



“Chiusura percutanea dei leaks paravalvolari: indicazioni, tecnica e risultati”

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Background (1)

- Depending leak size, regurgitation can cause ***congestive heart failure*** (69% \geq NYHA III) and ***pulmonary edema***, can increase the ***risk for endocarditis***, and often provokes mild to substantial ***transfusion-requiring hemolysis***
- Redo surgery has been considered the ***first choice*** to treat PVLs but carries a higher operative risk compared to that of the initial procedure with mortality rates between **4%** and **14%**.
(13% :1st reoperation; *15% 2nd reoperation; *37% 3th reoperation)

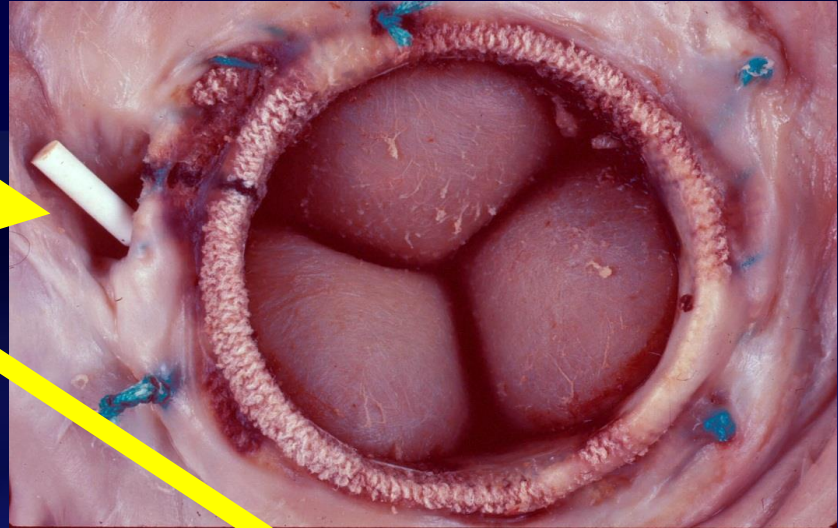
Background (2)

- Available clinical results are promising showing low complication rates and high technical or clinical success rates of ***catheter-based closure*** of PVL (**60-90%**).
- Compared to surgical closure of PVL, lower mortality rates (30-days mortality rate: **4,6%**) have been documented in patients treated by catheter-based closure of PVL in clinical practice.
- Therefore ***interventional closure*** seems to be a promising option, which need to be discussed with every symptomatic patient suffering from PVL prior to therapeutical decision making.

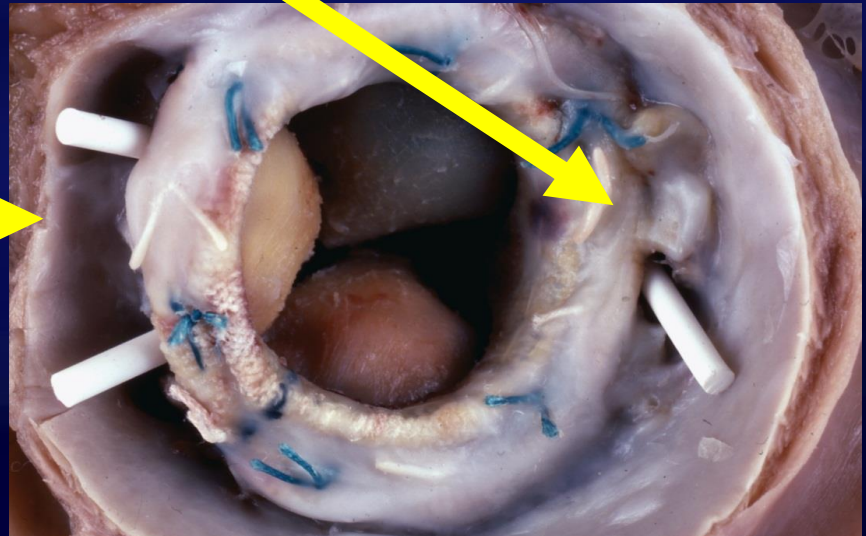
Indications

- ✓ **Good candidates** : patients with previously implanted surgical prosthetic/bioprosthetic heart valves, symptomatic paravalvular regurgitation (equal or greater than moderate) associated with hemolysis, need for recurrent blood transfusions, or hemodynamically significant heart failure who are deemed to be at **high risk** for further surgical intervention *after surgical consultation* (!!)
- ✓ **Exclusion criteria** : active bacterial and/or viral infection or any type of serious infection < 1 month prior to the procedure; lack of suitable access route; valve dehiscence to such an extent that device manipulation would likely cause disruption of the entire valve apparatus*
 - *there is insufficient experience to define the percentage of the ring without suitable attachment to meet this criterion, but a **rocking valve apparatus** with large areas of dehiscence would fall into this category.*

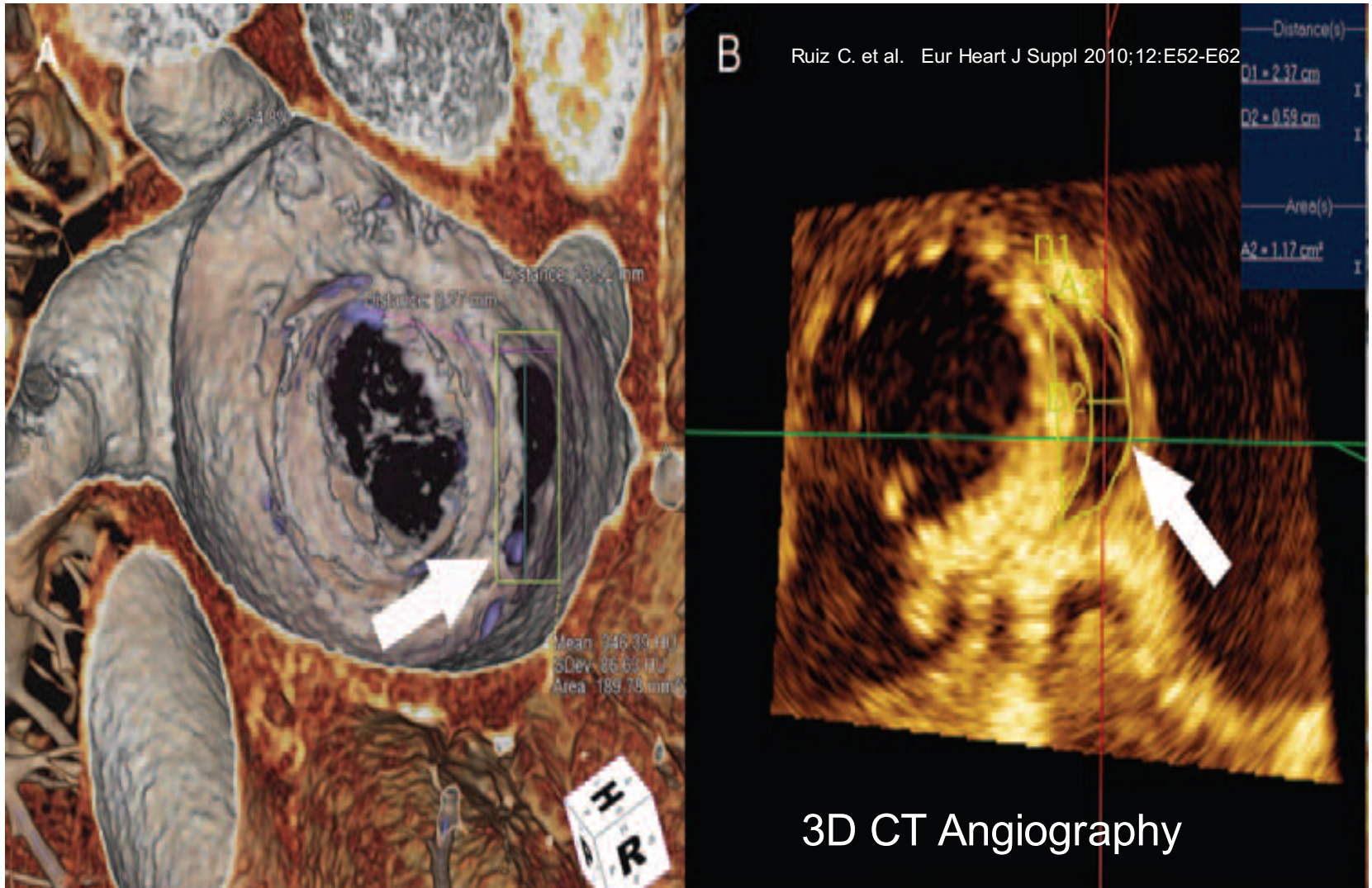
Favorable



Unfavorable

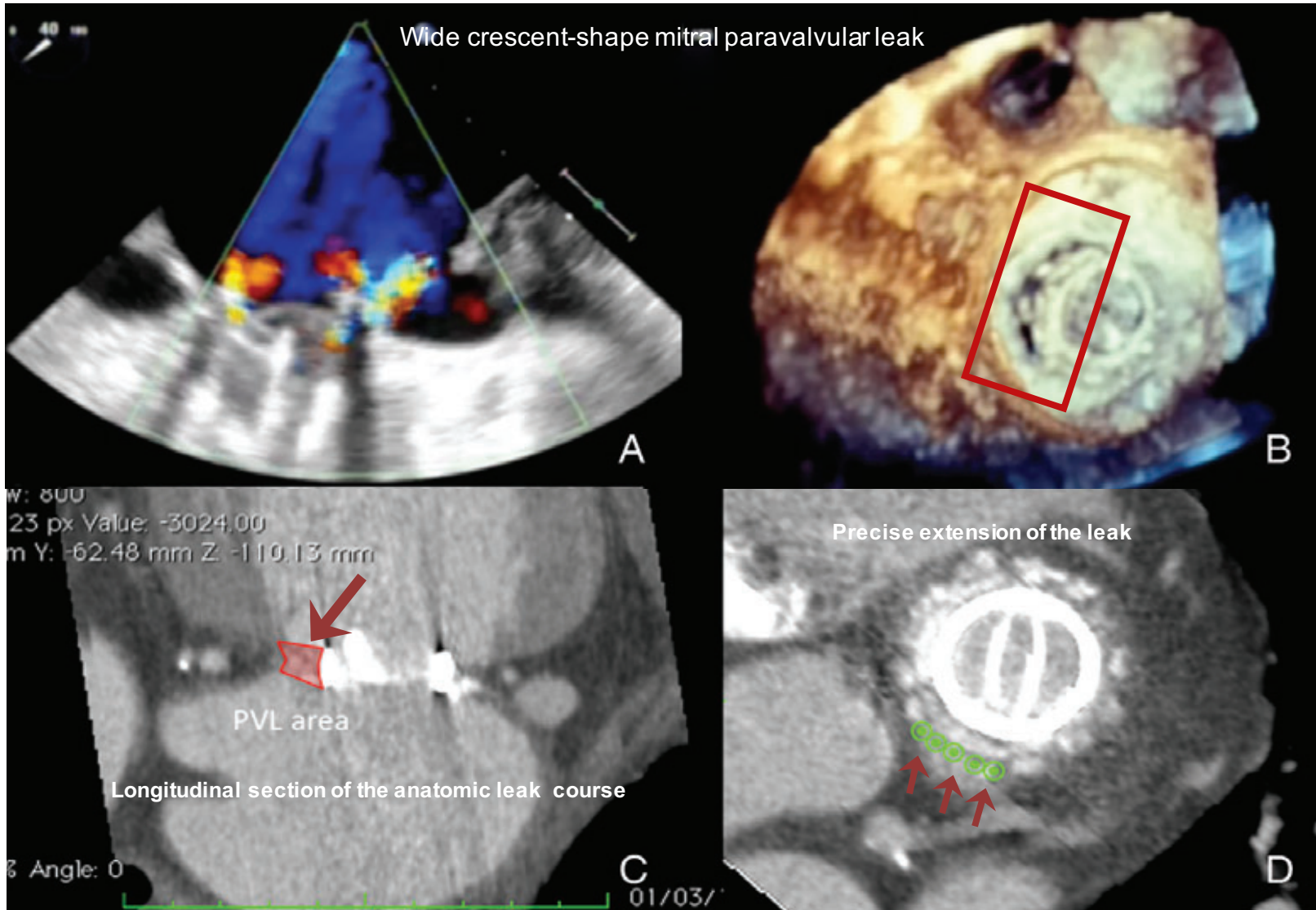


Preprocedural planning

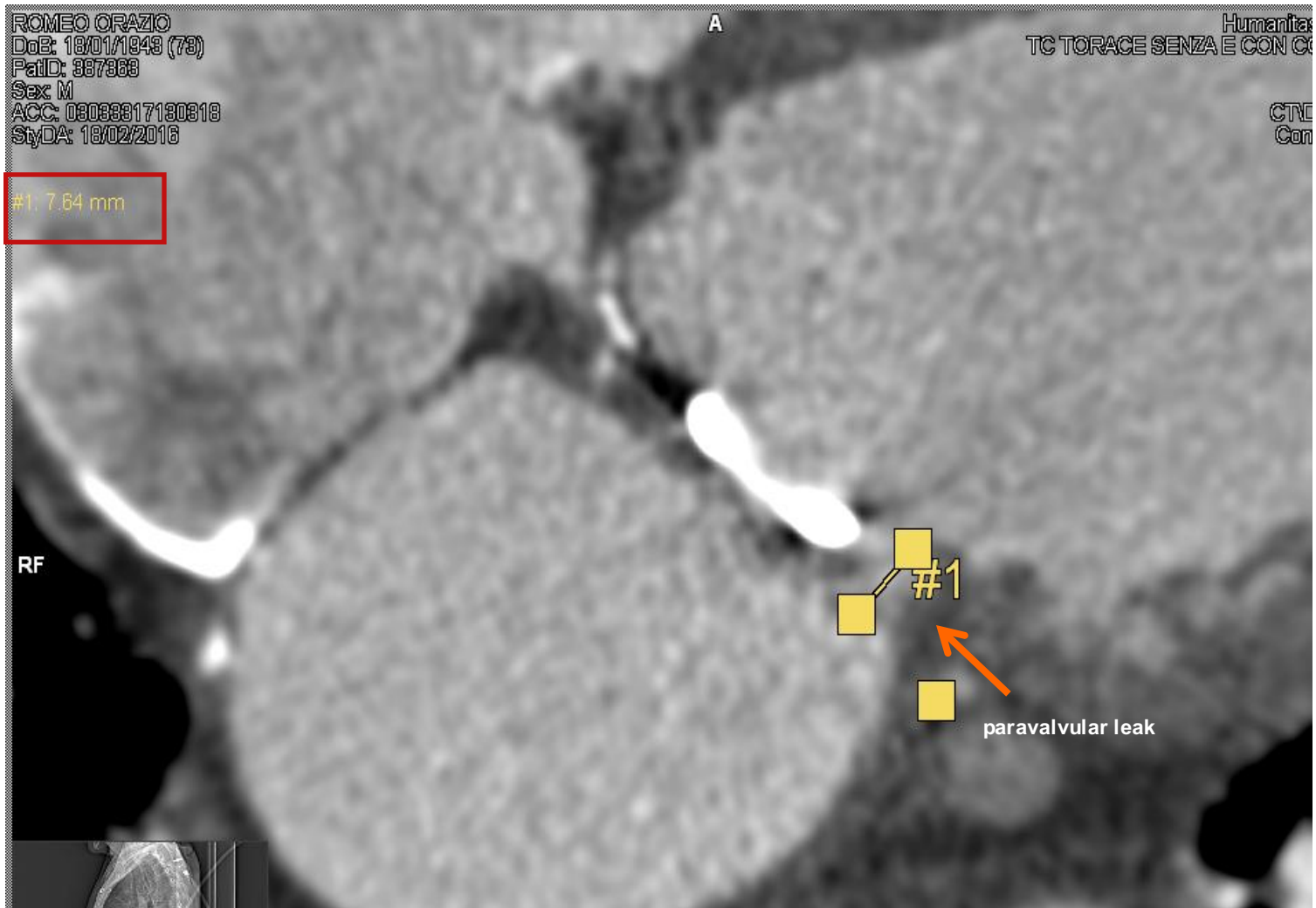


excellent anatomical leak characterization (number, size, location, orientation)

Preprocedural planning

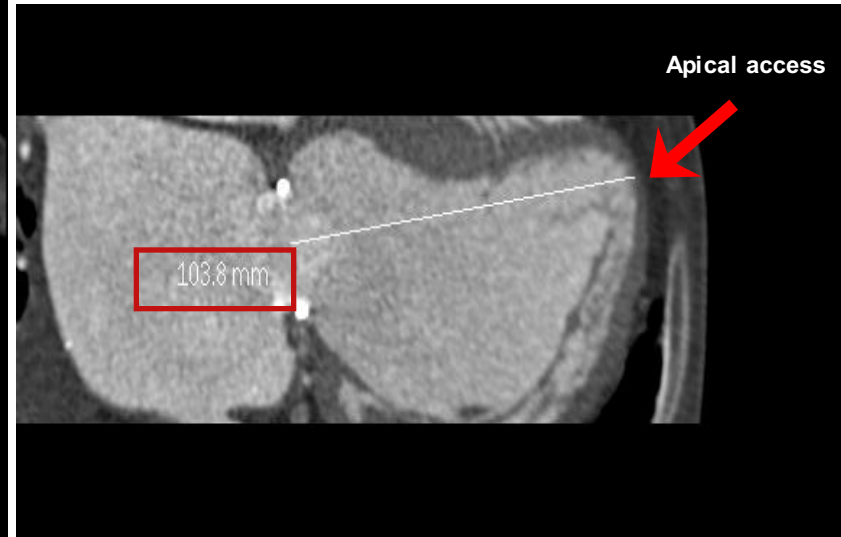


Preprocedural planning



Axial CT- scan section

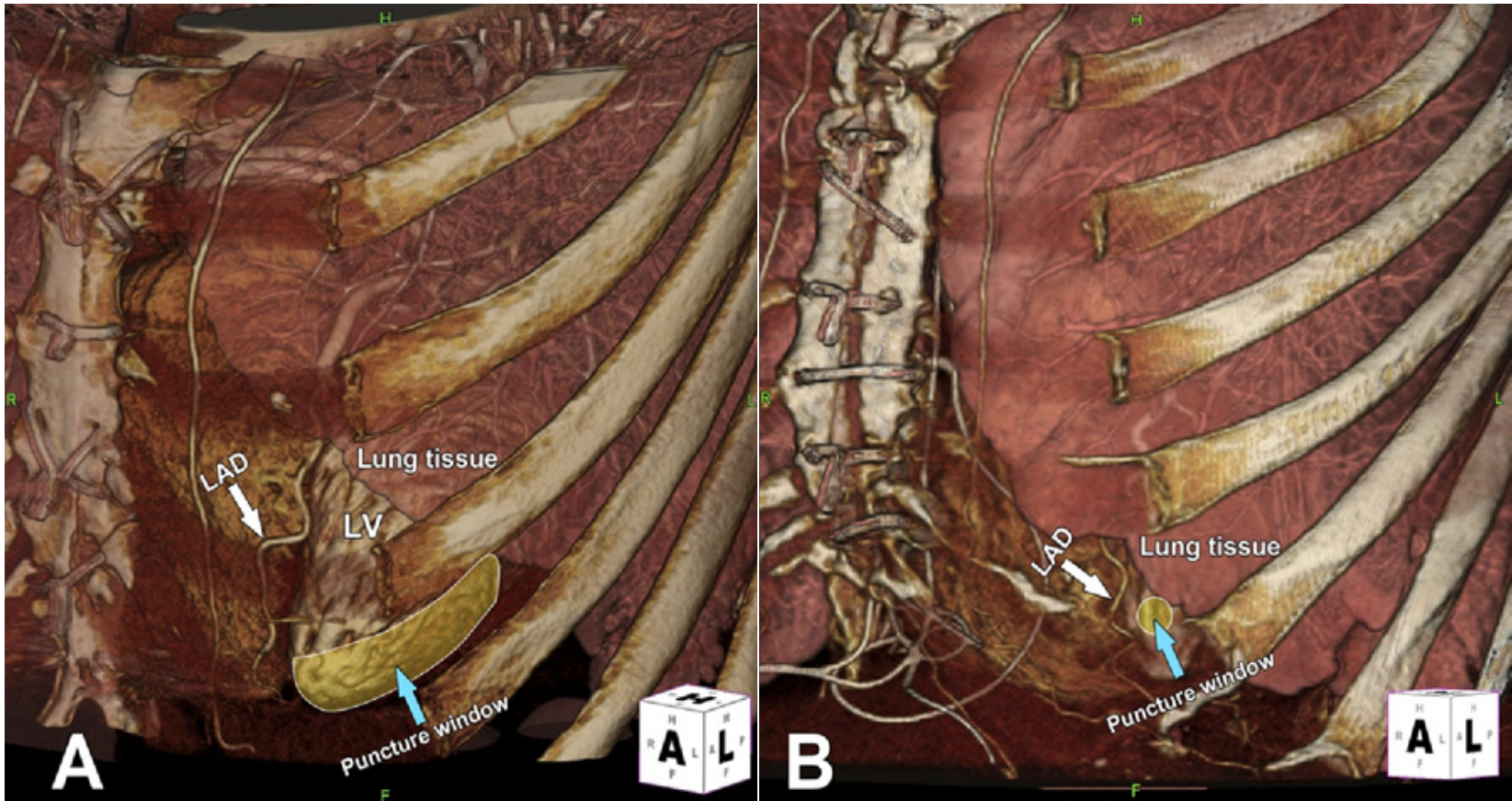
Preprocedural planning



Axial CT- scan section

Preprocedural planning

3D Volume-Rendered CTA:
variation of the “Safe Puncture Window” among different patients

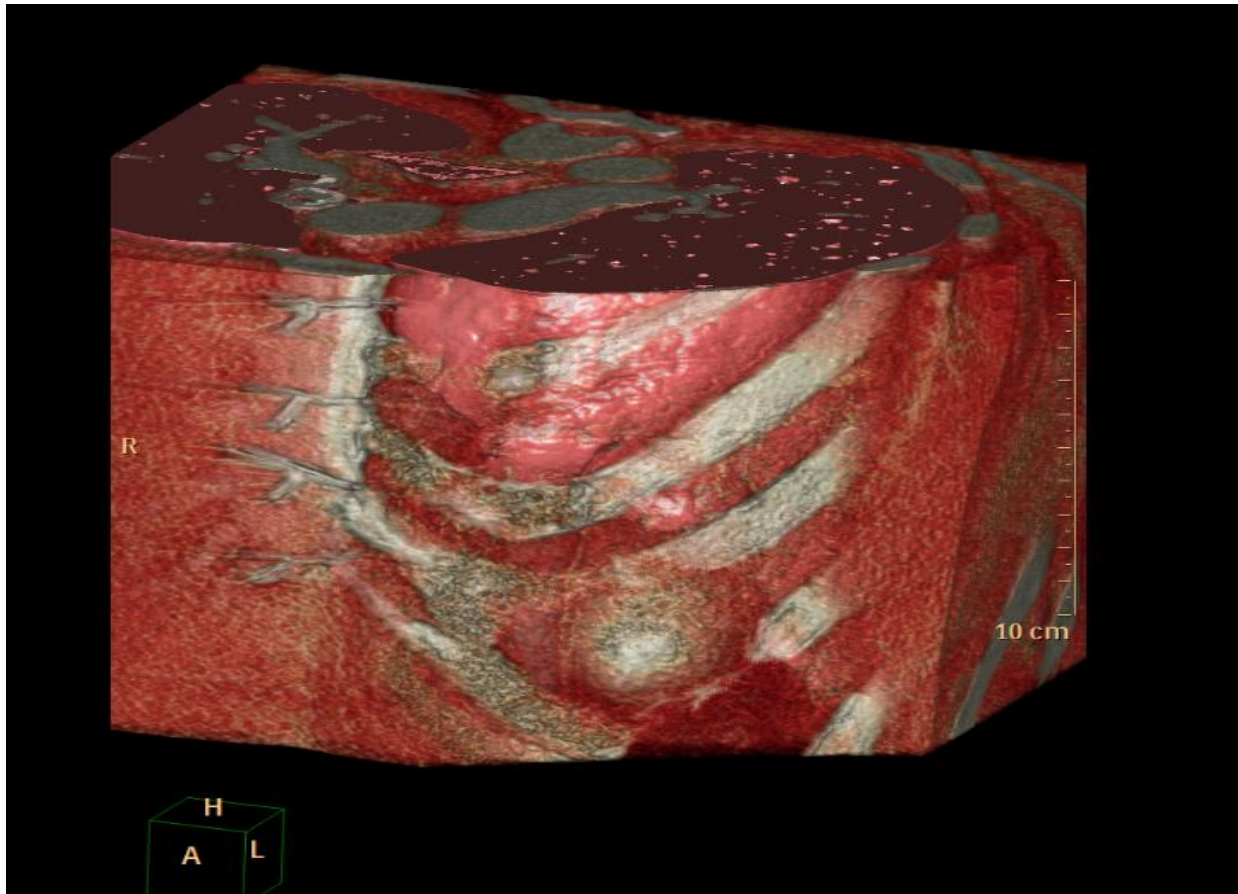


A) **Good exposure of LV apex** : large puncture window

B) **Small puncture window** : lung overlap and close proximity of coronary artery

Preprocedural planning

3D Volume-Rendered CTA:
variation of the “Safe Puncture Window” among different patients



Good exposure of LV apex : large puncture window

PROCEDURAL PRINCIPLES

Choice of approach

- ✓ valve involved
- ✓ vascular access difficulties
- ✓ paravalvular calcification
- ✓ operator experience and preference
- ✓ ***location of the leak****

PROCEDURAL PRINCIPLES

Difficulties affecting technical success

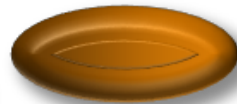
Inability to access PVL

- presence of mechanical valves
- vascular access difficulties
- leak location: mPVL (septal/posterior)

Inability to cross

- serpiginous tracks
- paravalvular calcification
- different orifice size on either side of valve

Shape



Oval



Round



Crescent



Undetermined

Track

- Parallel
- Perpendicular
- Serpiginous

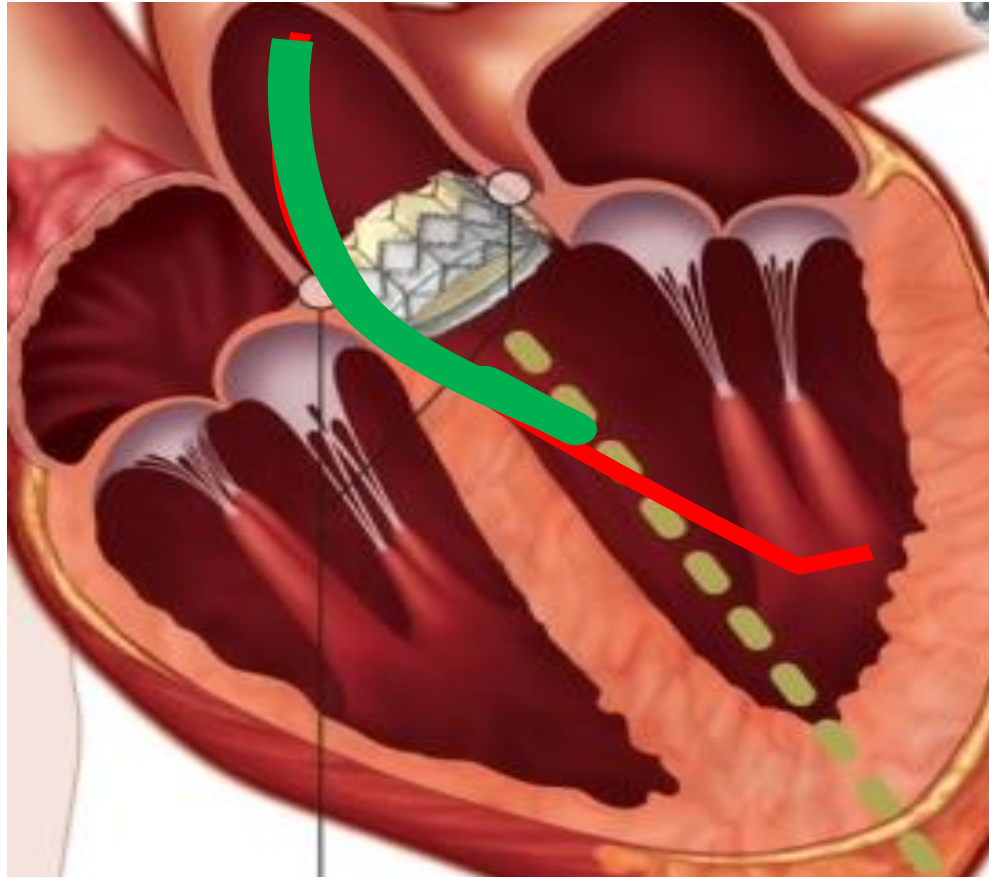
AORTIC PARAVALVULAR LEAK

Choice of approach :

- ✓ Retrograde trans-aortic**
- ✓ Antegrade trans-septal
- ✓ Retrograde trans-apical*

AORTIC PARAVALVULAR LEAK

↙ Retrograde trans-aortic from femoral artery approach **

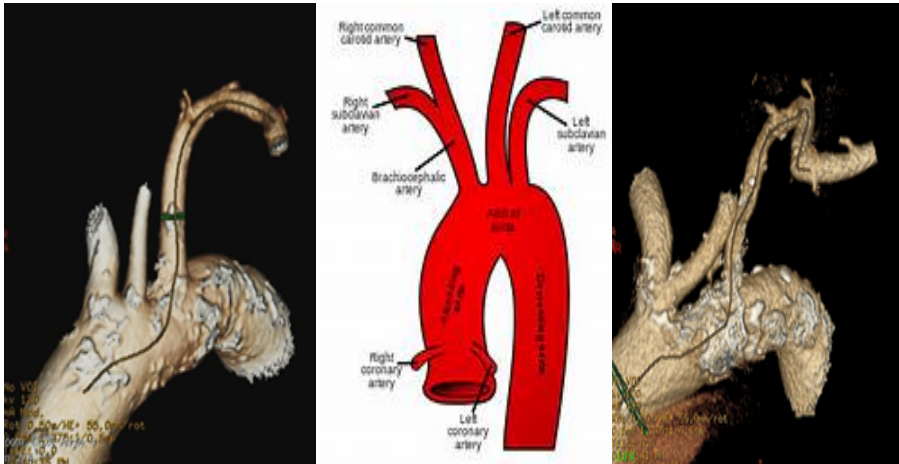


↙ Retrograde trans-apical*

AORTIC PARAVALVULAR LEAK

Retrograde trans-aortic from **subclavian artery** approach *

second-choice access : shorter distance to the aortic valve, perhaps making the procedure easier, or with safer positioning, and potentially less radiation and contrast agent



AORTIC PARAVALVULAR LEAK

General considerations

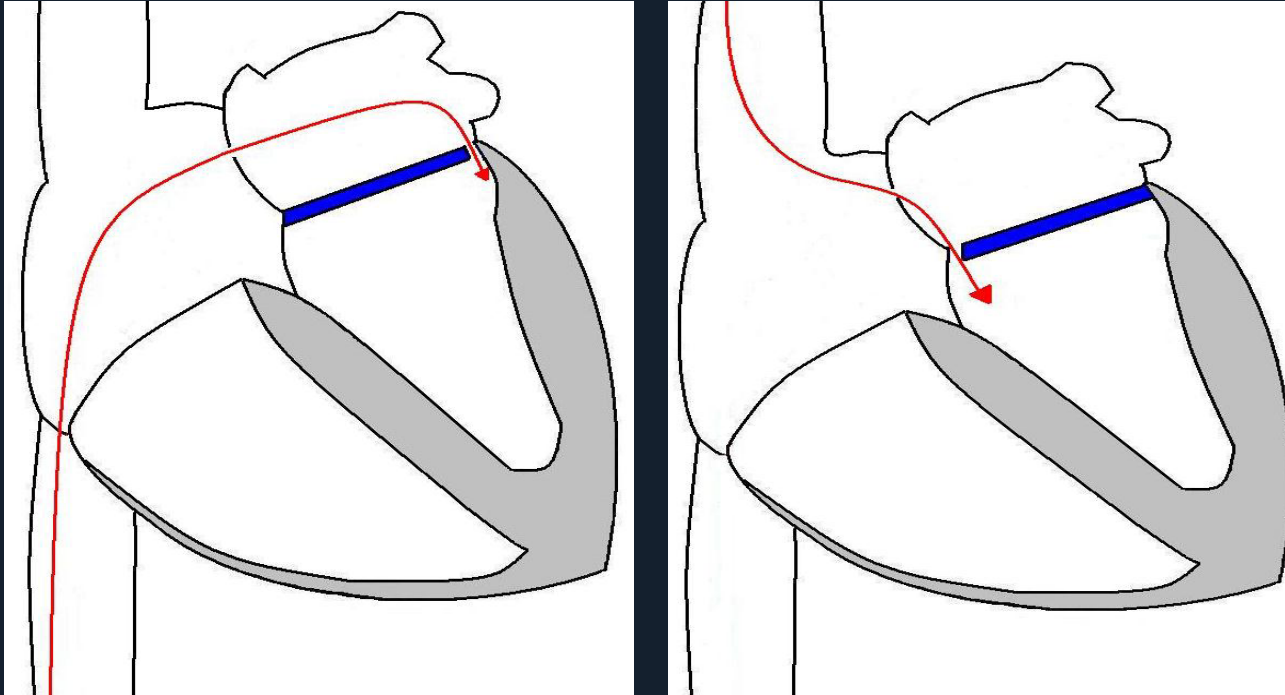
- Most frequent locations : left and **noncoronary** sinus
- Echocardiography : most important before, not during the procedure
- Percutaneous repair is feasible in most patient
- Should be the first therapeutic option

MITRAL PARAVALVULAR LEAK

Choice of approach :

- ✓ Antegrade trans-septal*
- ✓ Retrograde trans-aortic
- ✓ Retrograde trans-apical**

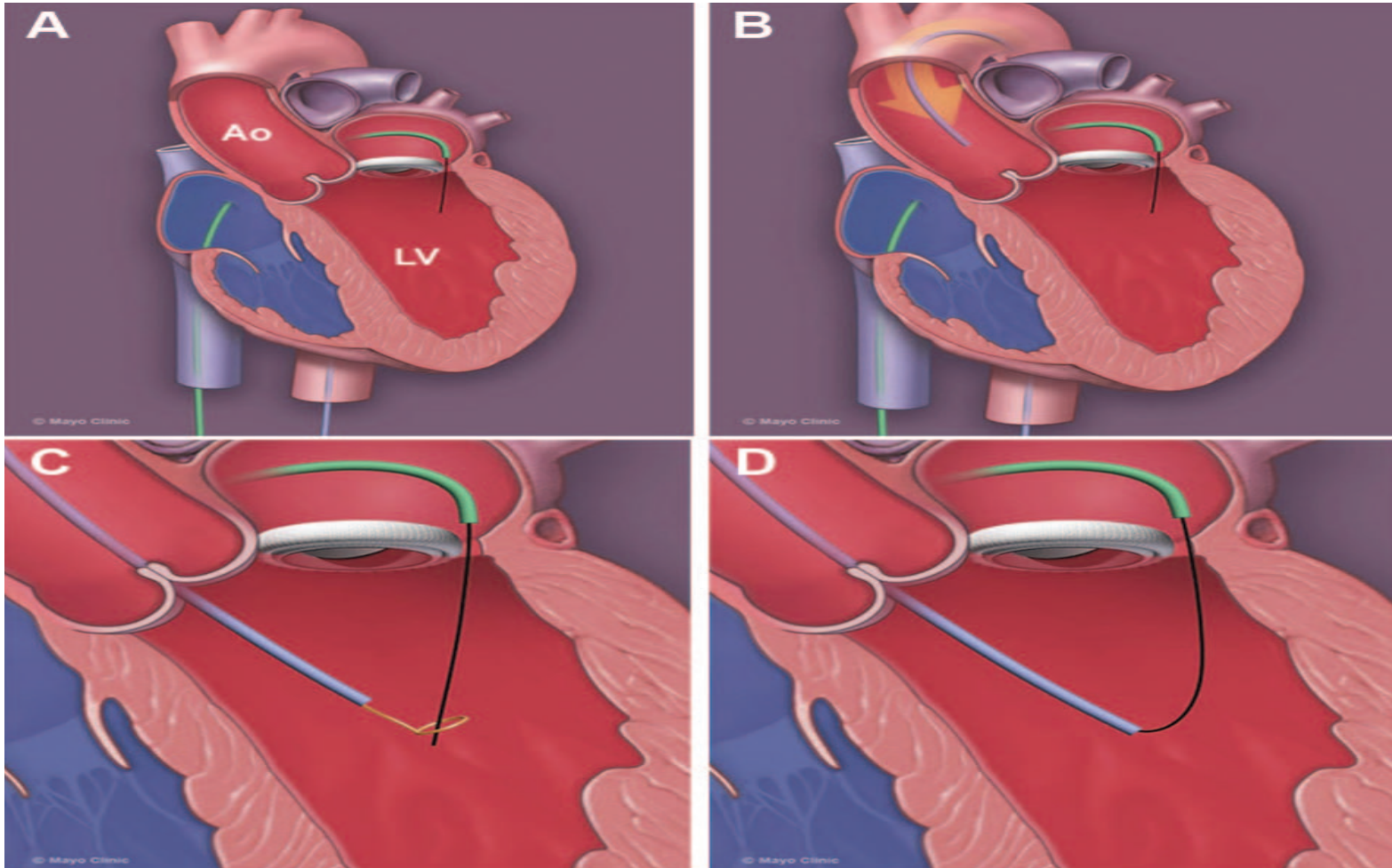
Antegrade approaches



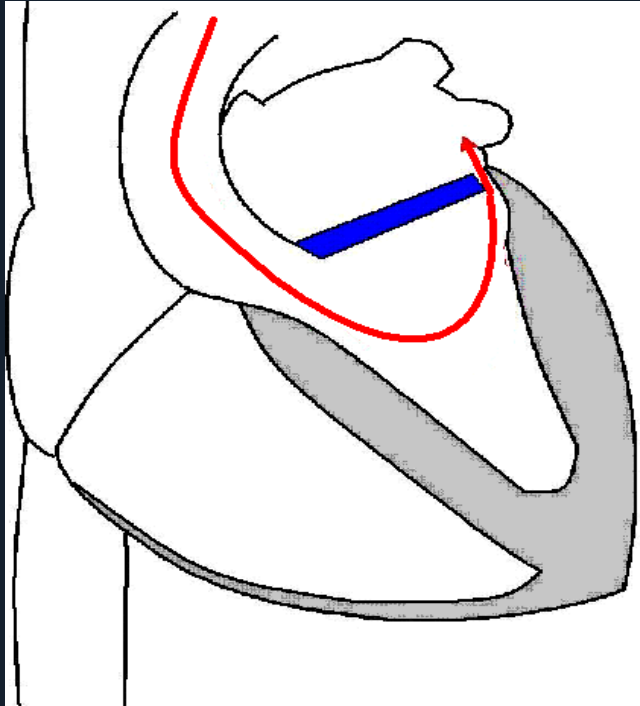
Anterograde trans-septal

- Difficult entry into LV
- Crossing **reverse** to the regurgitant flow through the leak
- Less wire **pushability** to cross

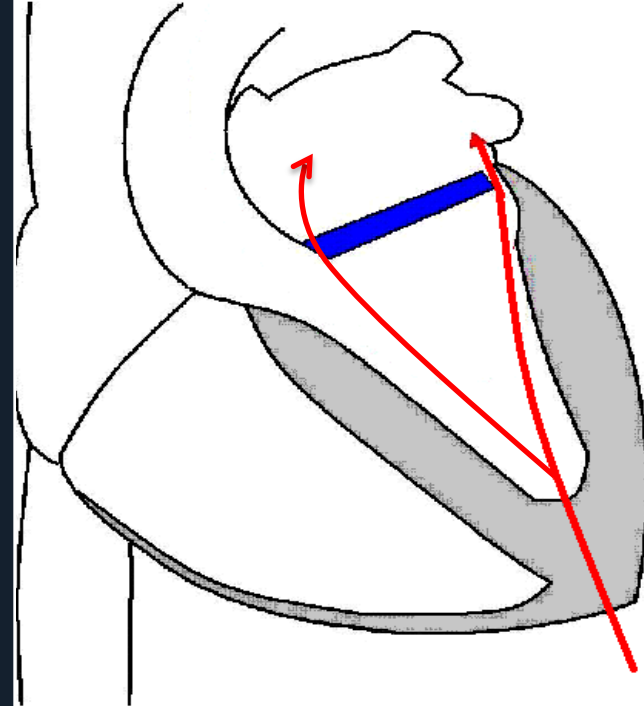
Antegrade transseptal approach



Retrograde approaches



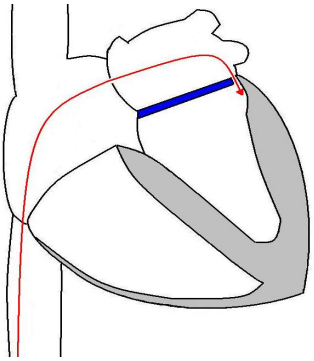
Retrograde from Ao-LV



Trans-apical

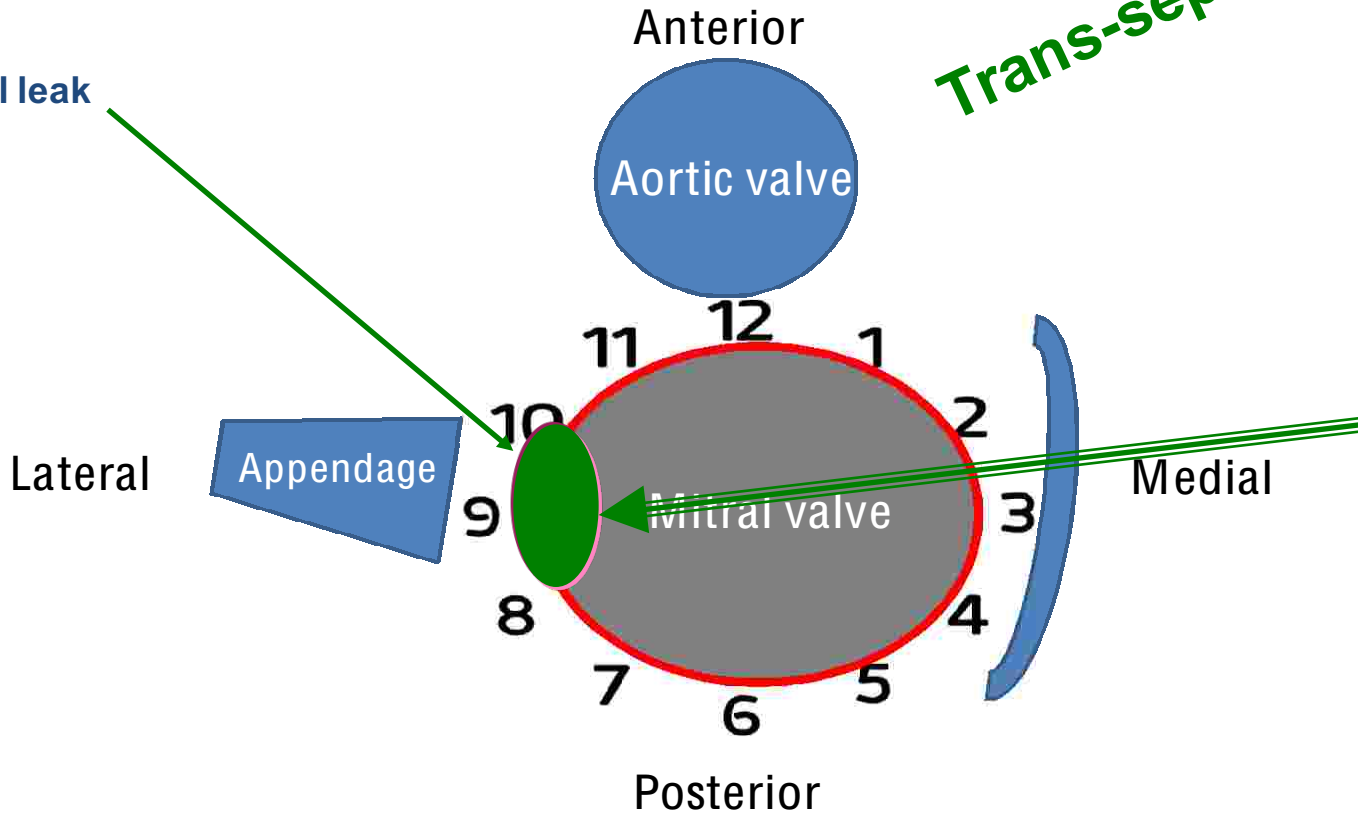
- Crossing on the **same** direction of the regurgitant flow through the leak
- Better wire **pushability**

MITRAL VALVE CLOCKFACE

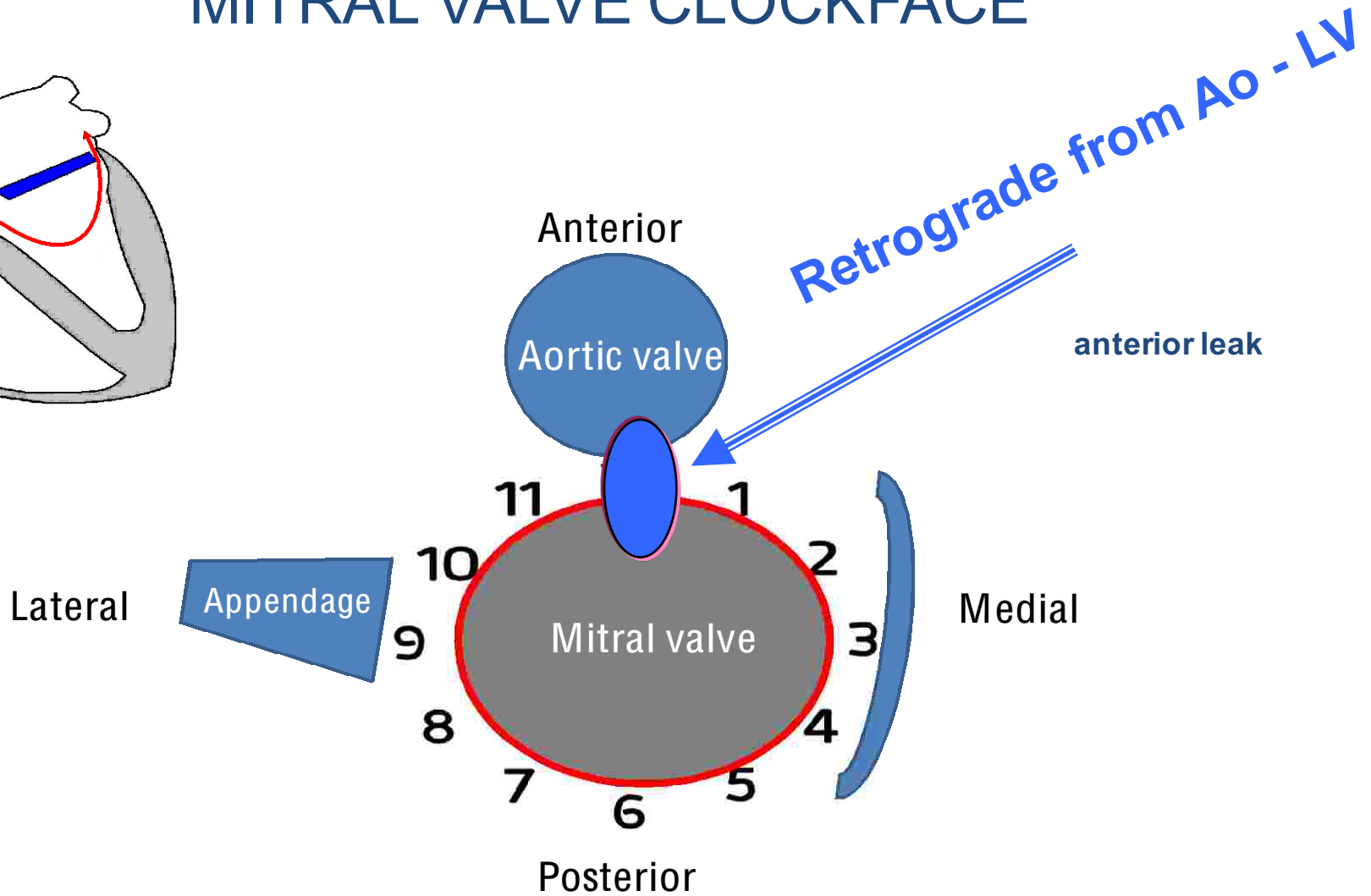
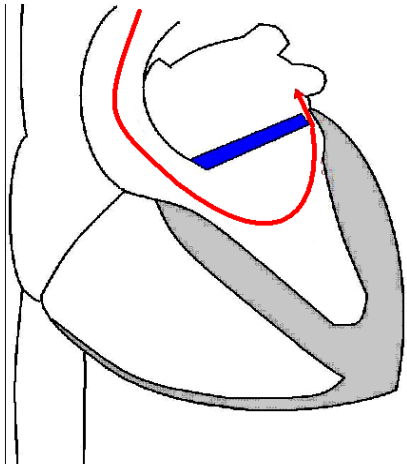


lateral leak

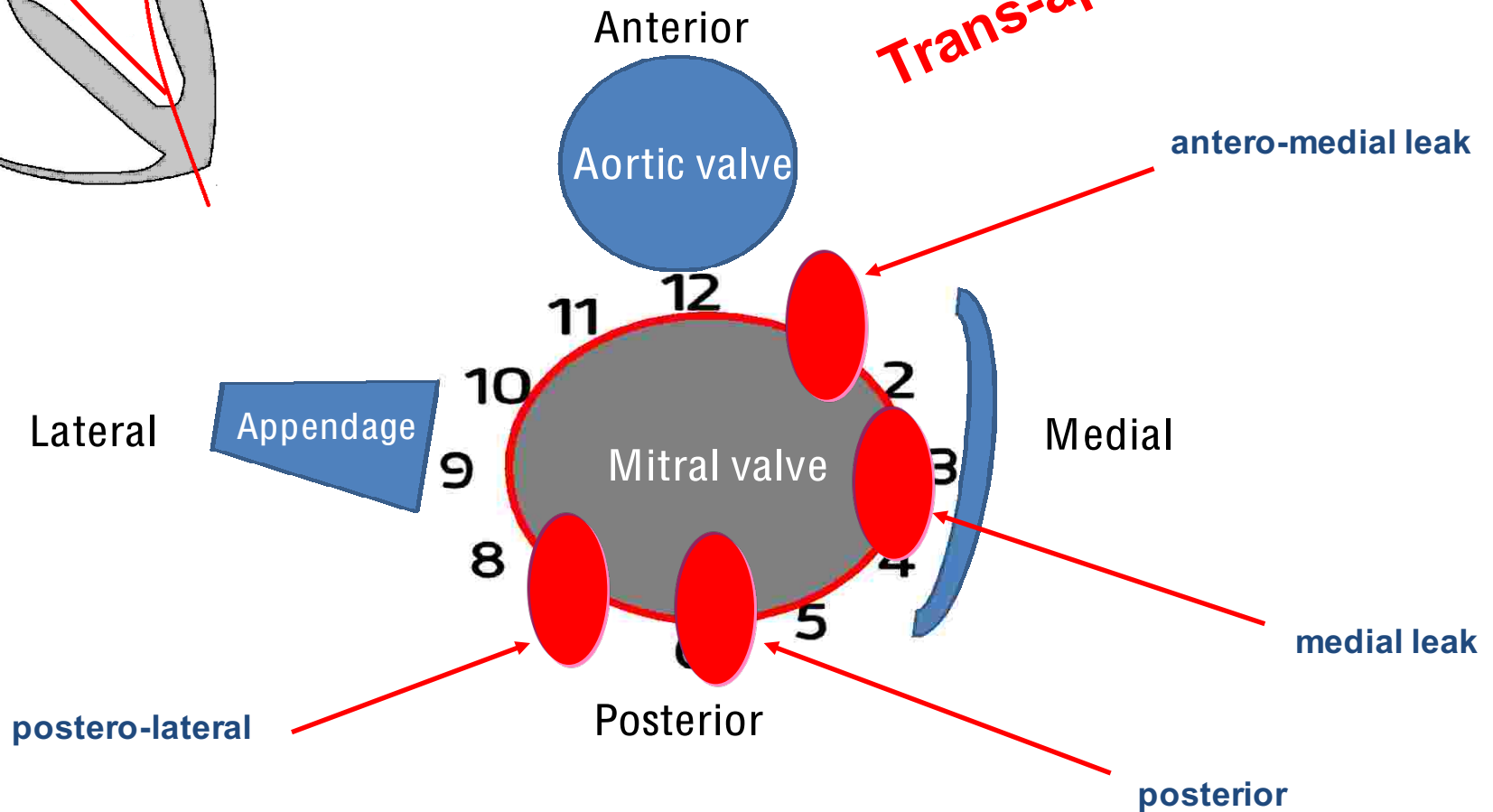
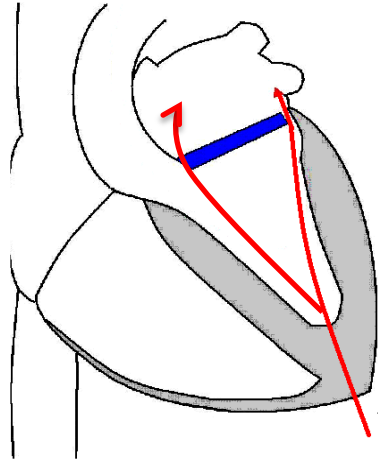
Trans-septal approach !



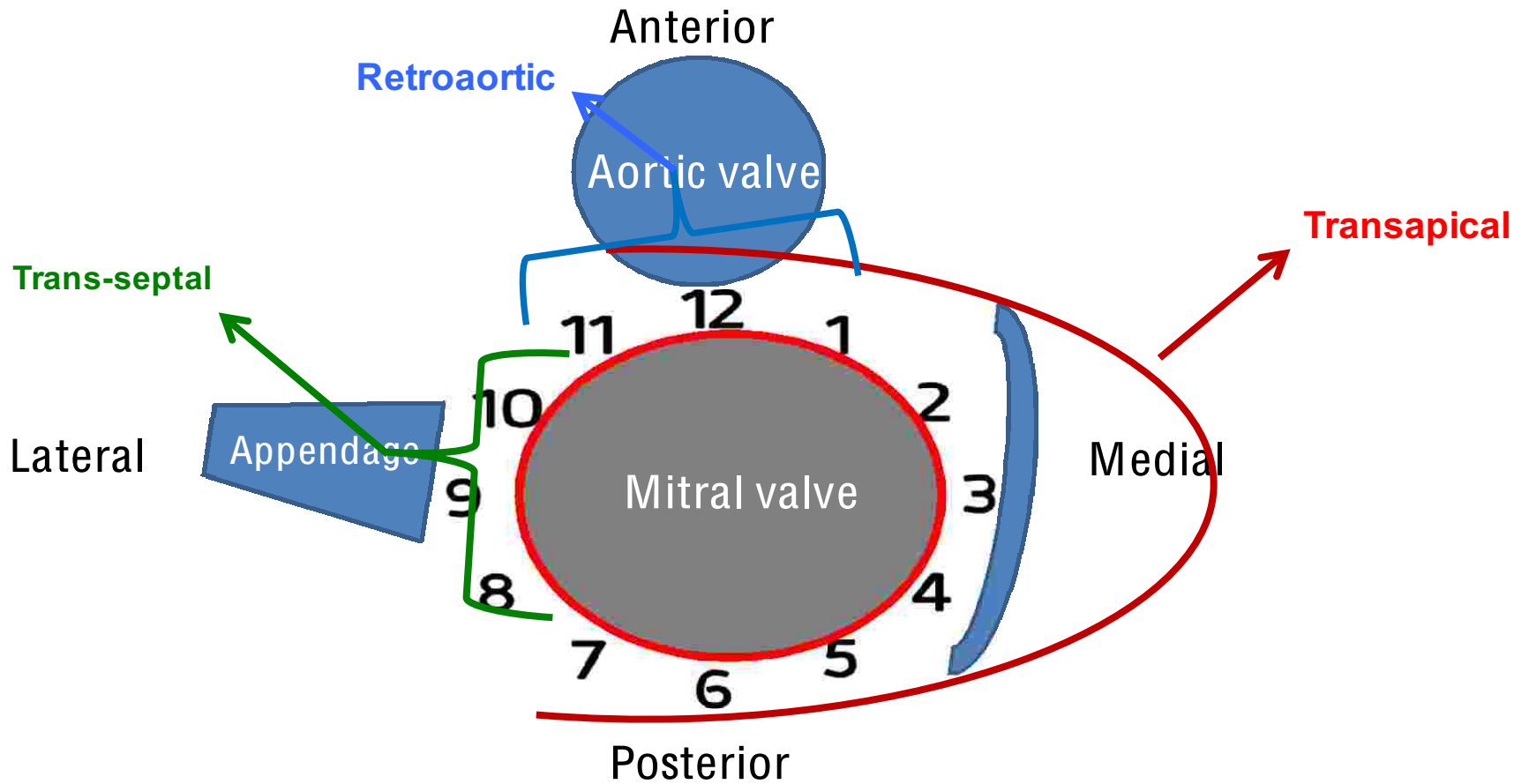
MITRAL VALVE CLOCKFACE



MITRAL VALVE CLOCKFACE



MITRAL VALVE CLOCKFACE

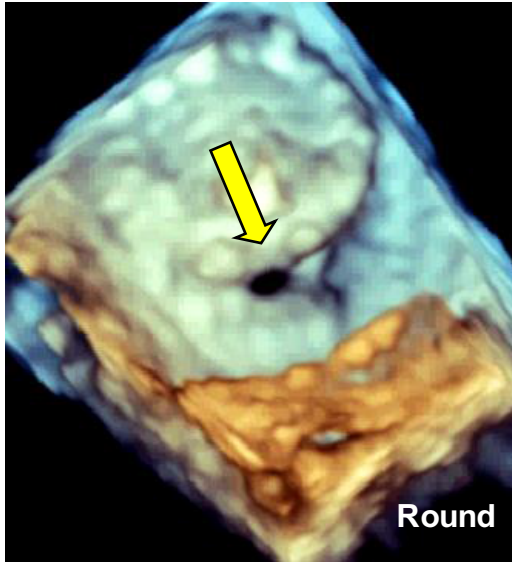


MITRAL PARAVALVULAR LEAK

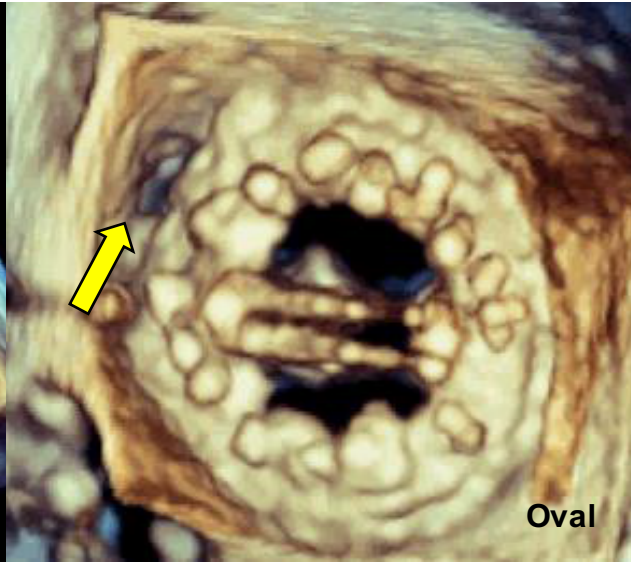
General considerations

- Transeptal puncture is the key step !
- New routes : **transapical**, retrograde
- Generous anticoagulation : heavy manipulation in the LA
- Cooperation between echo team – interventionalist **mandatory !!**
- Mitral paravalvular leak repair is more technically demanding

Shapes of paravalvular leaks



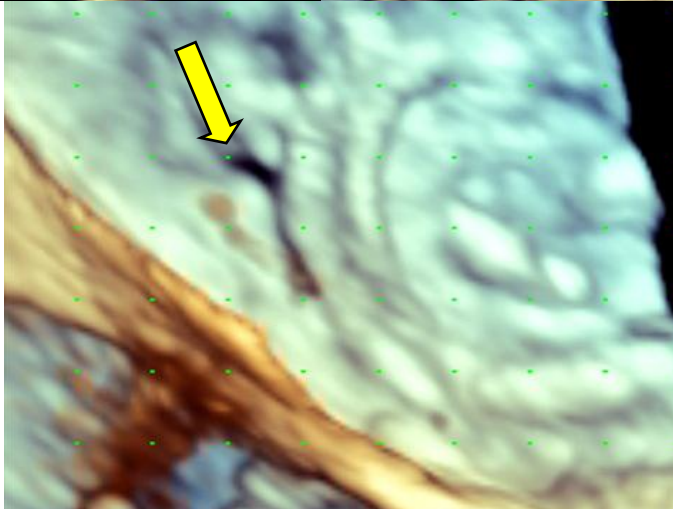
Round



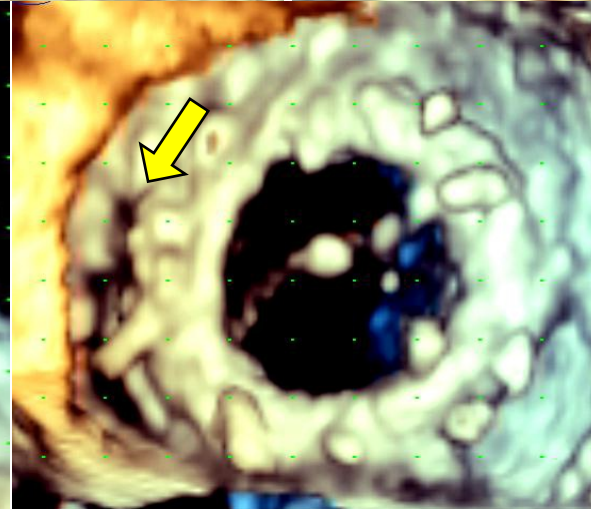
Oval



Crescentic

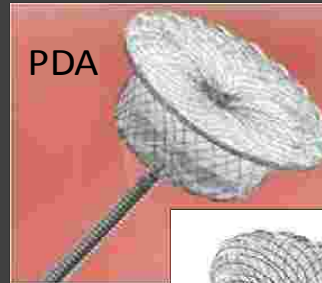
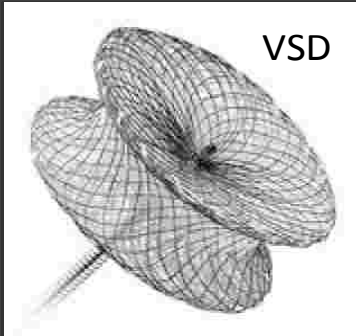


Slit-like



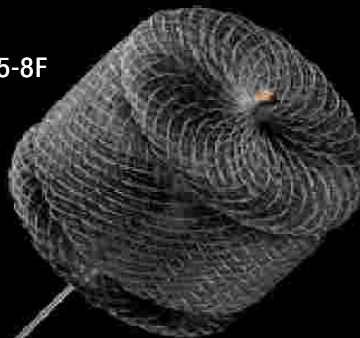
Crescent cutting edge

PARAVALVULAR LEAK TREATMENT



AVP

Delivery sheath 5-8F



AVP3



AVP4

4-8mm

Delivery catheter 4-5F



Amplatzer Family

PARAVALVULAR LEAK TREATMENT

Optimal Device

- PFO-ASD
 - Big discs to anchor
 - Big discs to interfere with adjacent structures
- PDA-VSD devices
 - Less anchor-may move-large devices
- Vascular plugs
 - AVP-2 lots of waist
 - AVP-3 perhaps the best currently
 - AVP-4 –soft device



PARAVALVULAR LEAK TREATMENT

- The currently available vascular closure devices available in the market are not always well fitted to the **irregular, crescent shape** of the PVL, which can lead to hemolysis, device embolization, interference with prosthetic leaflets, or coronary occlusions*
- In addition to the crescentic appearance by cross section, PVL have a ***serpentine, longitudinal aspect***, which can be challenging with regards to wire and catheter crossing, and in obtaining an effective seal with self-expanding devices

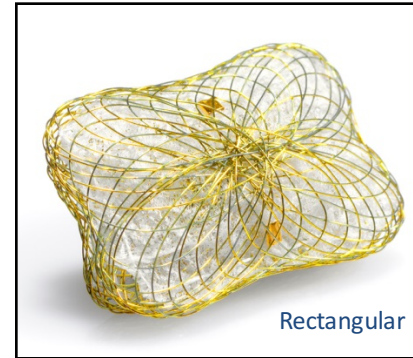
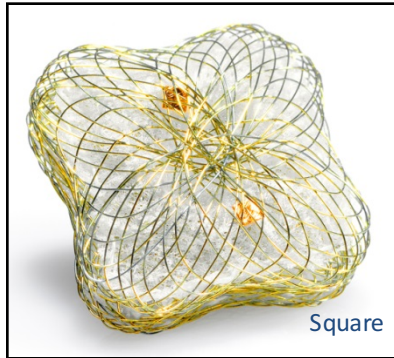
PARAVALVULAR LEAK TREATMENT

- Until 2014 there have been no devices available specifically designed and indicated for PVL closure and which are CE marked

Occlutech Paravalvular Leak Device (PLD®)

(Occlutech GmbH, Jena, Germany)

- Two different shapes:



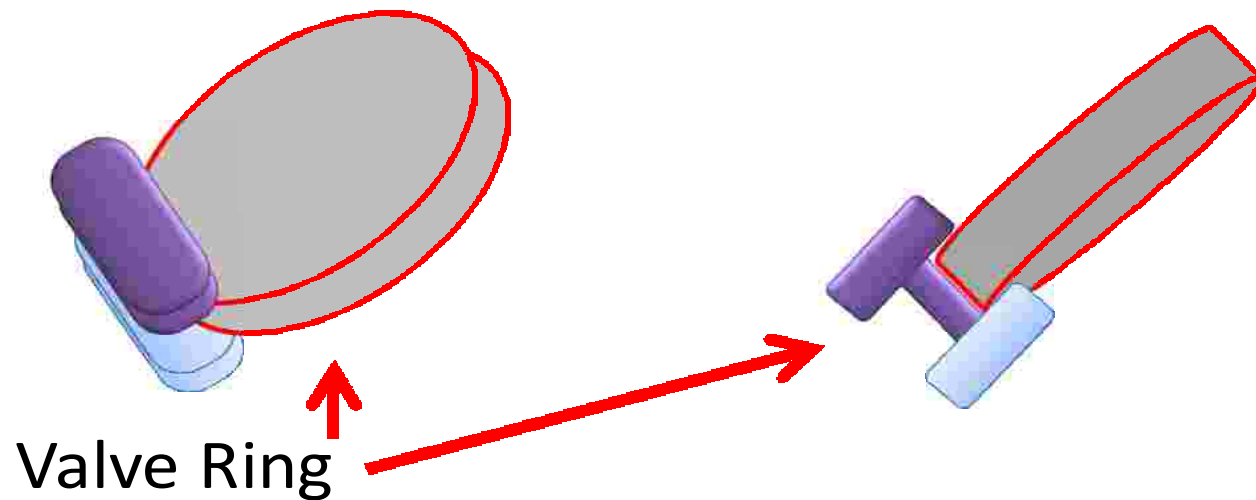
- Two different disc – connections:



Two PET patches One in each disc

ADVANTAGES (1)

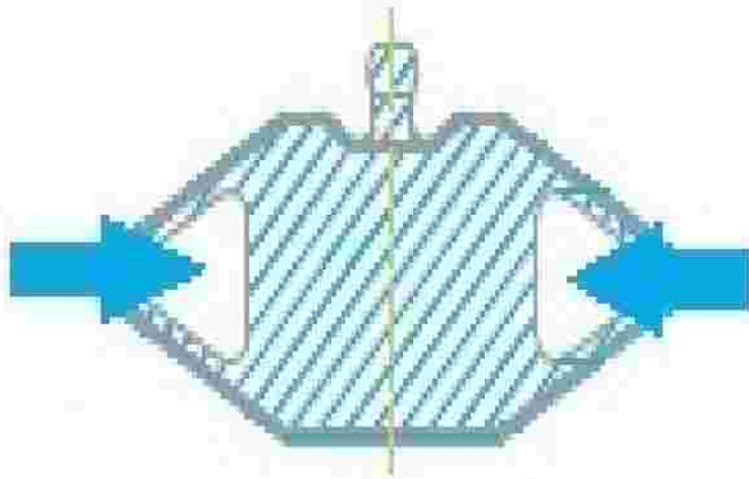
Occlutech Paravalvular Leak Device (PLD®)



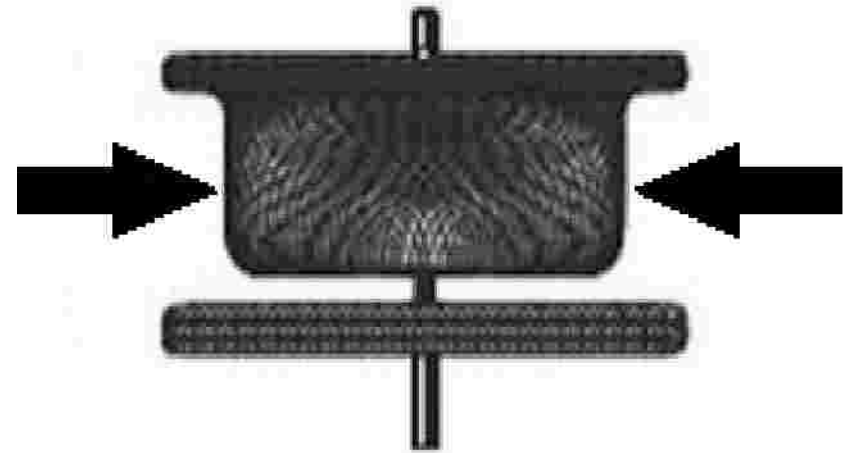
Occlutech PLD has clamping force to keep the prosthetic valve and tissue together after closing the defect, AVP III has no clamping force

ADVANTAGES (2)

Occlutech Paravalvular Leak Device (PLD®)

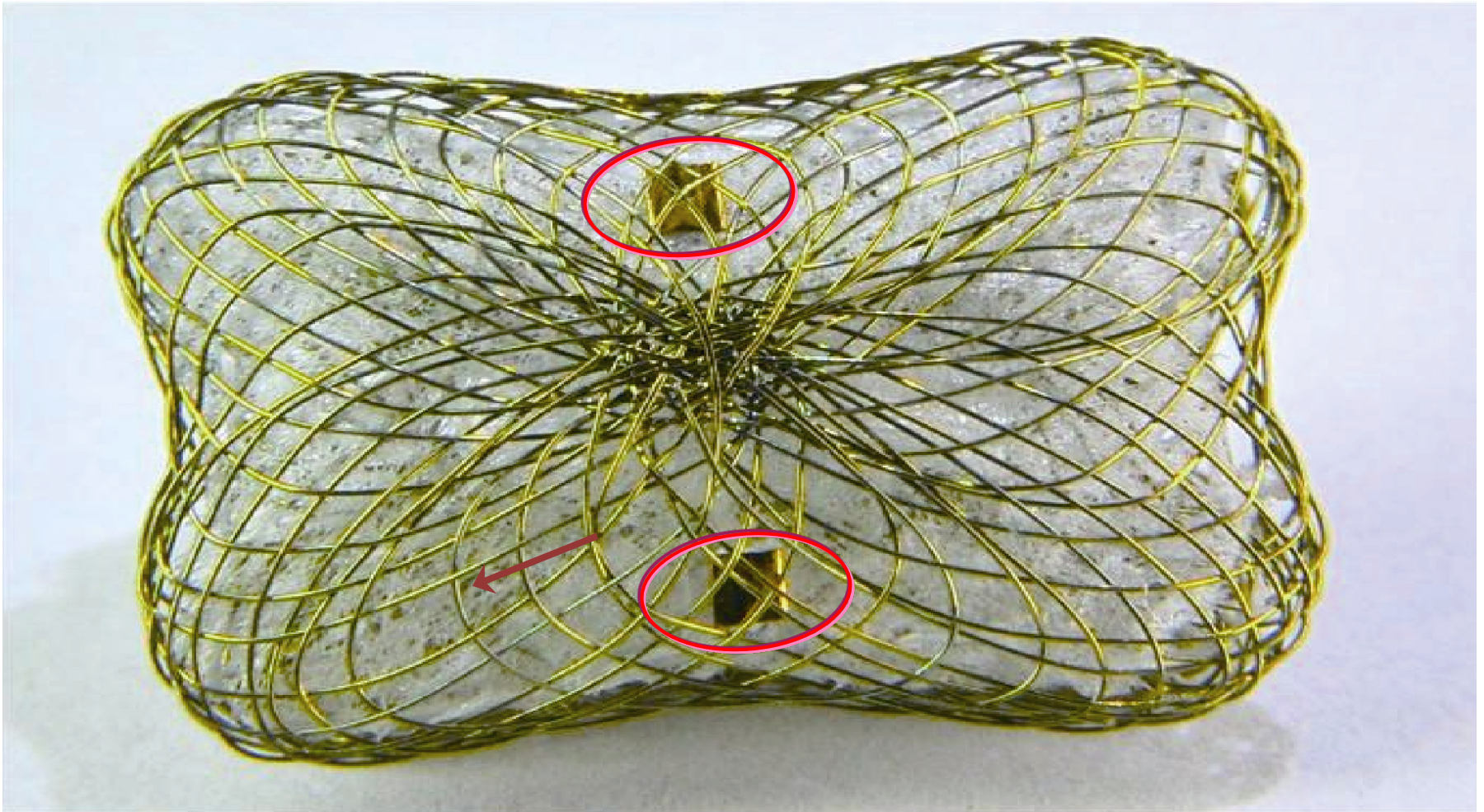


No Radial Strength



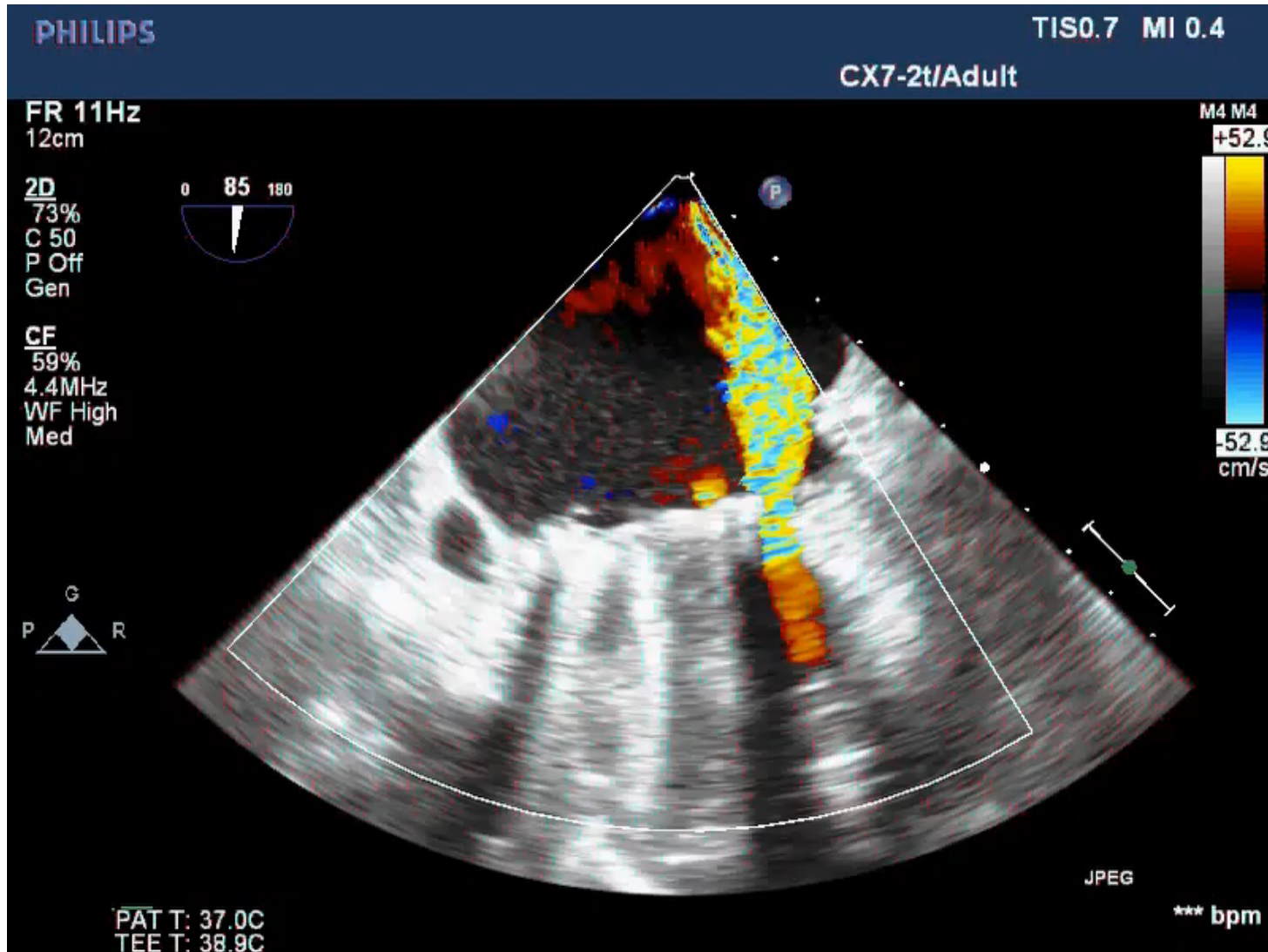
High Radial Strength

Occlutech Paravalvular Leak Device (PLD®)



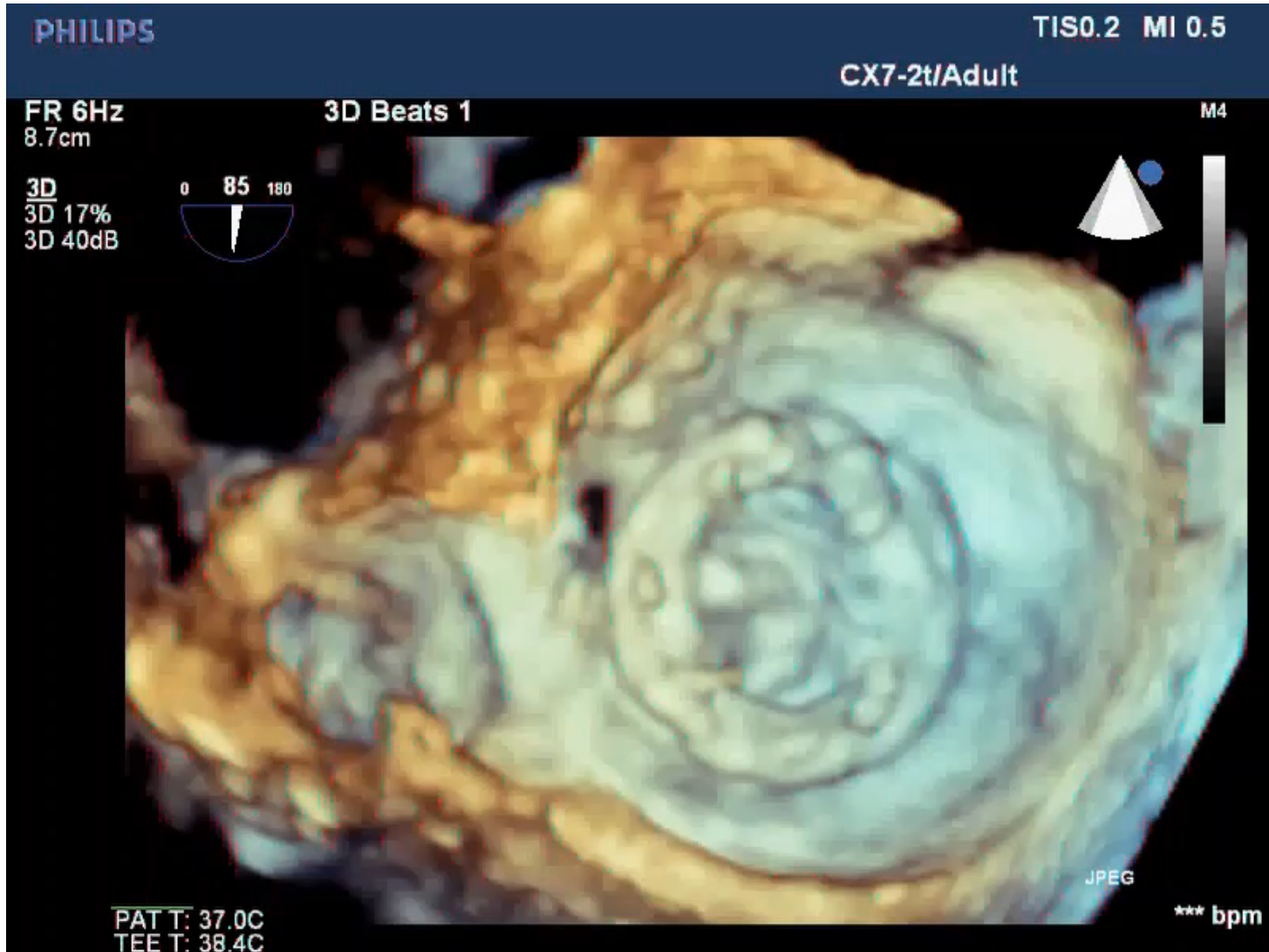
Radiopaque markers for secure device positioning

Preprocedural planning (2D TEE)



Antero-lateral Mitral Paravalvular Leak

Preprocedural planning (3D RT TEE)



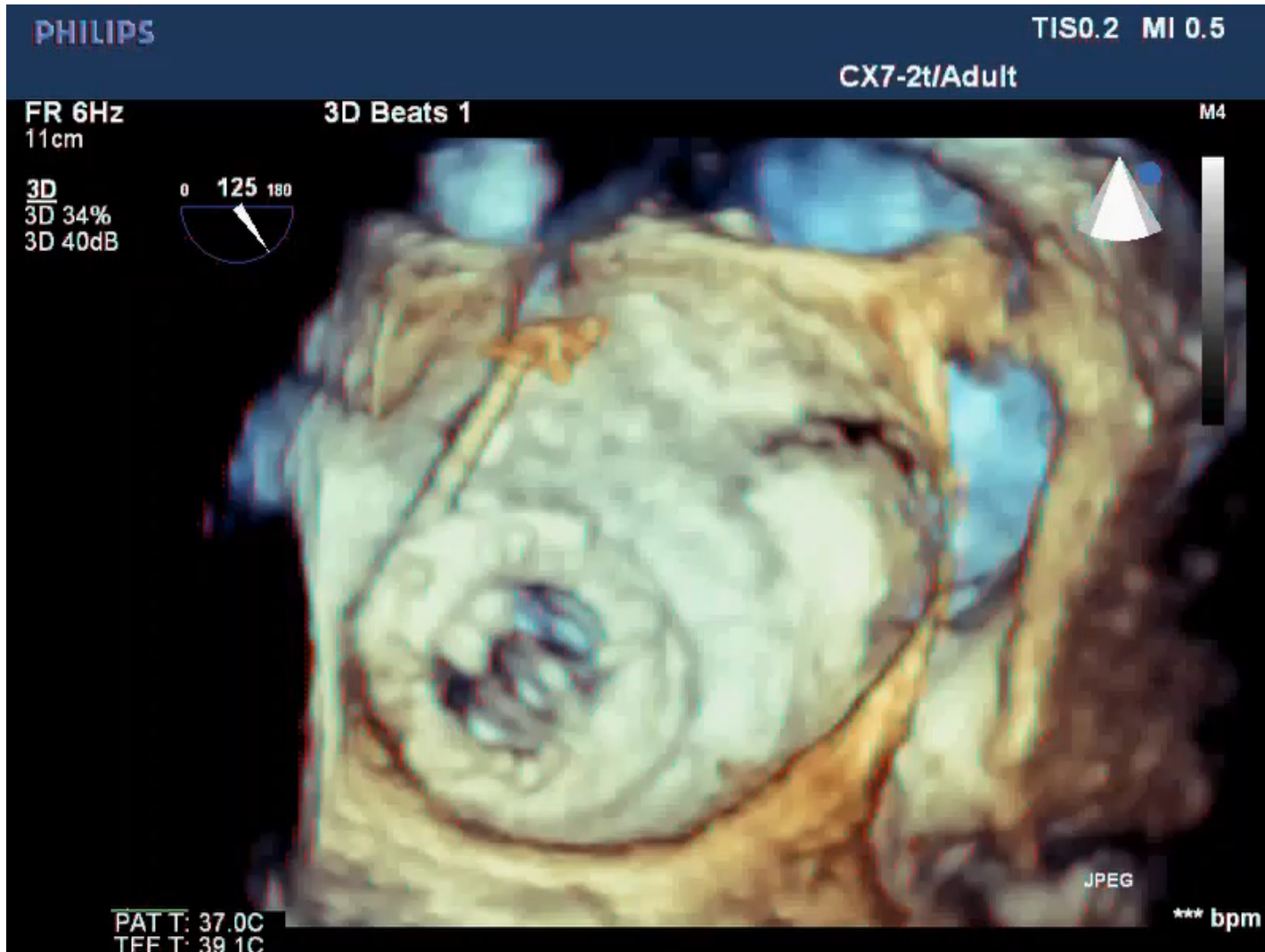
Antero-lateral Mitral Paravalvular Leak

Preprocedural planning (3D RT TEE)



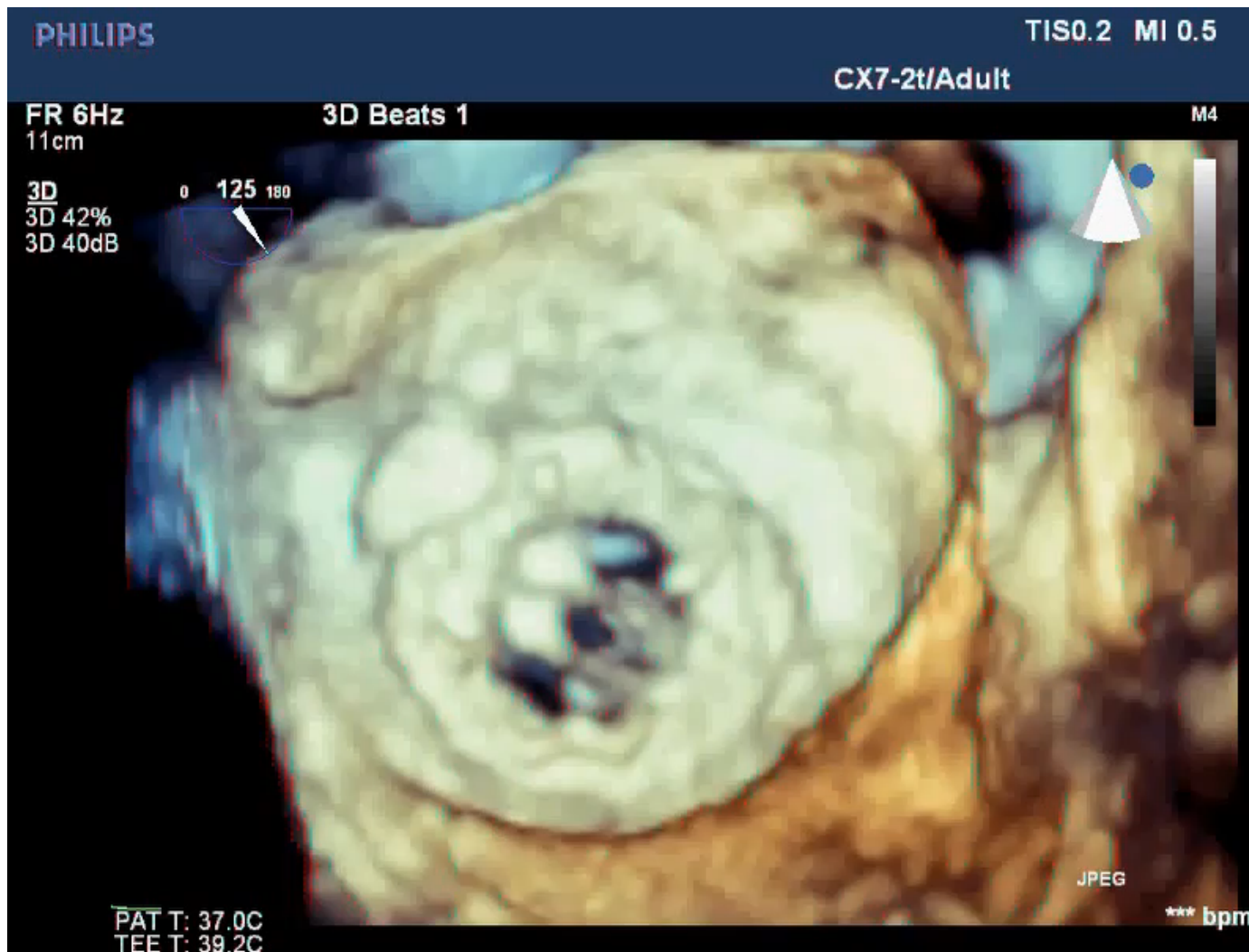
Antero-lateral Mitral Paravalvular Leak

Procedural Imaging (3D RT TEE)



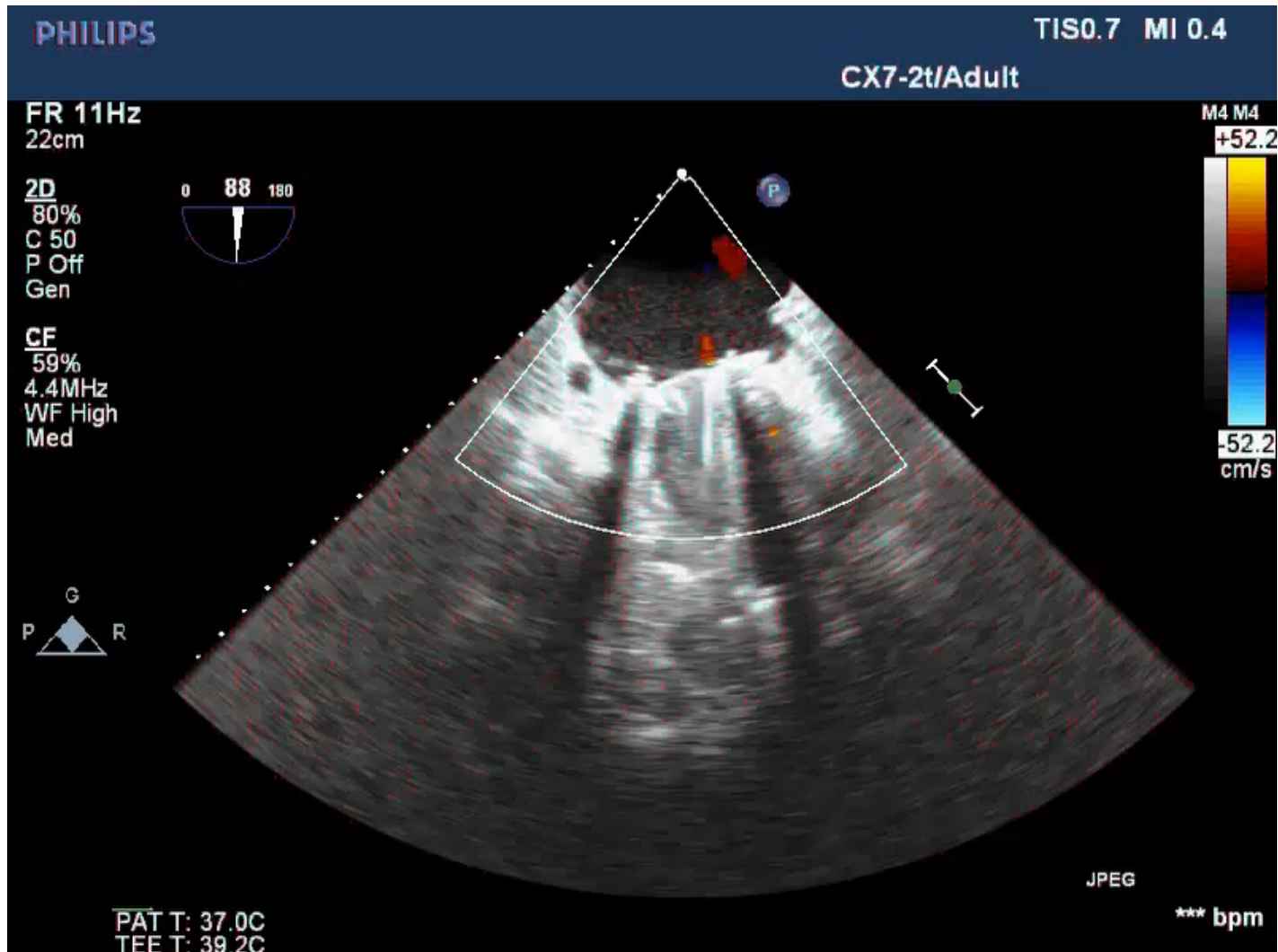
Opening the distal disc in the LA and pushing it towards the mitral prosthetic annulus

Procedural Imaging (3D RTTEE)



Final position of the Occlutech *PLD® Rectangular Waist 10x4 mm*

Procedural Imaging (2D TEE)



Occlutech *PLD® Rectangular Waist 10x4 mm* in situ, no residual shunt

PARAVALVULAR LEAK TREATMENT

Clinical Experience

Author (Year)	Patients (Aortic, Mitral)	Technical Success	Clinical Success
Hourihan (1992)	4 (A: 4, M: 0)	3 (100%)	2 (50%)
Pate (2006)	10 (A: 1, M: 9)	7 (70%)	4 (40%)
Hein (2007)	21 (A: 8, M: 13)	20 (95%)	14 (67%)
Shapira (2007)	11 (A: 2, M: 9)	10 (91%)	6 (54%)
Cortes (2008)	27 (A: 0, M: 27)	17 (63%)	10 (37%)
Alonso-Briales (2009)	8 (A: 4, M: 4)	7 (88%)	4 (50%)
Garcia-Barbolla (2009)	8 (A: 0, M: 8)	5 (63%)	4 (50%)
Neitlispach (2010)	5 (A: 1, M: 4)	5 (100%)	5 (100%)
Sorajja (2011)	115 (A: 25, M: 90)	88 (77%)	77 (67%)
Ruiz (2011)	43 (A: 10, M: 33)	37 (86%)	33 (77%)
Total/Average	252	80%	63%

PARAVALVULAR LEAK TREATMENT

Clinical Experience

Author	Year	PVL Type	Device Used	No. of Defects
Hourihan et al. (7)	1992	AV	Double-Umbrella Rashkind	4
Moore et al. (19)	2000	MV	Gianturco coil	1
Eisenhauer et al. (20)	2001	MV	Gianturco-Grifka Vascular Occlusion Device	1
Kort et al. (8)	2004	MV	Amplatzer Duct Occluder	1
Webb et al. (12)	2005	AV	Amplatzer Duct Occluder	1
Pate et al. (2)	2006	MV (9); AV (1)	Amplatzer Septal Occluder, Amplatzer Duct Occluder, coils	10
Hildick-Smith et al. (15)	2007	AV	Amplatzer Muscular VSD Occluder	1
Momplaisir et al. (16)	2007	MV	Amplatzer Septal Occluder	1
Shapira et al. (17)	2007	MV (9); AV (2)	Amplatzer occluder	13
Sorajja et al. (13)	2007	MV (17); AV (2)	Amplatzer Septal Occluder or Amplatzer Duct Occluder	19
Cortes et al. (14)	2008	MV	Amplatzer Duct Occluder	27

AV = aortic valve; MV = mitral valve; n/a = information not available; PVL = paravalvular leaks; VSD = ventricular septal defect.

PARAVALVULAR LEAK TREATMENT

Clinical Experience

Table 3 Current Publications

First Author (Ref. #)	Year	Type (n)	Patients (n)	Leaks (n)	Technical Success	Clinical Success	Repeat Procedures	Mean Fluoroscopy Time (min)
Hourihan et al. (10)	1992	A	3	3	3 (100%)	2 (67%)	1 (33%)	n/a
Pate et al. (20)	2006	M (9) A (1)	10	10	7 (70%)	4 (57%)	4 (40%)	62
Hein et al. (18)	2006	M (13) A (8)	21	26	24 (92%)	14 (67%)	9 (43%)	31
Shapira et al. (21)	2007	M (9) A (2)	11	13	11 (85%)	6 (54%)	1 (8%)	60
Sorajja et al. (22)	2007	M (14) A (2)	16	19	17 (89%)	12 (75%)	0 (0%)	55
Cortes et al. (19)	2008	M	27	27	17 (63%)	10 (59%)	0 (0%)	n/a
García-Borbolla Fernández et al. (11)	2009	M	8	8	5 (63%)	4 (80%)	0 (0%)	n/a
Nietlispach et al. (25)	2010	A (1) M (4)	5	5	5 (100%)	5 (100%)	0 (0%)	15

A = aortic paravalvular leak; M = mitral paravalvular leak; n/a = not available.

Early experience of percutaneous paravalvular leak closure using a novel Occlutech occluder



Omer Goktekin^{1*}, MD; Mehmet Akif Vatankulu¹, MD; Hakan Ozhan², MD; Yasin Ay³, MD; Mehmet Ergelen¹, MD; Abdurrahman Tasal¹, MD; Cemalettin Aydin³, MD; Ziya İsmail¹, MD; İsmail Ates⁴, MD; Ziyad Hijazi⁵, MD

1. Department of Cardiology, Bezmialem University, Istanbul, Turkey; 2. Department of Cardiology, Duzce University, Duzce, Turkey; 3. Department of Cardiovascular Surgery, Bezmialem University, Istanbul, Turkey; 4. Medline Antalya Hospital, Antalya, Turkey; 5. Rush Center for Congenital & Structural Heart Disease, Rush University Medical Center, Chicago, IL, USA

Conclusion

The novel **Occlutech PLD®**, which was designed specifically for mitral and aortic paravalvular regurgitation, is an additional tool in the device armamentarium for the treatment of PVL seems to satisfy the expectations of a specifically designed PVL closure

Original Studies

A New Specific Device in Transcatheter Prosthetic Paravalvular Leak Closure: A Prospective Two-Center Trial

Aydin Yildirim,¹ MD, Omer Goktekin,² MD, Sevket Gorgulu,^{3*} MD, Tugrul Norgaz,³ MD, Emre Akkaya,¹ MD, Unal Aydin,⁴ MD, Hale Unal Aksu,¹ MD, and Ihsan Bakir,⁴ MD

Cardiology Department, Bezmialem University ; Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training & Research Hospital, Istanbul, Turkey

- Between April 2012 and January 2015, prospective two-center study , **52** patients with hemodynamically significant PVL underwent percutaneous closure. Group I (**32**): closure with currently available devices (off-label); Group II (**20**): treated with new specifically designed **Occlutech PLD®**
- Transapical approach was the most commonly used route for Group II
- Procedural success : **100%** (29 of 29 leaks) in Group II
92% (39 of 42 leaks) in Group I
- More secondary events observed in Group I

With its high procedural success rate and encouraging outcome results, the **Occlutech PLD®** seems to satisfy the expectations of a specifically designed PVL closure

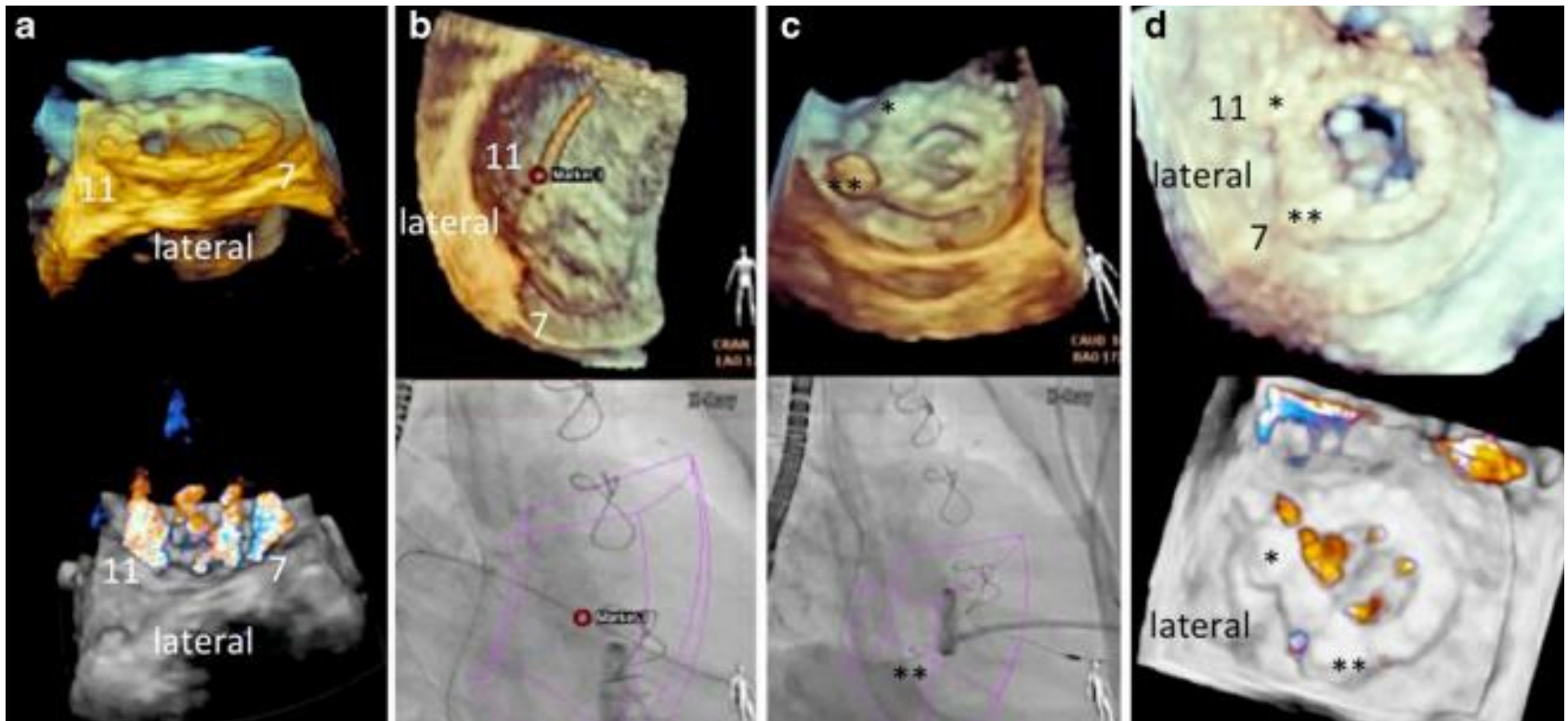
Concluding Remarks (1)

- ✓ PVL closure technically challenging procedure: complex catheter techniques and large interventional armamentarium, significant learning curve
- ✓ For the high-risk symptomatic PVL patient, catheter closure is a viable therapeutic alternative strategy to surgical PVL repair
- ✓ Novel approaches to complex PVLs are now improving procedural success and complication rates
- ✓ Residual PV regurgitation is the key determinant of outcome !

Concluding Remarks (2)

- ✓ These procedures can be technically demanding, but are clearly facilitated by a **“team approach”**
- ✓ Requires *multiple imaging modalities* and the ability to visualize the 3D relationships of intracardiac structures : a collaborative effort with a **skilled interventional team** (interventionalist, echocardiographer skilled in 3D echo and a CT specialist skilled in 4D reconstruction) and **surgeons**

The “fusion” of different imaging modalities may facilitate the procedure !



EchoNavigator Philips Healthcare



EchoNavigator Philips Healthcare



Multi - Institutional Experience - Occlutech PLD®

Coordinating Investigator: Eustaquio M. Onorato, MD,FSCAI

29 Occlutech® PLD were implanted
in 21 patients from January 2015

- Santariskiu Klinikos, Vilnius - Lithuania (8)
- Centro Cardiologico Monzino, Milan – Italy (4)
- American Heart Institute, Nicosia - Cyprus (2)
- Centru Cardiovascular Monza, Bucarest - Romania (1)
- Humanitas Gavazzeni, Bergamo – Italy (1)
- Catholic Hospital, Campobasso (1)
- San Gaudenzio Clinic, Novara – Italy (1)
- San Michele Clinic, Maddaloni – Italy (1)
- Castle Hill Hospital, Cottingham - UK (1)
- CHU Charles Nicole, Rouen – France (1)
- National Heart Center – Budapest, Hungary (1)

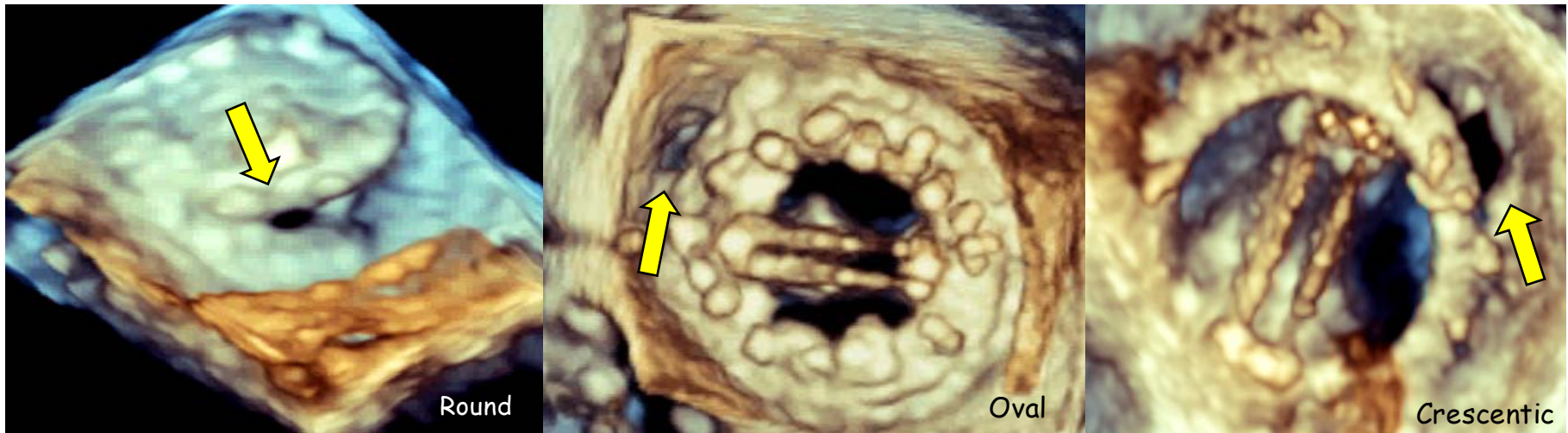


Baseline Characteristics

21 patients implanted from January 2015

all 15 mitral cases performed by **trans-apical approach**

Age years (range) / (mean)	43 - 88 / (67,7)
female / male	4 / 17
Leak location	
Aortic	6 (28,5%)
Mitral	15 (71,4%)
Mitral+Aortic	0
Time from implant to repair (years)	11 (\pm 5)



“A Multicenter International Follow-Up Study to Monitor the Efficacy and Safety of the Occlutech® Paravalvular Leak Device (PLD) in Patients with Mitral or Aortic Paravalvular Leaks”

“A Multicenter International Follow-Up Study to Monitor the Efficacy and Safety of the Occlutech® Paravalvular Leak Device (PLD) in Patients with Mitral or Aortic Paravalvular Leaks”

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