

# **Valvular Heart Disease and Adult Congenital Intervention.**

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**Washington Hospital Center.**

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**Georgetown University.**

# **Conflict of Interest**

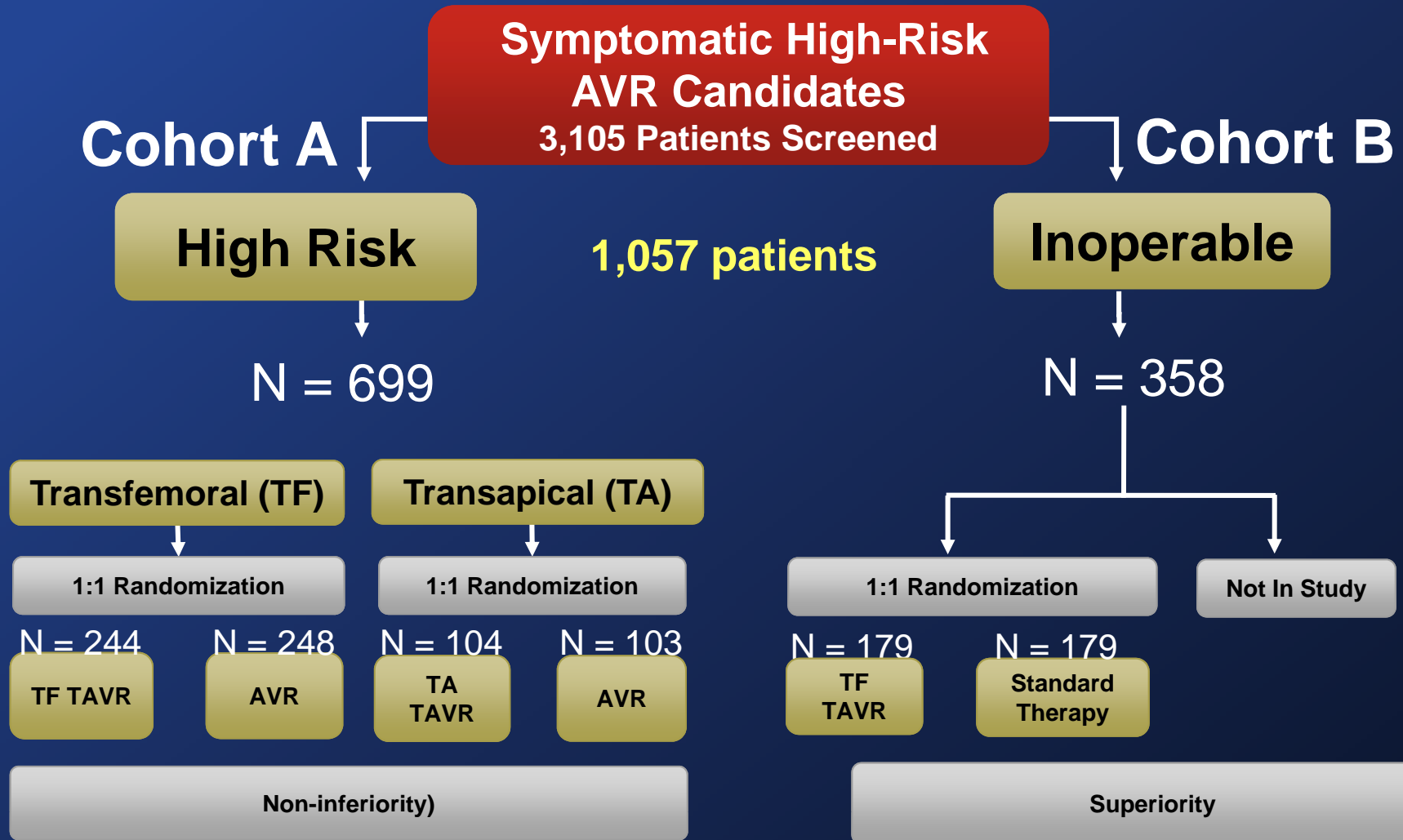
**Proctor for Edwards Lifesciences**

**Speaker Bureau St Jude Medical**

# T-AVR

- **Percutaneous Valve Replacement has initiated a “revolution” in the treatment of Valvular Heart Disease.**
- **The “Heart Team” concept has been established as indispensable for success.**
- **Precise, collective data collection and analysis is needed to trace the future.**

# PARTNER Study Design



# PARTNER Trial Cohort B Inoperable Patients. TCT 2010

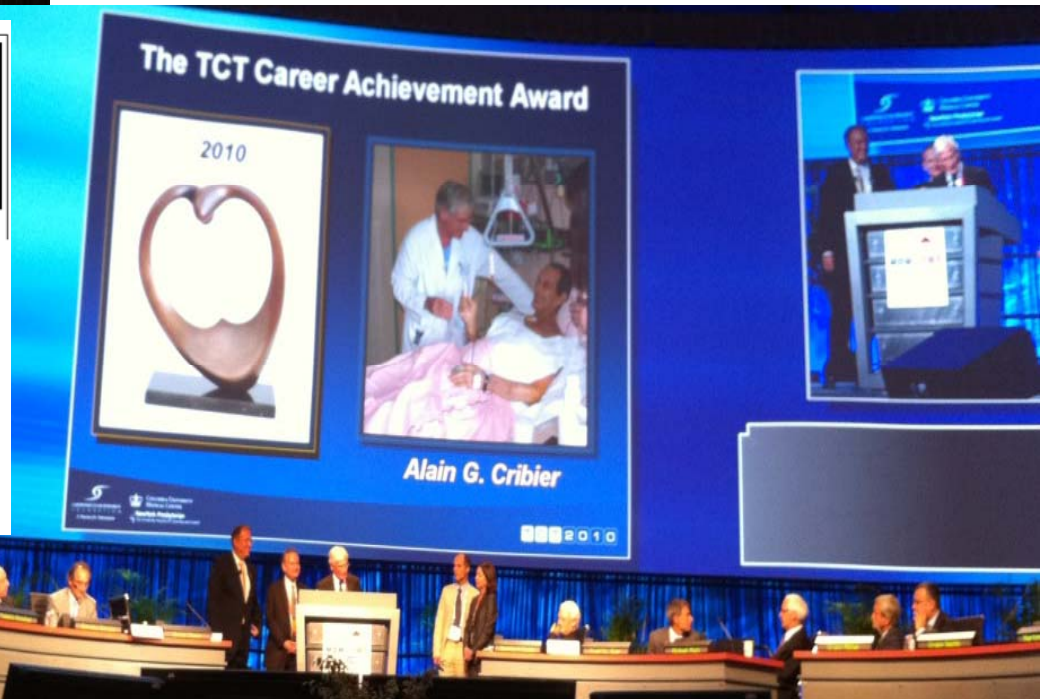


The NEW ENGLAND  
JOURNAL of MEDICINE

September 22, 2010

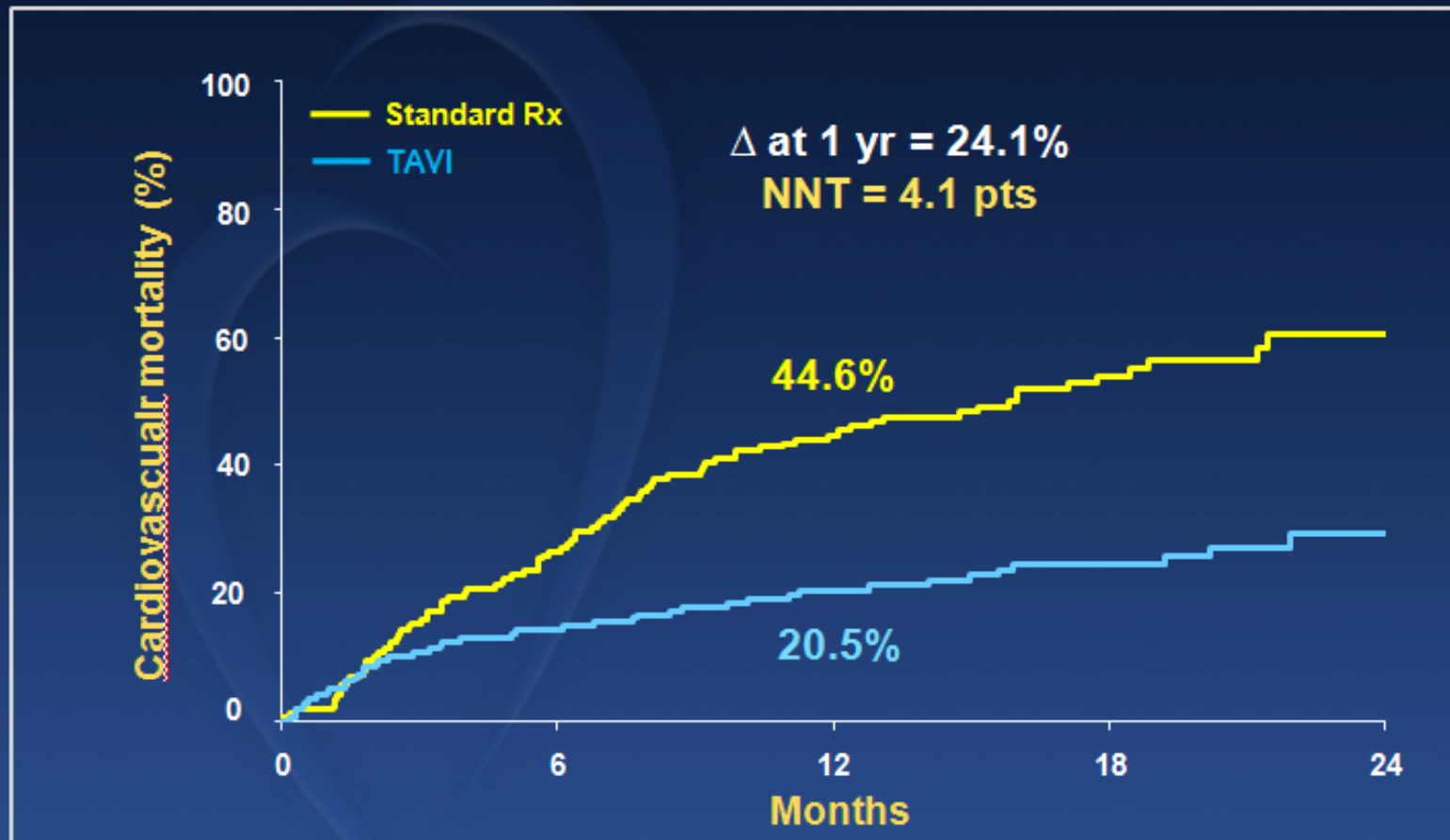
## Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,  
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,  
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,  
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D.,  
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,  
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators\*



# Cohort B. Inoperable Patients

## Cardiovascular Mortality



Numbers at Risk					
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

# **Partner Cohort B Conclusion**

**T-AVR is the now the  
“Gold Standard”  
for the treatment of  
symptomatic AS in patients not  
amenable to surgical AVR.**

# Partner Trial Cohort A: High Surgical Risk ACC 2011



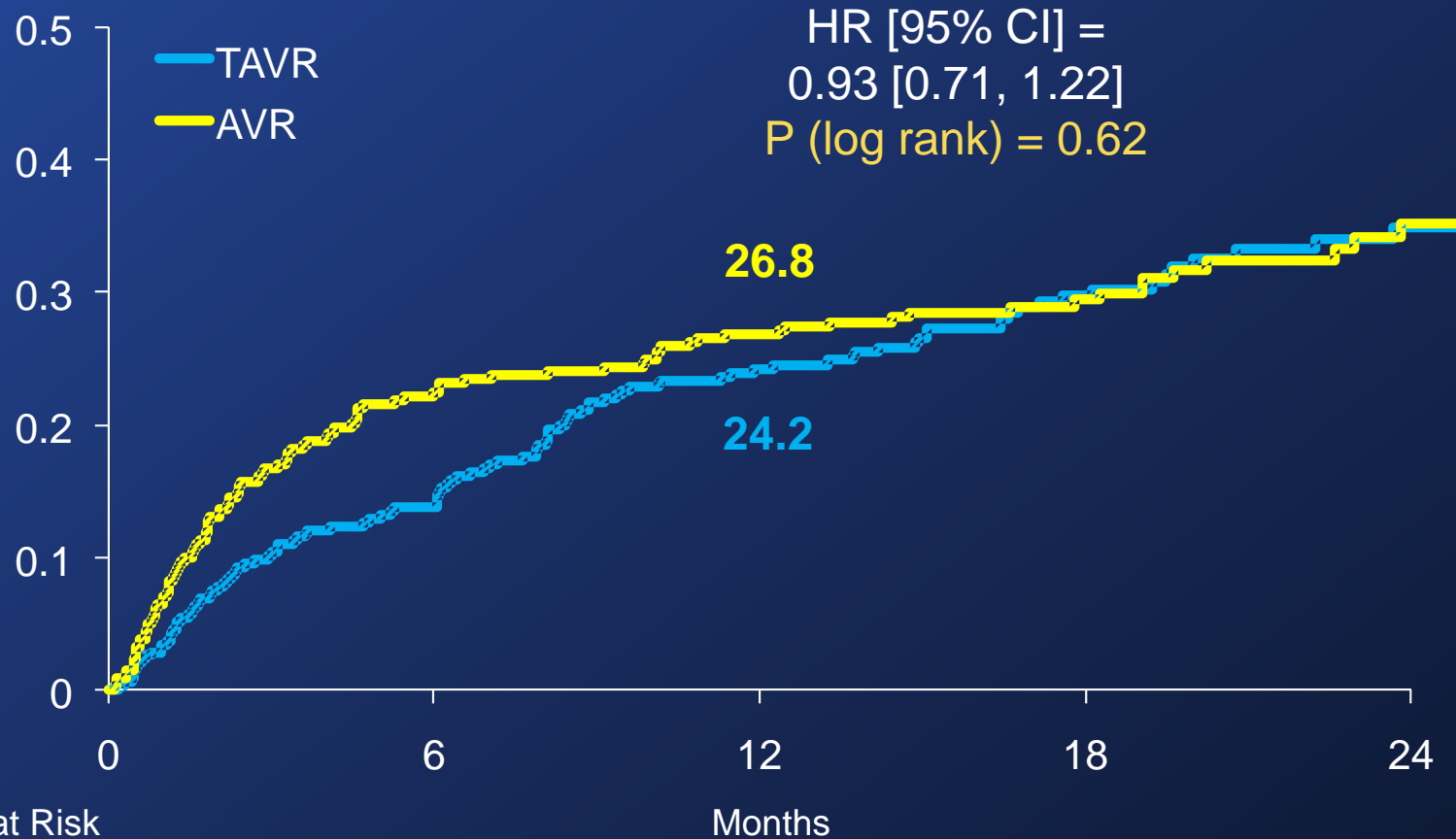
**Robert Bonow**



**Craig Smith**



# Cohort A: High risk patients. All-Cause Mortality at 1 Year

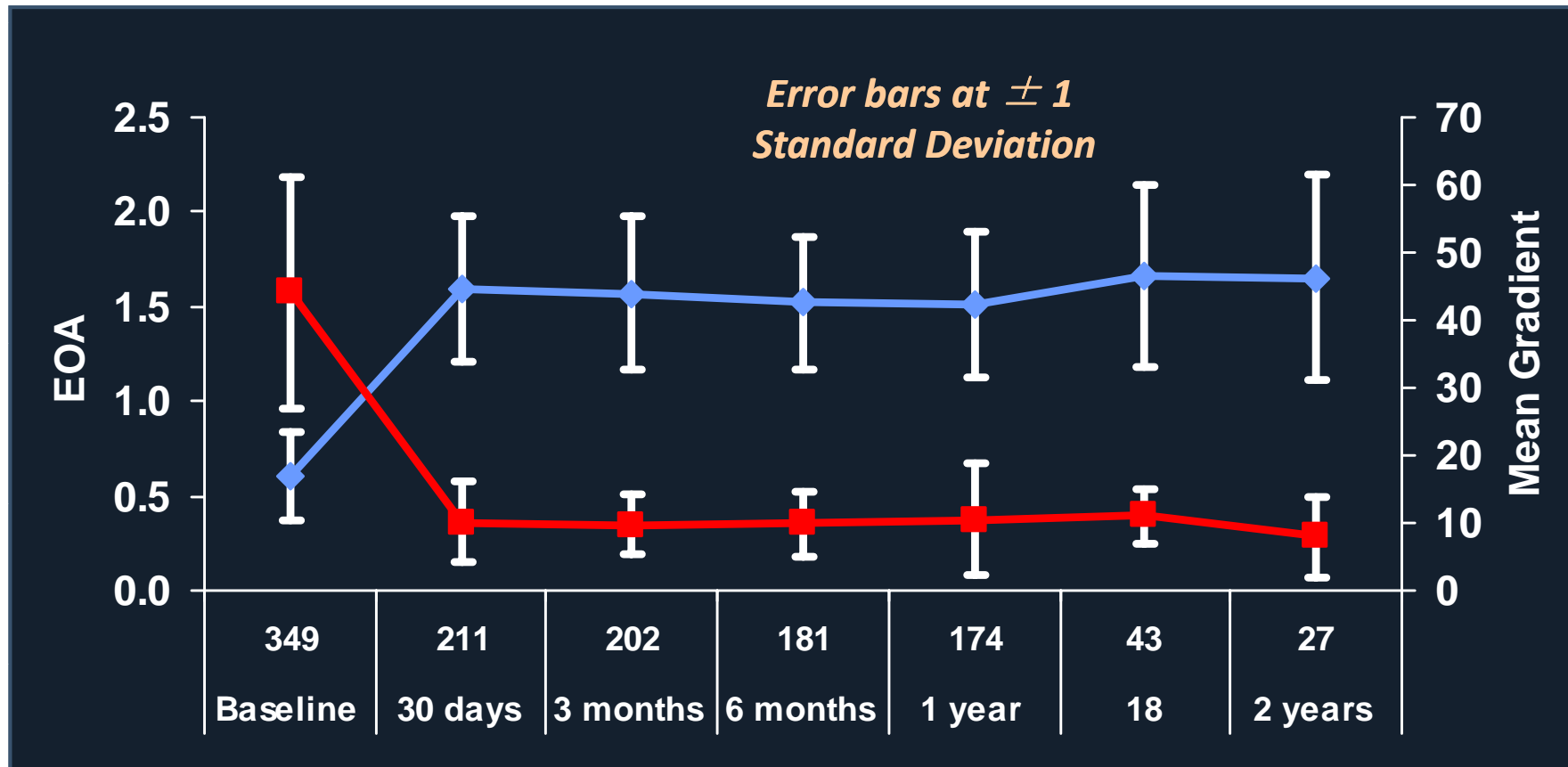


(Age 84, STS 12, EuroScore 29)

# **Partner Trial Cohort A Conclusion**

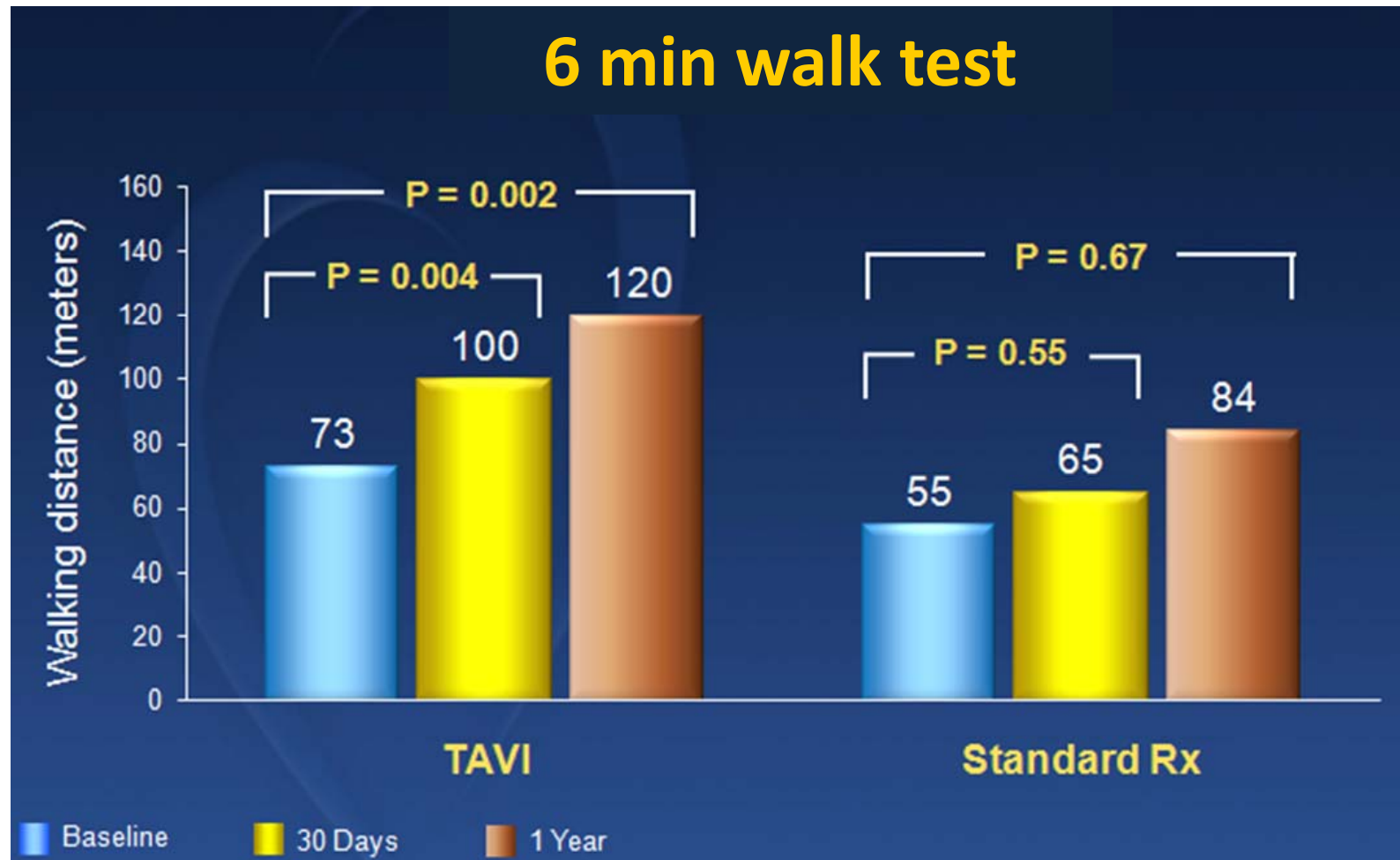
**T-AVR (trans-femoral and trans-apical) is non-inferior to surgical AVR for patients with severe AS and high surgical risk.**

# Hemodynamics at 2 years. Edwards Valve

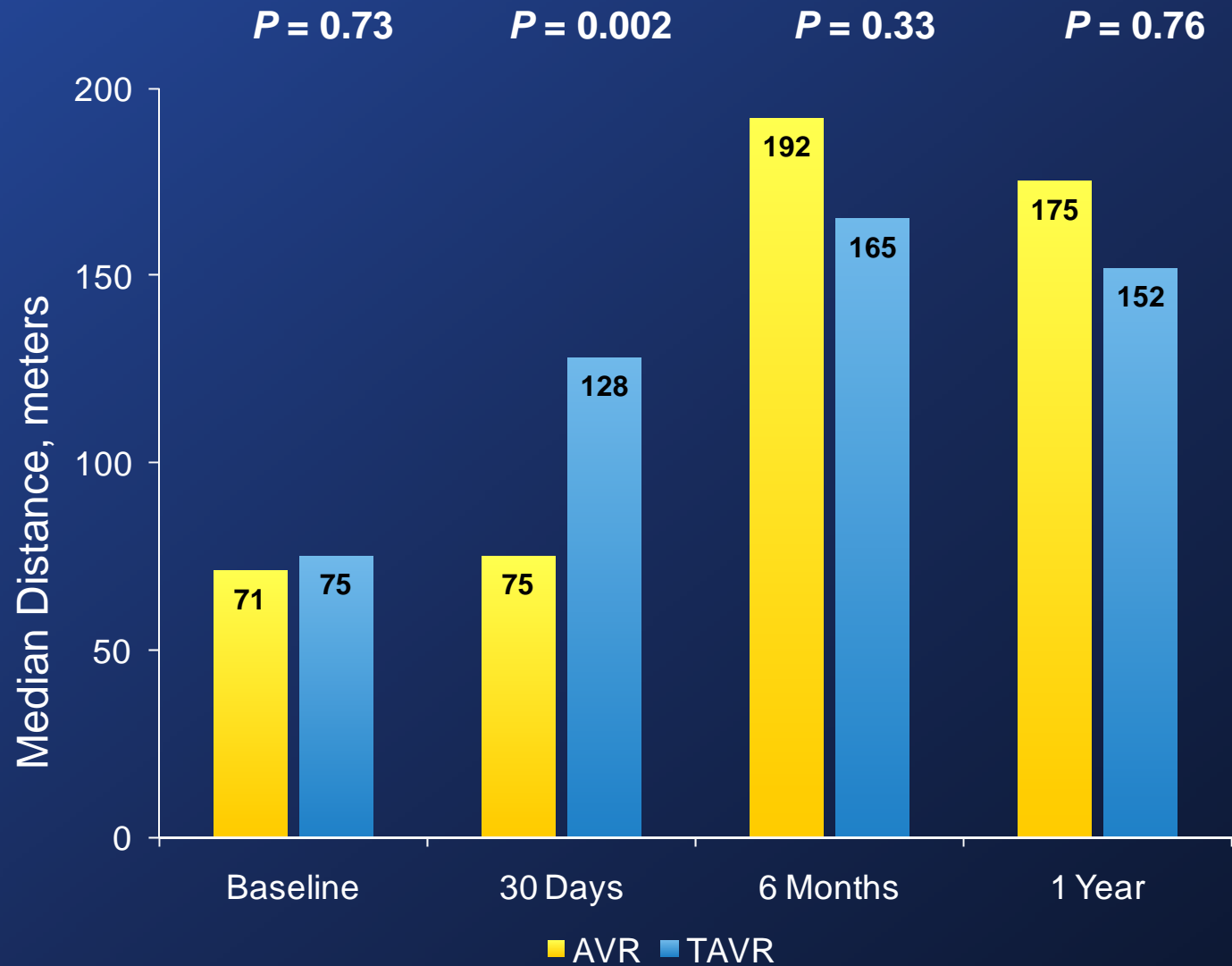


*\* REVIVE, REVIVAL, TRAVERCE and PARTNER EU*

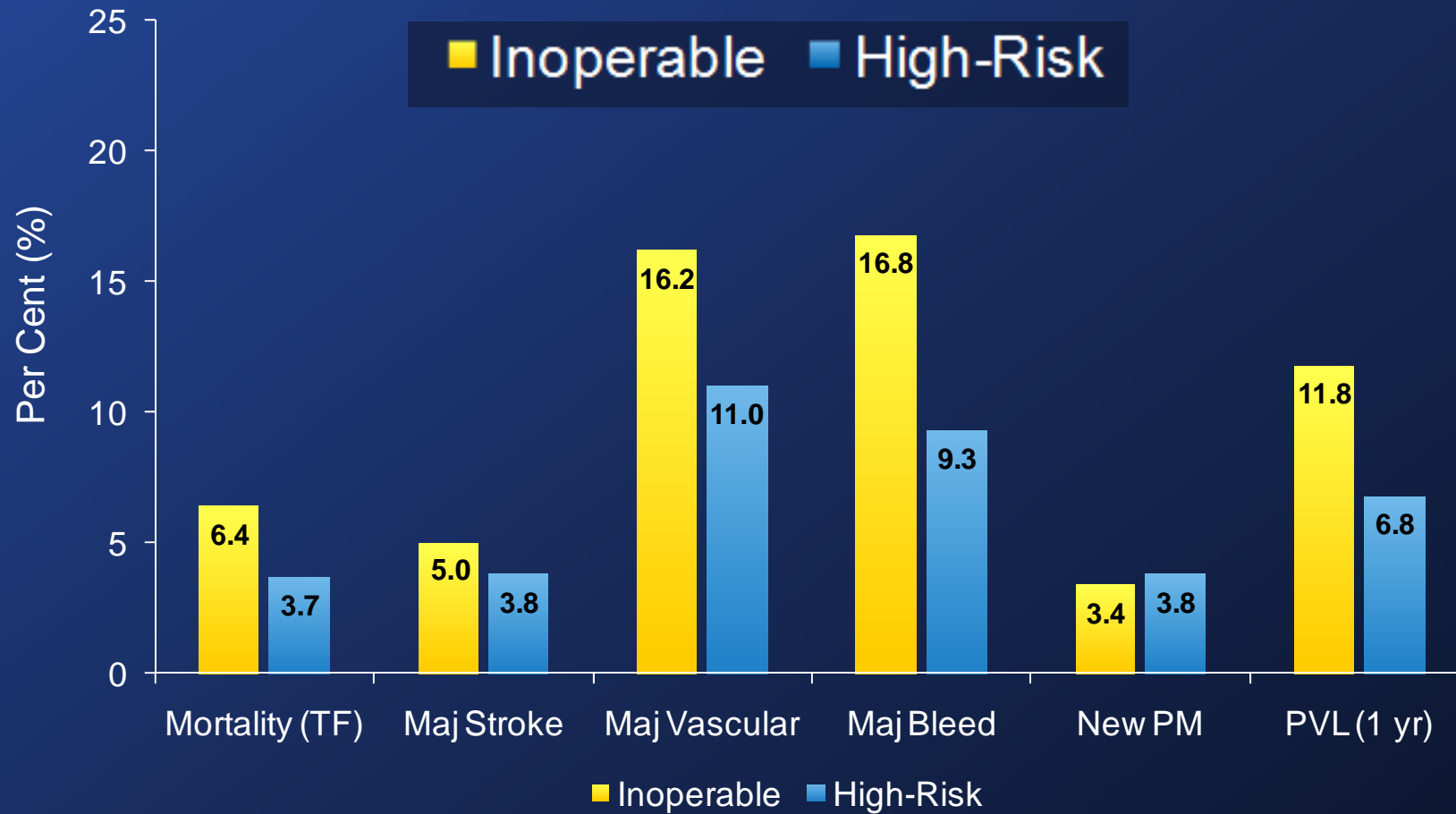
# Partner Trial Cohort B. Functional Recovery



# Six-Minute Walk Test Cohort A (n=699)

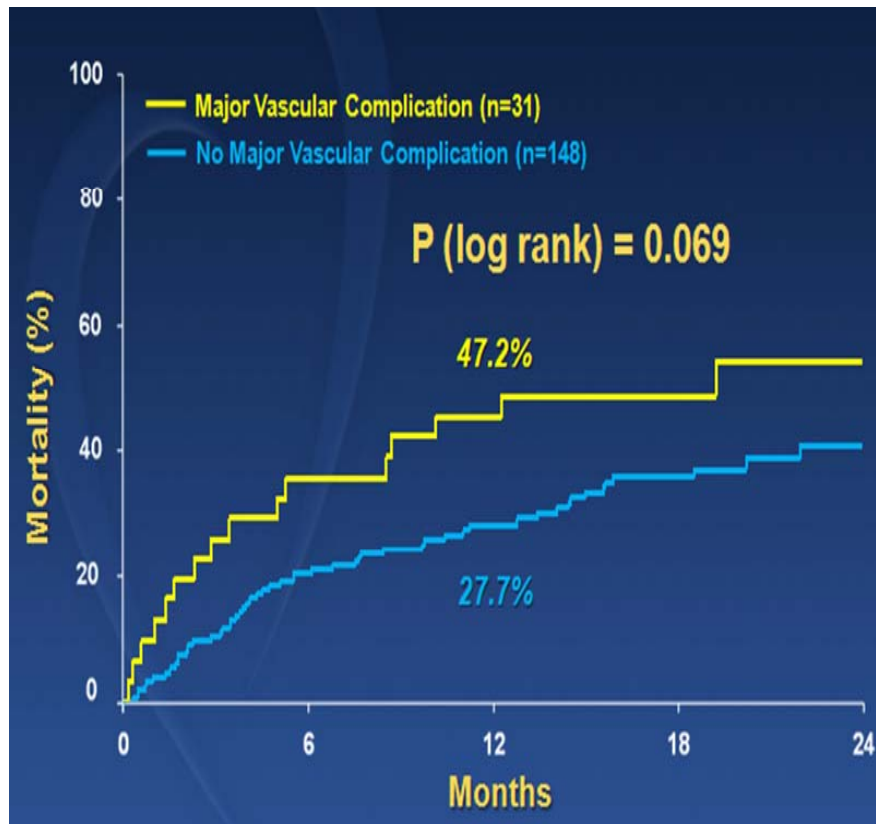


# PARTNER TRIAL: Complications.

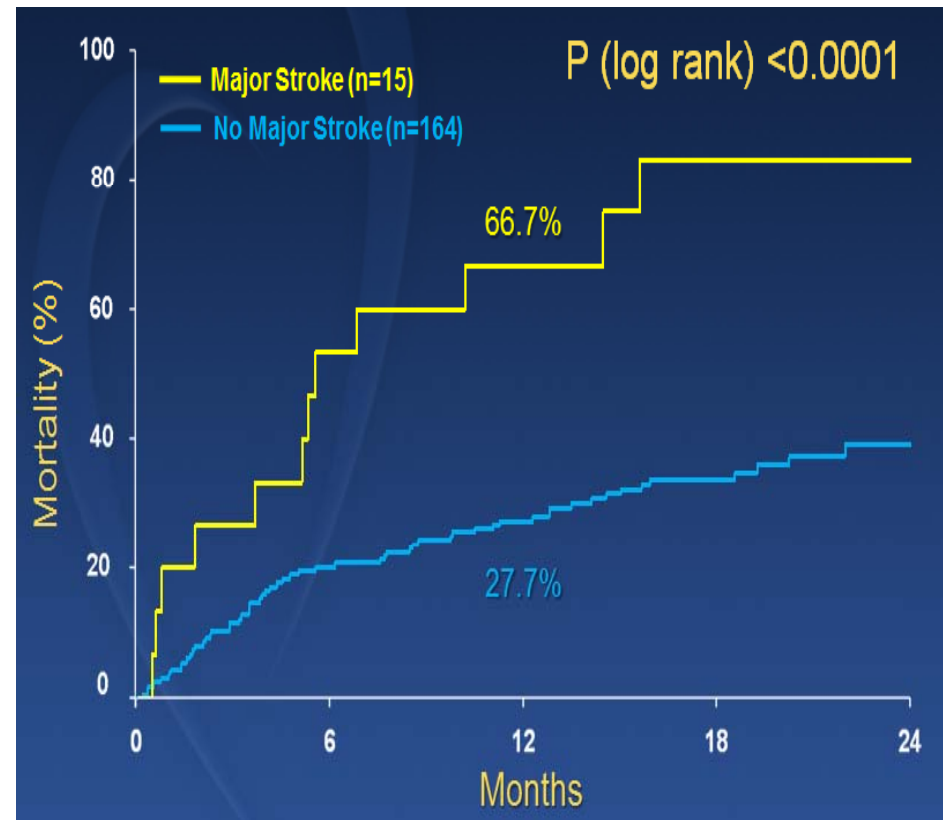


# Complications of T-AVR are associated with higher mortality

## Major Vascular Complications



## Major Stroke



# Eliminating Stroke

- Protection devices (SMT, Embrella, Claret).



- Most strokes occur after the procedure:
  - new anticoagulation strategies been evaluated



# **“Valve in Valve”**

## **(Percutaneous Valve for degenerated Bioprosthetic Valve)**

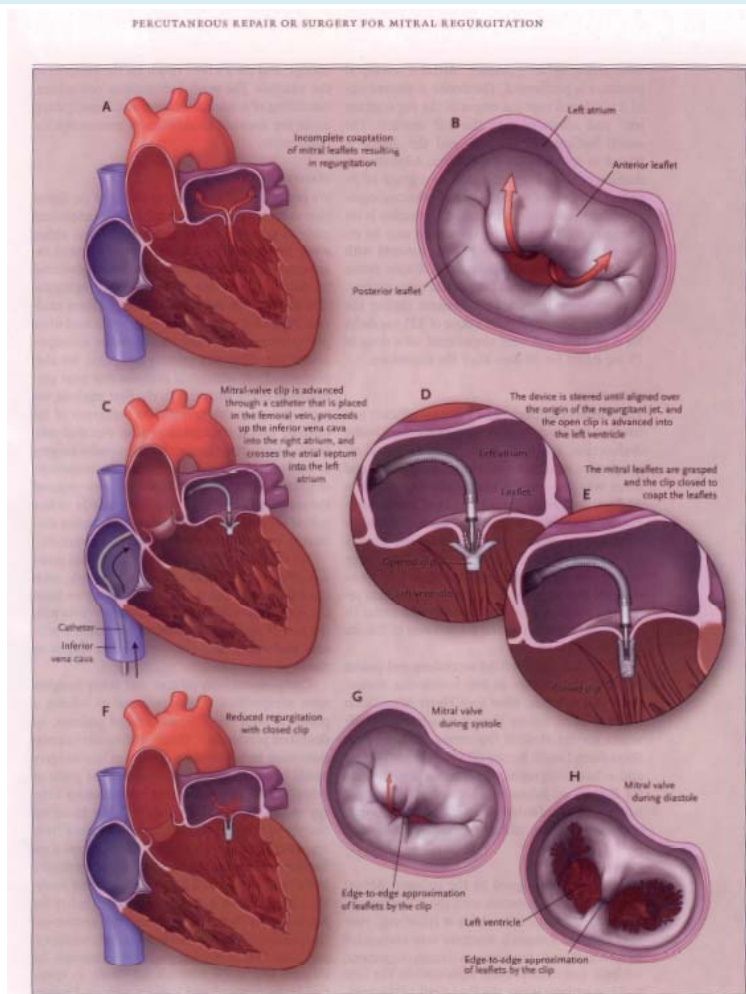
- **Simple and safe option.**
- **Surgeons have decreased or almost eliminated the use of mechanical valves.**
- **Dedicated percutaneous valves for this use are in development.**

# T-AVR for Aortic Regurgitation

- **Number of Centers using the Corevalve for this purpose, with success.**
- **No series published yet.**

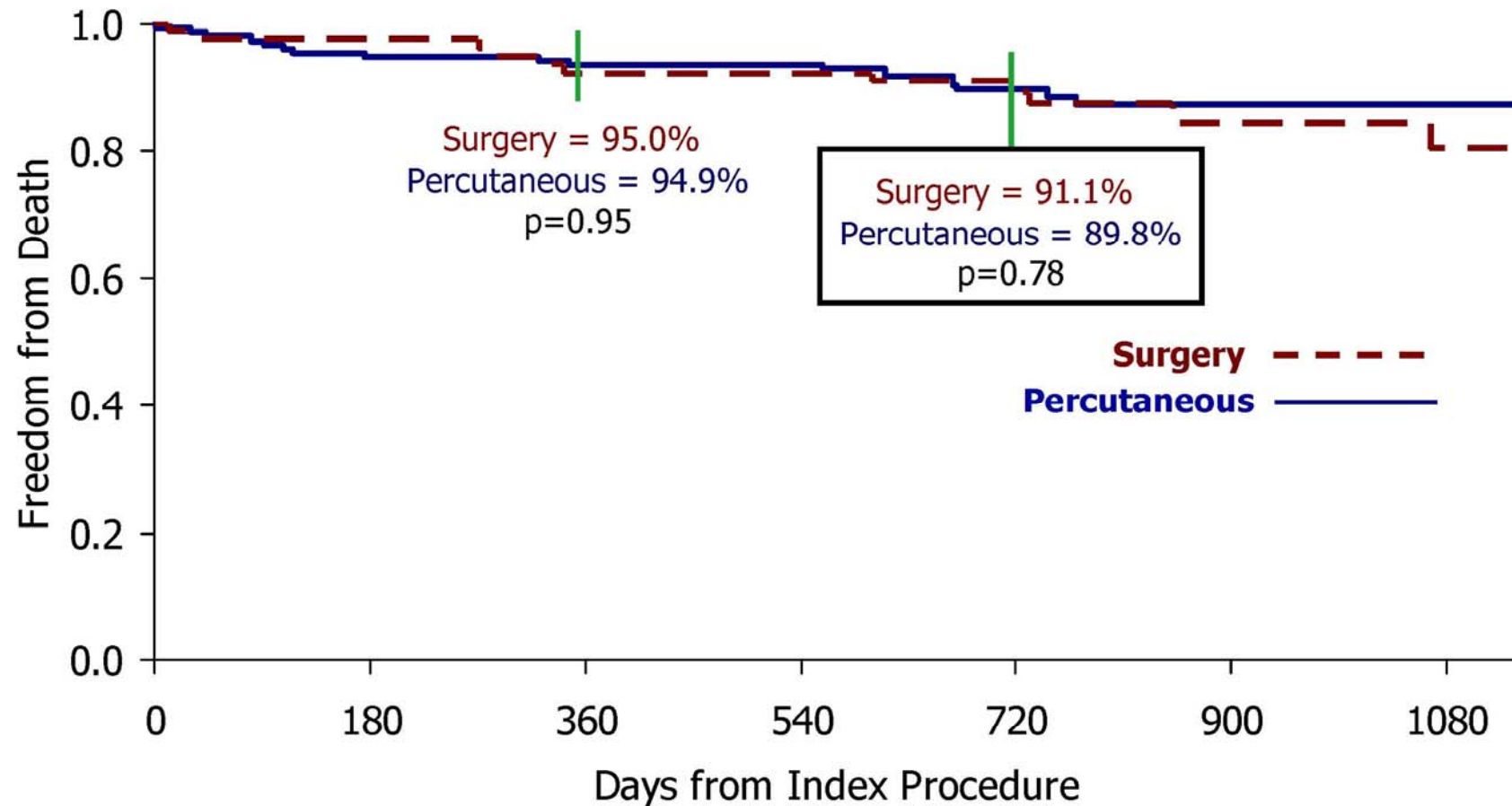
# **Percutaneous Mitral Valve Repair**

# MitraClip. Everest II Randomized Trial ACC 2011



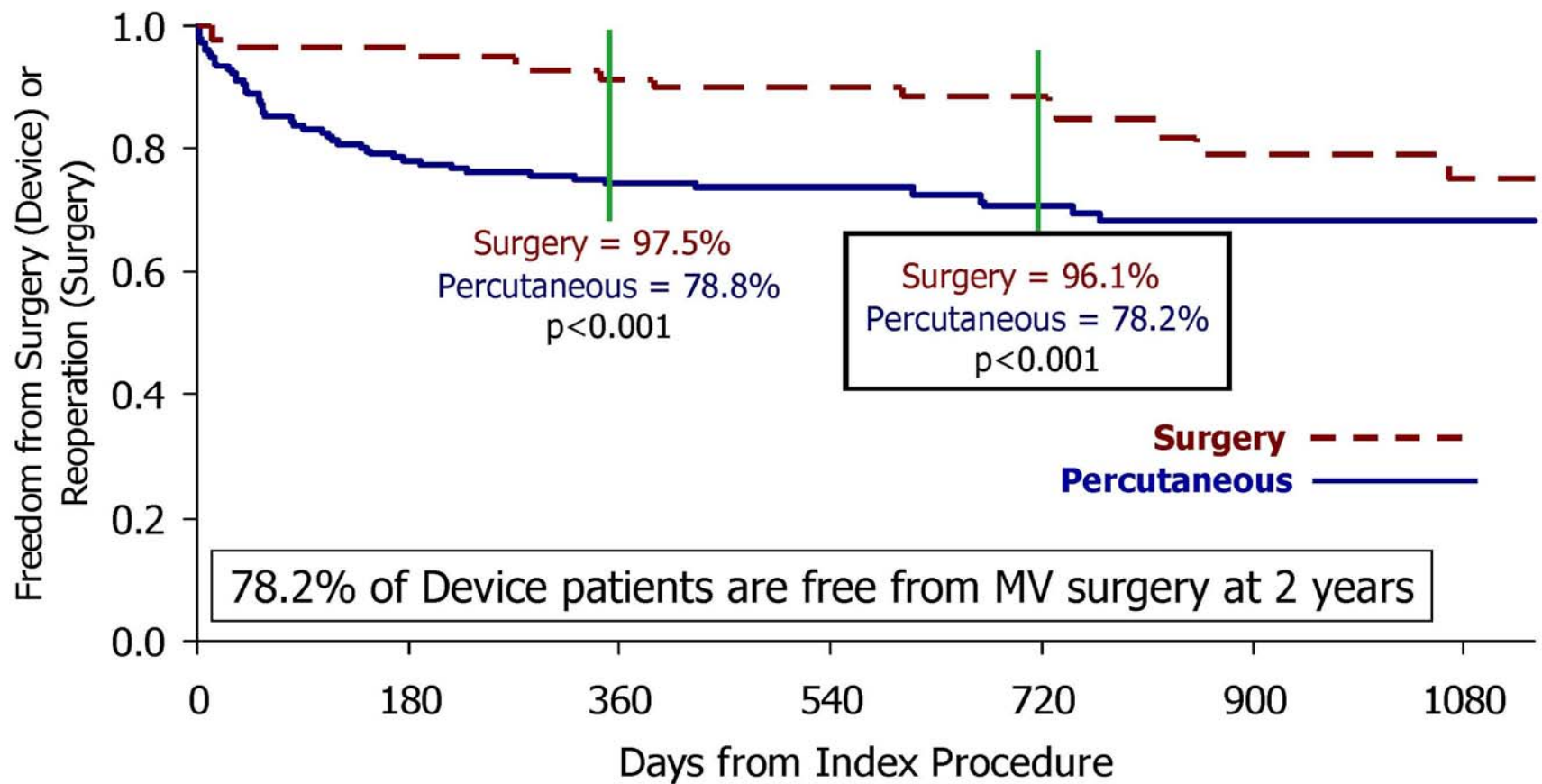
Feldman et al. New England J of Medicine. April 2011

# Everest II Randomized Trial Survival



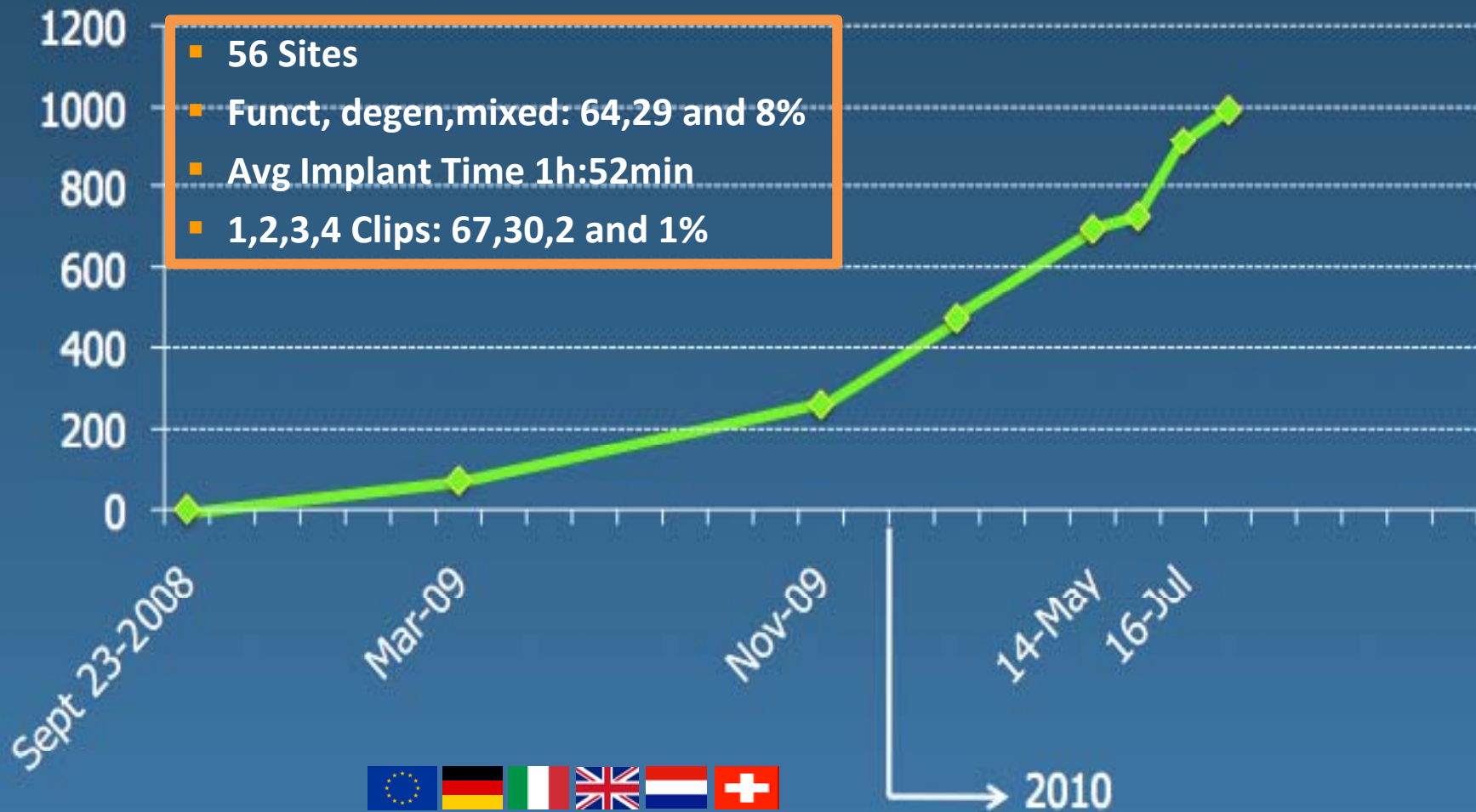
At Risk:	0 Days	6m	1yr	1.5yr	2yr	3yr
Percutaneous	184	166	163	153	133	52
Surgery	95	78	74	71	63	25

# Freedom from Surgery (Clip arm) or Reoperation (Surgical arm).



At Risk:	0 Days	6m	1yr	1.5yr	2yr	3yr
Percutaneous	184	138	131	124	109	44
Surgery	95	77	72	69	69	24

# Mitral Clip. European Experience

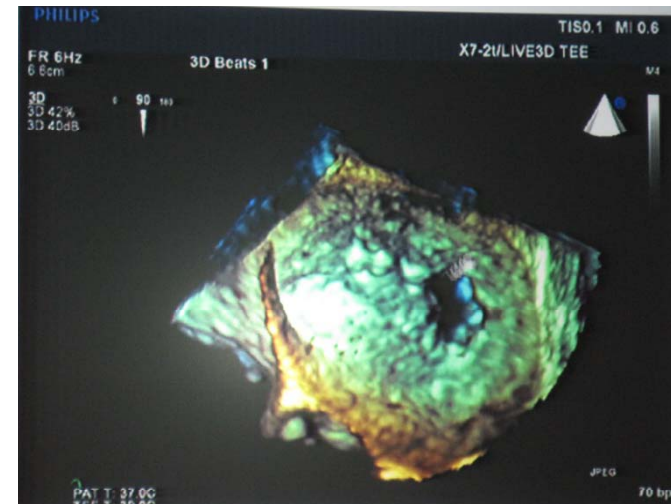
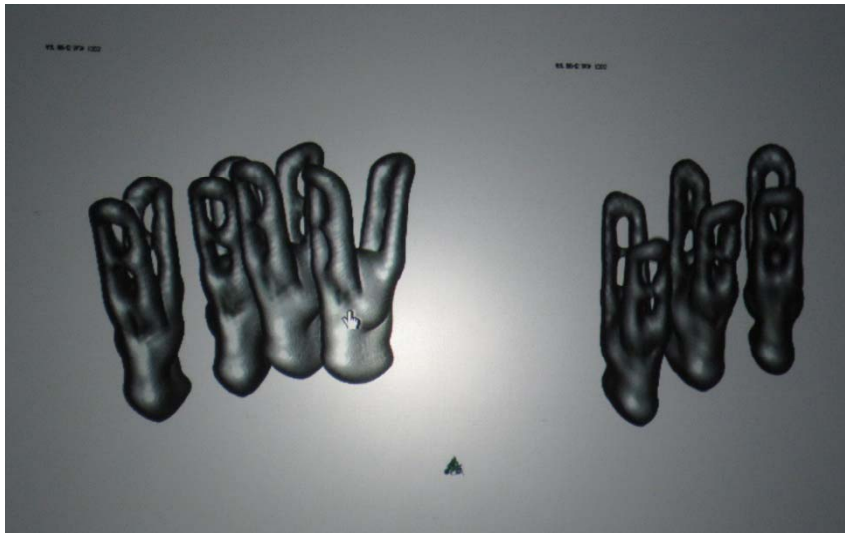


# Multiple MV Clips for severe MR

Huseyin Ine and Christoph Nienaber

Rostok Group.Snowmass 2011

EF 18%, 4+MR. Got 4 clips. Final  
MVA 2.8 cm<sup>2</sup>

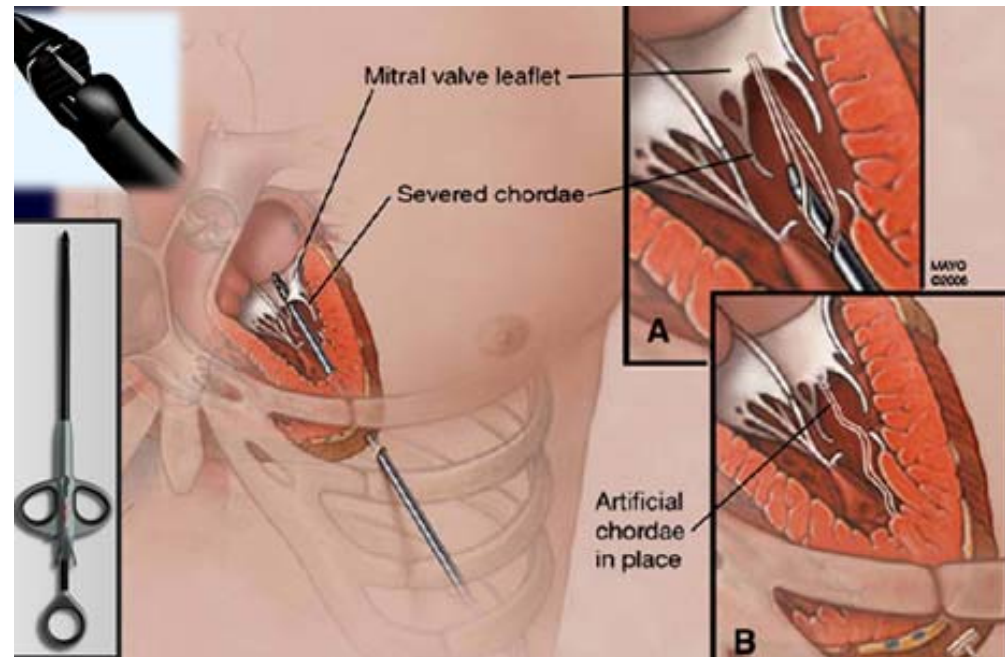


21% 1 clip, 60% 2 clips, 12% 3 clips, 7% 4 clips  
2/3 functional MR



# Neo Chord for Ruptured Chordae.

Bajona et al. JTCVS 2009;137:188-93



# Trans Apical MV Repair for MVP

Seeburger et al; Circ CV Interv 2010;3;611-2

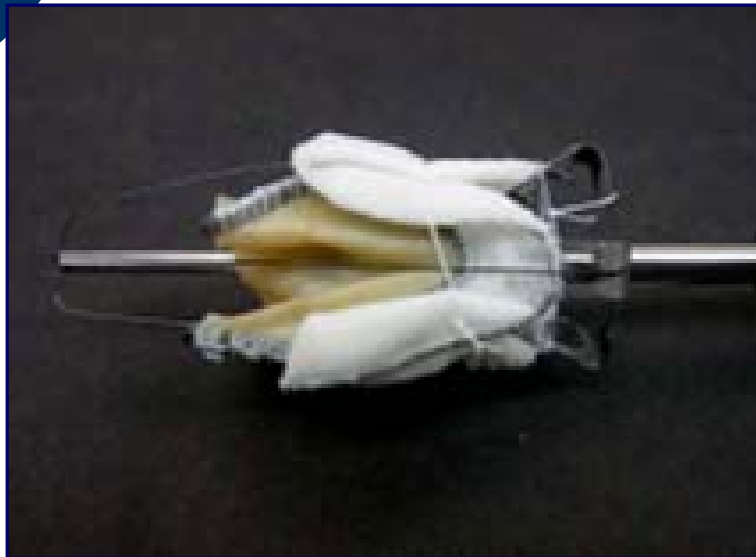
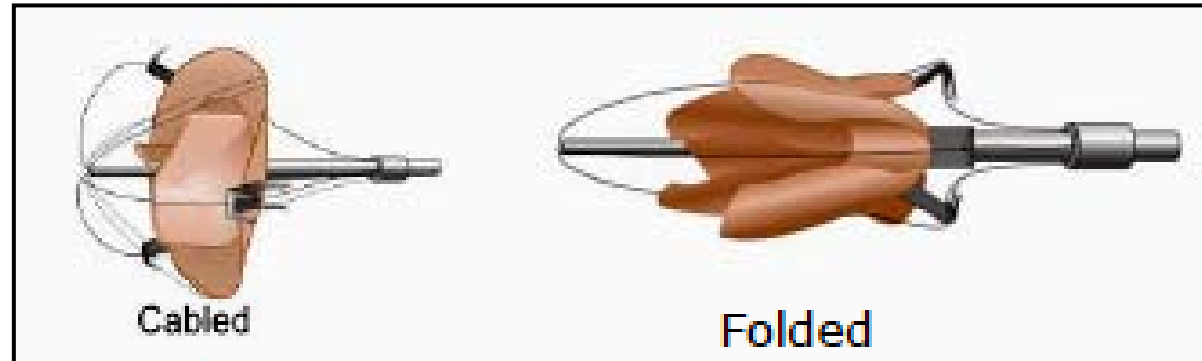
# Percutaneous MV Implantation

**Preclinical work making rapid progress.**

- Edwards**
- Medtronic**
- Endovalve**
- Mitraltech**
- CardiacQ**

**We should soon have a mitral valve prosthesis to implant percutaneously**

# Transcatheter Mitral Valve Implantation Engineering Prototype – Sheep Implant



- *No MR at 6 hours post CPB*
- *Mean transmitral gradient = 2 mm Hg*
- *No LVOT gradient*

endo**Valve**

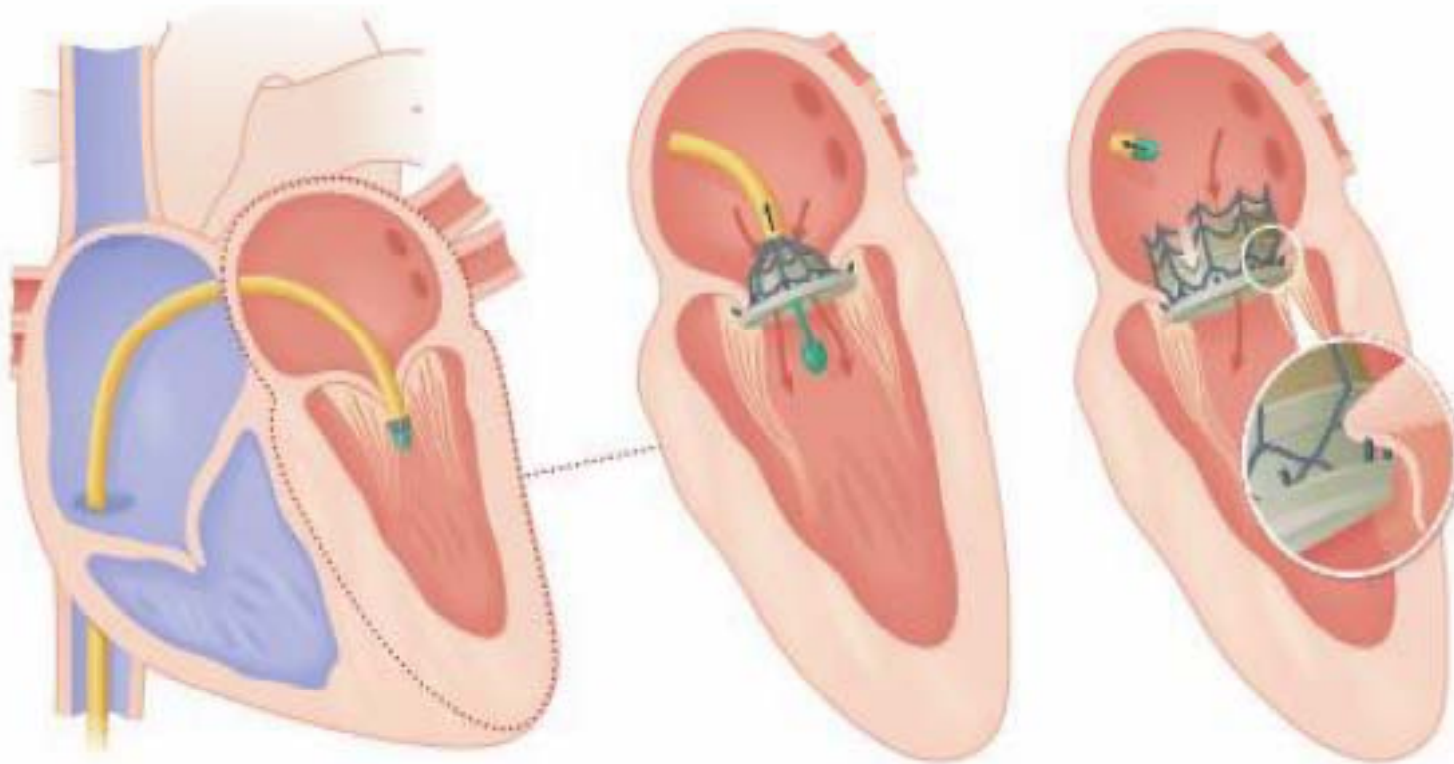
# CardiaQ Valve Technologies

## Transcatheter Mitral Valve Implantation (TMVI)

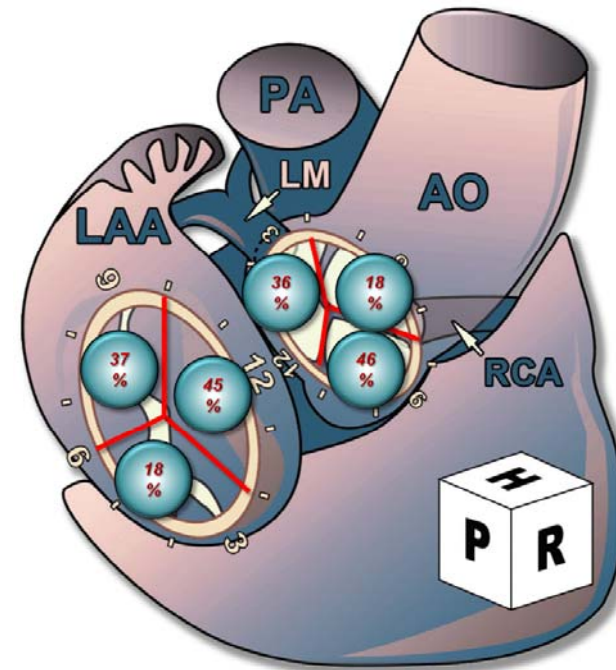
1. TRANSSEPTAL  
ACCESS of MV

2. SUB-ANNULAR  
POSITIONING

3. ANCHORING



# Percutaneous Closure of Perivalvular Leaks



## Indications:

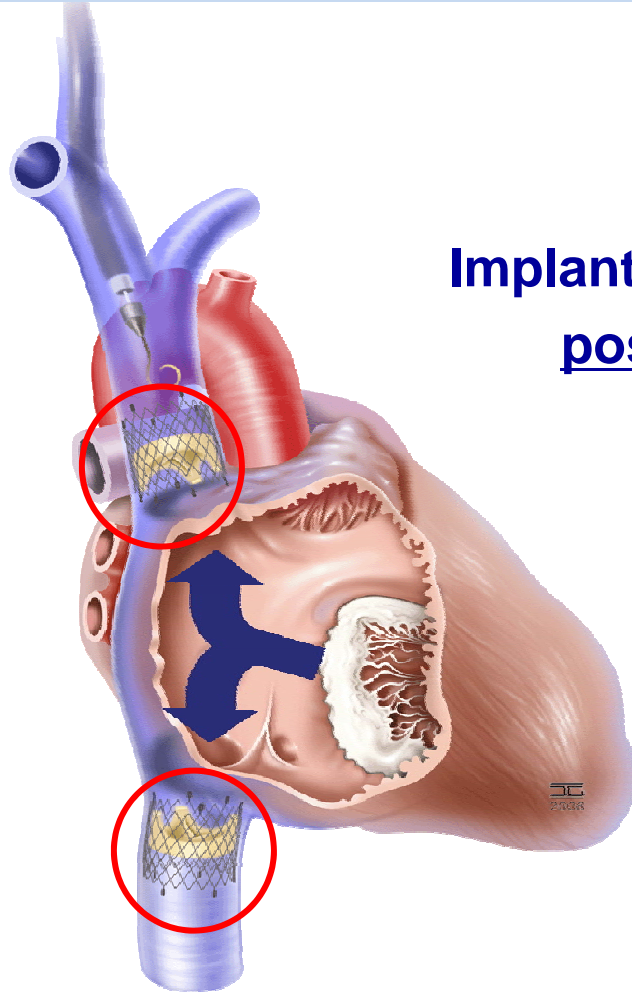
- Severe MR with significant symptoms
- Severe Hemolysis requiring transfusions

# Percutaneous Closure of Perivalvular Leaks. Carlos Ruiz. CRT 2011.

- **Success rate (66 patients):**
  - 76% aortic
  - 89% mitral
- **30-day all cause mortality: 3.4%**
- **Hemolysis**
  - Resolved – 46/50 (92%) in 1 week to 6 months
  - Deteriorated and required surgical correction - 2 pts
- **NYHA Functional Class: 3.0 pre, 1.9 post**

# Percutaneous Valves for Severe Tricuspid Regurgitation.

Hans Figula. CRT 2011



Implantation of valved stents in central venous position to reduce venous congestion

European Heart Journal Advance Access published February 15, 2011



European Heart Journal  
doi:10.1093/eurheartj/ehr028

**FASTTRACK CLINICAL**

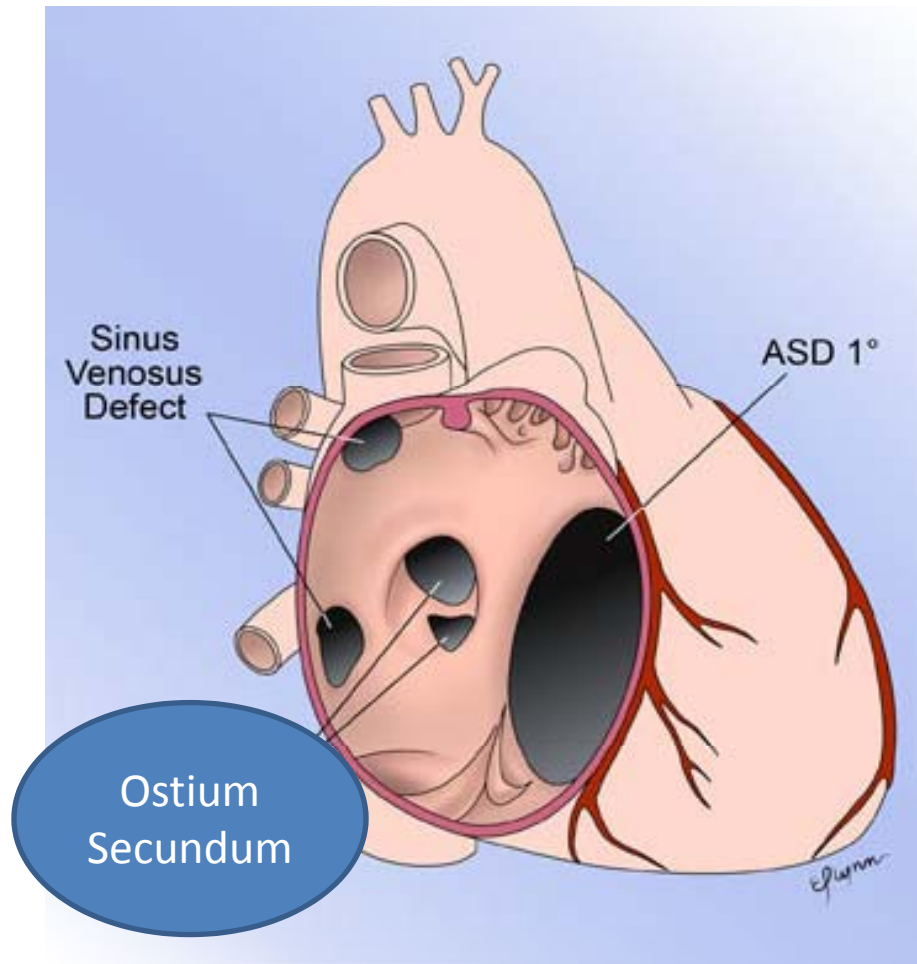
**Heterotopic transcatheter tricuspid valve implantation: first-in-man application of a novel approach to tricuspid regurgitation**

Alexander Lauten<sup>1</sup>, Markus Ferrari<sup>1</sup>, Khosro Hekmat<sup>2</sup>, Ruediger Pfeifer<sup>1</sup>, Gudrun Dannberg<sup>1</sup>, Andreas Ragoschke-Schumm<sup>3</sup>, and Hans R. Figulla<sup>1\*</sup>

# **Adult Congenital Heart Disease**



## ASD Percutaneous Closure

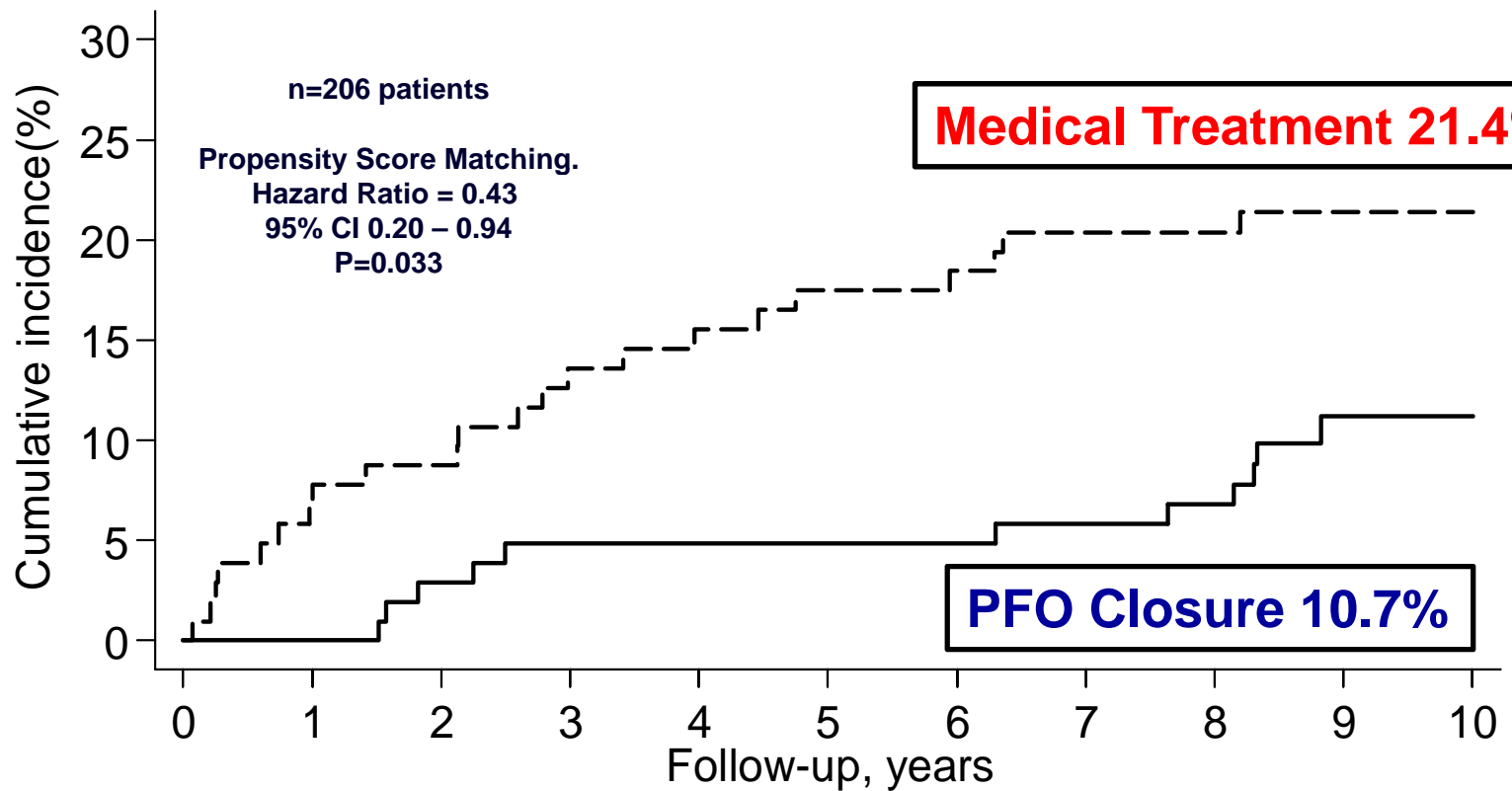


**Percutaneous Closure of Ostium Secundum  
ASD is now the Standard of Care**

# PFO Closure in Cryptogenic Stroke

Windecker S, JACC 44: 750-8, 2004

Stroke,  
TIA or  
Periph  
Embolism



No. at risk	0	1	2	3	4	5	6	7	8	9	10
PFO closure	103	103	100	98	98	98	98	97	96	60	29
Medical	103	96	94	89	87	85	84	82	82	54	28

## Randomized Controlled Trials on PFO Closure to Prevent Recurrent Paradoxical Ischemic Events

	<b>Device Used</b>	<b>Starting Year</b>	<b>Target Enrollment, n</b>	<b>Final Status</b>	<b>Projected Publication</b>
<b>PC*</b>	Amplatzer PFO occluder	2000	450	Finished enrollment at 420	2011
<b>Closure-I</b>	STARFlex occluder	2003	1600	Finished enrollment	Negative Trial
<b>RESPECT</b>	Amplatzer PFO occluder	2004	900 (endpoint driven)	Enrolling	2013
<b>CLOSE</b>	Free choice	2007	900	Enrolling	2014
<b>Gore REDUCE</b>	HELEX occluder	2008	664	Enrolling	2016

# Randomized Controlled Trials for PFO Closure in Migraine Headache Patients

Acronym	Place	Sham Procedure	Device	Status
MIST	UK	+	STARFlex	Negative Trial
PRIMA	Global	-	Amplatzer	Recruiting
PREMIUM	US	+	Amplatzer	Recruiting
MIST II	US	+	BioSTAR*	Abandoned
ESCAPE	US	+	Premere†	Abandoned
?	Global	+	FlatStent‡	Planned

# Conclusions

- **Percutaneous treatment of valvular and adult congenital heart disease has revolutionized Medicine.**
- **New technology will improve safety and efficacy.**
- **Cardiac “team” approach required.**
- **Careful data collection, trial interpretation and training are indispensable for sustainable success and definitive patient benefit.**

**The end**