Transcatheter Aortic Valve Replacement

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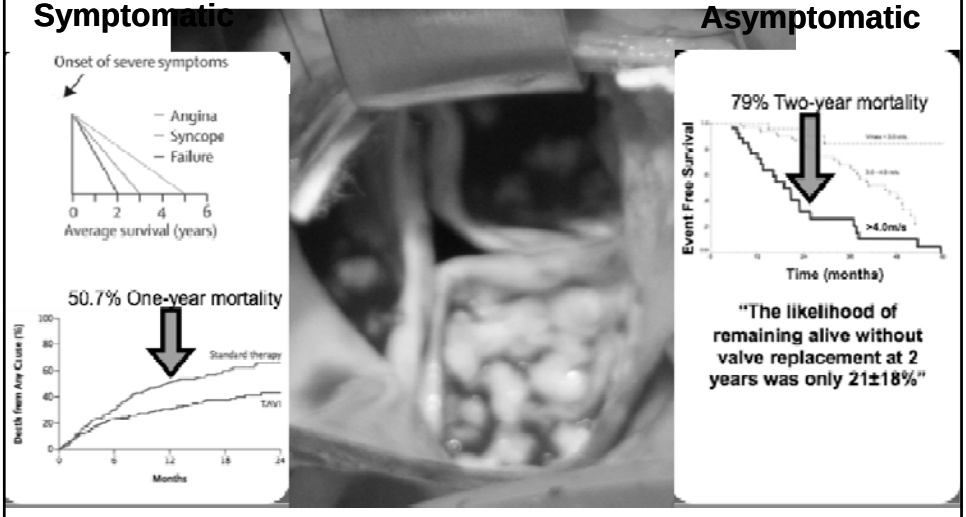
Associate Professor
Division of Cardiac Surgery
The Ohio State University Wexner Medical Center

Aortic Stenosis

Symptomatic

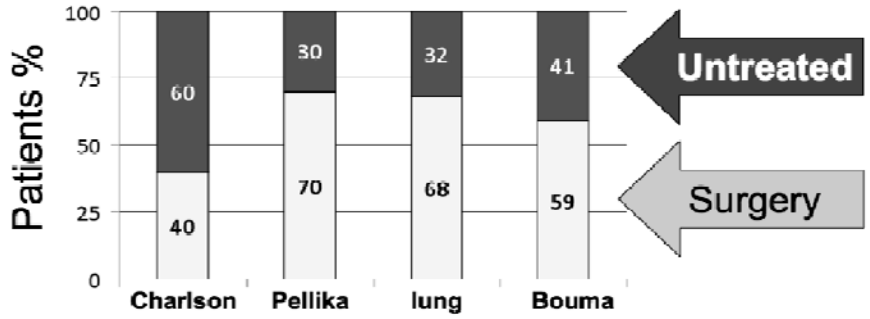


Asymptomatic

Leon ME et al. NEJM 2010, Otto CM et al. Circulation 1997

Transcatheter AVR

Patients with Severe AS Treated with Surgery



- Advanced age
- Left ventricular dysfunction
- Multiple comorbidities
- Frailty
- Increased "surgical risk"

Transcatheter AVR

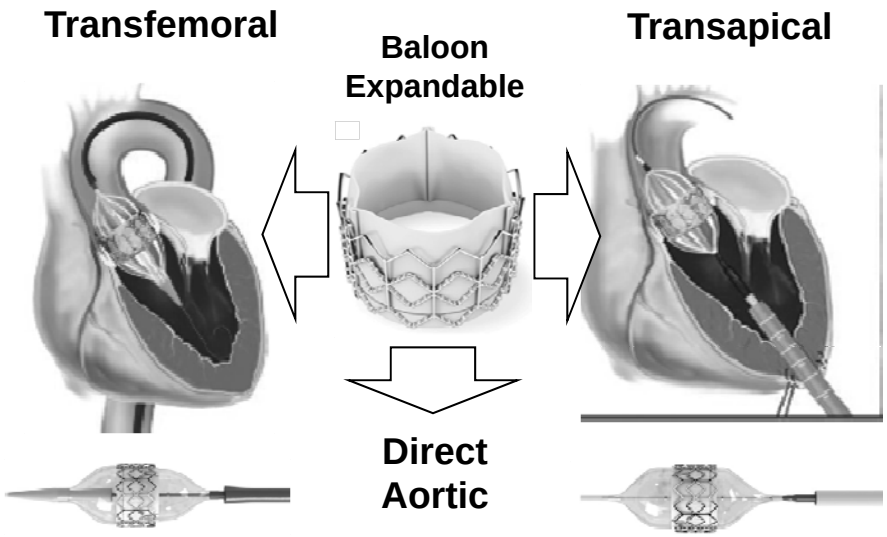
Edwards Sapien

FDA approved

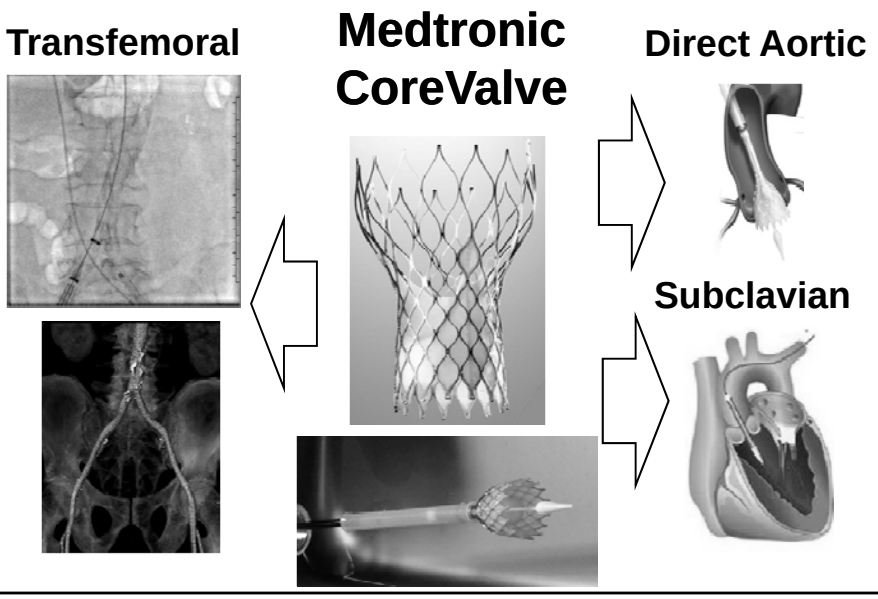
Medtronic CoreValve

Inoperable FDA approved
High risk: in trials

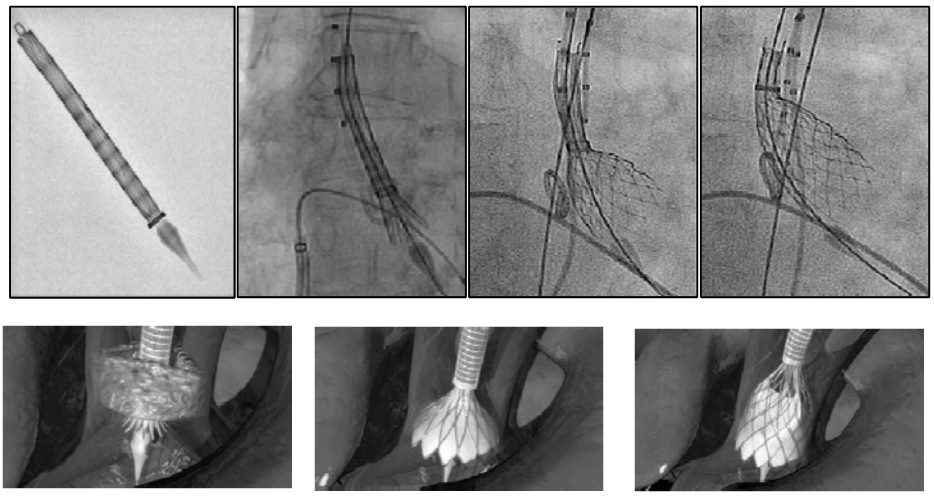
Edwards Sapien TAVR



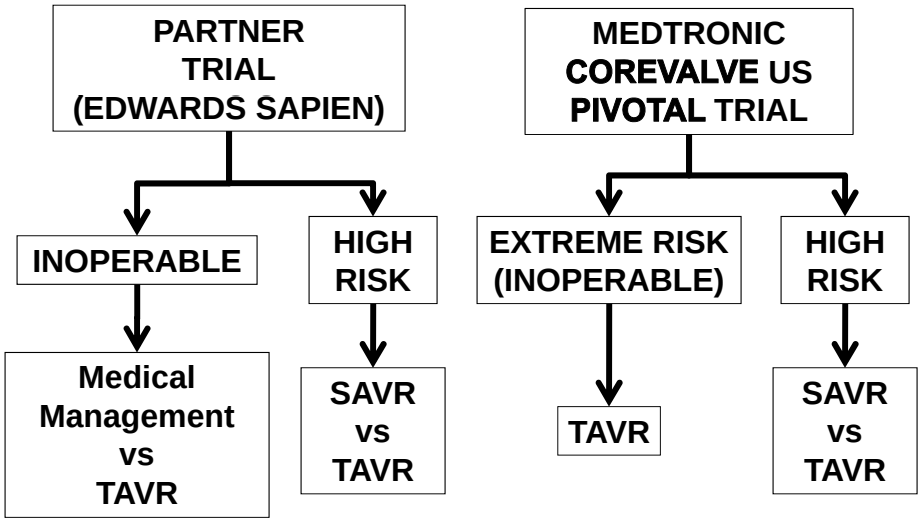
Transcatheter AVR



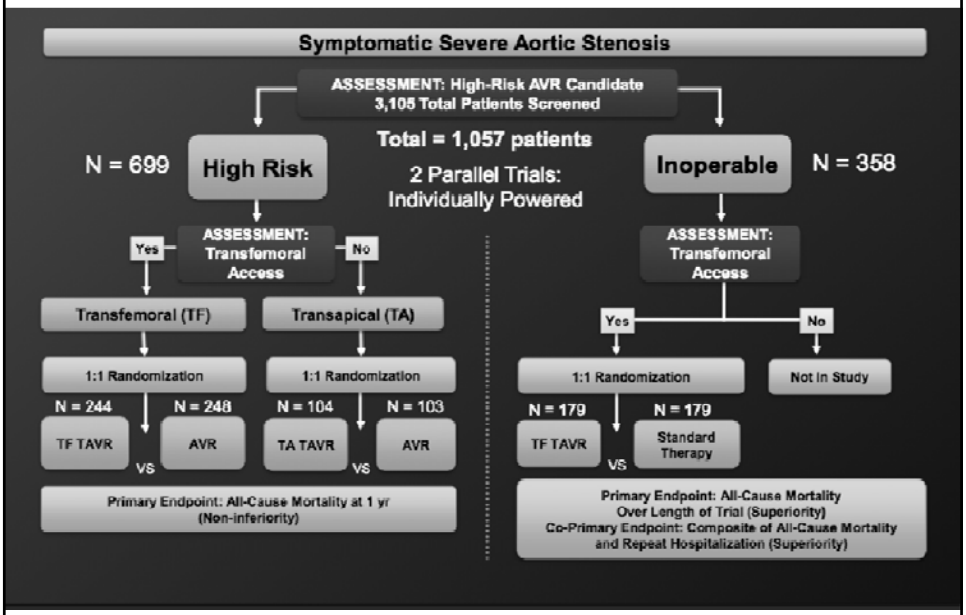
CoreValve Deployment
Self Expandable



The Trials



PARTNER TRIAL



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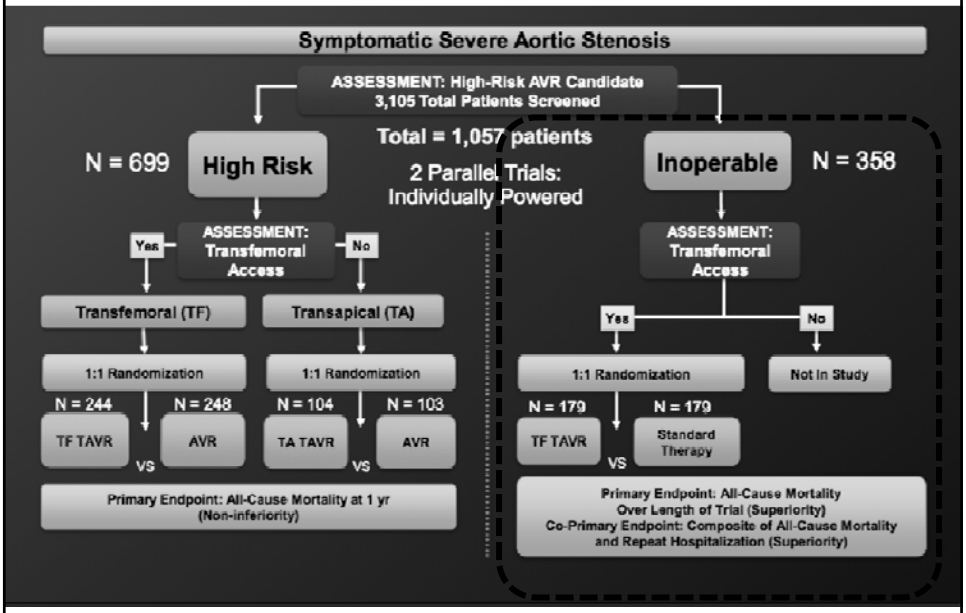
PARTNER TRIAL



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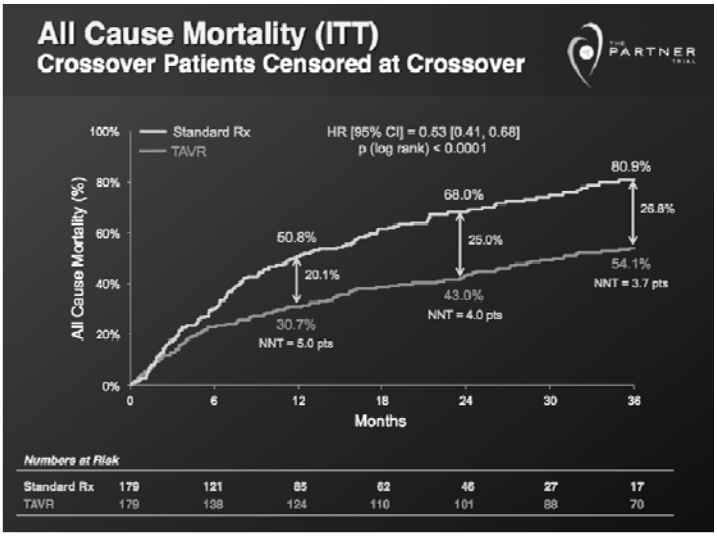
Inoperable Aortic Stenosis
TAVR vs. Medical Management



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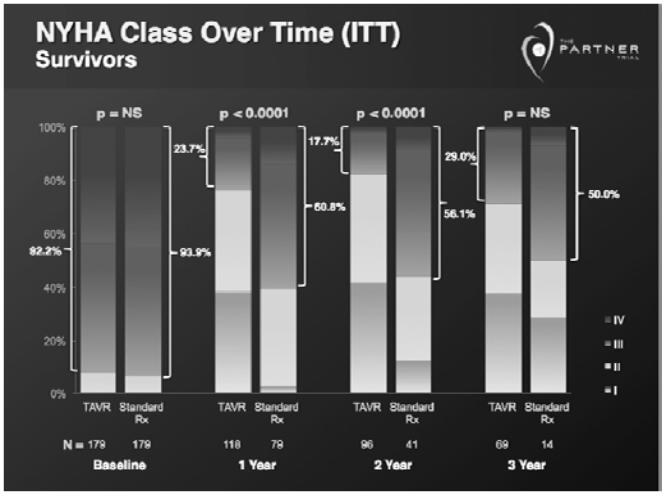
Inoperable Aortic Stenosis
TAVR vs. Medical Management



TAVR: 80% on NYHA class I or II

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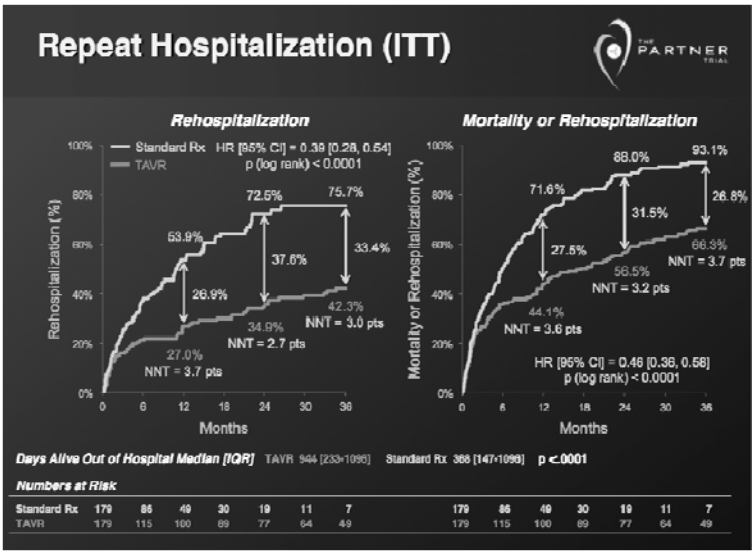
Inoperable Aortic Stenosis
TAVR vs. Medical Management



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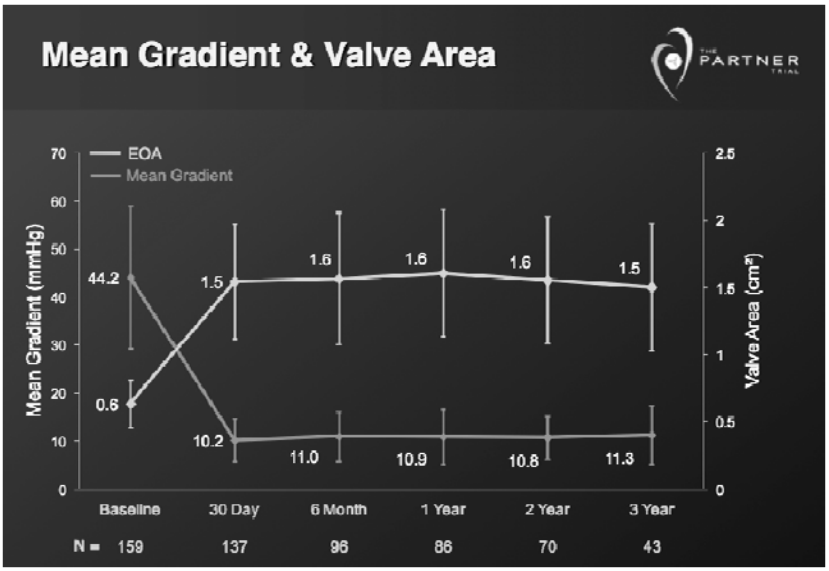
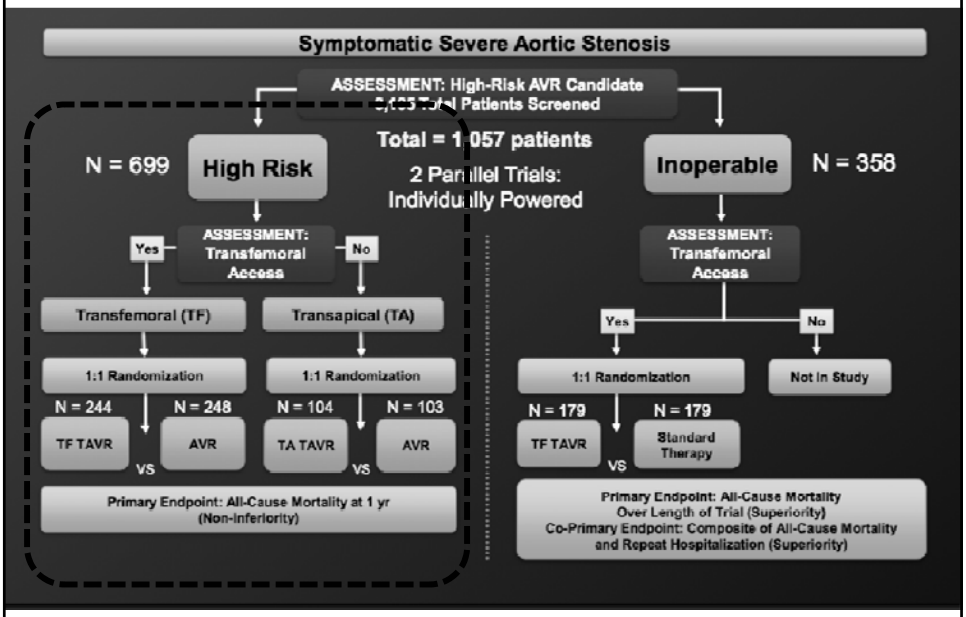
Inoperable Aortic Stenosis
TAVR vs. Medical Management



Inoperable Aortic Stenosis
TAVR vs. Medical Management

- **Medical management did not change the natural history of aortic stenosis**
- **TAVR relieved aortic stenosis**
- **TAVR was superior to medical therapy:**
  - **Decreased all cause mortality**
  - **Decreased cardiovascular mortality**
  - **Decreased rate of rehospitalization**
  - **Improved NYHA functional class**

PARTNER TRIAL



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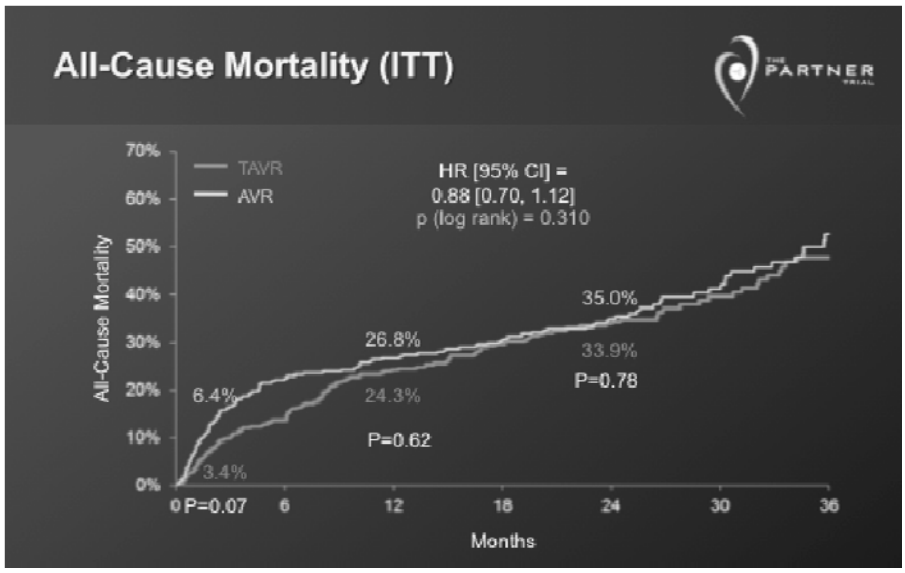
High Risk Aortic Stenosis
TAVR vs. AVR



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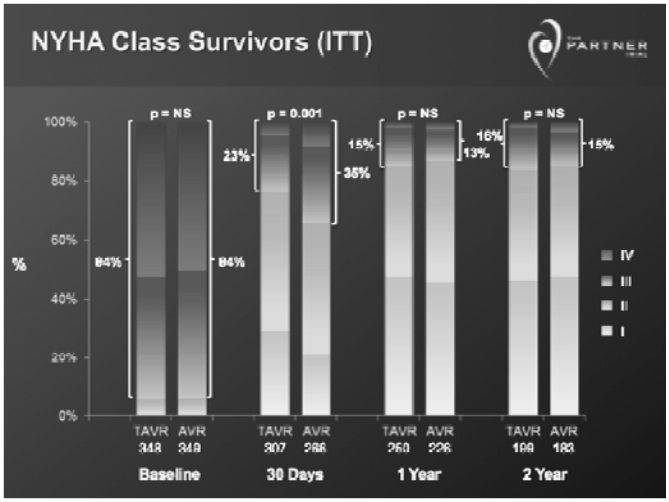
High Risk Aortic Stenosis
TAVR vs. AVR



80% on NYHA class I or II

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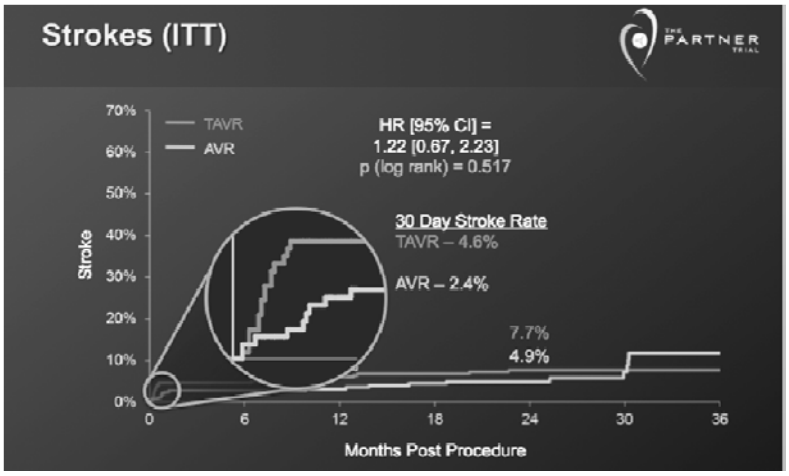
High Risk Aortic Stenosis
TAVR vs. AVR



TAVR increased risk of early stroke

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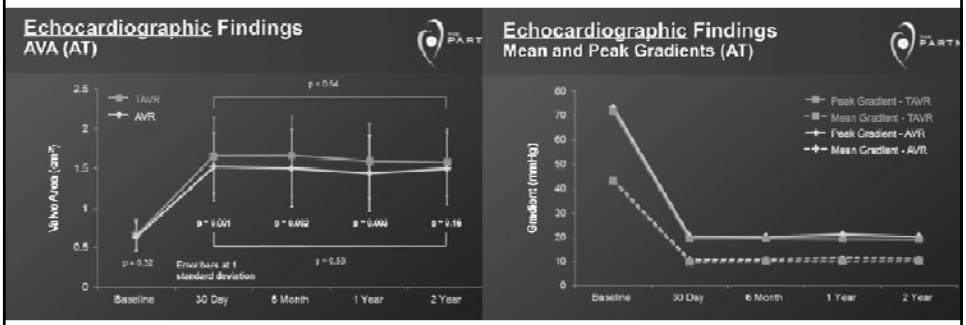
High Risk Aortic Stenosis
TAVR vs. AVR



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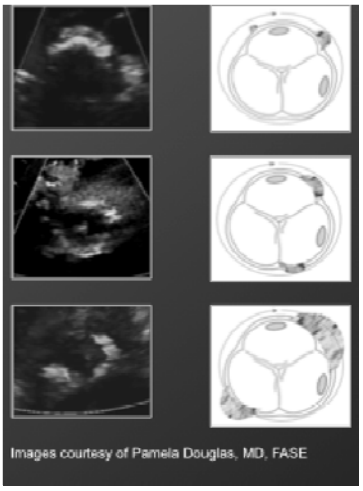
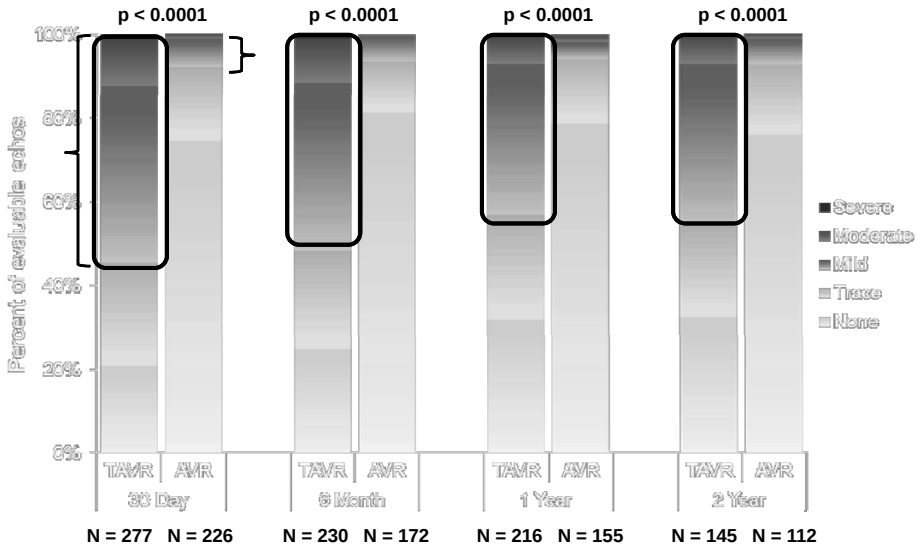
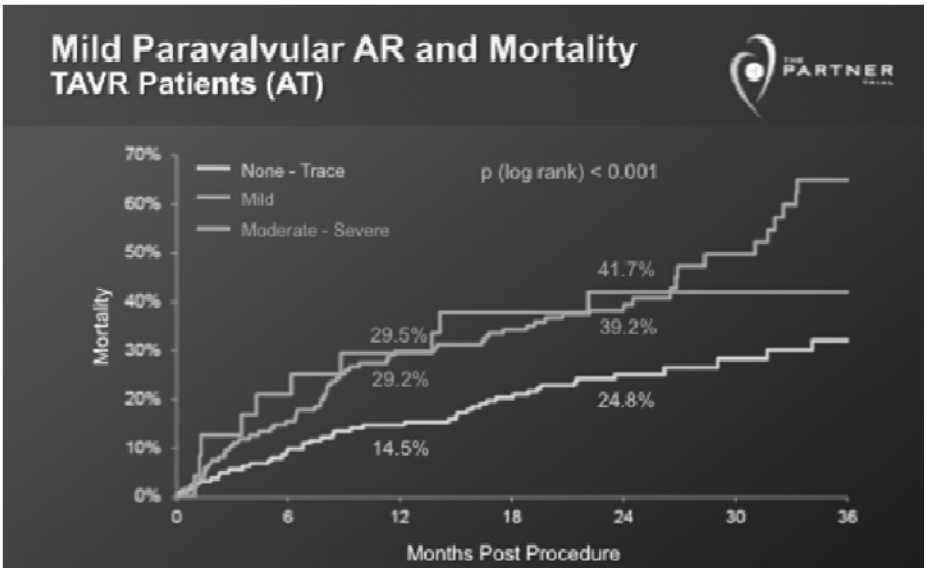
High Risk Aortic Stenosis
Paravalvular Aortic Regurgitation



Paravalvular Aortic Regurgitation



High Risk Aortic Stenosis
Paravalvular Aortic Regurgitation



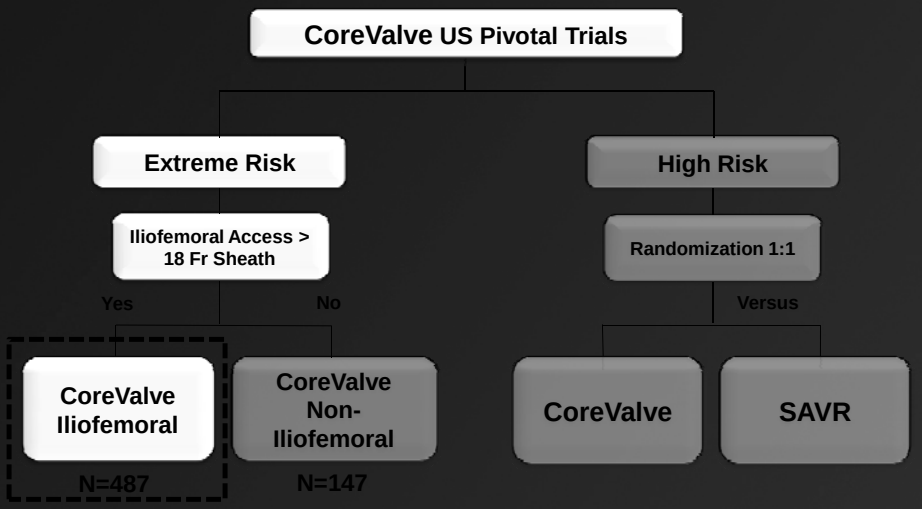
High Risk Aortic Stenosis
TAVR vs. SAVR

- **TAVR and SAVR effectively relieved AS**
- **Mortality was similar up to 2 years**
- **NYHA class was similar**
- **30 day stroke rate was higher in TAVR**
- **TAVR was associated with PVL**
- **Mild moderate and severe PVL resulted in increased mortality**

CoreValve Trial

CoreValve US Clinical Trials

Pivotal Trial Design

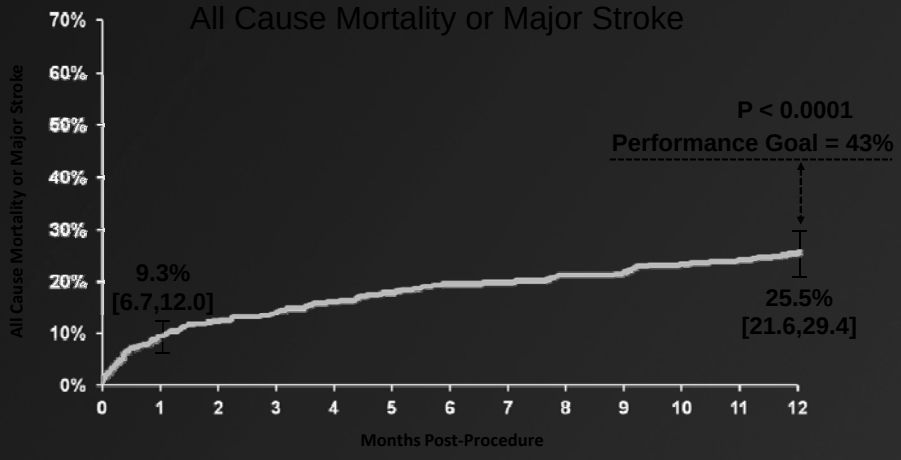


Jeffrey J. Popma, MD. CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study Results. Data presented at TCT. San Francisco, California. October 2013.

Aortic Stenosis Extreme Risk

CoreValve US Clinical Trials

Primary Endpoint



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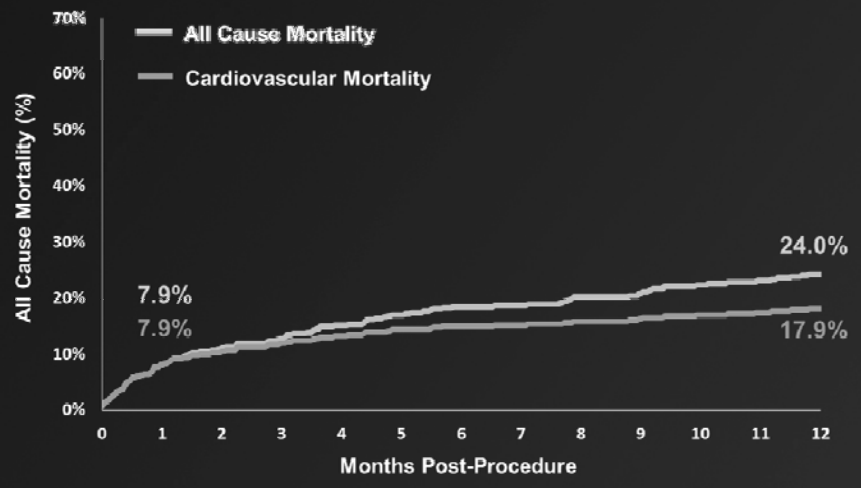
CoreValve US Clinical Trials

Aortic Stenosis Extreme Risk

1 Year Mortality



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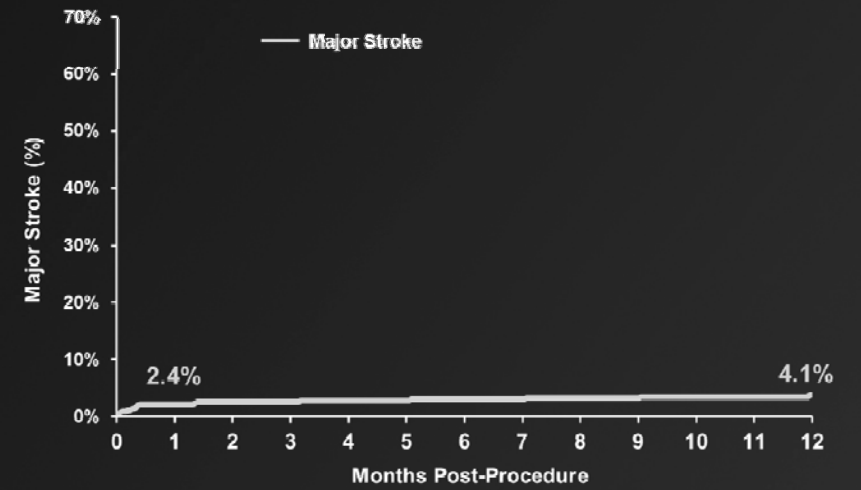
Aortic Stenosis Extreme Risk

Major Stroke



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Aortic Stenosis Extreme Risk

CoreValve US Clinical Trials

Secondary Endpoints

Events*	1 Month	1 Year
Any Stroke, %	3.9	6.7
Major, %	2.4	4.1
Minor, %	1.7	3.1
Myocardial Infarction, %	1.3	2.0
Reintervention, %	1.3	2.0
VARC Bleeding, %	35.1	41.4
Life Threatening or Disabling, %	11.7	16.6
Major, %	24.1	27.6
Major Vascular Complications, %	8.3	8.5
Permanent Pacemaker Implant, %	22.2	27.1
Per ACC Guidelines, %	17.4	19.9

* Percentages obtained from Kaplan Meier estimates

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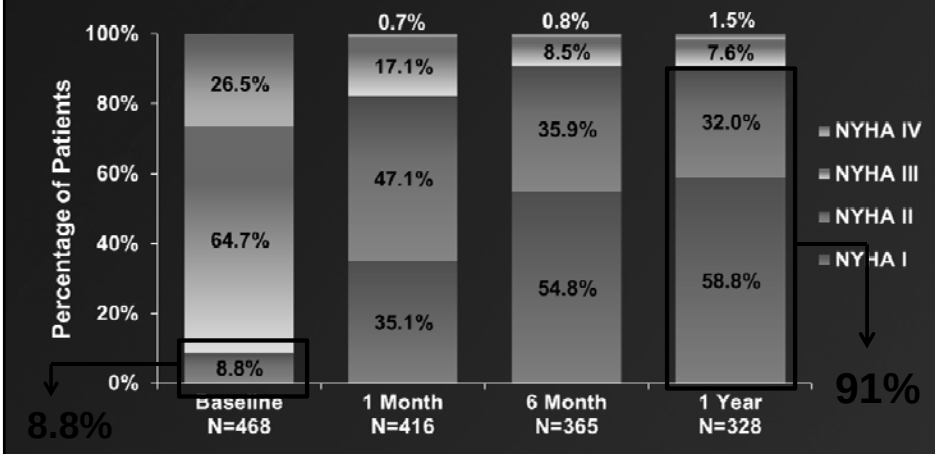
Aortic Stenosis Extreme Risk

CoreValve US Clinical Trials

NYHA Class Survivors

90% of Patients Improved at Least 1 NYHA Class by 1 Year

60% of Patients Improved at Least 2 NYHA Classes by 1 Year



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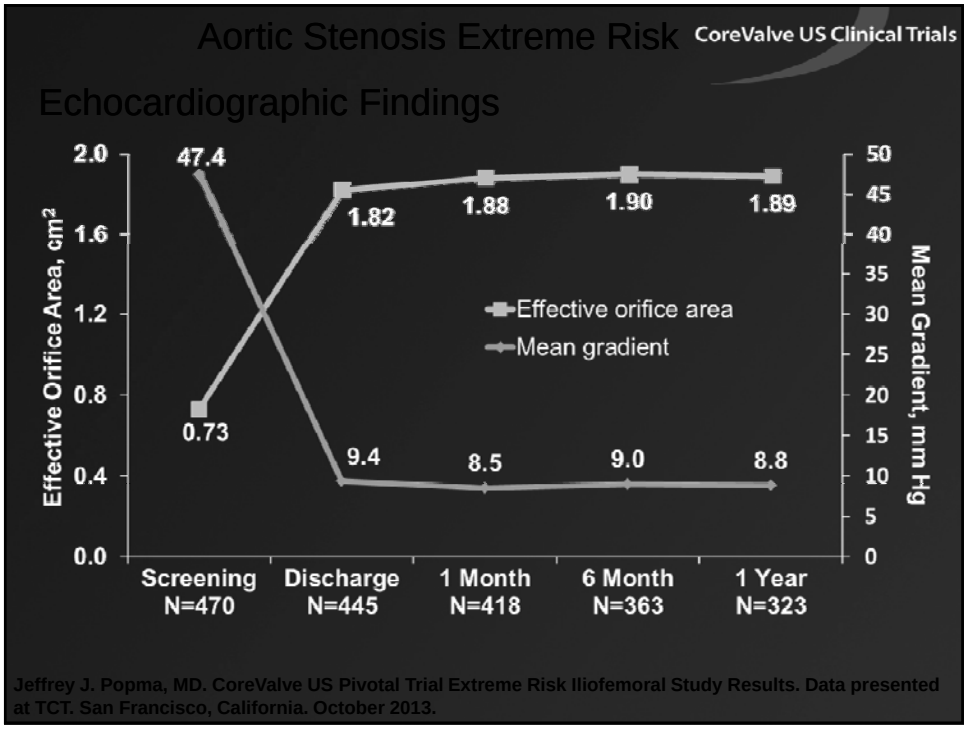
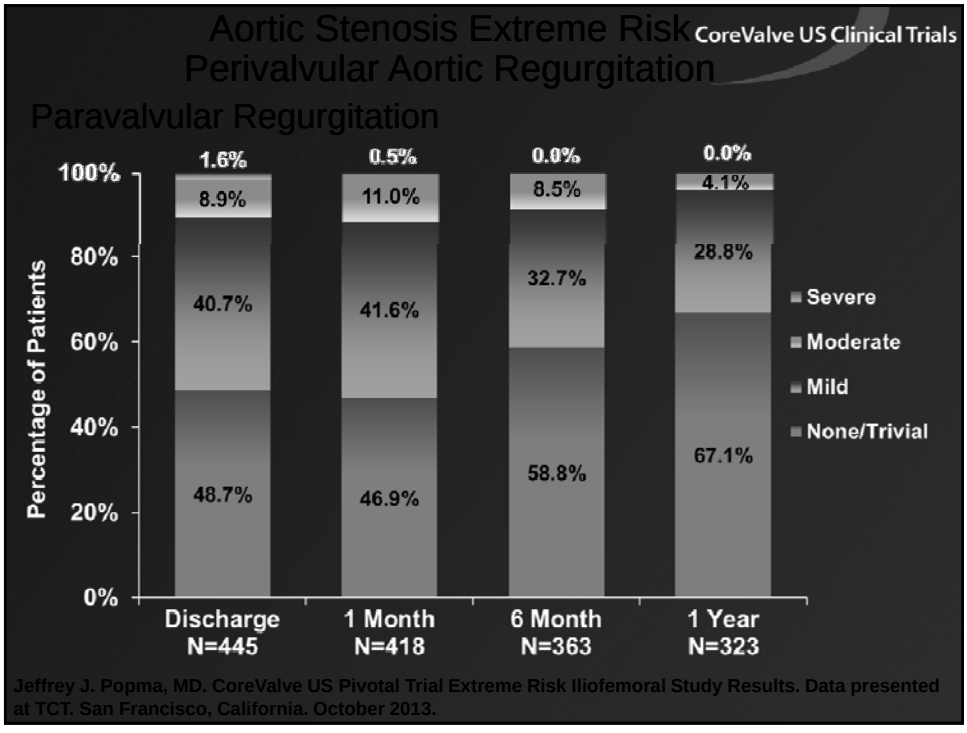
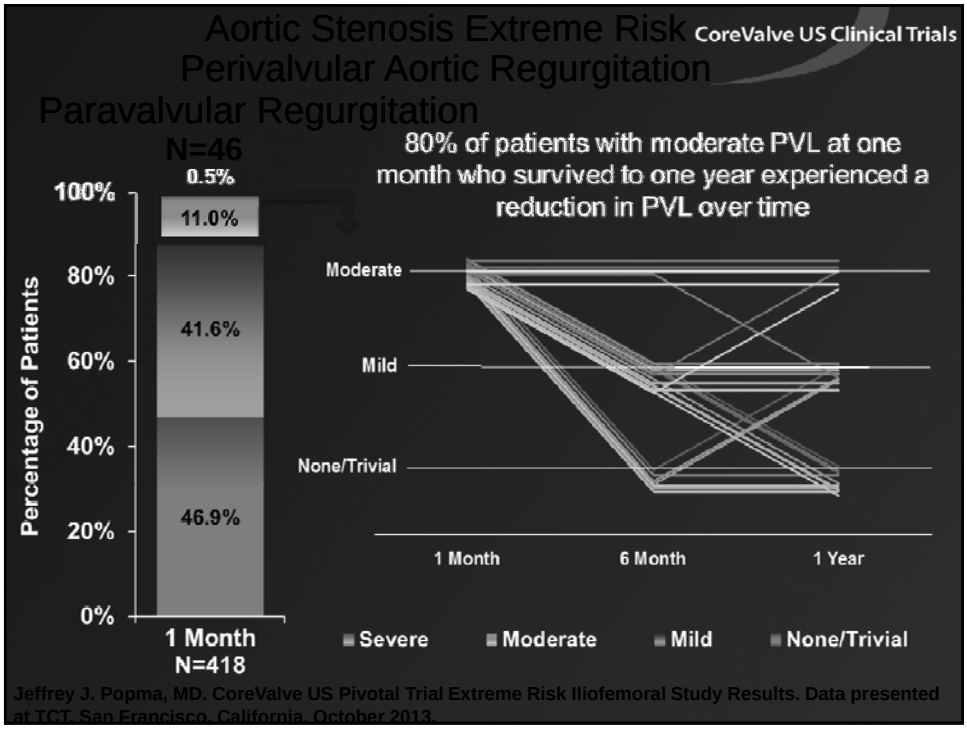
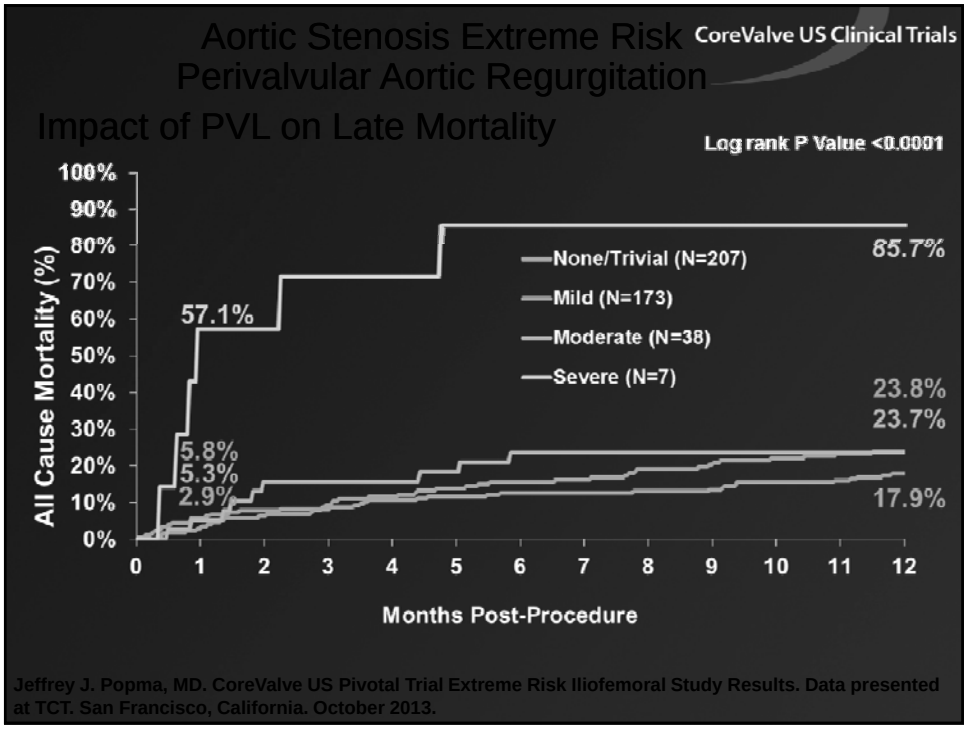

Aortic Stenosis Extreme Risk
CoreValve US Clinical Trials
Echocardiographic Findings
Effective Orifice Area, cm²
Mean Gradient, mm Hg
47.4
1.82
1.88
1.90
1.89
0.73
9.4
8.5
9.0
8.8
Effective orifice area
Mean gradient
Screening N=470
Discharge N=445
1 Month N=418
6 Month N=363
1 Year N=323
Jeffrey J. Popma, MD. CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study Results. Data presented at TCT. San Francisco, California. October 2013.

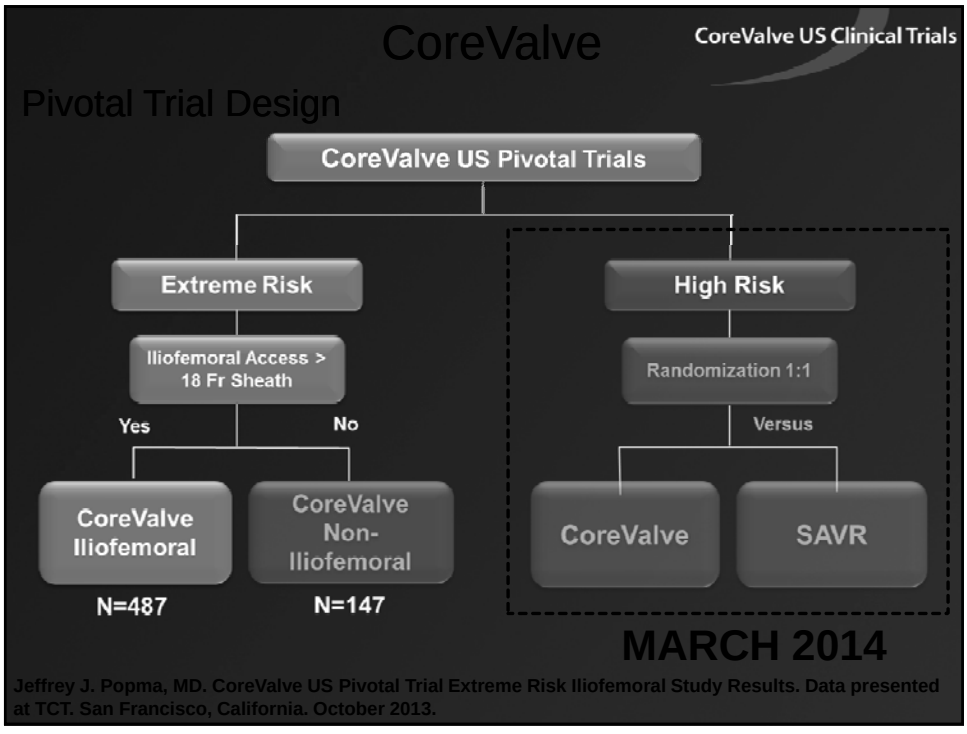

Aortic Stenosis Extreme Risk
CoreValve US Clinical Trials
Perivalvular Aortic Regurgitation
Paravalvular Regurgitation
Percentage of Patients
1.6%
8.9%
40.7%
48.7%
0.5%
11.0%
41.6%
46.9%
0.0%
8.5%
32.7%
58.8%
0.0%
4.1%
28.8%
67.1%
Severe
Moderate
Mild
None/Trivial
Discharge N=445
1 Month N=418
6 Month N=363
1 Year N=323
Jeffrey J. Popma, MD. CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study Results. Data presented at TCT. San Francisco, California. October 2013.


Aortic Stenosis Extreme Risk
CoreValve US Clinical Trials
Perivalvular Aortic Regurgitation
Paravalvular Regurgitation
N=46
80% of patients with moderate PVL at one month who survived to one year experienced a reduction in PVL over time
0.5%
11.0%
41.6%
46.9%
100%
80%
60%
40%
20%
0%
Percentage of Patients
1 Month
N=418
Moderate
Mild
None/Trivial
1 Month
6 Month
1 Year
Severe
Moderate
Mild
None/Trivial
Jeffrey J. Popma, MD. CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study Results. Data presented at TCT. San Francisco, California. October 2013.


Aortic Stenosis Extreme Risk
CoreValve US Clinical Trials
Perivalvular Aortic Regurgitation
Impact of PVL on Late Mortality
Log rank P Value <0.0001
All Cause Mortality (%)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0
1
2
3
4
5
6
7
8
9
10
11
12
Months Post-Procedure
None/Trivial (N=207)
Mild (N=173)
Moderate (N=38)
Severe (N=7)
65.7%
57.1%
23.8%
23.7%
17.9%
5.8%
5.3%
2.9%
Jeffrey J. Popma, MD. CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study Results. Data presented at TCT. San Francisco, California. October 2013.

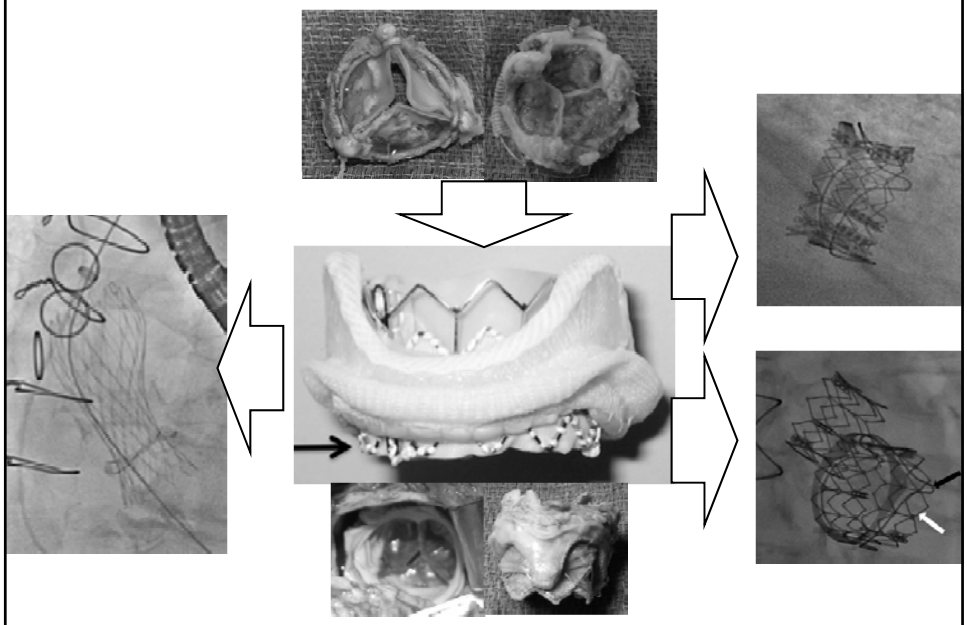
CoreValve
Extreme Risk

- **TAVR relieved aortic stenosis**
- **TAVR reduced mortality and stroke rate at one year**
- **Low rate of stroke**
- **Mild and moderate PVL was not associated with increased mortality**



Jeffrey J. Popma, MD. CoreValve US Pivotal Trial Extreme Risk Iliofemoral Study Results. Data presented at TCT. San Francisco, California. October 2013.

Valve in Valve



Ongoing and Upcoming Trials

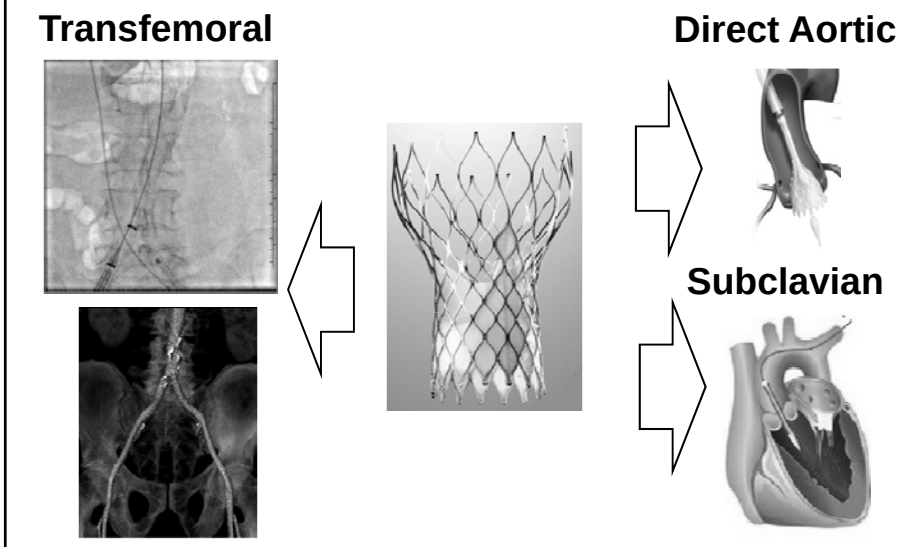
Intermediate Risk	High Risk	Extreme Risk
SURTAVI Trial	CoreValve Pivotal Trial	CoreValve Pivotal Trial
	Expanded Use	Expanded Use
PARTNER II	PARTNER A	PARTNER B

The Structural Heart Disease Team

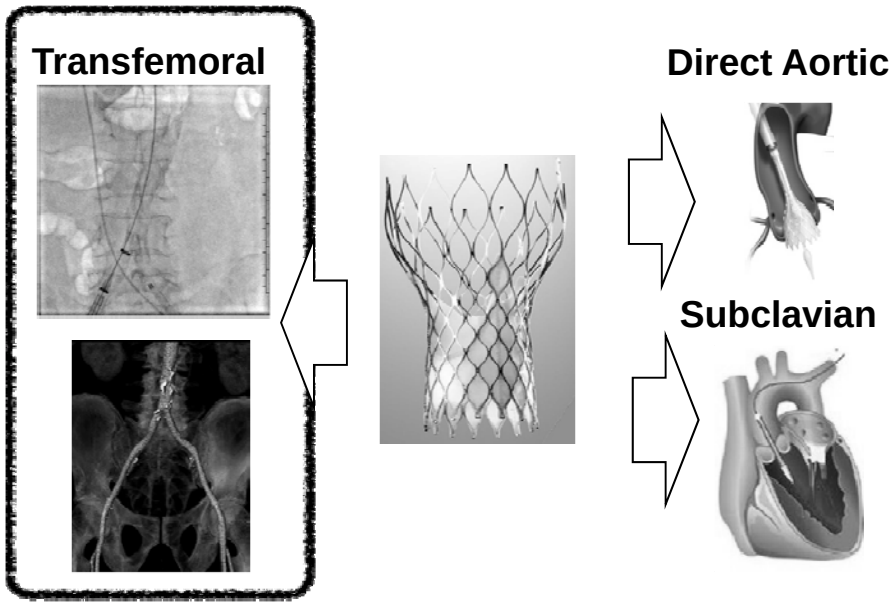
TAVR with Medtronic CoreValve: Femoral Approach

Barry George, MD
Director
Advanced Catheter-Based Therapeutics
and Structural Heart Disease
Associate Professor – Clinical
Department of Cardiovascular Medicine
The Ohio State University Wexner Medical Center

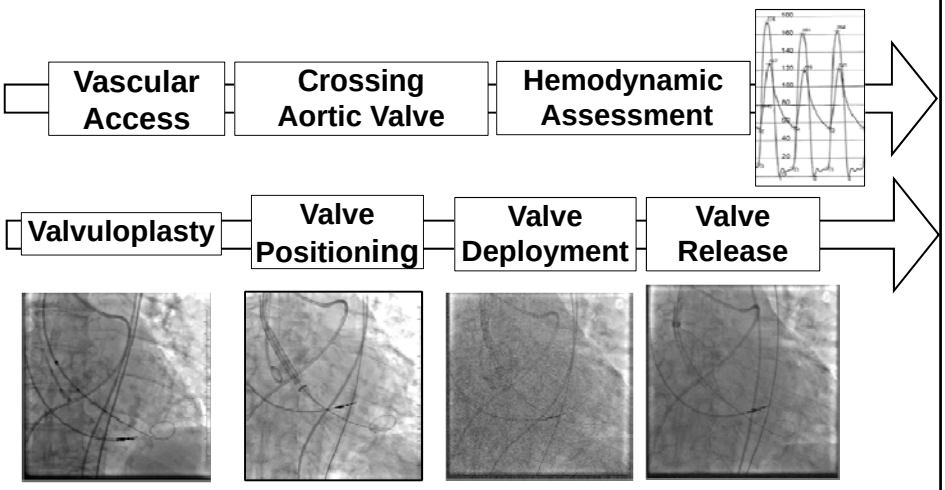
CoreValve Delivery Options



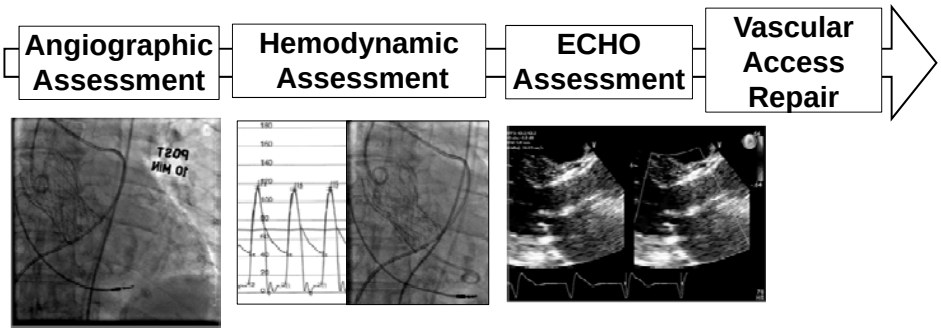
CoreValve Delivery Options



Transfemoral Step by Step



Transfemoral Step by Step



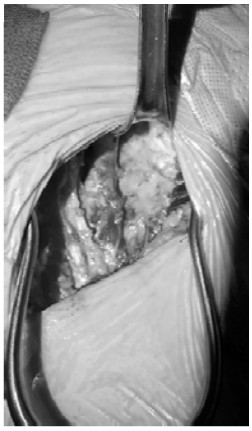
Vascular Access

Vascular Access

- Femoral artery cut down (percutaneous) for delivery sheath
- Contralateral femoral artery placement of 6F sheath.

Vascular Access

- **Femoral artery cut down (percutaneous) for delivery sheath**



Vascular Access

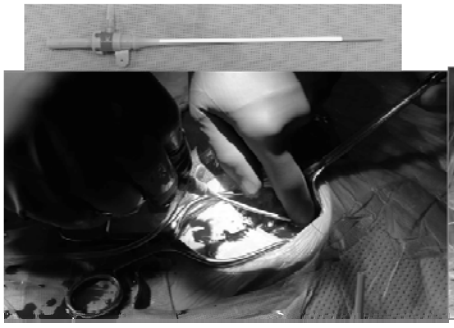
- **Femoral artery cut down (percutaneous) for delivery sheath**

5-0 Prolene purse string **Needle and guidewire**

Administer Heparin to achieve ACT>300 s

Vascular Access

- Femoral artery cut down (percutaneous) for delivery sheath

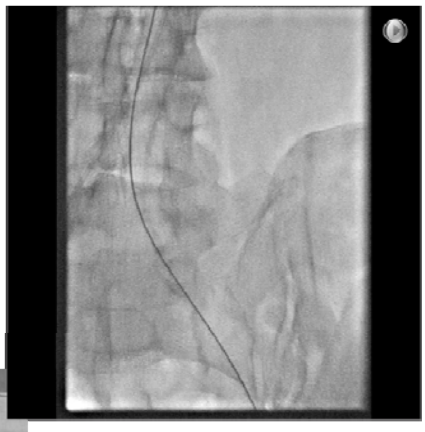


6 French Sheath placement

Pigtail placement into descending thoracic aorta

Vascular Access

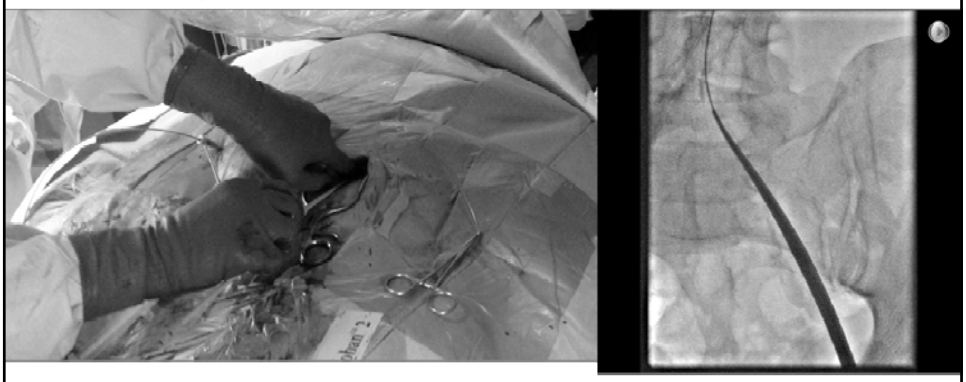
- Femoral artery cut down (percutaneous) for delivery sheath



Insertion
Amplatz Super Stiff guidewire
over pigtail catheter

Vascular Access

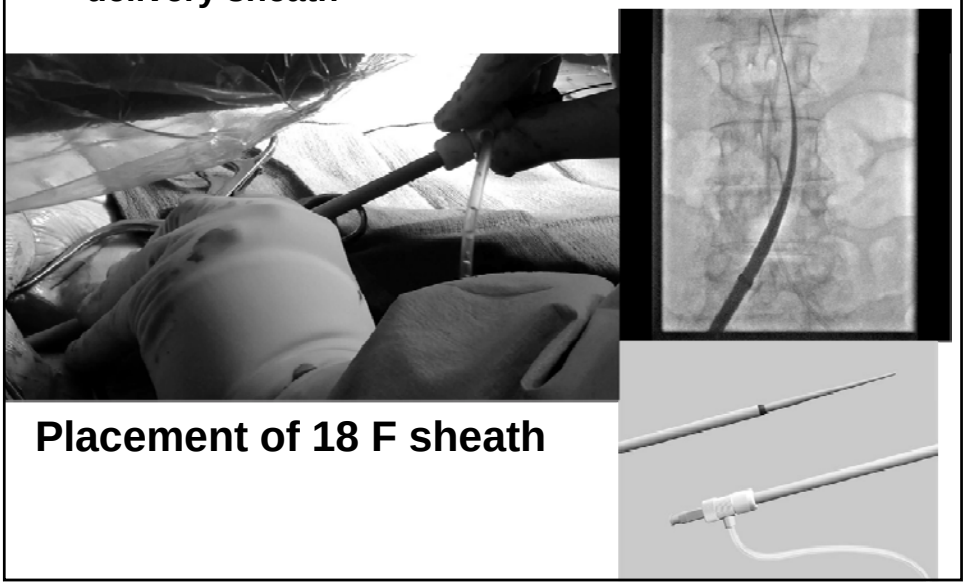
- Femoral artery cut down (percutaneous) for delivery sheath



Arterial dilatation with 12,14 and 18 F dilators over Amplatz Super Stiff guidewire

Vascular Access

- Femoral artery cut down (percutaneous) for delivery sheath



Placement of 18 F sheath

Vascular Access

- **Contralateral femoral artery placement of 6F sheath.**

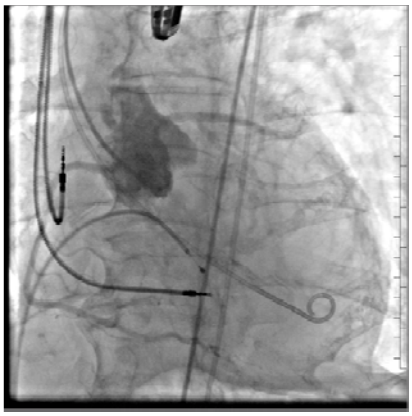
Percutaneous arterial access

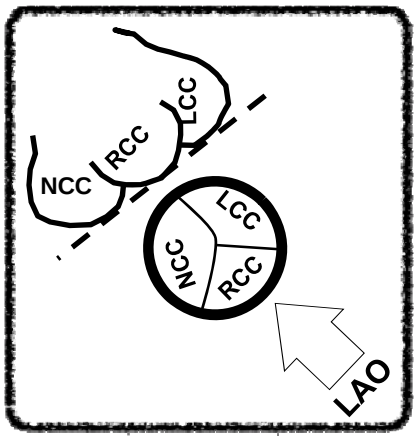
6F Sheath and pigtail

Implant projection

Determination of implantation projection

- Alignment of all 3 cusps of aortic valve in a single plane.





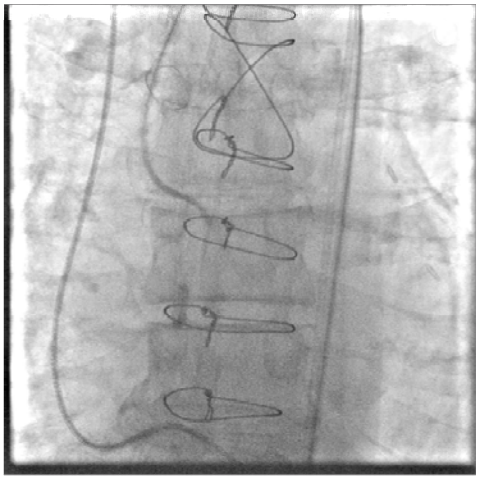
Pigtail advance to non-coronary sinus

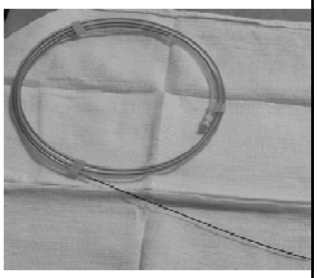
Crossing Aortic Valve

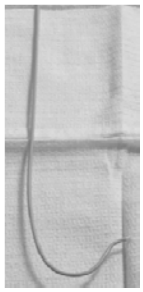
Initial Hemodynamic Assessment

Crossing the Aortic Valve

- AL 2 catheter with straight guidewire
- AP projection

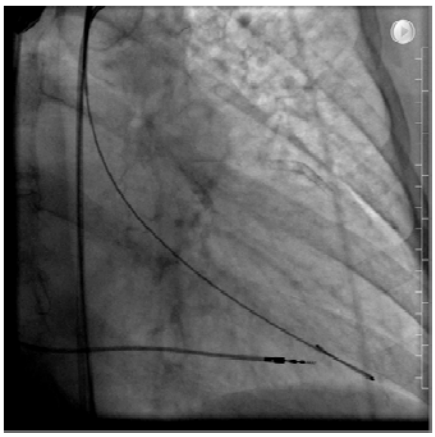






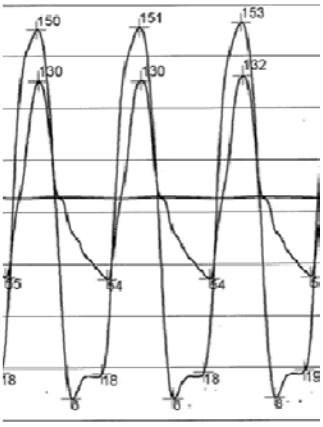
Crossing the Aortic Valve

- Exchange guidewire
- ROA projection
- Pigtail placement in LV apex



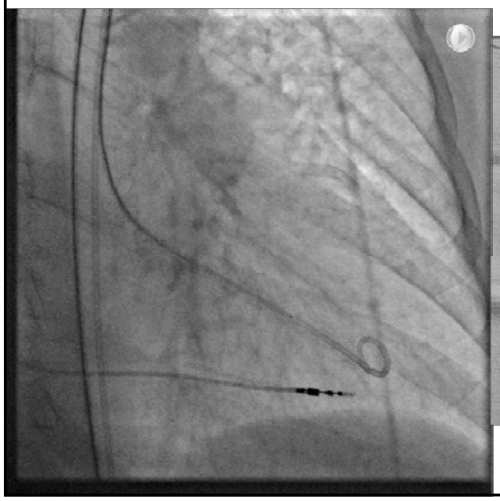
Initial Hemodynamic Assessment

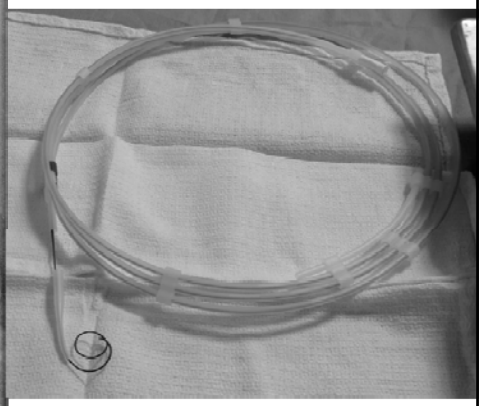
- LV and Aortic pressure



Placement of stiff guidewire in the LV apex

- RAO projection
- Amplatz Super Stiff ST1 (pigtail configuration)





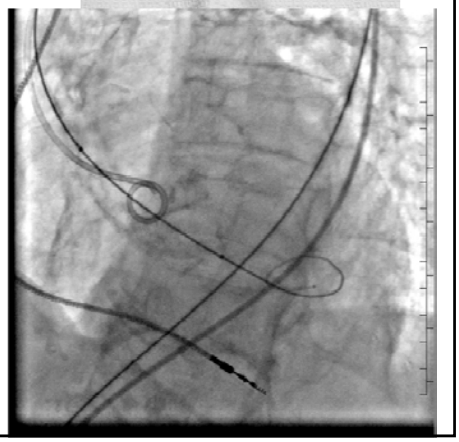
Aortic Valvuloplasty

Aortic balloon valvuloplasty

- **Balloons:**
  - **Z MED (NuMED Inc)**
  - **NuCLEUS Ballon (NuMED Inc)**
  - **True Balloon (Loma Vista Medical)**
- **Balloon size: smaller diameter of aortic annulus**
- **Pacing rate: 160-180 bpm**
- **Screw-in temporary pacing lead**
- **If patient has a PPM,transvenous pacer in the OR.**
- **No valvuloplasty in:**
  - **Low EF patients <30-35%**
  - **Large plaque-calcifications in the aorta or sinus of Valsalva**
  - **Valve in valve**

Aortic balloon valvuloplasty

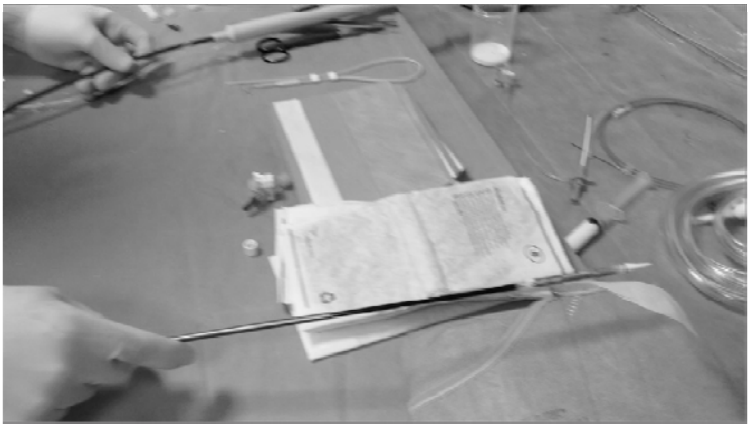
- Pacer on
- Balloon up
- Ballon down
- Pacer off



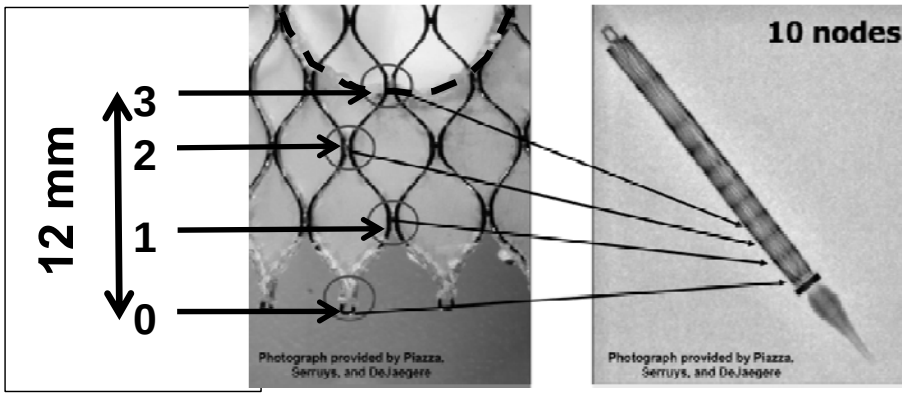
CoreValve Implantation

CoreValve Implantation

- CoreValve is loaded into the delivery system before the valvuloplasty

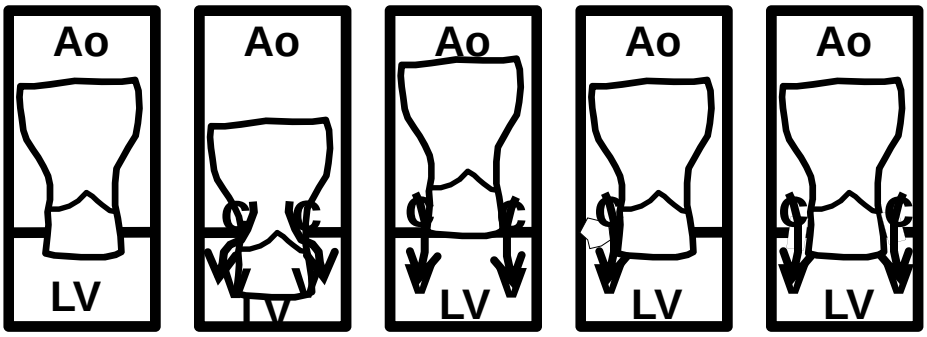


CoreValve in the delivery capsule



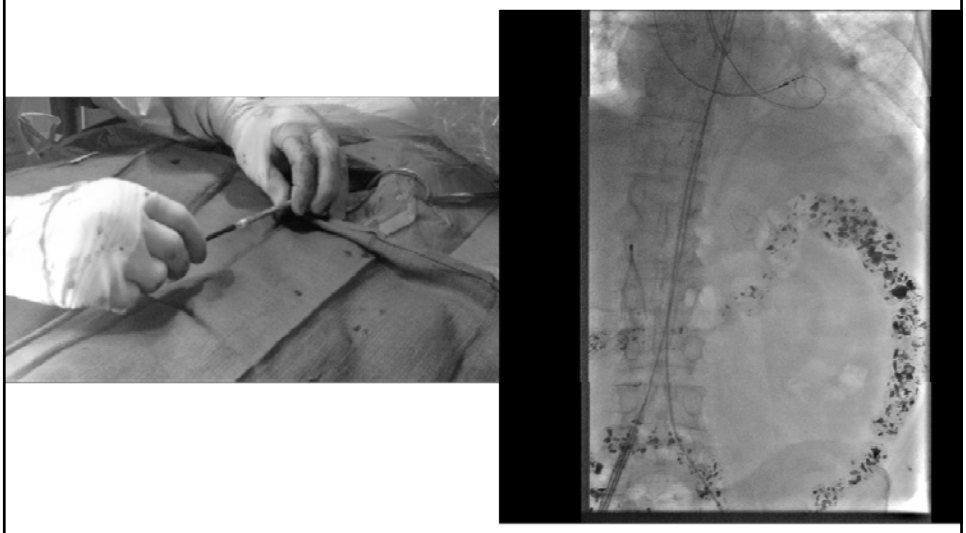
Optimal implantation depth 2 to 6 mm

Depth of implantation

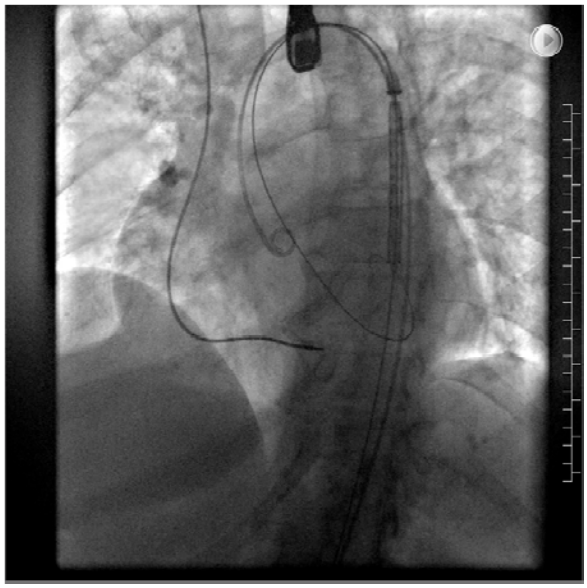


Correct	**Too deep**	**Too shallow**	**Irregular**	**Large**
No AI	AI AV block	AI Pop out	annulus AI	annulus AI

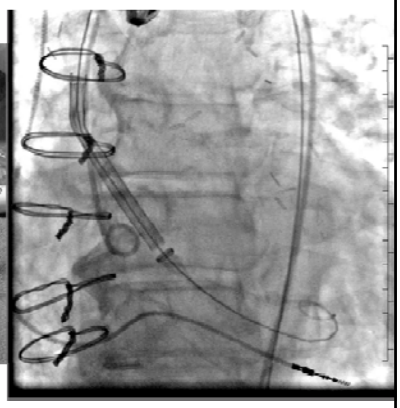
CoreValve insertion and advancement into the aortic root



CoreValve insertion and advancement into the aortic root

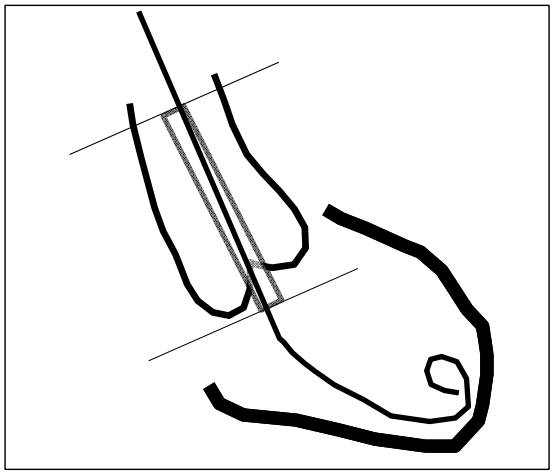


CoreValve Deployment

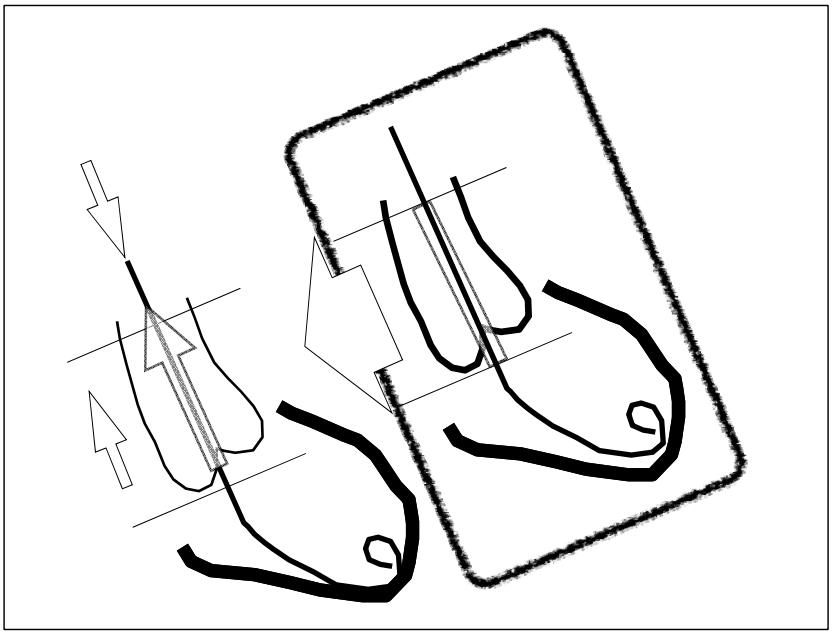


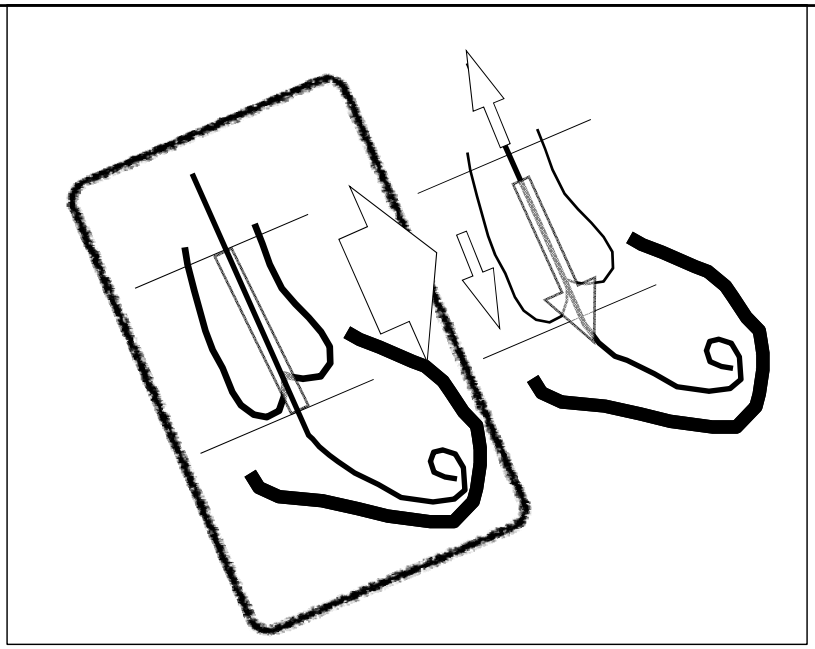
CoreValve Deployment

- **Position adjustments**
  - **Operator #1: Pulling or pushing delivery catheter**
  - **Operator #2: Pulling or pushing guidewire**



Pushing guidewire: CoreValve moves out (toward the aorta)

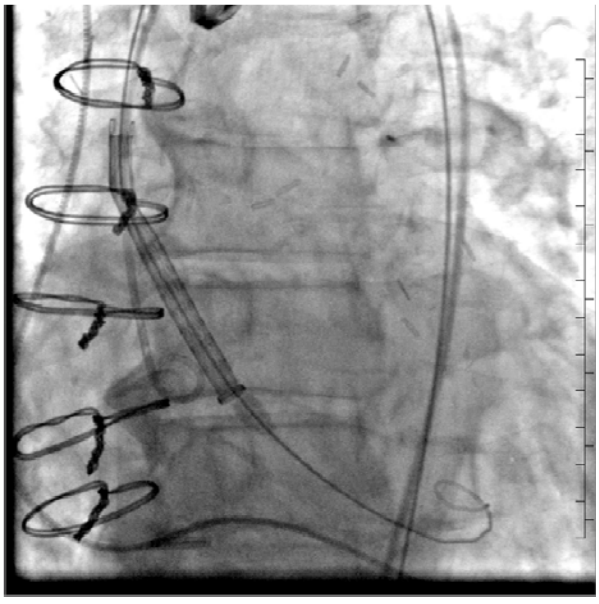




Pulling guidewire: CoreValve moves in (toward ventricle)

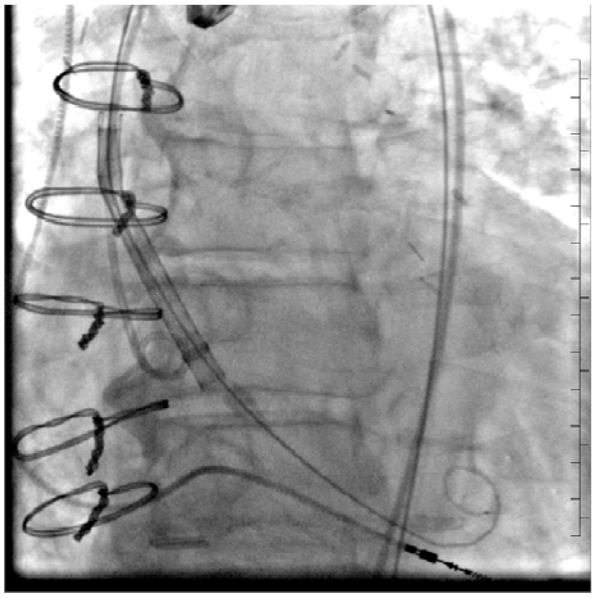
CoreValve Deployment

- Node 0



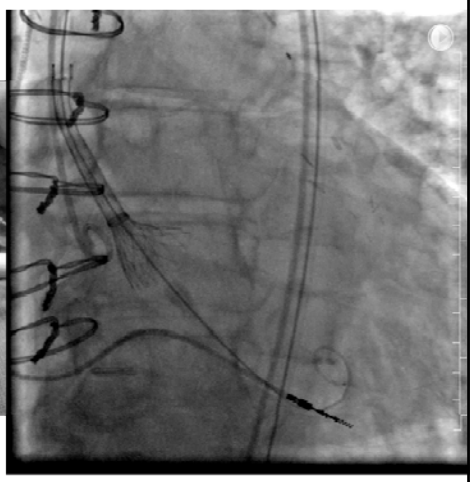
CoreValve Deployment

- Node 1



CoreValve Deployment

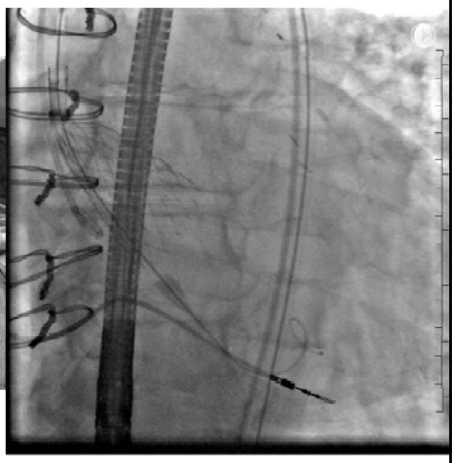
- Node 2 to 3/4



- Rapid ventricular pacing

CoreValve Deployment

- **Final release**



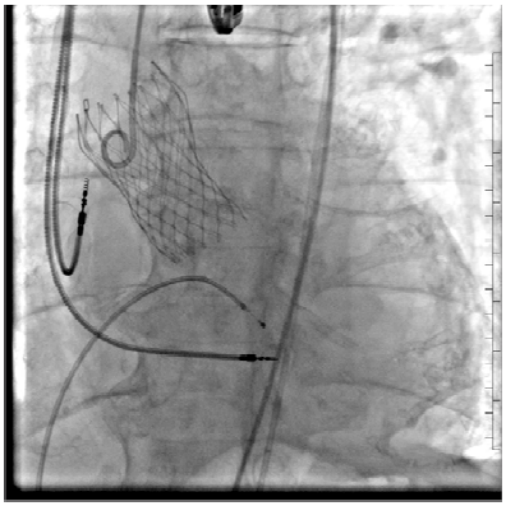
Nosecone

- **Recapture of the nosecone in the descending aorta and removal of the delivery catheter**

Valve Function Assessment

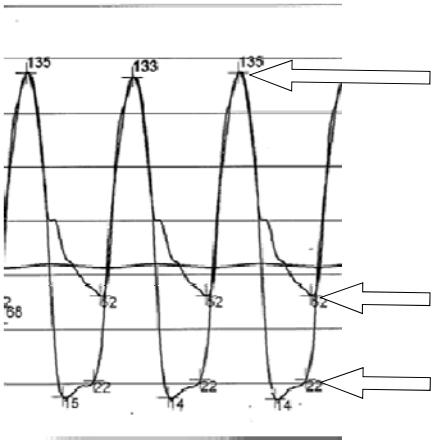
Valve Function Assessment

- **Angiography**



Valve Function Assessment

- Hemodynamics



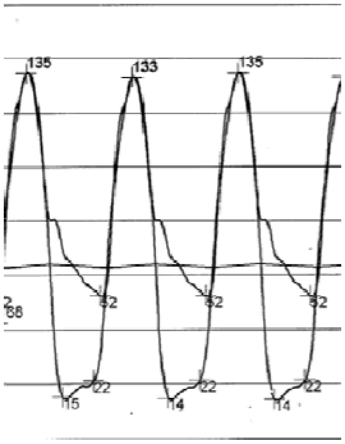
Aortic Systolic Pressure

Aortic Diastolic Pressure

Left Ventricular End-diastolic Pressure

Valve Function Assessment

- Hemodynamics



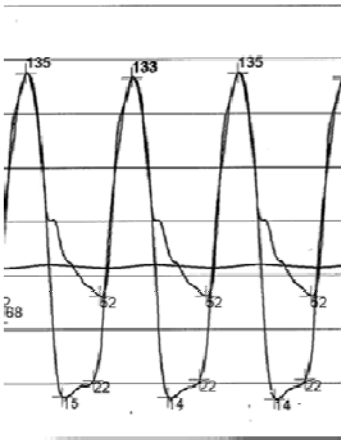
Aortic Regurgitation Index

$$\frac{\text{Ao Diastolic - LVEDP}}{\text{Ao Systolic}} > 0.25$$

Aortic Diastolic Pressure >40 mmHg

Valve Function Assessment

- **Hemodynamics**



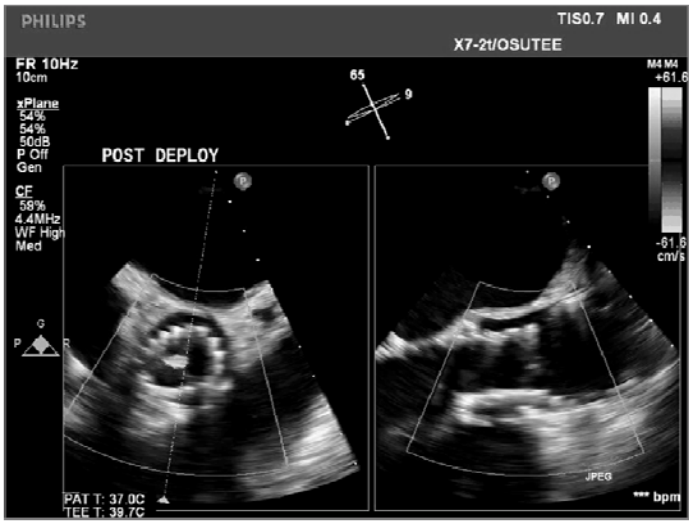
Aortic Regurgitation Index

$$\frac{\text{Ao Diastolic - LVEDP}}{\text{Ao Systolic}} \quad \underline{>0.25}$$

$$\frac{(62-22)}{135} = 0.29$$

Valve Function Assessment

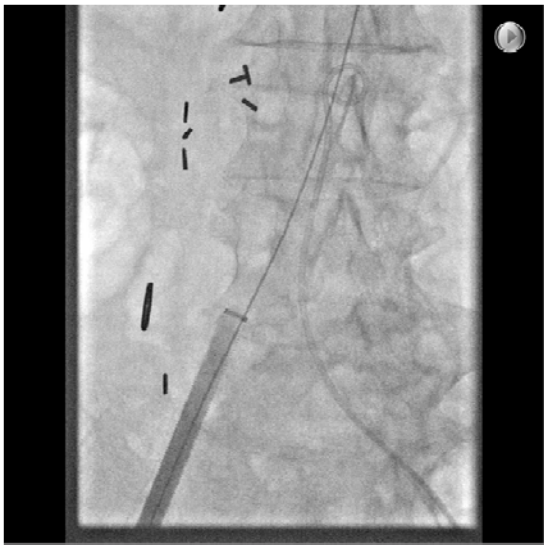
- **Echocardiography**



Sheath Removal Access Repair

Sheath removal

- Over stiff guidewire
- Inject contrast through sheath
- Contralateral pigtail in the aortic bifurcation



Sheath removal

- If iliac artery rupture:
  - Advance sheath and dilator over stiff guidewire
  - Place Coda aortic occlusion balloon through contralateral pigtail (arterial sheath may need to be exchange)
  - Place coverstent through ipsilateral sheath

Arteriotomy repair