



**SOLACI
CACI '14**

ARGENTINA

In partnership with **TCT**

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Hilton Hotel, Buenos Aires

“Cierre de Orejuela Auricular Izquierda: Técnica y Resultados”

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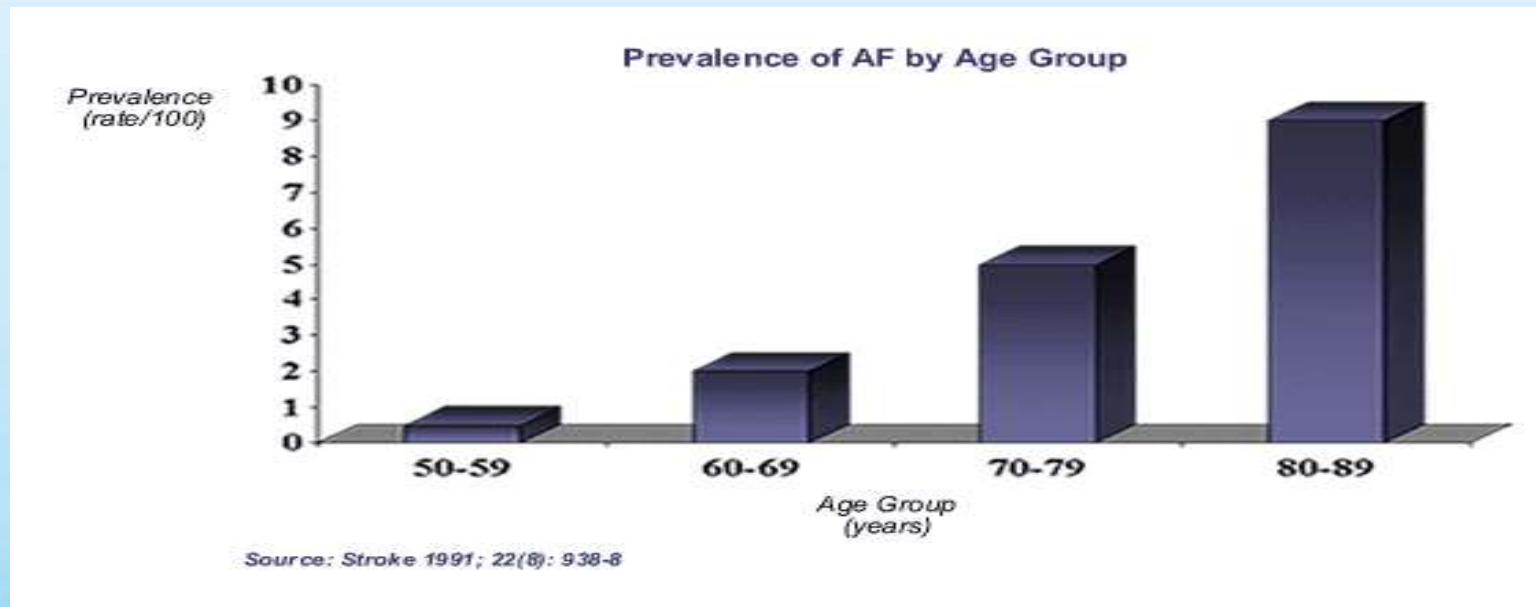


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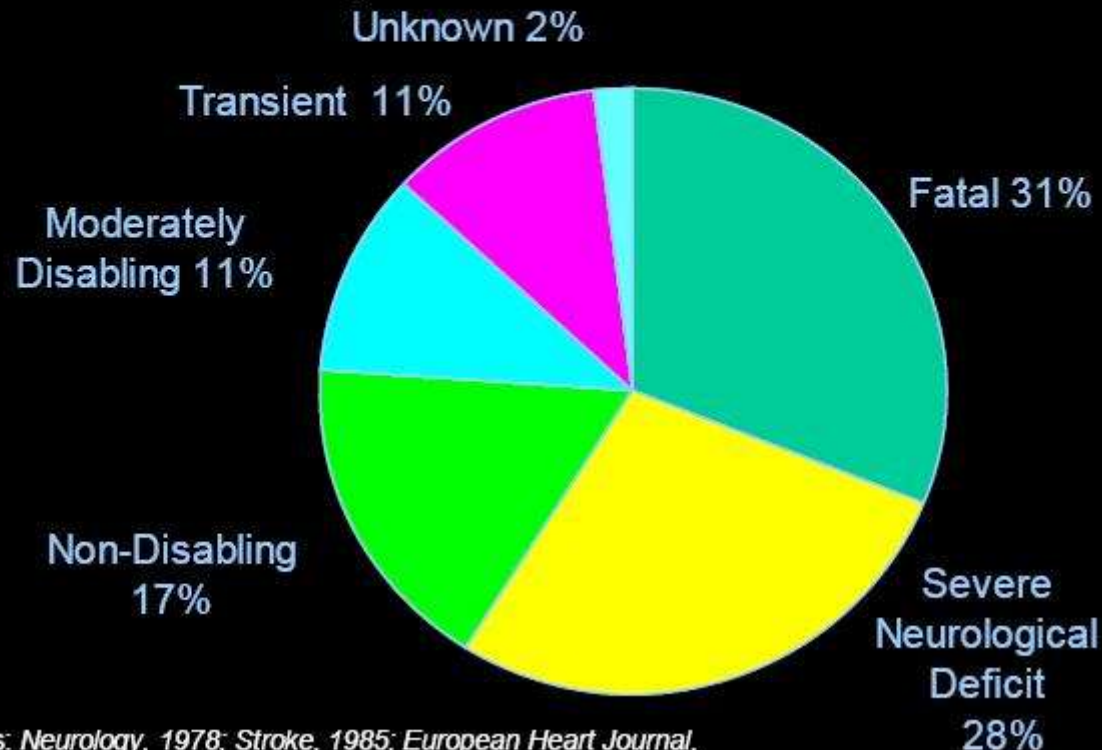
Introducción

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



Introducción: Stroke relacionado a FA

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

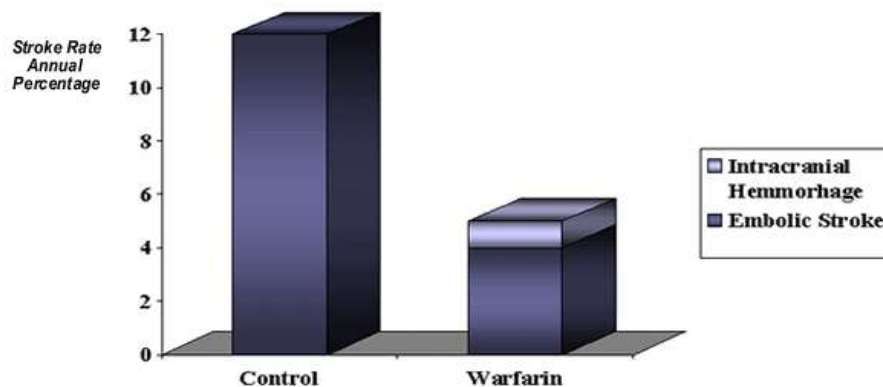


Sources: *Neurology*, 1978; *Stroke*, 1985; *European Heart Journal*, 1987; *Lancet*, 1987; Fisher. *Geriatrics*. 1979;34:59

Introducción

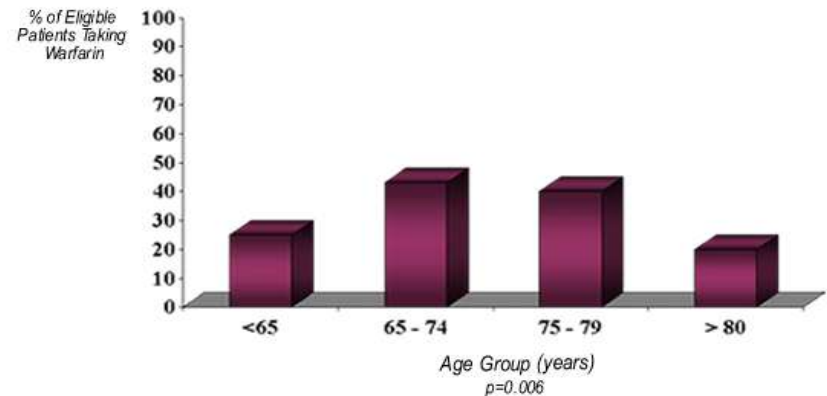
- Los ACO son actualmente el método más efectivo de prevención del stroke en pacientes con FA permanente, pero:
 - 1) Rango terapéutico estrecho – Interacciones con otros fármacos
 - 2) Insuficientemente controlados en alto % de pacientes
 - 3) Subutilizados
 - 4) Frecuentemente contraindicados
- A pesar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

Warfarin vs. Placebo in High Risk Patients With AF and Prior Stroke



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

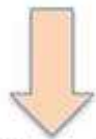
Warfarin Underutilization



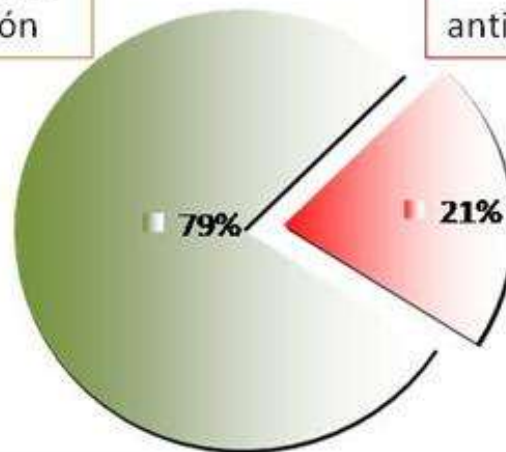
Source: Arch. Int. Med. 1996; 156(22): 2537-41

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 hemorrágico	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

Which patients benefit optimally from LAA Occlusion

3.8 Million patients with AF¹, in Europe¹

75% are at High Risk of Stroke²

50% are insufficiently treated³

15% contraindicated for Warfarin⁴

3% severe bleeding complications. Cannot take warfarin or alternatives⁵

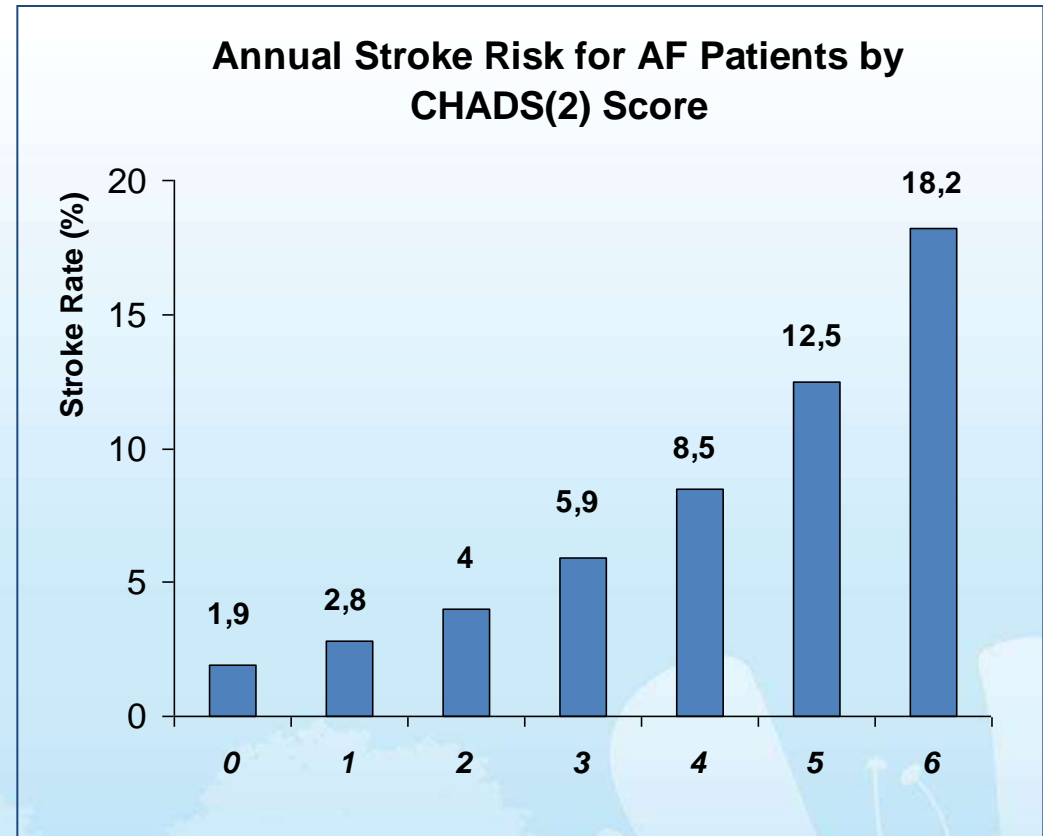


Europe : European Union + Western Balkan, Norway, Switzerland

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 Eng J Medicine 2009; DOI:10.1056/NEJM0905561

Stroke risk stratification of AF patients: The CHADS2 score

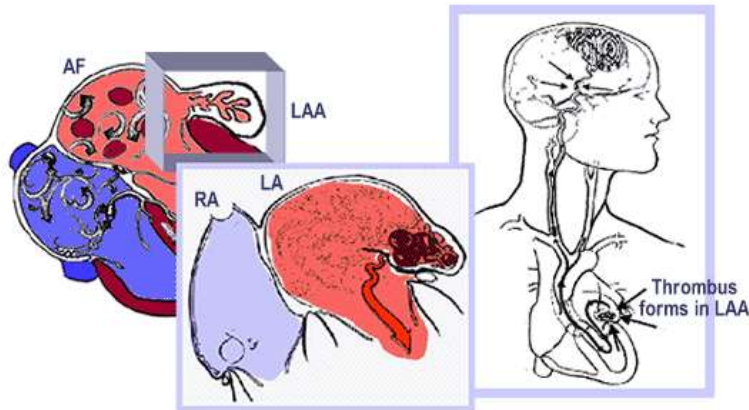
CHADS₂ Score	CHADS₂
C ongestive heart failure	+1
H ypertension	+1
A ge 75>	+1
D iabetes Mellitus	+1
S troke or History of Cerebral Ischemia	+2



Stroke Risk Assessment: CHA2DS2-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 diseasea	1
A	- Age 65–74	1
Sc	- Sex-category (i.e. female sex)	1
	Maximum score	9

Cuál es la fuente embolígena en pacientes con FA 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)

Options for Stroke Prevention



Medical Management: Anticoagulants¹

6 stroke risk reduction
of narrow therapeutic window
caution: bleeding



Excision of LAA² (Appendectomy)

Success rate: 10%
Poor outcomes due to incomplete exclusion
Residual thrombus with stagnant blood flow
Recurrence of thromboembolism



Device Closure

Minimally invasive nature
Percutaneous closure of the LAA in prevention of clot embolization that originates from the LAA
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

WATCHMAN



WATCHMAN System



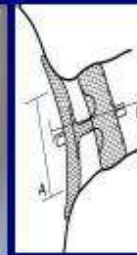
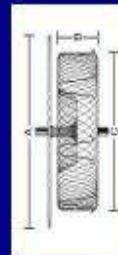
$\frac{1}{2}$ -Rugbyball type

PLAATO



Soccerball type

ACP



Puck&Disc type

Case Presentation

“Technical Steps for Left Atrial Appendage Closure”

Clinical Presentation

76 year-old male.

History of **hypertension**.

Previous AMI, CABG in 1999

Chronic atrial fibrillation since 2007,
on chronic anticoagulation therapy.

Hospitalized in 2009 for **CHF**.

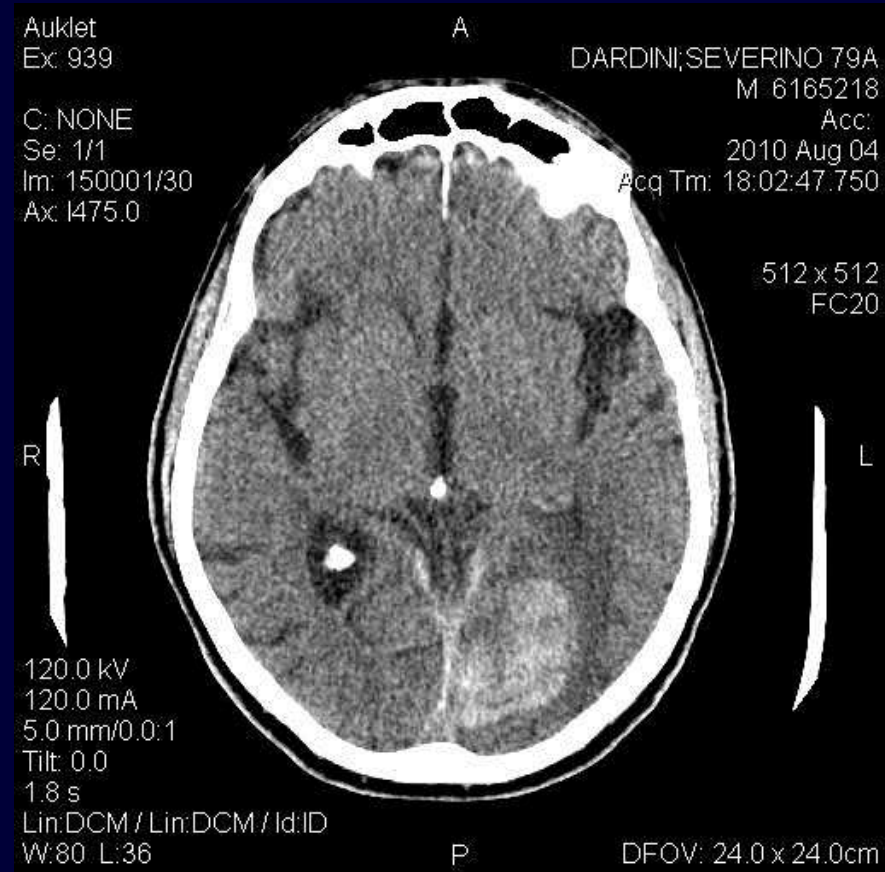
He was admitted in August 2010 with
ICH

Diagnosis: Chronic AF

CHADS2 Score 3

Contraindication to ACO

Plan: Closure of LAA with the ACP



Amplazter Cardiac Plug - ACP

- * Tire shaped
- * Separation
- * Concave disc
- * Orientation of device



Device design:

- Sealing the LAA ostium
- Independent from body shape
- Not attempting to “fill” the LAA

Table 2. Sizing chart

Landing Zone ^a U	Distance from Orifice V	Device Size C	Device Order Number
mm	mm	mm	
12.6 - 14.5	≥ 10	16	9 - ACP - 007 - 016
14.6 - 16.5	≥ 10	18	9 - ACP - 007 - 018
16.6 - 18.5	≥ 10	20	9 - ACP - 007 - 020
18.6 - 20.5	≥ 10	22	9 - ACP - 007 - 022
20.6 - 22.5	≥ 10	24	9 - ACP - 007 - 024
22.6 - 24.5	≥ 10	26	9 - ACP - 007 - 026
24.6 - 26.5	≥ 10	28	9 - ACP - 007 - 028
26.6 - 28.5	≥ 10	30	9 - ACP - 007 - 030

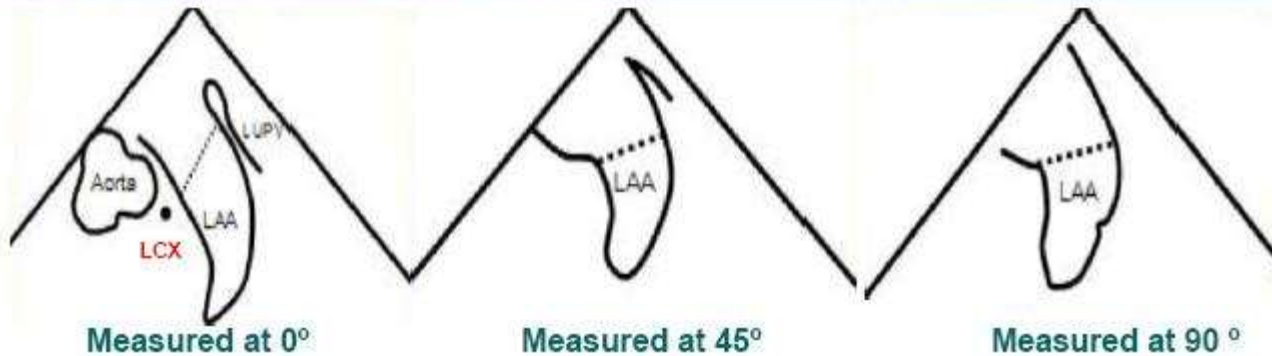
a. The landing zone is where the lobe of the device will be placed in the left atrial appendage.

Pre procedure evaluation

- Clinical – Neurological examination
- Baseline TTE: EF 33%
No significant valvulopathy
- Baseline TEE: Rule out LAA thrombus
Classification of LAA type
LAA dimensions (orifice, landing zone, depth)
PFO – ASD?

Pre procedure evaluation - TEE

TEE Measurement of the LAA Neck



Landmarks—the references for echo measurements:

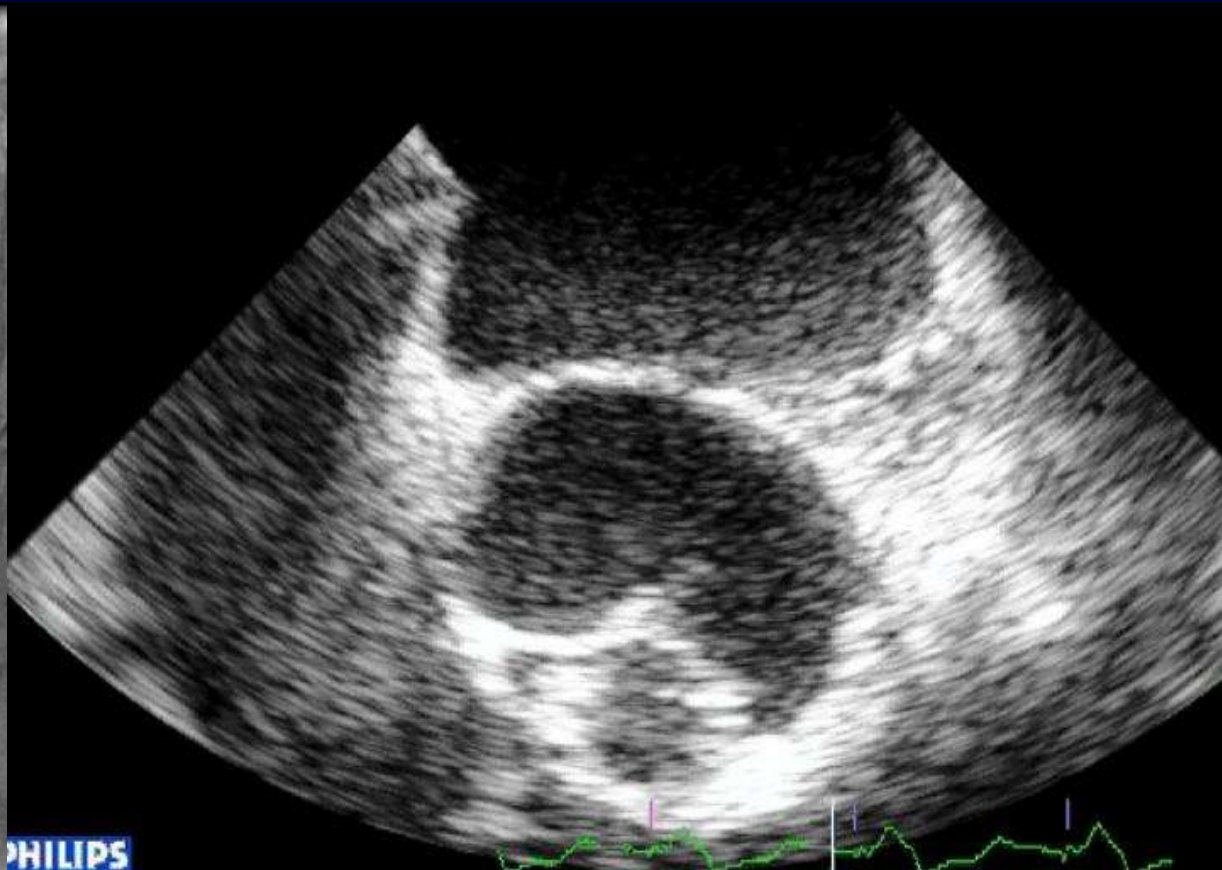
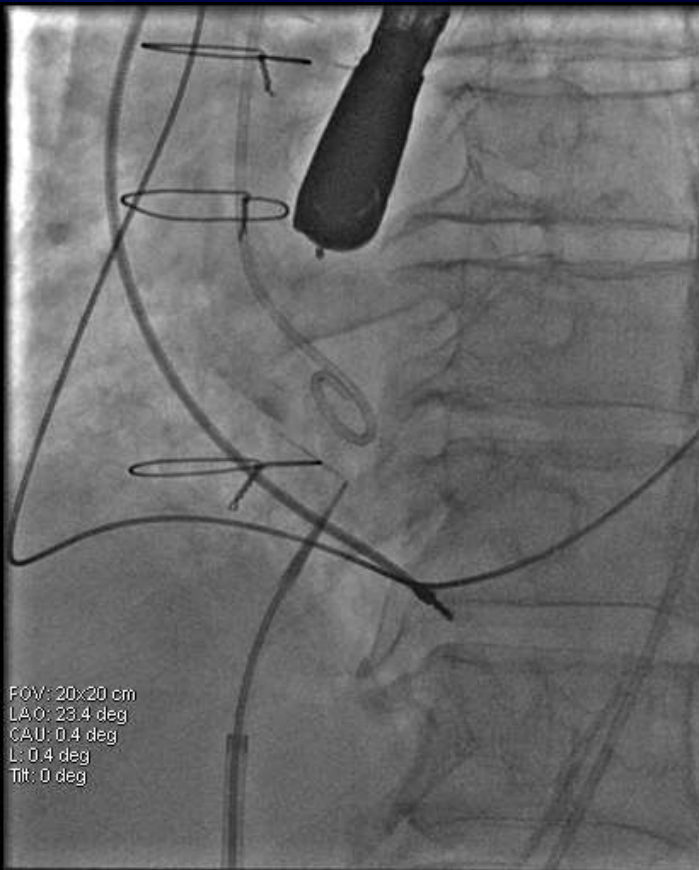
- Left circumflex coronary artery (LCX)
- 1-2 cm below LUPV rim

Nina Wunderlich, M.D. Frankfurt, Germany
Steven Almany, M.D. Royal Oak, MI

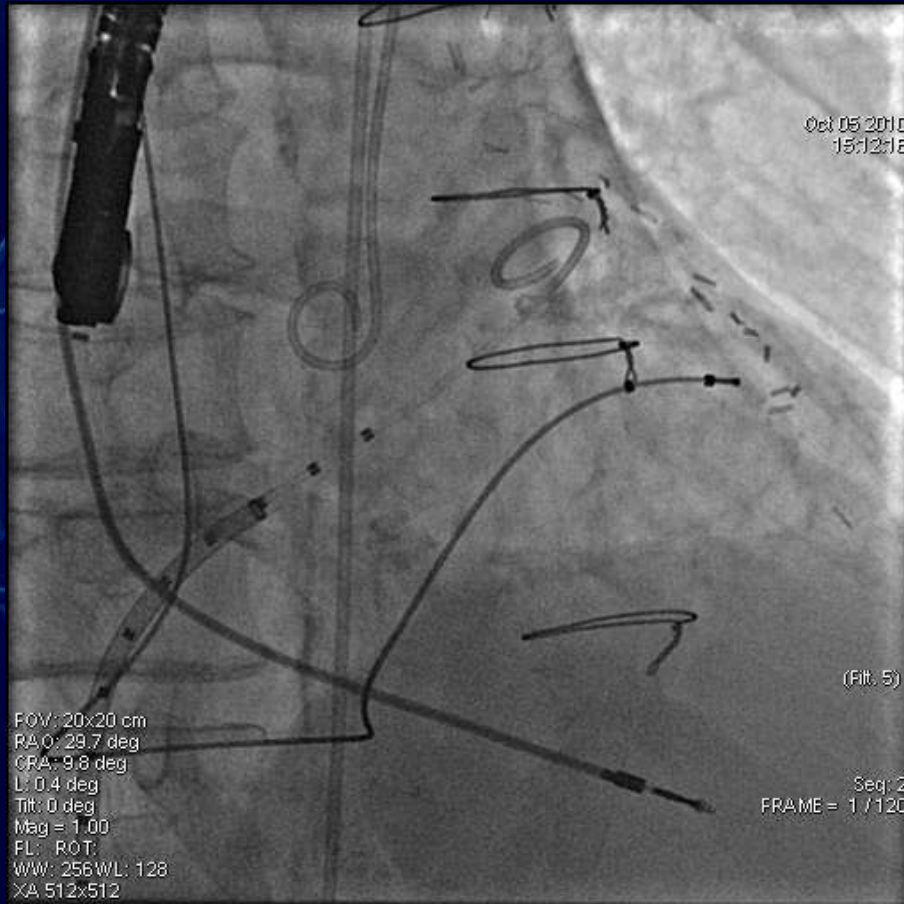
LAA Closure Strategy

- Premedication: ASA – Clopidogrel
- General Anesthesia
- TEE Guidance:
 - Trans septal puncture
 - LAA dimensions
 - Sheath alignment
 - Device deployment
 - Post release assessment
- Heparin after TSP: ACT >250
- Angio assessment of LAA using marked pigtail
- Determine sheath and device size
- Device deployment

TEE guidance - Trans septal Puncture

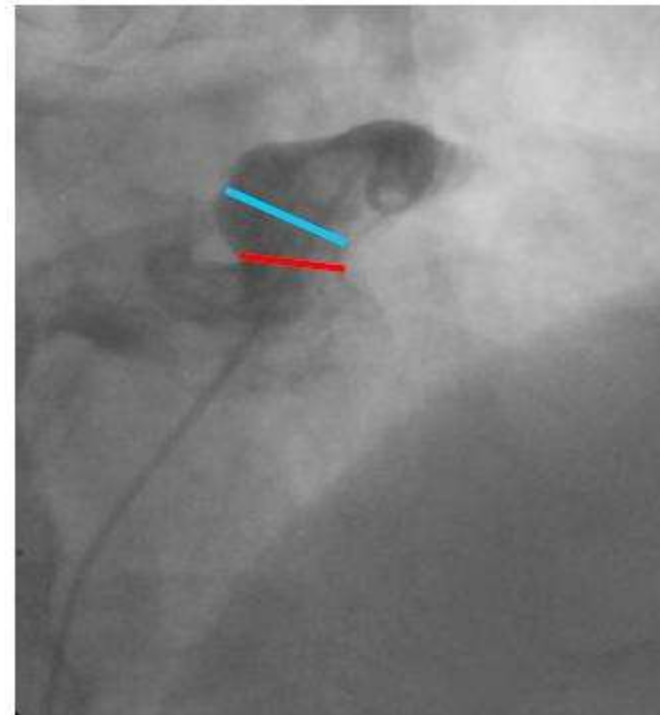
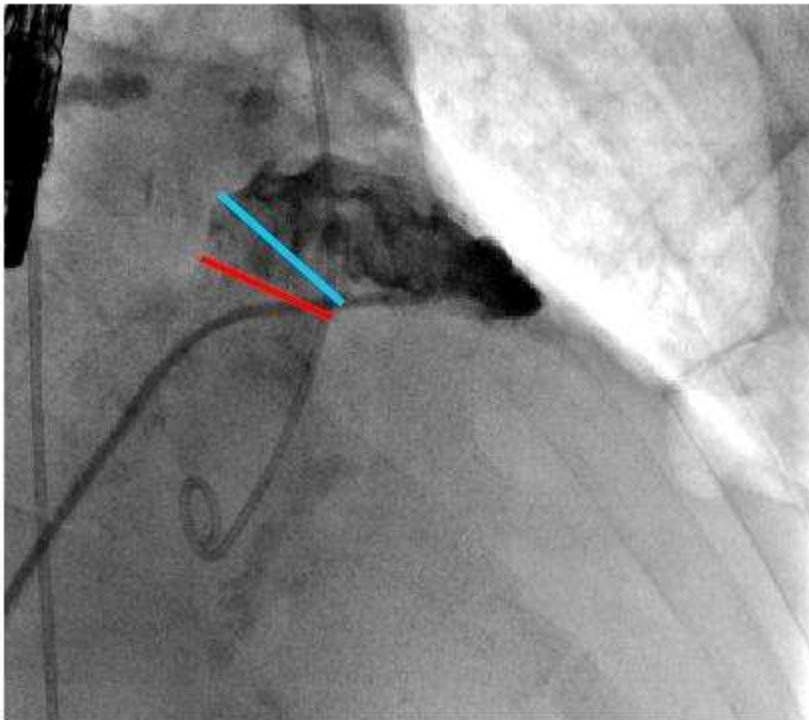


Angiographic Assessment



Definition of the Landing Zone

- Approximate 10 mm (projected line) inside the orifice
- Maximal dimension around the projected line



 ACP Disc >>>>> LAA Orifice
 ACP lobe >>>>> The width at landing zone

PHILIPS

05/10/2010 14:32:18 TIs1.3 MI 0.7

PHILIPS

05/10/2010 14:34:33 TIs1.2 MI 0.6

de Rosario S7-2omni/Adultos

de Rosario S7-2omni/Adultos

FAdq 49Hz
14cm

2D
56%
C 50
P Des.
Gral.



G
P R

M3 FAdq 65Hz
10cm

2D
52%
C 50
P Des.
Gral.



G
P R

PHILIPS

05/10/2010 14:35:06 TIs1.2 MI 0.6

PHILIPS

05/10/2010 14:35:31 TIs1.2 MI 0.6

de Rosario S7-2omni/Adultos

de Rosario S7-2omni/Adultos

FAdq 65Hz
10cm

2D
52%
C 50
P Des.
Gral.



G
P R

M3 FAdq 65Hz
10cm

2D
52%
C 50
P Des.
Gral.



G
P R

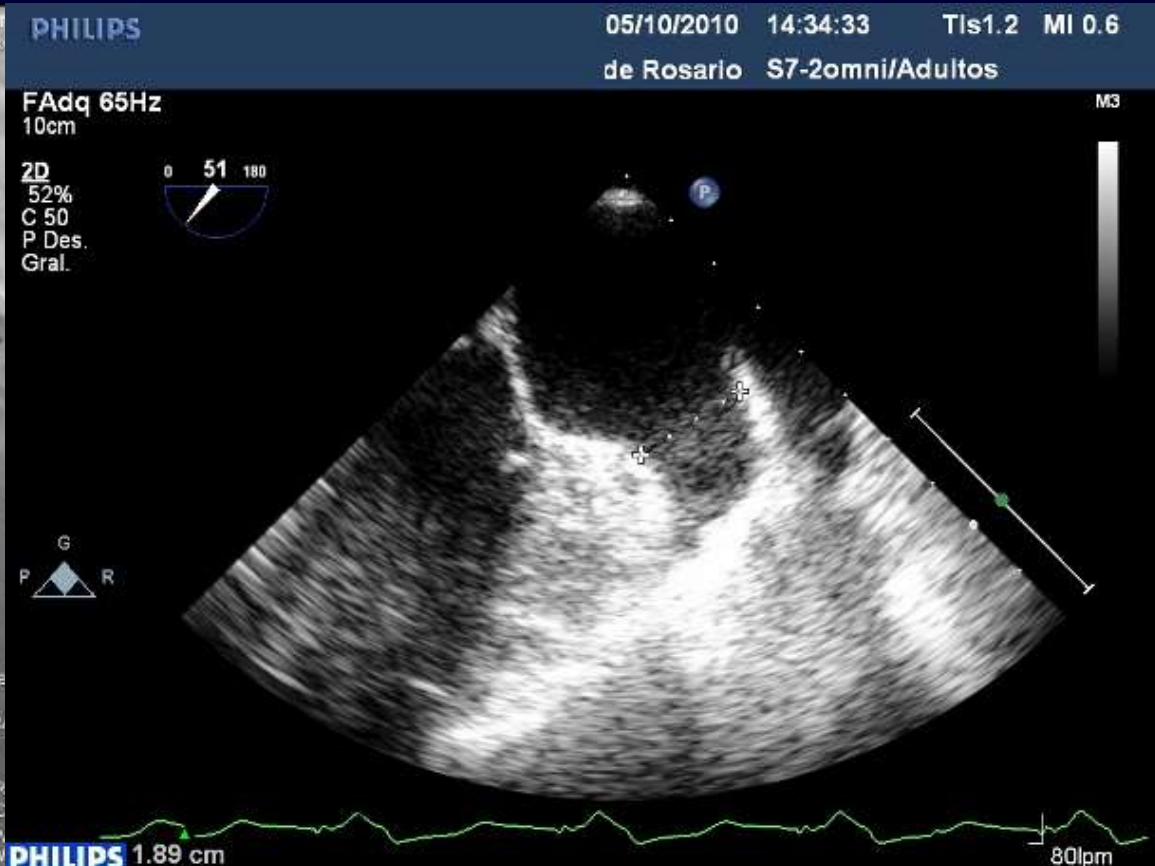
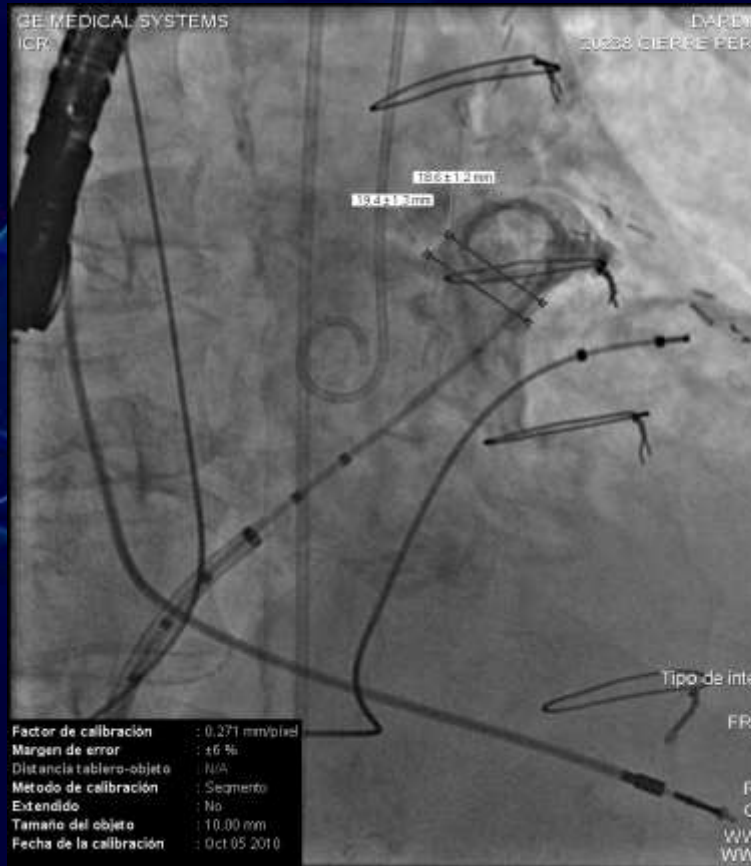
PHILIPS 1.62 cm

73lpm

PHILIPS 1.80 cm

80lpm

LAA dimensions: Angio vs TEE



Determine ACP size

- * Tire shaped
- * Separation
- * Concave disc
- * Orientation of device



Device design:

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- Independent from body shape
- Not attempting to “fill” the LAA

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a. The landing zone is where the lobe of the device will be placed in the left atrial appendage.

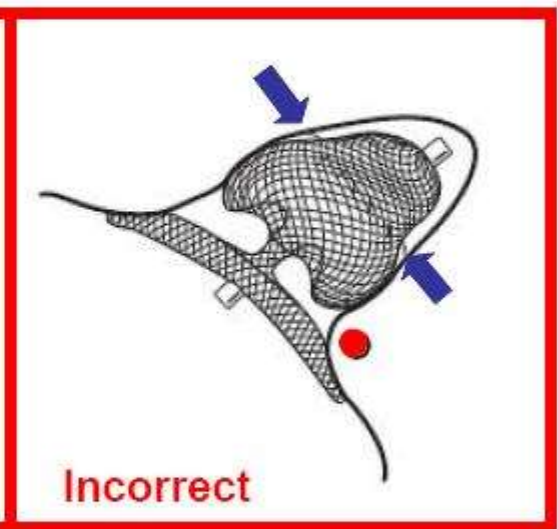
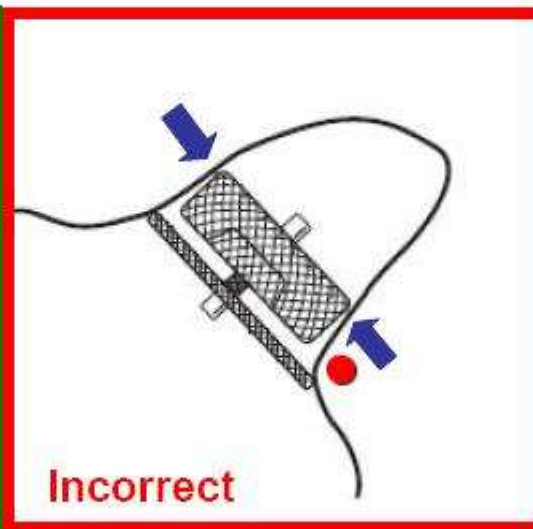
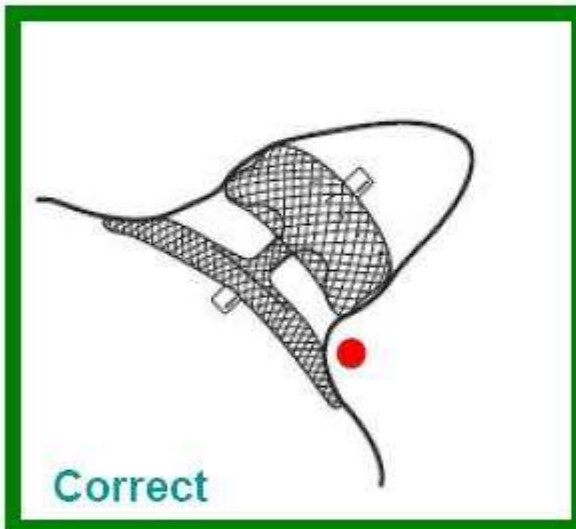
Determine ACP size

Larger is NOT always better

Tire Shaped

Puck Shaped

Strawberry Shaped



Stable

Unstable

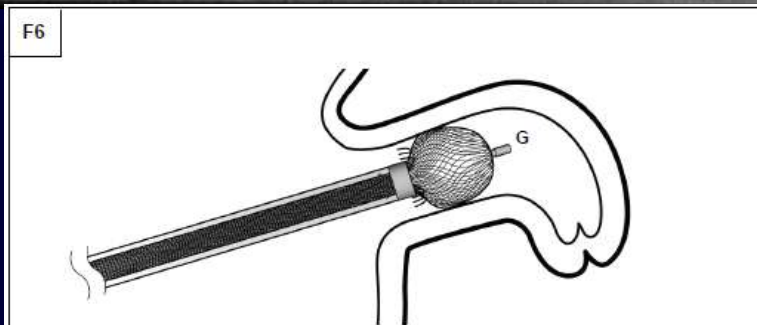
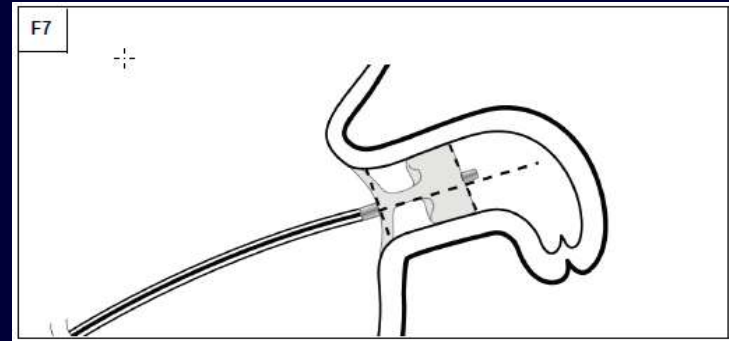
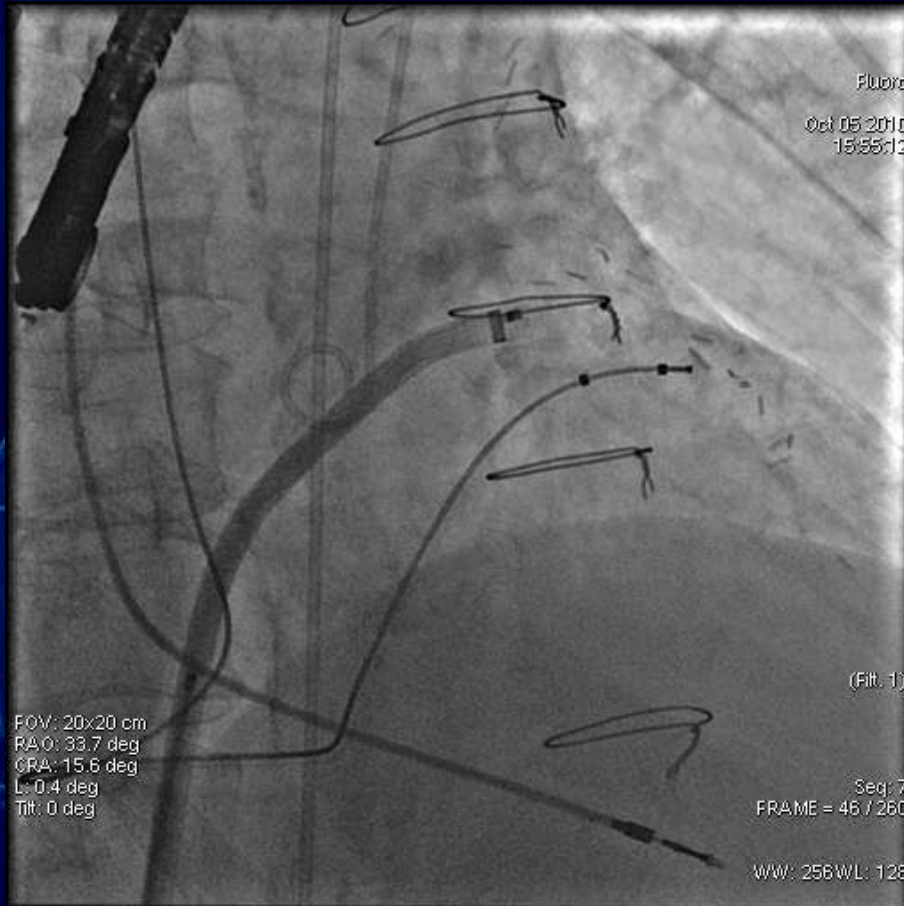
Stabilizing wires engaged

Stabilizing wires unengaged

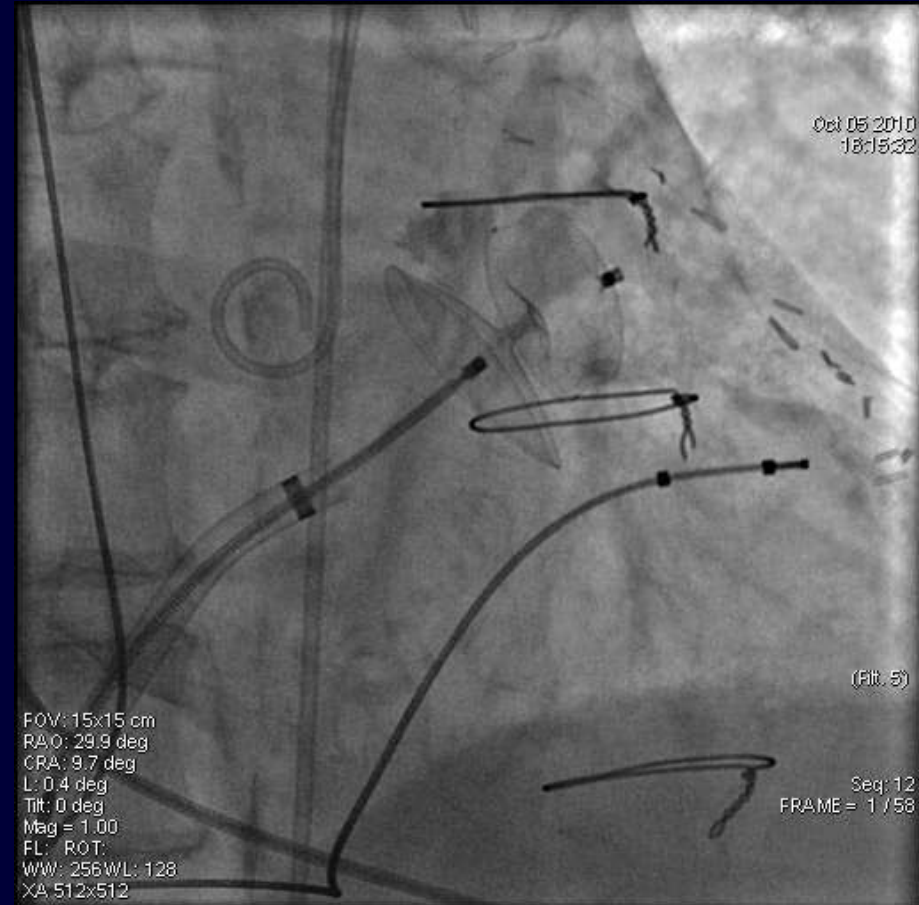
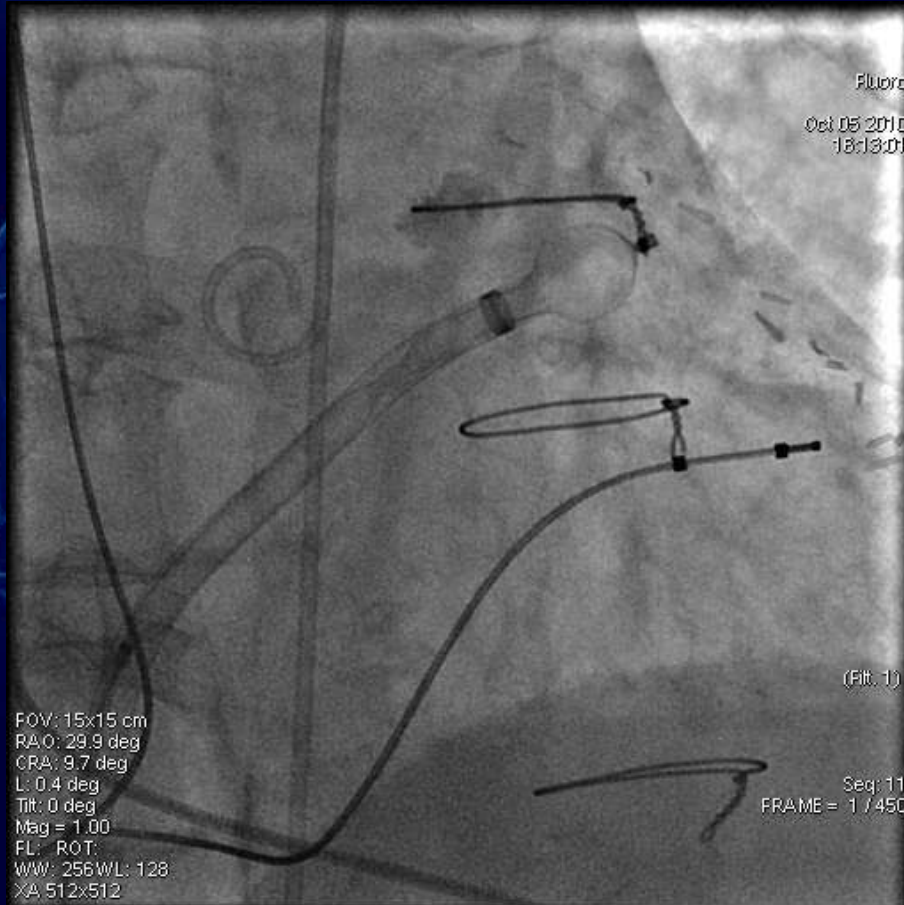
TEE guidance – Sheath alignment



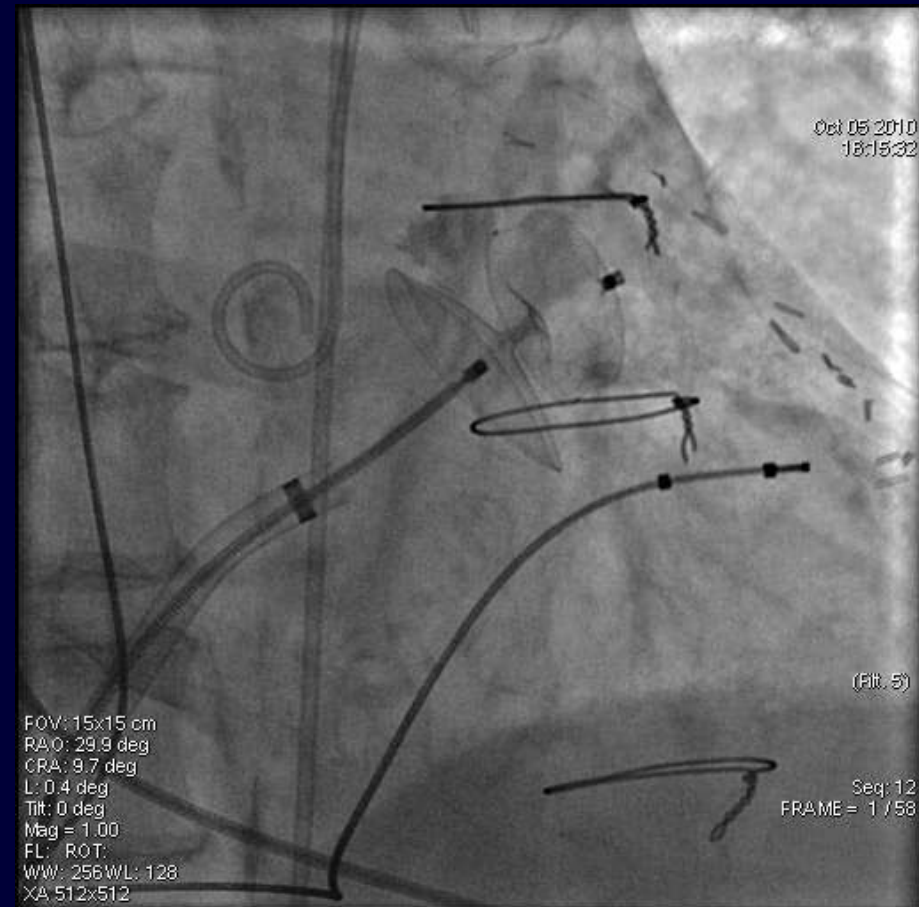
Device Deployment



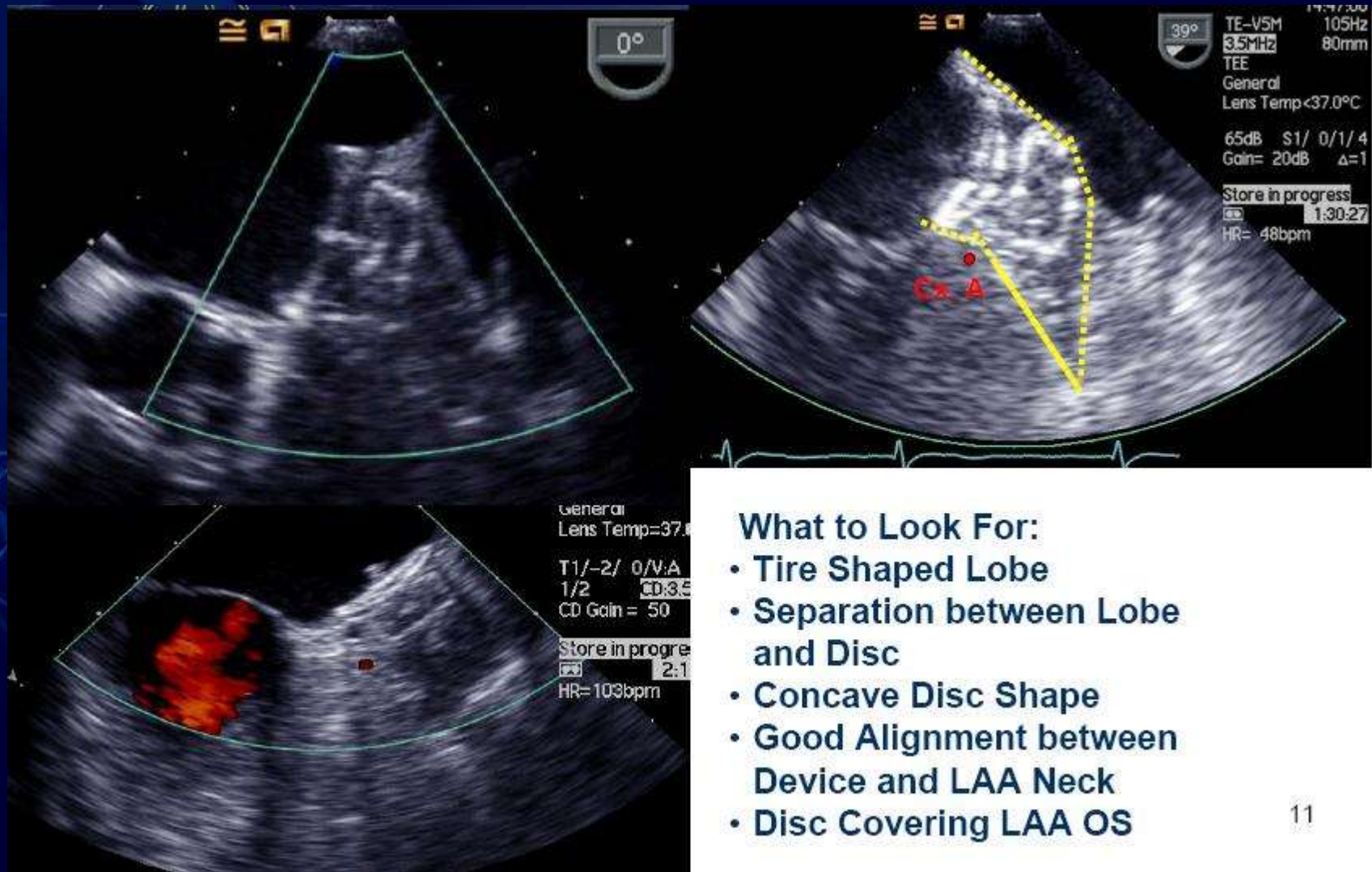
Device Deployment – 2nd attempt



1st Deployment – 2nd Deployment

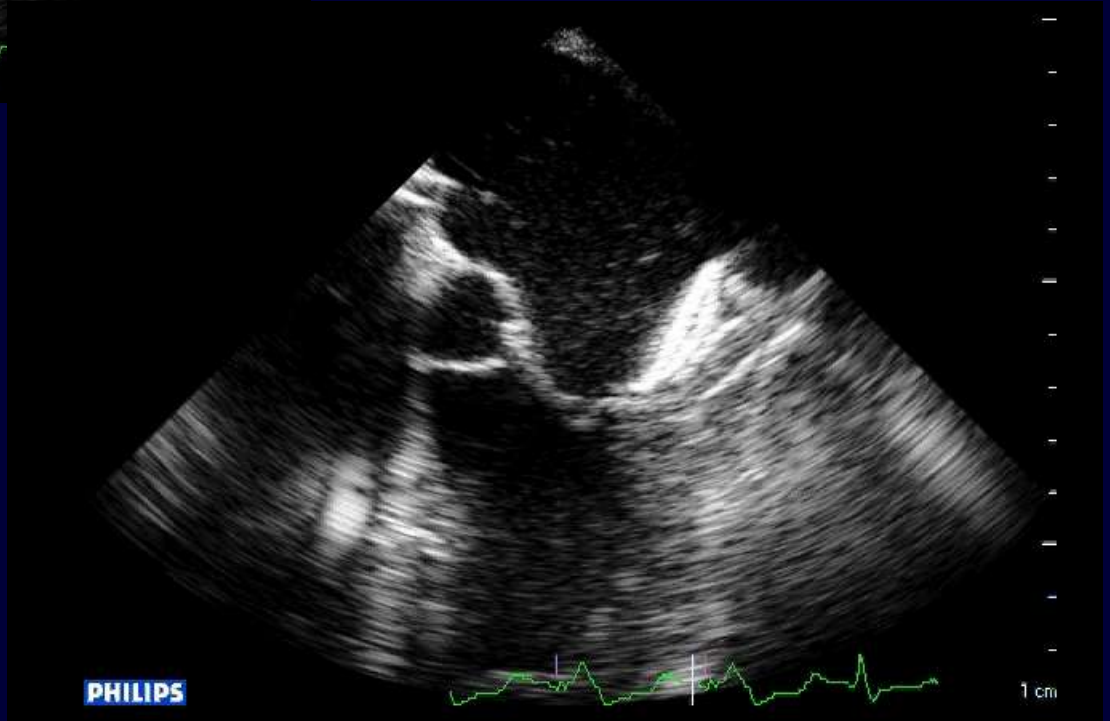
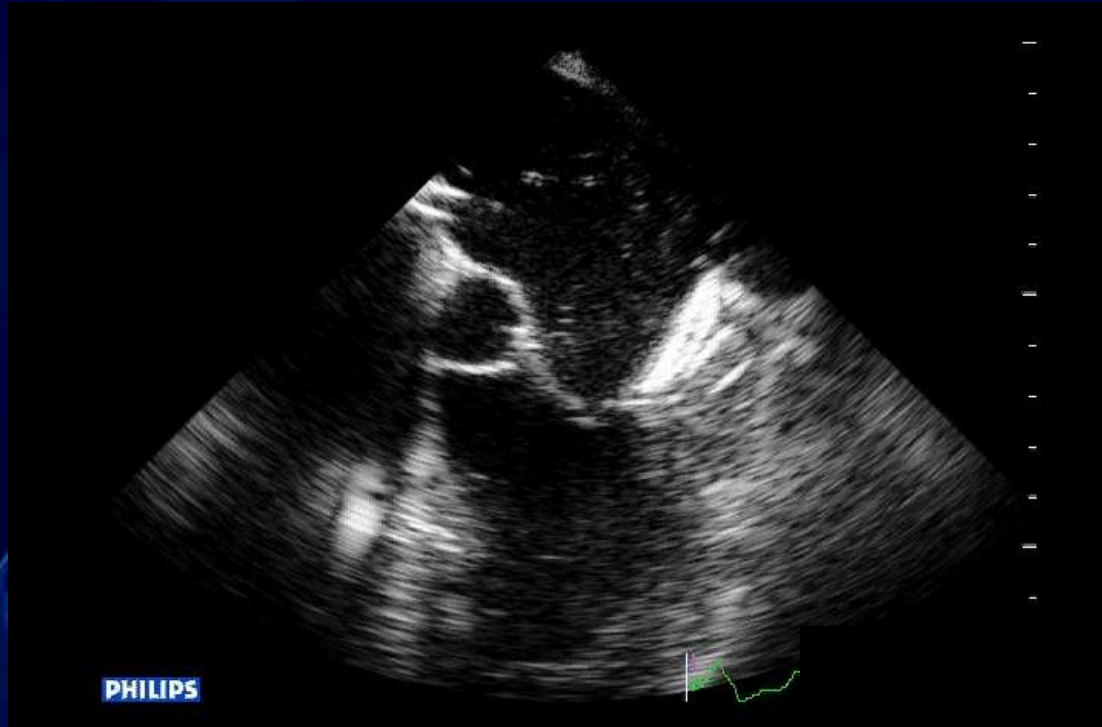


TEE guidance – Device deployment



What to Look For:

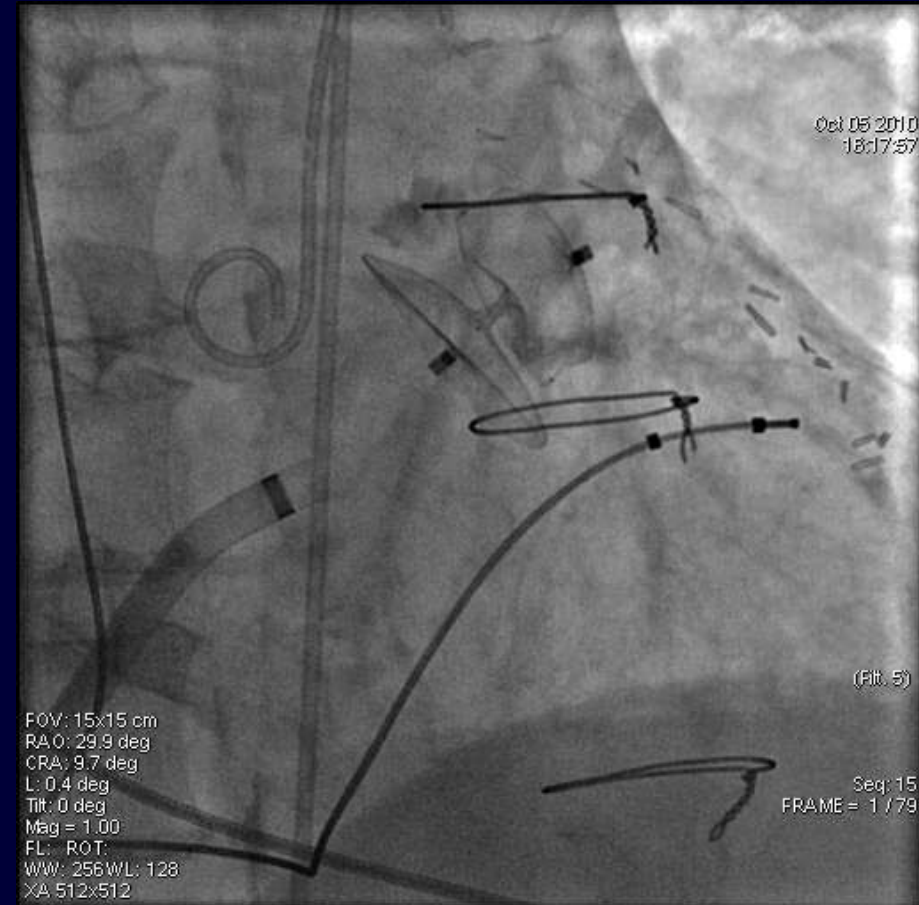
- Tire Shaped Lobe
- Separation between Lobe and Disc
- Concave Disc Shape
- Good Alignment between Device and LAA Neck
- Disc Covering LAA OS



TEE guidance – Device deployment



Device release and angio control

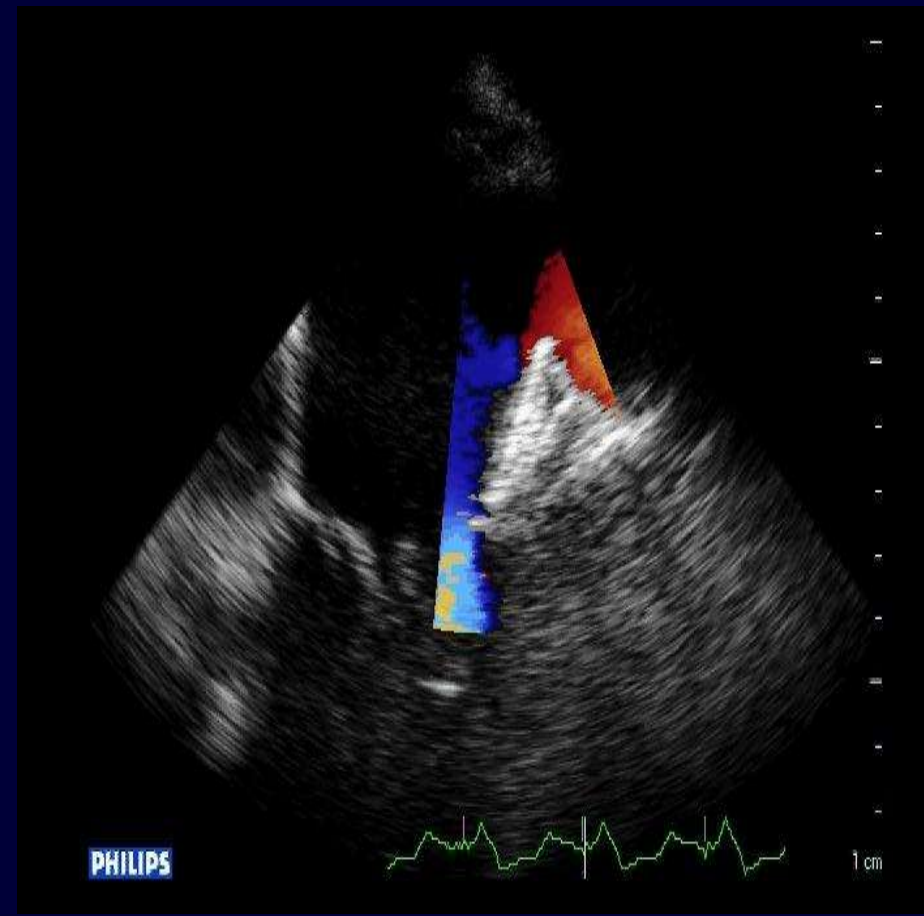
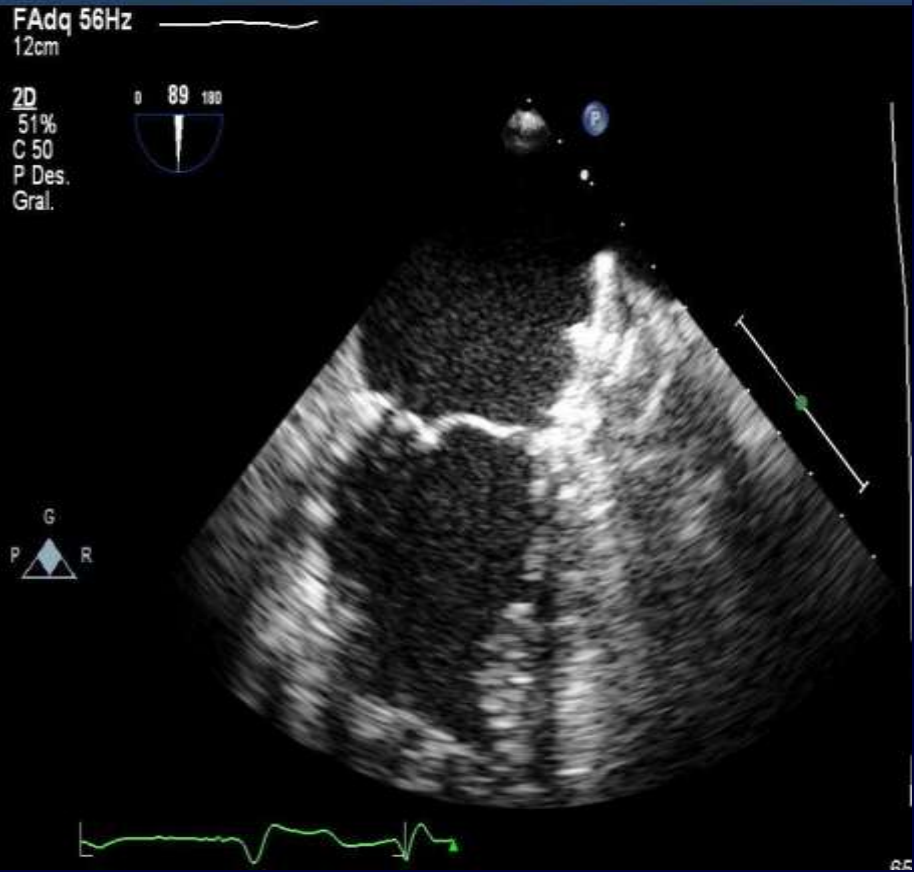


Post Procedure therapies

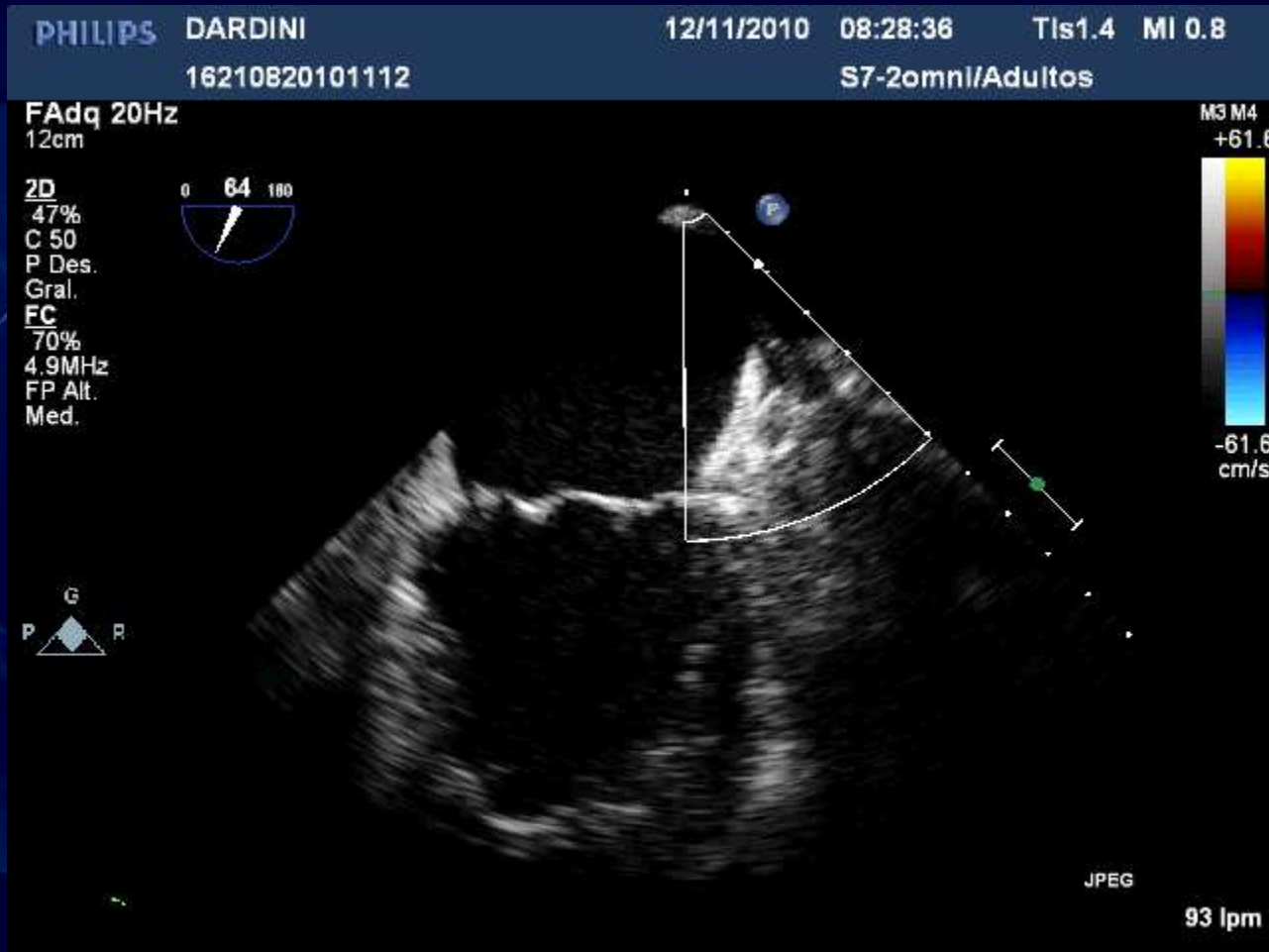
- Aspirin (or an alternate antiplatelet) is recommended for patients for 6 months post implant. Discontinuation at 6 months is at discretion of the physician.
- Clopidogrel (or an alternate antiplatelet) is recommended for patients for 1 month post implant. Discontinuation at 1 month is at discretion of the physician.
- Appropriate endocarditis prophylaxis is recommended.

TEE at 45 days

16210820101112 Inst.Cardiovas de Rosario S7-2omni/Adultos



TEE at 45 days



TEE at >1 year

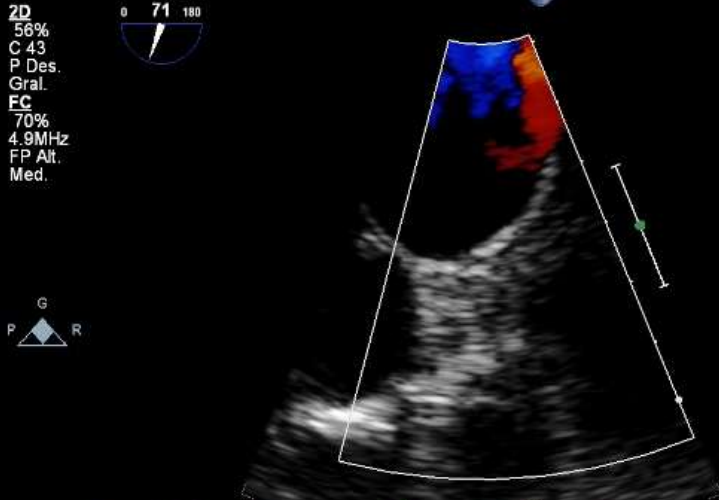
PHILIPS

12/12/2011 12:23:10 Tis1.2 MI 0. PHILIPS
de Rosario S7-2omni/Contr. OVI

12/12/2011 12:26:40 Tis1.2 MI 0.8
de Rosario S7-2omni/Contr. OVI

FAdq 28Hz
9.5cm

2D
56%
C 43
P Des.
Gral.
FC
70%
4.9MHz
FP Alt.
Med.



FAdq 41Hz
17cm

2D
59%
C 43
P Des.
Gral.

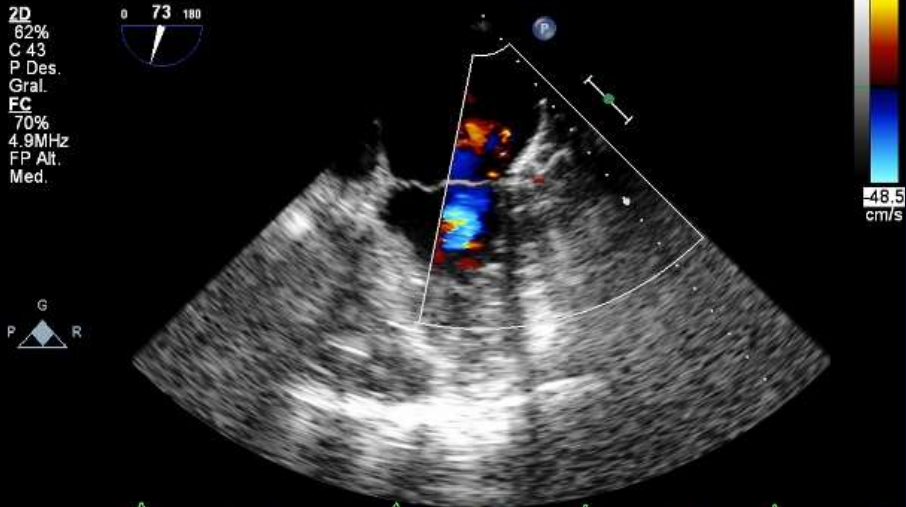


PHILIPS

12/12/2011 12:29:52 Tis1.4 MI 0.7
de Rosario S7-2omni/Contr. OVI

FAdq 14Hz
17cm

2D
82%
C 43
P Des.
Gral.
FC
70%
4.9MHz
FP Alt.
Med.



LIPS

online.com



PHILIPS

77bpm

PHILIPS

5 mm

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

Resultados de los Estudios Clínicos

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

Seefan 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 Osman, 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 Poppos, 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; Shreveport, Louisiana; 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 fluoroscopia → 18 ± 9 minutos
- Complicaciones :
 - Mortalidad → 1 (0.9%)
 - ACV → 0
 - T. Cardíaco → 3 (2.7%)
 - Vasculares → 3

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%

CLINICAL RESEARCH

Percutaneous Left Atrial Appendage Occlusion for Patients in Atrial Fibrillation Suboptimal for Warfarin Therapy

5-Year Results of the PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) Study

Peter C. Block, MD,* Steven Burstein, MD,† Paul N. Casale, MD,‡ Paul H. Kramer, MD,§
Paul Teirstein, MD,|| David O. Williams, MD,¶ Mark Reisman, MD#

*Atlanta, Georgia; Los Angeles and San Diego, California; Lancaster, Pennsylvania;
Shawnee, Kansas; Providence, Rhode Island; and Seattle, Washington*

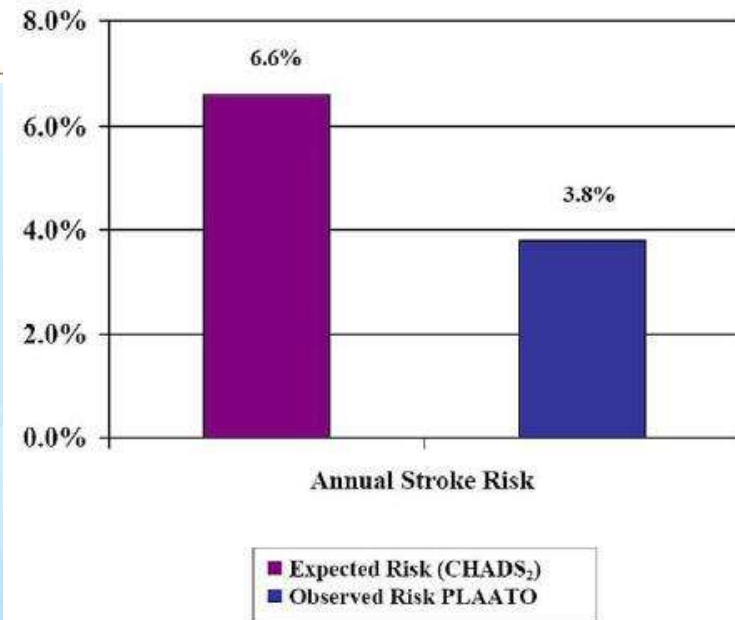


Figure 1. Difference Between the Expected Versus Observed Stroke/TIA Rates in the PLAATO U.S. Feasibility Study

PROTECT - AF

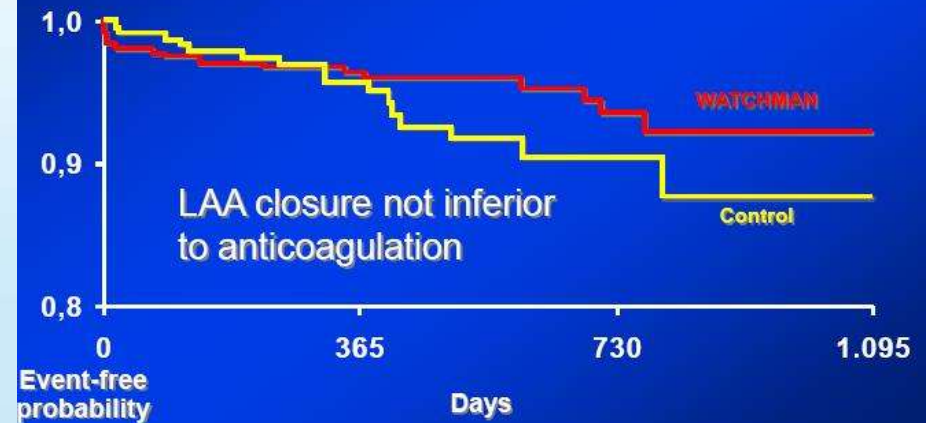
Safety

Freedom from device embolization, pericardial effusion, Severe bleeding



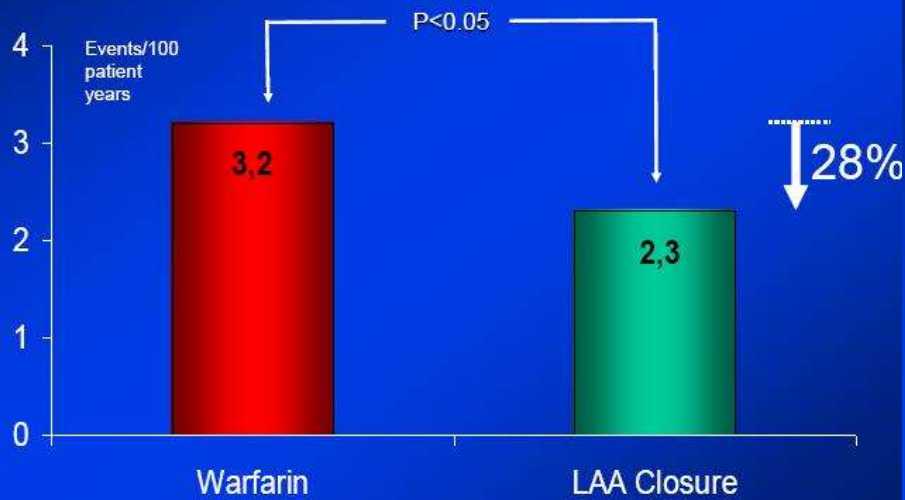
Primary Efficacy Endpoint

Freedom from Stroke, Death, Systemic Embolization

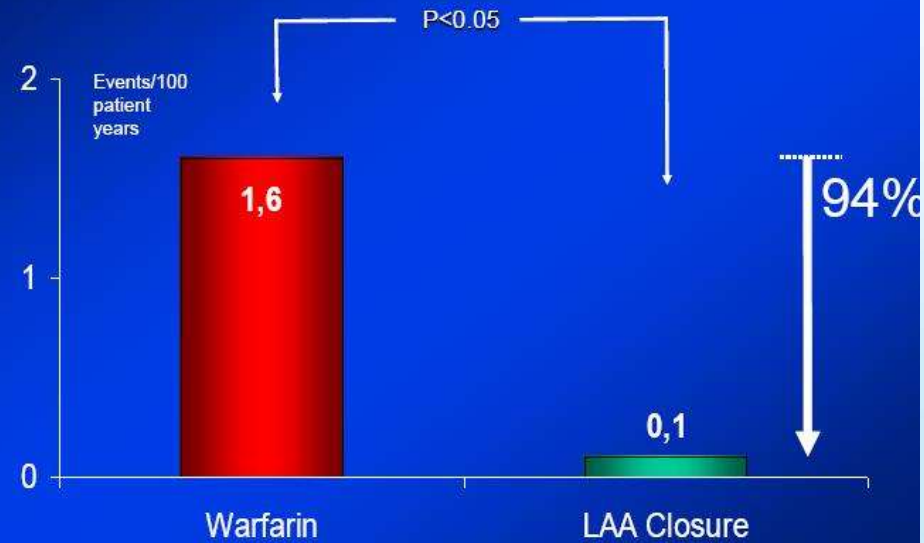


PROTECT - AF

All Stroke



Hemorrhagic Stroke



LAA Closure: Effect of Learning Curve

Safety Event Rates *PROTECT AF vs CAP*

	PROTECT AF	PROTECT AF		CAP	p-value*	p-value
		Early	Late			
Procedure/Device Related Safety Adverse Events within 7 Days	42/542 (7.7%)	27/271 (10.0%)	15/271 (5.5%)	17/460 (3.7%)	0.007	0.006
Serious Pericardial Effusions within 7 Days	27/542 (5.0%)	17/271 (6.3%)	10/271 (3.7%)	10/460 (2.2%)	0.019	0.018
Procedure Related Stroke	5/542 (0.9%)	3/271 (1.1%)	2/271 (0.7%)	0/460 (0.0%)	0.039	0.039

*From tests comparing the PROTECT AF cohort with CAP ±From tests for differences across three groups (early PROTECT AF, late PROTECT AF, and CAP)

PROTECT AF: The Mortality Effects of LAA Closure vs. Warfarin for Stroke Prophylaxis in A-fib

Four-year results for patients with nonvalvular A-fib randomized to percutaneous LAA closure with Watchman (n = 463) or warfarin alone (n = 244).

- At 4 years, the primary efficacy event rate per 100 patient years was lower with Watchman (2.3%) than controls (3.8%; RR 0.60; 95% CI 0.41-1.05)
- Compared with warfarin, Watchman was linked with lower risk of all-cause (3.2% vs. 4.8%; HR 0.66; $P = 0.0379$) and cardiovascular mortality (1.0% vs. 2.4%; HR 0.40; $P = 0.0045$)
- Efficacy results confirmed through intention-to-treat, post-procedure, per-protocol, and terminal therapy analyses

Conclusion: For patients with nonvalvular A-fib, closing the LAA with the Watchman device has been shown to be superior to warfarin alone.

Reddy VY. Heart Rhythm 2013;
Denver, CO.

WATCHMAN ASAP Registry

Patients with nonvalvular atrial fibrillation
and CHADS₂ Score ≥1
Contraindicated for Warfarin

Exclude

- Echo: LVEF <30%, intracardiac thrombi, complex aortic atheroma, high-risk PFO, aneurysm >15mm, or length ≥15mm
- Symptomatic carotid artery disease
- History of stroke/TIA within last 30d

150 Patients Enrolled

Unsuitable LAA anatomy (n=7)
Procedural complication (n=1)

Untreated

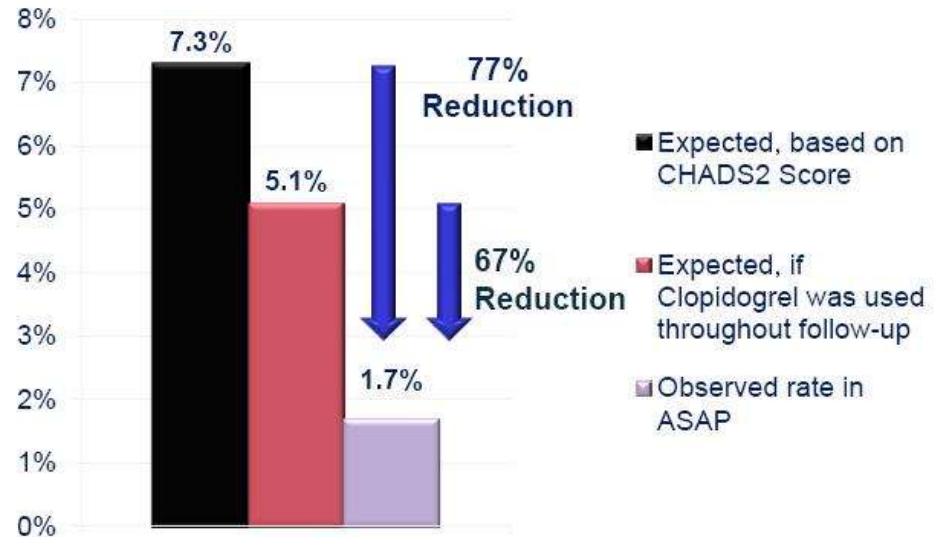
Device Implanted: 142 Patients

Primary Endpoint: Occurrence of stroke (including ischemic and hemorrhagic), cardiovascular death, and systemic embolism



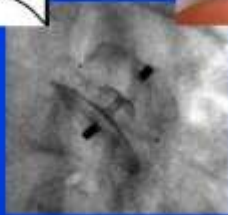
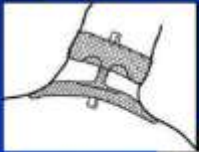
In partnership with TCT

ASAP Efficacy Outcome

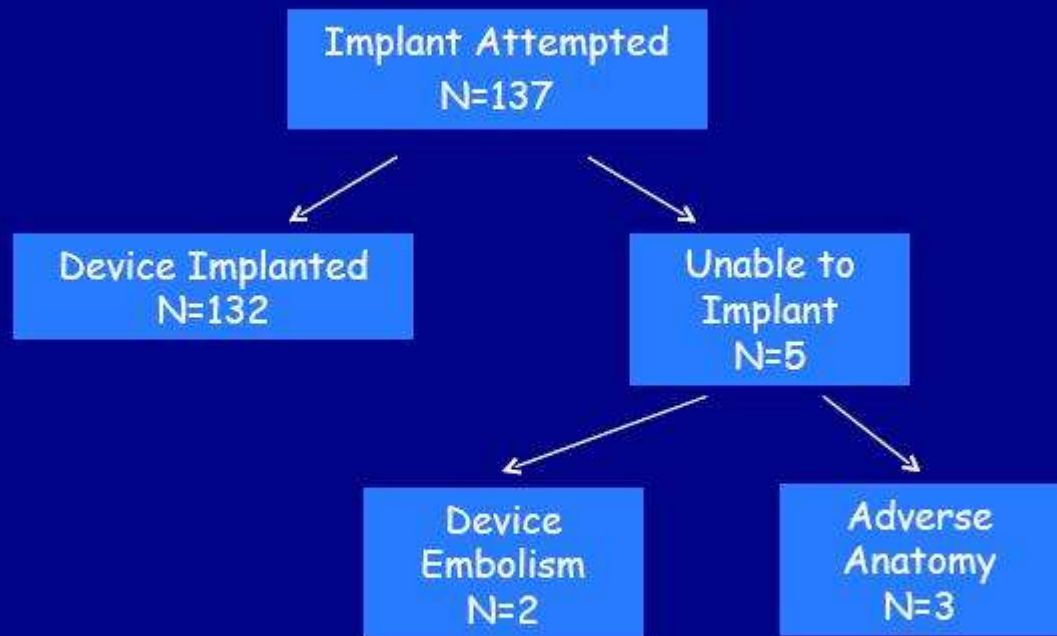


Dispositivo - ACP

Concept of Amplatzer Cardiac Plug ACP



Initial ACP European Experience



**Implant Successful in 96.4%
(132/137) of Attempts**

Dispositivo - ACP

Initial ACP European Experience N=143

24-h Procedure Related Complications

Serious complications

Serious Pericardial Effusion*	N=5 (3.5%)
Device Embolization	N=2 (1.4%)
Ischaemic Stroke (Embol. of air or thrombus?)	N=3 (2.1%)

Minor complications

Trivial Pericardial effusion	N=4 (2.8%)
Transient Myocardial Ischemia (Air Embolism)	N=2 (1.4%)
Device snared from femoral vein	N=1 (0.7%)

Dispositivo - ACP



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%)

¹Park, 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

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.

“Percutaneous closure of the left atrial appendage: Initial Experience in Latin America”

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Results

- Age $72 \pm 8,7$
 - Male 70 %
 - HTA 78 %
 - DBT 17 %
 - CHF 32,17 %
 - Contraindic. ACO 64,29 %

 - **CHADS2 score** $3,15 \pm 1,12$
-

In Hospital and FU Results

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

- In hospital Complications:

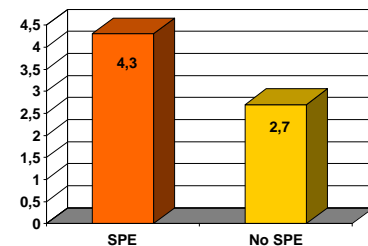
5 patients (8,3%)

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

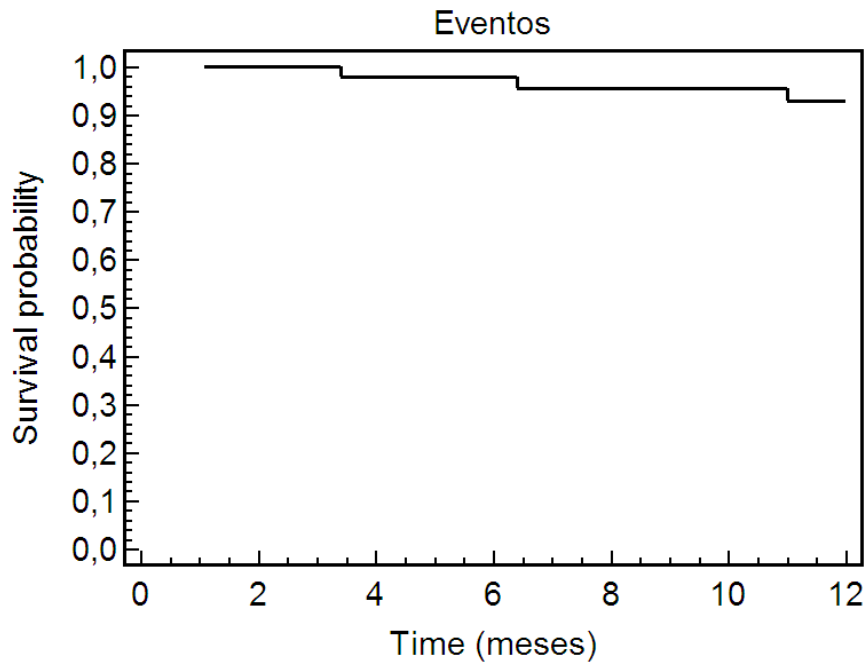


	Protect AF ⁽¹⁾ N= 463	Protect AF(early) ⁽¹⁾ N=271	ACPIIn.Eu.Ex ⁽²⁾ N= 143	ACP LatAm N= 60
Successfull implant (%)	90.9	88.2	96.4	100
Severe peric. effussion (%)	5.0	6.3	3.5	6.6
Emboliztion of device (%)	0.2	N/A	1.4	1.6
Stroke/TIA (%)	0.9	1.1	2.1	0
Major complic. (%)	7.7	10	7.0	8.3

⁽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

Guidelines - NICE

Issue date: June 2010

NHSNational Institute for
Health and Clinical ExcellencePercutaneous occlusion of the left atrial
appendage in non-valvular atrial fibrillation
for the prevention of thromboembolism

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.

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

Recommendations for LAA closure/occlusion/excision

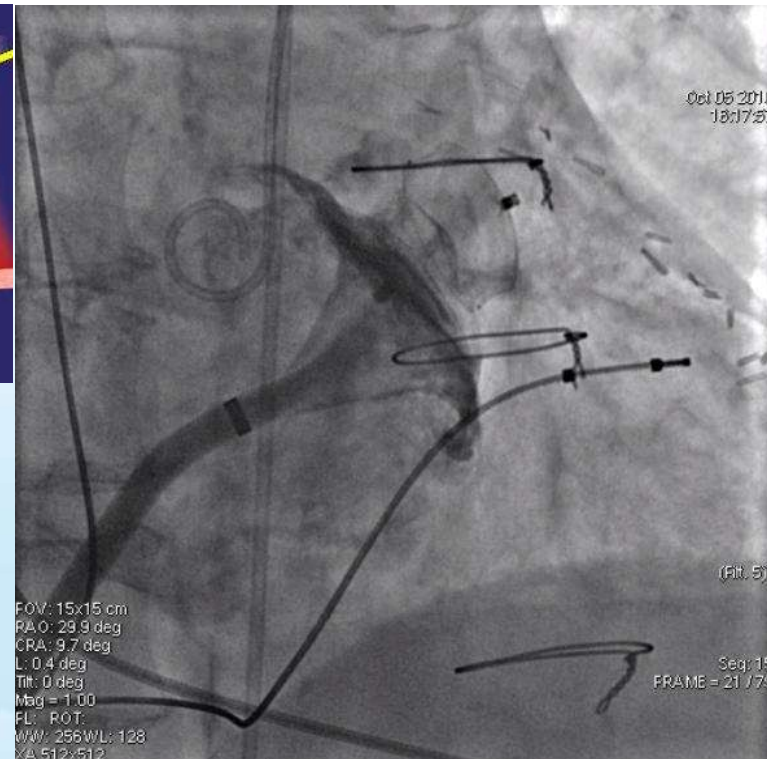
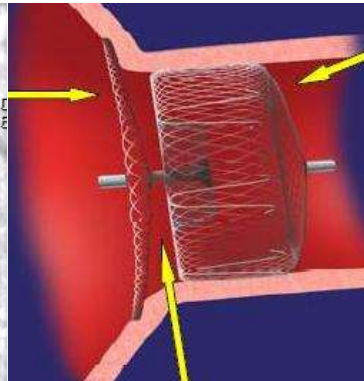
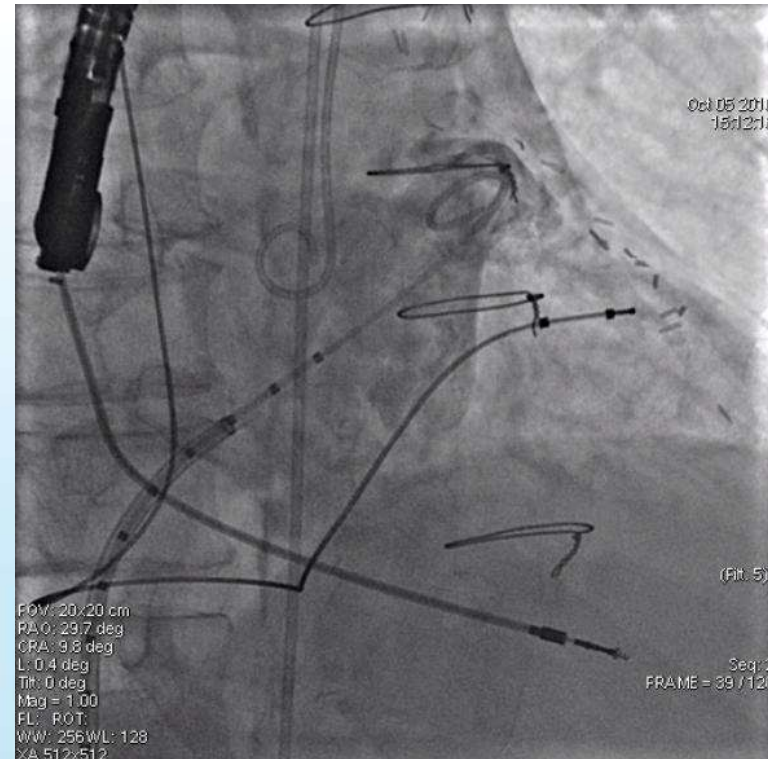
Recommendations	Class ^a	Level ^b	Ref ^c
Interventional, percutaneous LAA closure may be considered in patients with a high stroke risk and contraindications for long-term oral anticoagulation.	IIb	B	115, 118
Surgical excision of the LAA may be considered in patients undergoing open heart surgery.	IIb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

Conclusiones

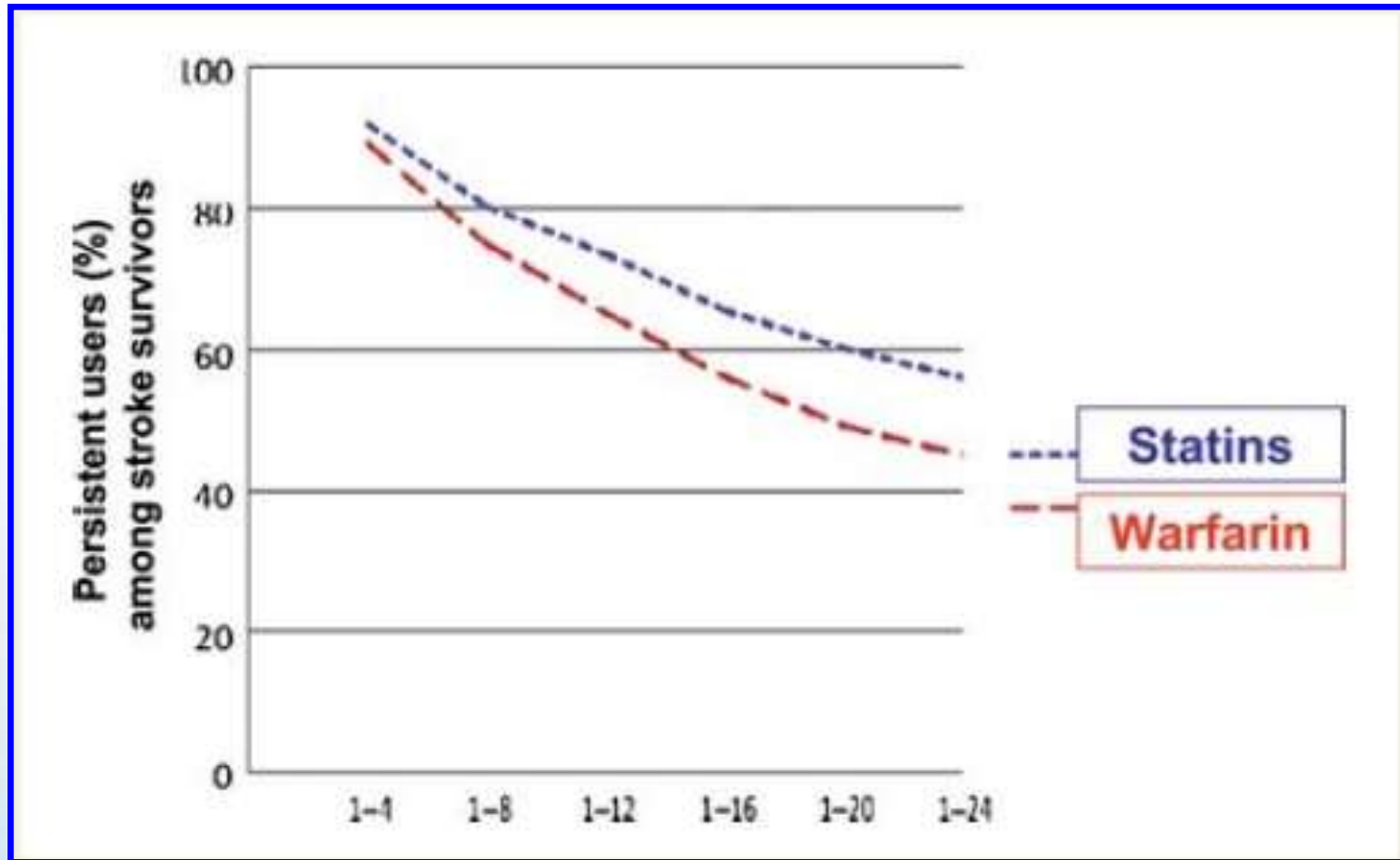


- La racionalidad del cierre percutáneo de la orejuela auricular izquierda en pacientes con FA permanente se basa en la evidencia que el 90% de los trombos se originan en ella.
- Diferentes estudios demostraron la factibilidad del procedimiento con alta tasa de implante exitoso en pacientes con contraindicación para ACO.
- El % stroke observado a 1 año y 5 años de seguimiento en los pacientes implantados fue 60% y 40% menor que el esperado de acuerdo a CHADS2 score.
- Datos del estudio PROTECT AF demuestran que en pacientes sin contraindicación para ACO, la oclusión de la orejuela no es inferior a warfarina en la prevención del stroke.
- Existen complicaciones tempranas inherentes al procedimiento y a la curva de aprendizaje, que disminuyen 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!!

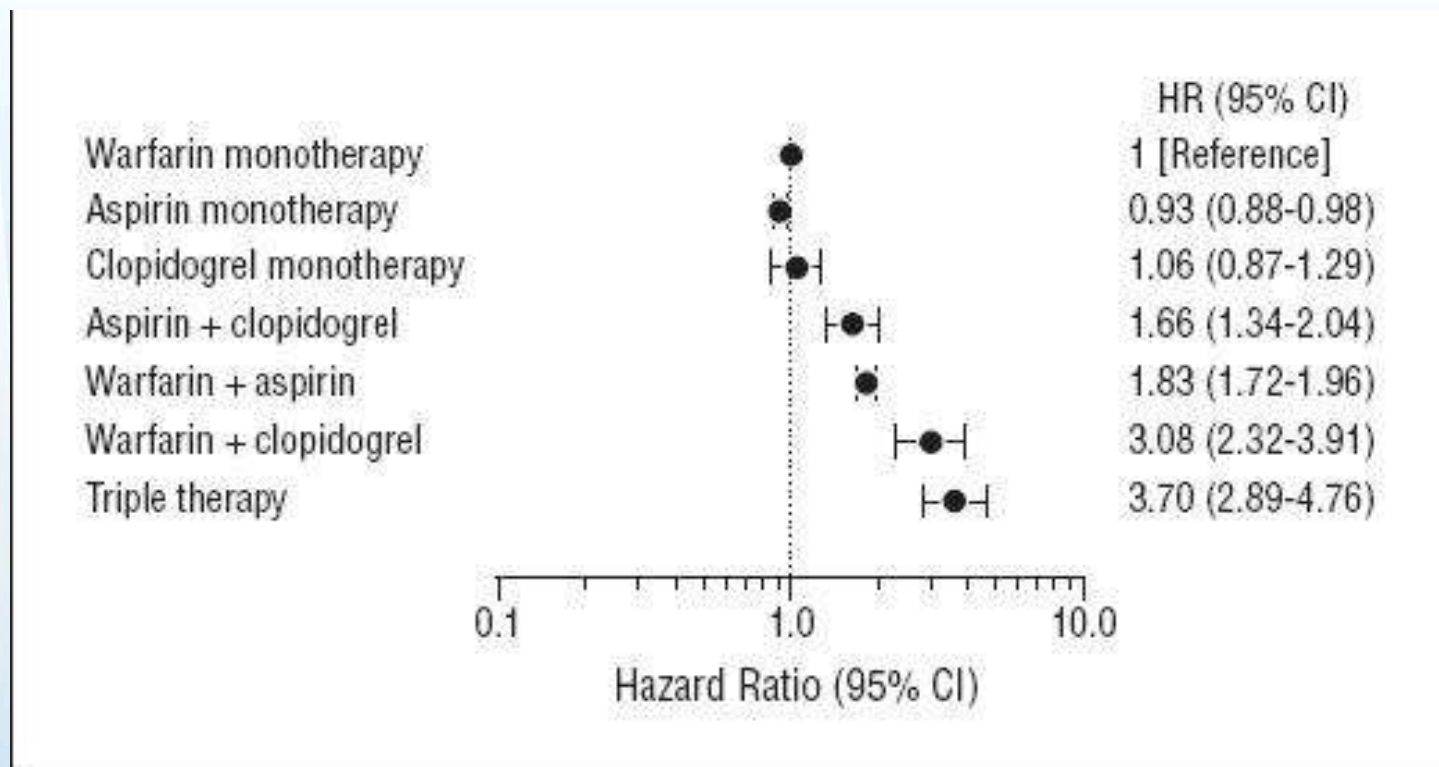


Swedish Stroke Registry



Efecto de múltiples antitrombóticos sobre el riesgo de sangrado

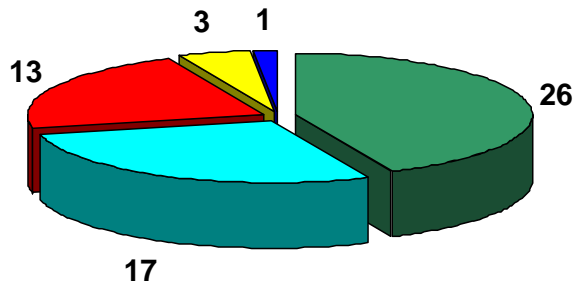
- Estudio de cohorte de 82854 pac en Dinamarca (13573 presentaron sangrado fatal o no fatal en el seguimiento a 2,6 años)



Results

N=60, June 2012

Procedures / Country



■ Brazil ■ Argentina ■ Chile ■ Venezuela ■ Uruguay





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

- 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.
- 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. 2 269-272
- Anticoagulant is not used (not prescribed and/or not taken), up to 60% of pts Gladstone et al. Stroke, 2009; 40:235-240
- The prevalence of contraindications is around 15% of clinical AF patients, Nijawlaat R. et al. Euroheart Survey, European Heart Journal (2005) 26, 2422-2434
- 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