

Interim Results of Perimembranous
VSD Closure Using ADO I -
Multicentric, Prospective,
Observational Study

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Background



- Major deterrent to TCC of PMVSD: Unpredictable occurrence of CHB
- 0 to 20% incidence with AAPMVSDO
- Immediate – in hospital
- Late onset

Background

- Probable Mechanisms
 - Clamp force which is inherent to the conventional PMVSD device with a double disk design.
 - Width of the waist
 - Stiffness of the discs
 - Radial force due to memory characteristics of Nitinol



Alternative strategies

- Double disk devices with wider waist
 - Amplatzer Muscular VSD occluder
 - Cocoon PMVSD device
 - Asymmetrical and symmetrical devices : Lifetech, Shanghai Steel Corp
- Double disk device with softer waist
 - ADO II
- Device with coil design
 - PFM Le device
- Devices with single disc design
 - ADO I



Our Study

- Use of ADO I
 - No clamp force
 - Persistent radial force (Presence of aneurysm)
 - Absence of second disc: Easy on the TV
- Prospective
- Multicentric (3/4)
- Non randomised, Observational
- Recruitment Period: Feb 2013 to Jan 2015
- FU Period Jan 2017



Our Study

- No funding
- Data management by operators and their associates
- Study protocol was approved by all the 3 IRB (Ethics committees)
- Informed consent was obtained from the parents in all the cases



Aims and Objectives



- Primary end points:
 - Closure rate to assess efficacy
 - Absence of CHB to assess safety

- Secondary end points:
 - Freedom from all complications during the follow-up period.
 - TV, Aortic valve, other conduction abnormalities, thrombus formation, device embolization

Inclusion Criteria

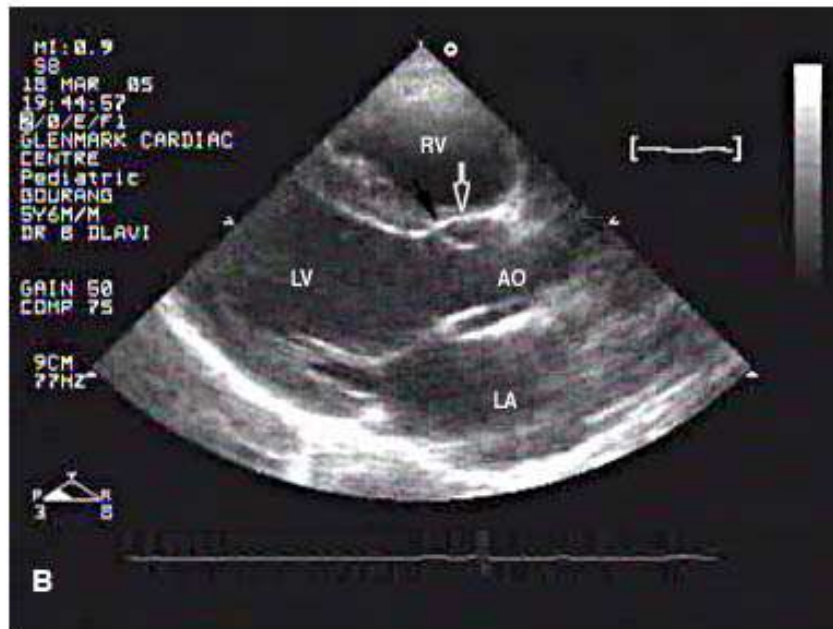
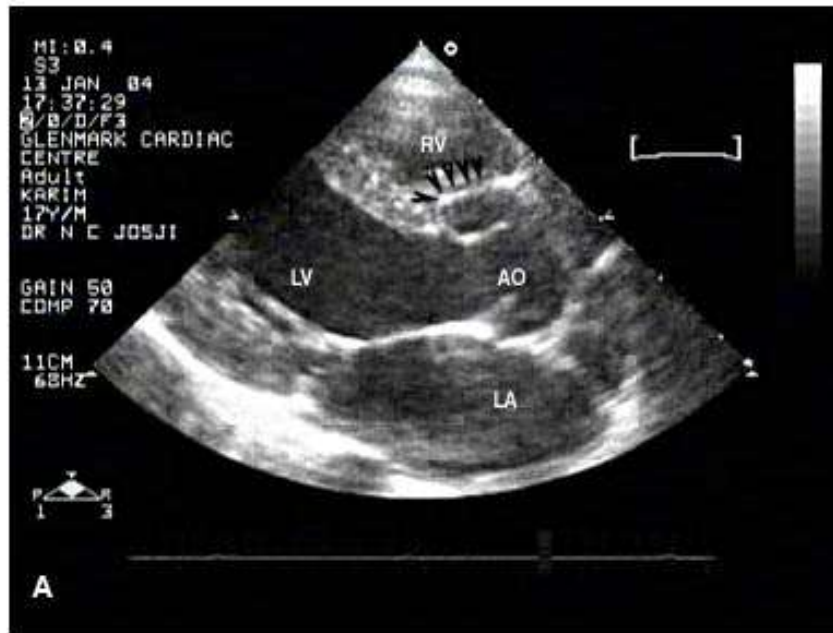


- Age > 6 month and weight > 8 kg
- Symptomatic status:
 - Repeated LRTI
 - FTT (< 10th percentile)
- Hemodynamically significant shunt
- PMVSD size \leq 12mm
- Separation from the aortic valve \geq 4mm.

Exclusion Criteria

- Severe PAH (PAP > 75% of the systemic pressure)
- Significant aortic valve prolapse with or without aortic regurgitation and
- Pre existing conduction disturbance.

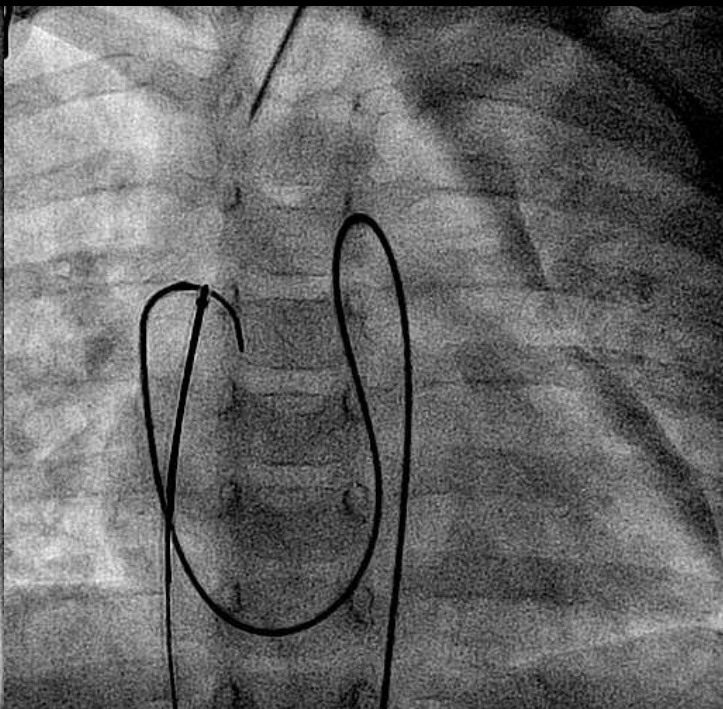
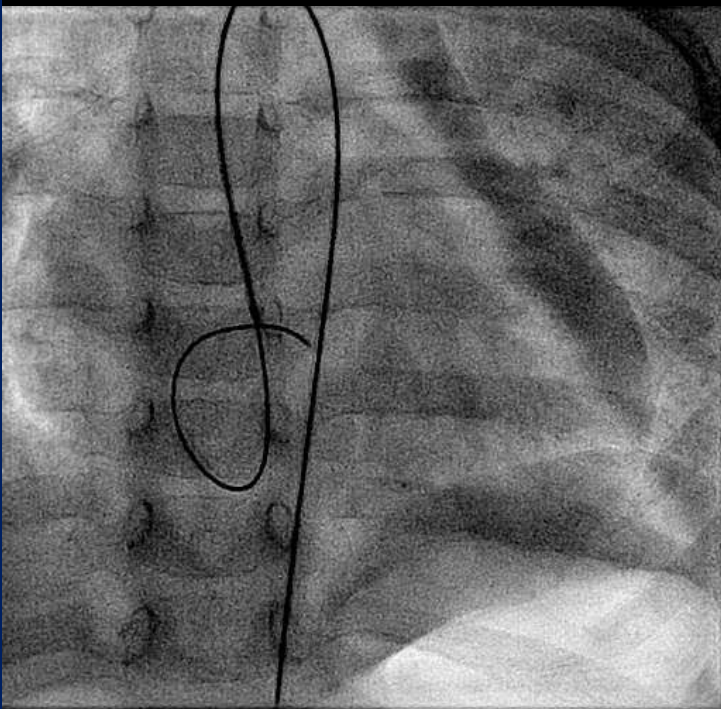
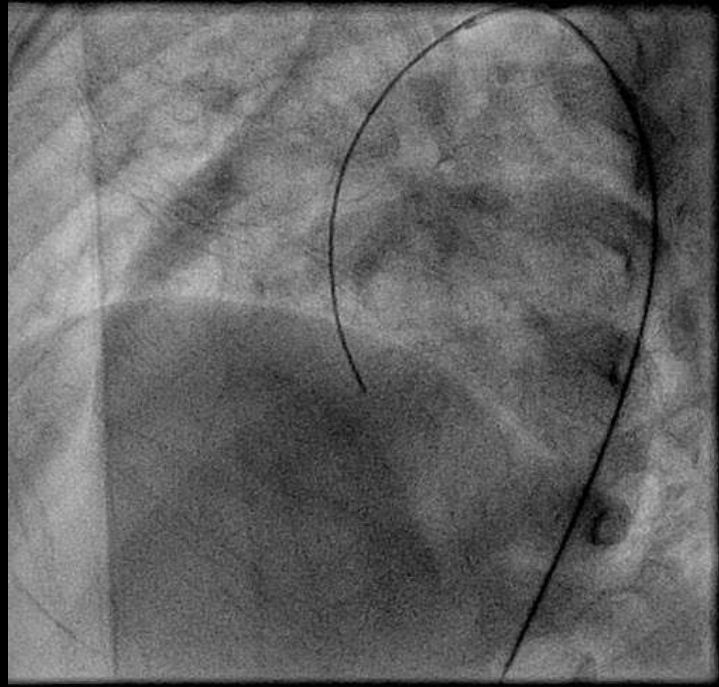
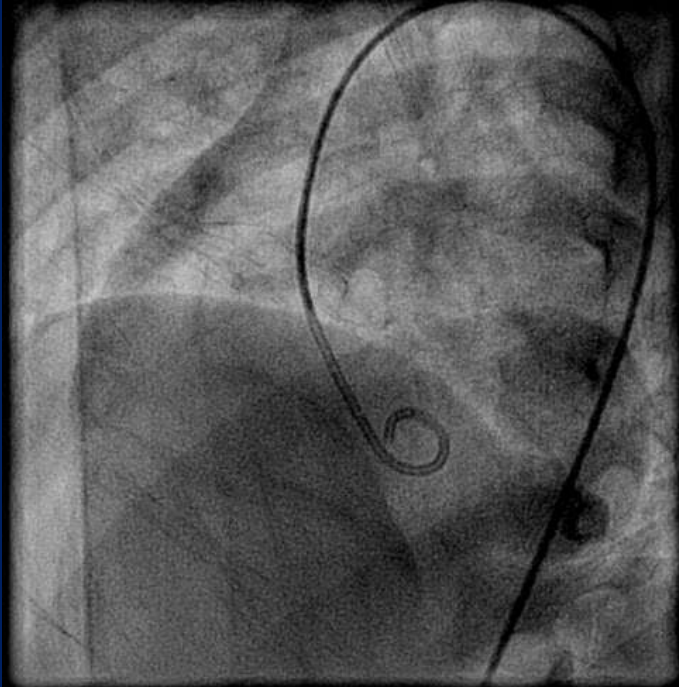


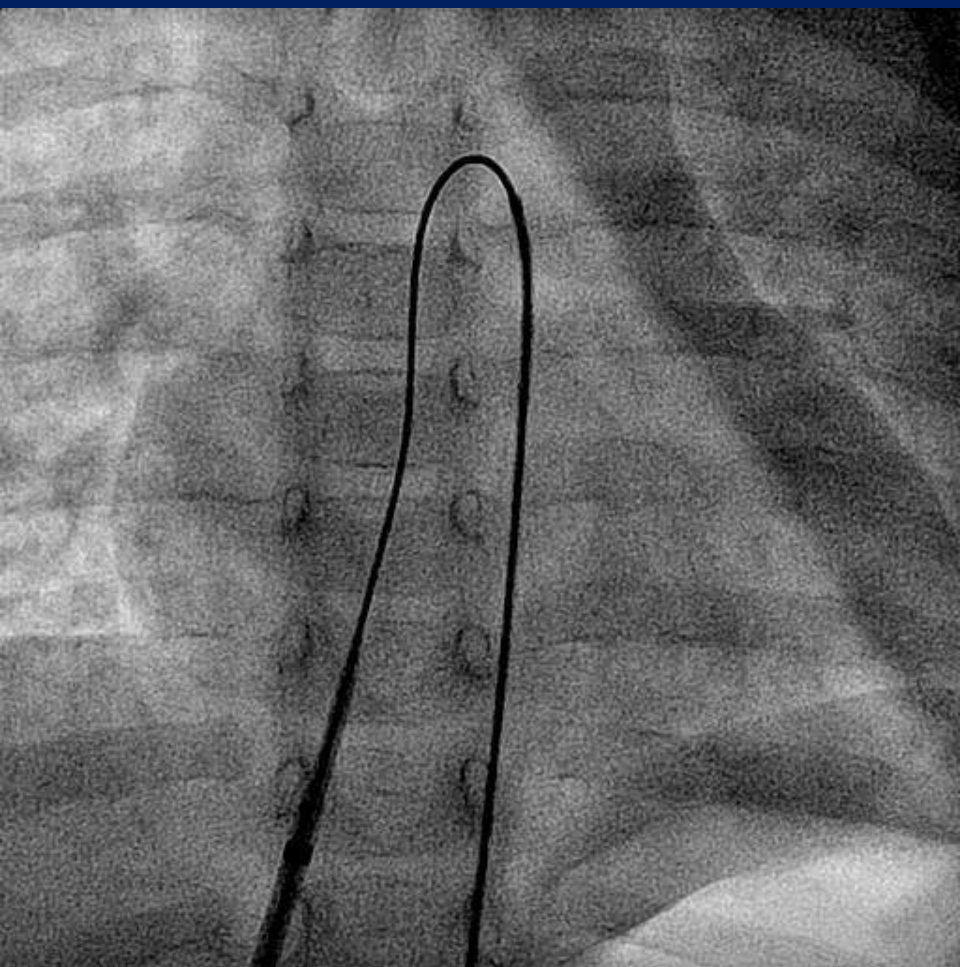
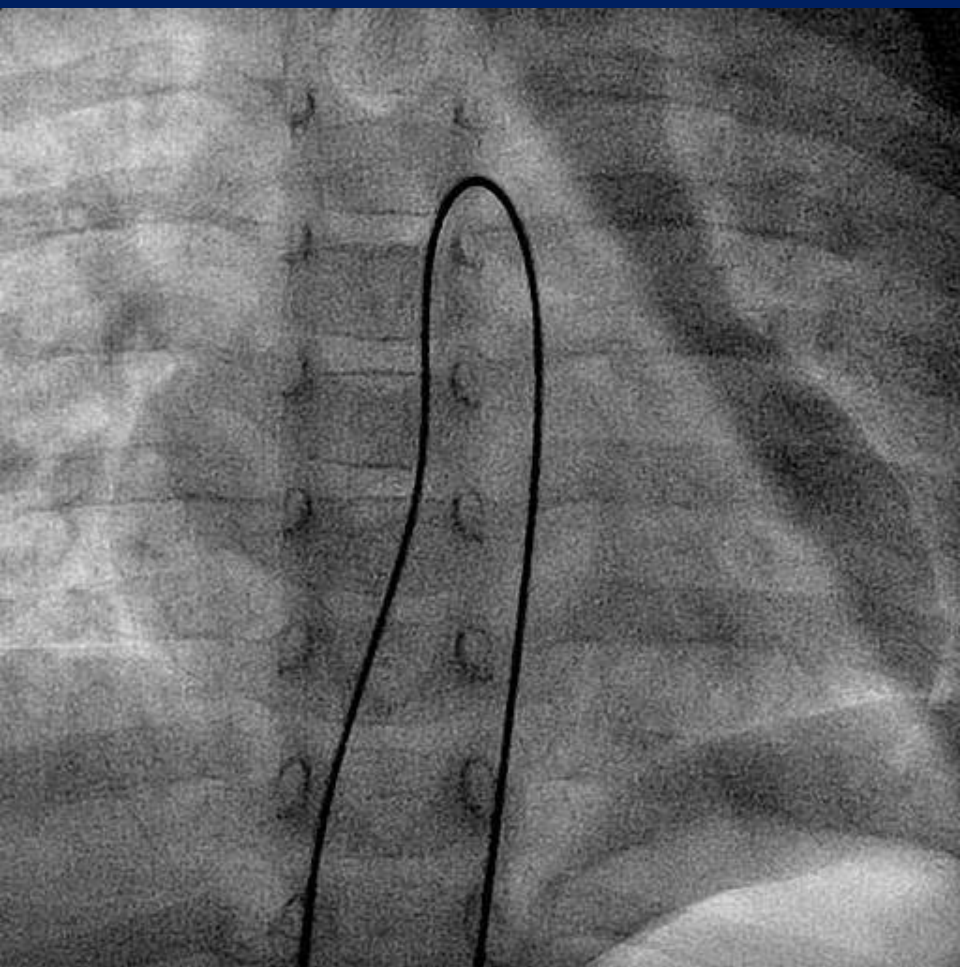


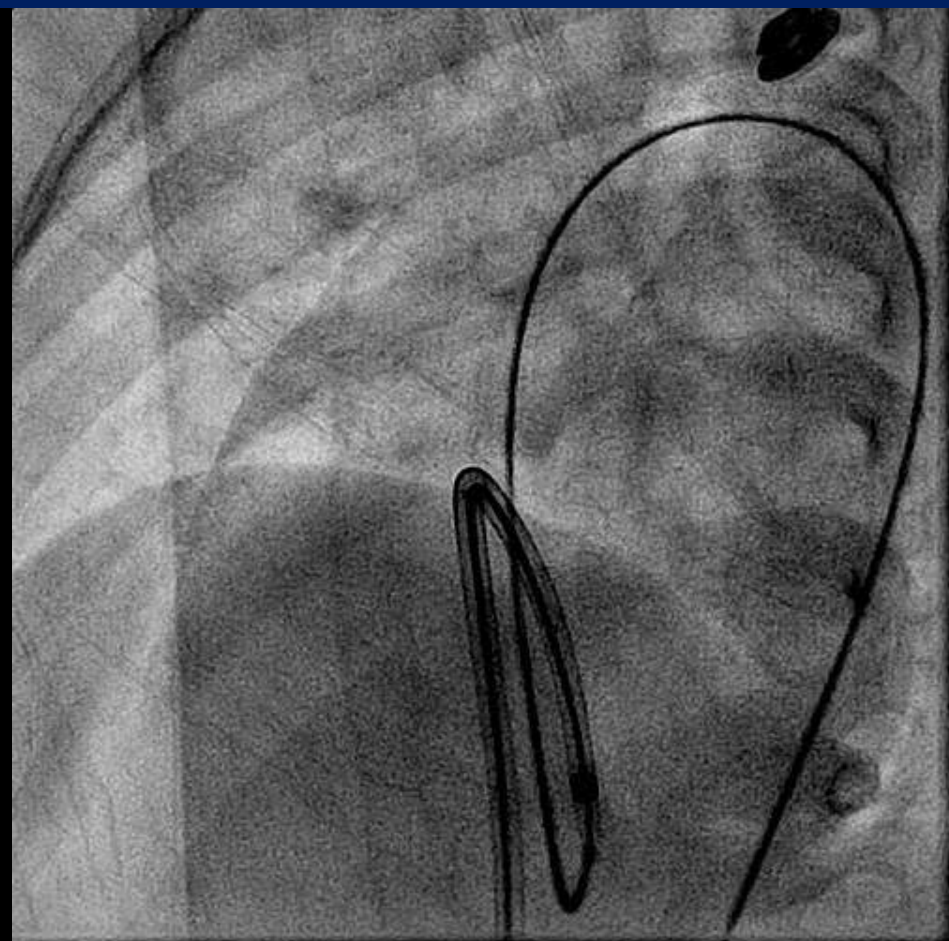
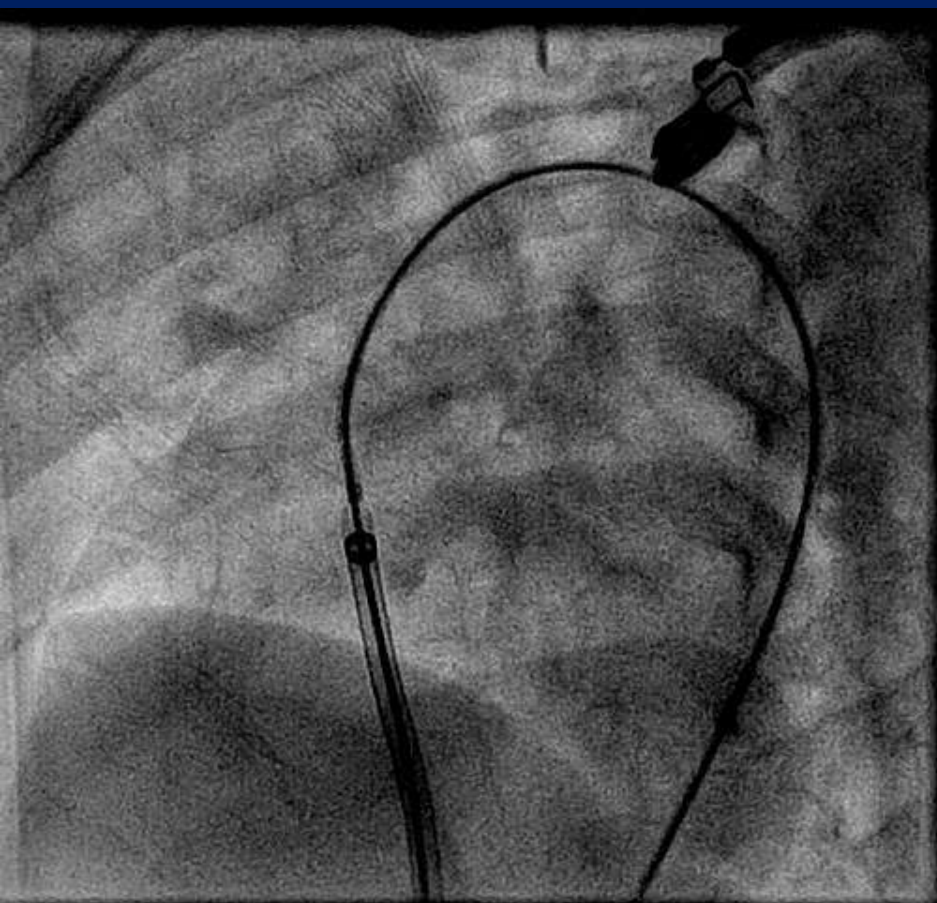
Materials and Method

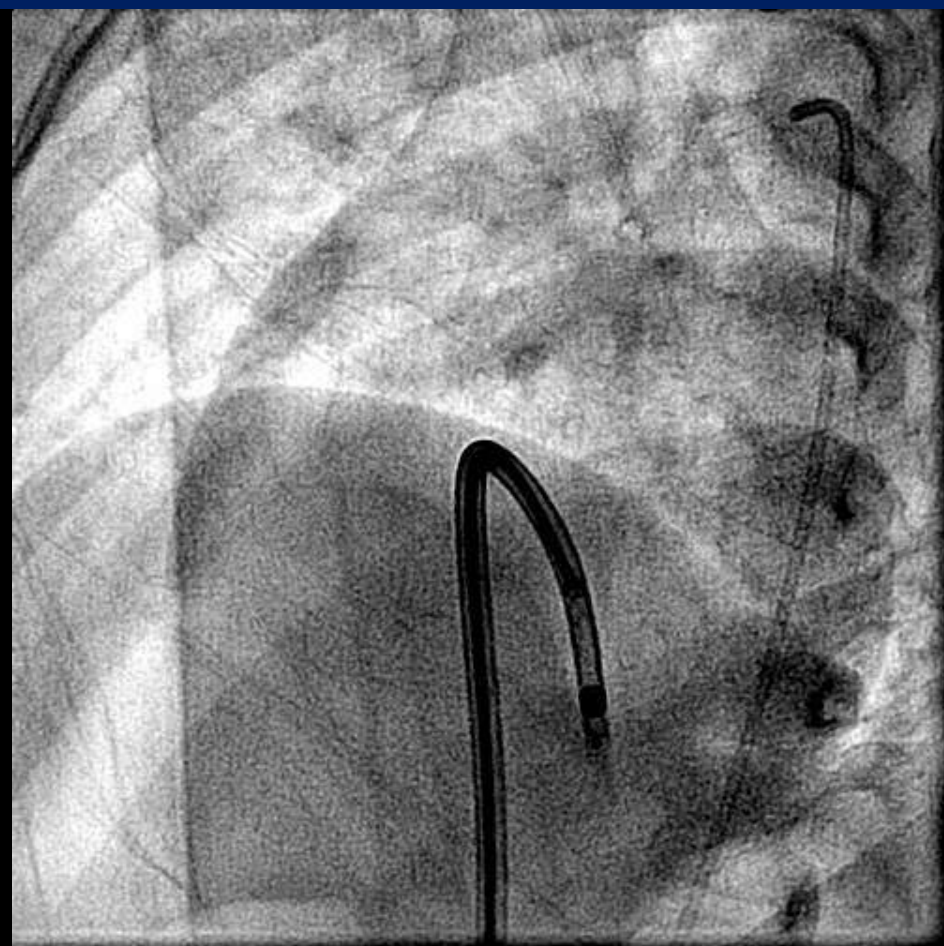
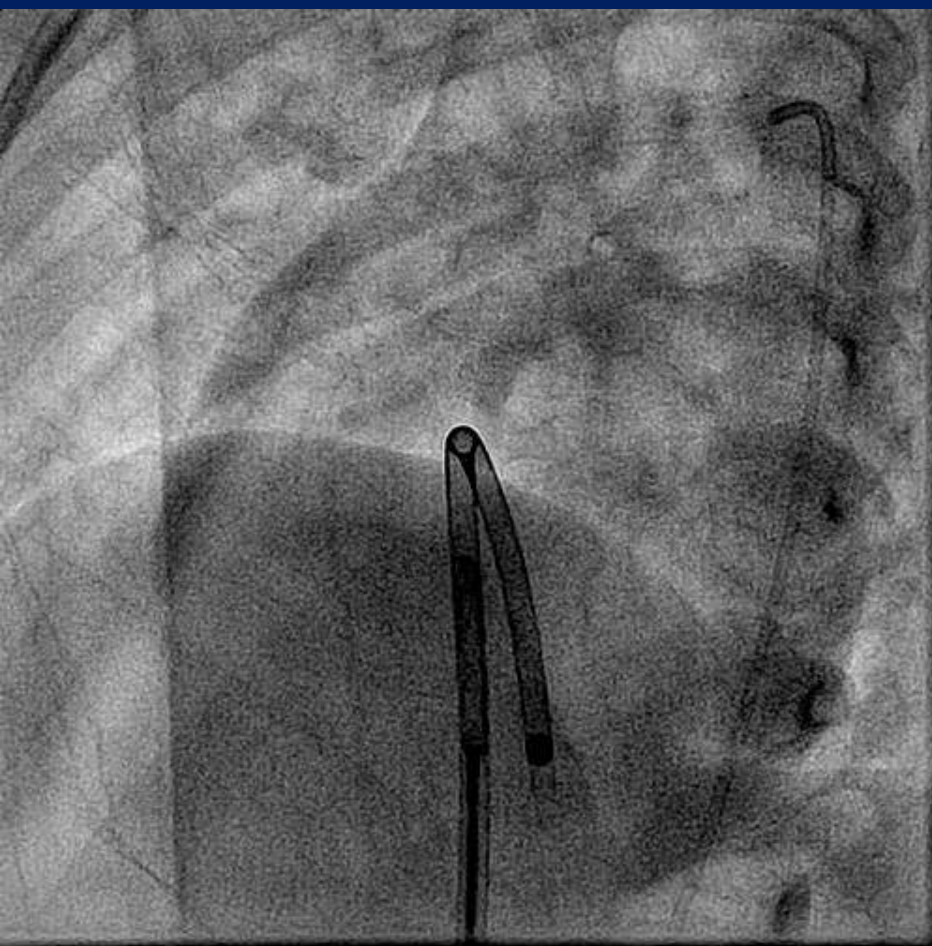


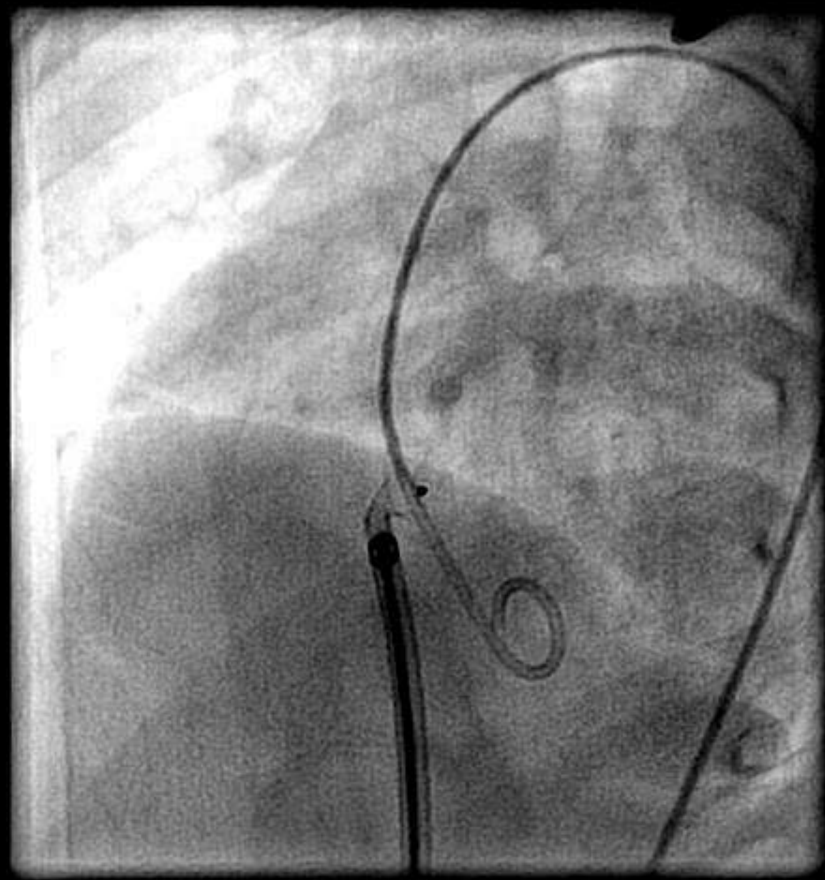
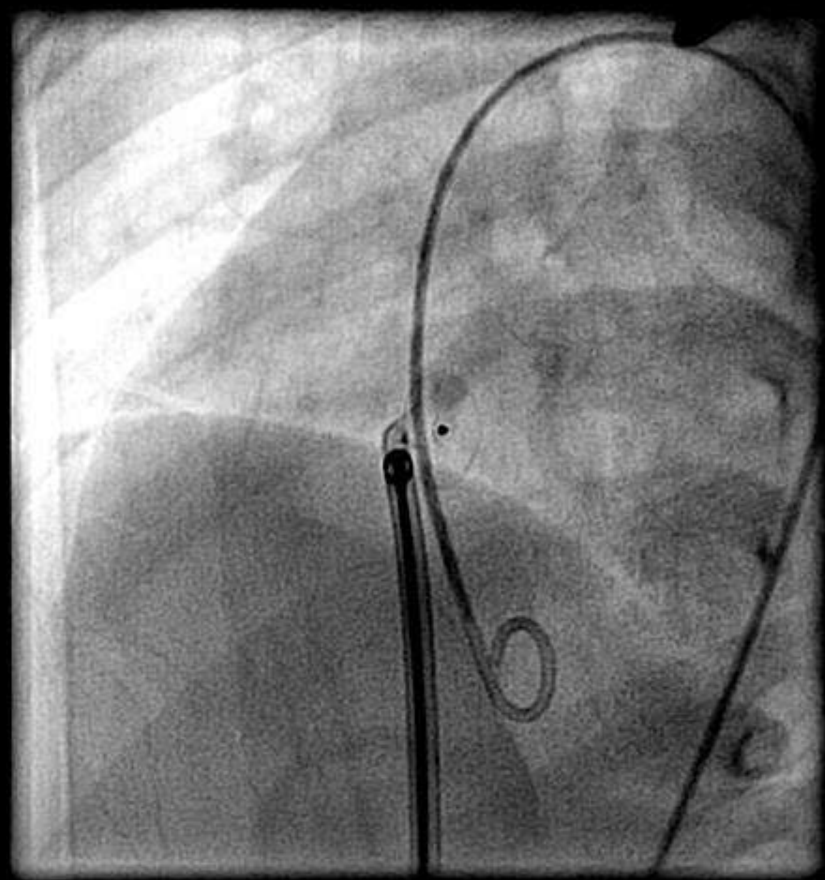
- ADO I deployed in an antegrade fashion from the LV
- Occasional use of modified technique
- Size of the device: RV site of exit + 1 or 2 mm = Pulmonary end of the device
- Oral/IV corticosteroids use - at the discretion of the operators.

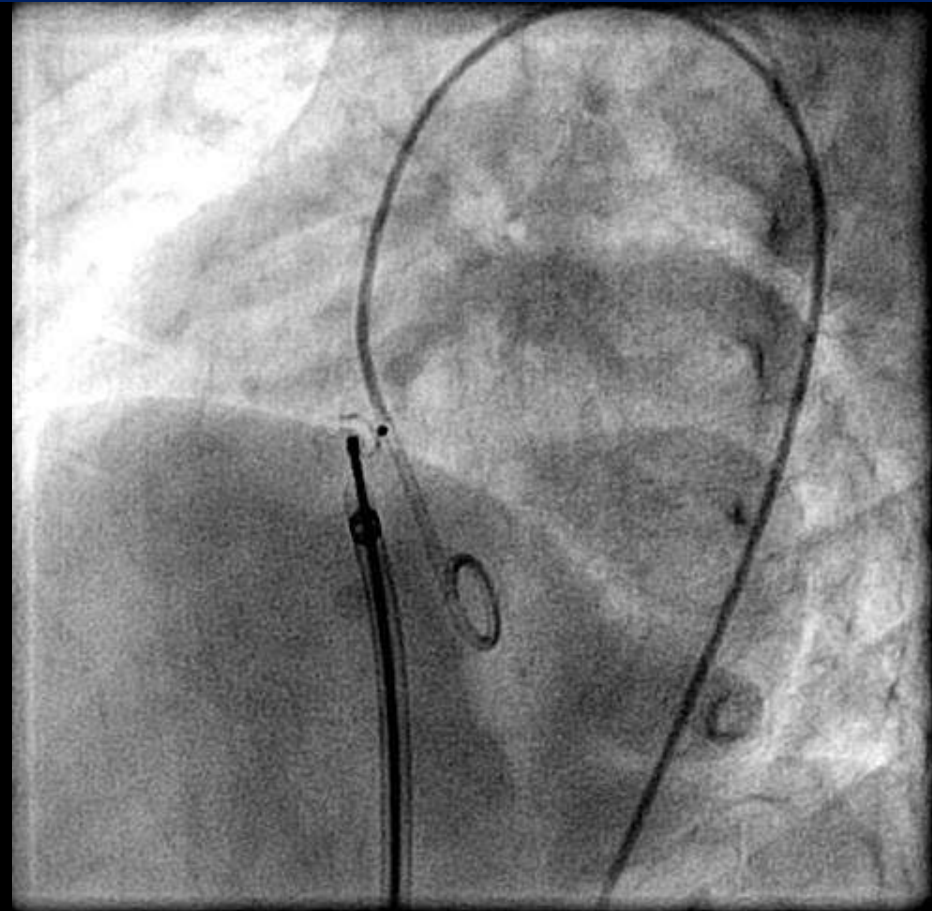
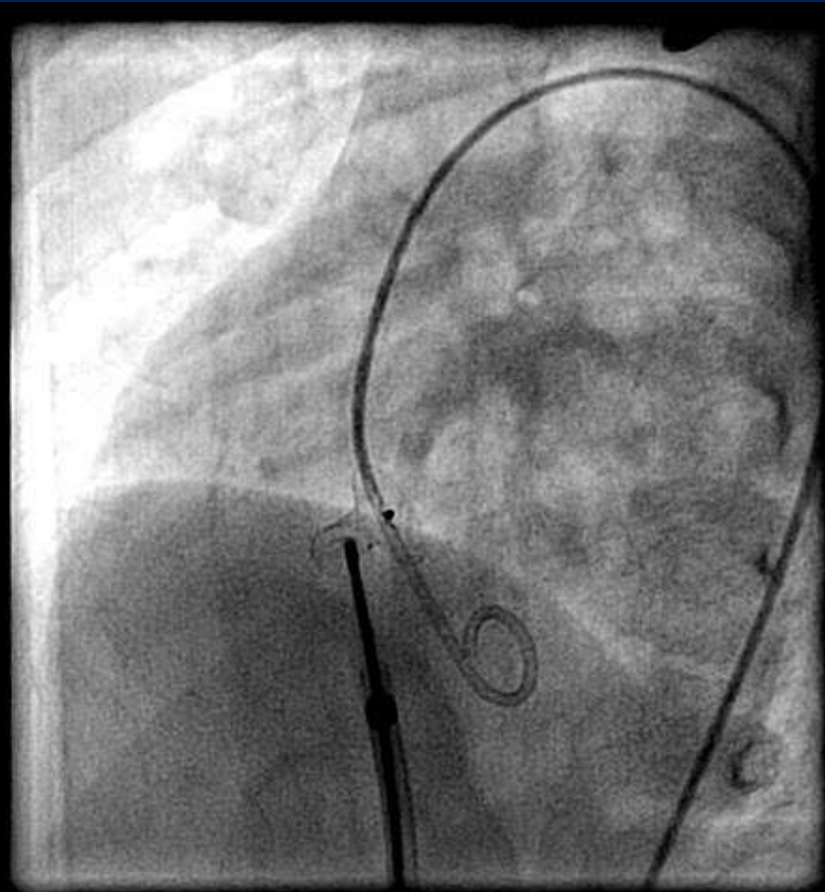


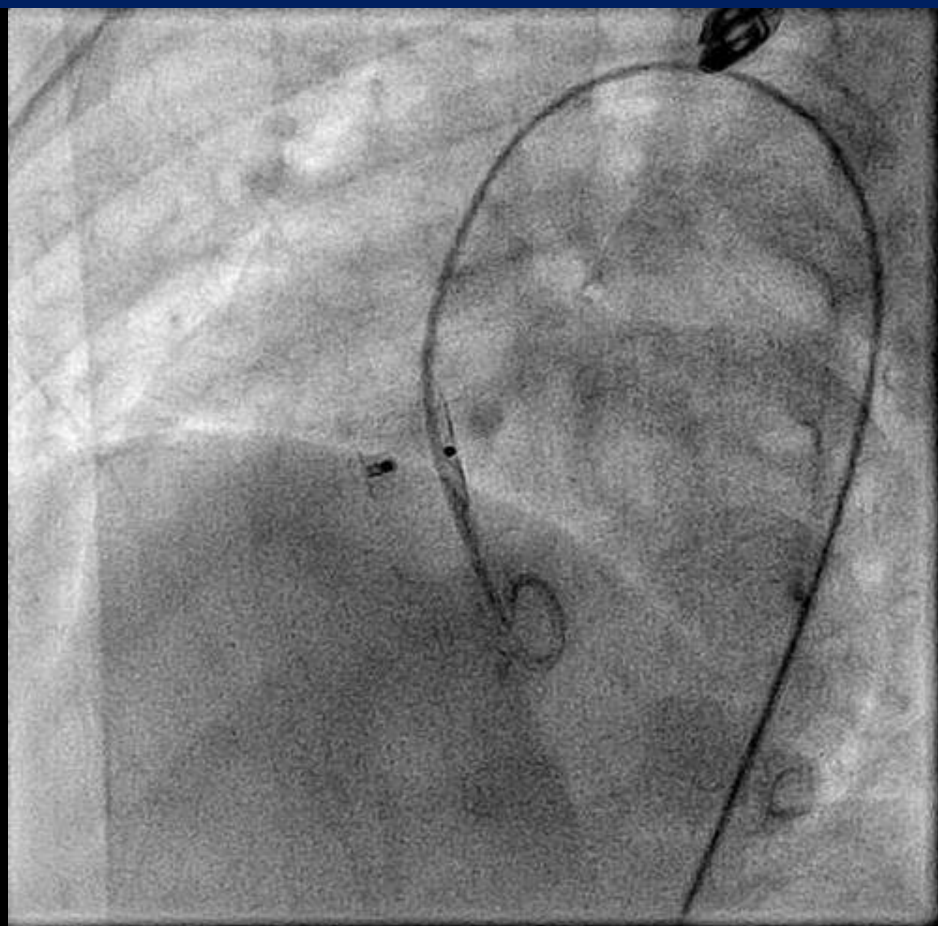
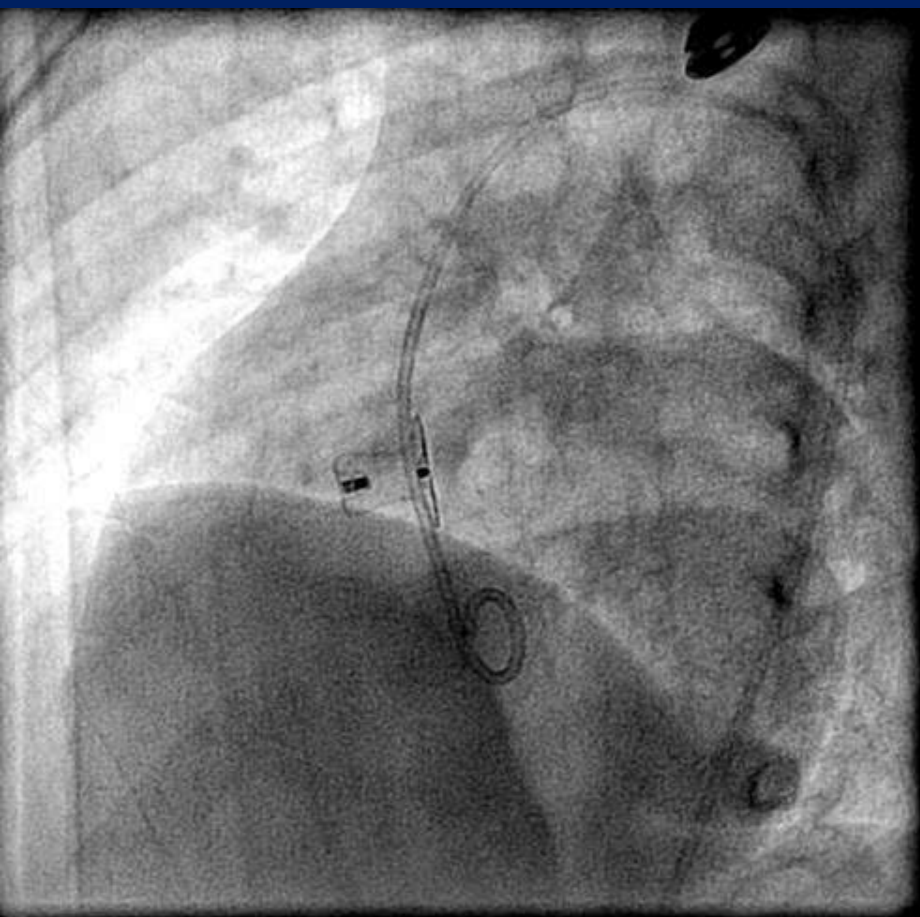




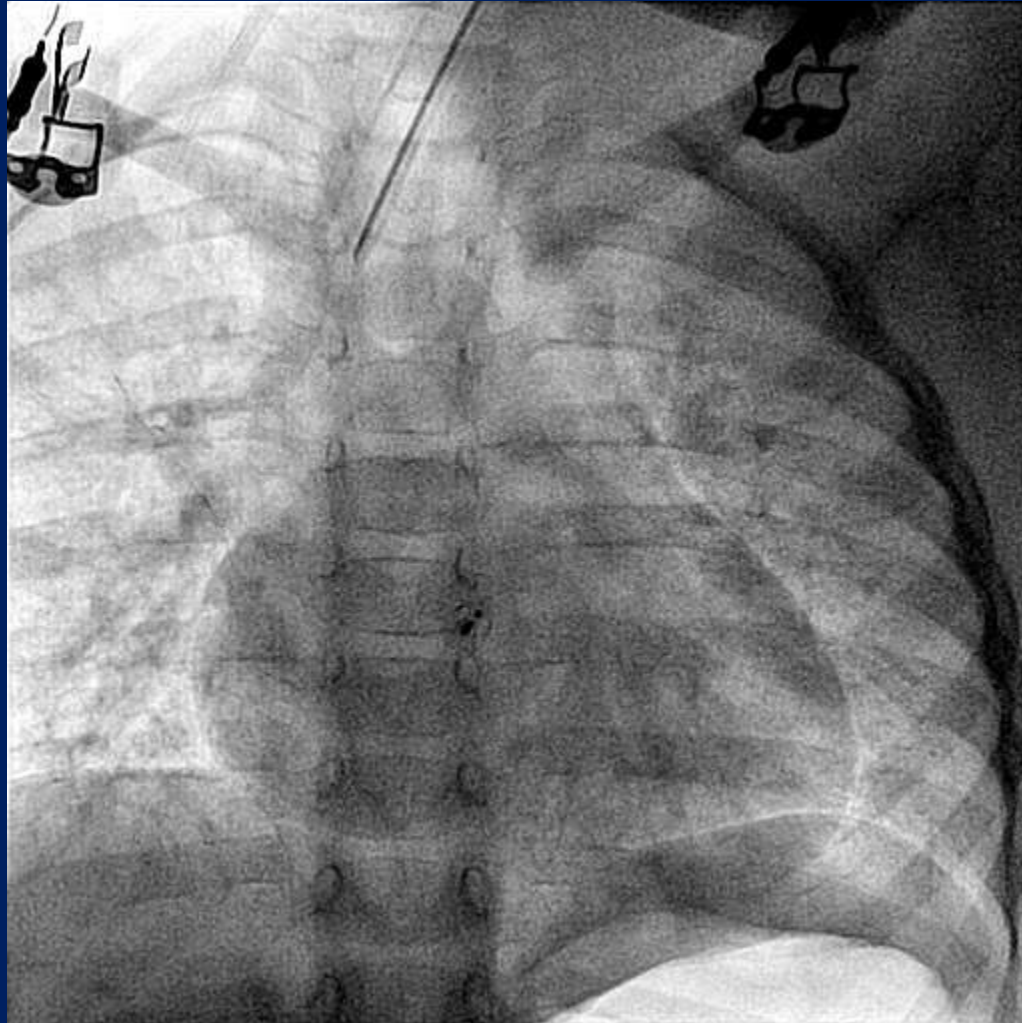




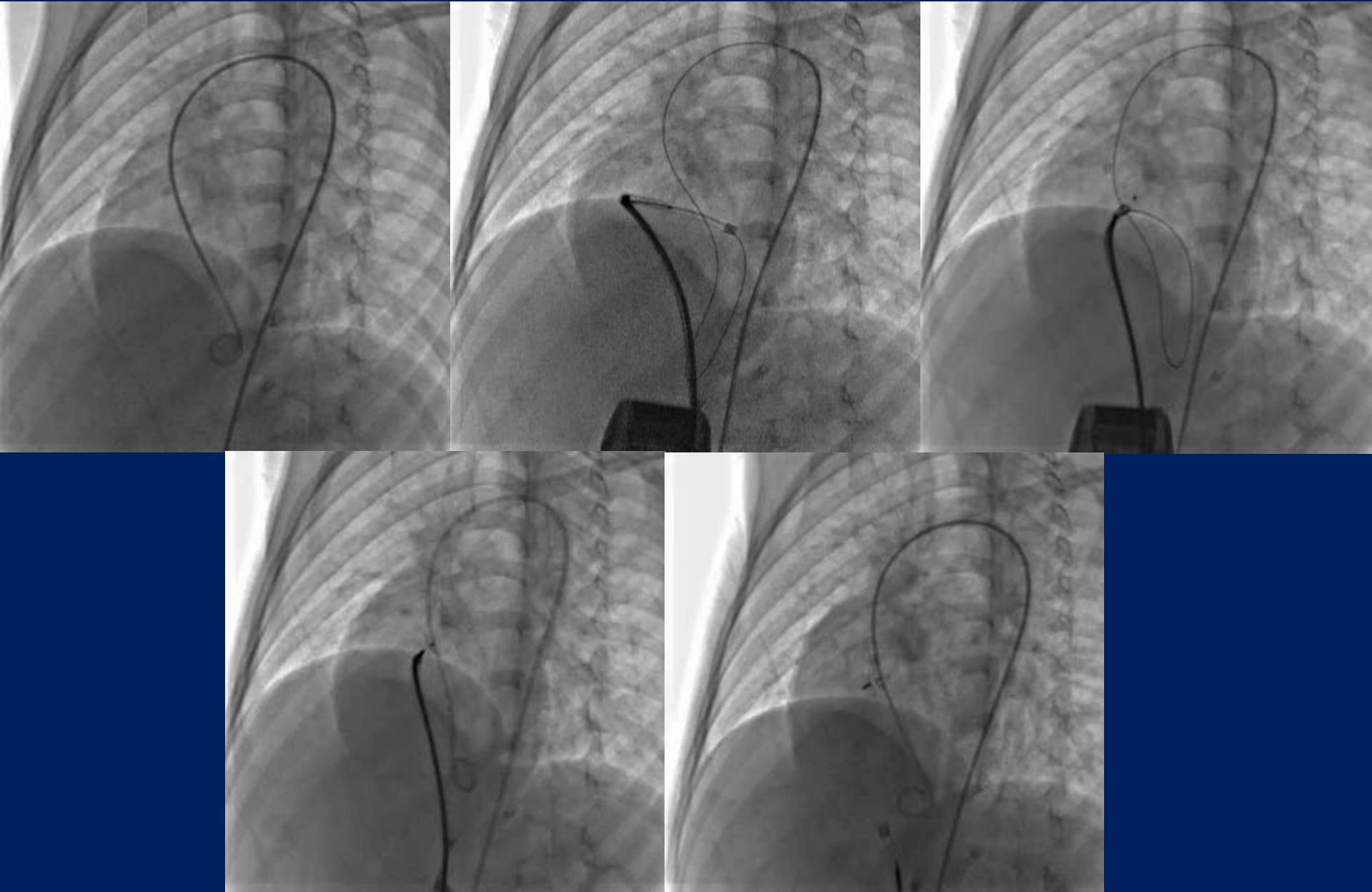




“Finger printing” the device



Modified deployment



Materials and Method



- Post closure: ICU for 24 hours and additional 24 hours in ward
- At discharge:
 - PredischARGE ECG and Echo
 - Aspirin 5mg/kg/day for 6 months
 - IE prophylaxis for 6 months
- Follow up :1 and 6 months and then every 1 year till the end of the study period.

Results



- N-94 patients enrolled from 3 centers
- 86 patients' data is uploaded
- M = 46, F = 40
- Mean age: 7.31 ± 4.01 years (range 2–16)
- Mean weight : 19.56 ± 9.57 kg (range 8.2-50).
- The mean defect size : 5.84 ± 1.52 mm (range 3.5 – 10 mm) on LV side and 4.76 ± 0.86 mm (range 2.3 – 6 mm) on RV side.

Results

- Multiple exits on RV side: 6 patients
- Septal aneurysm of tricuspid leaflet : 32 patients
- TR: Absent -7, Trivial -6, Mild -65, Moderate -8
- Aortic rim : 4.77 ± 1.26 mm
- AV prolapse – 8
- AR – 6; all trivial

Results

- Baseline ECG abnormality: 2 (IRBBB)
- Most common device used: 8 × 6 mm
- Mean fluoroscopy time: 13.80 ± 5.44 min (4.22–32.36)
- Procedural Success: 98.9% (1 Device embolization)



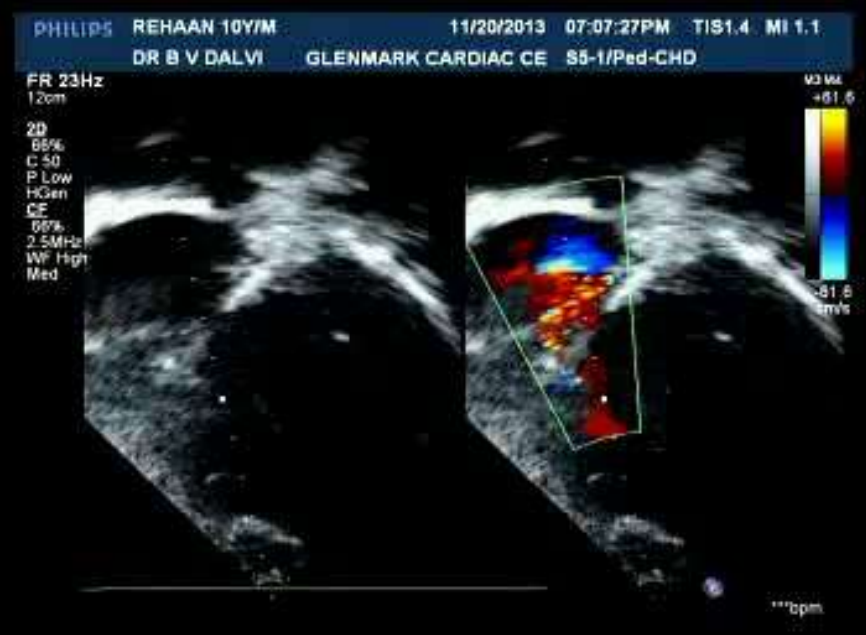
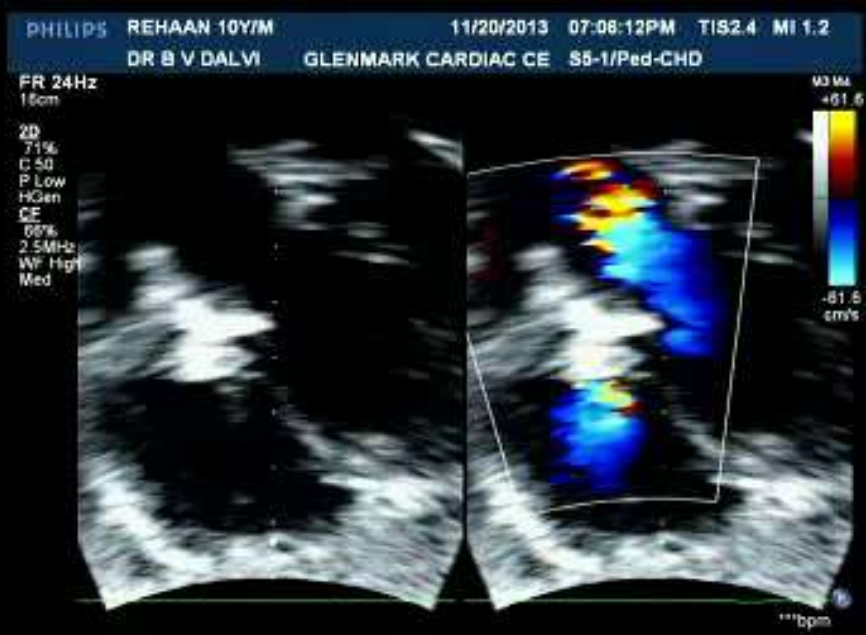
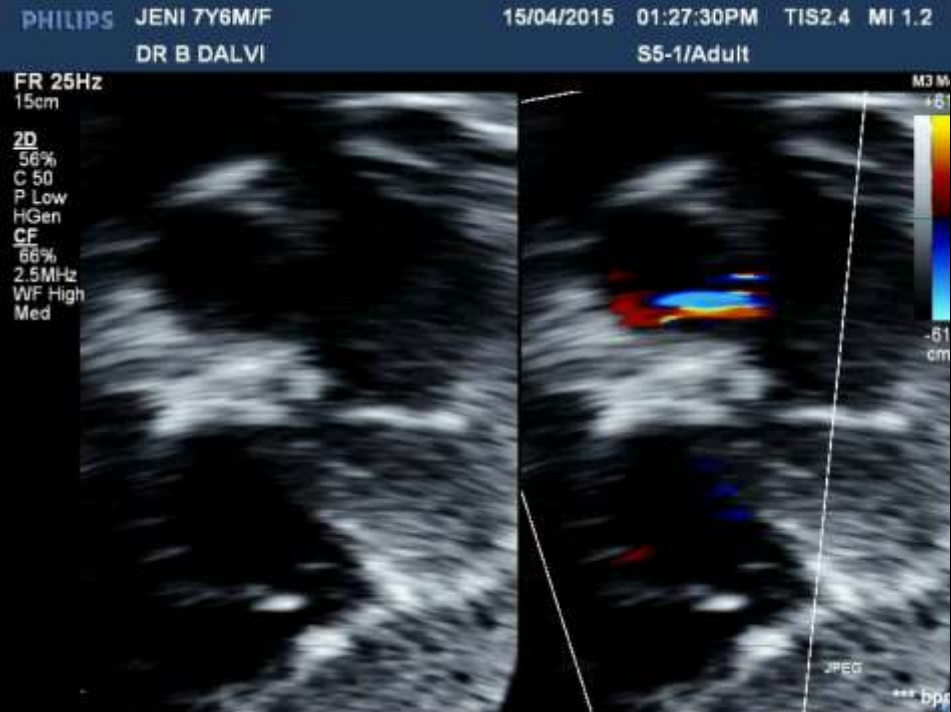
Follow up: (n=85)



- Duration: 582.1 ± 203.4 days
- Primary end points : Residual shunt
 - 11/85 (12.942 %) patients immediately, 1/85 (1.6%) at the time of last FU
- High grade AV block including CHB: No Patient

Follow up: (n=85)

- AR: 4 patients, 2 trivial, 1 mild and 1 moderate
- TR: Increased by 1 grade in 15 patients, 1 severe
- Asymptomatic new conduction abnormality – 7
 - Intermittent junctional rhythm – 3
 - Intermittent 2:1 AV block – 2
 - RBBB – 1
 - LBBB – 1
 - All transient except 1
- No delayed embolization
- No thrombus formation



Conclusion



- Selective patients with PMVSD can be closed using ADO I with high degree of efficacy and ??safety
- CHB does not seem to complicate the procedure at least in short and intermediate term.
- Aortic and tricuspid valve dysfunction remain a major concern