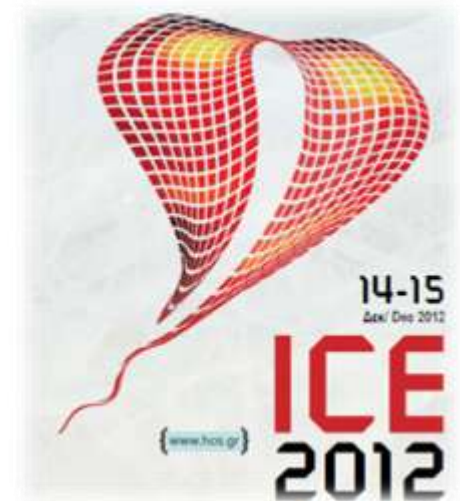


# TAVI – Current practice

## Review of the latest data



Γεώργιος Λάτσιος, MD, PhD, FESC, MEAPCI

Επιμελητής Β΄

Α΄ Πανεπιστημιακή Καρδιολογική Κλινική

ΓΝΑ 'Ιπποκράτειο'



# Trans-catheter therapy for AoVS

- Introduction



# *lung, B, et al. Eur Heart J 2005;26:2714-20*

ELSEVIER

EUROPEAN  
SOCIETY OF  
CARDIOLOGY

## A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease

ng<sup>a</sup>, Gabriel Baron<sup>b</sup>, Eric G. Butchart<sup>c</sup>, François Delahaye<sup>d</sup>,  
hike-Bärwolf<sup>e</sup>, Olaf W. Levang<sup>f</sup>, Pilar Torros<sup>g</sup>,  
Vanoverschelde<sup>h</sup>, Frank Vermeer<sup>i</sup>, Eric Boersma<sup>j</sup>,  
avaud<sup>k</sup>, Alec Vahanian<sup>l</sup>

**31.8% did not undergo intervention, despite NYHA class III/IV symptoms**

**Aims** To identify the characteristics, treatment, and outcomes of contemporary patients with valvular heart disease (VHD) in Europe, and to evaluate adherence to guidelines. **Methods and results** The Euro Heart Survey on VHD was conducted from April to July 2001 in 92 centres from 25 countries; it included prospectively 5001 adults with symptoms or signs of aortic regurgitation (AR), aortic stenosis (AS), or previous valve intervention. VHD was native to 71.3% of patients and 28.7% had had a previous intervention. Mean age was 64.14 years. Degenerative aetiologies were the most frequent in aortic VHD and mitral regurgitation while most cases of mitral stenosis were of rheumatic origin.

Coronary angiography was used in 80.2% of patients before intervention. Of the 1269 patients who underwent intervention, percutaneous replacement was performed in 54.0% of aortic VHD, percutaneous aortic valve in 12.8% of aortic stenosis, and valve repair in 46.5% of mitral regurgitation; 71.7% of patients had at least one associated procedure. Of patients with severe, symptomatic, single VHD, 31.8% did not undergo intervention, most frequently because of comorbidity. In multivariate patients, association with guidelines (logistic regression) was 1.2 and 1.5, respectively. Operative mortality was <1% for single VHD. **Conclusions** This survey provides unique contemporary data on characteristics and treatment of patients with VHD. Adherence to guidelines is globally satisfactory as regards diagnosis and intervention.

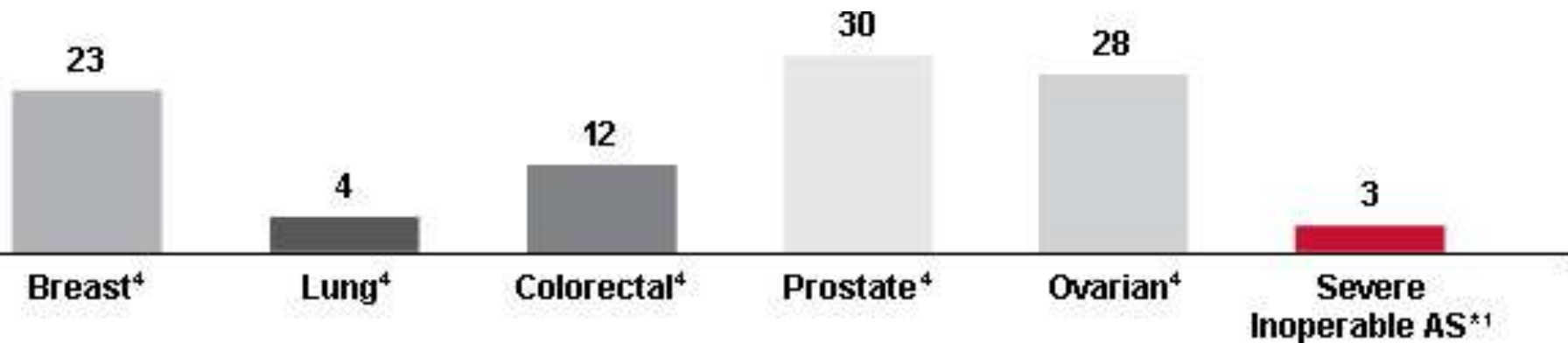
© The European Society of Cardiology. Published by Elsevier Ltd. All rights reserved.

Correspondence: Dr B. Lung, Department, Bichat Hospital, 46 rue Henri Richer, 75018 Paris, France.  
E-mail: lung@hopitalbichat.ap-hopital.org

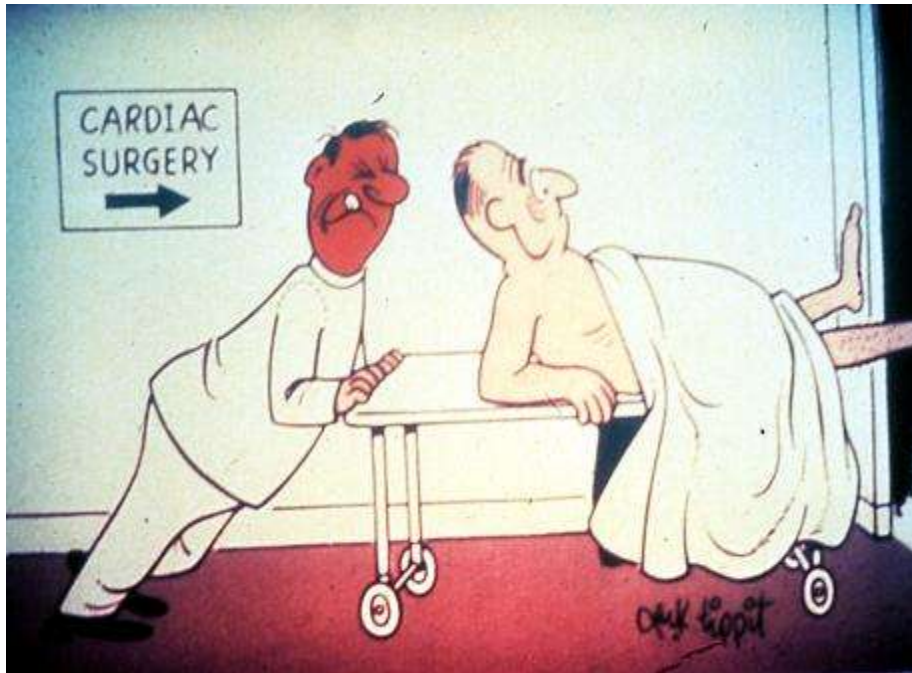
- 92 hospitals from 25 countries
- 5,001 patients from April-July, 2001



# 5 Year Survival Rate, %



# Less Invasive Alternatives are Needed for Several Reasons...



# First 'live' attempt

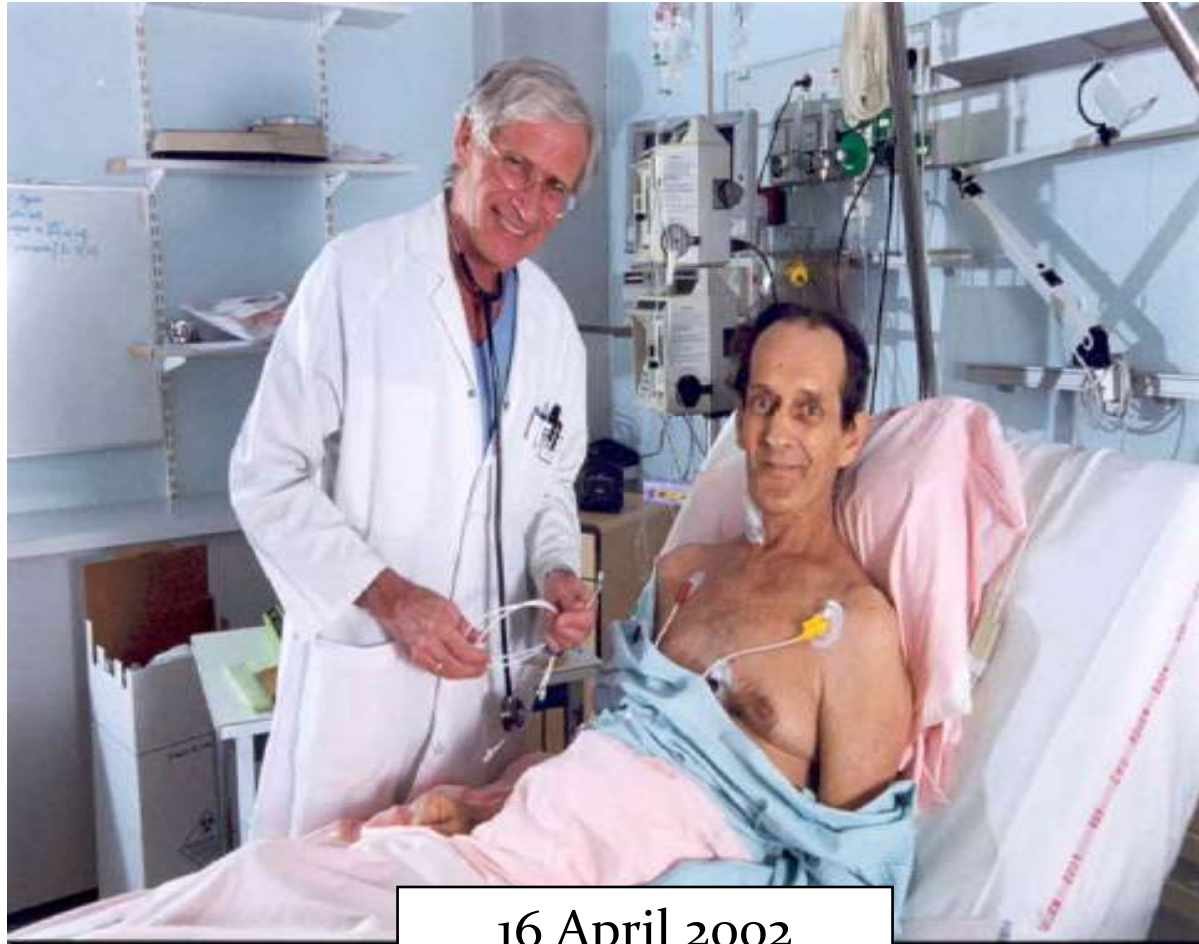
“A total of nine retrograde implantations of a balloon expandable aortic valve were performed in seven alive closed chest pigs.”

*Department of Cardiology, Skejby University  
Hospital, Aarhus, Denmark.*





# First in Man



16 April 2002



## EXPEDITED REVIEW

# Treatment of Calcific Aortic Stenosis With the Percutaneous Heart Valve Mid-Term Follow-Up From the Initial Feasibility Studies: The French Experience

Alain Cribier, MD, FACC,\* Helene Eltchaninoff, MD,\* Christophe Tron, MD,\* Fabrice Bauer, MD,\*  
Carla Agatiello, MD,\* Deborah Nercolini, MD,\* Sydney Tapiero, MD,\* Pierre-Yves Litzler, MD,†  
Jean-Paul Bessou, MD,† Vasilis Babaliaros, MD\*

*Rouen, France*

**Procedural success in 27 (75%) patients**





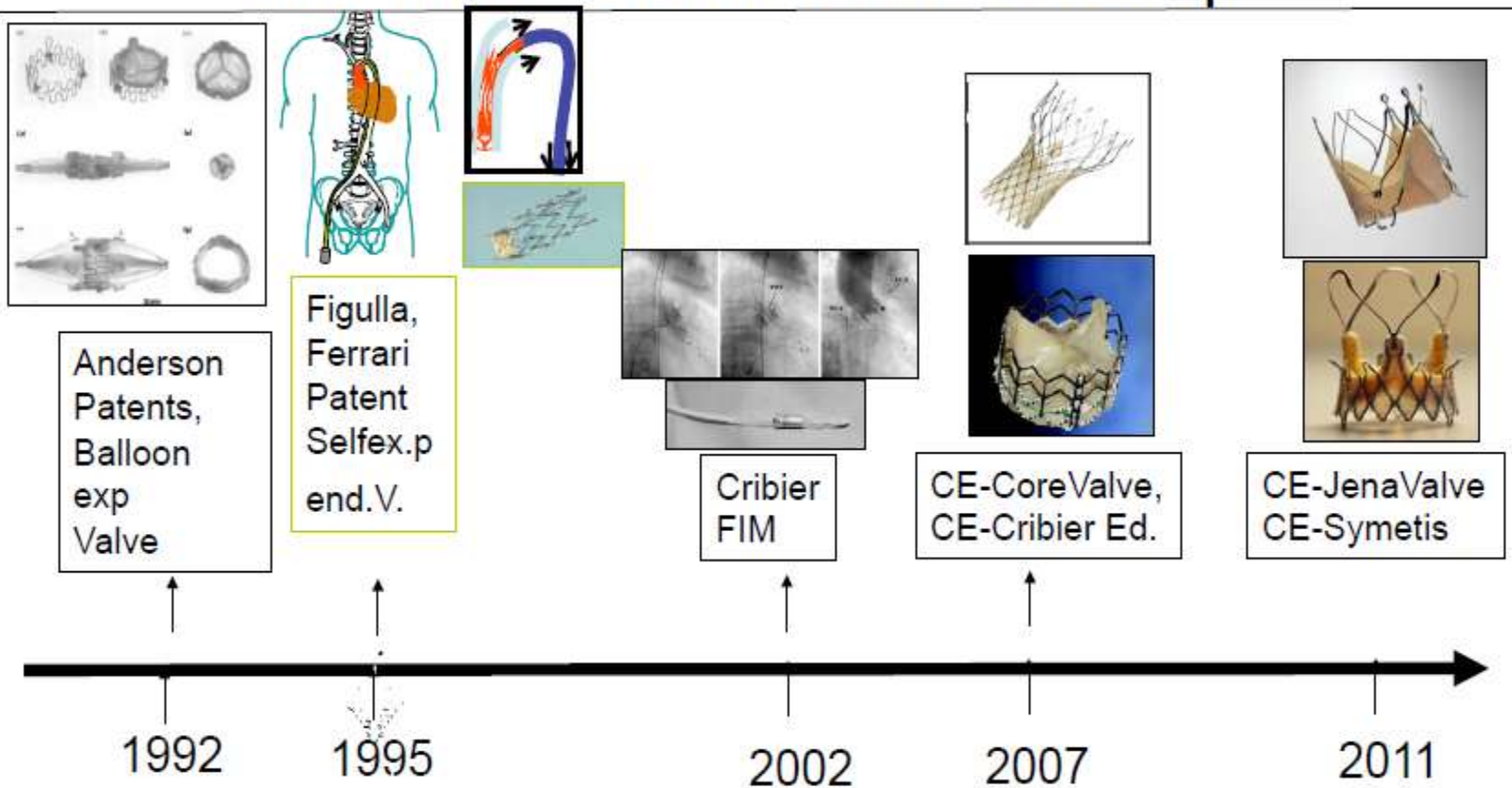
## **Percutaneous Implantation of the CoreValve Self-Expanding Valve Prosthesis in High-Risk Patients With Aortic Valve Disease: The Siegburg First-in-Man Study**

Eberhard Grube, Jean C. Laborde, Ulrich Gerckens, Thomas Felderhoff, Barthel Sauren, Lutz Buellesfeld, Ralf Mueller, Maurizio Menichelli, Thomas Schmidt, Bernfried Zickmann, Stein Iversen and Gregg W. Stone

**Procedural success in 21 (84%) patients**



# Historical Data of TAVI in Europe



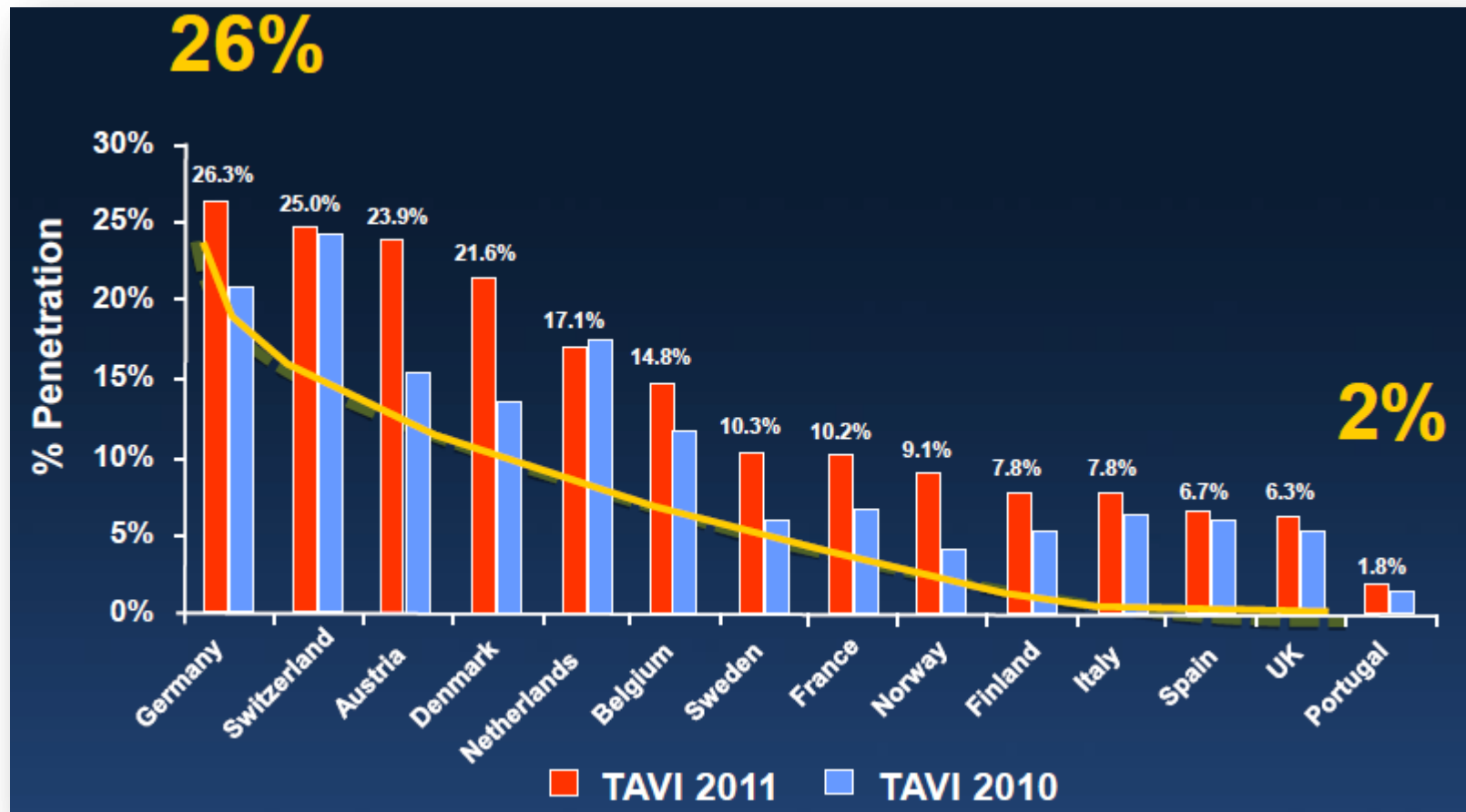
# 2002-2012

## 10 year TAVI anniversary

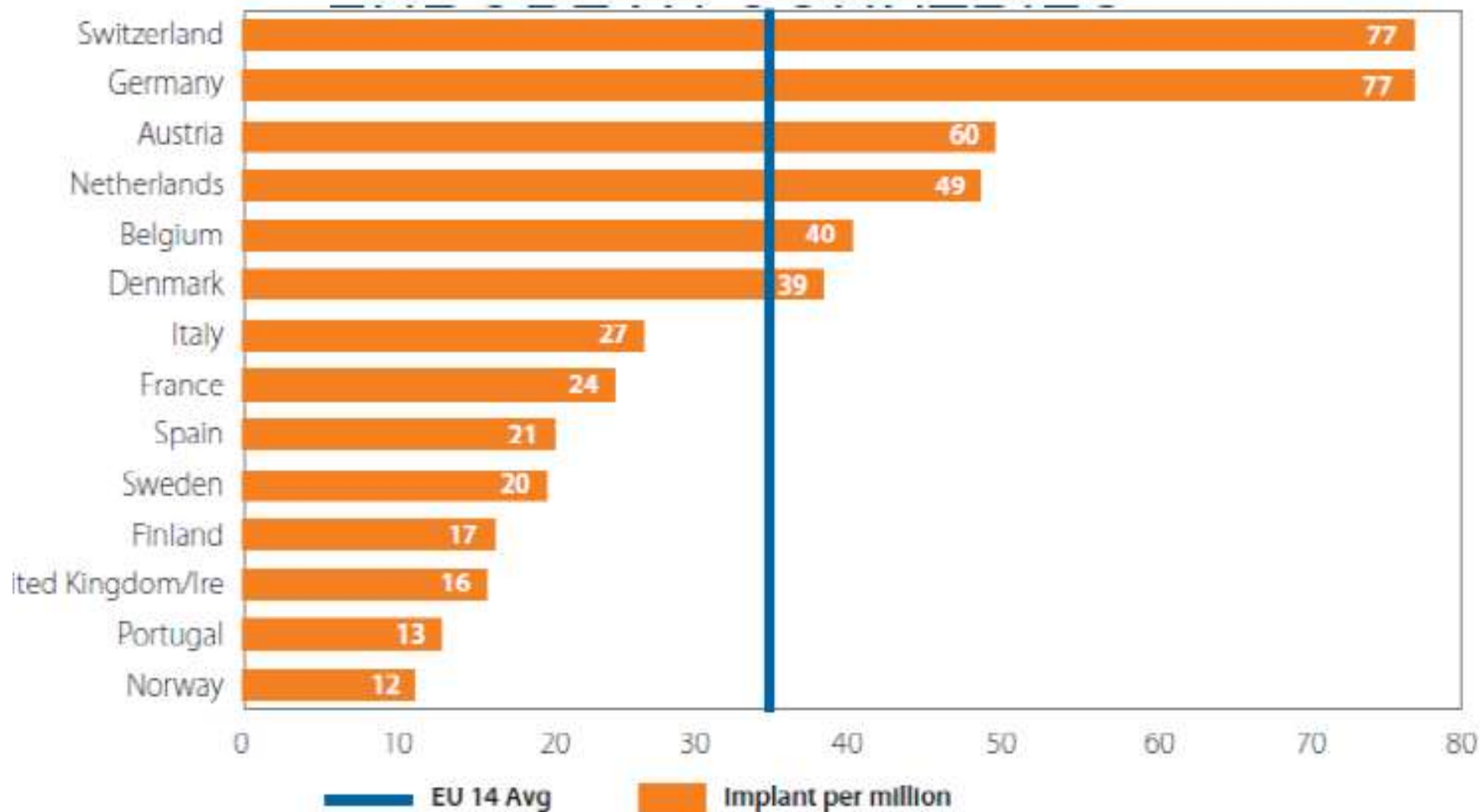
- > 50.000 implantations
- > 40 countries performing TAVI
- PARTNER A 2-yr results published
- PARTNER B 3-yr results published
- Several ongoing trials, awaiting results of PARTNER II, SURTAVI, ADVANCE, GARY



# TAVI cases per total AVR procedures

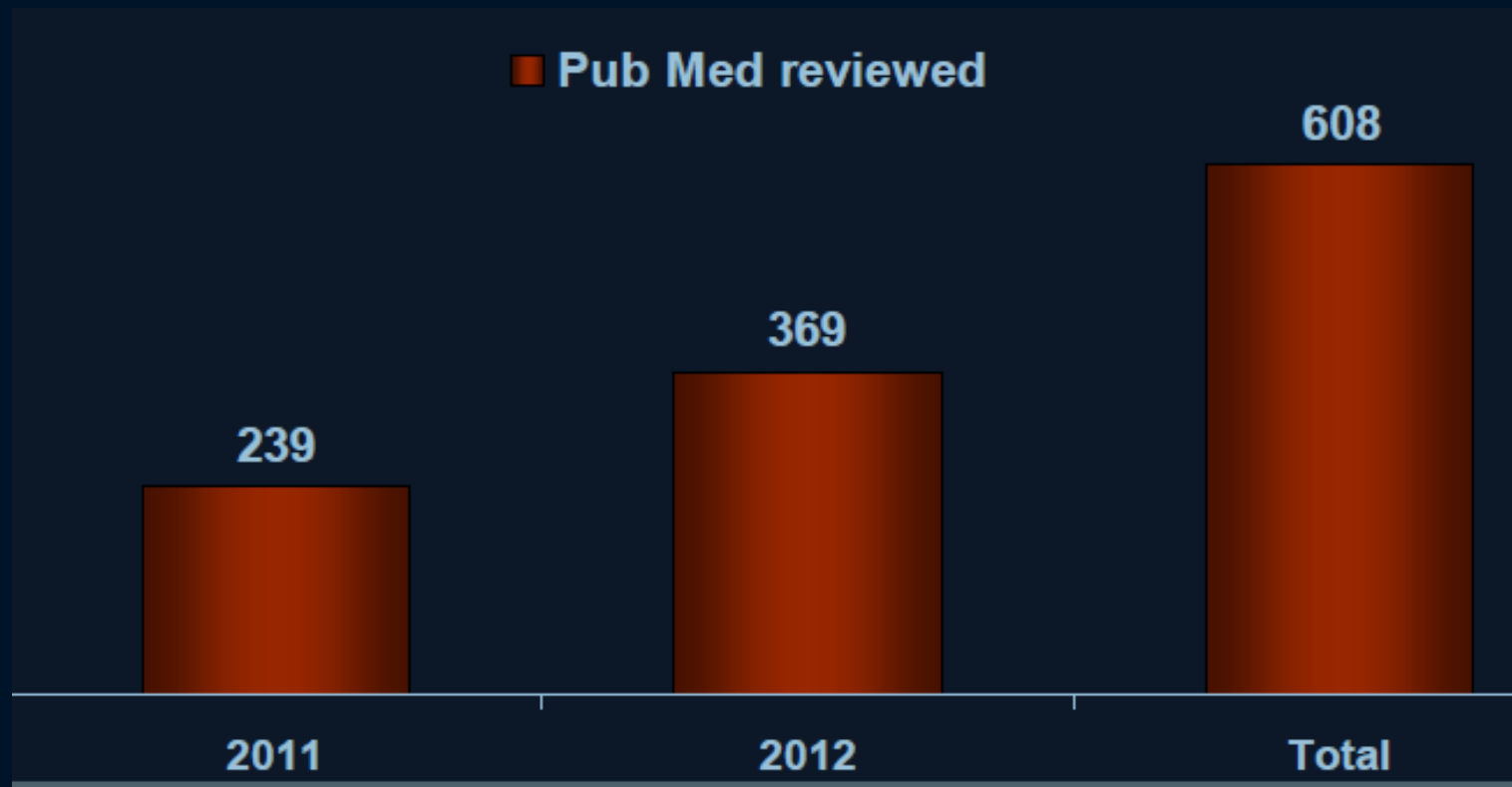


# TAVI cases per million inhabitants





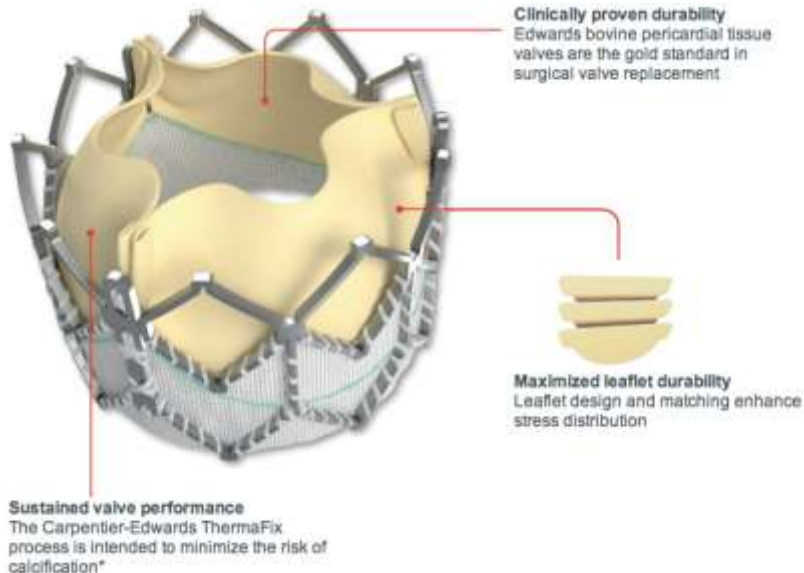
# TAVI-TAVR Pub Med results



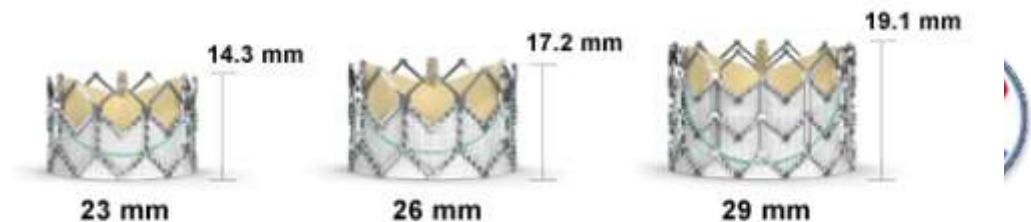
# Devices currently in use



# Edwards Sapien XT



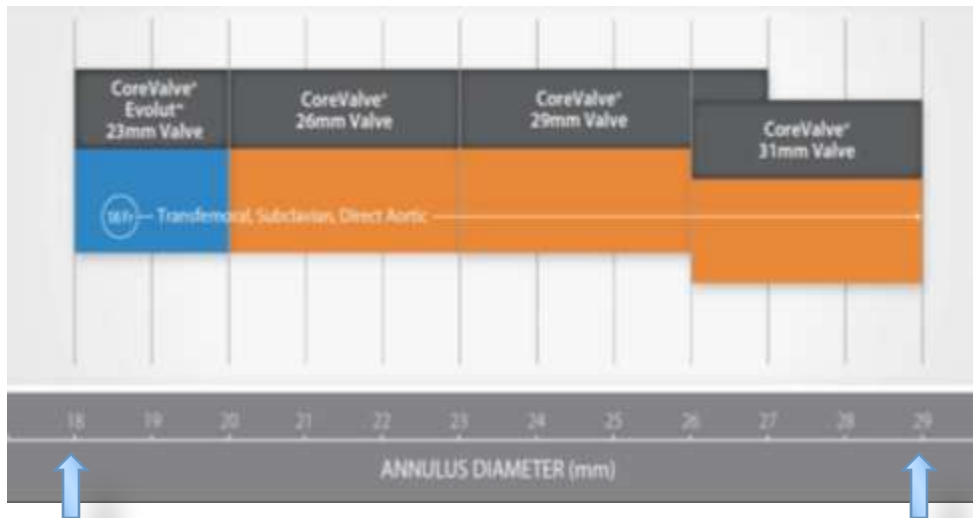
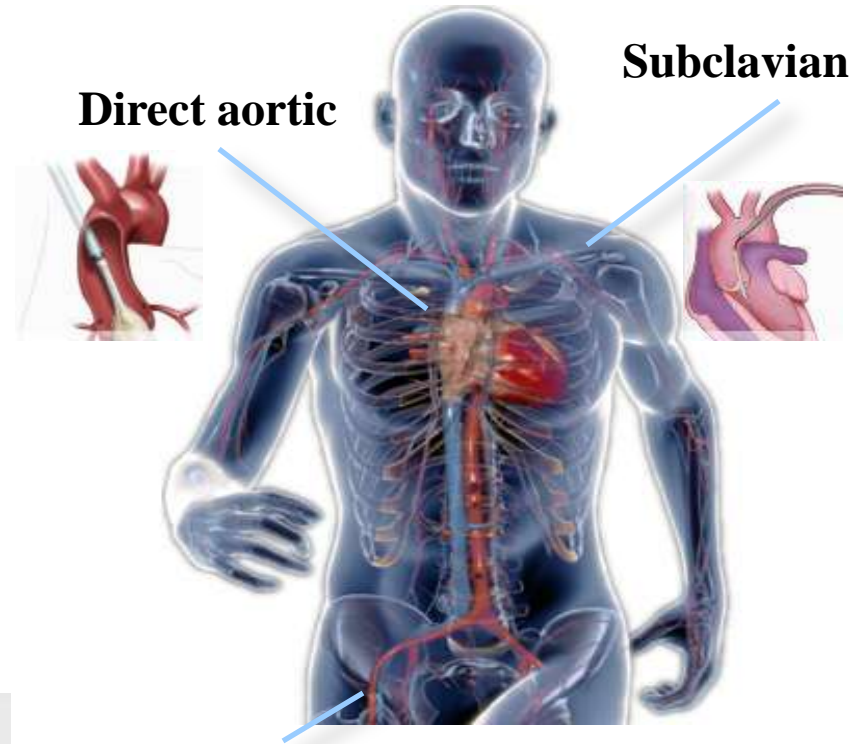
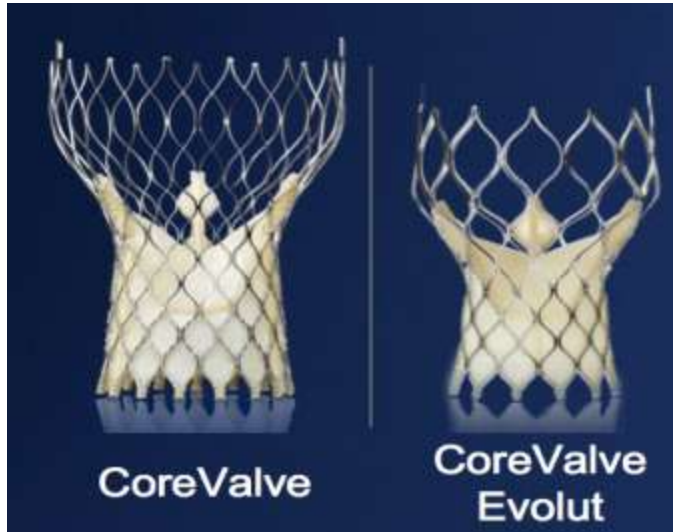
- Available for transfemoral and transapical delivery
- 16 eFlex or 18 Fr delivery sheath
- CE and FDA approved



The SAPIEN XT valve treats an annulus size range of 18 mm to 27 mm



# Medtronic CoreValve



Transfemoral

- 18 Fr delivery sheath
- Repositionable



# Differences between MCV and EXT

Features	CoreValve	Sapien
Manufacturer	Medtronic	Edwards Lifesciences
Stent	Nitinol	Cobalt chromium
Repositionable	Partially	No
Fixation	Aortic annulus and aorta	Aortic annulus
Diameters (mm)	23, 26, 29, 31	23, 26, 29



Latsios G, Gerckens U, Grube E. Hellenic J Cardiol. 2010 Jul-Aug;51(4):348-55.

Toutouzas K, Stathogiannis K, Latsios G, Synetos A, Stefanadis C. Recent Pat Cardiovasc Drug Discov. 2012 Oct 31.





# Trans-catheter therapy for AoVS

- Guidelines



# Recommendations for TAVI use

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B	99
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B	97



# 2012 ACCF/AATS/SCAI/STS Expert Consensus Document on TAVI

Treatment	Indication	Major Complications
Surgical Aortic Valve Replacement	<ul style="list-style-type: none"> <li>• Symptomatic severe AS (Class I, LOE: B)</li> <li>• Severe AS undergoing CABG, aortic surgery or other valve surgery (Class I, LOE: C)</li> <li>• Symptomatic moderate AS undergoing CABG, aortic surgery or other valve surgery (Class IIa, LOE: C)</li> <li>• Asymptomatic severe AS with hypotensive response to exercise (Class IIb; LOE: C)</li> <li>• Asymptomatic extremely severe AS (AVA &lt;0.6 cm<sup>2</sup>, mean gradient ≥50 mm Hg, or jet velocity ≥5 m/s) (Class IIb; LOE: C)</li> </ul>	<ul style="list-style-type: none"> <li>• Mortality (3%)</li> <li>• Stroke (2%)</li> <li>• Prolonged ventilation (11%)</li> <li>• Thromboembolism and bleeding</li> <li>• Prosthetic dysfunction</li> <li>• Perioperative complications are higher when surgical AVR is combined with CABG</li> </ul>
Transcatheter Aortic Valve Replacement	<ul style="list-style-type: none"> <li>• TAVR is recommended in patients with severe, symptomatic, calcific stenosis of a trileaflet aortic valve who have aortic and vascular anatomy suitable for TAVR and a predicted survival &gt;12 months, and who have a prohibitive surgical risk as defined by an estimated 50% or greater risk of mortality or irreversible morbidity at 30 days or other factors such as frailty, prior radiation therapy, porcelain aorta, and severe hepatic or pulmonary disease.</li> <li>• TAVR is a reasonable alternative to surgical AVR in patients at high surgical risk (PARTNER Trial Criteria: STS ≥8%*)</li> </ul>	<ul style="list-style-type: none"> <li>• Mortality (3% to 5%)</li> <li>• Stroke (6% to 7%)</li> <li>• Access complications (17%)</li> <li>• Pacemaker Insertion               <ul style="list-style-type: none"> <li>○ 2% to 9% (Saplen)</li> <li>○ 19% to 43% (CoreValve)</li> </ul> </li> <li>• Bleeding</li> <li>• Prosthetic dysfunction</li> <li>• Paravalvular AR</li> <li>• Acute kidney injury</li> <li>• Other               <ul style="list-style-type: none"> <li>○ Coronary occlusion</li> <li>○ Valve embolization</li> <li>○ Aortic rupture</li> </ul> </li> </ul>
Balloon Aortic Valvuloplasty	<ul style="list-style-type: none"> <li>• Reasonable for palliation in adult patients with AS in whom surgical AVR cannot be performed because of serious comorbid conditions (Class IIb, LOE: C)</li> <li>• Bridge to surgical AVR (Class IIb, LOE: C)</li> </ul>	<ul style="list-style-type: none"> <li>• Mortality</li> <li>• Stroke</li> <li>• Access complications</li> <li>• Restenosis</li> </ul>
Medical Therapy	<ul style="list-style-type: none"> <li>• No specific therapy for asymptomatic AS</li> <li>• Medical therapy not indicated for symptomatic severe AS</li> <li>• Appropriate control of blood pressure and other risk factors as indicated</li> <li>• Statins not indicated for preventing progression of AS</li> <li>• Diuretics, vasodilators and positive inotropes should be avoided in patients awaiting surgery because of risk of destabilization</li> </ul>	<ul style="list-style-type: none"> <li>• Hemodynamic instability</li> </ul>



# October 2012: FDA approves TAVI for high-risk operable patients



**U.S. Food and Drug Administration**  
Protecting and Promoting *Your* Health

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### FDA NEWS RELEASE

**For Immediate Release:** October 19, 2012

**Media Inquiries:** Michelle Bolek, 301-796-2973, [michelle.bolek@fda.hhs.gov](mailto:michelle.bolek@fda.hhs.gov)

**Consumer Inquiries:** 888-INFO-FDA

### FDA expands approved use of Sapien artificial heart valve

The U.S. Food and Drug Administration today expanded the approved indication for the Sapien Transcatheter Heart Valve (THV) to include patients with aortic valve stenosis who are eligible for surgery, but who are at high risk for serious surgical complications or death.

The FDA first approved the Sapien THV in 2011 for patients with inoperable aortic valve stenosis, a progressive, age-related disease. Calcium deposits on the aortic valve that cause it to narrow are a common cause of aortic valve stenosis. As the heart works harder to pump enough blood through the smaller opening, it eventually weakens. Aortic valve stenosis can lead to fainting, chest pain, heart failure, irregular heart rhythms (arrhythmias), or cardiac arrest.

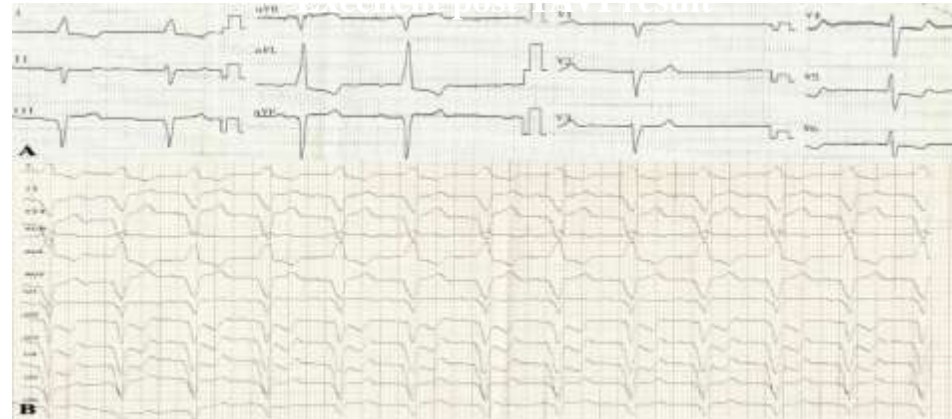
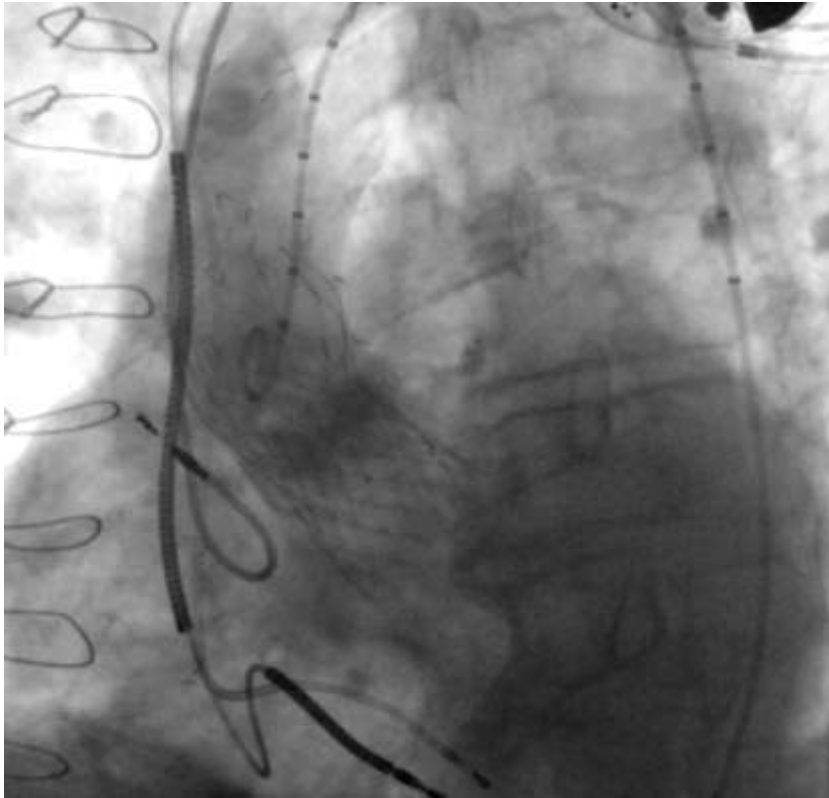
Those with severe aortic valve stenosis must have a heart valve replacement to restore normal blood flow. Patients who are in good enough health to tolerate surgery usually undergo open-chest, open-heart surgery or a minimally invasive surgery, in which surgeons gain access to the heart through an incision between the ribs.





# Off label TAVI use??

TAVI during the acute phase of MI



Toutouzas K, Michelongona A, Synetos A, Latsios G, Drakopoulou M, Stefanadis C., Int J Cardiol. 2011 Nov 3;152(3):398-400. Epub 2011 Sep 15.





# Off label TAVI use??

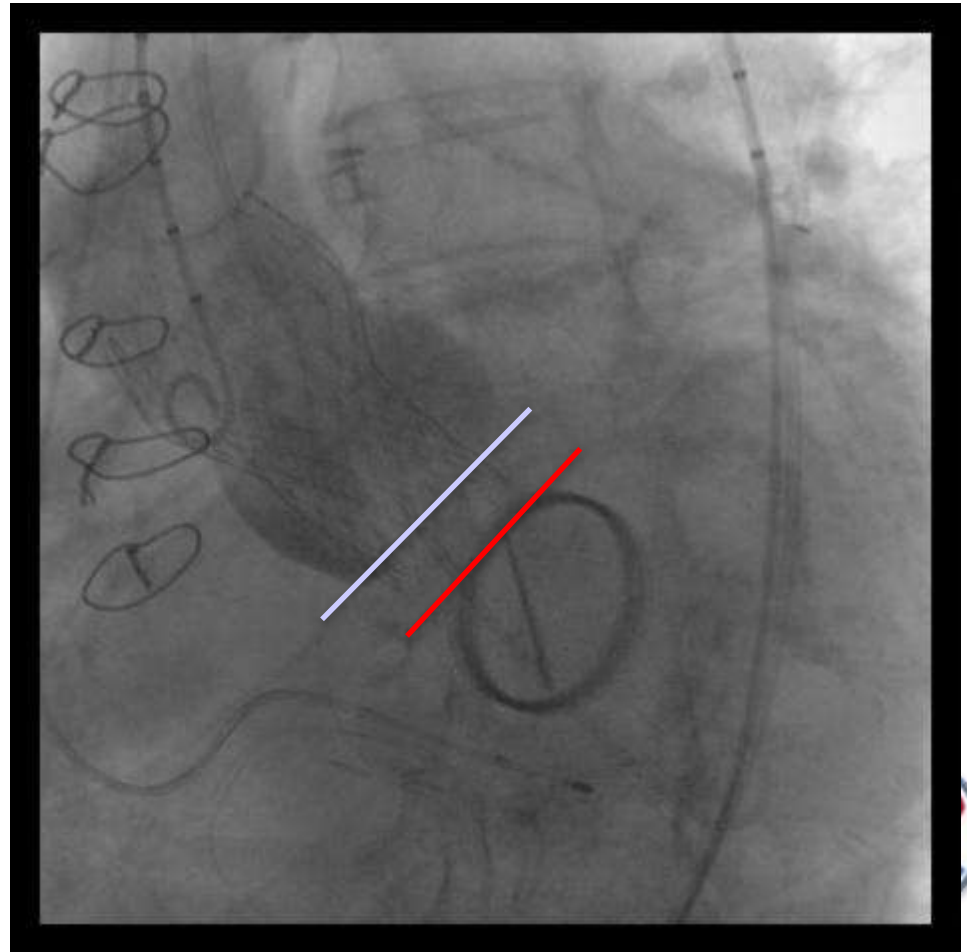
## TAVI in a patient with prosthetic mitral valve

Implantation **level** according to non-coronary cusp pigtail

**Metallic mitral valve**  
**LVOT adjunction level**

The CoreValve prosthesis is in optimal position, in respect

1. to the native valve (~6 mm deep)
2. to the metallic mitral valve (not interfering with each other)



# Clinical assessment Scores

Relationship between this... Google Adwords... New EuroSCORE II (2011) PCR London Values 2012

www.euroscore.org/calc.html

Entres-PubMed GLatsios@Gmail.com Twitter Torrent Search Engine Atlantis Tennis Club e-syntagorafi Yropoyco Δωδεκ...

HOME euroSCORE SCORING CALCULATOR REFERENCES

euroSCORE interactive calculator

Important. The previous additive <sup>1</sup> and logistic <sup>2</sup> EuroSCORE models are out of date. A new model has been prepared from fresh data and is launched at the 2011 EACTS meeting in Lisbon. The model is called EuroSCORE II <sup>3</sup> - this online calculator has been updated to use this new model. If you need to calculate the older "additive" or "logistic" EuroSCORE please visit the old calculator by [clicking here](#).

Patient related factors		Cardiac related factors	
Age <sup>1</sup> (years)	0	NYHA	select
Gender	select	CCS class 4 angina <sup>8</sup>	no
Renal impairment <sup>2</sup> See calculator below for creatinine clearance	normal (CC >85ml/min)	LV function	select
Extracardiac arteriopathy <sup>3</sup>	no	Recent MI <sup>9</sup>	no
Poor mobility <sup>4</sup>	no	Pulmonary hypertension <sup>10</sup>	no
Previous cardiac surgery	no	<b>Operation related factors</b>	
Chronic lung disease <sup>5</sup>	no	Urgency <sup>11</sup>	elective
Active endocarditis <sup>6</sup>	no	Weight of the intervention <sup>12</sup>	isolated CABG
Critical preoperative state <sup>7</sup>	no	Surgery on thoracic aorta	no
Diabetes on insulin	no		

EuroSCORE I EuroSCORE II

Calculate Clear

Task: This is the 2011 EuroSCORE II

12:35 pm 14/12/2012

Roques F, Nashef S, Michel P, et al. Risk factors and outcome in European cardiac surgery: analysis of the EuroSCORE multinational database of 19030 patients. Eur J Cardio-Thoracic Surg 1999; 15: 816–823.



# Clinical assessment Scores

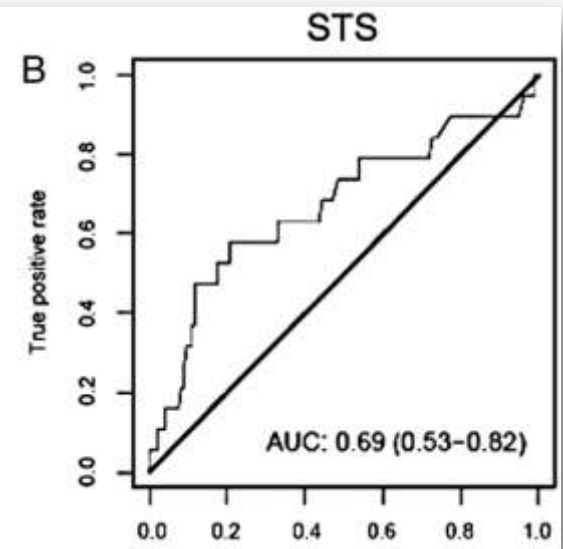
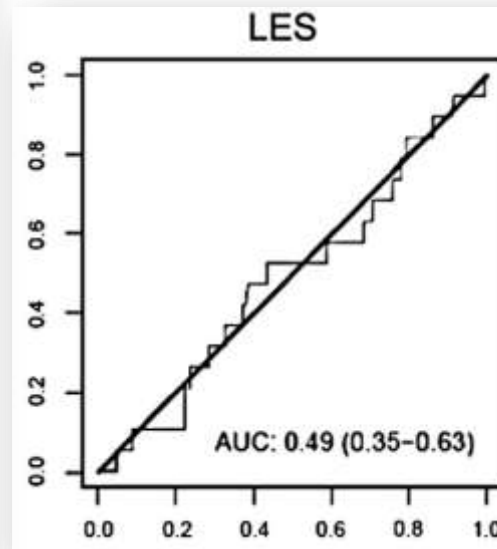
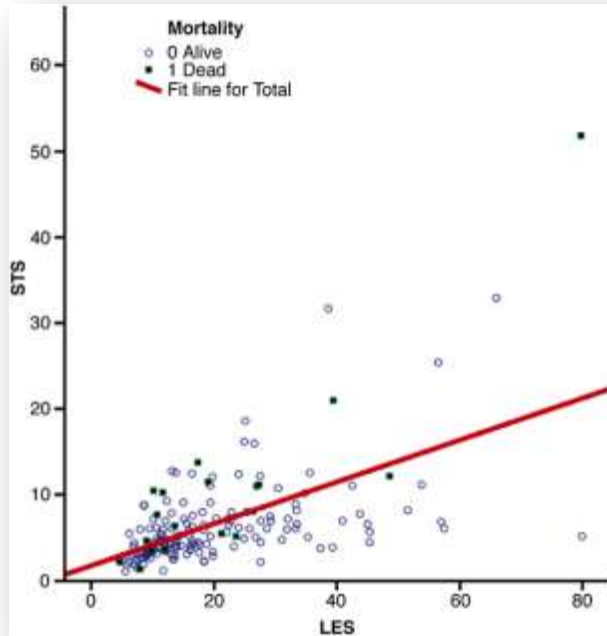


Roques F, Nashef S, Michel P,  
EuroSCORE multinational data

The Society of Thoracic Surgeons. Executive Summary: Society of Thoracic Surgeons Spring 2007 Report. Chicago,IL: The Society of Thoracic Surgeons; 2007.



# Clinical assessment Scores



# Clinical assessment

## *Frailty*



Same **age** and predicted **risk**

Pre-procedural **Karnofsky index** (functional performance status) emerged as the only independent predictor of outcome.

Buellesfeld L, Wenaweser P, Gerckens U, Mueller R, Sauren B, Latsios G, Zickmann B, Hellige G, Windecker S, Grube E. Eur Heart J. 2010 Apr;31(8):984-91.





# Clinical assessment

## Heart team



Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	

### ESC/EACTS GUIDELINES



# Trans-catheter therapy for AoVS

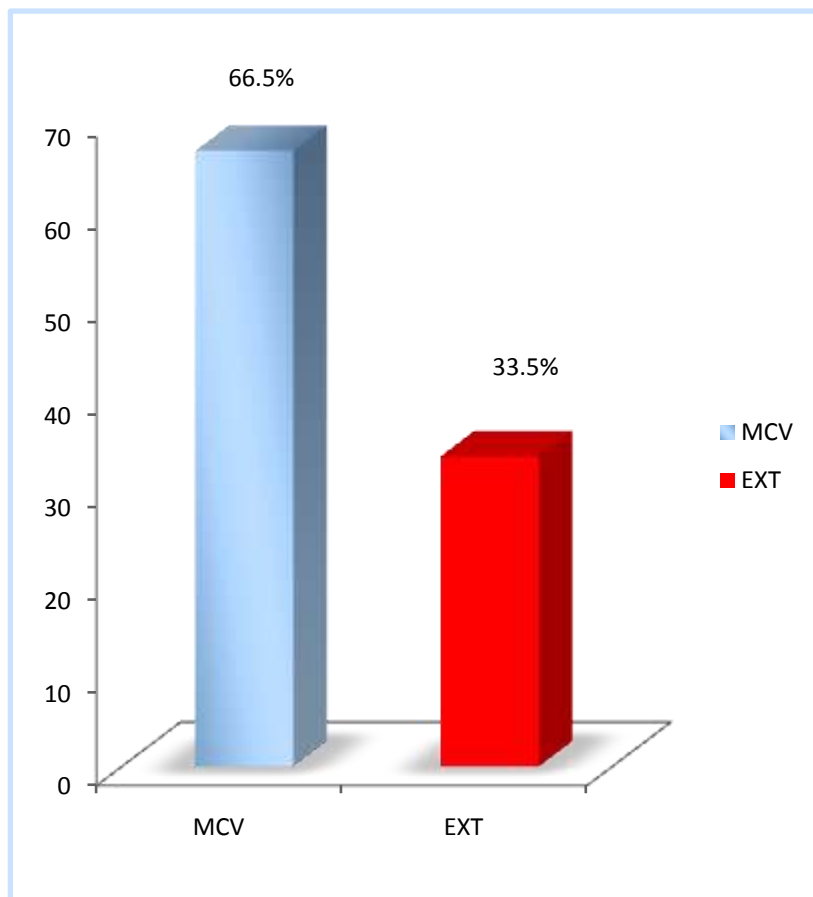
- Results





# Ελλάδα (06/2012)

Αριθμός βαλβίδων  
N= 170 (113 MCV, 57 EXT)



Ιπποκράτειο  
Υγεία  
Ωνάσειο  
Αττικόν  
Αγ. Λουκάς



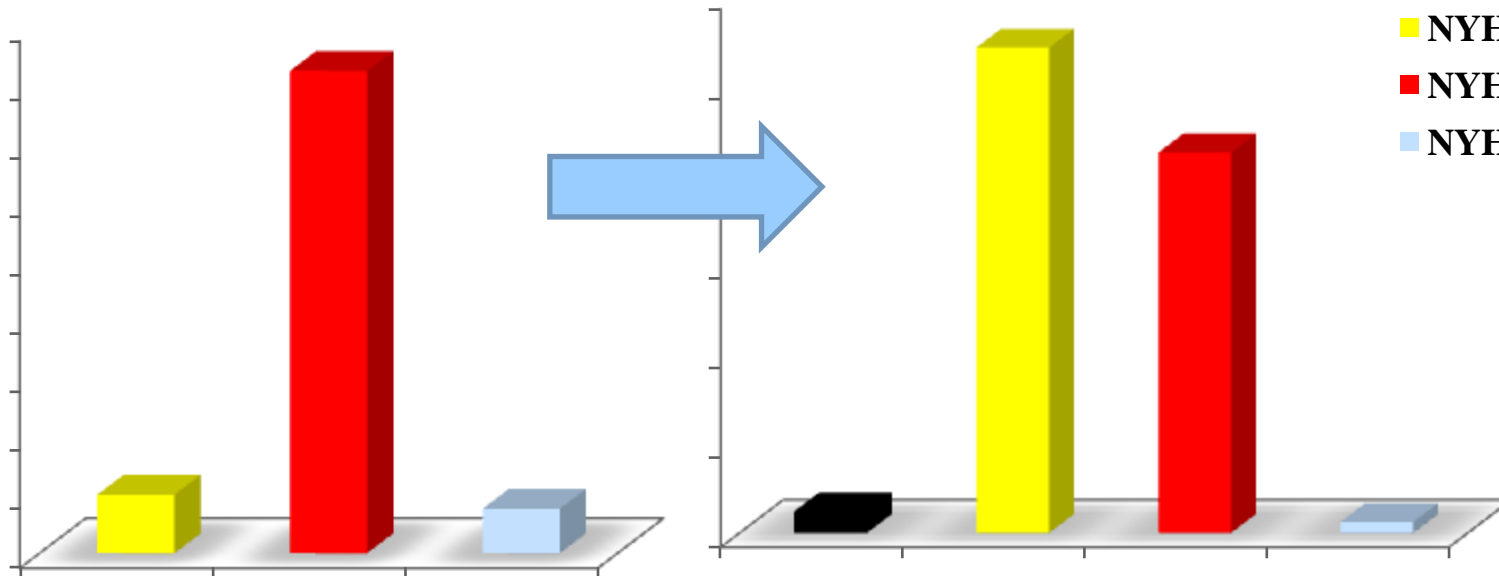


# Ελλάδα (06/2012)

NYHA Class

Pre TAVI

Post TAVI

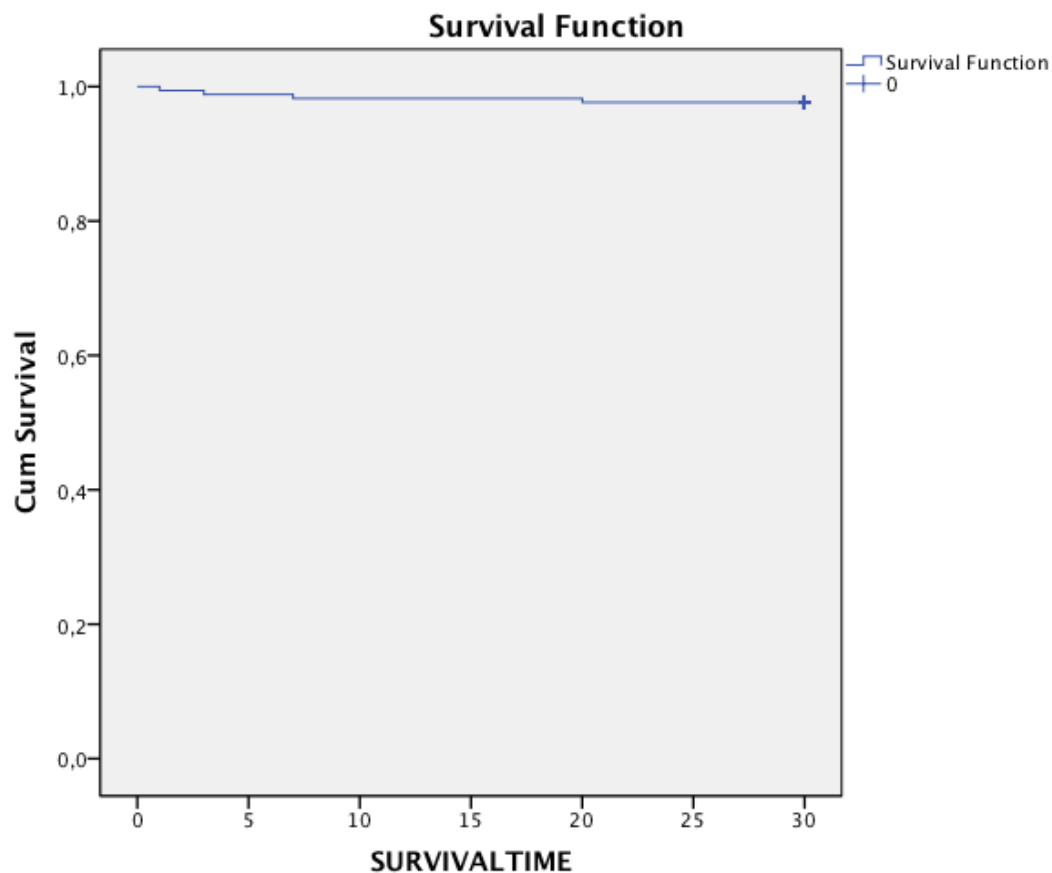


- NYHA I
- NYHA II
- NYHA III
- NYHA IV





# Ελλάδα (06/2012)



**4** deaths ie  
1 ischemic CVA  
1 aspiration pneumonia  
1 foot gangrene  
1 LV perforation







# German Aortic Valve Registry

Inclusion from 01/01/2011 to 31/12/2011

53 cardiac surgery units

69 cardiology units

13.860 patients

6.523 surgical AVR  
without CABG

3.462 surgical  
AVR with CABG

2.694 transvascular  
TAVI

1.181 transapical  
TAVI

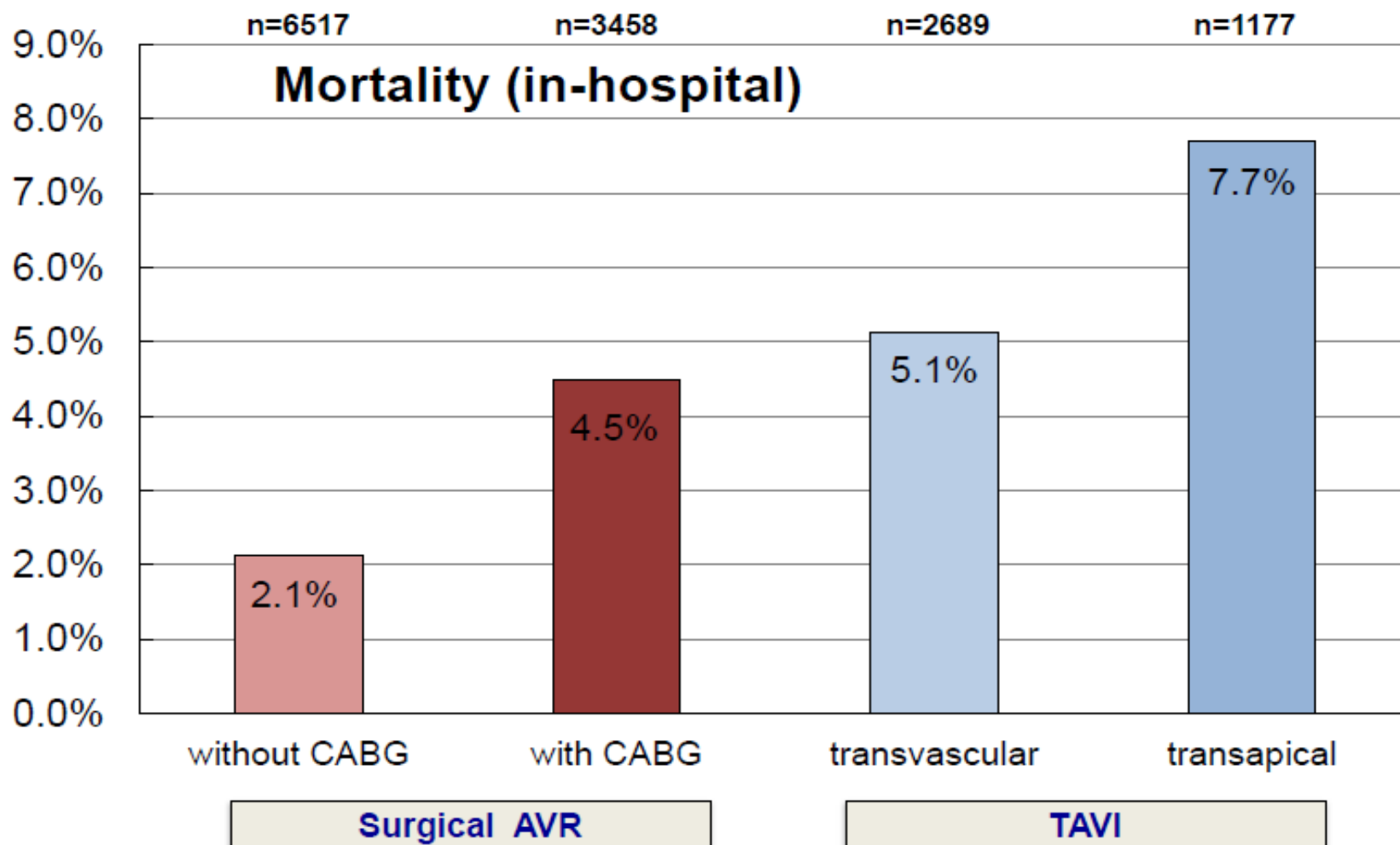


# German Aortic Valve Registry

GARY



Deutsches  
Aortenklappenregister

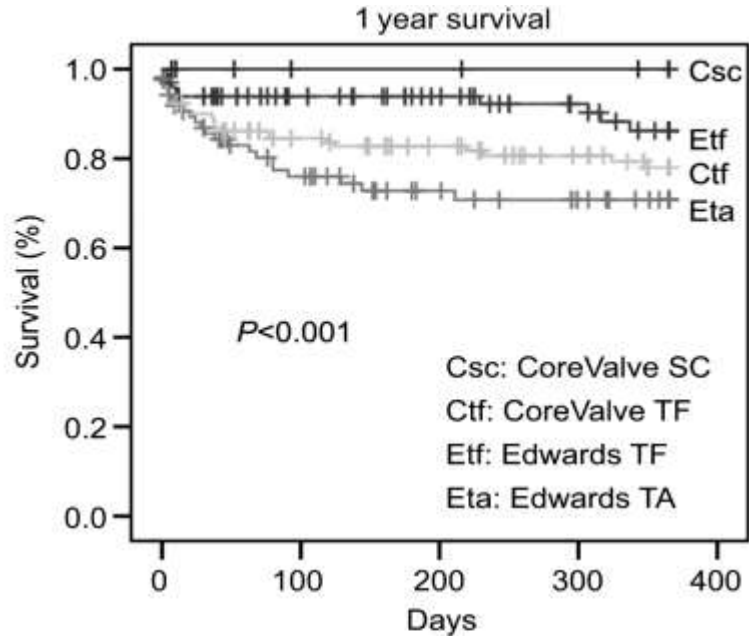
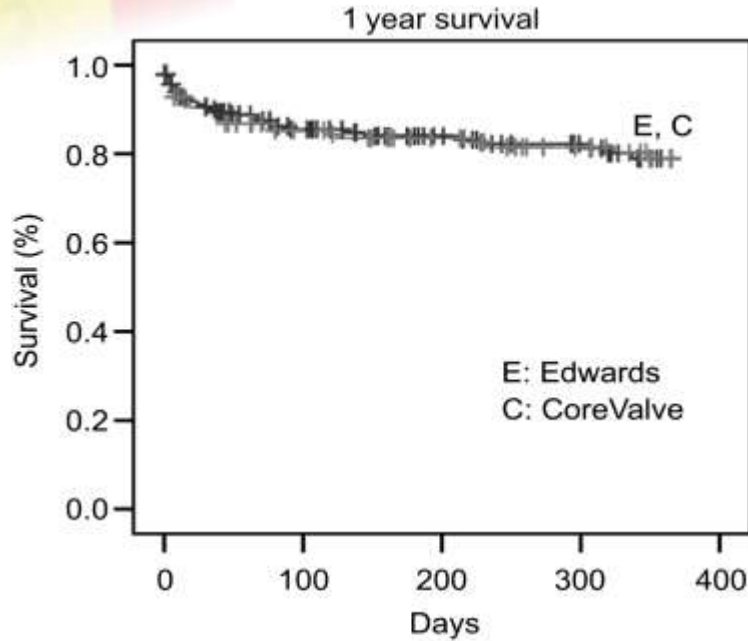




# Belgian Registry 1 yr outcomes

CoreValve,  
Edwards

## Mid-term mortality mainly related to age-related, non-cardiac complications



%	CoreValve	Edwards TF	Edwards TA
1 month survival	91	94	86
6 month survival	82	91	71
1 year survival	79	82	63





# FRANCE 2 Registry

**Mortality rate  
(total and cardiovascular)**

**33% MCV  
67% ESV**

	30-day		6-month		12-month	
<b>Global</b>	<b>367</b>	<b>9.5 %</b>	<b>640</b>	<b>18 %</b>	<b>762</b>	<b>24.1 %</b>
<b>CV</b>	<b>269</b>	<b>7.0 %</b>	<b>389</b>	<b>11 %</b>	<b>430</b>	<b>13.6 %</b>

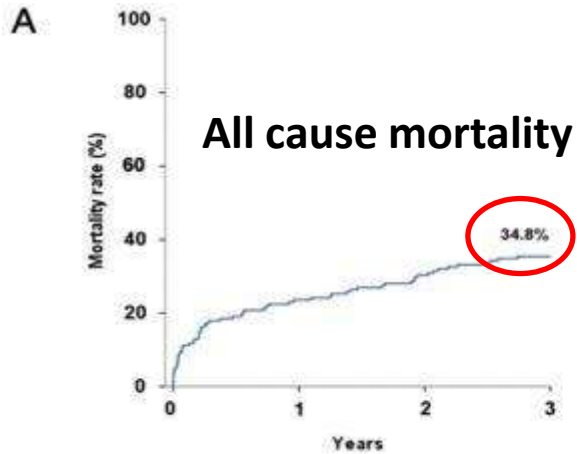




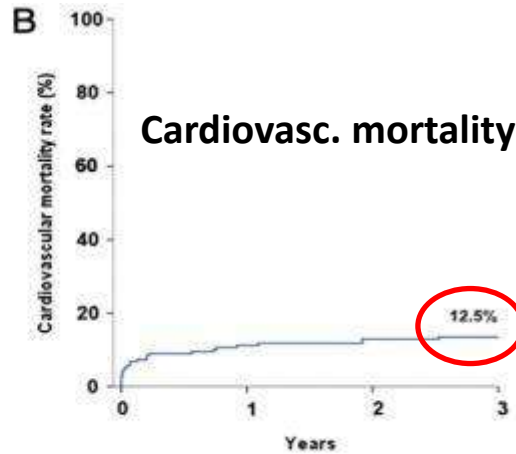
# Italian Registry: 3 yr outcomes

CoreValve

N= 181



Number at risk 181 136 124 116



Number at risk 181 158 156 155

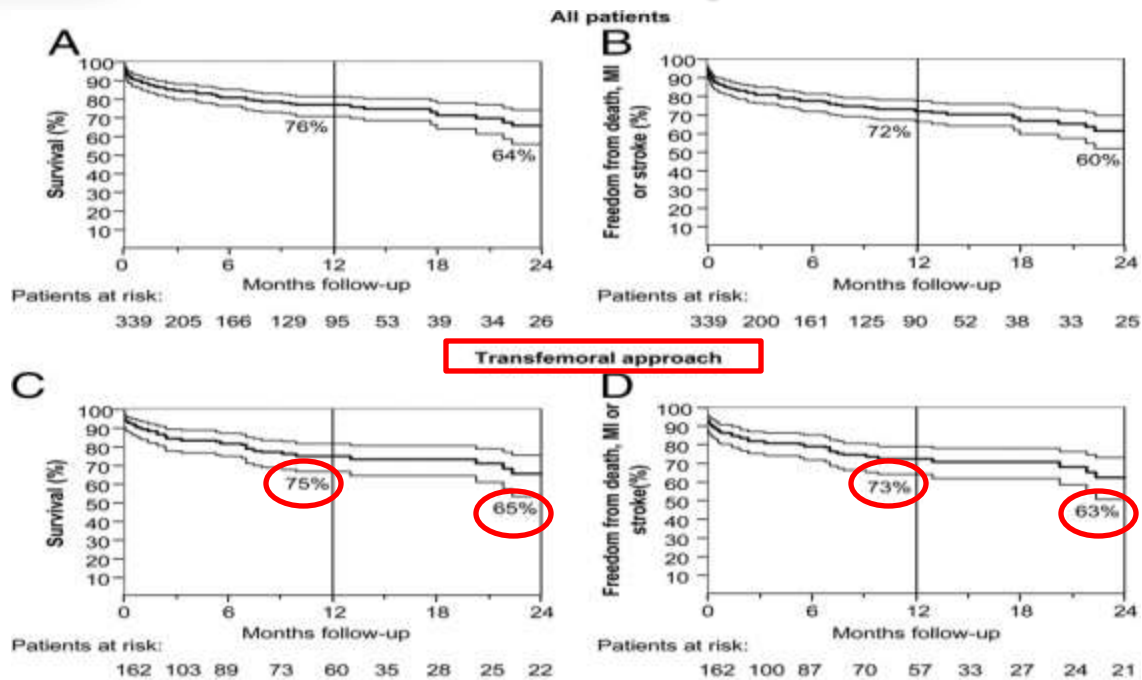
Ussia G P et al. Eur Heart J 2012







# Canadian Registry: Survival and event rates at 1 and 2 yr



Rodes-Cabau et al, JACC, 2010

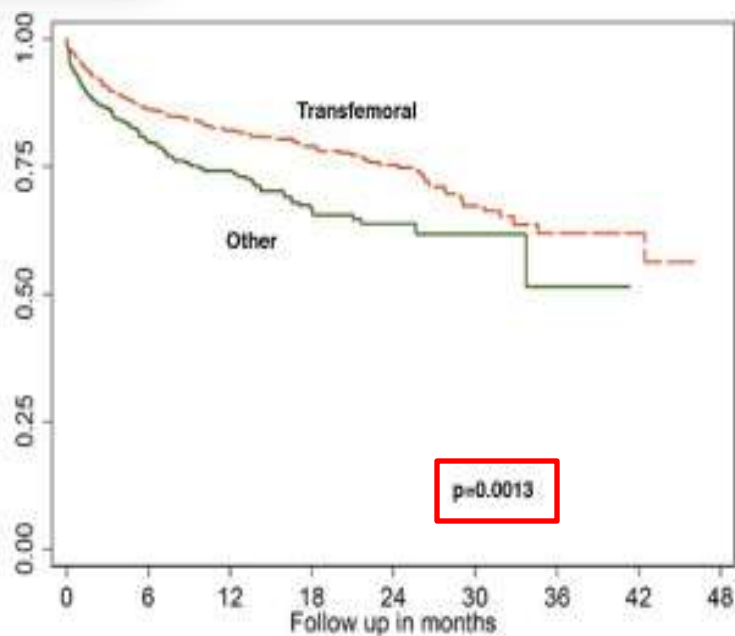




# UK TAVI Registry

CoreValve,  
Edwards

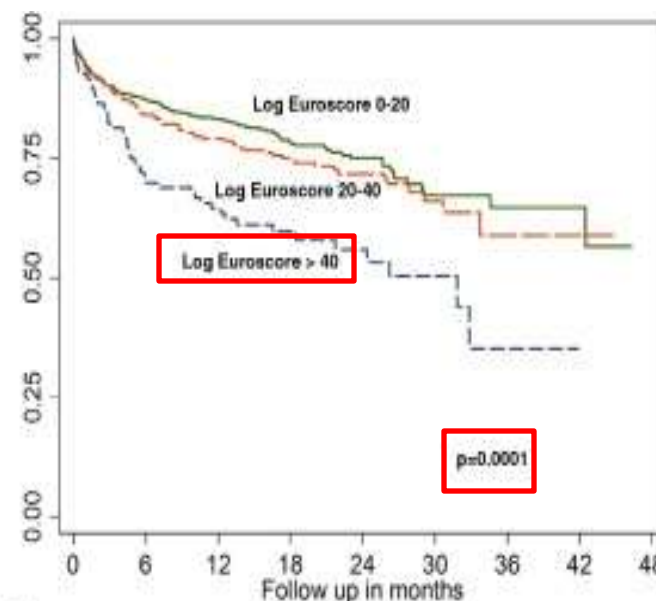
N= 870



Number at risk		0	6	12	18	24	30	36	42	48
Other	271	211	190	108	46	18	3	0	0	0
Transfemoral	599	503	461	285	167	80	27	11	0	0

Increased survival in the transfemoral compared to the nontransfemoral route

Moat et al, JACC 2011

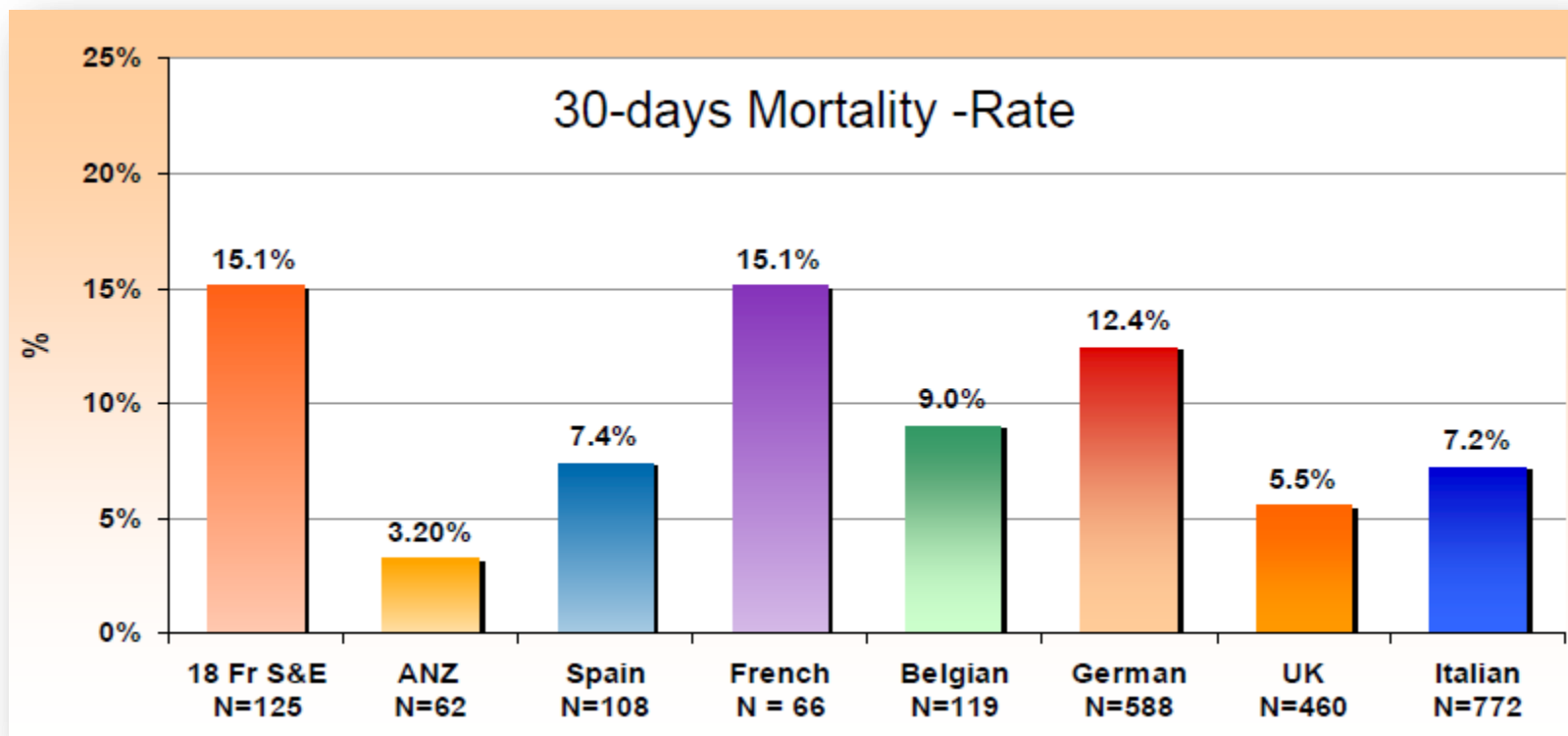


Number at risk		0	6	12	18	24	30	36	42	48
Log Euroscore 0-20	470	398	367	221	111	53	20	8	0	0
Log Euroscore 20-40	301	249	226	135	79	32	7	3	0	0
Log Euroscore > 40	99	67	58	37	23	11	3	0	0	0

Reduction in midterm survival for patients with a log EuroSCORE of >40



# EU 30 day TAVI mortality



# Trans-catheter therapy for AoVS

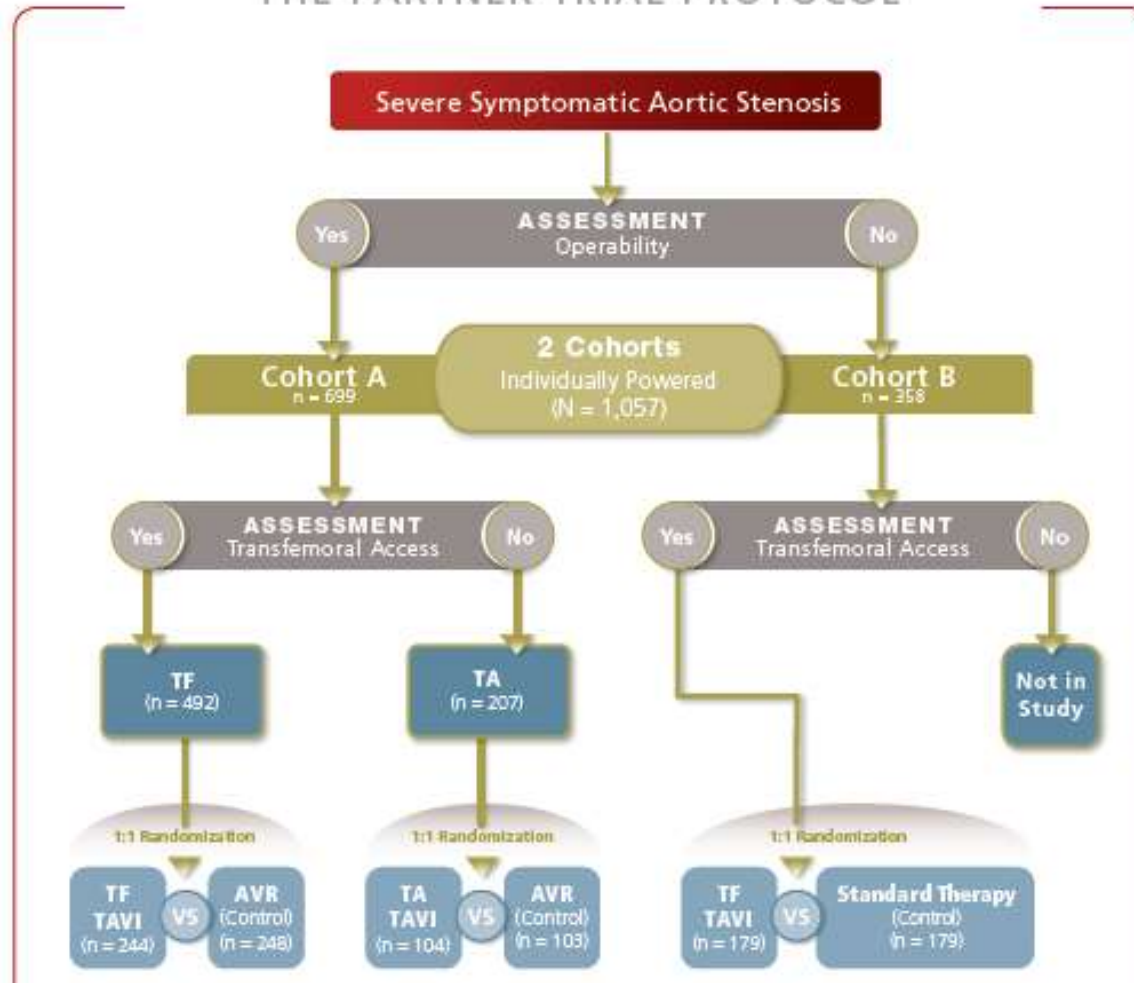
- Evidence Based Medicine → PARTNER



# PARTNER trial

## Evidence Based Medicine

### THE PARTNER TRIAL PROTOCOL<sup>1</sup>





# PARTNER inclusion criteria

## COHORT A INCLUSION CRITERIA<sup>1,2</sup>

STS score	≥ 10
and/or Predicted operative mortality	≥ 15%
NYHA functional class	≥ II
AVA or Mean AVG or Peak jet velocity	< 0.8 cm <sup>2</sup> > 40 mm Hg > 4.0 m/s

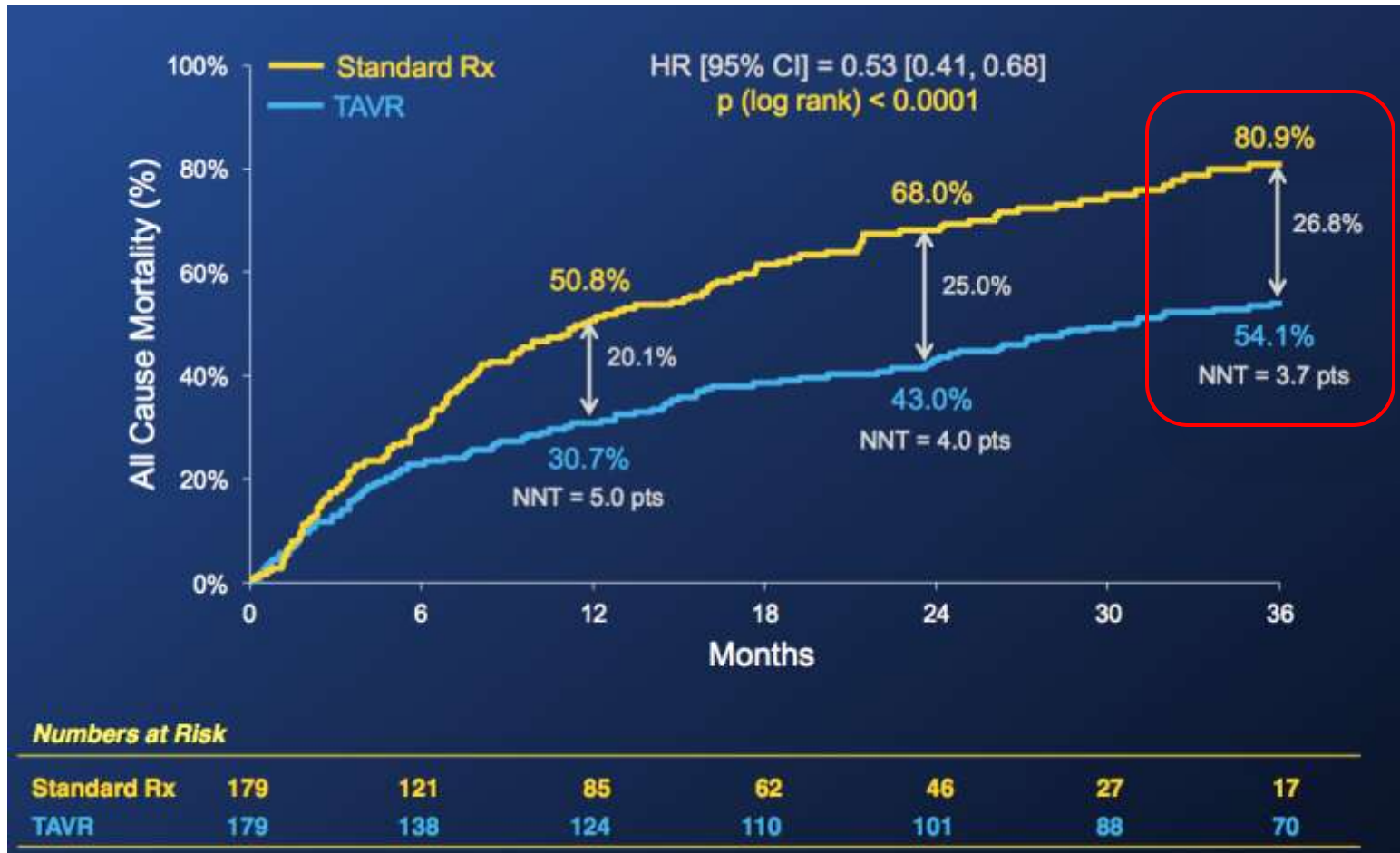
## COHORT B INCLUSION CRITERIA<sup>3</sup>

STS score	11.6 <sup>*</sup>
Predicted operative mortality	> 50% <sup>†</sup>
NYHA functional class	≥ II
AVA or Mean AVG or Peak jet velocity	< 0.8 cm <sup>2</sup> > 40 mm Hg > 4.0 m/s



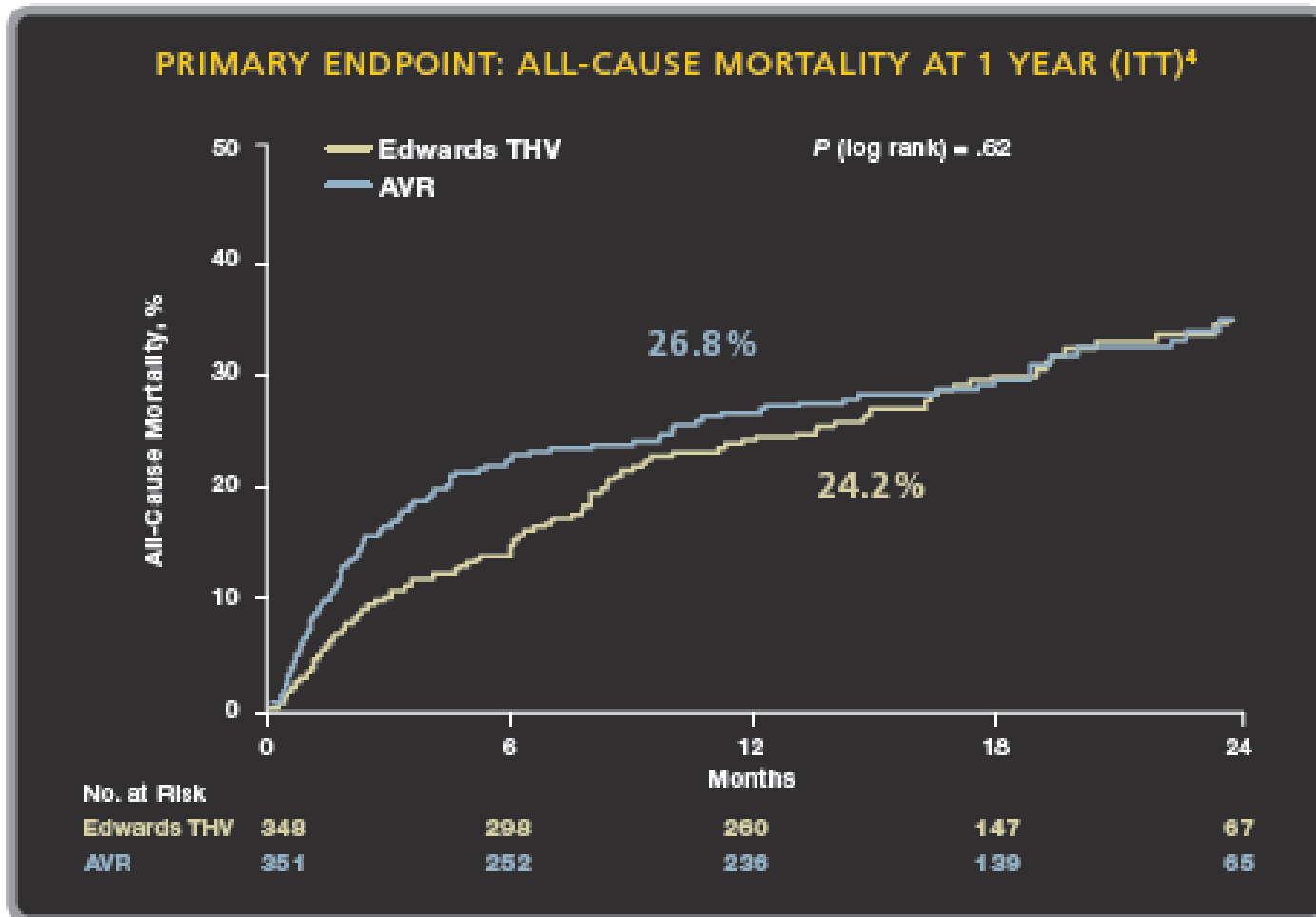
# PARTNER B: 3 yr results

All cause mortality lower for TAVI patients



# PARTNER A 1 YR RESULTS

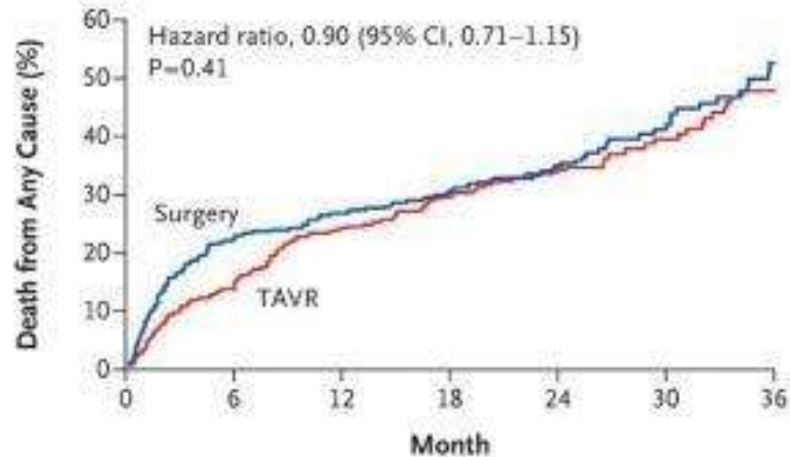
## TAVI vs Surgery: No difference in survival



# PARTNER A 2 YR RESULTS

## TAVI vs Surgery: No difference in survival

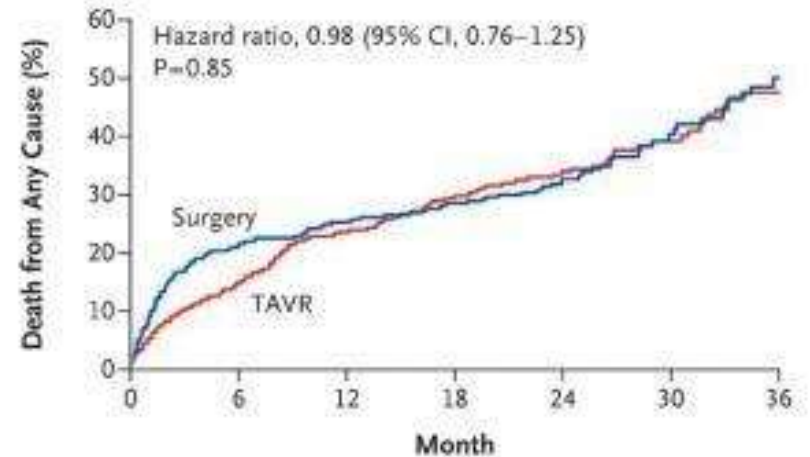
**A** Death from Any Cause, Intention-to-Treat Population



No. at Risk

TAVR	348	298	260	234	172	70	31
Surgery	351	252	236	217	165	65	32

**B** Death from Any Cause, As-Treated Population



No. at Risk

TAVR	344	291	259	232	155	70	29
Surgery	313	243	229	211	143	63	28

Kodali SK et al. N Engl J Med 2012



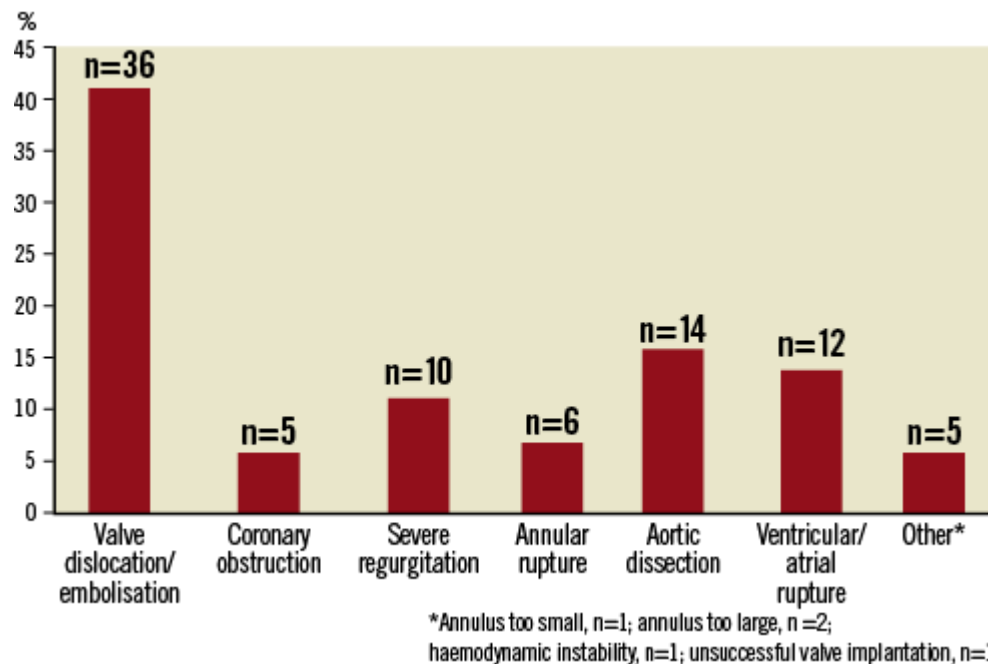
# Trans-catheter therapy for AoVS

- Complications



# Emergency conversion to open heart surgery

9.251 patients from 46 studies: **1.1%**

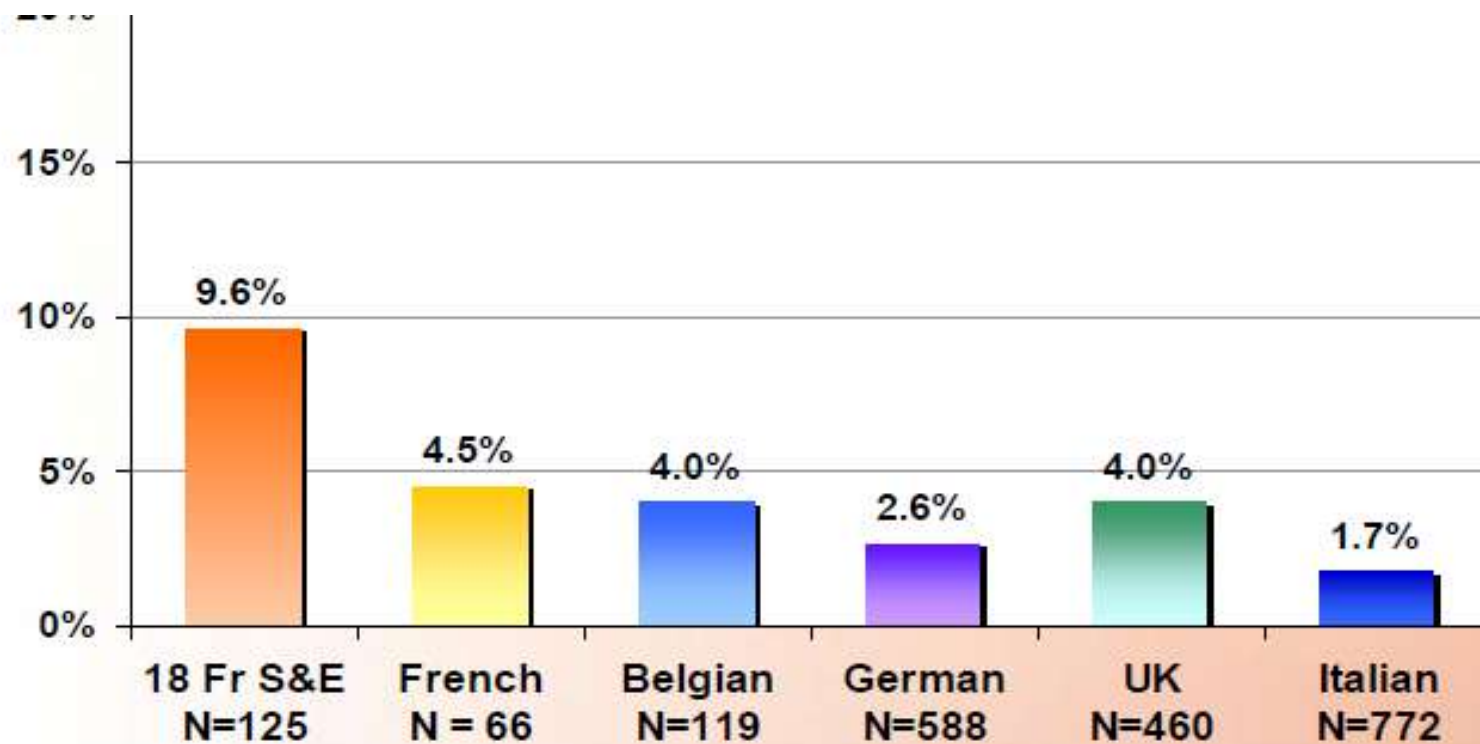




# Stroke

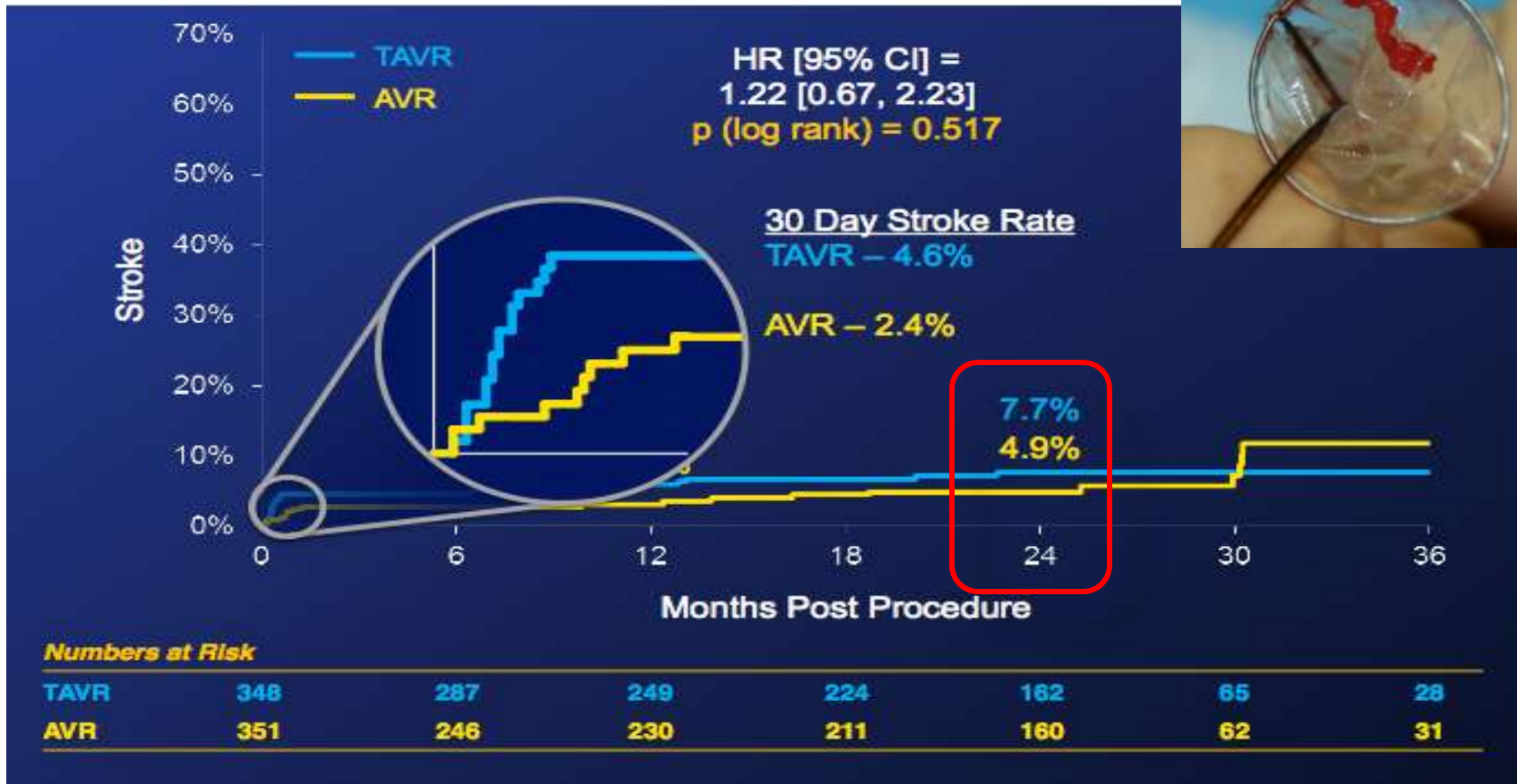


# EU stroke rate at 30 days



# PARTNER A: 2 yr results

## Higher rates seen in TAVI compared to SAVR



# PARTNER B: 3 yr results

## Stroke rates higher in TAVR than in medical Tx

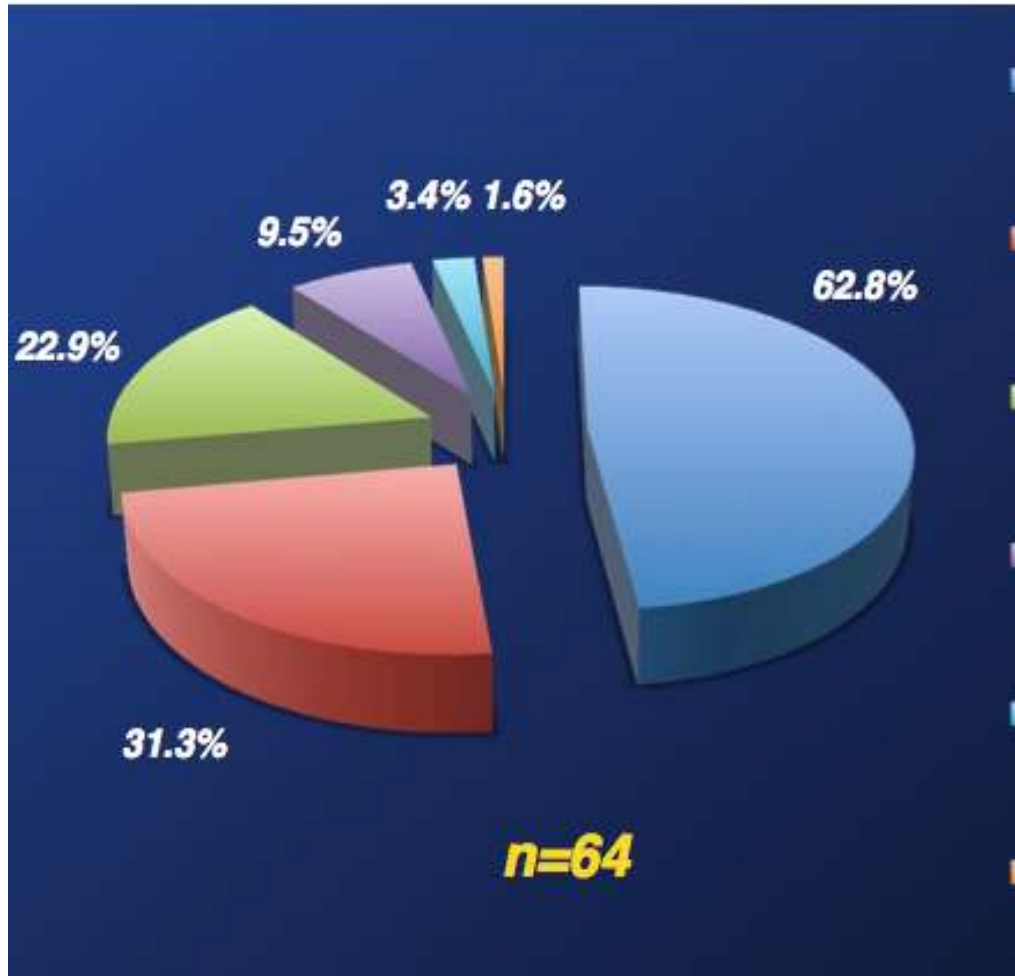


# Major vascular events



# PARTNER

## Major vascular complications



Διαχωρισμός αγγείων

Ρήξη αγγείων

Αιμάτωμα στο χώρο εισόδου

Οπισθοπεριτοναϊκό αιμάτωμα

Ψευδές ανεύρυσμα

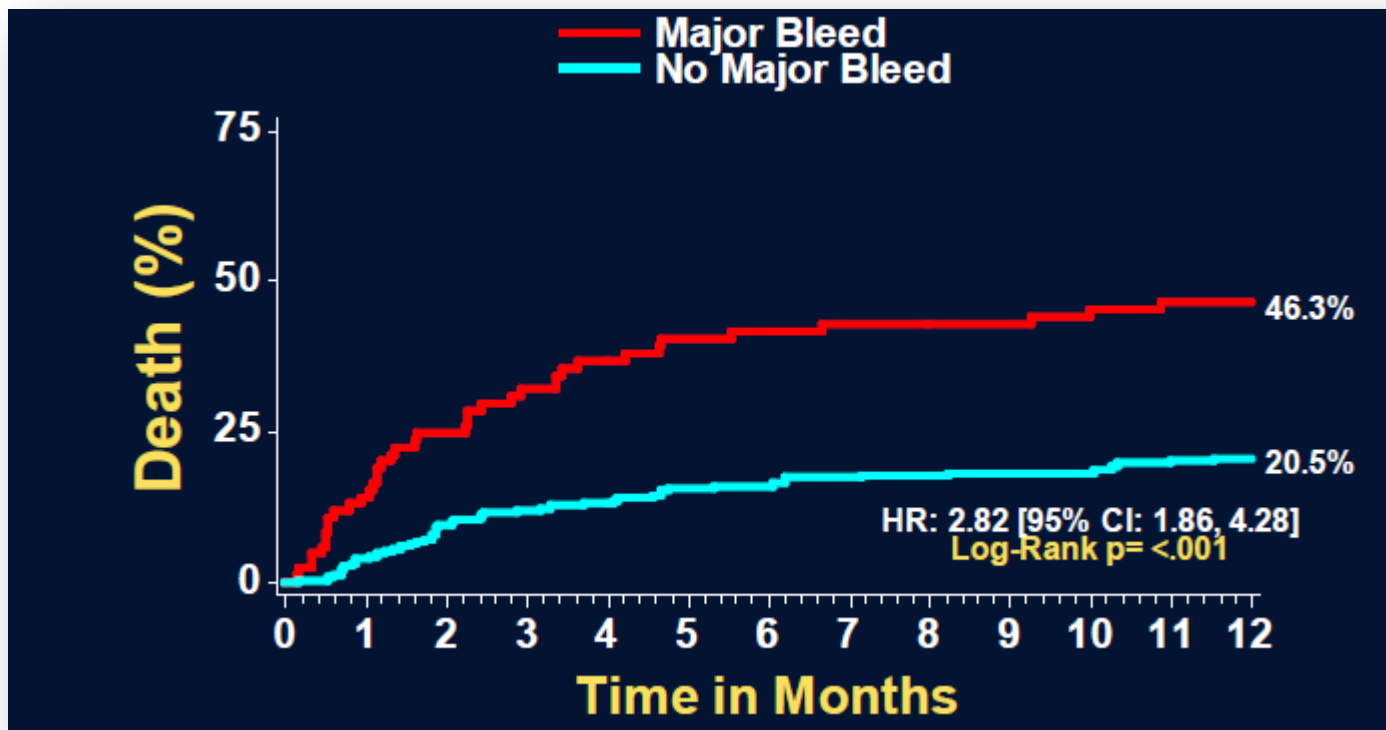
Γαστρεντερολογική ισχαιμία



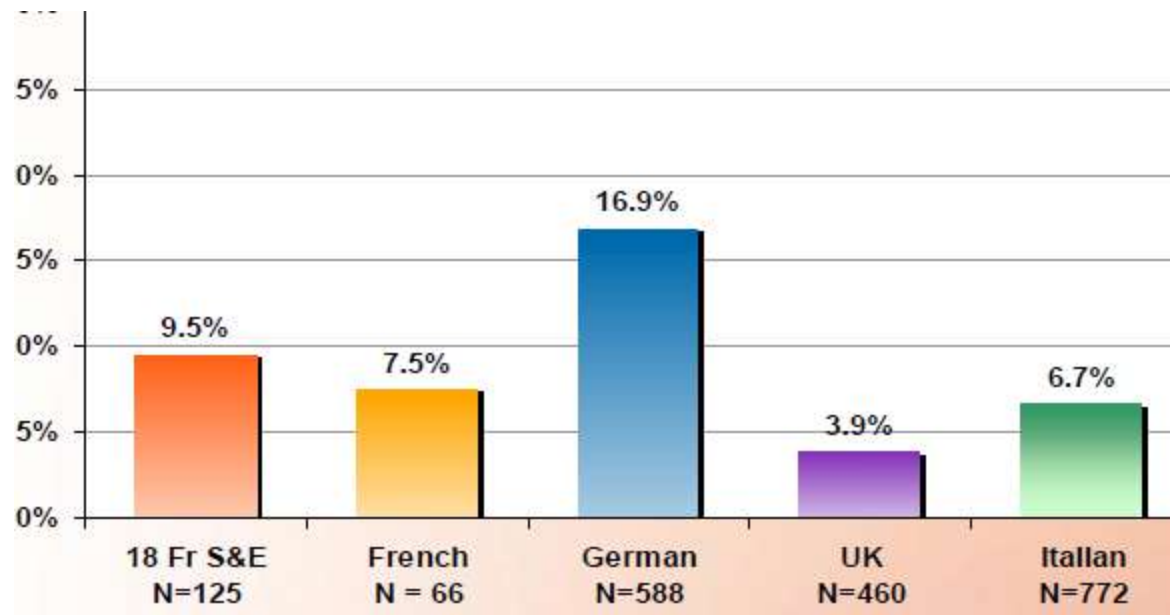


# PARTNER A

## Bleeding increases mortality



# EU vascular complications



# Greece: MCV vs EXT in 1 month

	MCV	EXT	p
Procedure success	100%	100%	
Device success (VARC)	92%	90%	0.76
30 day mortality, n	2	0	0.36
Major vascular complications (VARC)	5	9	0.04
New pacemaker	32	5	<0.01
Valve-in-valve	5	1	0.23



# Independent Predictors of VARC major vascular complications

1. **Sheath to Femoral Artery Ratio (SFAR)**

HR=1.86 (p=0.006)

2. **Early center experience**

HR=3.66 (p=0.023)

3. **Femoral artery calcium score**

HR=3.44 (p=0.026)

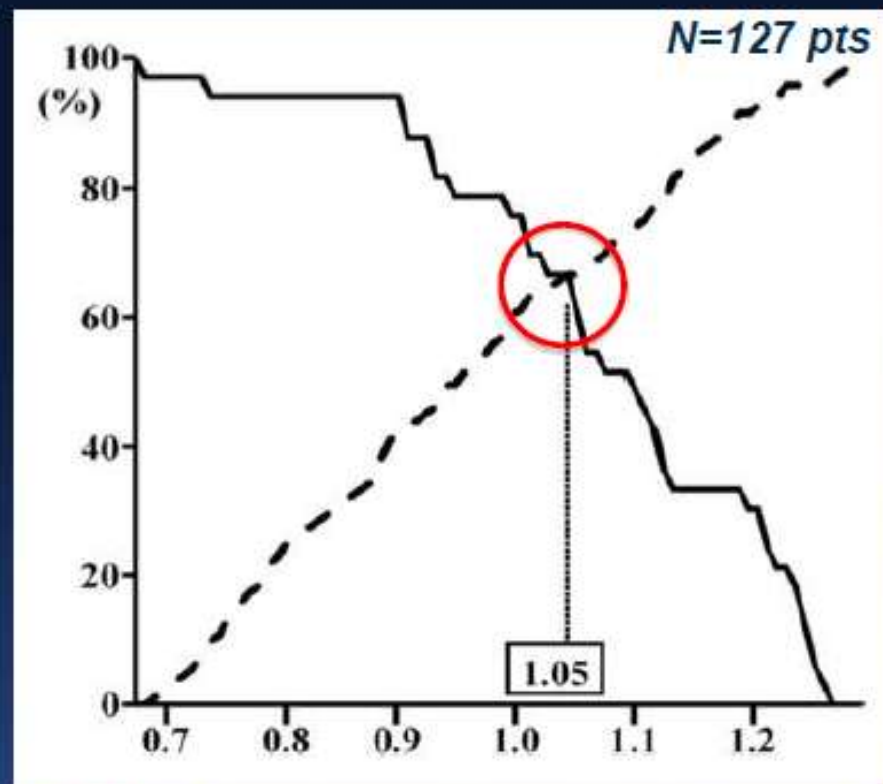
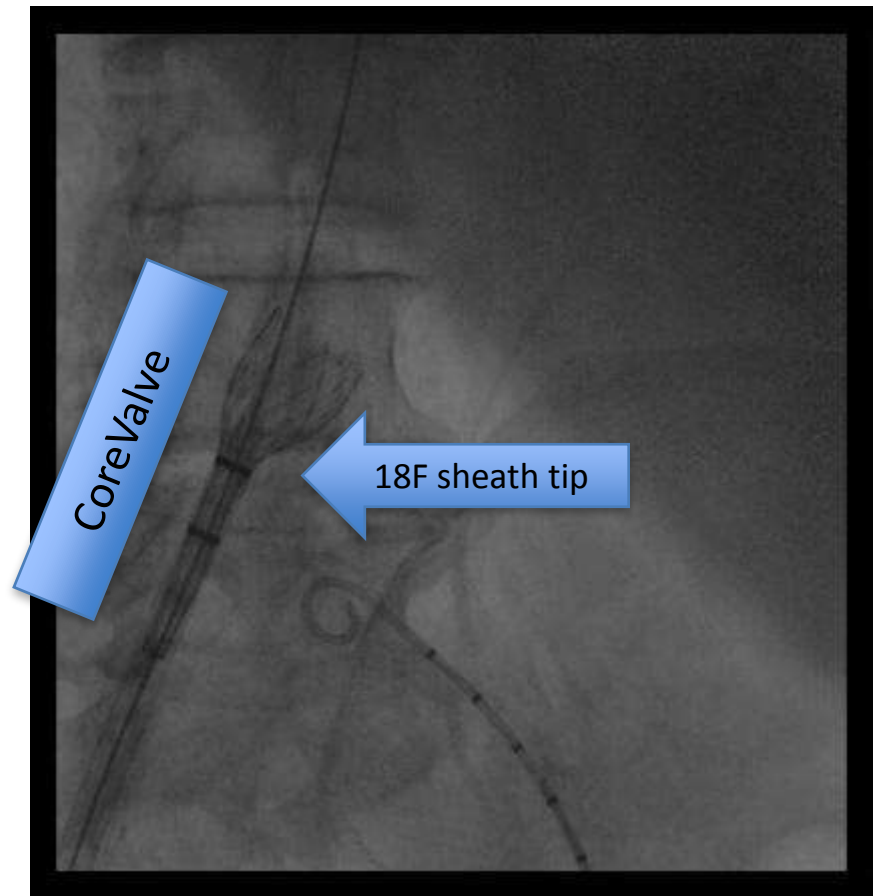


Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

*The sensitivity and specificity curve identified the threshold SFAR of 1.05 as predictive of VARC major vascular complications*

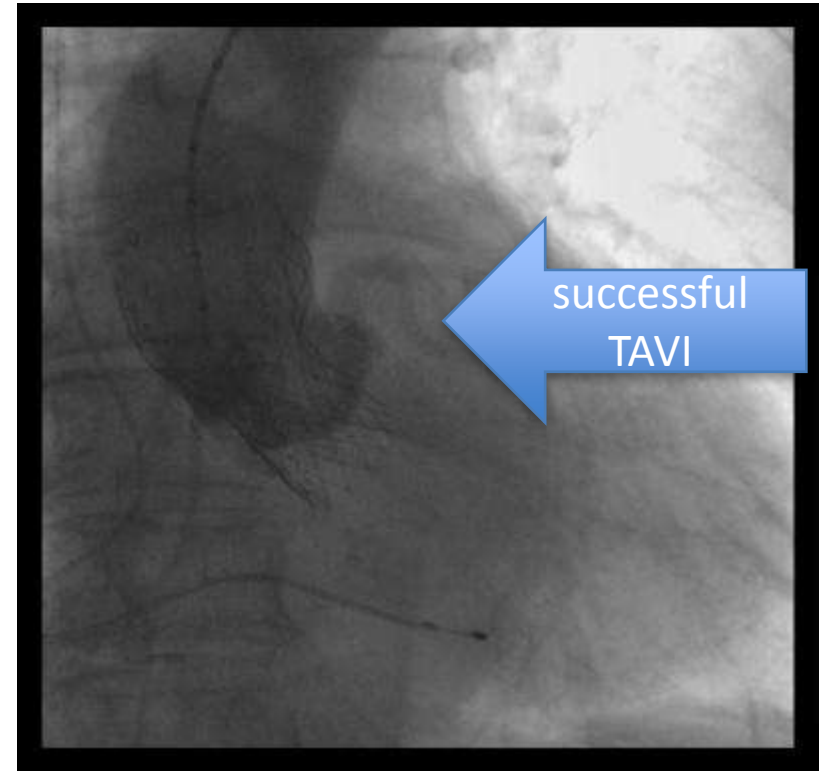
# Various vascular complications

Initial MCV slipped to abdominal aorta.  
Attempt to **retrieve** it through the 18F sheath by the delivery catheter **unsuccessful**



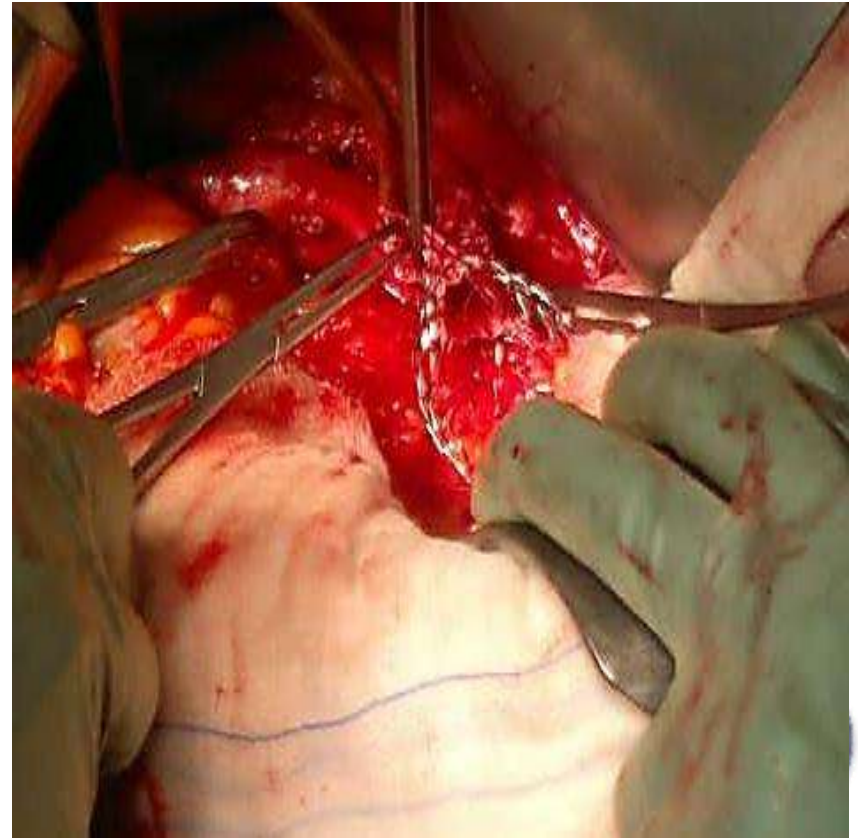
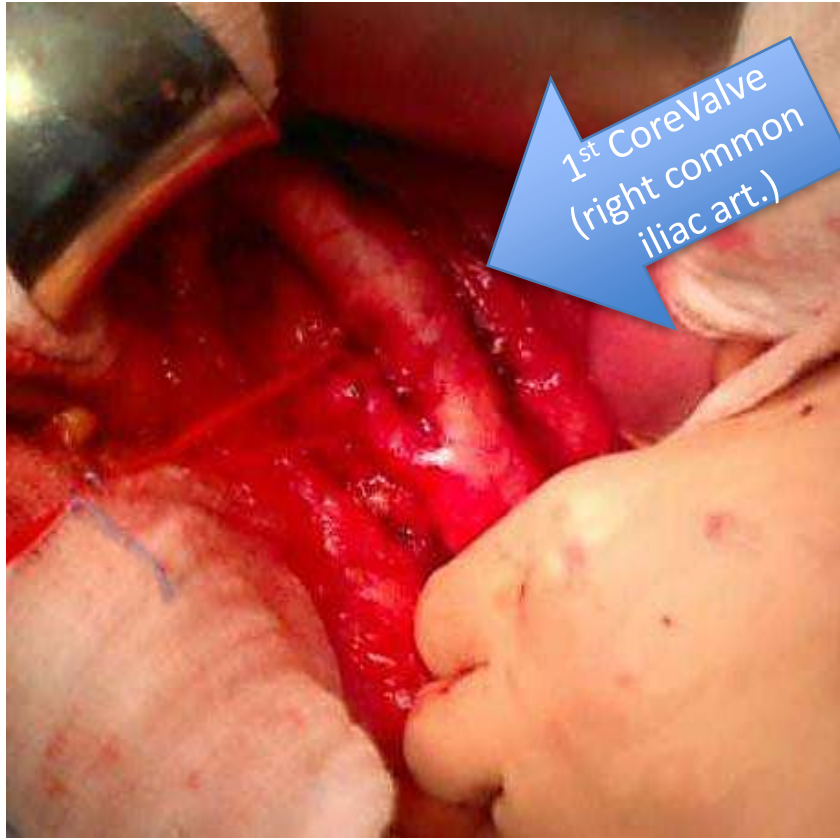


# 2<sup>nd</sup> MCV through the 1<sup>st</sup>: “Valve-through” technique





# 1<sup>st</sup> prosthesis: successful surgical removal



# Conduction abnormalities



# Surgical Aortic Valve Replacement

Up to **8.5%** isolated AVR

Dawkins et al. Ann Thorac Surg 2008;85:108-112

*Table 3. Summary of Previous Studies Investigating the Incidence of Permanent Pacemaker After Valvular Surgery*

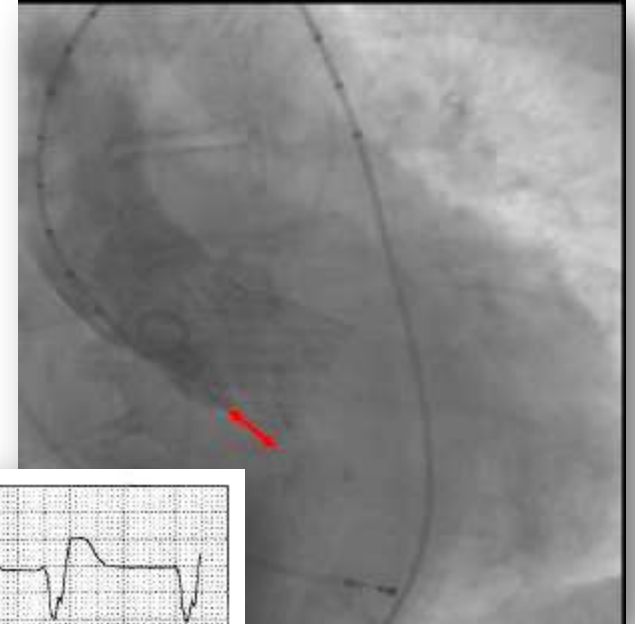
Author	Date Reported	Number Studied	Isolated AVR	Comments	Incidence of PPM
Morell et al [20]	1996	46	No	AVR ± CABG in the elderly	6.5%
Lewis et al [17]	1998	558	No	Reoperative cardiac surgery	9.7%
Kolh et al [19]	1999	83	No	AVR ± CABG in the elderly	6%
Limongelli et al [8]	2003	276	No	AVR ± CABG	3.2%

The permanent PM is implanted after 6 – 10 days of watchful observation and safe epicardial pacing.

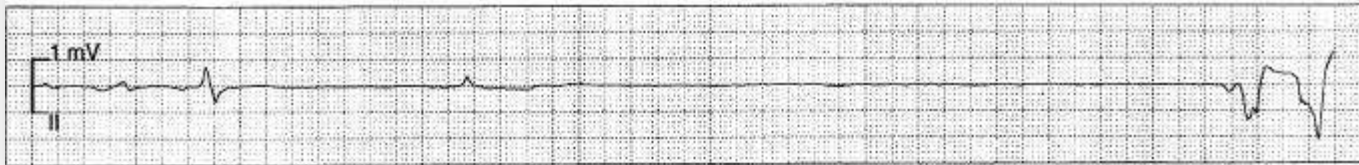
AVR = aortic valve replacement; CABG = coronary artery bypass grafting; PPM = permanent pacemaker.



# How long should I wait? Late 3<sup>rd</sup> AV block after TAVI

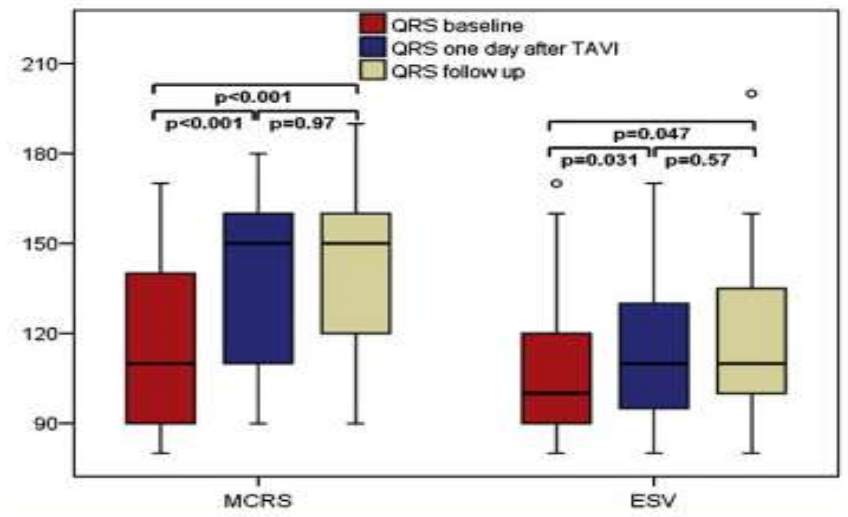
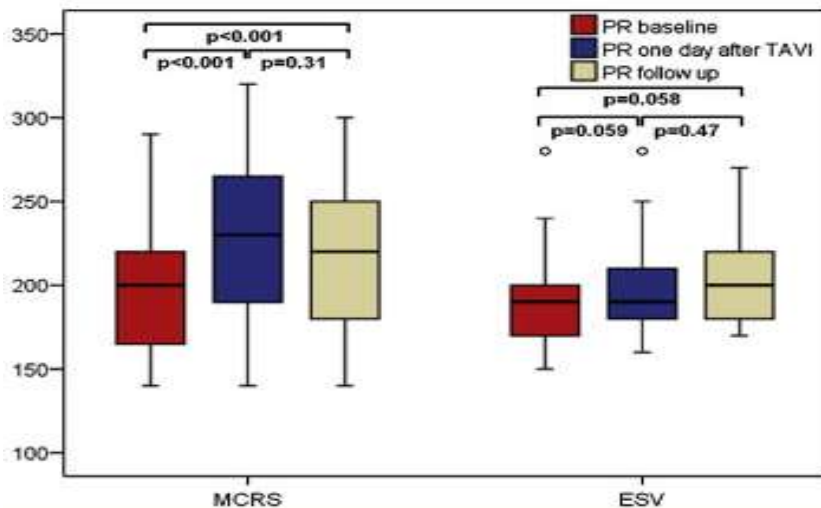
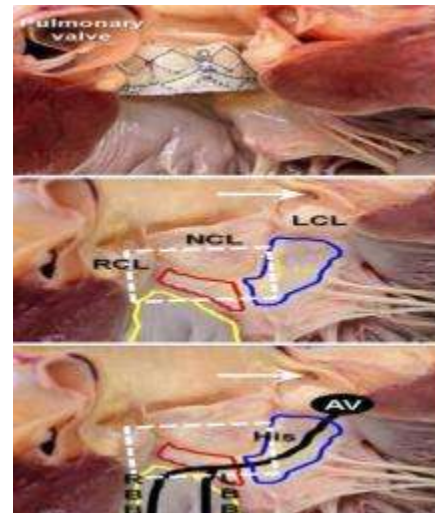
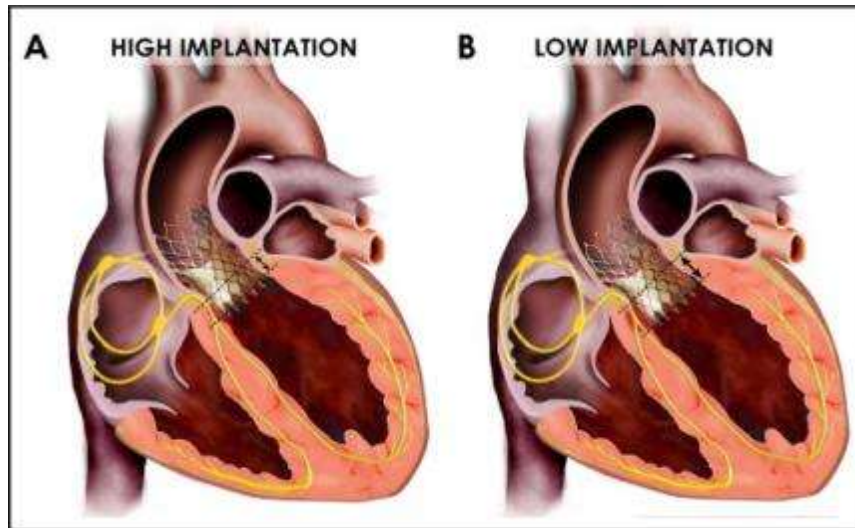


9 days post TAVI

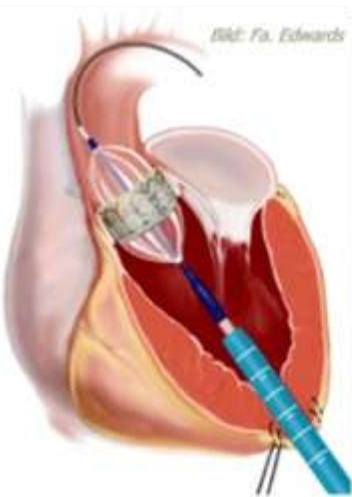
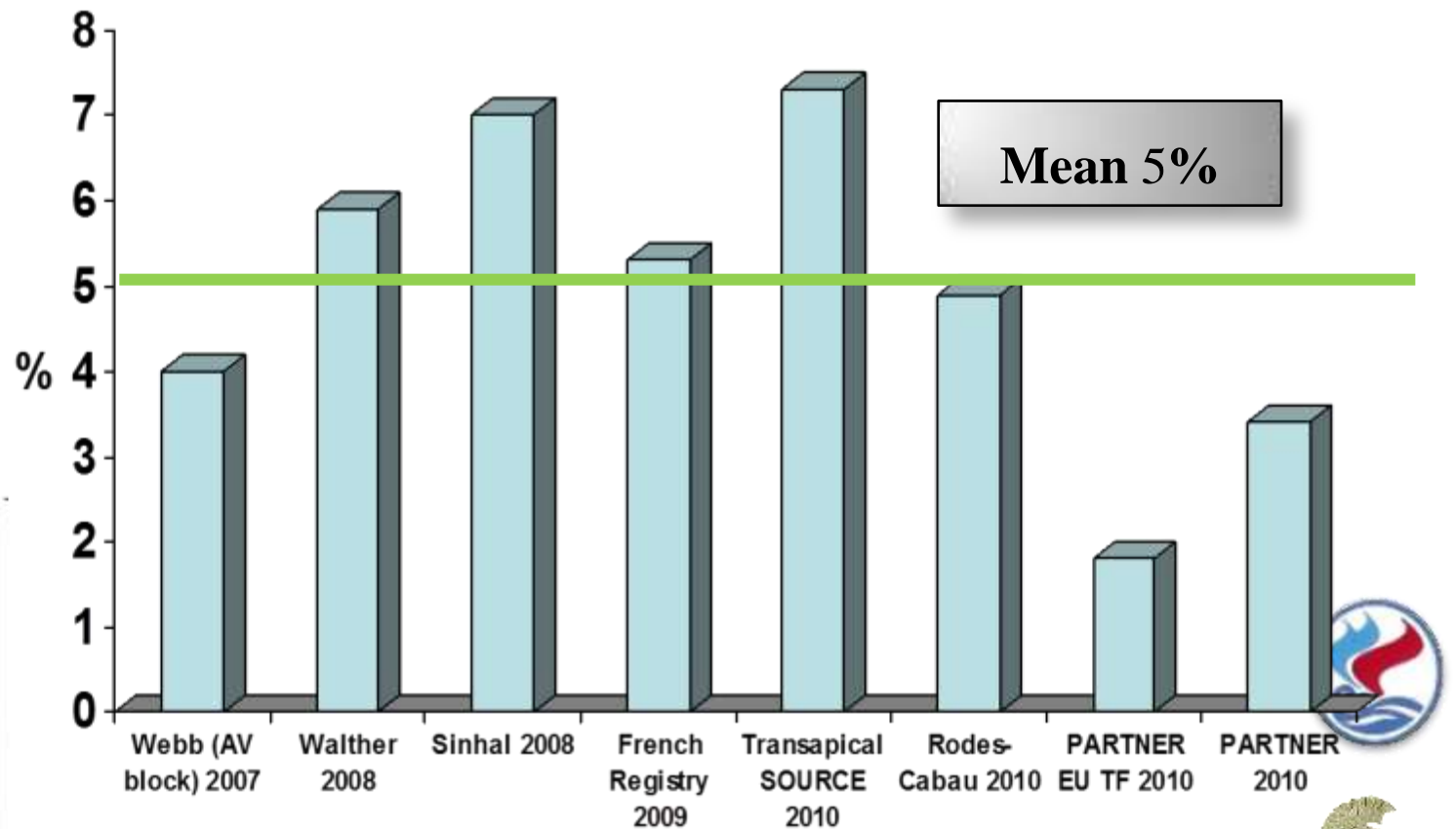




# MCV impairs AV conduction to a greater extent compared to EXT

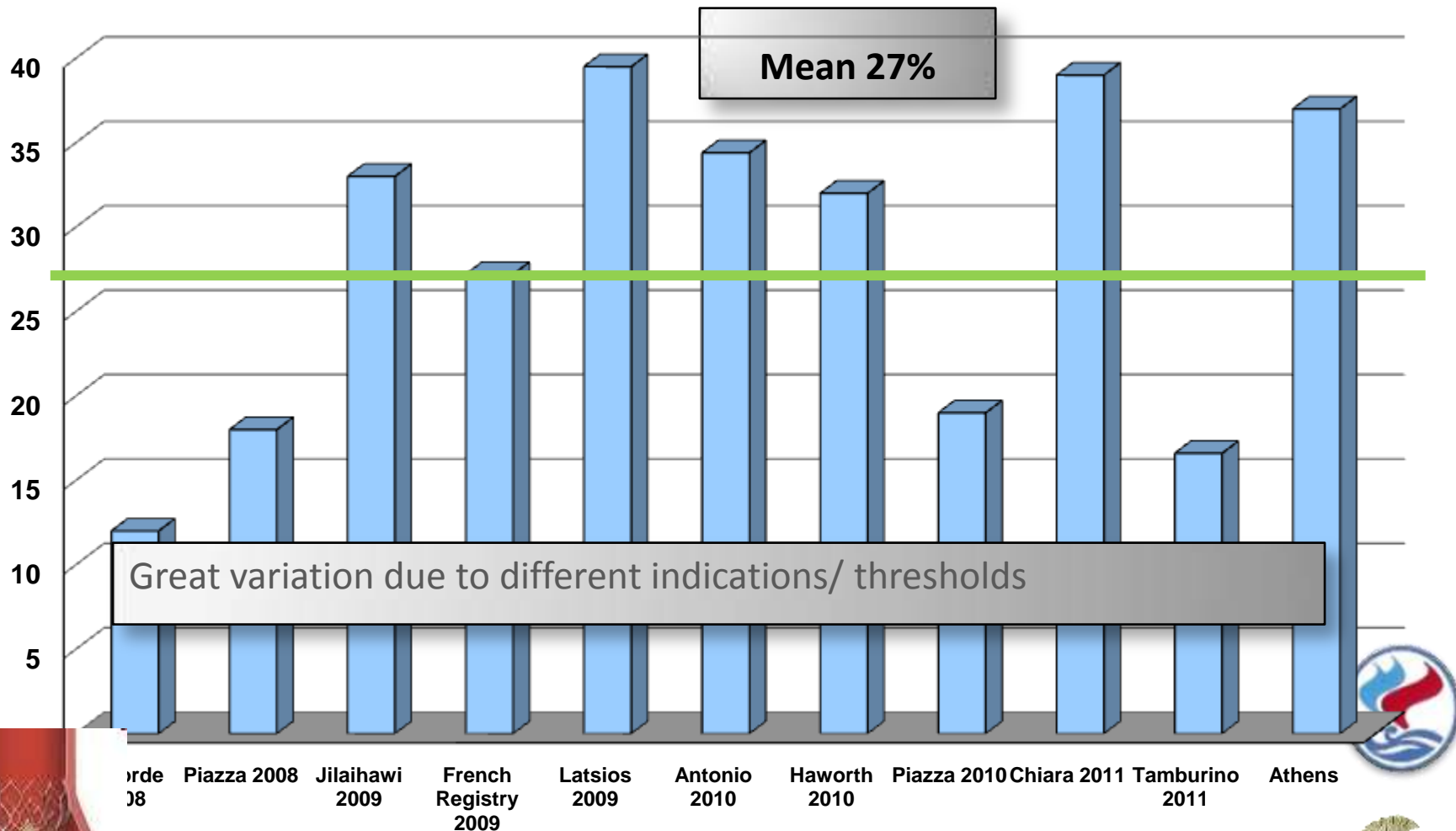


# PM after Edward – Sapien





# PM after Medtronic-CoreValve



# Indications for pacemaker post TAVI:

Siegburg – Bonn ‘Helios’ recommendations

Absolute indications	3rd degree AV block, 2nd degree AV block, LBBB and grade 1 AV block atrial fibrillation: pause >4 sec in the absence of rate lowering medications
‘Prophylactic’ indications	new onset bundle branch block, even without AV delay RBBB and long PQ (>240 msec), alternating PQ times during monitoring.

**Latsios G, ...Grube E. Cath Card Interv 2010 Sep 1;76(3):431-9**

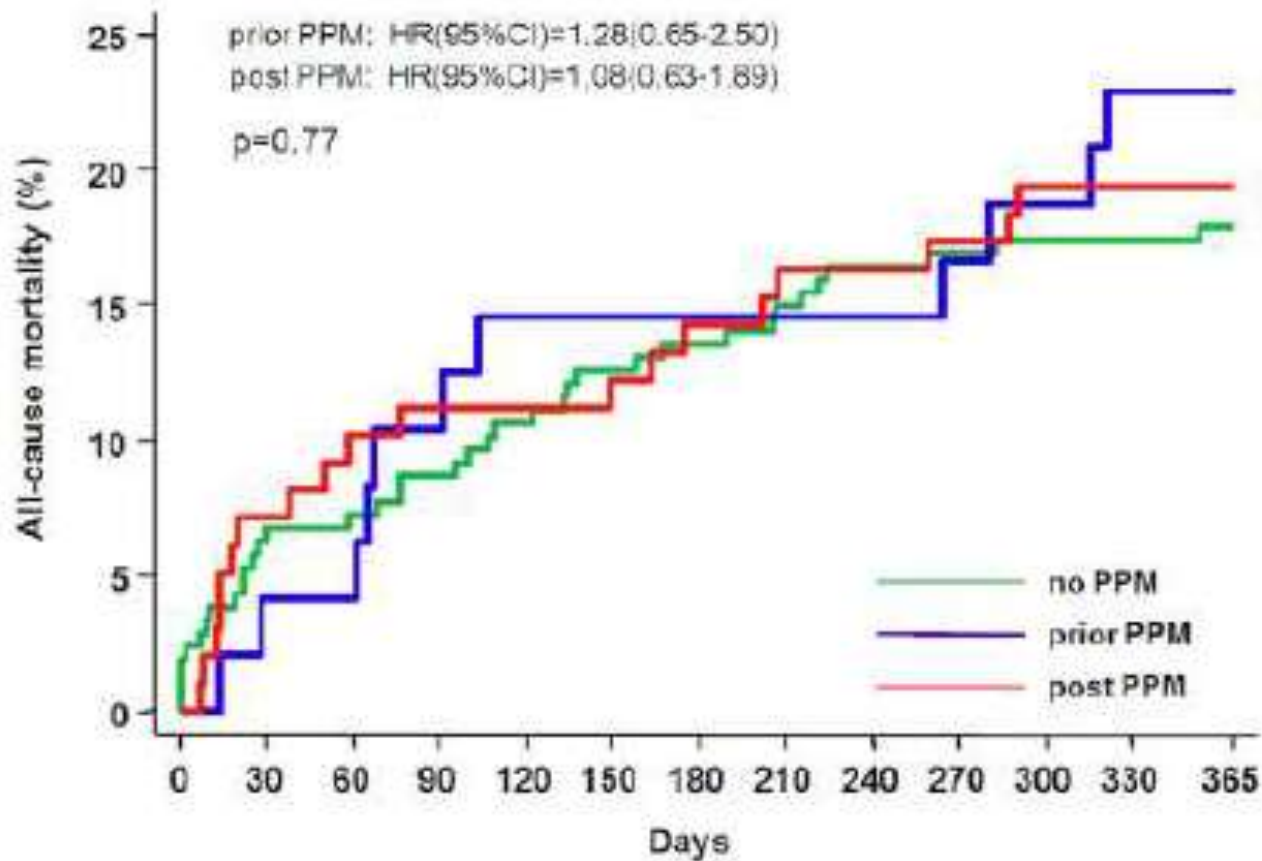
**Gerckens U, May 2011, EuroPCR 2011, Paris**

**Piazza N, June 2011, TVT2011, Vancouver**

**Bonan R, June 2011, TVT2011, Vancouver**



# Impact of PPM post TAVI



Buellesfeld L et al, J Am Coll Cardiol. 2012 Aug 7;60(6):493-501.



# Trans-femoral Leadless Pacing

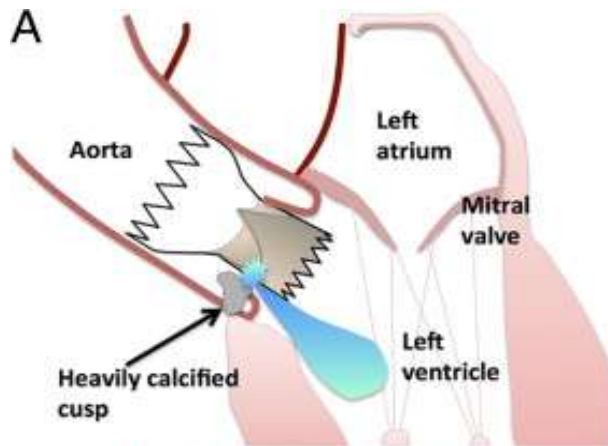


# Paravalvular regurgitation

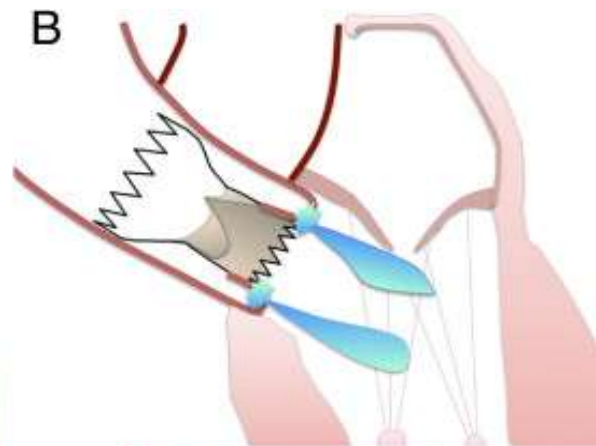


# Mechanisms of Peri-Prosthetic Aortic Regurgitation After TAVI with MCV

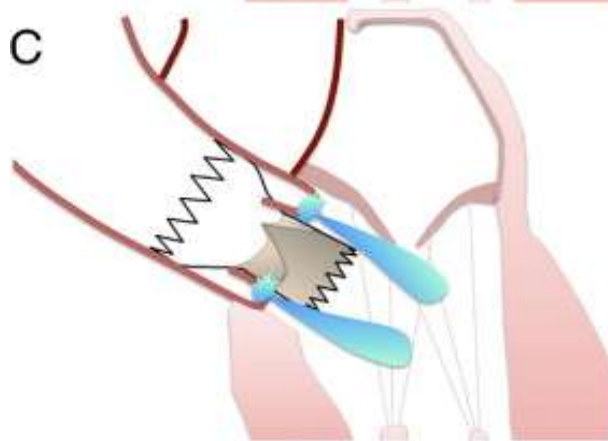
Calcifications of the cusps of the native valve



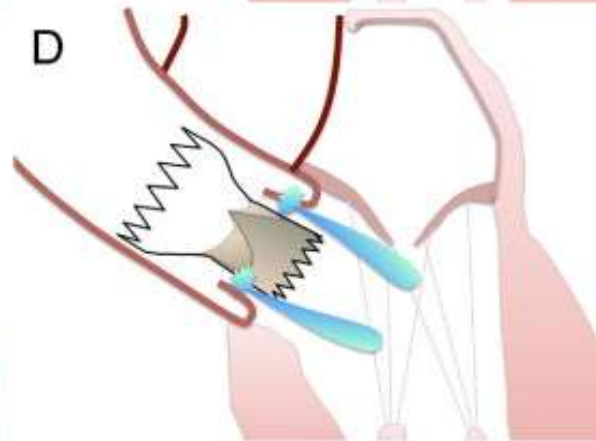
Too shallow valve malposition



Too deep valve malposition

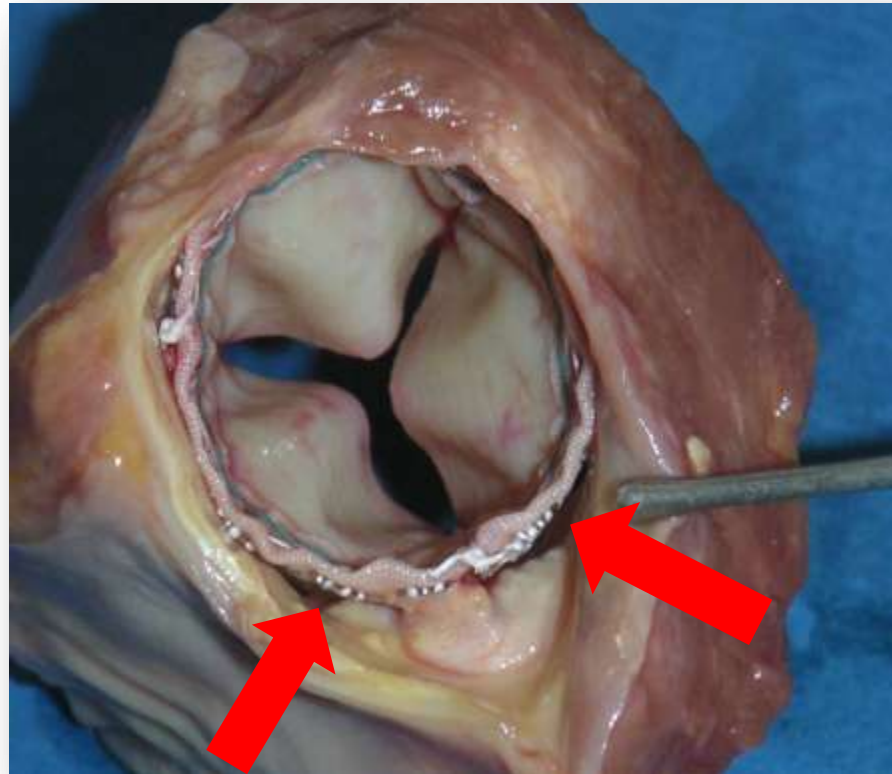


Annulus-prosthesis-size mismatch





# Aortic paravalvular regurgitation



# >2+/4+ PVL after TAVI increases mortality

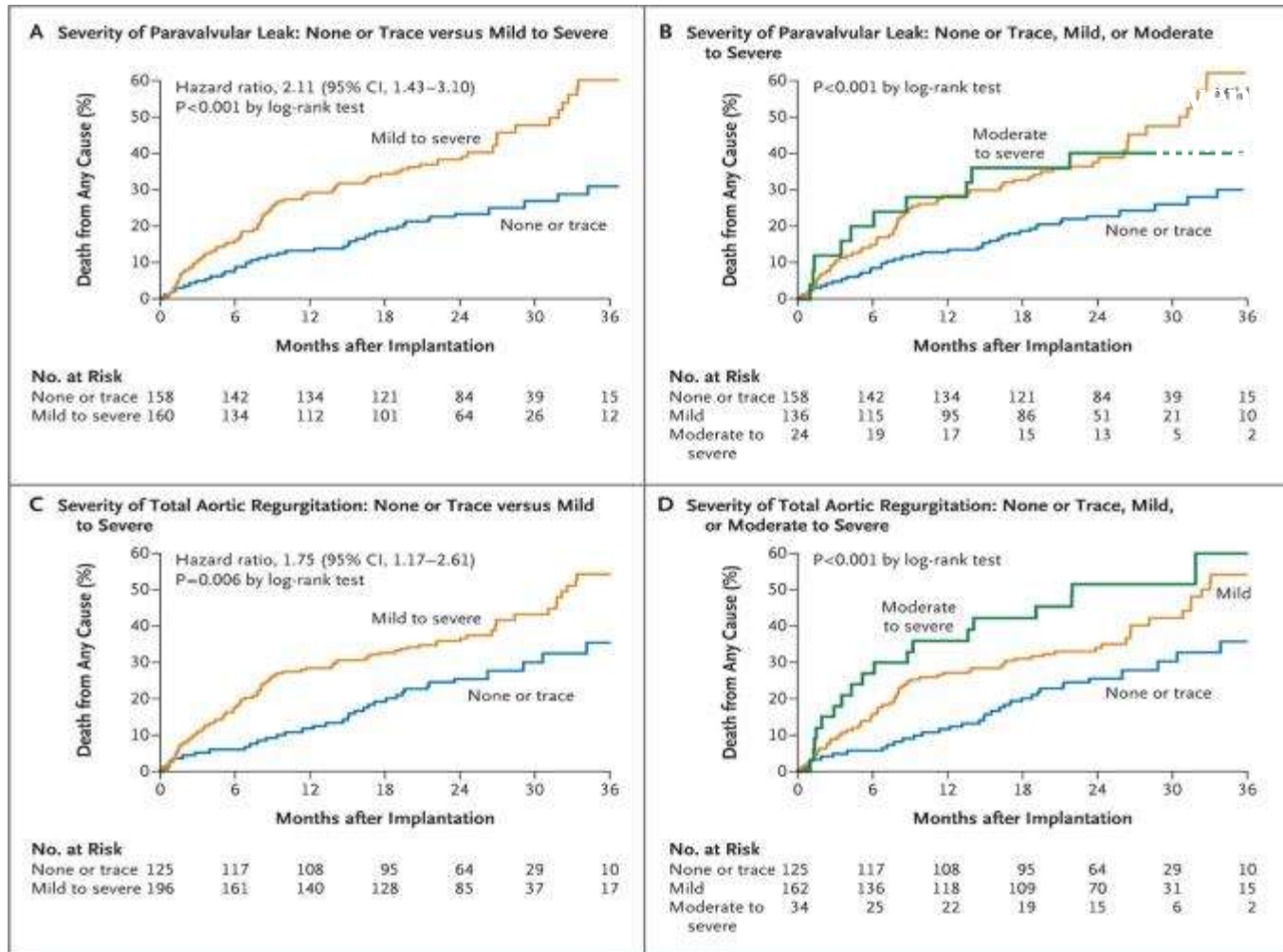
Author (journal)	# patients	TAVR Type	Predicts mortality
Abdel-Wahab (Heart 2011)	690	MCV 84% ES 16%	≥ 2/4 - mortality in-hospital
Tamburino (Circulation 2011)	603	MCV 100%	≥ 2/4 - mortality 30 days – 1 year
Gotzman (AHJ 2011)	145	MCV 100%	≥ Mod - mortality @ 6 mos
Moat (JACC 2011)	870	MCV 52% ES 48%	≥ Mod - mortality @ 1 year



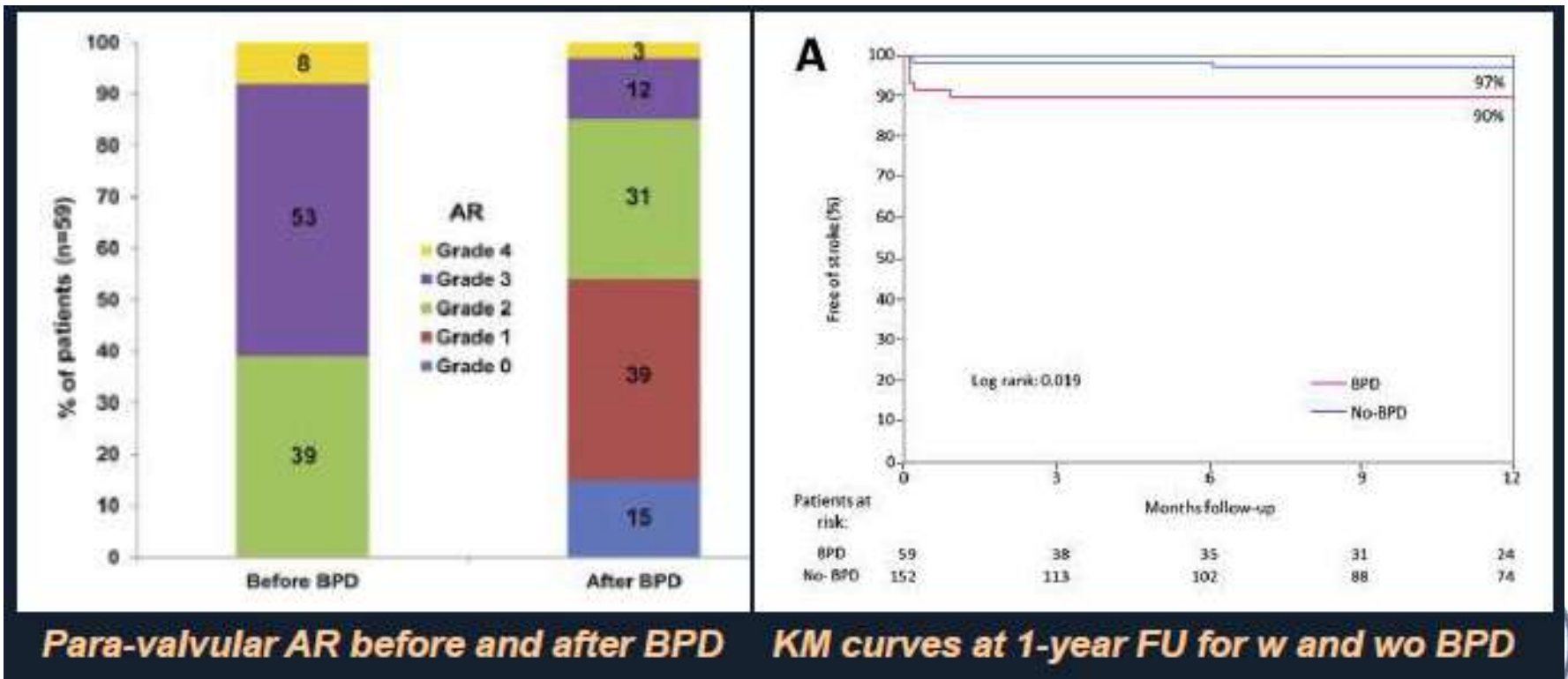
# PARTNER A

The effect of PVL on **mortality**

is *proportional* to the severity of AR



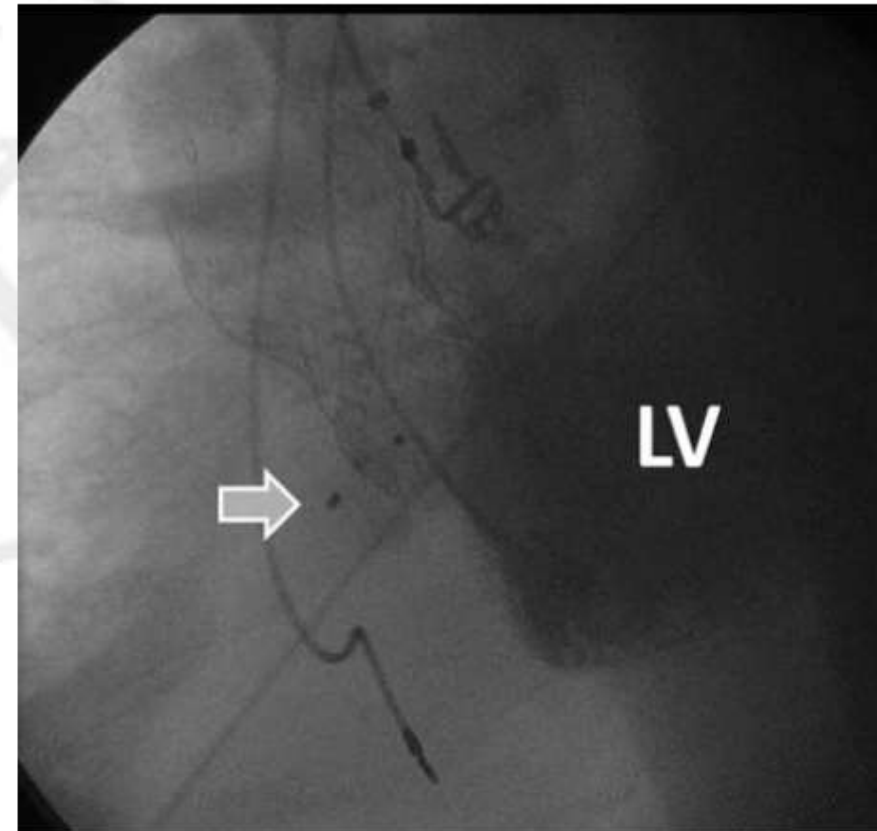
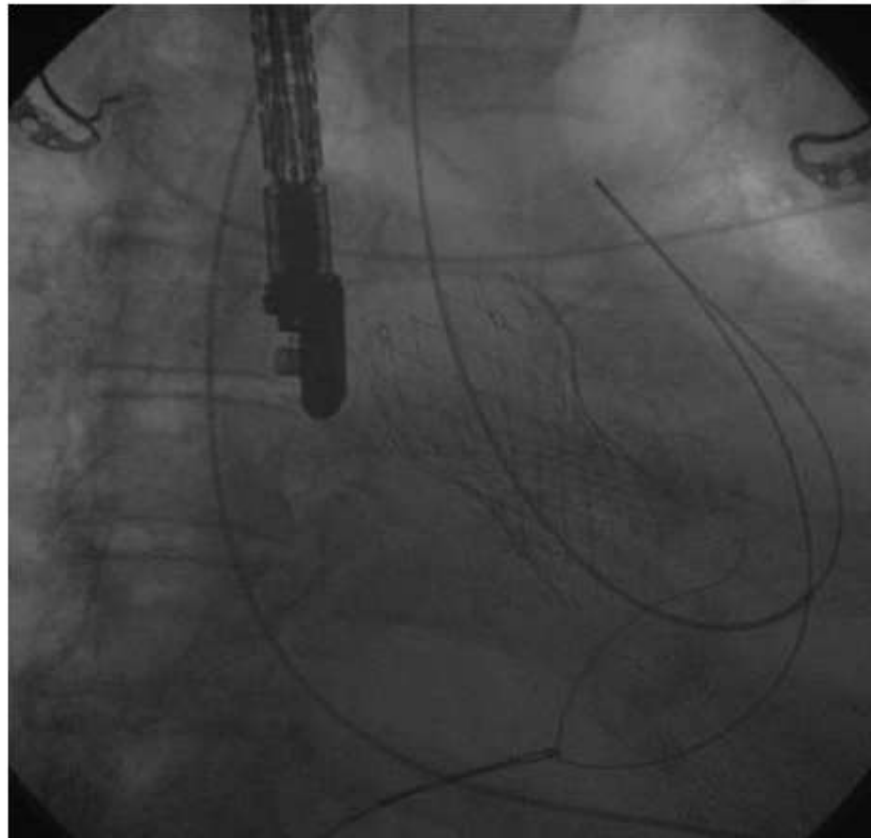
# Post TAVI balloon dilatation



Nombella-Franco L.O. et al in JACC Cardiovasc Interv. 2012 May;5(5):499-512.



# Percutaneous treatment of an iatrogenic post TAVI VSD



# Trans-catheter therapy for AoVS

- Future developments

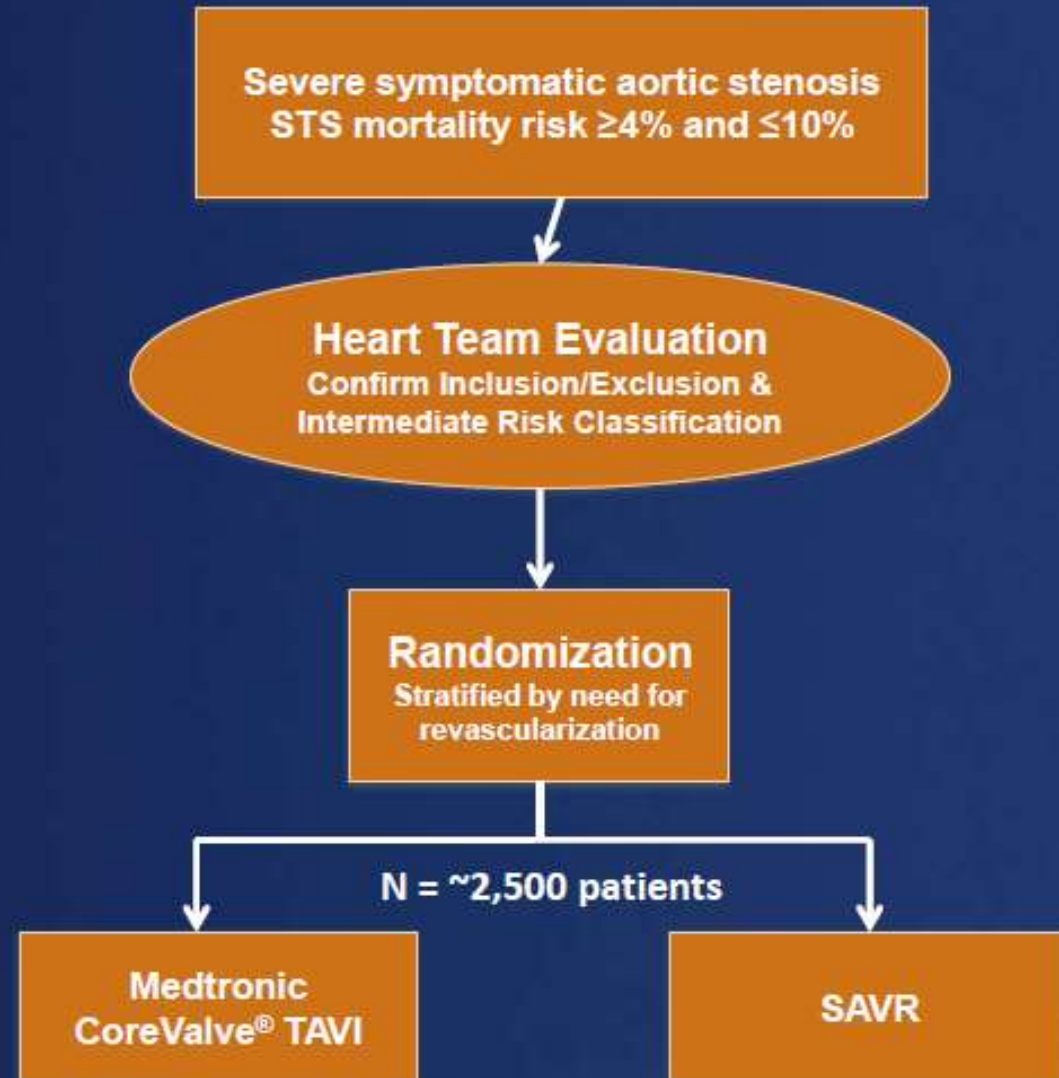




# CoreValve® SURTAVI Trial

## Study Design<sup>1</sup>

- Randomized 1:1, non-inferiority study
- The trial will be conducted at up to 75 worldwide centers
  - Europe
  - Canada
  - United States
- Long-term follow-up through 5 years
- Approx 2,500 total number of trial subjects



# The PARTNER IIA Trial: Study Design



Symptomatic Severe Aortic Stenosis

**ASSESSMENT** by Heart Valve Team

n=2000  
Randomized  
Patients

**Operable**  
(STS  $\geq 4$ )

**ASSESSMENT:**  
Transfemoral  
Access

Yes

No

**Transfemoral (TF)**

**Transthoracic (TA/TAO)**

1:1 Randomization

1:1 Randomization

TF TAVR  
SAPIEN  
XT

VS

Surgical  
AVR

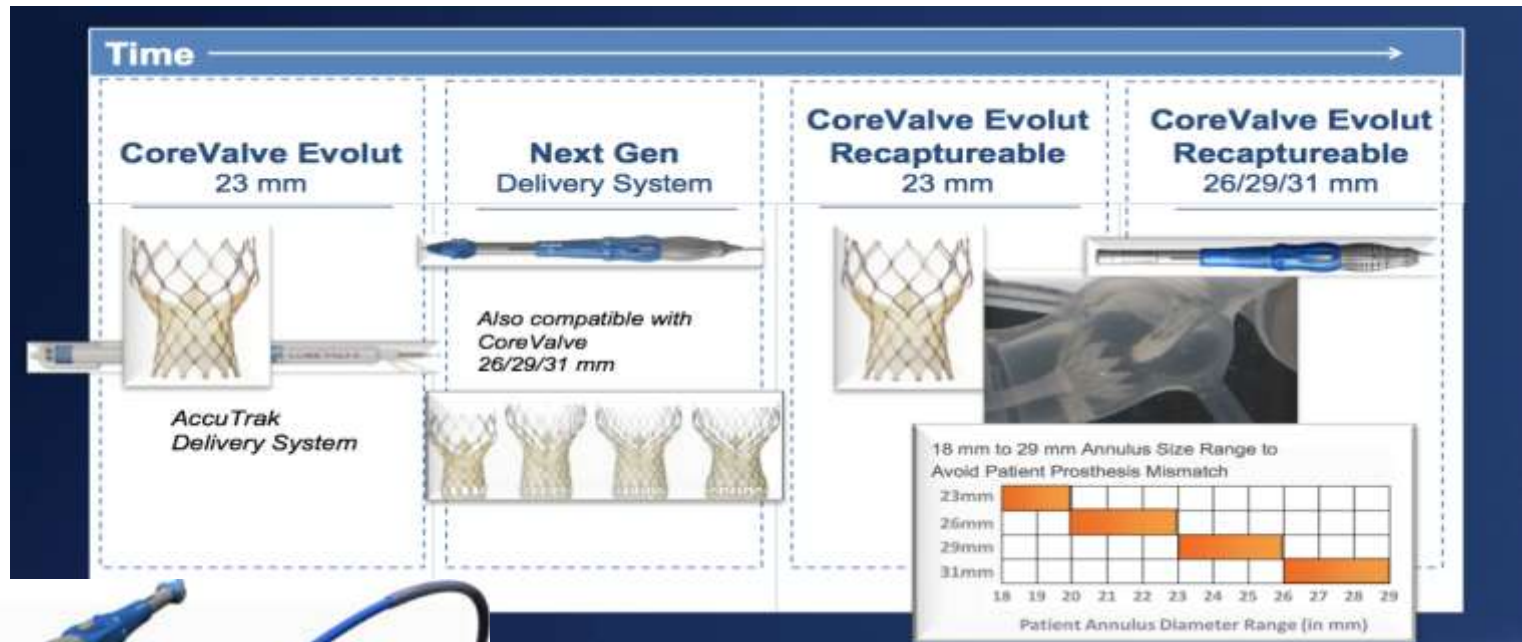
TAVR:  
TA / TAO

VS

Surgical  
AVR

**Primary Endpoint: All-Cause Mortality +  
Major Stroke at Two Years  
(Non-inferiority)**

# Next generation valves and systems I



**Retrievable, Repositionable, Resheathable**





# Next generation valves and systems II



**Cribier-Edwards**



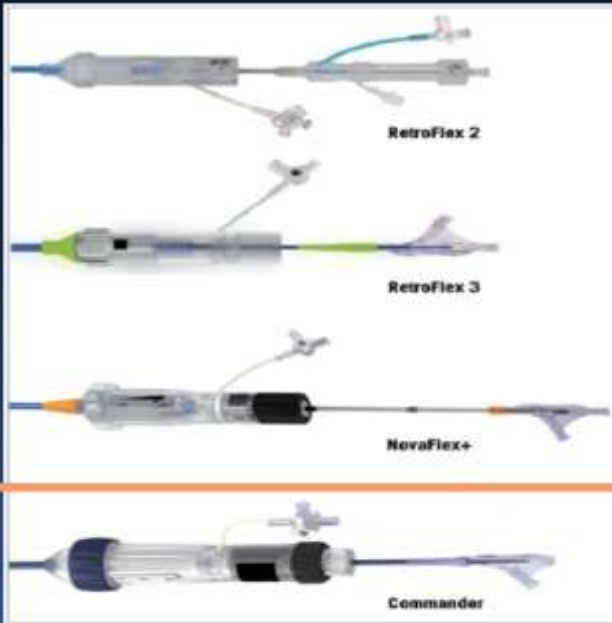
**SAPIEN**



**SAPIEN XT**



**SAPIEN 3**



**RetroFlex 2**

**RetroFlex 3**

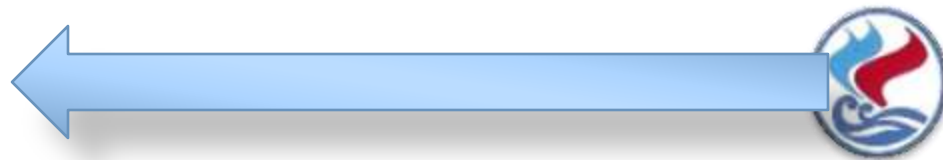
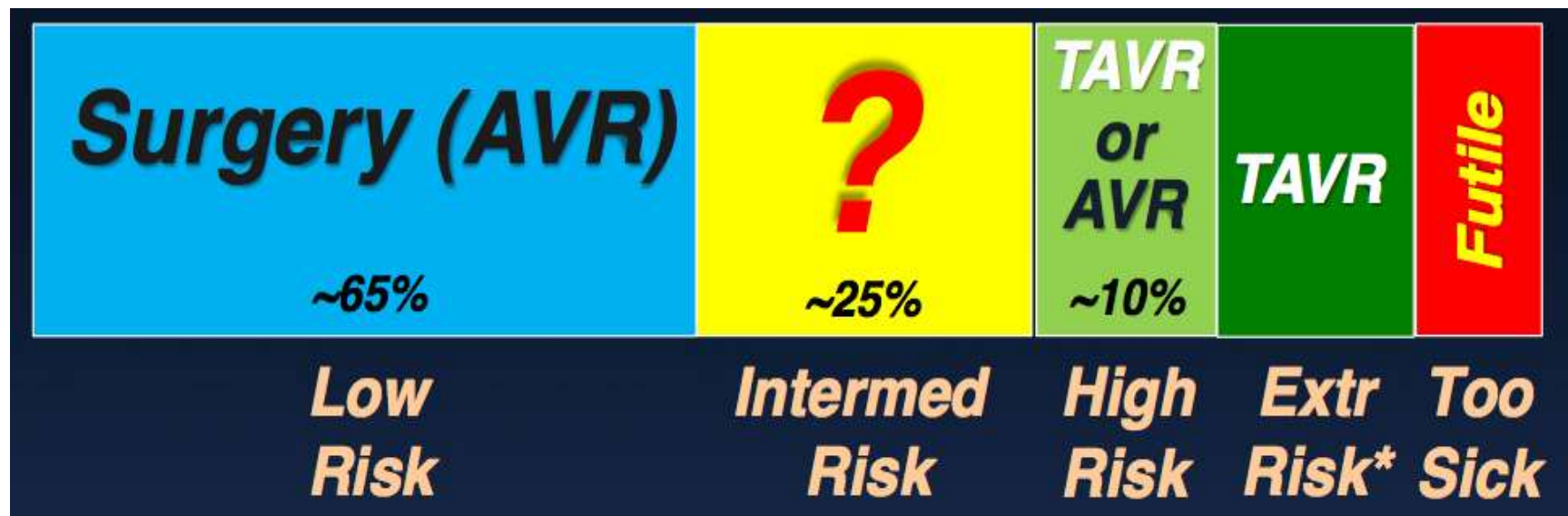
**NevaFlex+**

**Commander**

**14F sheath**



# TAVI is moving towards intermediate risk patients



# Large Vessel Closure Landscape

## Category

## Company

## Technology

Emerging Suture Based Technologies

Interventional Therapies

MediGlobe

SpiRx

Vivasure

ePacing

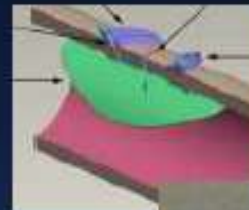
Sealing Solutions

Vascular Closure Systems

Apica Cardiovascular



Emerging Patch or Plug Technologies



*Medtronic, Inc.*

*Abbott Vascular*

*St. Jude Medical*

*Cook/Cardica*

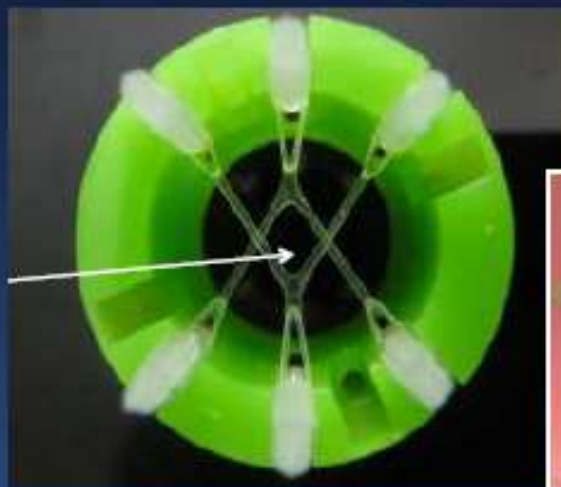
Strategic Players





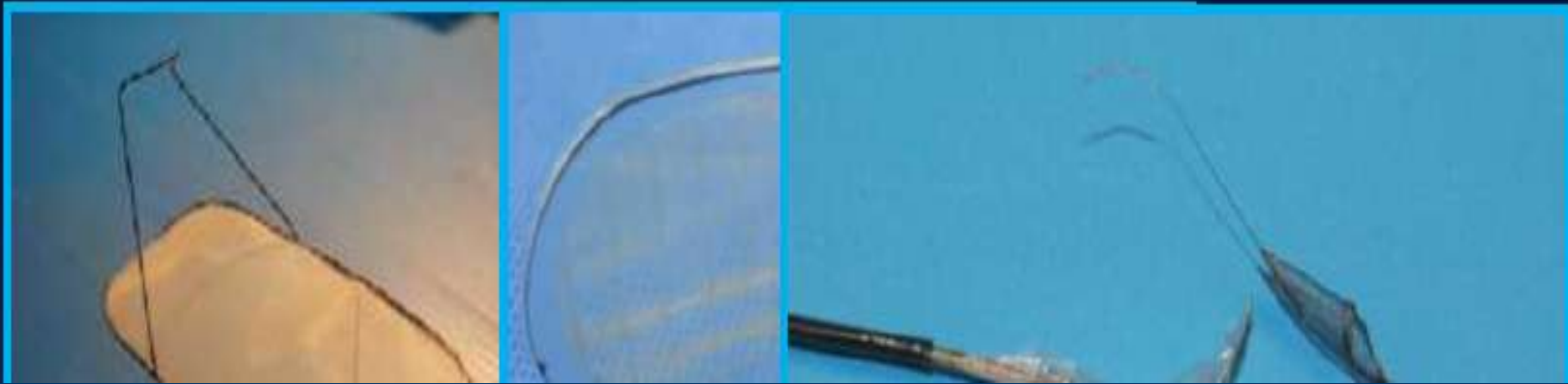
# Transcutaneous Ventricular Access and Closure (TVAC)

- *Apica*
- *Entourage CardioClose*
- *MID Permaseal*
- *Novogate*
- *SpiRx*
- *Cardiapex*



# Cerebral Embolic Protection Devices

## *Deflectors and Filters*



POUR UN CLAIR  
FOR VICTORIA  
TRIUMPH

WANT MORE  
SIGHTS &  
SMELLS

# THE VANCOUVER SUN



*Dr David  
Wood from St-  
Paul  
Hospital:  
Same day  
discharge  
after TAVR!*



*A 97 years old women discharged the same day  
after a TAVR procedure stretching while waiting  
for the bus to get home... read more on page 3.*

**Is this  
the  
future?**

