AOD en Rythmologie

Points clés des recommandations EHRA 2018

CNCH - CNCF

Dr Franck Halimi

H.P. Parly 2, Le Chesnay

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Consensus d'expert - Practical Guide EHRA 2018

EHRA
European Heart Rhythm Association

European Heart Journal (2018) **00**, 1-64
doi: 10.1093/eurheartj/ehy 136

The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation

Jan Steffel, Peter Verhamme, Tatjana S. Potpara, Pierre Albaladejo, Matthias Antz, Lien Desteghe, Karl Georg Haeusler, Jonas Oldgren, Holger Reinecke, Vanessa Roldan-Schilling, Nigel Rowell, Peter Sinnaeve, Ronan Collins, A. John Camm, and Hein Heidbüchel.

www.NOACforAF.eu

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AOD et interventions chirurgicales

Classification of elective surgical interventions according to bleeding risk (1)

Interventions with minor bleeding risk
Dental interventions
Extraction of 1 to 3 teeth
Paradontal surgery
Incision of abscess
Implant positioning
Cataract or glaucoma intervention
Endoscopy without biopsy or resection
Superficial surgery (e.g. abscess incision; small dermatologic excisions; ...)
Interventions with low bleeding risk (i.e. infrequent or with low clinical impact)
Endoscopy with biopsy
Prostate or bladder biopsy
Electrophysiological study or catheter ablation (except complex procedures, see below)
Non-coronary angiography (for coronary angiography and ACS: see Section 12)
Pacemaker or ICD implantation (unless complex anatomical setting, e.g. congenital heart disease)

Steffel ... Heidbüchel, EHRA Practical Guide, European Heart Journal 2018

EHRA European Society of Cardiology

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AOD et interventions chirurgicales

Classification of elective surgical interventions according to bleeding risk (2)

Intervention with high bleeding risk (i.e. frequent and/or with high impact)
Complex endoscopy (e.g. polypectomy, ERCP with sphincterotomy etc.)
Spinal or epidural anaesthesia; lumbar diagnostic puncture
Thoracic surgery
Abdominal surgery
Major orthopaedic surgery
Liver biopsy
Transurethral prostate resection
Kidney biopsy
Extracorporeal shockwave lithotripsy (ESWL)
Complex left-sided ablation (pulmonary vein isolation; some VT ablations)

Steffel ... Heidbüchel, EHRA Practical Guide, European Heart Journal 2018

EHRA European Society of Cardiology

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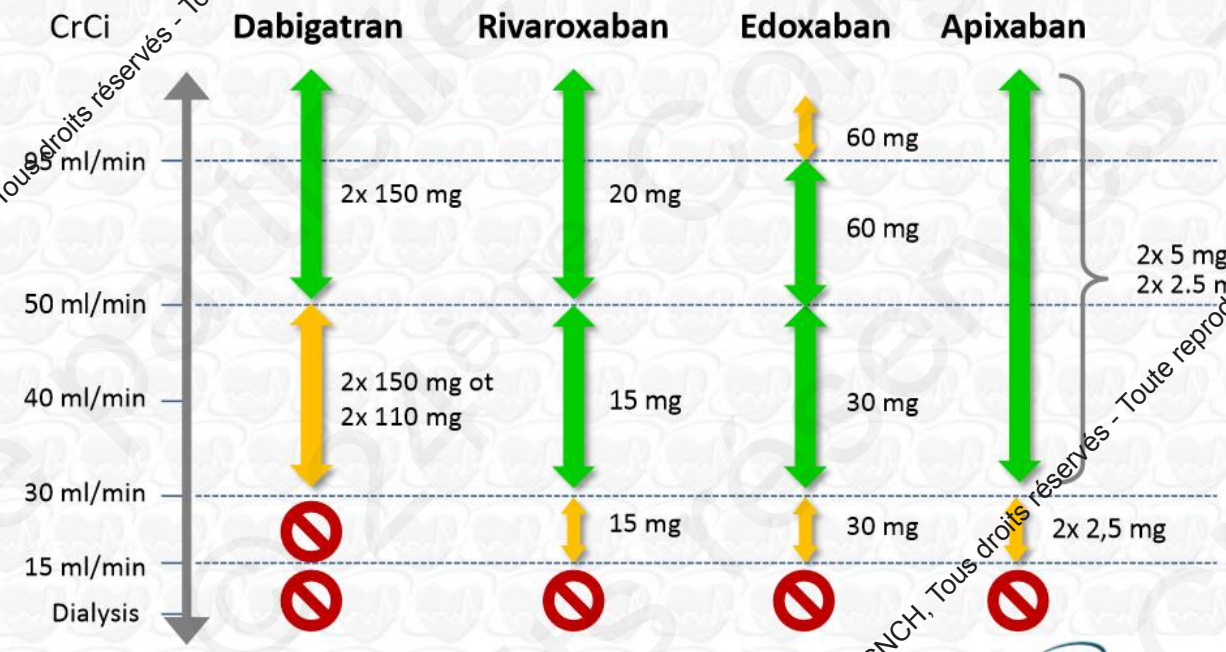
NOACs in renal insufficiency



Steffel ... Heidbüchel, EHRA Practical Guide, European Heart Journal 2018

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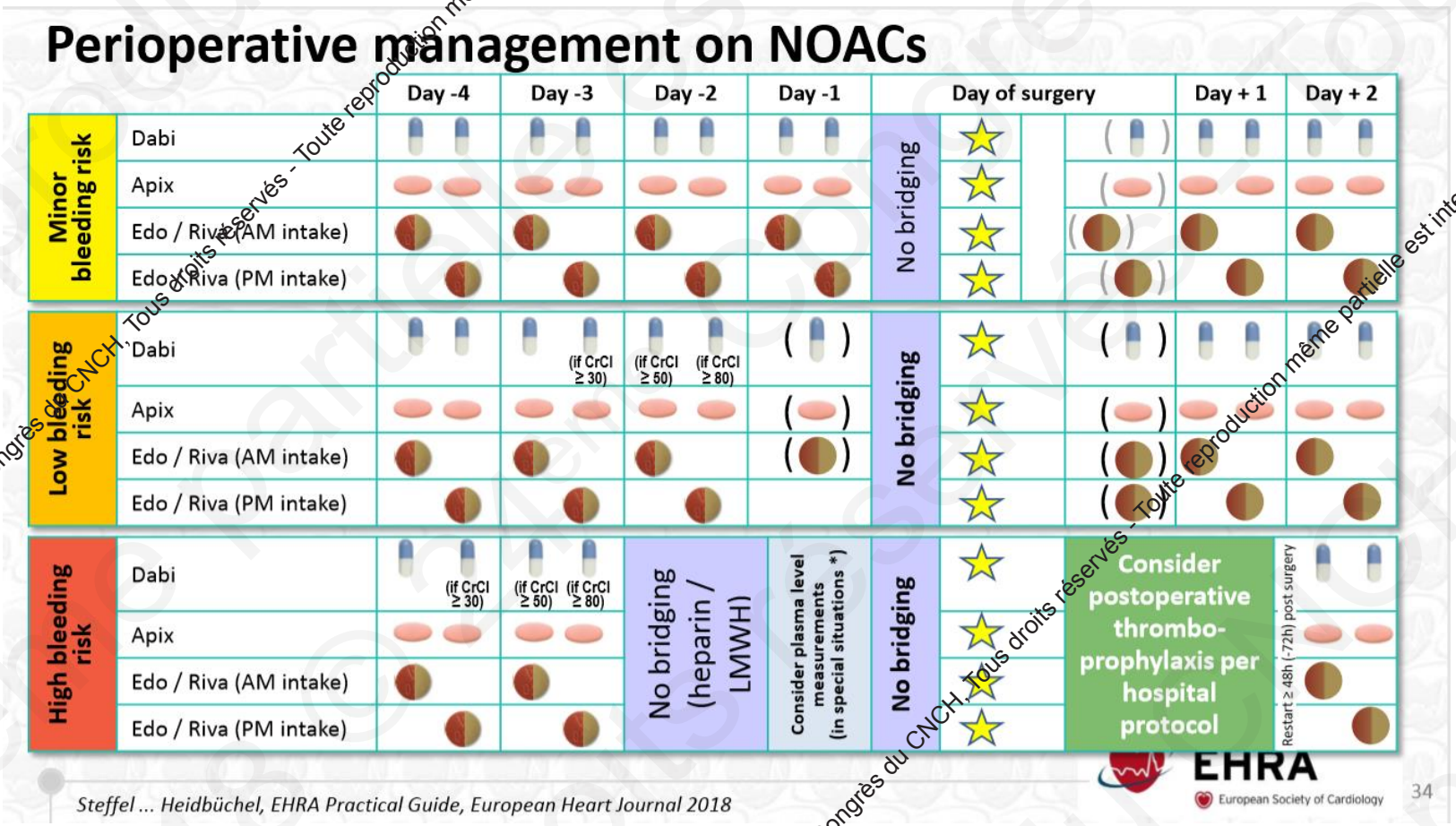
Stratégie périopératoire



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La Stimulation Cardiaque
(PM / DAI)

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Steffel ... Heidbüchel, EHRA Practical Guide, European Heart Journal 2018

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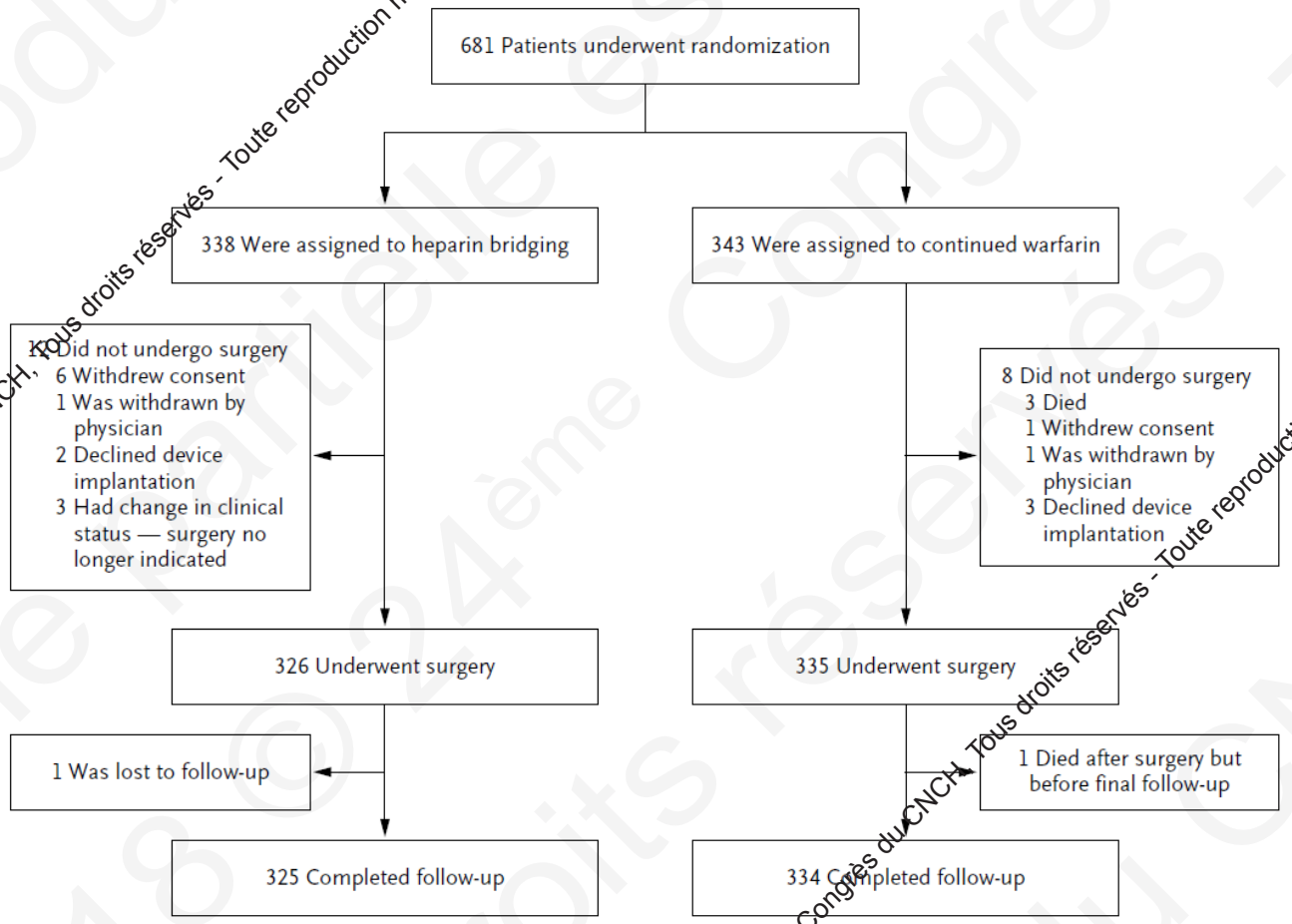
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Pacemaker or Defibrillator Surgery without Interruption of Anticoagulation

David H. Birnie, M.D., Jeff S. Healey, M.D., George A. Wells, Ph.D., Atul Verma, M.D., Anthony S. Tang, M.D., Andrew D. Krahn, M.D., Christopher S. Simpson, M.D., Felix Ayala-Paredes, M.D., Benoit Coutu, M.D., Tiago L.N. Leiria, M.D., and Vidal Essebag, M.D., Ph.D., for the BRUISE CONTROL Investigators*

BRUISE CONTROL: Trial enrollment and FU



Results

Table 3. Primary and Secondary Outcomes.*

Outcome	Heparin Bridging (N=338)	Continued Warfarin (N=343)	Relative Risk (95% CI)	P Value
Primary outcome				
Clinically significant hematoma — no. (%)	54 (16.0)	12 (3.5)	0.19 (0.10–0.36)	<0.001
Components of primary outcome				
Hematoma prolonging hospitalization — no. (%)	16 (4.7)	4 (1.2)	0.24 (0.08–0.72)	0.006
Hematoma requiring interruption of anticoagulation — no. (%)	48 (14.2)	11 (3.2)	0.20 (0.10–0.39)	<0.001
Hematoma requiring evacuation — no. (%)	9 (2.7)	2 (0.6)	0.21 (0.05–1.00)	0.03
Secondary outcomes				
Death from any cause — no. (%)	0	4 (1.2)		0.12
Pneumothorax — no. (%)	1 (0.3)	1 (0.3)		1.00
Hemothorax — no. (%)	0	0		—
Cardiac tamponade — no. (%)	1 (0.3)	0		0.50
Transient ischemic attack — no. (%)	0	1 (0.3)		1.00
Stroke — no. (%)	0	1 (0.3)		0.50
Non-CNS embolism — no. (%)	0	0		—
Deep-vein thrombosis — no. (%)	0	0		—
Pulmonary embolism — no. (%)	0	0		—
Valve thrombosis — no. (%)	0	0		—
Lead dislodgement — no. (%)	4 (1.2)	1 (0.3)		0.21
Superficial wound infection — no. (%)	3 (0.9)	1 (0.3)		0.37
Infection related to device system — no. (%)	6 (1.8)	2 (0.6)		0.17
Myocardial infarction — no. (%)	1 (0.3)	0		0.50
Patient-satisfaction score†	5.9±1.8	6.4±1.5		<0.001

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L’ablation de la FA

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Classification of elective surgical interventions according to bleeding risk (2)

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Steffel ... Heidbüchel, EHRA Practical Guide, European Heart Journal 2018

EHRA
European Society of Cardiology

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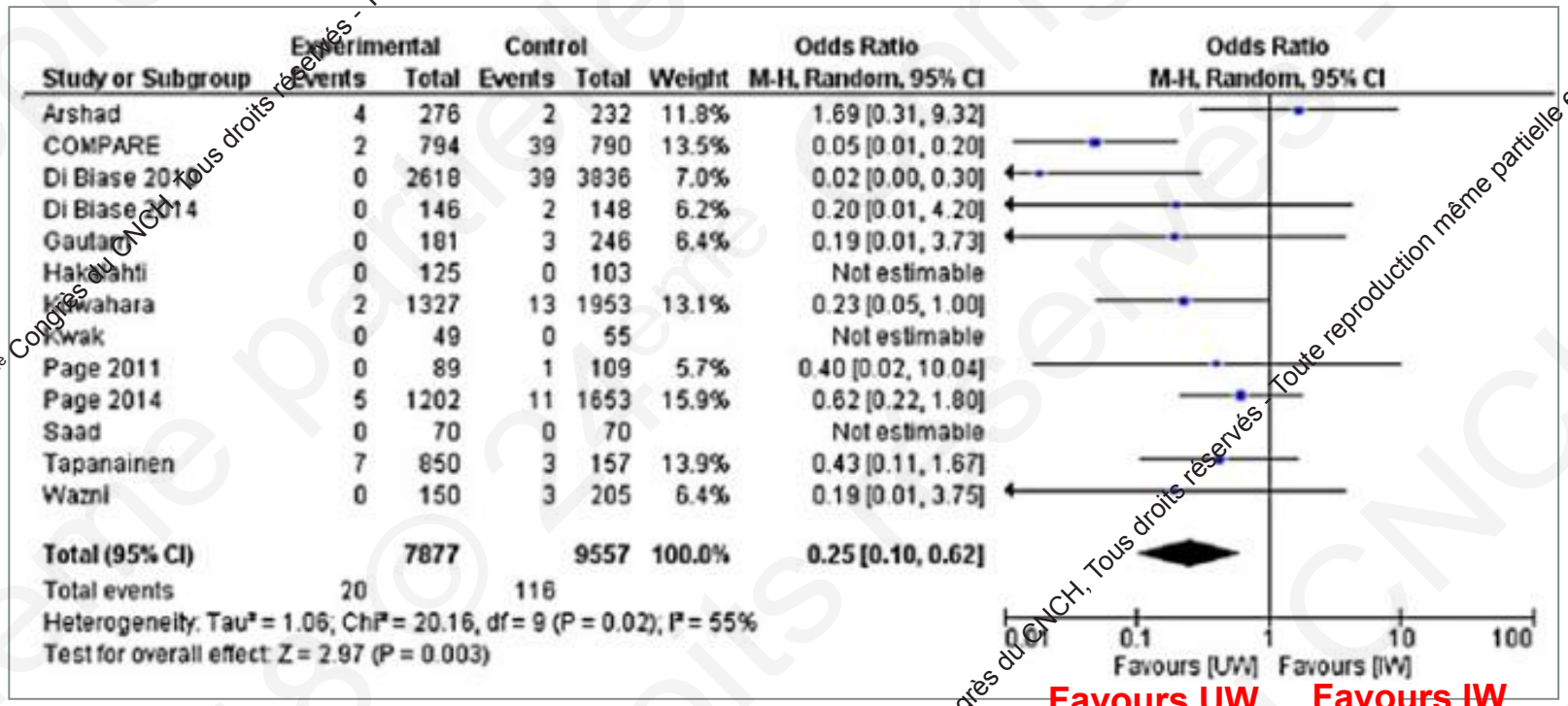
Meta-analysis of major bleeding with uninterrupted warfarin compared to interrupted warfarin and heparin bridging in ablation of atrial fibrillation

Ramez Nairooz [a,*], Partha Sardar [b], Jason Payne [a], Wilbert S. Aronow [c], Hakan Paydak [a]

Stroke/TIA



Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Arshad	4	276	2	232	11.8%	1.69 [0.31, 9.32]
COMPARE	2	794	39	790	13.5%	0.05 [0.01, 0.20]
Di Biase 2010	0	2618	39	3836	7.0%	0.02 [0.00, 0.30]
Di Biase 2014	0	146	2	148	6.2%	0.20 [0.01, 4.20]
Gautam	0	181	3	246	6.4%	0.19 [0.01, 3.73]
Hakalahti	0	125	0	103		Not estimable
Kiviwahara	2	1327	13	1953	13.1%	0.23 [0.05, 1.00]
Kwak	0	49	0	55		Not estimable
Page 2011	0	89	1	109	5.7%	0.40 [0.02, 10.04]
Page 2014	5	1202	11	1653	15.9%	0.62 [0.22, 1.80]
Saad	0	70	0	70		Not estimable
Tapanainen	7	850	3	157	13.9%	0.43 [0.11, 1.67]
Wazni	0	150	3	205	6.4%	0.19 [0.01, 3.75]
Total (95% CI)		**7877**		**9557**	**100.0%**	**0.25 [0.10, 0.62]**
Total events	20		116			

Heterogeneity: Tau² = 1.06; Chi² = 20.16, df = 9 (P = 0.02); I² = 55%
Test for overall effect: Z = 2.97 (P = 0.003)

Int J Cardiol 2015

Meta-analysis of major bleeding with uninterrupted warfarin compared to interrupted warfarin and heparin bridging in ablation of atrial fibrillation

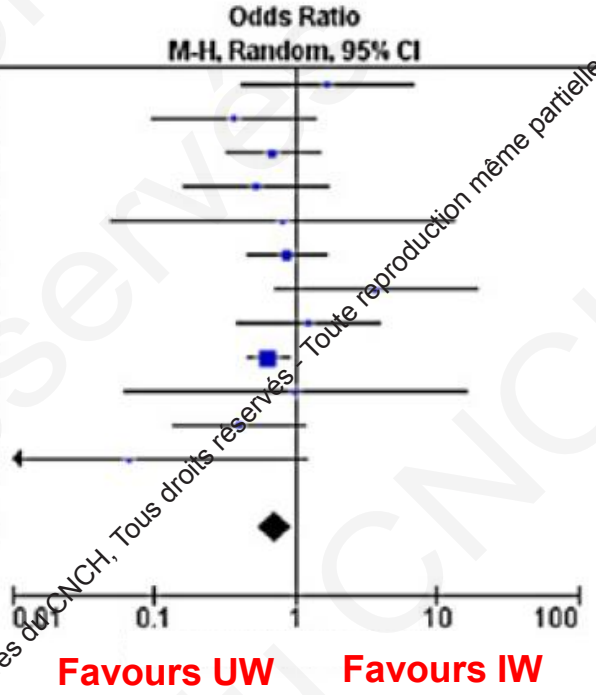
Ramez Nairooz [a,*], Partha Sardar [b], Jason Payne [a], Wilbert S. Aronow [c], Hakan Paydak [a]

Major bleeding

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Arshad	6	276	3	232	3.9%	1.70 [0.42, 6.86]
COMPARE	3	794	8	790	4.3%	0.37 [0.10, 1.40]
Di Biase 2010	10	2618	21	3836	12.3%	0.70 [0.33, 1.48]
Gautam	4	181	10	246	5.4%	0.53 [0.16, 1.73]
Hakalahti	1	125	1	103	1.0%	0.82 [0.05, 13.31]
Kuwahara	15	1327	25	1953	16.2%	0.88 [0.46, 1.68]
Kwon	6	49	2	55	2.8%	3.70 [0.71, 19.26]
Page 2011	6	89	6	109	5.5%	1.24 [0.39, 3.99]
Page 2014	48	1202	100	1653	40.2%	0.65 [0.45, 0.92]
Saad	1	70	1	70	1.0%	1.00 [0.06, 16.31]
Tapanainen	11	850	5	157	6.5%	0.40 [0.14, 1.16]
Wazni	0	150	9	205	1.0%	0.07 [0.00, 1.19]
Total (95% CI)		**7731**		**9409**	**100.0%**	**0.72 [0.54, 0.95]**
Total events	111		191			

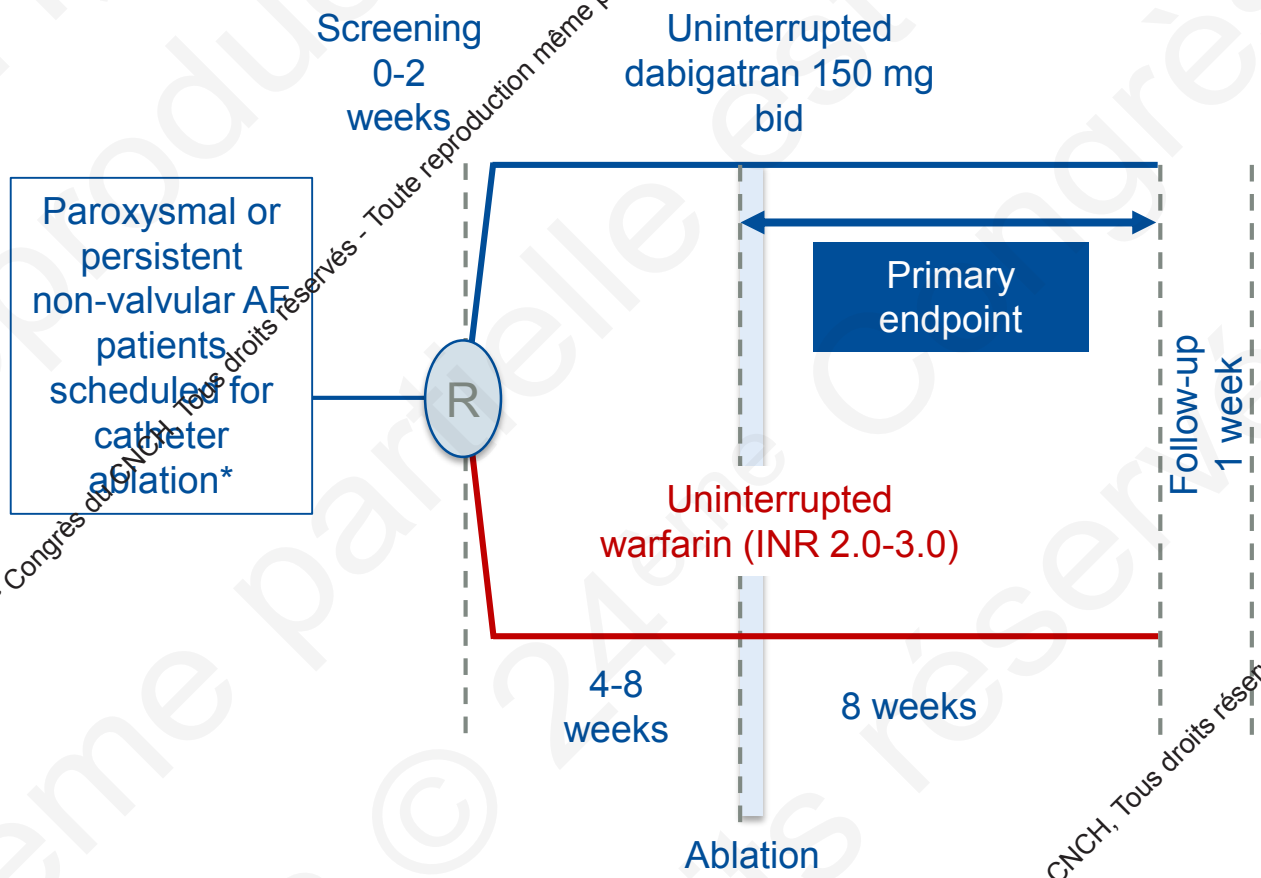
Heterogeneity: Tau² = 0.02; Chi² = 11.85, df = 11 (P = 0.38); I² = 7%

Test for overall effect: Z = 2.34 (P = 0.02)



Int J Cardiol 2015

RE-CIRCUIT™: study design

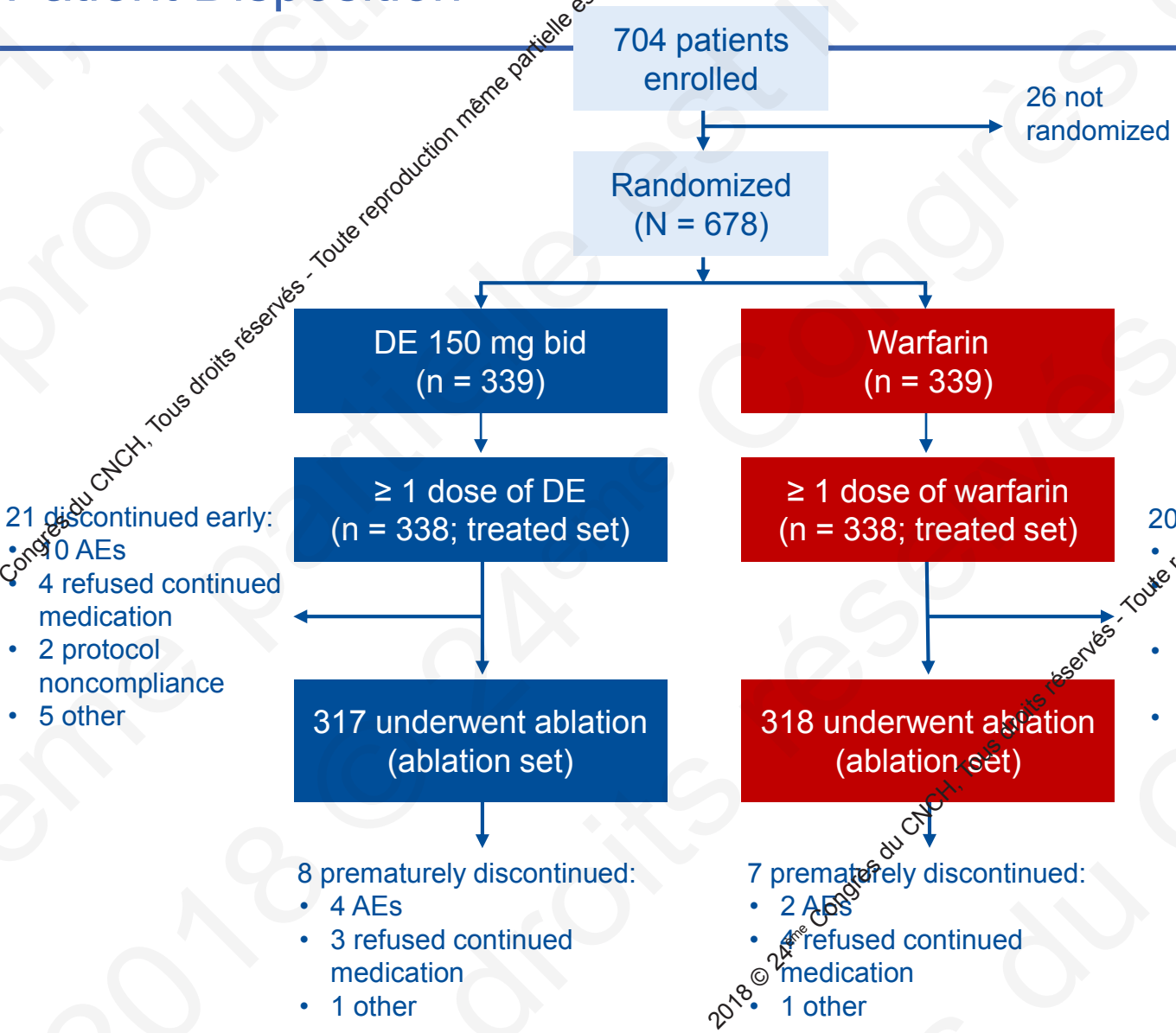


- **Primary endpoint:** incidence of adjudicated ISTH MBEs from venous access up to 8 weeks post-ablation†
- **Secondary endpoints** included adjudicated thromboembolic events from venous access to 8 weeks post-ablation†

*And eligible for dabigatran 150 mg bid according to local prescribing information.

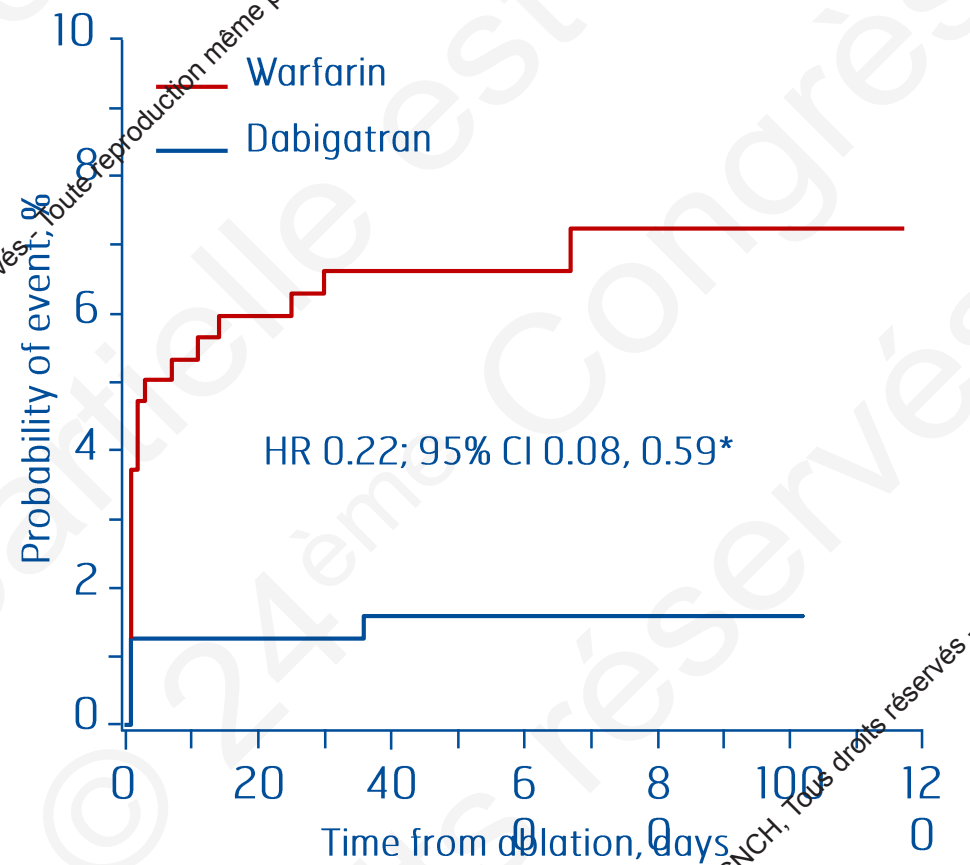
†Primary end point assessed from the start of the ablation procedure and up to 8 weeks post-ablation.

Patient Disposition



AE, adverse event; DE, dabigatran etexilate.

Fewer MBEs from the Time of Ablation



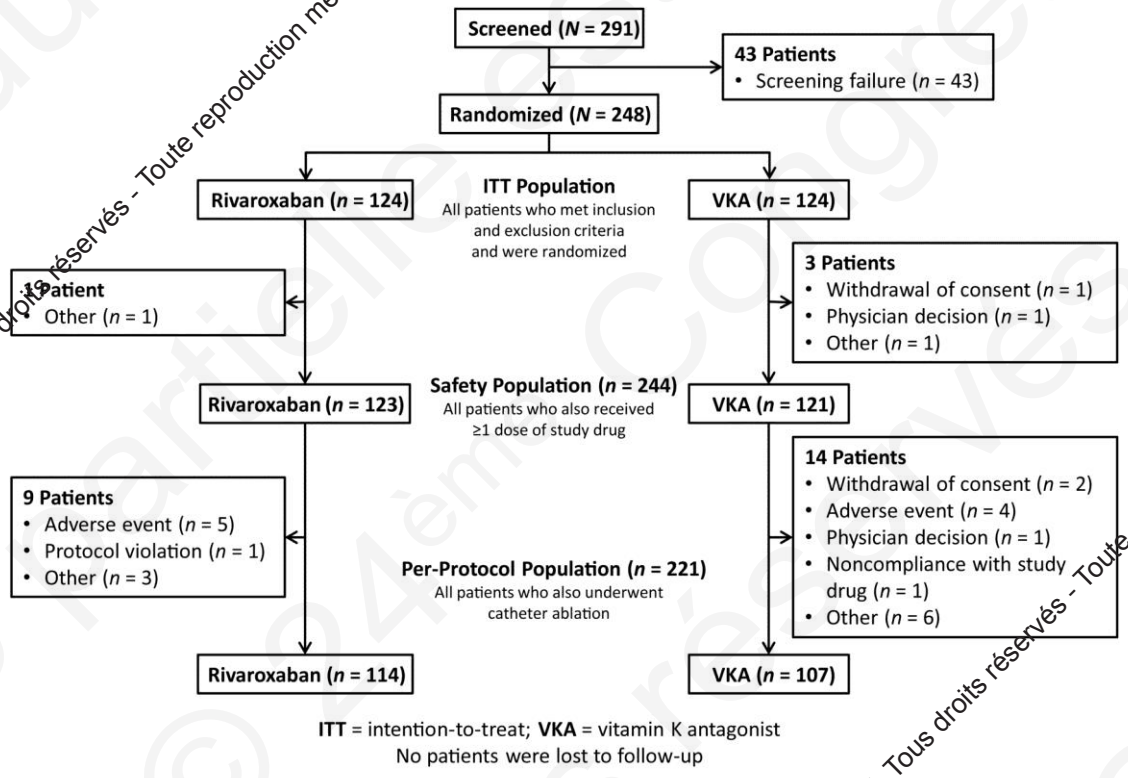
Patients at risk													
Dabigatran	317	313	311	311	306	305	297	83	3	2	1	0	0
Warfarin	318	301	297	296	295	295	278	85	13	5	3	1	0

*Cox proportional hazard model and Wald confidence limits.

VENTURE-AF

Uninterrupted rivaroxaban vs. uninterrupted vitamin K antagonists for catheter ablation in non-valvular atrial fibrillation

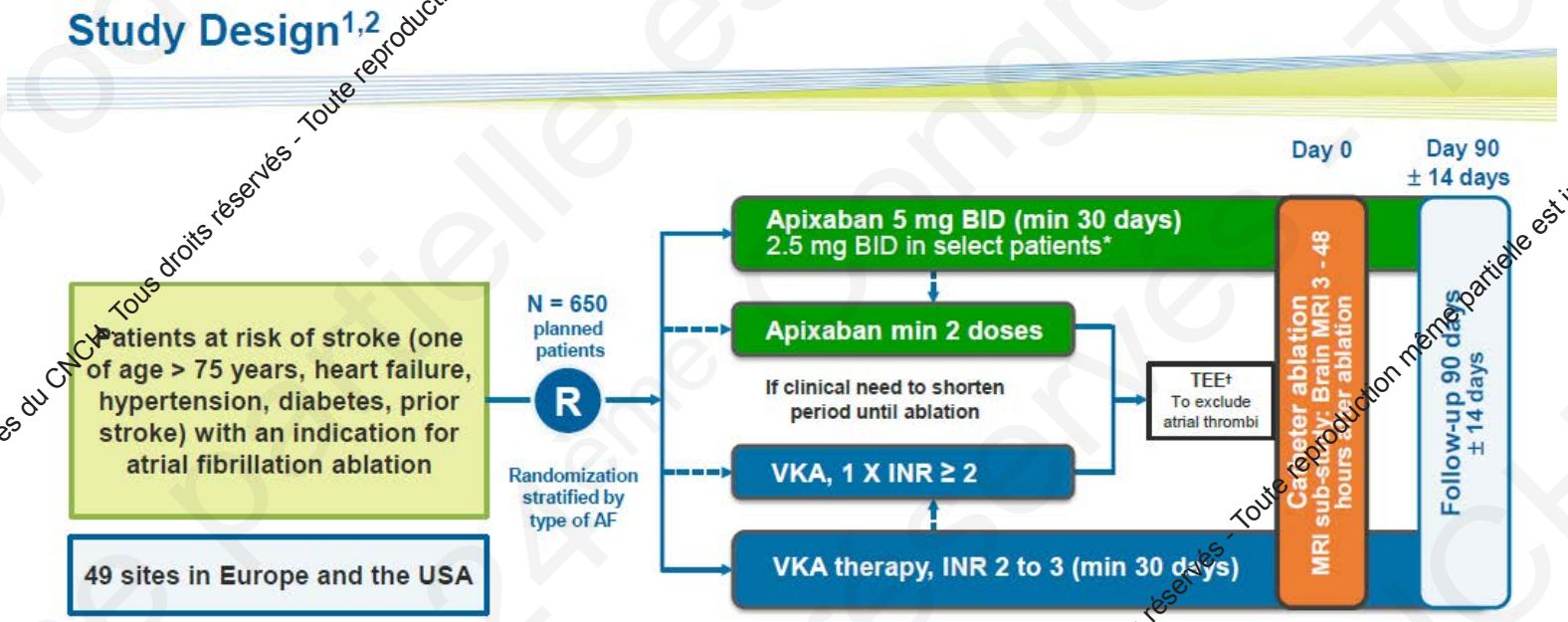
Riccardo Cappato[1,2], Francis E. Marchlinski[3], Stefan H. Hohnloser[4],



Conclusion In patients undergoing CA for AF, the use of uninterrupted oral rivaroxaban was feasible and event rates were similar to those for uninterrupted VKA therapy.

European Heart Journal (2015) **36**, 1805–1811
doi:10.1093/eurheartj/ehv177

AXAFA – AFNET 5 Trial

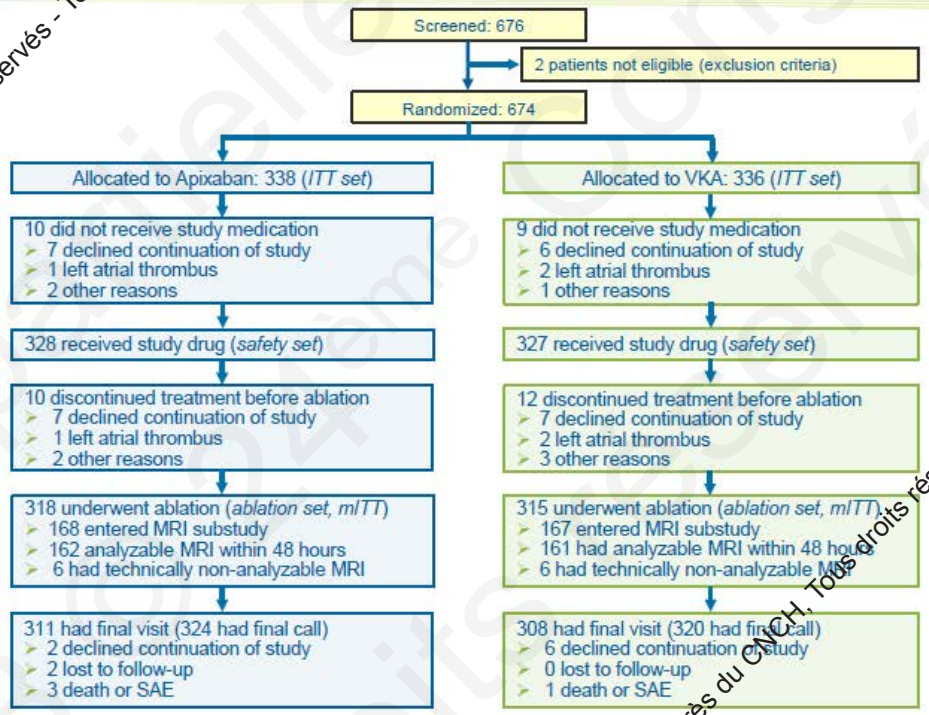


* Dose reduction if two of the following criteria: age ≥ 80 years, weight ≤ 60kg or serum creatinine ≥1.5 mg/dL (133 µmol).
† In patients where a clinical decision is made to shorten the period until ablation a TEE should be performed

AF, atrial fibrillation; BID, twice daily; ECG, electrocardiogram; INR, international normalized ratio; MRI, magnetic resonance imaging; R, randomized; TEE, transesophageal echo; VKA, vitamin K antagonist.

1. Kirchhof P et al. Oral presentation at EHRA 18th to 20th March 2018, Barcelona, Spain. Oral abstract 951.
2. Adapted from Di Base et al. *Europace* 2017;19:132-138

Consort Diagram



mITT, modified intention to treat; MRI, magnetic resonance imaging; SAE, serious adverse event; ITT, intention to treat; VKA, vitamin K antagonist.

Kirchhof P et al. Oral presentation at EHRA 18th to 20th March 2018, Barcelona, Spain. Oral abstract 951.

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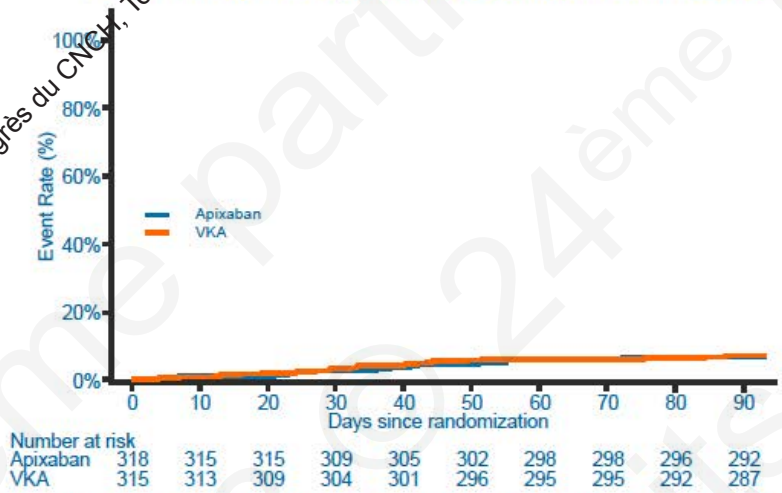
Primary Outcome (Ablation Set)

- Difference in primary outcome rate -0.38%, 90% confidence interval -4.0%, -3.3%, non-inferiority $P = 0.0002$).
- Apixaban was also non-inferior to VKA among all randomized patients as assessed by Cox proportional hazards model comparison between treatment groups using a relative non-inferiority margin of 1.44 (hazard ratio = 0.88, 90% CI 0.55, 1.41, $P = 0.042$).

Cumulative Primary Outcome Events in the Ablation set



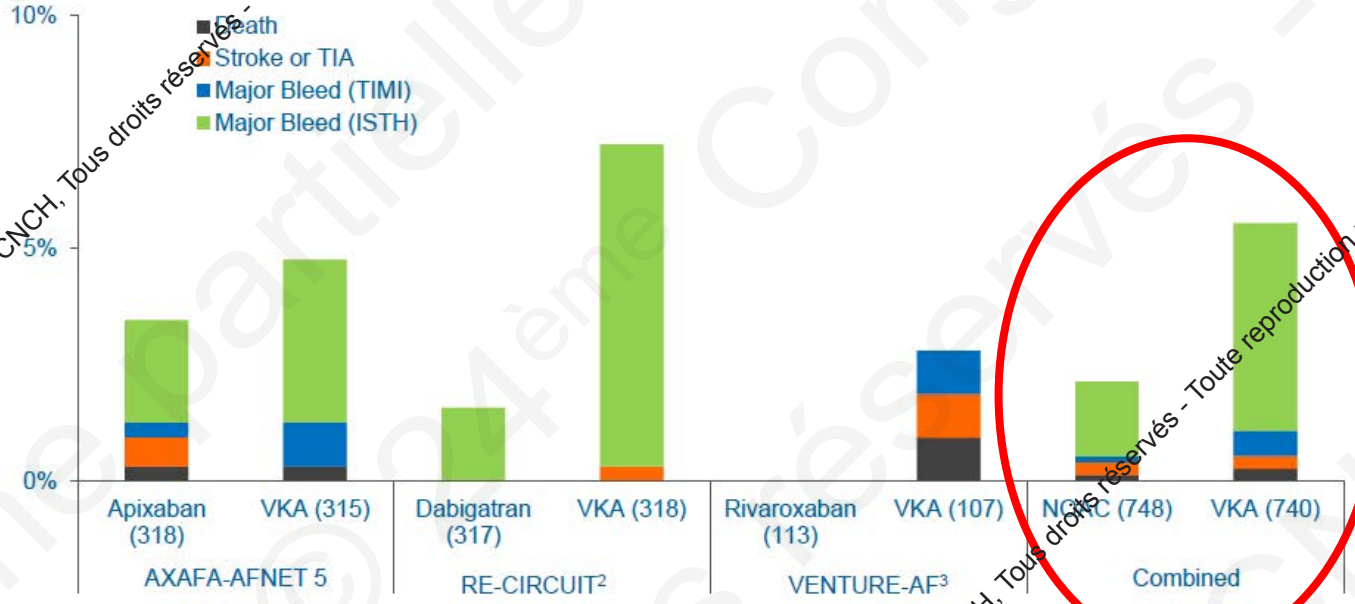
	Apixaban	VKA
Patients with primary endpoint: composite of all-cause death, stroke or major (BARC 2 to 5) bleeding	22/318 (6.9%), non-inferiority $P = 0.0002$	23/315 (7.3%)
Death	1 (0.3%)	1 (0.3%)
Stroke or TIA	2 (0.6%)	0
Intracranial hemorrhage	0	1 (0.3%, fatal)
TIMI major bleeding	1 (0.3%)	3 (1%)
ISTH major bleeding	10 (3.1%)	14 (4.4%)
Tamponade	2 (0.6%)	5 (1.6%)

BARC, Bleeding Academic Research Consortium; CI, confidence interval; ISTH, International Society on Thrombosis and Haemostasis; TIA, transient ischemic attack; TIMI, Thrombolysis in Myocardial Infarction; VKA, vitamin K antagonist oral anticoagulant.

Kirchhof P et al. Oral presentation at EHRA 18th to 20th March 2018, Barcelona, Spain. Oral abstract 951.

Les trois études

Event Rates in AXAFA – AFNET 5, RE-CIRCUIT, and VENTURE-AF (Ablation Sets)



ISTH, International Society on Thrombosis and Haemostasis; NOAC, non-vitamin K antagonist oral anticoagulant; TIA, transient ischemic attack; TIMI, Thrombolysis in Myocardial Infarction; VKA, vitamin K antagonist oral anticoagulant.

1. Kirchhof P et al. Oral presentation at EHRA 18th to 20th March 2018, Barcelona, Spain. Oral abstract 951.
2. Adapted from Calkins H et al. *N Engl J Med.* 2017;376:1627-1636

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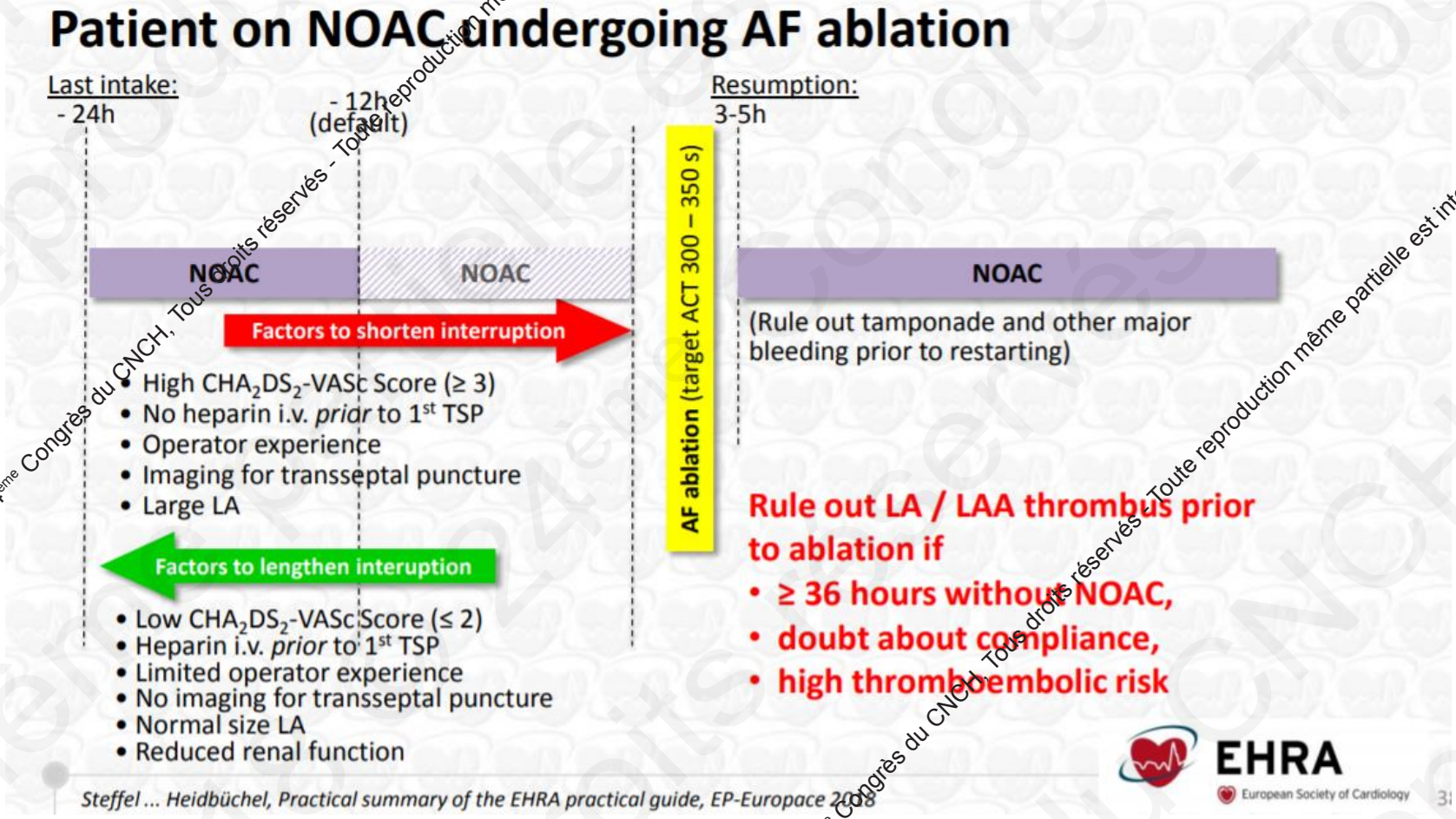
Consensus EHRA



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La cardioversion électrique externe

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Prospective NOAC Studies in Cardioversion in NVAF

Trial name	NOAC	Study overview	Primary outcome(s)
X-VeRT[1]	Rivaroxaban	◆ Rivaroxaban 20/15 mg od vs VKA in 1504 patients undergoing electrical or pharmacological cardioversion of NVAF (optional use of parenteral anticoagulant with VKA)	◆ Composite of stroke, TIA, peripheral embolism, MI and cardiovascular mortality ◆ Rivaroxaban 0.51% vs VKA 1.02%; RR 0.50 (95% CI 0.15–1.73)
ENSURE AF[2]	Edoxaban	◆ Edoxaban 60/30 mg od vs enoxaparin–warfarin in 2199 patients undergoing electrical cardioversion for NVAF	◆ Composite of stroke, SE, MI and cardiovascular mortality ◆ Edoxaban <1% vs enoxaparin–warfarin 1%; OR 0.46 (95% CI 0.12–1.43)
EMANATE[3]	Apixaban	◆ Ongoing study of efficacy and safety of apixaban vs heparin and/or VKA in patients with NVAF undergoing cardioversion	

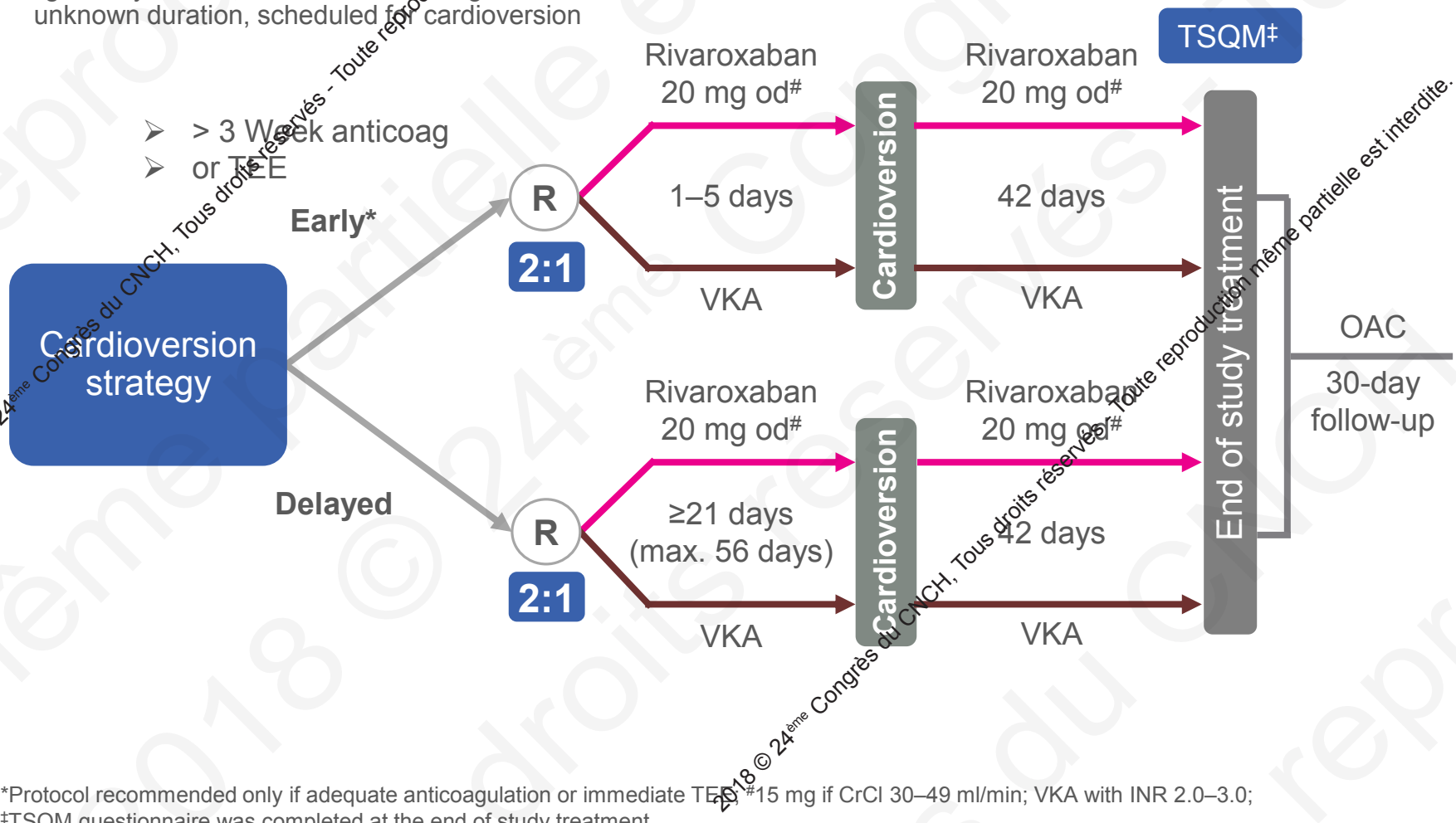
1. Cappato R *et al, Eur Heart J* 2014;35:3346–3355; 2. Goette A *et al, Lancet* 2016;388:1995–2003; 3. https://clinicaltrials.gov/ct2/show/NCT02100228

X-Vert: Randomized, Open-Label, Parallel-Group, Active-Controlled Multicentre Study

Inclusion criteria:

Age ≥18 years, non-valvular AF lasting >48 h or unknown duration, scheduled for cardioversion

- > 3 Week anticoag
- or TEE

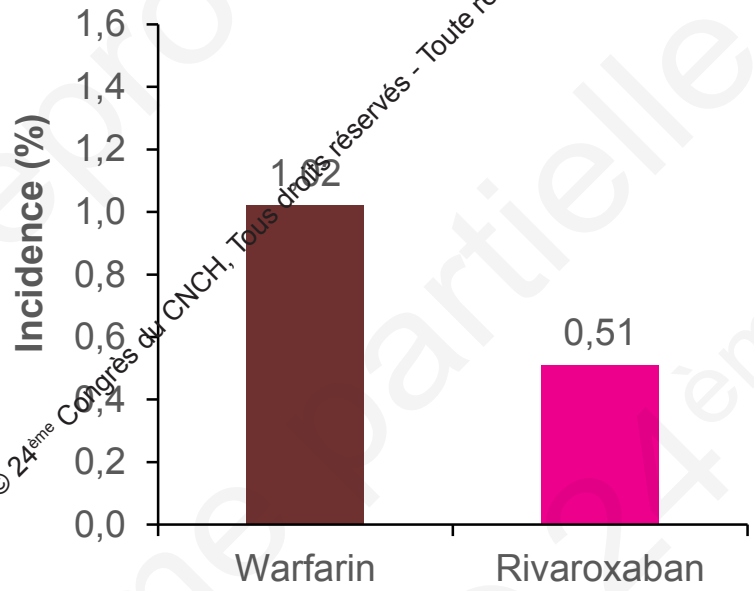


*Protocol recommended only if adequate anticoagulation or immediate TEE; #15 mg if CrCl 30–49 ml/min; VKA with INR 2.0–3.0;
‡TSQM questionnaire was completed at the end of study treatment

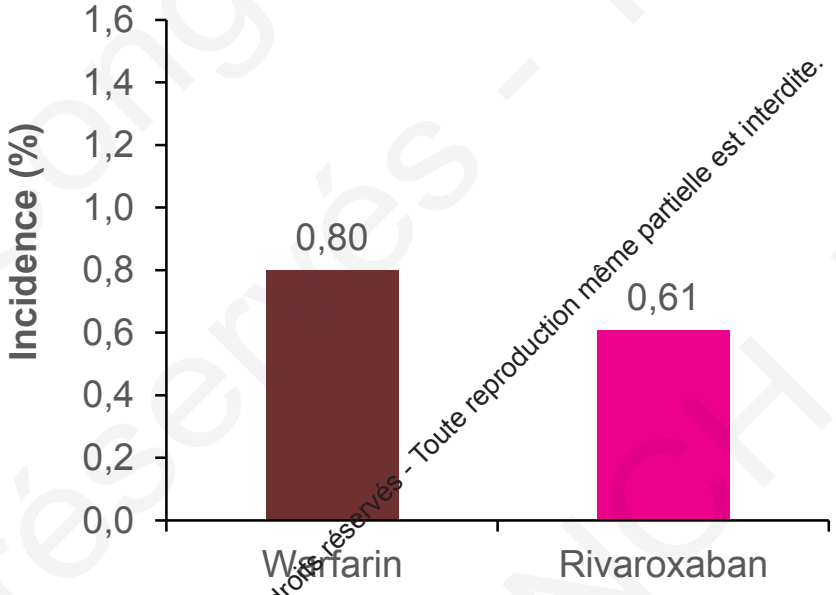
Cappato R *et al*, *Eur Heart J* 2014;35:3346–3355

X-VeRT: Rates of Thromboembolic and Bleeding Events Were Similarly Low in Both Treatment Arms

Primary efficacy outcome (stroke/TIA/SE/MI/CV death)



Primary Safety Outcome (major bleeding)

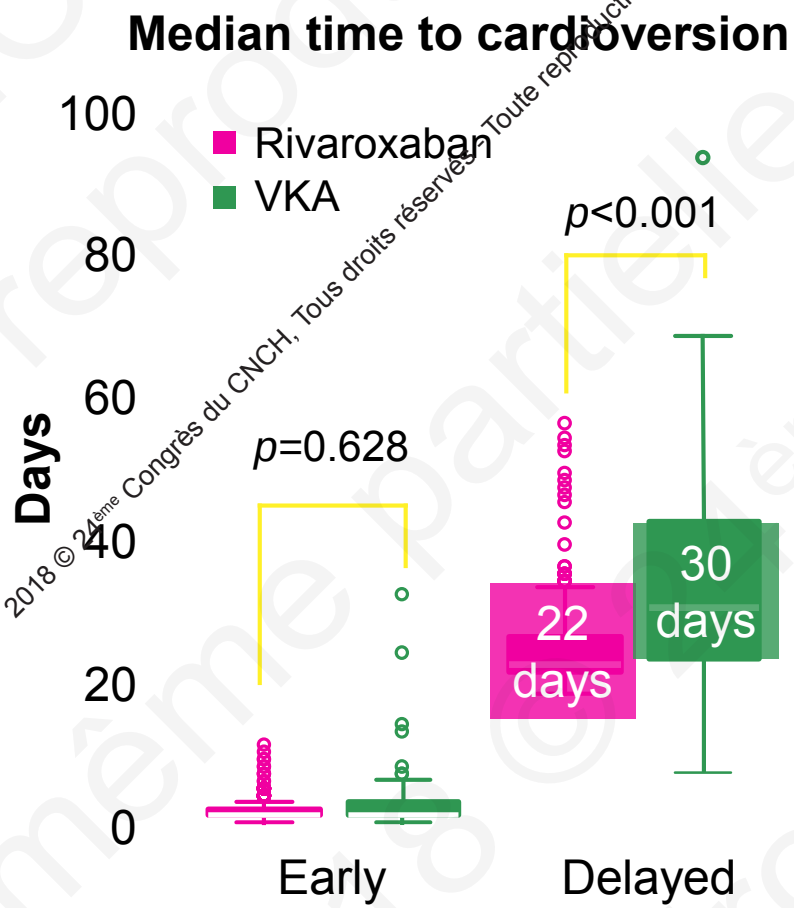


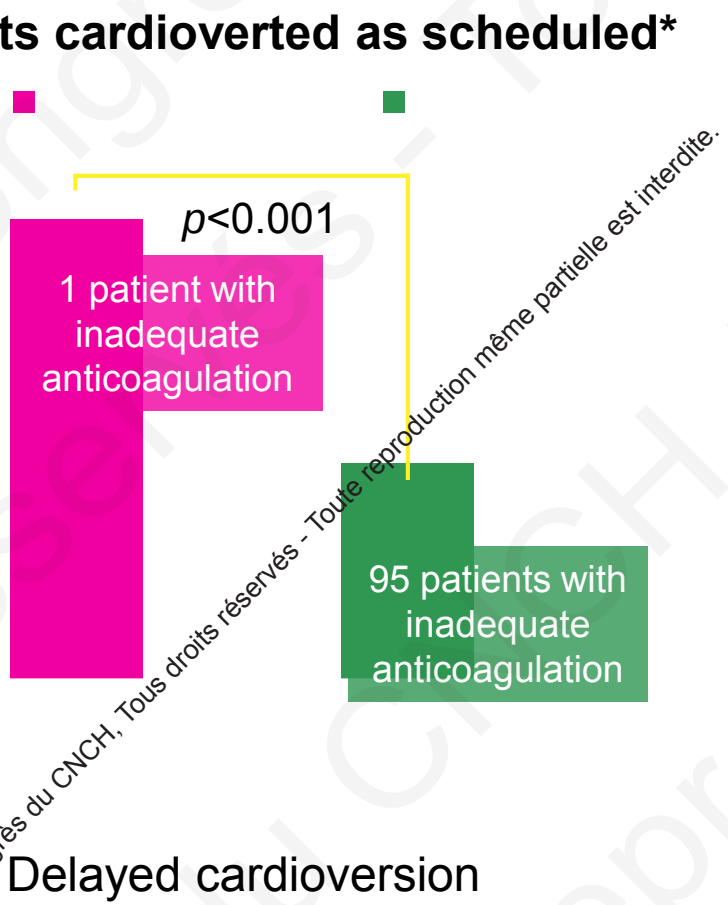
In X-VeRT:

- Rivaroxaban appears to be an effective and safe alternative to VKA
- Rivaroxaban provided important practical advantages over VKAs, with significantly more patients able to undergo cardioversion as planned and after a significantly shorter duration of pre-cardioversion anticoagulation

Primary efficacy outcome: composite of composite of stroke, TIA, non-CNS SE, MI, and cardiovascular death; primary safety outcome: major bleeding Observations applied to both the early and delayed cardioversion strategies. Cappato R *et al, Eur Heart J* 2014;35:3346–3355

X-VeRT: time to cardioversion by cardioversion strategy





*Reason for not performing cardioversion as first scheduled from 21–25 days primarily due to inadequate anticoagulation (indicated by drug compliance <80% for rivaroxaban or weekly INRs outside the range of 2.0–3.0 for 3 consecutive weeks before cardioversion for VKA)

Apixaban Compared to Heparin/Vitamin K Antagonist in Patients With Atrial Fibrillation Scheduled for Cardioversion: The EMANATE Trial

Michael D. Ezekowitz,[1,2,3] Charles V. Pollack Jr,[4] Jonathan L. Halperin,[5] Richard D. England,[6] Sandra VanPelt Nguyen,[6] Judith Spahr,[4] Maria Sudworth,[7] Nilo B. Cater,[8] Andrei Breazna,[8] Jonas Oldgren,[9] and Paulus Kirchhof.[10]

[1]Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, PA, USA; [2]Lankenau Heart Center, Wynnewood, PA, USA; [3]Bryn Mawr Hospital, Bryn Mawr, PA, USA; [4]Thomas Jefferson University, Philadelphia, PA, USA; [5]Icahn School of Medicine, New York, NY, USA; [6]Pfizer, Groton, CT, USA; [7]Pfizer, London, UK; [8]Pfizer, New York, NY, USA; [9]Uppsala Clinical Research Centre and Department of Medical Sciences, Uppsala University, Uppsala, Sweden; and [10]University of Birmingham Institute of Cardiovascular Sciences, SWBH and UHB NHS Trusts, Birmingham, UK.

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Ezekowitz MD et al. *Eur Heart J.* April 2018 doi:10.1093/eurheartj/ehy148 [Epub ahead of print]

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Key Eligibility Criteria

Key Inclusion Criteria	Key Exclusion Criteria
▪ Anticoagulation-naïve patients with AF (<48 hours of parenteral and/or oral anticoagulation) indicated for cardioversion.	▪ Contraindications to apixaban or heparin/VKA ▪ Mitral stenosis or previous valve surgery ▪ Other conditions requiring anticoagulation ▪ Dual antiplatelet therapy

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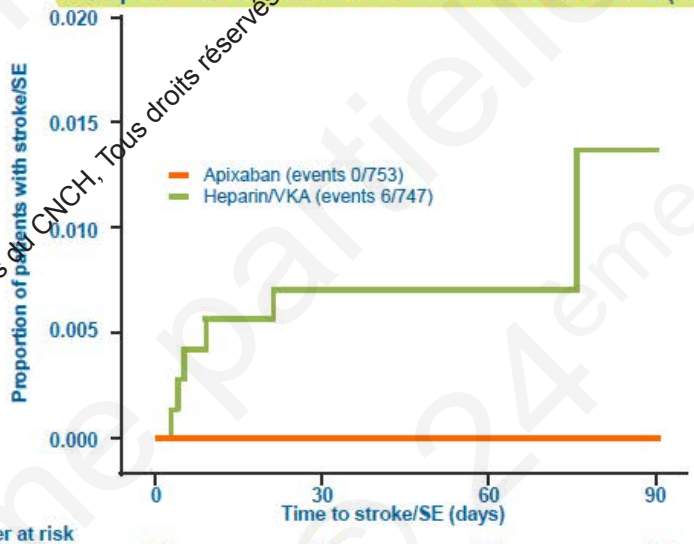
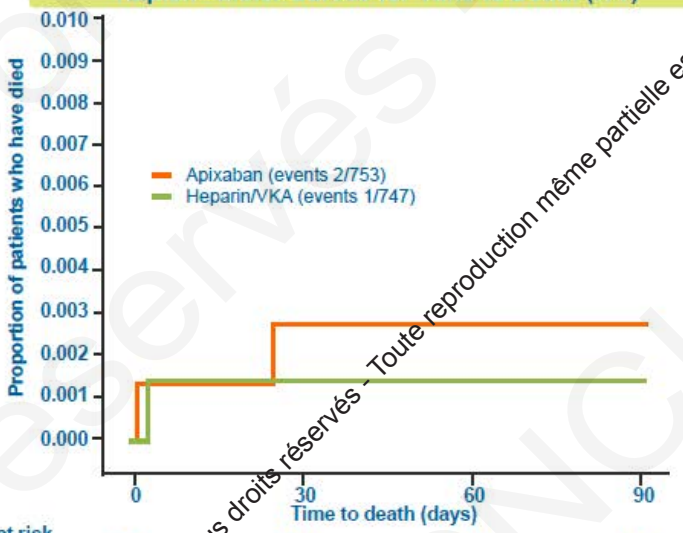
EMANATE Results: Kaplan - Meier Curves for Time to First Event

Kaplan - Meier Curves for Time to First Stroke/SE (ITT)



Number at risk				
Apixaban	752	614	199	55
Heparin/VKA	747	565	231	88

Kaplan - Meier Curves for Time to Death (ITT)



Number at risk				
Apixaban	752	614	199	55
Heparin/VKA	747	567	232	89

CI, confidence interval; ITT, intention to treat; RR, relative risk; SE, systemic embolism; VKA, vitamin K antagonist.

Even though some *P* values are significant, statistical conclusions should not be drawn, as the study was not sufficiently powered to detect a differences in efficacy outcomes.

Summary

- In the intention-to-treat population, no patients randomized to apixaban developed stroke (0%; 95% CI, 0 to 0.5%), compared to 6 in the heparin/VKA group (0.8%; 95% CI, 0.3 to 1.7%); RR 0; 95% CI, 0 to 0.64; nominal *P* = 0.015. There were no SE events in either group.
- There were two deaths in the apixaban arm (0.27%, 95% CI, 0.03 to 0.96%) and 1 in the heparin/VKA arm (0.13%; 95% CI, 0 to 0.74%; RR = 1.98; 95% CI, 0.19 to 54.00; *P* > 0.9999.

Ezekowitz MD et al. *Eur Heart J*. April 2018 doi:10.1093/eurheartj/ehy148 [Epub ahead of print]

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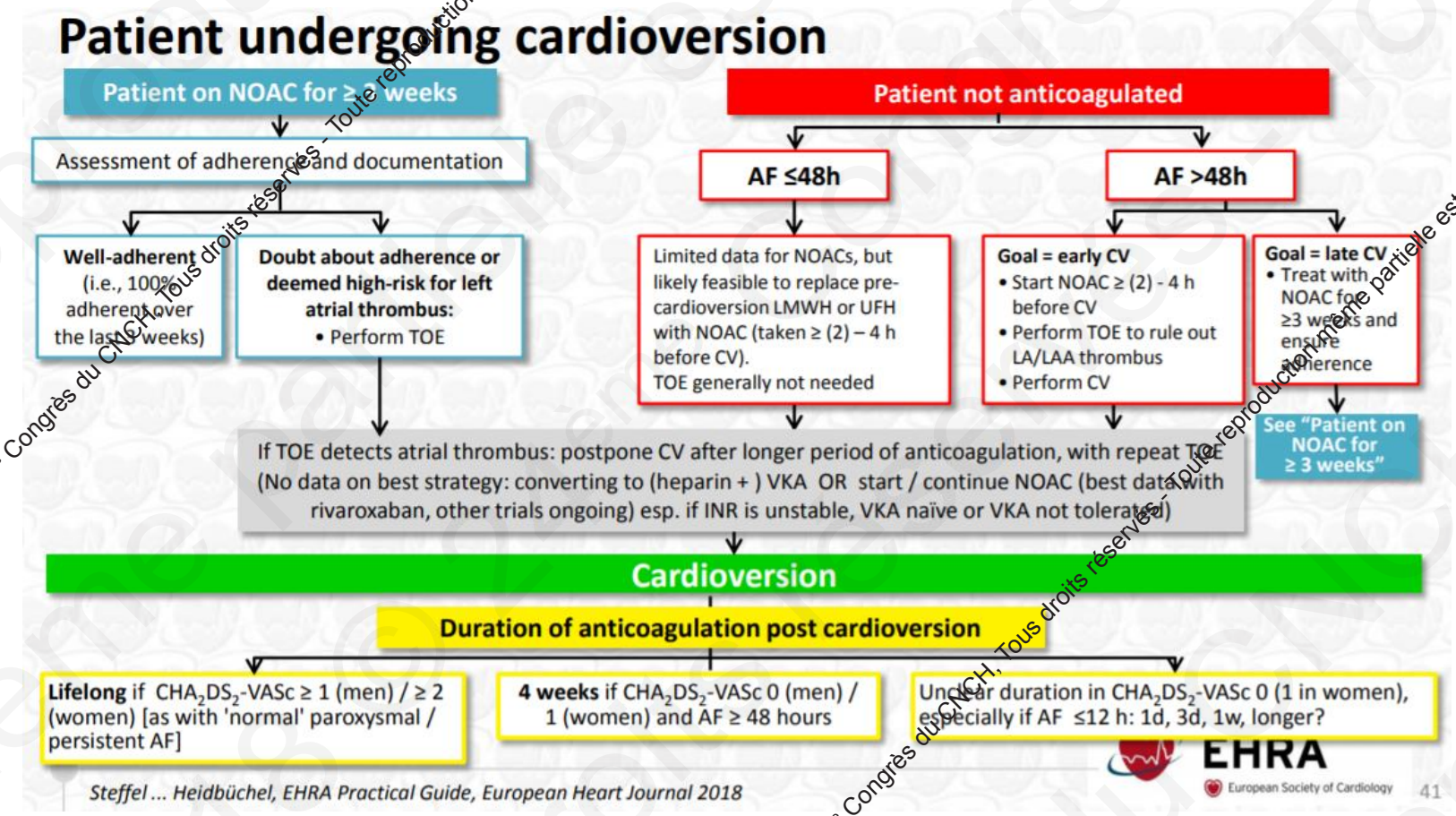
Consensus EHRA



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Pour Conclure

- L'implantation des PM et DAI ainsi que les explorations EP et ablations simples présentent un risque hémorragique modérés
  - Pas de prise le matin
  - Eviter les relais +++
- Les ablations complexes (FA+++) peuvent désormais être réalisées sous AOD
  - Arrêt 12h avant et reprise 3 à 5h après
  - Tenir compte des facteurs de modulation (expérience, ETO, CHADS…)
- La cardioversion électrique externe
  - Les AOD sont validés (schéma précoce et différé)
  - Place de l'ETO précisée

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