FA:
Quoi faire quand on ne peut plus anticoaguler?

Montréal, 21 septembre 2018

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Adult Congenital Heart Disease Center
Montreal Heart Institute, Université de Montréal

Conflits d’intérêt

- Bourses de recherche:
    - ✓ Boston Scientific

- Honoraires/consultants:
    - ✓ Boston Scientific
    - ✓ Medtronic
    - ✓ Abbott
    - ✓ Servier
    - ✓ Boehringer
    - ✓ Bayer

Objectifs

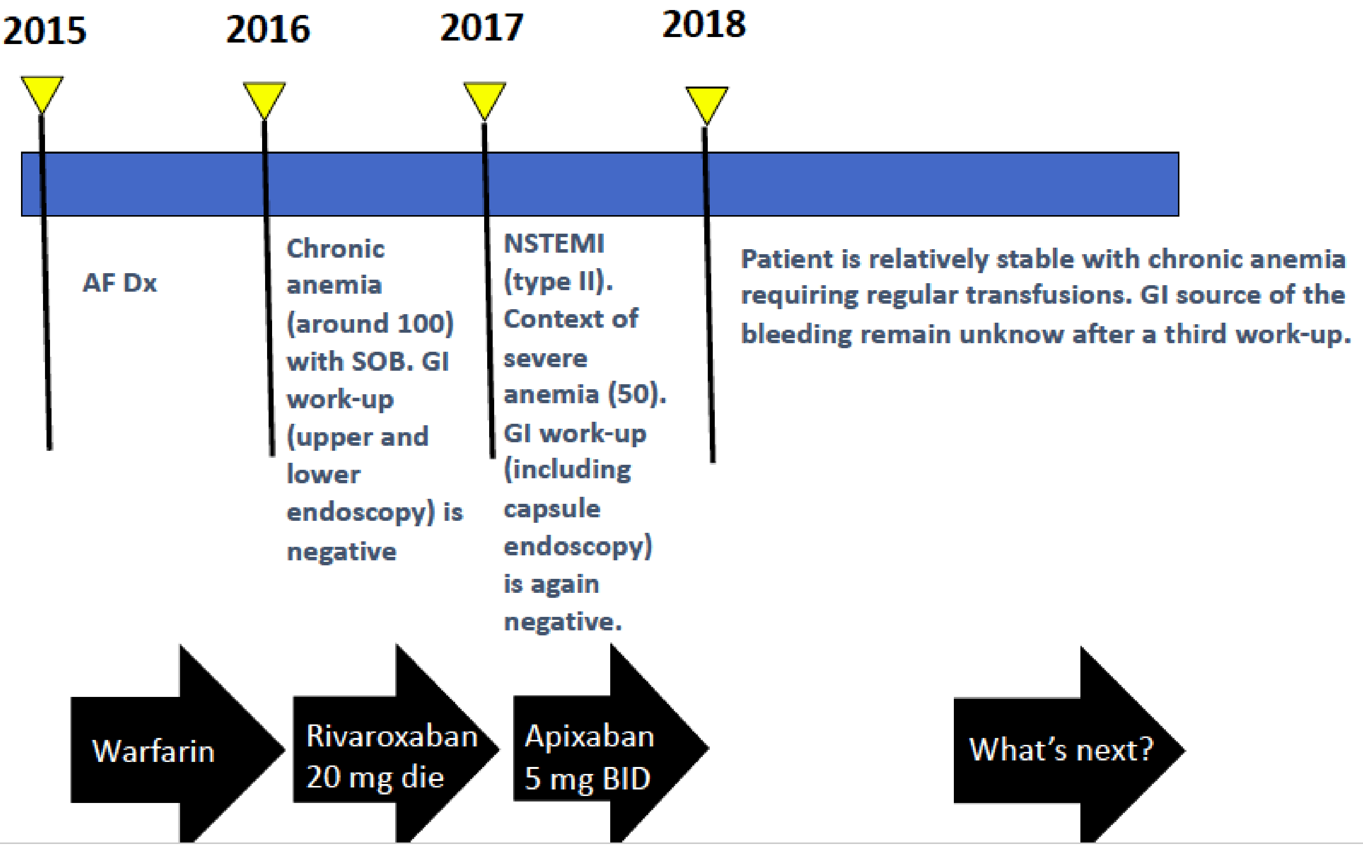
- Connaître les options prévenant l'AVC pour la FA pour le patient non « anticoagulable »
- Savoir sélectionner le patient pour les approches invasives et comment référer en spécialité
- Comprendre l'essentiel de la technique et le suivi requis dans la communauté.

Cas Clinique n1

- Homme de 76 ans
- FA non valvulaire
- Diabète, HTA contrôlée, coronarien
- Fonction rénale normale (GFR>60)

Cas Clinique n1

Case #1 – Sequence of events



2015

AF Dx

2016

Chronic anemia (around 100) with SOB. GI work-up (upper and lower endoscopy) is negative

2017

NSTEMI (type II). Context of severe anemia (50). GI work-up (including capsule endoscopy) is again negative.

2018

Patient is relatively stable with chronic anemia requiring regular transfusions. GI source of the bleeding remain unknow after a third work-up.

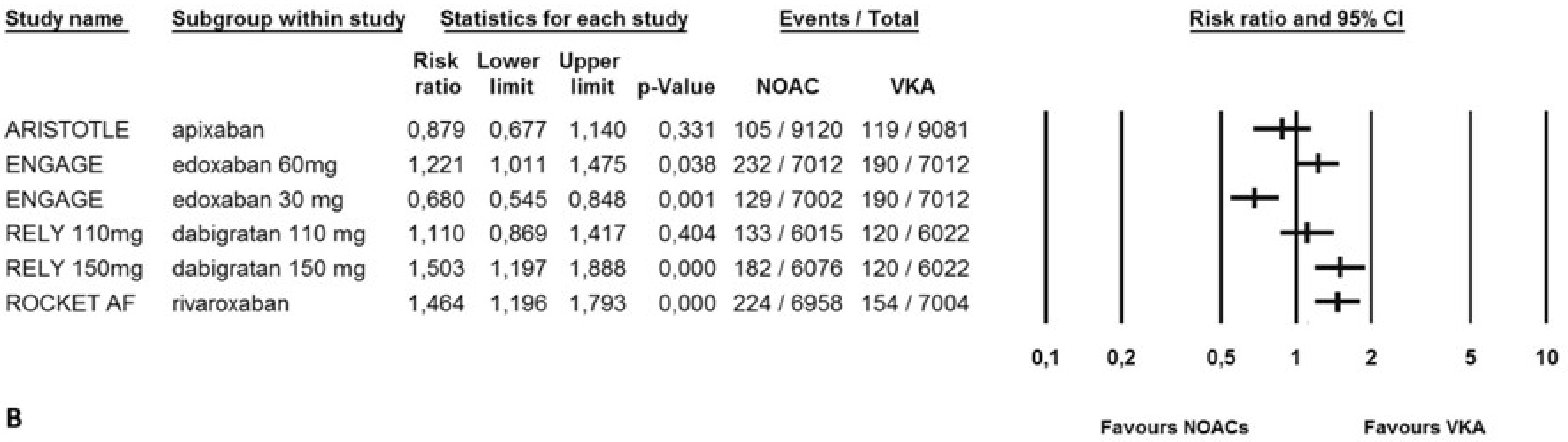
Warfarin

Rivaroxaban 20 mg die

Apixaban 5 mg BID

What's next?

Saignements digestifs



Study name	Subgroup within study	Risk ratio	Lower limit	Upper limit	p-Value	NOAC	VKA
ARISTOTLE	apixaban	0,879	0,677	1,140	0,331	105 / 9120	119 / 9081
ENGAGE	edoxaban 60mg	1,221	1,011	1,475	0,038	232 / 7012	190 / 7012
ENGAGE	edoxaban 30 mg	0,680	0,545	0,848	0,001	129 / 7002	190 / 7012
RELY 110mg	dabigratan 110 mg	1,110	0,869	1,417	0,404	133 / 6015	120 / 6022
RELY 150mg	dabigratan 150 mg	1,503	1,197	1,888	0,000	182 / 6076	120 / 6022
ROCKET AF	rivaroxaban	1,464	1,196	1,793	0,000	224 / 6958	154 / 7004

Statistics for each study
Events / Total
Risk ratio and 95% CI
0,1
0,2
0,5
1
2
5
10
B
Favours NOACs
Favours VKA

Apixaban = no more GI bleeding than warfarin (12% less, p=NS)

Dabigatran 150 BID and rivaroxaban 20 mg die = at least 40% more GI bleeding than warfarin (p=signif)

Edoxaban 60 mg die = + 20% (p=NS)

L. Loffredo et al. / Digestive and Liver Disease 47 (2015)

Cas Clinique n1

Recommanderiez-vous une fermeture d'appendice auriculaire?

A. Oui

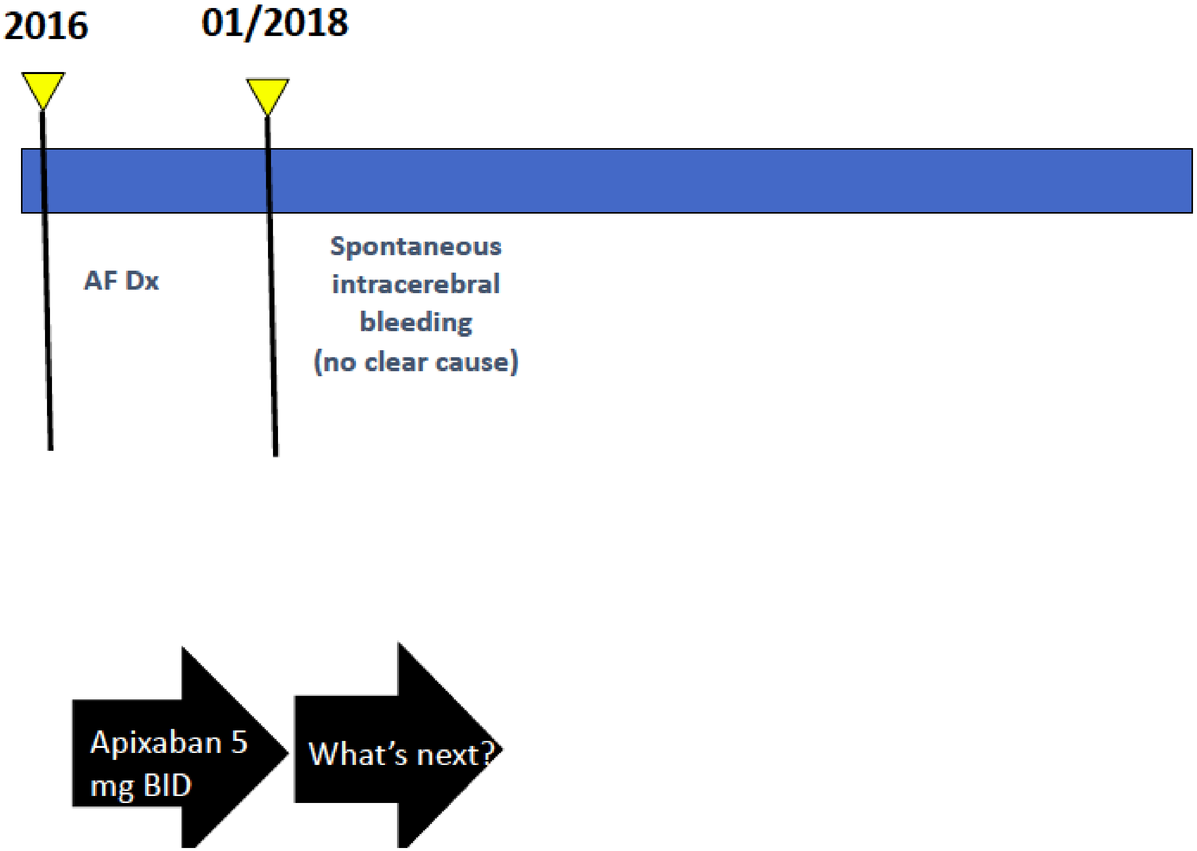
B. Non

Cas Clinique n2

- Homme de 72 ans
- HTA
- FA non valvulaire
- GFR>60

Cas Clinique n2

Case #2 – Sequence of events



2016

01/2018

AF Dx

Spontaneous intracerebral bleeding (no clear cause)

Apixaban 5 mg BID

What’s next?

Cas Clinique n2

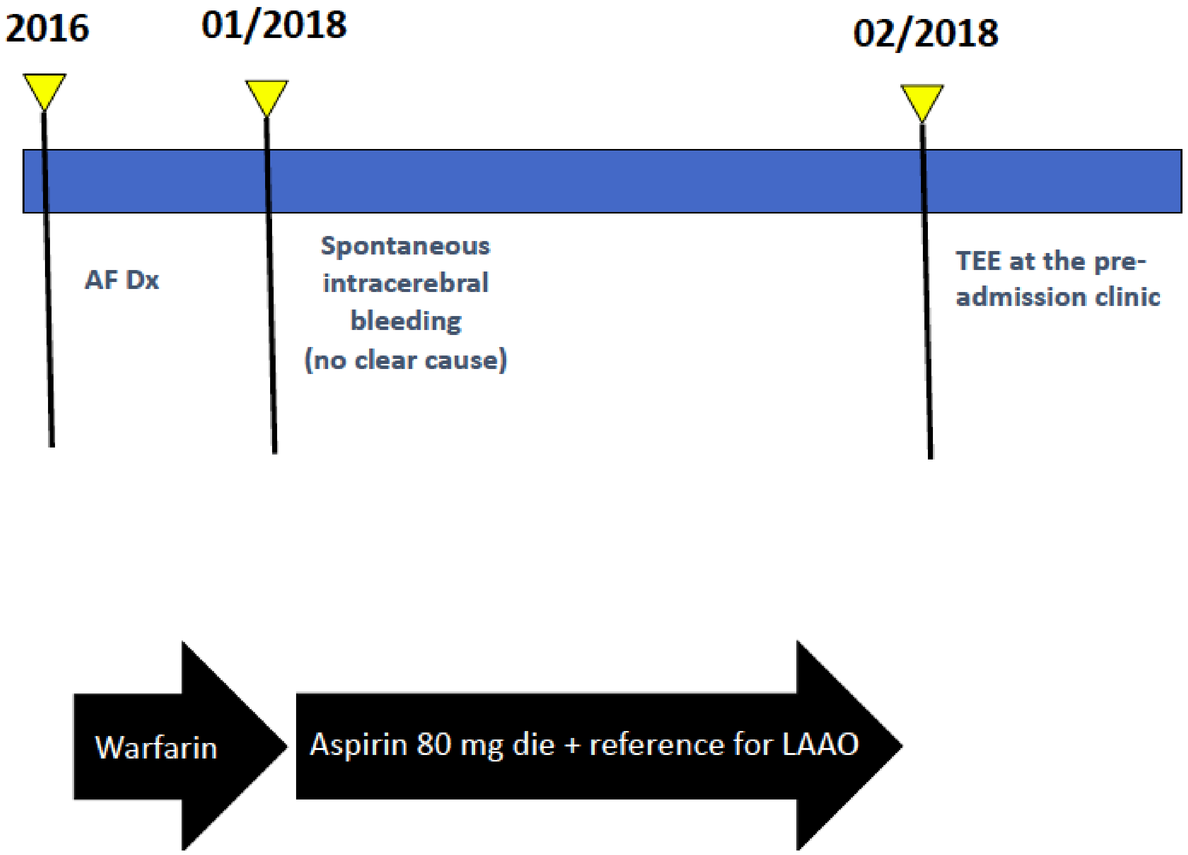
A. Je ré-anticoagule le patient (patient réfractaire)

B. J’arrête l’anticoagulation sans fermer l’appendice auriculaire

C. J’arrête l’anticoagulation et réfère la patient pour fermeture de l’appendice auricualaire

Cas Clinique n2

Case #2 – Sequence of events



2016

01/2018

02/2018

AF Dx

Spontaneous intracerebral bleeding (no clear cause)

TEE at the pre-admission clinic

Warfarin

Aspirin 80 mg die + reference for LAAO

Thrombus

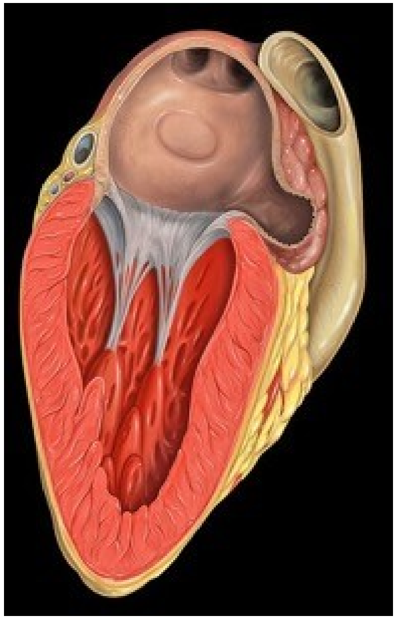
Localisation du Thrombus dans la FA non-valulaire: 91% (201/222) LAA

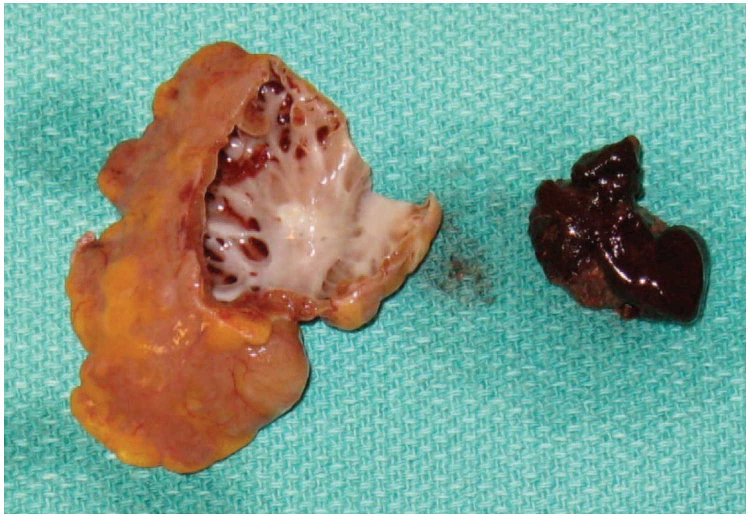
Setting	N	Appendage	%	LA Body	%	Reference
TEE	317	66	21	1	0.3	Stoddard; JACC, 1995
TEE	233	34	15	1	0.4	Manning; Circ, 1994
Autopsy	506	35	7	12	2.4	Aberg; Acta Med Scan, 1969
TEE	52	2	4	2	3.8	Tsai; JFMA, 1990
TEE	48	12	25	1	2.1	Klein; Int J Card Image, 1993
TEE & Operation	171	8	5	3	1.8	Manning; Circ, 1994
SPAF III TEE	359	19	5	1	0.3	Klein; Circ, 1994
TEE	272	19	7	0	0.0	Leung; JACC, 1994
TEE	60	6	10	0	0.0	Hart; Stroke, 1994
Total Thrombus		**201**		**21**		

Blackshear JL and Odell JA, Ann Thorac Surg 1996

Thrombus

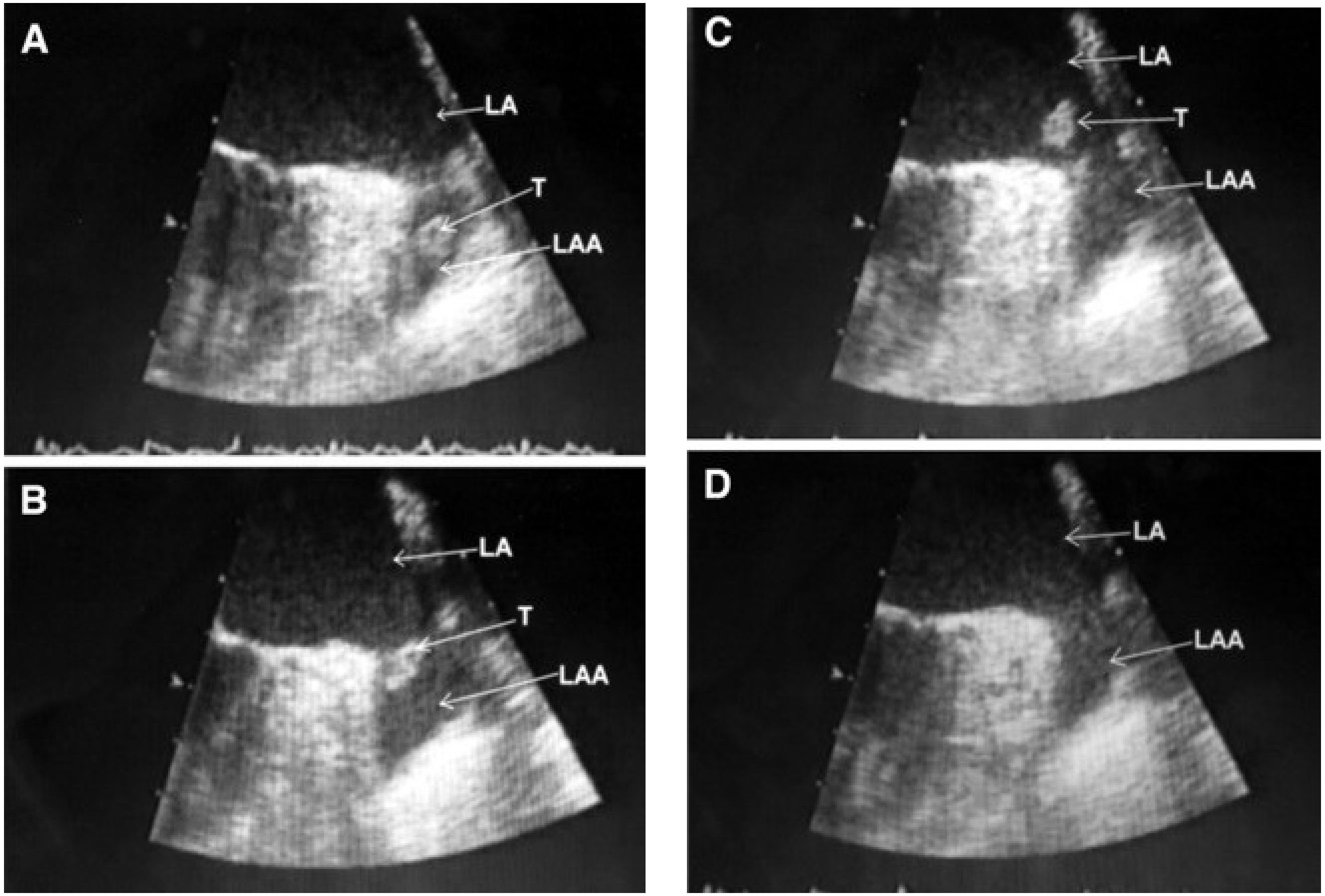
Le caillot qui se forme dans l'auricule est souvent volumineux = AVC significatif





Blackshear JL and Odell JA, Ann Thorac Surg 1996

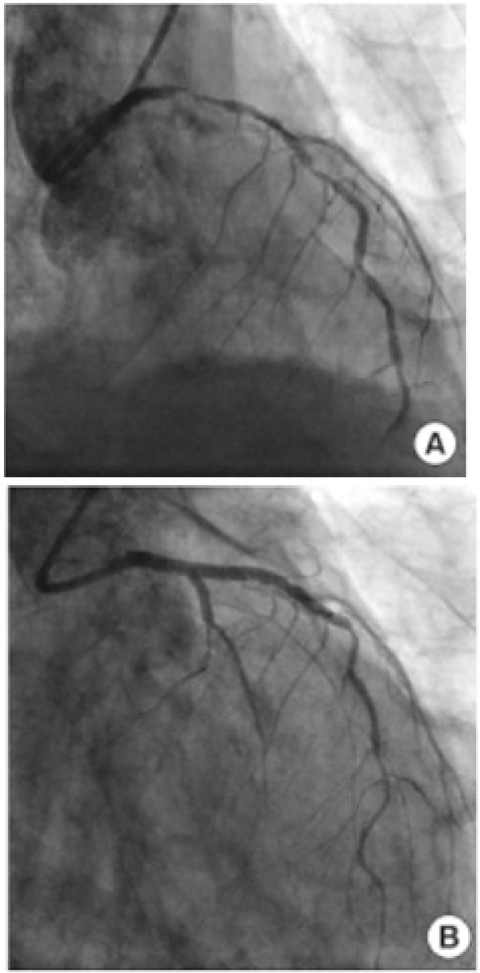
Migration d’un thrombus de l’AAG


A
LA
T
LAA
B
LA
T
LAA
C
LA
T
LAA
D
LA
LAA

Parekh A et al. Circulation 2006;114:e513-e514

Cas Clinique n3

- Femme de 77 ans
- STEMI avec DES sur IVA
- Diabète, tabagisme actif
- FA sous Rivaroxaban 20mg
- Fonction rénale normale (GFR>60)



Cas Clinique n3

Quel traitement?

A. ASA+CLOPIDOGREL+OAC

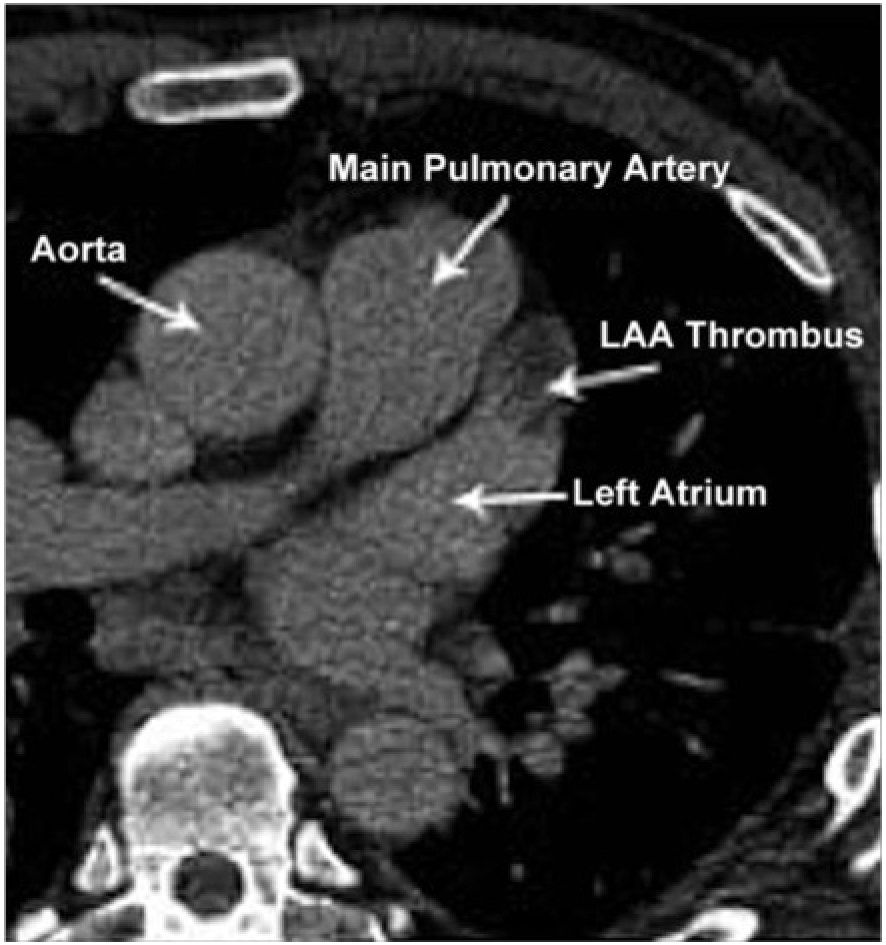
B. CLOPIDOGREL+OAC

C. Fermeture AAG pour permettre ASA+TICAGRELOR

Cas Clinique n4

- Femme de 83 ans
- Référée pour TAVI
- FA permanente sous Apixaban 2.5mg BID
- Coronarienne, diabète, hypertension
- Insuffisance rénale chronique

Cas Clinique n4


Main Pulmonary Artery
Aorta
LAA Thrombus
Left Atrium

Cas Clinique n4

Quelle est l'incidence d'un thrombus dans l'AAGau CT scan chez les patients référés pour TAVI?

A. <5%

B. >10%

C. Pas de relation avec des VAC périprocéduraux

Cas Clinique n4

Quelle est l'incidence d'un thrombus dans l'AAGau CT scan chez les patients référés pour TAVI?

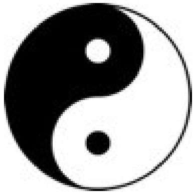
A. <5%

B. >10%: 11% chez tous les patients, 32% chez les patients en FA

C. Pas de relation avec des VAC périprocéduraux

J Am Coll Cardiol Intv 2017;10:176–84

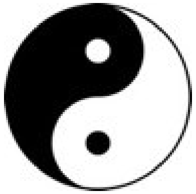
Limitations des DOACs



- Risque intrinsèque de saignement
- Compliance
- Coût
- Prescription limitée par la fonction rénale
- Pas d'antidote sauf pour le dabigatran…

EMERGENCY USE ONLY
ANTIDOTE LOCKER

Limitations des DOACs



- Risque intrinsèque de saignement
- Compliance
- Coût
- Prescription limitée par la fonction rénale
- ~~Pas d'antidote sauf pour le dabigatran…~~

EMERGENCY USE ONLY
ANTIDOTE LOCKER

Impact du saignement

- Symptômes chroniques: fatigue, anémie, insuffisance cardiaque
- Hospitalisations
- Transfusions
- Coût et risques des tests

Les patients les plus à risque

- ATCD d’hémorragie cérébrale
- Angiopathie amyloïde cérébrale, micro-saignements cérébraux
- Cirrhose, saignements digestifs récurrents (angiodysplasie, source inconnue, post radiation)
- Insuffisance rénale sous dialyse, hématurie récidivante (tumeur)
- Rendu-Osler-Weber

Procédure fermeture d'AG

Développée comme alternative à l'ACO chez les patients avec

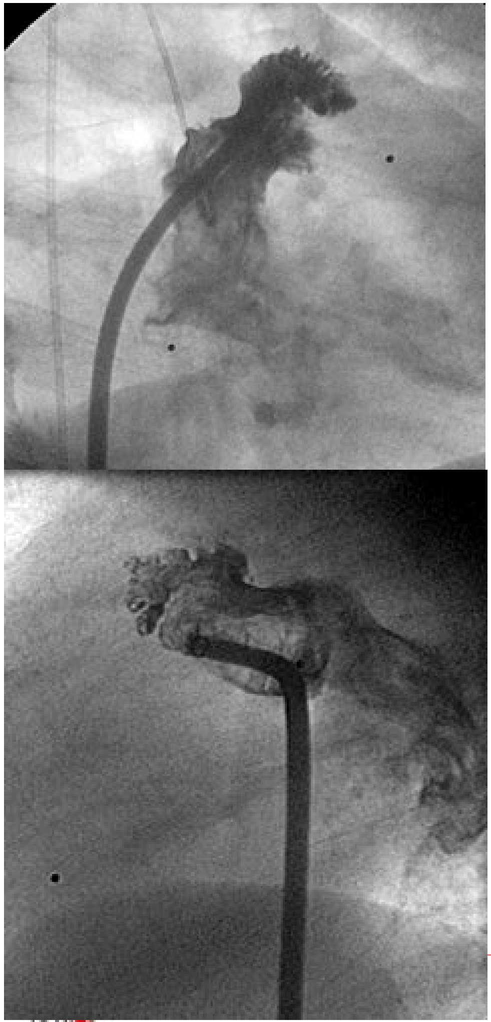
- FA non valvulaire à risque d'événements thrombo-emboliques (CHADS $\geq$1)
- qui ne tolèrent pas l'anticoagulation ou qui sont à haut risque de saignement

Options pour exclusion d’auricule

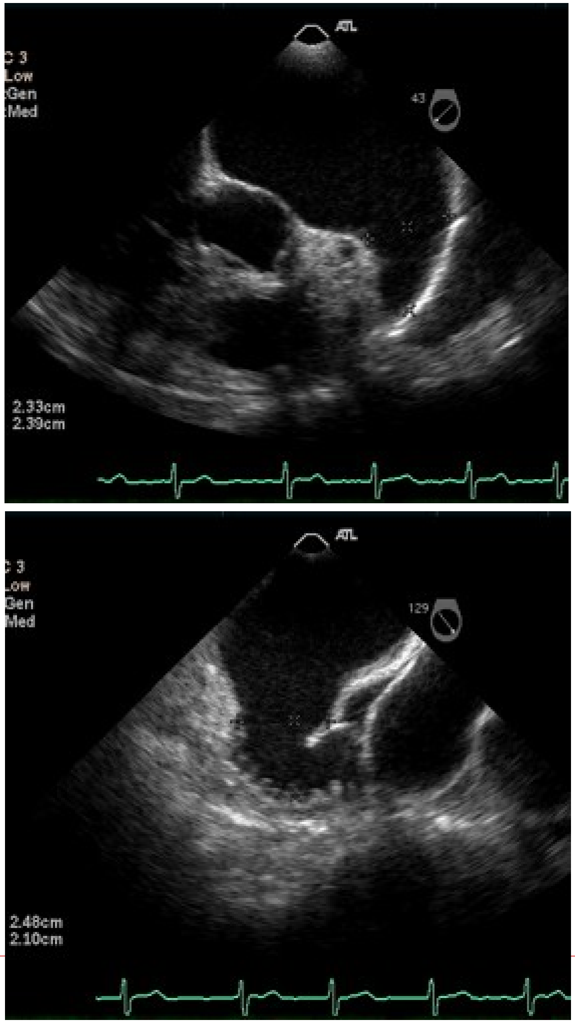
- Chirurgie
- Approches percutannées
  - ✓ Méthodes endocavitaires avec installation de prothèses
  - ✓ Méthodes extra-cardiaques avec installation de suture (LARIAT)

Université de Montréal

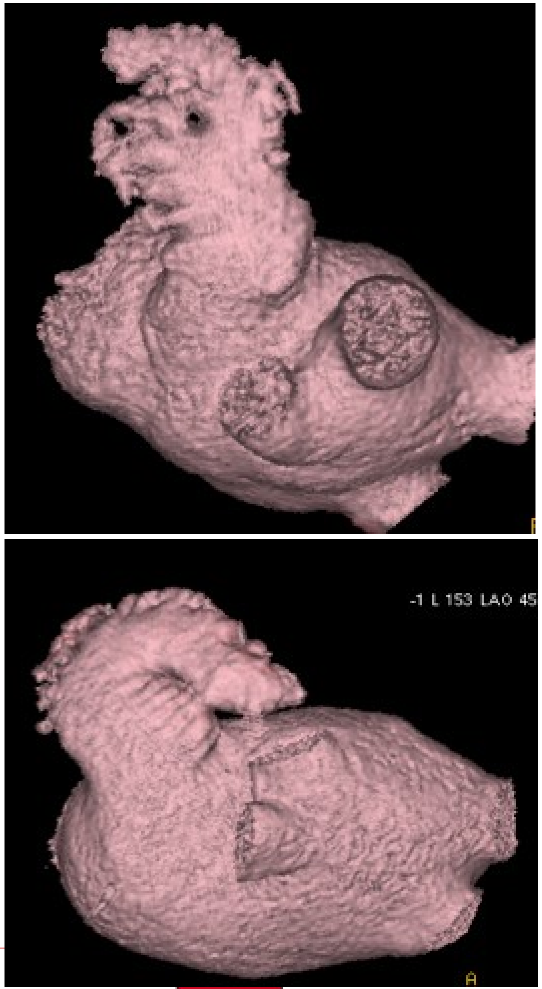
Différentes formes d'AAG



Fluoro


ATL
C 3
Low
Gen
Med
43
2.33cm
2.39cm
ATL
C 3
Low
Gen
Med
129
2.48cm
2.10cm

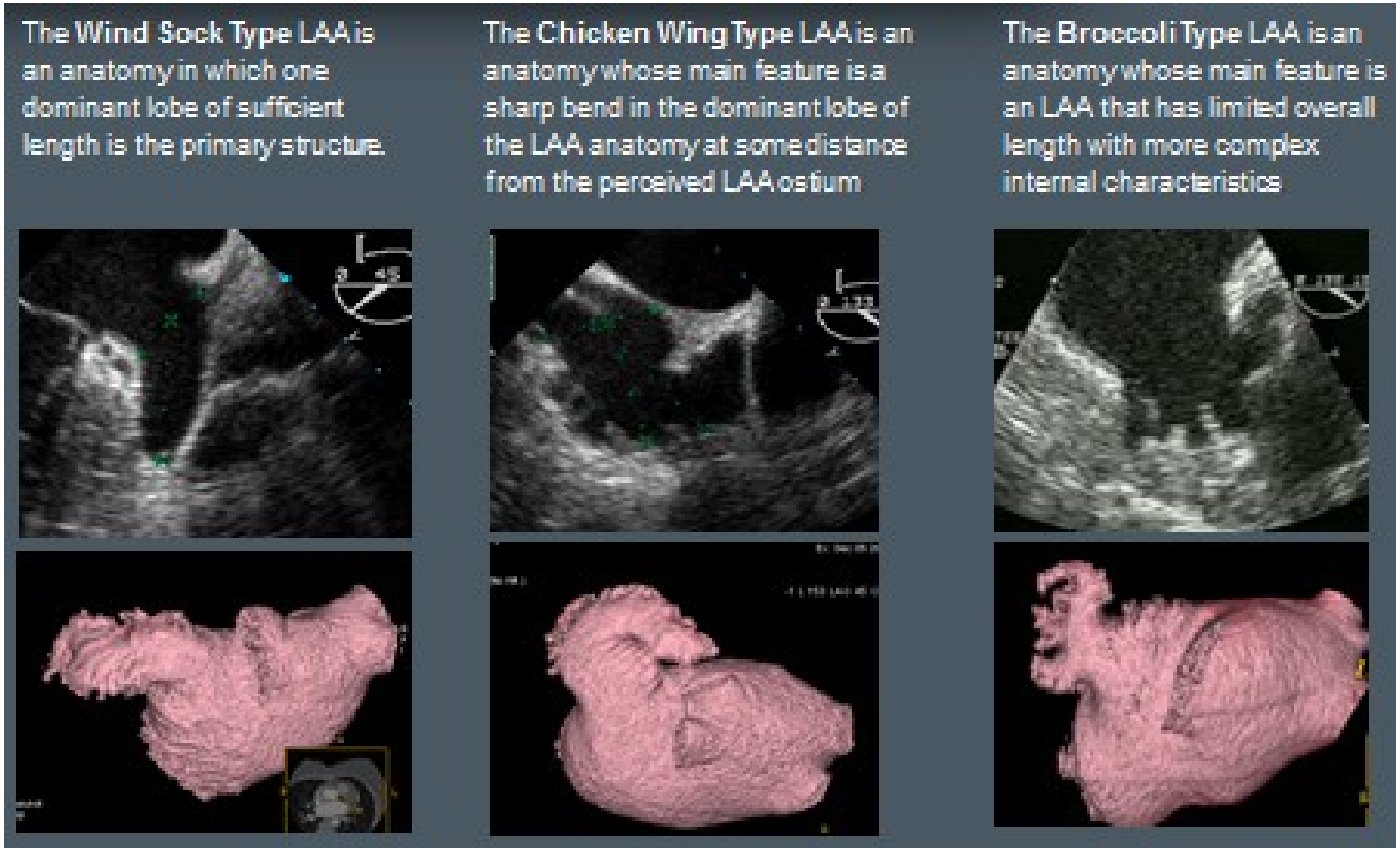
TEE


-1 L 153 LAO 45

CT

INSTITUT DE CARDIOLOGIE DE MONTRÉAL

Différentes formes d'AAG



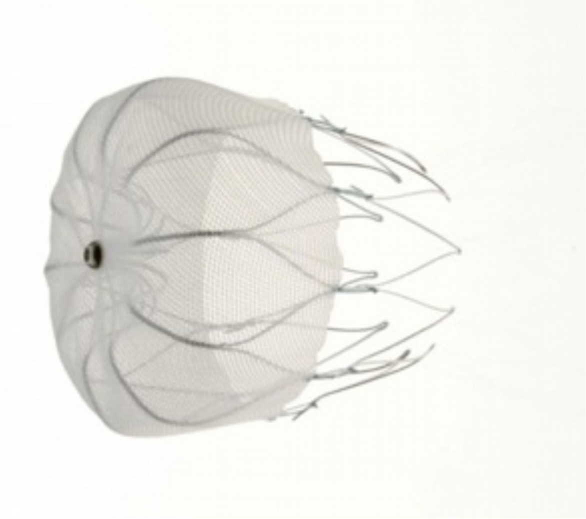
The **Wind Sock Type** LAA is an anatomy in which one dominant lobe of sufficient length is the primary structure.

The **Chicken Wing Type** LAA is an anatomy whose main feature is a sharp bend in the dominant lobe of the LAA anatomy at some distance from the perceived LAA ostium

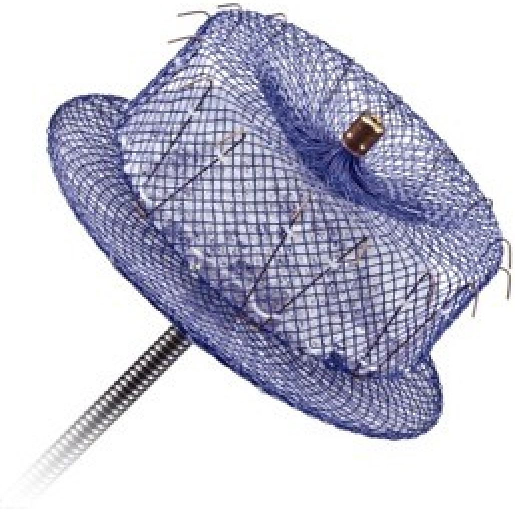
The **Broccoli Type** LAA is an anatomy whose main feature is an LAA that has limited overall length with more complex internal characteristics

Prothèses intra-cardiaques

- Watchman (Atritech ▭ Boston Scientifics)
- AMPLATZER Cardiac Plug - Amulet (2è génération (AGA ▭ St-Jude Medical ▭ Abbott)

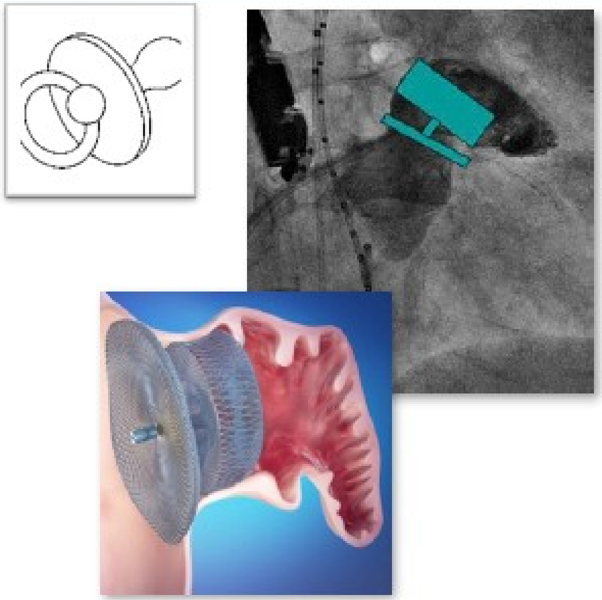


CE mark since 2005
FDA approved since March 2015



CE mark since 2008
FDA approved since 2017

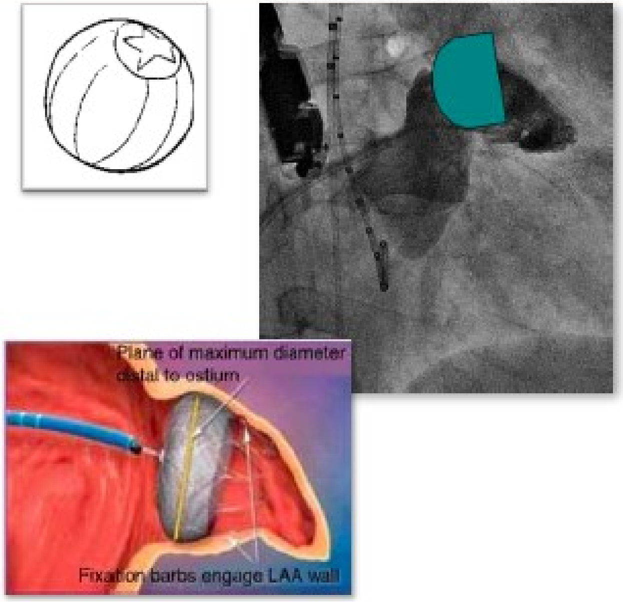
Même but, philosophie différente



AMPLATZER Amulet

(Abbott)

"pacifier principle"[1]


Plane of maximum diameter
distal to ostium
Fixation barbs engage LAA wall

Watchman

(Boston Scientific)

"half football principle"[2]

Park at CSI 2011. "Current Status of Left Atrial Appendage Closure Devices – Amplatzer ACP Occluder", Frankfurt, June 23-25, 2011.

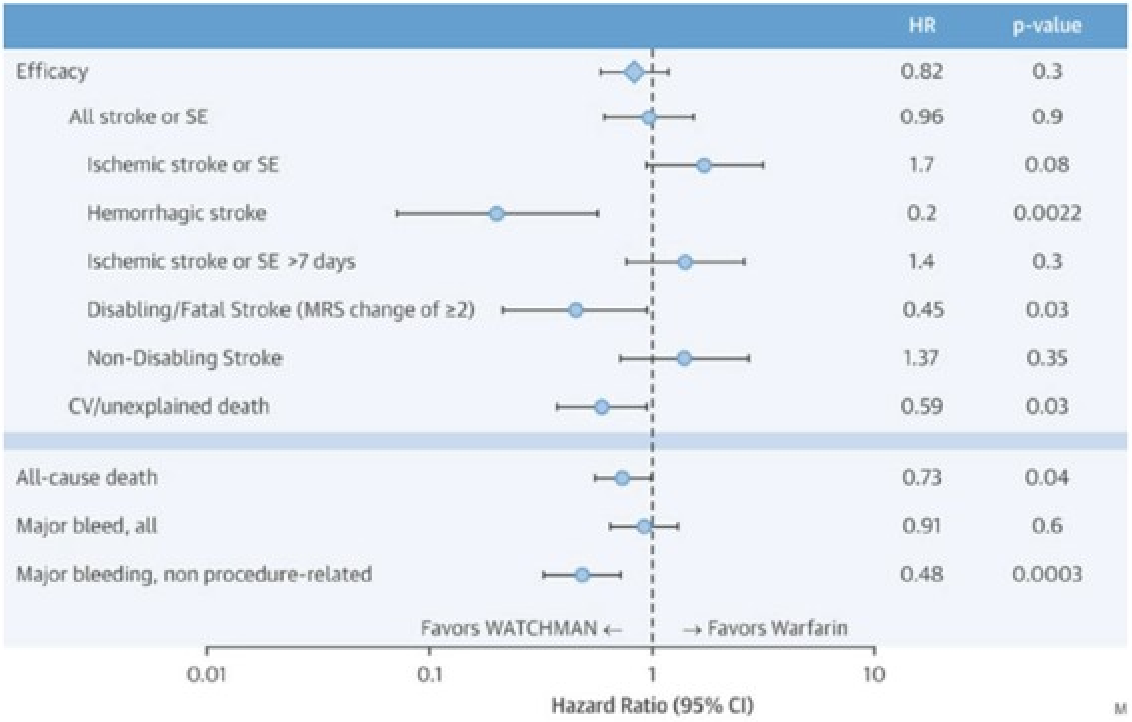
Bénéfices

- Chez des patients NON ELIGIBLE à l'anticoagulation
  - ✓ Réduction de 80% du risque d'AVC hémorragique à 5 ans
  - ✓ Etudes randomisées WATCHMAN contre warfarine: PROTECT-AF et PREVAIL

Vivek Y. Reddy et al. JACC 2017

Bénéfices

Long-Term (5 years) Patient-Level Meta-Analysis of PROTECT AF and PREVAIL



	HR	p-value
Efficacy	0.82	0.3
All stroke or SE	0.96	0.9
Ischemic stroke or SE	1.7	0.08
Hemorrhagic stroke	0.2	0.0022
Ischemic stroke or SE >7 days	1.4	0.3
Disabling/Fatal Stroke (MRS change of ≥2)	0.45	0.03
Non-Disabling Stroke	1.37	0.35
CV/unexplained death	0.59	0.03
All-cause death	0.73	0.04
Major bleed, all	0.91	0.6
Major bleeding, non procedure-related	0.48	0.0003

Vivek Y. Reddy et al. JACC 2017;j.jacc.2017.10.021

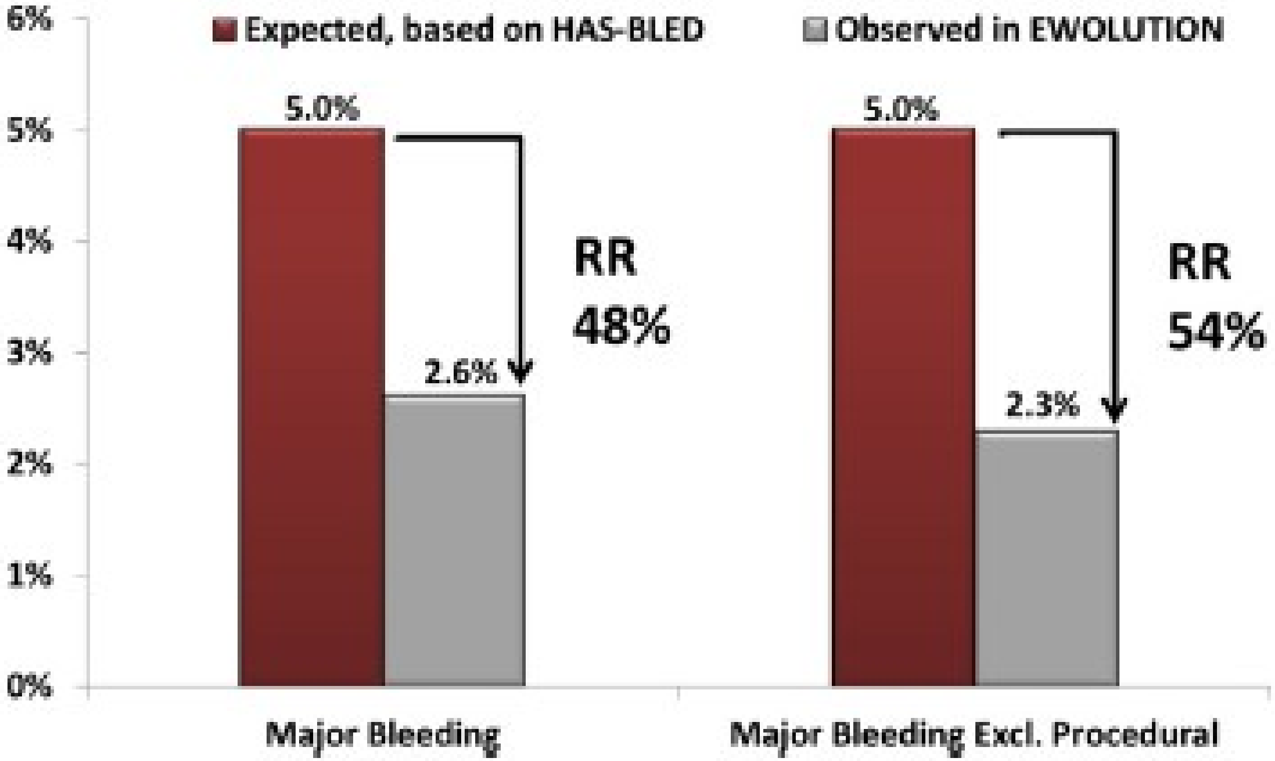


Figure 4 Actual major bleeding rate excluding procedural bleeding events, and calculated major bleeding risk based on HAS-BLED score, and the relative risk reduction for the total EWOLUTION patient cohort after 1-year follow-up. RR = relative risk; SE = systemic embolism; TIA = transient ischemic attack.

Boersma L, HR 2017

Bénéfices

- Chez des patients NON ELIGIBLE à l’anticoagulation

  - ✓ Réduction de 60% du risque attendu d’AVC et d’embolies systémiques

  - ✓ Registres: ASAP et EWOLUTION, ACP et AMULET

Vivek Y. Reddy et al. JACC 2017

Comparaison des registres

	ACP Registry[1]	Watchman EWOLUTION[2]	Amulet (Current Study)
Implant Success	97.3%	98.5%	98.8%
LAA Closure Rate (1-3 months) $\leq$ 5 mm	98.1%	99.3%	100.0%
Device or Procedure-Related Complications	5.0%	2.7%	2.7%
Early Mortality	0.8% (30-day)	0.7% (30-day)	0.3% (7-day)

[1] Tzikas et al. *EuroIntervention.* 2015;10
[2] Boersma et al. *Eur Heart J*. 2016 Aug;37(31):2465-74

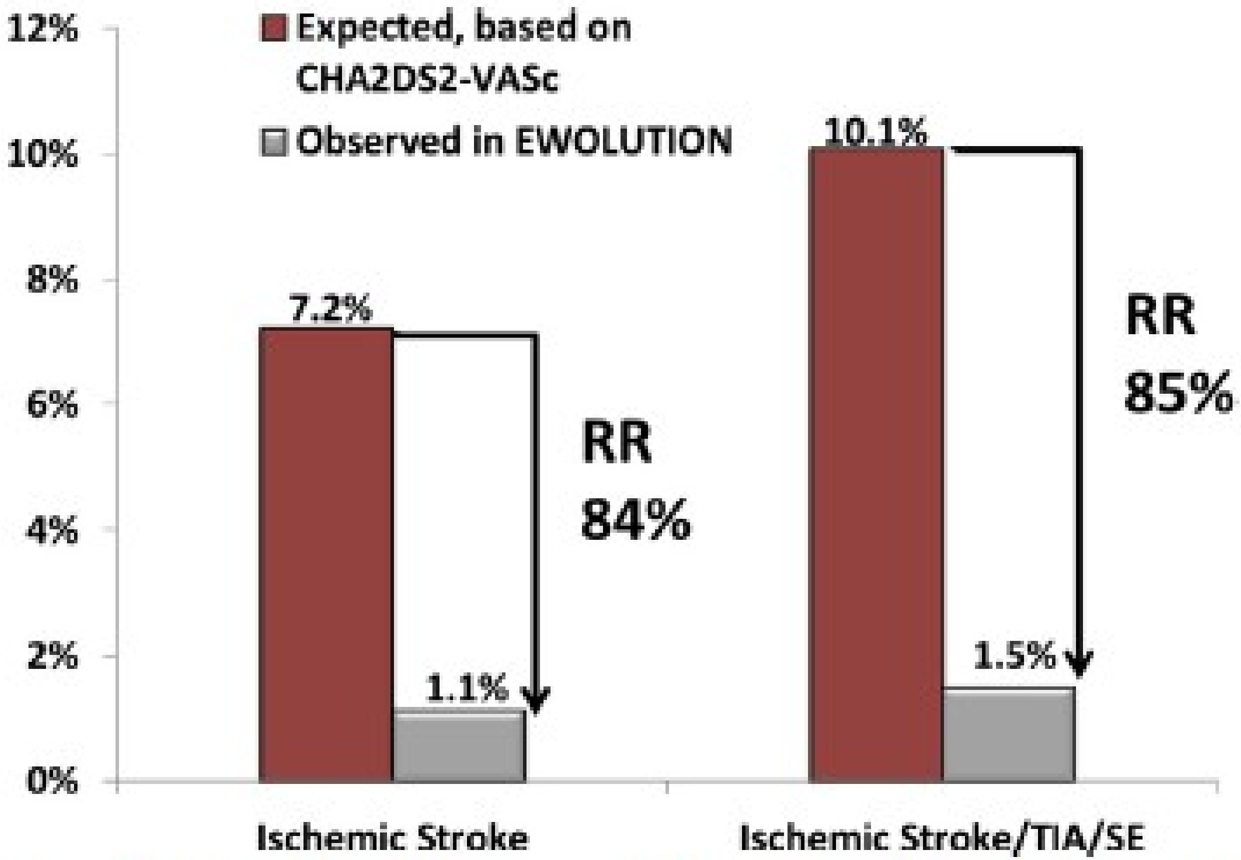


Figure 3 Actual stroke rate, and calculated stroke risk based on CHA_2DS_2-VASc score, and the relative risk reduction for the total EWOLUTION patient cohort after 1-year follow-up. RR = relative risk; SE = systemic embolism; TIA = transient ischemic attack.

Boersma L, HR 2017

Expérience Canadienne

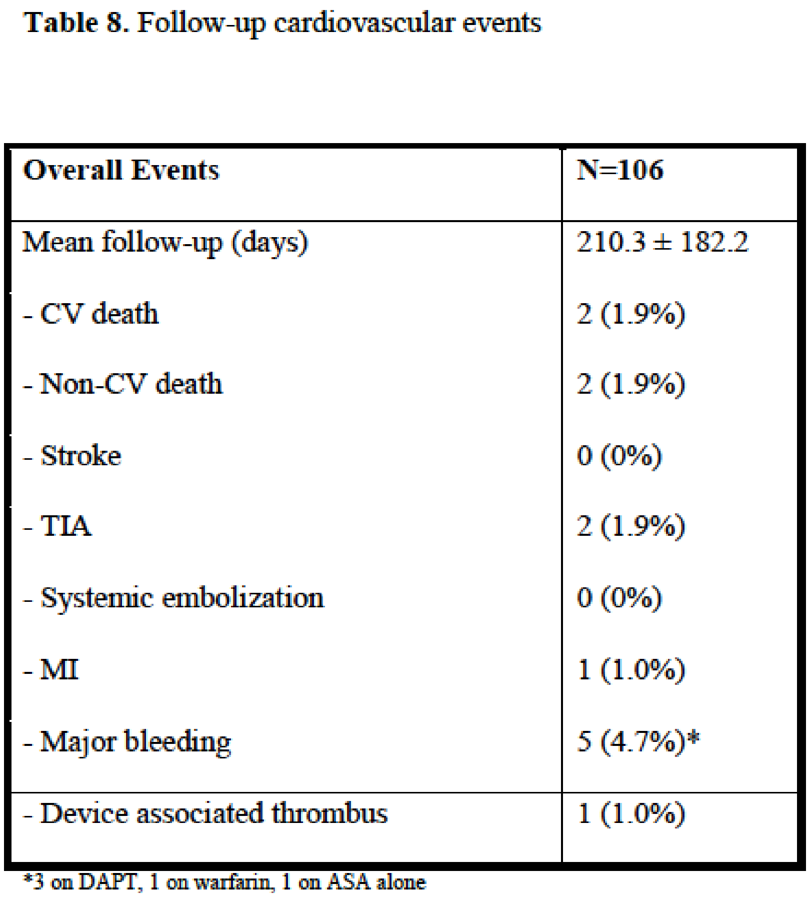


Table 8. Follow-up cardiovascular events

Overall Events	**N=106**
Mean follow-up (days)	210.3 ± 182.2
- CV death	2 (1.9%)
- Non-CV death	2 (1.9%)
- Stroke	0 (0%)
- TIA	2 (1.9%)
- Systemic embolization	0 (0%)
- MI	1 (1.0%)
- Major bleeding	5 (4.7%)*
- Device associated thrombus	1 (1.0%)

*3 on DAPT, 1 on warfarin, 1 on ASA alone

Saw J, JCE 2017

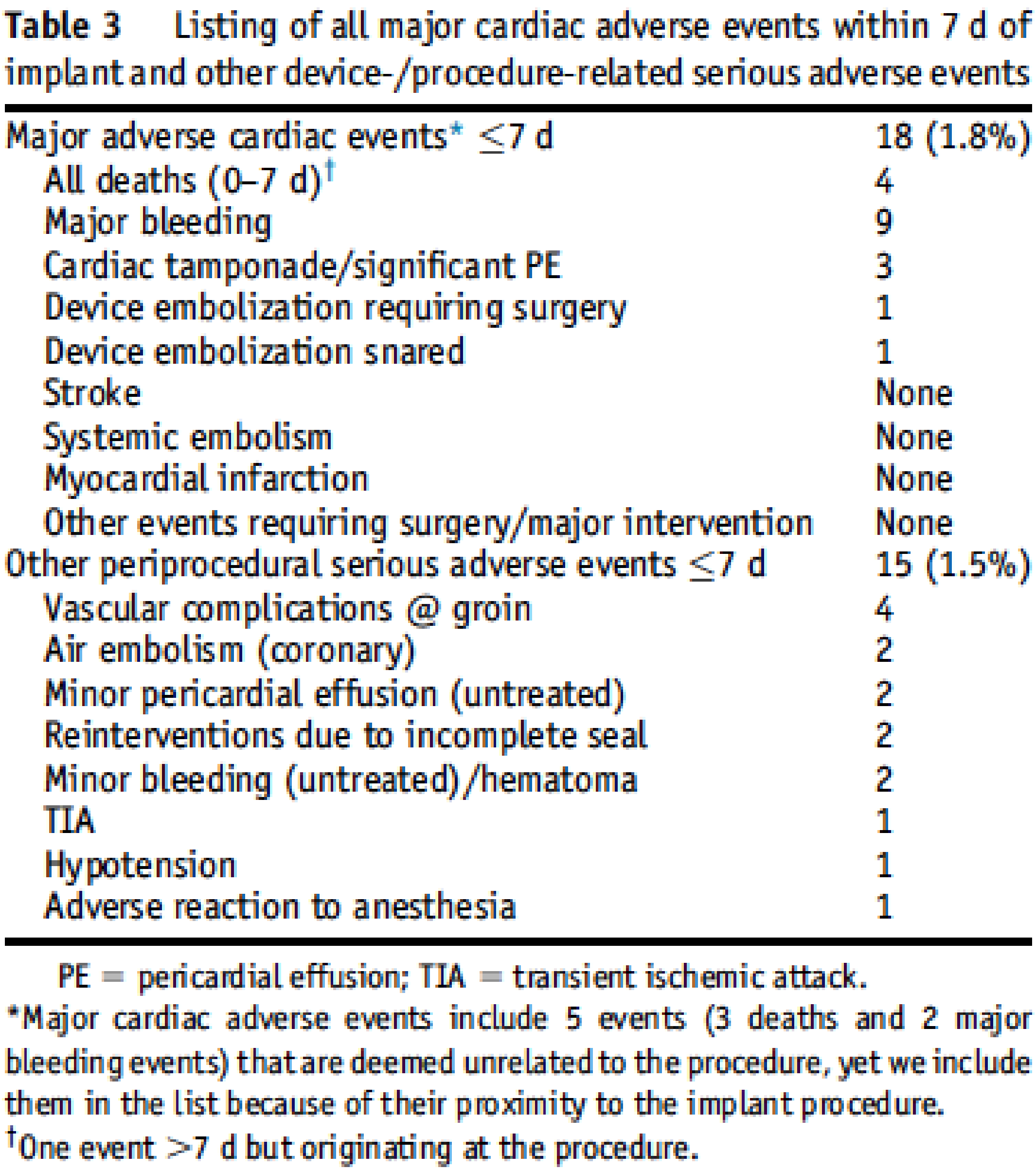


Table 3 Listing of all major cardiac adverse events within 7 d of implant and other device-/procedure-related serious adverse events

Major adverse cardiac events* ≤7 d	18 (1.8%)
All deaths (0–7 d)†	4
Major bleeding	9
Cardiac tamponade/significant PE	3
Device embolization requiring surgery	1
Device embolization snared	1
Stroke	None
Systemic embolism	None
Myocardial infarction	None
Other events requiring surgery/major intervention	None
Other periprocedural serious adverse events ≤7 d	15 (1.5%)
Vascular complications @ groin	4
Air embolism (coronary)	2
Minor pericardial effusion (untreated)	2
Reinterventions due to incomplete seal	2
Minor bleeding (untreated)/hematoma	2
TIA	1
Hypotension	1
Adverse reaction to anesthesia	1

PE = pericardial effusion; TIA = transient ischemic attack.

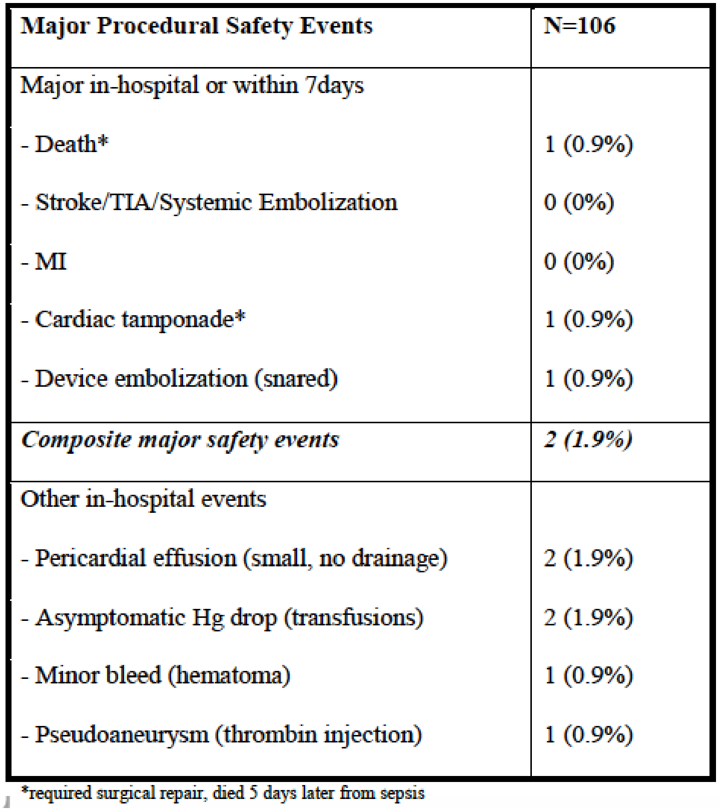
*Major cardiac adverse events include 5 events (3 deaths and 2 major bleeding events) that are deemed unrelated to the procedure, yet we include them in the list because of their proximity to the implant procedure.

†One event >7 d but originating at the procedure.

Boersma L, HR 2017

Expérience Canadienne

Table 7. Major procedural safety events

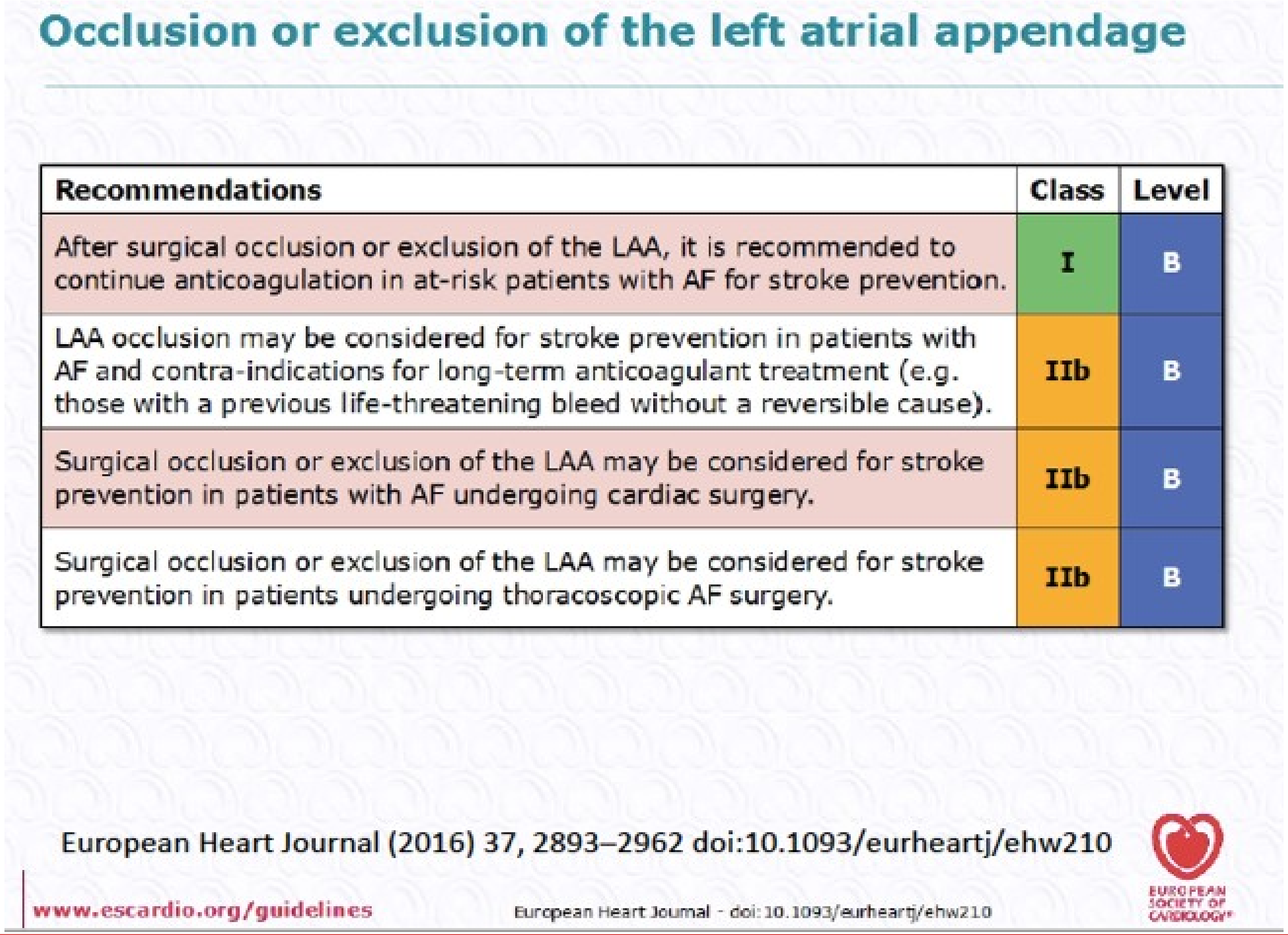


Major Procedural Safety Events	**N=106**
Major in-hospital or within 7days	
- Death*	1 (0.9%)
- Stroke/TIA/Systemic Embolization	0 (0%)
- MI	0 (0%)
- Cardiac tamponade*	1 (0.9%)
- Device embolization (snared)	1 (0.9%)
Composite major safety events	***2 (1.9%)***
Other in-hospital events	
- Pericardial effusion (small, no drainage)	2 (1.9%)
- Asymptomatic Hg drop (transfusions)	2 (1.9%)
- Minor bleed (hematoma)	1 (0.9%)
- Pseudoaneurysm (thrombin injection)	1 (0.9%)

*required surgical repair, died 5 days later from sepsis

Saw J, JCE 2017

ESC Guidelines FA



Occlusion or exclusion of the left atrial appendage

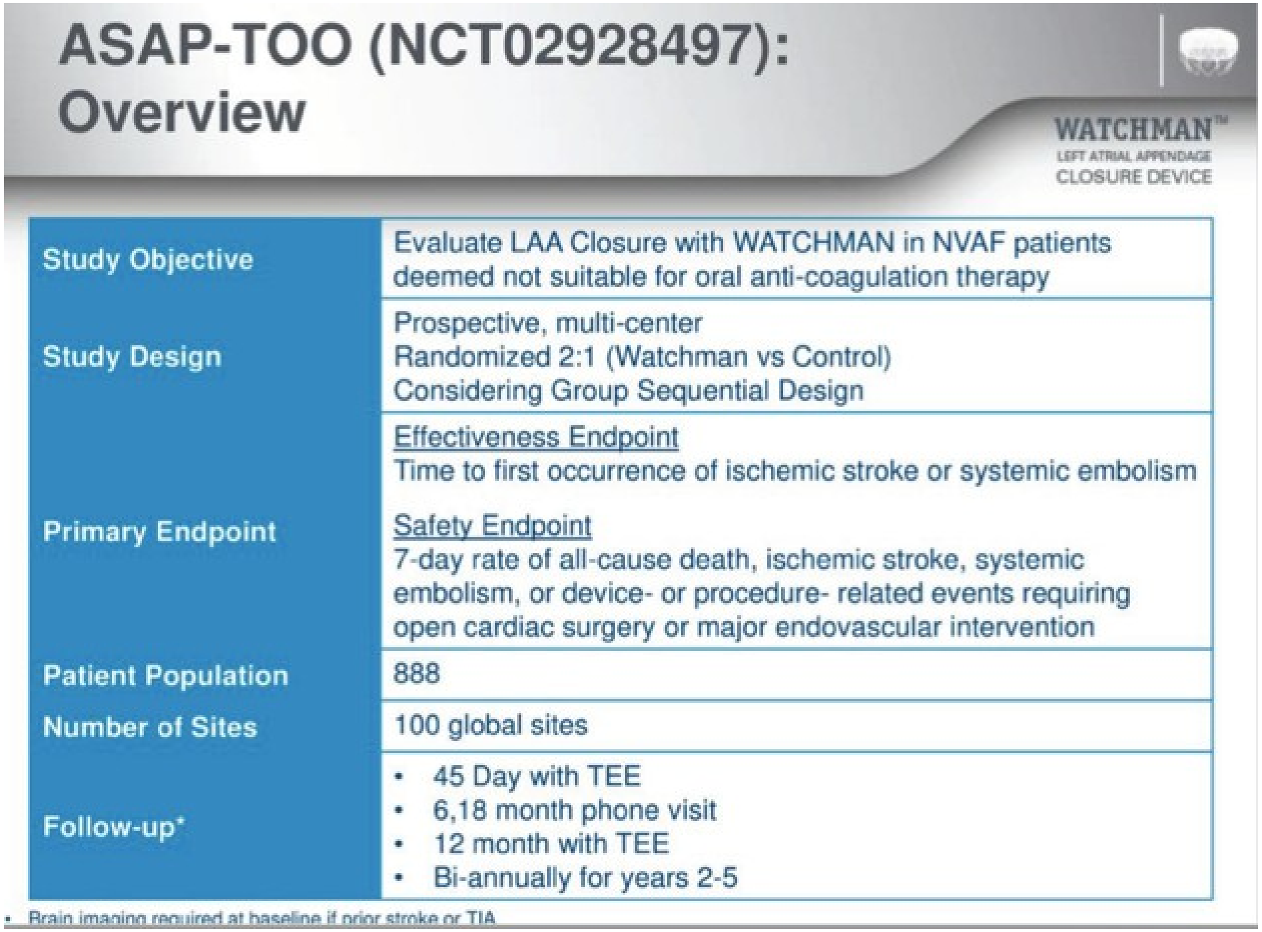
Recommendations	Class	Level
After surgical occlusion or exclusion of the LAA, it is recommended to continue anticoagulation in at-risk patients with AF for stroke prevention.	I	B
LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term anticoagulant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

European Heart Journal (2016) 37, 2893–2962 doi:10.1093/eurheartj/ehw210

www.escardio.org/guidelines

European Heart Journal - doi:10.1093/eurheartj/ehw210

Etudes à venir



ASAP-TOO (NCT02928497): Overview

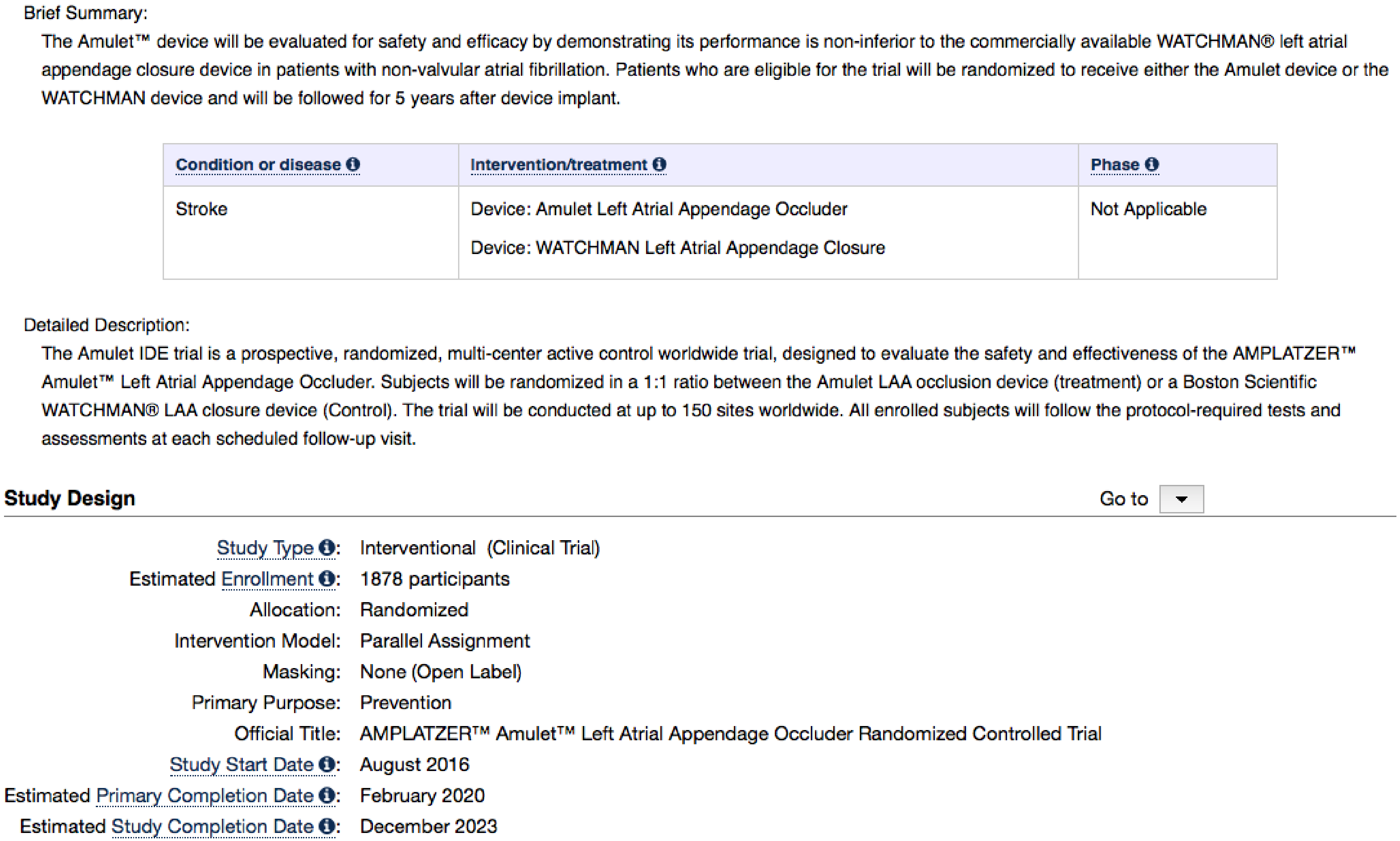
WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Study Objective	Evaluate LAA Closure with WATCHMAN in NVAF patients deemed not suitable for oral anti-coagulation therapy
Study Design	Prospective, multi-center Randomized 2:1 (Watchman vs Control) Considering Group Sequential Design
Primary Endpoint	Effectiveness Endpoint Time to first occurrence of ischemic stroke or systemic embolism Safety Endpoint 7-day rate of all-cause death, ischemic stroke, systemic embolism, or device- or procedure- related events requiring open cardiac surgery or major endovascular intervention
Patient Population	888
Number of Sites	100 global sites
Follow-up*	• 45 Day with TEE • 6,18 month phone visit • 12 month with TEE • Bi-annually for years 2-5

- Brain imaging required at baseline if prior stroke or TIA

Am Heart J. 2017 Jul; 189:68-74

AMULET IDE TRIAL



Brief Summary:

The Amulet™ device will be evaluated for safety and efficacy by demonstrating its performance is non-inferior to the commercially available WATCHMAN® left atrial appendage closure device in patients with non-valvular atrial fibrillation. Patients who are eligible for the trial will be randomized to receive either the Amulet device or the WATCHMAN device and will be followed for 5 years after device implant.

Condition or disease	Intervention/treatment	Phase
Stroke	Device: Amulet Left Atrial Appendage Occluder Device: WATCHMAN Left Atrial Appendage Closure	Not Applicable

Detailed Description:

The Amulet IDE trial is a prospective, randomized, multi-center active control worldwide trial, designed to evaluate the safety and effectiveness of the AMPLATZER™ Amulet™ Left Atrial Appendage Occluder. Subjects will be randomized in a 1:1 ratio between the Amulet LAA occlusion device (treatment) or a Boston Scientific WATCHMAN® LAA closure device (Control). The trial will be conducted at up to 150 sites worldwide. All enrolled subjects will follow the protocol-required tests and assessments at each scheduled follow-up visit.

Study Design

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	1878 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	AMPLATZER™ Amulet™ Left Atrial Appendage Occluder Randomized Controlled Trial
Study Start Date:	August 2016
Estimated Primary Completion Date:	February 2020
Estimated Study Completion Date:	December 2023

NCT02879448

Etudes à venir

LAOOS III Trial NCT01561651

(PI = Richard Whitlock, McMaster University)

- Surgical LAAC with suture and/or stapler or a regulatory approved device vs standard therapy
- Inclusion:
  - 1. Greater than 18 years of age
  - 2. Undergoing cardiac surgical procedures with the use of cardiopulmonary bypass
  - 3. Have a documented history of atrial fibrillation or atrial flutter
  - 4. CHA2DS2-VASc score ≥ 2
- Primary outcomes:
  - Stroke or systemic arterial embolism [Time Frame: Common termination point (median follow-up of 4 years)]
  - First occurrence of ischemic stroke or transient ischemic attack with positive neuroimaging or systemic arterial embolism

En pratique

- Le plus souvent chez patients dont l’anticoagulation a été cessée (pas de liste d’attente)

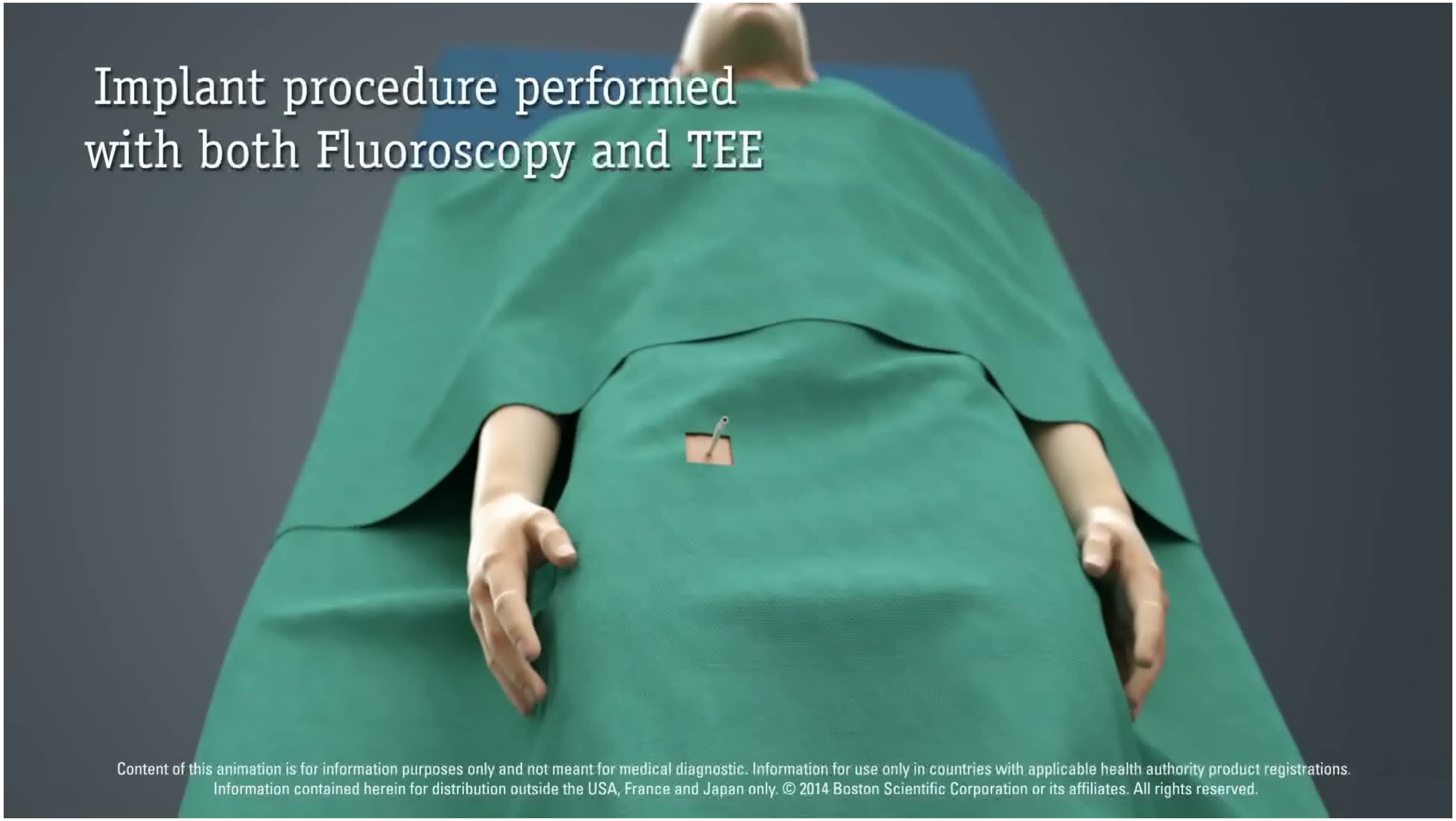
- ETO et/ou CT scanner quelques jours avant pour r/o un thrombus et définir l’anatomie

- Hospitalisation de courte durée

En pratique

- Sous anesthésie générale et guidance ETO
- Alternative = Anesthésie locale et ICE
- Ponction trans-septale – 40 cc de colorant

Procédure



Implant procedure performed with both Fluoroscopy and TEE

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Post-procédure

- ETO à 4-6 semaines pour exclure thrombus et/ou fuite résiduelle

- Prophylaxie de l'endocardite infectieuse

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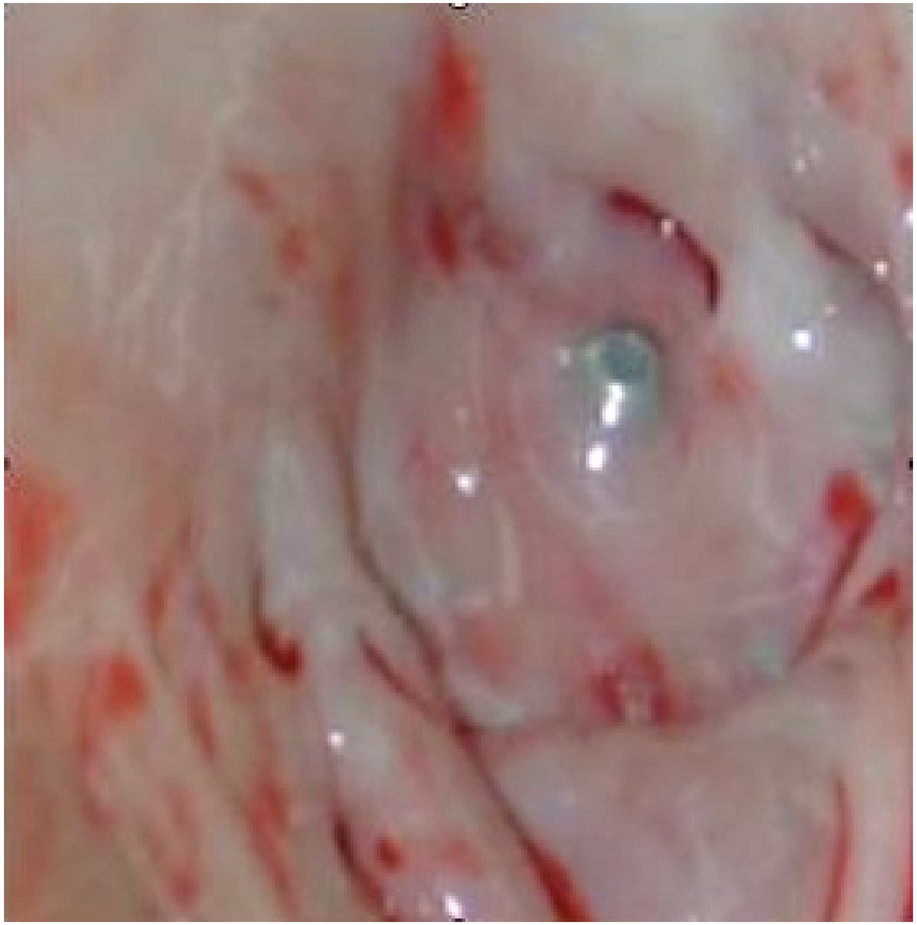

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Thrombus post-procédure

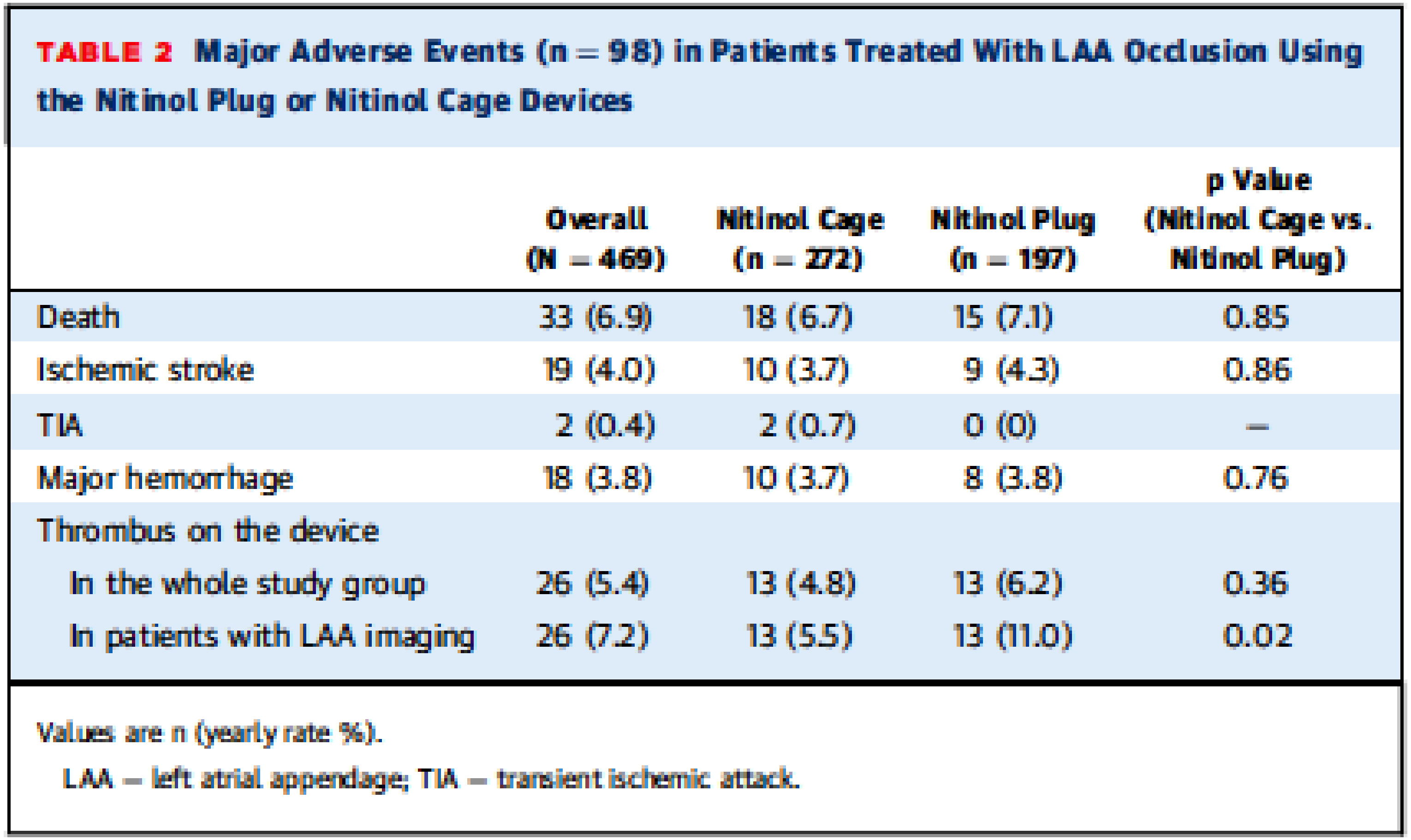

TABLE 2 Major Adverse Events (n = 98) in Patients Treated With LAA Occlusion Using the Nitinol Plug or Nitinol Cage Devices

	Overall (N = 469)	Nitinol Cage (n = 272)	Nitinol Plug (n = 197)	p Value (Nitinol Cage vs. Nitinol Plug)
Death	33 (6.9)	18 (6.7)	15 (7.1)	0.85
Ischemic stroke	19 (4.0)	10 (3.7)	9 (4.3)	0.86
TIA	2 (0.4)	2 (0.7)	0 (0)	–
Major hemorrhage	18 (3.8)	10 (3.7)	8 (3.8)	0.76
Thrombus on the device				
In the whole study group	26 (5.4)	13 (4.8)	13 (6.2)	0.36
In patients with LAA imaging	26 (7.2)	13 (5.5)	13 (11.0)	0.02

Values are n (yearly rate %).

LAA = left atrial appendage; TIA = transient ischemic attack.

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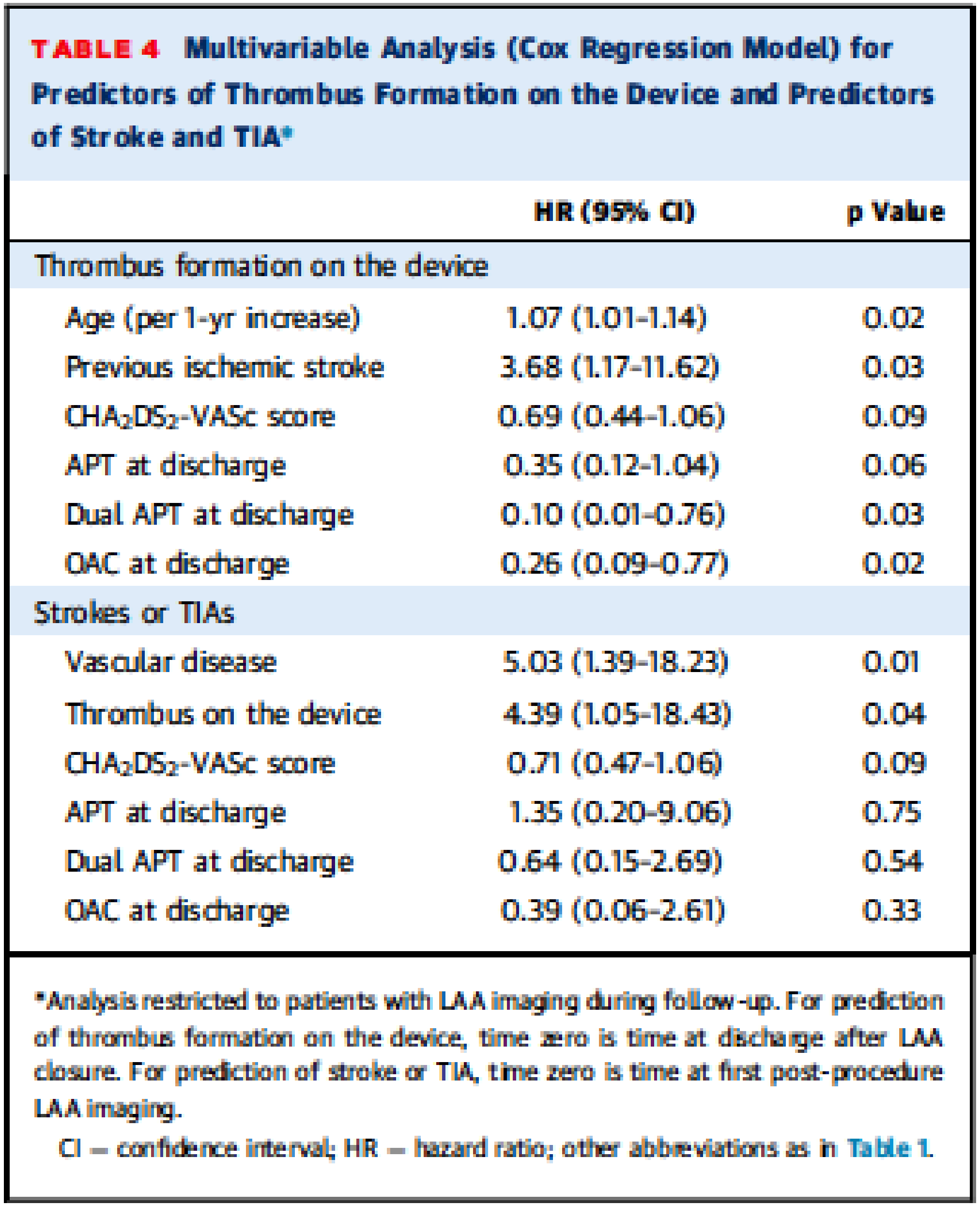

TABLE 4 **Multivariable Analysis (Cox Regression Model) for Predictors of Thrombus Formation on the Device and Predictors of Stroke and TIA***

	HR (95% CI)	p Value
Thrombus formation on the device		
Age (per 1-yr increase)	1.07 (1.01-1.14)	0.02
Previous ischemic stroke	3.68 (1.17-11.62)	0.03
CHA_2DS_2-VASc score	0.69 (0.44-1.06)	0.09
APT at discharge	0.35 (0.12-1.04)	0.06
Dual APT at discharge	0.10 (0.01-0.76)	0.03
OAC at discharge	0.26 (0.09-0.77)	0.02
Strokes or TIAs		
Vascular disease	5.03 (1.39-18.23)	0.01
Thrombus on the device	4.39 (1.05-18.43)	0.04
CHA_2DS_2-VASc score	0.71 (0.47-1.06)	0.09
APT at discharge	1.35 (0.20-9.06)	0.75
Dual APT at discharge	0.64 (0.15-2.69)	0.54
OAC at discharge	0.39 (0.06-2.61)	0.33

*Analysis restricted to patients with LAA imaging during follow-up. For prediction of thrombus formation on the device, time zero is time at discharge after LAA closure. For prediction of stroke or TIA, time zero is time at first post-procedure LAA imaging.

CI = confidence interval; HR = hazard ratio; other abbreviations as in Table 1.

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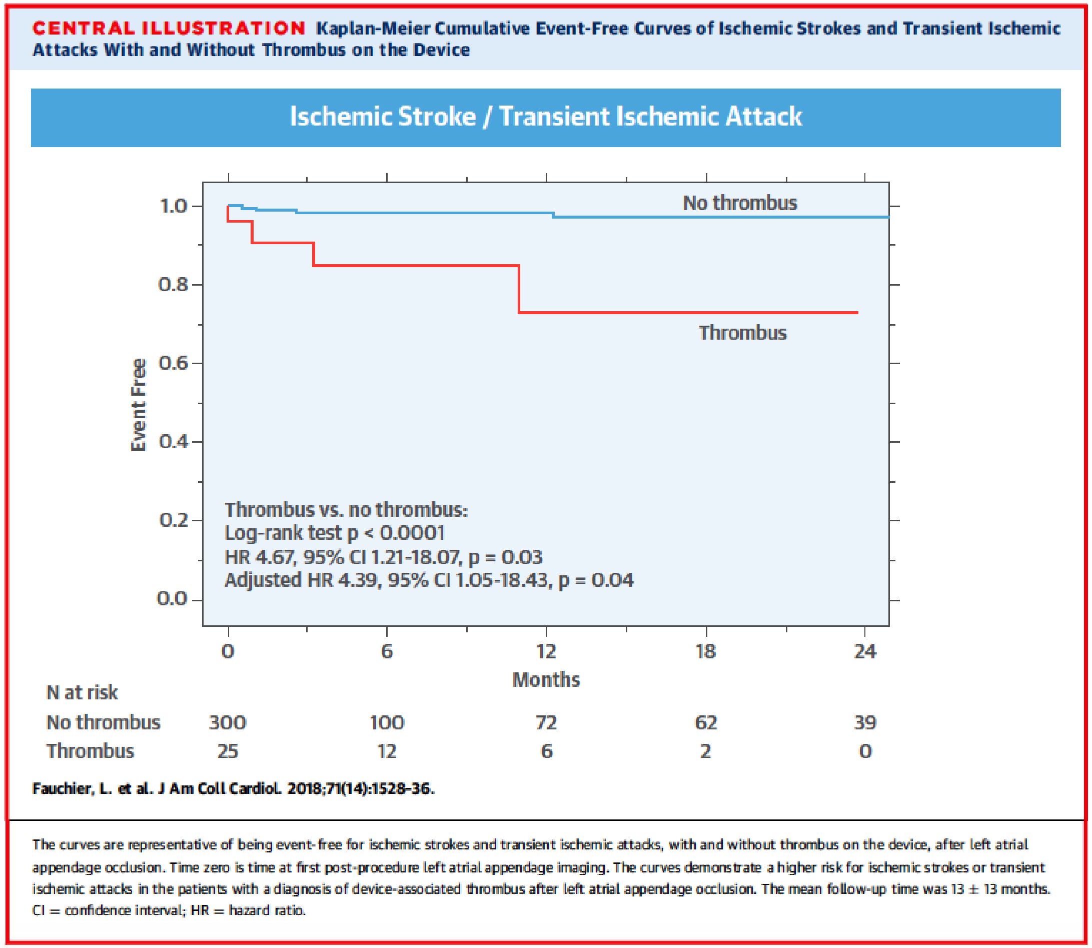
Thrombus post-procédure



CENTRAL ILLUSTRATION Kaplan-Meier Cumulative Event-Free Curves of Ischemic Strokes and Transient Ischemic Attacks With and Without Thrombus on the Device

Thrombus vs. no thrombus:
Log-rank test p < 0.0001
HR 4.67, 95% CI 1.21-18.07, p = 0.03
Adjusted HR 4.39, 95% CI 1.05-18.43, p = 0.04

N at risk	0	6	12	18	24
No thrombus	300	100	72	62	39
Thrombus	25	12	6	2	0

Fauchier, L. et al. J Am Coll Cardiol. 2018;71(14):1528-36.

The curves are representative of being event-free for ischemic strokes and transient ischemic attacks, with and without thrombus on the device, after left atrial appendage occlusion. Time zero is time at first post-procedure left atrial appendage imaging. The curves demonstrate a higher risk for ischemic strokes or transient ischemic attacks in the patients with a diagnosis of device-associated thrombus after left atrial appendage occlusion. The mean follow-up time was 13 ± 13 months. CI = confidence interval; HR = hazard ratio.

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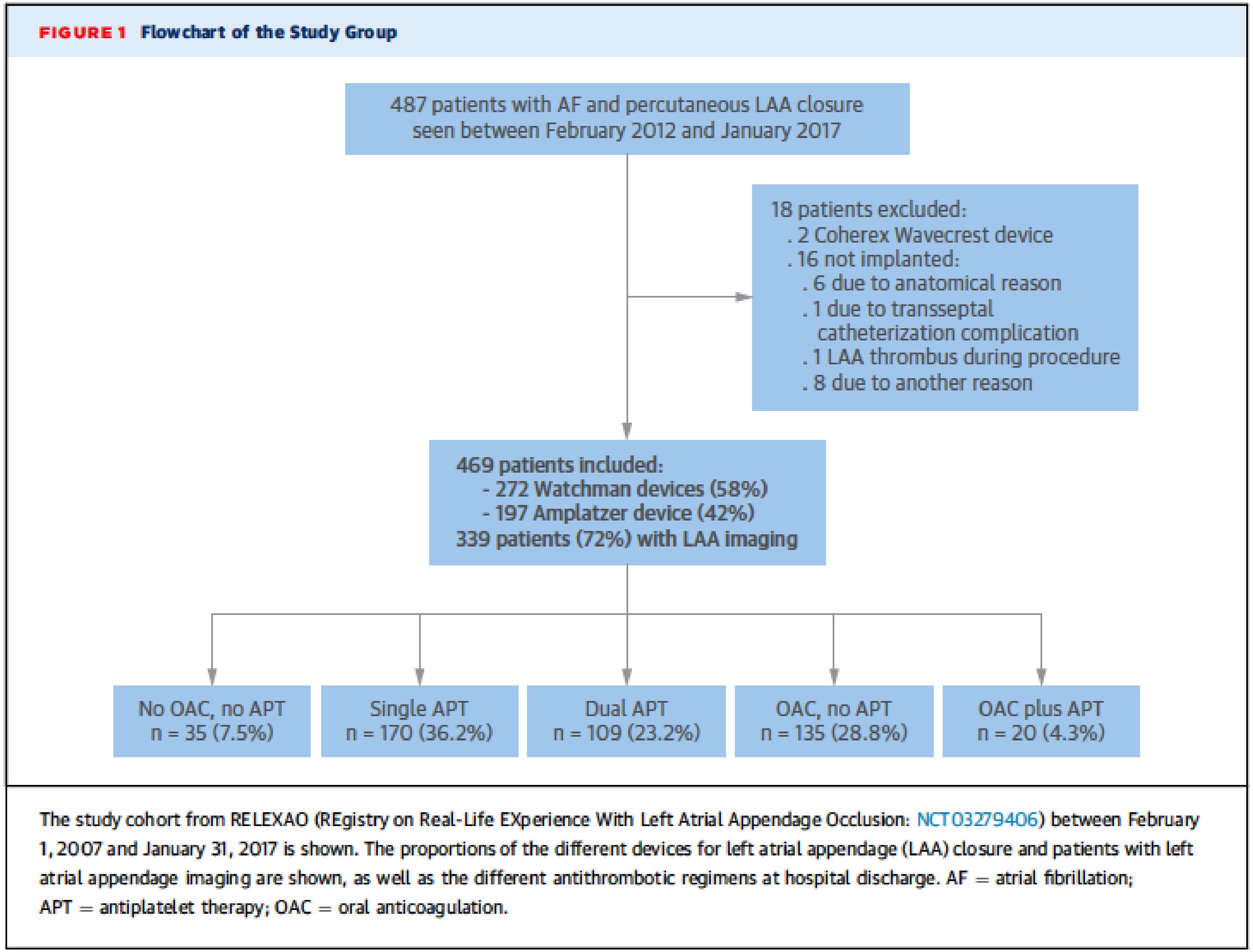

FIGURE 1 **Flowchart of the Study Group**

487 patients with AF and percutaneous LAA closure seen between February 2012 and January 2017

18 patients excluded:
- . 2 Coherex Wavecrest device
- . 16 not implanted:
  - . 6 due to anatomical reason
  - . 1 due to transseptal catheterization complication
  - . 1 LAA thrombus during procedure
  - . 8 due to another reason

469 patients included:
- 272 Watchman devices (58%)
- 197 Amplatzer device (42%)

339 patients (72%) with LAA imaging

No OAC, no APT
n = 35 (7.5%)

Single APT
n = 170 (36.2%)

Dual APT
n = 109 (23.2%)

OAC, no APT
n = 135 (28.8%)

OAC plus APT
n = 20 (4.3%)

The study cohort from RELEXAO (REgistry on Real-Life EXperience With Left Atrial Appendage Occlusion: NCT03279406) between February 1, 2007 and January 31, 2017 is shown. The proportions of the different devices for left atrial appendage (LAA) closure and patients with left atrial appendage imaging are shown, as well as the different antithrombotic regimens at hospital discharge. AF = atrial fibrillation; APT = antiplatelet therapy; OAC = oral anticoagulation.

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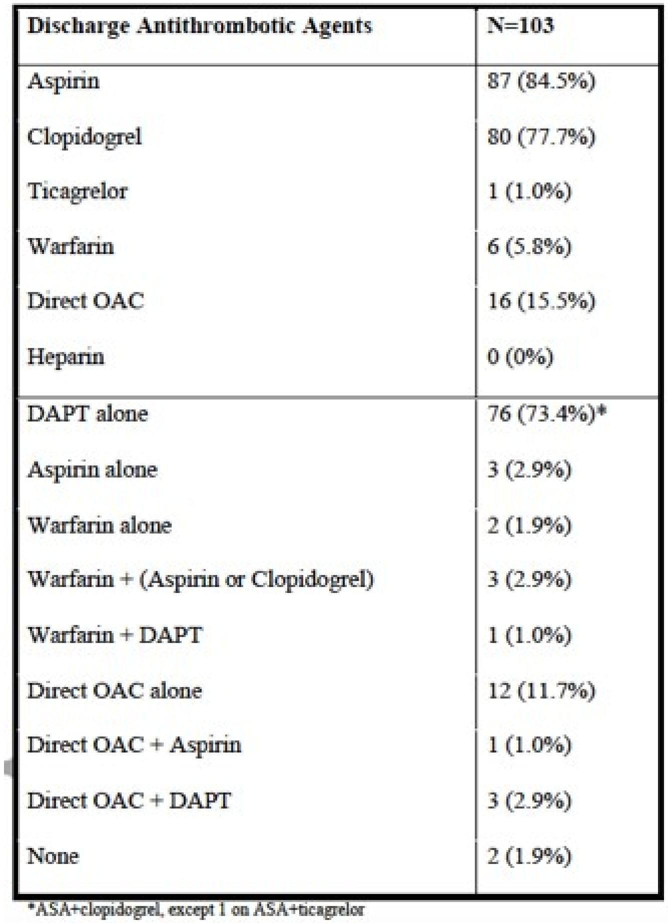
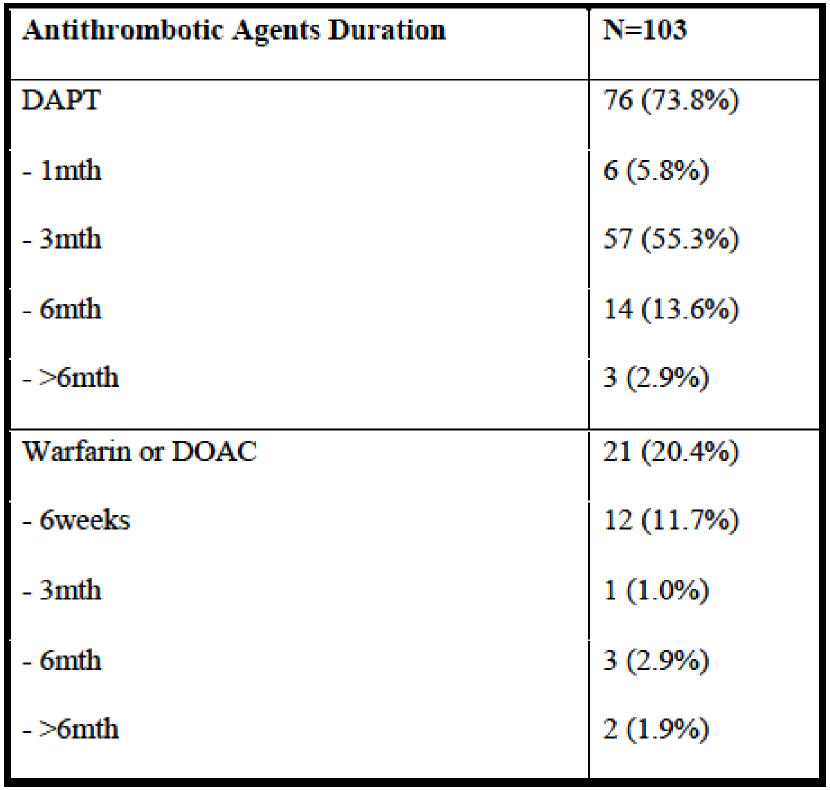
Expérience Canadienne



Discharge Antithrombotic Agents	N=103
Aspirin	87 (84.5%)
Clopidogrel	80 (77.7%)
Ticagrelor	1 (1.0%)
Warfarin	6 (5.8%)
Direct OAC	16 (15.5%)
Heparin	0 (0%)
DAPT alone	76 (73.4%)*
Aspirin alone	3 (2.9%)
Warfarin alone	2 (1.9%)
Warfarin + (Aspirin or Clopidogrel)	3 (2.9%)
Warfarin + DAPT	1 (1.0%)
Direct OAC alone	12 (11.7%)
Direct OAC + Aspirin	1 (1.0%)
Direct OAC + DAPT	3 (2.9%)
None	2 (1.9%)

*ASA+clopidogrel, except 1 on ASA+ticagrelor



Antithrombotic Agents Duration	N=103
DAPT	76 (73.8%)
- 1mth	6 (5.8%)
- 3mth	57 (55.3%)
- 6mth	14 (13.6%)
- >6mth	3 (2.9%)
Warfarin or DOAC	21 (20.4%)
- 6weeks	12 (11.7%)
- 3mth	1 (1.0%)
- 6mth	3 (2.9%)
- >6mth	2 (1.9%)

Saw J, JCE 2017

Thrombus post-procédure

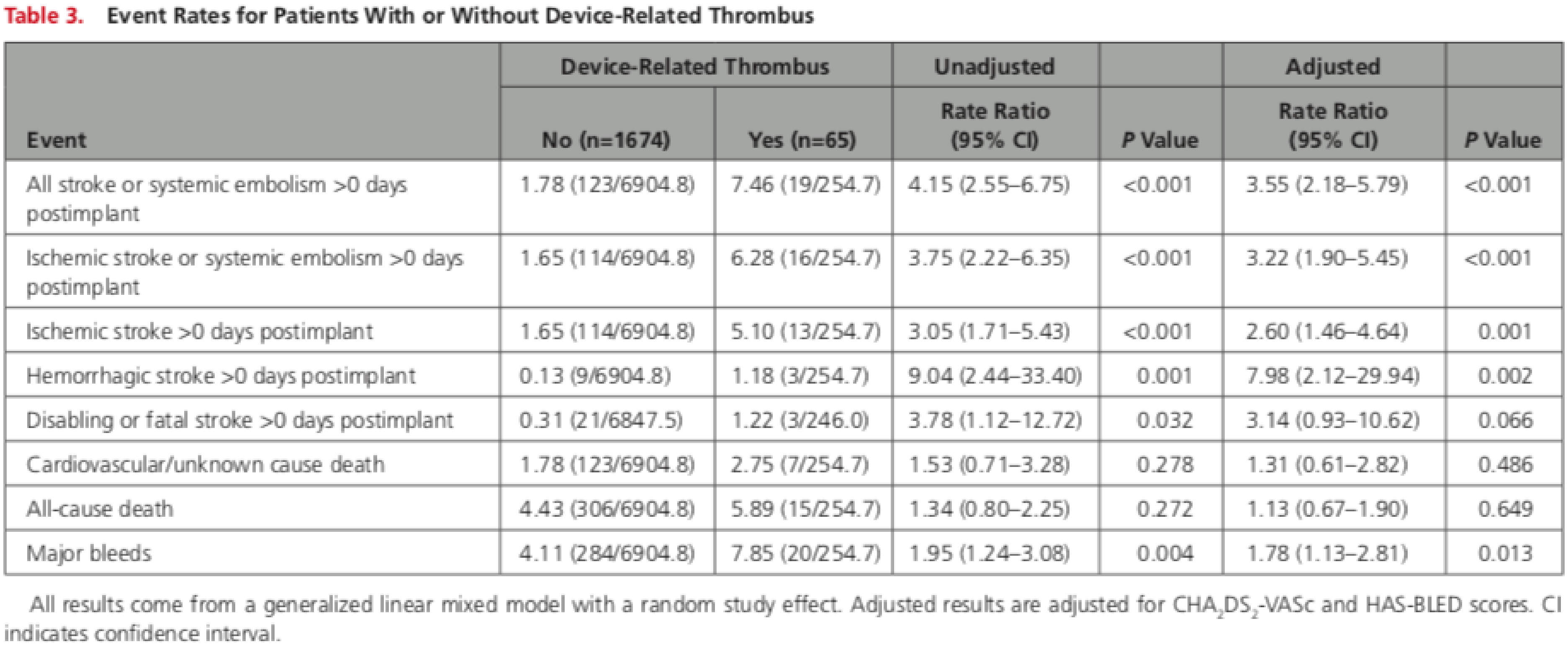


Table 3. Event Rates for Patients With or Without Device-Related Thrombus

Event	Device-Related Thrombus No (n=1674)	Device-Related Thrombus Yes (n=65)	Unadjusted Rate Ratio (95% CI)	*P* Value	Adjusted Rate Ratio (95% CI)	*P* Value
All stroke or systemic embolism >0 days postimplant	1.78 (123/6904.8)	7.46 (19/254.7)	4.15 (2.55–6.75)	<0.001	3.55 (2.18–5.79)	<0.001
Ischemic stroke or systemic embolism >0 days postimplant	1.65 (114/6904.8)	6.28 (16/254.7)	3.75 (2.22–6.35)	<0.001	3.22 (1.90–5.45)	<0.001
Ischemic stroke >0 days postimplant	1.65 (114/6904.8)	5.10 (13/254.7)	3.05 (1.71–5.43)	<0.001	2.60 (1.46–4.64)	0.001
Hemorrhagic stroke >0 days postimplant	0.13 (9/6904.8)	1.18 (3/254.7)	9.04 (2.44–33.40)	0.001	7.98 (2.12–29.94)	0.002
Disabling or fatal stroke >0 days postimplant	0.31 (21/6847.5)	1.22 (3/246.0)	3.78 (1.12–12.72)	0.032	3.14 (0.93–10.62)	0.066
Cardiovascular/unknown cause death	1.78 (123/6904.8)	2.75 (7/254.7)	1.53 (0.71–3.28)	0.278	1.31 (0.61–2.82)	0.486
All-cause death	4.43 (306/6904.8)	5.89 (15/254.7)	1.34 (0.80–2.25)	0.272	1.13 (0.67–1.90)	0.649
Major bleeds	4.11 (284/6904.8)	7.85 (20/254.7)	1.95 (1.24–3.08)	0.004	1.78 (1.13–2.81)	0.013

All results come from a generalized linear mixed model with a random study effect. Adjusted results are adjusted for CHA$_2$DS$_2$-VASc and HAS-BLED scores. CI indicates confidence interval.

Thrombus post-procédure

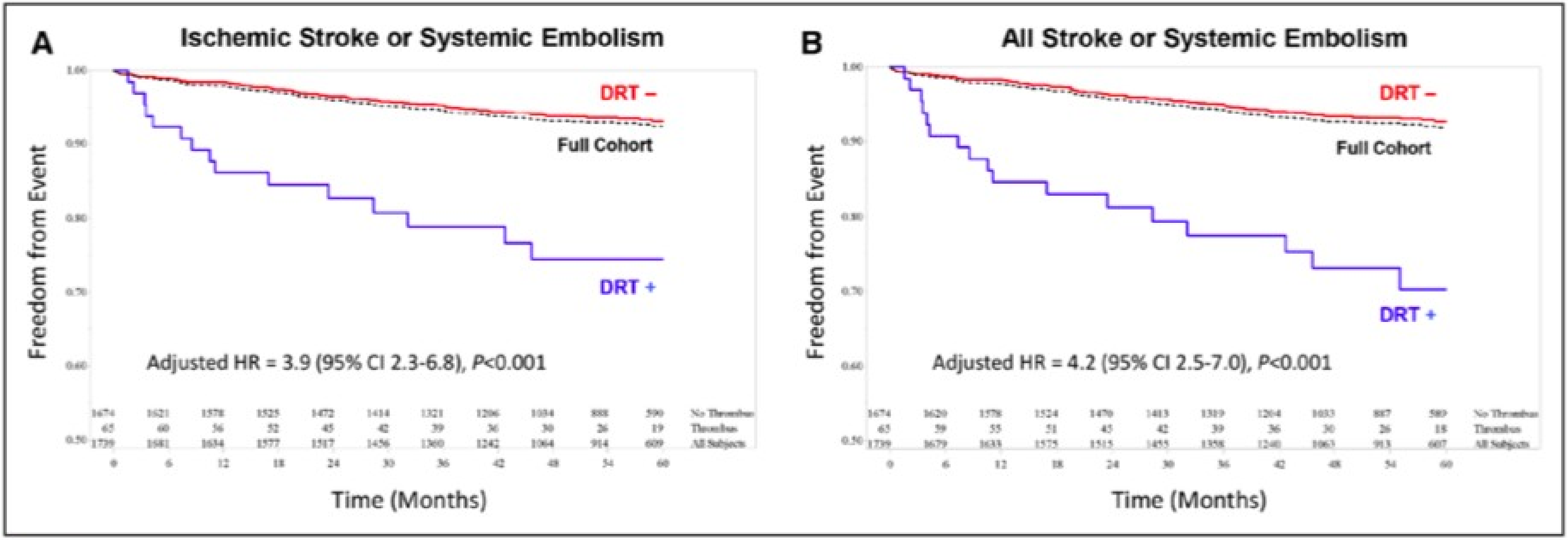


Figure 3. Kaplan-Meier survival curves for thromboembolic events as a function of device-related thrombus (DRT).
A, The presence of DRT is associated with higher rates of ischemic stroke or systemic embolism. **B**, Similarly, the rates of all-cause stroke or systemic embolism are also higher if DRT is present. CI indicates confidence interval; and HR, hazard ratio.

Thrombus post-procédure

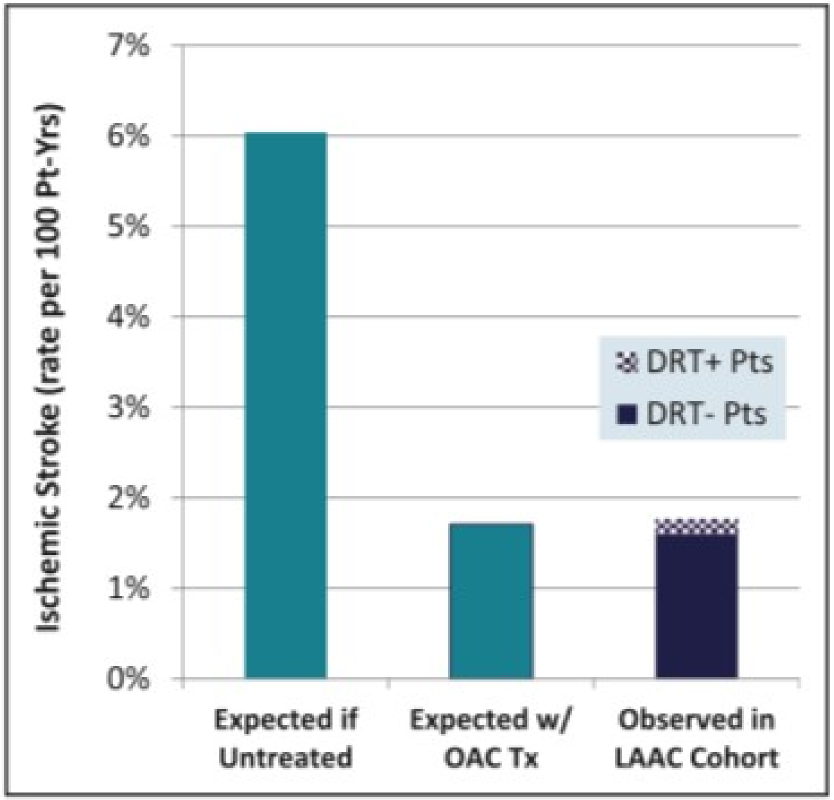


Figure 6. Ischemic stroke rates after Watchman implant versus expected rate with oral anticoagulants.

Dukkipati et al. Circuation 2018

Anticoagulants/Anti-agrégants post procédure?

- Si patient était anticoagulé:
  - ✓ ASA à vie
  - ✓ ACO 6 semaines (Watchman)
- Si patient n'était plus anticoagulé:
  - ✓ Aspirine à vie si possible
  - ✓ Clopidogrel 6-12 semaines
- La vraie vie….

Conclusions

- Thérapie locale alternative raisonnable à l’anticoagulation orale (un traitement systémique)
- Prévenir les AVCs chez les pts avec FA à haut risque thrombo-embolique **ET** à haut risque de saignement

- Avant d’envisager un remplacement diffus de l’anticoagulation en pratique clinique
- Comparaison de l’efficacité des prothèses vs le nouveau standard de traitement (NOACs)

EQUIPE MULTIDISCIPLINAIRE

First Amplatz in Canada (2009)

First Watchman in Canada (2012)

Together
Everyone
Achieves
More

Merci!

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