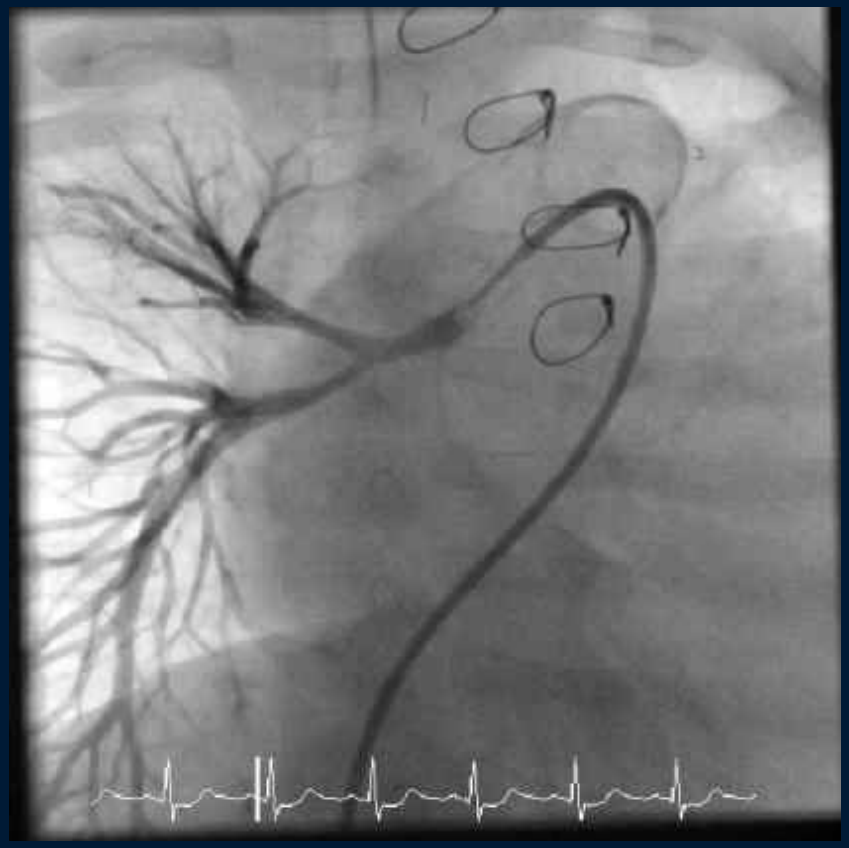
Pulmonary Artery Angioplasty – Conventional and Cutting Balloons



Matthew J. Gillespie MD, FSCAI
The Children's Hospital of Philadelphia
SCAI Fellows Course
December 9, 2014

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Affiliated with Penn Medicine
University of Pennsylvania School of Medicine

Presenter Disclosure Information

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No Disclosures

Background

- Pulmonary artery stenosis, distortion, hypoplasia
  - TOF, TOF/PA, Truncus Arteriosus, Fontan, etc, etc.
  - Major impact on patient outcome
- Historically difficult to treat surgically

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Goals

- Spectrum of pulmonary artery pathology ✔
- Indications for catheter treatment ✔
- Treatment strategy decision-making ✔
- Technique ✔
- Outcomes ✔

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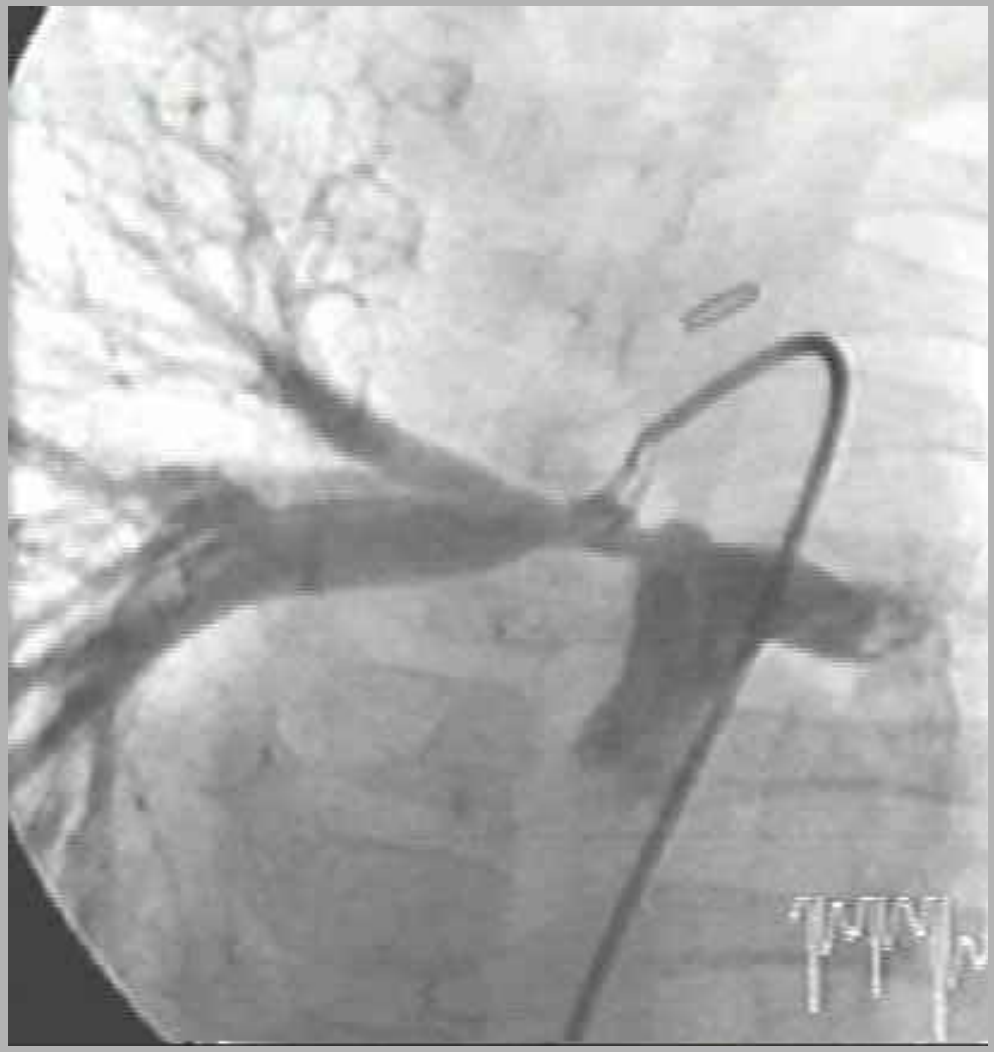
Pulmonary Artery Pathology: 4 General categories

I. **Isolated Focal Stenosis**

- Well-developed distal pulmonary arteries
- Usually occurs post-operatively
- Excellent outcomes –
  - usually end up with stent



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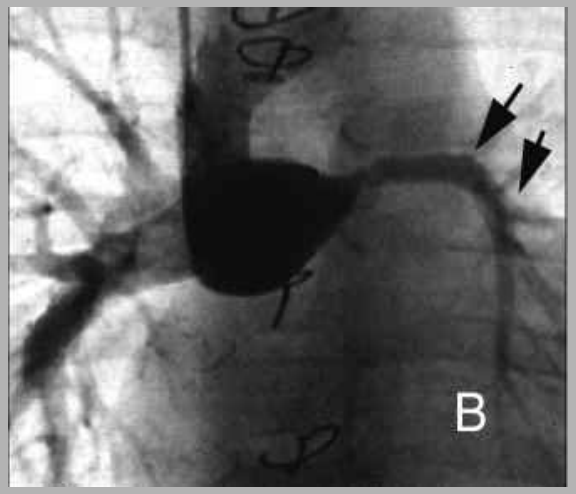
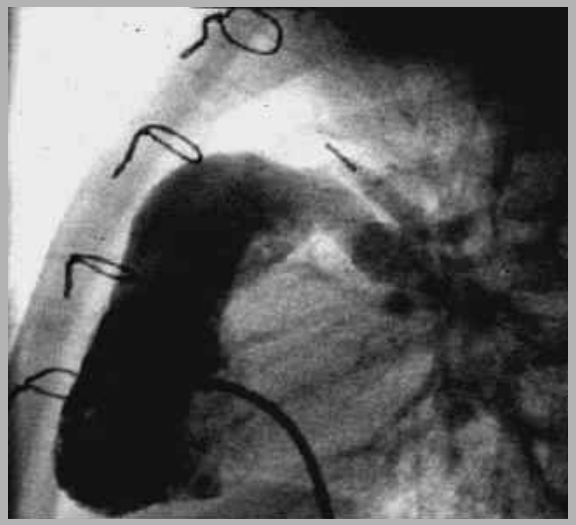
Pulmonary Artery Pathology: 4 General categories

I. Isolated Focal Stenosis, well-developed distal pulmonary arteries

II. Focal Stenosis with associated distal pulmonary artery hypoplasia

- Often in setting of low flow early in life
  - examples: tetralogy of Fallot; post surgical shunt with asymmetric flow





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Pulmonary Artery Pathology: 4 General categories

I. Isolated Focal Stenosis, well-developed distal Pas

II. Focal Stenosis with associated PA hypoplasia

III. Multiple Branch Stenoses

- Usually abnormal vessel wall at stenoses
- Common in TOF/PA with collaterals
- also seen in **arteriopathies** like Williams and Alagille

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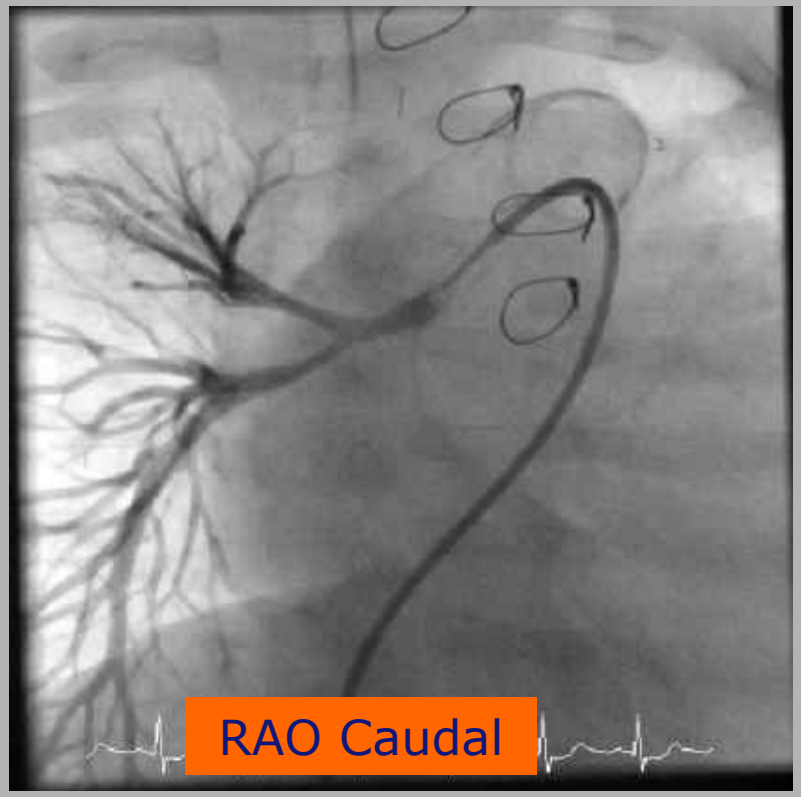
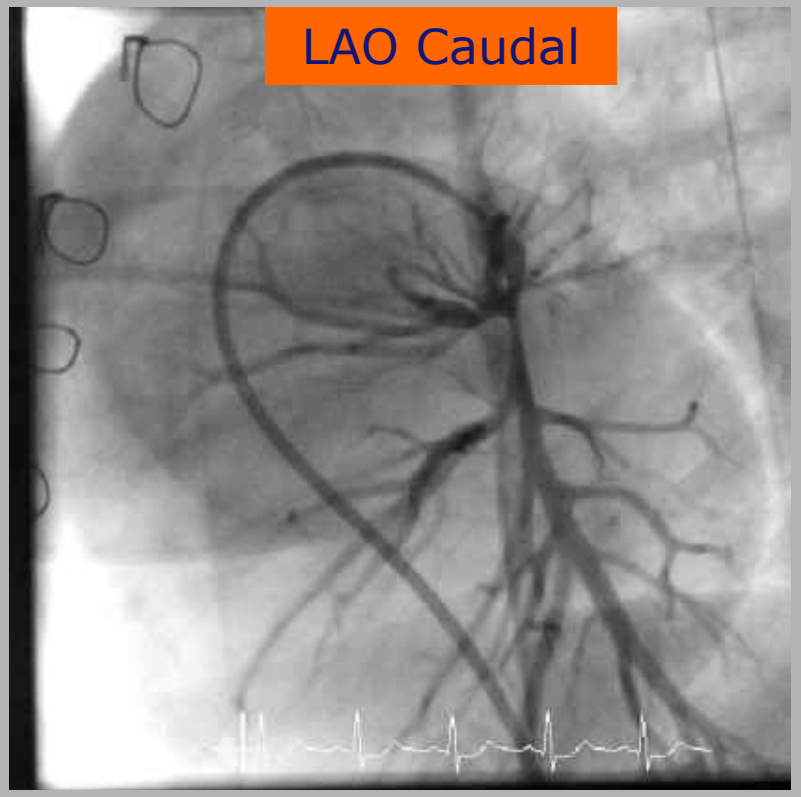
Pulmonary Artery Pathology: 4 General categories

IV. Diffuse Hypoplasia

- Usually from intrinsic vascular abnormality: most common in arteriopathies





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Pulmonary Artery Pathology: 4 General categories

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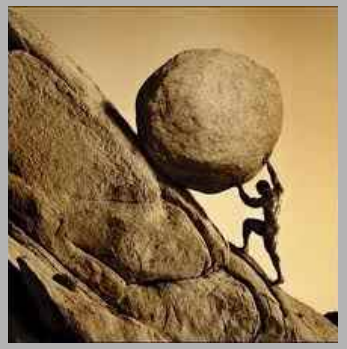

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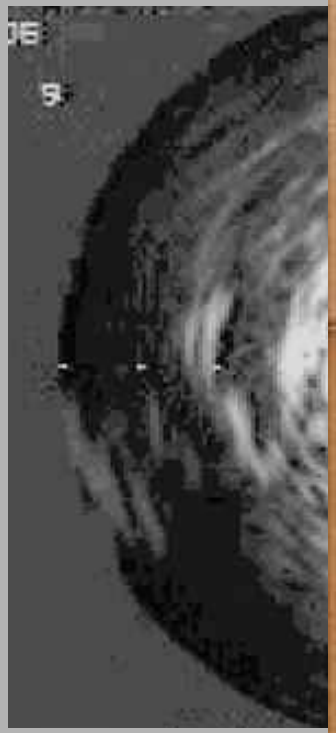
Diffuse PA Hypoplasia: IVUS



Decision-making: 1. Indications for Rx

Single Ventricle

—Anatomic obstruction with any gradient

Biventricular Circulation

- No intracardiac shunts
  - Right ventricular hypertension
  - segmental PAH
  - Significantly decreased lung flow (MRI, nuc med)
  - PI in TOF
- With intracardiac shunt (ie TOF/PA with VSD)
  - More complex equation taking into account Qp and gradients

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Decision-making 2: Type of Rx - Angioplasty vs Stent

Factors to consider

- Site of obstruction - central vs distal pa branch
- Patient age - future growth of vessels
- Vessel/stent size - risk of ISR, outgrowing stent
- Mechanism of obstruction (intrinsic stenosis v external compression or kinking)

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Technique: Preparation

- Equipment needs
  - Stock appropriate selection of balloons, wires, long sheaths, covered stents and embolization materials for bail-out)
- Diagnostics
  - Flow distribution assessment in biventricular circulation (MRI or Nuc Med)
- Risk-Stratification
  - General anesthesia for all but simpler cases
  - High risk patients (suprasystemic RVp, right heart failure) ECMO back-up
  - Multiple PA branch obstruction – LONG CASES…be prepared to suffer…..

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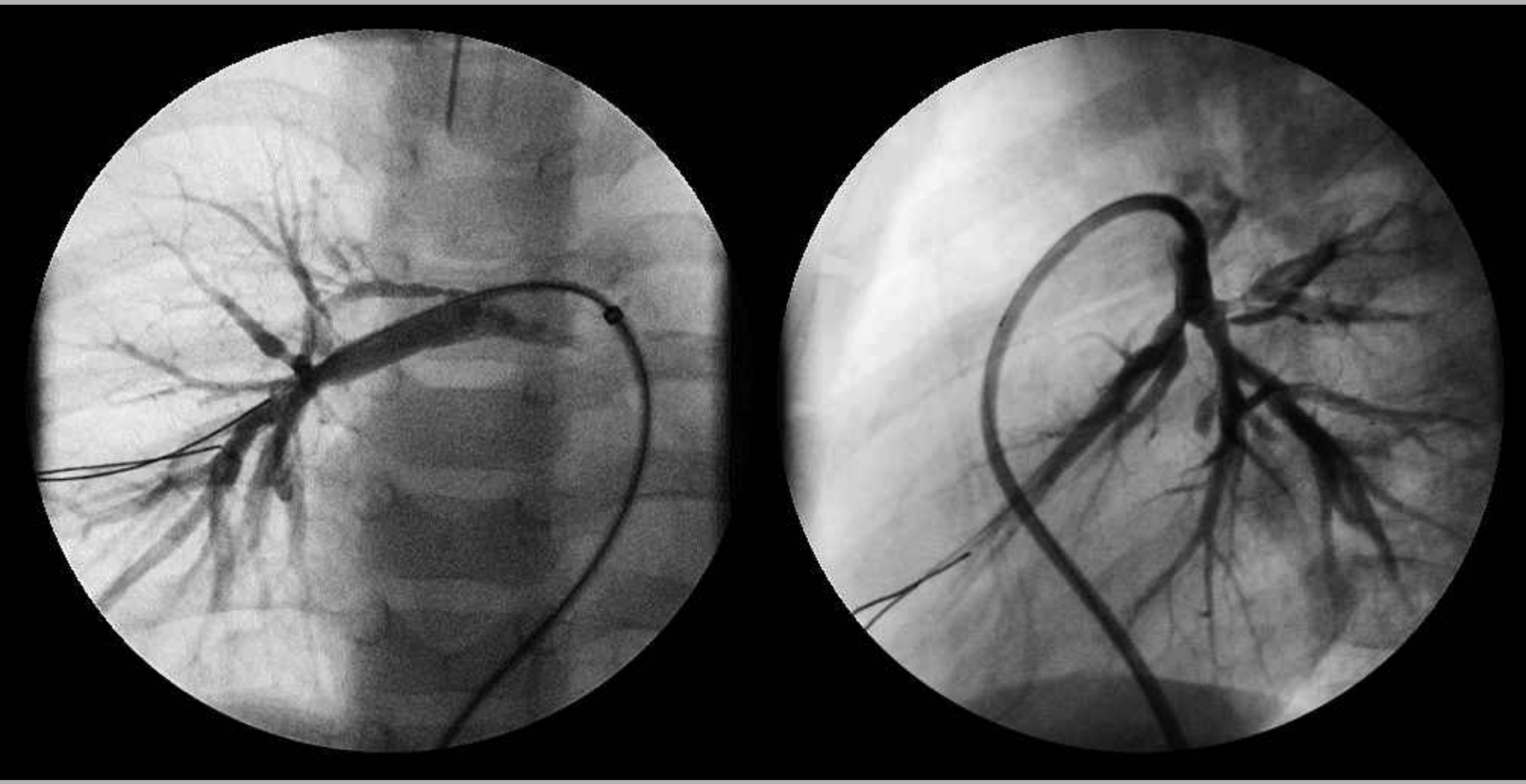
Procedure

- Catheter diagnostics
  - Risk stratify more precisely:
    - Mixed venous saturation
    - RA pressure
    - RV pressure
    - Impact of catheter in RVOT/PA
  - If High Risk based on above
    - what is your plan?
      - ECMO candidate?
      - Prophylactic transseptal and ASD creation
      - Prophylactic CPS (infrequent but not unheard of in our experience)
    - Supportive measures
      - 100% O2, optimize O2 carrying capacity, etc.
    - Targeted angiography
      - Don’t flood both lungs with contrast

Dilation: Approach

- Selective angiography: lateral / LAO caudal for distal



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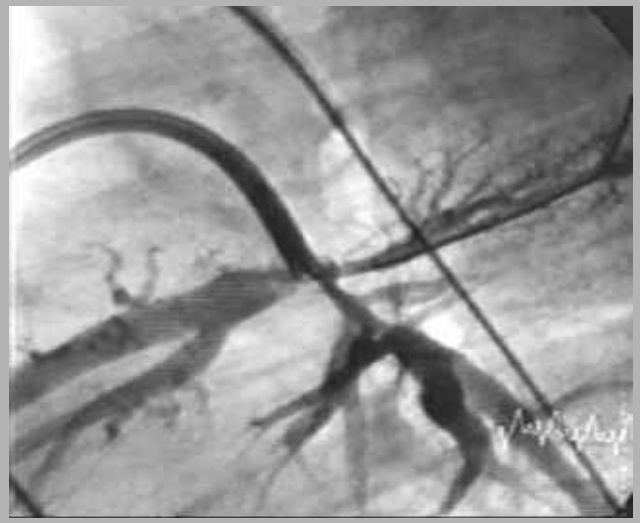
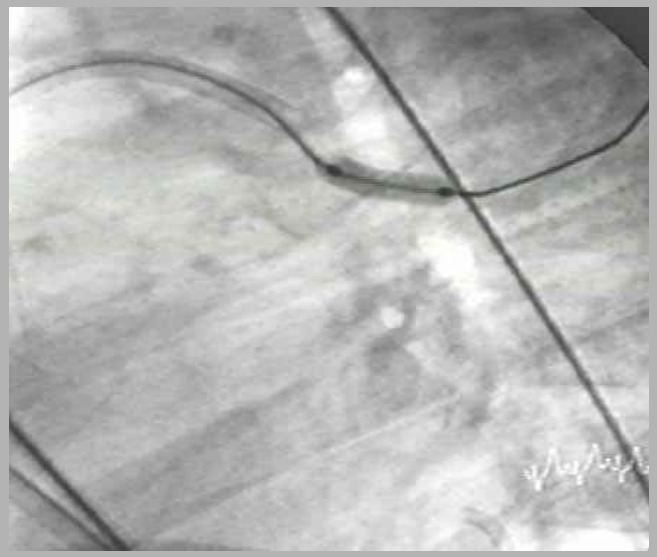
Dilation: Approach

- Be efficient - pre-shaped Mullins to proximal pa branch
  - allows for rapid angiographic assessment and repositioning





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Dilation: Approach

- Wire position, wire position, wire position
- Balloon size - start at <150% normal vessel
  - balloon:stenosis diameter ratio < 4
  - In arteriopathy patients be more conservative
- High pressure versus cutting balloon angioplasty?
  - Standard balloon angioplasty is faster, simpler, and probably lower procedural risk
  - It also doesn't work as well
  - Cutting balloon angioplasty on average more effective
    - Also increased risk of dissection and other complications.

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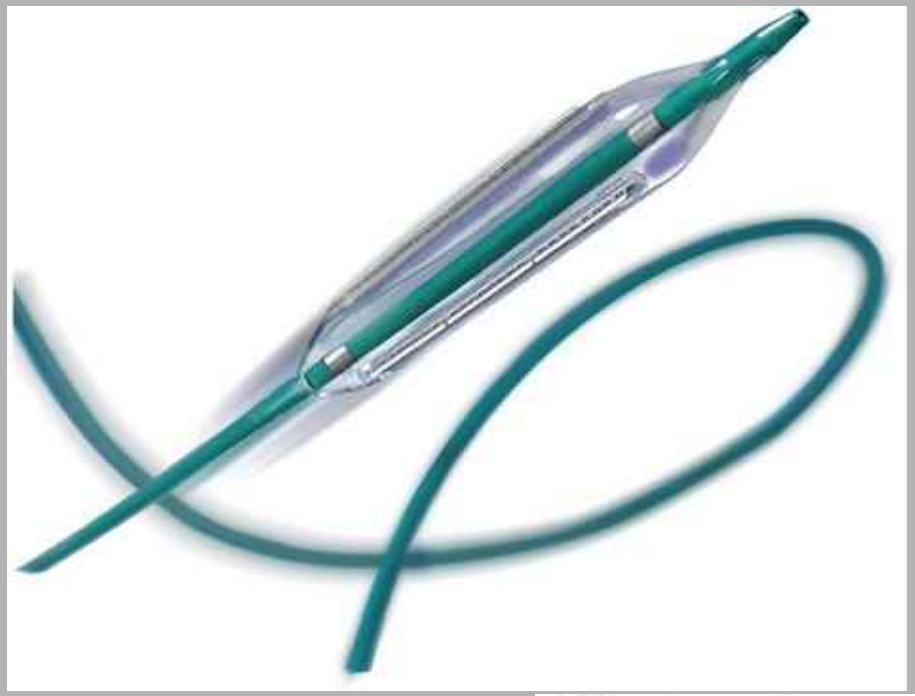
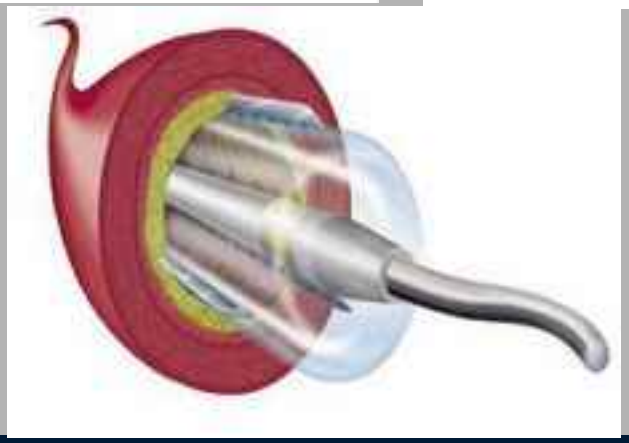
Approach: Standard Balloon

- Vessel size ~4 mm or less
  - Wires – 0.014 – 0.018” high torque exchange length
  - Balloons
    - Sterling (Boston Scientific) or equivalent (available 4-10mm) reasonably high pressure (14 atm)
- Larger Vessels
  - 0.035” wires (Rosen is our preferred)
  - Noncompliant balloon: Ultrathin Diamond (Boston Scientific) or equivalent

Cutting Balloons

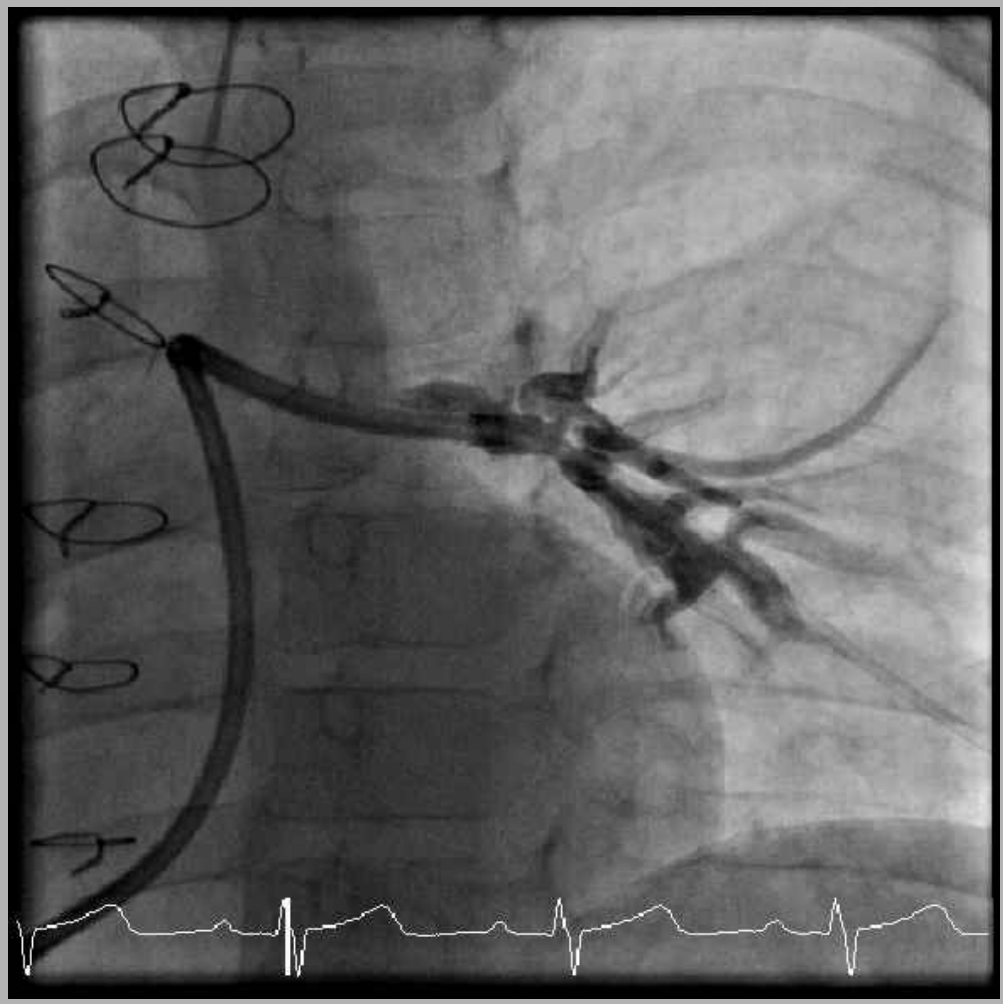




Cutting Balloon Technique

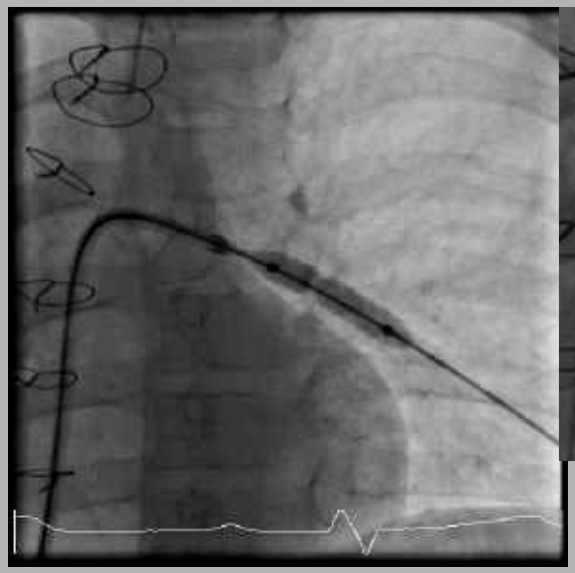
Equipment

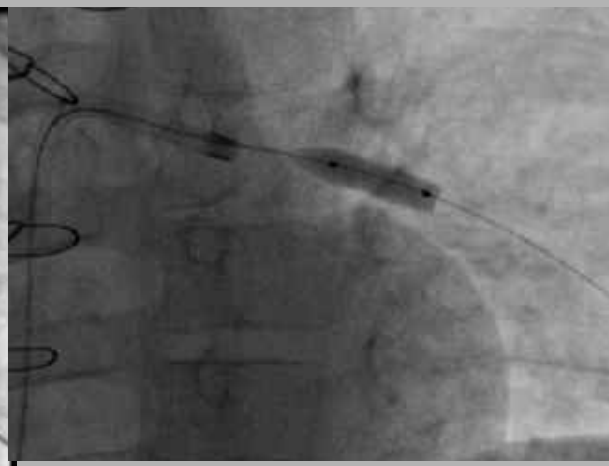
- Balloon ≤ 4 mm
  - Sheath at least 5 F; 0.014” wire (Extra support Boston Scientific)
- > 4 mm
  - 7 F sheath, 0.018” wire (High torque floppy)



Choosing correct cutting balloon size

- Safest (more laborious) is low pressure balloon-sizing.
  - Std angioplasty balloon (size based on prev criteria) at 6 atm
  - Cutting balloon diameter 1 mm greater than waist up to 1 mm > normal distal vessel size.





Special Considerations: Multiple Distal Stenoses with Severe Obstruction

- Careful monitoring, anesthesia
- Hemodynamic instability with balloon inflation
  - approach most severe lesions first
- Risk of reperfusion edema
  - dilate as many lesions as possible at each procedure to distribute flow
  - don’t be too aggressive with individual vessels
- Efficiency essential

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Complication Management

- Dissection/ Aneurysm
  - Relieve residual obstruction
- Perforations/Rupture
  - embolization

Balloon Angioplasty: Results from Literature

- **"Success"**: Variable results – early series 50%, recently 75-up to 90%.

- ***Criteria for success***:
  - angiographic diameter ↑ of > 50%,
  - > 20% ↓ in RV/AO pressure,
  - > 20% ↑ in relative flow by lung scan.

- ***THESE CRITERIA DO NOT EQUAL CLINICAL SUCCESS***

- Complications: 6-10%, mortality 1%
- Restenosis: ???

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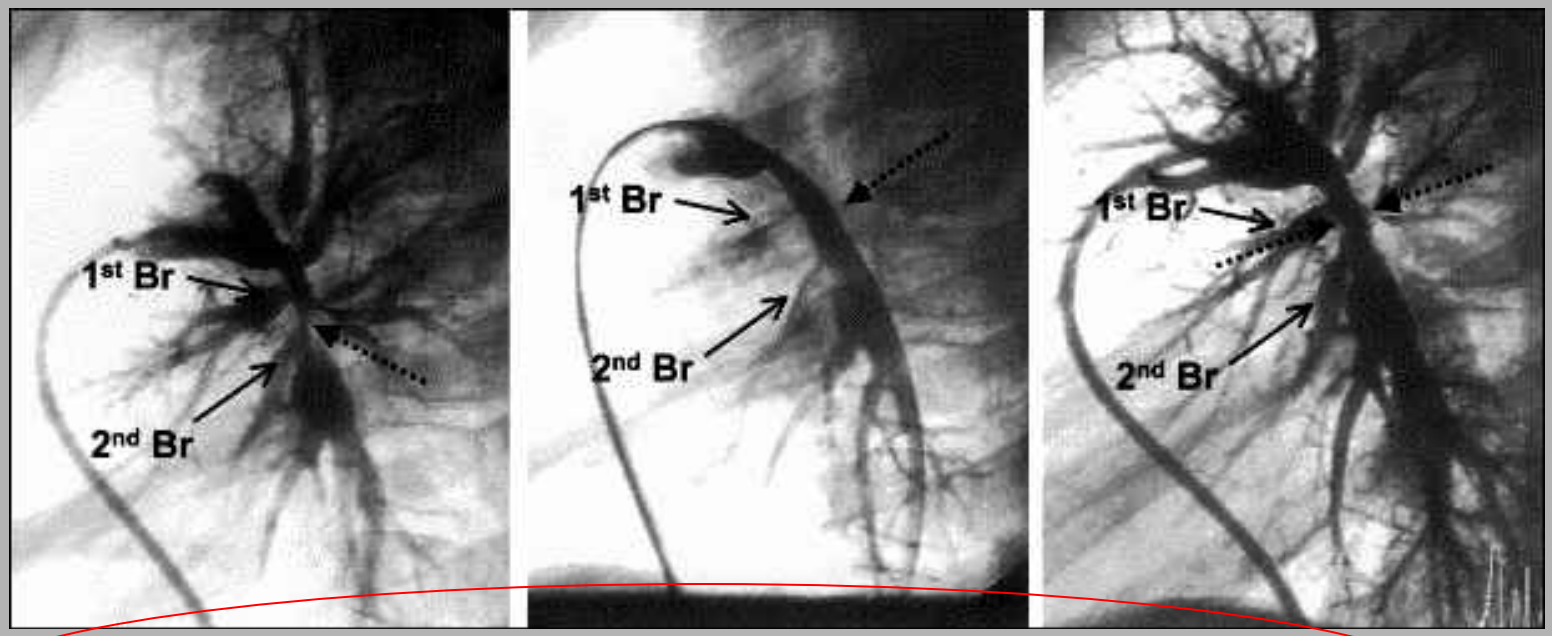
Restenosis After Angioplasty

Pre-dilation Post-dilation Follow-up

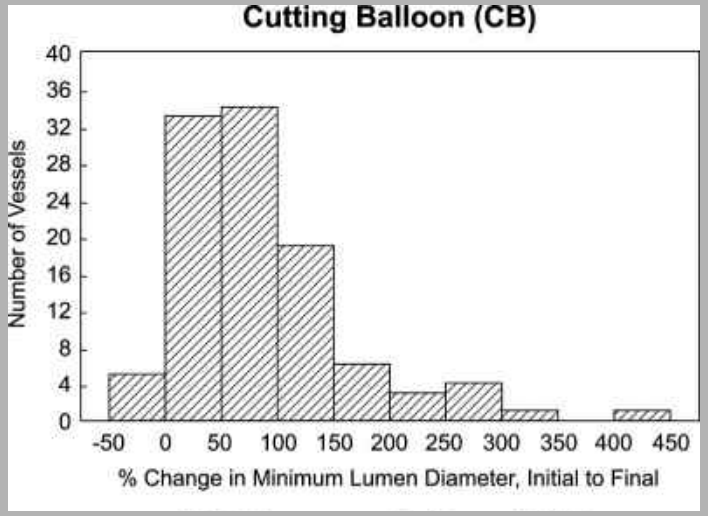


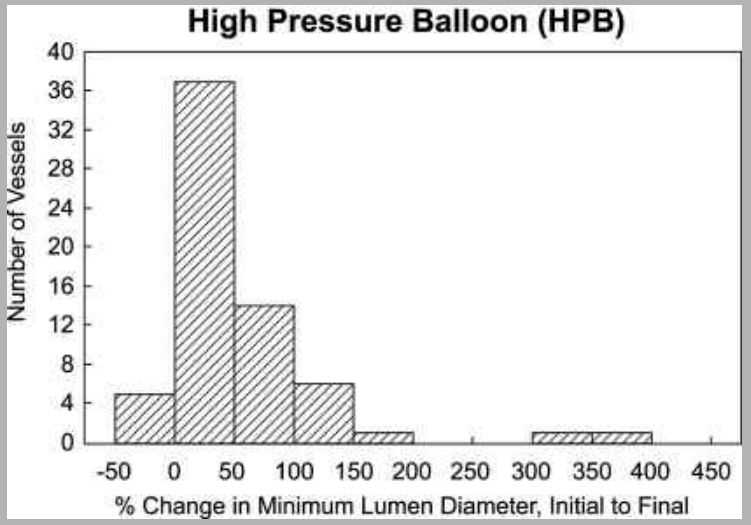
Incidence of restenosis = 35%

Unable to define specific predictors

Cutting Balloon Outcomes

Bergersen, L. et al. Circulation. 2011;124:2388-2396





- **85%** increase min lumen diameter CB

  vs

- **52%** for HBP

Table 5. Primary and Secondary Safety Outcomes

Primary and Secondary Safety Outcomes	Cutting Balloon (n=107), n (%)	High-Pressure Balloon (n=66), n (%)	*P*
Primary safety outcome			
Any serious event in a study vessel	0 (0)	0 (0)	
Secondary safety outcomes			
Any serious event definitely attributable to balloon angioplasty in a study vessel	0 (0)	0 (0)	
Any somewhat serious or serious adverse event resulting from balloon angioplasty in a study vessel	3 (3)	1 (2)	0.85
Any adverse event resulting from balloon angioplasty in a study vessel*	12 (11)	4 (6)	0.19

*Thirteen events in 12 vessels, including 1 patient with 2 events in 1 vessel (both device malfunction). One adverse event in a vessel randomized to high-pressure balloon therapy occurred after crossover (balloon rupture); here, it is attributed to the high-pressure balloon.

Conclusions: Pulmonary Angioplasty

- PA dilation remains a challenging intervention for several reasons
  - Has potential for substantial risk
  - Procedures are lengthy, and often frustrating in patients with multiple distal obstructions
  - Results remain suboptimal particularly in arteriopathies
- But for many lesions, it is the best we have, in current practice even with its limitations, remains an essential an tool.

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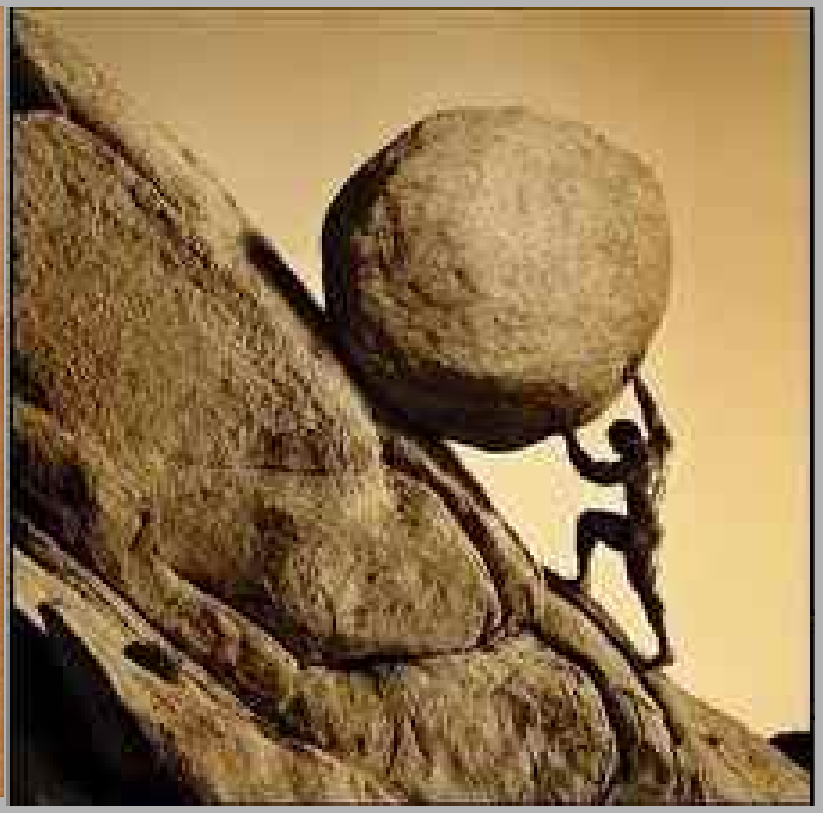
Conclusions (continued)



Acknowledgement

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For sharing his slides

Thank You