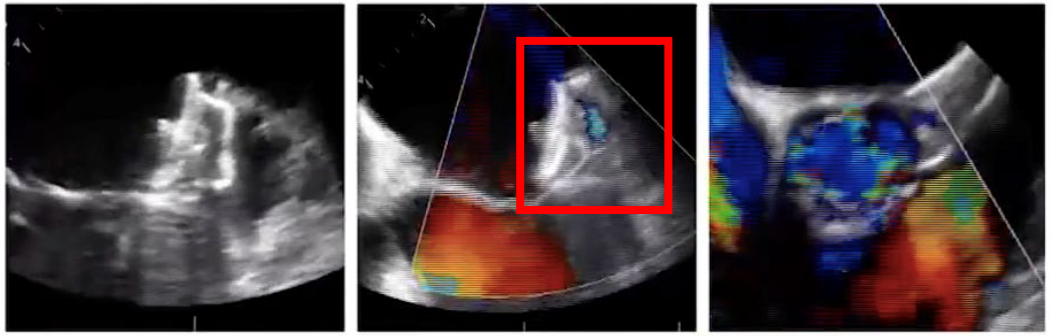
LAAO: What´s the best management of peridevice leak?



- *Dr. Aníbal Damonte (damontea@icronline.com)*
- *Director of the Department of Interventional Cardiology; Instituto Cardiovascular de Rosario, Argentina*
- *Former President CACI; Former President SOLACI*

✓ I do not have any potential conflict of interest related to this presentation

Agenda

What is a PDL leak and how to assess it?

Incidence of PDLs.

Association with thromboembolic events.

Differences between devices.

How to avoid PDLs?

How can we treat them?

Peri-device Leak

Clinically relevant communication between distal LAA and LA.

Presence of contrast at distal LAA per se, does not mean a clinically relevant communication exists.

A tunnel or gap through which a clot can pass throug is needed to define a clinically relevant peridevice leak.

PDL – DEFINITIONS

Europace Advance Access published August 18, 2016

Europace
doi:10.1093/europace/euw141

EHRA POSITION PAPER

Percutaneous left atrial appendage occlusion: the Munich consensus document on definitions, endpoints, and data collection requirements for clinical studies

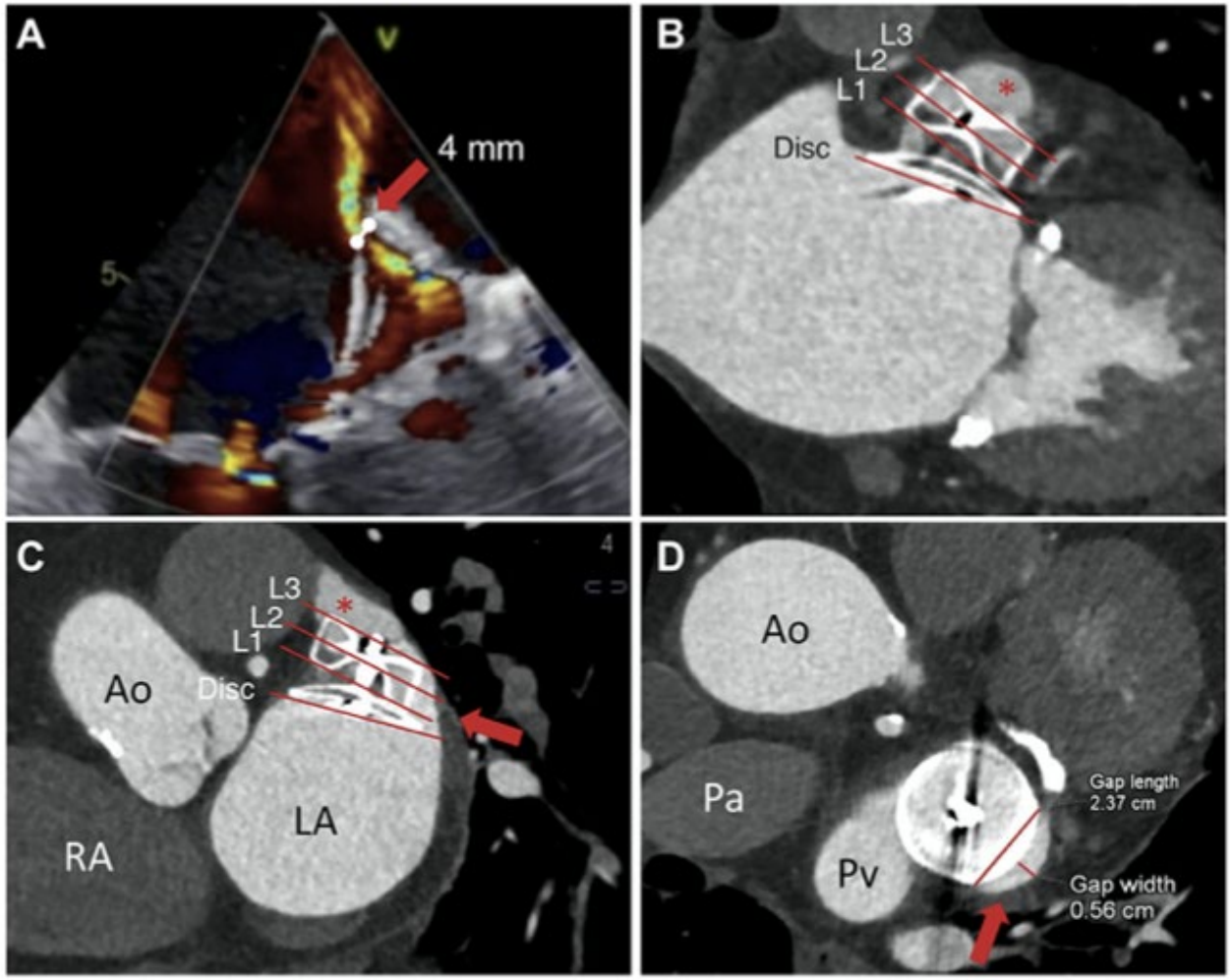
Apostolos Tzikas[1*], David R. Holmes Jr[2], Sameer Gafoor[3], Carlos E. Ruiz[4], Carina Blomström-Lundqvist[5†], Hans-Christoph Diener[6], Riccardo Cappato[7,8], Saibal Kar[9], Randal J. Lee[10], Robert A. Byrne[11‡], Reda Ibrahim[12], Dhanunjaya Lakkireddy[13], Osama I. Soliman[14], Michael Nabauer[15†], Steffen Schneider[16], Johannes Brachmann[17], Jeffrey L. Saver[18], Klaus Tiemann[19], Horst Sievert[3], A. John Camm[20], and Thorsten Lewalter[21*]

Table 14 Methodology suggested for assessment of residual leaks after LAA exclusion

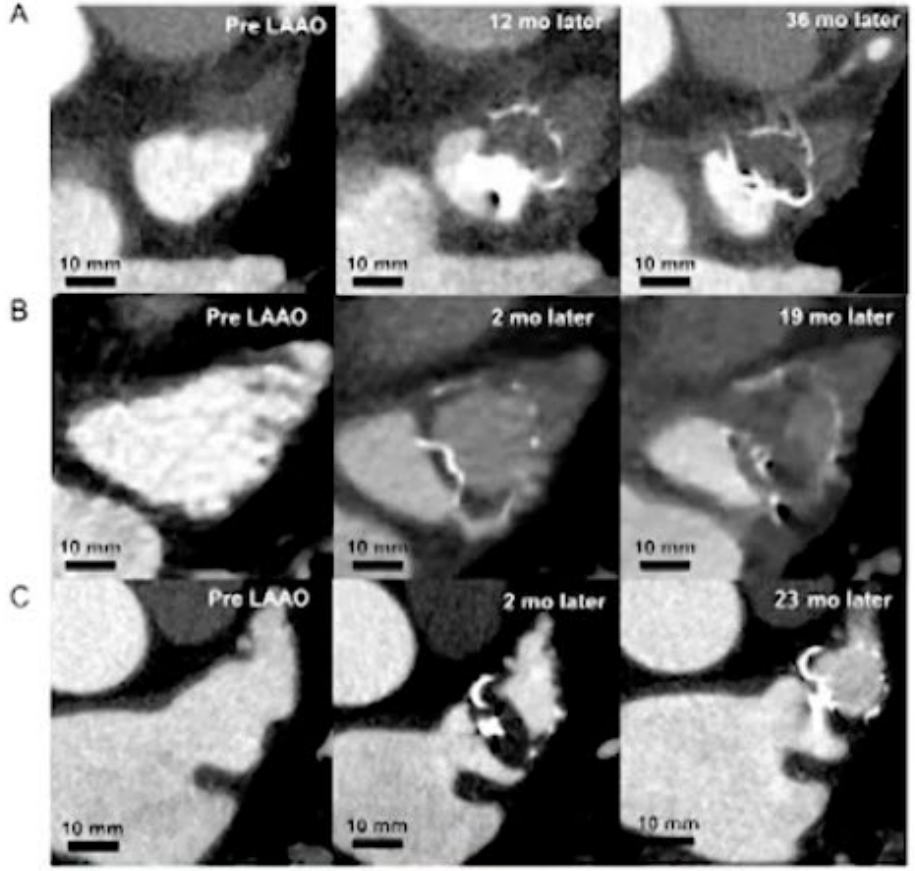
Imaging modalities	• TEE (echo-Doppler, preferably 3D) and/or • Cardiac CT[a]
Global observations	• Identify uncovered lobes • Describe device implantation (location, orientation, deployment, and/or compression)—endocardial devices only • Location of the observed leak(s)—correlation to device components • Compare position and sealing with previous studies
Measurements	• Use multiple TEE views (0°, 45°, 90°, and 135°) or 3D-TEE • Echo colour Doppler TEE: set Nyquist limit to detect low velocity flow (20–30 cm/s). If leak is present, measure only the mosaic (high-velocity) colour of a communicating flow in multiple projections • Use same settings during implantation and follow-up • Document largest measurement as size of leak and achieved angle of measurement by TEE or CT

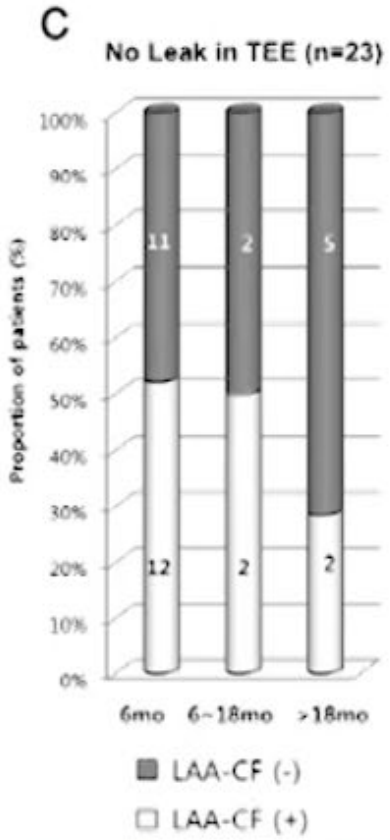
TEE, transoesophageal echocardiography; CT, computed tomography.
[a]To avoid radiation, CT is recommended only in patients receiving Cardio-CT for other purposes or if no other technology (e.g. TEE) is available or indicated.

PDL assessment on TEE vs MSCT



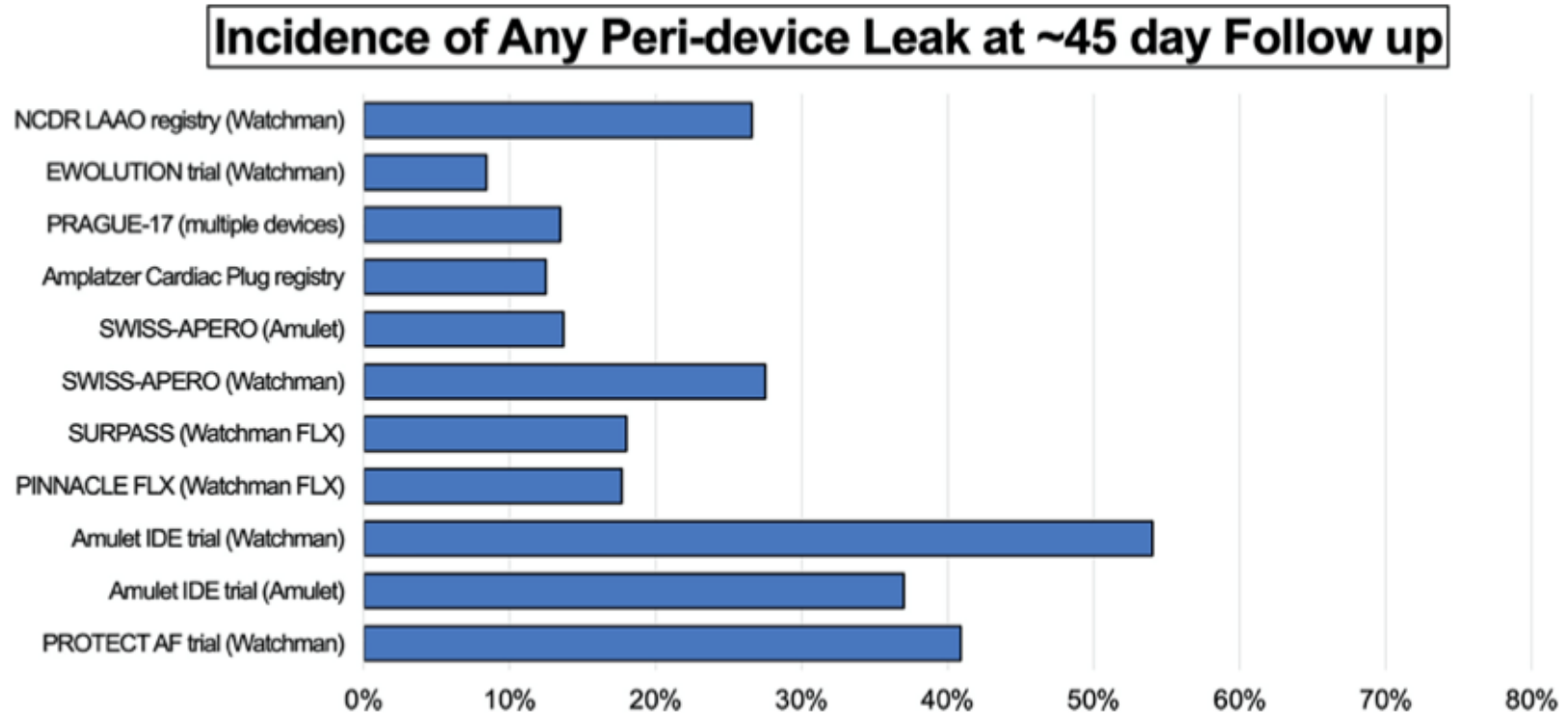
RESIDUAL LEAK ON CT - WATCHMAN





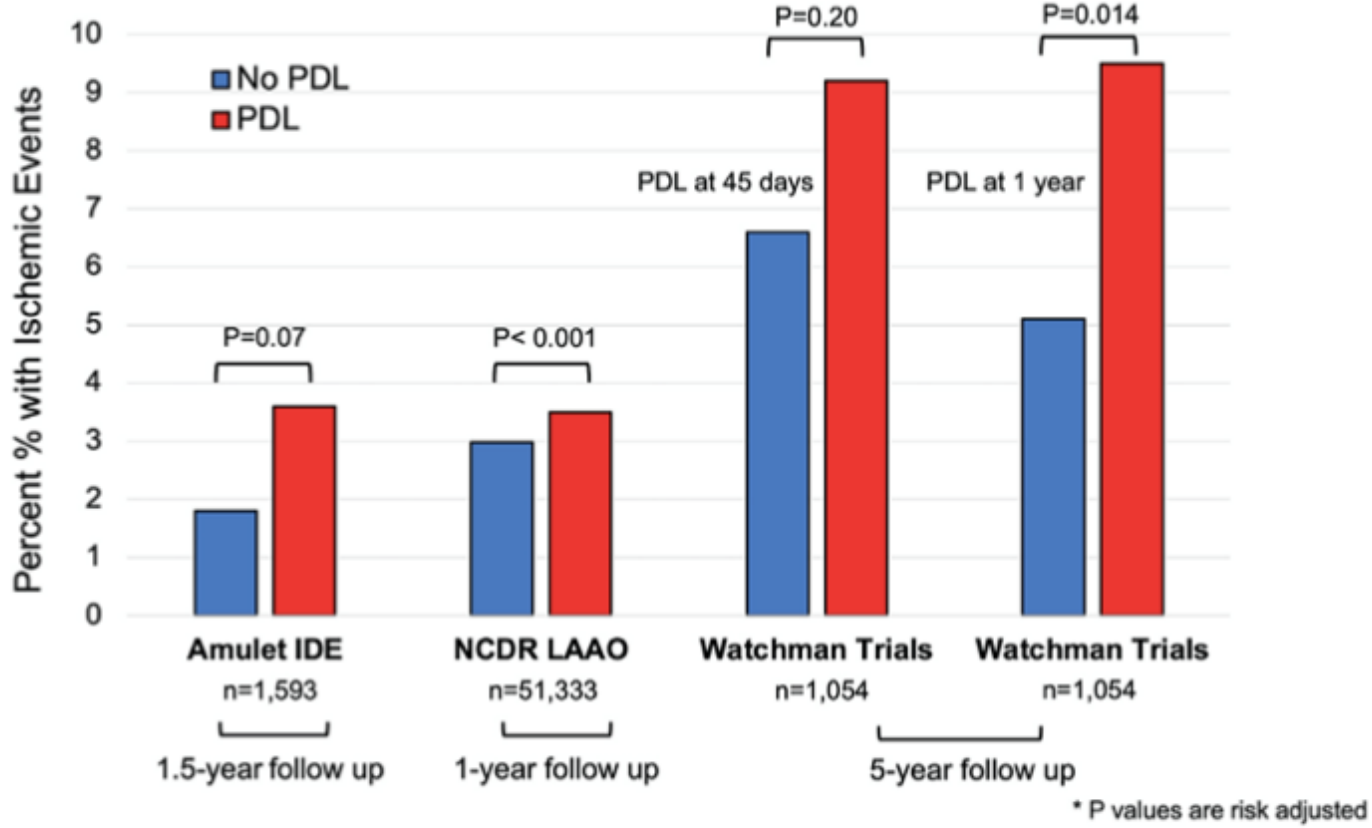
Leak
vs
Contrast Filling

Y-M. Lim et al. / Journal of Cardiology 2017



Amulet IDE = Amplatzer™ Amulet™ Left Atrial Appendage Occluder Randomized Controlled Trial; EWOLUTION = Registry on Watchman Outcomes in Real-Life Utilization; LAAO = left atrial appendage occlusion; NCDR = National Cardiovascular Data Registry; PINNACLE FLX = Protection Against Embolism for Nonvalvular AF Patients: Investigational Device Evaluation of the Watchman FLX LAA Occluder; PRAGUE-17 = Left Atrial Appendage Closure vs Novel Anticoagulation Agents in High-Risk Atrial Fibrillation Patients; PROTECT AF = Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation; SURPASS = Real-World Safety and Efficacy of Watchman FLX; SWISS-APERO = Comparison of Amplatzer Amulet and Watchman Device in Patients Undergoing Left Atrial Appendage Closure.

Summary of recent studies documenting association of PDL with ischemic events



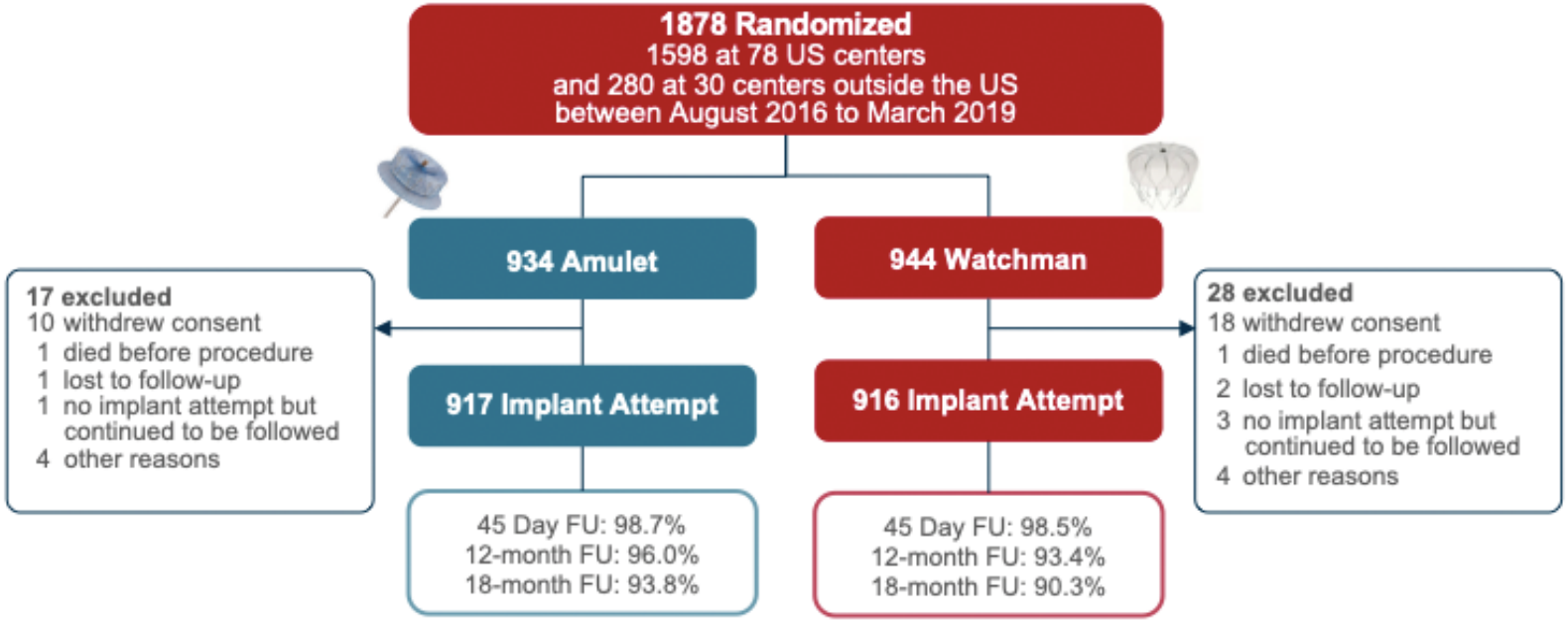
Ischemic events include ischemic stroke or systemic embolization (Amulet IDE trial); stroke, transient ischemic attack, or systemic embolization (NCDR LAAO Registry); and ischemic stroke or systemic embolization (Watchman trials). PDL = peridevice leak; other abbreviations as in Figure 1.

Alkhouli, et al; JACC C.Int 2023

Dhanunjaya Lakkireddy, MD - David Thaler, MD, PhD - Christopher Ellis, MD - Vijendra Swarup, MD
Lars Sondergaard, MD - John Carroll, MD - Michael R. Gold, MD, PhD - James Hermiller, MD
Hans-Christoph Diener, MD, PhD - Boris Schmidt, MD - Lee MacDonald, MD - Moussa Mansour, MD
Brijeshwar Maini, MD - Stephan Windecker, MD

on behalf of the Amulet IDE investigators

AMULET IDE TRIAL: PATIENT FLOW

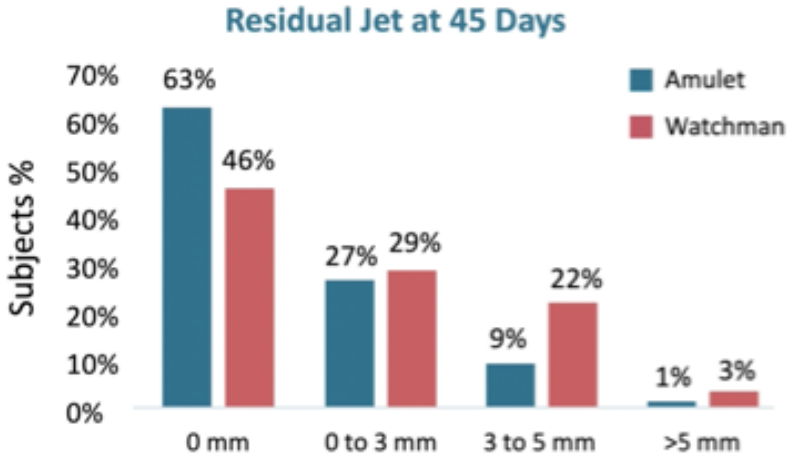


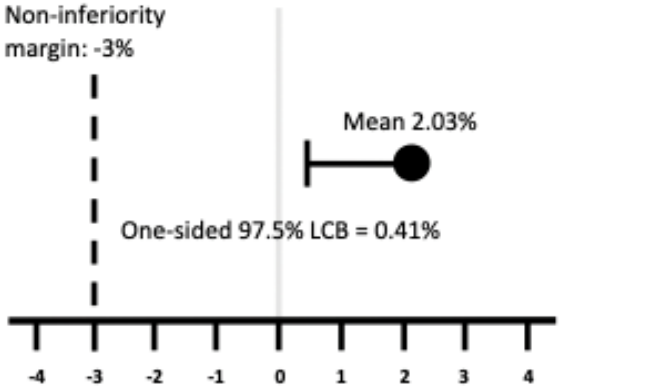
ITT= Intention-to-Treat; OAC = oral anticoagulation

Circulation. 2021;144:1543–1552.

MECHANISM OF ACTION PRIMARY ENDPOINT

LAA OCCLUSION AT 45 DAYS (RESIDUAL JET AROUND THE DEVICE ≤5 MM)





Difference in Mechanism of Action Primary Endpoint Rates

p (non-inferiority) < 0.0001

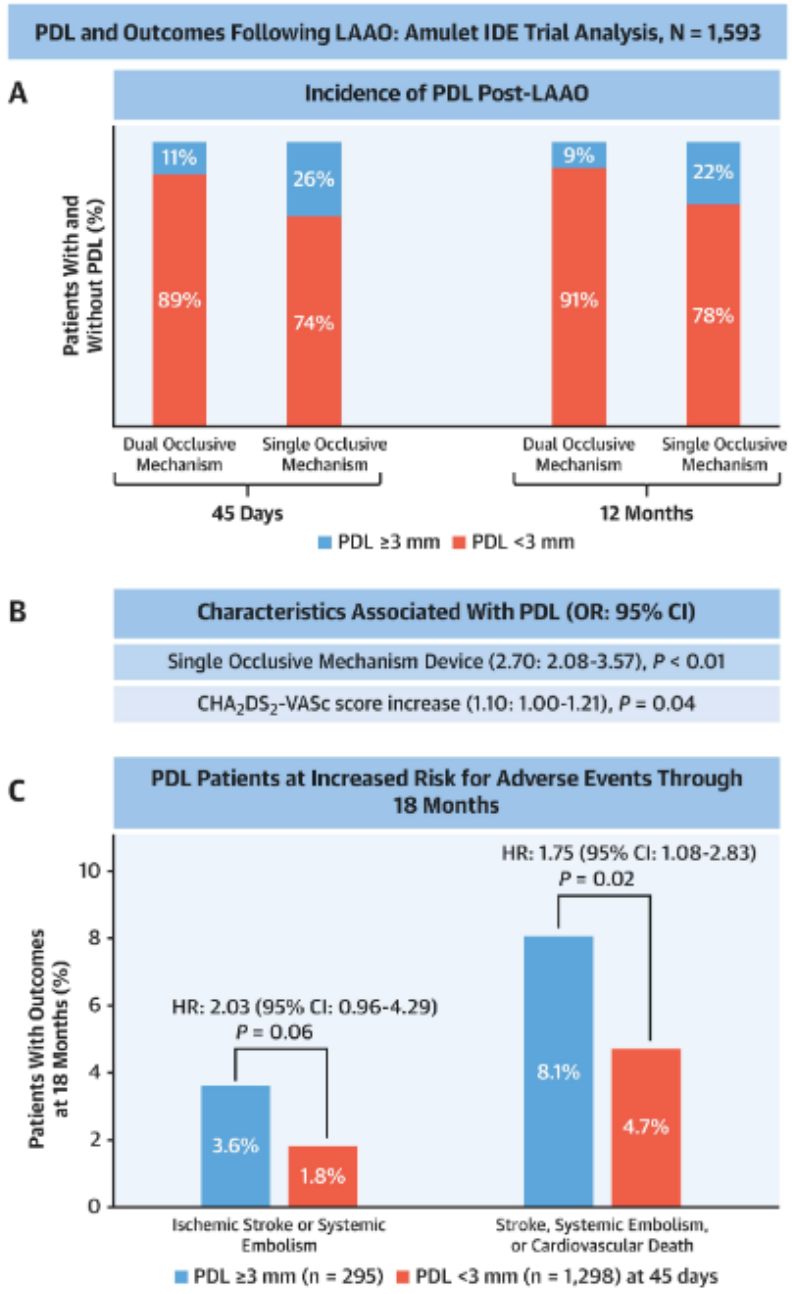
Amulet LAA occluder was superior to Watchman device for LAA occlusion at 45 days

Leak Size	Amulet	Watchman	p(superiority)
Residual jet ≤5mm	98.9% (792/801)	96.8% (767/792)	0.0025
Residual jet ≤3mm	89.8% (719/801)	75.1% (595/792)	<0.0001*

*post hoc analysis

ESC CONGRESS 2021
THE DIGITAL EXPERIENCE

CENTRAL ILLUSTRATION: Peridevice Leak Following Left Atrial Appendage Occlusion



Price MJ, et al. J Am Coll Cardiol Intv. 2022;15(21):2127-2138.

WATCHMAN™

Transcatheter LAA closure has emerged as a minimally invasive option to prevent thrombus embolization from the LAA in NVAF.
Safety & efficacy - 15 years/6,000 patient years studied
100,000 implants worldwide

2002 Pilot
N=66
Non-randomized
Feasibility and Safety

2010 PREVAIL
N=407
Randomized
Comparison: warfarin

Mar 2015
FDA Approval

2002 — 2020

2005 PROTECT AF
N=707
Randomized
Comparison: warfarin

2018 PINNACLE FLX
N=400
Non-randomized
FLX Device,US IDE

WATCHMAN FLX™

Next Generation Device designed to improve procedural performance, safety, and expand the eligible patient population

Circulation

ORIGINAL RESEARCH ARTICLE

Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device

Results From the PINNACLE FLX Trial

LAA Closure (Core Lab)

	Implant	45 Days	12 Months	PROTECT-AF/PREVAIL 12 Months (n=526)[1]
Jet Size ≤ 5mm	100% (376/376)	100% (389/389)	100% (344/344)	99.3%
Complete Seal	92.6% (348/376)	82.8% (322/389)	89.5% (308/344)	66%
Jet Size > 0 and ≤ 5mm	7.4% (28/376)	17.2% (67/389)	10.5% (36/344)	
Jet Size > 5mm	0% (0/376)	0% (0/389)	0% (0/344)	
TEE deemed not evaluable for leak by Core Laboratory*	2.3% (9/385)	0.8% (3/392)	0.9% (3/347)	

Kar S et al; Circulation 2021;143:1754-62

Journal of the Society for Cardiovascular Angiography & Interventions 2 (2023) 100577

JSCAI
The official journal of the Society for Cardiovascular Angiography & Interventions

Standards and Guidelines

SCAI/HRS Expert Consensus Statement on Transcatheter Left Atrial Appendage Closure

Jacqueline Saw, MD, FSCAI, Chair[a,*], David R. Holmes, MD, FSCAI, (Vice-Chair)[b], João L. Cavalcante, MD[c], James V. Freeman, MD, MPH, MS[d], Andrew M. Goldsweig, MD, MS, FSCAI[e], Clifford J. Kavinsky, MD, PhD, MSCAI[f], Issam D. Moussa, MD, MBA, FSCAI[g], Thomas M. Munger, MD[b], Matthew J. Price, MD, FSCAI[h], Mark Reisman, MD, FSCAI[i], Matthew William Sherwood, MD, MHS, FSCAI[j], Zoltan G. Turi, MD, MSCAI[k], Dee Dee Wang, MD, FSCAI[l], Brian K. Whisenant, MD, FSCAI[m]

10. The clinical impact and management of peridevice leaks are not fully understood, and all efforts should be made to minimize such leaks at the time of implantation.

Table 5. Imaging surveillance modality and optimal imaging at different postdevice implantation time points.

Imaging timing	Immediate postdevice implant	Prehospital discharge	45-d follow-up	1-y follow-up (optional)
Transthoracic echocardiogram	–	+++	–	–
Transesophageal echocardiogram	+++	–	++	++
CCTA	–	–	+++	+++
Complication surveillance	**Pericardial effusion**	**Device embolization**	**Peridevice leak**	**Device-related thrombus**
Transthoracic echocardiogram	+++	+	–	–
Transesophageal echocardiogram	+++	+++	++	+++
CCTA	+++	+++	+++	+++

+++, strongly recommended; ++, less strongly recommended; +, recommended; –, not required.
CCTA, cardiac computed tomography angiography.

How to avoide peridevice leaks?

Residual leaks, can, and should be avoided by:

- Adequate patient planning with 3D imaging technique: MSCT or 3DTEE.
- Careful device selection based on LAA anatomic features.
- Optimal procedural TEE and angio assessment.
- LAAO technique optimization.

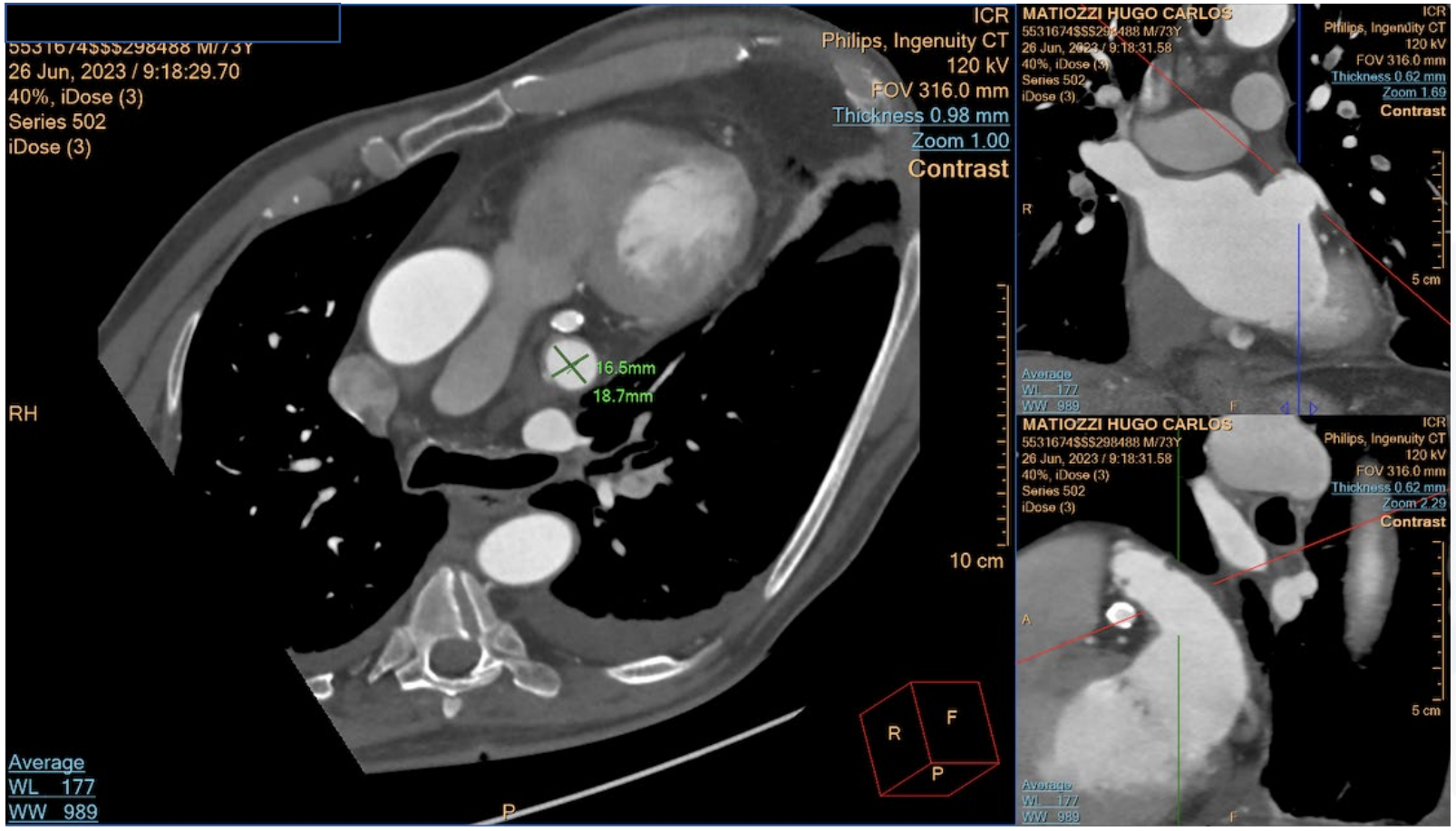
Residual leaks can be treated by percutaneous implantation of another closure device (plugs/coils)

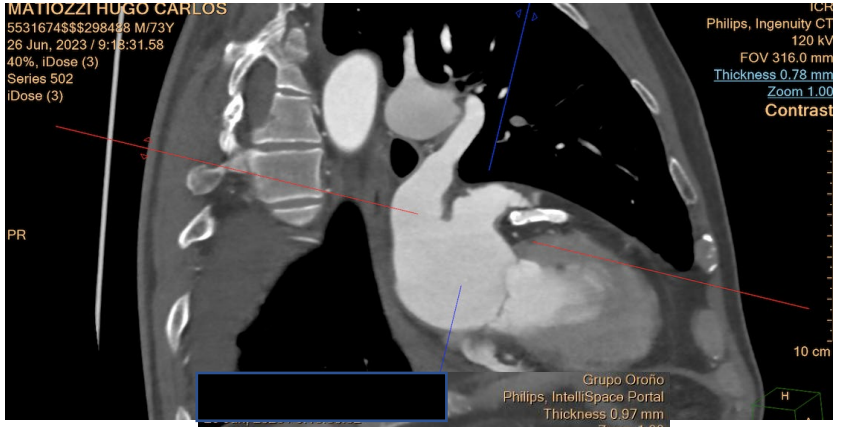
Clinical Case

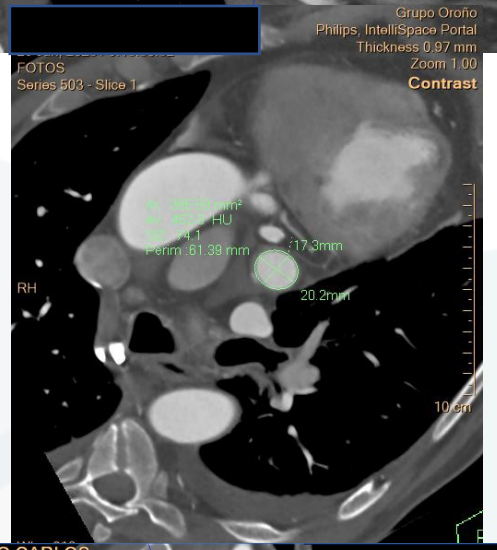
- 74 year-old male, HTA, DLP
- Permanent AF, DOAC
- STEMI 2015 primary PCI.
- Ischemic stroke 2018 successfully treated with thrombolysis.
- Hospitalized 06/2023 for GI bleeding with hypovolemic shock.

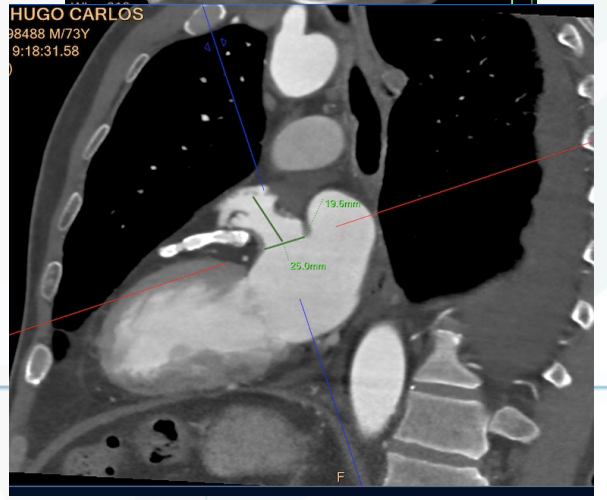
- CHA2DS2VASC = 5 HASBLED = 4
- Referred for LAAO

Planning with MSCT

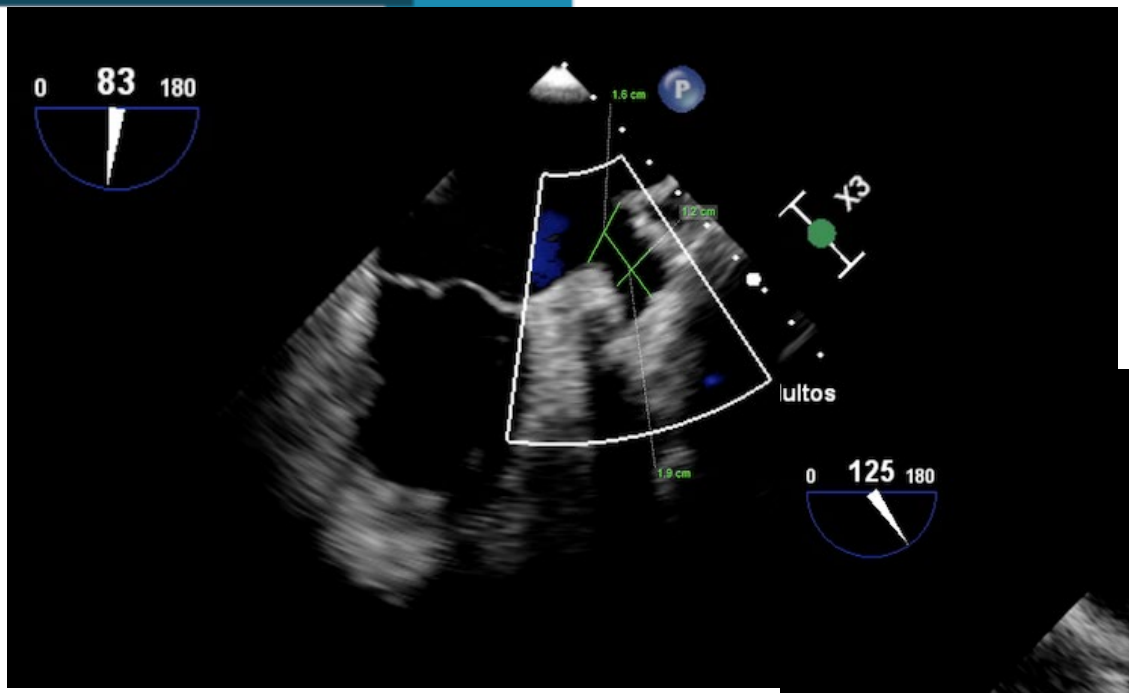


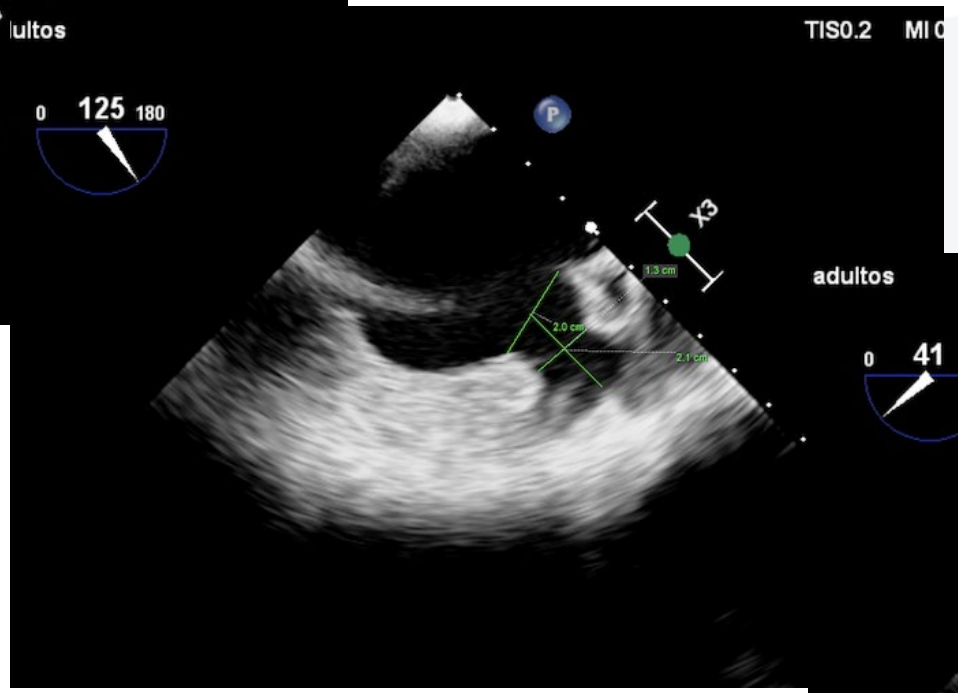


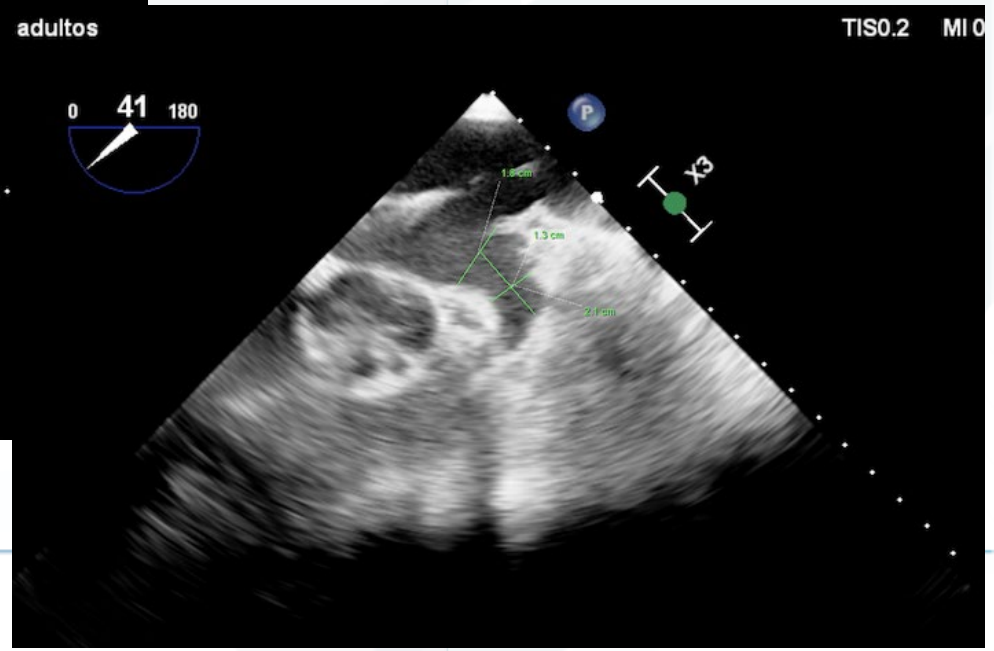




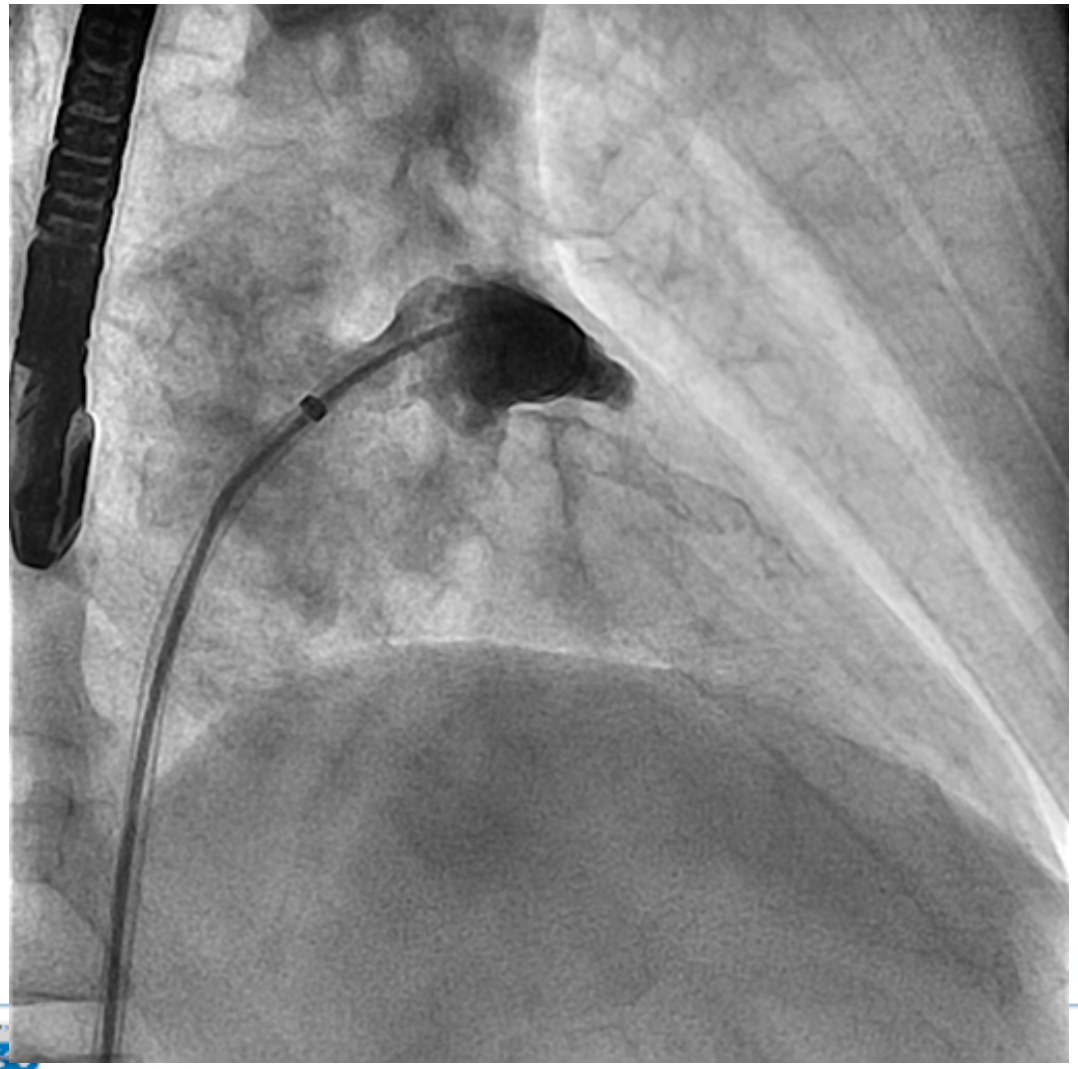
Procedure guided with TEE

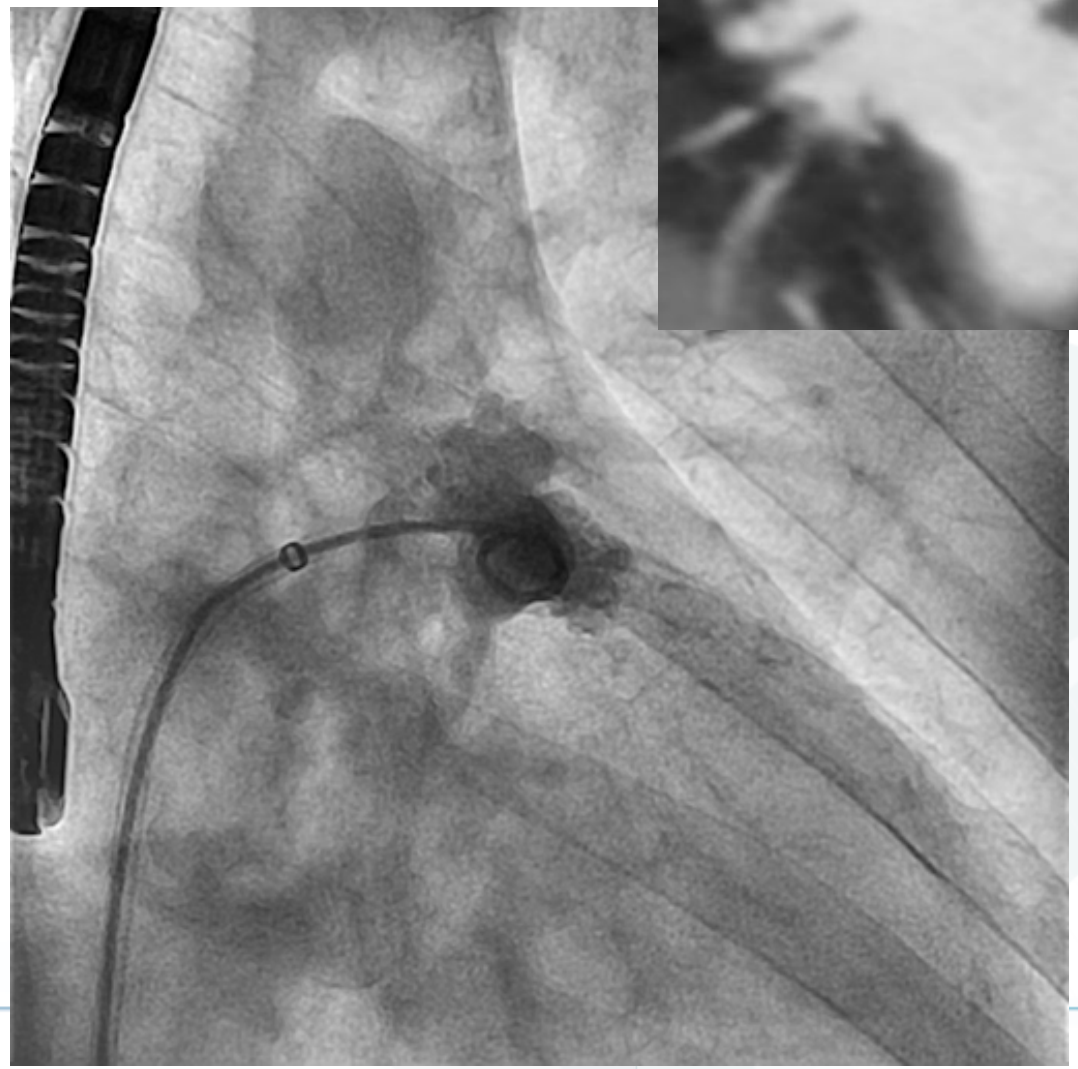


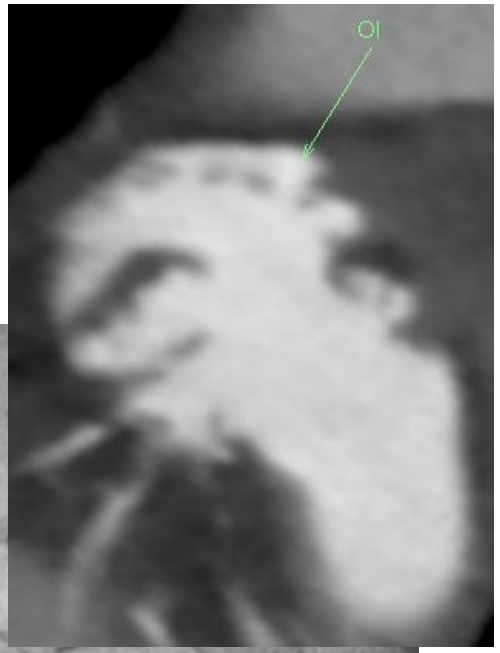




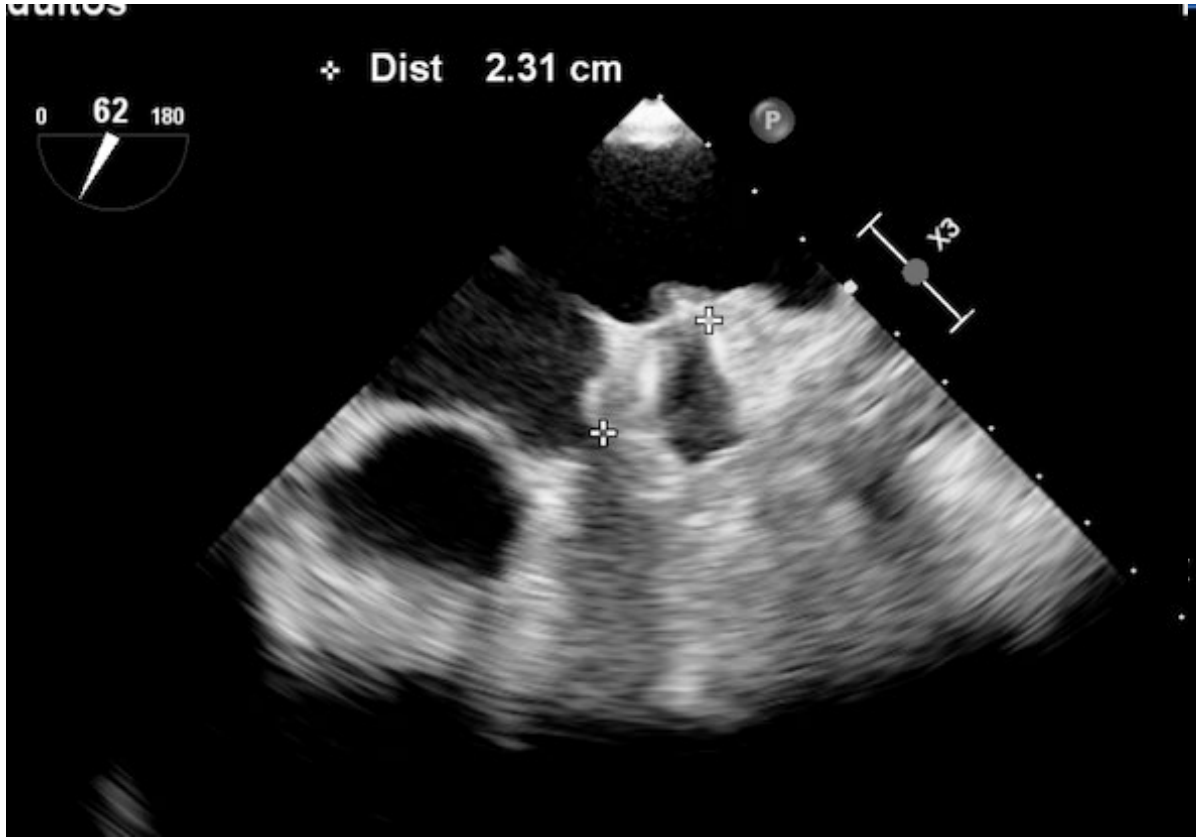
Procedure

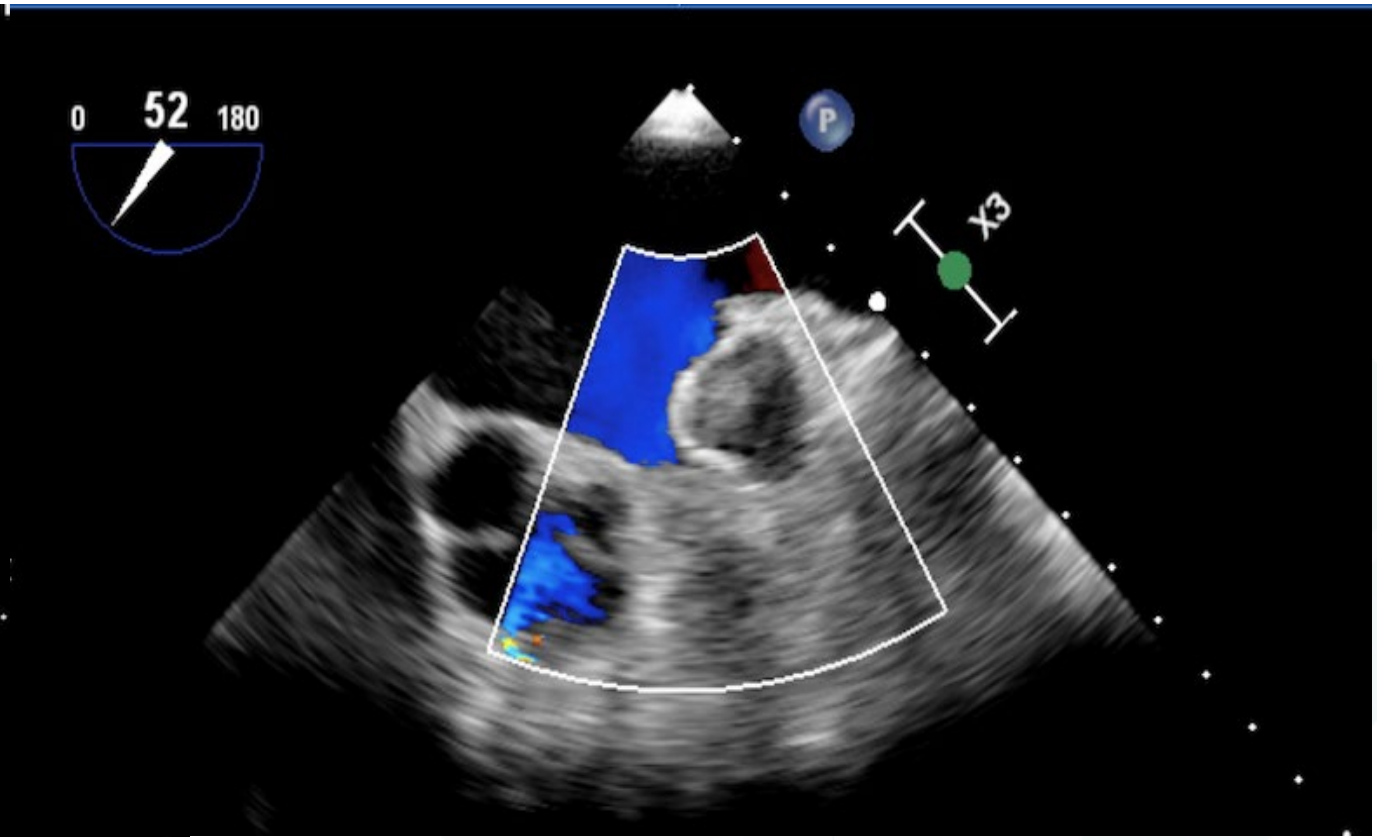




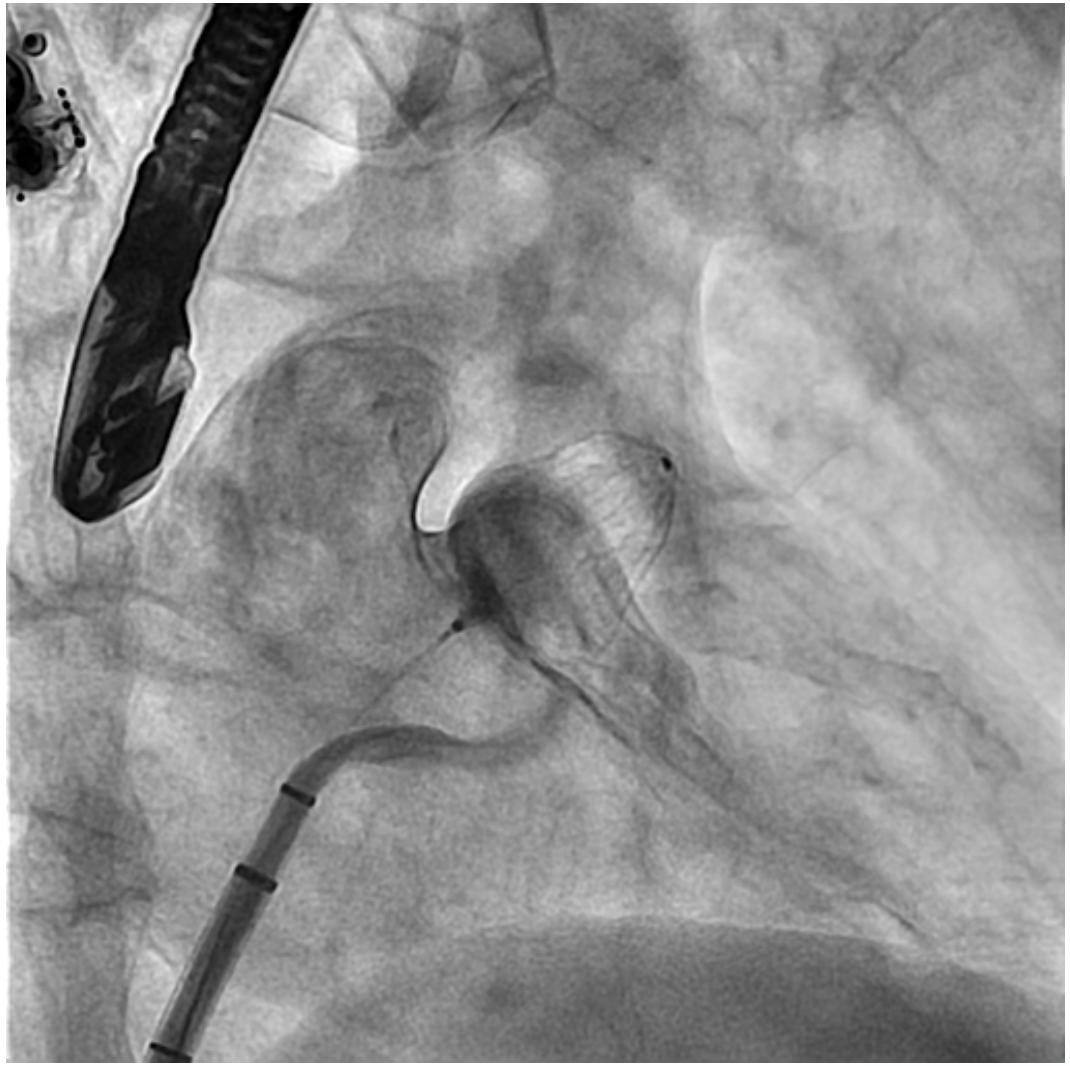


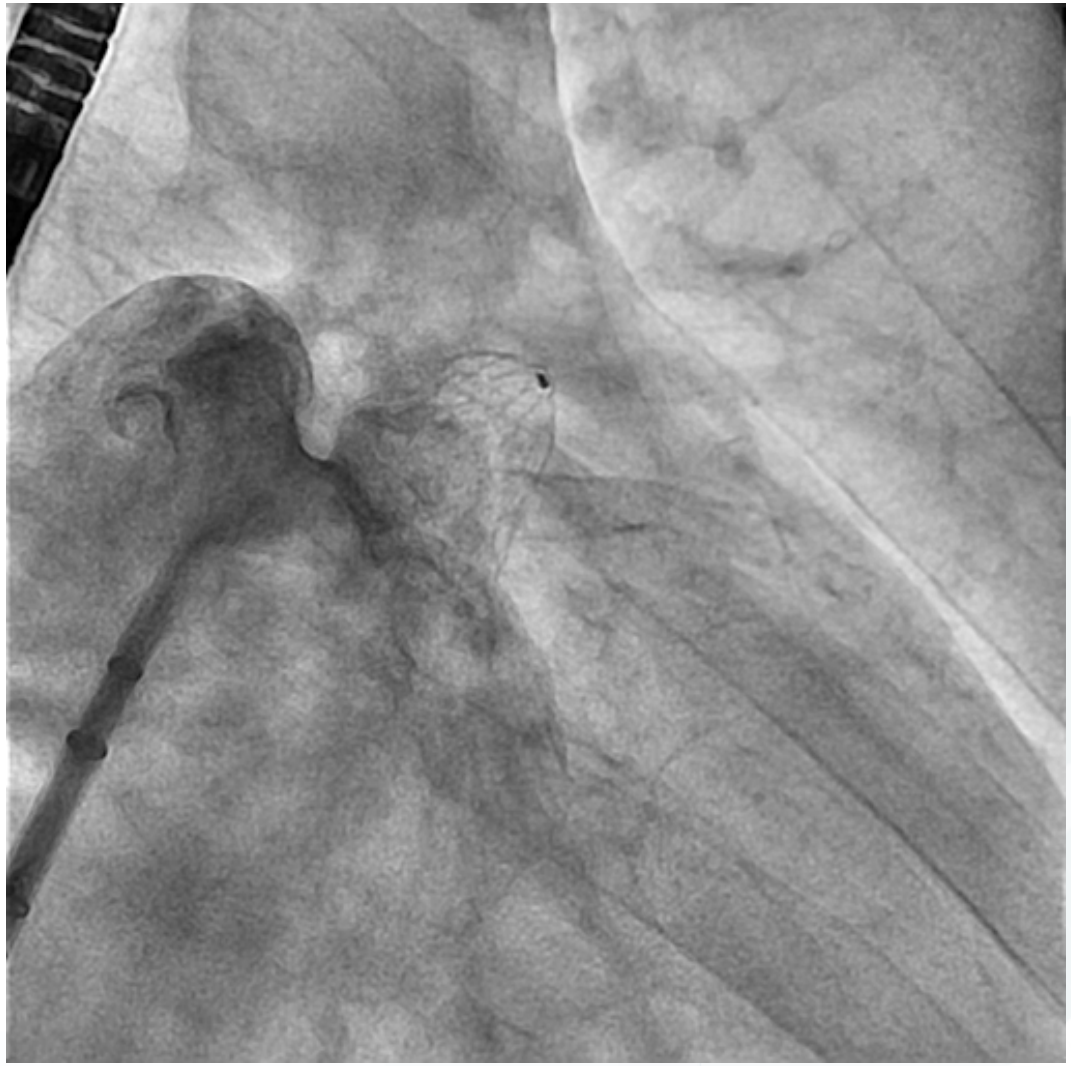
TEE



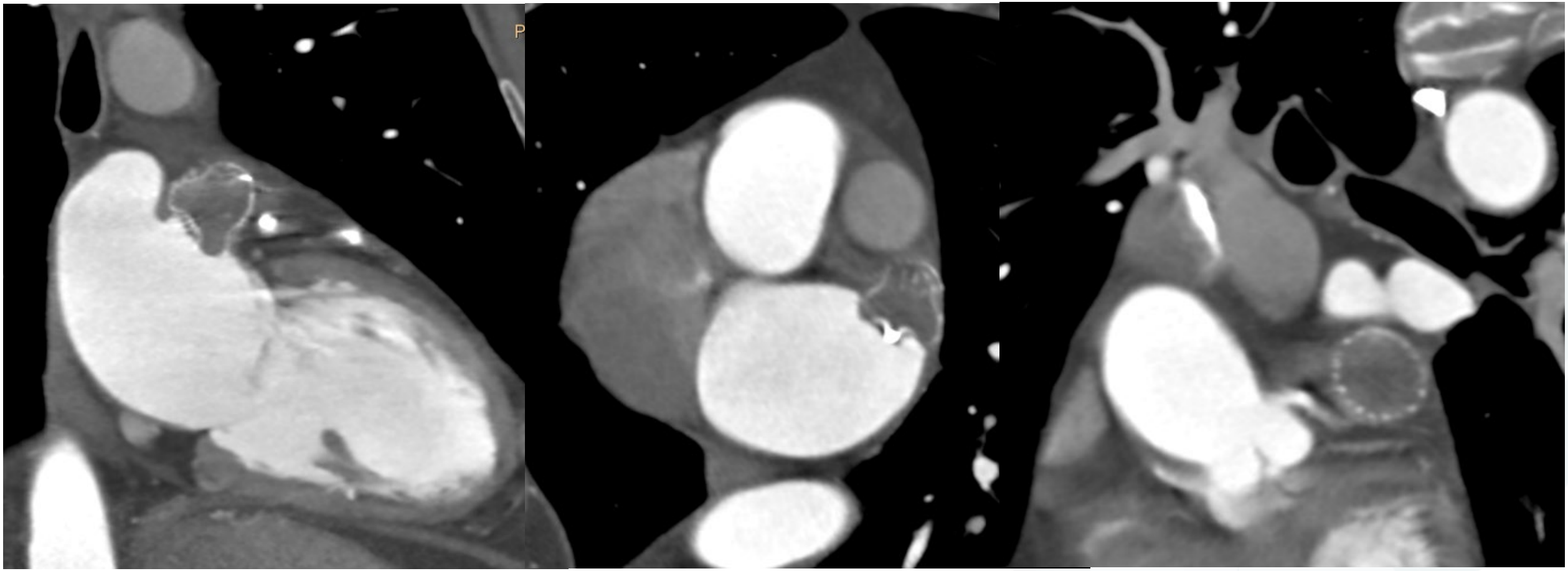


Final Angio



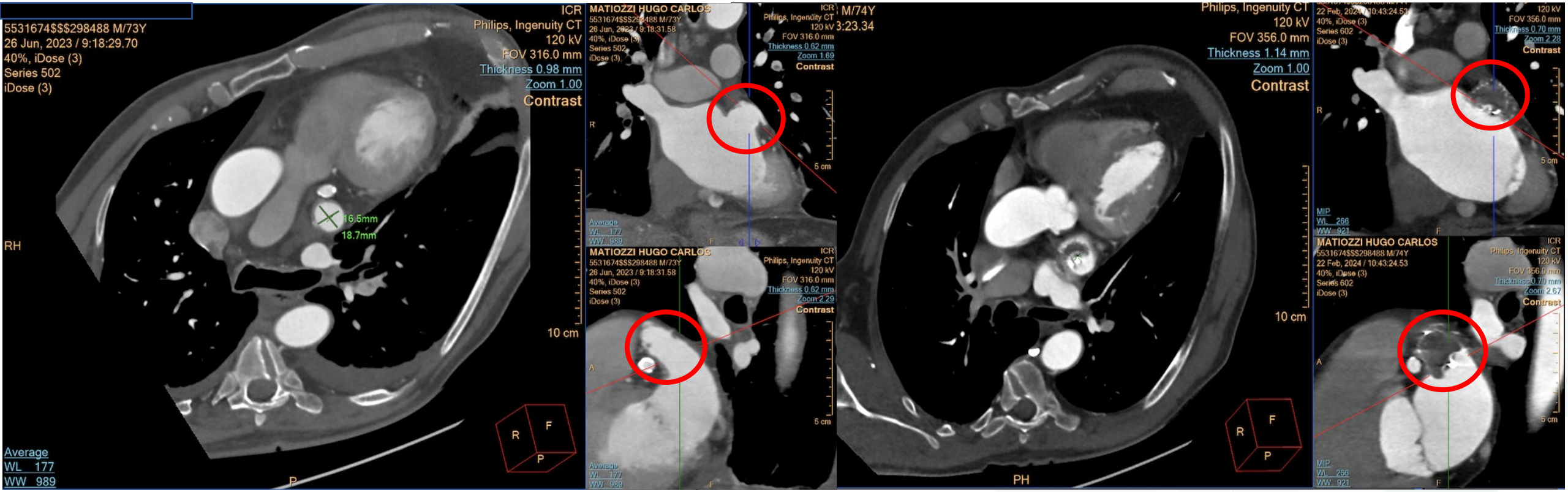


MSCT at 45 days



MSCT pre procedure

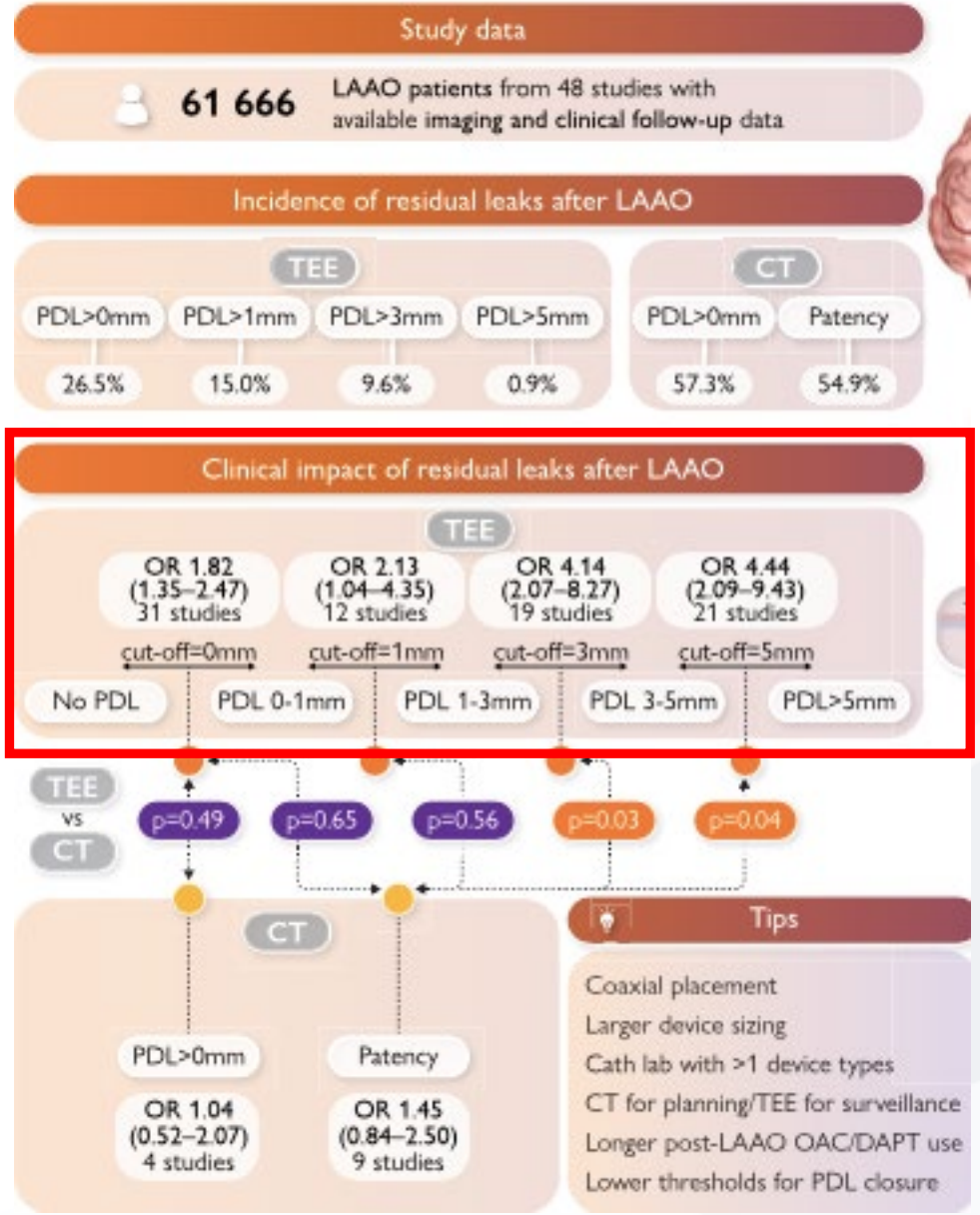
MSCT 45 days: No leak; no DRT



ESC European Society of Cardiology
European Heart Journal (2024) **45**, 214–229
https://doi.org/10.1093/eurheartj/ehad828

META-ANALYSIS
Interventional cardiology

Residual leaks following percutaneous left atrial appendage occlusion and outcomes: a meta-analysis



Residual leaks after LAAO are neither infrequent nor benign. Optimized personalizes approaches for pre procedural planning, peri procedural techniques, and post procedural management are warranted, to prevent complications of incomplete LAA closure.

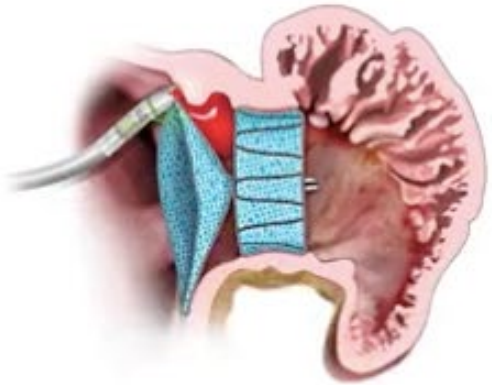
Samaras A, et al; EHJ 2024

Peri-device Leak Treatment

Second LAAO device

Delivery of embolic coils

Plugs & occluders



Radiofrequency ablation

Alkhouli, et al; JACC C.Int 2023

Take home message

- Not all peri-device leaks are the same.
- Clinically relevant communication between distal LAA and LA.
- Peri-device leaks matter and shoud be avoided.
  1) Adequate planning
  2) Carefull device selection
  3) Optimal TEE and angio assessment
  4) LAAO technique optimization
- Until the clinical significance of residual leaks has been clearly revealed, use of the term complete closure seems only justified in case of complete absence of residual flow.