

Managing TAVR Complications

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Disclosure Statement of Financial Interest

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

Affiliation/Financial Relationship

- Consulting Fees/Honoraria

Company

- Abbott Vascular, Cardiovascular System Inc. Edwards Lifescience

Most Common Complications

- **Stroke**
- **Valve embolization**
- **Annulus rupture**
- **Coronary Obstruction**
- **Conductions disorders**
- **Para-Valvular Leak**
- **Vascular Complications/Bleedings**
- **Others...(Tamponade,VSD,...)**

How to avoid them?

How to treat them?

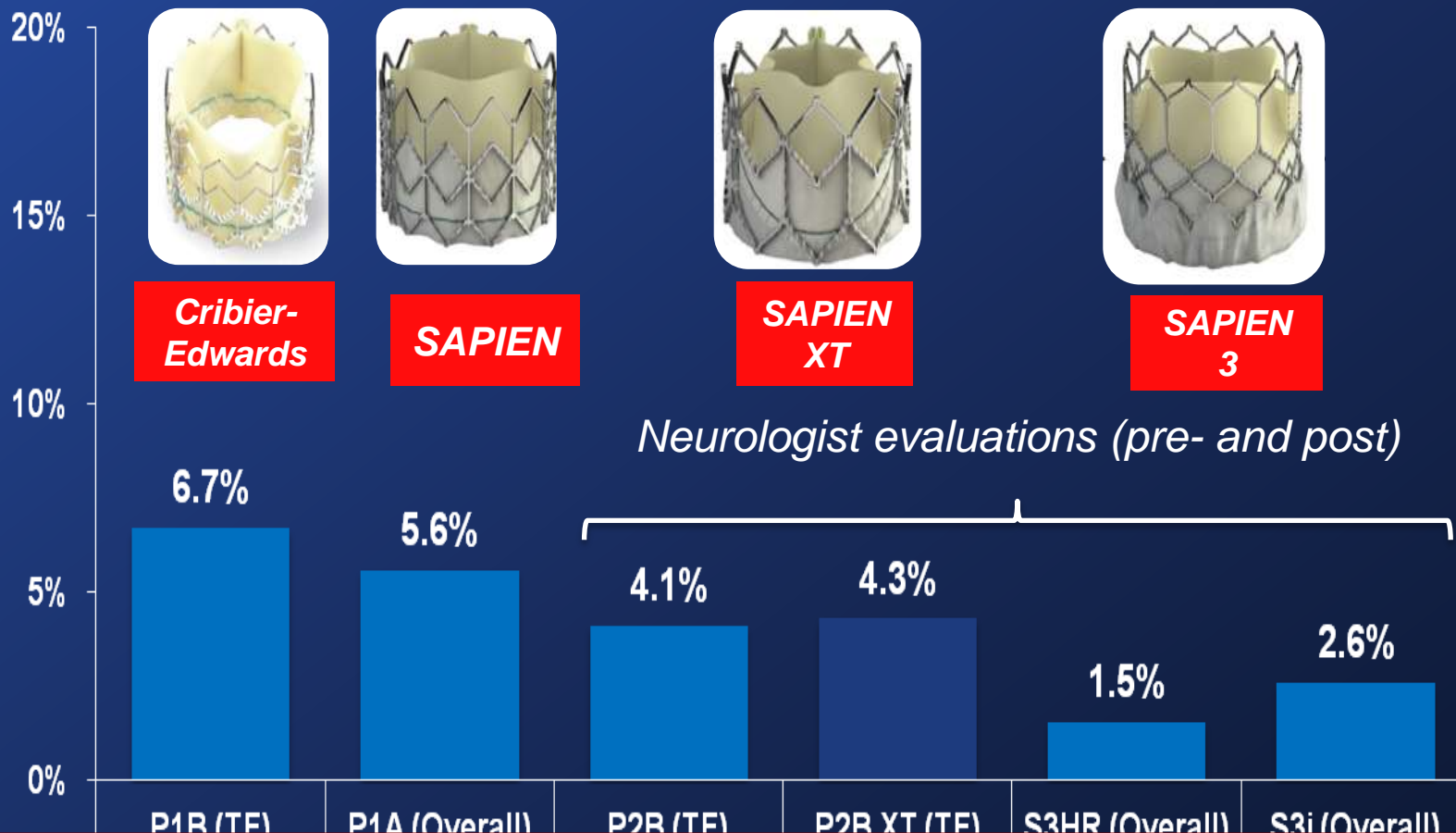
1. Stroke

All Strokes at 30 Days

Edwards SAPIEN Valves



PARTNER I and II Trials



Lower Risk Patients
Lower Profile devices

Strokes

At 30 Days (As Treated Patients)

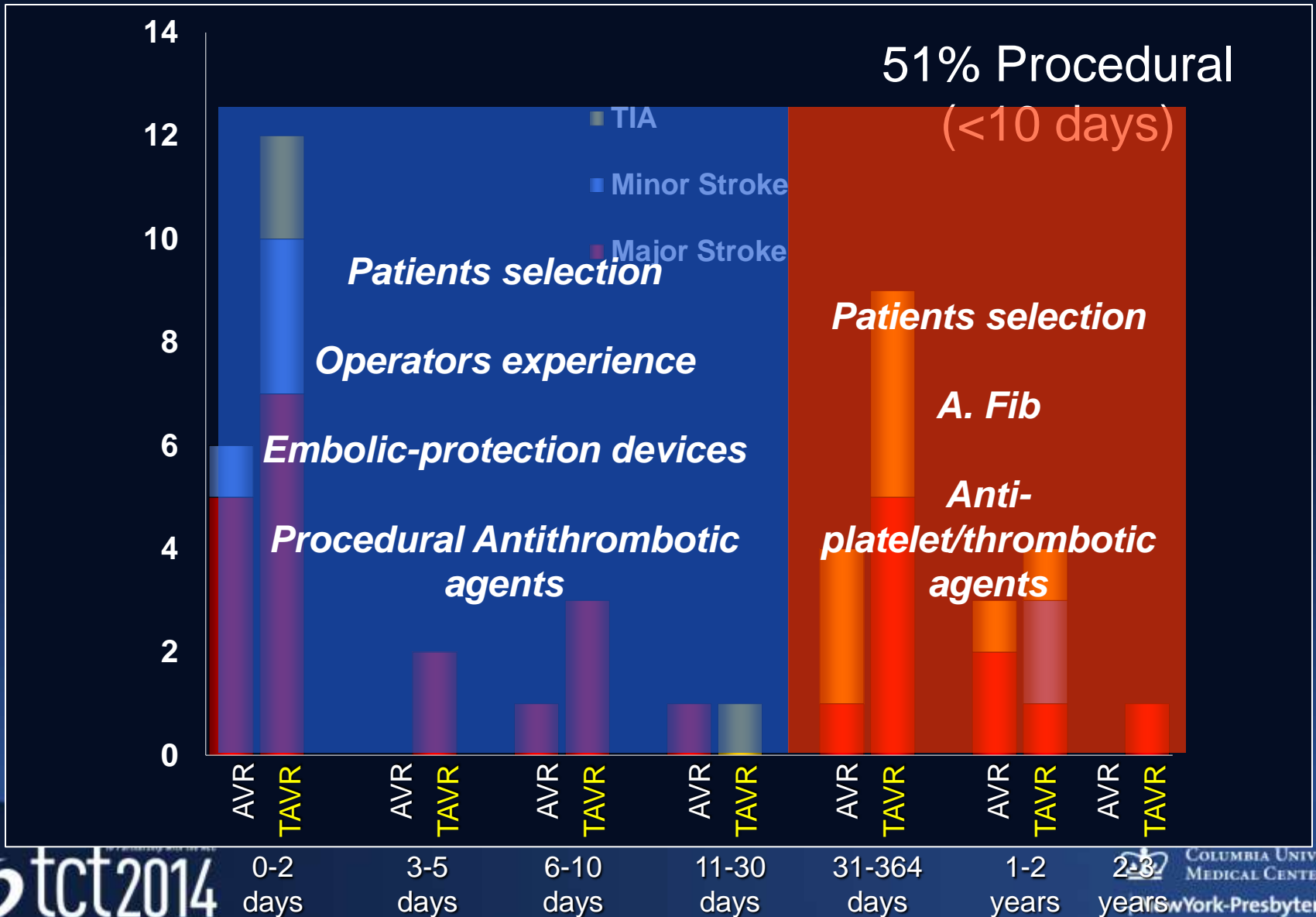


Events (%)	S3HR	S3HR	S3HR	S3i	S3i	S3i
	Overall I (n=583)	TF (n=491)	TA/TA o (n=92)	Overall (n=1076)	TF (n=951)	TA/TAo (n=125)
All	1.54	1.63	1.09	2.60	2.42	4.00
Disabling*	0.86	0.81	1.09	1.02	0.95	1.60
Non-Disabling	0.69	0.81	0	1.58	1.47	2.40
TIA	0.69	0.61	1.09	0.37	0.42	0

*CEC adjudicated or Modified Rankin Score ≥ 2 at 30 days



Timing and Types of Neurologic Events (strokes and TIAs)



Antithrombotic Treatment in Transcatheter Aortic Valve Implantation

Insights for Cerebrovascular and Bleeding Events

Josep Rodés-Cabau, MD,* Harold L. Dauerman, MD,† Mauricio G. Cohen, MD,‡
Roxana Mehran, MD,§ Eric M. Small, PhD,|| Susan S. Smyth, MD, PhD,¶
Marco A. Costa, MD, PhD,# Jessica L. Mega, MD, MPH,** Michelle L. O'Donoghue, MD, MPH,**
E. Magnus Ohman, MB, BS,†† Richard C. Becker, MD††§§

*Quebec City, Quebec, Canada; Burlington, Vermont; Miami, Florida; New York and Rochester, New York;
Lexington, Kentucky; Cleveland, Ohio; Boston, Massachusetts; and Durham, North Carolina*

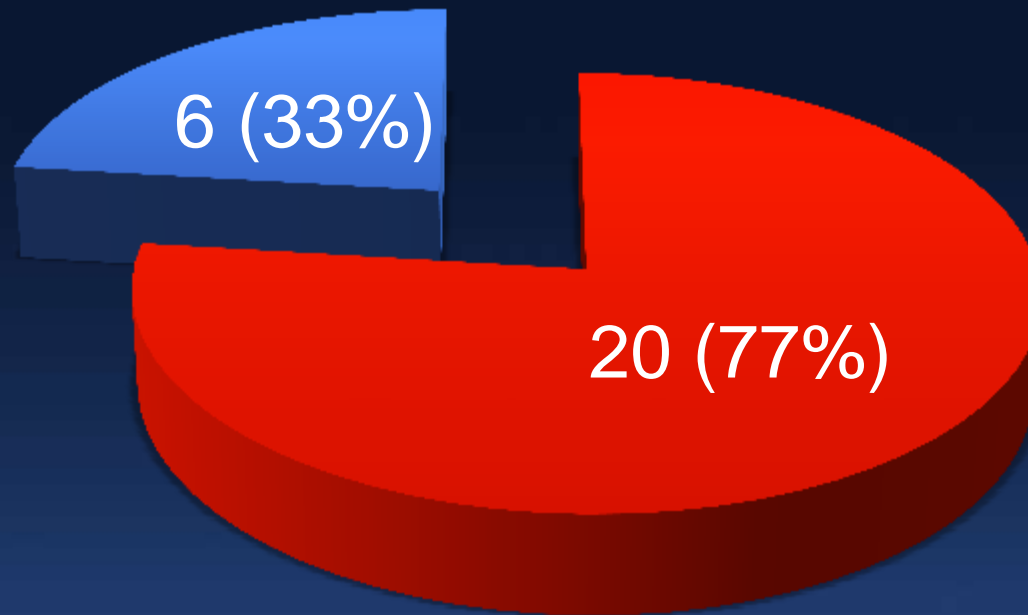
“Randomized trials are the best path forward to determine the balance between the efficacy and risks of antithrombotic treatment in this high risk population”

2. Valve Embolization

US PARTNER trials Expandable Valve n= 2554 consecutive patients

- Data from cohort B (inoperable), Cohort A (high risk) and Continuous access
- **26 valves embolization (1.0%)**
 - 10 left ventricle
 - 10 descending aorta
 - 3 Aortic arch
 - 3 peri-annular
- 14 (53.8%) were managed percutaneously and 12 (46.2%) by surgery

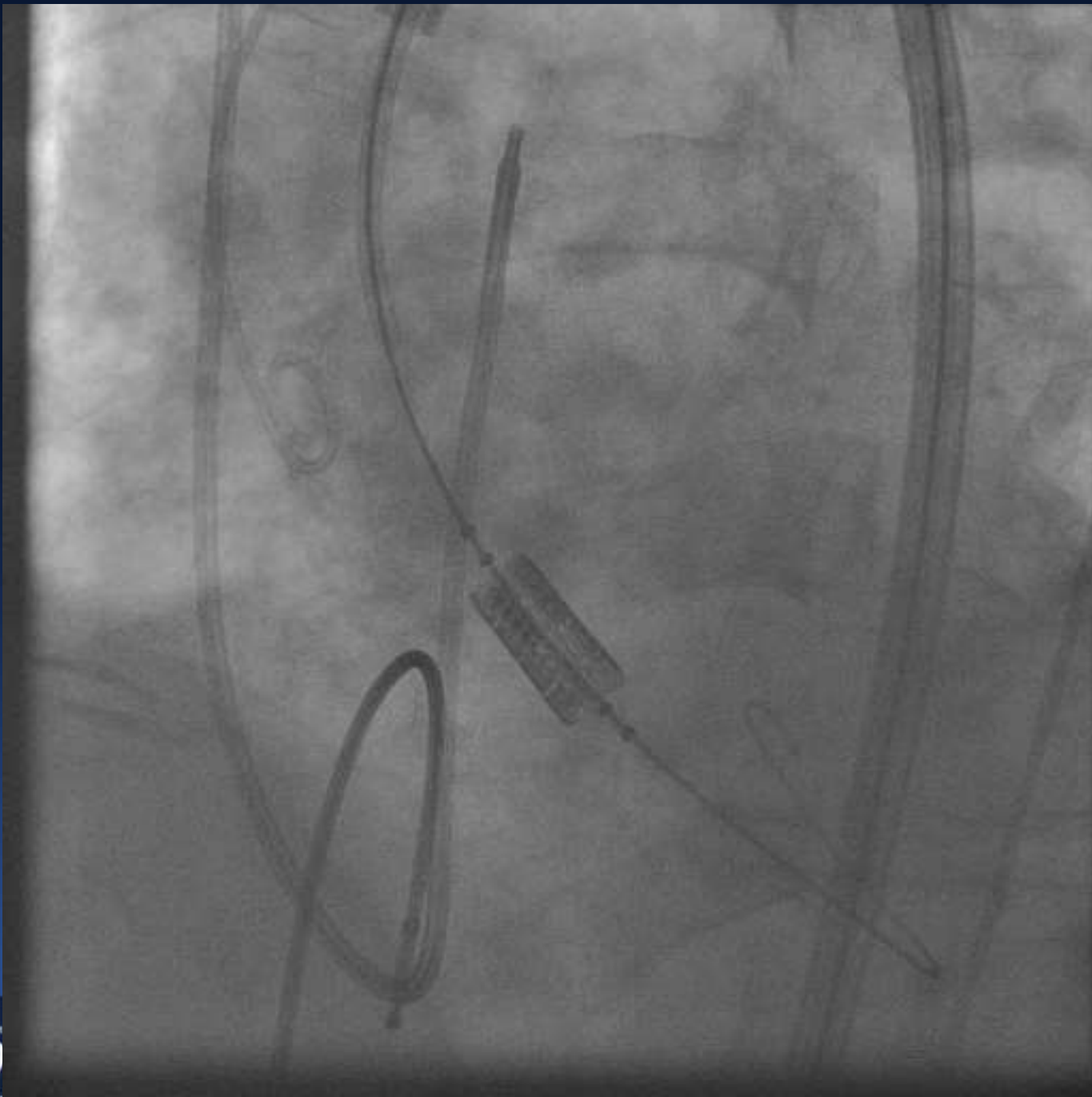
Valve Embolization n=26

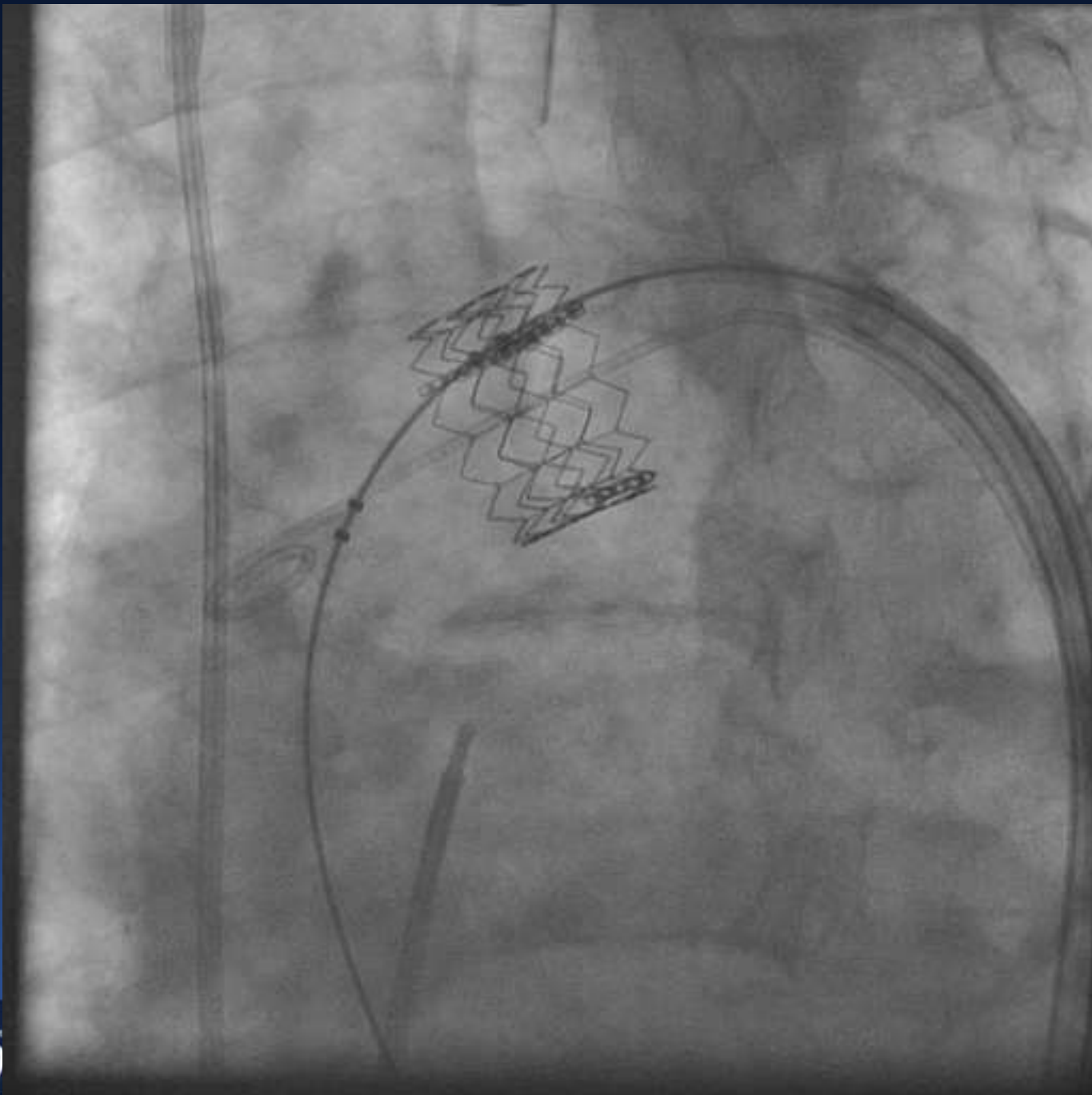


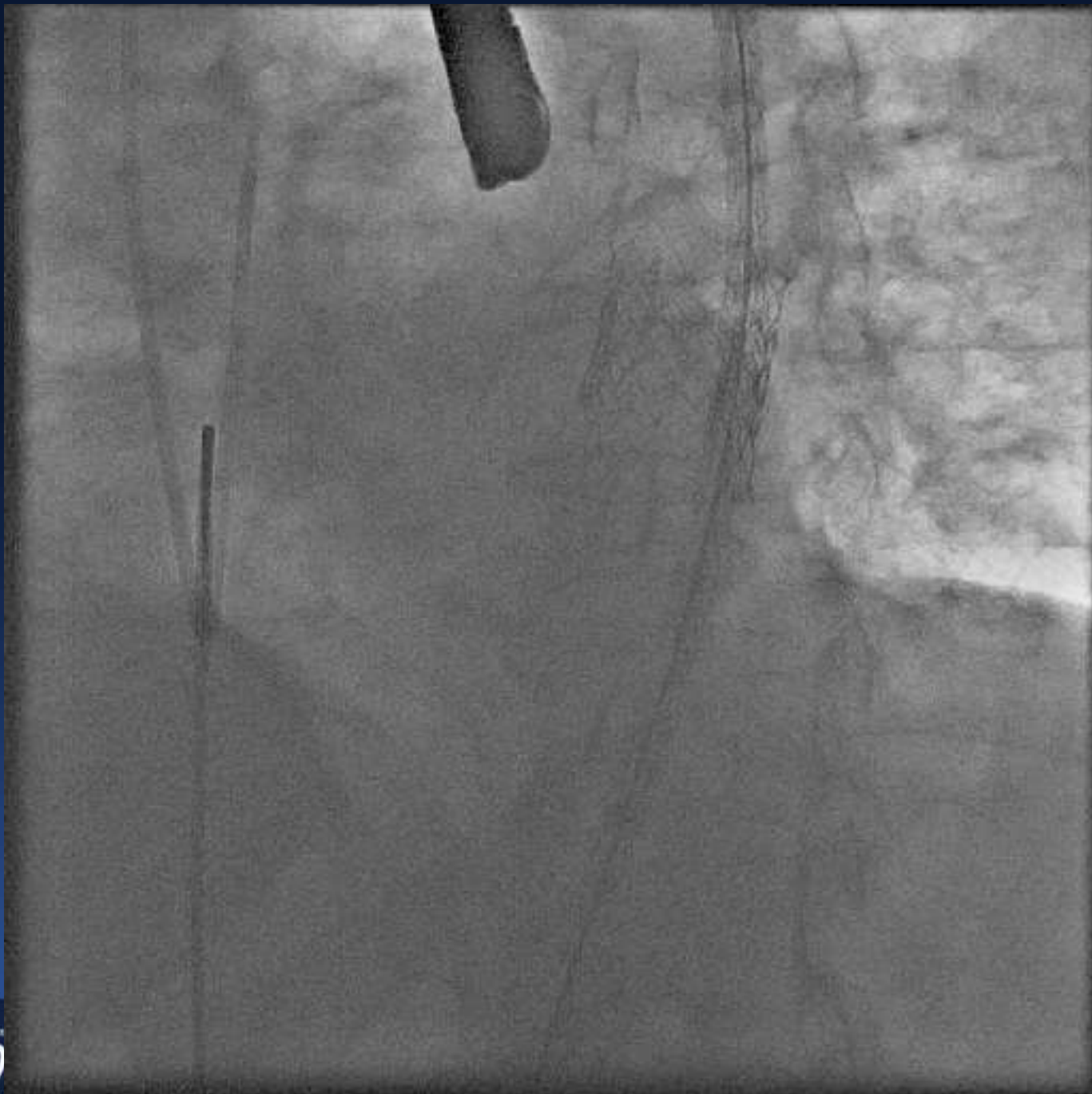
■ Trans Femoral ■ Trans Apical

Causes

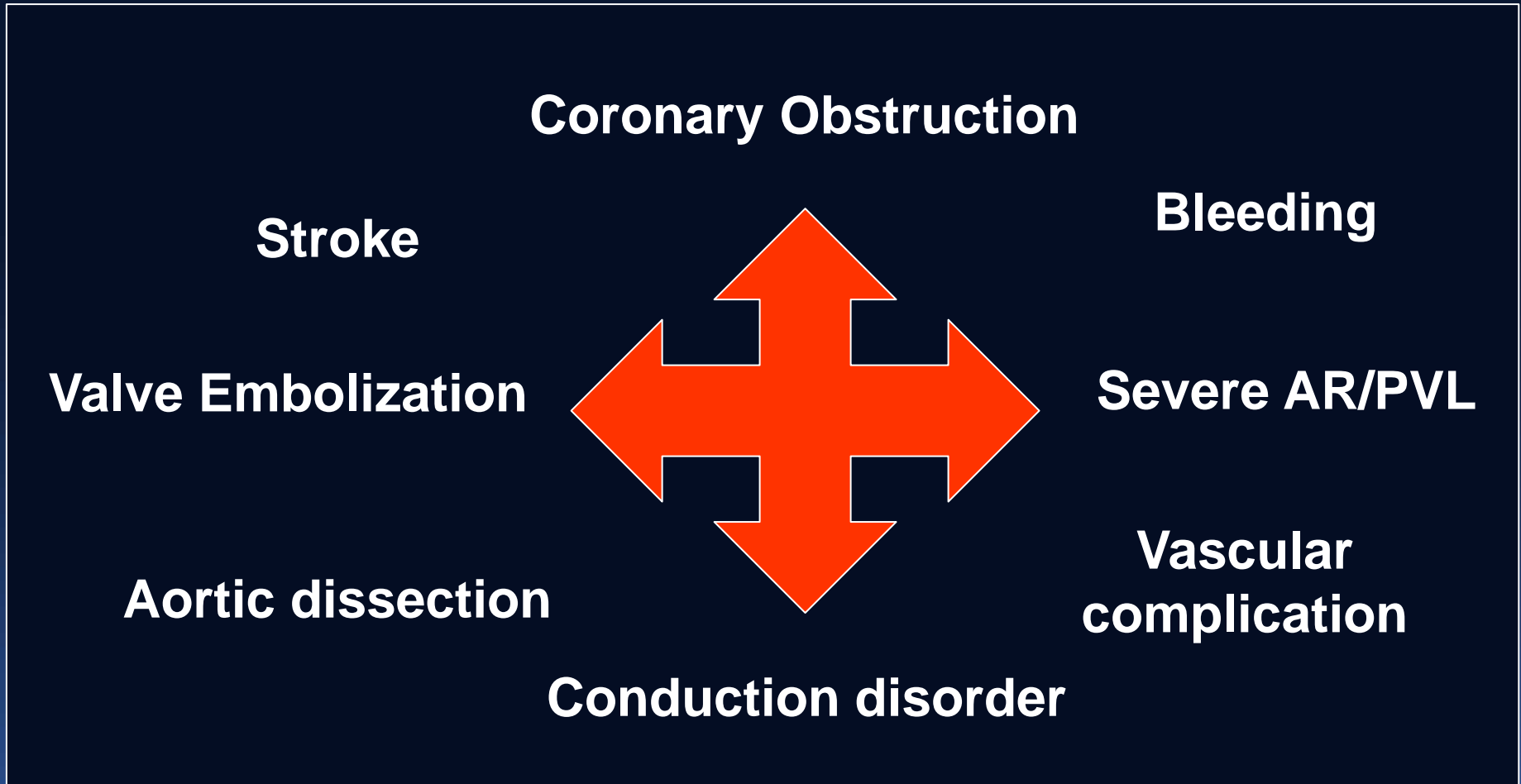
- ***Technical factor***
 - Malpositioning (too high, too low, lack of co-axiality)
 - Undersizing
 - Pacing failure
 - Post implantation manipulation (post dilatation)
- ***Anatomical factor***
 - Complex valvular complex anatomy
 - Prior mitral bioprosthesis
 - Septal bulge
 - Horizontal aorta



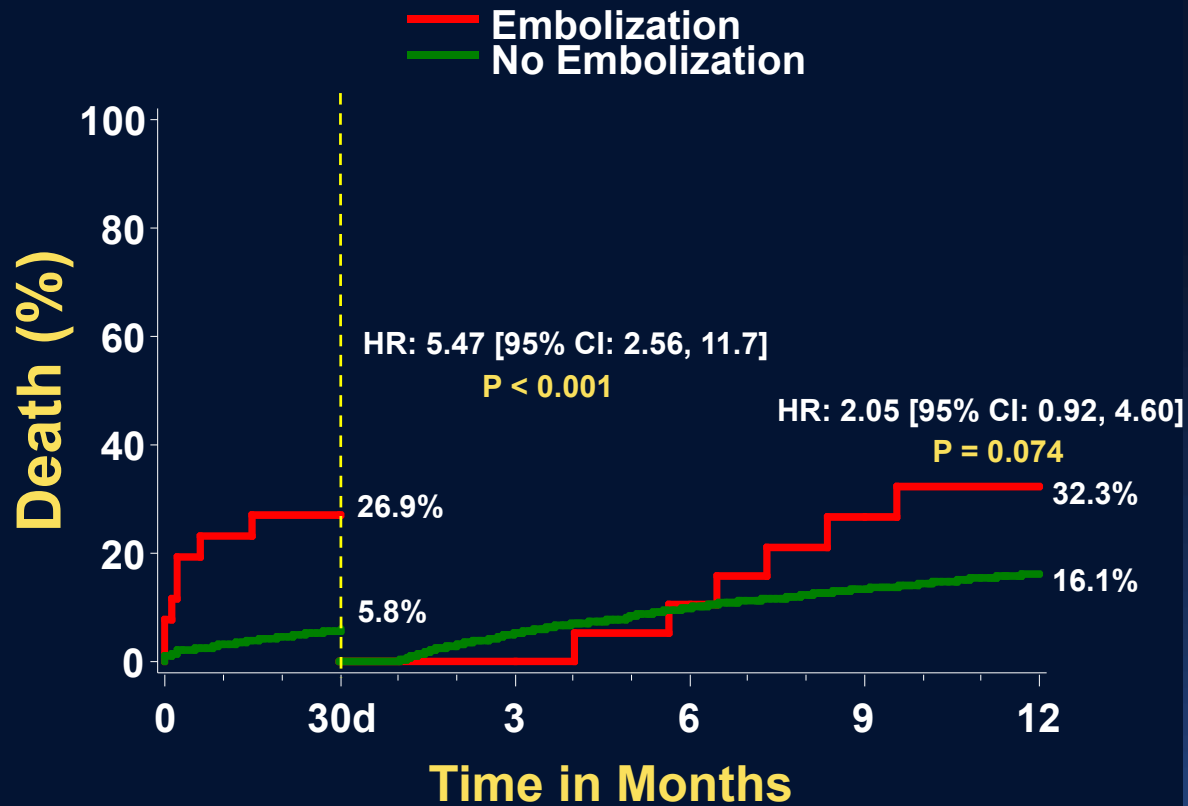




Consequences of Valve Malposition



Death Valve Embolization



Number at risk:

Embolization	26	19	19	17	13	11
No Embolization	2528	2367	2218	1961	1751	1330

If valve embolization occurred?

- **Prevention:** Sizing-positioning-slow inflation
- Keep **wire in position**
- Different technique for **repositioning** (snaring: Self expandable)
- **Deployment of embolized THV** in place free of major side branches
 - Re-inflate the balloon with shoulder at the leading edge for atraumatic repositioning (Balloon expandable)
- **Surgery**
- **Valve in Valve (THV-in-THV)**

3. Annulus Rupture



Anatomical and Procedural Features Associated With Aortic Root Rupture During Balloon-Expandable Transcatheter Aortic Valve Replacement

Marco Barbanti, Tae-Hyun Yang, Josep Rodès Cabau, Corrado Tamburino, David A. Wood, Hasan Jilaihawi, Phillip Blanke, Raj R. Makkar, Azeem Latib, Antonio Colombo, Giuseppe Tarantini, Rekha Raju, Ronald K. Binder, Giang Nguyen, Melanie Freeman, Henrique B. Ribeiro, Samir Kapadia, James Min, Gudrun Feuchtner, Ronen Gurtvich, Faisal Alqoofi, Marc Pelletier, Gian Paolo Ussia, Massimo Napodano, Fabio Sandoli de Brito, Jr, Susheel Kodali, Bjarne L. Norgaard, Nicolaj C. Hansson, Gregor Pache, Sergio J. Canovas, Hongbin Zhang, Martin B. Leon, John G. Webb and Jonathon Leipsic

N=31; Aortic rupture n=20; Peri-aortic hematoma n=11

Moderate/severe LVOT/subannular calcifications

(OR 10.92; 95% CI 3.23-36.91; P <0.001)

Prosthesis oversizing ≥ 20%

(OR, 8.38; 95% CI, 2.67-26.33; P <0.001)

Mortality: 48.4% in-hospital

Predictors

- Oversizing $\geq 20\%$
- **Calcifications (LVOT-Sub annular)**
- Post dilation
- Annulus Eccentricity?

- **Prevention: Sizing/Slow inflation/Self Expandable if adverse features present**

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View size: 662 x 662
WL: 128 WW: 179

Cardiaque - Coro G. 15 Fs Low
RA201408731101
39

**Heavily
Calcified**

Eccentricity 1.7

Oversizing 12%

THV 26



Zoom: 129% Angle: 0
Im: 1/396
Uncompressed

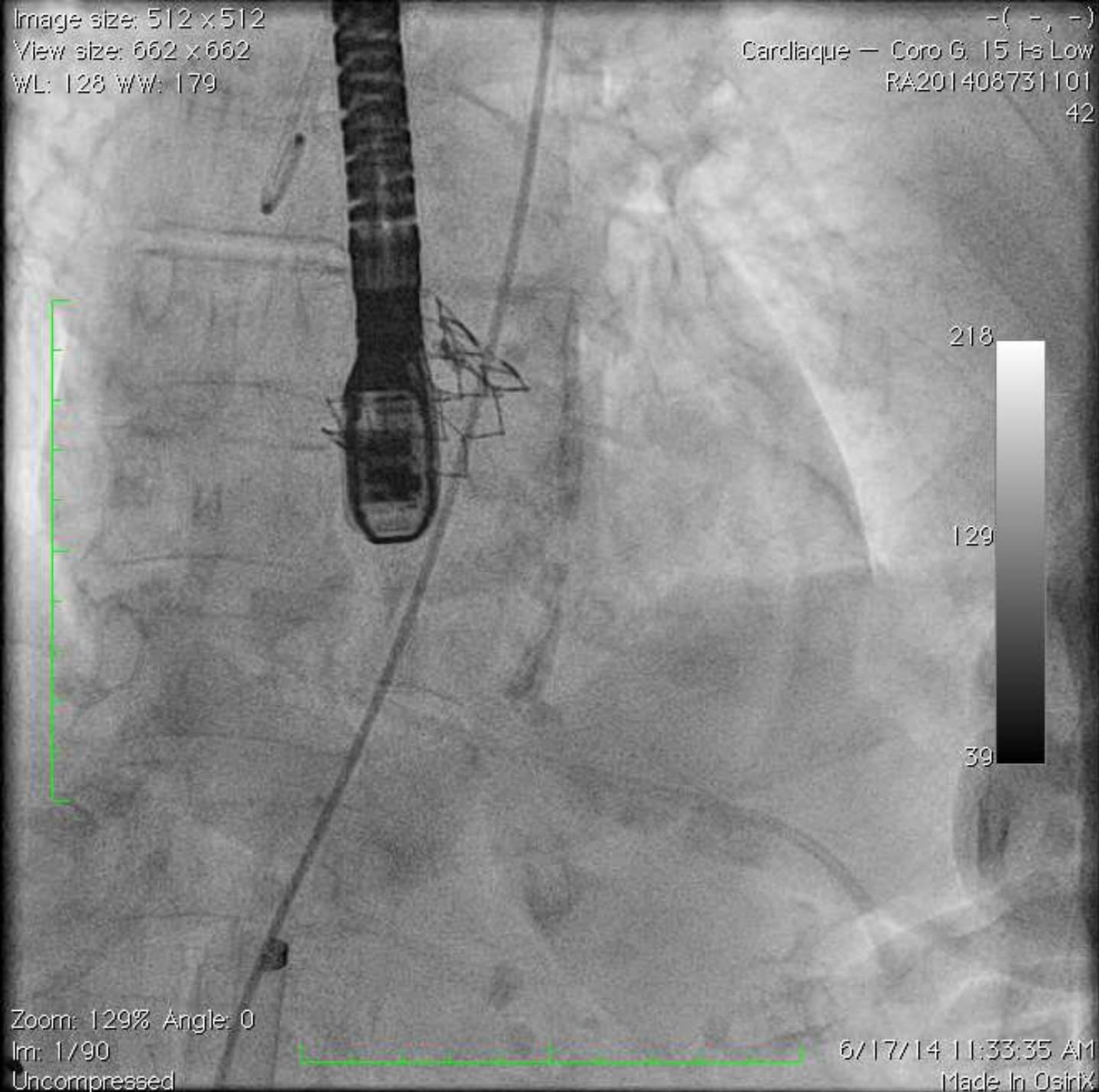
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View size: 662 x 662
WL: 128 WW: 179

Cardiacque — Coro G: 15 fs Low
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42

**Pericardial
effusion**

Hypotensive



Zoom: 129% Angle: 0
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Uncompressed

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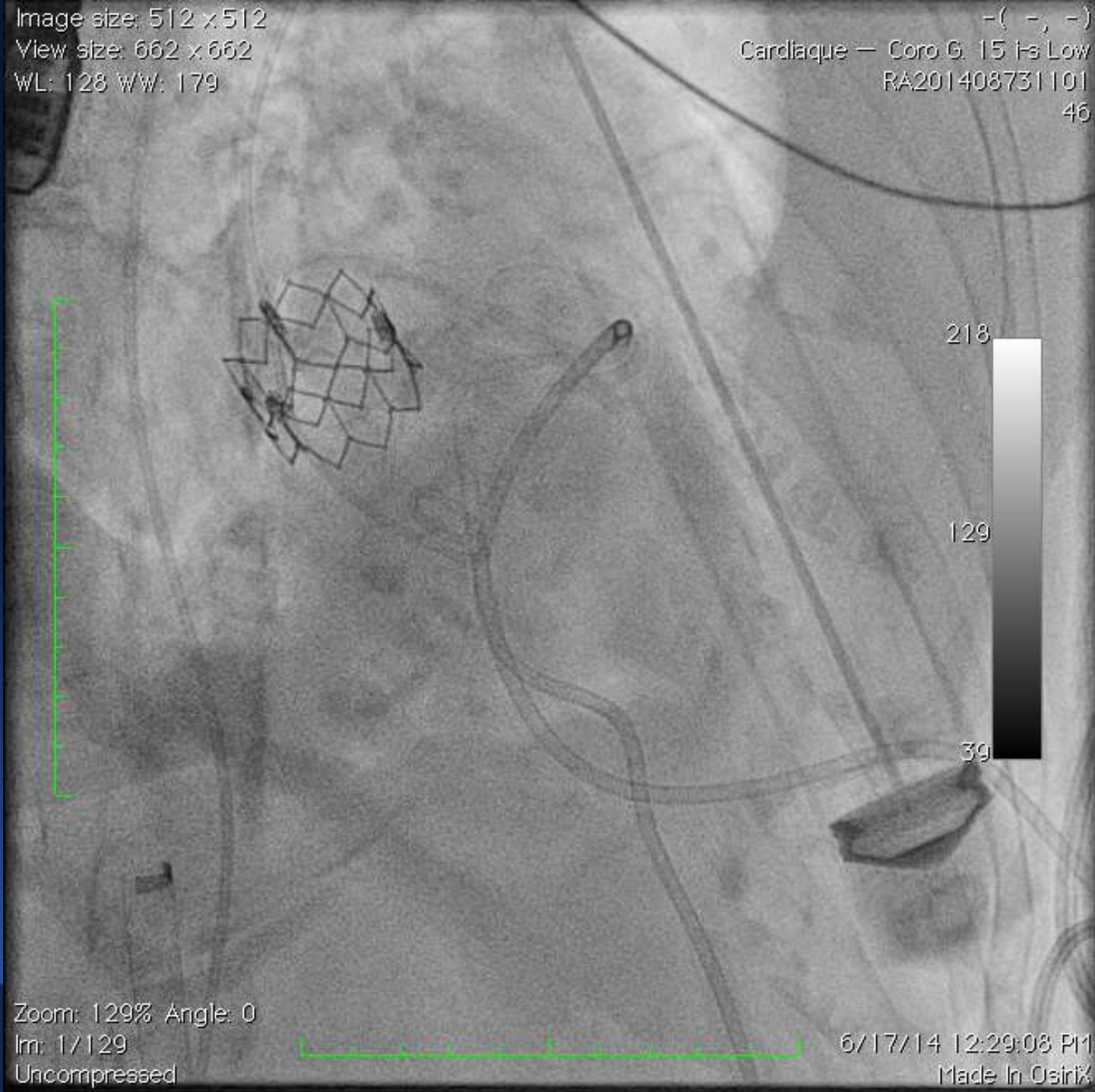
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WL: 128 WW: 179

-(-, -)
Cardiaque — Coro G. 15 fs Low
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46

Pericardiocentesis
x 2

Options:

- 1) ViV
- 2) Surgery

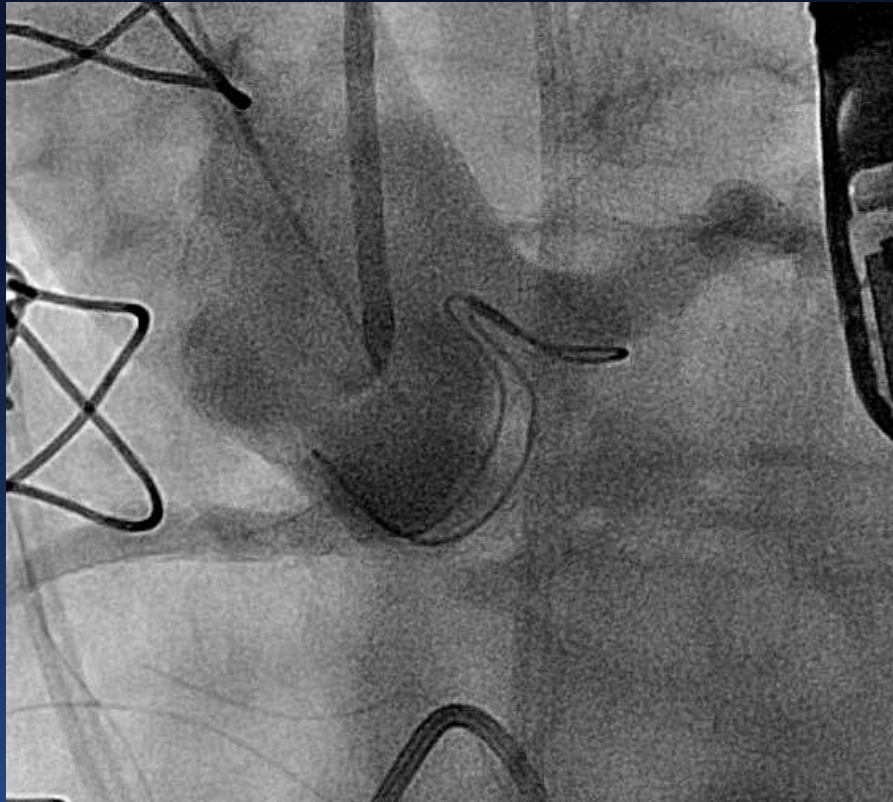


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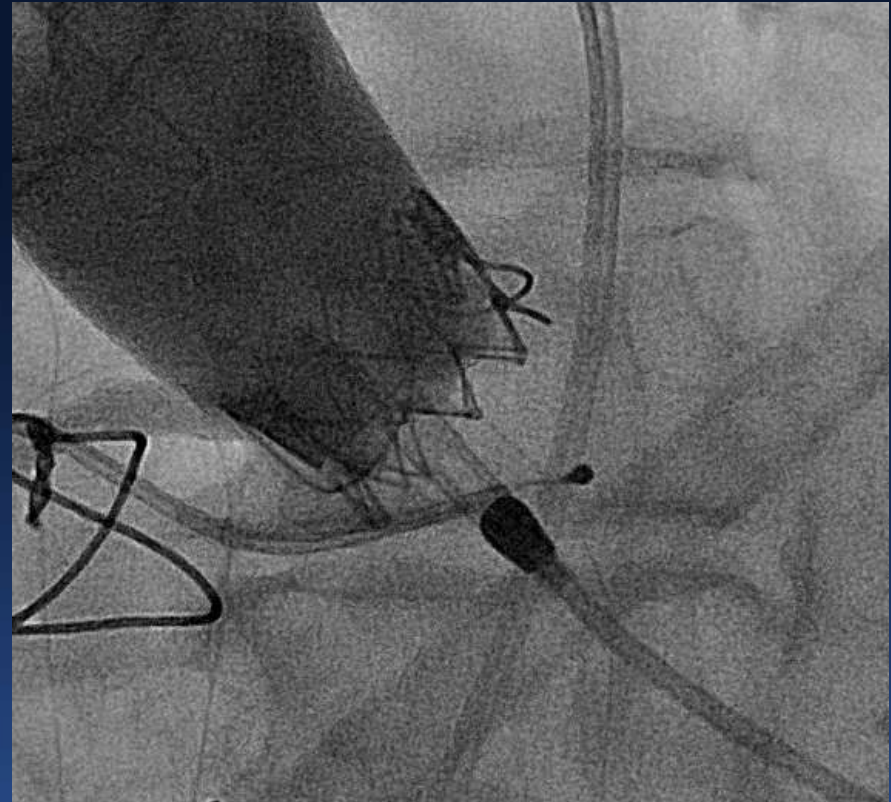
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4. Coronary Obstruction

Coronary obstruction



Supra-annular stented valve



Left main occlusion

Predictive Factors, Management, and Clinical Outcomes of Coronary Obstruction Following Transcatheter Aortic Valve Implantation

Insights From a Large Multicenter Registry

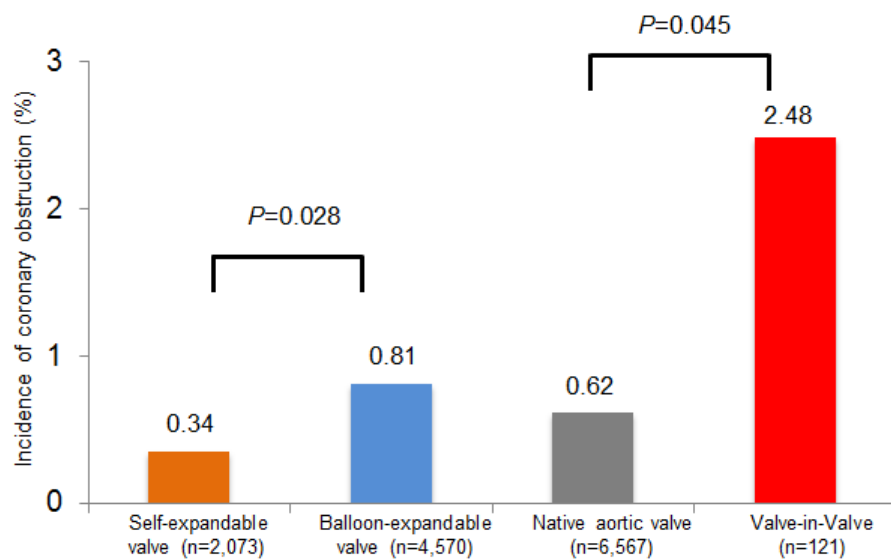
Henrique B. Ribeiro, MD,* John G. Webb, MD,† Raj R. Makkar, MD,‡ Mauricio G. Cohen, MD,§ Samir R. Kapadia, MD,|| Susheel Kodali, MD,¶ Corrado Tamburino, MD,# Marco Barbanti, MD,‡# Tarun Chakravarty, MD,‡ Hasan Jilaihawi, MD,‡ Jean-Michel Paradis, MD,¶ Fabio S. de Brito, JR, MD,** Sergio J. Cánovas, MD,†† Asim N. Cheema, MD,‡‡ Peter P. de Jaegere, MD,§§ Raquel del Valle, MD,||| Paul T. L. Chiam, MD,¶¶ Raúl Moreno, MD,## Gonzalo Pradas, MD,*** Marc Ruel, MD,††† Jorge Salgado-Fernández, MD,‡‡‡ Rogerio Sarmiento-Leite, MD,§§§ Hadi D. Toeg, MD,††† James L. Velianou, MD,|||| Alan Zajarias, MD,¶¶¶ Vasilis Babaliaros, MD,### Fernando Cura, MD,**** Antonio E. Dager, MD,†††† Ganesh Manoharan, MD,‡‡‡‡ Stamatios Lerakis, MD,### Augusto D. Pichard, MD,§§§§ Sam Radhakrishnan, MD,||||| Marco Antonio Perin, MD,** Eric Dumont, MD,* Eric Larose, MD,* Sergio G. Pasian, MD,* Luis Nombela-Franco, MD,* Marina Urena, MD,* E. Murat Tuzcu, MD,|| Martin B. Leon, MD,¶ Ignacio J. Amat-Santos, MD,¶¶¶¶ Jonathon Leipsic, MD,† Josep Rodés-Cabau, MD*

Quebec City, Quebec, Toronto, Ottawa, Hamilton, Ontario, and Vancouver, British Columbia, Canada; Los Angeles, California; Miami, Florida; Cleveland, Ohio; New York, New York; Catania, Italy; Sao Paulo, and Porto Alegre, Brazil; Valencia, Oviedo, Madrid, Vigo, La Coruna, and Valladolid, Spain; Rotterdam, the Netherlands; Singapore; St. Louis, Missouri; Atlanta, Georgia; Buenos Aires, Argentina; Cali, Colombia; Belfast, Northern Ireland; and Washington, DC

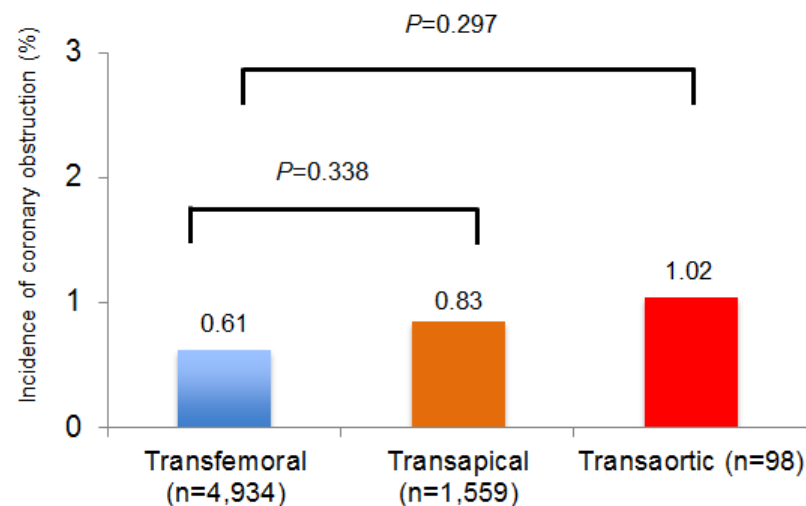
Results: Incidence of coronary obstruction (%)

N=44 (0.66%)

According to valve type and procedure



According to approach



Mortality 30-day (40.9%)

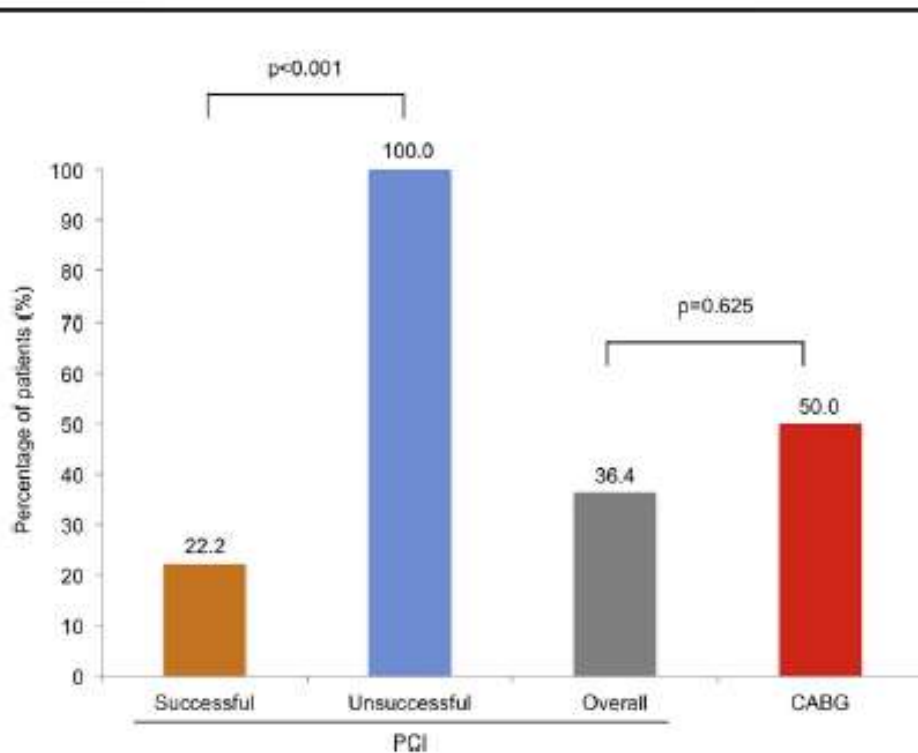


Figure 4

Mortality Rate at 30 Days According to the Type and Results of the Treatment for Coronary Obstruction

Mortality at 30 days following successful percutaneous coronary intervention (PCI), unsuccessful PCI, or coronary artery bypass graft (CABG) after the occurrence of coronary obstruction.

Predictors of Coronary obstruction

- 1) Female
- 2) Balloon Expandable
- 3) Small aortic root (<30 mm)
- 4) Coronary height (<12mm LM)

Prevention:

- 1) Coronary wire/balloon/Stent in coronary pre-TAVR
- 2) BAV pre TAVR +/- abortion of TAVR
- 3) Repositionable valve?
- 4) Off pump LIMA pre-TAVR?

5. Conductions Disorders

Conduction Disorders

- Pre-existing LBBB, RBBB, AF
- Low implantation
- Calcification
- *Prevention:*
- 1) Proper positioning

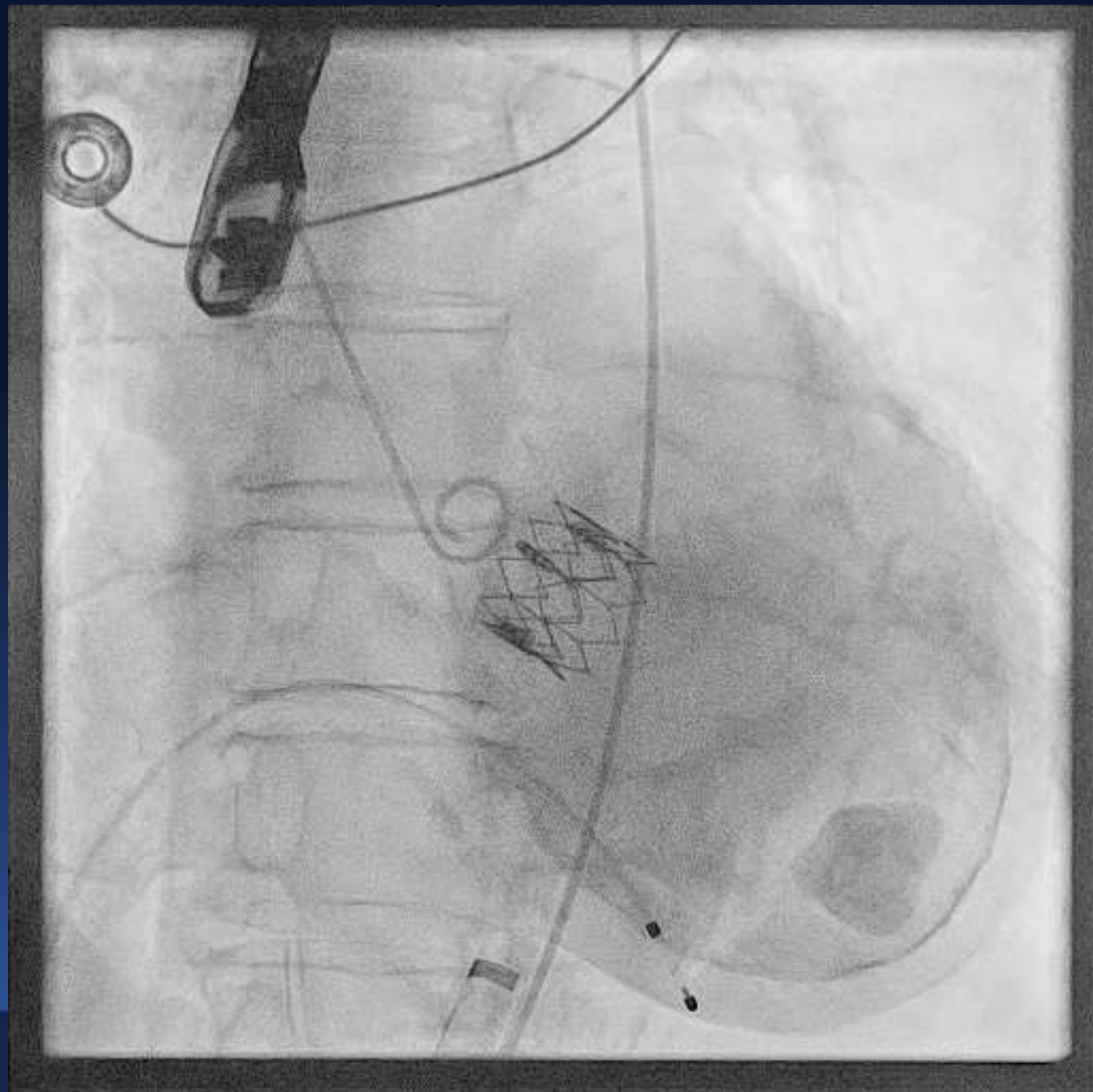
6. Para-Valvular Leak

Severely Calcified

Oversizing 10%

**Fracture of native
leaflets
overhanging
above prosthesis**

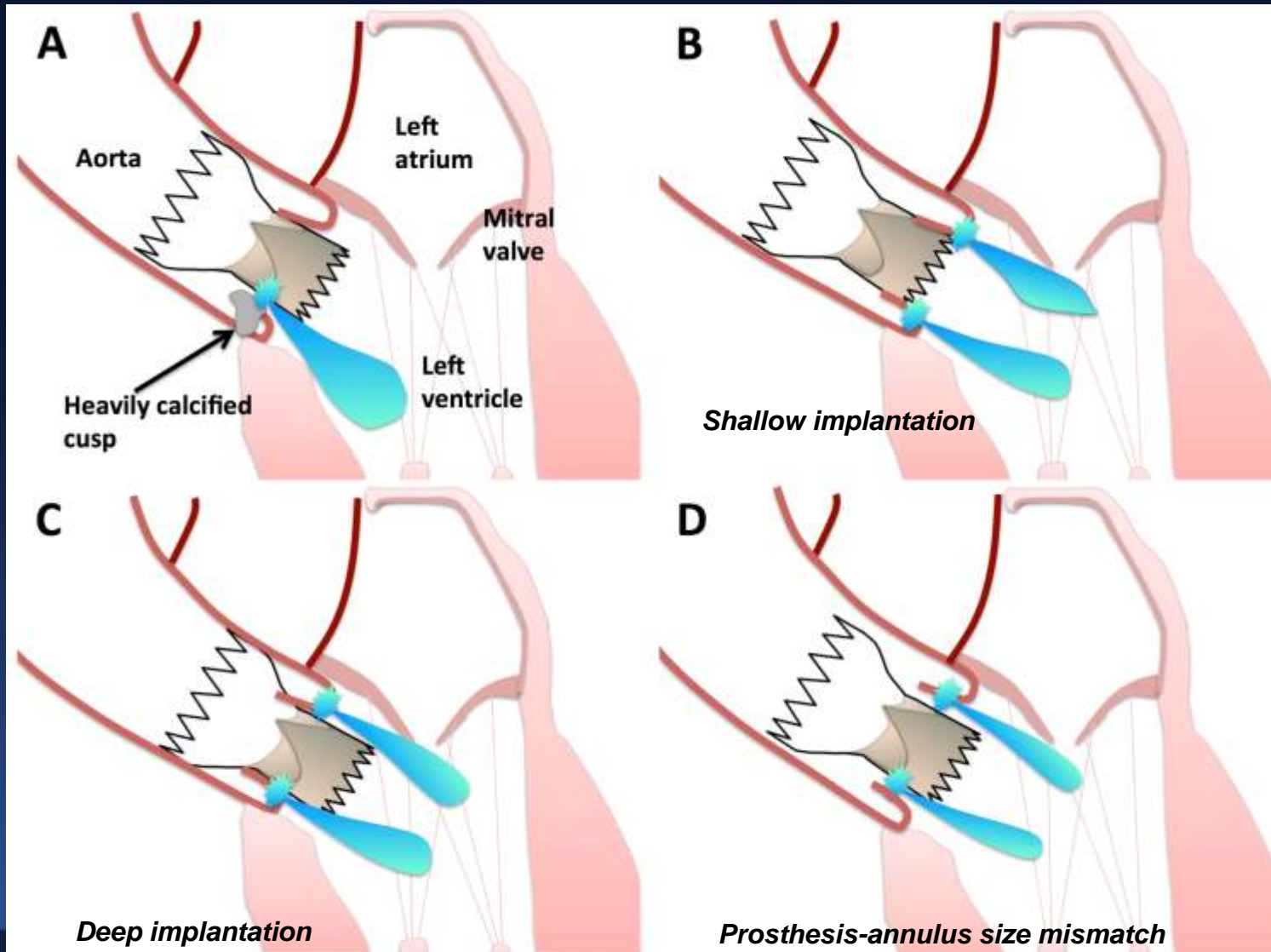
Mild-Moderate PVL



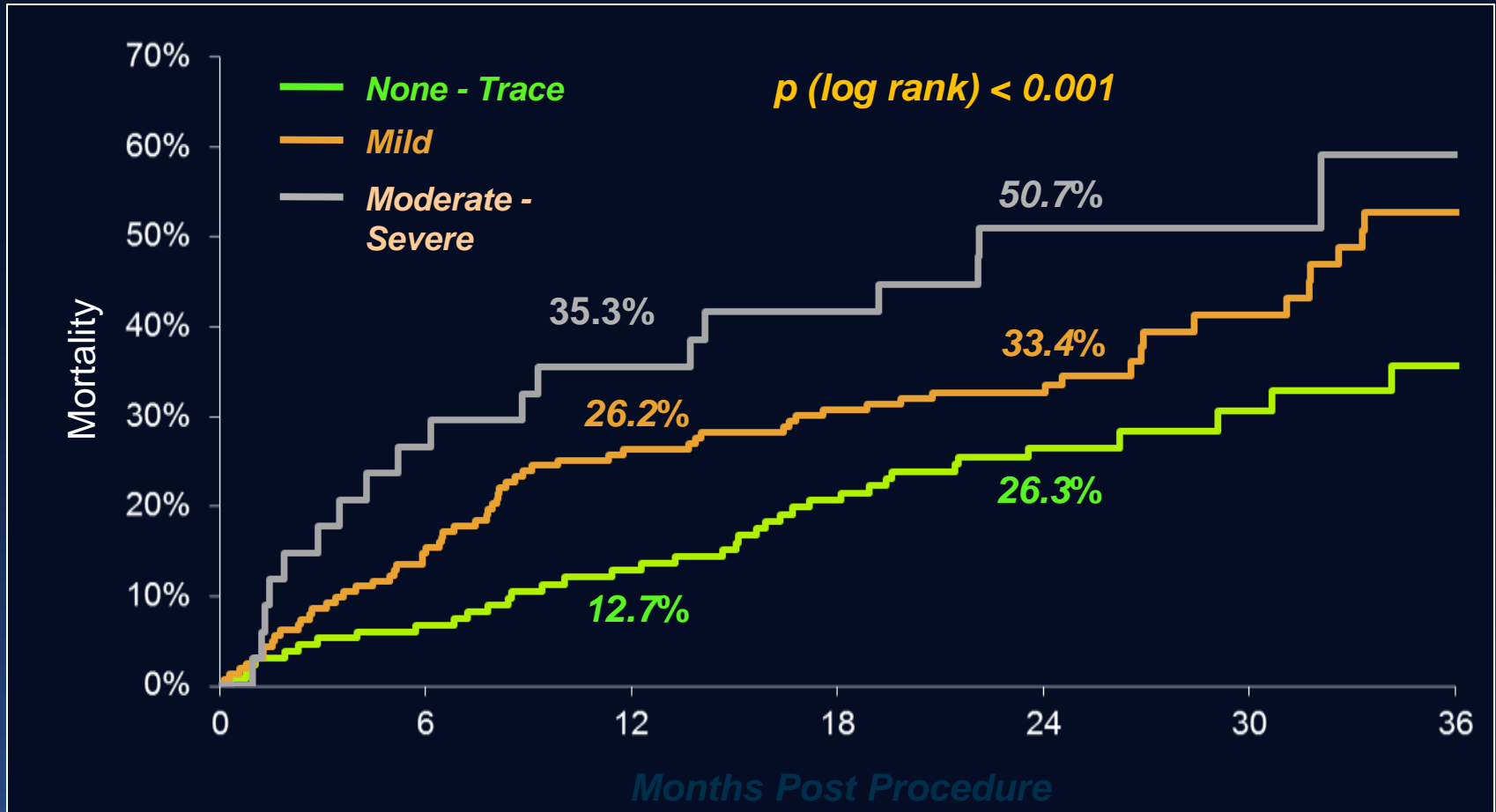
Predictors: Key concepts

- ***Incomplete prosthesis apposition***
 - Patterns or extent of calcification
 - Annular eccentricity
- ***Undersizing of the device***
- ***Depth of implantation (malpositioning)***

Mechanisms of PVR



Total AR and Mortality TAVR Patients (AT)



Numbers at Risk

AR Severity	0	6	12	18	24	30	36
None-Tr	135	125	115	101	68	31	11
Mild	165	139	121	111	71	33	16
Mod-Sev	34	25	22	19	15	6	2

How to avoid PVL?

Imaging: Planning/Sizing/Positioning

CLINICAL RESEARCH

Interventional Cardiology

Aortic Annular Sizing for Transcatheter Aortic Valve Replacement Using Cross-Sectional 3-Dimensional Transesophageal Echocardiography

Hasan Jilaihawi, MD, Niraj Doctor, MBBS, Mohammad Kashif, MD, Tarun Chakravarty, MD, Asim Rafique, MD, Moody Makar, MD, Azusa Furugen, MD, PhD, Mamoo Nakamura, MD, James Mirocha, MS, Mitch Gheorghiu, MD, Jasminka Stegic, MS, ANP-BC, CCRN, ACNP, Kazuaki Okuyama, MD, Daniel J. Sullivan, MD, Robert Siegel, MD, James K. Min, MD, Swaminatha V. Gurudevan, MD, Gregory P. Fontana, MD, Wen Cheng, MD, Gerald Friede, BS, MS, Takahiro Shiota, MD, Raj R. Makkar, MD

Los Angeles, California

CLINICAL RESEARCH

Imaging in Transcatheter Aortic Valve Replacement

Cross-Sectional Computed Tomographic Assessment Improves Accuracy of Aortic Annular Sizing for Transcatheter Aortic Valve Replacement and Reduces the Incidence of Paravalvular Aortic Regurgitation

Hasan Jilaihawi, BSc (HONS), MBChB,* Mohammad Kashif, MD,* Gregory Fontana, MD,† Azusa Furugen, MD, PhD,* Takahiro Shiota, MD,* Gerald Friede, BS, MS,* Rakhee Makhija, MD,* Niraj Doctor, MBBS,* Martin B. Leon, MD,‡ Raj R. Makkar, MD*

Los Angeles, California; and New York, New York

3-Dimensional Aortic Annular Assessment by Multidetector Computed Tomography Predicts Moderate or Severe Paravalvular Regurgitation After Transcatheter Aortic Valve Replacement

A Multicenter Retrospective Analysis

Alexander B. Willson, MBBS, MPH,* John G. Webb, MD,* Troy M. LaBounty, MD,† Stephan Achenbach, MD,‡ Robert Moss, MBBS,* Miriam Wheeler, MBBS,* Christopher Thompson, MD,* James K. Min, MD,† Ronen Gurvitch, MBBS,* Bjarne L. Norgaard, MD,§ Cameron J. Hague, MD,* Stefan Toggweiler, MD,* Ronald Binder, MD,* Melanie Freeman, MBBS,* Rohan Poulter, MBBS,* Steen Poulsen, MD,§ David A. Wood, MD,* Jonathon Leipsic, MD*

Vancouver, Canada; Los Angeles, California; Giessen, Germany; and Aarhus, Denmark

Willson et al. J Am Coll Cardiol 2012;59

Jilaihawi et al. J Am Coll Cardiol 2012;59:1275–86

Jilaihawi et al. J Am Coll Cardiol 2013;61:908–16

CTA Imaging and PVL

3-Dimensional Aortic Annular Assessment by Multidetector Computed Tomography Predicts Moderate or Severe Paravalvular Regurgitation After Transcatheter Aortic Valve Replacement

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Rohan Poulter, MBBS,* Steen Poulsen, MD,§ David A. Wood, MD,* Jonathon Leipsic, MD*
Vancouver, Canada; Los Angeles, California; Giessen, Germany; and Aarhus, Denmark

Conclusion:

- MSCT derived 3D-annular measurements predicts mod-severe PVL after TAVR; 35.3% cases undersized valve based on MSCT
- **Oversizing THV size using 3D-MSCT will reduce mod-severe PVL**

Adequate positioning per procedure

- ***Co-planar view***
 - **Angio (3 cups same plane)**
 - **Dyna CT**
 - **Paieon Medical**
 - **TEE guided**

Management of PVL TAVR

Treatment Depends on Etiology

- ***Malposition (too high or too low)***
 - consider valve-in-valve
- ***Severe calcification***
 - consider post-dilatation
 - consider PVL occluder (usually staged)
- ***Under-sizing***
 - consider post-dilatation a/o PVL occluder
 - consider surgical AVR

7. Vascular Complications

Predictors of Major Vascular Complications

- Hayashida et al. JACC Intv 2011; n=130
 - *SFAR HR 186.2 [4.41, 7,855.11]*
 - *Early experience HR 3.66 [1.17, 11.49]*
 - *Femoral calcification HR 3.44 [1.16, 10.17]*
- Van Mieghem N et al. Am J Cardiol 2012; n=986
 - *Female gender HR 1.63 [1.12, 2.36]*
 - *>19Fr system 2.87 [1.68, 4.91]*
- Généreux et al. JACC 2012; n=419
 - *Female gender HR 2.31 [1.08, 4.98]*

Sapien 3: Sheath sizes



20mm

23mm

26mm

29mm

eSheath Size

14F

14F

14F

16F

Outer Diameter

6.0 mm

6.0 mm

6.0 mm

6.7 mm

SAPIEN 3

Minimum artery

5.5 mm

5.5mm

5.5 mm

6.0 mm

SAPIEN XT

Minimum artery

6.0 mm

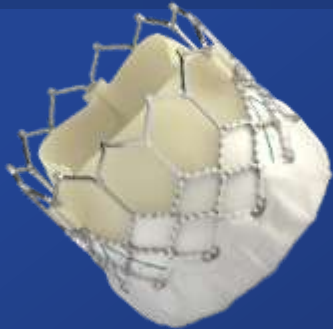
6.0 mm

6.5 mm

7.0 mm

Vascular Complications and Bleedings

At 30 Days (As Treated Patients)



Events (%)	S3HR	S3HR	S3HR	S3i	S3i	S3i
	Overall I (n=583)	TF (n=491)	TA/TA o (n=92)	Overall (n=1076)	TF (n=951)	TA/TA o (n=125)
Major Vascular Comps.	5.0	5.3	3.3	5.6	5.9	3.2
Bleeding - Life Threatening	6.3	5.5	10.9	5.4	4.4	12.9
Endocarditis	0.2	0.2	0	0.1	0.1	0

Vascular Complications:

What can we do to prevent them?

- ***Appropriate screening***
 - Angio
 - CT scan/IVUS
 - Respecting iliac and femoral diameter
 - Calcium
 - Tortuosity
- ***Adjunctive techniques***
 - US guided puncture
 - Cross-over balloon occlusive technique (CBOT)

Adjunctive technique

Catheterization and Cardiovascular Interventions 75:784-793 (2010)

VALVULAR AND STRUCTURAL HEART DISEASE

Original Studies

A New Technique for Vascular Access Management in Transcatheter Aortic Valve Implantation

Andrew S.P. Sharp, ^{MD, PhD}, Iassen Michev, ^{MD}, Francesco Maisano, ^{MD},
Maurizio Taramasso, ^{MD}, Cosmo Godino, ^{MD}, Azeem Latib, ^{MD, PhD}, Paulo Dentí, ^{MD},
Enrica Dorigo, ^{MD}, Andrea Giacomini, ^{MD}, Giuseppe Iacì, ^{MD}, Mario Manca, ^{MD},
Alfonso Ielasi, ^{MD}, Matteo Montorfano, ^{MD}, Ottavio Alfieri, ^{MD},
and Antonio Colombo, ^{MD}

Clinical Outcomes Using a New Crossover Balloon Occlusion Technique for Percutaneous Closure After Transfemoral Aortic Valve Implantation

Philippe Genereux, MD, Susheel Kodali, MD, Martin B. Leon, MD, Craig R. Smith, MD, Yanai Ben-Gal, MD, Ajay J. Kirtane, MD, SM, Benoit Daneault, MD, George R. Reiss, MD, Jeffrey W. Moses, MD, Mathew R. Williams, MD

New York, New York

Catheterization and Cardiovascular Interventions 81:579-583 (2013)

VALVULAR AND STRUCTURAL HEART DISEASES

Editor's Choice

A "Modified Crossover Technique" for Vascular Access Management in High-Risk Patients Undergoing Transfemoral Transcatheter Aortic Valve Implantation

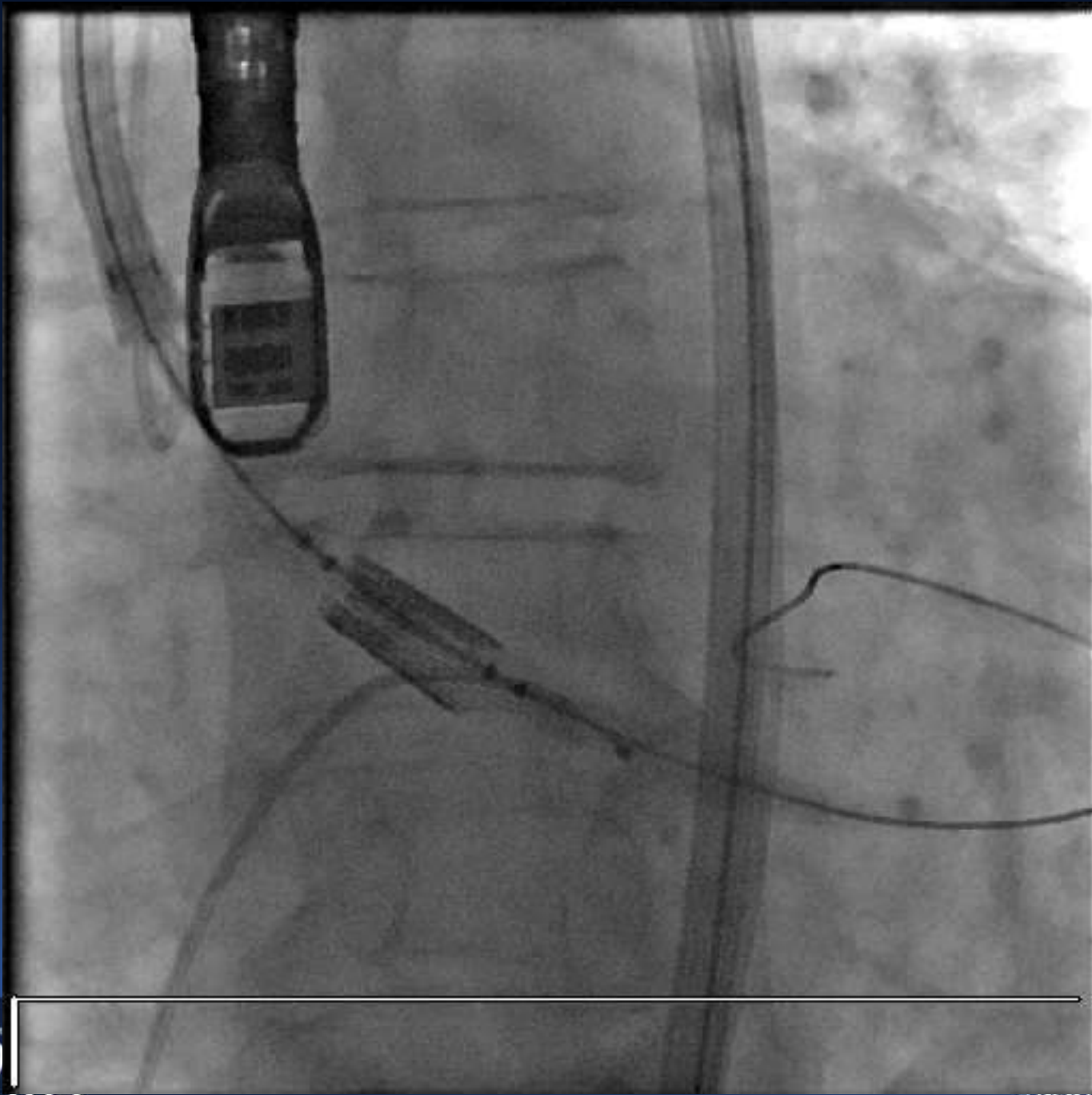
Gill Louise Buchanan, ^{MD, PhD}, Alaide Chieffo, ^{MD}, Matteo Montorfano, ^{MD},
Davide Maccagni, ^{MD}, Francesco Maisano, ^{MD}, Azeem Latib, ^{MD},
Remo Daniel Covello, ^{MD}, Antonio Grimaldi, ^{MD}, Ottavio Alfieri, ^{MD},
and Antonio Colombo, ^{MD}

















Summary: TAVR Complications Management

- Patient selection, increased operator experience and improved devices technology are key to prevent complications
- Pre TAVR imaging (CT, 3D TEE)
- Adjunctive technique helped to control and manage catastrophic situation
- Accessibility to *alternative access site*
 - TA vs. TAO vs. Sub-clavian
- Heart Team with knowledgeable and complementary members