

2023.06.24. (Sat)
15:15~16:45 15 min (ENG)

KHRS 2023
June 23(Fri.) - 24(Sat.), 2023
Grand Walkerhill Seoul, Korea
The 15th Annual Scientific Session of the Korean Heart Rhythm Society

Cross Specialty 3: Surgery vs. Catheter for AF Treatment

Recent Update of LA Appendage Closure

Seung Yong Shin, M.D., PhD.

Professor of Medicine, Chung-Ang University, Seoul, KOREA

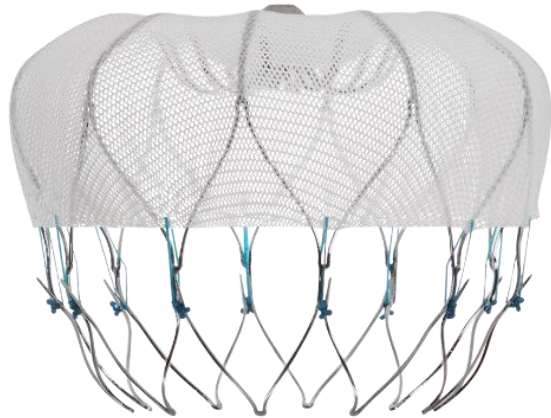
Director of EP Division, Cardiovascular & Arrhythmia Center, Chung-Ang University Hospital, Seoul, KOREA

Adj. Prof. of Grad. Sch. of Convergence and Innovation in Technology and Engineering (CITE), POSTECH, Pohang, KOREA

Center for Precision Medicine Platform Based-on Smart Hemo-Dynamic Index (SHDI), Seoul, KOREA



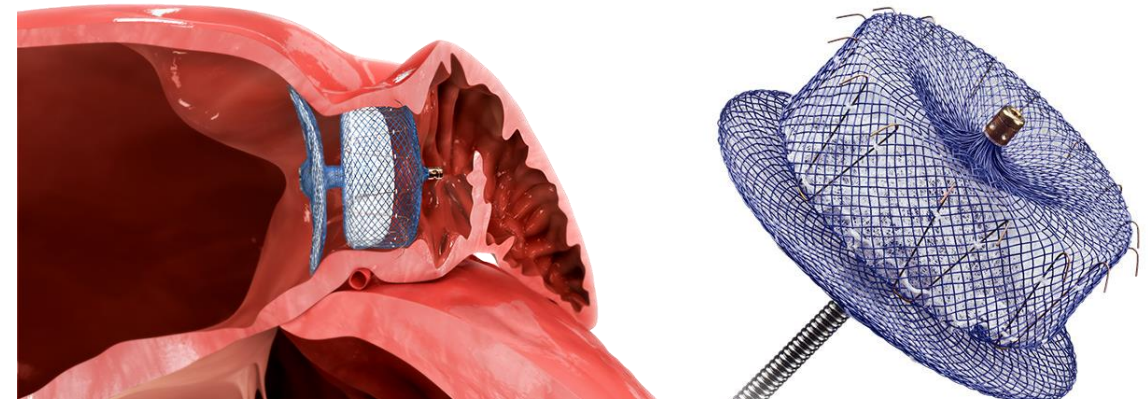
Available LAAO Devices in KOREA



WATCHMAN™



WATCHMANFLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE



Amplatzer™ Amulet™



LAMBRE™



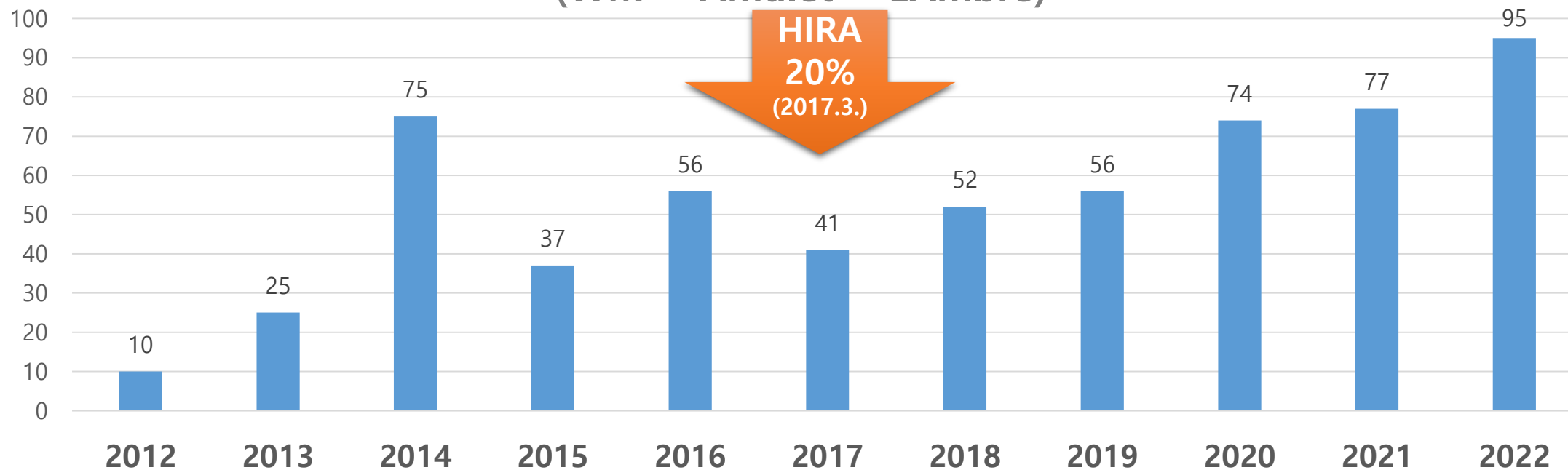
The Same Repositioning Ability
Inherent with All AtriClip Devices

LAAC Devices were Introduced in Korea

Annual CASE Volume

(WM + Amulet + LAmbre)

Total: 583 cases
 (204 + 379)



■ LAAC

2005
PROTECT AF
N=707
 Randomized
 Comparison: warfarin



2013
 Amulet acquired CE

March 2015
 FDA Approval

Total of **204**
 cases before
 partial coverage



2020
 WM FLX FDA

2021
 Amulet acquired FDA

2008
 ACP acquired CE

Global Watchman Procedure Overview

Case Number By Country / 17-22(6yrs)







WM's annual sales became greater than coronary stents' annual sales

국가	2017	2018	2019	2020	2021	2022	Total
 U.S.			41,000	40,500	62,600	69,000	213,100
 E.U.			6,100	6,600	7,500	8,400	28,600
 CHN	2,000	4,700	7,700	8,700	11,000	12,000	46,100
 JPN			179	500	1,100	1,650	3,429
 KOREA	41	52	56	74	77	95 <small>Estimation</small>	395 <small>(WM: 117)</small>

WM + Amulet in KOREA

+ LAmbre (+16)
launched in 2022.7.

Global 'Amulet' Case by country (2017-2022)

Country	2017	2018	2019	2020	2021	2022	Total
 U.S.	NA	NA	NA	NA	1,000	1,750	2,750
 E.U.	6,000	6,500	7,000	7,500	8,500	9,500	45,000
 CHN	NA	NA	NA	NA	NA	200	200
 JPN	NA	NA	NA	NA	NA	NA	
 HKG	100	105	120	112	100	115	652
 KOR	40	27	42	38	39	44	230

- **U.S.:** Amulet launched in 2021
- **CHN:** Amulet launched in 2022
- **JPN:** Not available (Plan: launch in 2027)

LAmbre Global Market



Region	2018	2019	2020	2021	2022	Total
Asia	937	2,302	1,957	2,480	3,407	11,083
EU	912	1,239	827	1,432	2,290	6,700
North America	-	-	4	8	8	20
South America	159	407	411	712	853	2,542
Africa	31	105	147	164	151	598
Korea					16	16
Total	2,039	4,053	3,346	4,796	6,709	41,902

Korean Gov't Covers **ONLY 20%** for LAAO

Since March 2017...

- Initial adequacy assessment period: 5 years (2017 ~ 2022)
- Re-Assessed in 2022 (Internal claim data analysis supports LAAO's benefit in Korean pts. – unpublished claim data)
- Extended coverage will be re-assessed in 2027
- Main reasons for extended initial adequacy assessment period
 - Guideline recommendation – IIB
 - Insufficient clinical data in KOREA
- Lack of supporting data... Inequality exists...
 - i.e. Atriclip 50%, extended coverage in TAVR (>80 YO)

Is it Reasonable?

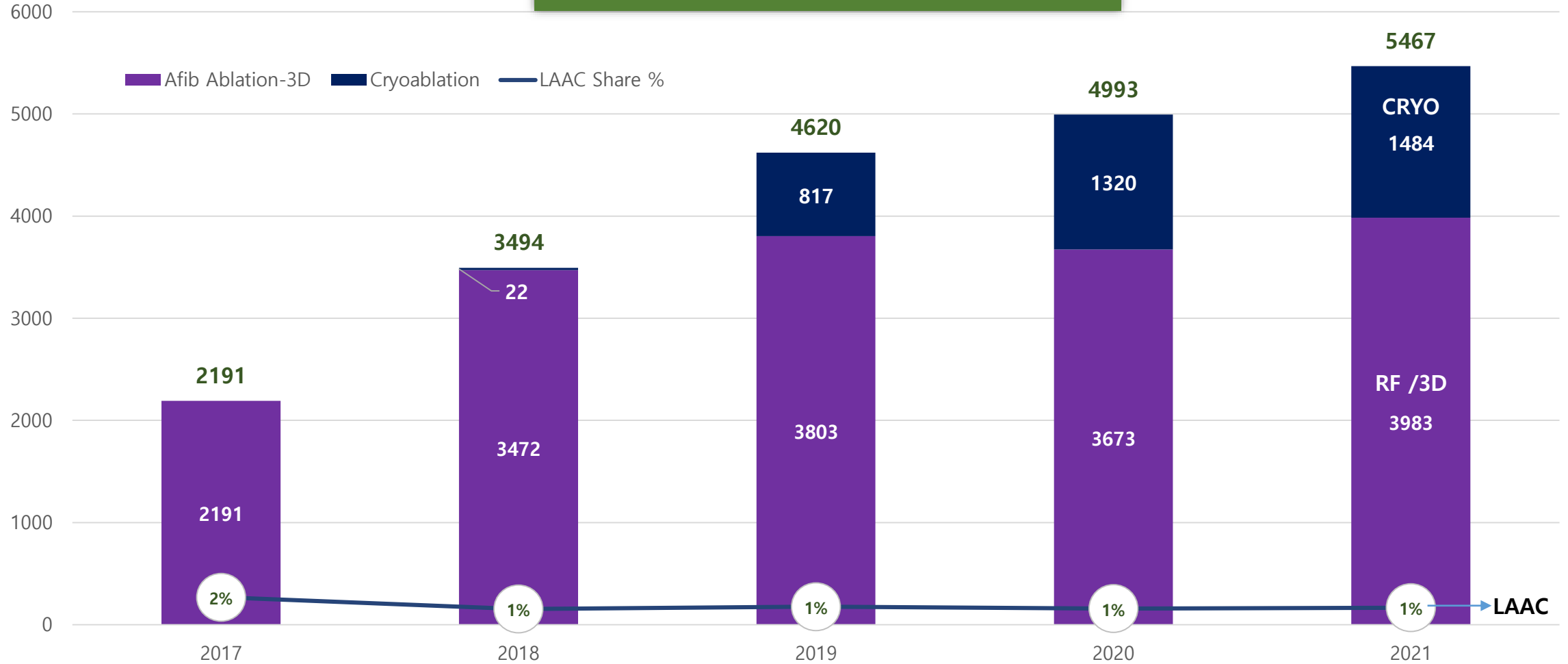
AF Procedure in Korea

2017-2021(5 yrs)

Ablation and LAAC are similar in total cost.
But ablation is fully covered by HIRA (90%).

단위(건수)

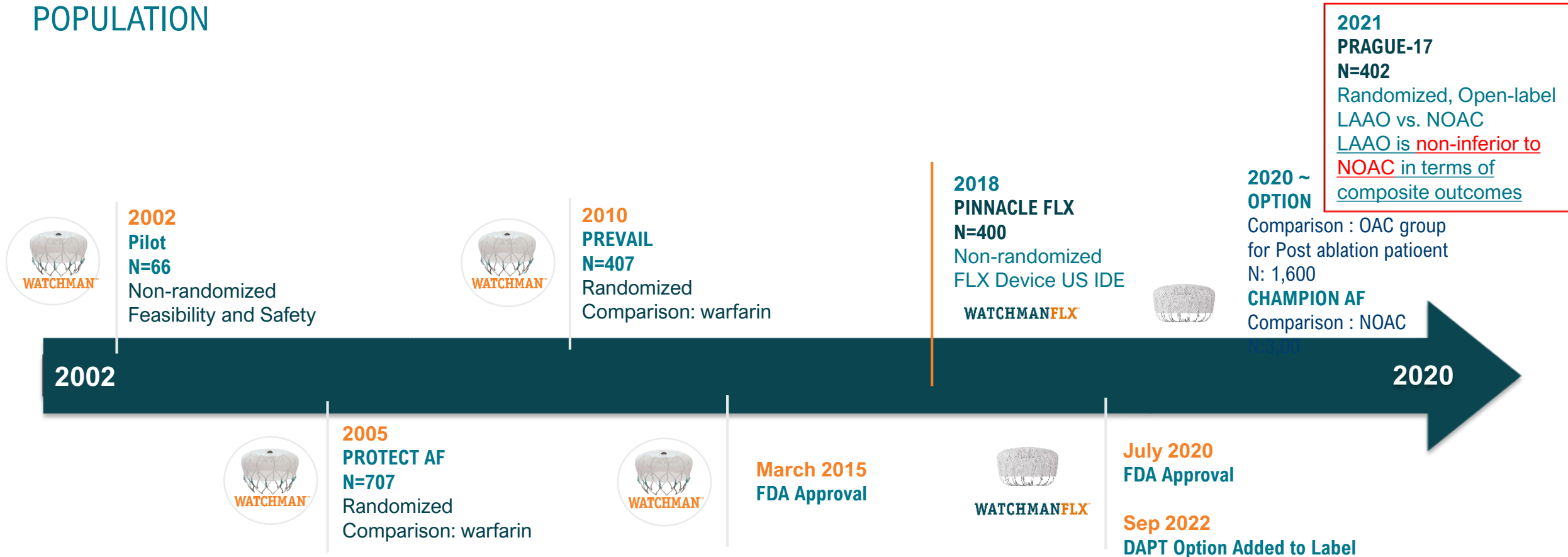
AF Ablation Procedure (RF +CRYO) vs. LAAC



Market Data by HIRA

WATCHMAN Clinical Data Overview

BUILT ON THE MOST STUDIED AND IMPLANTED LAAC DEVICE IN THE WORLD WATCHMAN FLX IS DESIGNED TO ADVANCE PROCEDURAL PERFORMANCE AND SAFETY WHILE EXPANDING THE TREATABLE PATIENT POPULATION



LAAC Studies Overview WM or WM FLX

WATCHMAN FLX™ LAAC Device

[PINNACLE FLX >](#)

[PINNACLE FLX Prohibitive Anatomy >](#)

[IDE Trials >](#)

[SEAL FLX Study >](#)

[SWISS APERO Study >](#)

[SURPASS 45-Day Results >](#)

[SURPASS 1-Year Results >](#)

[Meta-Analysis >](#)

[ALSTER-FLX Registry >](#)

[Safety and Acute Procedural Outcomes of LAAO >](#)

[CHAMPION-AF Clinical Trial >](#)

[OPTION Clinical Trial >](#)

[DAPT FLX >](#)

Legacy WATCHMAN™

[PROTECT-AF and PREVAIL Clinical Trials >](#)

[NCDR-LAAO Registry™ >](#)

[PROTECT-AF, PREVAIL, CAP2 Leak Analysis >](#)

LAAC Therapy

[LAA Occlusion Study \(LAAOS III\) Trial >](#)

[PRAGUE 17 4-Year Outcomes >](#)

Study Overview

LAAO vs NOAC for stroke prevention
in patients with non-valvular atrial fibrillation (NCT03108872)
From 5 tertiary cardiovascular centers
(Sejong General Hospital, Chung-ang university Hospital, Severance Cardiovascular Hospital,
Korea University Anam Hospital, Ulsan university hospital)



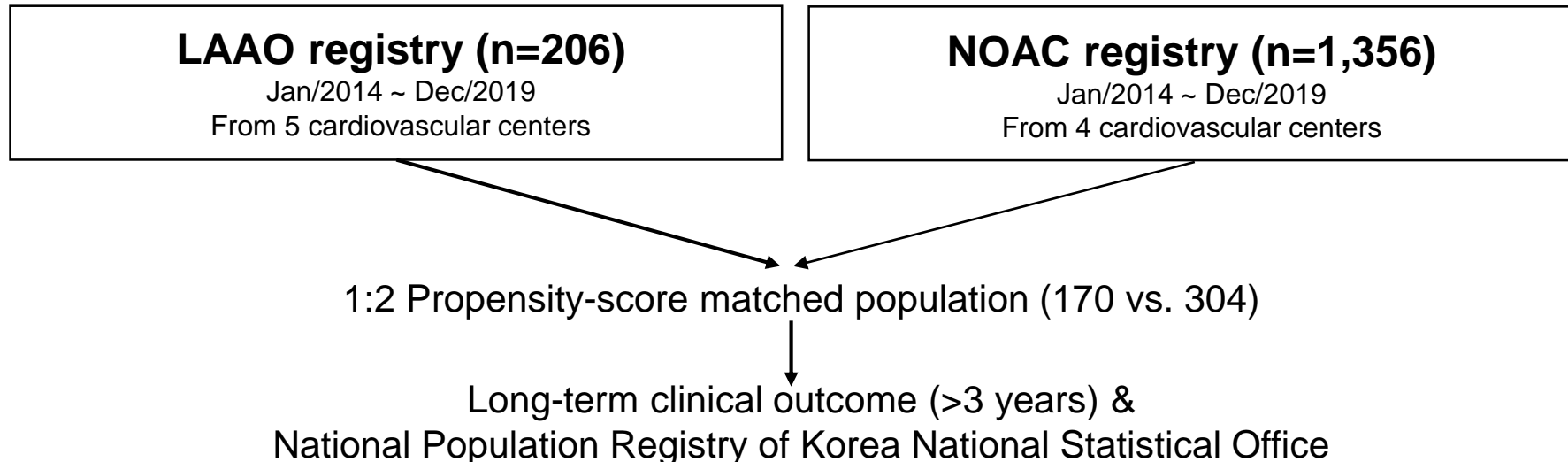
**Korean
LAAO
Registry
[KoLAR]**

**Successful
LAAO**

**NOAC with
similar risk**

Exclusion criteria

1. Patients who failed to successfully implant LAAO
2. Patients who receive NOAC less than 6 months without clinical events
3. Patients with mitral stenosis more than mild grade
4. Patients with prosthetic heart valve

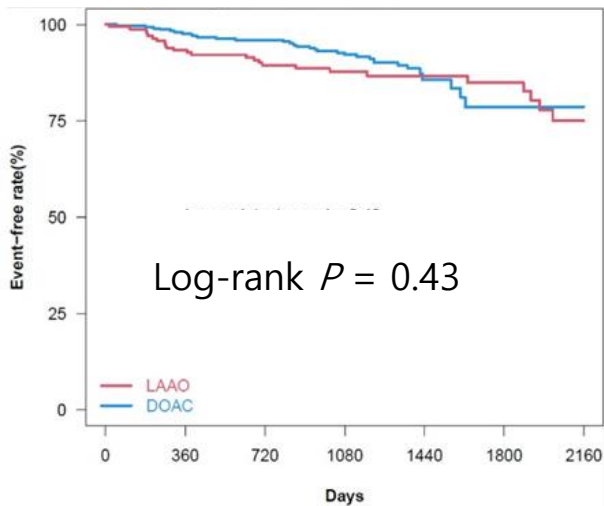




- Plug type device (Watchman®) 34.6%
- Lobe and disc type device (ACP or Amulet™) 65.4%
- Mean procedure time: 97 ± 35 minutes
- Median hospital stay: 5 days (range: 4–8 days)
- Mean dimension of device: 27 ± 3.5 mm
- Anticoagulation at discharge: 72.8%
- Mean duration of post-procedural anticoagulation: 83 days (48–184)
- **ANY Peri-device leak: 10.2%** (mean jet width: 1.4 ± 1.2 mm)

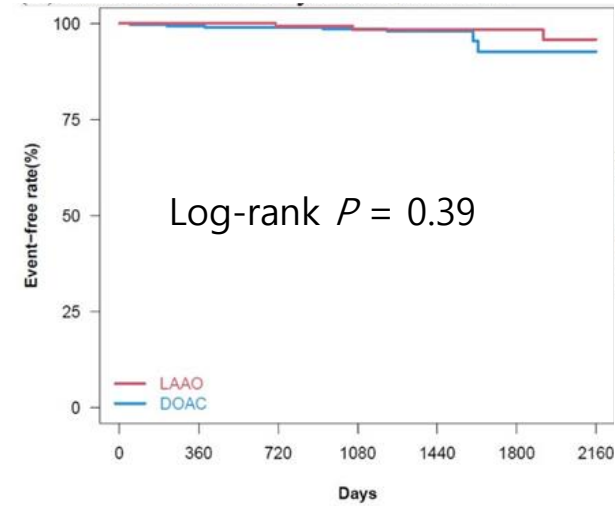
Similar in Composite/Individual Outcomes btw. LAAO & NOAC

A. Primary composite outcomes



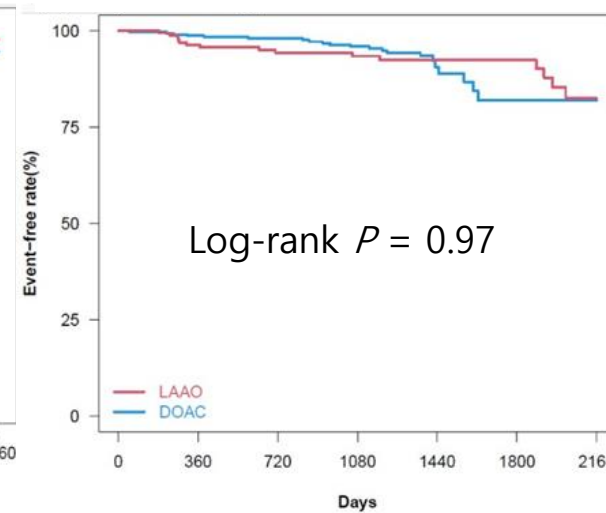
No. at Risk (no. of events)	
LAAO	170(0) 151(11) 127(6) 96(2) 58(1) 43(1) 13(4)
DOAC	304(0) 290(7) 249(5) 201(9) 50(8) 18(3) 5(0)

B. Ischemic stroke or systemic embolism



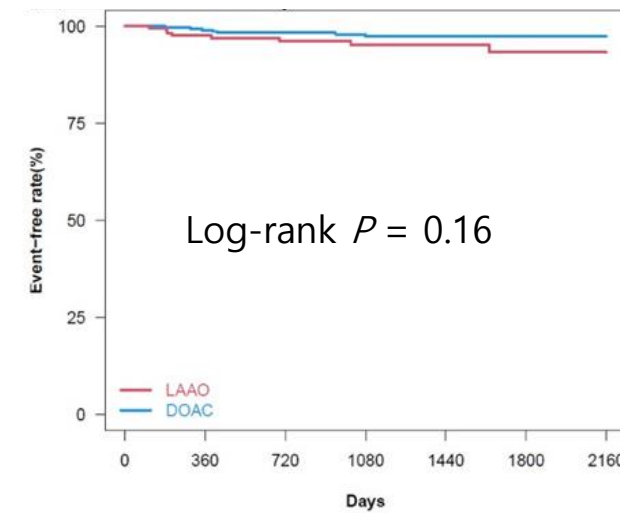
No. at Risk (no. of events)	
LAAO	170(0) 155(0) 133(1) 101(1) 62(0) 47(0) 15(1)
DOAC	304(0) 293(2) 255(1) 206(1) 53(1) 19(2) 5(0)

C. Major bleeding



No. at Risk (no. of events)	
LAAO	170(0) 155(6) 133(3) 101(1) 62(1) 47(0) 15(4)
DOAC	304(0) 293(4) 255(2) 206(5) 53(6) 19(4) 5(0)

D. All cause mortality



No. at Risk (no. of events)	
LAAO	170(0) 151(4) 127(2) 97(1) 58(0) 43(1) 13(0)
DOAC	304(0) 290(3) 250(2) 203(2) 51(0) 19(0) 5(0)

A. Primary composite outcomes = Ischemic stroke or systemic embolism + all cause mortality + major bleeding

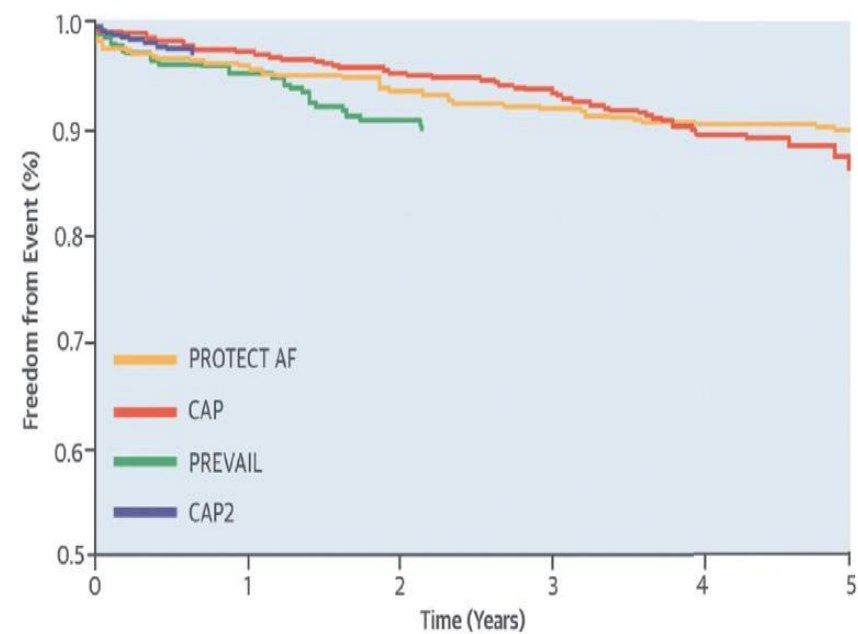
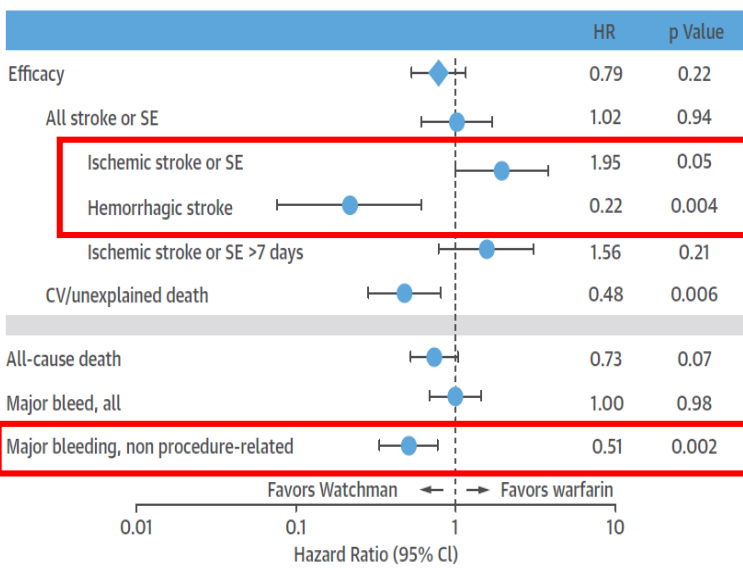
Clinically Proven Efficacy & Safety

1.8

WM/pt

- Non-inferiority in comparison with VKA & NOAC

FIGURE 2 PROTECT AF/PREVAIL Combined: Meta-Analysis Shows Comparable Primary Efficacy Results to Warfarin



	AF	SE	CV Death	Stroke, TIA, SE, CV Death, Bleeding, or Complications	Major + NMCB Bleeding	Total
PROTECT AF	463	382	360	337	321	235
CAP	566	503	468	435	293	59
PREVAIL	269	234	182	37	0	
CAP2	579	116	0			

CENTRAL ILLUSTRATION: The PRAGUE-17 Trial

PRAGUE-17 Randomized Clinical Trial

- 402 High-Risk AF Pts → Randomized
- CHA₂DS₂-VASc = 4.7 ± 1.5
- HAS-BLED = 3.1 ± 0.9
- Follow-up: 20.8 ± 10.8 mo (695 pt-year)

Primary Endpoint
Stroke, TIA, SE, CV Death, Bleeding, or Complications

Cumulative Incidence (%)

Time Since Randomization (Months)

Non-inferiority: p = 0.004

	sHR (95% CI)	p value
Primary Endpoint		
mITT	0.84 (0.53-1.31)	0.44
Per Protocol	0.82 (0.52-1.30)	0.40
On-Treatment	0.79 (0.49-1.25)	0.31
All-Stroke/TIA	1.00 (0.40-2.51)	0.99
CV Death	0.75 (0.34-1.62)	0.46
Major + NMCB Bleeding		
All	0.81 (0.44-1.52)	0.51
Nonprocedural	0.53 (0.26-1.06)	0.07

Osmancik, P. et al. J Am Coll Cardiol. 2020;75(25):3122-35.

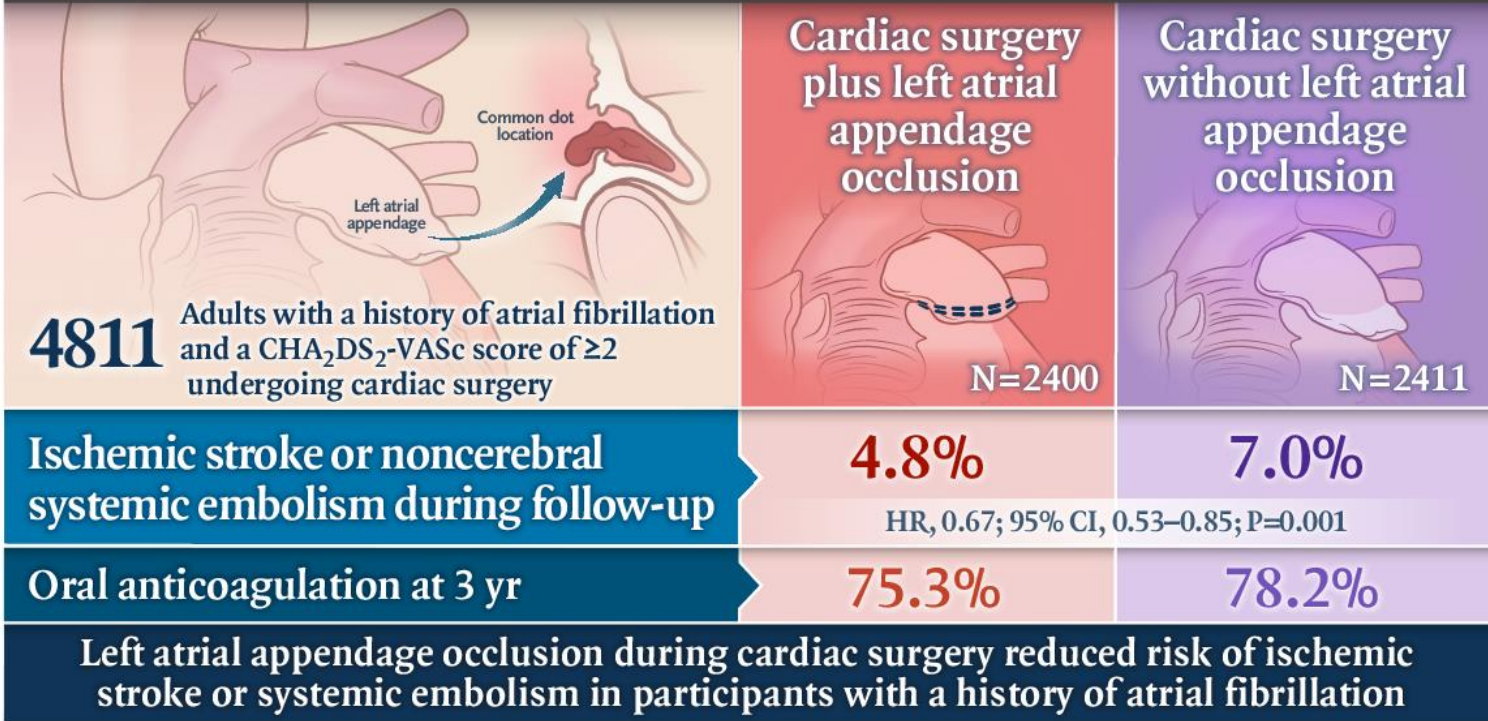
→ Composite Outcome benefit mainly driven by **reduced major bleeding events, esp. hemorrhagic stroke, non-procedure-related**

Is Peri-device Leakage (PDL) a Culprit?

The NEW ENGLAND JOURNAL of MEDICINE

Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke

MULTICENTER, RANDOMIZED, CONTROLLED TRIAL

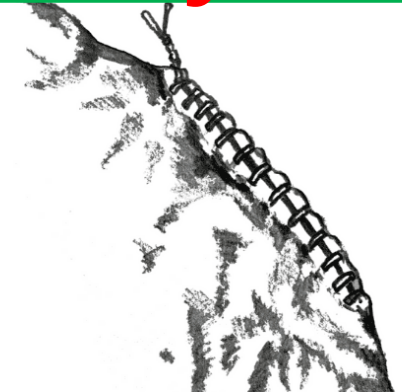


R.P. Whitlock et al. 10.1056/NEJMoa2101897

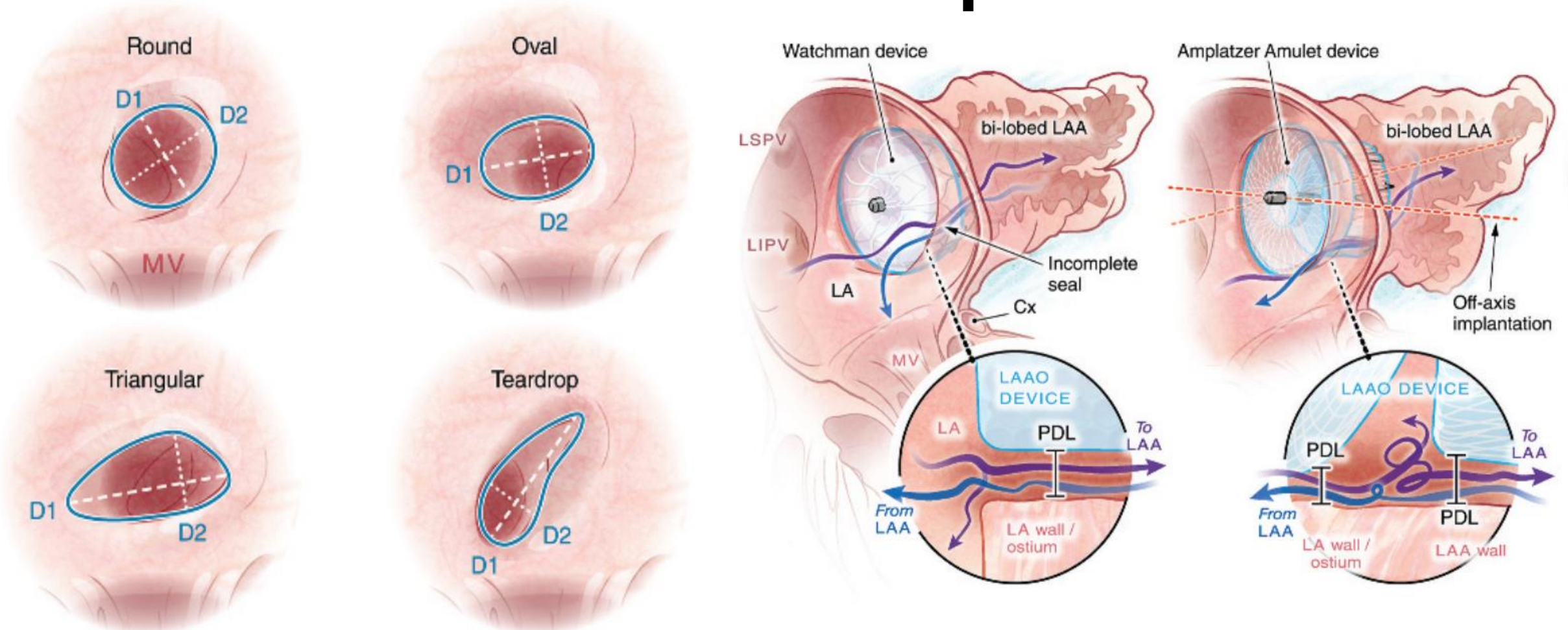
Copyright © 2021 Massachusetts Medical Society



**Complete Excision
 Reduced Ischemic
 Stroke by 33 %**



If PDL is Small, Is it acceptable?



Wide anatomical variation & Circular device → PDL!

Clinical Impact of PDL

- FDA approved **PDL < 5 mm accepted "sufficient LAA closure"**
- Re-categorized PROTECT-AF, PREVAIL, CAP2 participants' TEE at 45 days & 1 year → Absence of PDL vs. PDL < 5 mm
- N = 1,054
- 404 (38.3%) PDL < 5 mm at 45 days TEE
- 272 (27.7%) **PDL < 5 mm at 1 year TEE** → increased 5 year stroke or SE risk (adjusted HR 1.94, 95% CI 1.15-3.29, P = 0.014)
- Mainly driven by **Non-fatal stroke**

Peri-Device Leakage (PDL) is More Prevalent than Our Expectation

Table 1. Summary of definitions, frequency, modality for detection, and impact on outcomes of PDL in percutaneous LAAO studies.

Device	Year	Patients (n)	Definition and Timing of PDL	Presence of PDL or Leak (LARIAT)	Anticoagulation Regimen	Imaging	Impact of PDL on outcomes
WATCHMAN (Boston)	2009	463	>5 mm, 45 days	14% ³¹	See notes below	TEE	N/A
				<1% ³⁰		TEE	None
				20%		CT	N/A
				32%		TEE	None
				33%		CT	N/A
				59% ³⁴		TEE	N/A
				34%		CT	N/A
				35%		TEE	N/A
				20%		CT	N/A
				8% ³⁶		TEE	N/A
				21%		CT	N/A
				20%		CT	N/A
				33%		CT	N/A
				29%		TEE	None
				37%		TEE	N/A
				32%		TEE	None
				38%		TEE	N/A
				5% ¹⁶		TEE	None
				7% ³⁹		TEE	N/A
				40%		TEE	N/A
				41%		TEE	N/A
				42%		TEE	N/A
				43%		TEE	N/A
				12%/3% ⁴⁴		TEE	N/A
				45%		N/A	N/A

Anticoagulation regimen in patients receiving LAAO by study:

³¹ 45 days warfarin (until no PDL or PDL<5 mm), 75 mg clopidogrel + 81–325 mg aspirin (until 6 month follow-up), 81–325 mg aspirin (indefinitely)

³⁰ 45 days warfarin (until no PDL or PDL<5 mm), clopidogrel + aspirin (until 6 month follow-up), aspirin (indefinitely).

²⁰ typically aspirin + clopidogrel for 1–3 months, followed by aspirin alone indefinitely.

³² Watchman: 45 days warfarin, oral antiplatelet agent for 6 months, continuation of either oral anticoagulants or antiplatelet agents “was left to the operator’s discretion”. Lariat: “oral anticoagulants and antiplatelet agents were discontinued immediately after the procedure in the majority and at 4–6 weeks in some. Subsequent continuation of these agents was left to the operator’s discretion based on patient situation”.

³³ Watchman: 45 days warfarin, dual-antiplatelet therapy for 6 months, single-antiplatelet therapy indefinitely.

ACP: dual-antiplatelet therapy for several weeks to months, and a single-antiplatelet drug or no medication thereafter.

³⁴ Oral anticoagulation for 45 days unless PDL >5 mm, clopidogrel up to 6 months, aspirin indefinitely.

³⁵ Dual anti-platelet therapy (aspirin 80 mg/day and clopidogrel 75 mg/day) for a minimum of three months followed by aspirin indefinitely.

³⁶ Following implantation, a loading dose (60 mg) of clopidogrel was administered, and treatment was started with 300 mg aspirin (ASA) on the first day and 100 mg daily thereafter. Clopidogrel was maintained for 6 months, barring no contraindications, in ASA for 6 months. If thrombolysis occurred, subcutaneous enoxaparin in a therapeutic dose was added for 2 weeks, clopidogrel was prolonged, and the TOE was repeated to check for disappearance. If the result was negative, the decision to prolong the treatment for another week or hospitalize the patient and begin treatment with intravenous heparin was evaluated.

²¹ Anticoagulation therapy was discontinued at discharge in all patients (one patient had thrombus treated with 3 weeks of LMWH).

²⁹ Anticoagulation therapy regimen initiated by the device manufacturer (LAA closure as a firm) 100 mg/day and clopidogrel 75 mg/day for 1 to 3 months, followed by aspirin 100 to 200 mg/day for at least 6 months. However, the choice and duration of oral anticoagulation therapy was individualized on the basis of physician preference and recorded at admission and last follow-up visit

- Antithrombotic therapy use post-LAA closure was available in 255 patients; of these, 159 were on dual-antiplatelet therapy, 79 were on single-antiplatelet therapy, 16 were on OAC, and 1 was receiving no antithrombotic agent post-LAA closure.

³⁷ Discharged on a single-antiplatelet agent (23.0%), dual antiplatelets (54.3%) or an oral anticoagulant (18.9%).

³⁸ Patients with a contraindication to warfarin remained off warfarin. Patients with a CHADS₂-VASC score of 2 or higher who could tolerate warfarin (i.e., noncompliant or labile international normalized ratio level) were recommended to continue warfarin or a NOAC. Patients with a CHADS₂-VASC score of 1, anticoagulation was left to the discretion of the referring physician.

¹⁶ Postprocedural medical therapy (including antithrombotic therapy) was prescribed according to physician preference

- 85% of patients were discharged on antithrombotic therapy: 50% on antiplatelet therapy (aspirin in 18%, clopidogrel in 2%, and dual-antiplatelet therapy in 30%) and 35% on OAC (warfarin in 26%, rivaroxaban in 5%, and dabigatran in 4%).
- At 6-month follow-up, 1% of patients were on OAC and 44% on antiplatelet therapy.
- At 12-month follow-up, 9% were on OAC and 44% on antiplatelet therapy. Patients were kept on OAC either because leaks were observed or because they underwent an ablation procedure at follow-up.

³⁹ Anticoagulation was resumed after LAA exclusion in all patients except those with prohibitive bleeding (67.4%) and high fall risk (11.6%). The other 21% patients were on OAC at 6 weeks, and all of them were off OAC at 6, 12, and 24 months, unless they were found to have a thrombus on follow-up TEE (n = 12) that required reinitiating of OAC.

⁴⁰ Clopidogrel 75 mg daily for 3 months then aspirin 100 mg daily indefinitely.

⁴¹ Dual antiplatelet therapy with aspirin 100 mg daily and clopidogrel 75 mg daily for 3 months, followed by aspirin alone. At 12-month a relevant leak of ≥5 mm was observed in 3/60 (5%) patients, which persisted during 12-month follow-up. After its detection, antiplatelet therapy was switched to oral anticoagulation.

⁴² 100 mg aspirin and 75 mg clopidogrel was recommended for 3 months

- 2 patients required warfarin for device thrombus and maintained INR > 2 until 3-month follow-up, then phenprocoumon.
- 2 patients required warfarin for device thrombus and maintained INR > 2 until 3-month follow-up, then phenprocoumon.

⁴³ Aspirin 81 mg/day and clopidogrel 75 mg/day for 3 months and single-antiplatelet therapy (usually aspirin) indefinitely.

⁴⁴ Most patients (~90%) were discharged on single or dual-antiplatelet therapy, whereas only 4% of patients received oral anticoagulation.

- 5 patients with device-related thrombosis received oral anticoagulation.
- 5 patients with device-related thrombosis received oral anticoagulation.

⁴⁵ Not reported.

Post-LAAO Anti-thrombotic regimens are not standardized!

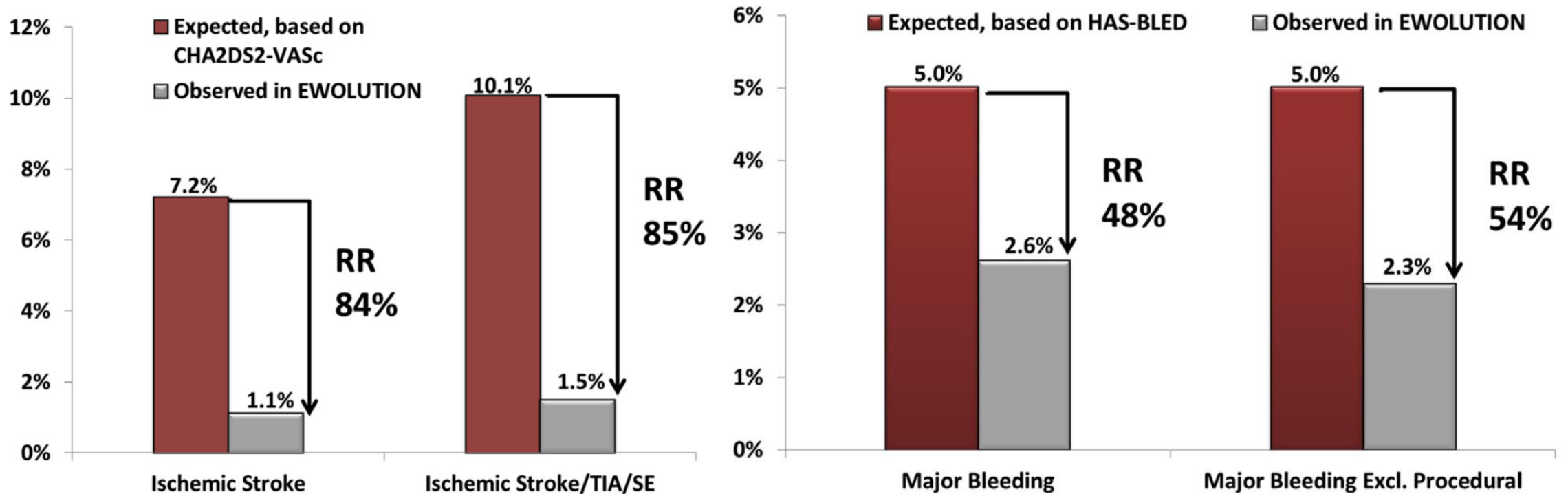
Should be individualized according to indication & procedural outcomes!



Notes. Abbreviations: PDL, peri-device leak; TEE, transesophageal echocardiography; CT, computed tomography.

Stroke Preventive Efficacy for LAAO

- EWOLUTION (Registry)
- At 1 Y, stroke rate 7.2 % (expected) vs. 1.1 % (observed)

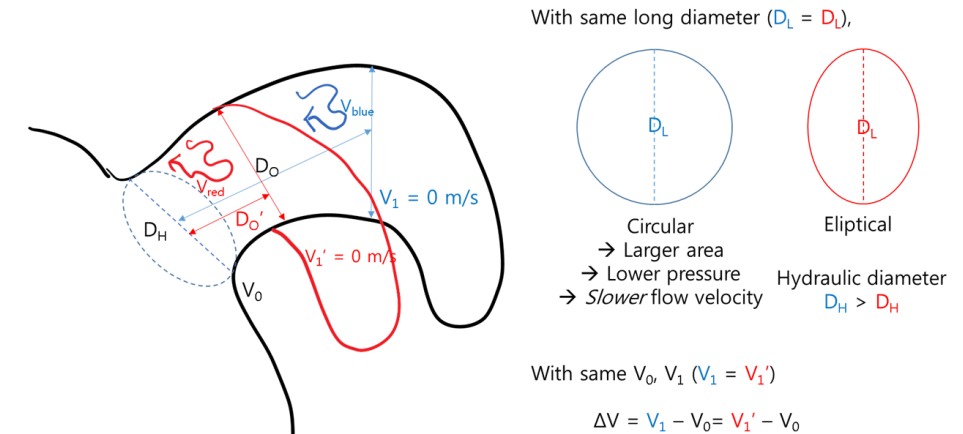


Largest Real World Data in the U.S.

- NCDR (National Cardiovascular Data Registry, U.S.)
- N = 38,158 (Jan. 2016 ~ Dec. 2018)
- Mean age 76.1 ± 8.1 Y
- **Mean CHA₂DS₂-VASc = 4.6 points (Prior stroke 27.3 %)**
- Mean HASBLED = 3 points
- Follow-up: 2 Y
- **Stroke = 0.17 %**
- Major bleeding = 1.25 %

Unanswered Questions?

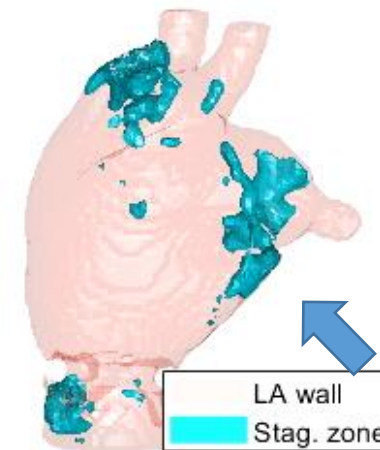
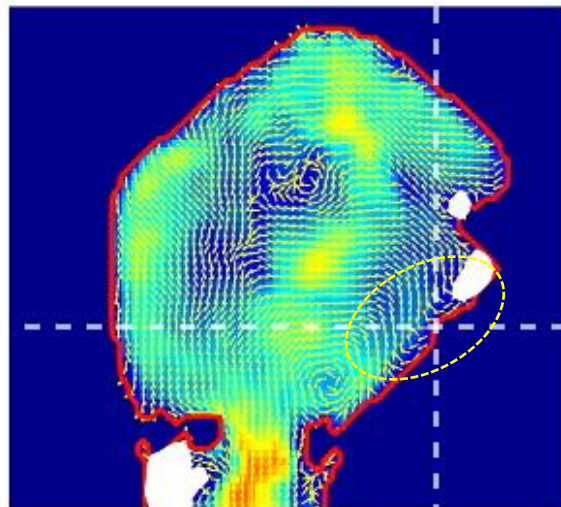
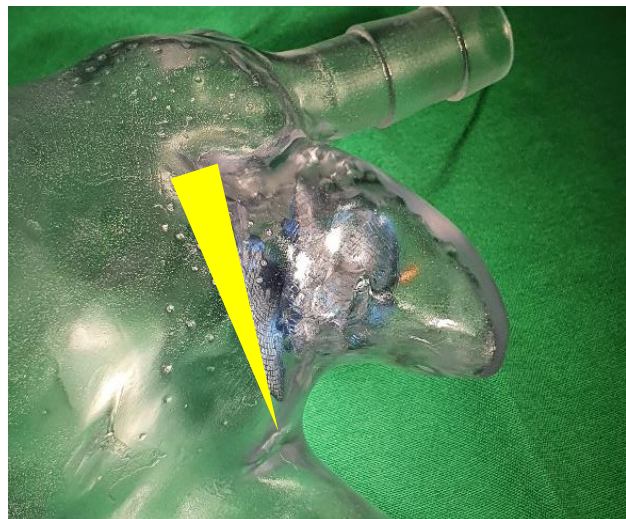
- Why results are contradictory?
 - Excision vs. Closure?
 - Ideal closure or not?
 - Peri-device leakage matters?
- What is appropriate **post-procedural anti-thrombotic therapy (ATT)** regimen? Are clinical factors enough for deciding ATT in a given patient?
- **Hemodynamic changes** within left atrium after LAAO?



Larger/Deeper = More thrombogenic

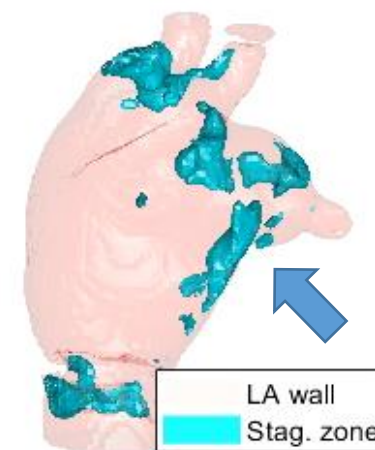
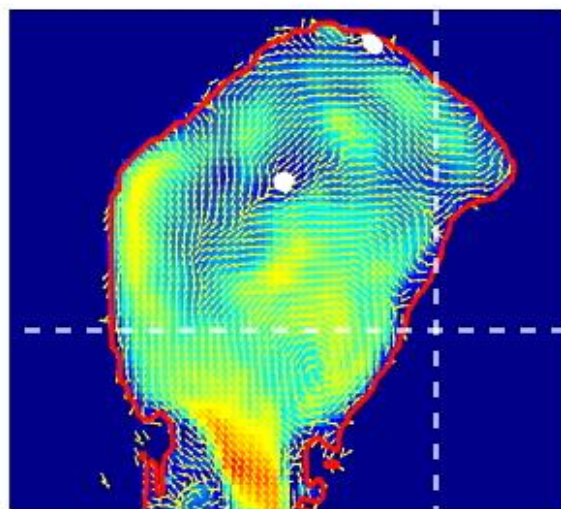
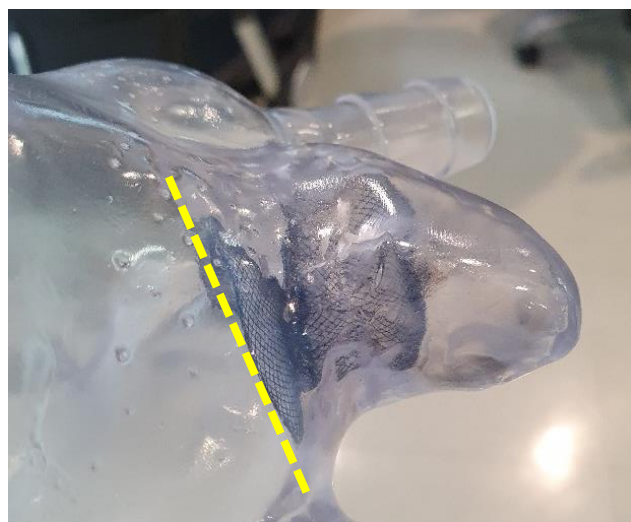
Shin SY, Park JW, *Int J Cardiol.* 2021; Feb.

Hemodynamic Difference & Remnant Pouch



Remnant pouch (+)

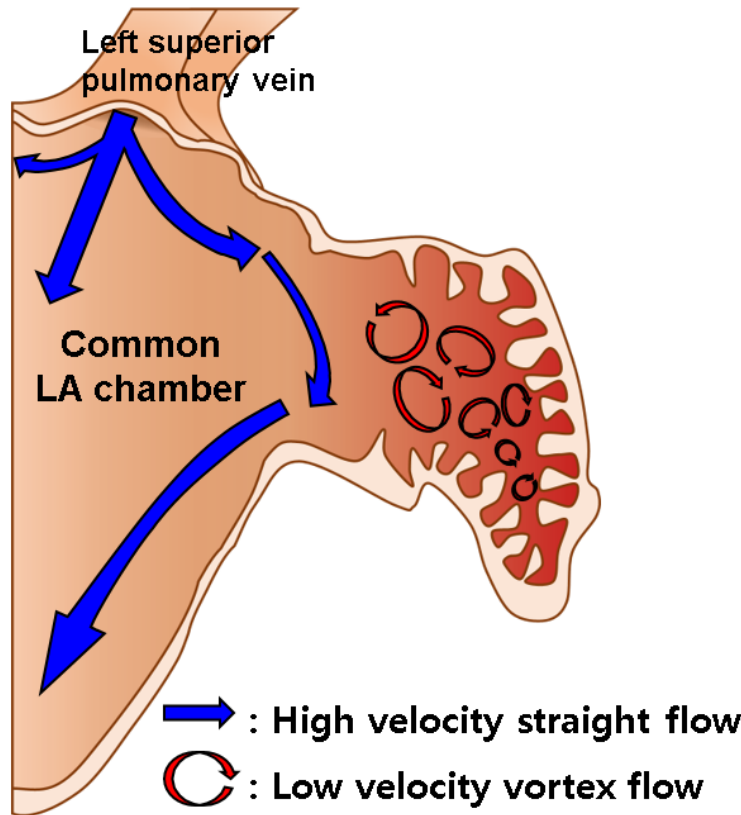
Larger stagnant zone



Remnant pouch (-)

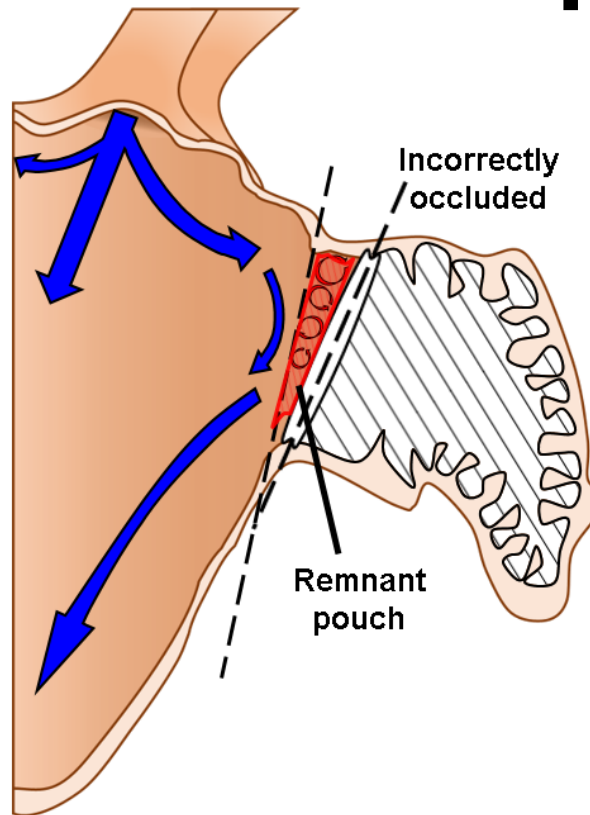
Smaller stagnant zone

Correct Closure Further Improve Outcomes



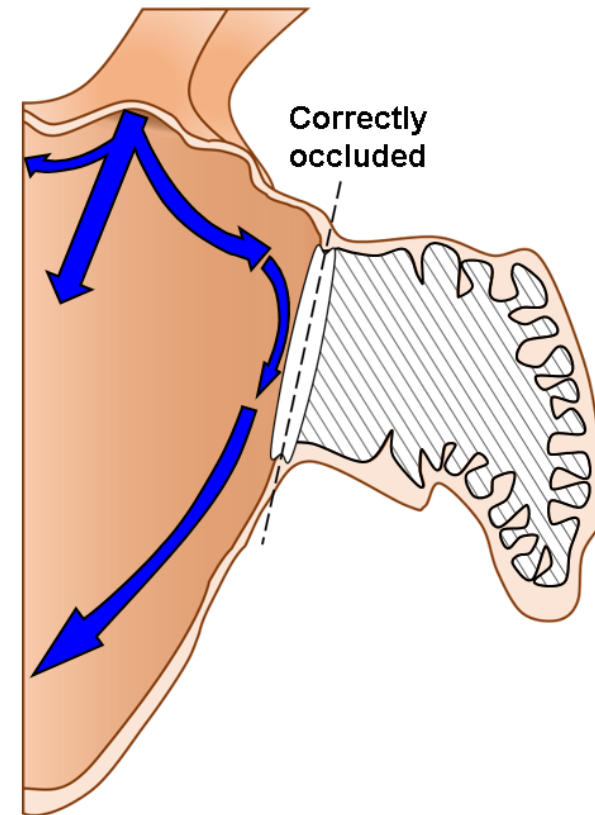
Pre-occluded state (PRE)

- Highest volume and percentage of flow stasis and thrombogenicity
- **LA appendage** is a main source of thrombosis



Incorrectly occluded state (INC)

- **Remnant pouch** has substantially high volume and percentage of flow stasis
- Potential source of thrombosis



Correctly occluded state (COR)

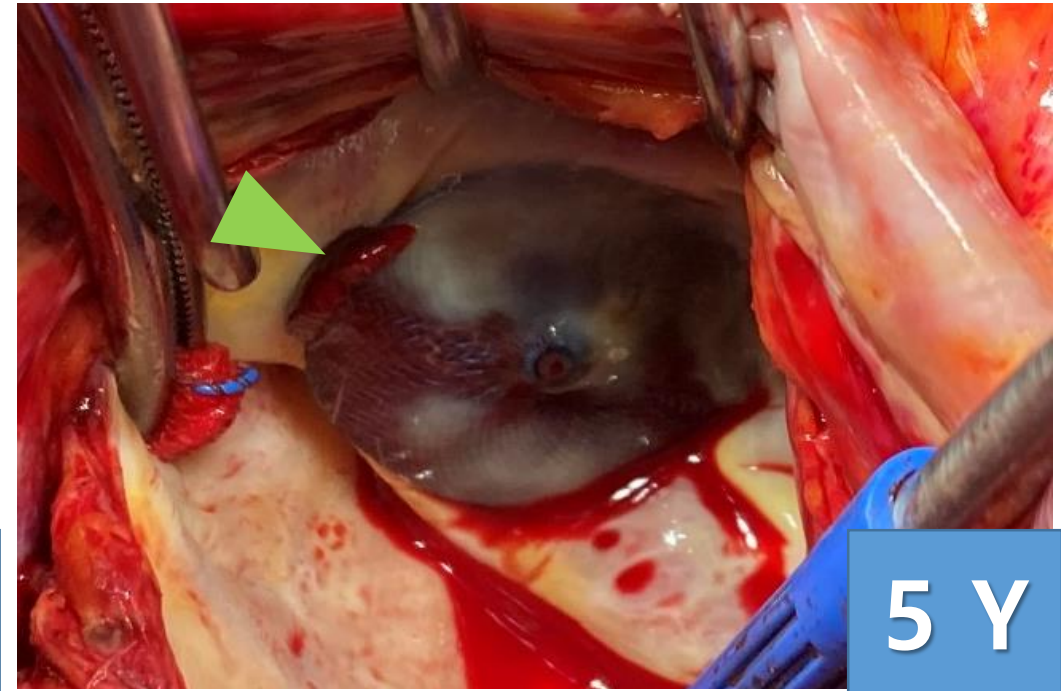
- **Common LA chamber** shows similar volume and percentage of flow stasis (PRE ≈ INC ≈ COR)
- Maximized reduction of flow stasis and thrombogenicity

→ Post-procedural anti-thrombotic treatment should be determined by both clinical and haemodynamic conditions

Long-Term Results *in vivo*



2 Y



5 Y

F/ 37

LV non-compaction (EF 28%)

Permanent AF

Recurrent SEE (renal infarct) during OAC & Chronic Anemia (Hb 8-9, associated with prolonged menstrual bleeding),

LAAO with **Amulet (2016) (No additional stroke or SEE)**

→ Heart transplantation in 2018

Courtesy of Y Cho

F/76

Persistent AF, Mitral valve regurgitation (MR)
LAAO d/t non-major recurrent bleeding (2016)
MR progression → MV replacement & Maze op. in 2021

Device related thrombi – Not detected in pre-op. TEE

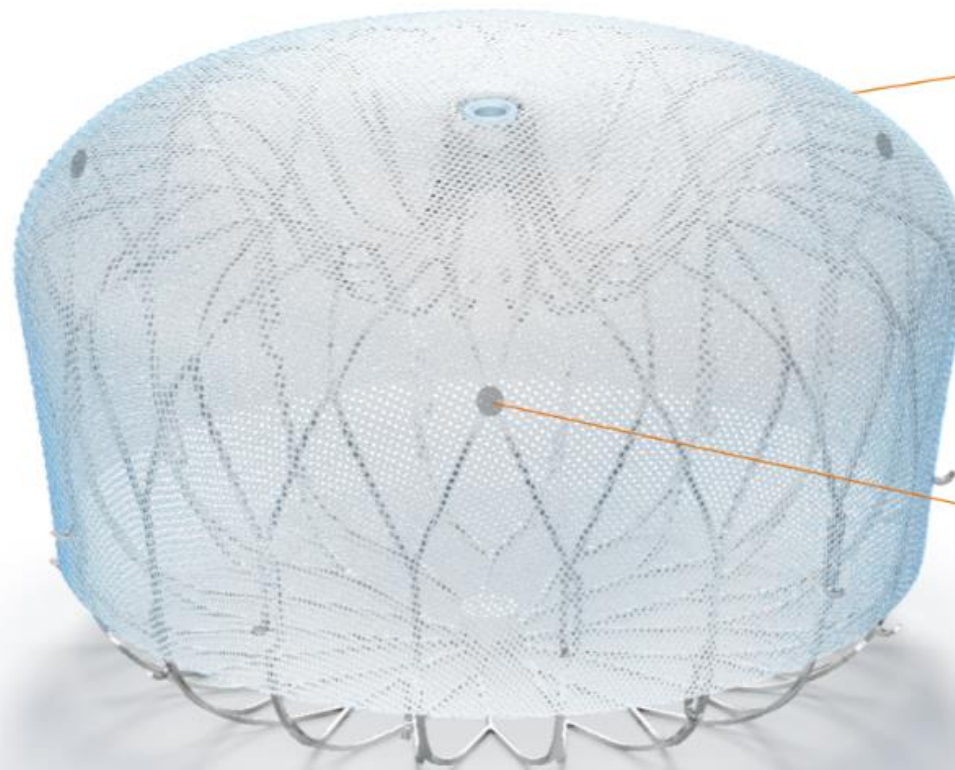
Kim YJ et al. JACC CV Intv. 2021;14(21):2405-2406.

Courtesy of J Hong

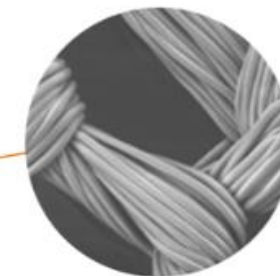
Effort to improve/facilitate endothelialization



WATCHMAN FLX Platform
with proven safety &
procedural performance



New 40mm device
to treat the widest range of anatomies



HEMOCOAT Technology
a hemocompatible coating to
promote faster, more complete
endothelialization



Three new radiopaque markers
help position and anchor device
with a new level of visual accuracy

More efficient ways using ICE?

CHORUS Minimalist Approach (MA)

- Comprehensive
- Hybrid
- Organized
- Resources
- Utilization
- Strategy

* Key Components for CHORUS MA

- Pre-procedural device size determination
- No Intra-procedural LAA angiography & no touch device delivery (minimize the risk of (micro) thromboembolism)
- By using ICE, general anesthesia becomes unnecessary
- Intra-procedural steps are minimized

* Advantages of CHORUS style minimalist approach

- Harmony of improved efficiency & minimized risk
- Minimize redundant (imaging tools/personnel, other personnel – anesthesiologist and accompanying personnel, etc.)

중앙심장혈관연구소 국제협력회의
CHORUS SEOUL 2019

일자 : 2019년 11월 1일(금), 11월 2일(토) 장소 : 중앙대학교 102관 11층 유니버시티 클럽

주관 : 순환기내과, 흉부외과, 심장혈관-부정맥센터, 심장혈관연구소

Minimalist approach vs. Conventional approach

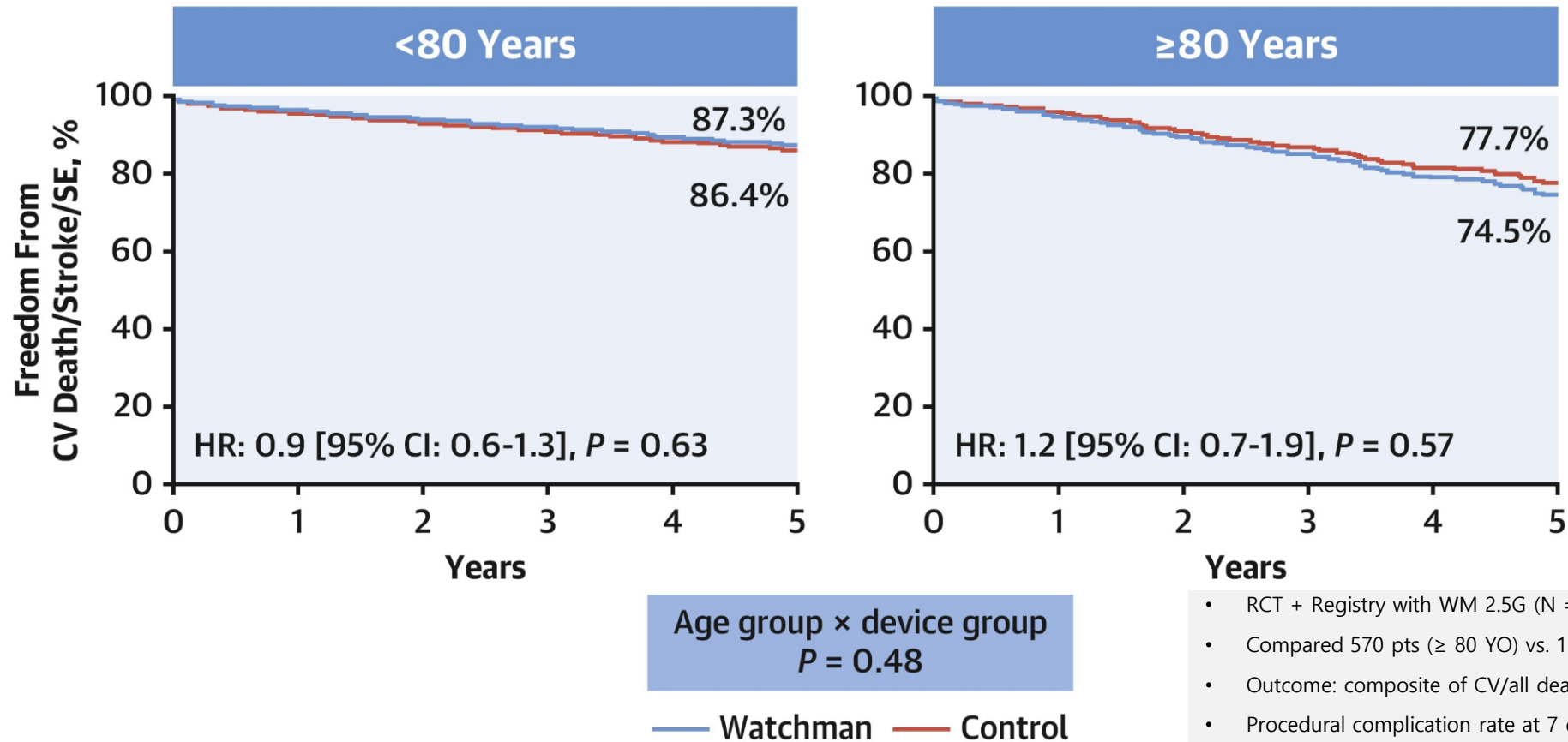
	Minimalist approach (n = 28)	Conventional approach (n = 53)	<i>P</i> value
Age (years)	74.8 ± 9.5	75.4 ± 11.4	0.815
Male (n, %)	14 (50.0 %)	28 (52.8 %)	0.993
CHA ₂ DS ₂ -VASc score (pts)	4.5 ± 1.4	4.1 ± 1.6	0.500
Prior Ischemic Stroke	14 (50.0 %)	21 (39.6 %)	0.509
HAS-BLED score (pts)	3.9 ± 0.6	3.9 ± 0.8	0.751
Procedure-Related Outcomes			
Success rate	28 (100 %)	52 (98.1 %)	0.455

	Minimalist approach (n = 28)	Conventional approach (n = 53)	<i>P</i> value
Procedure-Related Outcomes			
Procedure duration (min)	88.7 ± 62.1	108.0 ± 37.6	0.141
Fluoroscopy time (min)	10.2 ± 4.8	20.6 ± 9.8	< 0.001
Radiation exposure (DAP)	44.0 ± 48.3	131.9 ± 128.8	0.001
Contrast (mL)	150.9 ± 73.2	296.5 ± 155.8	0.002
Device size (mm)	26.8 ± 3.0	27.9 ± 3.7	0.443
# of Implantation Attempt	1.6 ± 0.9	2.8 ± 2.1	< 0.001
# of Angiography	2.0 ± 1.3	5.7 ± 4.7	< 0.001
Pericardial effusion	1 (14.3 %)	3 (6.8 %)	1.000
Peri-device leakage			0.935
Insignificant (< 3mm)	11 (39.2 %)	28 (59.6 %)	
Significant (≥ 3mm)	0	3 (5.7 %)	
Device embolization	0	1 (1.9 %) *	0.455
Peri-procedural Stroke	0	1 (1.9%) **	0.455

In Elderly Patients (≥ 80 years old), LAAO is similarly effective

Extended Application – Elderly (>80 Y)

CENTRAL ILLUSTRATION: 5-Year Kaplan-Meier Curves for the Primary Composite Outcome of CV Death, Stroke, or Systemic Embolism Stratified by Age

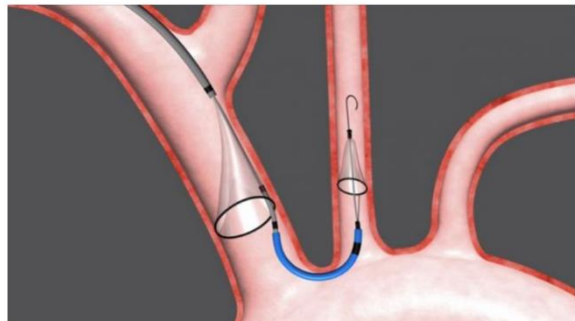


Sulaiman S, et al. J Am Coll Cardiol EP. 2023;9(5):669-676.

- RCT + Registry with WM 2.5G (N = 2,258)
- Compared 570 pts (≥ 80 YO) vs. 1688 (<80 YO)
- Outcome: composite of CV/all death + stroke/SE at 5 years
- Procedural complication rate at 7 days: similar in both groups
- In <80 YO group: 12.0% in device group vs. 13.8% in control group (HR 0.9, 95% CI: 0.6-1.4)
- In ≥ 80 YO group: 25.3% vs. 21.7% (HR 1.2, 95% CI: 0.7-2.0)
- Interaction P = 0.48 (no interaction between age and treatment)

In Cases with LAA Thrombi...

- (N)OAC failure?
- In spite of appropriate anticoagulation, LAA thrombi persists
- Lobe & disc type m/c (85%)
- Cerebral protection device (CPD) use: 29%



Sentinel device
Not applicable to LAAO
Only for TAVR!!

CENTRAL ILLUSTRATION LAAO Devices

Persistent LAA thrombus despite adequate oral anticoagulation

OR

Contraindication to oral anticoagulation

LAAO devices can be successfully implanted with some modifications in standard procedure such as

- limited LAA angiography
- minimal or no touch technique
- consideration for cerebral protection device

Amulet, ACP, and Watchman FLX have distinct advantages over Watchman

Current evidence mostly limited to distally located thrombus

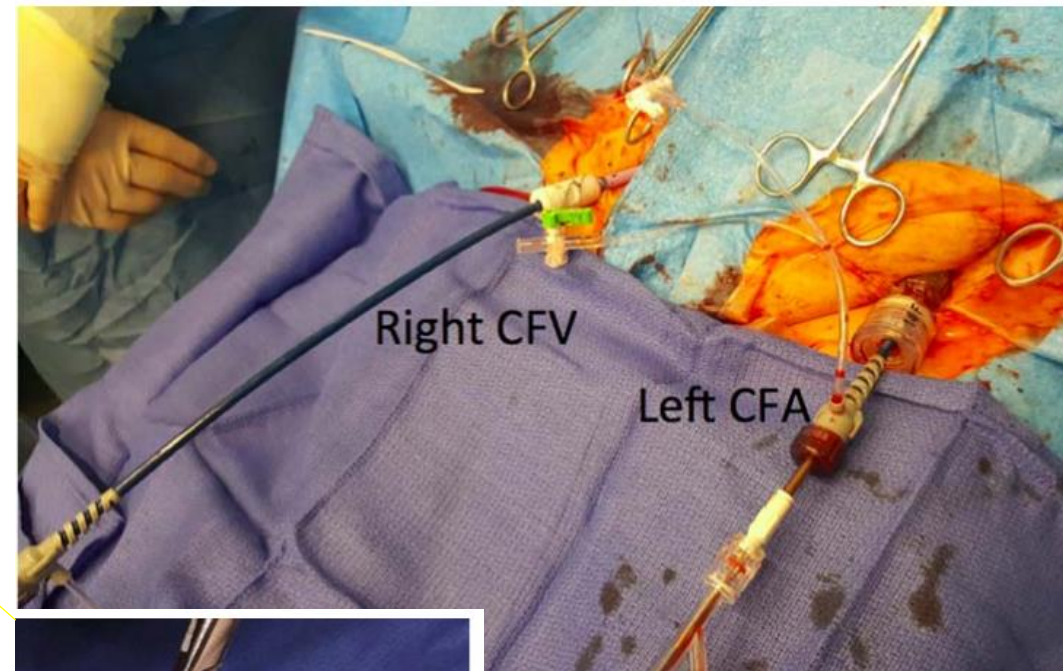
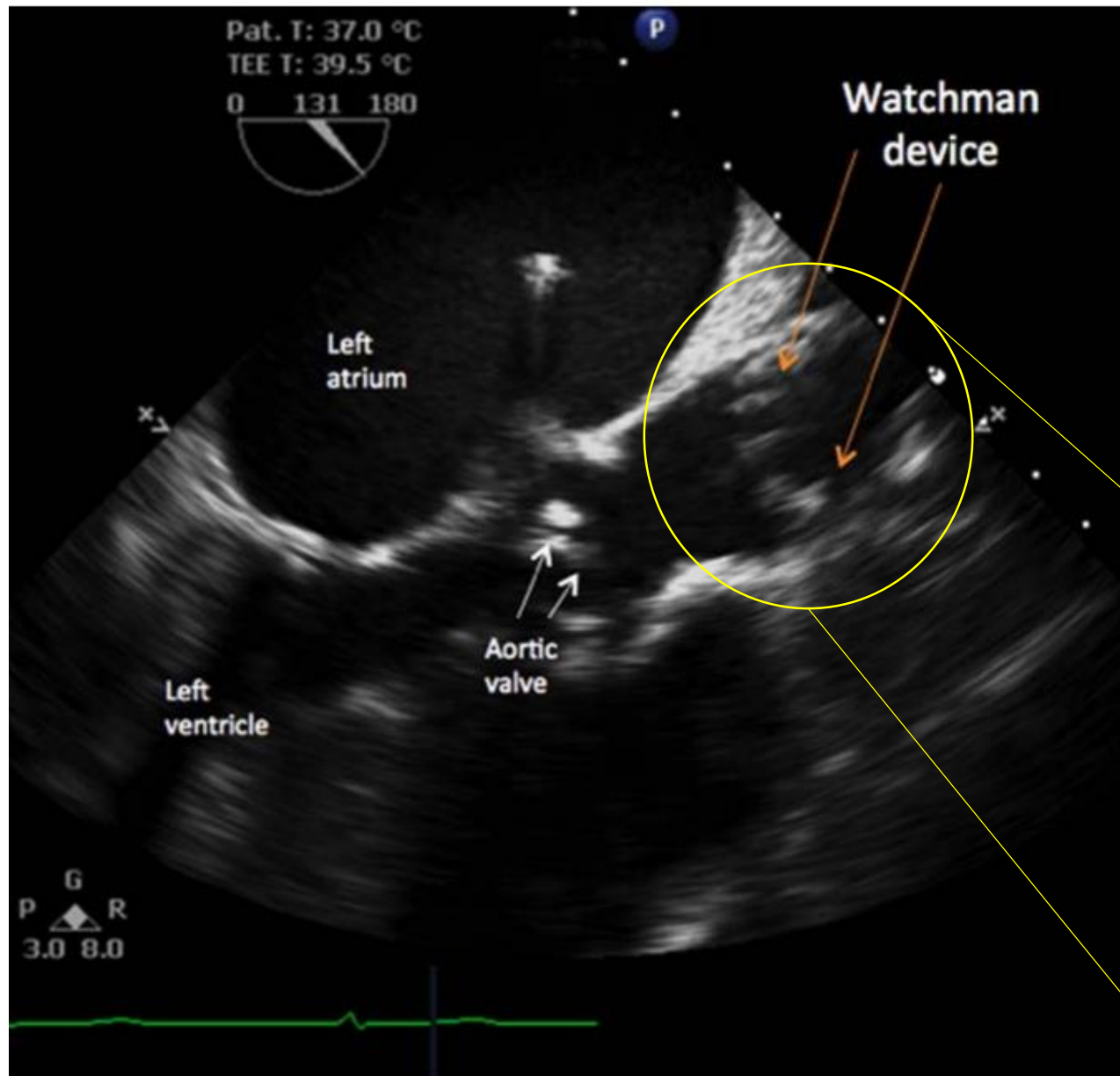
TYPES OF LAAO DEVICES USED

Device	Percentage
Amulet	50%
ACP	26%
Watchman	15%
Lambre	9%

Sharma, S.P. et al. J Am Coll Cardiol EP. 2020;6(4):414-24.

Left atrial appendage occlusion (LAAO) devices can be successfully placed with some procedural modifications in patients with persistent left atrial appendage (LAA) thrombus. The Amulet, Amplatzer Cardiac Plug (ACP), and newer Watchman FLX devices may provide benefits in such cases.

WM Used as CPD



Anchoring barbs were manually inverted!

Yadav et al. Catheterization and Cardiovascular Interventions 2018; 92:433–436.

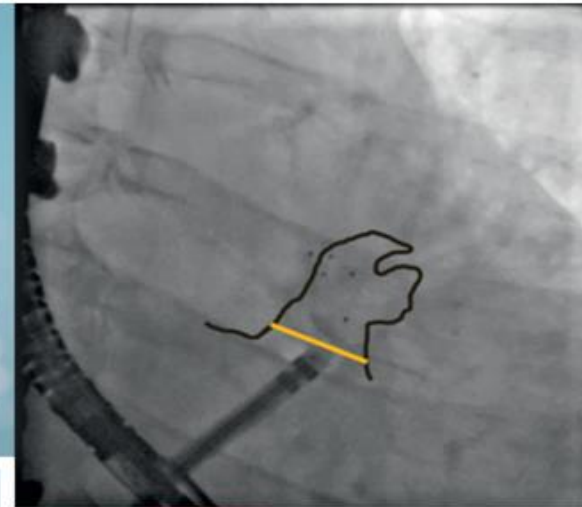
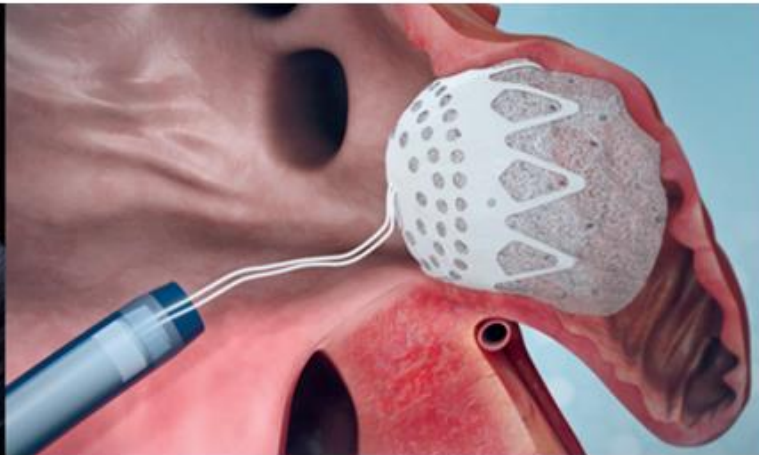
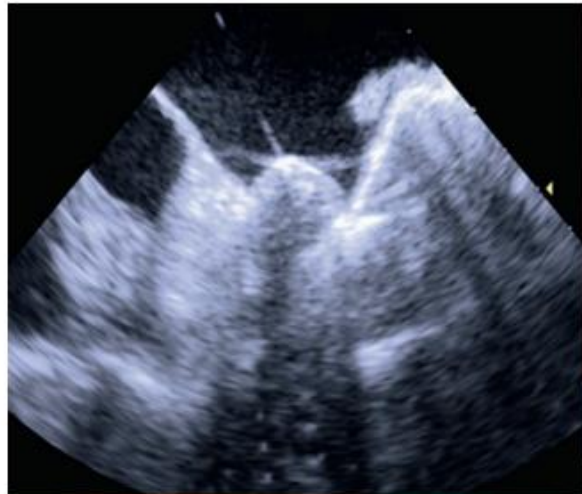
More Conformability & Generous Sizing

CENTRAL ILLUSTRATION Left Atrial Appendage Occlusion With the Novel Conformable Device Using Intracardiac Echocardiography

FIGURE

Smol

A



At

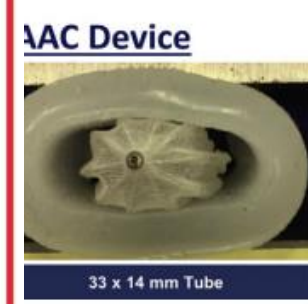
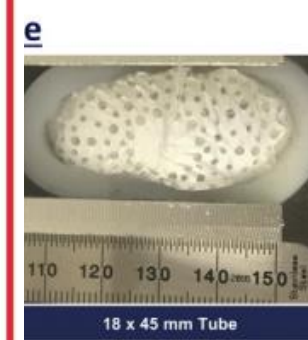
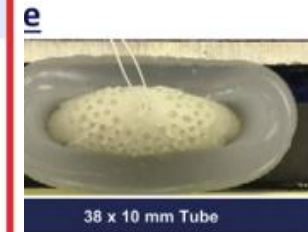
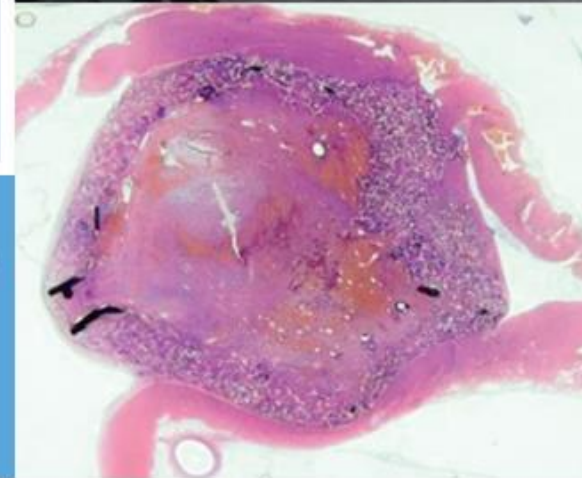
E

Reg



15 AF pts underwent left atrial appendage occlusion using intracardiac echocardiography
CHA₂DS₂-VASc score 4.1 ± 1.7
All pts received dual antiplatelet therapy post left atrial appendage occlusion

Technical success 100%
Major procedure related complications 0%
Peri device leak ≥5 mm 0%
Device related thrombus 1 pt (6.6%)
Stroke/thromboembolism 0%
Device embolization 0%



LAA Device

(A) Left
foam, el

LAAO is Usual Practice, More in the Future!

- Growing evidences support LAAO's efficacy & safety, globally
- Better outcomes by achieving correct closure
- Better safety by embolic protection devices esp. in OAC failure
- New devices with improved design and function will be available soon – improved conformability, generous sizing
- Adopt deflectable delivery system – BSc, Abbott, Lifetech, etc.
- Improved workflow by minimalist approach, ICE, newer trans-septal system – direct approach with delivery system

Take Home Messages

- **LAAO** became a part of usual clinical practice with concrete & growing evidences regardless of gov't policy in KOREA
- **LAAO** is **NOT** merely an alternative option for OAC contraindication, **BUT** a non-pharmacological adjunctive tool for thrombotic burden reduction
- LAAO's safety & efficacy is dramatically improving in association with imaging & engineering (3DP simulation, CFD analysis, ICE (2D → 3/4D) materials facilitating endothelialization & improved device design)
- For facilitated adoption, close collaboration between cardiology and neurology (NU, NS) is critical!



**Thank you
for
Your Attention**

E-mail: theshin04@cau.ac.kr

theshin04@naver.com

+82 - 10-8863-1078