



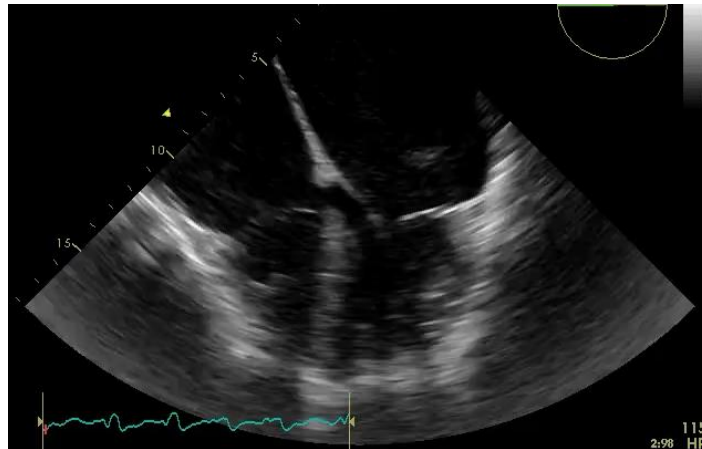
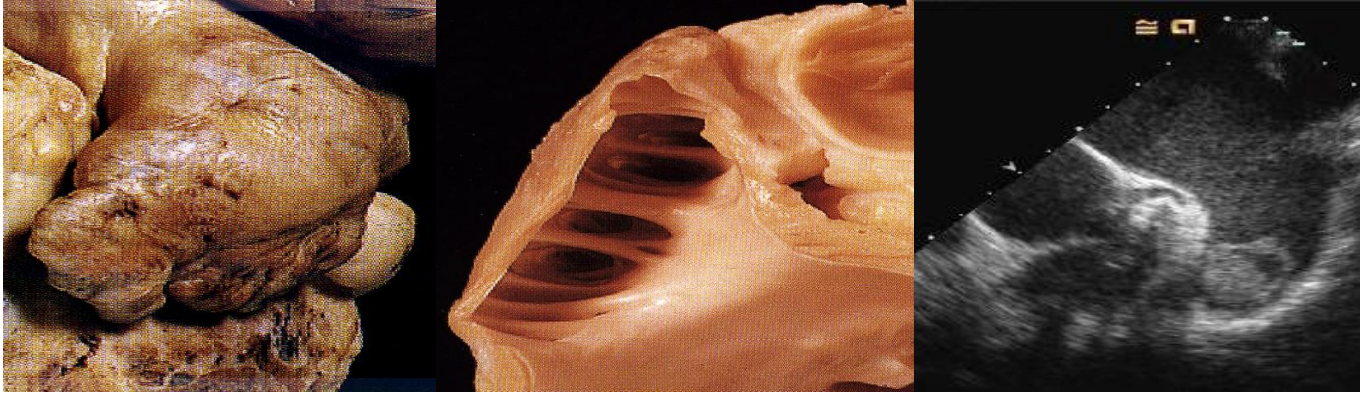
***Fermeture percutanée de l'auricule
gauche
Où en est-on en 2022??***

**ACCA
Nice
Avril 2022**

Pascal DEFAYE



Left atrial appendage : the real culprit

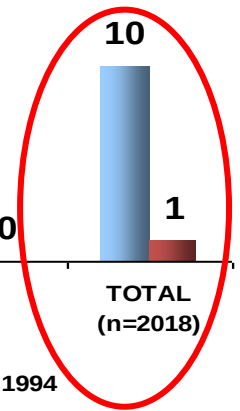
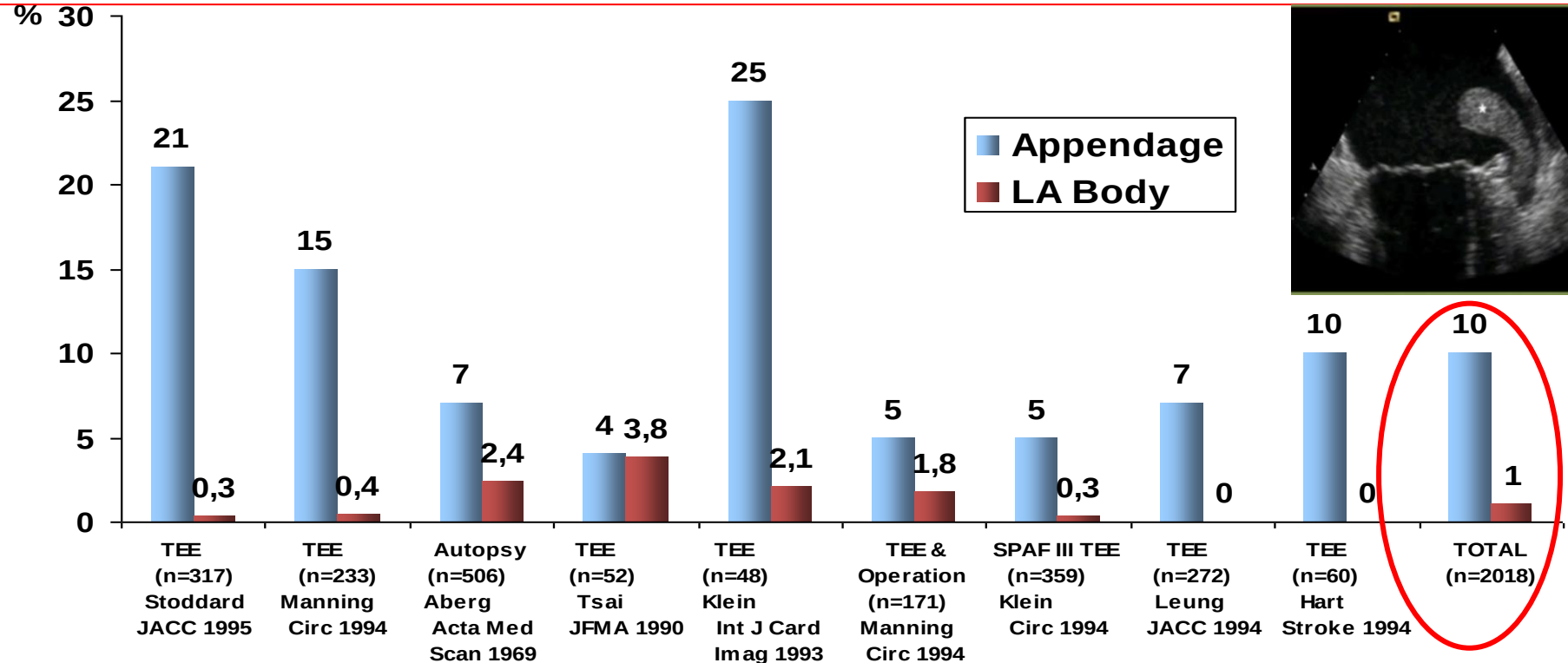


Appendage Obliteration to Reduce Stroke in Cardiac Surgical Patients With Atrial Fibrillation

Joseph L. Blackshear, MD, and John A. Odell, FRCS(Ed)

Division of Cardiovascular Diseases, Mayo Clinic Jacksonville, Jacksonville, Florida and Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minnesota

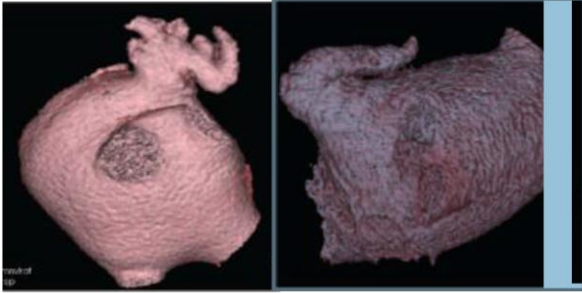
91% of stroke in AF is caused by blood clots that form in the LAA



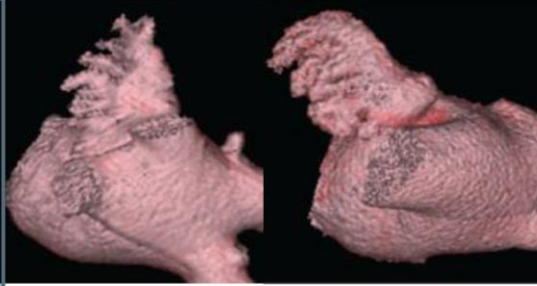
JL Blackshear, Ann. Thorac Surg 1996; 61:755-59

Shapes of LAA and orifice

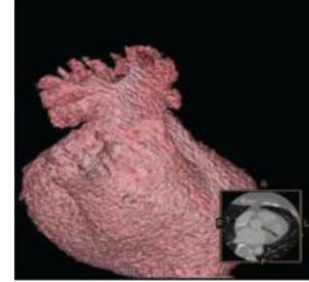
Chicken Wing



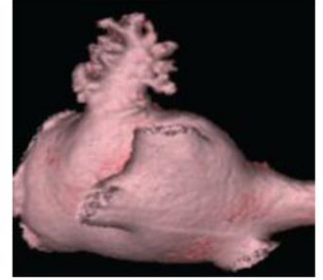
Wind Sock



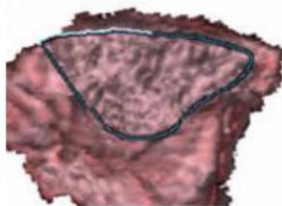
Cauliflower



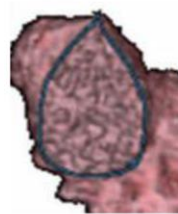
Cactus



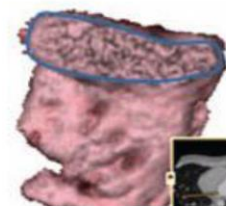
Oval



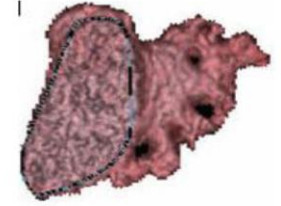
Triangular



Water drop



Round

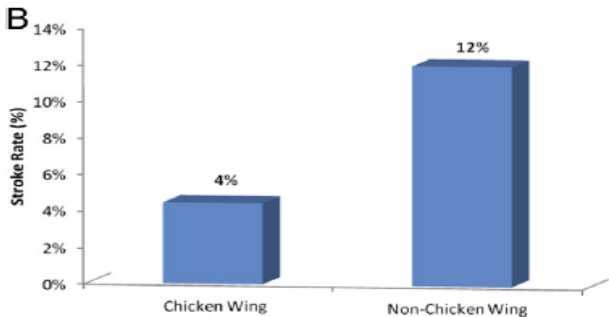
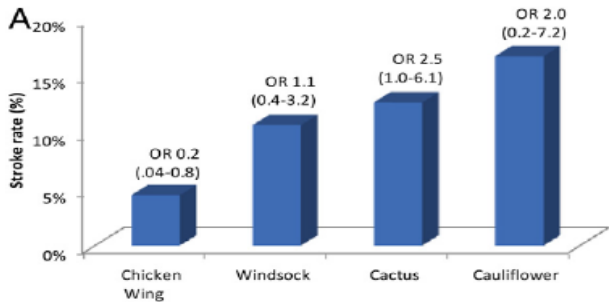


Foot

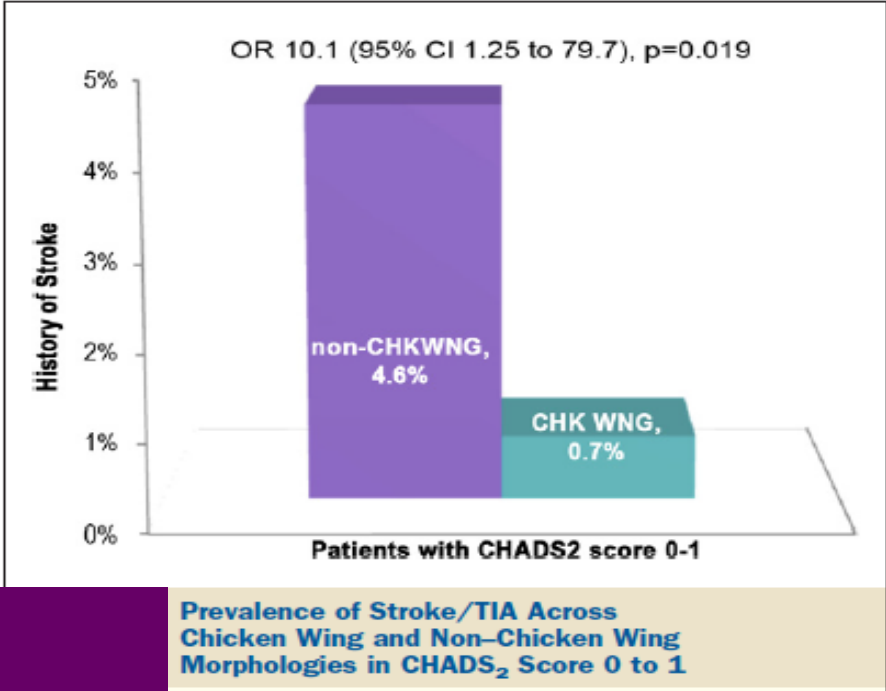
Does the Left Atrial Appendage Morphology Correlate With the Risk of Stroke in Patients With Atrial Fibrillation?

Results From a Multicenter Study

Luigi Di Biase, MD, PhD,*†‡ Pasquale Santangeli, MD,*‡ Matteo Anselmino, MD, PhD,§ Prasant Mohanty, MBBS, MPH,* Ilaria Salvetti, MD,§ Sebastiano Gili, MD,§ Rodney Horton, MD,* Javier E. Sanchez, MD,* Rong Bai, MD,* Sanghamitra Mohanty, MD,* Agnes Pump, MD,* Mauricio Cereceda Brantes, MD,* G. Joseph Gallingerhouse, MD,* J. David Burkhardt, MD,* Federico Cesarani, MD,|| Marco Scaglione, MD,¶ Andrea Natale, MD,*† Fiorenzo Gaita, MD§

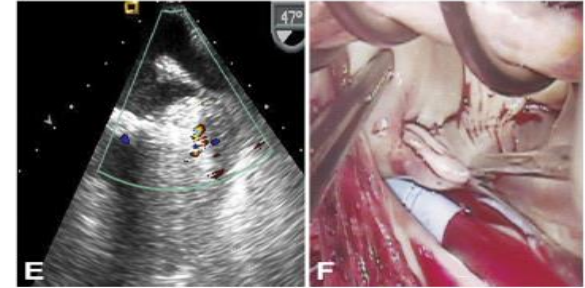
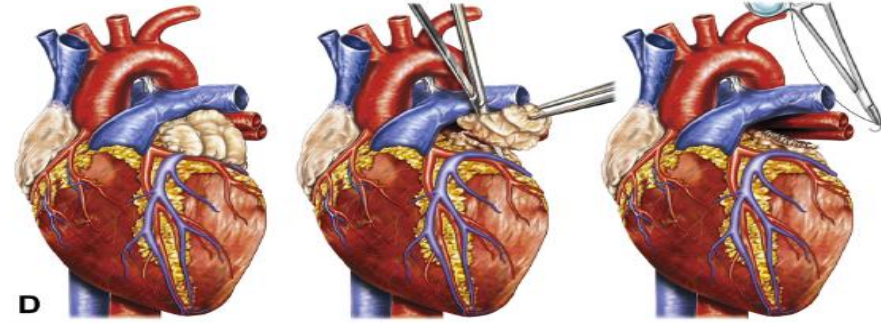
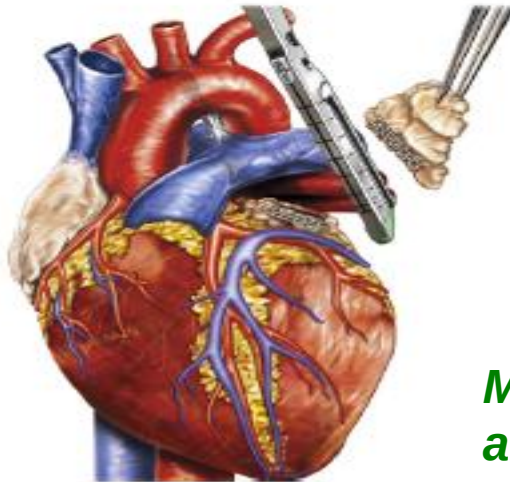
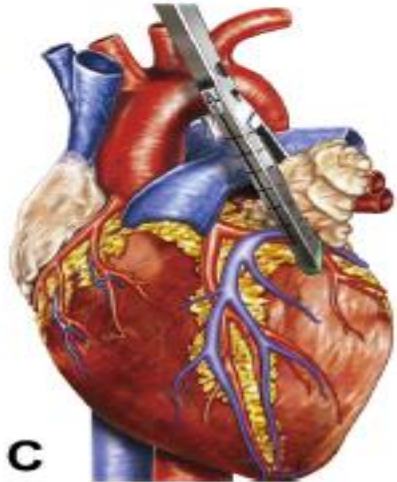
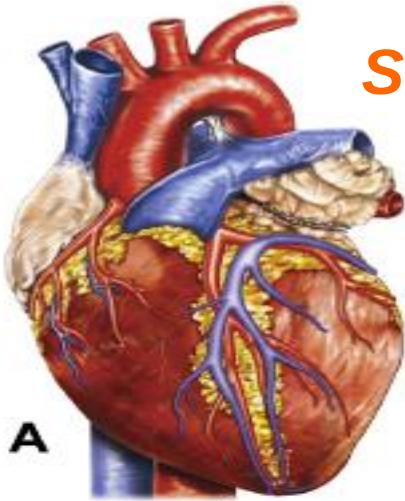


Prevalence of Prior Stroke/TIA According to Different LAA Morphologies and in Chicken Wing Versus Non-Chicken Wing Morphologies



Prevalence of Stroke/TIA Across Chicken Wing and Non-Chicken Wing Morphologies in CHADS₂ Score 0 to 1

Surgical techniques



A: Epicardial suture exclusion

B : Endocardial suture exclusion

C: Stapled exclusion

D: Exclusion with removal and oversew

***Madden JL. Resection of the LAA :
a prophylaxis for recurrent arterial emboli
JAMA 1949; 140: 769-72***

**WATCHMAN
and
WATCHMAN FLX
device comparison**

First generation
percutaneous left
atrial appendage
closure device

Next generation
percutaneous left
atrial appendage
closure device



Large size range
and shorter device



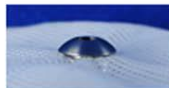
Distal tines folded back



Greater number of struts



Dual-row
anchors



Reduced metal
exposure



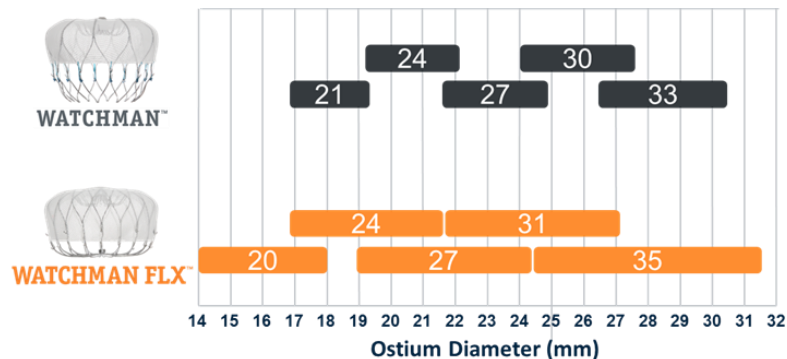
Design Changes from WATCHMAN to WATCHMAN FLX



Closed distal end with fluoro marker



May be partially recaptured and advanced into LAA



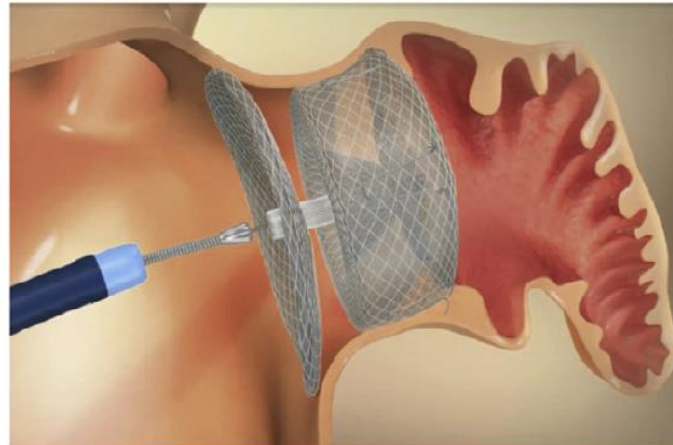
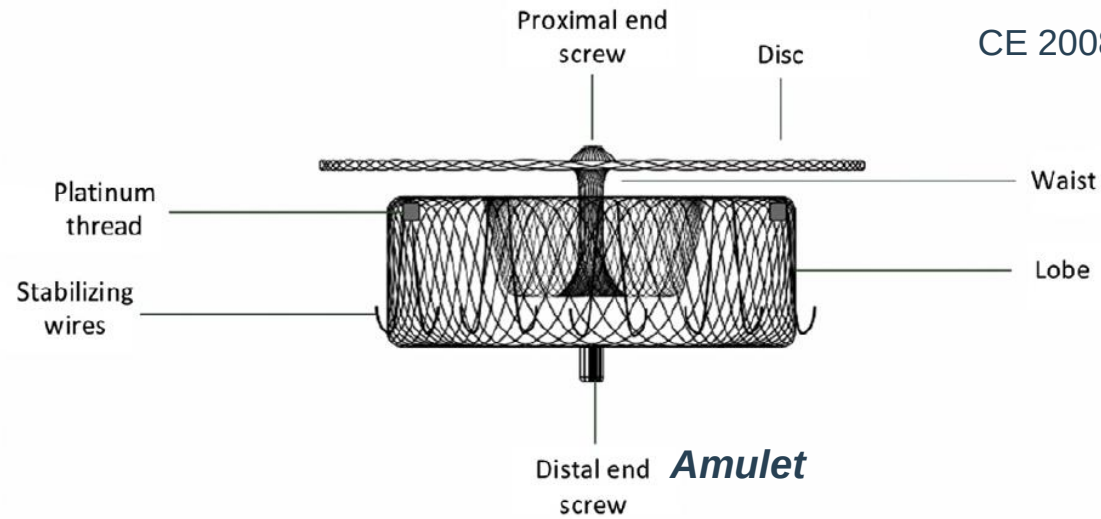
Wider LAA ostium range of 15-31.5mm

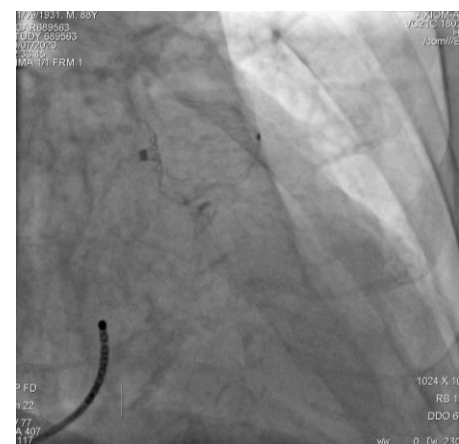
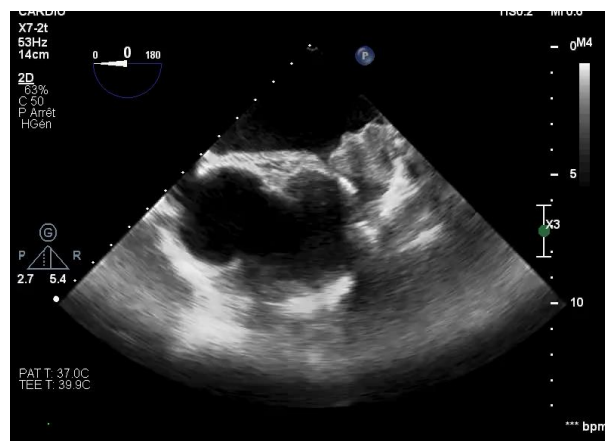
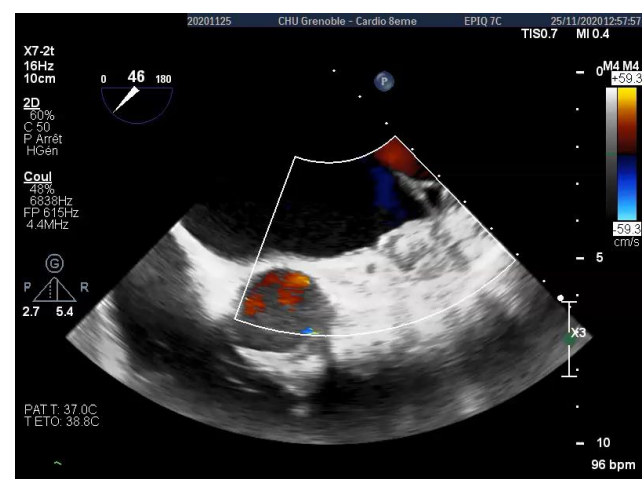
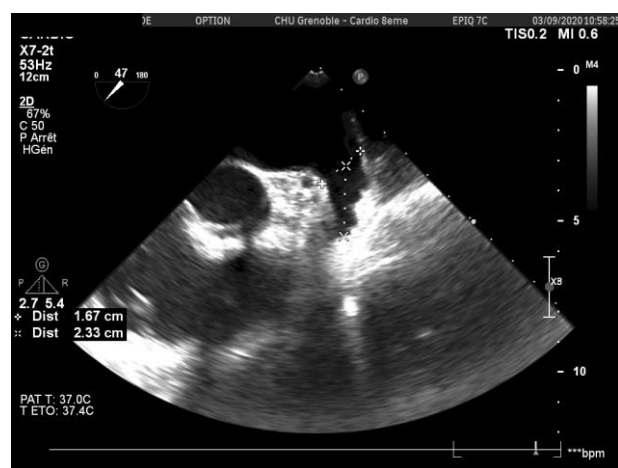


WATCHMAN 27mm

WATCHMAN FLX 27mm

Shorter device length





Difficult match to win in advance: Challenge ++++

Need of randomized studies versus gold standard : oral anticoagulants

- Are there other causes of thrombus in the LA?
 - Responsibility of aortic plaques, carotid plaques?
 - Only for **non-valvular AF**
 - Surgical results mitigated
 - The proportion of thrombi localised out of the LAA increases (10 à 20 %) if :
 - Valvular AF+++++
 - Heart Failure
 - Previous stroke
 - Non controlled INR
- Chatterjee S et al. Ann Thorac Surg 2011; 92: 2283-92*
Mahajan et al. Heart 2000; 98: 1120-26

WATCHMAN: Device endothelialization



Canine Model - 30 Day



Canine Model - 45 Day



*Human Pathology - 9 Months Post-implant
(Non-device related death)*

Long-Term Safety and Efficacy in Continued Access Left Atrial Appendage Closure Registries

David R. Holmes, Jr, MD,^a Vivek Y. Reddy, MD,^b Nicole T. Gordon, BSEE,^c David Delurgio, MD,^d Shephal K. Doshi, MD,^e Amish J. Desai, MD,^f James E. Stone, Jr, MD,^g Saibal Kar, MD^h

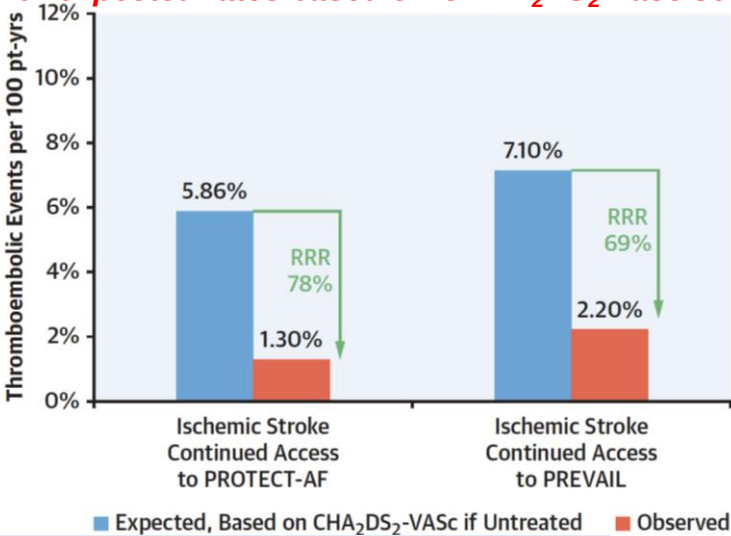
2 registries associated their respective RCT : PROTECT-AF and PREVAIL

5 years follow-up

Composite efficacy and component details

	CAP		CAP2	
	Rate per 100 Patient-Yrs (n Events/Patient-Yrs)	95% CI	Rate per 100 Patient-Yrs (n Events/Patient-Yrs)	95% CI
Primary efficacy	3.05 (70/2,292.5)	2.4–3.9	4.80 (102/2,125.8)	4.0–5.8
All stroke	1.48 (34/2,296.0)	1.1–2.1	2.25 (48/2,131.1)	1.7–2.9
Ischemic stroke	1.30 (30/2,300.1)	0.9–1.9	2.20 (47/2,135.4)	1.7–2.9
Hemorrhagic stroke	0.17 (4/2,359.9)	0.06–0.5	0.09 (2/2,221.3)	0.0–0.3
Systemic embolism	0.04 (1/2,359.8)	0.01–0.3	0.09 (2/2,221.9)	0.0–0.3
CV/unexplained death	1.69 (40/2,363.2)	1.2–2.3	2.92 (65/2,227.2)	2.3–3.7
Primary safety	3.05 (66/2,160.9)	2.4–3.9	N/A	N/A
All-cause mortality	4.27 (101/2,363.0)	3.5–5.2	6.24 (139/2,227.2)	5.3–7.3

Relative ischemic reduction compared with expected rates based on CHA₂DS₂-Vasc score



CONCLUSIONS These registries, which contain the longest and largest follow-up data of patients with the Watchman device, support LAAC as a safe and effective therapy for long-term anticoagulation in patients with nonvalvular atrial fibrillation, and document the lowest rate of hemorrhagic stroke identified in this population.

Watchman versus NOACs Strokes

Study	CHADS ₂ Mean±SD	Ischemic Stroke	Hemorrhagic Stroke
PROTECT AF +CAP	2,3±1,2	1,26%	0,11%
RE-LY (Dabigatran 110 mg)	2,1±1,1	1,34%	0,12%
RE-LY (Dabigatran 150 mg)	2,2±1,2	0,92%	0,1%
ROCKET-AF (Rivaroxaban arm)	3,48±0,94	1,34%	0,26%
ARISTOTLE (Apixaban Arm)	2,1±1,1	0,97%	0,24%

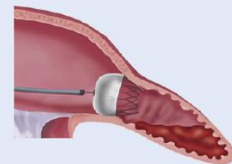
4-Year Outcomes After Left Atrial Appendage Closure Versus Nonwarfarin Oral Anticoagulation for Atrial Fibrillation

Pavel Osmancik, MD, PhD,¹ Dalibor Herman, MD, PhD,² Petr Neuzil, MD, PhD,³ Pavel Hala, MD,⁴ Milos Taborsky, MD, PhD,⁵ Petr Kala, MD, PhD,⁶ Martin Poloczek, MD,⁷ Josef Stasek, MD, PhD,⁸ Ludek Haman, MD, PhD,⁹ Marian Branny, MD, PhD,¹⁰ Jan Chovancik, MD,¹¹ Pavel Cervinka, MD, PhD,¹² Jiri Holy, MD,¹³ Tomas Kovarik, MD, PhD,¹⁴ David Zemanek, MD, PhD,¹⁵ Stepan Havranek, MD, PhD,¹⁶ Vlastimil Vancura, MD, PhD,¹⁷ Petr Pechl, MD, PhD,¹⁸ Petr Tousek, MD, PhD,¹⁹ Veronika Lekesova, MD,²⁰ Jiri Jarkovsky, PhD,²¹ Martina Novackova, MSc,²² Klara Benesova, MSc,²³ Petr Widimsky, MD, PhD,²⁴ Vivek Y. Reddy, MD,²⁵ on behalf of the PRAGUE-17 Trial Investigators

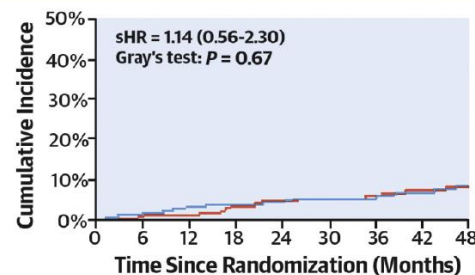


PRAGUE-17 Trial: Long-Term (4-Year) Follow-Up

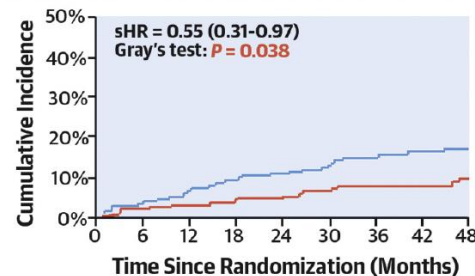
- 402 High-risk AF pts → Randomized
- CHA₂DS₂-VASc = 4.7 ± 1.5
- HAS-BLED = 3.1 ± 0.9
- Median Follow-up: 3.5 years (IQR 2.6-4.3), 1,354 pt-year



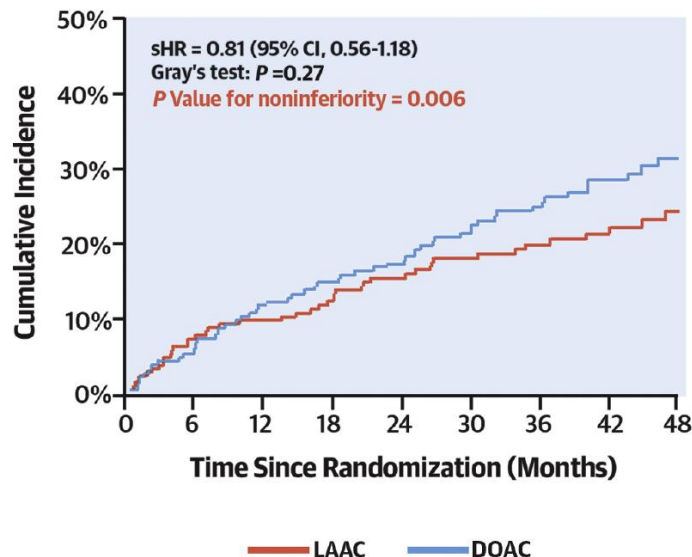
Stroke or TIA

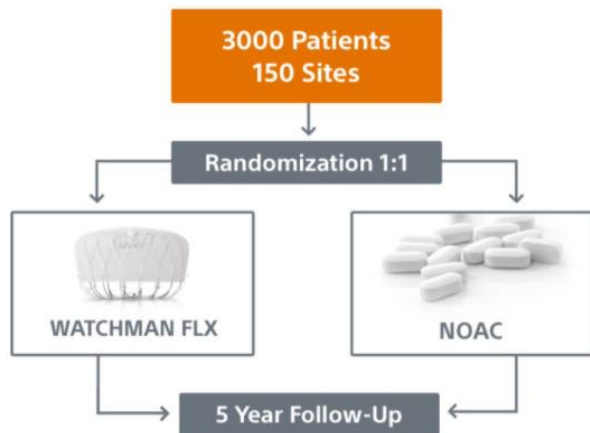


Non-Procedural Clinically Relevant Bleeding



Primary Endpoint Stroke, TIA, SE, CV Death, Bleeding or Complications





Primary Endpoints:

- WATCHMAN FLX™ is non-inferior for the occurrence of stroke (including ischemic and/or hemorrhagic), cardiovascular (CV) death (including unexplained death), and systemic embolism at 36 months.
- WATCHMAN FLX is superior for non-procedural bleeding (ISTH major bleeding and clinically relevant non-major bleeding) at 36 months.
- WATCHMAN FLX is non-inferior for the occurrence of ischemic stroke and systemic embolism at 60 months.

CHAMPION-AF Patient Selection

- Patient has documented non-valvular AF (i.e., AF in the absence of moderate or greater mitral stenosis or a mechanical heart valve)
- CHA₂DS₂-VASc score of ≥ 2 for men and ≥ 3 for women
- Patient is deemed to be suitable for long-term NOAC

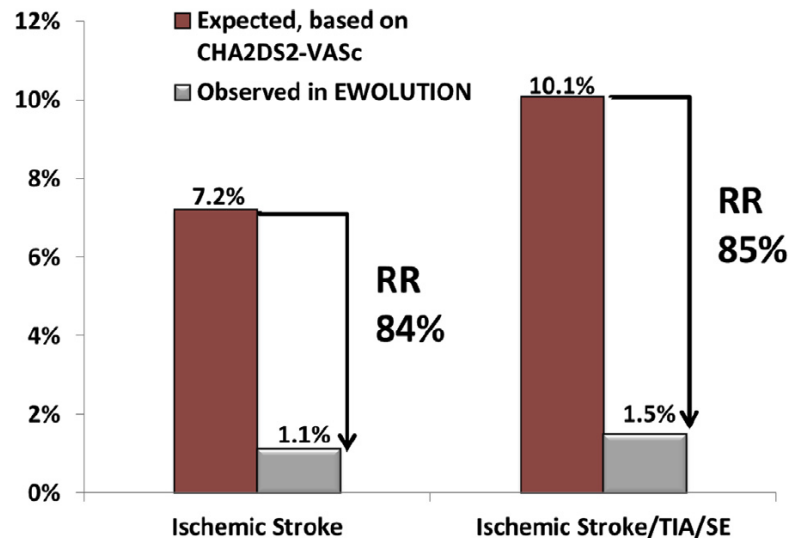
- ASAP registry (n=150) : Reddy JACC 2013
- Ewolution registry (n= 627/1014) Boersma EHJ 2016
- ACP registry (n=860/1047) : Tzikas Eurointervention 2015
- Amulet registry (n=880/1073) Landmesser Eurointervention 2017

*Compared to the risk calculated by CHADSVASC
efficacy and safety were similar to the Watchman RCTs*

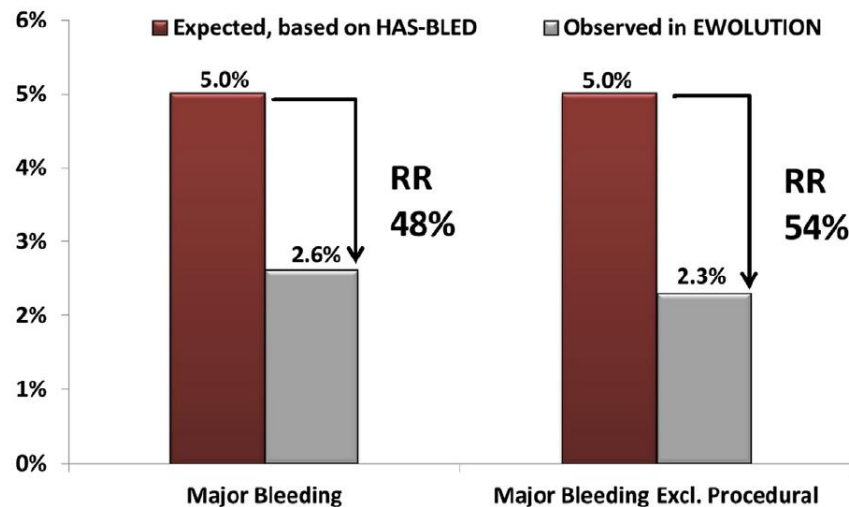
Efficacy and safety of left atrial appendage closure with WATCHMAN in patients with or without contraindication to oral anticoagulation: 1-Year follow-up outcome data of the EWOLUTION trial

Lucas V. Boersma, MD, PhD, FESC,* Hueseyin Ince, MD,[†] Stephan Kische, MD,[‡] Evgeny Pokushalov, MD, PhD,[§] Thomas Schmitz, MD,^{||} Boris Schmidt, MD,[¶] Tommaso Gori, MD,[‡] Felix Meincke, MD,^{**} Alexey Vladimir Protopopov, MD, PhD,^{††} Timothy Betts, MD,^{‡‡} David Foley, MD, PhD, FRCPI, FACA, FACC, FESC,^{§§} Horst Sievert, MD,^{|||} Patrizio Mazzone, MD,^{¶¶} Tom De Potter, MD,^{|||} Elisa Vireca, MS,^{***} Kenneth Stein, MD, FHRS,^{†††} Martin W. Bergmann, MD, PhD, FESC,^{†††} for the EWOLUTION Investigators

1025 pts/47 centers
73% unsuitable for OA therapy
CHADS Vasc = 4.5 ± 1.6



Stroke rate



Major bleeding (HASBLED)

Heart Rhythm 2017;14:1302-08

Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device

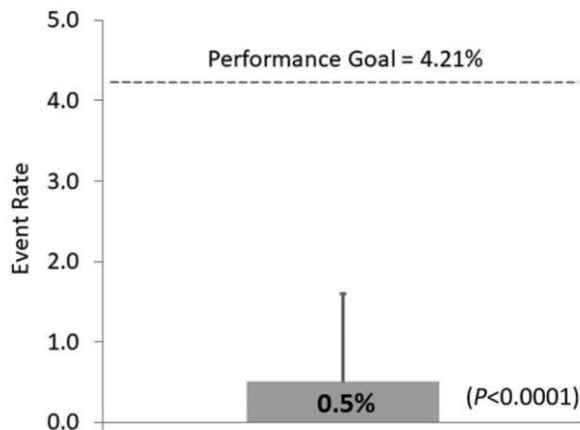
Results From the PINNACLE FLX Trial

Saibal Kar^{ID}, MD
Shephal K. Doshi, MD
Ashish Sadhu, MD

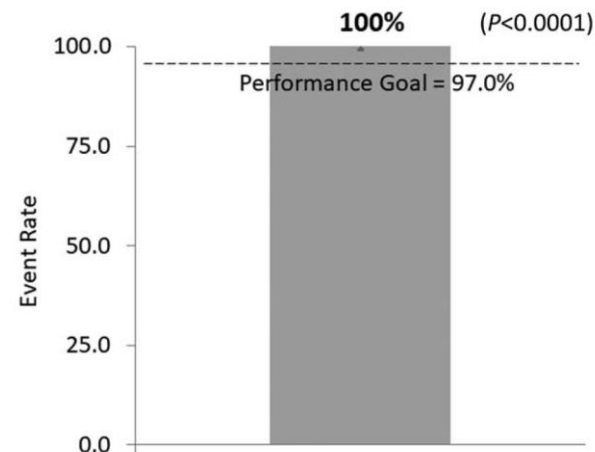
Watchman FLX
Pts contraindicated to OAC

Measure	N=400
Age	73.8±8.6 (400) [44.0, 98.0]
Female sex	35.5% (142/400)
Race/ethnicity	
American Indian or Alaska native	0.3% (1/382)
Asian	0.5% (2/382)
Black or African heritage	4.7% (18/382)
White	93.7% (358/382)
Hispanic or Latino	2.6% (10/382)
Native Hawaiian or other Pacific Islander	0.0% (0/382)
Other	0.0% (0/382)
Atrial (AF) pattern	
Paroxysmal AF	51.8% (207/400)
Persistent AF	36.5% (146/400)
Permanent AF	10.5% (42/400)
Paced Rhythm	1.3% (5/400)
CHA ₂ DS ₂ -VASc score	4.2±1.5 (400) [2.0, 9.0]
HAS-BLED score	2.0±1.0 (400) [0.0, 5.0]

A Primary Safety Endpoint



B Primary Effectiveness Endpoint

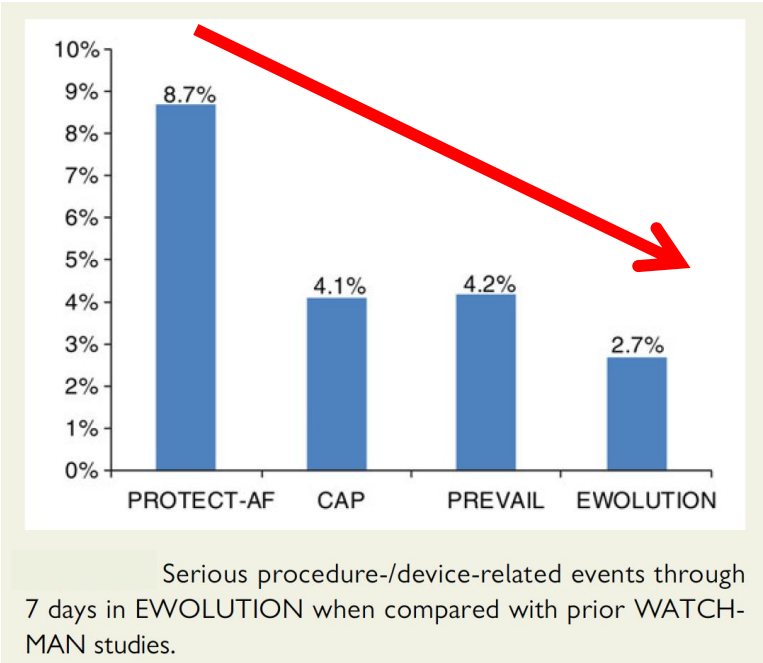
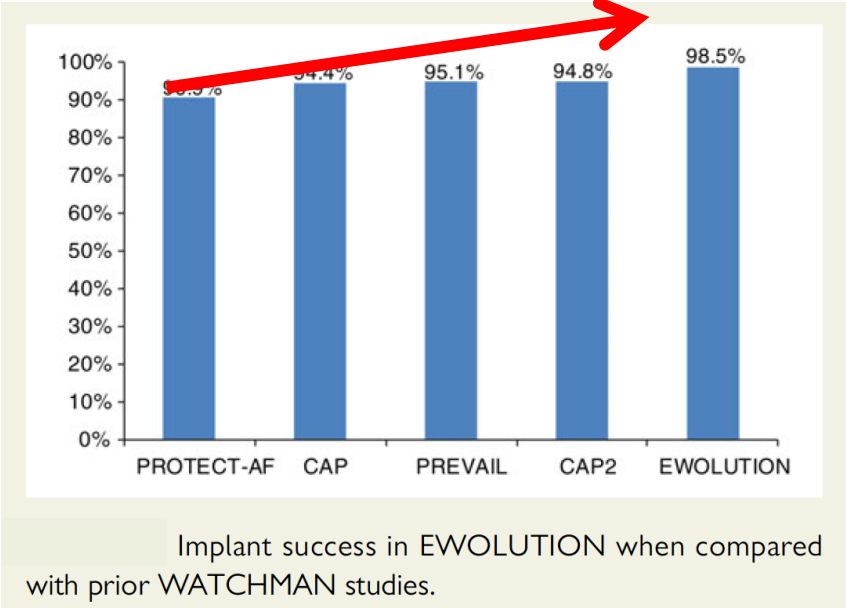


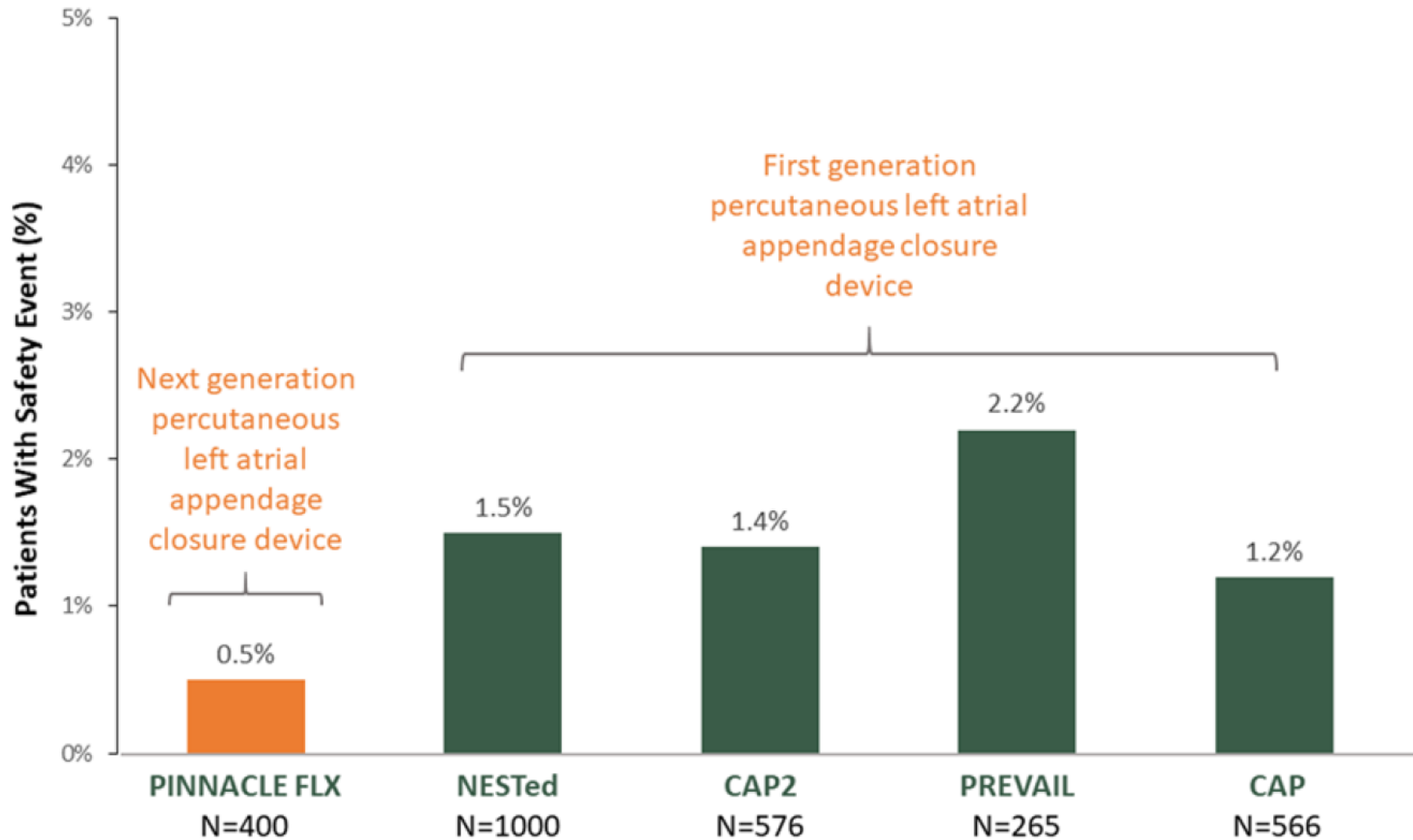
Circulation. 2021;143:1754–1762

Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry

Lucas V.A. Boersma^{1*}, Boris Schmidt², Timothy R. Betts³, Horst Sievert⁴, Corrado Tamburino⁵, Emmanuel Teiger⁶, Evgeny Pokushalov⁷, Stephan Kische⁸, Thomas Schmitz⁹, Kenneth M. Stein¹⁰ and Martin W. Bergmann¹¹, on behalf of the EWOLUTION investigators

1021 subjects

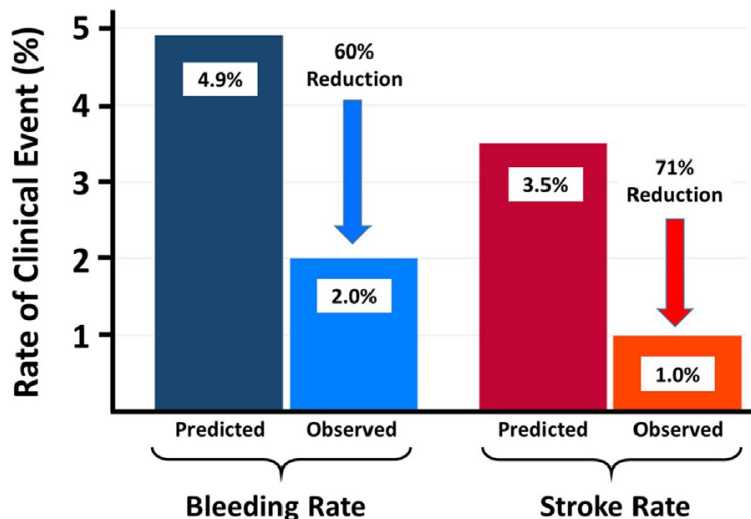




Cryoballoon pulmonary vein ablation and left atrial appendage closure combined procedure: A long-term follow-up analysis

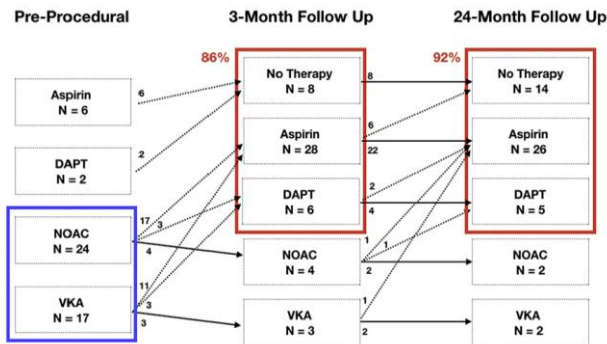
Gaetano Fassini, MD,* Alessio Gasperetti, MD,* Gianpiero Italiano, MD,* Stefania Riva, MD,* Massimo Moltrasio, MD,* Antonio Dello Russo, MD, PhD,* Michela Casella, MD, PhD,* Anna Maltagliati, MD,* Fabrizio Tundo, MD, PhD,* Benedetta Majocchi, MD,* Luca Arioli, MD,* Ghaliyah Al-Mohani, MD,*† Gianluca Pontone, MD, PhD,* Mauro Pepi, MD, PhD,* Claudio Tondo, MD, PhD*†

49 pts

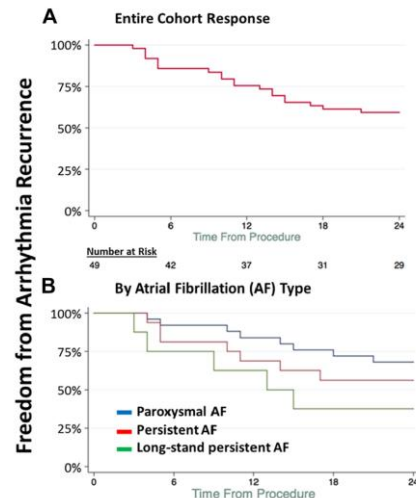


Annualized bleeding and stroke rate reduction from HAS-BLED and CHA₂DS₂-VASc score predicted rates in our population after the combined procedure.

OPTION study : résultats attendus 2022



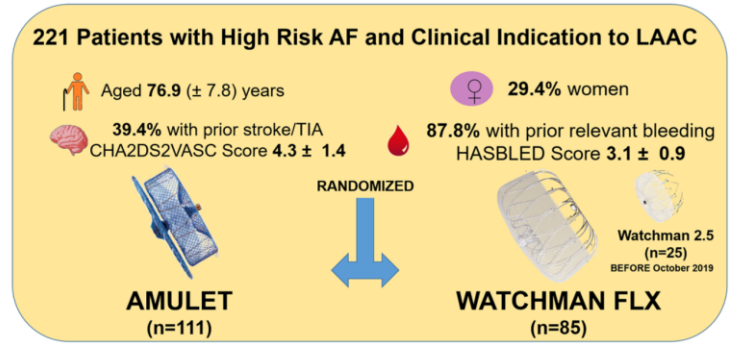
Changes in antithrombotic regimens during the study. *Full lines* indicate confirmed therapy; *dashed lines* indicate change in therapy. DAPT = dual antiplatelet therapy; NOAC = non-vitamin K oral antagonist; VKA = vitamin K antagonist.



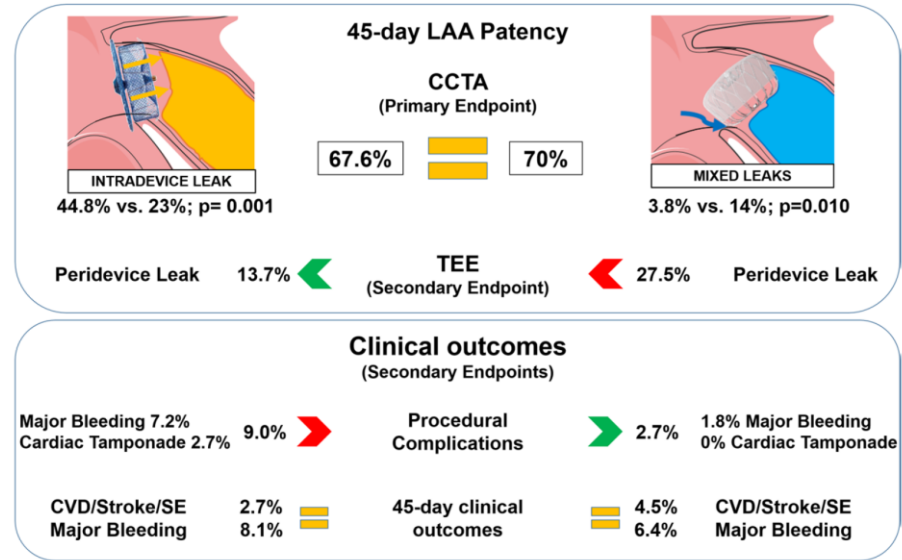
Heart Rhythm 2019;16:1320–1326

Amulet or Watchman Device for Percutaneous Left Atrial Appendage Closure: Primary Results of the SWISS-APERO Randomized Clinical Trial

Roberto Galea, MD; Federico De Marco, MD; Nicolas Meneveau, MD; Adel Aminian, MD; Frédéric Anselme, MD, PhD; Christoph Gräni, MD, PhD; Adrian T. Huber, MD, PhD; Emmanuel Teiger, MD, PhD; Xavier Iriart, MD; Flora Babongo Bosombo, PhD; Dik Heg, PhD; Anna Franzone, MD, PhD; Pascal Vranckx, MD, PhD; Urs Fischer, MD; Giovanni Pedrazzini, MD; Francesco Bedogni, MD; Lorenz Räber, MD, PhD; Marco Valgimigli, MD, PhD



Circulation. 2022;145:724–738



CONCLUSIONS: Amulet was not associated with a lower rate of the composite of crossover or residual LAA patency compared with Watchman at 45-day CCTA. Amulet, however, was associated with lower peridevice leak rates at transesophageal echocardiography, higher procedural complications, and similar clinical outcomes at 45 days compared with Watchman. The clinical relevance of CCTA-detected LAA patency requires further investigation.

Device-Associated Thrombus Formation after Left Atrial Appendage Occlusion: A Systematic Review of Events Reported with the Watchman, the Amplatzer Cardiac Plug and the Amulet

Mathieu Lempereur,^{1*} MD, Adel Aminian,² MD, Xavier Freixa,³ MD, PhD, Sameer Gafoor,^{4,5} MD, Joelle Kefer,⁶ MD, PhD, Apostolos Tzikas,⁷ MD, PhD, Victor Legrand,¹ MD, PhD, and Jacqueline Saw,⁸ MD

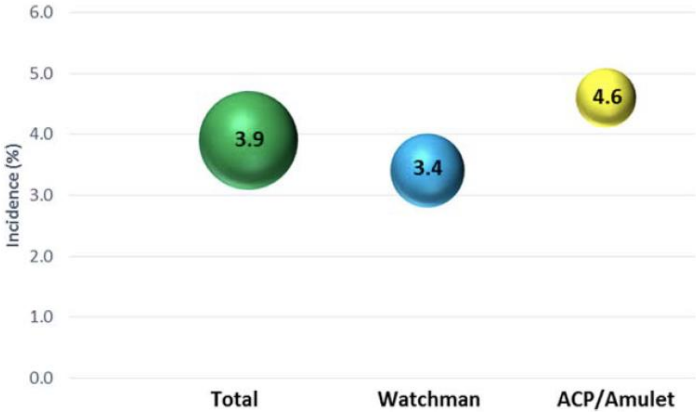


Fig. 2. Incidence of DAT (%) for all devices, Watchman and ACP/Amulet with relative size based on the sample size.

TABLE II. Potential Risk Factors for Device-Related Thrombosis

Characteristics	Risk factors
Patient characteristics	High CHADS ₂ score [8] High CHA ₂ DS ₂ -VASc score [8] High platelet count [8] Early discontinuation of antithrombotic medication [9, 29] Poor treatment compliance or under-target INR [12, [27, 30]]
Echocardiogram findings	Low ejection fraction [[8], [24]] Spontaneous echo or dense smoke in LA [4, 13, 24, 27, 31] Markedly enlarged LA [24, 31]
Procedure results	Deep implantation [32] Incomplete LAA occlusion [33] Poor inferior disc-apposition (ACP) [34]
Device	Thrombus on screw, on connector pin or at fabric insert site [7, 23, 30, 35]

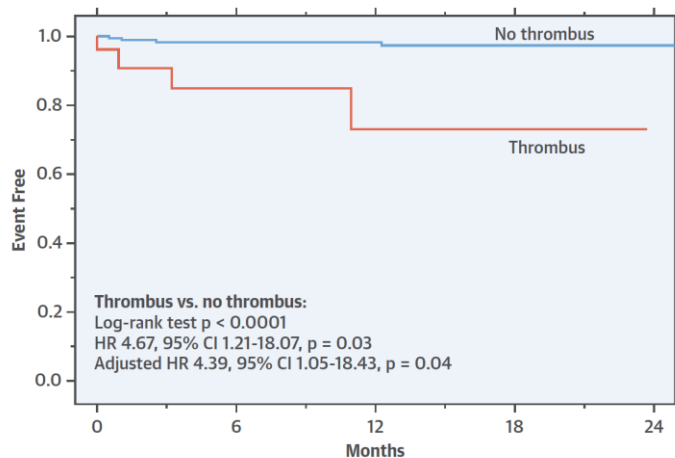
Device-Related Thrombosis After Percutaneous Left Atrial Appendage Occlusion for Atrial Fibrillation



Laurent Fauchier, MD,¹ Alexandre Cinaud, MD,² François Brigadeau, MD,³ Antoine Lepillier, MD,⁴ Bertrand Pierre, MD,⁵ Selim Abbey, MD,⁴ Marjaneh Fatemi, MD,⁶ Frederic Franceschi, MD,⁷ Paul Guedeney, MD,⁸ Peggy Jacon, MD,¹ Olivier Pazioud, MD,⁹ Sandrine Venier, MD,¹⁰ Jean Claude Deharo, MD,¹ Daniel Gras, MD,¹¹ Didier Klug, MD,¹² Jacques Mansourati, MD,¹³ Gilles Montalescot, MD,¹⁴ Olivier Piot, MD,¹⁵ Pascal Defaye, MD¹⁶

487 pts : 272 Watchman/ 197 Amplatzer

Ischemic Stroke / Transient Ischemic Attack



N at risk

No thrombus	300	100	72	62	39
Thrombus	25	12	6	2	0

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

- Older age and history of stroke : predictors of thrombus formation on the devices,
- Dual antiplatelet therapy and oral anticoagulation at discharge : protective factors.
- Thrombus on the device and vascular disease independent predictors of ischemic stroke and TIA

J Am Coll Cardiol 2018;71:1528–36

Predictors of Device-Related Thrombus Following Percutaneous Left Atrial Appendage Occlusion

Trevor Simard, MD,^{1,2} Richard G. Jung, BSc,^{1,2} Kyle Lehenbauer, MD,³ Kerstin Playda, MD,^{1,2} Radoslaw Pracota, MD, PhD,¹ Gregory G. Jackson, MD,² Eduardo Flores-Umanzor, MD,¹ Laurent Faroux, MD,¹ Kasper Korsholm, MD, PhD,¹ Julian K.R. Chun, MD,² Shaojie Chen, MD,¹ Moniek Maarse, MD,^{1,2} Kristi Montrella, CRNP,¹ Zakeih Chaker, MD,²



- 711 patients :
-237 with and 474 without DRT/matched
in 37 international centers

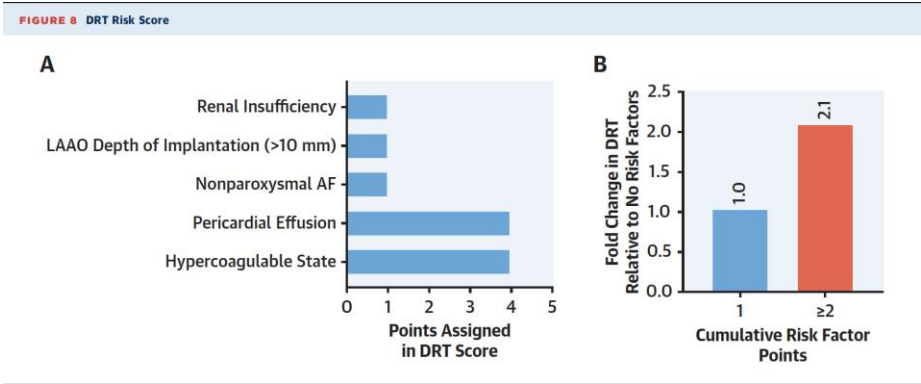
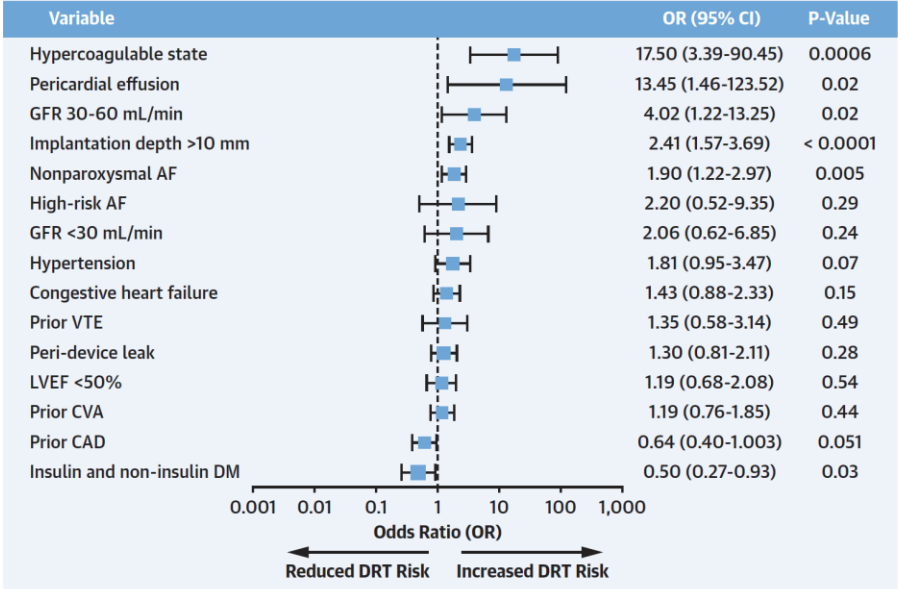


FIGURE 7 Predictors of DRT Following LAAO



Half-Dose Direct Oral Anticoagulation Versus Standard Antithrombotic Therapy After Left Atrial Appendage Occlusion

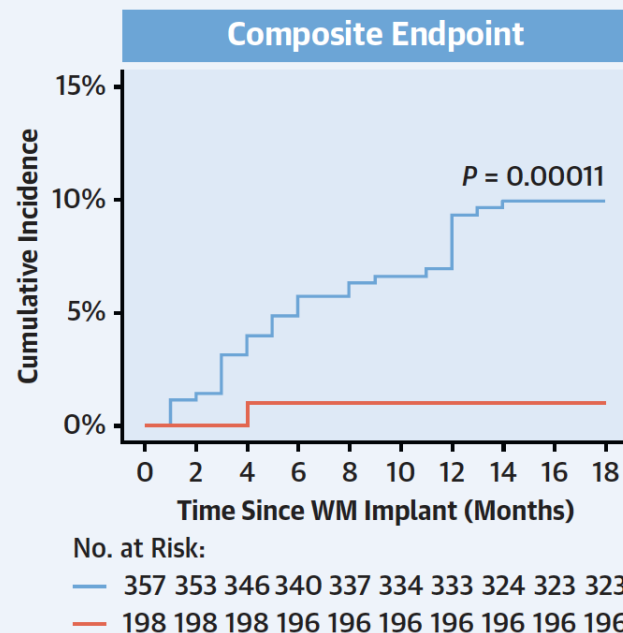
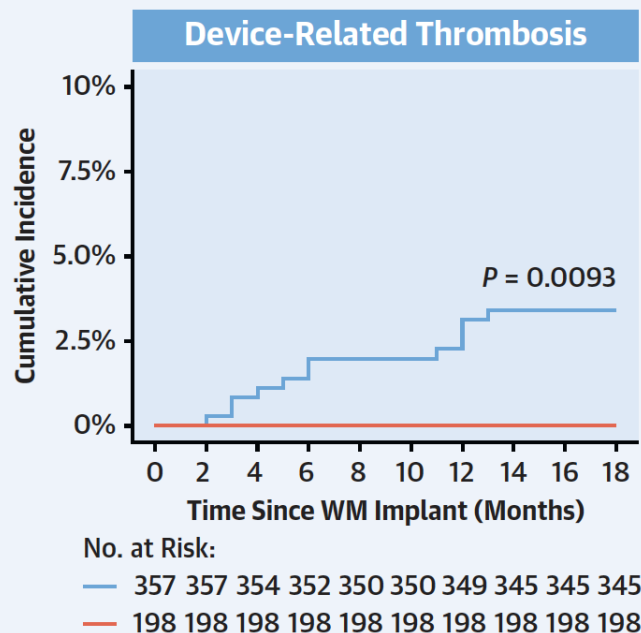
Domenico G. Della Rocca, MD,¹ Michele Magnocavallo, MD,^{1,2} Luigi Di Biase, MD, PhD,^{1,3,4} Sanghamitra Mohanty, MD,⁵ Chintan Trivedi, MD, MPH,⁶ Nicola Tarantino, MD,⁷ Carola Gianni, MD, PhD,⁸ Carlo Lavalley, MD,⁹ Christoffel Johannes Van Niekerk, MD,¹⁰ Jorge Romero, MD,¹¹ David F. Briceño, MD,¹² Mohamed Bassiouny, MD,¹³ Amin Al-Ahmad, MD,¹⁴ I. David Burkhardt, MD,¹⁵ Veronica N. Natale, MPH,¹⁶ G. Joseph Gallinghouse, MD,¹⁷ Armando Del Prete, MD,¹⁸ Giovanni B. Forleo, MD, PhD,¹⁹ Javier Sanchez, MD,²⁰ Dhanunjaya Lakireddy, MD,²¹ Rodney P. Horton, MD,²² Douglas N. Gibson, MD,²³ Andrea Natale, MD^{1,24}

555 Consecutive Watchman Patients

**Group SAT
(n = 357)**
Long-Term Antiplatelet Therapy

Age: 75 ± 8 years
CHA₂DS₂-VASc: 4 [IQR: 3-6]
HAS-BLED: 3 [IQR: 2-4]
Follow-up: 13 [IQR: 12-15]

**Group hdDOAC
(n = 198)**
Long-Term Half-Dose DOAC



Percutaneous occlusion of the left atrial appendage: An expert consensus statement

Consensus d'experts sur les modalités de l'occlusion percutanée de l'auricule gauche

Didier Klug^{a,*,}, Philippe Commeau^{b,}, Pascal Defaye^{c,},
Jean-Benoît Thambo^{d,}, Daniel Gras^{e,}, Pierre Aubry^{f,},
Jean-Luc Pasquie^{g,}, Patrice Guerin^{h,},
Emmanuel Teiger^{i,}, René Koning^{j,}, Olivier Piot^{k,},
for the Heart Rhythm, Pacing Group, the Atheroma,
Interventional Cardiology Group of the French
Society of Cardiology



Arch Cardiovasc Dis. 2015;108:460-7.

HAS

HAUTE AUTORITÉ DE SANTÉ

COMMISSION NATIONALE D'EVALUATION
DES DISPOSITIFS MEDICAUX ET DES TECHNOLOGIES DE SANTE

AVIS DE LA CNEDIMTS
03 juin 2014

CONCLUSIONS

WATCHM/ auriculaire gauche

Demandeur : BOSTON SCIENTIFIC SAS (France)

Fabricant : ATRITECH (Etats Unis d'Amérique)

Les modèles et références retenus sont ceux proposés par le demandeur (cf. page 5)

transcutanée de l'appendice

Indications retenues : Prévention des événements thromboemboliques chez les patients en fibrillation auriculaire non valvulaire à haut risque thromboembolique avec un score CHA₂DS₂-VASc ≥ 4 et une contre-indication formelle et permanente aux anticoagulants (validée par un comité pluridisciplinaire).

La fermeture transcutanée de l'Appendice Auriculaire Gauche (AAG) n'est pas une alternative aux anticoagulants oraux que ce soit en prévention primaire ou en prévention secondaire après un accident ischémique sous traitement bien conduit. Le refus des traitements anticoagulants oraux (AVK ou anticoagulant non-AVK) constitue une non-indication à la fermeture de l'appendice auriculaire gauche.

Modalités de
prescription et
d'utilisation :

Environnement technique

Les établissements doivent être autorisés à proposer les activités interventionnelles, sous imagerie médicale de type 1, 2 ou 3. Les plateaux techniques de cardiologie interventionnelle et de chirurgie cardiaque doivent être regroupés sur le même site, au cas où une conversion en urgence serait nécessaire.

Les établissements doivent disposer :

- en salle d'intervention des techniques d'échographie trans-oesophagienne (ETO) et de fluoroscopie indispensables pour guider l'implantation du DM. L'utilisation de l'angiographie seule n'est pas recommandée.
- dans l'établissement d'une technique de dosage de l'ACT (activated coagulation time).

Composition des équipes

Doivent être présents en salle d'intervention :

- 2 opérateurs qualifiés (cardiologues interventionnels et/ou des rythmologues interventionnels) dont au moins 1 ayant acquis une compétence dans la ponction transseptale,
- 1 cardiologue échographiste,
- 1 anesthésiste-réanimateur,
- 2 infirmières.

Une formation spécifique dédiée pour chacun des DM implantés par le centre est indispensable pour tous les opérateurs, incluant une formation théorique et sur simulateur proposée par le fabricant du dispositif, une formation théorique initiale dans un centre habilité et une formation pratique par compagnonnage (avec au moins 5 patients).

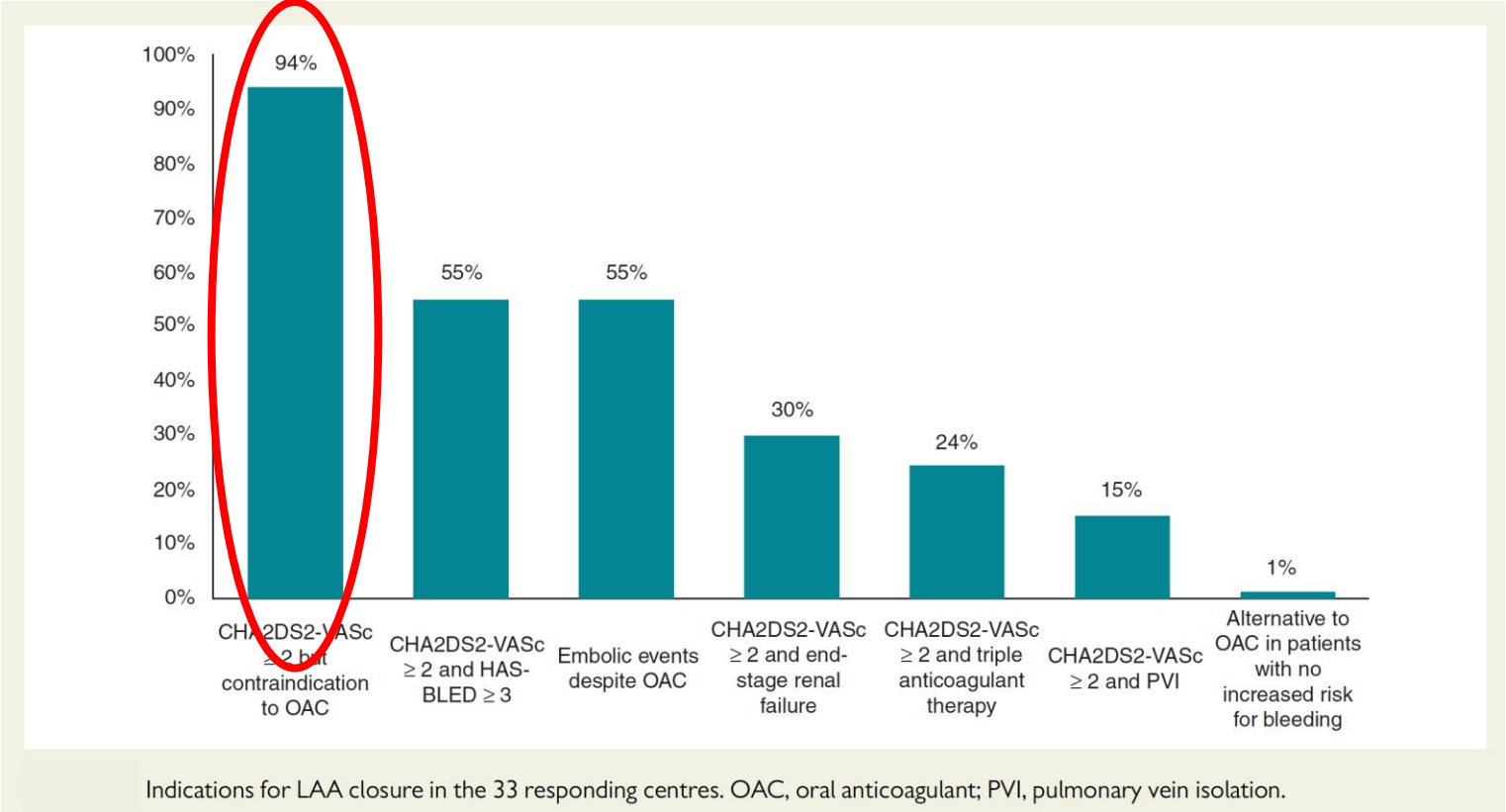
21 juin 2016

JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE

3110611	Implant exovasculaire, fermeture AAG, BOSTON, WATCHMAN.	6 120,00
3192307	Implant exovasculaire, fermeture AAG, SAINT JUDE, AMPLATZER AMULET.	4 850,00

Left atrial appendage closure—indications, techniques, and outcomes: results of the European Heart Rhythm Association Survey

Laurent Pison^{1*}, Tatjana S. Potpara², Jian Chen³, Torben B. Larsen⁴, Maria Grazia Bongiorni⁵, and Carina Blomström-Lundqvist⁶, Conducted by the Scientific Initiative Committee, European Heart Rhythm Association



2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS)

The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC

Recommendations for occlusion or exclusion of the LAA

LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (e.g. intracranial bleeding without a reversible cause).^{448,449,481,482}

IIb

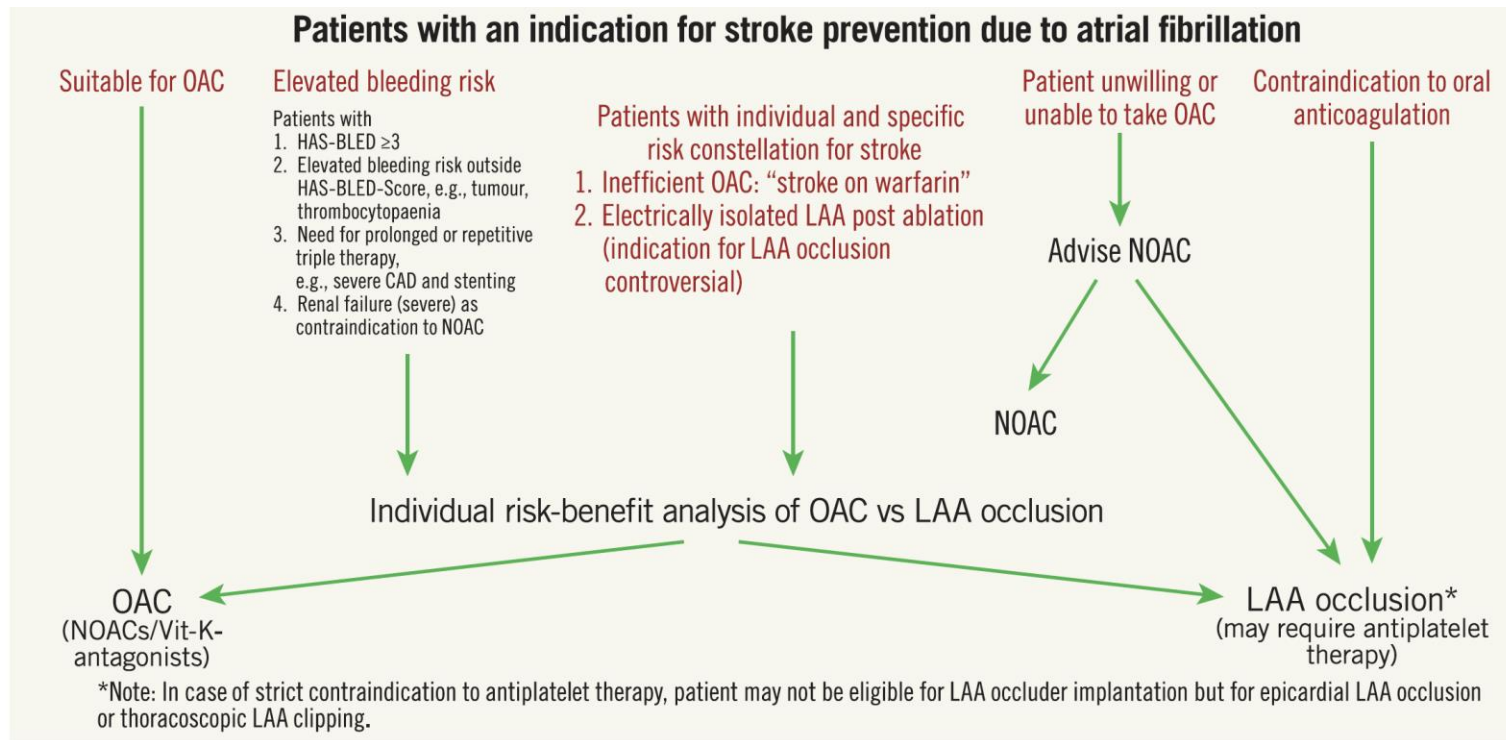
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Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients with AF undergoing cardiac surgery.^{459,483}

IIb

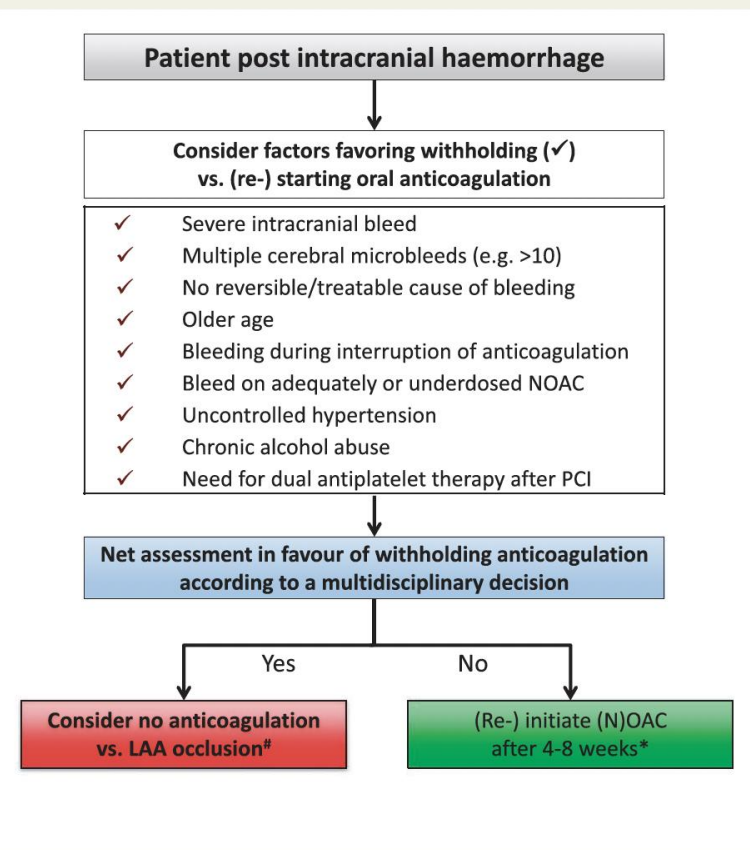
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Decision tree for LAAO closure



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^{1*}, Peter Verhamme², Tatjana S. Potpara³, Pierre Albaladejo⁴,
Matthias Antz⁵, Lien Desteghe⁶, Karl Georg Haeusler⁷, Jonas Oldgren⁸,
Holger Reinecke⁹, Vanessa Roldan-Schilling¹⁰, Nigel Rowell¹¹, Peter Sinnaeve²,
Ronan Collins¹², A. John Camm¹³, and Hein Heidbüchel^{6,14}

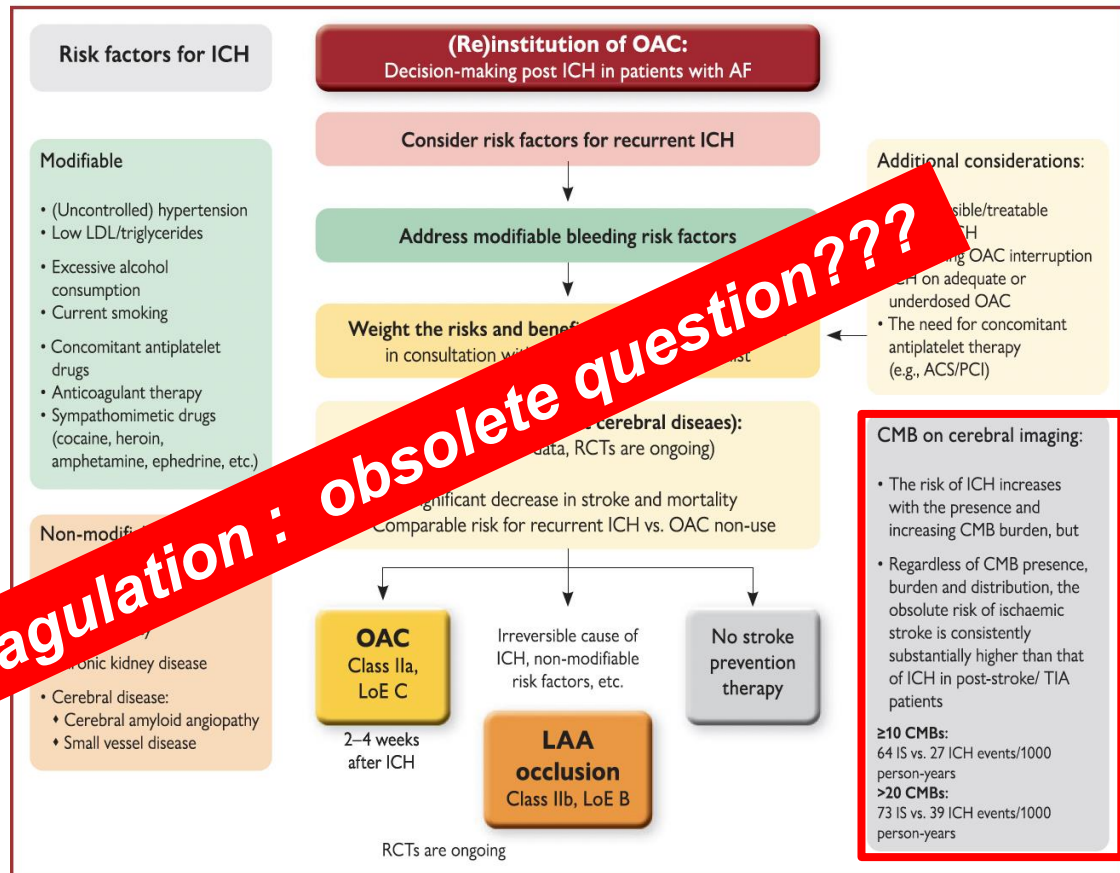


(Re-) initiation of anticoagulation post intracranial bleeding. [#]Without evidence; ideally include the patient in an ongoing trial. ^{*}Brain imaging (CT/MRI) should be considered before (re-)initiation of (non)-vitamin K antagonist oral anticoagulant.

European Heart Journal 2020

Re-initiation of anticoagulation post-intracranial bleeding

CMB : cerebral m...



Recommendations for stroke prevention in AF patients after intracranial haemorrhage

In AF patients at high risk of ischaemic stroke, (re-)initiation of OAC, with preference for NOACs over VKAs in NOAC-eligible patients, should be considered in consultation with a neurologist/stroke specialist after:

- A trauma-related ICH
- Acute spontaneous ICH (which includes subdural, subarachnoid, or intracerebral haemorrhage), after careful consideration of risks and benefits^c

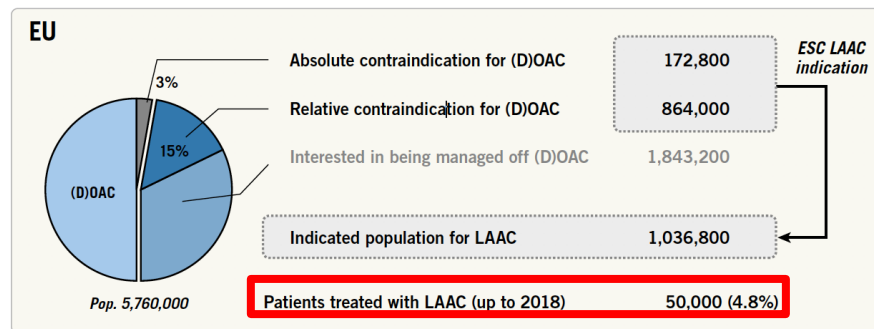
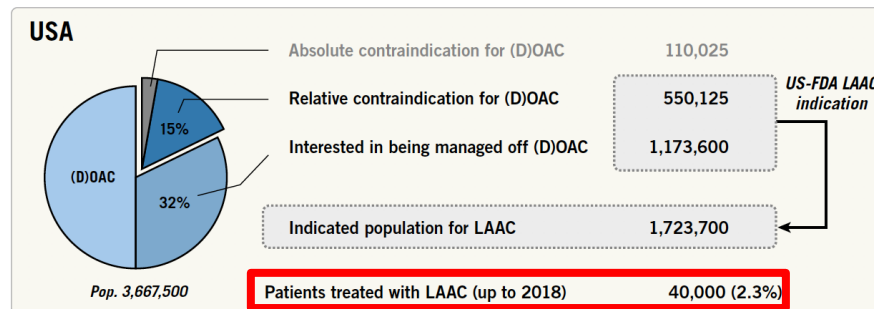
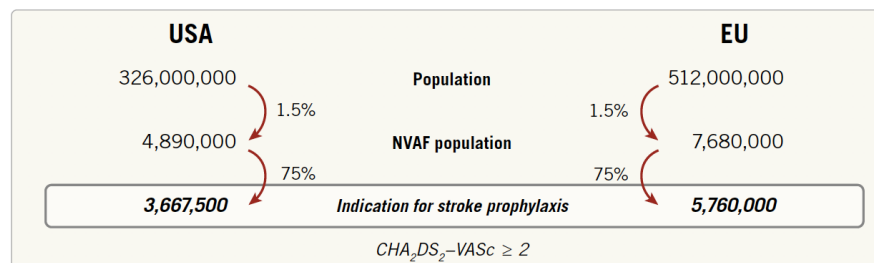
11a

C

Indications, current adoption and future perspectives for percutaneous left atrial appendage closure



Motoki Fukutomi, MD, PhD; Ole De Backer, MD, PhD; Lars Sondergaard*, MD, DMSc
The Heart Center, Rigshospitalet, Copenhagen, Denmark



Indications and current use of LAAC in USA and EU

Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke

R.P. Whitlock, E.P. Belley-Cote, D. Paparella, J.S. Healey, K. Brady, M. Sharma, W. Reents, P. Budera, A.J. Baddour, P. Fila, P.J. Devereaux, A. Bogachev-Prokophiev, A. Boening, K.H.T. Teoh, G.I. Tagarakis, M.S. Slaughter, A.G. Royse, S. McGuinness, M. Alings, P.P. Punjabi, C.D. Mazer, R.J. Folkeringa, A. Colli, Á. Avezum, J. Nakamya, K. Balasubramanian, J. Vincent, P. Voisine, A. Lamy, S. Yusuf, and S.J. Connolly, for the LAAOS III Investigators*

- **Multicenter RCT**
- **AF**
- **CHA2DS2-VASc >2**
- **Scheduled to undergo cardiac surgery for another indication**



- **2379 participants in the occlusion group**
- **2391 in the no-occlusion group,**
- **Mean age : 71 years**
- **Mean CHA2DS2-VASc score = 4.2**

The Closing Argument for Surgical Left Atrial Appendage Occlusion

Richard L. Page, M.D.

Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke

R.P. Whitlock, E.P. Belley-Cote, D. Paparella, J.S. Healey, K. Brady, M. Sharma, W. Reents, P. Budera, A.J. Baddour, P. Fila, P.J. Devereaux, A. Bogachev-Prokophiev, A. Boening, K.H.T. Teoh, G.I. Tagarakis, M.S. Slaughter, A.G. Royse, S. McGuinness, M. Alings, P.P. Punjabi, C.D. Mazer, R.J. Folkerling, A. Colli, A. Avezum, J. Nakamya, K. Balasubramanian, J. Vincent, P. Voisine, A. Lamy, S. Yusuf, and S.J. Connolly, for the LAAOS III Investigators*

Variable	Occlusion (N = 2379)	No Occlusion (N = 2391)
Participants		
Age — yr	71.3±8.4	71.1±8.3
Male sex — no. (%)	1617 (68.0)	1601 (67.0)
Type of atrial fibrillation — no. (%)		
Permanent	692 (29.1)	707 (29.6)
Persistent	577 (24.3)	508 (21.3)
Paroxysmal	1110 (46.7)	1176 (49.2)
Medical history — no. (%)		
Previous myocardial infarction	567 (23.8)	583 (24.4)
Previous stroke	214 (9.0)	219 (9.2)
Rheumatic heart disease	165 (6.9)	162 (6.8)
Peripheral arterial disease	236 (9.9)	256 (10.7)
History of heart failure	1348 (56.7)	1372 (57.4)
Diabetes mellitus	770 (32.4)	765 (32.0)
Aortic plaque	240 (10.1)	231 (9.7)
Smoking, former or current	1127 (47.4)	1173 (49.1)
Hypertension	1960 (82.4)	1941 (81.2)
CHA ₂ DS ₂ -VASc score†		
Mean	4.2±1.5	4.2±1.5
Median (interquartile range)	4 (3–5)	4 (3–5)
Atrial fibrillation on baseline ECG — no. (%)	1392 (58.5)	1338 (56.0)
Left ventricular ejection fraction <50% — no./total no. (%)	671/2179 (30.8)	669/2188 (30.6)
Anticoagulant therapy within 7 days before surgery		
Vitamin K antagonist — no. (%)	541 (22.7)	542 (22.7)
Direct oral anticoagulant — no. (%)	674 (28.3)	705 (29.5)
Neither direct oral anticoagulant nor vitamin K antagonist — no. (%)	1164 (48.9)	1144 (47.8)

Cardiac surgery

Surgical procedure performed — no. (%)

Isolated CABG	482 (20.3)	522 (21.8)
Isolated valve replacement	552 (23.2)	572 (23.9)
Other	1344 (56.5)	1296 (54.2)
Any valve procedure	1565 (65.8)	1614 (67.5)
Mitral	856 (36.0)	880 (36.8)
Aortic	837 (35.2)	858 (35.9)
Tricuspid	397 (16.7)	427 (17.9)
Pulmonic	2 (0.1)	4 (0.2)
Any aortic procedure	146 (6.1)	134 (5.6)

Concomitant surgical ablation of atrial fibrillation — no. (%)

Received assigned procedure — no. (%)	2131 (89.6)	2262 (94.6)
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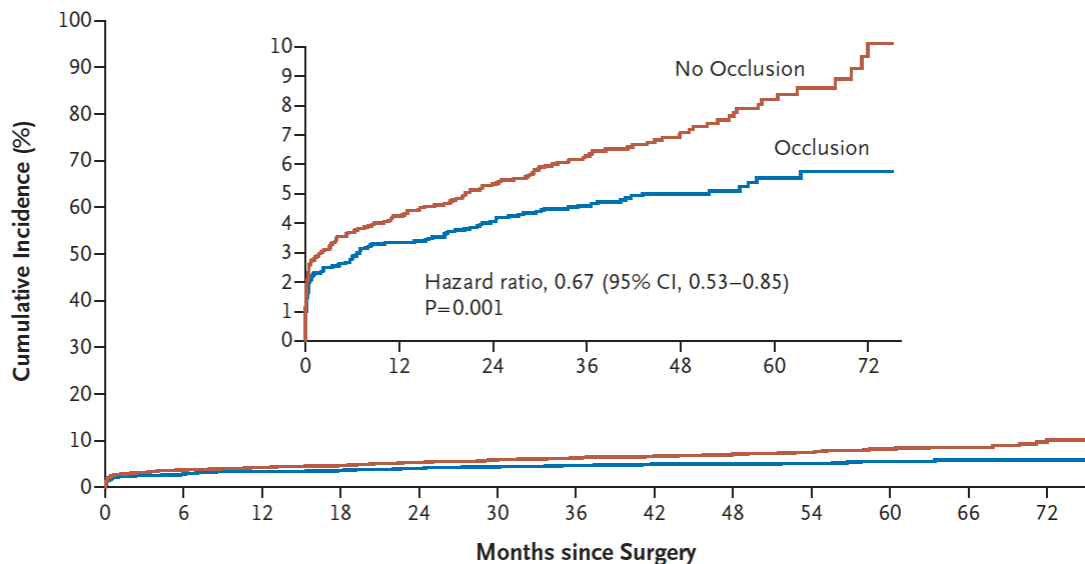
Variable

Left atrial appendage occlusion‡

Occlusion attempted — no. (%)	2131 (89.6)	NA
Occlusion method — no./total no. (%)§		
Cut and sew	939/1685 (55.7)	NA
Stapler	189/1685 (11.2)	NA
Closure device	255/1685 (15.1)	NA
Closure from within	233/1685 (13.8)	NA
Other approved techniques	69/1685 (4.1)	NA

Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke

R.P. Whitlock, E.P. Belley-Cote, D. Paparella, J.S. Healey, K. Brady, M. Sharma, W. Reents, P. Budera, A.J. Baddour, P. Fila, P.J. Devereaux, A. Bogachev-Prokophiev, A. Boening, K.H.T. Teoh, G.I. Tagarakis, M.S. Slaughter, A.G. Royse, S. McGuinness, M. Alings, P.P. Punjabi, C.D. Mazer, R.J. Folkeringa, A. Colli, A. Avezum, J. Nakamya, K. Balasubramanian, J. Vincent, P. Voisine, A. Lamy, S. Yusuf, and S.J. Connolly, for the LAAOS III Investigators*



No. at Risk

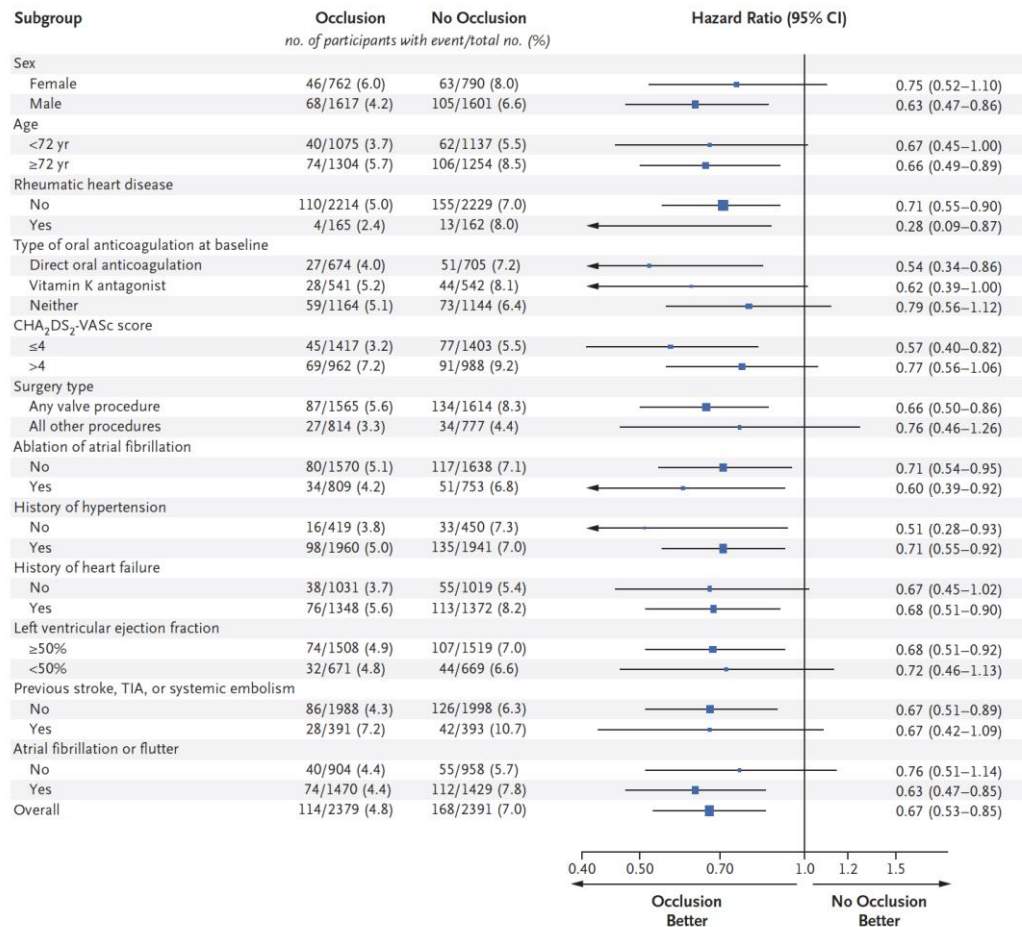
No Occlusion	2391	2134	2081	2030	1981	1897	1607	1291	1016	751	540	348	205
Occlusion	2379	2163	2105	2059	2020	1948	1642	1322	1046	781	550	349	199

Figure 1. Cumulative Incidence of Stroke or Systemic Arterial Embolism.

The participants in the occlusion group underwent left atrial appendage occlusion at the time of cardiac surgery for another indication, and those in the no-occlusion did not undergo left atrial appendage occlusion at the time of cardiac surgery; all participants were expected to receive usual care. The inset shows the same data on an enlarged y axis.

Left Atrial Appendage Occlusion during Cardiac Surgery to Prevent Stroke

R.P. Whitlock, E.P. Belley-Cote, D. Paparella, J.S. Healey, K. Brady, M. Sharma, W. Reents, P. Budera, A.J. Baddour, P. Fila, P.J. Devereaux, A. Bogachev-Prokophiev, A. Boening, K.H.T. Teoh, G.I. Tagarakis, M.S. Slaughter, A.G. Royse, S. McGuinness, M. Alings, P.P. Punjabi, C.D. Mazer, R.J. Folkeringa, A. Colli, A. Avezum, J. Nakamya, K. Balasubramanian, J. Vincent, P. Voisine, A. Lamy, S. Yusuf, and S.J. Connolly, for the LAAOS III Investigators*



- Fermeture percutanée auricule G : alternative fiable et validée aux anticoagulants / FA N
- Registres récents/ progrès technologiques avec nouvelles prothèses/ équipes entraînées



Excellents résultats à long terme

- Actuellement en France : **Fermeture percutanée auricule G = CHADSVASC ≥ 4 + CI définitive AC**

- Eudes importantes en cours :

- LAAO vs AOD s après ablation FA avec Watchman : OPTION / résultats 2022 +++++
- LAAO (Watchman) vs AOD : étude CHAMPION-AF



- **extension des indications??? (CHADSVASC ≥ 2 + CI définitive AC)**
- **Alternative???**