TAVR 2015

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Professor of Medicine

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Cleveland Clinic

Outline

- **Aortic Stenosis**
  - **TAVR**
    - **Who should be considered for TAVR**
    - **What are the treatment options?**
      - **Valves, Approaches**
    - **What to expect, Follow up**
  - **BAV**
    - **Current indications**

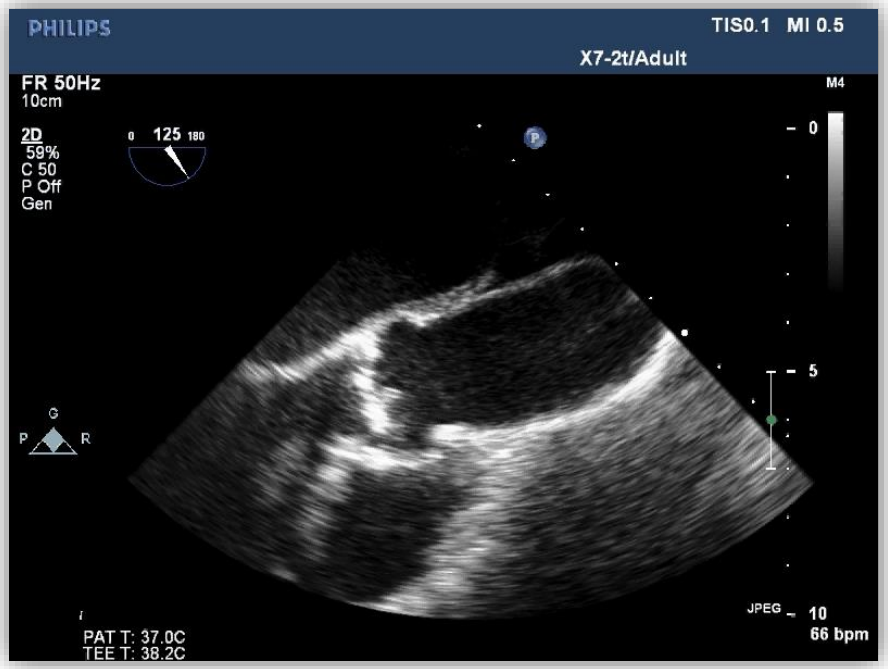
What is new and here?

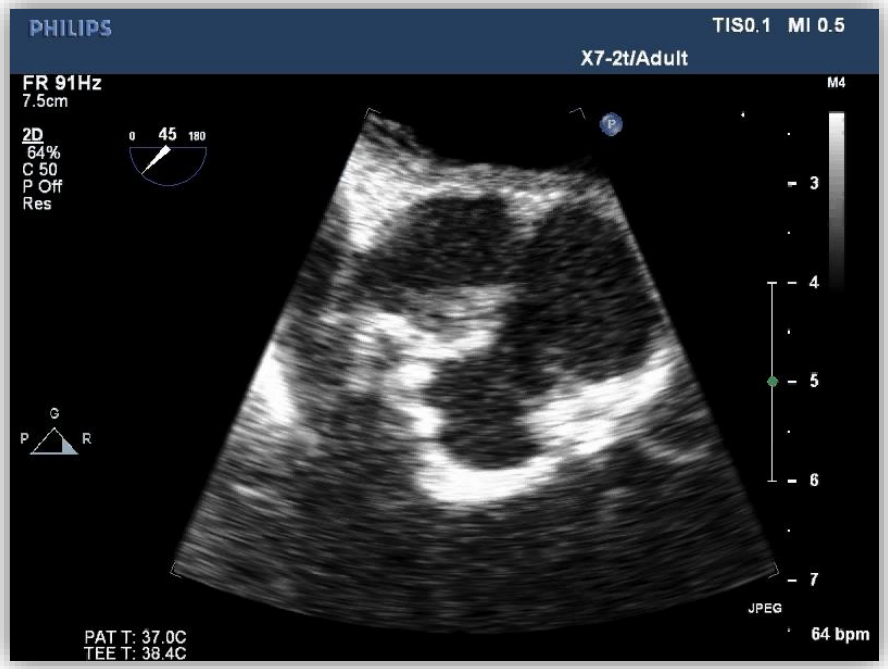
Emboli prevention
Appendage occlusion

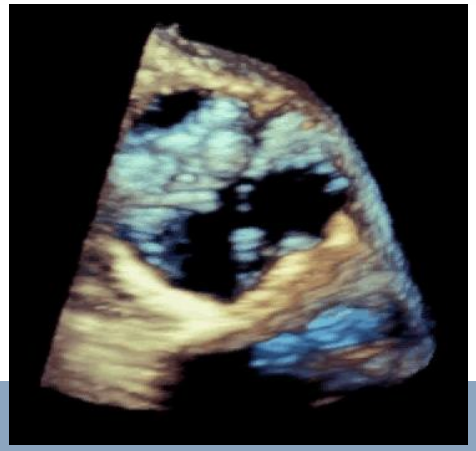
Aortic Stenosis

- 75 year old patient
- No prior cardiac history
- Presents with shortness of breath with exertion
- No CP
- No lightheadedness
- O/E BP 120/80, HR 90
- No JVD
- S1 normal A2 not heard, late peaking systolic murmur
- No edema
- Lungs clear

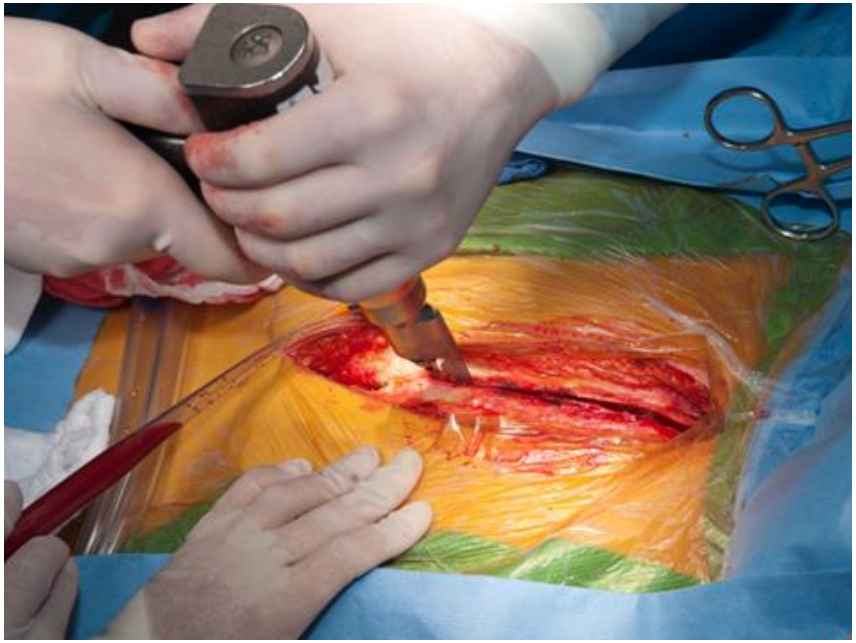
Echocardiography





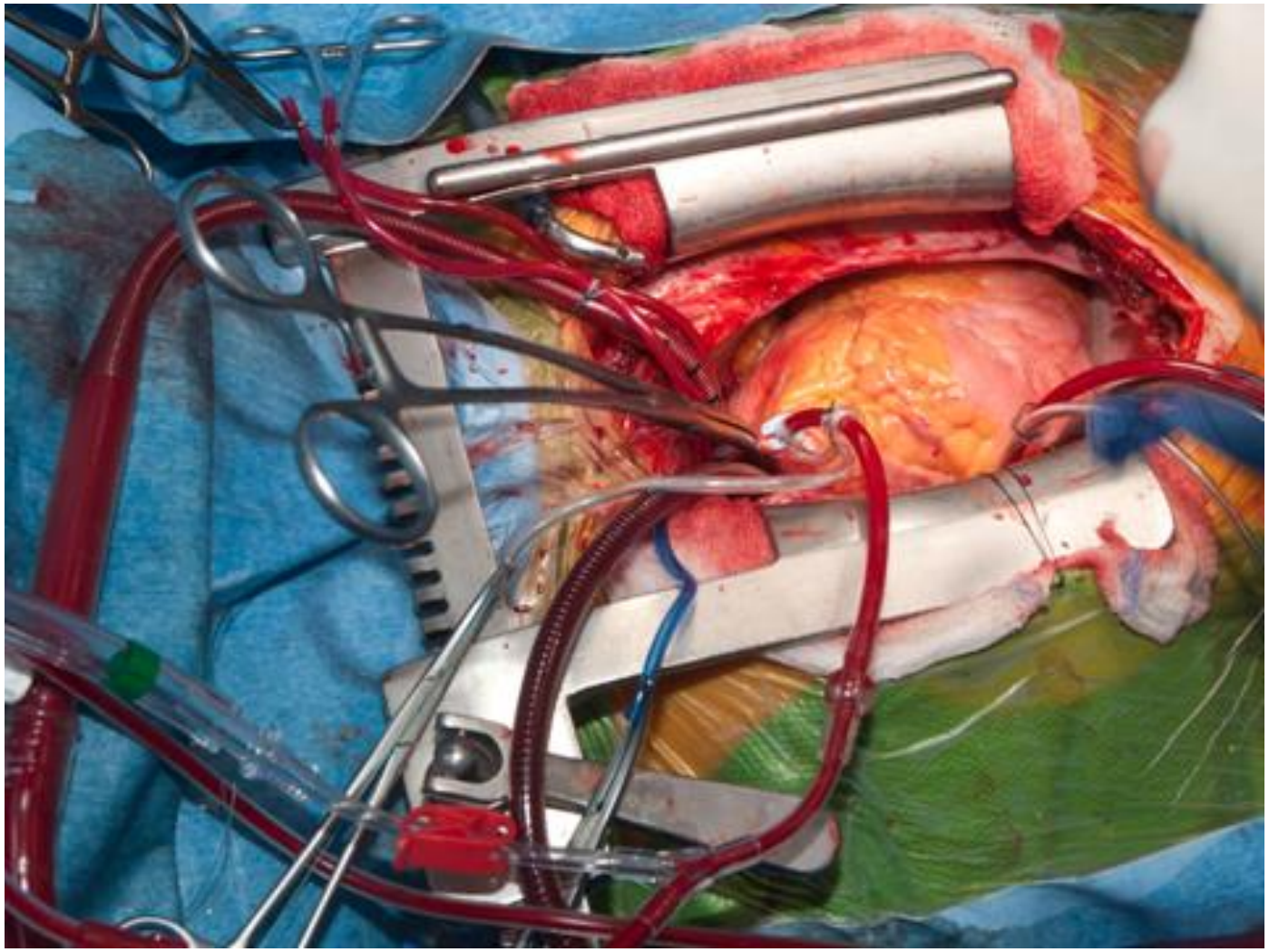


Sternotomy

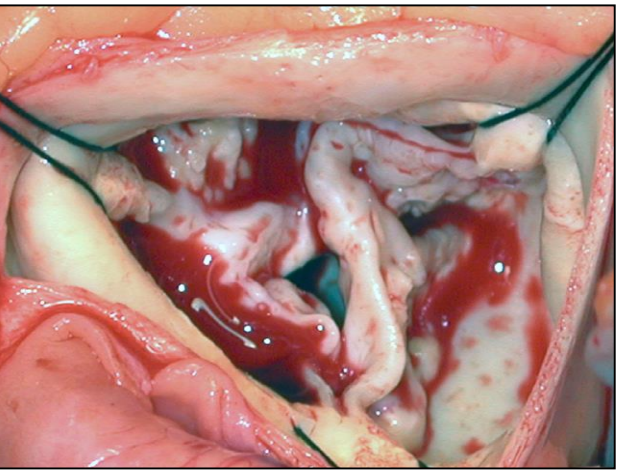
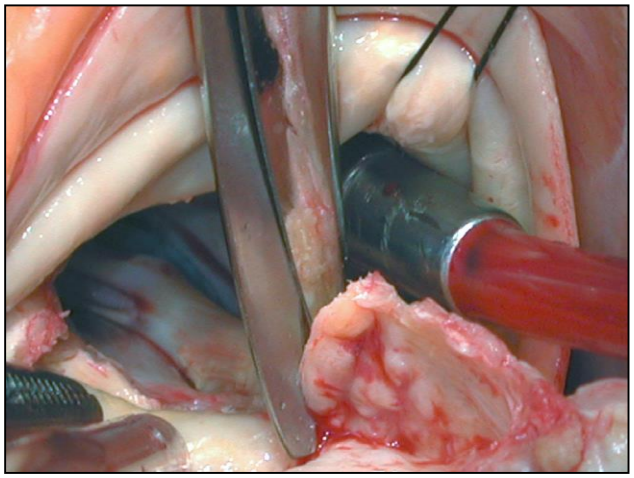
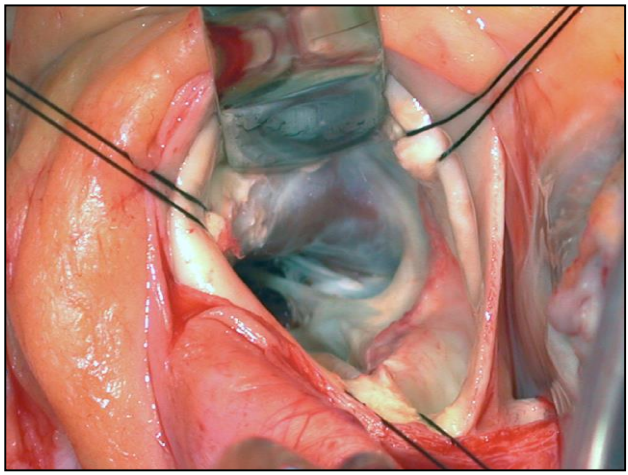
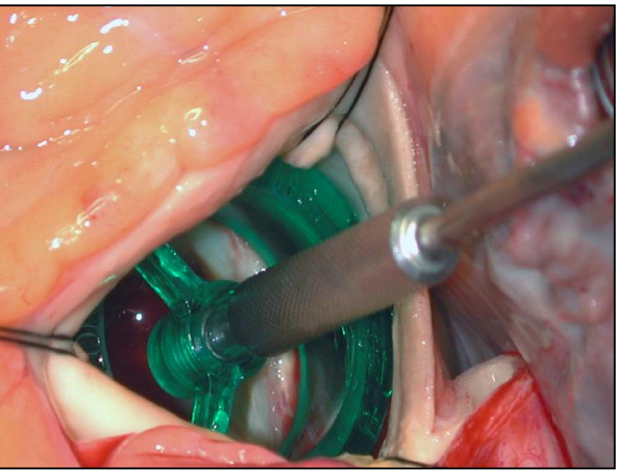
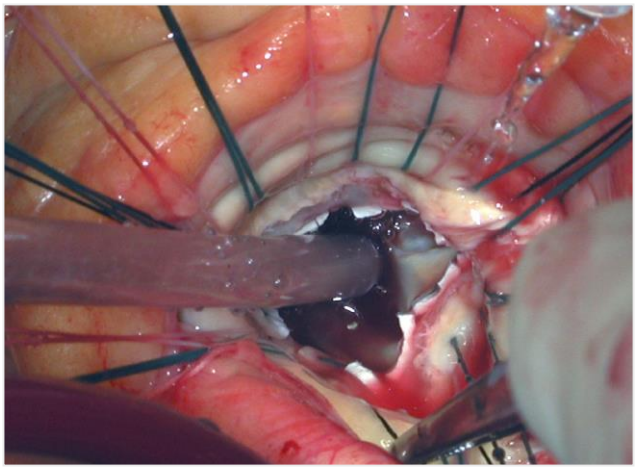
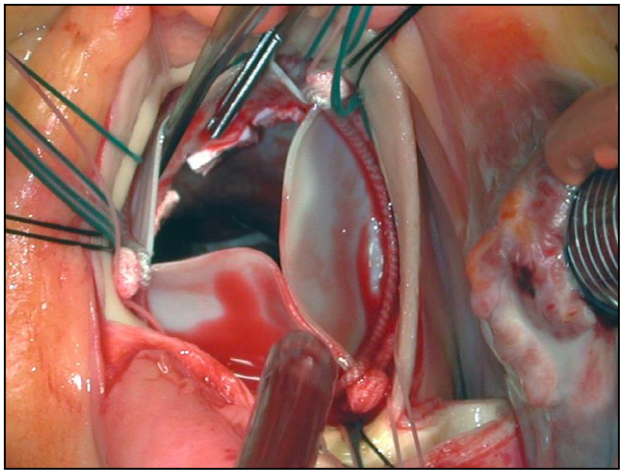


Courtesy Dr. Mick

Aorta Cross-clamped



Surgical Aortic Valve Replacement

Courtesy of Dr. Gosta Pettersson

Surgical AVR

Clinical Presentation

- 88 yr old, male Ht:171.5cm Wt: 70.1kg BMI: 23
- NYHC III
- HTN, CAD, A fib
- Mild CAD
- Former Smoker- Quit 1973
- Hb:12.3 Ht: 37.1
- FEVI: 1.5 L
- Cr 1.8
- EF 45%
- AVA 0.7, peak gradient 64, mean gradient 40 mm

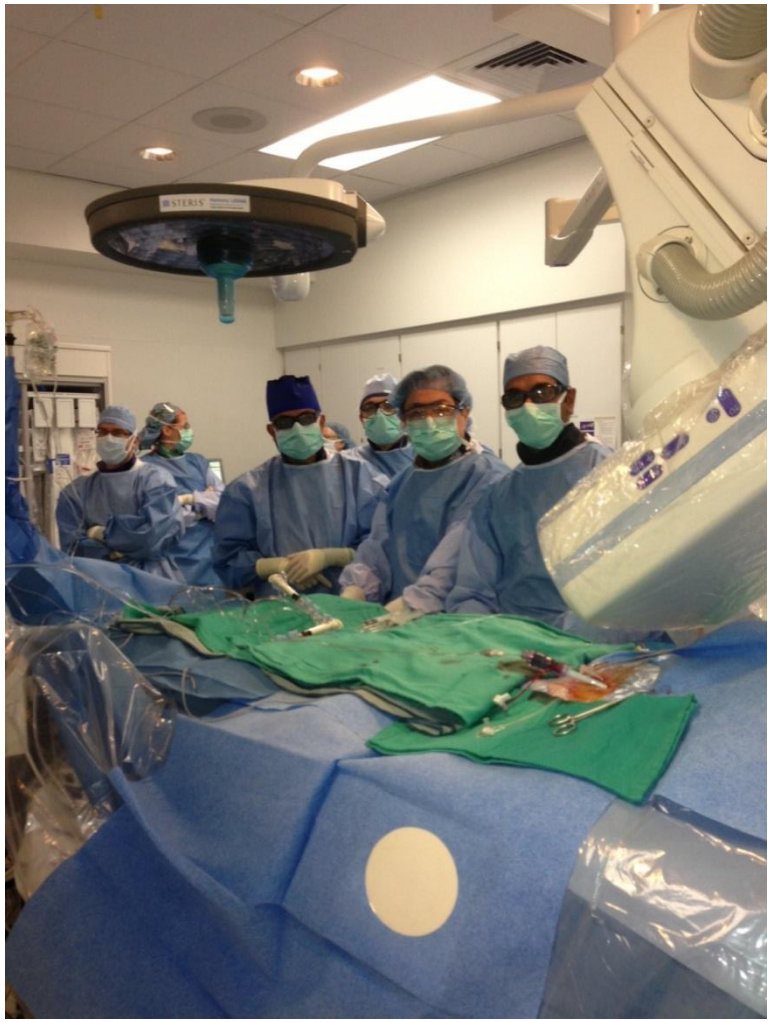
- STS score 8

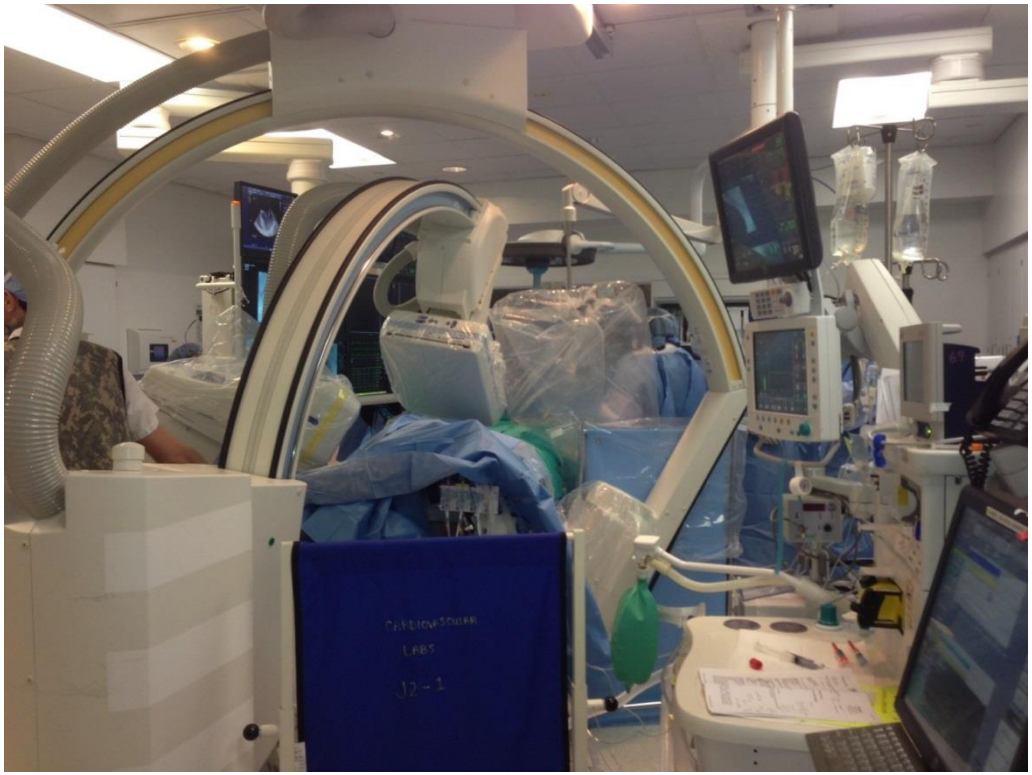
Planning : Heart Team

Cardiologist – Surgeon Collaboration

- Co-leadership
- Continuous and open communication
- Early conflict resolution
- Consensus building
- Shared resources
- Shared credits
- Great facility

Setup





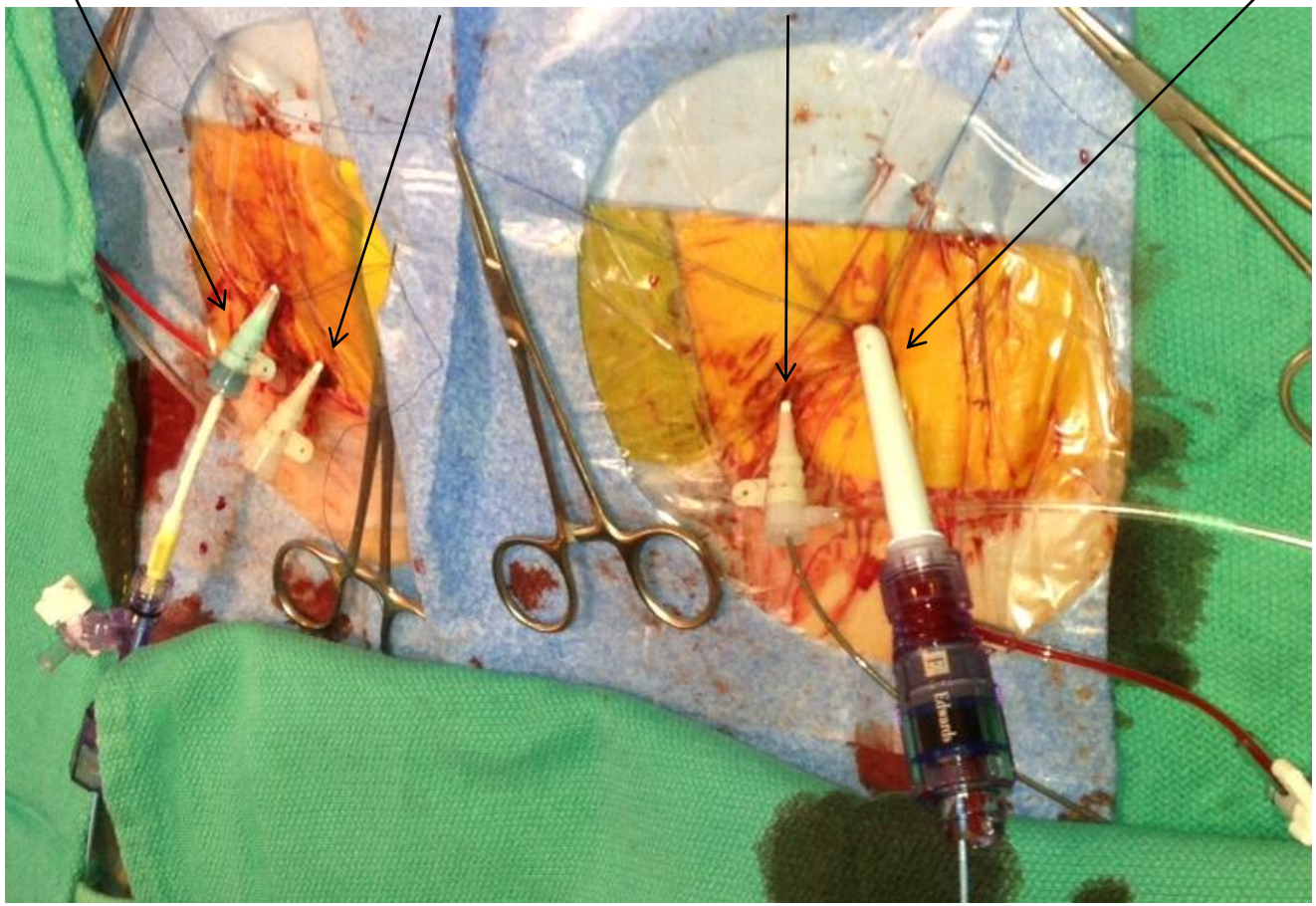
Typical Access

RFA - 8 F Sheath
Pigtail and contralateral wire

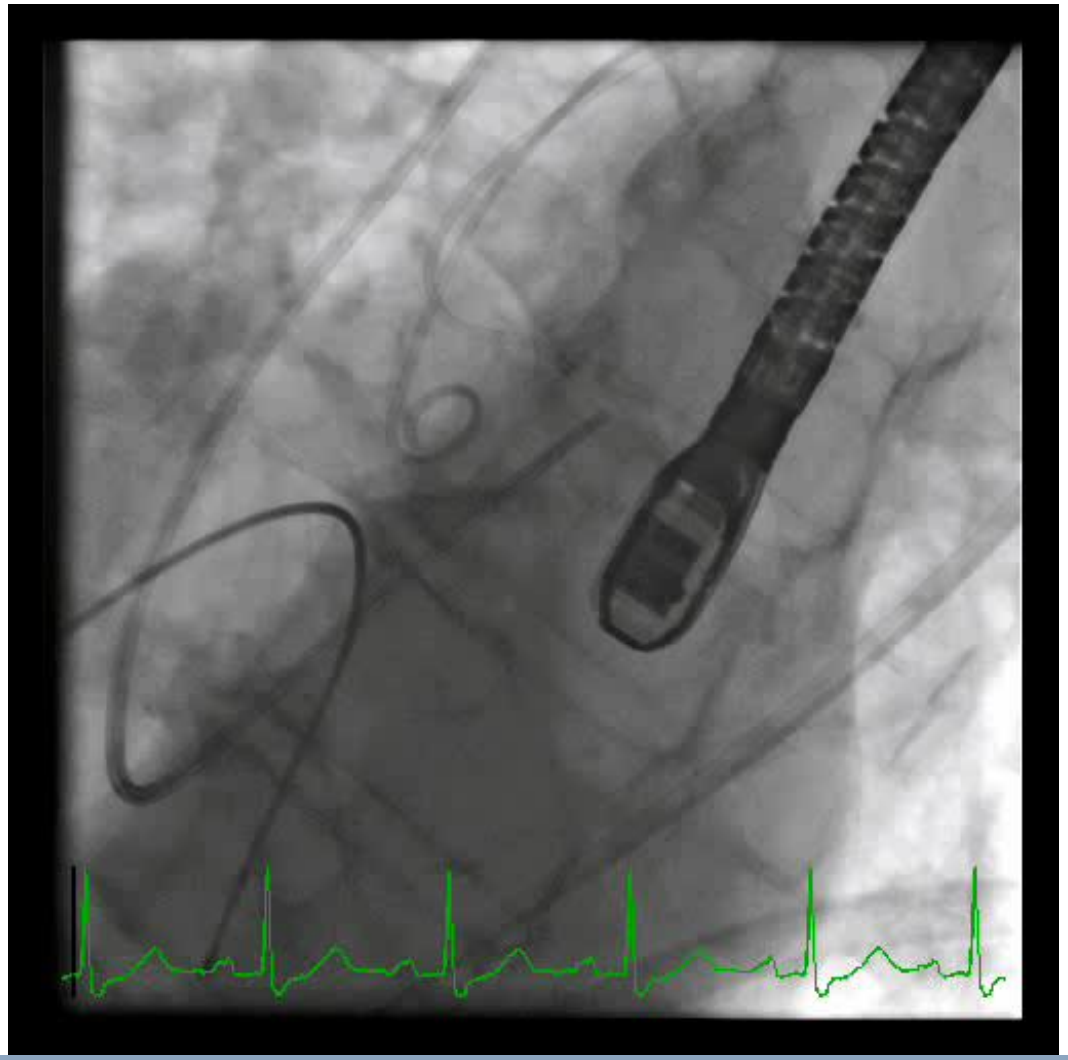
RFV - 5 F Sheath
For CPS

LFV - 5 F Sheath
Temp Pacemaker

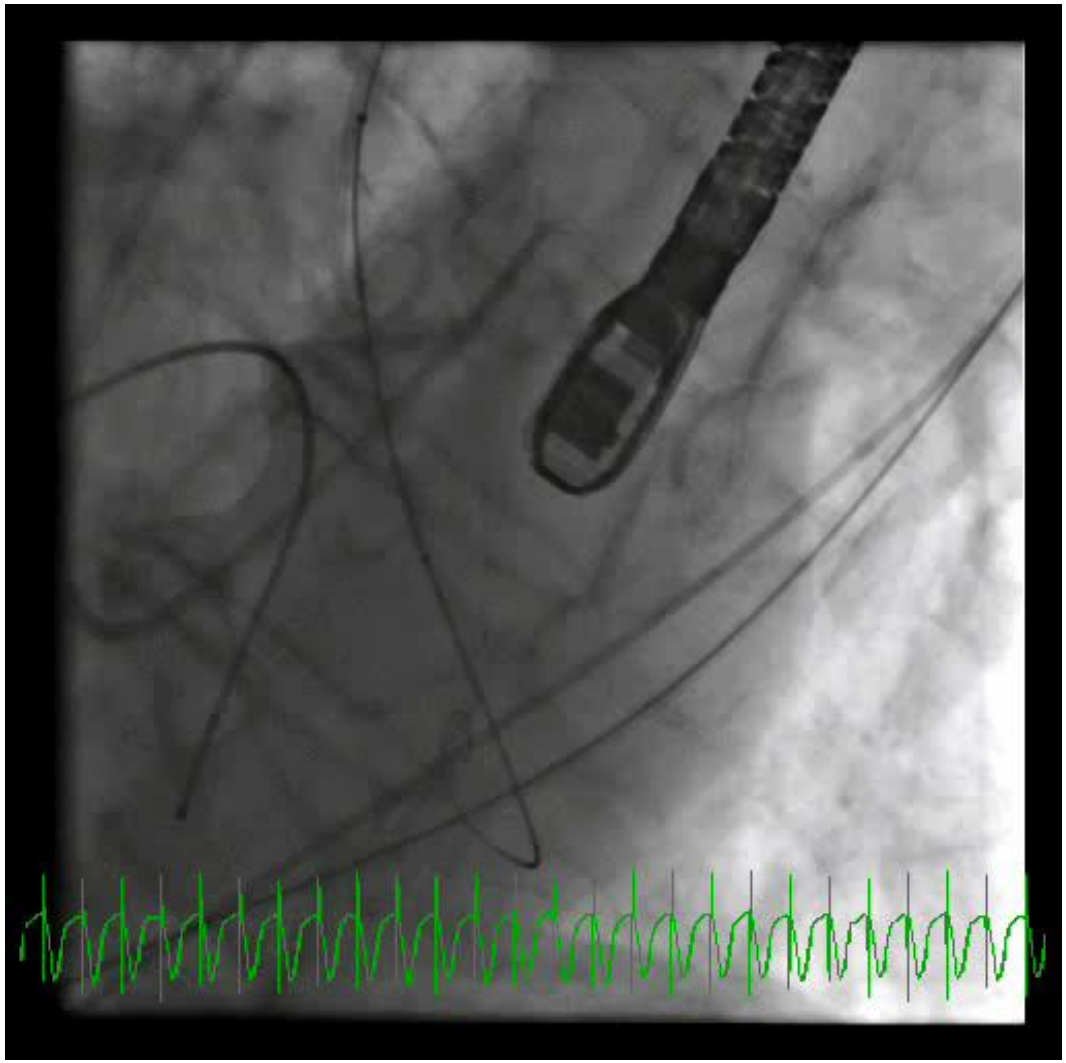
LFA- Valve Access Sheath



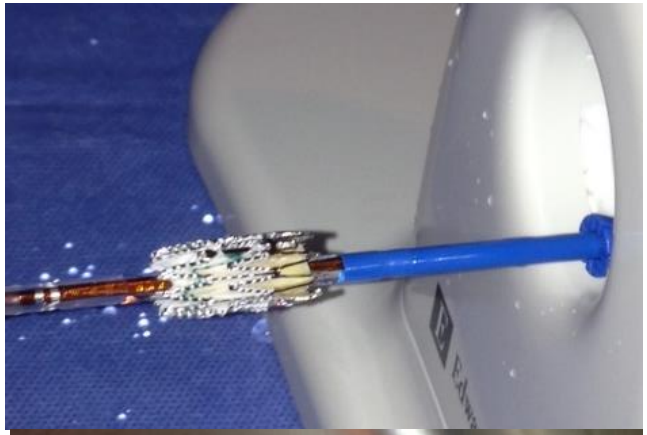
Aortic Root Injection

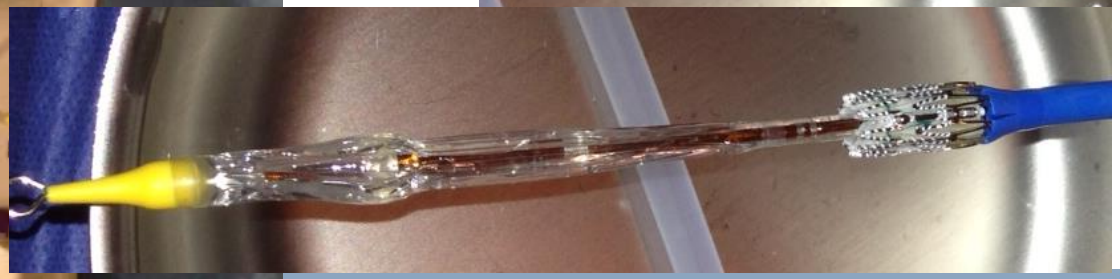


Balloon Aortic Valvulplasty



Valve Preparation

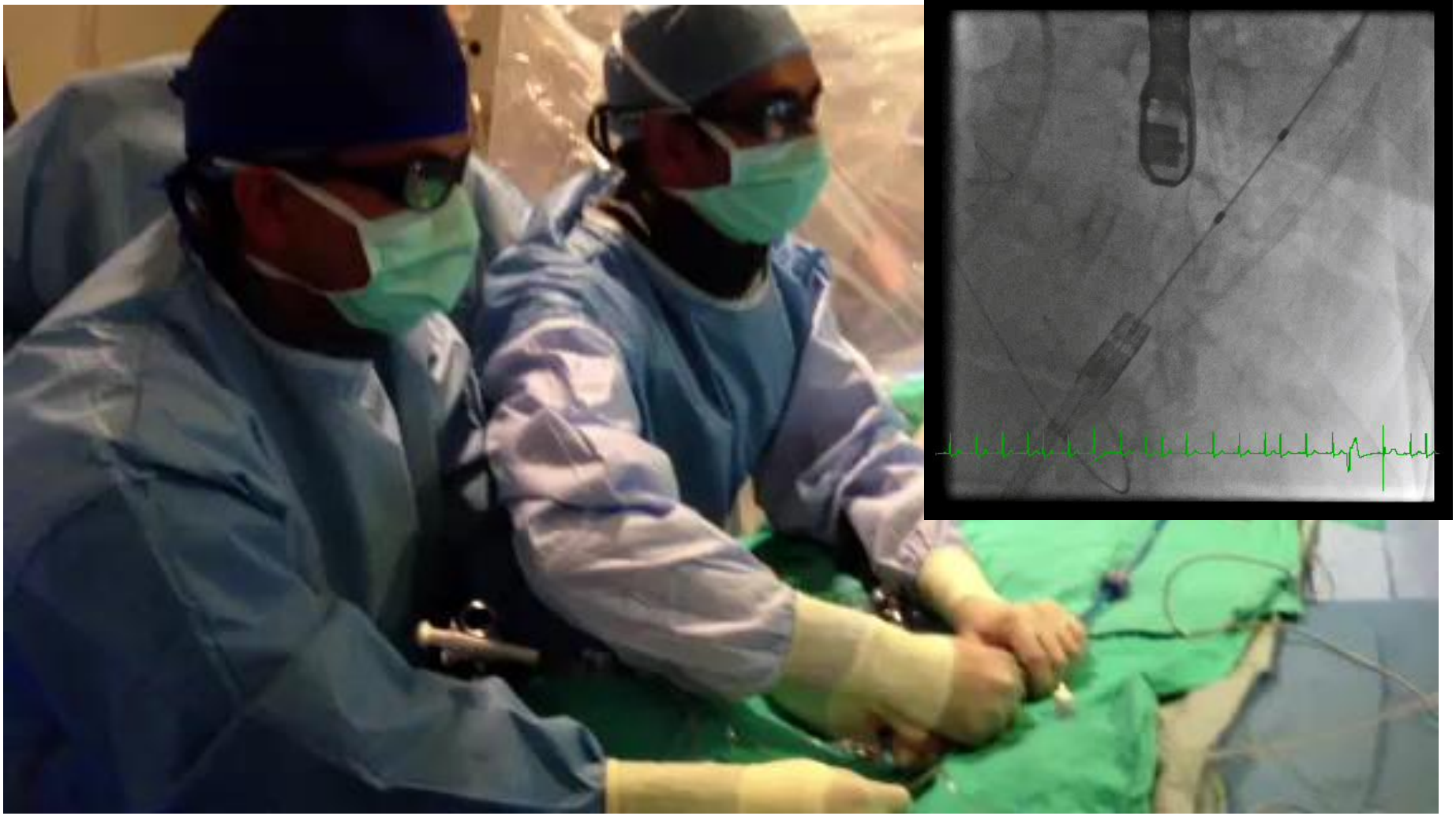




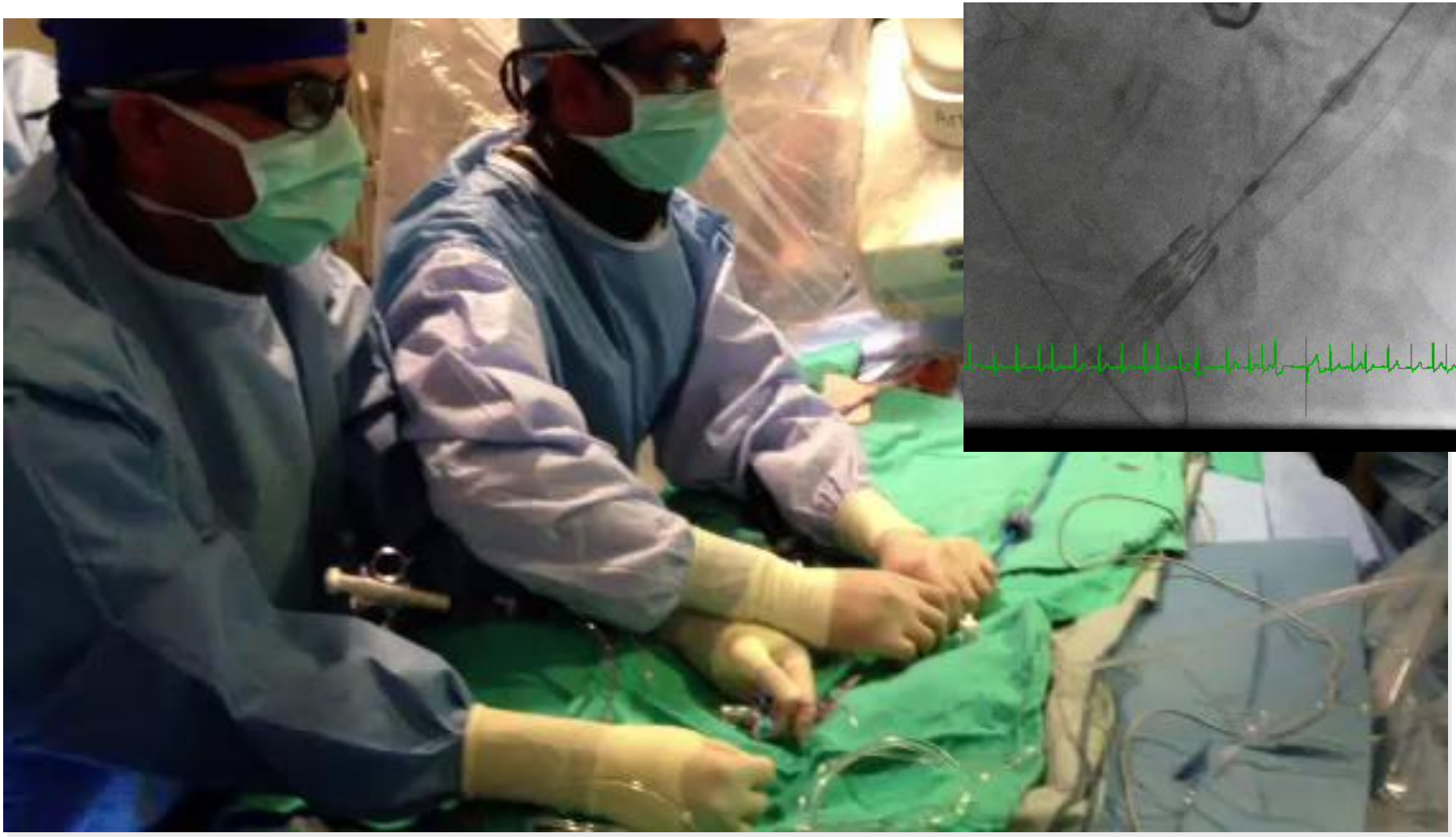
SIEMENS

PAT T: 37.0C
TEE T: 39.1C
JPEG
52 bpm

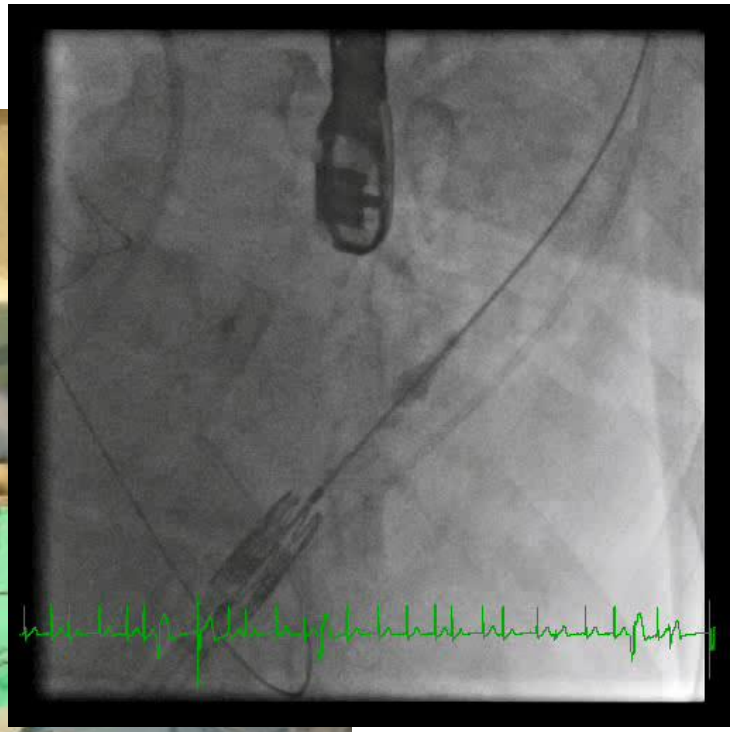
Loading of Sapien XT



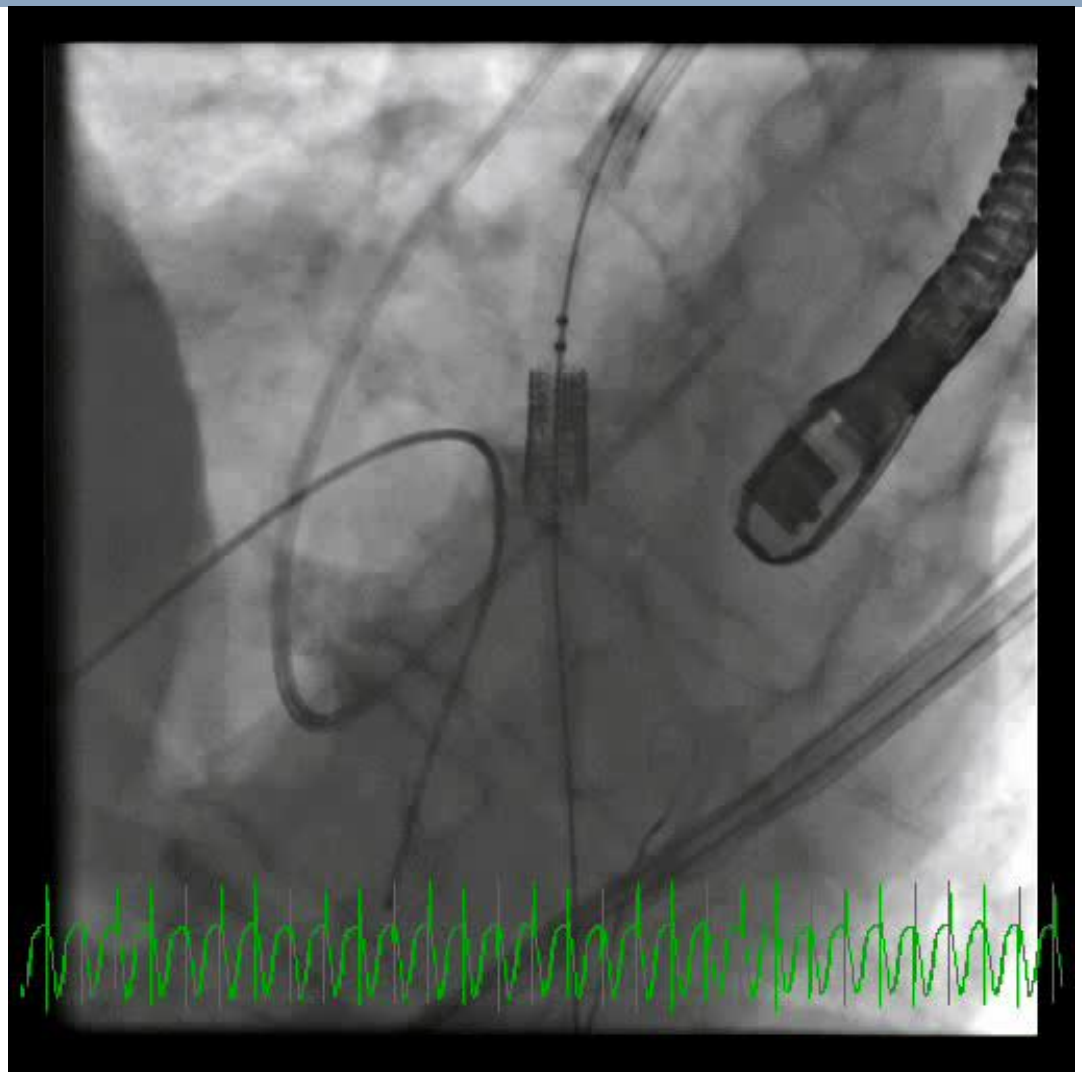
Fine Adjusting



Crossing the Arch

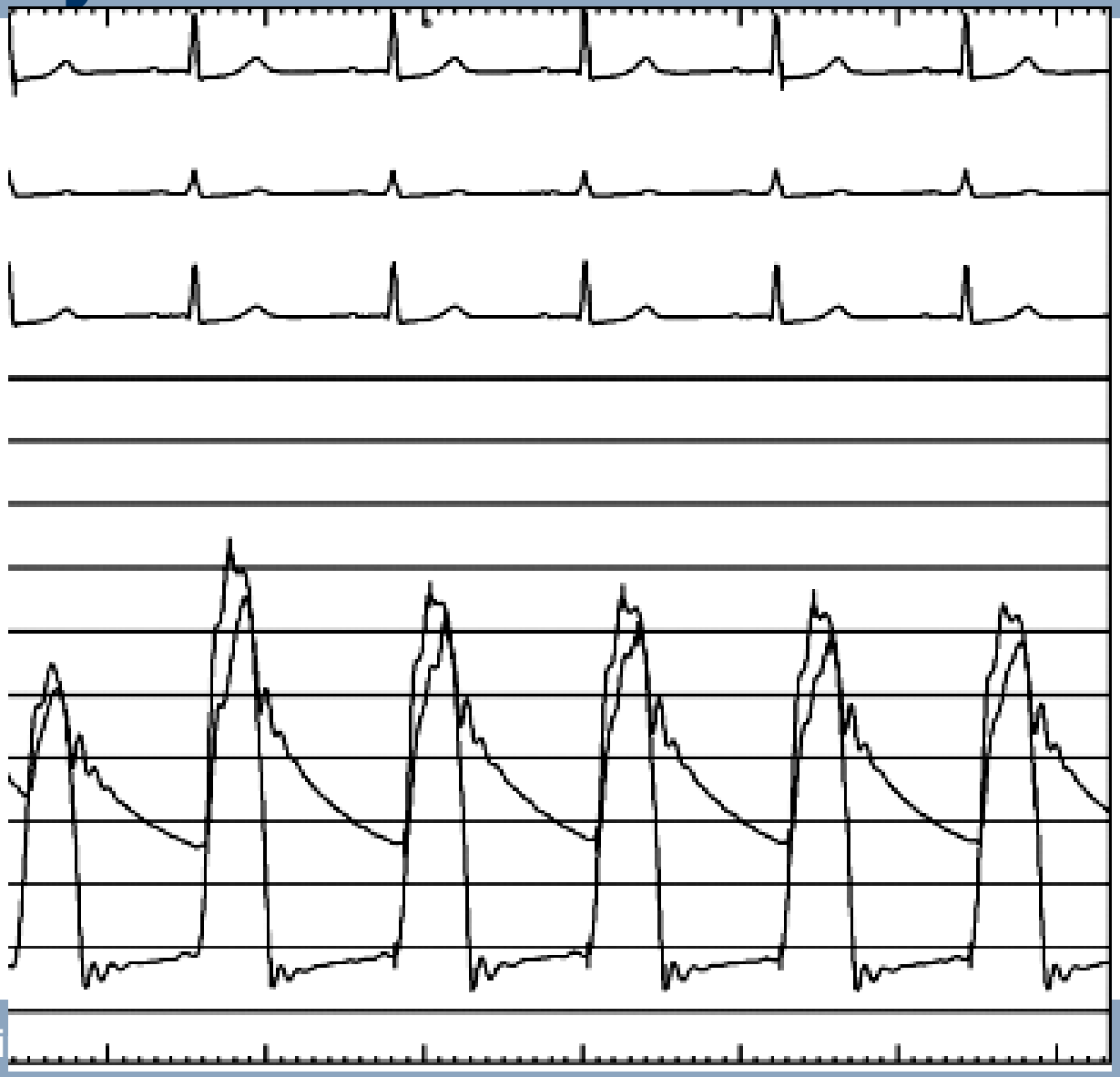


Valve Deployment



Post Aortogram

Hemodynamics



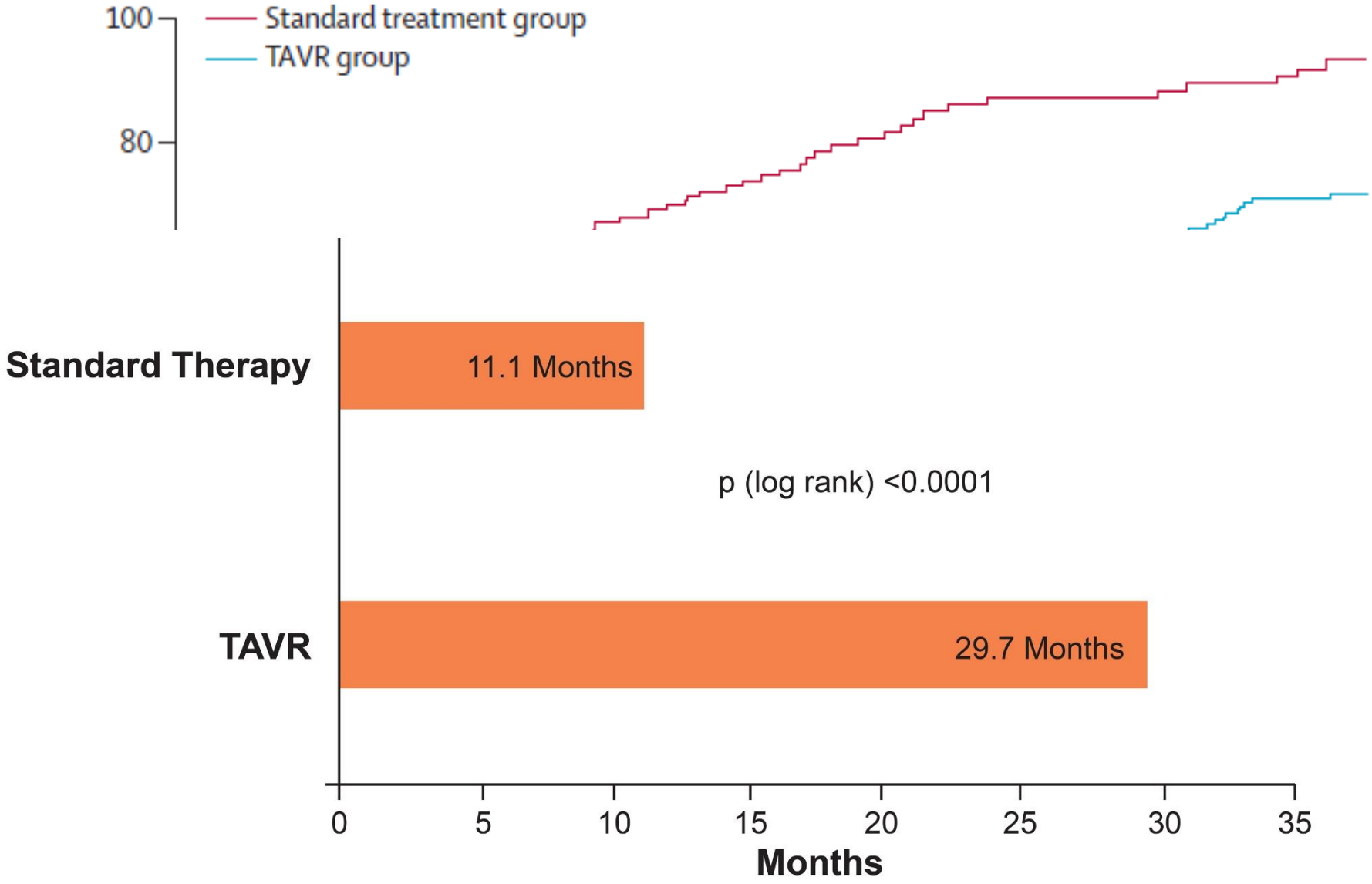
Final Result

Which Patients?

RCT

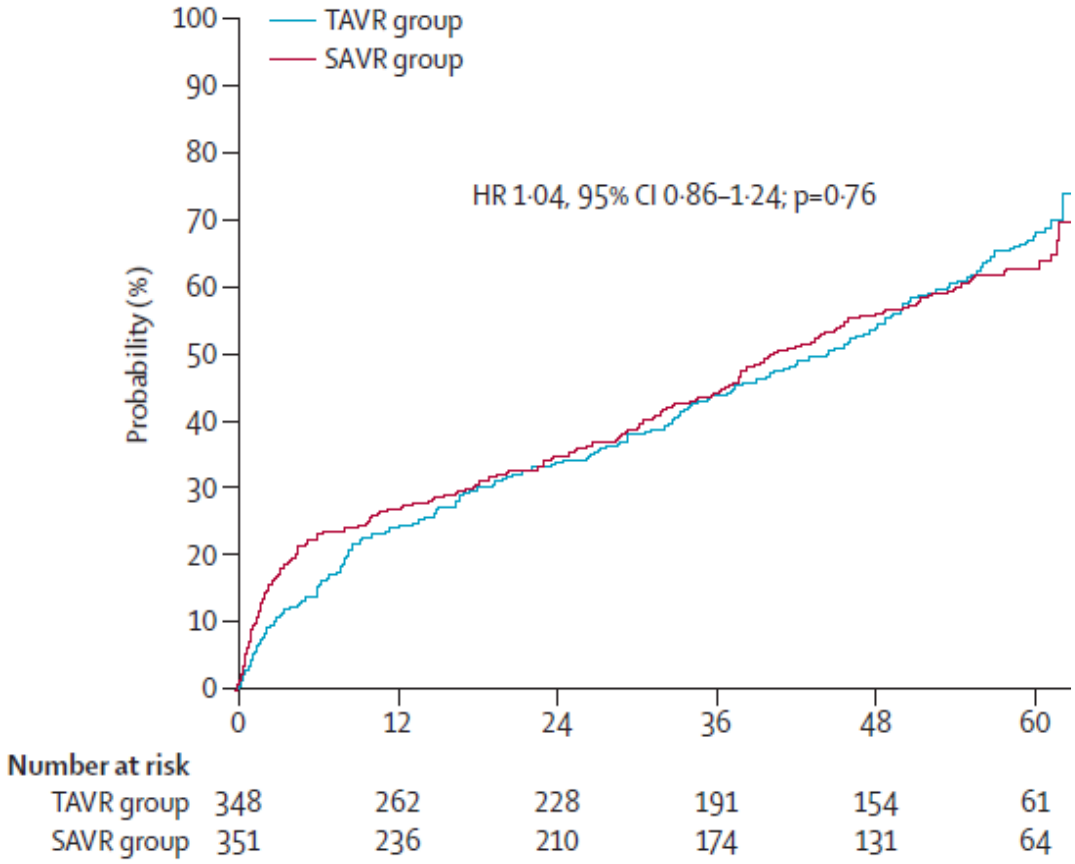
PARTNER1B	PARTNER1B CoreValve	S3i	NOTION
Standard Vs TAVR	SAVR Vs TAVR	SAVR Vs TAVR	SAVR Vs TAVR

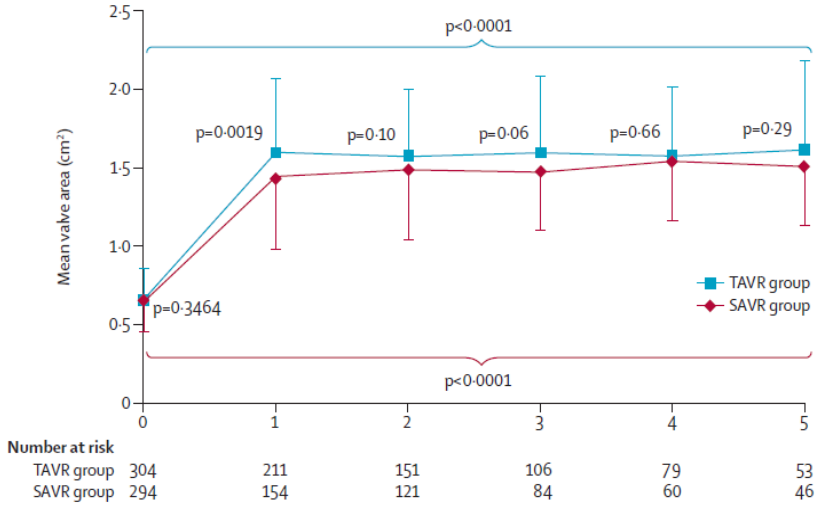
PARTNER IB


100
80
Standard treatment group
TAVR group
Standard Therapy
11.1 Months
p (log rank) <0.0001
TAVR
29.7 Months
0
5
10
15
20
25
30
35
Months

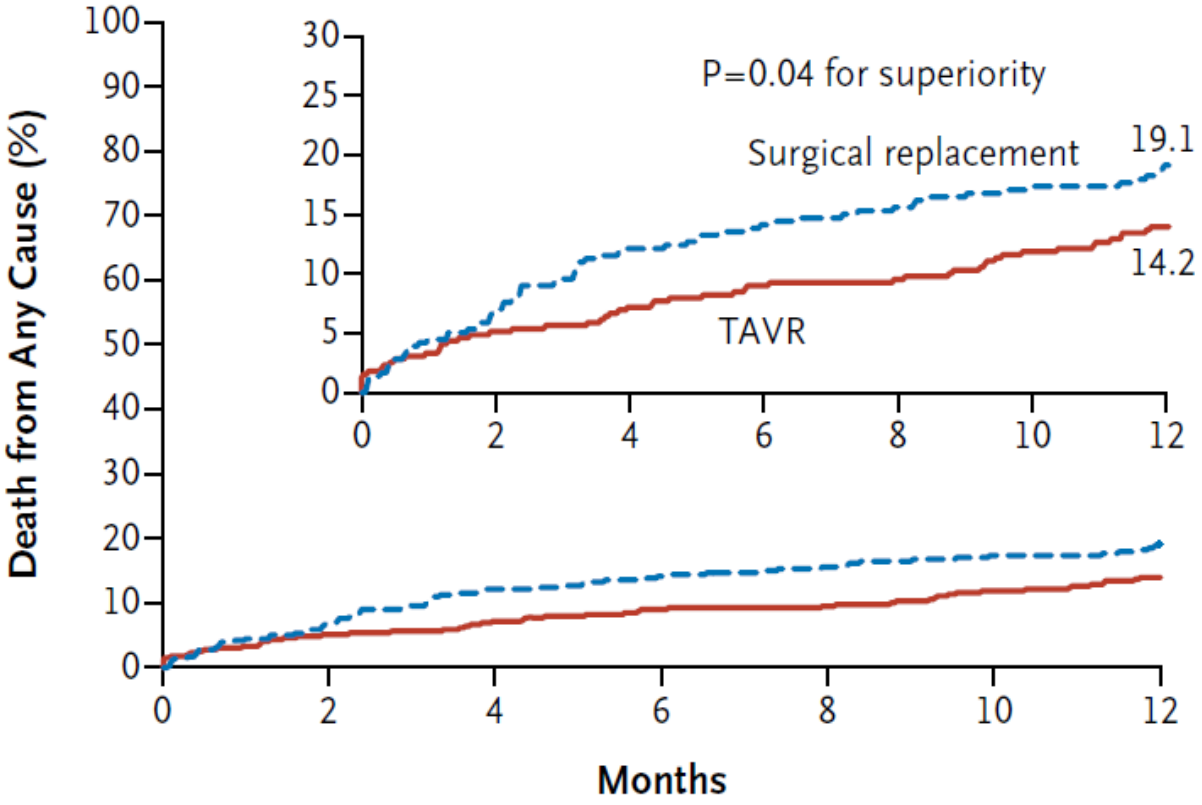
PARTNER 1 A

5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial





CoreValve



No. at Risk

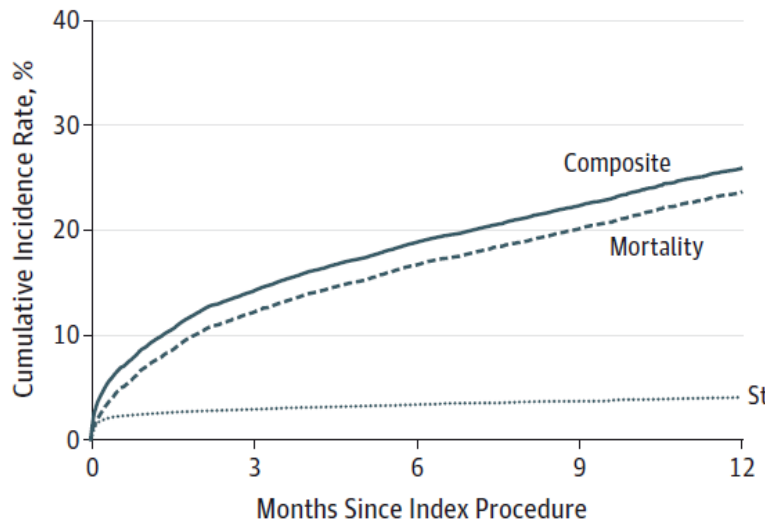
TAVR	390	377	353	329
Surgical replacement	357	341	297	274

TVT Registry

Original Investigation

Clinical Outcomes at 1 Year Following Transcatheter Aortic Valve Replacement

Mortality and stroke

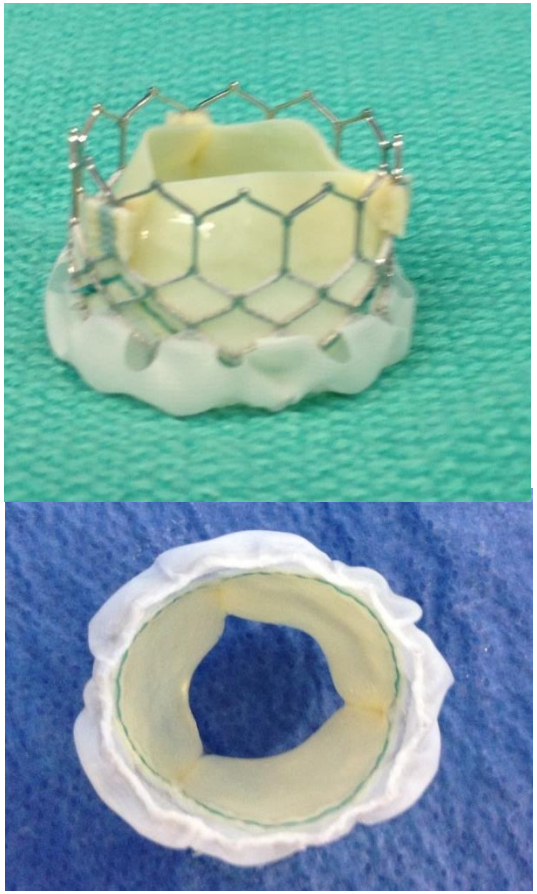


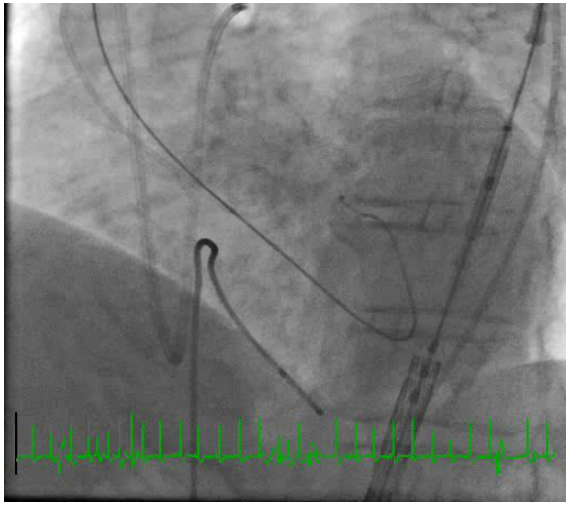
No. at risk					
Mortality	12 182	9669	7724	6190	479(
Stroke	12 182	9508	7585	6063	4681
Composite	12 182	9445	7531	6027	4656

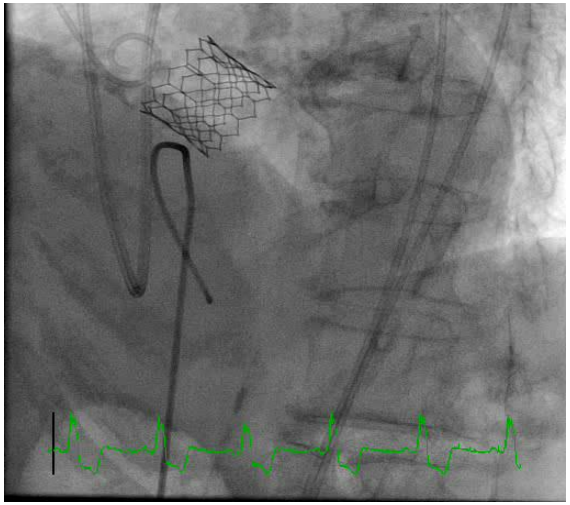
Events by Time From Index Procedure to Event	No. of Events	Rate, % (95% CI)
Mortality		
30 d	847	7.0 (6.5-7.4)
6 mo	1911	16.7 (16.1-17.4)
1 y	2450	23.7 (22.8-24.5)
Stroke		
30 d	298	2.5 (2.2-2.7)
6 mo	402	3.4 (3.1-3.7)
1 y	455	4.1 (3.7-4.5)
Heart failure		
30 d	525	4.3 (4.0-4.7)
6 mo	1272	11.1 (10.5-11.7)
1 y	1525	14.3 (13.6-15.0)

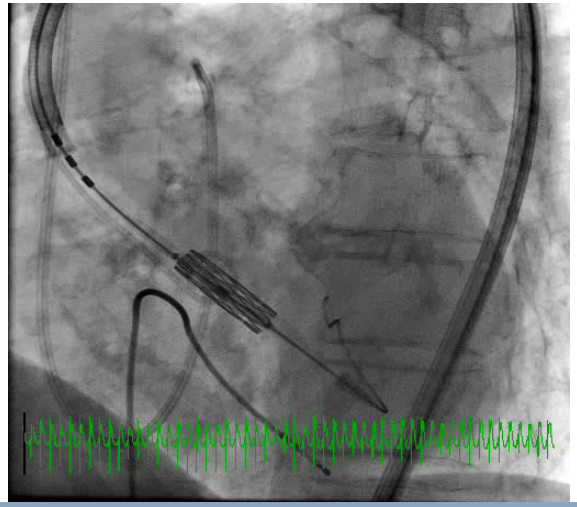
JAMA. 2015;313(10):1019-1028

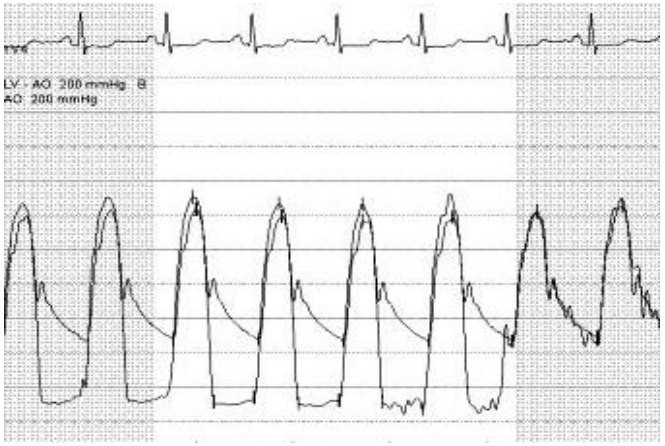
Newer Valve Designs - S3







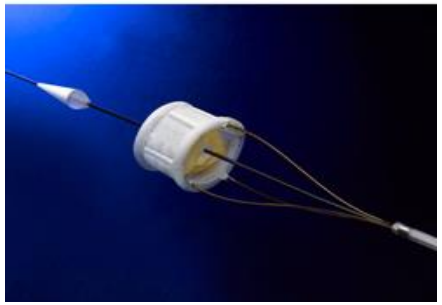


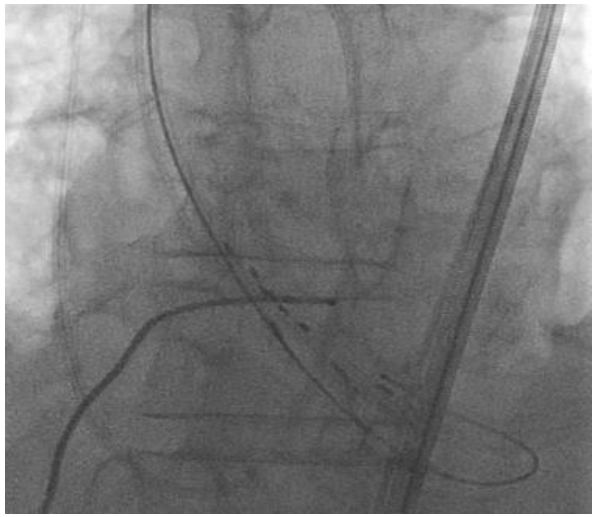


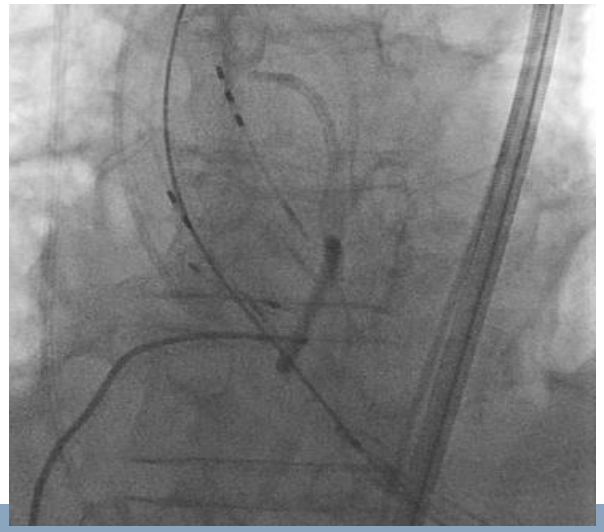
S3 Data – 30 Days

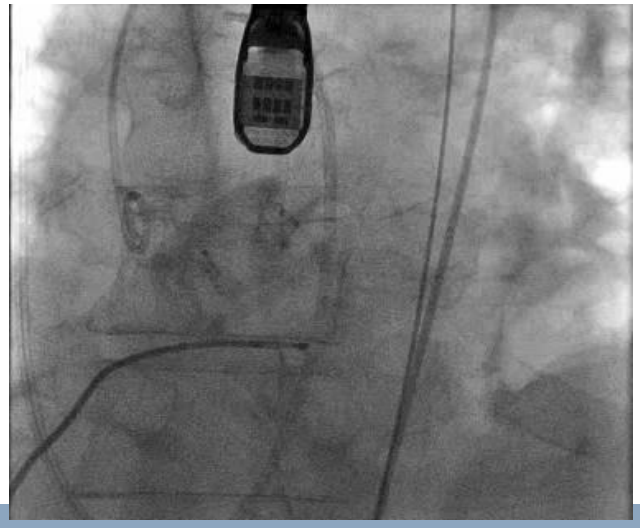
	SAPIEN 3 High-Risk (n=583) Average age: 82.6 years Average STS score: 8.6%			SAPIEN 3 Intermediate-Risk (n=1,076) Average age: 81.9 years Average STS score: 5.3%		
Outcome	All	TF	TA/TAo	All	TF	TA/TAo
All-cause mortality - %	2.2	1.6	5.4	1.1	1.1	1.6
Stroke: all - %	1.54	1.63	1.09	2.6	2.42	4.00
Stroke: disabling - %	0.86	0.81	1.09	1.02	0.95	1.60

Newer Valve Design – Direct Flow









Hybrid Room

Our Setup

Cleveland Clinic Experience

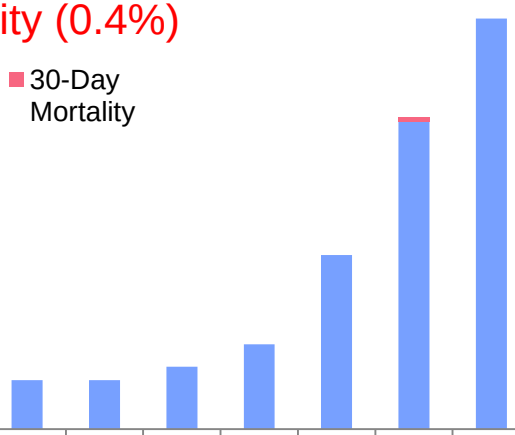
Single Center TAVR Experience With a Focus on the Prevention and Management of Catastrophic Complications

Samir R. Kapadia, MD, FACC, Lars G. Svensson, MD, PhD, Eric Roselli, MD, Paul Schoenhagen, MD, Zoran Popovic, MD, Andrej Alfirevic, MD, Benico Barzilai, MD, FACC, Amar Krishnaswamy, MD, FACC, William Stewart, MD, FACC, Anand Mehta, MD, Kanhaiya lal Poddar, MD, Akhil Parashar, MD, Dhruv Modi, MD, Alper Ozkan, MD, Umesh Khot, MD, FACC, Bruce W. Lytle, MD, and E. Murat Tuzcu,* MD, FACC

Catheter Cardiovasc Interv. 2014 Jan 9. doi: 10.1002/ccd.25356. [Epub ahead of print]

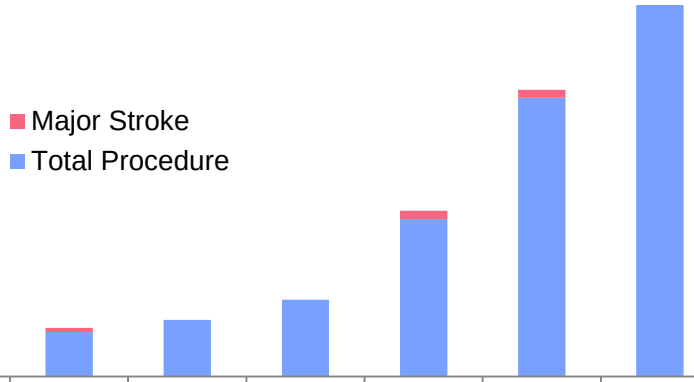
Outcome of Patients TF-TAVR at Cleveland Clinic

30 day mortality (0.4%)



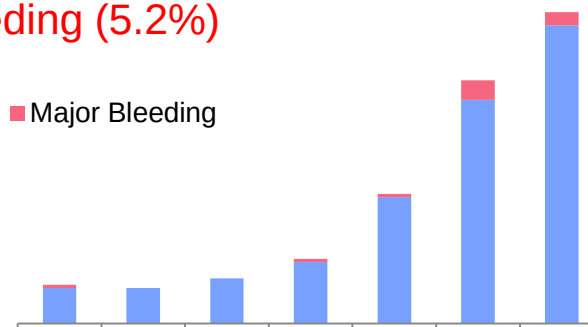
	2006	2007	2008	2009	2010	2011	2012
30-Day Mortality	0	0	0	0	0	1	0
Total Procedure	11	11	14	19	39	69	92

Stroke (2.0%)



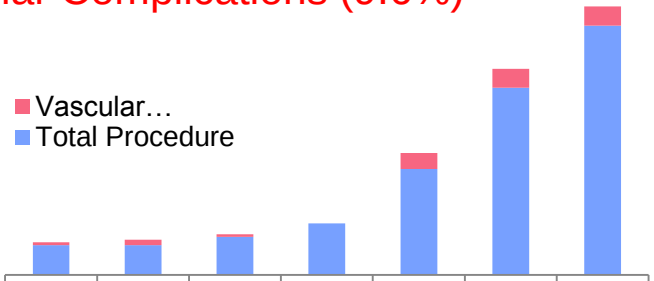
	2006	2007	2008	2009	2010	2011	2012
Major Stroke	0	1	0	0	2	2	0
Total Procedure	11	11	14	19	39	69	92

Major bleeding (5.2%)



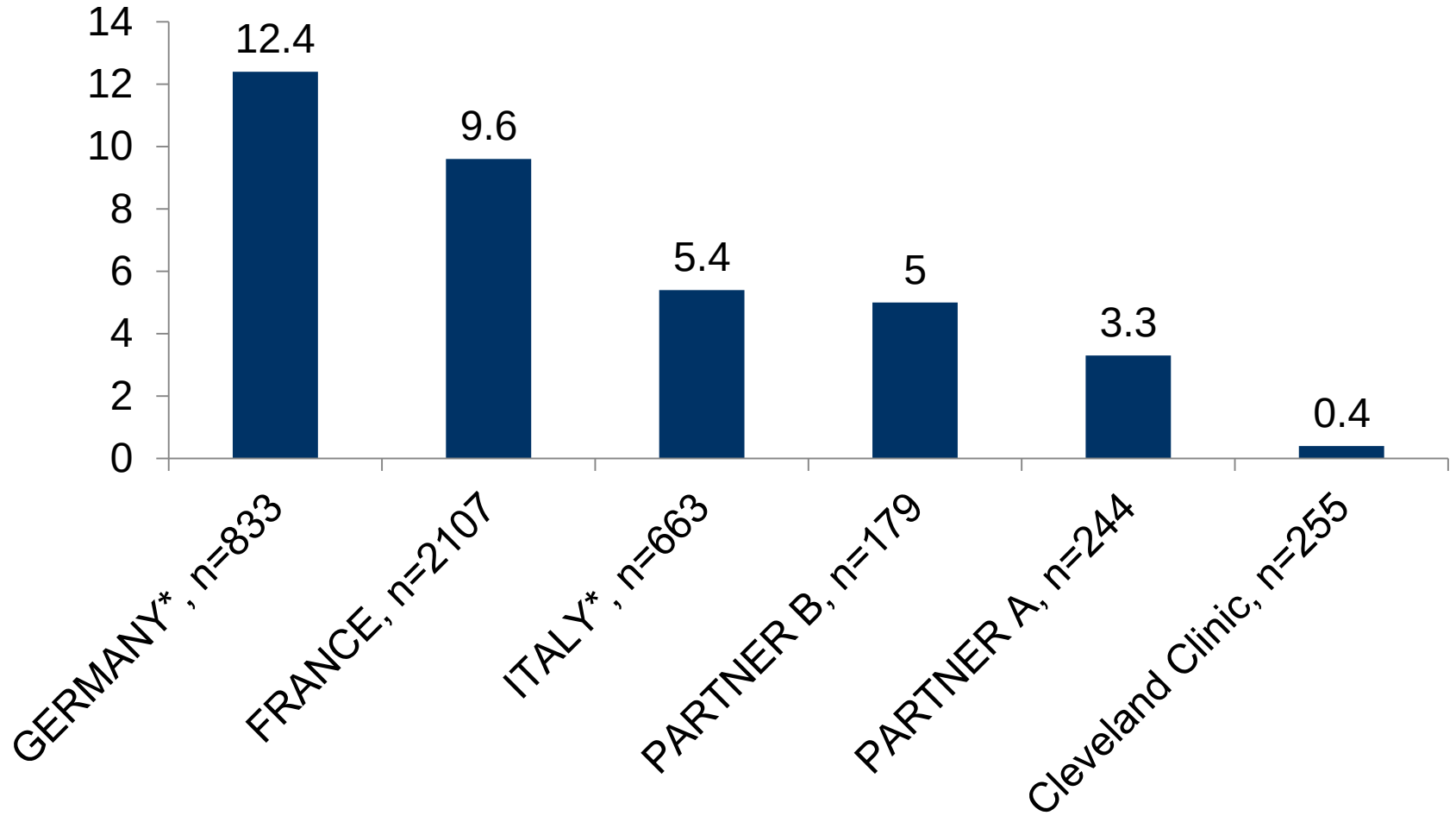
	2006	2007	2008	2009	2010	2011	2012
Major Bleeding	1	0	0	1	1	6	4
Total Procedure	11	11	14	19	39	69	92

Vascular Complications (9.6%)



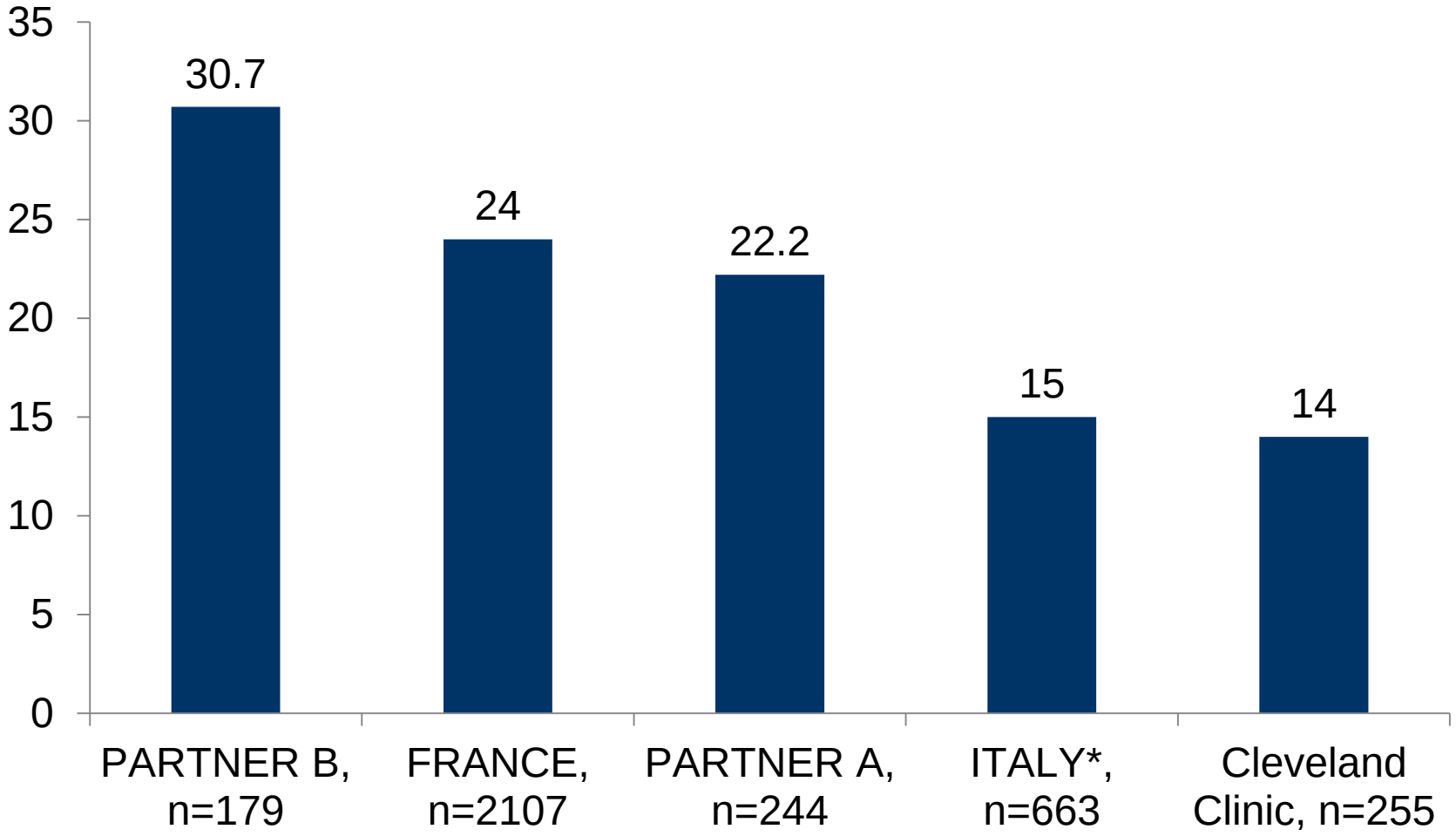
	2006	2007	2008	2009	2010	2011	2012
Vascular Complications	1	2	1	0	6	7	7
Total Procedure	11	11	14	19	39	69	92

30 Day Mortality with TF-TAVR



* Includes TF and TA, all others TF on

1 Year Mortality with TF-TAVR



* Includes TF and TA, all others TF on

Follow Up

- **Typical hospital stay**
  - **2 days for TF**
  - **4-5 days for TA**
- **ASA 81 mg**
- **Clopidogrel 75 mg for 1 – 6 months**
- **Only ASA and Warfarin if patients are on Warfarin**
- **Clinic visit at 1, 6, 12 months and then yearly**

Role of BAV

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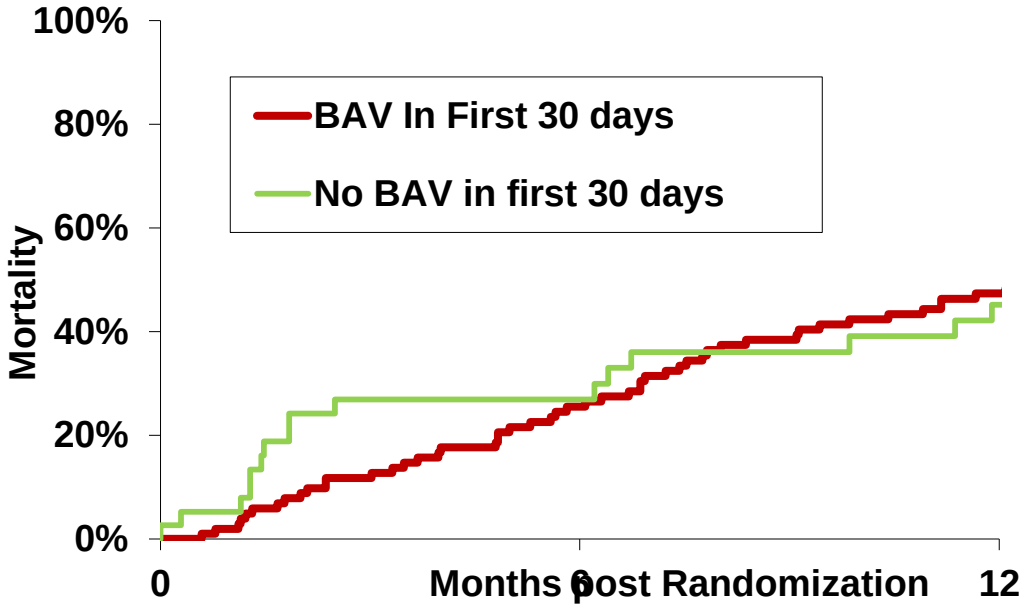
Outcomes of Inoperable Symptomatic Aortic Stenosis Patients Not Undergoing Aortic Valve Replacement

Insight Into the Impact of Balloon Aortic Valvuloplasty From the PARTNER Trial (Placement of AoRtic TraNscathetER Valve Trial)

Samir Kapadia, MD,* William J. Stewart, MD,* William N. Anderson, PHD,† Vasilis Babaliaros, MD,‡ Ted Feldman, MD,§ David J. Cohen, MD, MSc,‖ Pamela S. Douglas, MD,¶ Raj R. Makkar, MD,# Lars G. Svensson, MD, PHD,* John G. Webb, MD,** S. Chiu Wong, MD,†† David L. Brown, MD,‡‡ D. Craig Miller, MD,§§ Jeffrey W. Moses, MD,‖‖ Craig R. Smith, MD,‖‖ Martin B. Leon, MD,‖‖ E. Murat Tuzcu, MD*



CONCLUSIONS BAV improves functional status and survival in the short term, but these benefits are not sustained. BAV for aortic stenosis patients who cannot undergo aortic valve replacement is a useful palliative therapy.

Current Indications
Bridge, Palliation and at times “diagnostic”