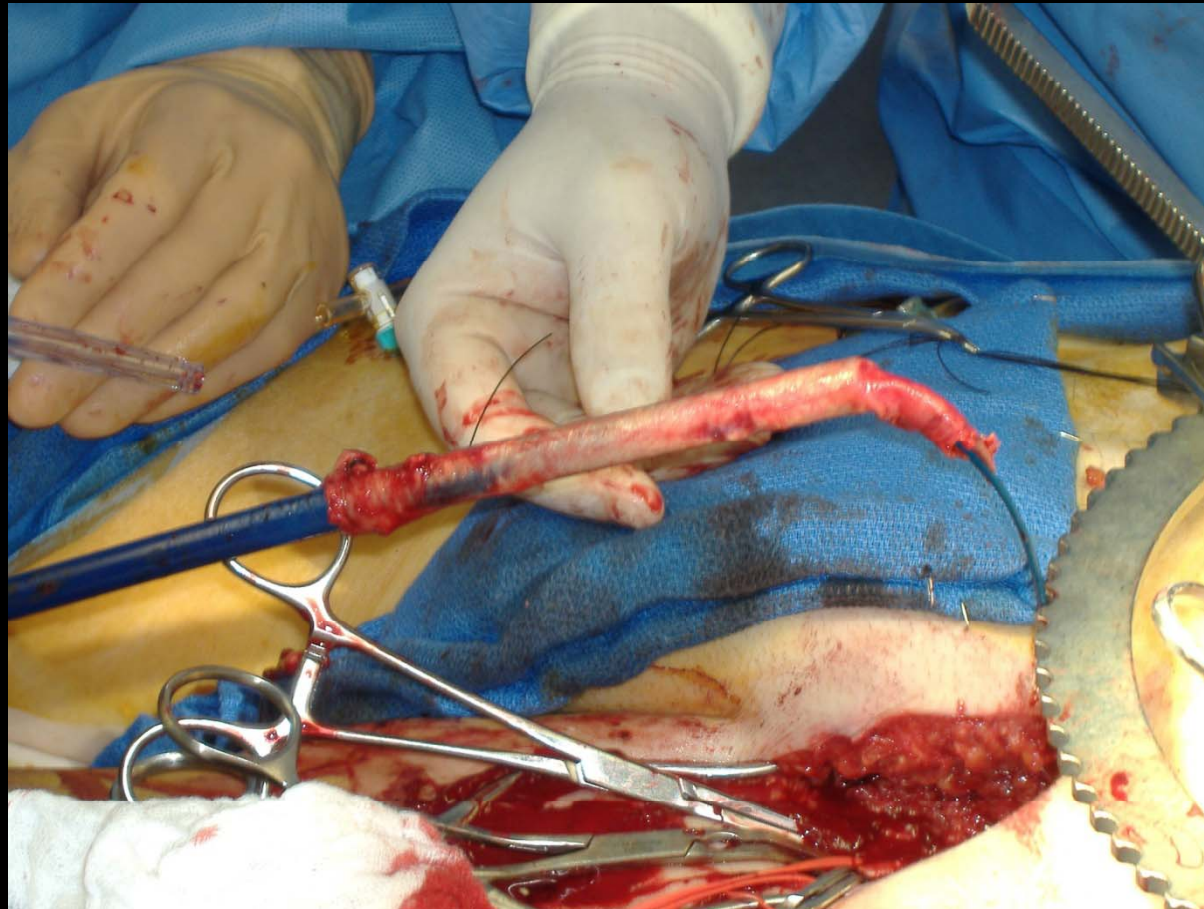
Stroke

Vascular complications

Pacemaker

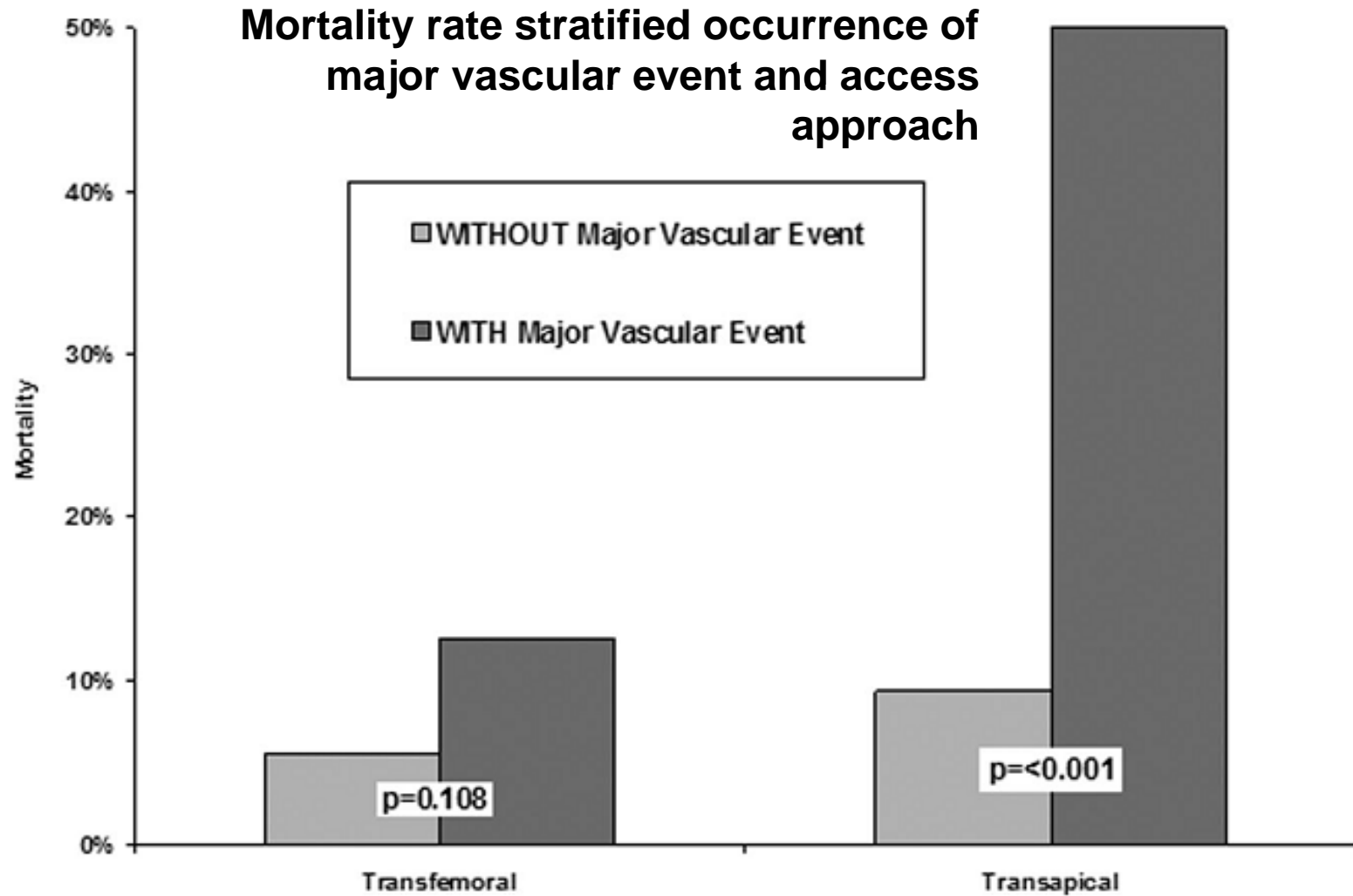
Paravalvular regurgitation

Early Generation TAVI with large profile resulting in ruptured iliac artery



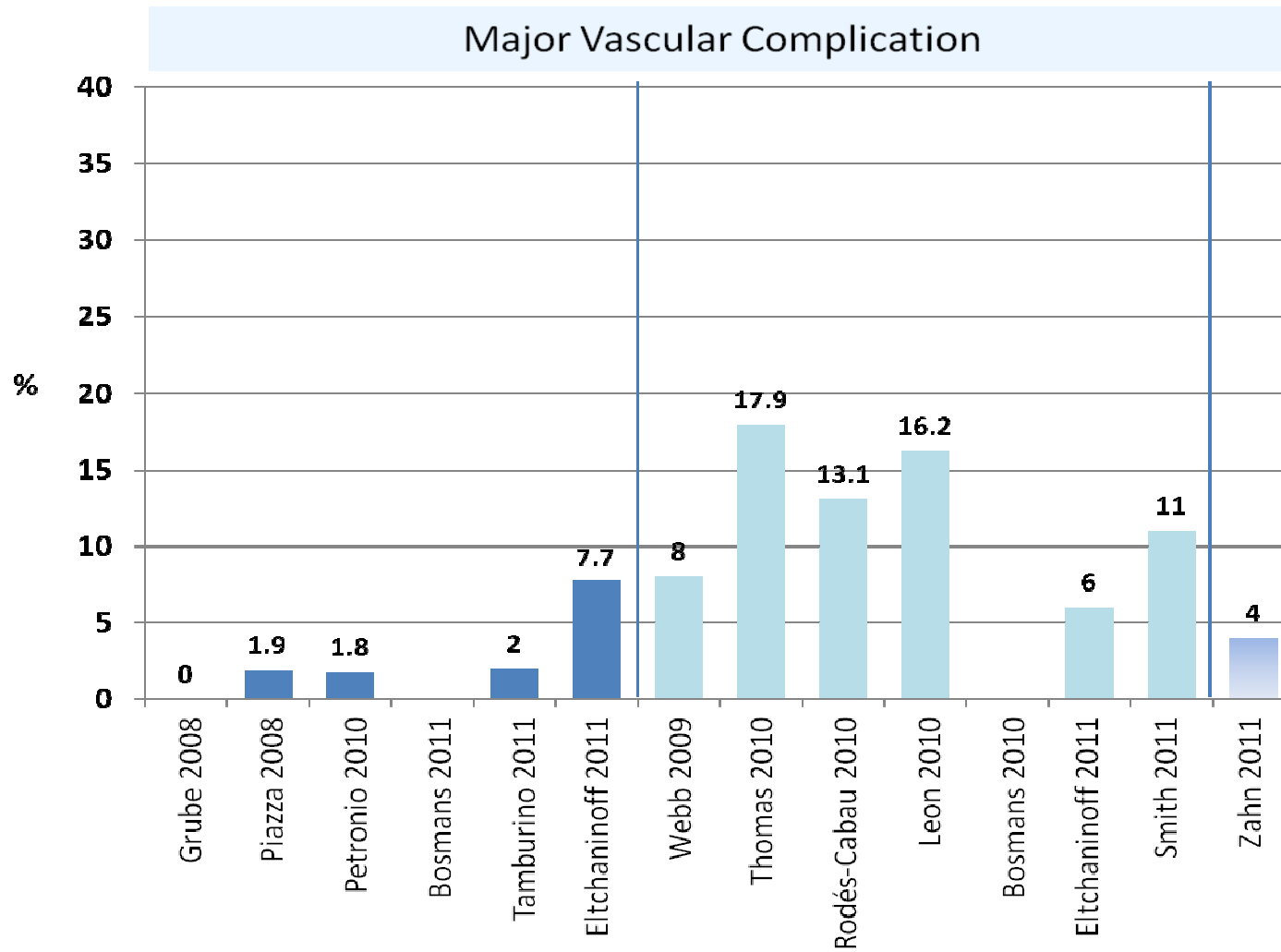
***Surgery is your best friend
- when you are struggling at the latest***

Complications in TAVI



SOURCE Trial

Complications in TAVI



NovaFlex transfemoral delivery system



18 Fr and 19 Fr delivery systems
Minimum ilio-femoral diameter:
6mm

Flexible nose cone

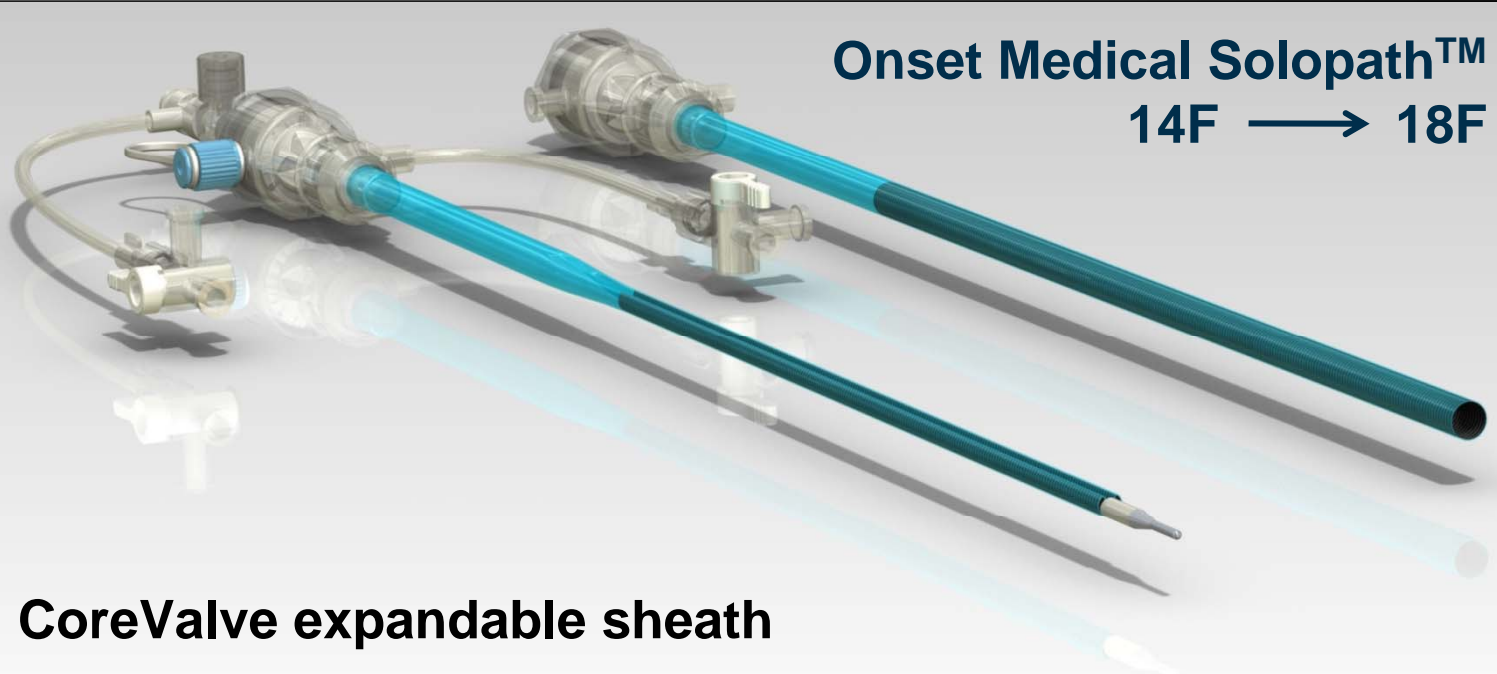


Shorter, softer tip

**New balloon processing for intra-aortic stent
mounting**



Expandable Sheath





Complications in TAVI

Mortality

Stroke

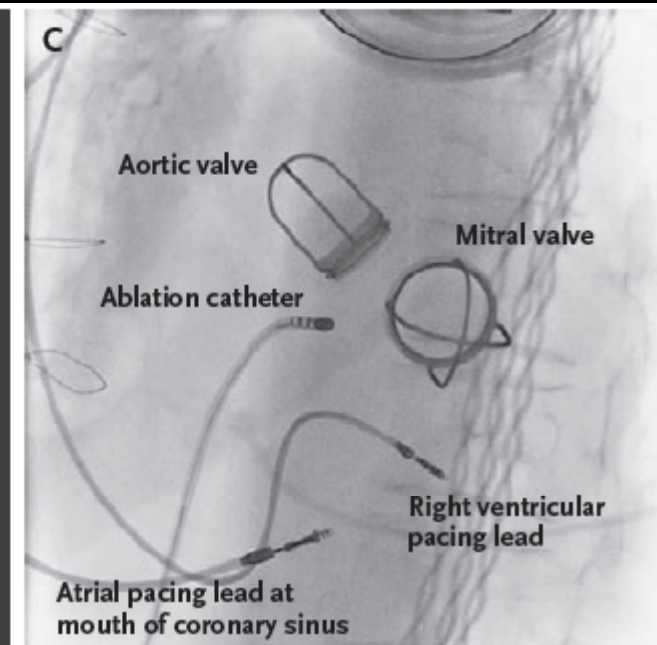
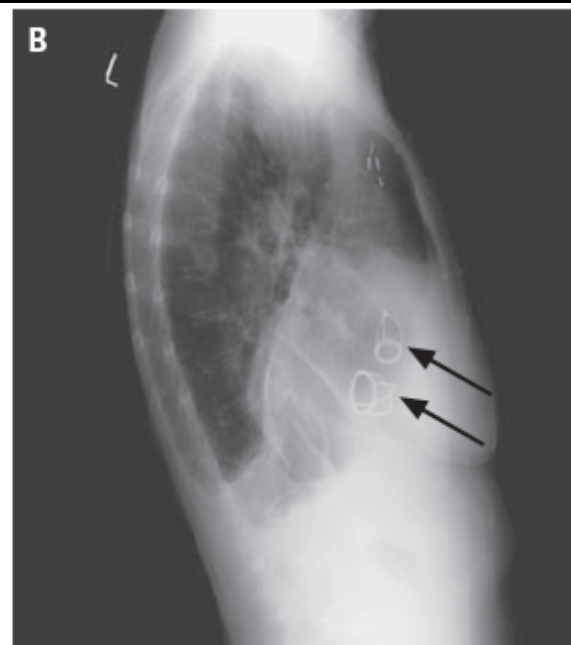
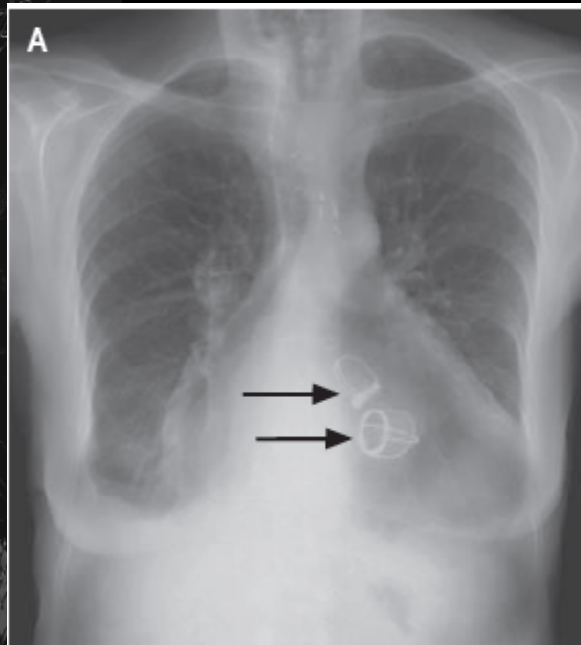
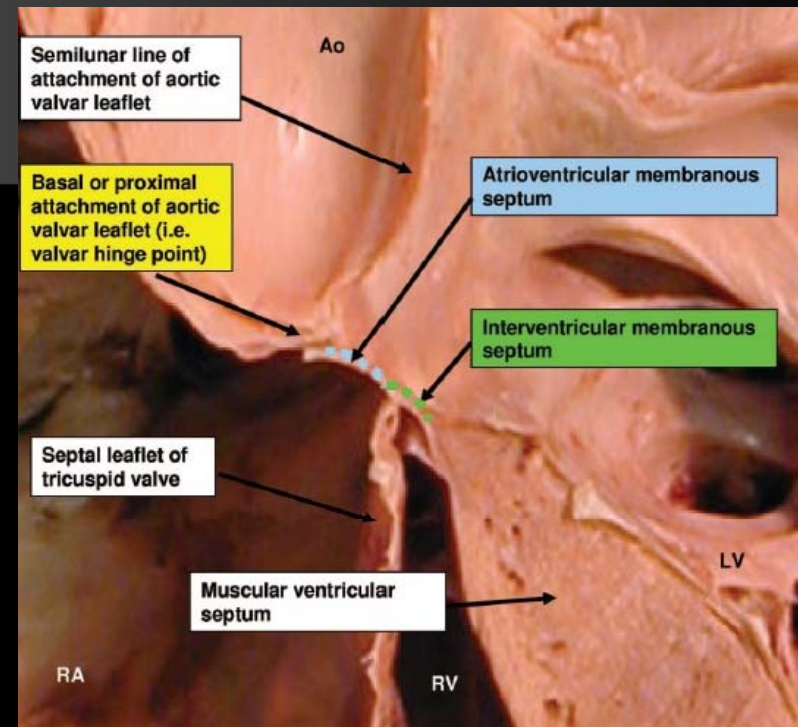
Vascular complications

Pacemaker

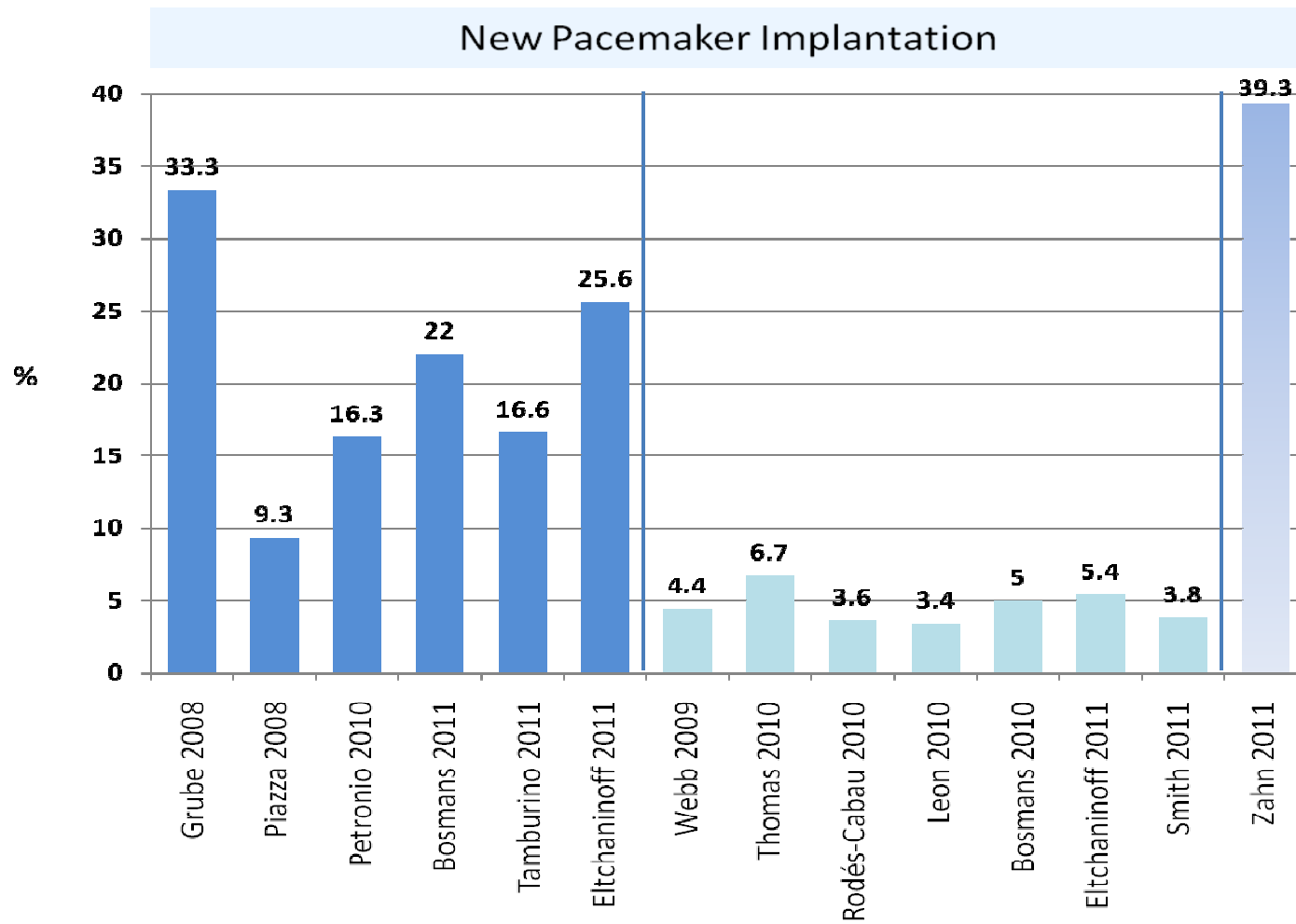
Paravalvular regurgitation

Relationship of the Aortic Valve and the Conduction System

Epstein A et al. *N Engl J Med* 2007;357:2706
Piazza N et al. *Circ Cardiovasc Interv* 2008;1:74-81

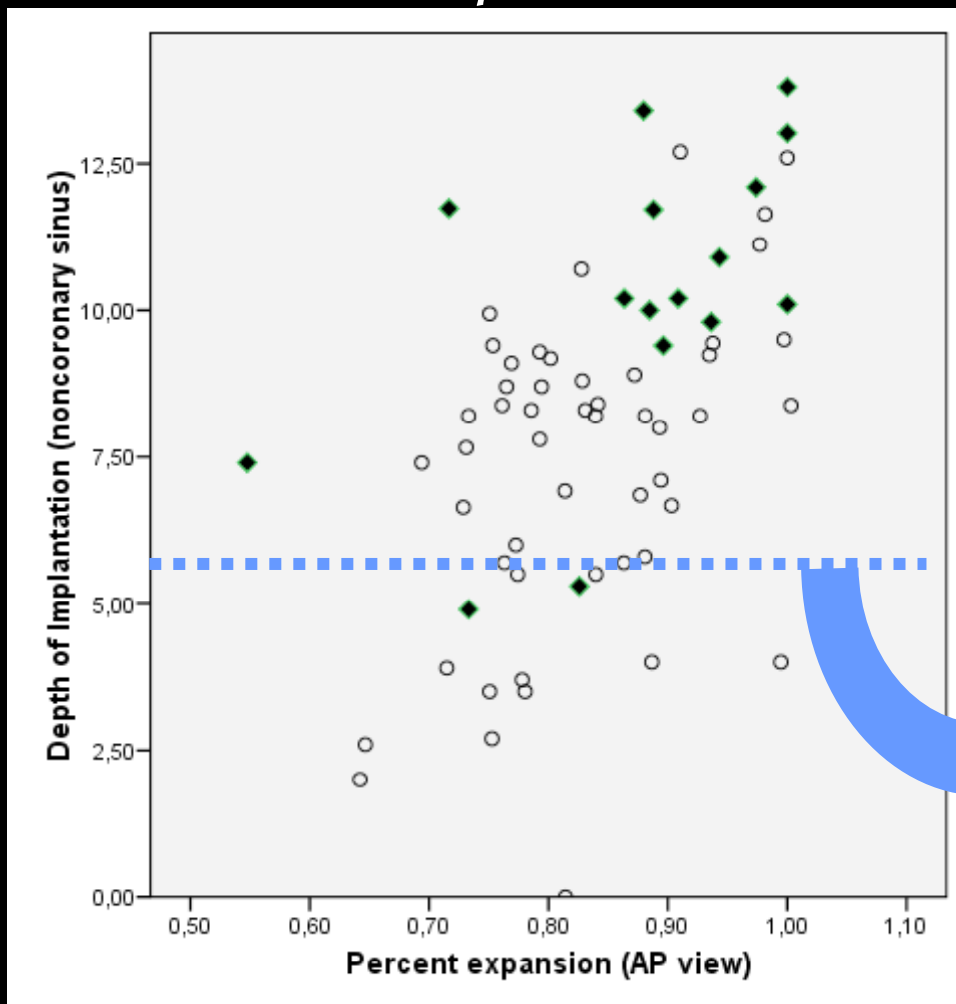


Complications in TAVI




Depth of Implantation May Play a Role in the Onset of Rhythm Disturbances

Rotterdam Experience (n=91)



 *New-onset LBBB acquired during or after valve implantation*
10.3 mm

 *No new-onset LBBB or new-onset LBBB acquired during procedure but before valve implantation*
7.3 mm

6.0 mm



Complications in TAVI

Mortality

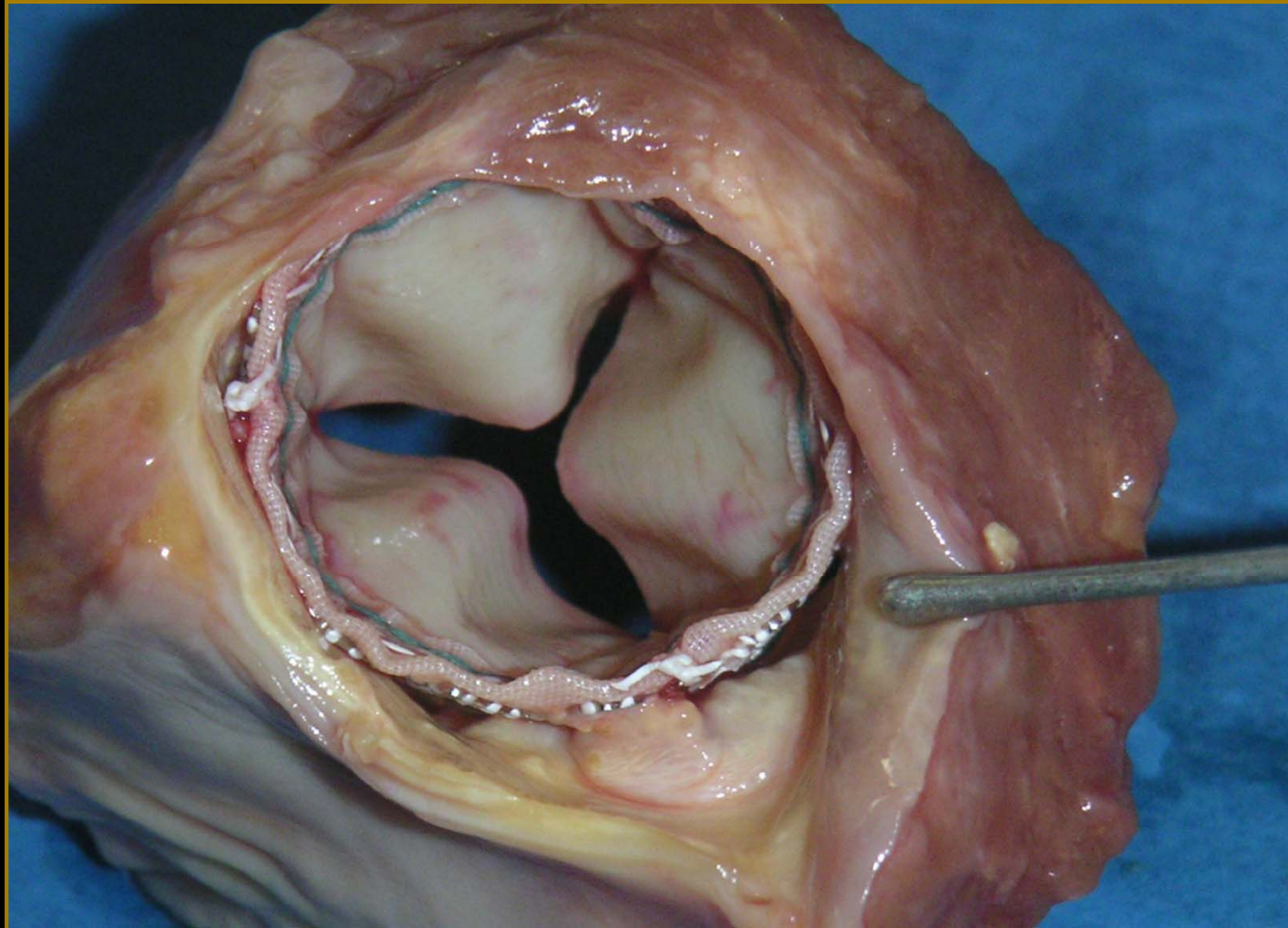
Stroke

Vascular complications

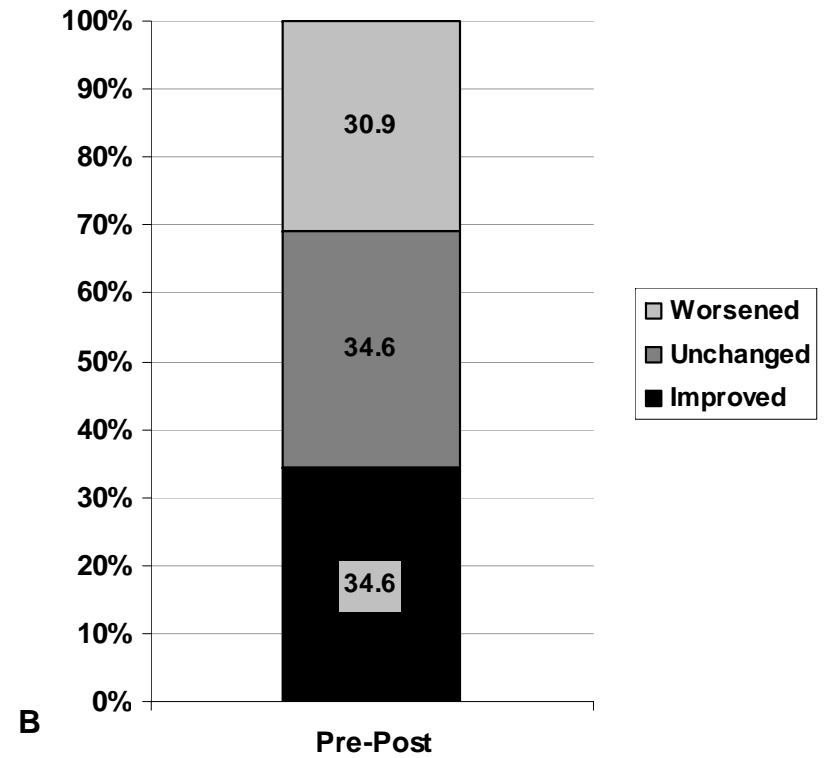
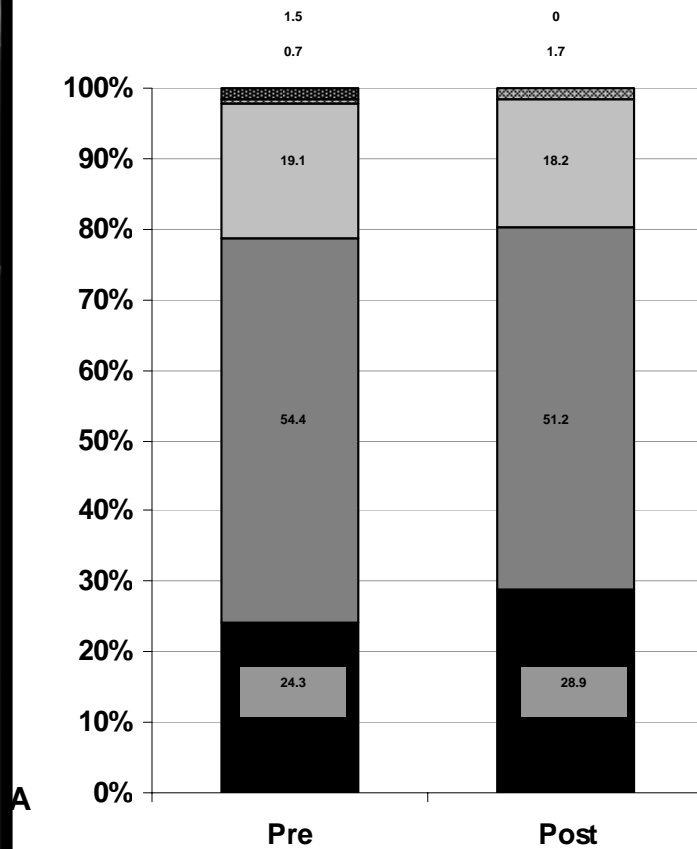
Pacemaker

Paravalvular regurgitation

Para-valvular Regurgitation

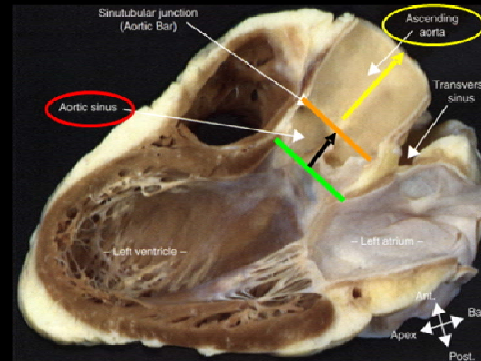


CoreValve Aortic Regurgitation post-interventional



Screening – Anatomy Assessment

Aortic Root



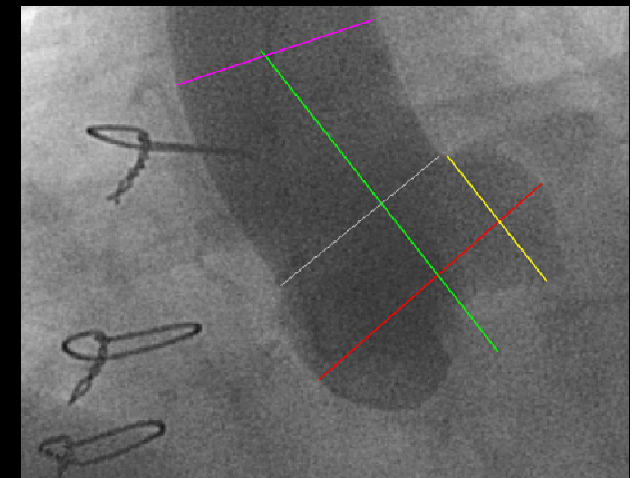
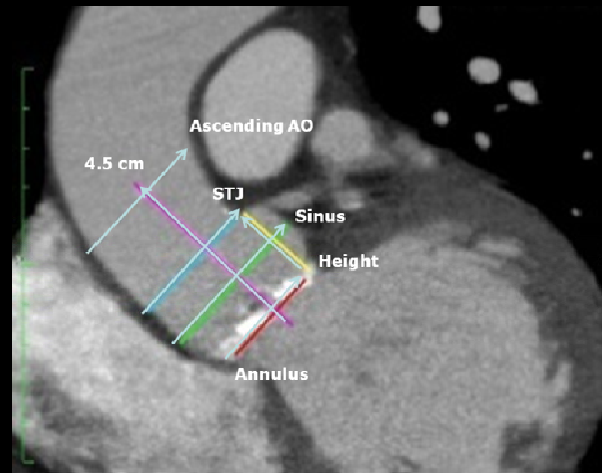
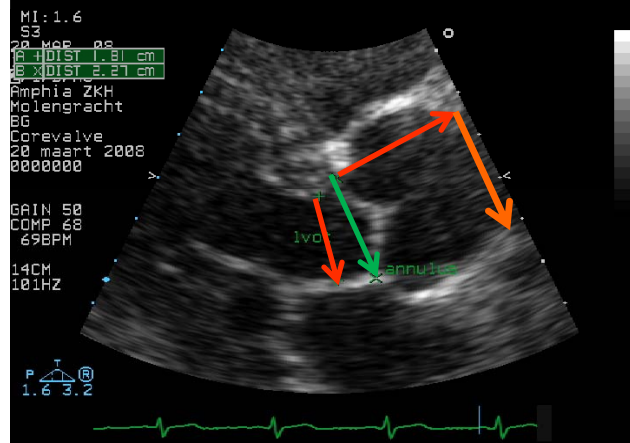
Sinotubular junction

Basal attachment of AV leaflets

Echo

CT

Angio



Future Directions...

- ***Technology enhancements***
 - Lower profile devices and delivery systems
 - Expanded range of valve sizes
 - ? Embolic protection devices
 - Improved vascular closure methodologies
 - Improved placement precision (? repositionable, advanced imaging approaches)
 - Improved Screening/Patient selection

TAVI without Predilation

Symptomatic, aortic valve stenosis qualifying for TAVI
Medtronic CoreValve prosthesis 26 and 29mm
Transfemoral

International, multi-center

**TAVI without
Predilation**
N=60

versus

**TAVI
18F CoreValve S&E study***
N=126

Follow-Up

Postprocedural

30 d

12 mo

Primary Endpoint: Safety at 30 days

Secondary Endpoints: Procedural Success, valve gradient,
paravalvular regurgitation, symmetry

PI: Eberhard Grube

Participating Sites

International Heart Center Rhein-Ruhr, Essen: E. Grube, Ch. Naber

Instituto Dante Pazzanese, Sao Paulo, Brazil: E. Souza, A. Abizaid

Hospital do Coração, Sao Paulo, Brazil: E. Sousa, A. Abizaid

Hospital Sírio Libanês, Sao Paulo, Brazil: P. Lemos, R. Kalil Filho

Hospital Beneficência Port., Sao Paulo, Brazil: J. Mangione, J. Manoel de Souza

Instituto de Cardiologia, Porto Alegre, Brazil: R. Sarmento Leite, P. Prates

Hospital Pró-Cardíaco, Rio de Janeiro, Brazil: L. Carvalho, N. Mattos

Hospital SOS Cardio, Floripa, Brazil: L. São Thiago

Hospital São Lucas da PUC/RS, Porto Alegre, Brazil: P. Caramori

Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil: E. Saadi, Alcides Zago

Hospital Mãe de Deus, Porto Alegre, Brazil: E. Saadi, A. Zago

Hospital do Coração de Natal, Natal, Brazil: E. Hipólito

Instituto do Coração de Natal, Brazil: I. Ribeiro

Fundación Favaloro, Buenos Aires, Argentina: O. Mendiz, L. Valdivieso

Imperial College Healthcare NHS Trust, London, United Kingdom: G. Mikhail

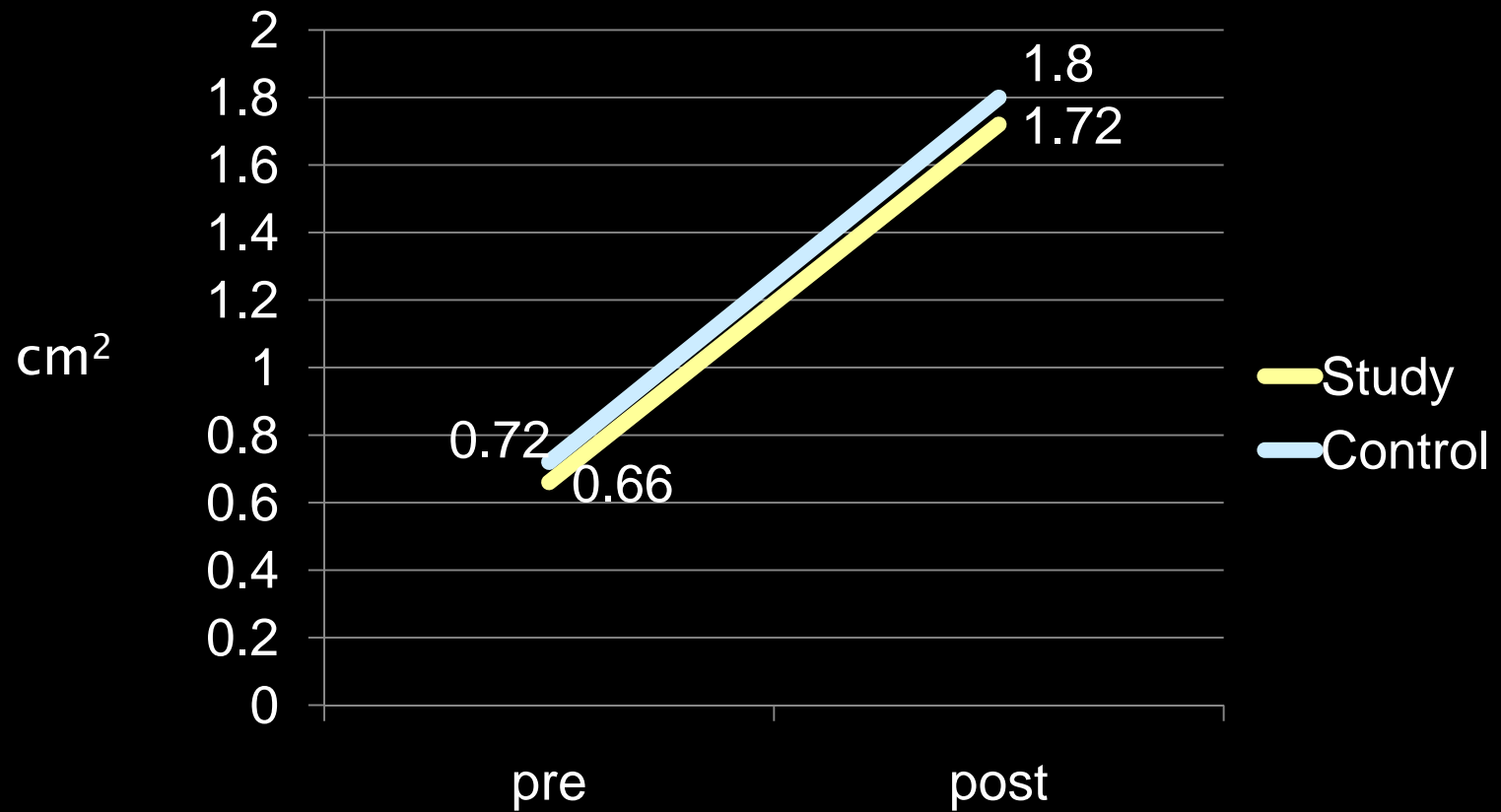
Procedrual Results

	Study Group n=60	Control Group n=126
Technical Success Rate	96.7% (58)	81.7% (103)
Valve embolization	0	0
Conversion to surgery	1.7% (1)	5.6% (7)
Postdilation	16.7% (10)	n.a.

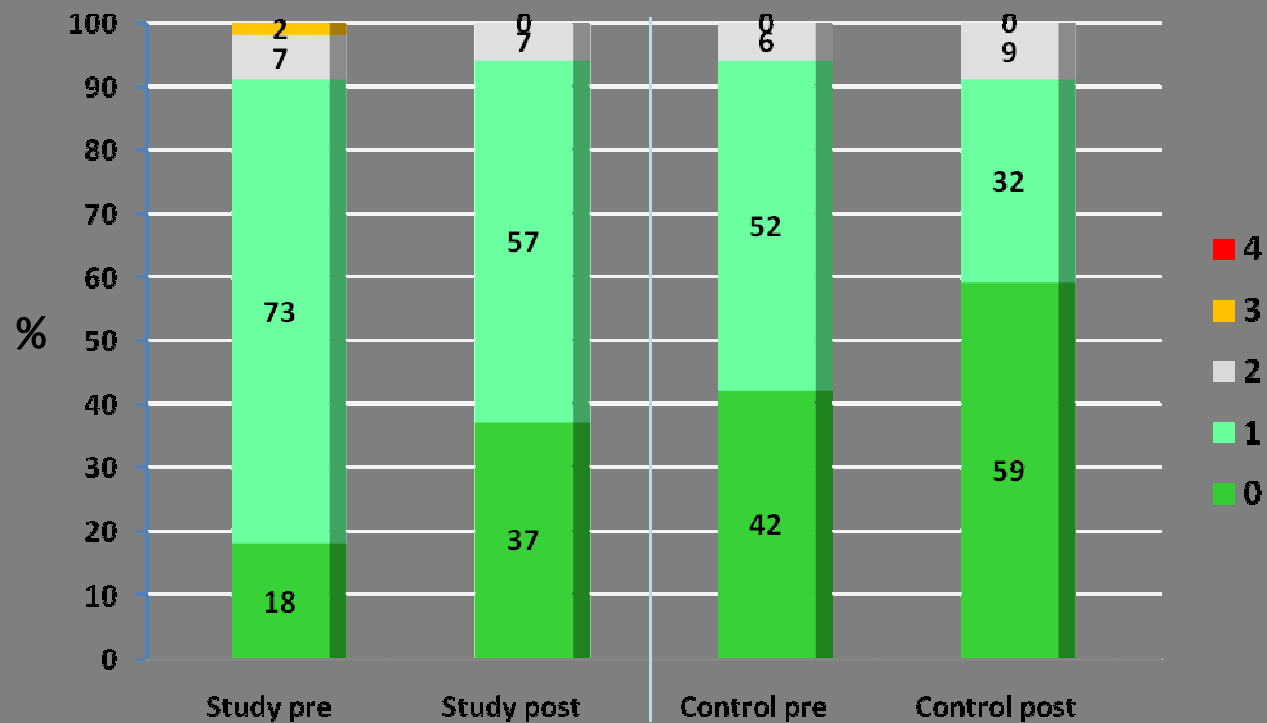
Clinical Outcome at 30days

	Study Group n=60	Control Group n=126
All-cause Mortality	6.7% (4)	14.3% (18)
Myocardial infarction	0	5.6% (7)
Stroke/TIA	5.0% (3)	11.9% (15)
Need for pacemaker implantation	11.7% (7)	27.8% (35)
Vascular Access Complication	10.0% (6)	9.5% (12)

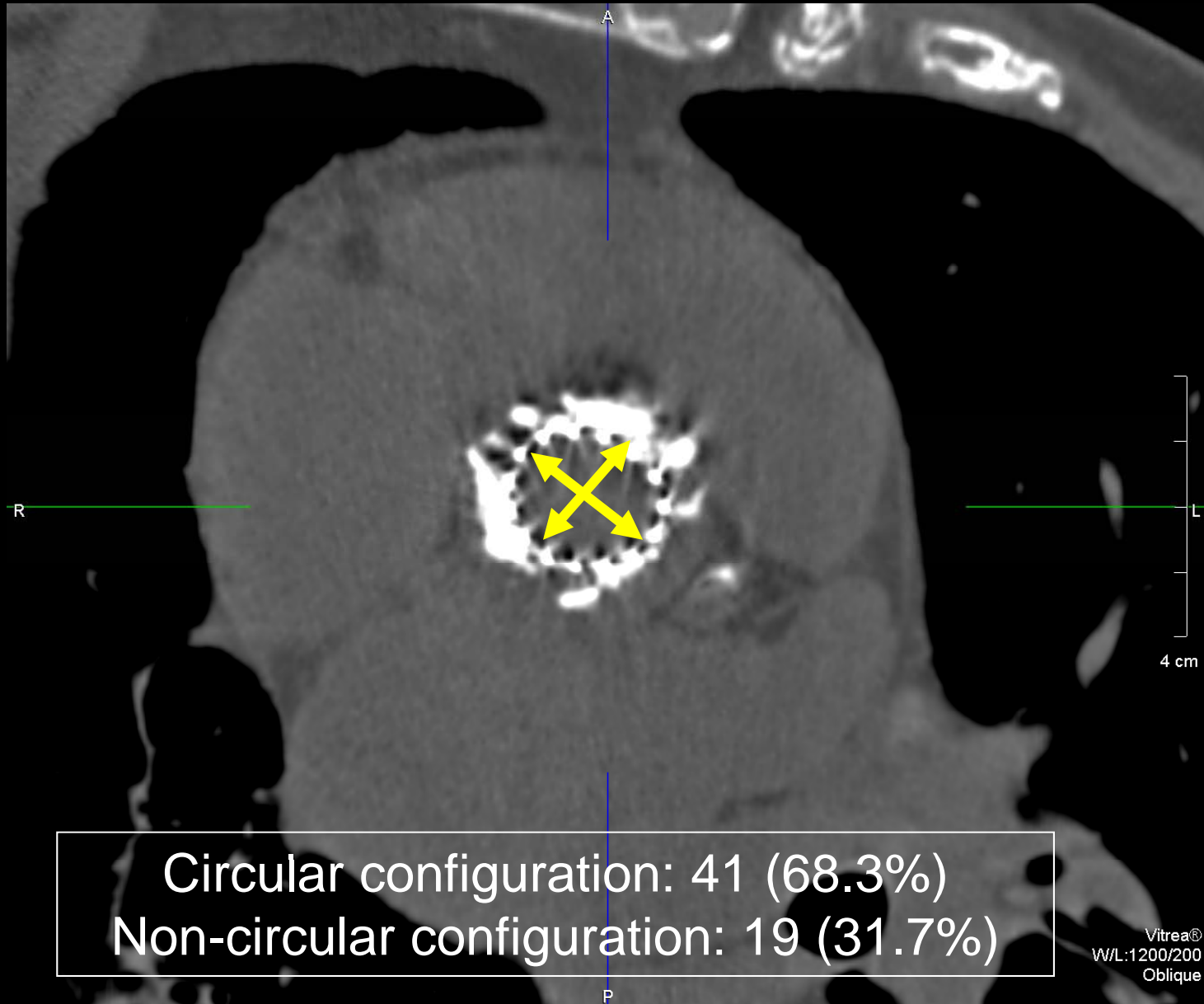
Echo Outcome Effective Orifice Area



Echo Outcome Aortic Regurgitation



Case Example - Symmetry





Thank you