Congreso de la **SAC24**
Sociedad Asturiana
de Cardiología

17 y 18 de mayo

SOCIEDAD ASTURIANA DE CARDIOLOGÍA

Intervencionismo transcateter en la profilaxis del ictus

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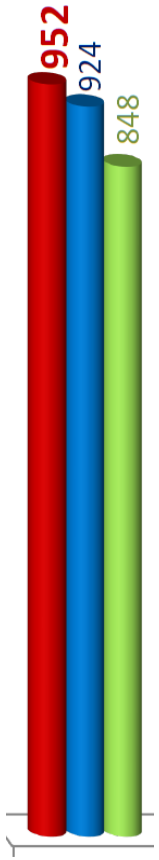
Hospital General Universitario de Alicante

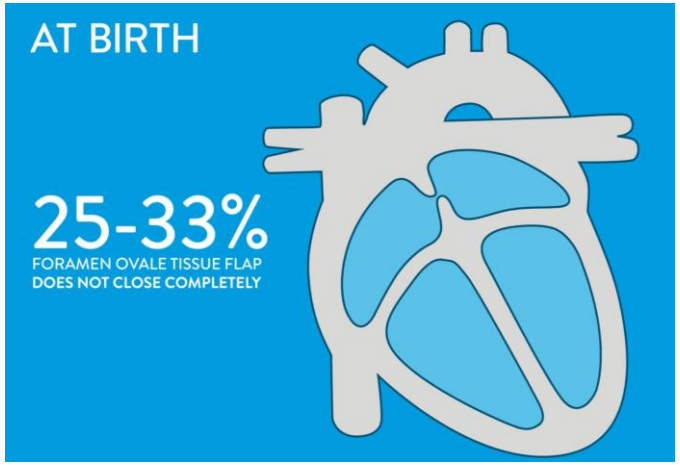
#AsturCardio2024

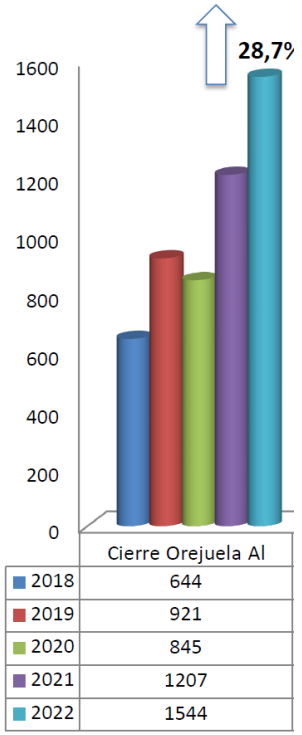
CONFLICTO DE INTERESES

Proctor en estructural de Abbott, Boston Scientific y Medtronic

¿Qué aporta el intervencionismo?

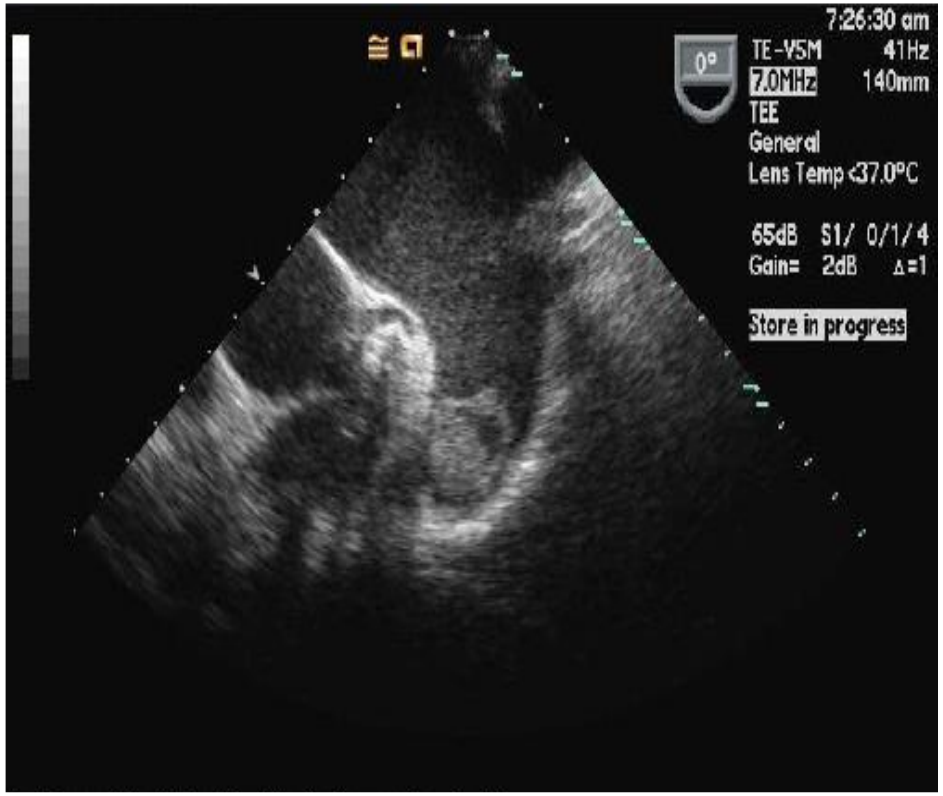


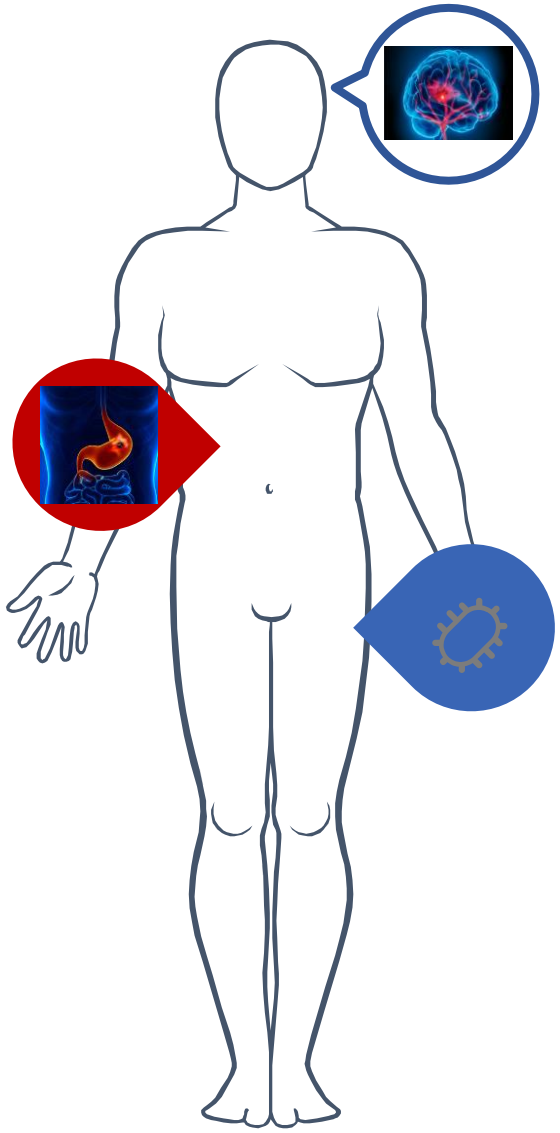




	Cierre Orejuela AI
2018	644
2019	921
2020	845
2021	1207
2022	1544

Abordaje local de un problema sistémico



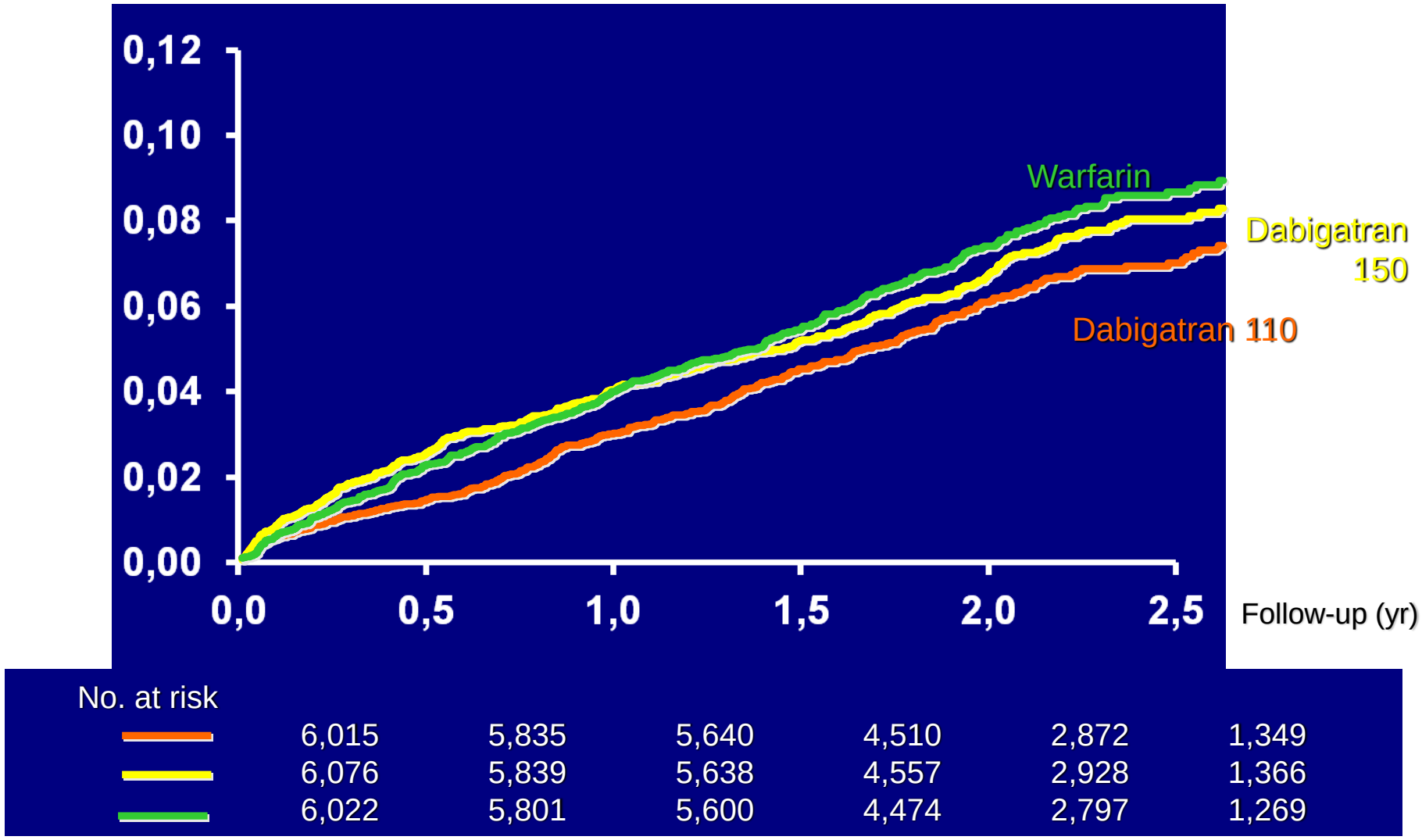


Anticoagulación crónica: Hemorragias mayores

Study	Treatment	Major Bleeding	Hemorrhagic Stroke
RE-LY[1]	Dabigatran (110 mg)	2.71%	0.12%
	Dabigatran (150 mg)	3.11%	0.10%
	Warfarin	3.36%	0.38%
ROCKET-AF[2]	Rivaroxaban	3.6%	0.5%
	Warfarin	3.4%	0.7%
ARISTOTLE[3]	Apixaban	2.13%	0.24%
	Warfarin	3.09%	0.47%

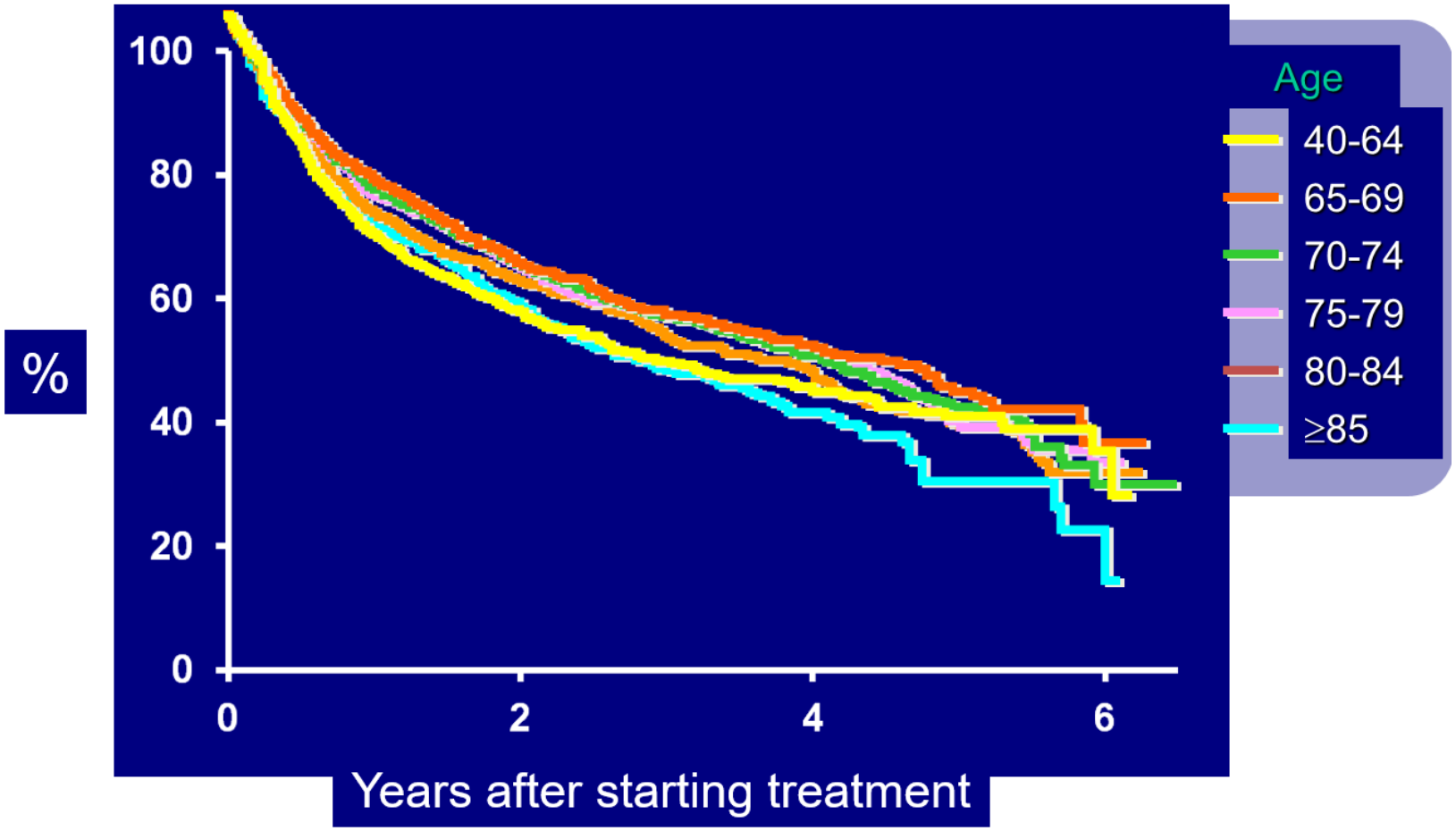
1. Connelly SJ et al, *NEJM* 2009; 361:1139-51
2. Patel MR et al, *NEJM* 2012; 365:883-91
3. Granger, J MD. *NEJM* 2012;365:981-92

Hemorragias mayores



Connolly SJ et al: NEJM 361:1139, 2009

Anticoagulación crónica: Discontinuación



Rivaroxaban	Warfarin
24%	22%

Apixaban	Warfarin
25%	28%

Gallagher et al. J Thromb Haemost 2008;6:1500

indice

1. Resultados actuales del LAAC
2. Comparación directa LAAC vs. ACOD
3. Qué pacientes indicar LAAC

Resultados actuales: éxito del implante

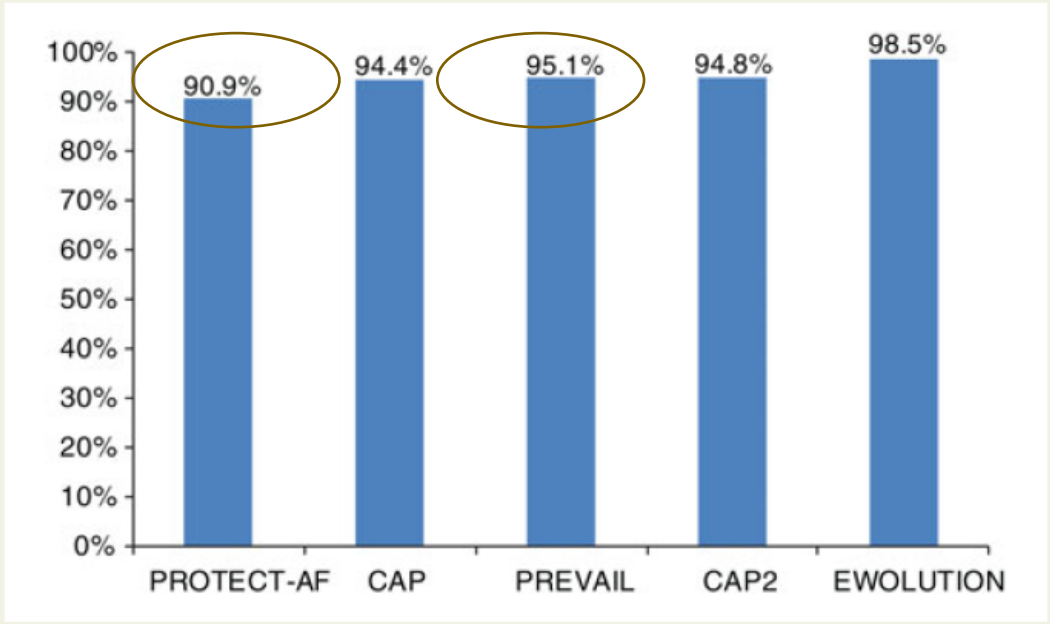


Figure 1 Implant success in EWOLUTION when compared with prior WATCHMAN studies.

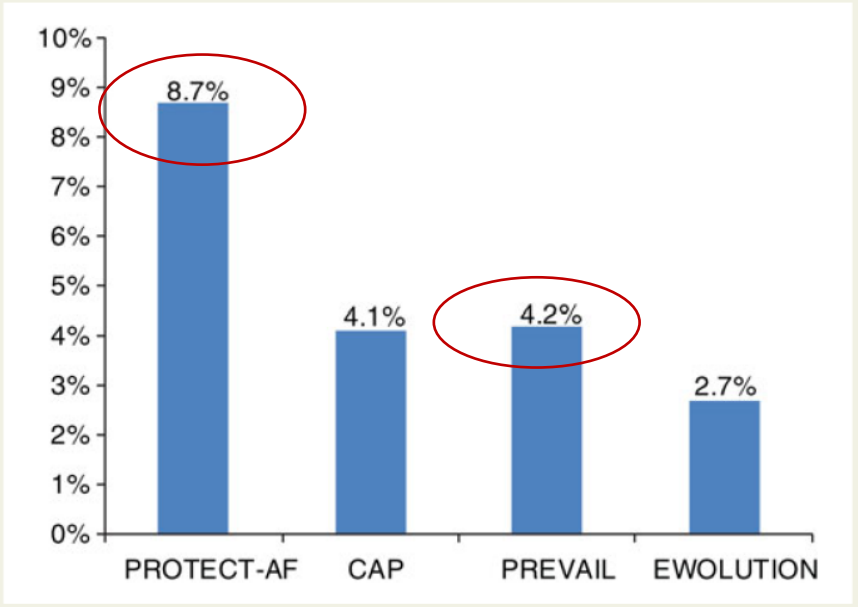


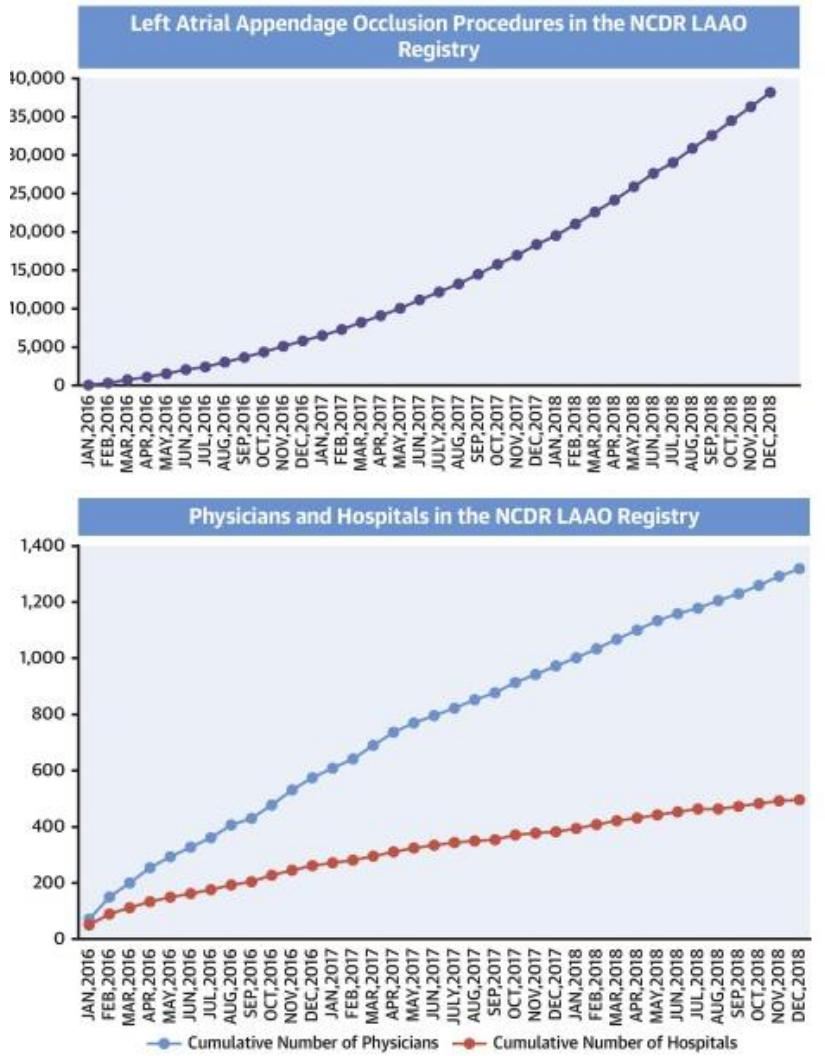
Figure 2 Serious procedure-/device-related events through 7 days in EWOLUTION when compared with prior WATCHMAN studies.

-Éxito: 98,5%

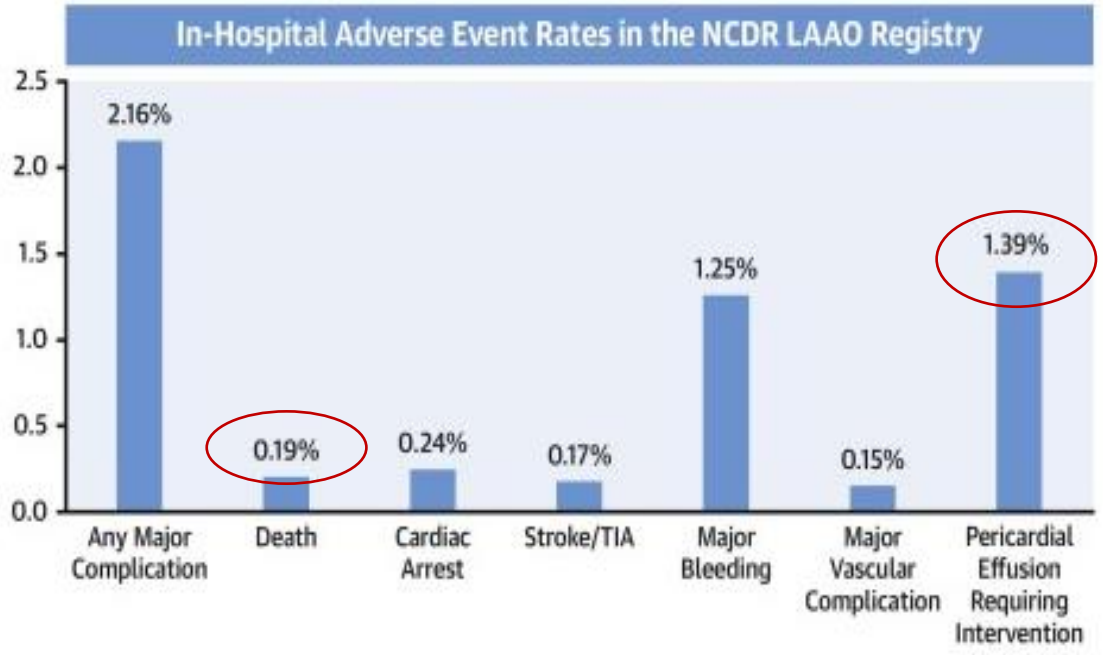
-Complicaciones < 2,7%

Boersma et al. European Heart Journal. doi:10.1093/eurheartj/ehv730

Más hospitales y más operadores

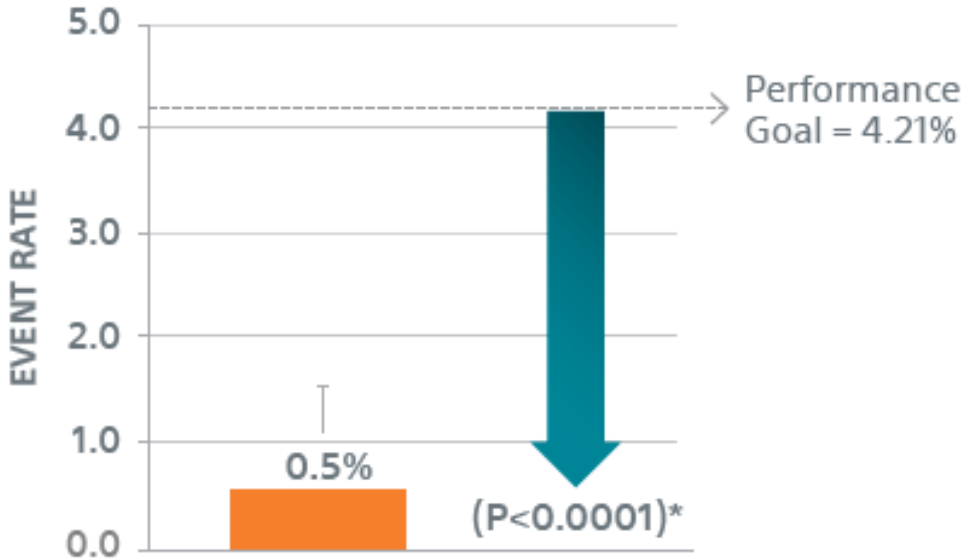


~70% new operators performed 50% of procedures



Freeman et al. JACC 2020;75:1503-18

PINNACLE: Primary Safety Endpoint met with low 0.5% event rate



0.5% Ischemic Stroke
(2/400)

0% All-cause Death

0% Pericardial Effusions Requiring Open Cardiac Surgery

0% Device Embolization

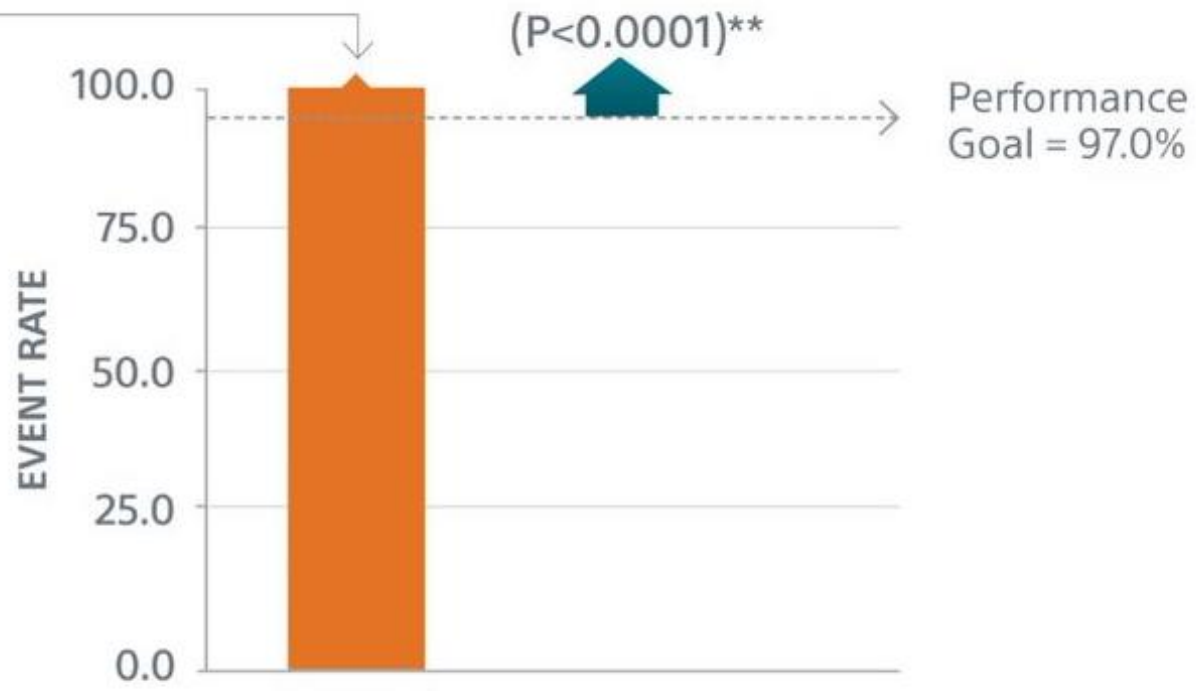
Occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later:* ***all-cause death, ischemic stroke, systemic embolism, or device or procedure* *related events requiring open cardiac surgery or major endovascular intervention*

Kar et ak, Circulation. 2021;143:1754–1762. DOI: 10.1161/CIRCULATIONAHA.120.050117

PINNACLE: Primary Effectiveness Endpoint

100%

of Subjects Demonstrated Effective LAA Closure at 12 Months*



** LAA closure at 12 months is defined as any peri-device flow with jet size ≤ 5mm per core laboratory-assessed TEE*

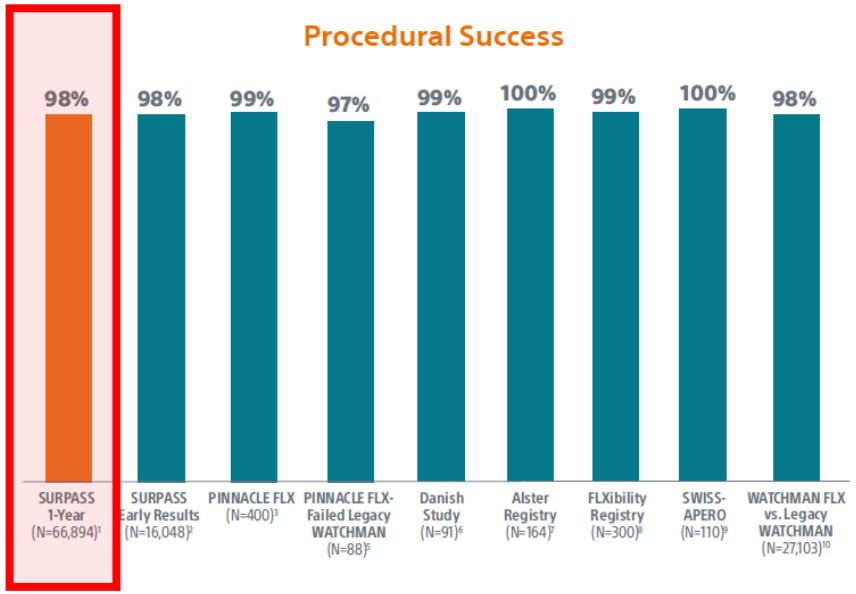
*** Performance goal based on the rates observed in PREVAIL(1) and CAP2(2) , minus a clinically relevant delta*

Kar et ak, Circulation. 2021;143:1754–1762. DOI: 10.1161/CIRCULATIONAHA.120.050117

SURPASS 1 year

n=66.894 pacientes

Exito

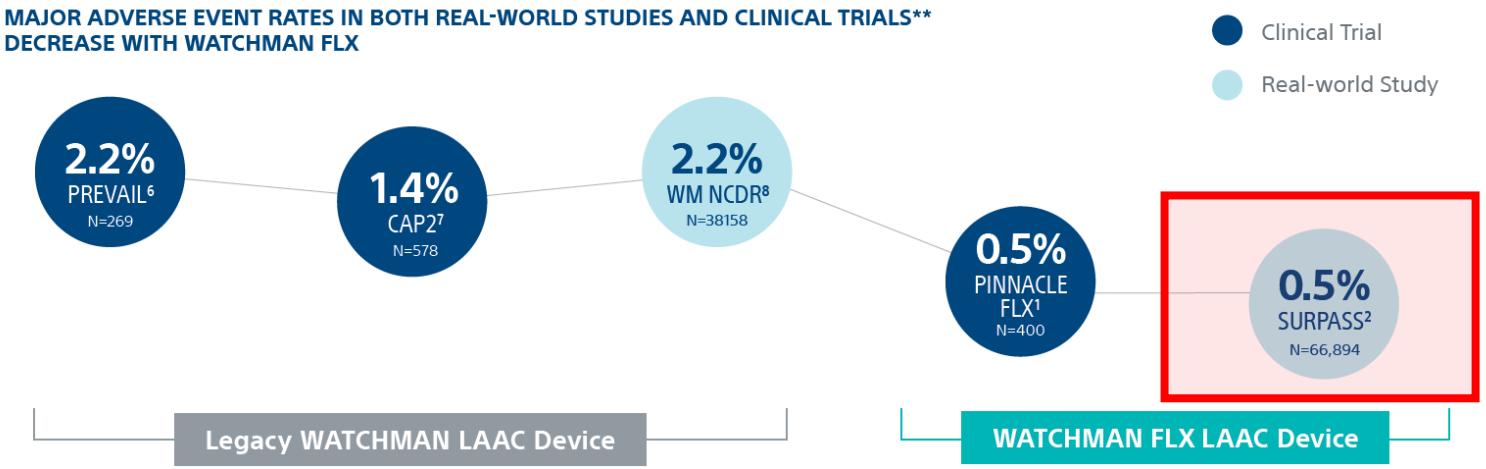


The WATCHMAN FLX Device delivers proven stroke reduction in the largest and highest-risk patient population studied to date across the WATCHMAN platform.

1.6% All Stroke

1.2% Ischemic Stroke

Compl. Mayores



Kapadie et al. Late Breaking Clinical Trial, CRT 2023

indice

1. Resultados actuales del LAAC
2. **Comparación directa LAAC vs. ACOD**
3. Qué pacientes indicar LAAC

The PRAGUE-17: Cierre Orejuela vs. ACOD

POBLACIÓN:
-eventos hemorrágicos previos
-fallo de la anticoagulación
-combinación de alto riesgo hemorrágico y tromboembólico

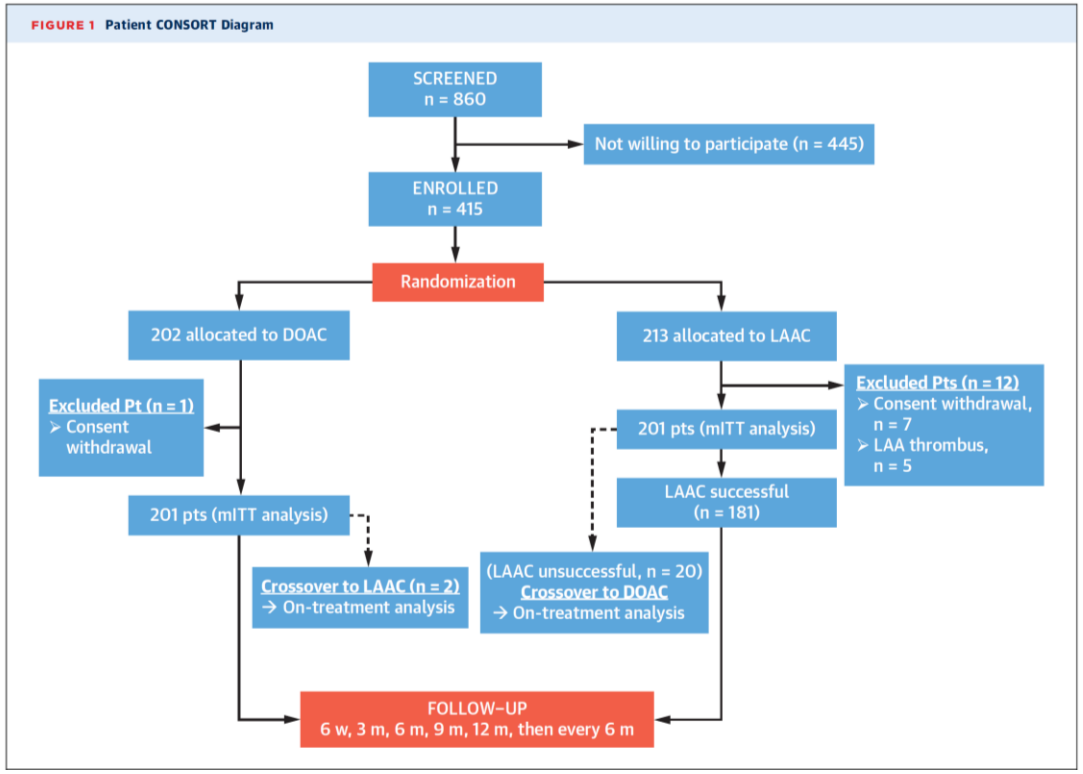


TABLE 1 Baseline Characteristics and Risk Factors of Participants

	DOAC (n = 201)	LAAC (n = 201)	Missing Values
Demographics			
Age, yrs	73.2 ± 7.2	73.4 ± 6.7	–
<75	122 (60.7)	116 (57.7)	–
>75	79 (39.3)	85 (42.3)	
Male	130 (64.7)	134 (66.7)	–
Weight, kg	88.1 ± 16.2	86.9 ± 17.6	–
Clinical history			
AF type			
Paroxysmal	67 (33.3)	53 (26.4)	–
Persistent	46 (22.9)	47 (23.4)	
Long-standing persistent	16 (8.0)	18 (9.0)	
Permanent	72 (35.8)	83 (41.3)	
CHA_2DS_2-VASc	4.7 ± 1.5	4.7 ± 1.5	–
CHA_2DS_2-VASc ≤3	50 (24.9)	48 (23.9)	–
CHA_2DS_2-VASc = 4	40 (19.9)	47 (23.4)	
CHA_2DS_2-VASc = 5	57 (28.4)	50 (24.9)	
CHA_2DS_2-VASc ≥6	54 (26.9)	56 (27.9)	
HAS-BLED	3.0 ± 0.9	3.1 ± 0.9	–
Heart failure	90 (44.8)	88 (43.8)	
Hypertension	186 (92.5)	186 (92.5)	–
Diabetes mellitus	90 (44.8)	73 (36.3)	–
History of cardioembolic event	69 (34.3)	73 (36.3)	–
Of which stroke	63 (91.3)	66 (90.4)	–
History of MI	39 (19.4)	30 (14.9)	–
Randomized at experienced centers	140 (69.7)	141 (70.1)	–
Prior antithrombotic treatment			
Warfarin	104 (51.7)	85 (42.3)	–
DOACs	55 (27.4)	66 (32.8)	–
If no OAC, new AF appearance	30 (71.4)	38 (76)	–
Aspirin	32 (15.9)	39 (19.4)	–
Clopidogrel	11 (5.5)	17 (8.5)	–
Dual antiplatelet treatment	6 (3.0)	7 (3.5)	–
Other (low-dose LMWH, none)	19 (9.5)	24 (11.9)	–

Osmancik et al. JACC 2020;75:3122-35

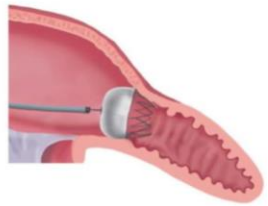
The PRAGUE-17: Cierre Orejuela vs. ACOD

"NO INFERIORIDAD"

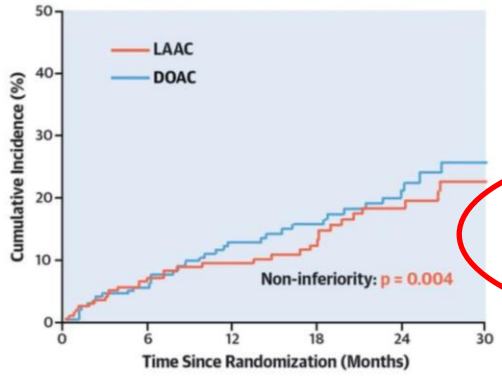
CENTRAL ILLUSTRATION: The PRAGUE-17 Trial

PRAGUE-17 Randomized Clinical Trial

- 402 High-Risk AF Pts ➡ Randomized
  - CHA_2DS_2-VASc = 4.7 ± 1.5
  - HAS-BLED = 3.1 ± 0.9
- Follow-up: 20.8 ± 10.8 mo (695 pt-year)



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

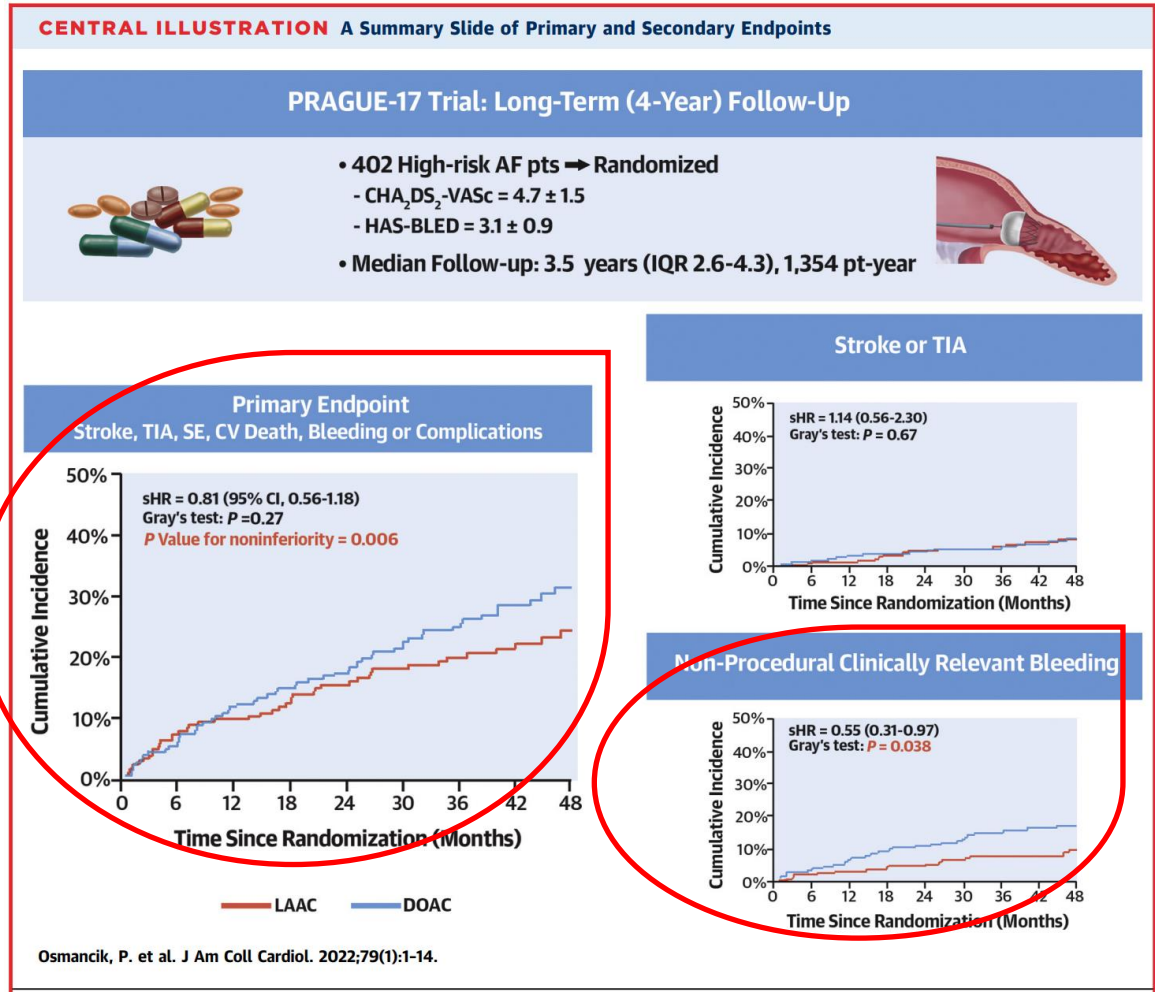


	sHR (95% CI)	p value
Primary Endpoint		
mITT	0.84 (0.53-1.31)	0.44
Per Protocol	0.82 (0.52-1.30)	0.40
On-Treatment	0.79 (0.49-1.25)	0.31
All-Stroke/TIA	1.00 (0.40-2.51)	0.99
CV Death	0.75 (0.34-1.62)	0.46
Major + NMCR Bleeding		
All	0.81 (0.44-1.52)	0.51
Nonprocedural	0.53 (0.26-1.06)	0.07

Osmancik, P. et al. J Am Coll Cardiol. 2020;75(25):3122-35.

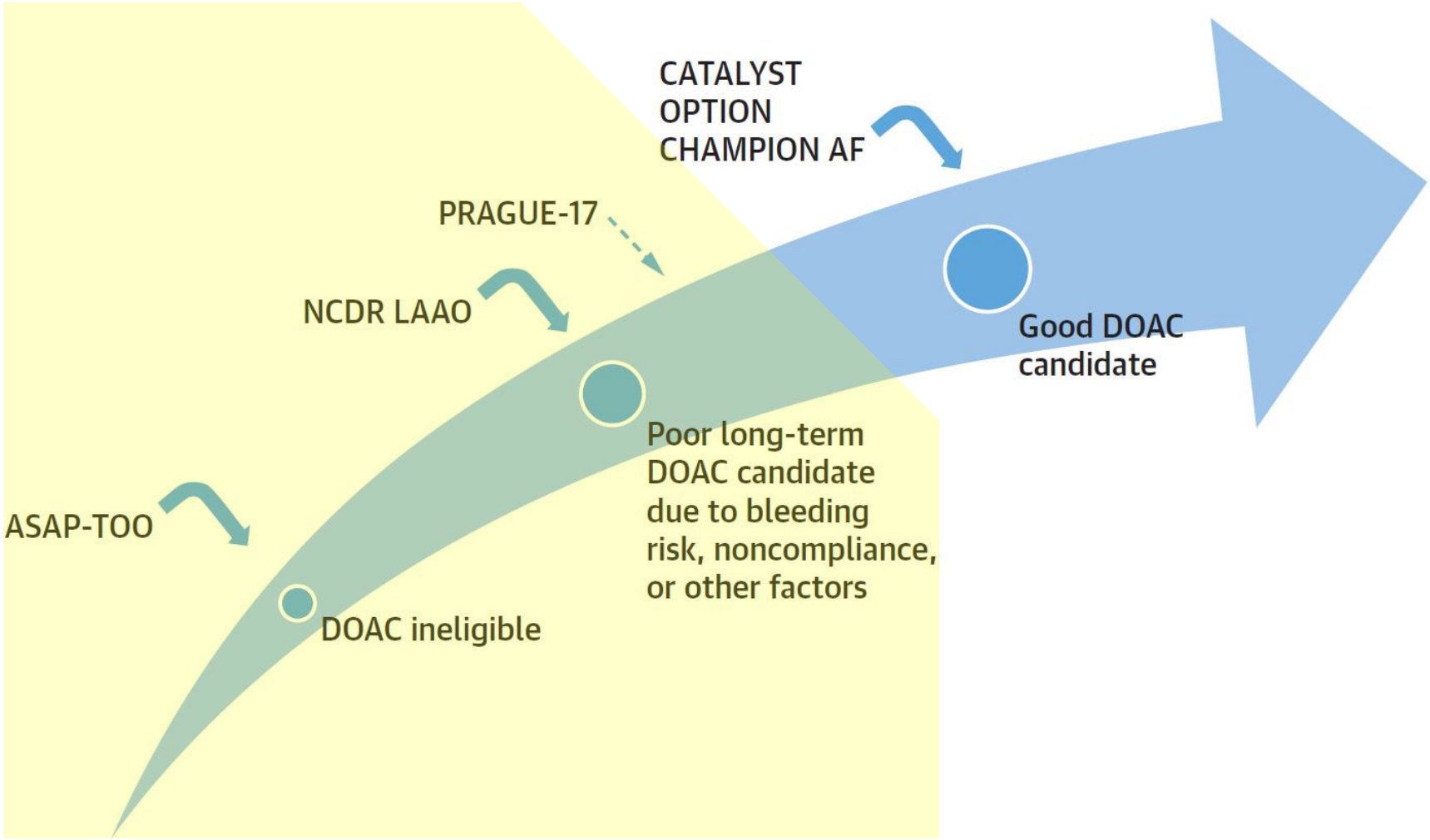
The PRAGUE-17: Seguimiento a 4 años

"NO INFERIORIDAD y MENOS SANGRADOS"



Osmancik et al. JACC 2022;79:1-14

¿Dónde estamos y haciendo donde vamos?



Price, et al. JACC 2020;75:3136-9

indice

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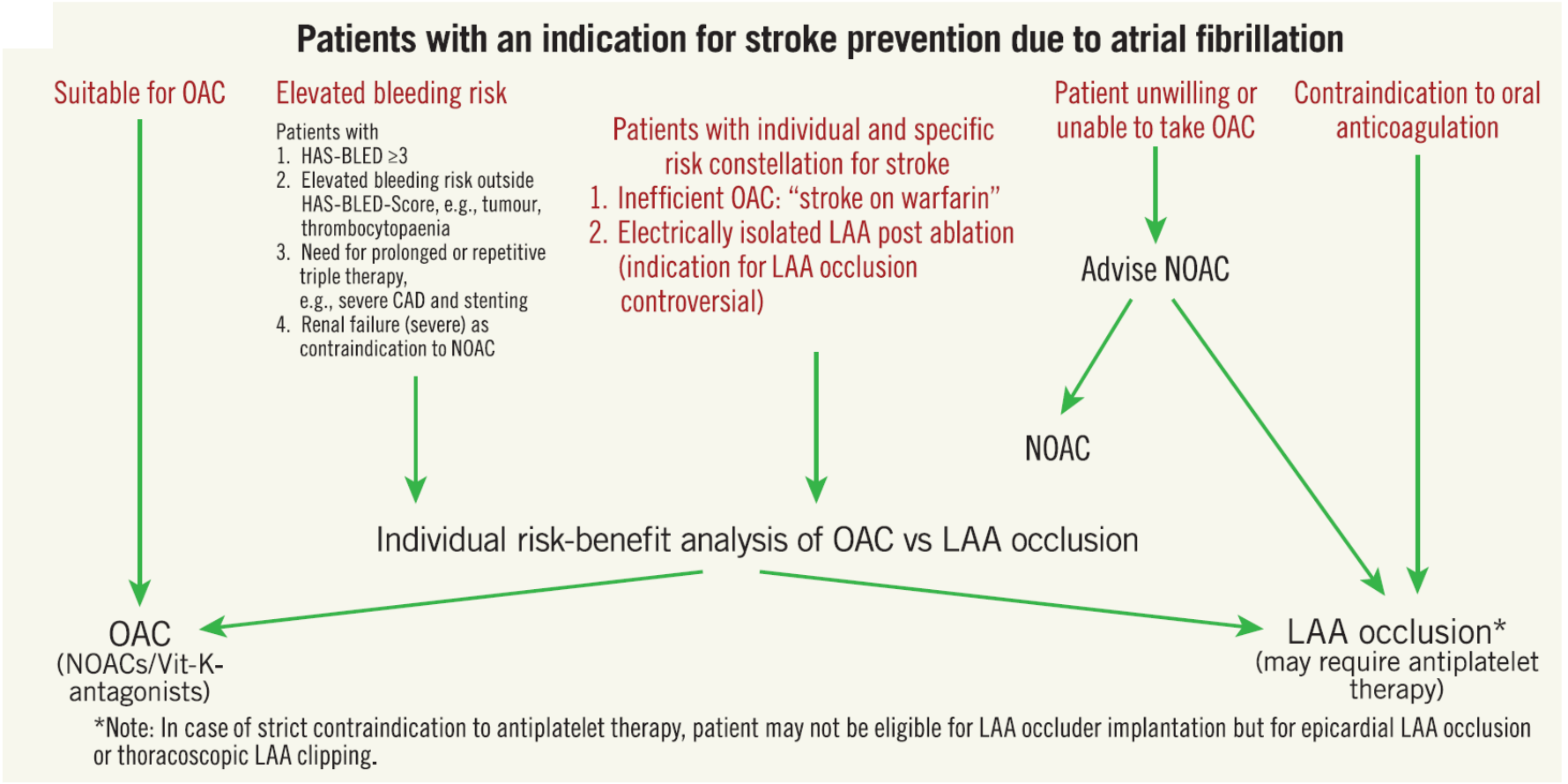
ESC European Society of Cardiology
Europace (2020) 22, 184
doi:10.1093/europace/euz258
EHRA POSITION PAPER

Arbol de decisión

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

Michael Glikson[1]*, Rafael Wolff[1], Gerhard Hindricks[2], John Mandrola[3], A. John Camm[4], Gregory Y.H. Lip[5,6], Laurent Fauchier[7], Tim R. Betts[8], Thorsten Lewalter[9,10], Jacqueline Saw[11], Apostolos Tzikas[12], Leonid Sternik[13], Fabian Nietlispach[14], Sergio Berti[15], Horst Sievert[16,17,18,19], Stefan Bertog[16], and Bernhard Meier[20]



Glikson et al. Europace. 2020;22:184

Contraindicación a la anticoagulación

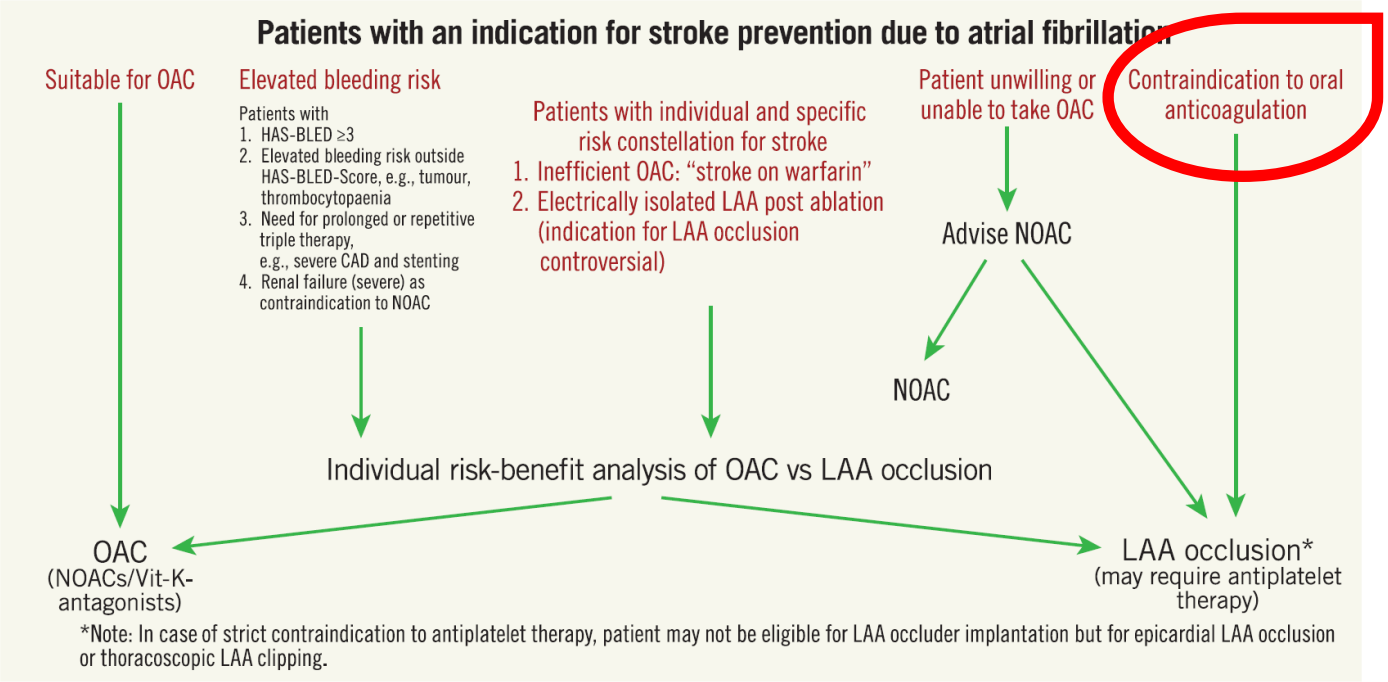


Table 15 **Atrial fibrillation patients who are not eligible ("contraindicated") for long-term oral anticoagulation and require prevention of stroke and embolism**

Clinical situation and therapeutic concept	Consensus statement	Icon
AF patients with CHA2DS2-VASc score ≥2 (3 in females) who have absolute contraindications for long-term OAC may be considered for LAAO if a minimum period (2-4 weeks) of a single antiaggregant can be given	"Should do this"	

Glikson et al. Europace. 2020;22:184

Alto riesgo hemorrágico

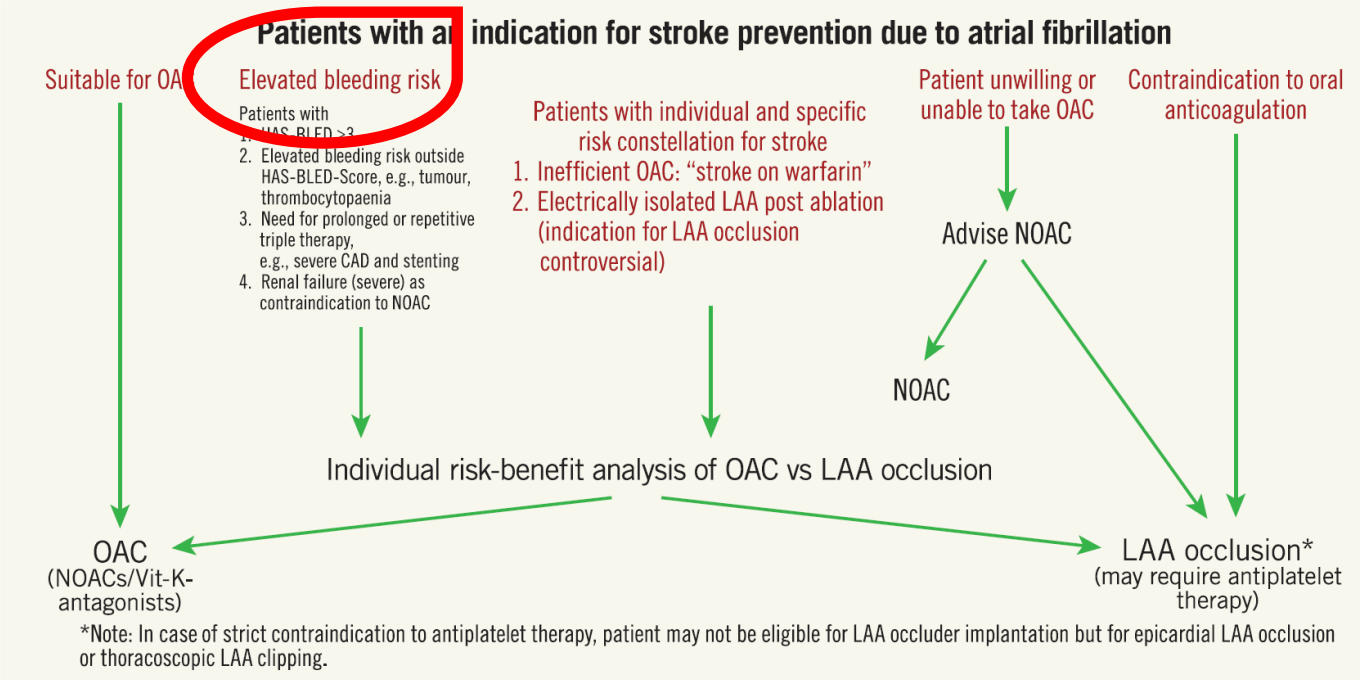


Table 16 Patients with an elevated bleeding risk during long-term oral anticoagulation

Clinical situation and therapeutic concept	Consensus statement	Icon
In patients with an elevated bleeding risk during long-term oral anticoagulation (e.g., post intracranial bleeding) an individual risk-benefit assessment needs to be carried out between oral anticoagulation and LAA occlusion	"Should do this"	
In patients with an elevated bleeding risk during long-term OAC, LAA occlusion may be considered	"May do this"	

Realidad en España

1,5-2 millones

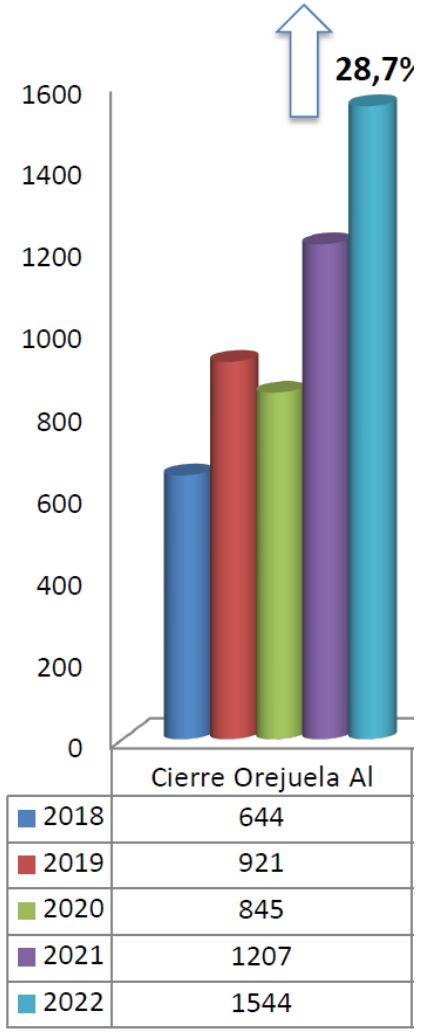
Pacientes con FA en España

200,000

No anticoagulados

1,544

Cierre de orejuela en España en 2022



	Cierre Orejuela Al
2018	644
2019	921
2020	845
2021	1207
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Conclusiones

1. El **cierre percutáneo de la orejuela** aporta una **eficacia similar** en reducción de eventros tromboembólicos a la anticoagulación en el paciente de alto riesgo hemorrágico.

2. El procedimiento es **seguro y reduce las complicaciones hemorrágicas** en el medio plazo.

3. Debemos plantear el cierre de orejuela a **todos** los pacientes con contraindicación a la ACO y a **muchos** con elevado riesgo de sangrado

Gracias