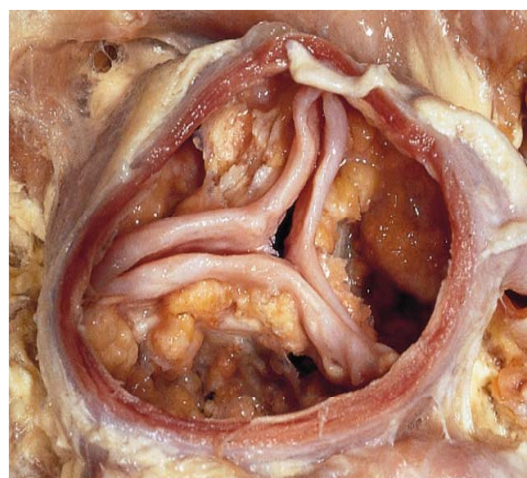


Complications after TAVI: VARC Definitions, Frequency and Management Considerations

Patrick W. Serruys, Nicolo Piazza,
Nicolas M. Van Mieghem, Yoshinobu Onuma, Martin B. Leon



TCT-AP 2011

April 27th, 2011 10:07 – 10:19

Main Arena Level B

*With the collaboration of the Working Group on Valvular Heart Disease
of the European Society of Cardiology*

Academic Research Organizations



Cardiology Societies



Surgery Societies



Myocardial infarction

Stroke

Bleeding

Mortality

Acute Kidney Injury

**Minimum Data Collection and
Endpoint Requirements after TAVI**

**Therapy specific
endpoints**

Vascular complications

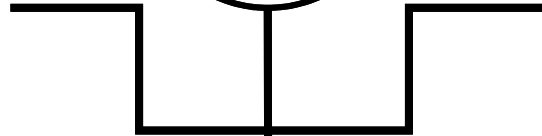
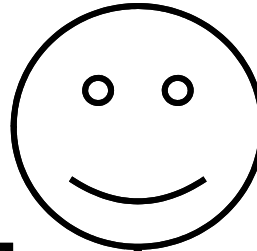
Composite endpoints

**Prosthetic valve associated
complications**

**Prosthetic valve
performance**

Neurological

Stroke



Cardiac

Conduction abnormalities

Aortic regurgitation



Stroke - VARC

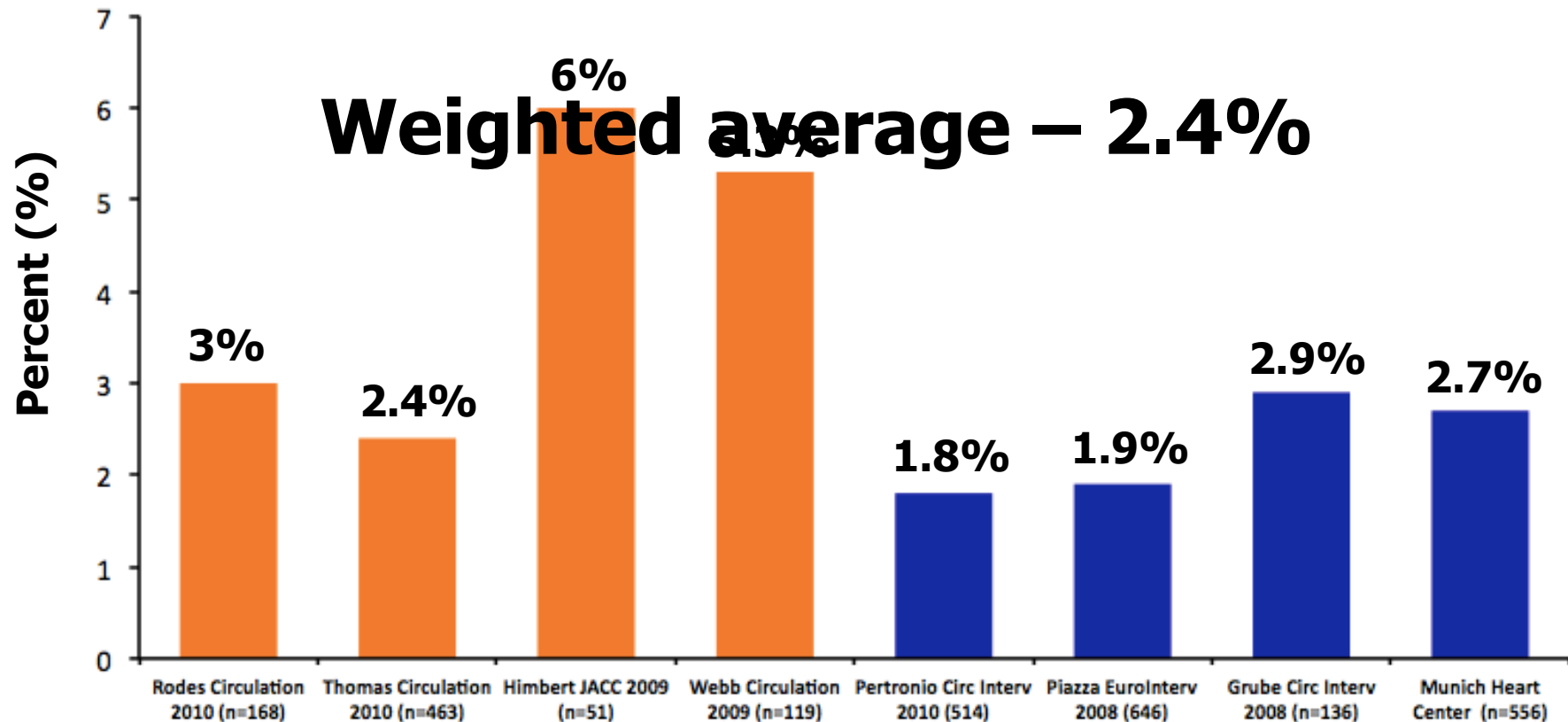
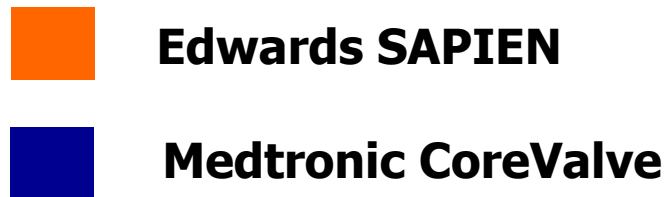
1. Rapid onset of a focal or global neurological deficit with signs or symptoms consistent with stroke
2. Typically
 - Duration of a focal or global neurological deficit **≥ 24 hours**;
 - OR **< 24 hours, if therapeutic intervention(s)** were performed (e.g. thrombolytic therapy or intracranial angioplasty);
 - OR available **neuroimaging**
OR the neurologic deficit results in **death**
3. Exclusion of other cause for the clinical presentation (e.g. infection, hypoglycemia, pharmacological influences...)
4. Confirmation by at least one of the following:
 - Neurology or neurosurgical specialist
 - Neuroimaging procedure (MR or CT scan or cerebral angiography)
 - Lumbar puncture (i.e. spinal fluid analysis diagnostic of intracranial hemorrhage)



More Stroke Definitions

- **Stroke:**
 - ✓ **Minor** – modified Rankin score < 2 at discharge
 - ✓ **Major** – modified Rankin score ≥ 2 at discharge
- **Transient ischemic attack:**
 - ✓ New focal neurologic deficit with rapid symptom **resolution** (usually 1-2 hours), always within 24 hours
 - ✓ Neuroimaging **without** tissue injury

Stroke at 30 days



#1 Stroke

Stroke at 30 days **Partner US Trial**

Cohort A

TAVI

3.8%

Surgery

2.1%

Cohort B

TAVI

6.7%

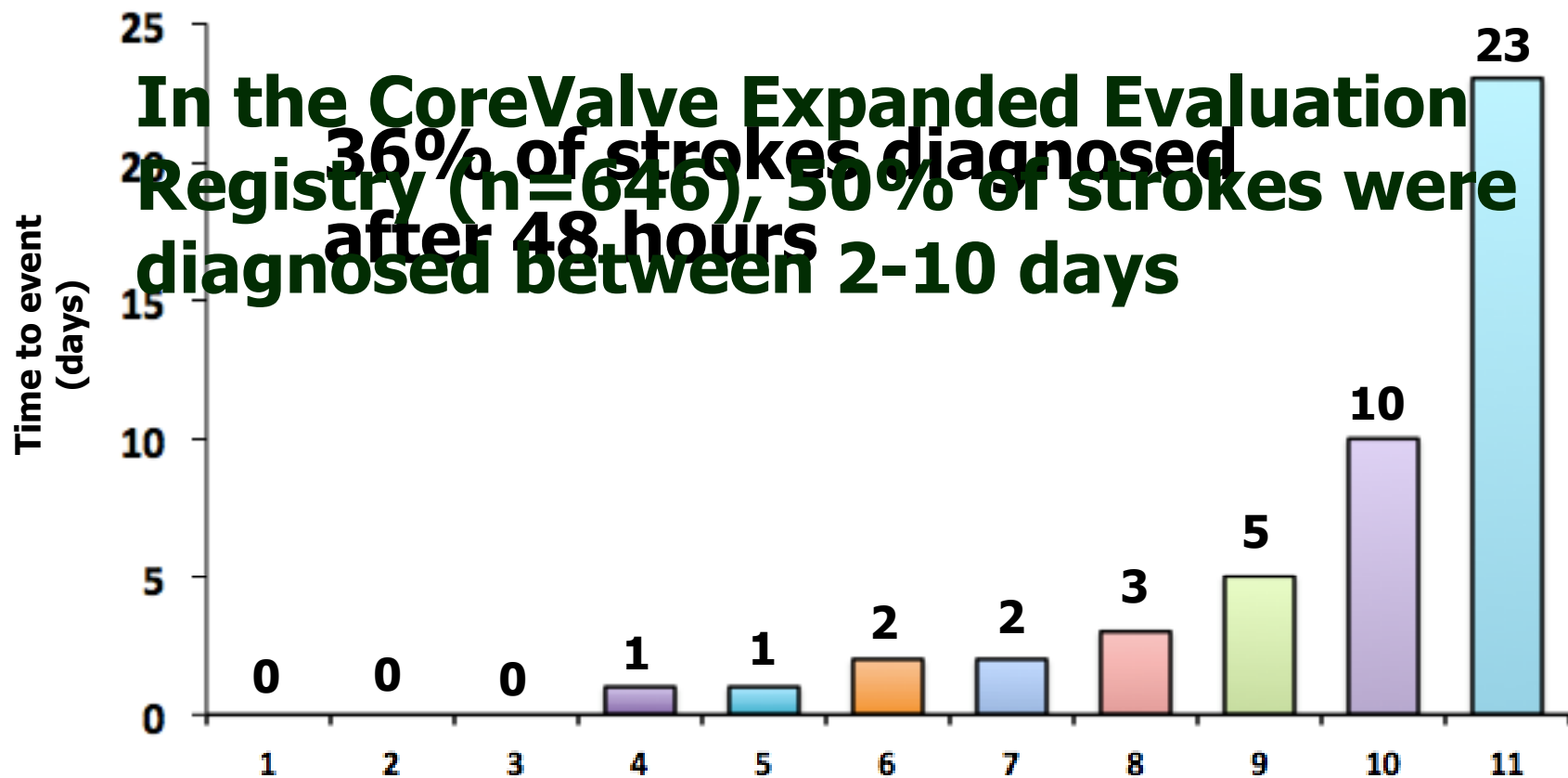
Medical Rx

1.7%

#1 Stroke

Time to stroke event within 30 days

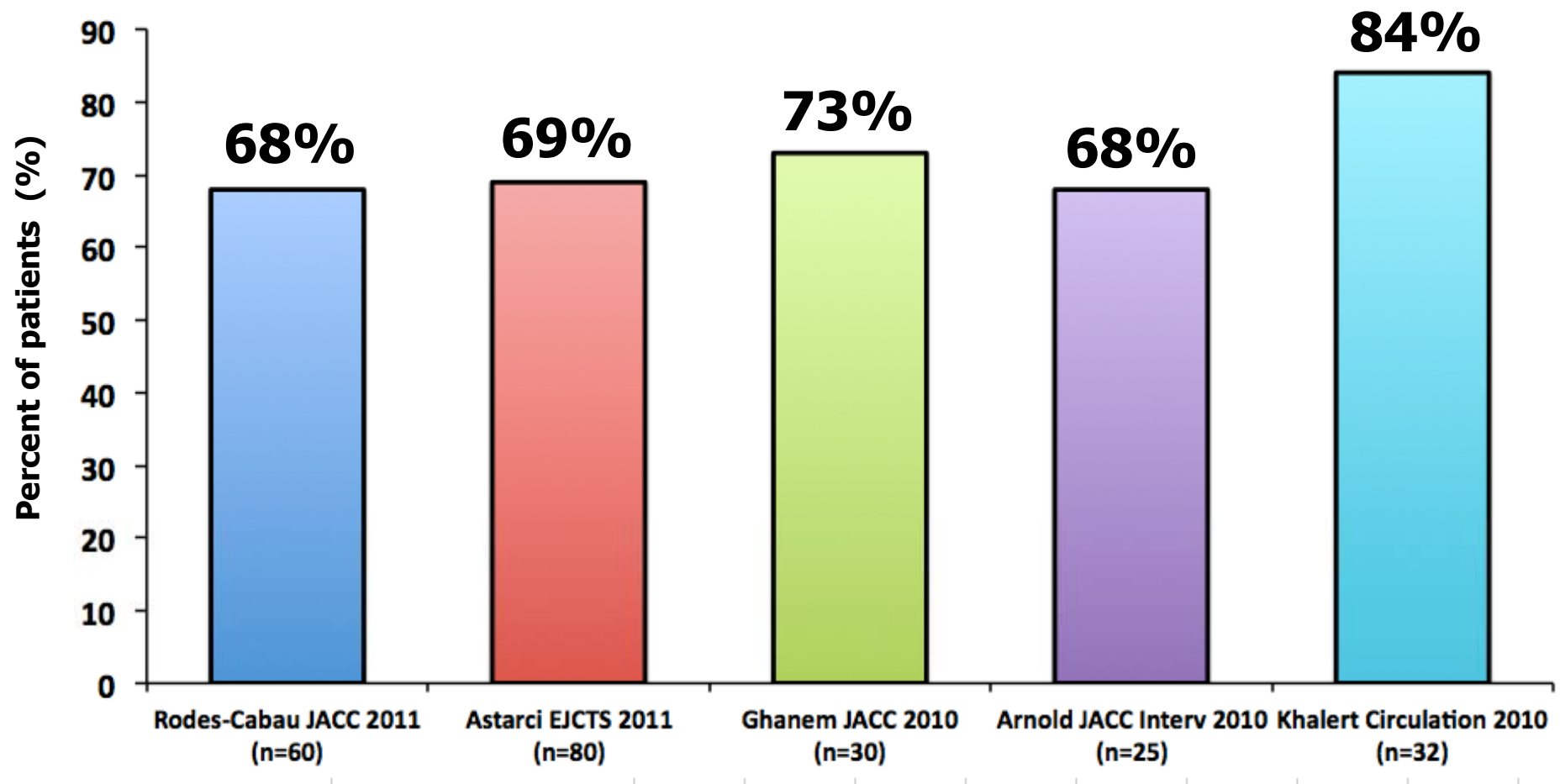
Partner US Cohort B



Major or minor stroke event (n=11) al. EuroIntervention 2008

#1 Stroke

Diffusion weighted MRI Silent Cerebral Insults after TAVI



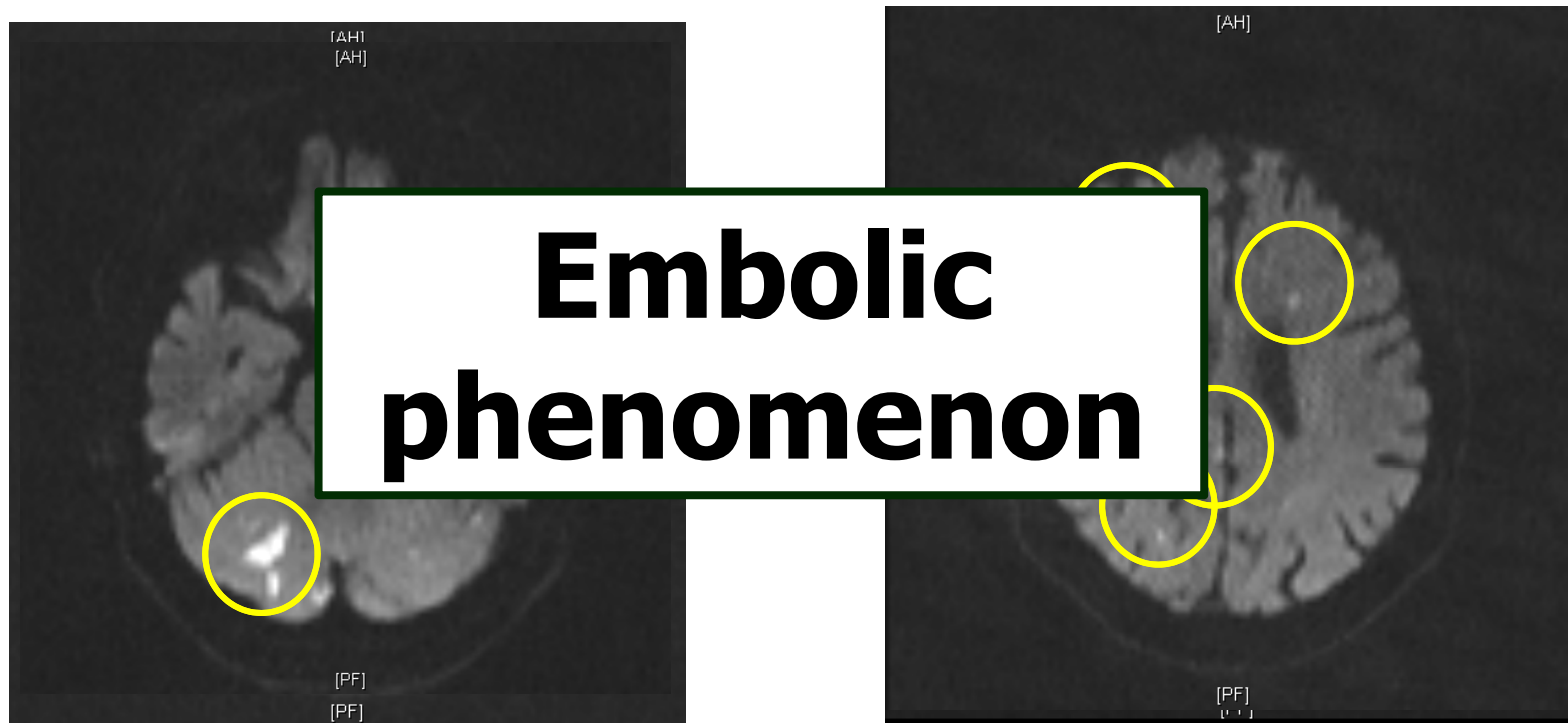
#1 Stroke

Diffusion-Weighted MRI Study

Philipp Kahlert, MD
West German Heart Center Essen

~~Post-TAVI~~

Example of an 82-year-old patient two days after successful TAVI



Courtesy of E. Grube, MD

Diffusion weighted MRI Silent Cerebral Insults after TAVI

No difference in the number of silent cerebral insults between:



Transfemoral vs. Transapical TAVI



Edwards SAPIEN vs. Medtronic CoreValve

**Rodes-Cabau JACC 2011
Astarci EJCTS 2011**

Khalert Circulation 2010

#1 Stroke

What is the clinical significance of silent cerebral insults after TAVI?

Silent cerebral insults had no influence on neurocognitive performance

Khalert Circulation 2010

Ghanem JACC 2010

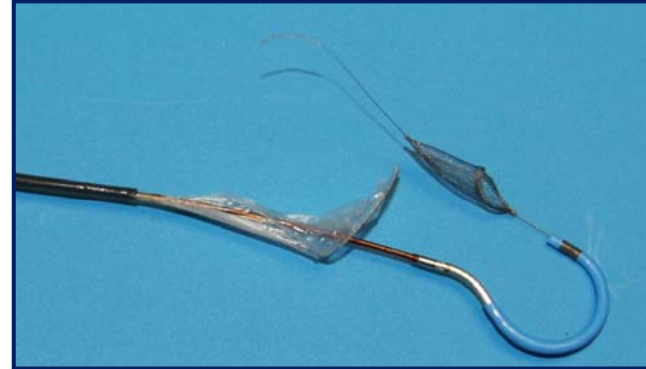
Rodes-Cabau JACC 2011

#1 Stroke

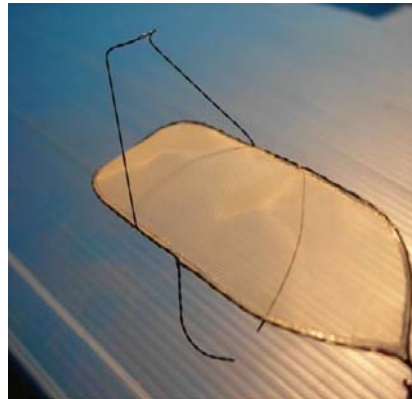
Will Cerebral Embolic Protection Devices be the solution?



**Embrella Cardiovascular
(deflector)**

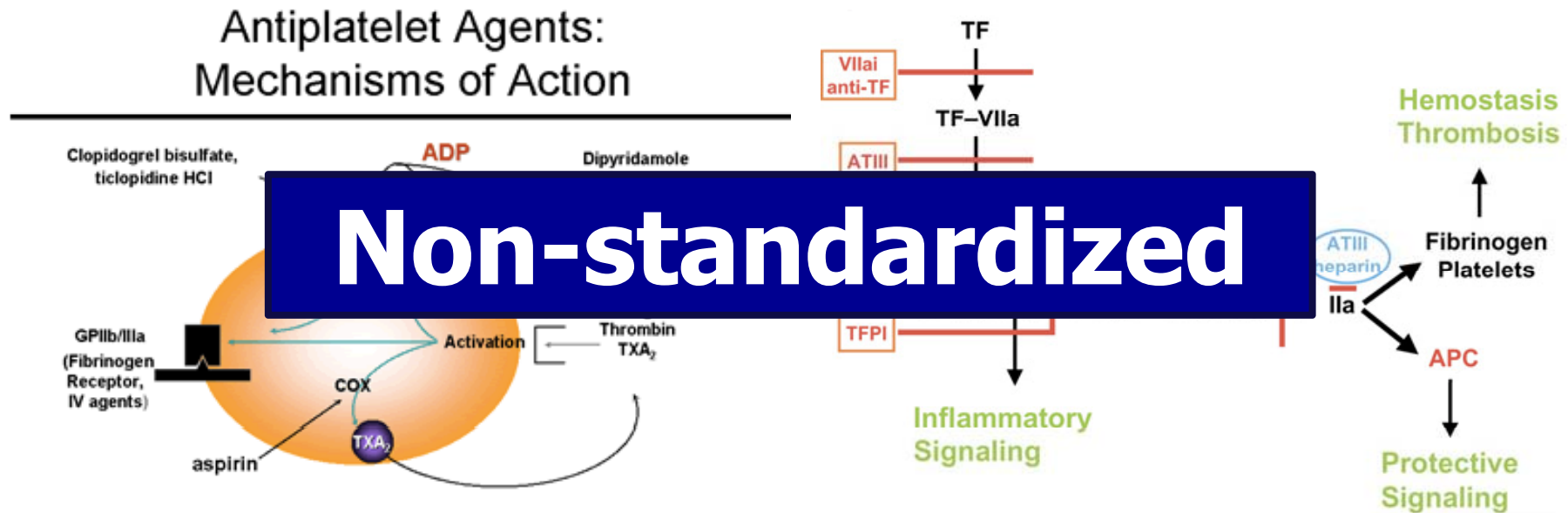


**Claret Medical
(capture)**



**SMT
(deflector
)**

Antiplatelet-Anticoagulant Rx Post TAVI



ASA and Plavix for 3 months

Coumadin and ASA (or Plavix) for 3 months

TAVI & Conduction Abnormalities

Piazza et al. JACC Interv 2008
(n=40)

Baan et al. Am Heart J 2010
(n=34)

Calvi et al. PACE 2009
(n=30)

Latsios et al. Cath Cardiovasc Interv 2010
(n=81)

Jilaihawi et al. Am Heart J 2009
(n=34)

Bleiziffer et al. JACC Interv 2010
(n=123)

Erkopic et al. Europace 2010
(n=50)

Piazza et al. EuroIntervention 2010
(n=91)

Haworth et al. CCI 2010
(n=50)

Roter et al. Am J Cardiol 2010
(n=67)

**Ferreira et al. Pacing Clin Electrophysiol
2010**
(n=32)

Fraccaro et al. Am J Cardiol 2011
(n=70)

How frequent is new-onset left bundle branch block (LBBB) after TAVI?

Medtronic CoreValve 30 to 65%

Edwards SAPIEN

Permanent pacing requirements

4 to 21%

Medtronic CoreValve

Permanent pacing requirements

≈ 18 to 47%

CoreValve Siegburg Experience

Indications for permanent pacemaking following TAVI

**Absolute
31%**

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

**Relative
16%**

new onset bundle branch block, even without AV delay
RBBB and long PQ (>240 msec),
alternating PQ times during monitoring.

Predictors PPM

Medtronic CoreValve

Pre-existing RBBB



**Depth of
implantation**



Small LVOT/annulus



Septal wall thickness



Calcification



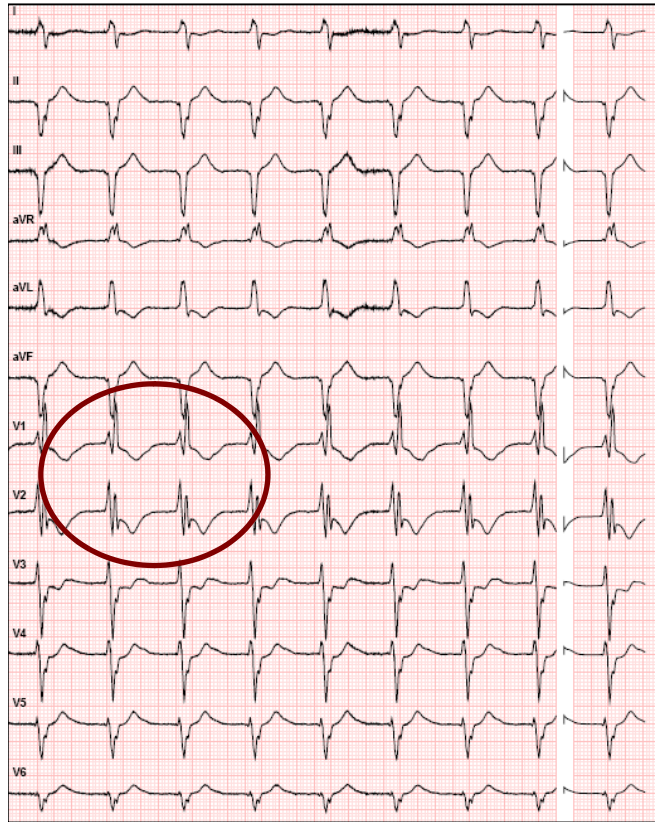
“Prophylactic” Pacemaker

Where do its origins lie?

Left bundle branch block following surgical AVR is associated with complete AV block and sudden cardiac death at 1 year follow-up

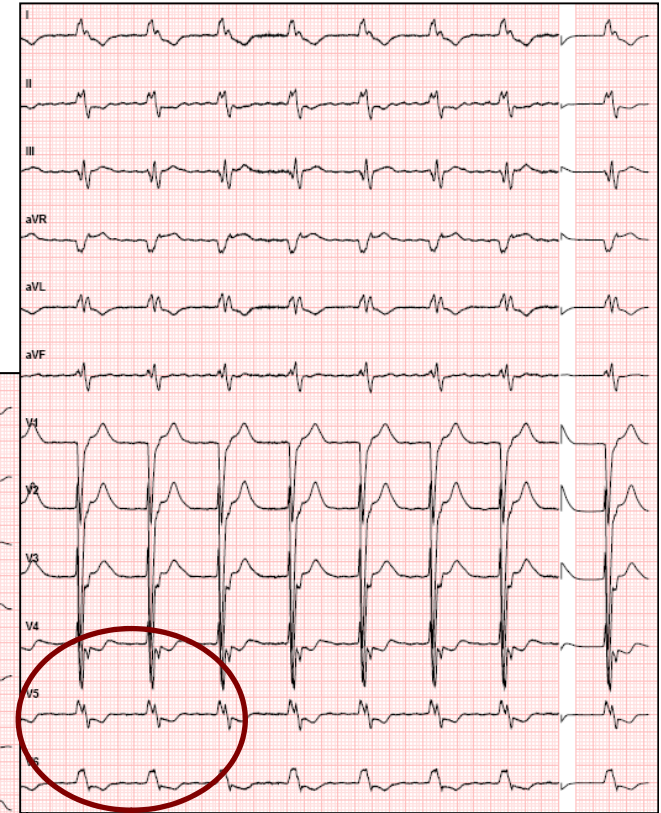
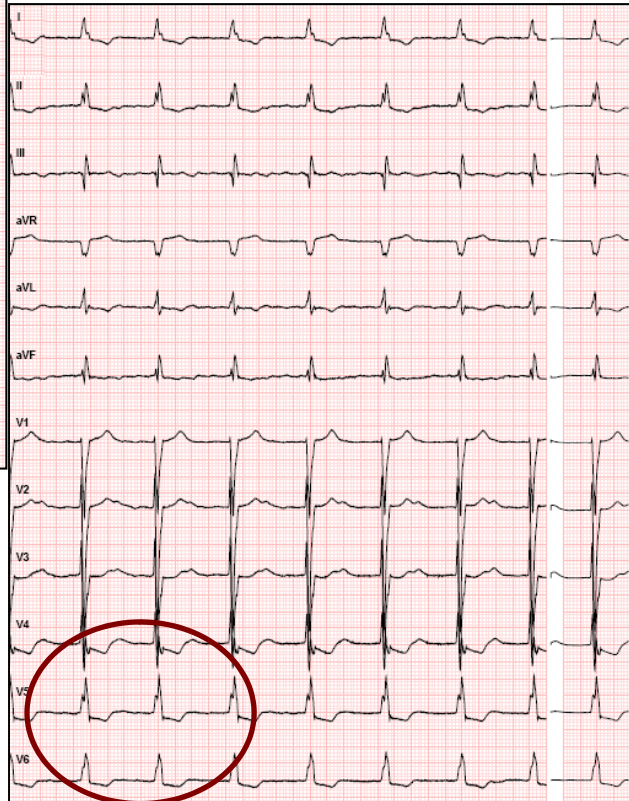
#2 Conduction Abnormalities

CoreValve Implantation Case



Pre-procedure
RBBB

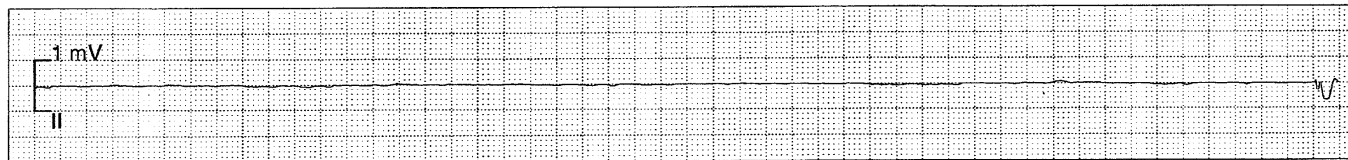
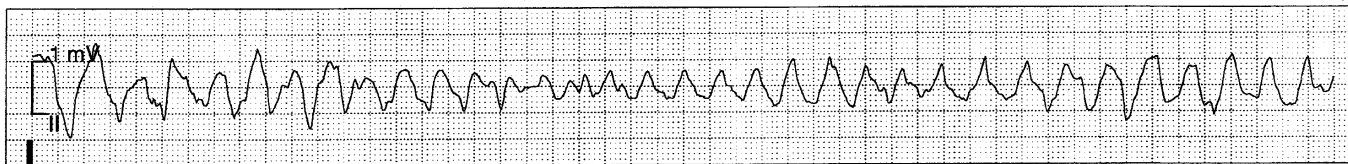
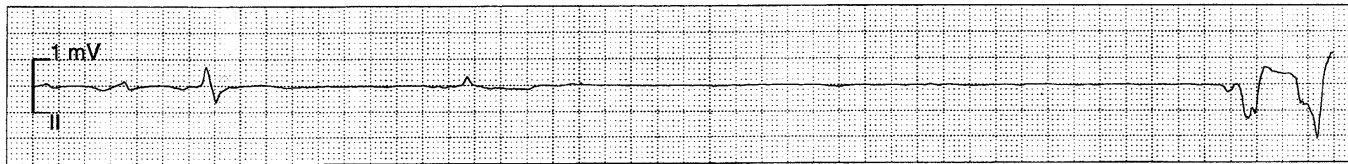
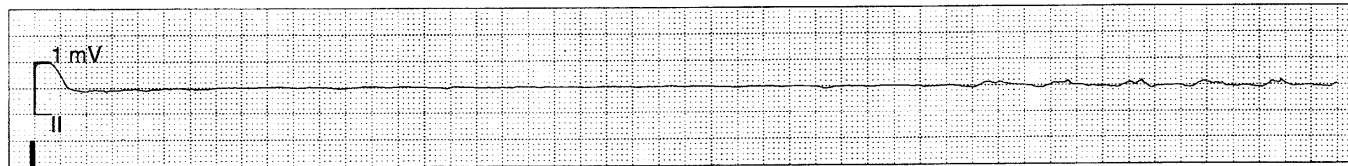
Day 1
post-procedure
LBBB



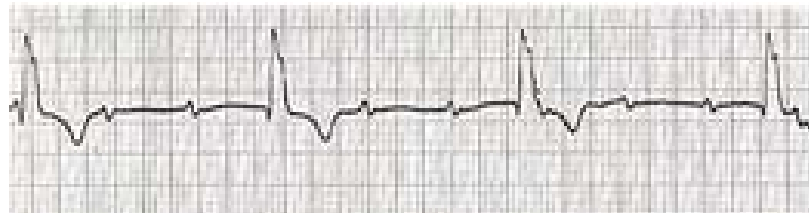
Day 3
Post-procedure
LBBB

#2 Conduction Abnormalities

Day 6 Post-implant



Recommendations

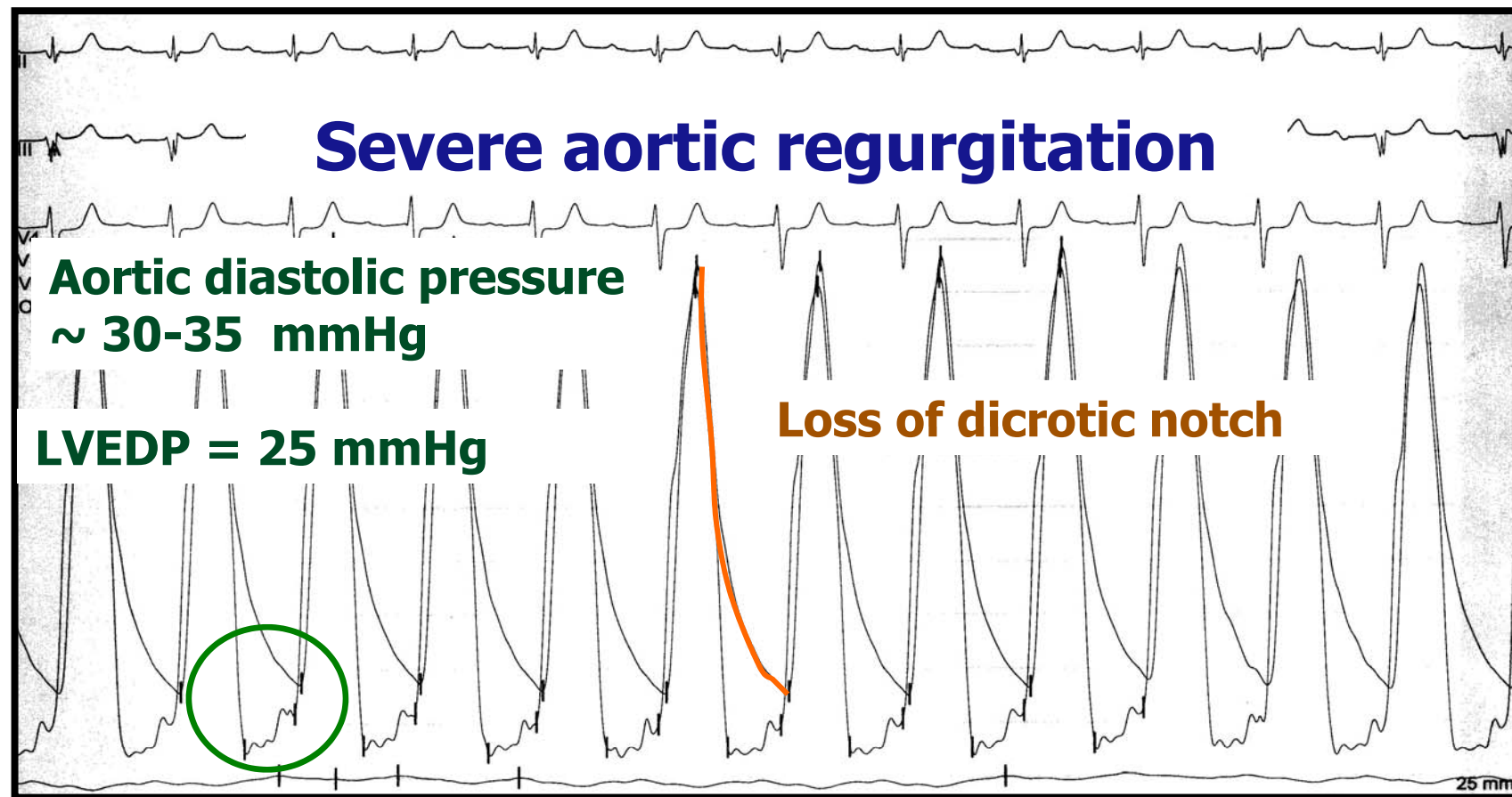


Temporary pacemaker for 48-72 hours

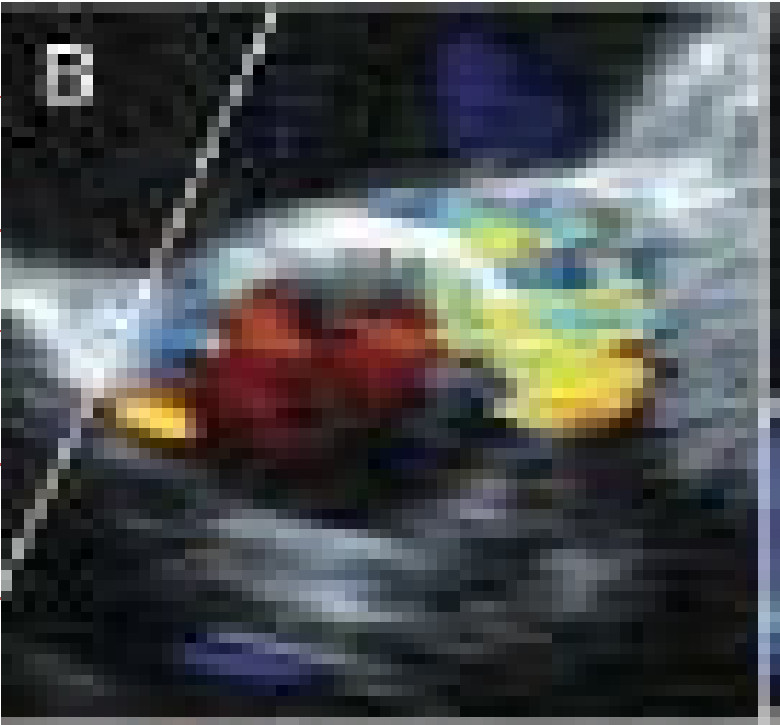
Continuous in-hospital rhythm monitoring

Indications for permanent pacemaker implantation should follow published guidelines

Immediately after CoreValve implantation . . .



Prosthetic Aortic Valve Regurgitation (JASE)

Parameter	Mild	Moderate	Severe
LV size			dilated
Jet width in central jets (% LVO diameter)			Large (≥ 65)
Jet density /CW Doppler			dense
Jet deceleration time (PHT, ms) CW Doppler			Steep (< 200)
LV outflow vs. pulmonary flow: PW Doppler			Greatly increased
Diastolic flow reversal in desc. aorta: PW Doppler			Prominent, holodiastolic
Circumferential extent of paravalvular AR (%)	< 10	10-20	> 20
Regurgitant volume (mL/beat)	< 30	30-59	> 60
Regurgitant fraction (%)	< 30	30-50	> 50

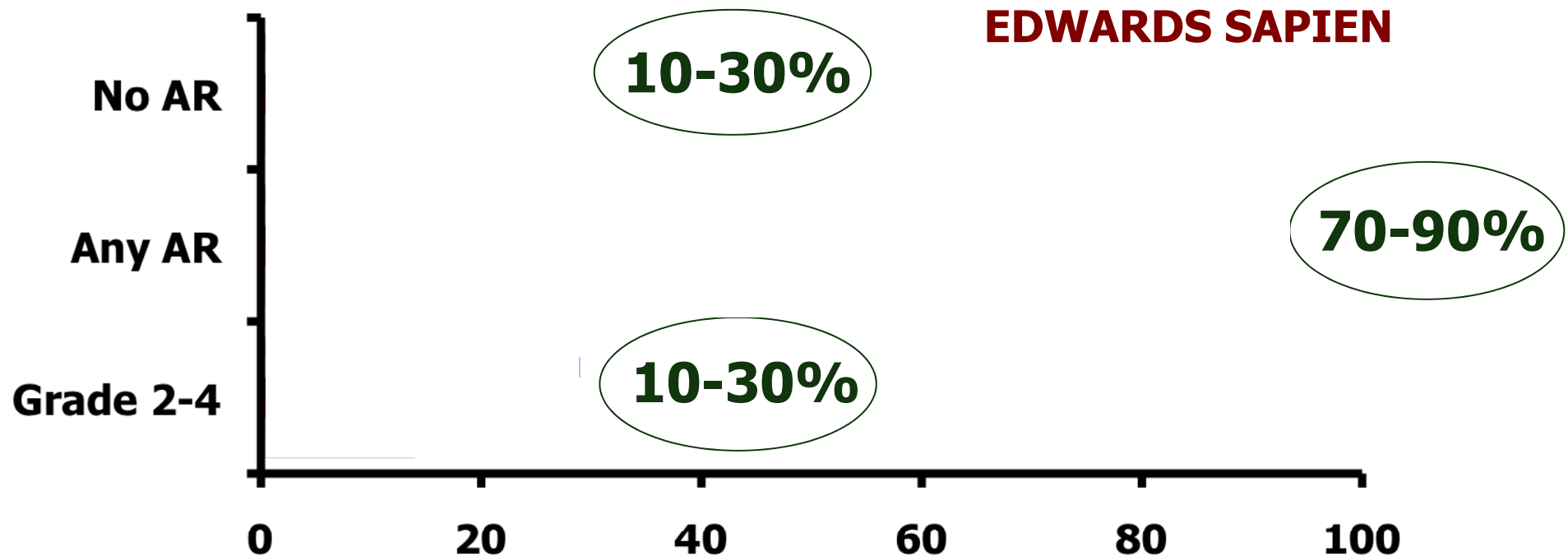
#3 Aortic regurgitation

Frequency of Aortic Regurgitation

(Peer-reviewed)

MEDTRONIC COREVALVE

EDWARDS SAPIEN



Rajan et al. Catheter Cardiovasc Interv 2009

Jilaihawi et al. Eur Heart J 2009

Moss et al. JACC Cardiovasc Imag 2008

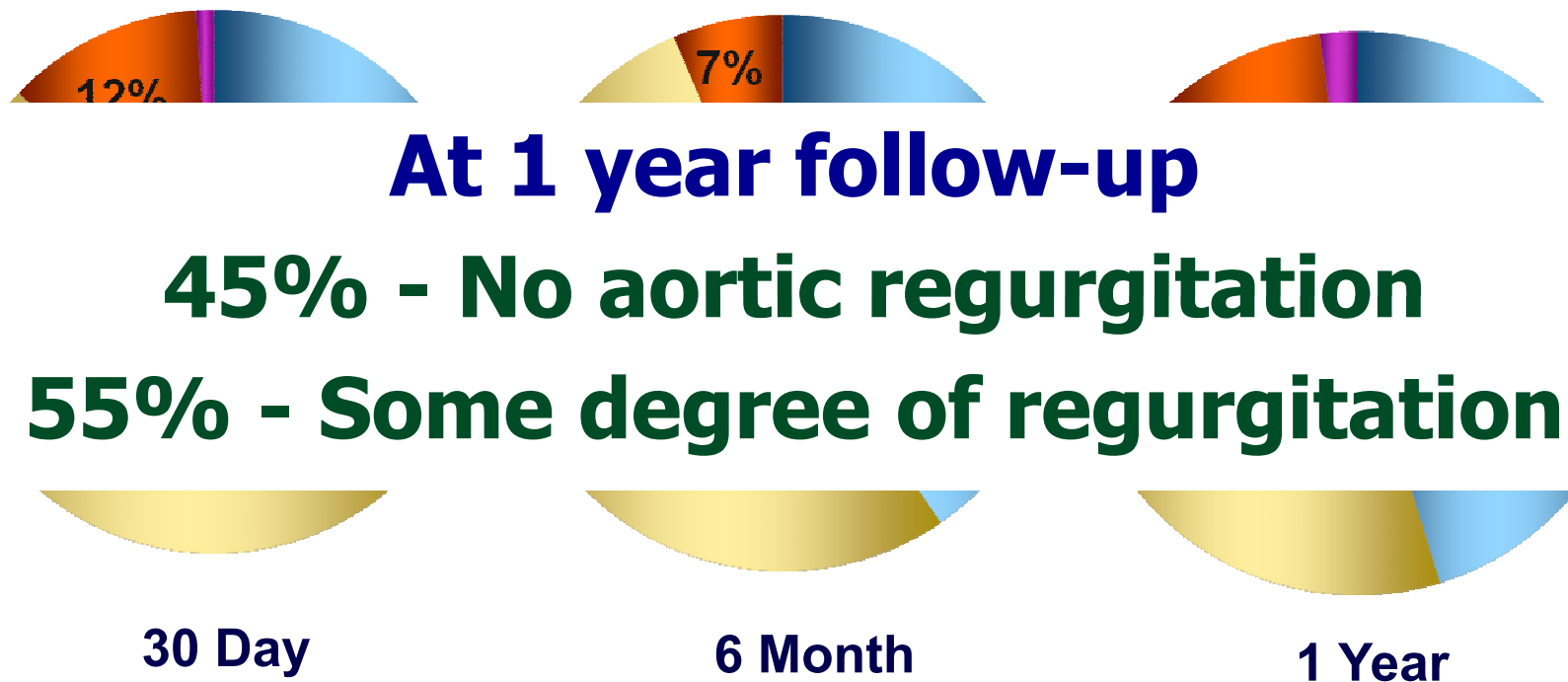
Clavel et al. J Am Coll Cardiol 2009

Himbert et al. J Am Coll Cardiol 2008

Detaint et al. JACC Cardiovasc Interv 2009

Paravalvular Aortic Regurgitation

PARTNER US Cohort B



#3 Aortic regurgitation

Image size: 512 x 512
View size: 572 x 572
WL: 130 WW: 150

33936826 (84 y , 83 y)
Coro — Coro
1
20

Zoom: 112% Angle: 0
Im: 1/160
Uncompressed
Position: HFS

10/27/09 12:55:14 PM
Made In OsiriX

Courtesy of the German Heart Center Munich (R. Lange)

Post-procedure

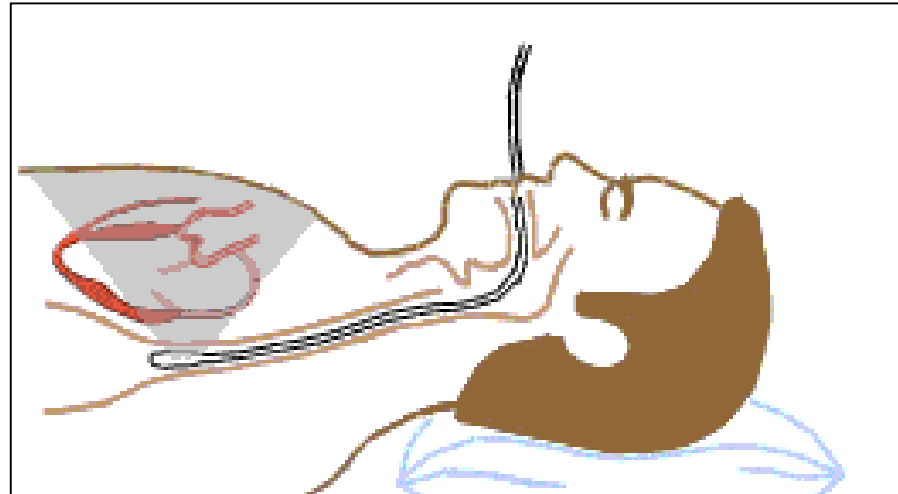
Intermittent hemodynamic instability

**Echocardiography - no relevant findings
during times hemodynamic stability**

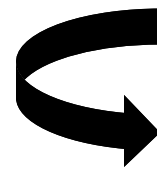
Post-procedural evolution



Post-operative day 3

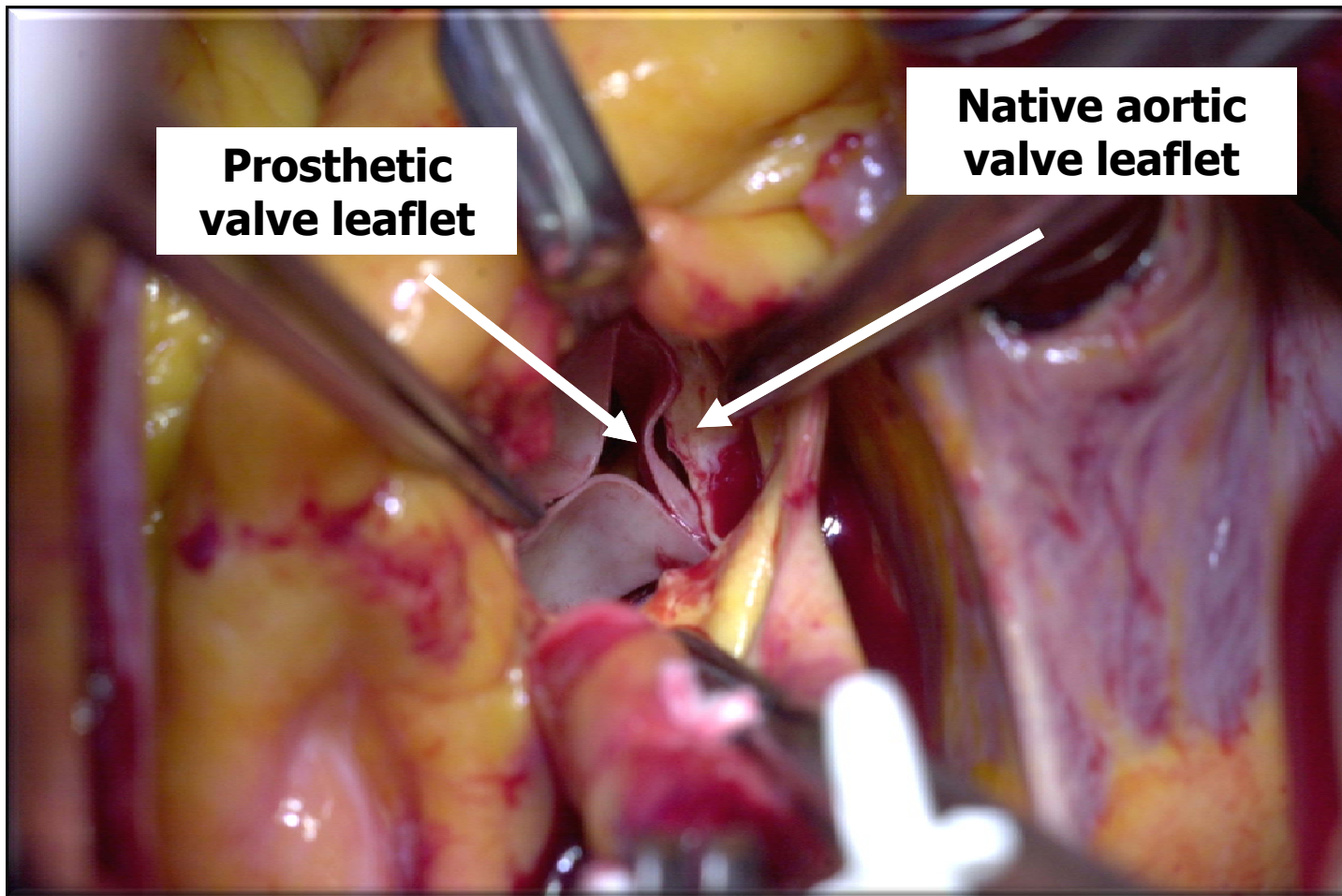


**Severe central aortic regurgitation
during HD instability**



Surgical exploration

Surgical Exploration



Native aortic valve leaflet impinging on prosthetic valve leaflet impeding normal leaflet motion

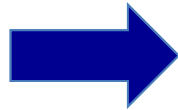
Mechanisms of Aortic Regurgitation

- **Malposition of prosthesis**
- **Undersizing prosthesis**
- **Underexpansion of prosthesis**
- **Malapposition of prosthesis**
- **Aggressive pre-dilatation during BAV**
- **Guidewire or pigtail catheter interfering with leaflet coaptation**

Predictors of AR

(Edwards SAPIEN)

Detaint et al.
JACC Interv 2009;2:82107



“Cover Index” (TEE)
1.22 (95% CI 1.03 to 1.52)

Operator experience
2.24 (95% CI 1.07 5.22)

Coli et al.
Circulation 2009;120:S982

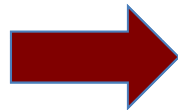


Sizing and calcium

Degree of valve calcification (TEE)
8.47 (95% CI 1.22 to 58.92)

Asymmetry of valve calcification (TEE)
13.70 (95% CI 1.52 to 122.40)

Delgado et al.
Circulation 2009;120;S957

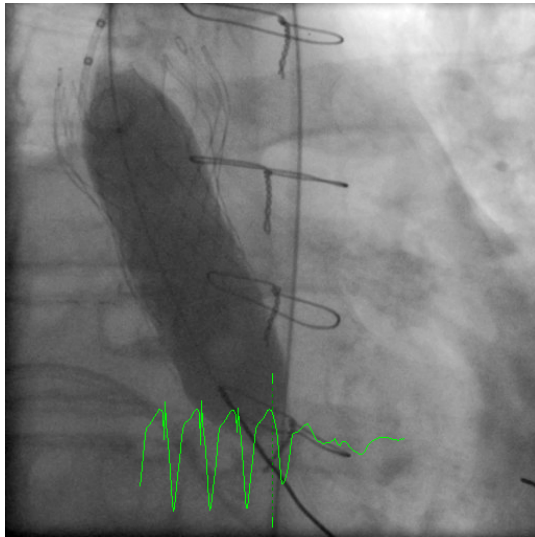


↑ Annulus size (MSCT)
(28.2 ± 1.8 mm vs. 24.8 ± 2.3 mm, $p=0.003$)

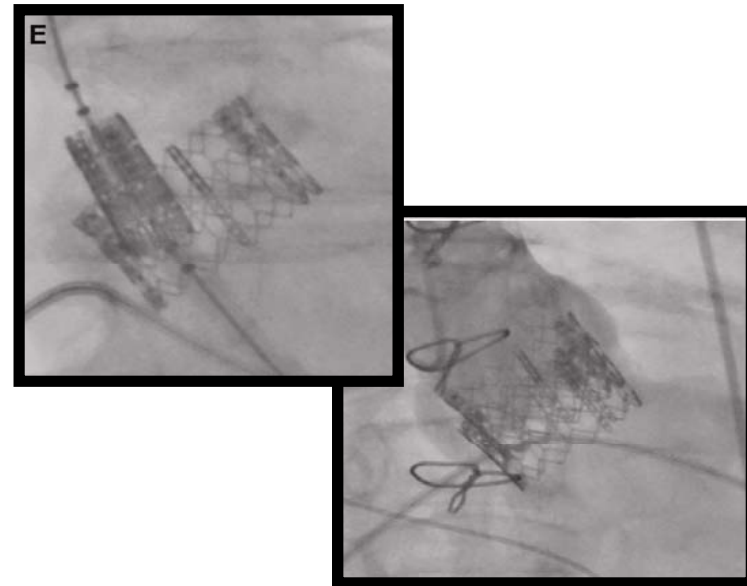
Degree of valve calcification (MSCT)
(4127 ± 2071 HU vs. 2470 ± 1264 HU, $p=0.037$)

#3 Aortic regurgitation

Treatment of paravalvular aortic regurgitation



**Post-implant
balloon dilatation**



Valve-in-valve

Moderate-severe aortic regurgitation should be treated if possible

Hypotension during or after TAVI

1. Cardiac tamponade (Echo)

2. Myocardial ischemia (ECG)

3. Major bleeding (MSCT)

Stepwise Care

- **24-36 hours in intensive care**
- **Transfer to medium care or general ward for 5 days**
- **Average length of stay 5-7 days.**

Overall Things to Watch For

Signs of stroke

Bleeding

Post-care TAVI needs that we acquire a new knowledge base of pathophysiological mechanisms that may lead to otherwise

ECG rhythm disturbances

Renal problems

Myocardial ischemia

Vascular access issues

common signs and symptoms

Cardiac tamponade