

# TAVI: Incidence and Prevention of Stroke and AV Block



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# Disclosure

## **Edwards Lifesciences**

Consultant

Training / proctoring activities

# France 2 Registry

*N Engl J Med 2012;366:1705-15*

## Major complications (30 Day)

	Global N=3185	Edwards N=2107	CoreValve N=1043
Vascular	9.7%	10.7%	9.2%
<b>Pacemaker</b>	<b>15.6%</b>	<b>11.5%</b>	<b>24.2%</b>
<b>Stroke</b>	<b>4.1%</b>	<b>3.8%</b>	<b>4.3%</b>
Bleeding	13.1%	11.4%	8.8%

# Permanent AV Block is a well known complication of Aortic Valve Replacement

## ➤ **Surgical Valve Replacement**

(SAVR): 7.2% (3.2% - 8.9%)

## ➤ **Transcatheter Aortic Valve Implantation**

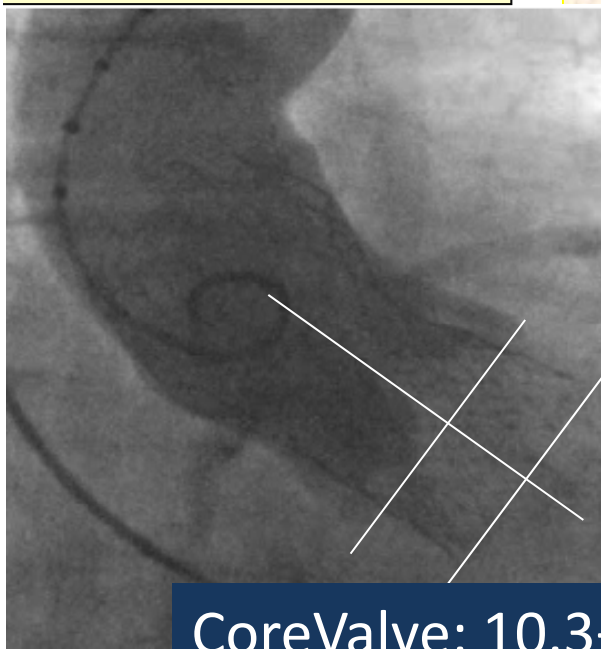
(TAVI): 15% (0% - 47%)

# TAVI and Conduction Disturbances

Related to the Proximity of the Aortic Valve  
to the Conduction System

Distance of the non-coronary cusp  
to the lower edge of the stent should be  $< 6\text{mm}$

Piazza et al  
JACC Cardiovasc Interv 2008



CoreValve:  $10.3 \pm 2.7\text{mm}$



Issue of the mitral valve  
in deep implantation

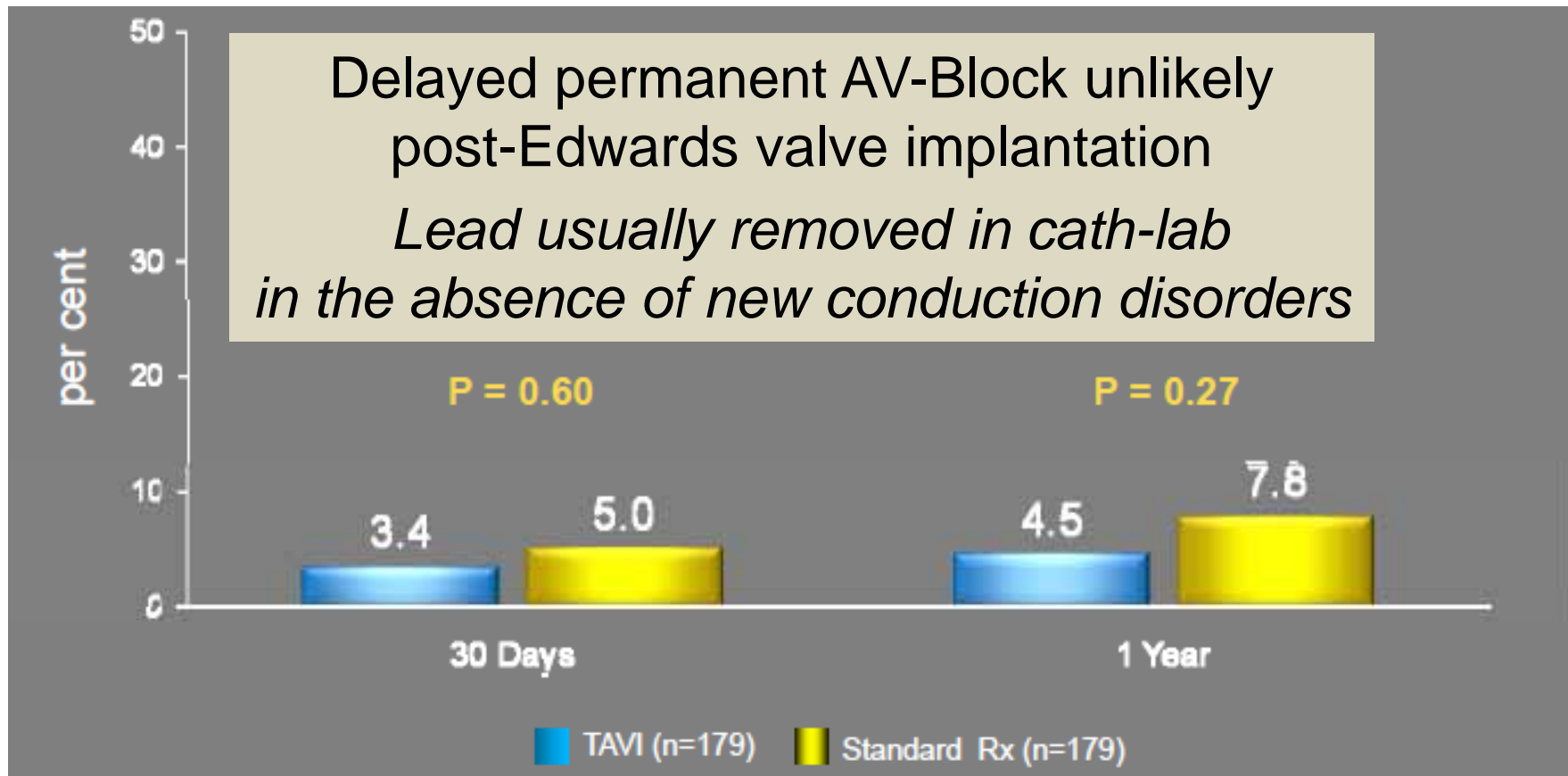
Caudron et al  
AmJ Med 2011



Edwards:  $2.4 \pm 2.5\text{mm}$

# PARTNER Trial (Edwards)

## Incidence of New Pacemakers at 30-Day and 1 Year



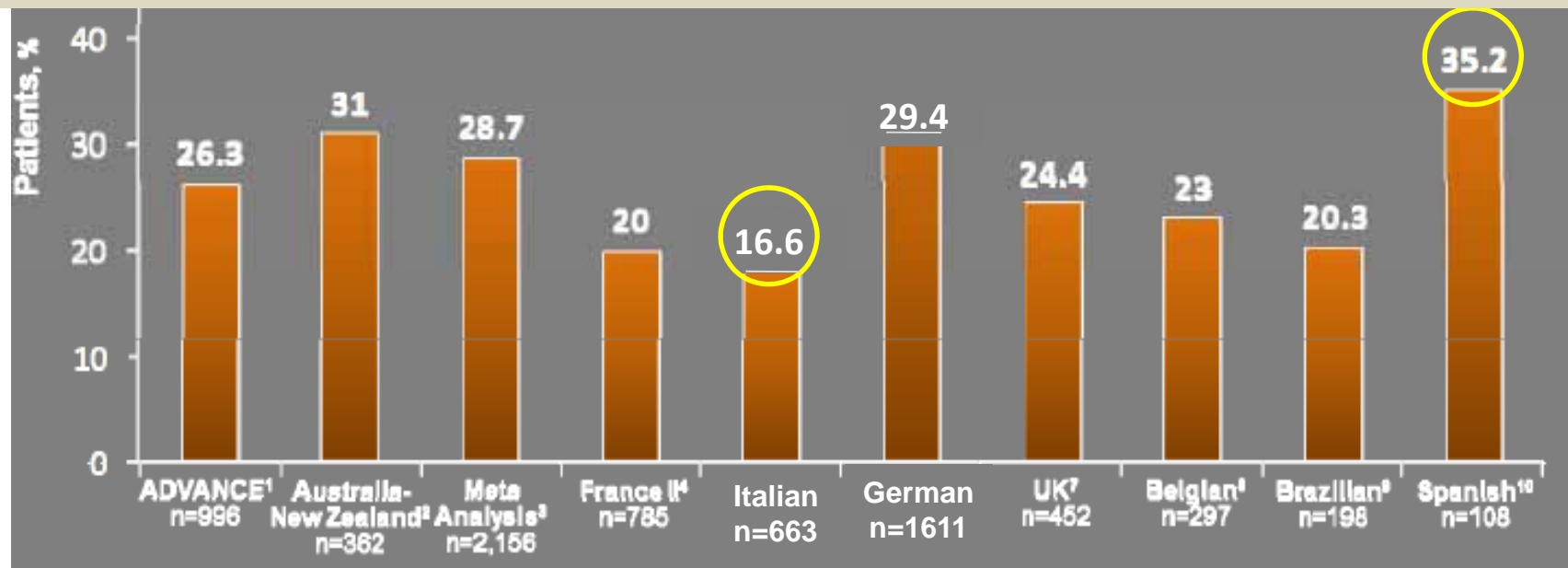
# CoreValve

## Incidence of new pacemakers across studies

Risk of delayed permanent AV-Block post-implantation due to persistent nitinol stent expansion

Temporary lead removed after several days

*Prophylactic PM to shorten the hospitalization stay?*



**Depth of prosthesis  
is an independent predictor of PM implant**

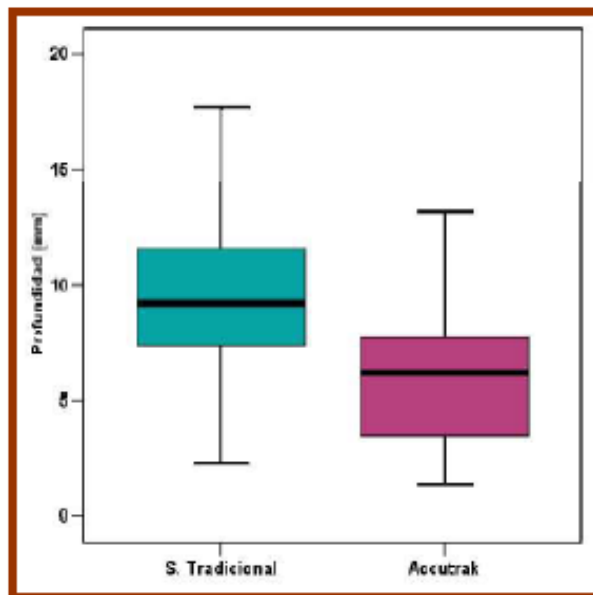
# CoreValve

## Improved positioning

### AccuTrack Study Results

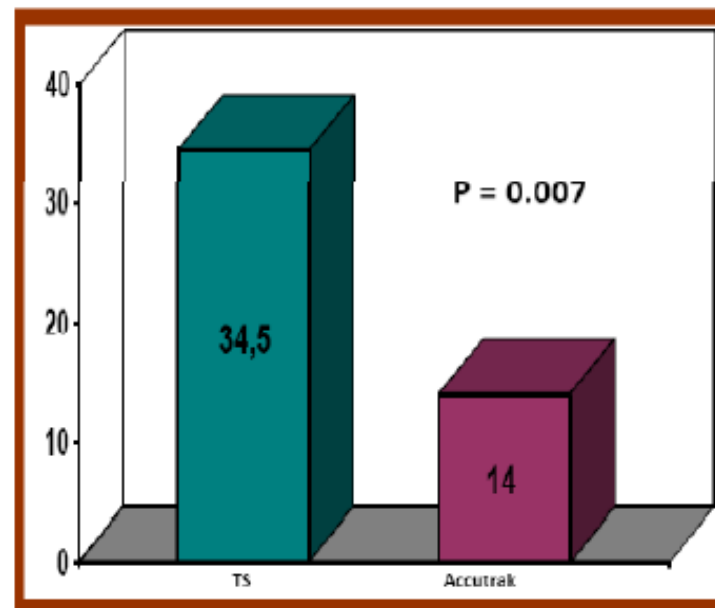
Munoz-Garcia PCR 2011

Depth of implantation



9.6 ± 3.1 mm vs. 6.5 ± 3.1; p < 0.001

Pacemaker (%)





# TAVI: Factors recognized to influence conduction disturbances

## Patient History

- Age
- Depressed LVEF
- Previous AR and MR
- Previous RBBB**
- Pulmonary hypertension

## Patient Anatomy

- Septal wall thickness
- Narrow LVOT
- Calcification of landing zone

## Procedural factors

- Onset of AV block per TAVI**
- Balloon & prosthesis : Annulus ratio
- CoreValve
- Depth of implantation**

# TAVI and Pacemakers

- Conduction disturbances are a frequent complication of TAVI, consequence of the proximity of the aortic valve to the conduction system
- Depth of implantation is a major predictive factor
- Some differences in PM requirement do exist between the two prosthesis. The rate of prophylactic PM Implantation with the CoreValve is unclear
- Advancements in technologies (stability, positioning, valve sizes, repositioning) are expected to decrease the incidence of this complication

# TAVI and Stroke

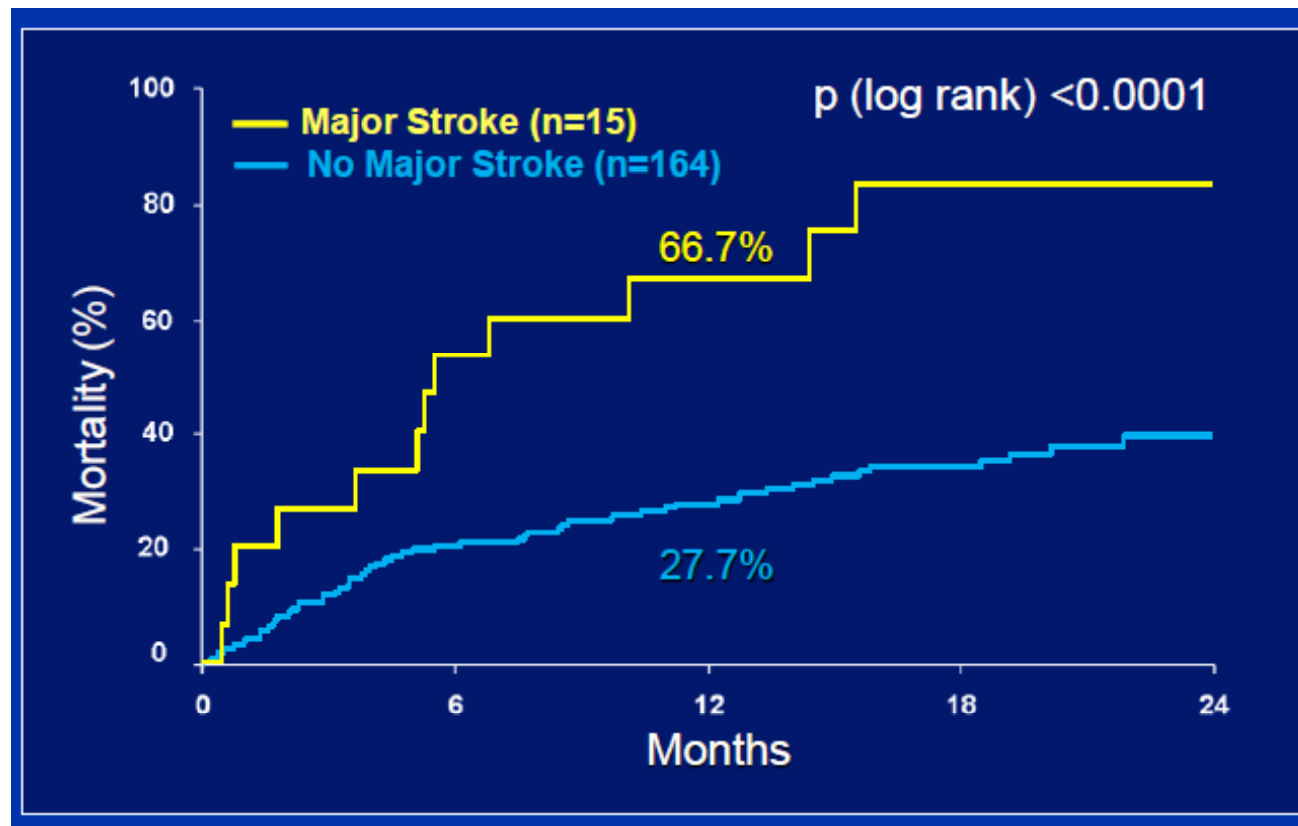
- Stroke is a rare but major complication of TAVI as it is of Surgical AVR and Balloon Valvuloplasty. It seriously affects survival and quality of life
- Stroke etiology is obviously multifactorial as shown by the occurrence of CV events either during, shortly after or even far from the TAVI procedure



Delay from TAVI to Stroke: PARTNER Trial

# TAVI and Stroke

## Impact of major stroke on mortality

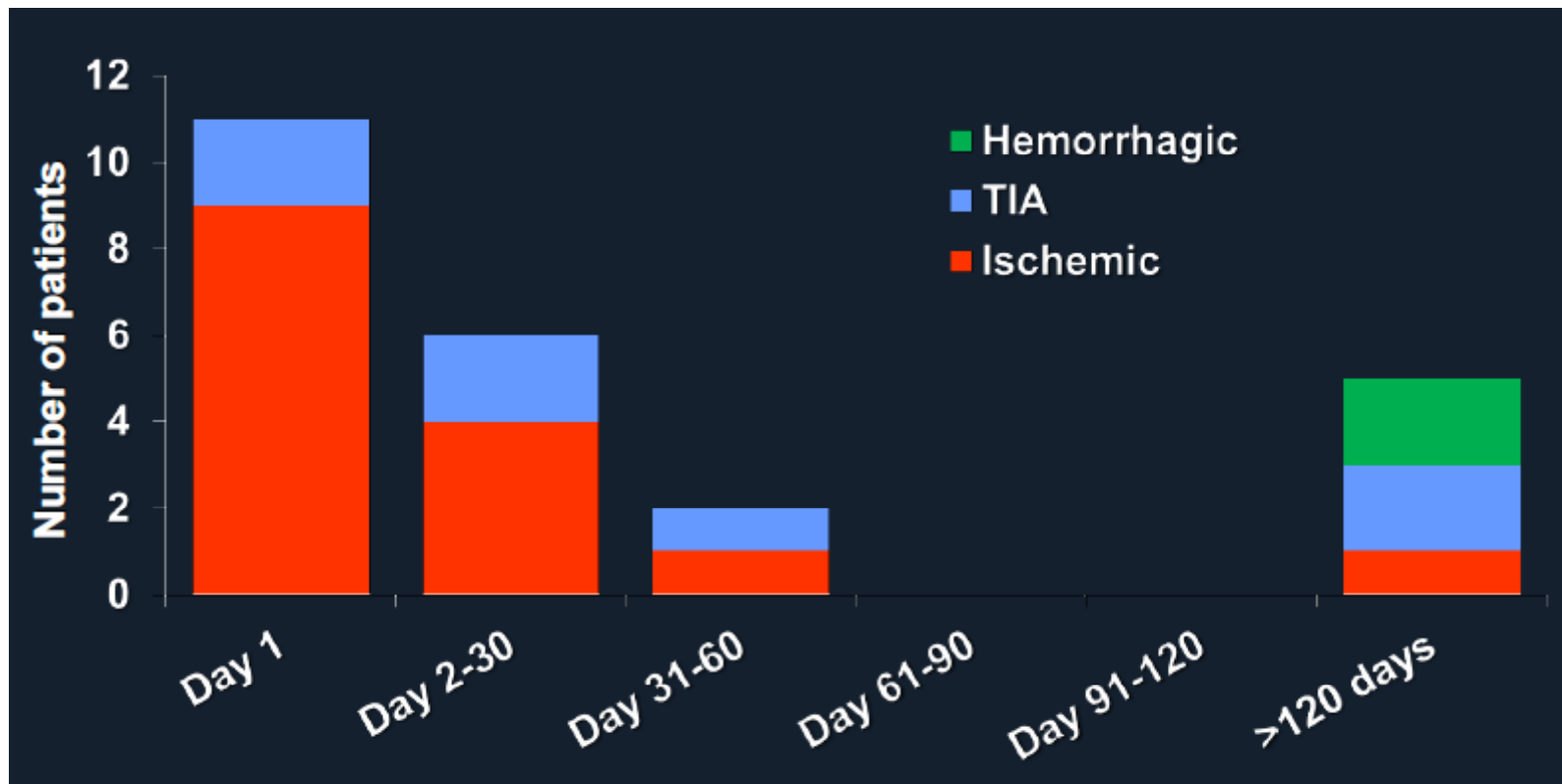


PARTNER B: Leon et al, NEJM 2010

# TAVI and Stroke

## *Timing of Neurologic Events*

Tay et Al, JACC Cardiovasc Interv 2012

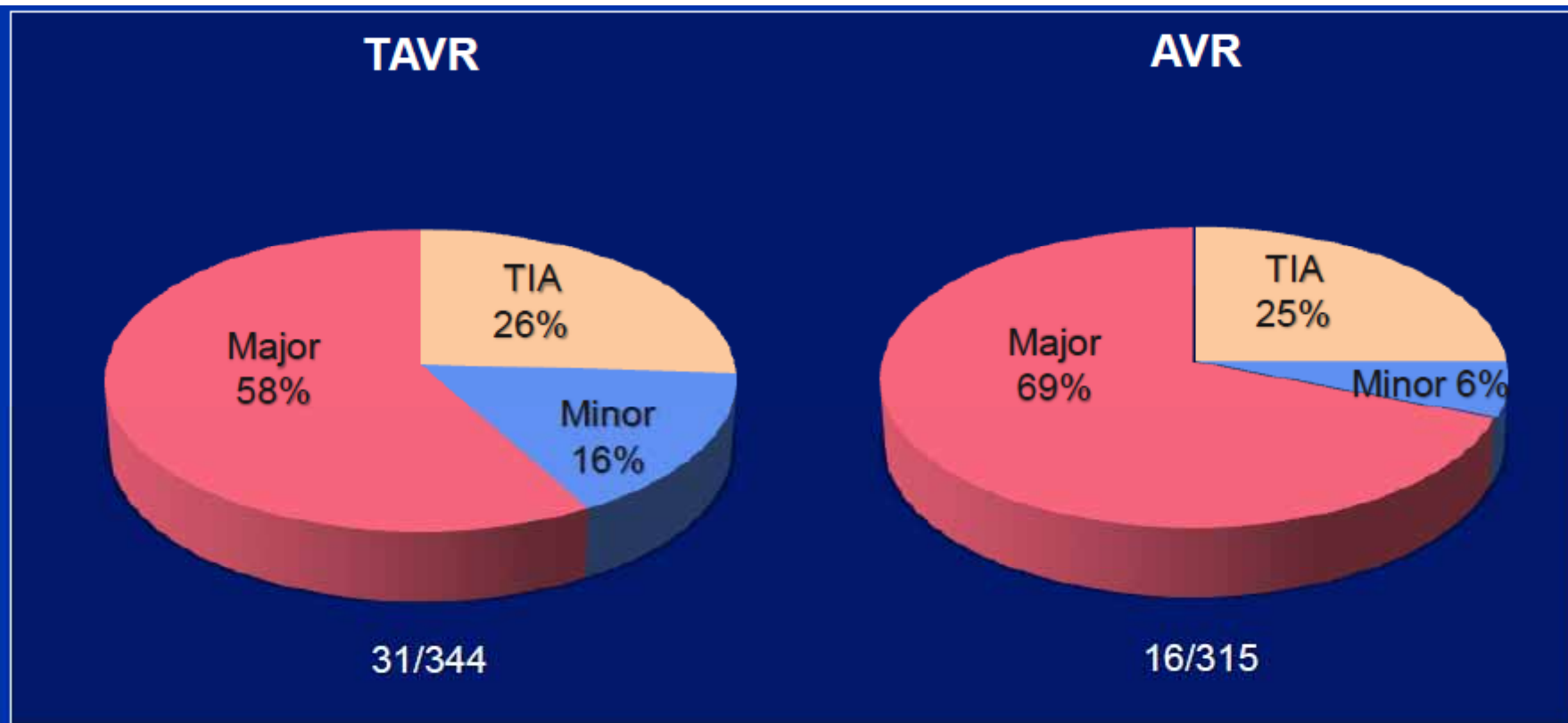


- 87% of strokes within the first 2 months post-TAVI
- 50% of strokes/TIA within 24h post-procedure
- Prior history of CVD is an independent predictor

# TAVI and Stroke

## *Type of Neurologic Events*

### *PARTNER A*

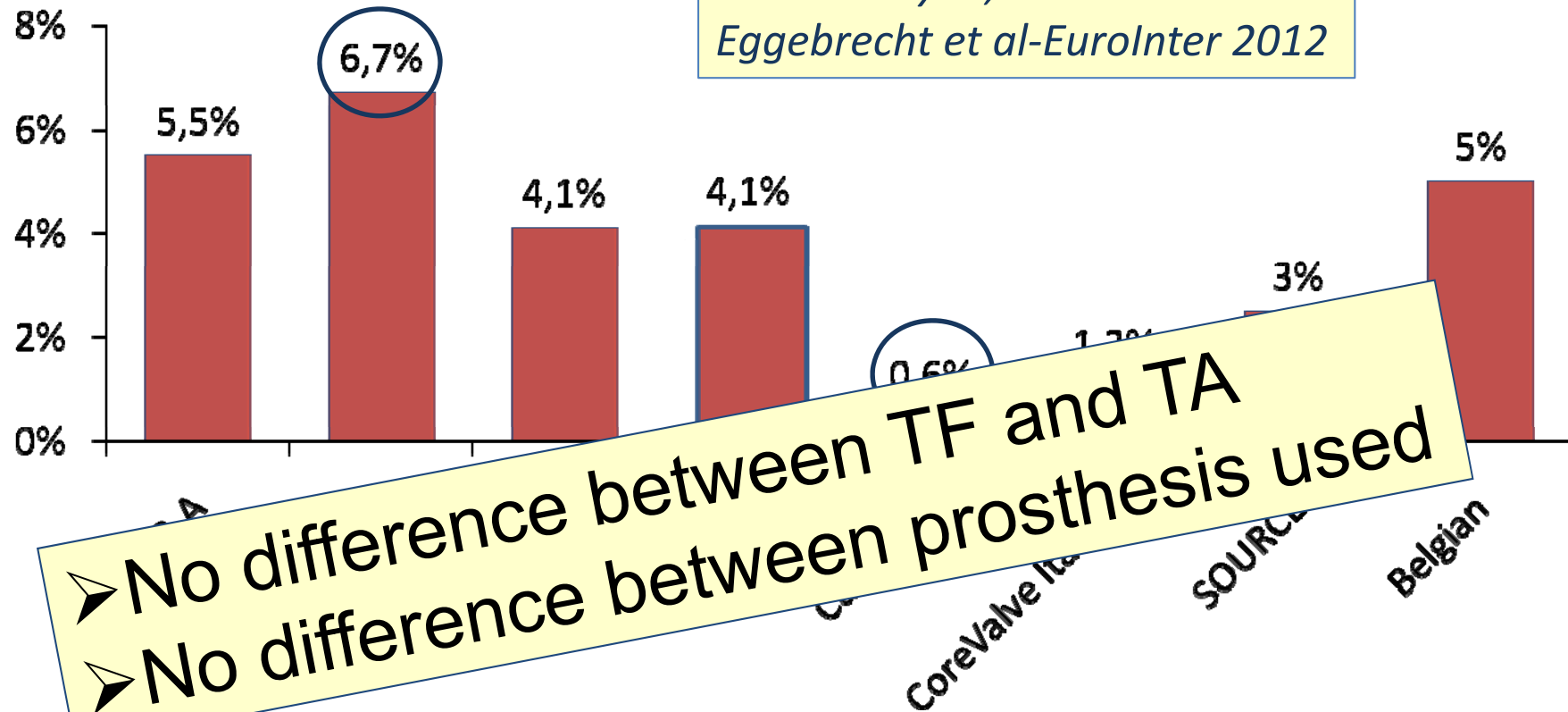


47 patients, 49 events

- Ischemic- 72%, hemorrhagic- 0%, (ischemic → hemorrhagic- 4%), unknown- 24%

# TAVI and Strokes (30-Day)\*

Meta-analysis, 10 037 Pts  
Eggebrecht et al-EuroInt 2012



- No difference between TF and TA
- No difference between prosthesis used

**AVC/AIT at 30-Day =  $3,3 \pm 1,8\%$**

\* Non homogeneous definitions  
Disparity of diagnostic procedures

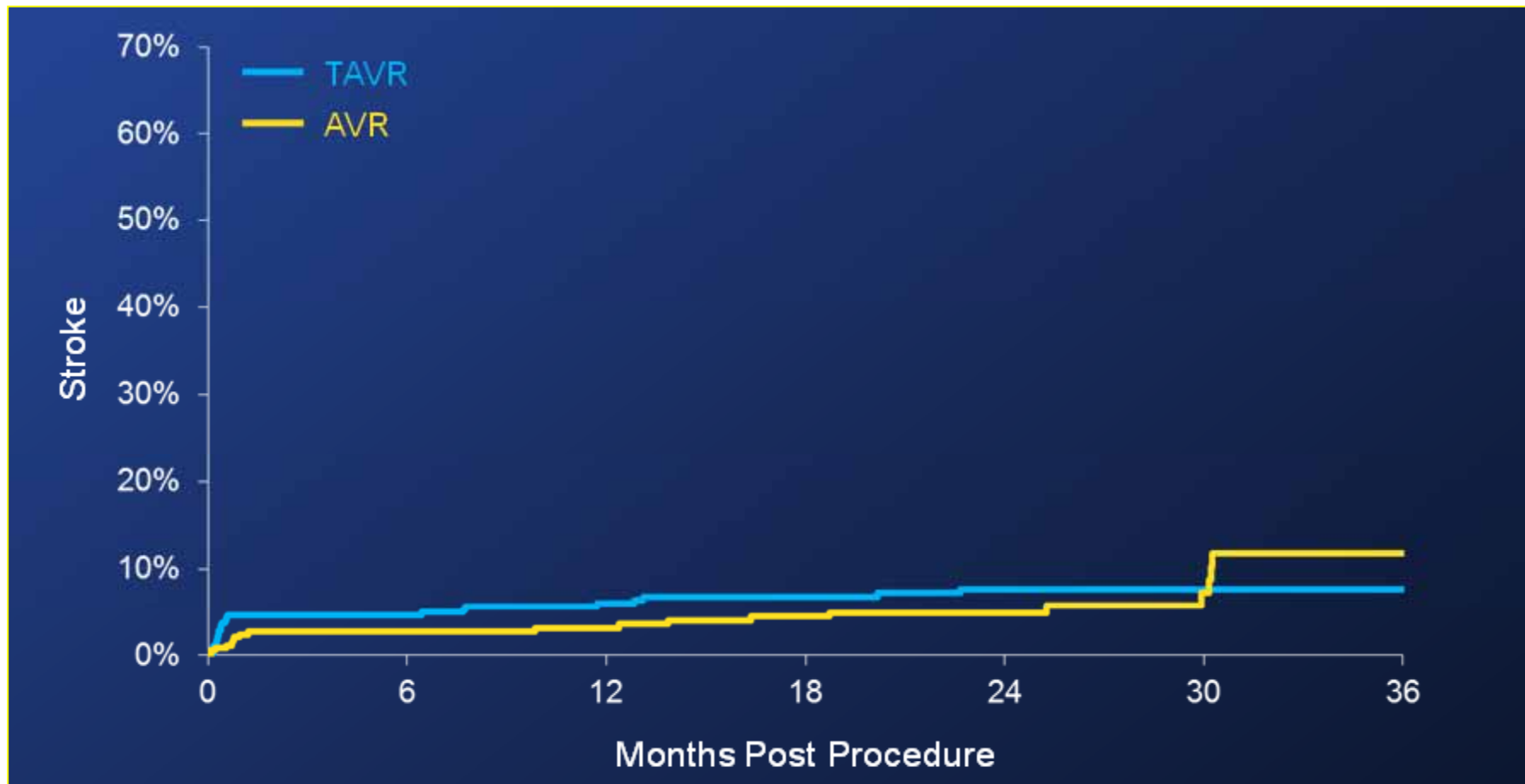
# More CVE after TAVI and surgical AVR at 30 Days and 1 Year in PARTNER A

<i>Outcome</i>	30 Days			1 Year		
	<i>TAVR</i> (N = 348)	<i>AVR</i> (N = 351)	<i>p-value</i>	<i>TAVR</i> (N = 348)	<i>AVR</i> (N = 351)	<i>p-value</i>
All Stroke or TIA – no. (%)	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
TIA – no. (%)	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
All Stroke – no. (%)	16 (4.6)	8 (2.4)	0.12	20 (6.0)	10 (3.2)	0.08
Major Stroke – no. (%)	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Minor Stroke – no. (%)	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Death/maj stroke – no. (%)	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68

**PARTNER: Results at 30 Days and 1year– Smith et al, NEJM 2011**

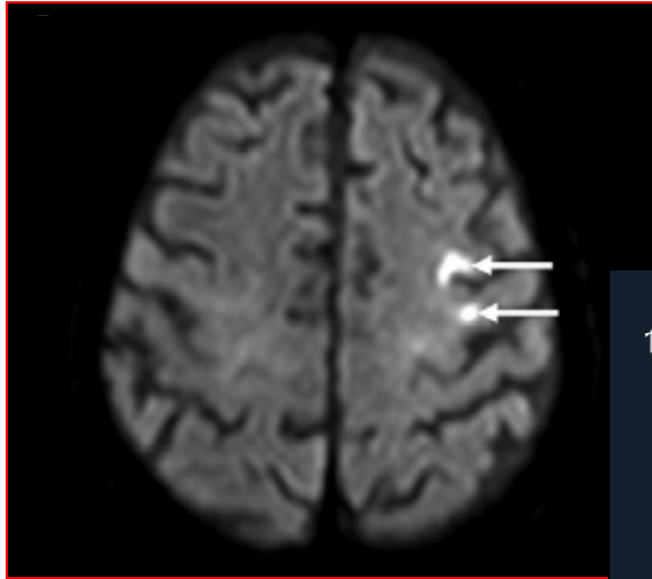


# Similar rate of CVE after TAVI and surgical AVR at 2 Years in PARTNER A

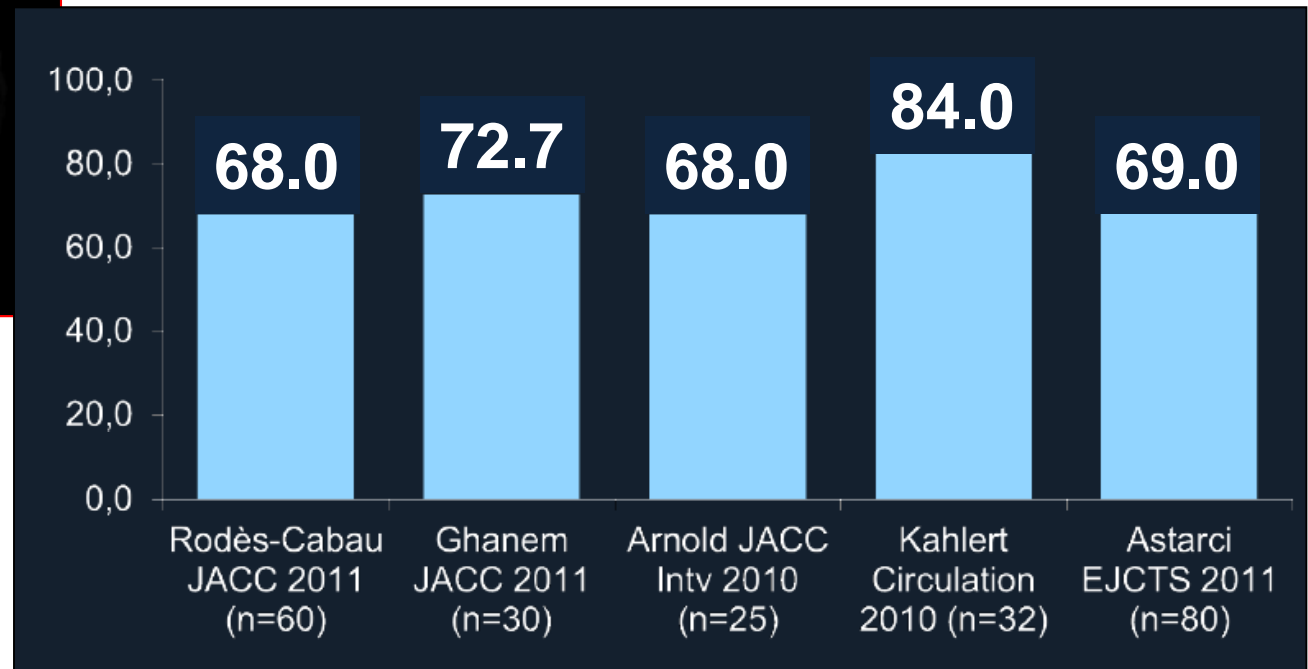


Kodali et al, NEJM 2012

# TAVI and Strokes



## Silent CVE post-TAVI



Up to 80% new cerebral ischemic lesions on MRI

# TAVI and Strokes

## Potential sources of CVE during the procedure

### Cerebral Embolism

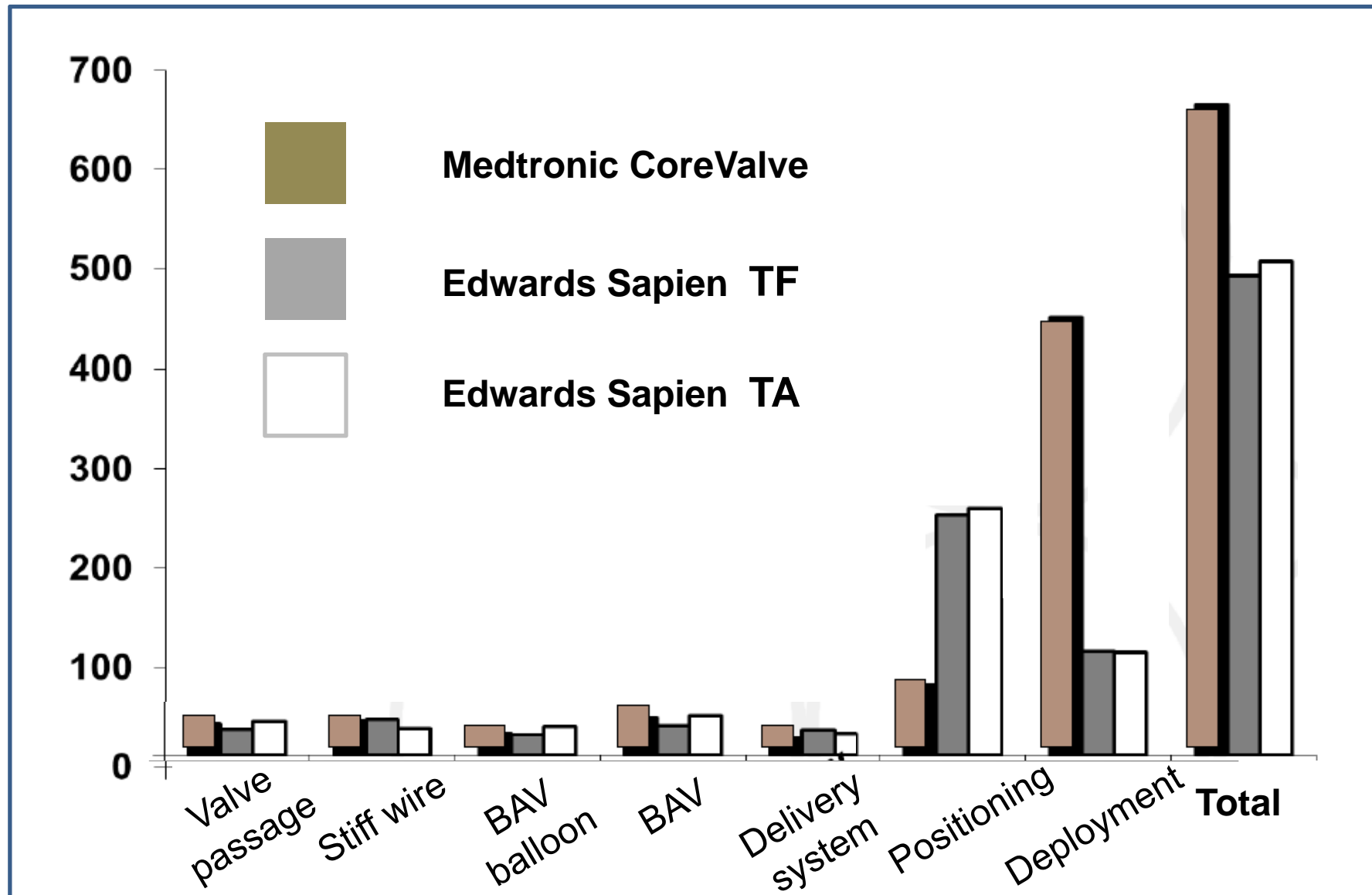
- Navigation of hardware through the aortic arch
- Crossing the aortic valve
- Balloon valvuloplasty
- Valve positioning
- Valve deployment

### Cerebral Ischemia

- Hemodynamic instability
- Prolonged hypotension (BAV, RVP)
- Arrhythmias

# Transcranial Doppler detected CVE

Kahlert- AHA 2010



# TAVI and peri-procedural Strokes

## A role for protection devices in the future?



<b>Feature</b>
<b>Access</b>
<b>Position</b>
<b>Coverage area</b>
<b>Mechanism</b>
<b>Size</b>

**Embrella Device**

CE Mark

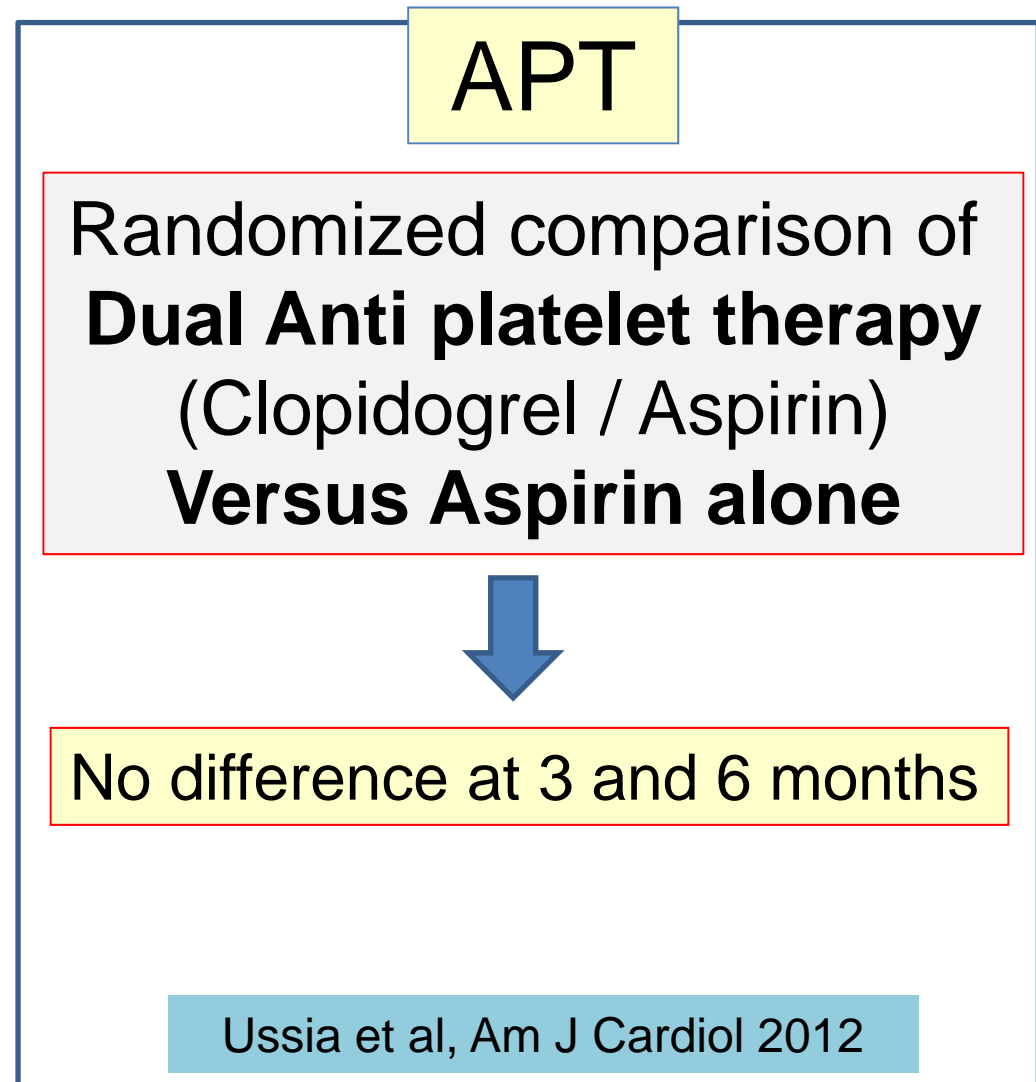
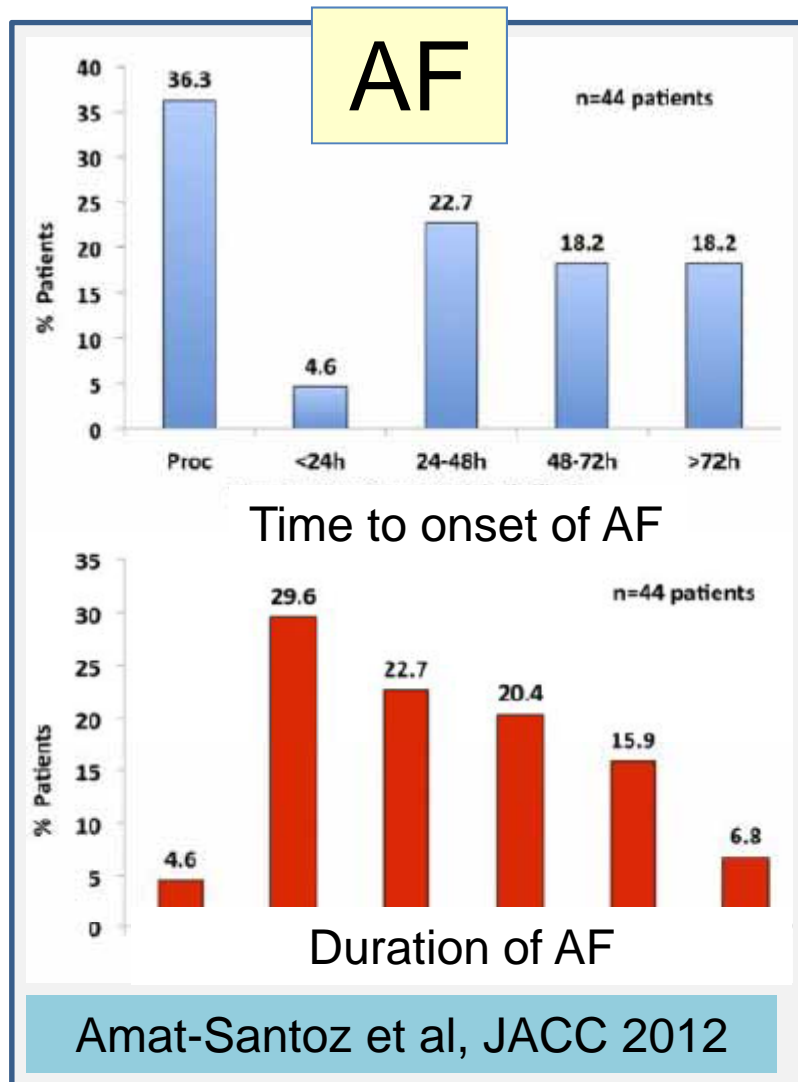
Randomized PRO-TAVI c

Study in Europe

	<b>Claret Medical</b>
	Radial
	Brachiocephalic Left common carotid
c &	Brachiocephalic & LCC
	Deflection
	6 Fr

# TAVI and Strokes

Potential role of AF and APT management in delayed CVE ?



# TAVI and Strokes

## Conclusions

- TAVI is associated with a high rate of clinically silent cerebral embolisms well detected by MRI
- Clinically apparent CVE are reported in 3% of cases at 30 days and > 50% of events occur within 24h of TAVI
- Causes of CVE are multifactorial, leaded by debris and/or thrombi embolization *during and shortly after the procedure* whereas etiologies remain uncertain at follow-up.
- Studies are on the way for evaluating *protection devices* and optimal *antithrombotic treatment* following TAVI

To date, the rates of permanent AV-Block and strokes are among the limiting factors to further extend TAVI to lower risk patients

# TAVI and Strokes

## Types of Cerebrovascular Events

