

# Feasibility and Risk of PMVSD Closure: Who Are Good Candidates for Device Closure

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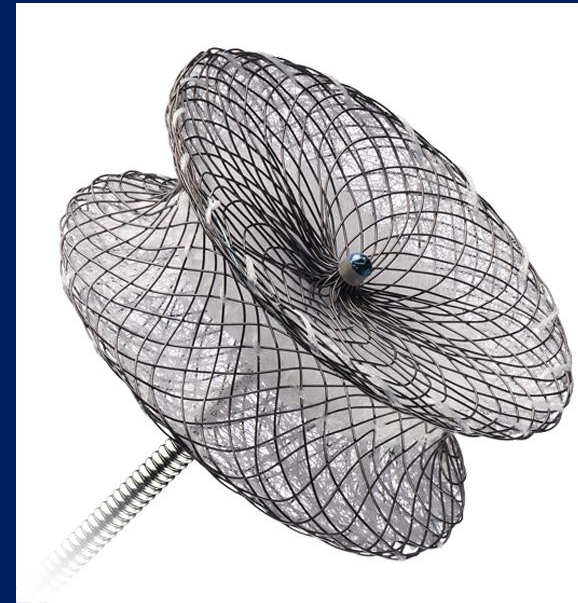
Glenmark Cardiac Centre

Mumbai, India

# 3 issues

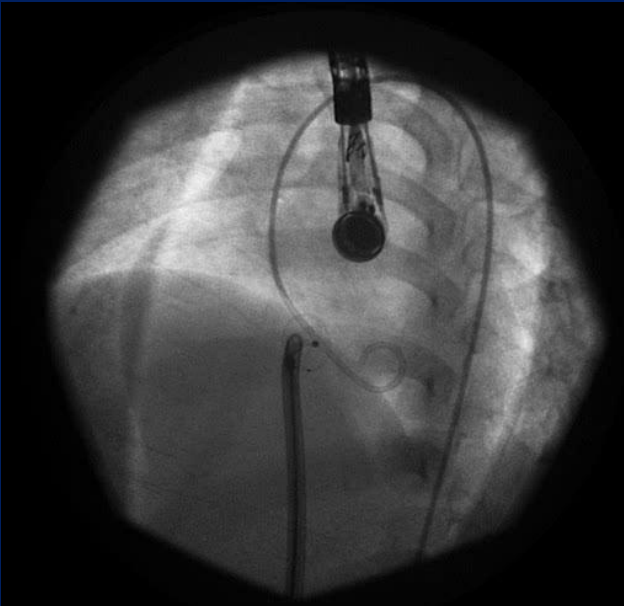
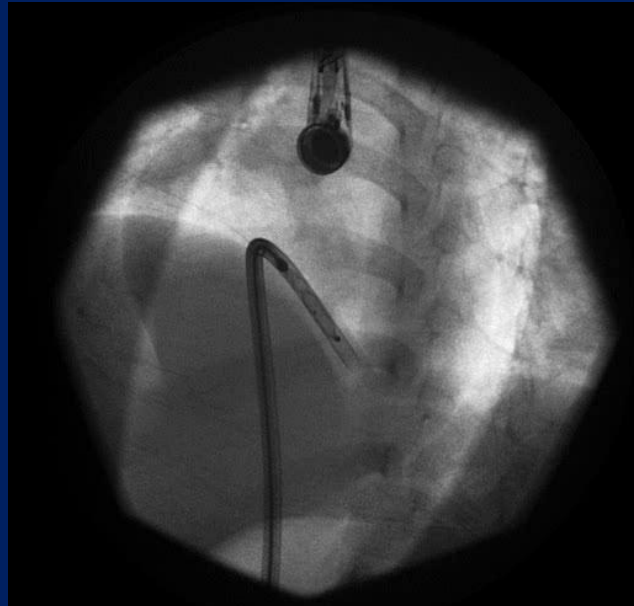
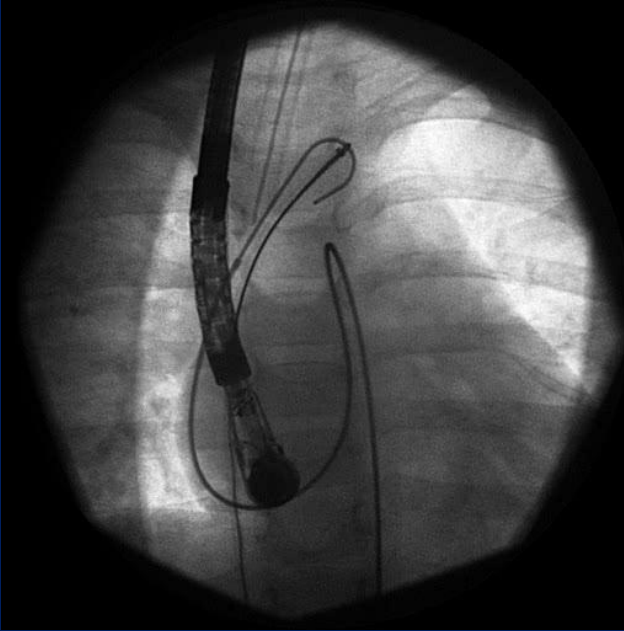
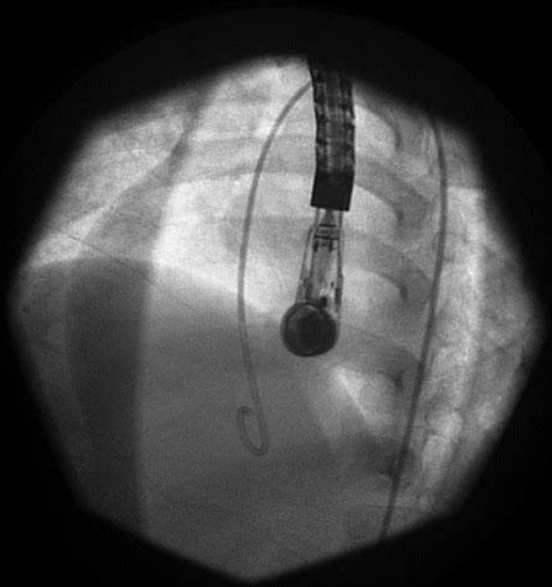
- How feasible is it to device close PMVSDs
- What are the risks
- Who are the good candidates
- Conclusions

# Devices used

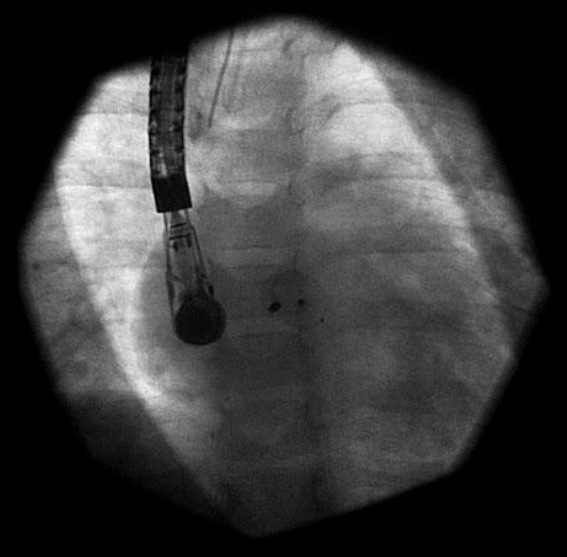
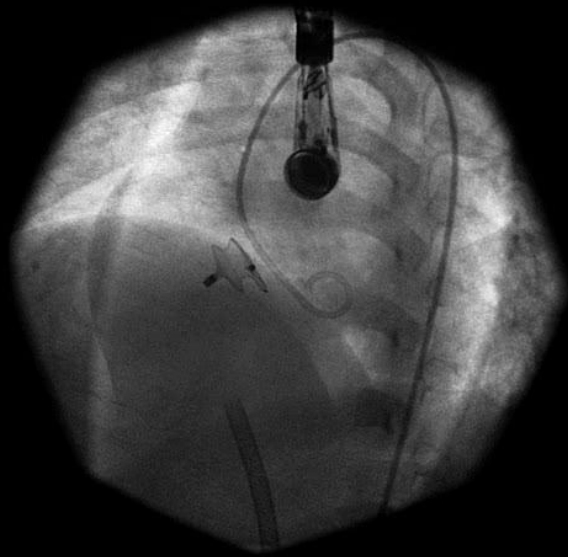
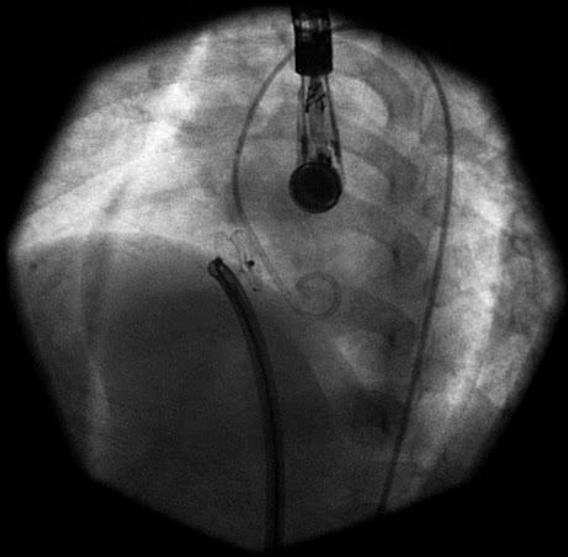
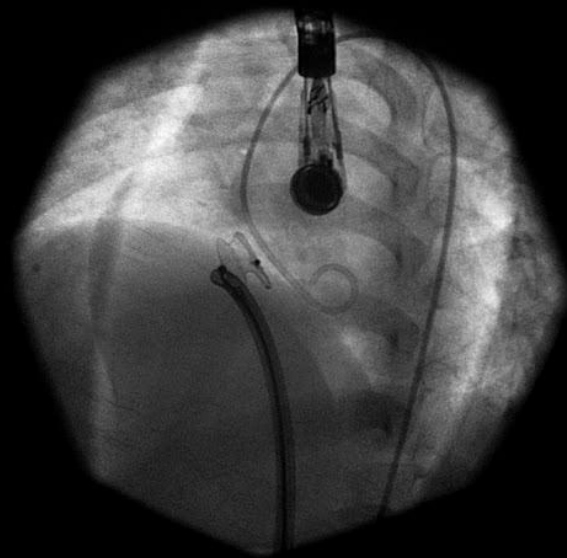
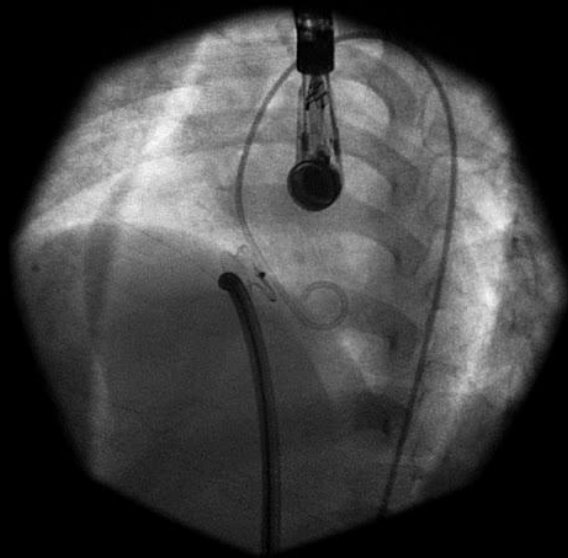
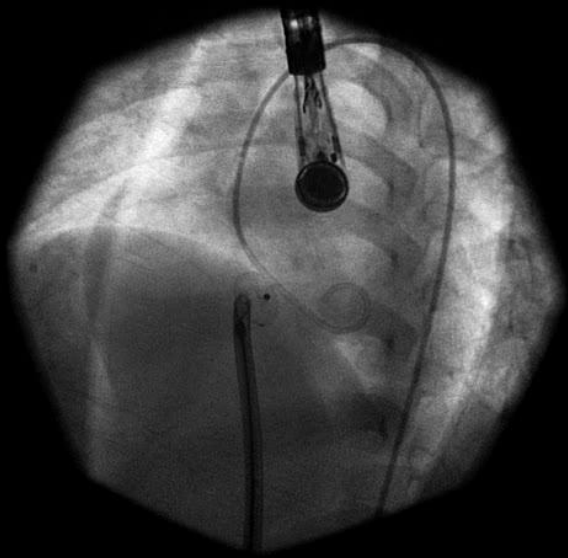


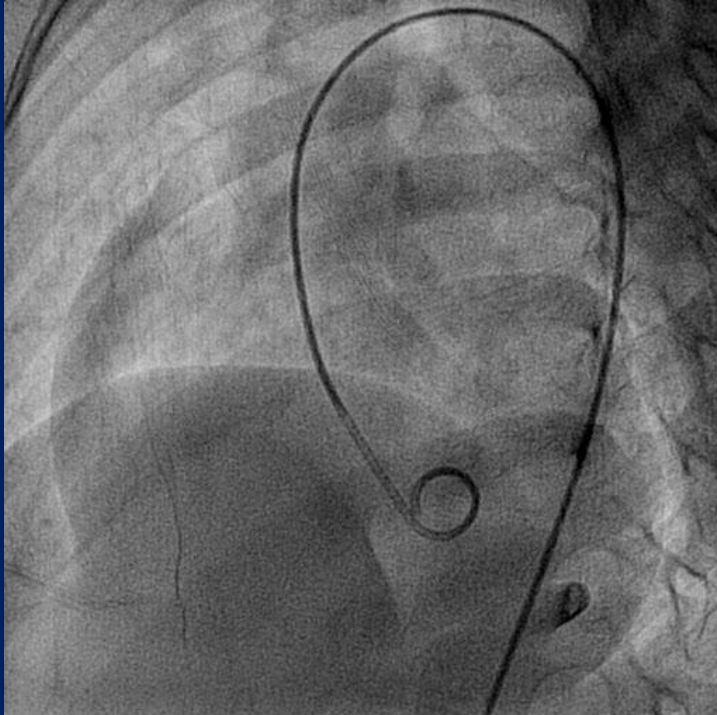
# Techniques of closure

- Transvenous
  - From the left ventricle
  - From the ascending aorta
- Transarterial



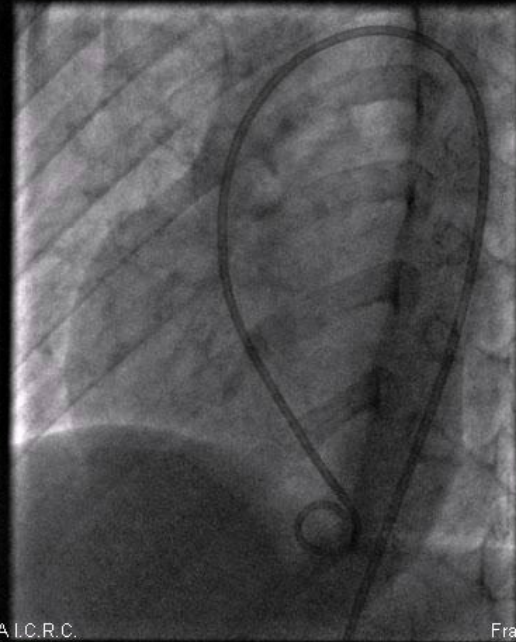






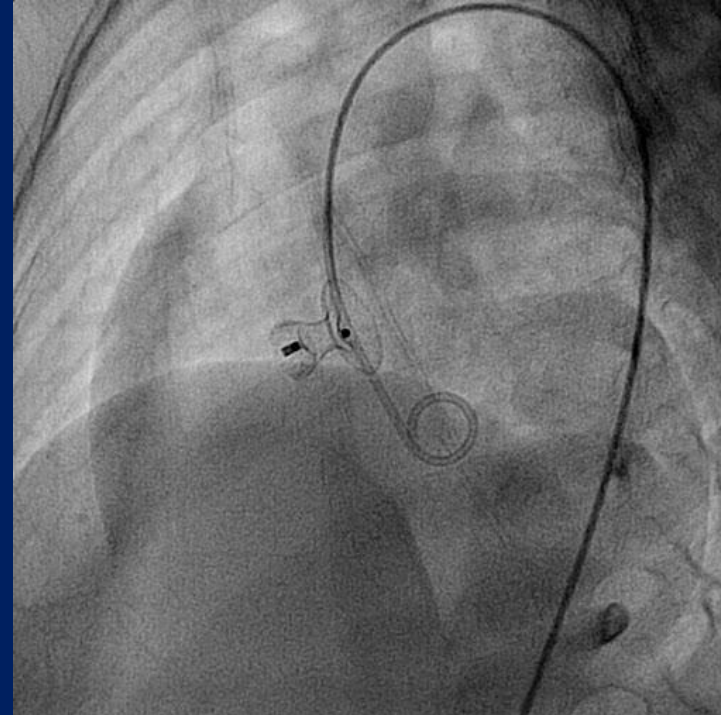
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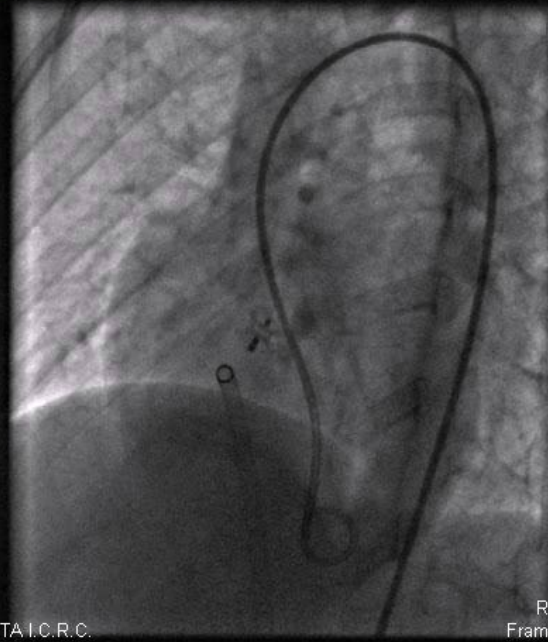
U.N.MEHTA I.C.R.C.  
Dr Bhavesh Thakkar

Run 1 Of 11  
Frame 1 Of 153  
Zoom: 99%



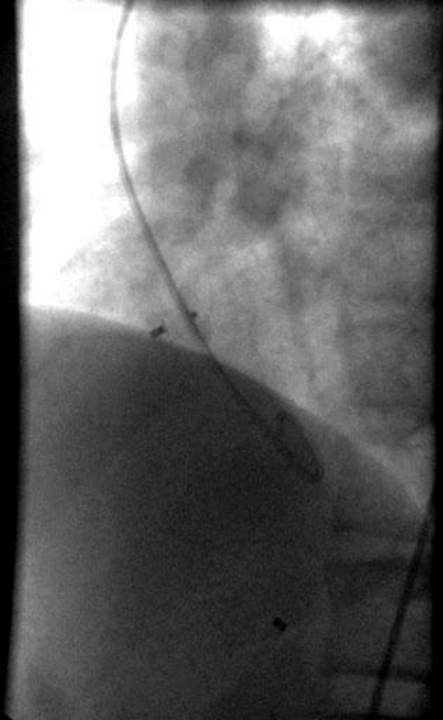
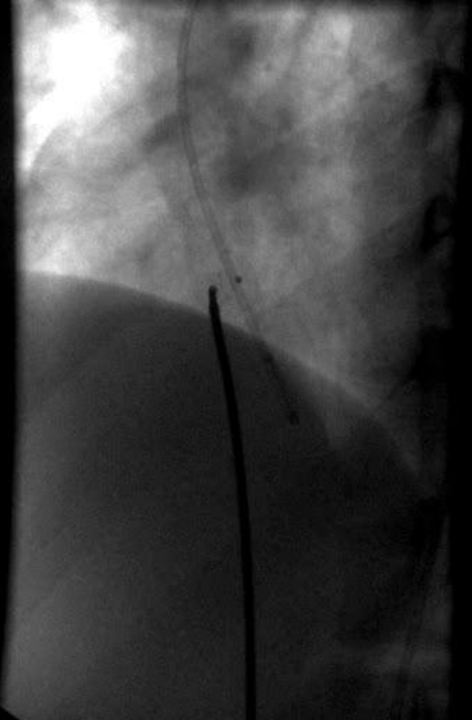
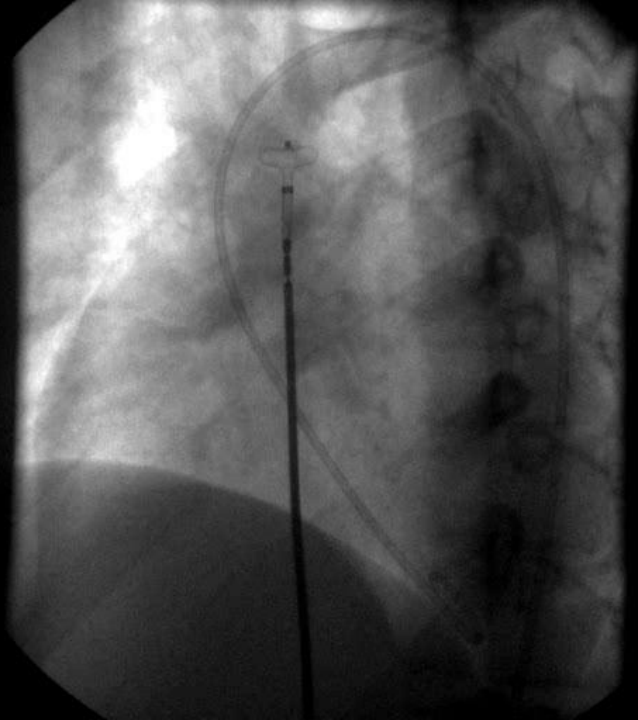
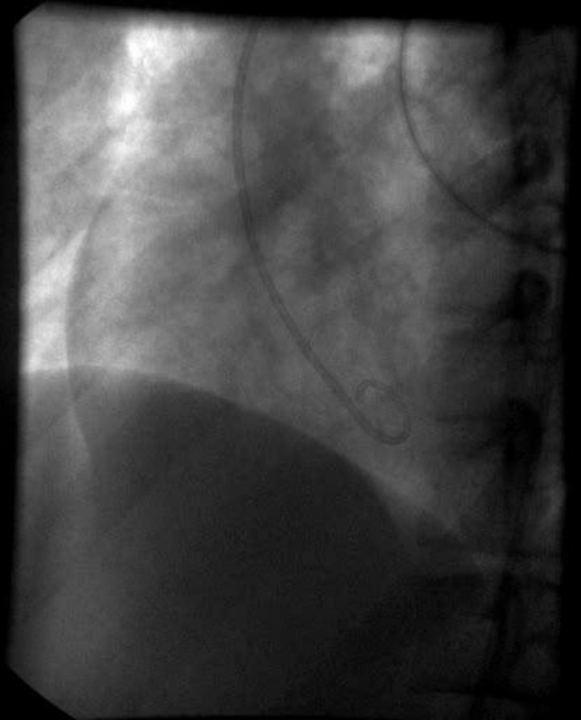
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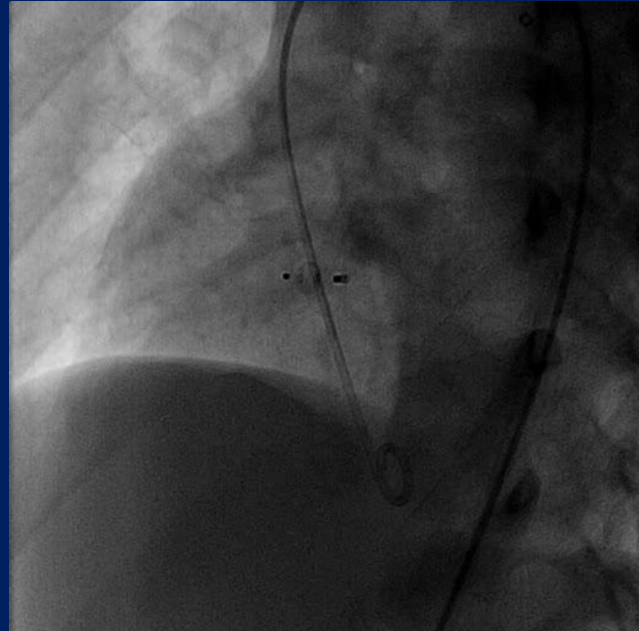
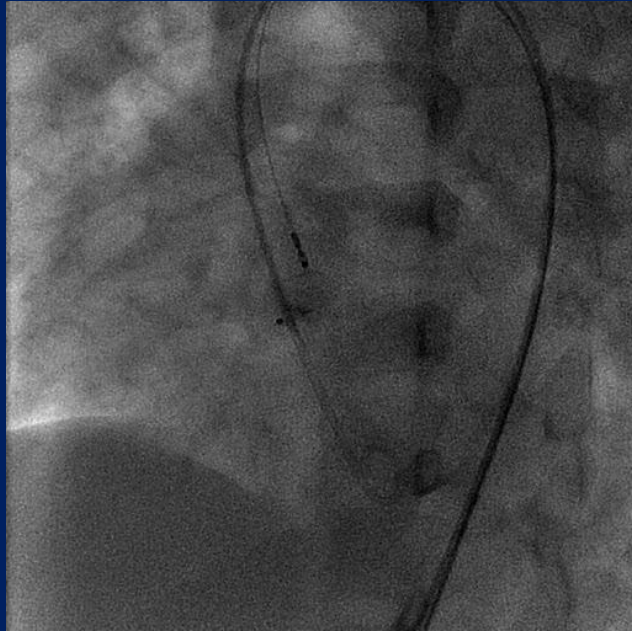
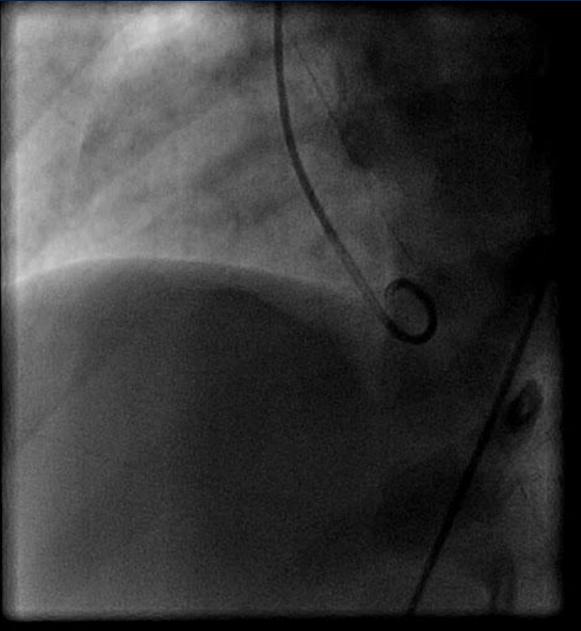


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Dr Bhavesh Thakkar

Run 9 Of 11  
Frame 1 Of 105  
Zoom: 99%







# 3 Periods

- Pre 2007: Cautious
- 2007-2008: Overboard
- Post 2008 : Realization

# Early Data (Pre 2007)

Study	Bass et al	Thanopoulos et al	Pedra et al	Miro et al	Fu et al
Year	2003	2003	2004	2005	2006
No. of patients	27	10	10	54	35
Age in yrs	1.25 - 32	1.5 - 12	6 - 32	0.5 - 61	1.2 - 54.4
Weight	8.5-80 kg	11-49 kg	19-80 kg	6-77 kg	8-110 kg
Qp:Qs	1.6	1.93±0.2 9	1.5-5.5(2)	1.7±0.6	(1.8)
Device size (mm)	4-12	4-8	8-18	6-18	6-16
Successful implant	93%	100%	100%	94%	91%

Study	Bass et al	Thanopoulos et al	Pedra et al	Miro et al	Fu et al
Residual shunt	2/27	0/10	1/10	9/54	1/35
CHB	0	0	0	3+2 (10%)	1
AR	2	0	0	1	12%
LBBB/RBBB	1	3 LBBB	1	NR	NR
Hemolysis	0	0	0	2	2
Others	1	0	LVOTO-2	0	2



# Game Changers

Study	European Registry	Butera et al	Predsecu et al		
Year	2007	2007	2008		
No. of patients	430	104	20		
Age in yrs	8 (0.4 to 70 years)	14 (0.6-63 years)	1.6 (0.5 – 16.2 years)		
Weight in kg	28 (4-124 kg)	26.5 (6.5 – 96 kg)	9.7 (6.2-43 kg)		
Qp:Qs	2.1 (1-8)	2 (1.3-5)			
Device size (mm)	7 (3-22)	8 (4-16)			
Successful implant	410/435 (95%)	100/104 (96.2%)	20/20 (100%)		

Study	European Registry	Butera et al	Predsecu et al		
Residual shunt	NA	1/104	0/20		
CHB	16/430 (3.7%)	6/104 (5.7%)	4/20 (20%)		
AR	14 (2)	0	0		
LBBB/RB BB	10	3	0		
Hemolysis	5 (1.2%)	0	0		
Others	NA	3			

- Skeptics went up in arms
- Damning the device and the procedure
- Radicals suffered
- Conservatives survived
- What almost killed the procedure

**“Overenthusiasm”**

# Introspection

- Patient selection
- Problems with AAPMVSDO
- Alternative devices



# Patient Selection

- Bigger and older children (> 10 kg and > 1year)
- Avoid
  - large PMVSDs
  - Down's
  - Inlet extension
  - Baseline ECG abnormality
  - More than trivial AR and mild TR
  - Short aortic rim

# Problems with AAPMVSDO

- Short waist 2 mm
- Stiff discs
- High “clamp force”
- Higher incidence with larger size

# Alternative devices

- PFM Le coils
- ADO I
- ADO II
- Modified devices

# Recent Data – 2008 and beyond

	Qin et al (Am J Cardiol 2008; 101:1781-86)	Yang et al (Eur Heart J 2010; 31:2238-45)
Period of Study	2002-2005	2002-2008
Total no of cases	412	848
Age	16.4 ± 9.1 years	9 (2-73 years)
Gender (M:F)	202 : 210	426 : 406
Weight		30.5 (10-88)



# Devices Used

	Qin et al (Am J Cardiol 2008; 101:1781-86)	Yang et al (Eur Heart J 2010; 31:2238-45)
AAPMVSDO	0	103
Symmetric/Assymmetric MVSDO (SSMA)	398	729

# Success

	Qin et al (Am J Cardiol 2008; 101:1781-86)	Yang et al (Eur Heart J 2010; 31:2238-45)
	398/412 (96.6%)	832/848 (98.2%)

# Complications

	Qin et al (Am J Cardiol 2008; 101:1781-86)	Yang et al (Eur Heart J 2010; 31:2238-45)
Device Embolization	3 (2 retrieved and redeployed)	2 (Surgical removal)
NeoAR	3 (device removed)	1 (Requiring Sx)
NeoTR	1 (Device removed)	1 (Requiring Sx)
		7 not requiring Sx
Residual shunt	0	405
LBBB	10	6
RBBB	16	15
Junctional rhythm		32
CHB	6 (Recovered in 3 weeks, No PPI)	5 (2 requiring PPI)

# Indian Data

	Thakker et al	Nageshwar Rao et al ( CCVI 2011; 77:252-59), (JACC 2012; 60:2421-22)	Jayrangnath et al	Dalvi et al (CCVI 2006; 68:145-52), (CCVI 2006; 68:620-28)
Period of Study	2007-2012	2006-2012	2010-2012	2003-2012
Total no of cases	310	108	136	76
Age	1 to 38 years (7.6 years)	1.2 to 22 years (4.6 years)	1.5 to 41 years (5.3years)	11m to 21 years (4.2 years)
Gender (M:F)	196:114	50:58	80:56	50:26
Weight	8.2 – 72 (20)	8.6 – 55 (14)	7.5 – 64 (21)	7.7 - 56 (16)

# Devices Used

	Thakker et al	Nageshwar Rao et al	Jayrangnath et al	Dalvi et al
AAPMVSDO	1	15	14	61
Symmetric VSDO	96 (SSM) + 135 (Starway)	1 (Lifetech)	0	0
ADO I	78	14	98	6
ADO II	0	78	24	9
ASO/MVSDO	0	0	0	0

# Complications

	Thakker et al	Nageshwar Rao et al	Jayrangnath et al	Dalvi et al
Device Embolization	4	3	1	1
NeoAR	4 (1)	3	1	6
NeoTR	3	2	5	12 (1)
Acute MR	0	0	0	0
Hypotension	0	1	0	1
CHB	5	0	1	0

# Conclusion

- Feasibility is not an issue
- Safety is getting better – Better patient selection and use of alternate devices
- Outstanding issues:
  - Short term: failure, embolization, hemolysis.
  - Long term: Aortic valve, tricuspid valve, conduction

# Conclusion

Resurgence of transcatheter closure of PMVSD

Right OR Wrong??????

Time will tell