Percutaneous VSD closure: Problems in the mid- and long-term

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SickKids®
The Labatt Family
Heart Centre

What post-procedural complications occur?

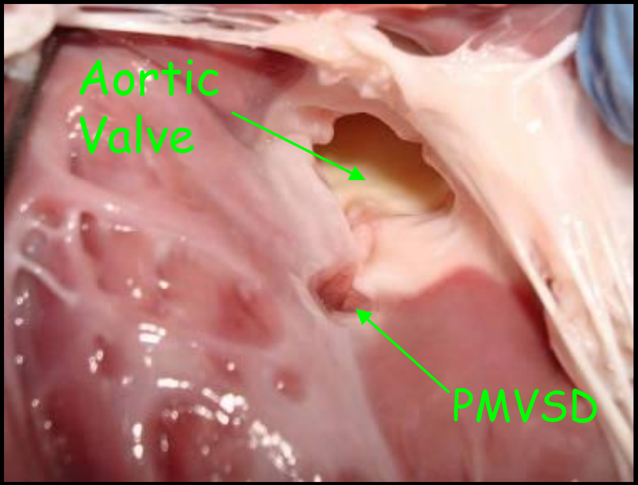
- Residual shunt
- Interference with AV or semilunar valve function
- Arrhythmias…particularly cAVB
- Embolization
- Hemolysis

What factor(s) influence adverse post-procedural events?

- Anatomical
- Patient selection (age, weight, hemodynamics)
- Device (design, materials)

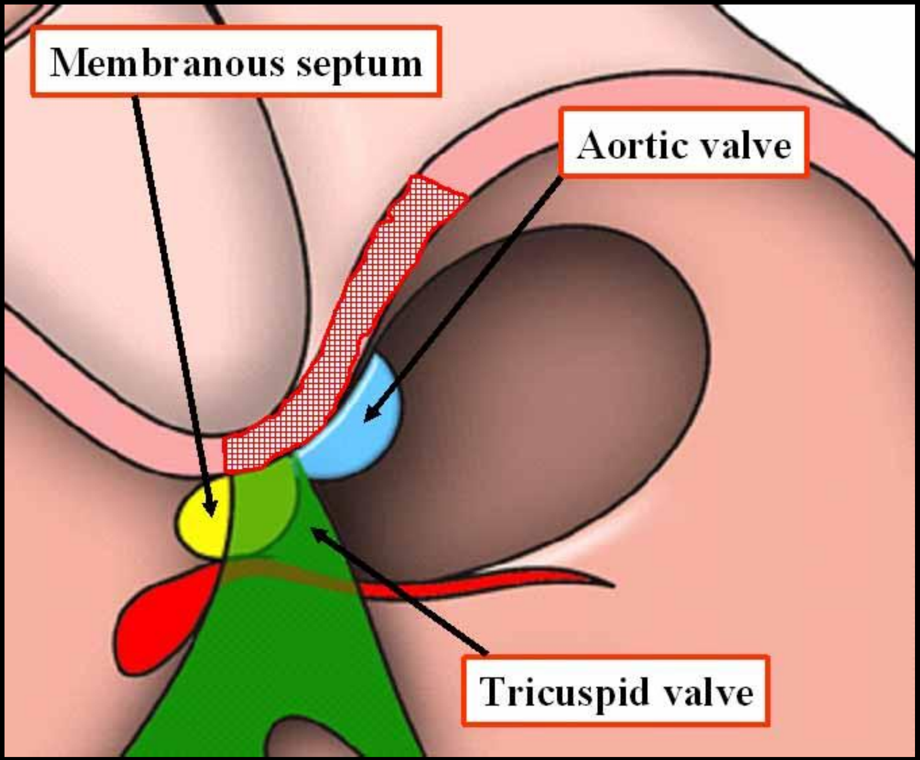
Perimembranous defects – anatomical considerations

- Location
  - Under chordae of TV
  - Rim between Ao V and defect can be non-existent
  - Bundle branch and AV node are near the defect rim
- Size of the defect
- Septal wall thickness
- Aneurysms



Perimembranous defects – complications

- Complete atrioventricular block (cAVB)
  - Early or late
  - Transient or permanent
  - Acute treatment options:
    - Abort procedure
    - Corticosteroids
    - Permanent pacemaker



Perimembranous defects – complications

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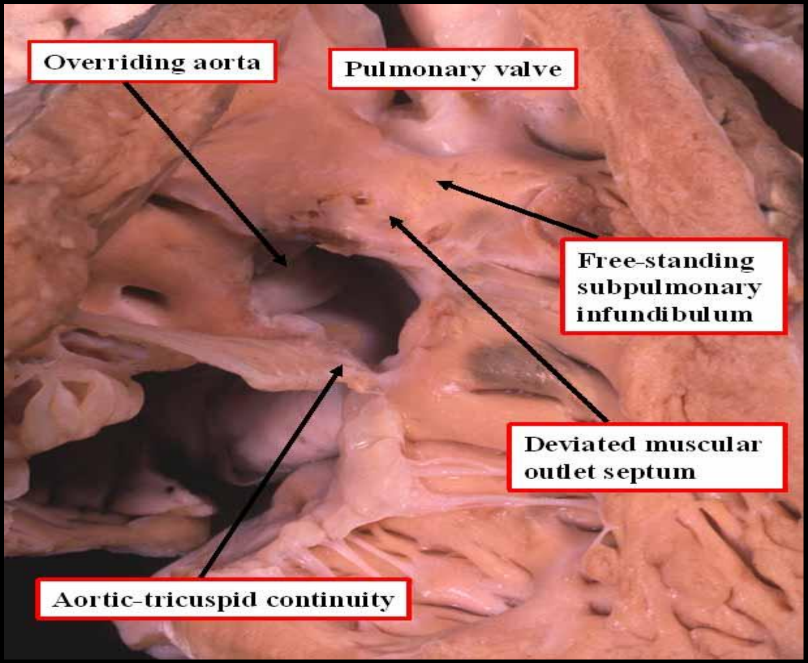
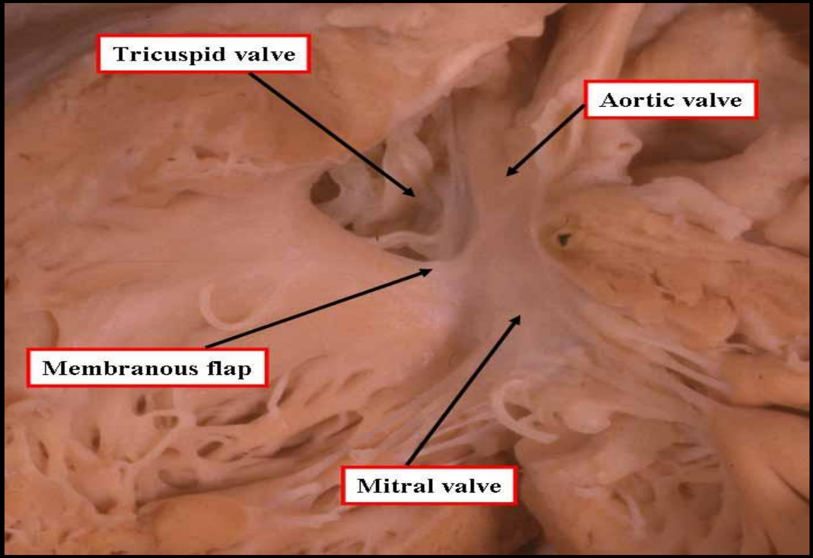
    - Permanent pacemaker
- Aortic or tricuspid insufficiency





Defects amenable to percutaneous closure

Apical, outlet and mid-muscular – technically relatively easy to close with devices

Post –MI VSD – complex procedure – high failure rate: dependent on patient hemodynamic status

Post operative residual defects – achievable closure, dependent on anatomical details

Perimembranous - more complex with greater incidence of acute and longer term complications due to anatomical relationships

Established Indications for VSD closure

Left – to – right shunt >1.5:1

LV enlargement z-score >2

Increased PAP

Intractable CHF

Failure to thrive

Previous infective endocarditis (second episode)

Other Indications for VSD closure

Psychosocial impact on patient and family

Avoid stigmata of having a heart defect

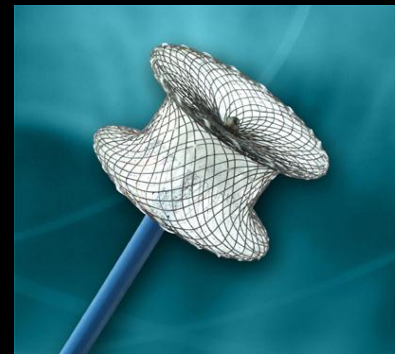
Employability

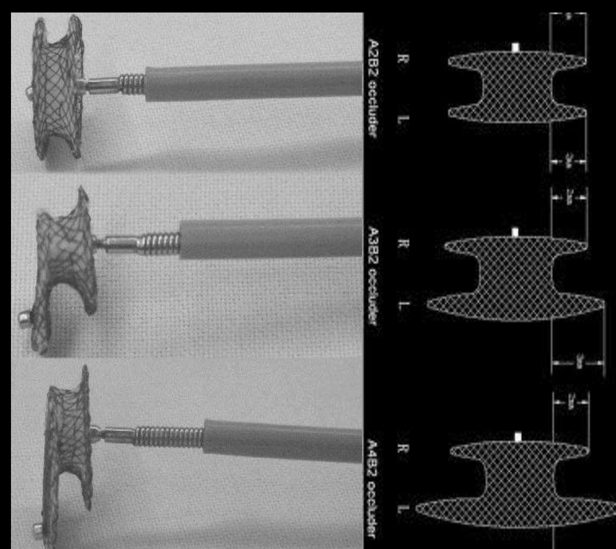
Health insurance

Heavy vehicle license

Sports participation

Devices available for percutaneous closure





Risks associated with pmVSD Closure

- Surgical closure
  - cAVB occurrence reported at ~1%

    Tucker 2007 JACC: 4432 pts with pVSD, 1.1% PPM

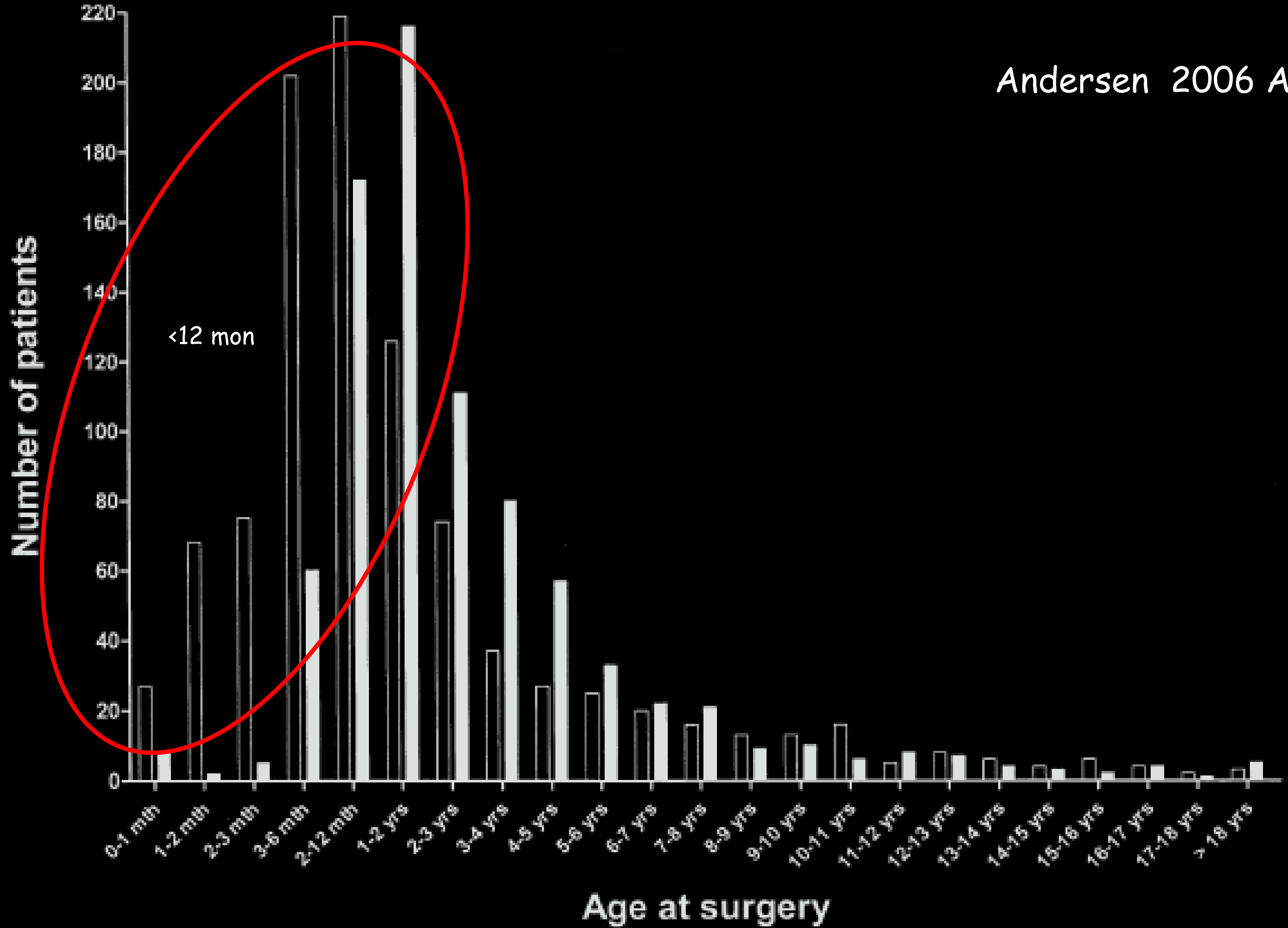
    Risk factors – Down syndrome (41% *vs.* 18%)

    Younger age 14 *vs.* 24 months

    If weight >8 kg incidence only 0.8% PPM

    Andersen 2006 ATS: 996 isolated pVSD, 0.7%
  - Significant residual VSD 1-5%
  - Reoperation 2%
  - Mortality 0.5%

Age distribution of surgical pmVSD closure



Transcatheter closure of congenital ventricular septal defects: results of the European Registry

Carminati et al European Heart Journal (2007) 28, 2361–2368

Table 1 General characteristics	23 centres
Number of patient	430
Median age and age distribution	8 years (0.4–70 years)
<2 years	77 pts (18%)
2–6 years	105 pts (24%)
7–14 years	103 pts (24%)
>14 years	145 pts (34%)
Weight	28 (4–124 kg)
VSD size	
Echo size	7 (3–22 mm)
Angio size	7 (2.5–18 mm)
QP/Qs	2.1 (1.1–8)
Defect types (muscular, pm, residual post-operative)	
Perimembranous	250
Muscular	119
(mid muscular 83, apical 20, high/outlet 16)	
Multiple	16
Residual post-surgery	45
Defect measure (by TEE)	
Median	7 (range 3–22)
Device used	
Membranous Amplatzer	213
Muscular Amplatzer	151
PDA Amplatzer	12
ASD Amplatzer	7
Starflex	7
Coil	9

Complications

Overall	*12.7%*
Significant	*6.5%*
death	0.2%
vascular	0.7%
hemolysis	1.2%
infection	0.5%
embolization	0.9%
TR	6.0% (mild/trival)
AR	3.3% (OR in 2 pts)

Residual shunt (requiring OR) 0.7%

Arrhythmias

tachyarrhythmias	0.7%
early cAVB	2.8%

6 /12 requiring PPM , <1 week after implant…presenting with syncope, asystole

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Follow up

2 yr (range 6/12 to 10 yr)

- death 1 pt
- late cAVB 4 pt (4, 7, 12, 18 mons p/c)
  2 – syncopal
  2 – asymptomatic

95% complete closure in FU

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Table 3 Characteristics of patients with complete atrio-ventricular block

Patient	Age (years)	Defect type	Post-surgical defect (yes/no)	Device type	Measure (mm)	Transient (Yes/No)	Therapy	Timing of occurrence post-procedure
1	4	pmVSD	No	A-ASD	4	No	Stop kt—surgery	
2	2	pmVSD	No	A-pmVSD	12	No	PM	1 day
3	11	pmVSD	No	A-pmVSD	8	No	PM	5 days
4	55	mVSD	Yes	A-mVSD	10	Yes		
5	3.4	pmVSD	No	A-pmVSD	8	Yes		
6	4.2	pmVSD	No	A-pmVSD	8	No	PM	5 days
7	8.1	pmVSD	No	A-pmVSD	6	No	PM	4 days
8	11.6	mVSD	Yes	A-pmVSD	10	Yes		
9	5.2	pmVSD	No	A-pmVSD	10	No	PM	3 days
10	1.5	mVSD	Yes	A-PDA	5/4	No	PM	5 days
11	1.2	mVSD	No	A-PDA	8/6	Yes		
12	1	pmVSD	no	A-pmVSD	8	Yes	Stop kt—surgery	
13	36	pmVSD	no	A-pmVSD	16	No	PM	7 months
14	1.2	pmVSD	No	A-pmVSD	8	No	PM	18 months
15	2.7	pmVSD	No	A-pmVSD	12	No	PM	12 months
16	2.6	pmVSD	No	A-pmVSD	8	No	PM	4 months

A-mVSD, Amplatzer muscular VSD occluder; A-pmVSD, Amplatzer perimembranous VSD occluder; A-ASD, Amplatzer atrial septal defect occluder; A-PDA, Amplatzer PDA occluder; PM, pace-maker implantation.

cAVB - 3.7% overall, PPM - 2.3% both early & late after implant

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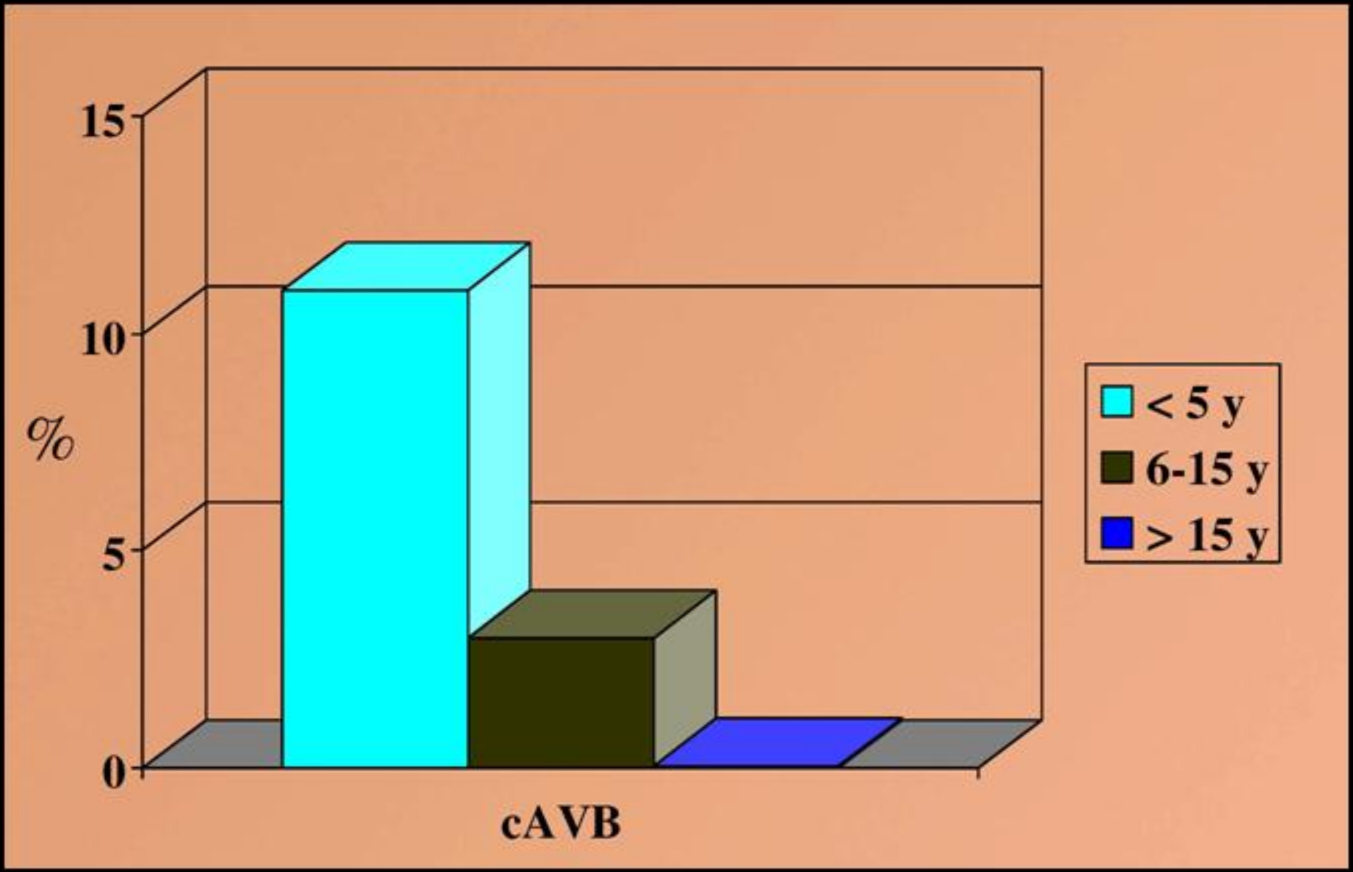
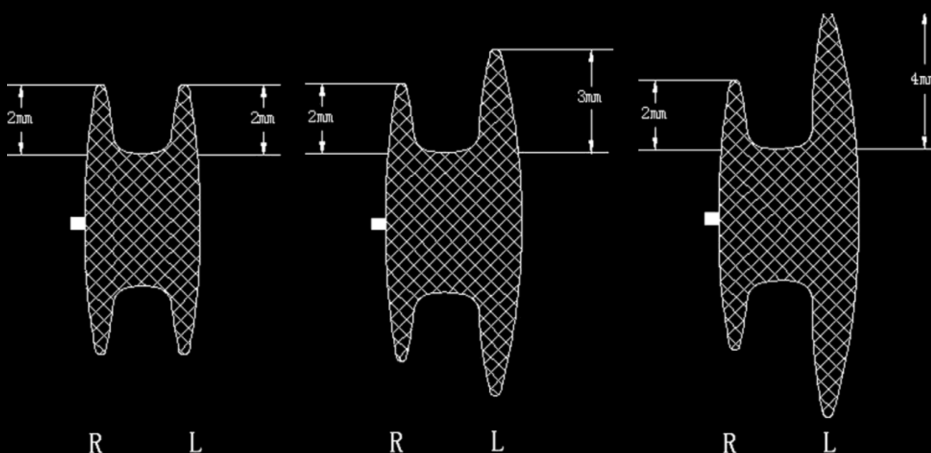
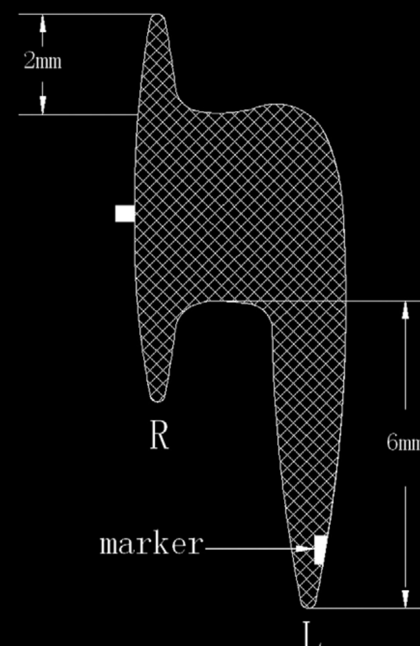


Multivariable analysis: factors associated with occurrence of complications: age & weight at the time of the procedure

The Chinese experience new implants for pmVSD

Modified double disk occluder - MDVO
Shanghai Shape Memory Alloy Ltd, China





The Chinese experience new implants for pmVSD

Inclusion criteria for closure

- age ≥3 years old
- maximum VSD diameter 16 mm by TTE
- defect located 9 to 11 o'clock in the short axis parasternal view
- left to right shunt
- PAP <70 mm Hg by TTE

Excluded were patients with

- AoV prolapse
- severe AR
- Right-to-left shunt
- Cyanosis
- PAP >70 mm Hg
- NYHA class IV

Qin et al AJC 2008

The Chinese experience with newer implants for pmVSD

- 5 centres in China, 412 patients, ages 3 -65, mean 16 years
- VSD's 3-18 mm
- Devices used were 4 - 20 mm, symmetric occluders in 312 pts, asymmetric occluders in 86 pts
- During and after device implant, 10 had LBBB and 16 RBBB…all recovered in <1 week
- 97% successful closure
- 6 patients (4 children and 2 adults) had cAVB (1.4%), recovered within 3 weeks with temp pacing and steroids
- Dislodgement rare: 3/412 (3/86; 0.03%) implants…asymmetric device
- No further complications in 0.5 to 2 years follow up

Qin et al AJC 2008

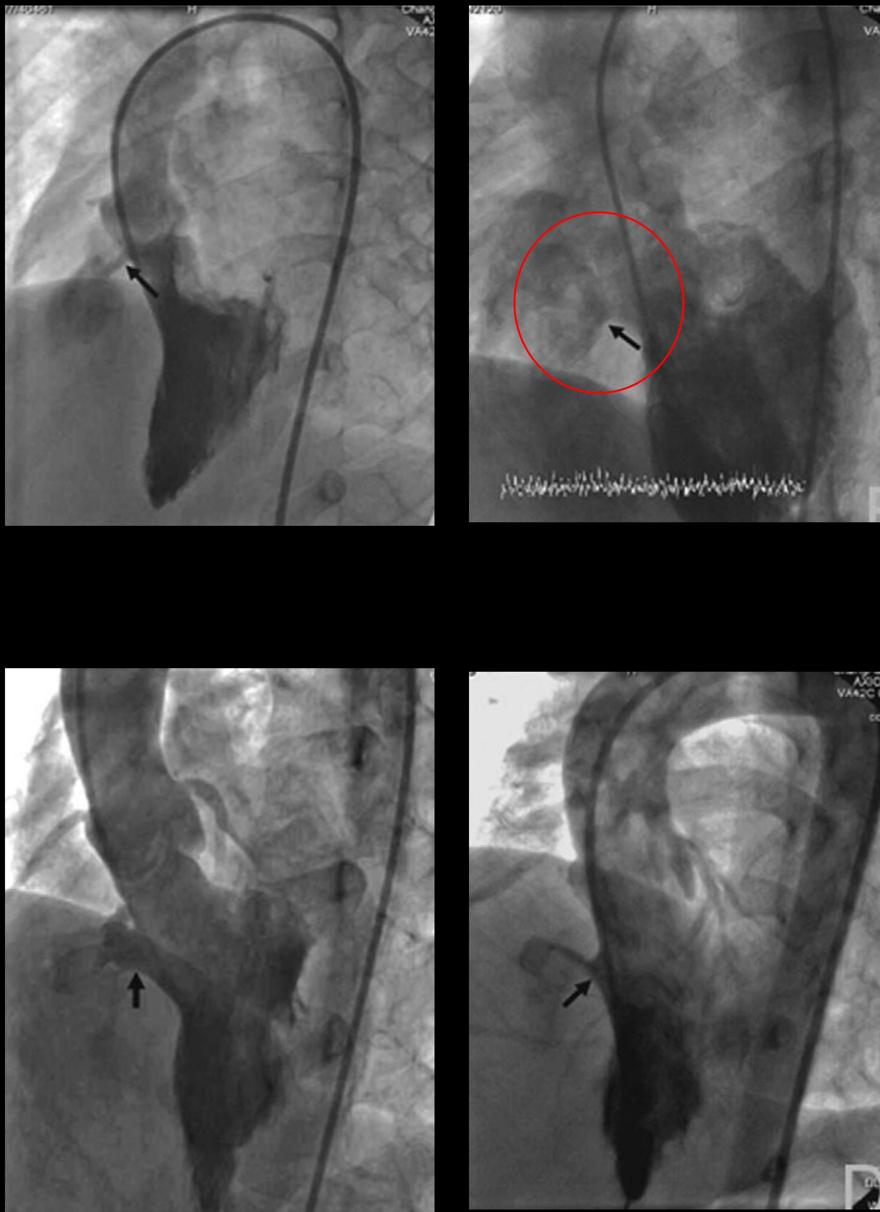


Table 1
Clinical charateristics of patients (n = 412)

Gender	
Men	202 (49.0%)
Women	210 (51.0%)
Age (yrs)	16.4 ± 9.1
<15	228 (55.3%)
≥15	184 (44.7%)
Pulmonary to systemic flow ratio	1.9 ± 0.4
Pulmonary pressure	
<40 mm Hg	296 (71.8%)
40 to 70 mm Hg	116 (28.2%)
Defect diameter by ventriculography (mm)	5.0 ± 2.7
Device diameter (mm)	7.1 ± 3.6
Rim below aortic valve (mm)	3.1 ± 1.2
Defect shape by ventriculography	
Infundibular	230 (55.8%)
Aneurysmal	96 (23.3%)
Tubular	49 (11.9%)
Window-like	37 (9.0%)

Qin et al *AJC* 2008

Risk Factors and Outcomes of Post-Procedure Heart Blocks After Transcatheter Device Closure of Perimembranous Ventricular Septal Defect

Yang JACC CV Interv 2012

- pmVSD closure in 228 patients
- Heart block occurred in 33 (14.5%) cases and average 3.0 days after the procedure
- The 3 cases with 3rd -degree AVB developed progressively from either a complete RBBB with a left anterior hemiblock or cLBBB with a 1st-degree AVB
- High-degree AVB in these 4 patients reverted to the NSR after administration of IV hydrocortisone and application of a temporary PM

Table 1. Number of Cases That Developed Heart Blocks After Closure of pmVSD

		Cases (n)	Average Time of Emergence of PPHBs (Days)
RBBB	57.6%	19	1–6
CRBBB		10	1–5
IRBBB		9	1–6
LBBB	24.2%	8	1–5
CLBBB		3	1–3
ILBBB		5	2–5
AVB	18.2%	6	3–7
First-degree AVB		1	3
Second-degree AVB		2	3
Mobitz type 1		1	3
Mobitz type 2		1	3
Third-degree AVB		3	4–7
Total		33	

Risk Factors and Outcomes of Post-Procedure Heart Blocks After Transcatheter Device Closure of Perimembranous Ventricular Septal Defect

Yang JACC CV Interv 2012

- Heart block reverted to normal in 21 prior to hospital discharge
- 12 cases (2-LBBB, 10-RBBB) did not recover by time of D/C…3 by 3 months follow up
- Follow up time was 58 months (83% completed follow up)

Risk factors for HB	Patients With No PPHB (n = 195)	Patients With PPHB (n = 33)	p Value
Age, yrs	13.6 ± 10.2	15.1 ± 10.9	0.71
Weight, kg	38.8 ± 18.9	40.2 ± 18.8	0.38
DLRD-SLTV, mm	3.8 ± 1.6	2.3 ± 0.6	<0.01
DAVD, mm	3.2 ± 1.5	3.9 ± 1.3	0.03
Diameter of pmVSD, mm	5.4 ± 2.1	5.3 ± 3.3	0.95
AVSDOs/SVSDOs*	91/104	15/18	0.90
SOD, mm	7.4 ± 2.6	8.8 ± 4.5	0.07
DDOV, mm	2.0 ± 0.7	3.5 ± 1.5	<0.01
PASP, mm Hg	31.8 ± 6.0	32.2 ± 7.0	0.13
LVDD before procedure, mm	43.5 ± 7.8	45.1 ± 6.9	0.69
LVDD after procedure, mm	41.3 ± 6.8	42.9 ± 6.9	0.66
Procedure time, min	86.5 ± 25.1	89.5 ± 29.8	0.52
Fluoroscopy time, min	18.2 ± 8.4	19.2 ± 11.2	0.22

Anatomical and device characteristics

DAVD the aortic valve to the defect
DDOV diameter difference between the occluder and VSD
DLRD-SLTV the distance from lower rim of the defects to the septal leaflet of the TV
SOD size of device

Why the difference in incidence of cAVB?

Age: Most patients were adults or older children

Anatomy: In children, device/ventricular septum area is larger

Device design: Waist is longer in the MDVO than the Amplatzer occluder (2 to 2.5 mm *vs.* 1.5 mm)

Risk of cAVB:

Age: children <10 years

Anatomy: true pmVSD, location of penetrating bundle to defect margins

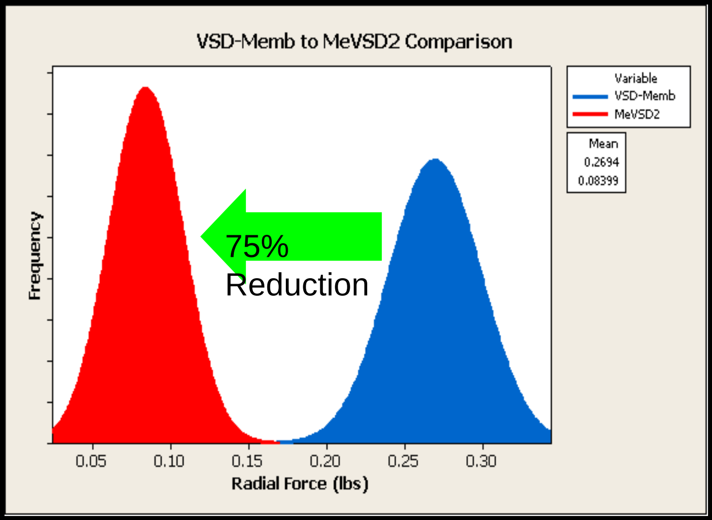
Technical: crossing the defect with difficulty or development of right bundle block (and left anterior hemiblock) during the procedure

AMPLATZER® Membranous VSD Occluder 2

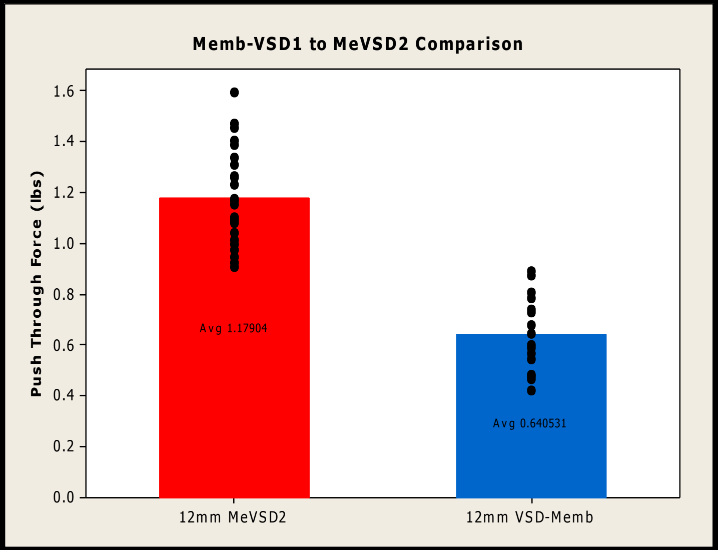
Promotes Closure and Stability

- Polyester-filled waist and discs promotes closure of the defect
- Inner braid layer and LV disc shape promotes stability

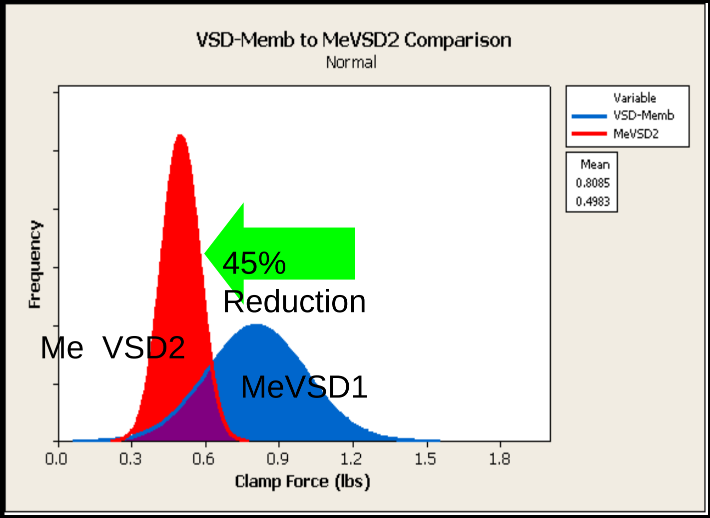
AMPLATZER® Membranous VSD Occluder 2



Radial Force



Device Stability



Clamp Force

Problems in assessing complications and outcomes

Inconsistent definition of anatomy: are you closing a….

- pmVSD
- muscular defect: in trabecular septum
- muscular outlet
  - infundibular
  - intracristal
- a VSD with aneurysm

Age and weight of patients treated

Indications for intervention

Despite these inconsistencies in assessing outcomes

Transcatheter techniques have improved due to a better understanding of:

- anatomy
- improved device design
- recognition of potential at risk populations

Cám ơn

Thank you

Incidence of Complete AV Block (cAVB)

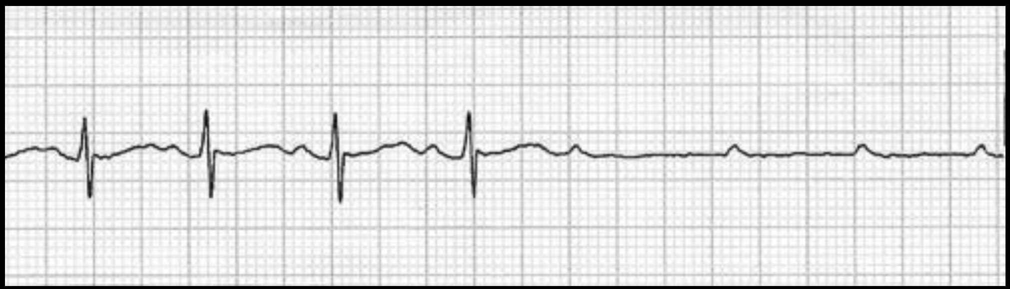
Source	Incidence	Outcome
Xunmim et al, Int J Cardiol 2007 (China)	1/72 (1.4%)	Transient
Butera G et al, JACC 2007 (Milan)	3/87 (3.4%)	SX or PPM
Pedra CAC et al, J Invasive Cardiol 2008 (Brasil)	1/39 (2.6%)	PPM
Zhou J et al, Clin Cardiol 2008 (China)	4/168 (2.4%)	Transient
Oses P et al, Ann Thorac Surg 2010 (Montreal)	2/35 (5.7%)	PPM
Zuo J et al, Am J Cardiol 2010 (China)	6/294 (2.0%)	SX or PPM
Yang R et al, Cath Cardiovasc Intervent 2011 (China)	1/60 (1.6%) [13 transient]	PPM
US Phase I Trial	2/35 (5.7%)	PPM
Survey – JLB 2007	12/486 (2.5%) [6 transient]	PPM
Tucker E et al, JACC 2007 Surgical >8kg Multicenter, PCCC	13/1739 (0.8%) [3 late]	PPM

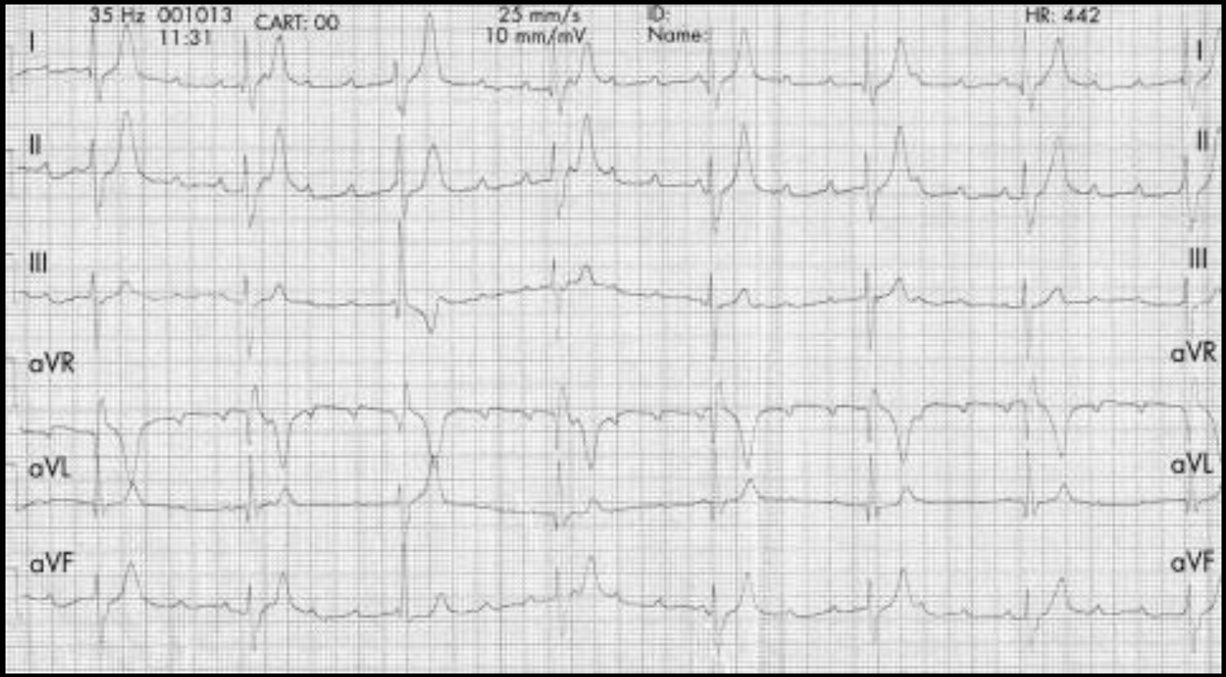
Slide Courtesy of Dr. John Bass

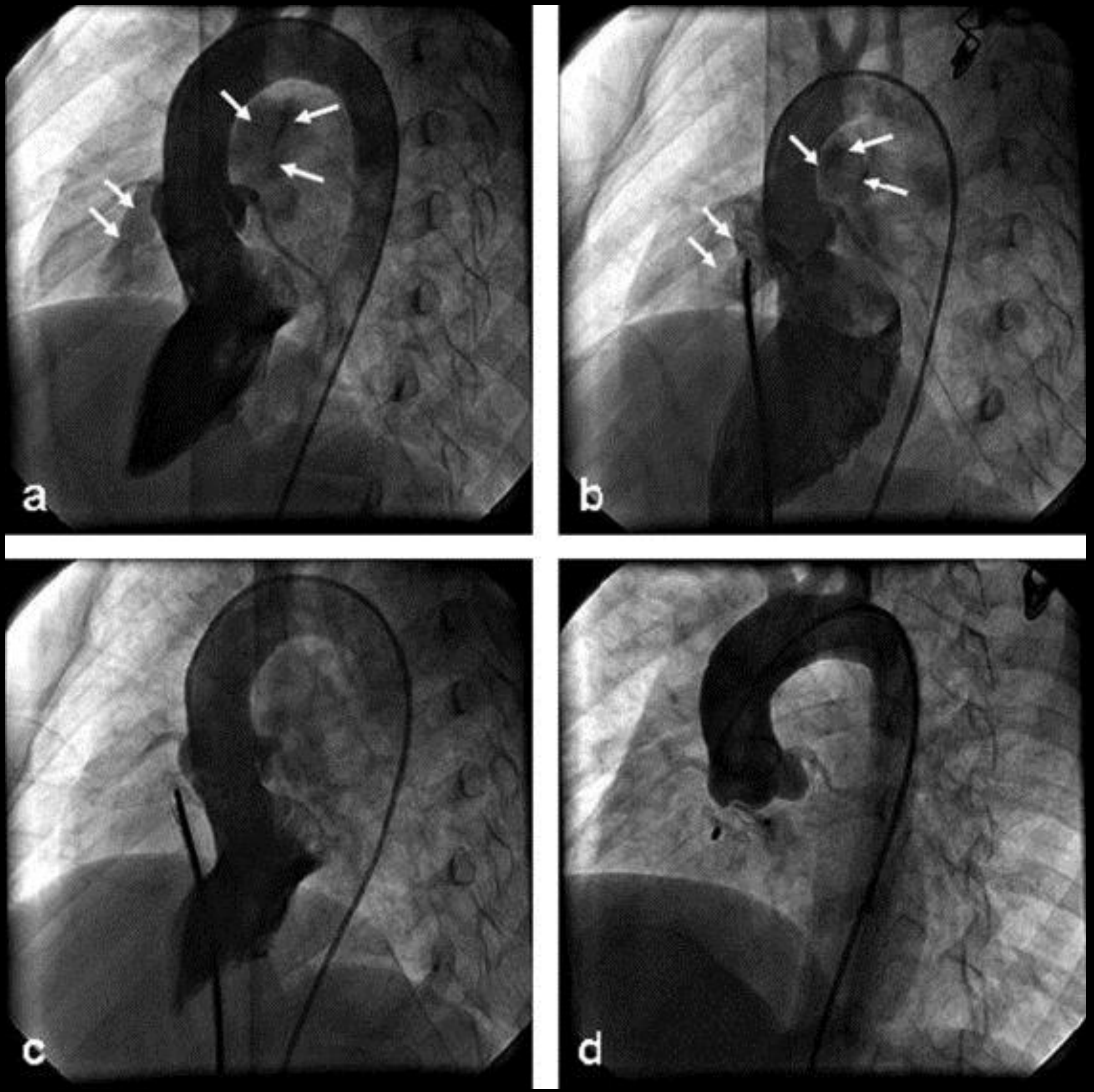
AMPLATZER® Membranous VSD Occluder I

- Had an eccentric shape, with the distal (LV) disk exceeding the connecting waist by 1 mm in its superior part and by 5.5 mm in its inferior part
- Proximal (RV) disk 2-mm l>the connecting waist, which was only 1.5 mm in length
- Available sizes range from 4 to 18 mm

Complete heart block



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