A.C.C.A.

Amicale des Cardiologues de la Côte d'Azur

FIBRILLATION AURICULAIRE ET APPAREILS CONNECTÉS: ACTUALITÉS ET PERSPECTIVES

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Paris

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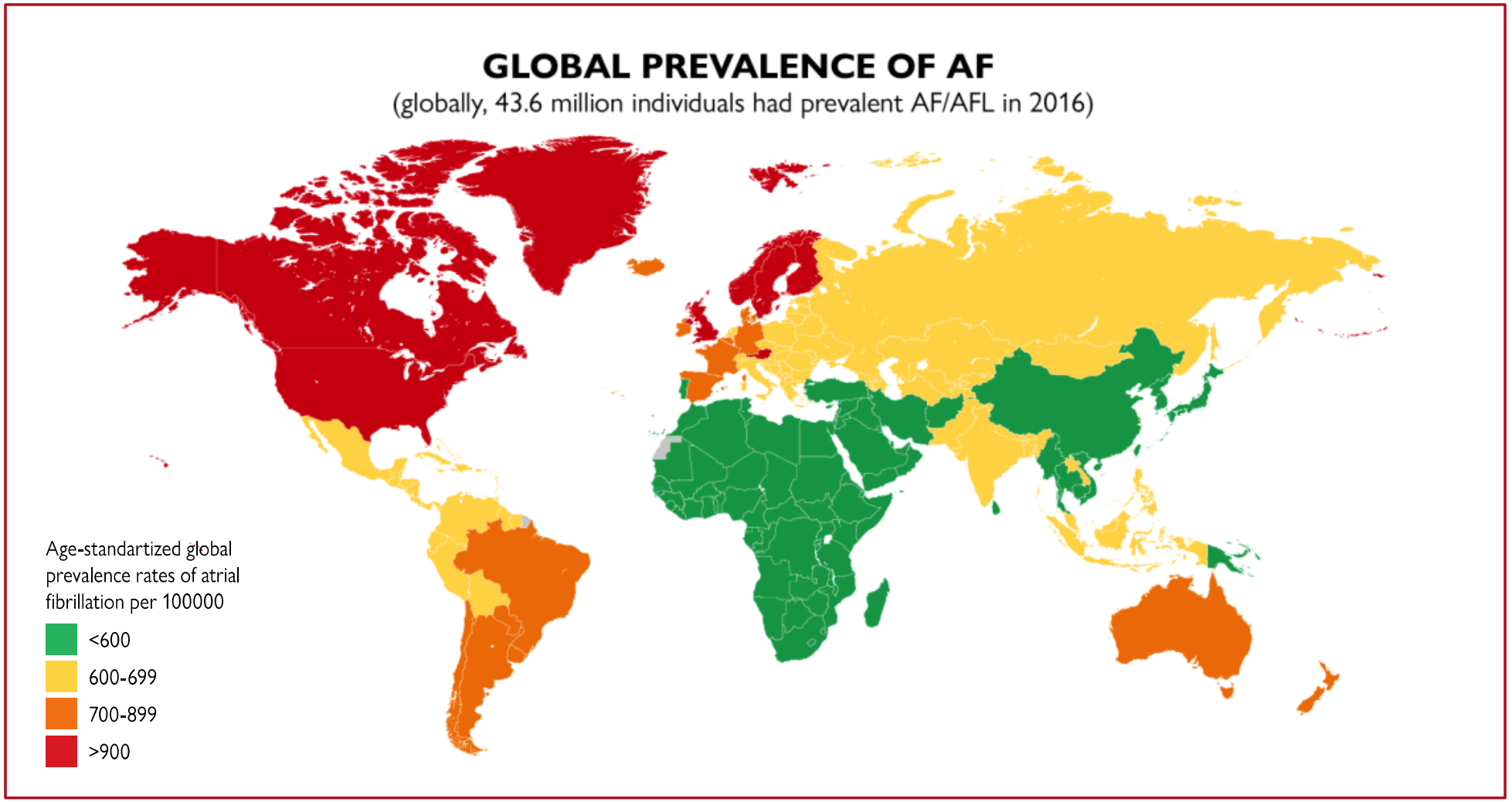
ESC 2020

Prise en charge de la FA

Figure 2 (1) Epidemiology of AF: prevalence



2020 ESC Guidelines for the diagnosis and management of atrial fibrillation
(European Heart Journal 2020-doi/10.1093/eurheartj/ehaa612)

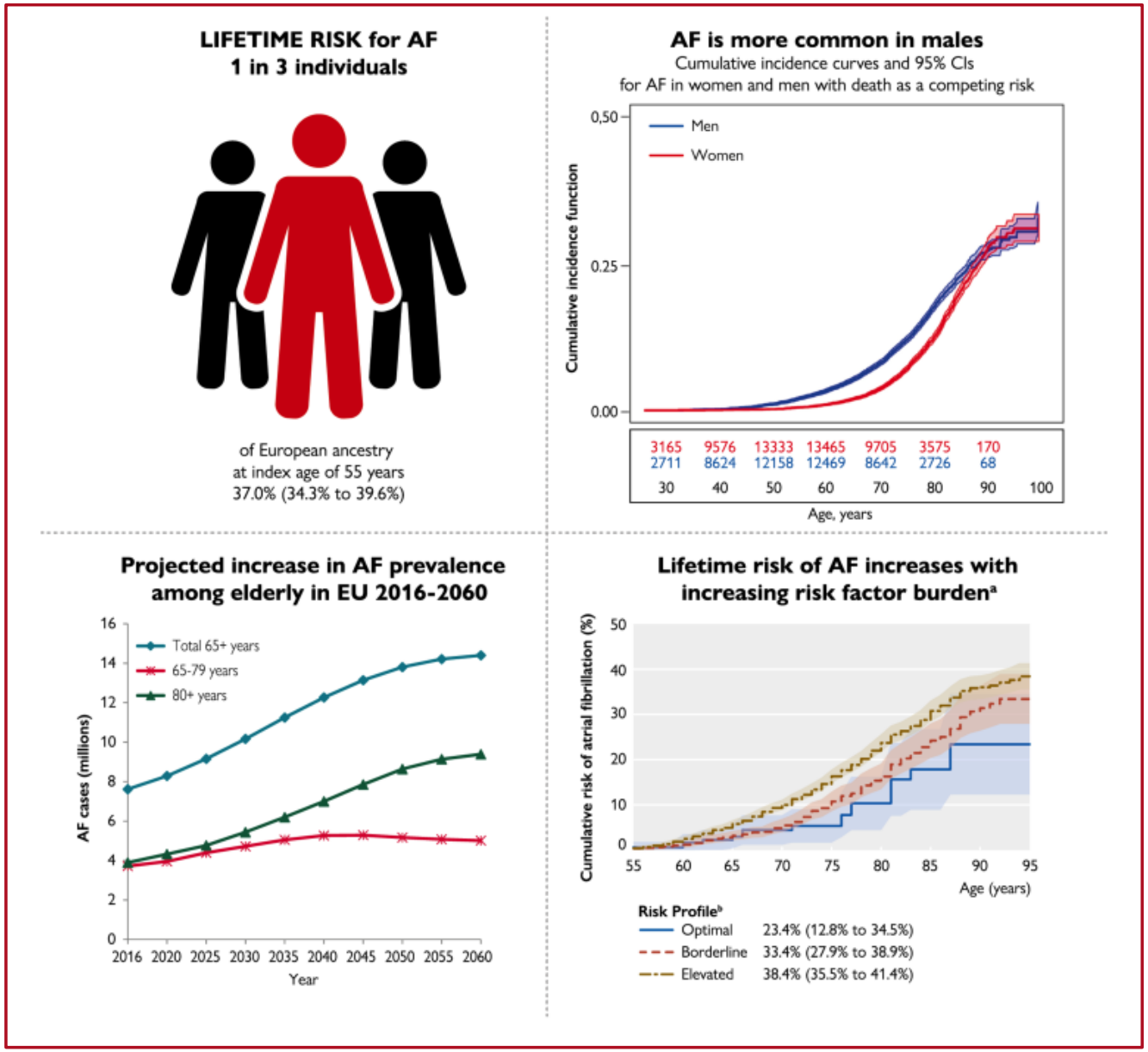


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Figure 2 (2)

Epidemiology of AF: lifetime risk and projected rise in the incidence and prevalence

[a]Smoking, alcohol consumption, body mass index, BP, diabetes mellitus (type 1 or 2), and history of myocardial infarction or heart failure. [b]Risk profile: *optimal* – all risk factors are negative or within the normal range; *borderline* – no elevated risk factors but >1 borderline risk factor; *elevated* – >1 elevated risk factor.

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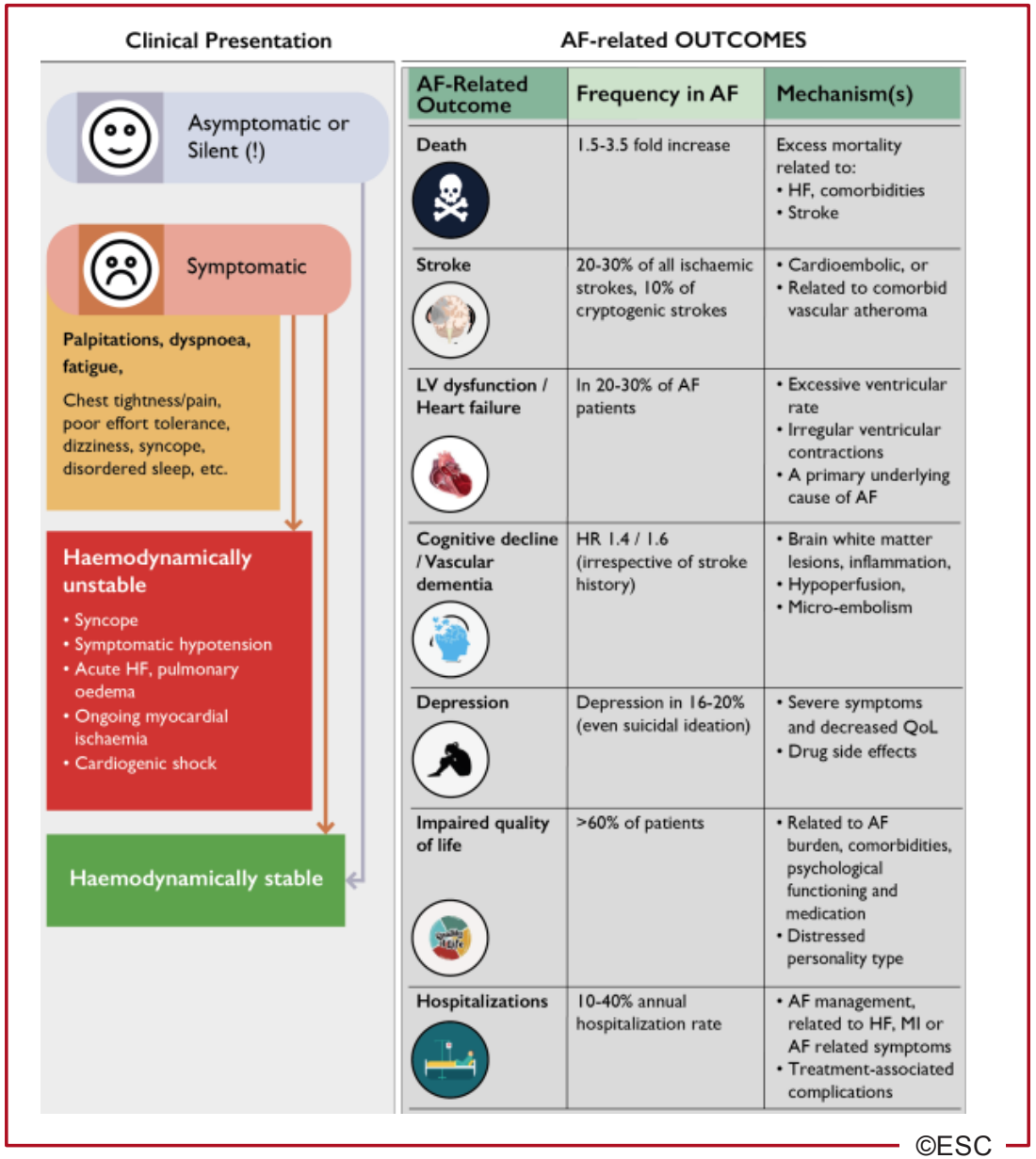

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Figure 4 Clinical presentation of AF and AF-related outcomes

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	Definition
AF	A supraventricular tachyarrhythmia with uncoordinated atrial electrical activation and consequently ineffective atrial contraction. *Electrocardiographic characteristics of AF include:* • Irregularly irregular R-R intervals (when atrioventricular conduction is not impaired), • Absence of distinct repeating P waves, and • Irregular atrial activations.
	Currently used terms
Clinical AF	*Symptomatic* or *asymptomatic* AF that is documented by surface ECG. The minimum duration of an ECG tracing of AF required to establish the diagnosis of clinical AF is at least 30 seconds, or entire 12-lead ECG.[1,2]
AHRE, subclinical AF	Refers to individuals *without symptoms attributable to AF*, in whom *clinical AF is NOT previously detected (that is, there is no surface ECG tracing of AF)*, see also *section 3.3*. **AHRE** - events fulfilling programmed or specified criteria for AHRE that are detected by CIEDs with an atrial lead allowing automated continuous monitoring of atrial rhythm and tracings storage. CIED-recorded AHRE need to be visually inspected because some AHRE may be electrical artefacts/false positives. **Subclinical AF** includes AHRE confirmed to be AF, AFL, or an AT, or AF episodes detected by insertable cardiac monitor or wearable monitor and confirmed by visually reviewed intracardiac electrograms or ECG-recorded rhythm.

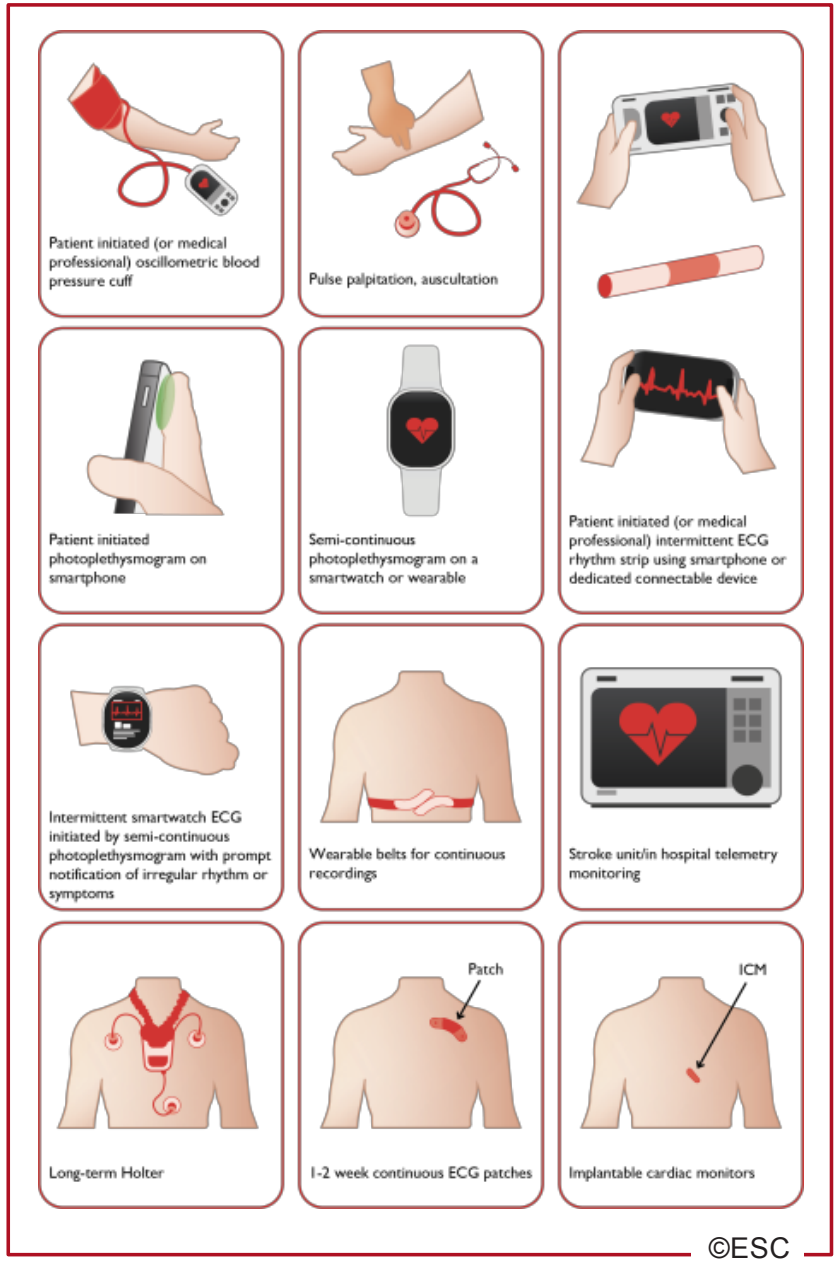

Figure 6 Systems used for AF screening

Table 5 Sensitivity and specificity of various AF screening tools considering the 12-lead ECG as the gold standard[173]

	Sensitivity	Specificity
Pulse taking[203]	87 - 97%	70 - 81%
Automated BP monitors[204–207]	93 - 100%	86 - 92%
Single lead ECG[208–211]	94 - 98%	76 - 95%
Smartphone apps[188,189,191,195,212,213]	91.5 - 98.5%	91.4 - 100%
Watches[196,198,213,214]	97 - 99%	83 - 94%

AF = atrial fibrillation; BP = blood pressure; ECG = electrocardiogram.

Pulse palpation, automated BP monitors, single-lead ECG devices, PPG devices, other sensors (using seismocardiography, accelerometers, and gyroscopes, etc.) used in applications for smartphones, wrist bands, and watches. Intermittent smartwatch detection through PPG or ECG recordings. Smartwatches and other 'wearables' can passively measure pulse rate from the wrist using an optical sensor for PPG and alerting the consumer of a pulse irregularity (based on a specific algorithm for AF detection analysing pulse irregularity and variability

Recommendations for screening to detect AF

Recommendation	Class[a]	Level[b]
Opportunistic screening for AF by pulse taking or ECG rhythm strip is recommended in patients ≥65 years of age.[188,211,223,225]	I	B
It is recommended to interrogate pacemakers and implantable cardioverter defibrillators on a regular basis for AHRE.[c 224,226]	I	B
When screening for AF it is recommended that:[217,218] • The individuals undergoing screening are informed about the significance and treatment implications of detecting AF. • A structured referral platform is organized for screen-positive cases for further physician-led clinical evaluation to confirm the diagnosis of AF and provide optimal management of patients with confirmed AF.	I	B
• Definite diagnosis of AF in screen-positive cases is established only after physician reviews the single-lead ECG recording of ≥30 s or 12-lead ECG and confirms that it shows AF.		
Systematic ECG screening should be considered to detect AF in individuals aged ≥75 years, or those at high risk of stroke.[212,224,227]	IIa	B

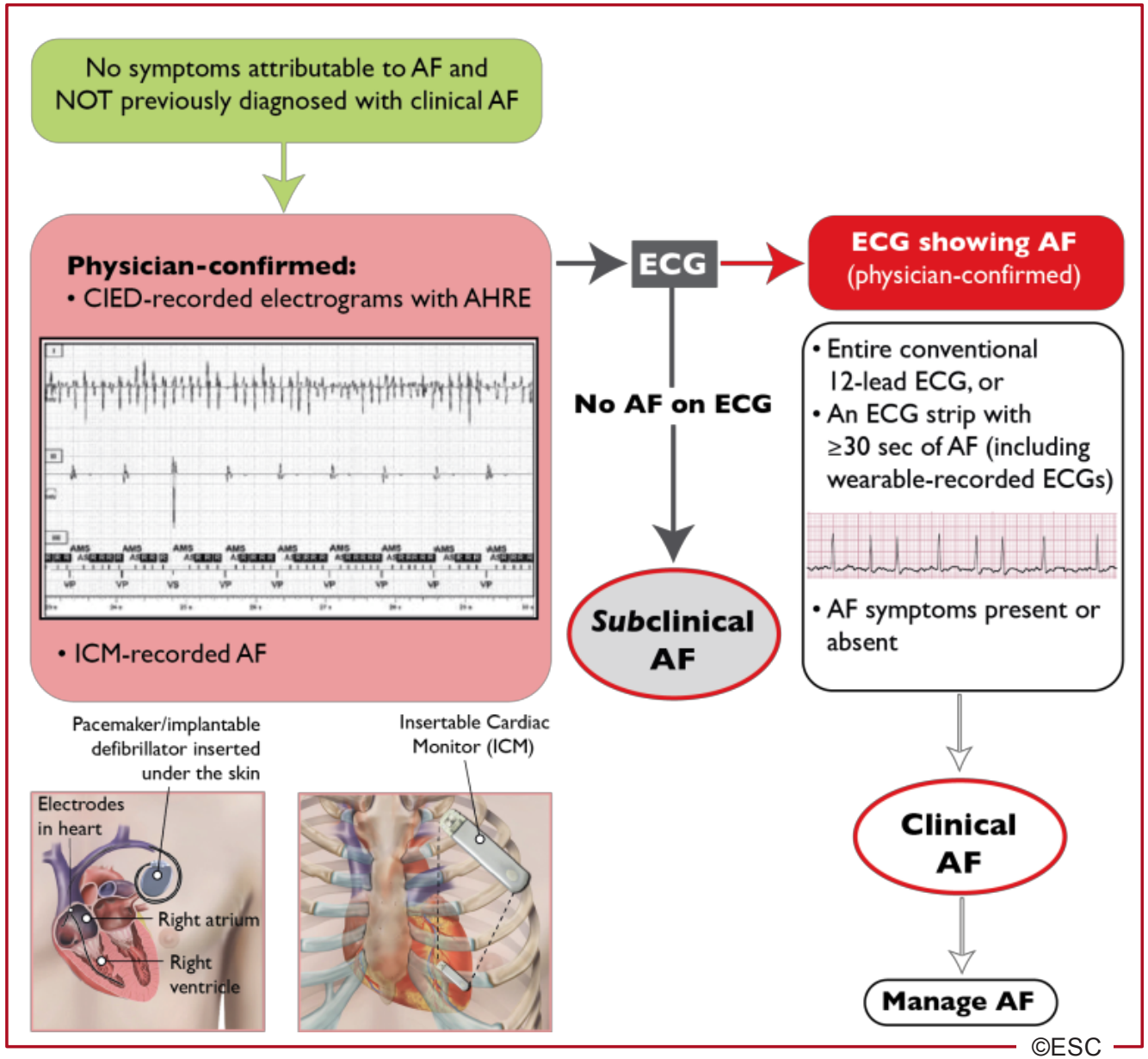

Figure 1 Diagnosis of AHRE/subclinical atrial fibrillation

CIEDs with an atrial lead can monitor atrial rhythm and store the tracings. ICM have no intra-cardiac leads but continuously monitor cardiac electrical activity by recording and analysing a single-lead bipolar surface ECG based on specific algorithm.
Left-bottom image: pacemaker with a right atrial lead, and a ventricular lead in the right ventricular apex. In addition to pacing at either site, these leads can sense activity in the respective cardiac chamber. The device can also detect pre-programmed events, such as AHRE.
Right-bottom image: subcutaneous ICM: these devices have no intra-cardiac leads and essentially record a single, bipolar, surface ECG with inbuilt algorithms for detection of AHRE or AF.

2020 ESC Guidelines for the diagnosis and management of atrial fibrillation
(European Heart Journal 2020-doi/10.1093/eurheartj/ehaa612)

ASSERT

Les AHRE

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Subclinical Atrial Fibrillation and the Risk of Stroke

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BACKGROUND

One quarter of strokes are of unknown cause, and subclinical atrial fibrillation may be a common etiologic factor. Pacemakers can detect subclinical episodes of rapid atrial rate, which correlate with electrocardiographically documented atrial fibrillation. We evaluated whether subclinical episodes of rapid atrial rate detected by implanted devices were associated with an increased risk of ischemic stroke in patients who did not have other evidence of atrial fibrillation.

METHODS

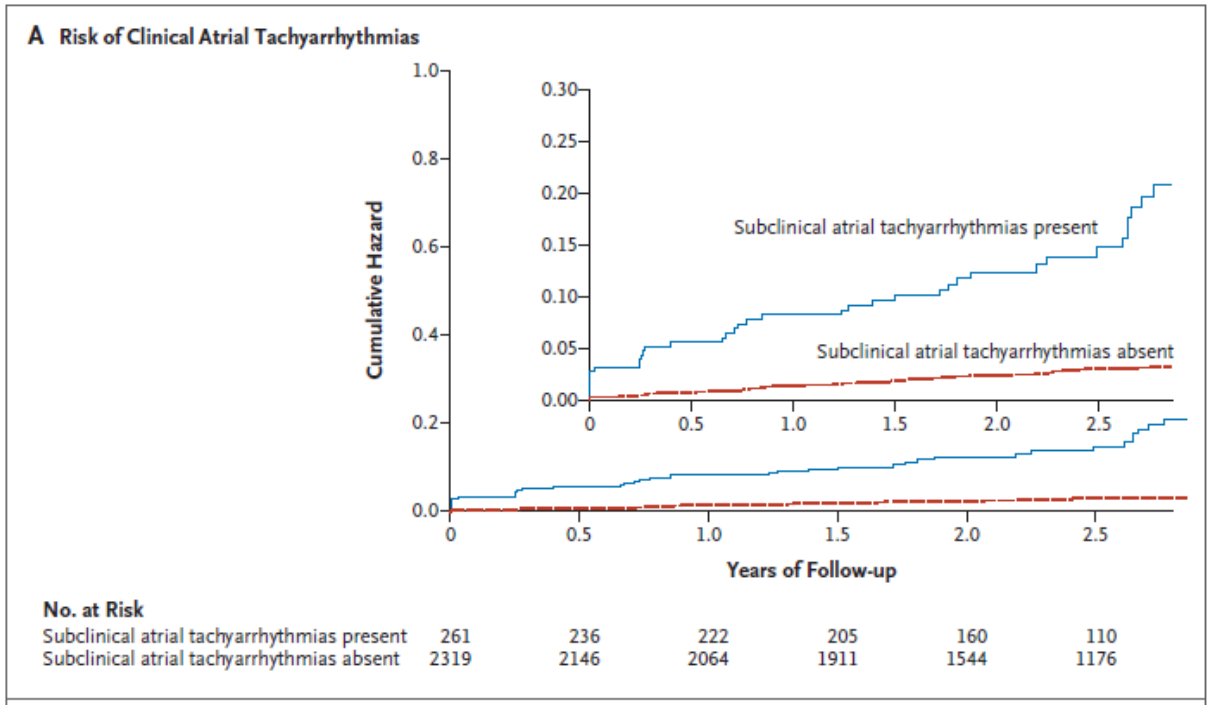
We enrolled 2580 patients, 65 years of age or older, with hypertension and no history of atrial fibrillation, in whom a pacemaker or defibrillator had recently been implanted. We monitored the patients for 3 months to detect subclinical atrial tachyarrhythmias (episodes of atrial rate >190 beats per minute for more than 6 minutes) and followed them for a mean of 2.5 years for the primary outcome of ischemic stroke or systemic embolism. Patients with pacemakers were randomly assigned to receive or not to receive continuous atrial overdrive pacing.

Table 1. Baseline Characteristics of the Patients.*

Characteristic	Device-Detected Subclinical Atrial Tachyarrhythmia			Continuous Atrial Overdrive Pacing†	
	Yes (N=261)	No (N=2319)	P Value	On (N=1164)	Off (N=1179)
Age — yr	77±7	76±7	0.13	76±7	76±7
Male sex — no. (%)	147 (56.3)	1359 (58.6)	0.48	687 (59.0)	658 (55.8)
Systolic blood pressure while sitting — mm Hg	137±20	138±19	0.38	139±20	138±19
Heart rate — beats/min	68±12	70±12	0.001	70±11	69±12
Body-mass index‡	28±5	27±5	0.43	27±5	27±5
Risk factors for stroke — no. (%)					
Prior stroke	18 (6.9)	168 (7.2)	0.84	80 (6.9)	88 (7.5)
Prior transient ischemic attack	13 (5.0)	113 (4.9)	0.94	52 (4.5)	60 (5.1)
History of heart failure	39 (14.9)	335 (14.4)	0.83	142 (12.2)	162 (13.7)
Diabetes mellitus	59 (22.6)	674 (29.1)	0.03	329 (28.3)	325 (27.6)
Prior myocardial infarction	32 (12.3)	427 (18.4)	0.01	175 (15.0)	200 (17.0)
$CHADS_2$ score§	2.2±1.1	2.3±1.0	0.47	2.2±1.0	2.3±1.1
Sinus-node disease, with or without atrioventricular-node disease — no. (%)	130 (49.8)	964 (41.6)	0.01	519 (44.6)	498 (42.2)
Atrioventricular-node disease, without sinus-node disease — no. (%)	132 (50.6)	1279 (55.2)	0.16	648 (55.7)	686 (58.2)
Atrial lead in septal position — no. (%)	101 (38.7)	972 (41.9)	0.32	492 (42.3)	498 (42.2)
Duration of hypertension >10 yr — no. (%)	115 (44.1)	965 (41.6)	0.45	486 (41.8)	505 (42.8)
Left ventricular hypertrophy on ECG — no. (%)	6 (2.3)	105 (4.5)	0.09	46 (4.0)	50 (4.2)
Time from implantation of pacemaker or ICD to enrollment — days	25±22	29±40	0.04	28±39	29±39
Medications — no. (%)					
Aspirin	160 (61.3)	1430 (61.7)	0.91	721 (61.9)	705 (59.8)
Beta-blocker	94 (36.0)	849 (36.6)	0.85	398 (34.2)	400 (33.9)
Statin	113 (43.3)	1112 (48.0)	0.15	544 (46.7)	537 (45.5)

Table 2. Clinical Outcomes Occurring after the 3-Month Visit, According to Whether Subclinical Atrial Tachyarrhythmias Were or Were Not Detected between Enrollment and the 3-Month Visit.

Clinical Outcome	Subclinical Atrial Tachyarrhythmias between Enrollment and 3 Months				Hazard Ratio with Subclinical Atrial Tachyarrhythmias (95% CI)	P Value
	Present (N=261)		Absent (N=2319)			
	no. of events	*%/yr*	*no. of events*	*%/yr*		
Ischemic stroke or systemic embolism*	11	1.69	40	0.69	2.49 (1.28–4.85)	0.007
Ischemic stroke	10	1.54	36	0.62	2.52 (1.25–5.08)	0.01
Systemic embolism	1	0.15	4	0.07	2.24 (0.25–20.10)	0.47
Myocardial infarction	7	1.07	39	0.67	1.52 (0.68–3.42)	0.31
Death from vascular causes	19	2.92	153	2.62	1.11 (0.69–1.79)	0.67
Stroke, myocardial infarction, or death from vascular causes	29	4.45	206	3.53	1.25 (0.85–1.84)	0.27
Hospitalization for heart failure	20	3.07	131	2.24	1.36 (0.85–2.19)	0.20
Clinical atrial fibrillation or flutter on surface electrocardiogram	41	6.29	71	1.22	5.56 (3.78–8.17)	<0.001



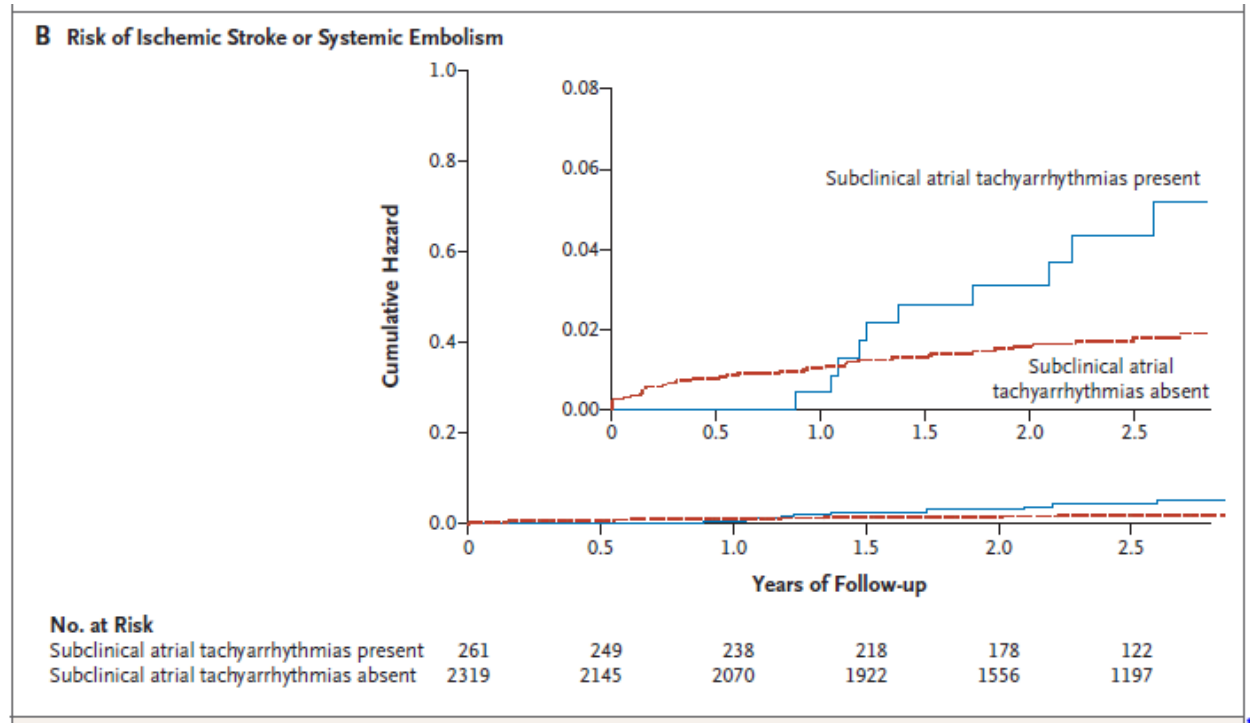


Figure 1. The Risk of Clinical Atrial Tachyarrhythmias and of Ischemic Stroke or Systemic Embolism, According to the Presence or Absence of Subclinical Atrial Tachyarrhythmias.

Panel A shows the risk of electrocardiographically documented clinical atrial tachyarrhythmias after the 3-month visit, according to whether subclinical atrial tachyarrhythmias were or were not detected between enrollment and the 3-month visit. Panel B shows the risk of ischemic stroke or systemic embolism after the 3-month visit, according to whether subclinical atrial tachyarrhythmias were or were not detected between enrollment and the 3-month visit. The insets show the same data on an enlarged y axis.

Table 3. Risk of Ischemic Stroke or Systemic Embolism after the 3-Month Visit, According to Baseline $CHADS_2$ Score and According to Whether Subclinical Atrial Tachyarrhythmias Were or Were Not Detected between Enrollment and the 3-Month Visit.

$CHADS_2$ Score	No. of Patients	Subclinical Atrial Tachyarrhythmias between Enrollment and 3 Months						Hazard Ratio for Ischemic Stroke or Systemic Embolism with Subclinical Atrial Tachyarrhythmias (95% CI)*
		Present			Absent			
		no. of patients	*no. of events*	*%/yr*	*no. of patients*	*no. of events*	*%/yr*	
1	600	68	1	0.56	532	4	0.28	2.11 (0.23–18.9)
2	1129	119	4	1.29	1010	18	0.70	1.83 (0.62–5.40)
>2	848	72	6	3.78	776	18	0.97	3.93 (1.55–9.95)

SOS AF project

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doi:10.1093/eurheartj/eht491

Device-detected atrial fibrillation and risk for stroke: an analysis of >10 000 patients from the SOS AF project (Stroke preventiOn Strategies based on Atrial Fibrillation information from implanted devices)

Giuseppe Boriani[1]*, Taya V. Glotzer[2], Massimo Santini[3], Teena M. West[4], Mirko De Melis[4], Milan Sepsi[5], Maurizio Gasparini[6], Thorsten Lewalter[7], John A. Camm[8], and Daniel E. Singer[9]

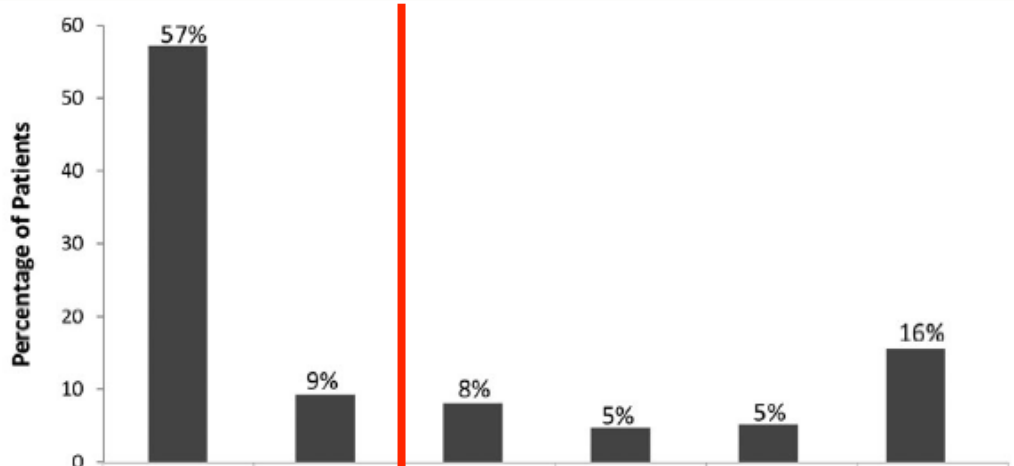
Objective The aim of this study was to assess the association between maximum daily atrial fibrillation (AF) burden and risk of ischaemic stroke.

Background Cardiac implanted electronic devices (CIEDs) enhance detection of AF, providing a comprehensive measure of AF burden.

Design, setting, and patients A pooled analysis of individual patient data from five prospective studies was performed. Patients without permanent AF, previously implanted with CIEDs, were included if they had at least 3 months of follow-up. A total of 10 016 patients (median age 70 years) met these criteria. The risk of ischaemic stroke associated with pre-specified cut-off points of AF burden (5 min, 1, 6, 12, and 23 h, respectively) was assessed.

Results During a median follow-up of 24 months, 43% of 10 016 patients experienced at least 1 day with at least 5 min of AF burden and for them the median time to the maximum AF burden was 6 months (inter-quartile range: 1.3–14). A Cox regression analysis adjusted for the $CHADS_2$ score and anticoagulants at baseline demonstrated that AF burden was an independent predictor of ischaemic stroke. Among the thresholds of AF burden that we evaluated, 1 h was associated with the highest hazard ratio (HR) for ischaemic stroke, i.e. 2.11 (95% CI: 1.22–3.64, $P = 0.008$).

FU médian 24 mois
Cut-off 1h



	0 to <5 minutes of AF burden	≥5 minutes to <1 hour AF burden	≥1 hour to <6 hours AF burden	≥6 hours to <12 hours AF burden	≥12 hours to <23 hours AF burden	≥23 hours AF burden
Median Follow Up, months	21	27	26	26	27	28
Person years	12966	2491	2077	1171	1375	4314
Stroke events, n(%)	31 (0.54%)	2 (0.21%)	7 (0.86%)	3 (0.65%)	4 (0.77%)	10 (0.64%)
Stroke rate, % per year	0.24%	0.08%	0.34%	0.26%	0.30%	0.23%
Stroke or TIA events, n(%)	41 (0.72%)	8 (0.86%)	14 (1.72%)	5 (1.08%)	6 (1.15%)	25 (1.61%)
Stroke or TIA rate, % per year	0.32%	0.32%	0.67%	0.43%	0.44%	0.49%

Figure 3 Distribution of patients according to maximum atrial fibrillation burden experienced during the follow-up. Stroke and transient ischaemic attack events and event rates are given in the table below the figure. Events were classified according to maximum atrial fibrillation burden experienced prior to event occurrence.

Table 3 Cox regression analysis performed on 8122 patients without oral anticoagulation at baseline, adjusted for the $CHADS_2$ score

	Total	Events	HR for AF burden ≥1 h vs. <1 h (95% CI)	*P*-value
Stroke	8122	44	2.09 (1.10, 3.96)	0.0239
Stroke + TIA	8122	69	2.05 (1.24, 3.39)	0.0051
Adjusting for $CHADS_2$ score				
Stroke	8122	44	1.90 (1.00, 3.61)	0.0487
Stroke + TIA	8122	69	1.89 (1.14, 3.12)	0.0135

TIA, transient ischaemic attack; HR, hazard ratio; CI, confidence interval.

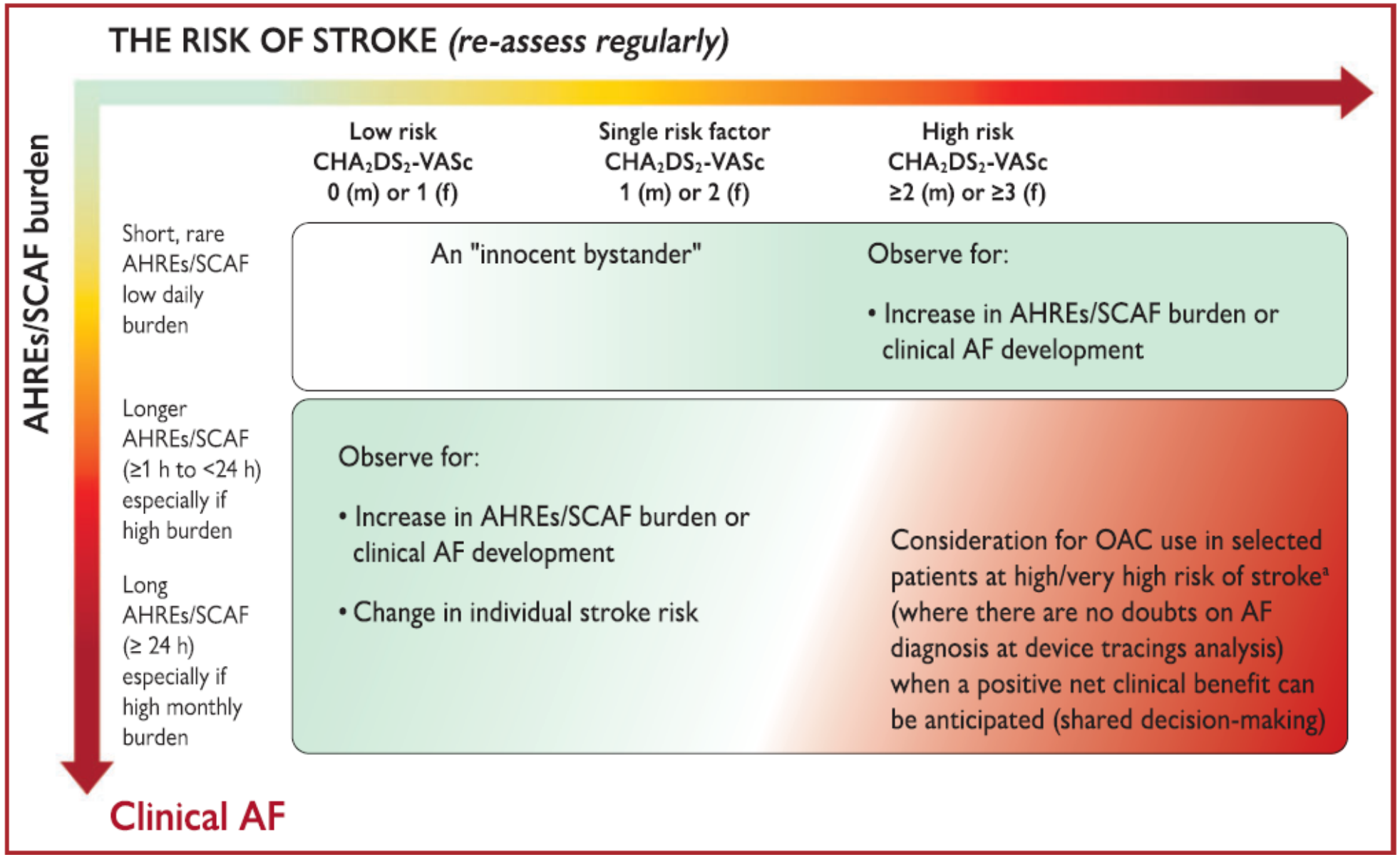
Conclusions Device-detected AF burden is associated with an increased risk of ischaemic stroke in a relatively unselected population of CIEDs patients. This finding may add to the basis for timely and clinically appropriate decision-making on anticoagulation treatment.

Table 1 Summary of studies investigating the association between AHREs and stroke risk

Trial	Study type and duration	Study population	Criteria for the diagnosis of AHRE	Outcomes
MOST[29]	Subgroup analysis of RCT, 6 years	$n = 312$, median age 74 years, 55% female, and 60% had a history of SND	Atrial rate >220 bpm for 10 consecutive beats	Compared with control, AHREs were associated with increased total mortality (HR 2.48 95% CI 1.25–4.91, $P = 0.0092$), death or non-fatal stroke (HR 2.79; 95% CI 1.51–5.15, $P = 0.0011$), and AF (HR 5.93; 95% CI 2.88–12.2, $P = 0.0001$)
TRENDS[30]	Prospective observational study, mean follow-up 1.4 years	$n = 2486$ with ≥ 1 risk factor for stroke	AT/AF burden = longest total AT/AF duration on any given day during the prior 30-day period and classified as subsets: zero, low (<5.5 h [median duration]), and high ($\geq$ 5.5 h)	Compared with zero burden, AF burden was associated with increased TE: HR 0.98; 95% CI 0.34–2.82, $P = 0.97$) and 2.20; 95% CI 0.96–5.05, $P = 0.06$), for low and high, respectively
ASSERT[31]	Prospective observational study, mean follow-up 2.5 years	$n = 2580$, age $\geq$ 65 years, with hypertension and no history of AF	Atrial rate >190 bpm for >6 min	By 3 months, AHREs occurred in 10.1%. AHREs were associated with an increased risk of clinical AF (HR 5.56; 95% CI 3.78–8.17; $P < 0.001$) and of ischaemic stroke or SE (HR 2.49; 95% CI 1.28–4.85; $P = 0.007$). After adjustment for predictors of stroke AHREs remained associated with stroke/SE (HR 2.50; 95% CI 1.28–4.89; $P = 0.008$)
Carelink/VA[34]	Case crossover study, analysis of data 30 days preceding a stroke	$n = 9850$, median age 68 years, 99% male, and 98% had a defibrillator	$\geq$5.5 h of AF on $\geq$1 day in the preceding 30 days	AHREs was associated with a four-fold increased risk of stroke within 30 days (OR = 4.33. 95% CI 1.19–23.7) Risk was highest in the 5–10 days after AHRE and rapidly declined after 10 days
Belgrade Atrial Fibrillation Study[35]	Single-centre registry study and mean follow-up 9.9 $\pm$ 6.1 years	$n = 1100$, mean age 52.7 $\pm$ 12.2 years, 13.3%) had asymptomatic AF	Asymptomatic presentation of first diagnosed AF	Ischaemic stroke risk (log-rank test = 6.2, $P = 0.013$) was significantly worse for patients with asymptomatic AF compared with those with symptomatic AF
SOS AF project[36]	Pooled analysis of individual patient data from five prospective studies	$n = 10\,016$, median age 70 years. Pts without permanent AF with ICDs were included if they had at least 3 months of follow-up	Device-detected AF. Cutoff points of AF burden defined as: 5 min, 1, 6, 12, and 23 h	AF burden 1 h was associated with the risk of ischaemic stroke (HR 2.11, 95% CI 1.22–3.64, $P = 0.008$)

AF, atrial fibrillation; AHRE, atrial high-rate event; AT, atrial tachycardia; bpm, beats per minute; RCT, randomized controlled trial; SE, systemic embolism; SND, sinus node; TE, thromboembolic event.

Europace (2017) **19**, 169–179
doi:10.1093/europace/euw279


THE RISK OF STROKE (re-assess regularly)
AHREs/SCAF burden
Low risk
CHA2DS2-VASc
0 (m) or 1 (f)
Single risk factor
CHA2DS2-VASc
1 (m) or 2 (f)
High risk
CHA2DS2-VASc
≥2 (m) or ≥3 (f)
Short, rare AHREs/SCAF low daily burden
An "innocent bystander"
Observe for:
• Increase in AHREs/SCAF burden or clinical AF development
Longer AHREs/SCAF (≥1 h to <24 h) especially if high burden
Long AHREs/SCAF (≥ 24 h) especially if high monthly burden
Observe for:
• Increase in AHREs/SCAF burden or clinical AF development
• Change in individual stroke risk
Consideration for OAC use in selected patients at high/very high risk of stroke[a] (where there are no doubts on AF diagnosis at device tracings analysis) when a positive net clinical benefit can be anticipated (shared decision-making)
Clinical AF
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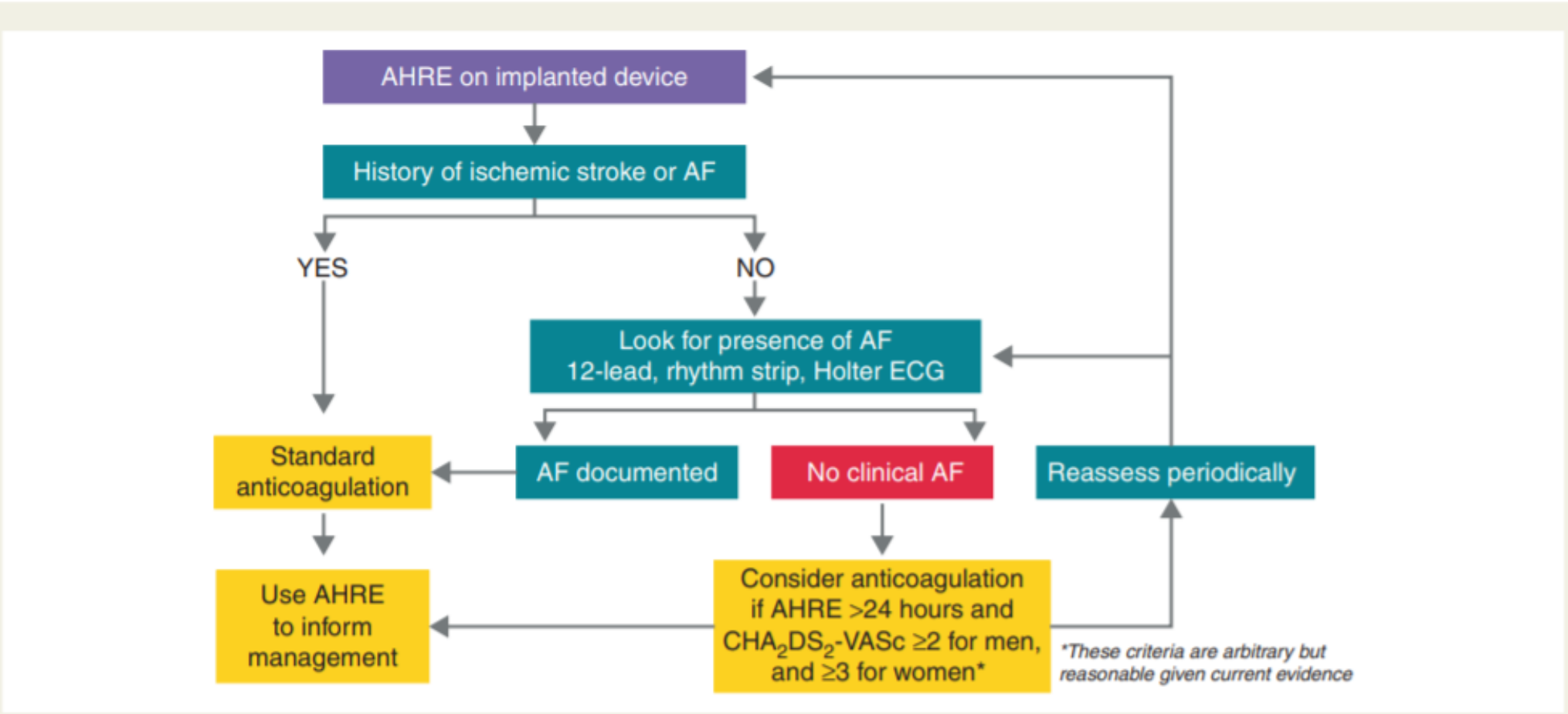


Figure 5 Suggested treatment algorithm for management of patients with AHREs. Adapted from Kirchhof *et al.*[70]

AFNET and EHRA 2012

Europace (2017) **19**, 169–179
doi:10.1093/europace/euw279

Apple Heart Study

I Watch

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation

Marco V. Perez, M.D., Kenneth W. Mahaffey, M.D., Haley Hedlin, Ph.D., John S. Rumsfeld, M.D., Ph.D., Ariadna Garcia, M.S., Todd Ferris, M.D., Vidhya Balasubramanian, M.S., Andrea M. Russo, M.D., Amol Rajmane, M.D., Lauren Cheung, M.D., Grace Hung, M.S., Justin Lee, M.P.H., Peter Kowey, M.D., Nisha Talati, M.B.A., Divya Nag, Santosh E. Gummidipundi, M.S., Alexis Beatty, M.D., M.A.S., Mellanie True Hills, B.S., Sumbul Desai, M.D., Christopher B. Granger, M.D., Manisha Desai, Ph.D., and Mintu P. Turakhia, M.D., M.A.S., for the Apple Heart Study Investigators*

BACKGROUND

Optical sensors on wearable devices can detect irregular pulses. The ability of a smartwatch application (app) to identify atrial fibrillation during typical use is unknown.

METHODS

Participants without atrial fibrillation (as reported by the participants themselves) used a smartphone (Apple iPhone) app to consent to monitoring. If a smartwatch-based irregular pulse notification algorithm identified possible atrial fibrillation, a telemedicine visit was initiated and an electrocardiography (ECG) patch was mailed to the participant, to be worn for up to 7 days. Surveys were administered 90 days after notification of the irregular pulse and at the end of the study. The main objectives were to estimate the proportion of notified participants with atrial fibrillation shown on an ECG patch and the positive predictive value of irregular pulse intervals with a targeted confidence interval width of 0.10.

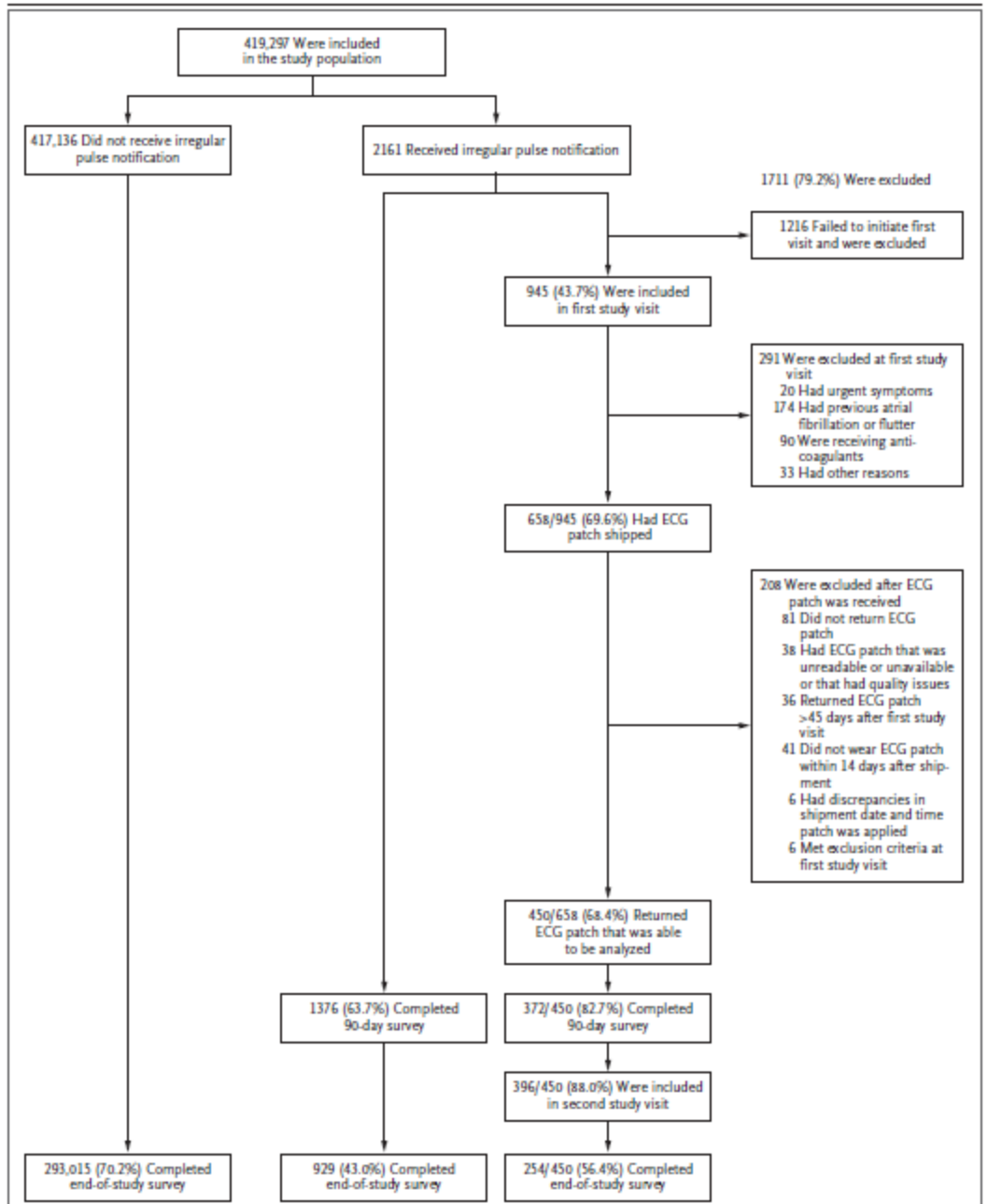


Figure 1. Participant Selection.

Of the 1216 potential participants who were excluded because they did not have a first study visit, 4 received an ECG patch. AF denotes atrial fibrillation, and ECG electrocardiography.

Table 1. Characteristics of Participants Enrolled in the Apple Heart Study at Baseline.*

Characteristic	Total Cohort (N=419,297)	Notification Subgroup (N=2161)	ECG Patch Subgroup (N=450)
Sex — no. (%)†			
Female	177,087 (42)	461 (21)	102 (23)
Male	238,700 (57)	1672 (77)	335 (74)
Other	396 (0.1)	0	0
Not reported	3,114 (0.7)	28 (1.3)	13 (2.9)
Age — yr	41±13	57±15	59±14
Age distribution — no. (%)			
≥65 yr	24,626 (5.9)	775 (36)	181 (40)
55–64 yr	42,633 (10)	556 (26)	114 (25)
40–54 yr	132,696 (32)	488 (23)	106 (24)
22–39 yr	219,179 (52)	341 (16)	49 (11)
Not reported	163 (<0.1)	1 (<0.1)	0
Race or ethnic group — no. (%)†			
White	286,190 (68)	1747 (81)	379 (84)
Hispanic	48,775 (12)	104 (4.8)	20 (4.4)
Black	32,275 (7.7)	106 (4.9)	16 (3.6)
Asian	26,156 (6.2)	87 (4.0)	8 (1.8)
American Indian	4,696 (1.1)	20 (0.9)	3 (0.7)
Pacific Islander	1,493 (0.4)	6 (0.3)	0
Middle Eastern	3,652 (0.9)	9 (0.4)	2 (0.4)
Other or mixed race	7,958 (1.9)	32 (1.5)	6 (1.3)
Not reported	8,102 (1.9)	50 (2.3)	16 (3.6)
Medical history — no. (%)			
Obesity	160,197 (38)	984 (46)	192 (43)
Hypertension	86,338 (21)	917 (42)	200 (44)
Diabetes	20,443 (4.9)	255 (12)	53 (12)
Heart failure	2,511 (0.6)	72 (3.3)	10 (2.2)
Stroke or TIA	4,153 (1.0)	66 (3.1)	10 (2.2)
Peripheral artery disease	2,596 (0.6)	52 (2.4)	10 (2.2)
CHA_2DS_2-VASc score ≥2‡	55,277 (13)	713 (33)	171 (38)
Current smoking — no. (%)	25,458 (6.1)	88 (4.1)	10 (2.2)
Alcohol: ≥1 drink/wk — no. (%)	190,463 (45)	1092 (51)	227 (50)

RESULTS

We recruited 419,297 participants over 8 months. Over a median of 117 days of monitoring, 2161 participants (0.52%) received notifications of irregular pulse. Among the 450 participants who returned ECG patches containing data that could be analyzed — which had been applied, on average, 13 days after notification — atrial fibrillation was present in 34% (97.5% confidence interval [CI], 29 to 39) overall and in 35% (97.5% CI, 27 to 43) of participants 65 years of age or older. Among participants who were notified of an irregular pulse, the positive predictive value was 0.84 (95% CI, 0.76 to 0.92) for observing atrial fibrillation on the ECG simultaneously with a subsequent irregular pulse notification and 0.71 (97.5% CI, 0.69 to 0.74) for observing atrial fibrillation on the ECG simultaneously with a subsequent irregular tachogram. Of 1376 notified participants who returned a 90-day survey, 57% contacted health care providers outside the study. There were no reports of serious app-related adverse events.

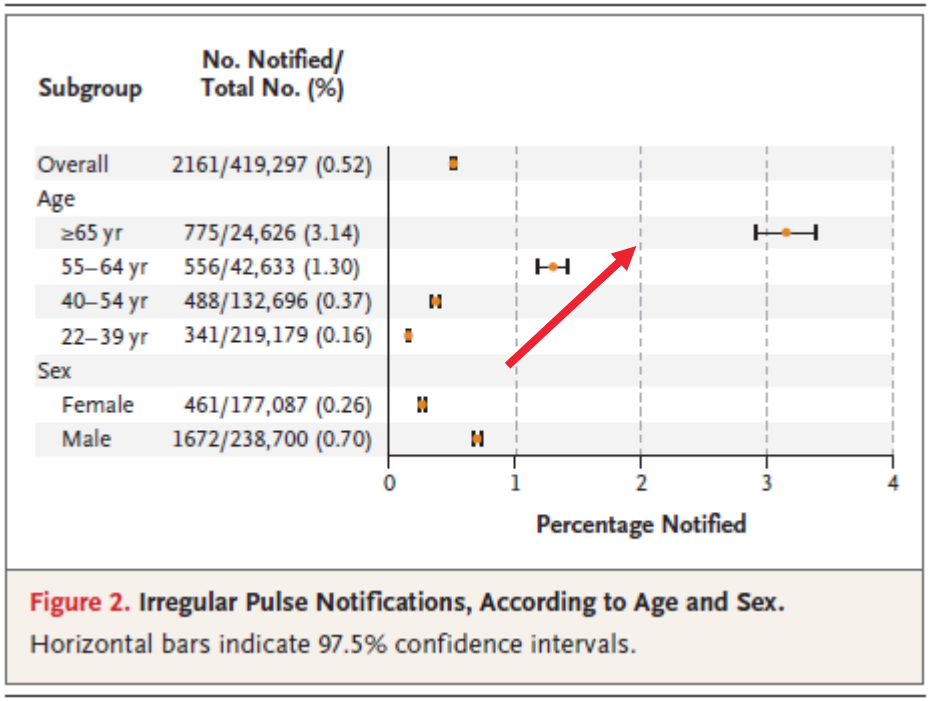


Figure 2. Irregular Pulse Notifications, According to Age and Sex.
Horizontal bars indicate 97.5% confidence intervals.

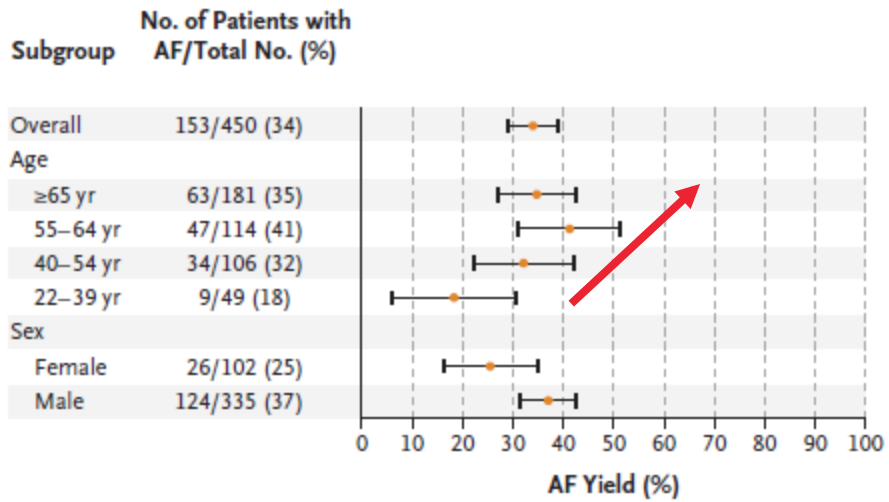


Figure 3. Yield of Atrial Fibrillation on ECG Patch Monitoring.
Horizontal bars indicate 97.5% confidence intervals.

Table 2. End-of-Study Survey.

Variable	Notification Subgroup (N=929)	Non-notification Subgroup (N=293,015)
New diagnosis — no. (%)		
Atrial fibrillation	404 (43)	3070 (1.0)
Stroke	7 (0.8)	321 (0.1)
TIA	12 (1.3)	498 (0.2)
Heart failure	30 (3.2)	648 (0.2)
Myocardial infarction	10 (1.1)	574 (0.2)
Major bleeding	7 (0.8)	842 (0.3)
Medication use — no. (%)*		
Warfarin	20 (2.2)	265 (0.1)
Direct oral anticoagulant	202 (22)	996 (0.3)
Aspirin	338 (36)	40,774 (14)

* This category refers to medication use since enrollment in the study, as reported by the participants.

CONCLUSIONS

The probability of receiving an irregular pulse notification was low. Among participants who received notification of an irregular pulse, 34% had atrial fibrillation on subsequent ECG patch readings and 84% of notifications were concordant with atrial fibrillation. This siteless (no on-site visits were required for the participants), pragmatic study design provides a foundation for large-scale pragmatic studies in which outcomes or adherence can be reliably assessed with user-owned devices. (Funded by Apple; Apple Heart Study ClinicalTrials.gov number, NCT03335800.)


ECG Detail
Sinus Rhythm
This ECG does not show signs of atrial fibrillation.
Export a PDF for Your Doctor
76 BPM
10:09
24sec
It helps to rest your arms on a table or your legs.


110 BPM
2:09
15sec
Note: Apple Watch never checks for heart attacks.

Moniteurs sous cutanés insérables

CRYSTAL AF

Reveal

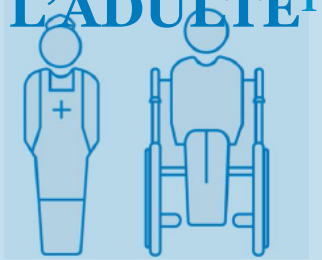
L'AVC en France

EN FRANCE

150 000

PATIENTS VICTIMES D'UN AVC **PAR AN[1]**

1ÈRE CAUSE DE SÉQUELLES **CHEZ L'ADULTE[1]**



L'AVC EST LA **2ÈME** CAUSE DE DÉCÈS **EN FRANCE[1]**

COÛT **8.6** MILLIARDS D'EUROS **PAR AN[2]**

1. Site internet France AVC : http://www.franceavc.com/
2. De Pouvourville, G. (2016) 'Coût de la prise en charge des accidents vasculaires cérébraux en France', *Archives of Cardiovascular Diseases Supplements*. Elsevier Ltd, 8(2), pp. 161–168. doi: 10.1016/S1878-6480(16)30330-5.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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*

Rationnel :

- 36% des AVC ischémiques sont dus à un mécanisme inconnu.[4]
- La détection de FA entraine généralement l'initiation d'un traitement anticoagulant à long-terme plutôt qu'un traitement antiagrégant plaquettaire
- La durée de surveillance pour une détection optimale de FA est inconnue.
- La FA peut être paroxystique, rare, asymptomatique, rendant les méthodes « conventionnelles » peu adaptée à sa détection.

4. Petty, G. W. *et al.* (1999) 'A Population-Based Study of Incidence and Risk Factors', pp. 2513–2516.

Objectifs :

- Prouver qu'une surveillance à long terme avec un MCI est supérieure aux examens standards de détection de la FA chez des patients avec antécédents d'AVC. L'objectif principal portait sur une période de 6 mois. La surveillance a été poursuivie sur une base semestrielle a minima jusqu'à 12 mois.
- Déterminer la proportion de patients ayant eu un AVC cryptogénique qui présente une FA sous-jacente
- Déterminer les actions entreprises après le diagnostic de la FA.

- **Inclusion:**

≥40 ans

AVC cryptogénique (ou AIT clinique) avec zone infarcie visible à l'IRM ou au CT dans les 90 jours précédents l'inclusion, et aucun diagnostic posé (incluant la FA) après :

- ECG 12 dérivations
- Surveillance ECG de 24h (ex : Holter)
- Echocardiographie trans-œsophagienne
- Imagerie cérébrale et cervicale pour exclure une cause vasculaire
- Recherche de thrombophilie (hypercoagulabilité) chez les patients <55 ans

- **Exclusion:**

Antécédents de FA ou de flutter atrial

Indication ou contre-indication d'anticoagulation

Indication de pacemaker ou de défibrillateur

Inclusion (n=447)

Exclusion (n= 6)
- Critères d'éligibilité non remplis (n=4)
- Retrait du consentement (n=2)

Randomisation (n=441)

Groupe Reveal (n=221)
- Dispositif implanté (n=208)
- Dispositif non implanté (n=13)

Groupe Contrôle (n=220)
- Prise en charge standard (n=220)

Cross-over vers Groupe Contrôle (n=12)
Sortie d'étude (n=12)
- Décès (n=3)
- Perdus de vue (n=1)
- Retrait patient (n=5)
- Retrait investigateur (n=3)

Cross-over vers Groupe Reveal (n=6)
Sortie d'étude (n=13)
- Décès (n=2)
- Perdus de vue (n=1)
- Retrait patient (n=7)
- Retrait investigateur (n=3)

Analyse en intention de traiter (n=221)

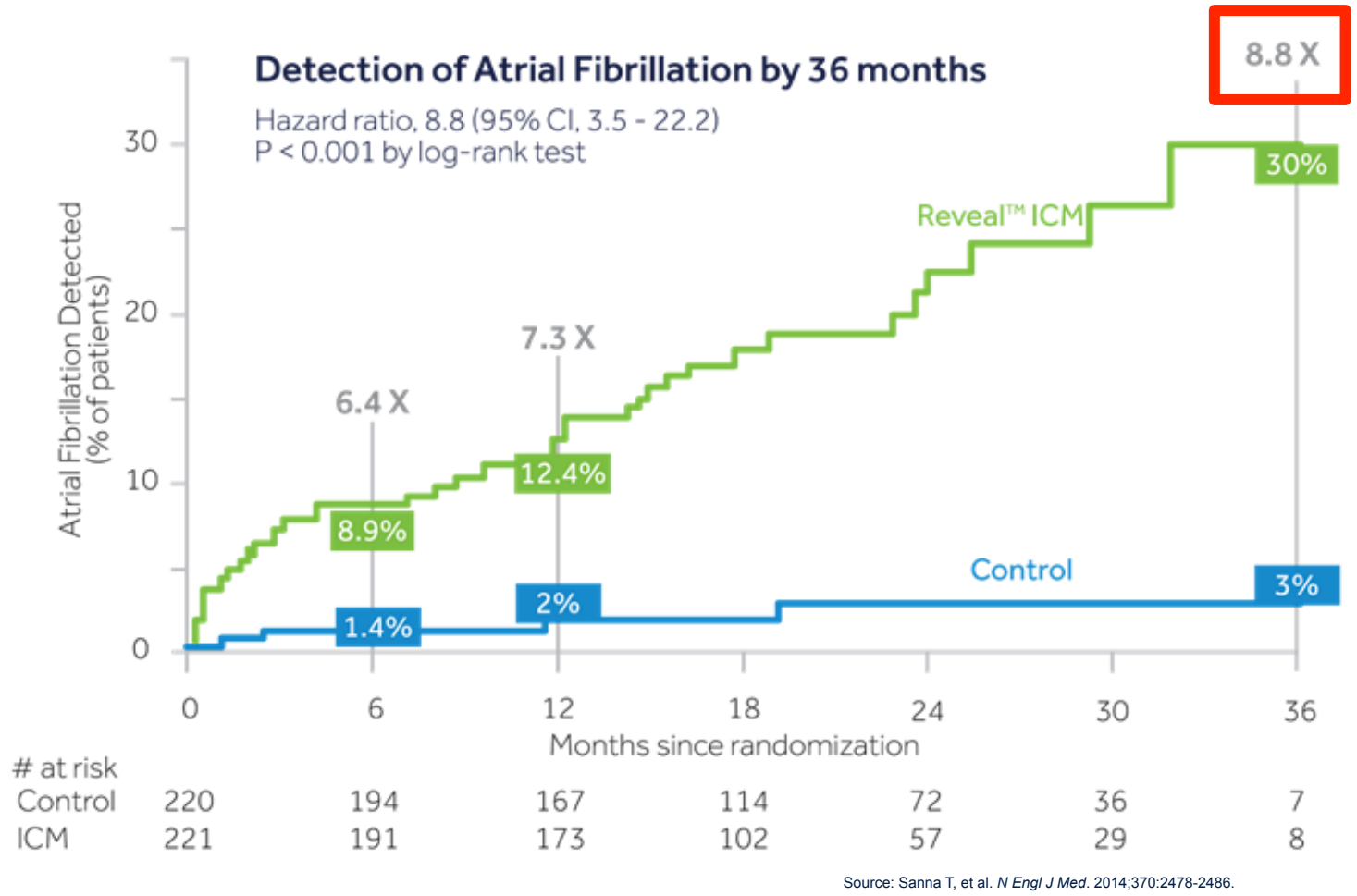
Analyse en intention de traiter (n=220)

RÉSULTATS

441 randomisés

221 groupe Reveal
- 208 dispositifs implantés
- 13 dispositifs non implantés

220 groupe Contrôle
- Prise en charge standard (n =220)



Source: Sanna T, et al. *N Engl J Med*. 2014;370:2478-2486.

CRYSTAL-AF

La surveillance à long terme par le biais d'un MCI est supérieure aux examens standards pour la détection de la FA chez des patients avec antécédents d'AVC.

- A 6 mois (objectif principal), le MCI a permis de détecter 6,4 fois plus de patient avec une FA (HR : 6,4 ; IC à 95% :[1,9 – 21,7] ; p<0,001)
- La surveillance continue détecte 7,3 fois plus de patient présentant de la FA à 12 mois. (HR, 7.3; IC à 95% [2,6 - 20.8]; p<0.001)
- Le monitoring à court-terme n'est pas suffisant, dans la mesure où le temps médian pour détecter la FA sur 12 mois était de 84 jours.
- 97% des patients présentant de la FA ont été placés sous anticoagulants.

Ces résultats sont confirmés à 36 mois depuis la parution des résultats spécifiques dans Circulation :

- La surveillance continue a permis de détecter 8,8 fois plus de patients présentant de la FA à 36 mois (HR : 8,8 ; IC à 95% :[3,5 – 22,2], p<0,001)
- Le monitoring à court-terme n'est pas suffisant, dans la mesure où le temps médian pour détecter la FA sur 36 mois était de 255 jours.
- Un traitement anti-coagulant a été initié pour 90,5% des patients présentant de la FA.

84 JOURS

Temps median de détection de la FA chez les patients avec AVC cryptogéniques

30%

Des patients présentaient une FA après 3 ans de monitorage cardiaque et 12,4% après 1 an

8,8x

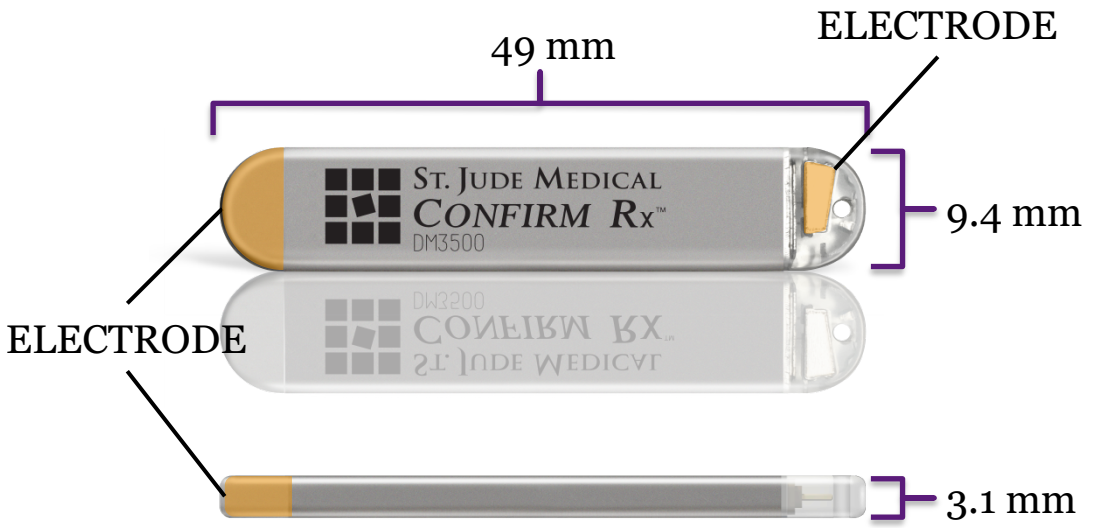
Plus de patient présentant de la FA ont pu être diagnostiqués à 36mois

Surveillance par télécardiologie: Carelink*

Confirm RX et connectivité

La connectivité

CONFIRM Rx

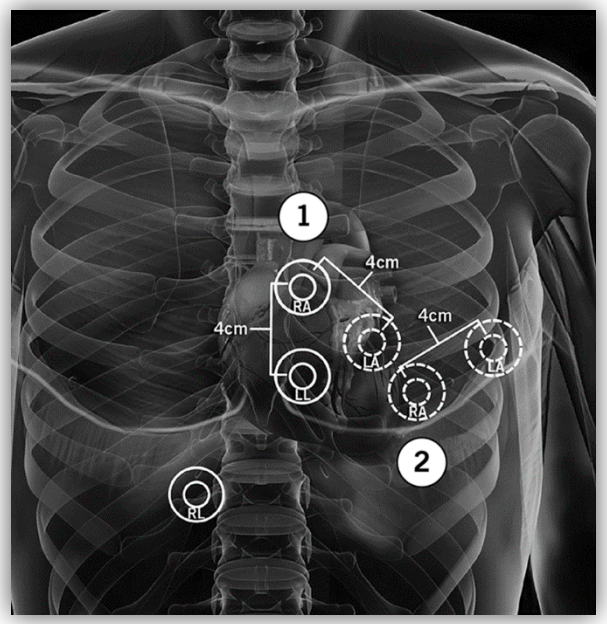


	SJM Confirm Rx
Anchoring	No active fixation. Customer feedback that device migration is not a major concern due to quick fibrosis post implant
Algorithms	94% Sensitivity, 59.1% PPV (from SJM Confirm)
EGM Storage	60 min total – up to 14 min pre trigger storage
Clinical Data and Results	DETECT-AF

LOCALISATION

Insertion sous la peau, dans la région pectorale gauche

Localisation	Mapping Recommandé
4ème espace intercostal, angle de 45° par rapport au sternum, le long de l'axe du coeur	Non
4ème espace intercostal, parallèle au sternum	Non
Antérolatéral, inframammaire entre la 5ème et la 6ème côte	Oui



Un objet du quotidien assure le monitoring

AVEC
L'APPLICATION
PATIENT
myMerlin™ :

Plus d'activateur

s de transmetteur encombrant

RIO 2

In-office insertion of a miniaturized insertable cardiac monitor: Results from the Reveal LINQ In-Office 2 randomized study

John D. Rogers, MD,[*] Prashanthan Sanders, MBBS, PhD, FHRS,[†‡] Christopher Piorkowski, MD, PhD,[‡‡] M. Rizwan Sohail, MD,[§] Rishi Anand, MD,[‖] Karl Crossen, MD,[¶] Farhat S. Khairallah, MD,[#] Rachelle E. Kaplon, PhD,[**] Kurt Stromberg, MS,[**] Robert C. Kowal, MD, PhD, FHRS[††]

From the [*]Scripps Green Hospital, La Jolla, California, [†]Centre for Heart Rhythm Disorders, University of Adelaide, Adelaide, Australia, [‡]Department of Cardiology, Royal Adelaide Hospital, Adelaide, Australia, [‡‡]Herzzentrum Dresden- Abteilung für Invasive Elektrophysiologie, Dresden, Germany, [§]Mayo Clinic College of Medicine, Rochester, Minnesota, [‖]Holy Cross Hospital, Fort Lauderdale, Florida, [¶]Cardiology Associates of North Mississippi, Tupelo, Mississippi, [#]Tallahassee Research Institute, Inc., Tallahassee, Florida, [**]Diagnostics, Cardiac Rhythm and Heart Failure, Medtronic, Inc., Mounds View, Minnesota, and [††]Baylor University Medical Center, Dallas, Texas.

BACKGROUND Recent miniaturization of an insertable cardiac monitor (ICM) may make it possible to move device insertion from a hospital to office setting. However, the safety of this strategy is unknown.

OBJECTIVES The primary objective was to compare the safety of inserting the Reveal LINQ ICM in an office vs a hospital environment. Ancillary objectives included summarizing device- and procedure-related adverse events and responses to a physician questionnaire.

METHODS Five hundred twenty-one patients indicated for an ICM were randomized (1:1 ratio) to undergo ICM insertion in a hospital or office environment at 26 centers in the United States in the Reveal LINQ In-Office 2 study (ClinicalTrials.gov identifier NCT02395536). Patients were followed for 90 days.

RESULTS ICM insertion was successful in all 482 attempted patients (office: 251; hospital: 231). The untoward event rate (composite of unsuccessful insertion and ICM- or insertion-related complications) was 0.8% (2 of 244) in the office and 0.9% (2 of 227) in the hospital (95% confidence interval, −3.0% to 2.9%; 5% noninferiority: $P < .001$). In addition, adverse events occurred during 2.5% (6 of 244) of office and 4.4% (10 of 227) of hospital insertions (95% confidence interval [office minus inhospital rates], −5.8% to 1.9%; 5% noninferiority: $P < .001$). Physicians indicated that for procedures performed in an office vs a hospital, there were fewer delays >15 minutes (16% vs 35%; $P < .001$) and patient response was more often "very positive." Physicians considered the office location "very convenient" more frequently than the hospital location (85% vs 27%; $P < .001$).

CONCLUSION The safety profile for the insertion of the Reveal LINQ ICM is excellent irrespective of insertion environment. These results may expand site of service options for LINQ insertion.

KEYWORDS Insertable cardiac monitor; Office; Reveal LINQ; Safety; Complication; Adverse event

(Heart Rhythm 2017;14:218–224)

VITAL AF Trial

AHA 2020

Steven Lubitz, M.D., MPH, cardiac electrophysiologist, Massachusetts General Hospital, presented the late-breaking **VITAL-AF Trial** at the 2020 **American Heart Association (AHA)** virtual meeting this week. The study looked at screening for **atrial fibrillation (AF)** in older adults at primary care visits using the AliveCor single-lead electrocardiogram (ECG) device that interfaces with a smartphone or iPad.

VITAL-AF is a pragmatic, population-based trial of a screening program for undiagnosed AF in older at-risk patients within a primary care network.

Le but de cette étude est de savoir si un enregistrement ECG une piste réalisé lors d'une visite en médecine primaire (premier accès généraliste) permet de détecter plus de fibrillation atriale (FA) qu'une prise en charge conventionnelle, chez des patients de plus de 65 ans.

Méthodes

Le dépistage de la FA a utilisé un enregistreur KardiaMobile (AliveCor). Les tracés étaient revus par un cardiologue dans les 7 jours suivant l'acquisition.

Le critère primaire était le nombre de nouvelles FA détectées à 12 mois. Le suivi des patients s'est fait à l'aide du système d'information électronique dans lequel sont renseignées habituellement les données.

L'originalité de cette étude réside dans le fait qu'il s'agit d'une étude pragmatique se déroulant en soins primaires et utilisant les ressources de la médecine clinique conventionnelle, et non celles de la recherche clinique.

Résultats

À partir de 22 centres de soins primaires, 16 ont été randomisés en deux groupes permettant d'inclure 30 722 patients n'ayant pas d'antécédent connu de FA. Le dépistage par ECG monopiste a concerné 15 397 patients, et les 15 325 autres ont été pris en charge de façon conventionnelle.

L'âge moyen était de 74 ans et le score de CHA_2DS_2VASc moyen de 3,4. La plupart des patients avaient un score de $CHA_2DS_2VASc \geq 2$.

Une FA possible a été dépistée par le système KardiaMobile dans 3% des cas. À 12 mois, une nouvelle FA a été retrouvée dans 1,74 % des cas dans le groupe « dépistage » et dans 1,60 % des cas dans l'autre groupe (p=NS).

C'est seulement dans le sous-groupe des patients d'âge >85 ans que la stratégie de dépistage se révèle beaucoup plus rentable que la stratégie conventionnelle, avec un nombre de patients à dépister de 53. Il n'a pas été observé de différence significative en ce qui concerne l'initiation d'un traitement anticoagulant.

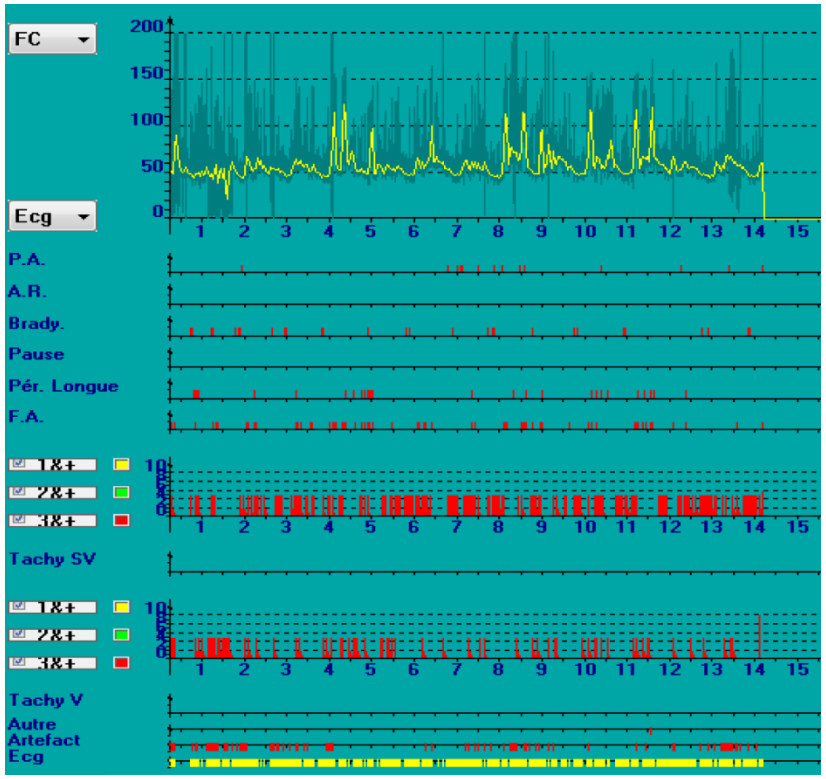
Conclusions

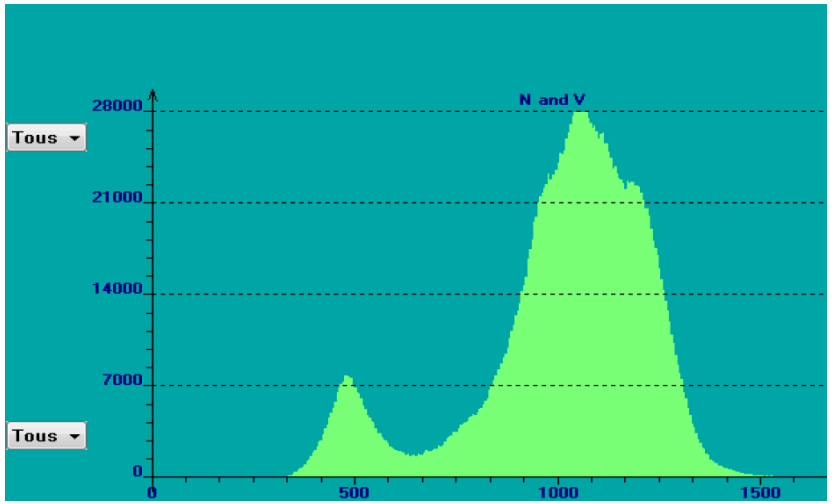
Les auteurs concluent qu'un dépistage pragmatique de la FA par un dispositif réalisant un enregistrement ECG une piste est possible en médecine primaire. C'est dans le sous-groupe patients ayant plus de 85 ans que cette stratégie de dépistage se révèle rentable.

Cas clinique

Loop Recorder externe

Validation de l'efficacité du traitement: Loop recorder externe 2 sem

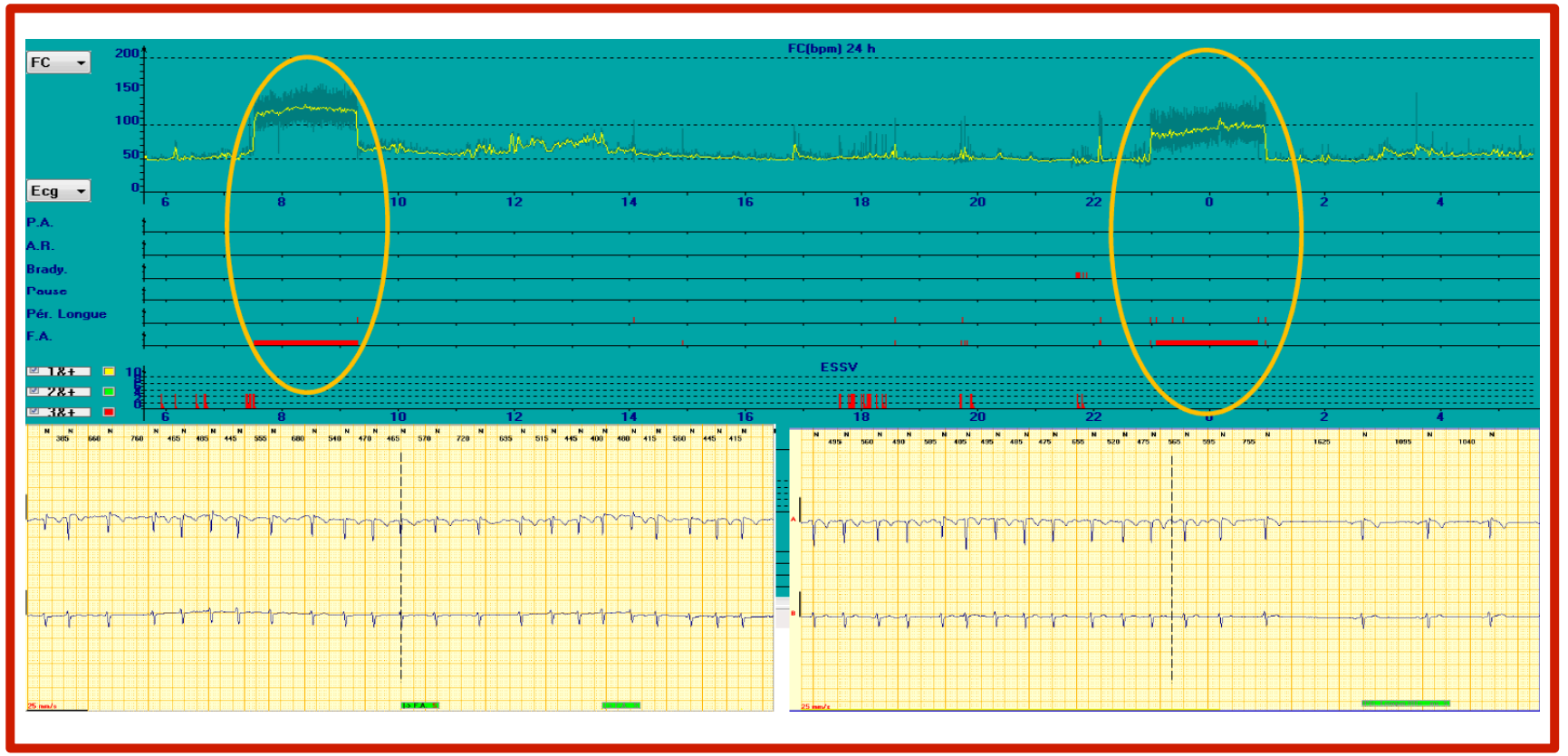




	N	V
Number	1153433	7567
HR (bpm)	58	49
Mean RR (ms)	1023	1212
SD (ms)	45	712

Homme, 62 ans, FAP sous Flécaïnide LP 150 et Rivaroxaban 20 mg/j

Zoom sur J5


FC
Ecg
FC(bpm) 24 h
200
150
100
50
0
6
8
10
12
14
16
18
20
22
0
2
4
P.A.
A.R.
Brady.
Pause
Pér. Longue
F.A.
ESSV
1&+
2&+
3&+
10
0

Collège National des Cardiologues Français

Atrial Fibrillation detection with long Term ECG Recording

Objectif primaire de l'Observatoire

Evaluer l'incidence du dépistage de la FA dans une population à risque de pts

- avec antcd de palpitations
- à l'aide d'un Holter de longue durée continu

Rationnel de l'étude

Le score CHA_2DS_2-VASc permet de stratifier le risque embolique chez un pt qui présente de la FA documentée

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

Rationnel de l'étude

Chaque élément constitutif du score CHA_2DS_2-VASc est aussi fortement et indépendamment associé à la FA

Characteristic/comorbidity	Association with AF
Genetic predisposition (based on multiple common gene variants associated with AF)	HR range 0.4–3.2
Older age 50-59 years 60-69 years 70-79 years 80-89 years	HR: 1.00 (reference) 4.98 (95% CI 3.49–7.10) 7.35 (95% CI 5.28–10.2) 9.33 (95% CI 6.68–13.0)
Hypertension (treated) vs. none	HR 1.32 (95% CI 1.08–1.60)
Heart failure vs. none	HR 1.43 (95% CI 0.85–2.40)
Valvular heart disease vs. none	RR 2.42 (95% CI 1.62–3.60)
Myocardial infarction vs. none	HR 1.46 (95% CI 1.07–1.98)
Thyroid dysfunction Hypothyroidism Subclinical hyperthyroidism Overt hyperthyroidism	(reference: euthyroid) HR 1.23 (95% CI 0.77–1.97) RR 1.31 (95% CI 1.19–1.44) RR 1.42 (95% CI 1.22–1.63)
Obesity (body mass index) None (<25 kg/m²) Overweight (25–30 kg/m²) Obese (≥31 kg/m²)	HR: 1.00 (reference) 1.13 (95% CI 0.87–1.46) 1.37 (95% CI 1.05–1.78)
Diabetes mellitus vs. none	HR 1.25 (95% CI 0.98–1.60)

HR = hazard ratio; RR = risk ratio

Continued on next slide

Characteristic/comorbidity	Association with AF
Chronic obstructive pulmonary disease FEV1 ≥80% FEV1 60–80% FEV1 <60%	RR: 1.00 (reference) 1.28 (95% CI 0.79–2.06) 2.53 (95% CI 1.45–4.42)
Obstructive sleep apnoea vs. none	HR 2.18 (95% CI 1.34–3.54)
Chronic kidney disease None Stage 1 or 2 Stage 3 Stage 4 or 5	OR: 1.00 (reference) 2.67 (95% CI 2.04–3.48) 1.68 (95% CI 1.26–2.24) 3.52 (95% CI 1.73–7.15)
Smoking Never Former Current	HR: 1.00 (reference) 1.32 (95% CI 1.10–1.57) 2.05 (95% CI 1.71–2.47)
Alcohol consumption None 1– 6 drinks/week 7–14 drinks/week 15–21 drinks/week >21 drinks/week	RR: 1.00 (reference) 1.01 (95% CI 0.94–1.09) 1.07 (95% CI 0.98–1.17) 1.14 (95% CI 1.01–1.28) 1.39 (95% CI 1.22–1.58)
Habitual vigorous exercise Non-exercisers <1 day/week 1–2 days/week 3–4 days/week 5–7 days/week	RR: 1.00 (reference) 0.90 (95% CI 0.68–1.20) 1.09 (95% CI 0.95–1.26) 1.04 (95% CI 0.91–1.19) 1.20 (95% CI 1.02–1.41)

Le « CHA2DS2-VASc virtuel »

Utiliser le score CHA_2DS_2-VASc, ci-après désigné score « CHA_2DS_2-VASc virtuel » afin de dépister précocement la FA

- dans une population de patients ciblés
- en consultation de cardiologie de ville
- sans FA documentée

Critères d'inclusion

Score de « CHA2DS2-VASc virtuel »

>= 3 chez la femme

>= 2 chez l'homme

Antcd de palpitations

Pas FA documentée

Critères d'exclusion

Antécédent de FA / flutter

Antcd AVC / AIT de moins de 3 mois

Pt porteur d'une stimulateur cardiaque

Pt sous anticoagulants pour une cause rythmologique

Pt incapable de gérer l'enregistrement du Holter

Age < 18 ans

Design de l'étude

Observatoire

- simple information du pt

Durée de l'étude : 1 an

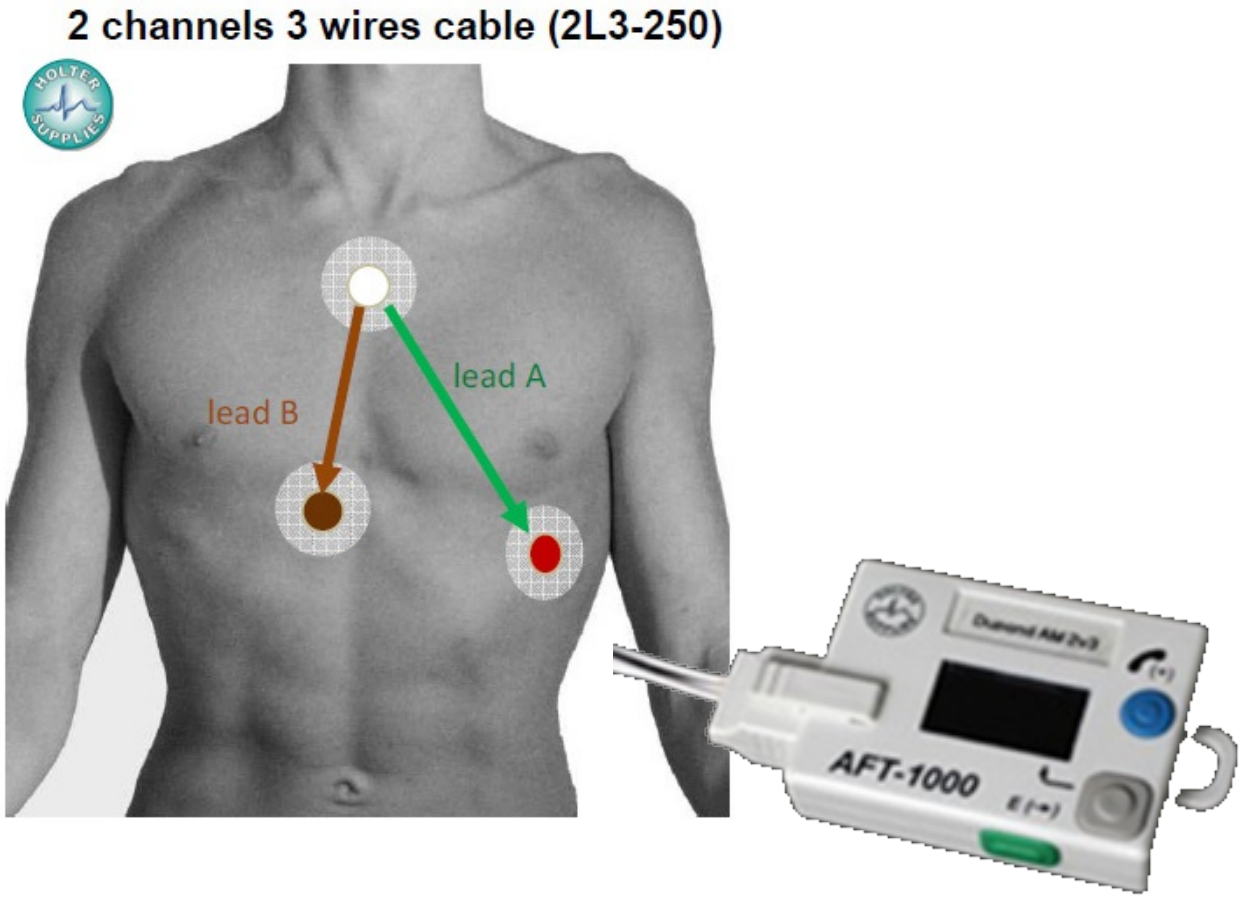
Cardiologues adhérents au CNCF

Un centre de lecture unique

Echantillon statistique significatif fixé à 500 enregistrements Holter analysables

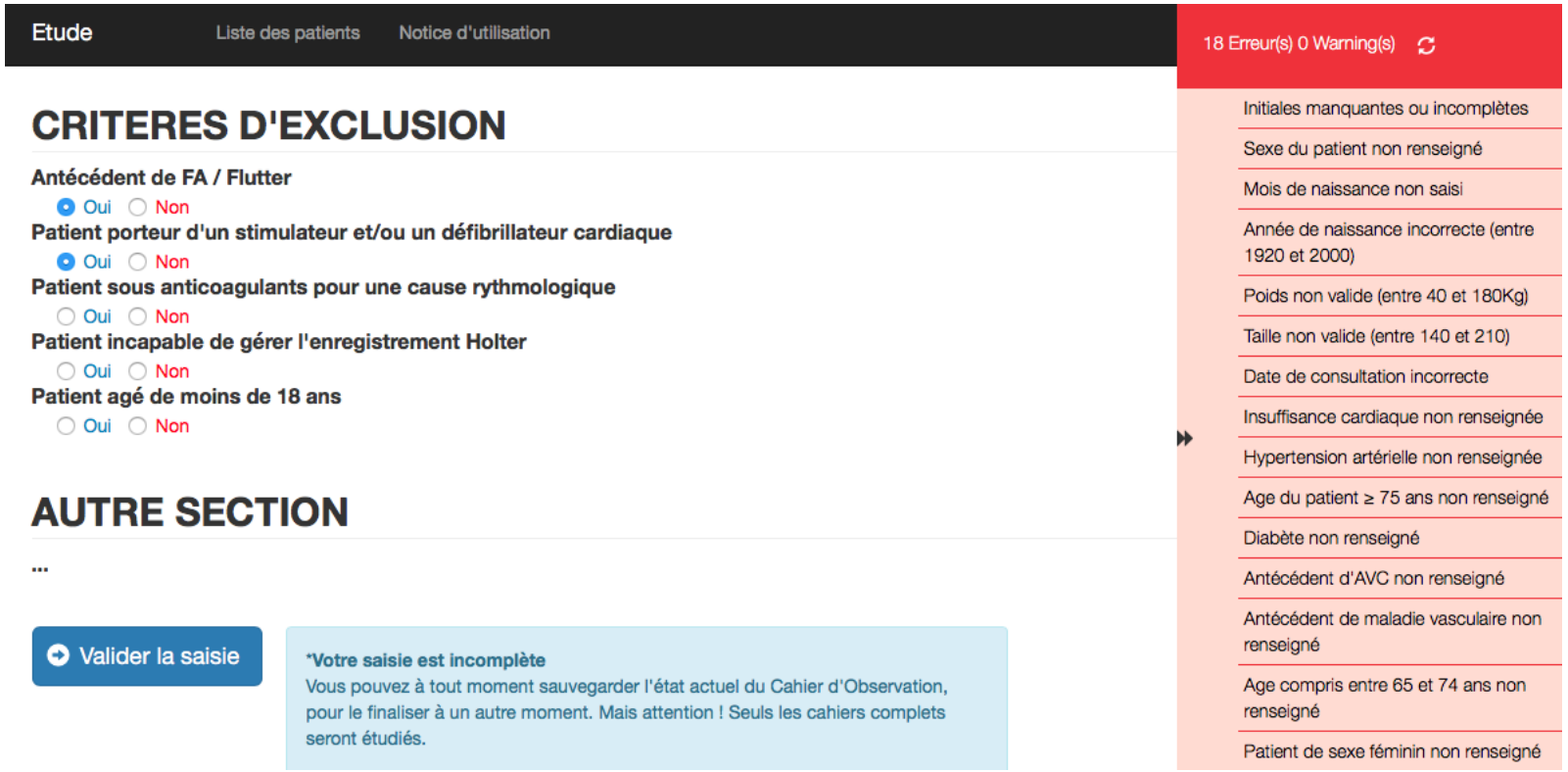
Holter de longue durée

Holter continu externe 14j



Cahier d'observation électronique (eCRF)

Mise en œuvre du contrôle de cohérence



Cahier d'observation électronique (eCRF)

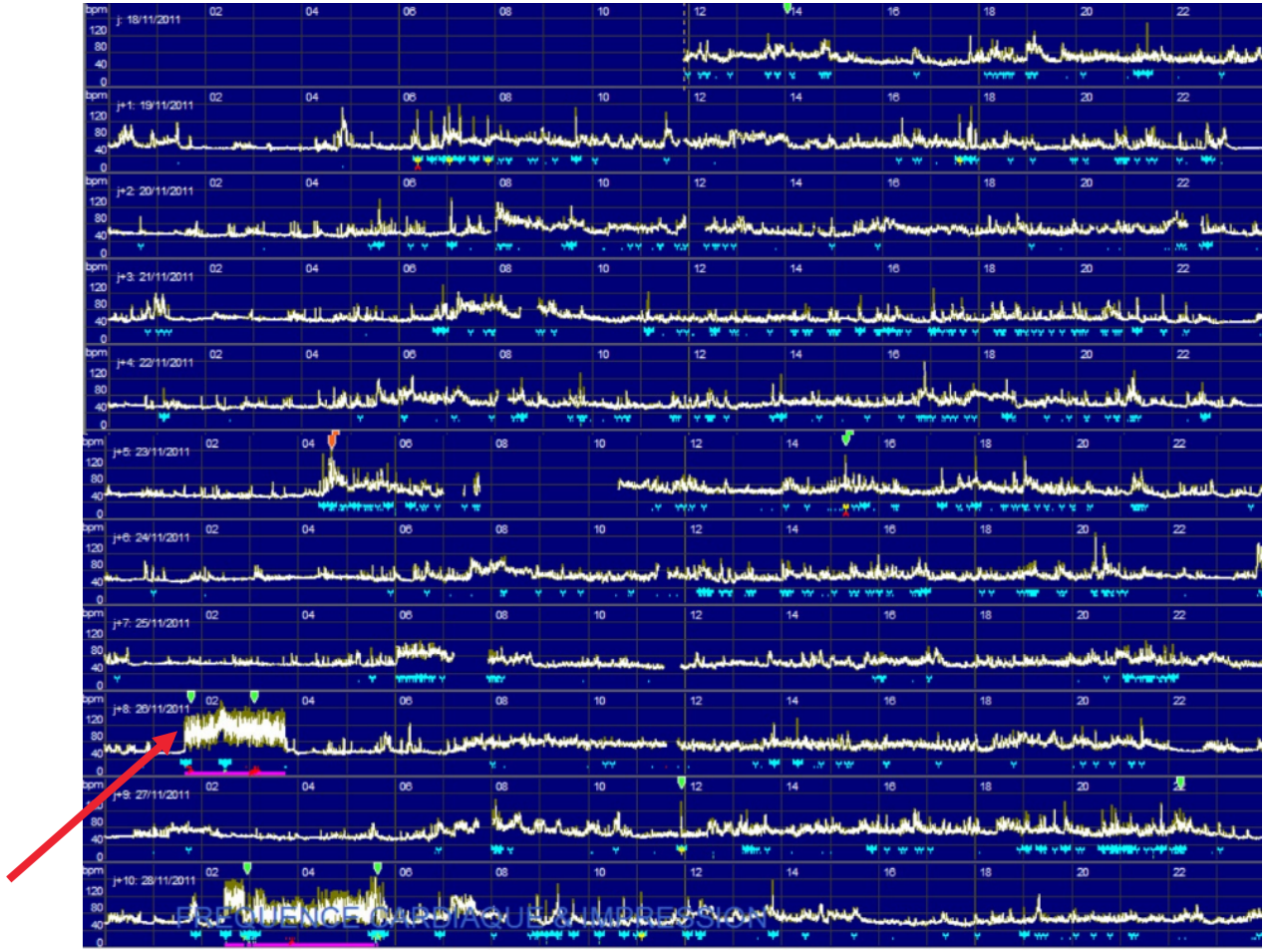
Lors du retour du Holter, les données seront transmises par internet de manière anonymisée au centre de lecture

Le centre de lecture renverra le rapport Holter

- au cardiologue en charge du pt
- exportation des données au centre d'analyse statistique

Holter de longue durée

Détection d'une FA à J9




cm/mV
N
M
<<
>>
Sélect.TOUS
<<x10
10x>>
Majeurs
Dur
N 300 N 370 N 410 N 346 N 294 N 388 N 296 N 298 N 328 N 524 N 336 N 360 N 304 N 312 N 302 N 268 N 392 N 306 N 282 N 394 N 276 N 300 N 264 N 266 N 334
RR irreg. début
FC=183.2 bpm (Min /2RR = 139.5 / Max /2RR = 226.4)
13:58:46 23/12/2020
FC=238 Tachycardie <4> 00:00:32 FC Max = 238bpm
13:55:17 23/12/2020
FC=160 Bigéminisme SV début
13:55:24 23/12/2020
FC=177 RR irreg. début
13:58:45 23/12/2020
FC=86 Période Longue RR=1326
14:38:33 26/12/2020
FC=68 ESSV
17:21:58 30/12/2020
FC=68 Salves SV8 RRMin=394ms (152bpm)
18:58:09 01/01/2021
FC Minimum = 50bpm
09:52:46 02/01/2021
FC=75 ESSV
17:29:02 02/01/2021
FC=102 Période Longue RR=1212
05:34:09 03/01/2021
FC Maximum = 238bpm
11:30:35 04/01/2021
FREQUENCE CARDIAQUE & IMPRESSION

Statistiques

Cabinet spécialisé

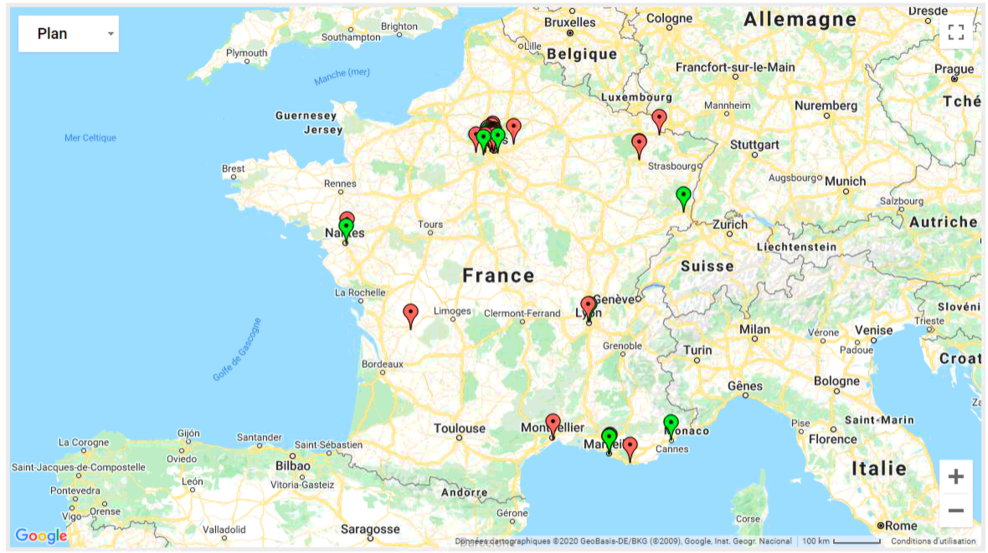
- INSERM Biostat Lariboisière

Caractéristiques de la population

- Antécédents
- Traitements en cours
- Comorbidités…

Objectif principal / secondaire +++

Carte des investigateurs



11% de détection de FA à ce jour!

Courbe d'inclusions

220 pts

Devenir de l'étude

Amélioration de nos pratiques

- Dépistage précoce de la FA

Promotion de la technique du Holter de longue durée externe

Présentation des résultats lors de congrès

Publication scientifique …

AFFIRM Study

The New England
Journal of Medicine

VOLUME 347 DECEMBER 5, 2002 NUMBER 23

A COMPARISON OF RATE CONTROL AND RHYTHM CONTROL IN PATIENTS WITH ATRIAL FIBRILLATION

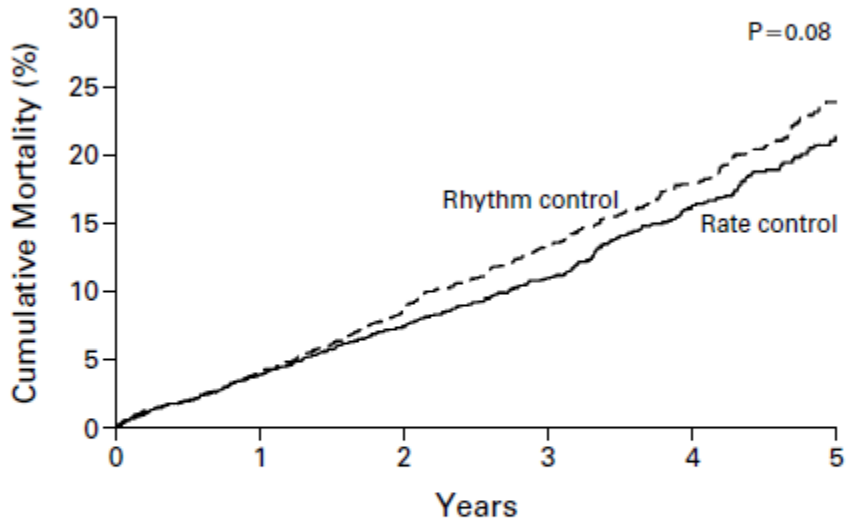
THE ATRIAL FIBRILLATION FOLLOW-UP INVESTIGATION OF RHYTHM MANAGEMENT (AFFIRM) INVESTIGATORS*

TABLE 2. DRUGS USED IN THE RATE-CONTROL GROUP AND THE RHYTHM-CONTROL GROUP.*

DRUG	RATE-CONTROL GROUP		RHYTHM-CONTROL GROUP	
	USED DRUG FOR INITIAL THERAPY	USED DRUG AT ANY TIME	USED DRUG FOR INITIAL THERAPY	USED DRUG AT ANY TIME
	no. of patients (%)			
Rate control				
Data available	1957	2027	1266	2033
Digoxin	949 (48.5)	1432 (70.6)	417 (32.9)	1106 (54.4)
Beta-blocker	915 (46.8)	1380 (68.1)	276 (21.8)	1008 (49.6)
Diltiazem	583 (29.8)	935 (46.1)	198 (15.6)	610 (30.0)
Verapamil	187 (9.6)	340 (16.8)	56 (4.4)	204 (10.0)
Rhythm control				
Data available	1265	2027	1960	2033
Amiodarone	2 (0.2)†	207 (10.2)	735 (37.5)	1277 (62.8)
Sotalol	1 (0.1)†	84 (4.1)	612 (31.2)	841 (41.4)
Propafenone	2 (0.2)†	45 (2.2)	183 (9.3)	294 (14.5)
Procainamide	0	30 (1.5)	103 (5.3)	173 (8.5)
Quinidine	2 (0.2)†	14 (0.7)	92 (4.7)	151 (7.4)
Flecainide	0	29 (1.4)	88 (4.5)	169 (8.3)
Disopyramide	0	7 (0.3)	42 (2.1)	87 (4.3)
Moricizine	0	2 (0.1)	14 (0.7)	35 (1.7)
Dofetilide	0	5 (0.2)	0	13 (0.6)

*Because of changes in the data forms during the study, information on initial therapy was not recorded for some patients; the denominators therefore vary. Percentages do not total 100 because more than one drug could have been tried at the beginning of treatment and because combination therapies were allowed.

†These patients immediately crossed over to the rhythm-control group, a crossover considered to be a protocol violation.



No. of Deaths						
	number (percent)					
Rhythm control	0	80 (4)	175 (9)	257 (13)	314 (18)	352 (24)
Rate control	0	78 (4)	148 (7)	210 (11)	275 (16)	306 (21)

Figure 1. Cumulative Mortality from Any Cause in the Rhythm-Control Group and the Rate-Control Group.

Time zero is the day of randomization. Data have been truncated at five years.

TABLE 3. ADVERSE EVENTS.*

EVENT	OVERALL (N=4060)	RATE-CONTROL GROUP (N=2027)	RHYTHM-CONTROL GROUP (N=2033)	P VALUE
		no. of patients (%)		
Primary end point (death)	666 (26.3)	310 (25.9)	356 (26.7)	0.08†
Secondary end point (composite of death, disabling stroke, disabling anoxic encephalopathy, major bleeding, and cardiac arrest)	861 (32.3)	416 (32.7)	445 (32.0)	0.33
Torsade de pointes	14 (0.5)	2 (0.2)‡	12 (0.8)	0.007
Sustained ventricular tachycardia	15 (0.6)	9 (0.7)	6 (0.6)	0.44
Cardiac arrest followed by resuscitation				
Ventricular fibrillation or ventricular tachycardia	19 (0.6)	10 (0.7)	9 (0.5)	0.83
Pulseless electrical activity, bradycardia, or other rhythm	10 (0.3)	1 (<0.1)	9 (0.6)	0.01
Central nervous system event				
Total	211 (8.2)	105 (7.4)	106 (8.9)	0.93
Ischemic stroke§	157 (6.3)	77 (5.5)	80 (7.1)	0.79
After discontinuation of warfarin	69	25	44	
During warfarin but with INR <2.0	44	27	17	
Concurrent atrial fibrillation	67	42	25	
Primary intracerebral hemorrhage	34 (1.2)	18 (1.1)	16 (1.3)	0.73
Subdural or subarachnoid hemorrhage	24 (0.8)	11 (0.8)	13 (0.8)	0.68
Disabling anoxic encephalopathy	9 (0.3)	4 (0.2)	5 (0.4)	0.74
Myocardial infarction	140 (5.5)	67 (4.9)	73 (6.1)	0.60
Hemorrhage not involving the central nervous system	203 (7.3)	107 (7.7)	96 (6.9)	0.44
Systemic embolism	16 (0.5)	9 (0.5)	7 (0.4)	0.62
Pulmonary embolism	8 (0.3)	2 (0.1)	6 (0.5)	0.16
Hospitalization after base line	2594 (76.6)	1220 (73.0)	1374 (80.1)	<0.001

*Percentages were derived from a Kaplan–Meier analysis. P values were derived from the log-rank statistic.

†The P value in the case of death was based on the square root of the log-rank statistic, adjusted for 10 interim monitoring analyses.

‡One patient had crossed over to the rhythm-control group and was taking quinidine, and one patient had torsade de pointes 72 hours after mitral-valve replacement.

§Information on warfarin therapy was missing for two patients in the rate-control group and three patients in the rhythm-control group. Information on the presence of atrial fibrillation with the event was missing for 16 patients in the rate-control group and 13 patients in the rhythm-control group.

CABANA

Etude CABANA

Une des plus grandes études sur l'ablation de FA

Objectif: Montrer la supériorité de l'ablation comparée au traitement médicamenteux dans la prise en charge de la FA

>2200 patients
>126 centres dans le monde

- → 81 aux USA
- → 15 en Allemagne
- → 5 au Royaume-Uni
- → 5 en Chine
- → 4 en Russie
- → 4 en Italie
- → 4 au Canada
- → 4 en République Tchèque
- → 2 en Corée du Sud
- → 2 en Australie

Inclusion à partir de 2009

FA paroxystique et FA persistante

Tous les patients ont été randomisés

ABLATION PAR CATHETER

N= 1108

VS

TRAITEMENT MÉDICAMENTEUX

N= 1096

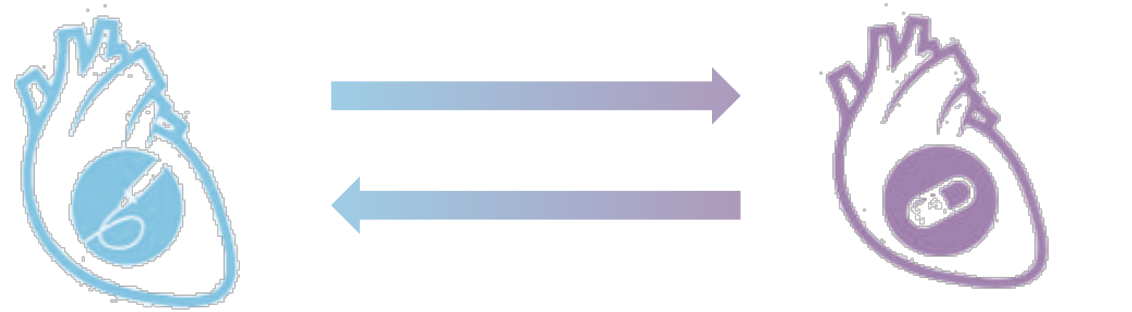
CRITÈRES D'INCLUSION

- Les patients devaient avoir un âge d'au moins 65 ans ou, si <65 ans, avoir au moins un facteur de risque thrombo-embolique
- Tous étaient éligibles pour recevoir, soit un traitement médicamenteux soit une ablation
- Le suivi a duré 5 ans

L'analyse statistique se fait en intention de traiter

34. Catheter Ablation vs. Antiarrhythmic Drug Therapy for Atrial Fibrillation: The Results of The Cabana Multicenter International Randomized Clinical Trial – HRS 2018 Late breaking clinical trials

Etude CABANA - Existence de Cross-Overs



ABLATION PAR CATHETER
N= 1108

TRAITEMENT MÉDICAMENTEUX
N= 1096

Les résultats de l'étude ont été affectés par des cross-overs entre les 2 groupes.

- 27,5% des patients du groupe traitement médicamenteux ont eu une ablation au cours du suivi
- 9,2% des patients du groupe ablation n'ont pas été ablatés

Etude CABANA - Résultats

L'objectif de l'analyse en intention de traiter (ITT) n'a pas été atteint

MAIS Les résultats sont très positifs:

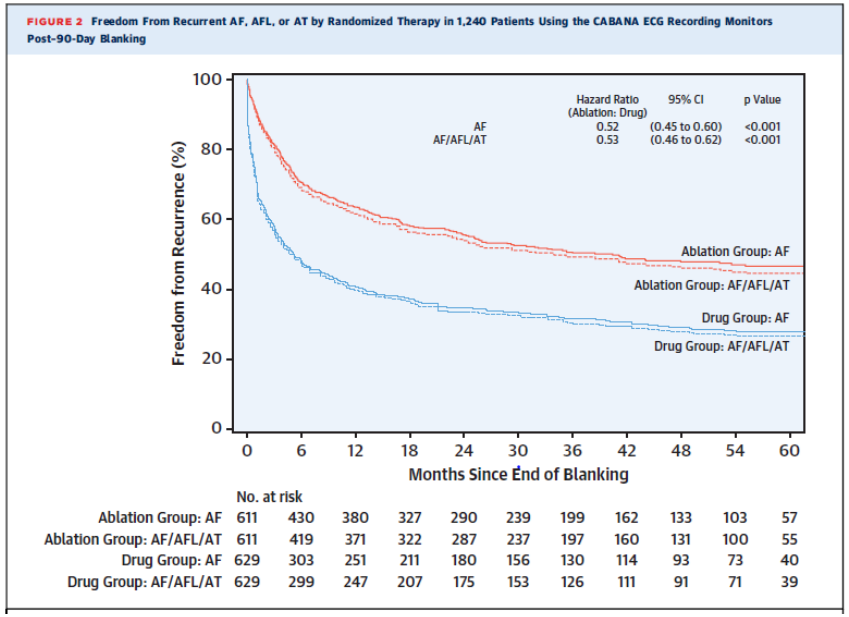
47% de diminution de récurrence de FA avec le traitement par ablation (en ITT)

40% de diminution du risque de décès chez les patients réellement traités

Bénéfices accrus pour les patients avec:

Âge < 65 ans: réduction du risque de décès de **48%**

Antécédents d'IC: réduction du risque de décès de **39%**



Recurrence of Atrial Fibrillation After Catheter Ablation or Antiarrhythmic Drug Therapy in the CABANA Trial

Jeanne E. Poole, MD,[a] Tristram D. Bahnson, MD,[b] Kristi H. Monahan, RN,[c] George Johnson, BSEE,[d] Hoss Rostami, BSMSE,[b] Adam P. Silverstein, MS,[b] Hussein R. Al-Khalidi, PhD,[b] Yves Rosenberg, MD, MPH,[e] Daniel B. Mark, MD, MPH,[b] Kerry L. Lee, PhD,[b] Douglas L. Packer, MD,[c] for the CABANA Investigators and ECG Rhythm Core Lab

EAST AF NET 4

ESC 2020

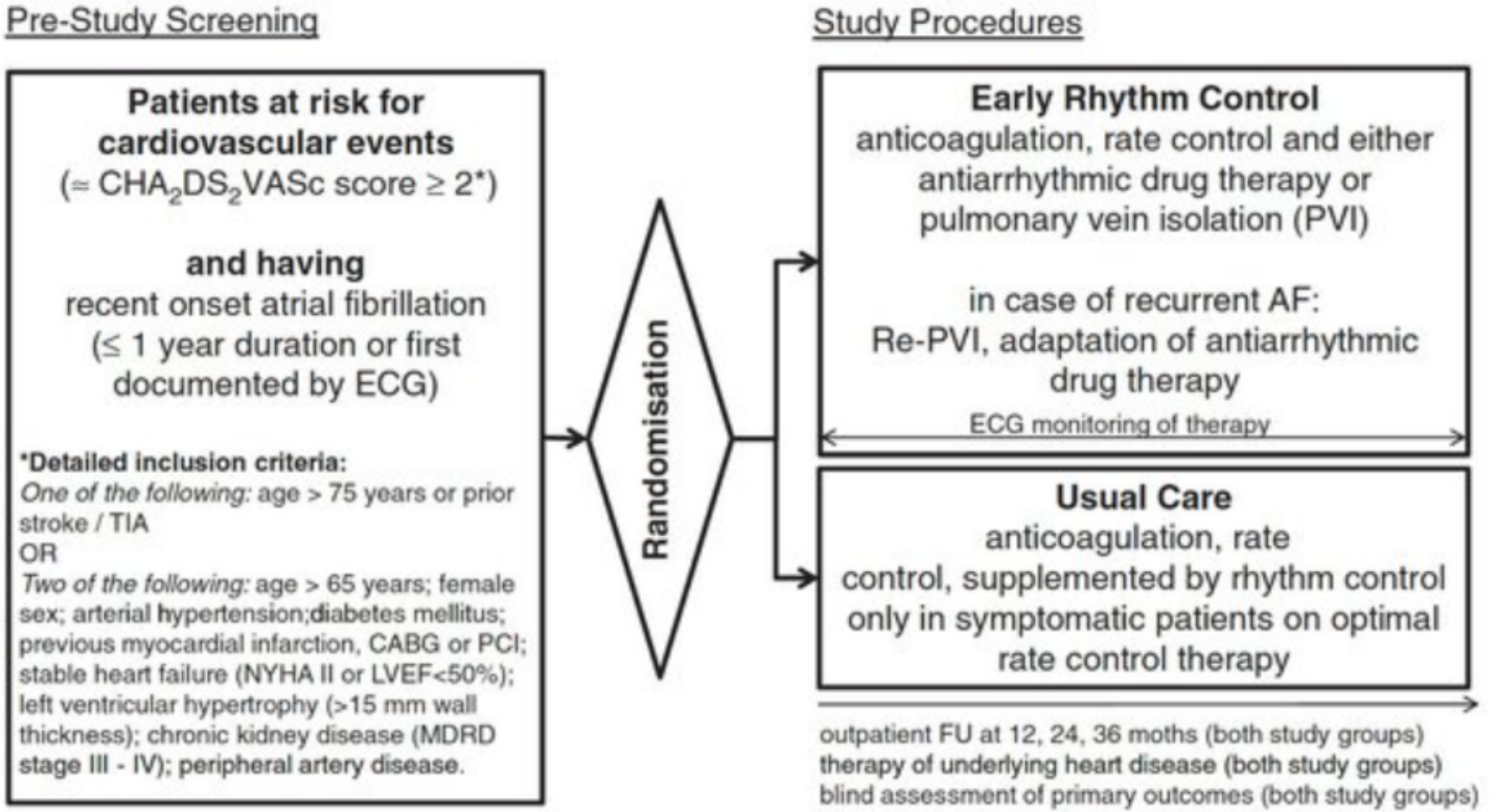
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 1, 2020 VOL. 383 NO. 14

Early Rhythm-Control Therapy in Patients with Atrial Fibrillation

P. Kirchhof, A.J. Camm, A. Goette, A. Brandes, L. Eckardt, A. Elvan, T. Fetsch, I.C. van Gelder, D. Haase, L.M. Haegeli, F. Hamann, H. Heidbüchel, G. Hindricks, J. Kautzner, K.-H. Kuck, L. Mont, G.A. Ng, J. Rekosz, N. Schoen, U. Schotten, A. Suling, J. Taggeselle, S. Themistoclakis, E. Vettorazzi, P. Vardas, K. Wegscheider, S. Willems, H.J.G.M. Crijns, and G. Breithardt, for the EAST-AFNET 4 Trial Investigators*

EAST AF NET 4


Pre-Study Screening
Patients at risk for cardiovascular events
(≈ CHA2DS2VASc score ≥ 2*)
and having
recent onset atrial fibrillation
(≤ 1 year duration or first documented by ECG)
*Detailed inclusion criteria:
One of the following: age > 75 years or prior stroke / TIA
OR
Two of the following: age > 65 years; female sex; arterial hypertension;diabetes mellitus; previous myocardial infarction, CABG or PCI; stable heart failure (NYHA II or LVEF<50%); left ventricular hypertrophy (>15 mm wall thickness); chronic kidney disease (MDRD stage III - IV); peripheral artery disease.
Randomisation
Study Procedures
Early Rhythm Control
anticoagulation, rate control and either antiarrhythmic drug therapy or pulmonary vein isolation (PVI)
in case of recurrent AF:
Re-PVI, adaptation of antiarrhythmic drug therapy
ECG monitoring of therapy
Usual Care
anticoagulation, rate control, supplemented by rhythm control only in symptomatic patients on optimal rate control therapy
outpatient FU at 12, 24, 36 moths (both study groups)
therapy of underlying heart disease (both study groups)
blind assessment of primary outcomes (both study groups)

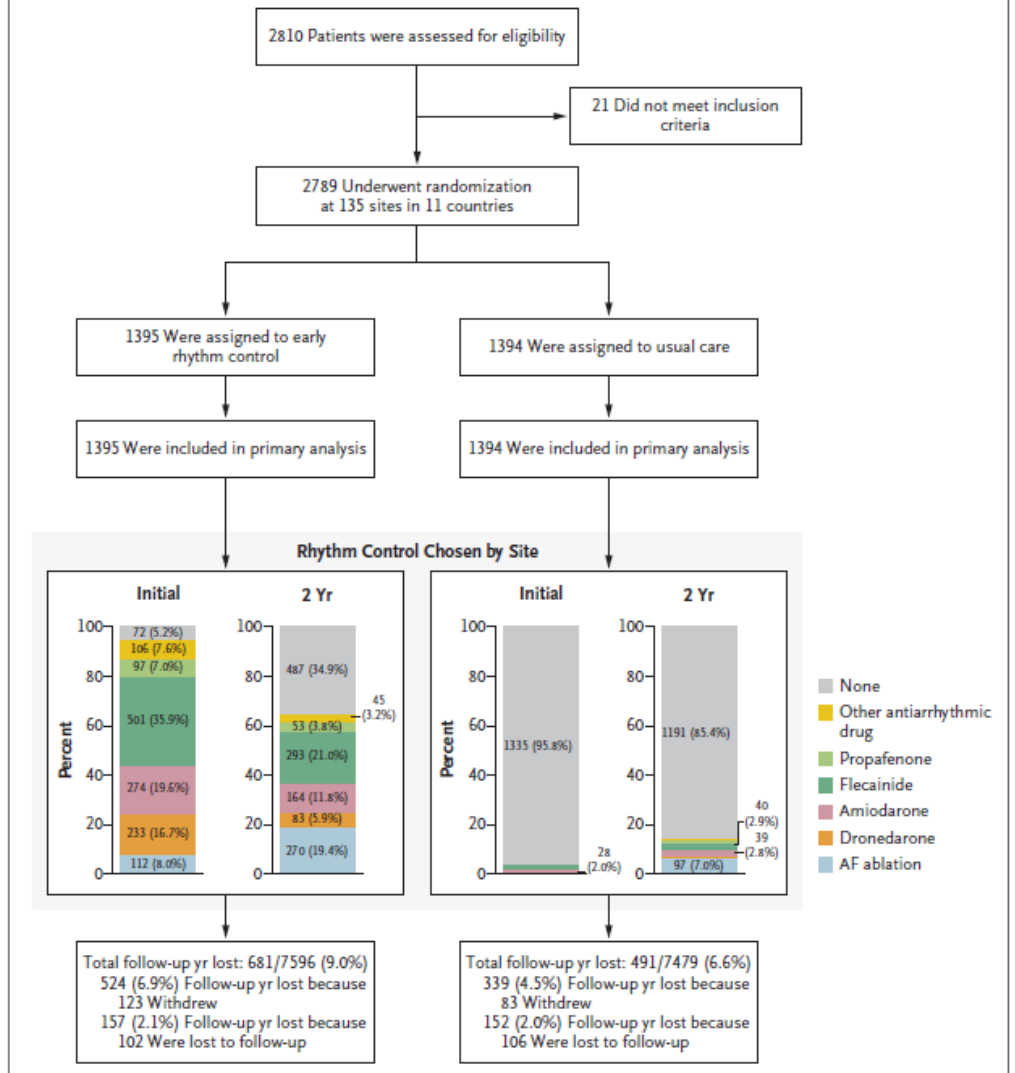


Figure 1. Screening, Randomization, Treatment, and Follow-up.

Most of the patients assigned to early rhythm-control therapy were initially treated with antiarrhythmic drugs, often flecainide. After 2 years of follow-up, 908 of the patients (65.1%) who had been randomly assigned to early rhythm-control therapy were still receiving active rhythm-control therapy (270 patients treated with atrial fibrillation [AF] ablation and 638 treated with antiarrhythmic drugs), and only 203 patients (14.6%) who had been randomly assigned to usual care were receiving rhythm-control therapy (97 treated with AF ablation and 106 treated with antiarrhythmic drugs). All patients who underwent randomization were included in the primary analysis.

Table 2. Efficacy Outcomes.*

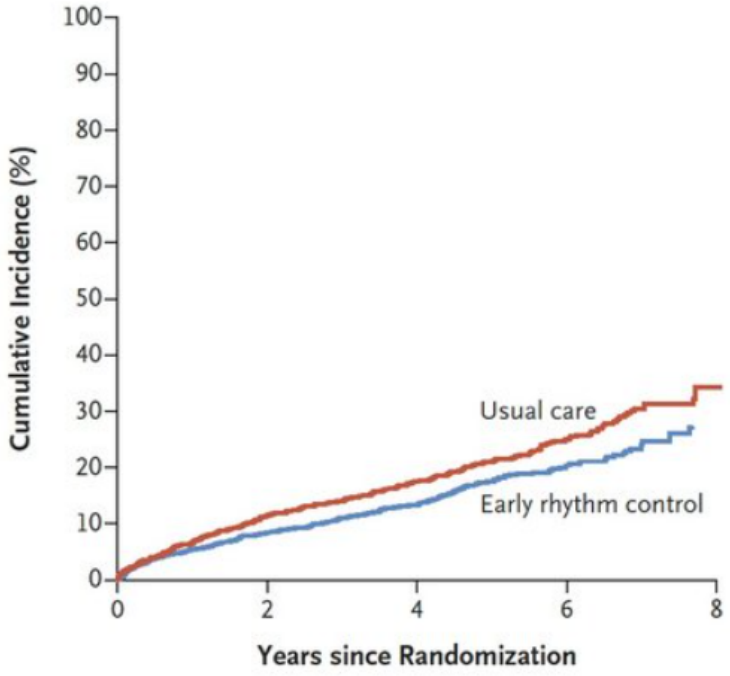
Outcome	Early Rhythm Control	Usual Care	Treatment Effect
First primary outcome — events/person-yr (incidence/100 person-yr)	249/6399 (3.9)	316/6332 (5.0)	0.79 (0.66 to 0.94)†
Components of first primary outcome — events/person-yr (incidence/100 person-yr)			
Death from cardiovascular causes	67/6915 (1.0)	94/6988 (1.3)	0.72 (0.52 to 0.98)‡
Stroke	40/6813 (0.6)	62/6856 (0.9)	0.65 (0.44 to 0.97)‡
Hospitalization with worsening of heart failure	139/6620 (2.1)	169/6558 (2.6)	0.81 (0.65 to 1.02)‡
Hospitalization with acute coronary syndrome	53/6762 (0.8)	65/6816 (1.0)	0.83 (0.58 to 1.19)‡
Second primary outcome — nights spent in hospital/yr	5.8±21.9	5.1±15.5	1.08 (0.92 to 1.28)§
Key secondary outcomes at 2 yr			
Change in left ventricular ejection fraction — %	1.5±9.8	0.8±9.8	0.23 (−0.46 to 0.91)¶
Change in EQ-5D score‖	−1.0±21.4	−2.7±22.3	1.07 (−0.68 to 2.82)¶
Change in SF-12 Mental Score**	0.7±10.6	1.6±10.1	−1.20 (−2.04 to −0.37)¶
Change in SF-12 Physical Score**	0.3±8.5	0.1±8.2	0.33 (−0.39 to 1.06)¶
Change in MoCA score	0.1±3.3	0.1±3.2	−0.14 (−0.39 to 0.12)¶
Sinus rhythm — no. of patients with feature/total no. (%)	921/1122 (82.1)	687/1135 (60.5)	3.13 (2.55 to 3.84)††
Asymptomatic — no. of patients with feature/total no. (%)‡‡	861/1159 (74.3)	850/1171 (72.6)	1.14 (0.93 to 1.40)††

Table 3. Safety Outcomes.*

Outcome	Early Rhythm Control (N=1395)	Usual Care (N=1394)
	number (percent)	
Primary composite safety outcome	231 (16.6)	223 (16.0)
Stroke	40 (2.9)	62 (4.4)
Death	138 (9.9)	164 (11.8)
Serious adverse event of special interest related to rhythm-control therapy	68 (4.9)	19 (1.4)
Serious adverse event related to antiarrhythmic drug therapy		
Nonfatal cardiac arrest	1 (0.1)	1 (0.1)
Toxic effects of atrial fibrillation–related drug therapy	10 (0.7)	3 (0.2)
Drug-induced bradycardia	14 (1.0)	5 (0.4)
Atrioventricular block	2 (0.1)	0
Torsades de pointes tachycardia	1 (0.1)	0
Serious adverse event related to atrial fibrillation ablation		
Pericardial tamponade	3 (0.2)	0
Major bleeding related to atrial fibrillation ablation	6 (0.4)	0
Nonmajor bleeding related to atrial fibrillation ablation	1 (0.1)	2 (0.1)
Other serious adverse event of special interest related to rhythm-control therapy		
Blood pressure–related event†	1 (0.1)	0
Hospitalization for atrial fibrillation	11 (0.8)	3 (0.2)
Other cardiovascular event	5 (0.4)	1 (0.1)
Other event	1 (0.1)	3 (0.2)
Syncope	4 (0.3)	1 (0.1)
Hospitalization for worsening of heart failure with decompensated heart failure	3 (0.2)	0
Implantation of a pacemaker, defibrillator, cardiac resynchronization device, or any other cardiac device	8 (0.6)	4 (0.3)

* Patients could have had more than one event, and therefore the total sum of events is higher than the number of patients with events. For dichotomous outcomes, mixed logistic-regression models with a random effect for site were used for comparison of random groups. Stroke was significantly less frequent (P=0.03) and serious adverse events of special interest significantly more frequent (P<0.001) in the group assigned to early rhythm control; the other safety outcomes did not differ significantly between the groups.
† Blood pressure–related events included hypotension and hypertension (excluding syncope).

EAST AF NET 4



No. at Risk					
Usual care	1394	1169	888	405	34
Early rhythm control	1395	1193	913	404	26

Figure 2. Aalen–Johansen Cumulative-Incidence Curves for the First Primary Outcome.

The first primary outcome was a composite of death from cardiovascular causes, stroke, or hospitalization with worsening of heart failure or acute coronary syndrome.

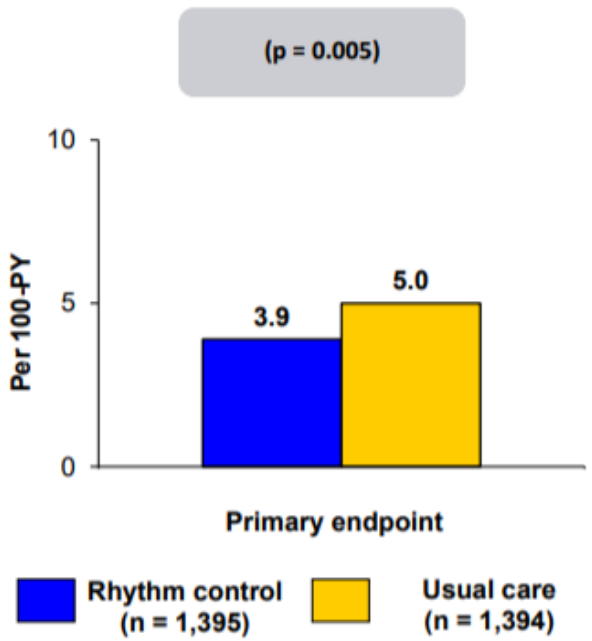
- Prise en charge précoce de la FA < 1 an dans une population à risque d'événement CV
- Importance de l'ablation pour le maintien du RS dans le bras « rhythm control »
- Anticoagulation en fct de la stratification du risque embolique (cf AFFIRM)

EAST-AFNET 4

#ESCCongress

AMERICAN COLLEGE of CARDIOLOGY

Trial Description: Patients with AF diagnosis within 1 year were randomized in a 1:1 fashion to either rhythm control or usual care. Early rhythm control required antiarrhythmic drugs/ablation/cardioversion. Usual care was initially treated with rate control therapy without rhythm control. Patients were followed for 5.1 years.



RESULTS

- Primary outcome, CV death, stroke, hospitalization for HF or ACS, rhythm control vs. usual care: 3.9 vs. 5.0/100 P-Y; HR 0.79, 95% CI 0.66-0.94 (p = 0.005)
- CV death: 1 vs. 1.3/100-PY; HR 0.72, 95% CI 0.52-0.98; stroke: 0.6 vs. 0.9/100-PY; HR 0.65; 95% CI 0.44-0.98; HF hospitalization: 2.1 vs. 2.6/100 P-Y
- Sinus rhythm: 82.1% vs. 60.5% (p < 0.05)

CONCLUSIONS

- A rhythm control strategy is superior to usual care (rate control in the majority of cases) in improving CV outcomes at 5 years among patients with recent diagnosis of AF and concomitant CV conditions; significant reductions were noted for the primary composite endpoint, as well as for CV death and stroke
- Results of this trial are different from other similar trials such as CABANA-AF, AFFIRM, and RACE; differences will need to be further assessed

Kirchhof P, et al. N Engl J Med 2020;383:1305-16

La FA: une prise en charge d'équipe

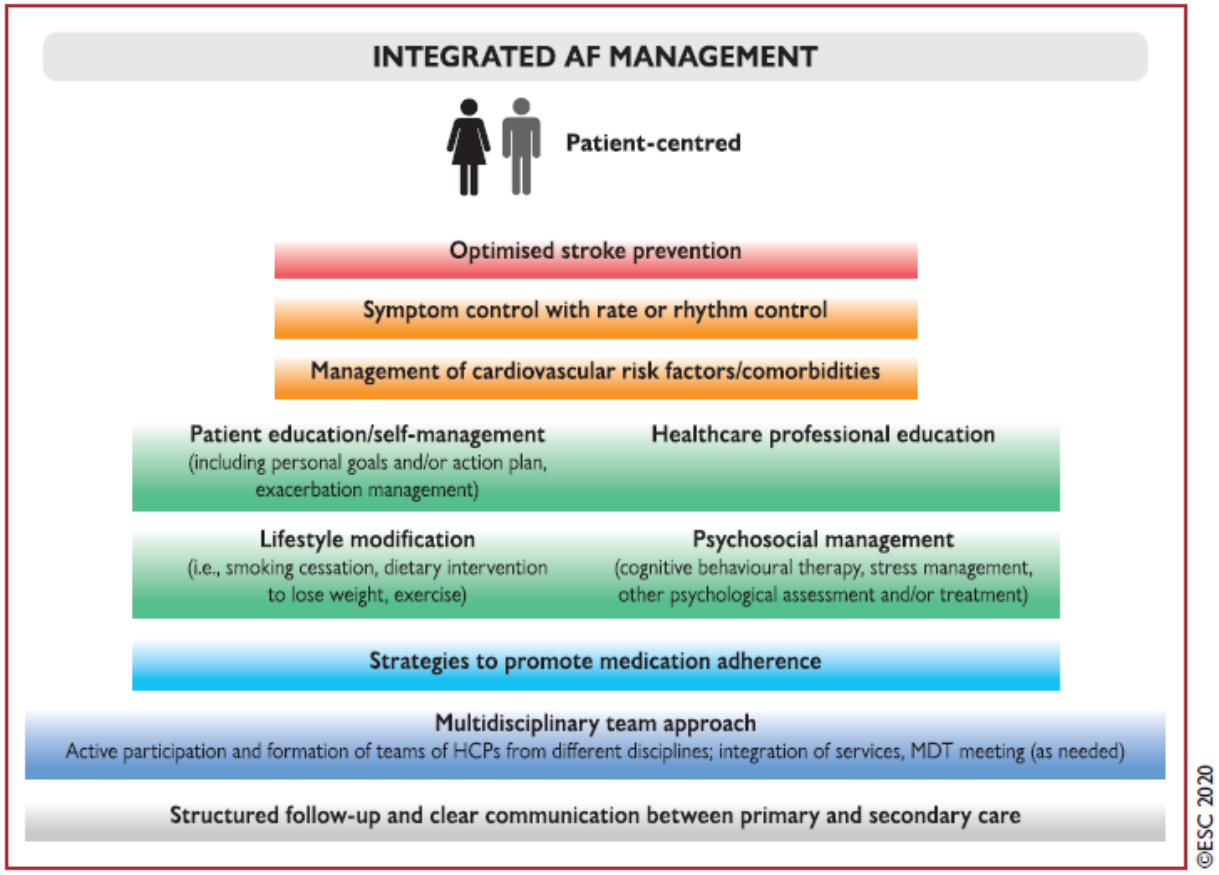
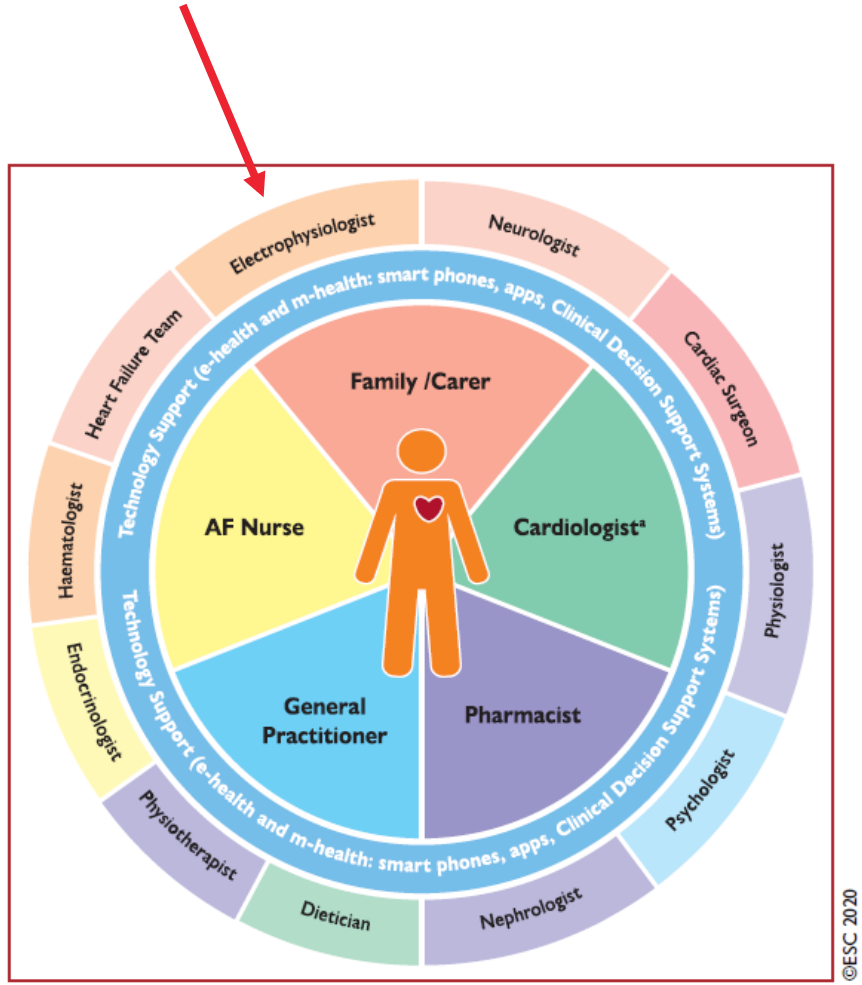
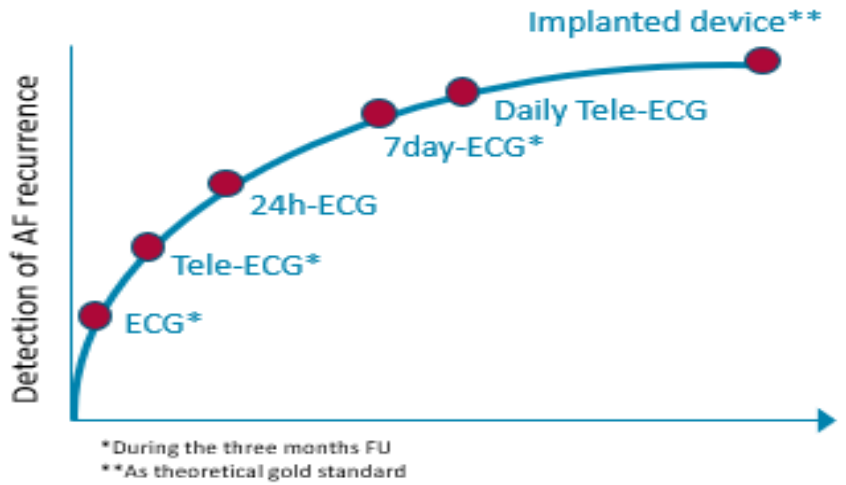


Figure 10 Components of integrated AF management. AF = atrial fibrillation; HCP = healthcare professional; MDT = multidisciplinary team.



Discontinuous vs. continuous recordings

Estimated correlation between follow up strategy and rate of AF detection after AF ablation



- **Poor correlation between symptoms and AF**
- **The longer the recording, the more sensitive it is for AF detection**

A. Arya. PACE 2007; 30: 458-462

Techniques de monitoring du rythme cardiaque

EVENT RECORDERS

HOLTER MONITOR	POST-EVENT RECORDER	EXTERNAL LOOP RECORDER ("ELR")	INSERTABLE LOOP RECORDER ("ILR")	MOBILE CARDIAC TELEMETRY	EMERGING SMART WEARABLE DEVICES
Portable external monitor that records a continuous ECG with 3 leads	Portable external monitor that requires activation to record	A wearable device that automatically detects, records and transmits abnormal heart rhythms	Inserted under the skin, automatically detects, records and transmits abnormal heart rhythms	Wearable monitor for comprehensive mobile, real time, outpatient telemetry ("MCOT")	Integrated sensors and apps on iWatches and other smart devices
For 1-2 days	Up to 30 days	Up to 30 days	Up to 5 years	Up to 30 days	

INCREASING DIAGNOSTIC YIELD

Arrhythm Electrophysiol Rev.2016 Aug; 5(2): 136–143


SI JE VOUS PARLE D'INTELLIGENCE ARTIFICIELLE VOUS PENSEZ À ?
À VOUS CHEF !
milon