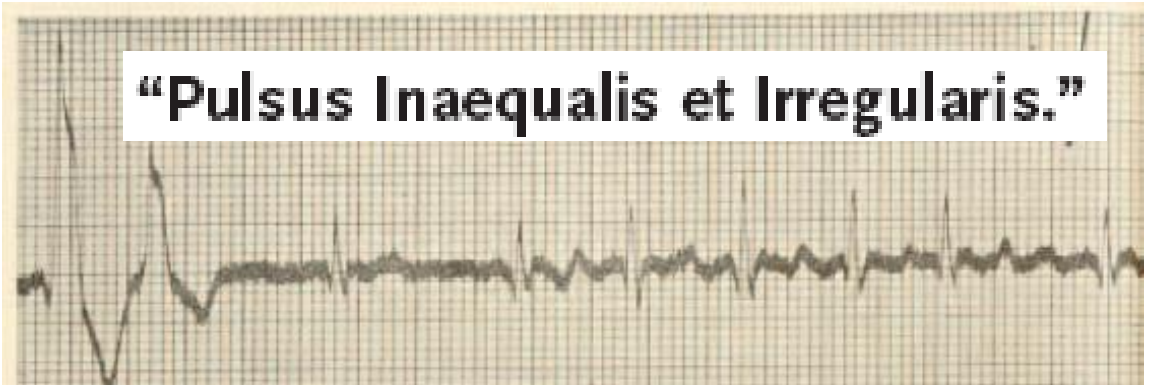
Fermeture de l'auricule gauche dans la FA non valvulaire

Groupe Jolimont

Antoine de Meester

Jolimont 22-2-2018

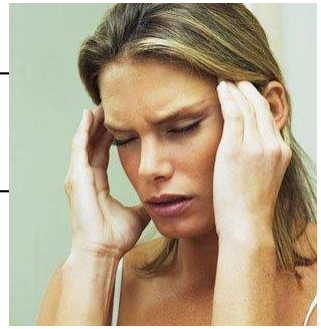
1er enregistrement de FA en 1906 - Einthoven

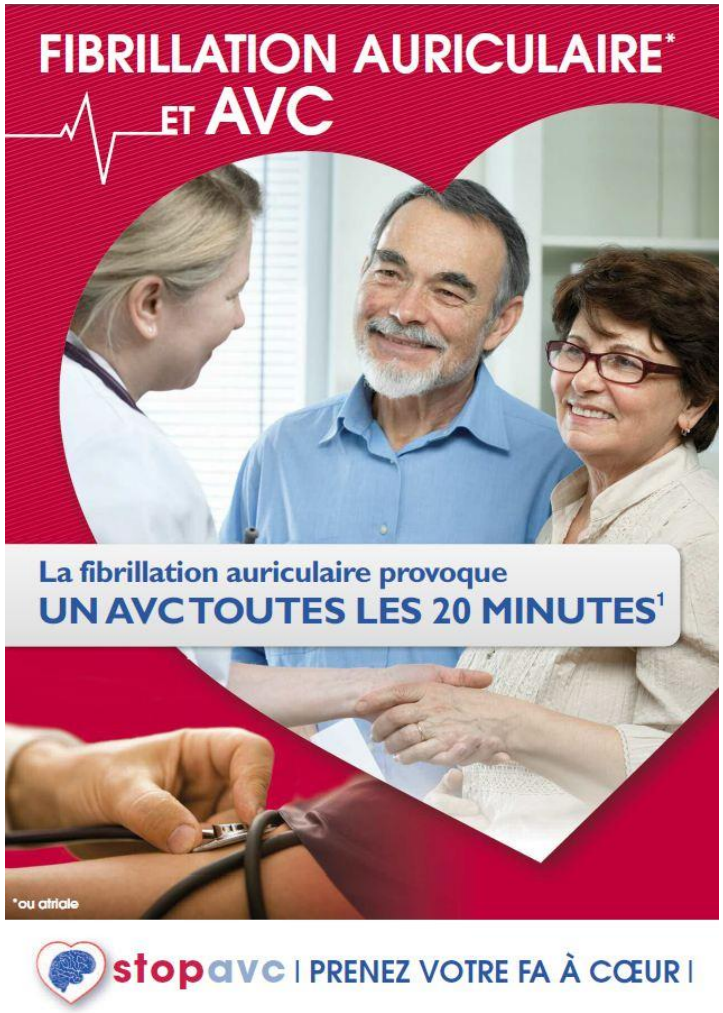


DEUX EPIDEMIES DE MALADIES CARDIOVASCULAIRES SONT A NOS PORTES : la décompensation cardiaque et la FA (E. BRAUNWALD NEJM 1997)

- Mortalité x2 indépendamment du risque de comorbidité cardiovasculaire
- Hospitalisation x2-3 ; la FA est l'arythmie la + exposée à une hospitalisation
- AVC x4.5 ; + des troubles cognitifs majeurs (micro-embols à l'IRM)
- Insuffisance cardiaque x3.5, tachycardiomyopathie
- Réduction de qualité de vie (QOL) vu les symptômes nombreux (fatigue, palpitation, dyspnée, ↓ tolérance à l'effort)

Risque MAJEUR = AVC





- La FA entraîne un risque d'AVC de 4-5x plus par rapport à un patient en RS[1]
- La FA est responsable d'1/3 des AVC[2]
- La FA est souvent asymptomatique
- L'absence de symptômes (pex. angor, dyspnée, palpitations) n'implique pas un faible risque d'AVC[3]

1. *Wolf et al. Stroke 1991; 22: 983-8.*
2. Hannon N et al. Cerebrovasc Dis 2010; 29: 43–9.
3. *Flaker et al. Am Heart J 2005; 149: 657-63.*

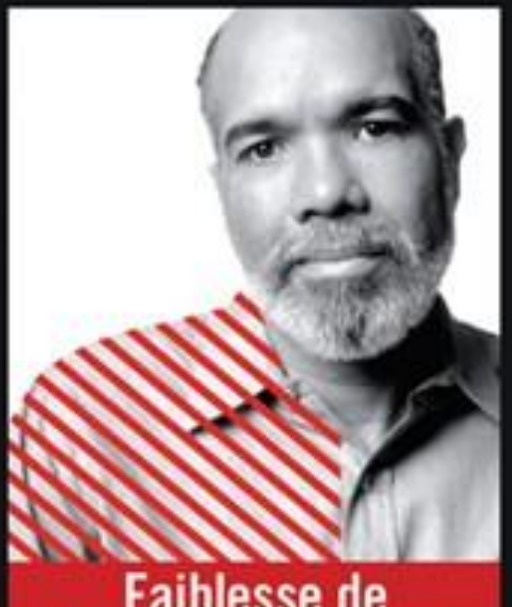
CENTRES HOSPITALIERS JOLIMONT ASBL

RECONNAÎTRE L'AVC

Apparition brutale de l'un de ces signes, n'attendez pas

Trouble de la parole

Bouche de travers



Faiblesse de la moitié du corps

Campagnes de prévention de la FA

La Semaine du Rythme Cardiaque
est une initiative du
Belgian Heart Rhythm Association

Créé en 1980, le BeHRA est un groupe de travail de la Société Belge de Cardiologie, rassemblant tous les cardiologues spécialisés dans les troubles du rythme cardiaque.

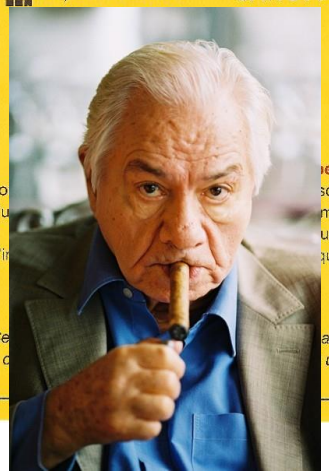
Ses principales missions sont la promotion de l'étude et du développement de la stimulation cardiaque, de l'électrophysiologie et de la rythmologie cardiaque au sens le plus large, par l'organisation de réunions scientifiques, l'échange d'informations et le soutien de la recherche fondamentale et clinique.

BeHRA
Belgian Heart Rhythm Association

Cette campagne est organisée avec le soutien de

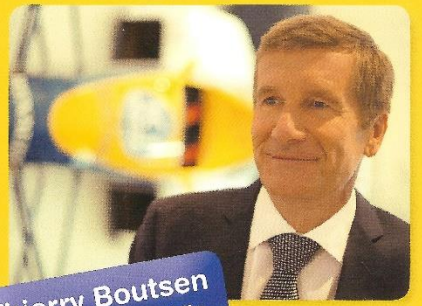
Boehringer Ingelheim

St. Jude Medical SANOFI



Editeur responsable : Dr. Yves Vandekerckhove

Mon cœur en pole position !



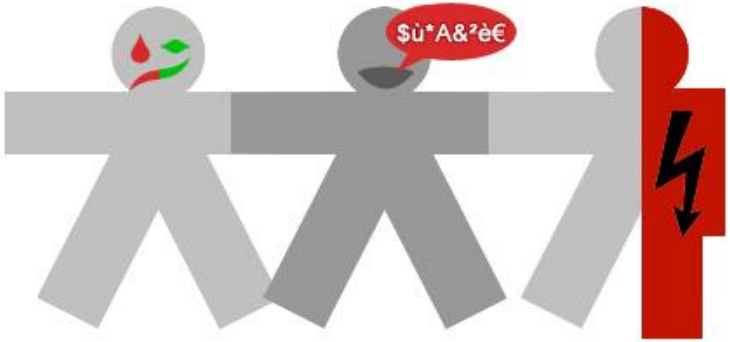
Thierry Boutsen
Champion automobile
Parrain de la Semaine
du Rythme Cardiaque

Rendez-vous sur
www.monrythmecardiaque.be

Semaine du Rythme Cardiaque
1 - 5 juin 2015
Test gratuit près de chez vous !

AVC
Accident Vasculaire Cérébral

Si vous constatez **BRUTALEMENT**



Déformation de la bouche | Trouble de la parole | Faiblesse d'un coté

C'est peut être un AVC ...

URGENCE

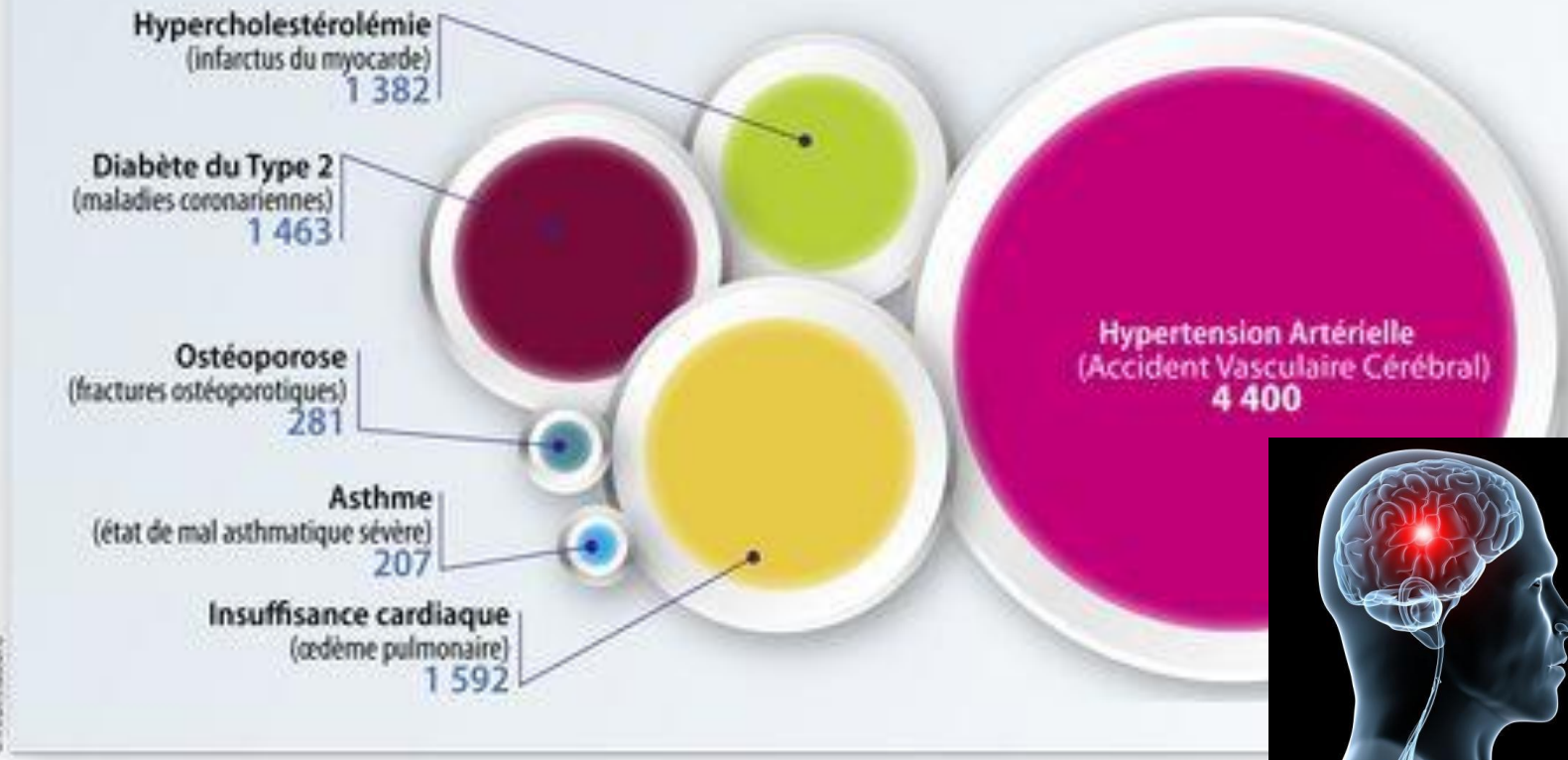
4H30 Maximum pour traiter et limiter les séquelles!

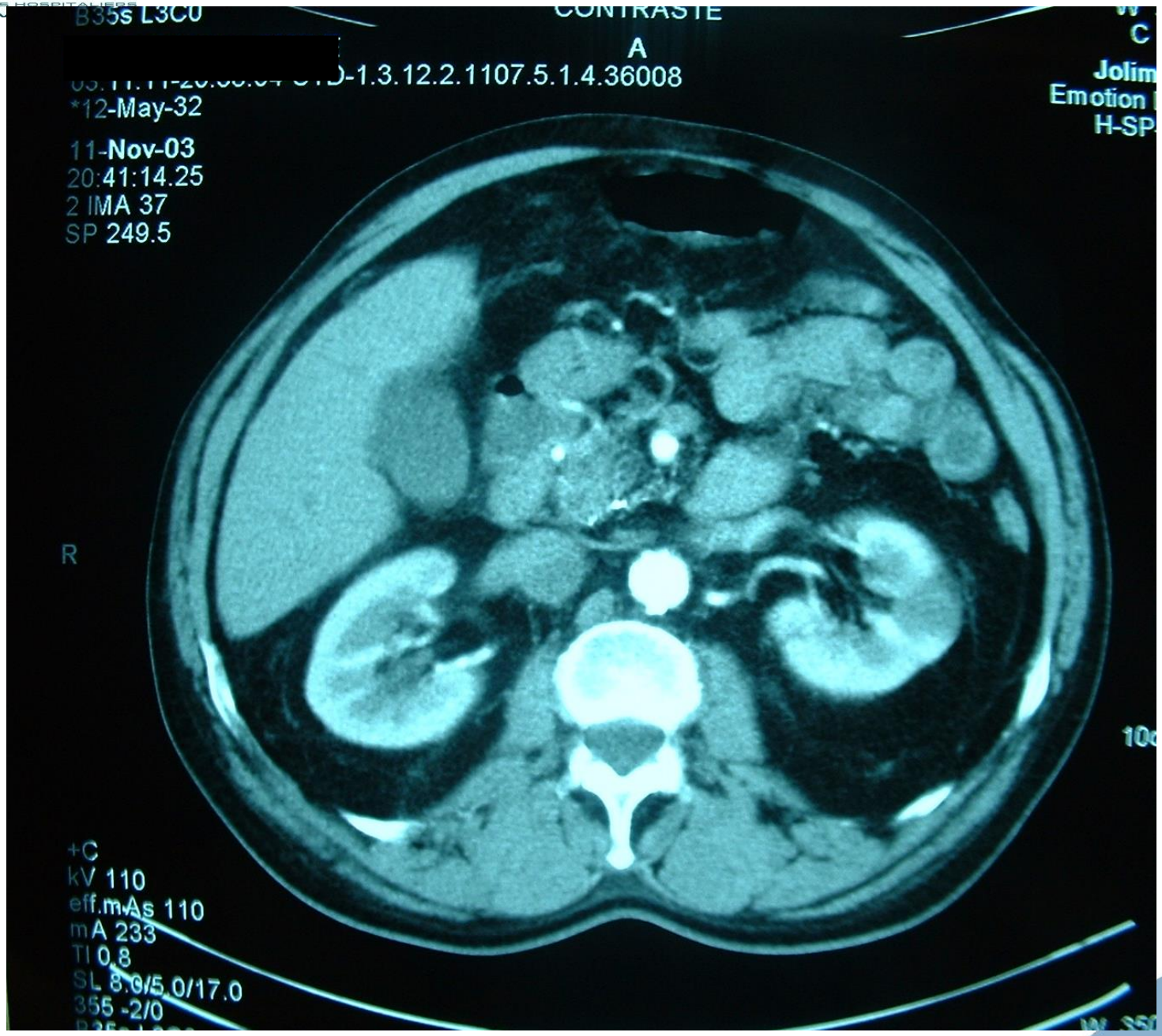
FAITES IMMEDIATEMENT le 15

Chaque minute compte !

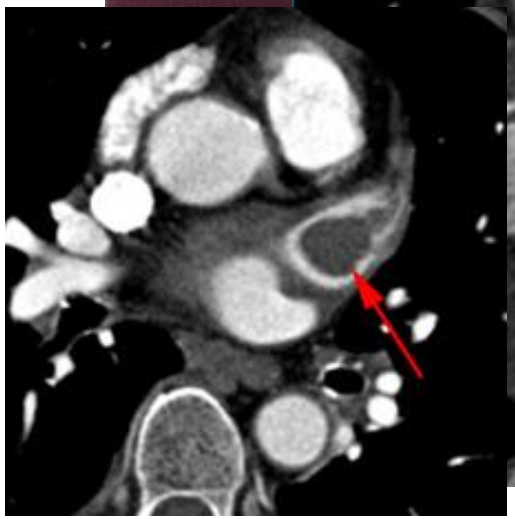
LES COUTS DES COMPLICATIONS PAR PATHOLOGIE (EN MILLIONS D'EUROS)

Dépenses de biens et services médicaux pour une année

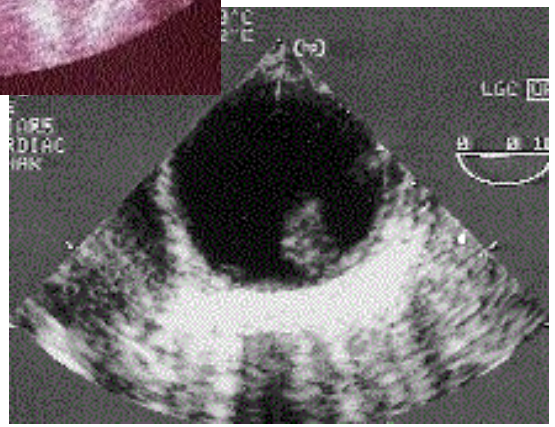



B35s L3C0
CONTRASTE
A
-1.3.12.2.1107.5.1.4.36008
*12-May-32
11-Nov-03
20:41:14.25
2 IMA 37
SP 249.5
Jolim
Emotion
H-SP
R
+C
kV 110
eff.mAs 110
mA 233
TI 0.8
SL 8.0/5.0/17.0
355 -2/0

Site de thrombus dans la FA



Facteurs de risque embolique dans la FA … à l'échocardiographie



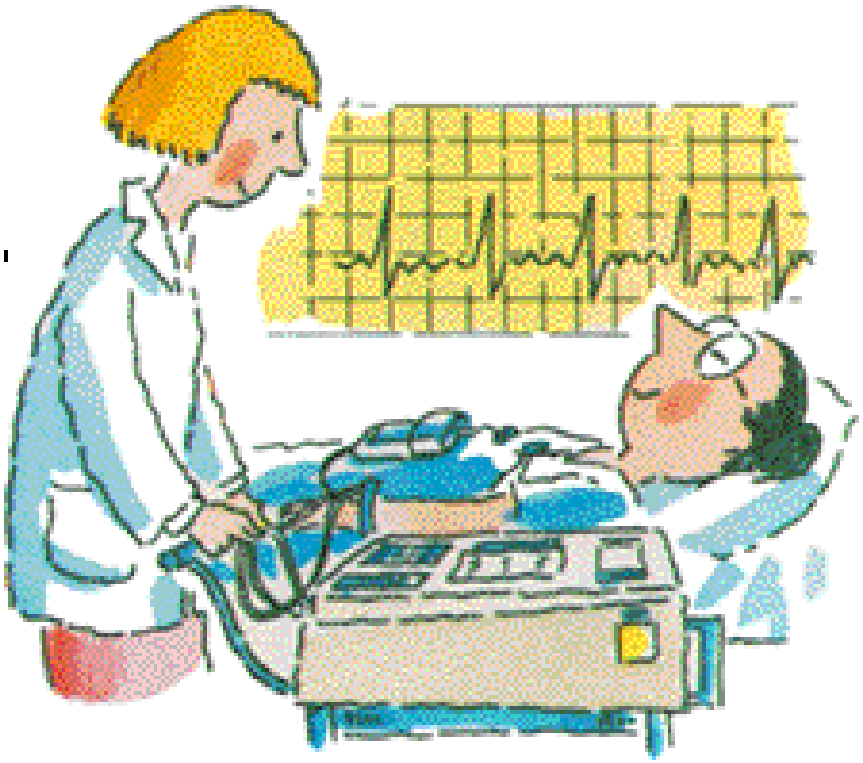
- Dilatation de l'O.G. > 45 mm
- Altération fonction VG - FE<40%
- Présence thrombus (10%)
- Présence contraste spontané (35%) : agrégats de GR
- Plaques d'athérome aortique complexes

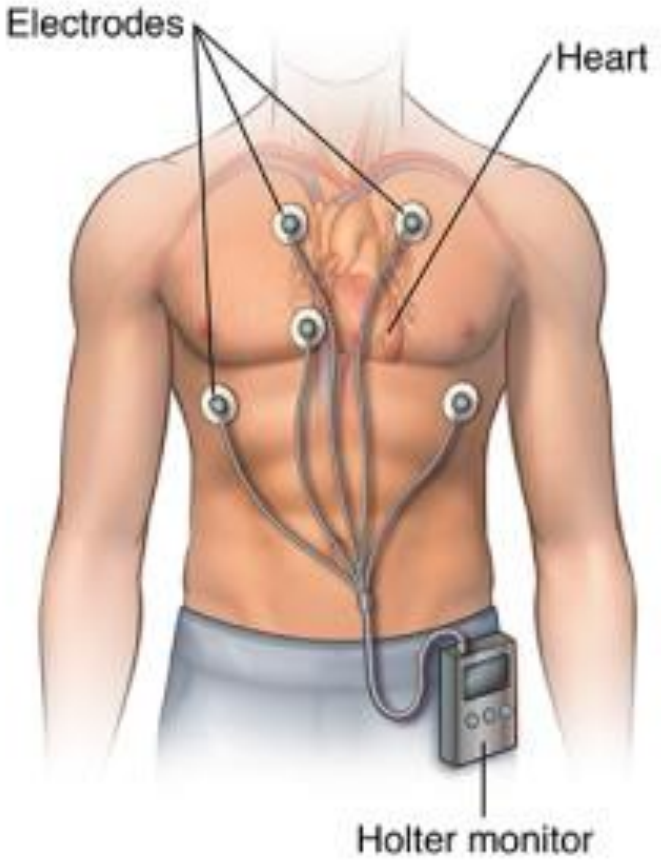
Notion de FA « valvulaire »

- Importance MAJEURE pour le type d'anticoagulation
  - ❑ FA « valvulaire » … Sintrom®
  - ❑ FA « non valvulaire » …. NOAC ou Sintrom®

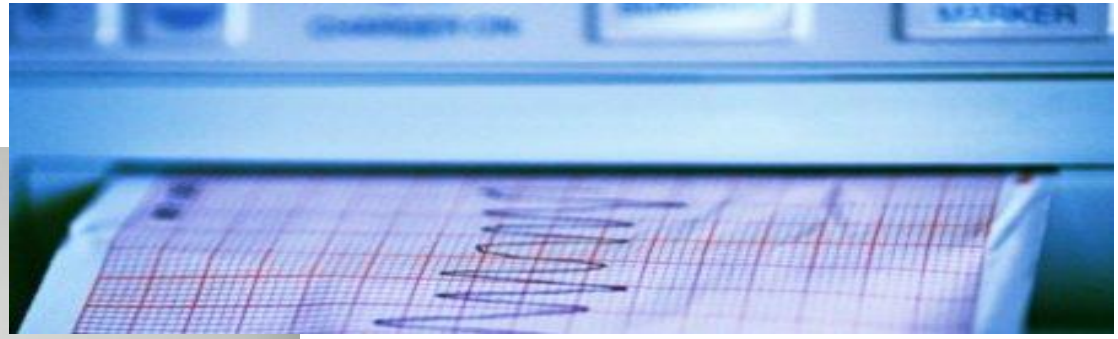
- FA « valvulaire » (référence de Caterina R, Camm J, Eur Heart J 2014)
  - ✓ Selon études … restrictions différentes
  - ✓ OUI
    - ✓ **Prothèses mécaniques**
    - ✓ **Sténose mitrale « rhumatismale » modérée à sévère**
  - ✓ NON (pas de risque TE majoré des NOAC vs Warfarine)
    - ✓ **valvulopathies comme IM, IAo, RAo**
    - ✓ **Cardiomyopathie hypertrophique**
    - ✓ **Bioprothèse ou plastie valvulaire**

1. Arythmie auriculaire irrégulière à l'ECG 12-dérivations
2. Définition :
   - FA suffisamment longue pour enregistrer un tracé ECG
   - FA > 30 secondes (Holter, PM ou ICD, …)



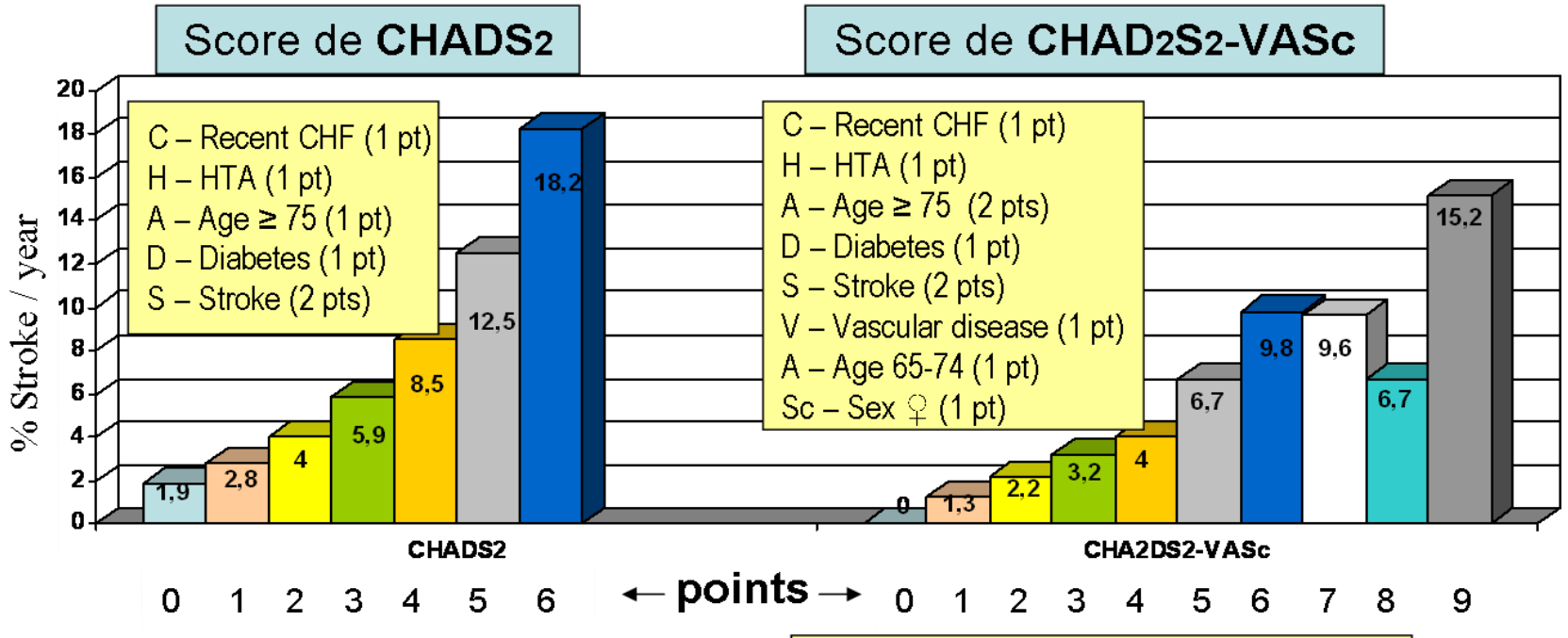


CENTRES HOSPITALIERS
JOLIMONT ASBL



Holter Monitor

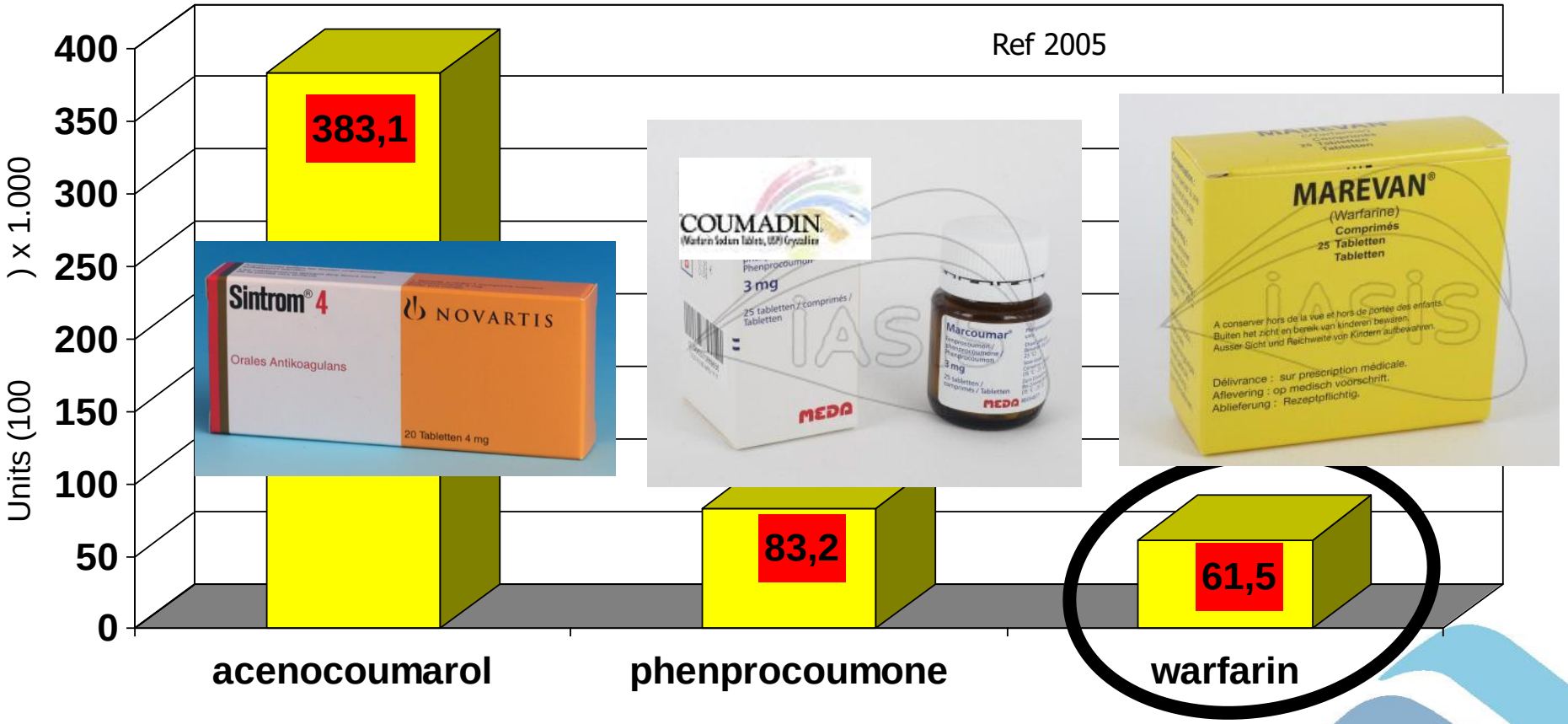
SCORES DE RISQUE THROMBO-EMBOLIQUE ET DE SAIGNEMENTS



HAS-BLED
Bleeding risk score

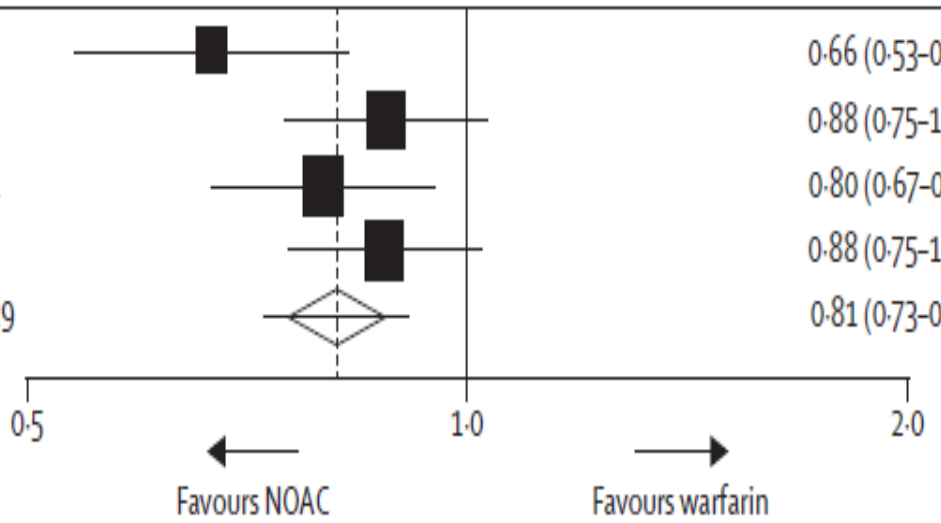
H – HTA (Systolic HTA > 160 mmHg) (1 pt)
A – Abnormal renal or liver function (1-2 pts)
S – Stroke (1 pt)
B – Bleeding (1 pt)
L – Labile INRs (1 pt)
E – Elderly (Age > 65 years) (1 pt)
D – Drugs or alcohol (1-2 pts)

Anticoagulants AVK en Belgique ... < 2010



Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with atrial fibrillation: a meta-analysis of randomised trials

	NOAC (events)	Warfarin (events)	RR (95% CI)	p
RE-LY[5]*	134/6076	199/6022	0·66 (0·53–0·82)	0·0001
ROCKET AF[6]†	269/7081	306/7090	0·88 (0·75–1·03)	0·12
ARISTOTLE[7]‡	212/9120	265/9081	0·80 (0·67–0·95)	0·012
ENGAGE AF-TIMI 48[8]§	296/7035	337/7036	0·88 (0·75–1·02)	0·10
Combined (random)	911/29312	1107/29229	0·81 (0·73–0·91)	<0·0001



71,683 pts

CT Ruff et al. ***Lancet* 2014; 383: 955–62**

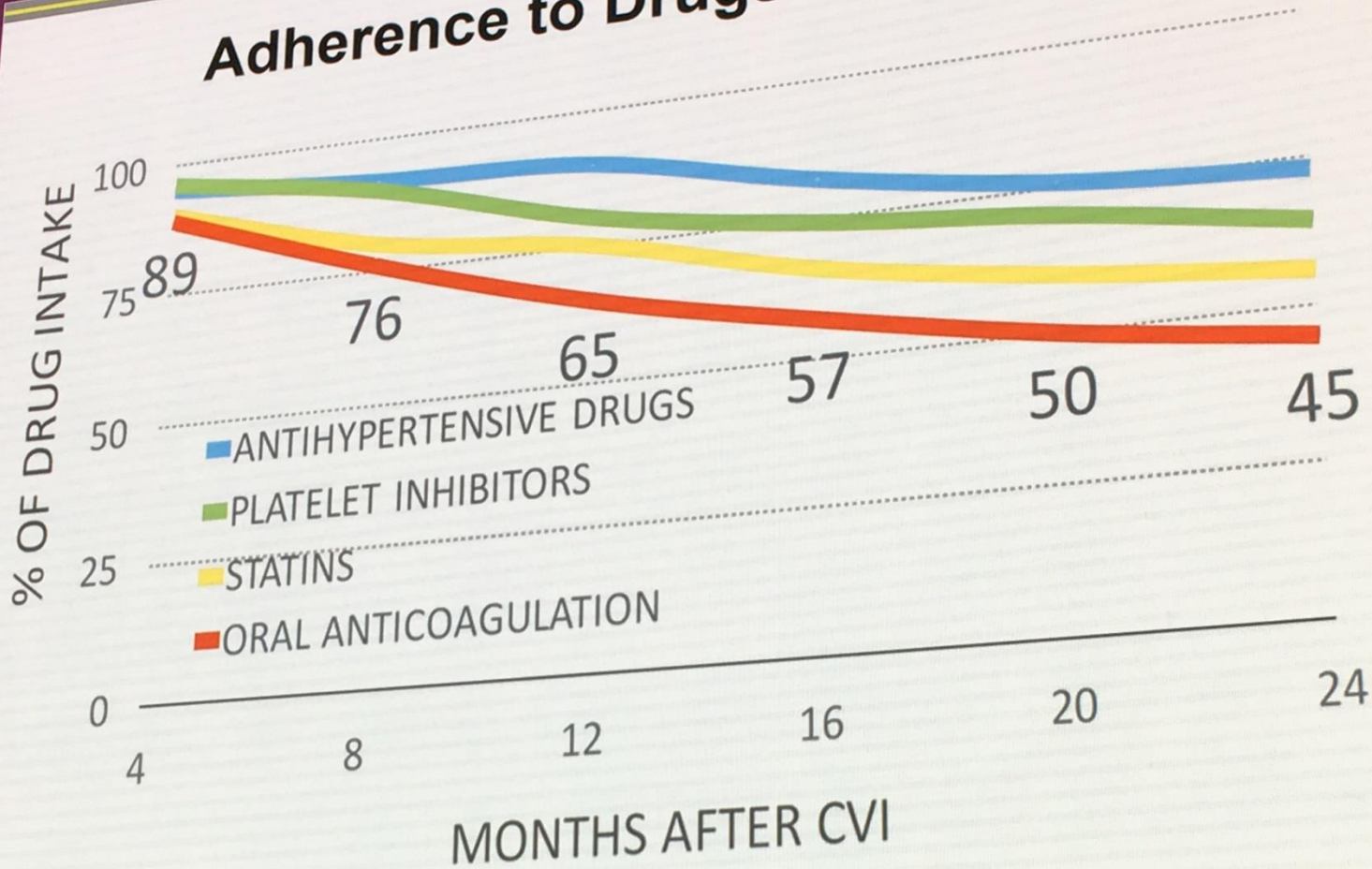
„Absolute“ Contraindication for Long-Term OAC

- „Untreatable“ source of
  - Intracranial/intraspinal bleeding (eg diffuse amyloid angiopathy)
  - severe gastroint. (diffuse angiodysplasia) or urogenital bleeding
- Severe side effects under vit-k-antagonists + contraindication for NOAC (severe renal insufficiency)

„Relative“ Contraindication for Long-Term OAC

- With or without significant bleeding event
  +
  - incomplete causal treatment options (rec. gastric ulcus disease, inflammatory bowel disease, cancer)
  - renal insufficiency, pts. on hemodialysis
  - recurrent falling with injuries and significant bleeding
  - Rec. need for triple therapy in severe CAD

Adherence to Drugs after Stroke



Glader et al. Stroke 2010

The New Oral Anticoagulants Reduce the Risk of Stroke…

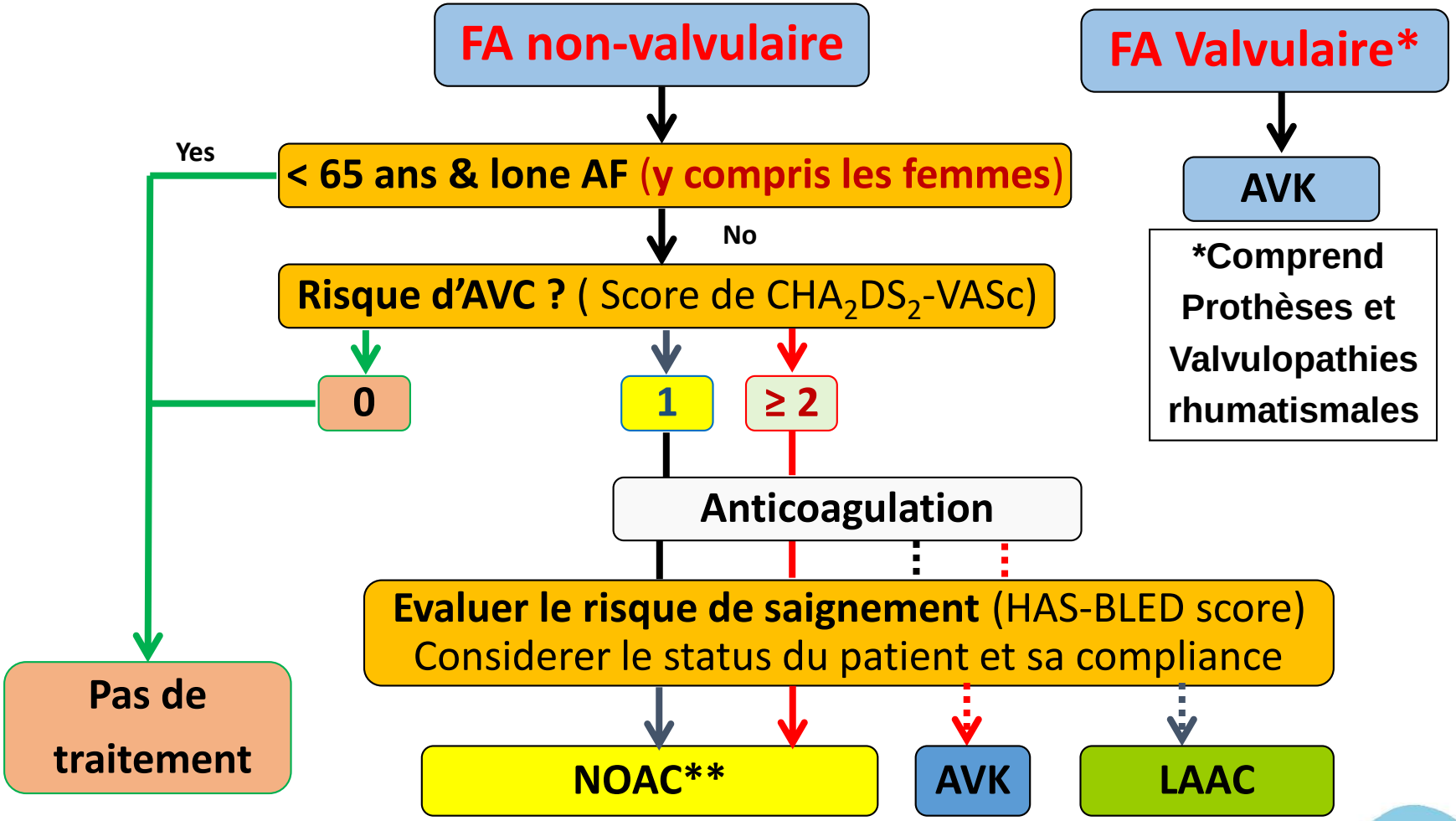
… But they have continued bleeding and discontinuation over time

Study	Treatment	Major Bleeding	Hemorrhagic Stroke	Discontinuation in the study
RE-LY[17]	Dabigatran (110mg)	2.71 %	0.12 %	20.7 %
	Dabigatran (150mg)	3.11 %	0.10 %	21.2 %
	Warfarin	3.36 %	0.38 %	16.6 %
ROCKET-AF[18]	Rivaroxaban	3.6 %	0.5%	23.7%
	Warfarin	3.4 %	0.7 %	22.2 %
ARISTOLE[3]	Apixaban	2.13 %	0.24 %	25.3 %
	Warfarin	3.09 %	0.47 %	nc

This chart is not based on a head-to-head trial and is not intended to suggest head-to-head comparisons of the separate trials or the therapies under study.

References 17, 18 page 39 of this presentation.

Recommandations de l'ESC en 2012 (upgrade)



****NOAC … à la place des AVK (INR 2-3) chez la plupart des patients ?**

Adapted from Camm et al. Guidelines 2016

Recommendations for LAA closure/occlusion/excision

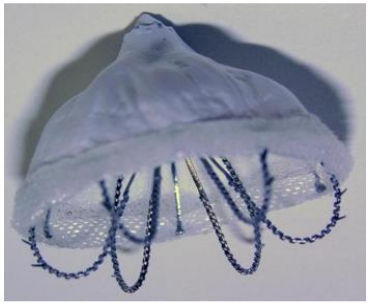
Recommendations	Class[a]	Level[b]	Ref[c]
Interventional, percutaneous LAA closure may be considered in patients with a high stroke risk and contraindications for long-term oral anticoagulation.	IIb	B	115, 118
Surgical excision of the LAA may be considered in patients undergoing open heart surgery.	IIb	C	

Camm et al. [illegible]sed Update 2012

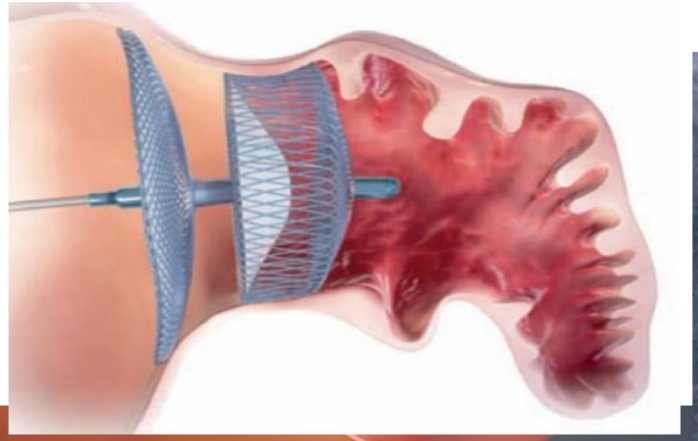
PLATTO system

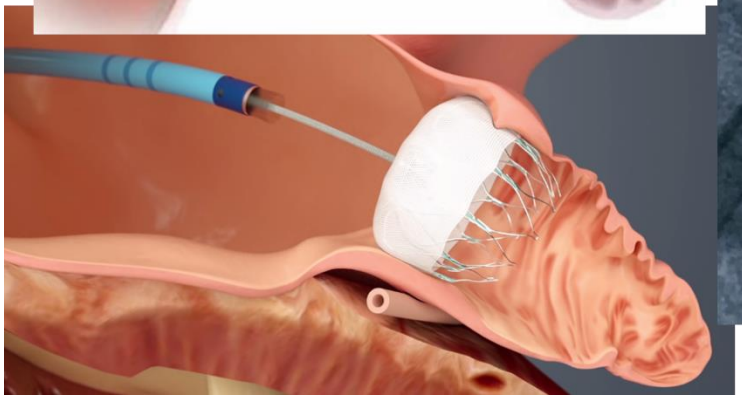
Watchman™

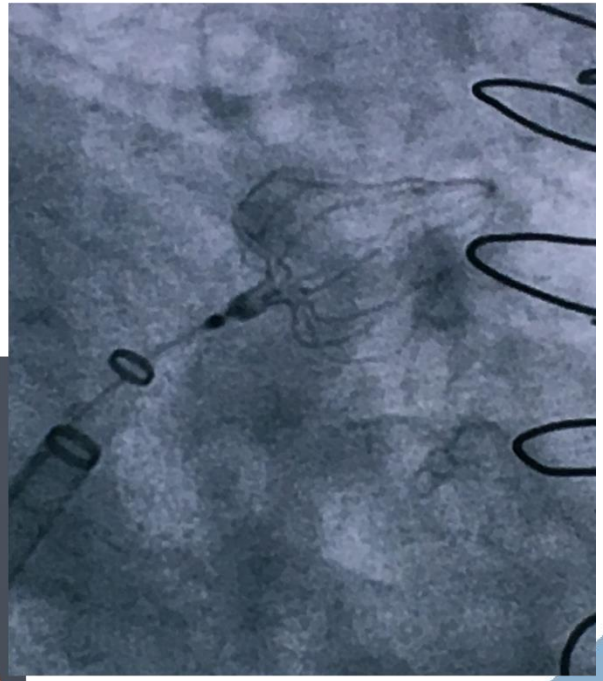
Amplatzer™



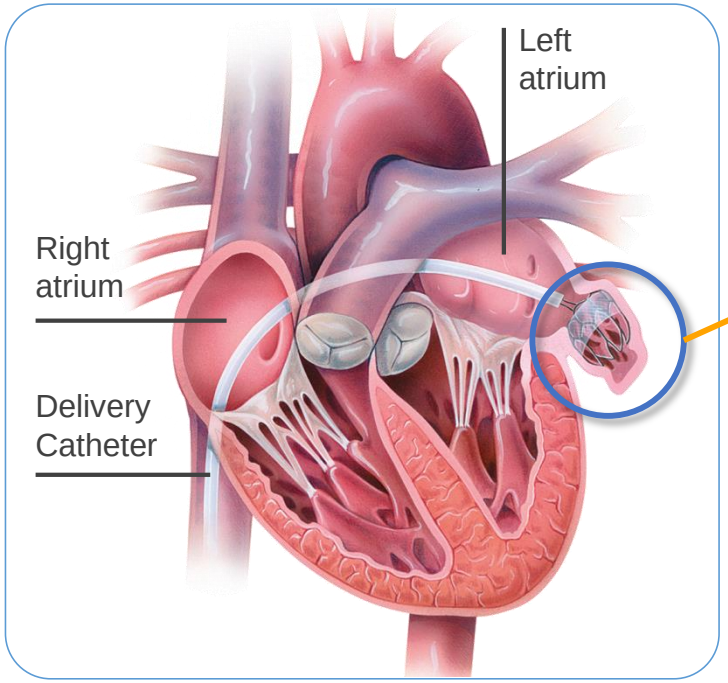
WaveCrest™

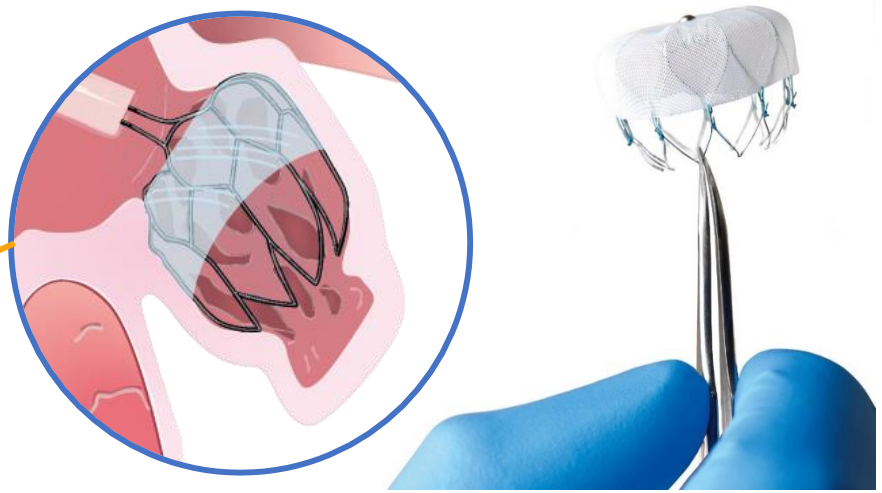






The WATCHMAN™ Technology



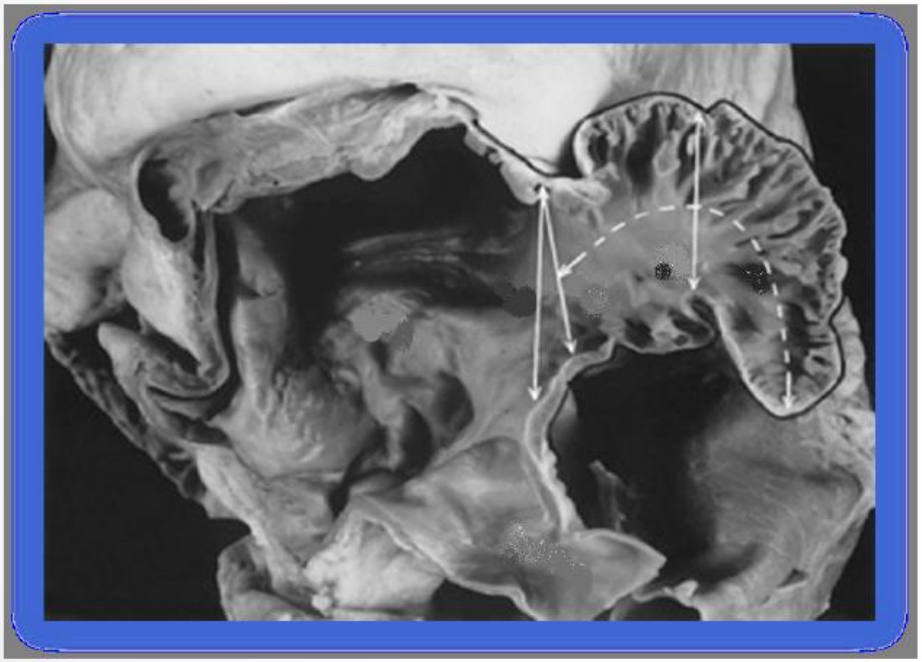


Left Atrial Appendage
with **WATCHMAN™** device implanted

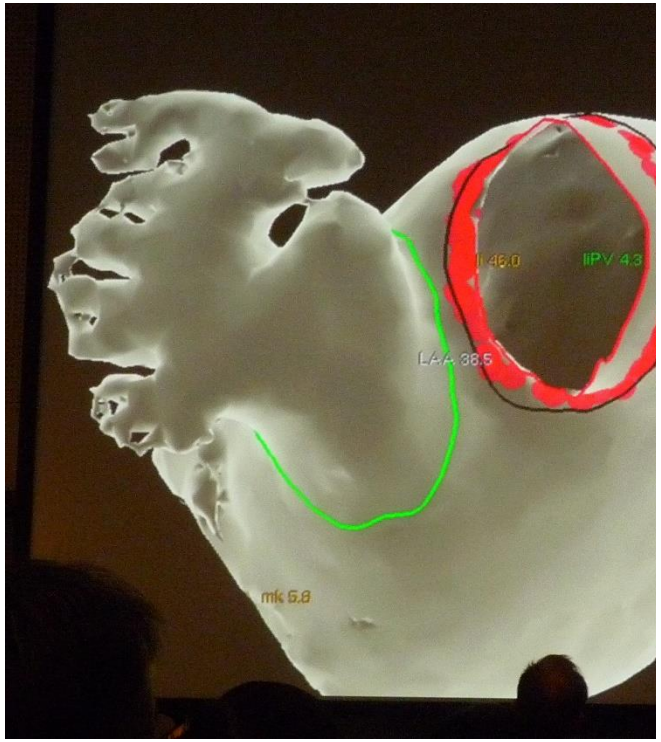
- Implanted via a transseptal approach
- The delivery catheter is capable of recapturing the device if necessary
- CE marked in 2005

- Self-expanding nitinol frame with fixation anchors and a permeable fabric cover
- Designed to be permanently implanted at or slightly distal to the opening of the LAA to trap potential emboli before they exit the LAA

ANATOMIE DE L'AURICULE GAUCHE



ANATOMIE DE L'AURICULE GAUCHE



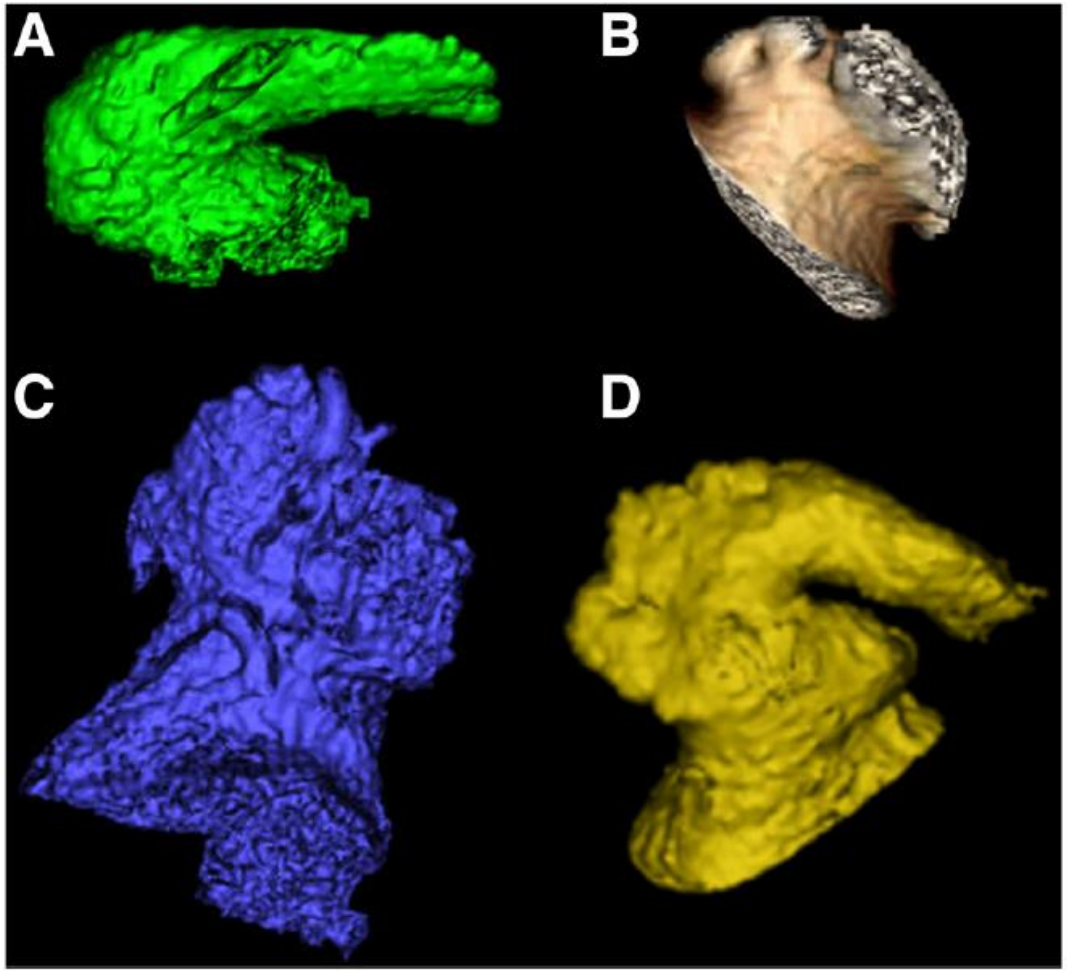
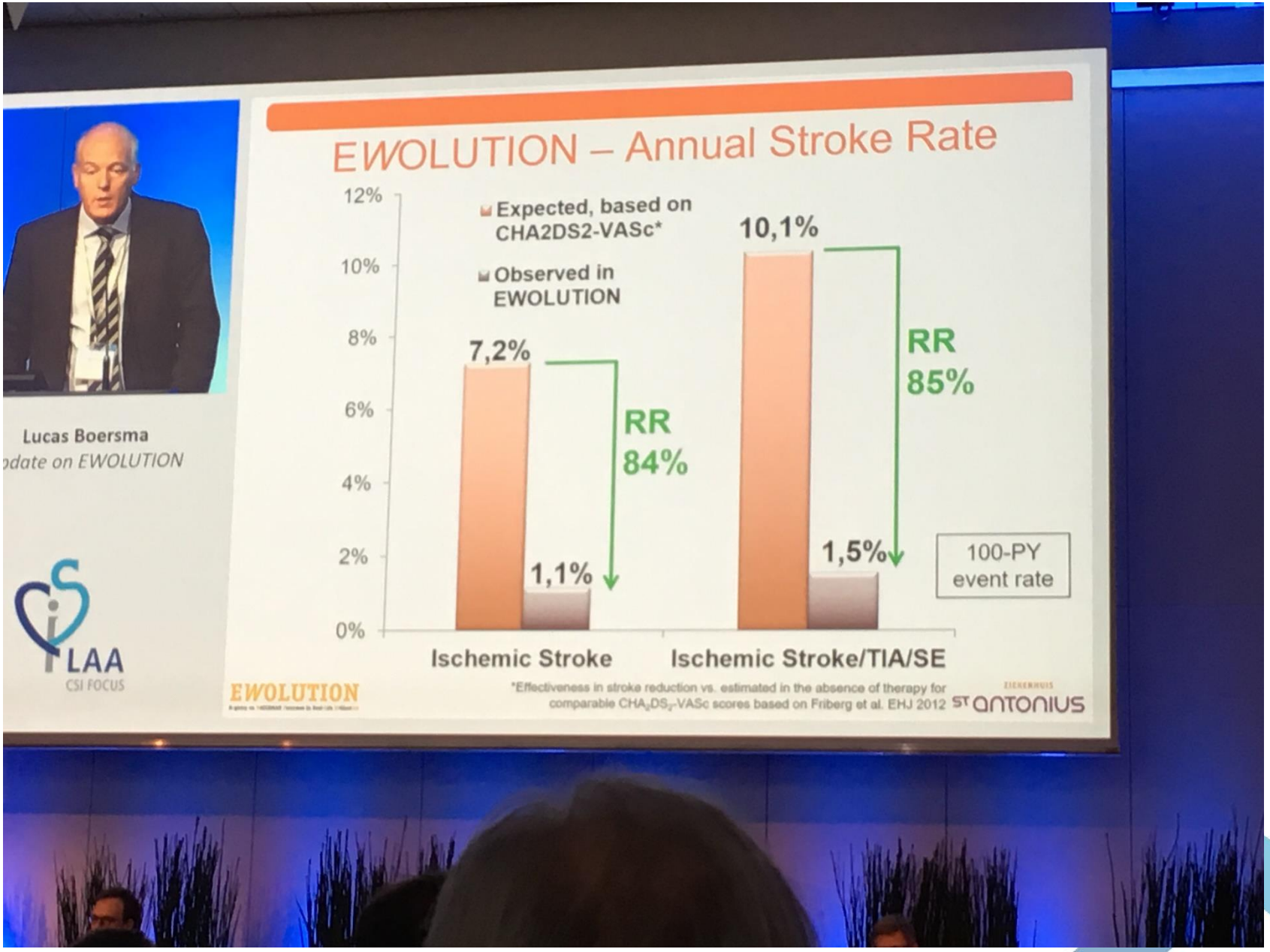
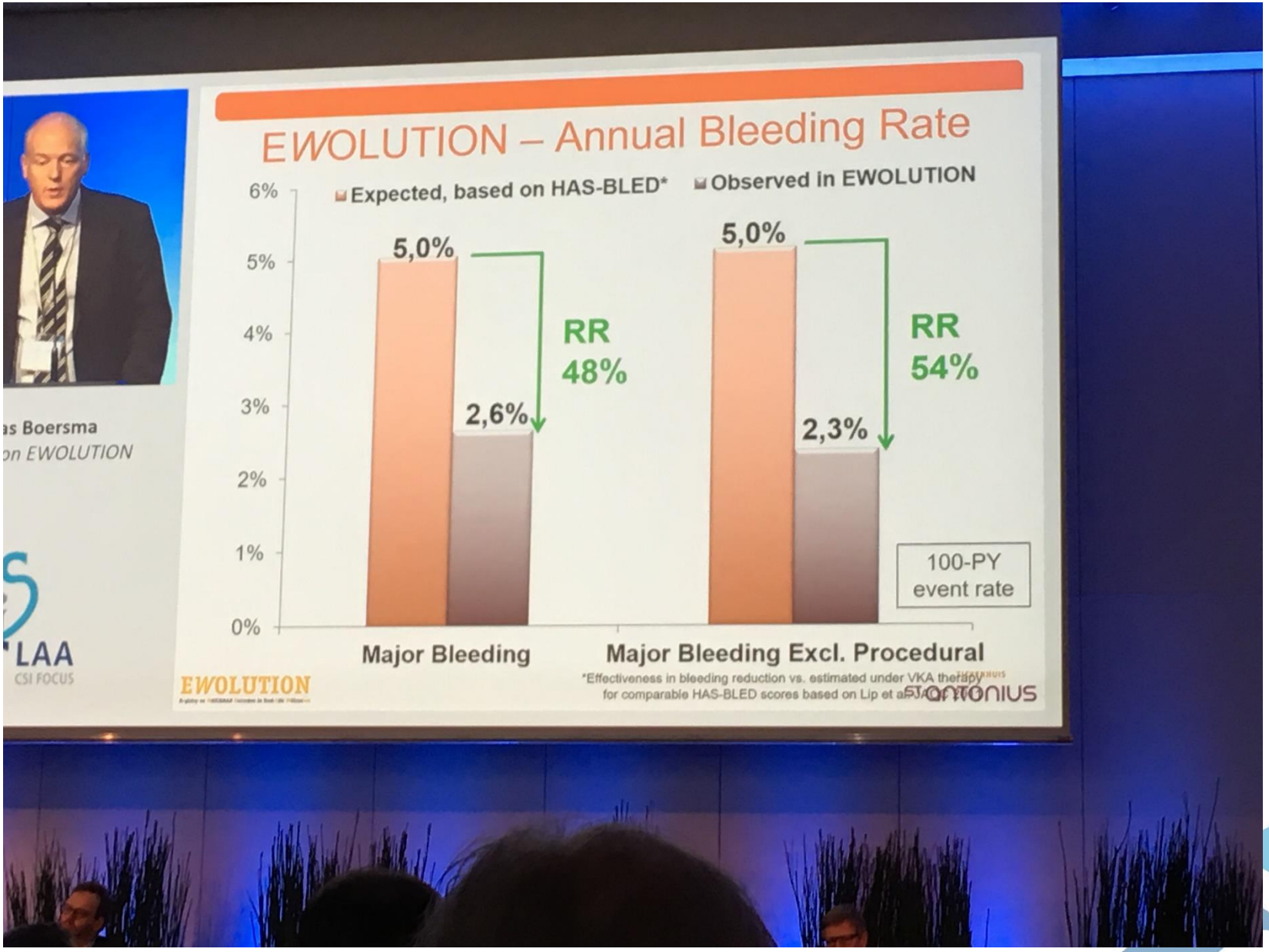


Fig. 2 Volume rendered cardiac CT angiography images demonstrating chicken wing (**a**), cauliflower (**b**), cactus (**c**), and windsock (**d**) morphologies


Lucas Boersma
pdate on EWOLUTION
LAA
CSI FOCUS
EWOLUTION – Annual Stroke Rate
12%
10%
8%
6%
4%
2%
0%
Expected, based on CHA2DS2-VASc*
Observed in EWOLUTION
7,2%
1,1%
RR 84%
10,1%
1,5%
RR 85%
100-PY event rate
Ischemic Stroke
Ischemic Stroke/TIA/SE
EWOLUTION
*Effectiveness in stroke reduction vs. estimated in the absence of therapy for comparable CHA2DS2-VASc scores based on Friberg et al. EHJ 2012
ZIEKENHUIS ST ANTONIUS


EWOLUTION – Annual Bleeding Rate
Expected, based on HAS-BLED*
Observed in EWOLUTION
6%
5%
4%
3%
2%
1%
0%
5,0%
2,6%
RR
48%
5,0%
2,3%
RR
54%
100-PY
event rate
Major Bleeding
Major Bleeding Excl. Procedural
*Effectiveness in bleeding reduction vs. estimated under VKA therapy
for comparable HAS-BLED scores based on Lip et al
EWOLUTION
antonius
LAA
CSI FOCUS

Alternative aux NOAC (AVK) : dispositifs de fermeture (occlusion) de l'auricule gauche

Les prestations 180272-180283 et 180294-180305 ne peuvent faire l'objet d'une intervention de l'assurance obligatoire que si elles sont effectuées dans **l'établissement hospitalier** qui répond aux critères suivants et qui a conclu la convention F-ACL-003 avec le Comité de l'assurance :

- agrément de soins cardiologiques B2-B3
- expérience de 50 procédures de novo structurelles gauches ou procédures d'ablation gauche, dont 25 par ponction par voie transseptale, par an
- coordinateur, échographiste spécialisé, Heart Team et fonctionnement 24h/24h, salle hybride avec ETO, biologie avec TCA sur place
- présence lors de la procédure : un interventionnel, un échographiste, un anesthésiste, deux infirmières
- concertation multidisciplinaire (Heart Team) concernant la pose d'indication et l'intervention de fermeture d'auricule sur le site hospitalier

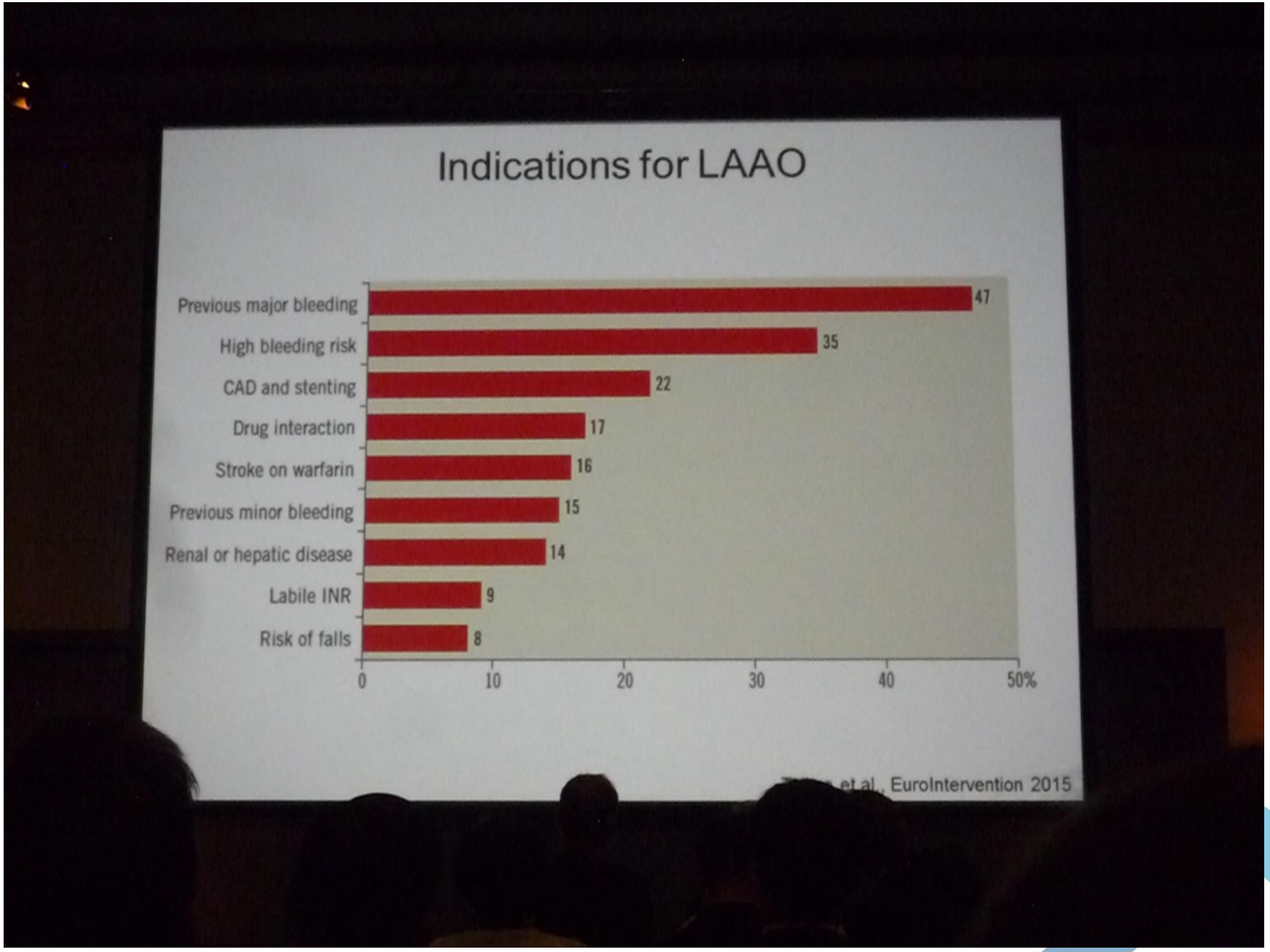
Alternative aux NOAC (AVK) : dispositifs de fermeture (occlusion) de l'auricule gauche

Les prestations 180272-180283 et 180294-180305 ne peuvent faire l'objet d'une intervention de l'assurance obligatoire que si le **bénéficiaire** répond aux critères suivants :

- FA non-valvulaire et score de CHA2DS2-VASc ≥2
- ET une des contre-indications formelles et permanentes aux anticoagulants (validée par l'équipe multidisciplinaire) (documentation et preuves à garder dans le dossier du patient) :
  - antécédents d'hémorragie spontanée majeure selon les critères BARC3
  - antécédents d'hémorragie cérébrale de tout type
  - hémorragie mineure spontanée et répétitive, considérée comme significative de façon clinique par l'équipe multidisciplinaire
  - insuffisance rénale grave (eGFR < 15 ml/min)
  - récidive d'AVC ou d'AIT sous anticoagulants

BARC (Bleeding Academic Research Consortium) (Mehran R. Circulation 2011 ; 123 : 2736-47)

- Type 3 : **hémorragie active sévère**
  - 3A : hémorragie active avec baisse d'hémoglobine de 3-5 g/dl nécessitant une transfusion,
  - 3B : hémorragie active avec baisse d'hémoglobine de ≥ 5 g/dl (avec preuve que la chute d'Hb est due aux saignements) ; tamponade cardiaque ; hémorragie nécessitant un traitement vasoactif ou une chirurgie (excepté dents, peau, nasal, hémorroïdes)
  - 3C : hémorragie intracrânienne (excepté microbleeds ou transformation hémorragique, inclus hémorragie intraspinale) ; autres catégories confirmées par autopsies ou imagerie ou ponction lombaire ; saignement intraoculaire avec atteinte de la vision


Indications for LAAO
Previous major bleeding
47
High bleeding risk
35
CAD and stenting
22
Drug interaction
17
Stroke on warfarin
16
Previous minor bleeding
15
Renal or hepatic disease
14
Labile INR
9
Risk of falls
8
0
10
20
30
40
50%
et al., EuroIntervention 2015

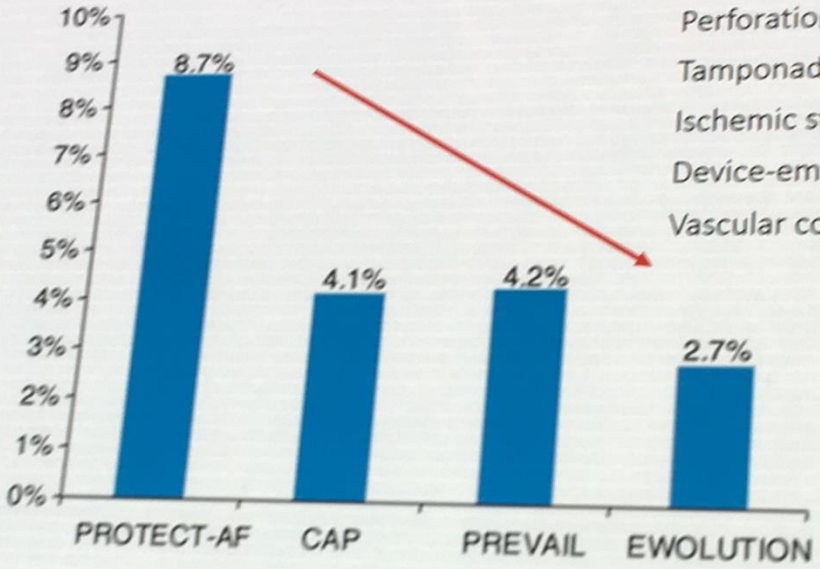
Clinical Adverse Events

Major Device- or Procedure-related Events				
	PROTECT AF n (%) N=463	CAP n (%) N=566	PREVAIL n (%) N=269	CAP2 n (%) N=579
Pericardial effusion with cardiac tamponade	13 (2.8)	7 (1.2)	4 (1.5)	8 (1.2)
Device embolism	3 (0.6)	1 (0.2)	2 (0.7)	0 (0.0)
Ischemic stroke - related to device thrombus - related to air embolism - related to procedure (excluding air embolism)	7 (1.5) 2 (0.4) 3 (0.6) 2 (0.4)	1 (0.2) 1 (0.2) 0 (0.0) 0 (0.0)	2 (0.7) 1 (0.4) 0 (0.0) 1 (0.4)	5 (0.9) 3 (0.5) 0 (0.0) 2 (0.3)
Systemic embolism	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.3)
Pericardial effusion - no intervention required	4 (0.9)	5 (0.9)	0 (0.0)	3 (0.5)
Cardiac perforation	7 (1.5)	1 (0.2)	1 (0.4)	3 (0.5)
Major bleeding requiring transfusion	1 (0.2)	5 (0.9)	2 (0.7)	4 (0.7)
Device thrombus	2 (0.4)	1 (0.2)	1 (0.4)	5 (0.9)

Note: Adverse events not listed include hematoma, arterio-venous fistula, arrhythmia, pseudoaneurysm, airway trauma, transient ischemic attack, chest pain, and infection.

LAA occlusion in the NOAC environment

Complication rates



- Perforation
- Tamponade
- Ischemic stroke
- Device-embolisation
- Vascular complications

Boersma et al., Eur Heart J 2016

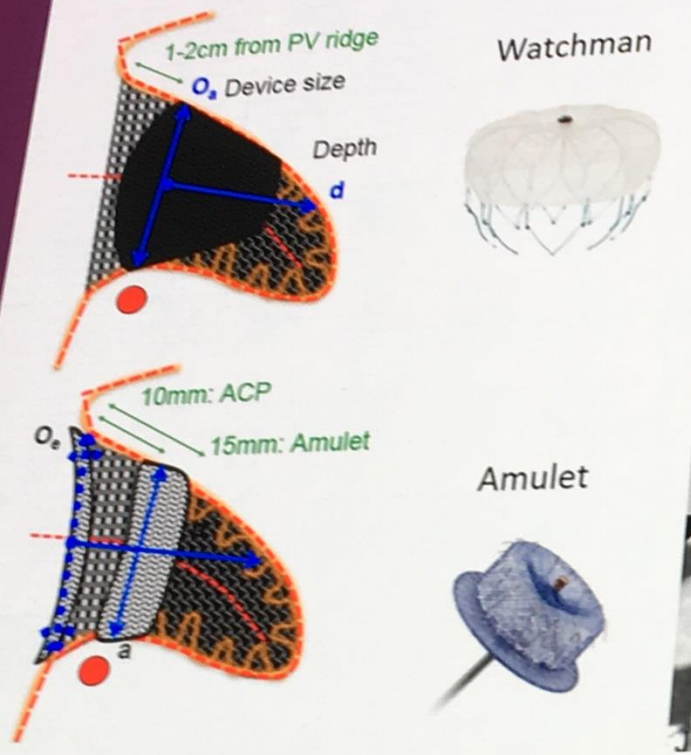
Table 2 Summary of data for left atrial appendage occlusion

	PROTECT-AF[46]	CAP[43]	ASAP[42]	EWOLUTION[49]	ACP[50]
Patients (*n*)	463	460	150	1021	1047
Follow-up	4 yr	16 mo	14 mo	30 d	13 mo
CHADS-score	2.2	2.4	2.8	2.8	n.a.
CHA2DS2-Vasc score	n.a.	n.a.	4.4	4.5	4.5
Procedural success	88.00%	95.00%	94.70%	98.50%	97.30%
Procedural stroke	1.30%	0	0.70%	n.a.	0.90%
Pericardial effusion	4.80%	2.20%	1.30%	0.50%	1.20%
Device embolization	0.60%	0	1.30%	0.20%	n.a.
Major bleeding	3.50%	n.a.	n.a.	1.60%	1.50%
Long-term stroke	2.30%	1.50%	0.70%	0.30%	2.30%

Table 3 Different aspects of left atrial appendage occlusio

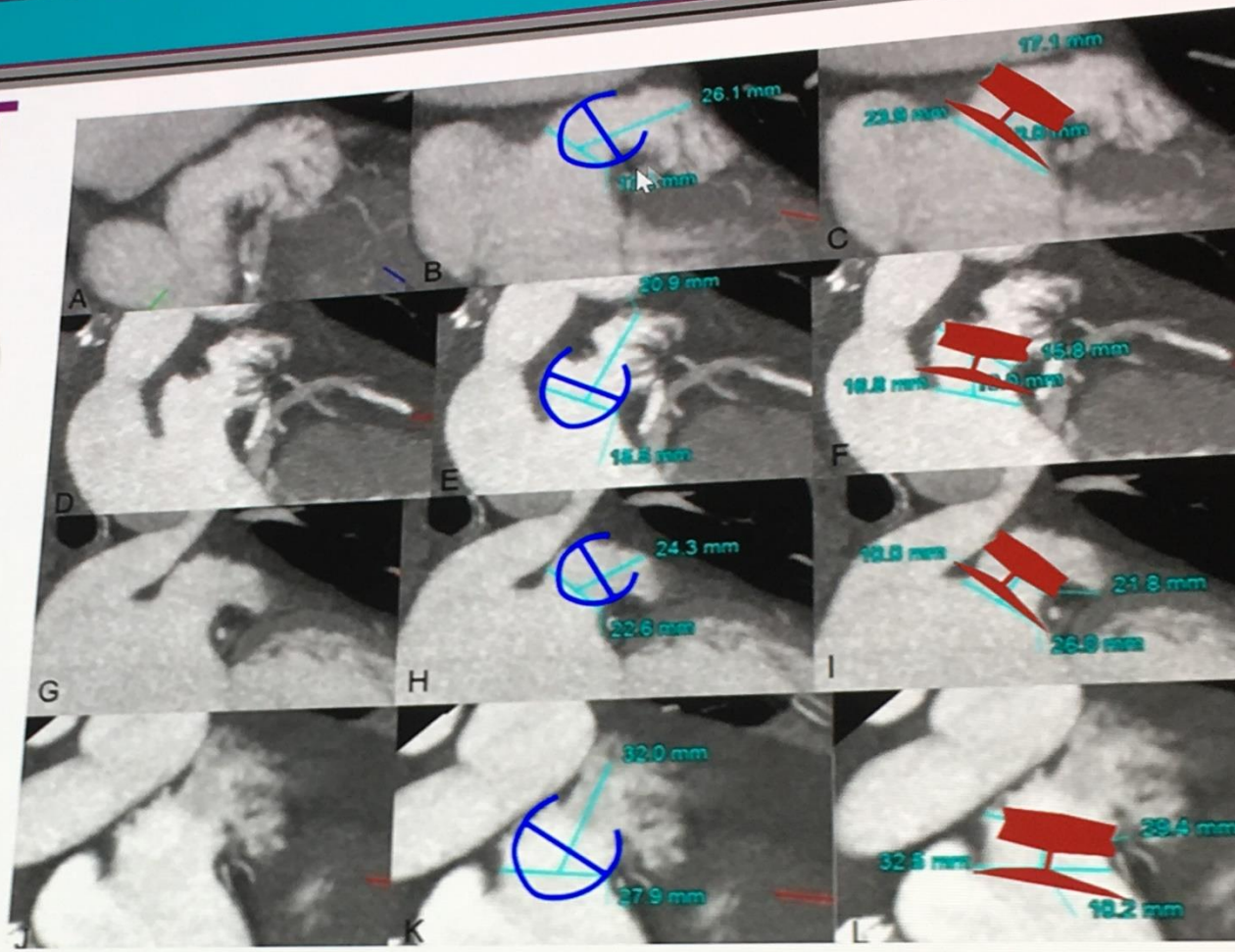
Pro	Contra
Non-inferiority to oral anticoagulation	Evaluation of other atherothrombotic sources
Alternative in patients with contraindication for anticoagulation	Unknown hemodynamic impact
Cost-effective	Postprocedural medical treatment not well defined
Reduced cumulative bleeding events during follow-up	No comparison between different devices
Good results in real-world registries	Undefined impact of residual leaks

Role of MSCT



Watchman

Amulet



Jacqueline Saw, LAA and PFO closure 2017

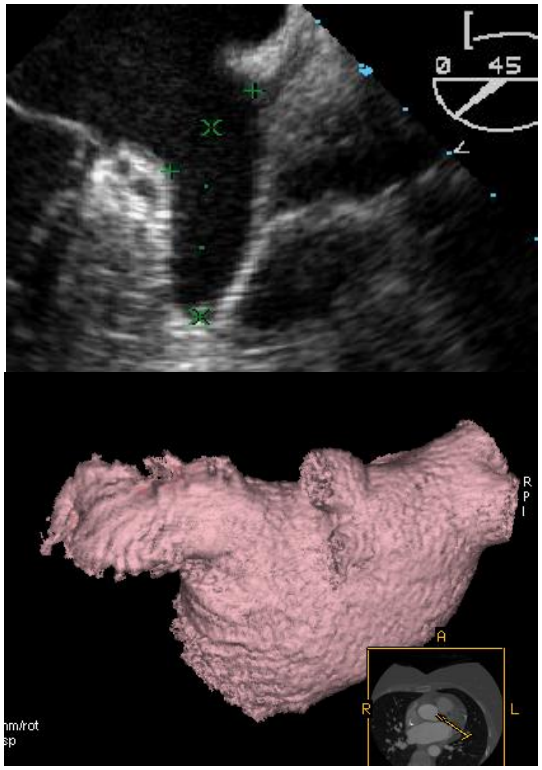
2. Baseline Echo Assessment

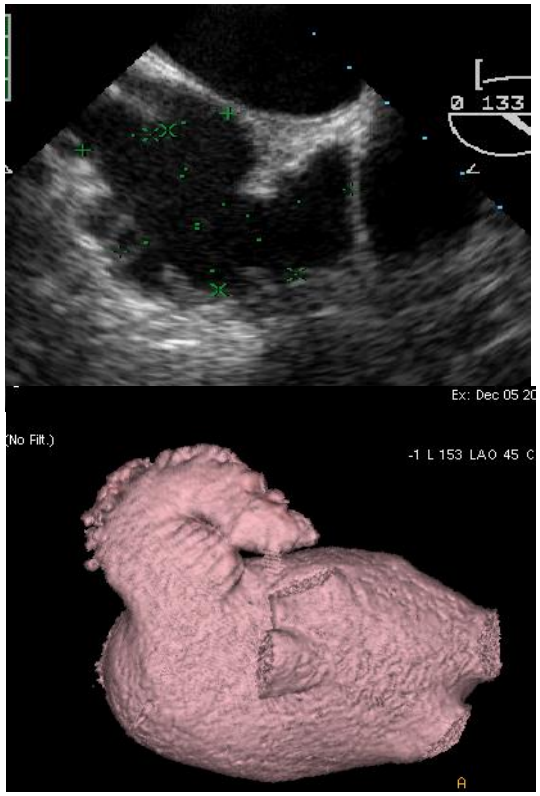
a. Morphology - Categorize by LAA Type

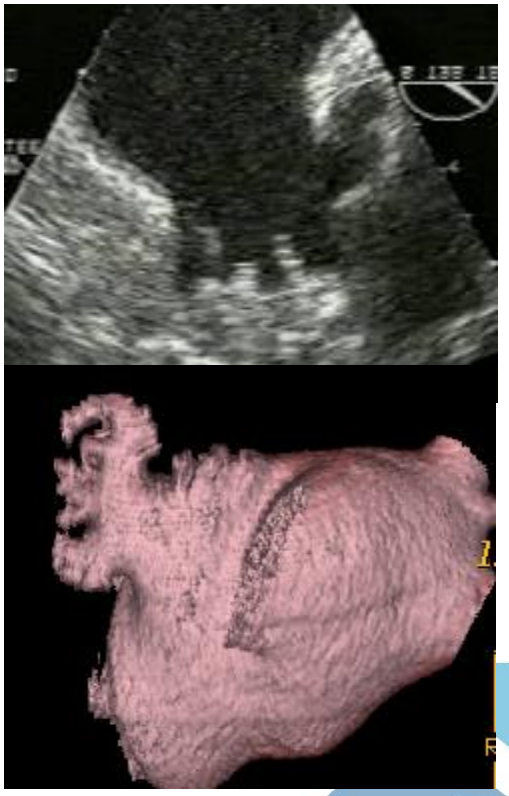
The **Wind Sock Type** LAA is an anatomy in which one dominant lobe of sufficient length is the primary structure.

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.







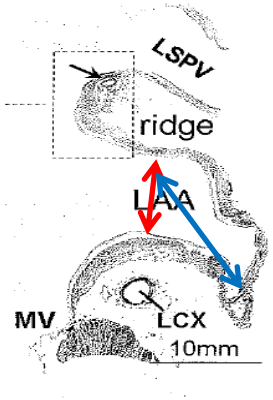
2. Baseline Echo Assessment

b. LAA Assessment – Ostial and length dimensions

Assess the following through multiple imaging planes (0 - 135 deg sweep):

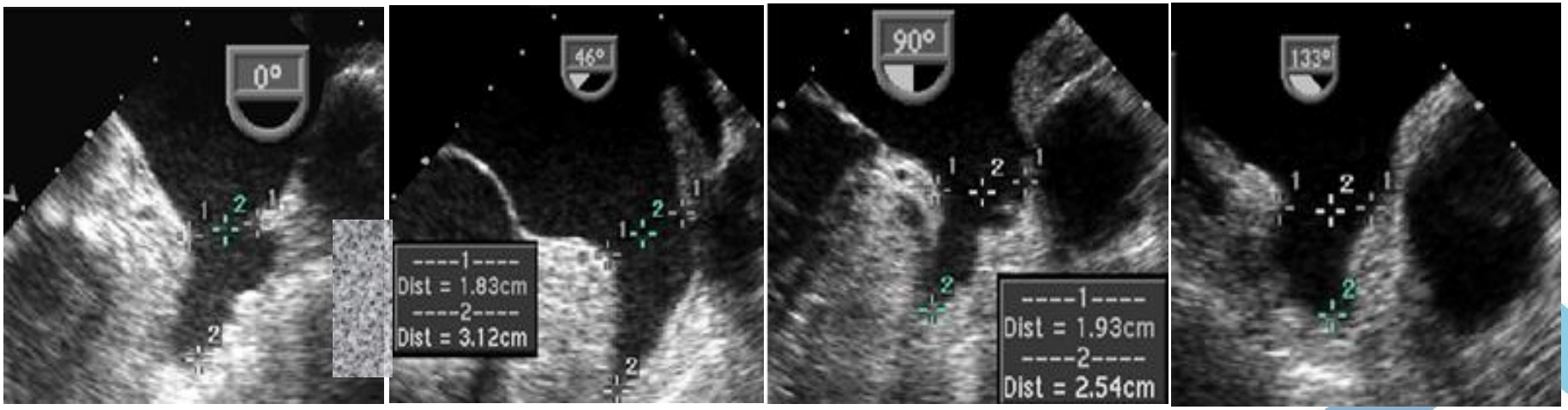
- *LAA size /shape, number of lobes in LAA and location of lobes to ostium*

Record LAA ostium and LAA length measurements (0 - 135 deg sweep):



- *Measure the **LAA ostium** at <u>approximately</u> these angles:*
  - **at 0º** measure from coronary artery marker to a point 2 cm from tip of the “limbus”
  - **at 45º**
  - **at 90º**
  - **at 135º**

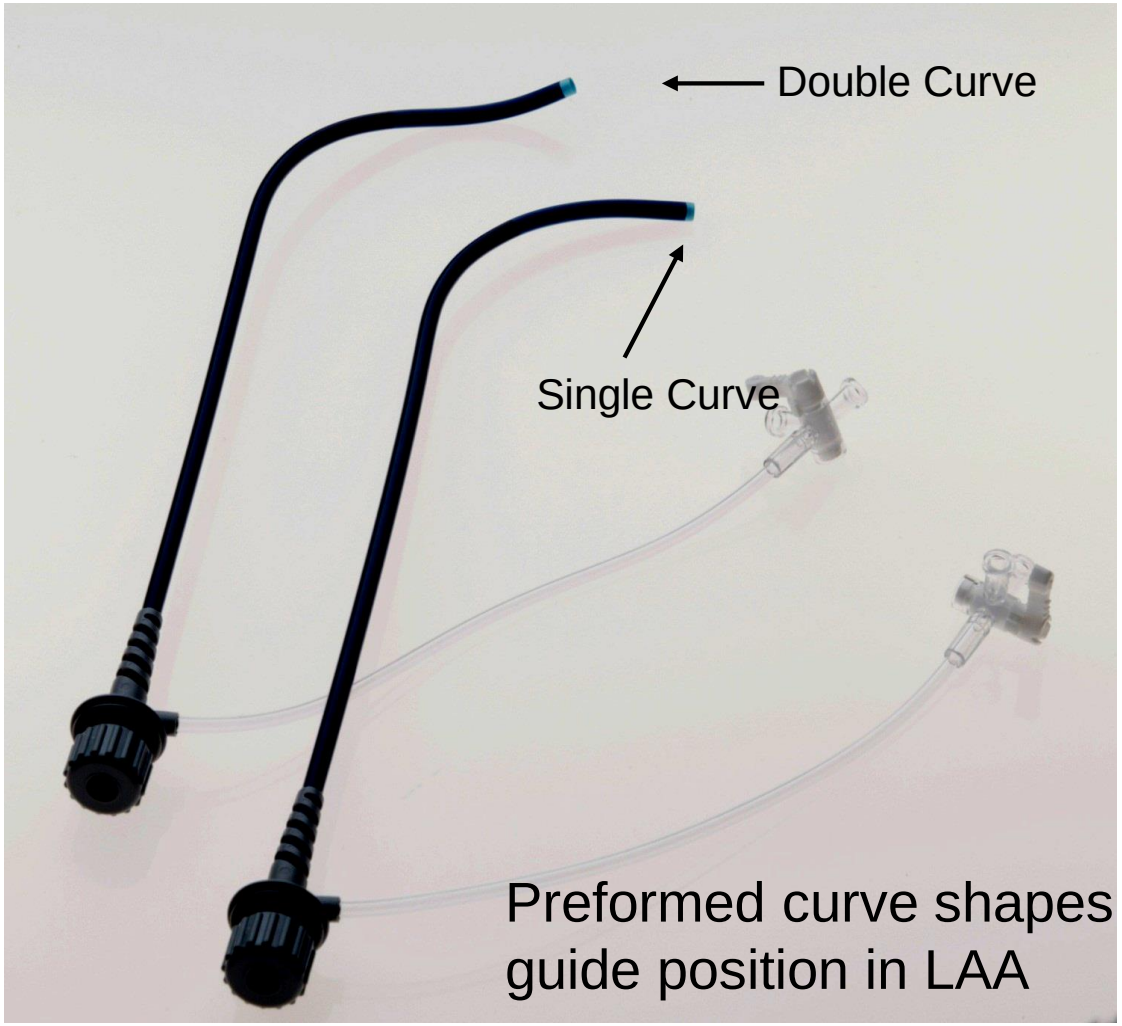
  } measure from top of the MV annulus to a point 2 cm from tip of the “limbus”
- *Measure the approximate **LAA usuable length** from the ostium line to the apex of the LAA*




PHILIPS

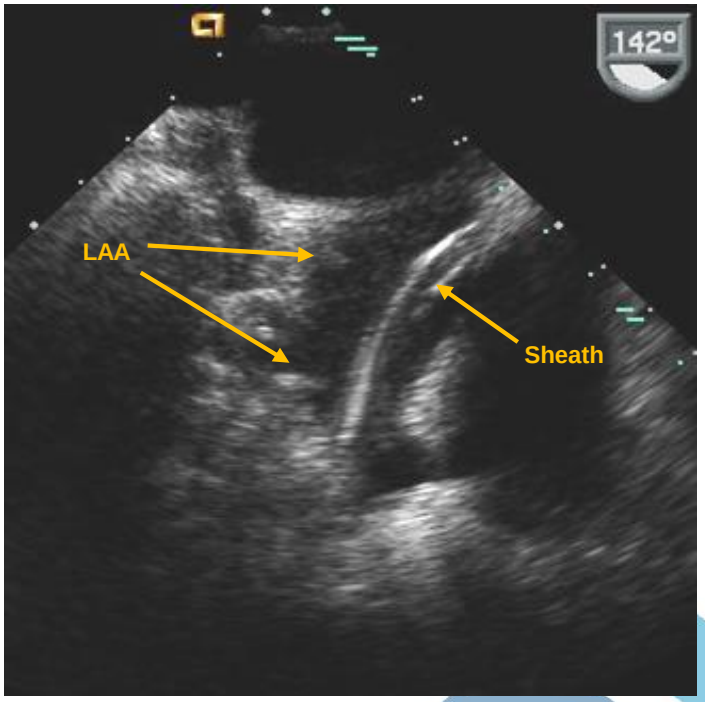
1. WATCHMAN LAA Closure System Components

WATCHMAN Access System

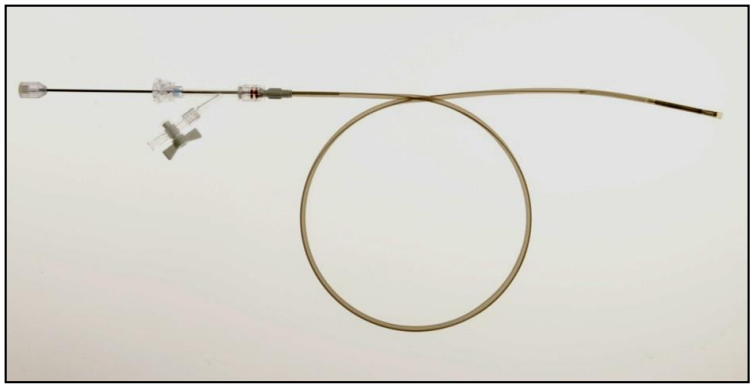


Transseptal Access System

- Double, Single, Anterior Curves
- 14F O.D. (4.7 mm), 12F I.D.
- 75 cm working length



1. WATCHMAN LAA Closure System Components
WATCHMAN Delivery System



12F O.D. (compatible with all 5 device sizes)

CENTRES HOSPITALIERS JOLIMONT ASBL

WATCHMAN™
Left Atrial Appendage Closure Device

Baseline TEE Imaging

1 Assess the following through multiple imaging planes - 0°– 135°sweep

LAA size/shape, number of lobes in LAA and location of lobes to ostium

Confirm the absence of thrombus (use Color Doppler and echo contrast as necessary)

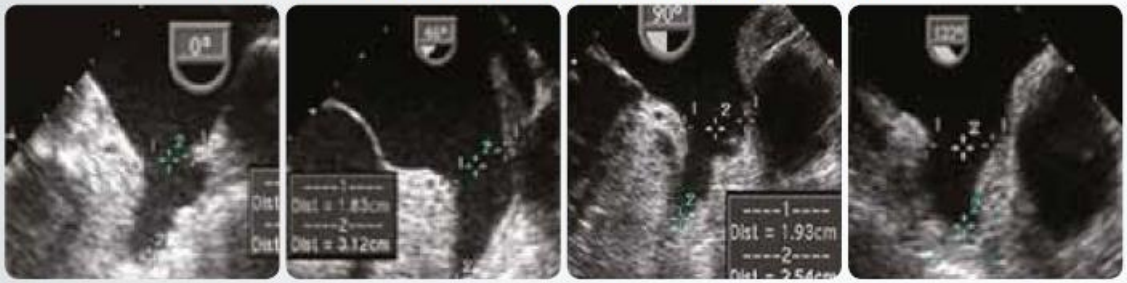
2 Record LAA ostium and LAA length measurements - 0°– 135°sweep

Measure the LAA ostium at approximately these angles

at	0°	Measure from coronary artery marker to a point 2cm from tip of the "limbus"
at	45°	Measure from top of the MV annulus to a point 2cm from tip of the "limbus"
at	90°	Measure from top of the MV annulus to a point 2cm from tip of the "limbus"
at	135°	Measure from top of the MV annulus to a point 2cm from tip of the "limbus"

Measure approximate LAA useable length in above angles

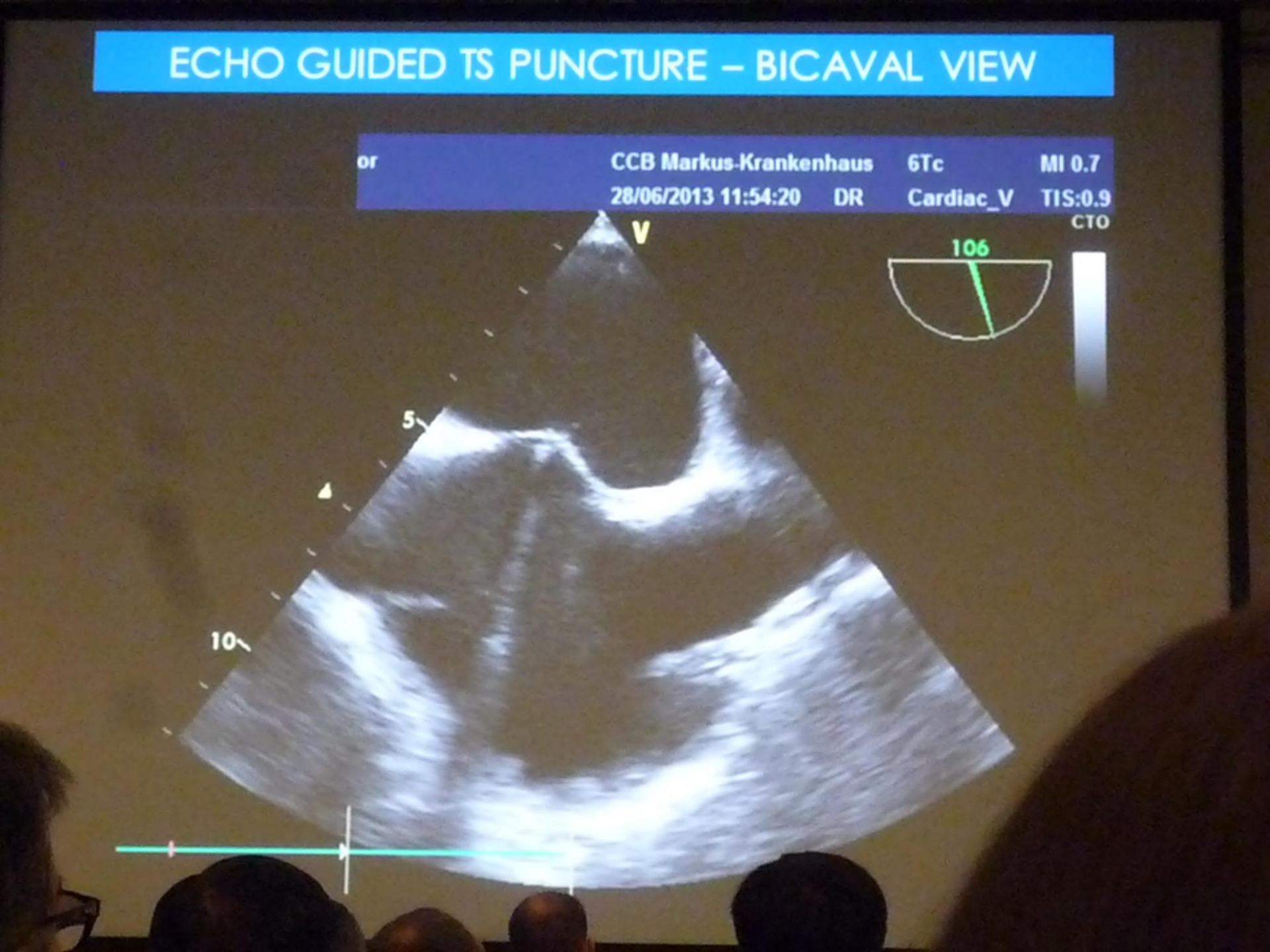
Measure from the ostium line to the apex of the LAA



Max LAA Ostium	Recommended Device Size
17 – 19	21 mm
20 – 22	24 mm
23 – 25	27 mm
26 – 28	30 mm
29 – 31	33 mm

Measured maximum LAA ostium width must be >17 mm and/or <32 mm to accommodate available device sizes.
Note: The maximum LAA ostium and LAA length measurements determine device size selection.

ECHO GUIDED TS PUNCTURE – BICAVAL VIEW



CENTRES HOSPITALIERS JOLIMONT ASBL

WATCHMAN™
Left Atrial Appendage Closure Device

Intra-Op TEE Imaging

Assessing Device Release Criteria

(recommend using both bicaval and short axis views)

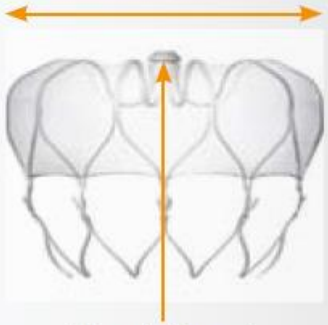
Correct

figure 4
widest diameter measured

Incorrect

figure 5
unable to completely visualize borders of device

figure 6
device not measured at widest point across



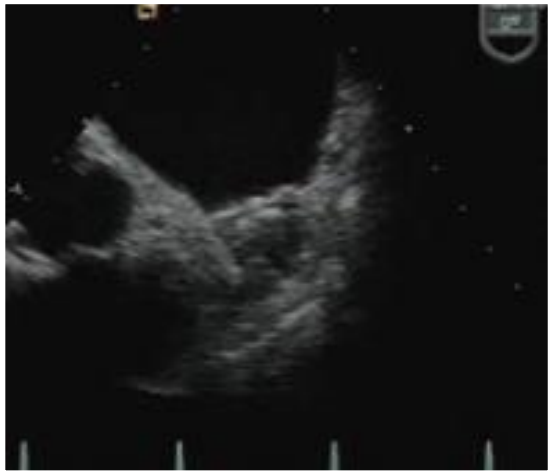
"threaded insert"
must be visible when measuring on echo to ensure device was measured at widest cross-section in all angles

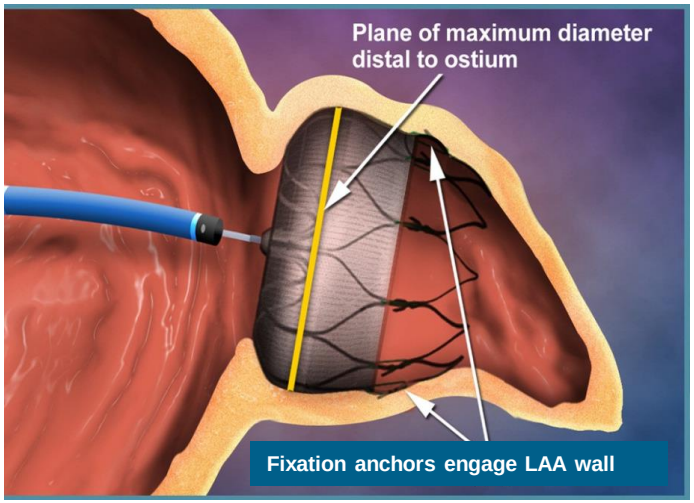
TABLE 1: WATCHMAN LAA CLOSURE DEVICE DIAMETER

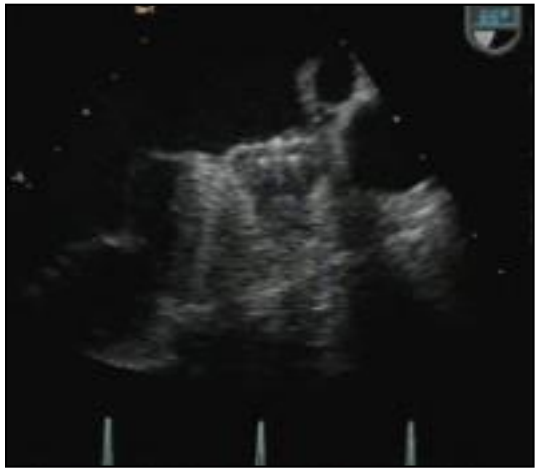
Original Device Diameter	Deployed Diameter
21 mm	16.8 mm – 19.3 mm
24 mm	19.2 mm – 22.1 mm
27 mm	21.6 mm – 24.8 mm
30 mm	24.0 mm – 27.6 mm
33 mm	26.4 mm – 30.4 mm

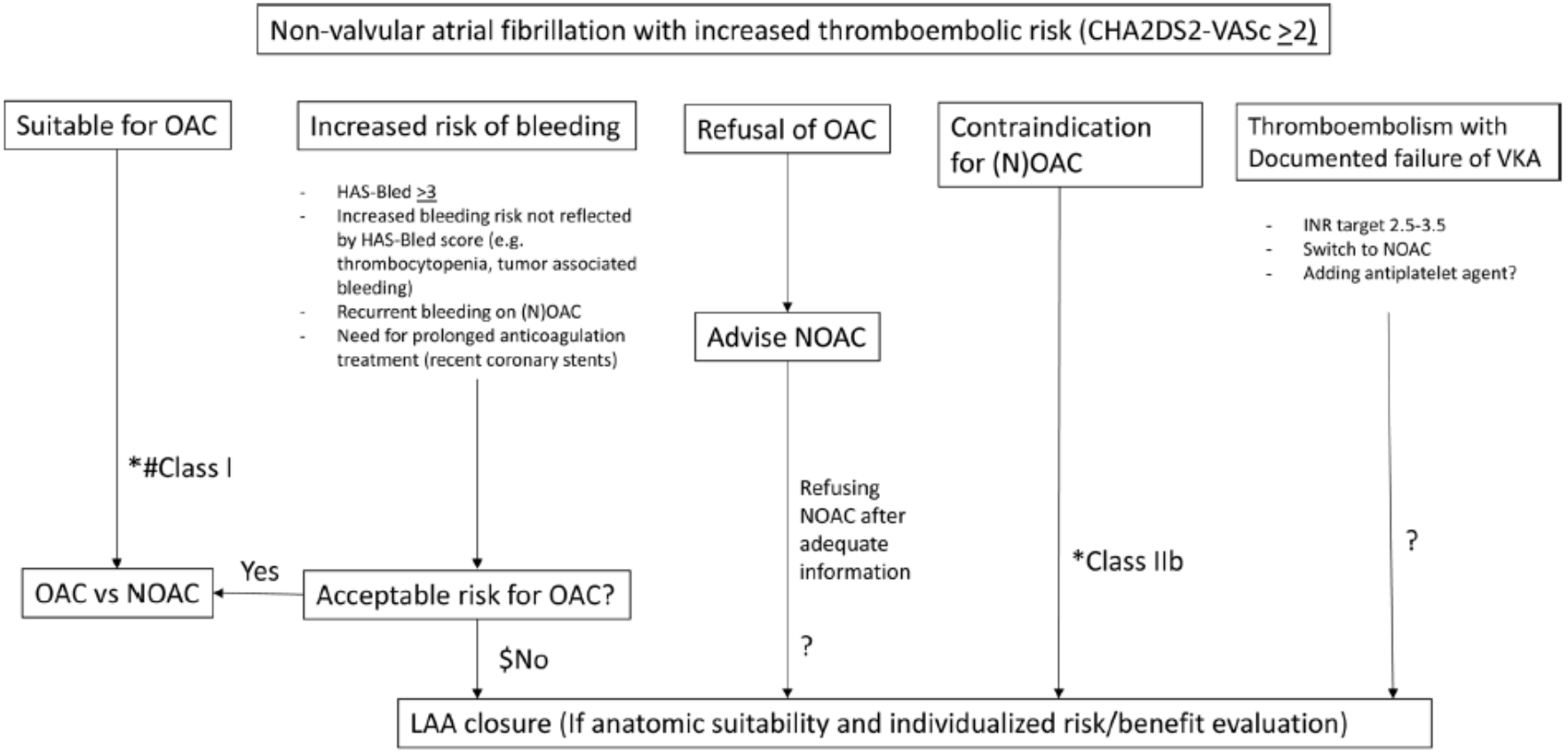
3. Procedure Echo Assessment

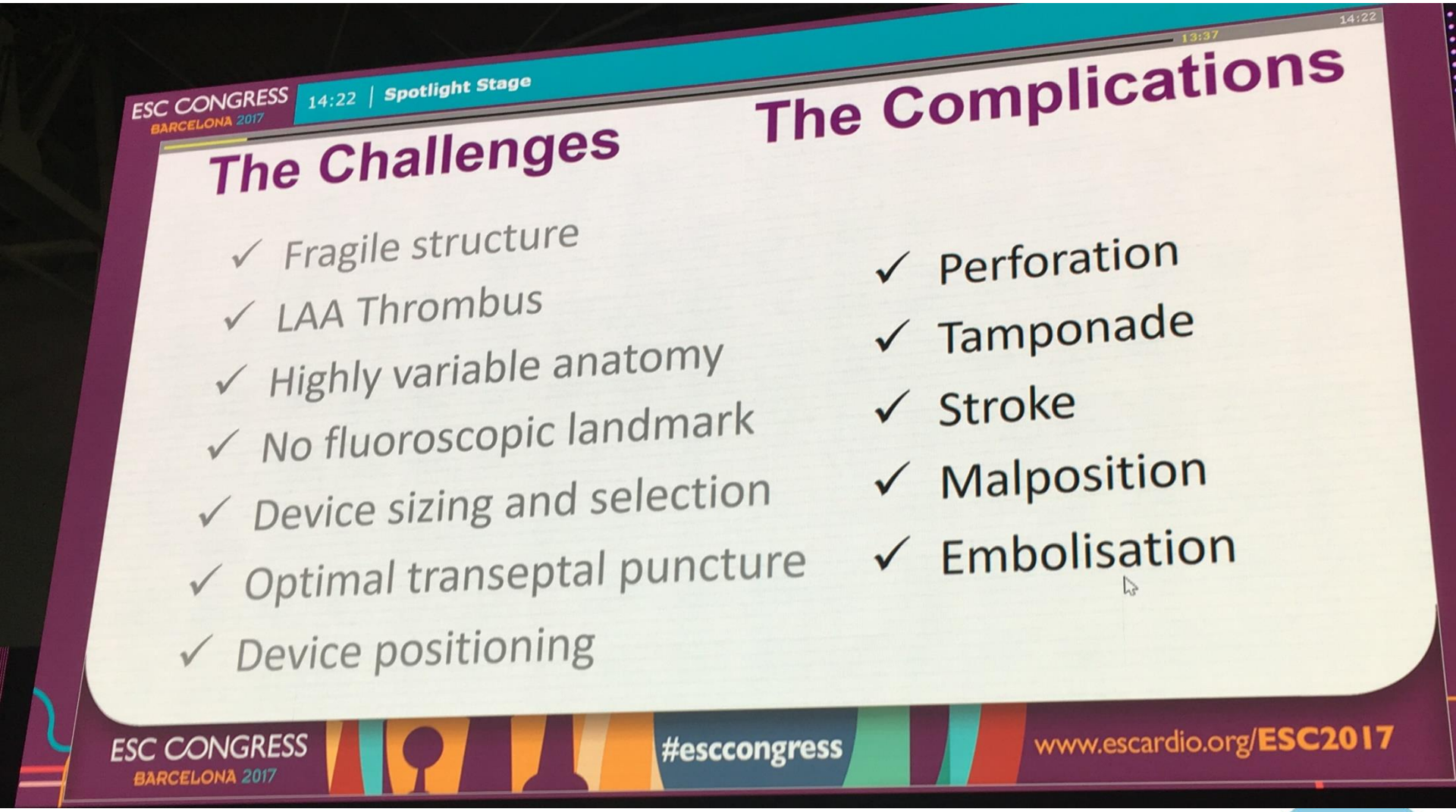
i. Device Position – OPTIMAL POSITION








Non-valvular atrial fibrillation with increased thromboembolic risk (CHA2DS2-VASc ≥2)
Suitable for OAC
Increased risk of bleeding
Refusal of OAC
Contraindication for (N)OAC
Thromboembolism with Documented failure of VKA
- HAS-Bled ≥3
- Increased bleeding risk not reflected by HAS-Bled score (e.g. thrombocytopenia, tumor associated bleeding)
- Recurrent bleeding on (N)OAC
- Need for prolonged anticoagulation treatment (recent coronary stents)
- INR target 2.5-3.5
- Switch to NOAC
- Adding antiplatelet agent?
Advise NOAC
*#Class I
Refusing NOAC after adequate information
*Class IIb
?
Yes
OAC vs NOAC
Acceptable risk for OAC?
$No
?
LAA closure (If anatomic suitability and individualized risk/benefit evaluation)


ESC CONGRESS
BARCELONA 2017
14:22 | Spotlight Stage
13:37
14:22
The Challenges
✓ Fragile structure
✓ LAA Thrombus
✓ Highly variable anatomy
✓ No fluoroscopic landmark
✓ Device sizing and selection
✓ Optimal transeptal puncture
✓ Device positioning
The Complications
✓ Perforation
✓ Tamponade
✓ Stroke
✓ Malposition
✓ Embolisation
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