VALVE FOR LIFE
An EAPCI initiative

Transcatheter closure of post-surgical paravalvular leaks

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ŚLĄSKI UNIWERSYTET MEDYCZNY
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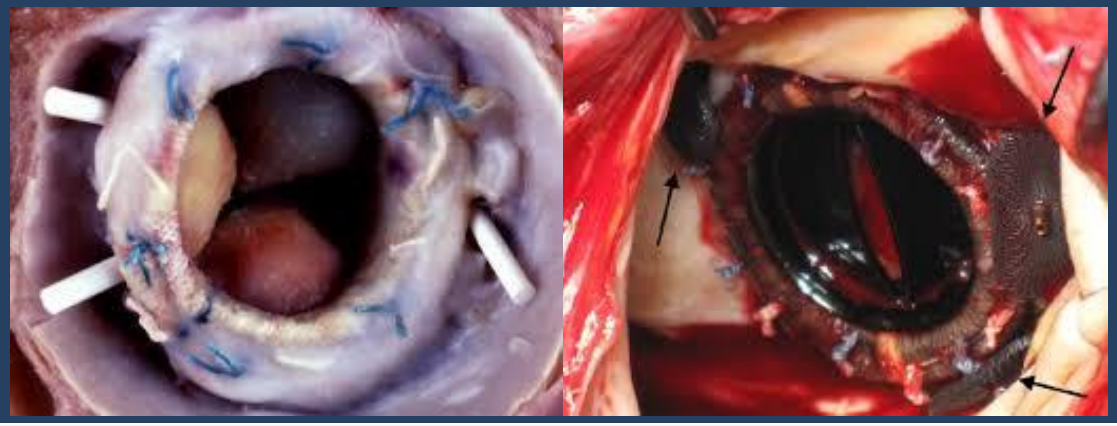
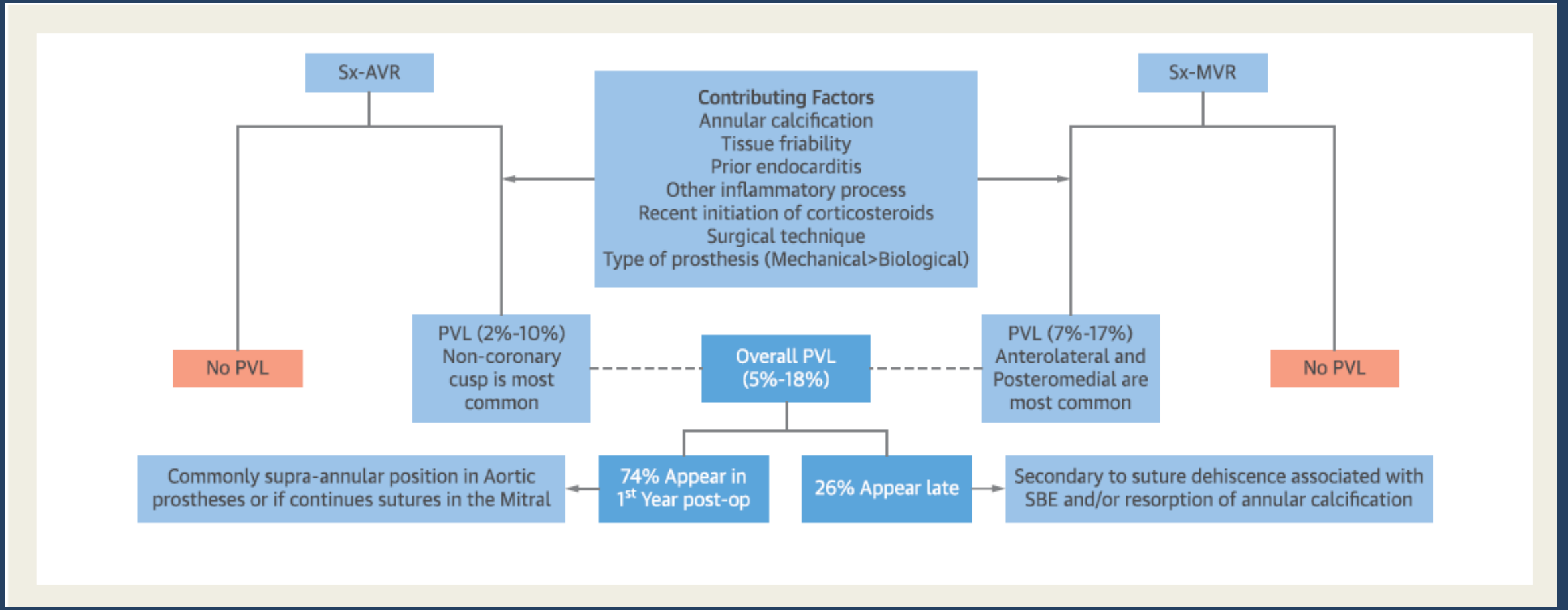
Disclosure Statement of Financial Interest

I, Wojciech Wojakowski: DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Transcatheter paravalvular leak closure





Eur Heart J. 2018 Apr 14;39(15):1224-1245

Transcatheter paravalvular leak closure

Redo surgery
- Valve rocking/instability
- Active IE
- Need for other valvuar/coronary procedures (CABG)

PVL

Tnanscatheter closure (IIa, B)
- Heart failure
- Hemolytic anemia
- High surgical risk
- Appropriate anatmy
- Experienced centers

2a	B-NR	3. In patients with prosthetic paravalvular regurgitation with the following: 1) either intractable hemolysis or NYHA class III or IV symptoms and 2) who are at high or prohibitive surgical risk and 3) have anatomic features suitable for catheter-based therapy, percutaneous repair of paravalvular leak is reasonable when performed at a Comprehensive Valve Center (5-9).

ACC/AHA 2020

Transcatheter closure should be considered for suitable paravalvular leaks with clinically significant regurgitation and/or haemolysis in patients at high or prohibitive surgical risk.[547]	IIa	B
Decision on transcatheter or surgical closure of clinically significant paravalvular leaks should be considered based on patient risk status, leak morphology, and local expertise.	IIa	C

ESC/EACTS 2021

- HF symptoms (NYHA II-IV class) despite optimal pharmacotherapy and/or hemolysis
- ≥ 2+ PVL jet in color Doppler mapping

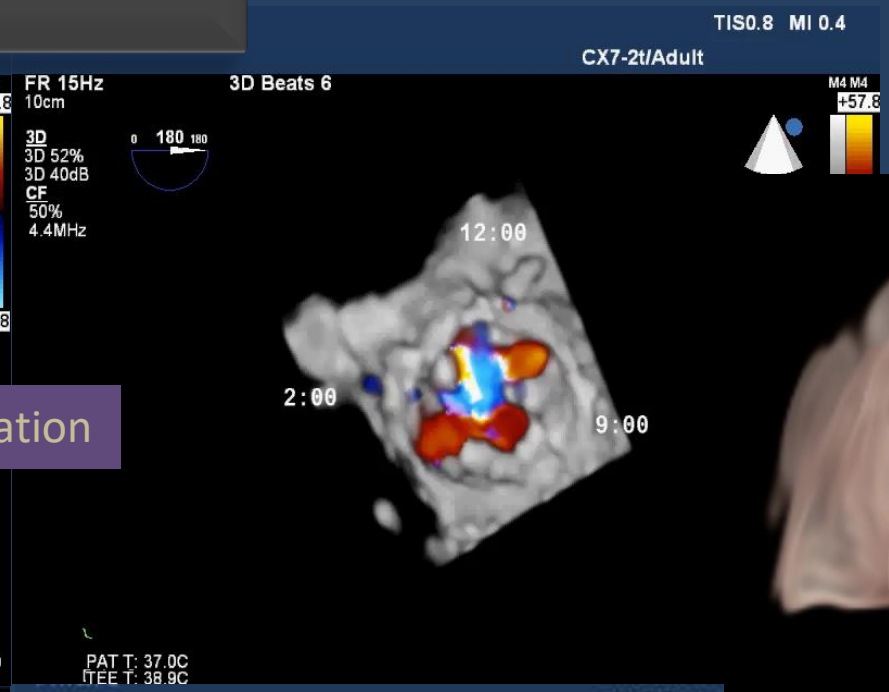
plus at least one of the following:

Mitral PVL:
- systolic flow reversal in at least one PV
- increased calculated PAP
- lack of left atrium (LA) size reduction after MVR or recurrent and progressive LA dilation
- forward transprosthetic flow velocity higher than expected with given prosthesis type and size, provided normal function of prosthetic leaflets

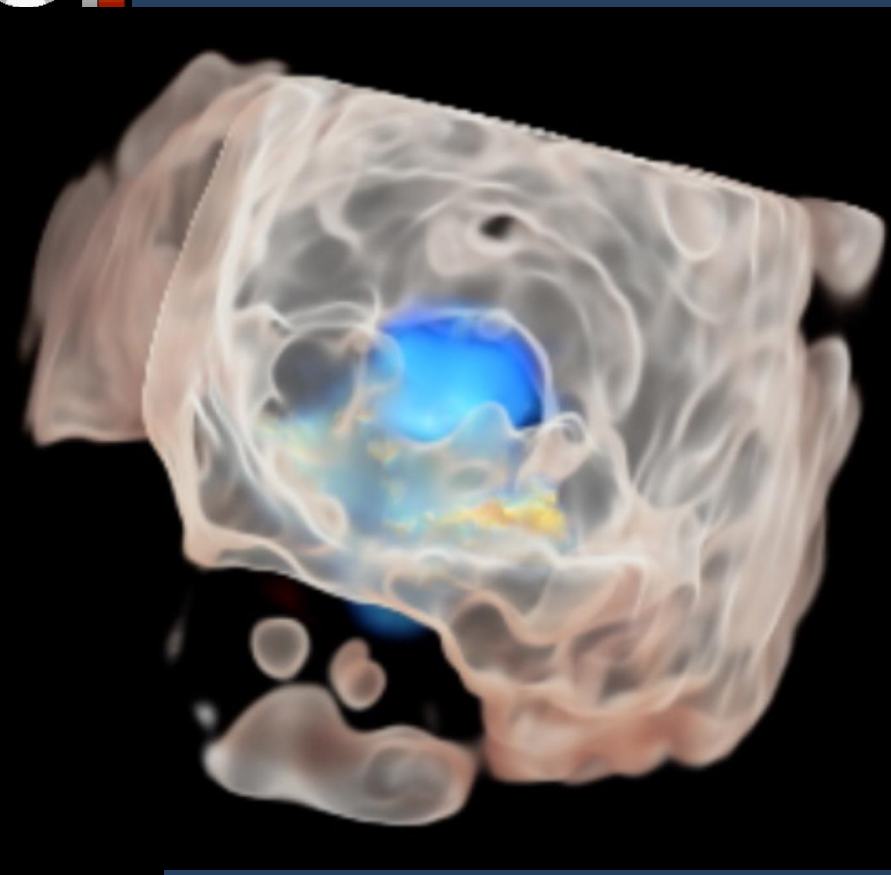
Aortic PVL:
- holodiastolic flow reversal in the proximal part of descending aorta
- lack of left ventricle (LV) size reduction after aortic valve replacement (AVR)
- recurrent and progressive LV dilation in postoperative course
- forward transprosthetic flow velocity higher than expected with given prosthesis type and size, provided normal function of prosthetic leaflets

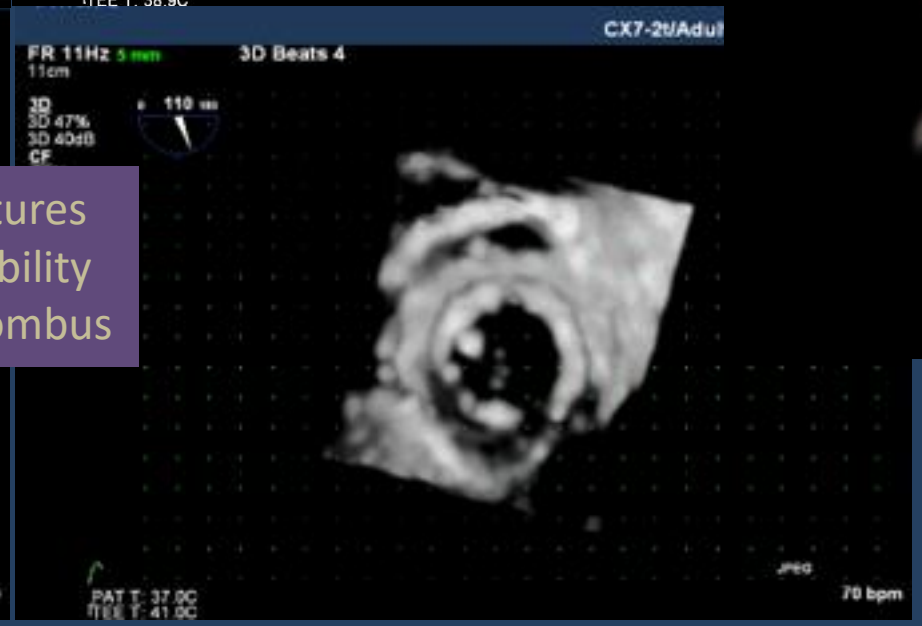
Eur Heart J. 2018 Apr 14;39(15):1224-1245
Transcatheter Paravalvular Leak Closure, Springer 2017

Diagnosis



Location





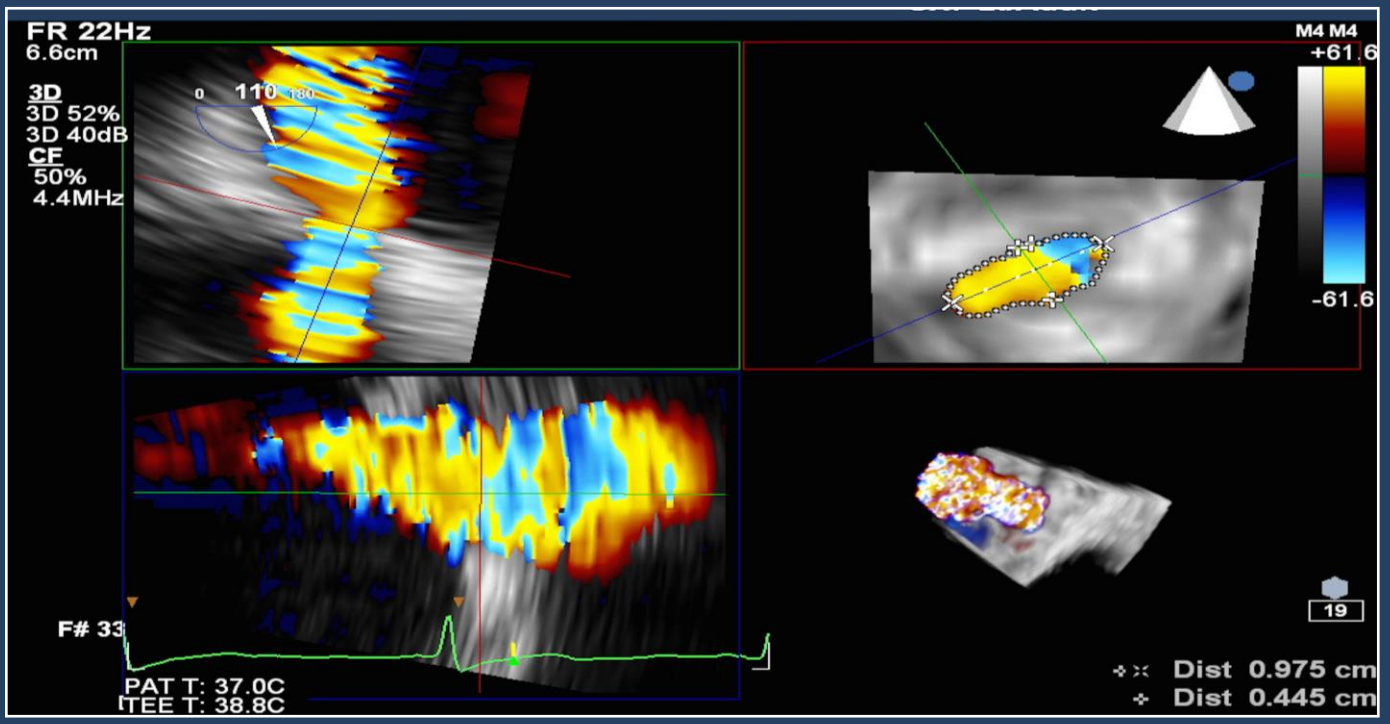
Sutures
Stability
Thrombus

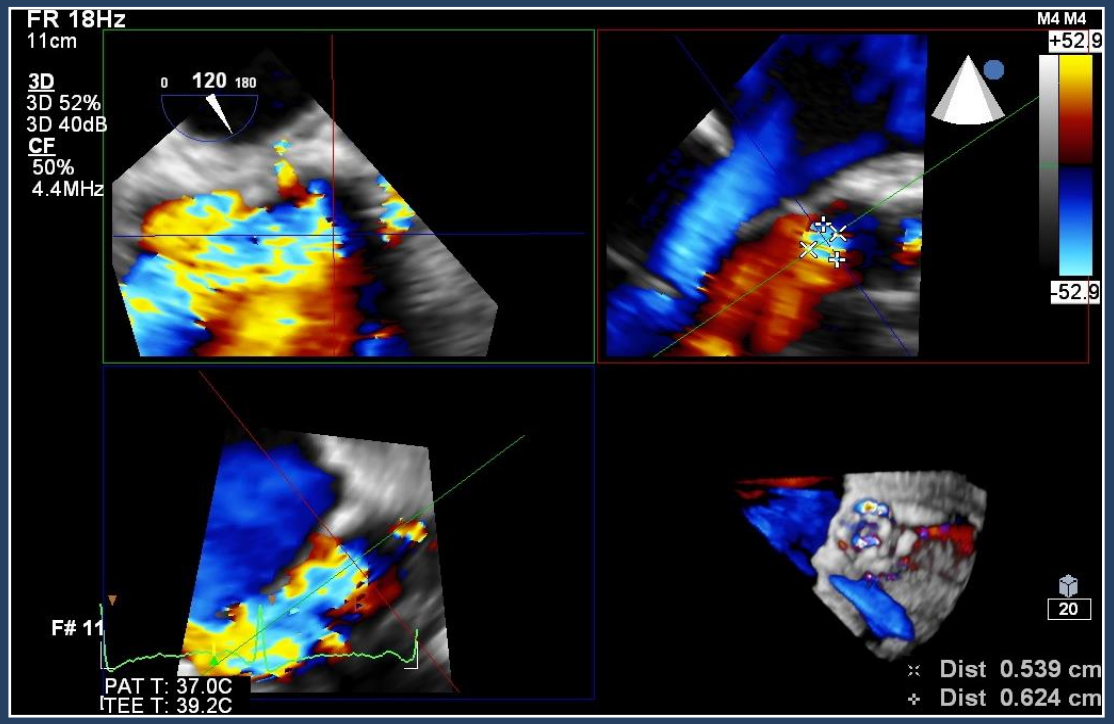
Sizing

MV

CSA in 3D TEE MPR

AV

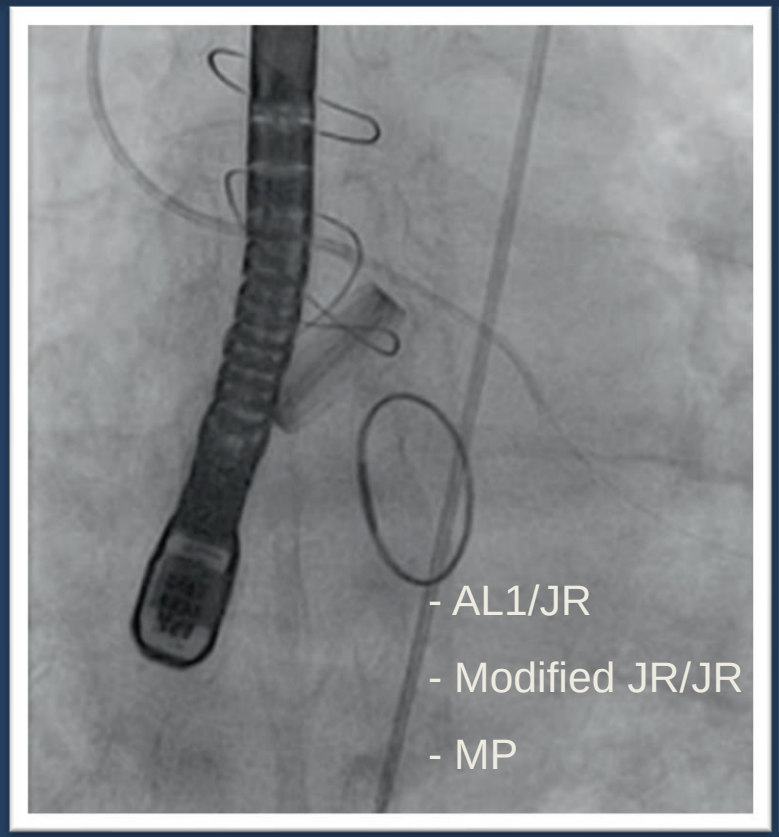


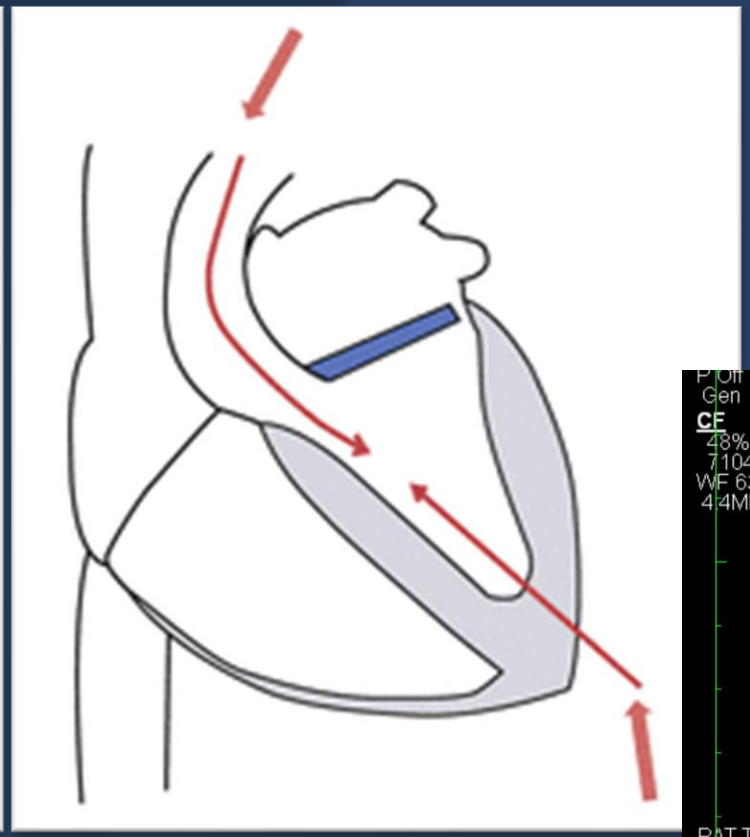


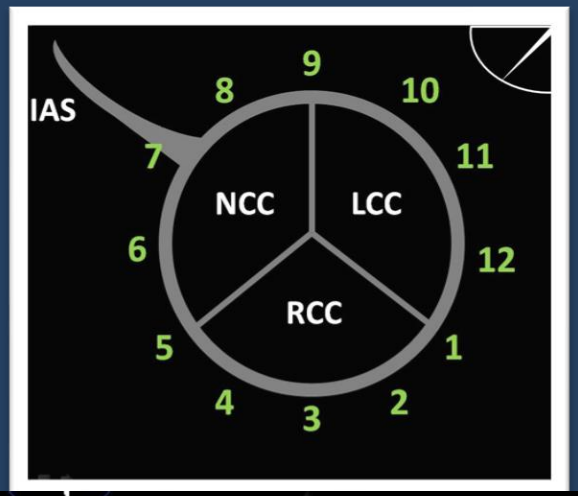
Technique	Benefit
Zoom mode + CD acquisition of small volume of tissue containing PVL channel only	Highest possible volume rate
Single-beat acquisition only	Avoidance of stitching artifacts
Multiplanar presentation	Measurements of CSA of VC, minimum and maximum dimensions of VC, channel length

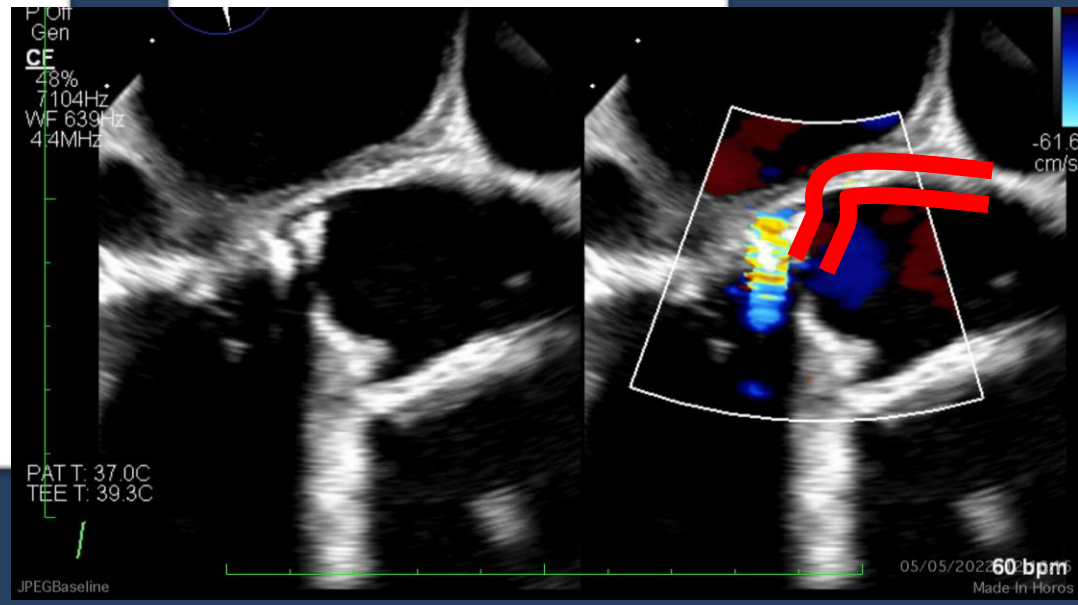
Pysz P, Kozłowski M, Malczewska M, Adamczyk-Filipek E, Wojakowski W, Smolka G. Adv Int Cardiol. 2019;15(2):203-210.

Aortic PVL





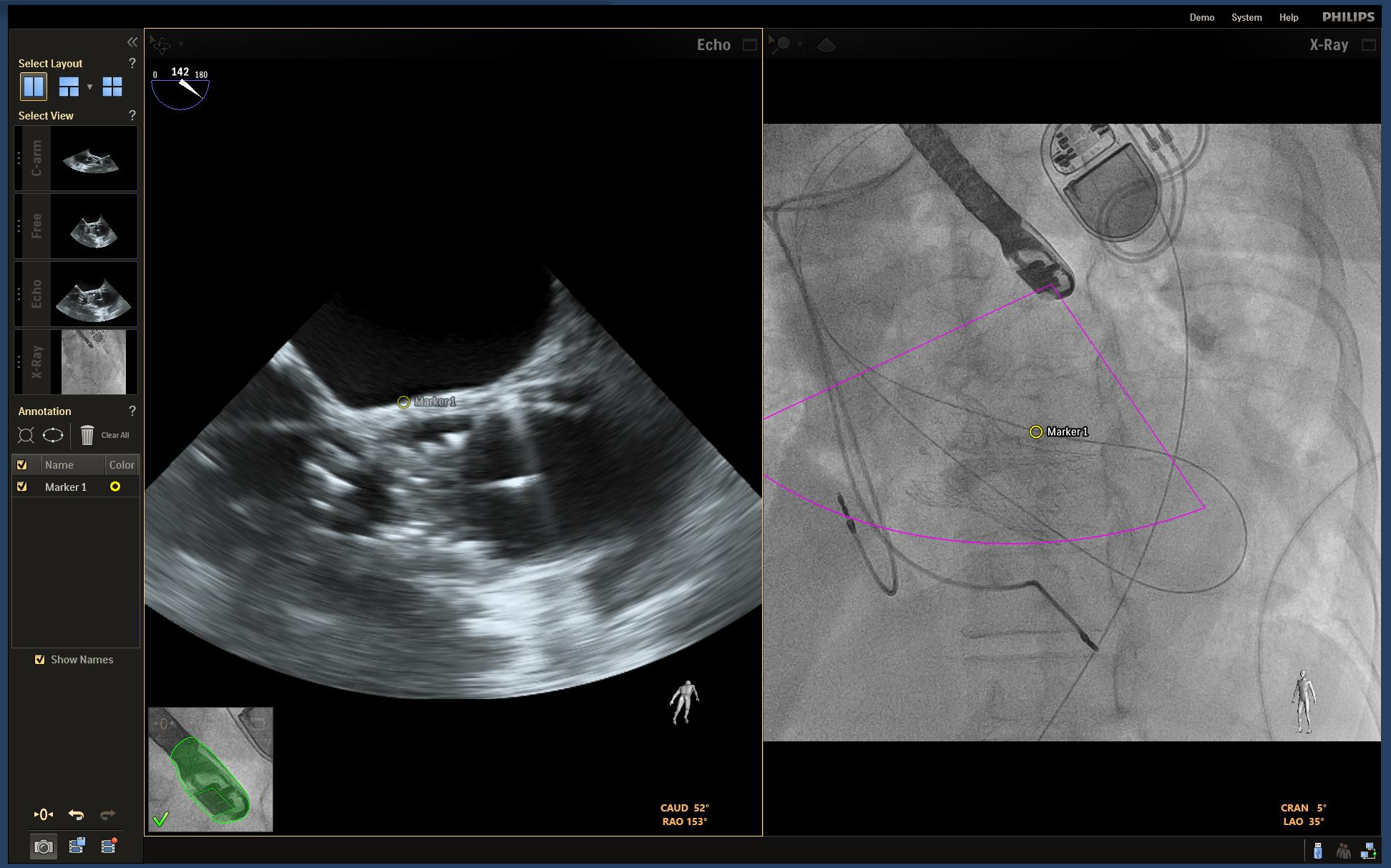




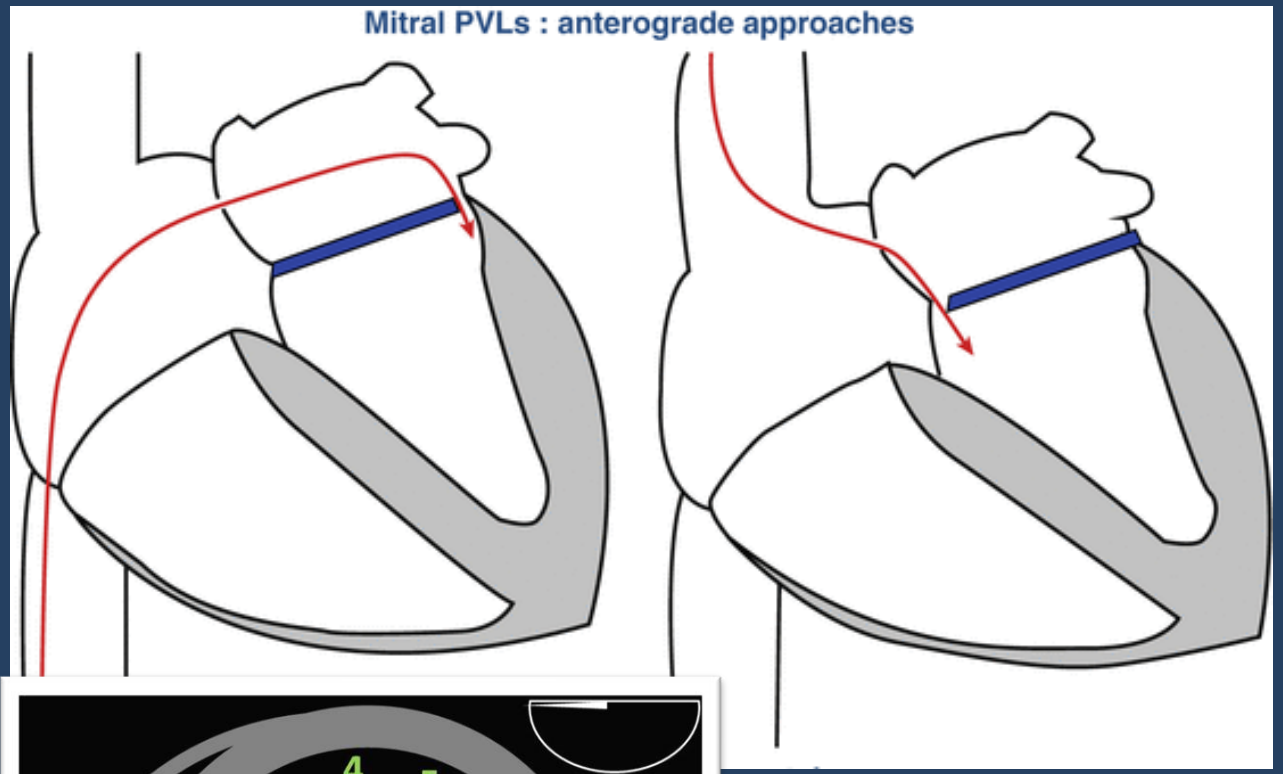
- Mother-and-a-child technique
- 6 F coronary guide catheter and 125 cm 5F coronary diagnostic catheter
- Delivery sheath (5-9F) over stiff wire
- Shadowing from prosthetic valve/3D not very useful

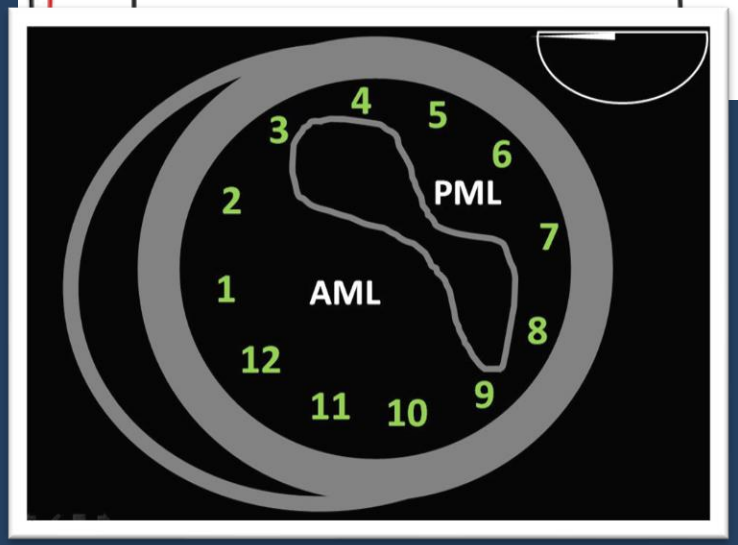
Smolka G, Wojakowski W. Transcatheter Paravalvular Leak Closure, Springer 2017

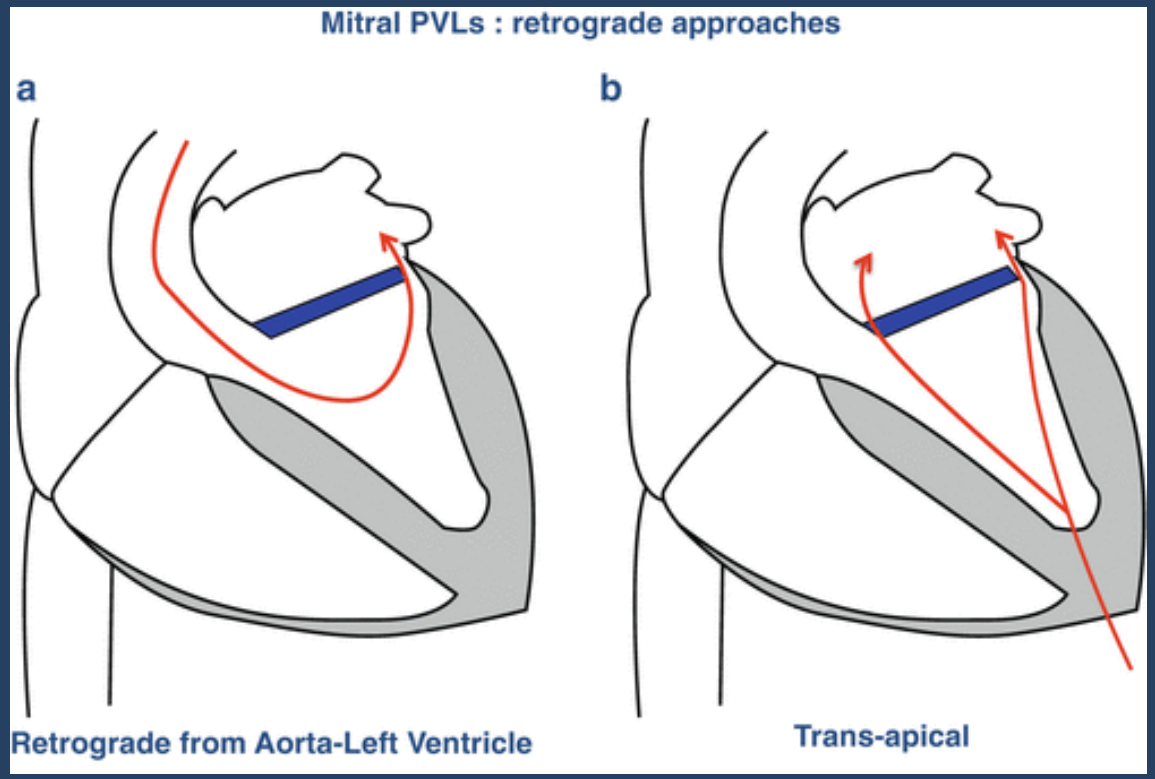
Hybrid imaging



Mitral PVL

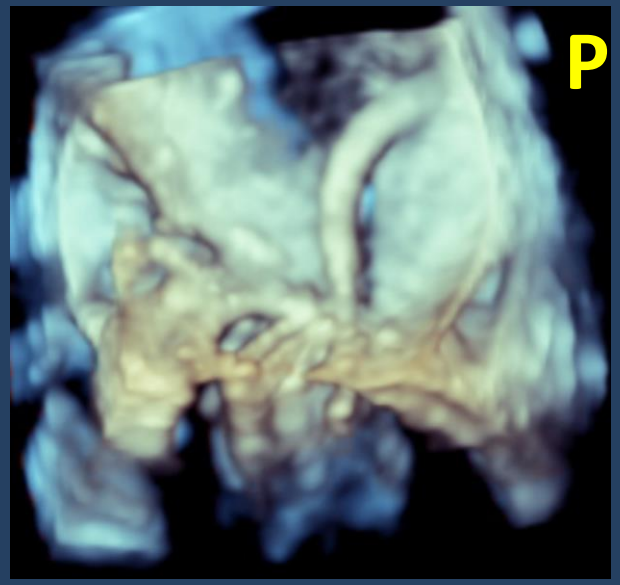


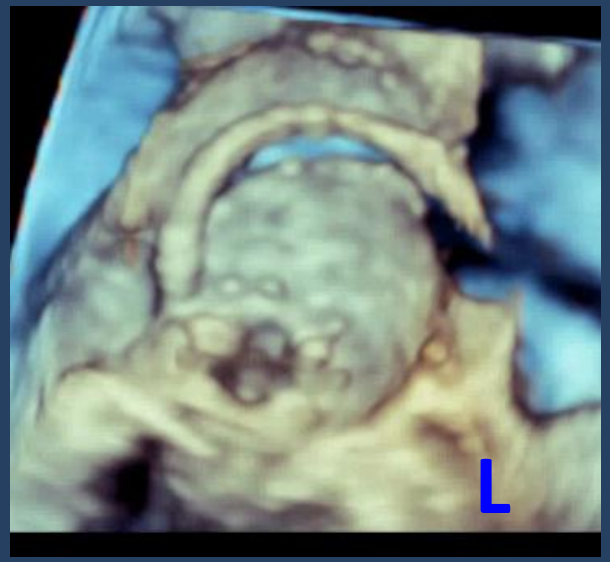


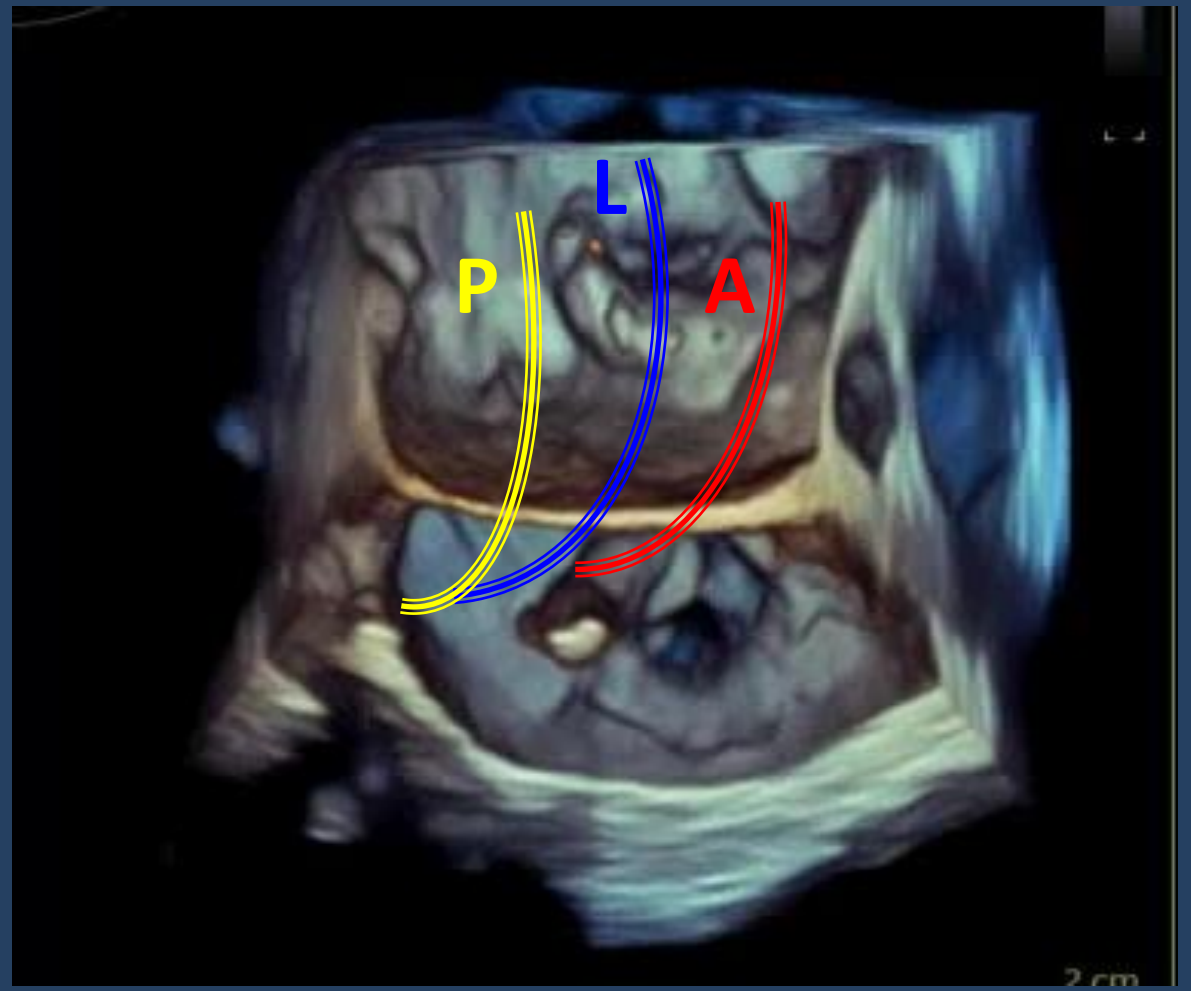


Smolka G, Wojakowski W. Transcatheter Paravalvular Leak Closure, Springer 2017

IVS Puncture

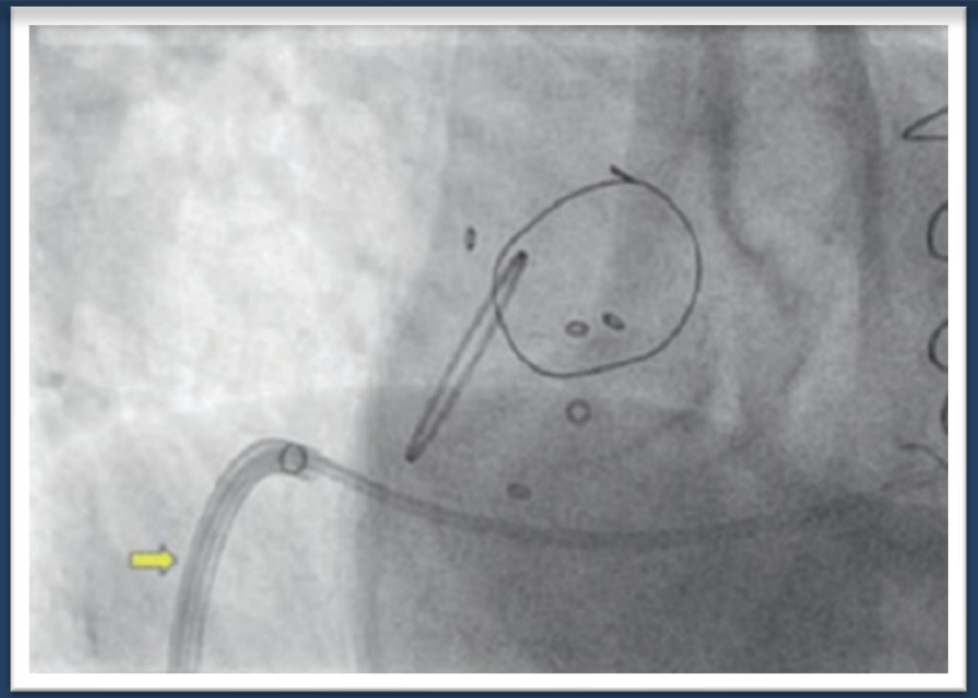






P. Pysz

COMBO technique for Mitral PVL



- Steerable sheath (8.5 Agilis; 12F Flexcath; 14F Occlutech)
- 6 F coronary guide catheter and 125 cm 5F coronary diagnostic catheter
- Delivery sheath (5-9F) over stiff wire or up to 3 coronary catheters
- Wire in the left atrium to provide distance of the tip

Smolka G, Wojakowski W. Transcatheter Paravalvular Leak Closure, Springer 2017

Current device selection

Vascular plugs (AVPII, AVPIII, AVPIV) and PDA occluders (Abbott)

(AVP III – approved for PVL)

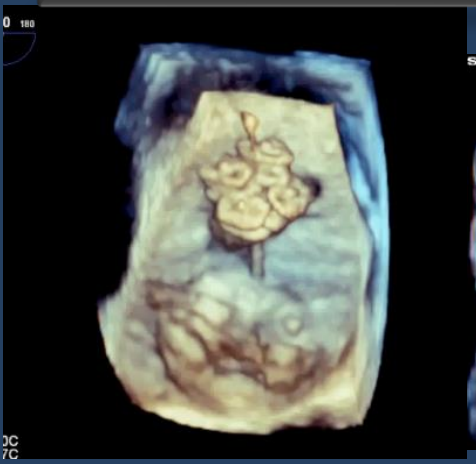
Sealing material

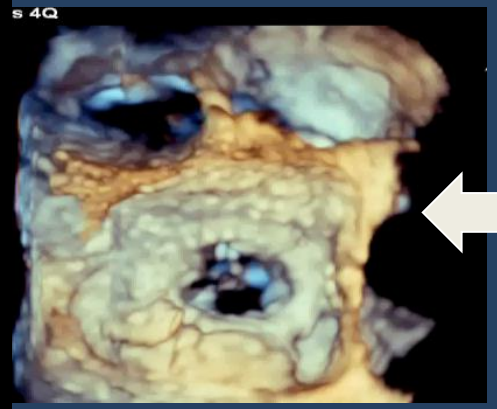
Controlled orientation

PLD device (Occlutech) (CE-Marked for PVL)

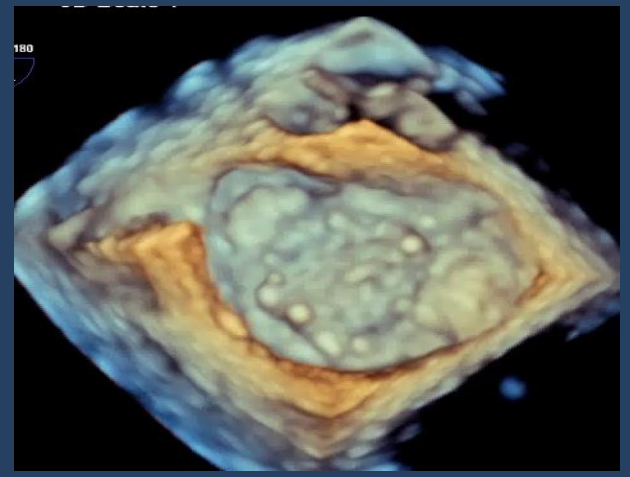
Smolka G, Wojakowski W. Transcatheter Paravalvular Leak Closure, Springer 2017

Current device selection





oversize



Delivery	Sizes [mm]
4F	4x2, 6x3
5F	8x4, 10x3
6F	10x5
7F	12x3, 12x5, 14x3, 14x5

Cover all anatomies

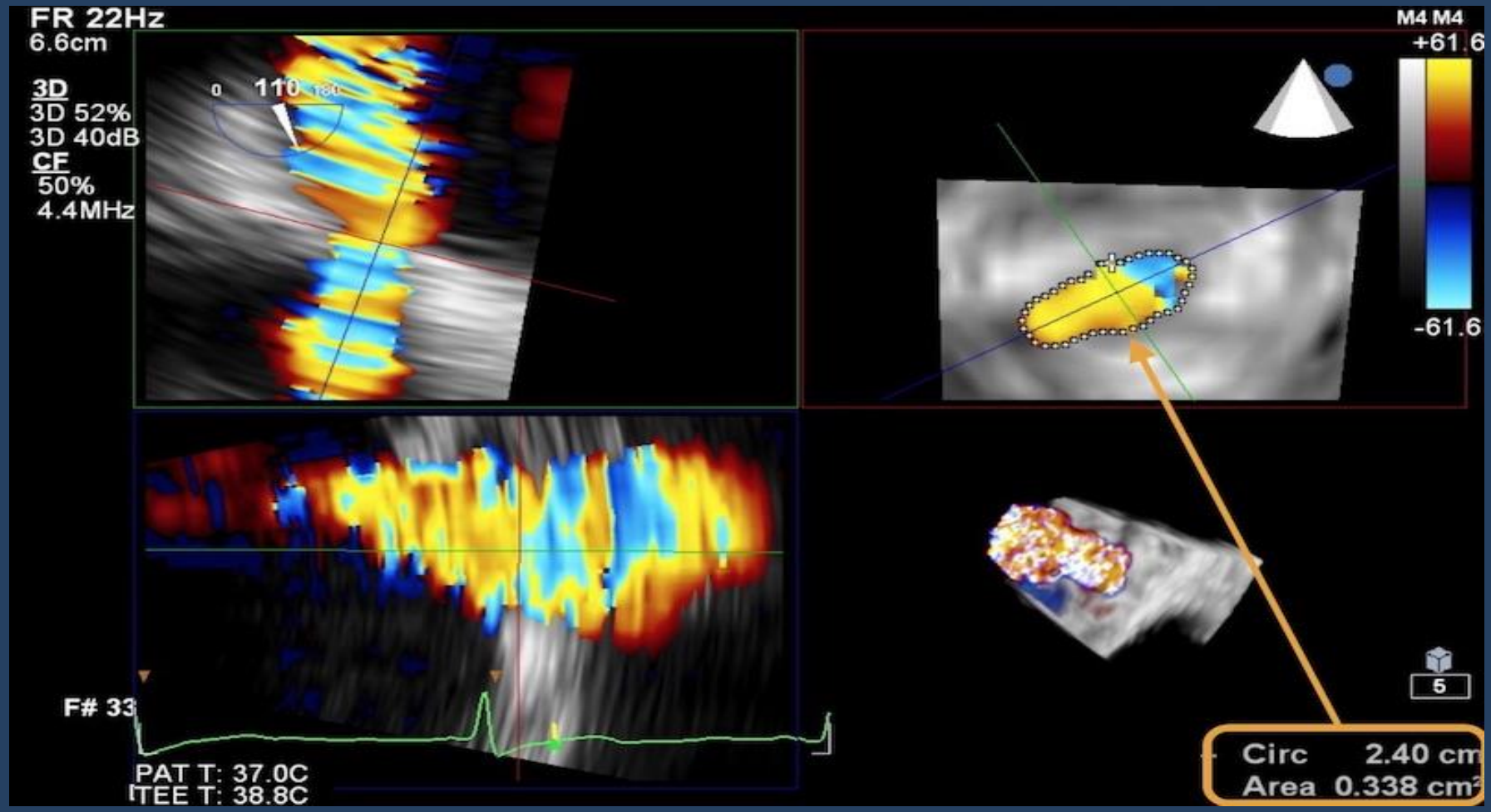
(long, crescent)

Occlutech® PLD RECTANGULAR_W*						
REF NO	D1 [mm]	D2 [mm]	AxB [mm]	Introducing system ** ID [mm]	Introducing system ** Size [F]	Flex Pusher Item no.
61 PLD 04W	11.5	10	4x2	2.21	6	50FP100L Dark Blue
61 PLD 06W	14	12.5	6x3	2.21	6	50FP100L Dark Blue
61 PLD 08W	16.5	15	8x4	2.54	7	50FP100L Dark Blue
61 PLD 10W	19	17	10x4	2.87	8	50FP100L Dark Blue
61 PLD 12W	21	19	12x5	3.20	9	50FP120L Dark Green
61 PLD 14W	24	22	14x6	3.20	9	50FP120L Dark Green
61 PLD 16W	26.5	24.5	16x8	3.40	10	50FP120L Dark Green
61 PLD 18W	28.5	26.5	18x10	3.40	10	50FP120L Dark Green

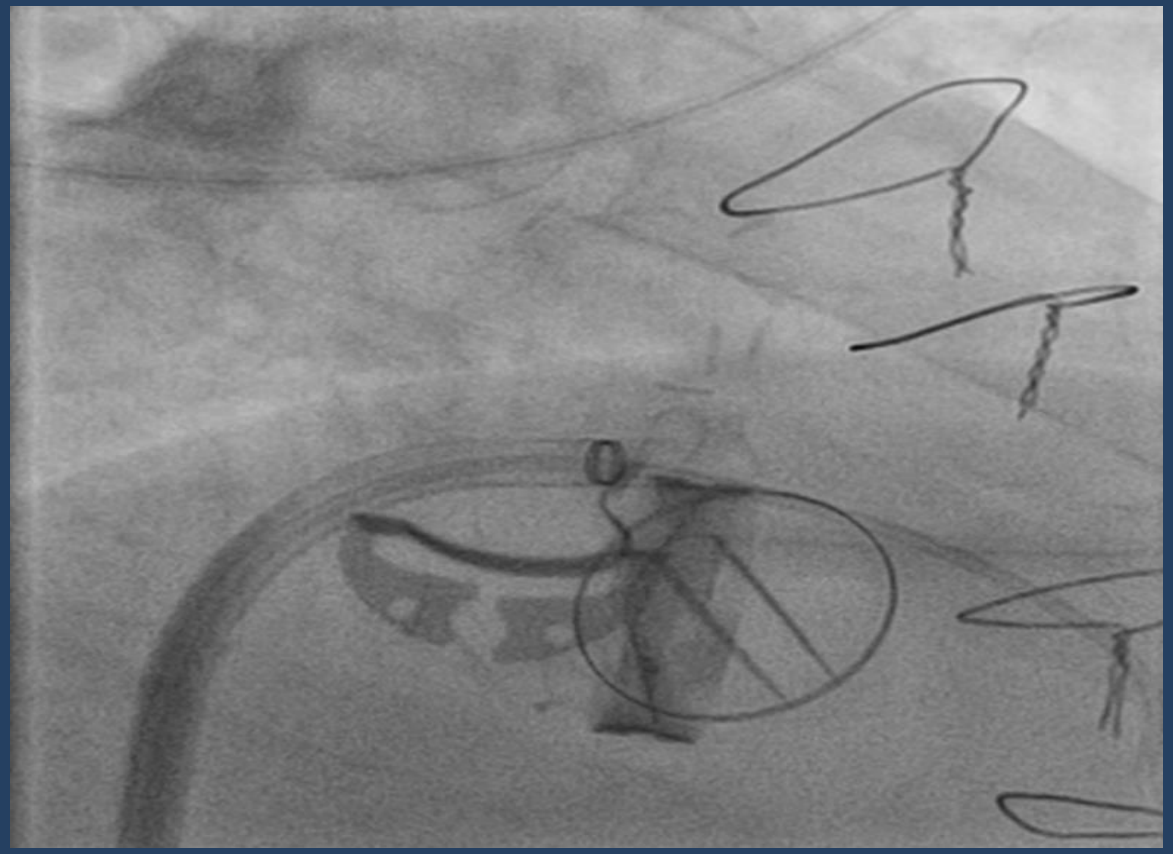
Suitable for multiplug AVP III	Suitable for single PLD
Irregular/crescent CSA of VC	Round /oval CSA of VC
Channel length >5 mm	Channel length ≤5 mm
Bulks of calcium within channel or surrounding structures that might impede full expansion of discs	No structures potentially impeding disc apposition

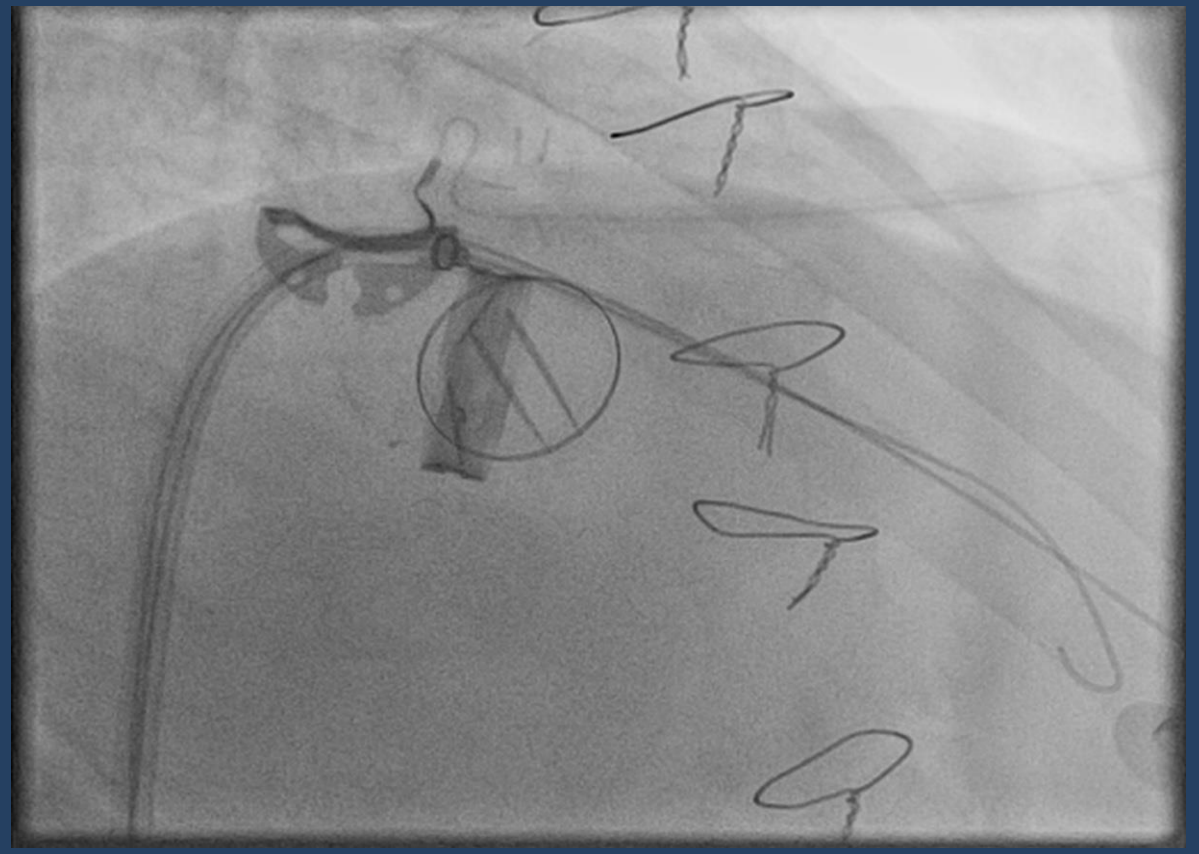
Smolka G, Wojakowski W. Transcatheter Paravalvular Leak Closure, Springer 2017

Case example



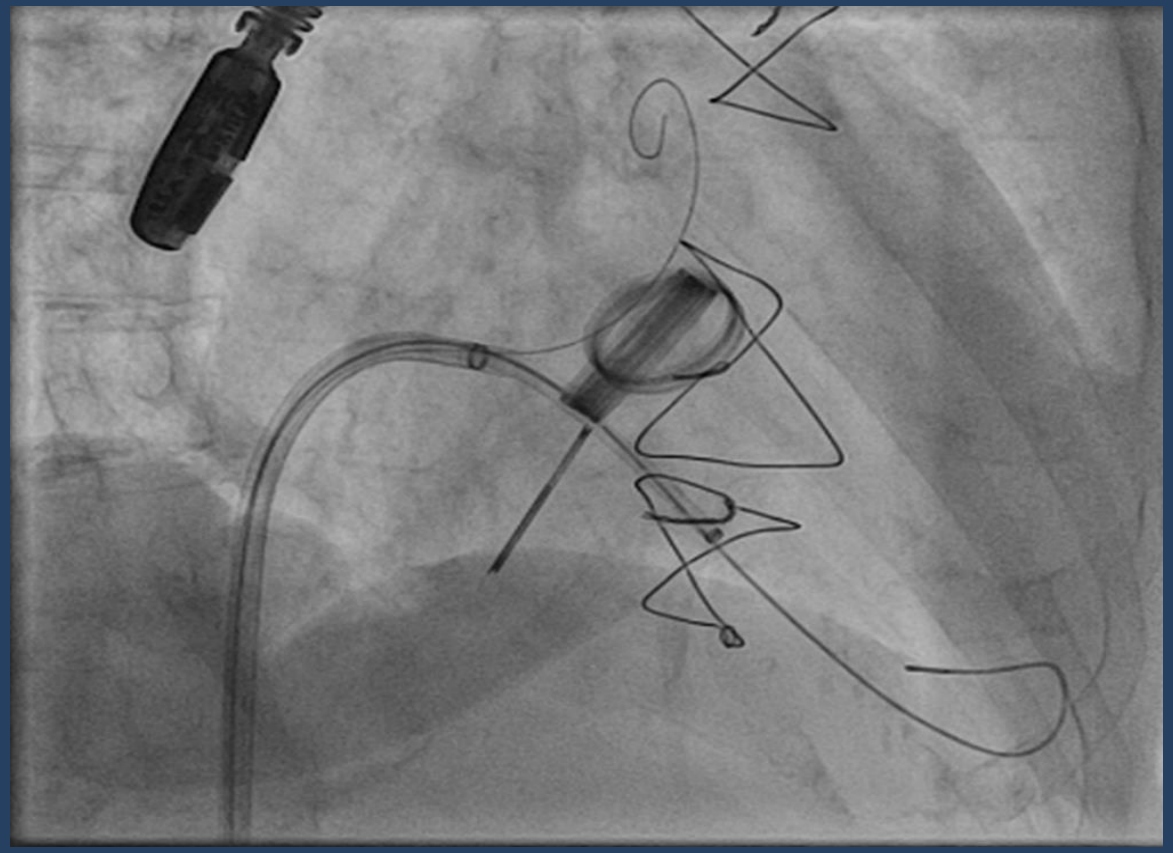
Case example

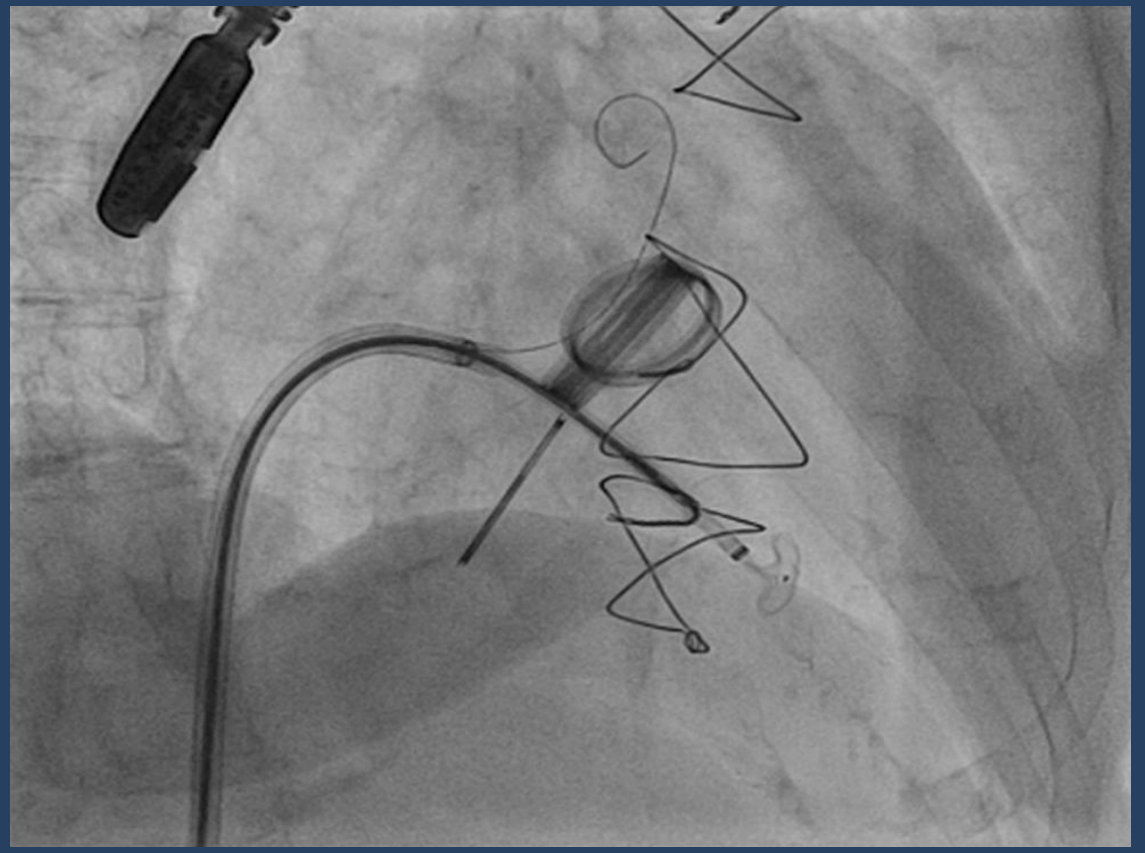




PVL crossing

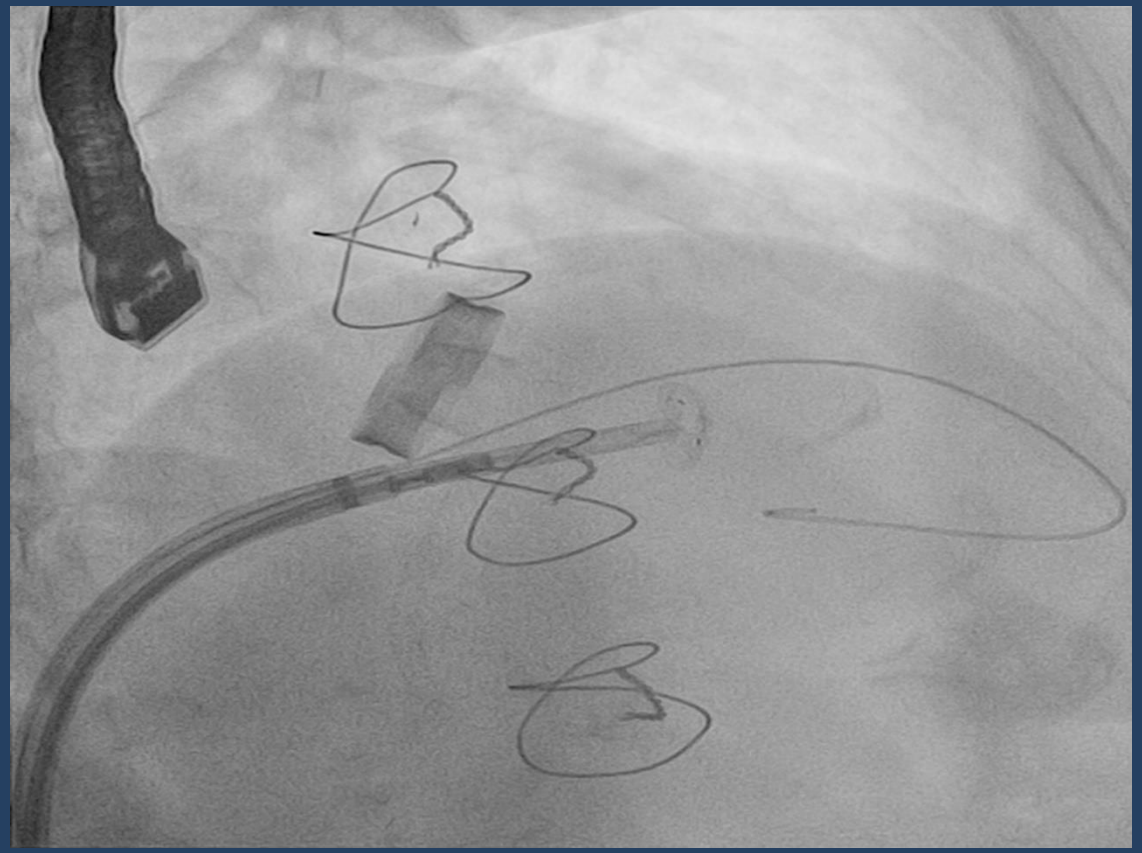
Case example

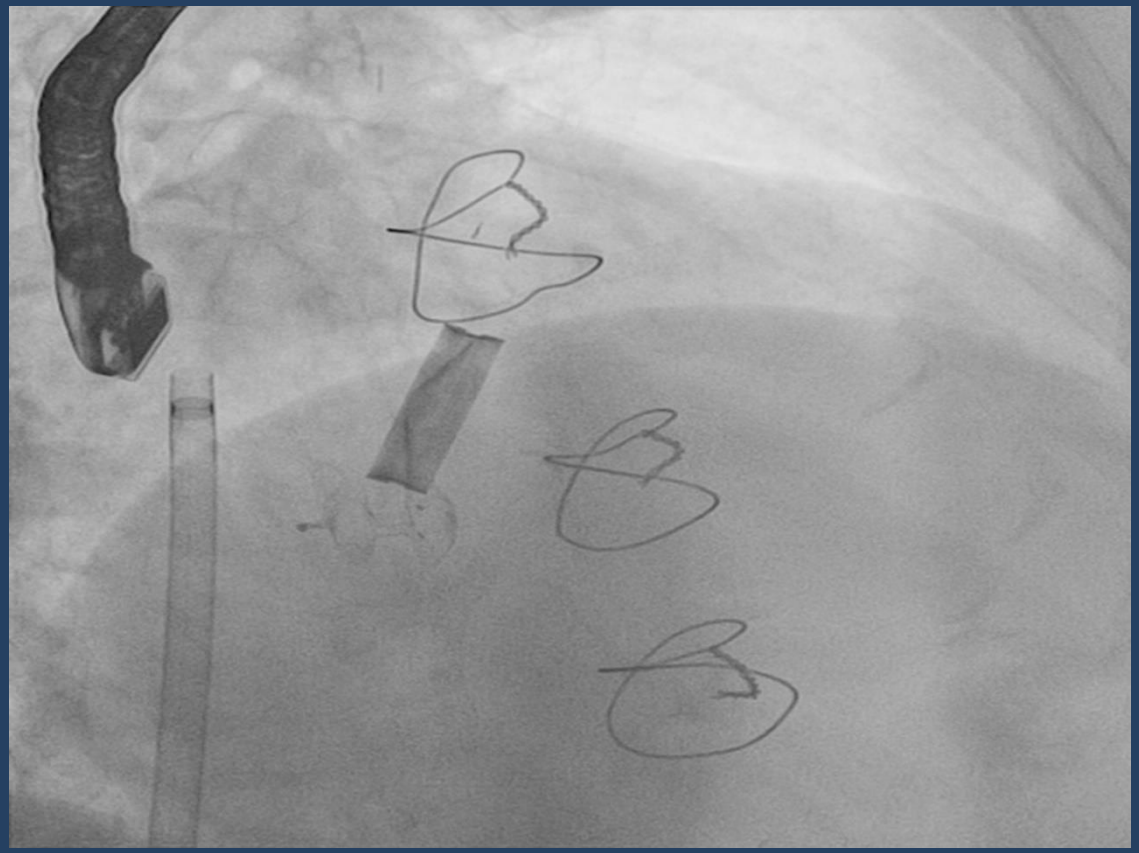




Plug delivery and positioning

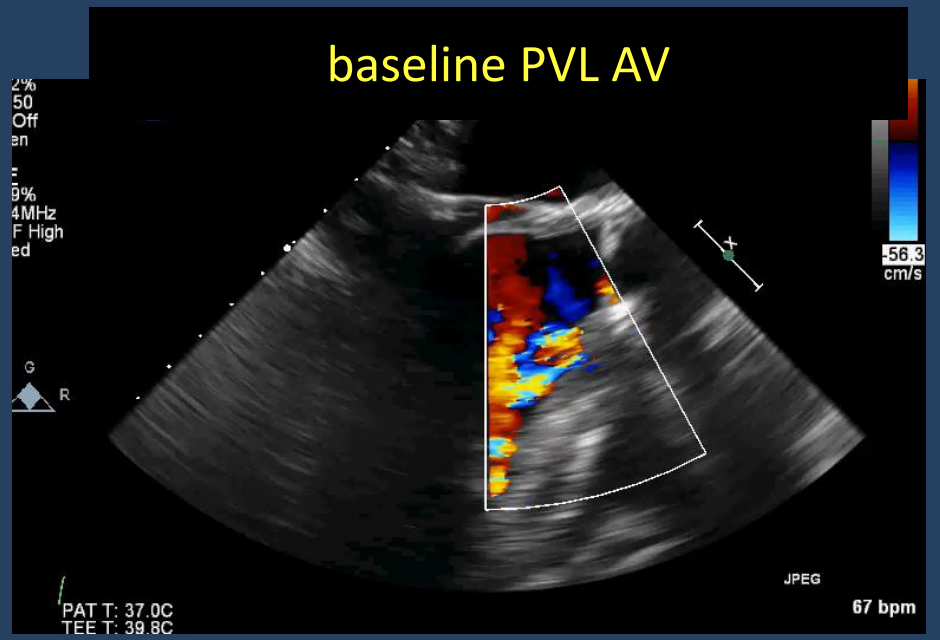
Case example

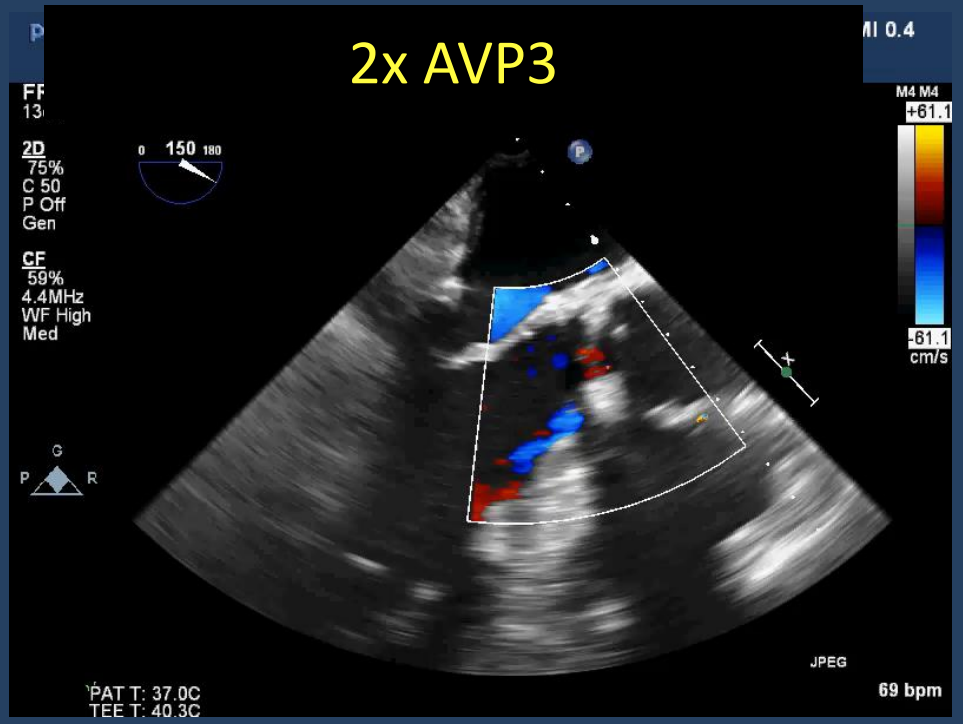




Plug delivery and positioning

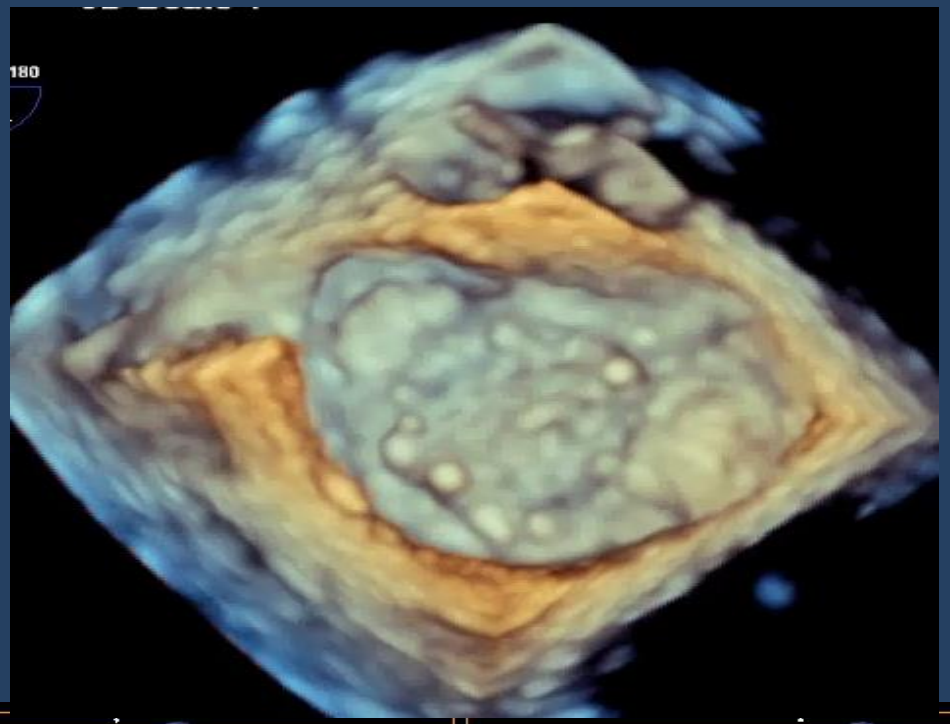
Multiplug approach

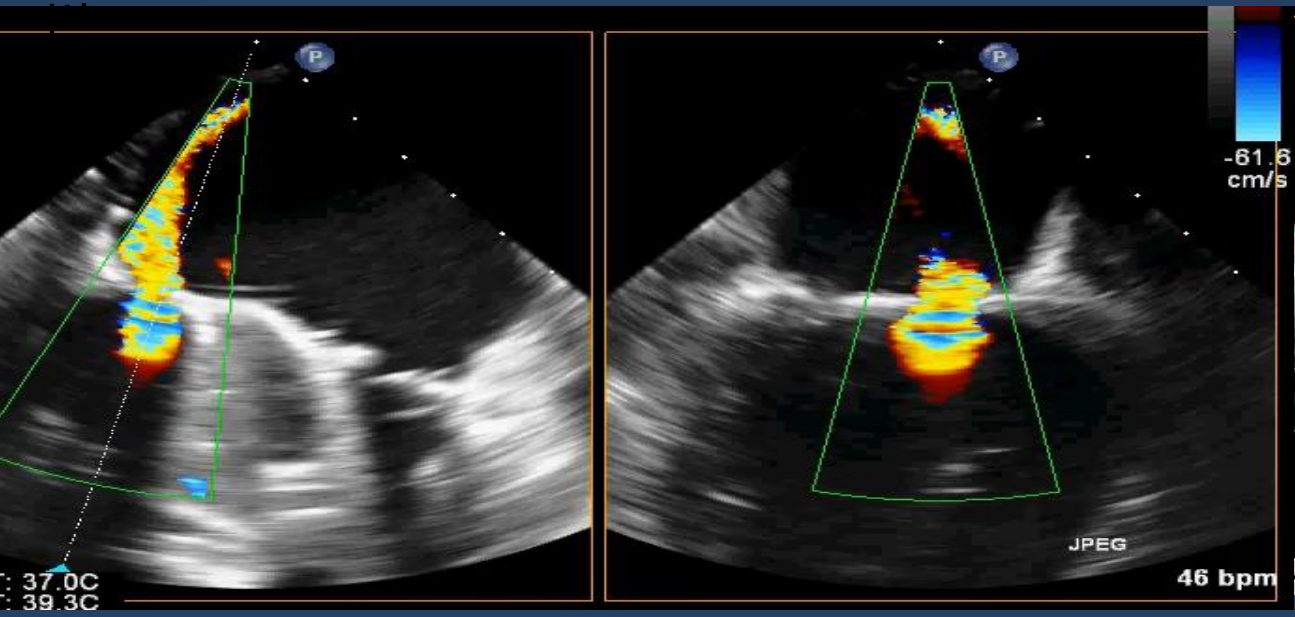




PLD device

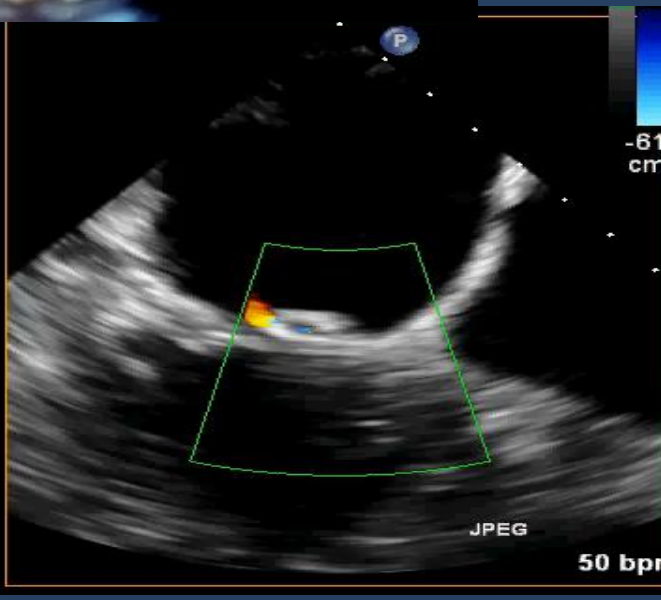

0
110
180


180


P
-61.6
cm/s
37.0C
39.3C

P
JPEG
46 bpm


P
37.0C
39.5C


P
JPEG
50 bpm

Registry data

Multiplug Paravalvular Leak Closure Using Amplatzer Vascular Plugs III: A Prospective Registry

Grzegorz Smolka,[1*] MD, Piotr Pysz,[2] MD, Marek Jasiński,[3] MD, PhD, Tomasz Roleder,[2] MD, Ewa Peszek-Przybyła,[1] MD, Andrzej Ochała,[1] MD, PhD, and Wojciech Wojakowski,[1] MD, PhD

TABLE II. Procedure Details

	Paramitral	Paraaortic
Numer of leaks	29	20
Numer of procedures	34	20
Second attempt after failed procedure	5	–
Transapical	9[a]	–
Number of leaks with 2/3/4 implanted plugs	13/14/2	14/6/0
CSA of simultaneously implanted in one PVL plugs (mm^2)	68 [95%CI: 60.9–96.0, min. 26, maks.280)	36 (95%CI: 32.0–47.6, min. 12, max.53)
PVL CSA (mm^2)	47 (95%CI: 39.1–55.5, min. 10, max. 165)	24 (95%CI: 21.2–26.8, min. 18.0–82.0)
No more than mild residual leak after TPVLC	26	20

Transcatheter closure of paravalvular leaks using a paravalvular leak device – a prospective Polish registry

Grzegorz Smolka[1], Piotr Pysz[2], Michał Kozłowski[1], Marek Jasiński[3], Radosław Gocoł[3], Tomasz Roleder[2], Agnieszka Kargul[4], Andrzej Ochała[1], Wojciech Wojakowski[1]

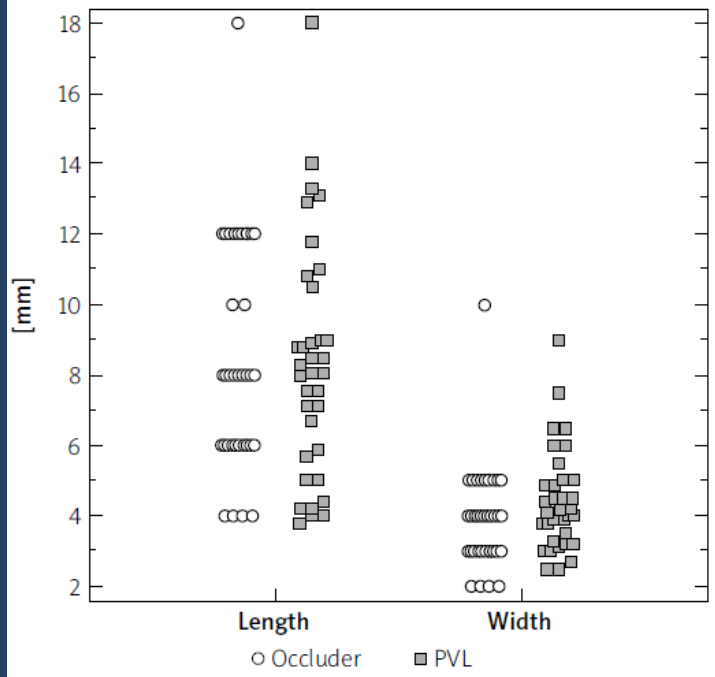


Figure 4. Correlation between the sizes of implanted PLDs and PVLs' dimensions (length and width of CSA) by RT 3D TEE

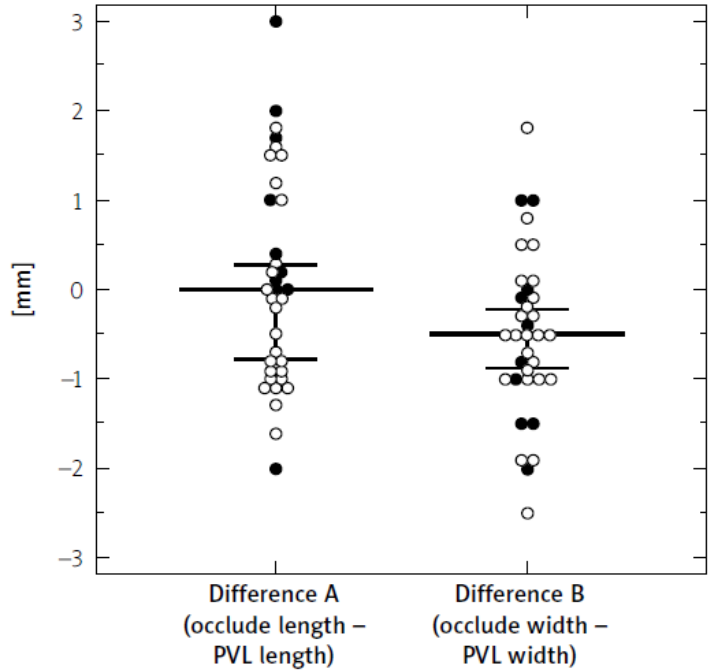


Figure 5. Influence of device oversizing on residual flow presence (filled circles) or absence (empty circles)

Adv Interv Cardiol 2016; 12, 2 (44): 128–134; Catheterization and Cardiovascular Interventions 87:478–487 (2016)

Registry data

Transcatheter paravalvular leak closure and hemolysis – a prospective registry

Grzegorz Smolka[1], Piotr Pysz[1], Andrzej Ochała[1], Michał Kozłowski[1], Wojciech Zasada[2,3], Zofia Parma[1], Michał Tendera[1], Wojciech Wojakowski[1]

Variable	Reduction of CSA < 90% *N* = 16	Reduction of CSA ≥ 90% *N* = 59	*P*-value
$\Delta HGB_{discharge - 1\ month}$ [g/dl]	0.7 ±1.1 0.7 (0.2–0.9)	1.3 ±1.0 1.2 (0.5–2.0)	0.0365
$\Delta HGB_{baseline - 6\ months}$ [g/dl]	0.0 ±1.8	1.6 ±1.6	0.0020
$\Delta RBCC_{discharge - 1\ month}$ [M/mm^3]	0.2 ±0.3 0.1 (–0.1 – 0.4)	0.5 ±0.3 0.5 (0.2–0.7)	0.0007
$\Delta RBCC_{baseline - 6\ months}$ [M/mm^3]	–0.1 ±0.7 0.0 (–0.9 – 0.4)	0.6 ±0.5 0.6 (0.2–0.9)	0.0003
$\Delta LDH_{discharge - 1\ month}$ [IU/l]	48.9 ±260.5 38.0 (36.8–108.0)	8.9 ±181.4 3.0 (–88.0 – 73.0)	0.3512
$\Delta LDH_{baseline - 6\ months}$ [IU/l]	–164.9 ±577.3 –6.0 (–290.0 – 117.0)	–296.9 ±508.1 –173.0 (–487.0 – 28.0)	0.2547

Improved Transseptal Access for Transcatheter Paravalvular Leak Closure Using Steerable Delivery Sheaths: Data From a Prospective Registry

Michał Kozłowski, MD, PhD[1]; Piotr Pysz, MD[2]; Wojciech Wojakowski, MD, PhD[1]; Grzegorz Smolka, MD[1]

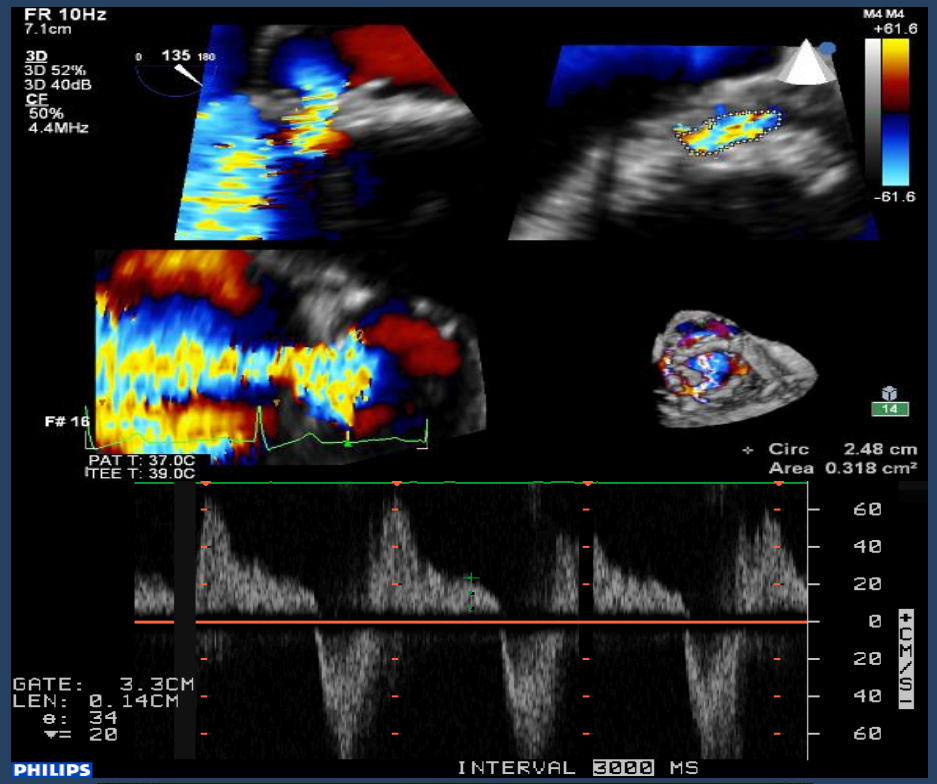
Implantation time (minutes)	28.5 (15-58)	64 (35-180)	<.05
Technical success rate	29 (93.5%)	16 (72.7%)	<.05
PVL location			
Anterior	10 (32.2%)	7 (31.8%)	NS
Medial	11 (35.5%)	8 (36.3%)	NS
Posterior	3 (9.7%)	4 (18.1%)	NS
Lateral	7 (22.6%)	3 (13.6%)	NS
Procedural failures	1	2	NS
Failure to cross the PVL	1	1	NS
Valve interference	0	1	NS
Total number of implanted devices	47	42	NA
Number of implanted PLDs	29	9	NA
Number of implanted AVP III devices	18	32	NA

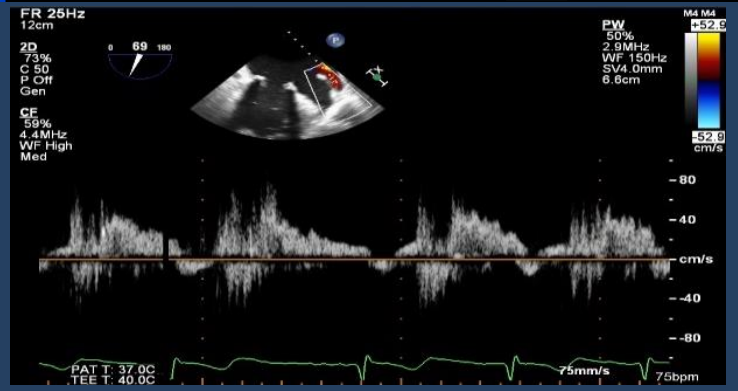
Other predictors: mitral location, calcifications

Arch Med Sci 2017; 13, 3: 575–584; J INVASIVE CARDIOL 2019 April 15 (Epub Ahead of Print).

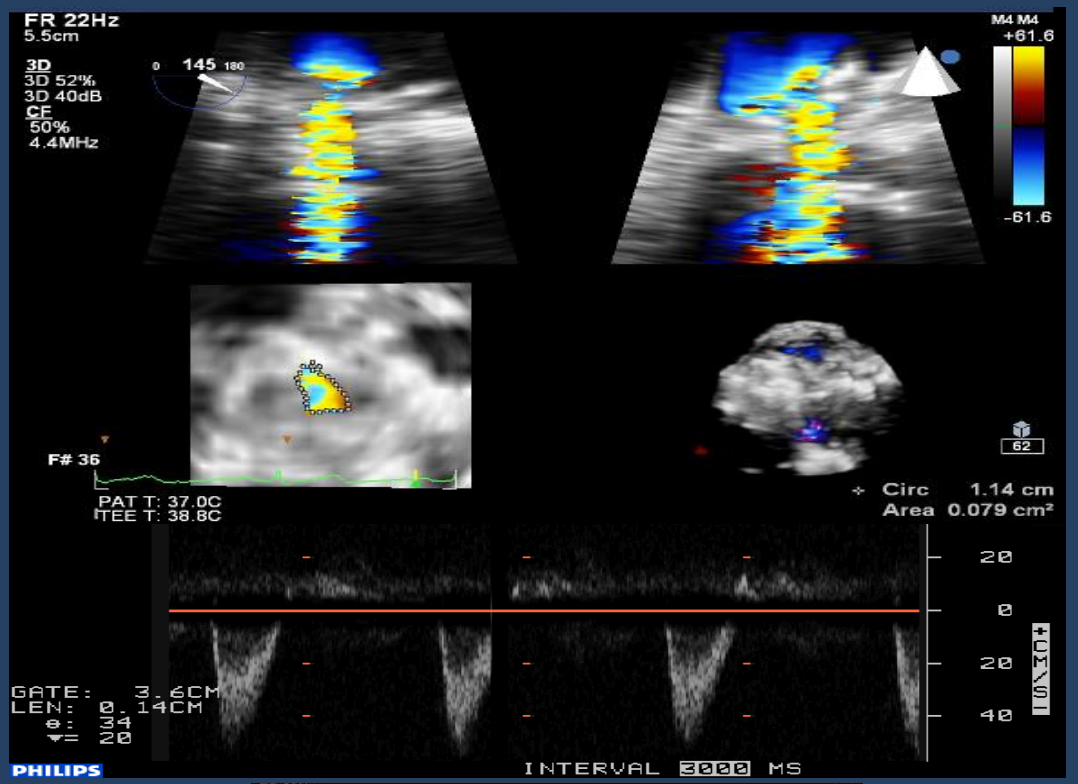
Post procedural assessment and follow-up

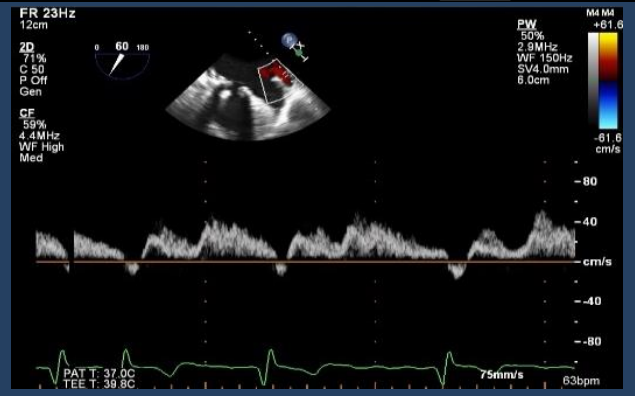
Baseline



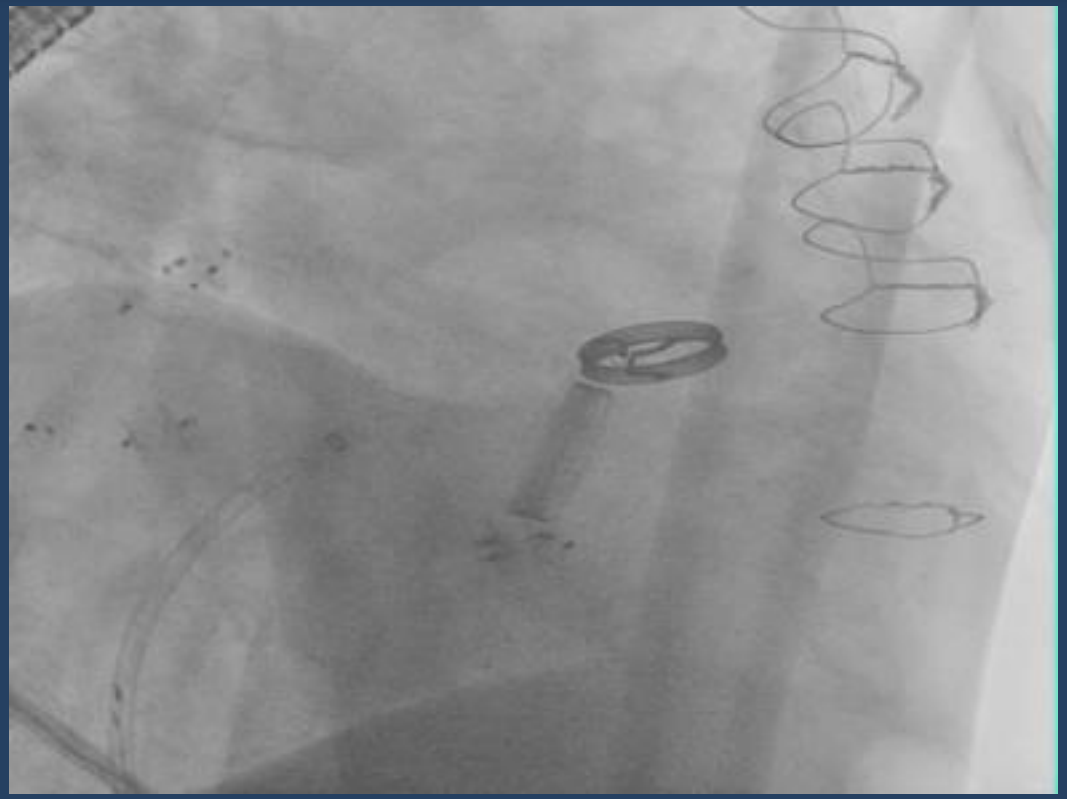


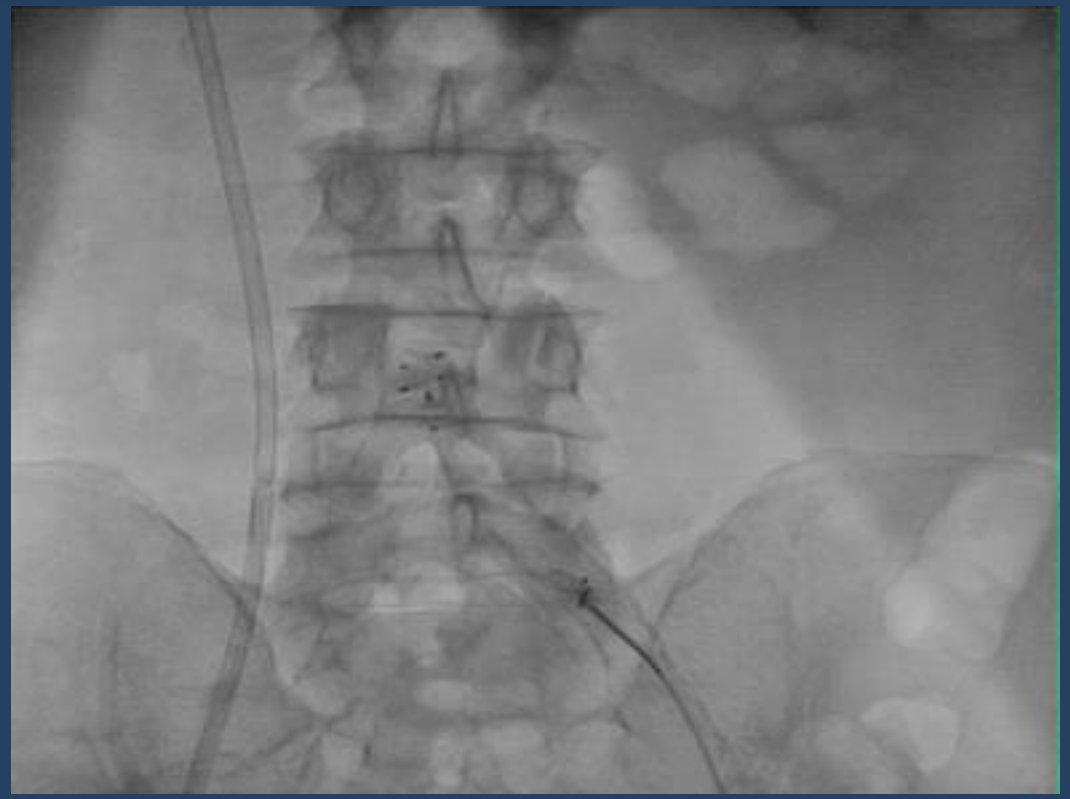
Post procedure





Troubleshooting





Snares

Large deflectable sheaths

Conclusions

- Clinical assessment: HF, hemolysis, exclusion of infectious endocarditis
- Transcatheter closure of PVL is preferred treatment for patients with HF or hemolytic anemia
- In majority of cases multiple plugs are necessary
- COMBO approach with large deflectable sheaths improves mitral PVL closure
- Optimal toolbox (delivery sheaths, guidewires, catheters, snares)
- TOE is a must preferably with 3D reconstruction
- Residual/recurrent leak and hemolysis (PVL can reoccur)
- Incomplete closure, even if reducing HF symptoms, may result in worsening of hemolysis
- Dedicated device which provides complete sealing is needed

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