

# **LAA Occlusion in Korean Multi-Center Registry**

**Jung-Sun Kim, MD, Ph D**

**Division of Cardiology, Severance Cardiovascular Hospital  
Yonsei University College of Medicine**

# Disclosure Information

## Jung-Sun Kim, MD, PhD

- Grants/Research Support: National Research Foundation of Korea, Ministry of Health & Welfare and Daewoong and CJ Pharmaceutical Co.
- Support/Consultant: St. Jude Medical, Boston Scientific and Pfizer
- Speaker's Bureau: ISU Abxis, Sanofi and AstraZeneca

# LAA Occlusion Korean Multi-Center Registry

- **5 Hospitals participated in Multi-Center Korean LAA Occlusion Registry**
  - Severance Cardiovascular Hospital, Yonsei University College of Medicine, Seoul (Jang Y, Pak HN and Kim JS)
  - Korea University Anam Hospital, Seoul (Lim DS and Yoo CW)
  - Sejong General Hospital, Seoul (Choi RK and Lee HJ)
  - Gil Hospital, Gachon University, Incheon (Kang WC)
  - Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan (Shin ES)

# Purpose of Study

- **Investigate overall incidence of death, stroke, systemic embolization and major bleeding in Korean Population**
- **Compare between 2 LAA occlusion devices (ACP and Watchman).**

Kim JS, Lee HC, et al. Circulation J 2016

# Available Devices in Korea

## WATCHMAN<sup>®</sup> System (Boston Scientific)

- *Nitinol with 160 micron PET filter)*
- *21, 24, 27, 30, 33 mm*
- *TEE, Angiography*
- *12 F*
- *45 days of Coumadin*



**Polyester polyethylene terephthalate (PET)**

## Amplatzer Cardiac Plug (St Jude Medical)

- More operator dependent
- Unique design – flexibility to work in varied anatomy
- Small profile - 9F to 13F delivery sheath



AMPLATZER<sup>®</sup> Cardiac Plug  
© ASA Medical Corporation

# Study Flow

99 consecutive patients from 5 centers in Korea  
Between Oct 2010 and Feb 2015

3 patients not implanted

96 patients was eligible

96 patients - Follow-up for 6 months  
93 patients - Follow-up TEE evaluation

3 patients was excluded for FU TEE analysis  
1 respiratory arrest, 1 cardiac tamponade and 1 device embolization

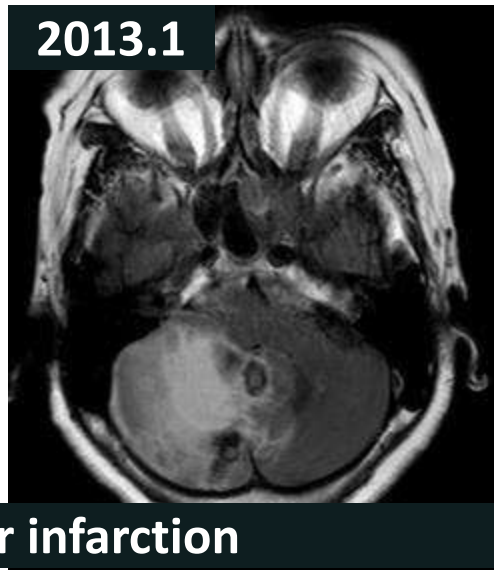
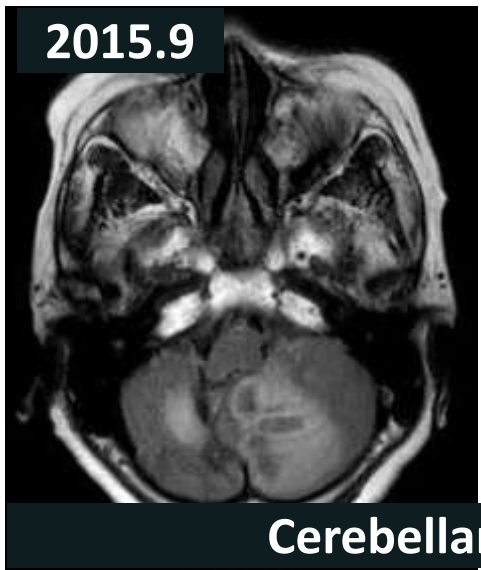
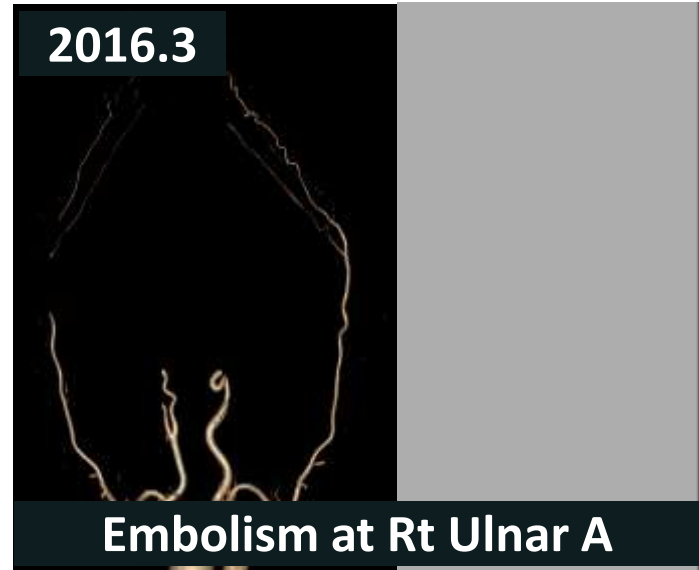
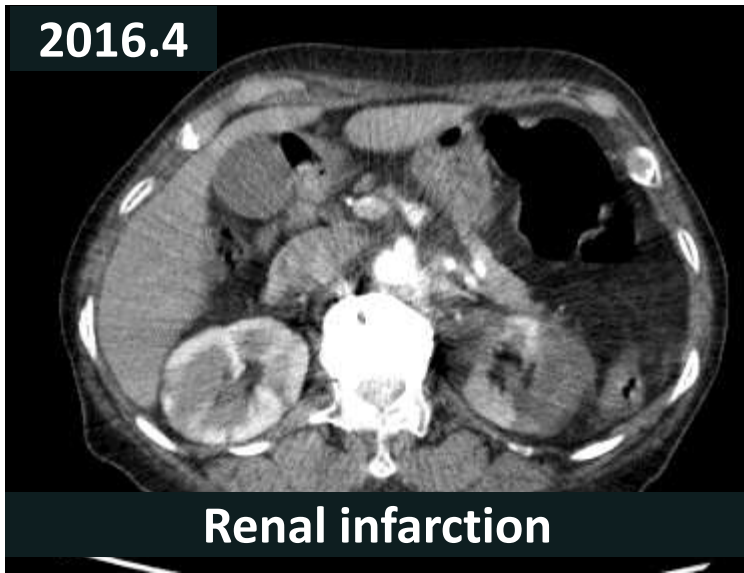
# Indication

**Non-valvular AF** (paroxysmal, persistent or permanent) with **CHADS<sub>2</sub> ≥ 1** or **CHADS<sub>2</sub>VASc score ≥ 2** and high risk of bleeding or contraindication to anti-coagulation.

## **High risk of bleeding or contraindications to warfarin**

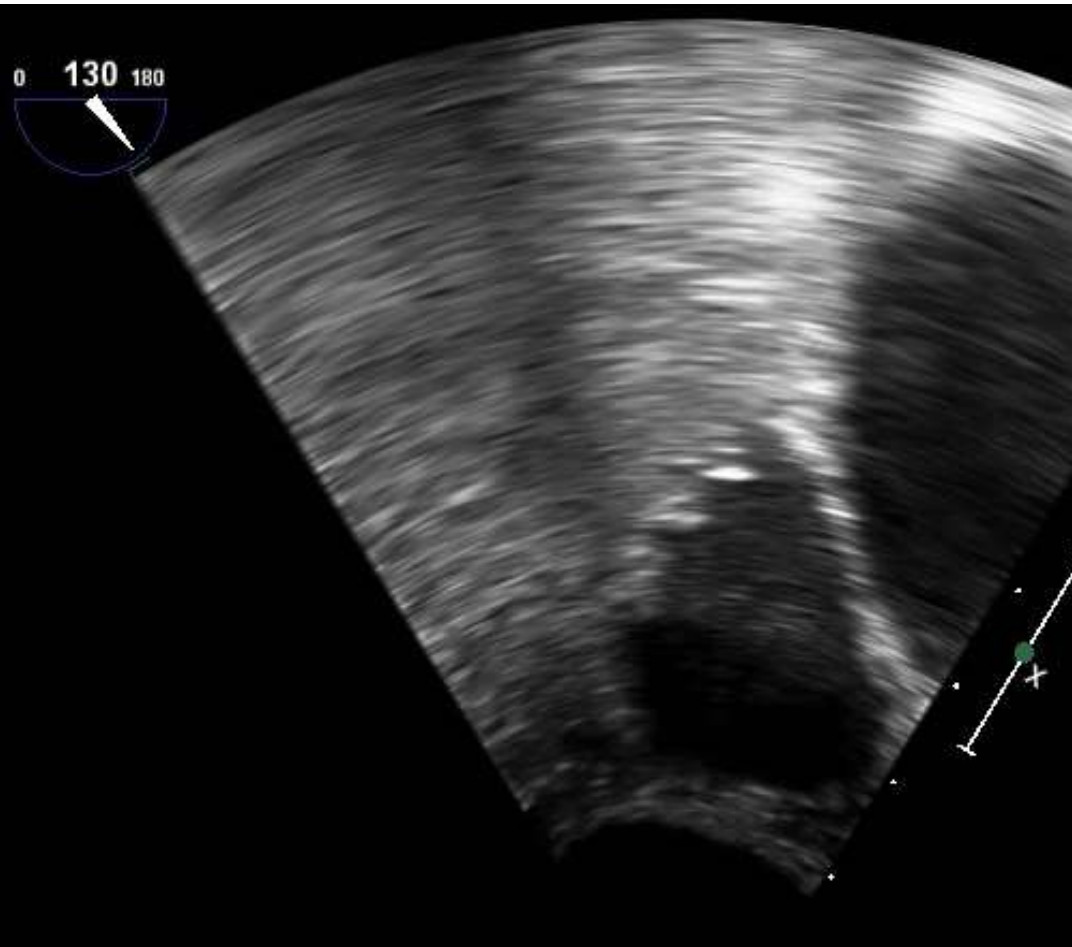
- 1) major or recurrent minor bleeding event on anticoagulation**
- 2) high risk of bleeding according to HAS-BLED score ≥3**
- 3) stroke during anti-coagulation**

# Recurrent Embolism during Anti-Coagulation

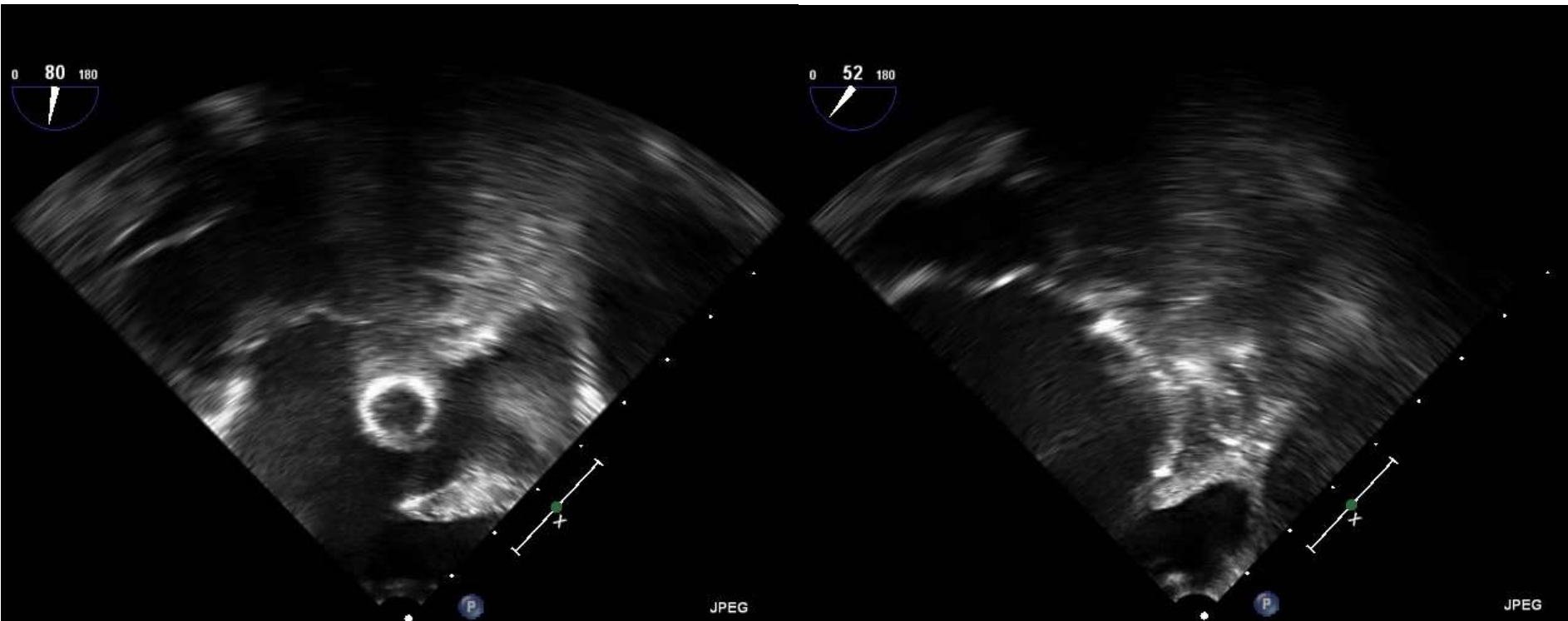




# LAA Thrombus

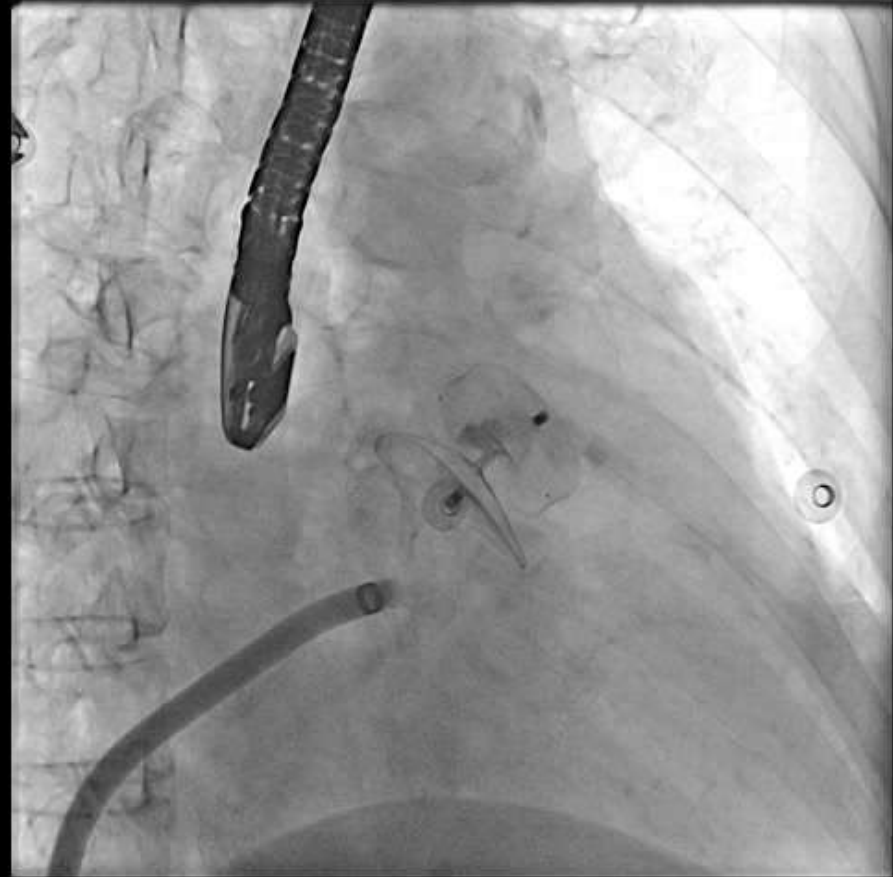
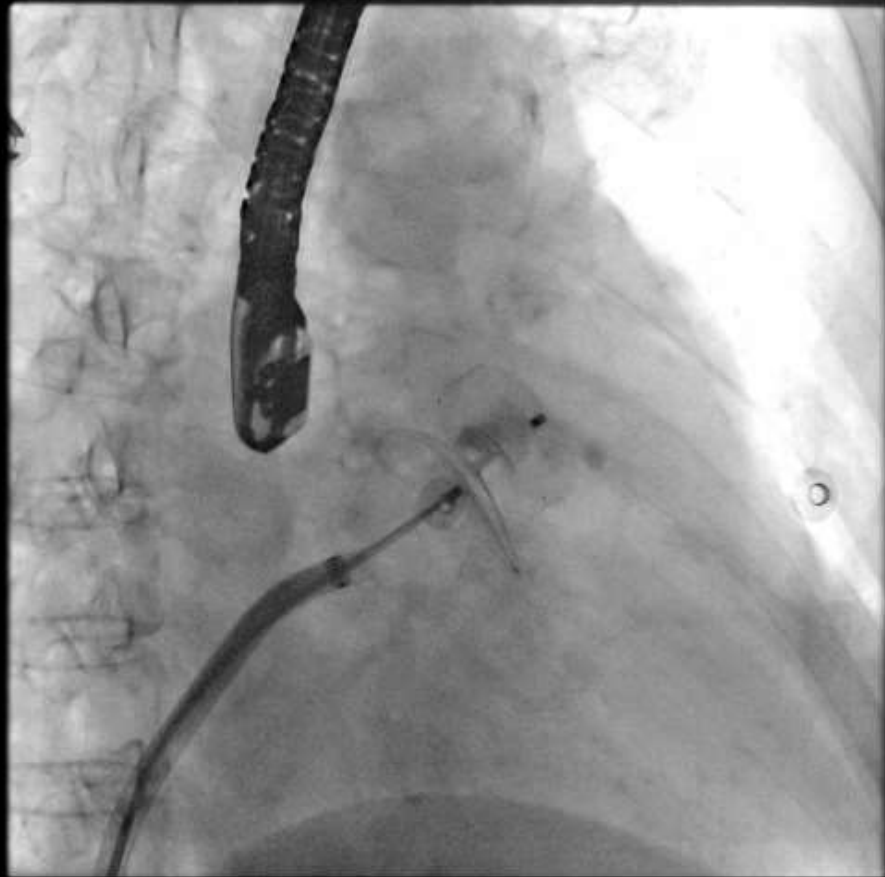


# Intra-Procedure TEE



Lobe and disc was implanted in LAA as gentle as possible.

# LAA occlusion



Device separation was performed. Sealing was maintained after separation.

# Coumadin toxicity of 88 Year-old Gentleman



**Rt. arm pain, PT INR 3.01 → 11.40**

# Post-Procedure CT



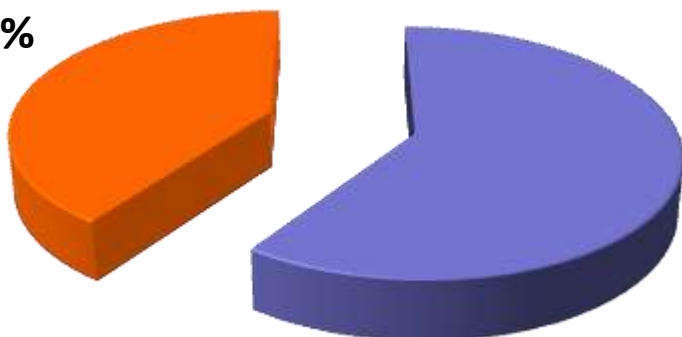
The device was well implanted in LAA.



# Baseline Characteristics

## Gender

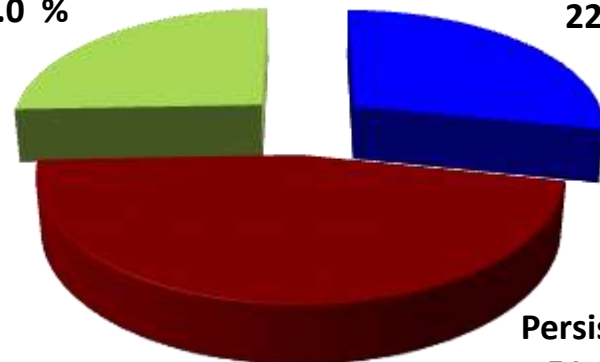
Female  
58.5 %



Male  
61.5 %

## Type of AF

Permanent  
26.0 %



Paroxysmal  
22.9 %

Persistent  
51.0 %

## Device

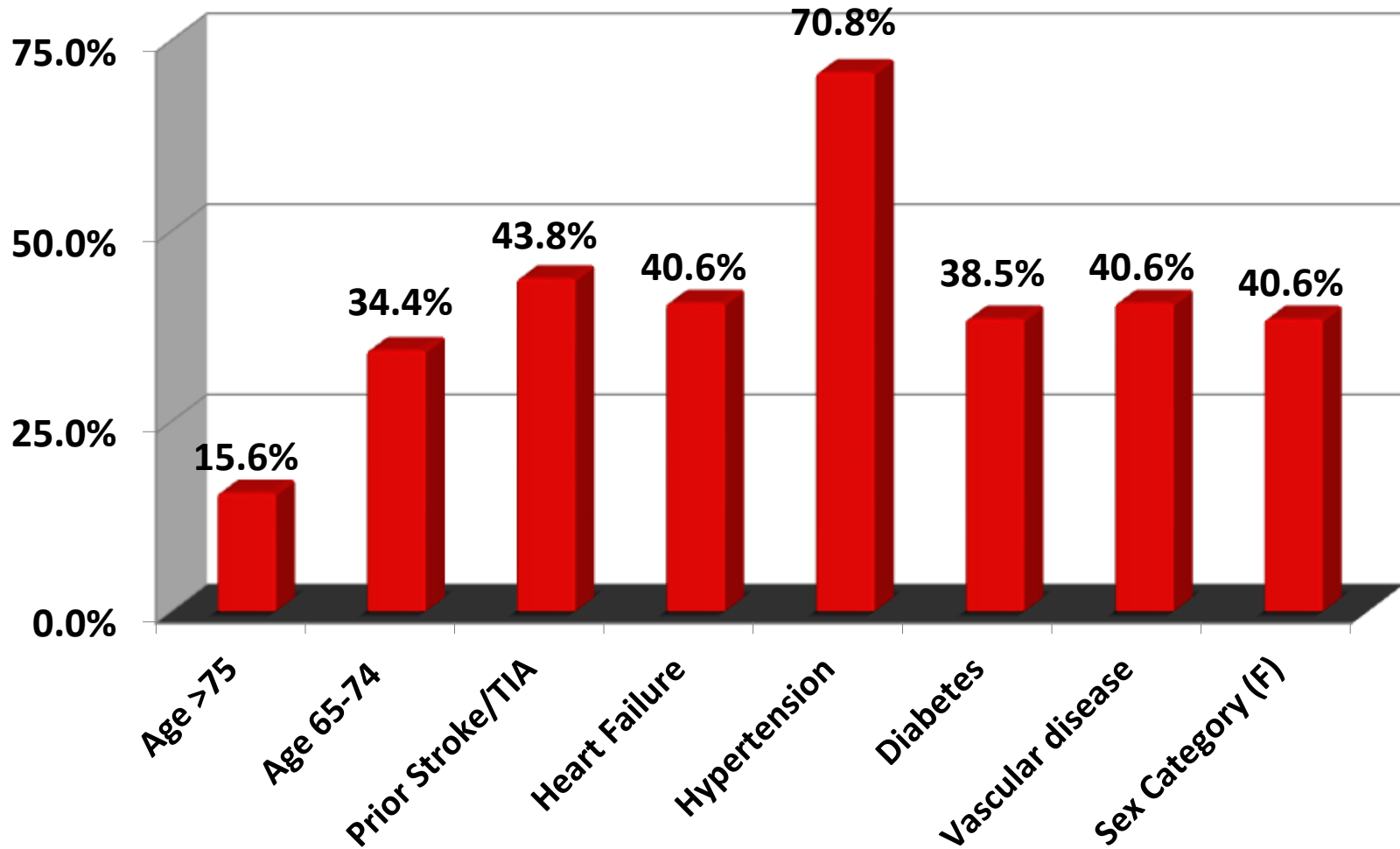
Watchman  
48.0 %



Amplatzer  
Cardiac Plug  
52.0%



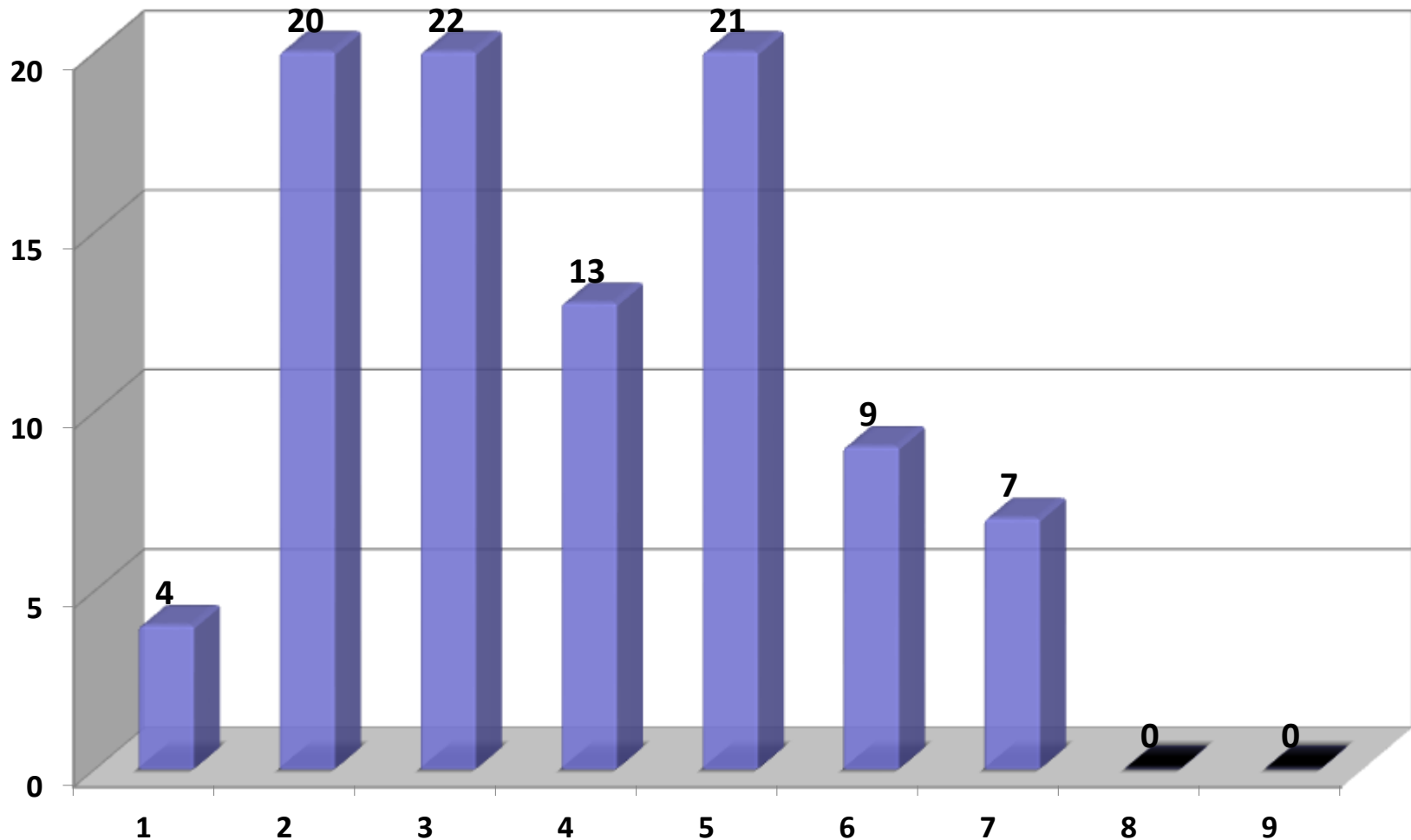
# Stroke Risk Factors



# Stroke Risk Assessment

CHA<sub>2</sub>DS<sub>2</sub>-VASc Score

Mean : 3.9 ± 1.6

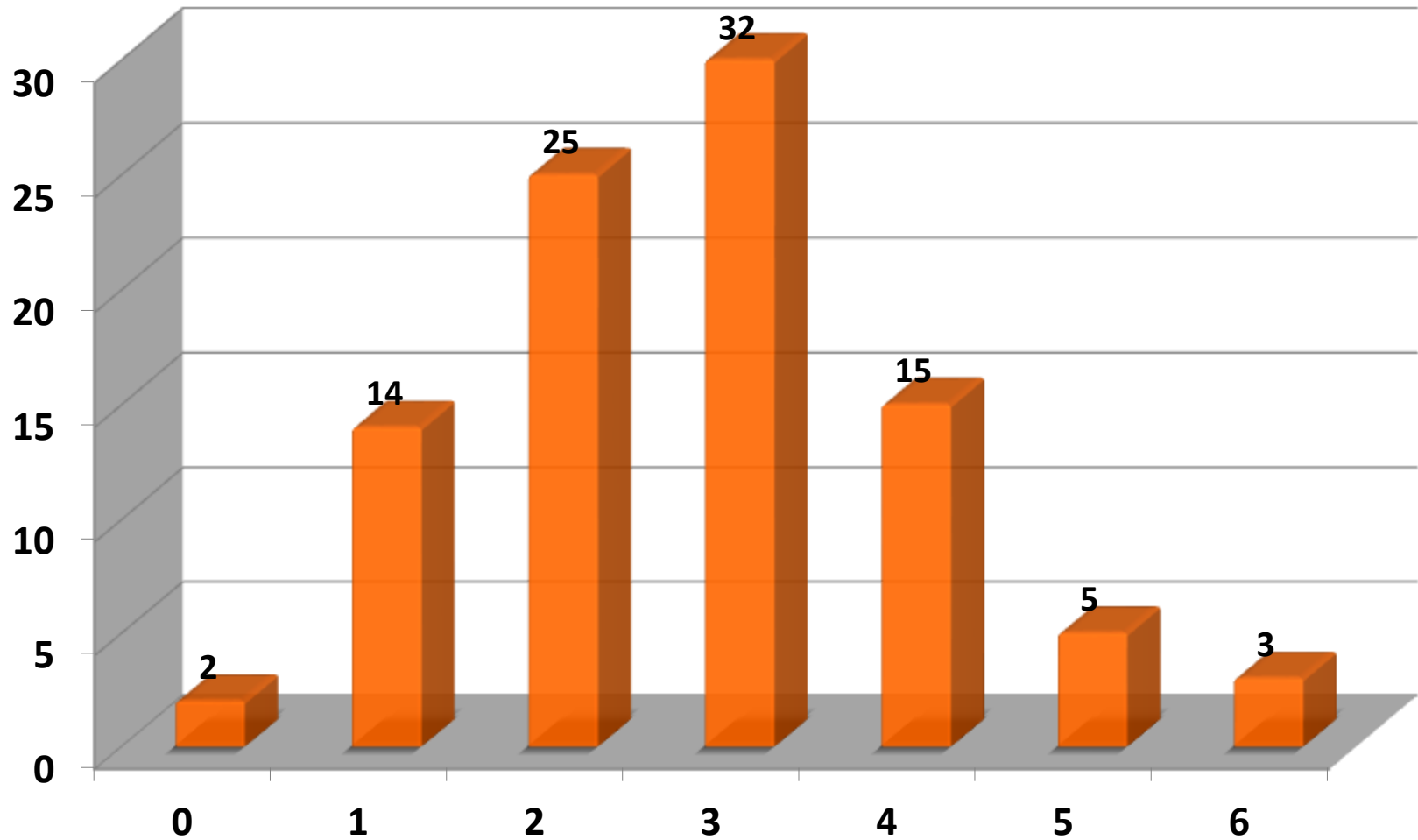




# Bleeding Risk Assessment

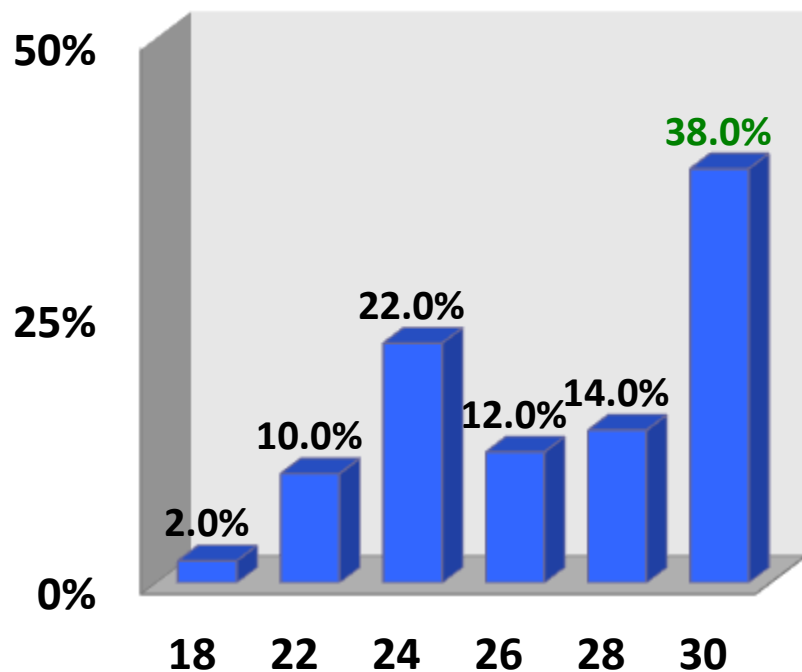
HAS-BLED Score

Mean :  $2.7 \pm 1.3$



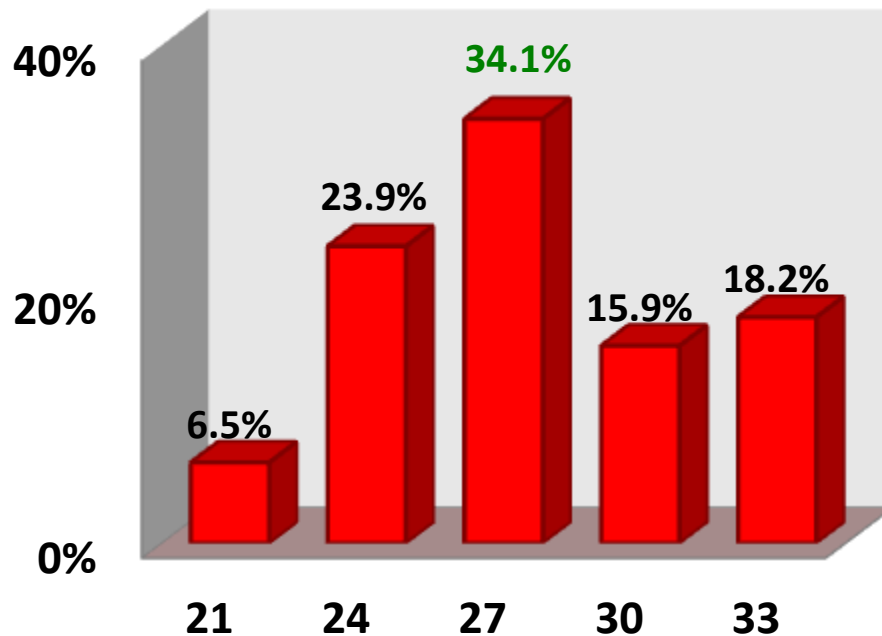
# Device Size

## ACP



Mean device size:  $26.8 \pm 3.2$

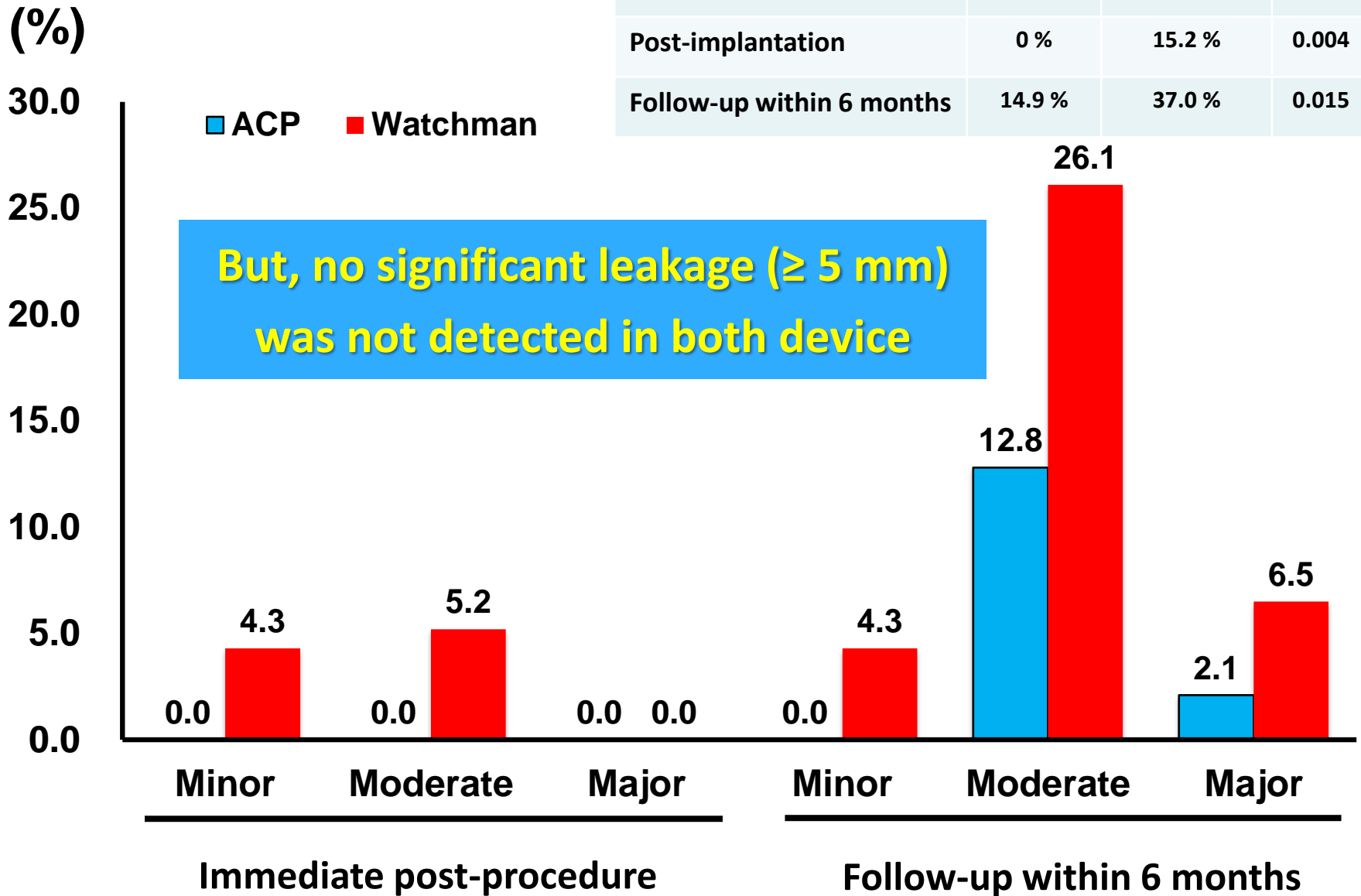
## Watchman



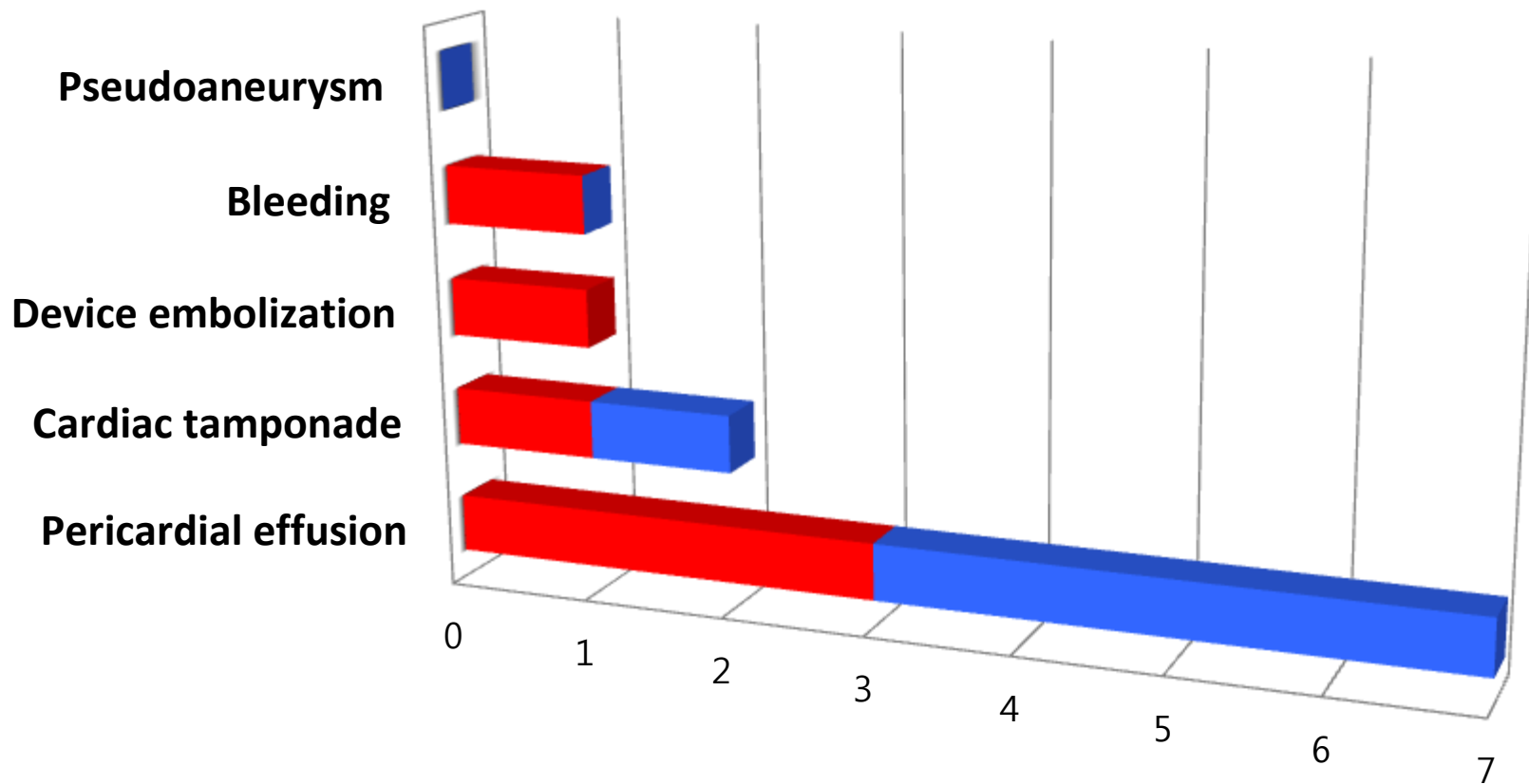
Mean device size:  $27.4 \pm 3.5$

Overall incidence of peridevice leakage

	ACP	Watchman	p
Post-implantation	0 %	15.2 %	0.004
Follow-up within 6 months	14.9 %	37.0 %	0.015

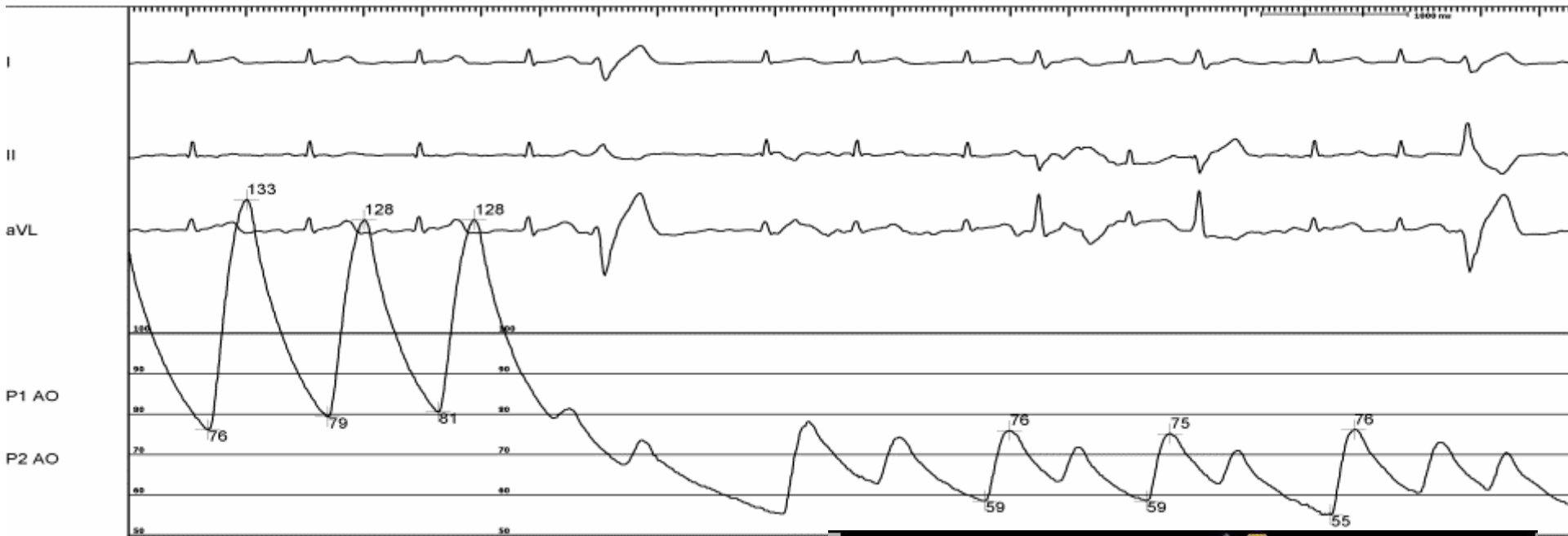


# Procedure-Related Complications

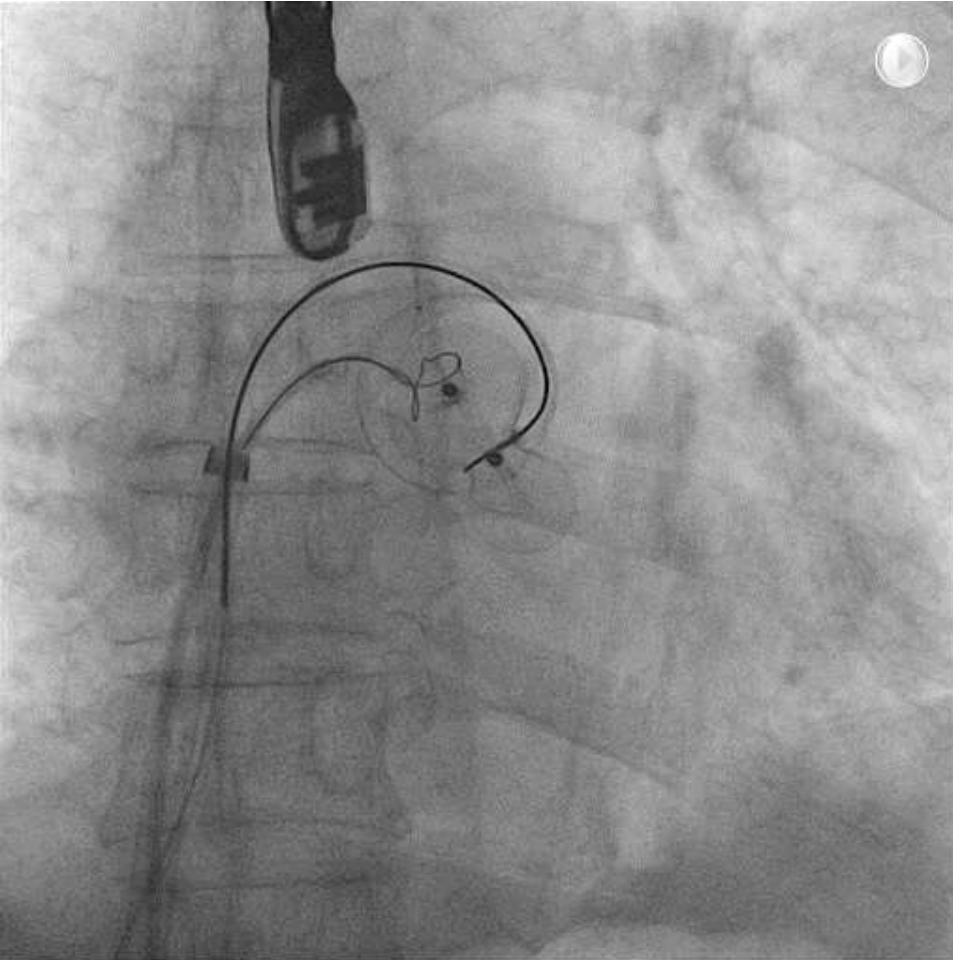


	PERICARDIAL EFFUSION	CARDIAC TAMPONADE	DEVICE EMBOLIZATION	BLEEDING	PSEUDOANEURYSM
■ ACP	3	1	1	1	0
■ WATCHMAN	4	1	0	0	0

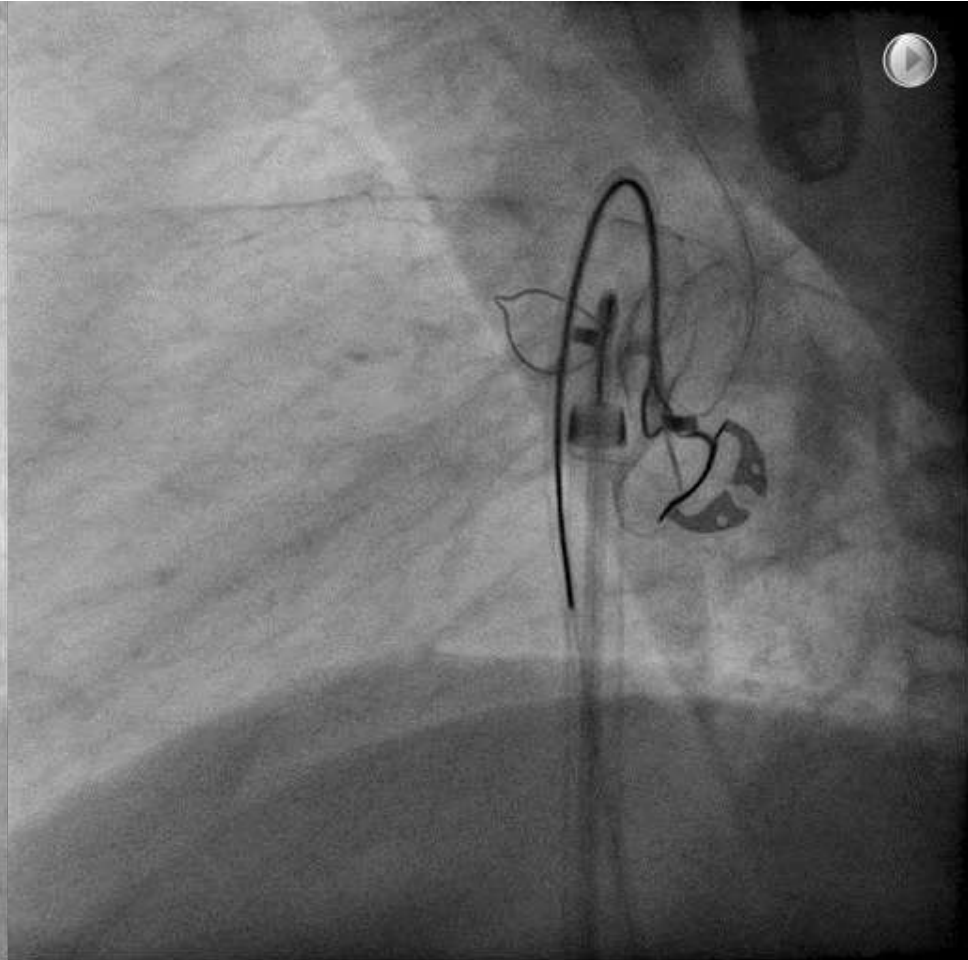
# Entrapping in Mitral Valve



# Capture of Device (distal screw) with Snare

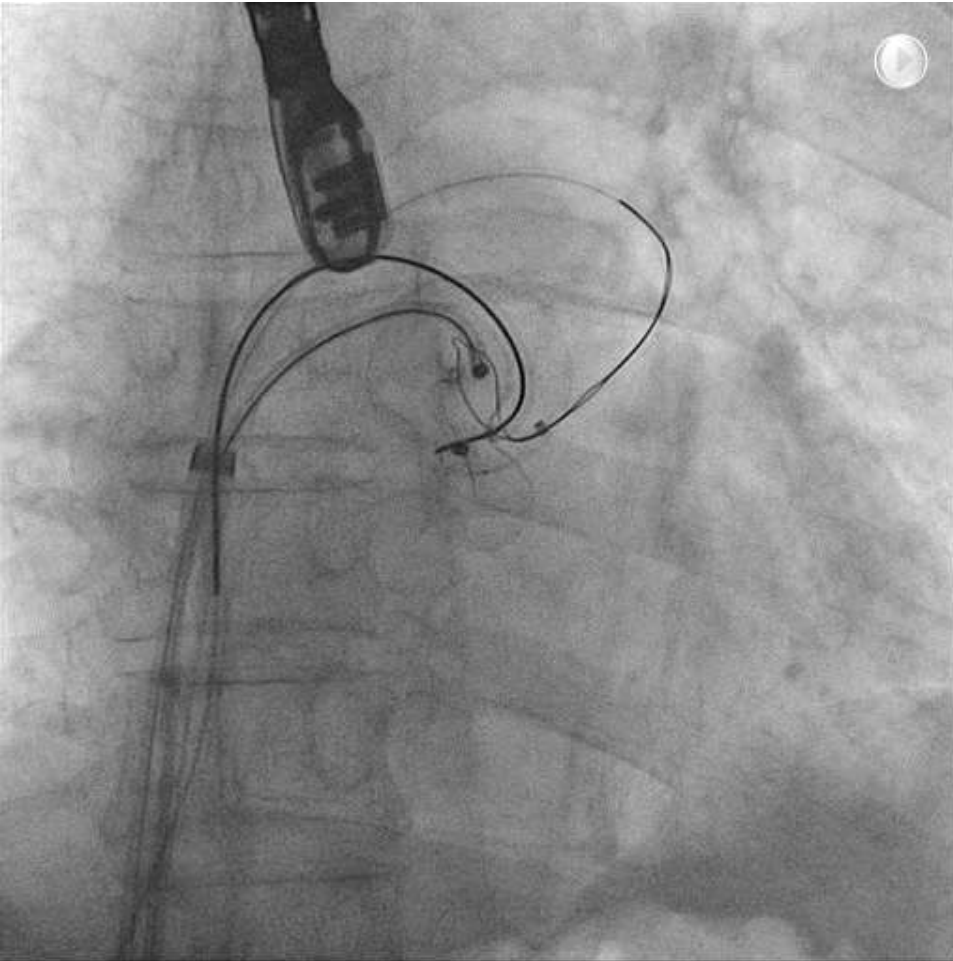


**PA**

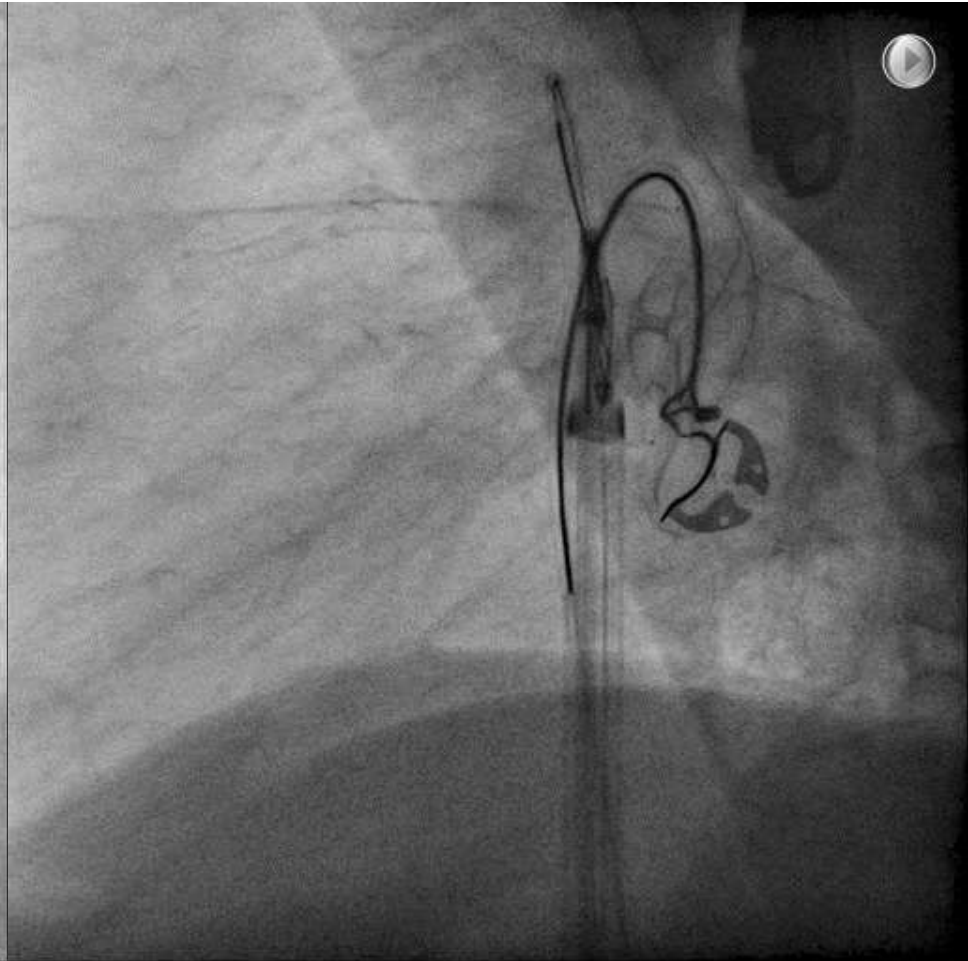


**LAO 90**

# Capture of Distal Screw



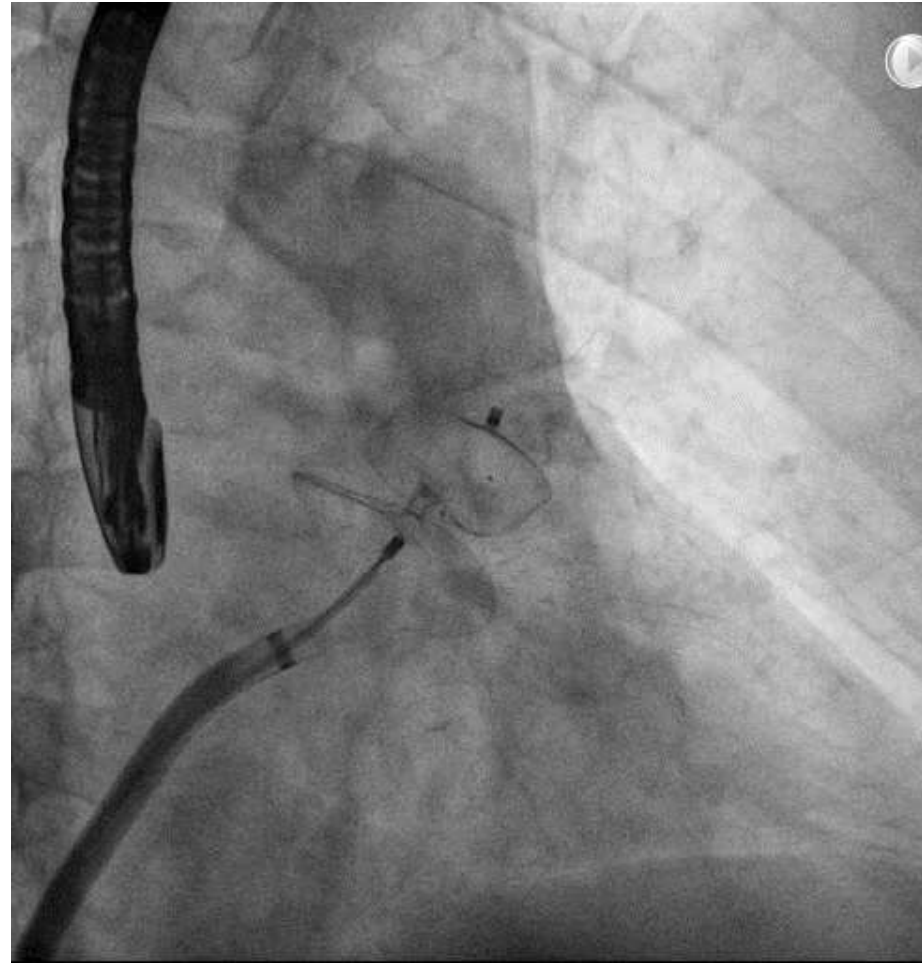
PA



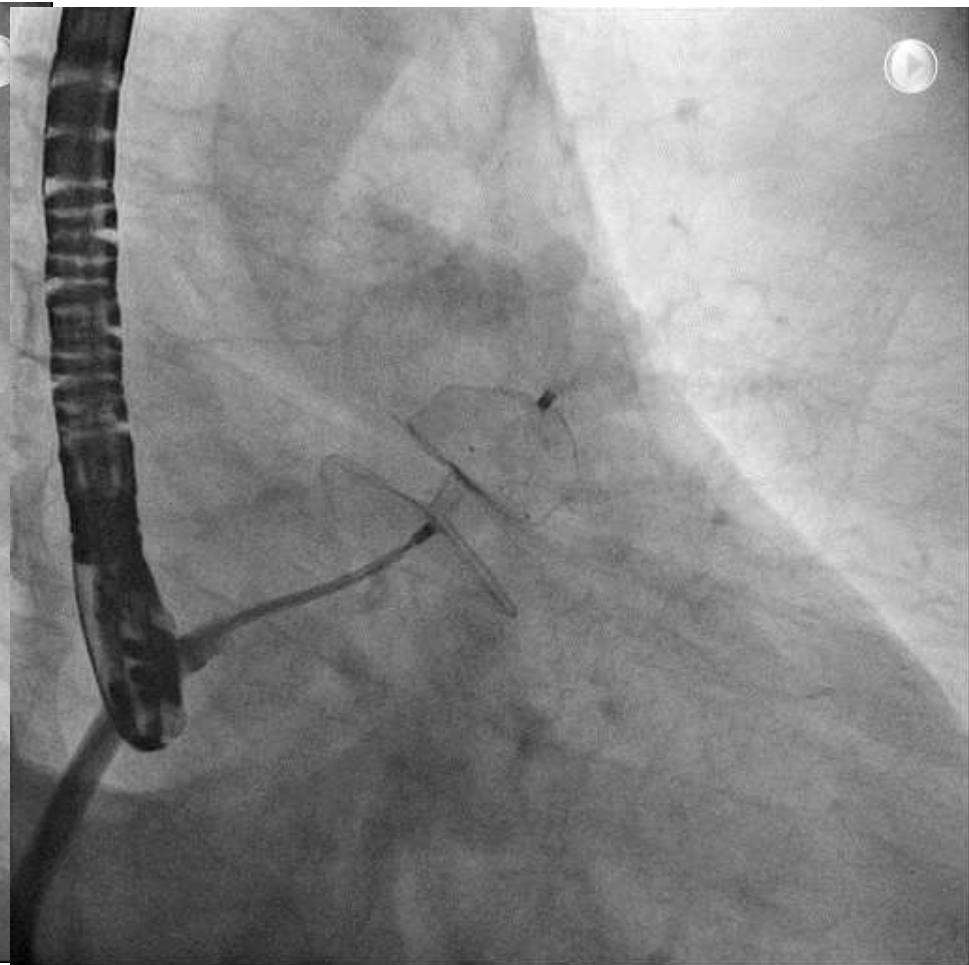
LAO 90



# Check Sealing

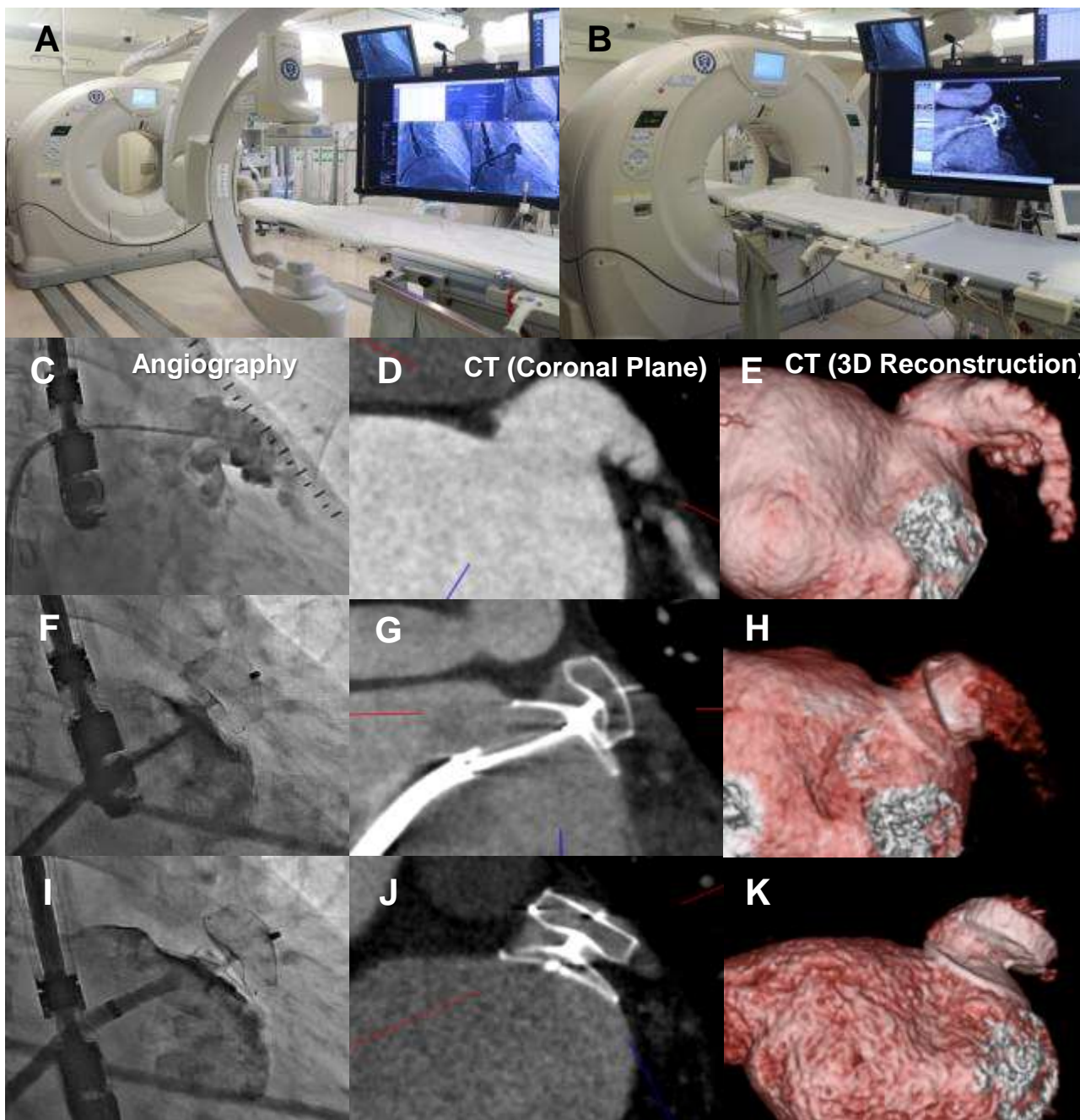


**RAO 30 CRA 20**



**RAO 30 CAU 20**

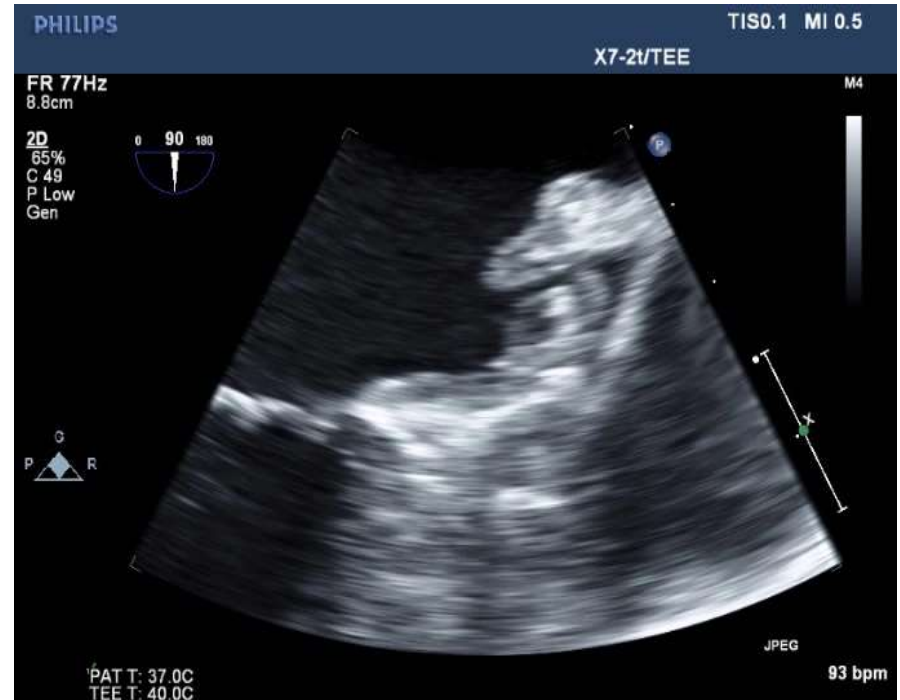




**Kim JS, et al.**  
**Eur Heart J**  
**2016**

# Device Thrombosis

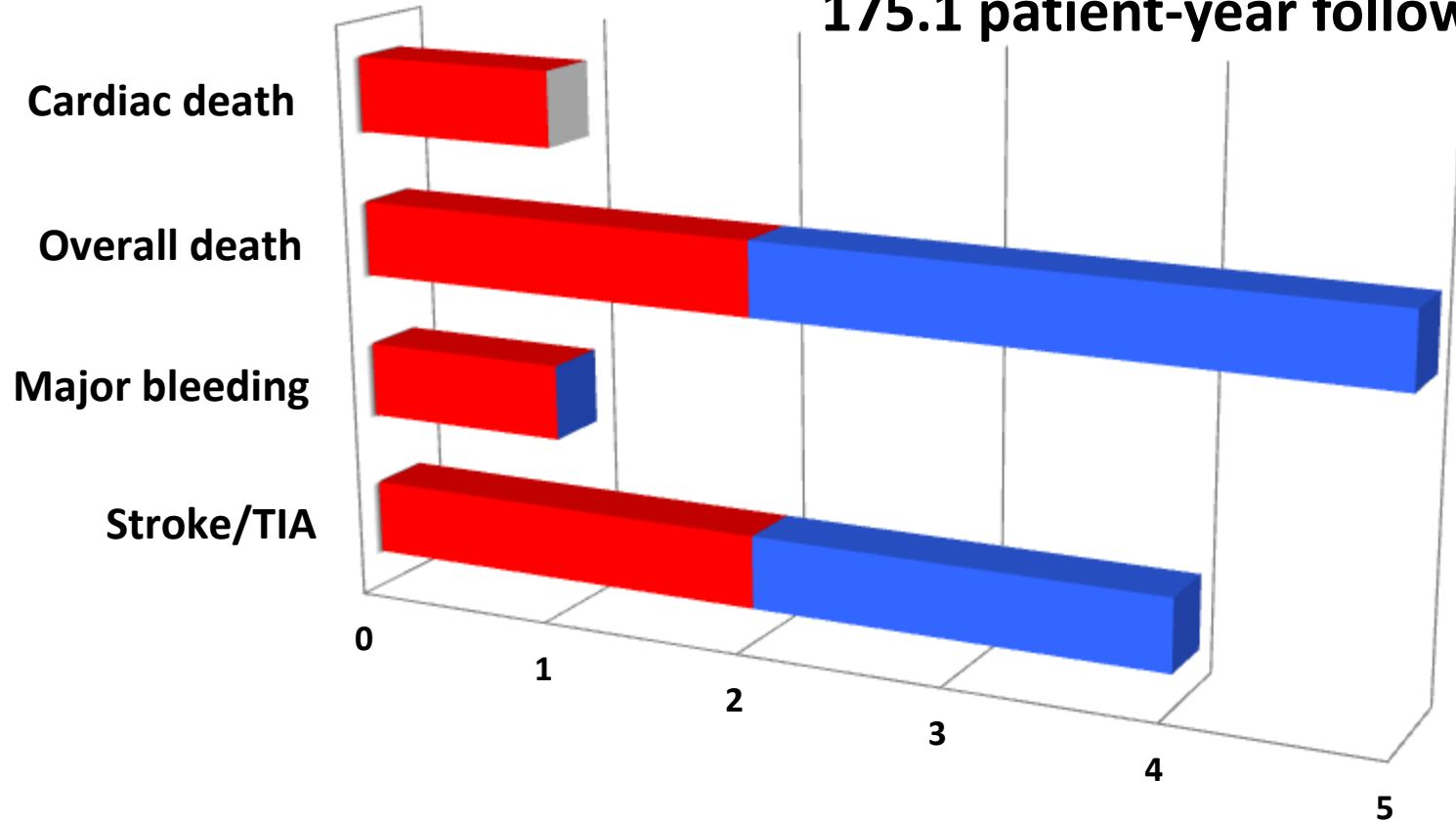
3/93 cases (3.2 %) 1 ACP and 2 Watchman



**Hypoechoic mass on Device**

# Major Events

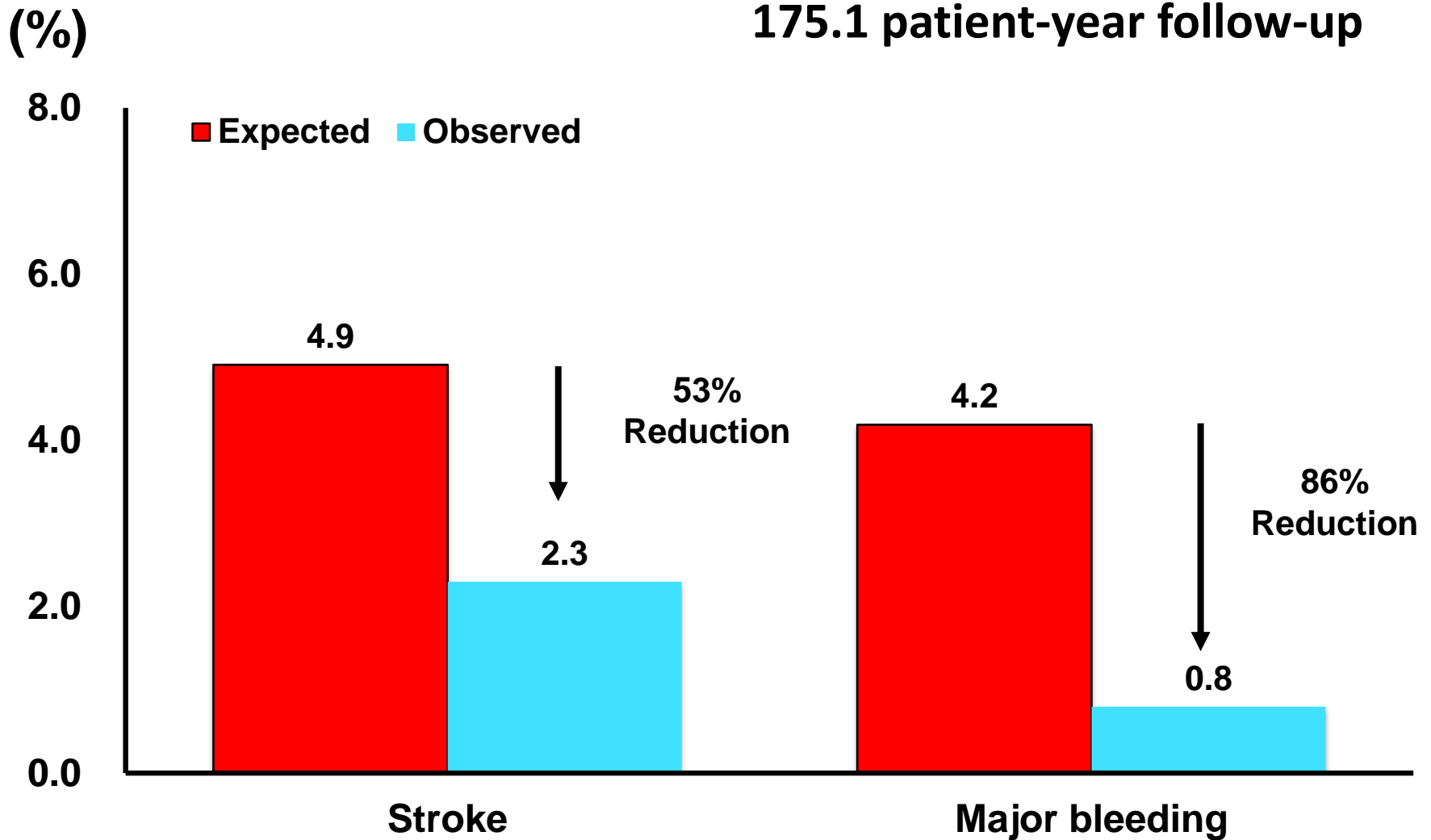
175.1 patient-year follow-up



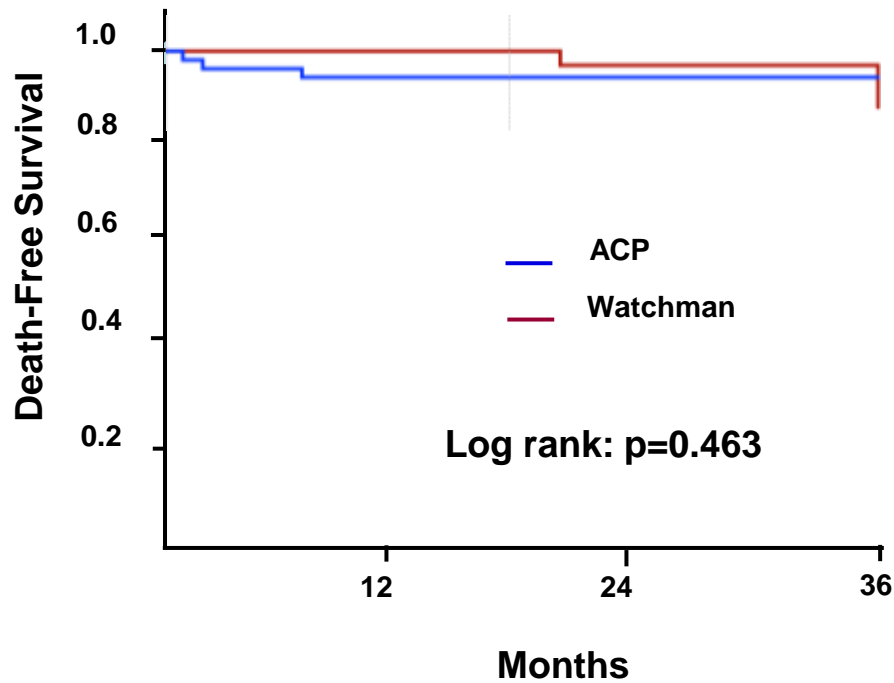
	STROKE/TIA	MAJOR BLEEDING	OVERALL DEATH	CARDIAC DEATH
■ ACP	2	1	2	1
■ WATCHMAN	2	0	3	0

# Stroke and Bleeding Reduction

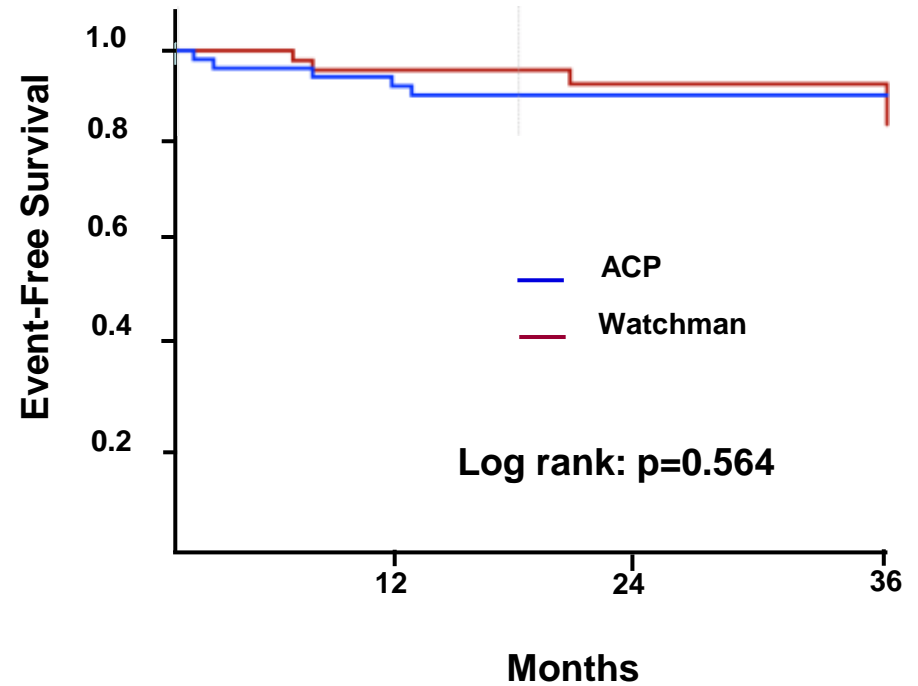
175.1 patient-year follow-up



## Major adverse cardiac events (MACE)



## All Cause Death



ACP	50	48	45	24	12	7	4
Watchman	46	46	45	37	27	18	10

ACP	50	49	44	22	10	5	2
Watchman	46	44	41	25	26	17	10

**MACE** was defined as cardiovascular death, ischemic stroke, systemic embolization, and major bleeding.

# Summary of Korean Multi-Center Registry

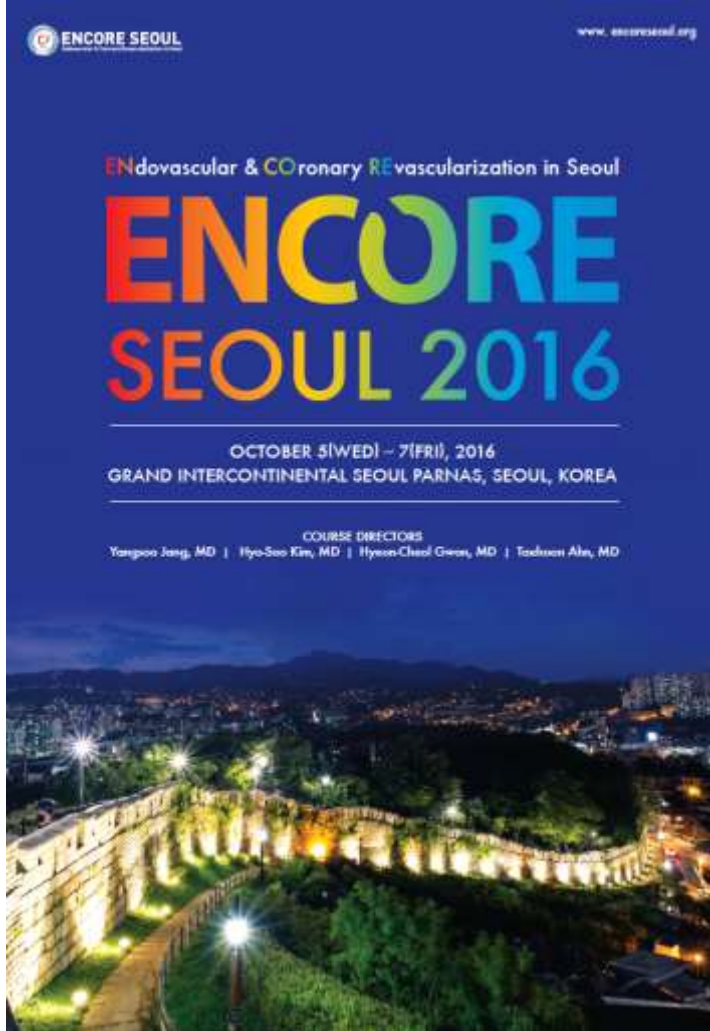
- **Multicenter 96 patients cohort, LAAO with ACP or Watchman:**
  - An acceptable immediate implant success rate of 96.9 %
  - Acceptable rate (4.1 %) of periprocedural major adverse events
- **During 175.1 patient-year follow-up**
  - 4 ischemic stroke
  - 1 cardiac death and 4 non-cardiac death
  - Anticoagulation cessation rate was 93.6 %

# Conclusion

- **LAA occlusion was feasible in patients with high risk of stroke and bleeding with non-valvular AF in Korean population.**
- **LAA occlusion might be an option to reduce the thrombus burden in the left atrium because all patients experienced stroke were fully recovered without any sequelae in current study.**
- **This benefit may be offset by complications related to the implantation of the device .**



# Thanks for Your Attention



## LAA Occlusion Multi-Center Study Team

- **Severance Cardiovascular Hospital**, Yonsei University College of Medicine, Seoul (Jang Y, Pak HN and Kim JS)
- **Korea University Anam Hospital**, Seoul (Lim DS and Yoo CW)
- **Sejong General Hospital**, Seoul (Choi RK and Lee HJ)
- **Gil Hospital, Gachon University**, Incheon (Kang WC)
- **Ulsan University Hospital, University of Ulsan College of Medicine**, Ulsan (Shin ES)

**Specially Thanks for Drs. Jai-Wun Park, Saibal Kar and YY Lam**