SURGICAL VS ELECTROPHYSIOLOGICAL INTERVENTIONS FOR CARDIAC ARRHYTHMIAS

DEBATE 2:

LAA CLOSURE IS BEST DONE WITH DEVICES

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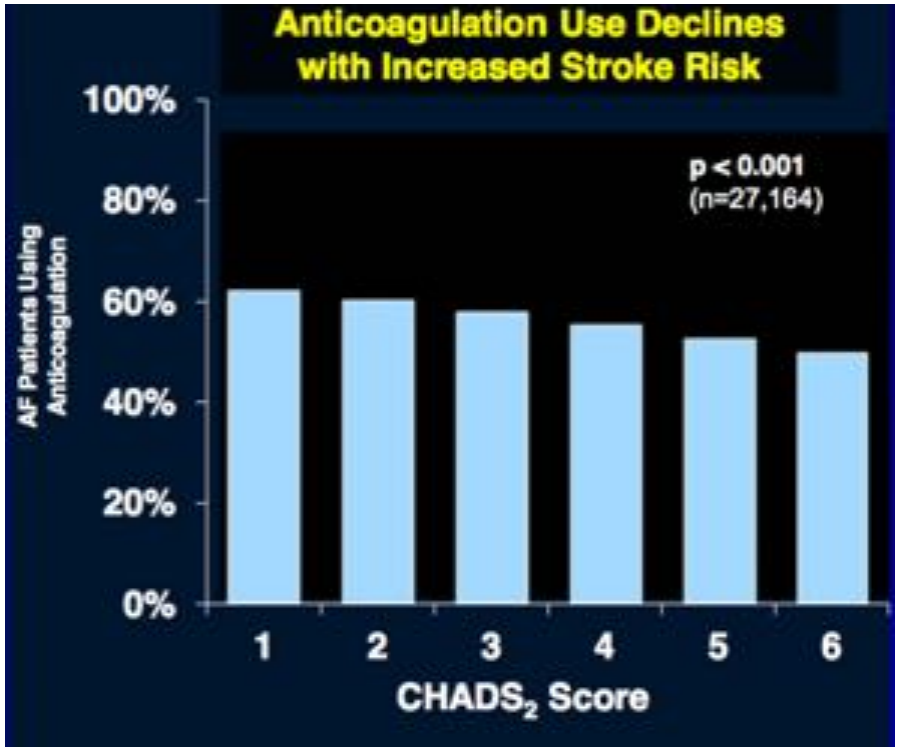
NO CONFLICT OF INTEREST TO DECLARE

Background

There are unmet clinical needs in AF patients with high thromboembolic risk:

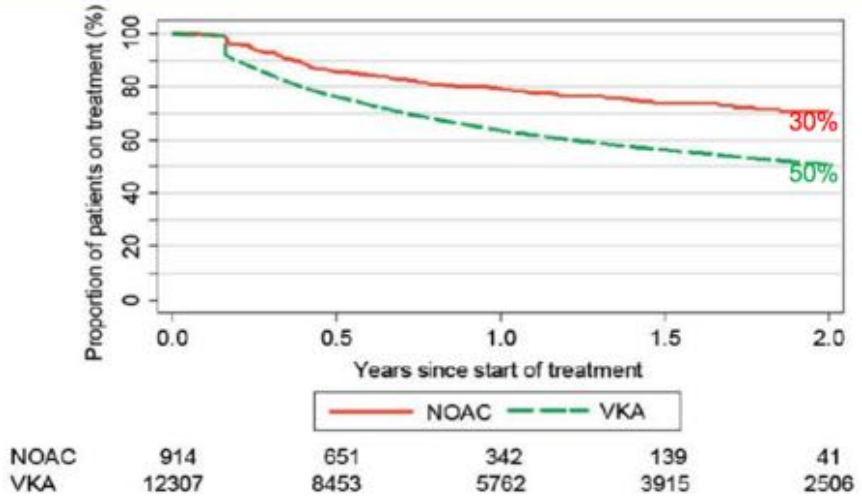
- **OAC undertreatmant**
- **Non-compliance**
- **Long term bleeding risk**

Background



Piccini et al, Heart Rhythm. 2012;9:1403-1408

OAC discontinuation



Martinez et al, Thromb Haemost 2015

Why should I close the LAA?

>90% of the thrombi in AF from the LAA

Local, mechanical therapy appears to be a reasonable approach for AF patients with an appropriate rationale to seek a permanent, non-pharmacological approach to stroke prevention

Why should I use LAA occlusion devices?

Over the past decade several pLAAC devices have been developed (PLAATO, Watchman, ACP, Amulet, Lariat, Wavecrest, Lambre LAA Okkluder, Occlutech LAA Occluder)

2 of them (Watchman, ACP/Amulet) have hit the market and are currently available for clinical practice

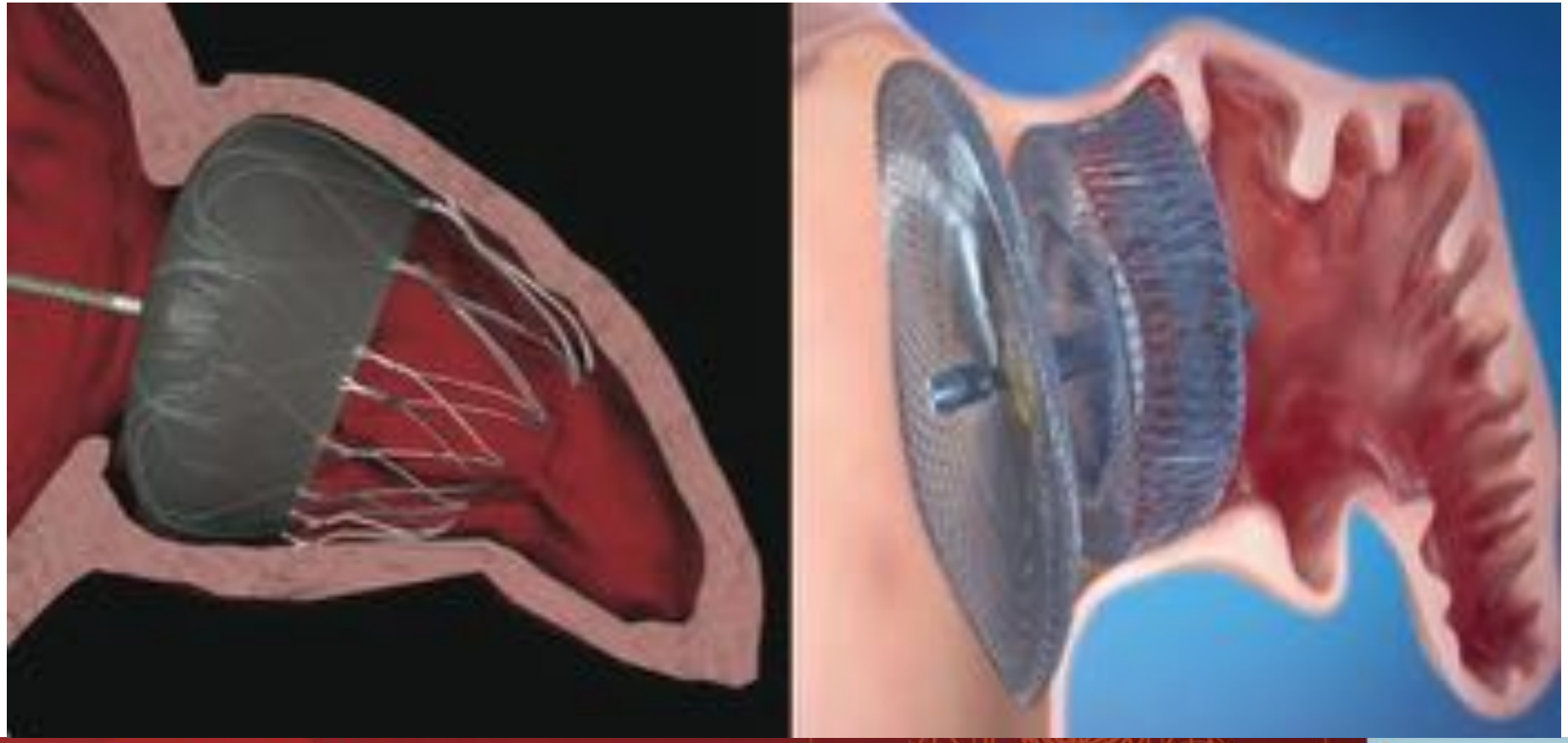
Proven procedural and long-term safety and efficacy

Why should I use LAA occlusion devices?

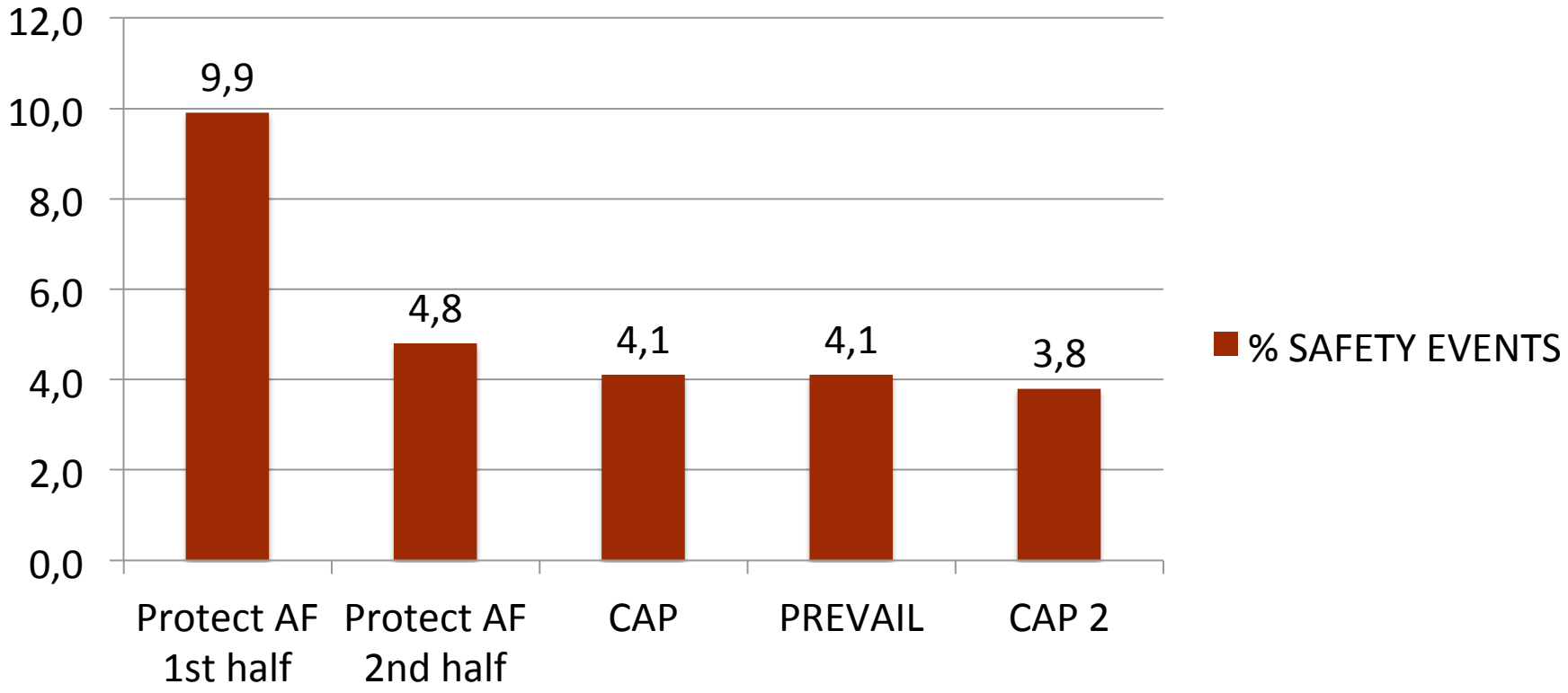
Procedural aspects

- Pre-procedural TEE to exclude LAA thrombi, LAA measures
- conscious sedation and fluoro/TEE guidance
- local anaesthesia and fluoro/ICE guidance (Berti et al, JACC Intv 2014;7:1036-44)
- fluoro only, fluoro/pediatric TEE (Ronco F, Pascotto A, Barbierato M, Grassi G Cardiovasc Revasc Med. 2012 Nov-Dec;13(6):360-1)
- Venous femoral access, trans-septal puncture, Pre-shaped guiding catheter for device delivery
- Mean procedural time: **48,4 min** (ACP post-market), **67-50 min** Watchman (Protect AF 1st half – CAP). Mean contrast use ≈120 mL.
- Successful implantation: ACP > 95%, Watchman 89,5%-95%

Why should I use LAA occlusion devices?



7 Days safety events, Watchman



Procedural safety events, Watchman

- Cardiac perforation requiring surgery:

  1,6%, 0,2%, 0,4% in PROTECT AF, CAP, PREVAIL respectively
- Pericardial effusion with tamponade requiring pericardiocentesis or window:

  2,9%, 1,2%, 1,5% in PROTECT AF, CAP, PREVAIL respectively
- Periprocedural stroke:

  1,1%, 0%, 0,4% in PROTECT AF, CAP, PREVAIL respectively

Left atrial appendage occlusion for stroke prevention in atrial fibrillation: multicentre experience with the AMPLATZER Cardiac Plug

EuroIntervention 2015;10-online publish-ahead-of-print January 2015

Table 3. Periprocedural adverse events.

Major adverse events (N=1,047)		%
Death	8	0.76
Major (intracranial) bleeding	Procedure	
Cardiac tamponade	Procedure	
Cardiac tamponade leading to multi-organ failure	Day 4*	
Arrhythmia	Day 2	
STEMI - hypoxia	Day 13*	
Device embolisation	Procedure	
Device embolisation	Day 6*	
Pneumonia	Day 10	
Stroke	9	0.86
Systemic embolism	0	0.00
Myocardial infarction	1 (day 5)	0.10
Cardiac tamponade	13	1.24
Major bleeding	13	1.24
Femoral artery (vascular closure)	(8)	
Pulmonary artery perforation	(1)	
Gastrointestinal	(2)	
Device embolisation requiring surgery	1	0.10
Device embolisation snared	7	0.67
Need for surgery**	0	0.00
Total	52	4.97
Other adverse events		
TIA	4	0.38
Air embolism (transient ST elevation and/or chest pain)	5	0.48
Device-related thrombus	3	0.29
Vascular complications	4	0.38
Femoral artery pseudoaneurysm	(3)	
Arteriovenous fistula	(1)	
Total	16	1.53

Variables are presented as n (%). *Adverse events occurred during the procedure but resulted in death a few days later. **Apart from device embolisation. STEMI: ST-elevation myocardial infarction; TIA: transient ischaemic attack

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ACP post-market observational Study

Presented by Jai-Wun Park EuroPCR 2015

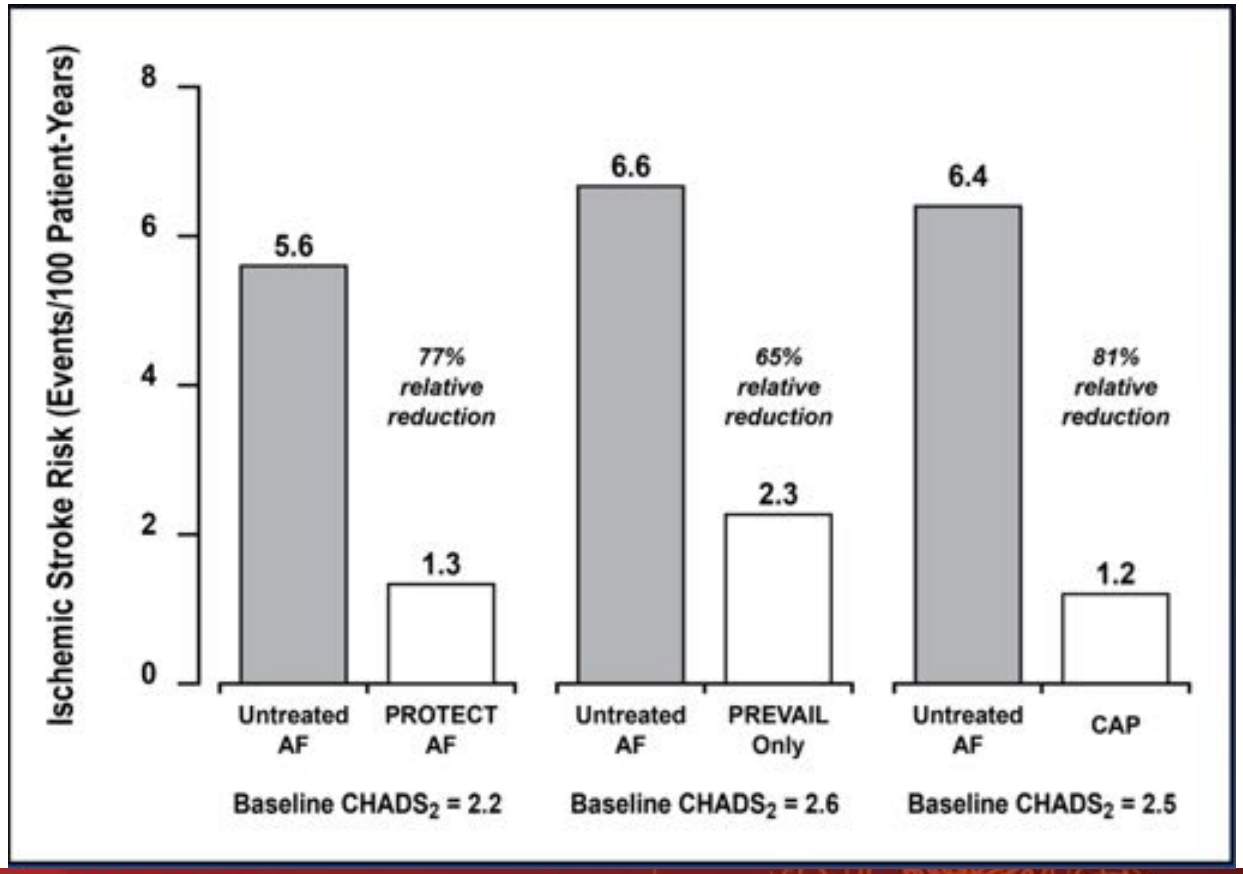
Device/Procedure Related Safety Events*:

– Stroke / TIA	0.0% (0/204; n=0)
– Serious Pericardial Effusion	1.5% (3/204; n=3)
– Device Embolization	1.5% (3/204; n=3)
– Thrombus	0.0% (0/204; n=0)

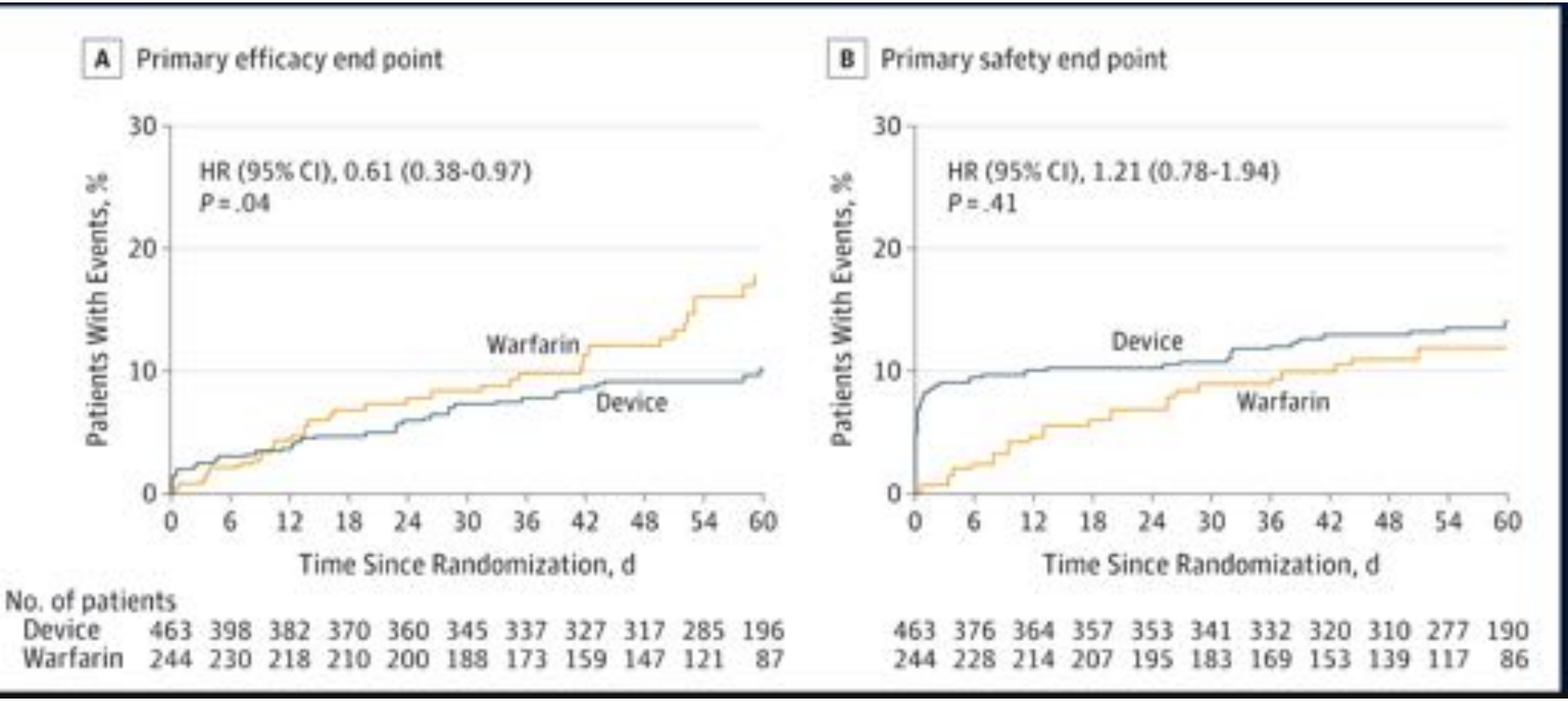
- Device embolizations occurred early in learning curve for each of the implanters
- Training, and focus on implant technique has mitigated the risk of embolization since early reports

*Acute follow-up within 7 days

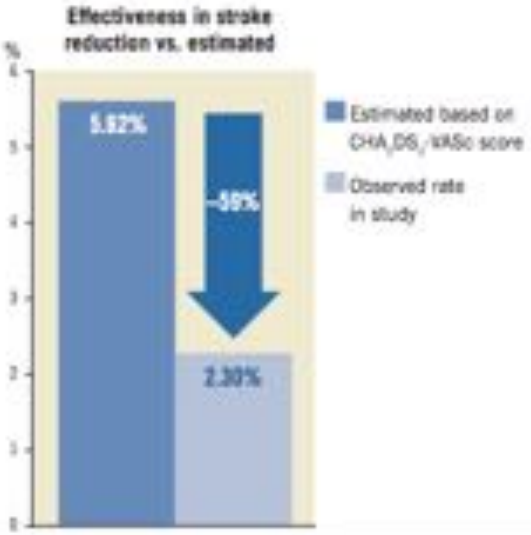
Efficacy data, Watchman vs expected ischemic stroke rate



Efficacy data,PROTECT AF 4 yrs

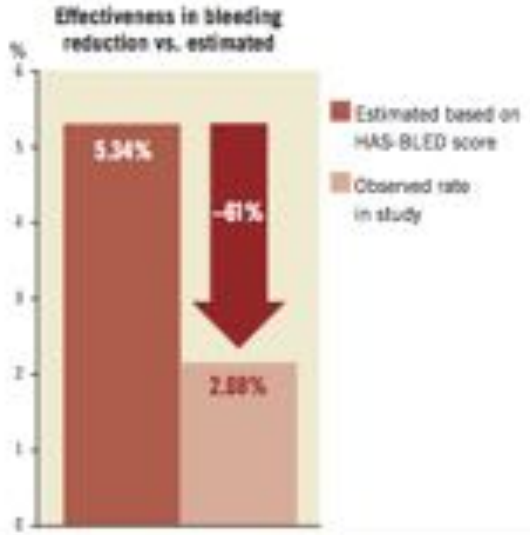


Efficacy data, ACP 1



Total patients	Total patient-years	CHA_2DS_2-VASc score
1,001	1,349	4.43

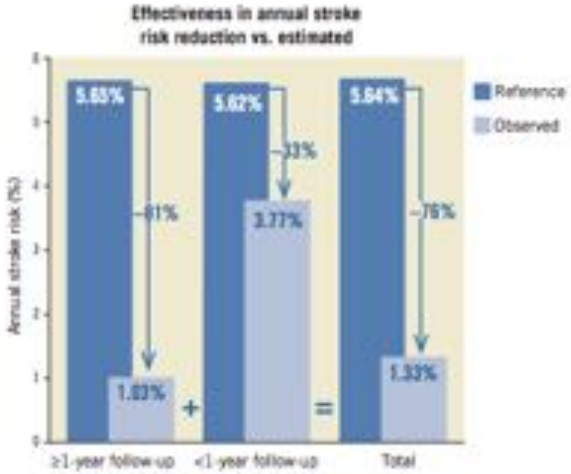
Estimated stroke rate per CHA_2DS_2-VASc	Actual annual stroke rate (No. strokes+TIA)
5.62%	2.30% (31)

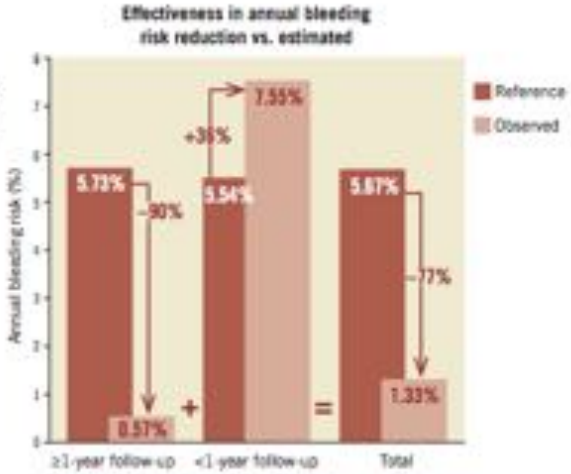


Total patients	Total patient-years	HAS-BLED score
1,001	1,349	3.12

Estimated bleeding rate per HAS-BLED	Actual annual bleeding rate (No. major bleeds)
5.34%	2.08% (28)

Efficacy data, ACP > 1yr





	Patients	Total patient-years	CHA_2DS_2-VASc score
≥1-year follow-up	432	871	4.4
<1-year follow-up	195	110	4.5
Total	627	981	4.4

	Estimated annual stroke rate per CHA_2DS_2-VASc	Observed annual stroke rate (No. strokes+TIA)
≥1-year follow-up	5.65%	1.03% (9)
<1-year follow-up	5.62%	3.77% (4)
Total	5.64%	1.33% (13)

	Patients	Total patient-years	HAS-BLED score
≥1-year follow-up	432	871	3.2
<1-year follow-up	195	110	3.2
Total	627	981	3.2

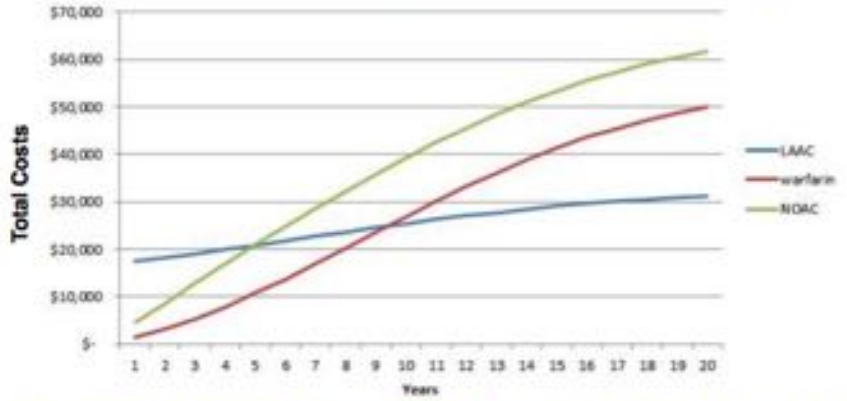
	Estimated annual bleeding rate per HAS-BLED	Observed annual bleeding rate (No. bleedings)
≥1-year follow-up	5.73%	0.57% (5)
<1-year follow-up	5.54%	7.55% (8)
Total	5.67%	1.33% (13)

Cost-effectiveness Watchman

Economic Analysis: Cost Effectiveness

Watchman *vs* NOACs *vs* Warfarin

- Patient level Markov micro-simulation decision analytic model
- Assess Time-to-Cost Effectiveness (not just Lifetime horizon – 20 yrs)
- Economic costs from the U.S. perspective, and costs in 2015 US$
  - For LAAC procedure, we used the new DRG 273/274 (US average: $16,109)
- Latest PROTECT AF data (4 yrs f/u)
- NOAC meta-analysis of all 4 NOACs (Ruff et al, *Lancet* 383:955, 2014)
- Incorporated costs based on the level of disability resulting from strokes



VY.Reddy, RL.Akehurst, SO.Armstrong, SL.Amarosi, SM.Beard, DL.Holmes (*in press*)

Surgical LAA closure

Ann Thorac Surg. 2015 Oct 7. pii: S0003-4975(15)01284-9. doi: 10.1016/j.athoracsur.2015.07.071. [Epub ahead of print]

Left Atrial Appendage Patency at Cardioversion After Surgical Left Atrial Appendage Intervention.

Cullen MW[1], Stulak JM[2], Li Z[3], Powell BD[4], White RD[5], Ammash NM[6], Nkomo VT[6].

Author information

Abstract

BACKGROUND: Surgical left atrial appendage (LAA) closure is often incomplete, with patients frequently requiring direct current cardioversion (DCCV) for atrial arrhythmias. Transesophageal echocardiography (TEE) is often performed before DCCV to exclude LAA thrombus. The impact of incomplete surgical LAA closure on patients referred for postoperative DCCV is unknown.

METHODS: We retrospectively reviewed patients undergoing TEE-guided DCCV within 30 days of cardiac surgery and surgical LAA closure. All pre-DCCV TEEs were reviewed to assess LAA patency and the presence of thrombus.

RESULTS: Ninety-three patients (mean age 68 years; 61 men [66%]) had a median time from surgery to DCCV of 6 days. Duration of atrial fibrillation was 48 hours or more in 85% (n = 79). On pre-DCCV TEE, a residual communication from the LAA was noted in 37% (n = 34). The rate of LAA patency was higher after suture closure than after surgical excision or staple closure. Thrombus was present in 26 of the 93 patients (28%), including 16 of 34 patients (47%) with incomplete closure of LAA. The strongest risk factor for thrombus was a patent, partially closed LAA (odds ratio 4.36, p = 0.003). Systemically accessible thrombus was present in 19 of the 93 patients (20%), and cardioversion was cancelled owing to thrombus in 15 (16%).

CONCLUSIONS: Surgical closure of the LAA is often incomplete. Interrogation of the residual LAA after surgical LAA intervention with TEE before DCCV frequently detects thrombus and alters clinical management. Patients undergoing DCCV after surgical LAA intervention require evaluation with TEE for LAA patency and thrombus.

Why is the LAA device closure better?

- Over the past decade it has been demonstrated that the pLAAC is a feasable, safe, efficacious therapy for stroke prevention and bleeding reduction in the long term
- In one RCT (PROTECT AF) it has even improved overall survival over VKA
- It has a class II b LOE B indication in 2 ESC guidelines (AF, myocardial revasc). The Watchman device has recently obtained FDA approval
- The procedure can be performed under local anaesthesia with Fluoro/ICE-guidance Possibility to choose the device, technical improvements will make the procedure easier and faster
- Expected long-term cost-effectiveness
- The surgical procedure can be performed only in pts undergoing cardiac surgery
- Still no randomized data (Class II b LOE C in ESC Revasc Guidelines AF guidelines in pts undergoing cardiac surgery)
- no clear data showing success rate and stroke reduction, high rate of incomplete LAA closure and thrombus

THANK YOU!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