VIII Congresso Nazionale
di Ecocardiochirurgia 2016

Minicorso sulle Patologie Cardioemboliche

Tecnica della chiusura per via percutanea dell'auricola sinistra e risultati

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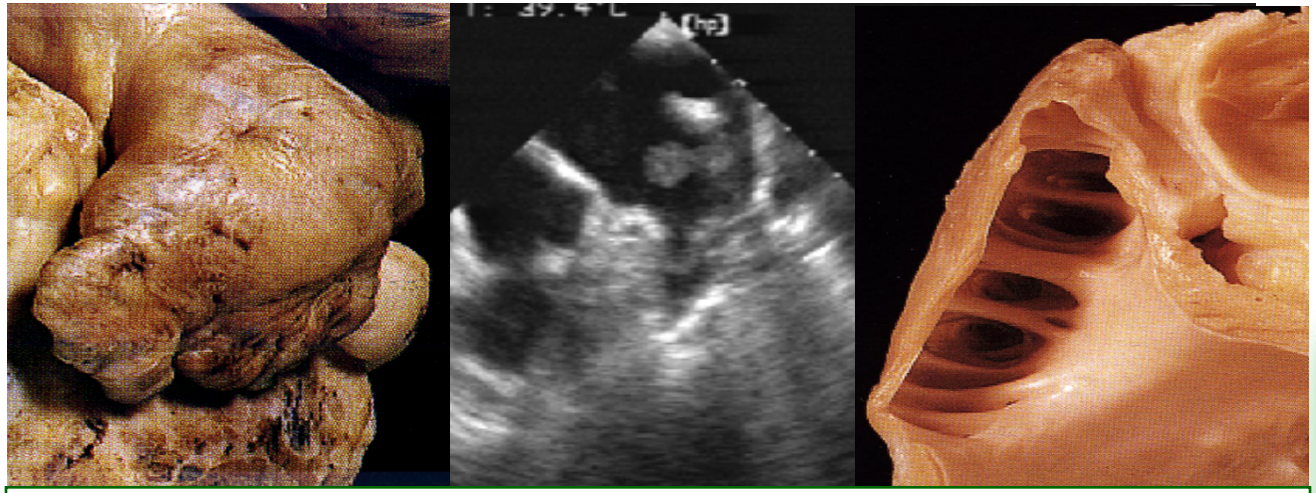
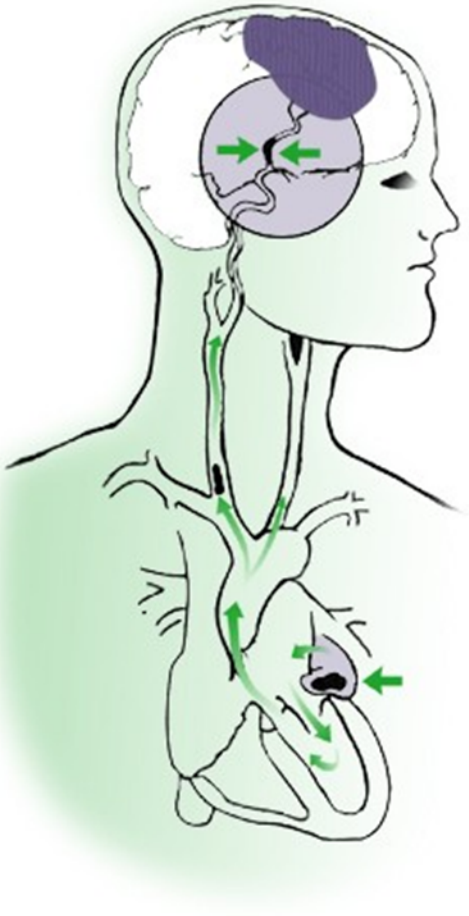
Trombosi dell'auricola sinistra all'Eco Trans-Esofageo (ETE)

- **L'auricola sinistra** rappresenta la sede di origine dei trombi in oltre il **90%** dei pazienti **con fibrillazione atriale (FA) non valvolare**





I **trombi** che si formano nell'auricola sinistra possono **embolizzare a livello cerebrale**

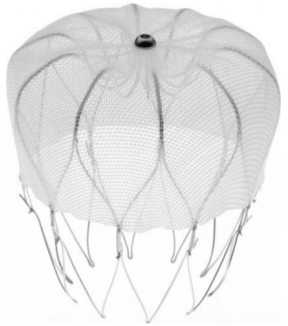
Utilizzazione della terapia anticoagulante orale (Warfarin) in pazienti con FA

~ 25% di tutti i pazienti con indicazione a **terapia anticoagulante orale** hanno una **controindicazione relativa o assoluta**

Bradley et al., Am J Cardiol 2000

- Questi pazienti possono richiedere una **terapia alternativa** per ridurre il rischio di stroke, come la **chiusura dell'auricola sinistra**

Devices per la Chiusura Percutanea dell'Auricola Sinistra

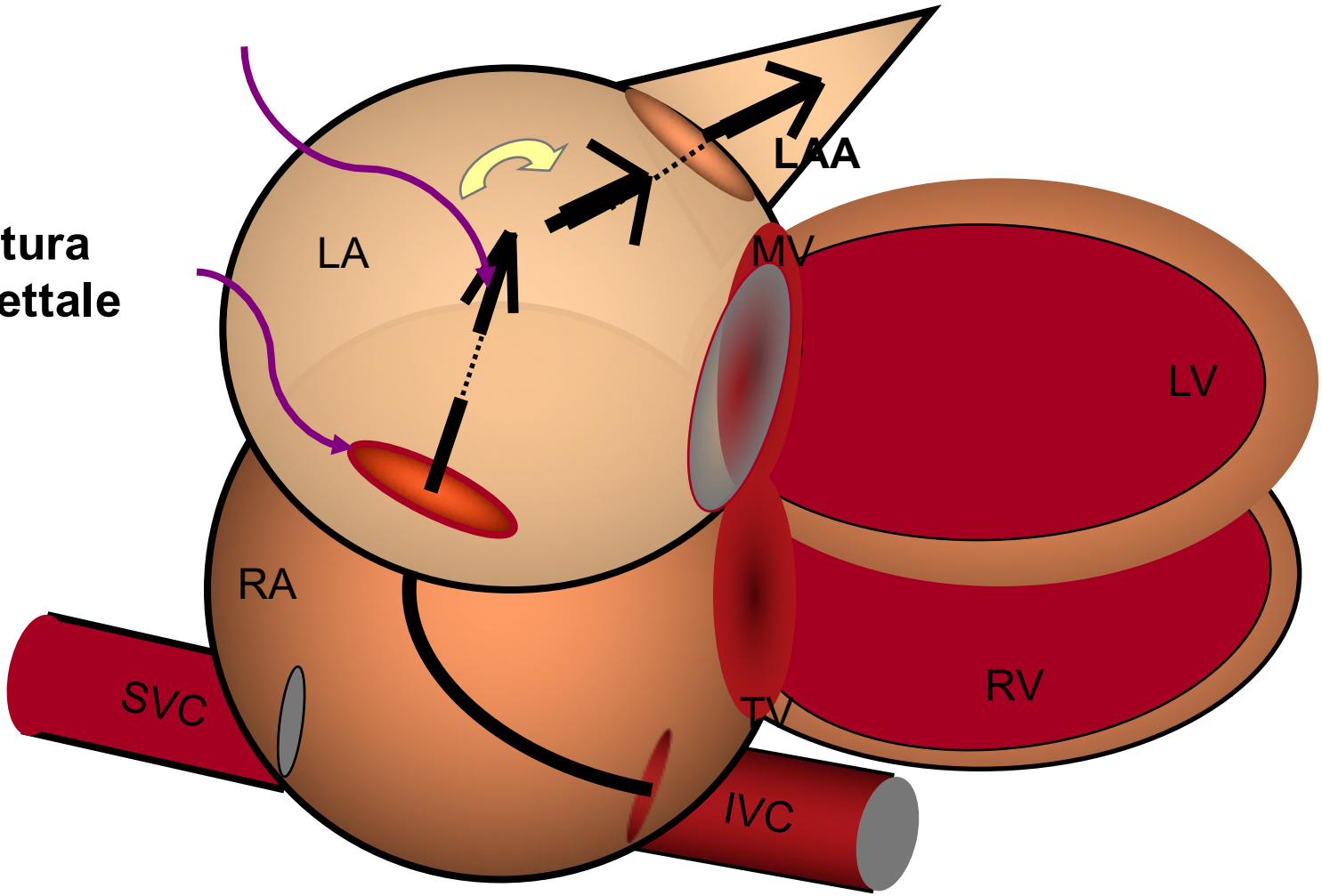
Amplatzer **AMULET**	**ACP**	**PLAATO**	**WATCHMAN**
 2013-2014			
CE Mark	September 2008	May 2002	October 2005
Device Materials	Braided nitinol frame	Nitinol cage frame	Nitinol basket frame
Device Anchoring System	Nitinol stabilizing wires/barbs	Nitinol stabilizing wires/barbs	Nitinol stabilizing wires/barbs
Occlusion Technology	Polyester patches	PTFE cover	Polyester cover
Device Sizes	16 - 30 mm	10 - 32 mm	21 - 33 mm
Delivery System Size	9-13 French	12-14 French	12-14 French

Chiusura Percutanea dell’ Auricola Sn

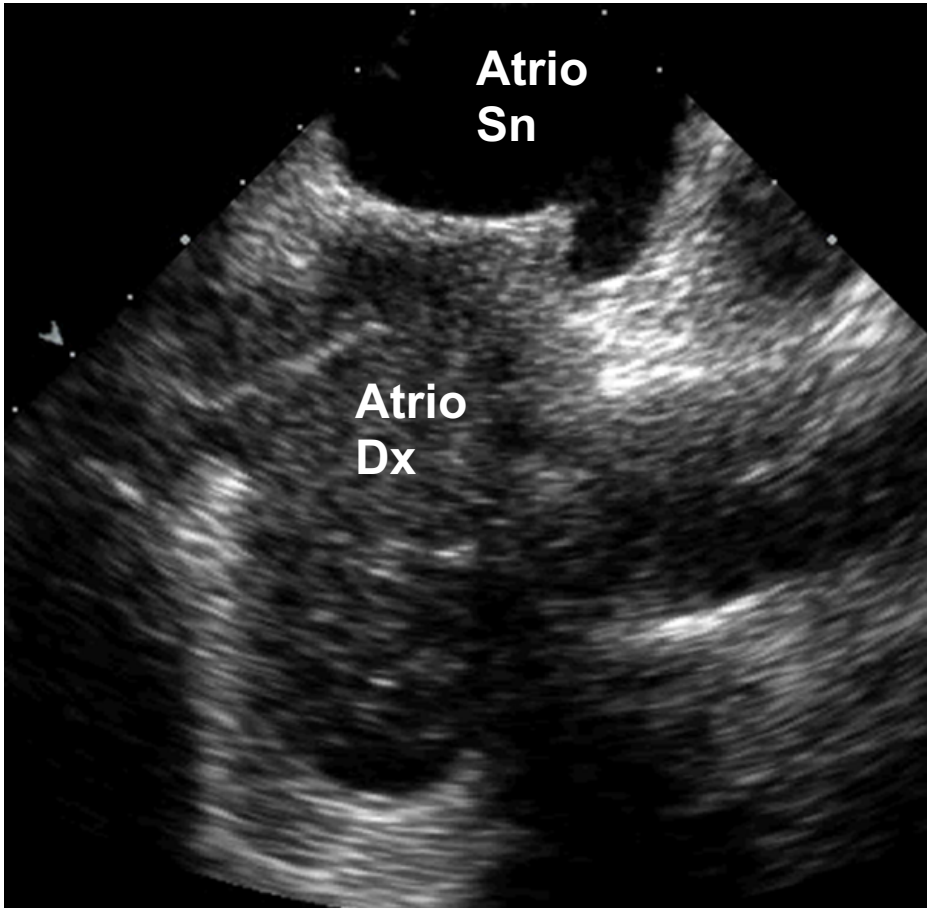
Tecnica di Impianto

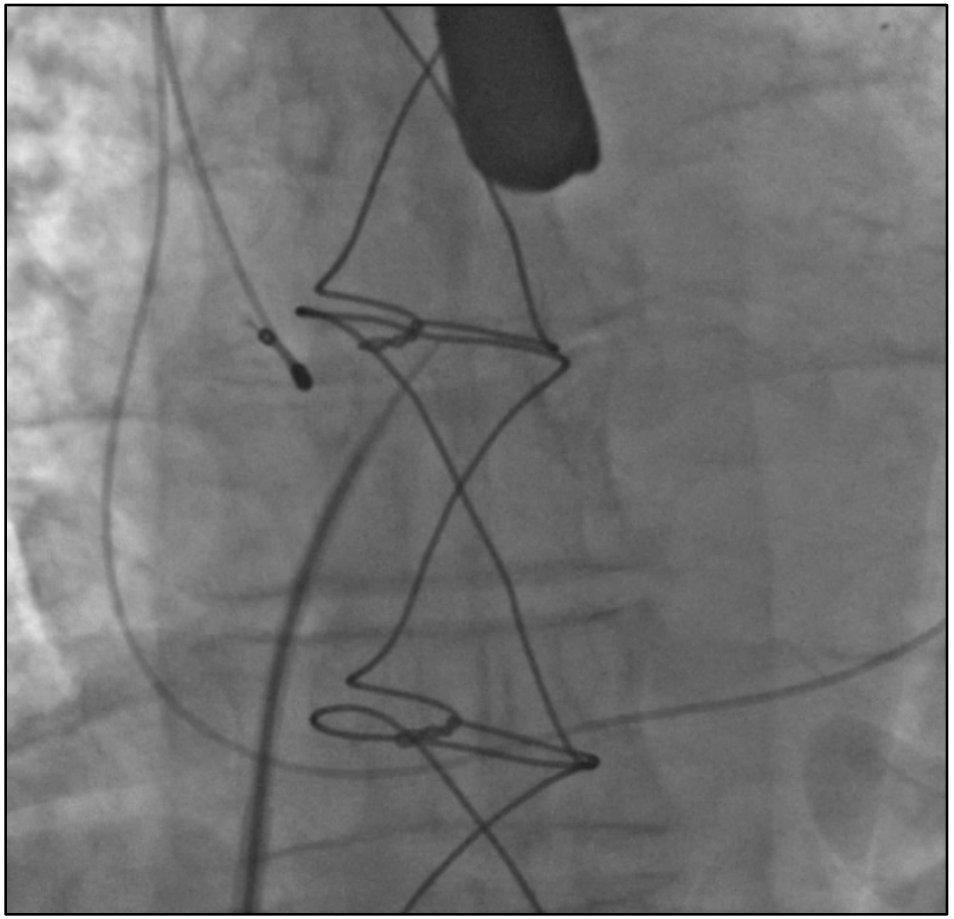
Orientamento verso L’auricola sinistra

Puntura transettale



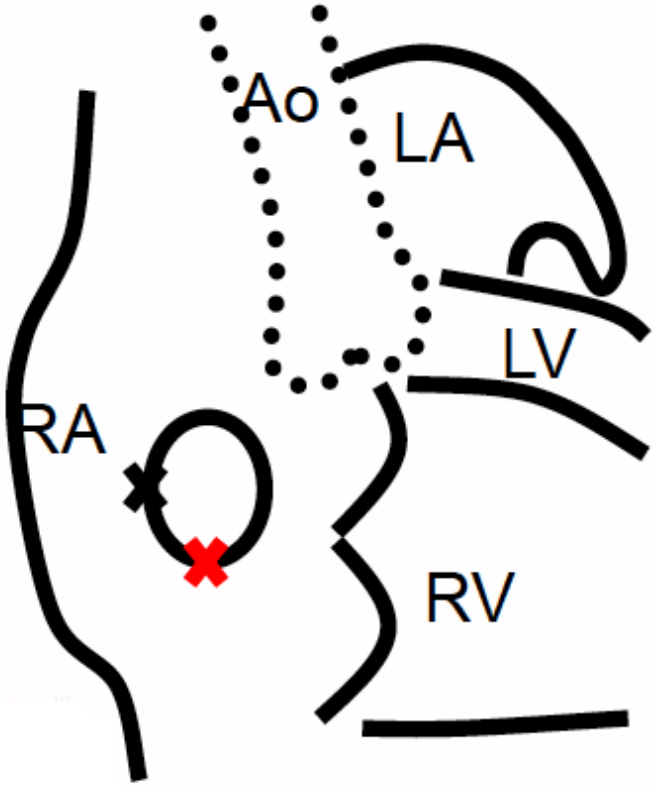
Puntura Transettale ETE guidata

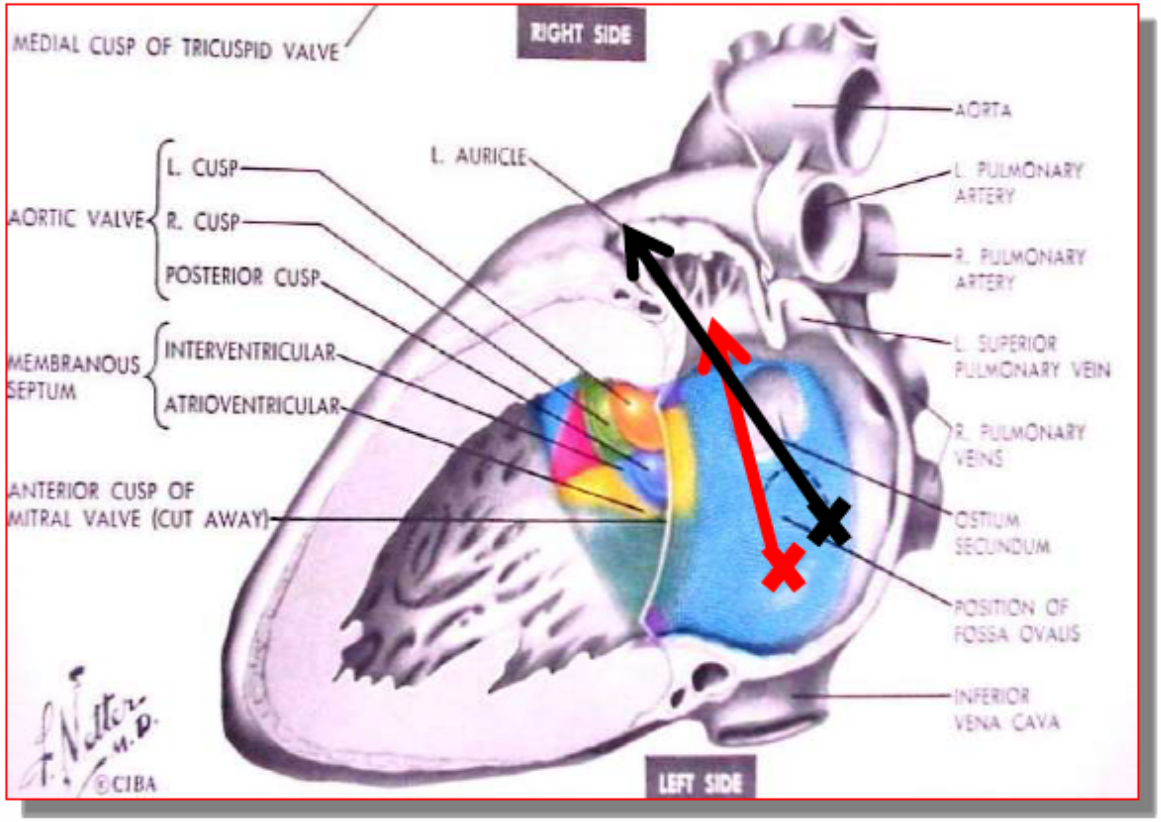




Puntura Transettale ETE guidata

- WATCHMAN
- ACP



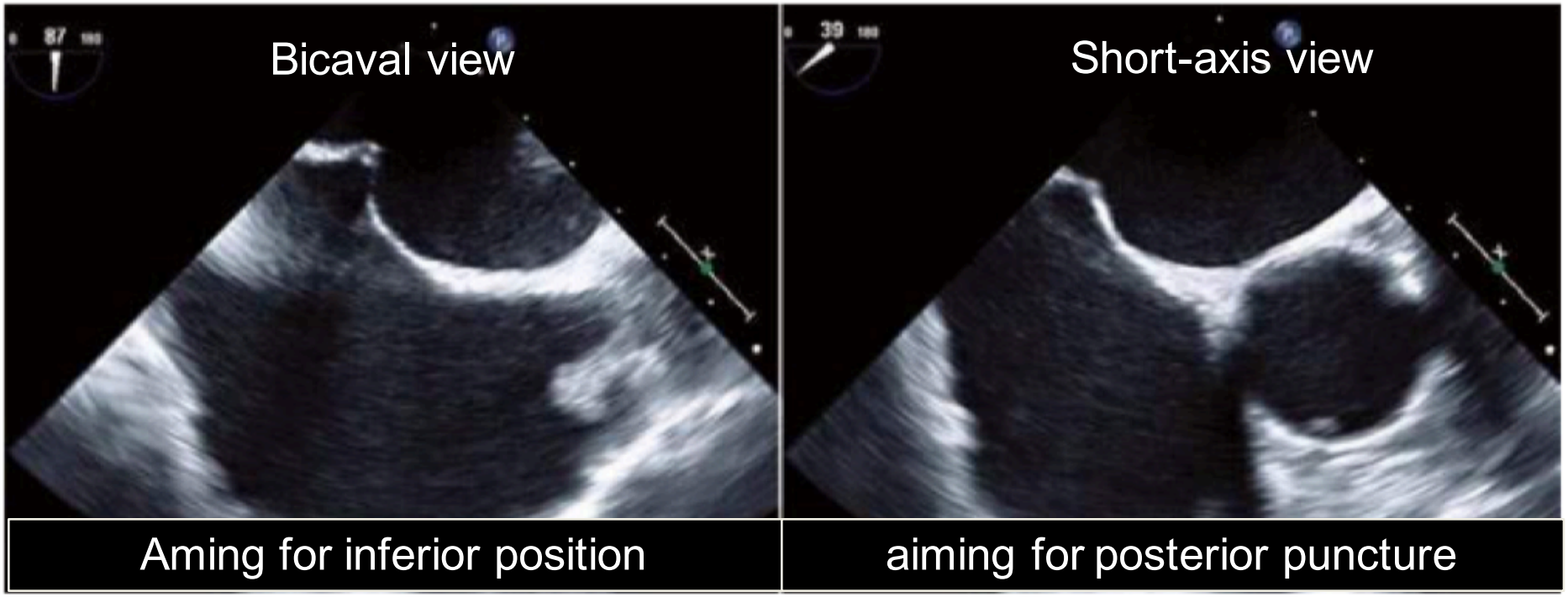


Imaging during transseptal puncture
Fluoroscopy and TEE are essential

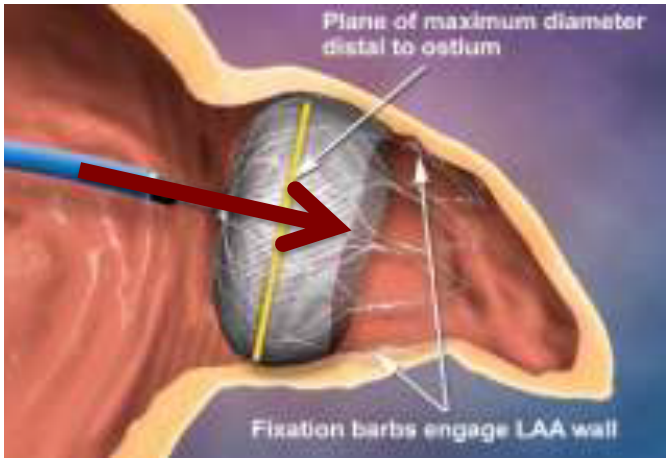
Fluoroscopy: AP view

+

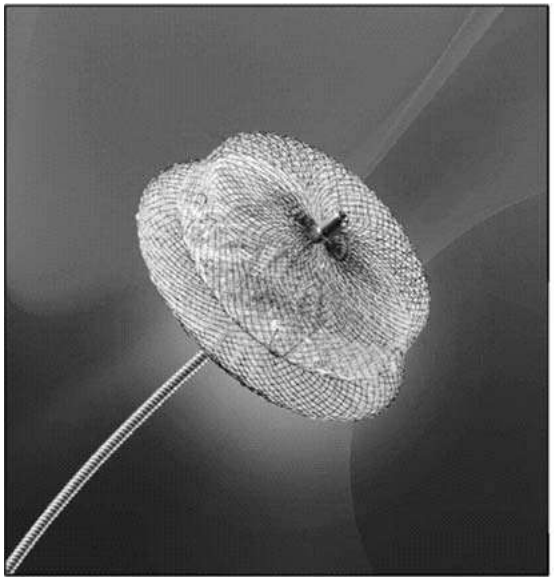
TEE

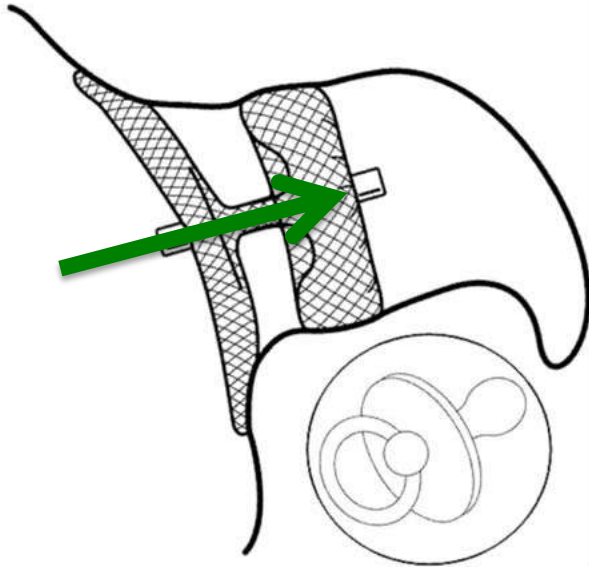


WATCHMAN

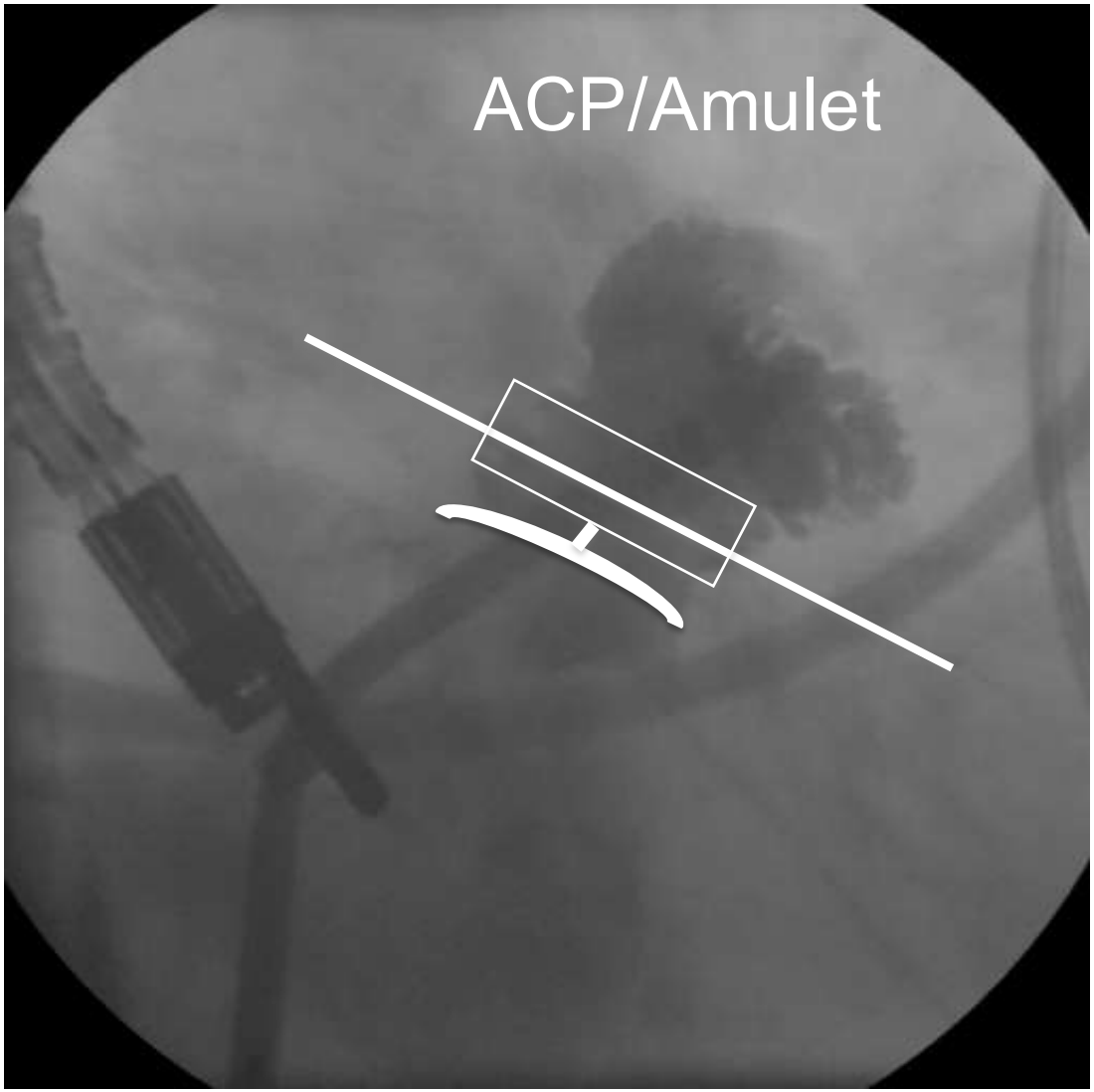


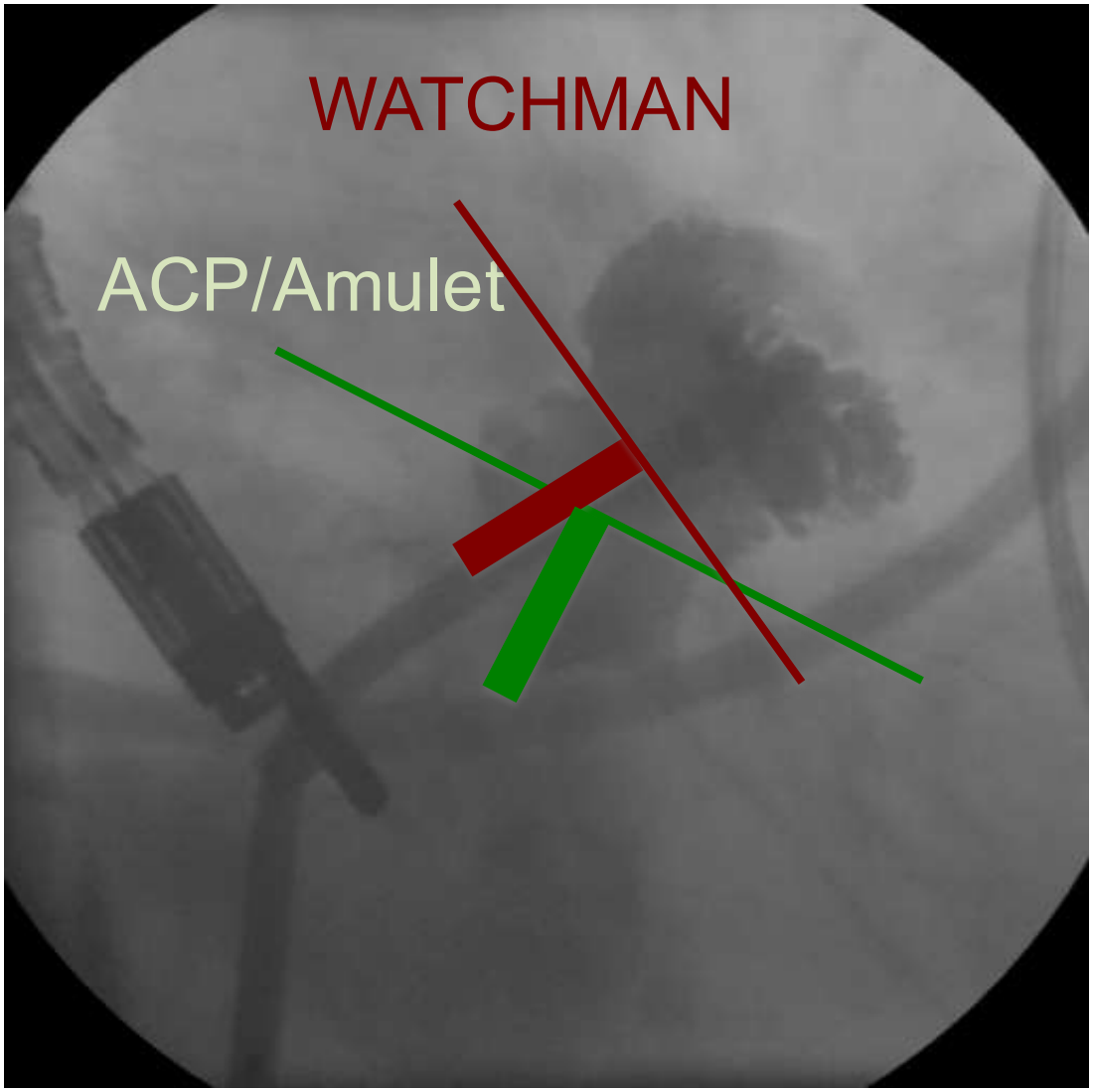
ACP/Amulet





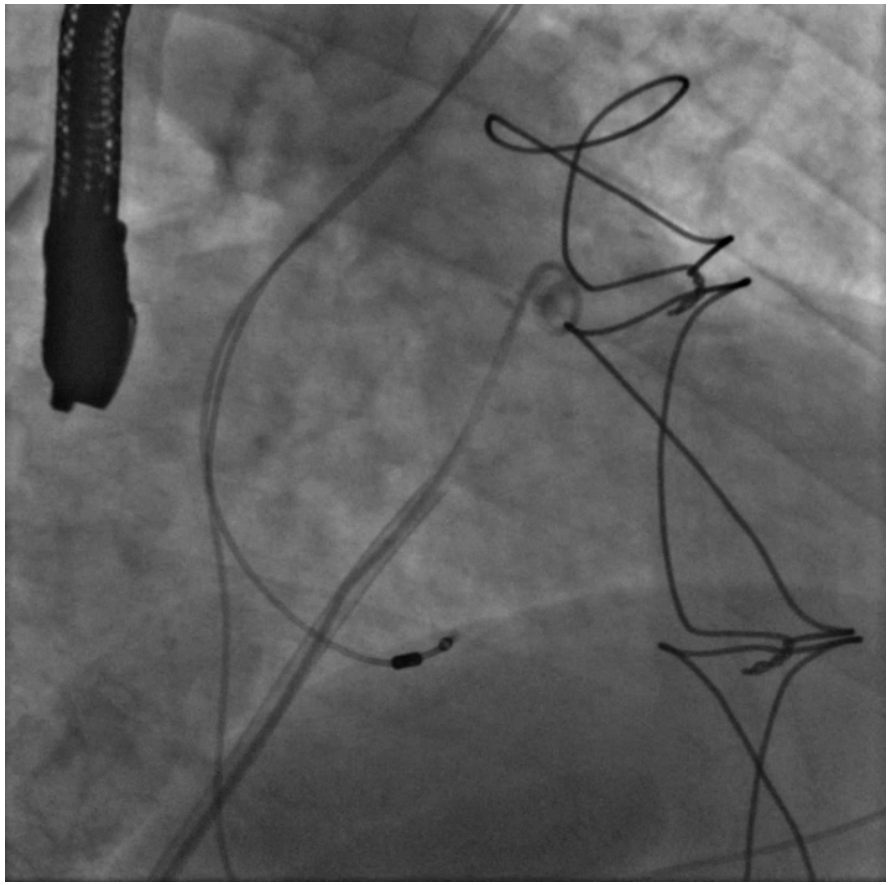

WATCHMAN


ACP/Amulet

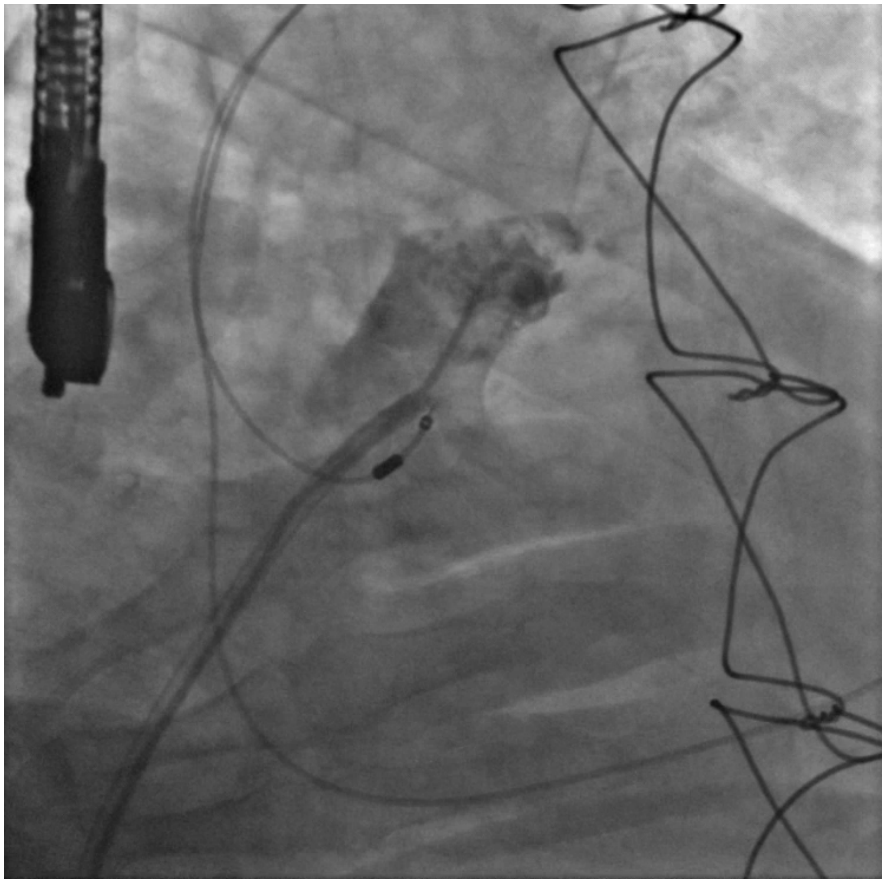

WATCHMAN
ACP/Amulet

AMPLATZER Cardiac Plug/Amulet

Tecnica di Impianto



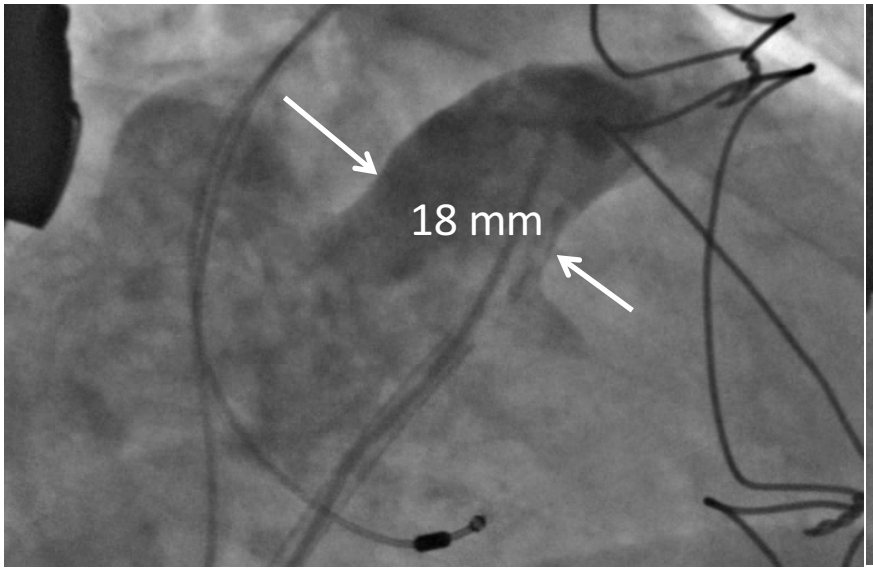
RAO 30 / Cran 20



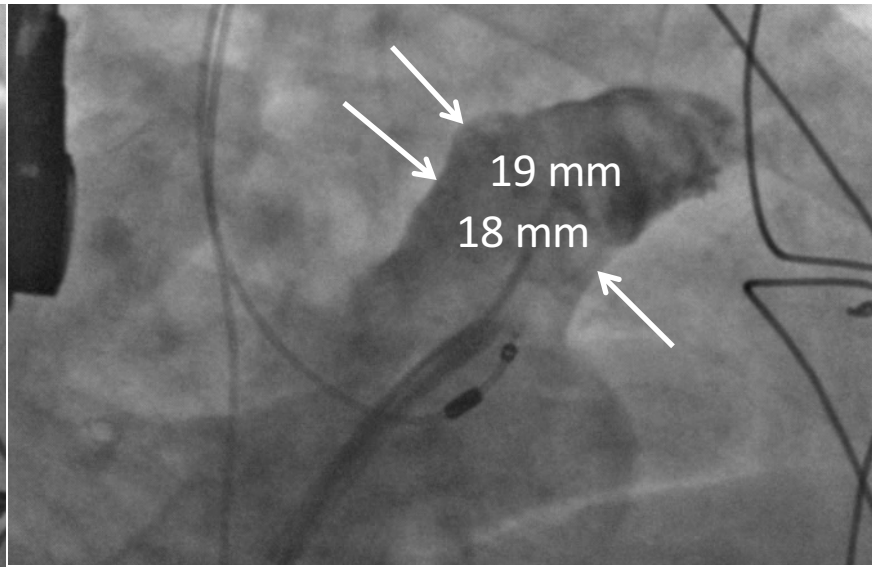
RAO 30 / Caud 20

Fluoroscopia

RAO 30 / Cran 20

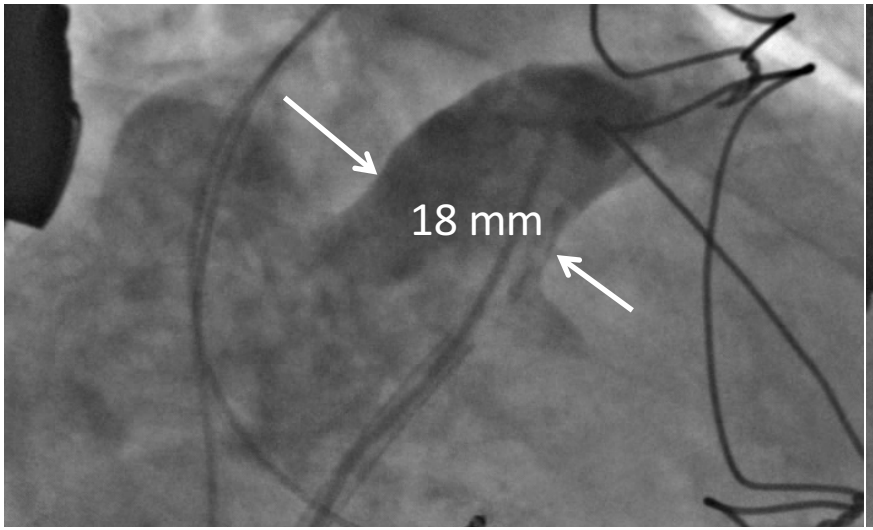


RAO 30 / Caud 20

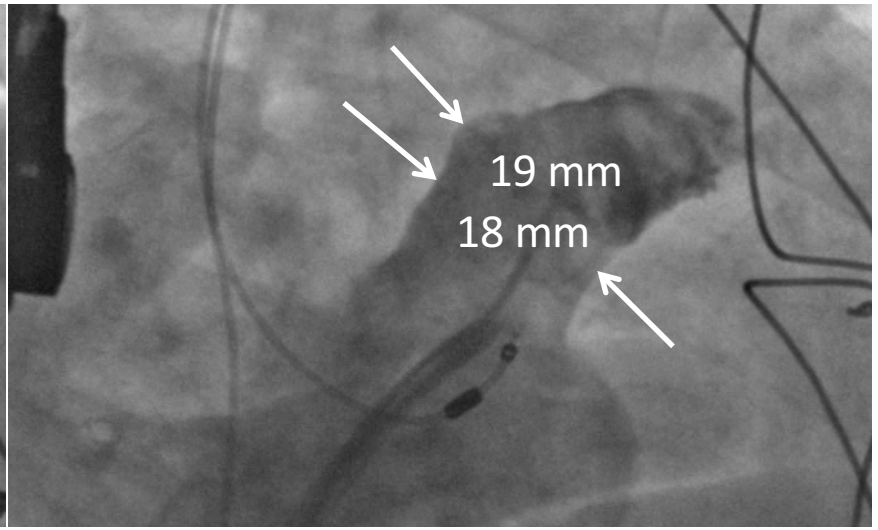


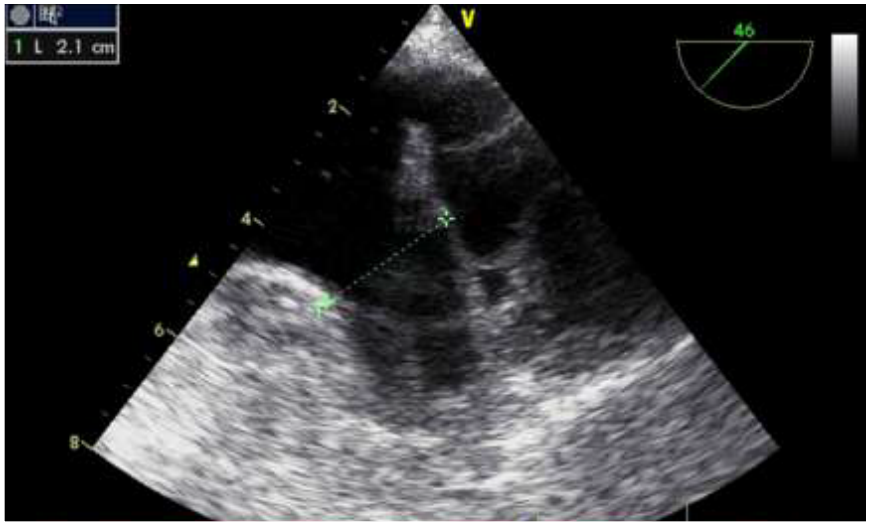
Fluoroscopia

RAO 30 / Cran 20

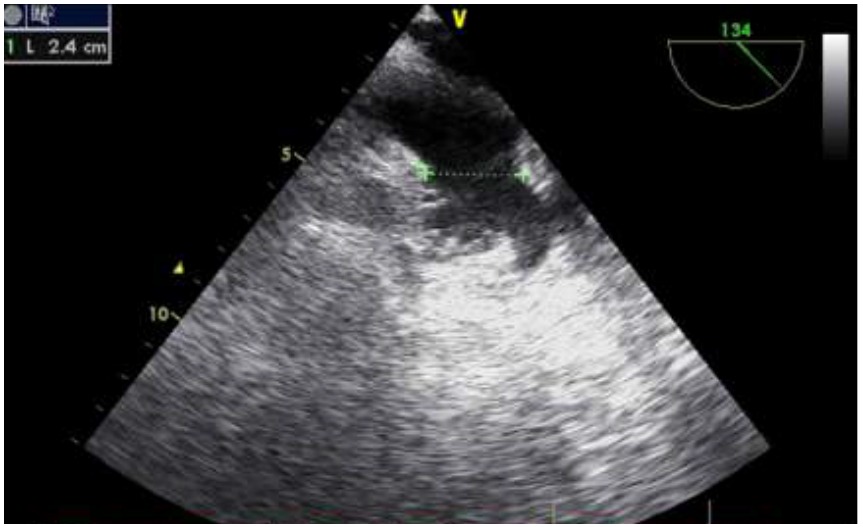


RAO 30 / Caud 20





45°



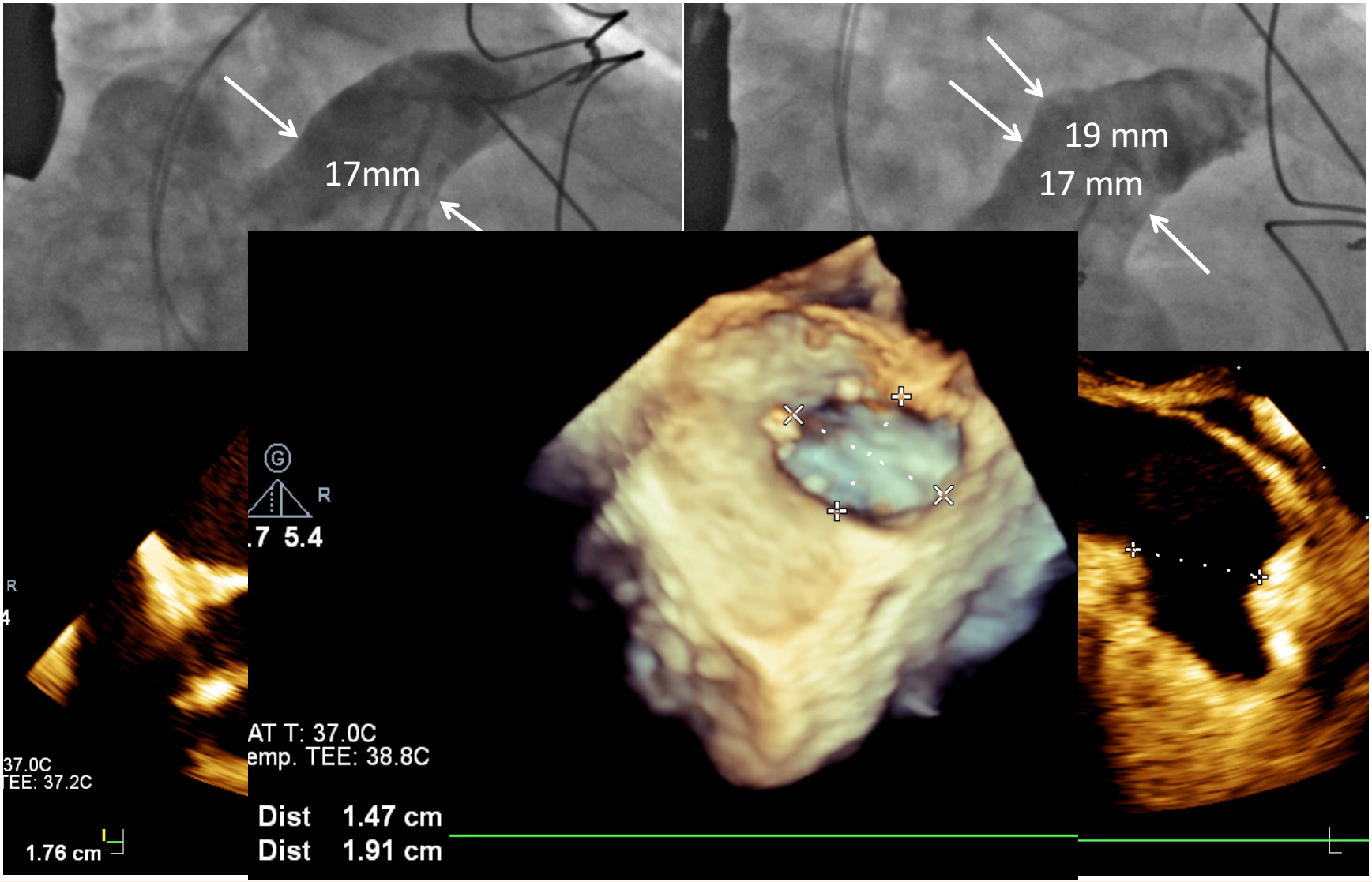
135°

ETE

Fluoroscopia

RAO 30 / Cran 20

RAO 30 / Caud 20

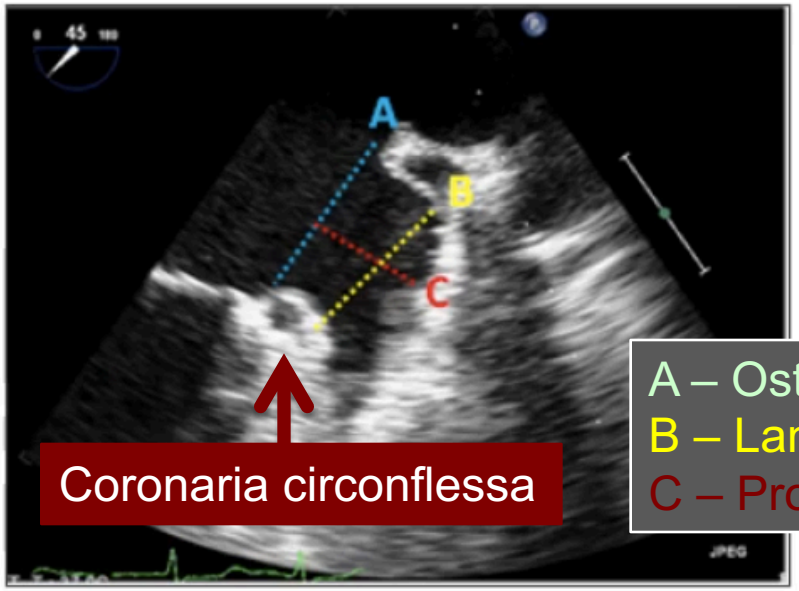


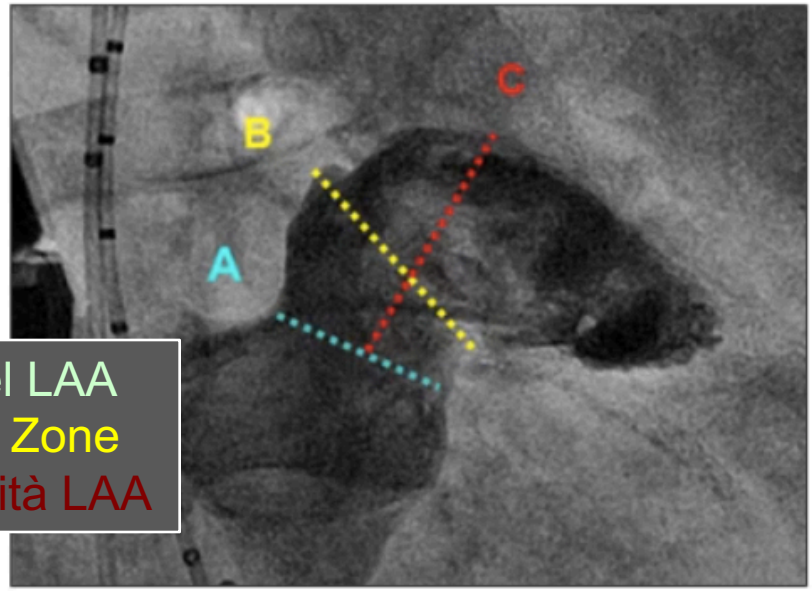
ETE

Misure dell'auricola (LAA)

Devono essere sia **ecocardiografiche** che **angiografiche**:

1. Diametro dell'**ostio** della LAA (**A**)
2. Diametro della **Landing Zone** (**B**)
   - 10-12 mm dall'ostio in relazione al tipo di device (ACP vs Amulet)
   - Parallelamento al collo della LAA
3. **Profondità** della LAA (**C**)

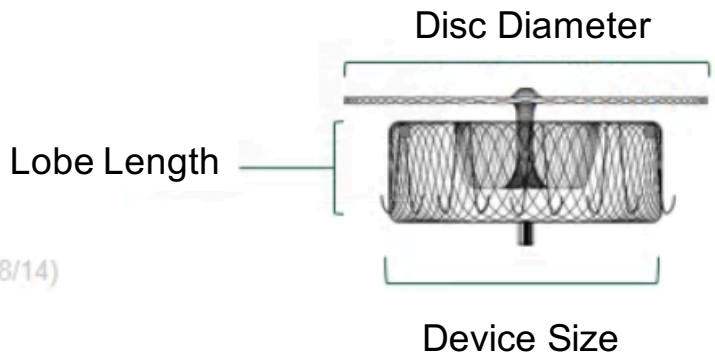




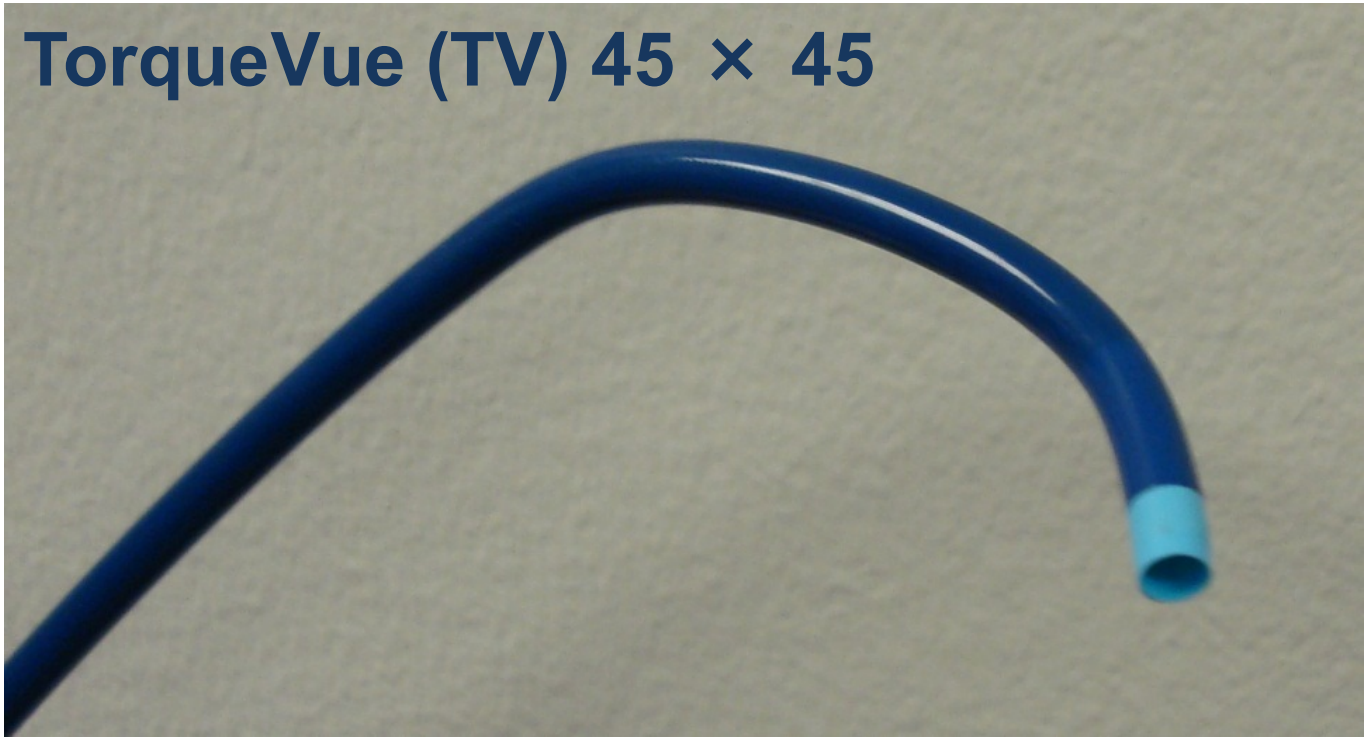
A – Ostio del LAA
B – Landing Zone
C – Profondità LAA

AMPLATZER Amulet Device Size Selection

Maximum Landing Zone Width (mm)	Amulet™ Device Size	Lobe Length (mm)	Minimum LAA Depth (mm)	Disc Diameter (mm)	Sheath Diameter
11.0 - 13.0	**16**	7.5	>10	22	12 F *or* 14 F (with adaptor)
13.0 - 15.0	**18**	7.5	>10	24	
15.0 - 17.0	**20**	7.5	>10	26	
17.0 - 19.0	**22**	7.5	>10	28	
19.0 - 22.0	**25**	10	>12	32	
22.0 - 25.0	**28**	10	>12	35	14 F
25.0 - 28.0	**31**	10	>12	38	
28.0 - 31.0	**34**	10	>12	41	



AMPLATZER ACP/Amulet Delivery Catheter



- 100 cm length (from 9F to 14F)
- 3D curve to facilitate access to LAA
- 0.035 guide wire compatible dilator

Device Specifications

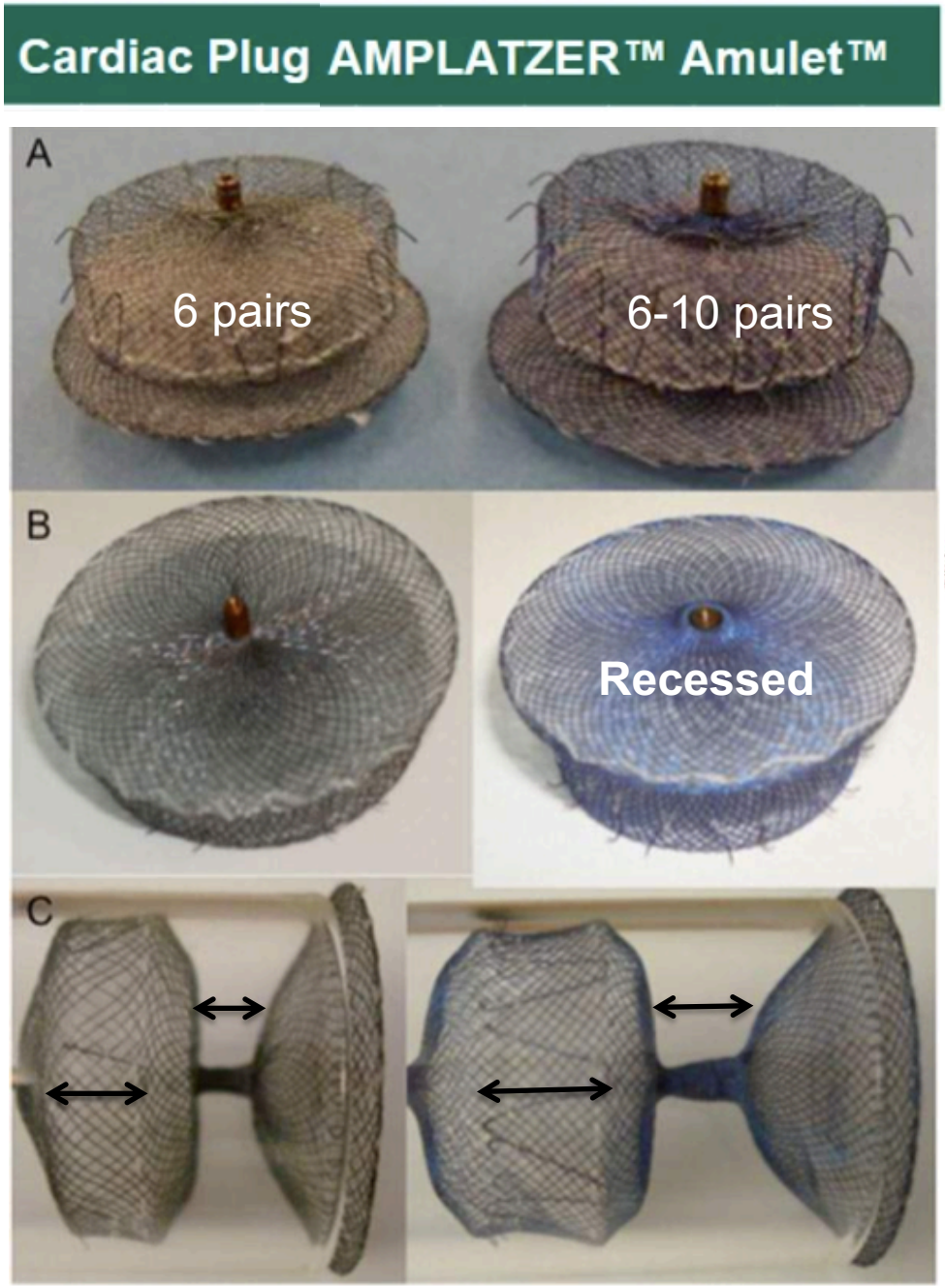
Feature	AMPLATZER™ Amulet™								AMPLATZER™ Cardiac Plug							
Size / Lobe Diameter (mm)	16	18	20	22	25	28	31	34	16	18	20	22	24	26	28	30
Disc Diameter	Lobe + 6 mm				Lobe + 7 mm				Lobe + 4 mm				Lobe + 6 mm			
Lobe Length	7.5 mm				10 mm				6.5 mm							
Waist Length	5.5 mm				8 mm				4 mm							
Stabilizing Wires	6 pairs		8 pairs			10 pairs			6 pairs							
Sheath Diameter	12F 14F (with Adaptor)					14F			9F		10F			13F		

Stabilizing Wires

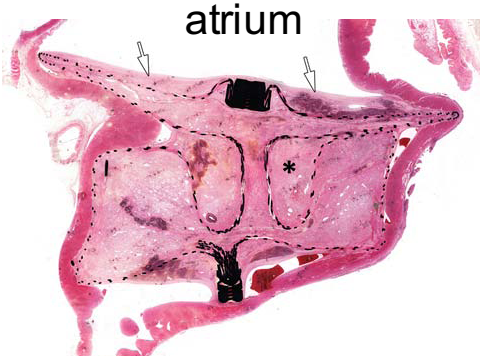
End Screw

Waist length

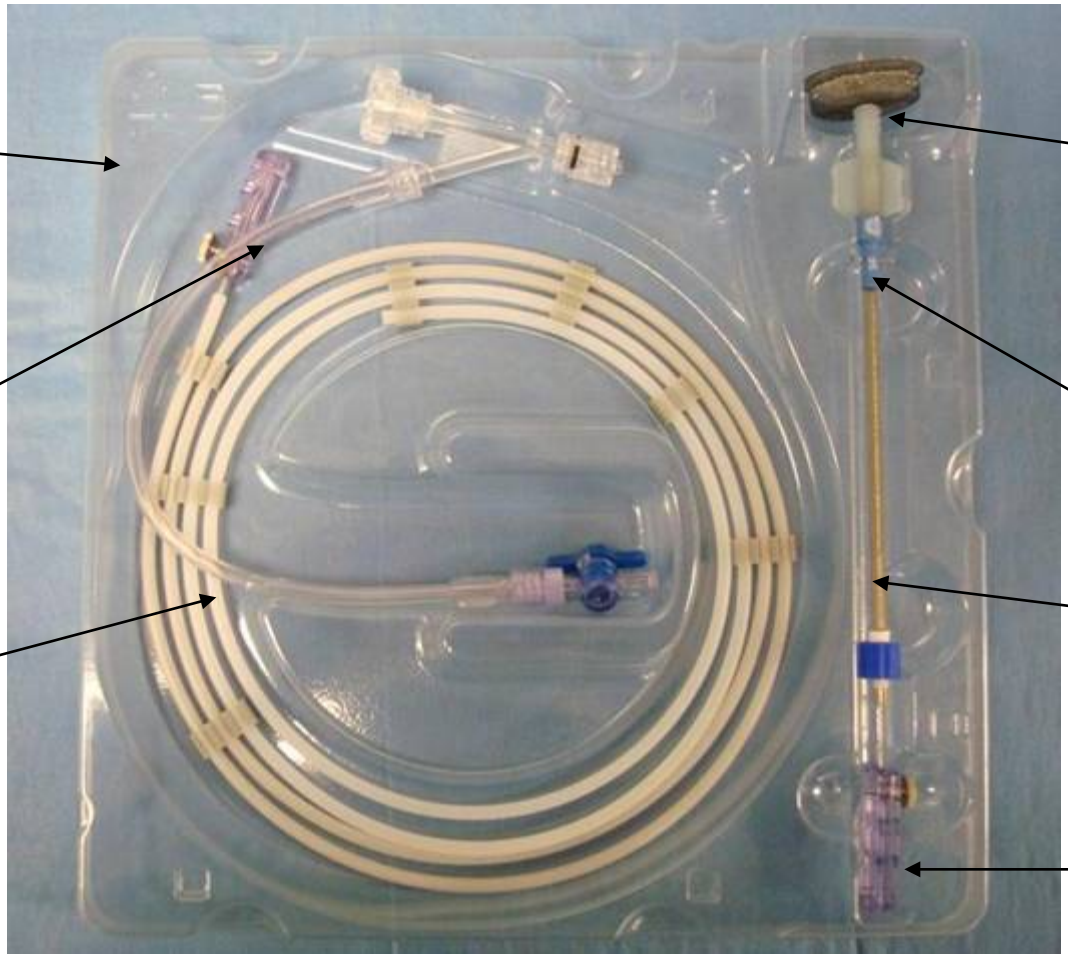
Lobe length



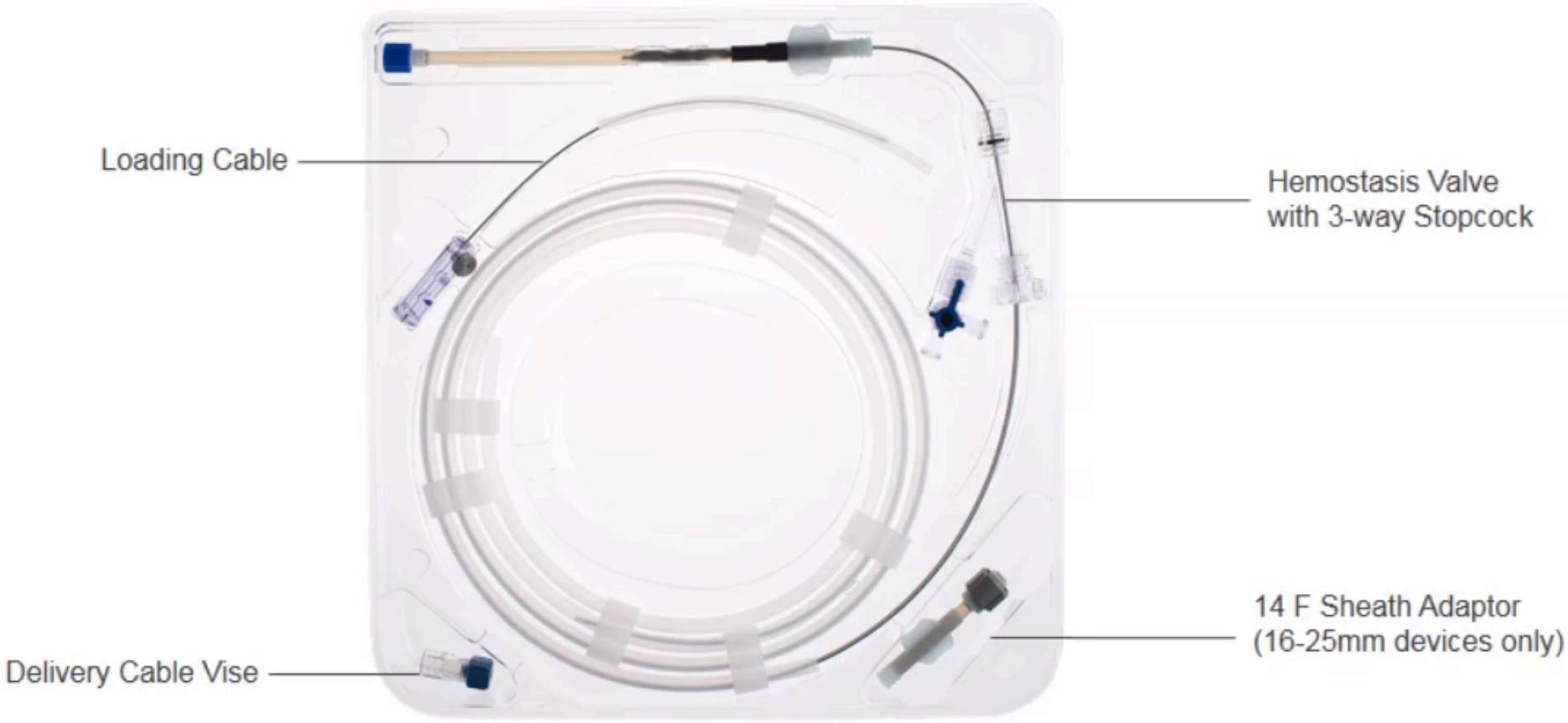
creates a uniform surface in the left atrium



AMPLATZER Cardiac Plug Laid out in a Plastic Tray

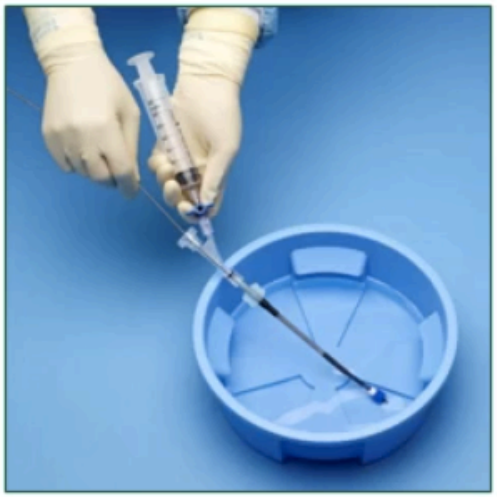


AMPLATZER Amulet Laid out in a Plastic Tray



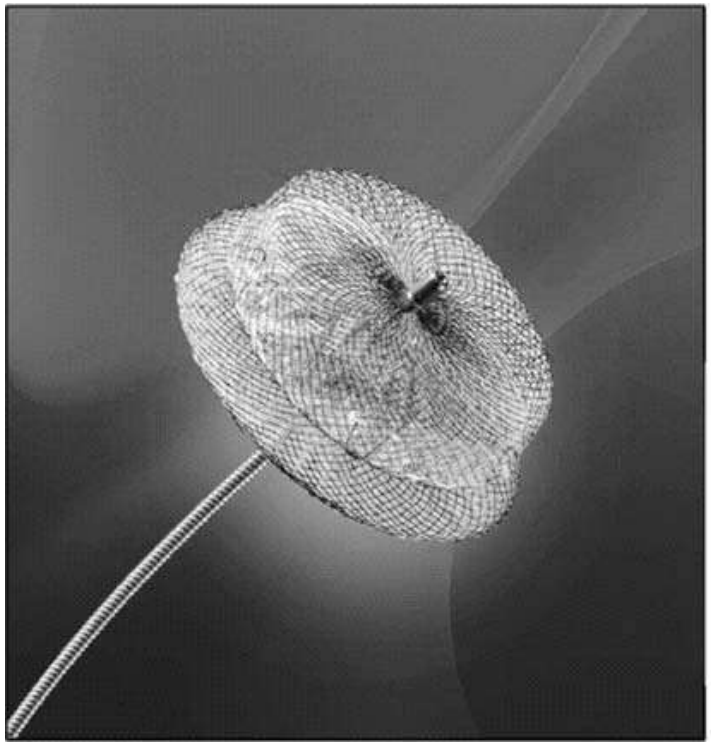
AMPLATZER Amulet Preparation

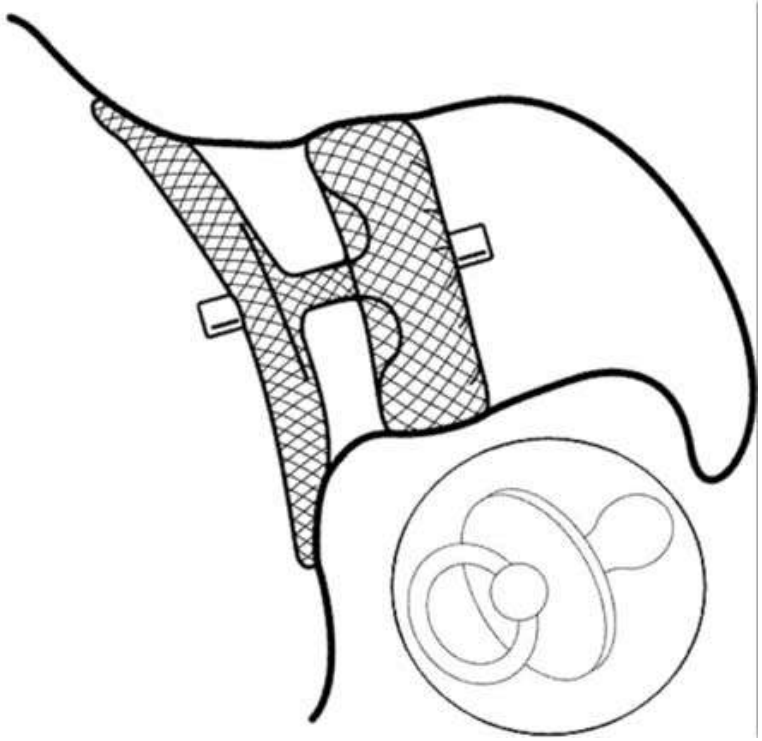
1. Connect the hemostasis valve to the loader.
2. Check and tighten all connections.
3. Advance the tip of the Amulet™ device to the tip of the loader.
4. De-air the hemostasis valve using a syringe of sterile saline.
5. Flush a 35 cc syringe of saline through the loader. Repeat.



6. Rapidly pull-back on syringe and then forward flush. Repeat.

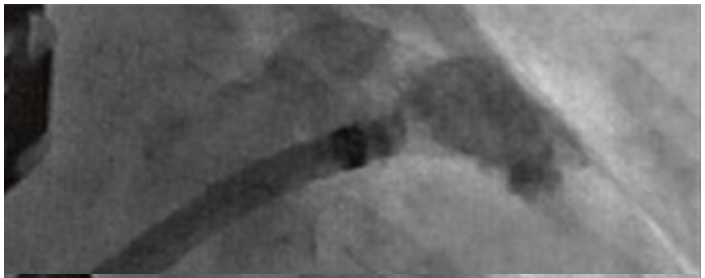
AMPLATZER Cardiac Plug & Amulet

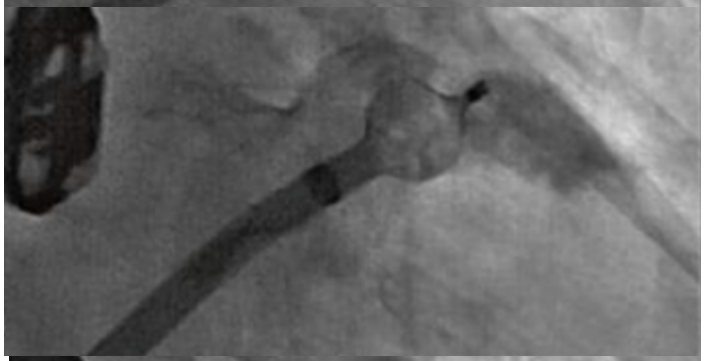


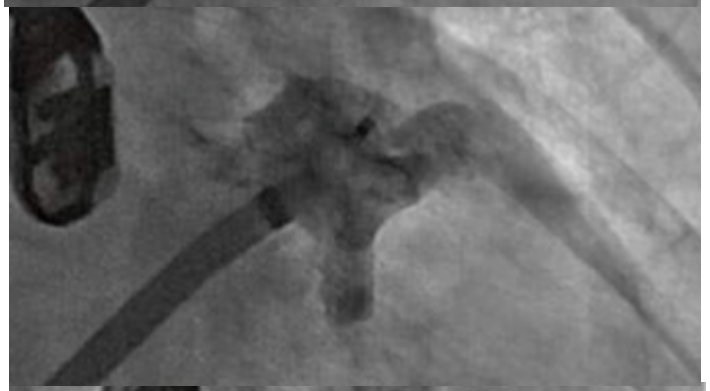


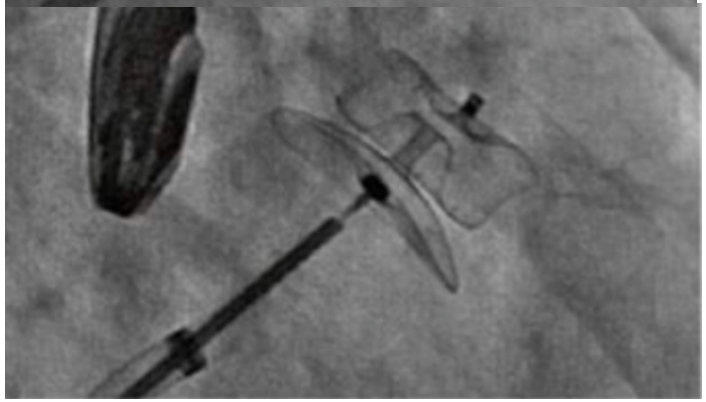
The **lobe** is deployed into the **LAA neck or directly distal to the LAA neck**

A complete sealing of the LAA-OS by the disc without remaining leakage is achieved because the **disc** and the **lobe** are **connected by a** short and narrow **waist** and can be separated and angulated









Steps della procedura di impianto (ACP/Amulet)

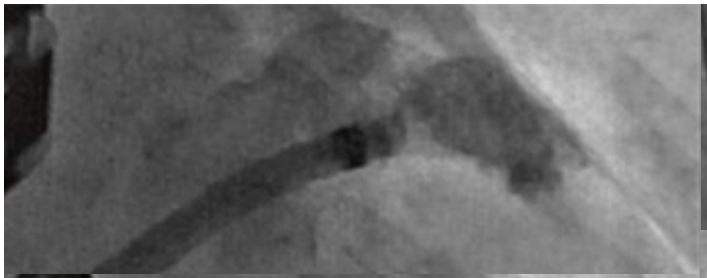
La punta dell ‘introduttore TorqueVue 45 × 45 sheath posizionata a livello della landing zone del lobo

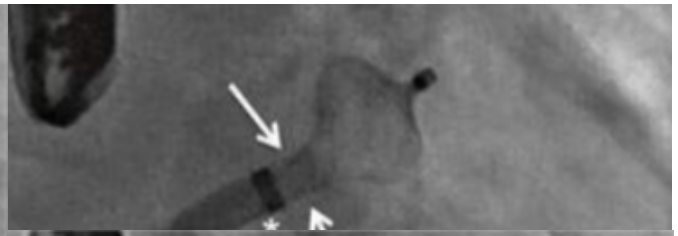
Iniziale rilascio del lobo (assume forma di palla)

Verifica del corretto impianto mediante i 5 segni

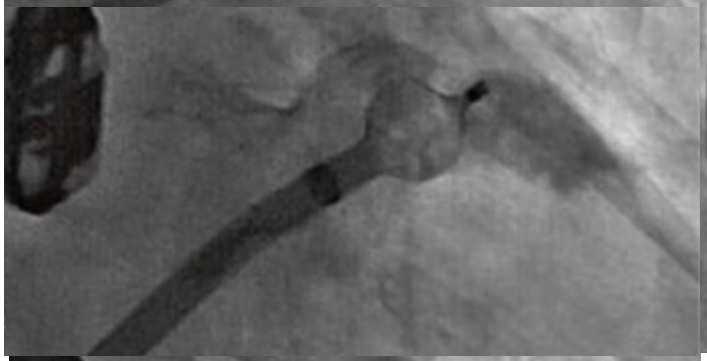
1. Il **lobo** deve essere leggermente **compresso** ✔
2. **Lobo** e **disco** devono essere **separati** ✔
3. Il **disco** deve essere **concavo** ✔
4. **Asse del lobo** deve essere **allineato** con **l’asse del collo** dell’auricola (LAA) ✔
5. **2/3 del lobo** devono essere oltre **l’arteria circonflessa** all’ETE ✗

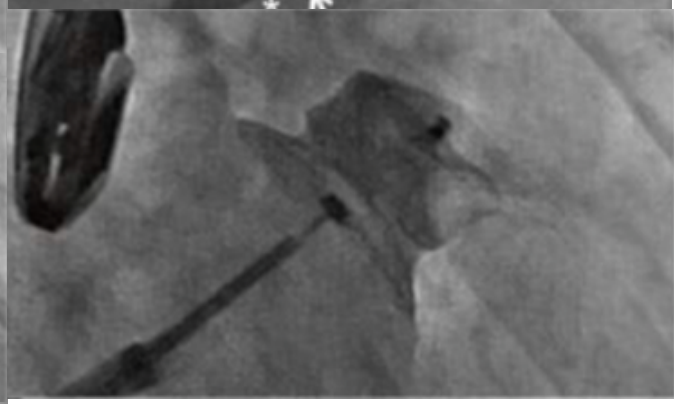
Se questi criteri non sono soddisfatti il device deve essere ricatturato



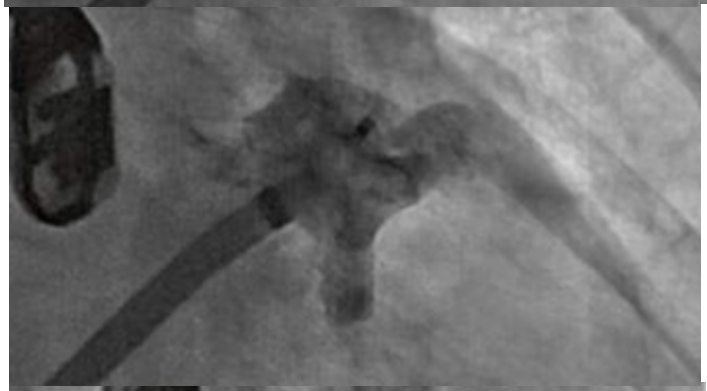


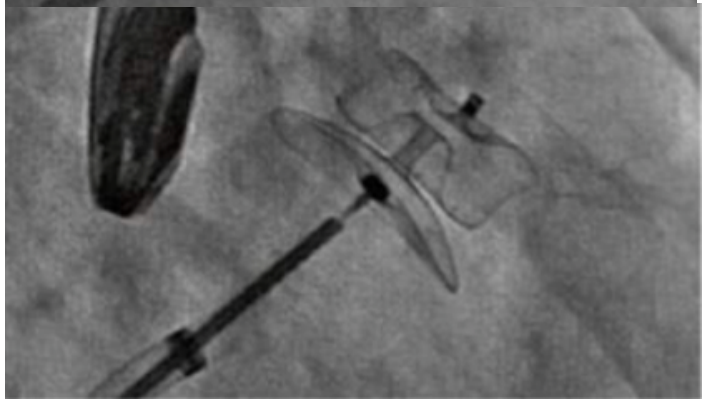
Ricattura completa del disco e parziale del lobo (riposizionamento)





Nuovo rilascio del disco in atrio sinistro

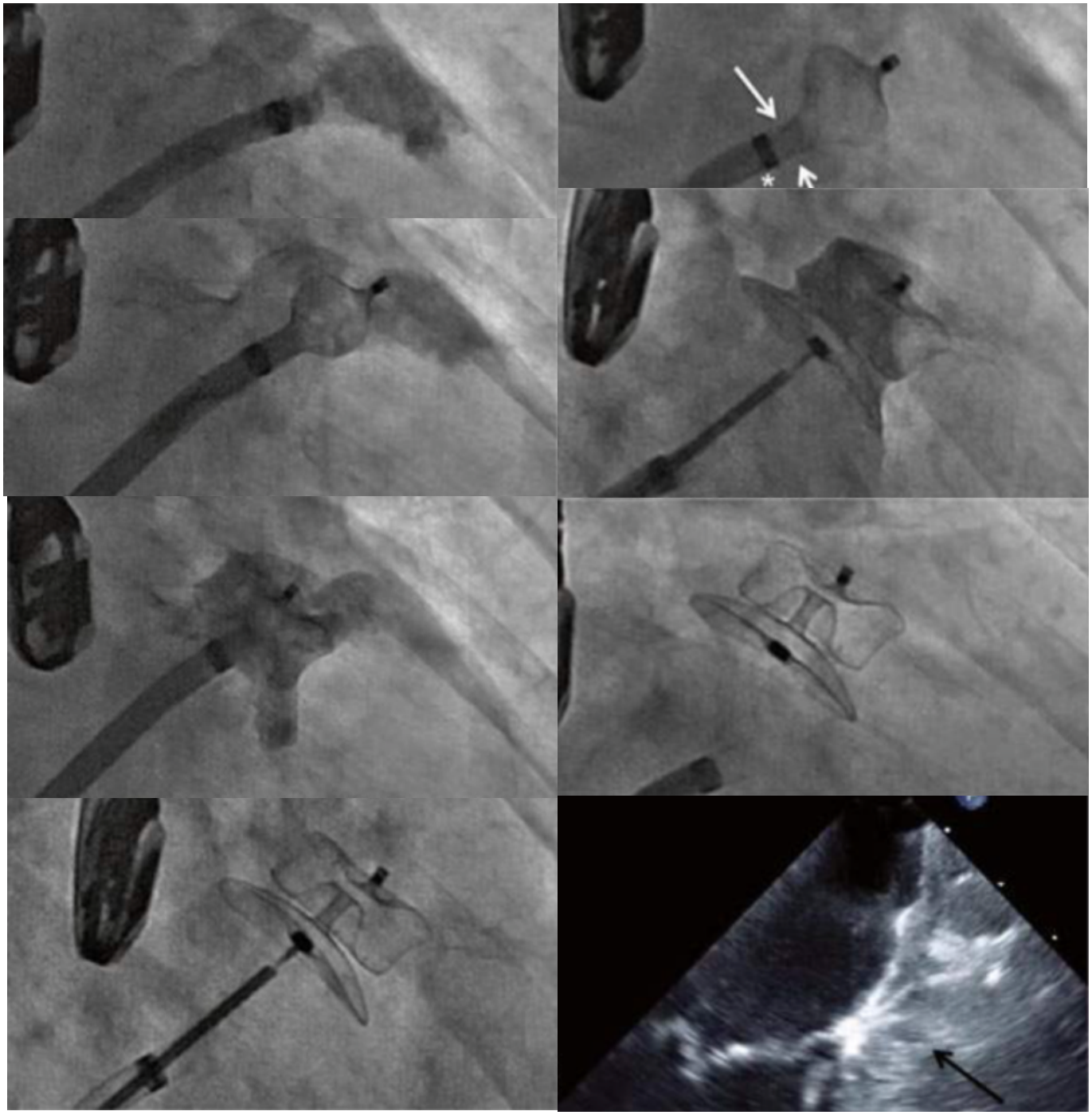




Verifica del corretto impianto mediante i 5 segni

1. Il **lobo** deve essere leggermente **compresso**
2. **Lobo** e **disco** devono essere **separati**
3. Il **disco** deve essere leggermente **concavo**
4. **Asse del lobo** deve essere **allineato** con **l'asse del collo** dell'auricola (LAA)
5. **2/3 del lobo** devono essere oltre **l'arteria circonflessa** all'ETE

Se questi criteri non sono soddisfatti il device deve essere ricatturato

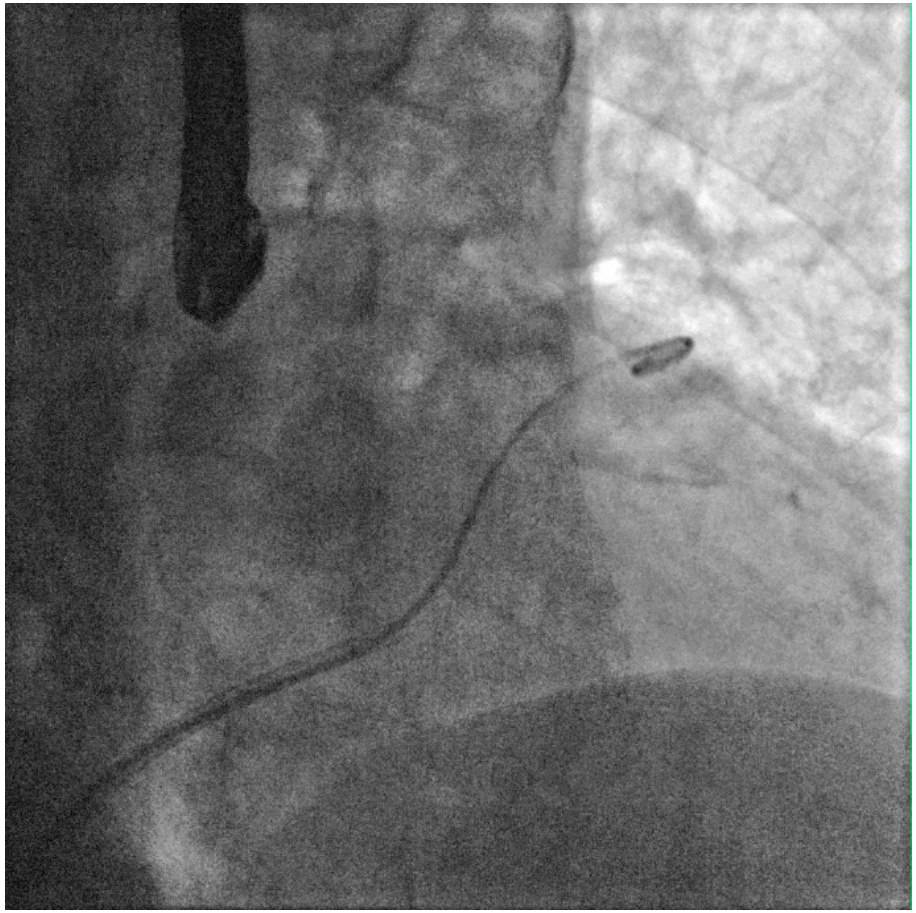


Rilascio del device

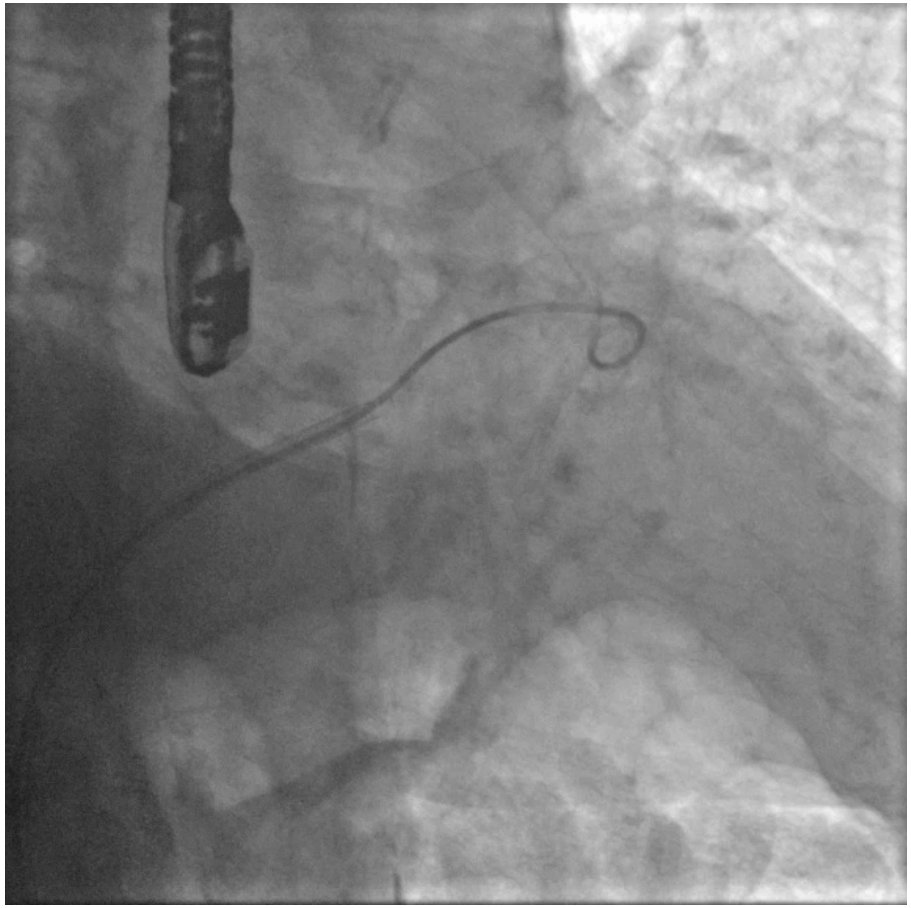
ETE mostra che il lobo del device è 2/3 oltre l’arteria circonflessa (freccia)

AMPLATZER Cardiac Plug

Il corretto posizionamento del device



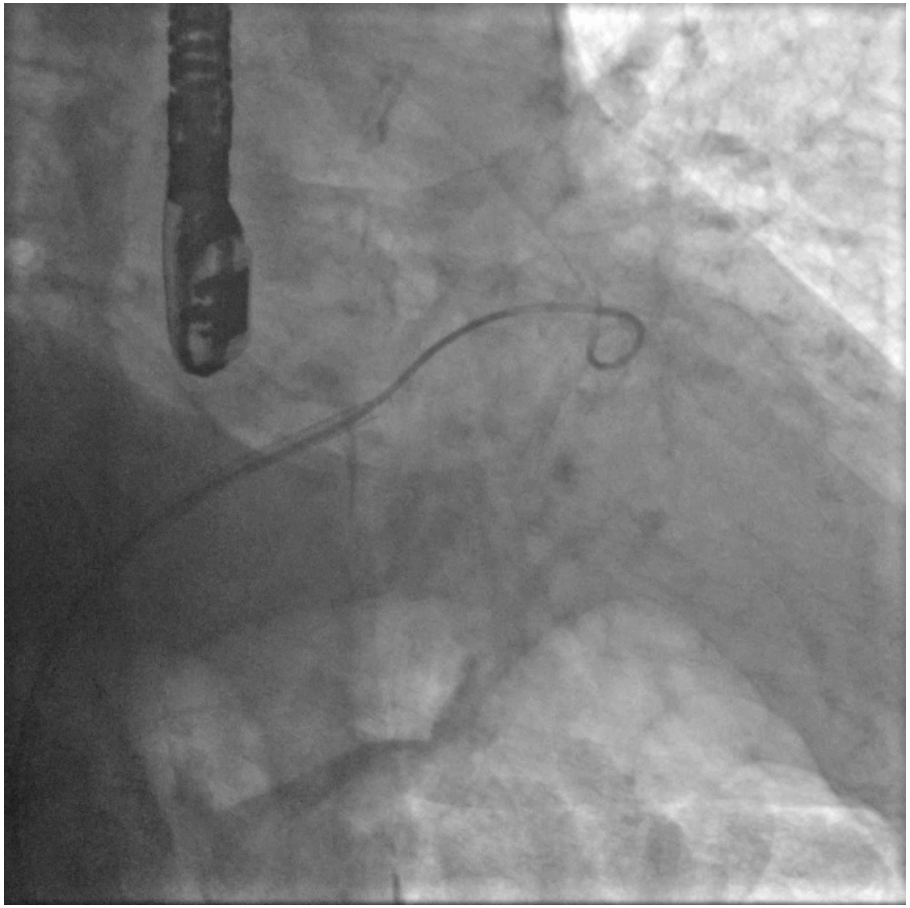
RAO 30 / Cran 20



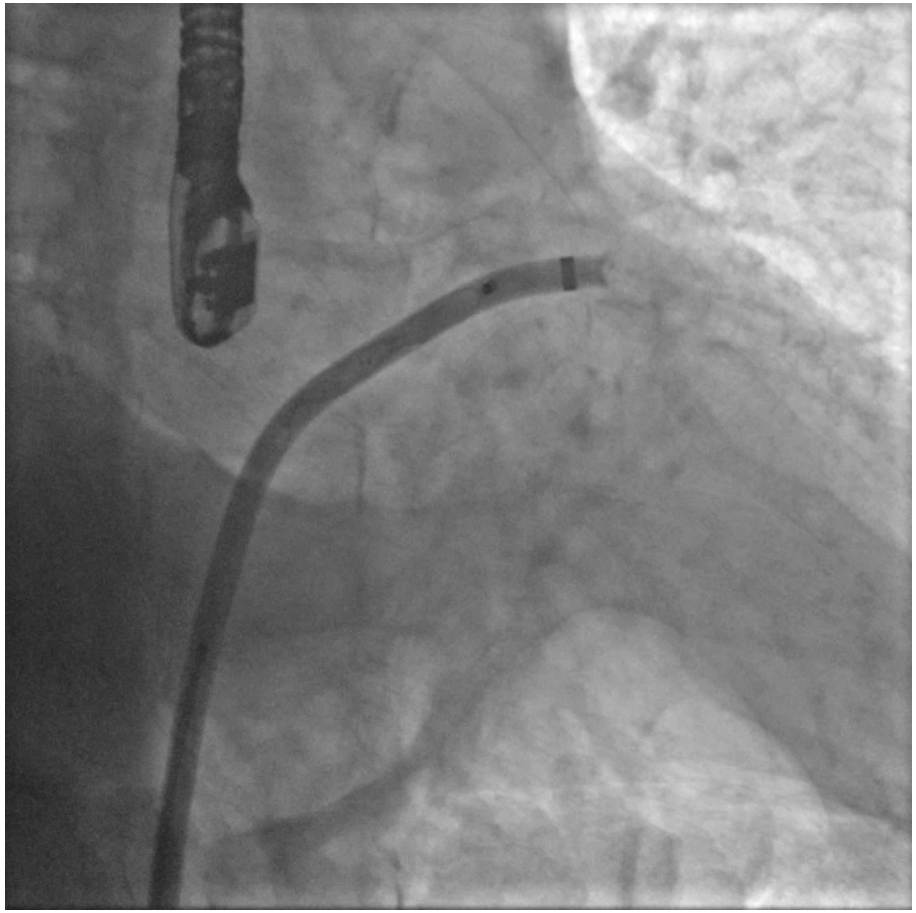
RAO 30 / Caud 20

AMPLATZER Cardiac Plug

Il corretto posizionamento del device



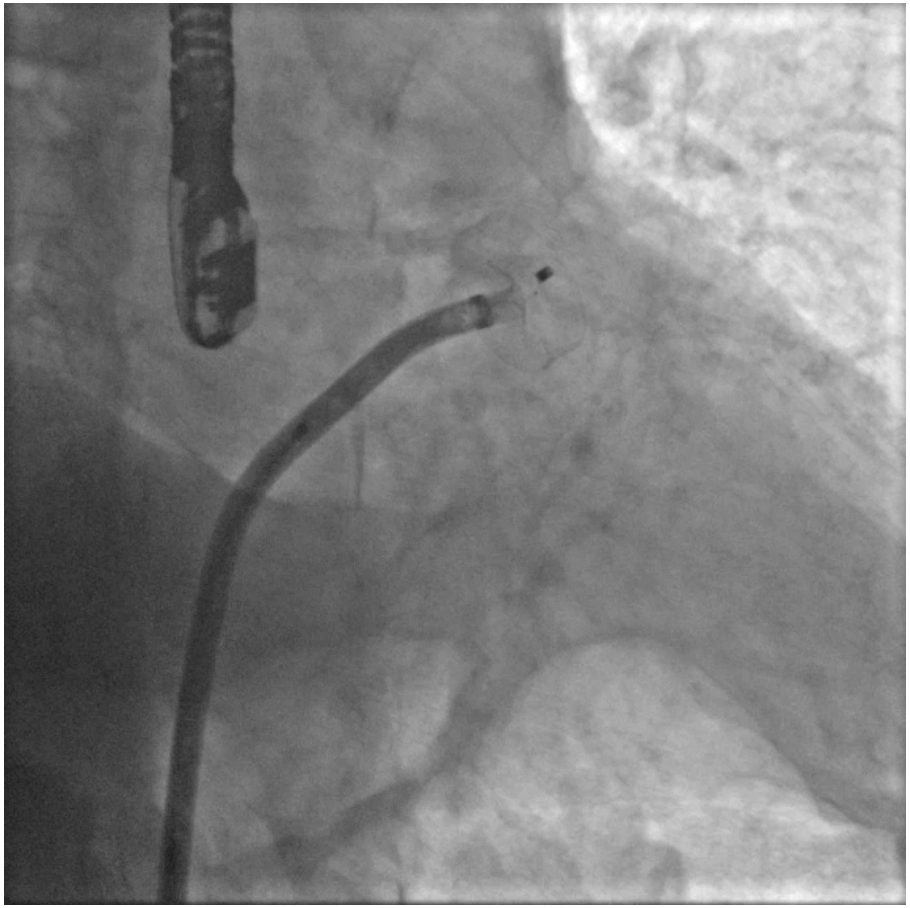
RAO 30 / Caud 20



Introduttore TorqueVue (TV) 45 × 45

AMPLATZER Cardiac Plug

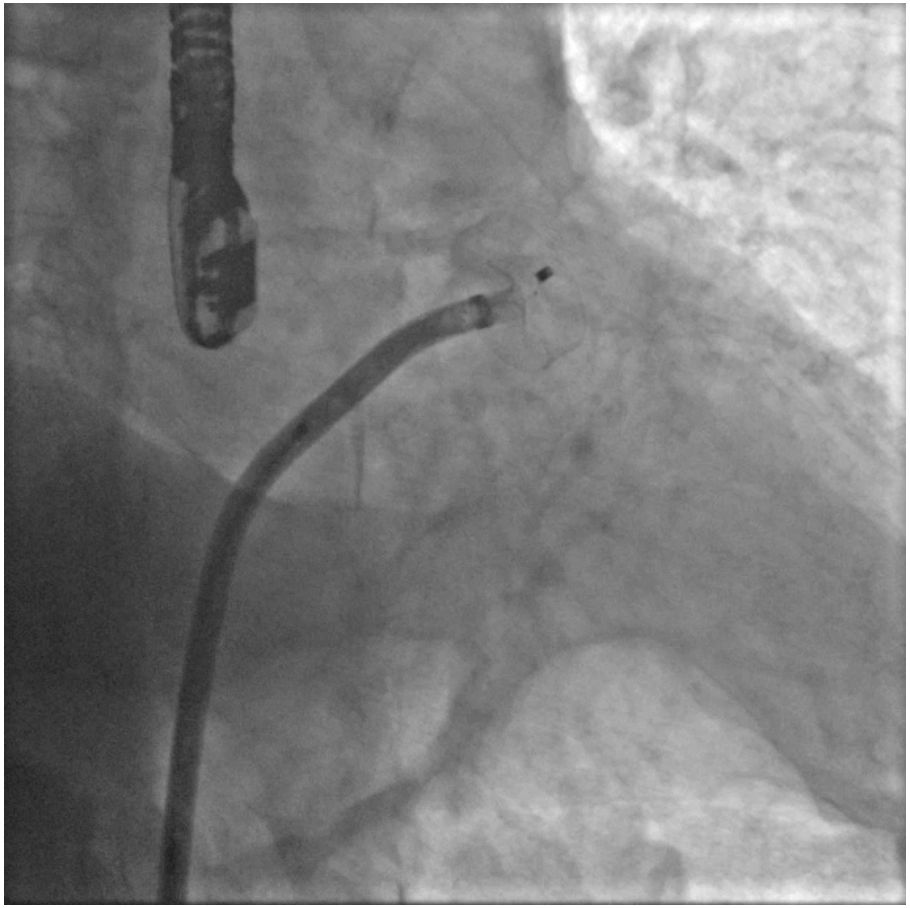
Il corretto posizionamento del device



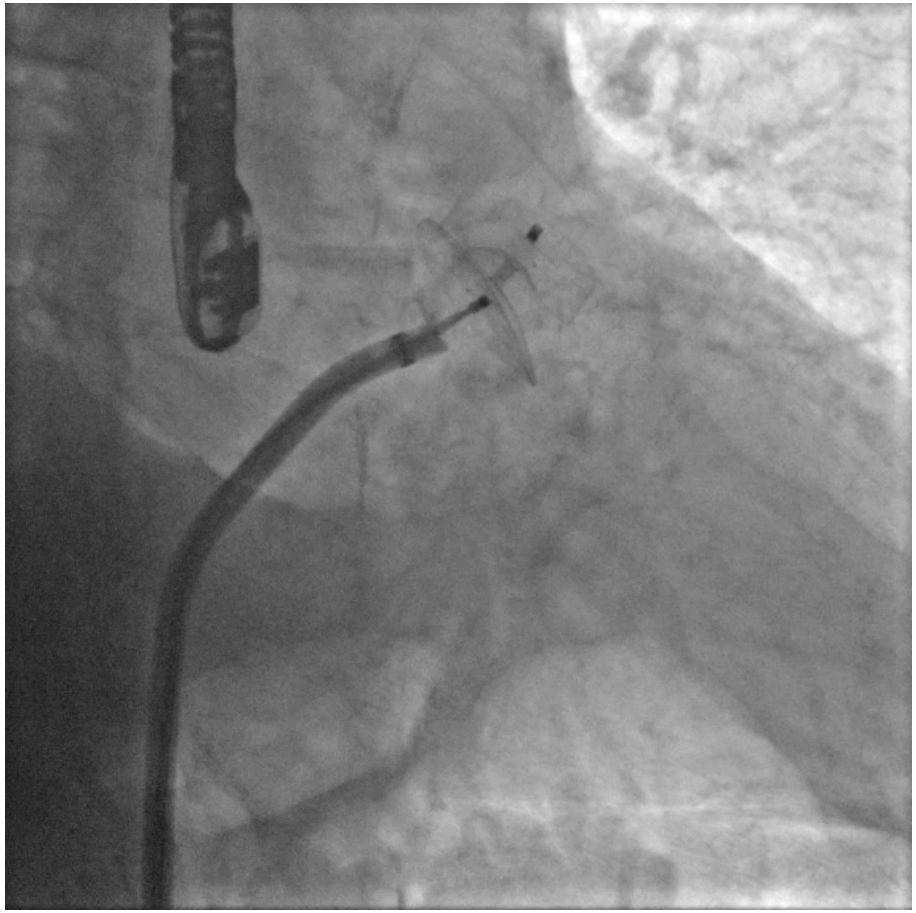
Impianto del device

AMPLATZER Cardiac Plug

Il corretto posizionamento del device



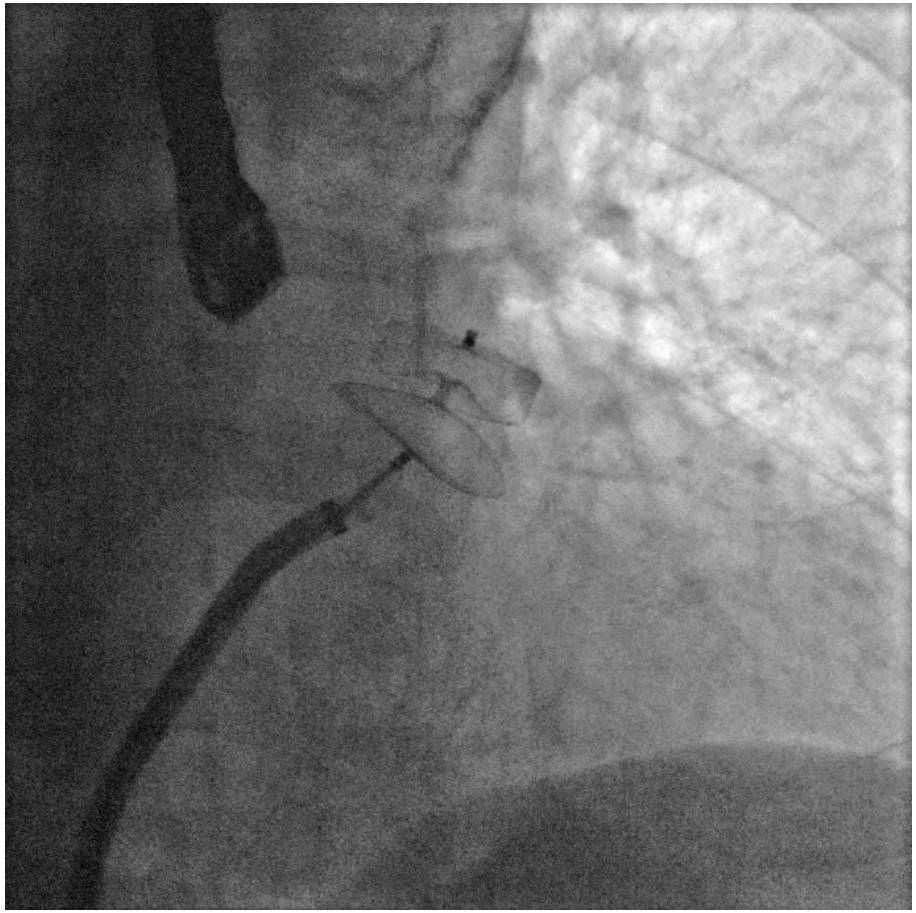
Impianto del device



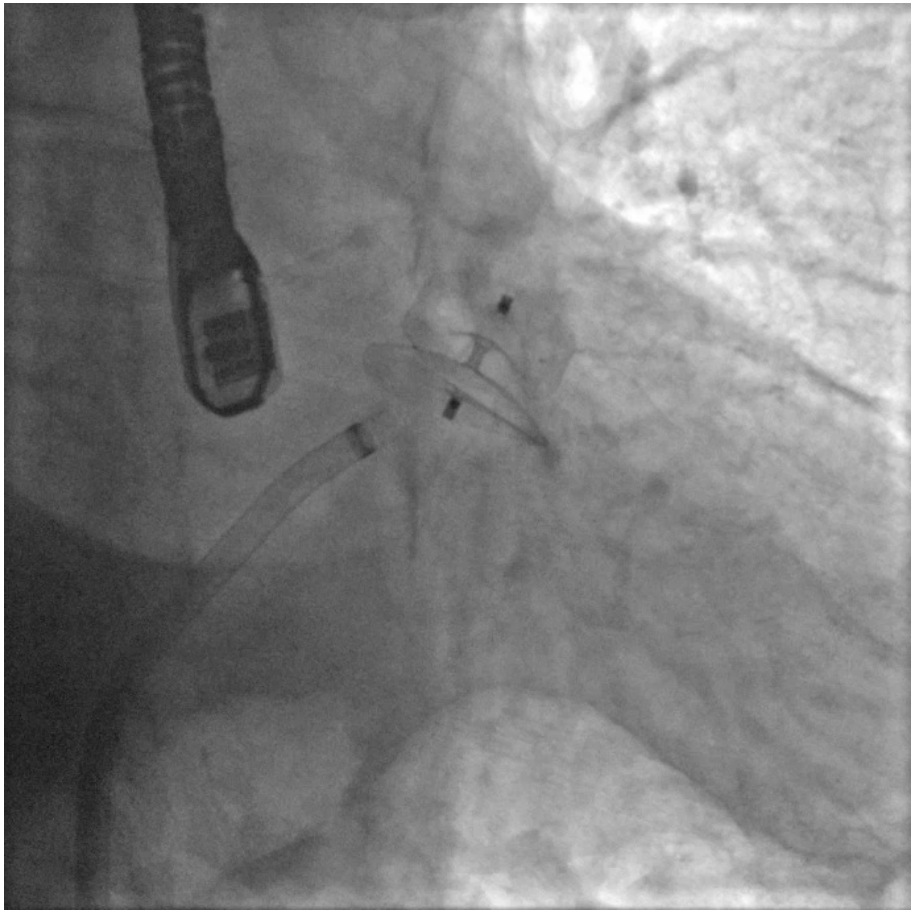
Controllo Angio
Disco (storto) all'interno dell'auricola

AMPLATZER Cardiac Plug

Il corretto posizionamento del device



Controllo PRE-rilascio
dopo riposizionamento

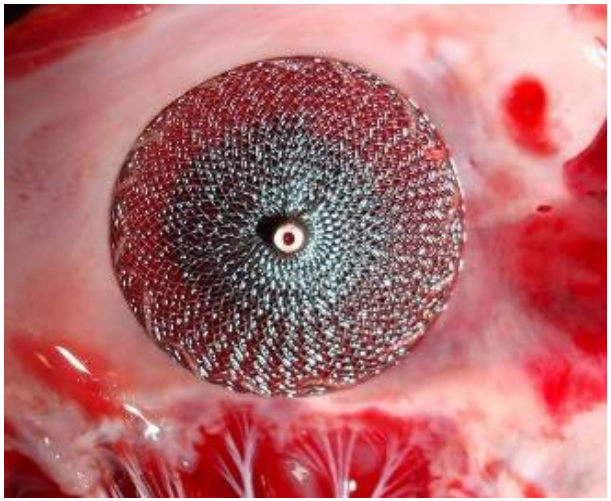


Controllo POST-rilascio

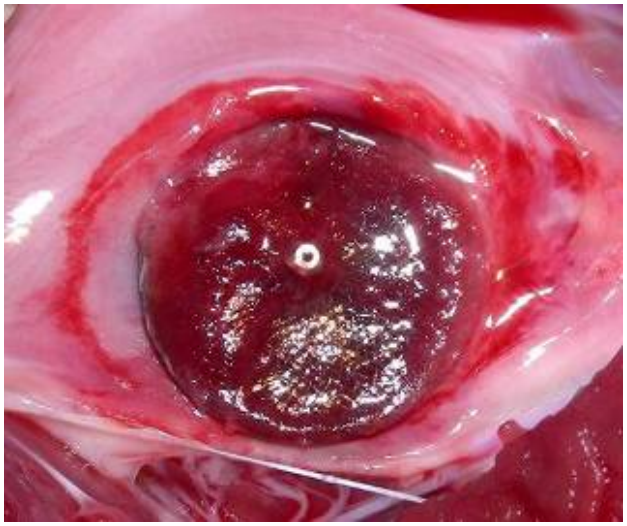
Endotelizzazione nel modello animale

Amplatzer Cardiac Plug (ACP)

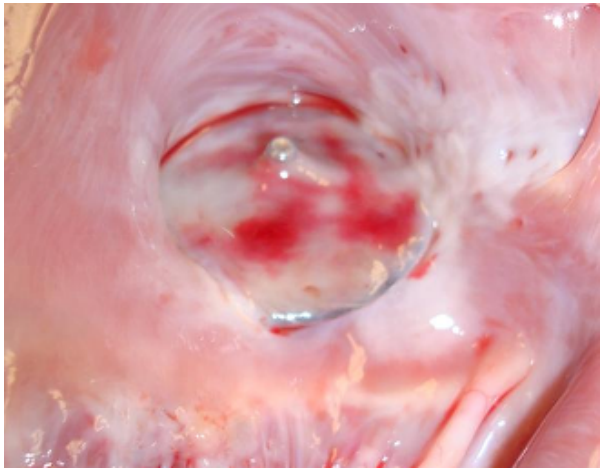
Post-impianto



2 giorni



1 mese



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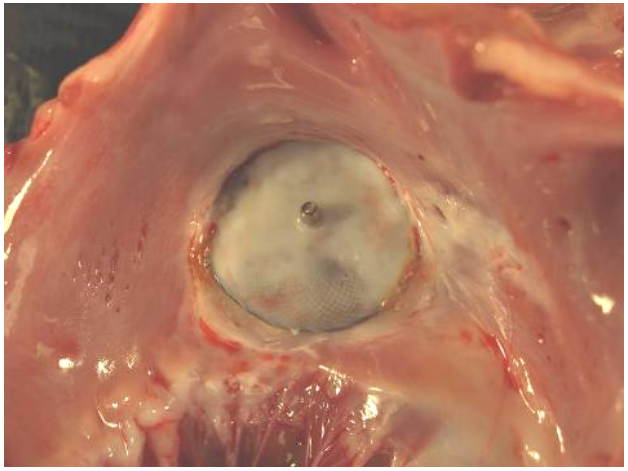
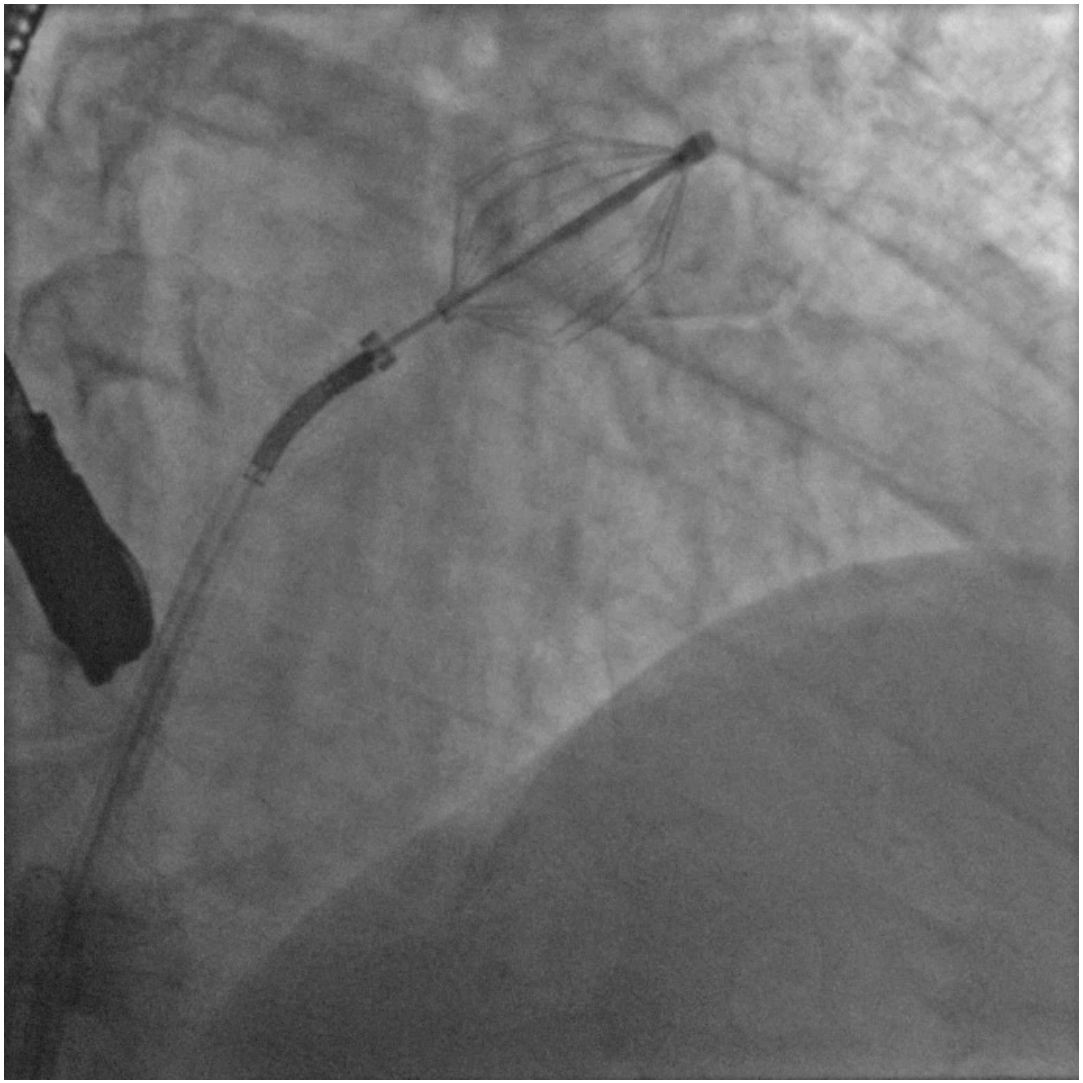
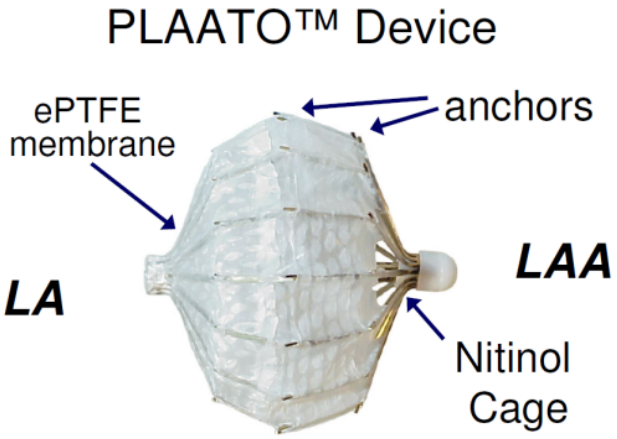
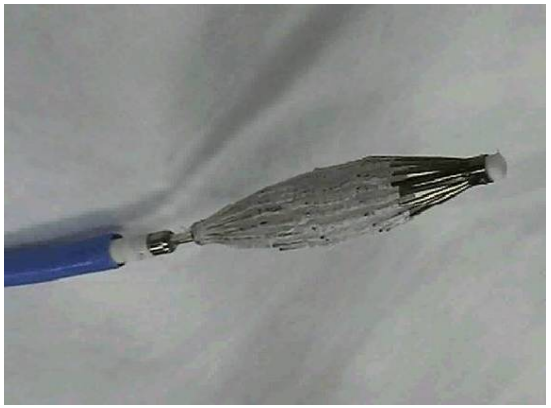


PLAATO Occluder

(Percutaneous Left Atrial Appendage Transcatheter Occluder)



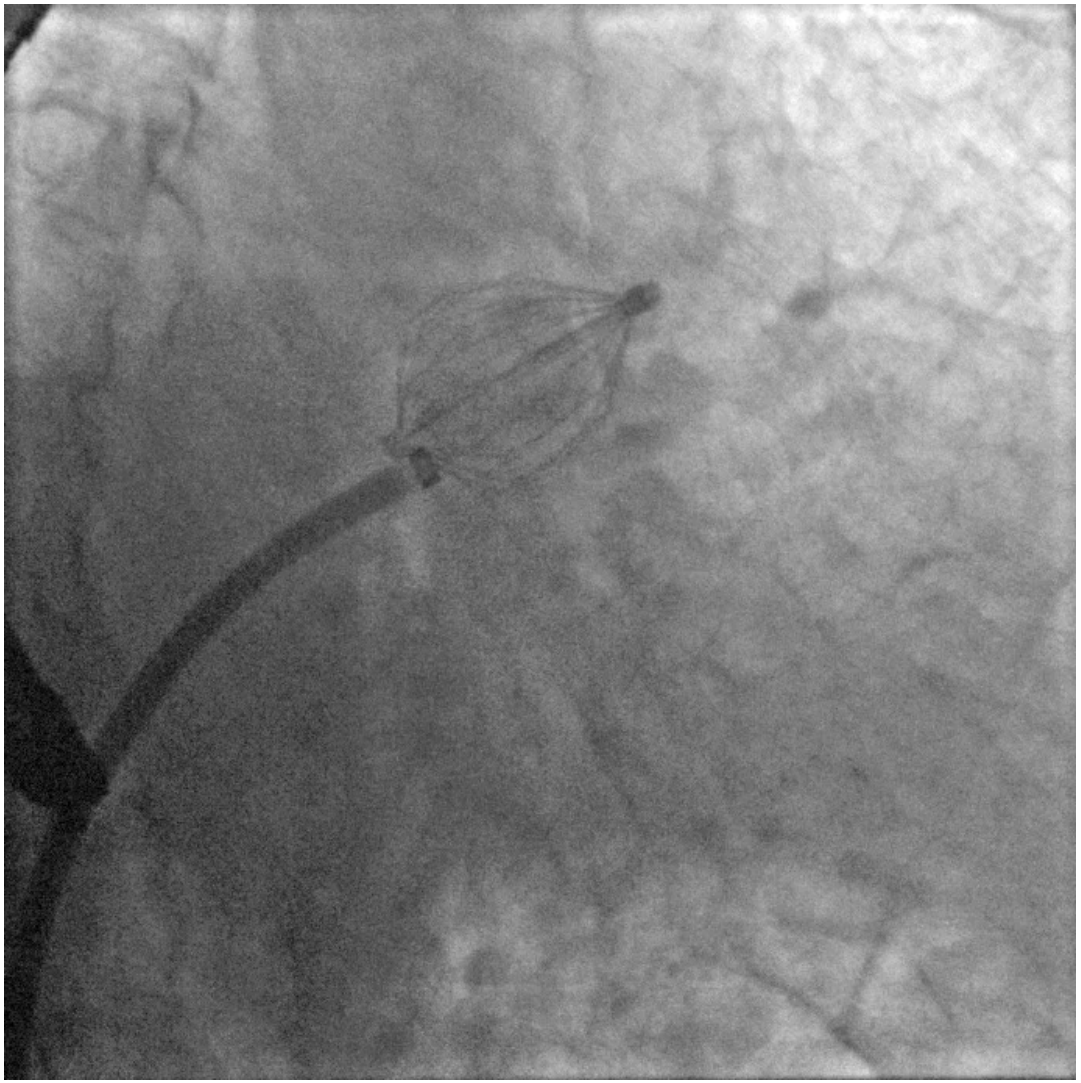


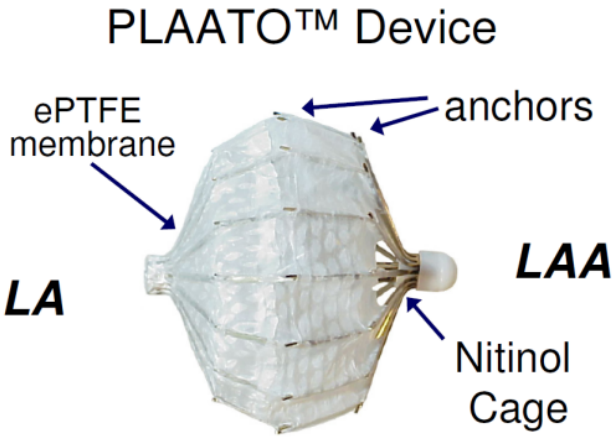


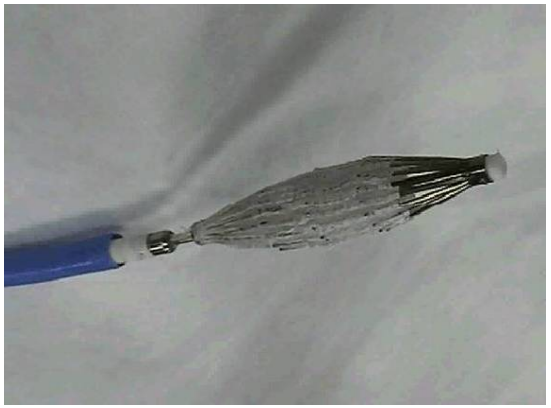
Il nostro 1° caso: Marzo 2005

PLAATO Occluder

(Percutaneous Left Atrial Appendage Transcatheter Occluder)



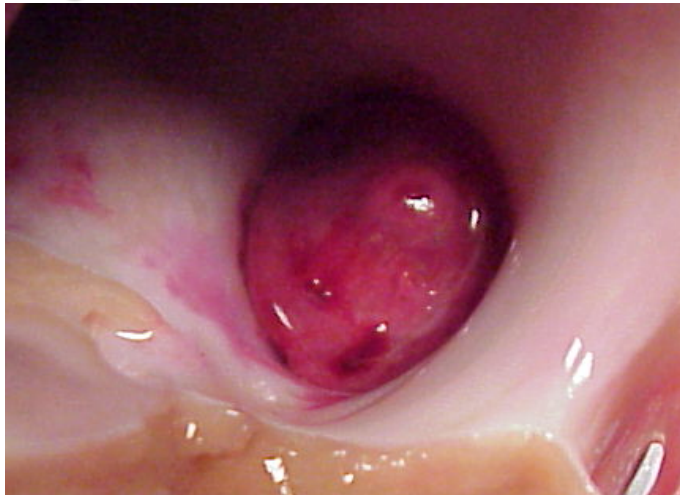




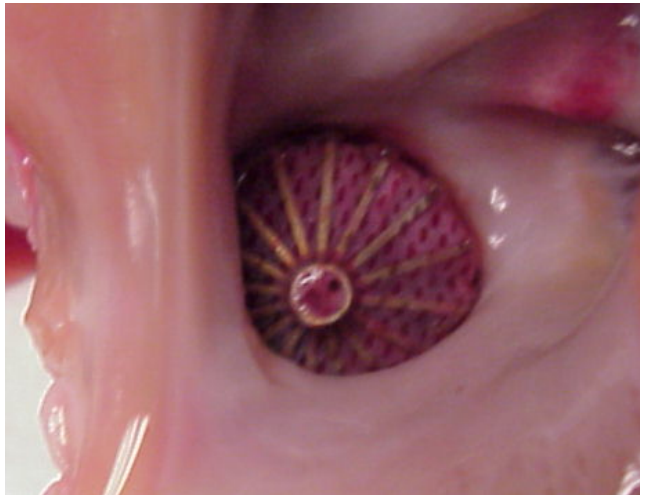
Il nostro 1° caso: Marzo 2005

Endotelizzazione del PLAATO

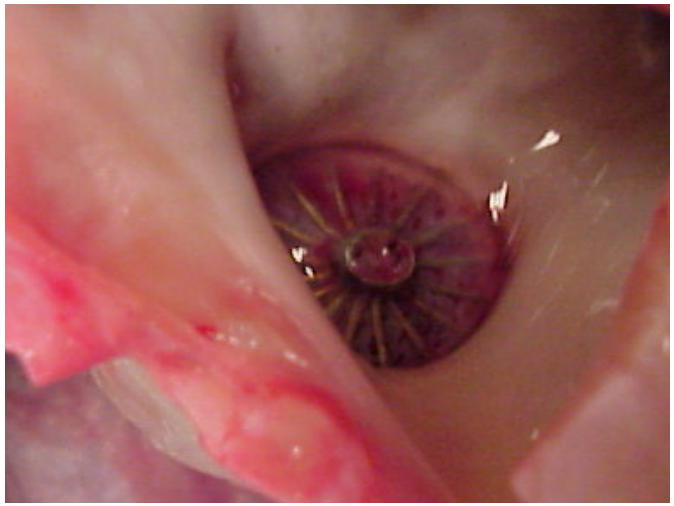
2 giorni



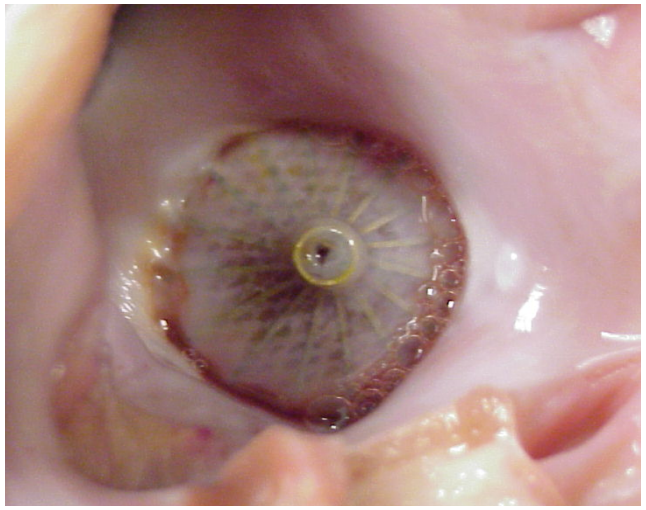
2 settimane



1 mese



3 mesi

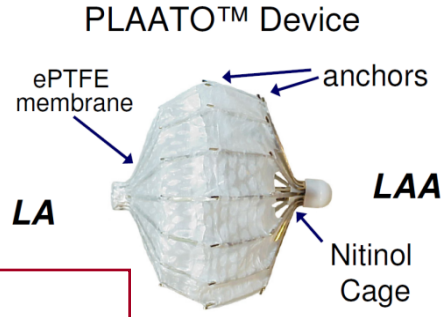


CLINICAL RESEARCH J Am Coll Cardiol Intv 2009;2:594–600)

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#



64 pazienti con FA
Studio Osservazionale, Multicentrico Prospettico

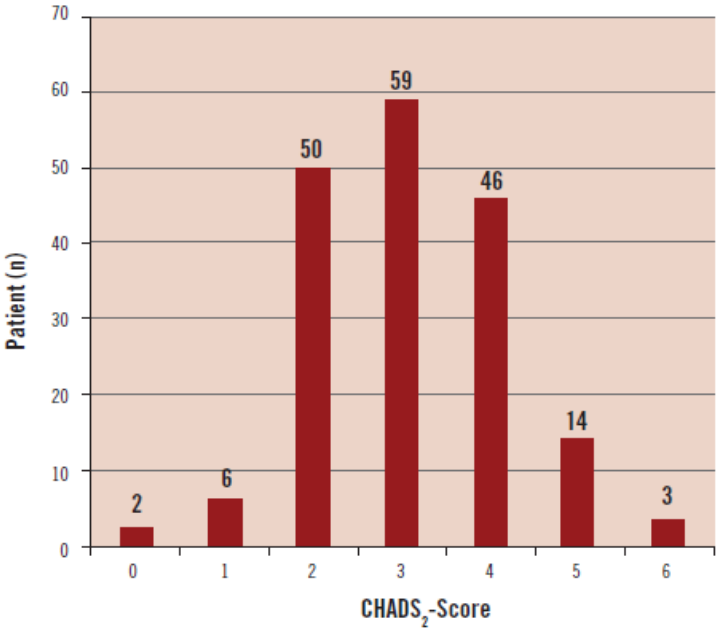
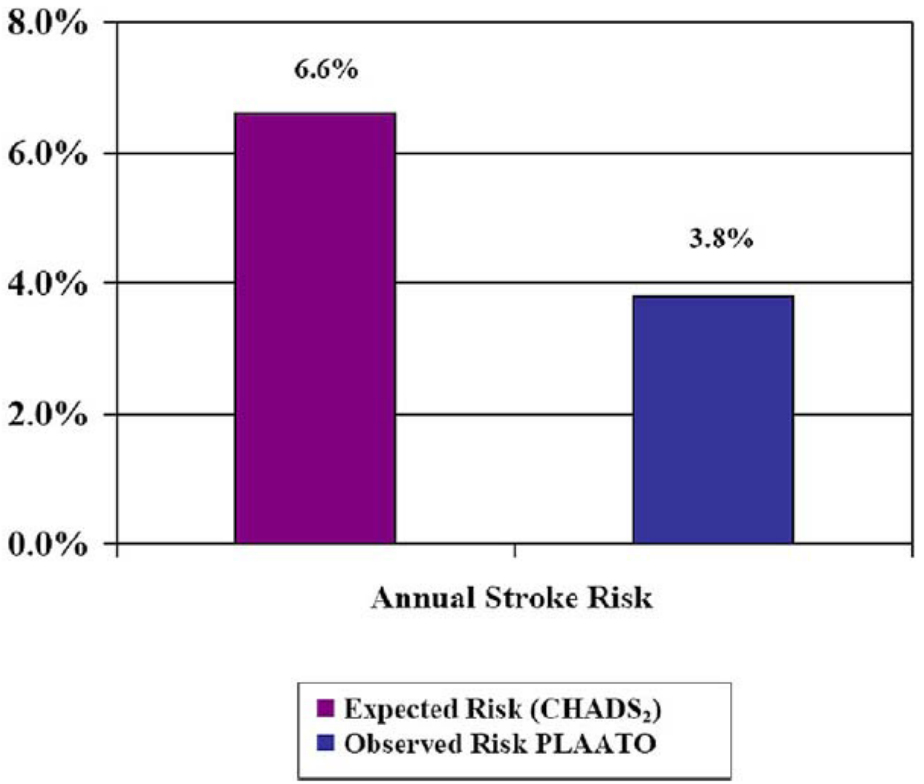


Figure 1. $CHADS_2$-Score distribution in 180 patients. Mean $CHADS_2$ score was 3.1±0.8, corresponding to a mean expected incidence of stroke of 6.6±0.8% per year.



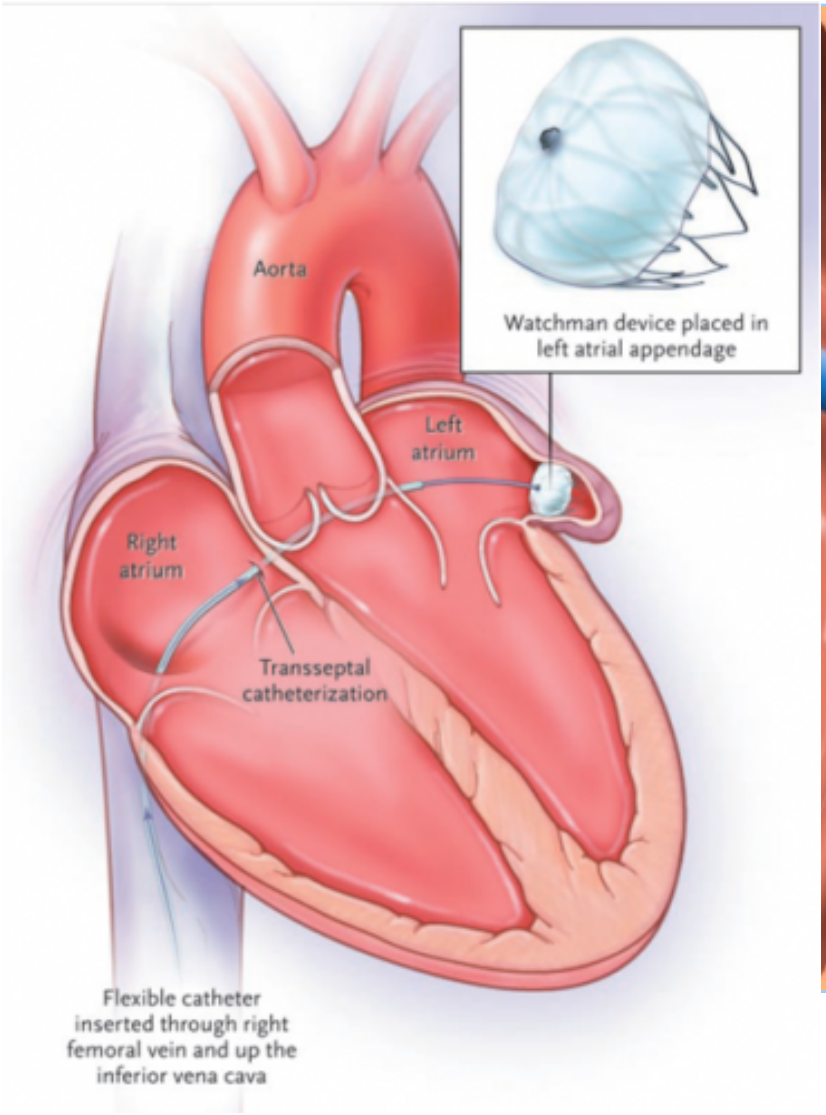
Chiusura Percutanea dell'Auricola Sinistra

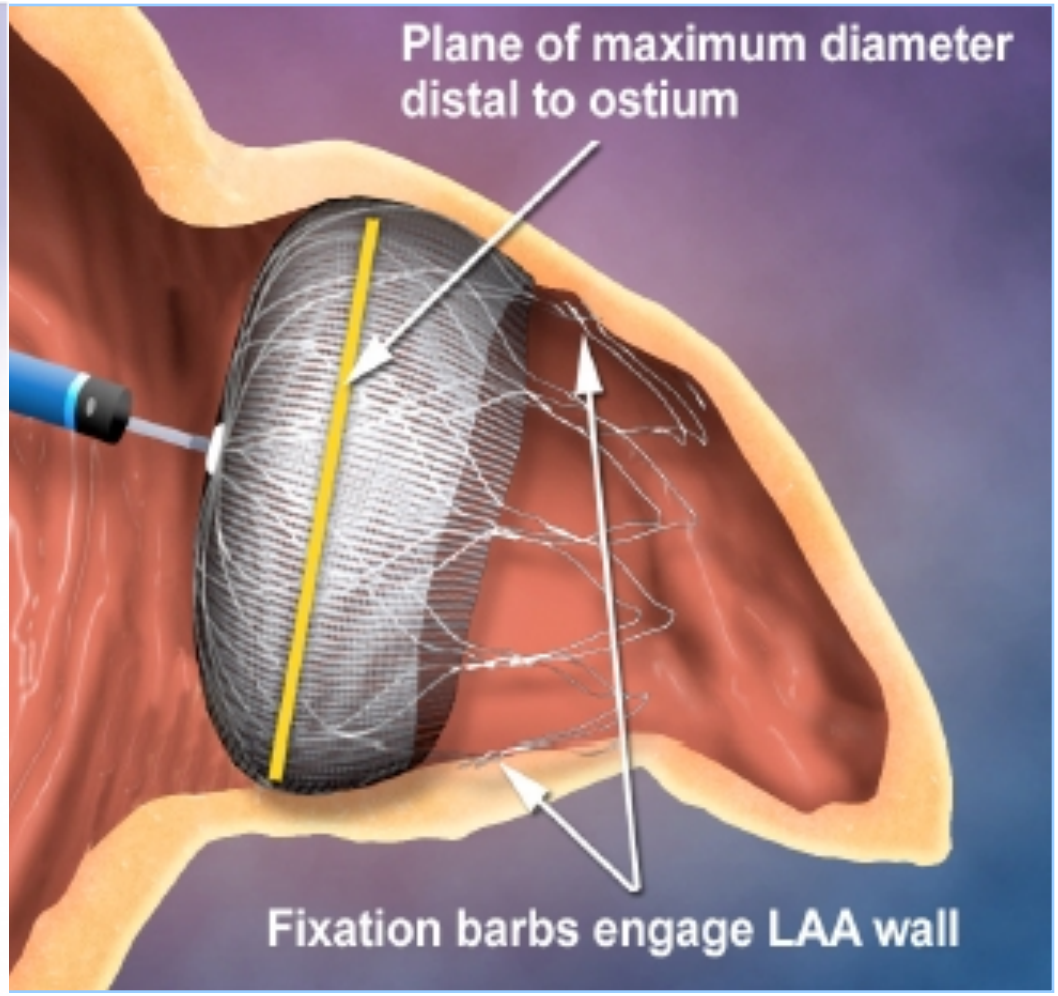
Lo **studio PROTECT AF**
(*WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation*)

Ha valutato l'efficacia e la sicurezza della chiusura percutanea dell'auricola sinistra rispetto alla terapia con warfarin in pazienti con fibrillazione atriale non valvolare

(Lancet 2009;374:534-542)

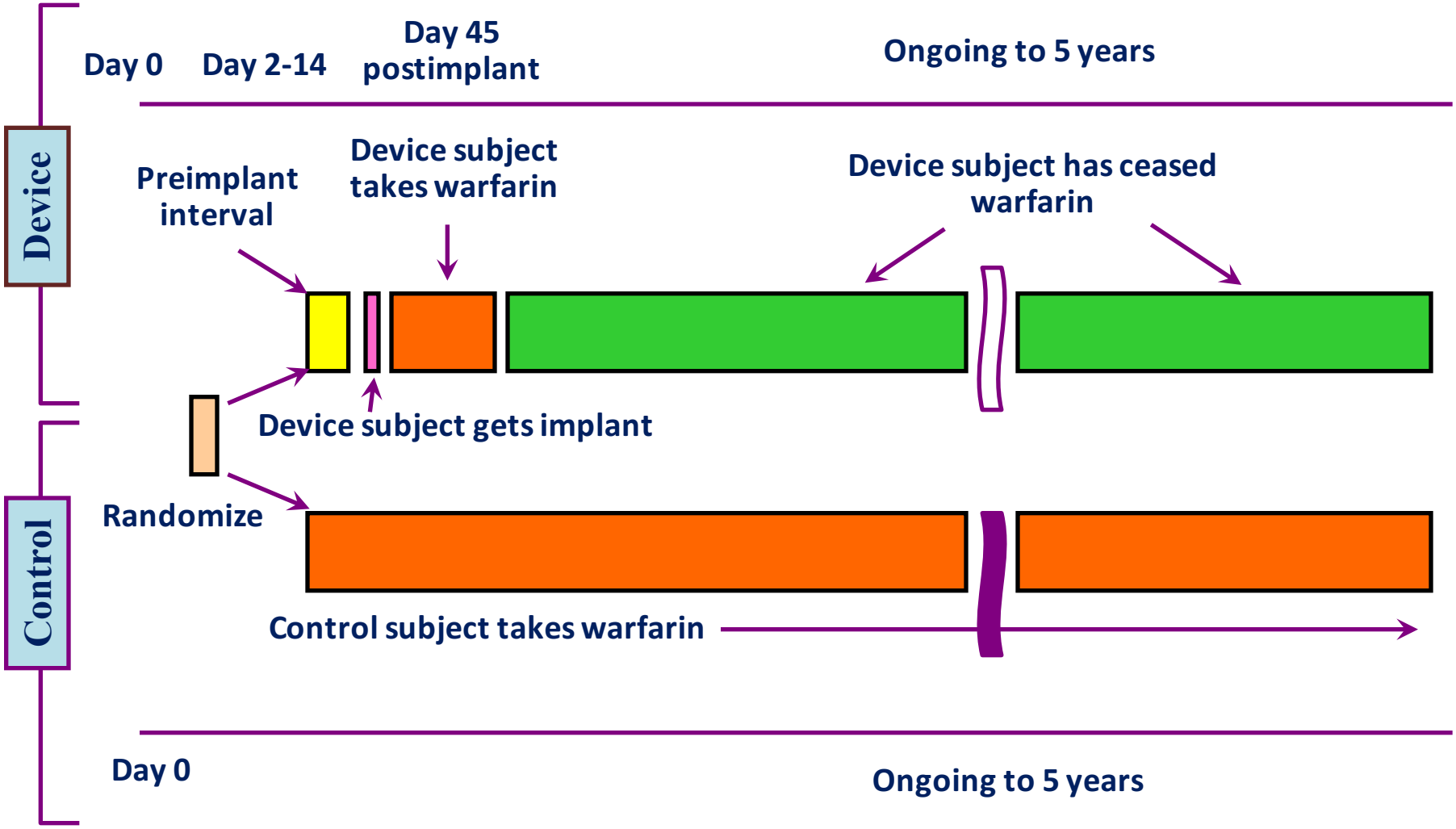
Sistema Occlusore dell'auricola sinistra Watchman





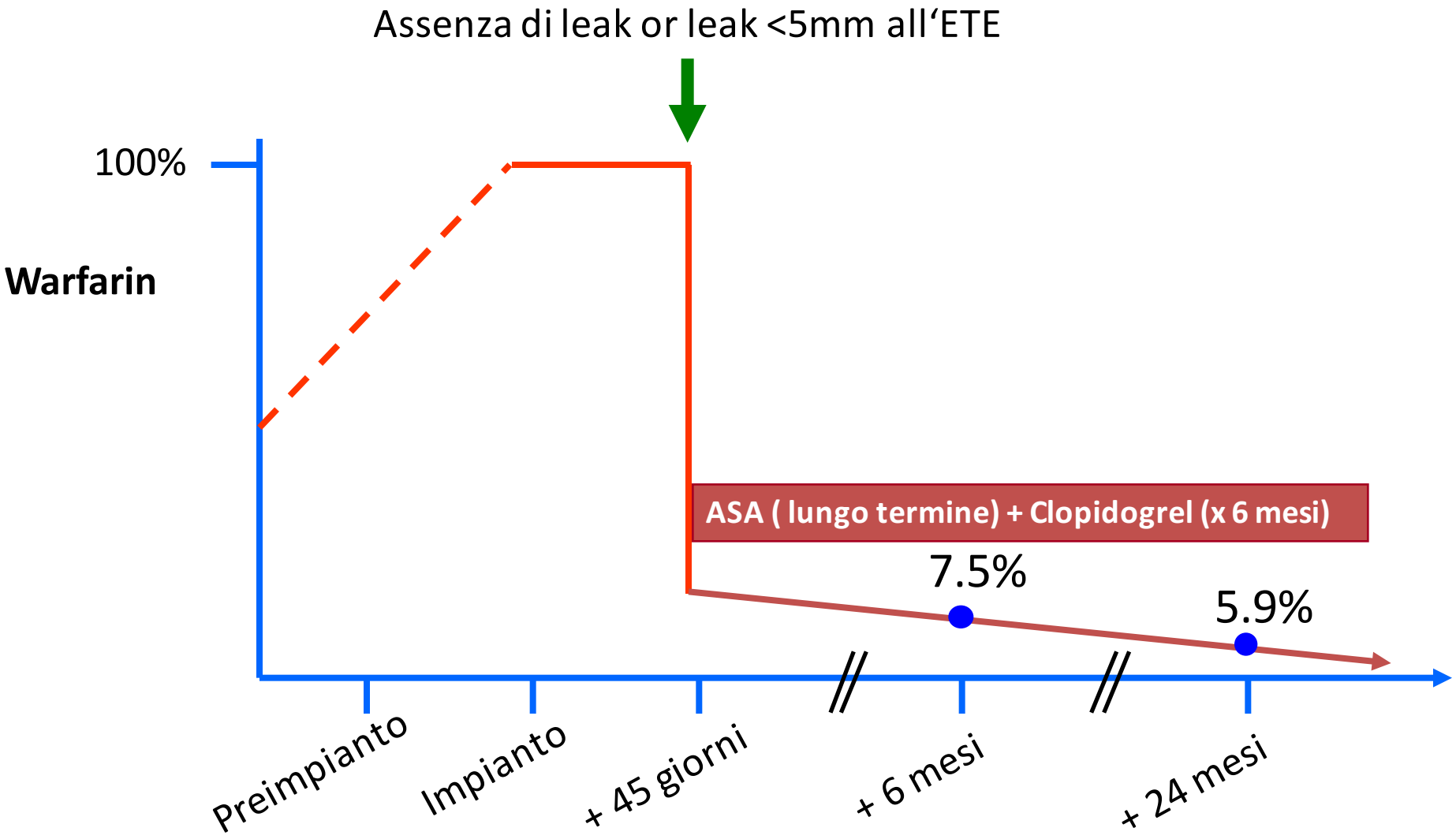
PROTECT AF

Disegno dello studio clinico



PROTECT AF

Sospensione del Warfarin



Holmes D. et al., LANCET 2009; 374: 534

PROTECT AF

Criteri di Inclusione

- Età > 18 anni
- Fibrillazione Atriale (FA) non-valvolare parossistica, persistente o permanente
- Punteggio $CHADS_2 \geq 1$

Criteri di Esclusione

- **Controindicazione alla terapia con Warfarin**
- Patologie concomitanti (diverse dalla FA) richiedenti terapia con Warfarin
- PFO con aneurisma del setto interatriale e shunt ds->sn
- Trombo in atrio sinistro (all' ETE)
- Stenosi carotidea sintomatica

Caratteristiche Cliniche

Baseline Demographics

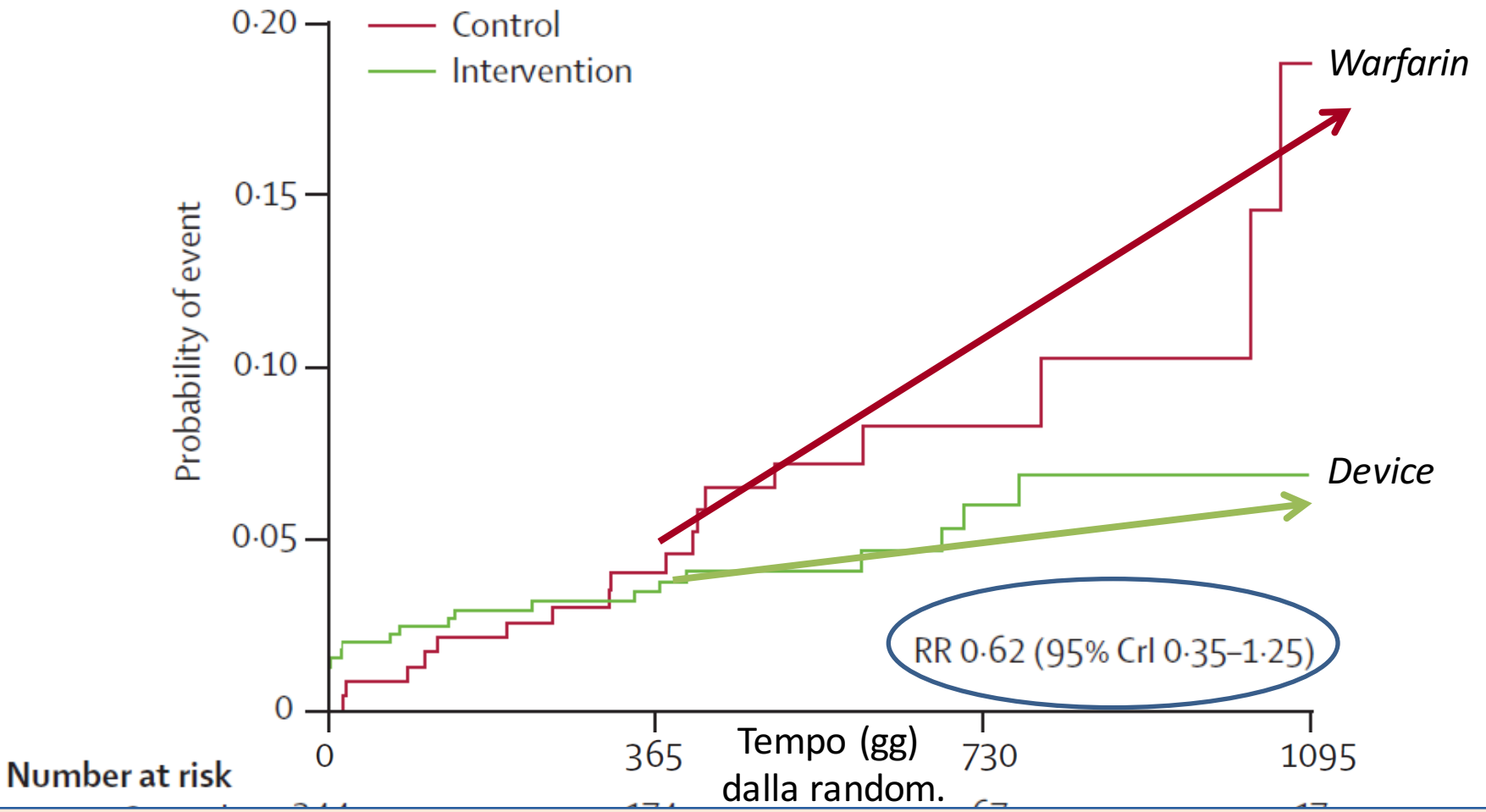
Characteristic	Device N= 463	Control N= 244	P-value
Age (years)	**71**.7 ± 8.8 463 (46.0, 95.0)	**72**.7 ± 9.2 244 (41.0, 95.0)	**0.1800**
Height (inches)	68.2 ± 4.2 462 (54.0, 82.0)	68.4 ± 4.2 244 (59.0, 78.0)	**0.6067**
Weight (lbs)	195.3 ± 44.4 463 (85.0, 376.0)	194.6 ± 43.1 244 (105.0, 312.0)	**0.8339**
Gender			
- Female	137/463 (29.6)	73/244 (29.9)	**0.9276**
- Male	326/463 (**70**.4)	171/244 (**70**.1)	

Caratteristiche Cliniche

Risk factors		
CHADS2 score*		
1	157 (33·9%)	66 (27·0%)
2	158 (34·1%)	88 (36·1%)
3	88 (19·0%)	51 (20·9%)
4	37 (8·0%)	24 (9·8%)
5	19 (4·1%)	10 (4·1%)
6	4 (0·9%)	5 (2·0%)
Congestive heart failure	124 (26·8%)	66 (27·0%)
History of hypertension	413 (89·2%)	220 (90·2%)
Age 75 years or more	190 (41·0%)	115 (47·1%)

End-point Primario di Efficacia (FU 3 anni)

(Stroke, Morte cardiovascolare o non spiegabile, Embolia sistemica)



Non differenza significativa tra i 2 gruppi *Device* e *Warfarin* mostrando che **il *device* è non-inferiore al *warfarin***

End-point Primario di Efficacia (FU 5 anni)

(Stroke, Morte cardiovascolare o non spiegabile, Embolia sistemica)

Event	Device Group (n = 463)		Warfarin Group (n = 244)		Device/Warfarin Rate Ratio (95% Credible Interval)	Posterior Probabilities, %	
	Events/Patient-Years	Observed Rate[a]	Events/Patient-Years	Observed Rate[a]		Noninferiority	Superiority
Primary efficacy end point[b]	39/1720.2	2.3 (1.7-3.2)	34/900.8	3.8 (2.5-4.9)	0.60 (0.41-1.05)	>99	96
Stroke	26/1720.7	1.5 (1.0-2.2)	20/900.9	2.2 (1.3-3.1)	0.68 (0.42-1.37)	>99	83
Ischemic	24/1720.8	1.4 (0.9-2.1)	10/904.2	1.1 (0.5-1.7)	1.26 (0.72-3.28)	78	15
Hemorrhagic	3/1774.2	0.2 (0.0-0.4)	10/916.2	1.1 (0.5-1.8)	0.15 (0.03-0.49)	>99	99
Disabling[c]	8/1771.3	0.5 (0.2-0.8)	11/912.7	1.2 (0.6-1.9)	0.37 (0.15-1.00)	>99	98
Nondisabling[c]	18/1723.7	1.0 (0.7-1.7)	9/907.7	1.0 (0.4-1.7)	1.05 (0.54-2.80)	89	94
Systemic embolization	3/1773.6	0.2 (0.0-0.4)	0/919.5	0	NA		
Cardiovascular or unexplained death	17/1774.3	1.0 (0.6-1.5)	22/919.4	2.4 (1.4-3.4)	0.40 (0.23-0.82)	>99	99
Primary safety end point[d]	60/1666.2	3.6 (2.8-4.6)	27/878.2	3.1 (2.0-4.3)	1.17 (0.78-1.95)	98	20

Abbreviation: NA, not applicable.

[a] Events per 100 patient-years (95% credible interval).

[b] Primary efficacy defined as composite of stroke, systemic embolization, or cardiovascular/unexplained death.

[c] Disabling or fatal strokes were those with a Modified Rankin Score of 3-6 after the stroke. Nondisabling strokes were those with Modified Rankin Scores of 0-2 after the stroke.

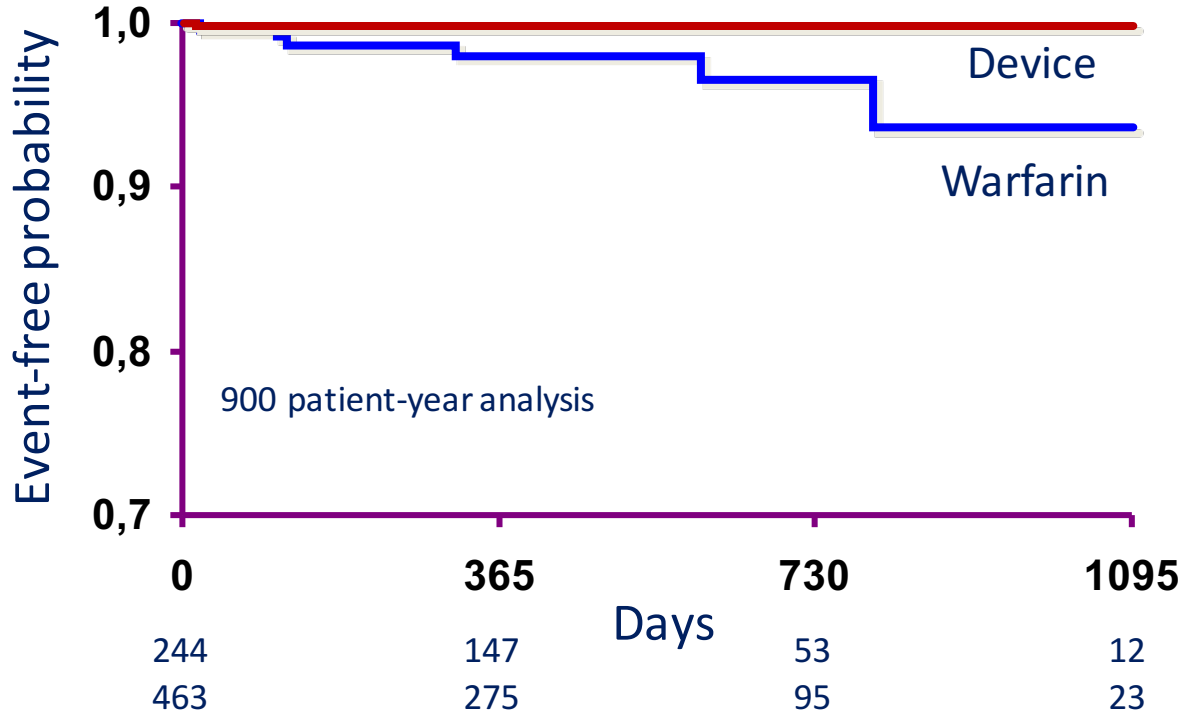
[d] Safety defined as procedure-related events (pericardial effusion requiring intervention or prolonged hospitalization, procedure-related stroke, or device embolization) and major bleeding (intracranial or bleeding requiring transfusion).

Differenza significativa tra i 2 gruppi *Device* e *Warfarin* mostrando che **il *device* è superiore al *warfarin***

FU a 3 anni

Stroke Emorragico

	Device			Control				Posterior probabilities	
Cohort	Events (no.)	Total pt-yr	Rate (95% CI)	Events (no.)	Total pt-yr	Rate (95% CI)	RR (95% CI)	Non-inferiority	Superiority
600 pt-yr	1	416.7	0.2 (0.0, 0.9)	4	224.7	1.8 (0.5, 3.9)	0.13 (0.00, 0.80)	0.998	0.986
900 pt-yr	1	593.6	0.2 (0.0, 0.6)	6	319.4	1.9 (0.7, 3.7)	0.09 (0.00, 0.45)	>0.999	0.998

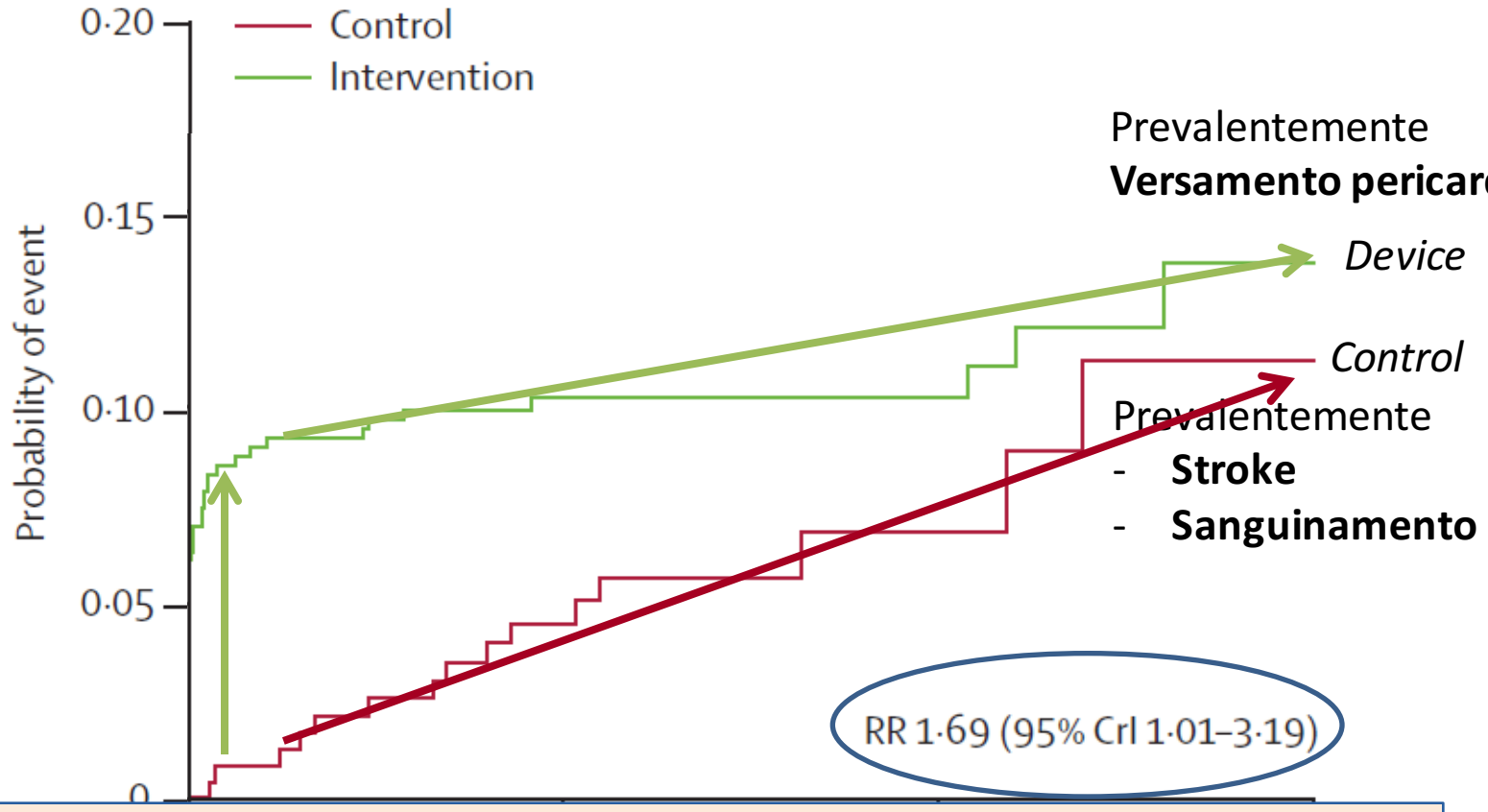


Randomization allocation (2 device:1 control)

ITT cohort: patients analyzed based on their randomly assigned group (regardless of treatment received)

End-point Primario di Sicurezza

(Sanguinamenti e complicanze correlate alla procedura)



E' risultato **più frequente nel gruppo trattato con il device**

- **Versamento pericardico** grave da richiedere un drenaggio (**4,8%**)
- **Stroke periprocedurale** prevalentemente embolia gassosa (**1,1%**)
- **Embolizzazione del device** (**0,6%**).

Versamento pericardico

- **22 classificati "seri" (4.8% dei pz)**
  - 7 drenaggio chirurgico: prolungamento ospedalizzaz. 6g
  - 15 drenaggio per via percutanea: prolungamento ospedalizzaz. 4g

Nessun versamento ha causato decesso

Continued ACCESS Protocol (CAP) Registry

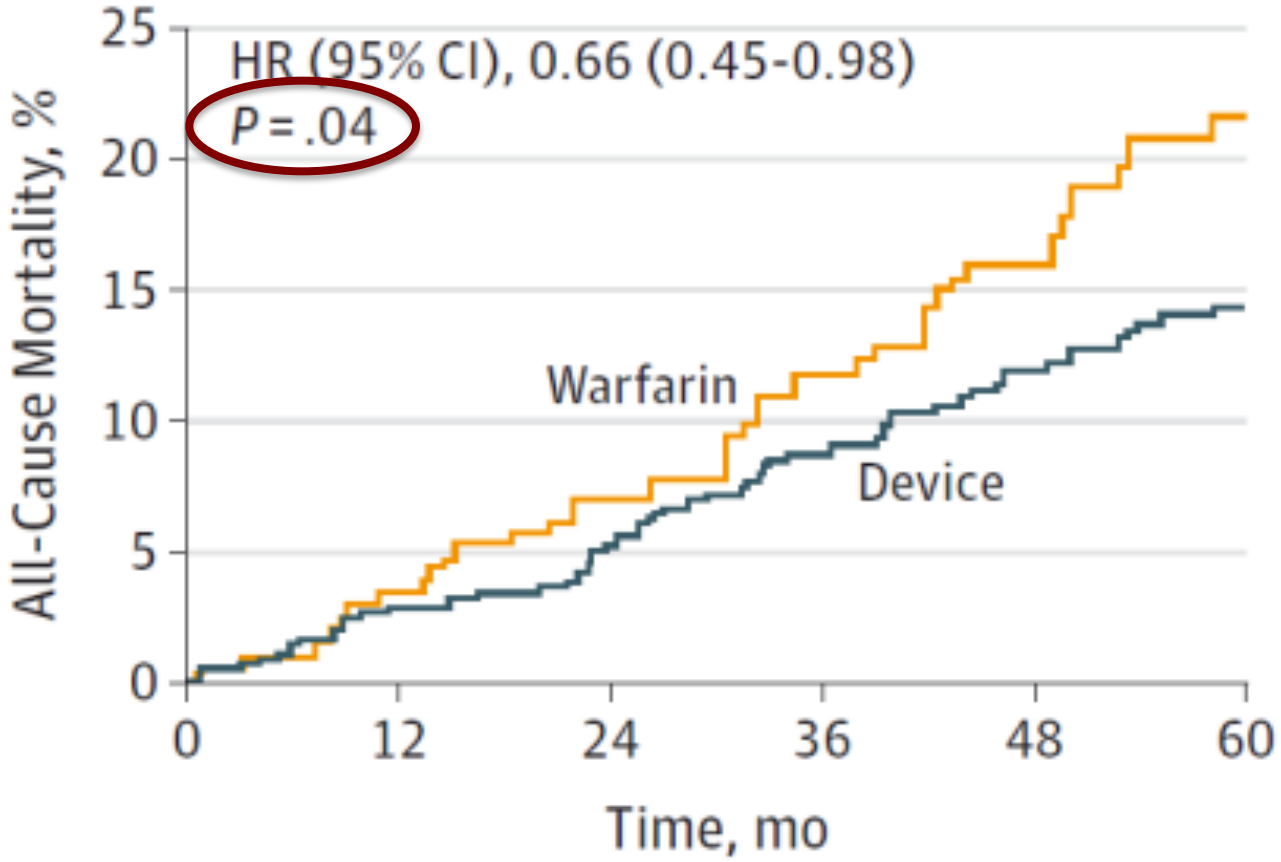
Tutti		"Seri"	
No.	%	No.	%
1/88	1.1	1/88	1.1

Stroke

- **Stroke ischemici: - 5** nel gruppo **Device**
  - Tutti **periprocedurali**: prolungamento ospedalizz. di 7 gg.
  - 3 erano correlati ad **embolia gassosa**
- **Stroke emorragici**: - **1** nel gruppo **Device**
  - **6** nel gruppo **Warfarin**
  - Lo stroke emorragico nel gruopp **Device** è avvenuto 15gg dopo l''impianto mentre il paziente era ancora in terapia con warfarin e ha **causato la morte** del paziente
  - **5/6** strokes emorragici nel gruppo di Controllo **hanno causato la morte**

Protect AF - FUp a 5 anni

Mortalità (per tutte le cause)

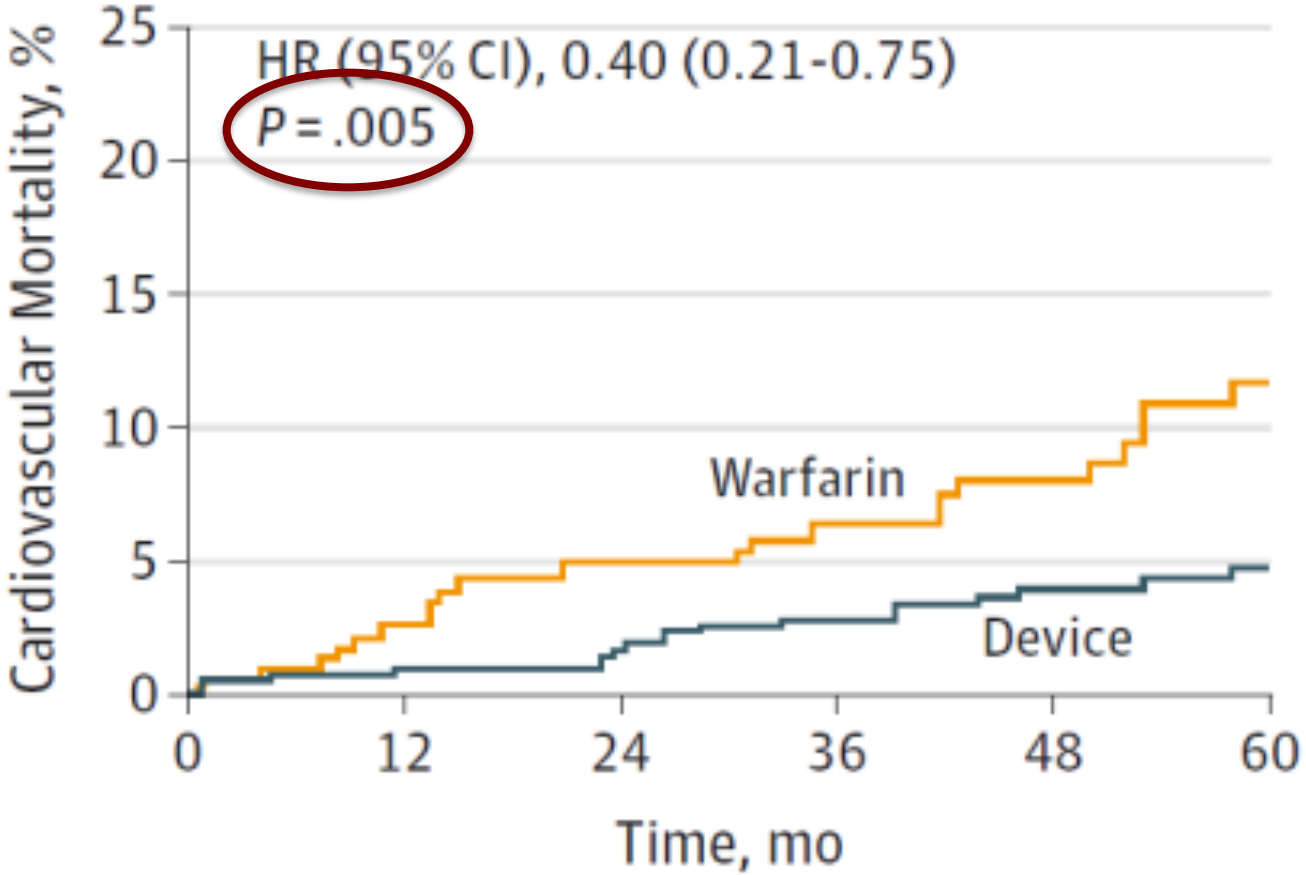


No. of patients

Device	463	389	373	352	330	202
Warfarin	244	222	204	177	150	92

Protect AF - FUp a 5 anni

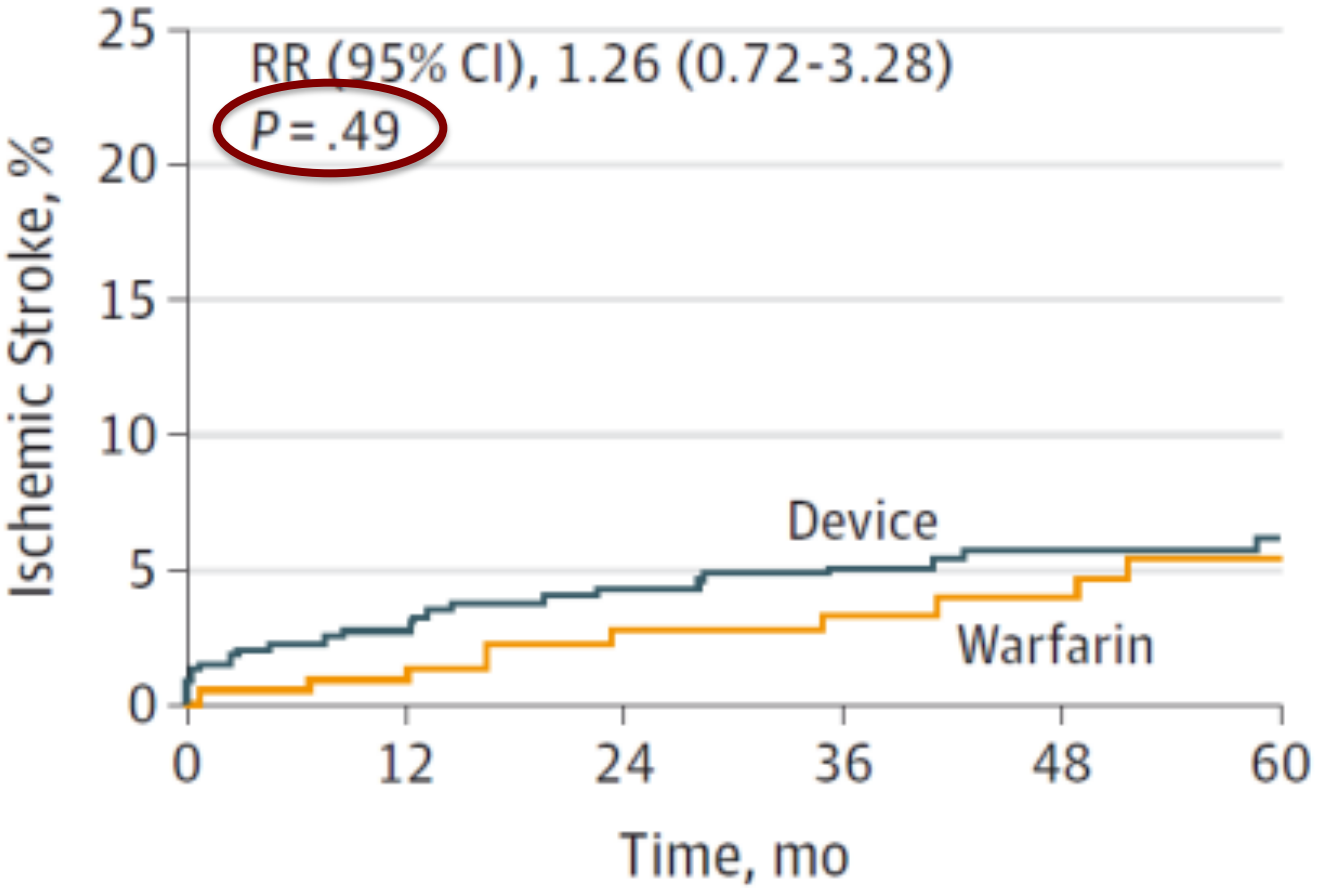
Mortalità (cardiovascolare)



No. of patients						
Device	463	389	372	351	328	165
Warfarin	244	222	204	176	147	69

Protect AF - FUp a 5 anni

Stroke Ischemico



No. of patients						
Device	463	382	360	336	314	156
Warfarin	244	220	200	172	144	64

PROTECT AF
Stroke Emorragico vs Eventi Procedurali

- Il rischio di **stroke emorragico** è significativamente **più basso** nel gruppo di pazienti **trattati con Device (Watchman)**
- Il rischio di **morte** *legata al sanguinamento* è marcatamente più elevato (6 sanguinamenti di cui 5 fatali [con normale INR]) **nel gruppo Warfarin**
- I più frequenti **eventi avversi** nel gruppo **Device** sono relativi alle **prime 24h post procedura**, in particolar modo il **versamento pericardico**;
  - Questi eventi mostrano un *trend significativamente decrescente nel tempo (vedi CAP Registry)*

PROTECT AF
Sicurezza della procedura

TABLE 7 Comparison of Outcomes in Device Patients in PROTECT AF, CAP, and PREVAIL

	PROTECT AF	CAP	PREVAIL	p Value
Implant success	90.9	94.3	95.1	0.04
All 7-day procedural complications	8.7	4.2	4.5	0.004
Pericardial effusion requiring surgery	1.6	0.2	0.4	0.03
Pericardial effusion with pericardiocentesis	2.4	1.2	1.5	0.318
Procedure-related strokes	1.1	0.0	0.7	0.02
Device embolization	0.4	0.2	0.7	0.368

Abbreviations as in Tables 3 and 6.

Sicurezza della chiusura dell'auricola sinistra mediante Amplatzer Cardiac Plug (ACP)

SAFETY	Park, Initial European Experience[1] (2011) N=143	Walsh, European Prospective Obs. Study2 (2012) N=203	Kefer, Belgium Registry[3] (2013) N=90	Urena, Canada Registry[4] (2013) N=52	Lopez-Minguez, Iberian Registry[5] (2014) N=167	Santoro, 4 yers Follow-up[6] (2014) N=134	Tzikas, Multicenter Experience[7] (2015) N=1047
Procedural Success	**132 (96.4%)**	**197 (96.6%)**	**89 (98.9%)**	**51 (98.1%)**	**158 (94.6%)**	**128 (95.5%)**	**1019 (97.3%)**
Stroke	3	0	0	0	0	0	9
TIA	0	0	0	1	2	1	0
MI/coronary air/ embolism	0	0	2	0	0	0	1
Device embolization	2	3	0	1	1	0	8
Major cardiac tamponade/ perforation/ effusion	5	3	3	0	2	3	13
Major bleeding	0	0	0	2	0	0	13
Other	0	0	0	0	4	0	8
Major periprocedural complication	**10 (7.3%)**	**6 (2.9%)**	**3 (3.6%)**	**2 (3.8%)**	**9 (5.4%)**	**4 (3.0%)**	**52 (5.0%)**

PROTECT AF
Conclusioni

- La chiusura per via percutanea dell'auricola sinistra con il device Watchman **rappresenta un'alternativa efficace e *relativamente* sicura alla terapia anticoagulante con Warfarin** nei pazienti con fibrillazione atriale (FA) non-valvolare a rischio di stroke (**in pazienti eleggibili alla terapia con Warfarin**) pur in presenza di un rischio di complicanze correlate alla procedura

PROTECT AF
Conclusioni

- Nell'**Editoriale** di commento dello studio **PROTECT AF** si sottolinea che la metodica **non diventi una scelta routinaria** fino a che non saranno disponibili risultati di studi a lungo termine.
- Per il momento il **warfarin rimane la terapia preferibile**

Issue date: June 2010

NHS
National Institute for
Health and Clinical Excellence

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

Linee Guida

1.1 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 (AF). With regard to **safety**, there is a **risk of life-threatening complications from the procedure, but the incidence of these is low**.

Issue date: June 2010

NHS
National Institute for
Health and Clinical Excellence

Linee Guida

1.2 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.

1.3 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**.

1.4 This procedure should be carried out only **in units with on-site cardiac surgery**.

European Heart Journal (2012) **33**, 2719–2747
doi:10.1093/eurheartj/ehs253

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

An update of the 2010 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

LAAOS Study

High risk of Incomplete Occlusion at FU TEE

- 52 patients in the LAA occlusion and 25 patients in the control group) evaluating safety and efficacy of LAA occlusion performed at the time of CABG surgery

Among patients having a postoperative TEE, **complete occlusion** of the LAA was achieved in:

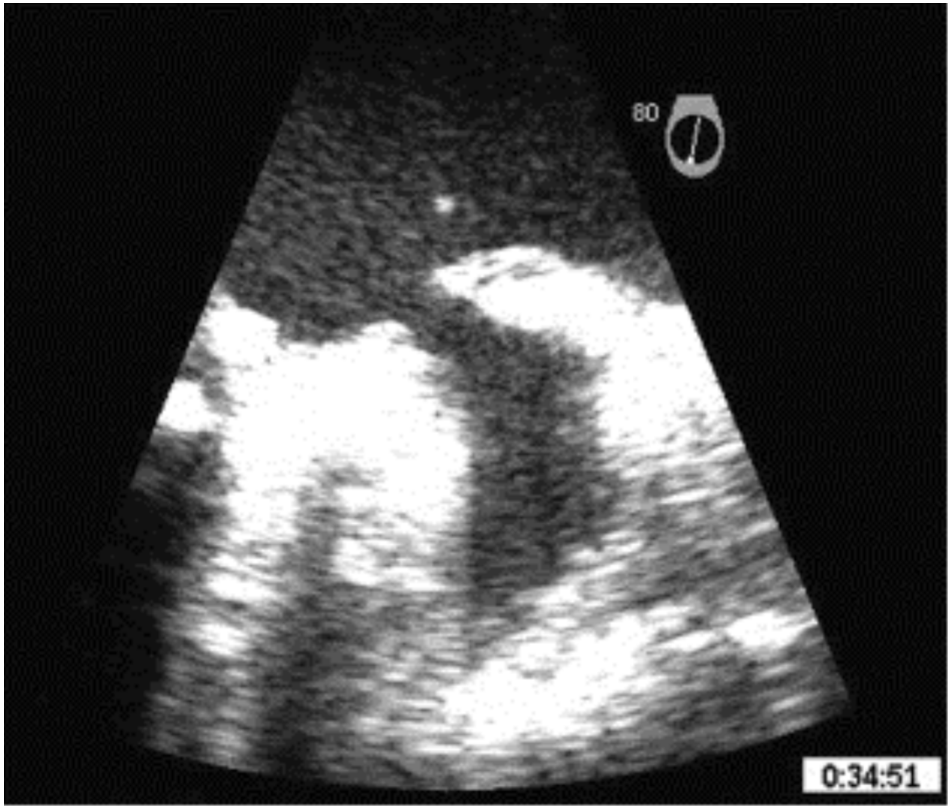
- **45%** (5/ 11) of cases using **sutures**
- **72%** (24/33) using a **stapler**

Healey JS.
Left atrial appendage occlusion study (LAAOS): results of a randomized controlled pilot study of left atrial appendage occlusion during coronary bypass surgery in patients at risk for stroke. Am Heart J. 2005; 150: 288–293.

Success of Surgical Left Atrial Appendage Closure: Assessment by TEE

Patent Left Atrial Appendage After Suture Exclusion

This left atrial appendage is an example of a patent appendage that was previously excluded by sutures that have now dehisced. There is persistent communication of the left atrial appendage with the left atrium.

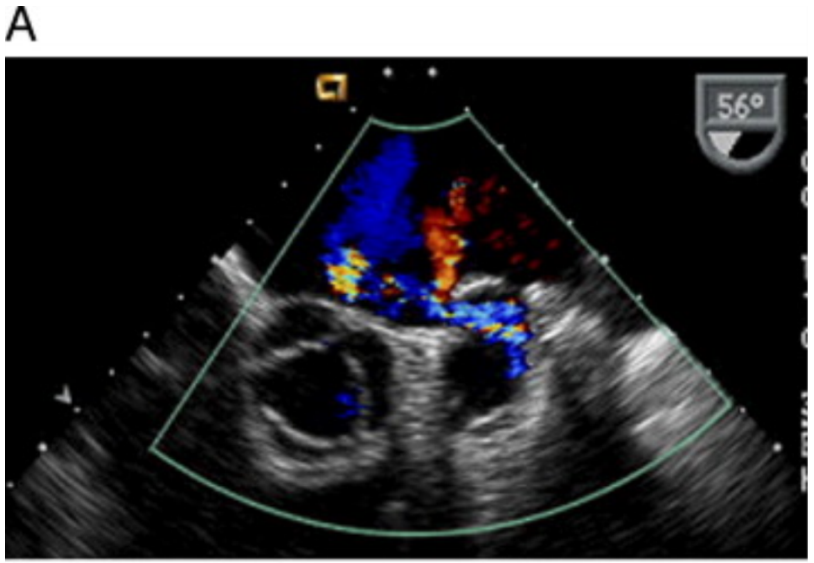


J Am Coll Cardiol. 2008;52(11):924-929

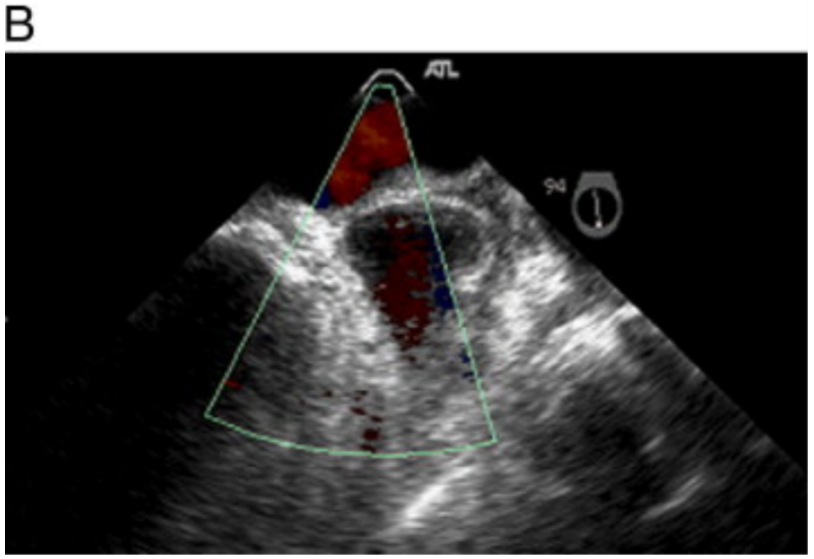
Success of Surgical Left Atrial Appendage Closure: Assessment by TEE

Persistent Flow Into the Left Atrial Appendage after Suture and Stapler Exclusion

(A) The left atrial appendage has been excluded by closing off the orifice of the appendage cavity from the atrium by **sutures**. There is a color flow jet observed between the atrium and the appendage suggesting persistent flow and communication.



(B) The left atrial appendage remains attached to the atrium and has been excluded by **stapling**. However, there is persistent flow in the appendage demonstrated by color Doppler, suggesting persistent communication between the atrium and the appendage.



J Am Coll Cardiol. 2008;52(11):924-929

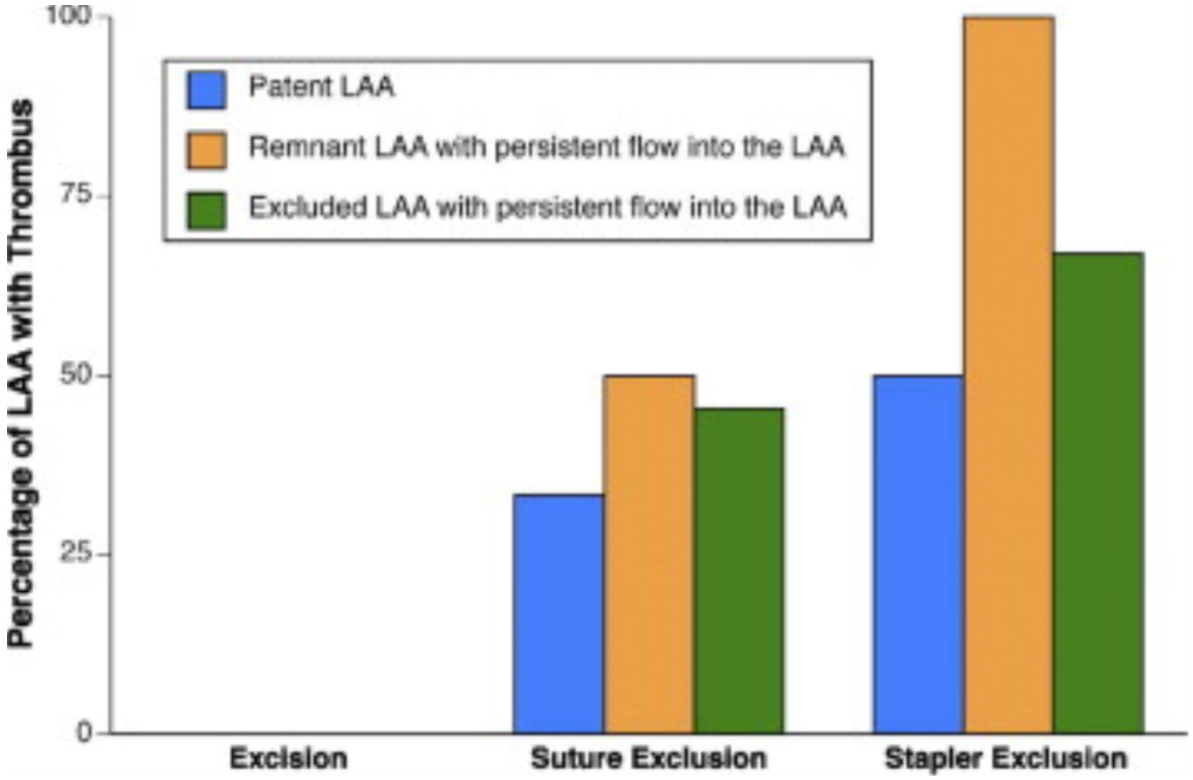
Success of Surgical Left Atrial Appendage Closure: Assessment by TEE

Occurrence of LAA Thrombus in Unsuccessful Surgical Closure

Shown is the presence of **left atrial appendage thrombus** with unsuccessful surgical left atrial appendage closure by the 3 techniques:

1. Excision
2. Suture exclusion
3. Stapler exclusion.

LAA = left atrial appendage.



J Am Coll Cardiol. 2008;52(11):924-929

European Heart Journal (2012) **33**, 2719–2747
doi:10.1093/eurheartj/ehs253

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

An update of the 2010 ESC Guidelines for the management of atrial fibrillation

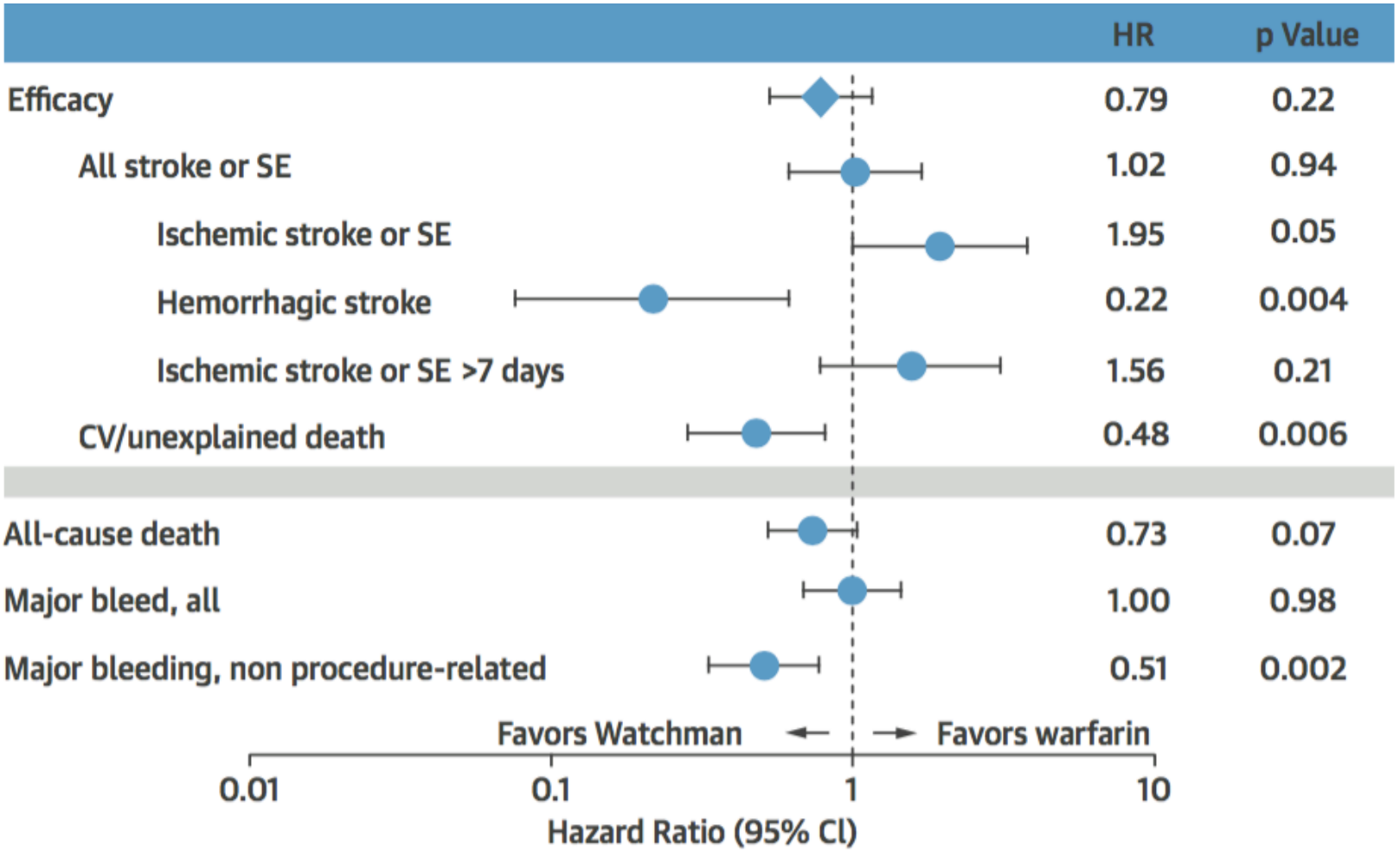
Recommendations for LAA closure/occlusion/excision

Surgical excision of the LAA may be considered in patients undergoing open heart surgery.	IIb	C	

Chiusura percutanea dell'auricola sinistra per la prevenzione dell'ictus nei pazienti con fibrillazione atriale (FA)

- Si tratta sicuramente di una **metodica promettente** che per il momento dovrebbe essere presa in considerazione **nei pazienti che presentano controindicazioni assolute all'uso del warfarin** o **un rischio elevato di sanguinamento**, in attesa che studi futuri ne confermino l'efficacia e la sicurezza nel lungo periodo

PROTECT AF/PREVAIL Combined:
Meta-Analysis Shows
Comparable Primary Efficacy Results to Warfarin



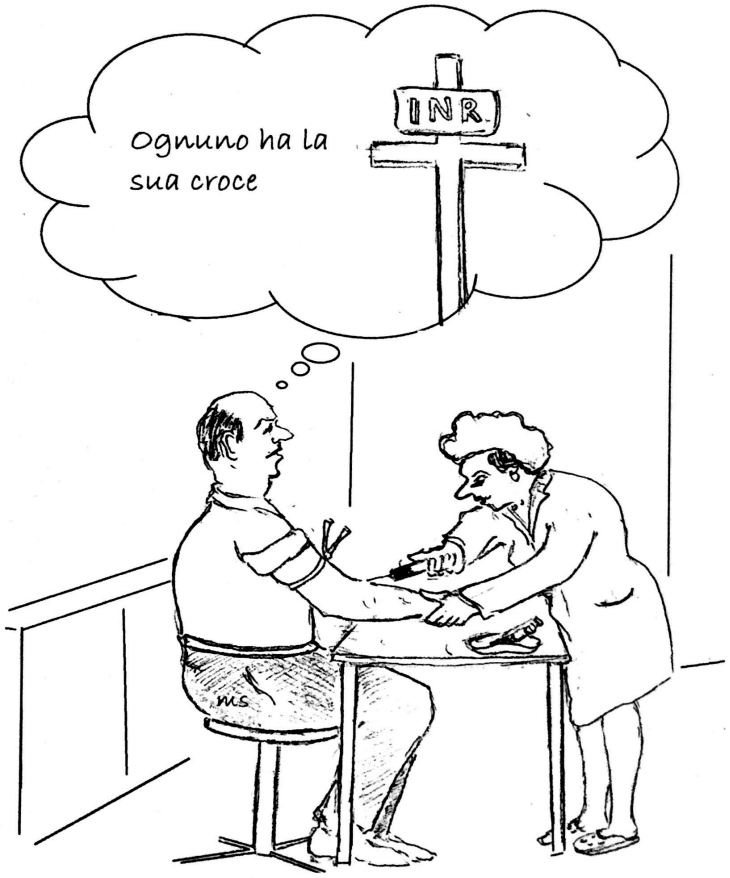
Holmes DR et al J Am Coll Cardiol 2015;65:2614–23

Conclusions

Potential Candidates for LAA occlusion

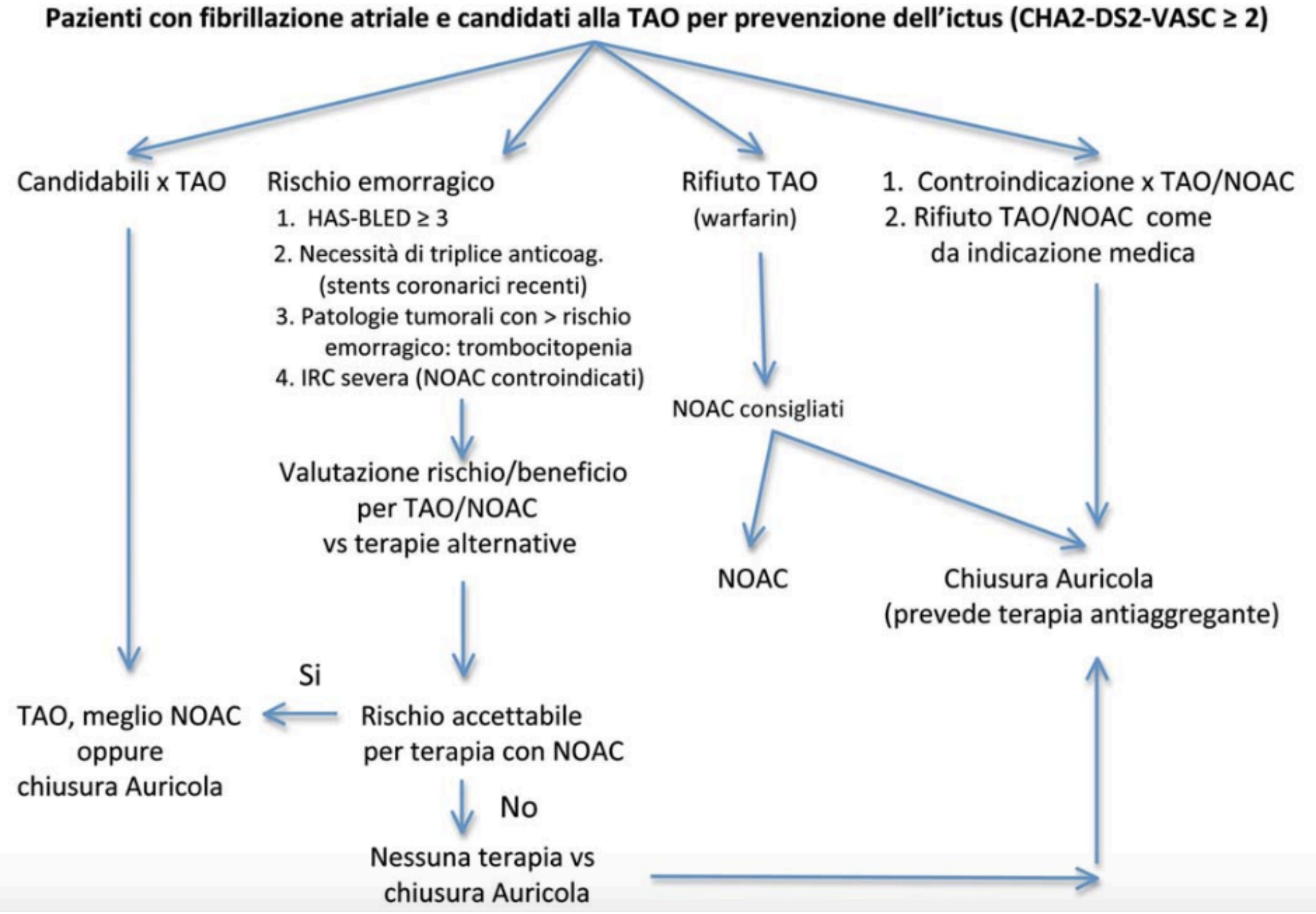
- Recurrent ischemic stroke despite well-controlled OAC
- Previous intracranial hemorrhage (ICH)
- Recurrent GI bleeding
- Comorbidities, such as uncontrolled hypertension, cerebral microbleeds and cerebral amyloid angiopathy
- Coagulopathies
- Patients intolerant to or refusing new (N)OAC drugs
- Patients undergoing PCI who may have indications for the combined use of antiplatelets and OAC

Terapia anticoagulante



Grazie per l'attenzione

Backup slides


Pazienti con fibrillazione atriale e candidati alla TAO per prevenzione dell'ictus (CHA2-DS2-VASC ≥ 2)
Candidabili x TAO
Rischio emorragico
1. HAS-BLED ≥ 3
2. Necessità di triplice anticoag. (stents coronarici recenti)
3. Patologie tumorali con > rischio emorragico: trombocitopenia
4. IRC severa (NOAC controindicati)
Rifiuto TAO (warfarin)
1. Controindicazione x TAO/NOAC
2. Rifiuto TAO/NOAC come da indicazione medica
NOAC consigliati
Valutazione rischio/beneficio per TAO/NOAC vs terapie alternative
NOAC
Chiusura Auricola (prevede terapia antiaggregante)
Si
TAO, meglio NOAC oppure chiusura Auricola
Rischio accettabile per terapia con NOAC
No
Nessuna terapia vs chiusura Auricola

Is dual platelet inhibition enough in the early post-implant weeks?

Patients (n)	85
Mean Age (years)	72±8
Females	31%
Mean CHADS2	2.6±1.1
Paroxysmal/Non-paroxysmal	28% vs. 72%
Contraindications for Warfarin: • Hx of severe bleeding • Hx of minor but recurrent bleeding • Other	 25% 35% 40%

Patients with contraindication to warfarin received LAA-occluder with dual platelet inhibition with ASA and clopidogrel for 6 months and ASA lifelong; prospective 4 center registry (ASAP); participating centres were Cardiovascular Center Frankfurt, Mount Sinai, New York; Heart Center Leipzig and Krankenhaus Barmherzige Brüder Regensburg.

Interim analysis presented at TCT September 2010 by Sievert et al.

Results from the ASA Plavix Registry (ASAP)

Mean follow-up time	6 months
Patients at 3 months	63 (74%)
Patients at 6 months	47 (55%)
Patients at 1year	27 (32%)
Thrombus on device, resolved by heparin	1 (1.1%)
TIA/Stroke Other serious adverse events	0 0

92% successfully implanted, mean procedure time 42min., mean fluoroscopy time 9min., 1 pericardial tamponade (500ml removed by pericardiocentesis).

Interim analysis presented at TCT September 2010 by Sievert et al.