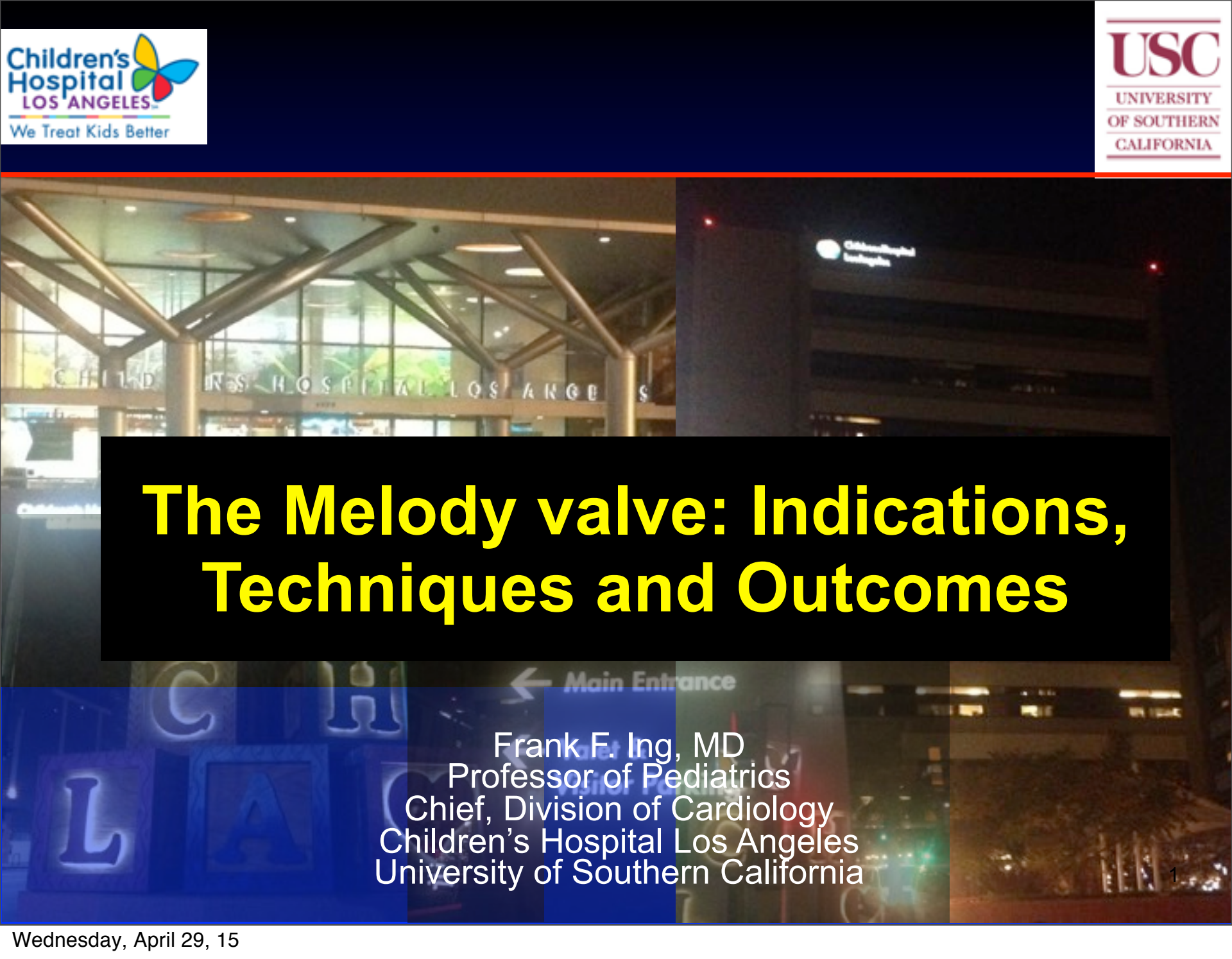


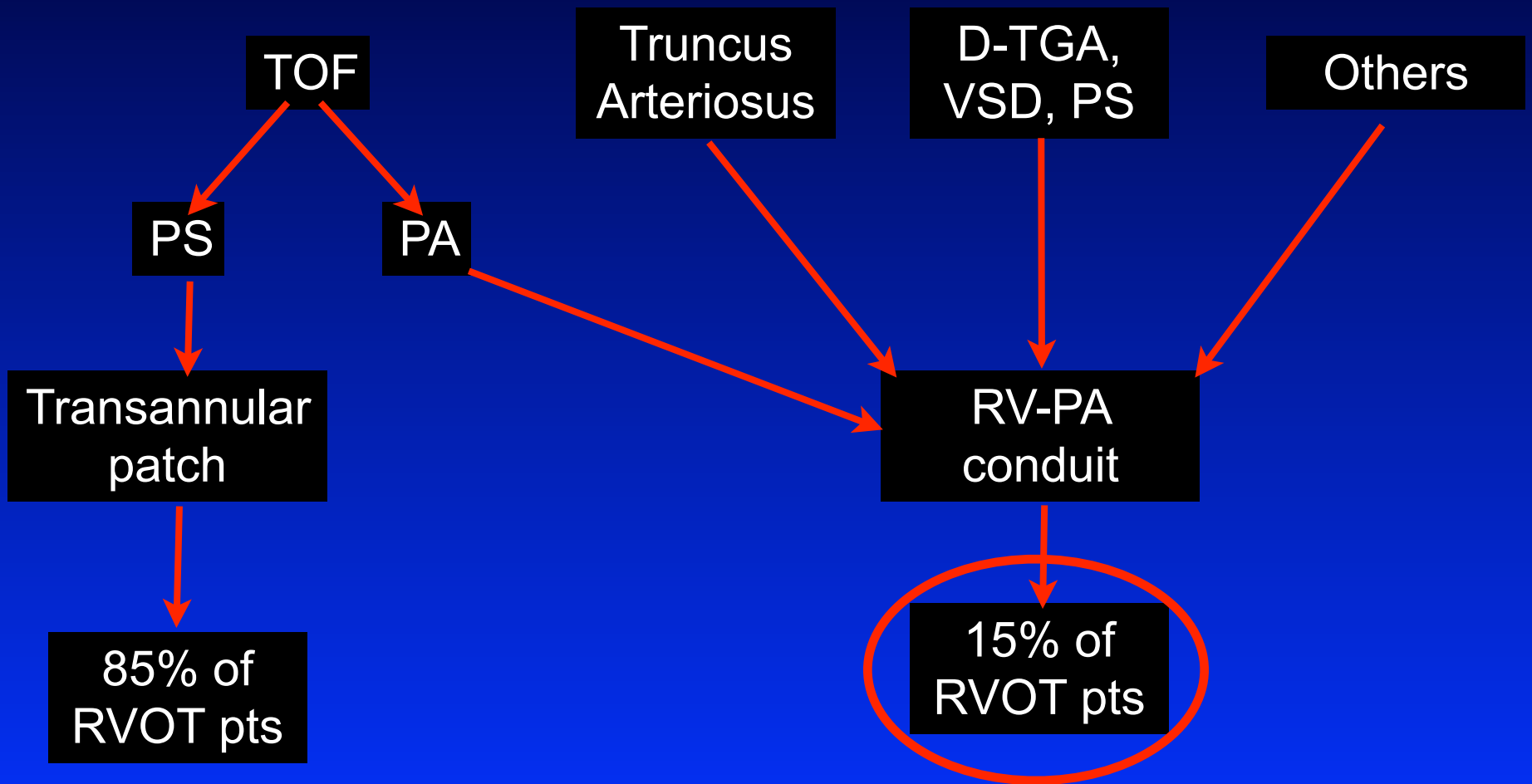
The Melody valve: Indications, Techniques and Outcomes

Frank F. Ing, MD
Professor of Pediatrics
Chief, Division of Cardiology
Children's Hospital Los Angeles
University of Southern California

Indications for use of the Melody® TPV

- The Melody TPV is intended for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:
  - Existence of a full (circumferential) RVOT conduit ≥16mm in diameter when originally implanted, AND
  - Dysfunctional RVOT conduits with a clinical indication for intervention:
    - Regurgitation: ≥ moderate regurgitation, AND/ OR
    - Stenosis: mean RVOT gradient ≥ 35 mmHg
- There are no known contraindications for the Melody TPV

Congenital Heart Defects



Patient Selection Criteria

Selection criteria

- Objective evidence of conduit dysfunction
  - Moderate or severe regurgitation
  - Right ventricular outflow obstruction
- Ability to accommodate the 22 Fr delivery catheter
- Conduit originally > 16mm
- Favorable RV-PA conduit morphology
  - Amenable to stent anchorage
  - Sizing balloon (waist) diameter
    - ≥ 14mm and ≤ 20mm

Exclusion criteria

- Active endocarditis
- Unsuitable anatomy
- Patch-repaired native outflow tract
- Risk of coronary occlusion

Results US IDE Study*

Event	Freedom From Event @ 1 year N=136	Freedom From Event @ 2 years
Death	>99%	>99%
Reoperation (Conduit exchange)	>99%	>99%
Catheter Reintervention	93.5%	87.6%
All Stent Fracture	77	

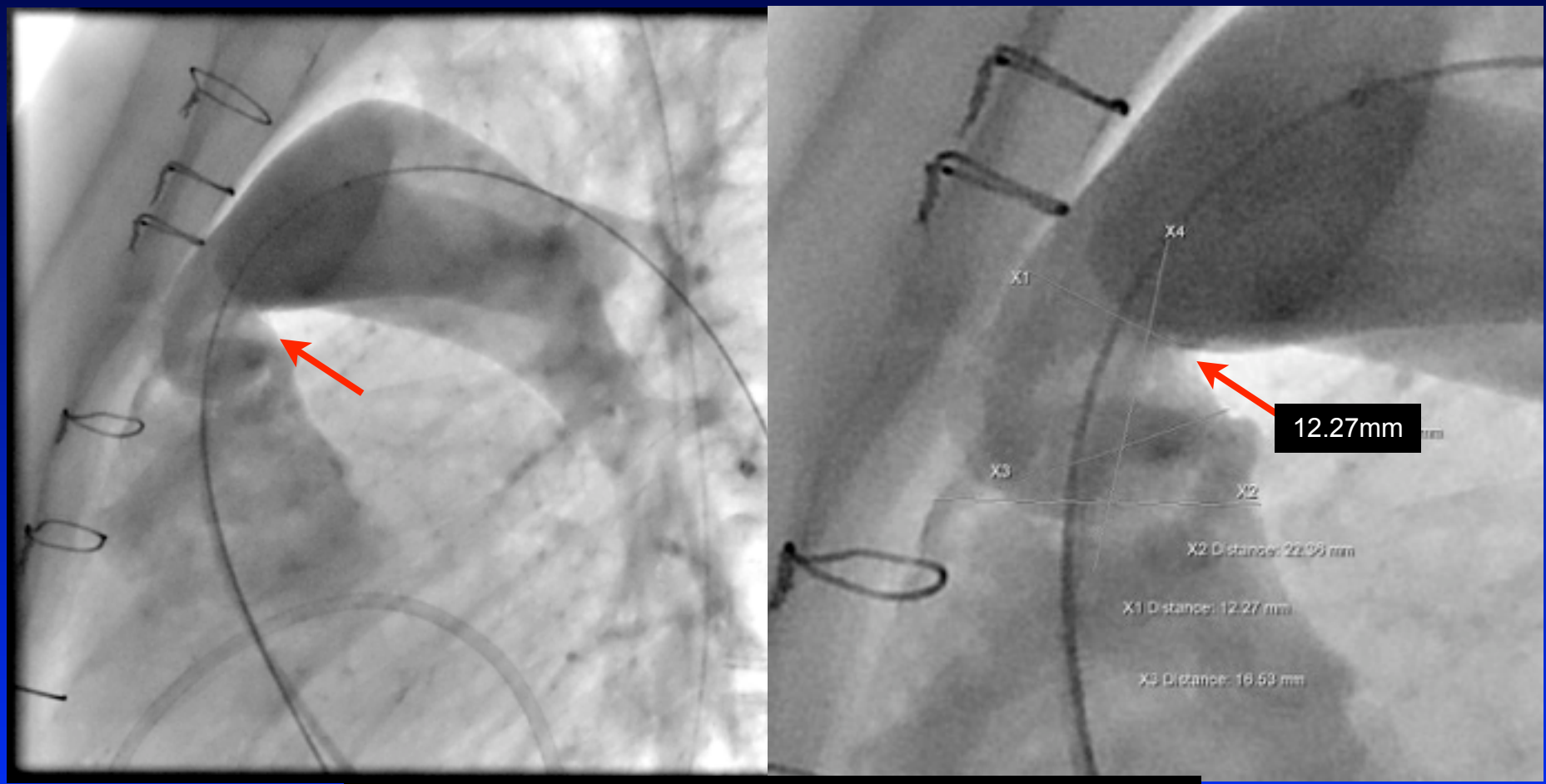
Safe

Effective

22% fracture rate

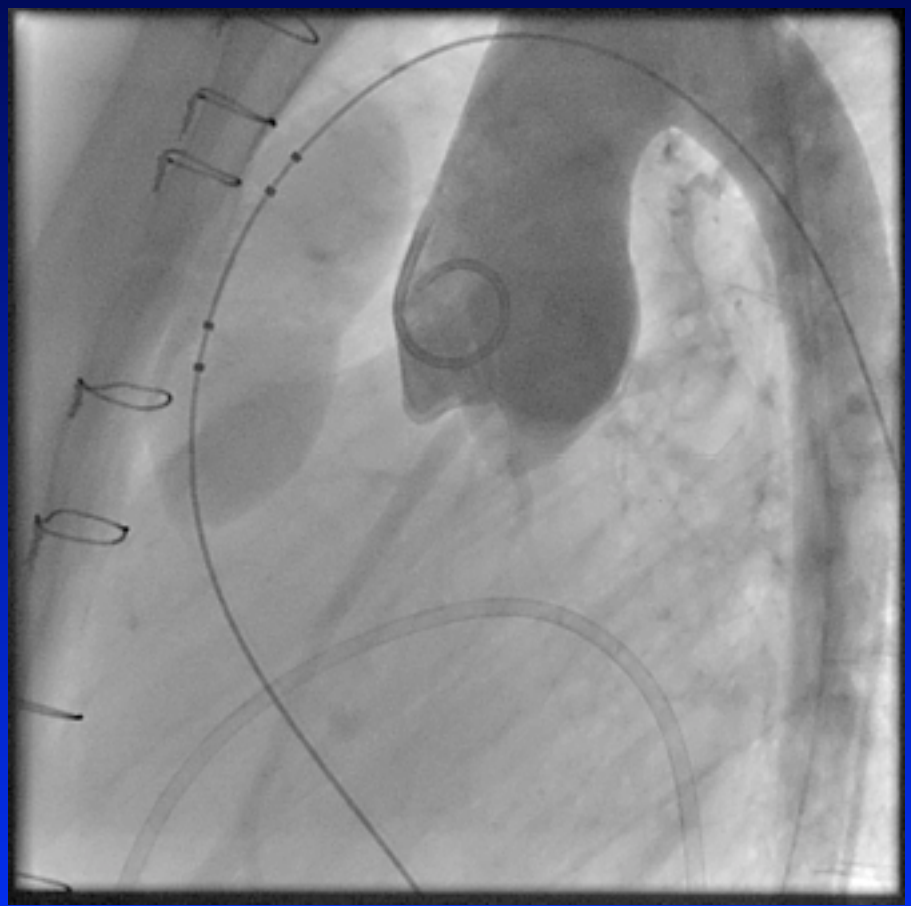
*McElhinney D, et al. Short and Medium Term Outcomes After Transcatheter Pulmonary Valve Placement in the Expanded Multi-Center US Melody Valve Trial. Circulation 2010;122:507-516.

Right heart catheterization for hemodynamics and anatomy



Conduit stenosis and regurgitation

Evaluate coronary artery course



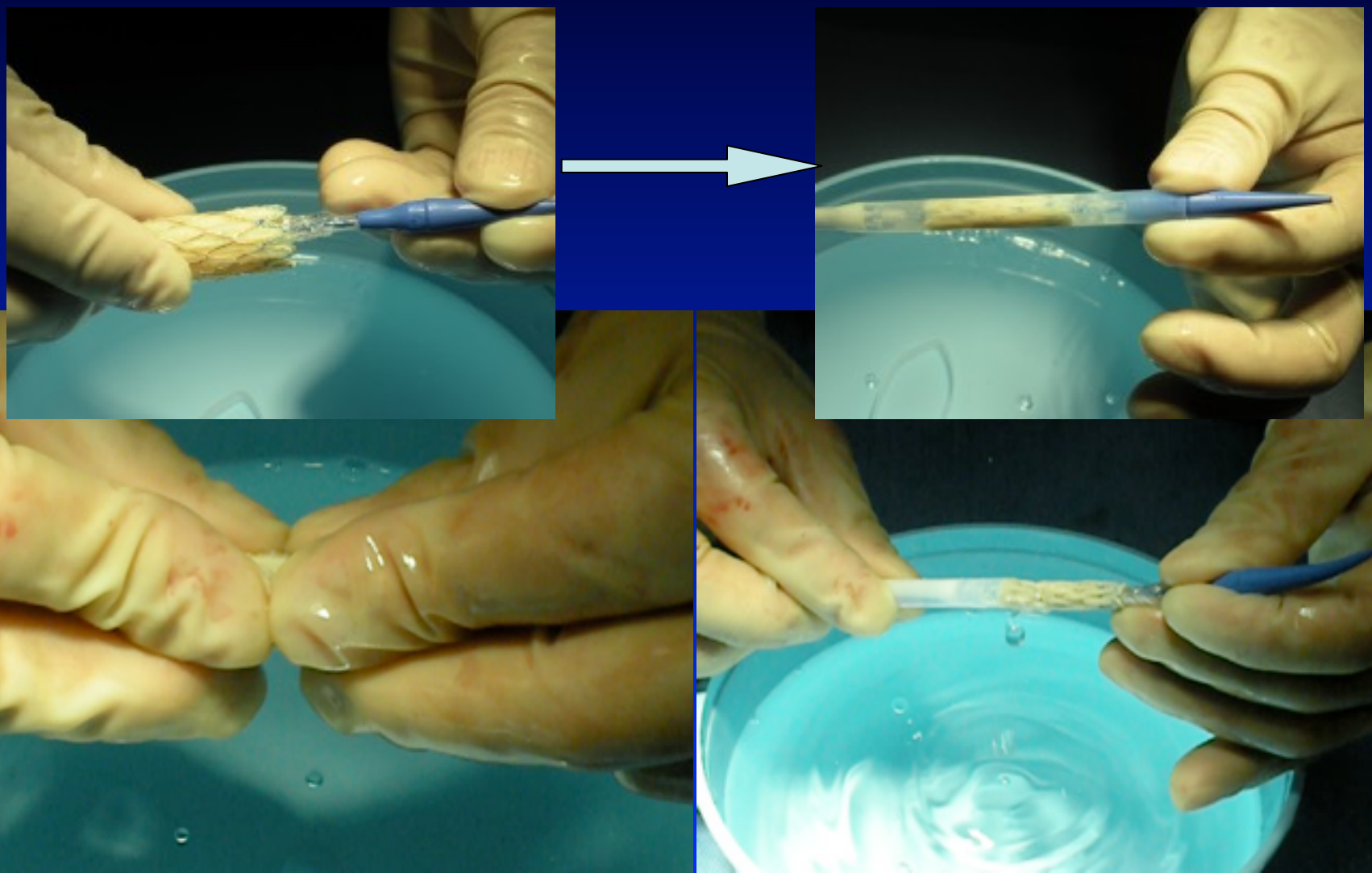
Preparing Melody valve

Rinse in saline wash

Crimping Melody valve

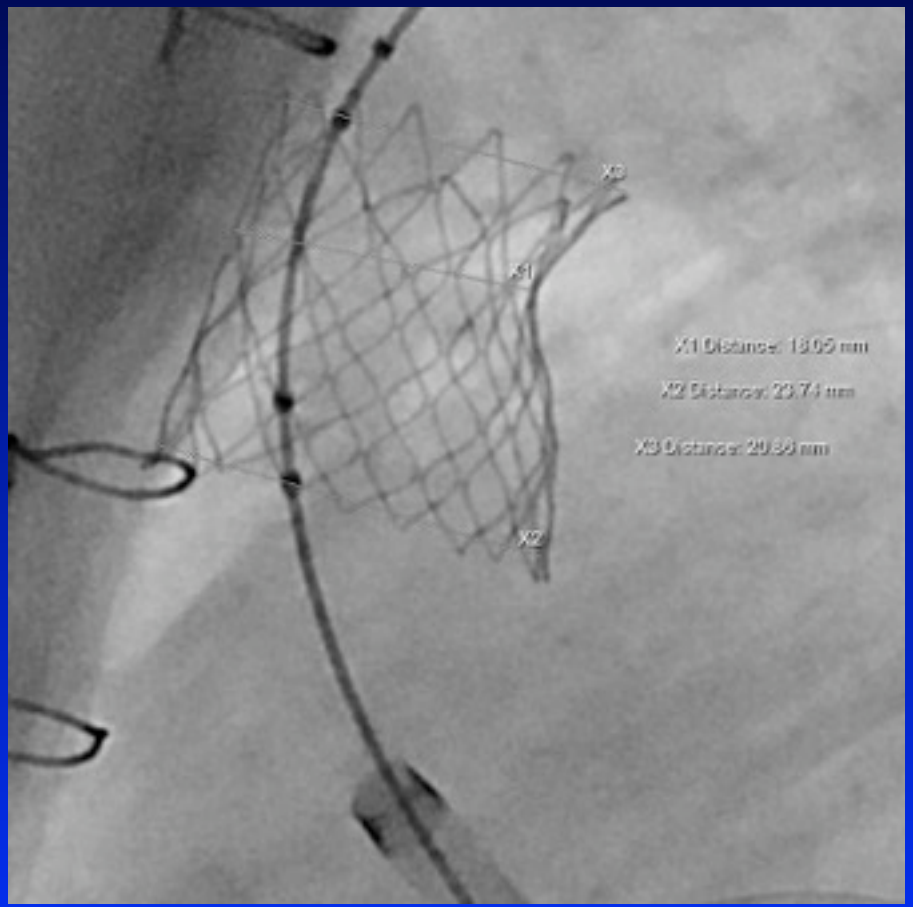
Crimp valve on
3cc syringe

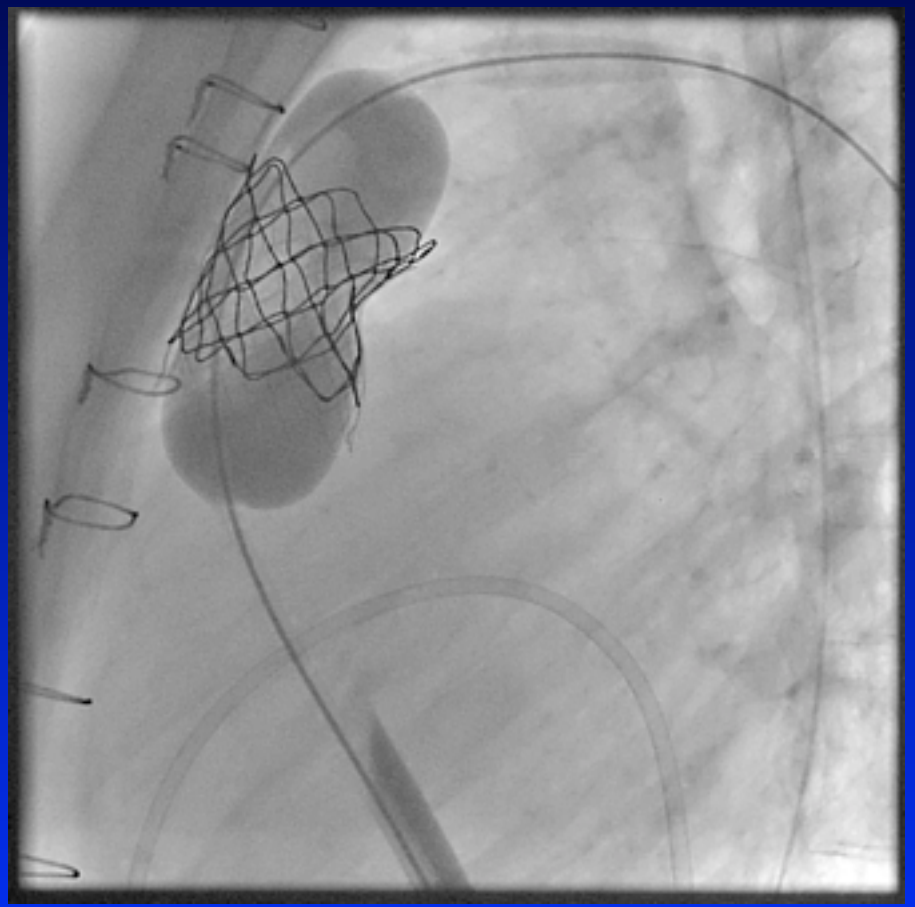
Crimp and load Melody valve



Upsize femoral venous sheath: 7-22 Fr dilators

Melody valve implant



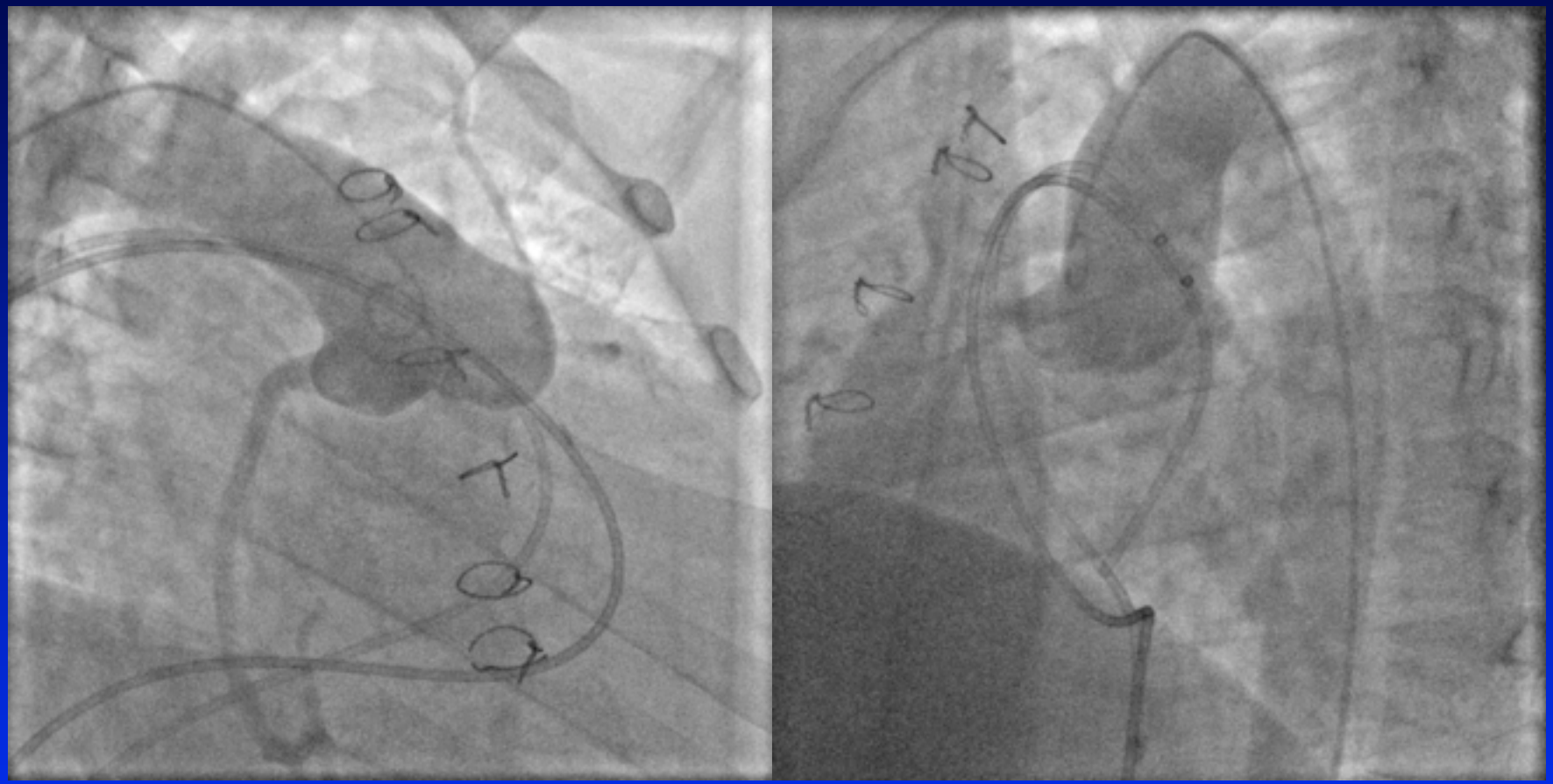


Post stent angiogram

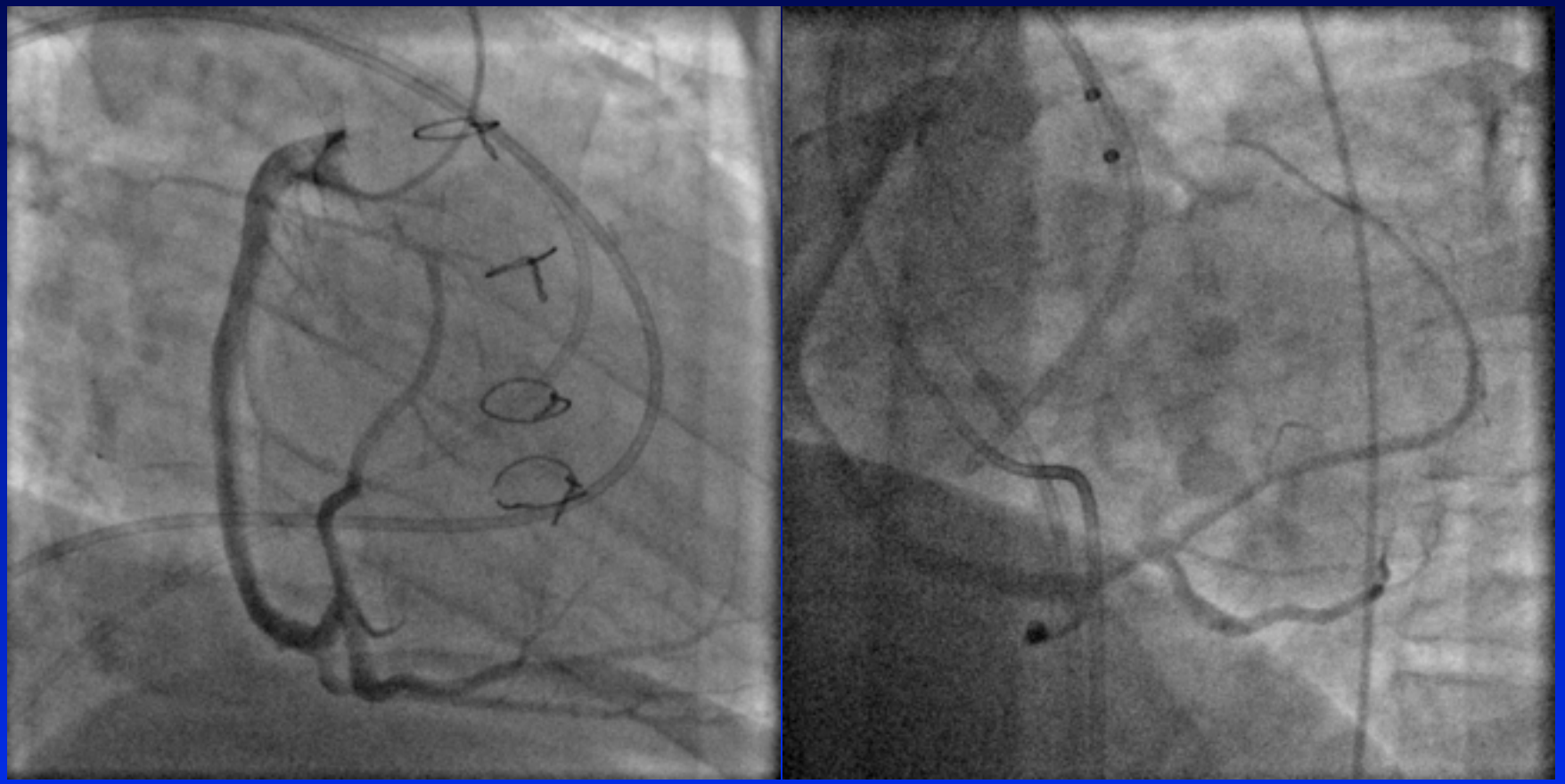
Problems and pitfalls

- Beware of coronary artery compression
- Melody valve delivery issues
- Melody valve stent fracture
- Conduit issues:
  - Calcified conduits; recoil, dissections & ruptures
  - Angulated conduits
  - Extending limits of homografts
- Vascular issues
  - Venous hemostasis
  - Vascular access
- Post Melody implant
  - Arrhythmias
  - Endocarditis issues
- Melody valve implant in other positions

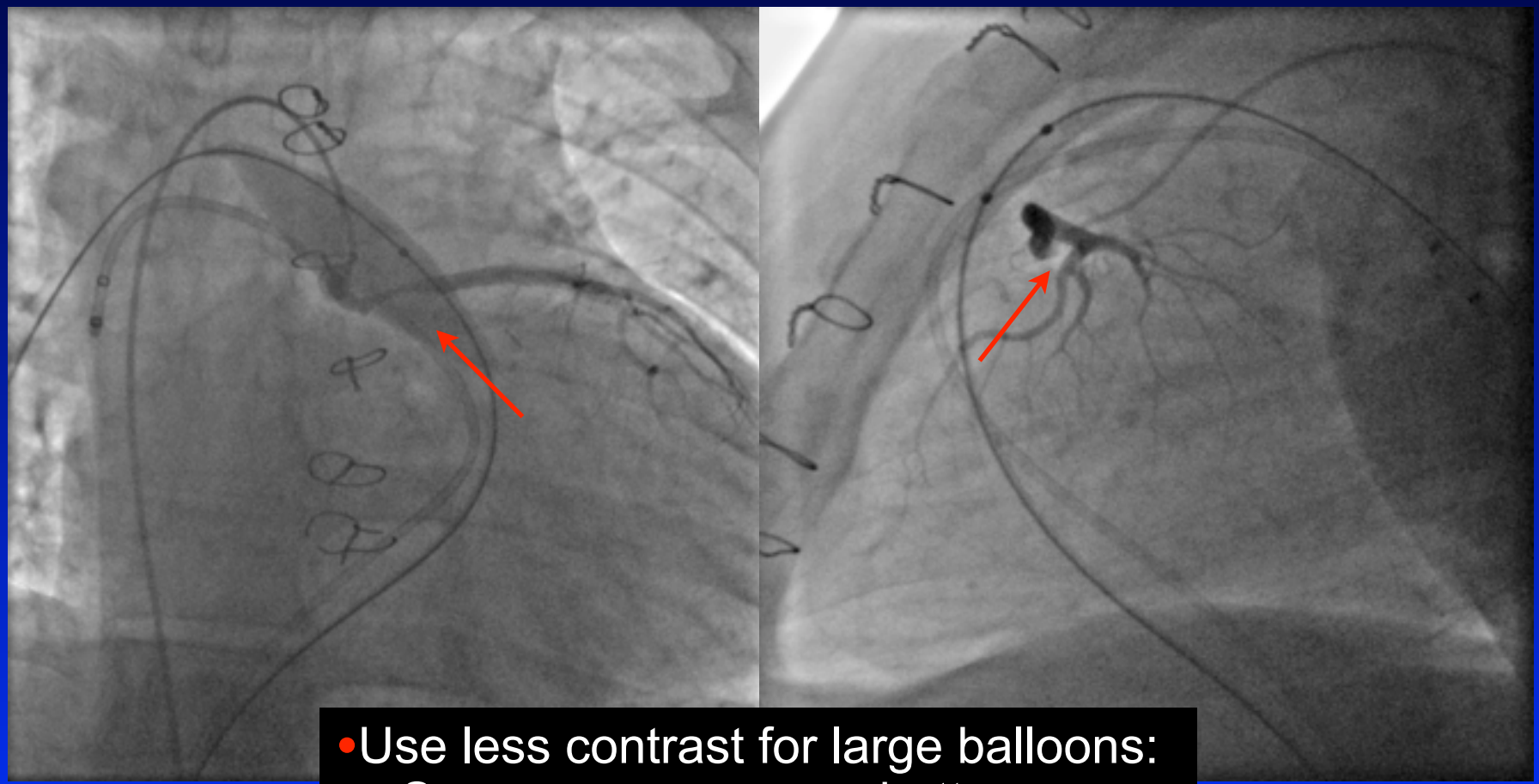
Aortogram-
CA course not clear



RCA angiogram

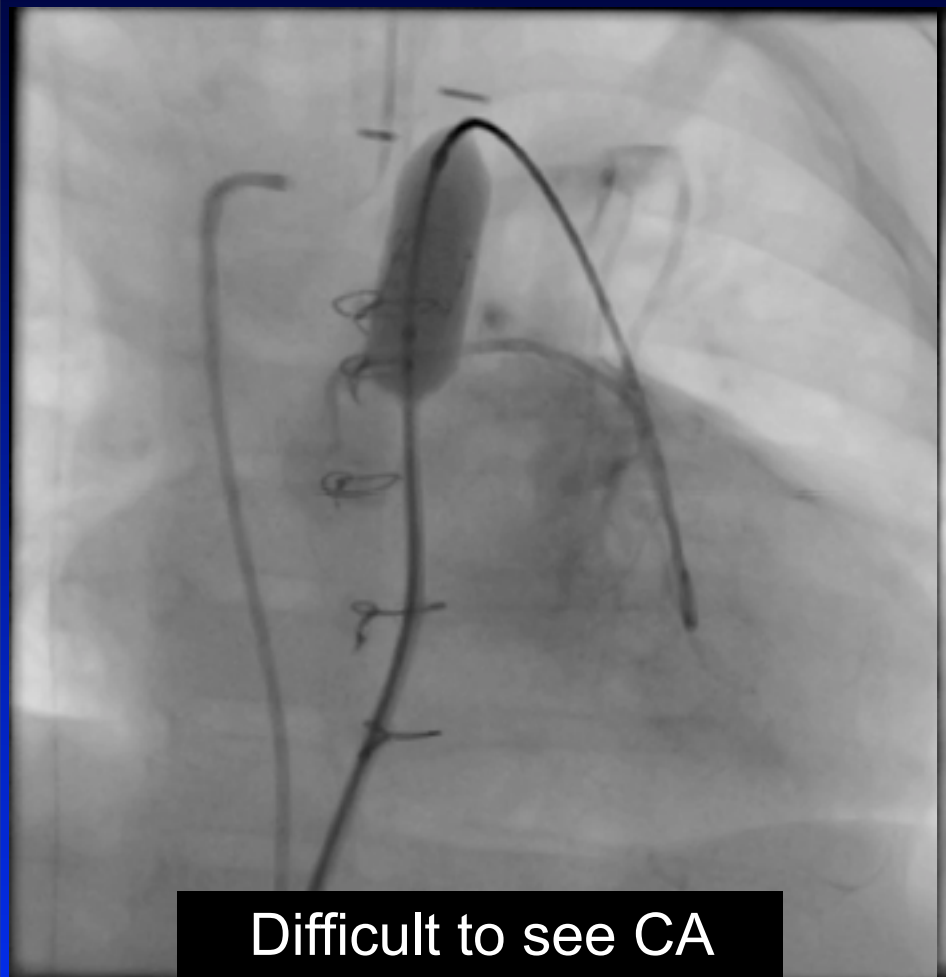


Balloon test inflation: LAD off right coronary sinus

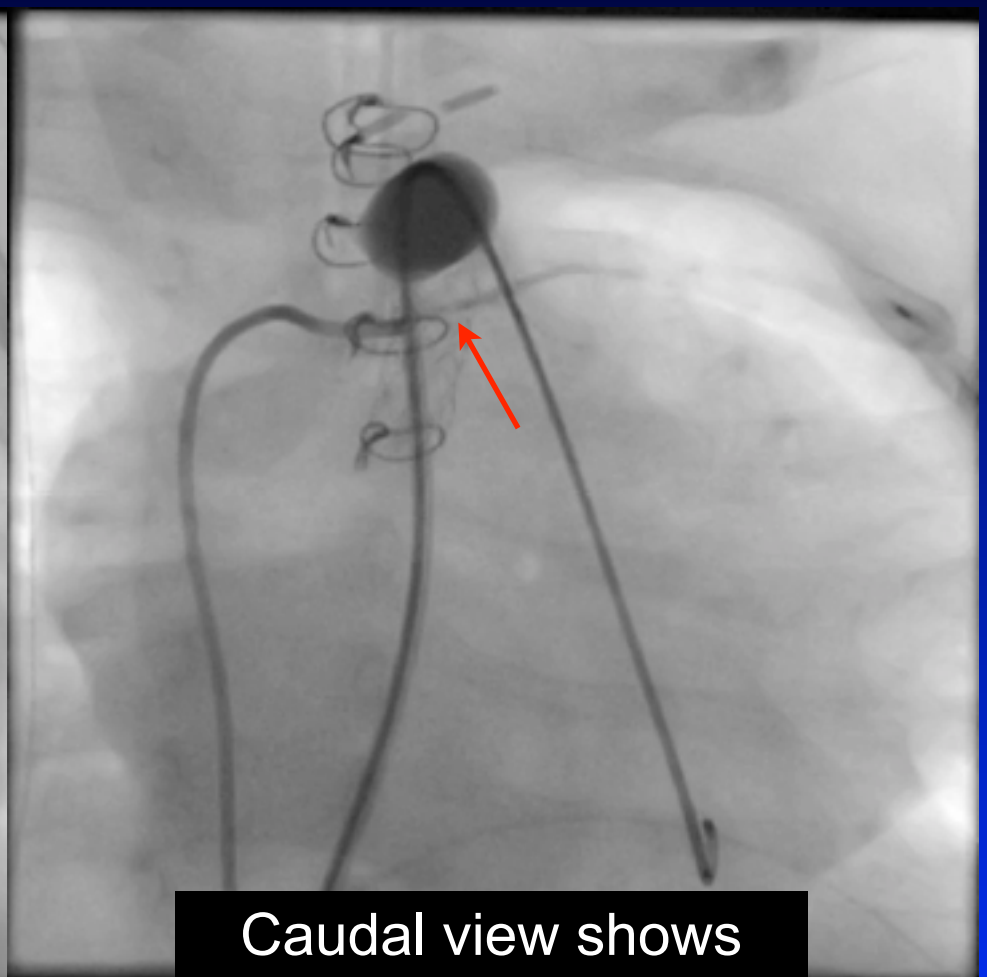


- Use less contrast for large balloons:
  - See coronary course better
  - Faster inflation and deflation

Cononary artery compression

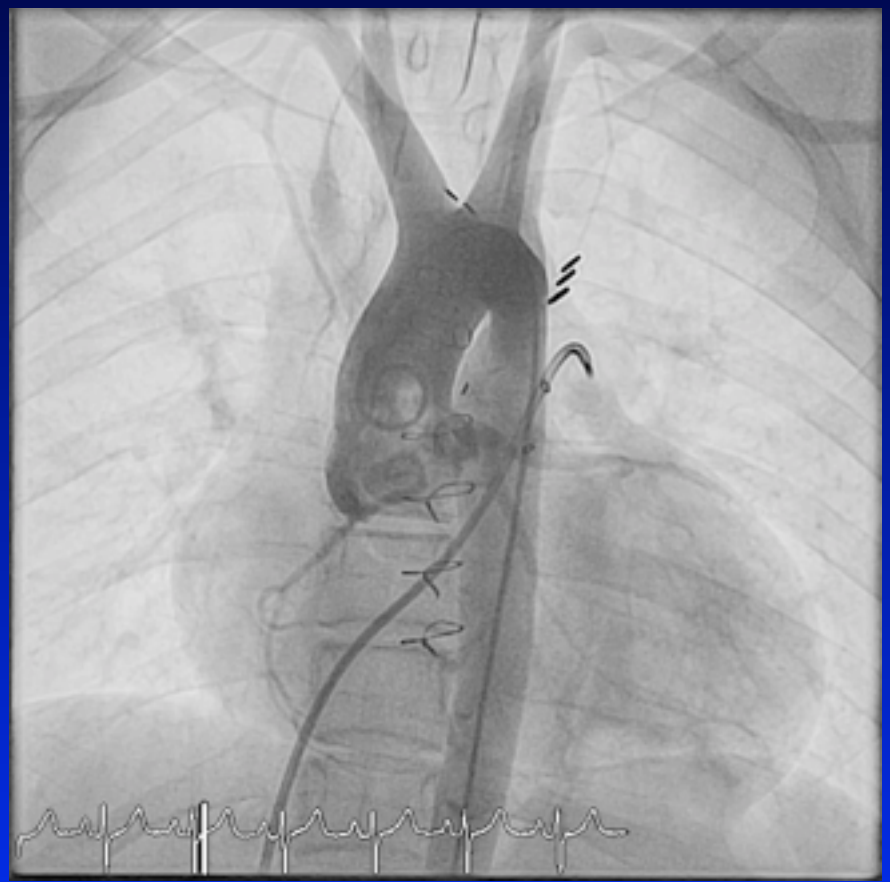


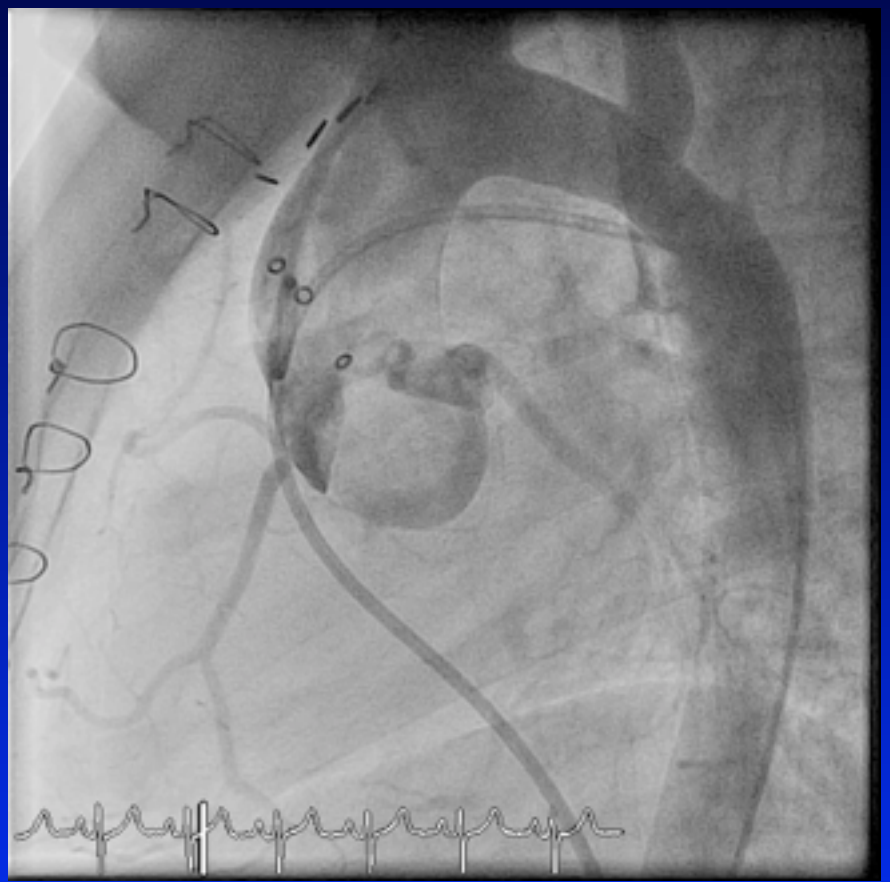
Difficult to see CA with dark balloon



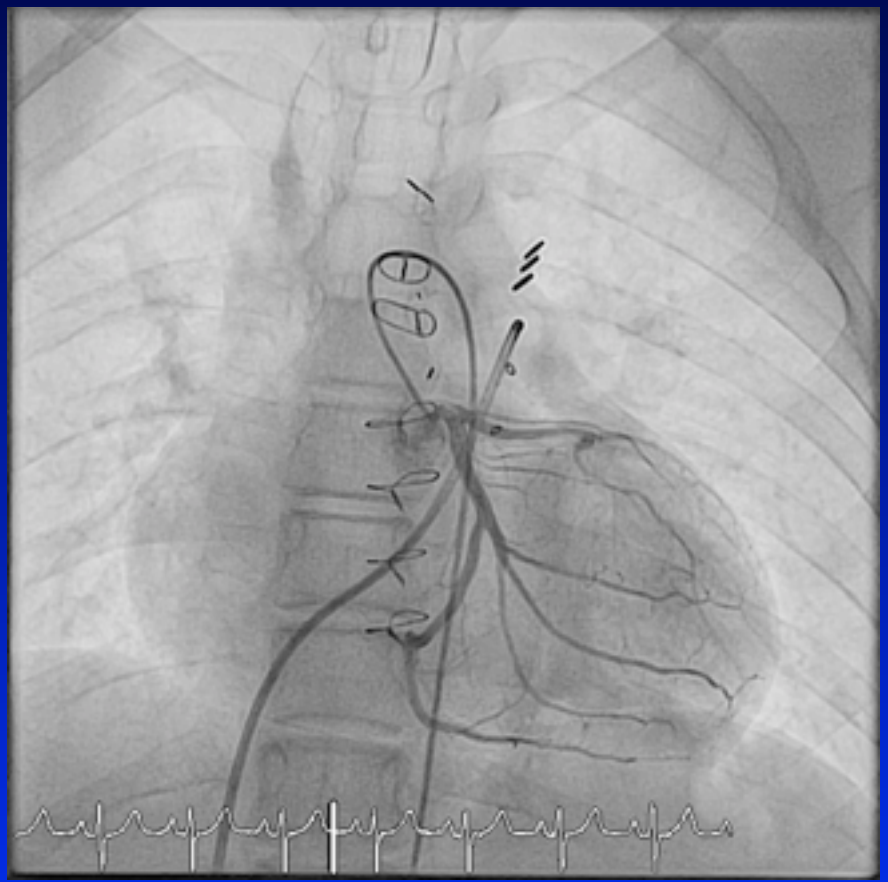
Caudal view shows CA under Balloon

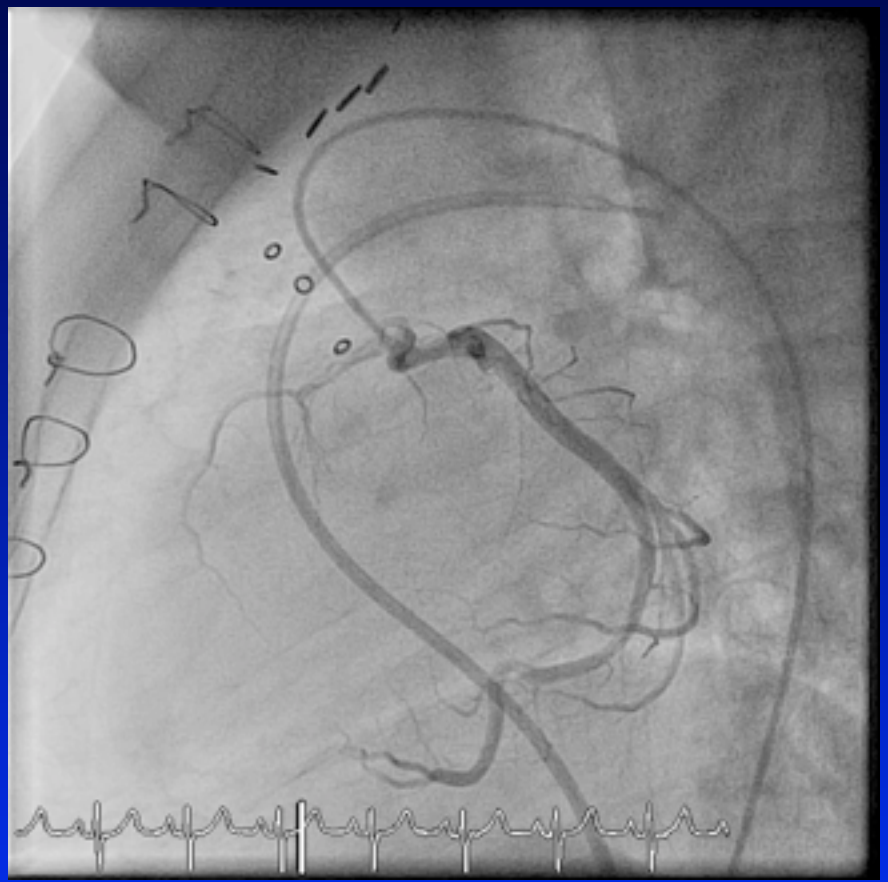
Aortogram: Coronary artery unclear



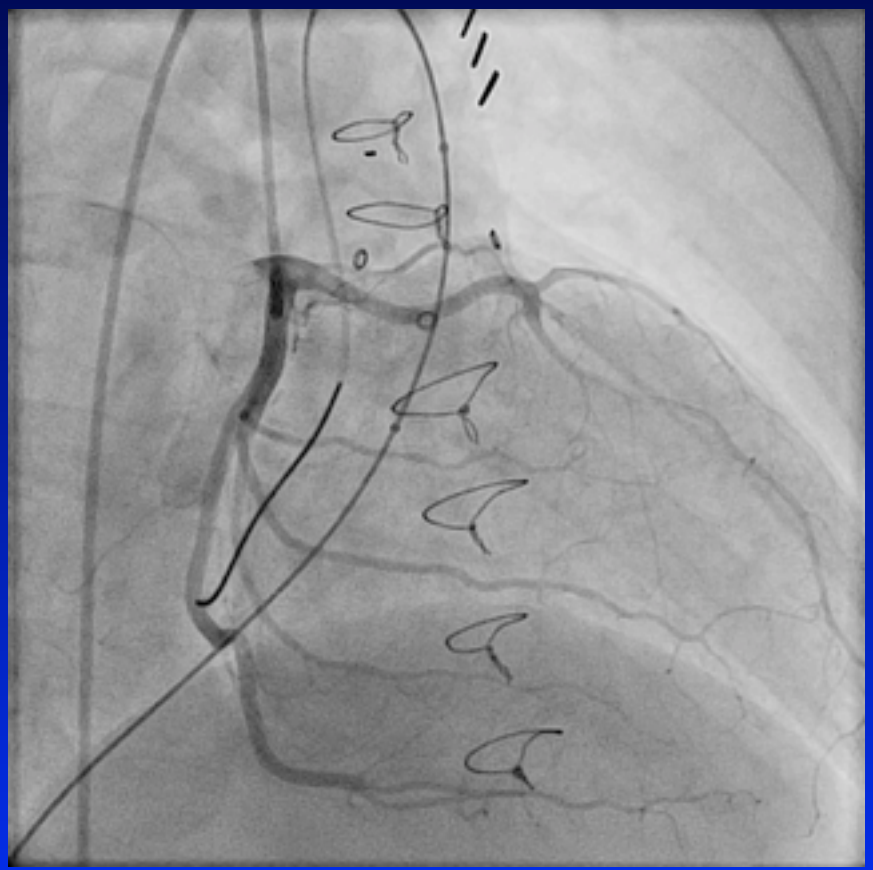


Proceed to Melody valve?

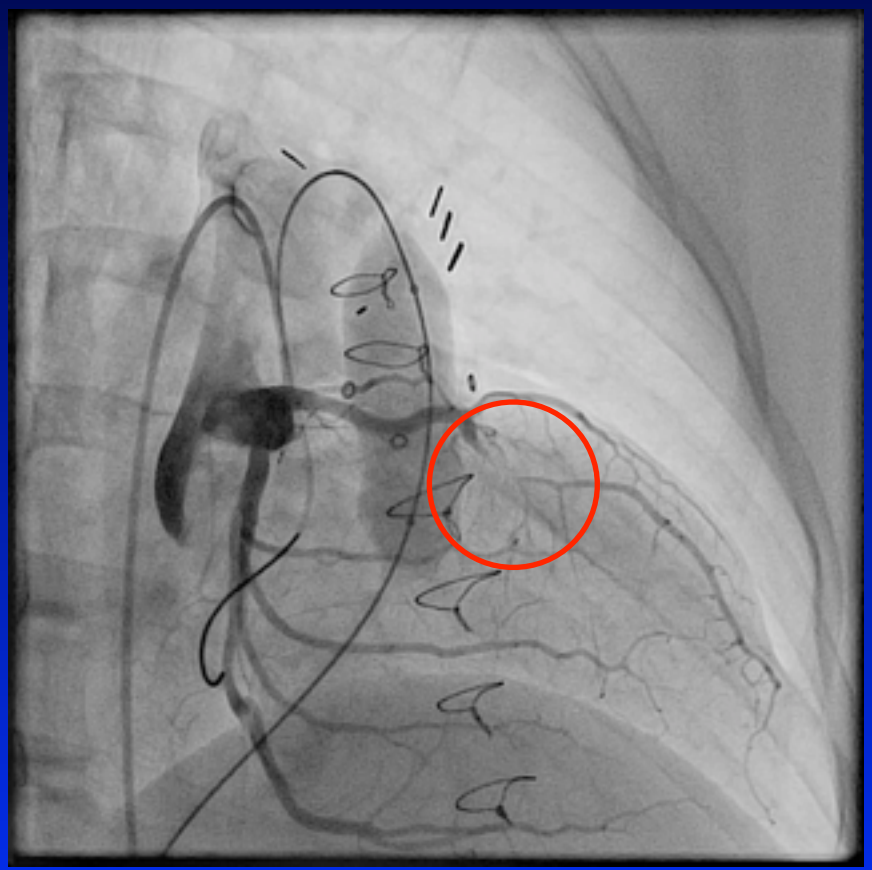




Rotational angiography



Balloon down



Balloon up: mid-LAD compression

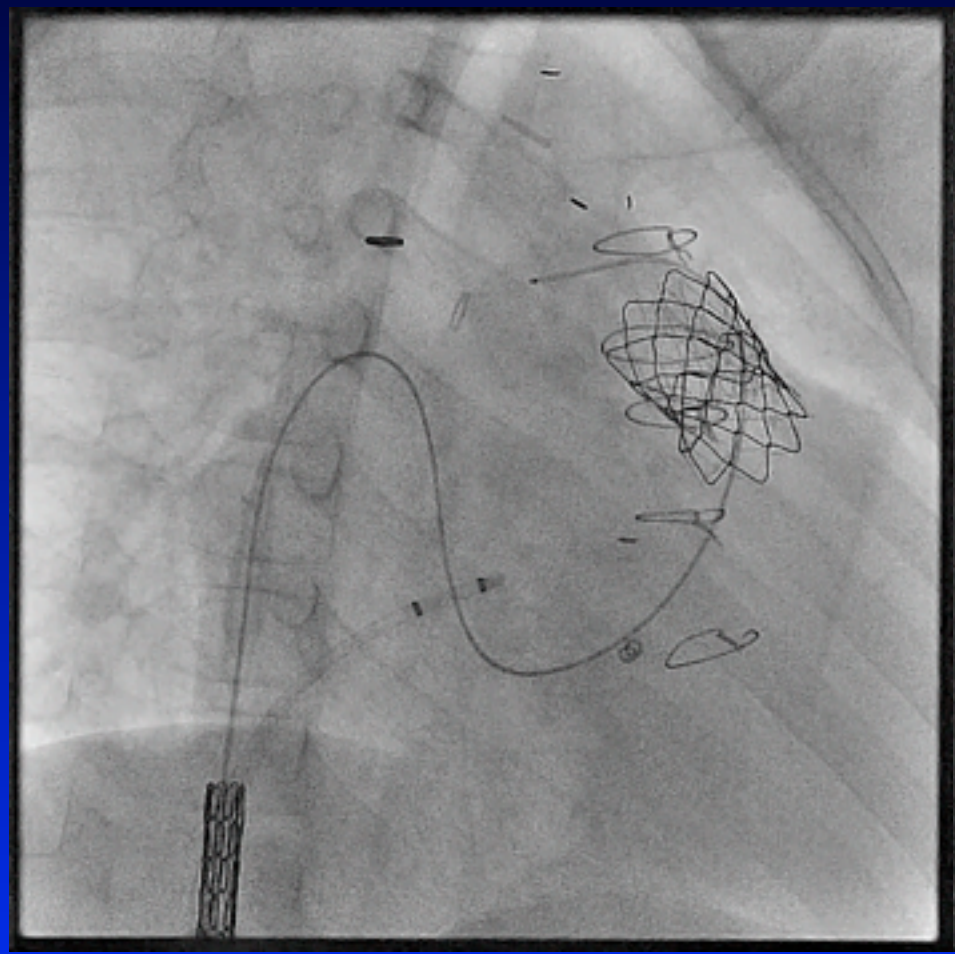
Problems and pitfalls

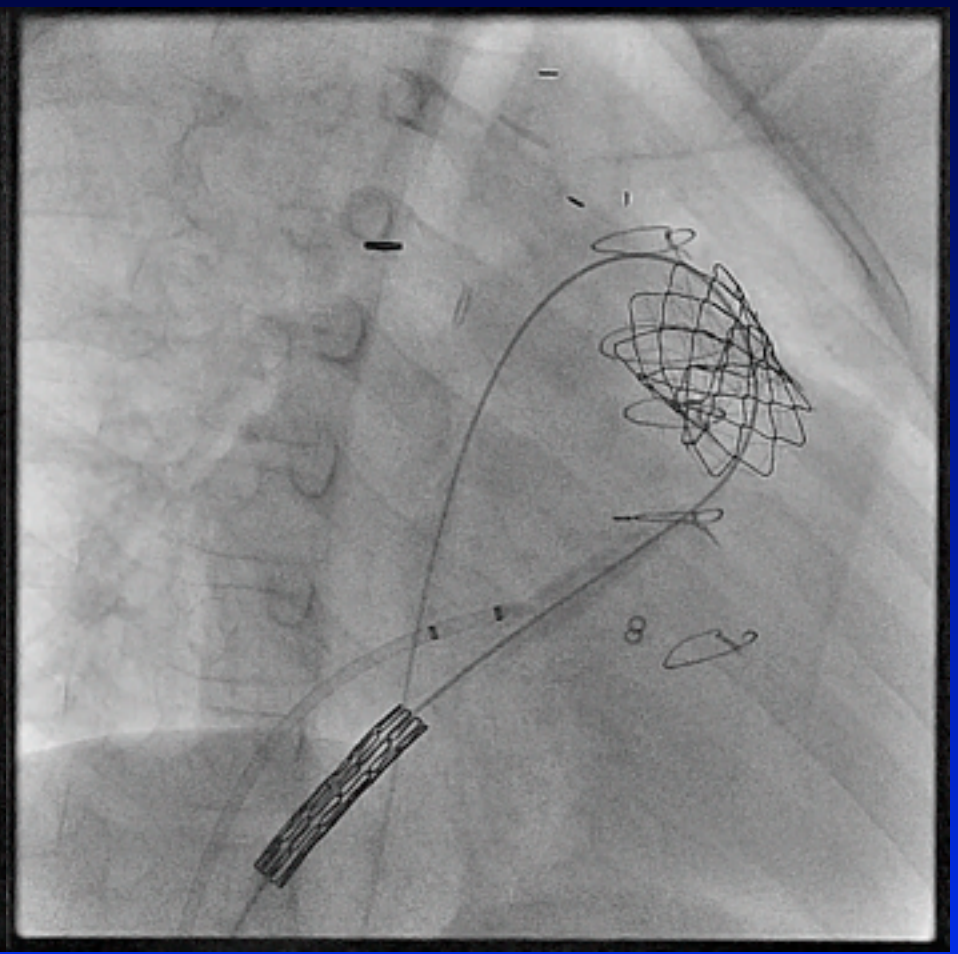
- Beware of coronary artery compression
- Melody valve delivery issues
- Melody valve stent fracture
- Conduit issues:
  - Calcified conduits; recoil, dissections & ruptures
  - Angulated conduits
  - Extending limits of homografts
- Vascular issues
  - Venous hemostasis
  - Vascular access
- Post Melody implant
  - Arrhythmias
  - Endocarditis issues
- Melody valve implant in other positions

Selection of wires

- Too soft: lose wire position when advancing Melody valve
- Too stiff: wire do not bend around curves as easily; delivery system get stuck at corners
- Sometimes, better to stiffer wires for better tracking of Melody valve
- Sometimes, better to use less stiff wires for better tracking of Melody valve
- If one wire doesn't work, try another wire

Rosen wire vs Superstiff wire

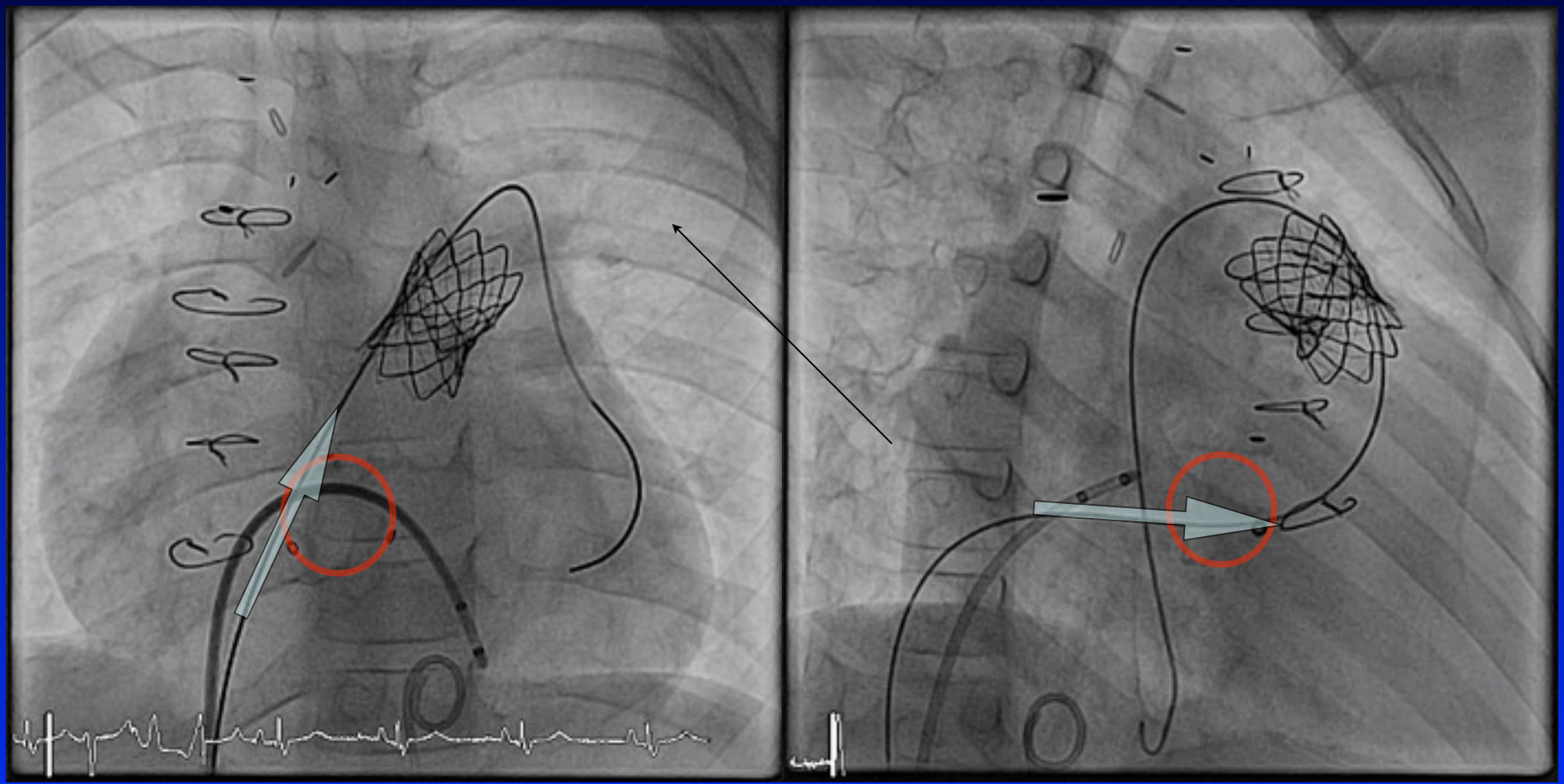




Softer Rosen wire

Stiffer Superstiff wire

Sometimes better to use a softer wire

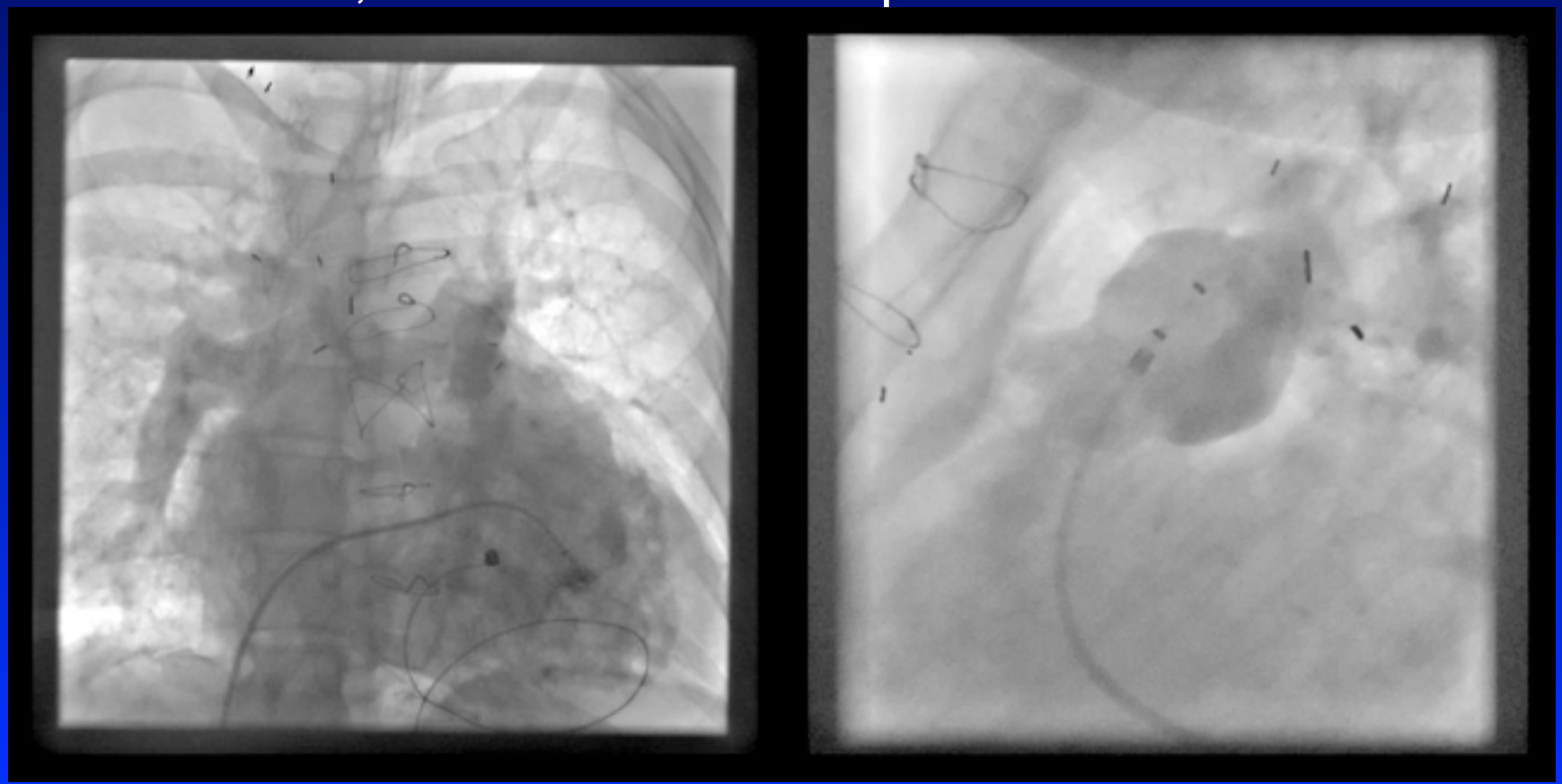


Stiff Lunderquist wire

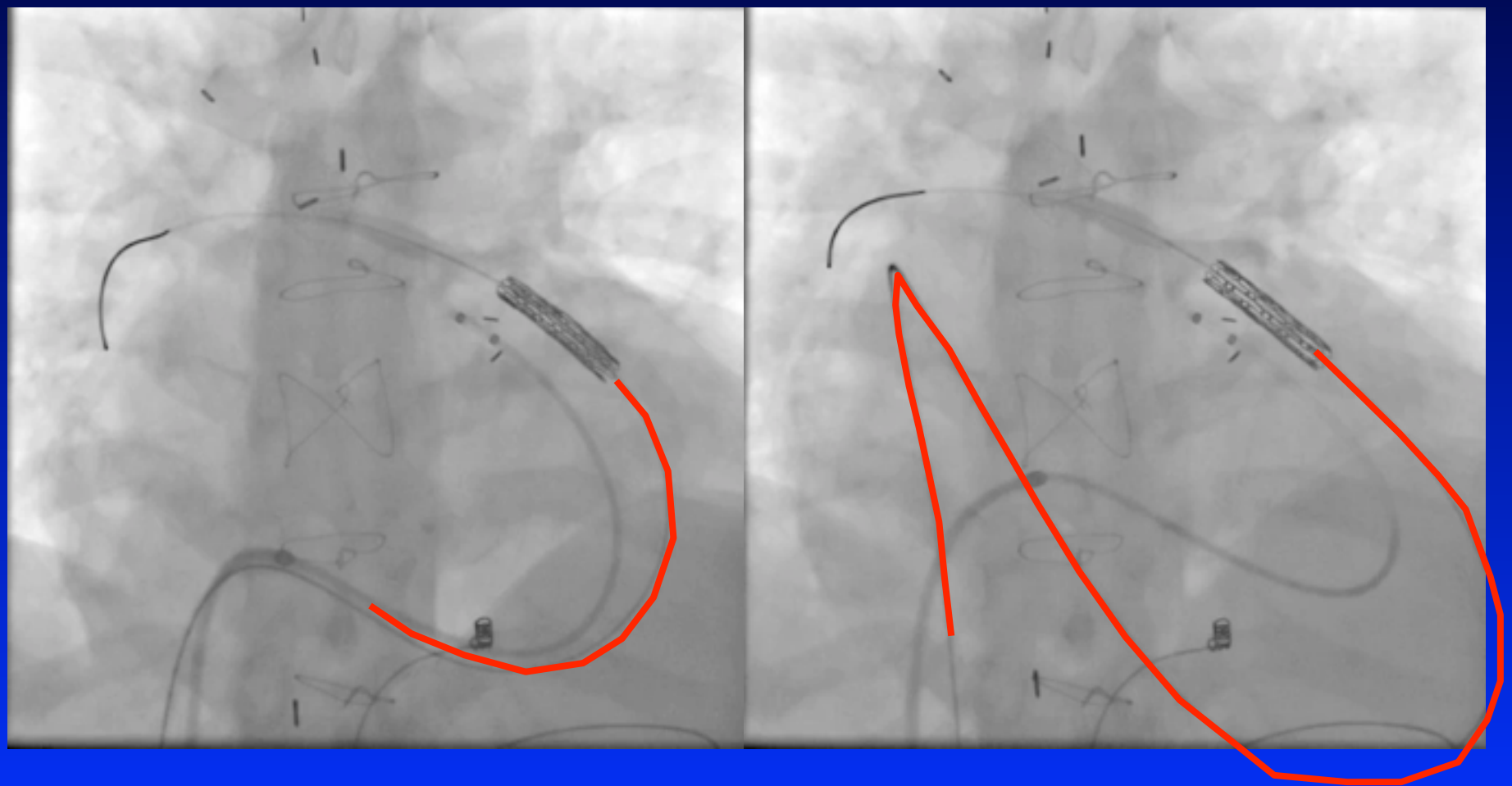
Softer Rosen wire

RIJ access

- When right atrium and ventricle are markedly dilated, wires bend and buckle.
- From RIJ, one less curve compared to femoral access

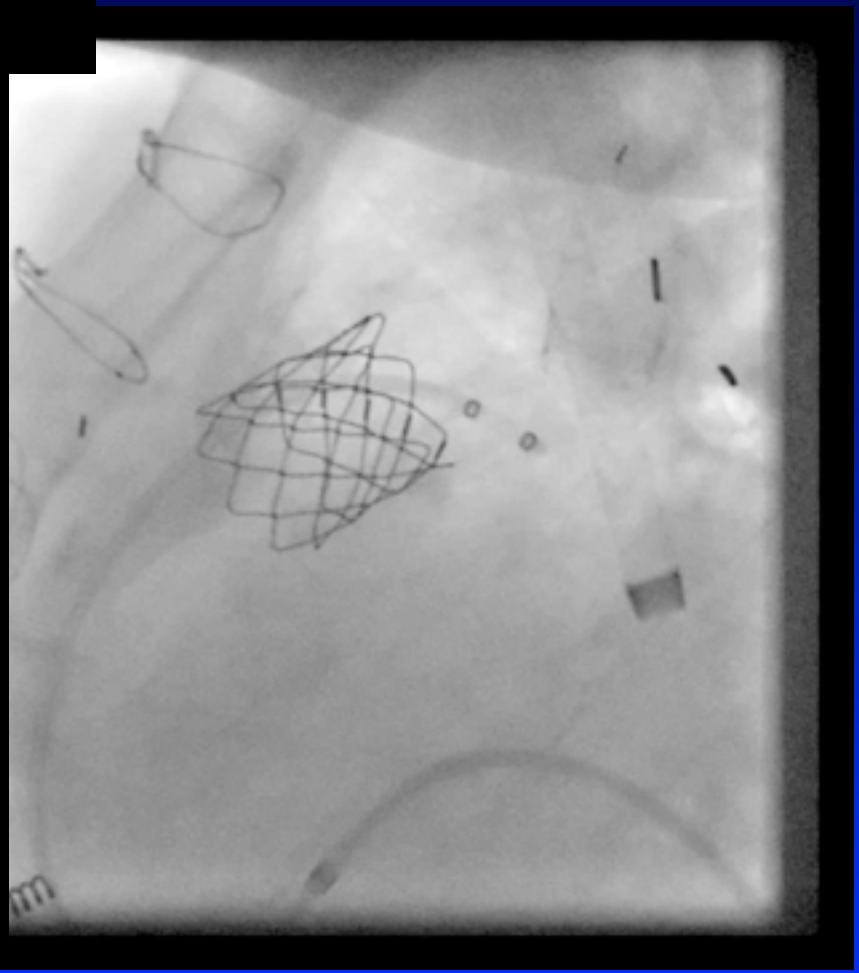


Lunderquist wire buckles in RA and RV



From RIJ, easy passage of Melody valve

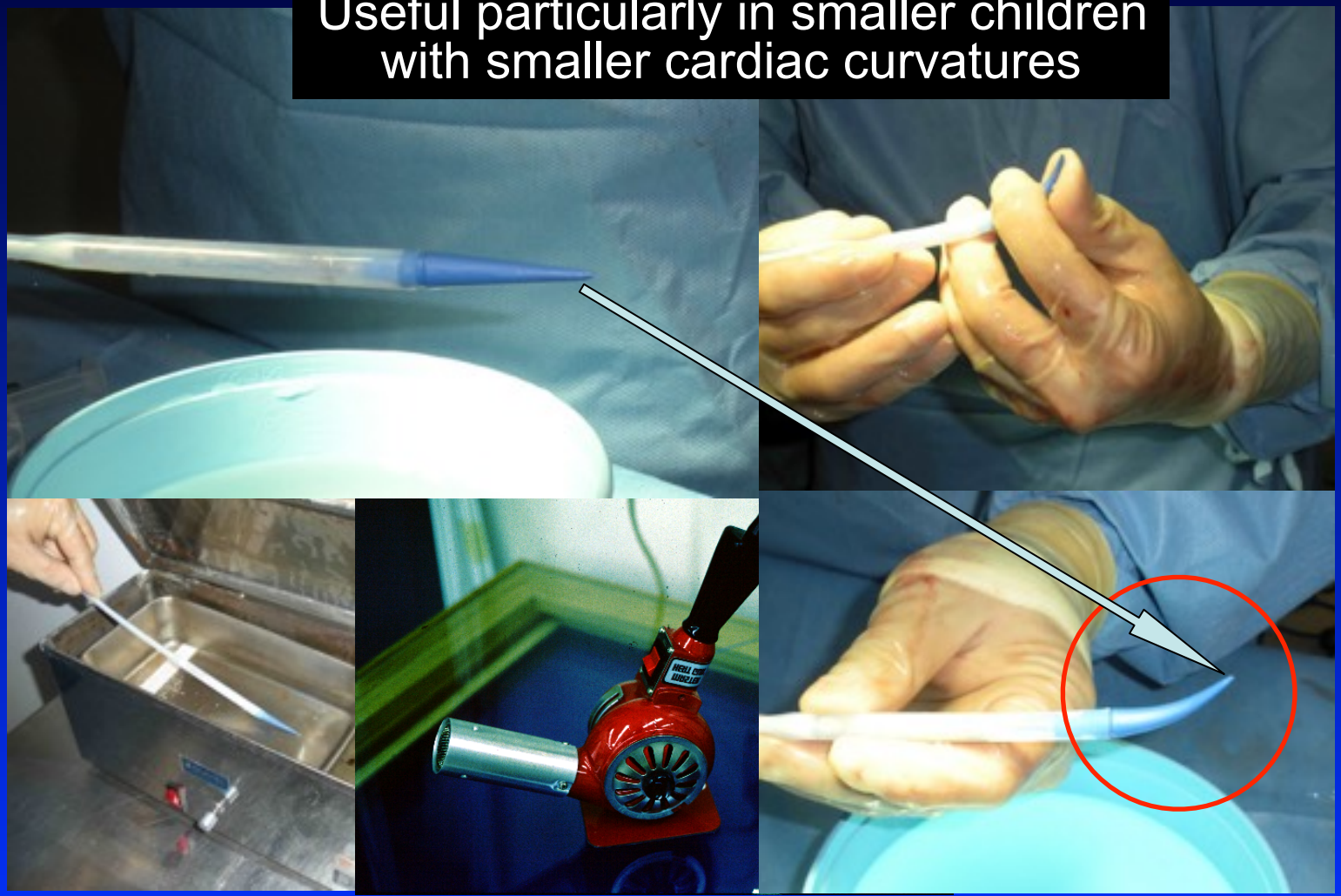
Wire cannot buckle when advancing stiff valve and delivery system



RV apex prevents wire buckling

Loading Melody valve
Tip: heat curve balloon tip

Useful particularly in smaller children with smaller cardiac curvatures



Problems and pitfalls

- Beware of coronary artery compression
- Melody valve delivery issues
- Melody valve stent fracture

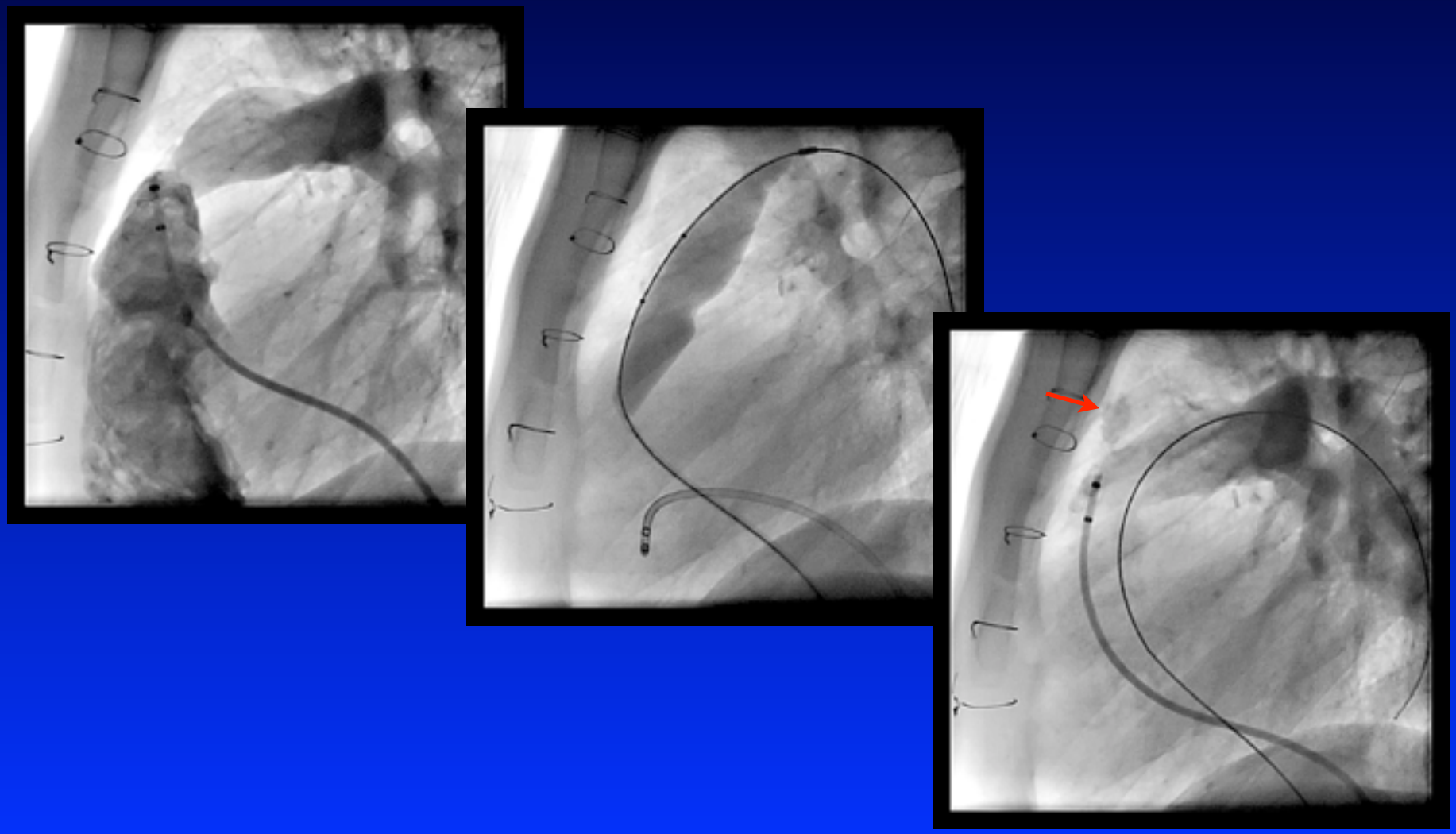
US IDE Study: 22% fracture rate

*McElhinney D, et al. Short and Medium Term Outcomes After Transcatheter Pulmonary Valve Placement in the Expanded Multi-Center US Melody Valve Trial. Circulation 2010;122:507-516.

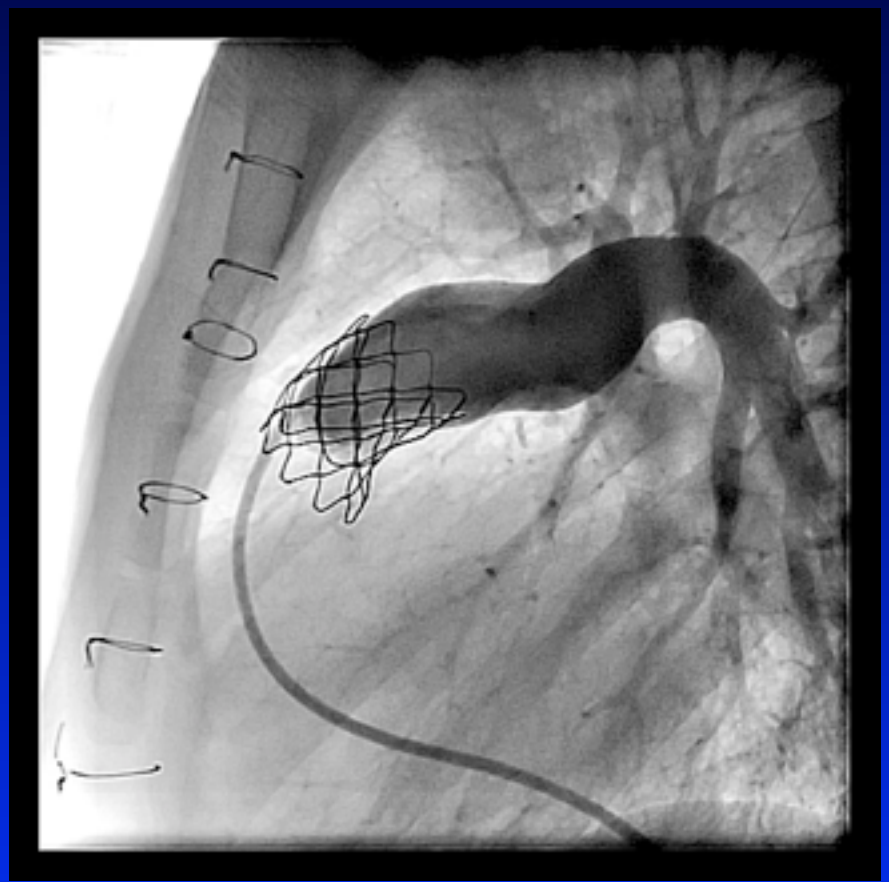
tures

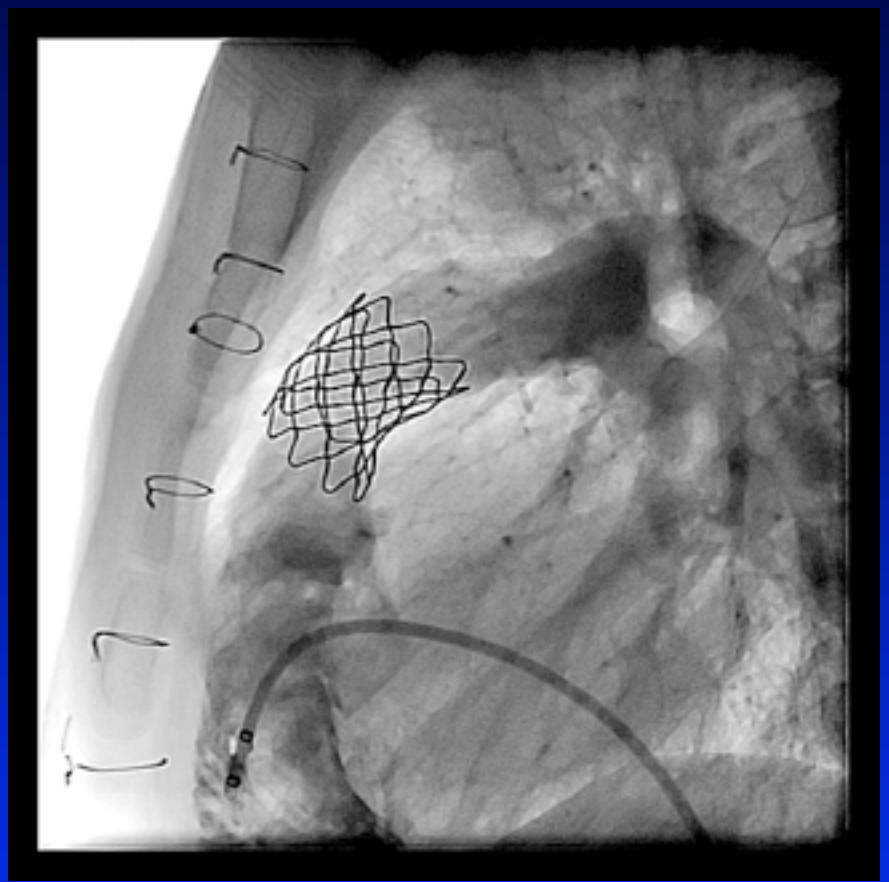
- Vascular issues
  - Venous hemostasis
  - Vascular access
- Post Melody implant
  - Arrhythmias
  - Endocarditis issues
- Melody valve implant in other positions

Conduit stenosis

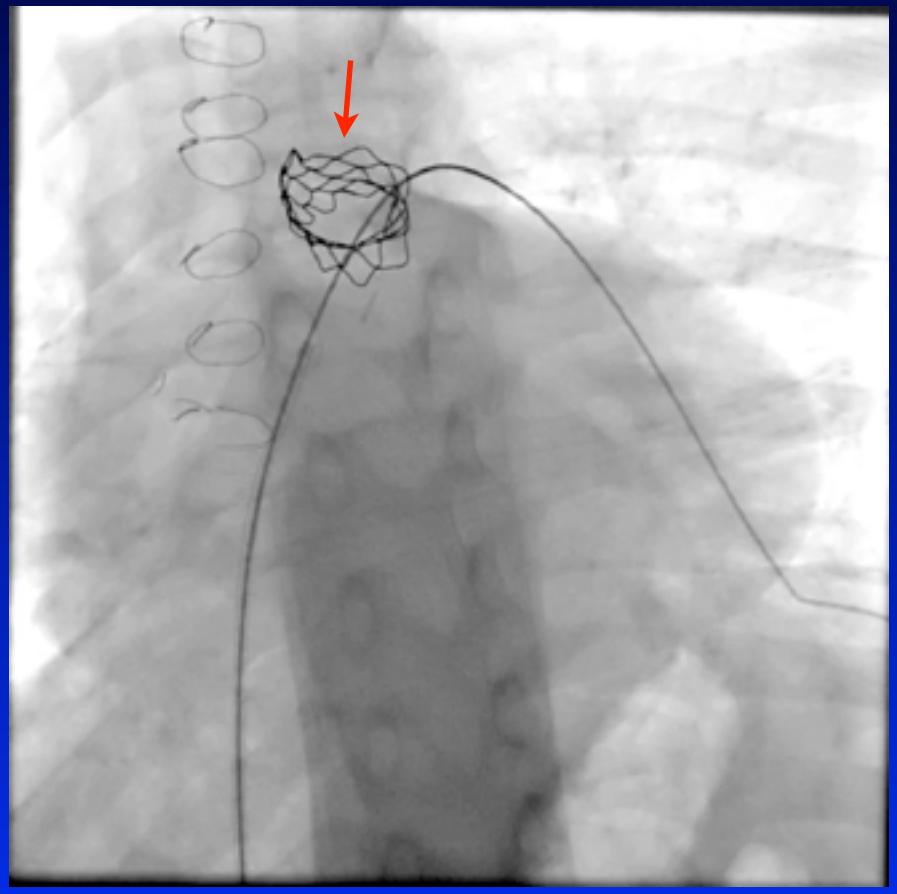


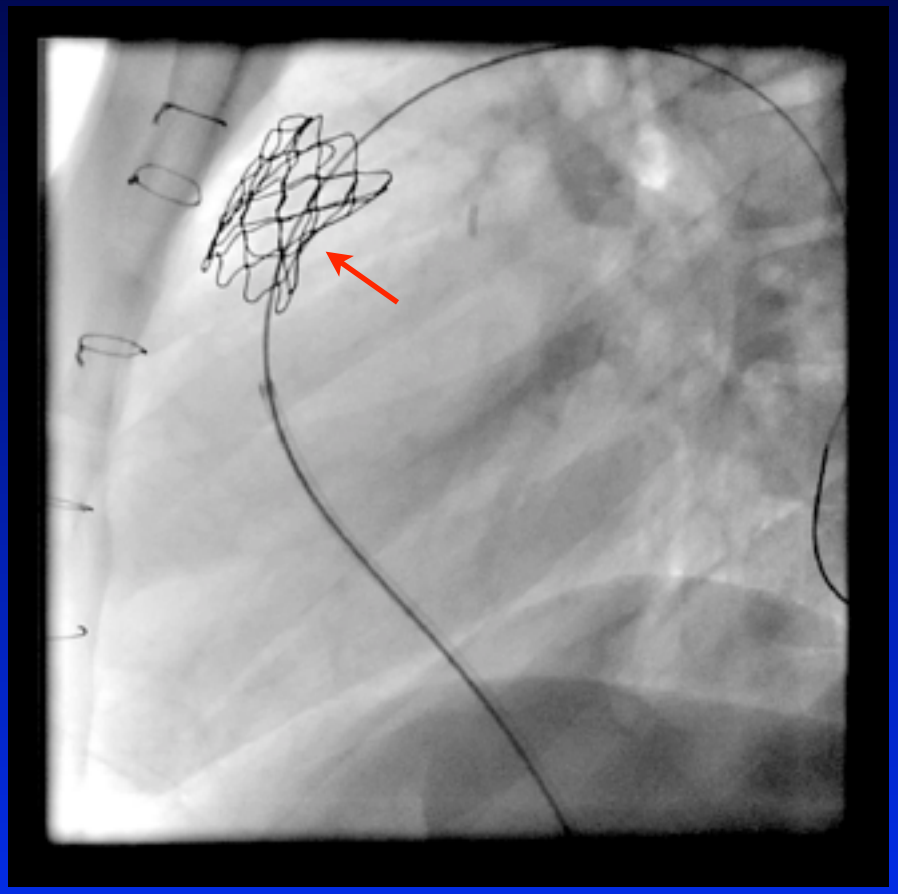
Post Melody implant





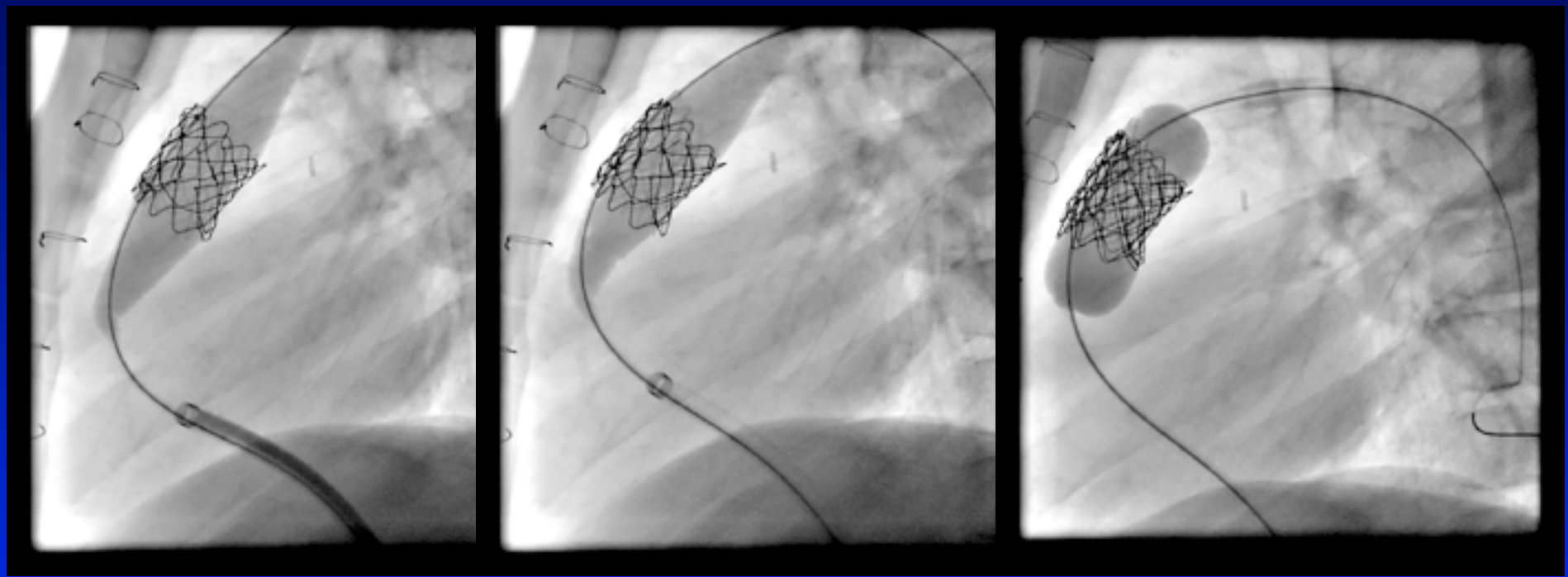
6 month later...



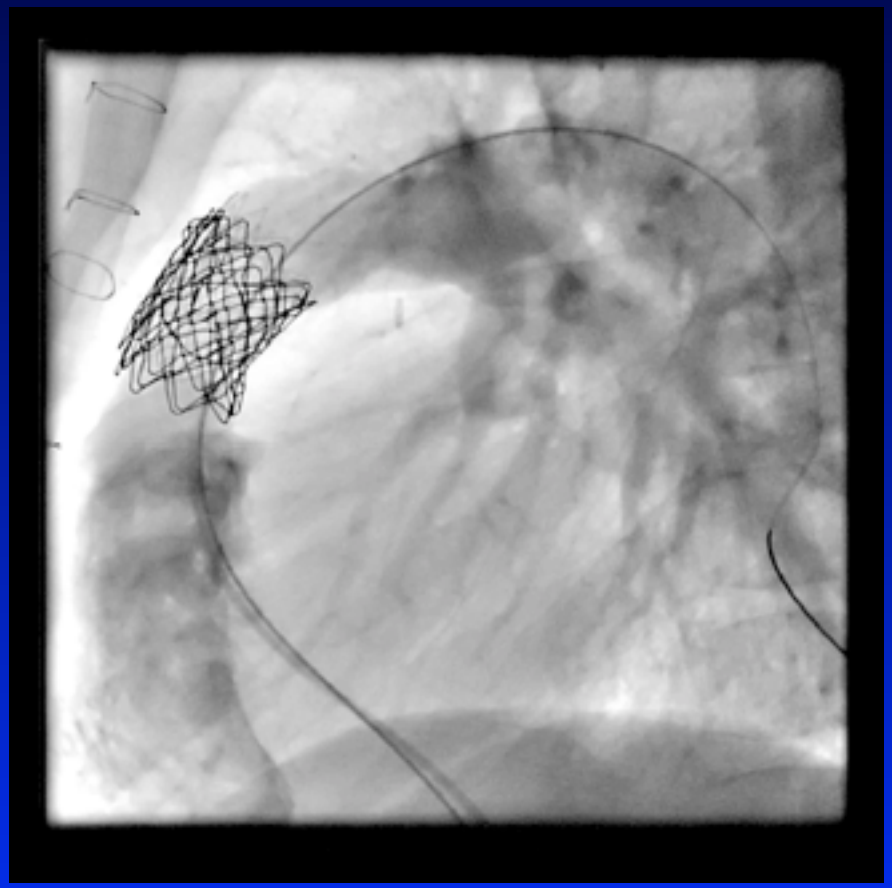


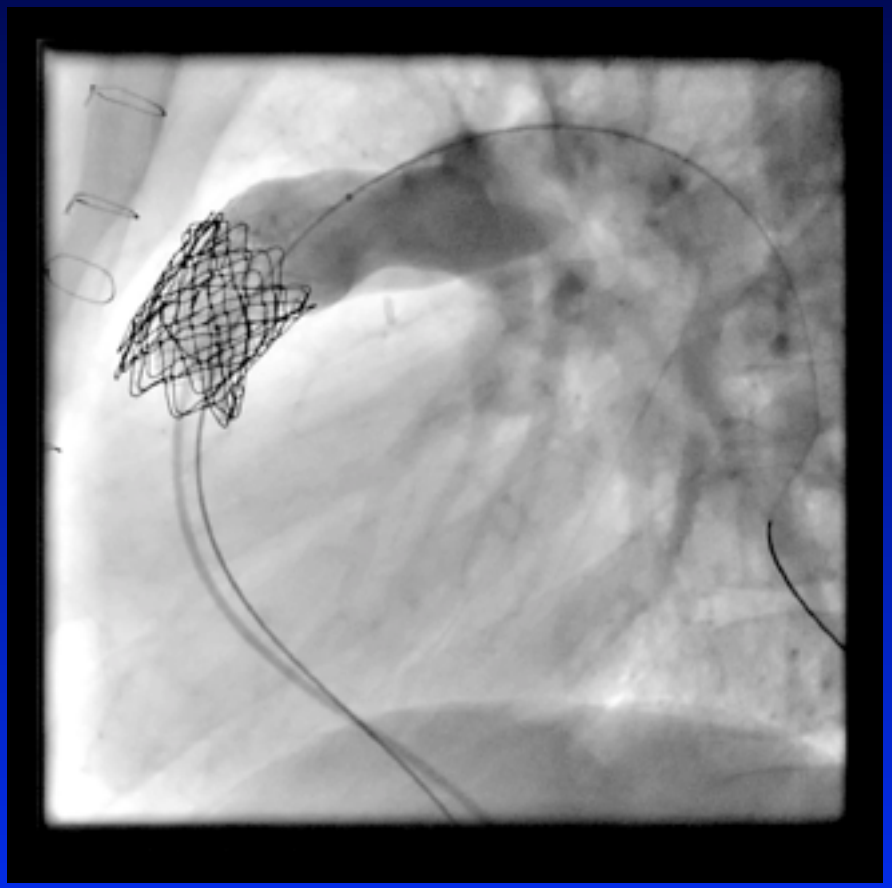
Reinforce with additional stents:
Observe recoil during balloon deflation

Stent #1 | Stent #2 | Second Melody valve



Post Melody implant



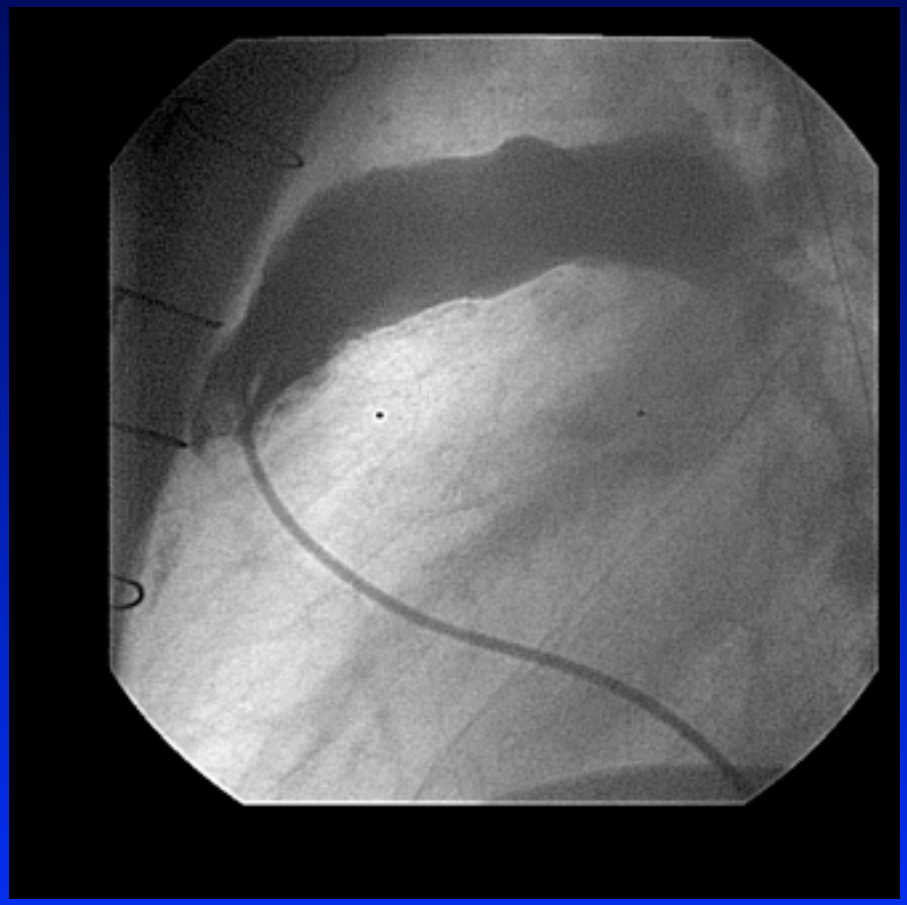


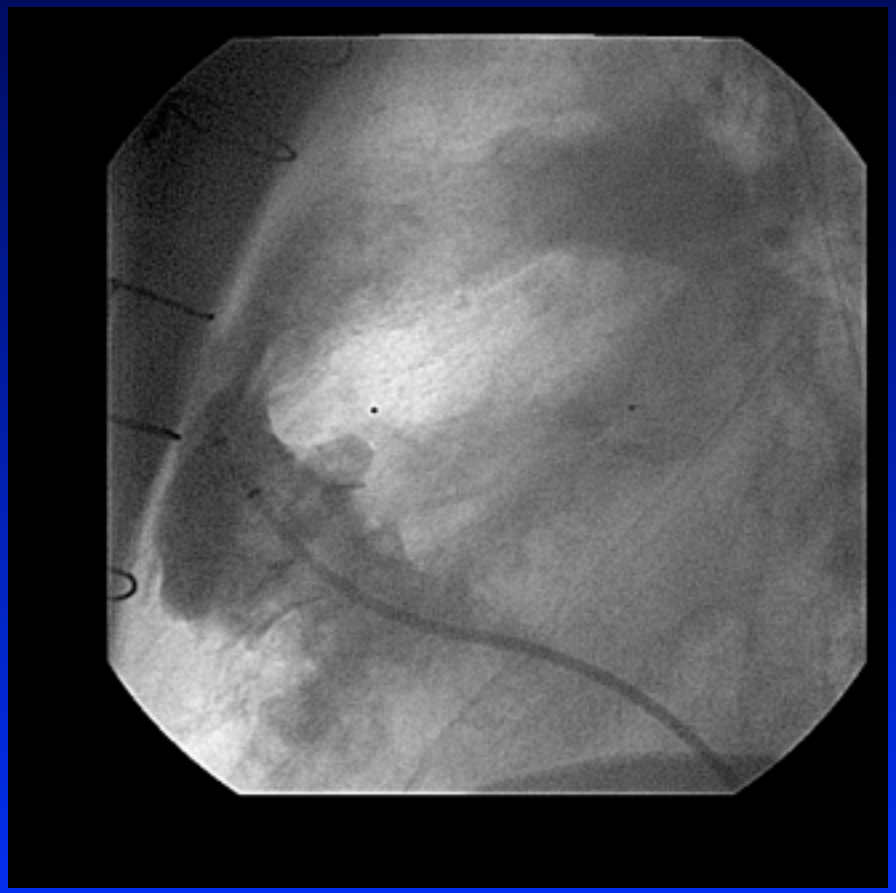
Problems and pitfalls

- Beware of coronary artery compression
- Melody valve delivery issues
- Melody valve stent fracture
- Conduit issues:
  - Calcified conduits; recoil, dissections & ruptures
  - Angulated conduits
  - Extending limits of homografts
- Vascular issues
  - Venous hemostasis
  - Vascular access
- Post Melody implant
  - Arrhythmias
  - Endocarditis issues
- Melody valve implant in other positions

D-TGA/VSD, s/p Rastelli w/ 20mm Hancock valve

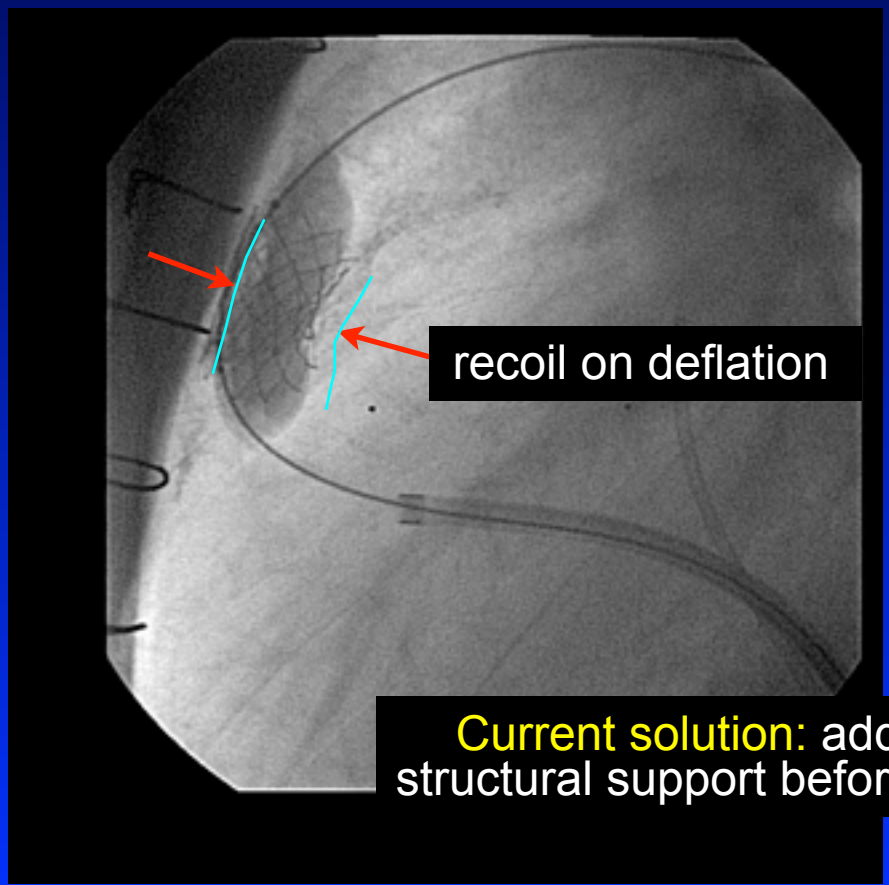
- Calcified stenotic conduit

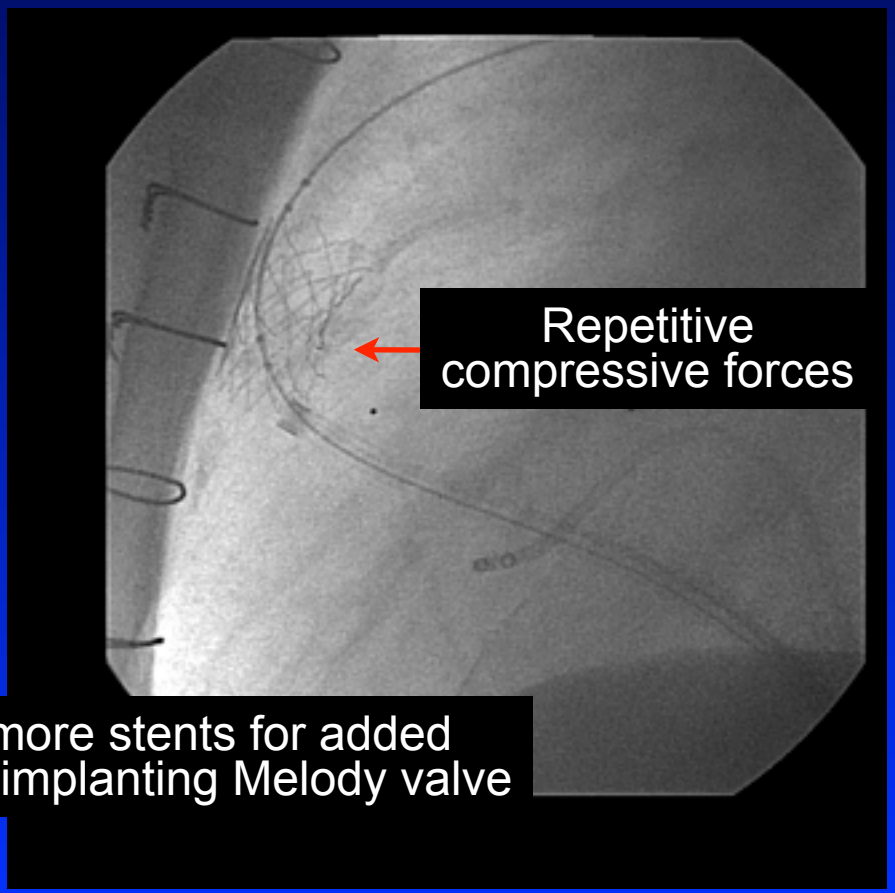




Implantation of Palmaz 3110 stent

- Stent implanted w/ 18mm BIB
- Stent being compressed

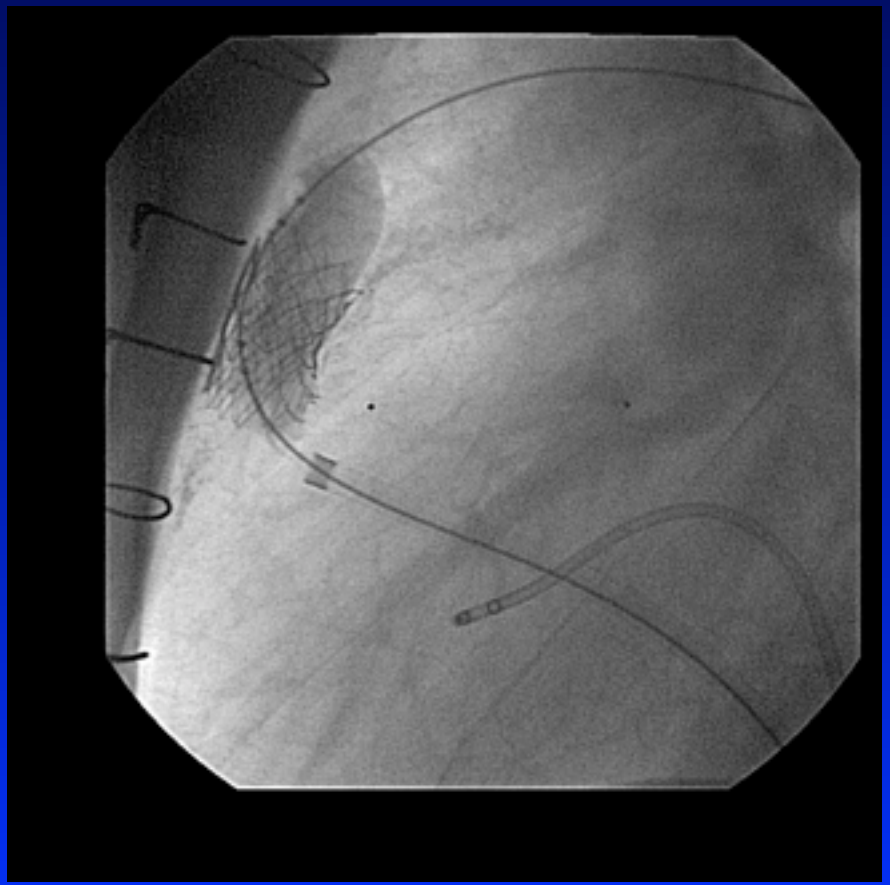


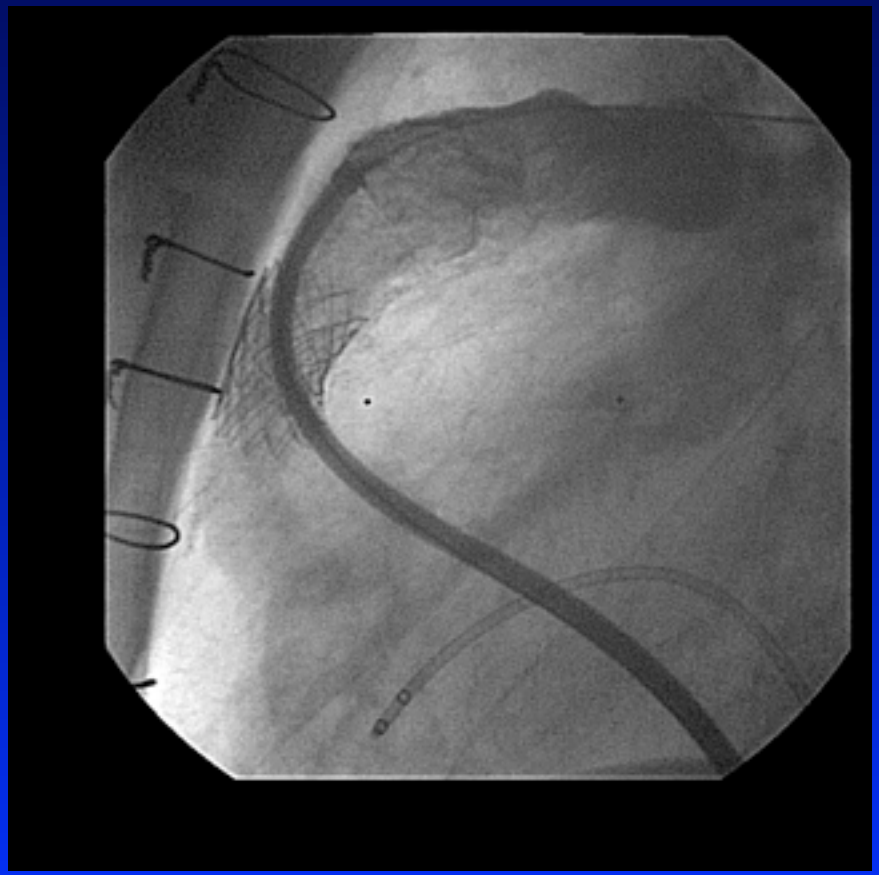


Current solution: add more stents for added structural support before implanting Melody valve

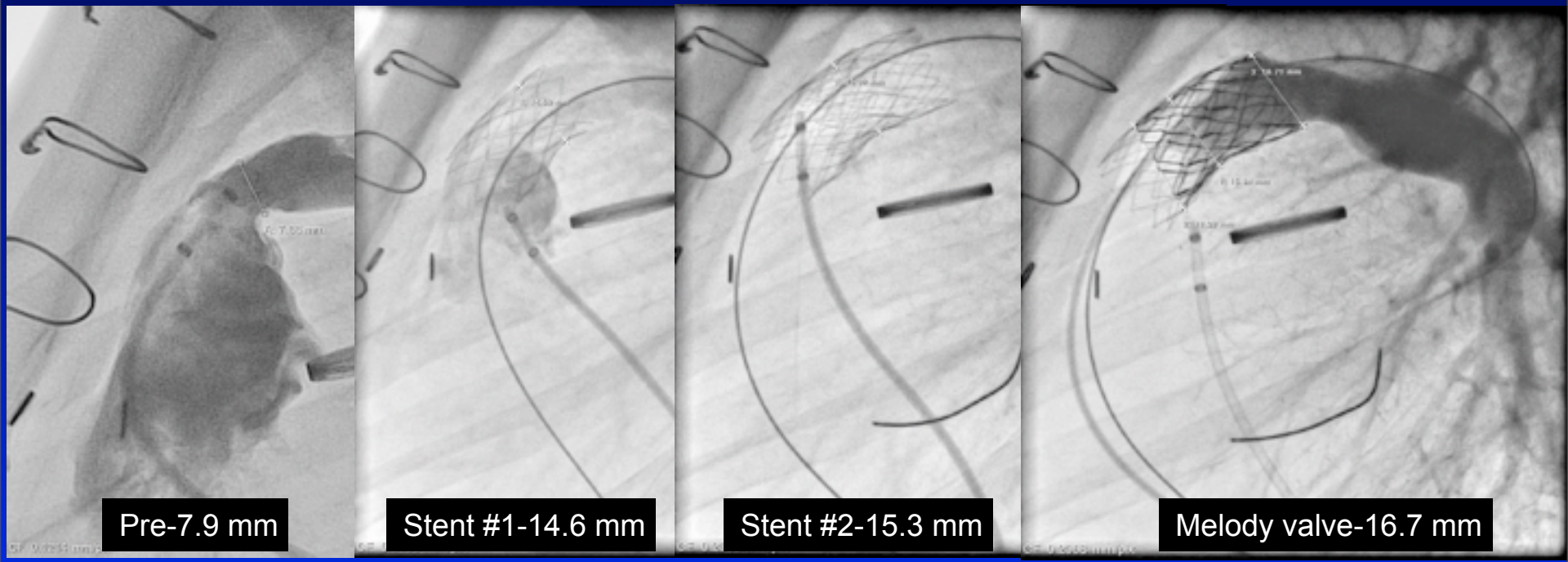
Second 3110 stent implanted

- Less stent compression after second stent

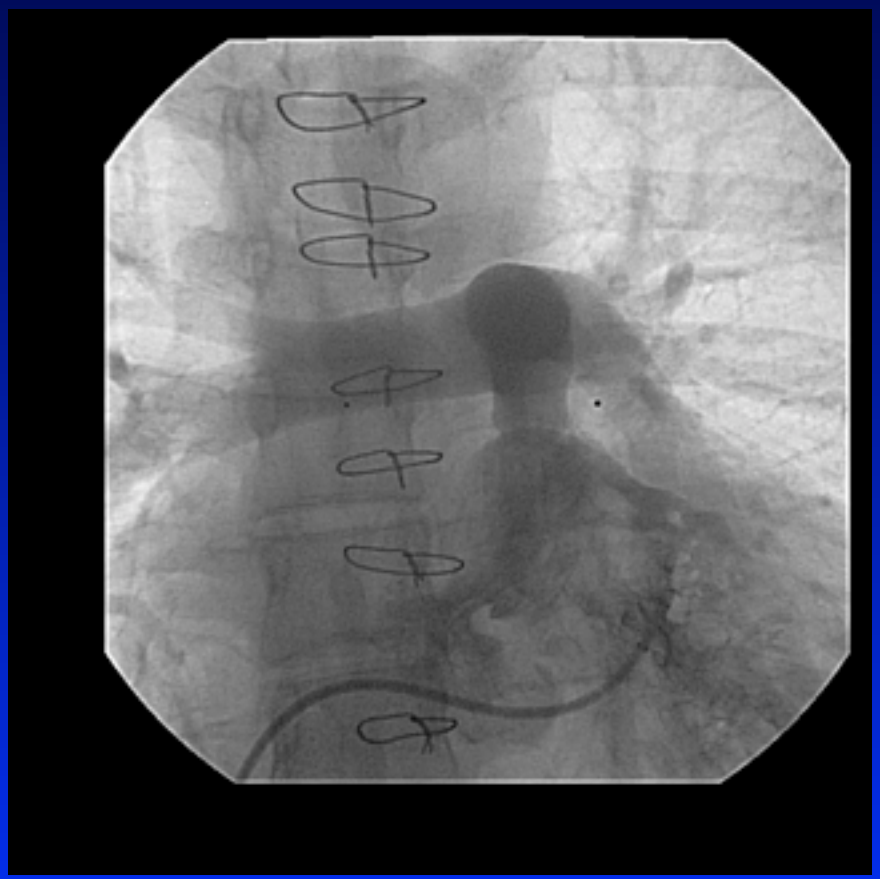




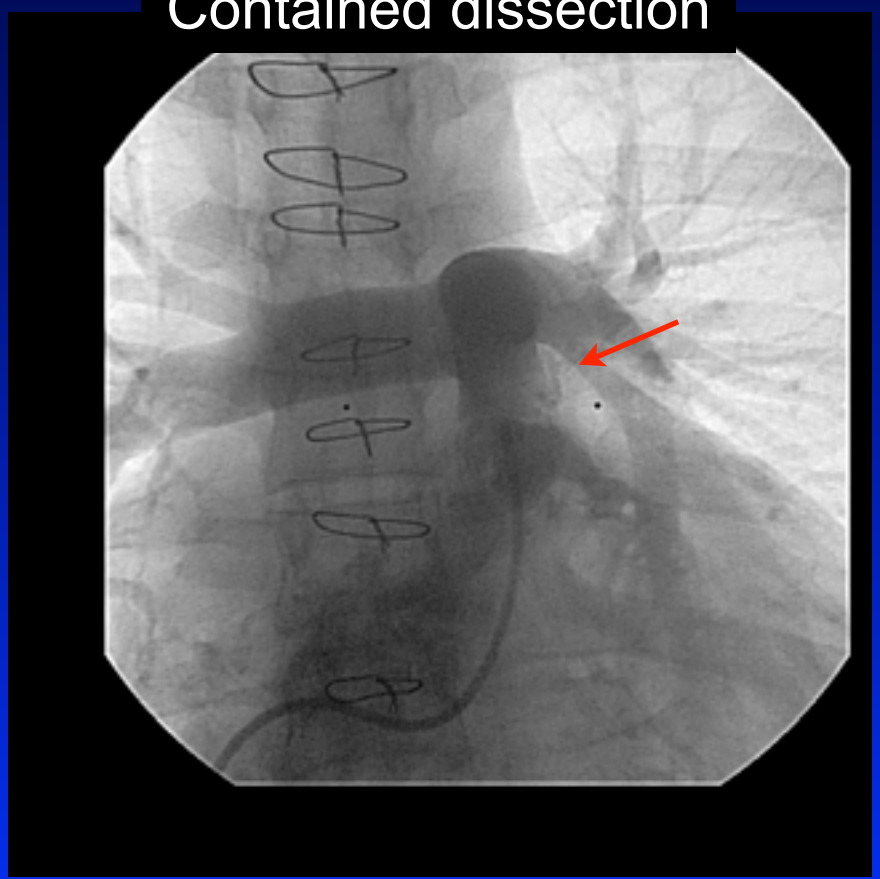
Overcoming recoil with more metal reinforcements



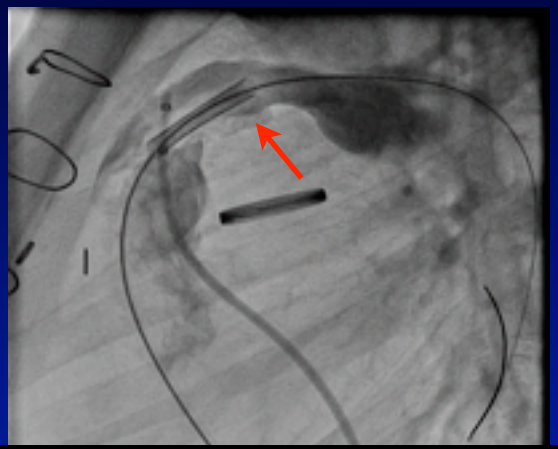
Complications: Dissections



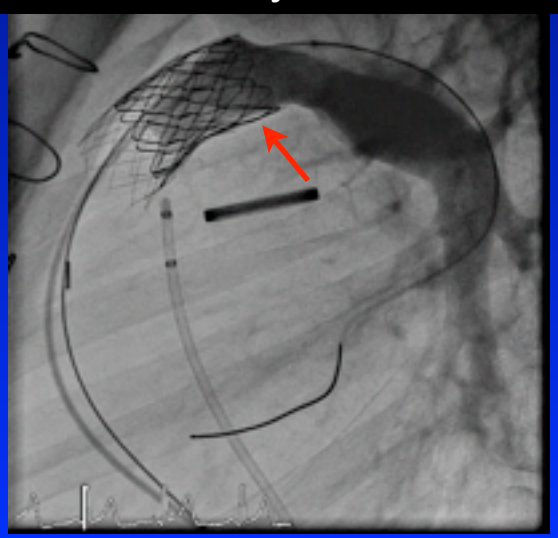
Contained dissection



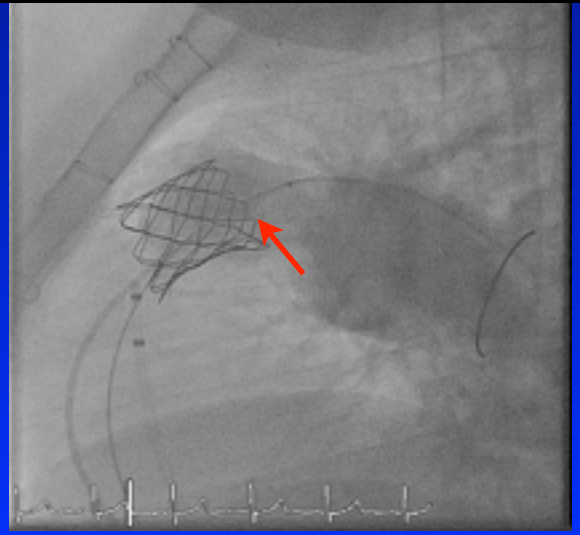
Conduit dissection/rupture pre and post Melody valve implant



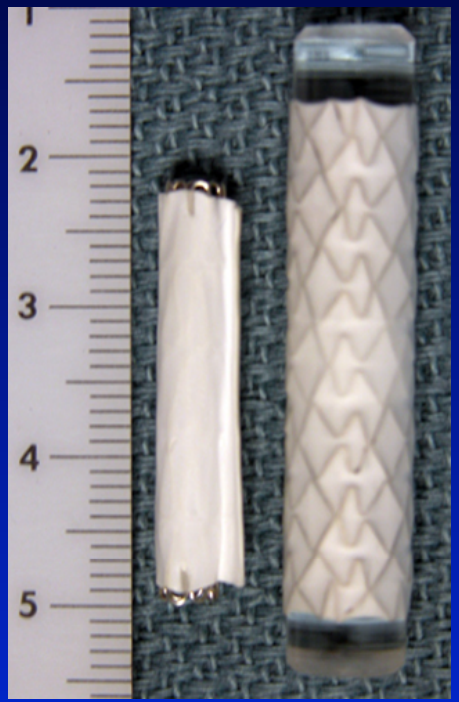
Dissection treated with Melody valve

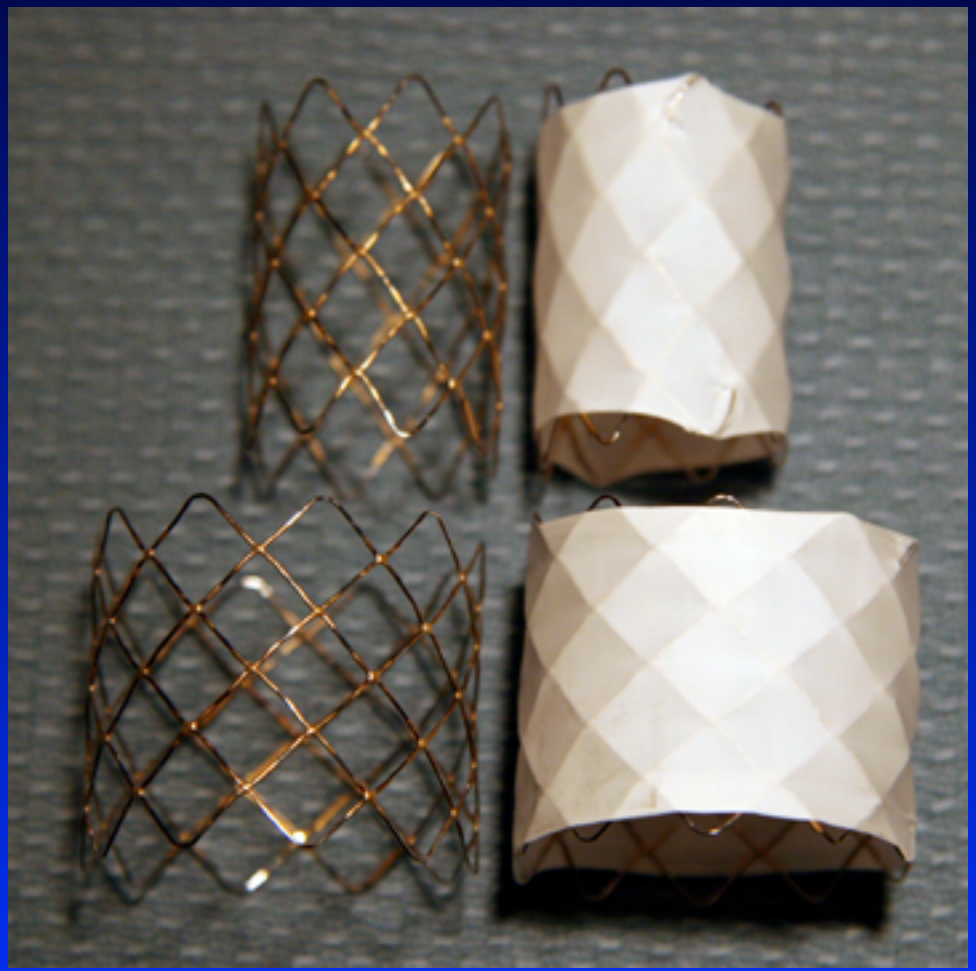


Dissection post Melody valve (at distal edge)



Covered stents





COAST II trial
PARCS trial

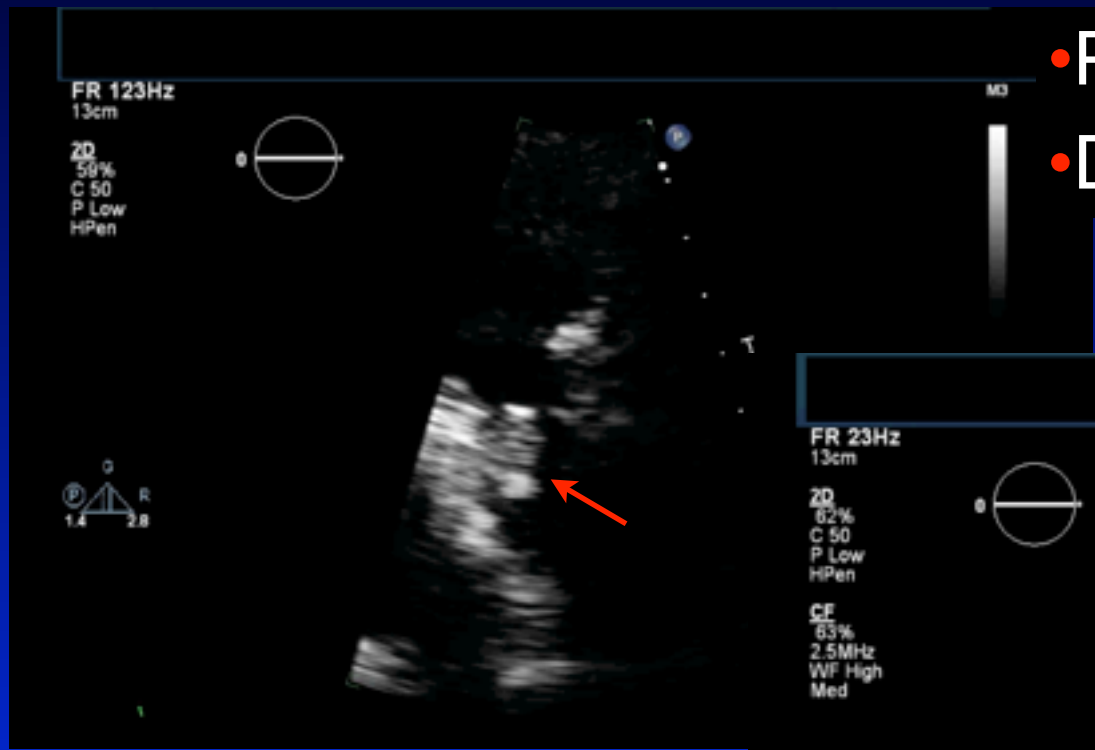
Problems and pitfalls

- Beware of coronary artery compression
- Melody valve delivery/venous access issues
- Melody valve stent fracture
- Conduit issues:
  - Calcified conduits; recoil, dissections & ruptures
  - Angulated conduits
  - Extending limits of homografts
- Vascular issues
  - Venous hemostasis
  - Vascular access
- Post Melody implant
  - Arrhythmias
  - Endocarditis issues
- Melody valve implant in other positions

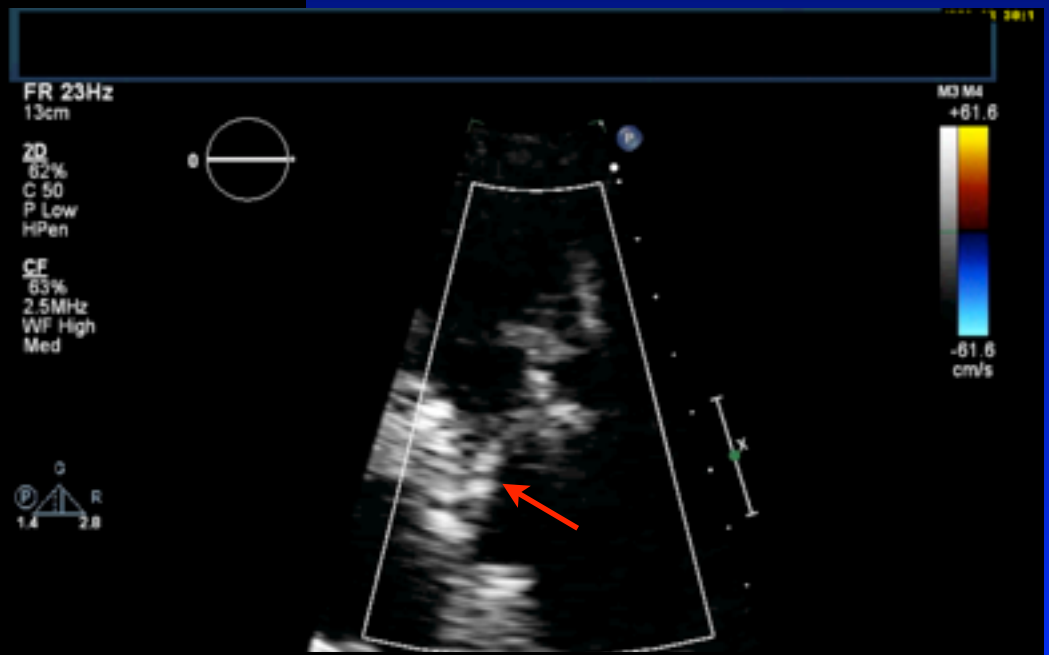
Post Melody implant arrhythmias

Treat with beta-blockers for 6 months, then discontinue and re-holter

Post Melody valve implant: fever and bacteremia-diagnosis?

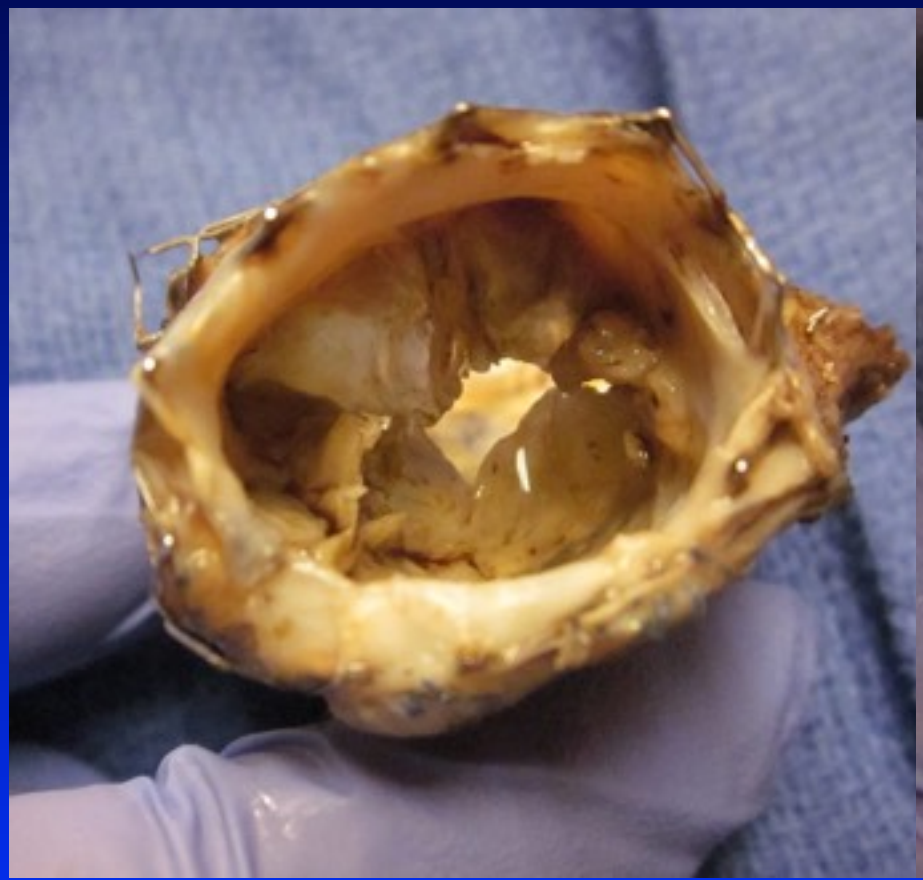


- Positive blood culture
- Dental flora



- Dental clearance before any device implant

Path specimen



- No standards for antibiotics coverage
- Pre-implant dental clearance; repair all cavities
- Pre-implant antibiotics x 1
- Change gloves when handling new Melody valve
- Lifetime SBE prophalaxis

Incidence of endocarditis

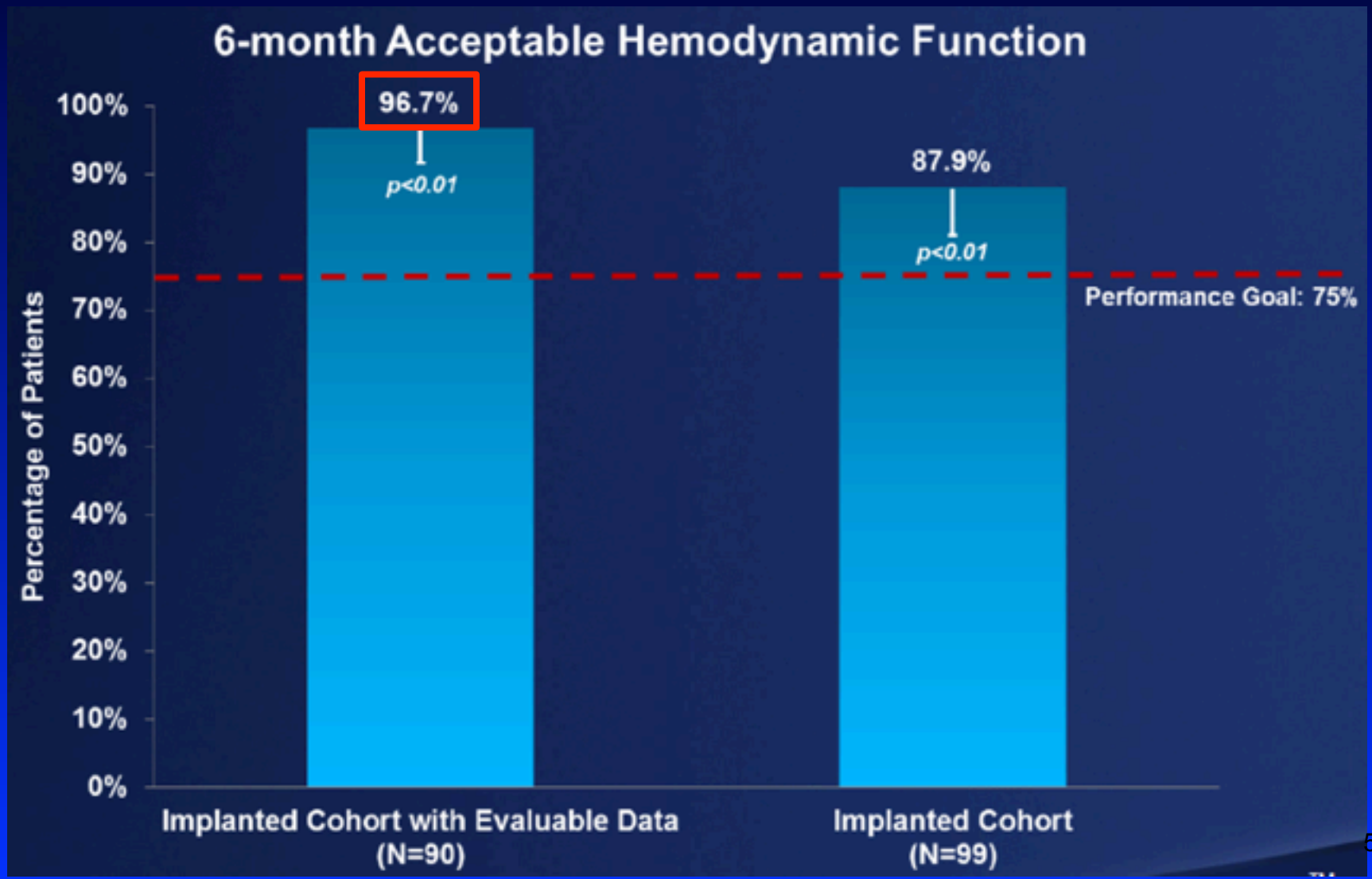
- McElhinney et al.- FU 300 pt (mean 2.5 yrs)
  - >600 pt-yrs
  - Incidence of endocarditis-0.88% pt-yrs
- FDA OPC: 1.2% pt-yr
- Medtronics->5000 cases
  - 93 cases reported (1.9% incidence)
- Villafane et al.- CCI summarized published data: 893 pts
  - 31 cases involving valves (incidence 3.5-5.7%)
  - 53% treated medically
- Surgical data (15 papers) :
  - All sternotomies 8%
  - Valves 2.1% (data on explanted valves only; no data on medical treatment only)

Melody TPV Post-approval Study- 1 yr follow-up

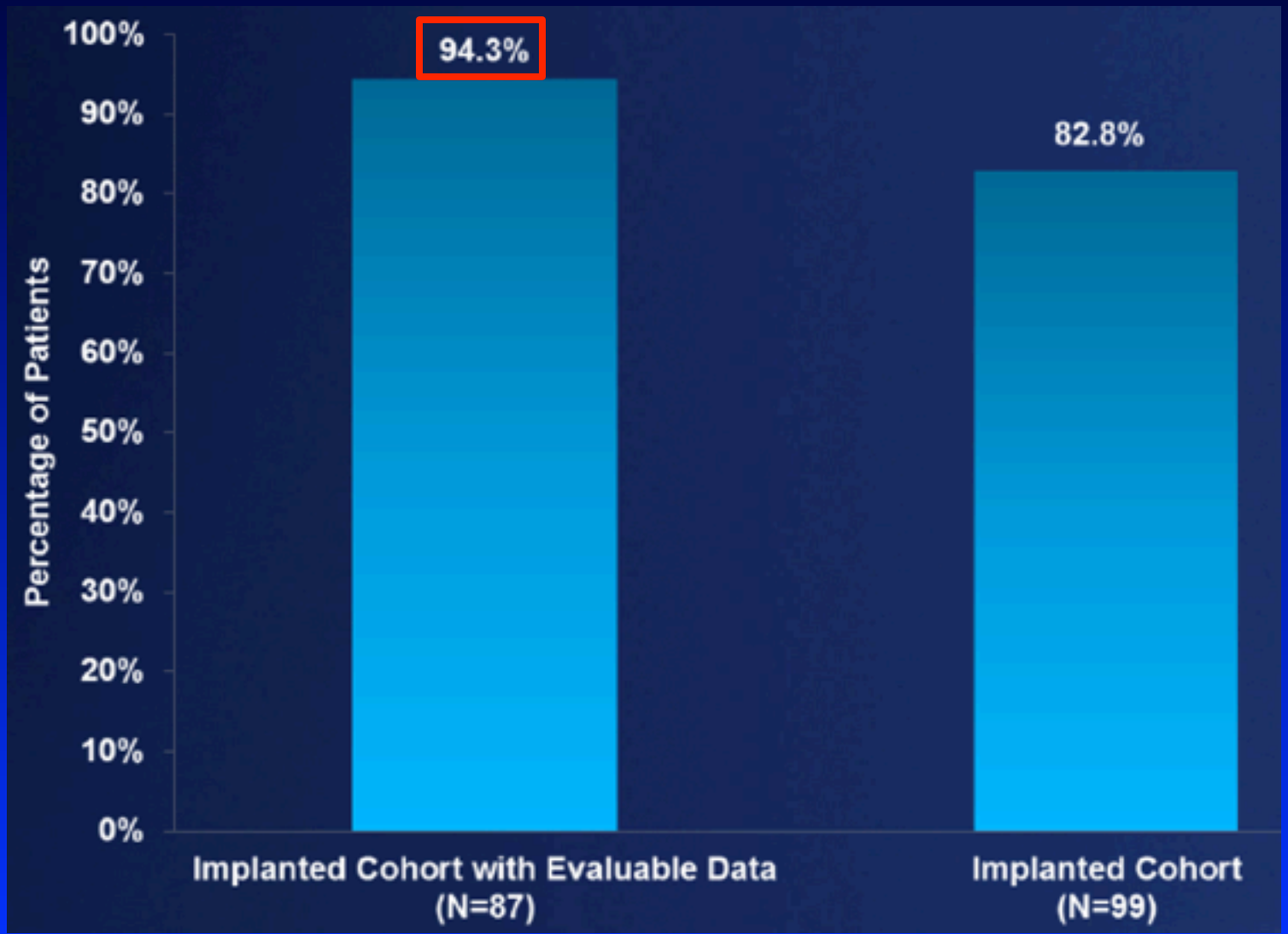
- To confirm short-term hemodynamic effectiveness of the Melody TVP achieved by all providers is equivalent to the results from the IDE trial
  - Primary endpoints: 6 month post implant
    - RVOT gradient < 30mmHg
    - Regurgitation < moderate by echo
    - Freedom from conduit reintervention/reoperation
  - Secondary endpoint:
    - Procedure success
    - Freedom from serious adverse events
    - Freedom from TPV dysfunction

Presented by Armstrong AK at Melody implanter's summit, 2014

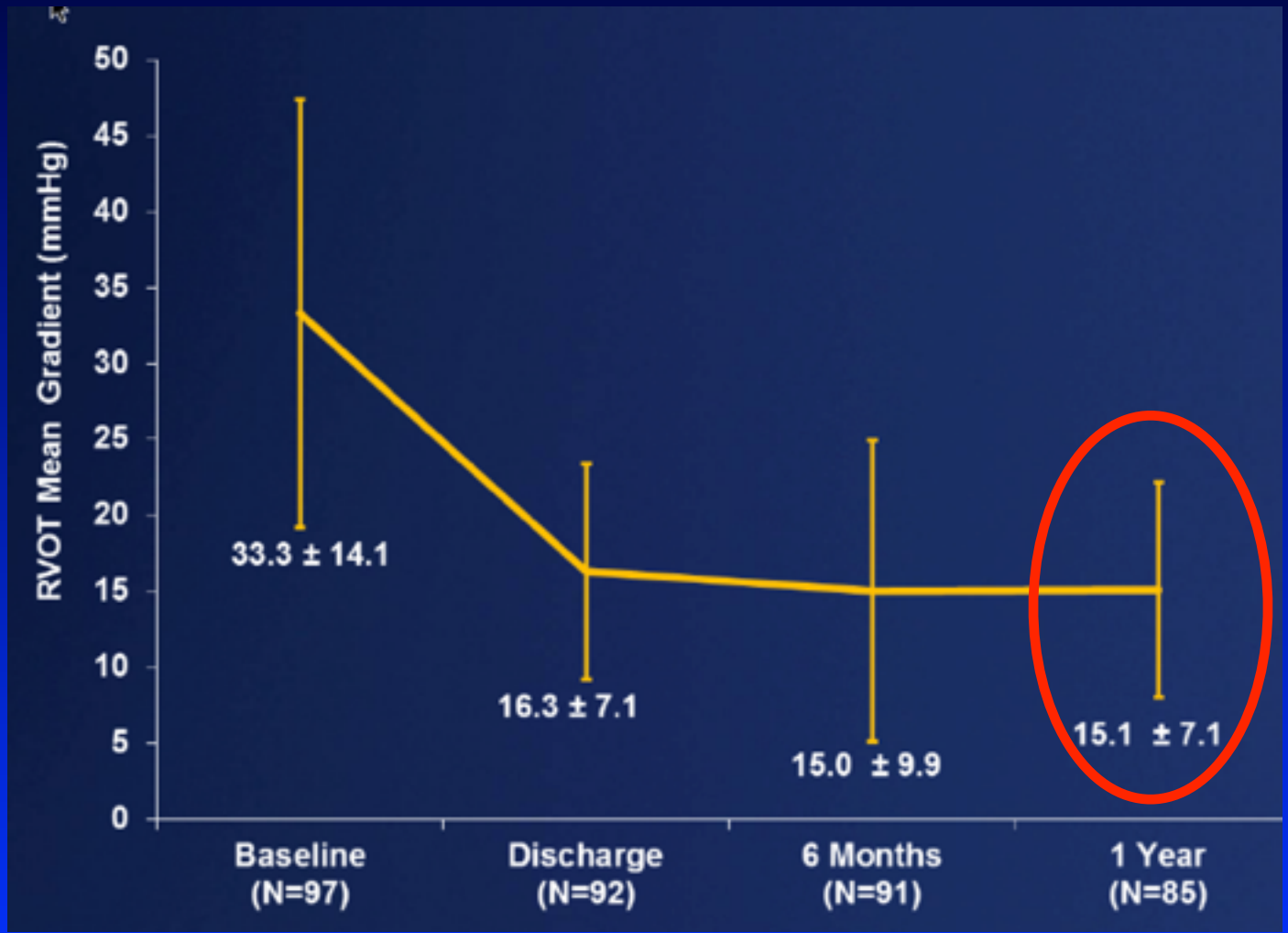
Primary endpoints



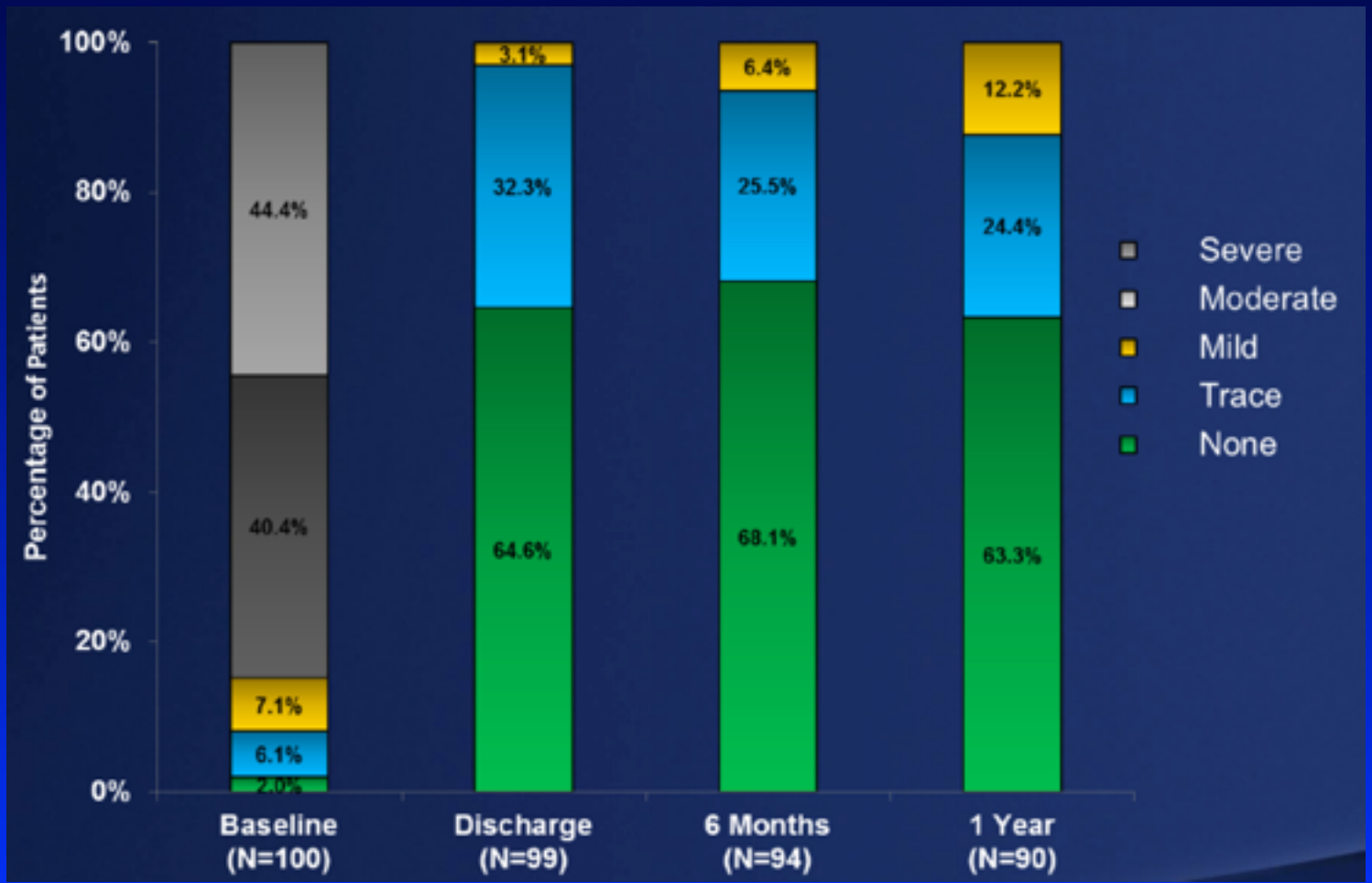
1-yr acceptable hemodynamic function



RVOT mean gradient



Pulmonary regurgitation



Conclusions

- This study confirms strong performance of the Melody TPV achieved by users with results comparable to the US IDE trial
  - Excellent hemodynamic function at 6 mos (96.7%)
  - High procedural success (98%)
  - Serious adverse events:
    - Procedural: 13.3%
    - 1st yr: 8.1%
  - High freedom from TPV dysfunction at 1 yr (96.9%)

Summary

- The Melody valve is a safe and effective palliative device to augment the lifespan of a RV-PA conduit
- Many potential problems and pitfalls encountered before,during and after procedure that needs algorithms to ensure safety and efficacy
- Pay attention to little details