WATCHMAN Device: Current Application and Future Indications

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Disclosure Information

The following relationships exist:

Grant support: Abbott, BSC, Cardiokinetics, Edwards, WL Gore
Consultant: Abbott, BSC, Mitralign, WL Gore

Off label use of products and investigational devices will be discussed in this presentation

Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation

A Patient-Level Meta-Analysis

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ABSTRACT

BACKGROUND The risk-benefit ratio of left atrial appendage closure (LAAC) versus systemic therapy (warfarin) for prevention of stroke, systemic embolism, and cardiovascular death in nonvalvular atrial fibrillation (NVAF) requires continued evaluation.

OBJECTIVES This study sought to assess composite data regarding left atrial appendage closure (LAAC) in 2 randomized trials compared to warfarin for prevention of stroke, systemic embolism, and cardiovascular death in patients with nonvalvular AF.

METHODS Our meta-analysis included 2,406 patients with 5,931 patient-years (PY) of follow-up from the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) and PREVAIL (Prospective Randomized Evaluation of the Watchman LAA Closure Device In Patients With Atrial Fibrillation Versus Long Term Warfarin Therapy) trials, and their respective registries (Continued Access to PROTECT AF registry and Continued Access to PREVAIL registry).

RESULTS With mean follow-up of 2.69 years, patients receiving LAAC with the Watchman device had significantly fewer hemorrhagic strokes (0.15 vs. 0.96 events/100 patient-years [PY]; hazard ratio [HR]: 0.22; $p = 0.004$), cardiovascular/unexplained death (1.1 vs. 2.3 events/100 PY; HR: 0.48; $p = 0.006$), and nonprocedural bleeding (6.0% vs. 11.3%; HR: 0.51; $p = 0.006$) compared with warfarin. All-cause stroke or systemic embolism was similar between both strategies (1.75 vs. 1.87 events/100 PY; HR: 1.02; 95% CI: 0.62 to 1.7; $p = 0.94$). There were more ischemic strokes in the device group (1.6 vs. 0.9 and 0.2 vs. 1.0 events/100 PY; HR: 1.95 and 0.22, respectively; $p = 0.05$ and 0.004, respectively). Both trials and registries identified similar event rates and consistent device effect in multiple subsets.

CONCLUSIONS In patients with NVAF at increased risk for stroke or bleeding who are candidates for chronic anticoagulation, LAAC resulted in improved rates of hemorrhagic stroke, cardiovascular/unexplained death, and nonprocedural bleeding compared to warfarin. (J Am Coll Cardiol 2015;65:2614-23) © 2015 by the American College of Cardiology Foundation.

Left Atrial Appendage Closure vs Warfarin in AF

A Patient-Level Meta-Analysis

TABLE 2 Patient Demographics Across Trials

	PROTECT AF (N = 707)	PREVAIL (N = 407)	CAP (N = 566)	CAP2 (N = 579)
Age, yrs	72.0 ± 8.9	74.3 ± 7.4	74.0 ± 8.3	75.3 ± 8.0
Male	70.3	70.0	65.5	61.0
Ethnicity/race				
Asian	0.7	0.5	1.6	0.7
Black/African American	1.6	1.7	1.9	1.2
White/Caucasian	91.5	94.4	91.9	94.1
Hispanic/Latino	5.7	2.7	3.5	2.1
Other	0.6	0.7	1.1	1.0
$CHADS_2$ score	2.2 ± 1.2	2.6 ± 1.0	2.4 ± 1.2	2.7 ± 1.1
$CHADS_2$ risk factors				
CHF	26.9	19.1	23.3	27.1
Hypertension	89.8	88.8	91.4	92.5
≥75 yrs of age	43.1	51.8	53.6	59.7
Diabetes	26.2	24.9	32.4	33.7
Stroke/transient ischemic attack	18.5	30.4	27.8	29.0
CHA_2DS_2-VASc	3.5 ± 1.6	4.0 ± 1.2	3.9 ± 1.5	4.5 ± 1.3
HAS-BLED = 0 (low risk)	6.4	1.7	2.8	2.8
HAS-BLED = 1-2 (moderate risk)	73.7	68.6	61.0	69.9
HAS-BLED = 3+ (high risk)	19.9	29.7	36.2	28.3

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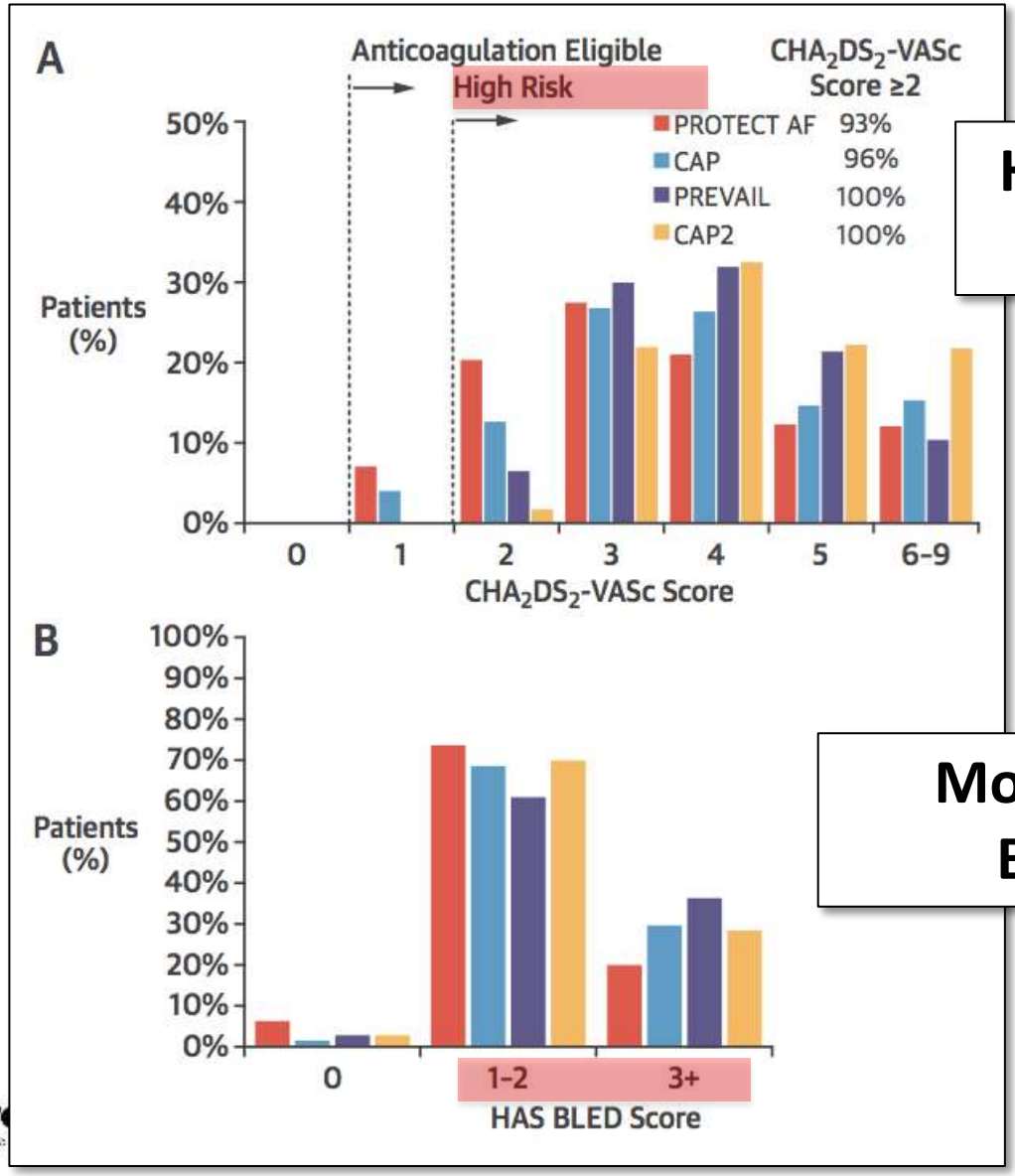
J Am Coll Cardiol 2015;65:2614–23

Left Atrial Appendage Closure vs Warfarin in AF

A Patient-Level Meta-Analysis



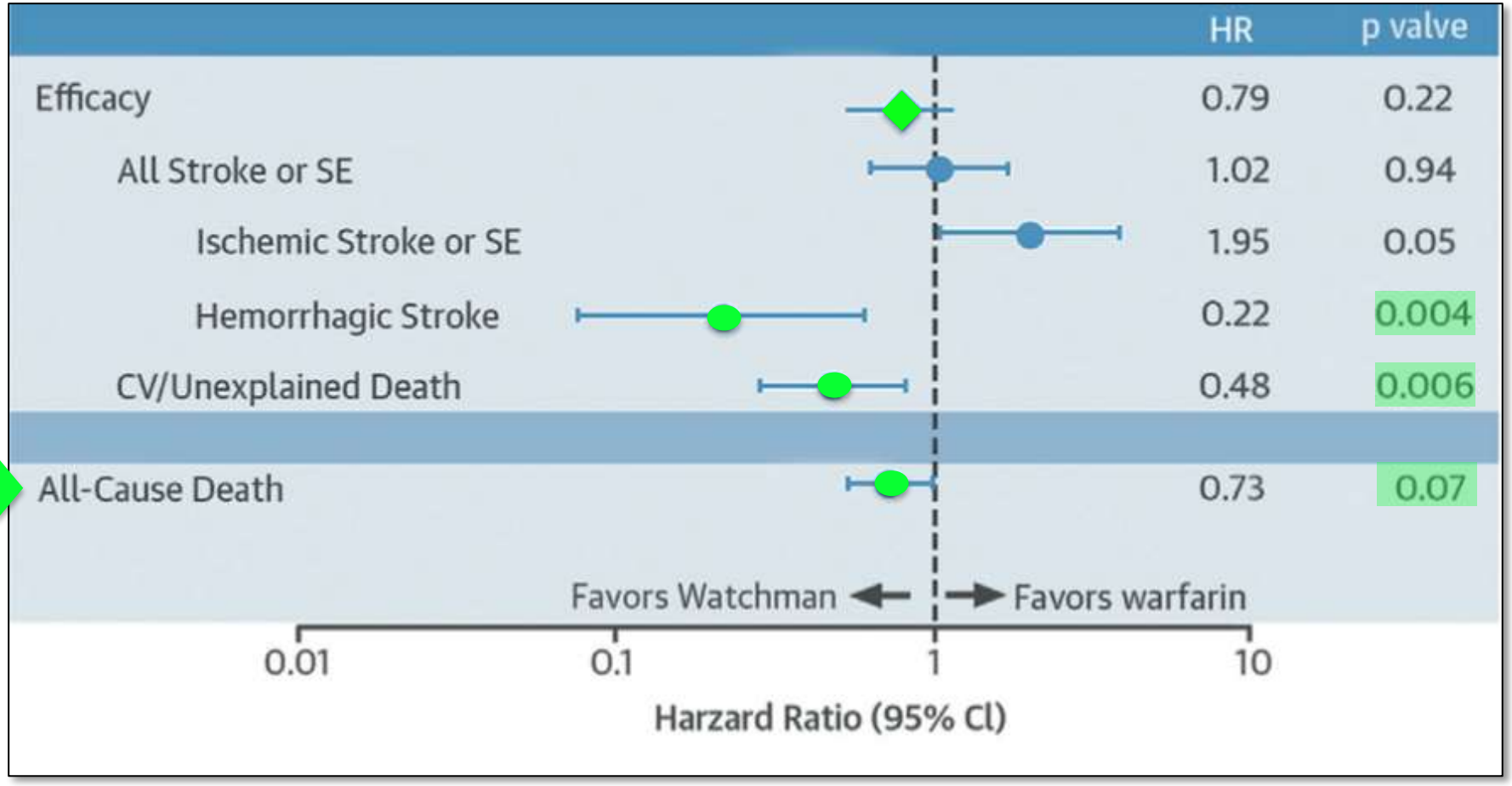
High Risk of Stroke

Moderate-to-High Bleeding Risk

J Am Coll Cardiol 2015;65:2614–23

Left Atrial Appendage Closure vs Warfarin in AF

A Patient-Level Meta-Analysis



Combination of PROTECT AF and PREVAIL patients receiving the Watchman device, vs warfarin for overall stroke, ischemic stroke, and all-cause death.

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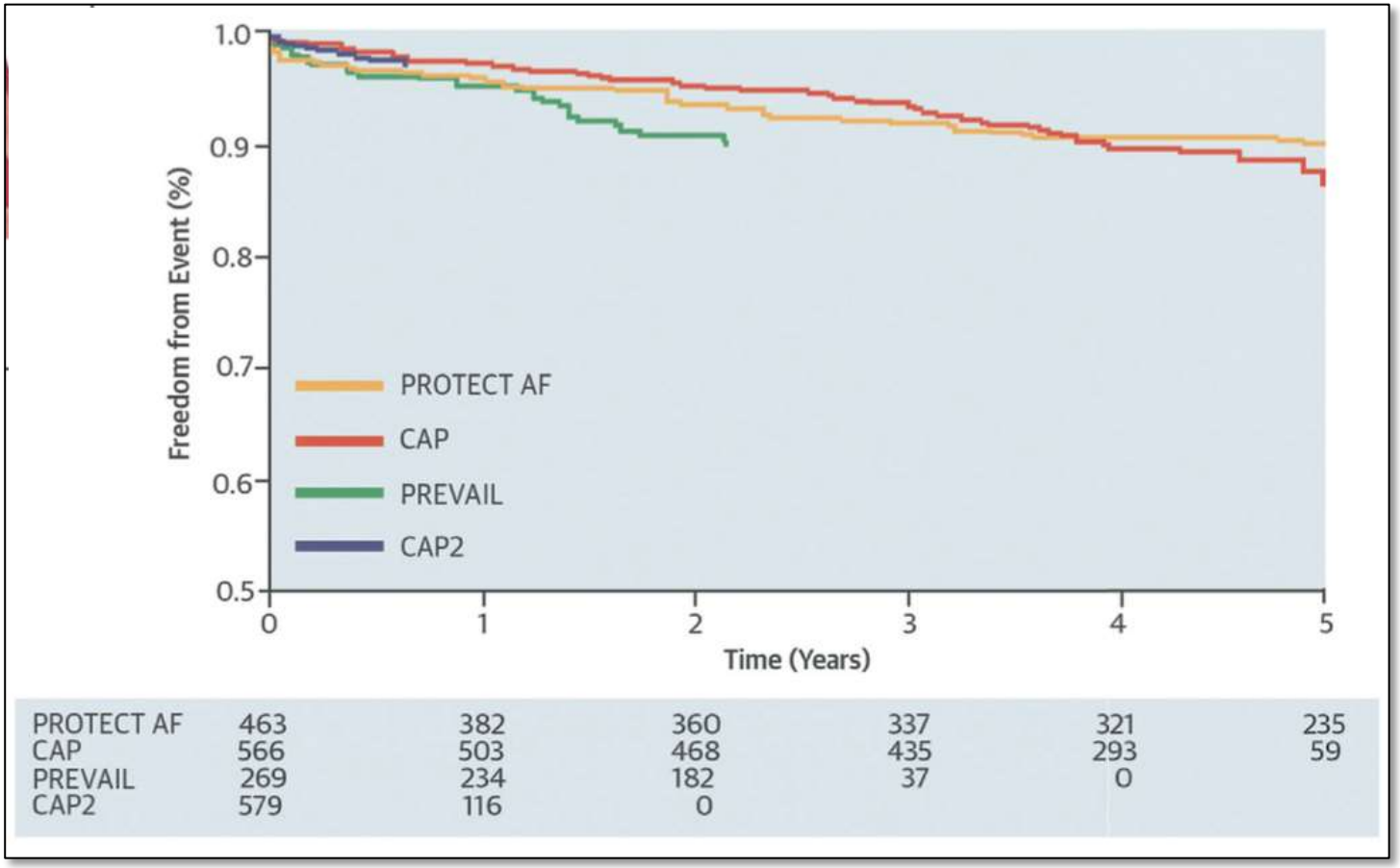
Left Atrial Appendage Closure vs Warfarin in AF

A Patient-Level Meta-Analysis



Watchman performance consistent across all 4 data sets. The duration of follow-up varied by trial enrollment periods, being shortest for the Continued Access to PREVAIL registry (CAP2), overall freedom from event was similar in all 4 groups treated with Watchman.

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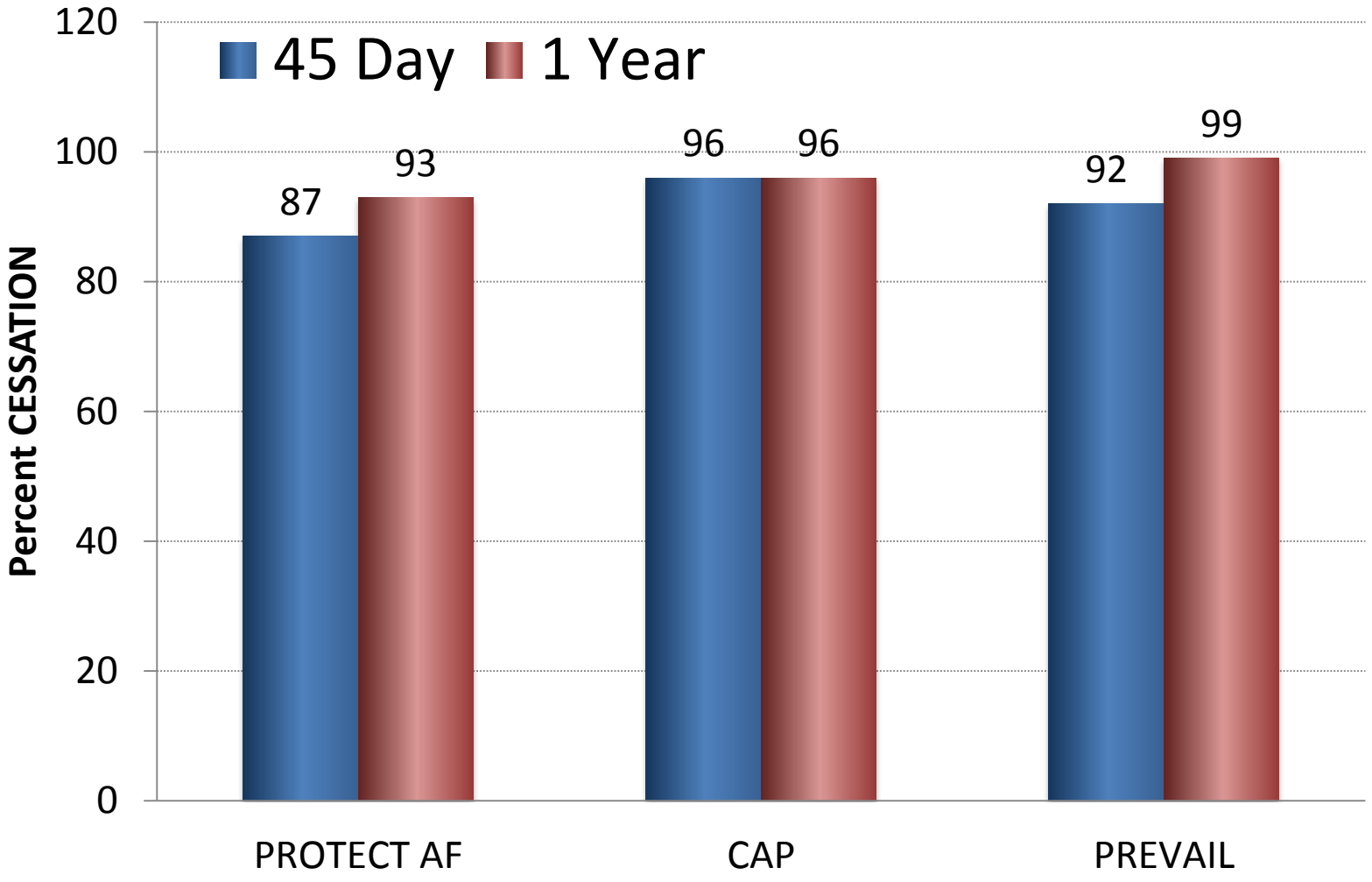
Warfarin Cessation after WATCHMAN



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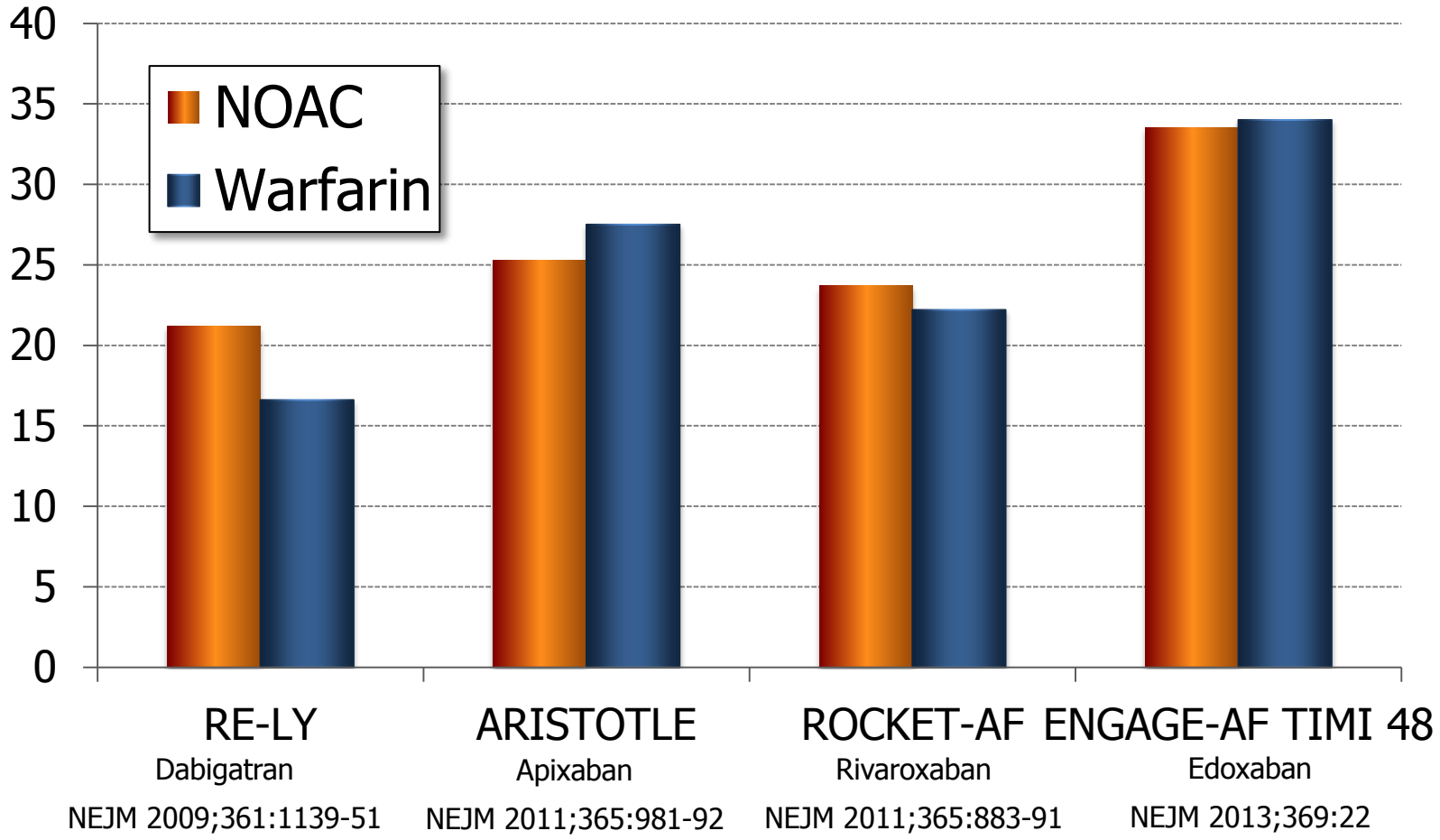
- Eligible patients must have a CHADS2 score ≥2 or a **CHA2DS2-VASc score ≥3**.
- Documented evidence of a formal **shared decision** interaction between the patient and an independent, **non-interventional physi**cian.
- **evidence-based decision tool** used in shared decision making
- Patients must be **suitable for short-term warfarin**, but deemed unable to take long-term oral anticoagulation.
- Established structural heart disease or electrophysiology program.
- Procedure must be performed by an interventional cardiologist or electrophysiologist meeting the following criteria:
  - Trained by the manufacturer
  - **≥25 interventional cardiac procedures involving transseptal** punctures through an intact septum
  - Continues to perform ≥25 transseptal punctures through an intact septum, with at least 12 being LAAC over a two year period
- Patients must be enrolled in **a prospective national registry**.

Oral Anticoagulants
DISCONTINUATION RATES



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AJC 110:453, 2012

Eligible patients must have a CHADS2 score ≥2

or a CHA2DS2-VASc score ≥3.

$CHADS_2$

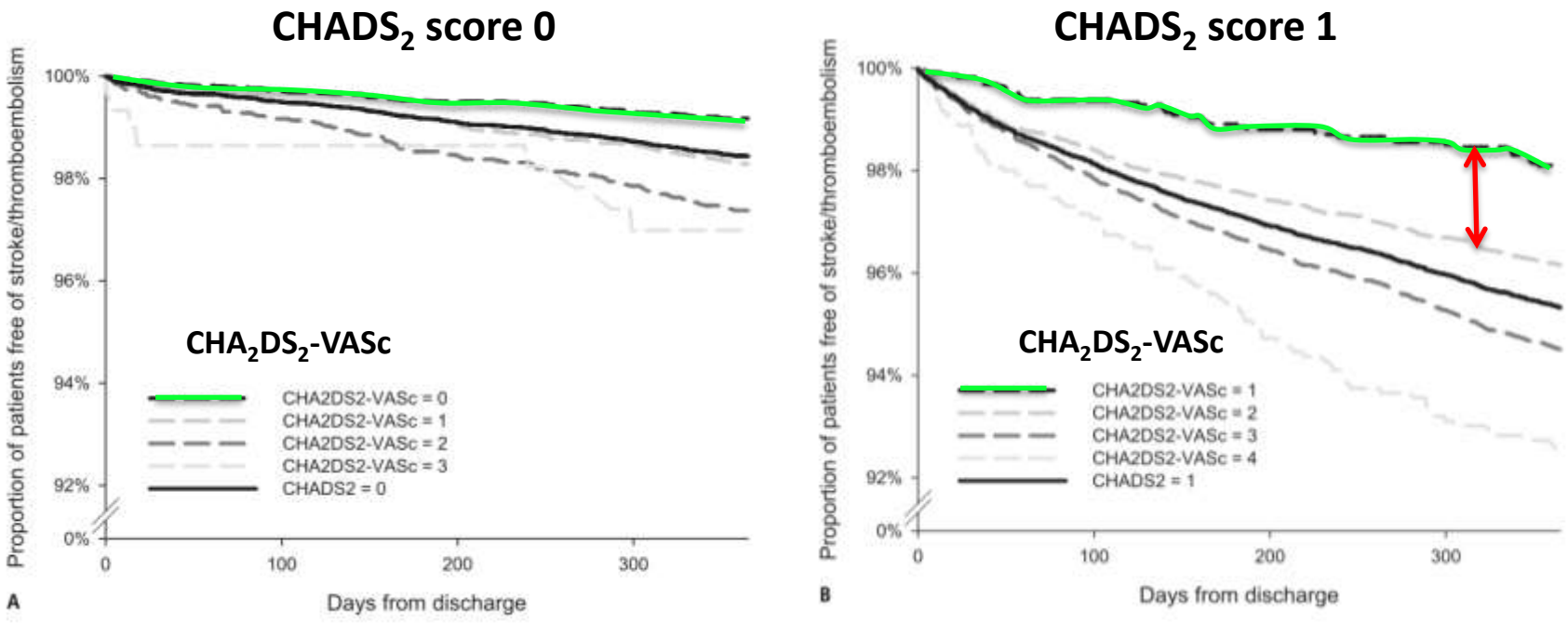
CHADS2 score	Patients (n = 1733)	Adjusted stroke rate %/ year
0	120	1.9
1	463	2.8
2	523	4.0
3	337	5.9
4	220	8.5
5	65	12.5
6	5	18.2

CHA_2DS_2VASc

CHA2DS2-VASc score	Patients (n = 7329)	Adjusted stroke rate %/ year
0	1	0
1	422	1.3
2	1230	2.2
3	1730	3.2
4	1718	4.0
5	1159	6.7
6	679	9.8
7	294	9.6
8	82	6.7
9	14	15.2

European Heart Journal (2010) 31, 2369–2429

The value of the CHA_2DS_2-VASc score for refining stroke risk stratification in AF with $CHADS_2$ score 0–1



Patients with a CHADS2 score=0 were not all 'low risk', with 1-year event rates ranging from 0.84 (CHA2DS2-VASc score=0) to 3.2 (CHA2DS2-VASc score=3).

Even in CHADS2 score=0, the CHA2DS2-VASc score significantly improved the predictive value of the CHADS2 score alone and a CHA2DS2-VASc score=0 could clearly identify 'truly low risk' subjects.

Thromb Haemost 2012; 107: 1172–1179

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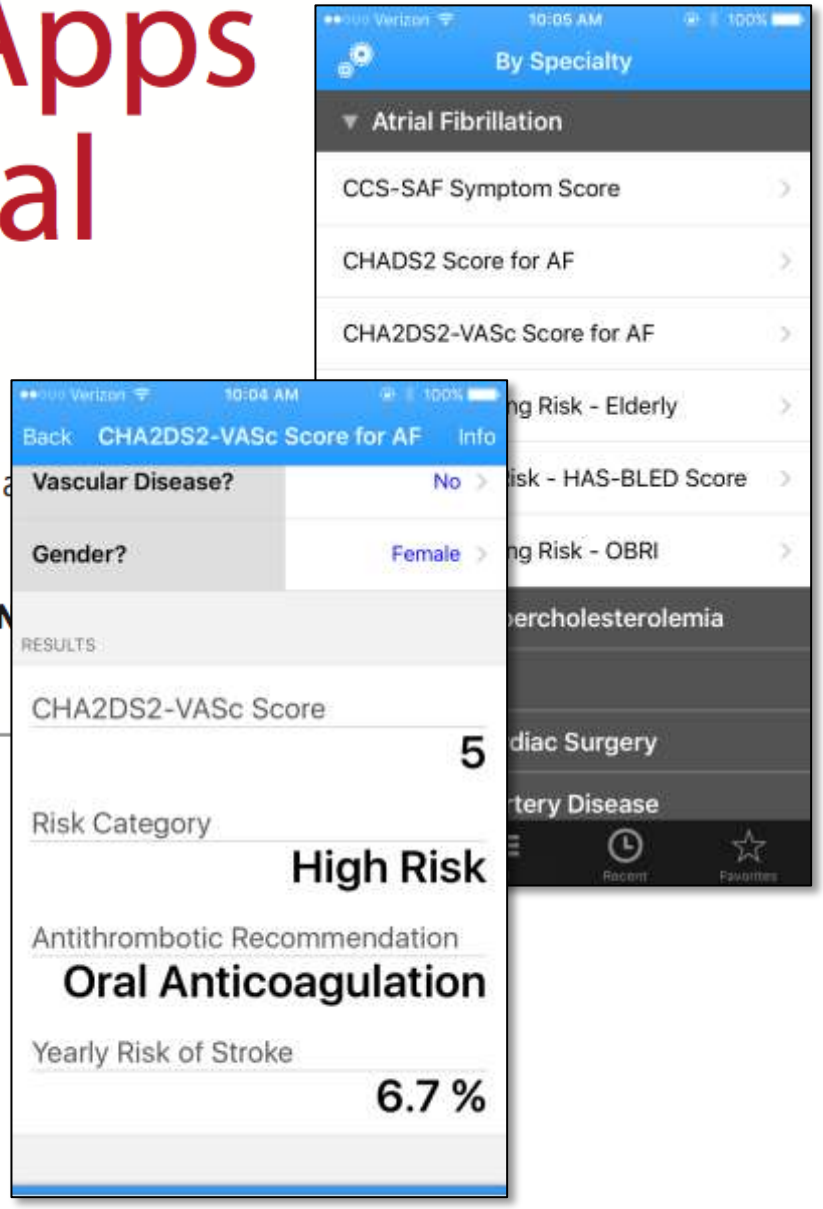
Mobile Device Apps for Interventional Cardiology

An overview of commonly used and clinically relevant medical a
facilitate and improve patient care.

BY JUSTIN P. LEVISAY, MD, FACC, FSCAI; MICHAEL H. SALIN

AND TED E. FELDMAN, MD, MSCAI, FACC, FESC



Calculate by QxMd

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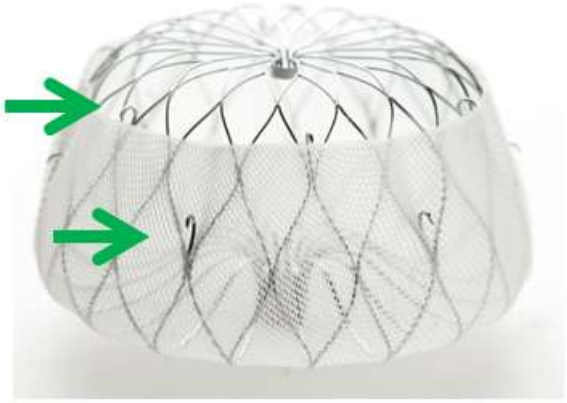
WATCHMAN FLX™ LAA Closure Device

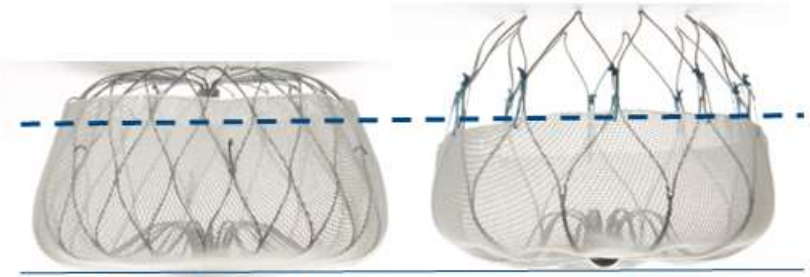
Next Gen Design Goals



'J' anchor

'Straight' anchor

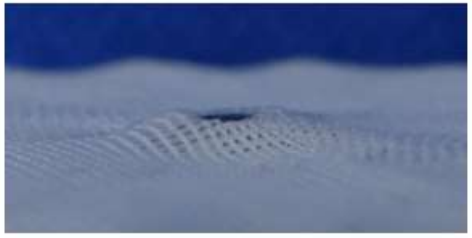
Two rows of 'J' shaped anchors
12 total anchors (vs. 10)



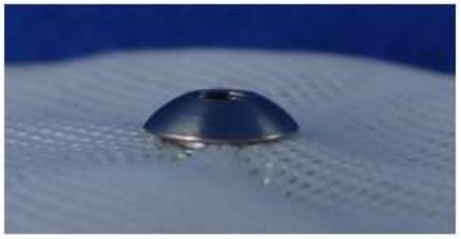
WATCHMAN FLX 27mm

WATCHMAN 27mm

Increased distal PET fabric coverage

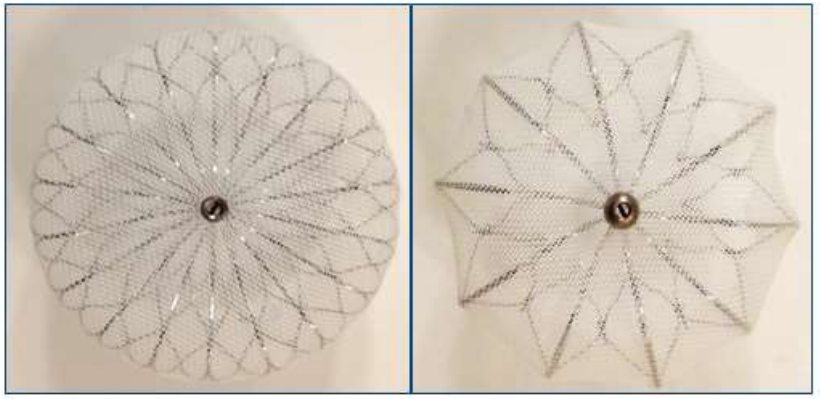


WATCHMAN FLX



WATCHMAN

Recessed metal screw on proximal face



WATCHMAN FLX

WATCHMAN

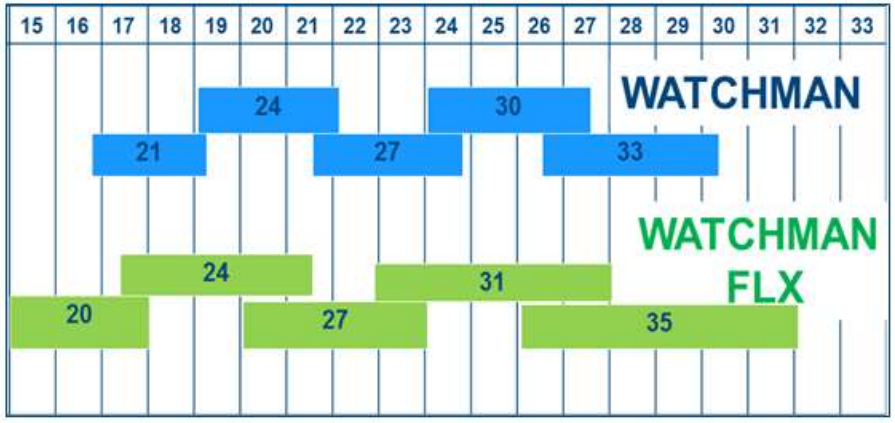
18 strut frame (vs. 10)

WATCHMAN FLX™ LAA Closure Device

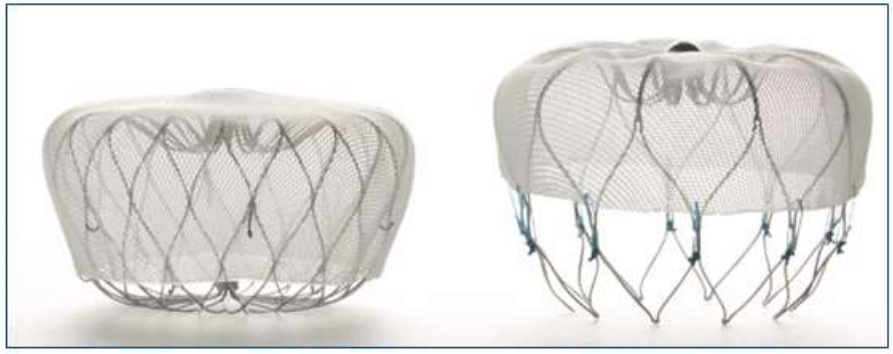
Next Gen Design Goals

Closed distal end with Fluoro marker

Allowed to be partially recaptured and advanced into LAA



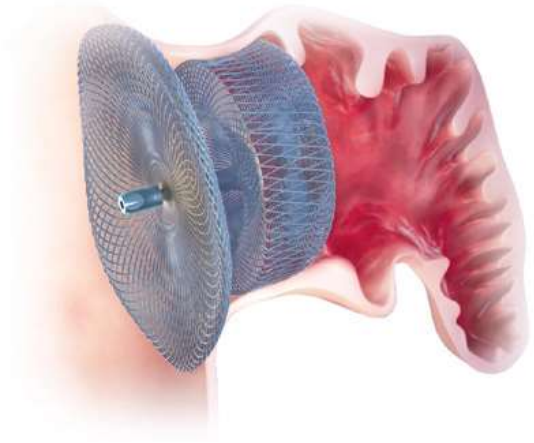
Increased treatable LAA ostium range to 15-32mm



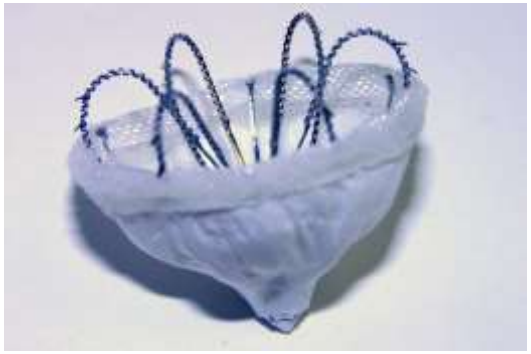
WATCHMAN FLX 27mm

WATCHMAN 27mm

Shorter device length



ACP

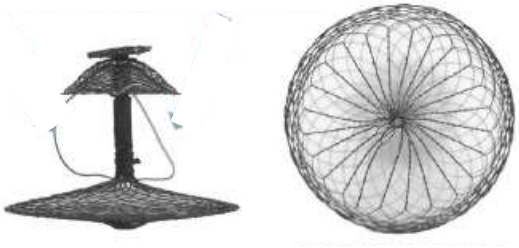


WaveCrest

Occulotech

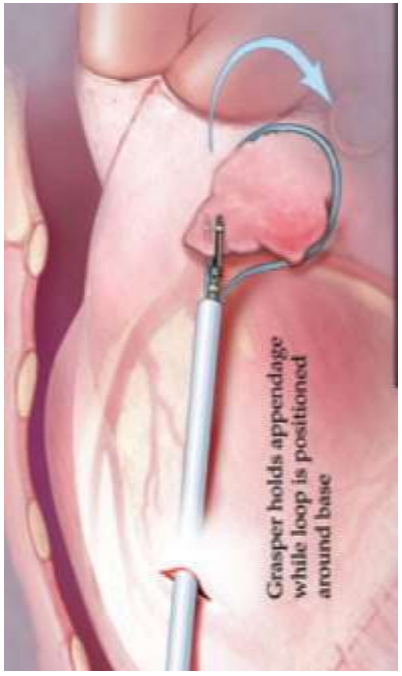
Sideris Patch

LifeTech



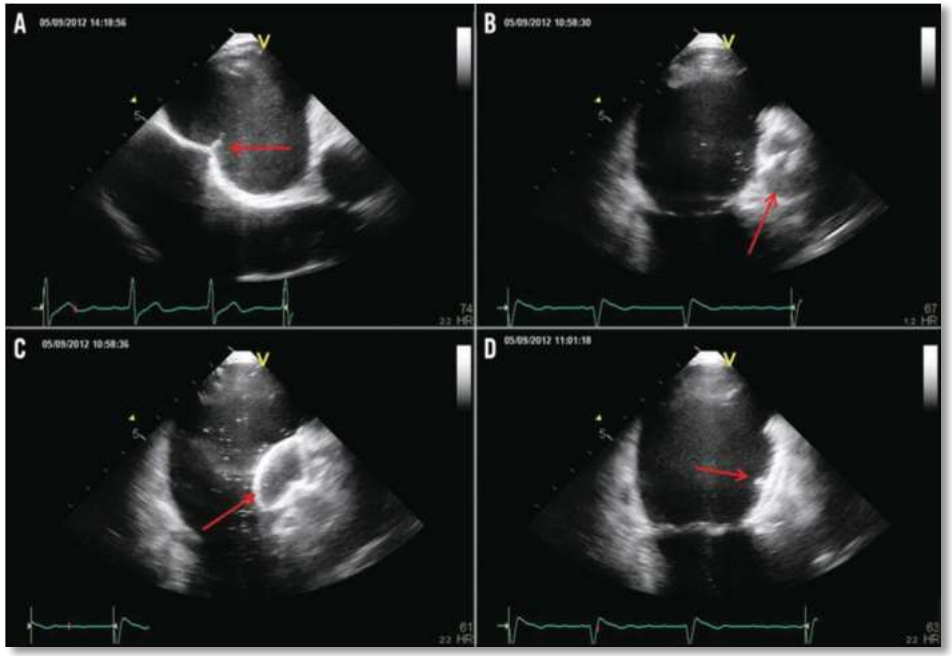
pfm

Cardia



AEGIS

Left atrial appendage closure monitoring without sedation: intracardiac echocardiography by the oesophageal route



- the cost per probe is prohibitive
- 3D and biplane capability are lost
- TEE probe is required anyway earlier to rule out thrombus
- Patient comfort – probe is often in for 30 minutes for a full LAA case

EuroIntervention 2015;11:936-941