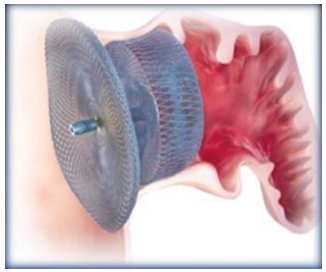
X SIMPOSIO CACI@FAC
VII SESIÓN CONJUNTA CACI-GACI
XXXVII CONGRESO NACIONAL DE CARDIOLOGÍA

Fibrilación auricular en pacientes con alto riesgo de sangrado: Cierre de orejuela izquierda



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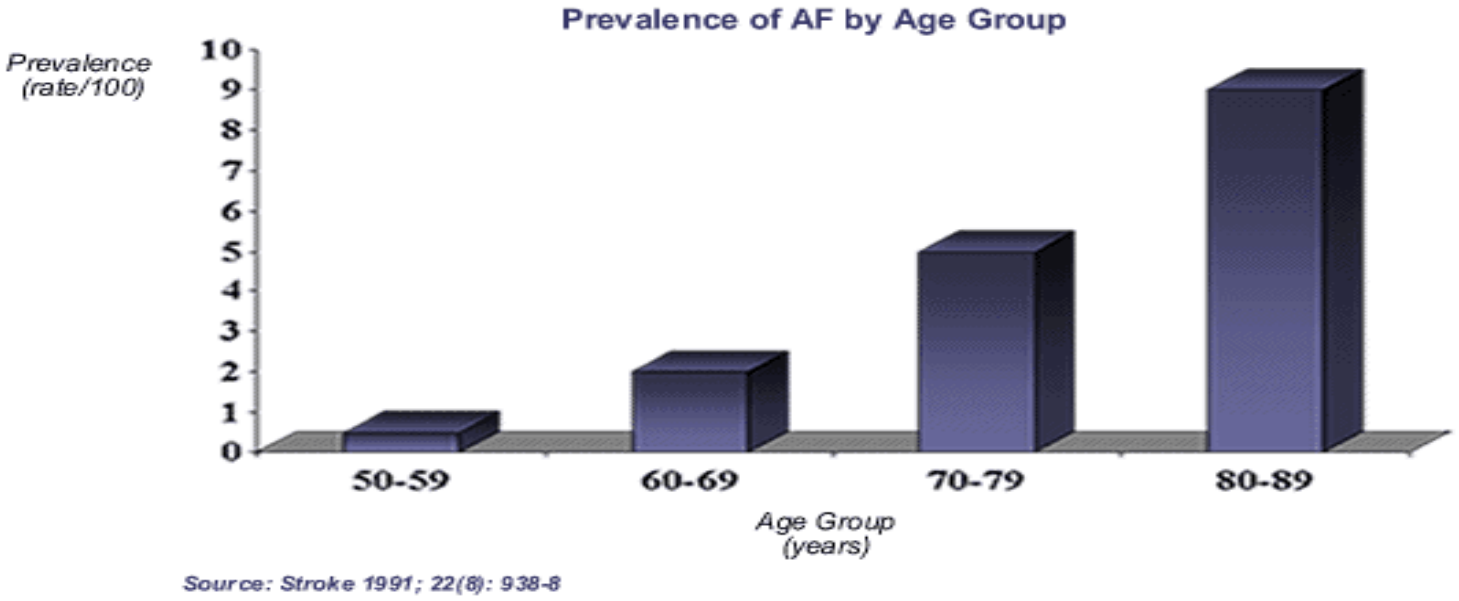
Nombre del Disertante: Aníbal Damonte

☑ No tengo conflictos de interés relacionados a esta presentación.

- Introducción
- Orejuela izquierda como fuente de cardioembolia en FA
- Resultados de los estudios clínicos-Evidencias
- Indicaciones de cierre de OAI
- Conclusiones

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

- Los ACO son actualmente el método más efectivo de prevención del stroke en pacientes con FA, pero:

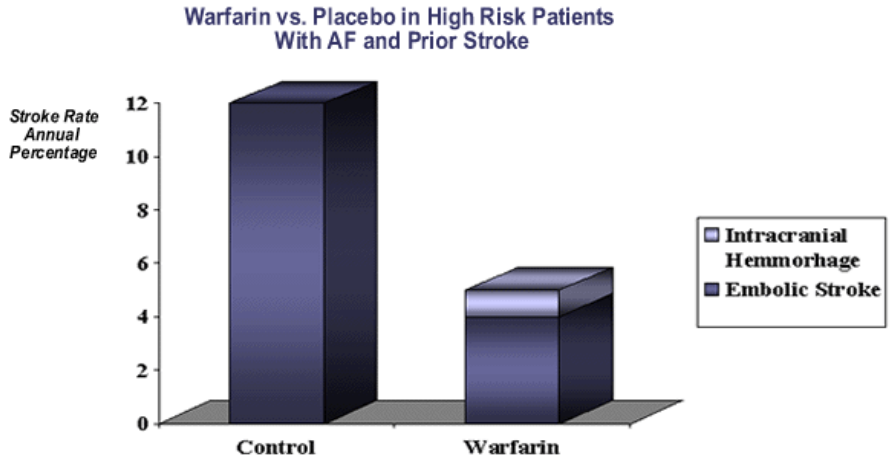
  1) Rango terapéutico estrecho – Interacciones con otros fármacos

  2) Insuficientemente controlados en alto % de pacientes

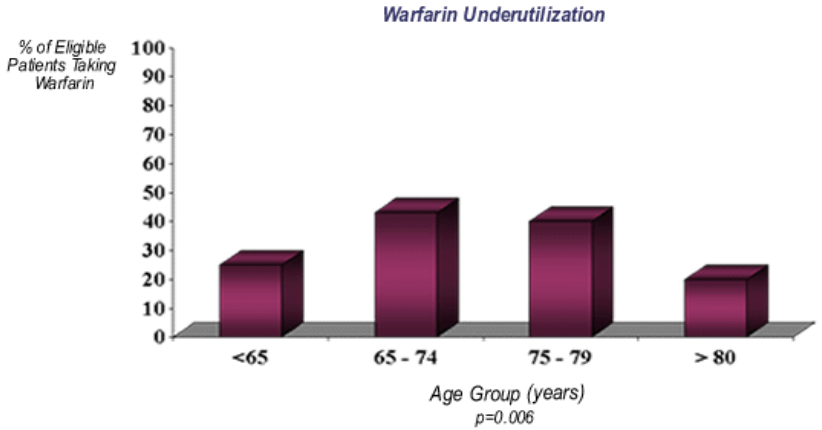
  3) Subutilizados

  4) Frecuentemente contraindicados

- A pesar de la introducción de nuevos fármacos, los beneficios siguen siendo contrarrestados por el riesgo de sangrado



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



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

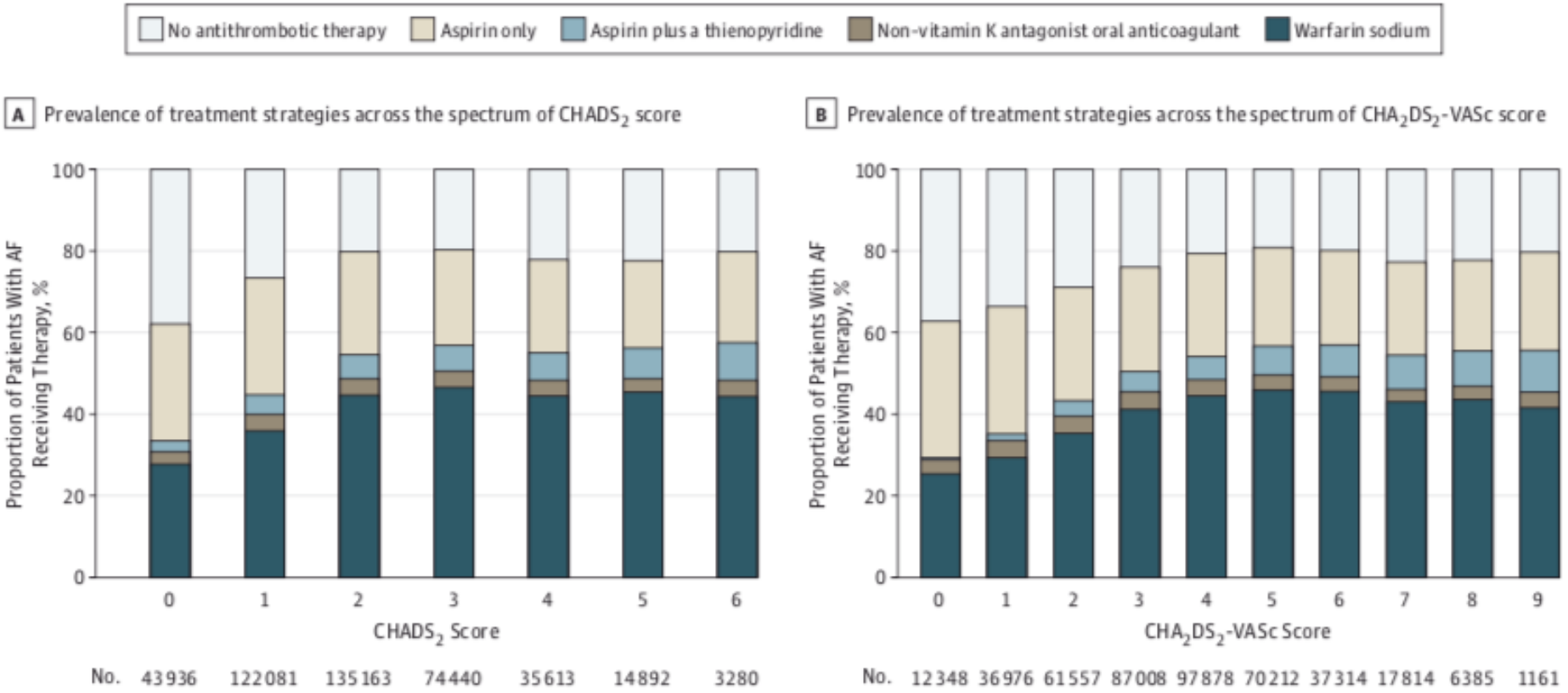
Original Investigation

Oral Anticoagulant Therapy Prescription in Patients With Atrial Fibrillation Across the Spectrum of Stroke Risk

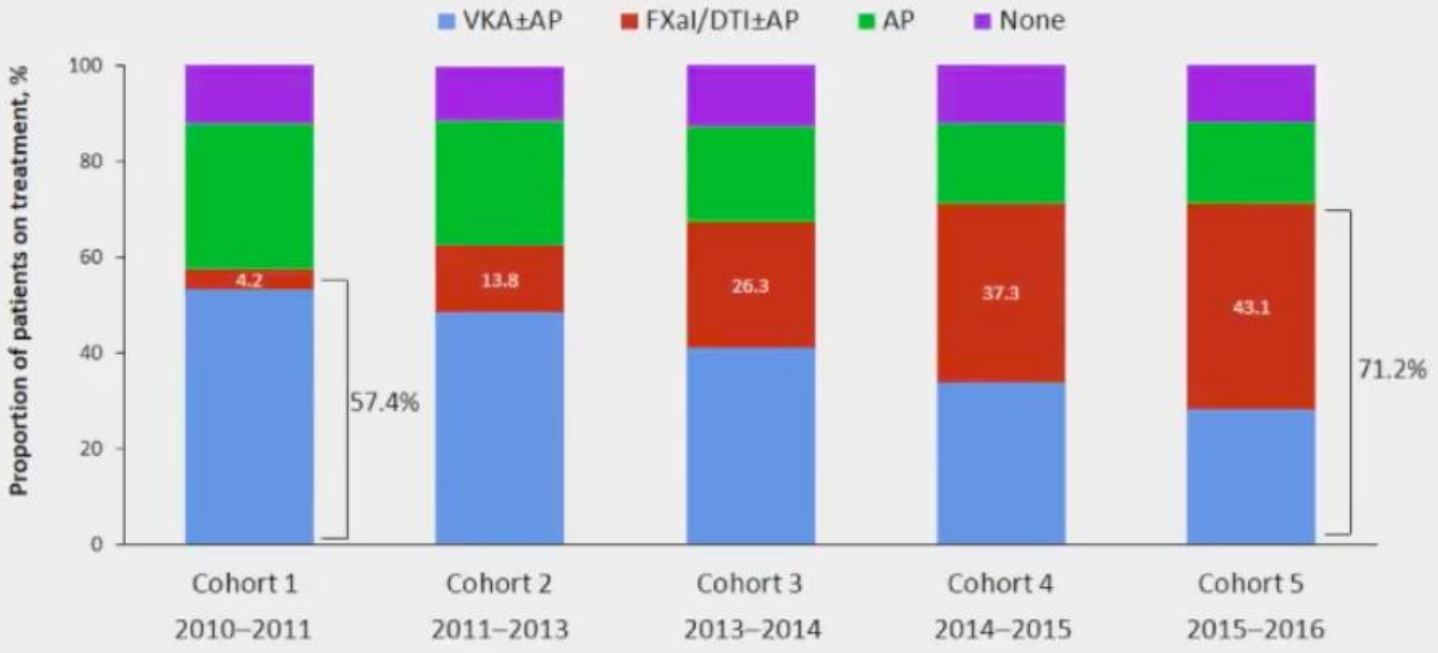
Insights From the NCDR PINNACLE Registry

Jonathan C. Hsu, MD, MAS; Thomas M. Maddox, MD, MSc; Kevin F. Kennedy, MS; David F. Katz, MD; Lucas N. Marzec, MD; Steven A. Lubitz, MD, MPH; Anil K. Gehi, MD; Mintu P. Turakhia, MD, MAS; Gregory M. Marcus, MD, MAS

Figure 2. Prevalence of Antithrombotic Therapies in Patients With Atrial Fibrillation (AF) Across the Spectrum of Stroke Risk by the $CHADS_2$ Score and the CHA_2DS_2-VASc Score



Evolution in baseline treatment for patients enrolled in sequential cohorts of GARFIELD-AF



Cohorts 1–5, N=52,081; AP, antiplatelet; DTI, direct thrombin inhibitor; FXaI, factor Xa inhibitor; VKA, vitamin K antagonist

TRI Thrombosis Research Institute

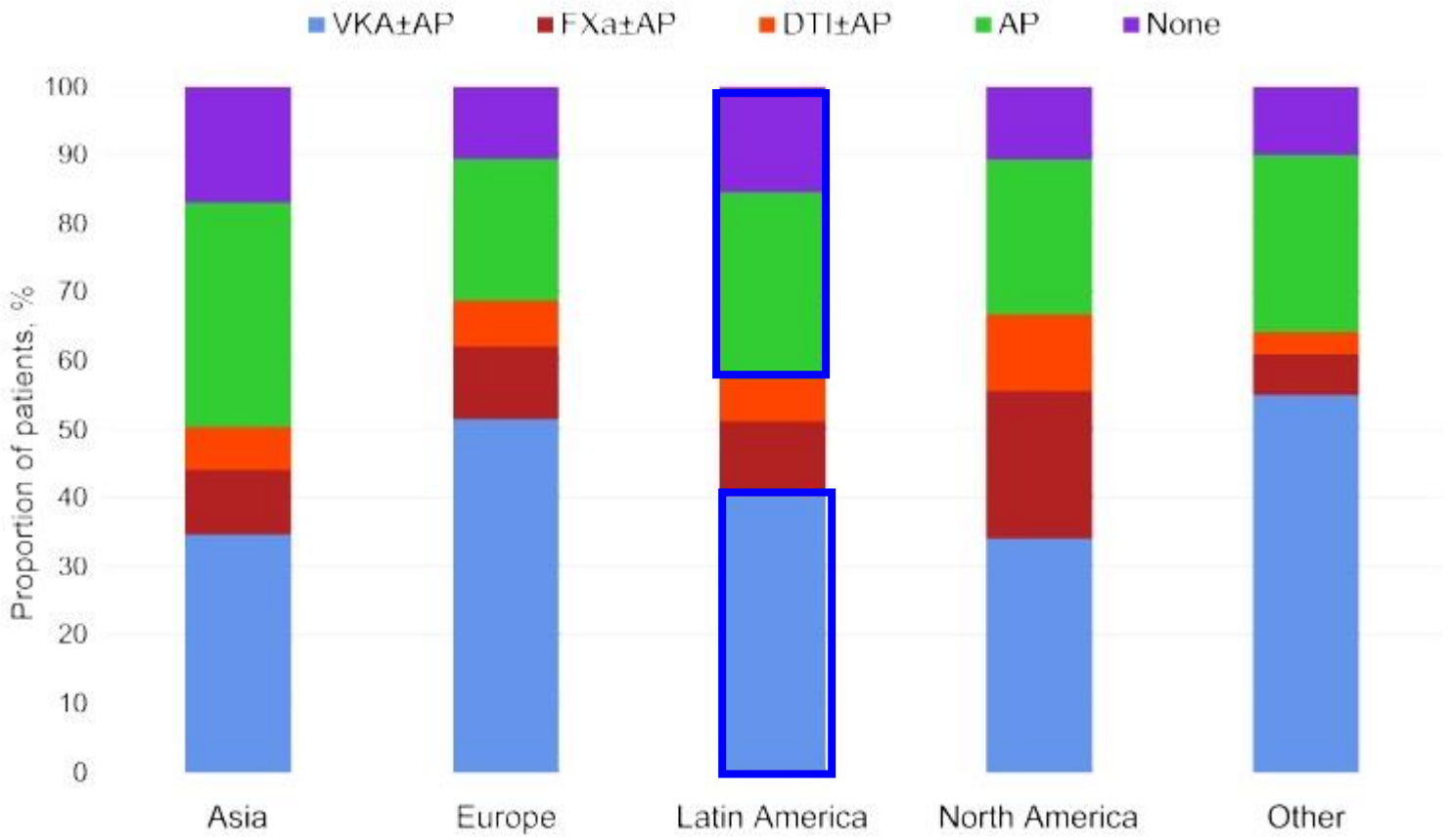
www.garfieldregistry.org

The GARFIELD-AF registry is funded by an unrestricted research grant from Bayer AG

AF Garfield global anticoagulant registry in the field

Kakkar,A. ESC 2017

Antithrombotic treatment in patients with AF by region



TRI Thrombosis Research Institute

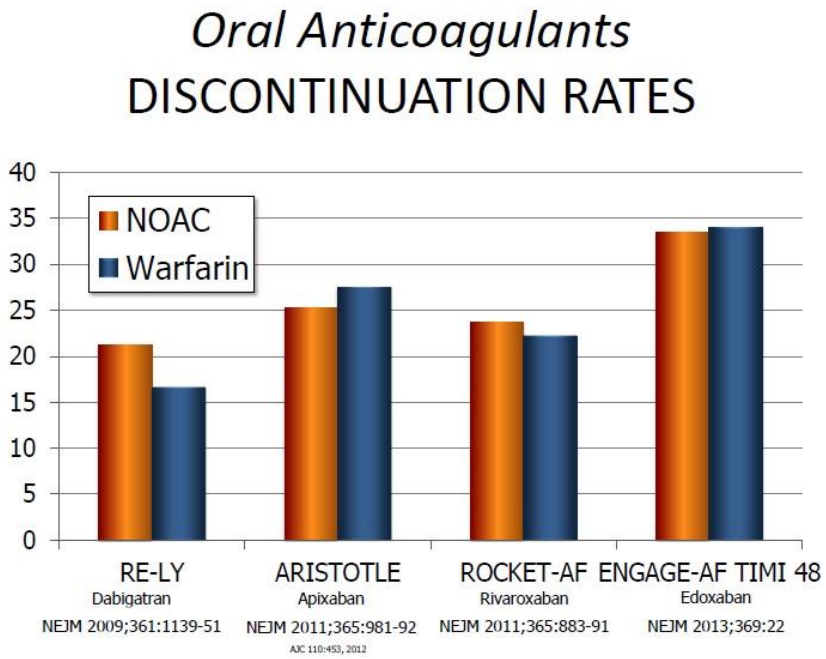
www.tri-london.ac.uk

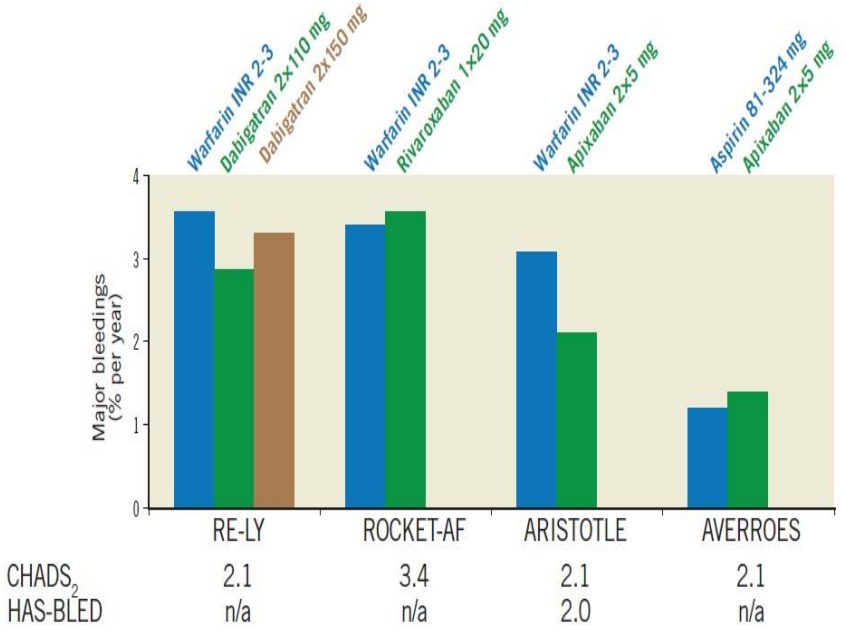
Cohorts 1–3, N=28,624

Garfield

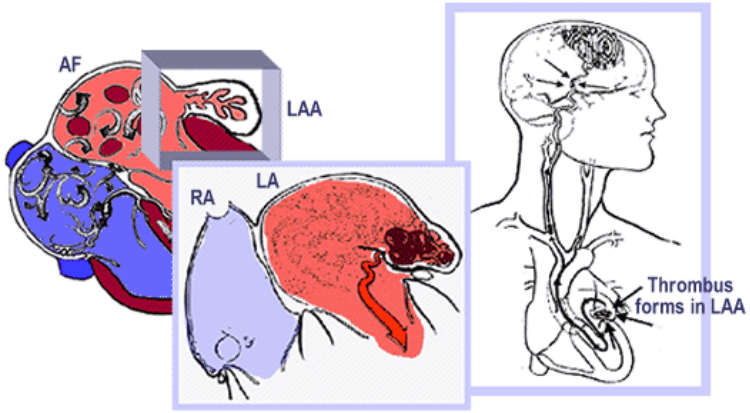
Goto S. ESC 2015

Limitaciones de NOACs





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



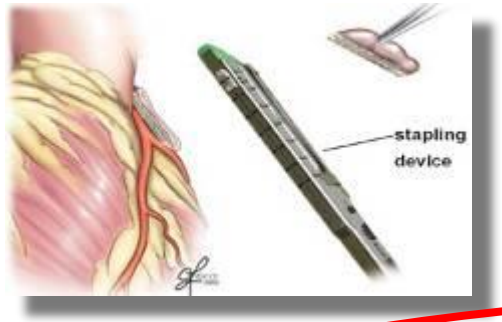
90% de los trombos localizaron orejuela auricular izquierda

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)
Total	2208	249 (11.3)	29 (1.3)	278 (12.6)

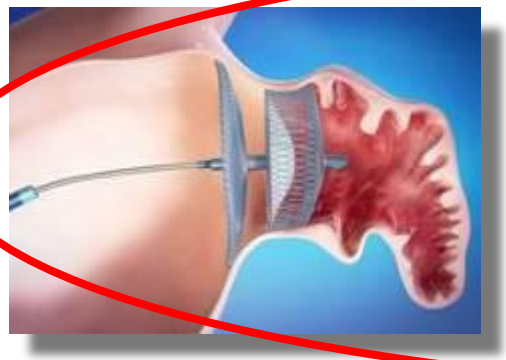
Onalan O; Stroke 2007

Options for Stroke Prevention

- **Pharmacological Management: Anticoagulants[1]**
  - Effective: 67% stroke risk reduction
  - Management of narrow therapeutic window
  - Major complication: bleeding



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

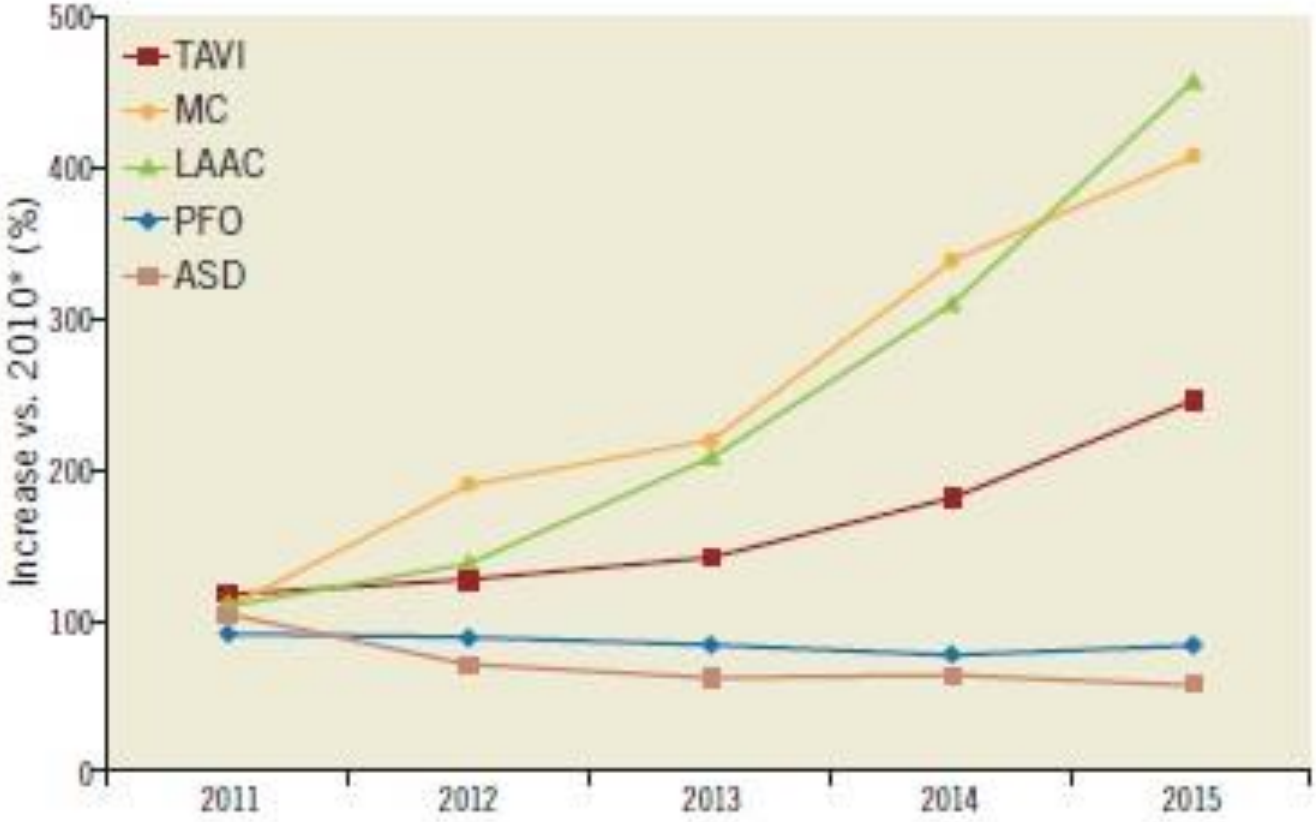


- **Transcatheter Device Closure**
  - Minimally invasive nature
  - Designed for percutaneous closure of the LAA in prevention of clot embolization that may form in the LAA
  - Intended as an alternative to warfarin therapy for patients with non-valvular atrial fibrillation

[1] Mobius-Winler, et al., Interventional treatments for stroke prevention in atrial fibrillation, Curr Opin Neurol 2008; 21(1): 64-69
[2] Dawson, et al., Should patients undergoing cardiac surgery with AF have LAA exclusion? Interactive Card.Vasc and Thoracic Surgery

Current trends in structural heart interventions: an overview of the EAPCI registries

Dariusz Dudek[1]*, MD, PhD, FESC; Emanuele Barbato[2,3], MD, PhD, FESC; Andreas Baumbach[4], MD, FESC; Stephan Windecker[5], MD, PhD, FESC; Michael Haude[6], MD, FESC

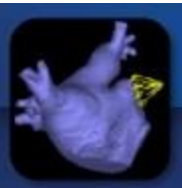


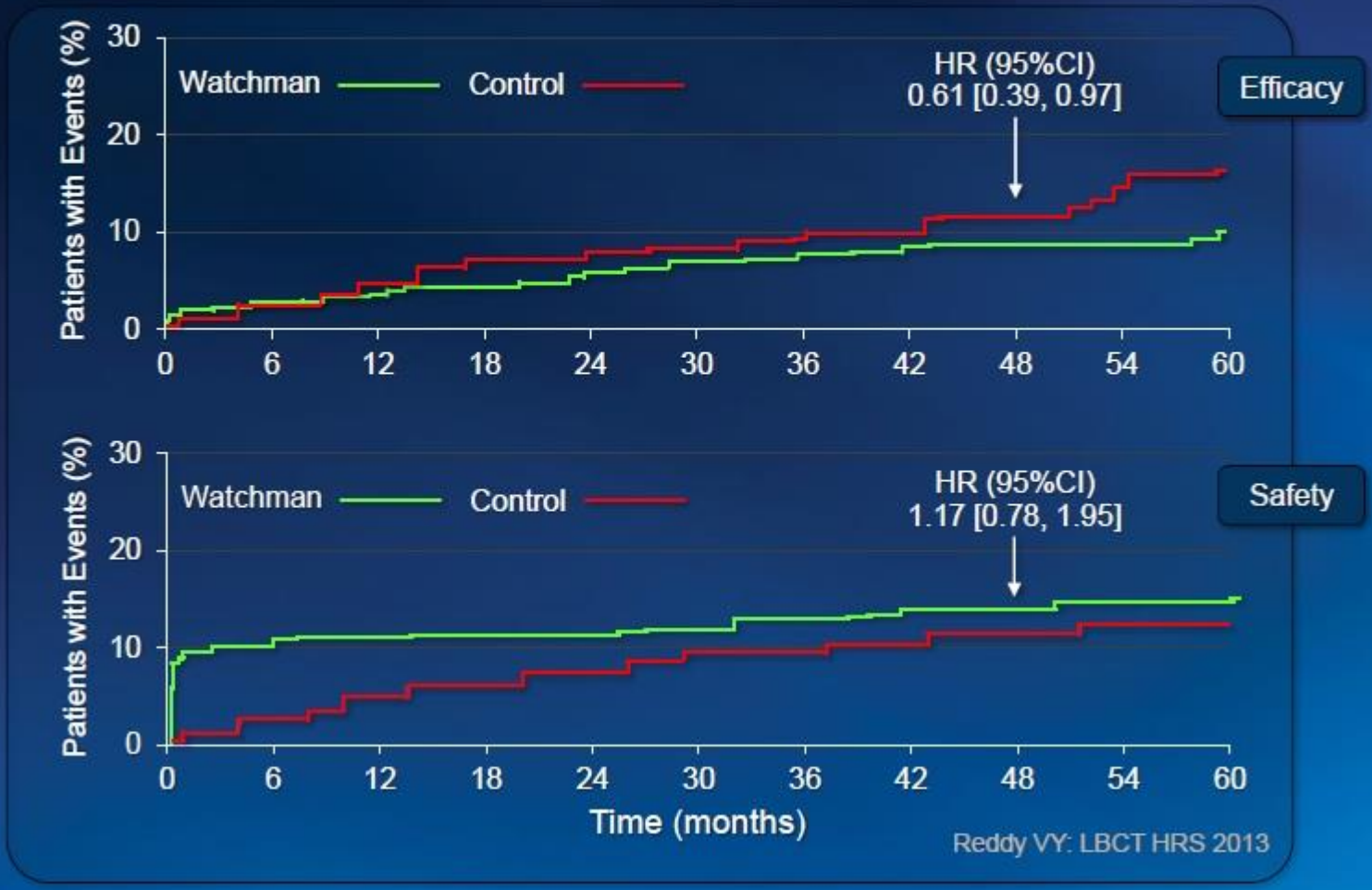
Cierre percutáneo de la orejuela auricular izquierda para prevención del ACV cardioembólico en pacientes con fibrilación auricular:

“Resultados de los Estudios Clínicos: Evidencias”

Watchman™

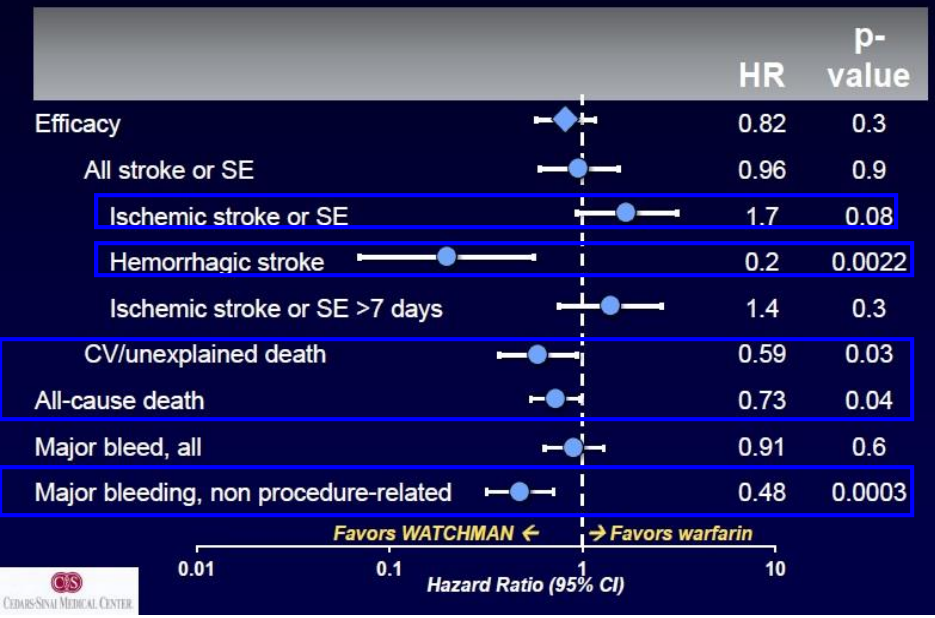
PROTECT AF 4-Year Data



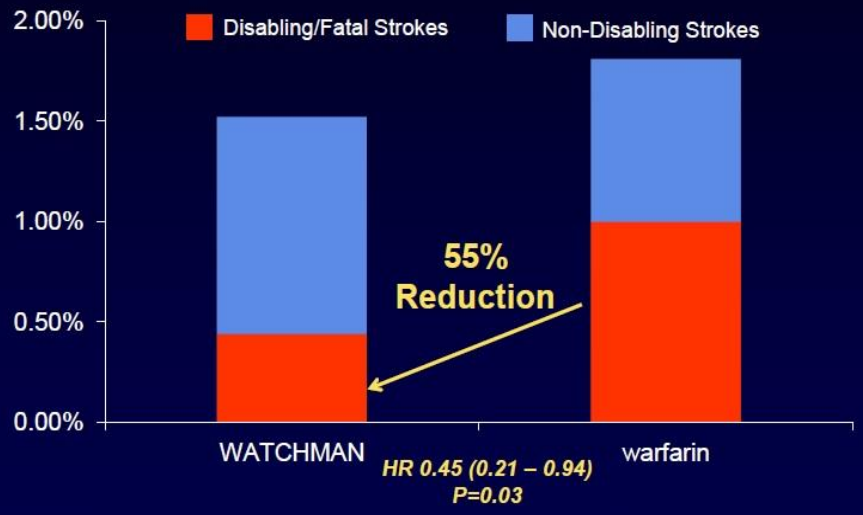


Reddy V, et al. JAMA 2014;312:1988-98

Patient-Level Meta-Analysis
PROTECT AF and PREVAIL 5 years



Patient-Level Meta-Analysis
WATCHMAN Superior Reduction in Disabling Strokes



Disabling Stroke defined as MRS ≥2
Two strokes in PREVAIL are excluded because the baseline MRS score was unavailable

Saibal Kar, TCT 2017

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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 $CHADS_2$ or CHA_2DS_2-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.

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

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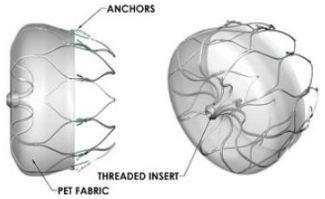
Products and Medical Procedures
- Device Approvals and Clearances
- Recently-Approved Devices
- 2015 Device Approvals
- 2014 Device Approvals

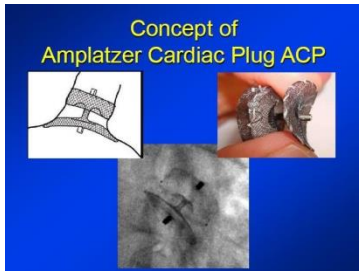
WATCHMAN LAA Closure Technology - P130013



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.

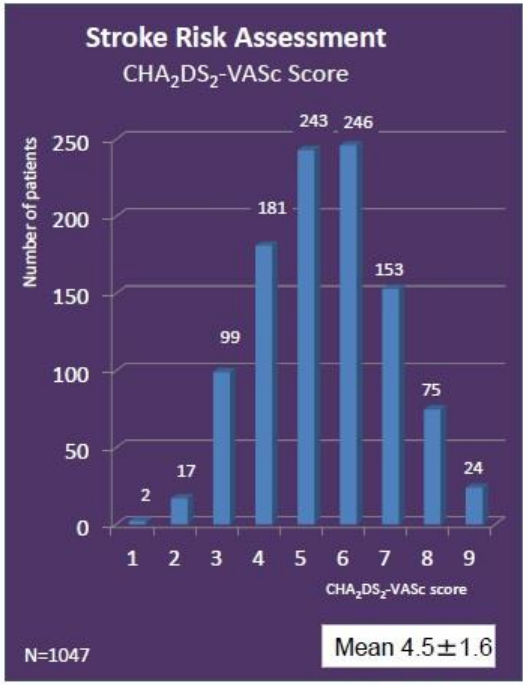
Product Name: WATCHMAN LAA Closure Technology
PMA Applicant: Boston Scientific Corporation
Address: One Scimed Place, Maple Grove, MN 55331-1566
Approval Date: March 13, 2015

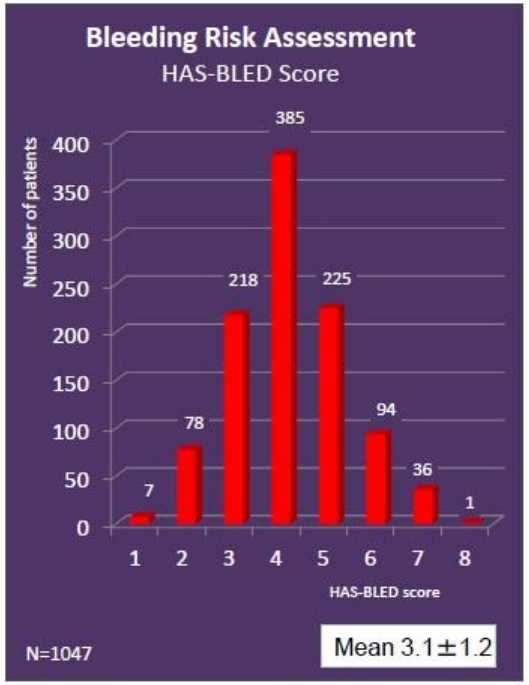
Multicenter Experience with the Amplatzer Cardiac Plug (ACP)



- 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



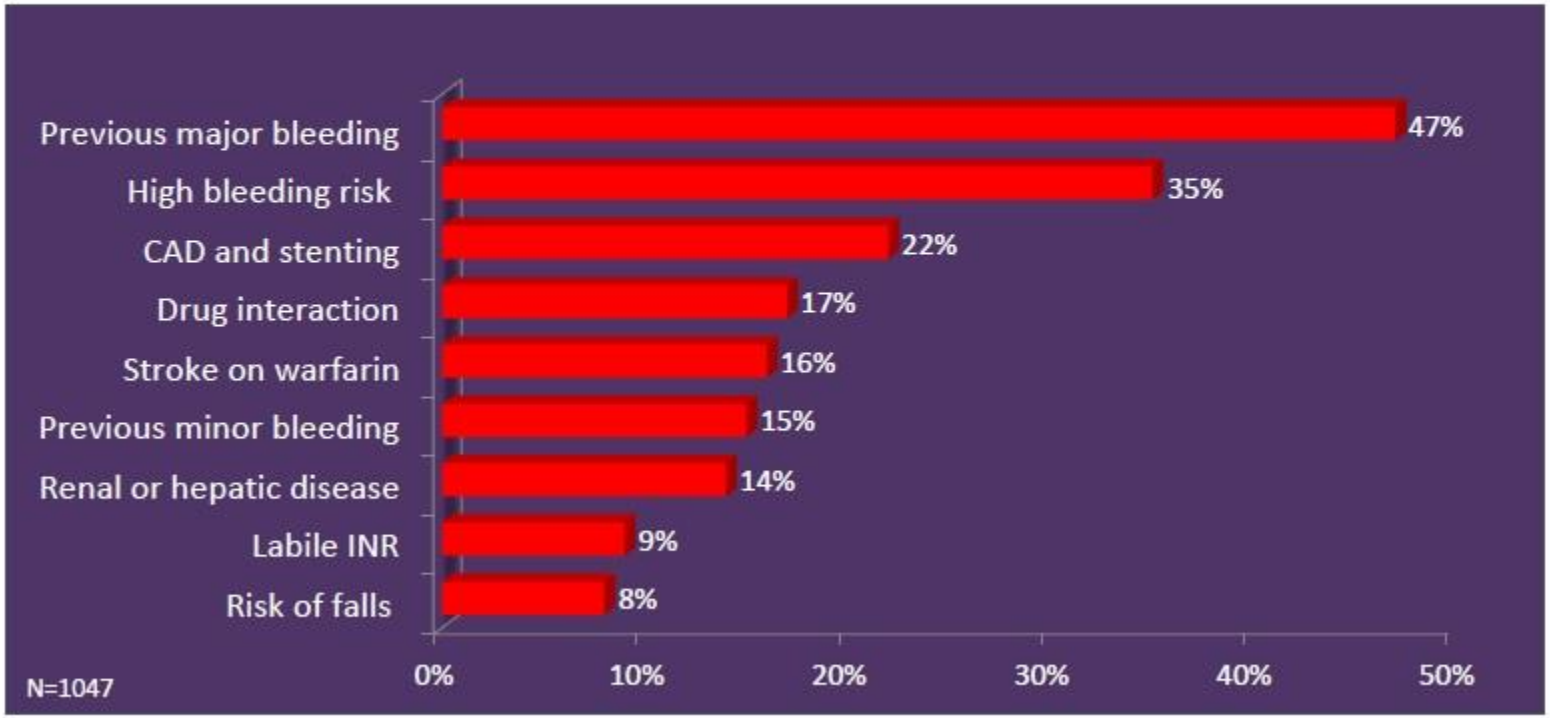


$CHADS_2$ Score=2.8±1.3

Tzikas 2014

Tzikas A, EuroInterv 2015

Indications for LAAO



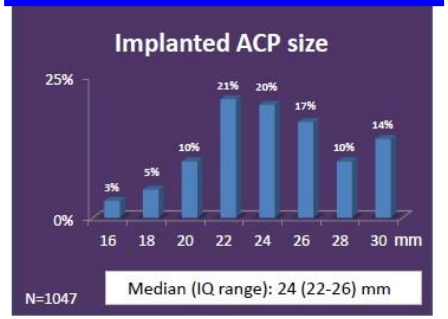
Composite of previous bleeding (major or minor) and high bleeding risk = 73%

Tzikas A, EuroInterv 2015

Implant Results

Success rates

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



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%
Total	**20.6%**

Tzikas 2014

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%
Total	**45**	**4.30%**

N=1047

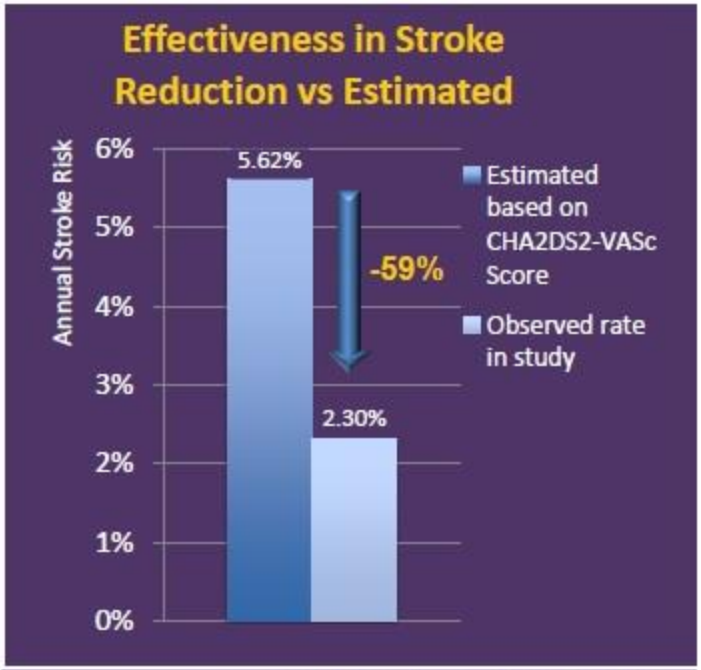
Complication	N	Remarks
Major (IC) bleeding	1	Procedure
Pericardial tamponade	2	Procedure, Day 4
Arrhythmia	1	Day 2
STEMI, hypoxia	1	Day 13
Device embolization	2	Procedure, Day 6
Pneumonia	1	Day 10

Tzikas 2014

* Holmes et al. ACC 2013 (PREVAIL Study)

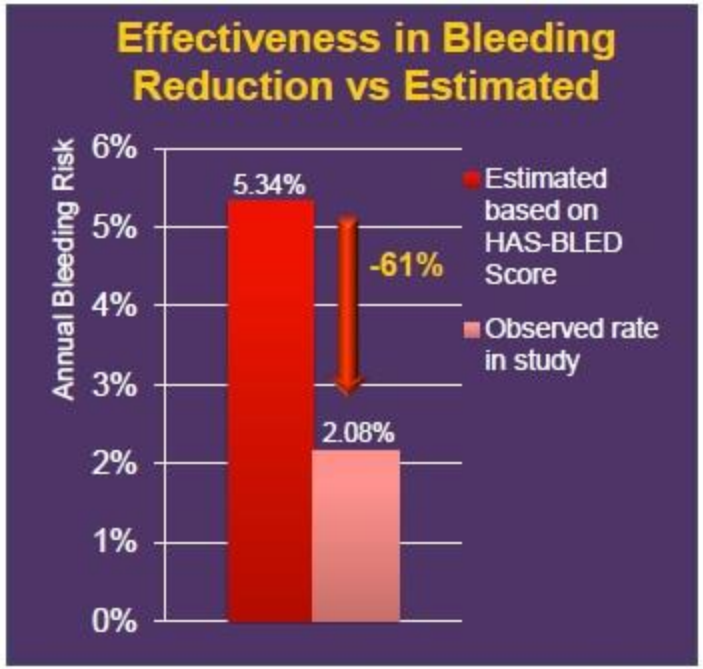
Tzikas A, EuroInterv 2015

Results



Total Patients	Total Patient Years	CHA_2DS_2-VASc Score
1001	1349	4.43

Estimated Stroke Rate per $CHA2DS_2$-VASc	Actual Annual Stroke Rate (N strokes + TIA)
5.62%	2.30% (31)



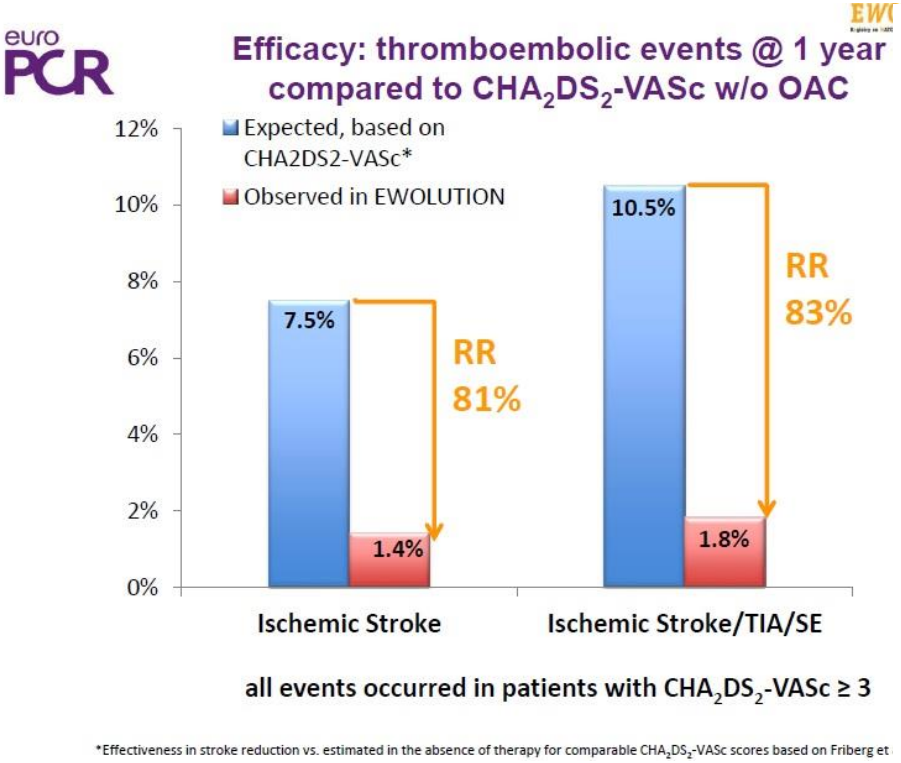
Total Patients	Total Patient Years	HAS-BLED Score
1001	1349	3.12

Estimated Bleeding Rate per HAS-BLED	Actual Annual Bleeding Rate (N major bleeds)
5.34%	2.08% (28)

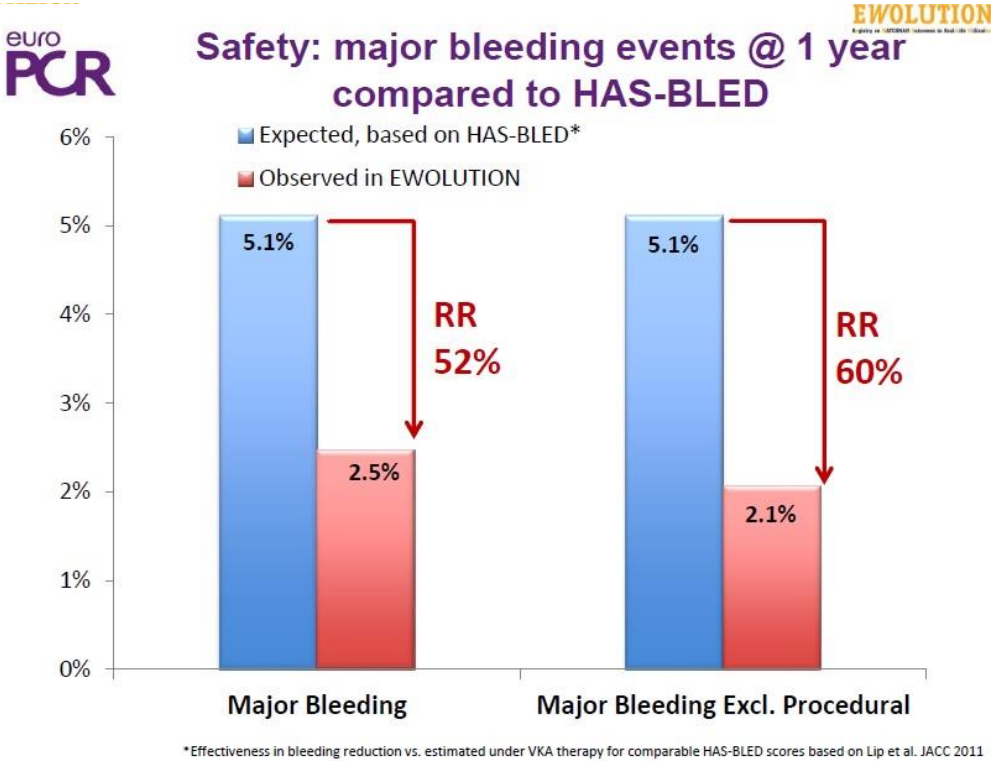
Tzikas 2014

Tzikas A, EuroInterv 2015

Safety and efficacy results in the EWOLUTION all-comers LAA closure study: DAPT subgroup



*Effectiveness in stroke reduction vs. estimated in the absence of therapy for comparable CHA_2DS_2-VASc scores based on Friberg et



*Effectiveness in bleeding reduction vs. estimated under VKA therapy for comparable HAS-BLED scores based on Lip et al. JACC 2011

Bergmann M. EuroPCR 2017

2019 euro PCR

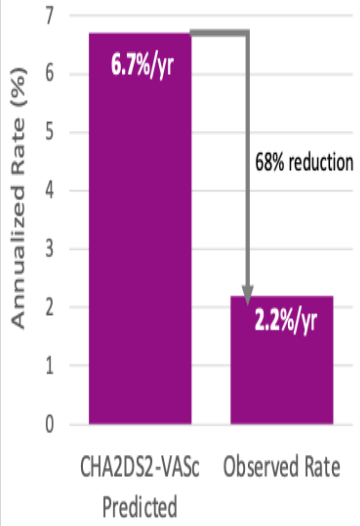
LAA Occlusion with the Amplatzer™ Amulet™ device: Primary results of the prospective global Amulet Observational Study

Dr. David Hildick-Smith, MD – Brighton and Sussex University Hospitals, Brighton, United Kingdom

Baseline Characteristic	All enrolled (N = 1,088)
Age (years)	75.2 ± 8.5
Gender - Male	64.5%
CHA_2DS_2-VASc Score	**4.2 ± 1.6**
HAS-BLED Score	**3.3 ± 1.1**
Prior Stroke	27.5%
Prior TIA	10.6%
Previous Major Bleed	**71.7%**
Contraindication to OAC	**82.8%**

Primary Endpoints	
Ischaemic Stroke rate at 2 years	
-Ischemic stroke	2.2%/year
-Systemic embolism	0.0%/year

Ischaemic Stroke Rate



TCT-689

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

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

[1]Instituto Cardiovascular de Rosario, Rosario, Argentina, [2]Hospital Cardiologico costantini, Curitiba, Brazil, [3]Instituto Dante Pazzanese, São Paulo, Brazil, [4]Hospital Clínico Pontificia Universidad Católica de Chile, Santiago, Chile, [5]Hospital de Niños Roberto del Río, Santiago, Chile, [6]Hospital Albert Einstein, São Paulo, Brazil, [7]centro medico de caracas, Caracas, Venezuela, [8]ICBA, Buenos Aires, Buenos Aires, [9]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 ecocardiography (TEE) and fluoroscopic guidance. Clinical and TEE follow up was performed at 30 days, and clinical follow up thereafter.

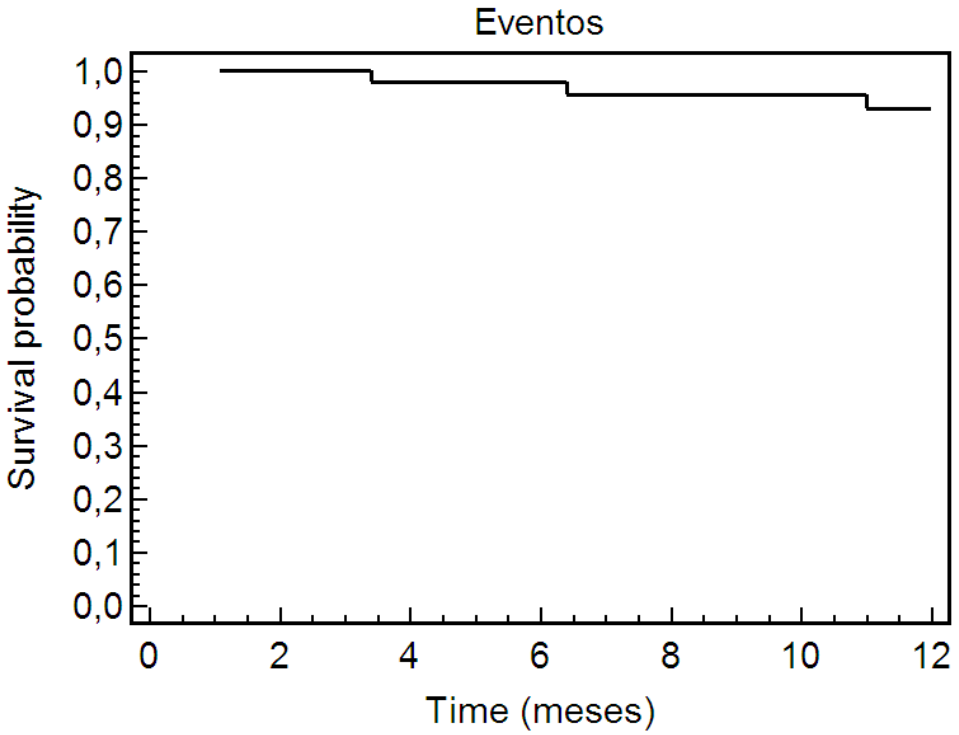
Results: 60 patients were included. Age 72±8.7 years;male70%; hypertensive78%;congestive heart failure32.17%; CHADS2 score 3.15±1.1; contraindications to oral anticoagulation 64.3% LAA neck diameter was 20.3±3.8 mm by TEE and 22.6±3.2 by angiography. LAA occlusion was attempted and successfully achieved in all 60 patients, and in 3 cases, simultaneous closure of the LAA and PFO was performed. The implanted device size was 25±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±1.25, vs 2.77±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



Damonte A,et al TCT2013

Cierre percutáneo de la orejuela auricular izquierda con Amplatzer Cardiac Plug: resultados hospitalarios y a 30 días

Percutaneous closure of the left atrial appendage with the Amplatzer Cardiac Plug: inhospital and 30 days follow-up results

Aníbal Damonte[1], Leandro Lasave[1], Alejadro Diego Fernández[2], León Valdivieso[3], Fernando Cura[4], Germán Henestrosa[5], Costantino Costantini[6], Christian Pincetti[7], Luis Alberto Pérez[8], Carlos Pedra[9]

TABLA 1. Características basales (n=91).

Edad	72±9
Masculino	65 (71,4%)
HTA	80 (88%)
DBT	30 (33%)
DLP	30 (33%)
TBQ	7 (7,6%)
Insuficiencia cardíaca	25 (27,5%)
ACV/AIT previo	31 (34%)
ACO previa	59 (65%)
Contraindicación para ACO	66 (72,5%)
$CHADS_2$	2,74±1,1
CHA_2DS_2VASC	3,64±1,25
HASBLED	3,34±1

ACV: Accidente cerebrovascular; AIT: Accidente isquémico transitorio; ACO: Anticoagulación oral.

TABLA 3. Cierre de OAI: resultados de diferentes estudios.

	PROTECT AF[20] n=463	PROTECT AF[20] cohorte inicial n=271	ACP Registro Europeo[23] n=143	Registro LatAm n=91
Implante exitoso %	89,5	88,2	96	100
Tapona-miento %	5	6,3	3,5	4,4
Embolia dispositivo %	0,2	N/A	1,4	1,1
ACV/AIT %	0,9	1,1	2,1	0
Complicaciones mayores %	7,7	10	7,0	5,5

ACV: accidente cerebrovascular. AIT: accidente isquémico transitorio.

Fibrilación auricular en pacientes con alto riesgo de sangrado: Cierre de orejuela izquierda

EHRA/EAPCI consensus statement on LAA occlusion

EuroIntervention 2015;10:1109-1125

Table 6 . Anticoagulation during and after LAA occlusion.

Device/ patient	Heparin (ACT ≥250)	Low-molecular-weight heparin	ASA	Warfarin	Clopidogrel	Comments
Watchman/ Low bleeding risk	Prior to or immediately after transseptal punctures	Post-procedure till INR ≥2	Load 500 mg prior to procedure if not on ASA, continue 100-325 mg/ day indefinitely	Start after procedure INR 2-3 till 45 days or continue till adequate occlusiona by TOE	Start when warfarin stopped continue till 6 months after the procedure	Some centres do not withhold warfarin and perform procedure on therapeutic INR (no data to support or dispute this approach)
Watchman/ High bleeding risk	Prior to or immediately after transseptal puncture	None	Load 500 mg prior to procedure if not on ASA, continue 100-325 mg/ day indefinitely	None	Load 300-600 mg prior to procedure if not on clopidogrel, continue 1-6 months while ensuring adequate occlusiona	Clopidogrel often given for shorter time in extremely high-risk situations. Clopidogrel may replace long-term ASA if better tolerated
ACP	Prior to or immediately after transseptal puncture	None	Load 500 mg prior to procedure if not on ASA, continue 100-325 mg/ day indefinitely occlusiona	None	Load 300-600 mg prior to procedure if not on clopidogrel, continue 1-6 months while ensuring adequate	Clopidogrel often given for shorter time in extremely high-risk situations. Clopidogrel may replace long-term ASA if better tolerated

ACT, activated clothing time; INR, international normalized ratio. aLess than 5 mm leak.

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MARZO 2015

Recomendaciones

CLASE IIa

1. La amputación de la OI durante la cirugía de reemplazo de la valvula mitral es razonable en aquellos pacientes con FA y puntuación ^{3} 2 y contraindicación para recibir ACO. (Nivel de evidencia B).
2. La oclusión percutánea mediante un dispositivo de la OI es razonable en aquellos pacientes con FA y puntuación ≥ 2 y contraindicación para recibir ACO. (Nivel de evidencia B).

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

“Indicaciones”

Europace (2013) **15**, 652–656
doi:10.1093/europace/eut043

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

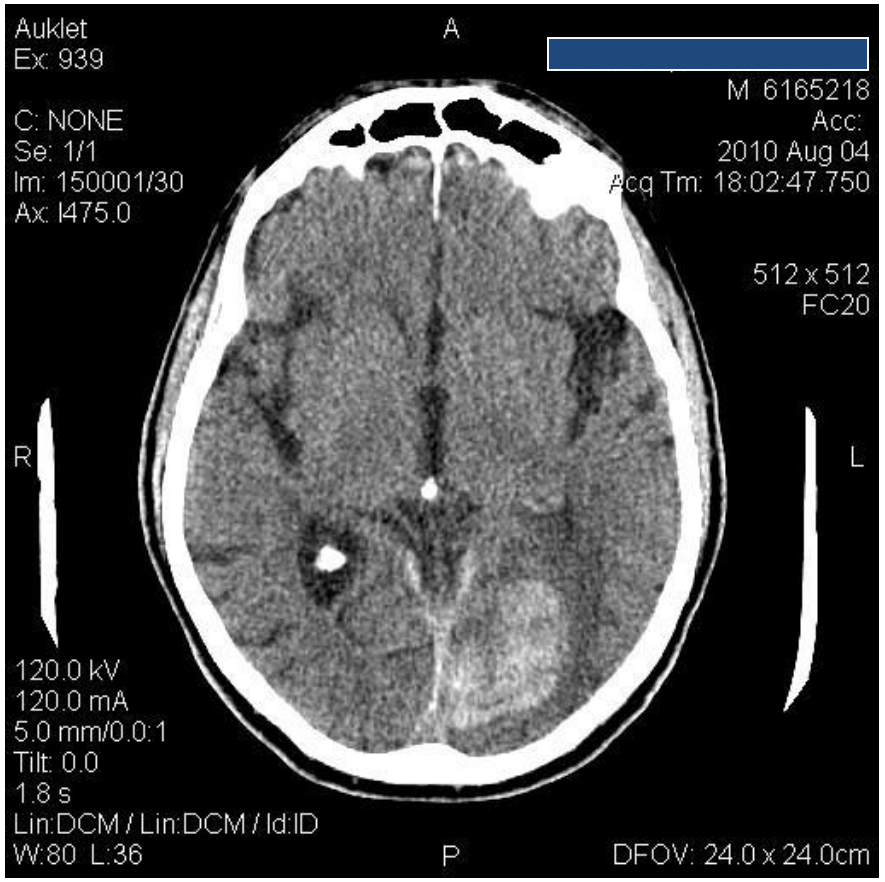
Thorsten Lewalter[1], Réda Ibrahim[2], Bert Albers[3], and A. John Camm[4]*

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: ICH on OAC

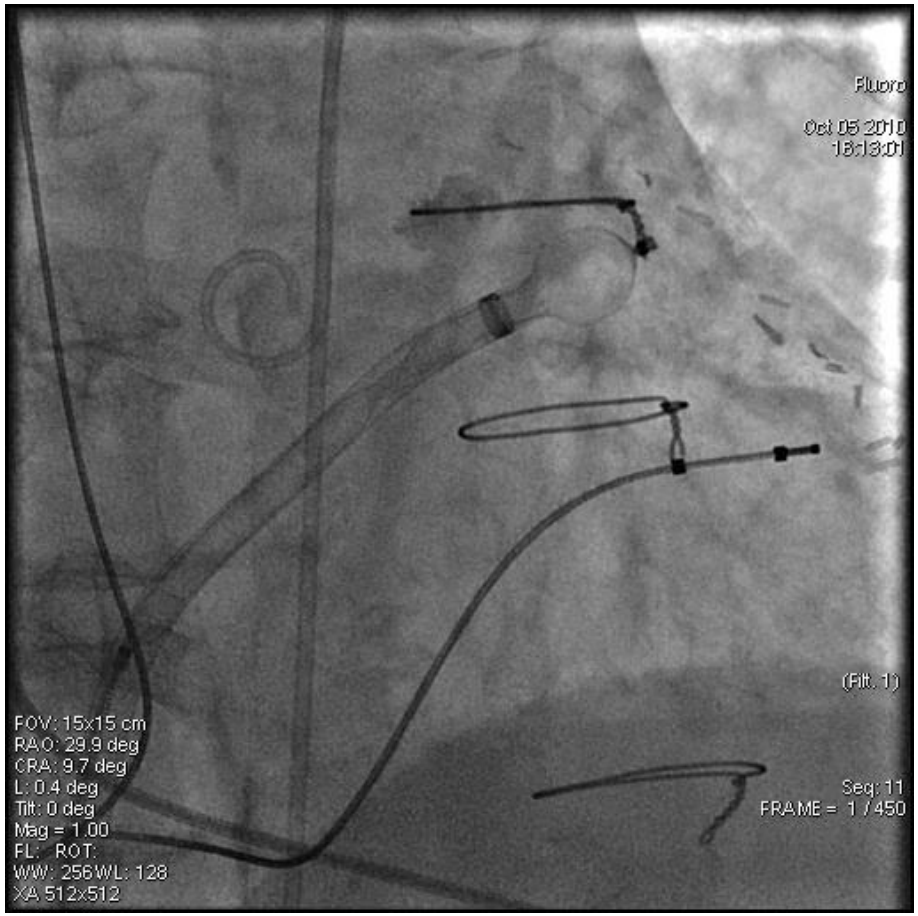
76 year-old male.
History of hipertension.
Previous AMI, CABG in 1999
Chronic atrial fibrilation since 2007, on chronic anticoagulation therapy.
Hospitalized in 2009 for CHF.
He was admited in August 2010 with ICH

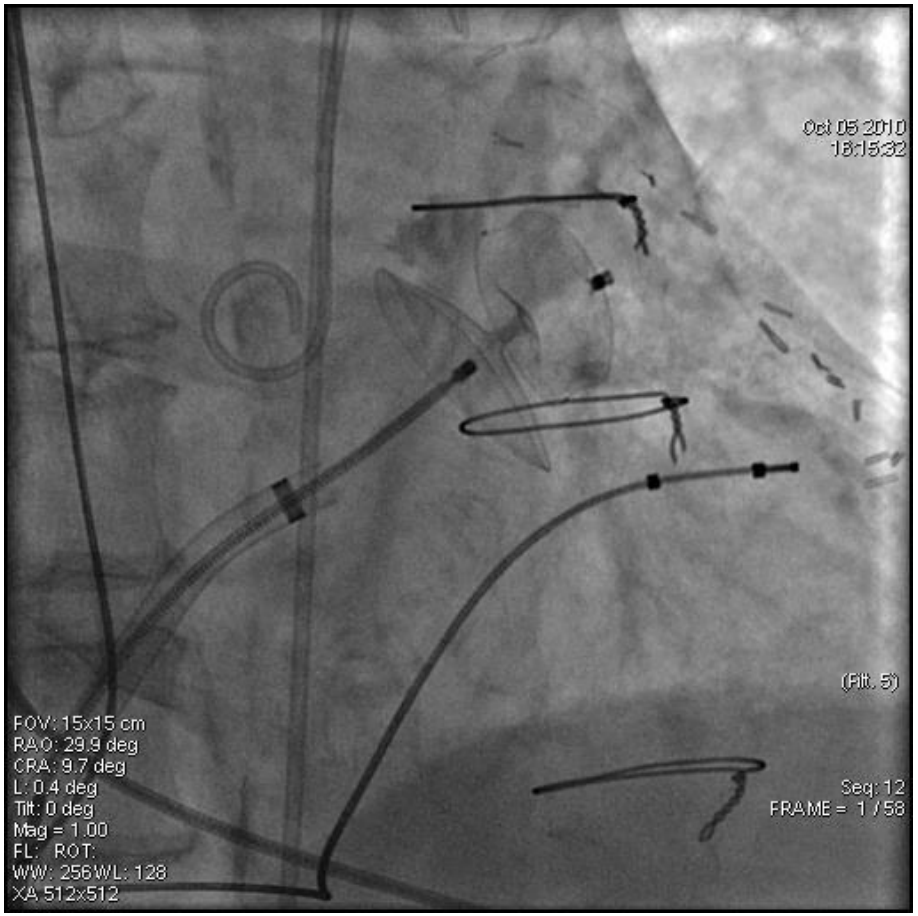


Diagnosis: Chronic AF
CHADS2 Score 3
Contraindication to ACO

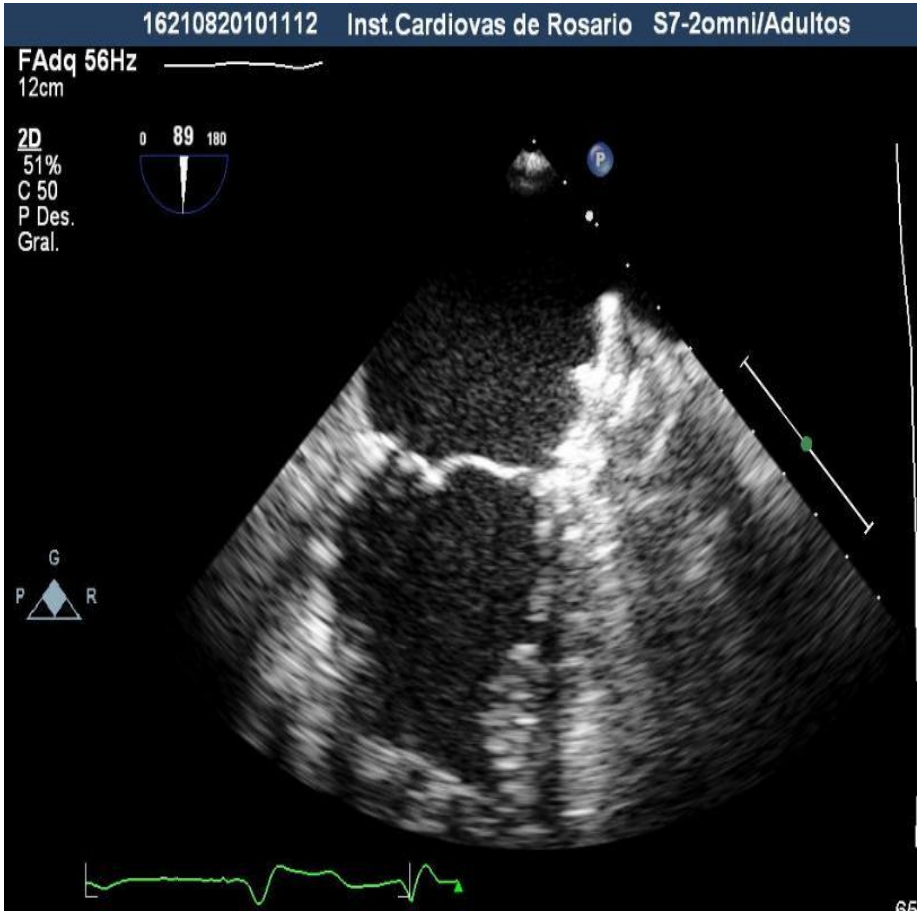
Plan: Closure of LAA with the ACP

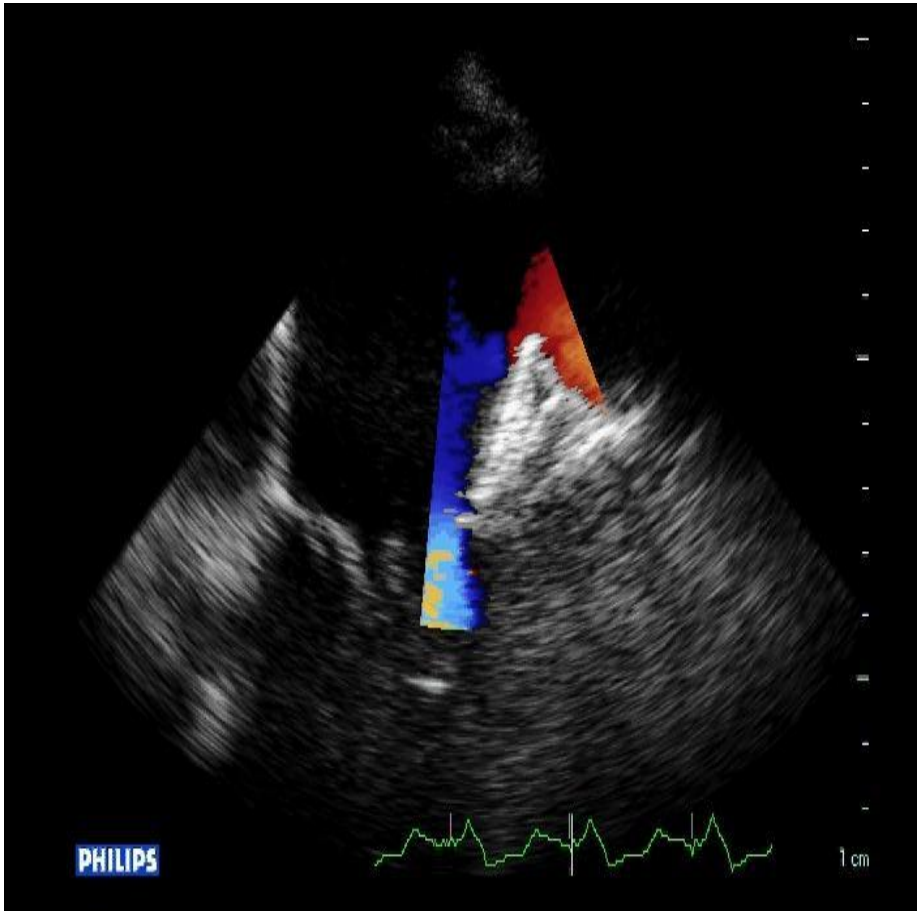
Device Deployment





TEE at 45 days





Left atrial appendage occlusion versus standard medical care in patients with atrial fibrillation and intracerebral haemorrhage: a propensity score-matched follow-up study

Jens Erik Nielsen-Kudsk[1]*, MD, DMSc; Søren Paaske Johnsen[2], MD, PhD; Per Wester[3], MD, PhD; Dorte Damgaard[4], MD, PhD; Juhani Airaksinen[5], MD, PhD; Juha Lund[5], MD; Ole De Backer[6], MD, PhD; Sami Pakarinen[7], MD, PhD; Jacob Odenstedt[8], MD, PhD; Saila Vikman[9], MD, PhD; Magnus Settergren[10], MD, PhD; Ole Kongstad[11], MD, PhD; Mårten Rosenqvist[12], MD, PhD; Derk W. Krieger[13], MD, PhD

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_2DS_2-VASc mean (SD)	**4.0** (1.5)	**3.9** (1.5)
HAS-BLED mean (SD)	**4.2** (0.8)	**4.2** (0.8)
Antithrombotic treatment	(during follow-up)	(at latest follow-up)
Warfarin	**20%**	**0%**
NOAC	**23%**	**0%**
Platelet inhibitors	**37%**	**71%**
No treatment	**44%**	**29%**

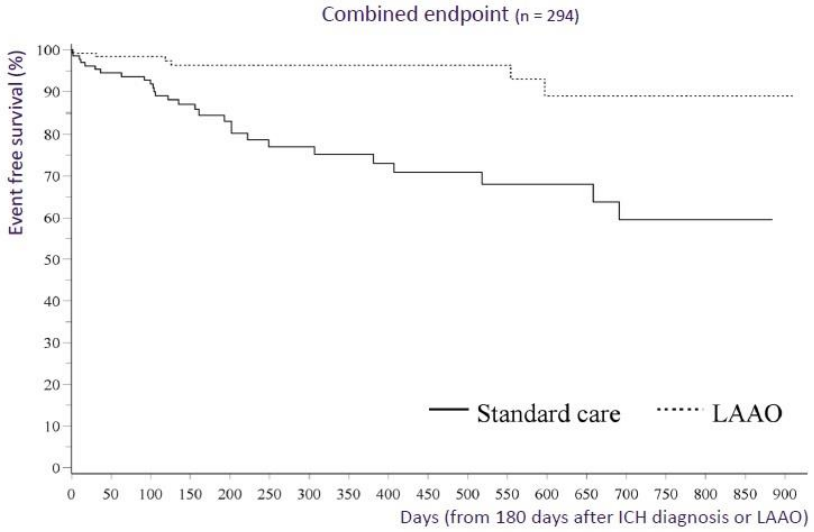
Median follow-up time: 166 days (25%/75% quartile: 70/458 days)
Median time from ICH to LAAO: 189 days (25-4533 days)

EuroIntervention 2017;13:371-378

Left atrial appendage occlusion versus standard medical care in patients with atrial fibrillation and intracerebral haemorrhage: a propensity score-matched follow-up study

Jens Erik Nielsen-Kudsk[1]*, MD, DMSc; Søren Paaske Johnsen[2], MD, PhD; Per Wester[3], MD, PhD; Dorte Damgaard[4], MD, PhD; Juhani Airaksinen[5], MD, PhD; Juha Lund[5], MD; Ole De Backer[6], MD, PhD; Sami Pakarinen[7], MD, PhD; Jacob Odenstedt[8], MD, PhD; Saila Vikman[9], MD, PhD; Magnus Settergren[10], MD, PhD; Ole Kongstad[11], MD, PhD; Mårten Rosenqvist[12], MD, PhD; Derk W. Krieger[13], MD, PhD

euro PCR Ischemic stroke/major bleeding/mortality



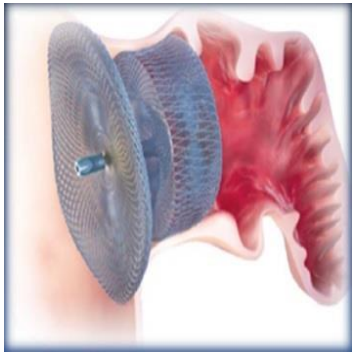
euro PCR Hazard ratios

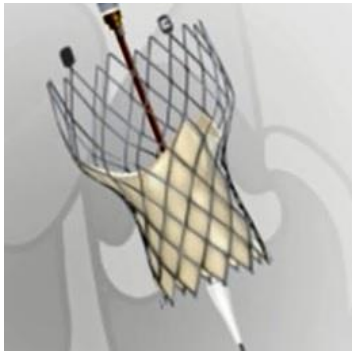
Clinical outcome HR by Cox-regression analysis n = 147 in each PS-matched patient group	LAAO vs. Standard care Hazard ratio (95% CI)	Relative risk reduction (%)
Ischemic stroke/major bleeding/mortality	**0.19** (0.08-0.46)*	81%
Ischemic stroke	**0.35** (0.07-1.79)	65%
Major bleeding	**0.39** (0.12-1.28)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

*p<0.05

EuroIntervention 2017;13:371-378

TAVI y Cierre de Orejuela Izquierda





Prevalencia de FA en estudios clinicos de TAVI

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

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

Riesgo de sangrado PARTNER 1

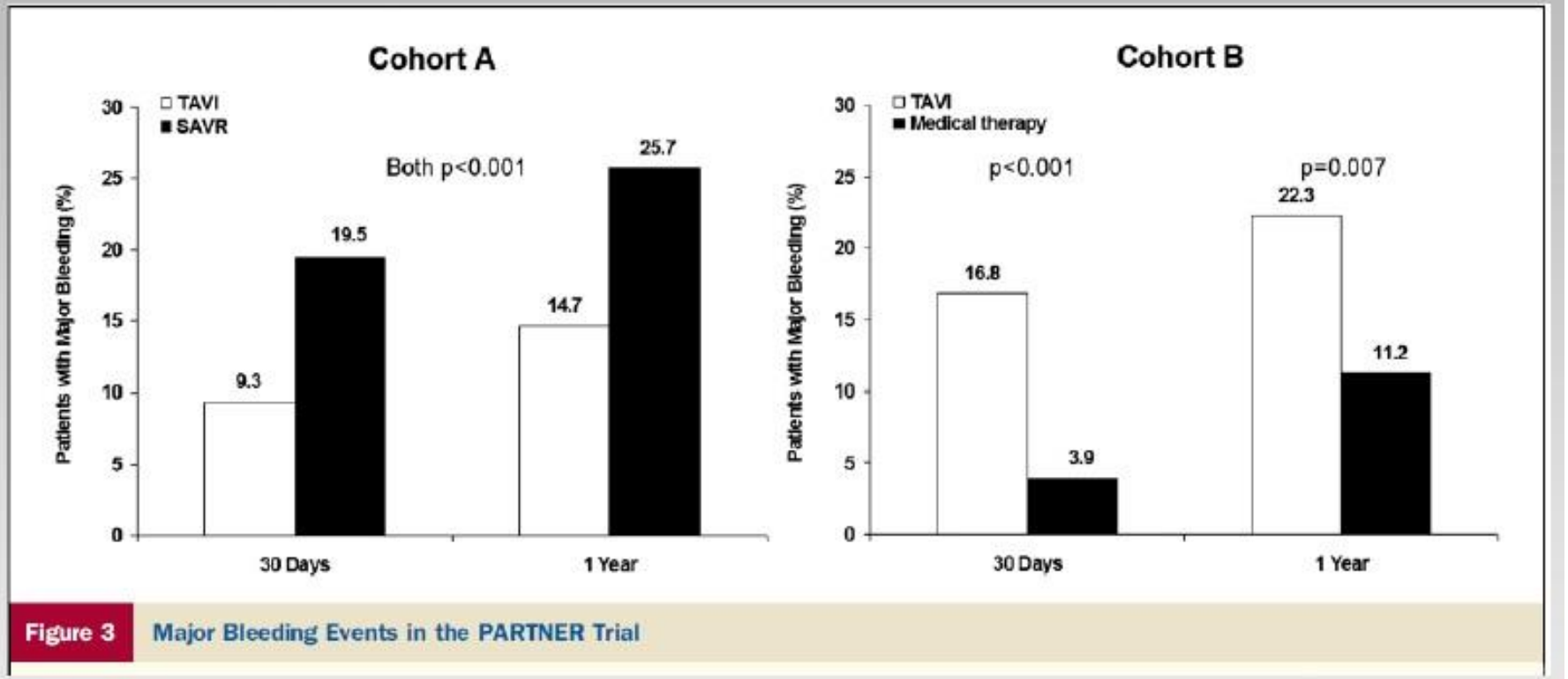
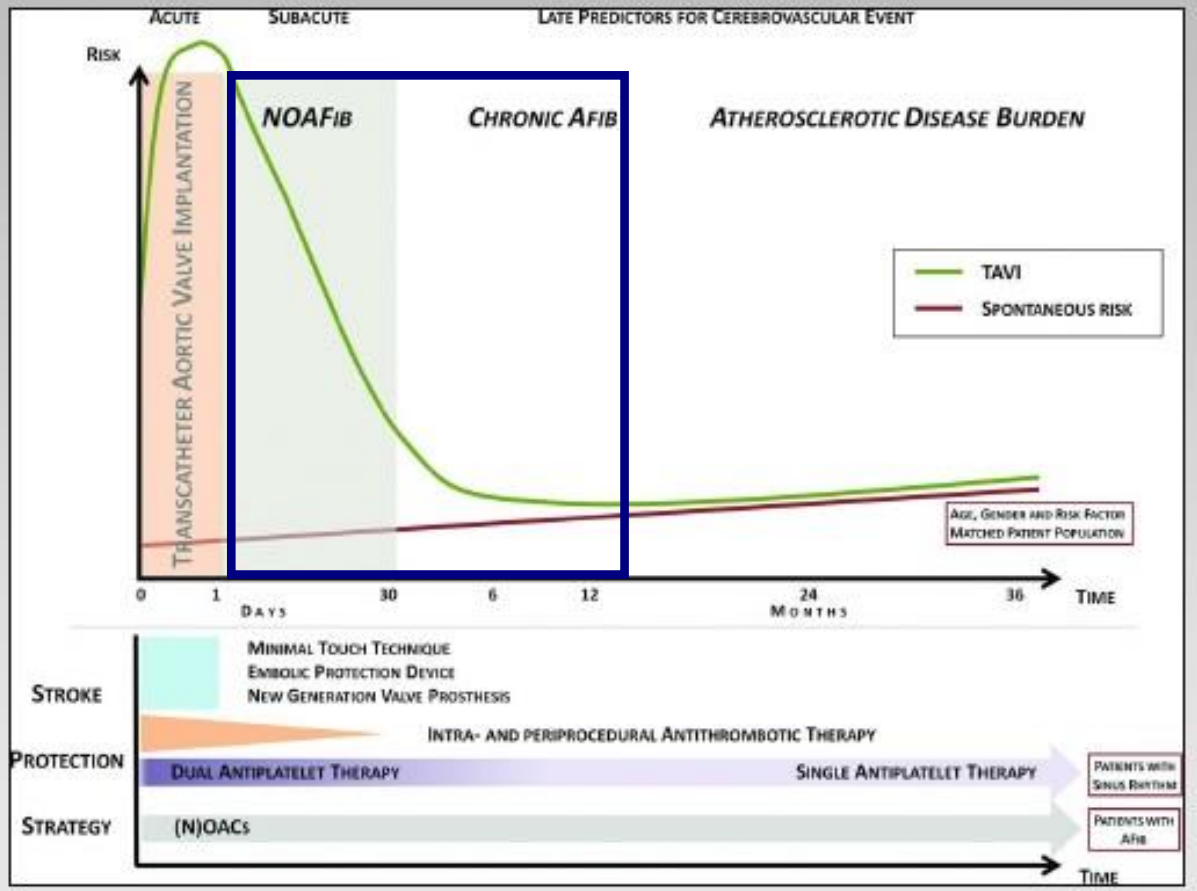


Figure 3 Major Bleeding Events in the PARTNER Trial

~ 5-6% rate of major bleeding from 30 days to 1 year

Rodes-Cabau J, et al. JACC 2013;62:2349-2359

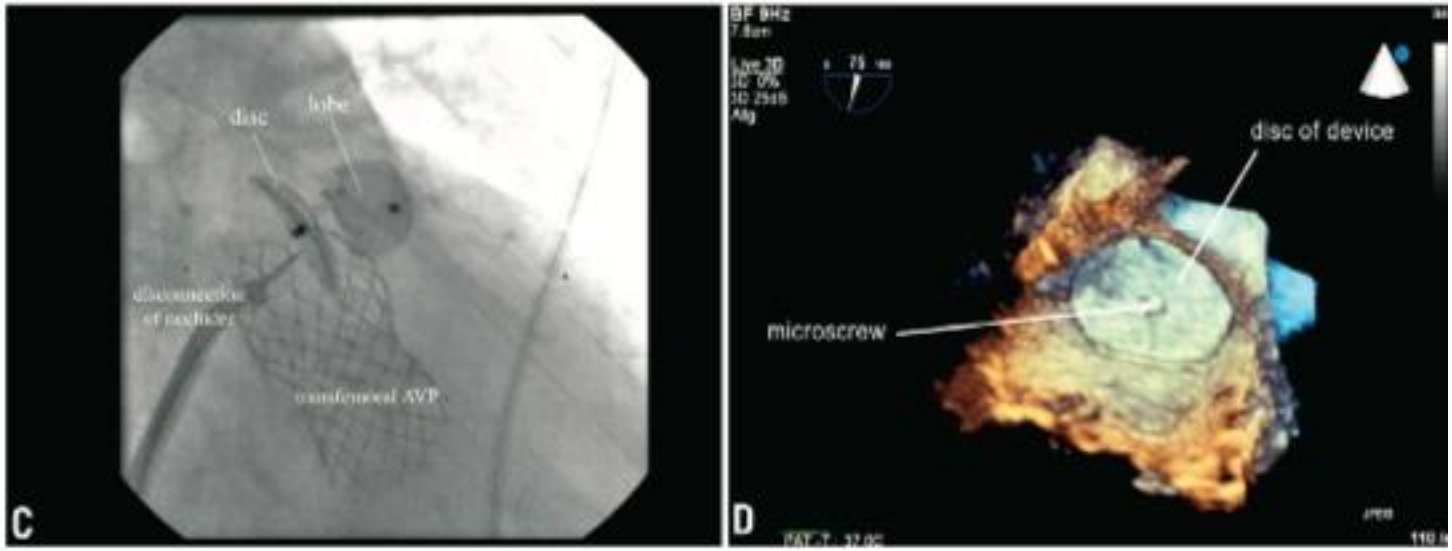
Etiologia del Stroke post TAVI



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

Percutaneous closure of left atrial appendage after transcatheter aortic valve implantation - an interventional approach to avoid anticoagulation therapy in elderly patients: TAVI and closure of LAA to avoid warfarin therapy

Nikola Bogunovic; Werner Scholtz, MD; Christian Prinz, MD; Lothar Faber, MD; Dieter Horstkotte, MD; Frank van Buuren*, MD



EuroIntervention 2012

Atrial fibrillation in the TAVR patient: a potential indication for LAA closure?

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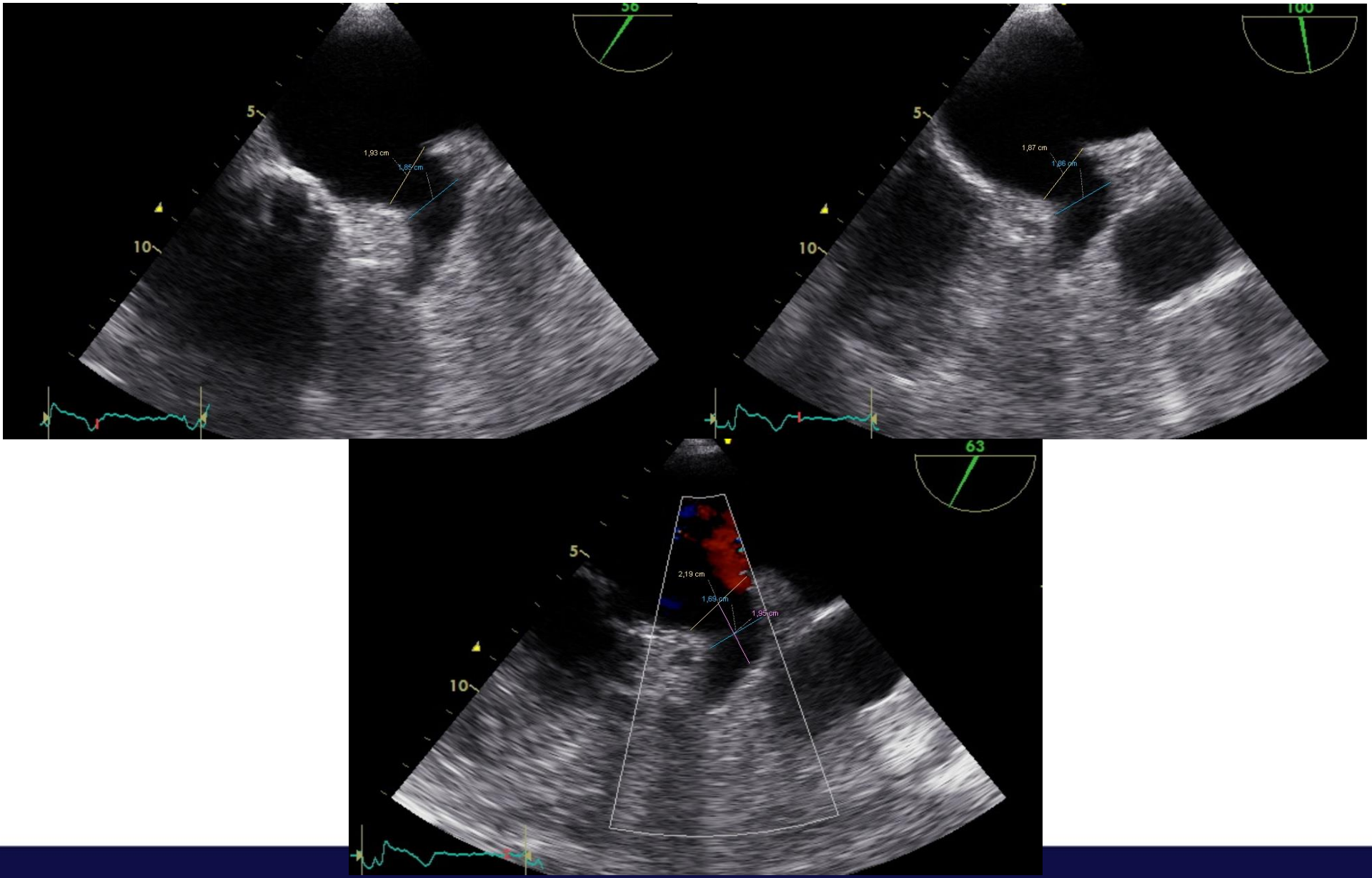
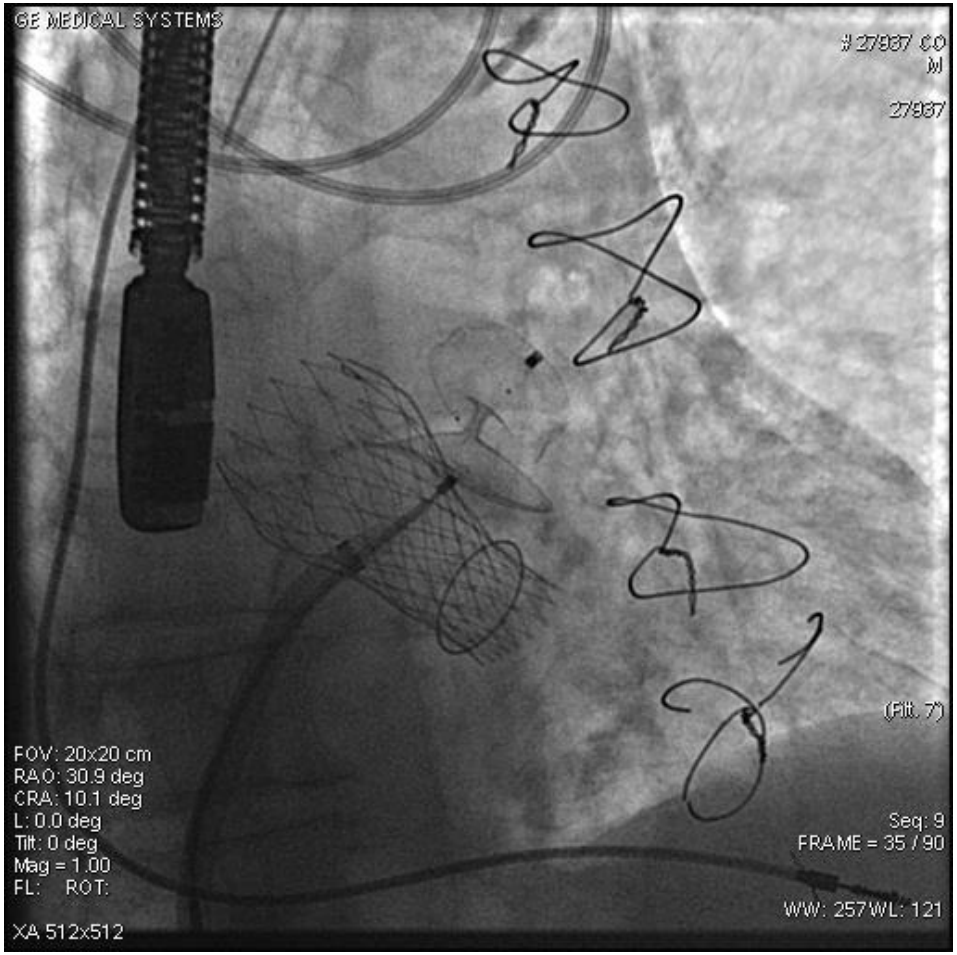
Case presentation

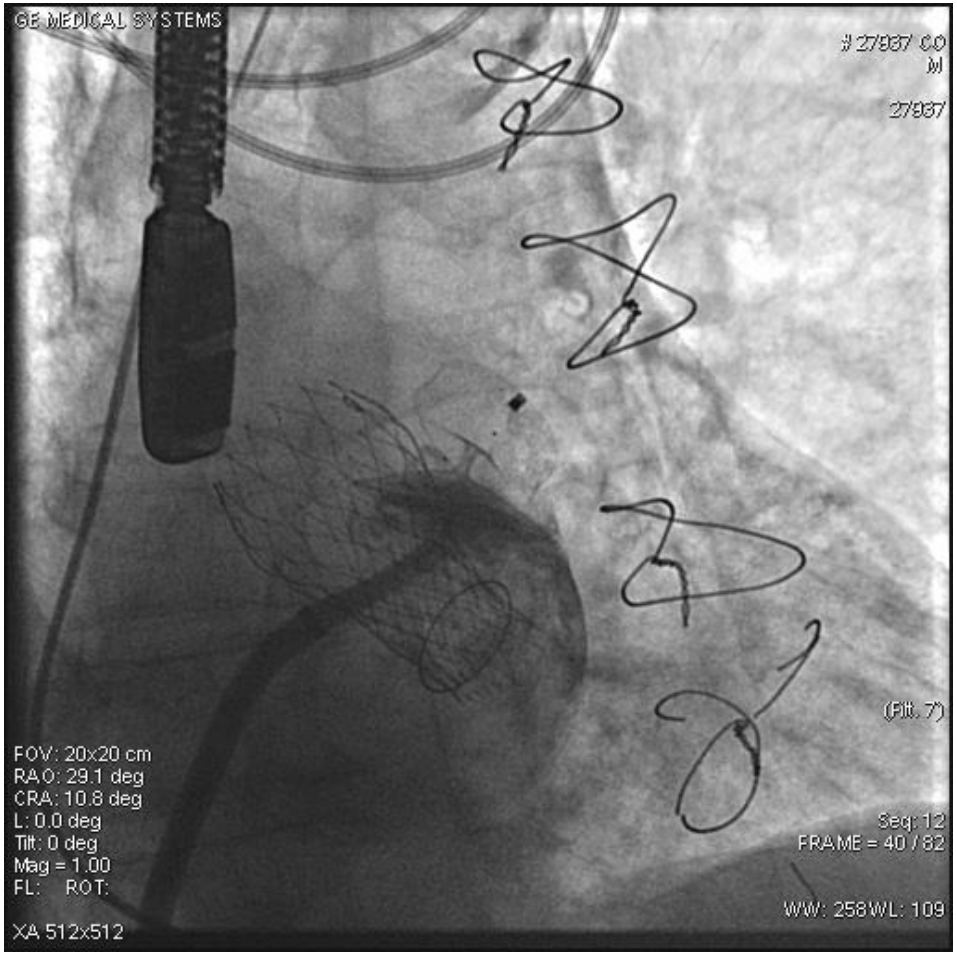
- 83 year-old male patient, with a history of hypertension and alcohol abuse.
- Aortic valve replacement in 2005 with a bioprosthesis.
- Permanent atrial fibrillation, under pharmacologic treatment for rate control and chronic anticoagulation therapy.
- Permanent pacemaker in 2013
- TAVI in January 2014, for severely symptomatic restenosis of the surgical bioprosthesis.
- Hospitalized in January 2015 for major gastrointestinal bleeding secondary to gastric Dieulafoy`s lesion, treated endoscopically, but considered to have high risk of re-bleeding.
- CHA_2DS_2VASC: 4
- HASBLED: 4
- Referred to our hospital for left atrial appendage (LAA) occlusion.

Pre procedural TEE

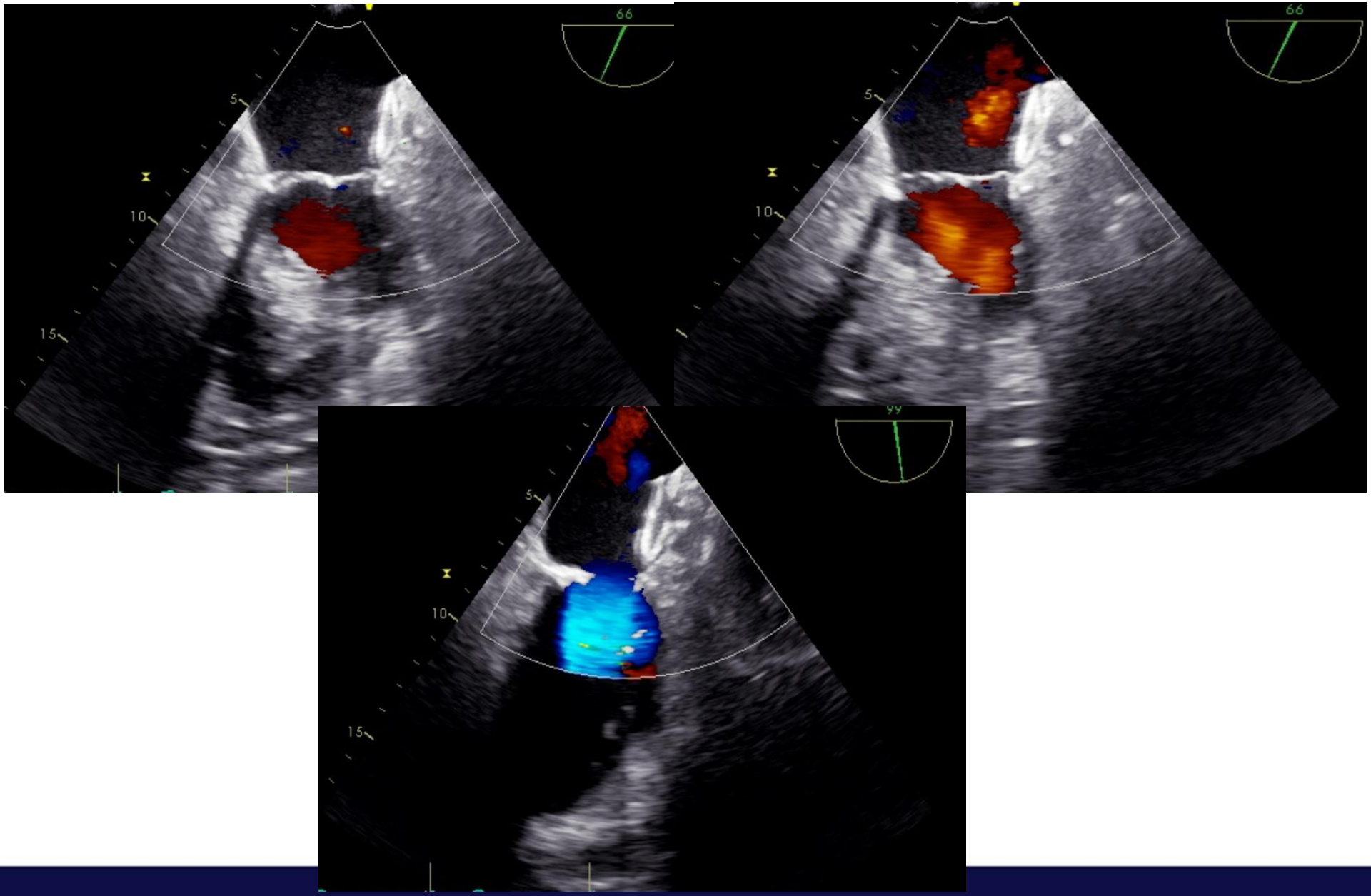


LAA closure with 24mm ACP device

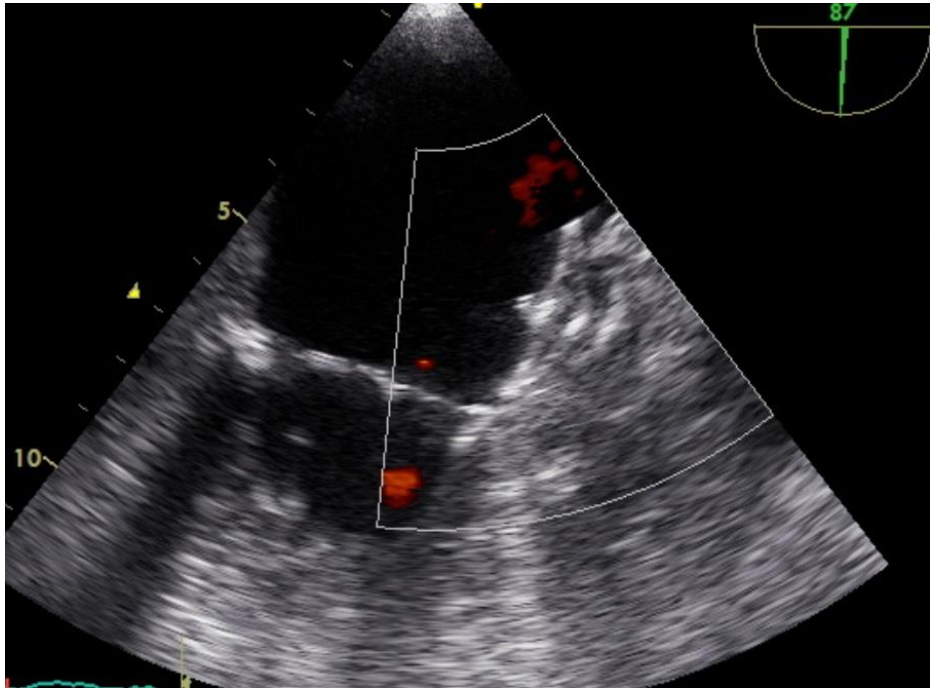


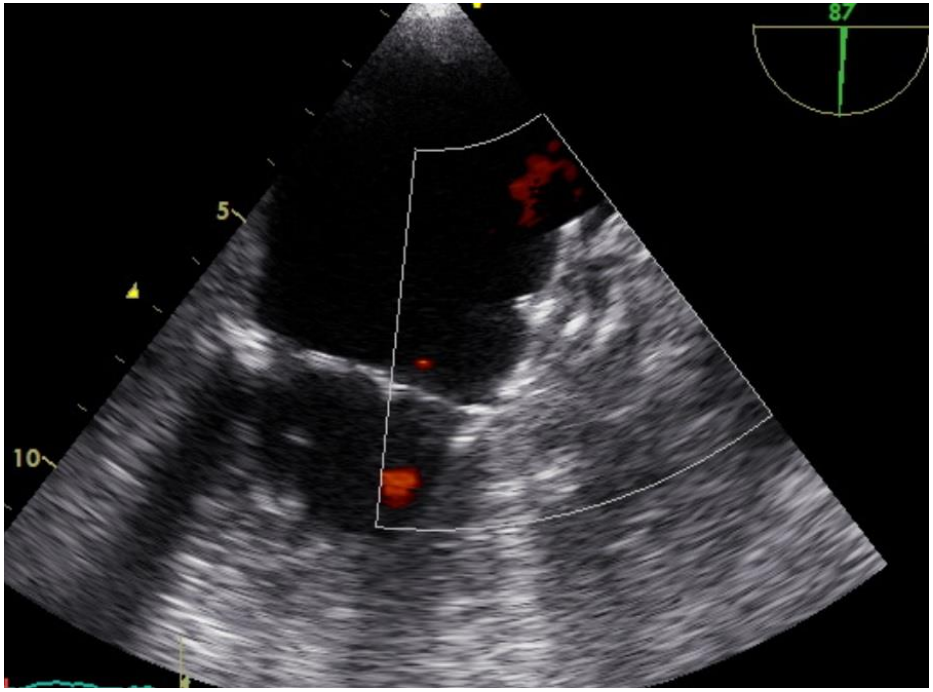


LAA Closure TEE evaluation



LAA Closure – 30 days TEE





"One-Stop Shop"

Safety of Combining Transcatheter Aortic Valve Replacement and Left Atrial Appendage Occlusion

Adrian Attinger-Toller, MD,[a] Francesco Maisano, MD,[a] Oliver Senn, MD,[b] Maurizio Taramasso, MD,[a] Samera Shakir, MD,[c] Mathias Possner, MD,[a] Steffen Gloekler, MD,[c] Stephan Windecker, MD,[c] Stefan Stortecky, MD,[c] Thomas F. Lüscher, MD,[a] Bernhard Meier, MD,[c] Fabian Nietlispach, MD, PhD[a]

ABSTRACT

OBJECTIVES The aim of this study was to investigate the safety and efficacy of combining transcatheter valve replacement (TAVR) and left atrial appendage occlusion (LAAO) versus TAVR alone.

BACKGROUND Patients with severe aortic stenosis and atrial fibrillation undergoing TAVR are at increased risk for stroke and bleeding complications.

METHODS A cohort of 52 patients undergoing concomitant TAVR and LAAO were compared with 52 patients undergoing isolated TAVR. A primary safety endpoint at 30 days, a clinical efficacy endpoint from day 30 to last follow-up, and an LAAO efficacy endpoint from the first post-interventional day to the last follow-up were chosen.

RESULTS The mean age of the study population was 85 ± 5 years. The mean CHA_2DS_2-VASc score and HAS-BLED score were 3.9 ± 1.1 and 2.6 ± 0.9, respectively. The mean Society of Thoracic Surgeons score was 7.8 ± 5.5. The median follow-up duration of the study population was 9.4 months (range 0 to 48 months). The primary safety endpoint occurred in 10 patients in the concomitant group and in 7 patients in the isolated TAVR group (19% vs. 14%; 95% confidence interval: 0.59 to 4.06). The clinical and LAAO efficacy endpoints were achieved in 81 (79%) (75% vs. 82%; 95% confidence interval: 0.49 to 2.92) and 75 (73%) patients (69% vs. 76%; 95% confidence interval: 0.54 to 2.51), respectively.

CONCLUSIONS This pilot study shows that concomitant TAVR and LAAO is feasible and seems to be safe among patients with severe aortic stenosis and atrial fibrillation. Larger trials and longer follow-up are needed to confirm the safety and efficacy of such an approach. (J Am Coll Cardiol Intv 2016;9:1487–95)

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 contemporaneos de manejo de ACO muestran la necesidad de una alternativa no farmacológica para la prevención del stroke en la FA

• Existe evidencia creciente y consistente 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.

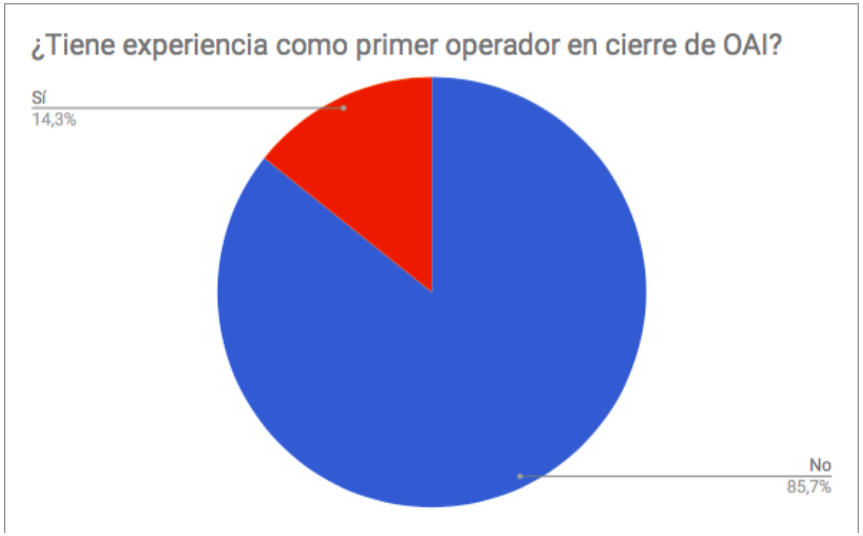
• Las guías nacionales, consideran el cierre de OAI, razonable en p con FA no valvular, alto riesgo cardioembólico y contraindicaciones para ACO (Clase IIa)

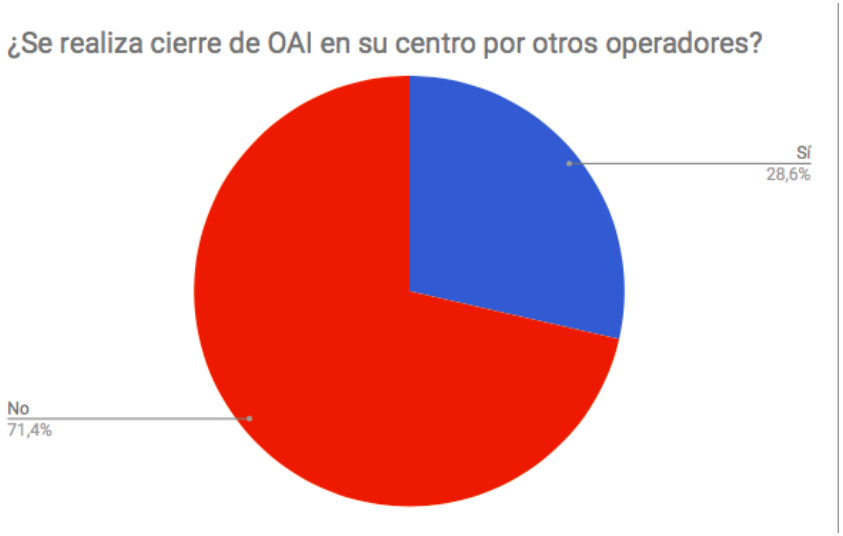
• La experiencia local, muesta resultados similares a registros internacionales.

• Para cada situación, los riesgos y beneficios deben ser cuidadosamente considerados y explicados al paciente.

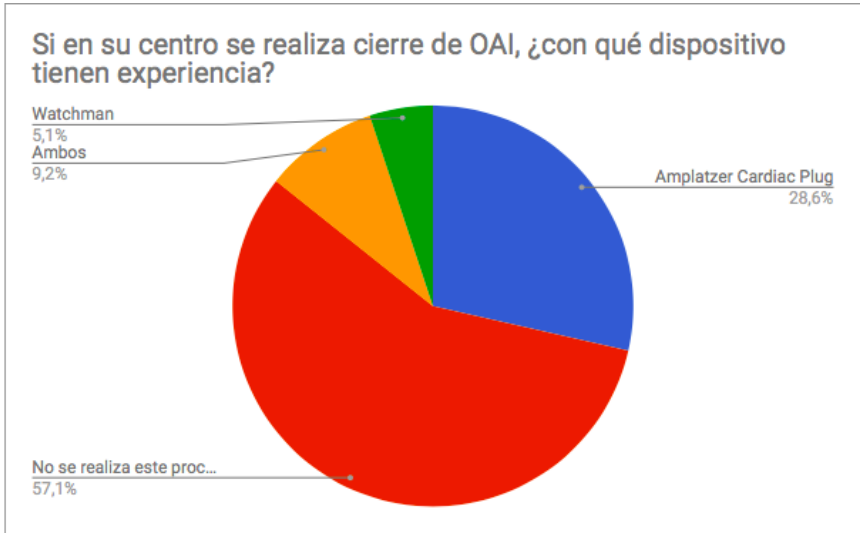
Muchas Gracias!!!!

Encuesta CACI 2017





Encuesta CACI 2017



Encuesta CACI 2017