순환기의공학회
BIOMEDICAL ENGINEERING SOCIETY FOR CIRCULATION

하계 학술대회 2017
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Perspective of LAAO
(Left Atrial Appendage Occlusion)

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중앙대학교
한국의 중앙에서 세계의 중앙으로
Toward the University of the world from Chung- Ang of Korea

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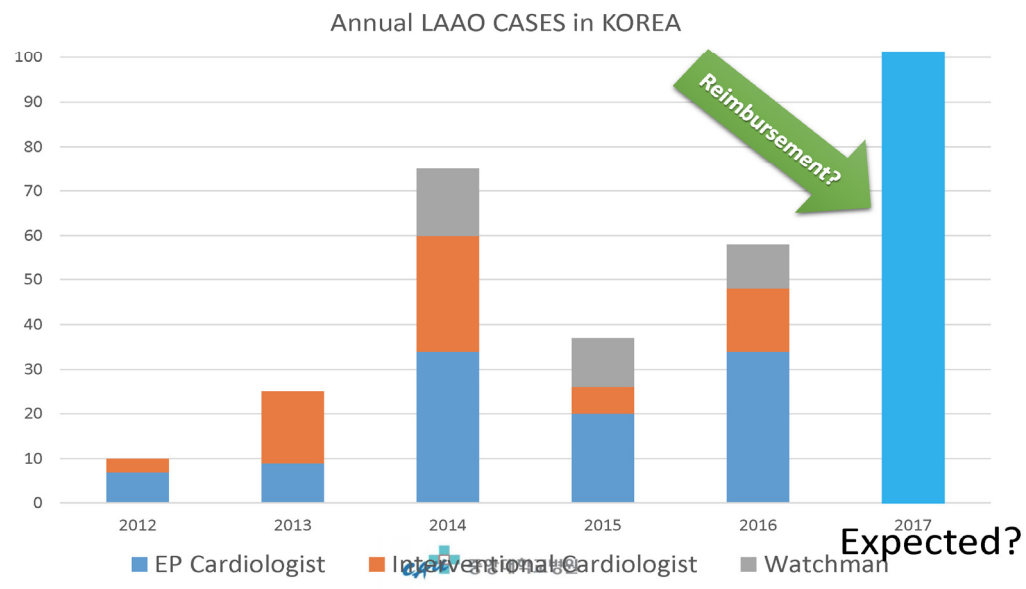
LAAO in KOREA



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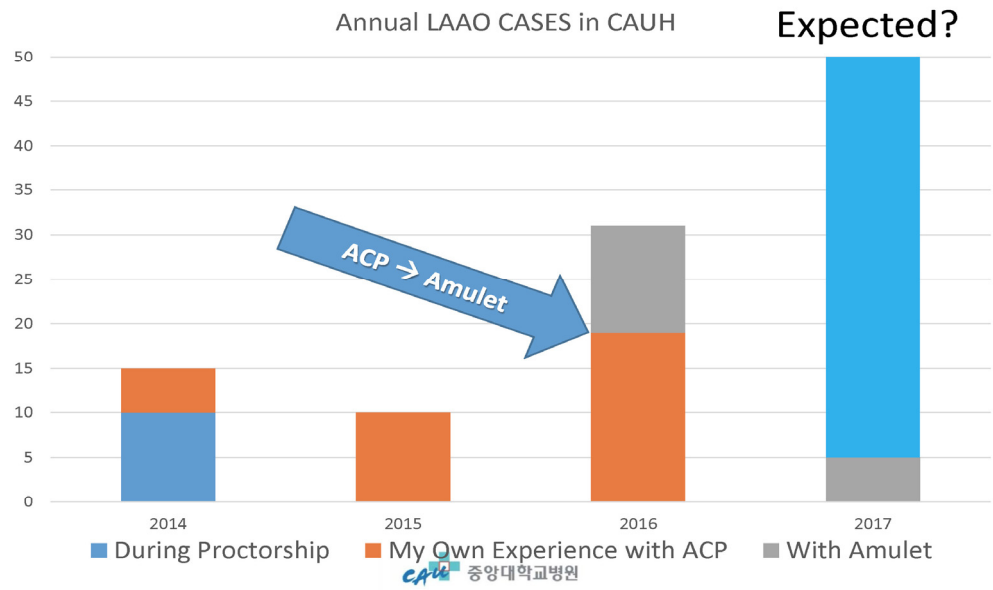
Chung-Ang LAAO Experience



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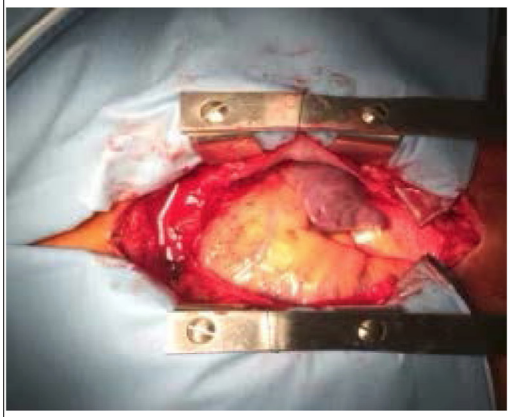
LAA During AF



Courtesy of Prof. J Hong

Most **thrombi (90%)** in NVAF develop **in LAA**

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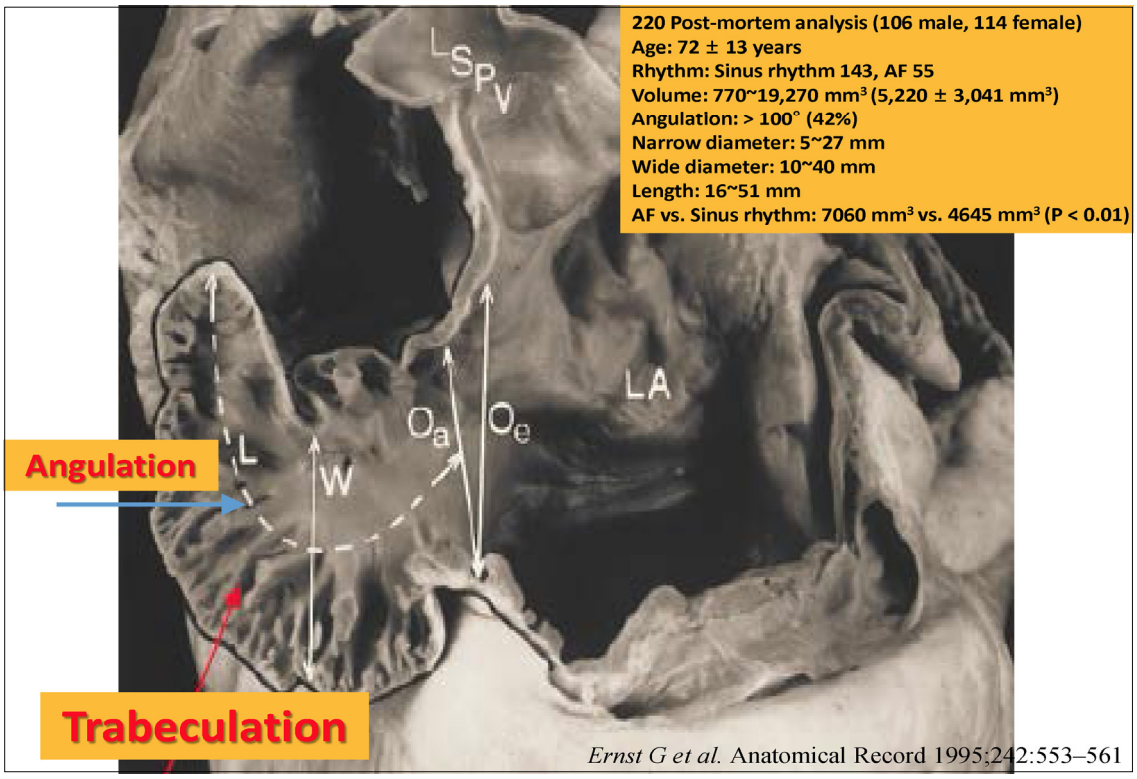

WHEN

is LAAO necessary?

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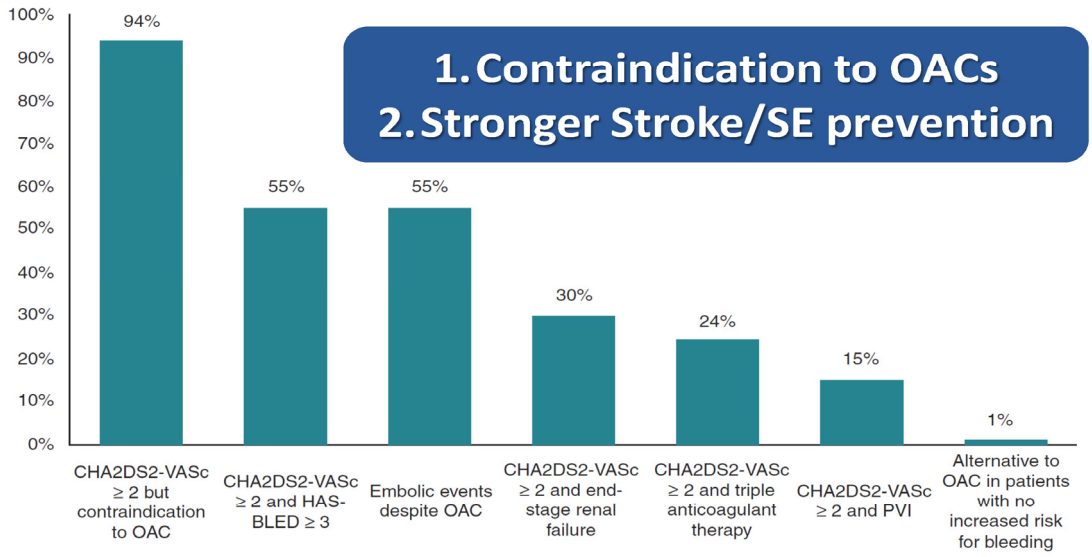
LAAO Major Indications in EU



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L Pison et al. Europace 2015;17:642-646

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CASE Examples

We Perform LAAO in Patients Such as...

1. Persistent AF with ESRD on HD, major bleeding
2. Persistent AF with traumatic SDH
3. Paroxysmal AF with severe depression
4. Paroxysmal AF with recurrent stroke during OAC
5. Persistent AF with severe pulmonary fibrosis
6. Persistent AF with malignant thrombi
7. Persistent AF with prior PCI (esp. DES)
8. Persistent AF with liver cirrhosis
9. Persistent AF after PV isolation
10. Etc.

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CASE 01

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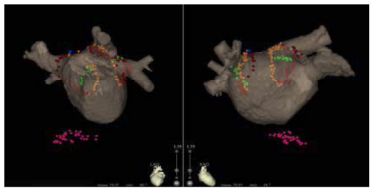
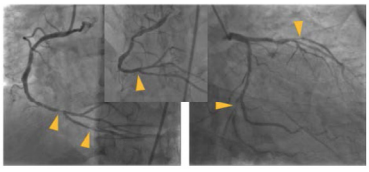
M/61, Paroxysmal AF



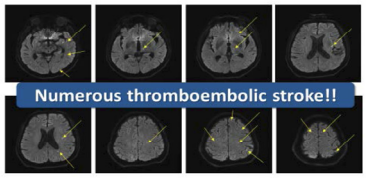
- Drug refractory AF especially during dialysis

1. RFCA for AF – Successful RFCA itself (2017.3.28.)
2. 3 Vessel disease

- Prior PCI with DES (3 stents, 2016.1.11.)



- VKA + Single APT
- GI bleeding → 약제 임의 중단 (4일간)
- Ischemic stroke & stress cardiomyopathy



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CASE 01

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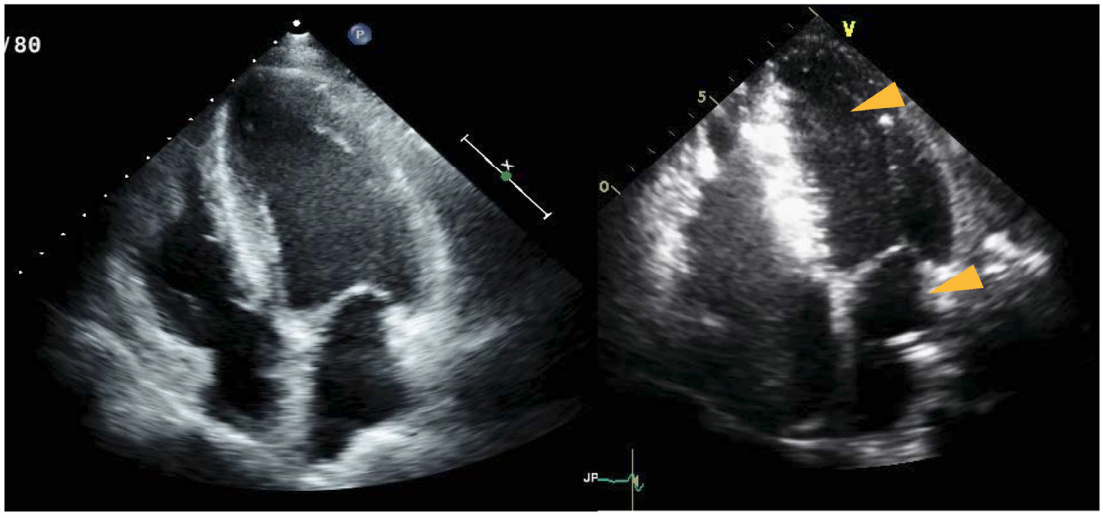
Echocardiography



LVEF = 55%

LVEF = 35%, **LV & LA thrombi**

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CASE 02

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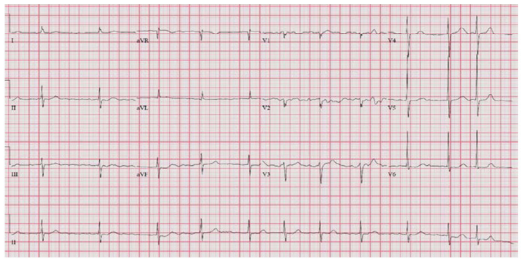
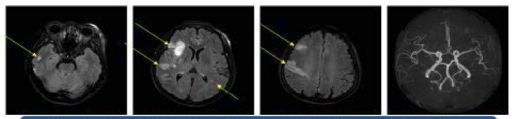
F/77, Persistent AF

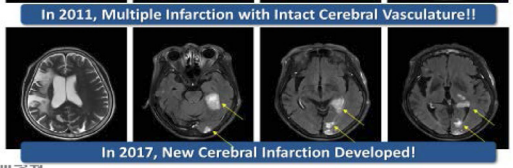
- Persistent AF
- s/p Cbr infarction (1st stroke - 2011.10.31)
- CHA2DS2-VASc = 5

  (Age>75, Stroke, Female)
- HASBLED = 3 (Stroke, Bleeding, Elderly)
- Maintained VKA since 2011
- **Drug refractory LAA thrombi**
- VKA → NOAC switch
- Recurrent embolic stroke (2017.4.15.)





In 2011, Multiple Infarction with Intact Cerebral Vasculature!!



In 2017, New Cerebral Infarction Developed!

CASE 02

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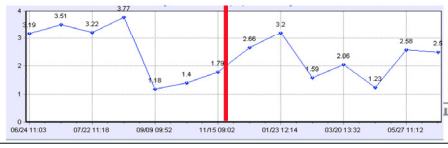
Transesophageal Echocardiography

In 2013,
On VKA, TTR < 60%

In 2014, (6 M later)
On VKA, TTR > 60%

In 2015, (10 M later)
On DE 150 mg



VKA switch to Dabigatran 150 mg

Recommend LAAO, Refused!

CASE 03

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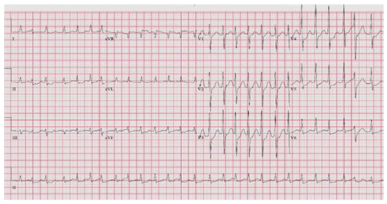
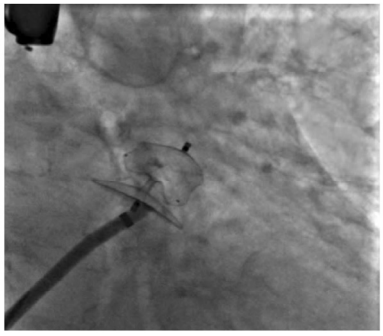
F/88, Paroxysmal AF



- ESRD on HD (DM nephropathy, 20Y)
- CHA2DS2-VASc= 6 (CHF, HTN, Age>75, DM, Female)
- HASBLED = 5 (HTN, ESRD, Elderly, Bleeding, Drug-ASA)
- s/p PCI with DES (2009)
- Multiple rib Fx & Hemothorax (2014)
- Two months after LAAO, ASA 100 mg
- Femur neck Fx (2016)
- Acute pancreatitis (2017)
- No bleeding or SEE



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CONTENTS

1. Which device is better?
2. Safe & Simple procedure
3. What is desirable procedural endpoint
4. Who can benefit most?
5. Post-procedural anti-thrombotic therapy

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1. Which Device Is Better?

Development of LAA

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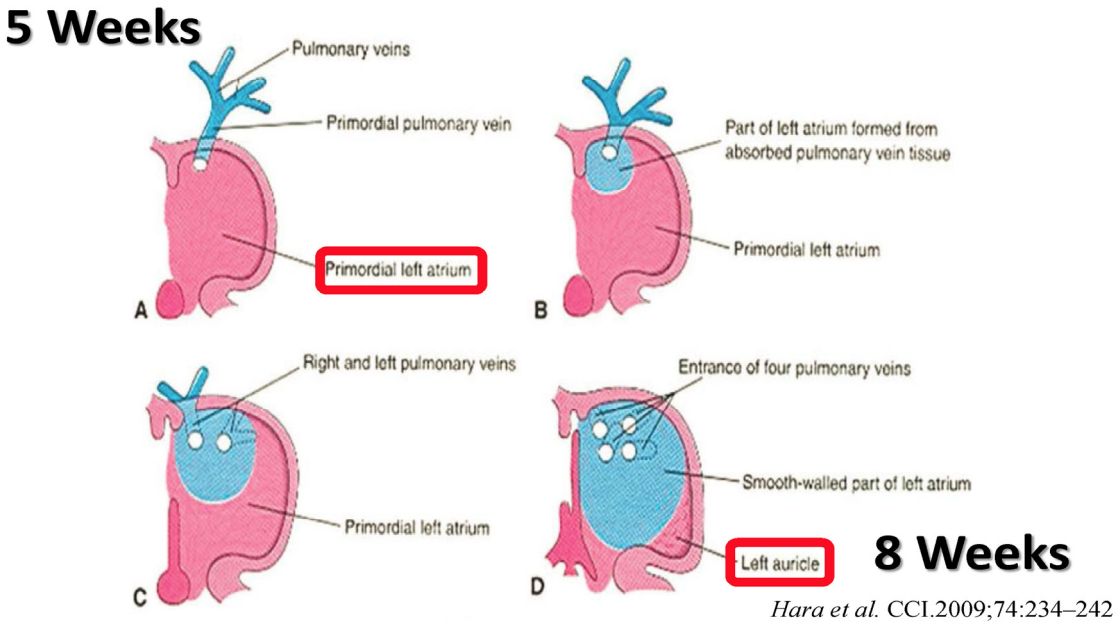

Hara et al. CCI.2009;74:234–242

Various Shapes of LAA

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cactus　　cauliflower　　chicken wing　　windsock

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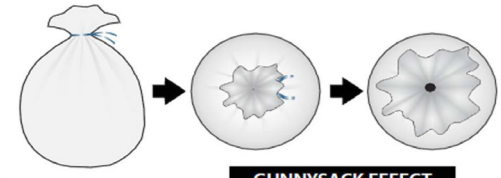
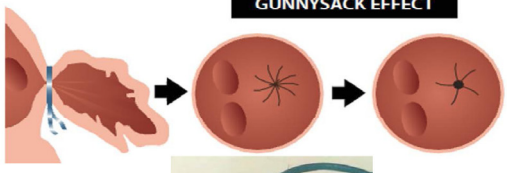
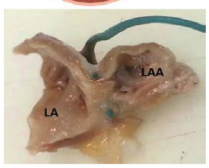
Pros & Cons by Device Type (1)

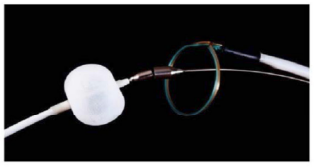
Epicardial Ligation
- percutaneous or thoracoscopy



GUNNYSACK EFFECT







Pros

Virtually all type of LAA can be closed
Irrespective of shape or thrombi (**One for all?**)

Cons

Intolerable for thoracoscopic procedure with general anesthesia
Recanalization (Gunnysack effect)
Technical issue - dry pericardial tap…

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Pillai et al. Heart Rhythm 2014;11:1877–1883

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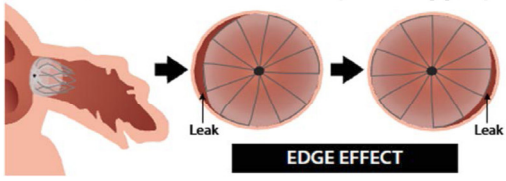
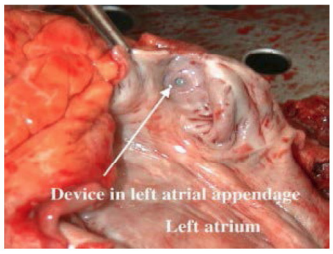
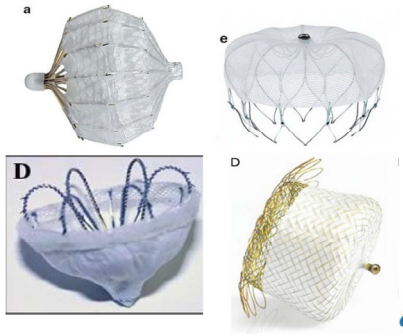
Pros & Cons by Device Type (2)

WATCHMAN DEVICE (Ball type)







Pros

Easy to perform

Cons

Incomplete sealing (peri-device leakage)
Dead space (most LAA have angulation)
Single barrier
Cannot fully cover anatomical ostium

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Pillai et al. Heart Rhythm 2014;11:1877–1883

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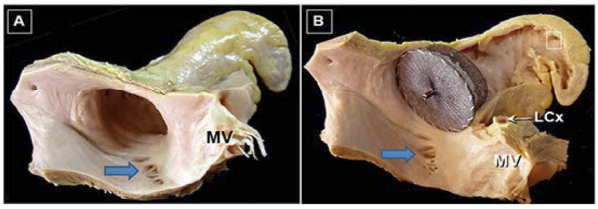
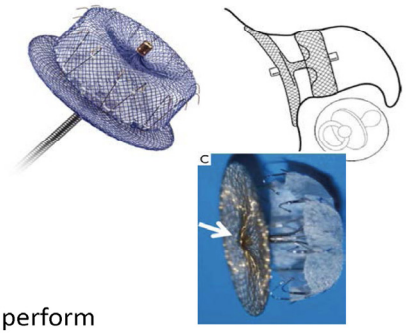
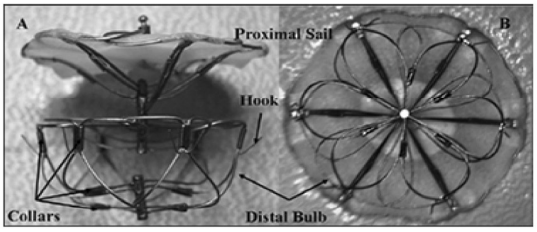
Pros & Cons by Device Type (3)

LOBE & DISC TYPE DEVICE (ACP, Amulet)







Pros

Easy to perform
- With ICE, can be done under local anesthesia

More suitable for angulated anatomy
More complete sealing
Double cover

Cons

Various implantation options and otucomes

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Pillai et al. Heart Rhythm 2014;11:1877–1883

2. Safe & Simple Procedure

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Many Ways to LAA Exclusion

1. Intra-procedural transesophageal echocardiography (TEE) under general anesthesia (G/A)
   – generally adopted?
2. Micro-TEE under light sedation
   – Not available in Korea
3. **Fluoroscopic guidance only strategy under L/A**
4. Intra-cardiac echocardiography (ICE) under local anesthesia (L/A)
5. **Pre-procedural computed tomographic (CT) assessment with #4 strategy under L/A**

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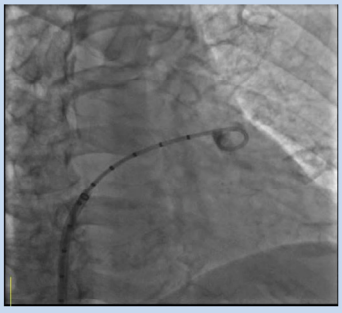
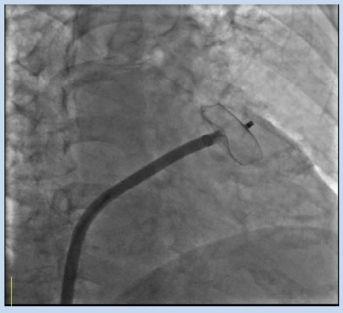
Fluoroscopic Guidance Only Strategy

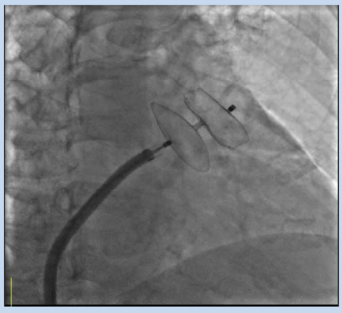
- Procedure **without G/A**
- Shorter procedure time
- **Non-inferior** procedural/clinical outcomes (SEE)



Atriography Measure



Land Lobe - Check anchoring



Expand disc - Tug test (3 times)

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Left Atrial Appendage Occlusion (LAAO) Without Intra-procedural Trans-Esophageal Echocardiography (TEE), Is It Feasible Approach? Single Center Experience

Seung Yong Shin[1], Hong Euy Lim[2], Ju Hyun Song[1], Yong Hyun An[1], Jin-Seok Kim[2], Jeong-Min Kim[3], Kwang-Yeol Park[3], Moon Ki Jung[1], Young Kim[1], Iksung Cho[1], Hoyoun Won[1], Wang-Soo Lee[1], Kwang Je Lee[1], Sang Wook Kim[1], Tae Ho Kim[1], Chee Jeong Kim[1]

1 Cardiovascular and Arrhythmia Center, Chung-Ang University Hospital, Seoul, Korea. 2 Department of Cardiology, Korea University Guro Hospital, Seoul, Korea 3 Department of Neurology, Chung-Ang University Hospital, Seoul, Korea

BACKGROUND

Left atrial appendage occlusion (LAAO) is frequently performed alternative antithrombotic treatment in patients with non-valvular atrial fibrillation who are intolerable to traditional oral anticoagulation. Because LAAO procedure is assisted by trans-esophageal echocardiography (TEE), general anesthesia is usually required. However, in high risk patients with multiple co-morbidities, who are not tolerable for general anesthesia, LAAO procedure without TEE under local anesthesia was tried and successfully performed without any serious complications.

OBJECTIVE

The aim of this study is to investigate the safety and feasibility of LAAO without TEE and to test the differences in long term results according to the intra-procedurally used imaging modalities.

METHODS

Between May 2014 and November 2016, all consecutive patients who underwent LAAO in Chung-Ang University Hospital, were included and analyzed retrospectively. The procedures were performed using the Amplatzer cardiac plug or Amulet device (St. Jude). Pre-procedural TEE was performed in all patients and LAA anatomy was carefully examined.

Atriography Measure | Land Lobe Check anchoring | Expand disc Tug test (3 times)

According to the intra-procedurally used imaging modalities, patients were divided into 2 groups (group 1: with intra-procedural TEE, group 2: without intra-procedural TEE). Between two groups, baseline characteristics, procedure related complications, clinical outcomes were compared.

RESULTS

Forty one patients were enrolled and analyzed. Mean follow up period was 310 ± 253 days.

Table 1. Baseline characteristics

Variables	With TEE (n = 10)	Without TEE (n = 31)	P value
Age (y)	72.3 ± 11.3	76.7 ± 6.4	0.266
Male (n, %)	3 (30.0)	13 (41.9)	0.712
Non-paroxysmal AF (%)	6 (60.0)	24 (77.4)	0.413
HF (n, %)	4 (40.0)	12 (38.7)	1.000
HTN (n, %)	10 (100.0)	30 (96.8)	1.000
DM (n, %)	3 (30.0)	4 (12.9)	0.332
Prior stroke or TIA (n, %)	3 (30.0)	15 (48.4)	0.467
Ischemic heart disease (n, %)	3 (30.0)	7 (22.6)	0.683
$CHADS_2$ score (point)	2.5 ± 1.6	2.8 ± 1.3	0.582
CHA_2DS_2-VASc score (point)	4.6 ± 1.8	4.9 ± 1.7	0.633
Major bleeding (n, %)	4 (40.0)	19 (61.3)	0.289
Liver disease (n, %)	0 (0.0)	2 (6.5%)	1.000
Chronic kidney disease (n, %)	5 (50.0)	16 (51.6)	1.000
eGFR (ml/min)	50.8 ± 36.8	57.4 ± 22.5	0.524
HASBLED score (point)	3.7 ± 1.9	3.8 ± 1.1	0.869
Echocardiography			
LVEF (%)	58.1 ± 7.8	57.4 ± 9.4	0.830
LA (mm)	45.1 ± 10.1	49.2 ± 7.4	0.175

Data are presented as mean ± SD (standard deviation). TEE: trans-esophageal echocardiography, AF: atrial fibrillation, HF: heart failure, HTN: hypertension, DM: diabetes mellitus, TIA: transient ischemic attack, CHADS2: Congestive heart failure, Hypertension, Age>75, Diabetes mellitus, Stroke, CHA_2DS_2-VASc: Congestive heart failure, Hypertension, Age>75, Diabetes mellitus, Stroke, Vascular disease, Age 65-74, Sex category (Female), eGFR: estimated glomerular filtration rate, HASBLED: Hypertension, Abnormal liver/renal disease, Stroke or TIA, Bleeding, Labile INR, Elderly (age > 70), Drugs (aspirin, NSAIDs, etc.), LVEF: left ventricular ejection fraction, LA: left atrium

Table 2. Procedure related outcomes

Variables	With TEE (n = 10)	Without TEE (n = 31)	P value
TEE			
LAA flow impairment (Grade 1–4)	1.9 ± 1.1	2.5 ± 6.8	0.141
SEC (Grade 0–4)	1.3 ± 1.6	1.7 ± 1.2	0.394
Device size			
Lobe size (mm)	25.1 ± 5.0	27.0 ± 2.5	0.198
Disc size (mm)	30.4 ± 6.0	32.9 ± 4.2	0.249
Total procedure time (min)	163.3 ± 39.8	142.2 ± 48.2	0.242
Net procedure time (min)	112.2 ± 30.8	98.6 ± 41.0	0.368
Fluoroscopy time (min)	26.9 ± 6.9	18.7 ± 11.7	0.067
Fluoroscopy dosage (mGy)	1369.9 ± 1152.4	2852.1 ± 9649.4	0.665
Any procedural complication (n, %)	0 (0.0)	2 (6.5)	1.000
Vascular complication (n, %)	0 (0.0)	1 (3.2)	
Pericardial effusion (n, %)	0 (0.0)	1 (3.2)	
Device migration (n, %)	0 (0.0)	0 (0.0)	
Stroke or TIA (n, %)	0 (0.0)	0 (0.0)	
Any follow up events (n, %)	1 (10.0)	4 (12.9)	1.000
Pericardial effusion (n, %)	0 (0.0)	3 (9.7)	
Device migration (n, %)	0 (0.0)	0 (0.0)	
Device thrombosis (n, %)	1 (10.0)	0 (0.0)	
Stroke or TIA (n, %)	0 (0.0)	1 (3.2)*	

Data are presented as mean ± SD (standard deviation). TEE: trans-esophageal echocardiography, LAA: Left atrial appendage flow grade 1 > 30 cm/sec, 2: 30–50 cm/sec, 3: 10–30 cm/sec, 4 < 10 cm/sec, SEC (spontaneous echo contrast) 0: none, 1 mild, 2 moderate, 3 severe, 4: thrombus, * 1 minor stroke at 3 months – might be related with incomplete endothelialization – follow-up TEE revealed no peridevice leakage

COUNCLUSION

Without intra-procedural TEE, LAAO can be performed with safety similar to LAAO with intra-procedural TEE and procedure related outcomes and clinical outcomes are not inferior to LAAO with intra-procedural TEE. In addition, general anesthesia can be omitted in LAAO without intra-procedural TEE and complications related with general anesthesia can be avoided in elderly patients with high risk for general anesthesia.

LAA 18-19 November 2016- Frankfurt, Germany

- Presented in LAAO Frankfurt in 2016

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Baseline Characteristics

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HTN (n, %)	10 (100.0)	30 (96.8)	1.000
DM (n, %)	3 (30.0)	4 (12.9)	0.332
Prior stroke or TIA (n, %)	3 (30.0)	15 (48.4)	0.467
Ischemic heart disease (n, %)	3 (30.0)	7 (22.6)	0.683
$CHADS_2$ score (points)	2.5 ± 1.6	2.8 ± 1.3	0.582
CHA_2DS_2-VASc score (points)	4.6 ± 1.8	4.9 ± 1.7	0.633
Major bleeding (n, %)	4 (40.0)	19 (61.3)	0.289
Liver disease (n, %)	0 (0.0)	2 (6.5%)	1.000
Chronic kidney disease (n, %)	5 (50.0)	16 (51.6)	1.000
eGFR (ml/min)	50.8 ± 36.8	57.4 ± 22.5	0.524
HASBLED score (points)	3.7 ± 1.9	3.8 ± 1.1	0.869
Echocardiography			
LVEF (%)	58.1 ± 7.8	57.4 ± 9.4	0.830
LA (mm)	45.1 ± 10.1	49.2 ± 7.4	0.175

Data are presented as mean ± SD (standard deviation). TEE: trans-esophageal echocardiography, AF: atrial fibrillation, HF: heart failure, HTN: hypertension, DM: diabetes mellitus, TIA: transient ischemic attack, $CHADS_2$: Congestive heart failure, Hypertension, Age>75, Diabetes mellitus, Stroke, CHA2DS2-VASc: Congestive heart failure, Hypertension, Age>75, Diabetes mellitus, Stroke, Vascular disease, Age 65~74, Sex category (female), eGFR: estimated glomerular filtration rate, HASBLED: Hypertension, Abnormal liver/kidney disease, Stroke or TIA, Bleeding, Labile INR, Elderly (age > 75), Drugs (aspirin, NSAIDs, etc.), LVEF: left ventricular ejection fraction, LA: left atrium

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Procedure Related Outcomes

Variables	With TEE (n = 10)	Without TEE (n = 31)	P value
TEE			
LAA flow impairment (Grade 1~4)	1.9 ± 1.1	2.5 ± 6.8	0.141
SEC (Grade 0~4)	1.3 ± 1.6	1.7 ± 1.2	0.394
Device size			
Lobe size (mm)	25.1 ± 5.0	27.0 ± 2.5	0.198
Disc size (mm)	30.4 ± 6.0	32.9 ± 4.2	0.249
Total procedure time (min)	**163.3 ± 39.8**	**142.2 ± 48.2**	**0.242**
Net procedure time (min)	**112.2 ± 30.8**	**98.6 ± 41.0**	**0.368**
Fluoroscopy time (min)	**26.9 ± 6.9**	**18.7 ± 11.7**	**0.067**
Any procedural complication (n, %)	**0 (0.0)**	**2 (6.5)**	**1.000**
Vascular complication (n, %)	**0 (0.0)**	**1 (3.2)**	
Pericardial effusion (n, %)	**0 (0.0)**	**1 (3.2)**	
Device migration (n, %)	**0 (0.0)**	**0 (0.0)**	
Stroke or TIA (n, %)	**0 (0.0)**	**(0 (0.0)**	
Any follow up events (n, %)	**1 (10.0)**	**4 (12.9)**	**1.000**
Pericardial effusion (n, %)	**0 (0.0)**	**3 (9.7)**	
Device migration (n, %)	**0 (0.0)**	**0 (0.0)**	
Device thrombosis (n, %)	**1 (10.0)**	**0 (0.0)**	
Stroke or TIA (n, %)	**0 (0.0)**	**1 (3.2)***	

Data are presented as mean ± SD (standard deviation). TEE: trans-esophageal echocardiography, LAA (left atrial appendage) flow: grade 1: > 50 cm/sec; 2: 30~50 cm/sec; 3: 10~30 cm/sec; 4: < 10 cm/sec, SEC (spontaneous echo contrast): 0: none; 1: mild; 2: moderate; 3: severe; 4: thrombus, *: 1 minor stroke at 3 months – might be related with incomplete endothelialization – follow-up TEE revealed no peridevice leakage

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Cardiac CT & 3D Image Support

- Especially useful in analyzing & planning in patients with complex LAA anatomy
- Can improve procedural outcomes
  - Pre-procedural device size expectation
  - **Best choice** among possible outcomes
  - Pre-procedural test performed ***ex vivo***
  - Minimize trial and errors ***in vivo***
- Enhanced procedural safety
  - Shorter / more concentrated procedure time
  - Fewer peri-procedural complications

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3D Printing of LAA

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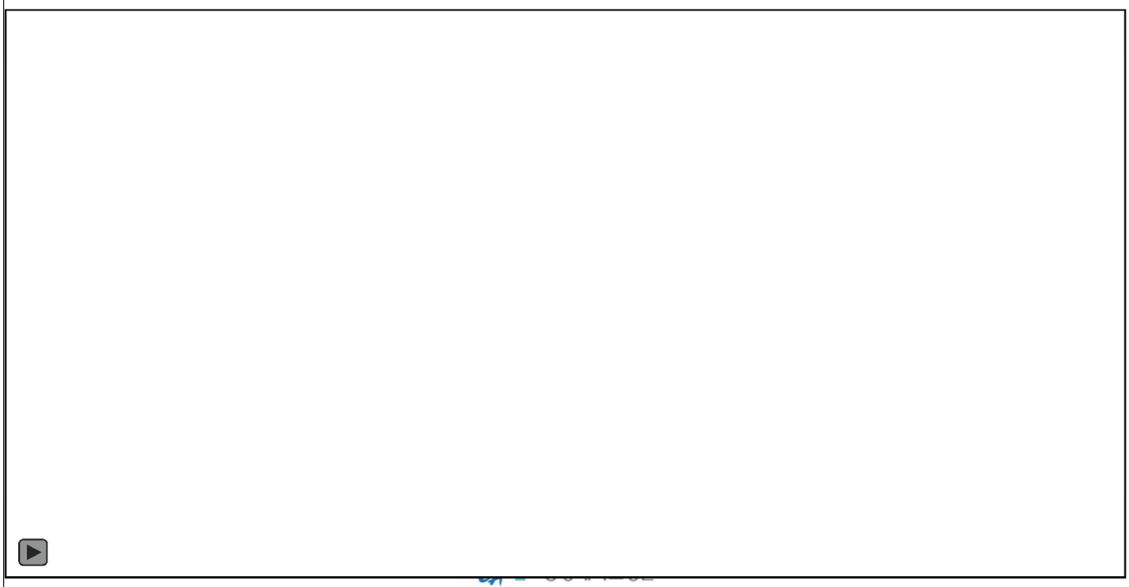
Pre-procedural Simulation



3. What is Desirable Procedural Endpoints?

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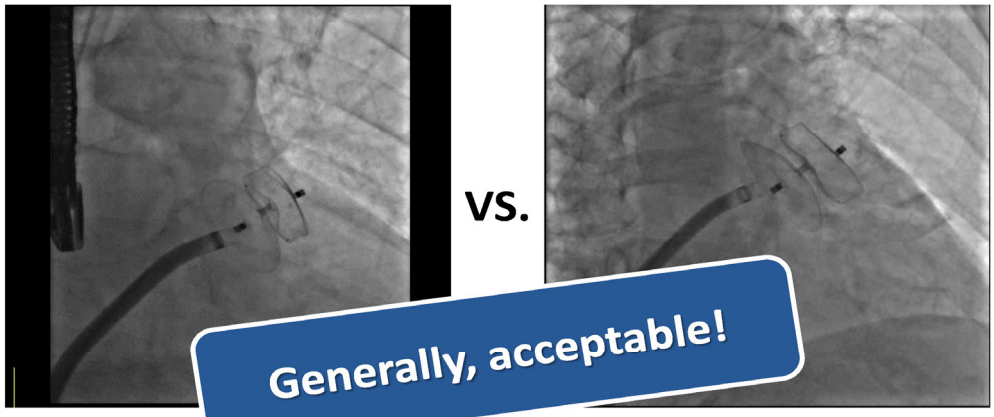
Acceptable Endpo

- Stable anchoring of device
- Complete sealing w/o leakage

Minimize or eliminate
Dead Space
→ **Better (?)**



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4. Who Can Benefit Most?

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Left Atrial Structure and Function After Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO)

Six-Month Echocardiographic Follow-Up

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Mark Reisman, MD, FACC,† William Gray, MD, FACC,† Peter C. Ri...
Atlanta, Georgia; and Seattle, Washington

PLAATO achieved an adequate seal of the neck of LAA w/o significant effect on the structure of the LA and LUPV

OBJECTIVES This study was d... transcat...

...and reduce ...arm. The impact of ...een reported.

...he ongoing study for evaluation of PLAATO ...echocardiographies at baseline, one, and six months were ... and LUPV dimensions, degree of mitral regurgitation, stability of ...peak MV E-wave velocity, and peak systolic and diastolic flow velocities in the ...LUPV. Data were analyzed by a linear mixed model for repeated measures.

Eleven patients (mean age of 72 ± 7 years) completed six months of follow-up. Left upper pulmonary vein diameter (mean: 1.55, 1.61, 1.54 cm, p = 0.13) and peak systolic (mean: 0.38, 0.34, 0.31 m/s, p = 0.72) and diastolic flow velocities (mean: 0.39, 0.40, 0.42 m/s, p = 0.46) did not differ over the follow-up period. Left atrial size, mitral regurgitation severity, and MV peak E-wave velocities (mean: 0.94, 0.94, 0.82 m/s, p = 0.58) showed no significant change from baseline. The devices remained stable at their sites of deployment with minimal residual flow around them.

CONCLUSIONS PLAATO achieved an adequate seal of the neck of the left atrial appendage without significant effect on the structure or function of the LA and LUPV. (J Am Coll Cardiol 2004;43:1868–72) © 2004 by the American College of Cardiology Foundation

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LAA Exclusion Can Worsen HF

Variables	LAAC group (n=47)	Non-LAAC group (n=141)	*P* value
Age (year)	75.1 ± 9.9	74.7 ± 9.7	0.799
Male (n, %)	20 (42.6%)	60 (42.6%)	1.000
BMI (kg/m^2)	24.4 ± 3.8	24.3 ± 3.7	0.953
Paroxysmal AF (n, %)	13 (27.7%)	34 (24.1%)	0.627
HAS-BLED score	2.55 ± 1.41	2.23 ± 1.34	0.156
CHA_2DS_2-VASc score	3.83 ± 1.98	3.32 ± 1.65	0.082
Labile INR (n, %)	6 (12.8%)	20 (14.2%)	0.807
Bleeding (n, %)	8 (17.0%)	23 (16.3%)	0.910
Stroke or TIA (n, %)	21 (44.7%)	49 (34.8%)	0.223
Hypertension (n, %)	32 (68.1%)	92 (65.2%)	0.722
Diabetes mellitus (n, %)	6 (12.8%)	21 (14.9%)	0.719
Congestive heart failure (n, %)	14 (29.8%)	35 (24.8%)	0.502
Chronic kidney disease (n, %)	5 (10.6%)	13 (9.2%)	0.775
Vascular diseases (n, %)	7 (14.9%)	14 (9.9%)	0.349

Abbreviations: TEE: transesophageal echocardiography; LAAC: left atrial appendage closure; BMI: body mass index; INR: international normalized ratio; TIA: transient ischemic attack; AF: atrial fibrillation; bpm: beats per minute; EF: left ventricular ejection fraction;

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- 47 LAAO vs. 141 Non-LAAO
- Retrospective Difference-in-Different analysis for hemodynamic changes before and after LAAO

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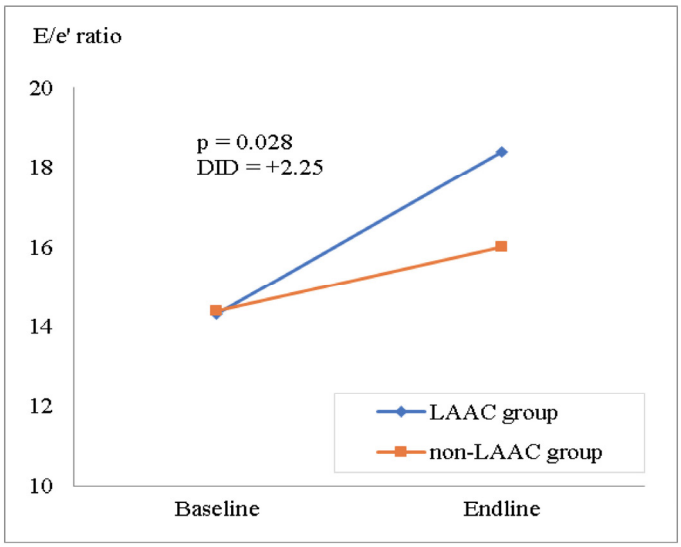
E/E' Elevation After LAAO



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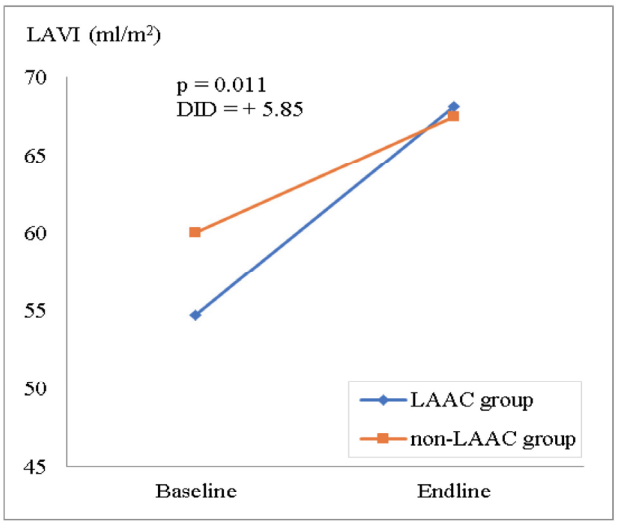
More LA Remodeling After LAAO



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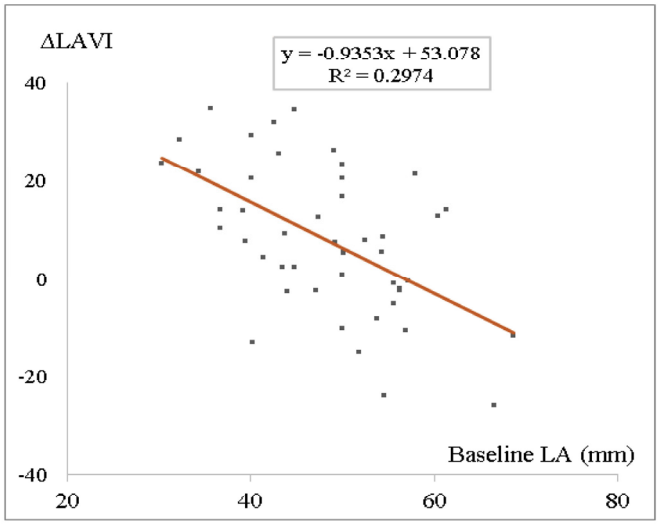
The Smaller LA, The Worse



- **Smaller LA** will experience the worse deterioration of the diastolic function after LAAO
- Patients with paroxysmal AF without LA enlargement (**less remodeled LA**) are more likely to experience the worsening of heart failure after LAAO

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5. Post-procedural Anti-thrombotic Therapy

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Switch from OAC to APT

- **No General Rule!**
- Timing (6 weeks)
- Procedural outcome
  - Peri-device leakage
  - Endothelialization
- Blood stasis (HF worsening)
- Indication for procedure

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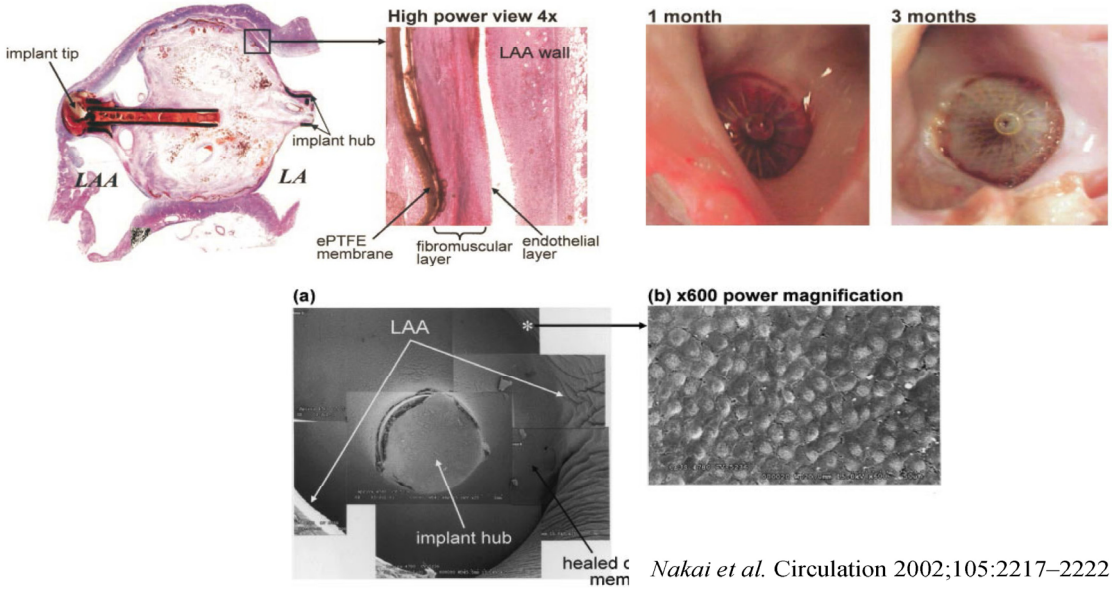
Endothelialization After LAA Occlusion
-PLAATO Device, Canine Model-



Nakai et al. Circulation 2002;105:2217–2222

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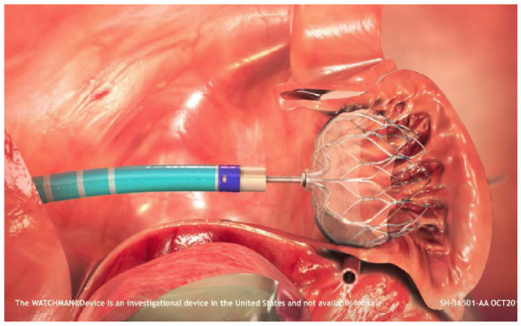
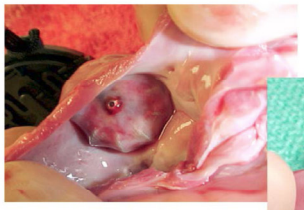
Endothelialization After WATCHMAN
In Canine Model





Implanted device

45 days

Complete endothelialization

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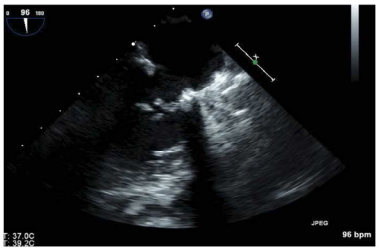
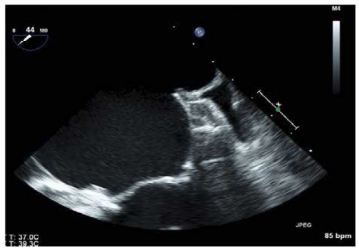
Endothelialization vs. Stasis?





Indication for LAAO
- Recurrent stroke & major bleeding during OAC
- Successful LAAO
- 2 M & 12 M f/u TEE

→ Complete sealing w/o thrombi during single APT

Endothelialization completion?

At 18 M after LAAO,
- HF exacerbation during stress cardiomyopathy
- LVEF 65% → 28%
- Thrombi on disc surface
- OAC and HF management

At 20 M after LAAO,
(OAC for 2 M & HF Mx)
LVEF 28% → 55%
Thrombi disappeared
OAC → APT
No further thrombotic events up to 36 M after LAAO

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CONCLUSIONS

1. Although LAAO is a safe alternative for OAC, **safer and simpler ways** to close must be sought
2. **Imaging analysis support** plays important roles in planning & performing LAAO. More comprehensive imaging analysis tool would be sought & validated
3. **Ideal procedural endpoint** should be clarified by future studies (Minimize dead space, etc.)
4. Not only careful **patient selection** before LAAO but also **thorough following-up** after LAAO is important
5. **Individualization anti-thrombotic strategy** depending on patients' condition (indication for LAAO, procedural outcome – leakage, endothelialization, presence or worsening of HF, etc.) is important.

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