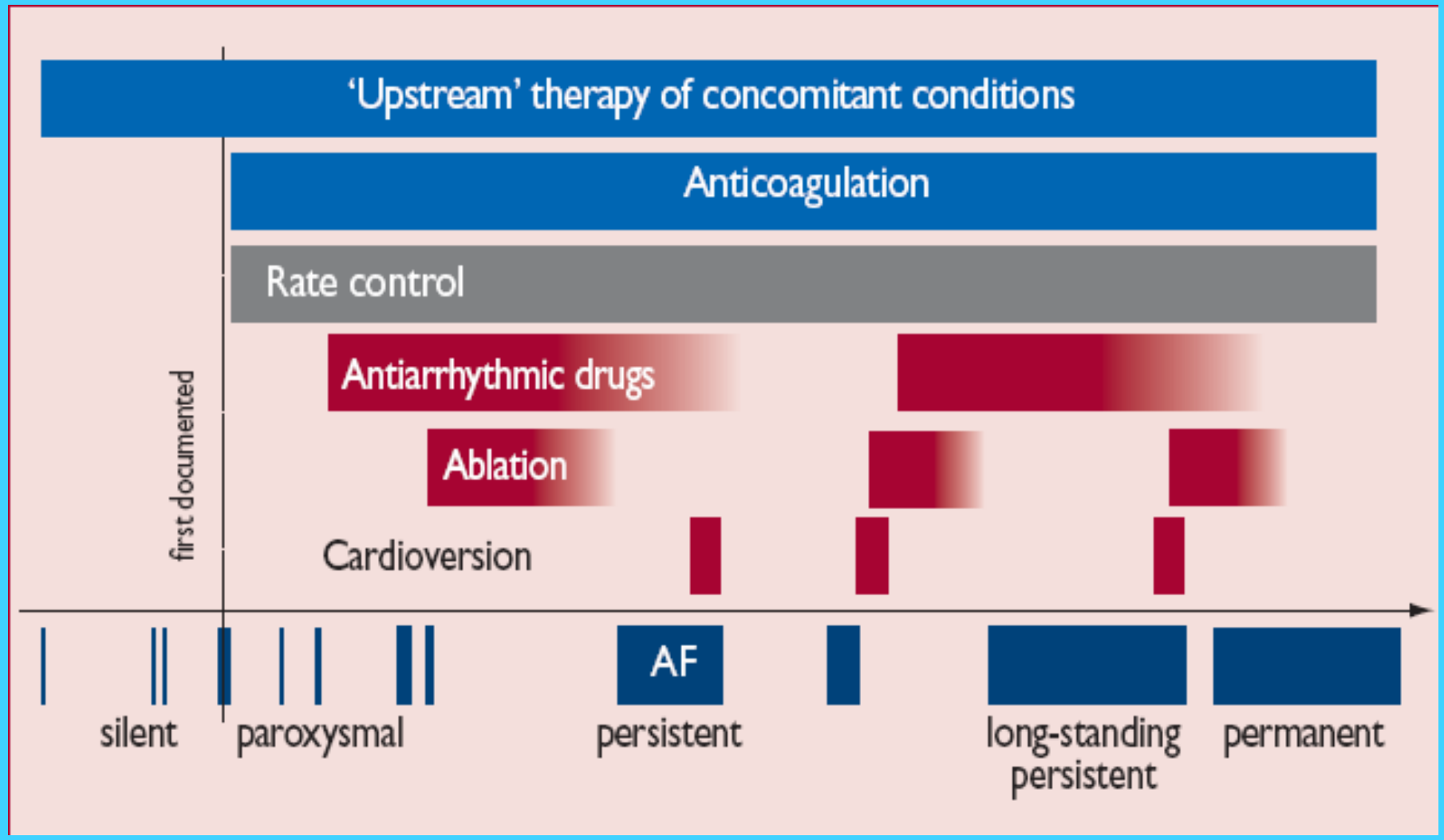
ABLAZIONI E CHIUSURA AURICOLA

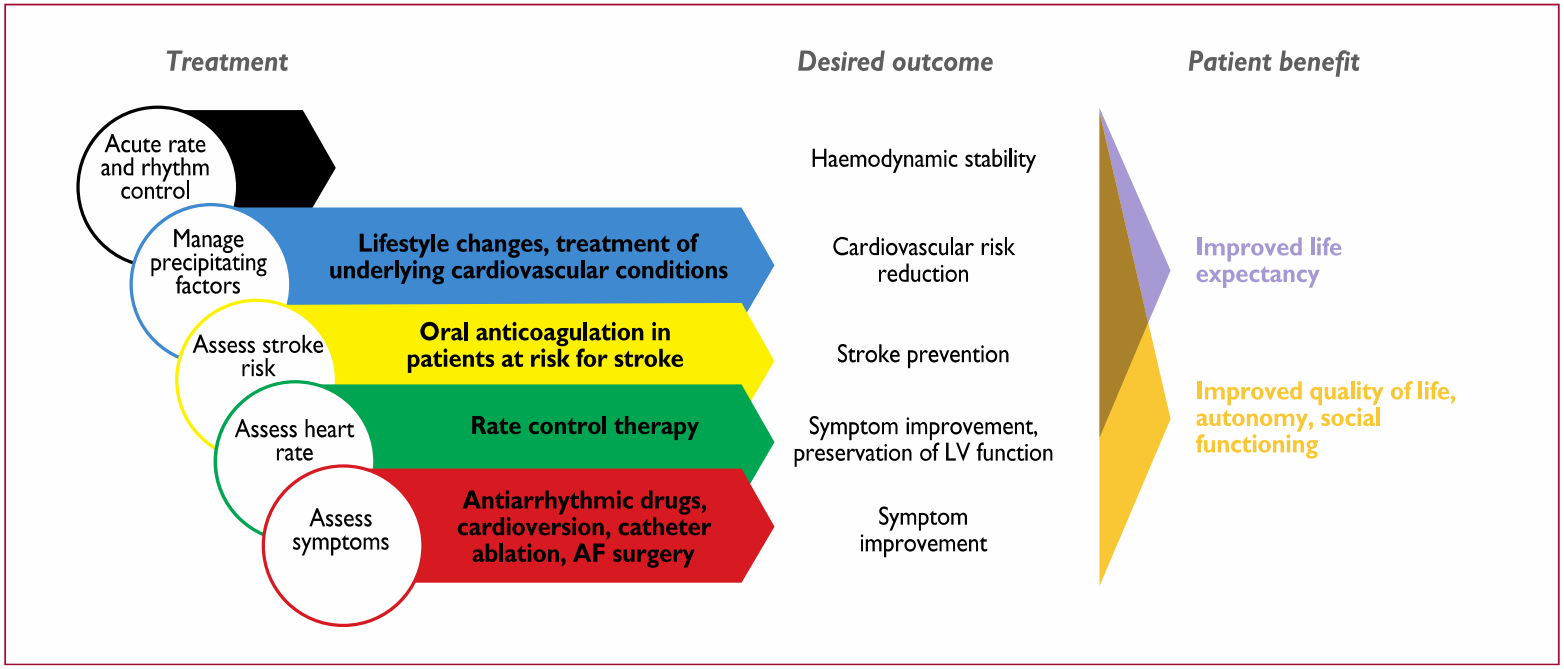
Gaetano Senatore

CARDIOLOGIA
CIRIE'

LABORATORIO di ELETTROFISIOLOGIA
A.S.L. 6 Ospedale di Ciriè


'Upstream' therapy of concomitant conditions
Anticoagulation
Rate control
Antiarrhythmic drugs
Ablation
Cardioversion
first documented
AF
silent
paroxysmal
persistent
long-standing persistent
permanent

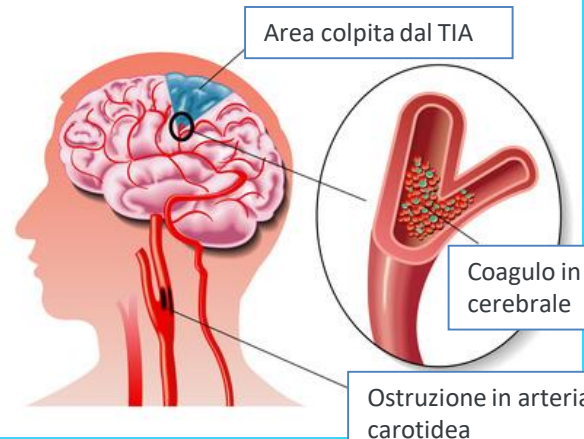
2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS



AF = atrial fibrillation; LV = left ventricular.

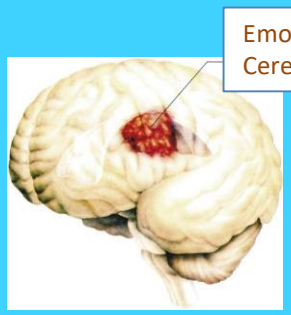
Figure 5 Acute and chronic management of atrial fibrillation patients, desired cardiovascular outcomes, and patient benefits. Adapted from the report on the 4th AFNET/EHRA consensus conference.[76]

Thromboembolism



CHA_2DS_2-VASc risk factor	Points
Congestive heart failure Signs/symptoms of heart failure or objective evidence of reduced left ventricular ejection fraction	+1
Hypertension Resting blood pressure >140/90 mmHg on at least two occasions or current antihypertensive treatment	+1
Age 75 years or older	+2
Diabetes mellitus Fasting glucose >125 mg/dL (7 mmol/L) or treatment with oral hypoglycaemic agent and/or insulin	+1
Previous stroke, transient ischaemic attack, or thromboembolism	+2
Vascular disease Previous myocardial infarction, peripheral artery disease, or aortic plaque	+1
Age 65–74 years	+1
Sex category (female)	+1

Bleeding risk



Modifiable bleeding risk factors:	Non-modifiable bleeding risk factors:
Hypertension (especially when systolic blood pressure is >160 mmHg)	Age (>65 years) (≥75 years)
Labile INR or time in therapeutic range <60% in patients on vitamin K antagonists	History of major bleeding
Medication predisposing to bleeding, such as antiplatelet drugs and non-steroidal anti-inflammatory drugs	Previous stroke
Excess alcohol (≥8 drinks/week)	Dialysis-dependent kidney disease or renal transplant
Potentially modifiable bleeding risk factors:	Cirrhotic liver disease
Anaemia	Malignancy
Impaired renal function	Genetic factors
Impaired liver function	**Biomarker-based bleeding risk factors:**
Reduced platelet count or function	High-sensitivity troponin
	Growth differentiation factor-15
	Serum creatinine/estimated CrCl

CASE PRESENTATION

76yrs man
Hypertension
SSS with atrial fibrillation recurrences
Thrombocytopenia
Thyroid disorder
PM in2008
Beta-blockers

CASE PRESENTATION

Thrombocytopenia

Controindication for VKA

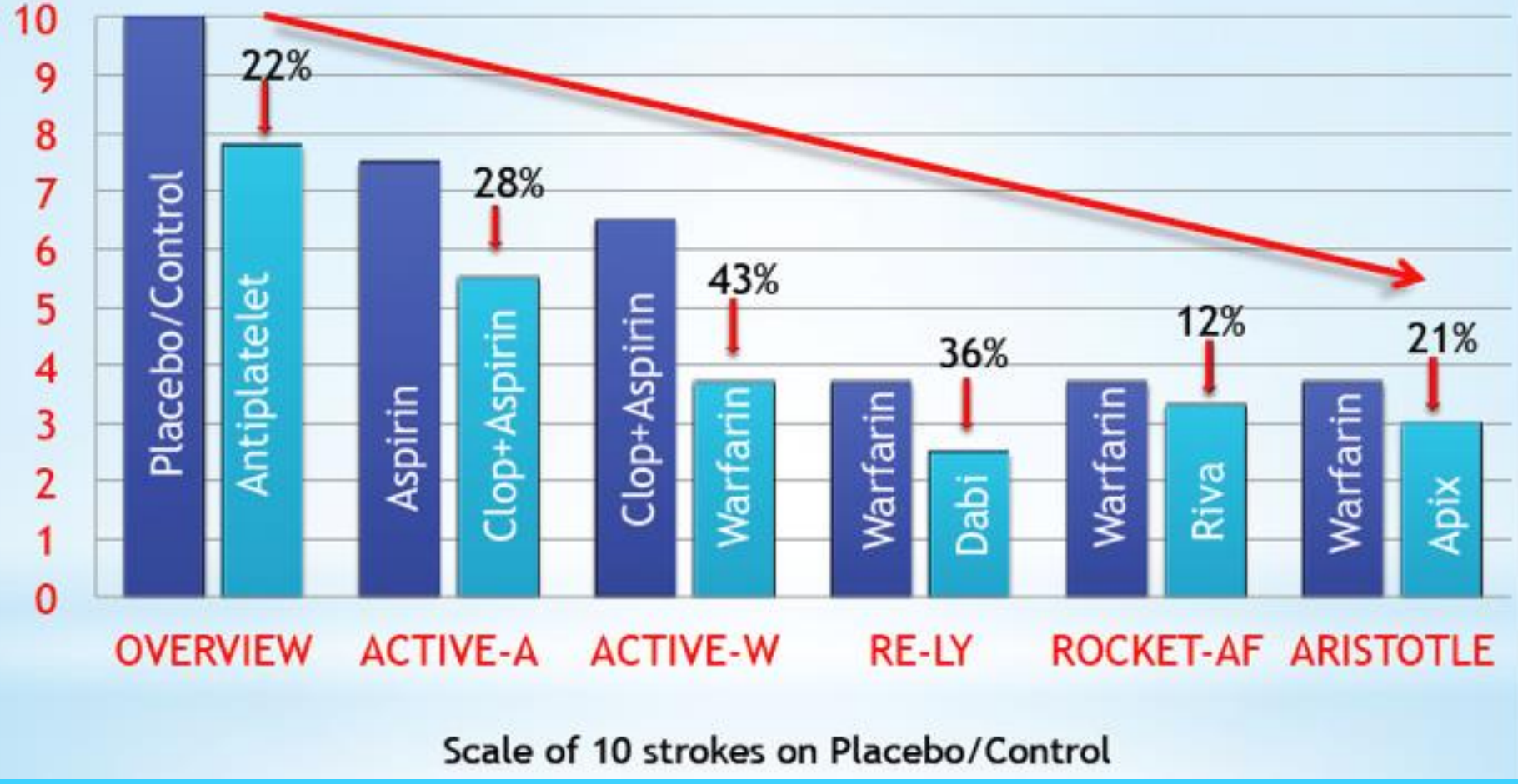
Flecainide 100 mg/die

G.P.

- Paroxysmal AF

- Controindication to anticoagulation

Evoluzione della Riduzione del rischio stroke con la terapia medica (Granger, Circ. 2012)



Recommendations for Selecting an Anticoagulant Regimen—Balancing Risks and Benefits
Referenced studies that support new or modified recommendations are summarized in Online Data Supplements 1 and 2.

COR	LOE	RECOMMENDATIONS
I	A	1. For patients with AF and an elevated CHA_2DS_2-VASc score of 2 or greater in men or 3 or greater in women, oral anticoagulants are recommended. Options include: ■ Warfarin (LOE: A) (S4.1.1-5-S4.1.1-7) ■ Dabigatran (LOE: B) (S4.1.1-8) ■ Rivaroxaban (LOE: B) (S4.1.1-9) ■ Apixaban (LOE: B) (S4.1.1-10), or ■ Edoxaban (LOE: B-R) (S4.1.1-11) MODIFIED: This recommendation has been updated in response to the approval of edoxaban, a new factor Xa inhibitor. More precision in the use of CHA_2DS_2-VASc scores is specified in subsequent recommendations. The LOEs for warfarin, dabigatran, rivaroxaban, and apixaban have not been updated for greater granularity as per the new LOE system. (Section 4.1. in the 2014 AF Guideline) The original text can be found in Section 4.1 of the 2014 AF guideline. Additional information about the comparative effectiveness and bleeding risk of NOACs can be found in Section 4.2.2.2.
I	B	
I	B	
I	B-R	

2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation

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(Continued)		
I	C	10. Reevaluation of the need for and choice of anticoagulant therapy at periodic intervals is recommended to reassess stroke and bleeding risks. MODIFIED: "Antithrombotic" was changed to "anticoagulant."

2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation

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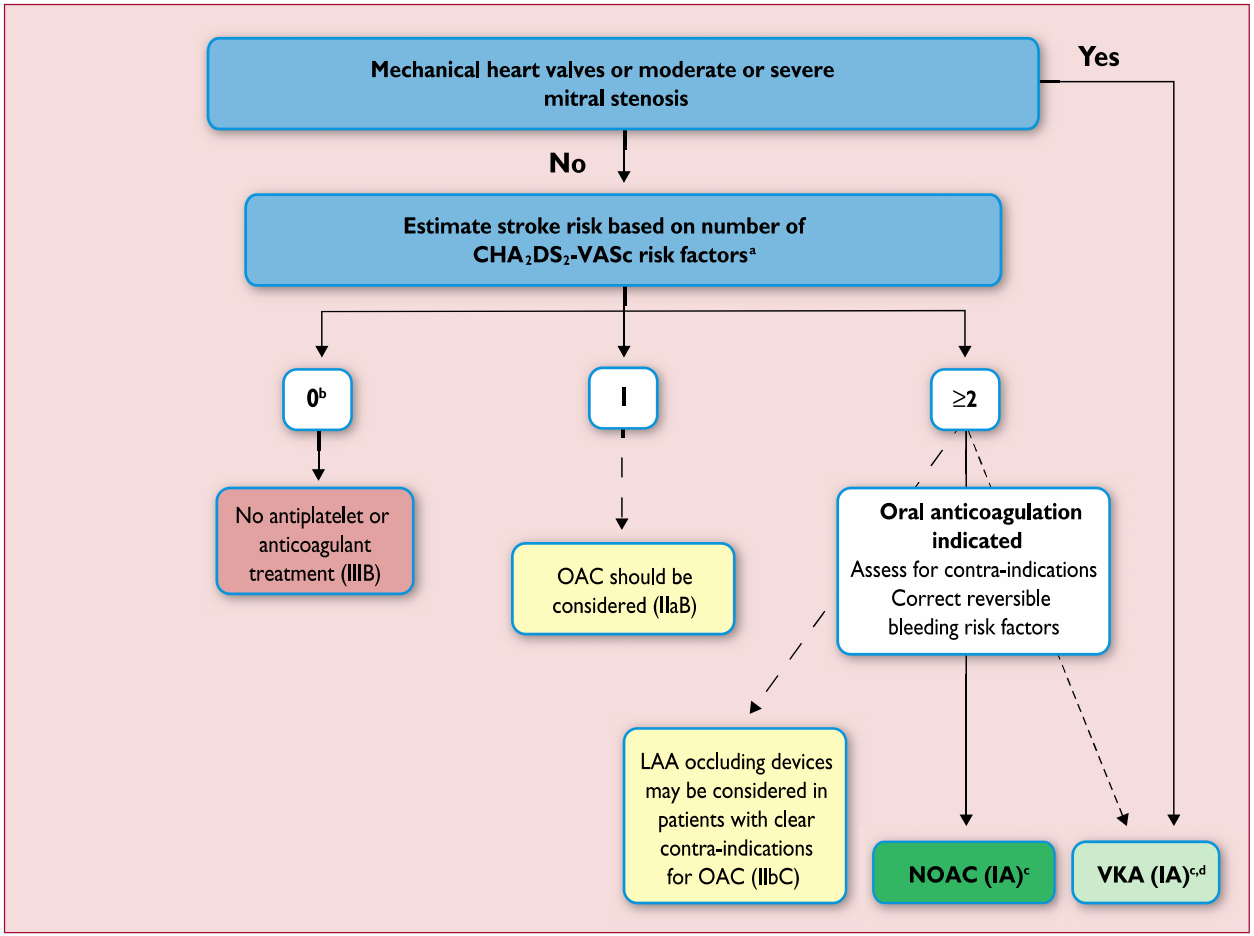
2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

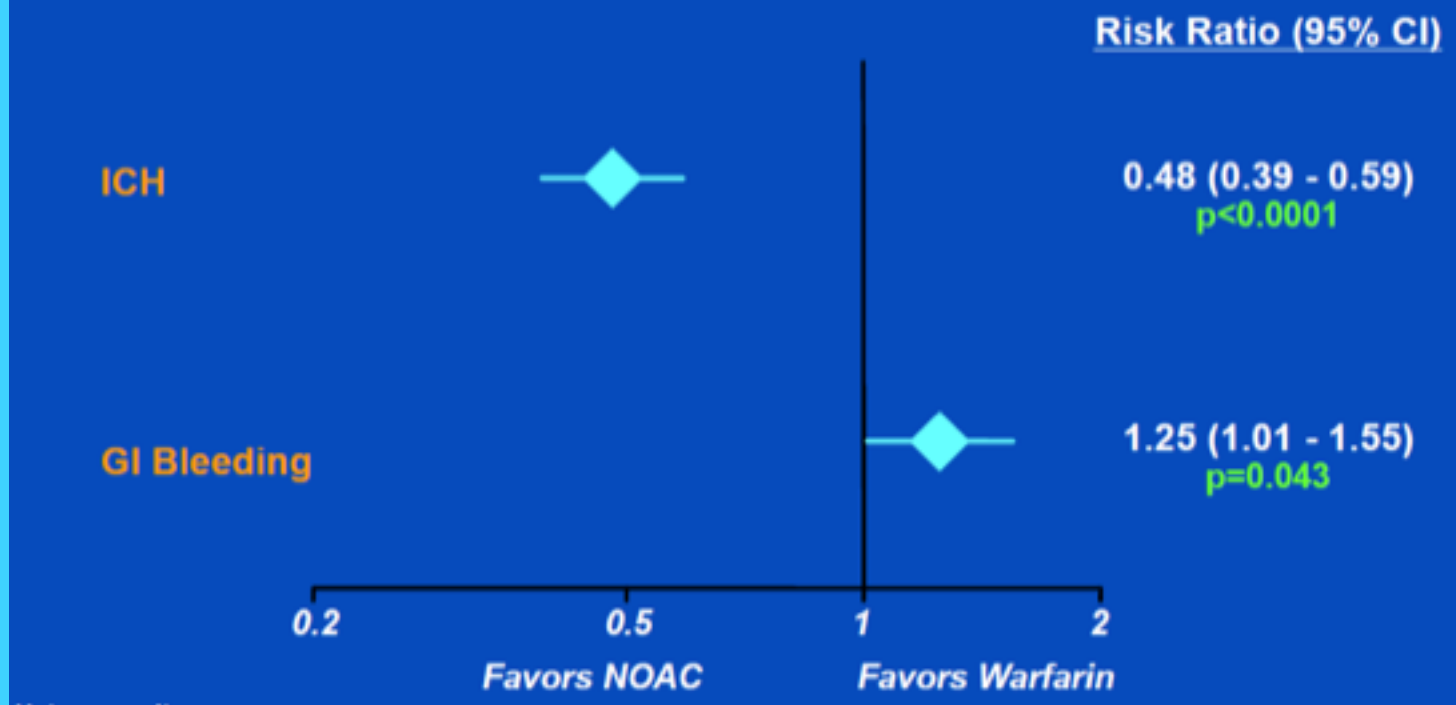


AF = atrial fibrillation; LAA = left atrial appendage; NOAC = non-vitamin K antagonist oral anticoagulant; OAC = oral anticoagulation; VKA = vitamin K antagonist.
[a]Congestive heart failure, Hypertension, Age ≥75 years (2 points), Diabetes, prior Stroke/TIA/embolus (2 points), Vascular disease, age 65–74 years, female Sex.
[b]Includes women without other stroke risk factors.
[c]IIaB for women with only one additional stroke risk factor.
[d]IB for patients with mechanical heart valves or mitral stenosis.

Figure 8 Stroke prevention in atrial fibrillation.

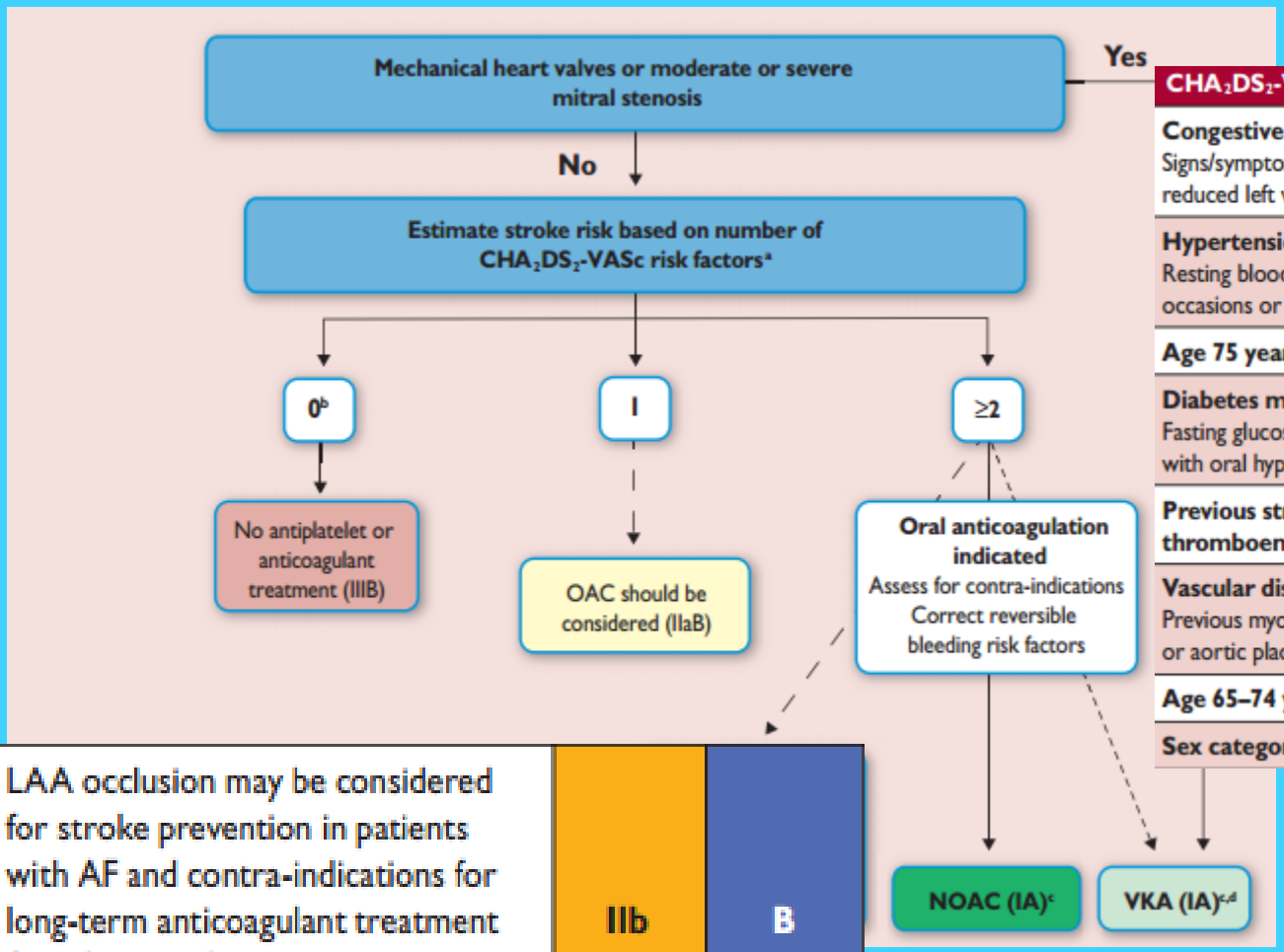
	Discontinuation Rate: Study Drug	Discontinuation Rate: Warfarin
RELY: Dabigatran	21%	18%
ROCKET AF: Rivaroxaban	24%	22%
ARISTOTLE: Apixaban	25%	28%

Secondary Safety Outcomes



Heterogeneity
ICH, p=0.22
GI Bleeding, p=0.009

Ruff CT, et al. Lancet 2013



CHA_2DS_2-VASc risk factor	Points
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Diabetes mellitus Fasting glucose >125 mg/dL (7 mmol/L) or treatment with oral hypoglycaemic agent and/or insulin	+1
Previous stroke, transient ischaemic attack, or thromboembolism	+2
Vascular disease Previous myocardial infarction, peripheral artery disease, or aortic plaque	+1
Age 65–74 years	+1
Sex category (female)	+1

LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term anticoagulant treatment (e.g. those with a previous life-threatening bleed without a reversible cause).	IIb	B

Benussi et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. European Heart Journal (2016) 37, 2893–2962

Recommendation for Percutaneous Approaches to Occlude the LAA
Referenced studies that support the new recommendation are summarized in Online Data Supplement 4.

COR	LOE	RECOMMENDATION
IIb	B-NR	1. Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation (S4.4.1-1–S4.4.1-5). NEW: Clinical trial data and FDA approval of the Watchman device necessitated this recommendation.

2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation

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Developed in Collaboration With the Society of Thoracic Surgeons

THE RATIONALE FOR THE QUEST TO CLOSE THE LEFT ATRIAL APPENDAGE

- the concept that atrial fibrillation causes strokes
- the concept that strokes are associated with thrombus formation in the LAA,
- these thrombi cause strokes by embolisation to the cerebral circulation

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

VIRCHOW TRIAD

- flow abnormalities or stasis
- changes in the inner layer of the atrium and LAA
- abnormalities in haemostasis

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

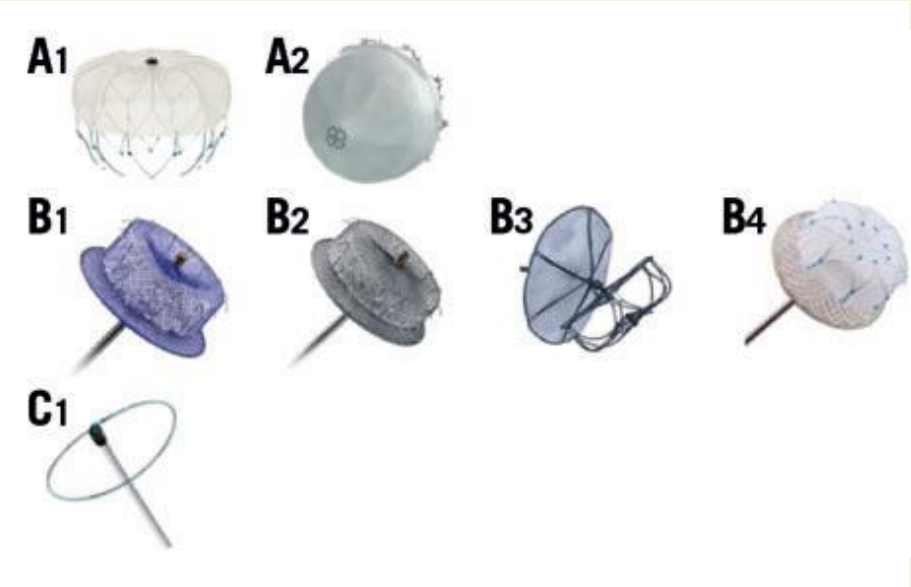


Figure 2 Commercially available, CE-mark approved devices. A1) WATCHMAN (Boston Scientific). A2) WaveCrest (Biosense Webster). B1) Amulet (Abbott Vascular). B2) AMPLATZER Cardiac Plug (Abbott Vascular). B3) Ultraseal LAA Occluder (Cardia). B4) LAmbre (Lifetech). C1) LARIAT (SentreHEART).

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

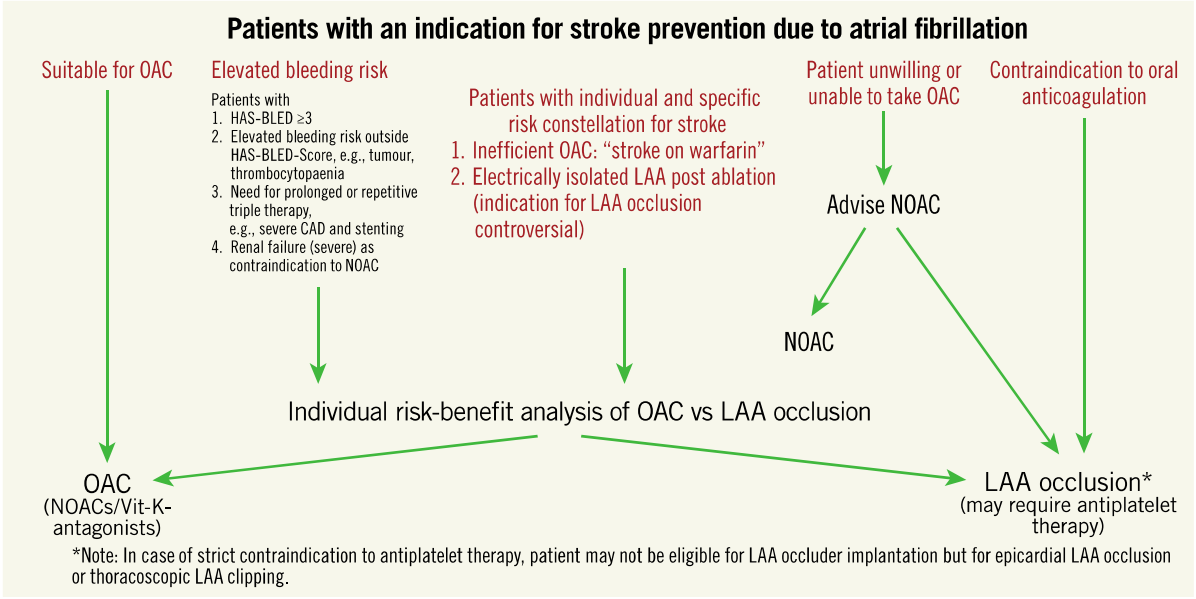


Figure 22 Decision tree for LAA closure.

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

CASE PRESENTATION

Incremental flecainide (daily atrial fibrillation recurrences) 200mg/die

Syncope due to VT episodes cardioverted

G.P.

- Paroxysmal AF
- Contraindication to anticoagulation 
- Contraindication to antiarrhythmic therapy 

CASE PRESENTATION

-rate-control ?

AFib : rhythm vs rate control

Rate- and rhythm-control strategies seem to be equally effective, **but**:

- sinus rhythm is achieved in only 40-60% of pts in the rhythm control arm of randomized CTs
- sinus rhythm maintenance can be associated with:
  - less atrial enlargement
  - QoL improvement
  - better exercise tolerance
  - reduced risk of LV dysfunction progression or appearance
  - lower mortality

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

Recommendations for rhythm control therapy

Recommendations	Class[a]	Level[b]	Ref[c]
General recommendations			
Rhythm control therapy is indicated for symptom improvement in patients with AF.	I	B	120, 586, 601
Management of cardiovascular risk factors and avoidance of AF triggers should be pursued in patients on rhythm control therapy to facilitate maintenance of sinus rhythm.	IIa	B	203, 204, 296, 312
With the exception of AF associated with haemodynamic instability, the choice between electrical and pharmacological cardioversion should be guided by patient and physician preferences.	IIa	C	

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

Recommendations for catheter ablation of atrial fibrillation and atrial fibrillation surgery

Recommendations	Class[a]	Level[b]	Ref[c]
Catheter ablation of symptomatic paroxysmal AF is recommended to improve AF symptoms in patients who have symptomatic recurrences of AF on antiarrhythmic drug therapy (amiodarone, dronedarone, flecainide, propafenone, sotalol) and who prefer further rhythm control therapy, when performed by an electrophysiologist who has received appropriate training and is performing the procedure in an experienced centre.	I	A	585–587, 713, 727
Ablation of common atrial flutter should be considered to prevent recurrent flutter as part of an AF ablation procedure if documented or occurring during the AF ablation.	IIa	B	827
Catheter ablation of AF should be considered as first-line therapy to prevent recurrent AF and to improve symptoms in selected patients with symptomatic paroxysmal AF as an alternative to antiarrhythmic drug therapy, considering patient choice, benefit, and risk.	IIa	B	585
All patients should receive oral anticoagulation for at least 8 weeks after catheter (IIaB) or surgical (IIaC) ablation.	IIa	B C	727
Anticoagulation for stroke prevention should be continued indefinitely after apparently successful catheter or surgical ablation of AF in patients at high-risk of stroke.	IIa	C	
When catheter ablation of AF is planned, continuation of oral anticoagulation with a VKA (IIaB) or NOAC (IIaC) should be considered during the procedure, maintaining effective anticoagulation.	IIa	B C	760, 768
Catheter ablation should target isolation of the pulmonary veins using radiofrequency ablation or cryothermy balloon catheters.	IIa	B	585, 715, 716, 734, 735
AF ablation should be considered in symptomatic patients with AF and heart failure with reduced ejection fraction to improve symptoms and cardiac function when tachycardiomyopathy is suspected.	IIa	C	185, 226–228, 720, 777–779, 828

Catheter ablation vs AAD success rate in RCTs

Reference	Pts treated with RFCA (n/N)	Success (%)	Pts treated with AAD s (n/N)	Success (%)
Krittayaphong et al., 2003	12/15	79	6/15	40
Oral et al., 2006	57/77	74	40/69	58
Wazni et al., 2005	28/32	87.5	13/35	37
Stabile et al., 2006	38/68	56	6/69	9
Jais et al., 2008	46/53	89	13/55	23
Pappone et al., 2006	85/99	86	22/99	22
Forleo et al., 2009	28/35	80	15/35	43
Wilber et al., 2010	70/106	66	10/61	16
Overall	**364/485**	**75%**	**125/ 438**	**28%**

Ablation vs AAD

Table 5. Safety Outcomes for Patients With AF Undergoing Catheter Ablation

Outcomes	t	n/N	%
Mortality			
Death overall	65	42/5781	0.7
Procedure-related	64	0/5192	0.0
Vascular access complications			
Arteriovenous fistula	32	1/2885	0.0
Bleeding	33	1/2960	0.0
Hematoma	38	17/3719	0.5
Pneumothorax	34	0/2974	0.0
Femoral artery pseudoaneurysm	34	15/3032	0.5
Periprocedure events			
Stroke, ischemic	62	17/5665	0.3
TIA	60	13/5467	0.2
Cardiac tamponade	63	45/5723	0.8
PE	60	3/5496	0.1
DVT	56	1/4758	0.0
Other embolism	57	10/5347	0.2
LA-esophageal fistula	60	0/5496	0.0
Other fistula	58	3/5407	0.1
Pericardial effusion	64	36/5719	0.6
PV stenosis*	65	91/5831	1.6
AV block	60	1/5496	0.0
CHF exacerbation	60	0/5496	0.0
Need for a pacemaker	46	4/3902	0.1
Total No. of patients with events	28	97/1964	4.9

t indicates No. of treatment groups; n, No. of patients with this adverse

Table 6. Safety Outcomes for Patients With AF Receiving AAD Therapy

	Overall		
Safety Outcomes	t	n/N	%
Mortality			
Death overall	33	120/4291	2.8
Sudden death	21	18/2900	0.6
Treatment-related death	22	15/3179	0.5
Not treatment-related death	20	40/3023	1.3
Adverse events			
CV events	10	58/1572	3.7
Bradycardia	19	44/2349	1.9
GI	16	97/1499	6.5
Neuropathy	4	48/969	5.0
Thyroid dysfunction	5	19/576	3.3
Torsades	12	16/2238	0.7
Q-T* prolongation	12	5/2034	0.2
Total No. of patients with events	24	989/3318	29.8
Discontinuations			
Total	32	1035/4347	23.8
Due to AE	32	384/3682	10.4
Due to inefficacy	12	229/1694	13.5
Due to noncompliance	4	19/457	4.2

t indicates No. of treatment groups; n, No. of patients with this adverse event; N, No. of patients evaluated in studies reporting this adverse event; %,

Calkins Het al, Circ Arrhythmia 2009

CIRIE' CARDIOLOGY

LABORATORIO di ELETTROFISIOLOGIA

A.S.L. 6 Ospedale di Cirié

Recommendations for occlusion or exclusion of the left atrial appendage

Recommendations	Class[a]	Level[b]	Ref[c]
After surgical occlusion or exclusion of the LAA, it is recommended to continue anticoagulation in at-risk patients with AF for stroke prevention.	I	B	461, 462
LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term anticoagulant treatment (e.g. those with a previous life-threatening bleed without a reversible cause).	IIb	B	449, 453, 454
Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients with AF undergoing cardiac surgery.	IIb	B	463
Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients undergoing thoracoscopic AF surgery.	IIb	B	468

AF = atrial fibrillation; LAA = left atrial appendage.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendations.

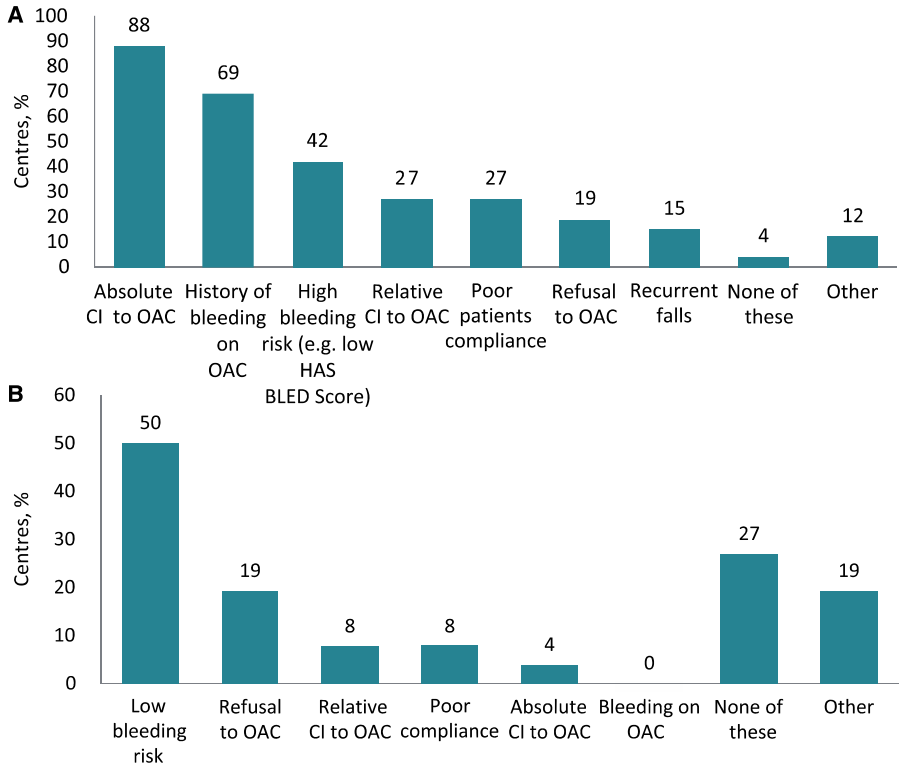


Figure 1 In patients with atrial fibrillation and a CHA_2DS_2-VASc score ≥2, indications for LAAO (A) and contraindications for LAAO (B) at your institutions are (multiple answers). "Other" included thrombus in the left atrial appendage (n=1), contraindications for general anaesthesia (n=1) and other reasons. LAAO, left atrial appendage occluder; NOAC, non-vitamin K antagonist oral anticoagulant; OAC, oral anticoagulation.

ESC European Society of Cardiology
Europace (2017) 19, 1737–1742
doi:10.1093/europace/eux254
EP WIRE

Left atrial appendage occluder implantation in Europe: indications and anticoagulation post-implantation. Results of the European Heart Rhythm Association Survey

Roland Richard Tilz[1]*, Tatjana Potpara[2,3], Jian Chen[4,5], Dan Dobreanu[6], Torben Bjerregaard Larsen[7], Kristina Herman Haugaa[8,9], and Nikolaos Dagres[10]

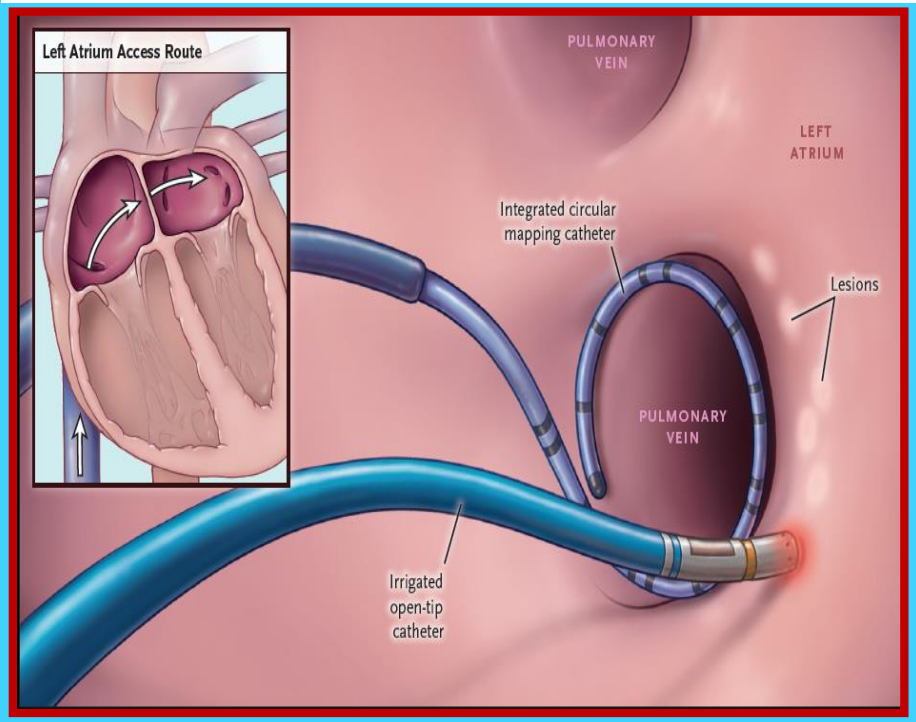
	Watchman	Amulet
Patients	89	33
M	59	16
CHADSVASC	3,5 ±1,47	3,2 ± 1,8
HASBLED	3 ± 1,08	3 ± 0,9

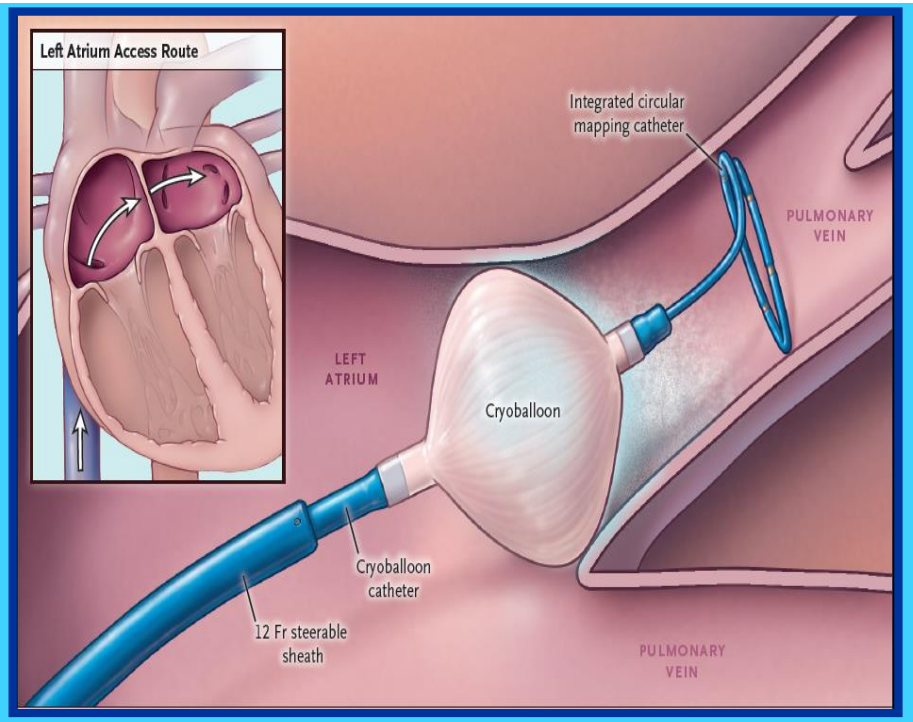
G.P.

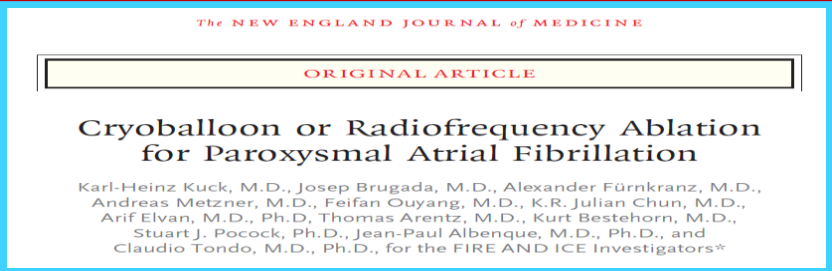
- Paroxysmal AF
- Contraindication to anticoagulation 
- Contraindication to antiarrhythmic therapy 

- **RFC Ablation (“FIRE”)**
  - Power was not to exceed
    - 40 W at A/I aspect
    - 30 W at P/S aspect
  - 3D electroanatomical mapping

- **Cryoballoon Ablation (“ICE”)**
  - Max. freeze duration of 240s recommended
  - Bonus freeze after isolation recommended
  - Phrenic nerve pacing required



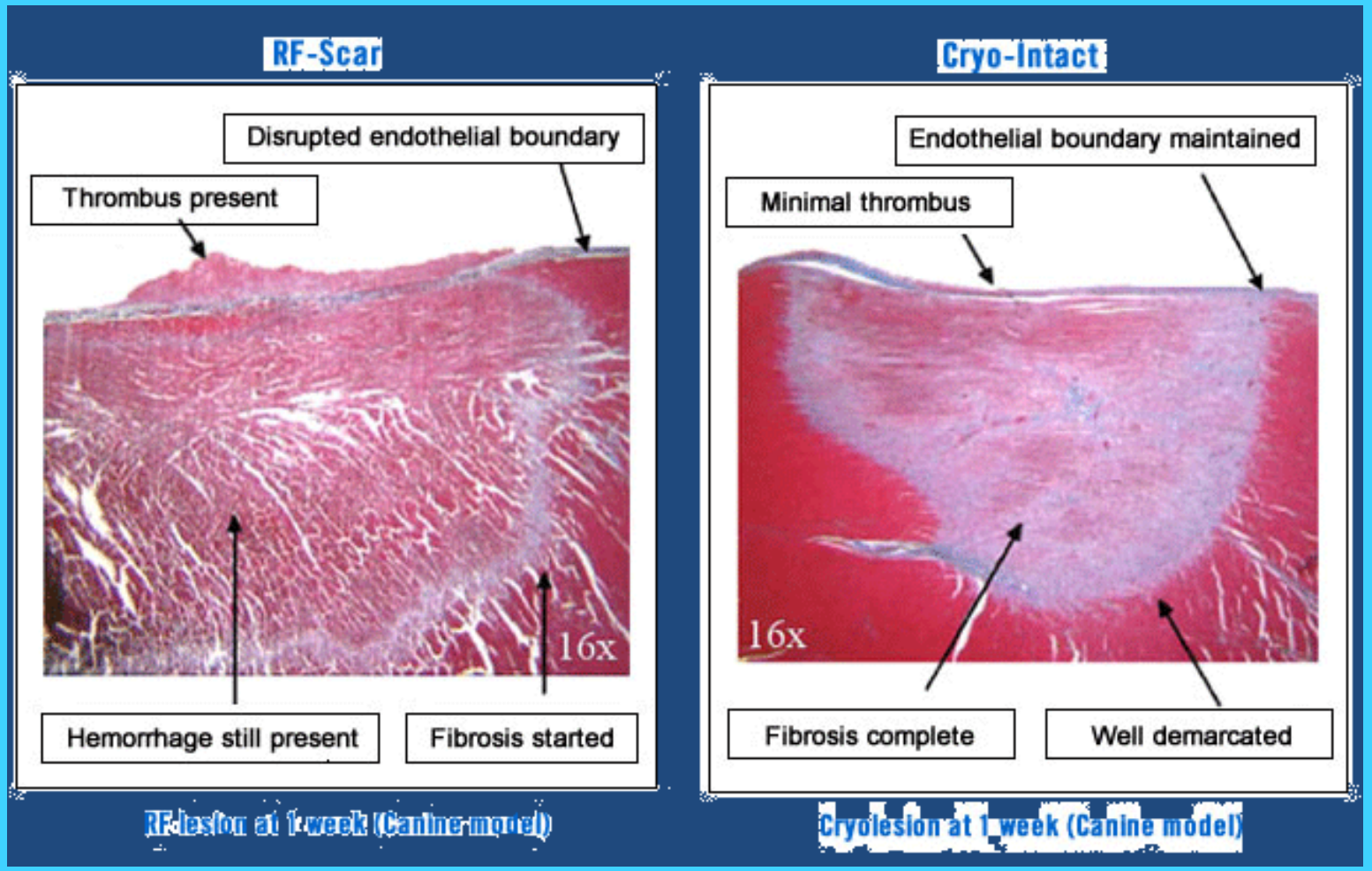



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation

Karl-Heinz Kuck, M.D., Josep Brugada, M.D., Alexander Fürnkranz, M.D., Andreas Metzner, M.D., Feifan Ouyang, M.D., K.R. Julian Chun, M.D., Arif Elvan, M.D., Ph.D, Thomas Arentz, M.D., Kurt Bestehorn, M.D., Stuart J. Pocock, Ph.D., Jean-Paul Albenque, M.D., Ph.D., and Claudio Tondo, M.D., Ph.D., for the FIRE AND ICE Investigators*

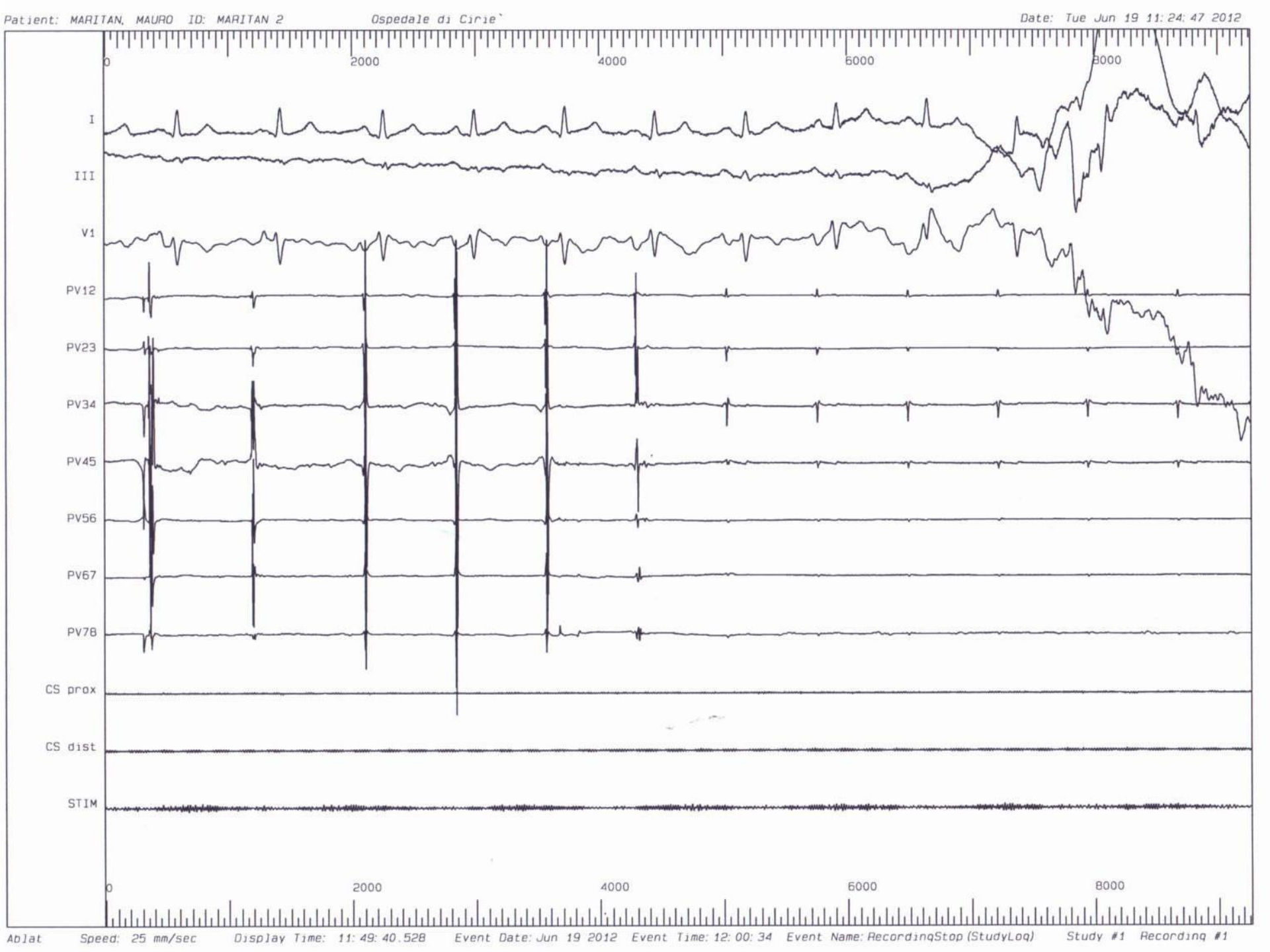


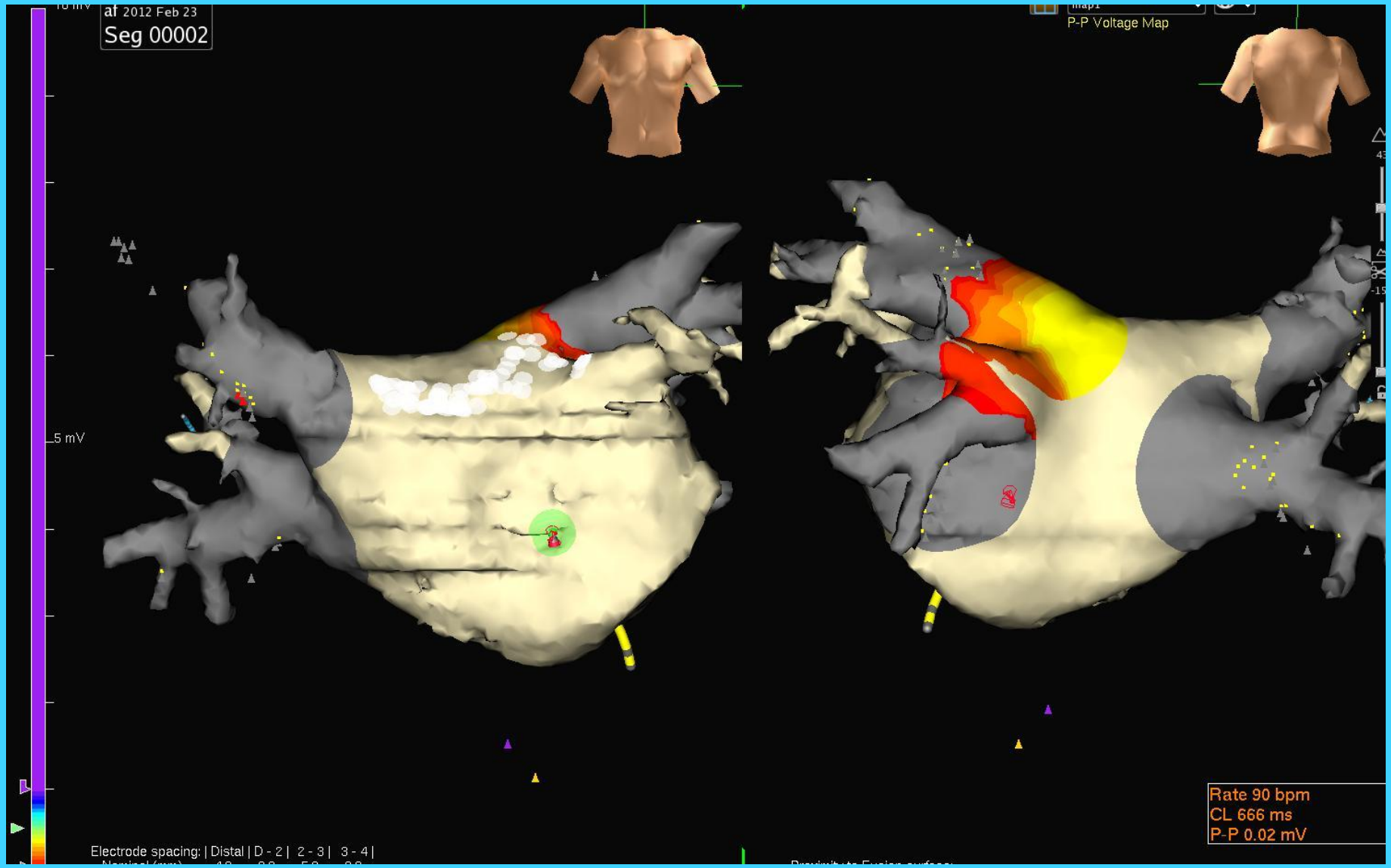
50 Watts, 43C, 60 sec

-75C, 240 seconds

CASE PRESENTATION

-*LAA closure & PVI with crio*
-*Dabigratan 110 mg bid 2 months*
-*TEE and ASA*


Patient: MARITAN, MAURO ID: MARITAN 2
Ospedale di Cirie`
Date: Tue Jun 19 11:24:47 2012
0
2000
4000
6000
8000
I
III
V1
PV12
PV23
PV34
PV45
PV56
PV67
PV78
CS prox
CS dist
STIM
Ablat
Speed: 25 mm/sec
Display Time: 11:49:40.528
Event Date: Jun 19 2012
Event Time: 12:00:34
Event Name: RecordingStop (StudyLog)
Study #1
Recording #1


af 2012 Feb 23
Seg 00002
P-P Voltage Map
5 mV
Rate 90 bpm
CL 666 ms
P-P 0.02 mV
Electrode spacing: | Distal | D - 2 | 2 - 3 | 3 - 4 |

CASE PRESENTATION

- *10 months follow-up no recurrences*

Procedura combinata di chiusura percutanea di auricola sinistra e ablazione di fibrillazione atriale: esperienza di un singolo centro

Elisa Pelissero[1], Marco Giuggia[1], Maria Chiara Todaro[2], Giuseppe Trapani[1], Benedetta Giordano[1], Gaetano Senatore[1]

[1]*Dipartimento di Cardiologia, Ospedale Civile di Ciriè, Ciriè (TO)*
[2]*Dipartimento di Cardiologia, Ospedale Civile di Ivrea, Ivrea (TO)*

G Ital Cardiol 2017;18 (11 Suppl 1):5S-11S

Baseline

Group 1 : ablation + LAAO N 21

Group 2 : ablation N 21

	Group 1	Group 2	p
Eta'	66.86 ± 10.35	68.42 ± 10.61	n.s.
CHA2DS2Vasc	2.81 ± 1.22	2.01 ± 0.93	n.s.
HASBLED	3.2 ± 0.83	3,1 ± 0.95	n.s.
FA persistente	80%	85%	n.s.

procedural data

Group 1 : ablation + LAAO N 21

Group 2 : ablation N 21

	Group 1	Group 2	p
Procedural time	68 ± 17	52 ± 15	< 0.05
Fluoroscopy	13 ± 5	5 ± 3	< 0.05
Device	14 Watchman 7 Amplatzer		
Type of ablation	19 PVI 8 Linear lesions 2 crio	18 PVI 6 Linear lesions 3 crio	

Safety

	Group 1	Group 2
Tamponade	0	0
Pericardial effusion	1	0
Vascular complications	1 (AVF)	0
TIA	0	0
Stroke	0	0
Air embolism	0	0
Dislodgement	0	0
Thrombus device	0	0
Leaks > 5 mm	0	0

Our experience

- 49 patients

LAA closure (Watchman or Amulet device under transesophageal and fluoroscopic guide in general anesthesia)

TC ablation (radiofrequency Carto 3 and NavX mapping, Cryo)

Atrial Fibrillation recurrence (loop recorder analysis)

Number of cases at long term follow- up (6-49 months) success rate 74%

The LAA device successful implanted in all pts did not interfere with ablation

LAAO & ABLATION

Ablation

Symptoms improvement
QOL improvement
CHF reduction

LAA closure

Thromboembolism reduction
Bleedings reduction

Conclusions

- LAA closure is safe ed effective in patients with high risk for embolism and bleedings
- Stop Antiplatelet therapy will increase indications for LAAO
- LAAO & Ablation is safe & effective

WATCHMAN Clinical Spectrum

Expand Patient Population

ASAP-TOO

Concomitant Procedures

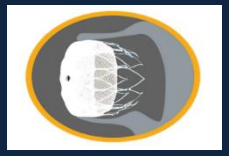
AF Ablation + LAAC

TAVR + LAAC

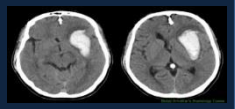
First Line in Specific Patient Populations

GI Bleeds

Renal Pts

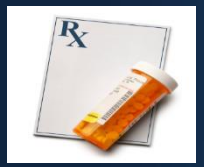


Prior ICH



First Line Therapy

WM vs NOAC ???



CIRIE' CARDIOLOGY

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