Dr Joaquim Miró
Hôpital Sainte-Justine
Montréal, Canada

Percutaneous Closure of Perimembranous VSDs

TCT Asia Pacific, Seoul, April 2007

Hôpital Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Pour l'amour des enfants

Université de Montréal

Plan

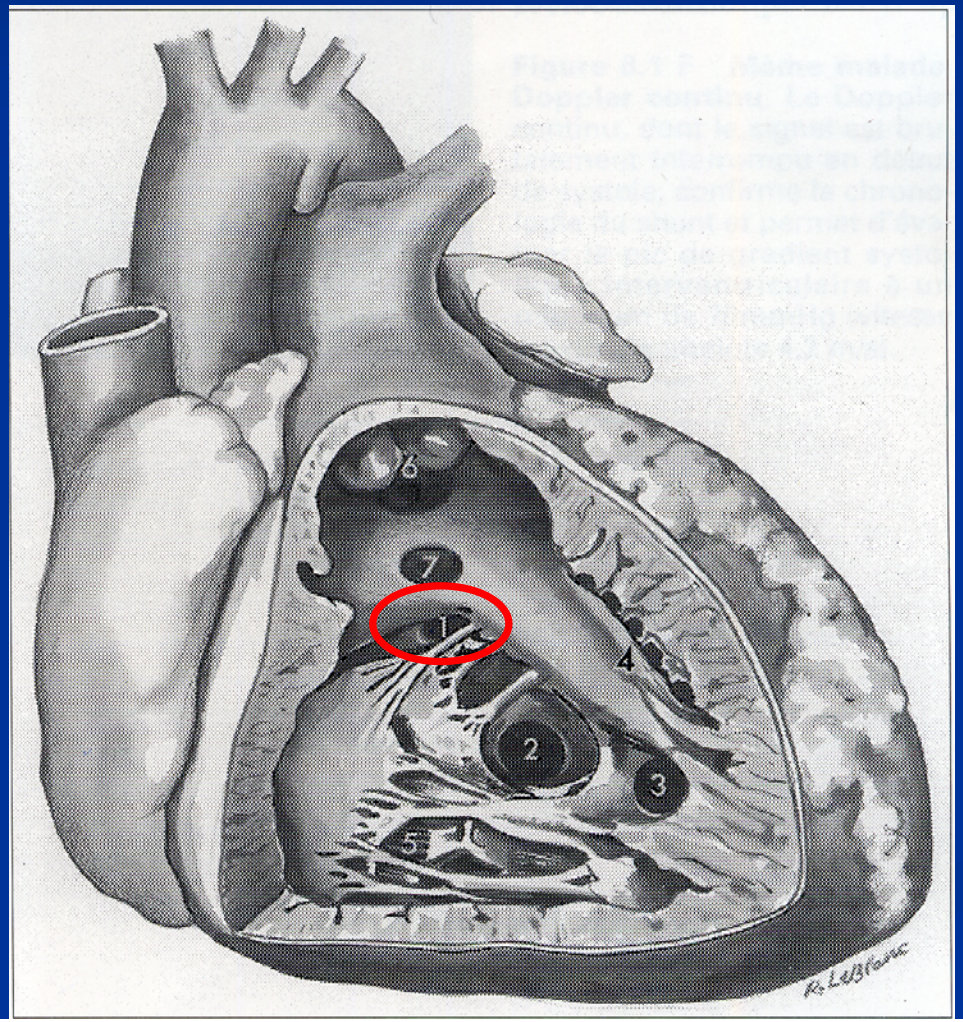
Recall of the Anatomy of the PMVSD

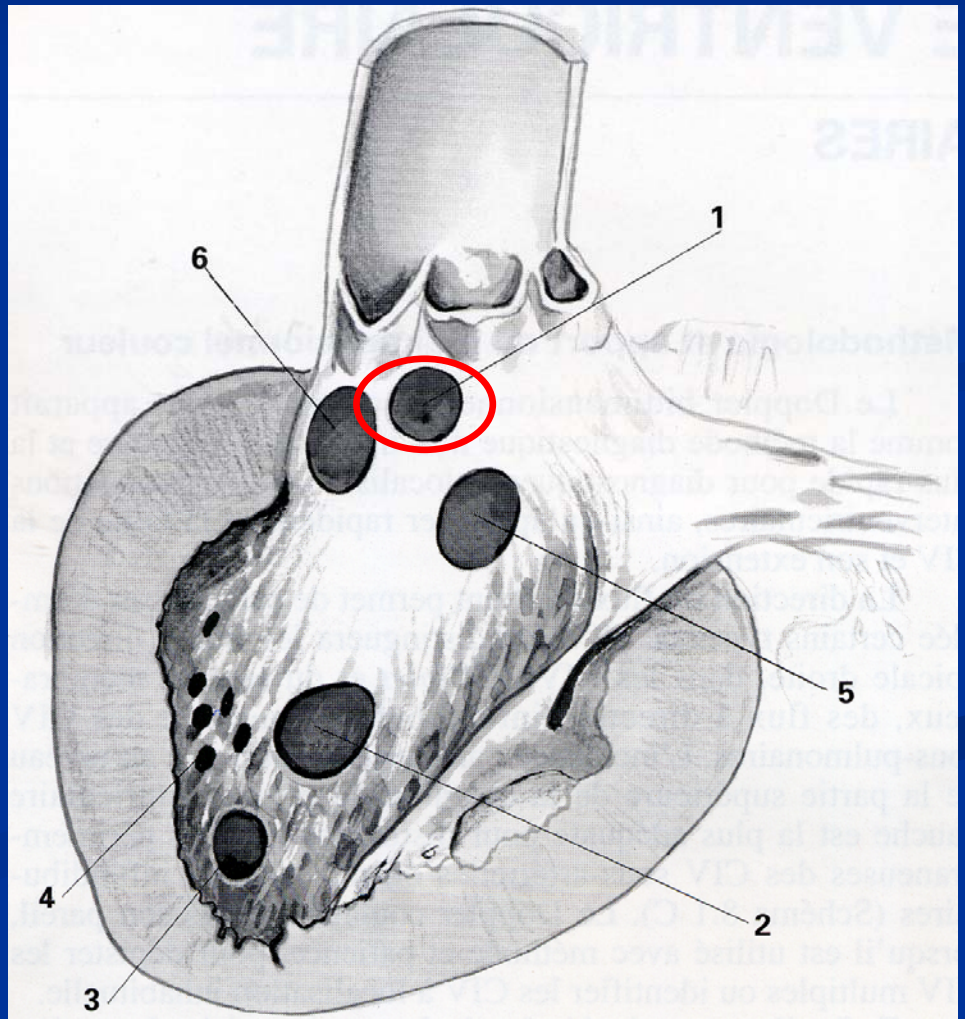
- Implications for percutaneous closure

- Step-by-Step review of the technique
- Results of the canadian and international experiences

Perimembranous VSDs
Recall of the Anatomy

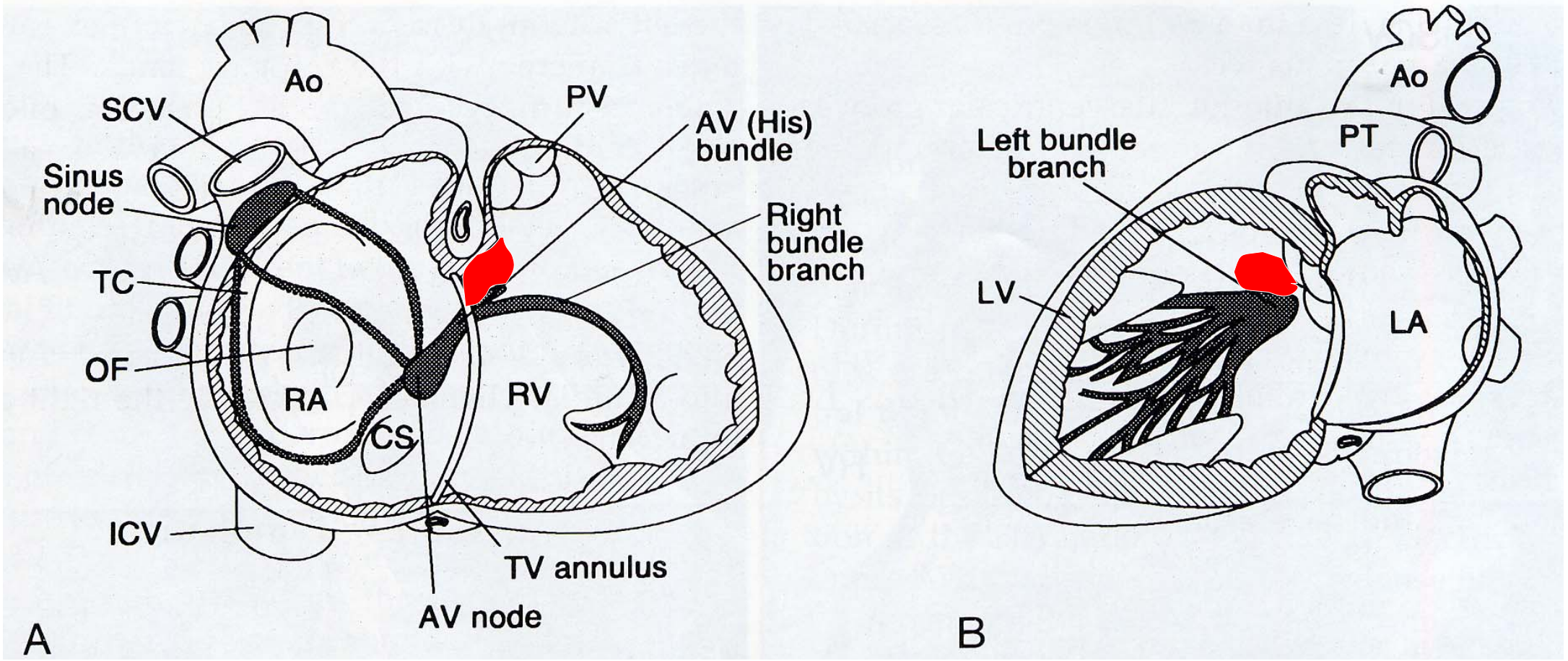
- Situated at the confluence of the inlet, outlet and muscular septae.
- In close anatomical relation to the aortic and tricuspid valves.





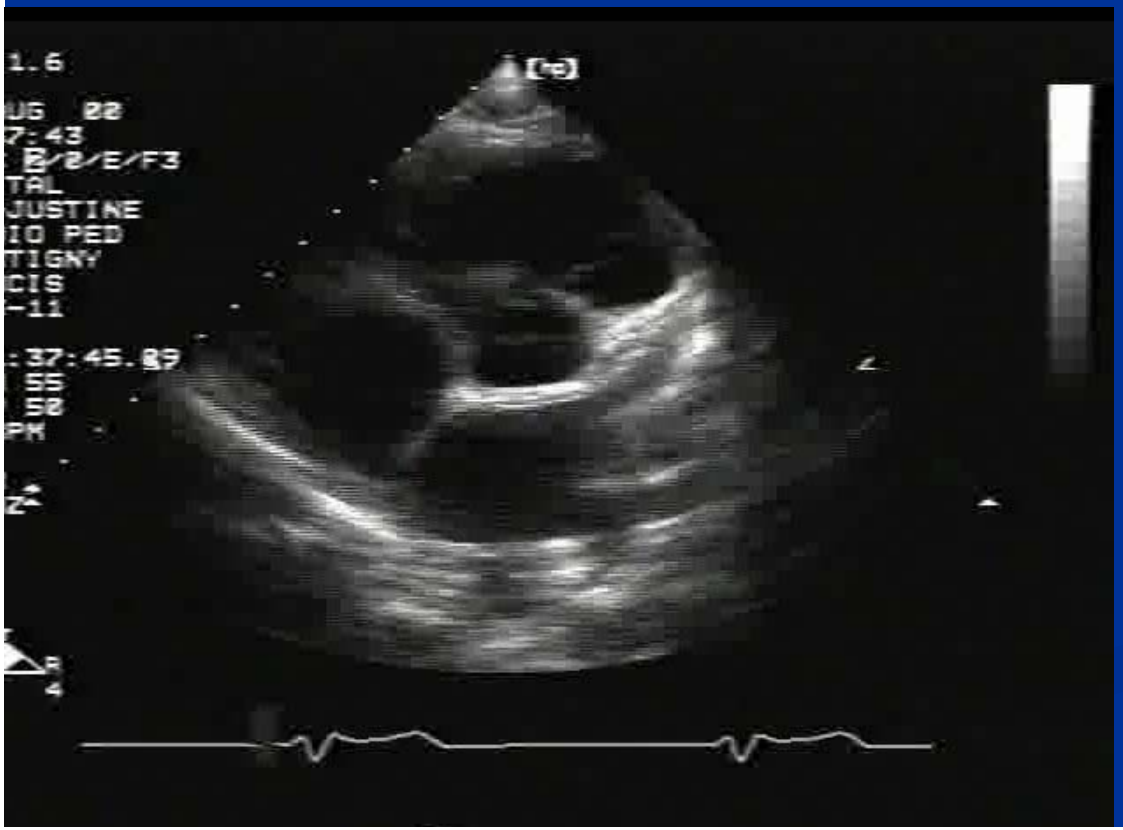
Perimembranous VSDs
Recall of the Anatomy

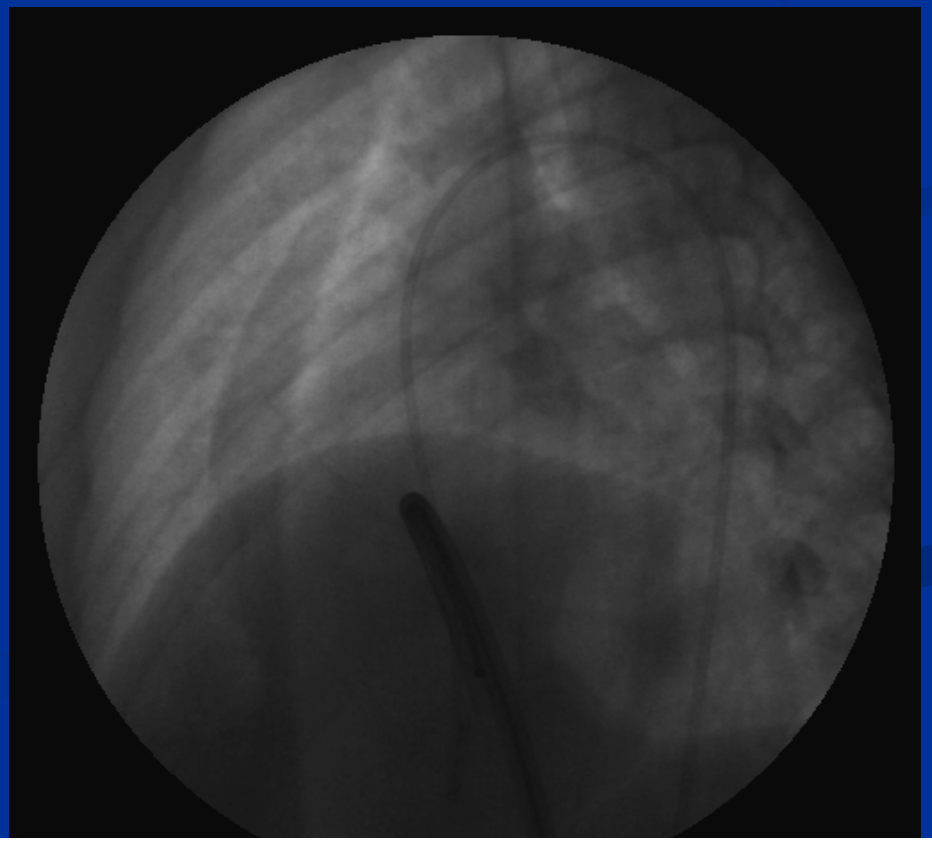
- A-V conduction system can run very close to the posterior-inferior margins of the defect.



Perimembranous VSDs
Recall of the Anatomy

- The defect can be partially or completely closed on the RV side by an “aneurysm”.
  - Genuine growth from the margins of the defect.
  - Tricuspid tissue.
- The “aneurysm” can have a single or multiple orifices





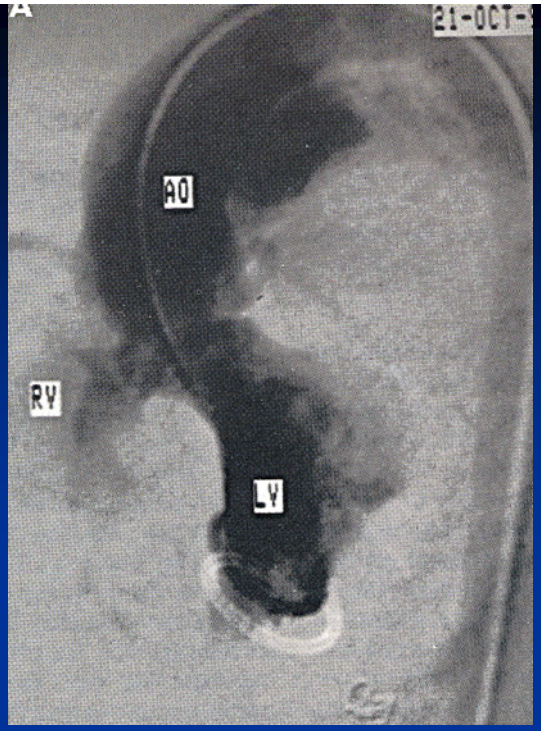
Anatomy of the PMVSD
Technical Implications

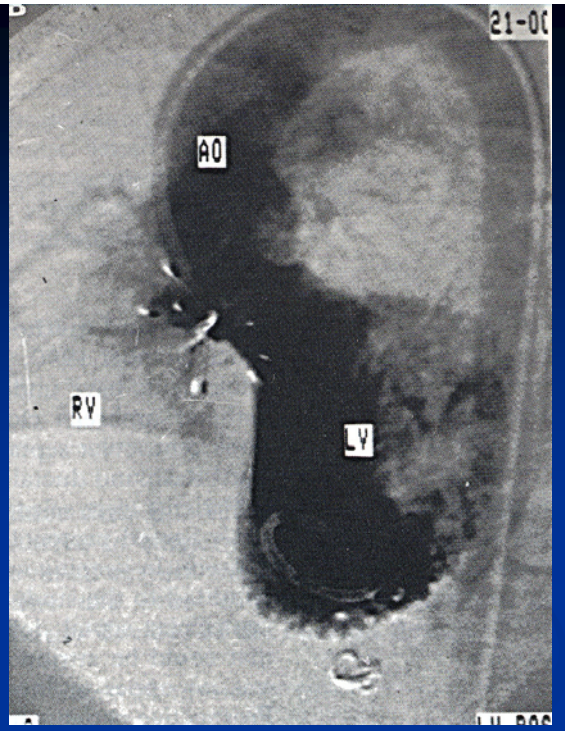
- Defect better crossed from the LV side (VSD behind the tricuspid valve).
- Device must be deployed from the RV side for precise positionning of the LV disk.
- Selection of device size delicate
  - Orifice through aneurysm on RV side (hemodynamic defect)
  - Septal defect on LV side (anatomical defect)
- Precise placement of device delicate
  - Upper edge of LV disk under Aortic valve
  - Placement of LV and RV disks can vary
    - Presence and size of aneurysm
    - Presence of aortic valve prolapse

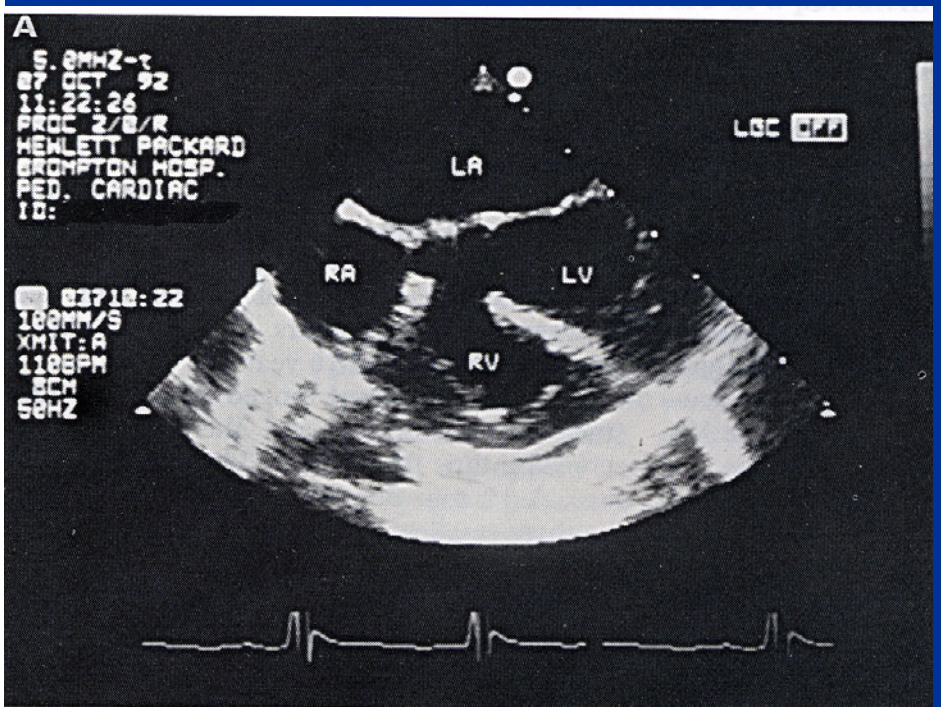
Device Closure of pmVSD

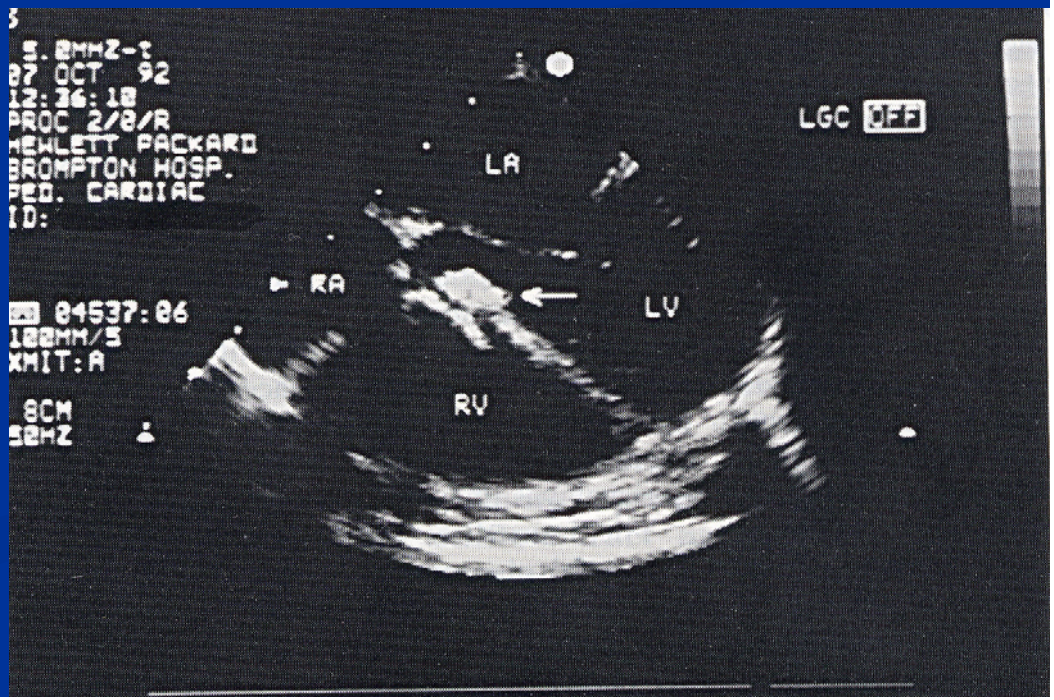
- Previous attempts with devices used for ASD, PDA or muscular VSD
  - Rashkind device
  - Clamshell-Cardioseal
  - Coils
  - Sideris Devices
  - Muscular VSD Amplatzer device
  - PFM coils
  - Others

Rashkind Device

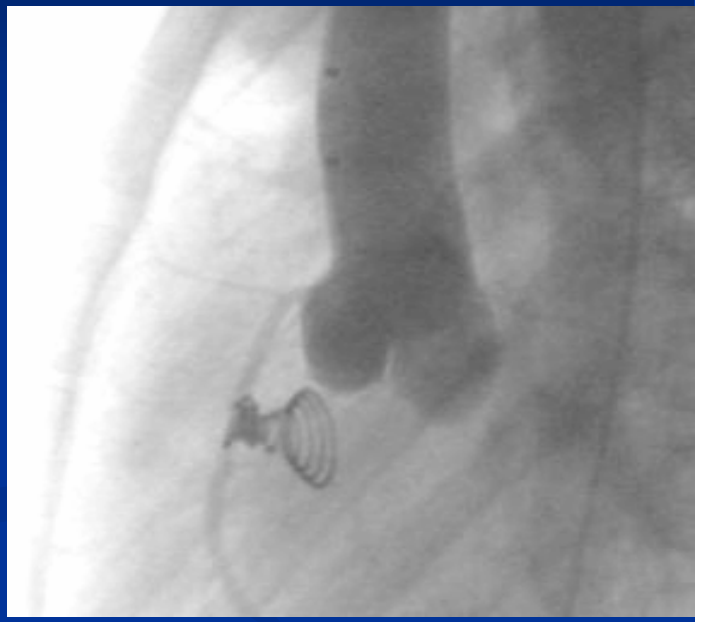








PFM Coil



Amplatzer PMVSD Device

- Muscular VSD device modified in order to adapt to membranous septum anatomy
  - LV disk eccentric with almost no aortic edge
  - Central part shorter than muscular VSD device (3 mm)
  - Less stiff than muscular VSD device
  - Directional delivery system

MEMBRANOUS VSDs: INDICATIONS

- Two questions to ask:
  - Does the VSD needs to be closed? >>>Indications for closure
  - Can the VSD be closed by the Amplatzer device? >>> Suitability

Closure of PMVSD
Clinical Indications

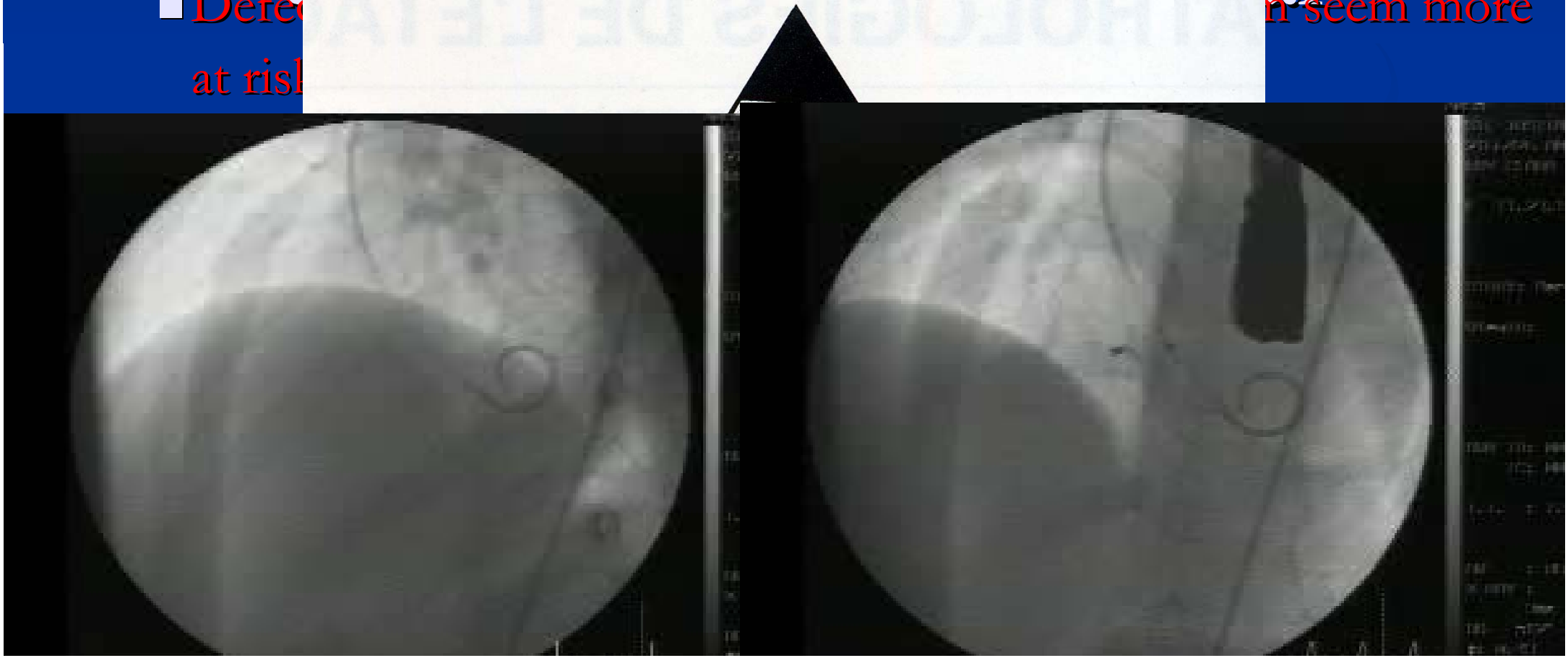
- *Indications for percutaneous closure should be the same as for surgery*
- Heart failure and/or failure to grow after 3 months of age.
- Left chambers dilation and/or pulmonary congestion after 1 year of age.
- Progressive aortic valve deformation and/or insufficiency.
- Previous endocarditis.
- Associated lesions: sub-aortic or sub-pulmonary stenosis.

Closure of PMVSD

Suitability for Percutaneous Closure

Canadian multicentric trial

- Maximal diameter of orifice 14 mm (by angiography).
- Defect located in the membranous or conal septum:
  - between 9:00 and 12:00 in parsternal short-axis view
  - Avoid defects touching to the pulmonary valve
  - Defe[illegible]n seem more at risk



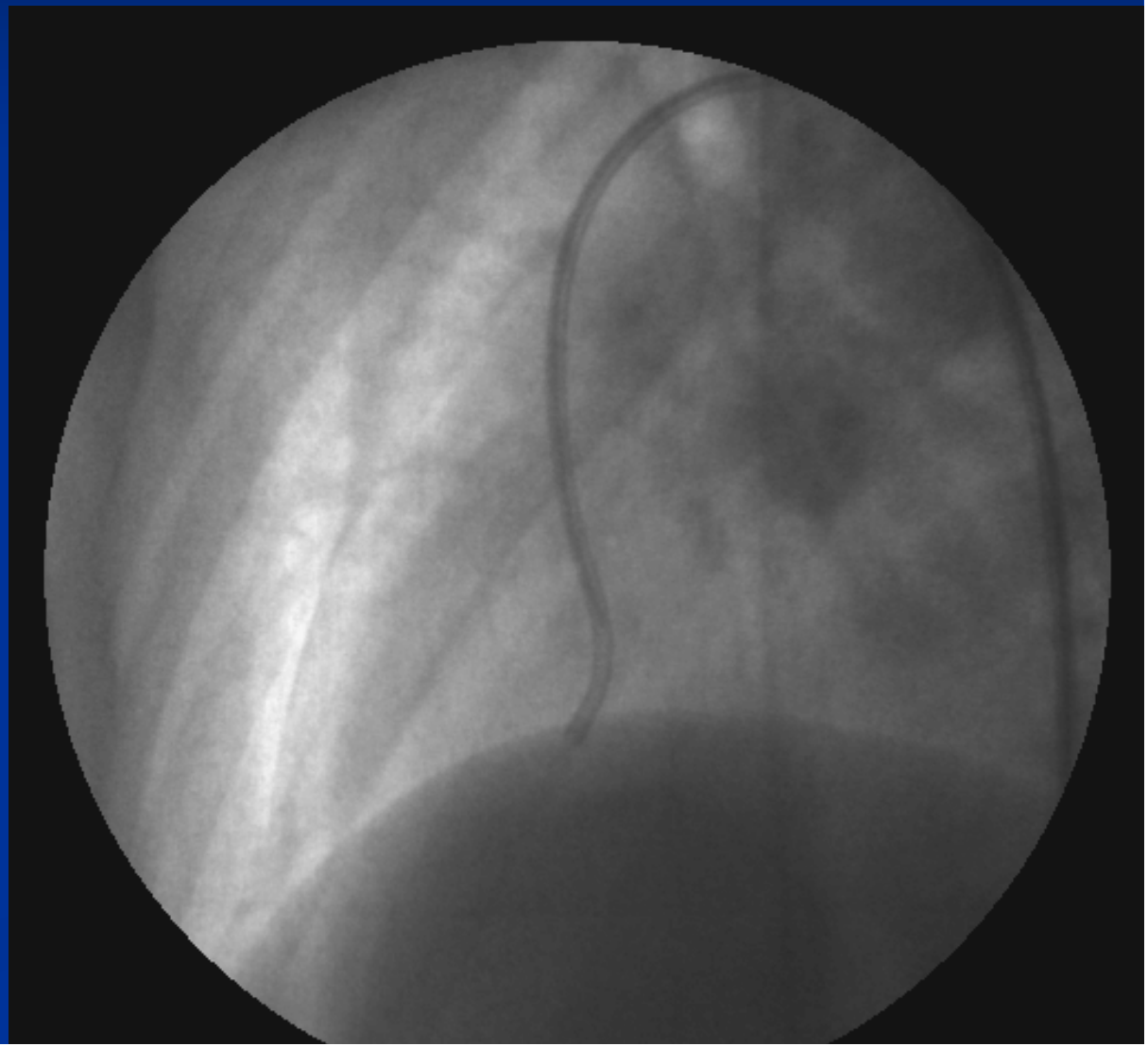
Step-by-step Review of the technique

Selecting Device Size

- Two critical measurements
  - Defect on LV side (base of aneurysm)
  - Orifice through aneurysm (if any)
- Minimal requirement: Device size (diameter of central waist) must be 0-2 mm larger than the orifice on RV side
- If significant aneurysm, and septal defect (LV side) much larger than orifice (RV side), a larger device can be selected, in order to cover the defect.
  - Allows better endothelialization
  - Avoids deployment of LV disk inside the aneurysm
  - Occludes multiple holes

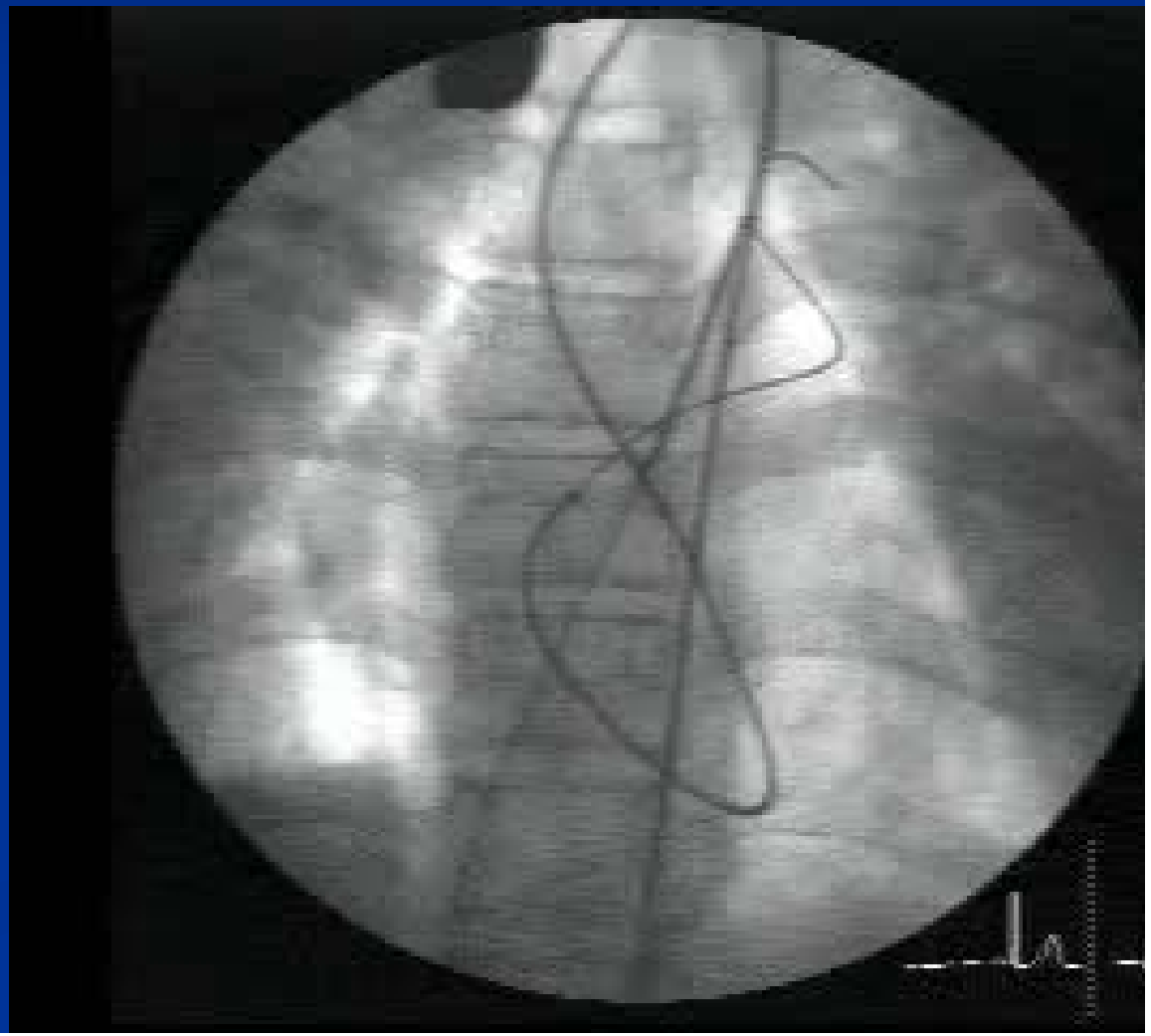
Step-by-step Review of the technique Crossing the defect

- 1st choice: JR 3,5 or 4,0
- Trying to cross defect just as finding right coronary... but lower.
- Once tip of catheter slightly in RV: advance noodle guidewire



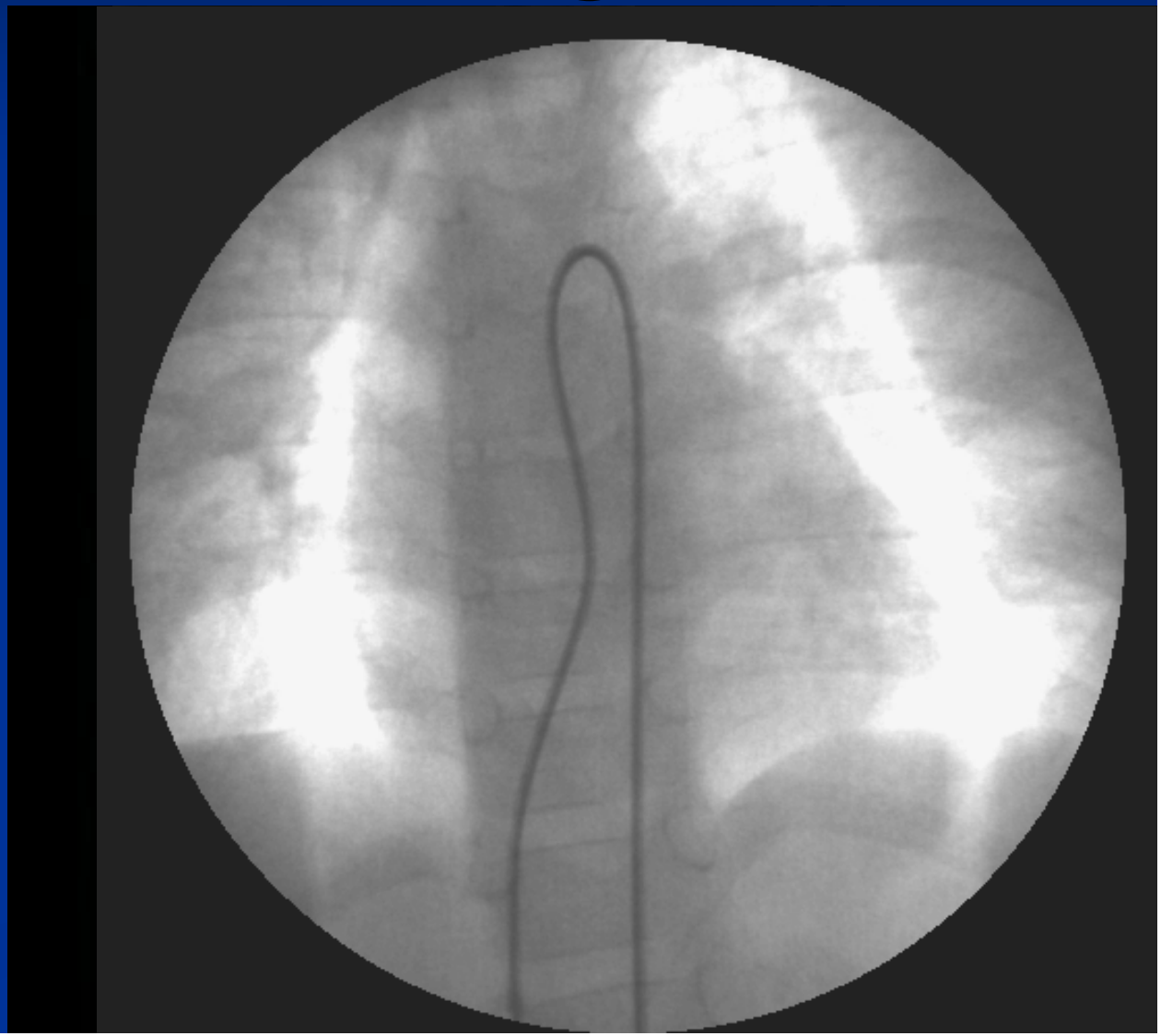
Step-by-step Review of the technique
Snaring the guidewire

- Snare Noodle guidewire at its tip
- Pull back gently to IVC and exteriorize through femoral vein
- Be sure that the guidewire loop is not through tricuspid apparatus

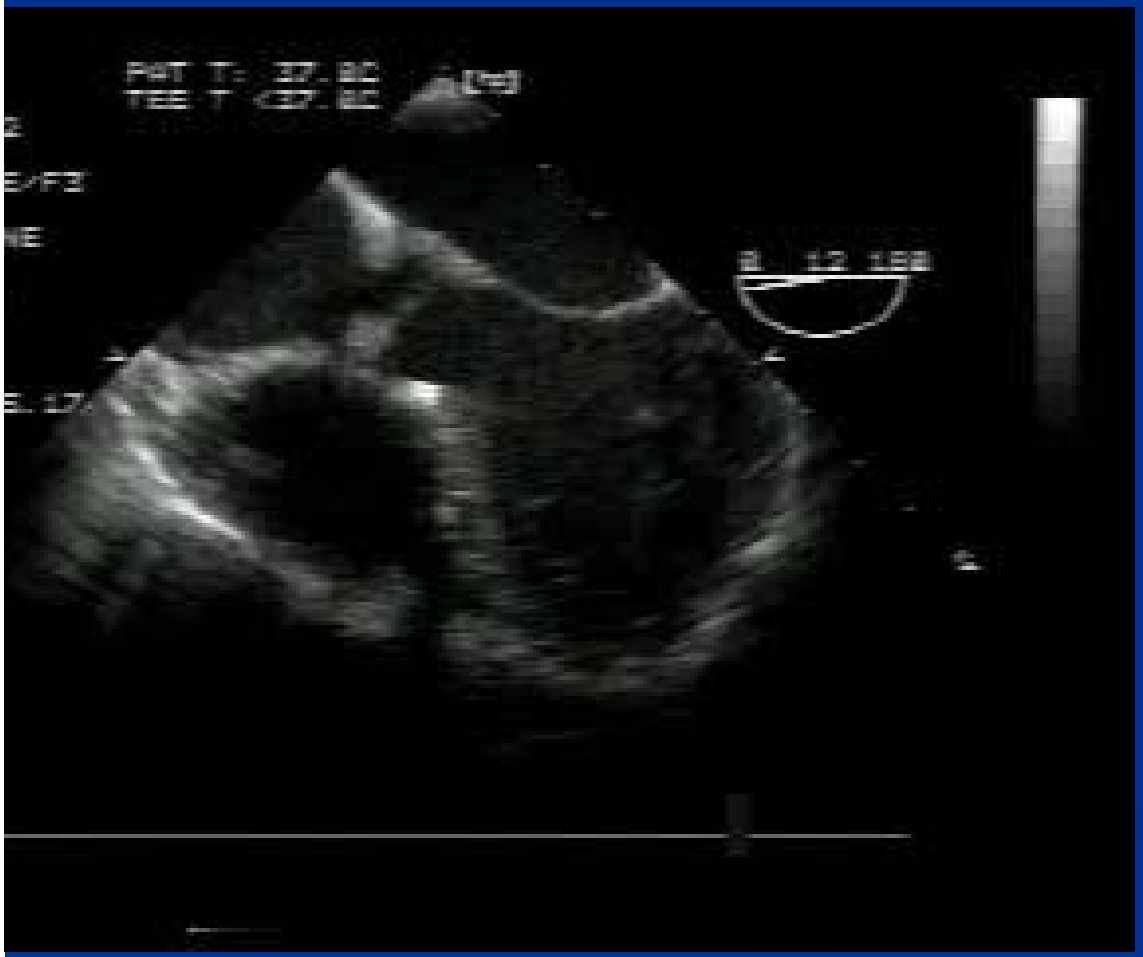


Step-by-step Review of the technique Pushing the sheath through VSD

- Advance sheath to ascending aorta, while applying traction on both ends of the guidewire.
- Push back sheath to LV with arterial catheter.

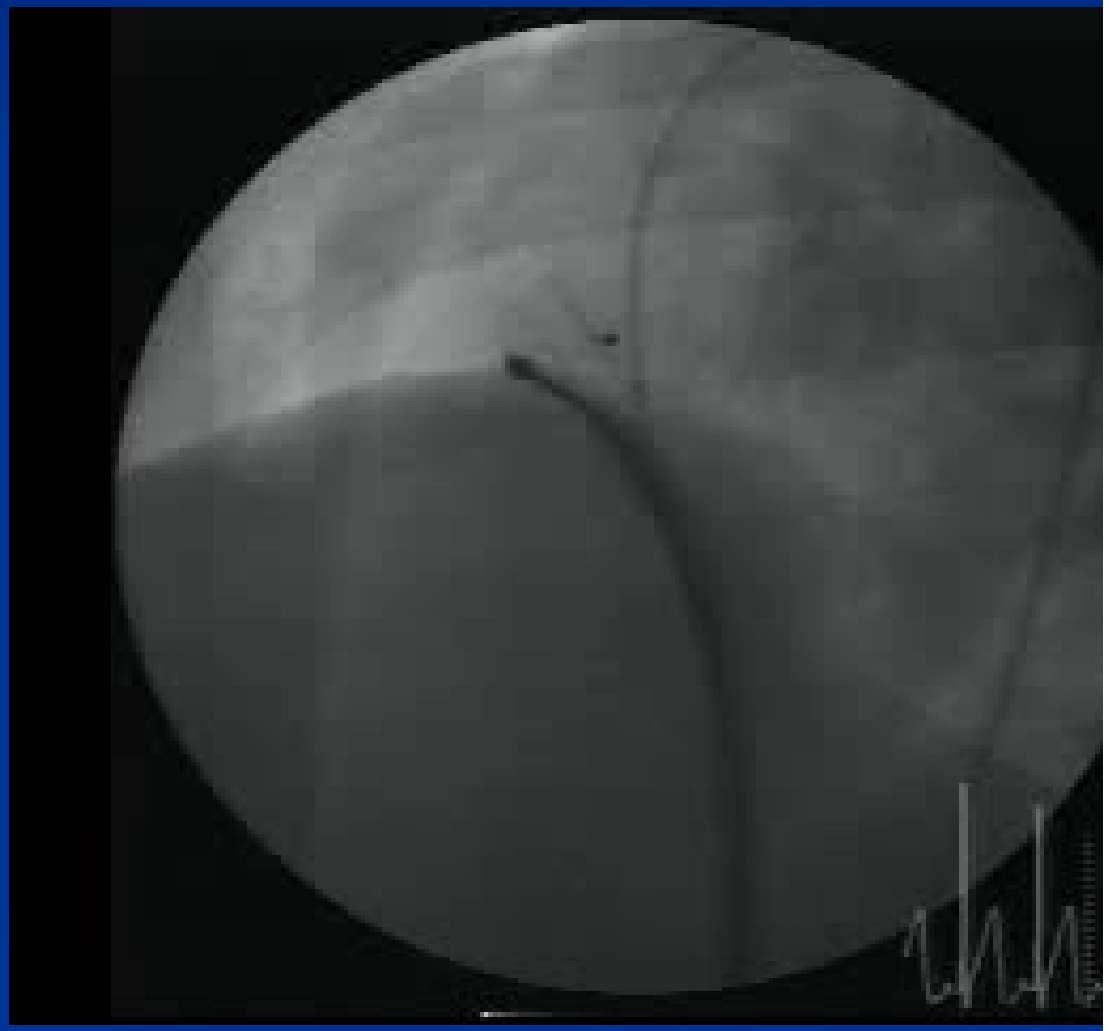


Step-by-step Review of the technique Deploying Device



Step-by-step Review of the technique
LV Angiogram post-deployment

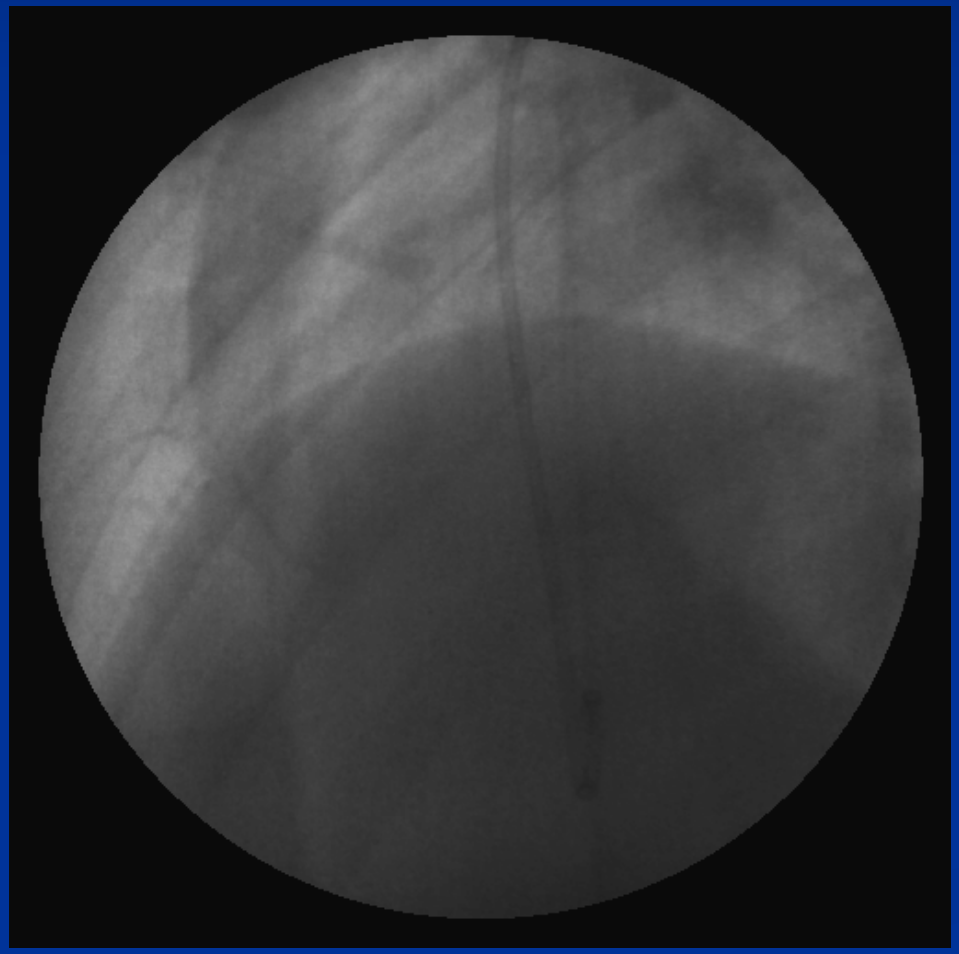
- Confirm adequate position of device.
- Foaming normal and quickly disappears.
- High velocity residual shunts through and around device have less chances to disappear.
- Ascending aortogram if contact of device with valve or Aortic insufficiency by echo.

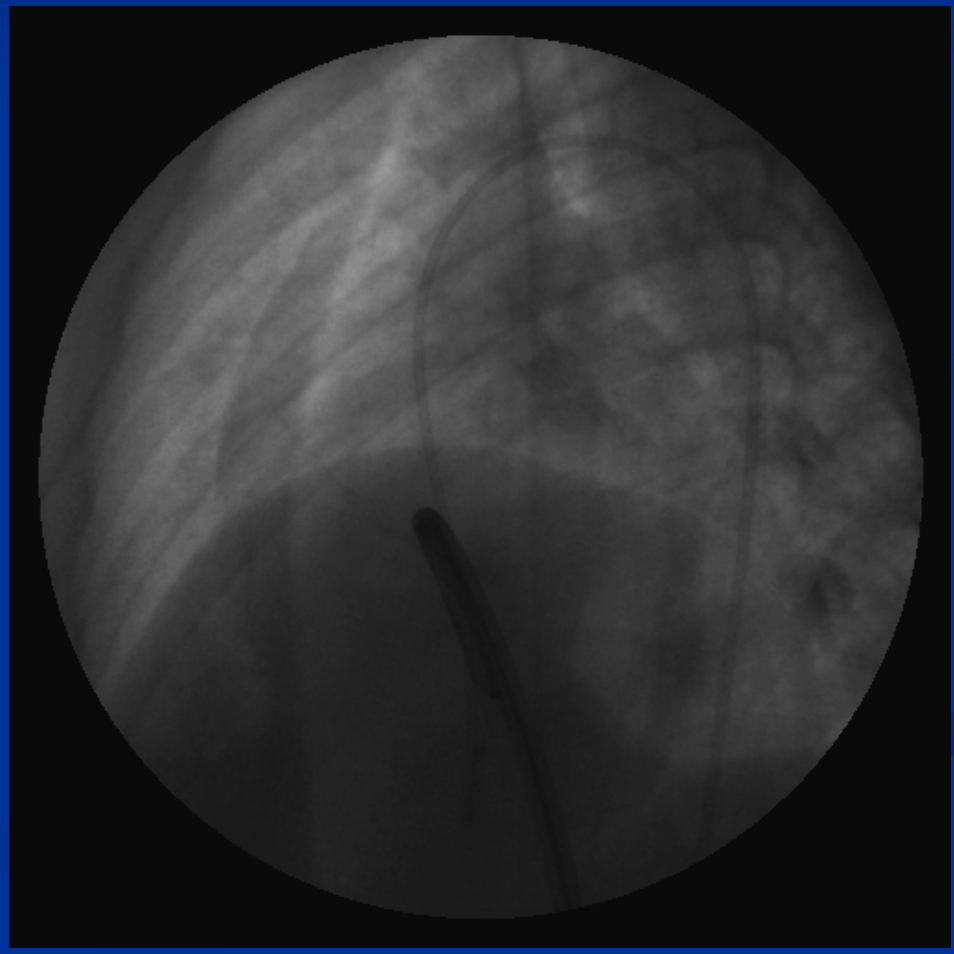


Step-by-step Review of the technique Device Release

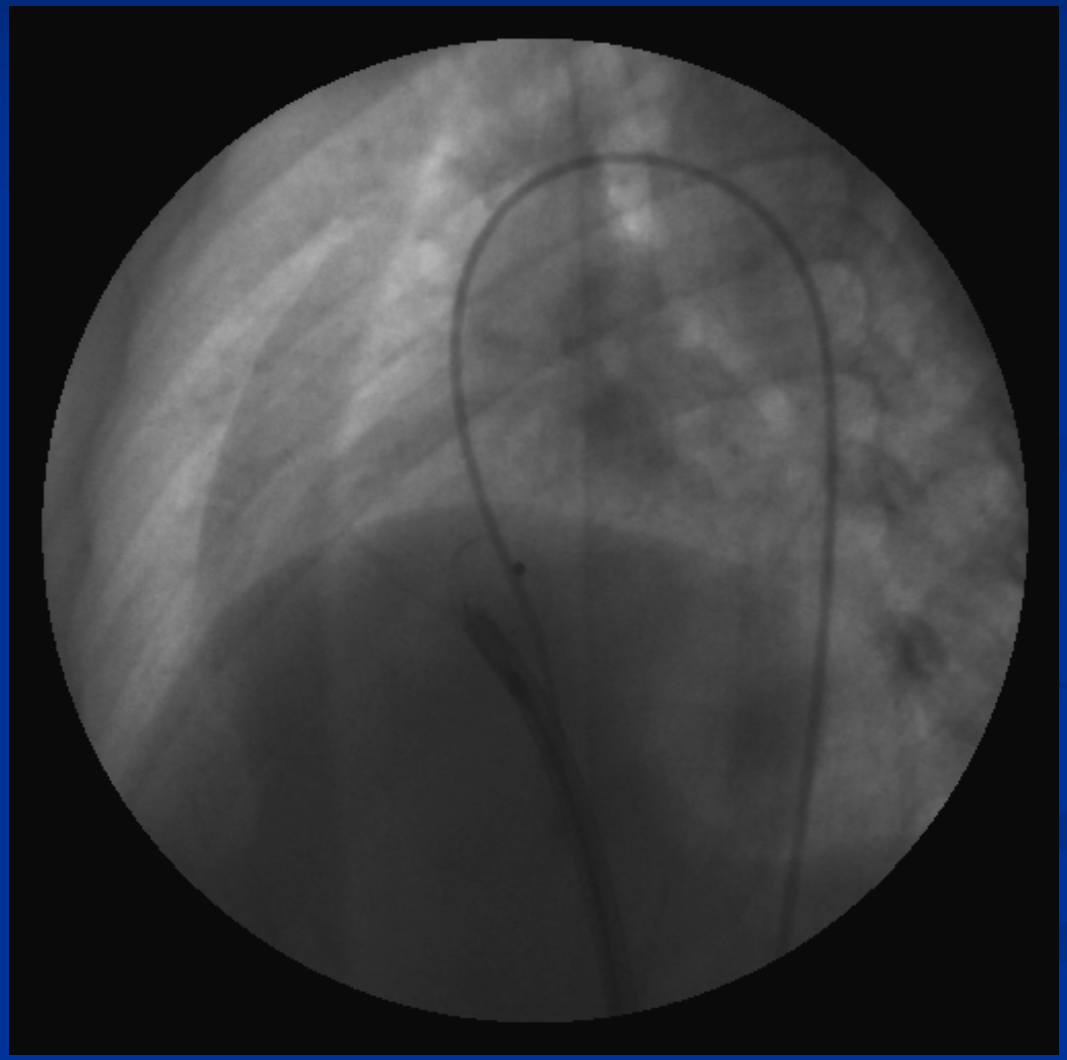
- Advance sheath close to device.
- Unscrew delivery cable.
- Pull delivery cable while holding pushing catheter.
- Pull pushing catheter while gently pushing the sheath.
- All those steps done with caution…

PMVSD with large aneurysm and multiple holes

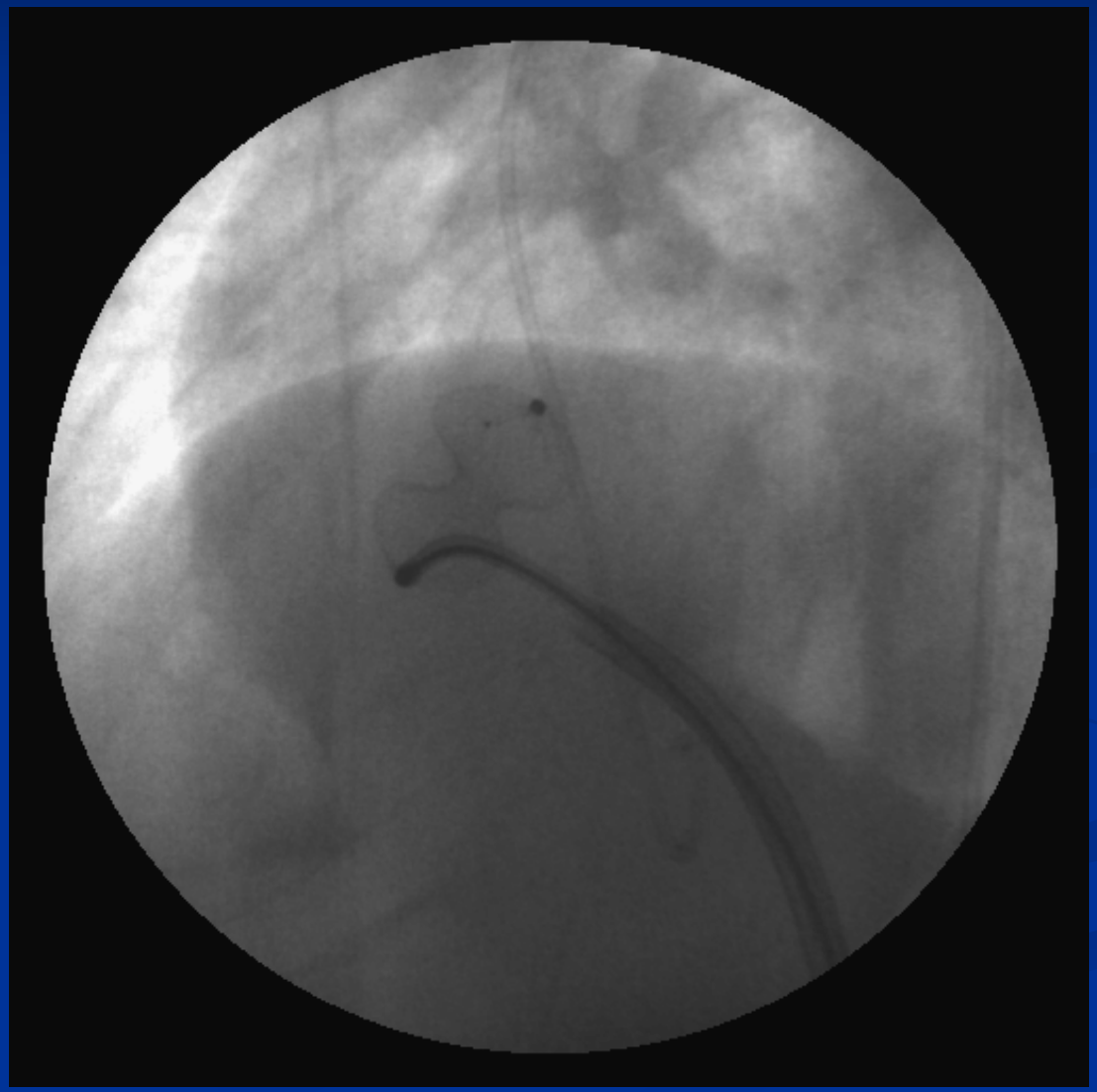




PMVSD with large aneurysm and multiple holes
Large residual shunt through superior hole

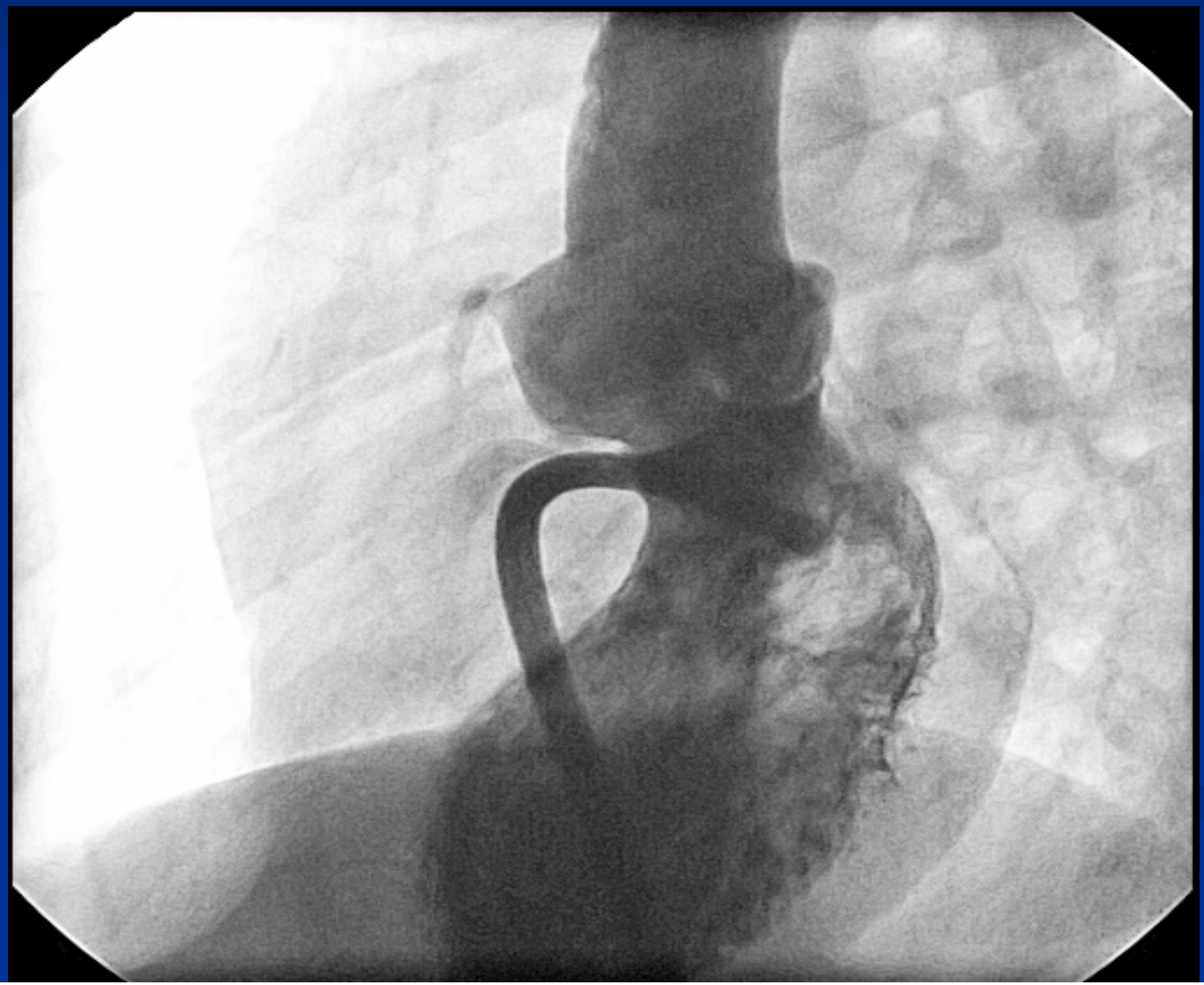


PMVSD with large aneurysm and multiple holes
Device rotated to cover superior hole

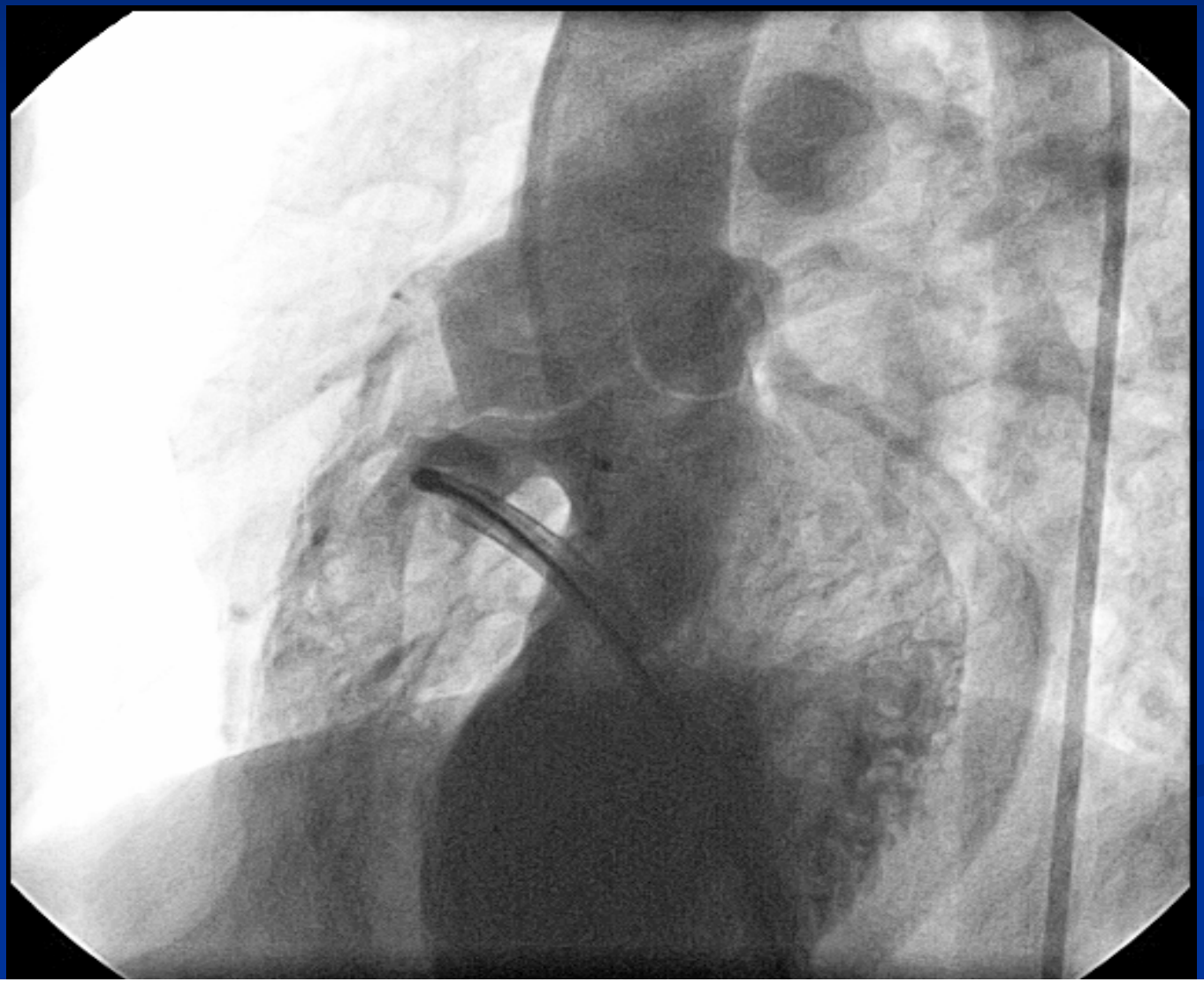


PMVSD with Ao valve prolapse

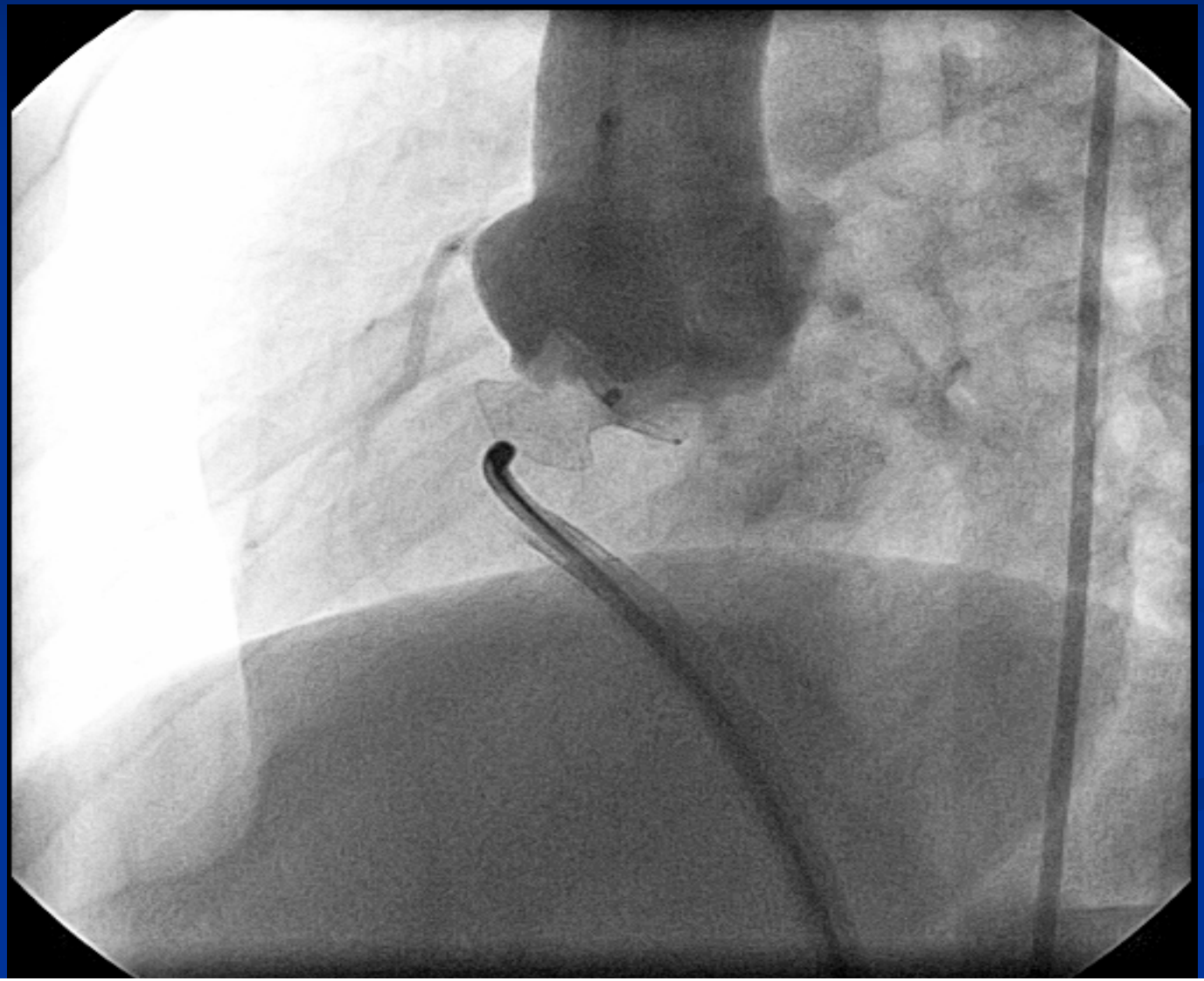
PMVSD with Ao valve prolapse
Prolapse improved by sheath



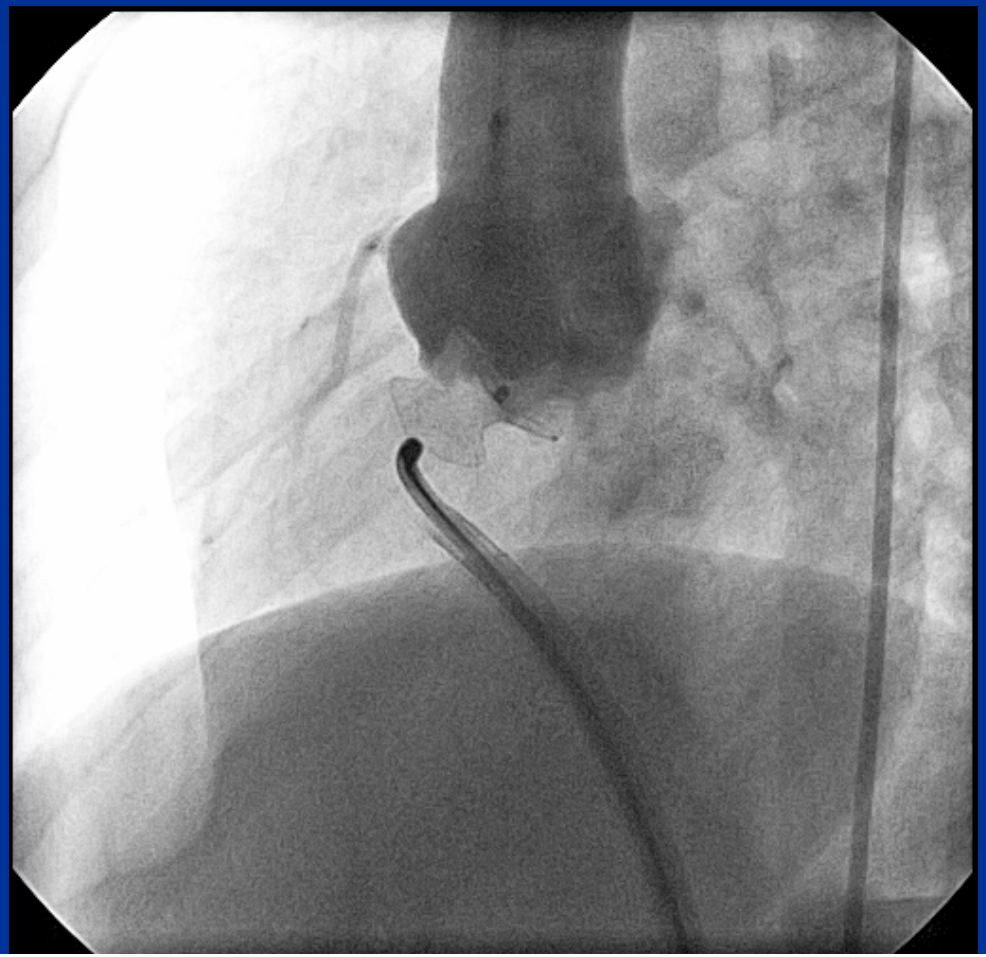
PMVSD with Ao valve prolapse
Device deployed too much in LV



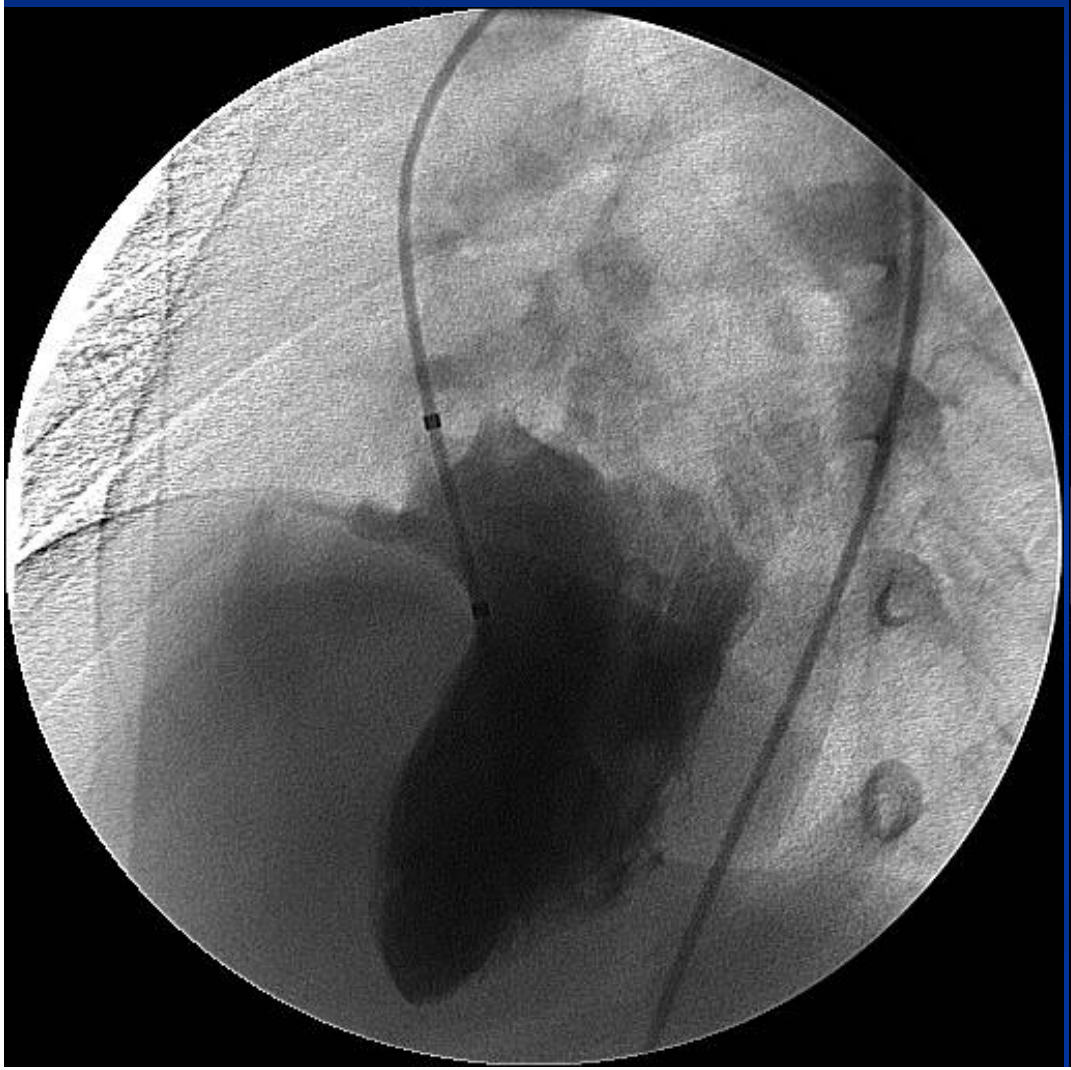
PMVSD with Ao valve prolapse
Device repositioned

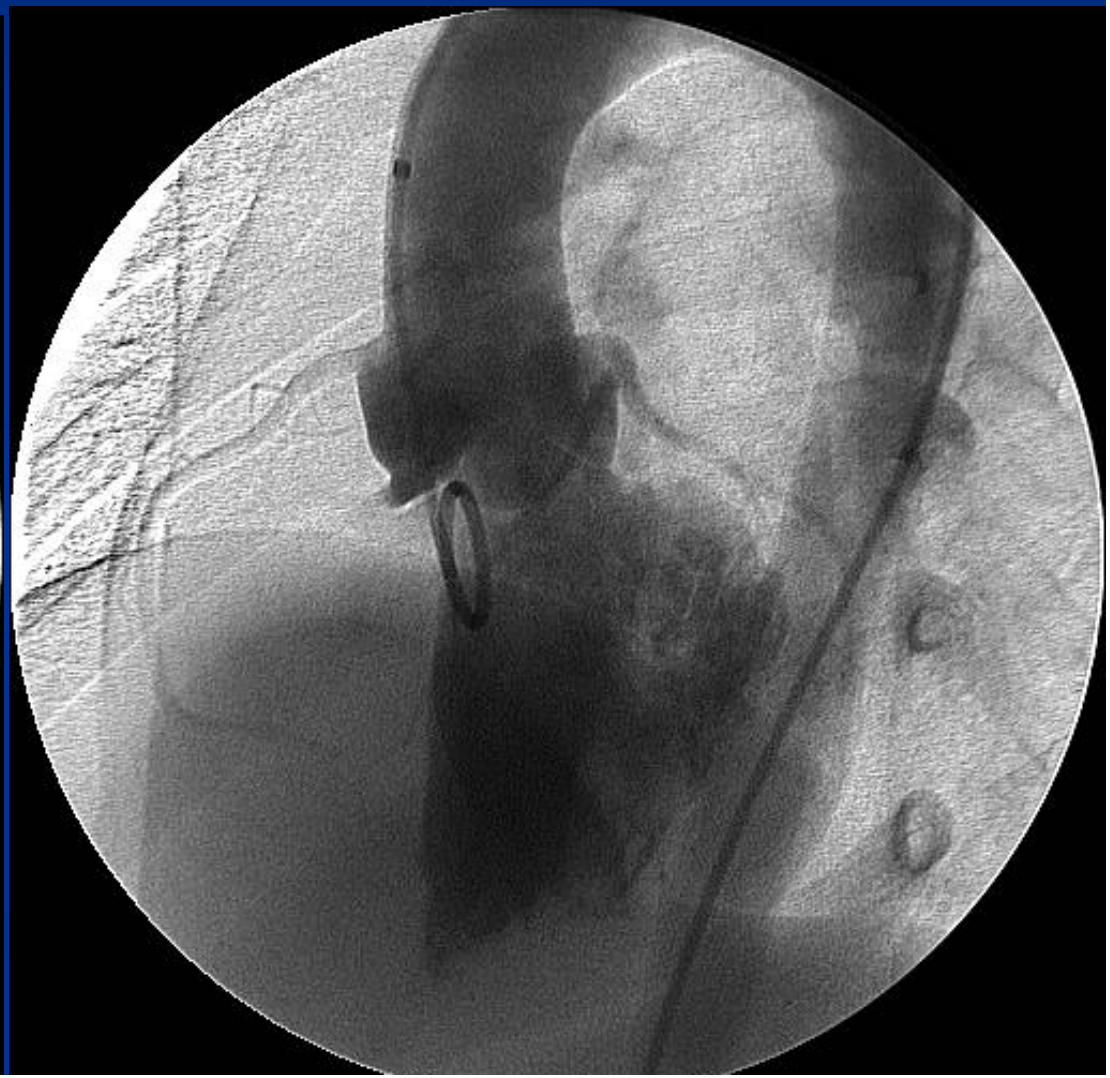


PMVSD with Ao valve prolapse
Mild AI, Mild foaming



Conal VSD with Ao valve prolapse





Conal VSD with Ao valve prolapse

pmVSD Device Closure: 5 years of clinical experience in humans

- Canadian multicentric experience
  - 7 centers
  - 67 patients
  - Age 10.7 yrs (0.5-61 yrs)
  - VSD size: 5.3 mm (1-12 mm)
  - f/up: 15.1 mo. (0.1-42 mo)

pmVSD Device Closure: 5 years of clinical experience in humans

- Pooled data from published 10 series (2003-2006)
  - 25 centers in 9 countries
  - 523 patients
  - Age 12.7 yrs (0.5-64 yrs)
  - VSD size: 5.8 mm (1-17 mm)
  - f/up: 12.1 mo (0.1-42 mo)

Procedural Success

- Canadian Multicentric Experience: 64/67 (95,5%)
- Combined international data: 503/523 (96,2%)

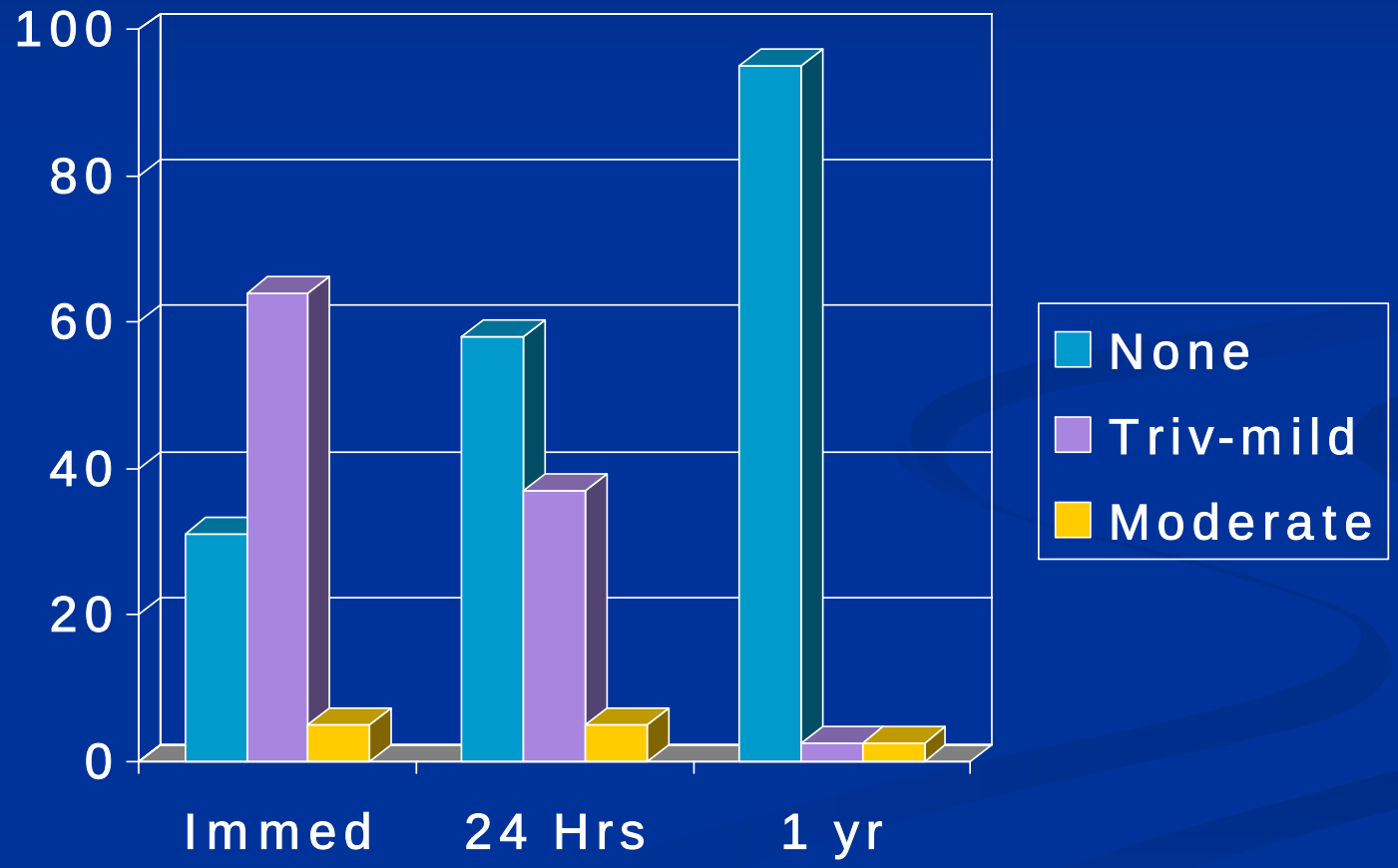
- Causes of failure
  - n = 6: Device recaptured for aortic regurgitation
  - n = 5: Procedure-related CAVB (all transient)
  - n = 5: Technical
  - n = 4: Other or non-specified

Device Migration

- Canadian Multicentric Experience: 0/67 (0 %)
- Combined international data: 4/523 (0,8 %)
  - Procedural or immediately after
  - All retrieved and repositioned

Residual Shunt

- Canadian Multicentric Experience



Residual Shunt

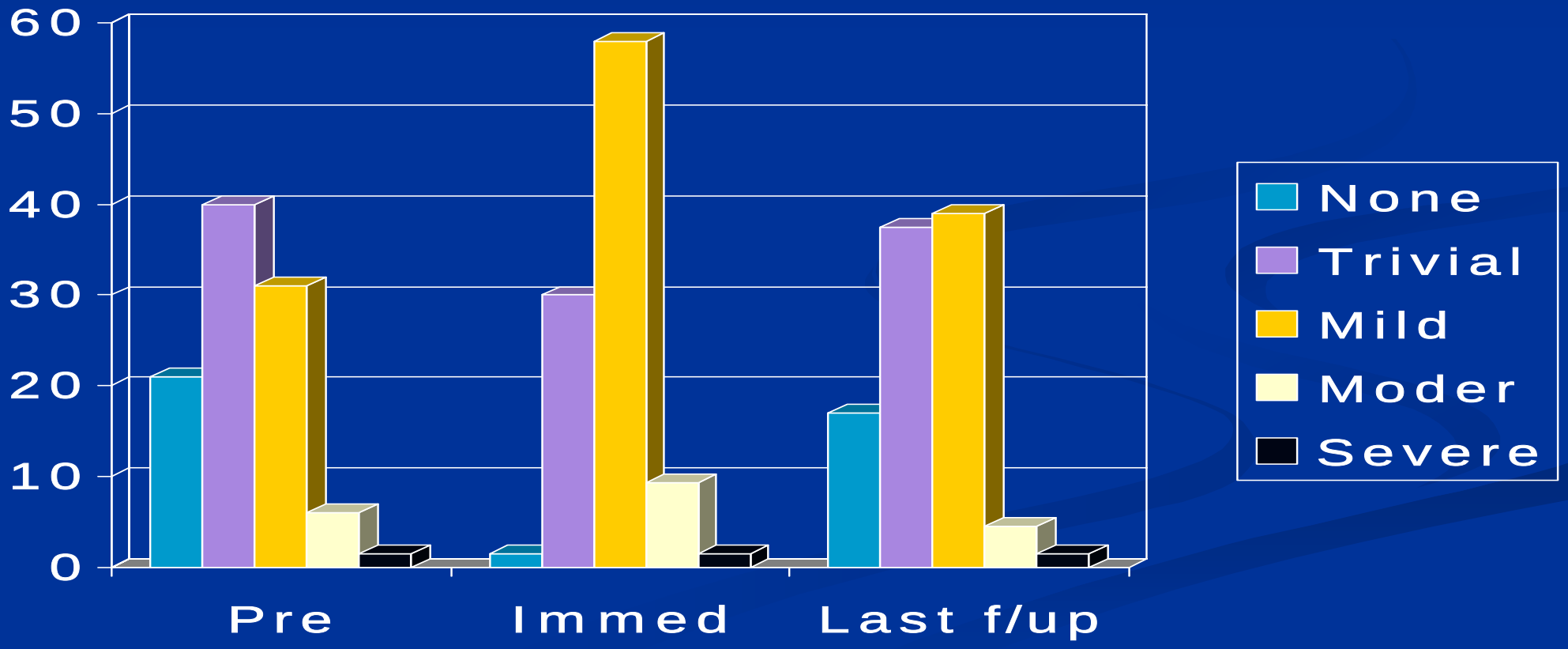
- Combined international data:
  - Immediate closure: 65 %
  - Complete closure at last f/up (avg 12 mo): 96%
- Persistent residual shunts: Usually multifenestrated aneurysmal defects
- No patient needing further intervention

Hemolysis and endocarditis

- Combined international data:
  - 8/523 cases of hemolysis reported (1,5 %)
  - 6/8 resolved
  - 2/8 sent to surgery
- No case of endocarditis reported

Tricuspid Regurgitation

- Canadian Multicentric Experience

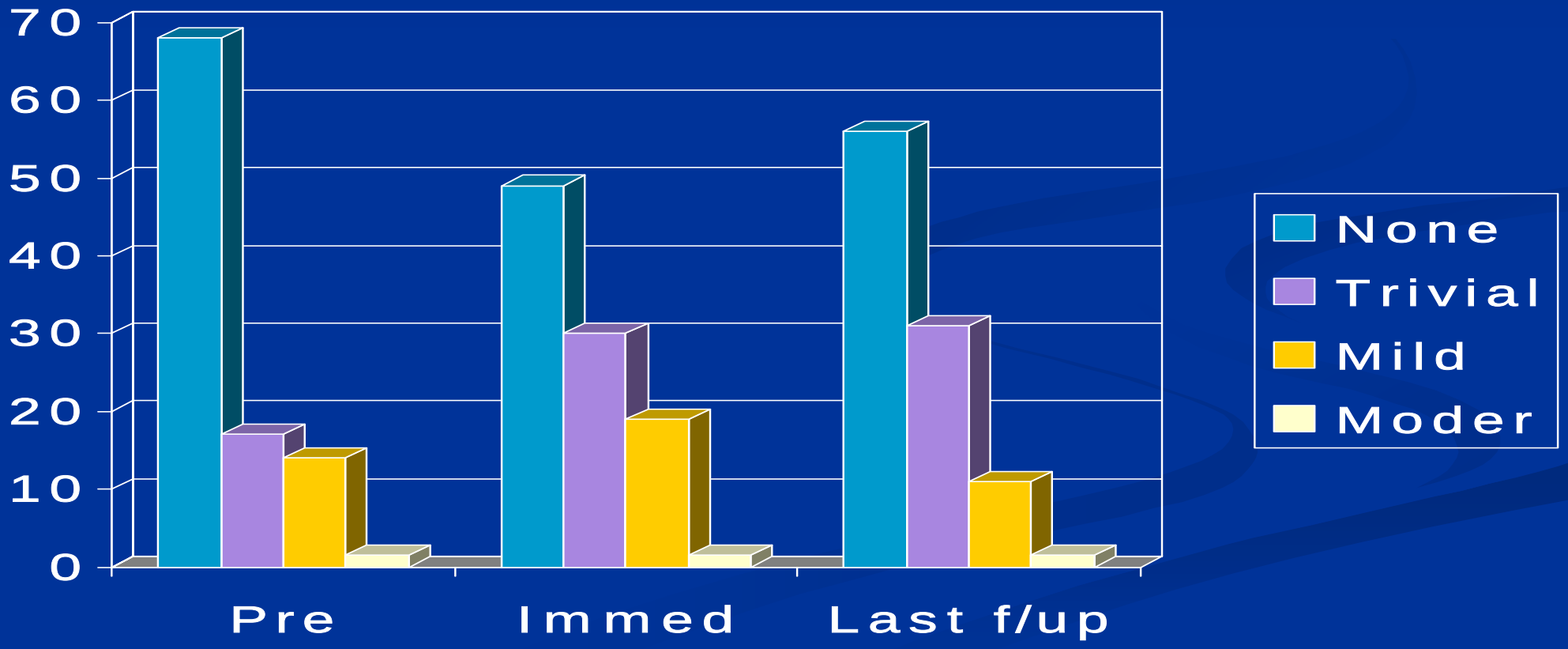


Tricuspid Regurgitation

- Combined international data:
  - 2 cases of tricuspid regurgitation needing surgery (0,4%)
    - Avulsion during procedure
    - Severe TR and pulmonary hypertension pre-cath: unchanged after 2 yrs
  - No case of progressive Tricuspid regurgitation over time

Aortic Regurgitation

- Canadian Multicentric Experience



Aortic Regurgitation

- Combined international data:
  - 6/523 cases of immediate significant aortic regurgitation
    - Device recaptured; no residual damage
  - Occasional case of mild progression of AR immediately after device deployment, with no further progression
  - No surgery for severe Aortic regurgitation

Complete AV Block

- Procedural: 5/523 (1,0%)
  - Case aborted and recovery in all
- ≤ 7 days post-procedure: 10/523 (1,9%)
  - 6/10: Recovered with steroids
  - 4/10: Pacemaker
- > 7 days post-procedure: 8/523 (1,6%)
  - Between 4-16 months
  - 8/8: Pacemaker
- Total: 23/523 (4,1%)
- Pacemaker 12/523 (2,1%)
  - 2/10 resumed normal conduction

Conduction Disturbances

d

- 45/523 (8,6%)
- Tendency to remain stable or improve with time
- Occasional progression to Complete AV Block

CAVB: Hypothetical risk factors

- Oversizing of device
- Extension of VSD towards the Inlet or high trabecular septum

- Absence of aneurysm ?
- Length of procedure ?
- Biocompatibility of device ?
- Others

Additional Complications

- Combined international data: 9/523
  - Brachial palsy, with complete recovery n = 2
  - Mild LVOT obstruction, with complete recovery n = 2
  - Mild cerebral emboli, with complete recovery n = 2
  - Mild tricuspid stenosis n = 2
  - Peri-hepatic bleeding n = 1

- Total Complications: 45 / 523 (8,6 %)
  - Requiring intervention or leaving potentially permanent sequelae: 16 / 523 (3,1 %)

Mortality

- No Procedure-related mortality
- Hospital mortality 1/523 (0,2%)
  - 61 year-old male
  - Multifenestrated VSD and moderate AI
  - Developed hemolysis and device excised
  - Died of surgical complication (aortic rupture)
- Late Mortality 1/523 (0,2%)
- AGA data: 2 mortalities / 4000 Implants

Future Improvements

- Most urgently, we need to concentrate on the CAVB issue and develop a strategy to decrease its incidence
  - Stratify the risk (anatomical variants)
  - Avoid oversizing
    - Odd-number devices now available
  - Redesign the device ?