

# Are the Complications of TAVR gone?

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# Disclosure Statement of Financial Interest

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

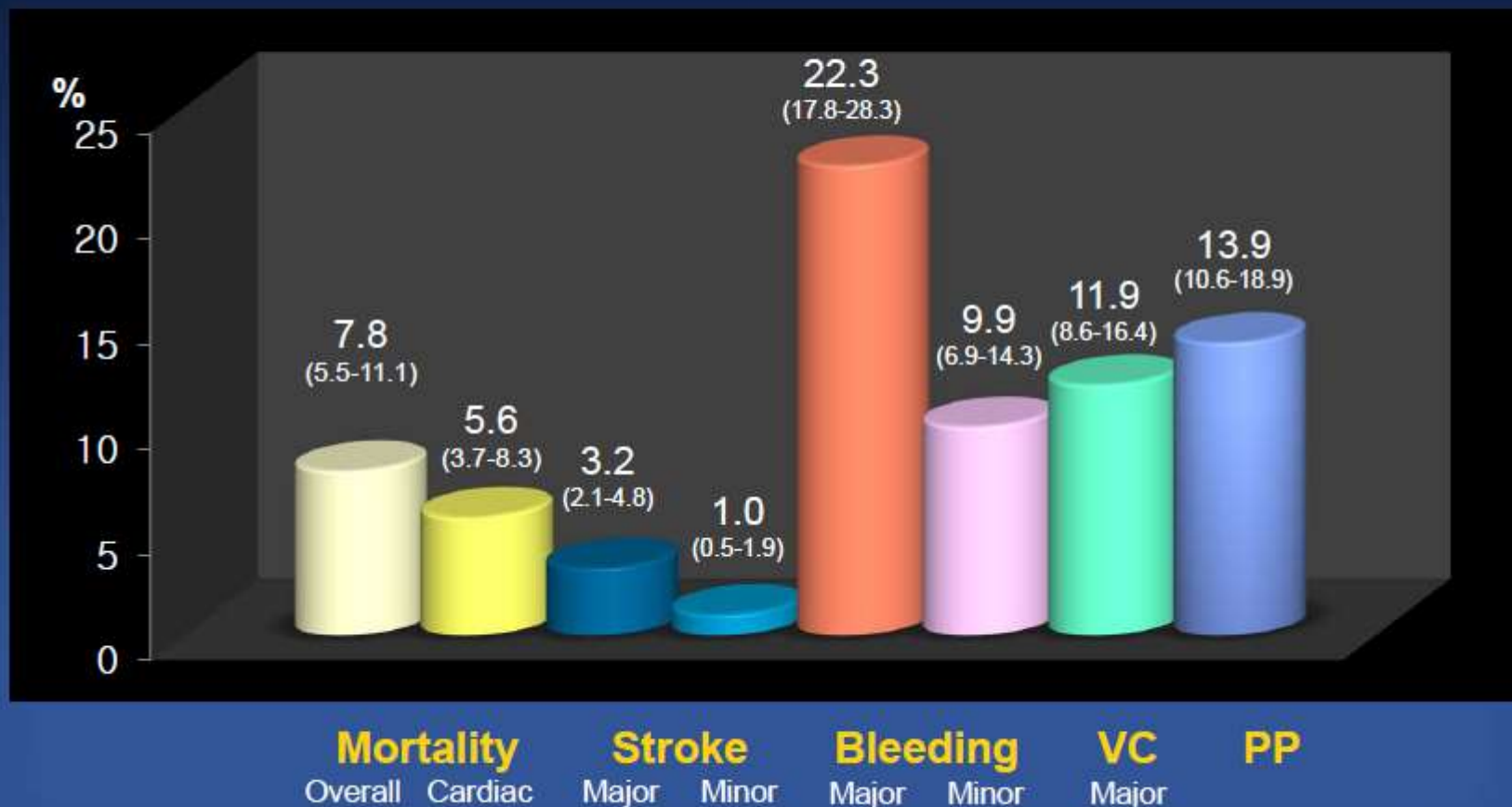
- Consulting Fees/Honoraria
- Proctoring–Training activities/Honoraria

## Company

- Edwards Lifesciences
- Edwards Lifesciences

# Complications: The Achilles' heel of TAVR

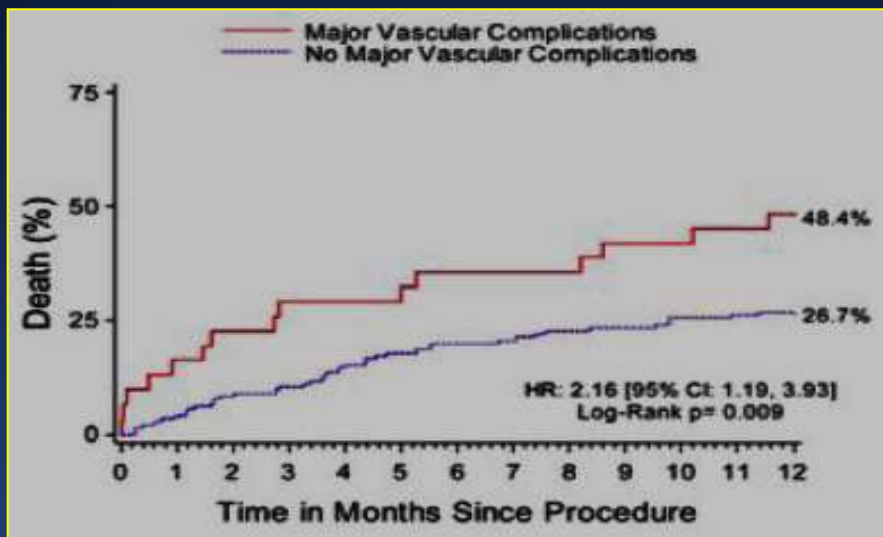
## TAVI Outcomes at 30 Days - VARC Meta-Analysis (16 studies; 3,519 patients)



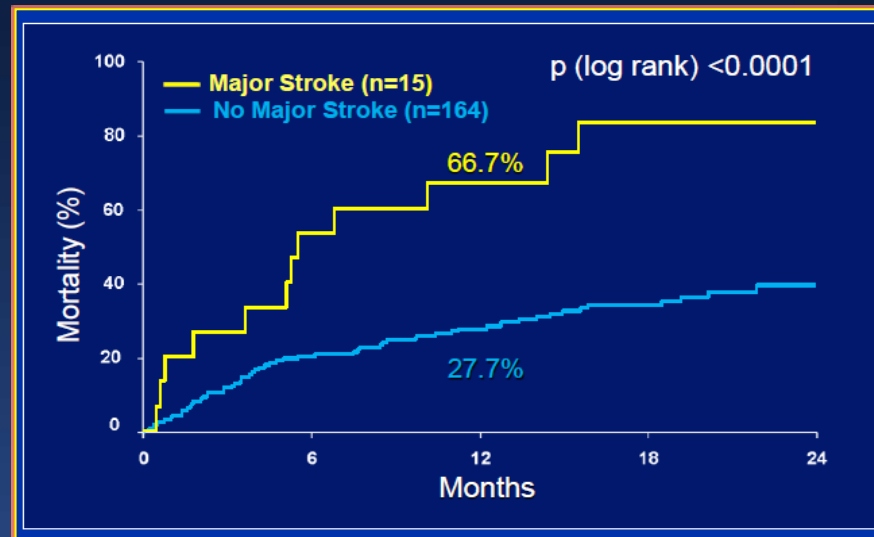
VC = vascular complication. PP = permanent pacemaker

Généreux P et al. JACC 2012

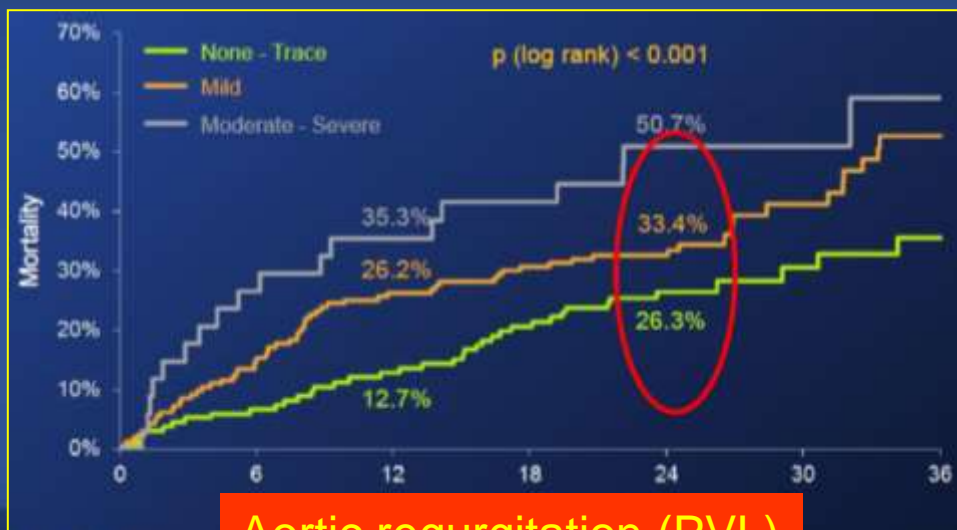
# Leading complications have a deleterious effect on clinical outcome



Vascular complications



Major stroke



Aortic regurgitation (PVL)

# Improving the safety of TAVR

## *Existing and ongoing strategies*

### Severe Vascular (3-16%)

- Lower size devices, new prosthesis
- Improved closure devices
- New approaches (TAO, Carot)

### Stroke (2-7%)

- Detection of high risk patients
- Embolic protection devices
- Modified anticoagulation strategy

### Paravalvular AR (5% > grade 2)

- CT for annulus sizing (area)
- New imaging technologies
- New prosthesis

### AV Block (PM) (Edwards 3-12% , CoreValve 16-35%)

- New prosthesis and delivery systems

# Improving the safety of TAVR

## *Developed and ongoing strategies*

### Rupture of the annulus ( $<1\%$ )

- Assessment of **aortic annulus size (MSCT & balloon sizing)**
  - **Undersize** if massive calcif.
- Age/gender

### Coronary occlusion (LM) ( $<1\%$ )

- Detection of **bulky leaflets**
- **Distance LM/annulus (MSCT)**
- **Aortogram per BAV**

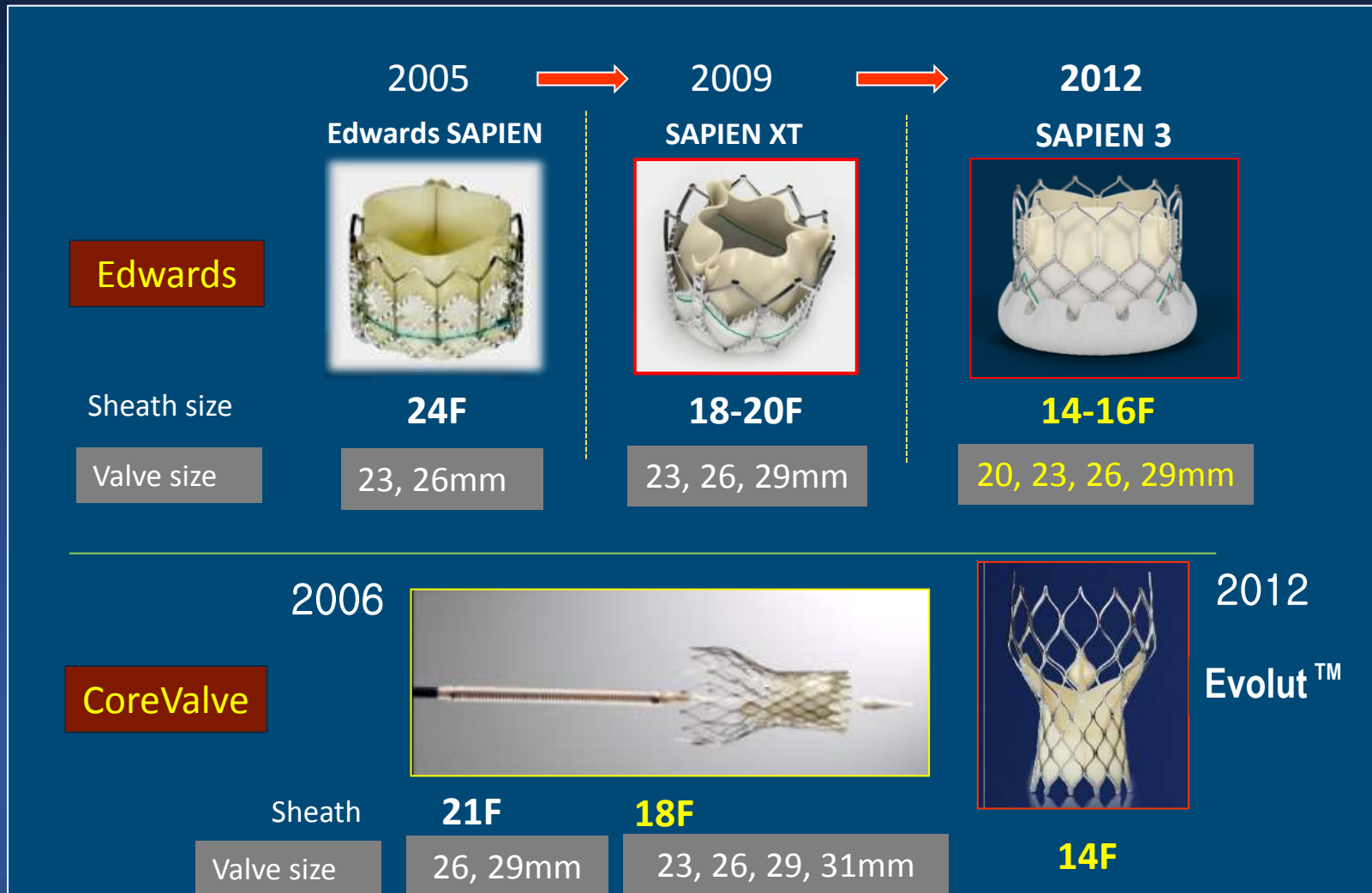
### Valve embolization (2-5%)

- Improved **valve sizing (MSCT)**
- Accurate **positioning**
- Slow / staged inflation?

### Pericardial tamponade ( $<1\%$ )

- Cautious **pacing lead placement**
- Avoid super stiff wire in LV

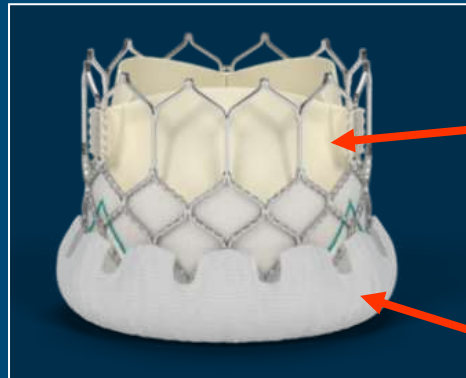
# New valves / delivery systems: Considerable improvement of safety



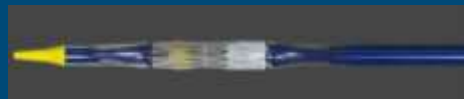


# 2014: Last Generation Devices

*A dramatic decrease of life threatening complications*  
*A new era for TAVR*



**SAPIEN 3**



E-Sheath 14-16F

**TF > 80%**  
**« Minimalist approach »**

## The SAPIEN 3 Trial

Early Experience (Learning Curve)

N= 150, Age: 83.6, TF & TA  
High and Intermediate Risk

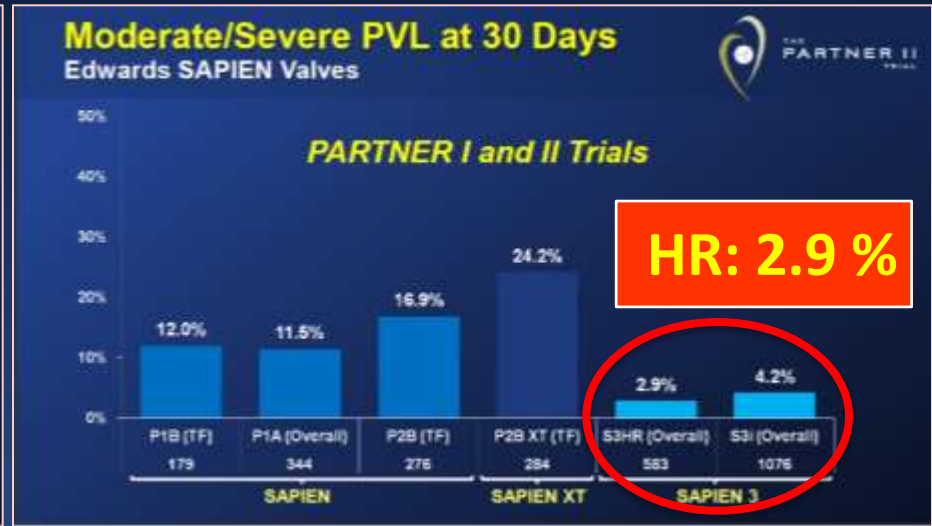
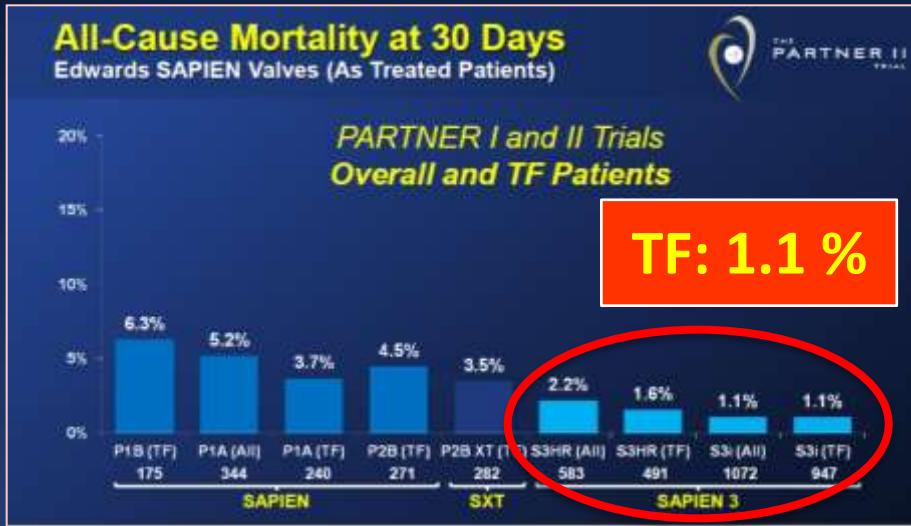
### TF results N= 96

30-D Mortality:	<b>1.1%</b>
Stroke:	<b>1.0%</b>
PVL moderate:	<b>2.6%</b>
Vascular complic:	<b>5.2%</b>
PPM:	12%
Preclosing:	96% TF

J. Webb, PCR 2014



# Decreased complications in high risk and intermediate risk patients with Sapien 3



Mortality at 30-D

PVL at 30-D

### Strokes At 30 Days (As Treated Patients)

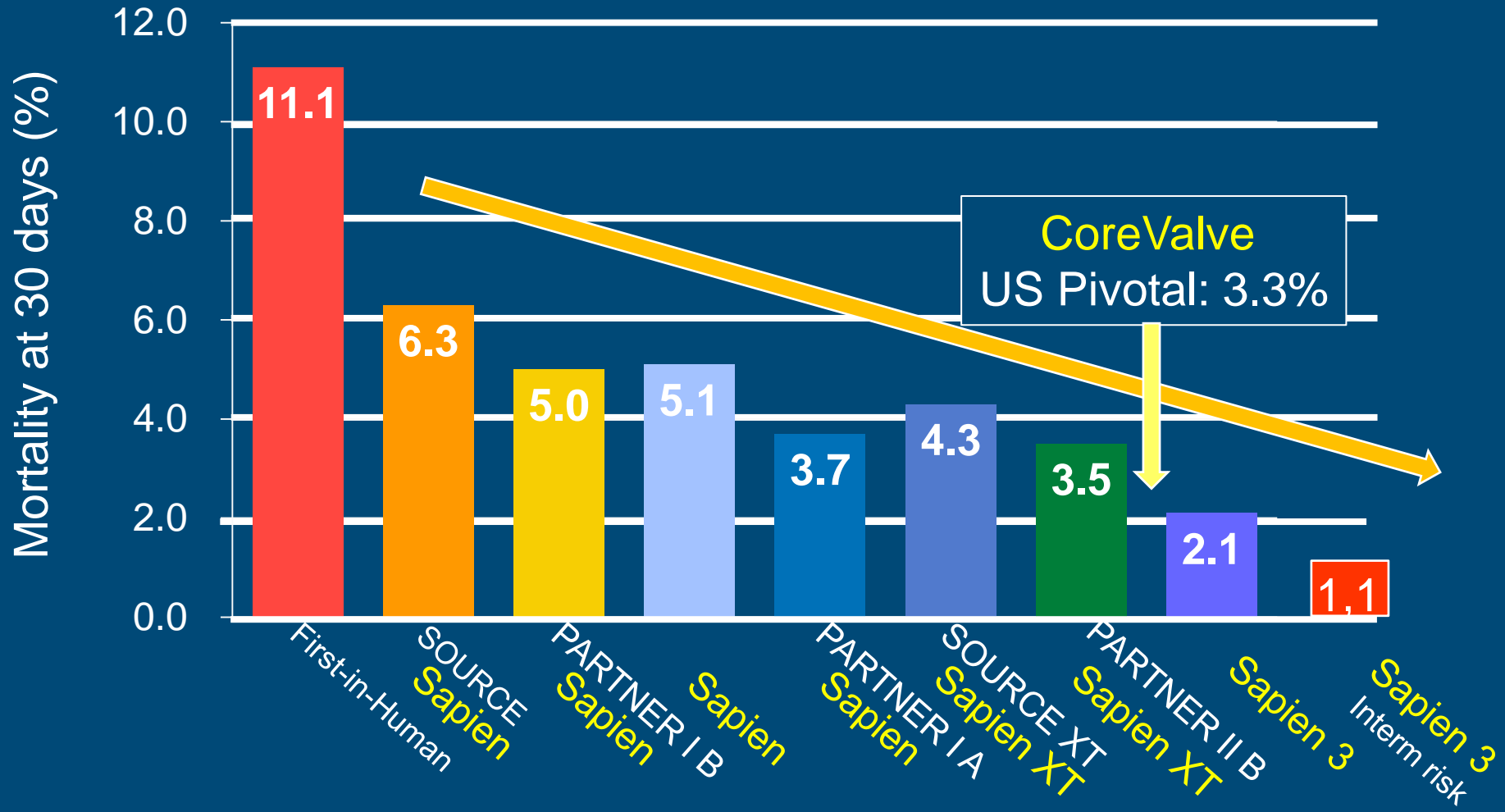
THE PARTNER II TRIAL

Events (%)	S3HR Overall (n=583)	S3HR TF (n=491)	S3HR TA/TAo (n=92)	S3I Overall (n=1076)	S3I TF (n=951)	S3I TA/TAo (n=125)
All	1.54	1.63	1.09	2.60	2.42	4.00
Disabling*	0.86	0.81	1.09	1.02	0.95	1.60
Non-Disabling	0.69	0.81	0	1.58	1.47	2.40
TIA	0.69	0.61	1.09	0.37	0.42	0

**Disabling  
Strokes  
TF < 1%**

Susheel Kodali, MD, Outcomes at 30 Days with the Sapien 3 TAVR System ACC 2015

# Mortality Across TAVR Studies



# Question: How will newer generation devices compare with SAPIEN 3 ?



CoreValve Evolut  
*Improved sealing*



DF medical  
*Repositionable, retrievable*



BS Sadra SJ Portico



Edw Centera Accurate  
*Self seating features*



Jena Valve Engager  
*Native leaflets incorporated*



# Conclusion

In 2015, all complications are not gone yet !

But they have markedly decrease with major advanced technologies, and this should allow a broad expansion of TAVR to lower / younger AS patients in the near future