



Centre for  
Heart Valve Innovation  
St. Paul's Hospital, Vancouver

# Transcatheter Aortic Valve Implantation Surgeon's Perspective

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# Disclosure

**Consultant:**

**Edwards Lifesciences  
JC Medical Inc.**

# Evolution of Indication

← TAVI

<b>Low risk</b>  Age <65	<b>Low risk</b>  STS <4% and Age > 65-70	<b>Int. risk</b>  STS 4-8	<b>High risk</b>  STS 8-12	<b>Very high risk</b>  STS >12	<b>Futile</b>  HT decision
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**Surgery  
> TAVI**

**Surgery  
= TAVI?**

**TAVI = Surgery**

**TAVI**

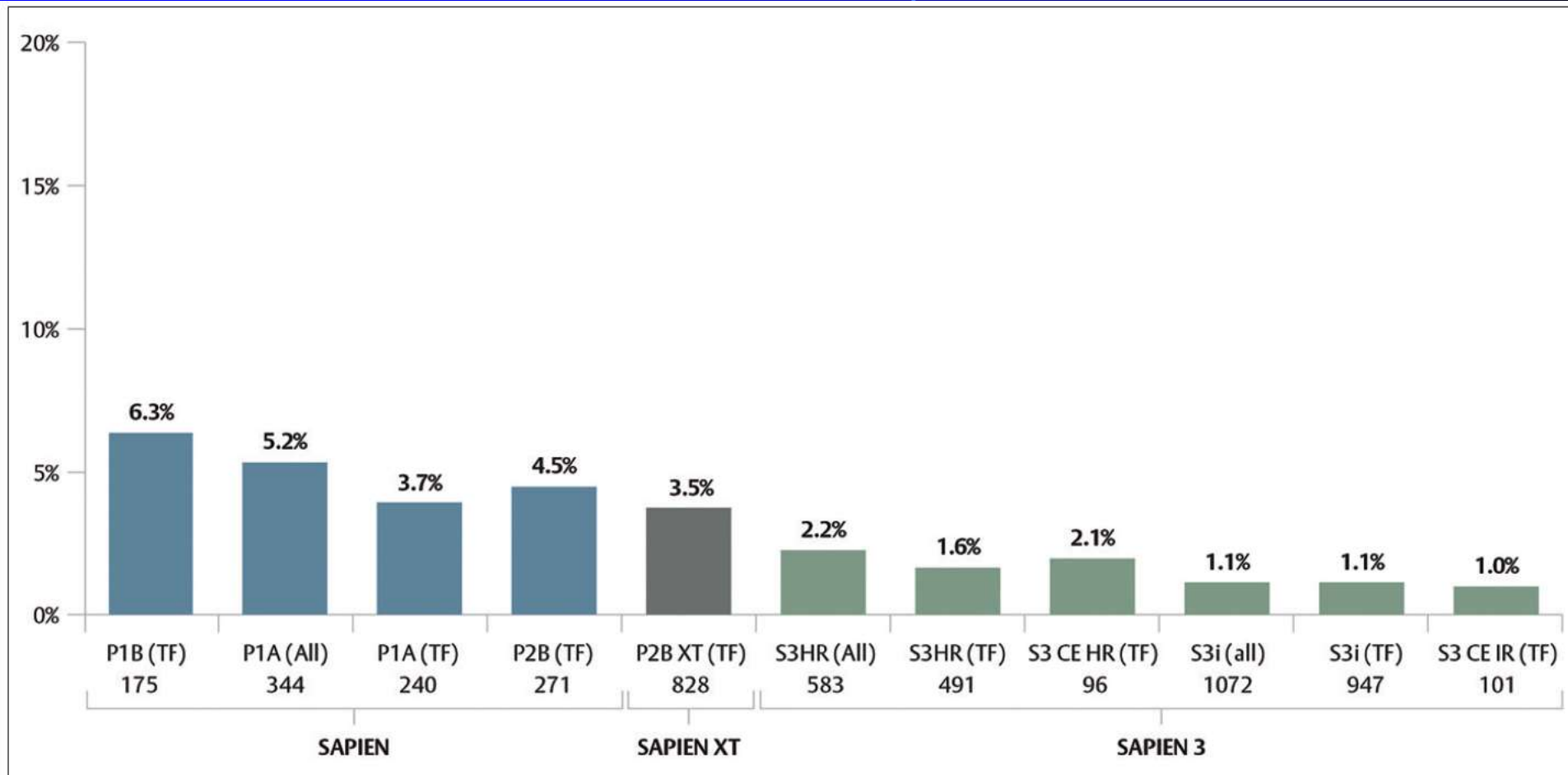
**TAVI**

**Med.**

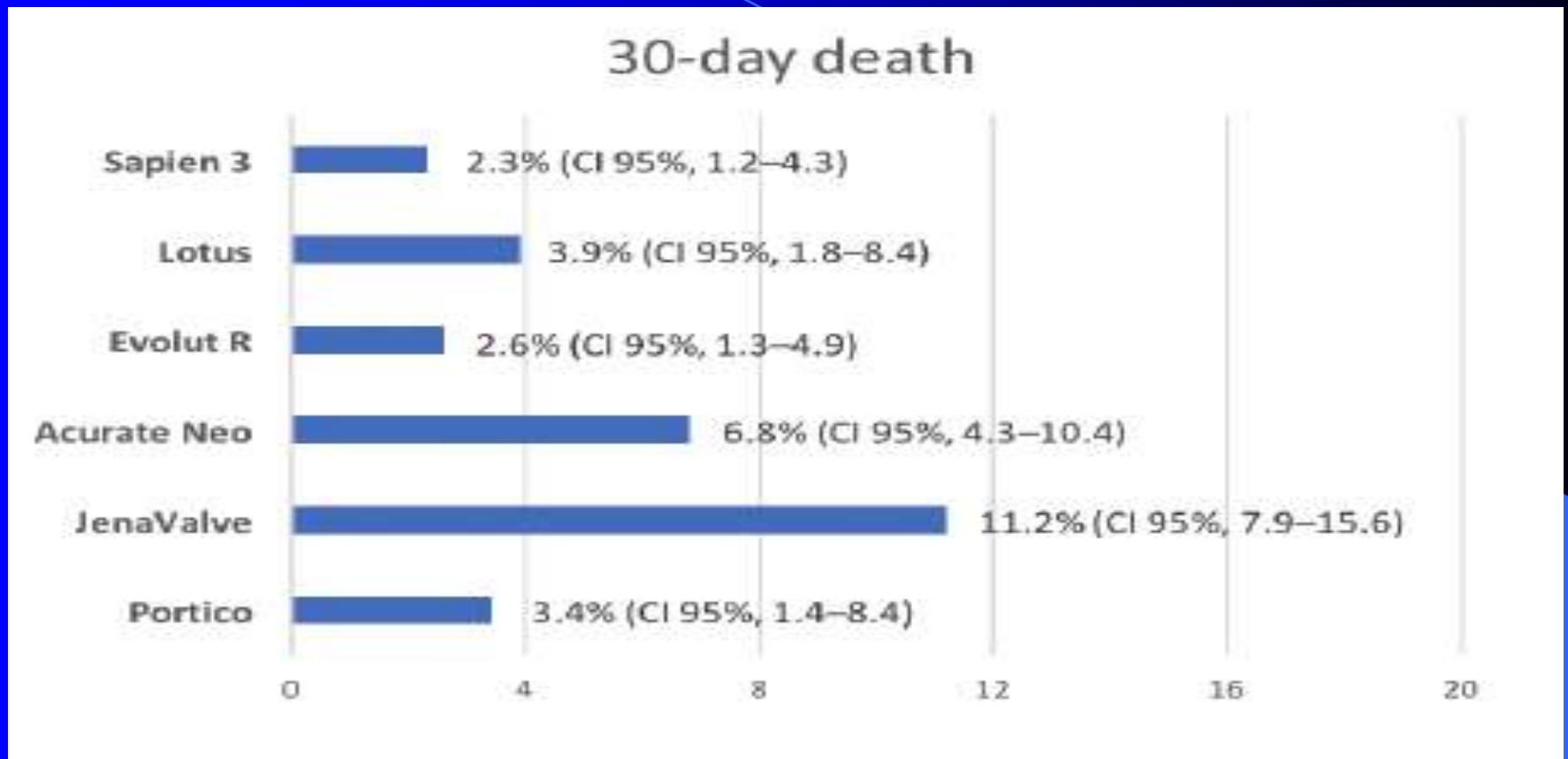
# Concerns in Young Patients

- **Mortality**
- **Stroke**
- **“Silent” embolic event**
- **Major vascular complication**
- **Paravalvular leak**
- **Pacemaker**
- **Bicuspid valve**
- **Valve thrombosis**
- **Valve durability**

# All-cause 30-day Mortality in the PARTNER Trials



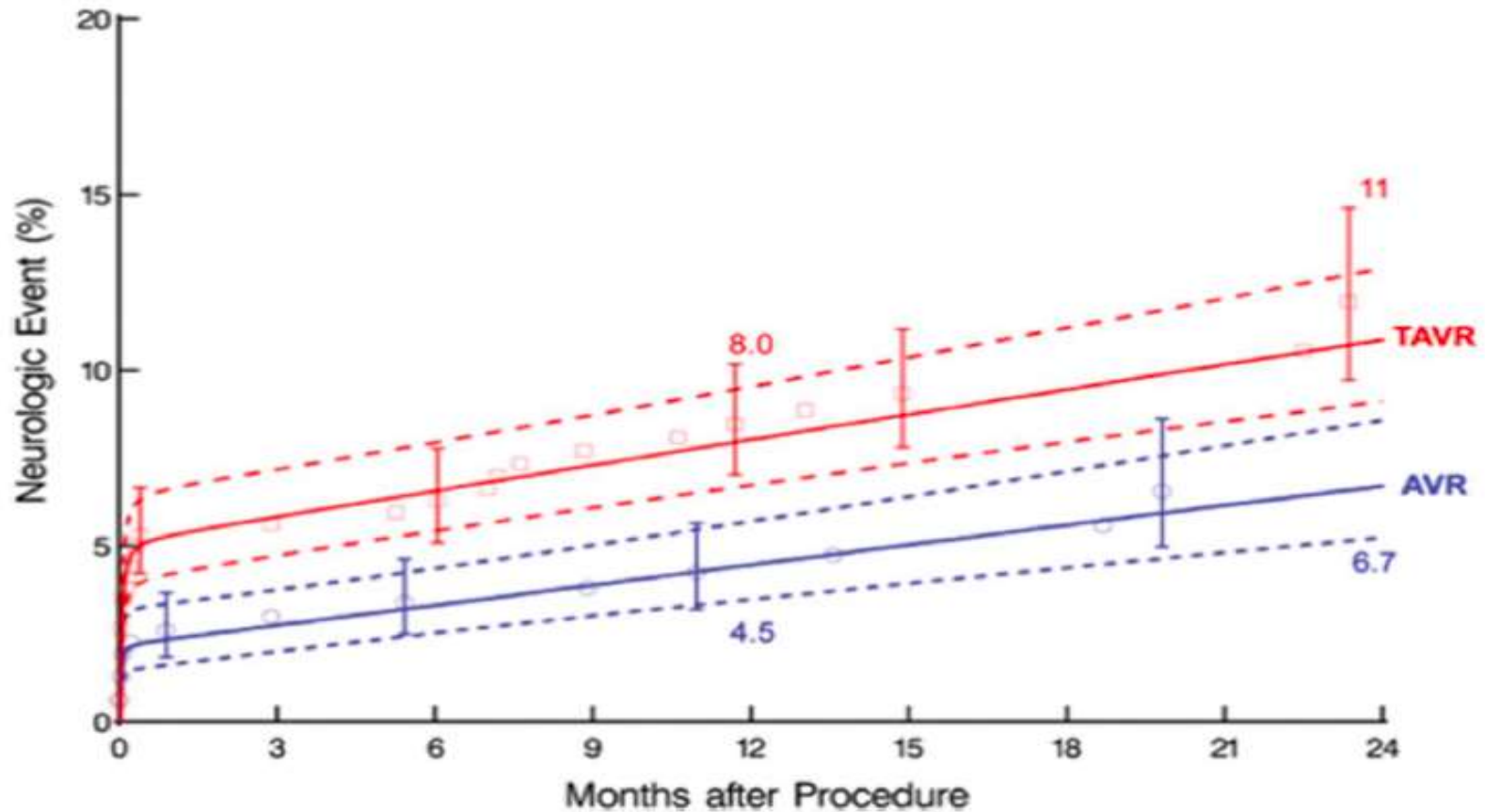
# All-cause 30-day Mortality



Outcomes from a weighted meta-analysis of 30 studies including 5,923 patients achieved with a comprehensive search of multiple Database from January 2011 to March 2016.

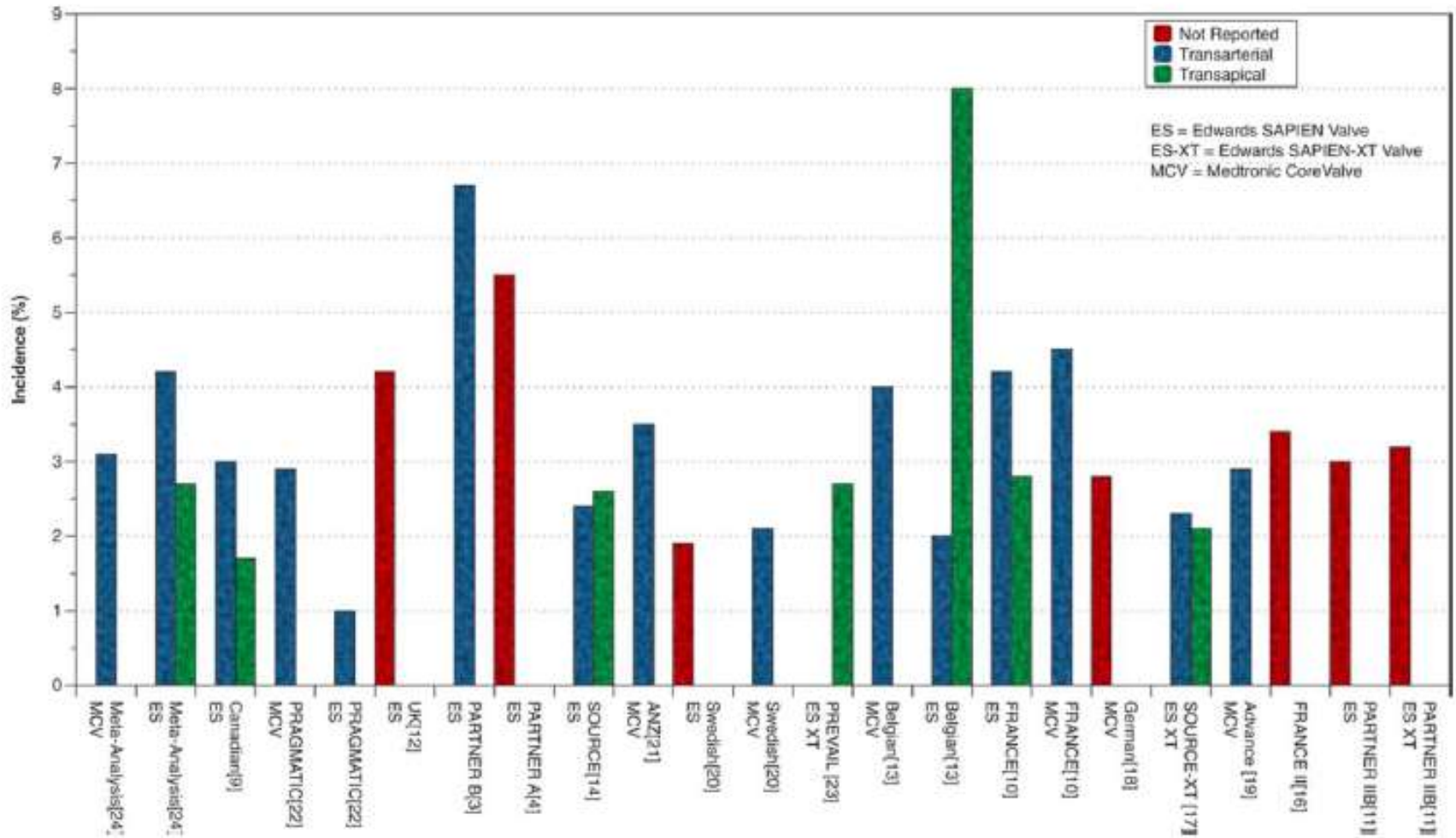
# Stroke following TAVR and SAVR

Timing of cerebrovascular events.



Jonathon P. Fanning et al. *Circulation*. 2014;129:504-515

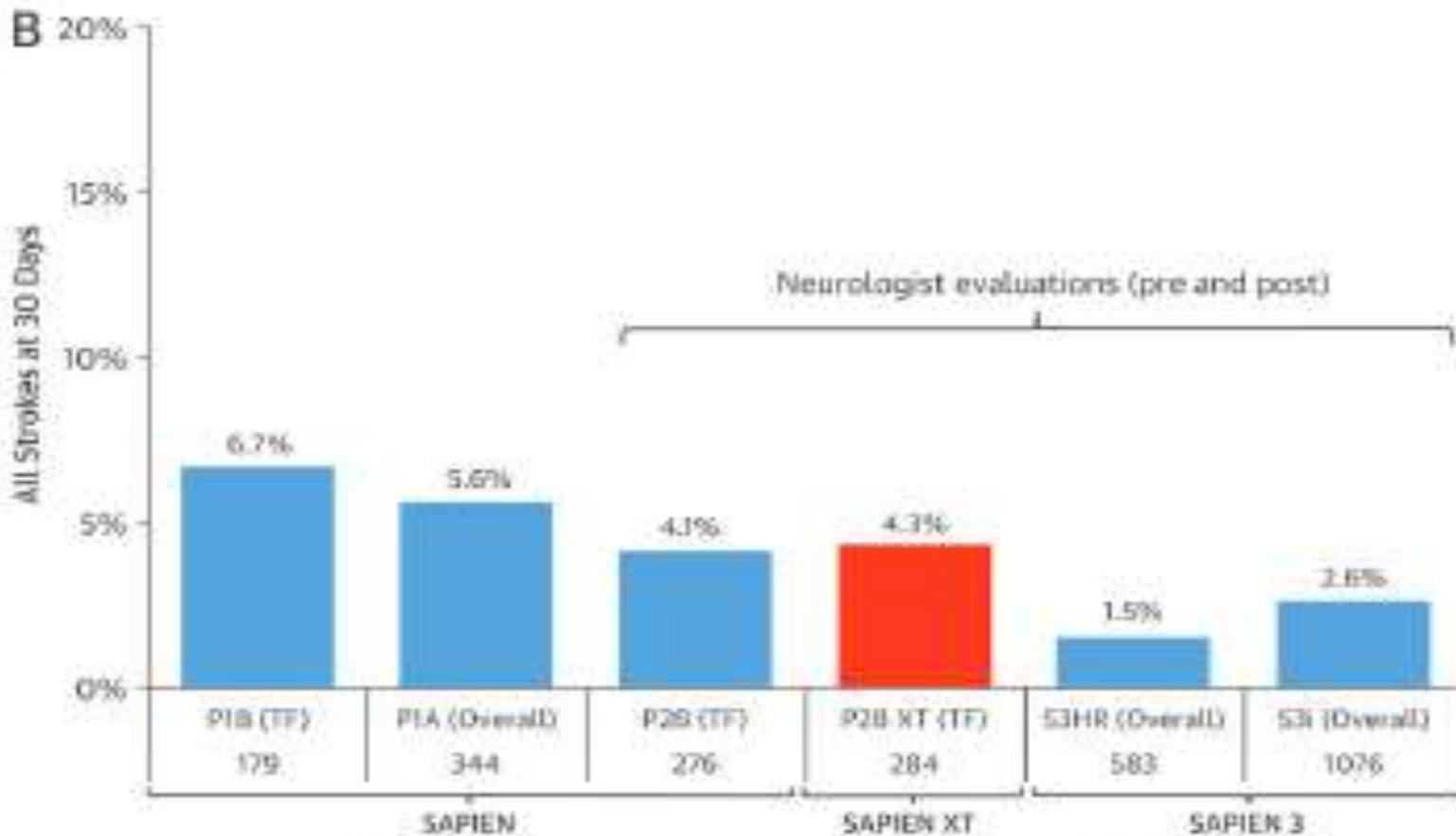
Thirty-day stroke incidence following TAVI. Studies arranged chronologically (from left to right) based on date of first patient recruitment.



Jonathon P. Fanning et al. *Circulation*. 2014;129:504-515



# Stroke in PARTNER Trials

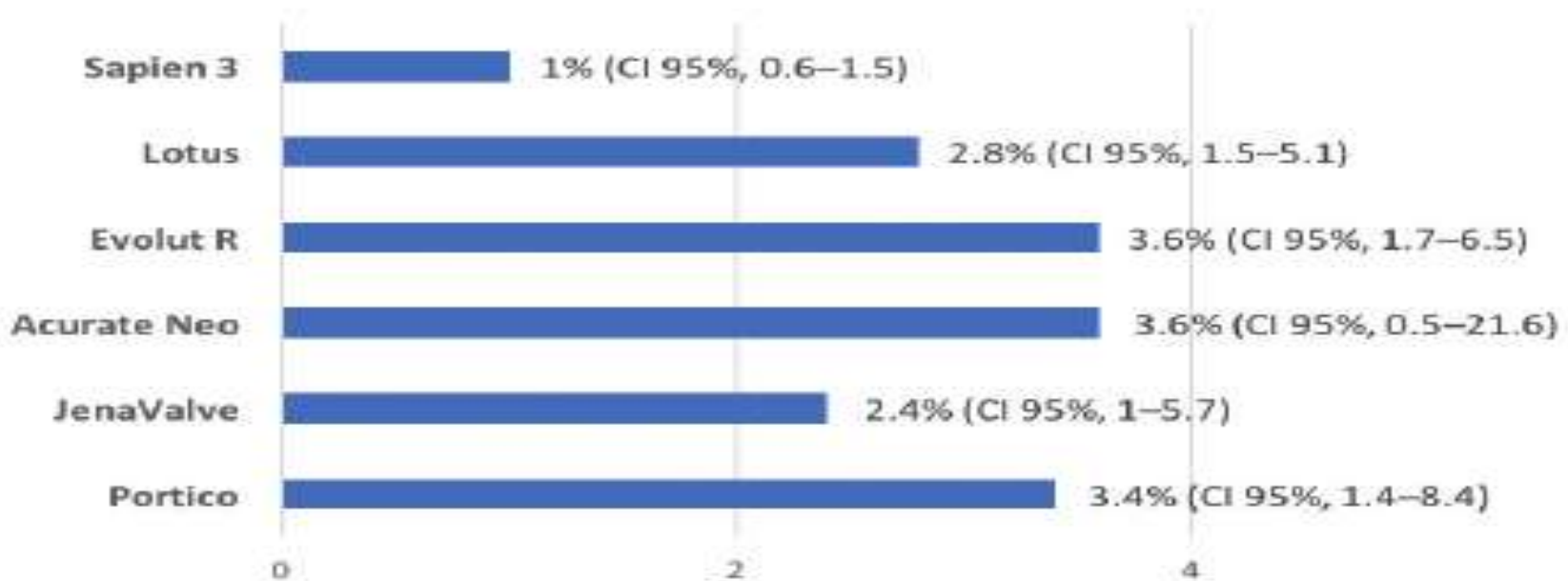


Torsten P. Vahl et al. JACC 2016;67:1472-1487

# Stroke

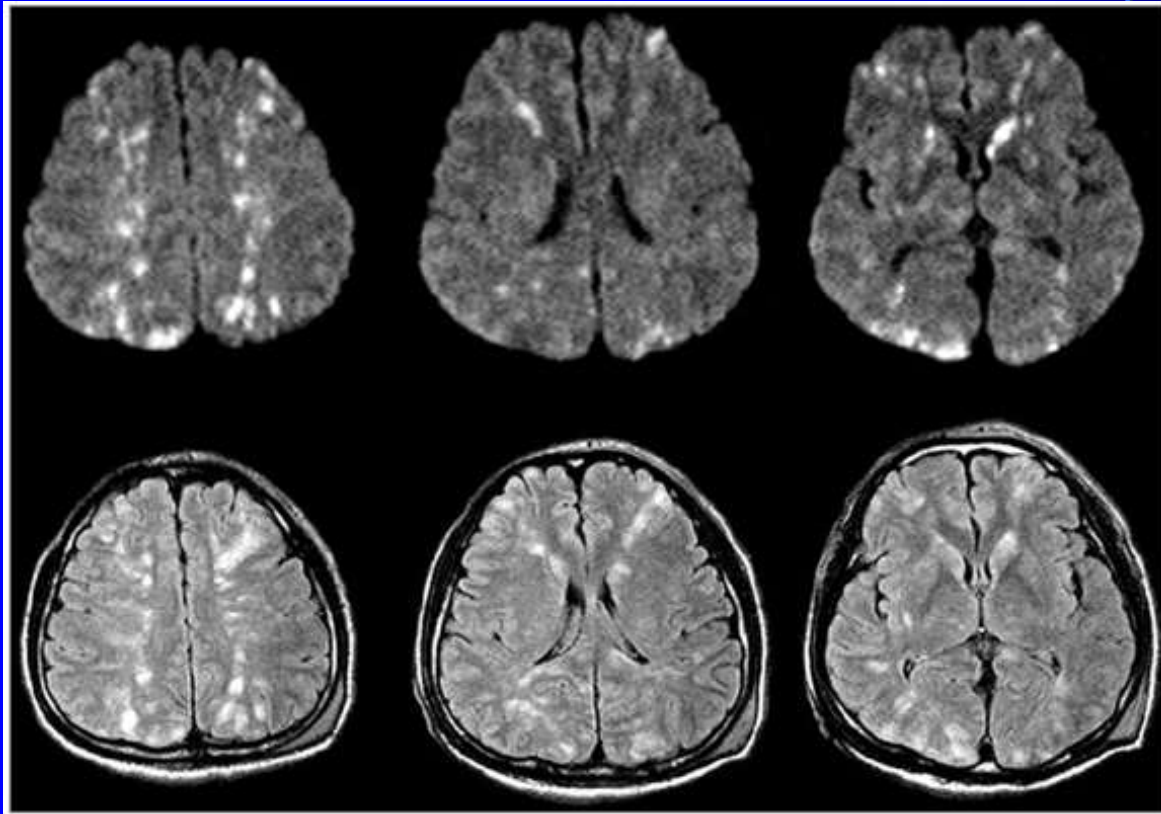
Current stroke rate is still 2-3%

## Major/disabling stroke



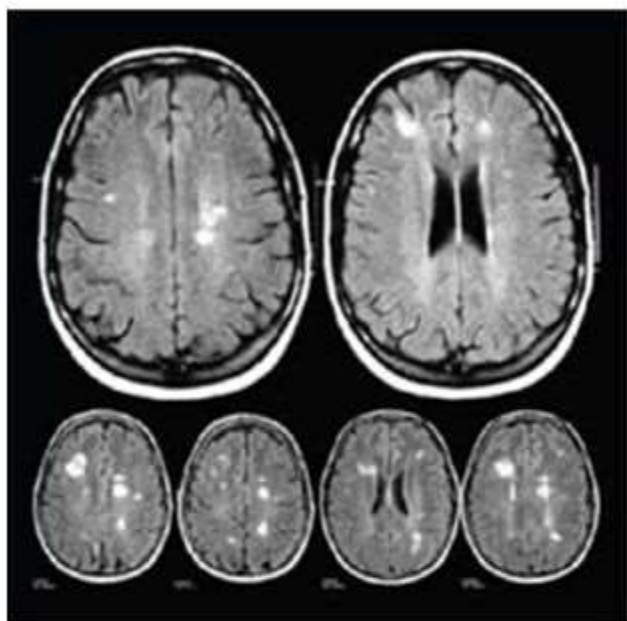
Outcomes from a weighted meta-analysis of 30 studies including 5,923 patients achieved with a comprehensive search of multiple Database from January 2011 to March 2016.

# Embolic Event

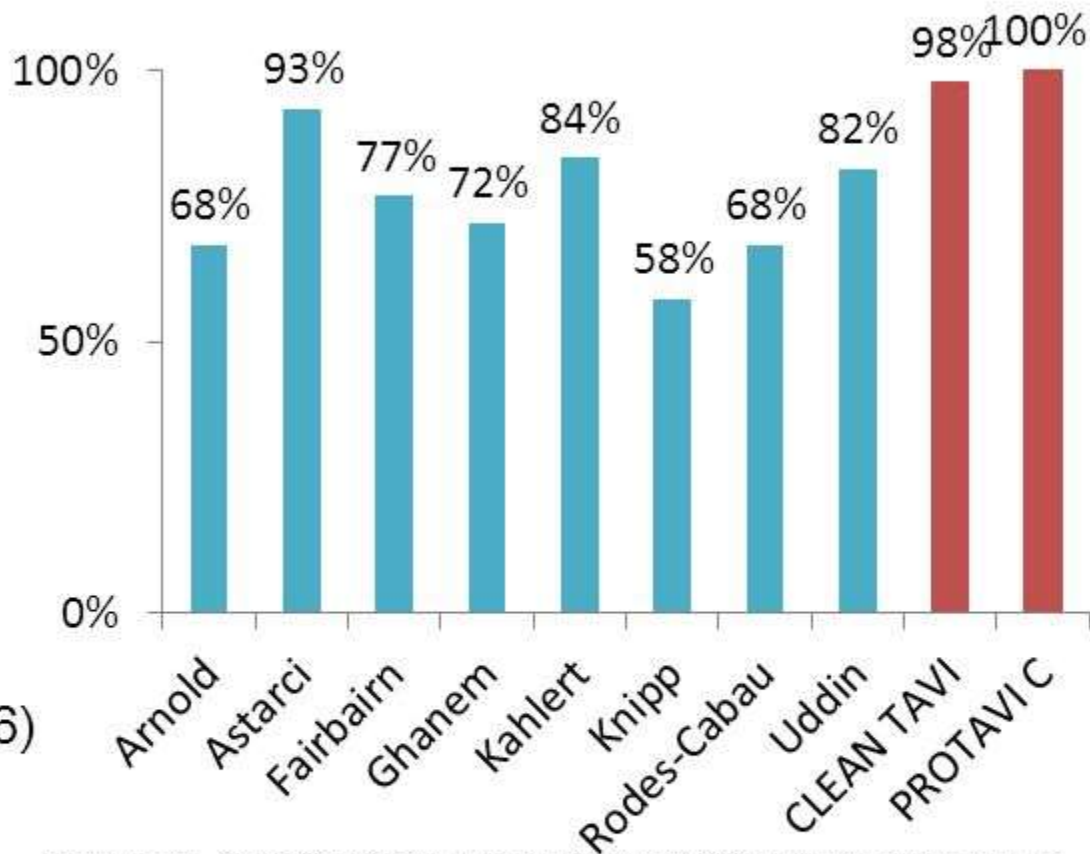


**Captured by embolic protection devices in 80-85% TAVI patients**

# Silent Embolic Events on DW-MRI after TAVR



% of Subjects with New Lesions

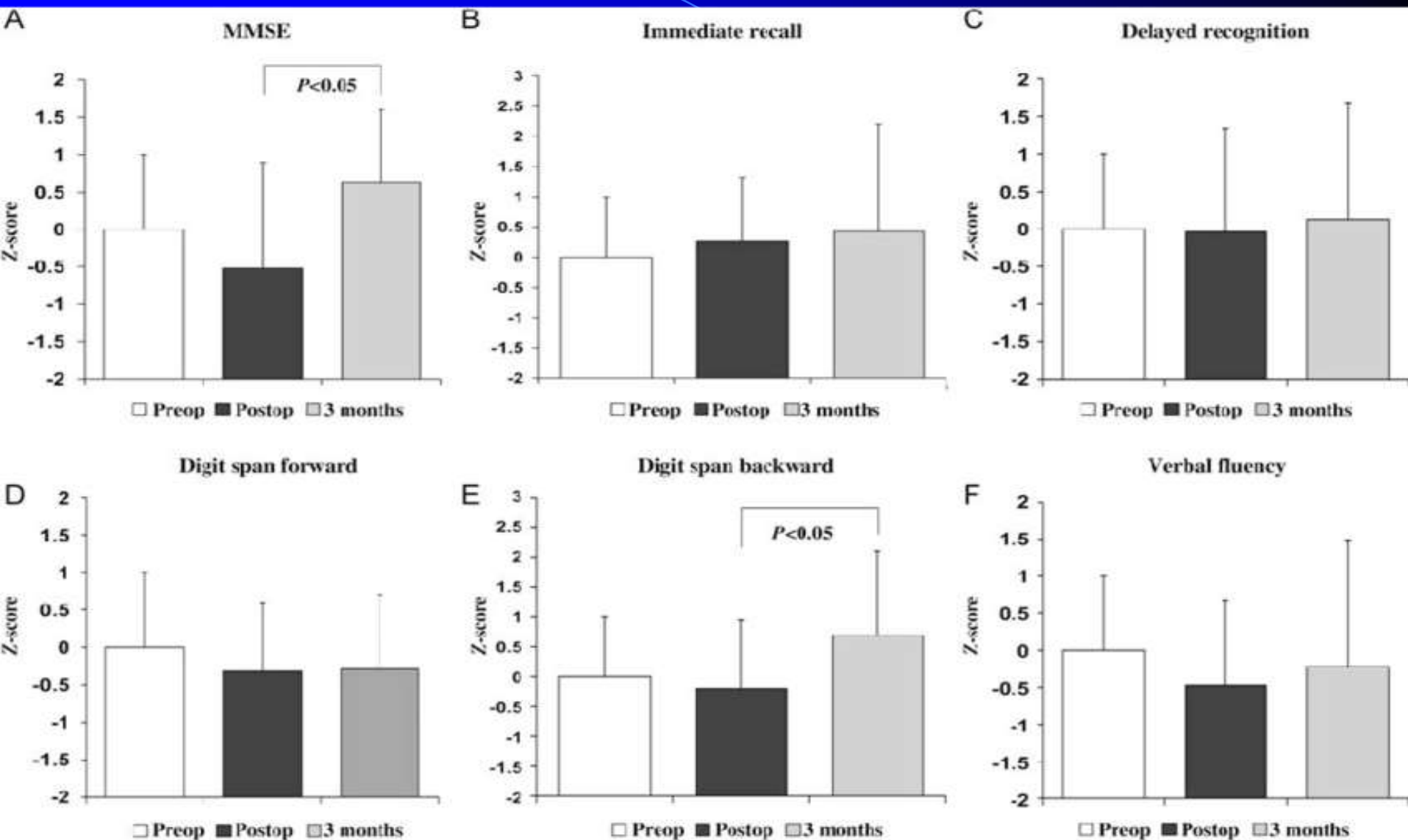


- Affect 58-100% of patients
- Multiple infarcts ( $\leq 36$ ,  $\bar{x} = 4.6$ )
- Associated with:
  - Neurocognitive decline
  - $>2$  fold risk of dementia
  - **$>3$  fold risk of stroke**

Restrepo et al. *Stroke* 2002;33:2909, Lund et al. *Eur Heart J*. 2005;26:1269, Schwarz et al. *Am Heart J* 2011;162:756, Knipp et al. *Ann Thorac Surg* 2008;85:872, Vermeer et al. *NEJM* 2003; 348:1215, Vermeer et al. *Stroke* 2003; 34:1126, Arnold et al. *JACC Cardiovasc Interv.* 2010;3:1126, Astarci et al. *J Heart Valve Dis.* 2013;22:79, Fairbairn et al. *Heart* 2012;98:18, Ghanem et al. *EuroIntervention*. 2013;8:1296, Kahlert et al. *Circ.* 2010;121:870, Knipp et al. *Interact Cardiovasc Thorac Surg.* 2013;16:116, Linke et al. TCT 2014, Rodes-Cabau et al. *JACC Cardiovasc Interv.* 2014;7:1145

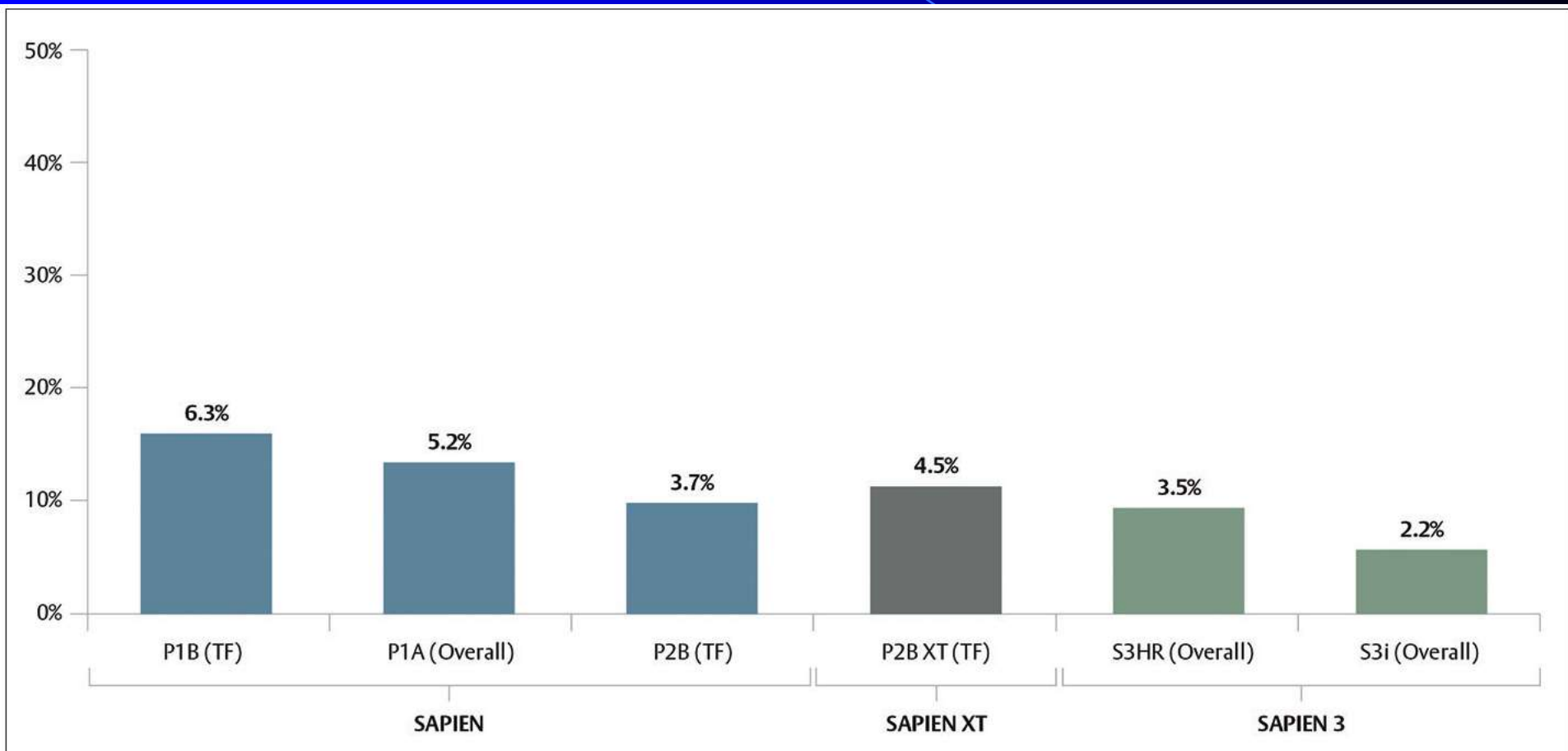


# Neurocognitive Changes

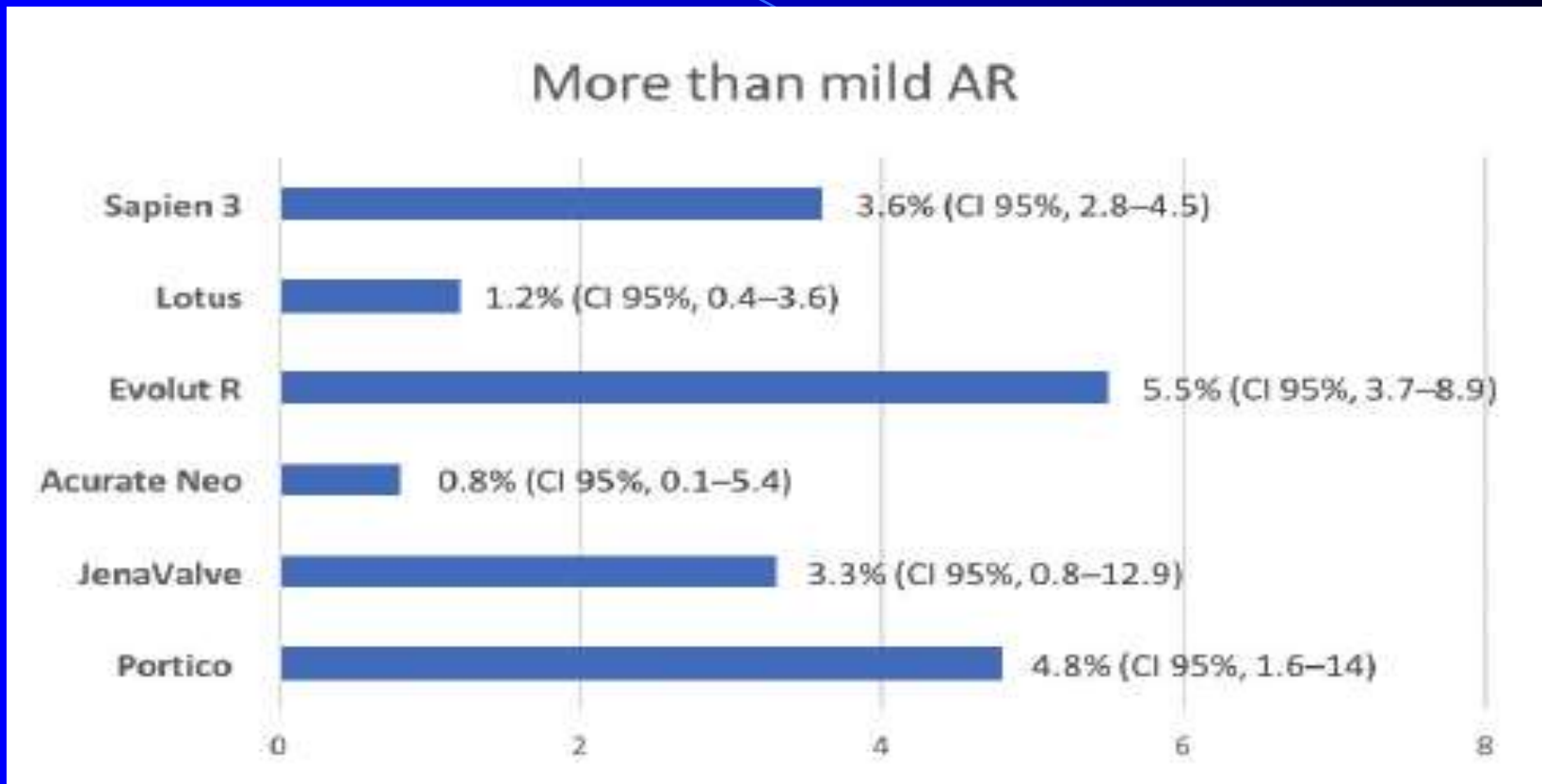




# Paravalvular Leak (>mild) in PATNER Trials

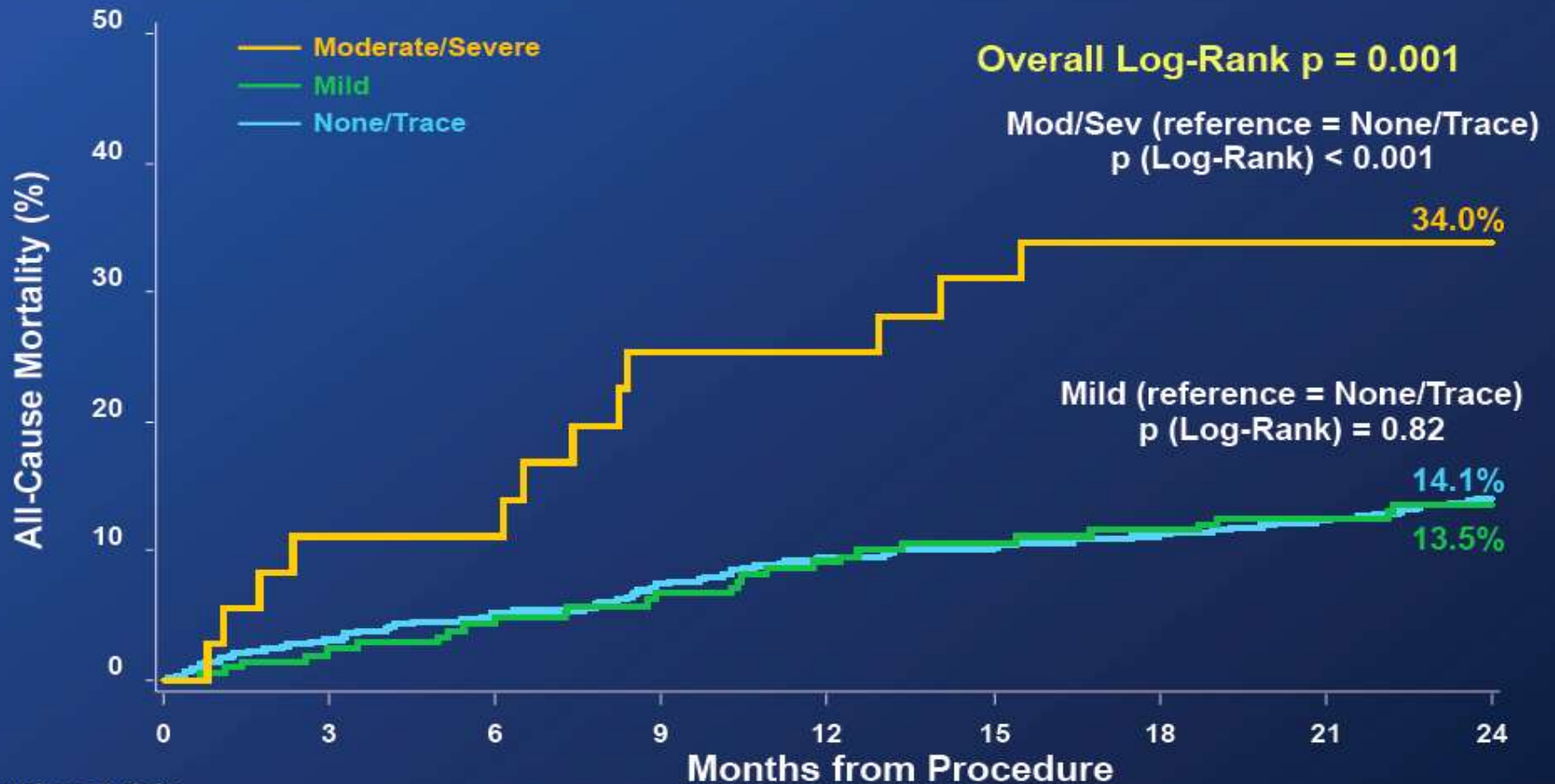


# Paravalvular Leak (>mild)



Outcomes from a weighted meta-analysis of 30 studies including 5,923 patients achieved with a comprehensive search of multiple Database from January 2011 to March 2016.

# Moderate and severe paravalvular leak is associated with increased mortality



Number at risk:

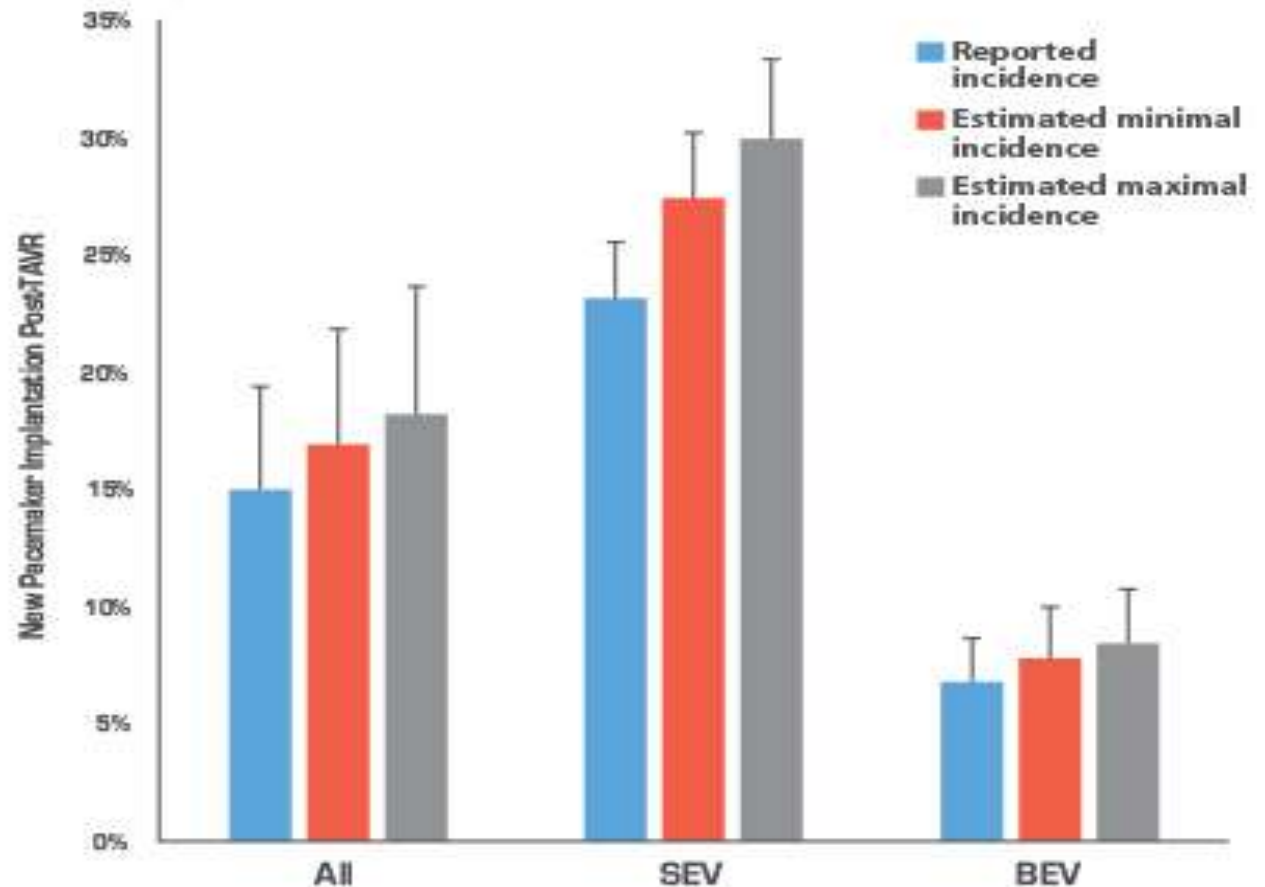
Moderate/Sev	36	32	32	26	26	24	22	22	21
Mild	210	204	199	194	188	184	182	180	175
None/Trace	701	678	664	647	628	621	612	605	585



# Pacemaker

## Incidence of New Pacemaker Implantation Post-TAVR

Researchers analyzed the incidence of new pacemaker implantation after TAVR as reported in multicenter registries and randomized trials. Some studies included both the self-expanding valve (SEV; Corevalve, Medtronic) and the balloon-expandable valve (BEV; Edwards Lifesciences) systems while others included only one of the systems.

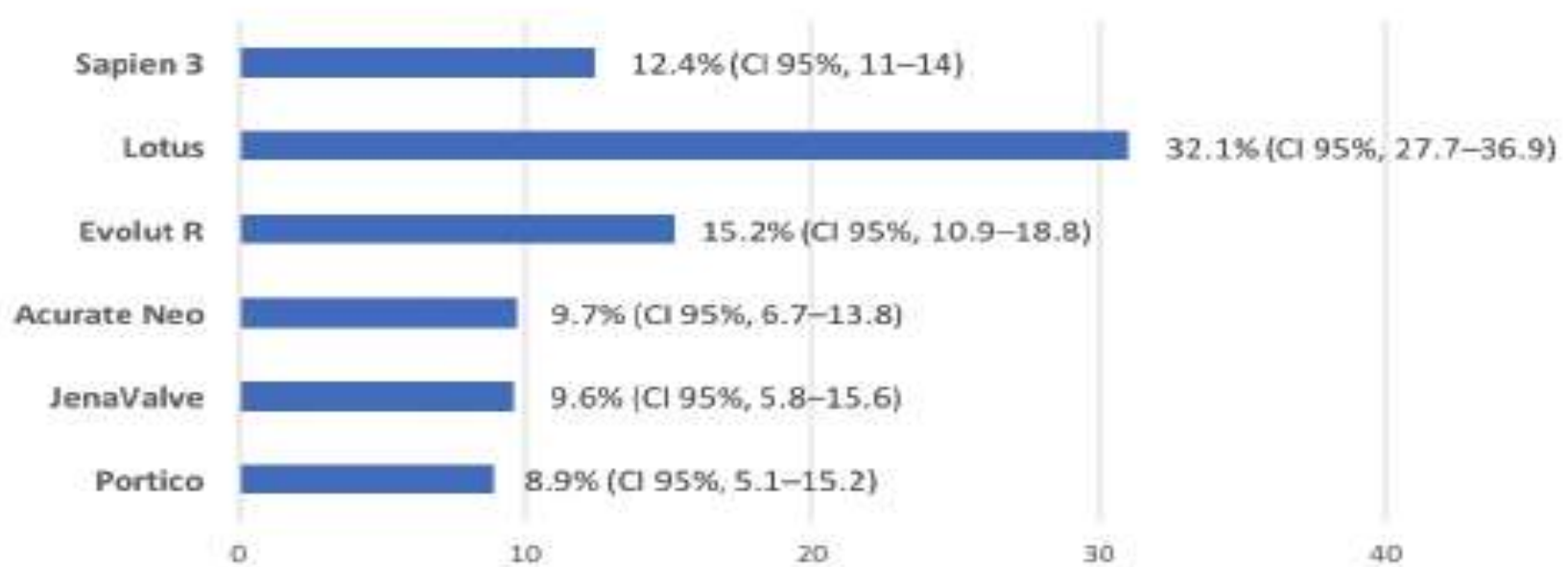


Mean reported vs. "real" estimated (minimal and maximal) incidence of pacemaker implantation post-transcatheter aortic valve replacement.

Source: J Am Coll Cardiol 2016;68(21):2387-9; reprinted with permission.

# Pacemaker

## New PPM

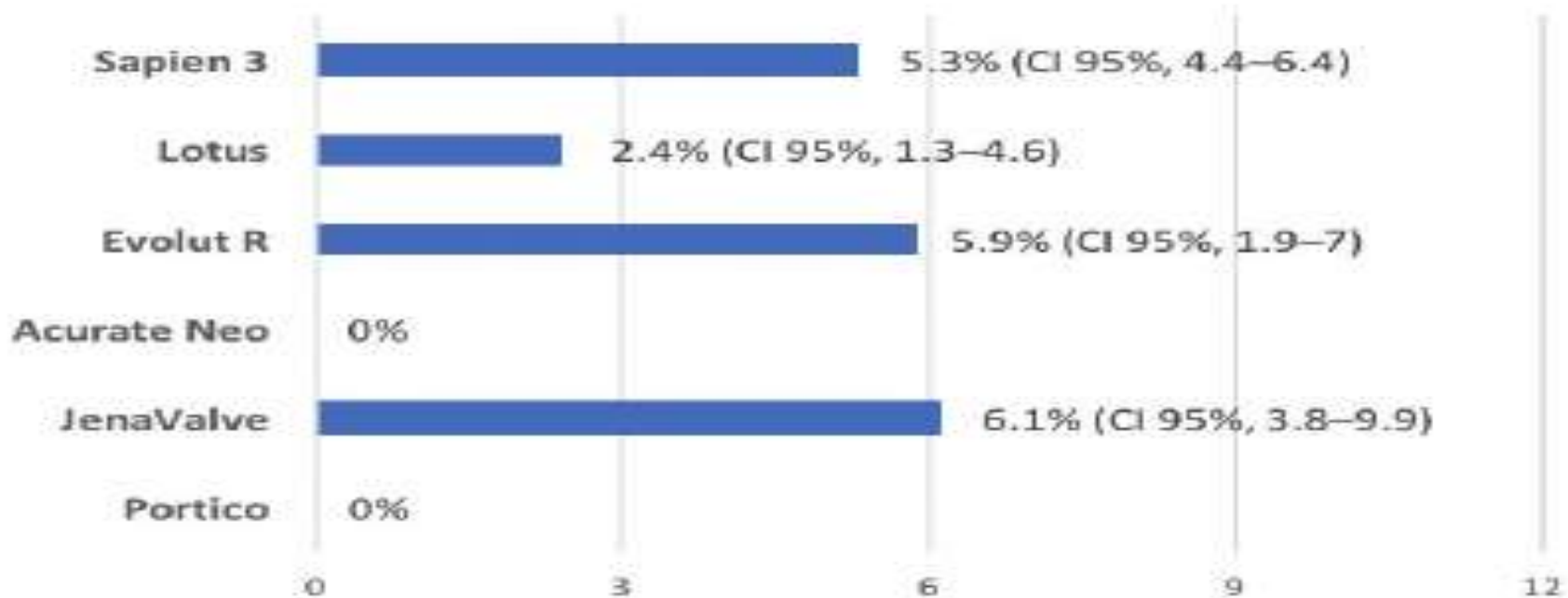


CARDIAC INTERVENTIONS TODAY MARCH/APRIL 2017 VOL. 11, NO. 2

Outcomes from a weighted meta-analysis of 30 studies including 5,923 patients achieved with a comprehensive search of multiple Database from January 2011 to March 2016.

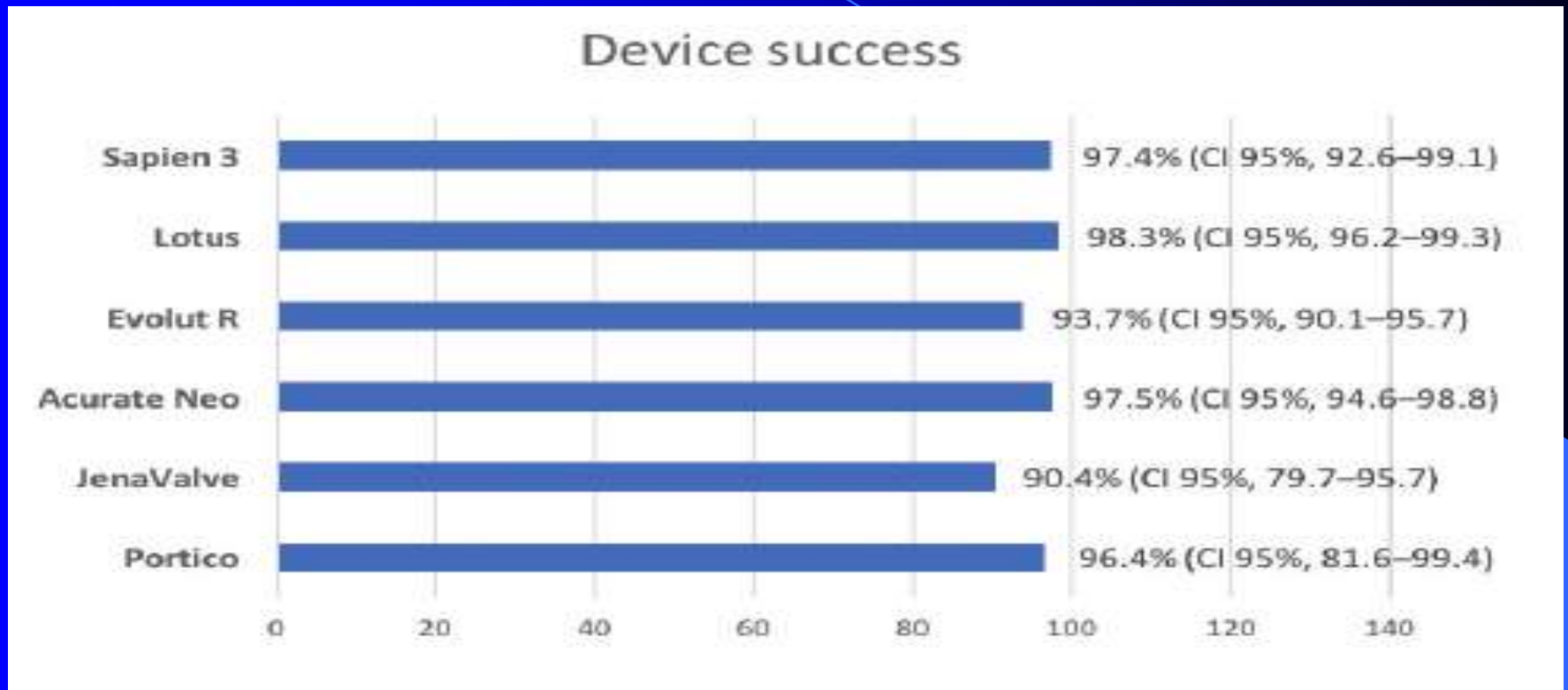
# Major Vascular Complication

Major vascular complication



Outcomes from a weighted meta-analysis of 30 studies including 5,923 patients achieved with a comprehensive search of multiple Database from January 2011 to March 2016.

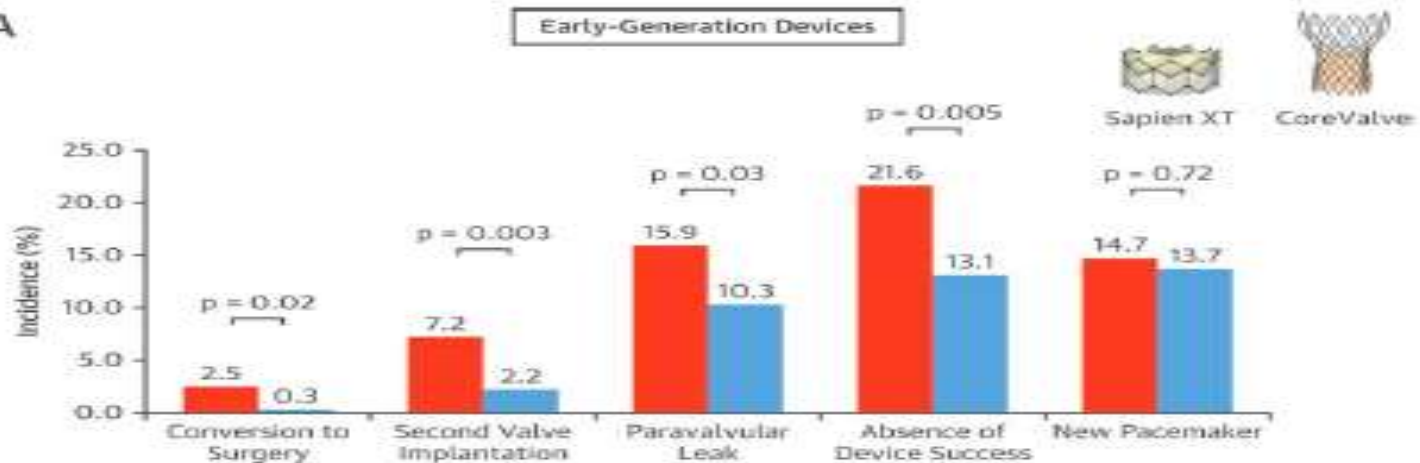
# Device Success Rate



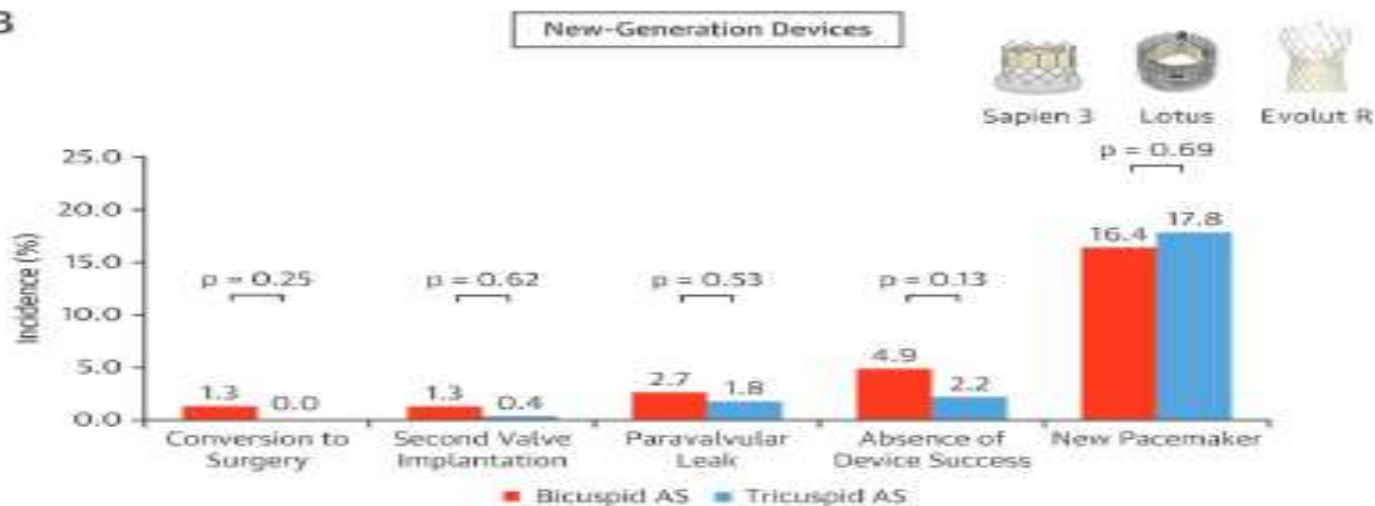
Outcomes from a weighted meta-analysis of 30 studies including 5,923 patients achieved with a comprehensive search of multiple Database from January 2011 to March 2016.

# More concerns in patients with bicuspid valve

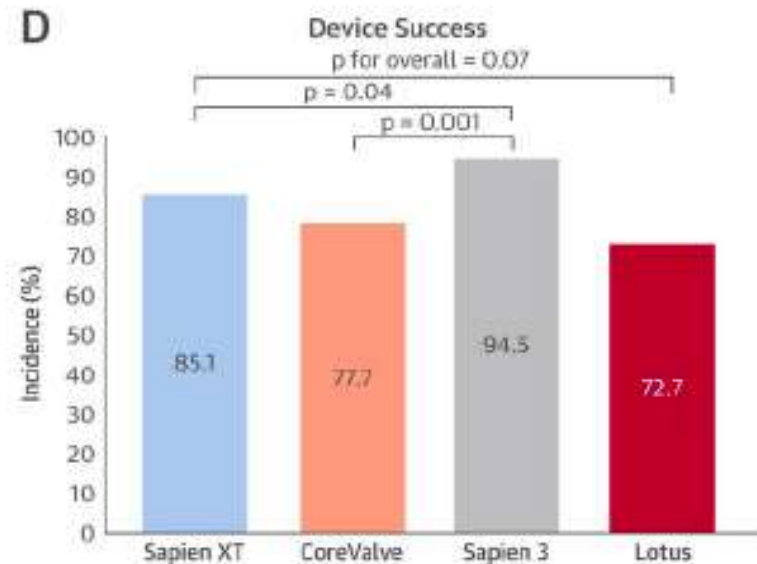
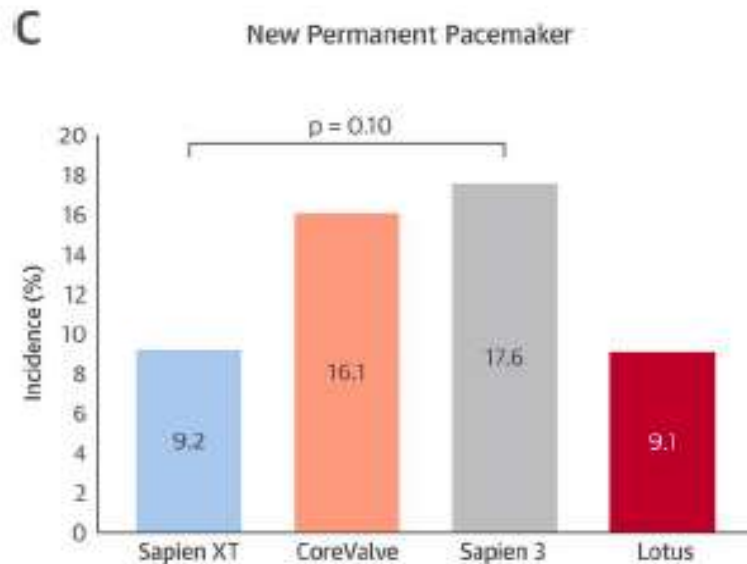
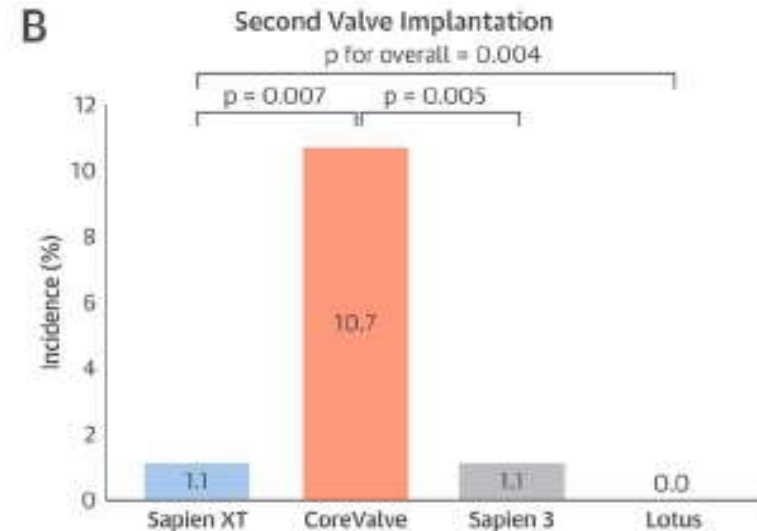
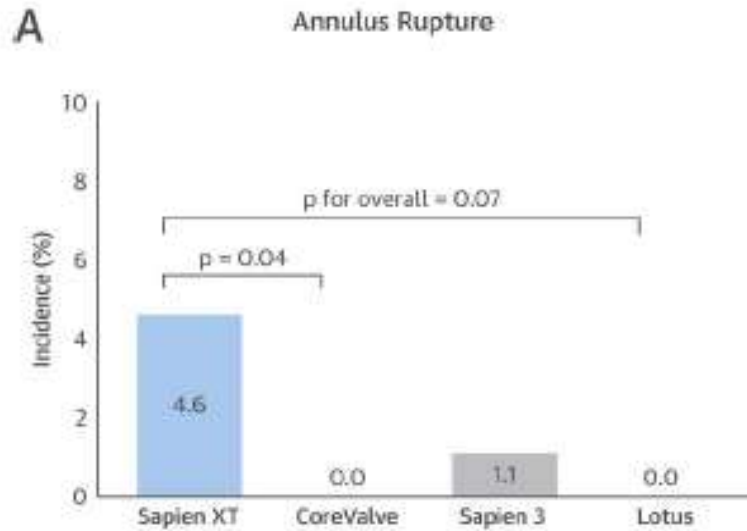
A



B



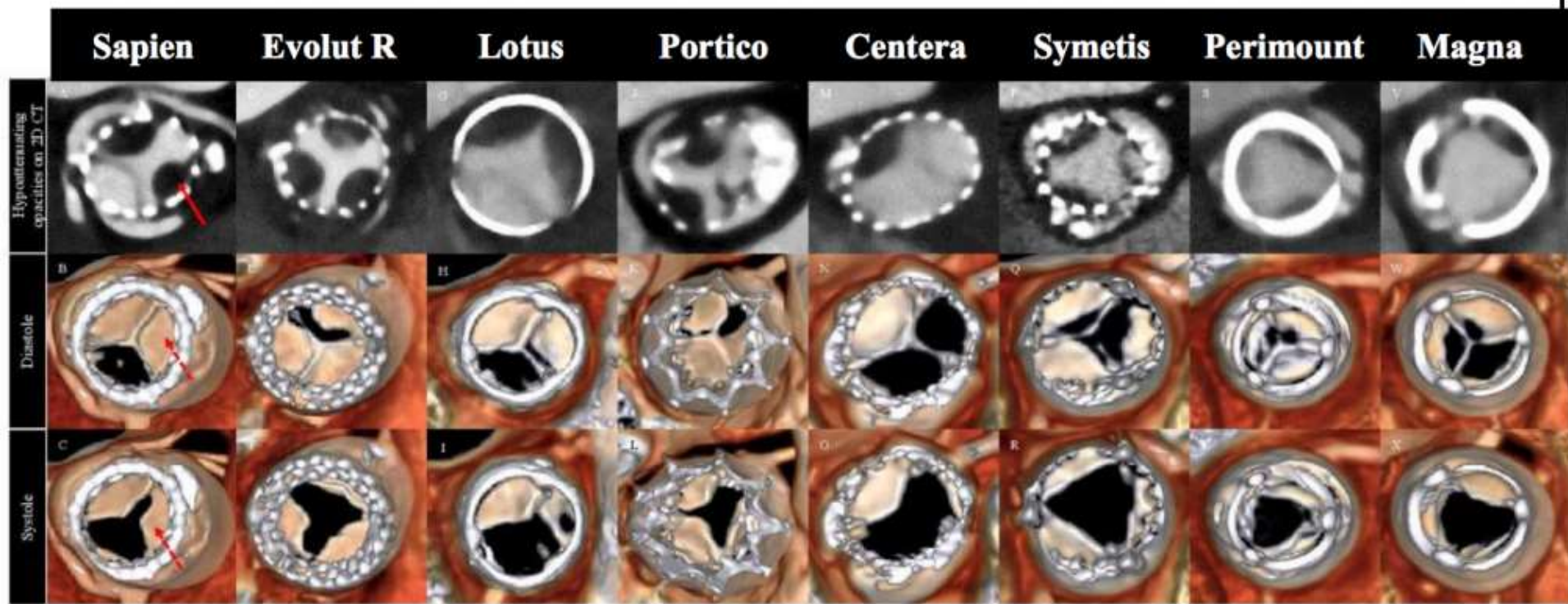
# More concerns in patients with bicuspid valve





# Valve Thrombosis

TAVR ~13% SAVR ~5%



# Durability of transcatheter valves remain unknown in young patients

- longest follow-up: ~5 years (mid-term) in the elderly patients only
- unknown durability in younger patients (<70 yrs)
- lack of long-term durability (>7 years) in any age group

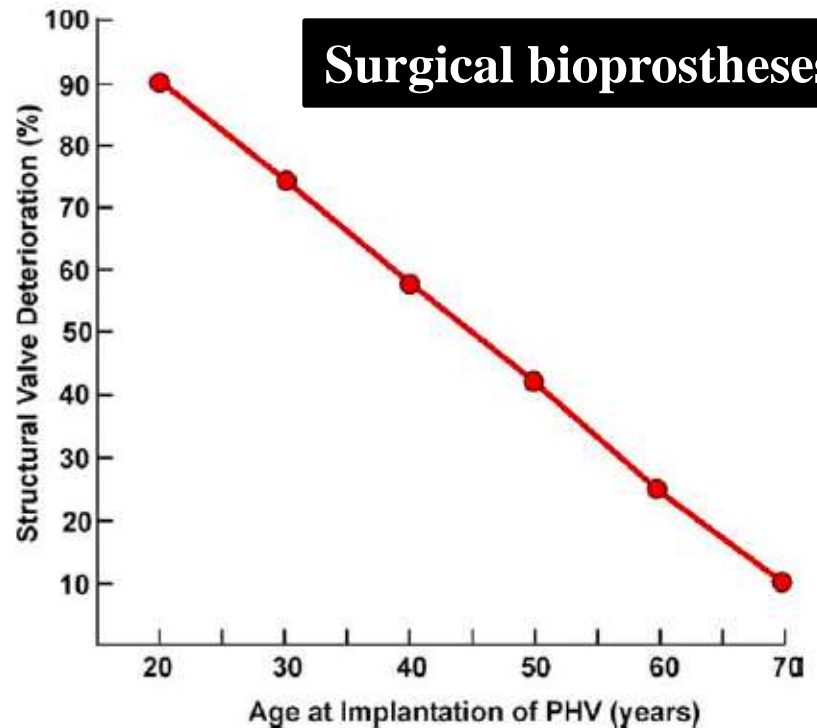


Figure 6

SVD of Biological Valves at 15 to 20 Years  
Based on Patient Age at Time of PHV Implantation



# High Structural failure rate of bioprostheses in young patients

**Table 5**

## Primary Valve Failure\* After Aortic Valve Replacement at 15 Years

### All patients

Bioprosthetic valve	23 ± 5%	
Mechanical valve	0 ± 0%	p = 0.0001

### Age <65 yrs

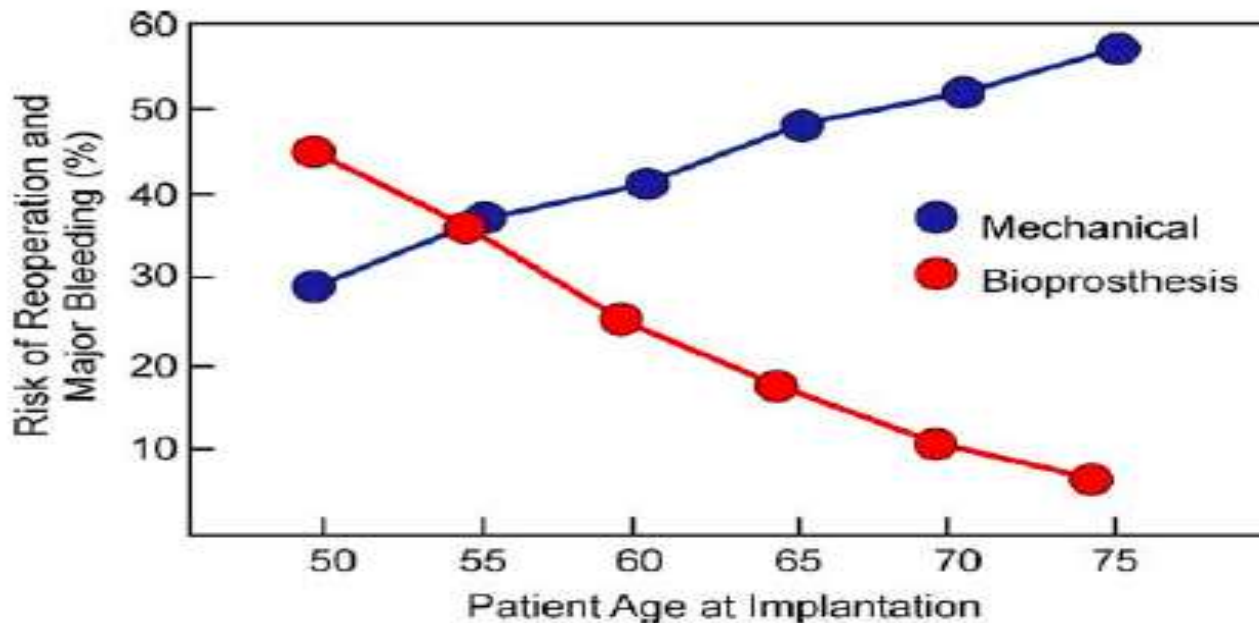
Bioprosthetic valve	26 ± 6%	
Mechanical valve	0 ± 0%	p = 0.001

### Age ≥65 yrs

Bioprosthetic valve	9 ± 6%†	
Mechanical valve	0 ± 0%	p = 0.10

\*Primary valve failure is now called structural valve degeneration (SVD). †The 1 instance of primary valve failure was actually not due to SVD but was due to reoperation for another cause. Data from Department of Veterans Affairs randomized trial (from Hammermeister et al. [3]).

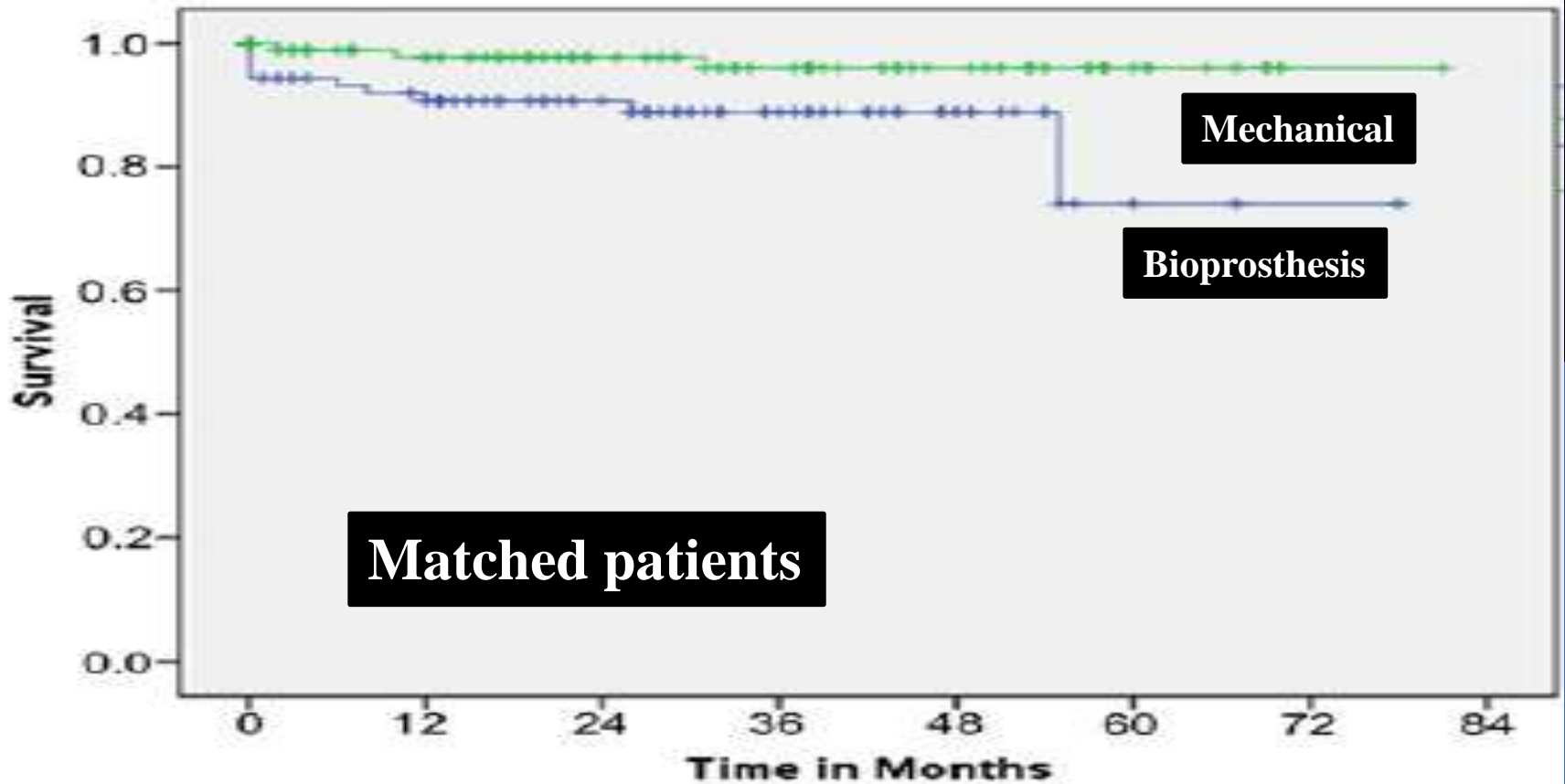
# Lifetime risk of reoperation with bioprostheses (red) is higher than lifetime risk of major bleeding with mechanical valve (blue) in young patients



**Figure 5**

**Comparison of Risks of Reoperation and Major Bleeding Between Mechanical and Bioprosthetic Heart Valves Based on Patient Age at Valve Implantation**

# Better survival with mechanical valve in young patients (<60 y/o)



J Thorac Cardiovasc Surg 2012;144:1075-83



# **Reduced anticoagulation after mechanical aortic valve replacement: Interim results from the Prospective Randomized On-X Valve Anticoagulation Clinical Trial randomized Food and Drug Administration investigational device exemption trial**

John Puskas, MD, MSc, FACS, FACC,<sup>a</sup> Marc Gerdisch, MD,<sup>b</sup> Dennis Nichols, MD,<sup>c</sup> Reed Quinn, MD,<sup>d</sup> Charles Anderson, MD,<sup>c</sup> Birger Rhenman, MD,<sup>e</sup> Lilibeth Fermin, MD,<sup>e</sup> Michael McGrath, MD,<sup>f</sup> Bobby Kong, MD,<sup>g</sup> Chad Hughes, MD,<sup>h</sup> Gulshan Sethi, MD,<sup>i</sup> Michael Wait, MD,<sup>j</sup> Tomas Martin, MD,<sup>k</sup> and Allen Graeve, MD,<sup>c</sup> on behalf of all PROACT Investigators

**Objective:** Under Food and Drug Administration investigational device exemption, the Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT) has been testing the safety of less aggressive anticoagulation than recommended by the American College of Cardiology/American Heart Association guidelines after implantation of an approved bileaflet mechanical valve.

**Conclusions:** INR can be safely maintained between 1.5 and 2.0 after aortic valve replacement with this approved bileaflet mechanical prosthesis. With low-dose aspirin, this resulted in a significantly lower risk of bleeding, without a significant increase in thromboembolism. (J Thorac Cardiovasc Surg 2014;147:1202-11)

# Surgeon's Perspectives

- TAVI will be the dominant therapy for AS patients.
- Surgical AVR will probably remain the preferable treatment for AS in young patients (<60 yrs).
- Mechanical valves is still a viable option in very young (<50 yrs) patients.
- To maintain excellent outcome of surgical AVR, surgical AVR should be performed only in large cardiac centers in the future.
- Young patients must be reviewed by a Heart Team or surgeons prior to offering TAVI. **Informed consent** is extremely important.

THANKS!