

# Intervenciones Estructurales Cardíacas: Cuando y porqué?

## Cierre de la orejuela auricular izquierda:



*Dr. Aníbal Damonte (damontea@icronline.com)*

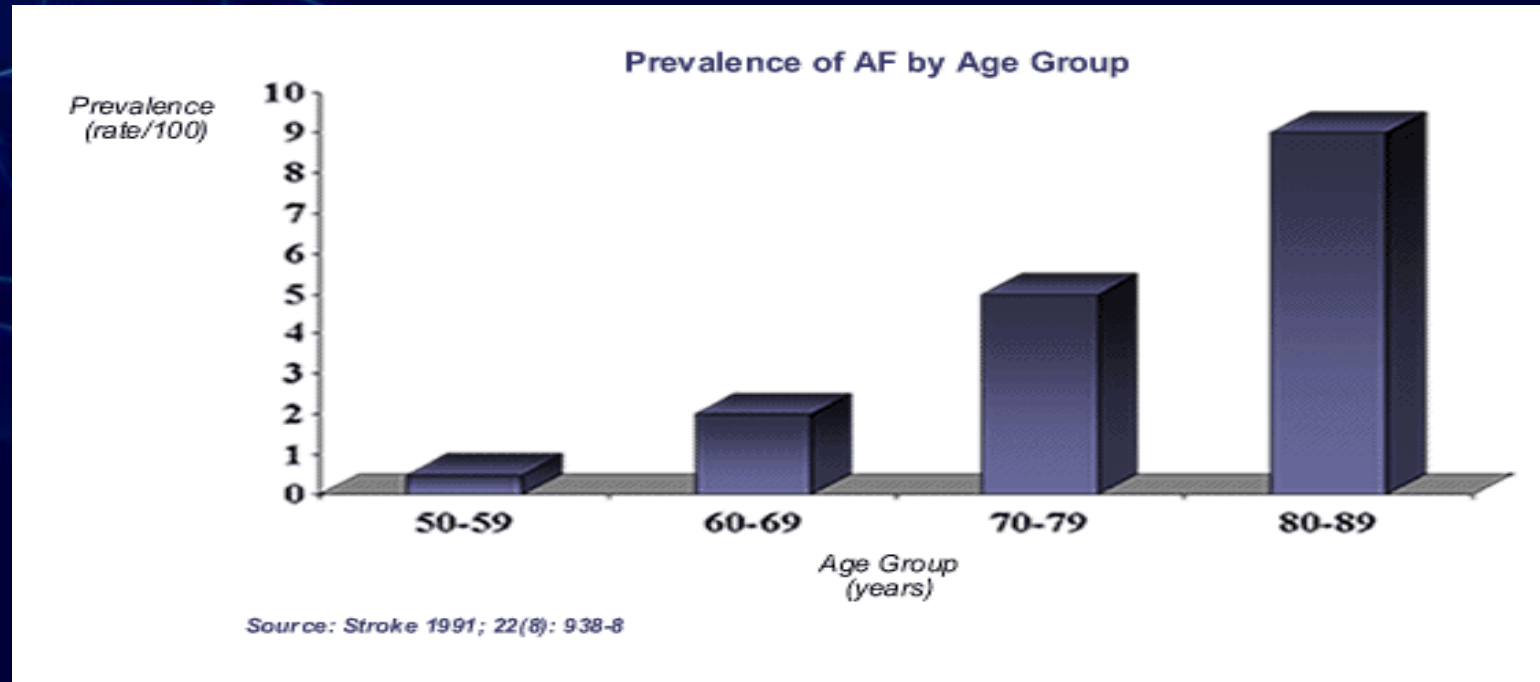
*Departamento de Cardiología Intervencionista*

*Instituto Cardiovascular de Rosario*

*Rosario, Argentina*

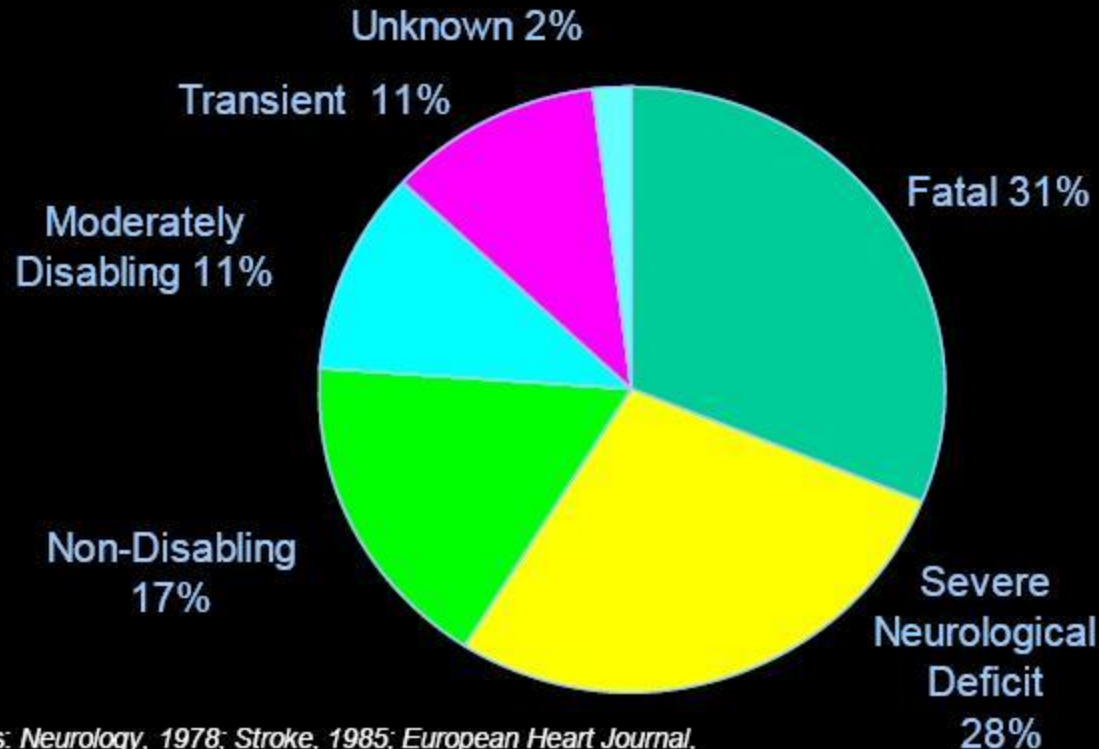
# Introducción

- La FA es la arritmia cardíaca más frecuente en la práctica clínica y es causa mayor de morbilidad y mortalidad debido a stroke cardioembólico.
- FA es responsable de 15-20% de los strokes isquémicos (Fuster et al, Circ 2006). Los pacientes con FA tienen 5 veces + riesgo de stroke.
- La incidencia de FA se incrementa con la edad.



# Introducción: Stroke relacionado a FA

- 500,000 strokes per year
- 15 – 20% of strokes/year are related to AF
- **Functional Impact of AF-Related Stroke:**

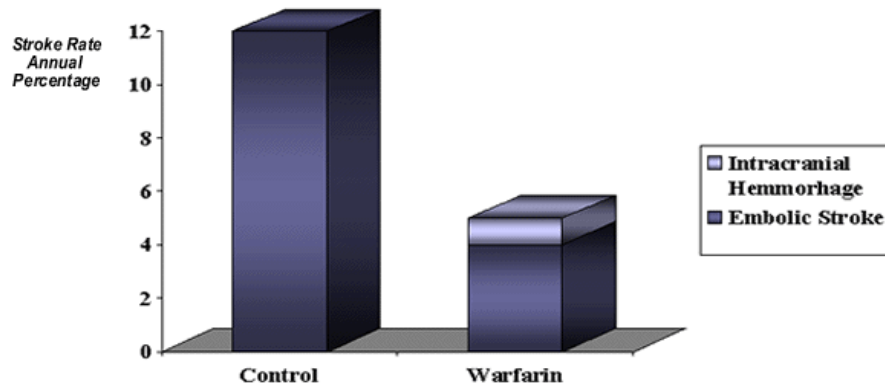


Sources: *Neurology*, 1978; *Stroke*, 1985; *European Heart Journal*, 1987; *Lancet*, 1987; *Fisher. Geriatrics*. 1979;34:59

# Introducción

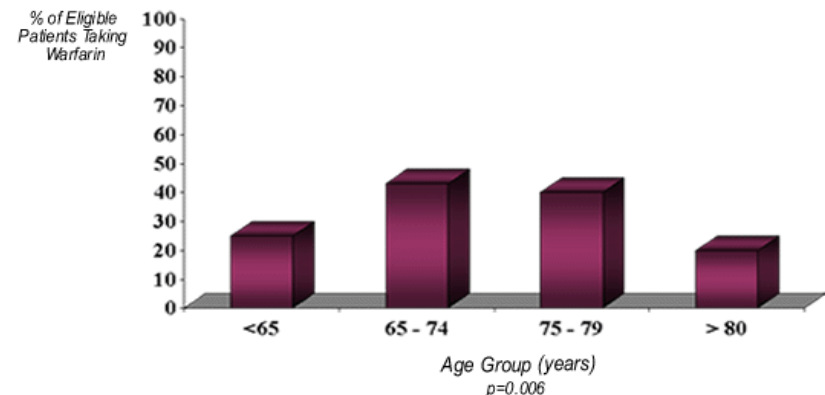
- Los ACO son actualmente el método más efectivo de prevención del stroke en pacientes con FA, pero:
  - 1) Rango terapéutico estrecho – Interacciones con otros fármacos
  - 2) Insuficientemente controlados en alto % de pacientes
  - 3) Subutilizados
  - 4) Frecuentemente contraindicados
- A pesar de la introducción de nuevos fármacos, los beneficios siguen siendo contrarrestados por el riesgo de sangrado

Warfarin vs. Placebo in High Risk Patients With AF and Prior Stroke



Source: Lancet; 1993; 342(8882): 1255-62

Warfarin Underutilization



Source: Arch. Int. Med. 1996; 156(22): 2537-41

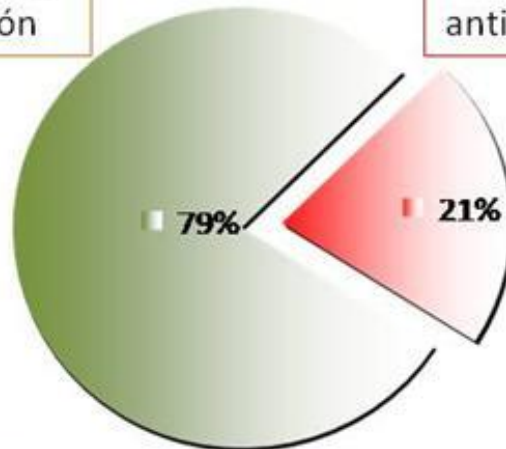
# Registro RENAFA

## Resultados. Estrategia tratamiento ACO

Sin contraindicaciones para anticoagulación



67.9% recibían anticoagulación



Alguna contraindicación para anticoagulación, a criterio del investigador\*

Contraindicación	%
Edad avanzada	13.1
Sangrado activo	1.1
ACV hemorrágico	0.5
Limitación social	4.6
Imposibilidad control RIN	2.2
Caídas frecuentes	1.7
Rechazo paciente - familia	2.6
Coagulopatía	1.1
HTA no controlada	0.3

Medico a cargo de ACO	%
Cardiólogo	31.4
Hematólogo	53.9
Clínico	1.3
Medico cabecera	3.2
NS-NC	10.2

\*Nota: de estos, 65.4% recibían antiagregantes

## Evolution in Baseline Treatment for Patients Enrolled in Sequential Cohorts of GARFIELD-AF

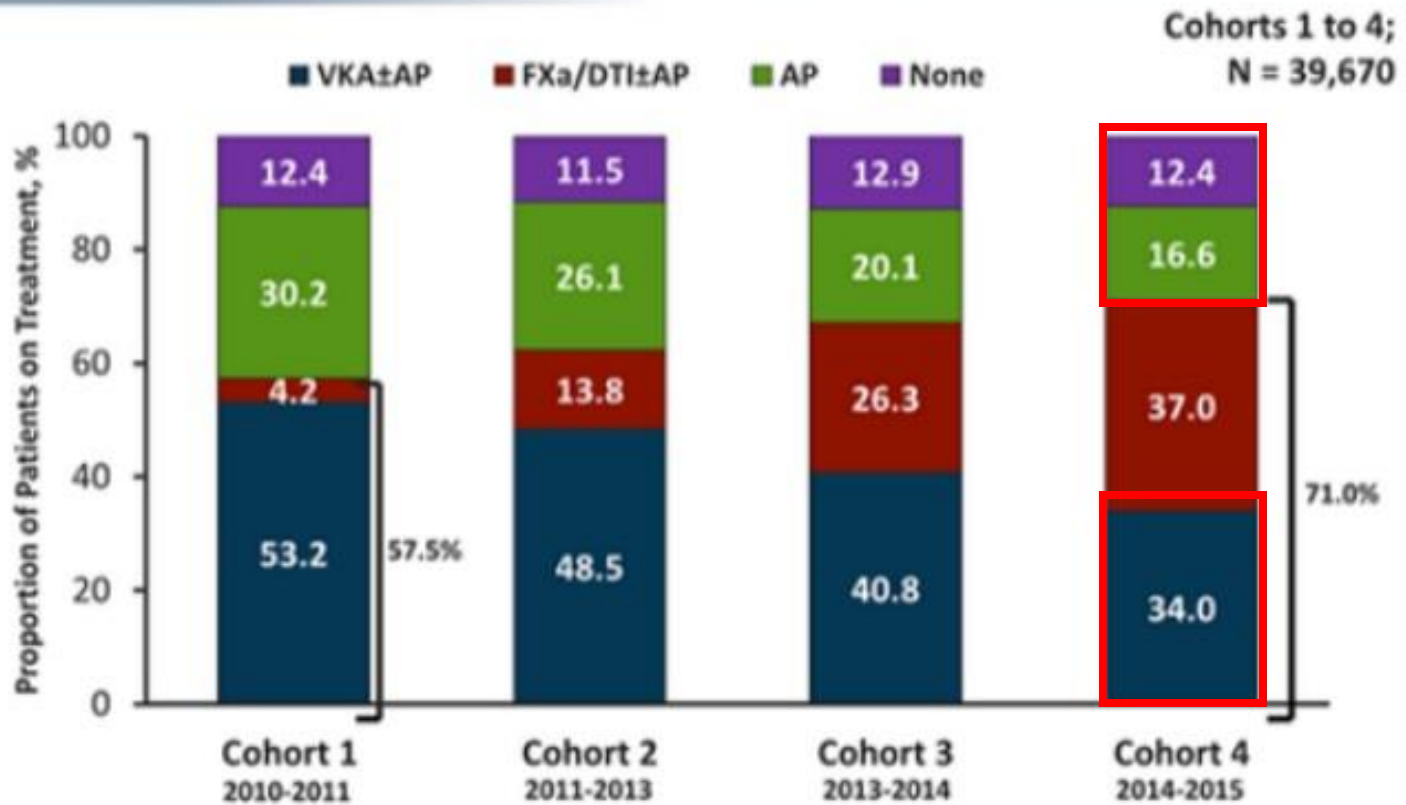
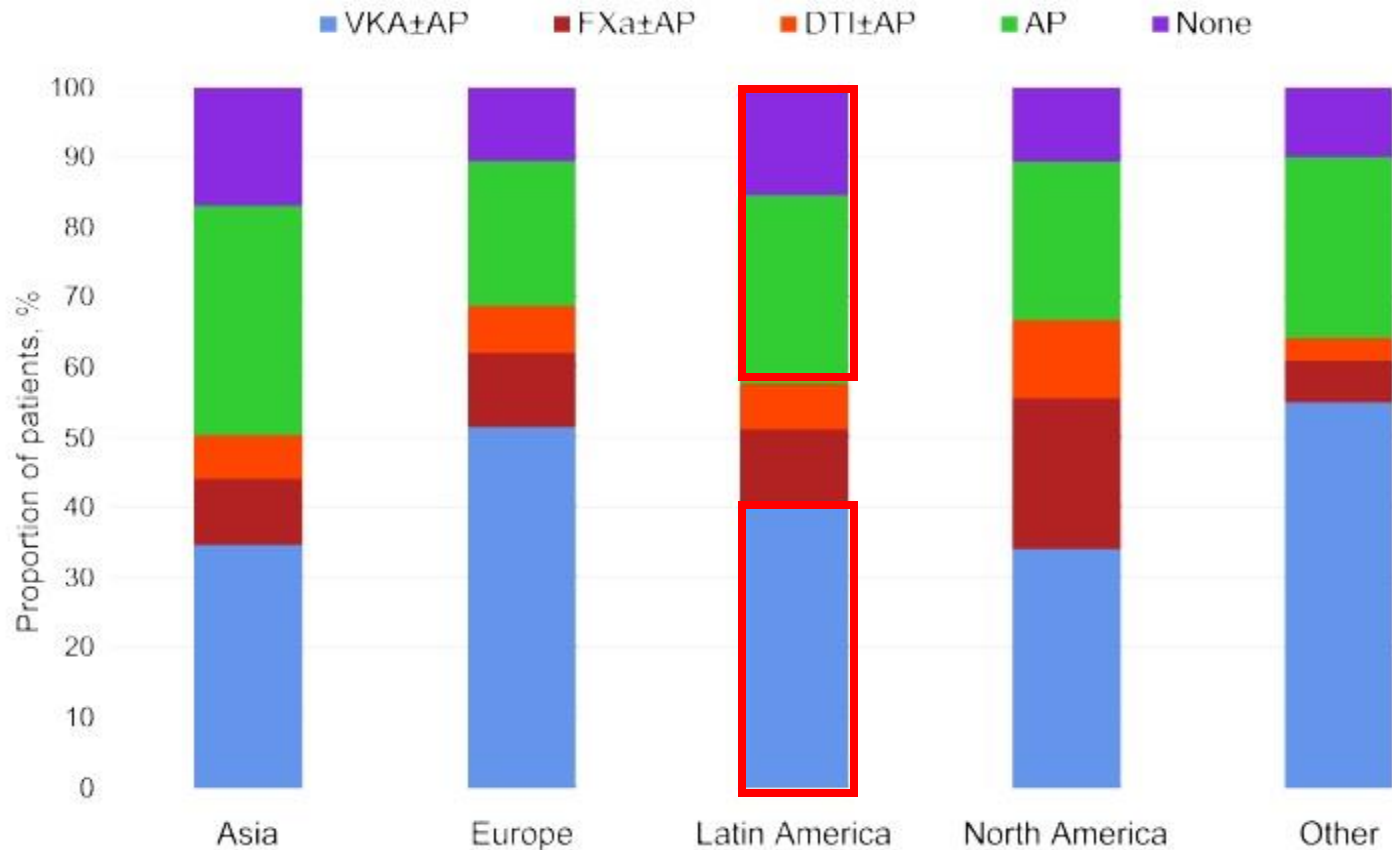


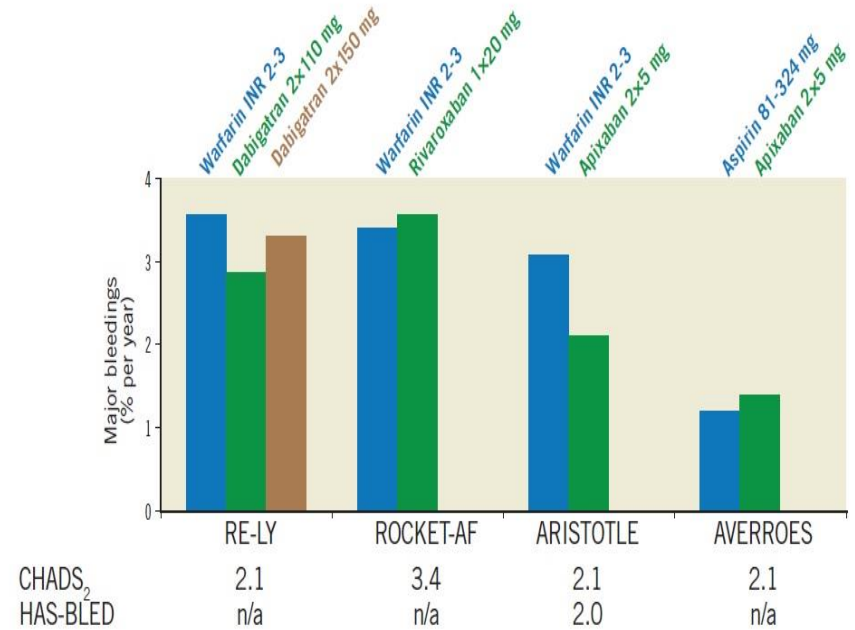
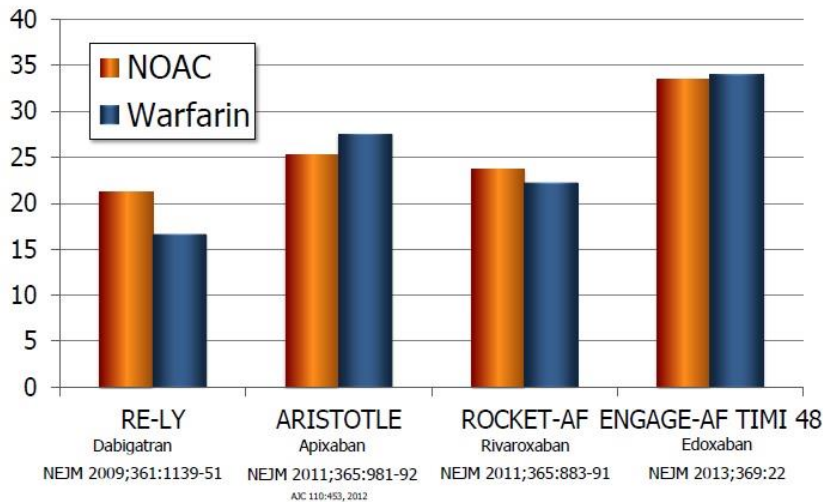
Figure provided courtesy of Lord Ajay K. Kakkar, MD, PhD.  |  CARDIOLOGY

# Antithrombotic treatment in patients with AF by region



# Limitaciones de NOACs

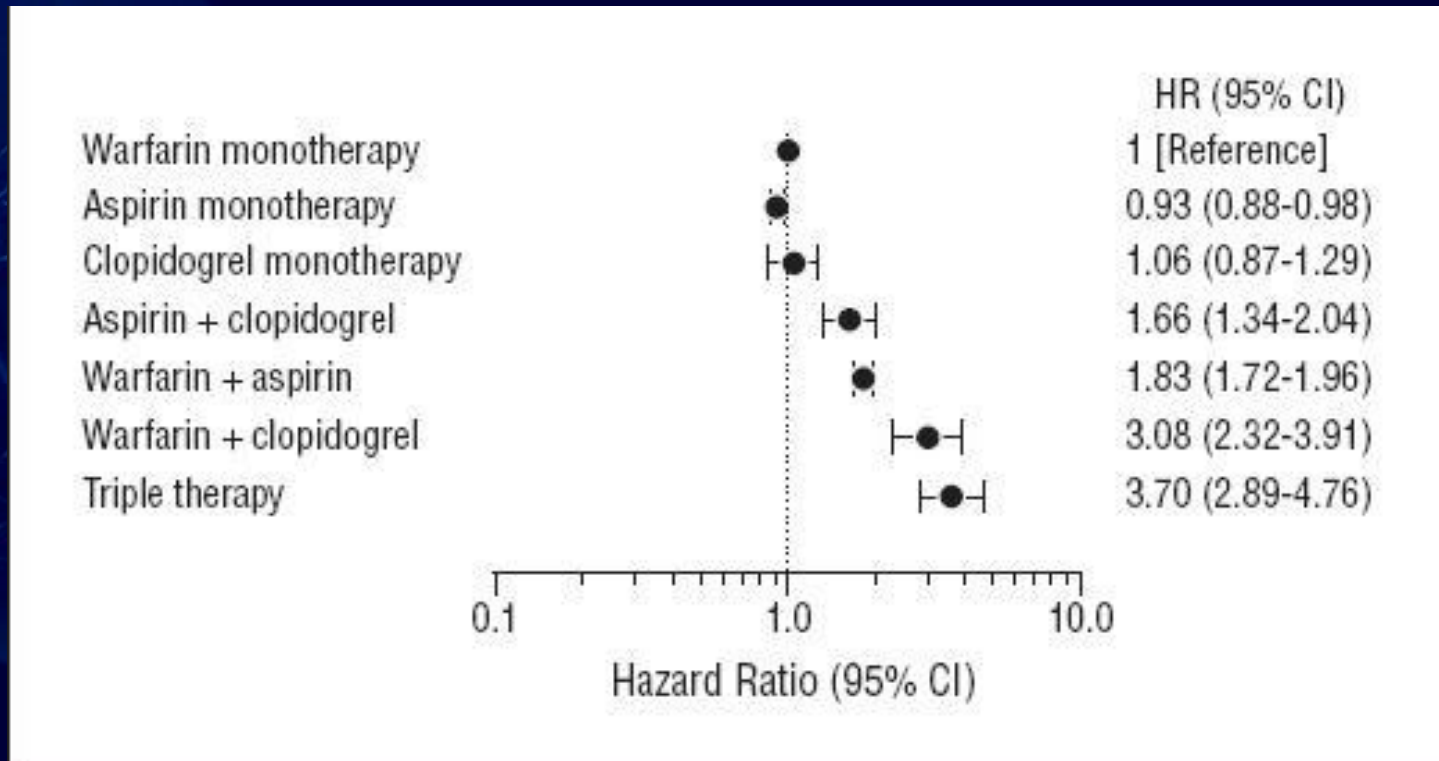
## Oral Anticoagulants DISCONTINUATION RATES



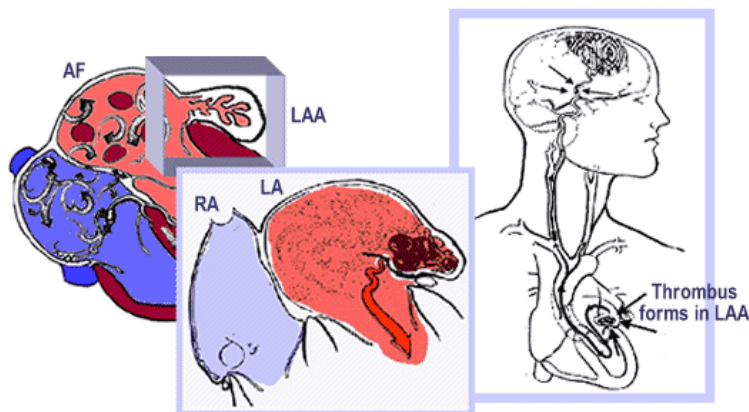


# Efecto de múltiples antitrombóticos sobre el riesgo de sangrado

Estudio de cohorte de 82854 pac en Dinamarca (13573 presentaron sangrado fatal o no fatal en el seguimiento a 2,6 años)



# Cuál es la fuente embolígena en pacientes con FA no reumática?



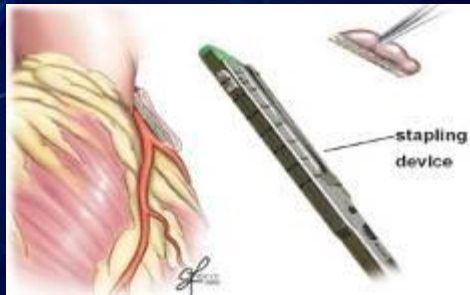
90% de los trombos localizaron en orejuela auricular izquierda

Setting	No. of Patients	Thrombus Location (n, %)		
		LA Appendage	LA Cavity	Total
TEE†	317	66 (20.8)	1 (0.3)	67 (21.1)
TEE	233	34 (14.6)	1 (0.4)	35 (15.0)
Autopsy	506	35 (6.9)	12 (2.4)	47 (9.3)
TEE	52	2 (3.8)	2 (3.8)	4 (7.7)
TEE	48	12 (25.0)	1 (2.1)	13 (27.1)
TEE and operation	171	8 (4.7)	3 (1.8)	11 (6.4)
ACUTE	549	67 (12.2)	9 (1.6)	76 (13.8)
TEE	272	19 (7.0)	0 (0)	19 (7.0)
TEE	60	6 (10.0)	0 (0)	6 (10.0)
<b>Total</b>	<b>2208</b>	<b>249 (11.3)</b>	<b>29 (1.3)</b>	<b>278 (12.6)</b>

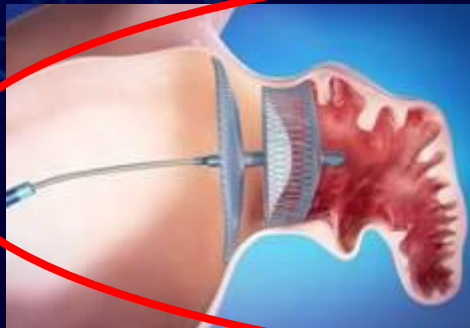
# Options for Stroke Prevention



- Pharmacological Management: Anticoagulants<sup>1</sup>
  - Effective: 67% stroke risk reduction
  - Management of narrow therapeutic window
  - Major complication: bleeding



- Surgical Excision of LAA<sup>2</sup> (Appendectomy)
  - Residual shunt: 10%
  - Inconsistent outcomes due to incomplete exclusion
  - Can create pouch with stagnant blood flow
  - High invasiveness



- Transcatheter Device Closure
  - Minimally invasive nature
  - Designed for percutaneous closure of the LAA in prevention of clot embolization that may form in the LAA
  - Intended as an alternative to warfarin therapy for patients with non-valvular atrial fibrillation

<sup>1</sup> Mobius-Winler, et al., Interventional treatments for stroke prevention in atrial fibrillation, Curr Opin Neurol 2008, 21(1): 64-69

<sup>2</sup> Dawson, et al., Should patients undergoing cardiac surgery with AF have LAA exclusion? Interactive Card.Vasc and Thoracic Surgery 10 (2010) 306-311

Cierre percutáneo de la orejuela  
auricular izquierda para prevención del  
ACV cardioembólico en pacientes con  
fibrilación auricular:

Resultados de los Estudios Clínicos

# Watchman™ Clinical Program

<b>Pilot</b>	Early feasibility with >6 years of follow-up	n=66
<b>PROTECT-AF</b>	Watchman™ primary efficacy, CV death, and all-cause mortality superior to warfarin at 4 years	n=707
<b>CAP Registry</b>	Significantly improved safety results	n=566
<b>ASAP</b>	Expected rate of stroke reduced by 77% in patients contraindicated to warfarin	n=150
<b>PREVAIL</b>	Improved implant success procedure safety confirmed with new and experienced operators	n=461
<b>CAP2</b>	Currently enrolling up to 750 patients at ~60 sites	n=537
<b>EWOLUTION</b>	Currently enrolling ~1000 patients, 50 sites, 16 countries	n=58
<b>WASP</b>	Currently enrolling ~300 patients, 6 Asia-Pacific countries	n=25

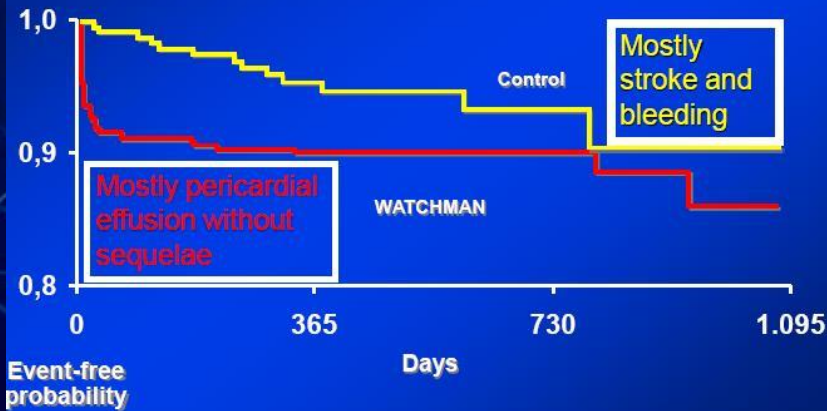
*Over 2500 patients with >5000 patient-years of follow-up*

03.17.2014

# PROTECT - AF

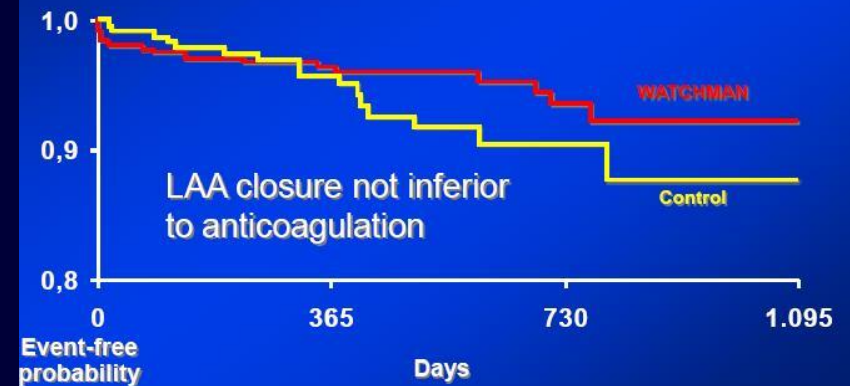
## Safety

Freedom from device embolization, pericardial effusion, Severe bleeding



## Primary Efficacy Endpoint

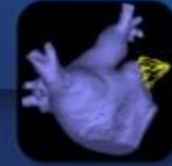
Freedom from Stroke, Death, Systemic Embolization



Holmes D; Lancet 2009

# Watchman™

## PROTECT AF 4-Year Data



Reddy VY: LBCT HRS 2013

## 2012 focused update of the ESC Guidelines for the management of atrial fibrillation

### Recommendations for LAA closure/occlusion/excision

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
Interventional, percutaneous LAA closure may be considered in patients with a high stroke risk and contraindications for long-term oral anticoagulation.	IIb	B	115, 118
Surgical excision of the LAA may be considered in patients undergoing open heart surgery.	IIb	C	



Original Investigation

## Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation: A Randomized Prospective Randomized Evaluation of the Watchman Left Atrial Appendage Closure Device

Vivek Y. Reddy, MD, Horst Sievert, MD, Petr Neuzil, MD, PhD, Kenneth H. Nicola, MD, Nicole Gordon, BSEE, David Holm

Prospective Randomized Evaluation of the Watchman Left Atrial Appendage Closure Device



Atrial Fibrillation Long-Term Outcomes: The PREVAIL Study

David R. Holmes Jr, MD, Shephal K. Doshi, MD, et al.

Left atrial appendage occlusion for stroke prevention in atrial fibrillation: multicentre experience with the AMPLATZER Cardiac Plug

Apostolos Tzikas<sup>1,2\*</sup>, MD; Sergio Berti<sup>3</sup>, MD; Genaro Jens Erik Nielsen-Kudsk<sup>4</sup>, MD; Prapa Kanagaratnam<sup>1,5</sup>, MD; Xavier Freixa<sup>6,7,8</sup>, MD; Friederike Stock<sup>9</sup>, MD; Wolfgang Schillinger<sup>12</sup>, MD

Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry

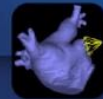
Lucas V.A. Boersma<sup>1\*</sup>, Boris Schmidt<sup>2</sup>, Timothy R. Betts<sup>3</sup>, Horst Sievert<sup>4</sup>, Corrado Tamburino<sup>5</sup>, Emmanuel Teiger<sup>6</sup>, Evgeny Pokushalov<sup>7</sup>, Stephan Kische<sup>8</sup>, Thomas Schmitz<sup>9</sup>, Kenneth M. Stein<sup>10</sup> and Martin W. Bergmann<sup>11</sup>, on behalf of the EWOLUTION investigators

# Prospective Randomized Evaluation of the Watchman Left Atrial Appendage Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy

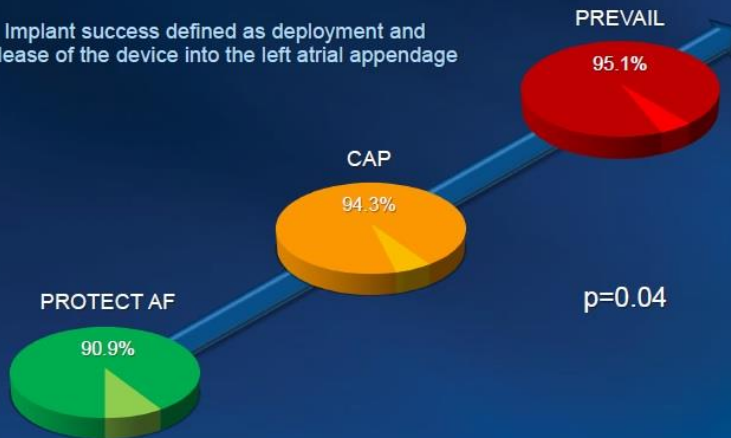
The PREVAIL Trial

David R. Holmes Jr, MD,\* Saibal Kar, MD,† Matthew J. Price, MD,‡ Brian Whisenant, MD,§ Horst Sievert, MD,¶ Shephal K. Doshi, MD,¶ Kenneth Huber, MD,# Vivek Y. Reddy, MD\*\*

## Watchman™ Implant Success



Implant success defined as deployment and release of the device into the left atrial appendage



Reddy VY: Circ 2011;123:417-424  
Holmes DR: CIT 2013

## Watchman™ Procedure Related Complications

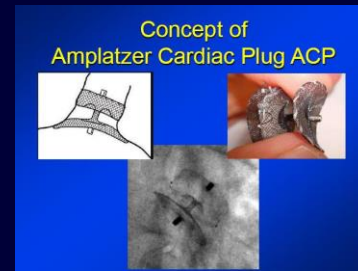
Composite cardiac perforation, pericardial tamponade, ischemic stroke, device embolization, and other vascular complications @ 7 days



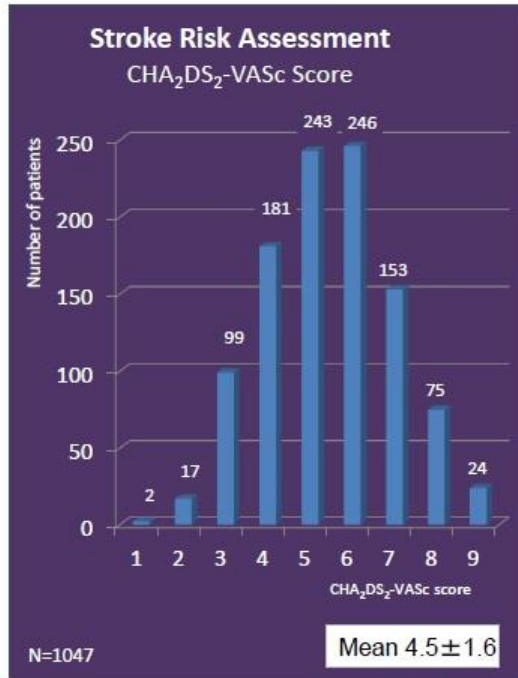
Composite of vascular complications includes cardiac perforation, pericardial effusion with tamponade, ischemic stroke, device embolization, and other vascular complications (Device-related @ 7 days)

# Multicenter Experience with the Amplatzer Cardiac Plug (ACP)

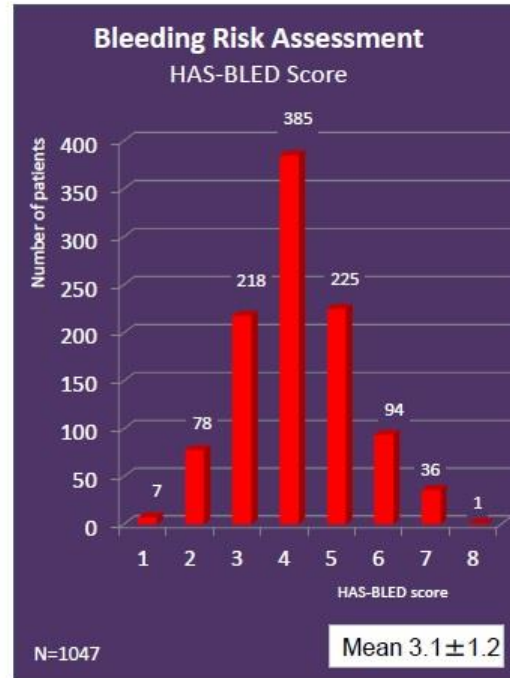
- To investigate the safety, feasibility, and efficacy of LAAO with the ACP for stroke prevention in patients with AF
- Prospectively collected, retrospectively analyzed, nonrandomized, multicenter study
- Real-life experience of 21 European & 1 Canadian center



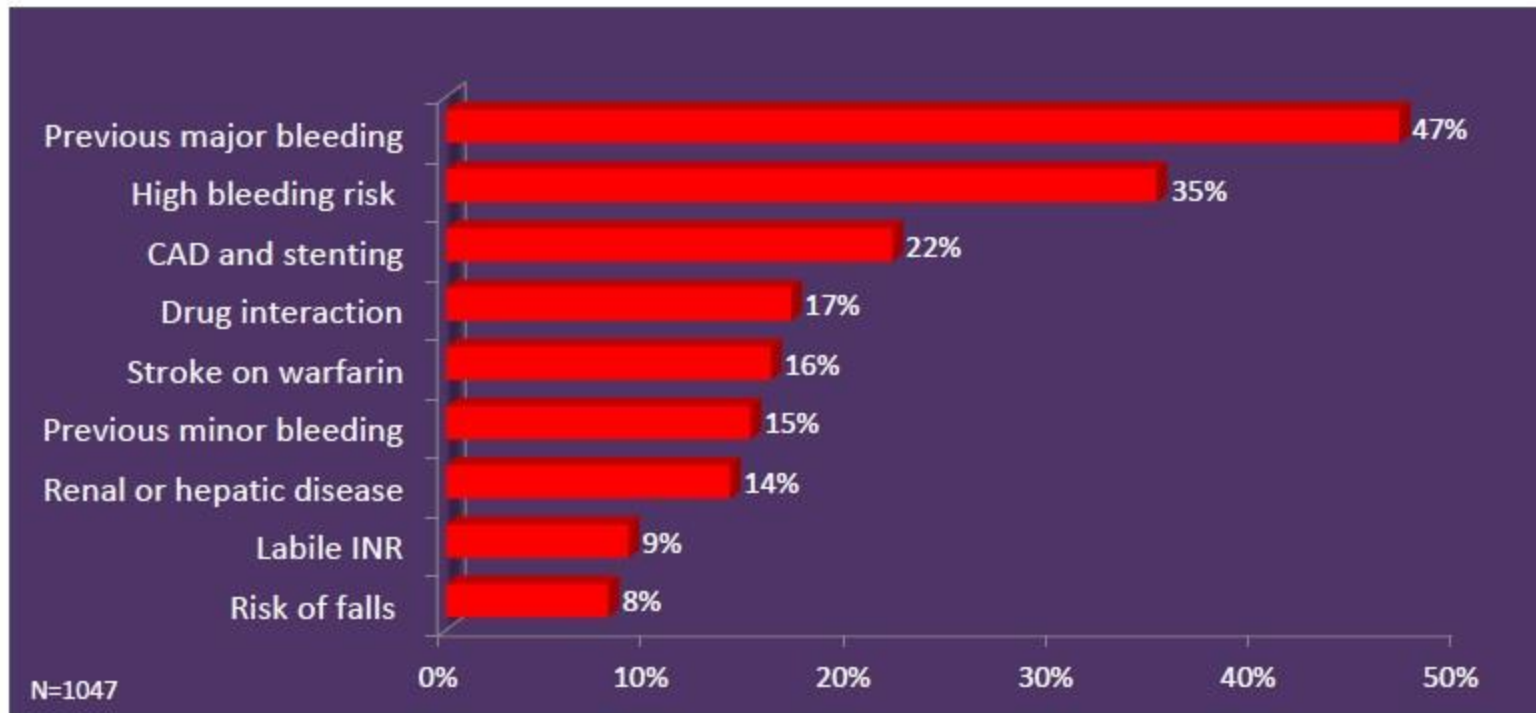
## Risk assessment



CHADS<sub>2</sub> Score=2.8±1.3



# Indications for LAAO



Composite of previous bleeding (major or minor) and high bleeding risk = 73%

## Implant Results

### Success rates

- 97.3% (1019/1047) attempted were successfully implanted
- In 93.3%, first device selected was implanted

### Implanted ACP size



Access	
TSP	90.7%
PFO	9.3%

Combined Procedure	
Coronary angiography	10.2%
PFO closure	5.8%
PCI	5.2%
AF ablation	1.7%
TAVI	1.5%
ASD closure	1.0%
Mitra-Clip	0.6%
<b>Total</b>	<b>20.6%</b>

## Peri-procedural complications

- MAEs: Acute (7-day) occurrence of death, ischemic stroke, systemic embolism and procedure or device related complications requiring major cardiovascular or endovascular intervention\*

MEA	N	%
Death	8	0.76%
Pericardial tamponade	13	1.24%
Major bleeding	13	1.24%
Stroke	9	0.86%
Device embolization	1	0.10%
MI	1	0.10%
<b>Total</b>	<b>45</b>	<b>4.30%</b>

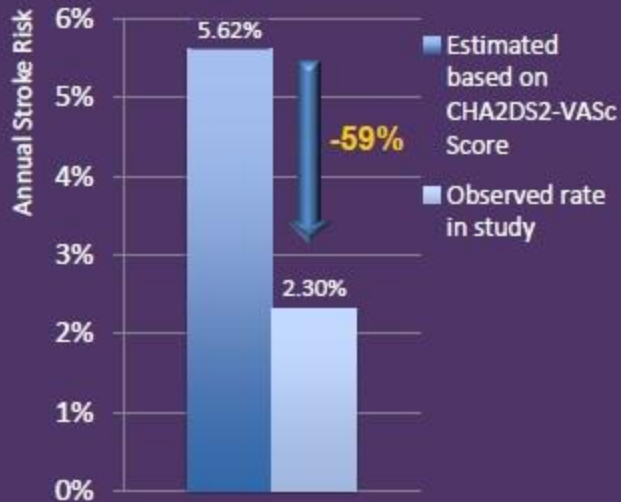
N=1047

Complication	N	Remarks
Major (IC) bleeding	1	Procedure
Pericardial tamponade	2	Procedure, Day 4
Arrhythmia	1	Day 2
STEMI, hypoxia	1	Day 13
Device embolization	2	Procedure, Day 6
Pneumonia	1	Day 10

\* Holmes et al. ACC 2013 (PREVAIL Study)

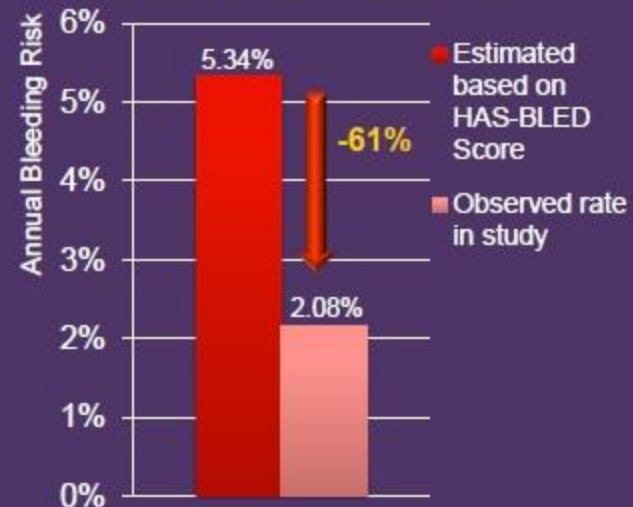
# Results

## Effectiveness in Stroke Reduction vs Estimated



Total Patients	Total Patient Years	CHA <sub>2</sub> DS <sub>2</sub> -VASc Score
1001	1349	4.43
Estimated Stroke Rate per CHA <sub>2</sub> DS <sub>2</sub> -VASc		Actual Annual Stroke Rate (N strokes + TIA)
5.62%		2.30% (31)

## Effectiveness in Bleeding Reduction vs Estimated



Total Patients	Total Patient Years	HAS-BLED Score
1001	1349	3.12
Estimated Bleeding Rate per HAS-BLED		Actual Annual Bleeding Rate (N major bleeds)
5.34%		2.08% (28)

TCT-689

### Percutaneous Closure Of The Left Atrial Appendage: Initial Experience In Latin America

Anibal A. Damonte<sup>1</sup>, Costantino Costantini<sup>2</sup>, Carlos Pedra<sup>3</sup>,  
Alejandro Martínez Sepúlveda<sup>4</sup>, Daniel Aguirre<sup>5</sup>, Fabio Brito<sup>6</sup>, Jose Condado<sup>7</sup>,  
Fernando Curá<sup>8</sup>, Leon Valdivieso<sup>9</sup>, Leandro I. Lasave<sup>1</sup>

<sup>1</sup>Instituto Cardiovascular de Rosario, Rosario, Argentina, <sup>2</sup>Hospital Cardiologico costantini, Curitiba, Brazil, <sup>3</sup>Instituto Dante Pazzanese, São Paulo, Brazil, <sup>4</sup>Hospital Clínico Pontificia Universidad Católica de Chile, Santiago, Chile, <sup>5</sup>Hospital de Niños Roberto del Río, Santiago, Chile, <sup>6</sup>Hospital Albert Einstein, São Paulo, Brazil, <sup>7</sup>centro medico de caracas, Caracas, Venezuela, <sup>8</sup>ICBA, Buenos Aires, Buenos Aires, <sup>9</sup>Fundación Favaloro, CABA, Argentina

**Background:** Atrial fibrillation (AF) is the most common cardiac arrhythmia and a major cause of morbidity and mortality secondary to cardioembolic stroke. Percutaneous closure of the left atrial appendage (LAA) has emerged as an alternative to anticoagulation therapy for the prevention of cerebrovascular events in patients with AF and a contraindication or difficulties for oral anticoagulation. This study describes the feasibility, in hospital and follow up results of the transcatheter closure of the LAA with the Amplatzer Cardiac Plug (ACP; StJude, Minneapolis; MN) in an initial Latin American experience.

**Methods:** Physician initiated voluntary registry, including 60 consecutive patients with AF at high risk for cardioembolic stroke, from different Latin American hospitals that were treated with the ACP, from August 2009 to June 2012. The procedures were performed under general anesthesia, transesophageal echocardiography (TEE) and fluoroscopic guidance. Clinical and TEE follow up was performed at 30 days, and clinical follow up thereafter.

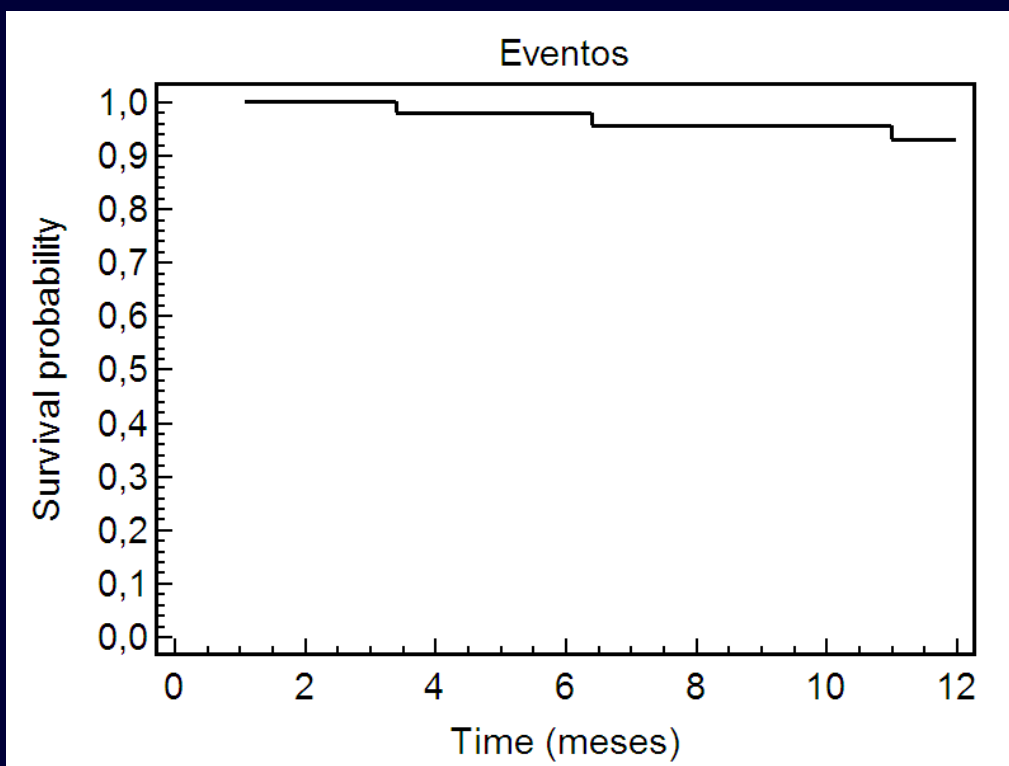
**Results:** 60 patients were included. Age  $72 \pm 8.7$  years; male 70%; hypertensive 78%; congestive heart failure 32.17%; CHADS2 score  $3.15 \pm 1.1$ ; contraindications to oral anticoagulation 64.3% LAA neck diameter was  $20.3 \pm 3.8$  mm by TEE and  $22.6 \pm 3.2$  by angiography. LAA occlusion was attempted and successfully achieved in all 60 patients, and in 3 cases, simultaneous closure of the LAA and PFO was performed. The implanted device size was  $25 \pm 2.9$  mm. There were serious in hospital complications in 5 patients (8.3%). 1 patient experienced device embolization that required surgical retrieval, and 4 (6.6%) patients presented severe pericardial effusion (SPE) requiring pericardiocentesis. For patients with (SPE) hospitalization was longer  $4.25 \pm 1.25$ , vs  $2.77 \pm 2.10$  days for patients without SPE  $p=0.174$ . There were not in hospital deaths, stroke, or myocardial ischemia. No new events were reported at 30 days clinical follow up. 88% of patients underwent TEE at 30-45 days without evidence of flow to the LAA or thrombus on device. Median follow up was 12.5 months, without strokes.

**Conclusions:** In this initial experience, percutaneous closure of the LAA with the ACP in patients with AF at high risk of stroke, was feasible, with a high technical success and in hospital complications rate similar to previous reports with these and other devices during the learning phase of the procedure. The results at follow up are encouraging.

Mean CHADS2 score 3,15

Expected annual risk of stroke 5,9%

Strokes at F/Up (Me 12,5 months) 0

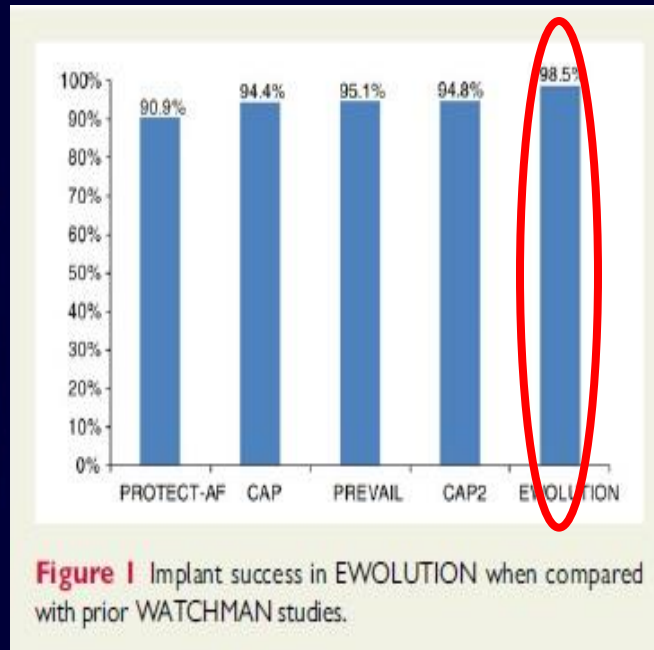


# Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry

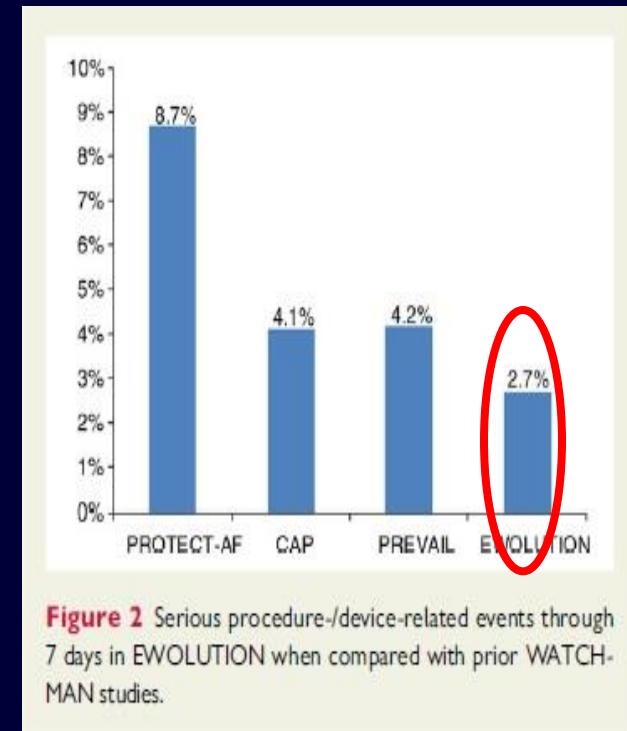
Lucas V.A. Boersma<sup>1\*</sup>, Boris Schmidt<sup>2</sup>, Timothy R. Betts<sup>3</sup>, Horst Sievert<sup>4</sup>, Corrado Tamburino<sup>5</sup>, Emmanuel Teiger<sup>6</sup>, Evgeny Pokushalov<sup>7</sup>, Stephan Kische<sup>8</sup>, Thomas Schmitz<sup>9</sup>, Kenneth M. Stein<sup>10</sup> and Martin W. Bergmann<sup>11</sup>, on behalf of the EWOLUTION investigators

**Table 1** Baseline characteristics

Characteristic	Summary statistics
Not eligible for OAT	61.8% (627/1014)
Age at time of consent (years)	73 ± 9
Median (range)	75 (39, 94)
Age ≥75	50.8% (519/1021)
Female gender	40.1% (409/1021)
History of TIA	10.7% (108/1014)
History of ischaemic stroke	19.7% (200/1014)
Congestive heart failure	34.2% (347/1014)
History of hypertension	81.7% (828/1014)
Diabetes	
Type I	1.3% (13/1014)
Type II	28.3% (287/1014)
Previous haemorrhagic stroke	15.0% (152/1014)
Vascular disease	41.8% (423/1013)
Abnormal renal function	15.6% (158/1014)
Abnormal liver function	4.2% (43/1014)
History of major bleeding	31.2% (316/1013)
Prior major bleeding or predisposition to bleeding	38.7% (392/1013)
Labile INRs	17.0% (172/1014)
Concomitant use of drugs	27.8% (282/1014)
Alcohol abuse	4.2% (43/1014)



**Figure 1** Implant success in EWOLUTION when compared with prior WATCHMAN studies.

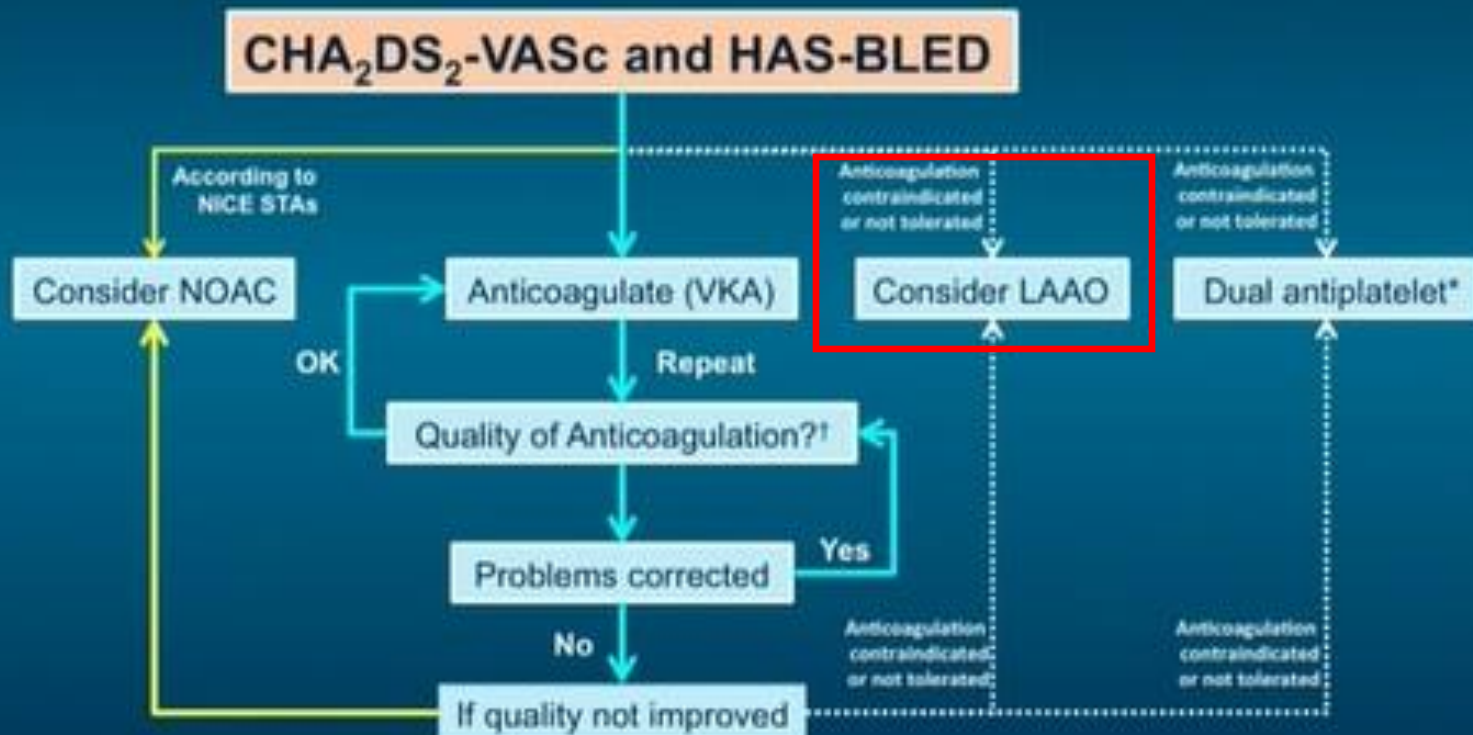


**Figure 2** Serious procedure-/device-related events through 7 days in EWOLUTION when compared with prior WATCHMAN studies.



# NICE 2014 AF Guidelines

## Algorithm 1: Stroke Prevention



<sup>1</sup> Poor anticoagulation = 2 INR >5 or 1 INR >8 within past 6 m, 2 INR values <1.5 within the past 6 m, TTR less than 65%

<sup>2</sup> Do not use aspirin monotherapy for stroke prevention in atrial fibrillation

NICE 2014<sup>1,2</sup>



March 13, 2015

Ms. Jennifer Bolton  
Regulatory Fellow  
Boston Scientific Corporation  
One Scimed Place  
Maple Grove, MN 55311-1566

Re: P130013  
WATCHMAN LAA Closure Technology  
Filed: May 14, 2013  
Procode: NGV

Dear Ms. Bolton:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the WATCHMAN LAA Closure Technology. This device is indicated to reduce the risk of thromboembolism from the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for warfarin; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

**FDA** U.S. Food and Drug Administration  
Protecting and Promoting *Your Health*

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#### Products and Medical Procedures

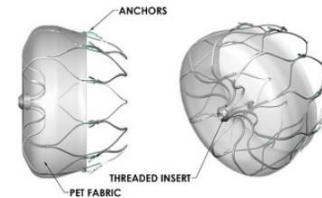
Device Approvals and Clearances

Recently-Approved Devices

2015 Device Approvals

2014 Device Approvals

## WATCHMAN LAA Closure Technology - P130013

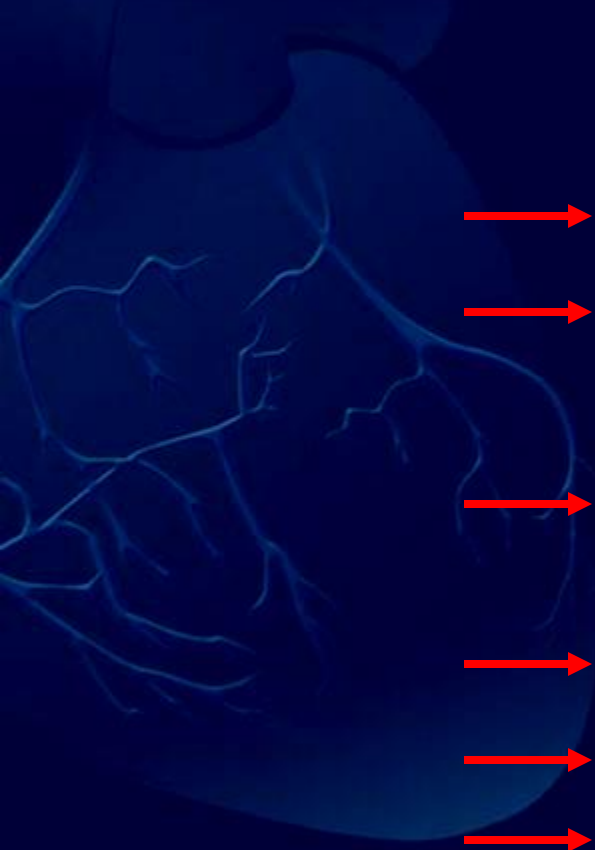


This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** WATCHMAN LAA Closure Technology  
**PMA Applicant:** Boston Scientific Corporation  
**Address:** One Scimed Place, Maple Grove, MN 55331-1566  
**Approval Date:** March 13, 2015

# An update and current expert opinions on percutaneous left atrial appendage occlusion for stroke prevention in atrial fibrillation

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**Table 4** Conditions in which percutaneous LAA occlusion may be considered

Condition	Details
Recurrent ischaemic stroke despite well-controlled therapeutic OAC	Percutaneous LAA occlusion may be considered after exclusion of other sources of embolism
Previous ICH	Percutaneous LAA occlusion may be considered as an alternative to the use of novel anticoagulants, acknowledging individual patient factors, and bleeding aetiology
Recurrent GI bleeding	Bleeding from unknown origin or intestinal angiodysplasia despite endoscopic therapy. Lesions that are not accessible for endoscopic therapy
Co-morbidities	Uncontrolled hypertension, cerebral microbleeds, cerebral amyloid angiopathy
Coagulopathies	Low platelet counts, myelodysplastic syndrome
Intolerance to new OAC drugs	GI intolerance, severe liver and kidney dysfunction. Vitamin K antagonists are the first option to consider, percutaneous LAA occlusion may be considered as a secondary alternative

# Clinical case 2: ICH on OAC

**76 year-old** male.

History of **hypertension**.

Previous AMI, CABG in 1999

Chronic atrial fibrillation since 2007,  
on chronic anticoagulation therapy.

Hospitalized in 2009 for **CHF**.

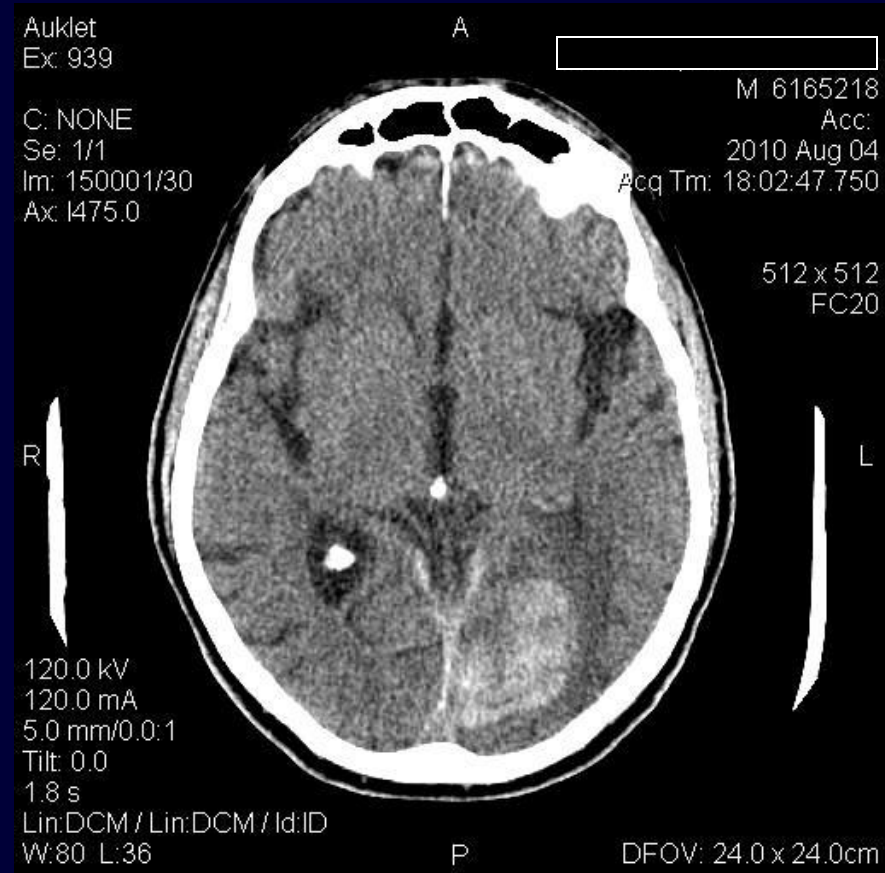
He was admitted in August 2010 with  
ICH

**Diagnosis:** Chronic AF

**CHADS2 Score 3**

Contraindication to ACO

**Plan:** Closure of LAA with the ACP



## LAA occlusion vs. standard care in patients with atrial fibrillation and intracerebral hemorrhage

A propensity score matched follow-up study

Jens Erik Nielsen-Kudsk, Ass. Prof., MD, DMSc  
Dept. Cardiology, Aarhus University Hospital, Skejby  
Denmark



## Patient characteristics

Characteristics (propensity score matched patients)	Standard care (n=147)	LAAO (n=147)
Age, mean (SD)	73.3 (9.1)	71.9 (8.7)
Gender (male) n (%)	97 (66.0)	96 (65.0)
CHA <sub>2</sub> DS <sub>2</sub> -VASc mean (SD)	4.0 (1.5)	3.9 (1.5)
HAS-BLED mean (SD)	4.2 (0.8)	4.2 (0.8)
<b>Antithrombotic treatment</b>	(during follow-up)	(at latest follow-up)
Warfarin	20%	0%
NOAC	23%	0%
Platelet inhibitors	37%	71%
No treatment	44%	29%

Median follow-up time: 166 days (25%/75% quartile: 70/458 days)

Median time from ICH to LAAO: 189 days (25-4533 days)

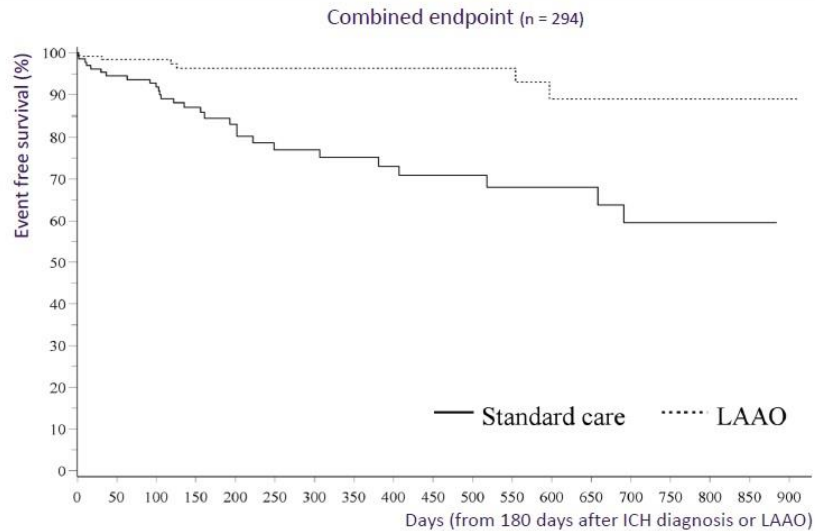
## LAA occlusion vs. standard care in patients with atrial fibrillation and intracerebral hemorrhage

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### euro PCR Ischemic stroke/major bleeding/mortality



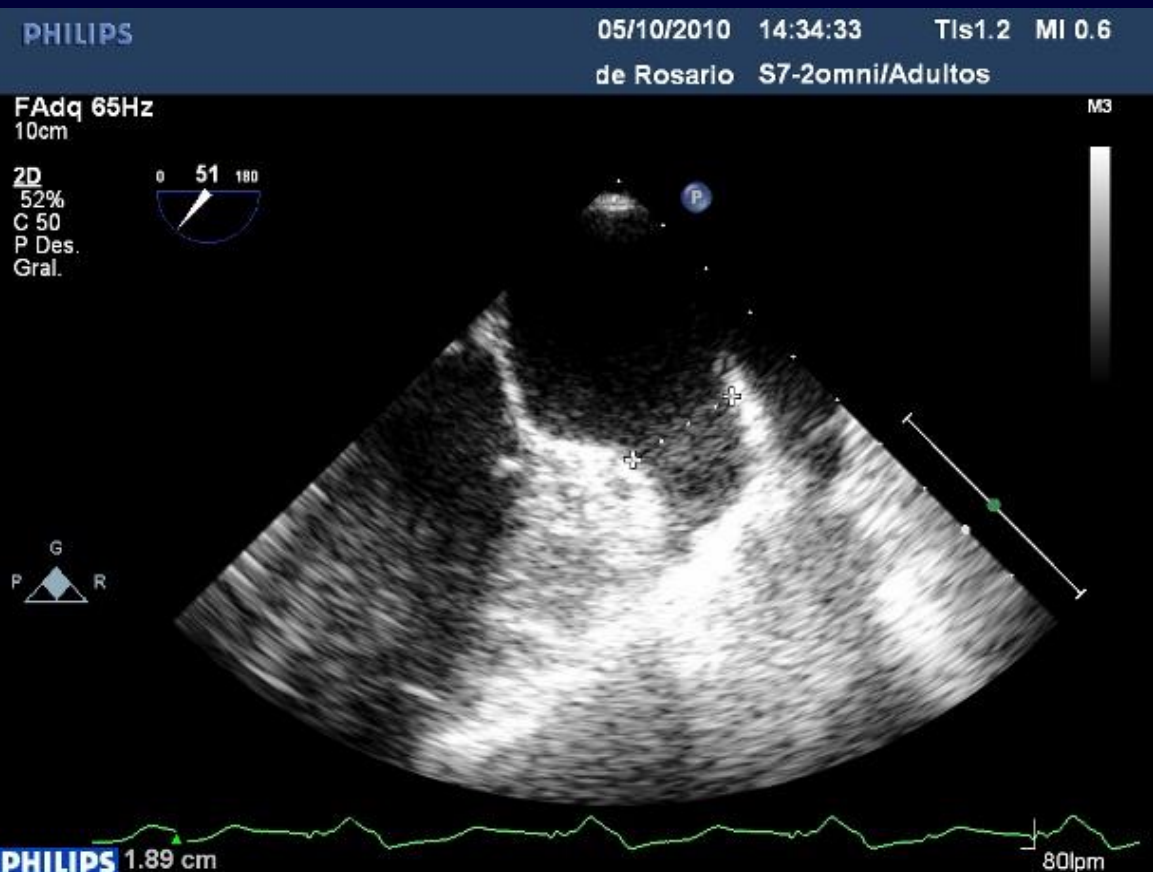
### euro PCR

### Hazard ratios

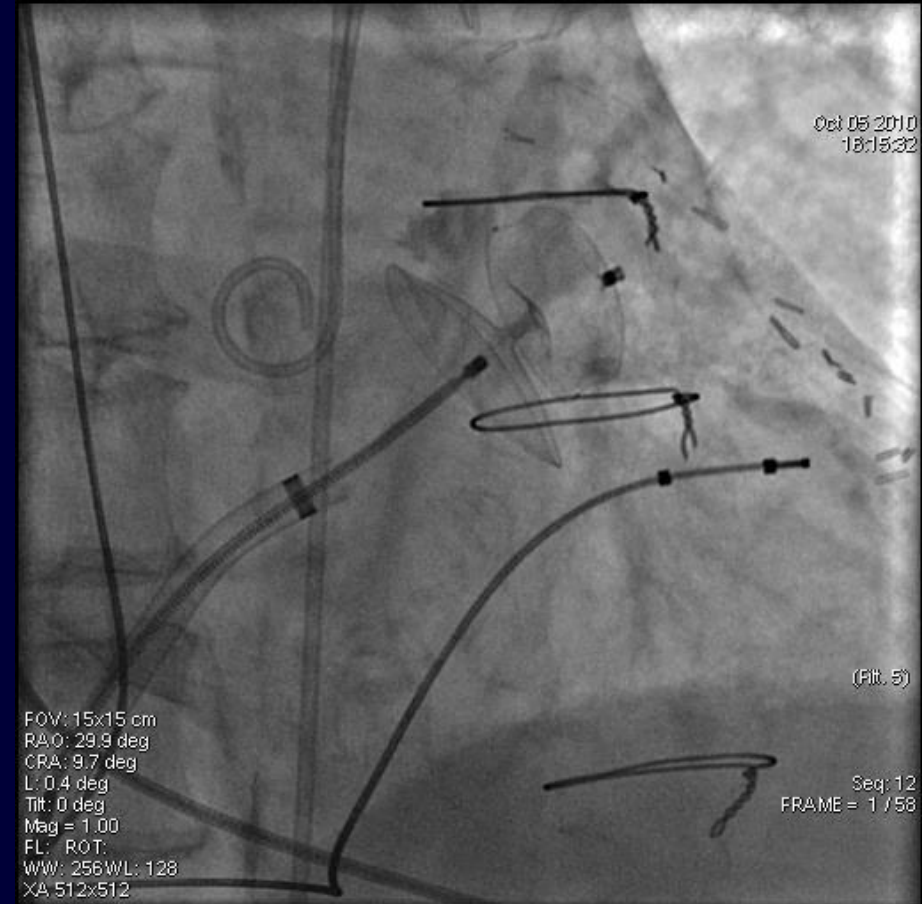
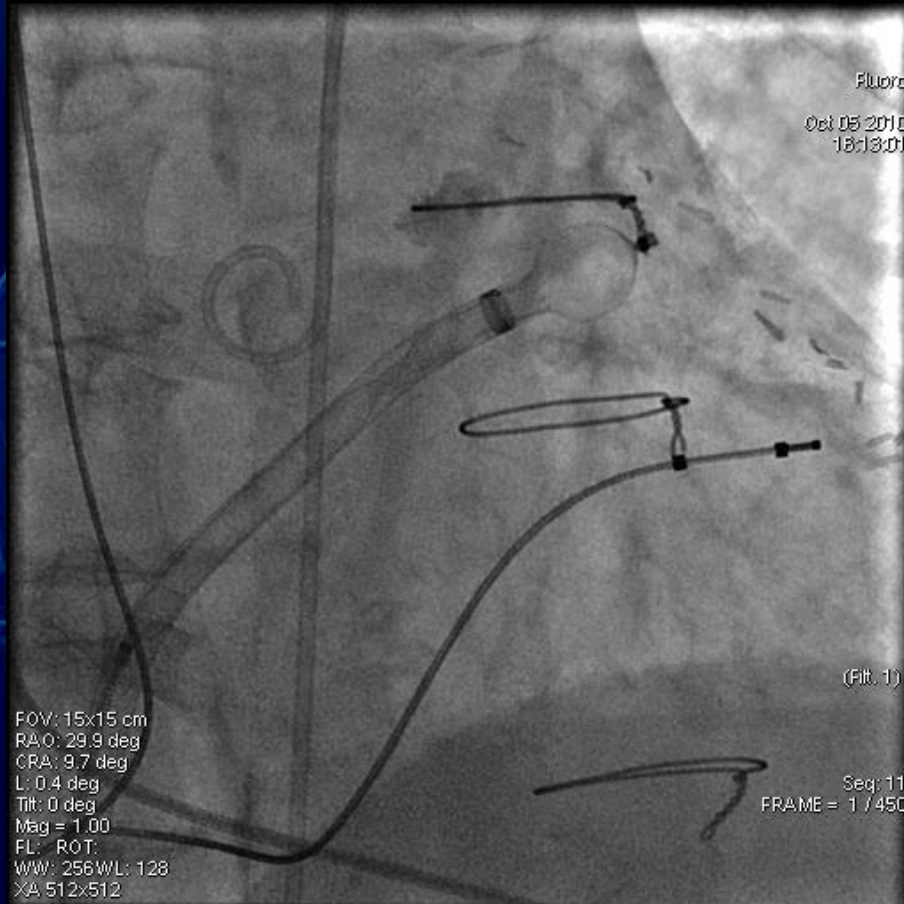
Clinical outcome HR by Cox-regression analysis n = 147 in each PS-matched patient group	LAAO vs. Standard care Hazard ratio (95% CI)	Relative risk reduction (%)
<b>Ischemic stroke/major bleeding/mortality</b>	<b>0.19 (0.08-0.46)*</b>	<b>81%</b>
Ischemic stroke	0.35 (0.07-1.79)	65%
Major bleeding	0.39 (0.12-1.28)	61%
ICH	0.29 (0.03-2.82)	71%
Mortality	0.08 (0.02-0.32)*	92%

\*p<0.05

# LAA dimensions: Angio vs TEE



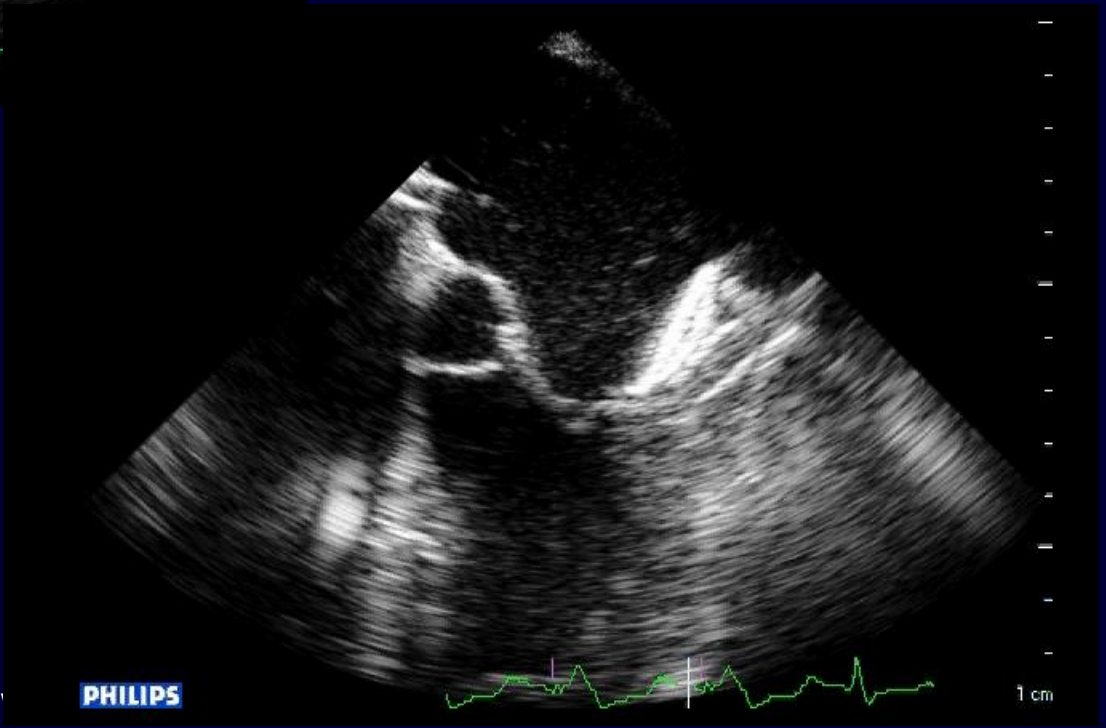
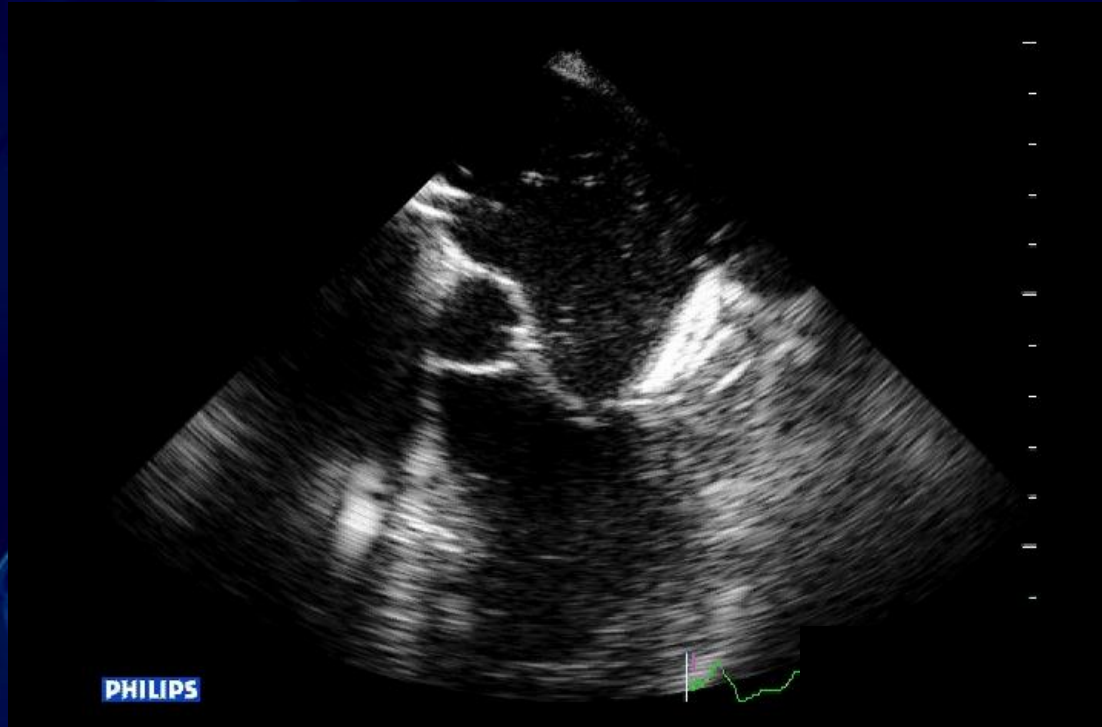
# Device Deployment





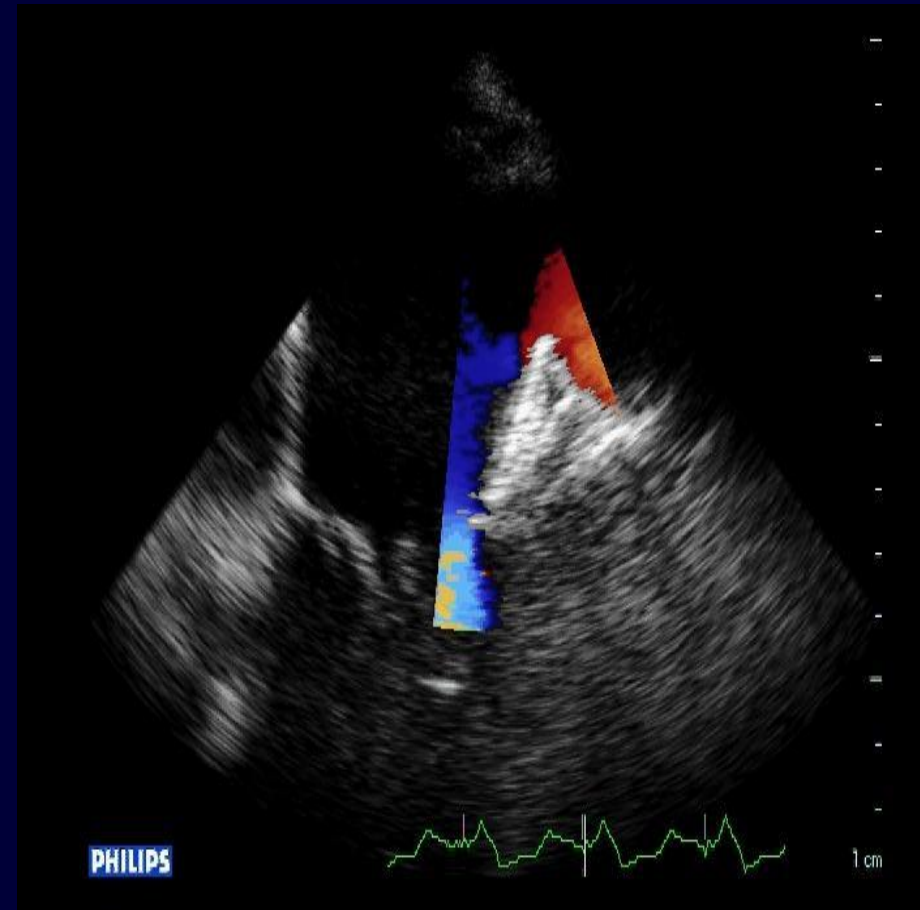
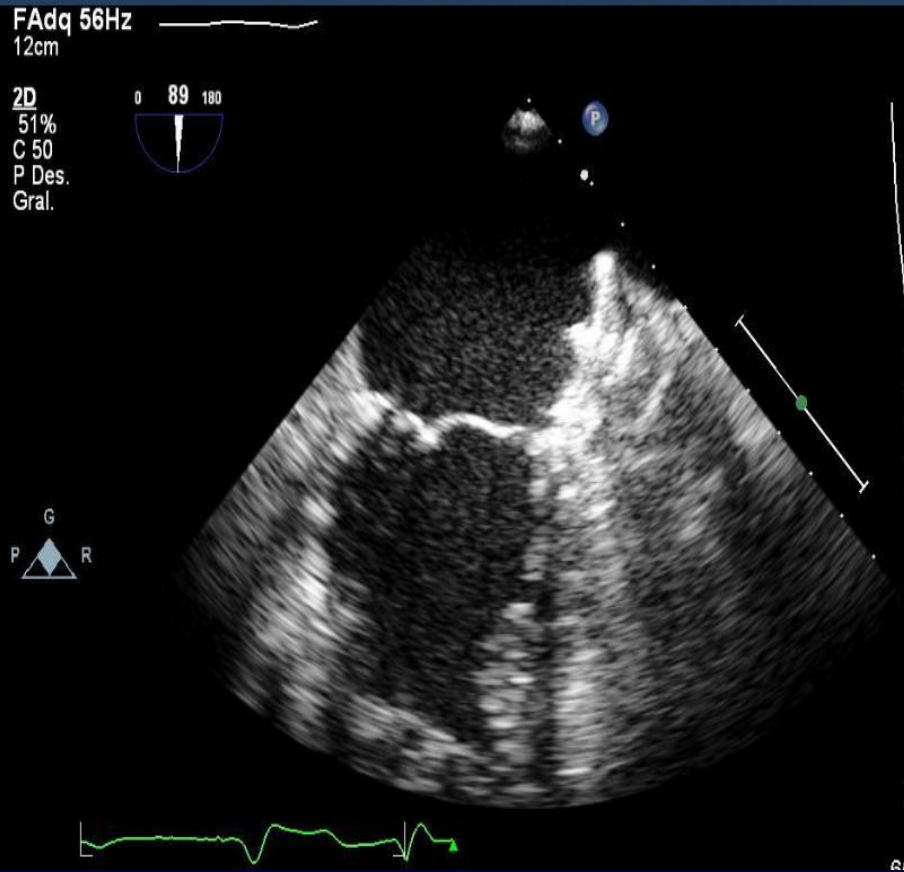


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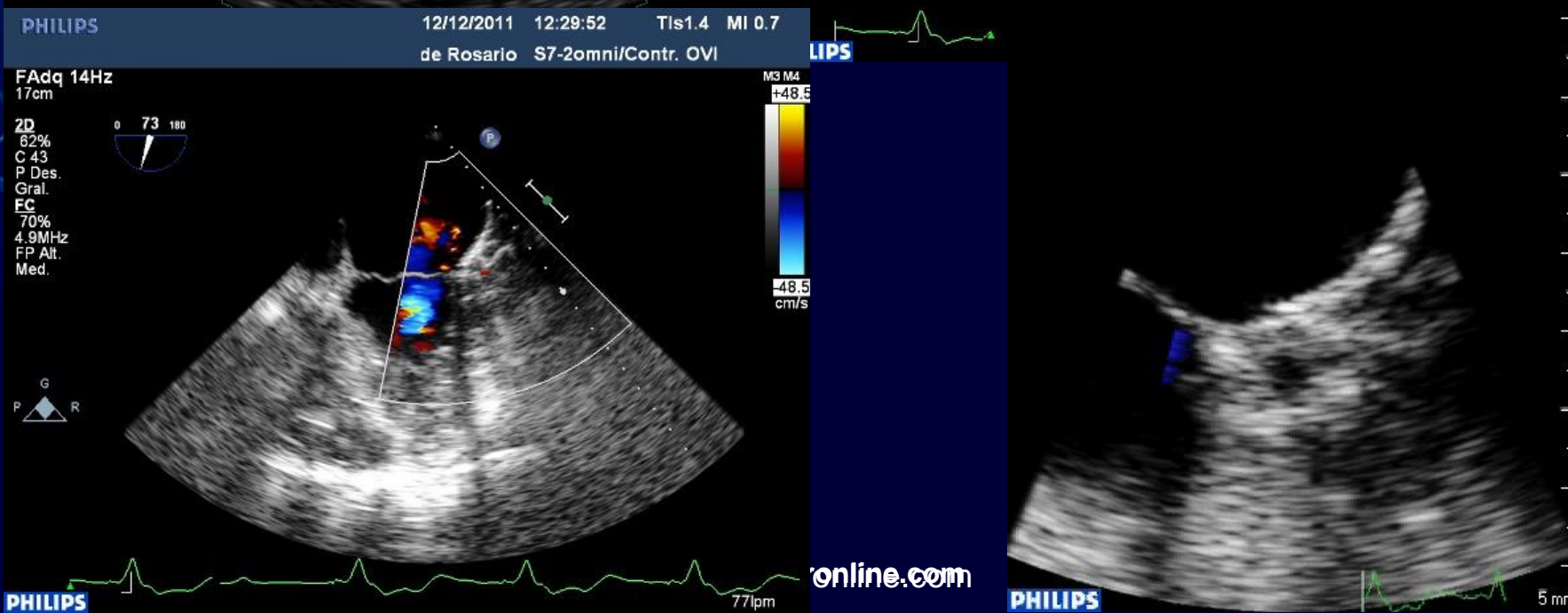


# TEE at 45 days

16210820101112 Inst. Cardiovas de Rosario S7-2omni/Adultos



# TEE at >1 year



# Clinical case 3: Recurrent GI bleeding

- **76 year-old** male patient, former smoker, with a history of **hypertension** and **alcohol abuse**.
- Recurrent episodes of paroxysmal atrial fibrillation for 3 years.
- Permanent atrial fibrillation during the last 9 months, under pharmacologic treatment for rate control.
- Rendu Osler Weber disease with **multiple episodes of gastrointestinal bleeding and chronic anemia**.
- CHA<sub>2</sub>DS<sub>2</sub>VASC: 3
- HASBLED: 4
- Referred to our hospital for left atrial appendage (LAA) occlusion.

# LAA closure procedure

- Transeptal puncture under transesophageal echo (TEE) guidance



- Angiographic and TEE measurements



Angiography:  
Orifice 26mm  
Neck 22mm

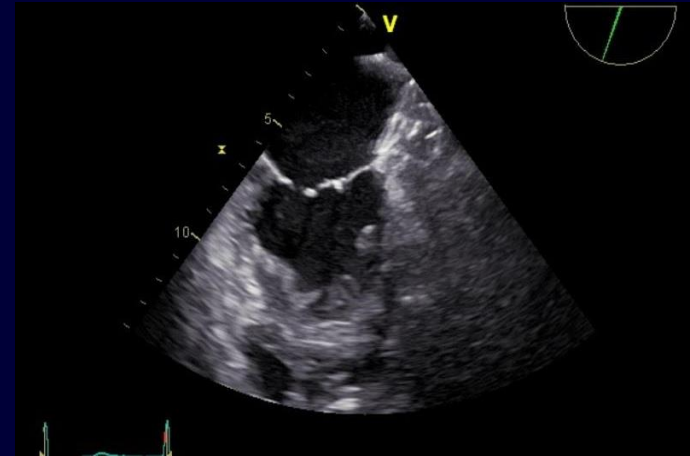
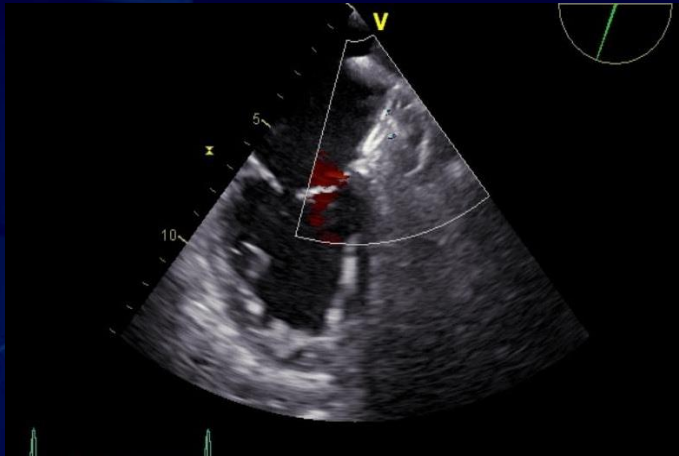
TEE:  
Orifice 28mm  
Neck 21mm

# LAA closure procedure

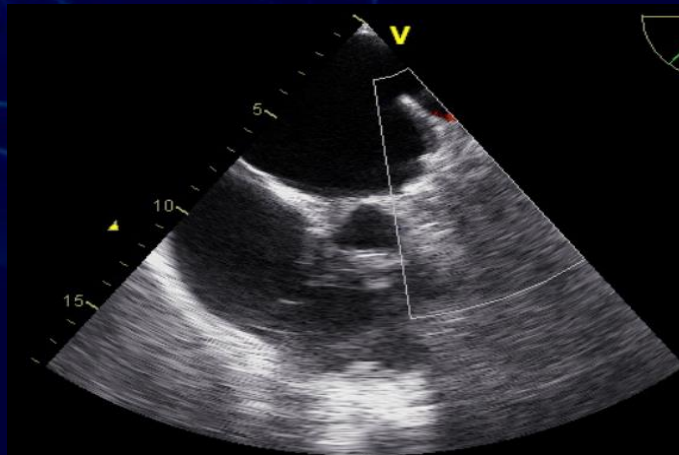


Final angio after deployment of  
a 24m ACP device

- Final TEE evaluation



- 30 days post procedure TEE



# Caso Clínico

- Paciente de 83 años, masculino, HTA, abuso ingesta de alcohol
- Reemplazo valvular aórtico con prótesis biológica N°23 en 01/2005
- FA permanente en control de FC y tto ACO
- MCP 09/2013
- 01/2014 IVAT CoreValve N°26 por reestenosis severa sintomática, de bioprótesis quirúrgica.
- 01/2015 internación por sangrado digestivo >, secundario a lesión de Dieulafoy en techo gástrico, tratado por endoscopia. Alta chance de resangrado
- **CHA<sub>2</sub>DS<sub>2</sub>VASC: 4**
- **HASBLED: 4**
- Referido por médico de cabecera para cierre de OAIzquierda.

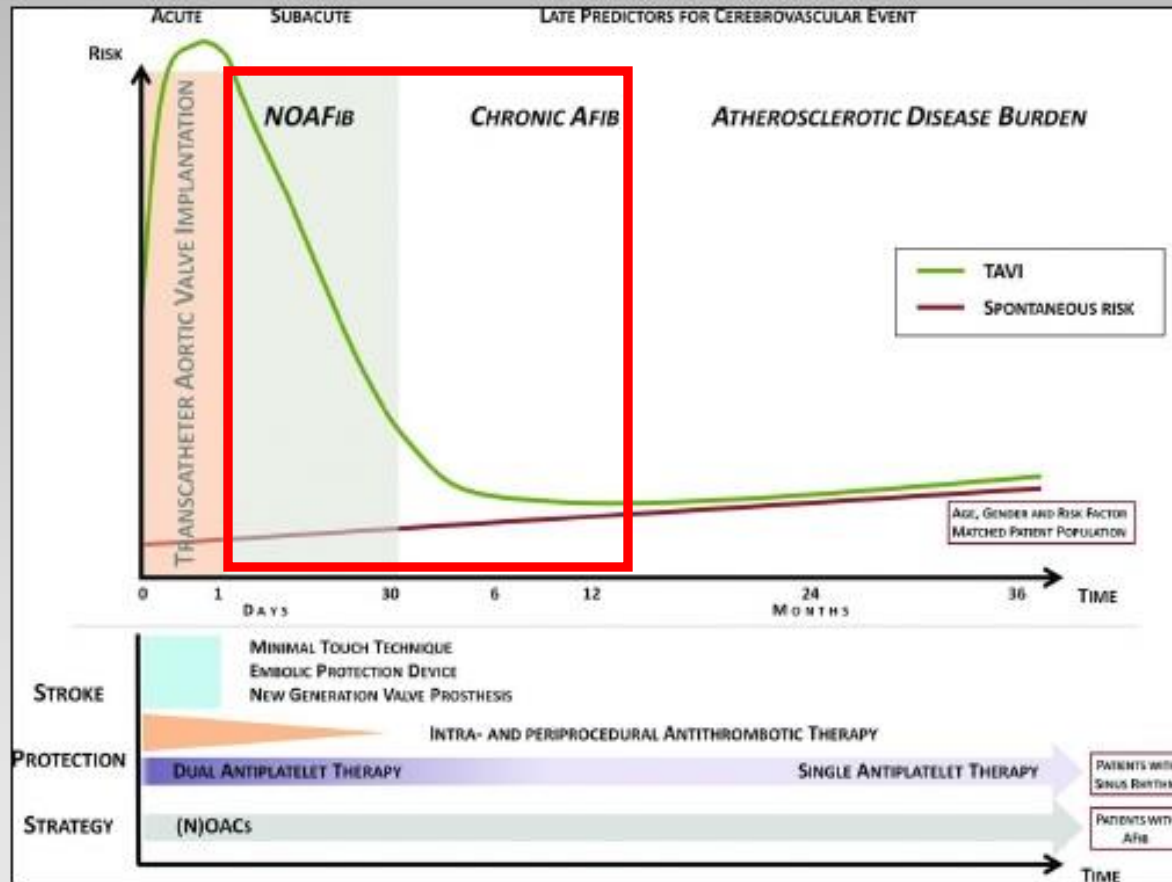


# Frecuencia de FA en estudios de IVAT

<b>Trial</b>	<b>Baseline AF</b>	<b>New AF 30 d</b>	<b>New AF 1 yr</b>
<b>PARTNER IA</b>	<b>40.8%</b>	<b>8.6%</b>	<b>12.1%</b>
<b>PARTNER IB</b>	<b>32.9%</b>	<b>0.6%</b>	<b>0.6%</b>
<b>CoreValve High-Risk</b>	<b>41.0%</b>	<b>11.7%</b>	<b>15.9%</b>
<b>CoreValve Extreme Risk</b>	<b>46.8%</b>	<b>--</b>	<b>--</b>

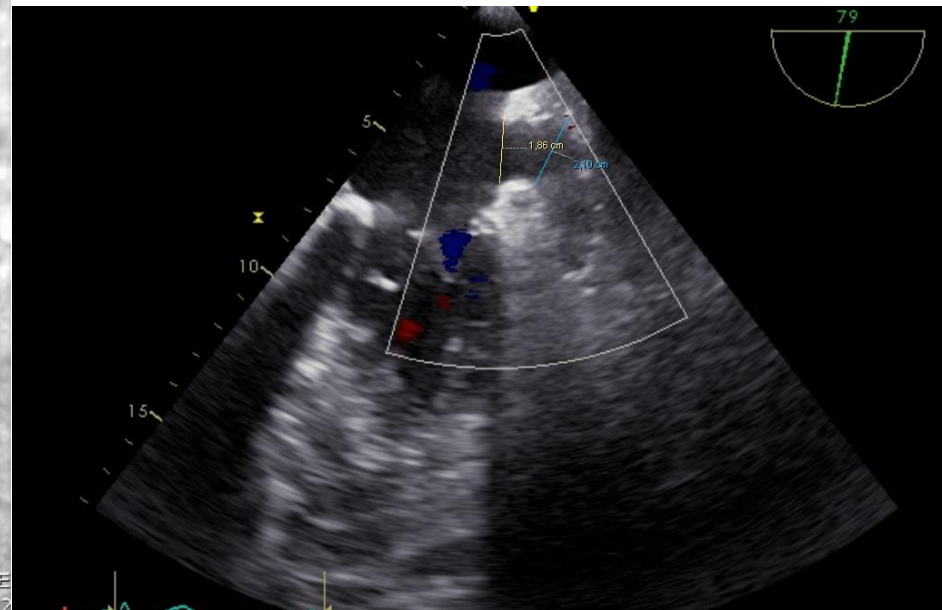
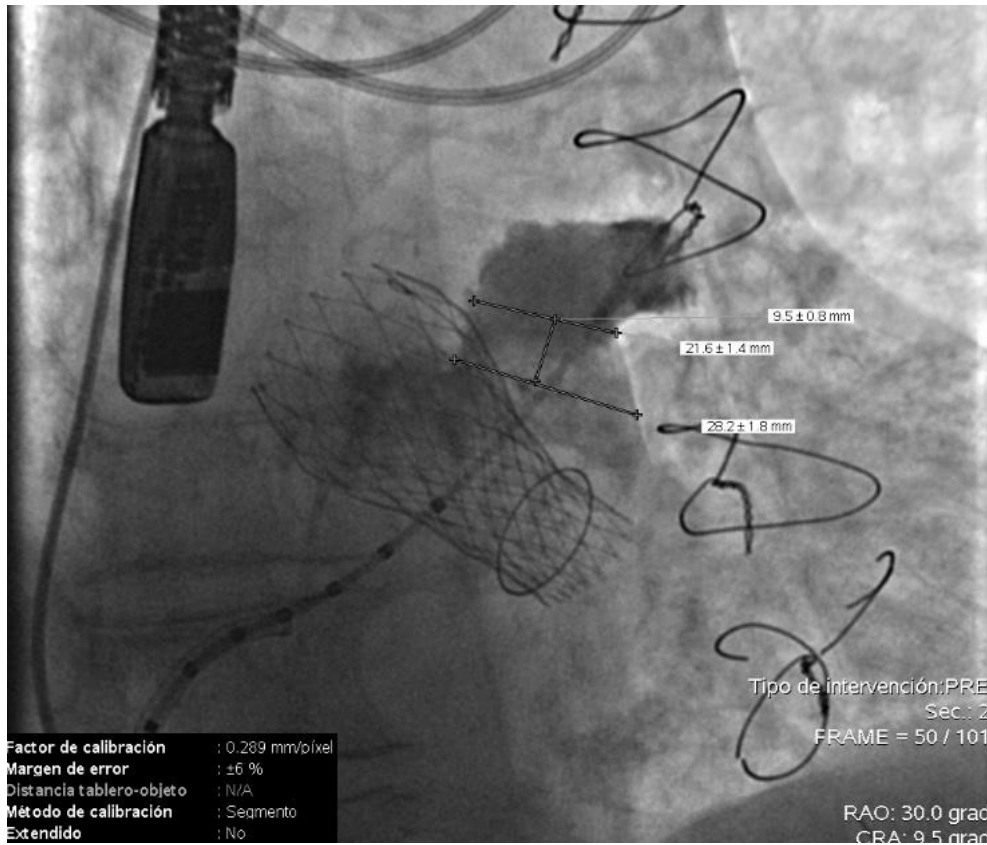
*Smith CR, et al. NEJM 2011;364:2187-2198*  
*Leon MB et al. NEJM 2010;363:1597—1607*  
*Adams D, et al. NEJM 2014;370:1790-1798*  
*Popma J, et al. JACC 2014;63:1972-1981*

# Etiología del Stroke post IVAT en función del tiempo

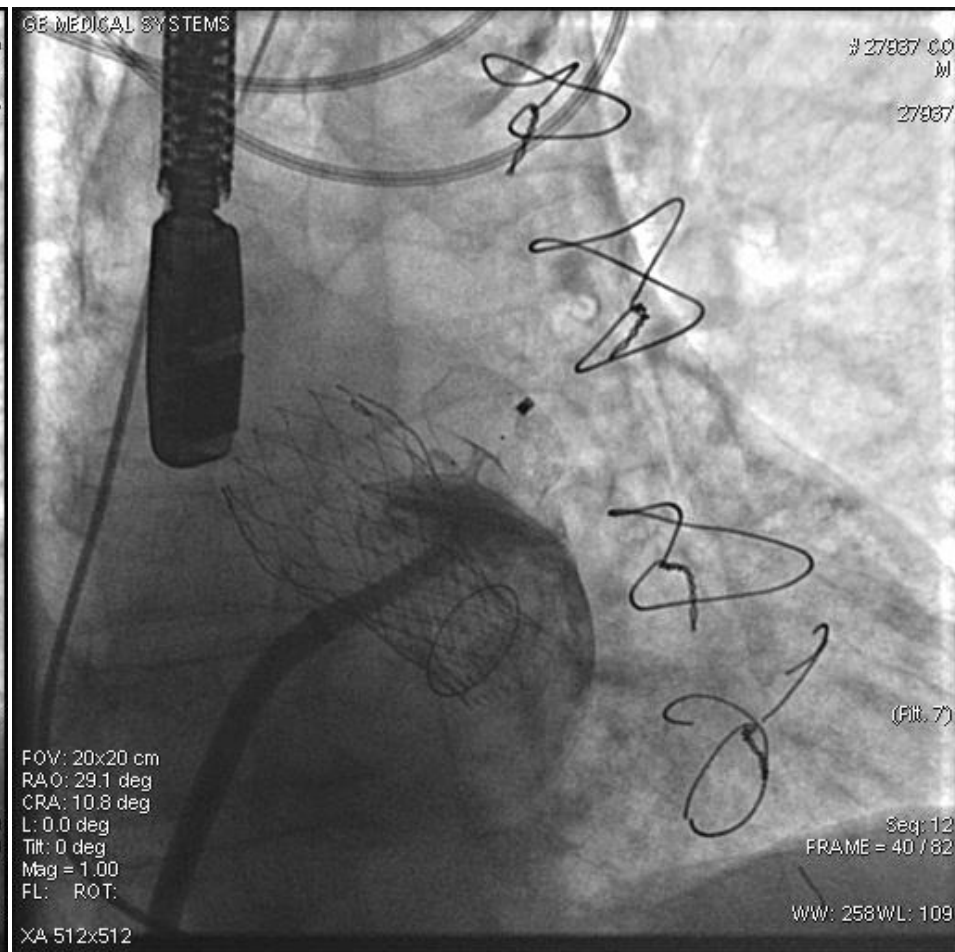
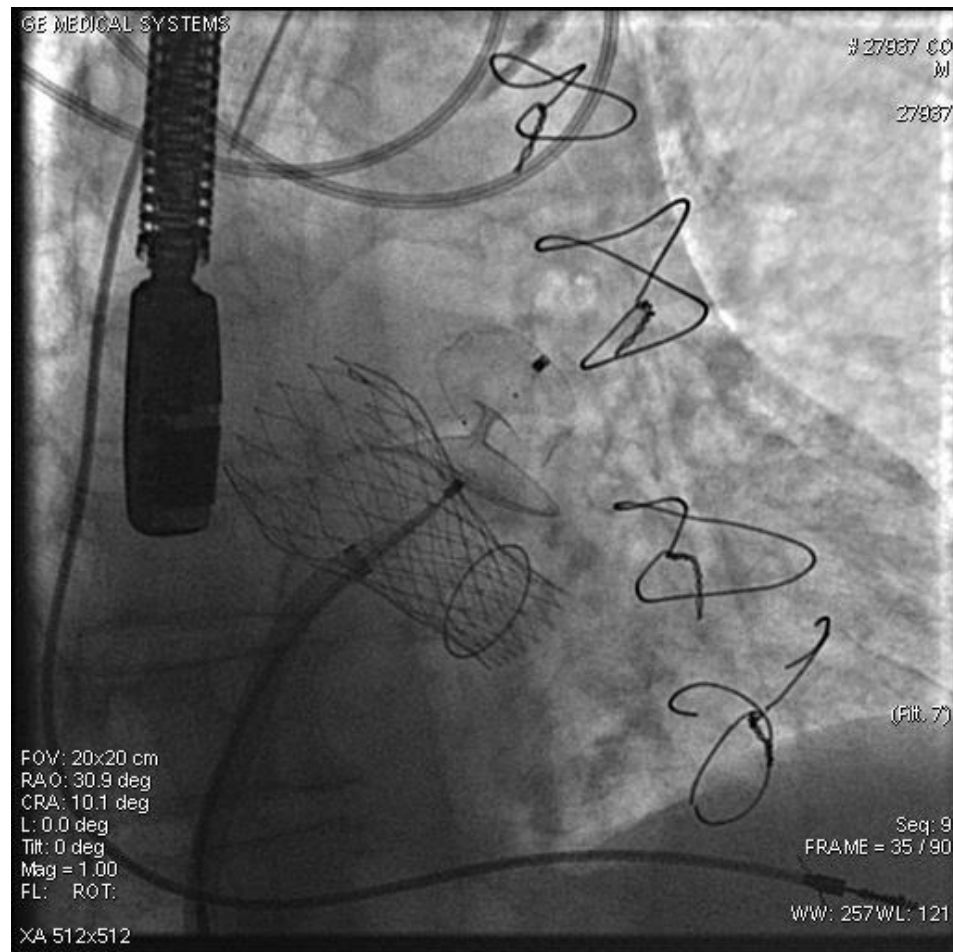


Stortecky S, Windecker S Circulation 2012;126:2921-2924

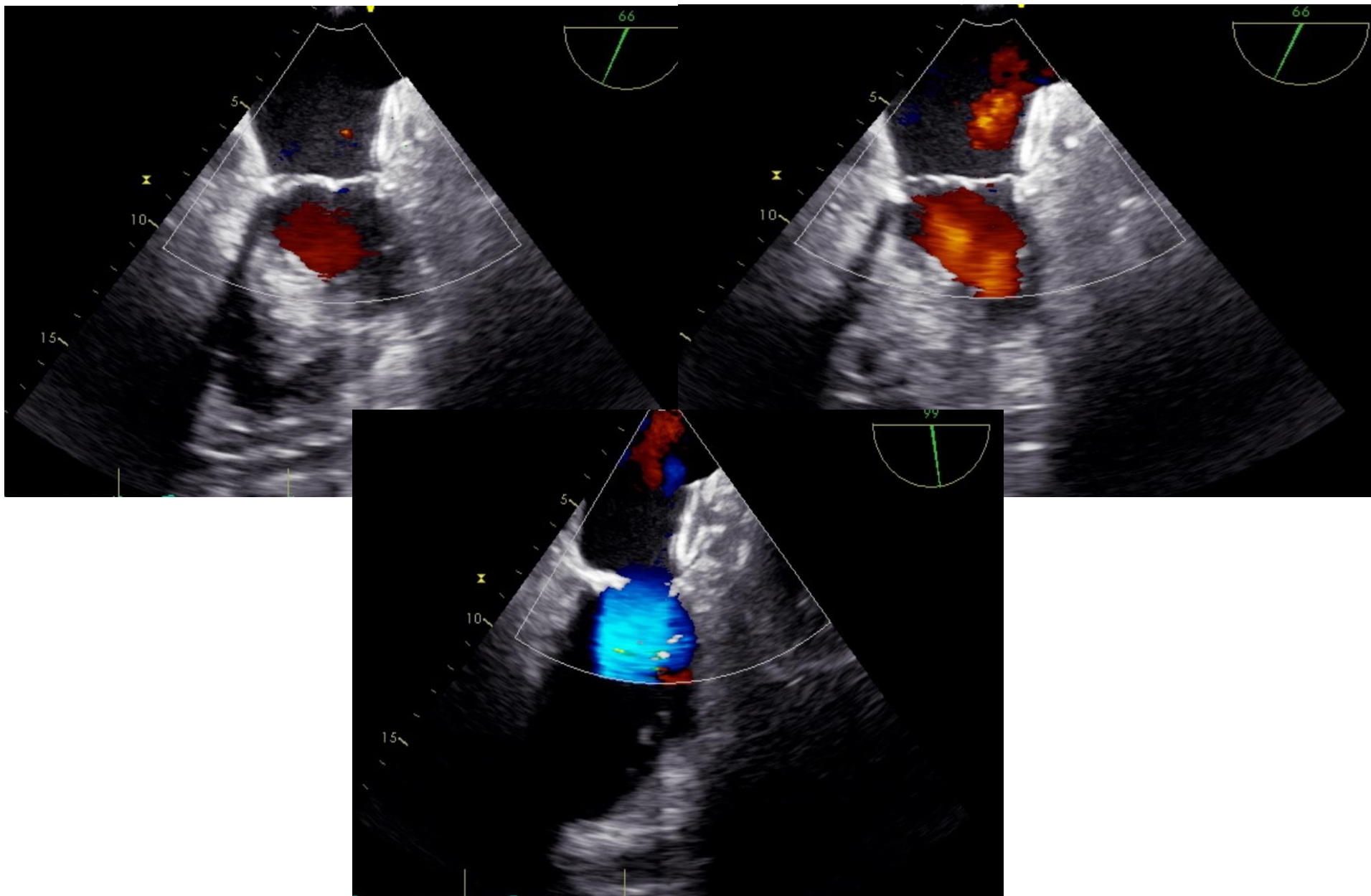
# Cierre de OAI



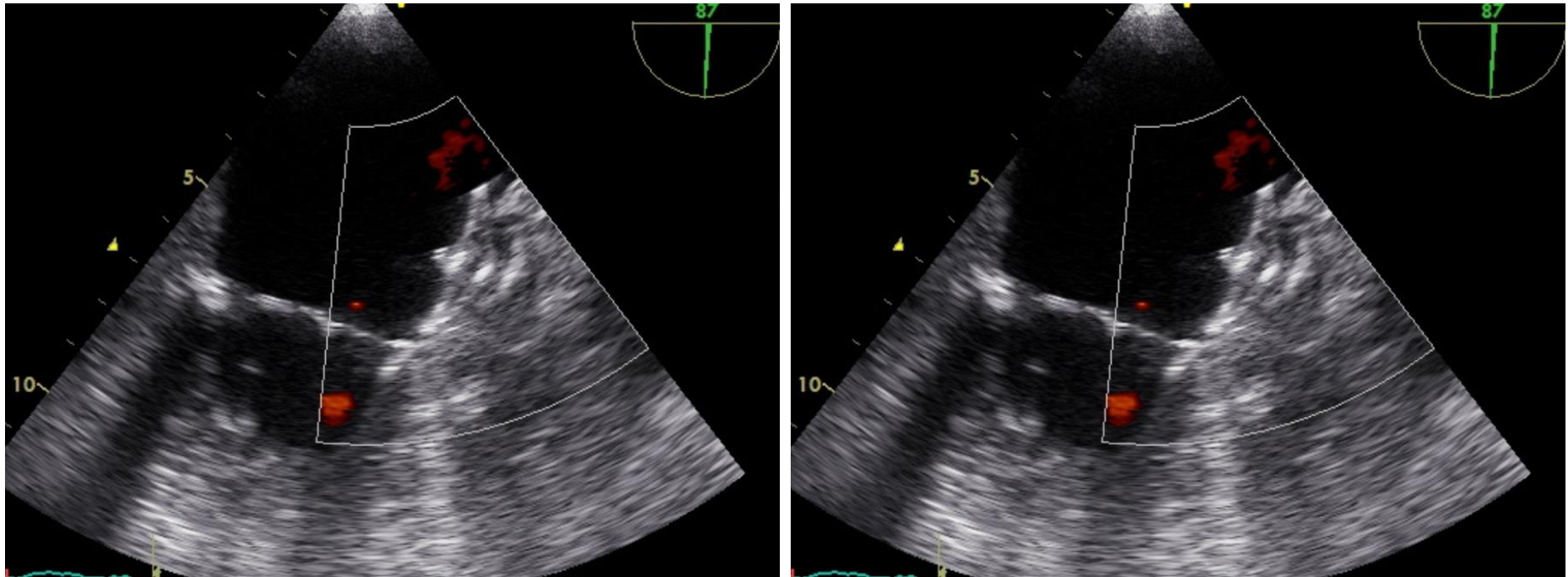
# Cierre de OAI



# Cierre de OAI



# Cierre de OAI- ETE 30 días



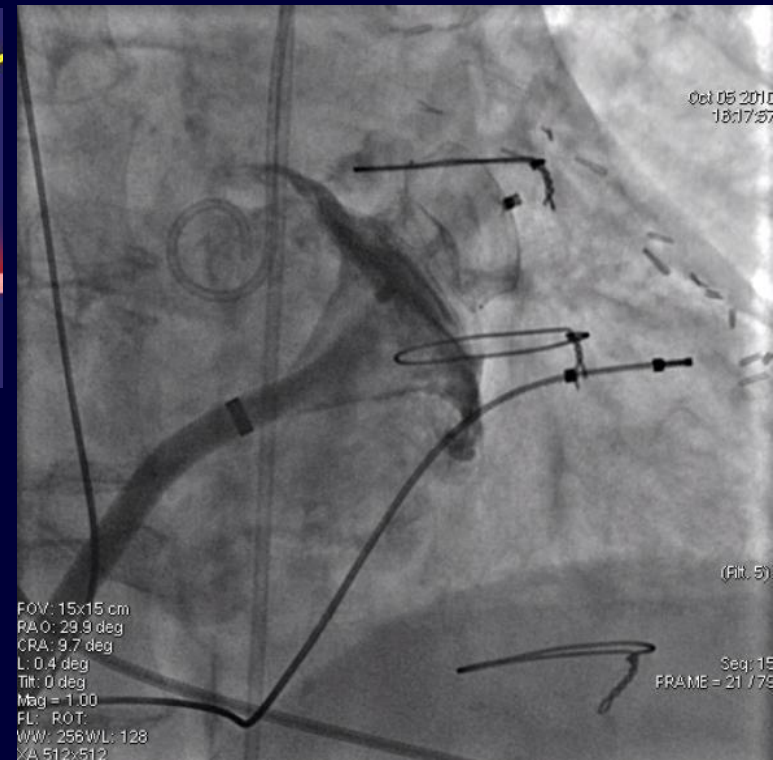
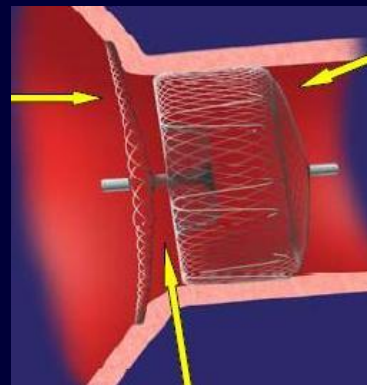
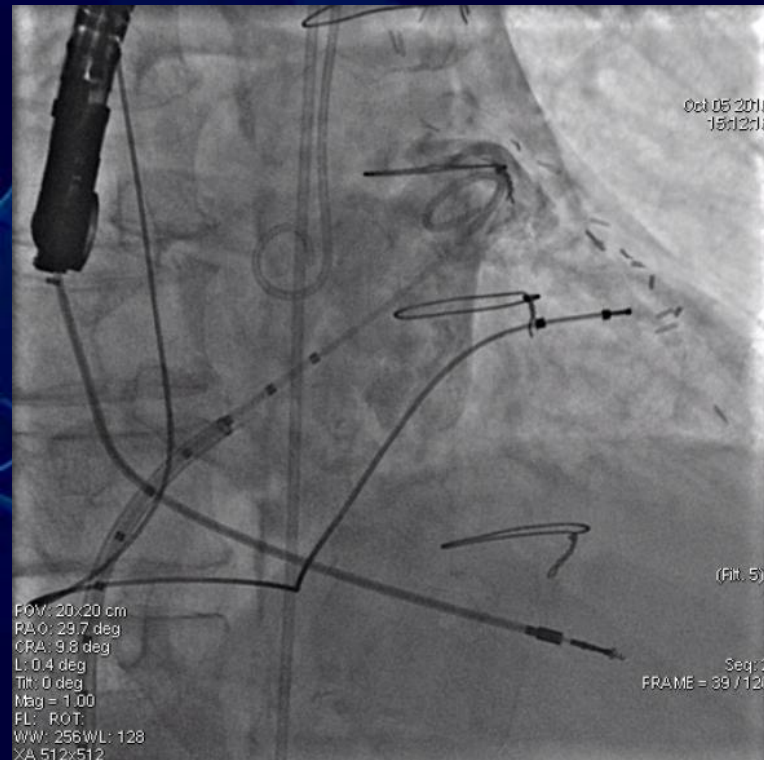
Suspensión de DAP y continúa con Clopidogrel 75 mgs/día

# Conclusiones



- La racionalidad del cierre percutáneo de la orejuela auricular izquierda en pacientes con FA se basa en la evidencia que el 90% de los trombos se originan en ella.
- Diferentes registros contemporáneos de manejo de ACO muestran la necesidad de una alternativa no farmacológica para la prevención del stroke en la FA
- Diferentes estudios demostraron la factibilidad del procedimiento con alta tasa de implante exitoso en pacientes con contraindicación para ACO , con reducción significativa en la tasa de strokes en el seguimiento en relación a lo esperado por scores.
- Existe evidencia creciente de estudios randomizados con seguimiento a largo plazo y registros multicéntricos que apoyan fuertemente el cierre de la orejuela auricular izquierda como alternativa a la ACO.
- **Constituye una opción terapéutica establecida, en pacientes con FA no valvular, con scores de alto riesgo para stroke y contraindicaciones o dificultad para la ACO. Los pacientes con sangrado intracraneano previo, y aquellos que han sufrido un stroke a pesar de ACO son los que obtienen el máximo beneficio de esta técnica.**
- Para cada situación, los riesgos y beneficios deben ser cuidadosamente considerados y explicados al paciente.

# Gracias!!







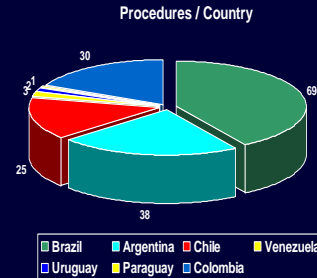
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# Amplatzer Cardiac Plug in LatAm

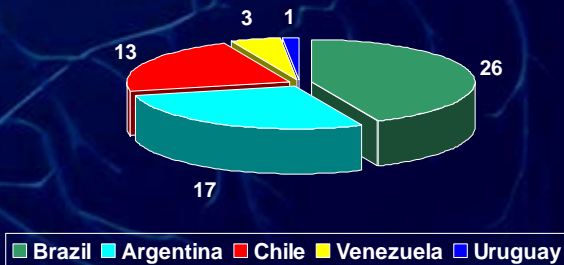


**N= 168, June 2014**



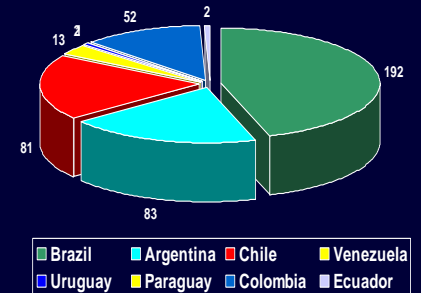
**N=60, June 2012**

Procedures / Country



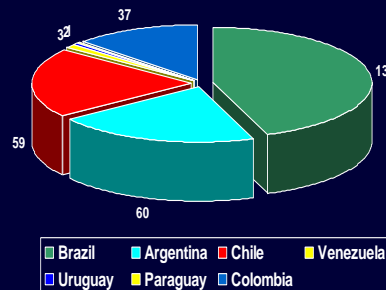
**N= 426, April 2016**

Procedures / Country



**N= 292, April 2015**

Procedures / Country



# Resultados del Primer Estudio Nacional, Multicentrico y Prospectivo de Fibrilacion Auricular Cronica en la Republica Argentina

CARLOS LABADET, GUILLERMO LINIADOT, ERNESTO R. FERREIROS\*, VICTOR MOLINA VIAMONTE\*, DARIO DI TORO, ROMAN CRAGNOLINO, RODOLFO SANSALONE, FERNANDO CHIMINELA, ALEJANDRO VILLAMIL, ALEJANDRA FRANCESIA, BERNARDO KAISER, OSVALDO MASOLI", CARLOS BOISSONNET", RUBEN KEVORKIAN\*, JUAN KRAUSS\*, en representaci6n de los Investigadores del Primer Estudio Nacional, Multicentrico y Prospectivo de Fibrilaci6n Auricular Cr6nica en la Republica Argentina y del Area de Investigaci6n de la Sociedad Argentina de Cardiologia

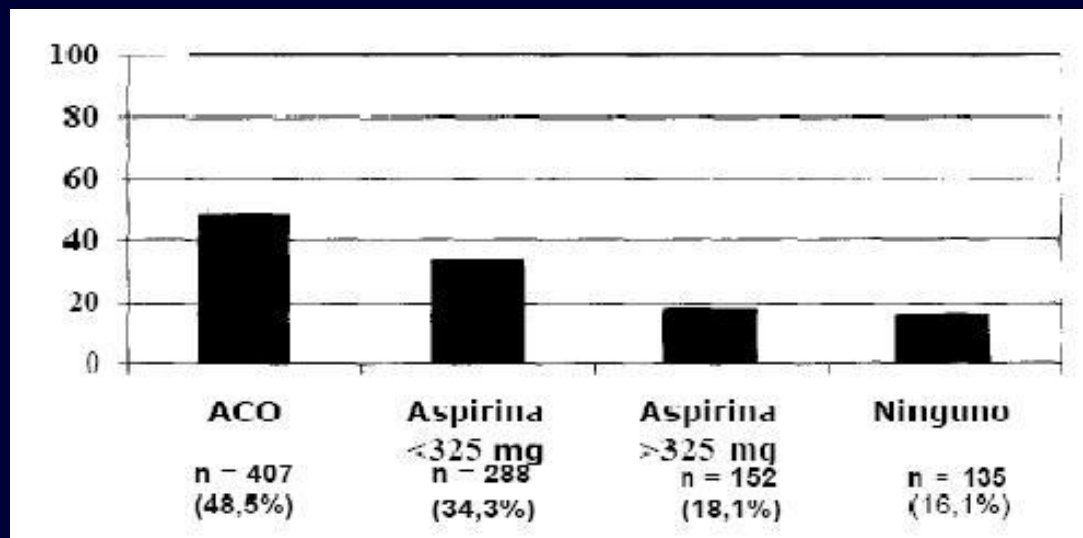
840 p consecutivos

65 centros

Ant. Emb6licos 115p (14%)

ACO/Ant Emb 20%

Contraindic ACO 144p (17%)



# EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion

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Document Reviewers: Gregory Y. H. Lip (UK), Jose Lopez-Minguez (Spain), Marco Roffi (Switzerland), Carsten Israel (Germany), Dariusz Dudek (Poland), Irene Savelieva (on behalf of EP-Europace, UK)

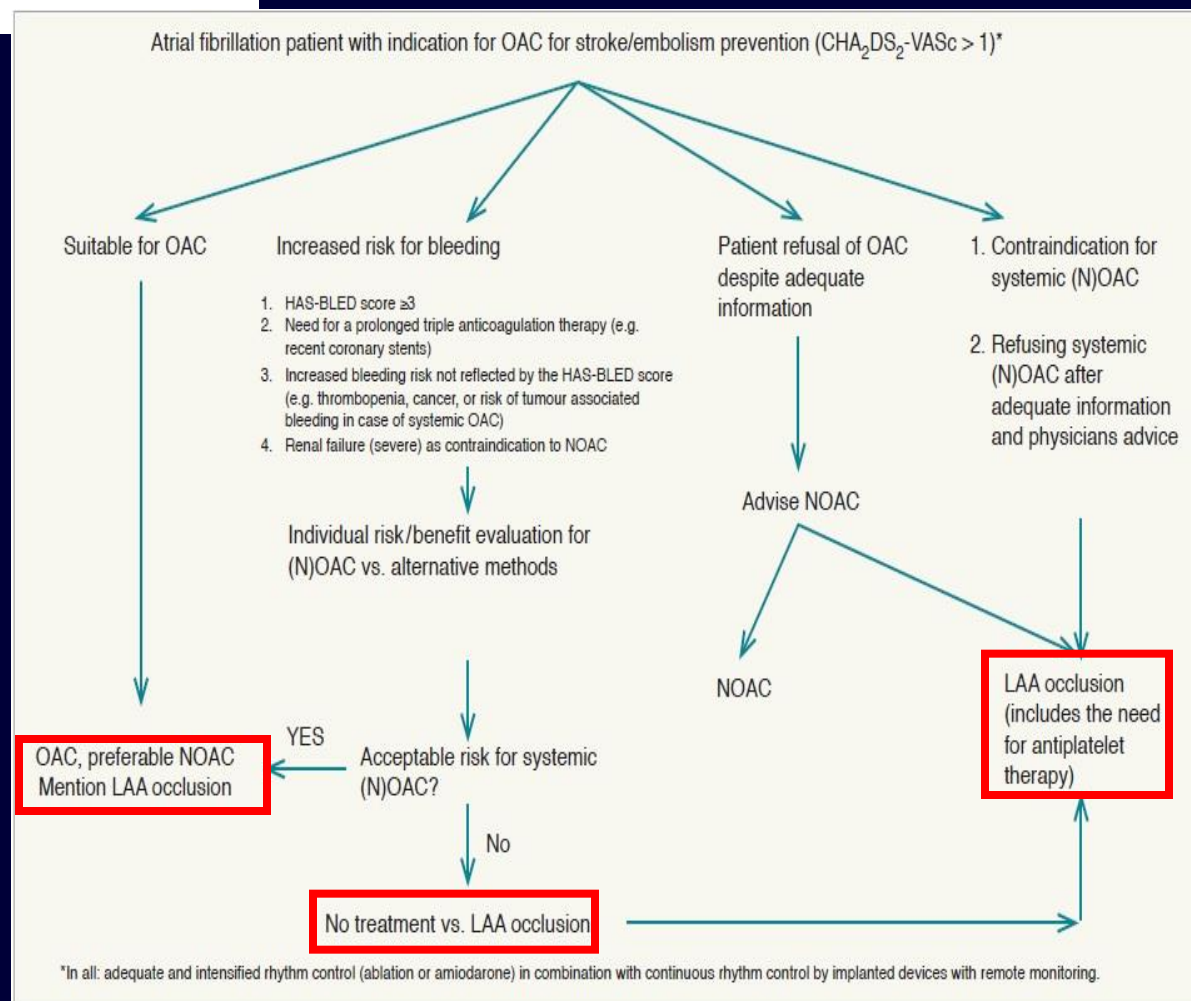


Figure 5. Algorithm of stroke protection in atrial fibrillation. LAA, left atrial appendage; NOAC, novel (non-Vitamin K antagonist) oral anticoagulant; OAC, oral anticoagulant.