30° CONGRESO URUGUAYO DE CARDIOLOGÍA

SOLACI

ICR

Estado Actual del Cierre Percutáneo de la Orejuela Auricular Izquierda

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Introducción

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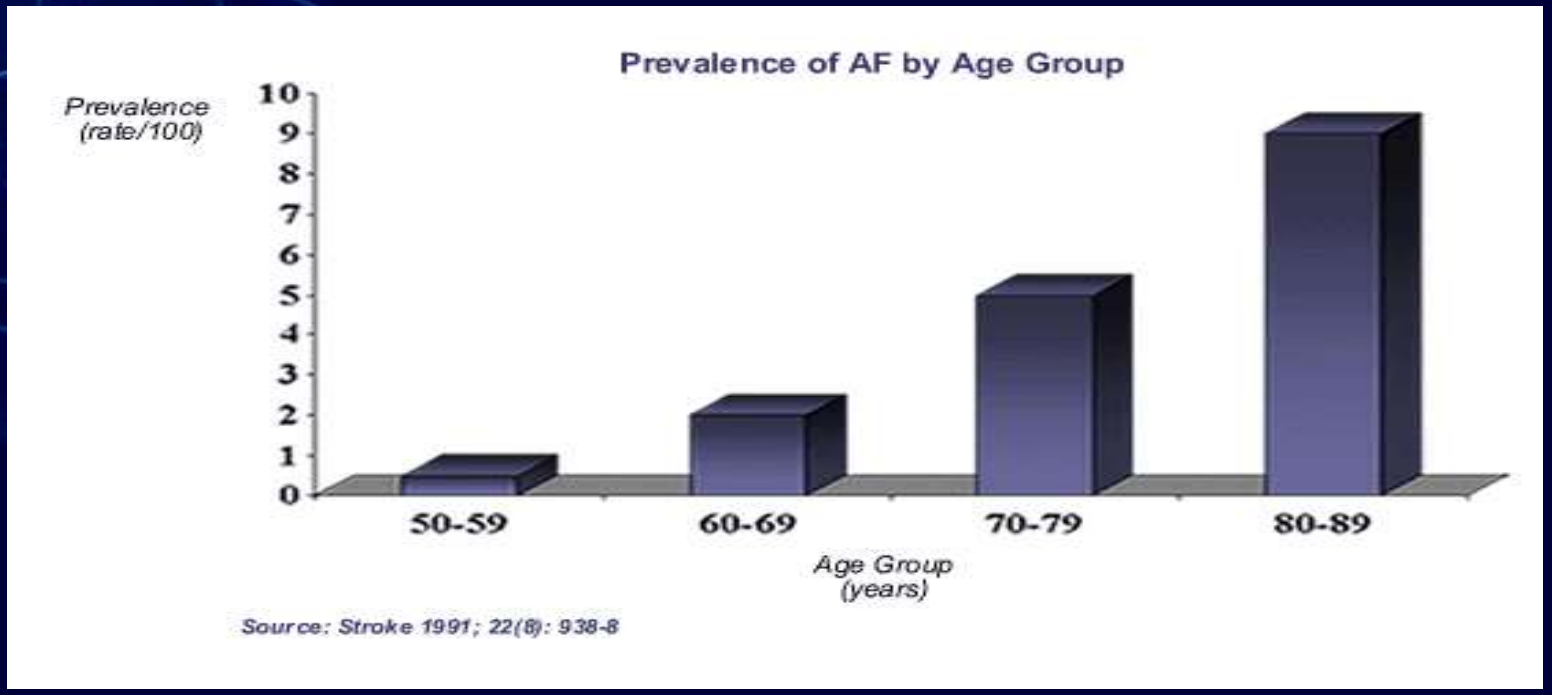
- La FA es la arritmia cardíaca más frecuente en la práctica clínica y es causa mayor de morbilidad y mortalidad debido a stroke cardioembólico.
- FA es responsable de 15-20% de los strokes isquémicos (Fuster et al, Circ 2006)
- La incidencia de FA se incrementa con la edad.



Introducción: Stroke relacionado a FA

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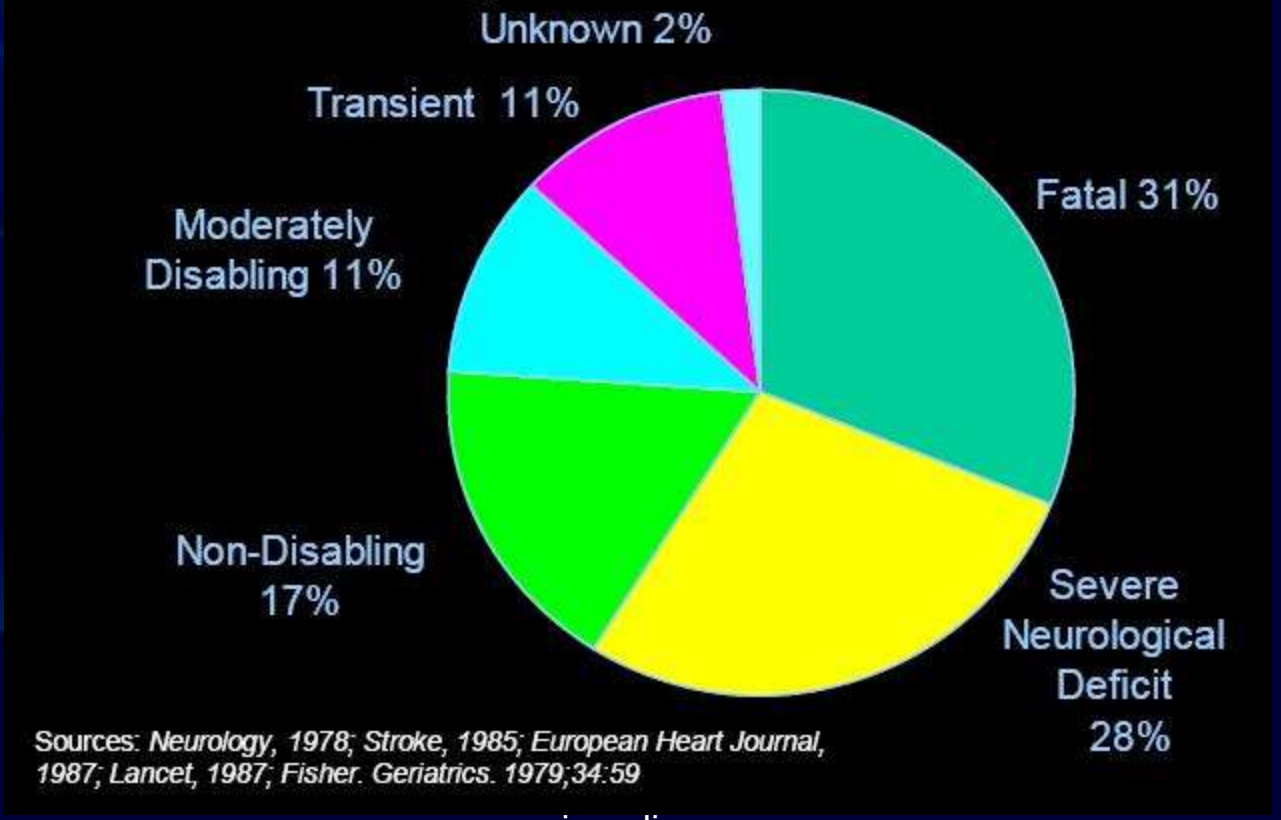
- 500,000 strokes per year
- 15 – 20% of strokes/year are related to AF
- Functional Impact of AF-Related Stroke:



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

Introducción

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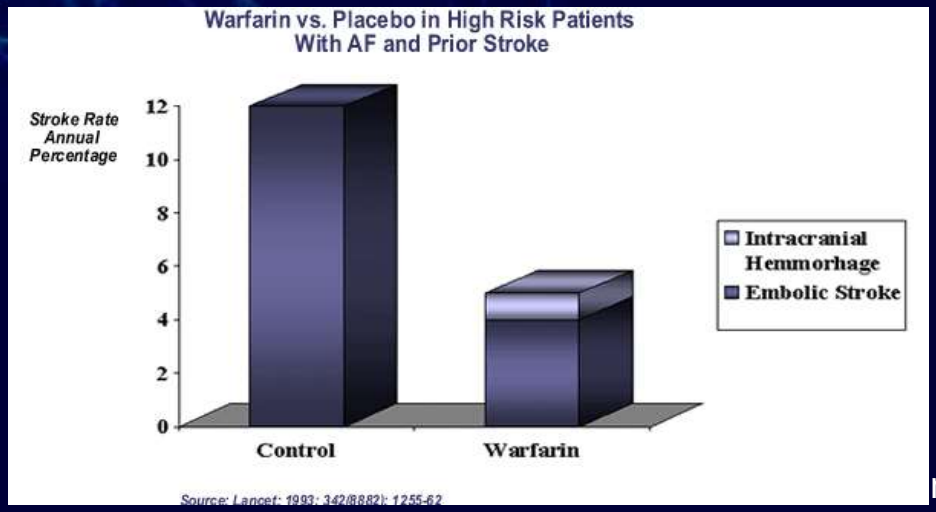
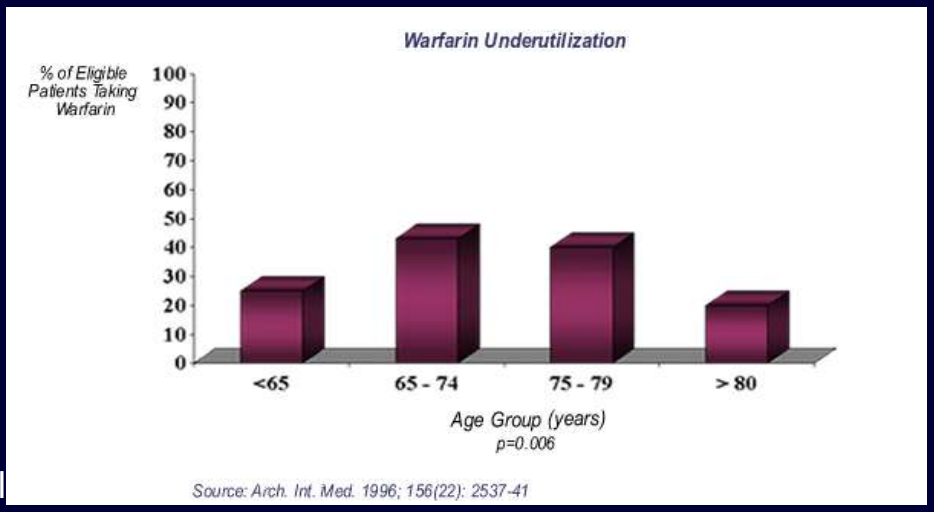
- Los ACO son actualmente el método más efectivo de prevención del stroke en pacientes con FA permanente, pero:
  1) Rango terapéutico estrecho – Interacciones con otros fármacos
  2) Insuficientemente controlados en alto % de pacientes
  3) Subutilizados
  4) Frecuentemente contraindicados
- A pesar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





Registro RENAFA

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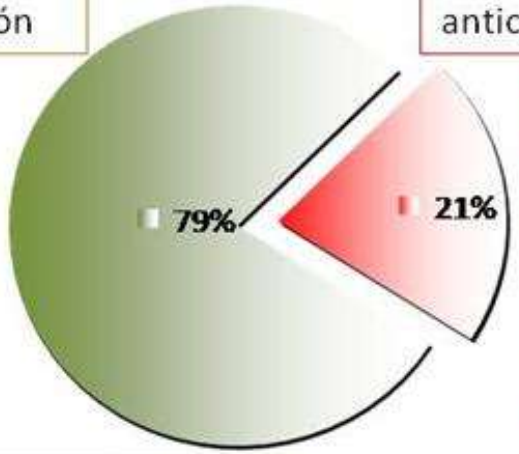
Resultados. Estrategia tratamiento ACO

Sin contraindicaciones para anticoagulación

67.9% recibían anticoagulación



Alguna contraindicación para anticoagulación, a criterio del investigador*

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

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

*Nota: de estos, 65.4% recibían antiagregantes

Di Tommaso F, y col; SAC 2011

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Which patients benefit optimally from LAA Occlusion

3.8 Million patients with AF[1], in Europe[1]

75% are at High Risk of Stroke[2]

50% are insufficiently treated[3]

15% contraindicated for Warfarin[4]

3% severe bleeding complications. Cannot take warfarin or alternatives[5]

Europe : European Union + Western Balkan, Norway, Switzerland

1. 2.3 million patients suffer from AF in the US, 4 million in EU - Fuster et al, ACC/AHA/ESC Practice Guidelines, Circulation. 2006;114:700-752.
2. 75% of patients are at high level of stroke (Euroheart survey, Birmingham/NICE score. CHADS2 = 73% high & intermediate), Lip et al., CHEST Feb 2010 vol. 137 no. 2 263-272
3. Anticoagulant is not used (not prescribed and/or not taken), up to 60% of pts Gladstone et al, Stroke, 2009; 40:235-240
4. The prevalence of contraindications is around 15% of clinical AF patients. Nieuwlaat R. et al. Euroheart Survey, European Heart Journal (2005) 26, 2422–2434
5. Major bleeding rate 3.36%/yr in warfarin group, 2.71%/year - 110 mg of Dabigatran and 3.11%/year - 150 mg of Dabigatran. Connolly, N Engl J Medicine 2009; DOI:10.1056/NEJMoa0905561

Patient Population per Country

(per 2010)	Population (million)	AF patients (x 1000)	Pts at High Risk for Stroke	Pts. NOT on Anticoagulation	Contraindicated Anticoagulation	Bleeding Complications (from total)	Bleeding complications (from treated)
US	311	2315	1736	868	260	52.1	26.0
Australia	22.6	168	126	63	19	3.8	1.9
Canada	34.4	256	192	96	29	5.8	2.9
Japan	128	953	715	357	107	21.4	10.7
EUROPE	508	3783	2837	1418	426	85	43
Austria	8.4	63	47	23	7	1.4	0.7
Belgium	10.8	80	60	30	9	1.8	0.9
Czech Republic	10.5	78	59	29	9	1.8	0.9
Denmark	5.6	42	31	16	5	0.9	0.5
Finland	5.3	39	30	15	4	0.9	0.4
France	65.8	490	367	184	55	11.0	5.5
Germany	81.8	609	457	228	68	13.7	6.8
Greece	11.3	84	63	32	9	1.9	0.9
Italy	60.6	451	338	169	51	10.1	5.1
Ireland	4.5	33	25	13	4	0.8	0.4
Netherlands	16.6	124	93	46	14	2.8	1.4
Norway	5.0	37	28	14	4	0.8	0.4
Poland	38.1	284	213	106	32	6.4	3.2
Portugal	10.6	79	59	30	9	1.8	0.9
Spain	46.2	344	258	129	39	7.7	3.9
Sweden	9.4	70	52	26	8	1.6	0.8
Switzerland	7.8	58	44	22	7	1.3	0.7
UK	62.0	461	346	173	52	10.4	5.2
West Balkan	20.9	156	117	58	18	3.5	1.8
Other	27	201	151	75	23	4.5	2.3
Percentage	Baseline	7443 pts.million-1	75%	50%	15%	3%	3%
Reference		1	2	3	4	5	5

1. 2.3 million patients suffer from AF in the US, 4 million in EU - Fuster et al, ACC/AHA/ESC Practice Guidelines, Circulation. 2006;114:700-752.
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Dabigatran as substitute for warfarin?

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- The Good News for Dabigatran (Pradaxa)
  - Reduced the annualized risk stroke/peripheral embolic events, by 34% ($p<0.001$)
  - Reduced risk of hemorrhagic stroke by 74% ($p<0.001$) compared with warfarin.
  - Patients don't require any form of monitoring
- The Not All Good News
  - Although the primary safety outcome is statistically significant better, in clinical practice Dabigatran may not prove better than warfarin. Patients still have bleeding complications.
  - At 1 year, in the RE-LY trial, 15% of pts were off Dabigatran vs. 10% for warfarin: GI Symptoms, Bleeding and Adverse Events
  - Reimbursement: patients have to pay up to €10 per day (> € 3500 Euro per year)

	Condition	Dabigatran 220mg		Dabigatran 300mg		Warfarin	
Primary Study Outcome	Stroke/ systemic embolism /year	1.53%	182 pts	1.11%	134pts	1.69%	199pts
Primary Safety Outcome	Major Haemorrhage/yr	2.71%	322pts	3.11%	375pts	3.36%	397pts
	Life threatening/yr	1.22%	145pts	1.45%	175pts	1.80%	212pts
	Non life threatening/yr	1.66%	198pts	1.88%	226pts	1.76%	208pts
	Gastro intestinal /yr	1.12%	133pts	1.51%	182pts	1.02%	120pts
	Intracranial Bleeding	0.23%	27pts	0.30%	36pts	0.74%	87pts
	Extracranial Bleeding	2.51%	299pts	2.84%	342pts	2.67%	315pts

1 Connolly, et al., RE-LY Dabigatran versus warfarin in patients with atrial fibrillation. N Engl J Medicine 2009; DOI:10.1056.NEJM0a0905561

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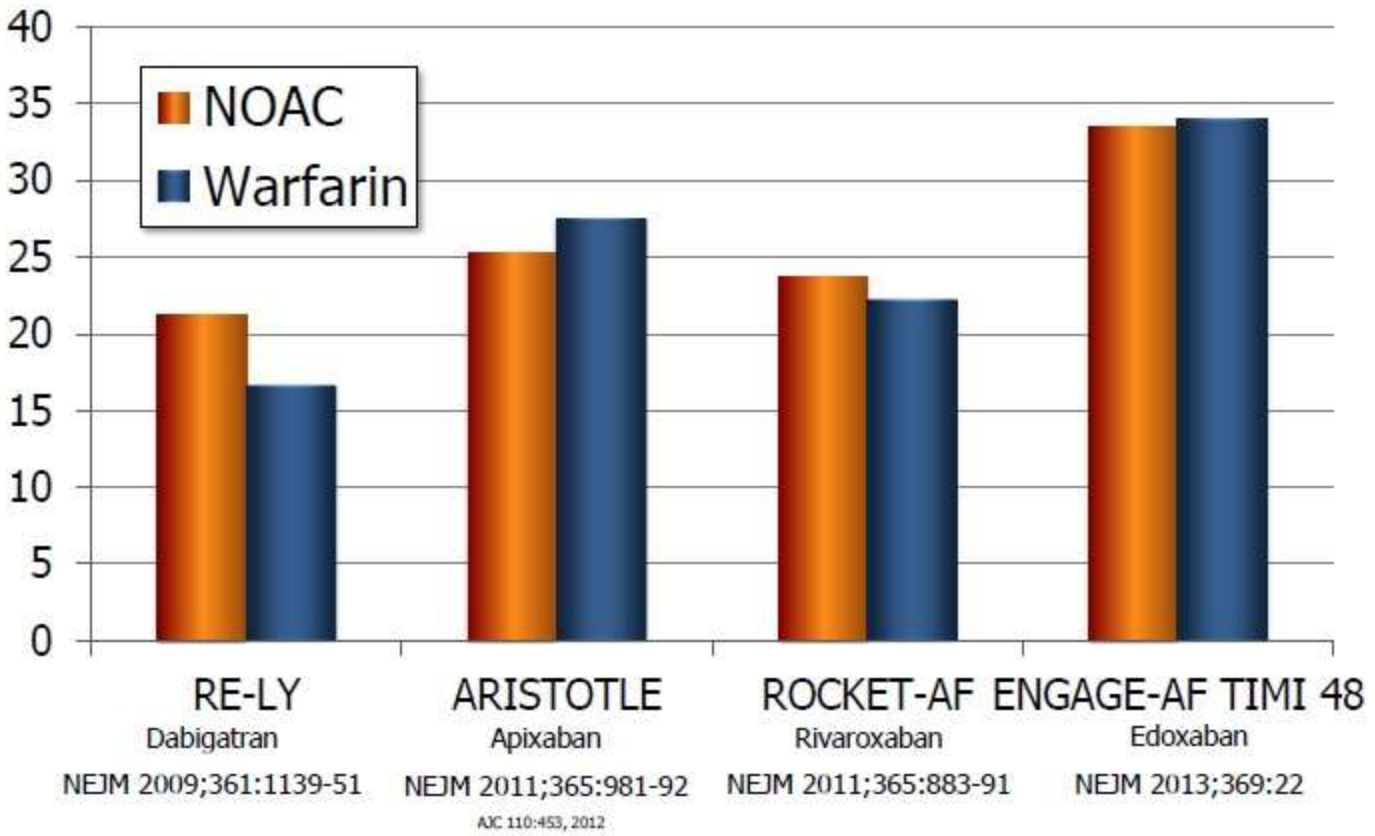
Oral Anticoagulants
DISCONTINUATION RATES



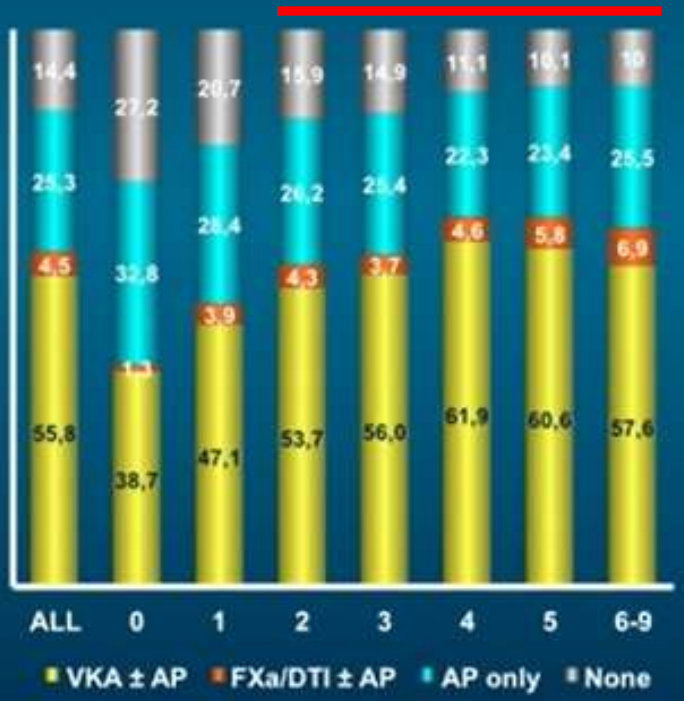
GARFIELD

Global Anticoagulant Registry in the FIELD

Antithrombotic Treatment according to CHA_2DS_2-VASc Score in GARFIELD Cohort 1 and 2

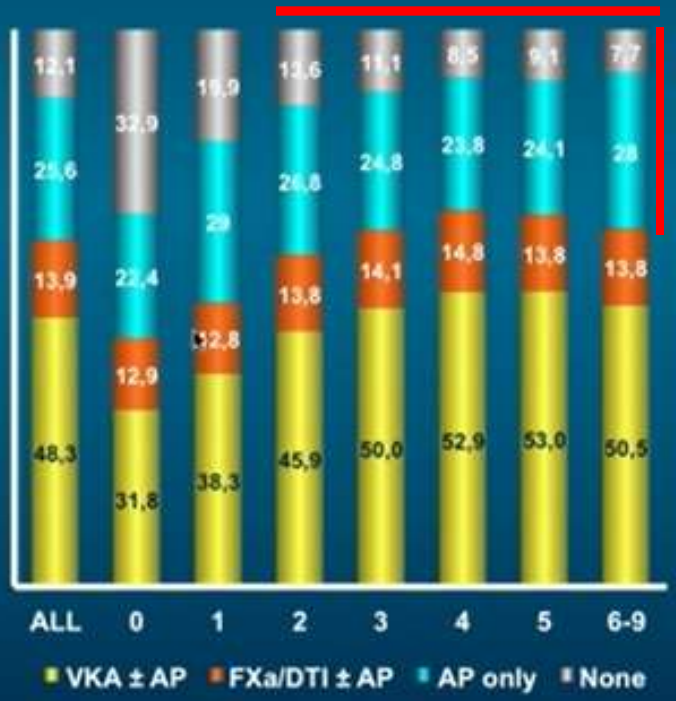
COHORT 1

December 2009 – October 2011 (n=10,614)



COHORT 2

October 2011 – May 2013 (Preliminary, n=10,544)

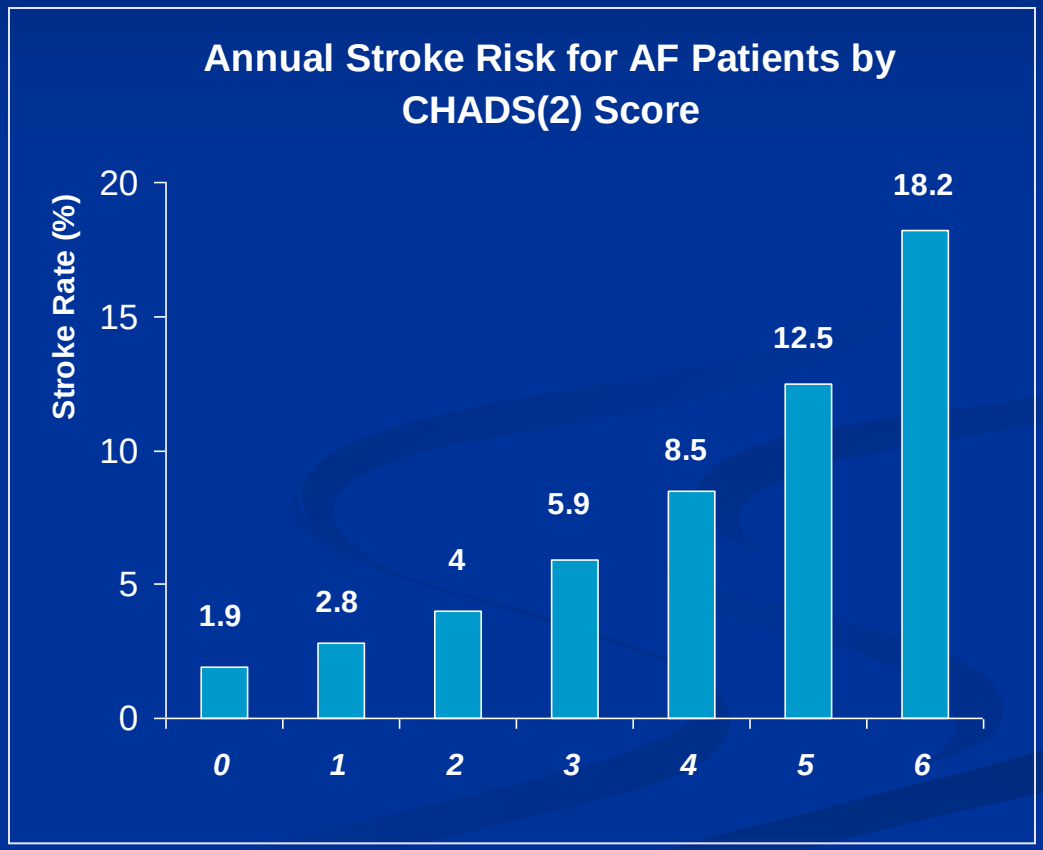


AP=antiplatelet; DTI=direct thrombin inhibitor; FXa=factor Xa inhibitor.

Haas, S. ESC 2013

Stroke risk stratification of AF patients: The $CHADS_2$ score

$CHADS_2$ Score	$CHADS_2$
Congestive heart failure	+1
Hypertension	+1
Age 75>	+1
Diabetes Mellitus	+1
Stroke or History of Cerebral Ischemia	+2



Gage, et al., Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA 2001; 285: 2864-2870

Stroke Risk Assessment: CHA_2DS_2-VASc score

Letter	Risk factor	Points awarded
C	- Congestive heart failure/LV dysfunction	1
H	- Hypertension	1
A	- Age >75	2
D	- Diabetes mellitus	1
S	- Stroke/TIA/thrombo-embolism	2
V	- Vascular disease	1
A	- Age 65–74	1
Sc	- Sex-category (i.e. female sex)	1
	Maximum score	9

Camm, et al., ESC 2010 Guidelines for the management of Atrial Fibrillation; European Heart Journal doi:10.1093/eurheartj/ehq278

Adjusted stroke rate according to CHA_2DS_2-VASc score

CHA_2DS_2-VASc score	Patients (*n* = 7329)	Adjusted stroke rate (%/year)
0	1	0.0%
1	422	1.3%
2	1230	2.2%
3	1730	3.2%
4	1718	4.0%
5	1159	6.7%
6	679	9.8%
7	294	9.6%
8	82	6.7%
9	14	15.2%

Lip, et al., Identifying patients at risk of stroke despite anticoagulation. Stroke 2010;in press.

Risk assessment 1 yr bleeding
HAS-BLED score

Letter	Clinical characteristic	Points awarded
H	- Hypertension (systolic blood pressure > 160 mmHg)	1
A	- Abnormal renal & liver function (1 point each)	1 or 2
S	- Stroke	1
B	- Bleeding	1
L	- Labile INRs	1
E	- Elderly (age > 65 yrs)	1
D	- Drugs or alcohol (1 point each)	1 or 2
	Maximum	9 points

Lip, et al., Refining clinical risk stratification for predicting stroke and thromboembolism in AF using a novel risk factor-based approach: the Euro Heart Survey on atrial fibrillation. Chest 2010;137:263–272.

Efecto de múltiples antitrombóticos sobre el riesgo de sangrado

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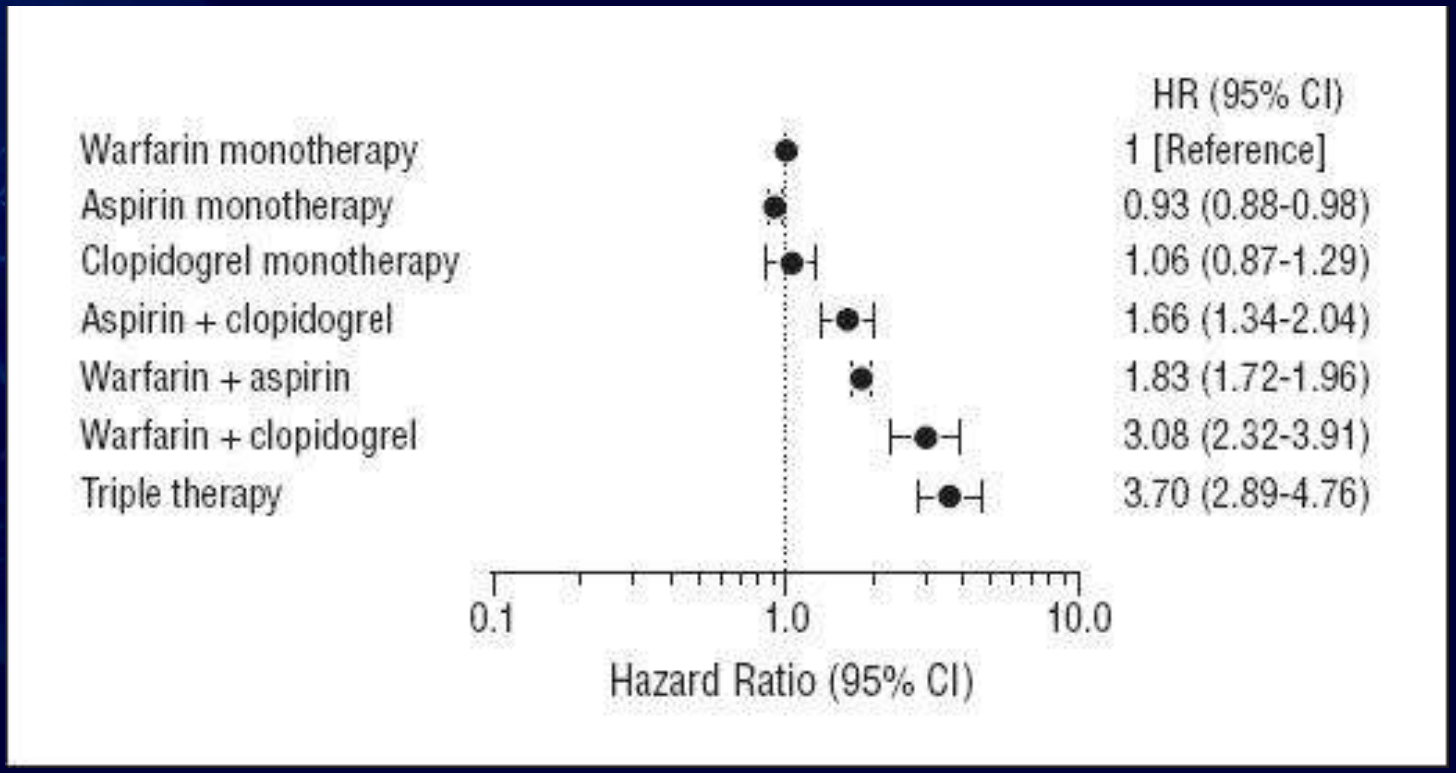
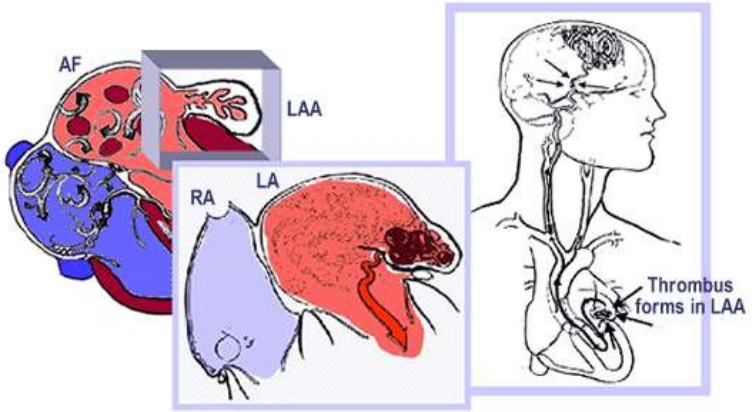
Estudio de cohorte de 82854 pac en Dinamarca (13573 presentaron sangrado fatal o no fatal en el seguimiento a 2,6 años)



Hansen M et al. Arch Intern Med 2010

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



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)

90% de los trombos localizaron en orejuela auricular izquierda

Onalan O; Stroke 2007

Options for Stroke Prevention

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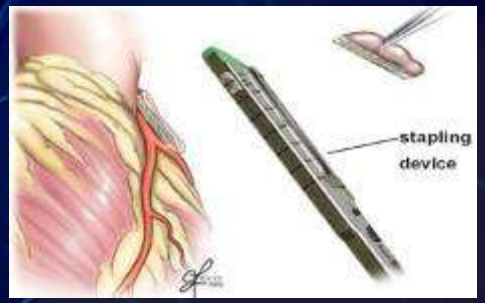
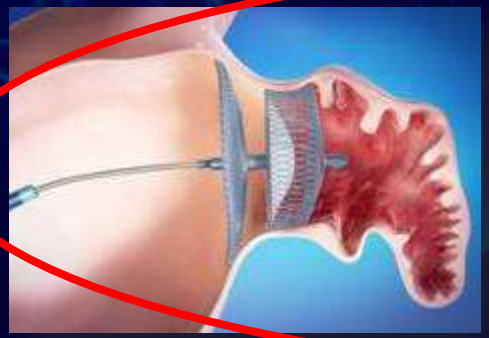
- Pharmacological Management: Anticoagulants[1]
  - Effective: 67% stroke risk reduction
  - Management of narrow therapeutic window
  - Major complication: bleeding



- 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 10 (2010) 306–311

Cierre de orejuela auricular izquierda - Dispositivos

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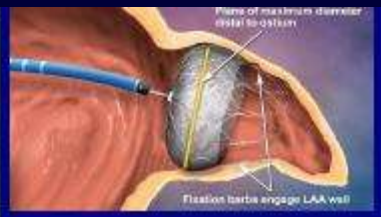
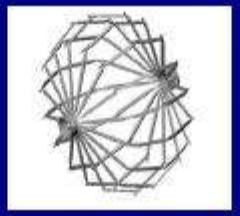
WATCHMAN



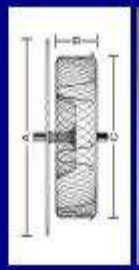
½-Rugbyball type

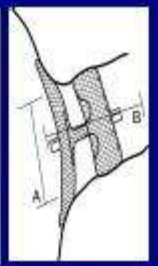
PLAATO



Soccerball type

ACP





Puck&Disc type

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

Resultados de los Estudios Clínicos

Journal of the American College of Cardiology
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ISSN 0735-1097/05/$30.00
doi:10.1016/j.jacc.2005.03.042

CLINICAL RESEARCH **Clinical Trials**

Percutaneous Left Atrial Appendage Transcatheter Occlusion (PLAATO System) to Prevent Stroke in High-Risk Patients With Non-Rheumatic Atrial Fibrillation

Results From the International Multi-Center Feasibility Trials

Stefan H. Ostermayer, MD,* Mark Reisman, MD, FACC,† Paul H. Kramer, MD, FACC,‡ Ray V. Matthews, MD, FACC,§ William A. Gray, MD, FACC,† Peter C. Block, MD, FACC,‖ Heyder Omran, MD,¶ Antonio L. Bartorelli, MD, FACC,# Paolo Della Bella, MD,# Carlo Di Mario, MD, FACC,** Carlo Pappone, MD,†† Paul N. Casale, MD, FACC,‡‡ Jeffrey W. Moses, MD, FACC,§§ Athena Poppas, MD, FACC,‖‖ David O. Williams, MD, FACC,‖‖ Bernhard Meier, MD, FACC,¶¶ Allan Skanes, MD,## Paul S. Teirstein, MD, FACC,*** Michael D. Lesh, MD,††† Toshiko Nakai, MD,††† Yves Bayard,* Kai Billinger, MD,* Thomas Trepels, MD,* Ulrike Krumsdorf, MD,* Horst Sievert, MD, FACC*

Frankfurt and Bonn, Germany; Seattle, Washington; Shawnee Mission, Kansas; Los Angeles, La Jolla, and San Francisco, California; Atlanta, Georgia; Milan, Italy; London, United Kingdom; Lancaster, Pennsylvania; New York, New York; Providence, Rhode Island; Bern, Switzerland; and London, Ontario, Canada

- Implante exitoso → 108 / 111 (97%)
- Tiempo de procedimiento → 68 minutos
- Tiempo de fluoroscopía → 18 ± 9 minutos
- Complicaciones :
  - Mortalidad → 1 (0.9%)
  - ACV → 0
  - T. Cardíaco → 3 (2.7%)
  - Vasculares → 3

Ostermayer S; JACC 2005

PLAATO - Resultados

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Results: Stroke risk reduction

Mean $CHADS_2$ score	2.5
Expected annual risk of stroke	5.5%
Strokes after PLAATO™ procedure (n)	2
Annual stroke rate in PLAATO™ patients	2.2%
Risk reduction by PLAATO™	**60%**

Ostermayer S; JACC 2005

Watchman™ Clinical Program

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

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

03.17.2014

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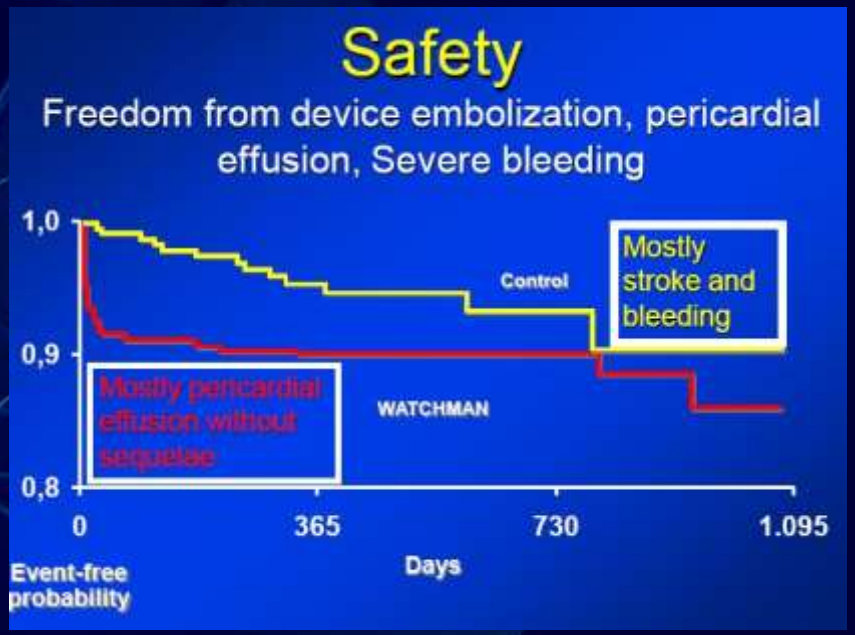
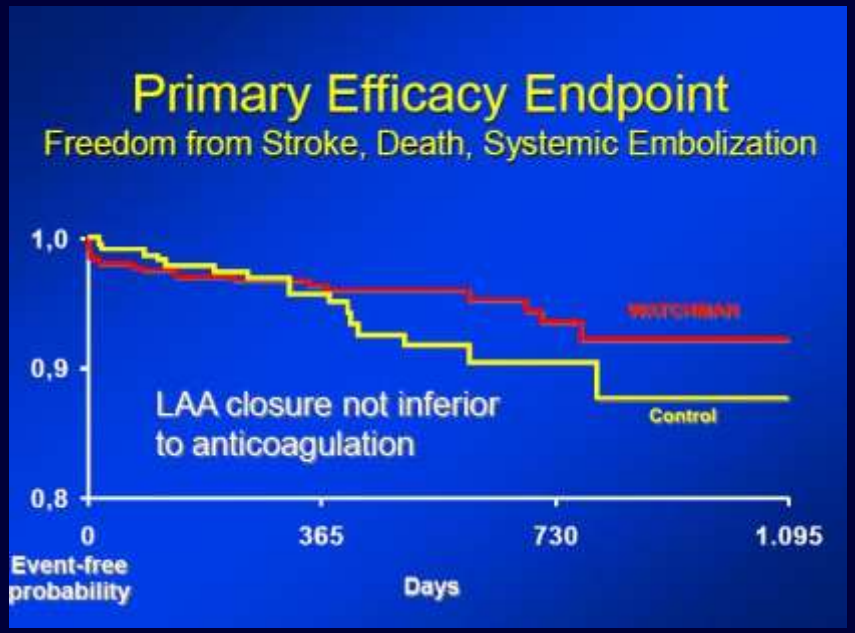
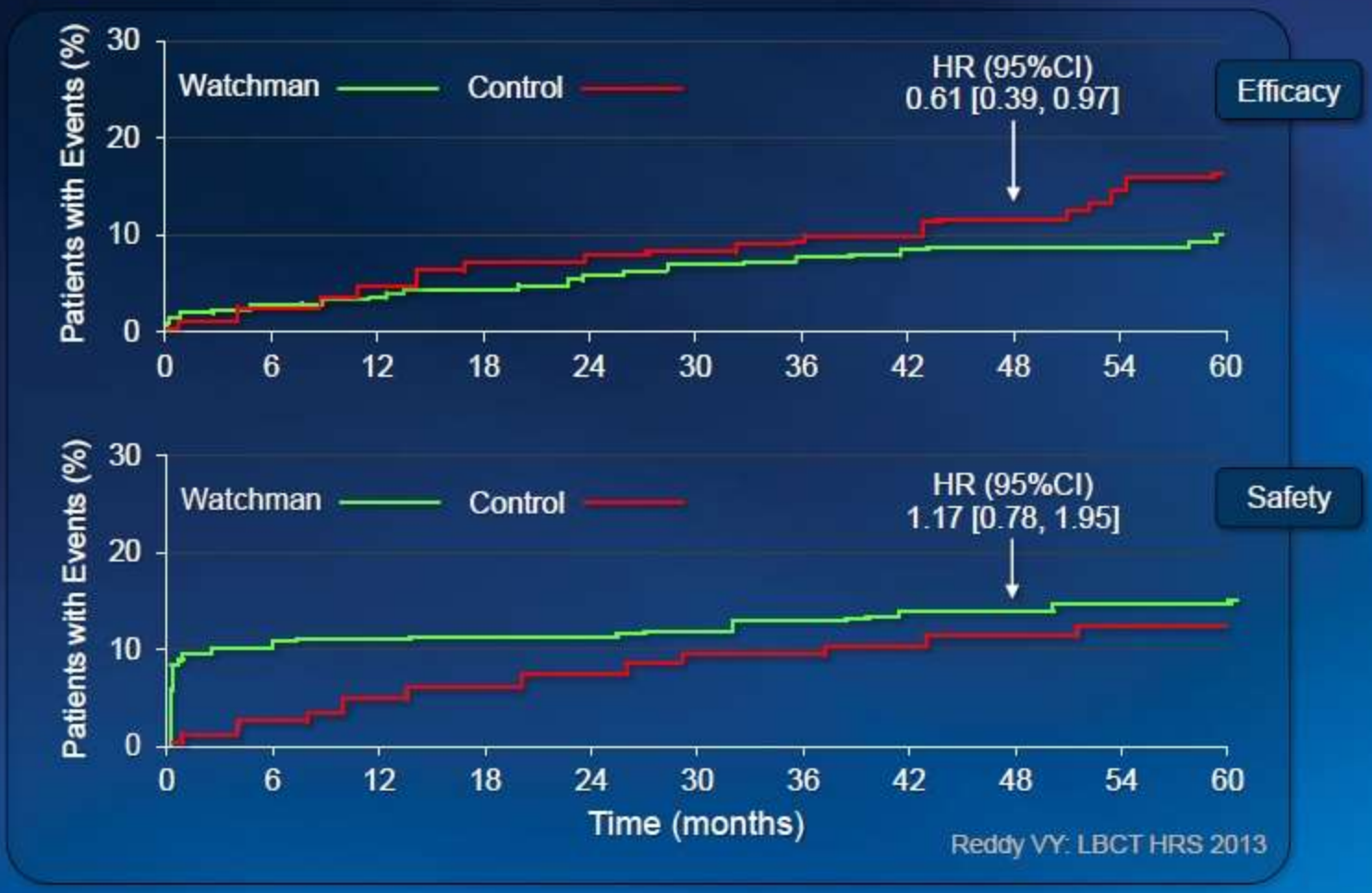
PROTECT - AF





Holmes D; Lancet 2009

Watchman™
PROTECT AF 4-Year Data



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

The PREVAIL Trial

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

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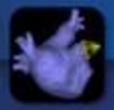
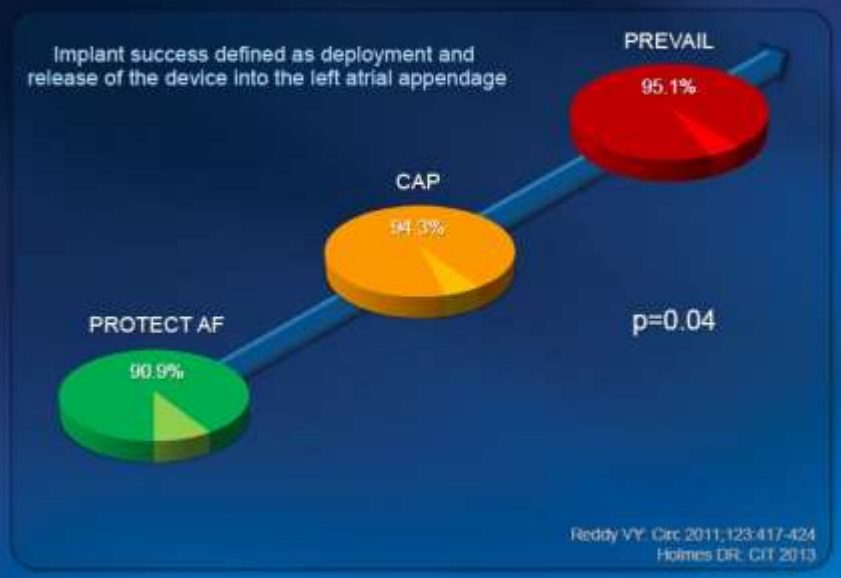
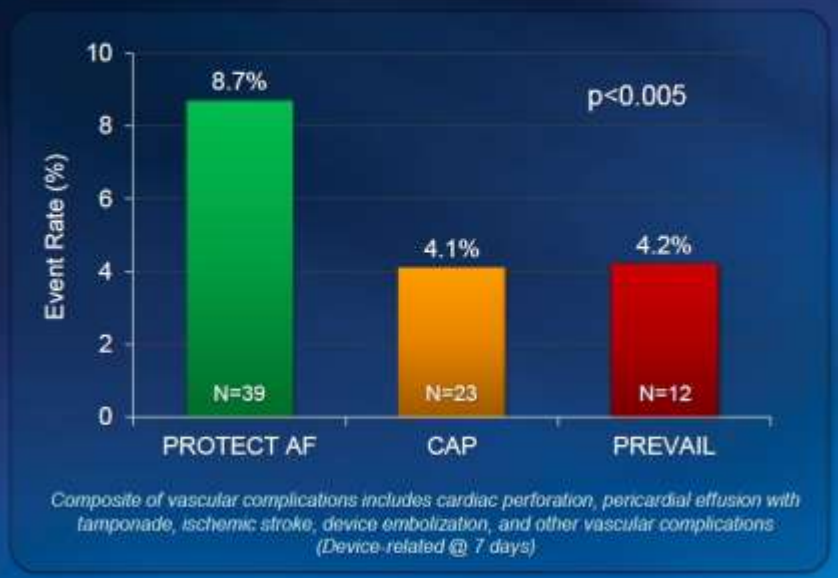
Watchman™ Implant Success



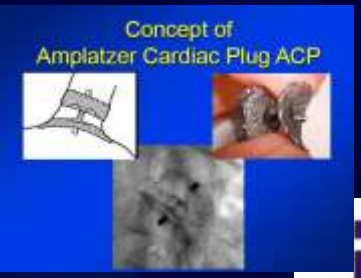


Watchman™ Procedure Related Complications

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



Holmes D; JACC 2014;64:1-12



Dispositivo - ACP

euro PCR

Learning curve confirmed

	Initial European Registry[1]	EU Post Market Observational Study
Number of patients (Follow-up period)	N = 143 (Discharge or < 24 hrs)	N = 204 (< 7 days)
Enrollment Period	December 2008 – December 2009	August 2009 – September 2011
Stroke	N = 3 (2.1%)	N = 0 (0.0%)
Serious Pericardial Effusion	N = 5 (3.5%)	N = 3 (1.5%)
Device Embolization	N = 2 (1.4%)	N = 3 (1.5%)
Device Related Thrombus	N= 0 (0.0%)	N = 0 (0.0%)
Total reported Safety Events	**N = 10 (7%)**	**N = 6 (2.9%)**

[1]Park, J.-W. et al. (2011), Left atrial appendage closure with Amplatzer Cardiac Plug in Atrial Fibrillation: Initial European experience. Catheterization and Cardiovascular Interventions, 77: 700–706. doi: 10.1002/ccd.22764

CL06181 Rev2

Dispositivo - ACP

ICR

euro PCR

Stroke Risk

	Total Patients	Total Patient years	$CHADS_2$ Score	Estimated Stroke Rate per $CHADS_2$	Actual annual stroke rate (number of events)
ACP EU Observational	204	101 yrs	2.6	5.6%*	1.98% (N=2)

- Patients had an expected annual stroke risk of 5.6%
- With 101 patient years the actual stroke rate was 1.98%
- 65% reduction in stroke risk from estimated stroke rate

1. Wann LS, Curtis AB, Ellenbogen K a, et al. 2011 ACCF/AHA/HRS focused updates incorporated into the ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidel. *Circulation*. 2011;123(10):e269-367.

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

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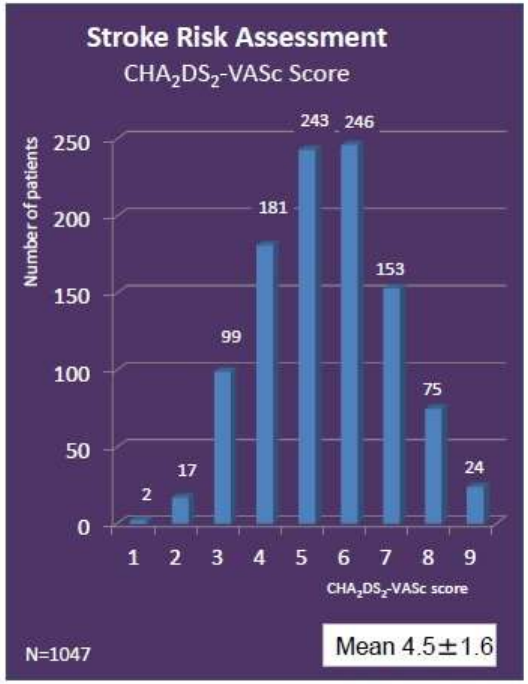
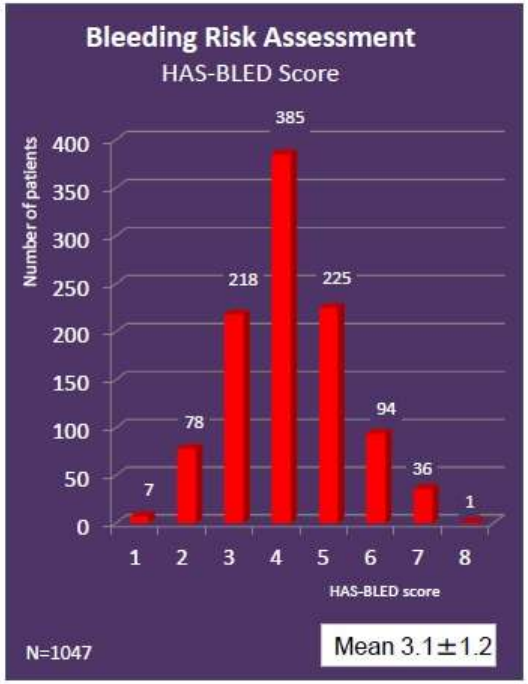
Risk assessment





$CHADS_2$ Score=2.8±1.3

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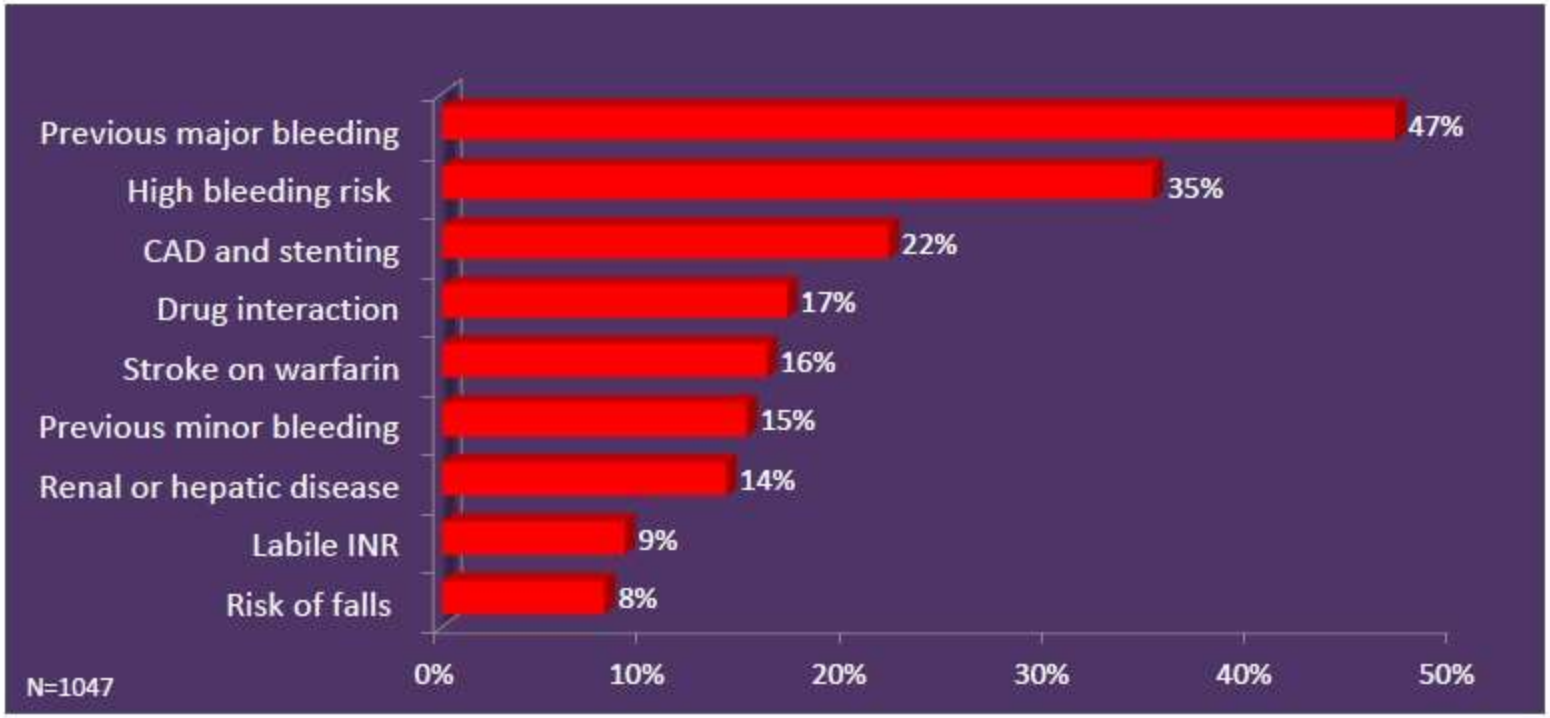
Indications for LAAO



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

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Implant Results

Success rates

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

Implanted ACP size

N=1047

Median (IQ range): 24 (22-26) mm

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%**

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*

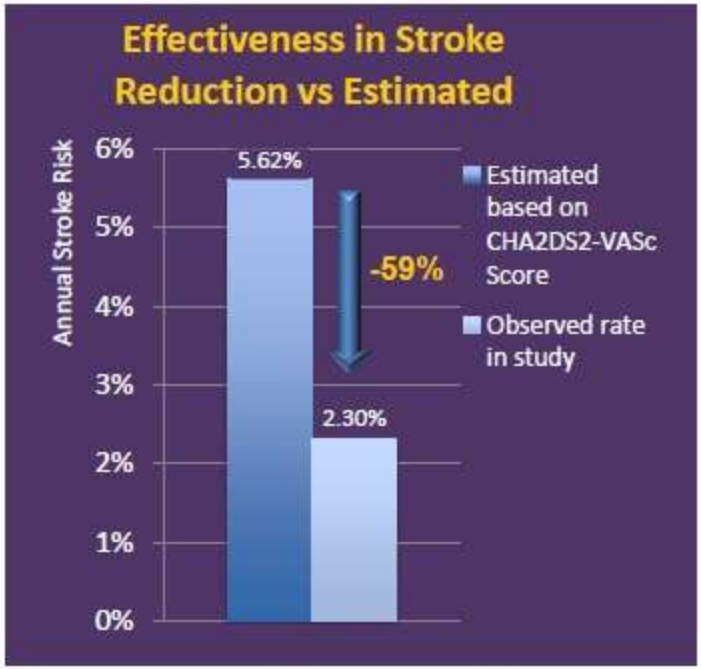
MEA	N	%
Death	8	0.76%
Pericardial tamponade	13	1.24%
Major bleeding	13	1.24%
Stroke	9	0.86%
Device embolization	1	0.10%
MI	1	0.10%
Total	**45**	**4.30%**

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

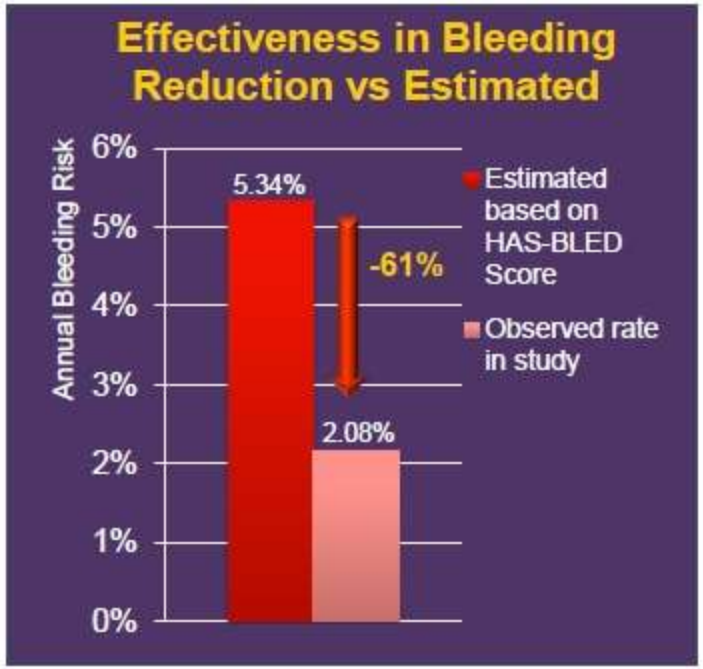
* Holmes et al. ACC 2013 (PREVAIL Study)

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)

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ACP: Resumen de Registros Recientes

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EFFICACY	Belgium[1] N=90	Canada[2] N=52	European prospective[3] N=203 6 mths	European prospective[4] N=47 2 years	Chun[5] N=40	Multicenter[6] N=969
Patient years	93	99	101	80.6	40	1216
$CHADS_2$ Score	-	3	2.6	-	-	
CHA_2DS_2Vasc Score	4.4	5	-	3.7	4.5±1.8	4.41
Estimated annual stroke/TIA rate	5.1%	6.7%	5.6%	5.33%	>4.2%	5.62%
Actual annual stroke/TIA rate	2.1%	2.1%	2%	1.24%	0%	2.06%
Risk reduction	**58%**	**68%**	**65%**	**78%**	**100%**	**63%**

1..Kefer, J. et al. (2013)) EuroPCR: May 24th Paris France.
2..Urena M, et al. (2013). J Am Coll Cardiol. Jul 9;62(2):96-102
3.Walsh, K. (2012) . Presented at EuroPCR. Paris May 17th.France
4.Sievert, H. et al (2013). Presented at ESC 2013 1st Sept: Amsterdam
5 Chun J. et al (2013). Heart Rhythm. 2013 Aug 22. [Epub ahead of print]
6 Tzikas,.TCT, San Francisco, October 2013

tct2014

Columbia University Medical Center
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"Percutaneous closure of the left atrial appendage: Initial Experience in Latin America"
Coauthors and Participating Hospitals

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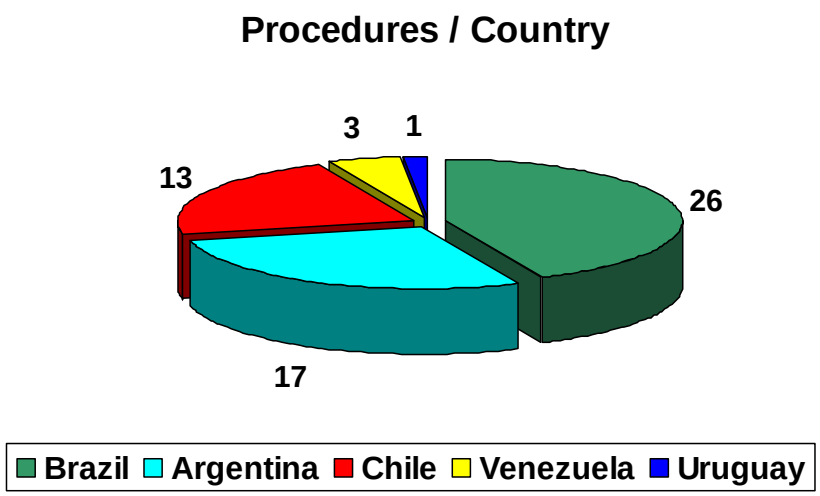
Results

N=60, June 2012



Results

• Age	72 ± 8,7
• Male	70 %
• HTA	78 %
• DBT	17 %
• CHF	32,17 %
• Contraindic. ACO	64,29 %
• **CHADS2 score**	3,15 ± 1,12

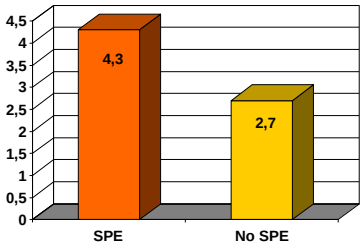
In Hospital and FU Results

Successfull Implant	60	(100%)
Simultaneous PFO Closure	3	(5%)

- In hospital Complications:

5 patients (8,3%)
1 embolization (retrieved surgically)
4 severe pericardial effussions – pericardiocentesis (6,6%)
No death, stroke or myocardial ischaemia.

Duration of Hospitalization with and w/out SPE



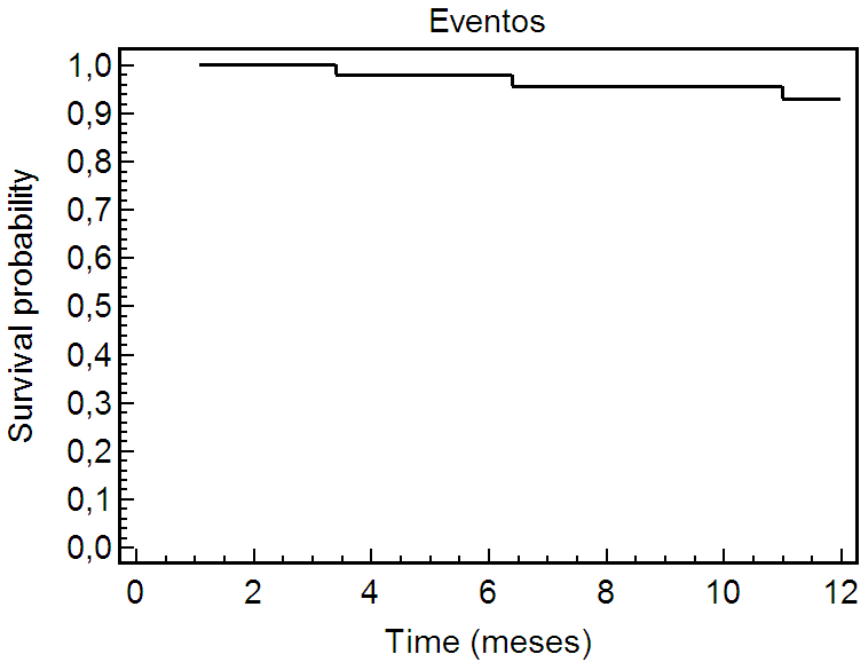
- Patients were discharged on DAT.
- No new events were reported at 30 days clinical follow up. 88% of patients underwent TEE at 30-45 days without evidence of flow to the LAA or thrombus on device.

Results

	Protect AF[1] N= 463	Protect AF(early)[1] N=271	ACPIn.Eu.Ex[2] N= 143	ACP LatAm N= 60
Successfull implant (%)	90.9	88.2	96.4	100
Severe peric. effussion (%)	5.0	6.3	3.5	6.6
Emboliztion of device (%)	0.2	N/A	1.4	1.6
Stroke/TIA (%)	0.9	1.1	2.1	0
Major complic. (%)	7.7	10	7.0	8.3

[1]*Reddy V, et al. Circ 2011;123:417-424* [2]*Park J, et al. CCI 2011;77:701-706*

Results at Follow Up



- Mean CHADS2 score 3,15
- Expected annual risk of stroke 5,9%
- Strokes at F/Up (Me 12,5 months) 0

Amplatzer Cardiac Plug en LatAm

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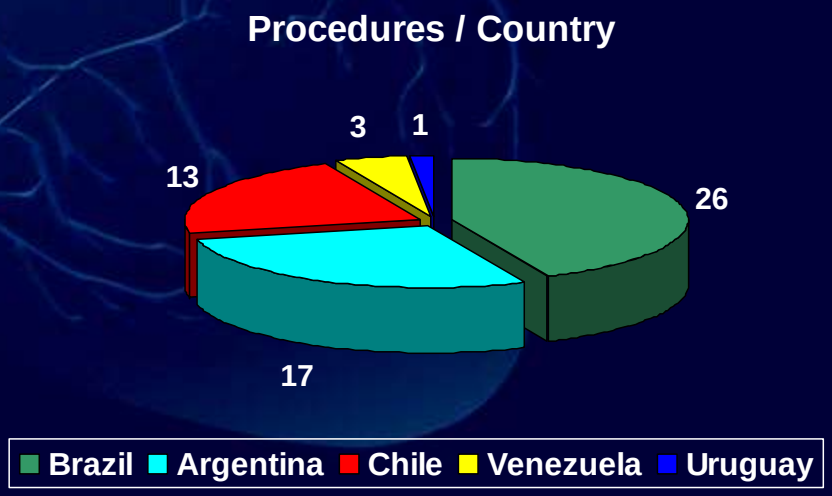
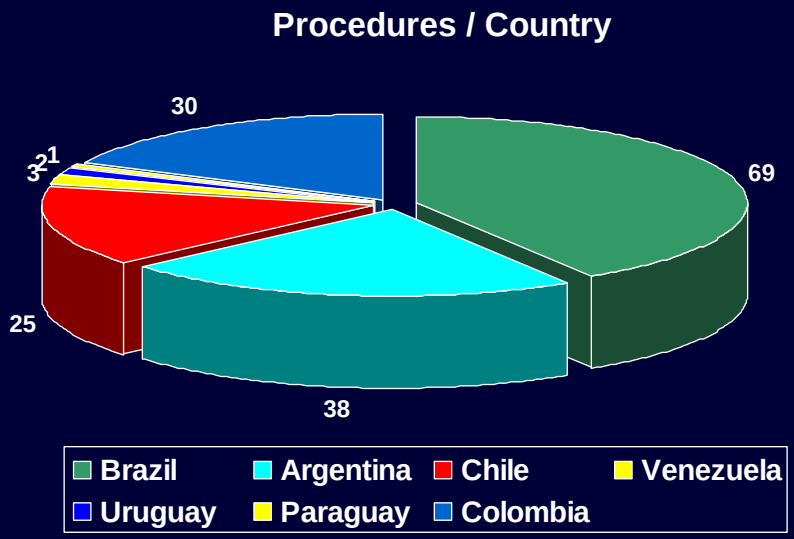
N=60, June 2012



N= 168, June 2014



Guidelines - NICE

Guidance

- Current evidence suggests that percutaneous occlusion of the left atrial appendage (LAA) is efficacious in reducing the risk of thromboembolic complications associated with non-valvular atrial fibrillation.
  - With regard to safety, there is a risk of life-threatening complications from the procedure, but the incidence of these is low.
  - Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.
- Patient selection should be carried out by a multidisciplinary team including a cardiologist and other appropriate clinicians experienced in the management of patients with AF at risk of stroke.
  - Patients should be considered for alternative treatments to reduce the risk of thromboembolism associated with AF, and should be informed about these alternatives.
- Percutaneous occlusion of the LAA is a technically challenging procedure which should only be carried out by clinicians with specific training and appropriate experience in the procedure.
- Procedure should be carried out only in units with on-site cardiac surgery.

National Institute for Health and Clinical Excellence, UK. Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism. Issue date: June 2010, Interventional procedure guidance 349

European Heart Journal
doi:10.1093/eurheartj/ehs253

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

Recommendations for LAA closure/occlusion/excision

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

Europace (2013) 15, 652–656
doi:10.1093/europace/eus043

REVIEW

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]*

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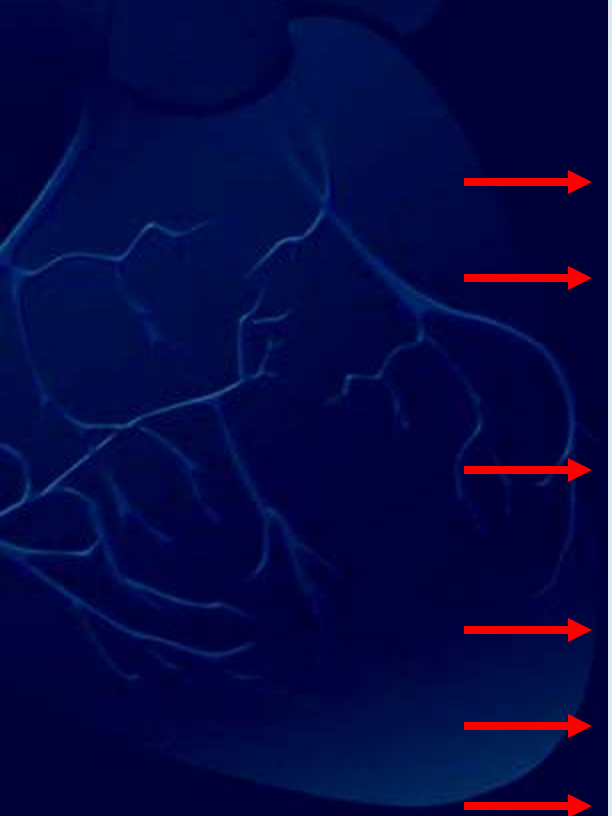

Table 4 Conditions in which percutaneous LAA occlusion may be considered

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

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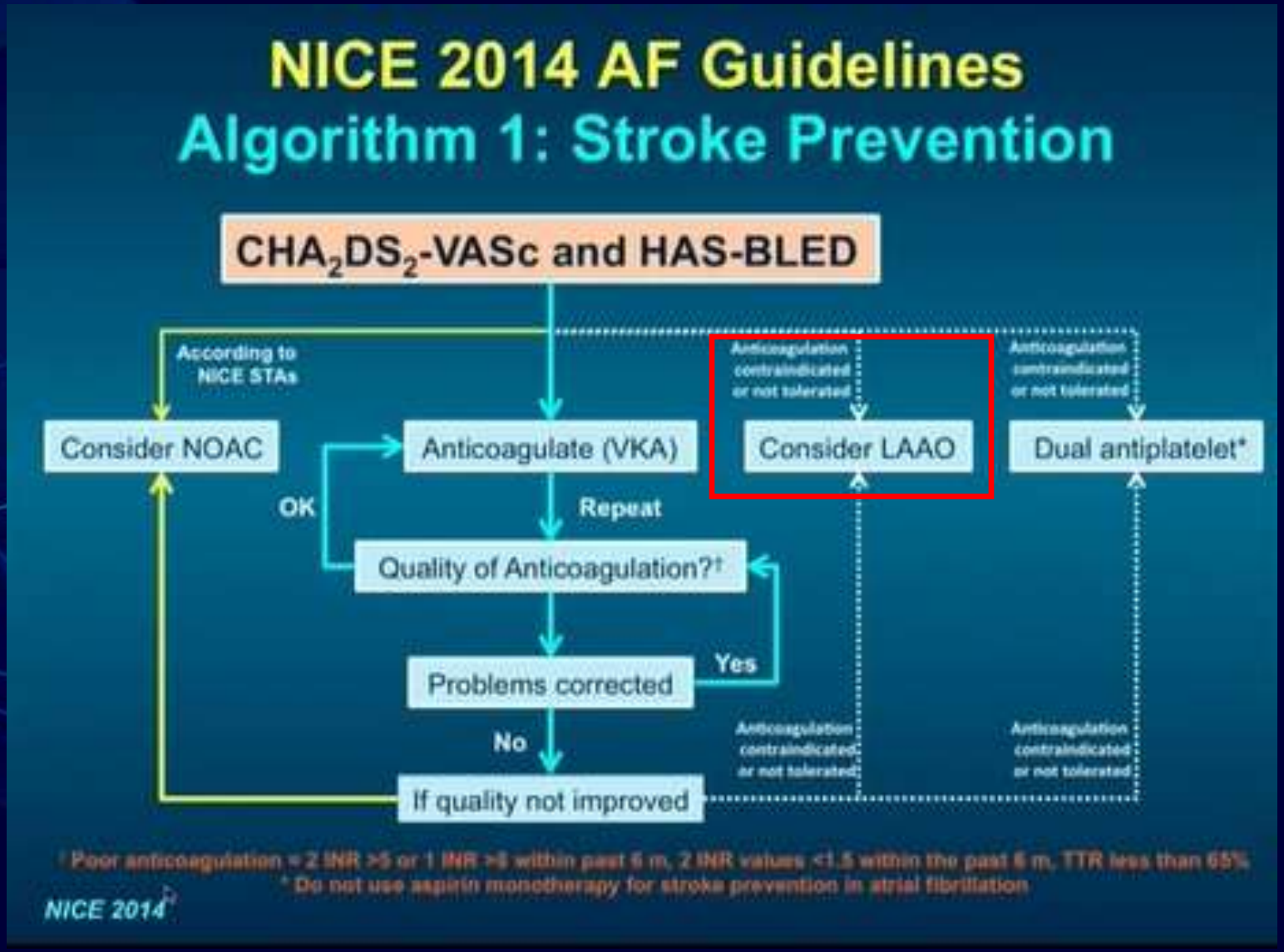
NICE 2014 AF Guidelines
Algorithm 1: Stroke Prevention



Conclusiones

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• 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 estudios demostraron consistentemente la factibilidad del procedimiento con alta tasa de implante exitoso en pacientes con contraindicación para ACO , con reducción significativa en la tasa de strokes en el seguimiento en relación a lo esperado por scores.

• Datos de los estudios randomizados PROTECT AF y PREVAIL demuestran que en pacientes sin contraindicación para ACO, la oclusión de la orejuela no es inferior a warfarina en la prevención del stroke. Resultados que se mantienen a 4 años de seguimiento.

• Existen complicaciones tempranas inherentes al procedimiento y a la curva de aprendizaje. La seguridad del procedimiento y el éxito del implante aumentan con la experiencia.

• Constituye una alternativa aceptable en pacientes con FA no valvular, con scores de alto riesgo para stroke y contraindicaciones o dificultad para la ACO.

Gracias!!

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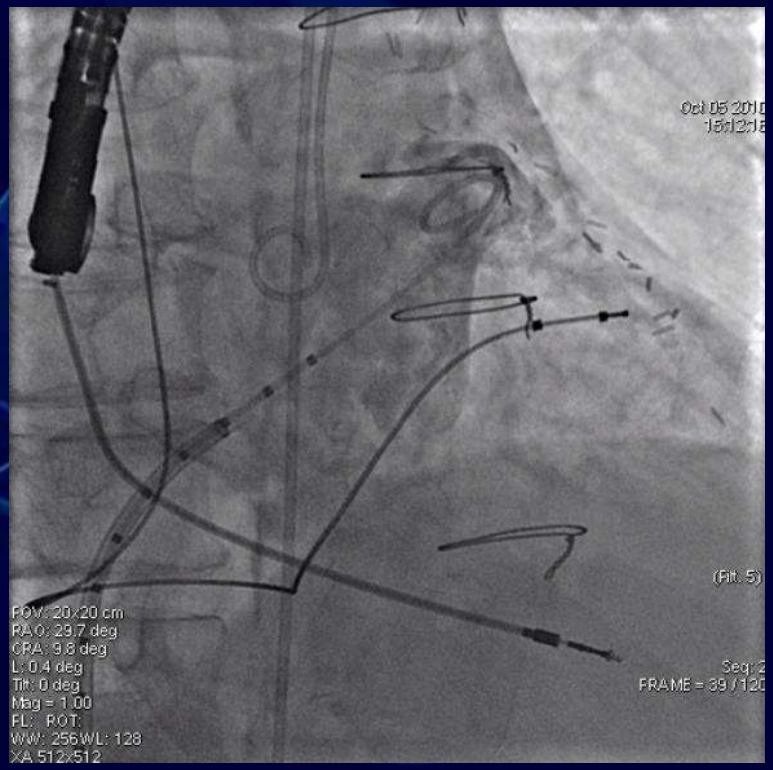
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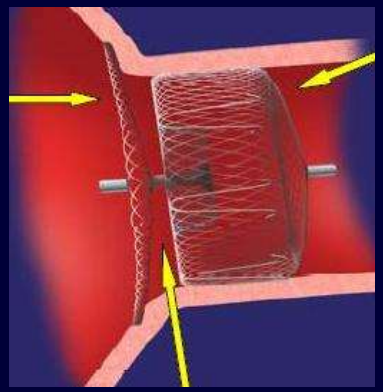
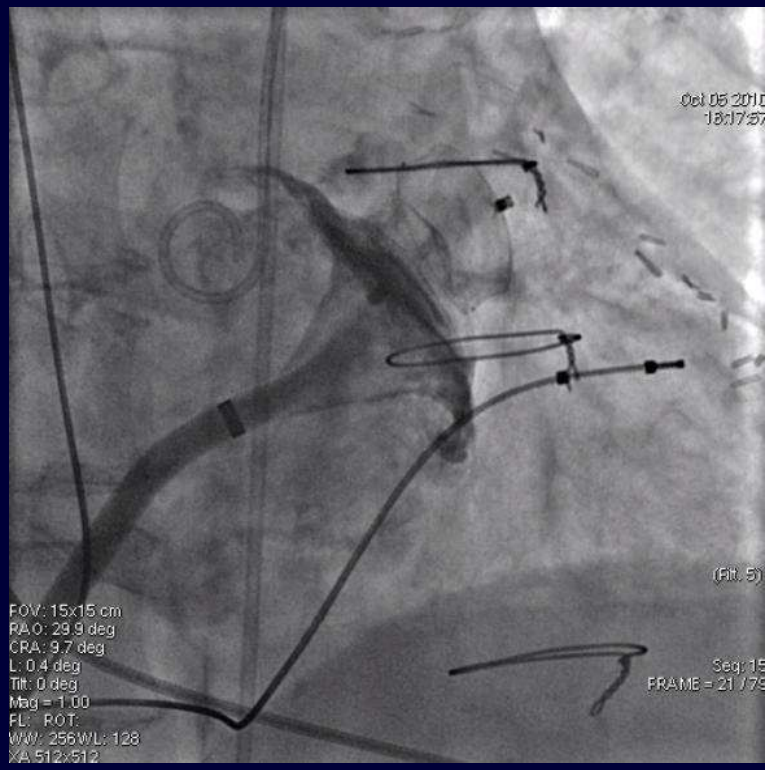
CRA: 9.8 deg
L: 0.4 deg
Tilt: 0 deg
Mag = 1.00
FL: ROT:
WW: 256 WL: 128
XA 512x512

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CRA: 9.7 deg
L: 0.4 deg
Tilt: 0 deg
Mag = 1.00
FL: ROT:
WW: 256 WL: 128
XA 512x512

ICR

"Percutaneous closure of the Left Atrial Appendage: Initial experience in Latin America"

Aníbal Damonte1, Costantino Costantini2, Carlos Pedra3, Alejandro Martinez4, Daniel Aguirre5, Fabio Brito6, Jose Condado7, Fernando Cura8, Leon Valdivieso9, Leandro Lasave1
Instituto Cardiovascular de Rosario, Rosario, Argentina1; Hospital Cardiologico Costantini, Curitiba, Brasil2; Instituto Dante Pazzanese, Sao Paulo, Brasil3; Universidad Catolica, Santiago, Chile4; Clinica Alemana, Santiago, Chile5; Hospital Albert Einstein, Sao Paulo, Brasil6; Hospital Perez Carreño, Caracas, Venezuela7; ICBA, Buenos Aires, Argentina8; Fundación Favaloro, Buenos Aires, Argentina9. **We DO NOT have any conflict of interest in the context of this abstract presentation**

Background:

Atrial fibrillation (AF) is the most common cardiac arrhytmia and a major cause of morbidity and mortality secondary to cardioembolic stroke.
In patients with non valvular AF 90% of intracacavitary thrombi form in the left atrial appendage (LAA).
Percutaneous closure of the LAA has emerged as a potential alternative to anticoagulation therapy for the prevention of cerebrovascular events in patients with AF and a contraindication or difficulties for oral anticoagulation

Objectives:

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,Minneapols,MN) in an initial Latin American experience.

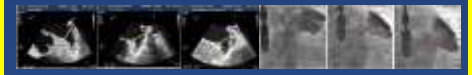
Methods:

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 anesthesya, transesophageal ecocardiography (TEE) and fluoroscopic guidance.
Clinical and TEE follow up was performed at 30 days, and clinical follow up thereafter.

Results:

Age	72 ± 8,7
Male	70 %
HTA	78 %
DBT	17 %
CHF	32,17 %
Previous Stroke/TIA	44,4 %
Contraindic. ACO	64,29 %
CHADS2 score	**3,15 ± 1,12**

LAA neck (TEE)	20,3 ± 3,8 mm
LAA neck (Angio)	22,6 ± 3,2 mm

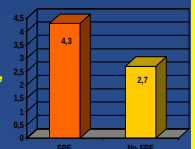


LAA Orifice (TEE)	21,4 ± 4,3 mm
LAA Orifice (Angio)	24,2 ± 4,6 mm
LAA 1 lobe	32 (53,3%)
LAA 2+ lobes	28 (46,7%)
Trans septal	57 (95%)
Vía PFO	3 (5%)
Selected ACP device	**25 ± 2,9 mm**

Successfull Implant	60 (100%)
Simultaneous PFO Closure	3 (5%)

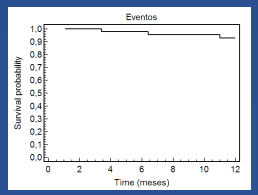
In hospital Complications:

5 patients (8,3%)
1 embolization (retrieved surgically)
4 (6,6%) severe pericardial effussions (SPE)
Hospitalization was longer for patients with SPE, 4,25±1,25 vs 2,77±2,10 days p=0,174
No death, stroke or myocardial ischaemia.



Patients were discharged on dual antiplatelet therapy. All patients were followed clinically at 30 days. No new events were reported. 88% of patients underwent TEE at 30-45 days without evidence of flow to the LAA or thrombus on device.

Median follow up 12,5 months



Mean CHADS2 score	**3,15**
Expected annual risk of stroke	**5,9%**
Strokes at F/Up (Me 12,5 months)	**0**

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 this and other devices during the learning phase of the procedure. The results at follow up are encouraging.

Swedish Stroke Registry

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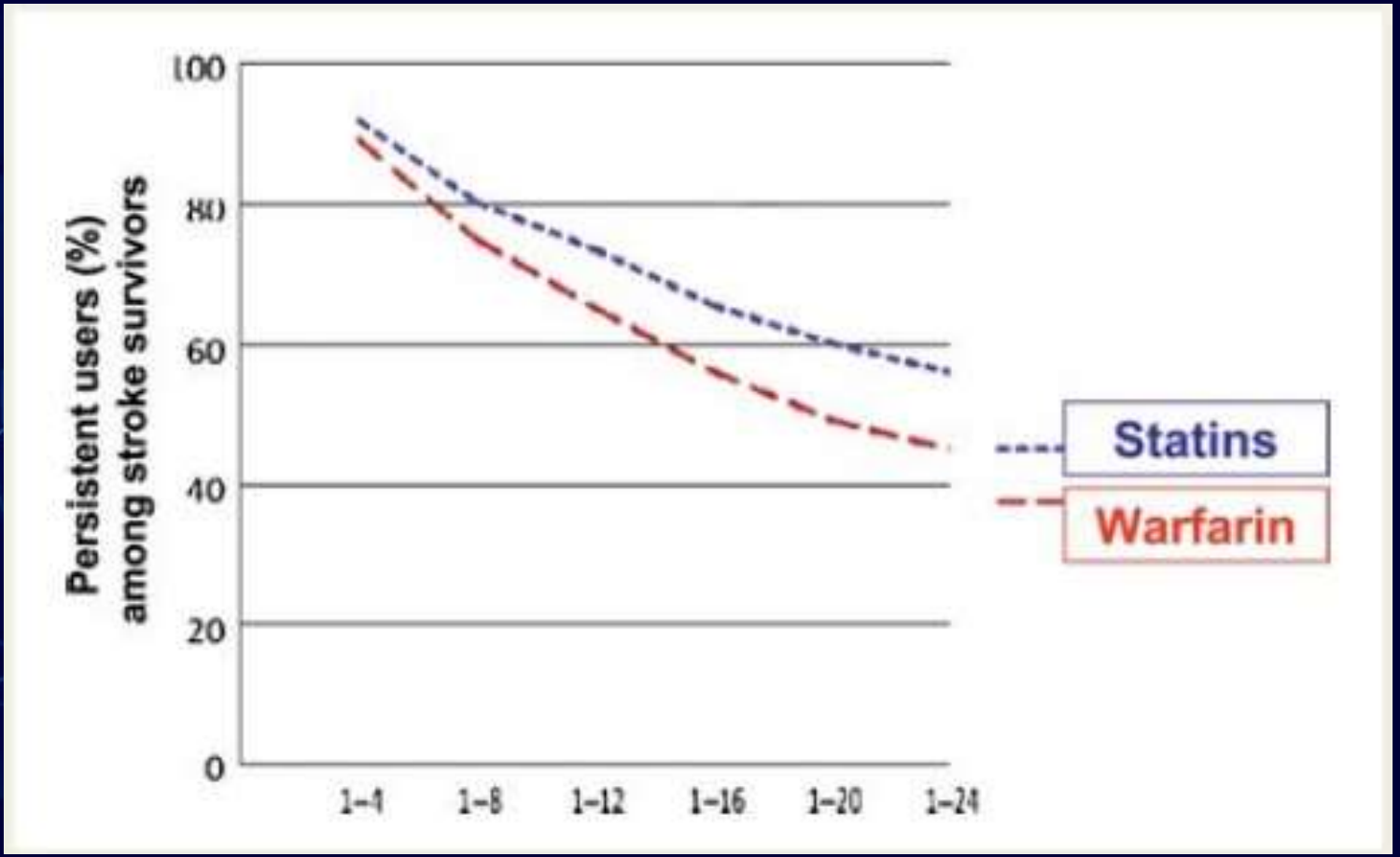

Glader E, et al; Stroke 2010