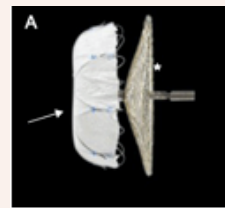
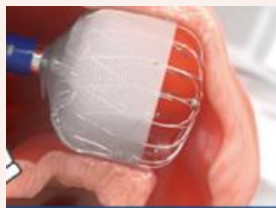
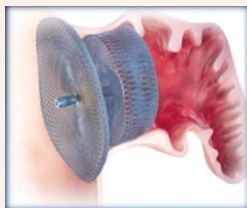


Cierre de Orejuela Auricular Izquierda 2025: Cambiará la nueva evidencia nuestra práctica?



Dr. Aníbal Damonte (damontea@icronline.com)

Jefe del Servicio de Hemodinamia y Cardiología Intervencionista, Instituto Cardiovascular de Rosario

Ex Presidente del CACI; Ex Presidente de la Sociedad Latino Americana de Cardiología Intervencionista (SOLACI)

Declaración de potenciales conflictos de interés:

Proctor y consultor Abbott (Cierre de orejuela izquierda)

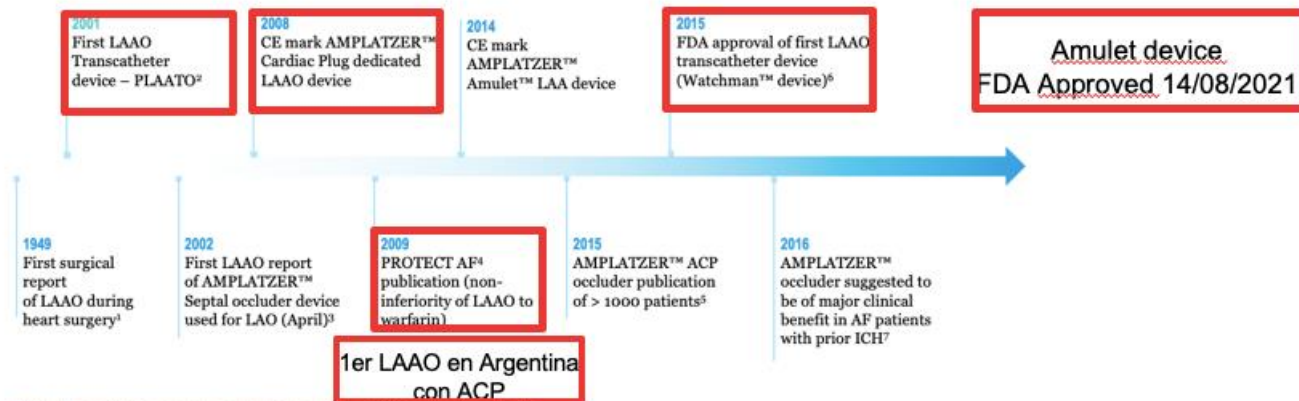
Proctor y consultor Medtronic (TAVI)

Agenda

- Introducción
- Cierre de OAI vs DOACs
- Comparación entre dispositivos
- Rol de la TAC multicorte en la planificación
- Indicaciones actuales
- Rol de los simuladores

Introducción

Left atrial appendage occlusion

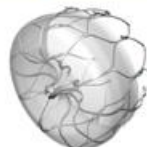


- [illegible]

Various types of occluding devices



PLAATO™ Device



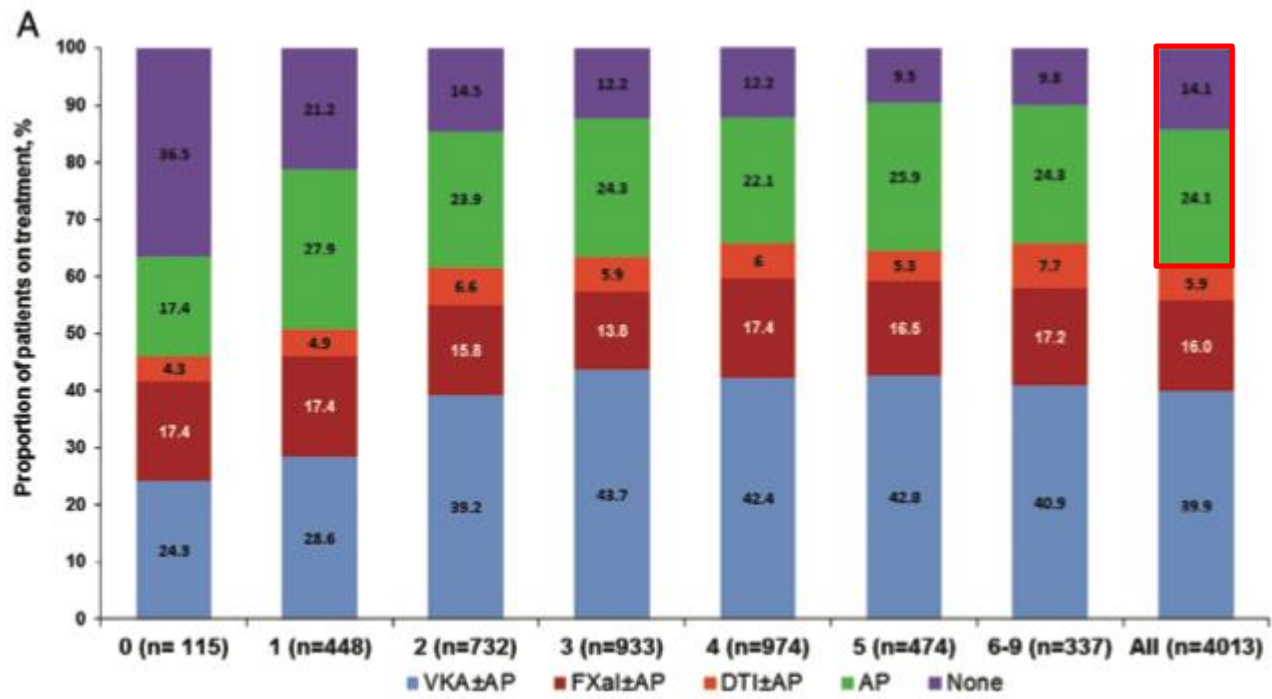
WATCHMAN™
LAA Closure Device



AMPLATZER™
Left Atrial Appendage
Occluders

Stroke prevention in patients from Latin American countries with non-valvular atrial fibrillation: Insights from the GARFIELD-AF registry

Carlos Jerjes-Sanchez¹ | Ramon Corbalan² | Antonio C. P. Barretto³ | Hector L. Luciardi⁴ | Jagan Allu⁵ | Laura Illingworth⁵ | Karen S. Pieper^{5,6} | Gloria Kayani⁵ | for the GARFIELD-AF Investigators[†]



Problemas de la ACO crónica

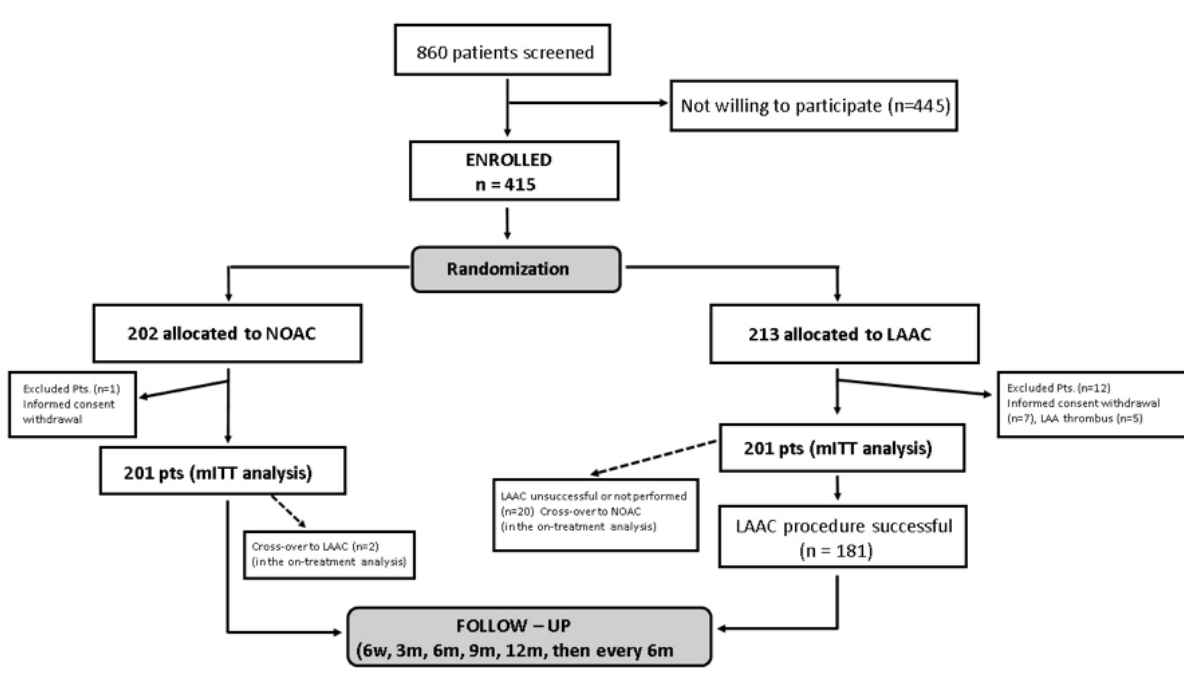
- Eficacia incompleta
- Sangrado intracerebral
- Otros sangrados mayores que amenazan la vida
- Interacciones medicamentosas y alimentarias
- Dosis inadecuadas
- Pobre adherencia y persistencia en la terapia
- Agentes de reversión costosos y poco disponibles

Resultados de los Estudios Clínicos:

Cierre de OAI vs DOACs

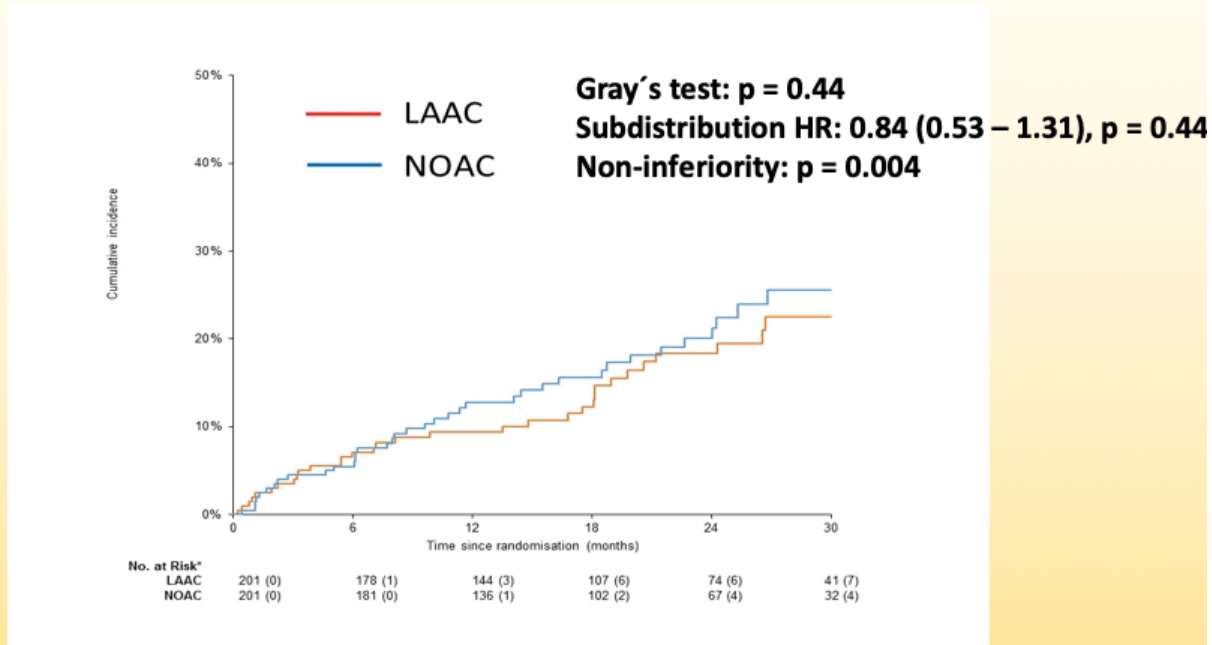
Percutaneous left atrial appendage closure versus novel anticoagulation agents in high-risk atrial fibrillation patients (*PRAGUE-17* study)

Pavel Osmancik, Dalibor Herman, Petr Neuzil, Pavel Hala, Milos Taborsky, Petr Kala, Martin Poloczek, Josef Stasek, Ludek Haman, Marian Branny, Jan Chovancik, Pavel Cervinka, Jiri Holy, Tomas Kovarnik, David Zemanek, Stepan Havranek, Vlastimil Vancura, Richard Rokyta, Petr Peichl, Petr Tousek, Veronika Leikesova, Jiri Jarkovsky, Martina Novackova, Klara Benesova, Petr Widimsky & Vivek Y. Reddy

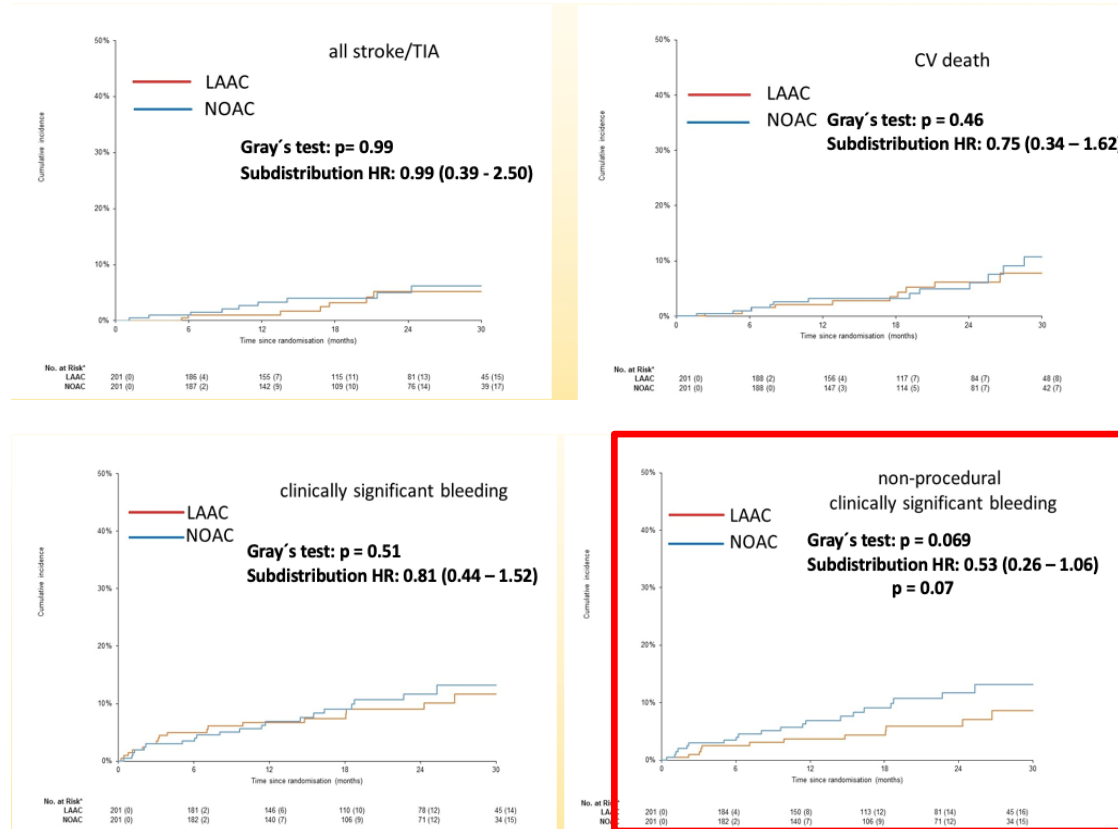


PRAGUE – 17 Study

Cumulative incidence function (CIF) for primary study endpoint in intention-to-treat populations



PRAGUE – 17 Study



PRAGUE-17 Trial: Long-Term (4-Year) Follow-Up

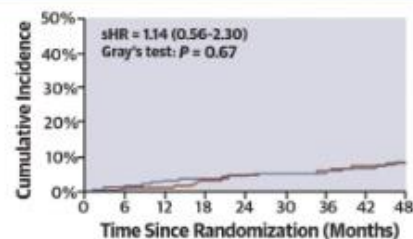
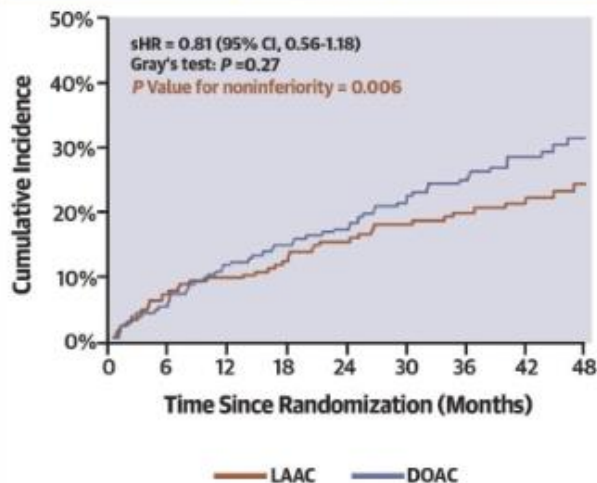


- 402 High-risk AF pts → Randomized
 - CHA₂DS₂-VASc = 4.7 ± 1.5
 - HAS-BLED = 3.1 ± 0.9
- Median Follow-up: 3.5 years (IQR 2.6-4.3), 1,354 pt-year

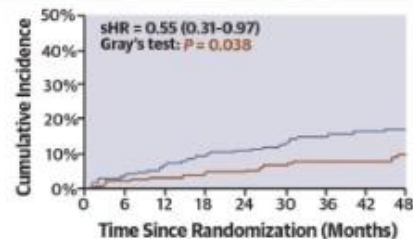


Stroke or TIA

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



Non-Procedural Clinically Relevant Bleeding



Clinical Outcomes Associated With Left Atrial Appendage Occlusion Versus Direct Oral Anticoagulation in Atrial Fibrillation

Jens Erik Nielsen-Kudsk, MD, DMSc,^a Kasper Korsholm, MD, PhD,^a Dorte Damgaard, MD, PhD,^b Jan Brink Valentin, MSc,^c Hans-Christoph Diener, MD, PhD,^d Alan John Camm, MD, PhD,^e Søren Paaske Johnsen, MD, PhD^c

Patient characteristics	LAO (n=1071)	NOAC (n=1184)
Age, mean (SD)	75.1 (8.5)	75.1 (10.5)
Gender (male) n (%)	64.2	61.4
Congestive heart failure (%)	16.6	18.9
Hypertension (%)	83.7	86.5
Diabetes mellitus (%)	31.1	35.8
Stroke (%)	31.1	31.8
Vascular disease (%)	37.2	37.6
Abnormal renal function (%)	13.9	14.3
Abnormal liver function (%)	4.8	6.5
Bleeding (%)	74.1	75.0
Drugs (%)	30.0	37.1
Alcohol (%)	4.7	5.1
CHA ₂ DS ₂ -VASc mean (SD)	4.2 (1.6)	4.3 (1.7)
HAS-BLED mean (SD)	3.3 (1.0)	3.4 (1.2)

Clinical outcome	LAO vs. NOAC	Relative HR reduction
Ischemic stroke/major bleeding/mortality (95% CI)	0.57 (0.49-0.67)	43%
Ischemic stroke (95% CI)	1.11 (0.71-1.75)	-
Major bleeding (95% CI)	0.62 (0.49-0.79)	38%
Mortality (95% CI)	0.53 (0.43-0.64)	47%

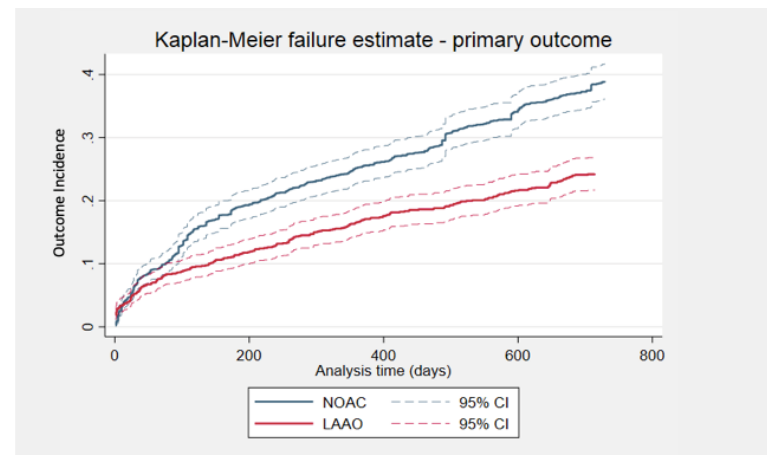
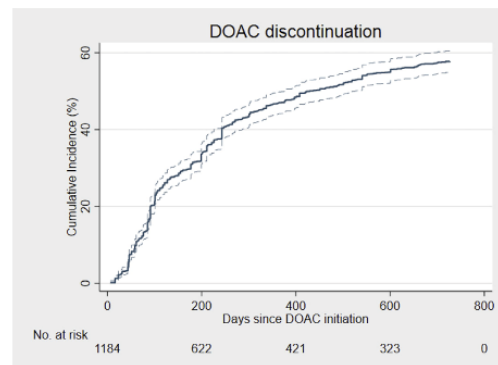


FIGURE 2 DOAC Discontinuation

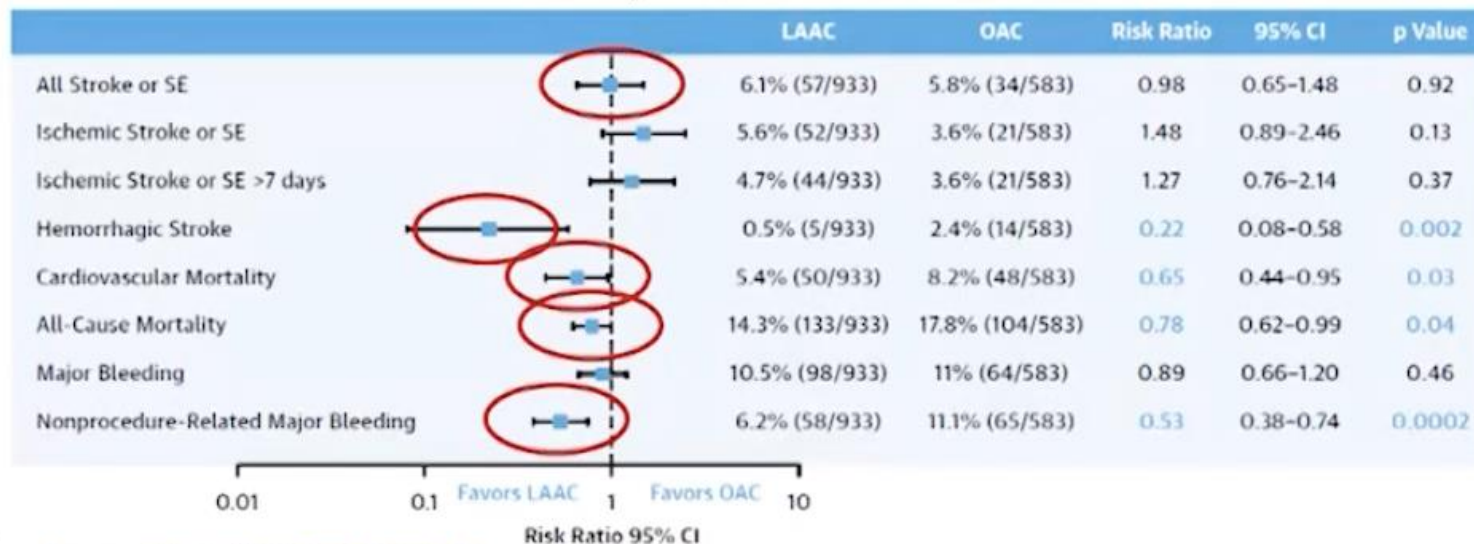


LAAC vs Oral Anticoagulants

A Meta-Analysis of Randomized Trials

1516 patients from PROTECT-AF, PREVAIL and PRAGUE-17: (LAAC:933, OAC:583), age was 73.3 $\pm$ 7.7 years, CHA2DS2-VASc 4.1 $\pm$ 1.4, and 41% had paroxysmal AF. In OAC group, 65% received warfarin and 35% NOAC

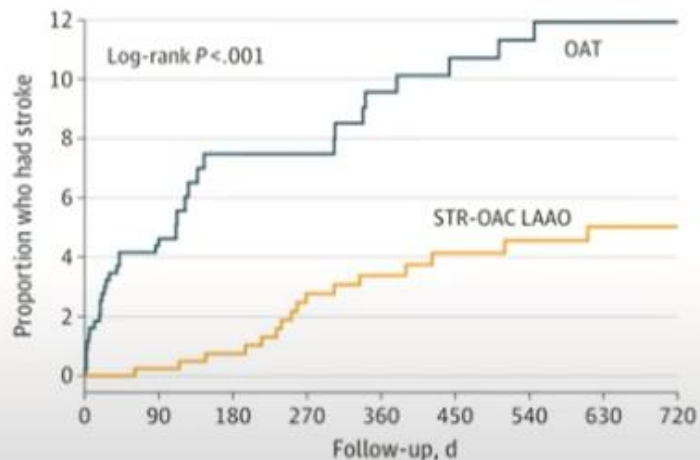
Summary Plot of Clinical Outcomes



COI en pacientes con ACV/ES bajo ACO

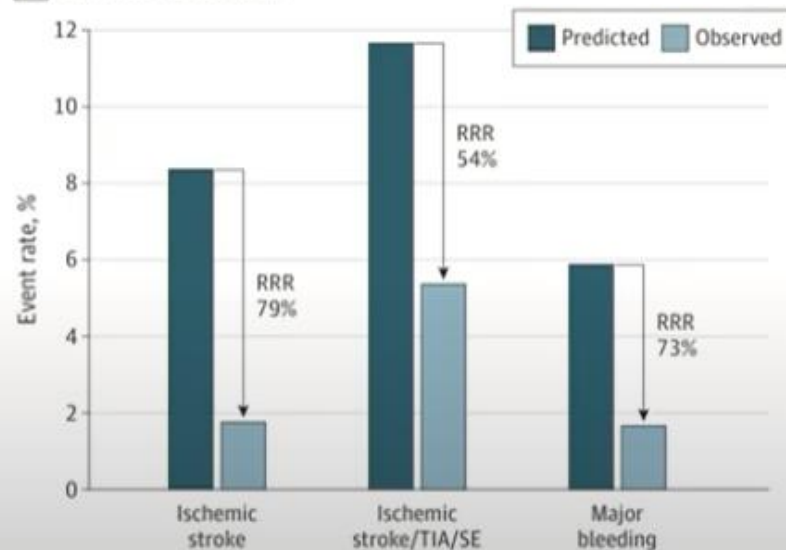
433 patients: LAAC after thromboembolic events despite OAC (propensity score-matched comparison)

A Ischemic stroke



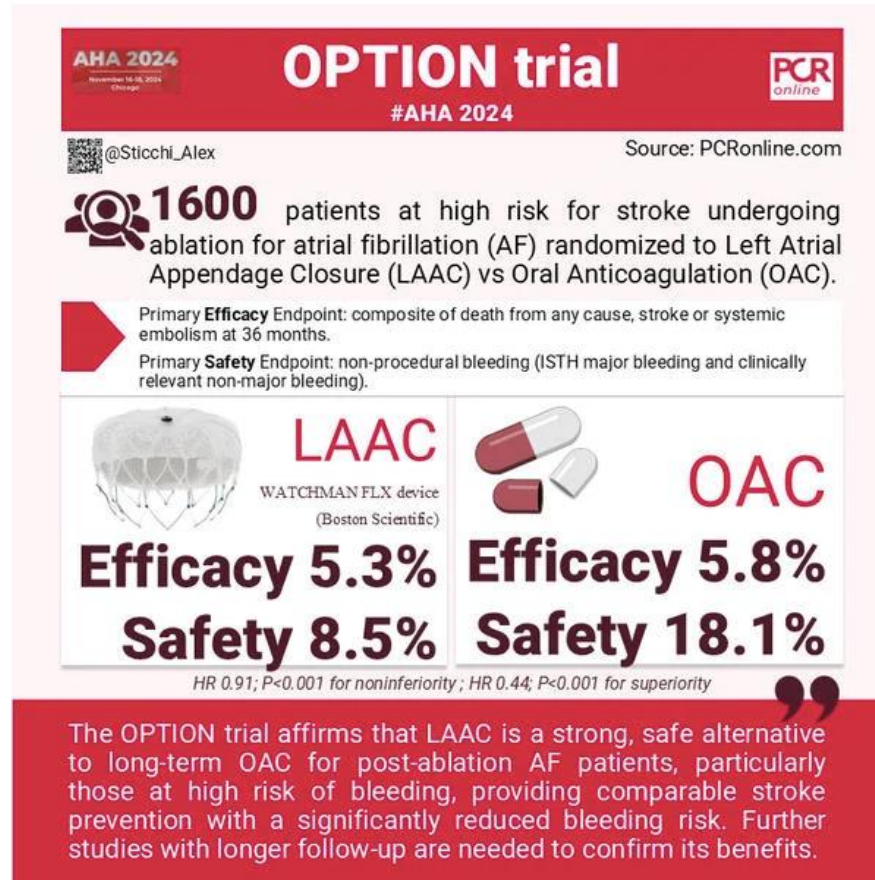
No. at risk									
OAT	433	414	191	180	165	153	147	140	78
STR-OAC LAAC	433	407	369	327	299	239	214	197	185

B STR-OAC LAAC cohort



[Maarse M et al., JAMA Neurology 2024]

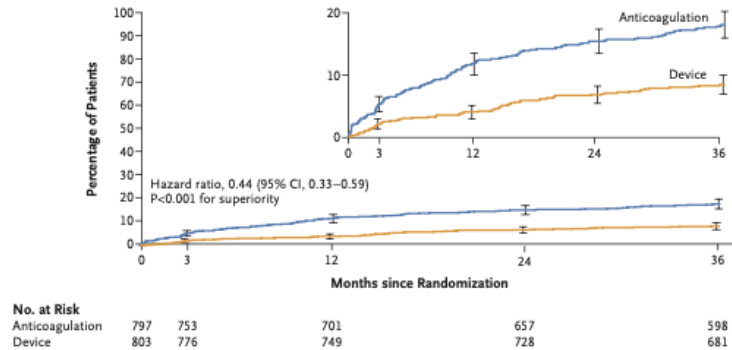
Cierre de orejuela izquierda vs DOAC's



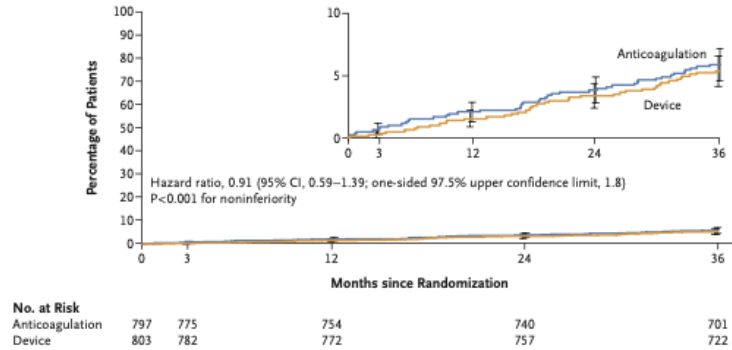
Left Atrial Appendage Closure after Ablation for Atrial Fibrillation

O.M. Wazni, W.I. Saliba, D.G. Nair, E. Marijon, B. Schmidt, T. Hounshell, H. Ebel, C. Skurk, S. Oza, C. Patel, A. Kanagasundram, A. Sadhu, S. Sundaram, J. Osorio, G. Mark, M. Gupta, D.B. DeLurgio, J. Olson, J.E. Nielsen-Kudsk, L.V.A. Boersma, J.S. Healey, K.P. Phillips, F.M. Asch, K. Wolski, K. Roy, T. Christen, B.S. Sutton, K.M. Stein, and V.Y. Reddy, for the OPTION Trial Investigators*

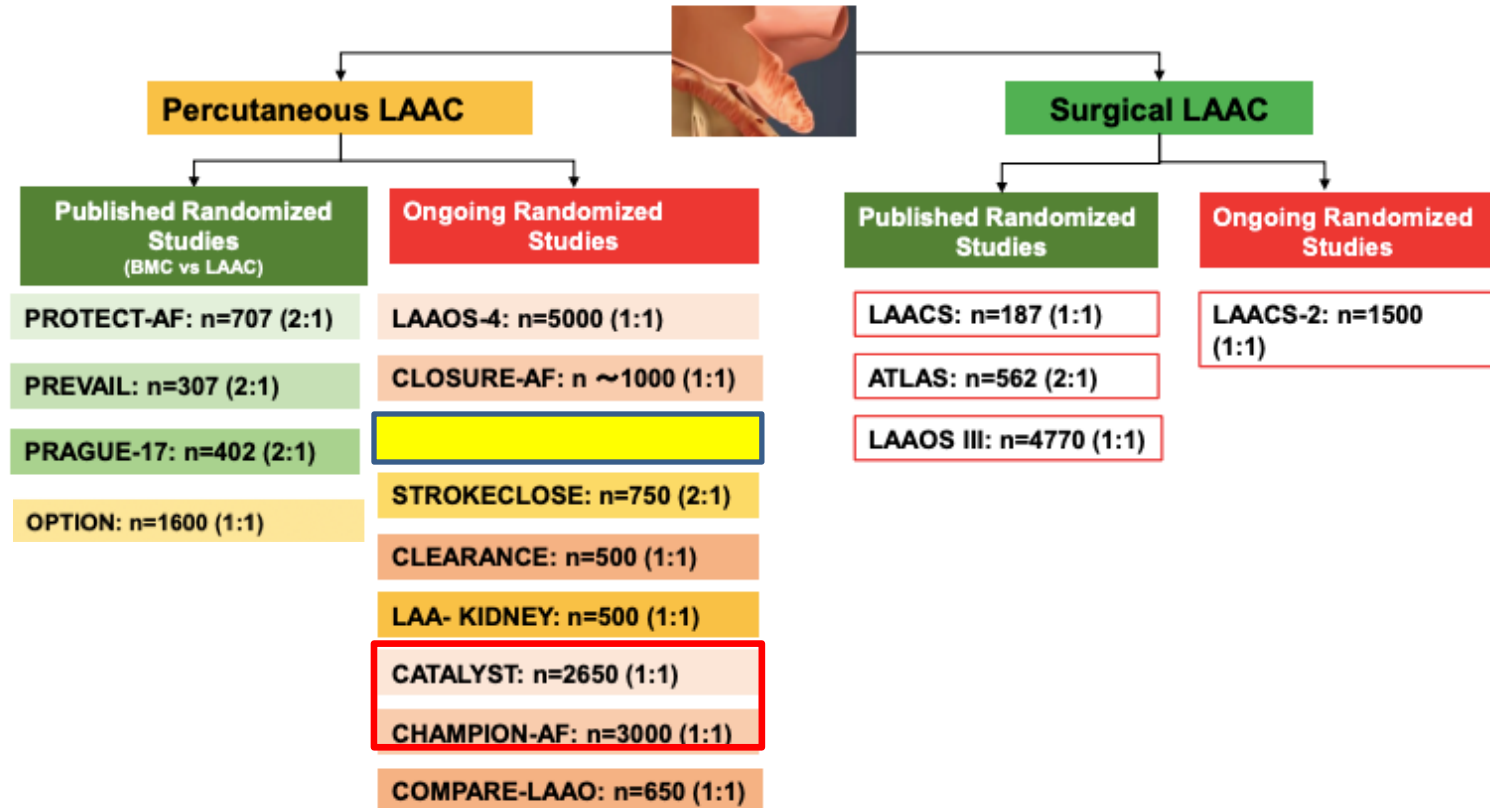
A Non-Procedure-Related Major Bleeding or Clinically Relevant Nonmajor Bleeding (primary safety end point)



B Composite of Death from Any Cause, Stroke, or Systemic Embolism (primary efficacy end point)

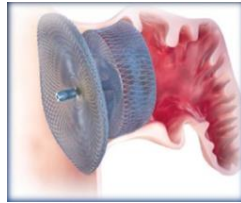


Estudios clínicos en curso: Cierre de OAI vs DOAC's



Resultados de los Estudios Clínicos:

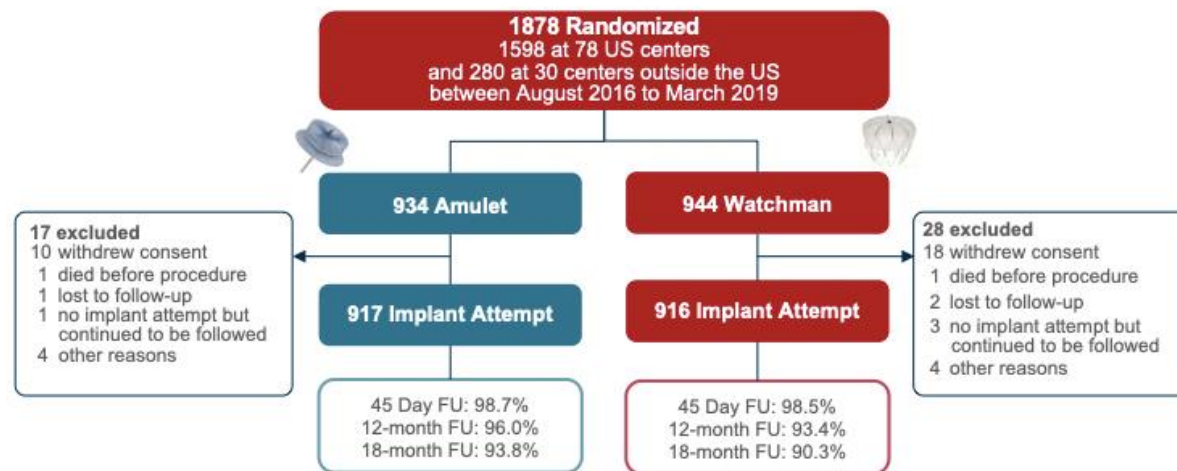
Comparación entre dispositivos



Dhanunjaya Lakkireddy, MD - David Thaler, MD, PhD - Christopher Ellis, MD - Vijendra Swarup, MD
Lars Sondergaard, MD - John Carroll, MD - Michael R. Gold, MD, PhD - James Hermiller, MD
Hans-Christoph Diener, MD, PhD - Boris Schmidt, MD - Lee MacDonald, MD - Moussa Mansour, MD
Brijeshwar Maini, MD - Stephan Windecker, MD

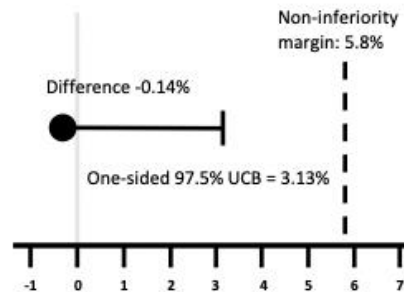
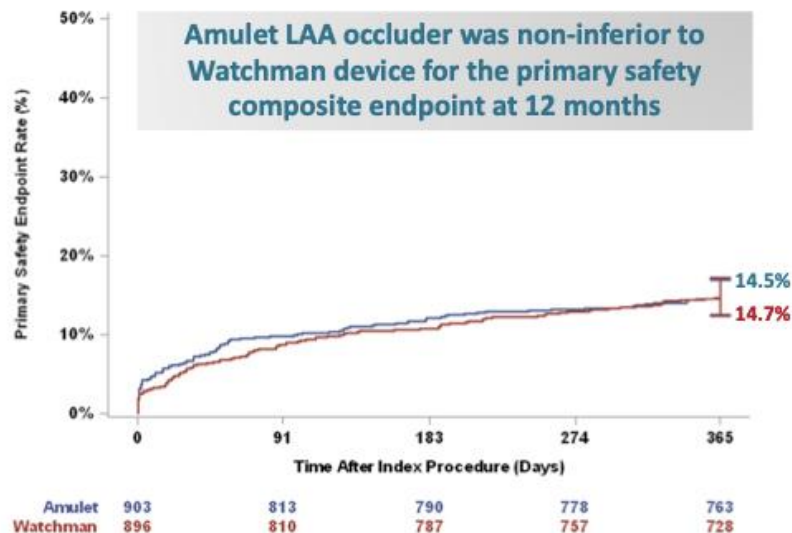
on behalf of the Amulet IDE investigators

AMULET IDE TRIAL: PATIENT FLOW



PRIMARY SAFETY ENDPOINT

COMPOSITE OF PROCEDURE-RELATED COMPLICATIONS, ALL-CAUSE DEATH, OR MAJOR BLEEDING AT 12 MONTHS

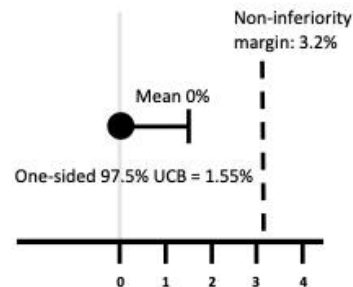
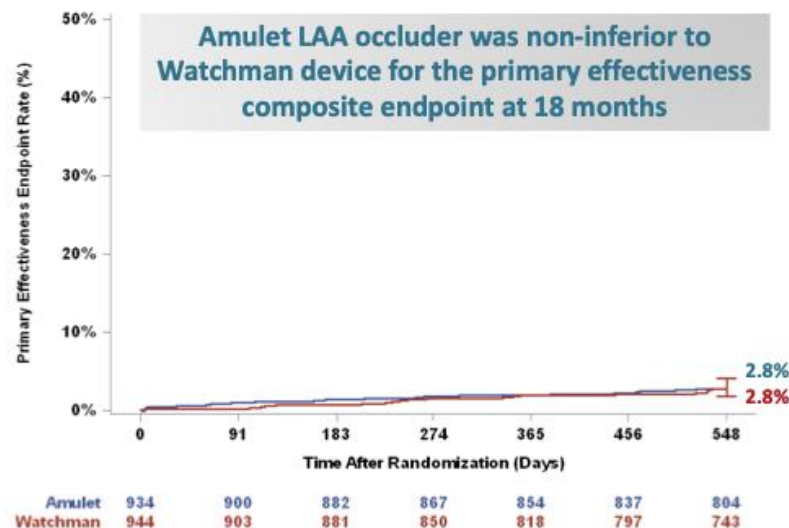


Difference in Primary Safety Endpoint Event Rates
p (non-inferiority) = 0.0002

Primary Safety Endpoint	Amulet	Watchman
Composite	14.5%	14.7%
Procedure-Related Complications	4.5%	2.5%
All-Cause Death	3.9%	5.1%
Major Bleeding (Type 3 or greater)	10.6%	10.0%
Non-Procedure Related	7.9%	8.0%

PRIMARY EFFECTIVENESS ENDPOINT

ISCHEMIC STROKE OR SYSTEMIC EMBOLISM AT 18 MONTHS



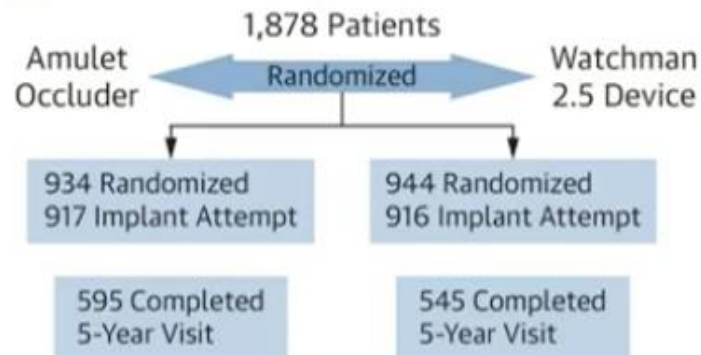
Difference in Primary Effectiveness Endpoint Event Rates

p (non-inferiority) = <0.0001

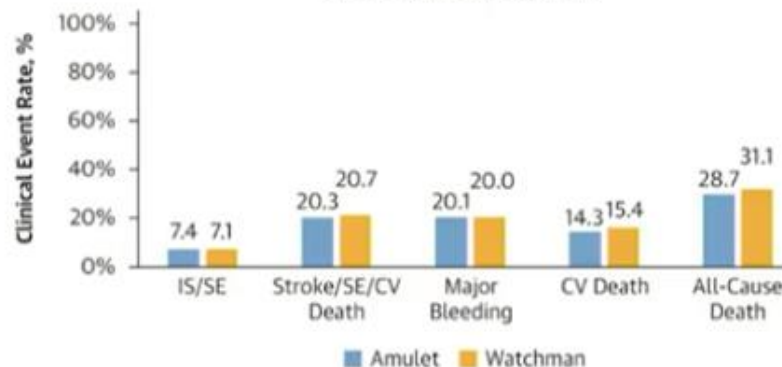
Primary Effectiveness Endpoint	Amulet	Watchman	Difference
Composite	2.8%	2.8%	0.0%
Ischemic Stroke	2.5%	2.7%	-0.2%
Systemic Embolism	0.3%	0.2%	0.1%

AMULET-IDE: Seguimiento a 5 años

IDE Trial for U.S. Approval of the Amulet Occluder



5-Year Clinical Outcomes

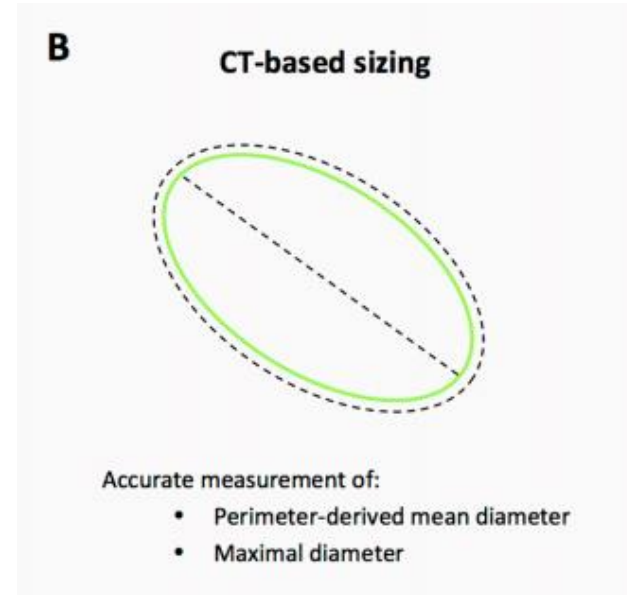
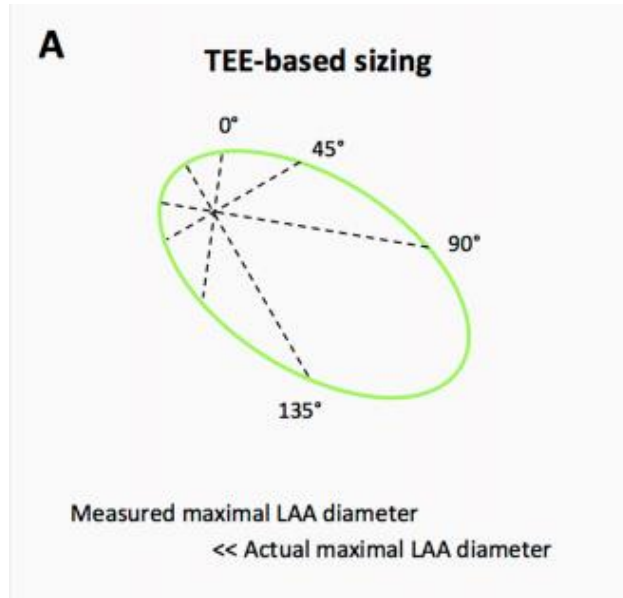


Clinical Factors Through 5 Years

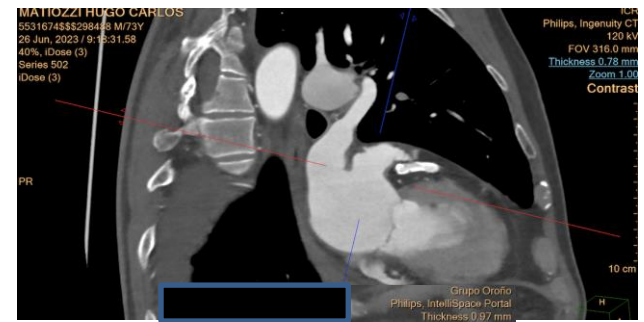
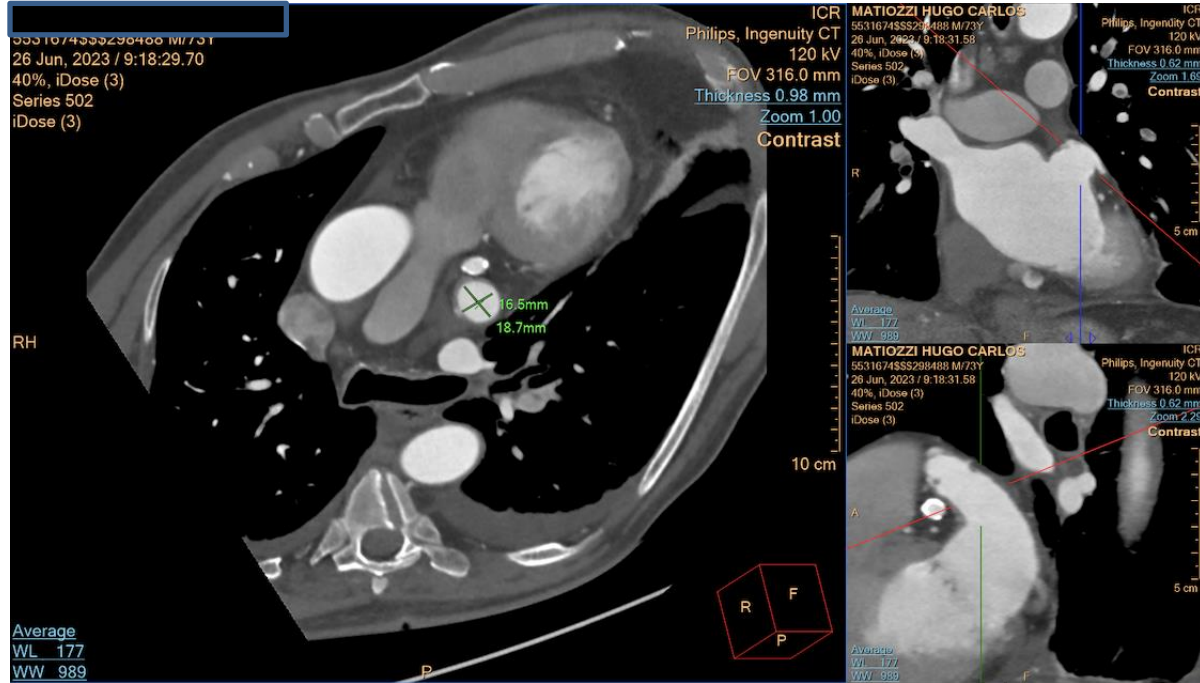
	Amulet Occluder	Watchman Device
Patients free from OAC at 5 years	94%	91%
Annualized ischemic stroke rate at 5 years	1.6%/year	1.6%/year
Number of fatal or disabling strokes through 5 years	22	39
Number of DRTs or PDLs preceding stroke or CV death	31	63

Rol de la TAC multicorte en la planificación de COI

Limitaciones del ETE



Planning with MSCT



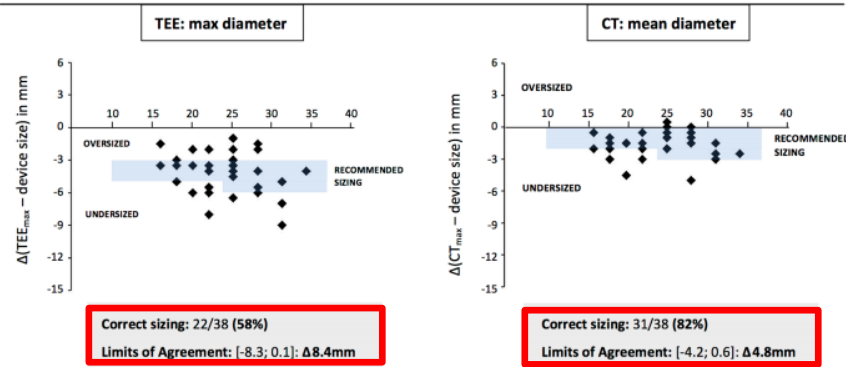
COI: Planificación ETE - TAC

openheart

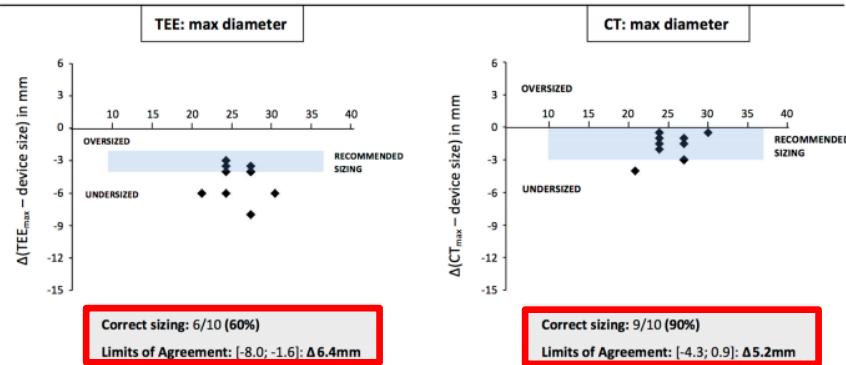
A comparative study of different imaging modalities for successful percutaneous left atrial appendage closure

Danny HF Chow, Gintautas Bieliauskas, Fadi J Sawaya, Oscar Millan-Iturbe, Klaus F Kofoed, Lars Søndergaard, Ole De Backer

(A) Successful LAA closure with Amulet™ device (n = 38)

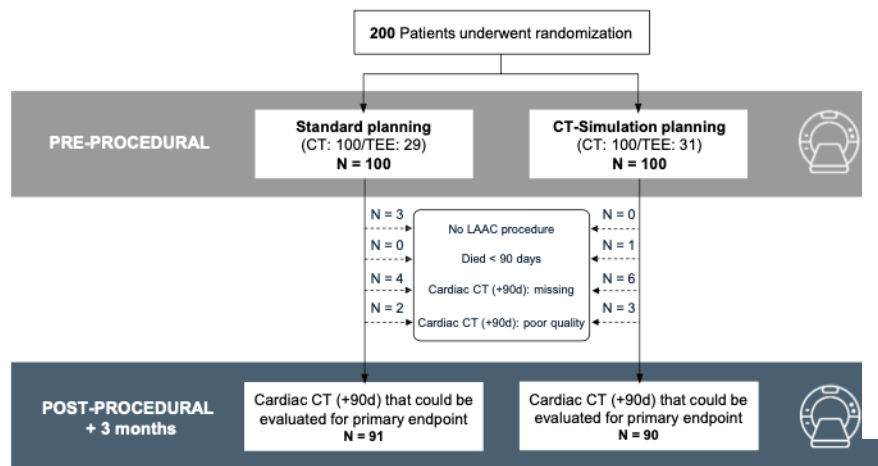


(B) Successful LAA closure with Watchman™ device (n = 10)

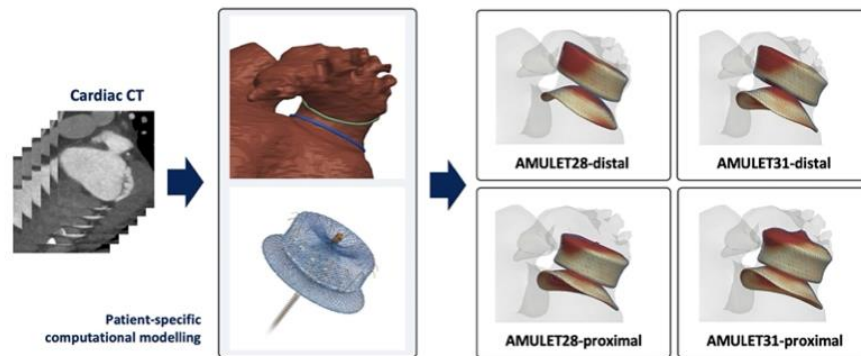


The **PREDICT-LAA** trial sought to assess whether use of **artificial intelligence (AI)-enabled computational modelling** when planning for LAA closure may impact **procedural efficiency** and **outcomes**.

Study Design and Population



Patient-Specific CT-Simulation Planning



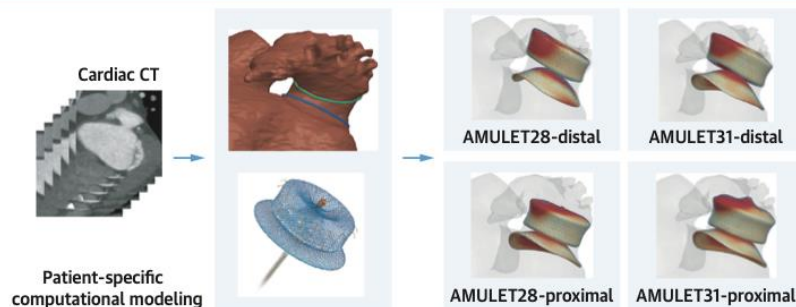
Impact of Computational Modeling on Transcatheter Left Atrial Appendage Closure Efficiency and Outcomes



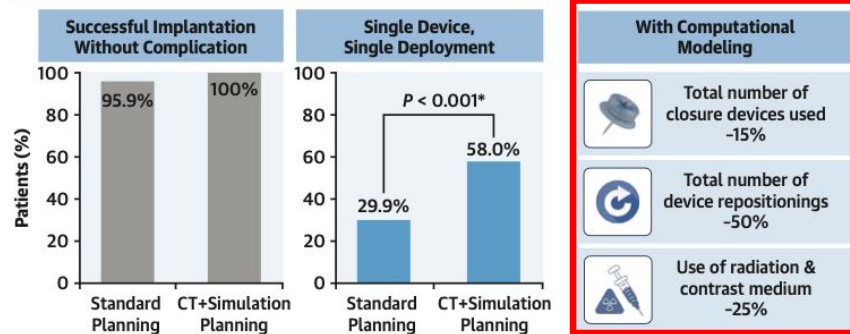
Ole De Backer, MD, PhD,^a Xavier Iriart, MD,^b Joelle Kefer, MD, PhD,^c Jens Erik Nielsen-Kudsk, MD, DMSc,^d
 Adel Aminian, MD,^e Liesbeth Rosseel, MD,^f Klaus Fuglsang Kofoed, MD, PhD,^g Jacob Odenstedt, MD, PhD,^h
 Sergio Berti, MD,^h Jacqueline Saw, MD,ⁱ Lars Søndergaard, MD, DMSc,^a Philippe Garot, MD^j

Assessment of CT-Based Computational Modeling for Planning of Transcatheter LAA Closure

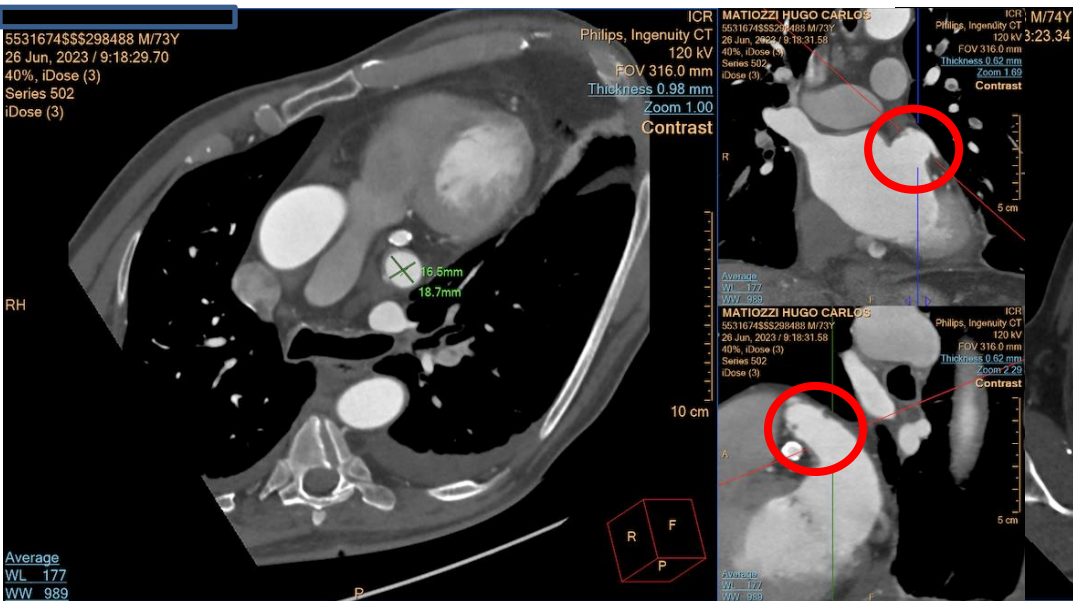
AI-Enabled Computational Modeling - FEops HEARTguide™



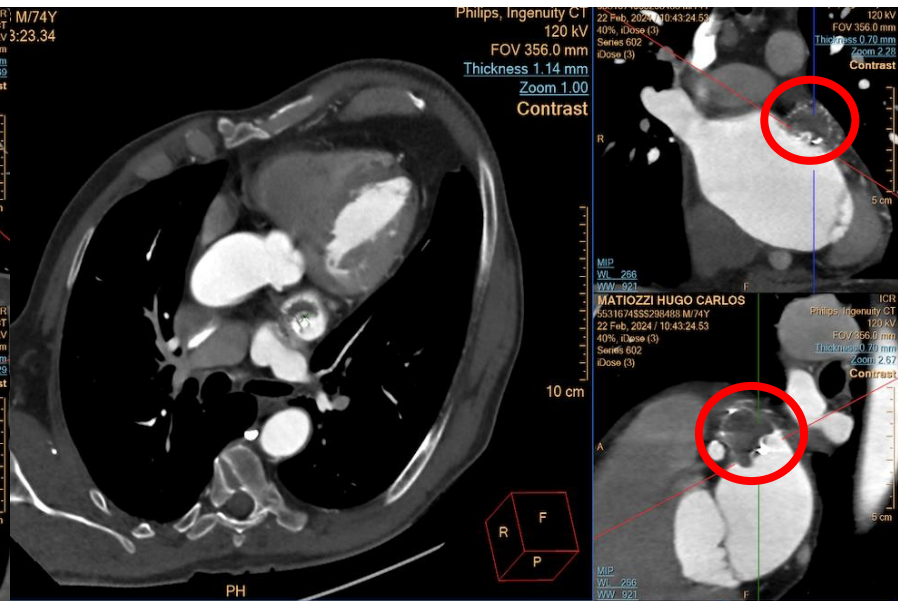
Procedural Efficiency



MSCT pre procedimiento



MSCT 45 días post COI



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

“Indicaciones”

CLINICAL PRACTICE GUIDELINE

2023 ACC/AHA/ACCP/HRS Guideline
for the Diagnosis and Management of
Atrial Fibrillation

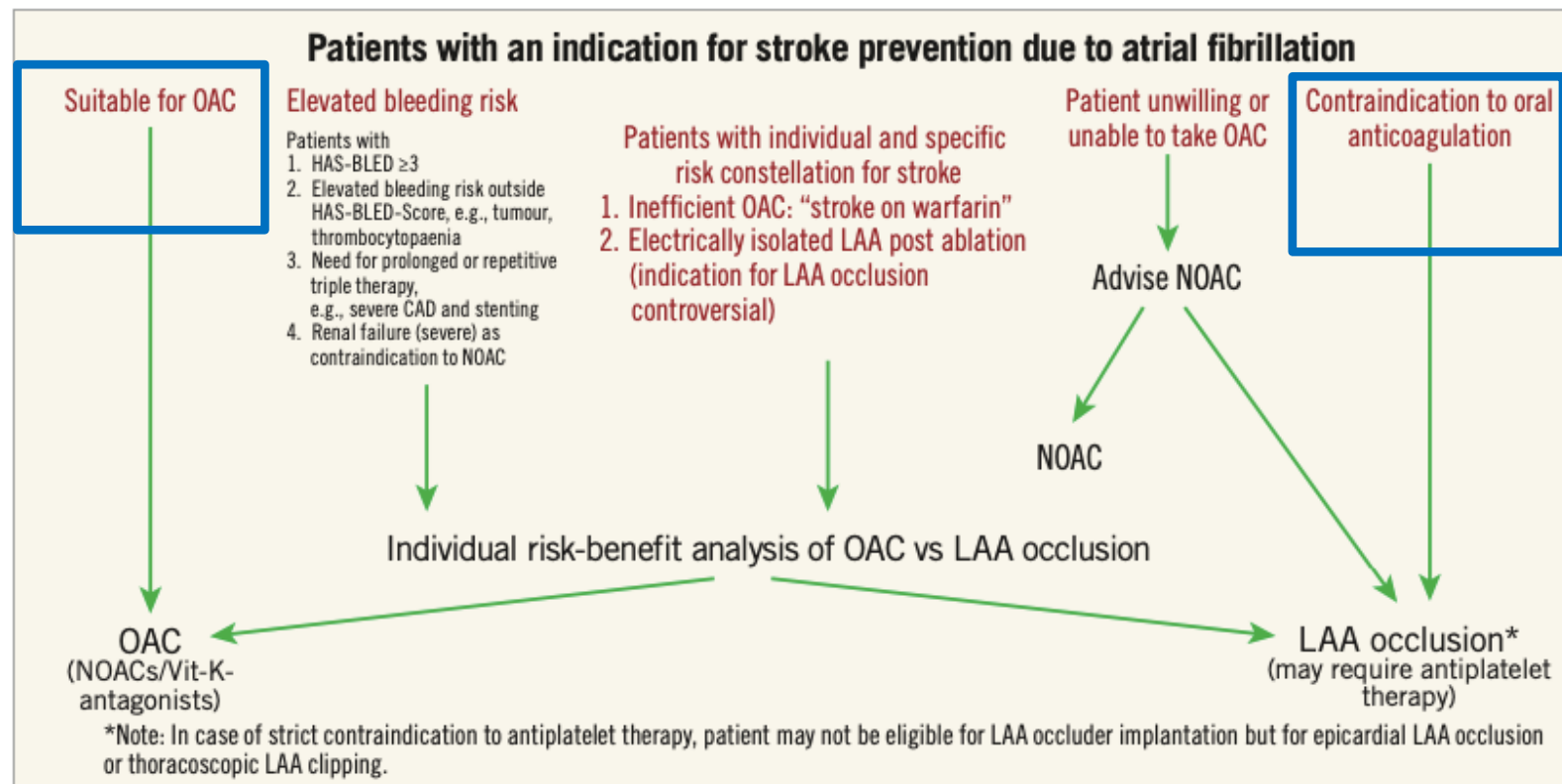
A Report of the American College of Cardiology/American Heart Association
Joint Committee on Clinical Practice Guidelines

Developed in Collaboration With and Endorsed by the American College of Clinical Pharmacy
and the Heart Rhythm Society

Recommendations for Percutaneous Approaches to Occlude the LAA
Referenced studies that support the recommendations are summarized in the [Online Data Supplement](#).

COR	LOE	RECOMMENDATIONS
2a	B-NR	1. In patients with AF, a moderate to high risk of stroke (CHA ₂ DS ₂ -VASc score ≥2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable. ¹⁻⁴
2b	B-R	2. In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive. ^{1-3,5,6}

EHRA/EAPCI expert consensus statement on catheter-based left atrial appendage occlusion – an update



ORIGINAL ARTICLE

Indications for Left Atrial Appendage Occlusion in the United States and Associated In-Hospital Outcomes: Results From the NCDR LAAO Registry

Usama A. Daimee¹, MD; Yongfei Wang², MS; Frederick A. Masoudi³, MD, MSPH; Paul D. Varosy, MD; Daniel J. Friedman, MD; Chengan Du, PhD; Cristina Koutras, RN; Vivek Y. Reddy⁴, MD; Jacqueline Saw⁵, MD; Matthew J. Price⁶, MD; Fred M. Kusumoto⁷, MD; Jephth P. Curtis⁸, MD; James V. Freeman⁹, MD, MPH, MS

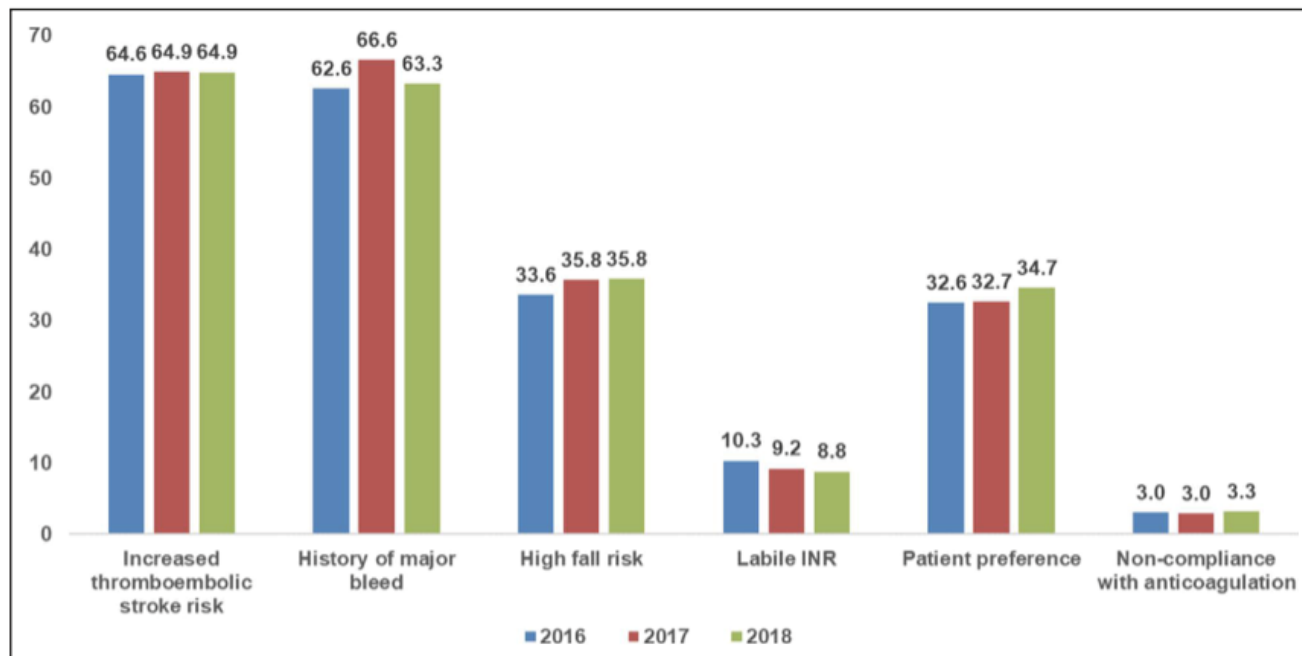


Figure 2. Percentage of patients with each site-reported procedural indication in the National Cardiovascular Data Registry Left Atrial Appendage Occlusion Registry, by year between 2016 and 2018 (categories are not mutually exclusive, and patients may contribute to multiple categories).

Formación de equipos de FA-Clínica de FA

Cardiólogo

Neurólogo

Hematólogo

Gastro

Urólogos

UTI

Arritmólogos

C.Intervencionista

CCV

Surpass Watchman FLX - Seguridad

US NCDR LAAO registry (n=97.185)

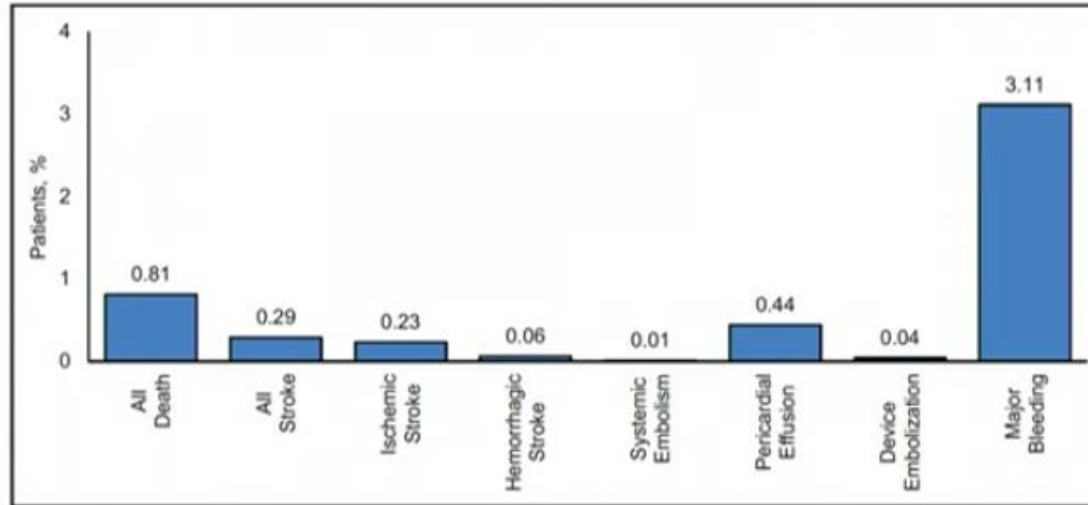


Figure 1. Clinical outcomes at 45 days.

Outcomes at 45 days (time-to-event rates) in patients implanted with WATCHMAN FLX.

Kapadia SR et al., *Circ. Cardiovasc Interv* 2024;17(9):e013750

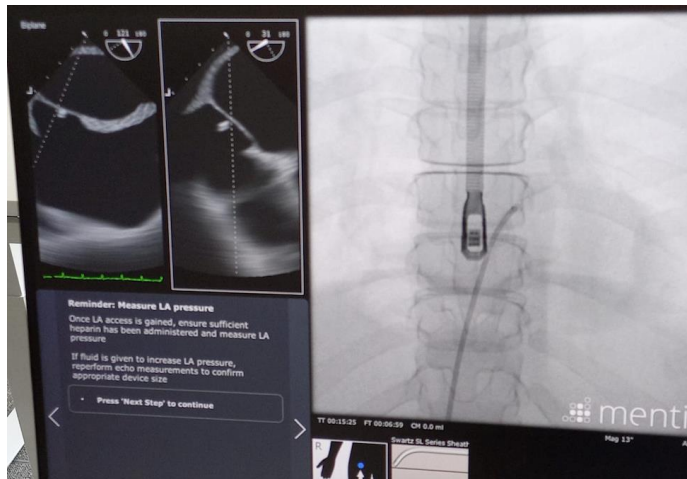
Left Atrial Appendage Closure Devices Market Size 2024 to 2034 (USD Billion)



Source: <https://www.precedenceresearch.com/left-atrial-appendage-closure-devices-market>

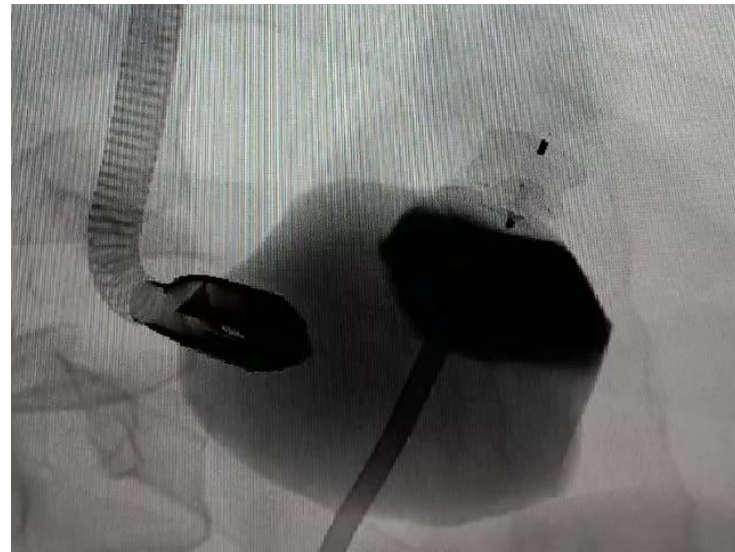
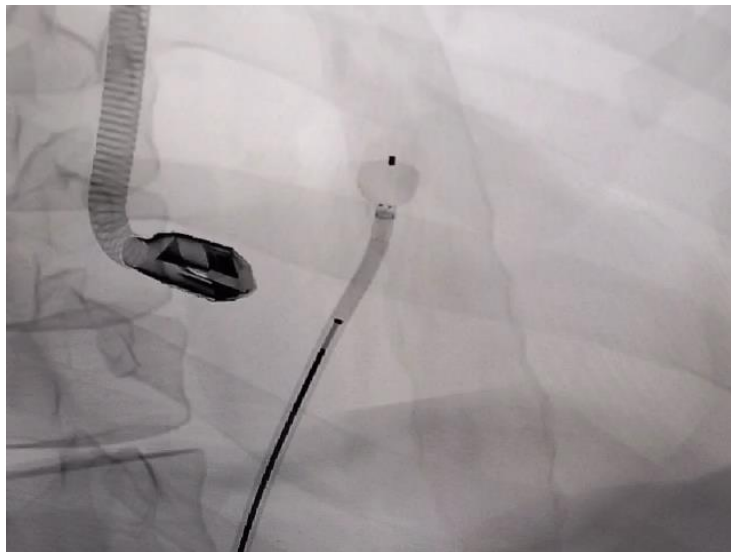
Rol de simuladores en el inicio de un programa de COI



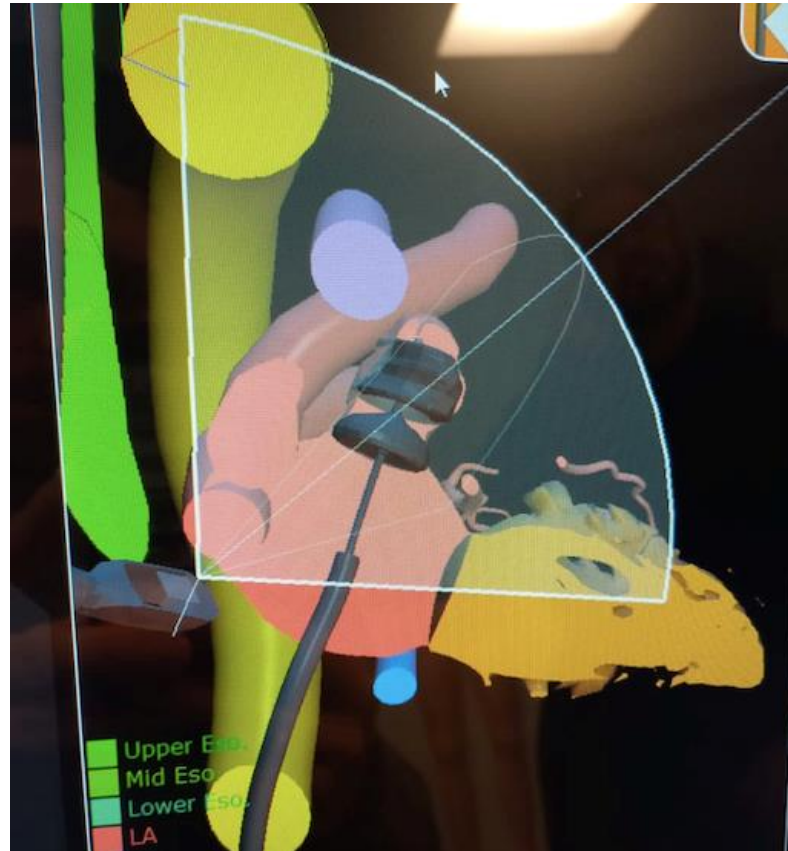


Entrenamiento en punción trans-septal

Posicionamiento y liberación del dispositivo



Simulación de posicionamiento y tamaño del dispositivo



Conclusiones



- El cierre percutáneo de la orejuela auricular izquierda, se ha consolidado como una alternativa válida para la prevención de la cardioembolia relacionada a la FA.
- Diferentes registros contemporáneos de manejo de ACO muestran la necesidad de una alternativa no farmacológica para la prevención del stroke y la embolia sistémica en estos pacientes.
- 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, aún ante la disponibilidad de DOAC´s
- Las técnicas de imágenes con capacidad de reconstrucción multiplanar constituyen una herramienta fundamental para la planificación del procedimiento y optimización de resultados.
- El entrenamiento en simuladores, desempeña un rol fundamental en el proceso de adquisición de habilidades en todos los campos del intervencionismo estructural

ELAACC – Clasificación

EuroIntervention

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EXPERT CONSENSUS

A new implanter classification system for left atrial appendage closure from the European Left Atrial Appendage Closure Club (ELAACC)

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ABSTRACT

This manuscript proposes a novel implanter classification system for left atrial appendage (LAA) closure, aimed at overcoming the limitations of current anatomical classifications. By integrating essential anatomical and functional details, this new classification system strives to provide a comprehensive framework that is both user-friendly and effective in distinguishing between complex and standard LAA anatomies, facilitating a common language among implanters and imagers, and predicting procedural risks.

ELAACC classification.

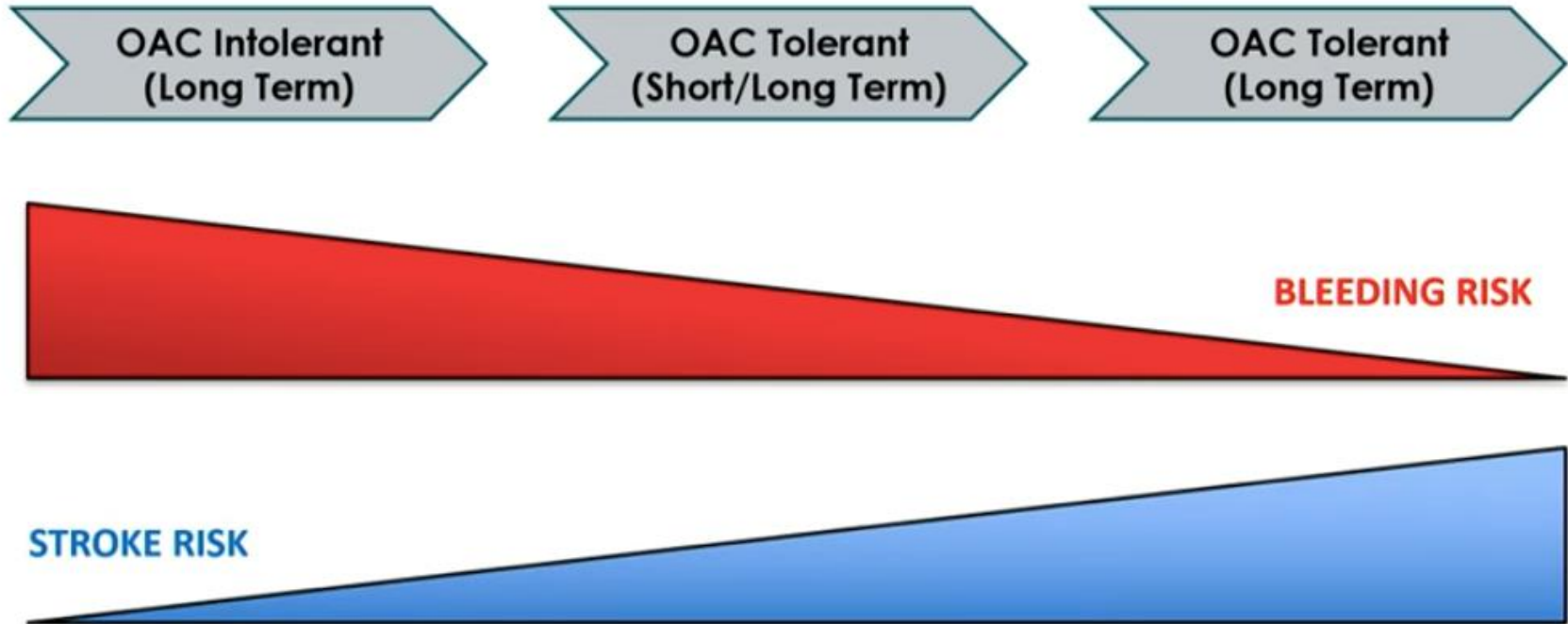
A

Parameters	Characteristics	Challenges/risks	Potential consequences
E L A A C	Entrance/ostium	Large Long PR Low ostium	Incomplete coverage Neo-LAA, uncovered proximal area Complex access/catheter manipulation-mitral valve proximity PDL DRT PDL/interference with mitral valve
	Landing zone	Large High eccentricity Proximal lobe Proximal bifurcation/protruberance	Incomplete coverage Device sizing/conformability Incomplete coverage PDL PDL Device embolisation
	Anatomy	Early sharp bend Short depth Funnel shape	Off-axis implantation Proper device engagement/stability Device sizing/proper device engagement/stability PDL Device embolisation PDL/device embolisation/LAA erosion
	Axis	Pronounced anterior or posterior	Complex access/catheter manipulation/off-axis implantation PDL
	Contraction	Hypercontractile	Device sizing/stability Device embolisation/LAA erosion

B



Cierre de orejuela izquierda: Expansión de indicaciones



POST-LAAC ANTITHROMBOTIC REGIMEN

WEAK

INTENSE

SAPT/low dose DOAC

DAPT/OAC

OAC+SAPT

Bleeding risk

Very high/prohibitive

High

Low

Indication to
LAAC

Contraindication to OAC

Thromboembolic events under OAC,
reduced OAC compliance/tolerance

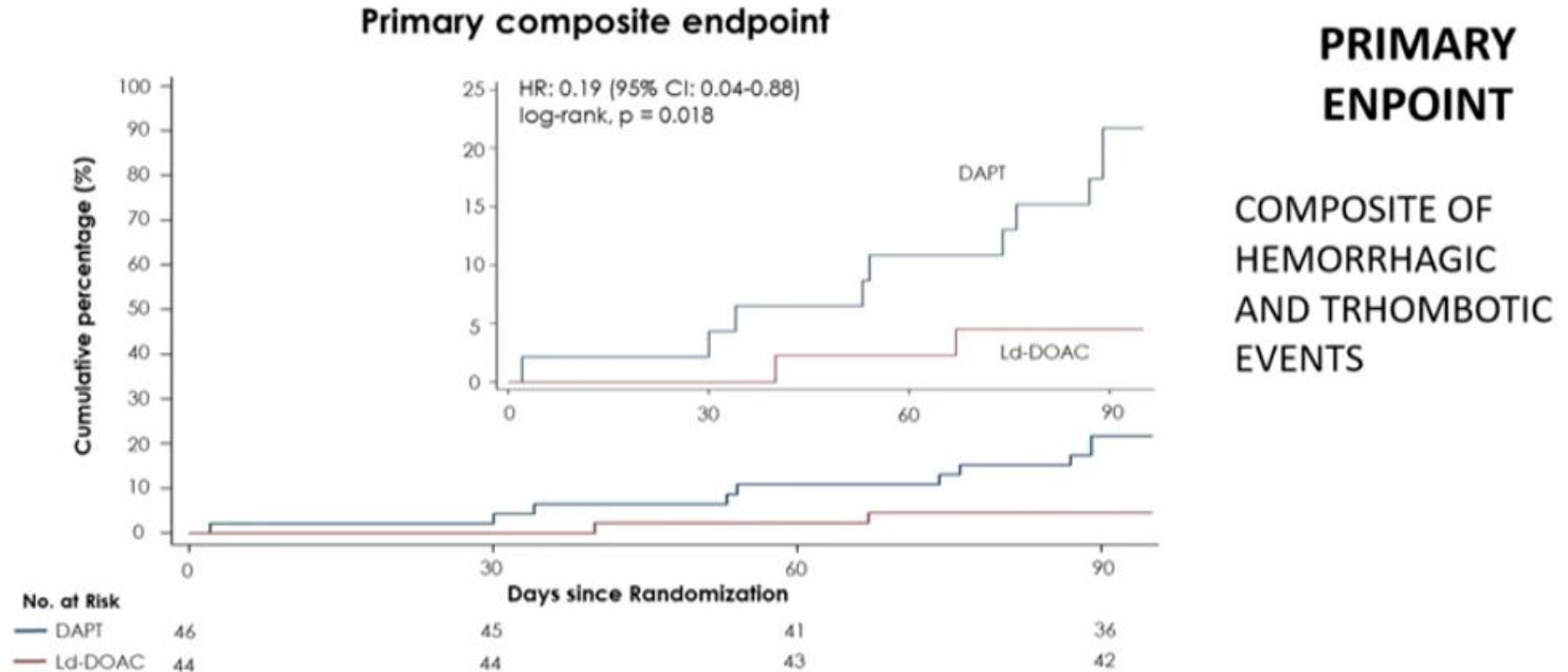
Patient
characteristics

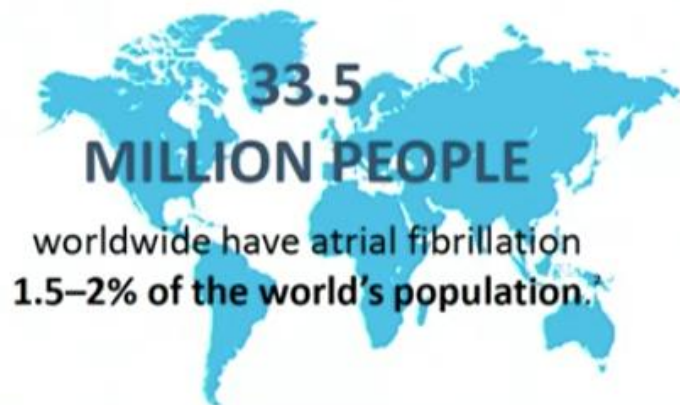
- Previous Intracranial bleeding
- Diffuse intracranial amyloid angiopathy
- Bowel angiodysplasia
- Blood cell dyscrasia
- History of major/minor bleeding
- HASBLED Score > 3
- High risk of falls, high risk occupation
- Severe renal insufficiency/hemodialysis
- Very high stroke risk (CHA2DS2Vasc > 39, > 20)
- Vascular disease
- Hypercoagulable state
- LAA thrombus on adequate OAC therapy

Imaging and
procedural
characteristics

- Procedural complications (major bleeding, pericardial effusion, CVE, vascular access complications, etc.)
- Concomitant intervention requiring DAPT (PCI, Stent implantation, PFO Occlusion, etc.)
- Residual PDL > 5mm
- DRT risk factors: reduced EF, deep device implantation, LAA thrombus/thrombus
- Concomitant AF-catheter ablation

Terapia antitrombotica post COI – ADALA Trial





AF prevalence
increases with age,
**UP TO 18% OF
THE POPULATION**
over the age of 85
experience AF.³

