LA CHIUSURA DELL'AURICOLA
NELLA PREVENZIONE
DELL' EMBOLIA CARDIOGENA

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LEFT ATRIAL APPENDAGE CLOSURE

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AF and Stroke

3 million in US and 4.5 million in the EU have AF[1]

2/3 of AF population are at high-risk of stroke[1]

35% of patients with AF will have a stroke in their lifetime[2]

AF is responsible for 15-20% of ischemic strokes[1]

AF Incidence increases with age[2]

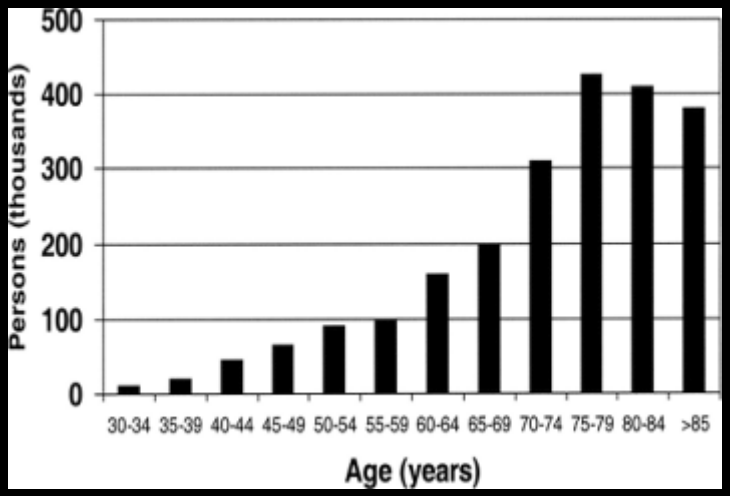
0.4% in general population

0.2% of 25-34 yrs of age

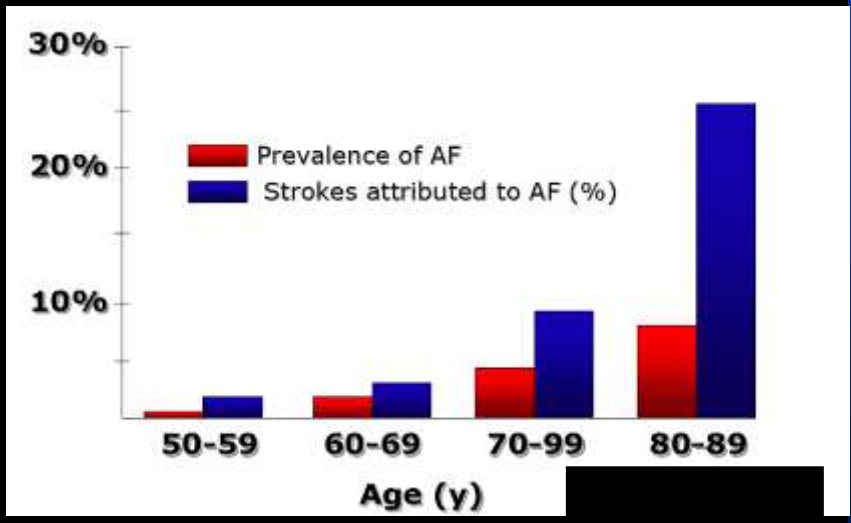
2-5% of >60 yrs of age

20% of > 80 yrs of age

Estimated age-specific AF prevalence[2]



Relationship of AF and stroke[2]



[1] Fuster et al., ACC/AHA/ESC Practice Guidelines, Circulation. 2006;114:700-752

[2] Wolf PA et al., Atrial fibrillation as an independent risk factor for stroke: the Framingham study. Stroke 1991;22:983–8

STROKE

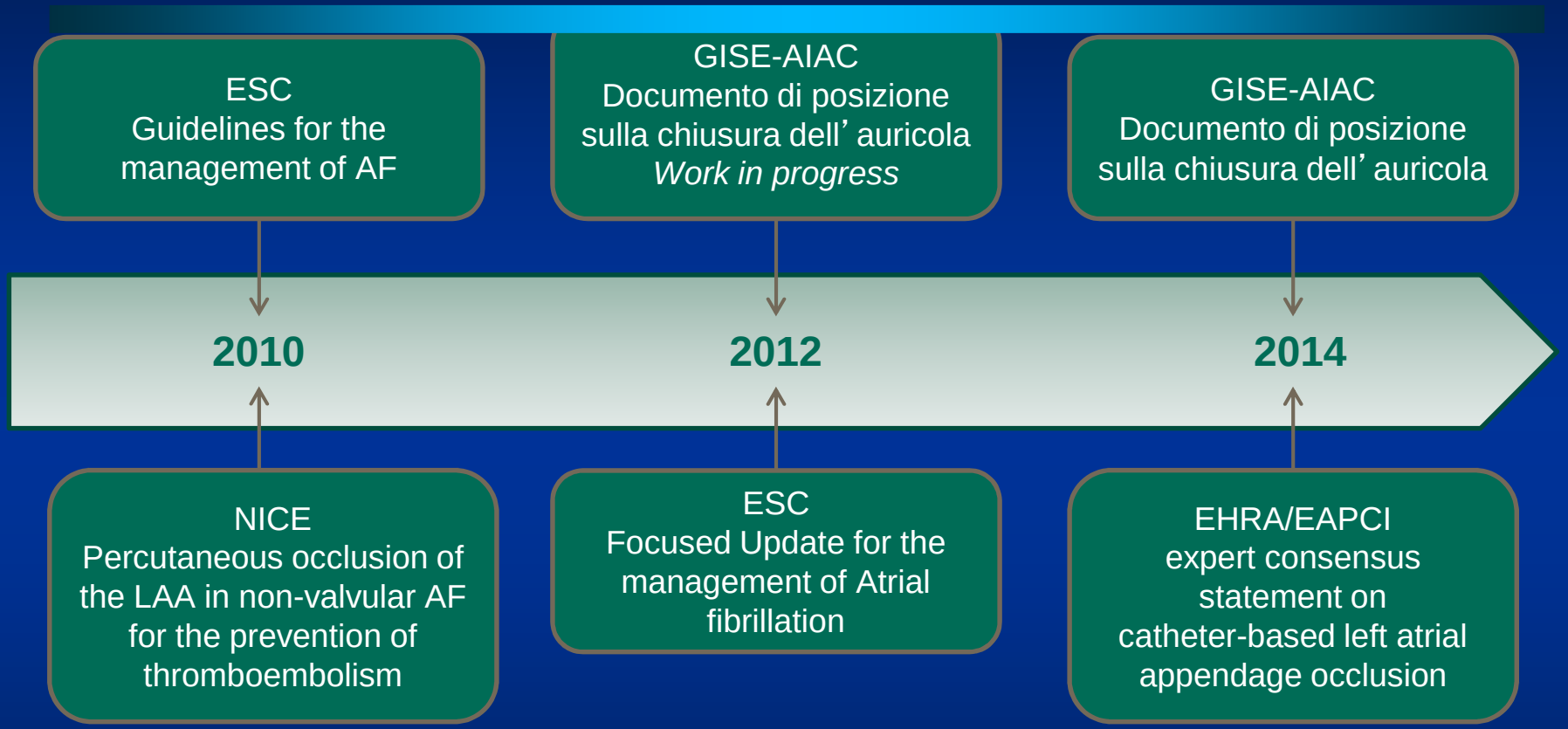
The percentage of strokes attributable to atrial fibrillation increase steeply from 1.5% at 50–59 years of age to more than 20% at 80–89 years of age.

The LAA has been the site in the left atrium where more than 90% of thrombi were detected in patients with non-valvular atrial fibrillation in transoesophageal studies.

Stroke prevention in patients with atrial fibrillation has largely been based on the use of anticoagulation with warfarin, which reduces the risk of stroke by 60%.

Striking a fine balance

Guidelines and documents for the management of AF and percutaneous occlusion of the LAA



NICE – National Institute for Health and Clinical Excellence
ESC – European Society of Cardiology
GISE – Società Italiana di Cardiologia Invasiva
AIAC – Associazione Italiana di Aritmologia e Cardistimolazione
EHRA – European Heart Rhythm Association
EAPCI – European Association of Percutaneous Cardiovascular Intervention

ESC 2012 – Guidelines

European Heart Journal
doi:10.1093/eurheartj/ehs253

ESC GUIDELINES

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
Developed with the special contribution of the European Heart Rhythm Association

5. Left atrial appendage closure

5.2 Results of left atrial appendage closure

Although the concept of LAA closure seems reasonable, the evidence of efficacy and safety is currently insufficient to recommend these approaches for any patients other than those in whom long-term OAC is contraindicated. However, in the absence of controlled clinical data this recommendation is based on expert consensus only.

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	

LAA = left atrial appendage.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.

RegioneEmilia-Romagna

AGENZIA SANITARIA E SOCIALE REGIONALE

COMMISSIONE CARDIOLOGICA E CARDIOCHIRURGICA REGIONALE

DOCUMENTO DI INDIRIZZO

CHIUSURA PERCUTANEA DELL'AURICOLA SINISTRA MEDIANTE DEVICE ENDOCAVITARIO

Data di pubblicazione: settembre 2012

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Indicazioni d'uso appropriato

Il Gruppo di Lavoro, sulla base della propria esperienza clinica e dei risultati della letteratura disponibile, ritiene di raccomandare la chiusura percutanea dell'auricola sinistra nei pazienti con FA cronica con le seguenti finalità:

- **prevenzione primaria di evento ischemico in:**
  - pazienti con indicazione a TAO che presentino tuttavia controindicazioni assolute a tale terapia;
  - pazienti con indicazione a TAO che hanno presentato un episodio di sanguinamento maggiore da causa non rimovibile durante TAO ben condotta
- **prevenzione secondaria di evento ischemico in:**
  - pazienti che hanno presentato un ictus durante TAO in range terapeutico, dopo workup diagnostico che abbia escluso la presenza di altre sorgenti emboligene

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Il trattamento mediante chiusura percutanea dell'auricola sinistra è indicato se coesistono le seguenti condizioni cliniche:

FA cronica persistente o parossistica, da almeno 3 mesi

Alto rischio trombo embolico (CHA2DS2VaSc >=3)

Controindicazioni alla TAO assolute (diatesi emorragica, emorragia cerebralei, ulcera peptica attiva, sanguinamento recente gastrointestinale/genitourinario/respiratorio, severa insufficienza epatica o renale, ipertensione severa, allergia alla TAO, demenza, alcolismo, disturbi psichiatrici)

Stroke Risk Assessment:
CHA_2DS_2-VASc score

Recommendation for Stroke Risk Assessment for Stroke Prophylaxis

- The 2012 guidelines also include a 1A recommendation that in non-valvular AF patients, stroke risk should be assessed using the CHA_2DS_2-VASc score.

CHA_2DS_2-VASc Score[2]

Risk factors for stroke and thrombo-embolism in non-valvular AF	
'Major' risk factors	'Clinically relevant non-major' risk factors
▪ Previous stroke, TIA, or systemic embolism ▪ Age ≥75 years	▪ Heart failure or moderate to severe LV systolic dysfunction (e.g., LV EF ≤40%) ▪ Hypertension ▪ Diabetes mellitus ▪ Female sex ▪ Age 65-74 years ▪ Vascular disease[a]

Risk factor-based approach as a point based scoring system with the acronym CHA_2DS_2-VASc (Note maximum score is 9 since age may contribute 0, 1 or 2 points)	
Risk Factor	Score
Congestive heart failure/LV dysfunction	1
Hypertension	1
Age ≥75	2
Diabetes mellitus	1
Stroke/TIA/thrombo-embolism	2
Vascular disease[a]	1
Age 65-74	1
Sex category (i.e., female sex)	1
Maximum Score	**9**

a. Prior myocardial infarction, peripheral artery disease, aortic plaque. Actual rates of stroke in contemporary cohorts may vary from these estimates.

Risk Assessment: Bleeding

HAS-BLED score

Letter	Clinical characteristics	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 INR	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.

Historically

Surgical Options

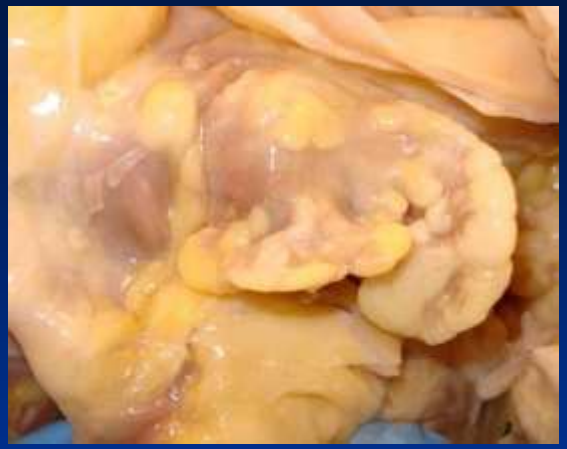
Madden carried out the first LAA surgical excision in humans in 1949

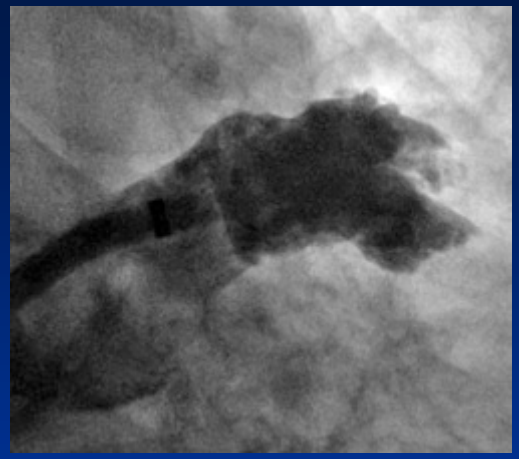
Excision of the LAA

Suture ligation of LAA

Percutaneous Management

New techniques have emerged which have enabled this process to be done percutaneously without exposing patients to high-risk invasive surgery





Multiple lobes of the LAA

Clinical Implication

Multiple lobes are commonly seen and often located in the distal of the LAA

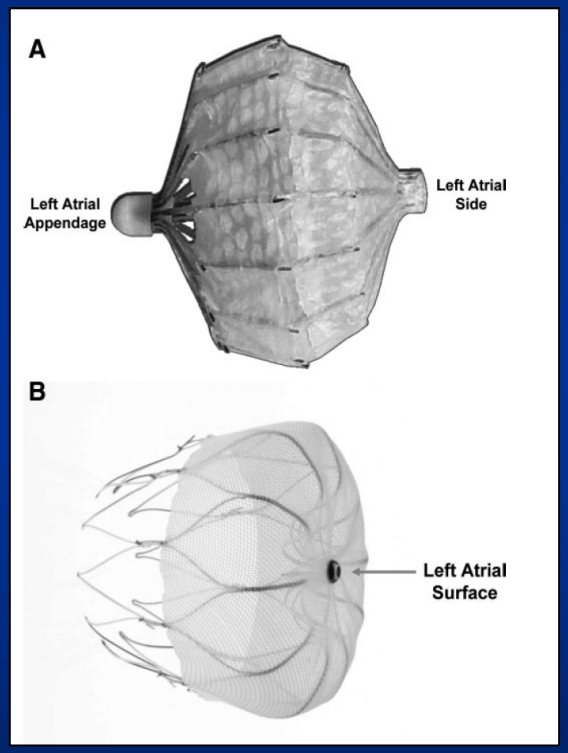
Thin walled LAA

Handle with care

Avoid direct contact of the LAA wall with sheath, dilator, and endscrew of constrained device in a delivery sheath

Percutaneous **DEVICE USED**

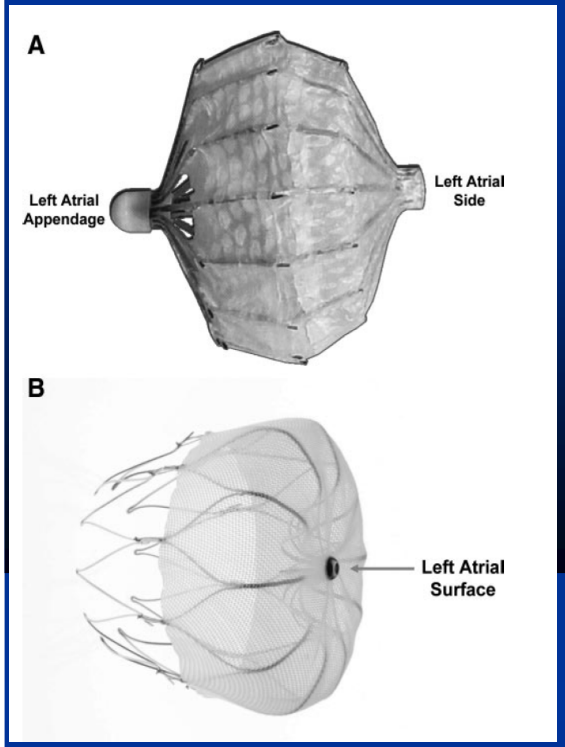
Ball shaped



Jellyfish shaped

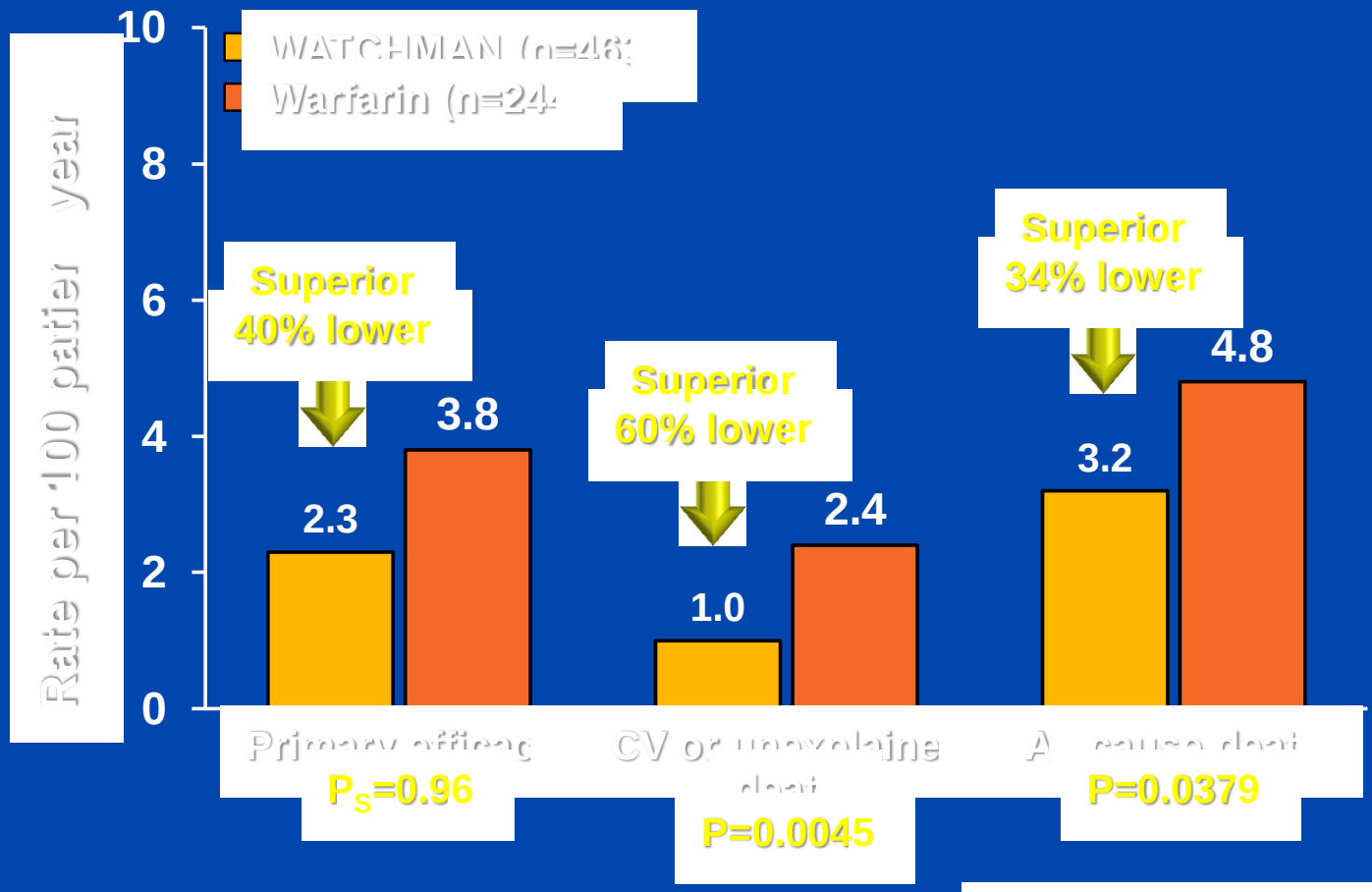
The LARIAT suture delivery system

Disc + lobe



Adverse events have been reported despite the device used and are related to the procedure… a standardized tecnique is crucial in order to decrease the learning curve effect.

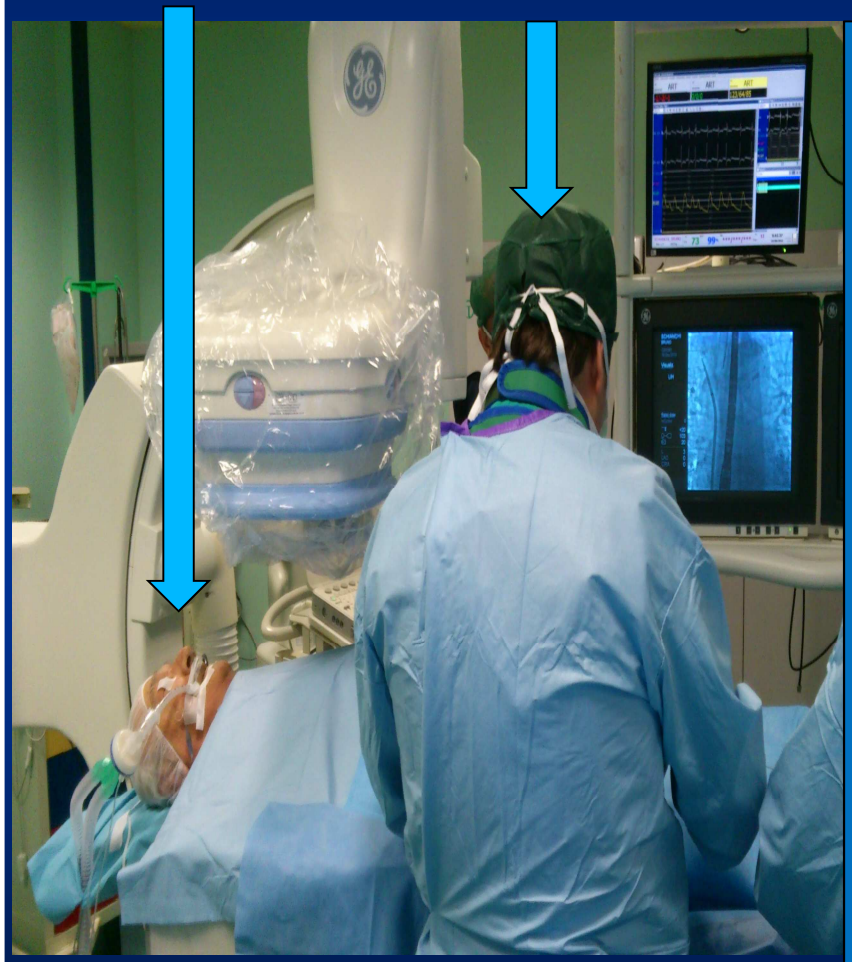
Background
PROTECT AF 4-Year Superiority

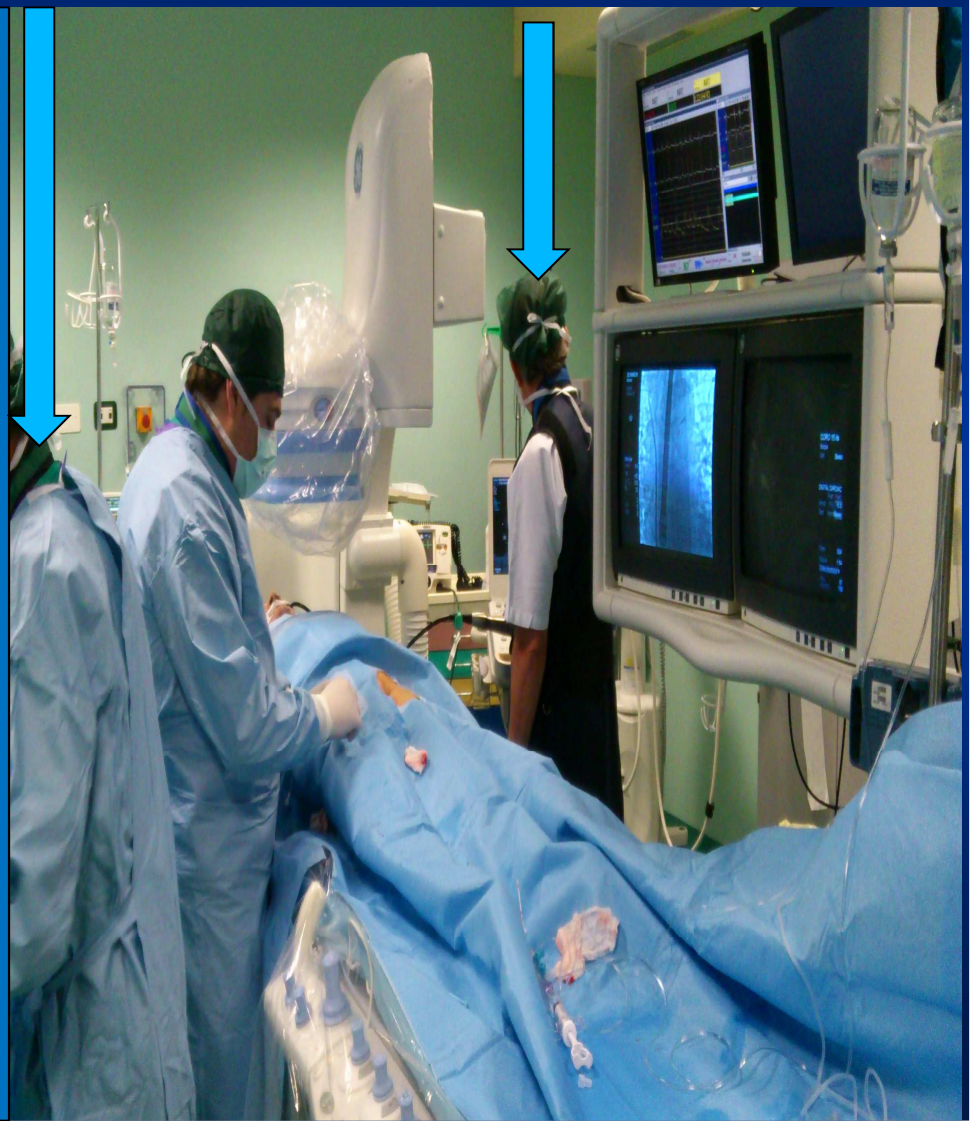


P_S = Posterior Superiority Probability
Reddy et al: HRS, 2013

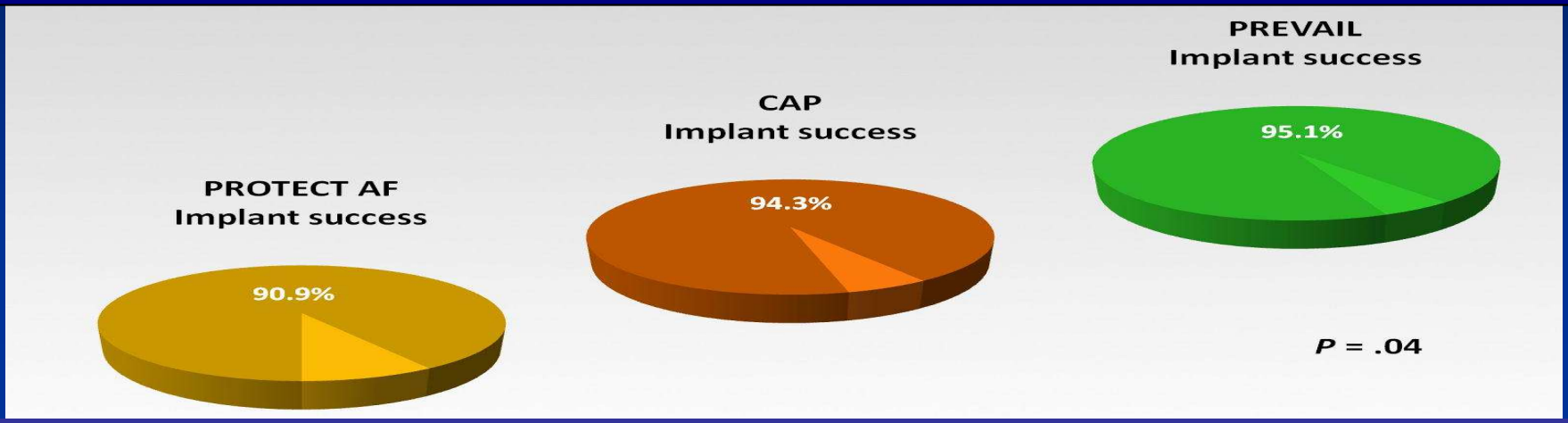
MAYO CLINIC

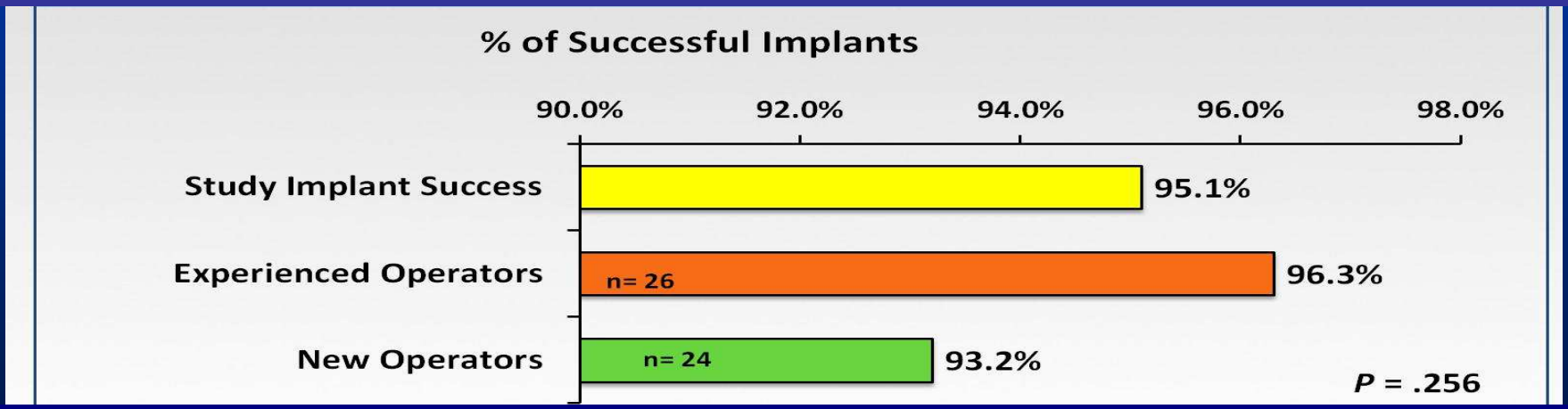
Cath-lab staff





Procedural Implant Success





Complications

PERICARDIAL EFFUSION

DEVICE EMBOLIZATION

ISCHAEMIC STROKE

TROMBUS FORMATION

Pericardial Effusion

Root Cause Analysis of the Pericardial Effusion in PROTECT AF

	Events, n(%)
Initial transseptal puncture	2/22 (9)
From adjunctive device to enter the LAA (such as a guidewire or catheter)	2/22 (9)
Manipulating delivery system within the LAA	3/22 (14)
Protruding delivery sheath from the Transseptal access site	2/22 (9)
Watchman deployment process	4/22 (18)
No definitive cause identified	7/22 (32)

Circulation. 2011;123:417-424.

Initial ACP Italian Experience

Procedural Complications (N=90)

Pericardial Effusion (documented in all 90 cases)	
Yes	1 (1.1 %)
No	89 (98.9 %)

Pericardial Tamponade (documented in all 90 cases)	
Yes	1 (1.1 %)
No	89 (98.9 %)

Minor Complications (documented in all 90 cases)	
Transient Thrombus on device cable	1 case
Air Embolism	1 case

Overall complications (documented in all 90 cases)	
Yes	4 (4.4 %)
No	86 (95.6 %)

Conclusion

A standardized tecnique is crucial in order to decrease the learning curve effect.

As with all interventional procedures, there is a significant improvement in the safety of LAA appendage closure with increased operator experience

GRAZIE
DELL’ATTENZIONE !