Aortic Valvular Incompetence, Asymptomatic, EF 45%, Age 60 Years

From Medical Therapy to Surgical AVR To Transcatheter AVR? The *Interventionalist's View*

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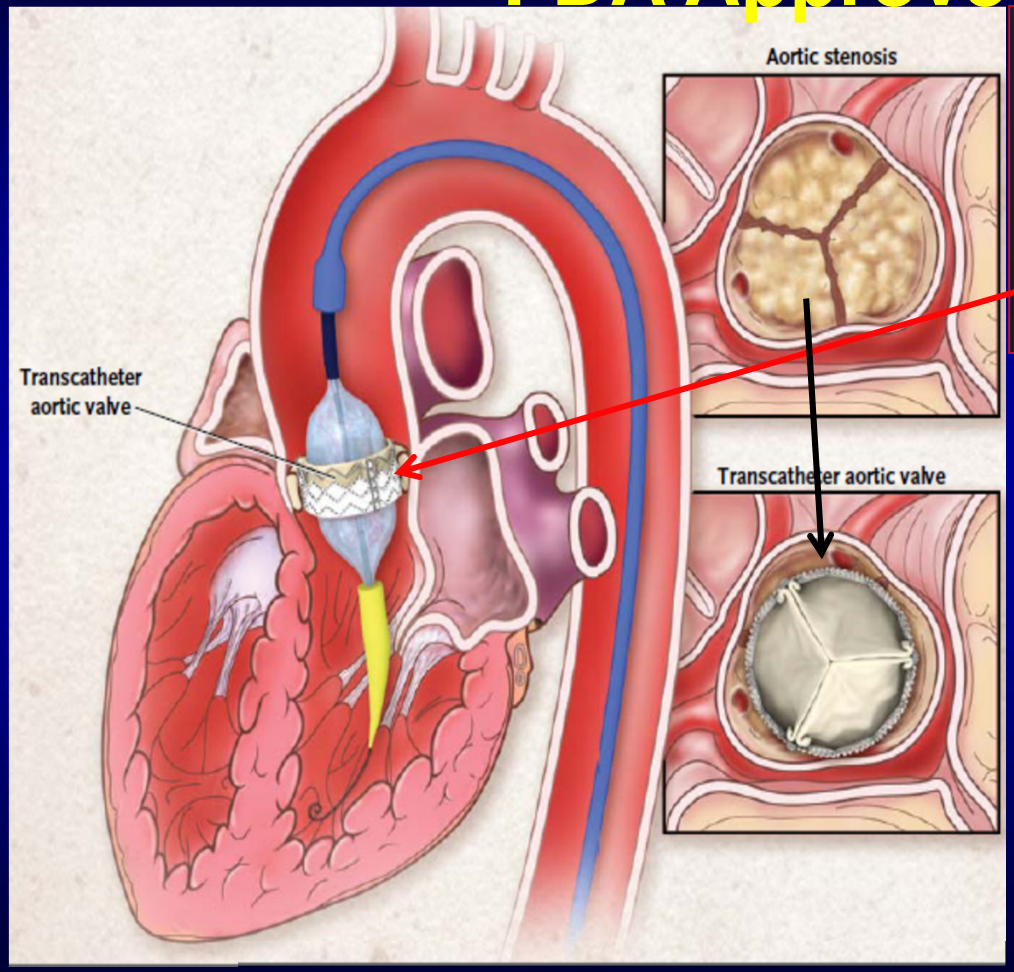
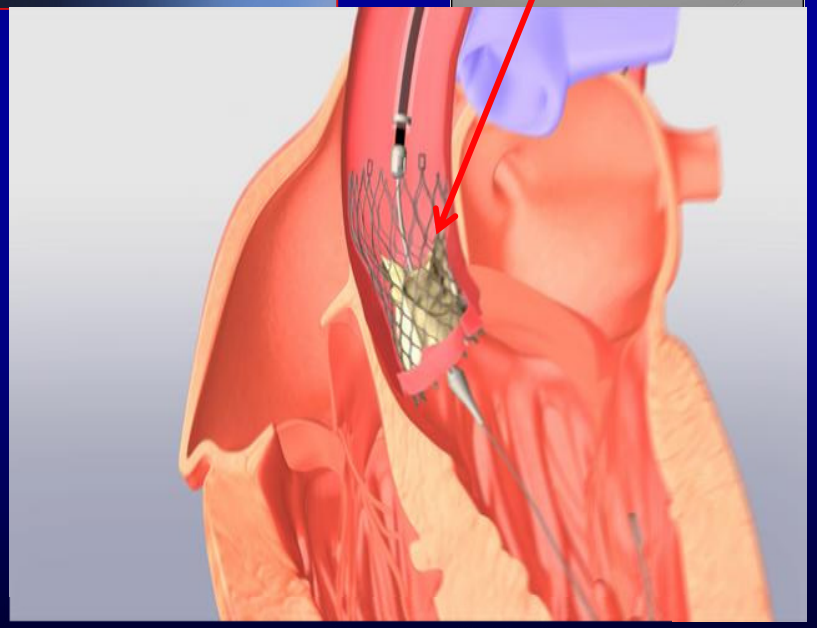
Director Clinical & Interventional Cardiology
Zena and Michael a Weiner Professor of Medicine
President Mount Sinai Heart Network
Mount Sinai Hospital, NY

Transcatheter Aortic Valves: FDA Approved Devices





Edwards-Sapien

CoreValve

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CLINICAL RESEARCH **Interventional Cardiology**

Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

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London and Brighton, United Kingdom; Tel Hashomer, Ramat-Gan, Israel; Bad Nauheim, Hamburg, and Leipzig, Germany; Toulouse, Lille, and Villeurbanne, France; Antwerp, Belgium; Pisa, Italy; Asturias, Spain; and Katowice, Poland

Results A total of 43 patients underwent TAVI with the CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) at 14 centers (mean age, 75.3 ± 8.8 years; 53% female; mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation), 26.9 ± 17.9%; and mean Society of Thoracic Surgeons score, 10.2 ± 5.3%). All patients had severe NAVR on echocardiography without aortic stenosis and 17 patients (39.5%) had the degree of aortic valvular calcification documented on CT or echocardiography. Vascular access was transfemoral (n = 35), subclavian (n = 4), direct

TAVI for Native Aortic Valve Regurgitation (N=43; All CoreValve)

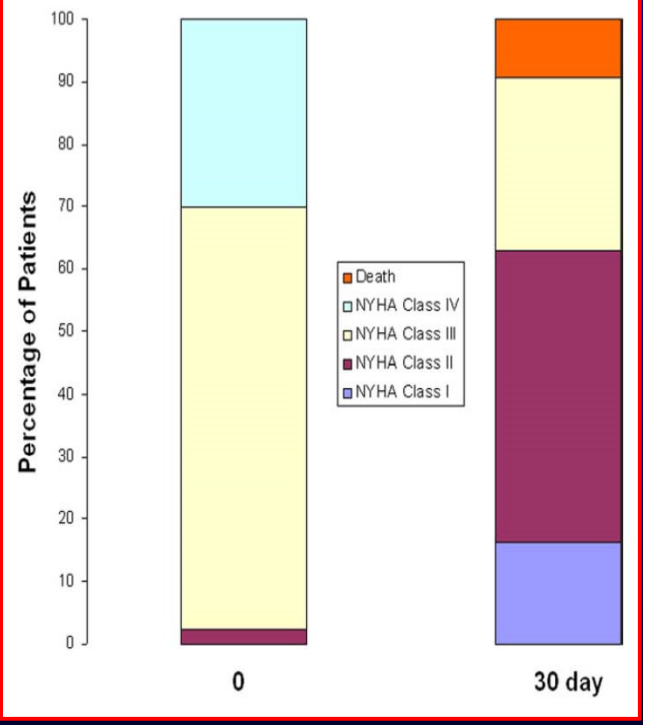
Procedural Results

Access	
Transfemoral	35 (81.4)
Subclavian	4 (9.3)
Direct aortic	3 (7.0)
Carotid	1 (2.3)
Implantation of prosthesis	42 (97.7)
Annulus size, mm	24.0 ± 2.3
Prosthesis size, mm	
29	22 (51.2)
26	14 (32.6)
31	7 (16.3)
Valve post-dilation	4 (9.3)
Second valve required	8 (18.6)
Post-procedure AR grade	
I or lower	34 (79.1)
II	7 (16.3)
III	2 (4.7)
New permanent pacemaker	7 (16.3)

Clinical and Safety Outcomes as per VARC

Mortality	
30-day all-cause	4 (9.3%)
30-day cardiovascular	1 (2.3%)
12 month all-cause	6/28 (21.4)
12-month cardiovascular	3/28 (10.7)
Major stroke (30 days)	2 (4.7)
Major bleeding	8 (18.6)
Acute kidney injury (stage 3)	2 (4.7)
Myocardial infarction	0
Access site complications	6 (14.0)
Major	3 (7.0)
Minor	3 (7.0)
VARC procedure success	32 (74.4)

NYHA Functional Status



Roy et al., JACC 2013;61:1577

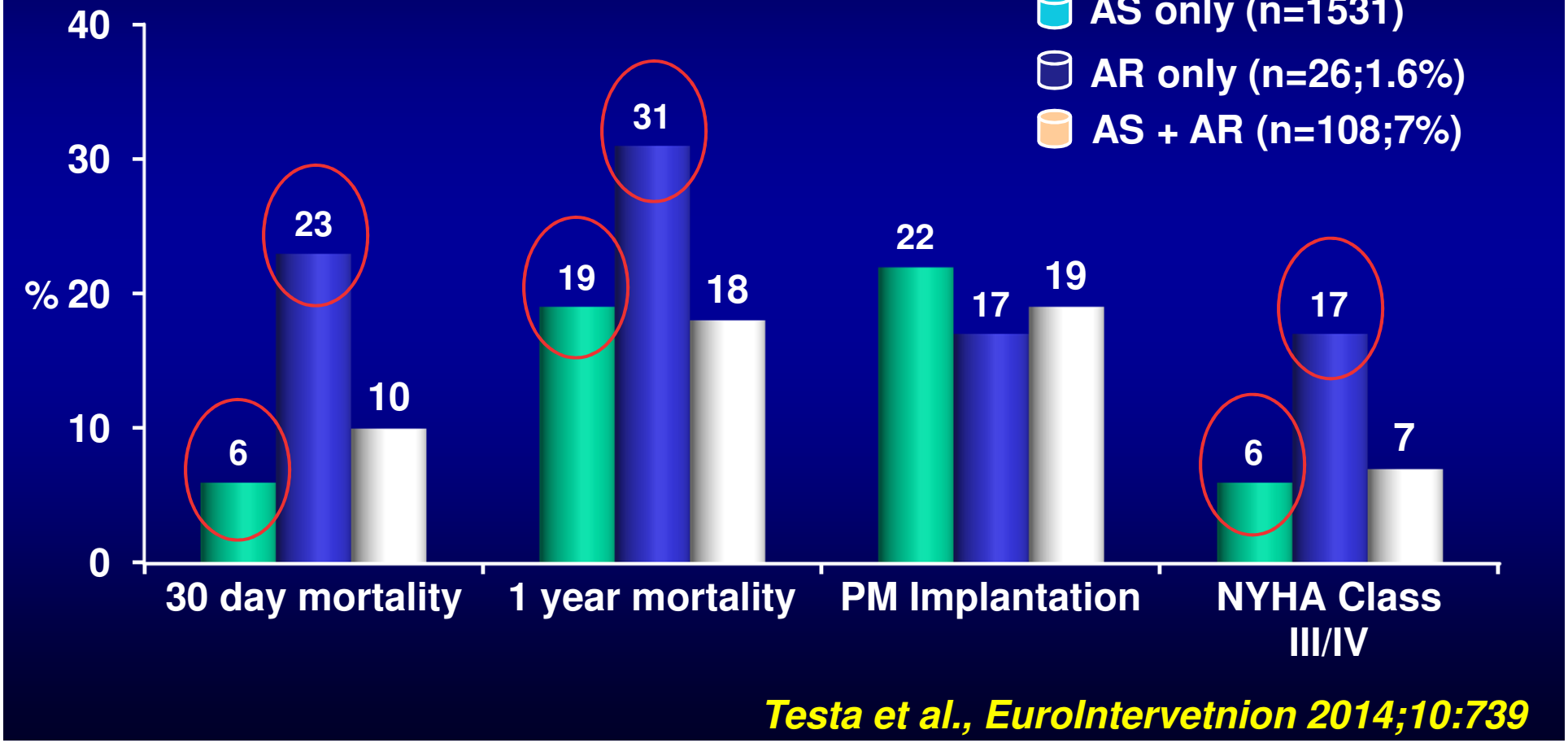
CLINICAL RESEARCH
INTERVENTIONS FOR STRUCTURAL HEART DISEASE

EuroIntervention 2014;10:739-745

CoreValve implantation for severe aortic regurgitation: a multicentre registry

Luca Testa[1]*, MD, PhD; Azeem Latib[2], MD; Marco Luciano Rossi[3], MD; Federico De Marco[4], MD; Marco De Carlo[5], MD; Claudia Fiorina[6], MD; Jacopo Oreglia[4], MD; Anna Sonia Petronio[5], MD; Federica Ettori[6], MD; Stefano De Servi[7], MD; Silvio Klugmann[4], MD; Gian Paolo Ussia[8], MD; Corrado Tamburino[8], MD; Paolo Panisi[1], MD; Nedy Brambilla[1], MD; Antonio Colombo[2], MD; Patrizia Presbitero[3], MD; Francesco Bedogni[1], MD

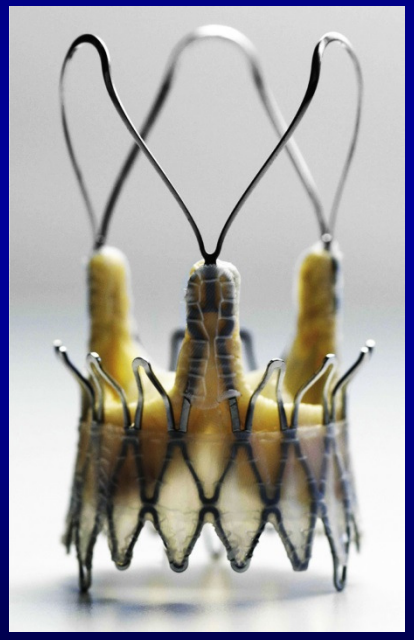
CoreValve Implantation for Severe AR: A Multicenter Registry



Testa et al., EuroIntervetnion 2014;10:739

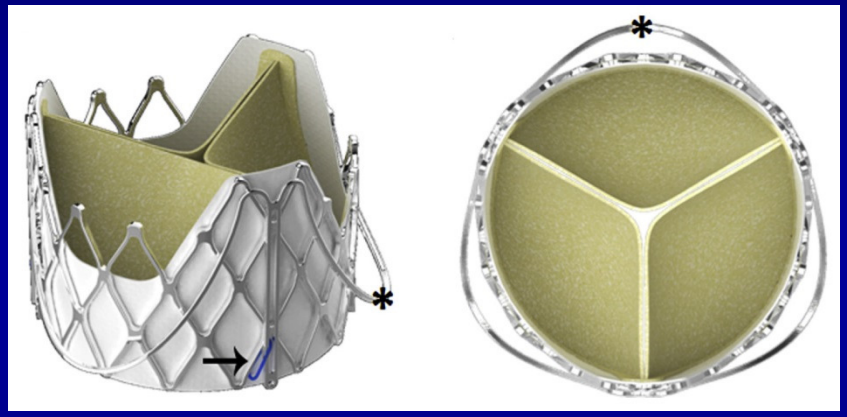
Transcatheter Aortic Valves

Self-Expabdable ACURATE TA Bioprosthesis



Wendt et al., J Am Coll Cardiol Intv 2014;7:1159

JenaValve™ Prosthesis



Kemfert et al., Eur J Cardiothoracic 2011;40:761

Engager™ Aortic Transcatheter Valve

Sündermann et al., Eur J Cardiothoracic 2012;42:e48

What if this 60yrs old AI pt gets Bio-prosthetic AV and could get TAVR Valve-in-Valve after 8-10 yrs for degenerative bio-prosthesis?

There is no clinical trial yet to answer this question

New TAVR Clinical Indications Valve-in-Valve

Mount Sinai Heart

Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

Transcatheter Aortic Valve Implantation for Failing Surgical Aortic Bioprosthetic Valve

From Concept to Clinical Application and Evaluation (Part 2)

Nicolo Piazza, MD,* Sabine Bleiziffer, MD,* Gernot Brockmann, MD,* Ruge Hendrick, MD,* Marcus-André Deutsch, MD,* Anke Opitz, MD,* Domenico Mazzitelli, MD,* Peter Tassani-Prell, MD, PHD,† Christian Schreiber, MD,* Rüdiger Lange, MD, PHD*

Munich, Germany

Piazza, MD et al., JACC 2011;4:733

Valve in Valve TAVI

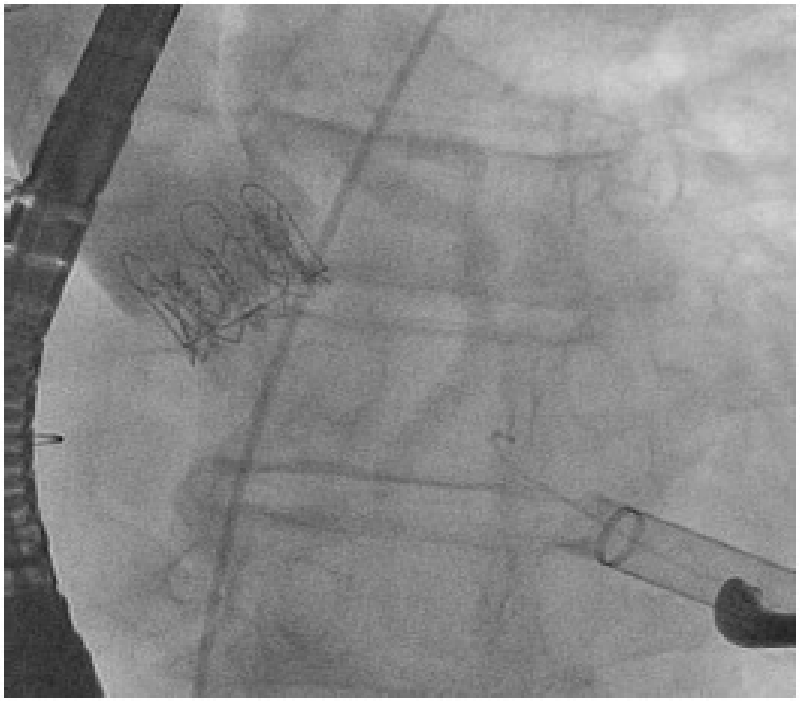


Figure 1. Post-Procedural Result of TA Viv-TAVI Using the Balloon-Expandable Edwards Sapien Valve

Viv-TAVI was performed for a failed Carpentier Edwards bioprosthesis. TA = transapical; TAVI = transcatheter aortic valve implantation; Viv = valve-in-valve.

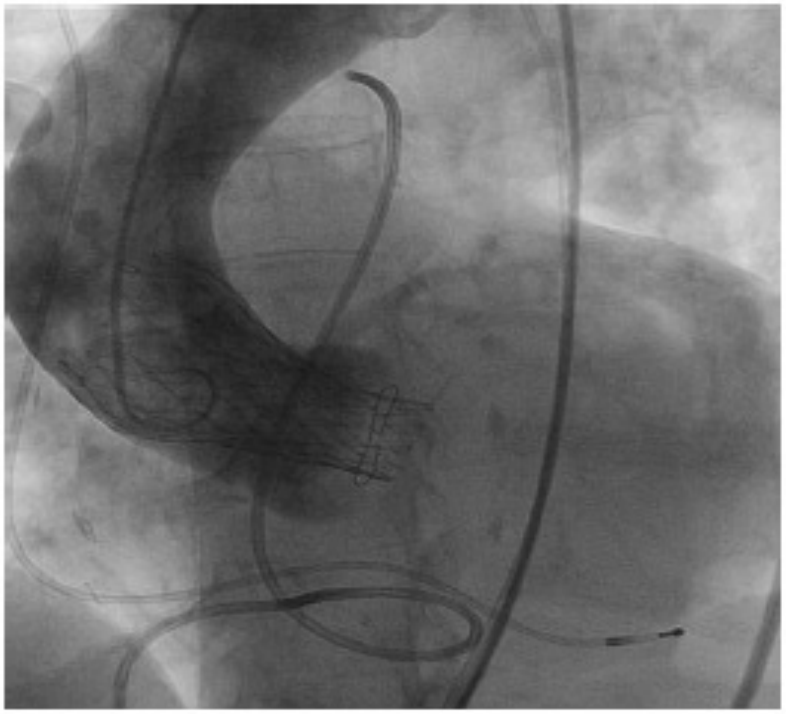


Figure 3. Post-Procedural Result of TF Viv-TAVI Using the Self-Expandable Medtronic CoreValve Revalving System

Viv-TAVI was performed for a failed Mitroflow bioprosthesis (Sorin Group, Milan, Italy). TF = transfemoral; other abbreviations as in Figure 1 (Online Video 1).

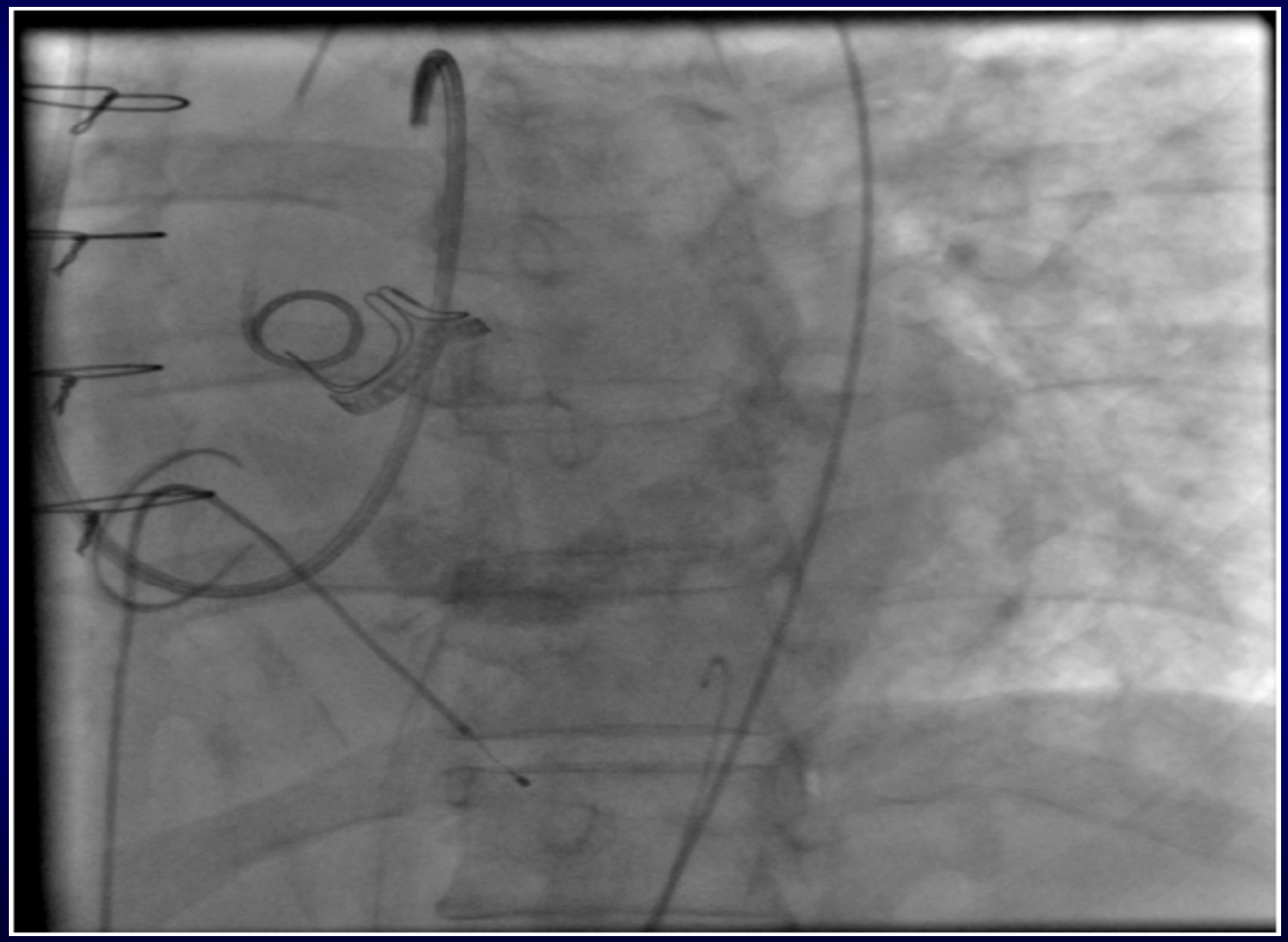
Eggebrecht et al., JACC 2011;4:1218

Treatment choice in a 78 Yr old pt for Class III CHF symptoms with prior Bioprosthetic AV 12 yrs ago & now severe AS with 42 mmHg mean gradient and moderate AI

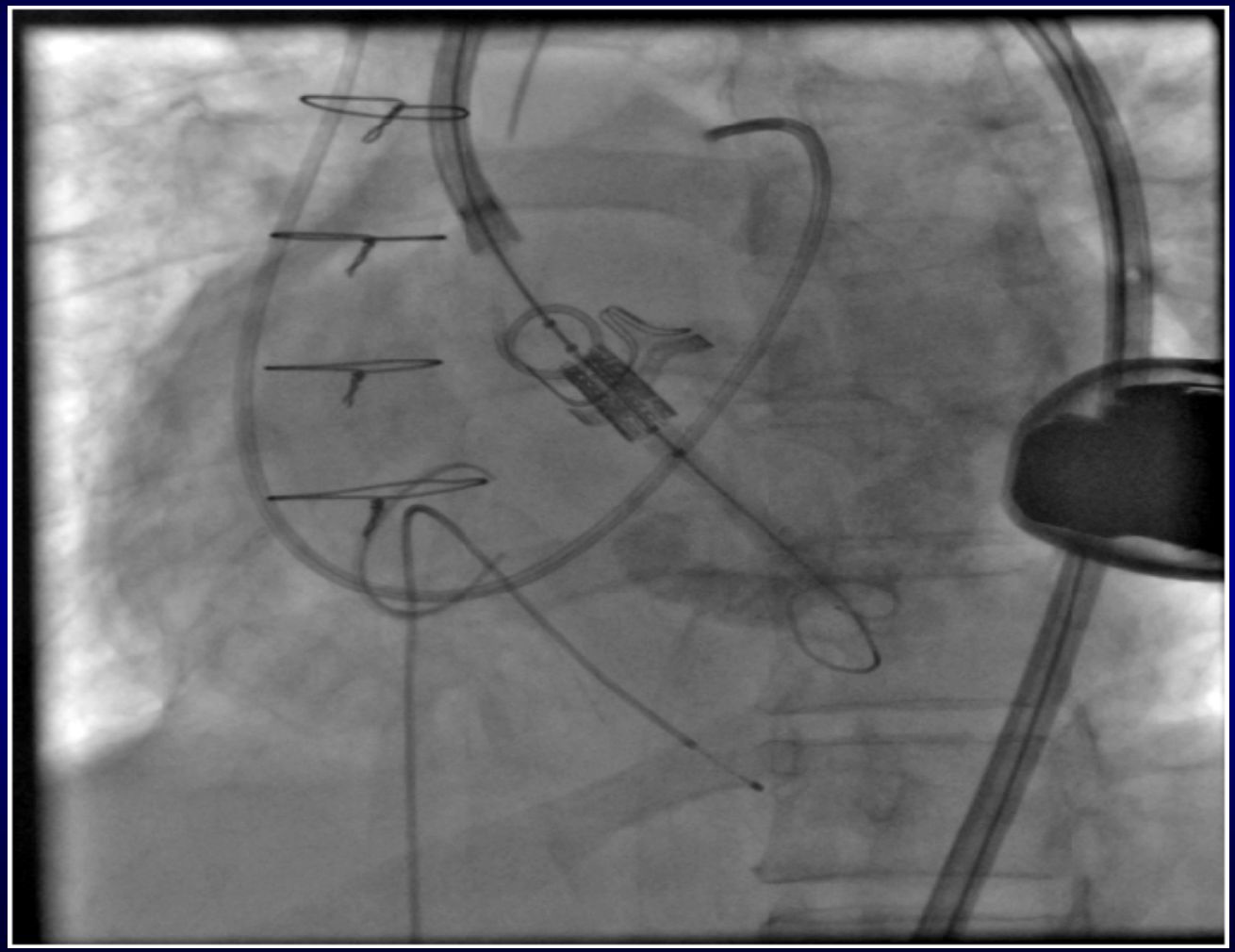
Risk Summary:
STS Score:
2.8% mortality
4.2% morbidity/mortality

Pt had low STS risk (<3) score and hence conventional redo-SAVR is indicated but pt had severe COPD (FEV1 48% predicted and hence underwent TAVR using 23mm Sapien XT without any complications and residual aortic gradient of 18 mmHg and AVA of 1.4cm2. No redo surgery needed and discharged home in 3 days

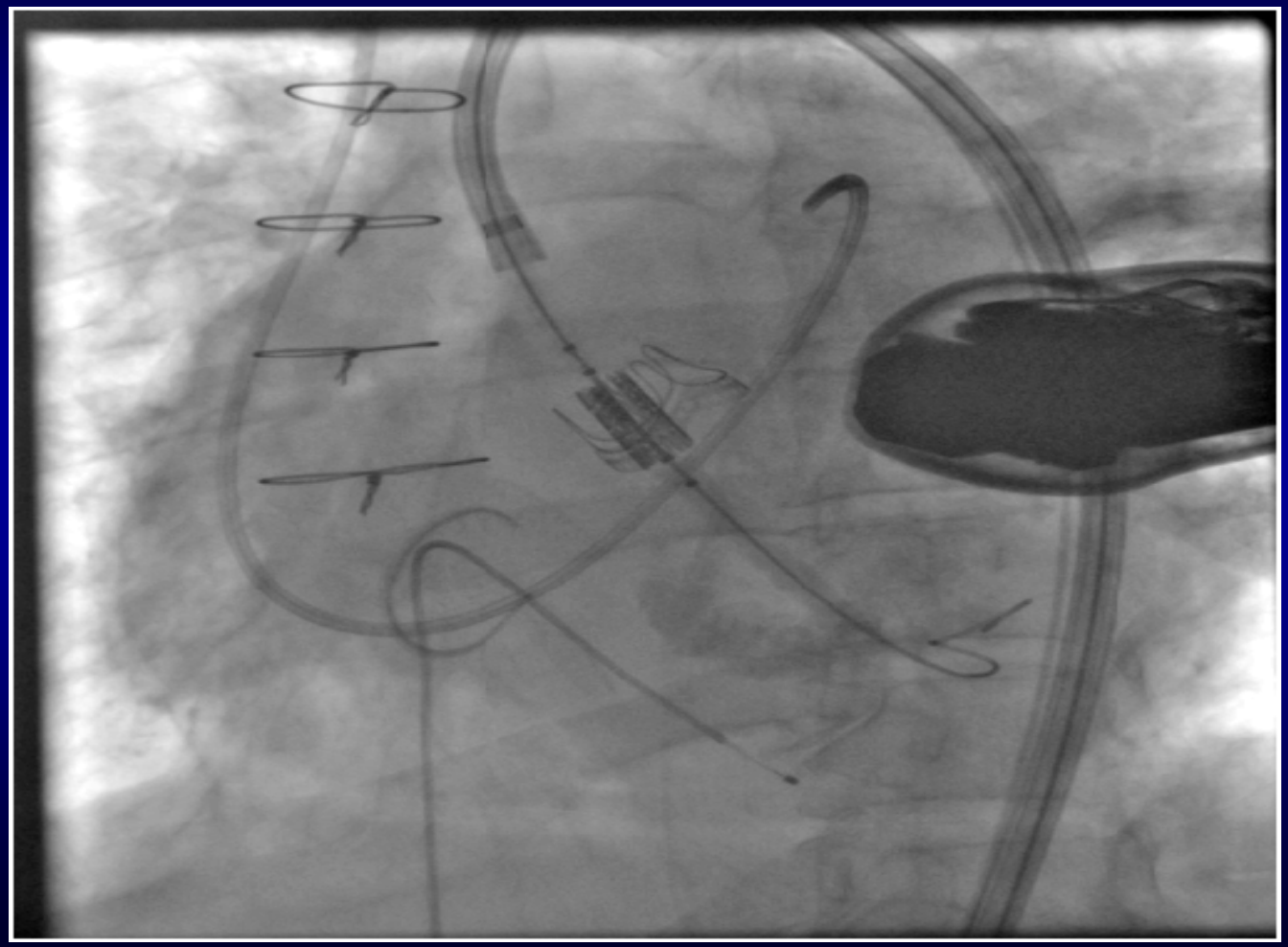
Valve-in-Valve for Bio-Prosthetic AS



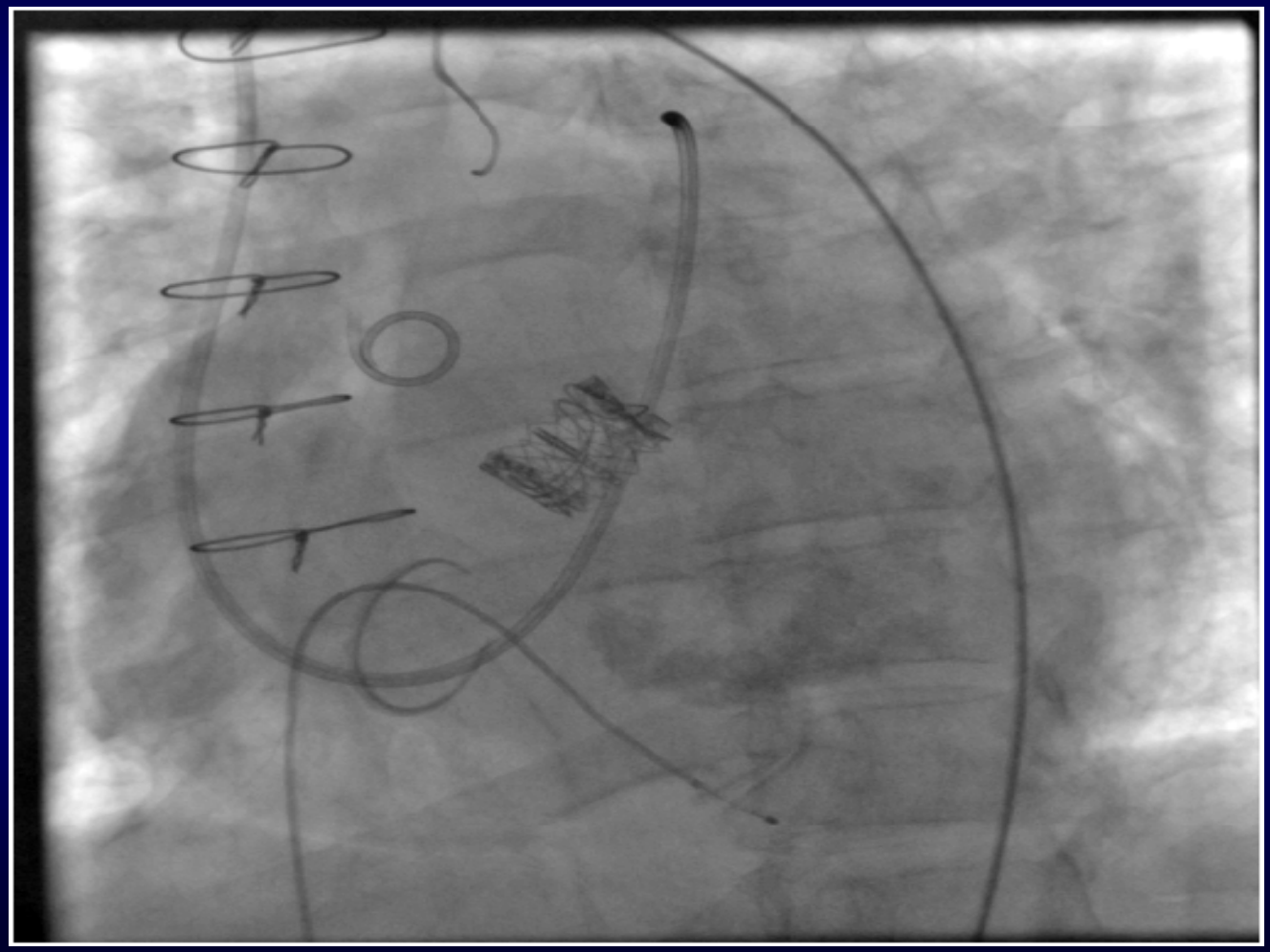
Valve-in-Valve for Bio-Prosthetic AS



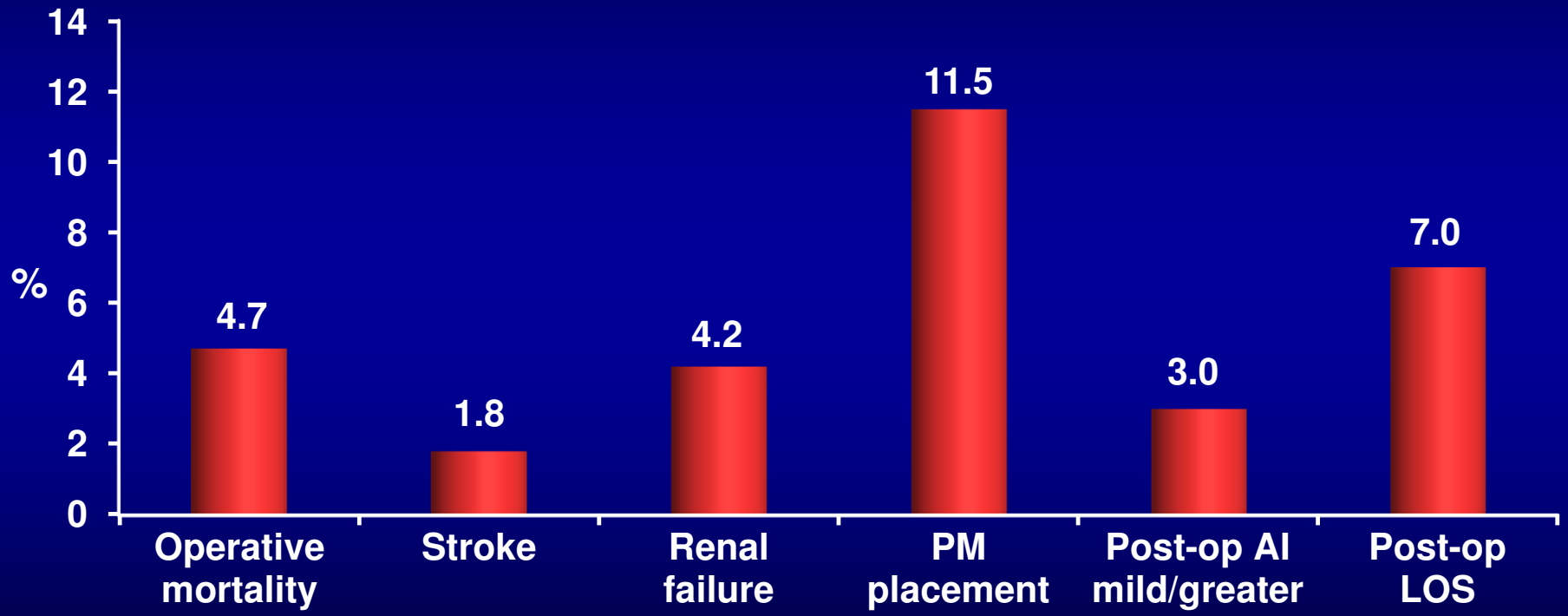
Valve-in-Valve for Bio-Prosthetic AS



Valve-in-Valve for Bio-Prosthetic AS



Postoperative Outcome for Bioprosthetic Valve Explanted (n=2,213)



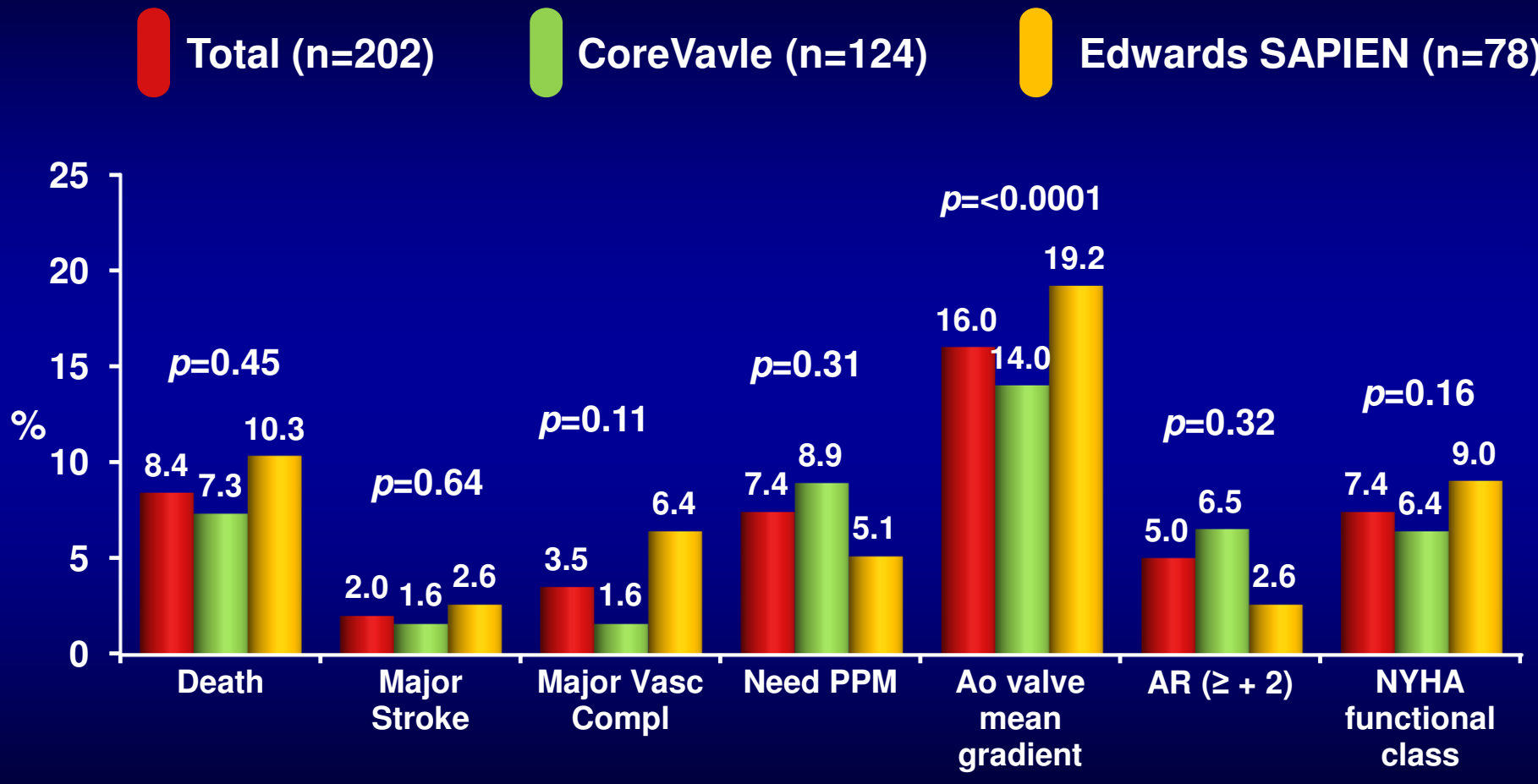
Kaneko et al., Ann Thorac Sur 2015;100:1298

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves: Results From the Global Valve-in-Valve Registry

Danny Dvir, John Webb, Stephen Brecker, Sabine Bleiziffer, David Hildick-Smith, Antonio Colombo, Fleur Descoutures, Christian Hengstenberg, Neil E. Moat, Raffi Bekeredjian, Massimo Napodano, Luca Testa, Thierry Lefevre, Victor Guetta, Henrik Nissen, José-María Hernández, David Roy, Rui C. Teles, Amit Segev, Nicolas Dumonteil, Claudia Fiorina, Michael Gotzmann, Didier Tchetche, Mohamed Abdel-Wahab, Federico De Marco, Andreas Baumbach, Jean-Claude Laborde and Ran Kornowski

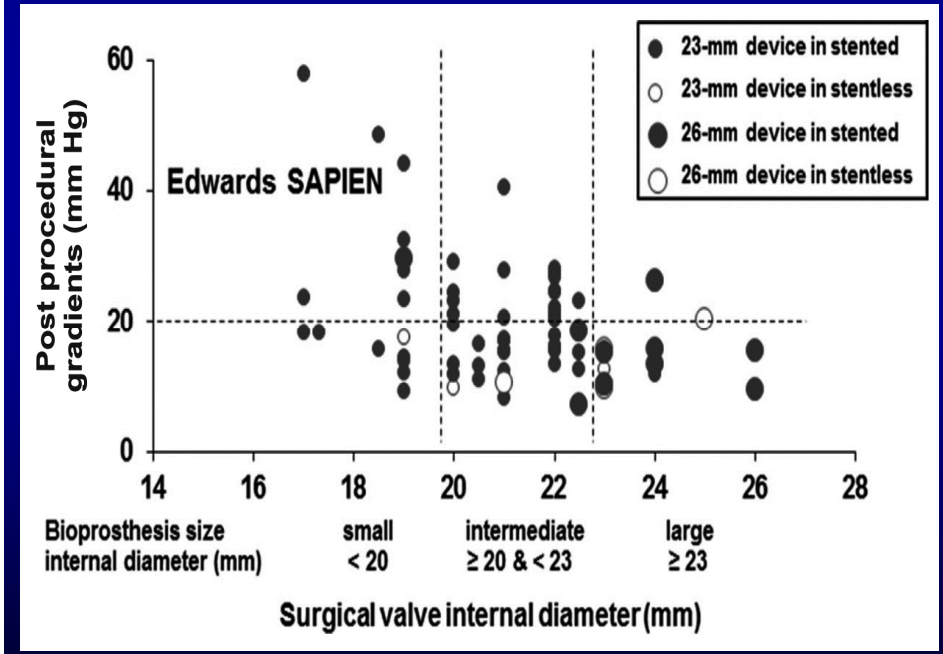
Procedural Characteristics and Early Results



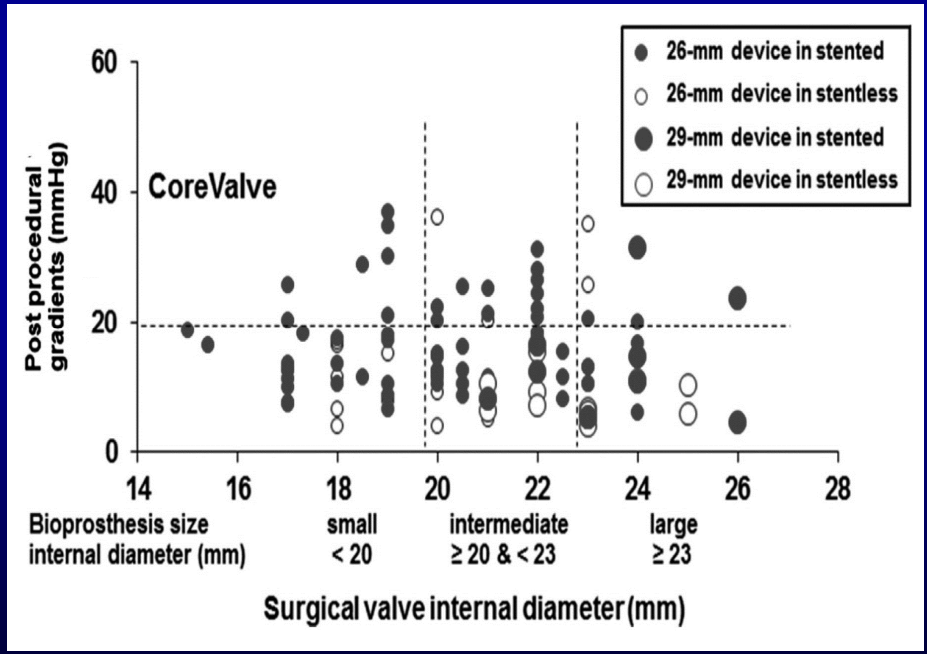
Dvir et al., Circulation 2012;126:2335

Analysis of High Post-procedural Gradients After Valve-in-Valve Procedure

Mean gradients after Edwards SAPIEN procedures – bioprosthesis size (r = 0.35, p = 0.28)



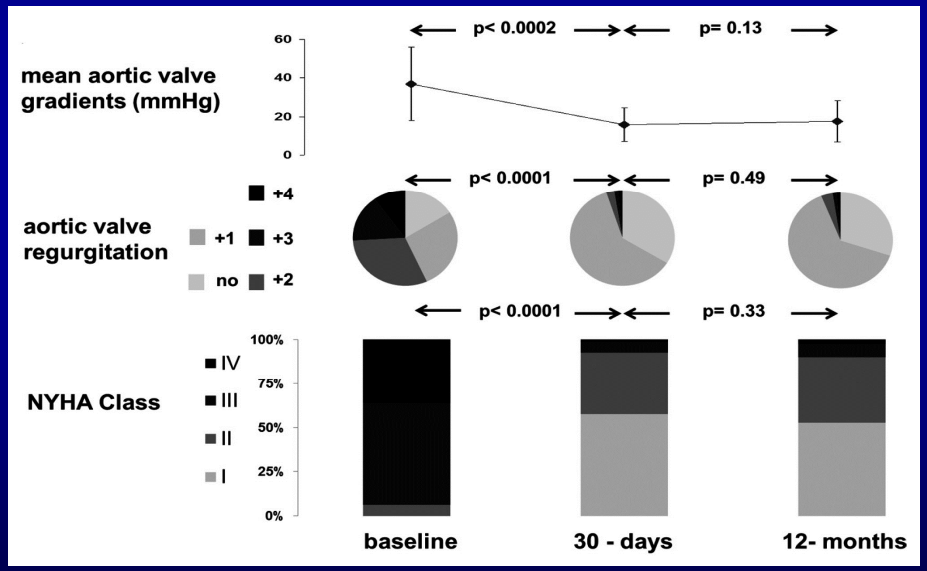
Mean gradients after CoreValve procedures – bioprosthesis size (r = 0.08, p = 0.40)



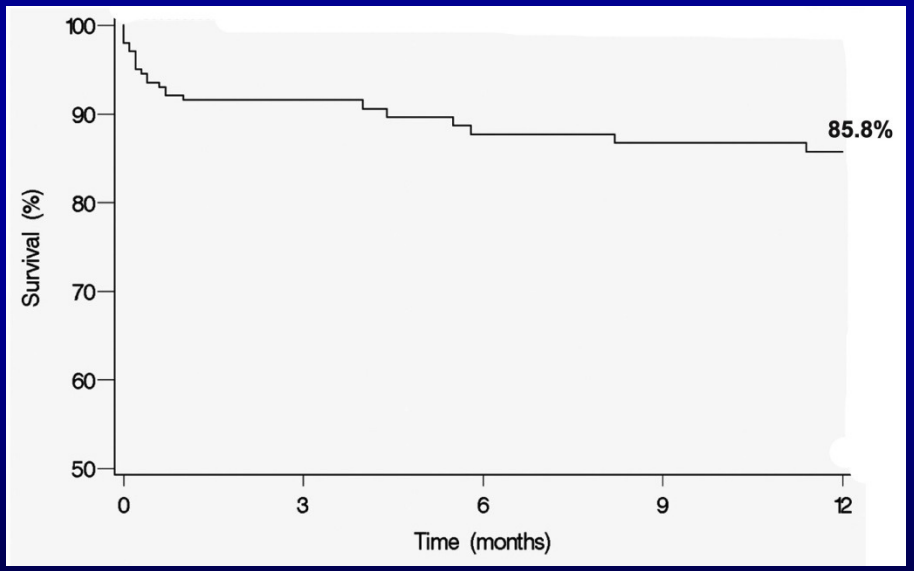
Dvir et al., Circulation 2012;126:2335

Clinical Results of Pts Undergoing TAVR for Degenerative Bioprosthetic Valves (VIV)

Clinical Hemodynamic Results



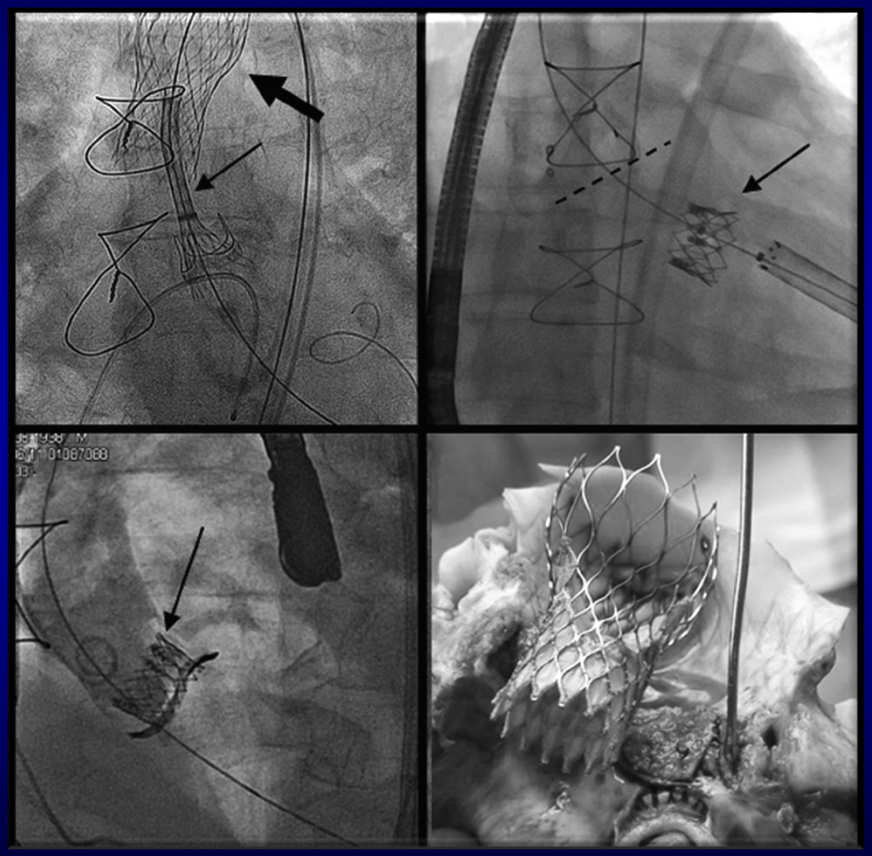
Kaplan-Meier Survival Curve



Dvir et al., Circulation 2012;126:2335

Case Examples of Device Malposition and Ostial Coronary Obstruction During Aortic VIV Implantations

CoreValve embolization during implantation inside a Perimount valve (thick arrow) followed by delivery of 2nd CoreValve in a correct position (thin arrow)



Edwards SAPIEN XT (arrow) dives into left ventricle during TA – implantation in a Mosaic valve (dotted line target for implantation); device reimplanted after conversion to open cardiac surgery.

TA-Edwards SAPIEN implantation in Mitoflow 25 mm device; surgical bioprosthetic valve leaflet (arrow) obstructing left coronary ostium

TF-CoreValve implantation in a Freedom stentless surgical bioprosthesis.

Dvir et al., Circulation 2012;126:2335

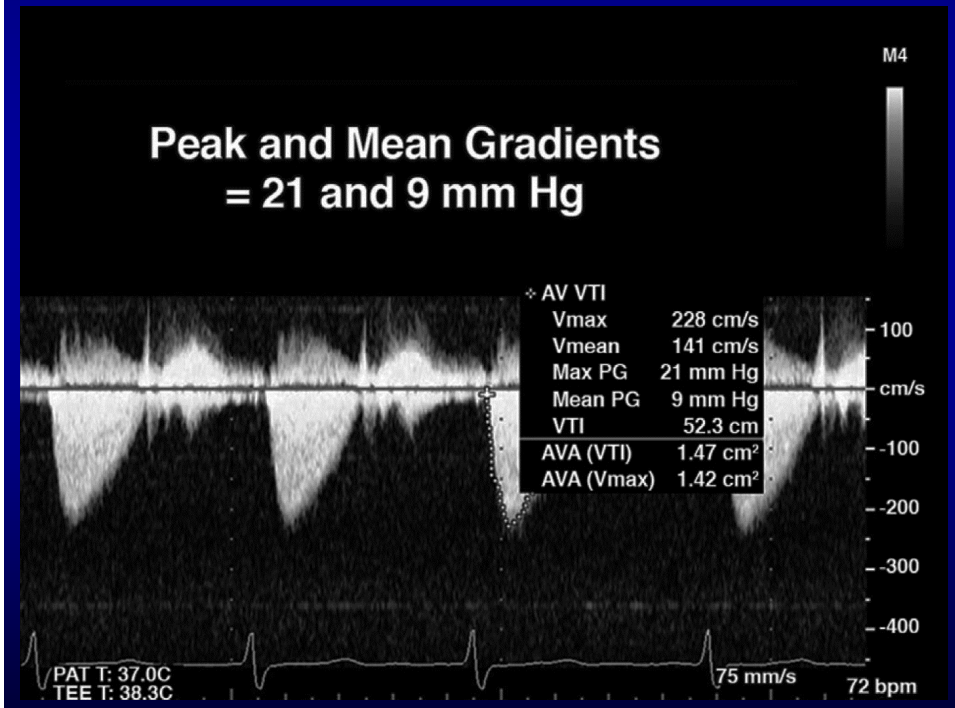
Adverse events Reported with Aortic Valve-in-Valve Procedures for Failed Bio-prosthesis

Risk Profile	Adverse Event
Lower risk than in native TAVR	Significant perivalvular leak Tamponande Annular rupture Aortic dissection Conduction defect
Higher risk than in native TAVR	Device malfunction Ostial coronary occlusion Elevated post-procedural gradients

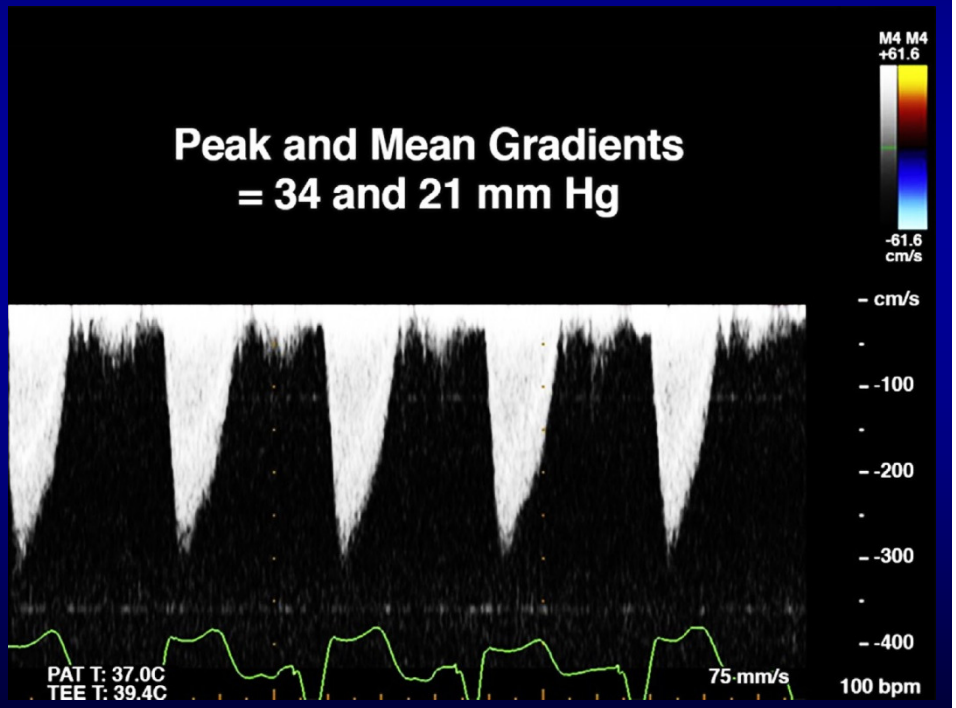
Hamid et al., J Am Coll Cardiol Img 2015;8:960

Continuous-Wave Doppler After Valve-in-Valve

#23 2nd Generation Balloon Expandable Valve for Stenotic 23-mm Bioprosthesis (Mosaic)
Calculated EOA of 1.5 cm^2



#23 Self-Expanding Valve for Stenotic 19-mm Bioprosthesis (Epic)
Calculated EOA of 1.1 cm^2



Hamid et al., J Am Coll Cardiol Img 2015;8:960

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Transcatheter Aortic Valve Implantation for Stenosed and Regurgitant Aortic Valve Bioprostheses

CoreValve for Failed Bioprosthetic Aortic Valve Replacements

Muhammed Z. Khawaja, MBBS,* Peter Haworth, MBBS,* Azad Ghuran, MBChB, MD,* Lorraine Lee, BSE,* Adam de Belder, MD,* Neville Hutchinson, MD,* Uday Trivedi, MBBS,* Jean-Claude Laborde, MD,† David Hildick-Smith, MD*

Brighton, United Kingdom; and Toulouse, France

Transcatheter aortic valve implantation is increasingly being used to treat severe aortic stenosis in patients with high operative risk. In an aging population the incidence of aortic stenosis is rising, and increasing numbers of elderly patients are undergoing aortic valve replacement with bioprosthetic valves. Therefore, there is a corresponding increase in prosthetic degeneration. This presents cardiologists with a cohort of patients for whom the risk of re-do aortic valve surgery is prohibitive. We present the first series of such patients with degenerative bioprosthetic stenosis or regurgitation successfully treated with CoreValve (Medtronic, Luxembourg) implantation. (J Am Coll Cardiol 2010;55:97–101) © 2010 by the American College of Cardiology Foundation

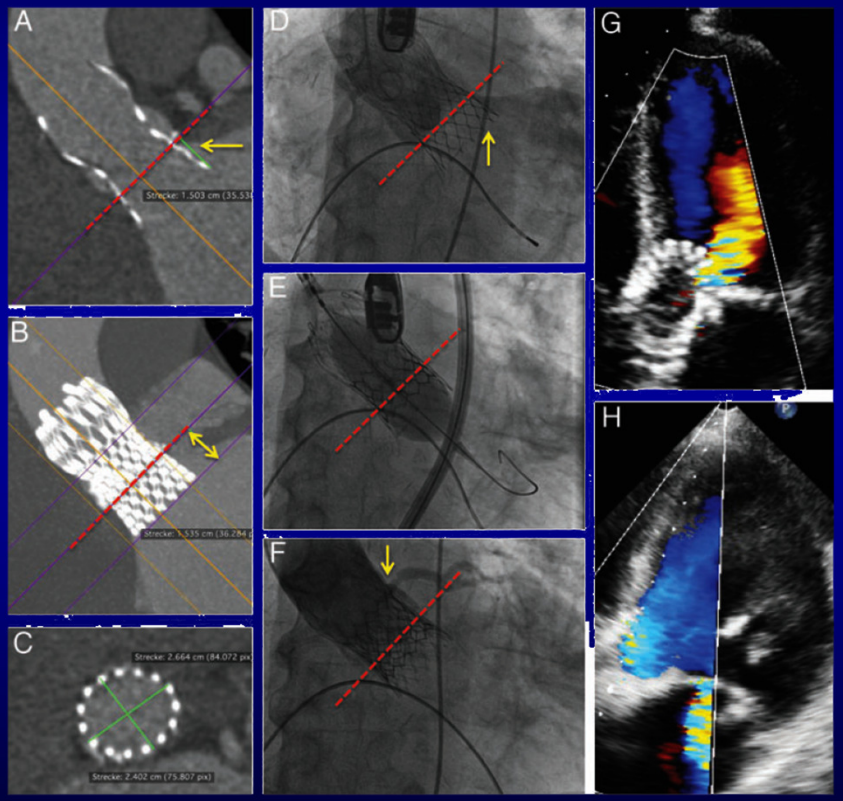
Vavle-in-Valve Transfemoral TAVR: Sapien 3 Valve within a Failed CoreValve Bioprosthesis

A. Longitudinal CT image – 29 mm CoV implanted 15 mm below the annulus (red line)

B. CoV skirt is 3 mm below the annulus and 12 mm from distal edge

C. Inadequately deployed CoV

D. High degree AI jet through the paravalvular gap noted on angiogrpaphy



E. 26 mm S3 valve deployed with placement of its outer skirt above CoV gap

F. S3 valve was placed slightly below the LM to avoid double stent layer at the LM coronary ostium

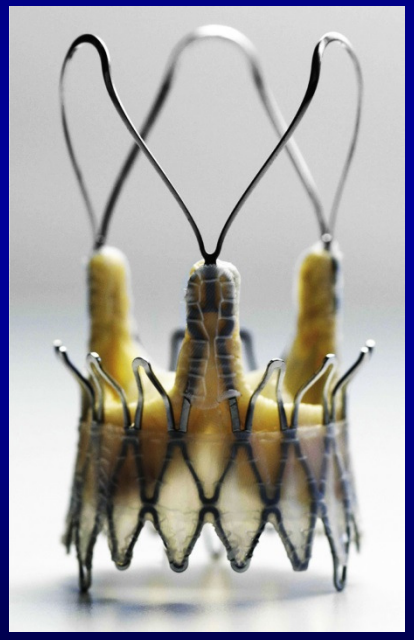
G. High degree, eccentric AI as noted on echo before the S3 valve implant

H. Eccentric AI successfully reduced to an insignificant AI post-procedure

Shivaraju et al., Eur Heart J Ahead-of-Print June 30, 2014

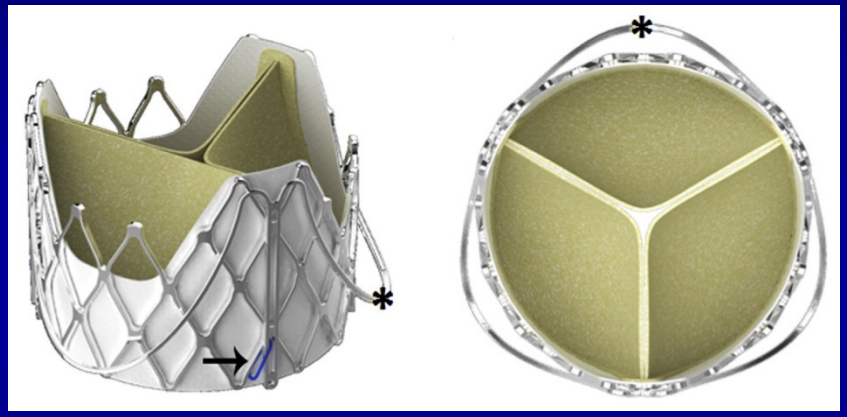
Transcatheter Aortic Valves

Self-Expabdable ACURATE TA Bioprosthesis



Wendt et al., J Am Coll Cardiol Intv 2014;7:1159

JenaValve™ Prosthesis



Kemfert et al., Eur J Cardiothoracic 2011;40:761

Engager™ Aortic Transcatheter Valve

Sündermann et al., Eur J Cardiothoracic 2012;42:e48