Ventricular Septal Defects: Closure, Devices & Techniques

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Disclosures

- None to declare

Objectives

- Introduction
- Indications/ contraindications
- Device timeline/ history
- Approach/ technique
- Outcomes

Introduction

- Diagnosis represents approximately 20%-30% of patients with congenital heart disease
- Large ventricular septal defects may be diagnosed prenatally or during infancy and may bring about congestive heart failure requiring surgical referral
- Smaller defects maybe moderate in dimension but over time may become smaller through the development of aneurysmal tissue

Introduction

- Yet despite being smaller, they too can be associated with long-term issues, such as:
  - Left ventricular dilation
  - Aortic valve insufficiency
  - Double chamber right ventricle
  - Arrhythmia
  - Pulmonary hypertension
  - Endocarditis

Anatomy of VSD's

- Divided into:
  - Atrioventricular canal type (inlet)
  - Muscular
  - Membranous
  - Conoventricular (hypoplasia or malalignment type)
  - Conal septal or RV outlet

- *Transcatheter* closure typically reserved for *membranous* and *muscular*

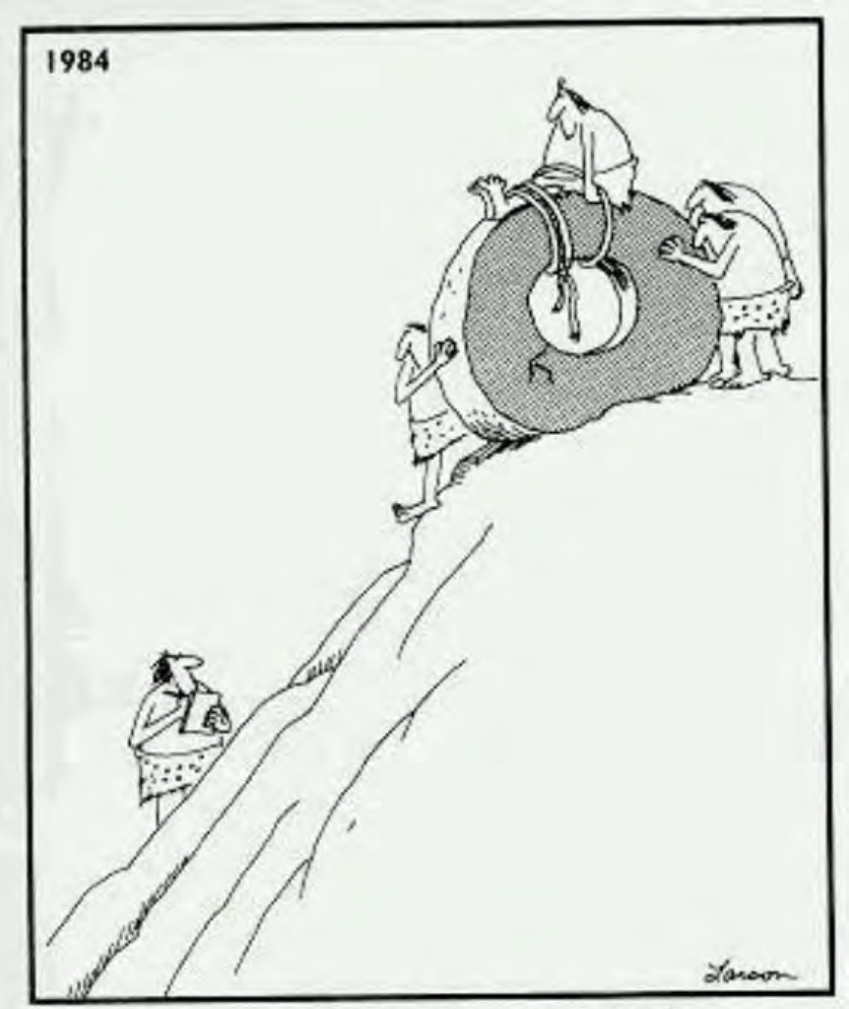
Indications for closure

- Typically outside of the neonatal period and not associated with other surgical indications
  - History of infective endocarditis
  - Failure to thrive
  - Worsening New York Heart association classification
  - Recurrent respiratory illnesses
  - Estimated Qp/Qs of >1.5

Contra-indication for transcatheter occlusion

- Irreversible pulmonary hypertension (PVRi >7 Woods units)
- Contra-indication to antiplatelet therapy
- Active infectious issues
- Anatomic concerns:
  - <2 mm rim below the aortic valve
  - Aortic valve prolapse
  - Malalignment type defects
  - Supra-cristal defects

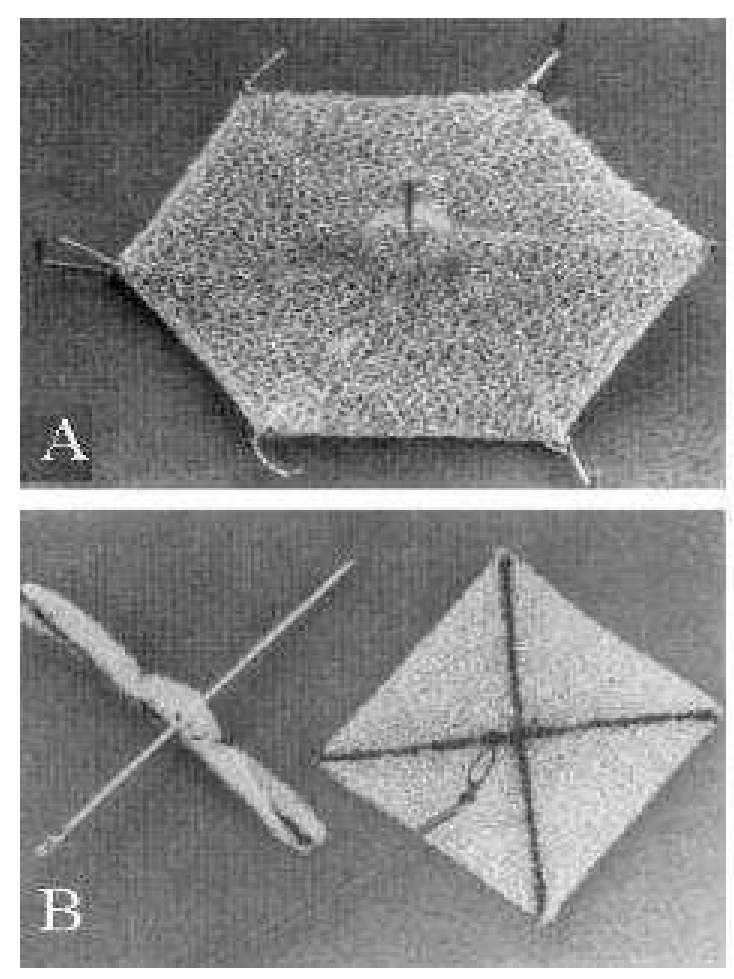
In the beginning….



Early experiments in transportation

Initial attempts

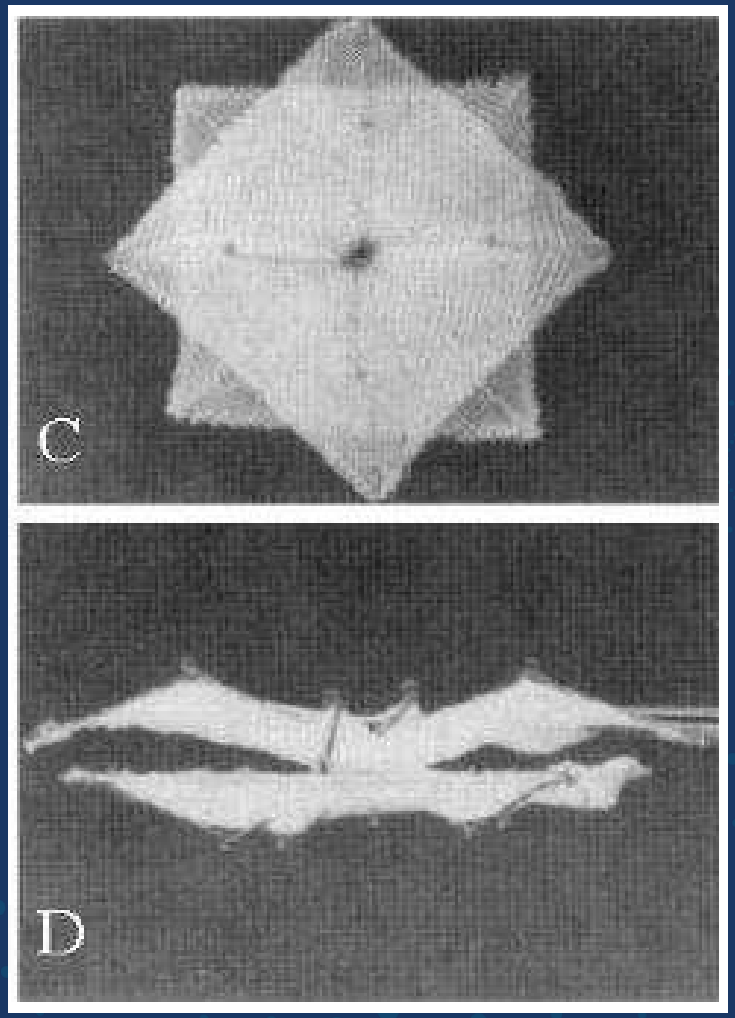
- A: double umbrella device
  - Polyurethane foam on hexagonal stainless steel frame (17mm device)
- B: Sideris buttoned device
  - Square sheet of polyurethane foam with diagonally oriented, independent wire arms and separate counter occluder (1997)



Rashkind WJ. Interventional cardiac catheterization in congenital heart disease. Int J Cardiol 1985;7:1-10

Initial attempts

- C & D: Bard clamshell device
  - Two opposing self-expanding umbrellas
  - Withdrawn from investigation due to arm fractures and unacceptably high incidence of residual shunts



Collection of initial studies….

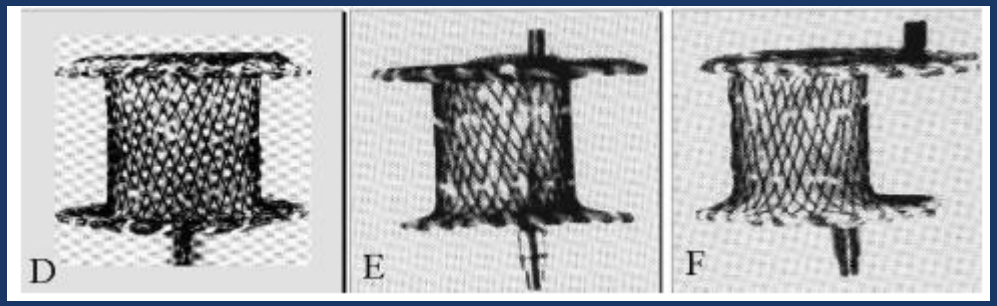
Table 1. Reports on transcather closure of ventricular septal defects in literature

Investigators	Time	Patient Number	Diagnosis	Devices	Closure Results and Complications
Lock JE, et al.[11]	1988	6	3 postinfraction, 2 peri VSDs, 1 musc VSD	Rashkind double umbrella	5/6 residual shunts, 4 pts died, 1 complete closure
O'Laughlin MP, et al [12]	1989	1	Residual VSD after Fontan	Rashkind double umbrella	Residual shunt became smaller
Bridges ND, et al [13]	1990	12	Congenital VSDs	Rashkind double umbrella	Residual shunt became smaller
Preminger TJ, et al. [14]	1994	7	Musc VSDs	Rashkind double umbrella	Residual shunt became smaller
van der Velde ME, et al [15]	1994	29	Musc VSDs	Bard Clamshell	17% complete closure
Rigby ML, et al. [16]	199[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Vogel M, et al. [17]	1996	1	Peri VSD	Rashkind double umbrella	Shunt persisted. Perforation of right aortic viave cusp needed surgery
Sideris EB, et al. [18]	1997	[illegible]	[illegible]	[illegible]	[illegible] deployed, 13/18 completely closed [illegible] AV3, 1 murmur recoured needing surgically device removal.
Lee EM, et al. [19]	1998	1	Postinfraction VSD	Amplatzer septal occluder	Trivial residual shunt
Tofeig M, et al. [21]	1998	1	Musc VSD	Amplatzer VSD occluder	Trivial residual shunt
Thanopoulos BD, et al. [22]	1999	6	Musc VSDs	Amplatzer VSD occluder	6 complete closure, 2 transient complete LBBB
Janorkar S, et al. [23]	1999	16	Musc VSDs	Rashkind double umbrella	2/16 died, 9/16, 5/16 and 5/16 had residual shunts immediately, 6 and 12 months after procedure
Latiff HA, et al. [24]	1999	1	Musc VSD	Gianturco coils	Small residual shunt
Kalra GS, et al. [25]	1999	30	28 peri VSDs, 2 musc VSDs	Rashkind double umbrella	87% successfully deployed, 30% residual shunts, 1 device embolization.
Rodes J, et al. [26]	2000	1	Musc VSD	Amplatzer duct occluder	Complete closure at 4 months

150 patients between 1988 to 2000

Zhong- Dong Du et al. Transcatheter Closure of Ventricular septal defects, https://test.fac.org.ar/scvc/llave/pediat/hijazi/hijazii.htm#tabla1

Refinement of technology



- Amplatzer devices
  - Comprised of “Nitinol”, 55% nickel and 45% titanium alloy with super-elasticity and biocompatability †
  - The Amplatzer muscular septal occluder is a double disc device
  - Nitinol thickness is 0.004” for devices <10mm & 0.005 for >10mm
  - The leading retention disc is 4mm greater than the waist and the proximal disc is 3mm larger than the waist
  - There is a securely sewn polyester thread into the two discs and waist of the device

† Liu X, Stice JD. Shape-memory alloys and their applications. J Appl Manufactur Syst 1990;3:65-72.

Amplatzer results

- Initially reported by Lee et al** in 1998
  - Deployment into a 50 year old male with a post-infarct VSD with complete occlusion & significant clinical improvement
  - ***Device was not FDA approved***
- Results of animal studies with surgically created VSD's demonstrated complete success and a 100% closure rate via perventricular approach ‡
- First human implantation, an 8 month old toddler after attempted surgical VSD closure

** *Lee EM, Roberts DH, Walsh KP. Transcatheter closure of a residual postmyocardial infarction ventricular septal defect with the Amplatzer septal occluder. Heart 1998;80(5):522-4.*

‡ *Amin Z, Gu X, Berry JM, et al. Periventricular closure of ventricular septal defects without cardiopulmonary bypass. Ann Thorac Surg 1999; 68: 149-154.*

Amplatzer results continued

- The first *transcatheter* approach was reported by Tofeig in 1999 ¥
  - 5 year old female with a mid-muscular defect .
  - 3 months post implantation a 1mm residual shunt was noted with excellent clinical improvement
- Largest cohort reported was published in 2000 by Hijazi et al⁒ with excellent closure rates and 100% complete occlusion at 6 month follow-up:
  - Noted complication/ observation was transient arrhythmia noted during and immediately post procedure

¥ Tofeig M, et al . Transcatheter closure of a mid-muscular ventricular septal defect with an Amplatzer VSD occlusion device. Heart 1999; 81: 438-440.

⁒ Hijazi ZM, et al. Transcatheter closure of single muscular ventricular septal defects using the Amplatzer Muscular VSD Occluder: Initial results and technical considerations. Cathet Cardiovasc Interv 2000;49:167-172

Advantages of the Amplatzer device

- Simple user-friendly delivery system
- Requires small sheaths
- Transcatheter device deployment & release from prograde or retrograde approach as well as perventricular
- Multiple device sizes
- Ability to reposition/ recapture device prior to release

Prior to intervention

- Delineation of patient candidacy is crucial
  - A complete hemodynamic assessment
    - +/- pulmonary hypertension study to delineate pulmonary vasoreactivity
- Imaging
  - Transesophageal or intracardiac echocardiography is important prior to, during and post device release (either in the cath lab or in the OR)
- Approach often dictated by:
  - Patient size
  - Defect location
  - Defect size
  - Vascular access history

Approach: *antegrade deployment & release*

- Establishment of an atrioventricular loop (A-V loop):
  - Used for membranous, muscular, post-surgical and post infarct defects
- A retrograde passage of a guidewire using either an angled glide catheter or Judkins right coronary catheter allowing for the an 0.035” exchange length guidewire snared from the pulmonary artery or the superior vena cava to be externalized to form the “A-V loop”
- The delivery catheter is then advanced over the wire from the venous access point into the descending aorta
- Transesophageal echocardiography can facilitate deployment of the device and interrogate the relationship of the surrounding structures with the device and document residual shunts

Approach: *retrograde deployment & release*

- An angled glide catheter or Judkins right coronary catheter is used to cross the defect
- An 0.035” guidewire is used to the externalize the catheter and allow for the introduction of the delivery sheath or coronary guide-catheter
- With adjunctive imaging, transesophageal echocardiography, the distal retention disc is deployed in the right ventricle
- The delivery sheath and device are retracted to the septum and the sheath is retracted to deploy the proximal disc

Approach: *hybrid/ perventricular*

- A sternotomy or limited sternotomy is performed to allow for exposure of the right ventricular free wall and placement of a purse-string suture placement for sheath introduction
- Transesophageal echocardiography or epicardial echocardiography can help guide wire crossing allowing for accurate positioning & advancement of a sheath into the left ventricle
- Deployment is visualized with echocardiography and defect & device relationship is reviewed

Outcomes

CATHETERIZATION & CARDIOVASCUL

Pediatric Intervention

Catheter closu
using the new
clinical experi

Ziyad M. Hijazi MD, Aktham Hiari MD, Qi-L

First published: 12 July

CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS

Pediatric and Congenital Heart Disease

Initial human experience with the Amplatzer perimembranous ventricular septal occluder device

John L. Bass MD, G.S. Kalra MD, Ramesh Arora MD, Jozef Masura MD, Pavlo Gavora MD, Basil D. Thanopoulos MD, William Torres MD, Horst Sievert MD, Mario Carminati MD ... See all authors

First published: 27 January 2003 | https://doi.org/10.1002/ccd.10406 | Cited by: 104

Journal of the American College of Cardiology

Volume 47, Issue 2, January 2006
DOI: 10.1016/j.jacc.2005.09.028

PDF Article

Transcatheter Closure of Perimembranous Ventricular Septal Defects Using the New Amplatzer Membranous VSD Occluder

Results of the U.S. Phase I Trial

Yun-Ching Fu, John Bass, Zahid Amin, Wolfgang Radtke, John P. Cheatham, William E. Hellenbrand, David Balzer, Qi-Ling Cao and Ziyad M. Hijazi

Outcomes

- Amplatzer membranous VSD occluder
  - Phase I clinical trial revealed a 91% closure rate with 96% complete closure rate at 6 month follow-up
  - One case of congenital heart block (CHB)

AMPLATZER Membranous VSD Occluder

- Self-expandable Nitinol mesh with polyester patches
- Non-concentric design to avoid interference with the aortic valve
- Sizes: 4 -18mm

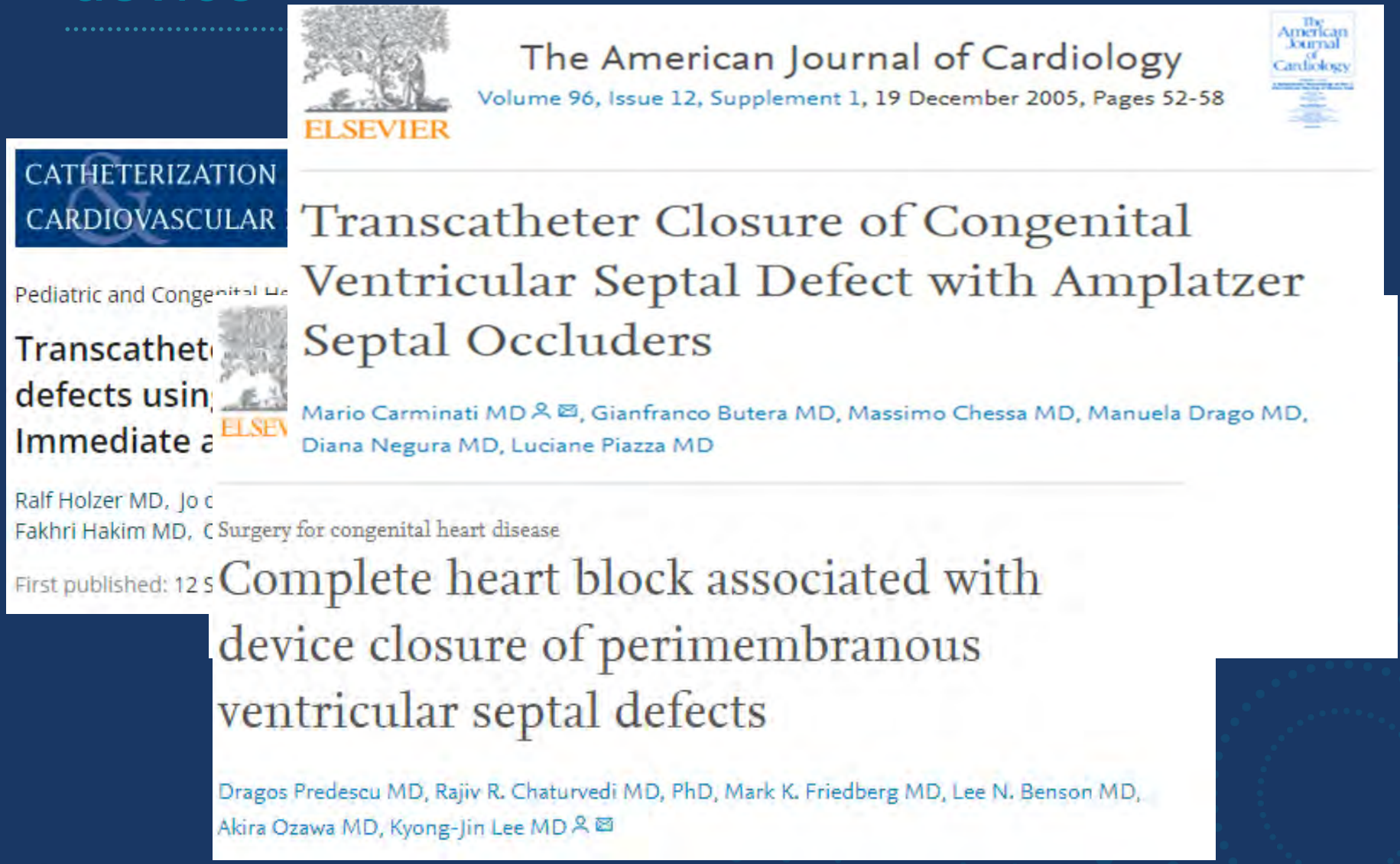
Legend

Device Size (Waist = A)
Right Ventricular Disc (B)
Left Ventricular Disc (C)

Device Size (Waist = A)	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
RV Disc (B)	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
LV Disc (C)	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

** Bass JL, et al. Initial human experience with Amplatzer perimembranous ventricular septal occluder device. Catheter Cardiovas Interv 2003;58(2)238-45

Further investigations with membranous device



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The American Journal of Cardiology

Volume 96, Issue 12, Supplement 1, 19 December 2005, Pages 52-58

CATHETERIZATION & CARDIOVASCULAR

Pediatric and Congenital He

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Ralf Holzer MD, Jo
Fakhri Hakim MD,

First published: 12 S

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Transcatheter Closure of Congenital Ventricular Septal Defect with Amplatzer Septal Occluders

Mario Carminati MD, Gianfranco Butera MD, Massimo Chessa MD, Manuela Drago MD, Diana Negura MD, Luciane Piazza MD

Surgery for congenital heart disease

Complete heart block associated with device closure of perimembranous ventricular septal defects

Dragos Predescu MD, Rajiv R. Chaturvedi MD, PhD, Mark K. Friedberg MD, Lee N. Benson MD, Akira Ozawa MD, Kyong-Jin Lee MD

Outcomes

- The longer term follow-up of patients began to identify an increasing incidence of post-procedural heart block.
- Rates of heart block between 2%-22%
- Predescu's investigation postulated the decreasing patient size was an important factor although it was difficult to identify this as the sole risk factor
- Given the identified concerns for unpredictable and late onset of heart block, the pmVSD device **was not approved** for use by the FDA

Modifcations for pmVSD device

CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS

Pediatric and Congenital Heart Disease | Free Access

Transcatheter closure of perimembranous ventricular septal defect with the Amplatzer® membranous VSD occluder 2: Initial world experience and one-year follow-up

Apostolos Tzikas MD, PhD, Reda Ibrahim MD, Daniel Velasco-Sanchez MD, Xavier Freixa MD, PhD, Marcela Alburquenque MD, Paul Khairy MD, PhD, John L. Bass MD, Juan Ramirez MD ... See all authors

First published: 22 May 2013 | https://doi.org/10.1002/ccd.25004 | Cited by: 15

- A structural modification reducing the radial force and increasing device stability performed well in a small study of 19 patients.
- Successful closure in 95% of patients with appreciable no aortic insufficiency, tricuspid valve insufficiency and no instances of heart block at 1 year follow-up

Amplatzer muscular occluder

New Device for Closure of Muscular

CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS

Pediatric Intervention

Transcatheter closure of single muscular ventricular septal defects using the Amplatzer muscular VSD occluder: Initial results and technical considerations

Ziyad M. Hijazi MD ✉, Fakhri Hakim MD, Fadel Al-Fadley MD, Jasim Abdelhamid MD, Qi-Ling Cao MD

First published: 20 January 2000 |
https://doi.org/10.1002/(SICI)1522-726X(200002)49:2<167::AID-CCD11>3.0.CO;2-S | Cited by: 123

- 2004 brought about the results of a multi-institutional registry

2004: Multicenter Registry

Journal of the American College of Cardiology

Volume 43, Issue 7, April 2004
DOI: 10.1016/j.jacc.2003.10.047

PDF Article

Device closure of muscular ventricular septal defects using the Amplatzer muscular ventricular septal defect occluder

Immediate and mid-term results of a U.S. registry

Ralf Holzer, David Balzer, Qi-Ling Cao, Ken Lock, Ziyad M Hijazi and Amplatzer Muscular Ventricular Septal Defect Investigators

- Cohort: 75 patients (83 procedures percutanesous & perventricular)
- Median age: 1.4 years (range 0.1-54 years)
- Defect size: median 7mm (3mm-16mm)
- Outome data:
  - Procedural success: 87%
  - Residual shunt (@ 12 mos): 8%
  - Procedure related complication: 10%

2004: Multicenter Registry

- Major adverse events:
  - 2 procedure related deaths (2.7%)
  - Conduction anomalies 20% with no incidence of heart block requiring pacemaker
  - Device embolization – 2 patient
  - Cardiac perforation – 1 patient

- Results:
  - 24 hour post-procedural occlusion rate: 47.2%
  - 6 month post-procedural occlusion rate: 69.6%
  - 12 month post-procedural occlusion rate: 92.3%

- **Device received FDA approval in 2007**

Off-label occlusive devices…

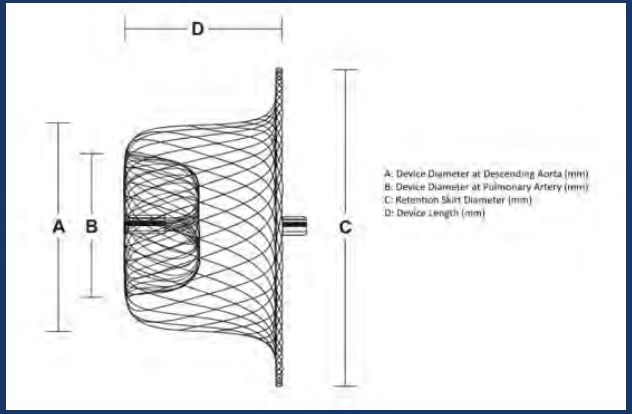
CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS

Pediatric and Congenital Heart Disease

Closure of perimembranous ventricular septal defects with aneurysmal tissue using the amplazter duct occluder I: Lessons learned and medium term follow up†

Howaida G. El Said MD, Andras Bratincsak MD, PHD, Brent M. Gordon MD, John W. Moore MD, MPH

First published: 20 August 2012 | https://doi.org/10.1002/ccd.23074 | Cited by: 29



- 19 of 21 patients with procedural success rate (90%)
- Median: F/U 1.9 yrs
- 83% with no or trivial shunt
- 94.7% without clinical complaints or signs of heart failure

Pictoral of ADO I implantation

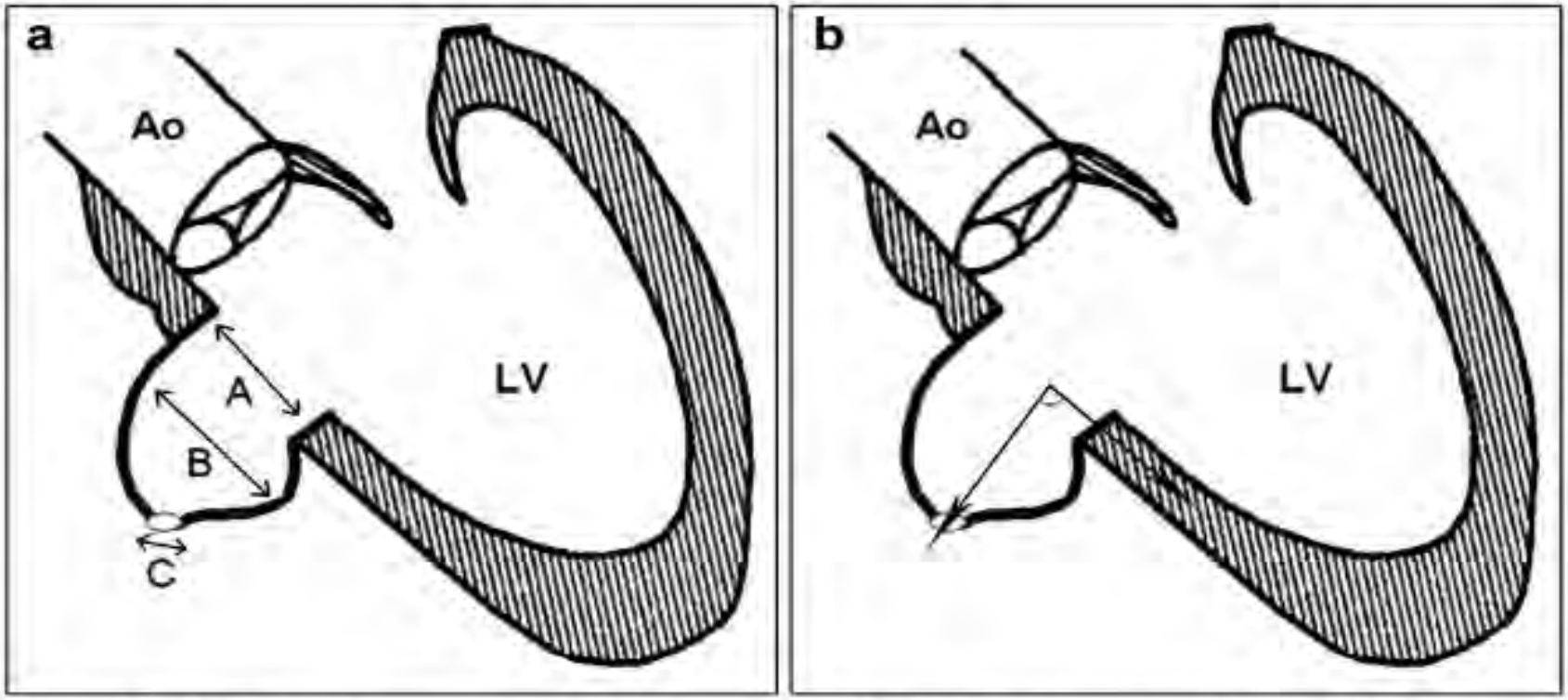
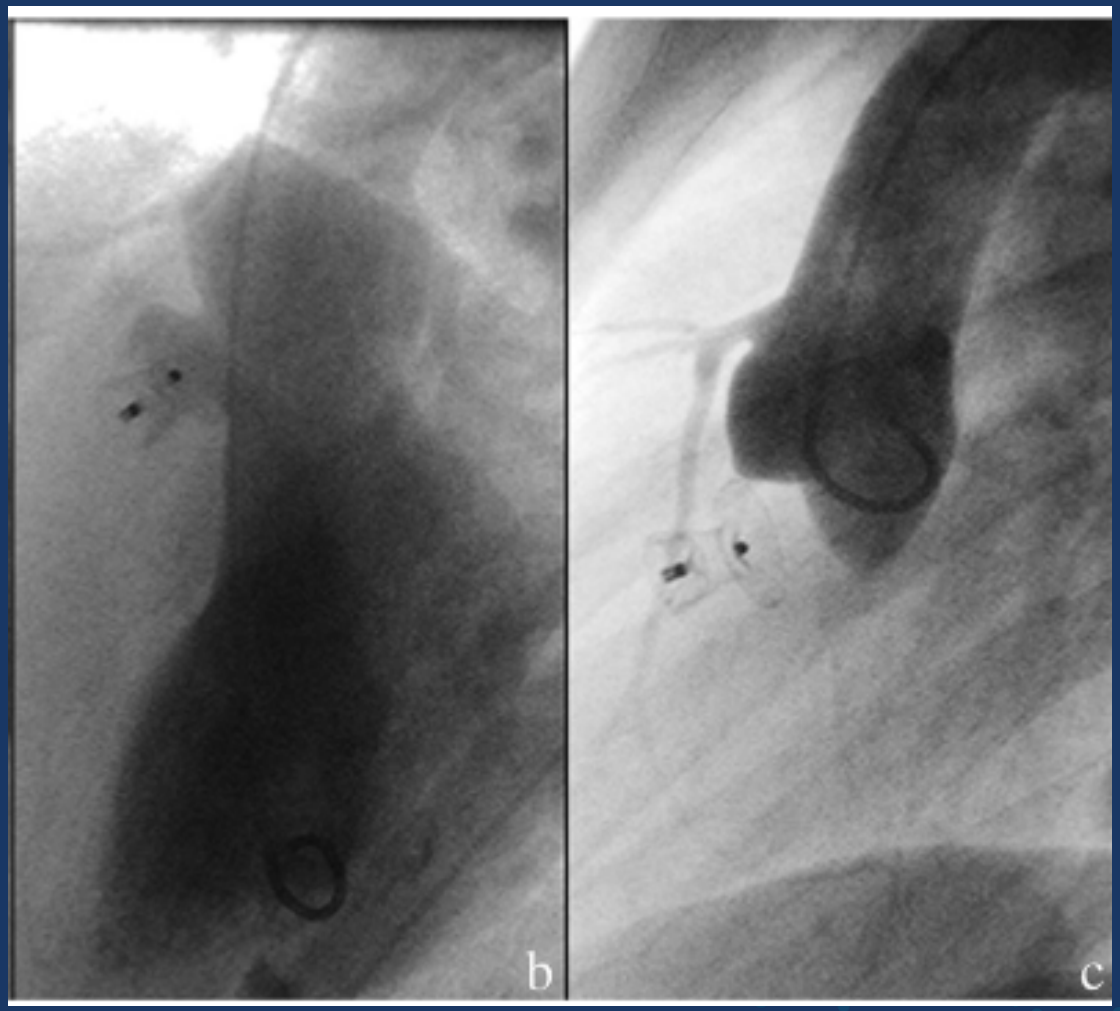


Fig. 1. Pictorial representation of the anatomy of PMVSD with aneurismal tissue. (a) Illustrates where the measurements were taken. A: measurement at the left ventricular opening of the VSD. B: largest diameter of the aneurysm, usually in the mid-segment of the aneurysmal socket. C: measurement at the right ventricular opening of the VSD aneurysm, usually the smallest diameter of the defect. (b) Illustrates the angle between the opening of the VSD and the interventricular septum.

(b) Angiogram in the same projection demonstrating the ADO I in the aneurysm with the whole retention disc well within the aneurysm.

El Said HG et al. Closure of perimembranous VSD with aneurysmal tissue using the Amplatzer Duct Occlude I: Lessons learned and Medium term follow-up. Catheter Cardiovasc Interv. 2012;80(6):900

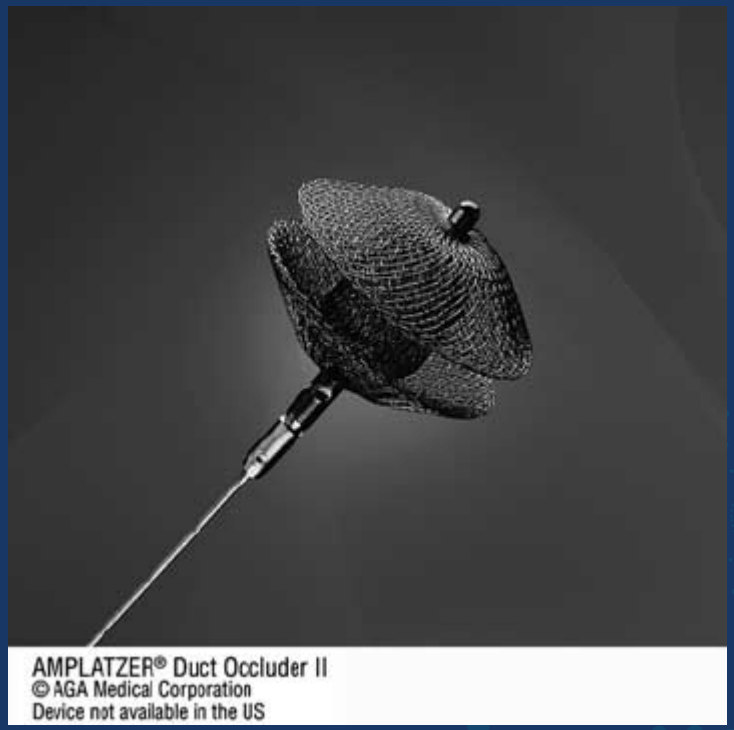
Off-label occlusive devices…



El Said HG et al. Closure of perimembranous VSD with aneurysmal tissue using the Amplatzer Duct Occluder I: Lessons learned and Medium term follow-up. Catheter Cardiovasc Interv. 2012;80(6):900

Off-label occlusive devices…

- Amplatzer Ductal Occluder II (ADOII)
  - Procedural success rates of 90%¥ - 93.5%#
  - Complete occlusion rates of 93.6% to 95% at f/u
  - Rare heart block incidence ‡



Kanaan M, et al. Follow-up with Interventional closure of VSD with ADOII. *Pediatr Cardio* 2015:36;379-385

¥ El Sisi A, et al. Perimembranous VSD closure: choosing between ADOI & II. *Pediatr Cardiol* 2017;38(3):596-602

‡ Ghosh S, et al. Complete heart block following transcatheter closure of pmVSD using ADOII. *Catheter Cardiovasc Interv* 2018;92(5):921-924

Off-label occlusive devices…

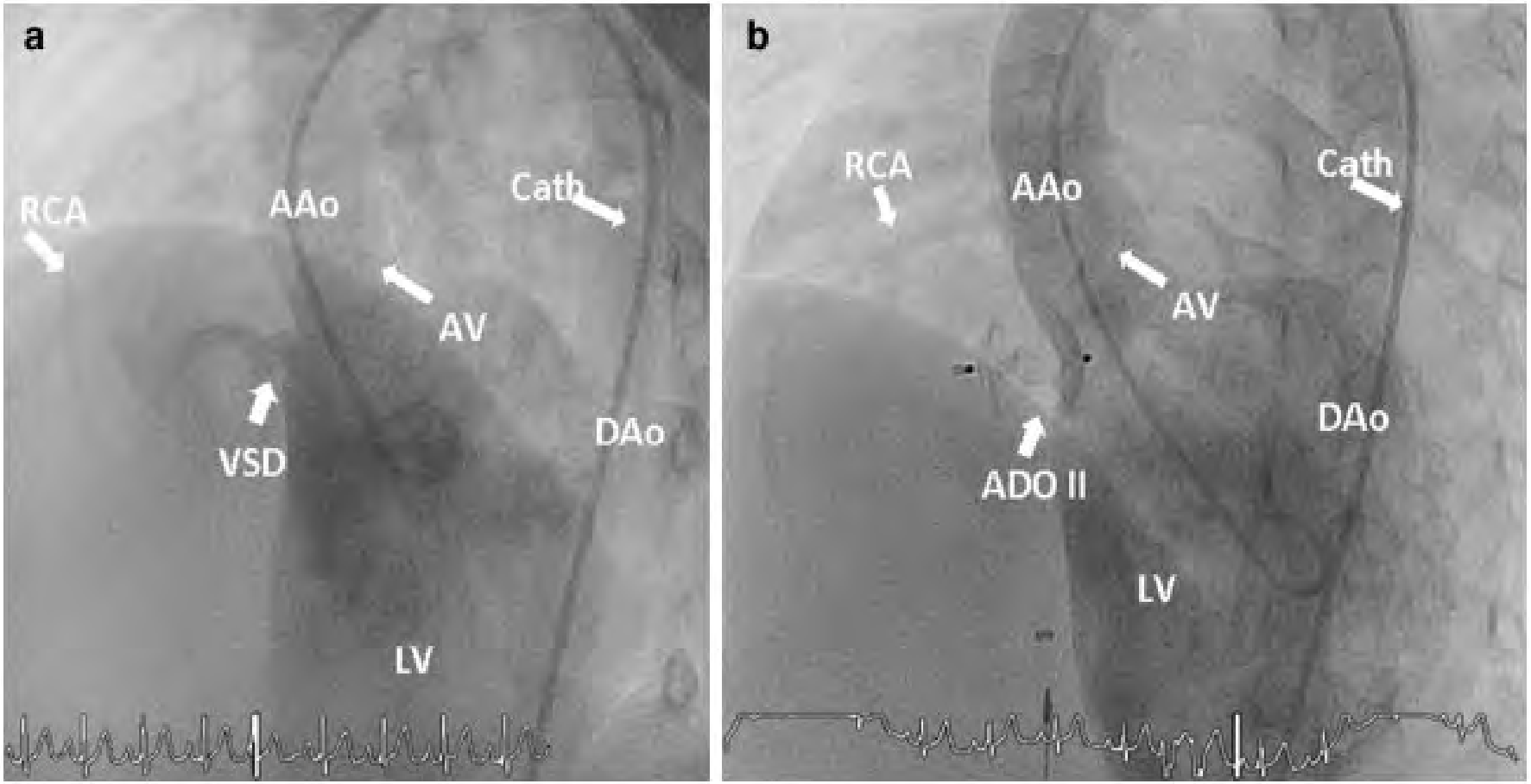


Fig. 1 Levogramm (4-year-old boy) in 60° RAO projection with VSD: **a** left to right shunt; **b** after closure of the VSD with ADO II (5/6 mm), no residual shunt was seen. *RCA* right coronary artery, *AV* aortic valve, *Cath* angiography catheter, *LV* left ventricle

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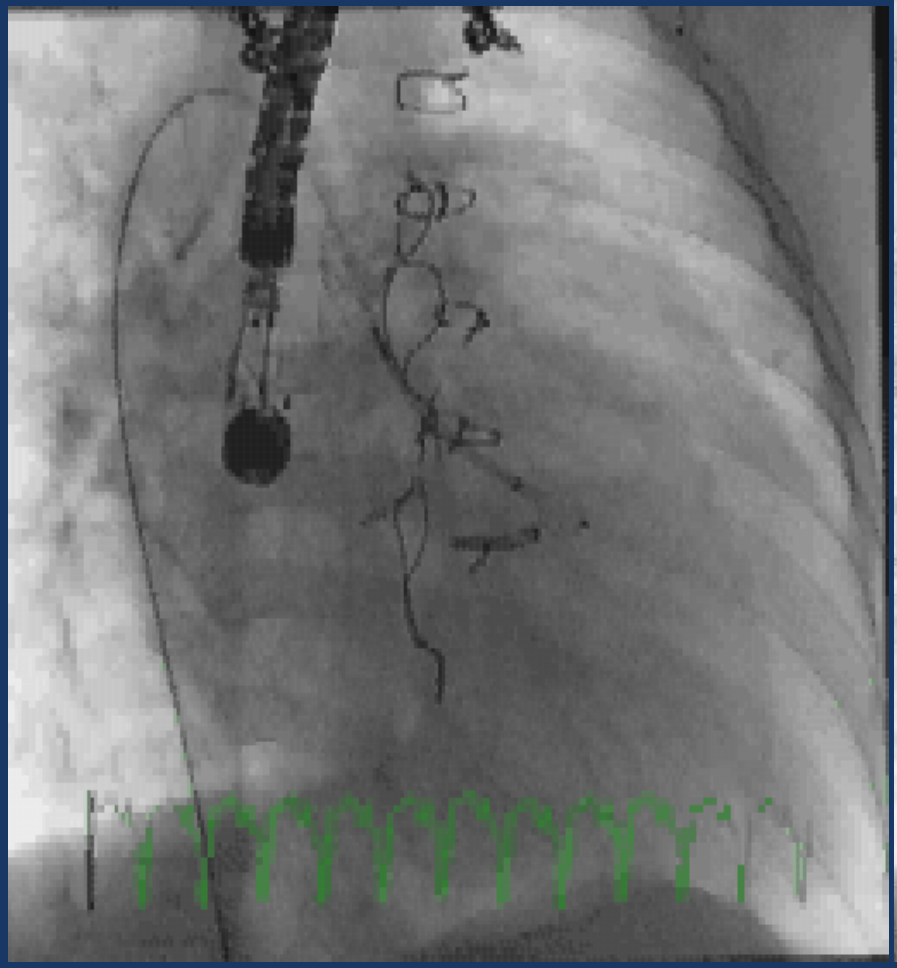
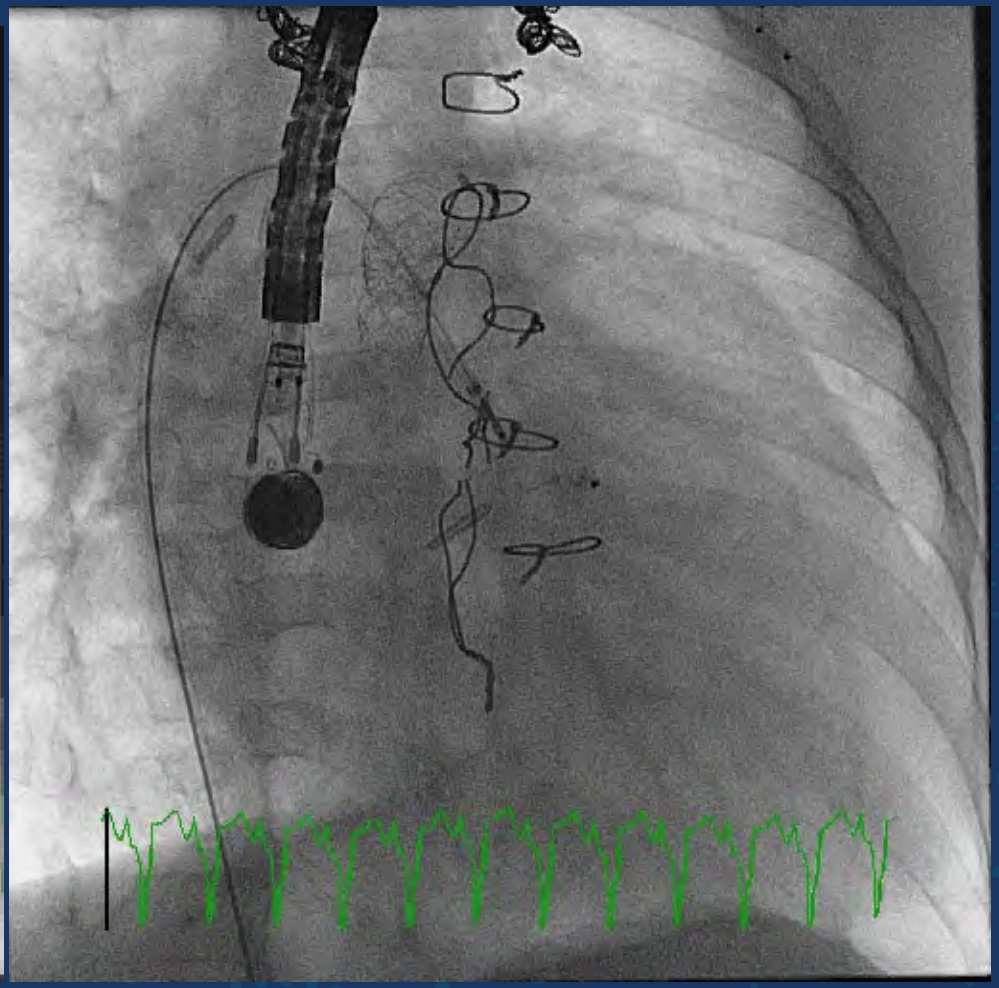
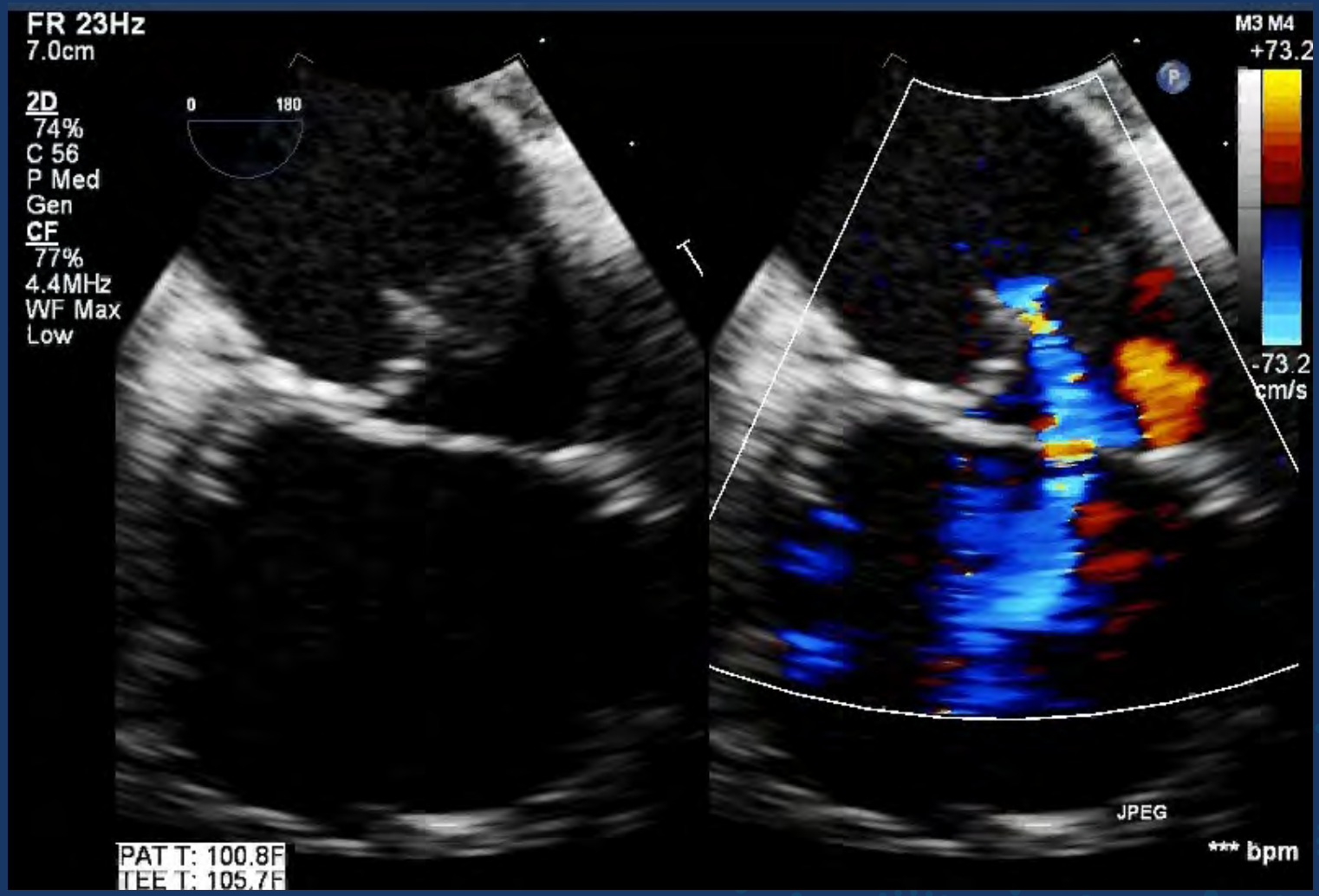
Kanaan M, et al. Follow-up with Interventional closure of VSD with ADOII. *Pediatr Cardio* 2015:36;379-385

ADOII deployment in retrograde fashion





TEE imaging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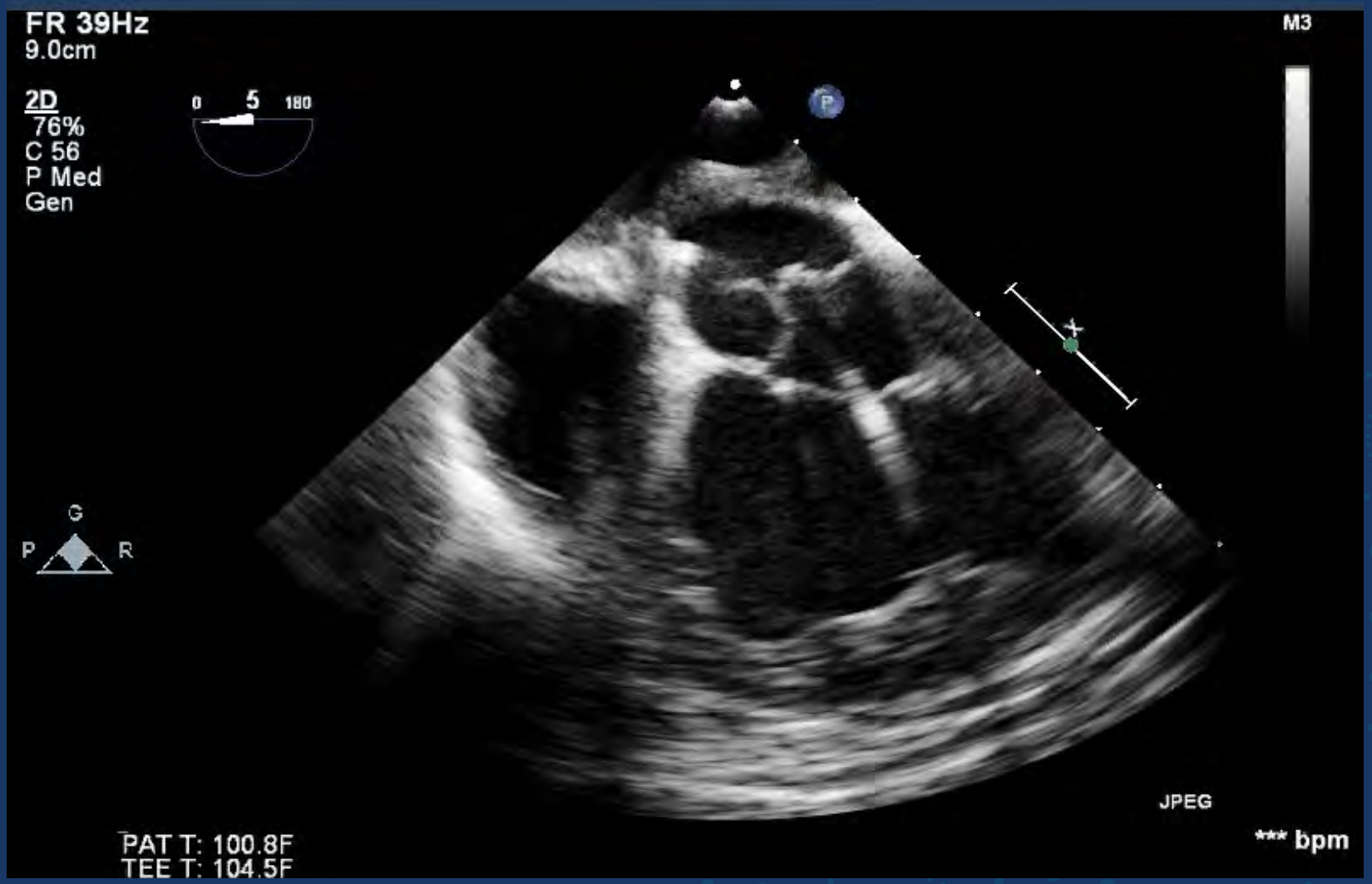
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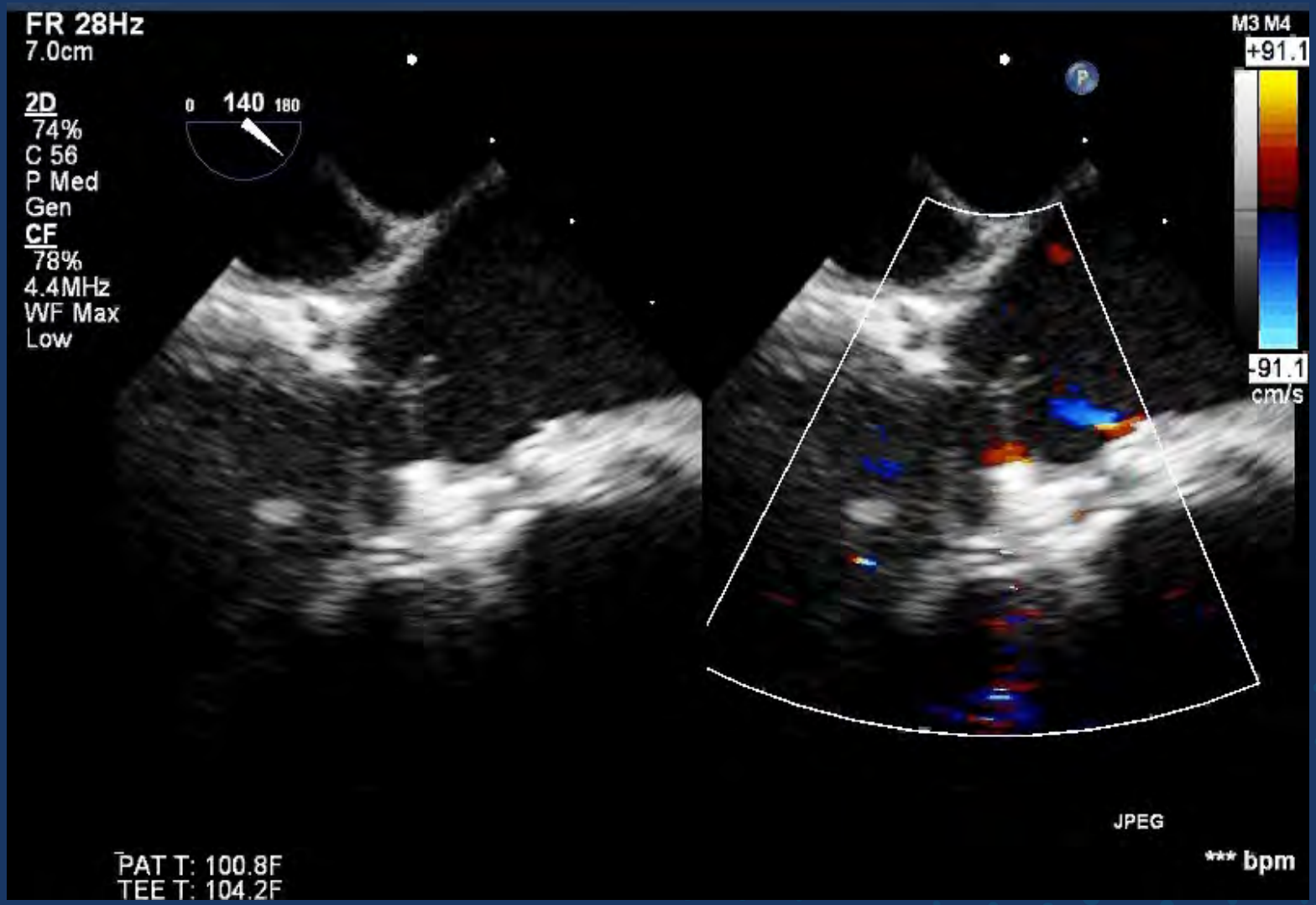
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Adverse events

- Conduction abnormalities
  - Risk factors have been difficult to identify
  - Postulated mechanism is the radial force of the device onto the conduction system
  - *Carminati et al*[≠], have proposed that smaller patients and device oversizing could lend to increased incidence of heart block
  - *Yang et al* [†] *,* suggested that an increased distance from the aortic valve, approximating the septal rim and tricuspid valve tended towards heart block

† Yang et al. Risk factors and outcomes of post-procedureheart blocks after transcatheter device closure of perimembranous VSD. JACC Cardiovasc Interv 2012;5(4):422-7

≠ Carminati et al. Transcatheter closure of pmVSD: early and long-term results. J Am Colle cardiol 2007;50(12):1189-95

Adverse events

- Hemolysis
  - 1-2% of cases
  - Self-resolving in 48-72 hours
  - Rarely need transfusions or referral for surgical explantation
- Aortic valve distortion
  - 9% of patients
  - Minimum distance estimated at 2mm
  - Careful considerations taken when using ADOII or Amplatzer mVSD occluder
  - Deployment within aneurysmal tissue is likely to lessen aortic valve distortion

Adverse events

- Endocarditis
  - Rare cases of endocarditis have been reported
  - Considered a serious adverse event if unable to be cleared medically
  - Risk factors have been difficult to identify

- Device embolization
  - Considered to be 1-2% of cases
  - Can typically be retrieved via transcatheter methods
  - Rarely require surgical intervention

Patient selection

- Patient fulfillment of criteria for an intervention
  - Elevated Qp/Qs
  - Echocardiographic criteria for left heart volume overload
  - Failure to thrive
  - Congestive heart failure (poor weight gain/ increasing medical therapy)
  - Discussion with CT surgical staff

Defect identification

- Aneurysmal tissue or “windsock” appearance
- Defect location
  - Apical
  - Mid-muscular
  - Anterior/ posterior
  - Sub-aortic rim tissue amount

Summary

- Percutaneous/ perventricular occlusion of ventricular septal defects can be performed safely with a variety of occlusive devices
- Currently, there is only one approved muscular VSD device in the United States
- “off-label” devices have been used to occlude ventricular septal defects
- Complications can occur:
  - Heart block or conduction anomalies
  - Hemolysis
  - Device embolization
  - Aortic valve distortion

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