Interactions Cardiologie/Neurologie:

Fermeture auricule et bilan AVC cryptogénique

4ème journée médicale AVC Normandie 22 juin 2017

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CHU de CAEN

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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

Authors/Task Force Members: A. John Camm (Chairperson) (UK)*, Gregory Y.H. Lip (UK), Raffaele De Caterina (Italy), Irene Savelieva (UK), Dan Atar (Norway), Stefan H. Hohnloser (Germany), Gerhard Hindricks (Germany), Paulus Kirchhof (UK)

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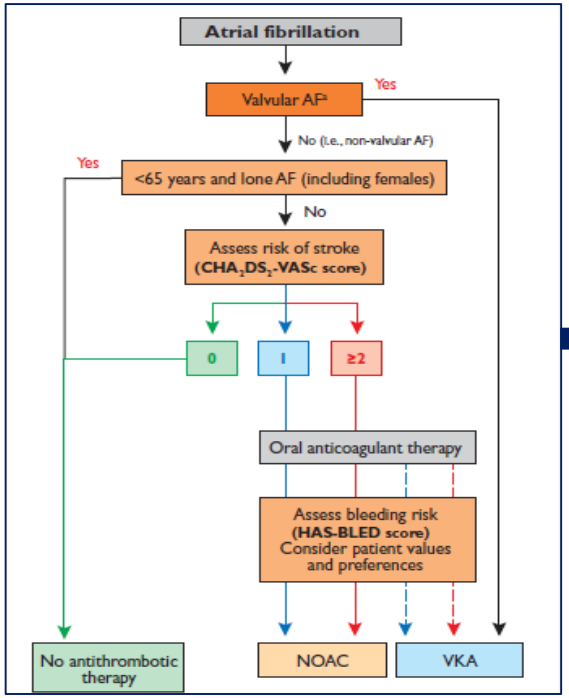
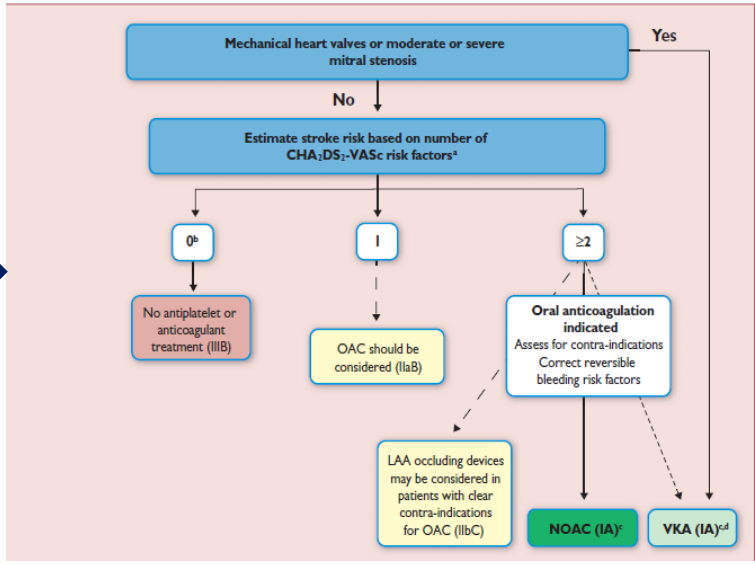
CHA_2DS_2-VASc risk factor	Points
Congestive heart failure Signs/symptoms of heart failure or objective evidence of reduced left ventricular ejection fraction	+1
Hypertension Resting blood pressure >140/90 mmHg on at least two occasions or current antihypertensive treatment	+1
Age 75 years or older	+2
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





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Recommendations	Class[a]	Level[b]	Ref[c]
Oral anticoagulation therapy to prevent thromboembolism is recommended for all male AF patients with a CHA_2DS_2-VASc score of 2 or more.	I	A	38, 318–321, 354, 404
Oral anticoagulation therapy to prevent thromboembolism is recommended in all female AF patients with a CHA_2DS_2-VASc score of 3 or more.	I	A	38, 318–321, 354, 404
Oral anticoagulation therapy to prevent thromboembolism should be considered in male AF patients with a CHA_2DS_2-VASc score of 1, considering individual characteristics and patient preferences.	IIa	B	371, 375–377
Oral anticoagulation therapy to prevent thromboembolism should be considered in female AF patients with a CHA_2DS_2-VASc score of 2, considering individual characteristics and patient preferences.	IIa	B	371, 376, 377
Vitamin K antagonist therapy (INR 2.0–3.0 or higher) is recommended for stroke prevention in AF patients with moderate-to-severe mitral stenosis or mechanical heart valves.	I	B	274, 435–440
When oral anticoagulation is initiated in a patient with AF who is eligible for a NOAC (apixaban, dabigatran, edoxaban, or rivaroxaban), a NOAC is recommended in preference to a vitamin K antagonist.	I	A	39, 318–321, 404
When patients are treated with a vitamin K antagonist, time in therapeutic range (TTR) should be kept as high as possible and closely monitored.	I	A	395, 432, 441-444
AF patients already on treatment with a vitamin K antagonist may be considered for NOAC treatment if TTR is not well controlled despite good adherence, or if patient preference without contra-indications to NOAC (e.g. prosthetic valve).	IIb	A	39, 318, 319, 404, 408
Combinations of oral anticoagulants and platelet inhibitors increase bleeding risk and should be avoided in AF patients without another indication for platelet inhibition.	III (harm)	B	429, 445
In male or female AF patients without additional stroke risk factors, anticoagulant or antiplatelet therapy is not recommended for stroke prevention.	III (harm)	B	368, 371, 376, 377
Antiplatelet monotherapy is not recommended for stroke prevention in AF patients, regardless of stroke risk.	III (harm)	A	38, 429, 430
NOACs (apixaban, dabigatran, edoxaban, and rivaroxaban) are not recommended in patients with mechanical heart valves (Level of evidence B) or moderate-to-severe mitral stenosis (Level of evidence C).	III (harm)	B C	318–321, 400, 404

Europace Advance Access published August 31, 2015

Europace
doi:10.1093/europace/euv309

EHRA PRACTICAL GUIDE

Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with non-valvular atrial fibrillation

Hein Heidbuchel[1]*, Peter Verhamme[2], Marco Alings[3], Matthias Antz[4], Hans-Christoph Diener[5], Werner Hacke[6], Jonas Oldgren[7], Peter Sinnaeve[2], A. John Camm[8], and Paulus Kirchhof[9,10]

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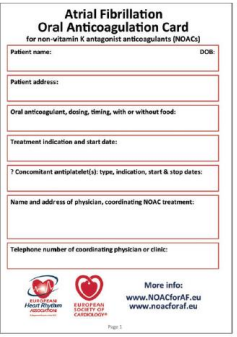
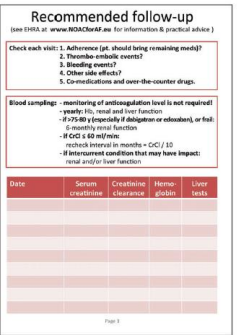
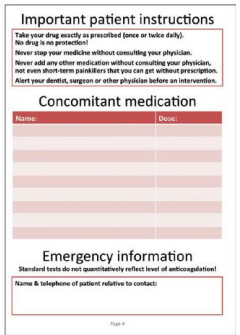
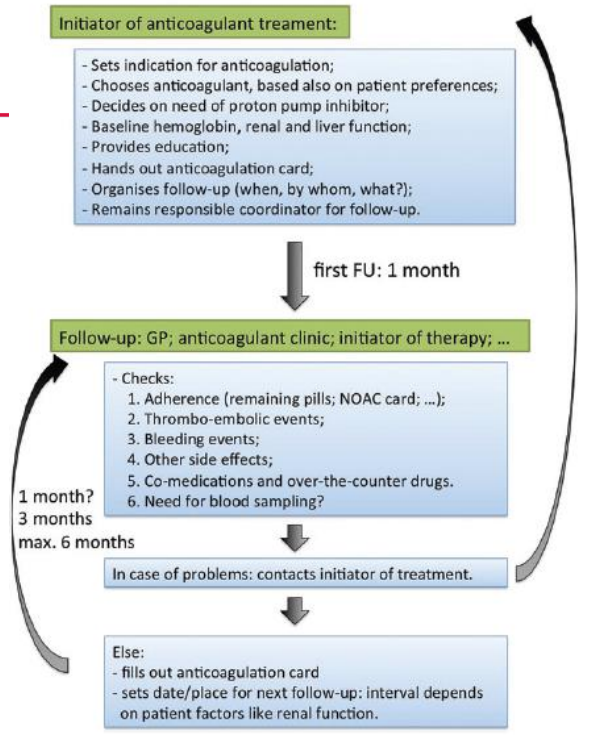
Table 1 Valvular indications and contraindications for NOAC therapy in AF patients

	Eligible	Contra-indicated
Mechanical prosthetic valve		✓
Moderate to severe mitral stenosis (usually of rheumatic origin)		✓
Mild to moderate other native valvular disease	✓	
Severe aortic stenosis	✓ Limited data. Most will undergo intervention	
Bioprosthetic valve[a]	✓ (except for the first 3 months post-operatively)	
Mitral valve repair[a]	✓ (except for the first 3–6 months post-operatively)	
PTAV and TAVI	✓ (but no prospective data; may require combination with single or double antiplatelets: consider bleeding risk)	
Hypertrophic cardiomyopathy	✓ (but no prospective data)	



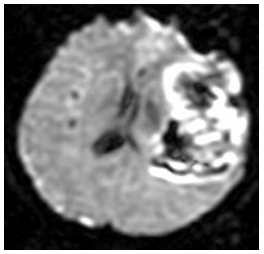






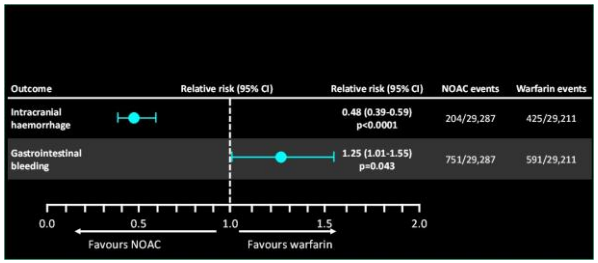
Risque hémorragique sous anticoagulants

- Il surviendra tous les ans une hémorragie cérébrale pour :
  - 91 patients sous aspirine
  - 143 patients sous AVK



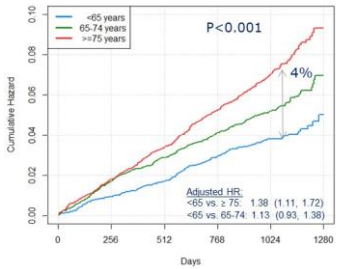
- Si reduction des hémorragies cérébrales avec les AOD, il existe une augmentation des risques de saignements digestifs

Ruff CT et al. Lancet 2013; doi: 10.1016/S0140-6736(13)62343-0

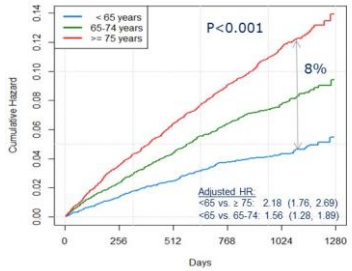


- Risque d'AVC et de saignements graves augmente avec l'âge

AVC/âge



Hémorragies sévères/âge



Adjusted for weight, gender, HTN, Dyslipidemia, DM, Smoking, Prior PCI, Prior stroke or TIA, Congestive HF, treatment arms, type of AF, CrCl, Race, Region, History of increased risk of falling, History of neuropsychiatric, and dose reduction

- Risque de saignements graves augmente avec les TTT AA associés

	DE 110	DE 150	Warfarin
No Antiplatelet	2.2%	2.6%	2.8%
With Antiplatelet	**3.9%**	**4.4%**	**4.8%**
HR (95% CI)	1.5 (1.2, 1.9)	1.6(1.3, 2.0)	1.7(1.3, 2.0)

	Rivaroxaban	Warfarin
No Antiplatelet	3.0%	3,0%
With Antiplatelet	**5.8%**	**4.8%**

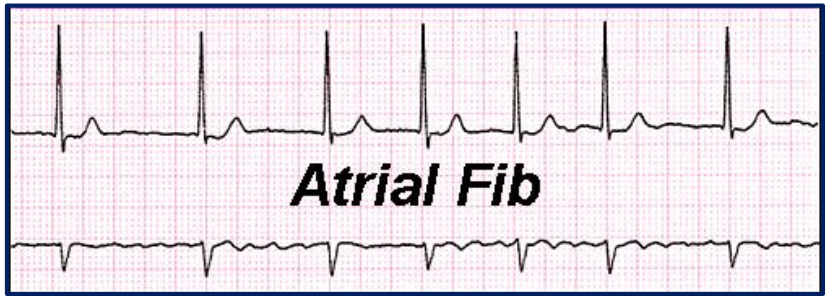
Interaction Cardiologie/Neurologie: Fermeture d'auricule

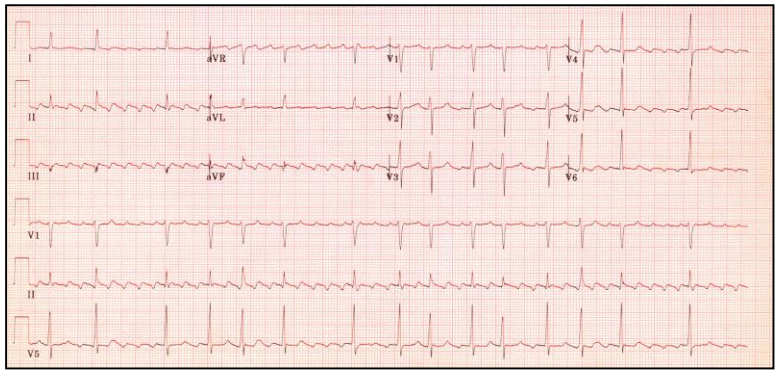
1. 20% des AVC sont d'origine cardioembolique: >90% des thrombus **auricule gauche+++**
2. AVC post-FA provoque AVC sévère car occlusion gros tronc artériels intra-craniens
3. AVC post FA plus mauvais prognostic et fréquentes récidives
4. Anticoagulation est un TTT à vie "palliatif" dans ce contexte d'AVC post-FA
5. Risque de saignement permanent et cumulative en fonction du temps
6. En conséquence, près de 40% des patients en FA ont des contre-indications à une anticoagulation à long terme
7. La fermeture de l'auricule est une option "curative", sans risque cumulative de saignement, et économiquement bénéfique à long terme

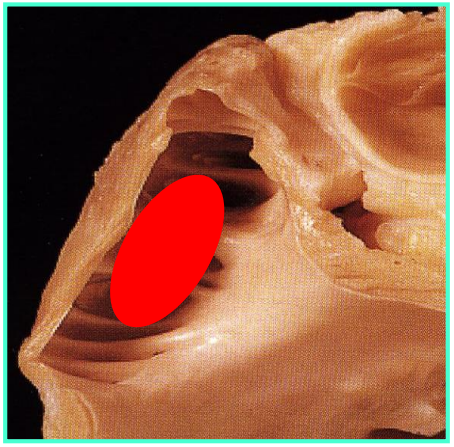
Recommendations for LAA closure/occlusion/excision

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	

Interaction Cardiologie/Neurologie: Fermeture d'auricule







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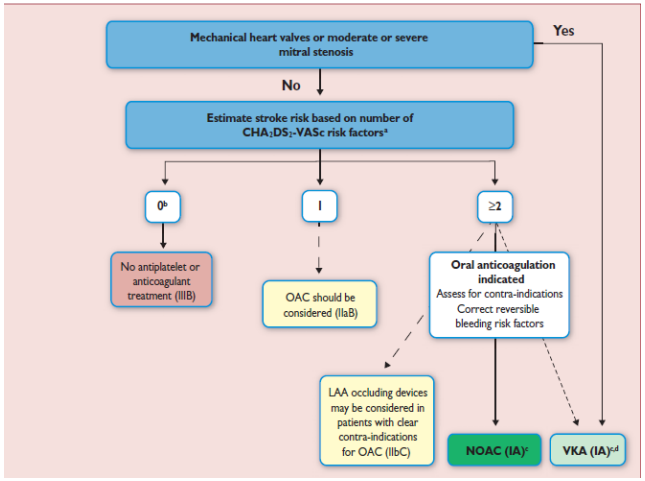
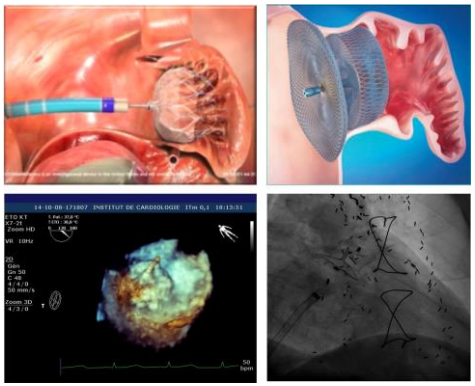


Interaction Cardiologie/Neurologie: Fermeture d'auricule

- Dispositifs
  - PLAATO®
  - WATCHMAN®
  - AMPLATZER CARDIAC PLUG®



- Encore en cours d'évaluation

- Données observationnelles
  - Faisabilité technique
  - Risque de complications

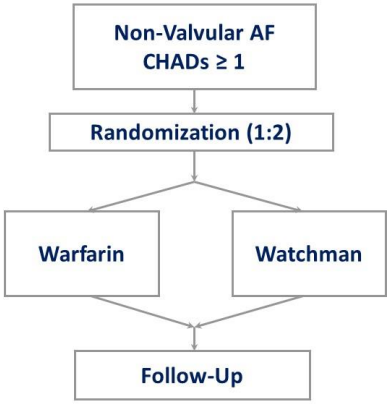
- Etude PROTECT- AF : étude randomisée (WATCHMAN)
- Etude ACP: prospective observationnelle (AMPLATZER CARDIAC PLUG®)

Fermeture de l'auricule gauche: les preuves?

PROTECT-AF: Overview

Holmes et al. Lancet 2009;374:534-42.

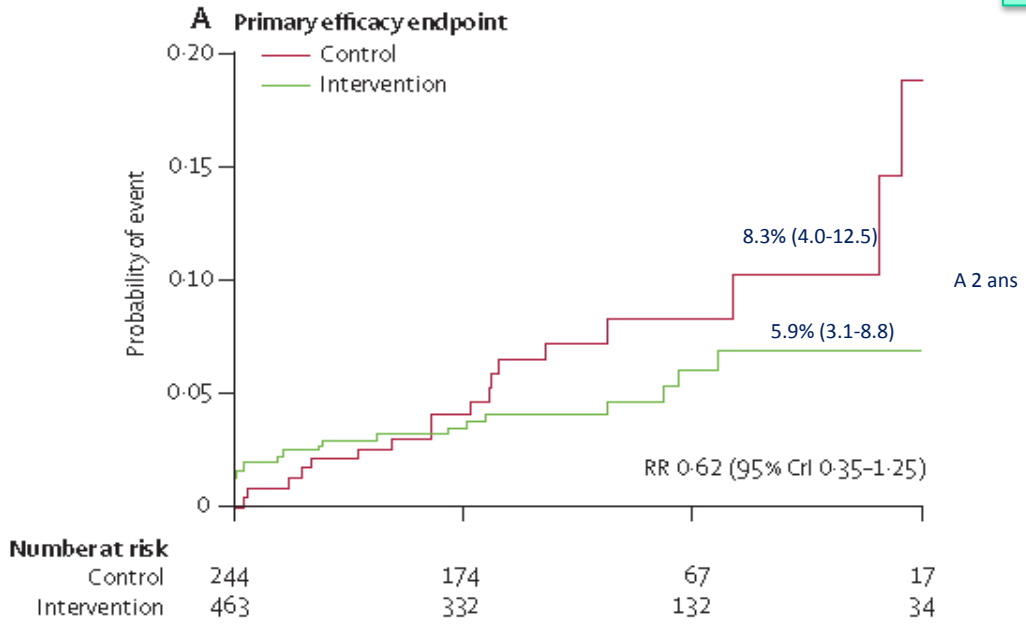
- Randomized FDA-IDE Trial
  - Can the WATCHMAN device ***replace*** Warfarin?
- Efficacy Endpoint:
  - Stroke
  - CV death (& Unknown)
  - Systemic embolism
- Safety Endpoint
- Non-inferiority & Superiority
  - Bayesian Sequential Design
  - Analysis at 600 pt-yrs & every 150 pt-yrs thereafter → **1500 pt-yr**
  - Follow-up till 5 years



707 patients en FA non-valvulaire et score $CHADS_2 \geq 1$

59 centres aux US
Suivi ETO à 45 jours, 6 mois, et 1 an
87% ont pu arrêter le traitement par warfarine à 45 jours de suivi

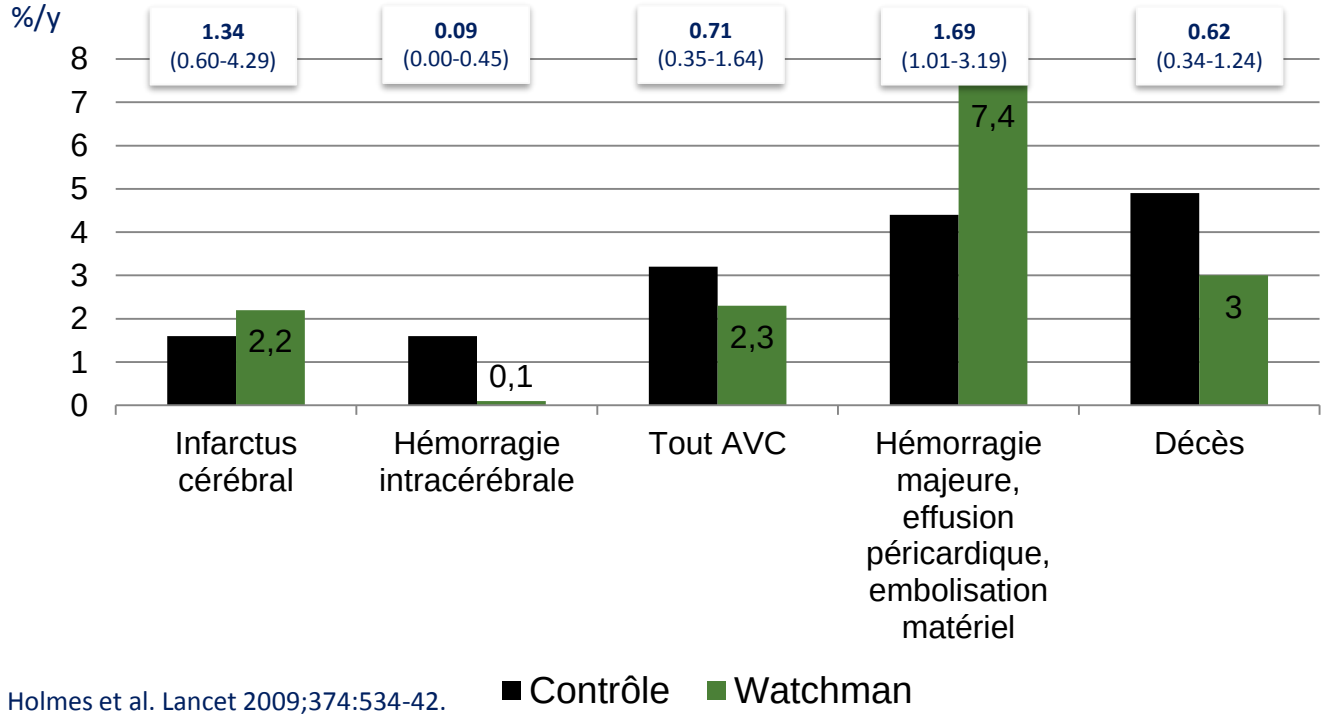
Taux de succès technique 91%



A 2 ans

Fermeture de l'auricule gauche: les preuves?

Complications procédurales	**10.6%**
• Effusion péricardique	4.8%
• Hémorragie majeure	3.5%
• Accident ischémique	1.1%
• Embolisation matériel	0.6%
• Hémorragie intracérébrale	0.2%
• Plaie œsophage	0.2%
• Arythmie	0.2%

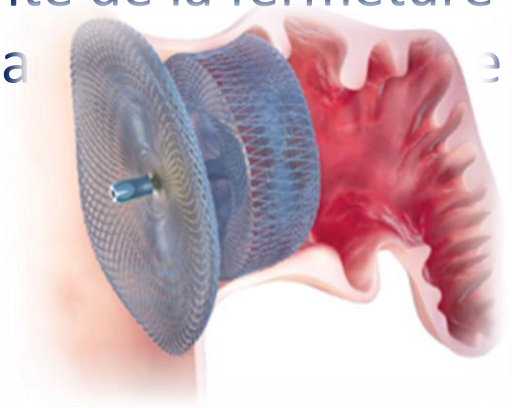


Holmes et al. Lancet 2009;374:534-42.

Fermeture de l'auricule gauche: les preuves?

AMPLATZER Cardiac Plug

- Marquage CE en 2008
- 1ère implantation en France en 2010
- Fondé sur la **technologie AMPLATZER** : treillis en fil de nitinol largement éprouvée
  - **+ 1M dispositifs implantés** depuis 15 ans
- Etudes de sécurité de la fermeture de l'auricule pour les patients en impa e



Fermeture de l'auricule gauche: les preuves?

Etude ACP EU Prospective Observationnelle

- Etude prospective, non randomisée, multicentrique
- Evaluer l'efficacité et la sécurité de la fermeture de l'auricule avec ACP
  - 15 centres participants
    - Allemagne, Espagne, UK, Irlande
  - 204 patients
  - 1214 mois de suivi
  - Patients contre-indiqués aux ACO (2,9% des patients sous AVK à l'inclusion)

- Etude rigoureusement réalisée avec un niveau élevé de qualité et d'intégrité des données :
  - 100% des données recueillies on été monitorées
  - Comité Independent d'adjudication des évènements indésirables

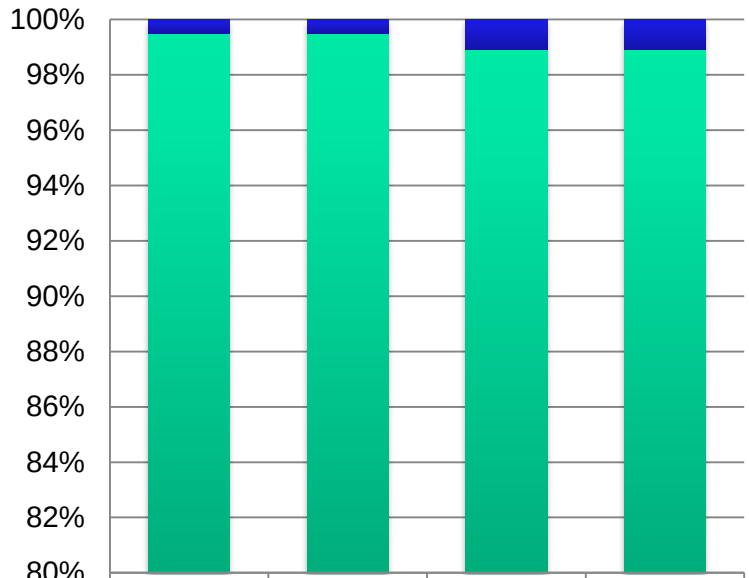
Source: Walsh K. "Left Atrial Appendage Closure With the AMPLATZER Cardiac Plug: Results of the European Post-Market Observational Study." EuroPCR; 2012 May 15-18; Paris, France.

Fermeture de l'auricule gauche: les preuves?

Etude ACP EU Prospective Observationnelle

- Succès de l'intervention
  - 96.6% (197/204) des patients ont pu recevoir un dispositif
- Dans 89.2% des cas, le 1er dispositif sélectionné a été implanté
- Taux d'occlusion*
  - A l'implantation: 99.5%
  - A 6 mois: 98.9%
  - Absence de fuites > 5 mm
- Taux d'occlusion resté constant à l'évaluation en ETT entre l'implantation et la visite à 6 mois.

Succès de l'occlusion



	Implant	D/C	1 Mo.	6 Mo.
Residual flow (>3 mm)	0,50%	0,50%	1,10%	1,10%
Closure	99,50%	99,50%	98,90%	98,90%

Source: Walsh K. "Left Atrial Appendage Closure With the AMPLATZER Cardiac Plug: Results of the European Post-Market Observational Study." EuroPCR; 2012 May 15-18; Paris, France.

* ClosOcclusion définie par l'absence de fuite ou fuite ≤ 3 mm dans l'auricule

Fermeture de l'auricule gauche: les preuves?

Etude ACP EU Prospective Observationnelle

	≤7 Jours Post Procédure	>7 jours Post Procédure	Total
AVC/AIT péri-procédure*	0 (0.0%)	0 (0.0%)	0 (0.0%)
Epanchement péricardique sévère	3 (1.5%)	0 (0.0%)	3 (1.5%)
Migration du dispositif	3 (1.5%)	0 (0.0%)	3 (1.5%)
Thrombus sur le dispositif	0 (0.0%)	5 (2.4%)	5 (2.4%)
Total évènements indésirables	**6 (2.9%)**	**5 (2.4%)**	**11 (5.4%)**

* Les AVC/AIT font référence aux évènements liés au dispositif ou à la procédure tels d'adjudiqués par le Comité indépendant de revue.

N=204

Source: Walsh K. "Left Atrial Appendage Closure With the AMPLATZER Cardiac Plug: Results of the European Post-Market Observational Study." EuroPCR; 2012 May 15-18; Paris, France.

Fermeture de l'auricule gauche: indications?

- Hémorragies intracraniales sous anticoagulation (AVK normodosés?; AODs)
- Hémorragies extra-cranial sous anticoagulation (AVK normodosés?; AODs): angiodysplasie
- Contre-indications à l'anticoagulation (AVK, AODs):
  - Microbleeds cérébraux ou angiopathie amyeloïde
  - Thrombopénie majeure
- Intolerance aux AOD
  - Insuffisance rénale ou hépatique
  - Intolerance gastrique
- AVC ischémique sous anticoagulation?

EHJ 2012	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

La HAS estime que la fermeture transcutanée de l'AAG a une place dans la stratégie thérapeutique en dernier recours et que le service attendu de l'acte de fermeture transcutanée de l'appendice auriculaire gauche est suffisant pour sa prise en charge en **prévention des évènements thromboemboliques chez des patients en FA non valvulaire, avec un score CHA2DS2-VASc ≥ 4 et une contre-indication formelle et définitive aux anticoagulants oraux**.

PROTECT-AF – Résultats à 4 ans

Original Investigation

Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation
A Randomized Clinical Trial

JAMA. 2014;312(19):1988-1998. doi:10.1001/jama.2014.15192

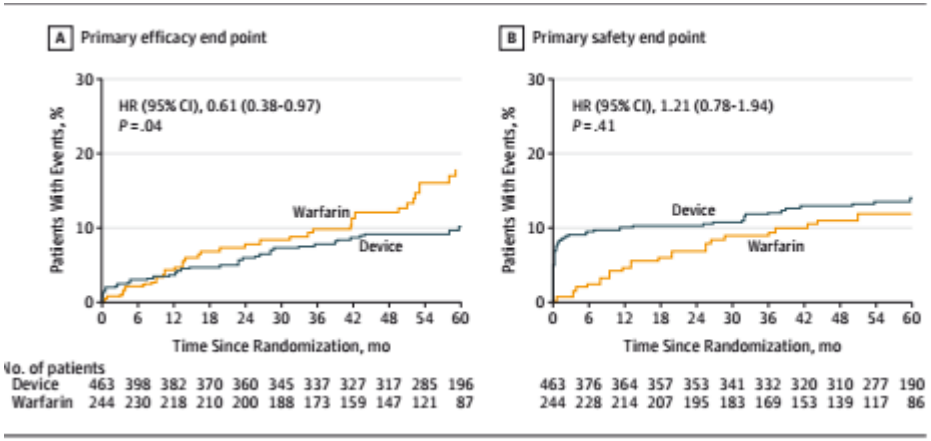
Vivek Y. Reddy, MD; Horst Sievert, MD; Jonathan Halperin, MD; Shephal K. Doshi, MD; Maurice Buchbinder, MD; Petr Neuzil, MD, PhD; Kenneth Huber, MD; Brian Whisenant, MD; Saibal Kar, MD; Vijay Swarup, MD; Nicole Gordon, BSEE; David Holmes, MD; for the PROTECT AF Steering Committee and Investigators

Table 1. Baseline Characteristics of the Study Participants by Treatment Group

	Device Group (n = 463)	Warfarin Group (n = 244)
Age, mean (SD) [range], y	71.7 (8.8) [46-95]	72.7 (9.2) [41-95]
Heart rate, mean (SD) [range], beats/min	73 (13) [37-120]	74 (13) [42-109]
Blood pressure, mean (SD) [range], mm Hg		
Systolic	135 (21) [90-229]	135 (19) [90-194]
Diastolic	77 (12) [32-117]	76 (12) [44-120]
Body mass index, mean (SD) [range][a]	31.6 (6.0) [14-54]	31.3 (6.2) [20-57]
Male sex, No. (%)	326 (70.4)	171 (70.1)
Race/ethnicity, No. (%)		
Asian	4 (0.9)	1 (0.4)
Black/African American	6 (1.3)	5 (2.0)
White	425 (91.8)	222 (91.0)
Hispanic/Latino	25 (5.4)	15 (6.1)
Hawaiian Pacific Islander	1 (0.2)	1 (0.4)
Other	2 (0.4)	0
$CHADS_2$ score[b]		
Mean (SD) [range]	2.2 (1.2) [1-6]	2.3 (1.2) [1-6]
Score, No. (%)		
1	156 (33.7)	66 (27.0)
2	158 (34.1)	88 (36.1)
≥3	149 (32.2)	90 (36.8)
Risk factors for stroke, No. (%)		
Congestive heart failure	124 (26.8)	66 (27.0)
History of hypertension	415 (89.6)	220 (90.2)
Age ≥75 y	190 (41.0)	115 (47.1)
Diabetes	113 (24.4)	72 (29.5)
Previous ischemic stroke or TIA	82 (17.7)	49 (20.1)
LV ejection fraction, mean (SD) [range], %	57.3 (9.7) [30-82]	56.7 (10.1) [30-86]
Classification of AF, No. (%)		
Paroxysmal	200 (43.2)	99 (40.6)
Persistent	97 (21.0)	50 (20.5)
Permanent	160 (34.6)	93 (38.1)
Unknown	6 (1.3)	2 (0.8)

Table 2. Intention-to-Treat Primary Efficacy and Safety Outcomes According to Treatment Group by Bayesian Model

Event	Device Group (n = 463) Events/Patient-Years	Device Group (n = 463) Observed Rate[a]	Warfarin Group (n = 244) Events/Patient-Years	Warfarin Group (n = 244) Observed Rate[a]	Device/Warfarin Rate Ratio (95% Credible Interval)	Posterior Probabilities, % Noninferiority	Posterior Probabilities, % 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	34
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



The primary efficacy outcome (A) was stroke, systemic embolization, or cardiovascular death. The primary safety outcome (B) was a composite of major bleeding events and procedure-related complications. Incident probabilities for the intention-to-treat analysis are shown. HR indicates hazard ratio.

PROTECT-AF – Résultats à 4 ans

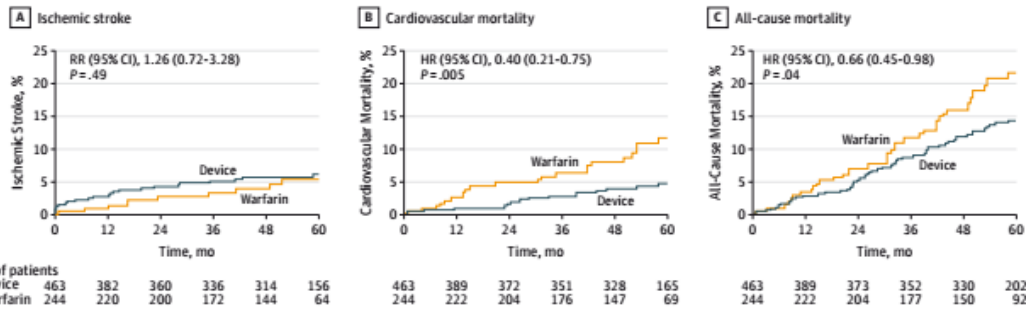
Original Investigation

Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation
A Randomized Clinical Trial

JAMA. 2014;312(19):1988-1998. doi:10.1001/jama.2014.15192

Vivek Y. Reddy, MD; Horst Sievert, MD; Jonathan Halperin, MD; Shephal K. Doshi, MD; Maurice Buchbinder, MD; Petr Neuzil, MD, PhD; Kenneth Huber, MD; Brian Whisenant, MD; Saibal Kar, MD; Vijay Swarup, MD; Nicole Gordon, BSEE; David Holmes, MD; for the PROTECT AF Steering Committee and Investigators

Figure 3. Kaplan-Meier Curves for Ischemic Stroke, Cardiovascular Mortality, and All-Cause Mortality



HR indicates hazard ratio; RR, rate ratio.

Source	Device Group No. of Events	Device Group No. of Patients	Warfarin Group No. of Events	Warfarin Group No. of Patients	HR (95% CI)
Sex					
Female	18	137	10	73	1.03 (0.48-2.23)
Male	21	326	24	171	0.45 (0.25-0.81)
Age					
≥ 75 y	22	190	22	115	0.63 (0.35-1.14)
< 75 y	17	273	12	129	0.67 (0.32-1.41)
$CHADS_2$ score					
1	NA	NA	NA	NA	0.29 (0.08-1.03)
>1	NA	NA	NA	NA	0.73 (0.44-1.20)
AF pattern					
Paroxysmal	18	200	14	99	0.62 (0.31-1.24)
Persistent	5	97	8	50	0.31 (0.10-0.95)
Permanent	16	160	12	93	0.84 (0.40-1.78)
History of TIA or stroke					
Yes	13	82	12	49	0.66 (0.30-1.45)
No	26	381	22	195	0.61 (0.35-1.08)
Prior years taking warfarin					
<1	25	226	19	125	0.72 (0.40-1.31)
≥1	14	230	14	116	0.52 (0.25-1.10)
LAA ostium					
≥ Median (21 mm)	18	249	18	128	0.52 (0.27-0.99)
< Median	20	208	16	111	0.67 (0.35-1.29)
LAA length					
≥ Median (30 mm)	16	235	16	124	0.49 (0.25-0.99)
< Median	22	222	18	115	0.68 (0.36-1.27)
LV ejection fraction					
≥ Median (60%)	19	236	14	123	0.70 (0.35-1.41)
< Median	20	224	19	116	0.56 (0.30-1.05)
All patients					0.61 (0.38-0.97)

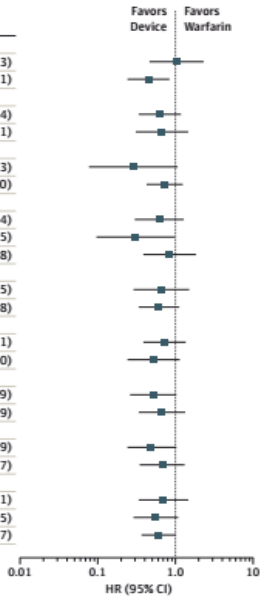


Table 5. Primary Efficacy and Safety Outcomes, According to Secondary Analyses by Cox Proportional Hazards Model

Analysis	Device Group (n = 463) Events/Patient-Years	Device Group (n = 463) Observed Rate[a]	Warfarin Group (n = 244) Events/Patient-Years	Warfarin Group (n = 244) Observed Rate[a]	Device/Warfarin, HR (95% CI)	*P* Value
Primary efficacy outcomes[b]						
Intention-to-treat	39/1720.2	2.3 (1.7-3.1)	34/900.8	3.8 (2.7-5.3)	0.61 (0.38- 0.97)	.04
Postprocedure	33/1710.1	1.9 (1.4-2.7)	34/900.8	3.8 (2.7-5.3)	0.52 (0.32-0.84)	.007
Per-protocol	29/1597.8	1.8 (1.3-2.6)	32/887.0	3.6 (2.6-5.1)	0.50 (0.30-0.83)	.008
Terminal therapy	24/1306.7	1.8 (1.2-2.7)	32/887.0	3.6 (2.6-5.1)	0.52 (0.30-0.89)	.02
Primary safety outcomes[c]						
Intention-to-treat	60/1666.2	3.6 (2.8-4.6)	27/878.2	3.1 (2.1-4.5)	1.21 (0.78- 1.94)	.41
Postprocedure	33/1656.2	2.0 (1.4- 2.8)	27/878.2	3.1 (2.1-4.5)	0.68 (0.41-1.13)	.13
Per-protocol	20/1604.4	1.2 (0.8-1.9)	27/864.4	3.1 (2.1-4.6)	0.42 (0.23-0.74)	.003
Terminal therapy	13/1321.8	1.0 (0.6-1.7)	27/864.4	3.1 (2.1-4.6)	0.32 (0.17-0.63)	<.001

Abbreviation: HR, hazard ratio.

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

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

[c] 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).

Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation

A Patient-Level Meta-Analysis

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 65, NO. 24, 2015

ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jacc.2015.04.025

TABLE 2 Patient Demographics Across Trials

	PROTECT AF (N = 707)	PREVAIL (N = 407)	CAP (N = 566)	CAP2 (N = 579)
Age, yrs	72.0 ± 8.9	74.3 ± 7.4	74.0 ± 8.3	75.3 ± 8.0
Male	70.3	70.0	65.5	61.0
Ethnicity/race				
Asian	0.7	0.5	1.6	0.7
Black/African American	1.6	1.7	1.9	1.2
White/Caucasian	91.5	94.4	91.9	94.1
Hispanic/Latino	5.7	2.7	3.5	2.1
Other	0.6	0.7	1.1	1.0
$CHADS_2$ score	2.2 ± 1.2	2.6 ± 1.0	2.4 ± 1.2	2.7 ± 1.1
$CHADS_2$ risk factors				
CHF	26.9	19.1	23.3	27.1
Hypertension	89.8	88.8	91.4	92.5
≥75 yrs of age	43.1	51.8	53.6	59.7
Diabetes	26.2	24.9	32.4	33.7
Stroke/transient ischemic attack	18.5	30.4	27.8	29.0
CHA_2DS_2-VASc	3.5 ± 1.6	4.0 ± 1.2	3.9 ± 1.5	4.5 ± 1.3
HAS-BLED = 0 (low risk)	6.4	1.7	2.8	2.8
HAS-BLED = 1–2 (moderate risk)	73.7	68.6	61.0	69.9
HAS-BLED = 3+ (high risk)	19.9	29.7	36.2	28.3

TABLE 1 PROTECT AF and CAP: Largest Data Sets to Evaluate Totality of Data

	PROTECT AF	PREVAIL	CAP	CAP2	Total
Enrollment	2005–2008	2010–2012	2008–2010	2012–2014	
Enrolled	800	461	566	579	2,406
Randomized	707	407	–	–	1,114
Watchman:warfarin (2:1)	463:244	269:138	566	579	1,877:382
Mean follow-up, yrs	4.0	2.2	3.7	0.58	N/A
Patient-years	2,717	860	2,022	332	5,931

CAP = Continued Access to PROTECT AF registry; CAP2 = Continued Access to PREVAIL registry; N/A = not applicable; PREVAIL = Prospective Randomized Evaluation of the Watchman LAA Closure Device In Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy; PROTECT AF = Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation.

Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation

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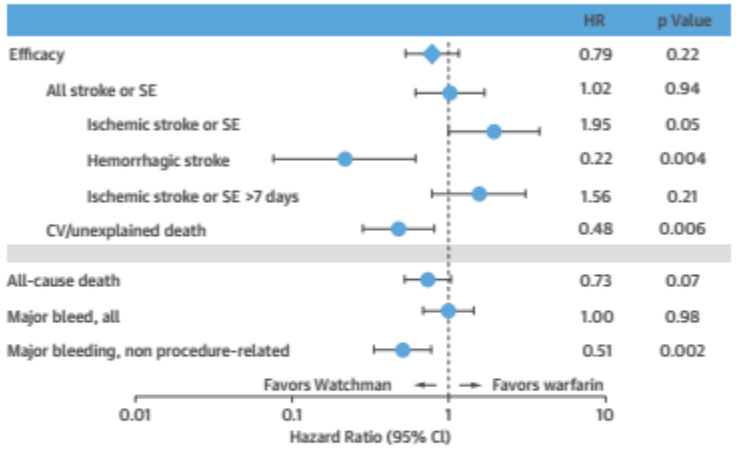
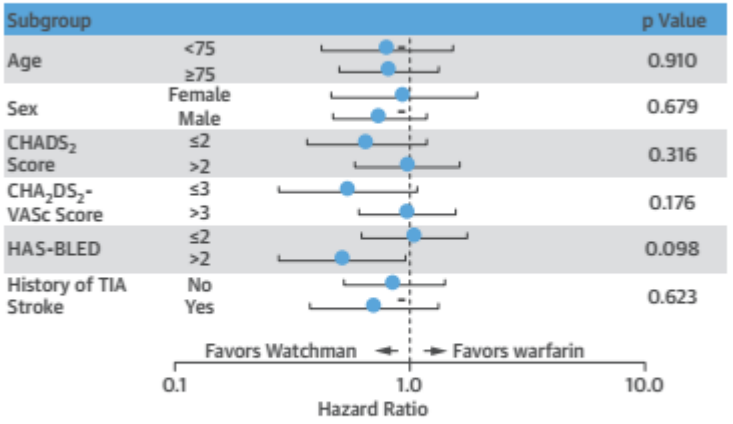
FIGURE 2 PROTECT AF/PREVAIL Combined: Meta-Analysis Shows Comparable Primary Efficacy Results to Warfarin



The combined data set of all PROTECT AF and PREVAIL Watchman patients versus chronic warfarin patients documented: 1) similarity in overall stroke or systemic embolism; 2) ischemic stroke slightly increased with Watchman but hemorrhagic stroke significantly decreased with warfarin; and 3) all-cause mortality and major nonprocedural bleeding both significantly improved with Watchman. CI = confidence interval; CV = cardiovascular; HR = hazard ratio; SE = systemic embolism; other abbreviations as in Figure 1.

FIGURE 3 Pooled Watchman Efficacy Performance in Randomized Clinical Trials (PROTECT AF/PREVAIL)



Documentation of the effect of Watchman versus chronic warfarin on the different subsets of patients enrolled. There was no significant difference in Watchman effect by patient subset. TIA = transient ischemic attack; other abbreviations as in Figure 1.

Time to Cost-Effectiveness Following Stroke Reduction Strategies in AF

Warfarin Versus NOACs Versus LAA Closure

Modèle de Markov

Vivek Y. Reddy, MD,* Ronald L. Akehurst, MFPHM,† Shannon O. Armstrong, BA,‡ Stacey L. Amorosi, MA,§
Stephen M. Beard, MSc,‖ David R. Holmes, Jr, MD¶

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FIGURE 1 Model Schematics Depicting LAAC and OAC Patient Pathways

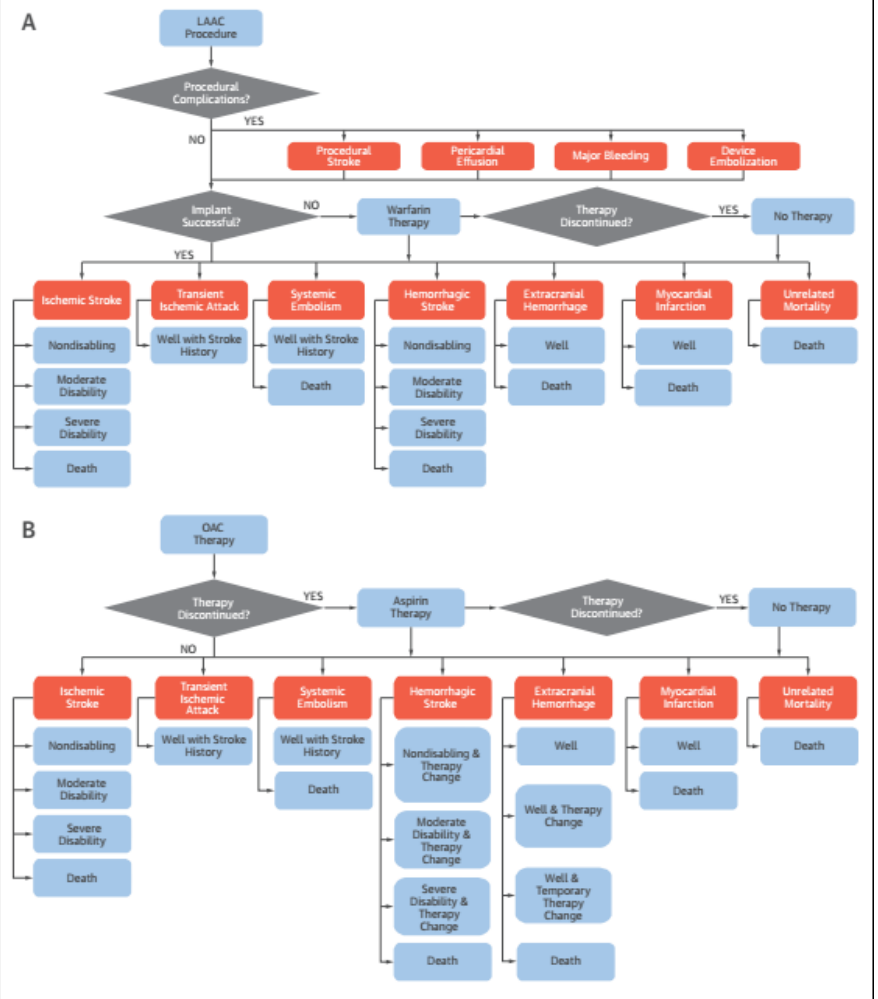

TABLE 3 Cost Inputs

Acute Events	Costs	Code (Ref. #)
LAAC procedure (including 2 TEEs)*	$16,109	DRG 273/274 (43)
Fatal ischemic stroke	$8,854	DRG 063 (38)
Severe ischemic stroke	$48,539	DRG 061/CMG 108-110 (38,39)
Moderate ischemic stroke	$33,235	DRG 062/CMG 101-104 (38,39)
Minor ischemic stroke	$23,236	DRG 063/CMG 105-107 (38,39)
Transient ischemic attack	$4,097	DRG 069 (38)
Systemic embolism (nonfatal)	$4,924	DRG 068 (38)
Systemic embolism (fatal)	$8,520	DRG 067 (38)
Fatal hemorrhagic stroke	$10,194	DRG 064 (38)
Severe hemorrhagic stroke	$42,562	DRG 064/CMG 108-110 (38,39)
Moderate hemorrhagic stroke	$28,595	DRG 065/CMG 101-104 (38,39)
Minor hemorrhagic stroke	$18,797	DRG 066/CMG 105-107 (38,39)
Major extracranial hemorrhage (nonfatal)	$5,877	DRG 377 (38)
Major extracranial hemorrhage (fatal)	$10,425	DRG 378 (38)
Minor bleeding	$427	CPT 42970 (44)
Myocardial infarction (nonfatal)	$6,862	DRG 280, 281, 282 (38)
Myocardial infarction (fatal)	$5,771	DRG 283, 284, 285 (38)
Quarterly costs		
Warfarin + INR monitoring	$91	CPT 85610, 99211 (44,45)
NOAC	$945	(45)
Independent post-stroke	$108	CPT 99214 (44)
Moderately disabled post-stroke	$9,293	(40–42)
Severely disabled post-stroke	$15,131	(40–42)

*Costs for the LAAC procedure reflect 2016 Centers for Medicare & Medicaid Services reimbursement rates. Weighting was obtained from 2012 U.S. hospital data (Healthcare Utilization Project [HCUP]) and reflects an 18%/82% split across DRG 250 and 251 (24).

CPT = Current Procedural Terminology; DRG = diagnosis-related group; INR = international normalized ratio; TEE = transesophageal echocardiogram; other abbreviations as in Table 1.

Time to Cost-Effectiveness Following Stroke Reduction Strategies in AF

Warfarin Versus NOACs Versus LAA Closure

Vivek Y. Reddy, MD,* Ronald L. Akehurst, MFPHM,† Shannon O. Armstrong, BA,‡ Stacey L. Amorosi, MA,§ Stephen M. Beard, MSc,‖ David R. Holmes, Jr, MD¶

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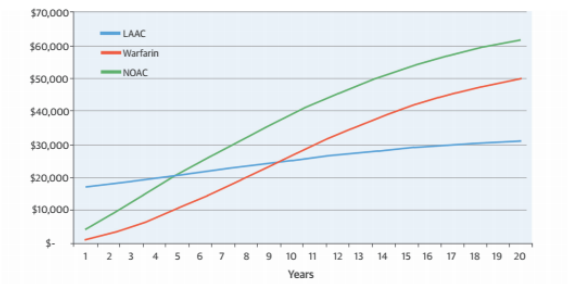
TABLE 4 QALY and Cost Results at 5, 10, 15, and 20 Years

	Total QALYs	Incremental QALYs (Relative to Warfarin)	Total Costs	Incremental Costs (Relative to Warfarin)	Incremental Cost per QALY Versus Warfarin	Incremental Cost per QALY Versus NOAC
5 yrs						
LAAC	3.455	0.068	$20,892	$10,128	$149,468	Dominant
Warfarin	3.387	–	$10,764	–	–	–
NOAC	3.448	0.061	$20,924	$10,160	$167,446	–
10 yrs						
LAAC	5.855	0.254	$25,425	-$1,409	Dominant	Dominant
Warfarin	5.601	–	$26,834	–	–	–
NOAC	5.751	0.150	$39,260	$12,426	$82,684	–
15 yrs						
LAAC	7.309	0.466	$29,075	-$12,251	Dominant	Dominant
Warfarin	6.843	–	$41,326	–	–	–
NOAC	7.077	0.234	$53,431	$12,105	$51,755	–
20 yrs						
LAAC	8.031	0.638	$31,198	-$18,748	Dominant	Dominant
Warfarin	7.392	–	$49,946	–	–	–
NOAC	7.682	0.290	$61,701	$11,755	$40,602	–

QALY = quality-adjusted life-year; other abbreviations as in Table 1.

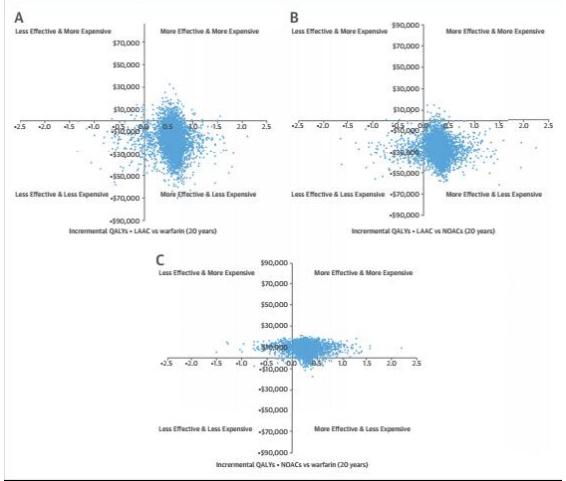
CENTRAL ILLUSTRATION Warfarin Versus NOACs Versus LAAC: Cumulative Cost and Time to Cost-Effectiveness Following Treatment Initiation



	Time to Clinical Effectiveness (Incremental QALYs)	Time to Cost-Effectiveness (Cost per QALY)	Time to Dominance (More Effective, Less Costly)
LAAC vs. warfarin	Year 3 (0.015)	Year 7 ($42,994/QALY)	Year 10
NOACs vs. warfarin	Year 1 (0.008)	Year 16 ($48,446/QALY)	N/A
LAAC vs. NOACs	Year 5 (0.007)	Year 5 (Dominant)	Year 5

Reddy, V.Y. et al. J Am Coll Cardiol. 2015; 66(24):2728–39.

FIGURE 3 Scatter Plots of Incremental Costs and Incremental QALYs at 20 Years for LAAC Versus Warfarin, LAAC Versus NOACs, and NOACs Versus Warfarin



Fermeture de l'auricule gauche: indications?

EHJ 2012	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

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

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

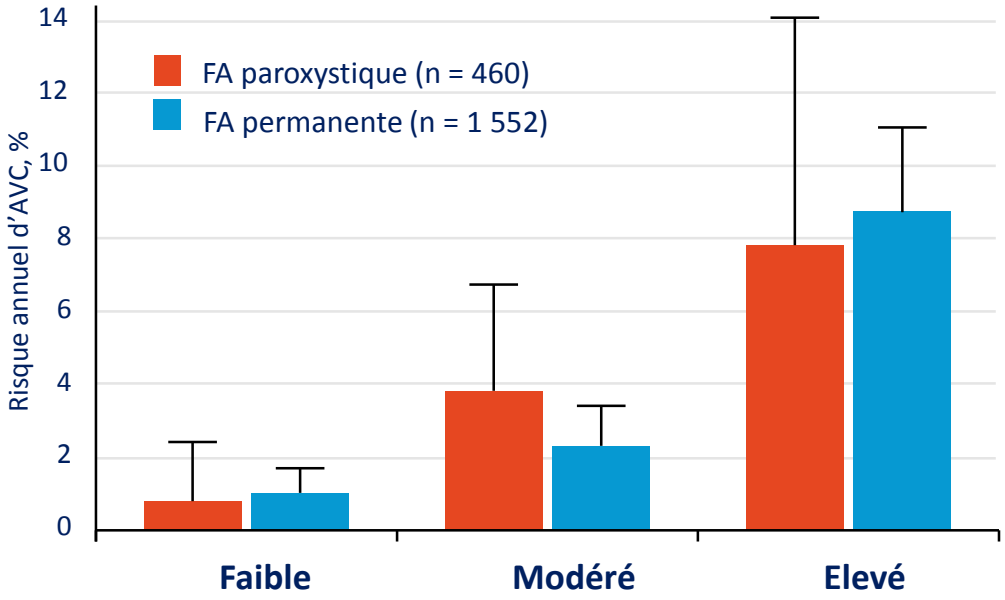
Indications: neurologie, gastro-entérologie, médecine interne, gériatrie, néphrologie

→ Staff décisionel pluridisciplinaire+++

Interaction Cardiologie/Neurologie: AVC cryptogéniques

.Tous âges confondus FA représente 20% des causes d'AVC et de plus de 50% les AVC d'origine cardio-embolique [1]

. Risque survenue d'AVC ischémique **FA paroxsytique = FA permanente** [2]



. **Détection FA** prévention secondaire AVC ischémique car AVK/AAP diminue 40% risque récidive [4]

1. Hart RG et al. Curr Cardiol Rep 2000;2:51-5
2.Marini C et al. Stroke 2005;36:1115-9
3. Falk RH. N Engl J Med 2001;344:1067-78
4. Hart RG et al. Etudes SPAF I, III

Interaction Cardiologie/Neurologie: AVC cryptogéniques

· **SITUATION IDEALE**: FA présente au moment AVC**:**

- Détection initiale FA sur ECG varie selon études entre 5% et 25%
- mais général. observée chez patients ayant déjà histoire de FA
- Détection nouvelle FA rare: 4.8%

Marini C et al. Stroke 2005;36:115-9

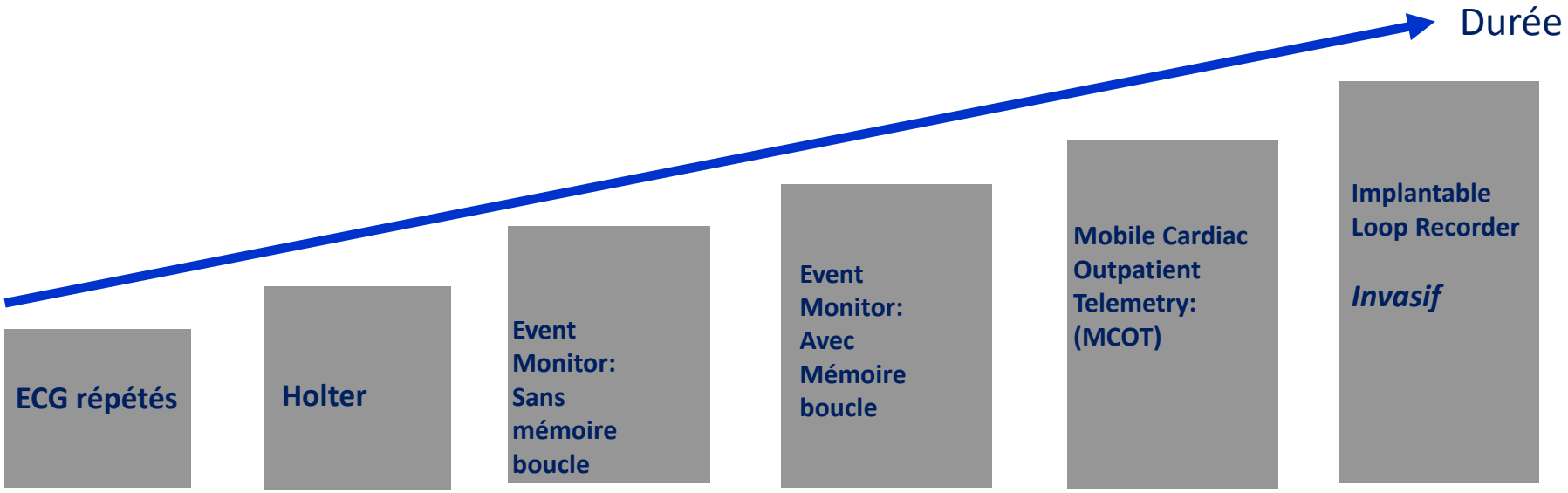
→ donc + de 75% patients sans diagnostic au moment de l'AVC

Ustrell X, Pellisé A. Cardiac workup of ichemic stroke. Curr Cardiol Rev 2010;6:175-83

FA: comment la détecter ?

. Examens non-invasifs:

- ECG (répétés), Holter (24 heures-7 jours), R-Test, Cardiatel, Holter implantable



. Examen invasifs:

- recherche vulnérabilité atriale, Holter implantable

FA: comment la détecter ?

- Résultats detection utilisant les moyens actuels

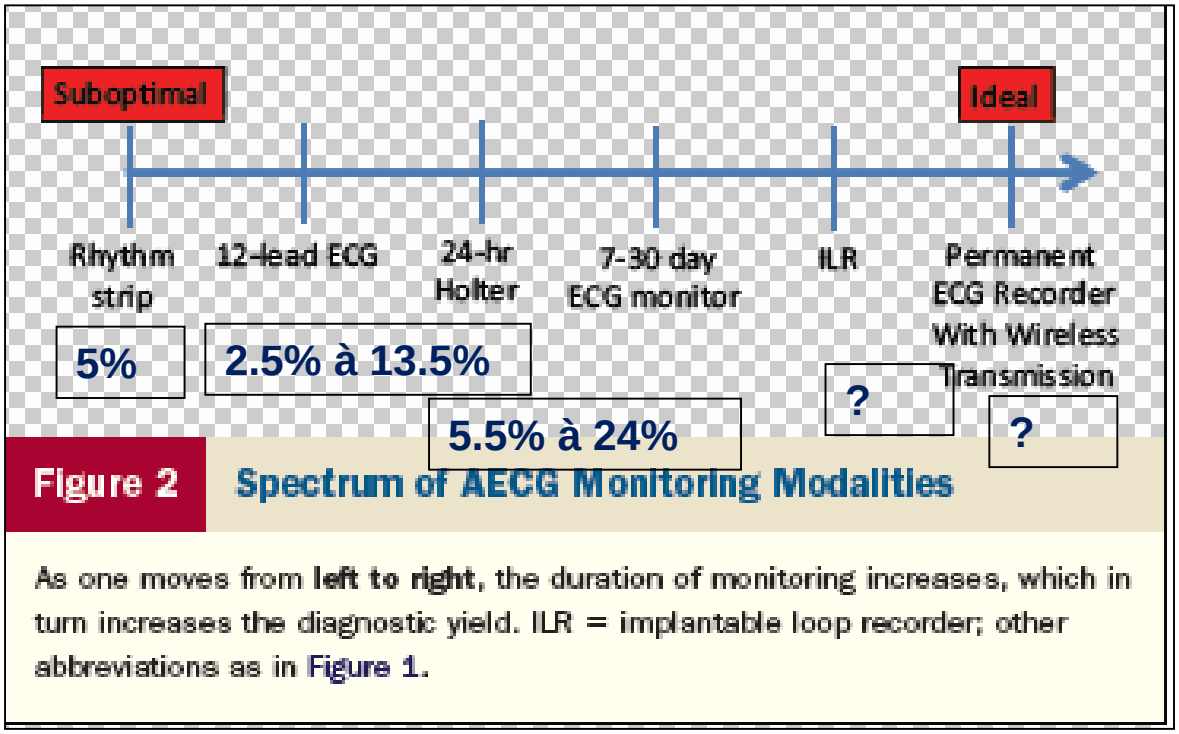


Figure 2 Spectrum of AECG Monitoring Modalities

As one moves from **left to right**, the duration of monitoring increases, which in turn increases the diagnostic yield. ILR = implantable loop recorder; other abbreviations as in Figure 1.

TOTAL:

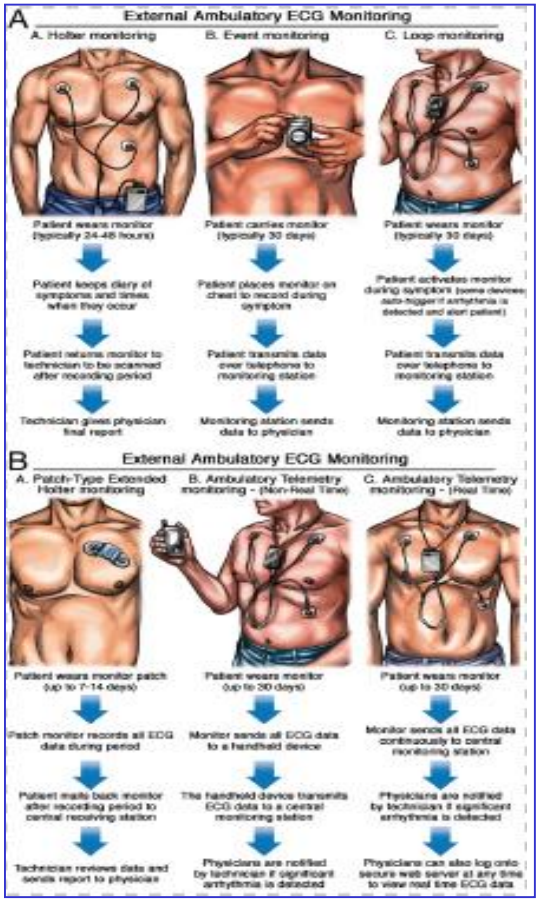
13% à 42%

→ DONC, plus d'un patient sur 2 restera sans diagnostic!!!

FA: comment la détecter ?

. Examen invasifs: si tout le bilan est négatif+++

- Nouveaux outils: Holter implantable et enregistreurs 30 jours



FA: comment la détecter ?

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

N ENGL J MED 370;26 NEJM.ORG JUNE 26, 2014

Cryptogenic Stroke and Underlying Atrial Fibrillation

Tommaso Sanna, M.D., Hans-Christoph Diener, M.D., Ph.D., Rod S. Passman, M.D., M.S.C.E., Vincenzo Di Lazzaro, M.D., Richard A. Bernstein, M.D., Ph.D., Carlos A. Morillo, M.D., Marilyn Mollman Rymer, M.D., Vincent Thijs, M.D., Ph.D., Tyson Rogers, M.S., Frank Beckers, Ph.D., Kate Lindborg, Ph.D., and Johannes Brachmann, M.D., for the CRYSTAL AF Investigators*

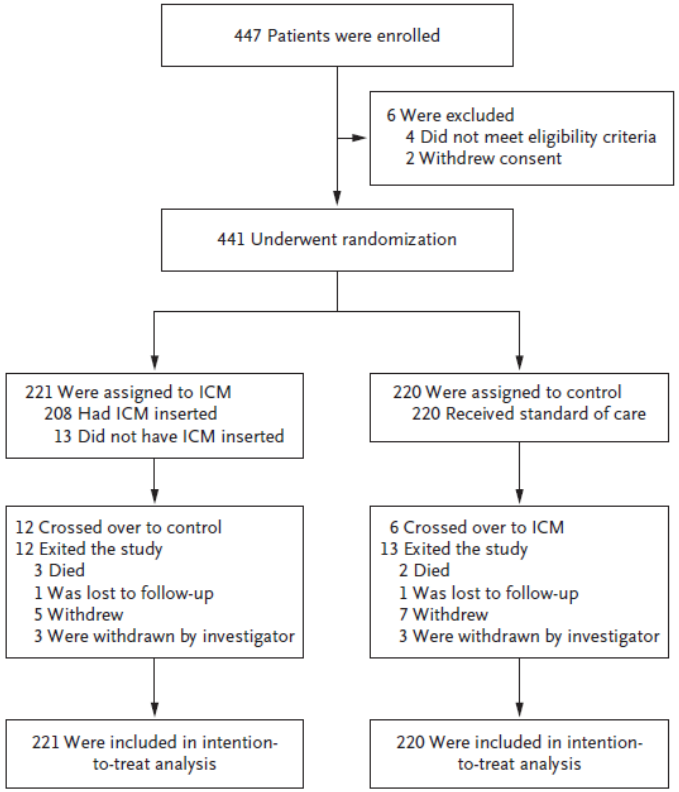


Table 1. Baseline Characteristics of the Study Participants.*

Characteristic	Insertable Cardiac Monitor (N=221)	Control (N=220)	P Value
Age — yr	61.6±11.4	61.4±11.3	0.84
Sex — no. (%)			0.77
Male	142 (64.3)	138 (62.7)	
Female	79 (35.7)	82 (37.3)	
Race or ethnic group — no. (%)†			0.60
Asian	3 (1.4)	2 (0.9)	
Black	7 (3.2)	10 (4.5)	
Hispanic or Latino	2 (0.9)	2 (0.9)	
White	194 (87.8)	191 (86.8)	
Other	0	3 (1.4)	
Not available	15 (6.8)	12 (5.5)	
Geographic region — no. (%)			0.32
North America	83 (37.6)	72 (32.7)	
Europe	138 (62.4)	148 (67.3)	
Patent foramen ovale — no. (%)	52 (23.5)	46 (20.9)	0.57
Index event — no. (%)			0.87
Stroke	200 (90.5)	201 (91.4)	
TIA	21 (9.5)	19 (8.6)	
Prior stroke or TIA — no. (%)			
Stroke	37 (16.7)	28 (12.7)	0.28
TIA	22 (10.0)	27 (12.3)	0.45
Score on modified Rankin scale — no. (%)‡			0.85
0–2	184 (83.3)	186 (84.5)	
>2	36 (16.3)	34 (15.5)	
Score on NIH Stroke Scale§	1.6±2.7	1.9±3.8	0.37
Hypertension — no. (%)	144 (65.2)	127 (57.7)	0.12
Diabetes — no. (%)	34 (15.4)	38 (17.3)	0.61
$CHADS_2$ score — no. (%)¶			0.17
2	69 (31.2)	81 (36.8)	
3	92 (41.6)	91 (41.4)	
4	50 (22.6)	34 (15.5)	
5	9 (4.1)	14 (6.4)	
6	1 (0.5)	0	
Hypercholesterolemia — no. (%)	125 (56.6)	128 (58.2)	0.77
Current smoker — no. (%)	43 (19.5)	44 (20.0)	0.91
Coronary artery disease — no. (%)	16 (7.2)	9 (4.1)	0.22
Use of antiplatelet agent — no. (%)	212 (95.9)	212 (96.4)	1.00

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

N ENGL J MED 370;26 NEJM.ORG JUNE 26, 2014

Cryptogenic Stroke and Underlying Atrial Fibrillation

Tommaso Sanna, M.D., Hans-Christoph Diener, M.D., Ph.D., Rod S. Passman, M.D., M.S.C.E., Vincenzo Di Lazzaro, M.D., Richard A. Bernstein, M.D., Ph.D., Carlos A. Morillo, M.D., Marilyn Mollman Rymer, M.D., Vincent Thijs, M.D., Ph.D., Tyson Rogers, M.S., Frank Beckers, Ph.D., Kate Lindborg, Ph.D., and Johannes Brachmann, M.D., for the CRYSTAL AF Investigators*

Implantation REVEAL dans les 3 mois post-AVC

Subgroup	No. of Patients (%)	Atrial Fibrillation Detected by 6 Mo (% of patients) ICM	Control	Hazard Ratio (95% CI)	P Value for Interaction
Overall	441 (100.0)	8.9	1.4		
Age					0.85
≤65 yr	276 (62.6)	4.4	0.8		
>65 yr	165 (37.4)	17.0	2.5		
Sex					0.99
Female	161 (36.5)	6.7	0.0	No estimate	
Male	280 (63.5)	10.1	2.3		
Race or ethnic group					1.00
White	385 (87.3)	8.0	1.6		
Other	29 (6.6)	9.1	0.0	No estimate	
Not available	27 (6.1)	20.0	0.0	No estimate	
Patent foramen ovale					0.99
No	343 (77.8)	8.0	1.8		
Yes	98 (22.2)	11.8	0.0	No estimate	
Index event					0.99
Stroke	401 (90.9)	8.3	1.6		
TIA	40 (9.1)	15.0	0.0	No estimate	
$CHADS_2$ score					0.73
2	150 (34.0)	3.0	0.0		
3	183 (41.5)	7.8	2.2		
4	84 (19.0)	15.4	3.2		
5	23 (5.2)	33.3	0.0		
6	1 (0.2)	0.0	NA		

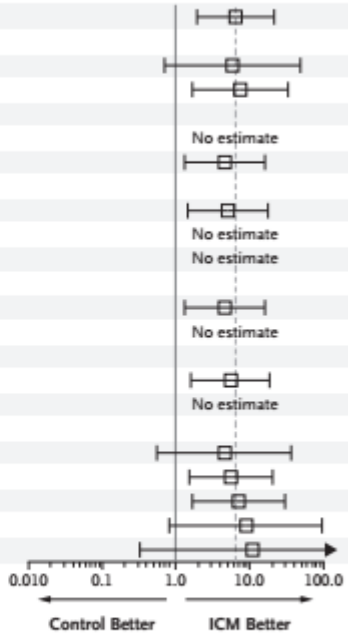
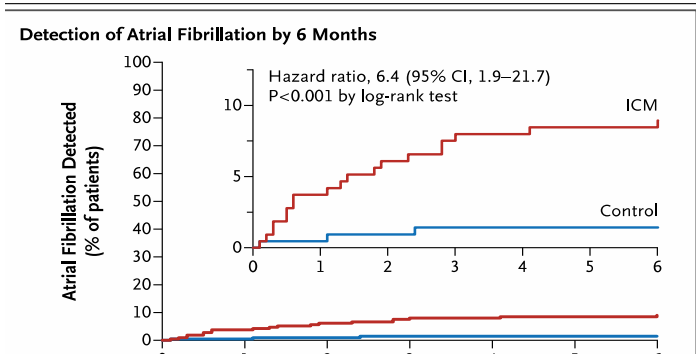
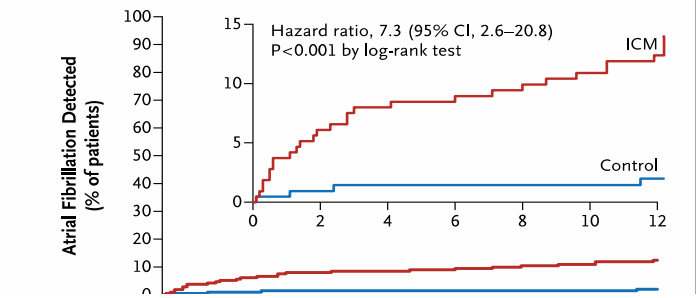


Figure 3. Subgroup Analysis of Time to First Detection of Atrial Fibrillation by 6 Months.



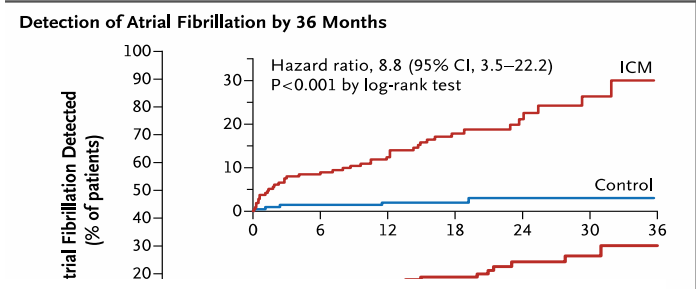
FA 9 % à 6 mois (vs 1.4 %)

Control	220	214	200	198	197	197	194
ICM	221	205	198	195	194	193	191



FA 12 % à 1 an (vs 2 %)

No. at Risk							
Control	220	200	197	194	184	184	167
ICM	221	198	194	191	186	182	173

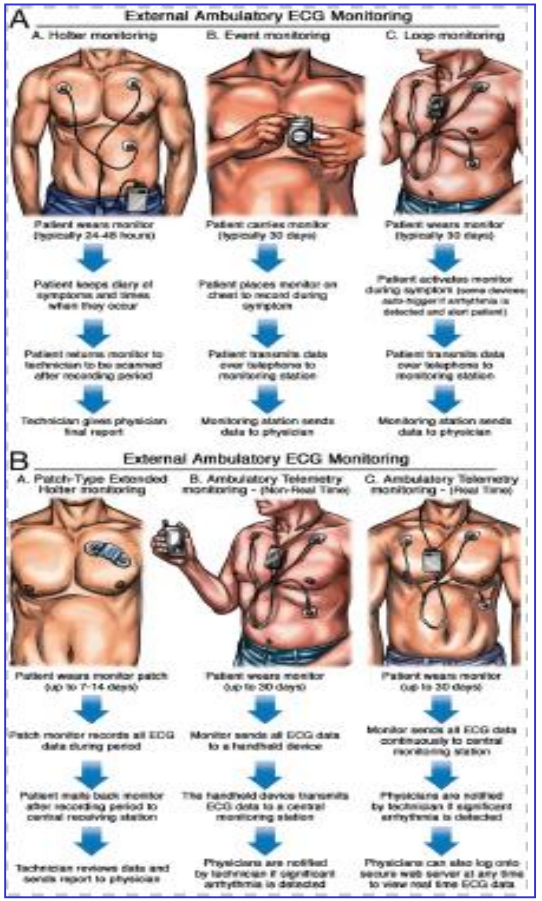


FA 30 % à 3 ans (vs 3 %)

FA: comment la détecter ?

. **Examen invasifs:** si tout le bilan est négatif+++

- Nouveaux outils: Holter longue durée



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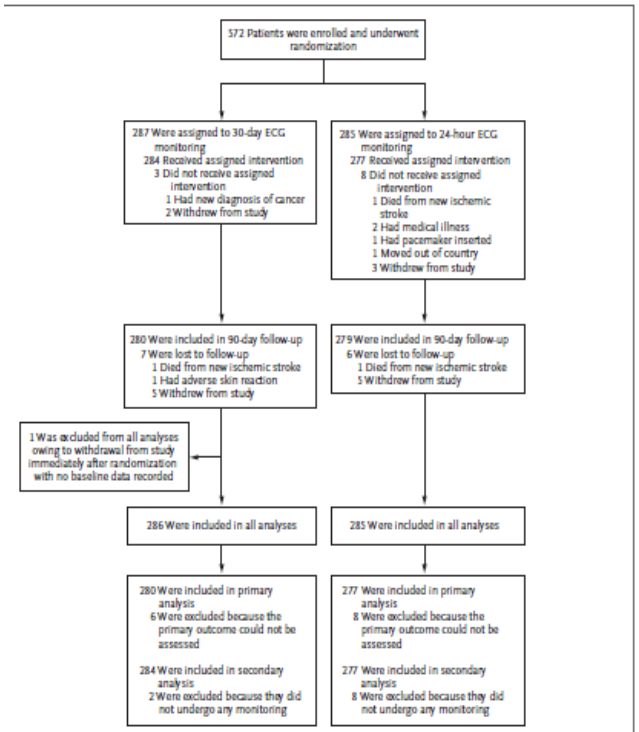
Atrial Fibrillation in Patients with Cryptogenic Stroke

David J. Gladstone, M.D., Ph.D., Melanie Spring, M.D., Paul Dorian, M.D., Val Panzov, M.D., Kevin E. Thorpe, M.Math., Judith Hall, M.Sc., Haris Vaid, B.Sc., Martin O'Donnell, M.B., Ph.D., Andreas Laupacis, M.D., Robert Côté, M.D., Mukul Sharma, M.D., John A. Blakely, M.D., Ashfaq Shuaib, M.D., Vladimir Hachinski, M.D., D.Sc., Shelagh B. Coutts, M.B., Ch.B., M.D., Demetrios J. Sahlas, M.D., Phil Teal, M.D., Samuel Yip, M.D., J. David Spence, M.D., Brian Buck, M.D., Steve Verreault, M.D., Leanne K. Casaubon, M.D., Andrew Penn, M.D., Daniel Selchen, M.D., Albert Jin, M.D., David Howse, M.D., Manu Mehdiratta, M.D., Karl Boyle, M.B., B.Ch., Richard Aviv, M.B., Ch.B., Moira K. Kapral, M.D., and Muhammad Mamdani, Pharm.D., M.P.H., for the EMBRACE Investigators and Coordinators*



Characteristic	Intervention Group (N=286)	Control Group (N=285)
Age		
Mean age — yr	72.5±8.5	73.2±8.8
≥75 yr — no. (%)	104 (36.4)	118 (41.4)
Female sex — no. (%)	132 (46.2)	125 (43.9)
Race — no. (%)†		
White	257 (89.9)	260 (91.2)
Asian	15 (5.2)	14 (4.9)
Black	6 (2.1)	2 (0.7)
Other	8 (2.8)	9 (3.2)
Modified Rankin scale score ≤2 — no. (%)‡	274 (95.8)	263 (92.3)
Medical history — no. (%)		
Hypertension	204 (71.3)	191 (67.0)
Diabetes	55 (19.2)	55 (19.3)
Hyperlipidemia	191 (66.8)	177 (62.1)
Smoking status		
Current smoker	19 (6.6)	24 (8.4)
Previous smoker	141 (49.3)	131 (46.0)
Previous ischemic stroke	45 (15.7)	36 (12.6)
>1 Previous stroke	12 (4.2)	12 (4.2)
Previous transient ischemic attack	42 (14.7)	46 (16.1)
Congestive heart failure	5 (1.7)	7 (2.5)
Myocardial infarction	48 (16.8)	42 (14.7)
Coronary angioplasty or stenting	24 (8.4)	23 (8.1)
Coronary bypass surgery	29 (10.1)	19 (6.7)
Cardiac-valve surgery	6 (2.1)	1 (0.4)
Type of index event — no. (%)		
Ischemic stroke	188 (65.7)	172 (60.4)
Transient ischemic attack	98 (34.3)	113 (39.6)
Oxfordshire classification[18] of the index event — no. (%)§		
Total anterior circulation syndrome	7 (2.4)	5 (1.8)
Partial anterior circulation syndrome	201 (70.3)	216 (75.8)
Posterior circulation syndrome	63 (22.0)	56 (19.6)
Lacunar syndrome	15 (5.2)	7 (2.5)
No. of days from index event to randomization	76.6±37.5	73.7±39.7

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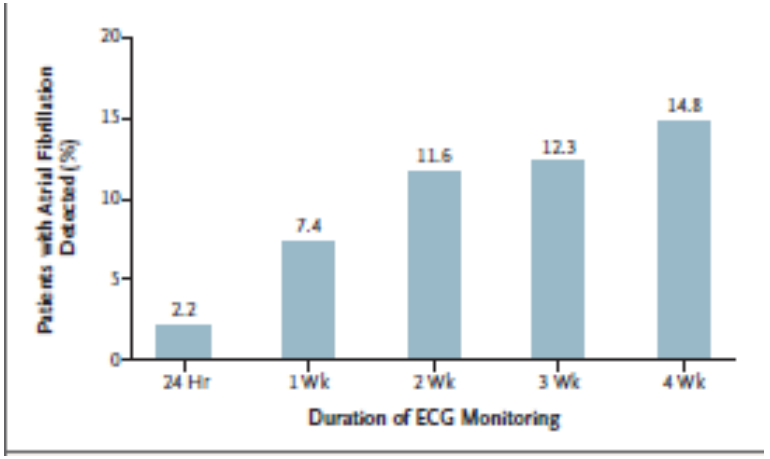
n = 572 patients avec AVC cryptogénique
(72 ans, 55 % homme, HTA dans 70 %) → R-Test 30 jours dans les 6 mois post-AVC

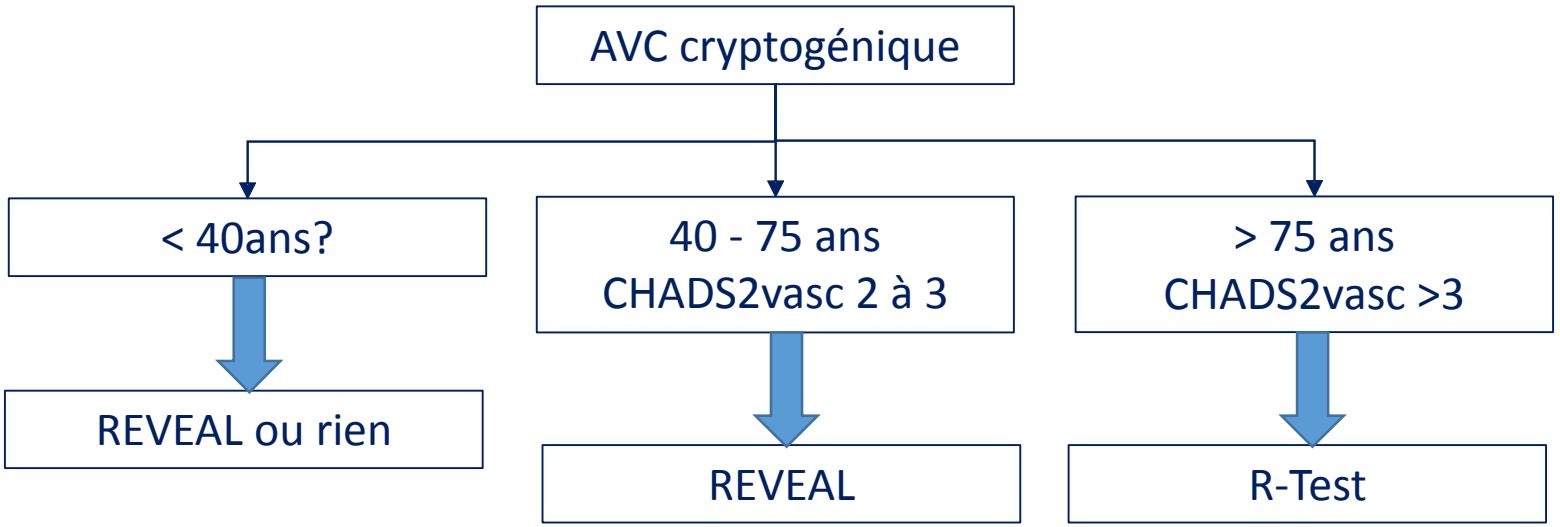
Outcome	Intervention Group (N=286)	Control Group (N=285)	Absolute Difference (95% CI)	P Value	No. of Patients Needed to Screen (95% CI)*
	number/total number (percent)		*percentage points*		
Primary outcome: detection of atrial fibrillation with duration ≥30 sec within 90 days†	45/280 (16.1)	9/277 (3.2)	12.9 (8.0–17.6)	<0.001	8 (5.7–12.5)
Secondary outcomes‡					
Detection of atrial fibrillation with duration ≥30 sec	44/284 (15.5)	7/277 (2.5)	13.0 (8.4–17.6)	<0.001	8 (5.7–11.9)
Detection of atrial fibrillation with duration ≥2.5 min	28/284 (9.9)	7/277 (2.5)	7.4 (3.4–11.3)	<0.001	14 (8.8–29.4)
Detection of atrial fibrillation of any duration	56/284 (19.7)	13/277 (4.7)	15.0 (9.8–20.3)	<0.001	7 (4.9–10.2)



Nbr de patients mis sous AVK suite au diagnostic a doublé+++

Implantation REVEAL/Pose R-Test: indications?

- Indications: neurologie



Staff décisionnel cardiologie/neurologie+++