

Residual Leak and Late Leak; How do we Treat?

Structural Heart Disease Session
24th April 2014, Thursday

Simon Lam, Horst Sievert, Stefan Bertog, Ilona Hofmann,
Laura Vaskelyte, Sameer Gafoor

CardioVascular Center Frankfurt - Frankfurt, Germany

Conflict of Interest

- Nothing to disclose

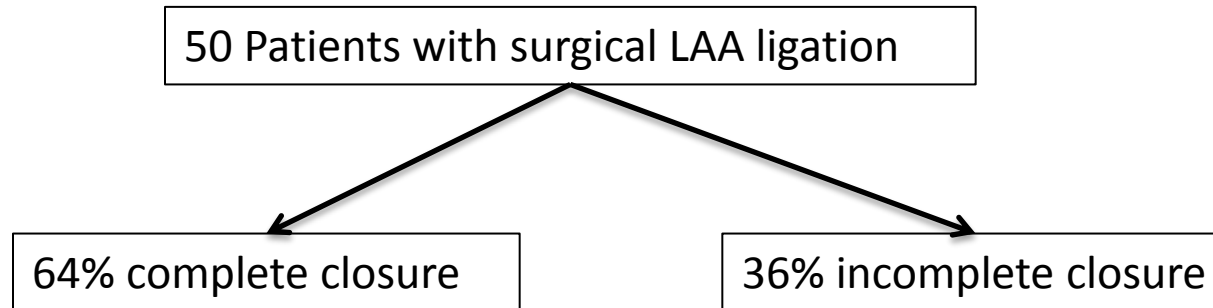
Surgical LAA Ligation

M/69 Mitral Annuloplasty + Surgical ligation; stroke at 2 weeks



Rosenzweig BP, Katz E, et al. Thromboembolus from a Ligated Left Atrial Appendage
J Am Soc Echocardiogr 2001;14:396-8

Experience from Surgical LAA Ligation



...In 50% of patients with incomplete closure spontaneous echocontrast was seen in the LAA

...In 2/3 of patients with spontaneous echocontrast in the LAA, the contrast was denser than that seen in the left atrium (thrombogenic milieu?)

Stagnant blood pool +

**Persistent Communication
to systemic circulation**

Catheter-based LAA Closure

- Possible causes of peri-device leak
 - shape of LAA ostium
 - geometrical complexity of LAA
 - device shape, design and selection
 - Sizing/procedure related
 - LAA pressure
 - rhythm (SR vs AF)
 - degree of compression

“Device-LAA Geometrical Mismatch”

Shall we close all leaks?

Prevalence

- PROTECT AF

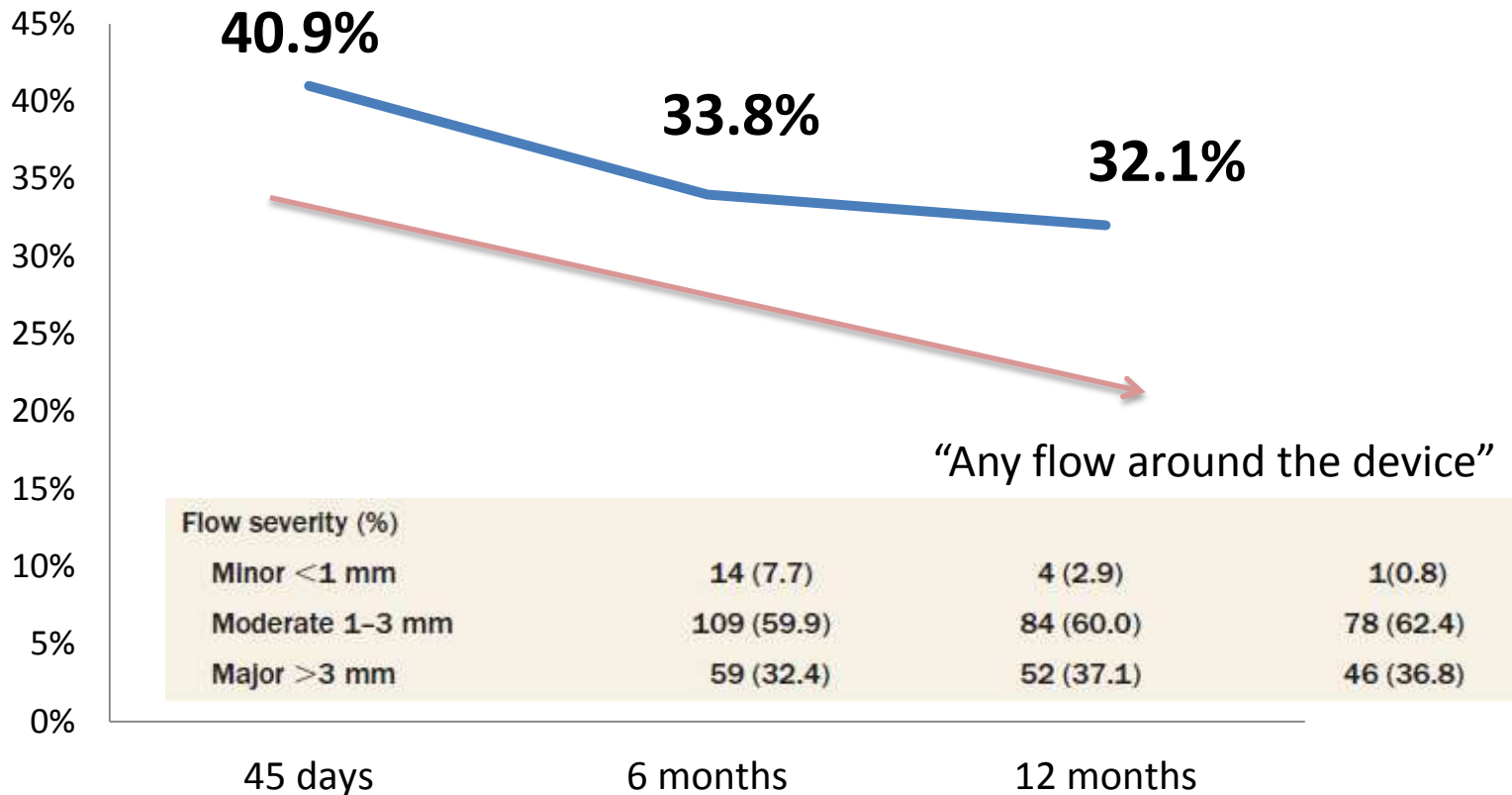
- **32%** at least some degree of peri-device flow at 12 months

- Definition of Leaks

- Minor (<1mm)
- Moderate (1-3mm)
- Major (>3mm)

Patients with **residual leaks** ≤ 5 mm in diameter by color Doppler were **treated identically to those with no leaks**

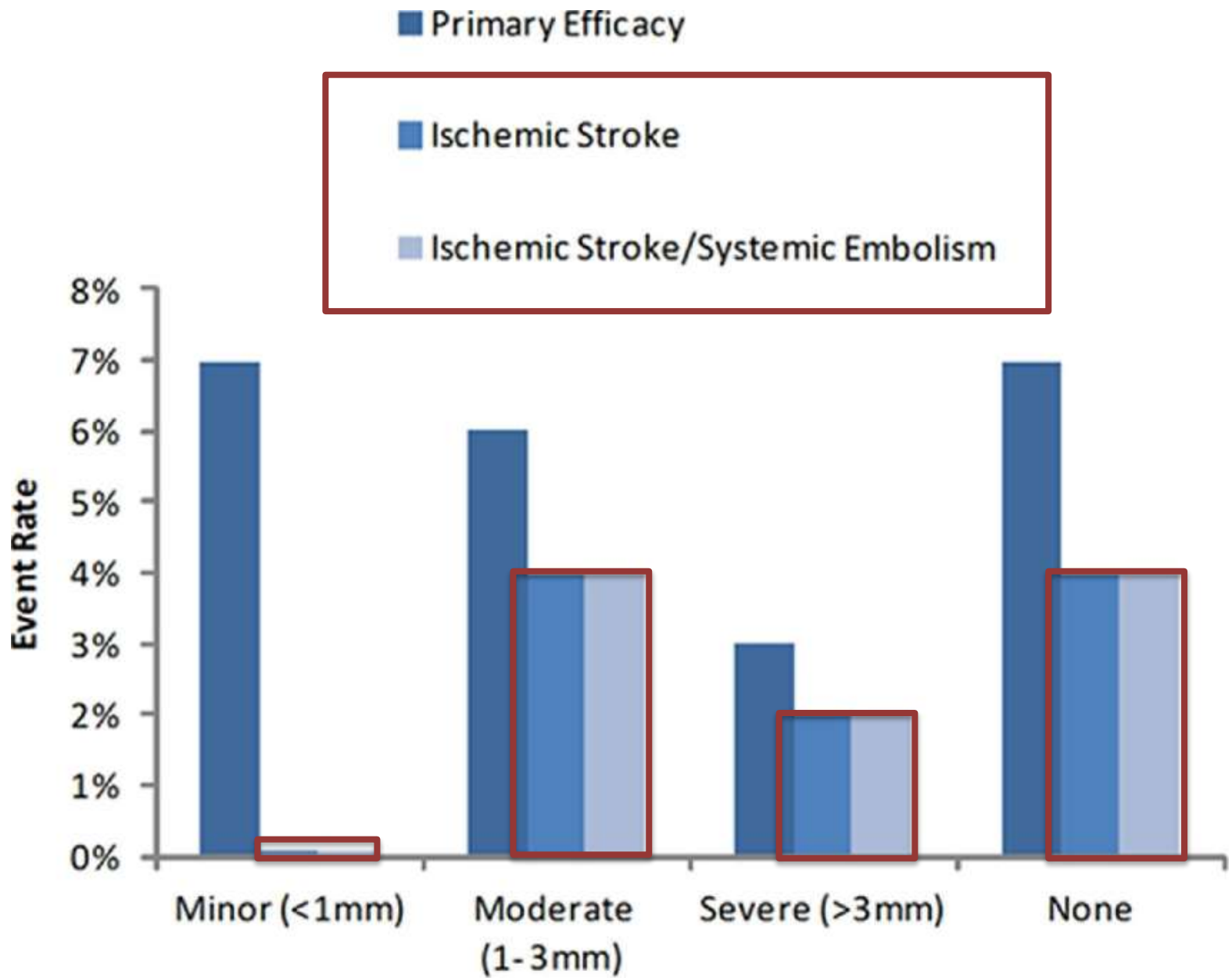
Prevalence of Leak over Time



Viles-Gonzalez JF, Kar S, Douglas P, Dukkipati S, Feldman T, Horton R, Holmes D, Reddy VY. The clinical impact of Incomplete Atrial Appendage Closure with the Watchman device in patients with atrial fibrillation. J Am Coll Cardiol. 2012;59:923-929

Catheter-based LAA Closure

- Evolution of leaks over time
 - Complex process
 - Possibilities
 - shrinkage
 - remodelling/dilation
 - change in position of device
 - fluid-dynamic effect of blood flow
 - endothelialization process/fibrotic tissues/organized microthrombus



Peridevice Leak & PLAATO Device

- PLAATO device (n=22)
 - 4/22 new ischaemic stroke
 - Peri-device leak
 - 3/4 *with* stroke
 - 7/9 *without* stroke
- (75% vs 77%, p = 0.706)*

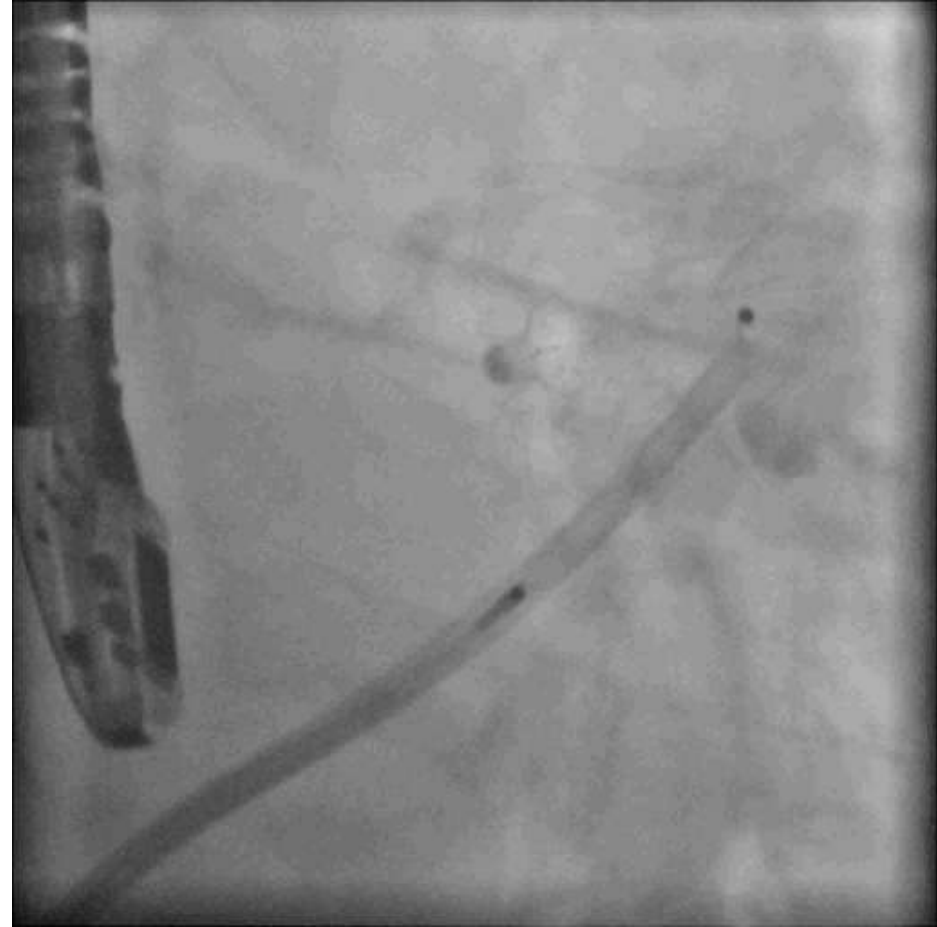
What about “bigger leaks”?

Case 1 – Watchman + AVP II



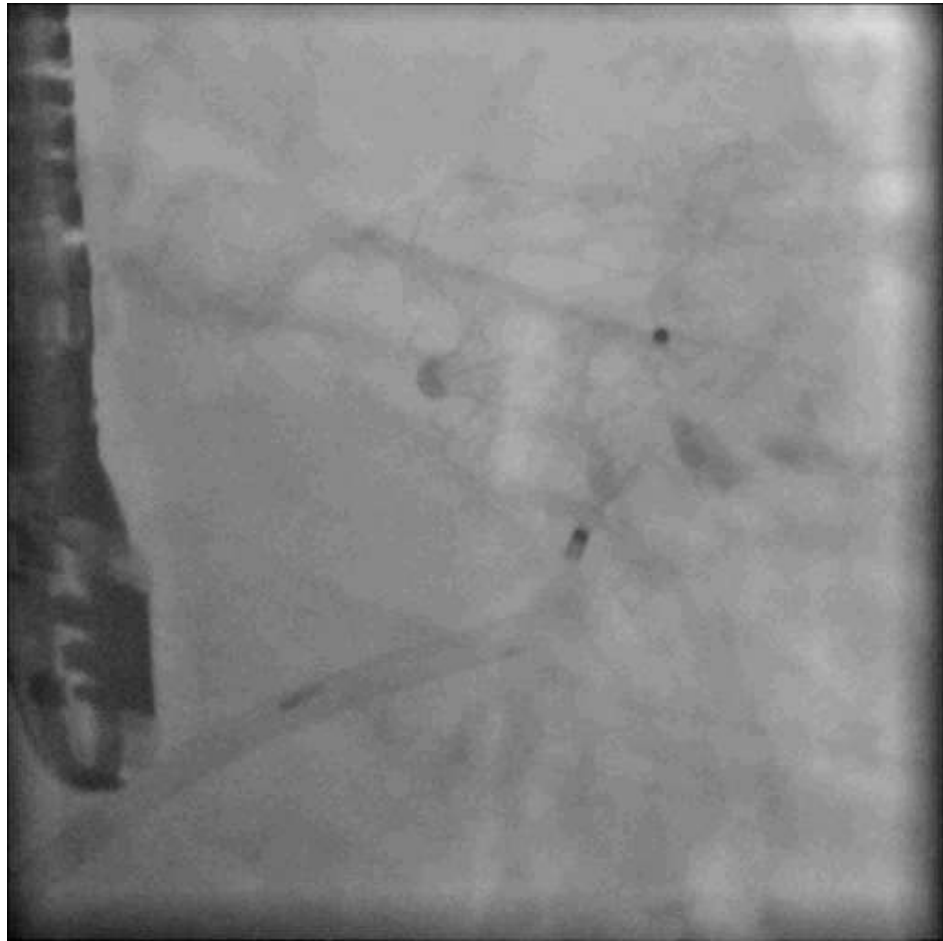
M/72 AF, TIA 2006, CAD, GI Bleeding

Watchman (31mm) Implantation 5.2011 – Leak at TEE 19 months later



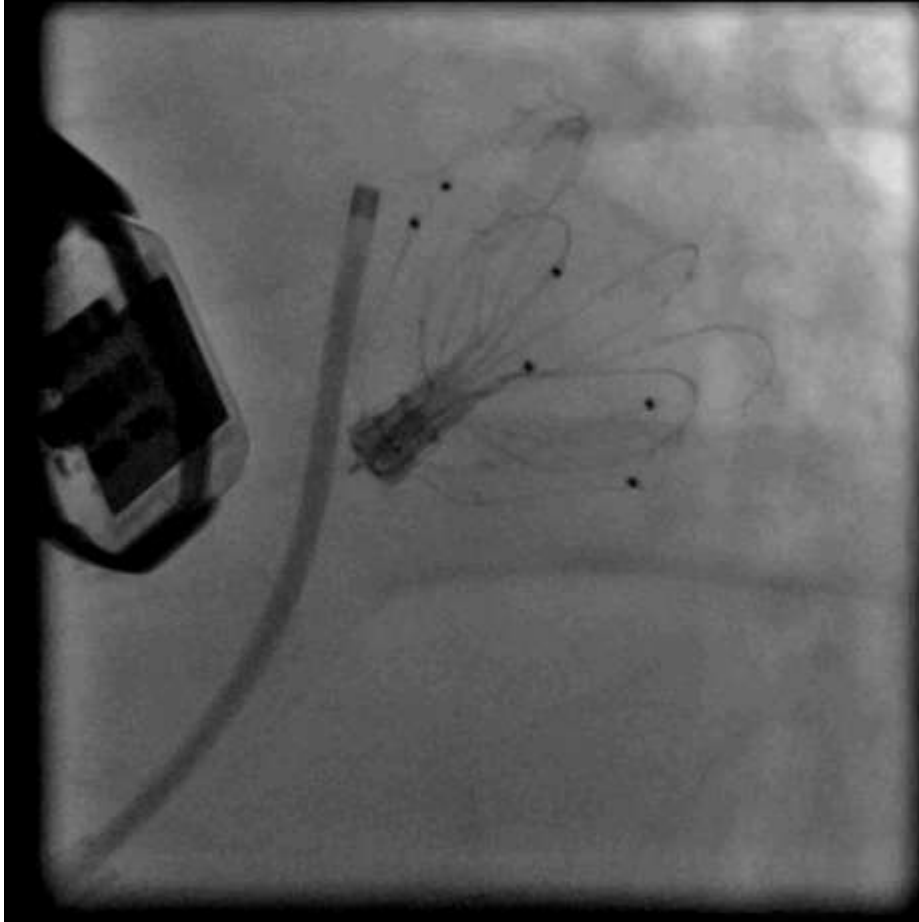
8Fr Introducer sheath, Amplatz Extra Stiff
Amplatzer Vascular Plug (AVP II) 10 mm



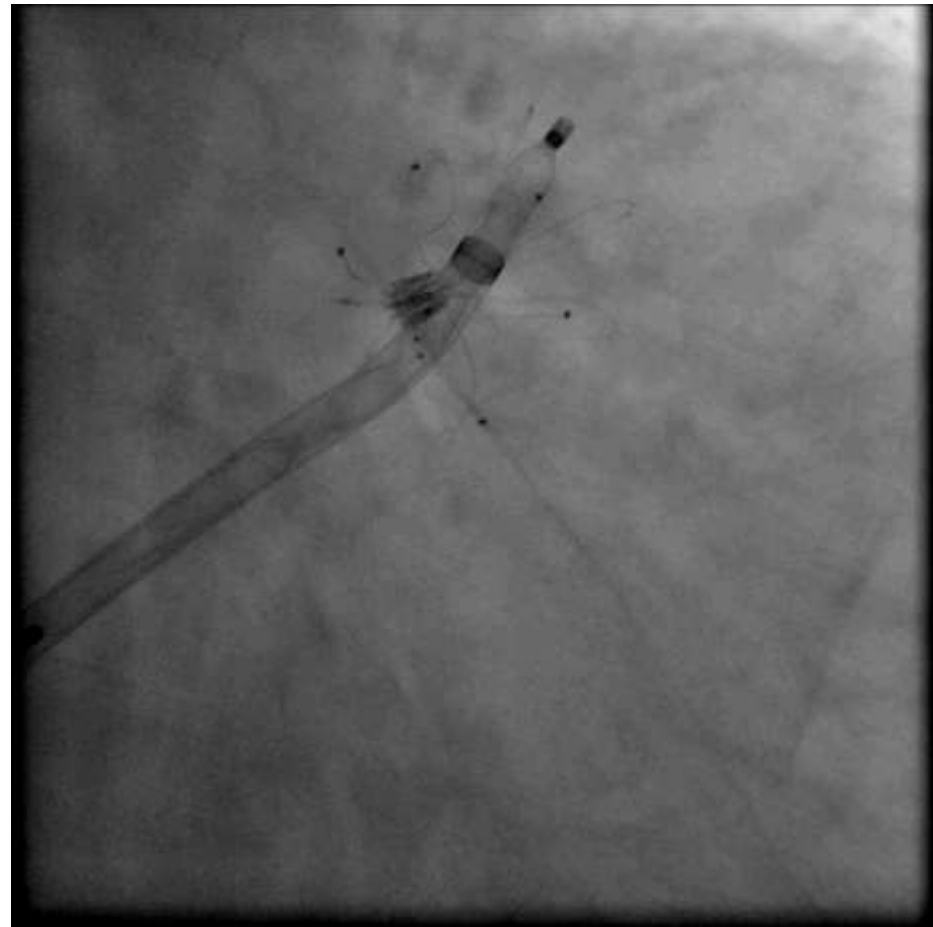
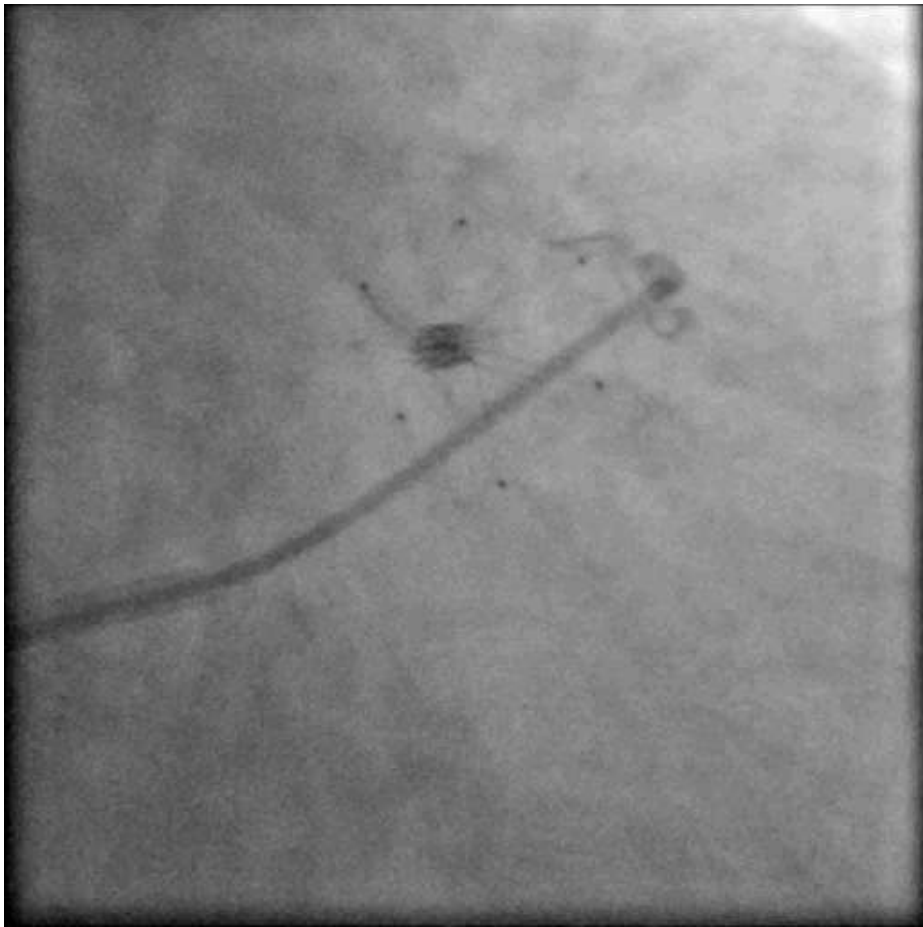


Final Result and Deployment of Device

Case 2 – Coherex + ACP

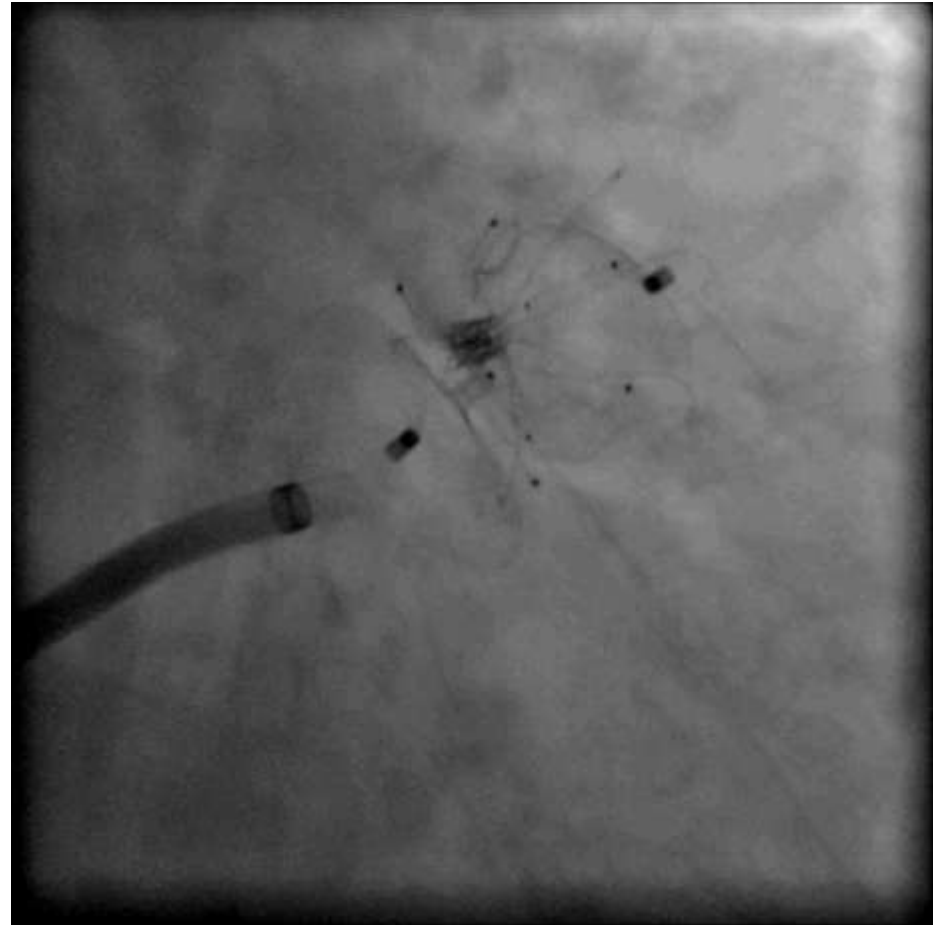
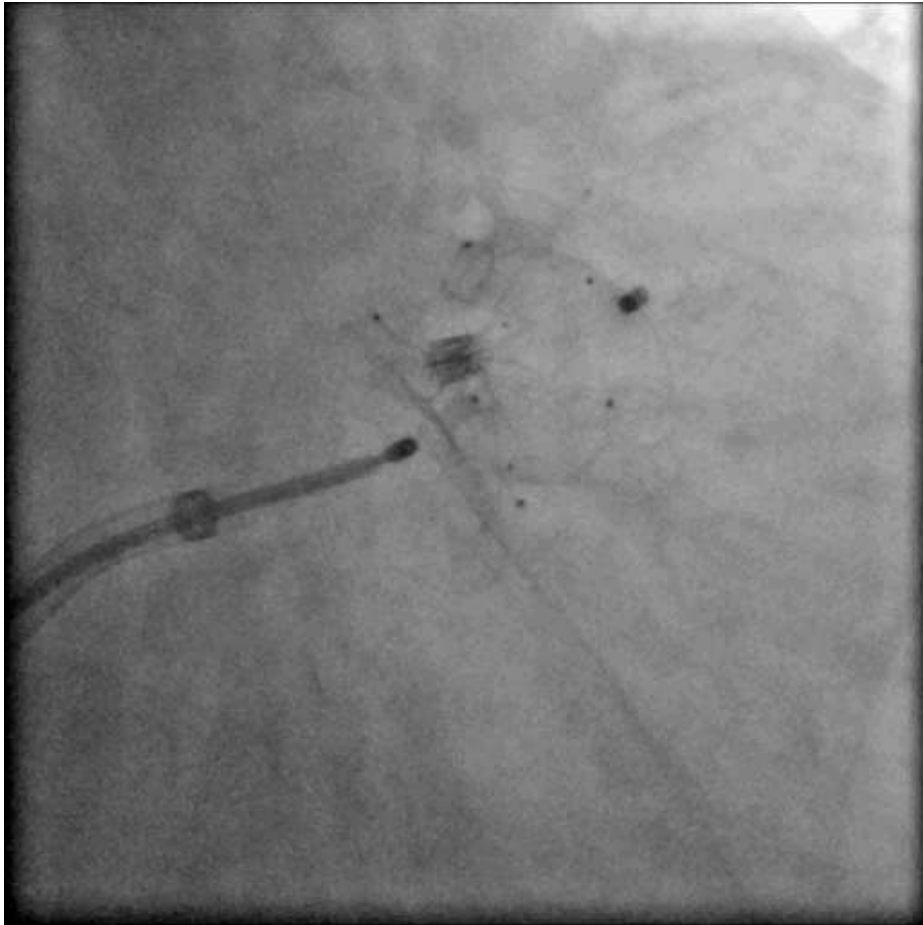


F/75 AF, HT, LAA Occlusion with Coherex 6/2011
Peri-device Leak – TEE at 1 year



Amplatz Extra Stiff GW, 10F Introductory sheath
Deployment of 22mm ACP Device, Distal lobe





Final Deployment and Release of Device

CATHETERIZATION & CARDIOVASCULAR INTERVENTIONS

Incomplete Left Atrial Appendage Occlusion and Thrombus Formation after Watchman Implantation Treated with Anticoagulation Followed by Further Transcatheter Closure with a Second-Generation Amplatzer Cardiac Plug (Amulet Device)

Cheung Chi Simon Lam MD, Dr. Stefan Bertog MD
and Dr. Horst Sievert MD, PhD Prof^{*}

DOI: 10.1002/ccd.25456

Copyright © 2014 Wiley Periodicals, Inc., a Wiley
company



+



Conclusion

- Residual leak is common
 - Etiology = *complex and multifactorial*
- No conclusive correlation to future events
 - still limitations of current studies
 - low event rates, sample size, power
- Probable Management Strategy
 - <= 5 mm leak – may left alone
 - > 5mm leak – remains unclear
 - Individual stroke risk and bleeding profile should be taken into considerations*
- Regular interval TEE reassessment is the key
- In selected patients, a second LAA occlusion procedure is a reasonable and feasible option



CardioVasculäres Centrum Frankfurt





CSI Congress

Focus LAA

Focus TRENDS



CSI 2014

Save the Date!

June 26 – 28, 2014 | Frankfurt, Germany

▼
Newsletter subscription

PodCase of the Month

Case 04 - Frankfurt

▼
watch now free of charge

2014
June 26 – 28, 2014
Frankfurt, Germany

Thank you!

BACK-UP SLIDES

[Catheter Cardiovasc Interv.](#) 2013 Oct 2. doi: 10.1002/ccd.25219. [Epub ahead of print]

Successful closure of residual leak following LARIAT procedure in a patient with high risk of stroke and hemorrhage.

[Yeow WL](#), [Matsumoto T](#), [Kar S](#).

Heart Institute, Cedars-Sinai Medical Center, Los Angeles, California, USA.

Abstract

Percutaneous left atrial appendage suture ligation with the LARIAT[®] device (Sentre HEART, Redwood City, California) was successfully performed on an 84-year-old woman with non-valvular atrial fibrillation who developed intracranial hemorrhage on warfarin. However, a large gap developed at follow-up precluding warfarin cessation. To the best of our knowledge, this case report represents the first description of the use of a Gore[®] Helex[®] Septal Occluder (W. L. Gore and Associates, Newark, Delaware) as a novel and effective approach to close a gap following percutaneous LAA suture ligation. © 2013 Wiley Periodicals, Inc.

Copyright © 2013 Wiley Periodicals, Inc., a Wiley company.

KEYWORDS: Cerebrovascular Accident, Left Atrial Appendage Closure, Transeptal cath

PMID: 24115231 [PubMed - as supplied by publisher]

LinkOut - more resources



A novel approach to treat residual peridevice leakage after left-atrial appendage closure.

[Wunderlich N](#), [Wilson N](#), [Sievvert H](#).

CardioVascular Center, Frankfurt, Germany. info@cvcfrankfurt.de

Abstract

Left atrial appendage (LAA) device closure has emerged as an alternative treatment to conventional anticoagulation therapy for the prevention of thromboembolic events in patients with atrial fibrillation. In 8-10% of patients with interventional LAA obliteration, relevant residual flow into the LAA persists due to incomplete seal. We present two cases in whom for the first time two different devices were placed to complete occlusion after residual leak with a first device.

© 2013 Wiley Periodicals, Inc.

KEYWORDS: atrial fibrillation, left atrial appendage closure, stroke, thromboembolism

Comment in

Left atrial appendage closure: does "leak" matter? [[Catheter Cardiovasc Interv.](#) 2013]

PMID: 23629764 [[PubMed](#) - in process]

LinkOut - more resources



Variation in Anticoagulation Regime

Group	n	Rate (Events/Pt-yrs)	HR	95% CI	Overall p-value
No flow, d/c warfarin	245	2.8 (17/601)	1		0.86
No flow, continued warfarin	18	2.4 (1/41)	0.89	0.12-6.73	
Any flow, d/c warfarin	141	2.1 (7/338)	0.74	0.31-1.79	
Any flow, continued warfarin	41	1.8 (2/112)	0.63	0.14-2.71	

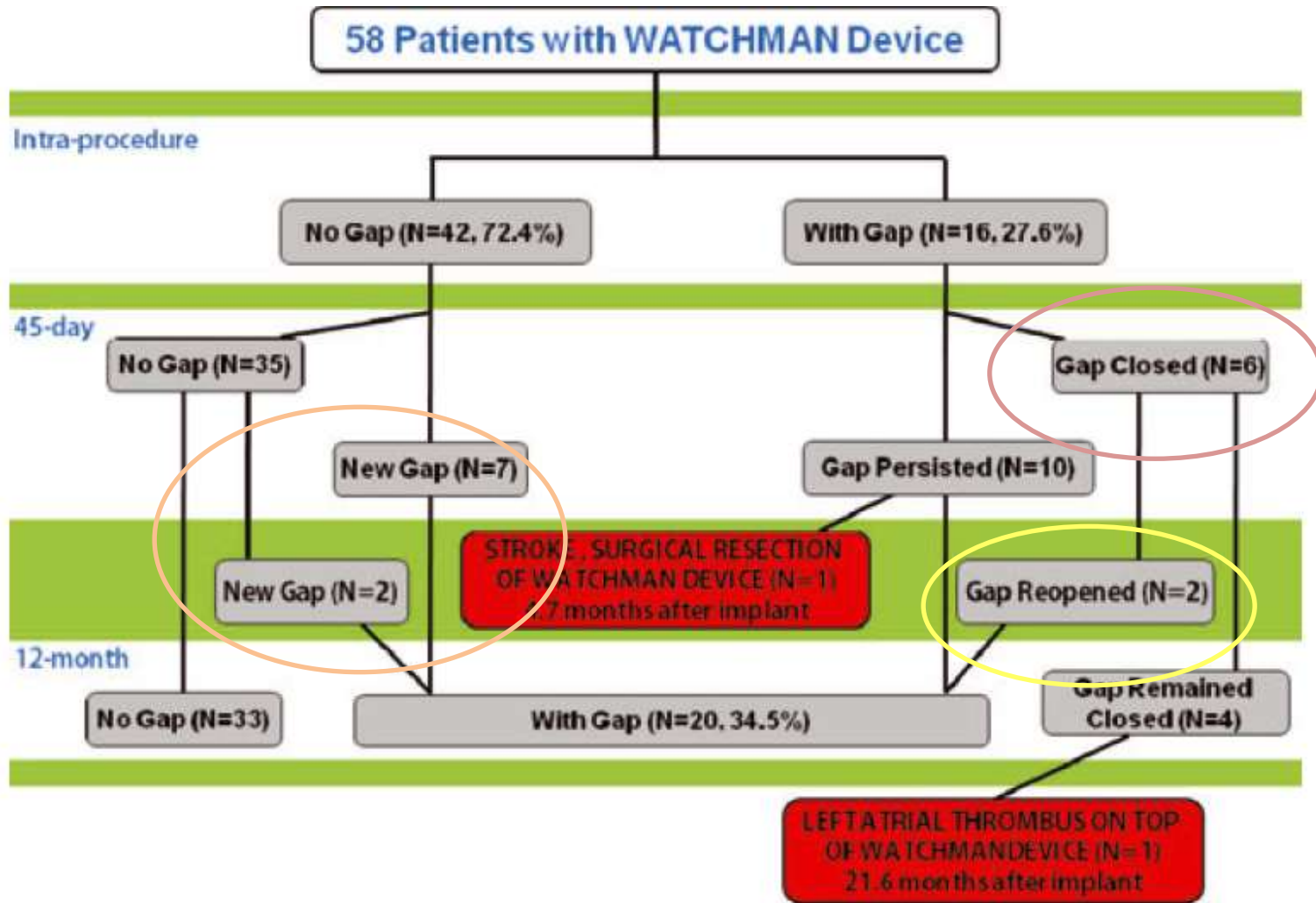
.....No difference whether there was a leak or no leak
regardless of whether the patient was treated with warfarin

Viles-Gonzalez JF, Kar S, Douglas P, Dukkipati S, Feldman T, Horton R, Holmes D, Reddy VY. The clinical impact of Incomplete Atrial Appendage Closure with the Watchman device in patients with atrial fibrillation. J Am Coll Cardiol. 2012;59:923-929

Limitations

- Retrospective nature of the study
- Relatively small number of patients and events with limited power and large confidence intervals
- The event rate for patients with leaks >5 mm was not specifically examined

Watchman Single Center

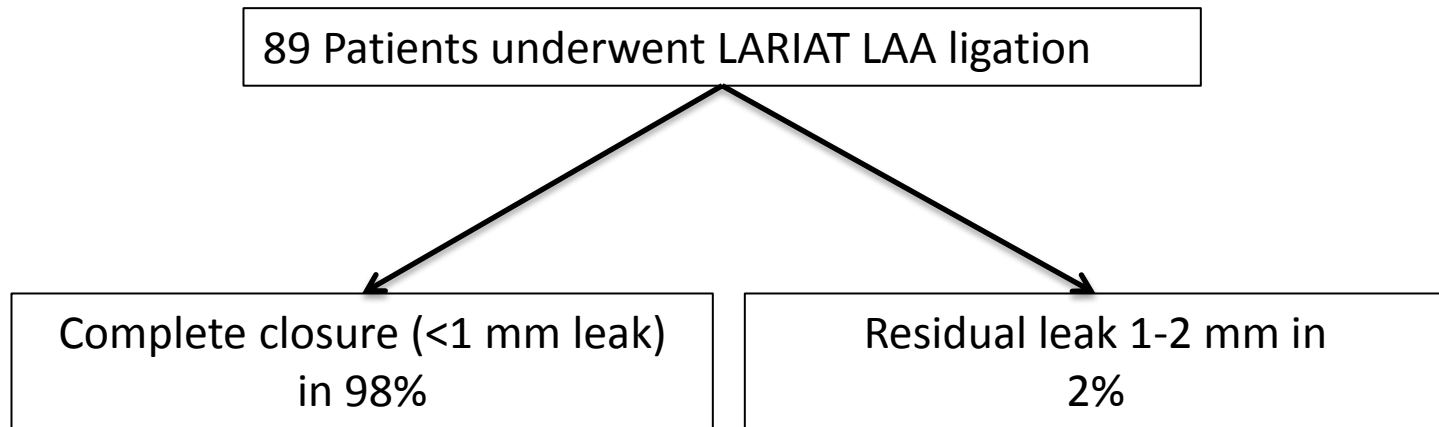


Bai R, Horton RP, et al. Intraprocedural and Long-term Incomplete Occlusion of the Left Atrial Appendage Following Placement of the WATCHMAN Device: a single Center Experience. J Cardiovasc Electrophysiol. 2012;23:455-461

PROTECT AF Trial – Mx for Leaks

- How were patients with residual leaks treated in the PROTECT AF trial?
 - Patients with *residual leaks ≤ 5 mm* in diameter by color Doppler were *treated identically to those with no leaks* (45 days of warfarin followed by aspirin and clopidogrel until 6 months followed by aspirin indefinitely)

Residual Leak & LARIAT



12 months, patient come back for TEE, N= 65

Case 3 – Watchman + Amulet



M/86

AF

Hx of TIA

HT

Bleeding risk

Watchman

30mm

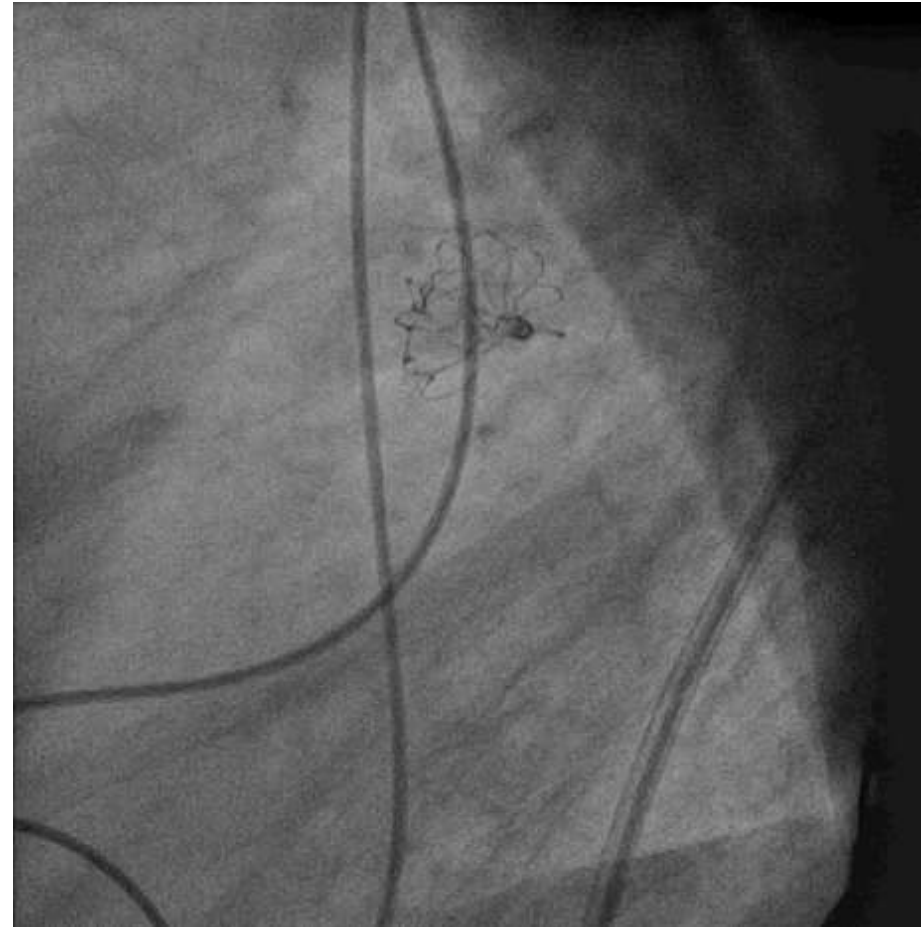
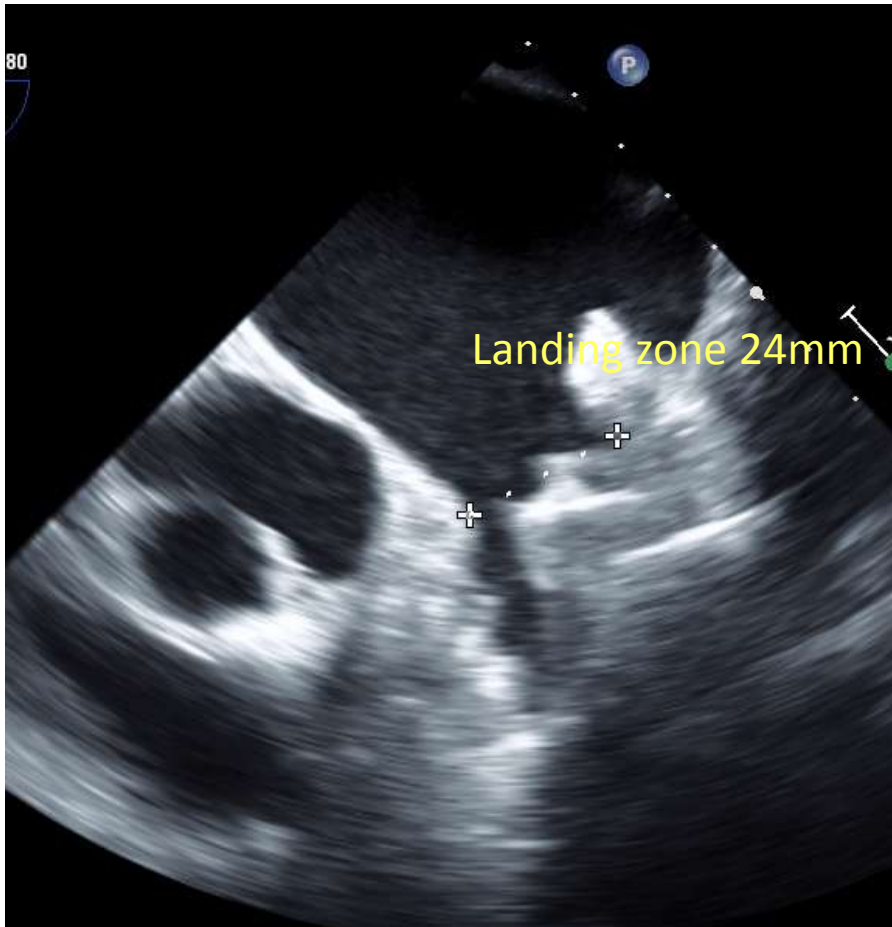
2009

TEE

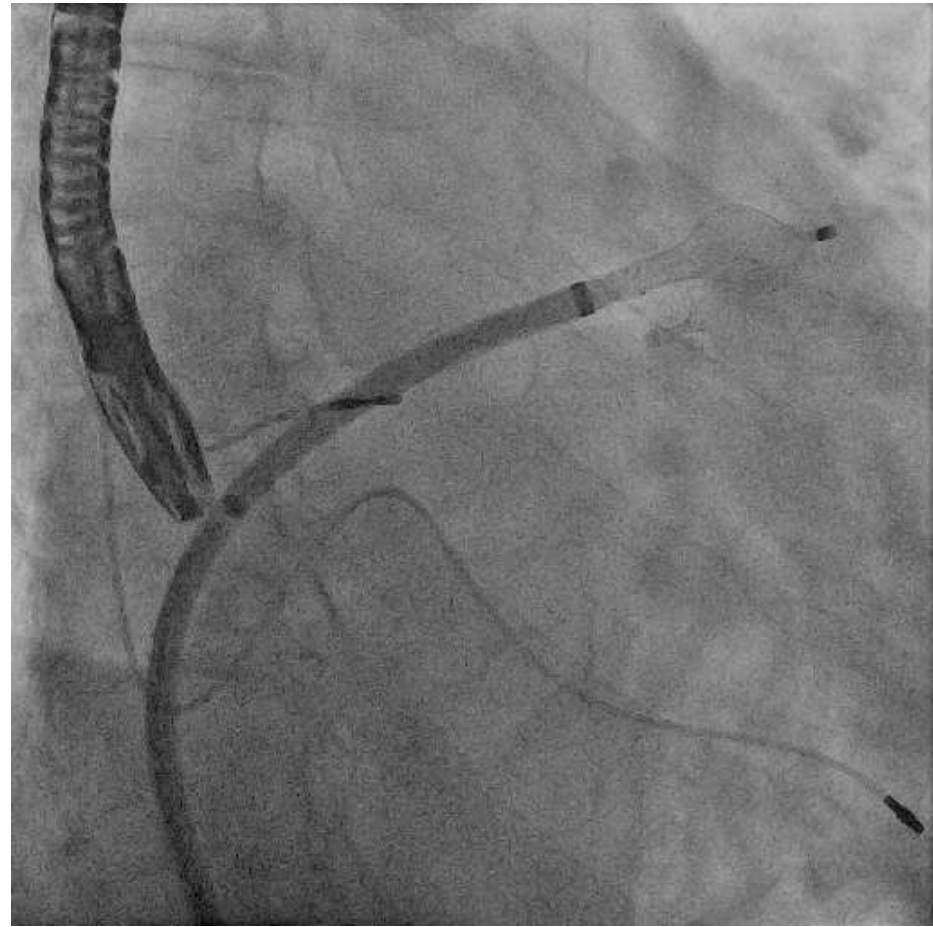
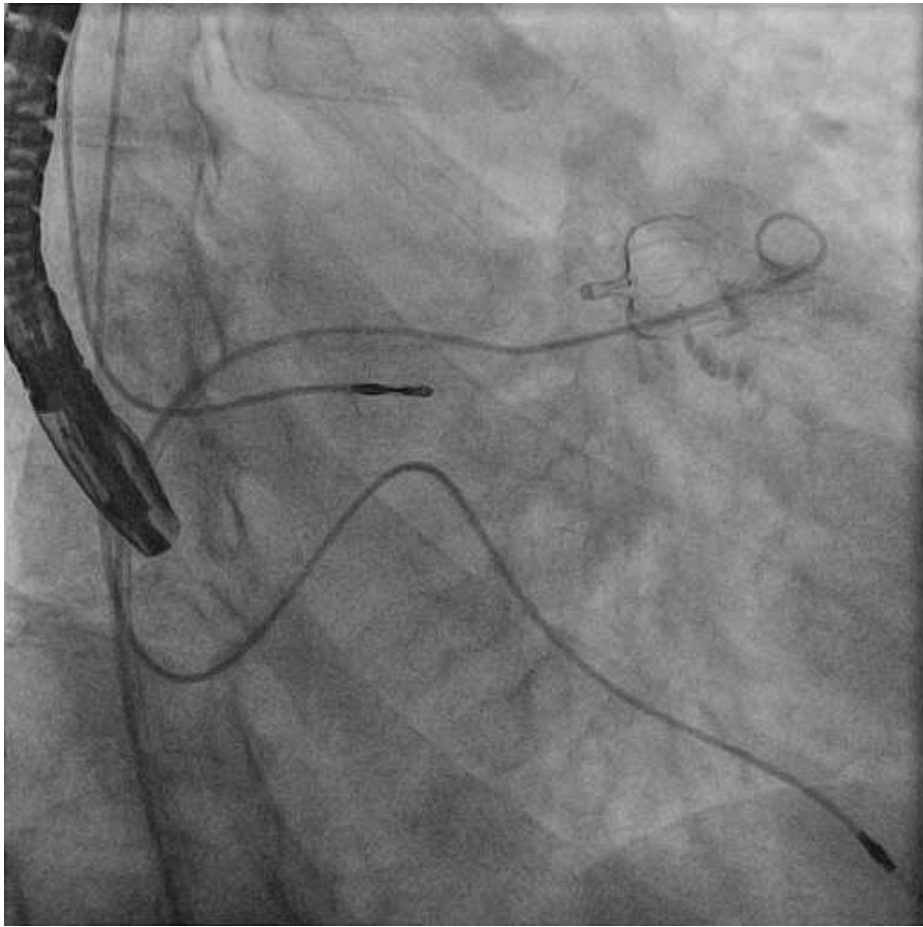
3 years

7mm gap

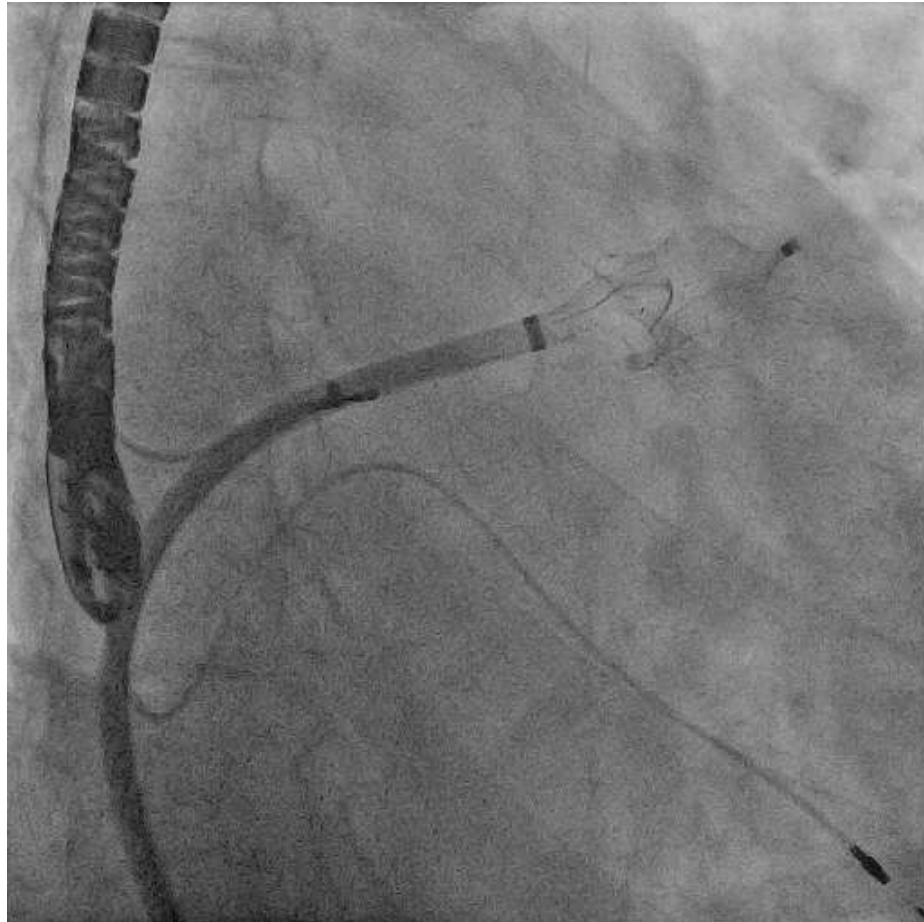
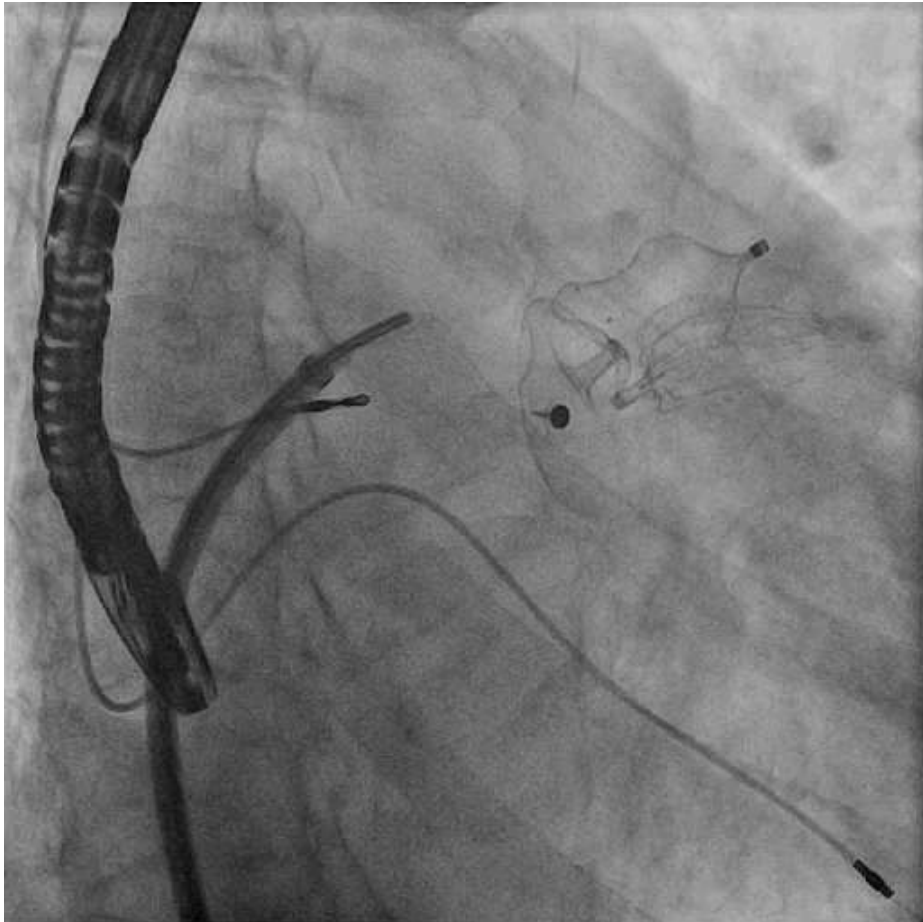
Thrombus



3 months anticoagulation – resolution of thrombus
2nd Procedure – Leak closure

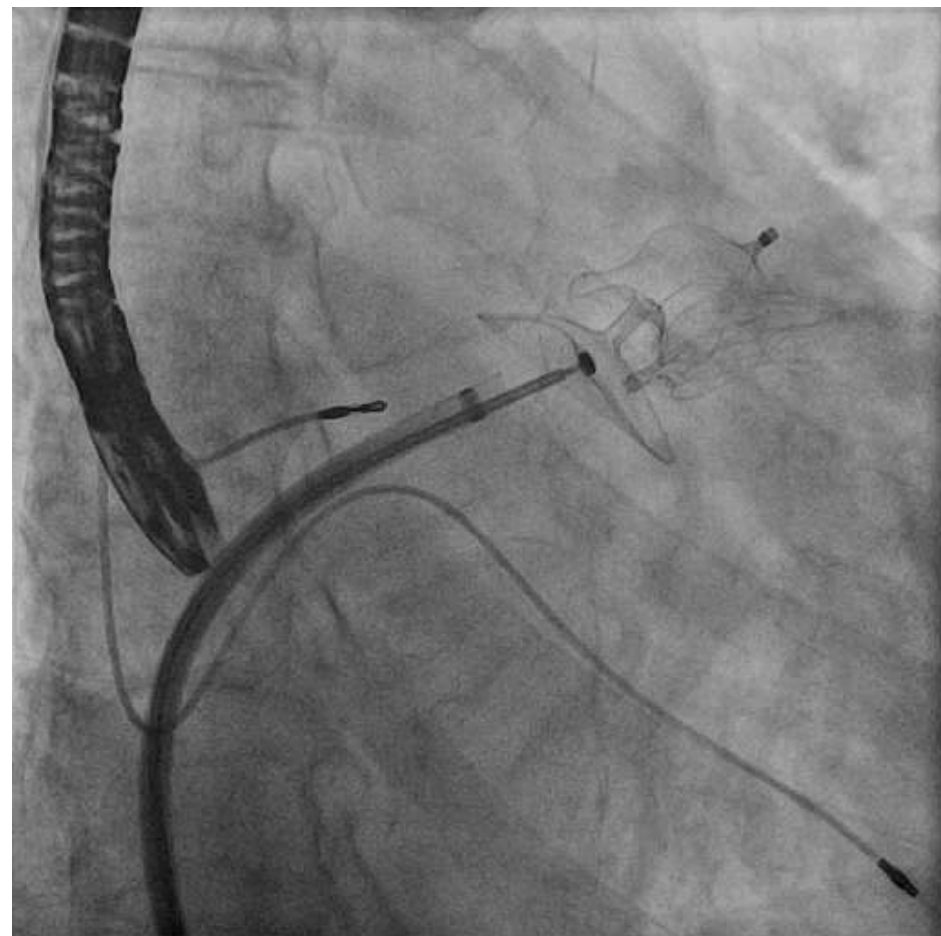


Deployment of 2nd Gen ACP (Amulet 28mm) – distal lobe

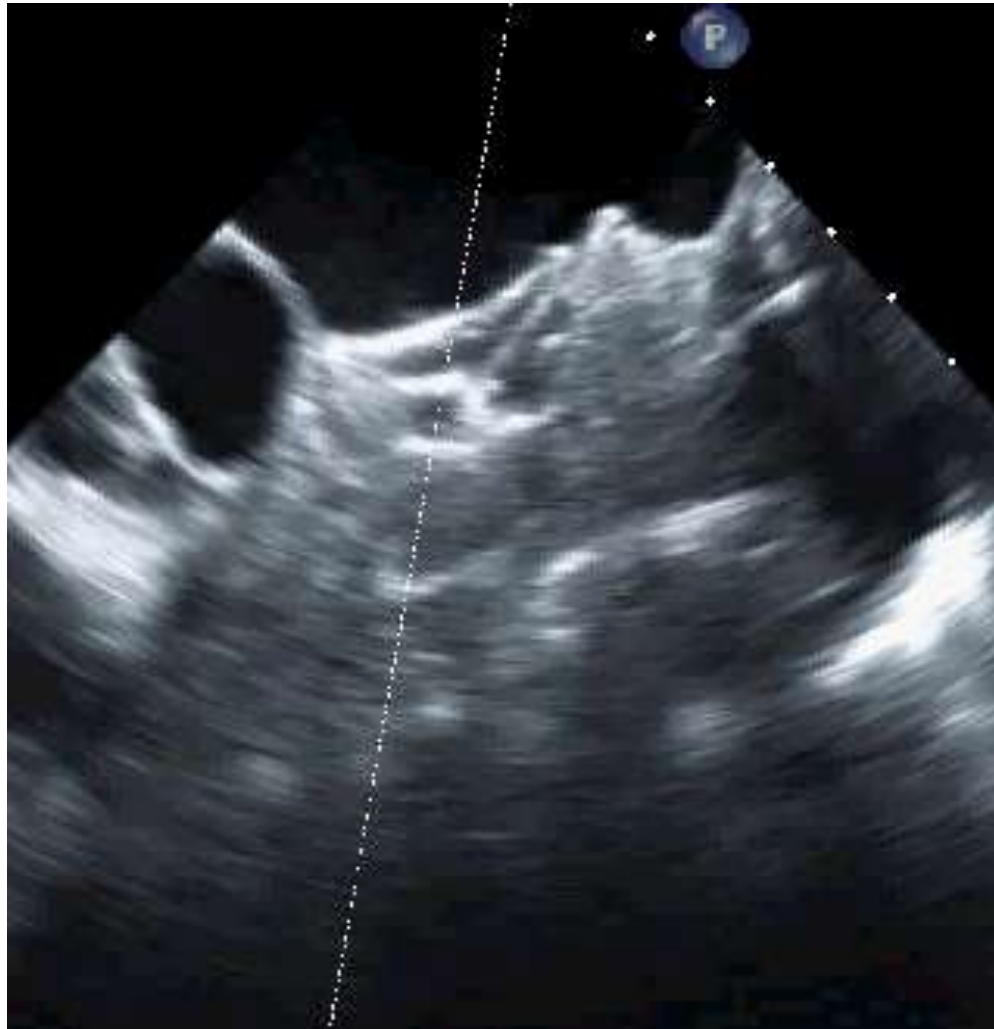


1st attempt of deployment – inner 0.014” wire
Recapture of proximal disc - redeployment





Final Results – post deployment



Final Results - Echo

Lam S, Bertog S, Sievert H. Incomplete Left Atrial Appendage Occlusion and Thrombus Formation after Watchman Implantation Treated with Anticoagulation Followed by Further Transcatheter Closure with Amulet Catheter Cardiovasc Interv 2014 Feb 19 [Epub ahead of print]



Final Results - Echo