CUANDO LA ANTICOAGULACIÓN ESTÁ CONTRAINDICADA. CIERRE DE LA OREJUELA IZQUIERDA.

Servicio de Medicina Interna

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INTRODUCCIÓN

- La fibrilación auricular no valvular es una arritmia frecuente, cuya incidencia aumenta con la edad.
- La fibrilación auricular es la causa de alrededor del 20% de los ictus isquémicos.
- La anticoagulación, ha demostrado reducir los eventos cardioembólicos a costa de incrementar el riesgo de hemorragias.
- Aproximadamente una tercera parte de estos pacientes no pueden recibir anticoagulantes, por el riesgo de sangrado.

INTRODUCCIÓN

- Los dispositivos de cierre de la orejuela izquierda representan una alternativa a la anticoagulación, en aquellos pacientes en los que está contraindicada o tienen alto riesgo de sangrado.
- Score HAS-BLED (hipertensión arterial, función renal /hepática alterada, ictus, antecedentes de hemorragia o predisposición al sangrado, labilidad en el INR, edad >65 años, toma concomitante de fármacos o alcohol).

ESCALA DE RIESGO EMBÓLICO

CHA_2DS_2-VASc

Risk factor-based approach expressed as a point based scoring system, with the acronym CHA_2DS_2-VASc *(Note: maximum score is 9 since age may contribute 0, 1, or 2 points)*

Risk factor	Score
Congestive heart failure/LV dysfunction	1
Hypertension	1
Age ≥ 75	2
Diabetes mellitus	1
Stroke/TIA/thrombo-embolism	2
Vascular disease[a]	1
Age 65–74	1
Sex category (i.e. female sex)	1
Maximum score	**9**

ESCALA DE RIESGO HEMORRÁGICO

HAS-BLED

Clinical characteristics comprising the HAS-BLED bleeding risk score

Letter	Clinical characteristic[a]	Points awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	Elderly (e.g. age > 65 years)	1
D	Drugs or alcohol (1 point each)	1 or 2
		Maximum 9 points

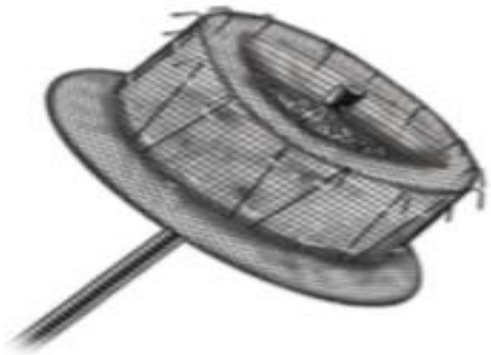
INTRODUCCIÓN

- La orejuela izquierda es un remanente embriológico, cuya principal función es el control de la volemia.
- Gran variabilidad anatómica de un paciente a otro, habitualmente más de un lóbulo.
- En la fibrilación auricular, la orejuela izquierda pierde su capacidad contráctil, dilatándose y produciéndose un enlentecimiento de la sangre, con el consecuente aumento del riesgo de trombosis.
- El 91% de los trombos localizados en la aurícula izquierda, se encuentran alojados en la orejuela izquierda.

DISPOSITIVOS

- PLAATO. Retirado del mercado.
- Sistema Watchman (Boston Scientific; Boston. Massachusetts. Estados Unidos).
- Amplatzer Cardiac Plug (ACP) (St. Jude Medical; Minneapolis, Minnesota, Estados Unidos). Variante Amulet.
- Se implantan por vía transeptal a través de la vena femoral.
- El sistema Watchman se implanta a 10 mm del ostium de la OI, sin llegar a cubrirla.

AMPLATZER



Feature	ACP								Amulet							
Sizes (mm)	16	18	20	22	24	26	28	30	16	18	20	22	25	28	31	34
Disc Diameter	Lobe + 4 mm				Lobe + 6 mm				Lobe + 6 mm				Lobe + 7 mm			
Lobe Length	6.5 mm								7.5 mm				10 mm			
Waist Length	4 mm								5.5 mm				8 mm			
Sheath Diameter	9Fr	10Fr			13Fr				12Fr						14Fr	
Stabilizing Wires	6 pairs								6 pairs		8 pairs		10 pairs			

TV45x45

TVLA1

TVLA2

FIGURE 3 ACP and Amulet Characteristics and Available Sheaths

ACP = Amplatzer Cardiac Plug; Fr = French.

WATCHMAN

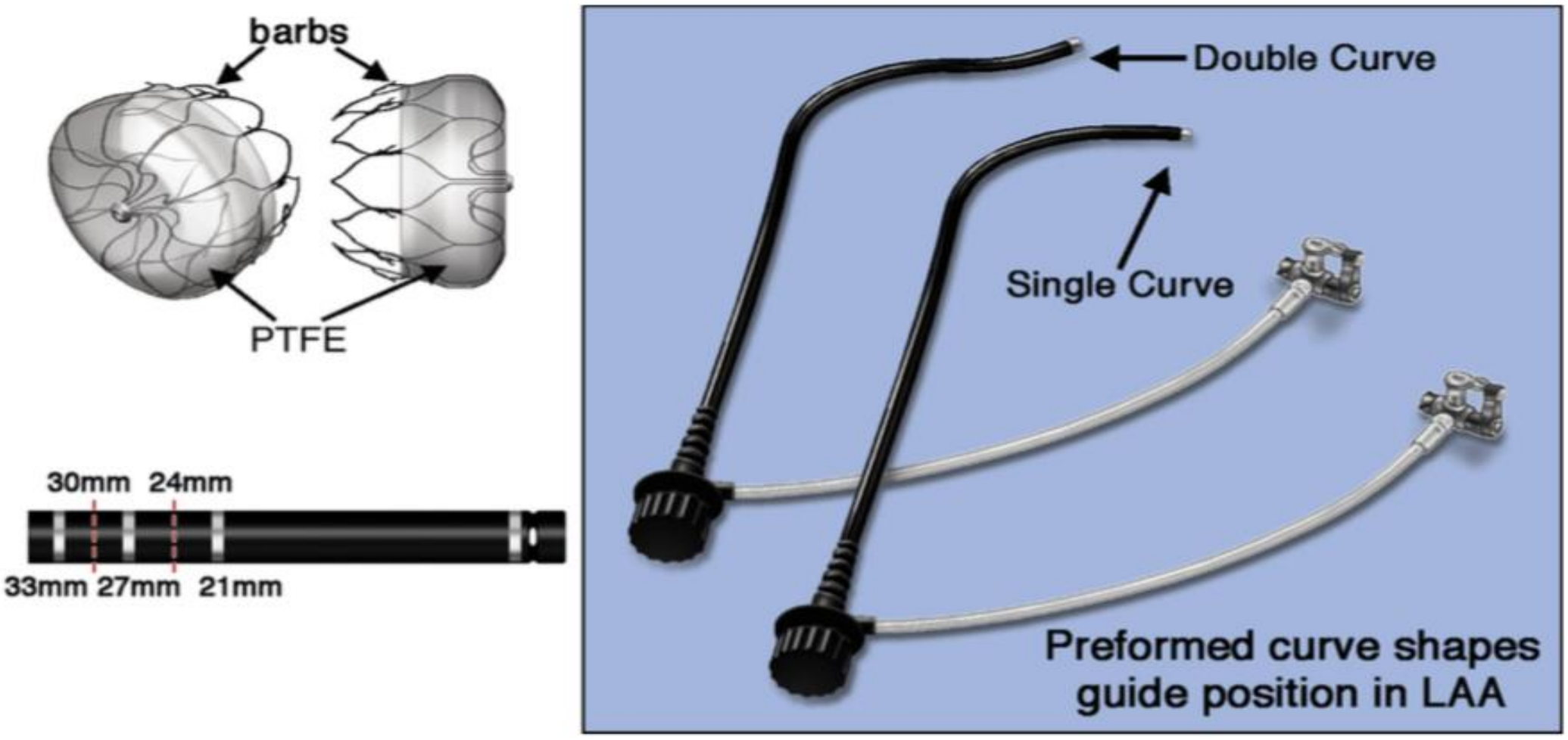


FIGURE 1 WATCHMAN and 14-F Access Sheaths (Double- and Single-Curve)

There are 3 radio-opaque marker bands (33, 27, and 21 mm) on the distal sheath, which should be aligned to the left atrial appendage (LAA) "ostium" according to the selected device. PTFE = polyethylene terephthalate.

IMPLANTACIÓN

- EL implante de ambos dispositivos, requiere de una curva de aprendizaje no despreciable.
- Antes del implante requiere de un estudio con ETE en la mayoría de los casos para visualizar y estudiar anatómicamente la orejuela izquierda, descartando trombos intracavitarios. TC en ocasiones.
- Se desconoce la importancia de hallar fugas periprotésicas durante el seguimiento, aunque se recomienda implantar dispositivos algo mayores que el tamaño de la orejuela, para evitarlas.

TERAPIA ANTITROMBÓTICA

- En el estudio PROTECT-AF se administraba warfarina durante 45 días y se suspendía según los hallazgos tras ETE.

- Actualmente la mayoría de centros recomiendan doble antiagregación con ASA y clopidogrel durante 1-3 meses.

- Posteriormente se recomienda antiagregación con un solo fármaco, de forma indefenida.

COMPLICACIONES

- Derivadas del implante o periprocedimiento: derrame pericárdico, taponamiento cardiaco, ictus isquémico, embolización del dispositivo, implante exitoso.

- Similar tasa de complicaciones para ambos dispositivos, en equipos con experiencia. Ictus < 0.5%, derrame pericárdico 1-2%, embolización dispositivo 0.5-1%.

- Durante el seguimiento: fugas periprotésicas, trombosis del dispositivo.

GUÍAS CLÍNICAS

Recomendaciones para el cierre/oclusión/escisión de la OI

Recomendaciones	Clase[a]	Nivel[b]
Se puede considerar el cierre de la OI por intervención percutánea para pacientes con alto riesgo de ACV y contraindicaciones para la anticoagulación oral a largo plazo	IIb	B
Se puede considerar la escisión quirúrgica de la OI para pacientes sometidos a cirugía a corazón abierto	IIb	C

ACV: accidente cerebrovascular; OI: orejuela izquierda.

[a]Clase de recomendación.

[b]Nivel de evidencia.

[c]Referencias.

GUÍAS CLÍNICAS

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CLINICAL PRACTICE GUIDELINE

2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society

Developed in Collaboration With the Society of Thoracic Surgeons

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GUÍAS CLÍNICAS

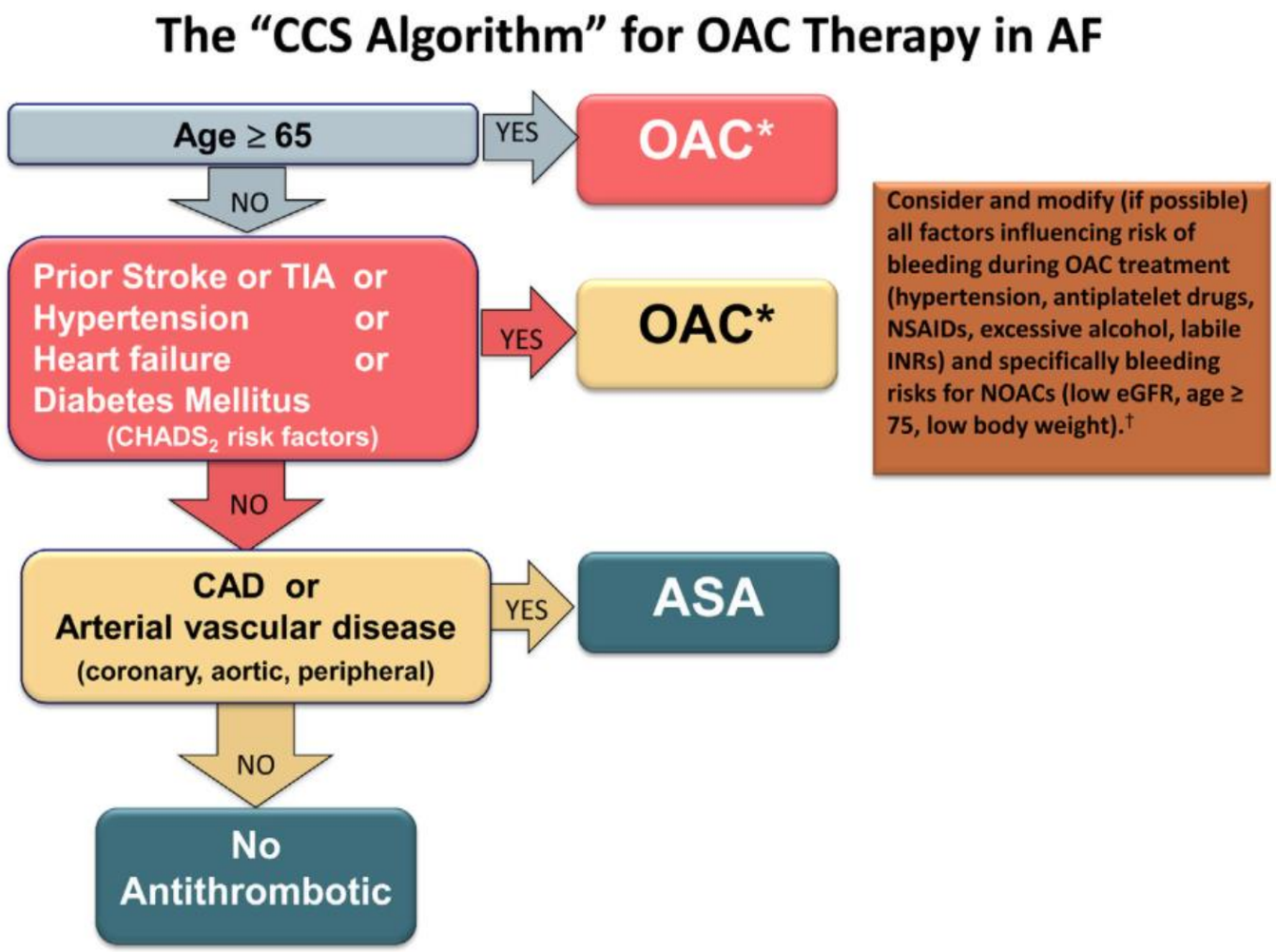

Figure 1. The simplified "CCS algorithm" for deciding which patients with atrial fibrillation (AF) or atrial flutter (AFL) should receive oral anti-coagulation (OAC) therapy. * We suggest that a NOAC be used in preference to warfarin for non-valvular AF. † Might require lower dosing. ASA, acetylsalicylic acid; CAD, coronary artery disease; CCS, Canadian Cardiovascular Society; $CHADS_2$, **C**ongestive Heart Failure, **H**ypertension, **A**ge, **D**iabetes, **S**troke/Transient Ischemic Attack; eGFR, estimated glomerular filtration rate; INR, international normalized ratio; NOAC, novel oral anticoagulant; NSAID, nonsteroidal anti-inflammatory drug; TIA, transient ischemic attack.

GUÍAS CLÍNICAS

RECOMMENDATION

5. We recommend that when OAC therapy is indicated for patients with nonvalvular AF, most patients should receive dabigatran, rivaroxaban, apixaban, or edoxaban (when approved) in preference to warfarin (Strong Recommendation, High-Quality Evidence)

RECOMMENDATION

11. We suggest these nonapproved LAA closure devices not be used, except in research protocols or in systematically documented use protocols in patients at high risk of stroke ($CHADS_2$ score ≥ 2) for whom antithrombotic therapy is precluded (Conditional Recommendation, Low-Quality Evidence).

GUÍAS CLÍNICAS

Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism

Issued: June 2010

NICE interventional procedure guidance 349

www.nice.org.uk/ipg349

Stroke

Percutaneous Left Atrial Appendage Closure for Stroke Prophylaxis in Patients With Atrial Fibrillation

2.3-Year Follow-up of the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) Trial

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Background—The multicenter PROTECT AF study (Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) was conducted to determine whether percutaneous left atrial appendage closure with a filter device (Watchman) was noninferior to warfarin for stroke prevention in atrial fibrillation.

Methods and Results—Patients (n=707) with nonvalvular atrial fibrillation and at least 1 risk factor (age >75 years, hypertension, heart failure, diabetes, or prior stroke/transient ischemic attack) were randomized to either the Watchman device (n=463) or continued warfarin (n=244) in a 2:1 ratio. After device implantation, warfarin was continued for ≈45 days, followed by clopidogrel for 4.5 months and lifelong aspirin. Study discontinuation rates were 15.3% (71/463) and 22.5% (55/244) for the Watchman and warfarin groups, respectively. The time in therapeutic range for the warfarin group was 66%. The composite primary efficacy end point included stroke, systemic embolism, and cardiovascular death, and the primary analysis was by intention to treat. After 1588 patient-years of follow-up (mean 2.3±1.1 years), the primary efficacy event rates were 3.0% and 4.3% (percent per 100 patient-years) in the Watchman and warfarin groups, respectively (relative risk, 0.71; 95% confidence interval, 0.44%–1.30% per year), which met the criteria for noninferiority (probability of noninferiority >0.999). There were more primary safety events in the Watchman group (5.5% per year; 95% confidence interval, 4.2%–7.1% per year) than in the control group (3.6% per year; 95% confidence interval, 2.2%–5.3% per year; relative risk, 1.53; 95% confidence interval, 0.95–2.70).

Conclusions—The "local" strategy of left atrial appendage closure is noninferior to "systemic" anticoagulation with warfarin. PROTECT AF has, for the first time, implicated the left atrial appendage in the pathogenesis of stroke in atrial fibrillation.

Clinical Trial Registration:—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00129545. (***Circulation.* 2013;127:720-729.**)

Key Words: anticoagulation ■ atrial fibrillation ■ catheters ■ left atrial appendage ■ pericardial effusion ■ stroke prevention ■ warfarin

ESTUDIO PROTECT-AF

- Único estudio aleatorizado que ha comparado antgonistas de la vitamina K (warfarina) con un dispositivo oclusor de la orejuela izquierda (Watchman) en la fibrilación auricular no valvular.
- Demostró que el cierre de la orejuela izquierda no es inferior a la warfarina en el objetivo primario: combinado de ictus, embolia sistémica o muerte de origen cardiovascular).
- Tasa inicial de complicaciones periprocedimiento iniciales altas.

REGISTROS ACP VS. WATCHMAN

Table 5 ACP registries in comparison with PROTECT AF

In-hospital											Follow-up				
Registry	Patients	Mean age (year 5)	Mean $CHADS_2$ score	Technical success	Stroke	Pericardial effusion conservative	Tamponade (Drainage)	Device embolization	Death (all cause)	Total adverse events	Device embolization	Pericardial effusion	Thrombus on device	Stroke	Death
Italian Registrty[101]	100			100/100 100%	0		2/100 2%	0	0	2/100 2%					
Dual Centre, Hamburg Bern[97]	131			131/131 100%	0	1/131 1%	0	0	0	1/131 0.8%					
ACP EU Post Market Registry[98]	204	74 ± 9	2.6 ± 1.3	197/204 97%	0		3/204 1.5%	3	0	6/204 2.9%	1	0	5/204 2.4%		
Spanish Registry[99]	35	75 ± 6	2.4 ± 1.3	34/35 97%	0	0	0	0	0	0	0	0	5/35 14%	1/35 3%	3/35 9%
Initial European Experience[48]	143	74 ± 9	–	132/137 96%	3/143 2.1%	4/143 3%	5/143 3.5%	2/143 1.4%	0	10/143 7%					
Bern LAA Occlusion Registry[100]	100	72 ± 10	2.5 ± 1.3	98/100 98%	1/100 1%	2/100 2%	1/100 1%	2/100 2%	0	6/100 6%					
Initial Asian Experience[68]	20	68 ± 9	2.3 ± 1.3	19/20 95%	0	0	0	0	0	*	–	–	–	–	–
Canadian Registry[105]	52	74 ± 8	3 (2–4)	51/52 98%	0	1/52 2%	1/52 2%	1/52 2%	0	2/52 4%	0	1/52 2%	0	1/52 2%	3/52 6%
PROTECT AF[45]	463	72 ± 9	2.2 ± 1.2	408/463 88%	5/463 1%	8/463 1%	22/463 5%	3/463 1%	0	36/463 8%	2/463 0.4%	0		16/694 2.3%	21/705 3.0%

*Air embolism in right coronary artery, one oesophageal injury during TOE.

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ENSAYOS CON WATCHMAN

Table 4 Results with the Watchman device

Trial	Patients	Patients device/ Control	Comments	Average $CHADS_2$ Score	Average CHA_2DS_2-VASc Score	Medical therapy	Efficacy events	Safety events	Successful implantation	Mean follow-up (months)	No warfarin	Primary efficacy event rate (per 100 patient-years)	Safety event rate
Pilot study[44,94]	66	66/0	Non-randomized cohort of patients undergoing Watchman implantation	1.8 ± 1.1		Warfarin plus ASA for 45 days, and ASA for life	Death, stroke, systemic embolism, and major bleeding		88%	73 ± 25	91%	Actual stroke rate of 0.5%	4 device embolizations
PROTECT AF[45,89]	707	463/244 warfarin	Randomized non-inferiority trial	2.2 ± 1.2	3.4	Warfarin plus ASA for 45 days, DAPT for 6 months, and ASA for life	Composite endpoint of stroke, cardiovascular death, and systemic embolism	Device embolization, major bleeding events, and pericardial effusion	88%	18 ± 10[45] 43.4 ± 21.7[89]	94%	3[45] 3[89] 2.3	7[45] 6[89]
CAP Registry[88]	460	460/0	Non-randomized registry of patients undergoing Watchman implantation	2.4 ± 1.2		Warfarin plus ASA for 45 days, DAPT for 6 months, and ASA for life	PROTECT AF protocol	PROTECT AF protocol	95%	25.4 ± 10.0	95%	2	
ASAP Registry[48]	150	150/0	Treat patients contra-indicated for warfarin	2.8	4.4 ± 1.7	DAPT for 6 months and ASA for life	Stroke rate per 100 patient-years		95%		100%	2	
Prevail[a]	407	269/138	Similar to PROTECT AF[a] with revised inclusion criteria	2.6 ± 1.0		Similar to PROTECT AF	Stroke, embolism, or unexplained death	Same as PROTECT AF within 7 days	95.1%	Modelled to 18 months, only 58 actually reached 18 months		1	4

DAPT, dual antiplatelet therapy; ASA, acetylsalicylic acid; AF, atrial fibrillation.
[a]Prevail data are preliminary and final validation is not yet complete.

SERIE ESPAÑOLA

Artículo original

Resultados inmediatos y a más de un año en 35 pacientes consecutivos a los que se realiza cierre de orejuela izquierda con el dispositivo Amplatzer Cardiac Plug

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Palabras clave:
Orejuela izquierda
Dispositivo oclusor
Fibrilación auricular
Cartografía electroanatómica no fluoroscópica
Tomografía computarizada
Resonancia magnética

RESUMEN

Introducción y objetivos: El cierre del apéndice auricular izquierdo puede ser una opción terapéutica atractiva para pacientes con fibrilación auricular no valvular y contraindicación para tomar anticoagulantes orales, siempre que se obtengan buenos resultados durante la implantación y en el seguimiento.
Métodos: Se analizó a 35 pacientes consecutivos y no elegibles para los estudios aleatorizados con anticoagulantes orales a los que se implantó el dispositivo oclusor Amplatzer. Tras los primeros 5 casos, se incorporó una técnica de imagen 3D. Se analizaron los resultados de la implantación y de seguimiento durante 1 año.
Resultados: La media de edad era 74,65 ± 7,61 años, con un $CHADS_2$ de 2,41 ± 1,53 y un CHA_2DS_2-VASc de 3,17 ± 1,60. No se pudo implantar el dispositivo en 1 caso y en 5 fue necesario cambiar la medida seleccionada. No hubo ninguna complicación cardiaca durante la implantación ni durante la estancia hospitalaria. Hubo una complicación vascular (fístula arteriovenosa). Se realizó seguimiento con ecocardiografía transesofágica a las 24 h y tras 1, 3, 6 y 12 meses; se documentaron 5 trombos, que se resolvieron con heparina. En el seguimiento de 21,14 ± 10,09 meses, hubo 3 muertes de pacientes mayores de 80 años, ninguna de ellas cardiológica, y un accidente isquémico transitorio sin secuelas.
Conclusiones: El cierre del apéndice auricular izquierdo por un operador con cierta experiencia puede ser una opción terapéutica con pocas complicaciones y con resultados a más de 1 año eficaces en la reducción de complicaciones tromboembólicas y hemorrágicas, incluso en poblaciones de muy alto riesgo.

SERIE ESPAÑOLA

Tabla 4
Comparación de algunos datos de interés clínico entre los principales estudios con nuevos anticoagulantes orales y dispositivos y nuestra serie

	Serie HIC	Dabigatrán (RE-LY)	Apixabán (ARISTOTLE)	Rivaroxabán (ROCKET AF)	PROTECT AF, DO frente a warfarina
Edad (años)	74,65	71,5	70	73	72
$CHADS_2$	2,41 ± 1,53	2,1	2,1	3,5	2,2±1,2
CHA_2DS_2-VASc > 2	42,8%	32,7%	30,2%	87%	31%
Sangrado postoperatorio	5,7%	16,4%	18,1%	14,9%	Sin datos
Sangrados mayores	2,87%[a]	3,11%	2,13%	3,60%	Sin datos
Ictus/embolias postoperatorias	2,85%[b]	1,11%	1,27%	1,7%	3,2% DO; 1,8% ACO
Abandono del tratamiento tras más de 1 año	0%	21%	Sin datos	24%	22%

ACO: anticoagulantes orales; ARISTOTLE: *Apixaban for Reduction In STroke and Other ThromboembоLic Events in atrial fibrillation*; DO: dispositivo oclusor; HIC: Hospital Infanta Cristina; PLAATO: *Percutaneous Left Atrial Appendage Transcatheter Occlusion*; PROTECT AF: PROTECTion in patients with Atrial Fibrillation; RE-LY: *Randomized Evaluation of Long term anticoagulant therapY*; ROCKET AF: *Rivaroxaban Once daily oral direct factor Xa inhibition Compared with vitamin K antagonist for the prevention of stroke and Embolism Trial in Atrial Fibrillation*.

[a] Pacientes que no pueden tomar acenocumarol y sólo por la doble antiagregación de los primeros meses.

[b] Pacientes que no pueden tomar acenocumarol y sólo por la doble antiagregación de los primeros meses; realmente el único caso es un accidente isquémico transitorio sin secuelas (en *Percutaneous Left Atrial Appendage Transcatheter Occlusion*, el 3,8% de ictus frente al esperado 6,6% para $CHADS_2$ 2,5).

REGISTROS CON AMPLATZER

TABLE 3 Procedural Success and Complications in ACP Registries

ACP Registries (Ref. #)	Enrollment Period	N	$CHADS_2$ Score, Mean ± SD	Procedural Success, %	Serious Pericardial Effusion, %	Embolization, %	Ischemic Stroke, %	Total Safety Events, %
Initial European registry (34)	December 2008-November 2009	143	NA	96	3.5	1.4	2.1	7
Asia-Pacific experience (35)	2009-2010	20	2.3 ± 1.3	95	0	0	0	1 air embolism, 1 thrombus
Latin America (36)	2009-2012	60	3.2 ± 1.1	100	6.6	1.7	0	8.3
Spanish experience (37)	2009-2011	35	2.4 ± 1.5	97.1	0	0	0	0
Polish experience (38)	2009-2012	21	CHA_2DS_2-VASc 4.4 ± 1.4	95.2	4.8	0	0	0
Iberia registry (42)	2009-2011	213	NA	92.5	1.4	1.9	0.5	5.6; 1.4 deaths
Bern experience (24)	2008-2012	120	CHA_2DS_2-VASc 3.4 ± 1.7	97.5	1.6	1.6	0.8	6.7 (2 TIA)
Canadian registry (39)	2009-2011	52	3.0 ± 1.0	98.1	0	1.9	0	1.9
Israel experience (40)	2009-2012	100	3.2 ± 1.2	100	1	0	0	1
Belgian registry (43)	2009-2012	90	CHA_2DS_2-VASc 4.4 ± 1.8	98.9	3.3	0	0	1.1 deaths
European post-marketing registry (41)	2009-2011	204	2.6 ± 1.3	96.6	2.4	1.5	0	2.9

CHA_2DS_2-VASc = congestive heart failure, hypertension, age ≥75 years, age 65 to 74 years, diabetes mellitus, stroke/transient ischemic attack/thromboembolism, vascular disease, sex female; NA = not available; TIA = transient ischemic attack; other abbreviations as in Tables 1 and 2.

REGISTRO ESPAÑOL

Heart Online First, published on January 8, 2015 as 10.1136/heartjnl-2014-306332

ORIGINAL ARTICLE

Two-year clinical outcome from the Iberian registry patients after left atrial appendage closure

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ABSTRACT

Aims The aim of this study was to observe the percentage of thromboembolic and haemorrhagic events over a 2-year follow-up in patients with non-valvular atrial fibrillation (NVAF) undergoing closure of the left atrial appendage (LAA) with an occlusion device.

Observed events and $CHADS_2$ (congestive heart failure, hypertension, age, diabetes, stroke history), CHA_2DS_2-VASc (also adding: vascular disease and sex) and HAS-BLED (hypertension, abnormal liver/renal function, stroke history, bleeding predisposition, labile international normalised ratios, elderly, drugs/alcohol use)-predicted

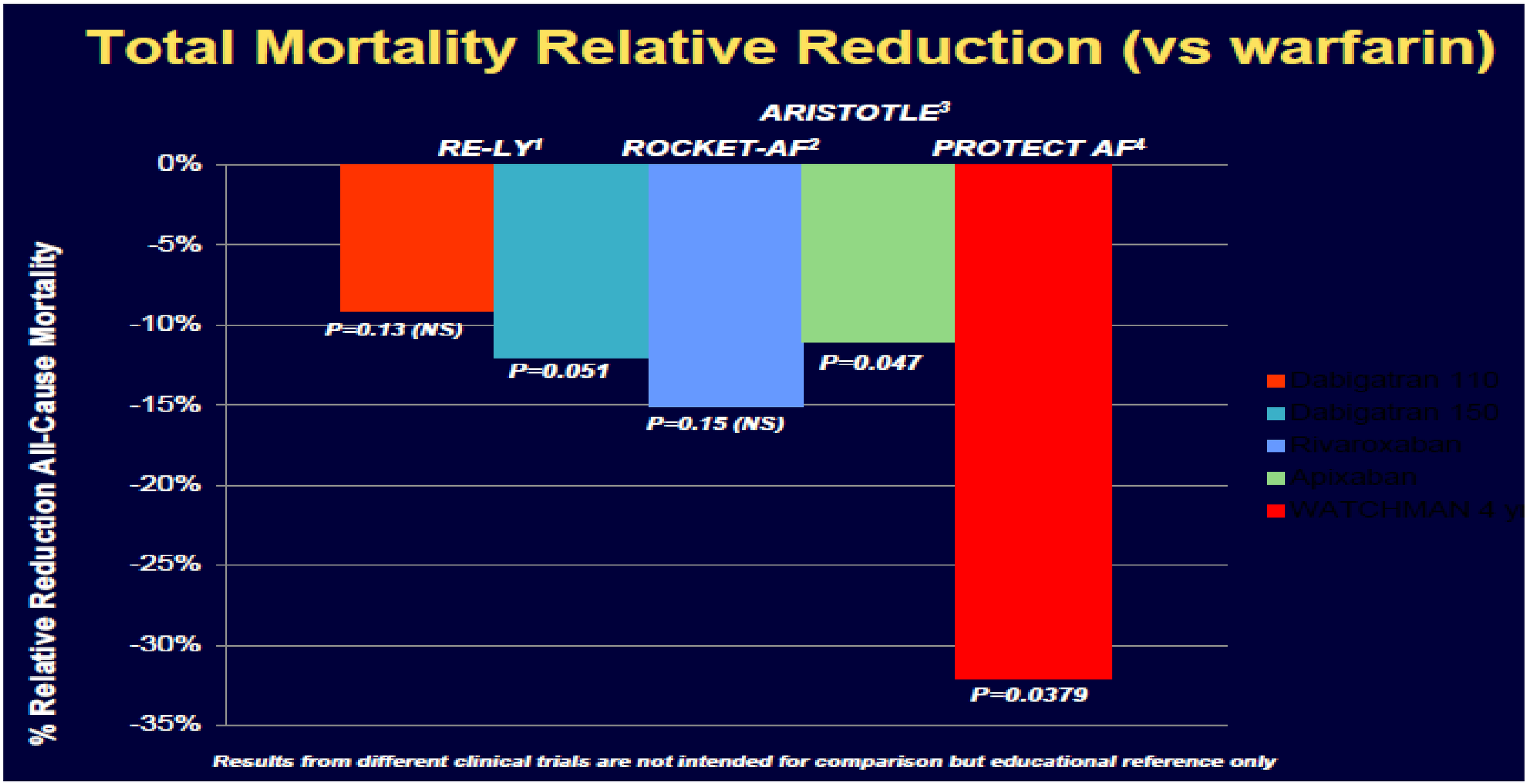
(INR) monitoring) are interesting, the risks inherent to their anticoagulant action remain unchanged, and they significantly increase the cost of surgery. The relative reduction in the number of events is striking but less relevant in absolute terms.[1]

Closure of the left atrial appendage (LAA), the site of over 90% of thrombi in these patients, has initially been shown to reduce incidence of intracranial haemorrhage. It is at least as effective as warfarin in reducing thromboembolic events,[2] but might be superior to warfarin in longer follow-up periods.[3 4] LAA occlusion is now starting to appear

CONCLUSIONES

- La evidencia científica actual sugiere que el cierre percutáneo de la orejuela izquierda es eficaz en la reducción de eventos tromboembólicos en la fibrilación auricular no valvular.
- Tasa de complicaciones periprocedimiento baja, aunque significativa, muy relacionada con la curva de aprendizaje. Centros con disponibilidad de cirugía cardiaca.
- Selección de pacientes cuidadosa y multidisciplinar.

NUEVOS ANTICOAGULANTES



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New Oral Anticoagulants Increase Risk for Gastrointestinal Bleeding: A Systematic Review and Meta-analysis

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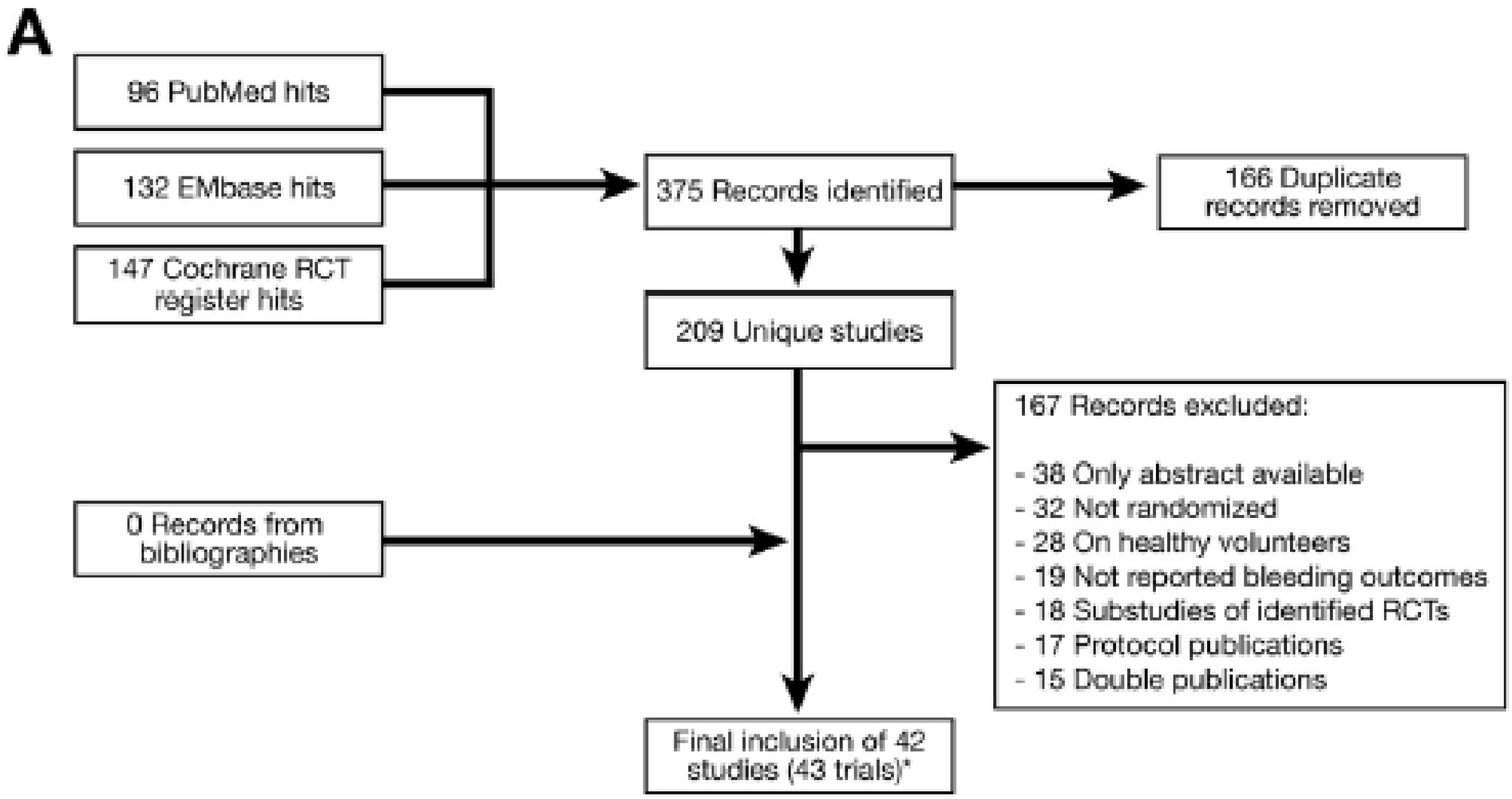
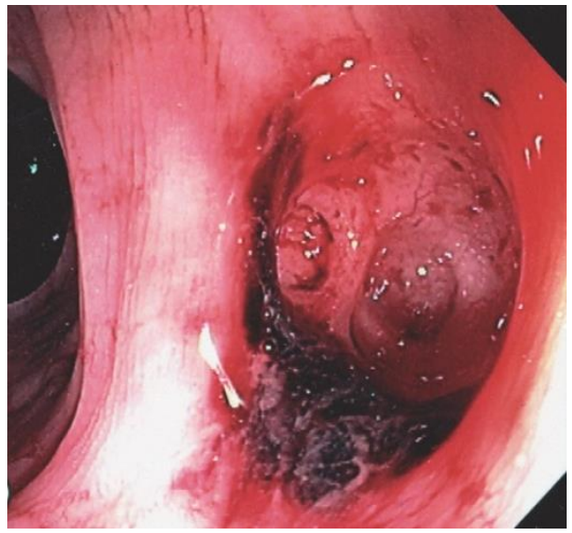
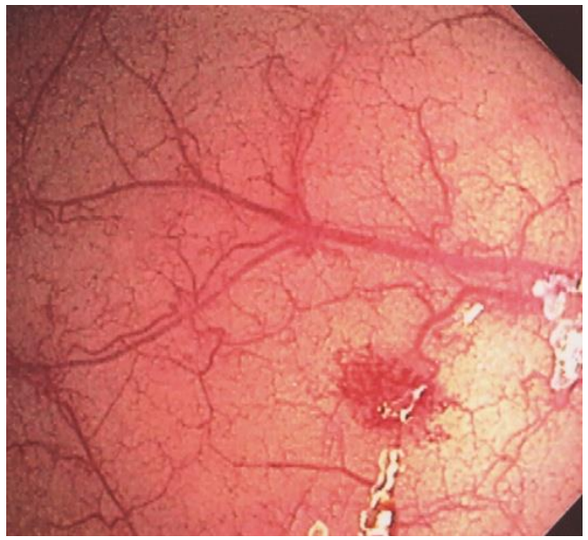
GASTROENTEROLOGY 2013;145:105–112



The role of anticoagulant & GI bleeding

- **Anticoagulants do not cause any lesion in the GI tract.**
- **However, anticoagulants are associated with a higher risk of bleeding from most lesions**





Recorded Drug Use	Peptic Ulcer Bleeding (N=1218)	Diverticular Bleeding (N=189)	Angiodysplasia (N=66)
NSAID	**30.7%**	**14.8%**	**16.7%**
LOW DOSE ASA	**15.8%**	**21.7%**	**6.1%**
Anticoagulant	**5.7%**	**14.3%**	**27.3%**

- **Occult GI bleeding and anticoagulants: 4 times higher**

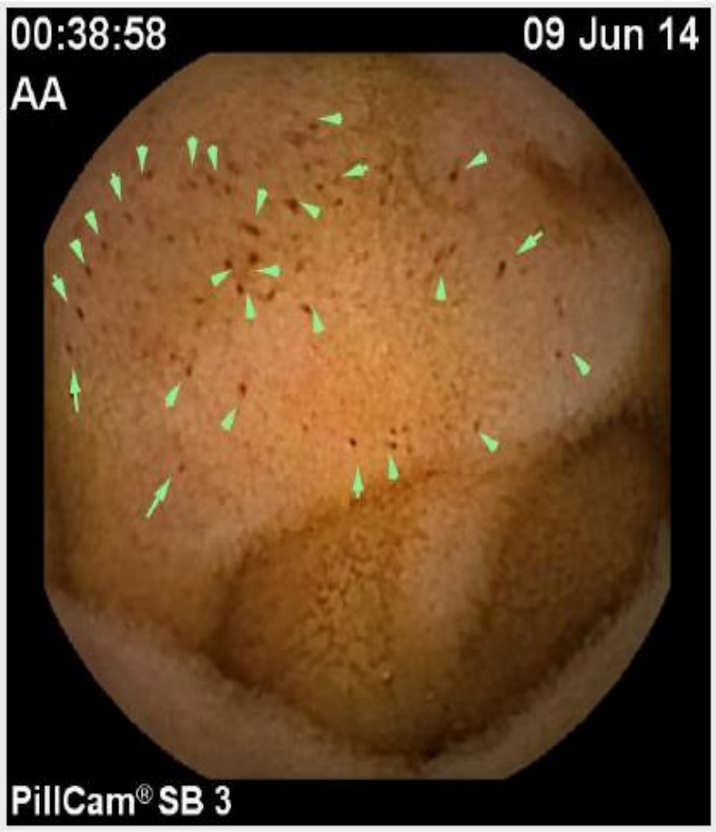
CASO CLÍNICO

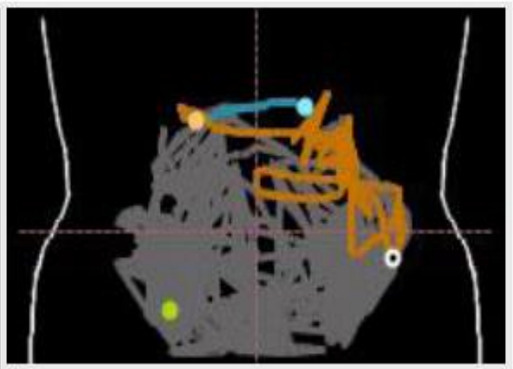
- Varón de 84 años. Hipertensión arterial. Diabetes mellitus tipo 2 en tratamiento con insulina y antidiabéticos orales.
- Ictus isquémico en territorio vertebrobasilar sin secuelas, de presumible etiología cardioembólica.
- Fibrilación auricular persistente no valvular anticoagulada con antagonistas de la vitamina k.
- Episodios de hemorragia digestiva grave, en forma de melenas, con necesidad de transfusión de hemoderivados.

CASO CLÍNICO

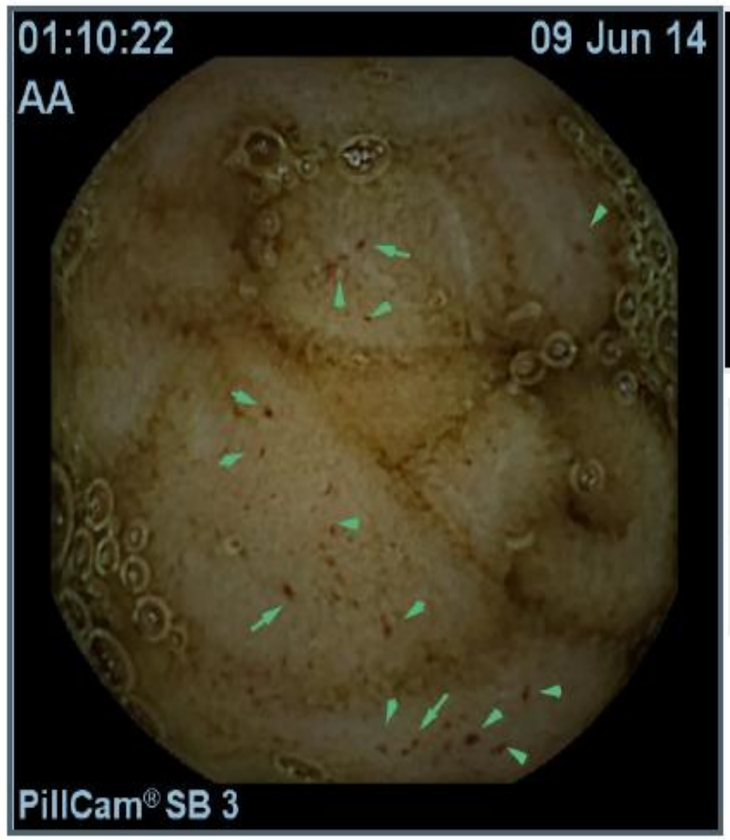
- El paciente tiene buena calidad de vida, con funciones corticales normales y buena clase funcional.
- Mantiene controles INR en rango.
- Estudio endoscópico: gastroscopia con hernia de hiato y gastritis crónica antral; colonoscopia con hallazgos de hemorroides internas y diverticulosis de colon no complicada.
- Cápsula-endoscopia: innumerables petequias de duodeno a yeyuno medio, que se asumen como responsables de los sangrados.

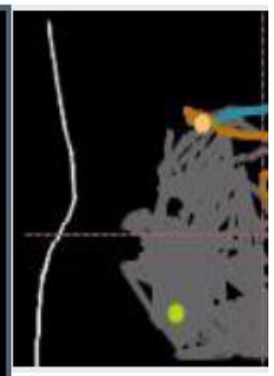
Firma _____



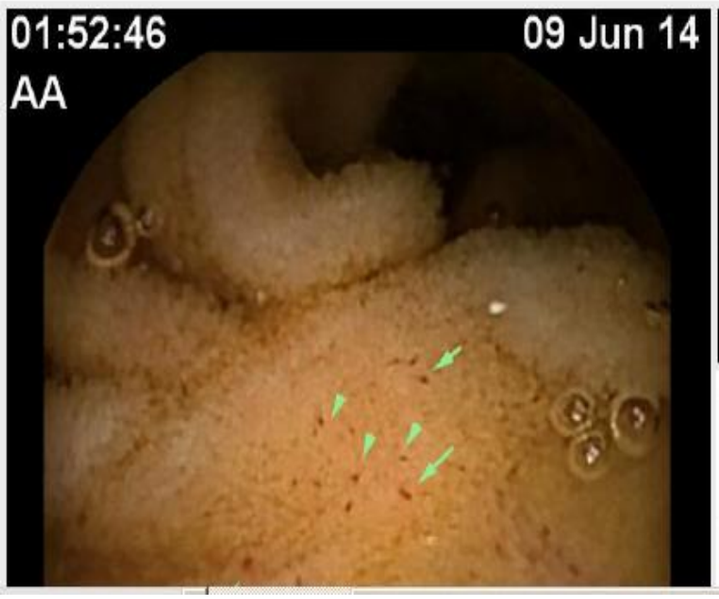


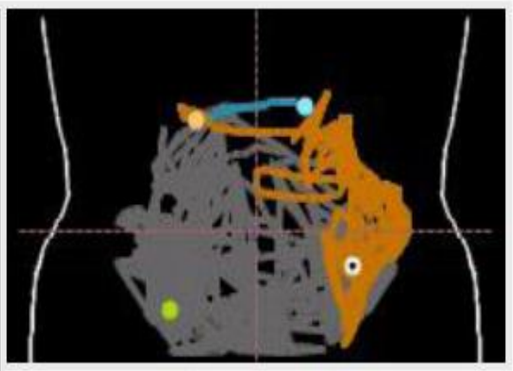
% de avance de la cápsula	11
% de tiempo de SB	9



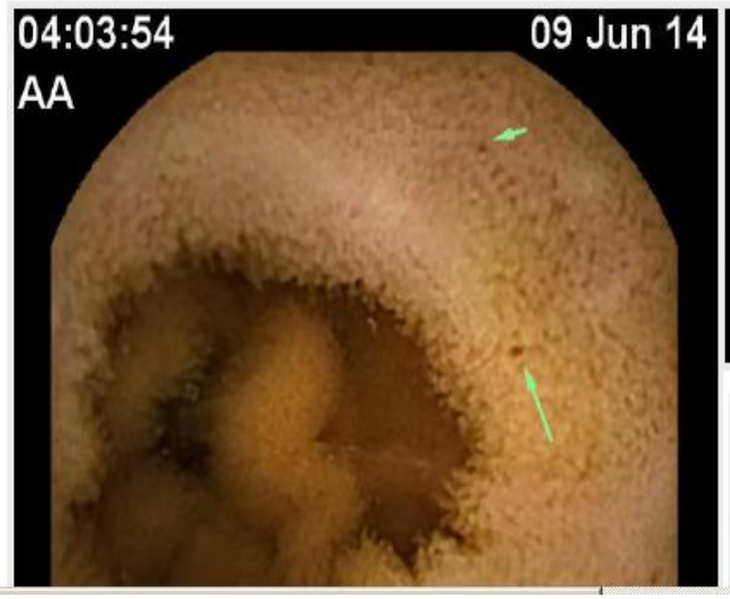


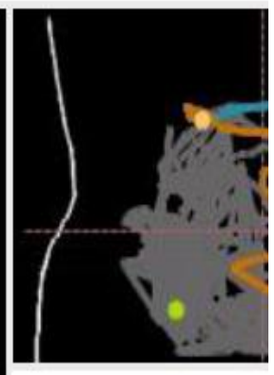
% de avance de cápsula	
% de tiempo de S	





% de avance de la cápsula	33
% de tiempo de SB	28





% de avance de cápsula	
% de tiempo de S	

APROBACIÓN FDA

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.

VIDEO AMPLATZER

AMPLATZER™ AMULET™

Left Atrial Appendage Occluder

ST. JUDE MEDICAL™

Not approved for sale in the US.

VIDEO WATCHMAN