



2<sup>a</sup> Edizione



**CHIUSURA  
PERCUTANEA  
DELL' AURICOLA  
SINISTRA:** dalle linee  
guida alla pratica clinica



# Chiusura dell'auricola sinistra: update 2018

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# Conflict of interest



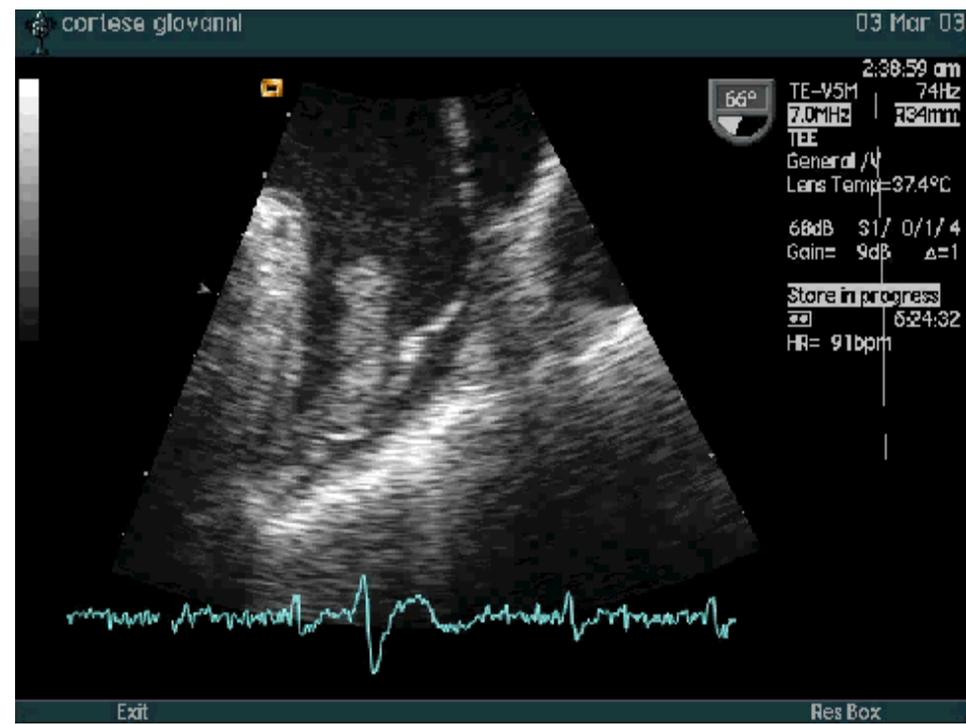
- **Proctor of Boston Scientific for LAAC**
- **Proctor of Abbott for LAAC**

# Agenda

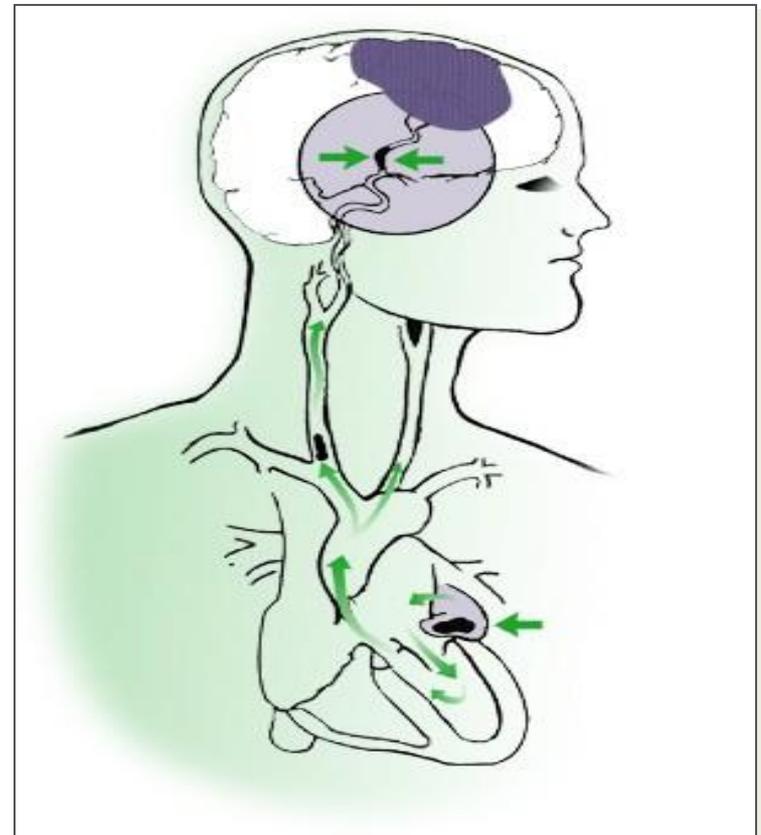


- Background
- State of the art
- Future perspectives

# Background



- **EcoTEE: thrombi in the LAA in 15% of patients with atrial fibrillation**



# Left atrial appendage closure devices

**PLAATO**



**ACP**



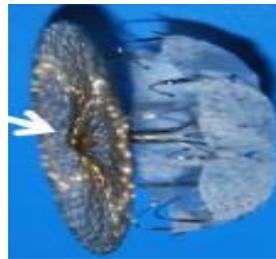
**Watchman**



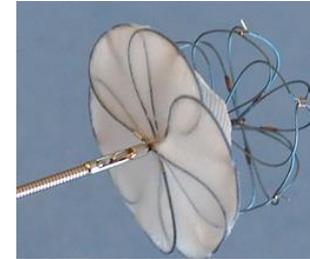
**Amulet**



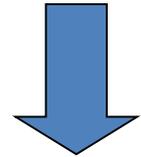
**Lambre**



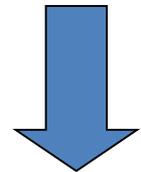
**Cardia**



PAST



PRESENT



FUTURE

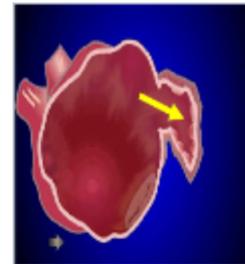
**Watchman FLX**



**Wavecrest**



**Other**



# State of the art

# Evaluation of the benefits



# Current PubMed publications

**Search results**

Sort by:

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Most recent

02/05/2018

## WATCHMAN™ Unique LAAC Design

	PROTECT AF (Randomizes Clinical Trial)		CAP <sup>5</sup> (Registry)	ASAP <sup>6</sup> (Registry)	PREVAIL <sup>7</sup> (Randomized Clinical Trial)
	18 mo's <sup>4</sup>	4 yrs. <sup>8</sup>			
Design	Prospective RCT with patients able to take warfarin		Prospective registry with patients able to take warfarin	Prospective registry with patients contraindicated for warfarin	Prospective RCT with patients able to take warfarin
Outcome	WATCHMAN was non-inferior to warfarin in pts. at high-risk of stroke	WATCHMAN was superior to warfarin in primary efficacy, cardiovascular death, hemorrhagic stroke & fatal/disabling stroke	Significantly improved safety results from early PROTECT AF experience	Ischemic stroke rate significantly reduced in warfarin contra-indicated pts.	WATCHMAN device was safely implanted by new operators
Mean age /CHADS <sub>2</sub>	72/2.2		74/2.4	72.4/2.8	74/2.6
Total Enrolled Subjects	707 randomized <sup>4</sup> 93 pts rolled in <sup>5</sup>		460	150	461
Total Patients Implanted	463		437	142	269
Implantation Success	88%		95%	94.7%	95.1%
Primary Efficacy (all-stroke, CV/unexplained death, and systemic embolism)	38% reduction vs. warfarin <sup>4</sup>	40% reduction vs. warfarin (superior) <sup>8</sup>	29% reduction vs. warfarin	N/A	18 months rate: 0.064 WATCHMAN and 0.063 for warfarin
All-Stroke	29% reduction vs. warfarin <sup>4</sup>	32% reduction vs. warfarin (non-inferior) <sup>8</sup>	23% reduction vs. warfarin	77% reduction vs. expected rate per CHADS <sub>2</sub> score	Data not yet available
Safety (7 day procedure-related*)	8.7% <sup>4</sup>		4.1% <sup>4</sup> 53% reduction vs. PROTECT AF	Pericardial effusion with tamponade=2.0% Major bleeding=2.7%	4.2% 52% reduction vs. PROTECT AF

1 Holmes DR et al. *Lancet* 2009;374:534-42;

2 Reddy VY et al. *Circulation*. 2011;123:417-424

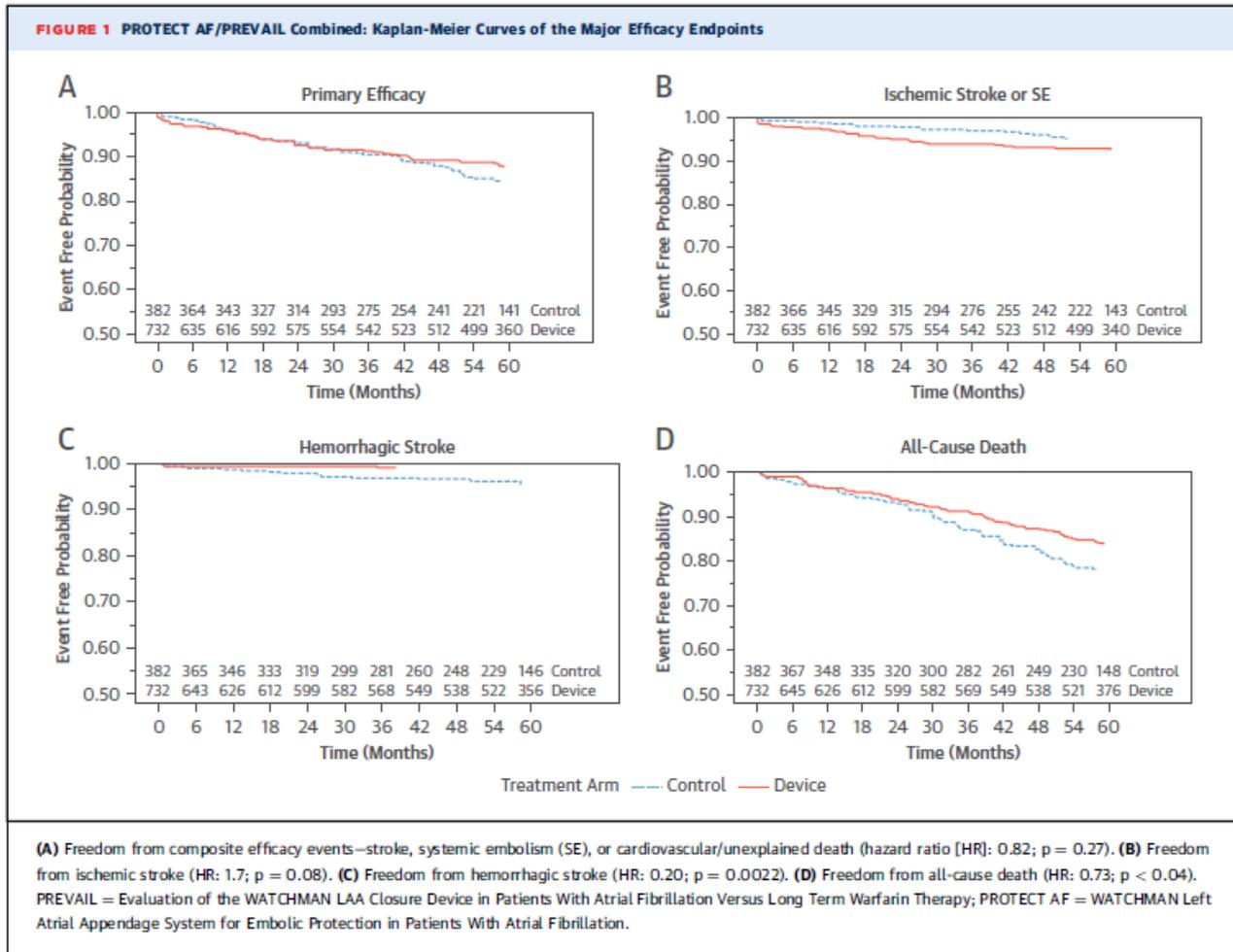
3 Reddy, *JACC* 2013;

4 Holmes DR et al. Randomized Trial of LAA Occlusion. *JACC*. Vol. 64: 1-12, 2014

5 Reddy, VY et al. *JAMA*. 2014; 312(19):1988-1998

\*Composite of vascular complications includes cardiac perforation, pericardial effusion with tamponade, ischemic stroke, device embolization, and Includes observed PE not necessitating intervention, AV fistula, major bleeding requiring transfusion, pseudoaneurysm, hematoma and groin bleeding

# Randomized trials: Follow-up up to 5 years



# WHY A REGISTRY?

Big trial



Real world



## **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,<sup>\*</sup> Hueseyin Ince, MD,<sup>†</sup> Stephan Kische, MD,<sup>‡</sup>  
Evgeny Pokushalov, MD, PhD,<sup>§</sup> Thomas Schmitz, MD,<sup>||</sup> Boris Schmidt, MD,<sup>¶</sup>  
Tommaso Gori, MD,<sup>#</sup> Felix Meincke, MD,<sup>\*\*</sup> Alexey Vladimir Protopopov, MD, PhD,<sup>††</sup>  
Timothy Betts, MD,<sup>‡‡</sup> David Foley, MD, PhD, FRCPI, FACA, FACC, FESC,<sup>§§</sup> Horst Sievert, MD,<sup>|||</sup>  
Patrizio Mazzone, MD,<sup>¶¶</sup> Tom De Potter, MD,<sup>##</sup> Elisa Vireca,<sup>\*\*\*</sup> Kenneth Stein, MD, FHRS,<sup>†††</sup>  
Martin W. Bergmann, MD, PhD, FESC,<sup>‡‡‡</sup> for the EWOLUTION Investigators

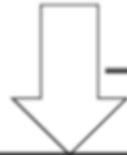
[Heart Rhythm.](#) 2017 Sep;14:1302-1308

## EWOLUTION - baseline characteristics

Characteristic	Percentage
Congestive heart failure	34%
Hypertension (uncontrolled or history)	86%
Age $\geq$ 80 years	26%
Diabetes	29%
Stroke Ischemic/Hemorrhagic	20% / 15%
Vascular disease	42%
Female Gender	40%
Abnormal renal/liver function	16% / 4%
Prior Major Bleeding or predisposition to bleeding	39%
CHA <sub>2</sub> DS <sub>2</sub> -VASc score $\geq$ 5	49%
HAS-BLED $\geq$ 3	40%
<b>Contra-indication (N)OAC</b>	<b>73%</b>

# EWOLUTION – OAT at Follow-Up

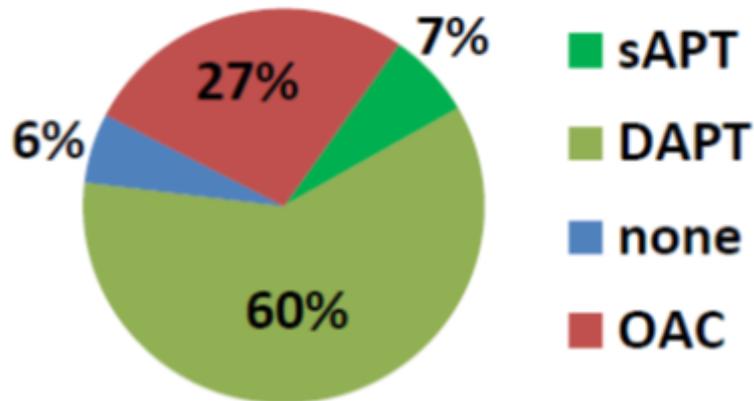
Pts with known medication: N = 997



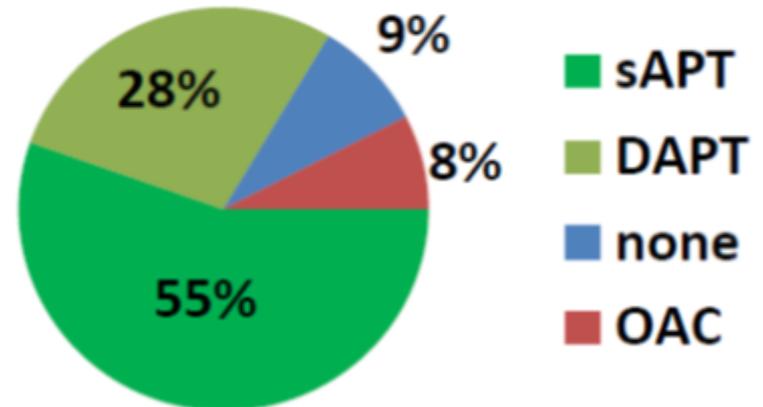
Pts without FU information: N = 52

Pts with first medication discontinuation info: N = 945

Post-implant

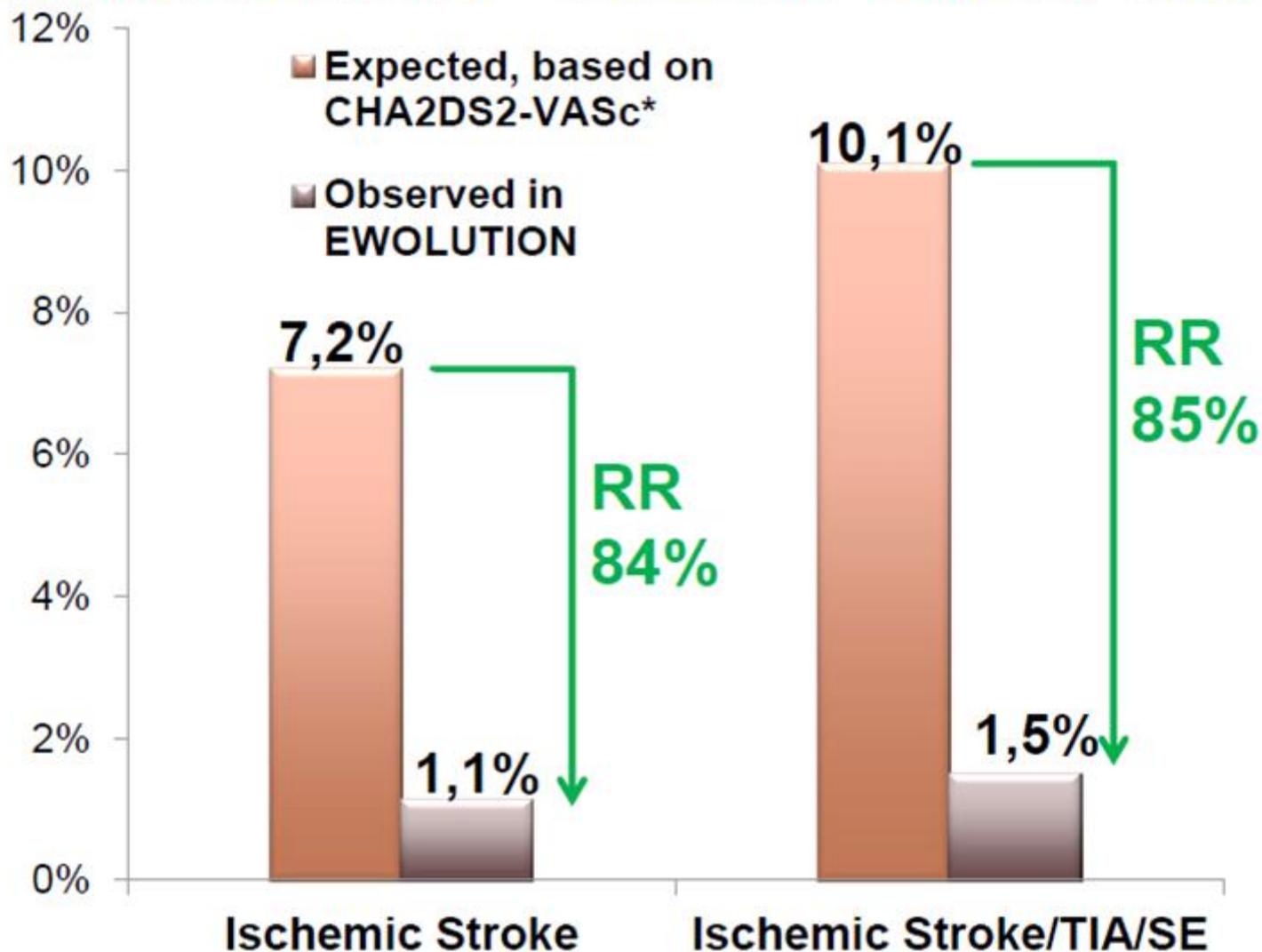


After first discontinuation



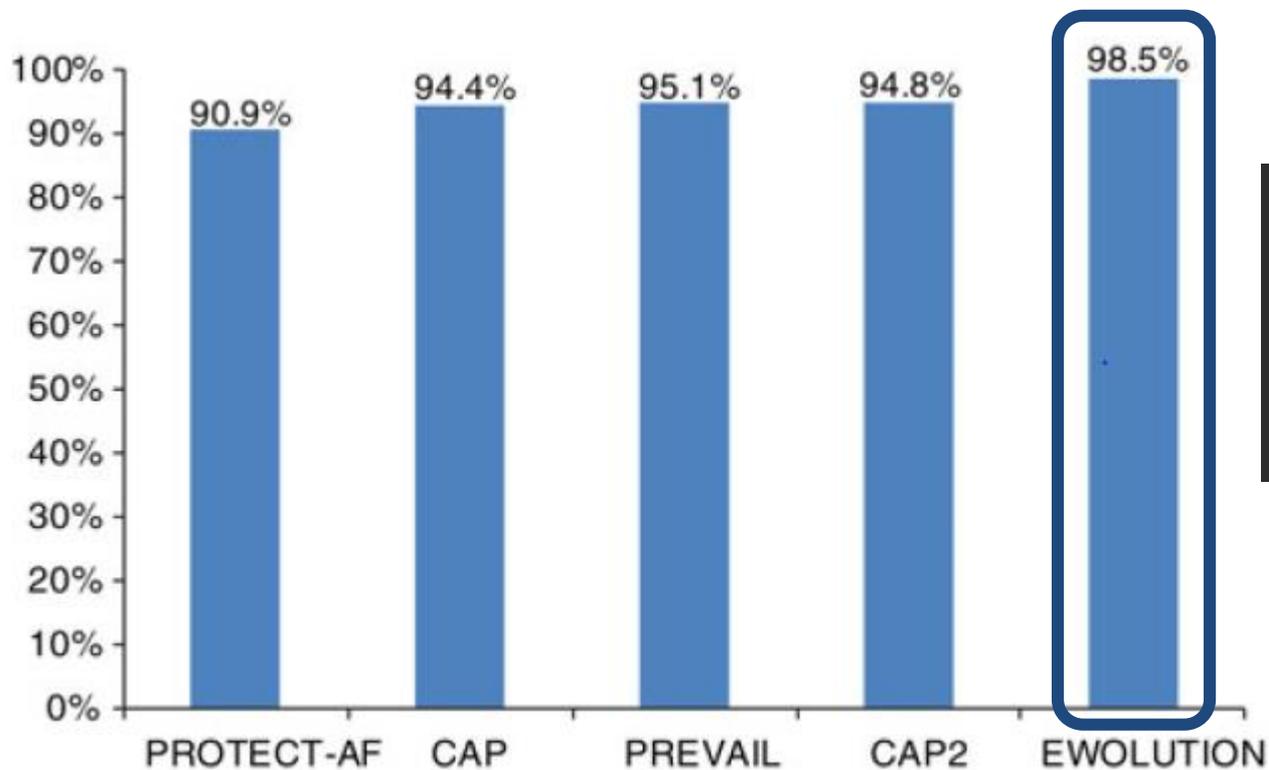
OAC drop within 3 mo  
DAPT drop within 6 mo

# EWOLUTION – Annual Stroke Rate



\*Effectiveness in stroke reduction vs. estimated in the absence of therapy for comparable CHA<sub>2</sub>DS<sub>2</sub>-VASc scores based on Friberg et al. EHJ 2012

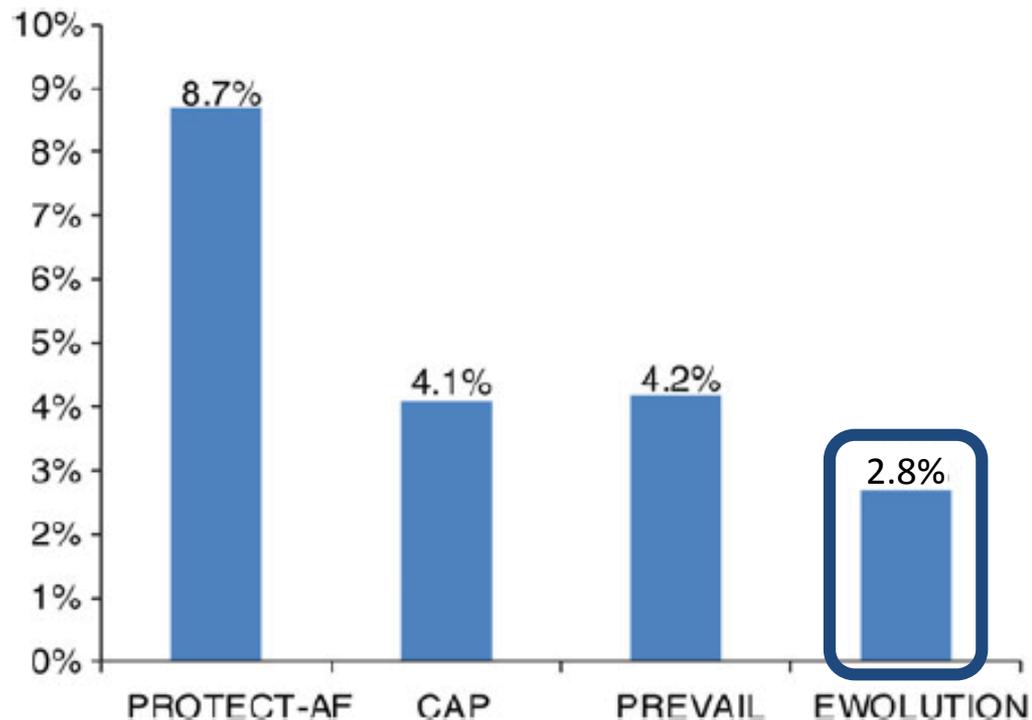
# Procedural Results



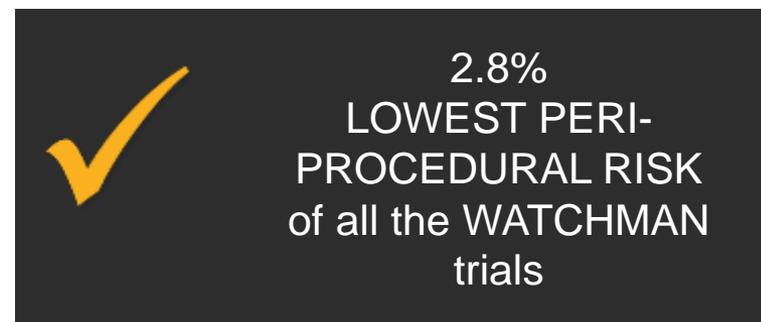
**98.5%**  
**HIGHEST IMPLANT  
SUCCESS RATE  
Of all the  
WATCHMAN trials**

**Implant success in EWOLUTION when compared to prior WATCHMAN studies**

## Implant Procedure Safety



**7-Day SAEs procedure/device-related in WATCHMAN studies.**



SAE: Serious Adverse Event - Composite of vascular complications includes cardiac perforation, pericardial effusion with tamponade, ischemic stroke, device embolization, and other vascular complications<sup>1</sup>

<sup>1</sup>Includes observed PE not necessitating intervention, AV fistula, major bleeding requiring transfusion, pseudoaneurysm, hematoma and groin bleeding



## Percutaneous Left Atrial Appendage Closure with WATCHMAN™ device: peri-procedural and mid-term outcomes from the TRAPS Registry

Patrizio Mazzone<sup>1</sup> · Giuseppe D'Angelo<sup>1</sup> · Damiano Regazzoli<sup>1</sup> · Giulio Molon<sup>2</sup> · Gaetano Senatore<sup>3</sup> · Salvatore Saccà<sup>4</sup> · Guido Canali<sup>2</sup> · Claudia Amellone<sup>3</sup> · Riccardo Turri<sup>4</sup> · Paolo Della Bella<sup>1</sup>

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### Abstract

**Purpose** The WATCHMAN device for Left Atrial Appendage Occlusion (LAAO) has proven to be an effective alternative to oral anticoagulation (OAC) in patients with atrial fibrillation (AF), and has now been adopted in clinical practice. In the present study, we analyzed the safety and efficacy profile of the LAAO procedure at mid-term follow-up.

**Methods** The TRAPS Registry is an observational, multicenter registry involving four Italian centers. Consecutive patients who had undergone LAAO with WATCHMAN device were enrolled. Clinical, demographic, and procedural data were collected at the time of implantation, and follow-up data were collected to assess the clinical outcome.

**Results** A total of 151 patients were included in the Registry from May 2012 to October 2015. Implantation of the device was successful in 150/151 patients, with no or minimal (< 5 mm) leakage as assessed by peri-procedural transesophageal echo. In the remaining patient, early device embolization was reported, with no sequelae. Overall, intra-procedural events were reported in 5 (3.3%) patients. During a median follow-up of 16 months (25th and 75th percentile, 10–25), 5 patients died of any cause. The annual rate of all-cause stroke was 2.2% (95% CI, 0.7–5.1), the rate of transient ischemic attack was 1.3% (95% CI, 0.3–3.8), and that of major bleeding 0.4% (95% CI, 0.01–2.4).

**Conclusions** LAAO for stroke prevention was safely and effectively achieved by implantation of the WATCHMAN device in patients with non-valvular AF. Moreover, regardless of the risk profile of the population, we observed low rates of death and thromboembolic and bleeding events over a median follow-up of 16 months. These findings were obtained in an unselected group of consecutive patients who were variably eligible for chronic OAC therapy.

**Keywords** Stroke · Left atrial appendage · Atrial fibrillation

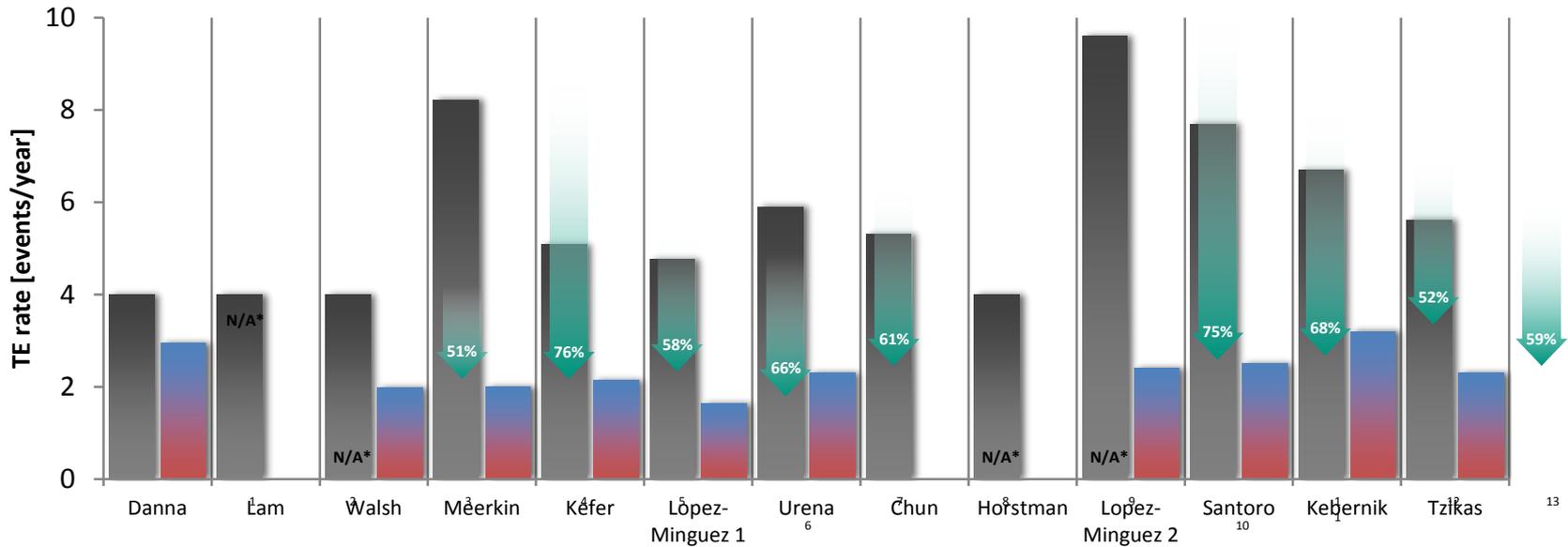
# Results on procedural success and safety of LAA occlusion with AMPLATZER™ LAAO devices

(≥ 100 patients)

Reported by	Nietlispach <sup>1</sup>	Park <sup>2</sup> (Multi)	Berti <sup>3</sup> (Italian)	Walsh <sup>4</sup> (Multiple)	Santoro <sup>5</sup> (Italy)	Tzikas <sup>6</sup> (Multi)	Lopez-Minguez <sup>7</sup> (Spain)	Meerkin <sup>8</sup> (Israel)
Enrollment period	2008	12/2008 – 2/2009	1/2009 – 4/2013	8/2009 – 9/2011	1/2009 – 12/2012	12/2008 – 11/2013	3/2009 – 2013	NR
CHADS <sub>2</sub> CHA <sub>2</sub> DS <sub>2</sub> -VASc	NR 3.7	-	NR 4.4	2.6 -	NR 4 (median)	2.8 4.5	3 (median) 4 (median)	3.2 -
Patients enrolled	120	143	121	204	134	1047	167	100
LAA occlusion attempted	120	137	121	204	133	1047	167	100
Successful device implantation	117 (97.5%)	132 (96.4%)	117 (96.7%)	197 (96.6%)	128 (95.5%)	1019	158 (94.6%)	100 (100%)
Major peri-procedural complications	7 (5.8%)	10 (7.3%)	4 (3.3%)	6 (2.9%)	4 (3.0%)	52 (4.97%)	9 (5.4%)	1 (1.0%)
▪ Stroke	1	3	1	0	0	9	0	0
▪ TIA	2	0	0	0	1	0	2	0
▪ MI / coronary air embolism	0	0	0	0	0	1	0	0
▪ Device embolization	2	2	0	3	0	8	1	0
▪ Major cardiac tamponade/effusion	2	5	3	3	3	13	2	1
	0	0	0	0	0	13	0	0
	0	0	0	0	0	8	4	0

**All studies include learning curve – increased success rates and reduced complication rates with increasing operator experience.**

# Expected and observed stroke rates in patients implanted with the AMPLATZER™ LAAO devices



<b>Patients</b>	34	20	204	30	75	35	52	40	20	158	128	89	1001
<b>Patient years</b>	34	21	101	50	75	62	87	NR	23	290	238	93	1349
<b>Strokes/TA</b>	1	0	2	1	2	1	2	0	0	7	5	3	31
<b>TE rate reduction [%]</b>	N/A*	N/A*	51	76	58	66	61	N/A*	N/A*	75	68	52	59

Expected stroke rates are based on the patients' CHA<sub>2</sub>DS<sub>2</sub>-VASc score for the results reported by Danna et al., Kefer et al., Chun et al., Horstmann et al., Santoro et al., Kebernik et al.

and Tzikas et al. and on the CHADS<sub>2</sub> score for the remaining studies. \*TE rate reduction (observed vs. expected) shown for studies with ≥ 50 patients-years only.

1. Danna et al. 2. Lam et al. 3. Walsh et al. 4. Meerkin et al. 5. Kefer et al. 6. López-Minguez et al. 7. Urena et al. 8. Chun et al. 9. Horstmann et al. 10. López-Minguez et al. 11. Santoro et al. 12. Kebernik et al. 13. Tzikas et al. (full references in Appendix 1).

# Left atrial appendage occlusion with the AMPLATZER Amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study

Ulf Landmesser<sup>1\*</sup>, MD; Boris Schmidt<sup>2</sup>, MD; Jens Erik Nielsen-Kudsk<sup>3</sup>, MD, DMSc; Simon Cheung Chi Lam<sup>4</sup>, MD; Jai-Wun Park<sup>5</sup>, MD; Giuseppe Tarantini<sup>6</sup>, MD; Ignacio Cruz-Gonzalez<sup>7</sup>, MD, PhD; Volker Geist<sup>8</sup>, MD; Paolo Della Bella<sup>9</sup>, MD; Antonio Colombo<sup>9</sup>, MD; Tobias Zeus<sup>10</sup>, MD; Heyder Omran<sup>11</sup>, MD; Christopher Piorkowski<sup>12</sup>, MD; Juha Lund<sup>13</sup>, MD; Claudio Tondo<sup>14</sup>, MD, PhD; David Hildick-Smith<sup>15</sup>, MD; on behalf of the Amulet Observational Study Investigators

1. Department of Cardiology, Charité Universitätsmedizin Berlin (CBF); Berlin Institute of Health (BIH); German Center of Cardiovascular Research (DZHK), Berlin, Germany; 2. Cardioangiologisches Centrum Bethanien, Agaplesion Markus-Krankenhaus, Frankfurt, Germany; 3. Aarhus University Hospital, Skejby, Aarhus, Denmark; 4. The University of Hong Kong (Queen Mary Hospital), Hong Kong, China; 5. Klinikum Coburg, Coburg, Germany; 6. Department of Cardiac, Thoracic and Vascular Sciences, University of Padua, Padua, Italy; 7. Hospital Universitario de Salamanca, Salamanca, Spain; 8. Segeberger Kliniken, Bad Segeberg, Germany; 9. Ospedale San Raffaele, Milan, Italy; 10. Universitätsklinikum Düsseldorf, Düsseldorf, Germany; 11. St. Marien-Hospital-Bonn, Bonn Venusberg, Germany; 12. Herzzentrum Dresden GmbH Universitätsklinik, Dresden, Germany; 13. Turku University Hospital, Turku, Finland; 14. Centro Cardiologico Monzino, Milan, Italy; 15. Sussex Cardiac Centre, Brighton and Sussex University Hospitals, Brighton, United Kingdom

# Study Design and Flowchart

## Design

- DESIGN:**

Prospective, multicenter, international observational study of the AMPLATZER™ Amulet™ LAA occluder.

- OBJECTIVES:**

- Assess acute serious adverse events (0 - 7 days post procedure)
- Assess late serious adverse events (> 7 days post-procedure through 2 years)
- Report ischemic stroke, systemic embolism and cardiovascular death (through 2 years)
- Report bleeding events (through 2 years)

- PRINCIPAL INVESTIGATOR**

David Hildick-Smith, Brighton, UK

1073 patients enrolled between Jun 2015 and Sept 2016 in 64 clinical sites in Europe, Middle East, Asia, Australia, South America

13 patients  
Device not implanted\*

1060 patients with AMPLATZER Amulet LAA Occluder implanted

Not completed 1<sup>st</sup> F/U @ database lock\*\* (N=349)

1-3 Month Follow Up Completed  
(N = 711)

* Device Not Implanted	N
Evidence of intracardiac thrombus in LA	7
Anatomical/Sizing Considerations	6

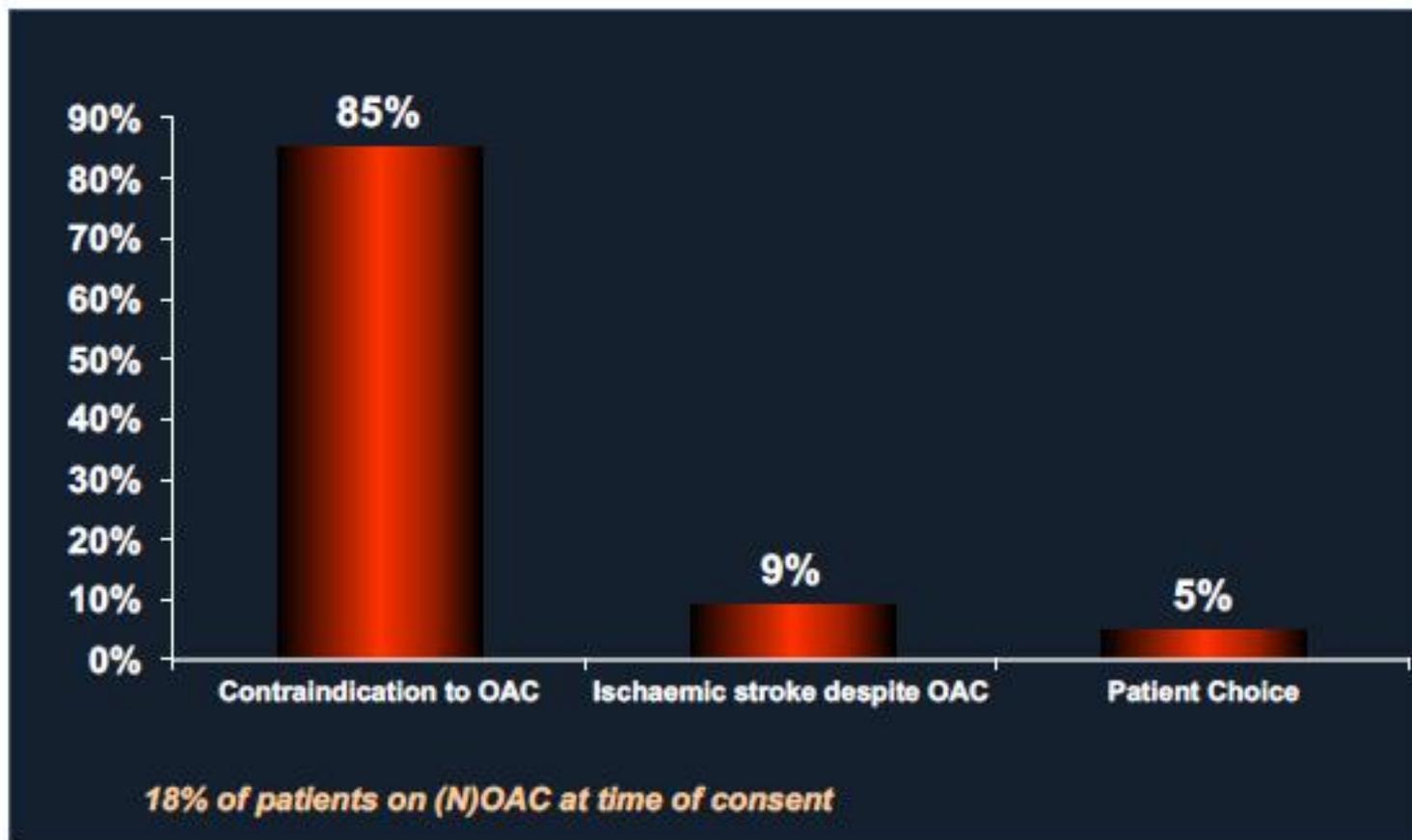
\*\* Database lock: October 3, 2016

# Results: Patient Population

	Mean $\pm$ SD or % n=1071*
Age (years)	75 $\pm$ 8
Gender - Female	35.6%
Prior Stroke	27.1%
Prior TIA	10.6%
Heart Failure	17.4%
Diabetes	31.4%
Hypertension	84.2%
Prior History of Major Bleeding	72.5%
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score $\geq$ 4	65%
HAS-BLED $\geq$ 3	58%

\*Baseline data unavailable in 2 patients

# Results: Indication for Procedure



# Major Adverse Events

Device/Procedure Related MAE	No.	%
Death	3	0.3%
<i>Related to Cardiac Perforation</i>	1	0.1%
<i>Related to Myocardial Infarction</i>	1	0.1%
<i>Related to Cardiorespiratory Arrest</i>	1	0.1%
Stroke	3	0.3%
Pericardial Effusion	5	0.5%
<i>Resulted in Pericardiocentesis</i>	4	0.4%
<i>Resulted in Surgical Intervention</i>	1	0.1%
Embolization	1	0.1%
Bleeding	10	0.9%
Other	7	0.7%
<b>TOTAL</b>	<b>29</b>	<b>2.7%</b>

# Antiplatelet and Anticoagulant therapy

## (1-3 months F/U)

	Baseline N = 1073	Discharge N = 1058	1-3 Month F/U N = 719
None	40.6%	14.7%	6.5%
Single Antiplatelet	20.5%	23.8%	31.3%
Dual Antiplatelet	14.4%	41.8%	45.6%
(N)OAC only	15.8%	7.3%	4.7%
(N)OAC plus Single Antiplatelet	1.5%	1.9%	1.3%
Triple Therapy	0.7%	2.2%	2.4%

# Comparison to Other Studies

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

# An updated systematic review and meta-analysis of early outcomes after left atrial appendage occlusion

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Varun Miryala MD<sup>4</sup> | Jae Kim MD<sup>3</sup> | Harsha Moole MD<sup>5</sup> |

Abhishek C. Sawant MD, MPH<sup>6</sup>  | Michael Morris MD<sup>2</sup> | Ashish Pershad MD<sup>2</sup>

**Background:** Left atrial appendage occlusion (LAAO) is a promising intervention for stroke prevention in patients with non-valvular atrial fibrillation (NVAF). Early outcomes following LAAO have been published in many studies with variable results.

**Objective:** This updated meta-analysis aims to provide a summary of the early outcomes of LAAO.

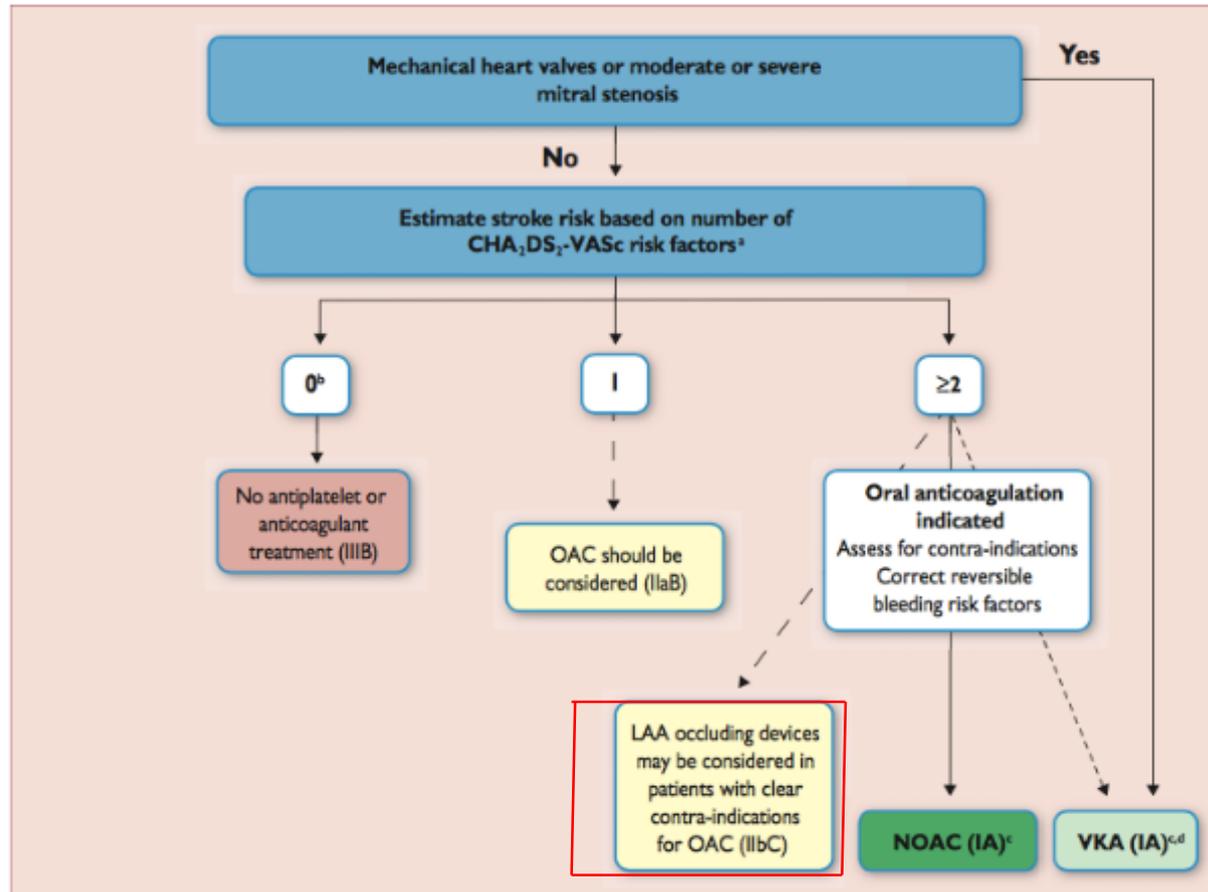
**Methods:** Medline/Pubmed, Ovid Journals, Clinical trials, Abstract meetings, Cochrane databases were searched from January 1st, 1999 to November 30th, 2016.

**Results:** This meta-analysis included 49 studies involving 12 415 patients. The median age was 73.5 years (IQR 72-75 years) and 43% were males. Hypertension and diabetes were present in 36% and 15% of the population, respectively. There was a prior history of stroke and congestive heart failure in 14% and 18% of the population, respectively. The median CHADS<sub>2</sub> score was 2.9 (IQR 2.6-3.3) and the median HASBLED score was 3.3 (IQR 3-4). LAAO implantation was successful in 96.3% of patients (95.40-97.08,  $I^2 = 76.1\%$ ). The pooled proportion of all-cause mortality was 0.28% (0.19-0.38,  $I^2 = 0\%$ ). The pooled proportion of all-cause stroke was 0.31% (0.22-0.42,  $I^2 = 9.4\%$ ), major bleeding requiring transfusion was 1.71% (1.13-2.41,  $I^2 = 73.2\%$ ), and pericardial effusion was 3.25% (2.46-4.14,  $I^2 = 79\%$ ). Sub analysis of randomized clinical trials comparing LAAO devices to warfarin showed lower mortality ( $P = 0.03$ ) with similar bleeding risk ( $P = 0.20$ ) with LAAO.

**Conclusions:** This meta-analysis concludes that LAAO occlusion is a safe and effective stroke prevention strategy in patients with NVAF.

## 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

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



Oral anticoagulation therapy to prevent thromboembolism is recommended for all male AF patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 2 or more.

I

A

Oral anticoagulation therapy to prevent thromboembolism is recommended in all female AF patients with a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 3 or more.

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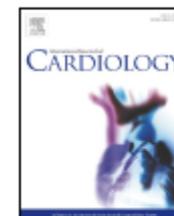
## **ANMCO/AIAC/SICI-GISE/SIC/SICCH Consensus Document: percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation patients: indications, patient selection, staff skills, organisation, and training**

Gavino Casu (Coordinator)<sup>1\*</sup>, Michele Massimo Gulizia, FACC, FESC (Coordinator)<sup>2</sup>, Giulio Molon<sup>3</sup>, Patrizio Mazzone<sup>4</sup>, Andrea Audo<sup>5</sup>, Giancarlo Casolo, FACC, FESC<sup>6</sup>, Emilio Di Lorenzo<sup>7</sup>, Michele Portoghese<sup>8</sup>, Christian Pristipino<sup>9</sup>, Renato Pietro Ricci<sup>10</sup>, Sakis Themistoclakis<sup>11</sup>, Luigi Padeletti<sup>12</sup>, Claudio Tondo<sup>13</sup>, Sergio Berti<sup>14</sup>, Jacopo Andrea Oreglia<sup>15</sup>, Gino Gerosa<sup>16</sup>, Marco Zanobini<sup>17</sup>, Gian Paolo Ussia<sup>18</sup>, Giuseppe Musumeci<sup>19</sup>, Francesco Romeo<sup>20</sup>, and Roberto Di Bartolomeo<sup>21</sup>

According to the current indications for percutaneous LAAO, which reflect the ESC guidelines,<sup>17</sup> the procedure is indicated (recommendation class IIb, level of evidence B) in patients with non-valvular AF with high-thromboembolic risk (CHA<sub>2</sub>DS<sub>2</sub>-VASc score  $\geq 2$ ) with long-term contraindication for OAT (e.g. history of intracranial bleeding, life-threatening bleeding, coagulation diseases).

The recent EHRA/EAPCI<sup>44</sup> consensus suggests that the spectrum of patients who could benefit from this technique should be extended (Table 4). Moreover, this therapy could also be considered in the following clinical situations:

- patients with non-valvular AF with high-thromboembolic risk and high-haemorrhagic risk (HAS-BLED  $\geq 3$ );
- patients requiring triple antithrombotic therapy indefinitely;
- patients with tumours with increased risk of haemorrhage, underestimated by the HAS-BLED score;
- patients in whom OAT is ineffective in providing protection against cerebral ischaemic events probably correlated to thromboembolisms originating from the LAA;
- patients with kidney failure or undergoing dialysis, bearing in mind that all NOACs are contraindicated with creatinine clearance  $< 15$  mL/min and that in these patients warfarin could increase tissue calcification and the degree of atherosclerosis;
- patients with major bleeding of the urogenital or gastrointestinal system, or any other districts, such as the ocular area;
- frail patients (the very old, dementia, neurodegenerative diseases, malnutrition, etc.);
- patients with difficulty in managing oral therapies (e.g. mental illnesses, vision impairment); and
- patients who, after being suitably informed about the OAT/NOACs therapy, refuse it and demand a 'definitive' therapy. In this context, it should be underlined that the Watchman has had approval by the US regulatory authority as a valid alternative to warfarin in patients who refuse or prefer not to take OAT.



## Implant success and safety of left atrial appendage occlusion in end stage renal disease patients: Peri-procedural outcomes from an Italian dialysis population☆



Simonetta Genovesi <sup>a,b,\*</sup>, Giorgio Slaviero <sup>c</sup>, Luca Porcu <sup>d</sup>, Gavino Casu <sup>e</sup>, Silvio Bertoli <sup>f</sup>, Antonio Sagone <sup>g</sup>, Federico Pieruzzi <sup>a,b</sup>, Giovanni Rovaris <sup>h</sup>, Monique Buskermolen <sup>i</sup>, Paolo Danna <sup>j</sup>, Alberto Montoli <sup>k</sup>, Jacopo Oreglia <sup>l</sup>, Gina Contaldo <sup>a</sup>, Patrizio Mazzone <sup>m</sup>

### A B S T R A C T

**Aims:** To estimate the safety and the efficacy of the off label left atrial appendage (LAA) occlusion in chronic dialysis patients with atrial fibrillation (AF). In this preliminary paper, we report the design of the study and the data on peri-procedural complications.

**Methods:** This is a prospective cohort study. Primary endpoints are i) incidence of peri-procedural complications, ii) cumulative incidence of two-year thromboembolic events iii) cumulative incidence of two-year bleedings iiiii) mortality at two years. Adverse events and death within 30 days of the procedure were recorded.

**Results:** Fifty patients who underwent LAA occlusion between May 2014 and September 2017 were recruited. Both the mean age of the sample study and the dialysis duration were high [71.8 (9.6) years and 59.4 (78.2) months, respectively]. Most patients (84%) were hypertensive and 62% suffered a previous major bleeding. About half of them presented cardiovascular diseases. CHA<sub>2</sub>DS<sub>2</sub>VASCs and HASBLED scores were 4.0 (1.5) and 4.4 (0.9), respectively. Most patients (88%) showed atrial dilatation and 44% left ventricular hypertrophy; 32% had left ventricular ejection fraction <50%. Fifty five percent of patients had permanent AF and 32% paroxysmal AF. All devices were implanted successfully. No deaths or major adverse events were reported during a 30-day follow-up. Three episodes of peri-procedural access site bleeding were reported, requiring no transfusion.

**Conclusions:** Our preliminary data suggest the feasibility and safety of LAA occlusion in patients undergoing dialysis. Only the follow-up of these patients over time can provide evidence that LAA occlusion is effective in preventing of thromboembolic events in this very high-risk population.

# Follow-up: current rate of incomplete LAA closure

With increased operator experience, standardisation of interventional techniques, improvement of imaging and devices, the rate of incomplete closure has dropped significantly. Current opinion is that an acceptable leak is < 5mm (better if <3mm)

## Left atrial appendage occlusion with the AMPLATZER Amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study



Ulf Landmesser<sup>1\*</sup>, MD; Boris Schmidt<sup>2</sup>, MD; Jens Erik Nielsen-Kudsk<sup>3</sup>, MD, DMSc; Simon Cheung Chi Lam<sup>4</sup>, MD; Jai-Wun Park<sup>5</sup>, MD; Giuseppe Tarantini<sup>6</sup>, MD; Ignacio Cruz-Gonzalez<sup>7</sup>, MD, PhD; Volker Geist<sup>8</sup>, MD; Paolo Della Bella<sup>9</sup>, MD; Antonio Colombo<sup>9</sup>, MD; Tobias Zeus<sup>10</sup>, MD; Heyder Omran<sup>11</sup>, MD; Christopher Piorkowski<sup>12</sup>, MD; Juha Lund<sup>13</sup>, MD; Claudio Tondo<sup>14</sup>, MD, PhD; David Hildick-Smith<sup>15</sup>, MD; on behalf of the Amulet Observational Study Investigators

Leak  $\geq$  3 mm: 1,8 % TEE  
follow-up  
Eurointervention 2017

## 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

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Leak  $\geq$  5 mm: 0,2 % TEE  
follow-up  
Heart Rhythm 2017

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



Laurent Fauchier, MD,<sup>a</sup> Alexandre Cinaud, MD,<sup>a</sup> François Brigadeau, MD,<sup>b</sup> Antoine Lepillier, MD,<sup>c</sup> Bertrand Pierre, MD,<sup>a</sup> Selim Abbey, MD,<sup>d</sup> Marjaneh Fatemi, MD,<sup>e</sup> Frederic Franceschi, MD,<sup>f</sup> Paul Guedeney, MD,<sup>g</sup> Peggy Jacon, MD,<sup>h</sup> Olivier Pазiaud, MD,<sup>c</sup> Sandrine Venier, MD,<sup>h</sup> Jean Claude Deharo, MD,<sup>f</sup> Daniel Gras, MD,<sup>d</sup> Didier Klug, MD,<sup>b</sup> Jacques Mansourati, MD,<sup>e</sup> Gilles Montalescot, MD,<sup>g</sup> Olivier Piot, MD,<sup>c</sup> Pascal Defaye, MD<sup>h</sup>

**BACKGROUND** Transcatheter left atrial appendage (LAA) occlusion is an alternative strategy for stroke prevention in patients with atrial fibrillation (AF).

**OBJECTIVES** This study sought to determine the incidence, predictors, and prognosis of thrombus formation on devices in patients with AF who were treated with LAA closure.

**METHODS** The study retrospectively analyzed data from patients treated with 2 LAA closure devices seen in 8 centers in France from February 2012 to January 2017.

**RESULTS** A total of 469 consecutive patients with AF underwent LAA closure (272 Watchman devices [Atritech, Boston Scientific, Natick, Massachusetts] and 197 Amplatzer devices [St. Jude Medical, Minneapolis, Minnesota]). Mean follow-up was  $13 \pm 13$  months, during which 339 (72.3%) patients underwent LAA imaging at least once. There were 98 major adverse events (26 thrombi on devices, 19 ischemic strokes, 2 transient ischemic attacks, 18 major hemorrhages, 33 deaths) recorded in 89 patients. The incidence of device-related thrombus in patients with LAA imaging was 7.2% per year. Older age (hazard ratio [HR]: 1.07 per 1-year increase; 95% confidence interval [CI]: 1.01 to 1.14;  $p = 0.02$ ) and history of stroke (HR: 3.68; 95% CI: 1.17 to 11.62;  $p = 0.03$ ) were predictors of thrombus formation on the devices, whereas dual antiplatelet therapy (HR: 0.10; 95% CI: 0.01 to 0.76;  $p = 0.03$ ) and oral anticoagulation at discharge (HR: 0.26; 95% CI: 0.09 to 0.77;  $p = 0.02$ ) were protective factors. Thrombus on the device (HR: 4.39; 95% CI: 1.05 to 18.43;  $p = 0.04$ ) and vascular disease (HR: 5.03; 95% CI: 1.39 to 18.23;  $p = 0.01$ ) were independent predictors of ischemic strokes and transient ischemic attacks during follow-up.

**CONCLUSIONS** Thrombus formation on the device is not uncommon in patients with AF who are treated by LAA closure. Such events are strongly associated with a higher risk of ischemic stroke during follow-up. (Registry on Real-Life Experience With Left Atrial Appendage Occlusion [RELEXAO]; [NCT03279406](#)) (J Am Coll Cardiol 2018;71:1528-36)

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## Percutaneous left atrial appendage occlusion in patients with atrial fibrillation and left appendage thrombus: feasibility, safety and clinical efficacy



Giuseppe Tarantini<sup>1\*</sup>, MD, PhD; Gianpiero D'Amico<sup>1</sup>, MD; Azeem Latib<sup>2,3</sup>, MD; Matteo Montorfano<sup>3</sup>, MD; Patrizio Mazzone<sup>4</sup>, MD; Gaetano Fassini<sup>5</sup>, MD; Anna Maltagliati<sup>5</sup>, MD; Federico Ronco<sup>6</sup>, MD; Salvatore Sacca<sup>7</sup>, MD; Ignatio Cruz-Gonzalez<sup>8</sup>, MD, PhD; Reda Ibrahim<sup>9</sup>, MD; Xavier Freixa<sup>10</sup>, MD, PhD

### Abstract

**Aims:** The aim of this study was to investigate the feasibility, safety and efficacy of percutaneous closure for prevention of thromboembolic events in patients with atrial fibrillation (AF) and left atrial appendage (LAA) thrombus.

**Methods and results:** The study included consecutive patients with AF and LAA thrombus who underwent transcatheter occlusion in eight high-volume centres. Clinical and transoesophageal echocardiography (TEE) follow-up was carried out as per each centre's protocol. Twenty-eight patients were included. The location of the LAA thrombus was distal in 100% of cases. Technical and procedural success was achieved in all patients. A cerebral protection device was used in six cases. There were no periprocedural adverse events. Follow-up was complete in all patients (total 32 patient-years). No death or thromboembolic events were reported. There was one major bleeding during follow-up. Among the 23 patients undergoing TEE, device thrombosis was present in one patient. No significant peri-device leaks were observed.

**Conclusions:** In this multicentre study, percutaneous closure in selected patients with distal LAA thrombus appears to be feasible and safe, and is associated with high procedural success and a favourable outcome for the prevention of AF-related thromboembolism. Special implant techniques avoiding mechanical mobilisation of the thrombotic mass and the liberal use of cerebral embolic protection devices are recommended.

J Cardiovasc Electrophysiol. 2018 May 3. doi: 10.1111/jce.13626. [Epub ahead of print]

## Incidence of pericardial effusion after left atrial appendage closure: The impact of underlying heart rhythm. data from the EWOLUTION study.

Schmidt B<sup>1</sup>, Betts TR<sup>2</sup>, Sievert H<sup>3</sup>, Bergmann MW<sup>4</sup>, Kische S<sup>5</sup>, Pokushalov E<sup>6</sup>, Schmitz T<sup>7</sup>, Meincke F<sup>8</sup>, Mazzone P<sup>9</sup>, Stein KM<sup>10</sup>, Ince H<sup>11</sup>, Boersma LVA<sup>12</sup>.

### ⊕ Author information

#### Abstract

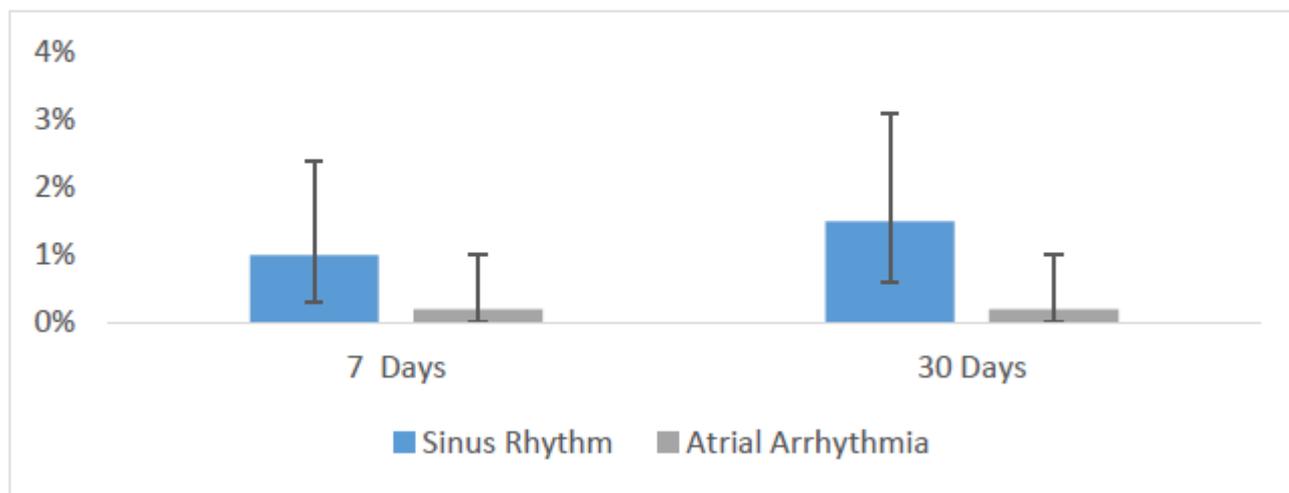
**INTRODUCTION:** Pericardial effusion/tamponade (PE/PT) is a rare but serious complication following left atrial appendage closure (LAAC). It may be speculated that LAA contraction during sinus rhythm (SR) exerts mechanical force on the device that eventually leads to PE. We sought to determine the incidence and predictors of PE following LAAC using Watchman with special emphasis on the underlying heart rhythm during implant.

**METHODS AND RESULTS:** From 47 centers in 13 European countries 1020 patients underwent LAAC and data on baseline rhythm were available from 1010 patients (mean age  $73 \pm 9$  years, 60% male, median CHA<sub>2</sub>DS<sub>2</sub>-VASc = 4). Data were collected via electronic case report forms. A Cox-proportional hazard model was calculated adjusting for multiple variables: age, gender, number of recaptures and device oversizing. During implant, 41% and 59% of patients were in SR and atrial fibrillation (AF), respectively. PE/PT rate was significantly lower in patients implanted during AF at day 30 post implant ( $n = 1$ ; 0.2% versus  $n = 6$ ; 1.5%;  $p = 0.02$ ). No PE requiring intervention occurred in the AF group compared to 5 events (1.2%) in the SR group ( $p = 0.01$ ). While univariate analysis identified SR and gender as predictors for PE/tamponade, multivariate analysis only showed a statistical trend for both variables.

**CONCLUSION:** The overall incidence of PE/PT was very low after LAAC using Watchman. Although SR was not identified as an independent predictor of PE/PT, all events requiring intervention occurred in patients with SR. It may be advisable to perform an extended echocardiographic follow-up in that patient population. This article is protected by copyright. All rights reserved.

# Incidence of Pericardial Effusion after Left Atrial Appendage Closure: The Impact of Underlying Heart Rhythm. Data from the EWOLUTION Study

Figure 1 – Incidence of Pericardial Effusion/Tamponade Over Time by Sinus Rhythm



# Future perspectives

# Dilemma

## POINT/COUNTERPOINT

### Percutaneous left atrial appendage closure is *not* ready for routine clinical use



John Mandrola, MD,<sup>\*</sup> Andrew Foy, MD,<sup>†</sup> Gerald Naccarelli, MD, FHRS<sup>†</sup>

*From the <sup>\*</sup>Baptist Health Louisville, Louisville, Kentucky, and <sup>†</sup>Penn State University College of Medicine, Hershey, Pennsylvania.*

#### LAA occlusion in anticoagulation-ineligible patients

There is an unmet need for prevention of stroke in patients unable to take anticoagulation therapy. These patients were excluded from the Watchman trials. Given the unconvincing evidence of Watchman relative to warfarin in PROTECT-AF, the inferiority of the device in PREVAIL, the systemic nature of stroke, and the bleeding-risk tradeoffs of antithrombotic therapy, we strongly believe a randomized trial comparing LAA occlusion to no anticoagulation is warranted *before* offering Watchman to anticoagulation-ineligible patients. Although implant safety has improved, this invasive procedure exposes patients to a finite risk of harm in trade for an unknown potential benefit in the future. Finally, any comparison of the efficacy and safety of Watchman vs NOACs should be based on prospective trials, not on extrapolation of PROTECT-AF and PREVAIL.

# Solution?

## The Assessment of the Watchman Device in Patients Unsuitable for Oral Anticoagulation (ASAP-TOO) trial



David R. Holmes, MD,<sup>a</sup> Vivek Y. Reddy, MD,<sup>b</sup> Maurice Buchbinder, MD,<sup>c</sup> Kenneth Stein, MD,<sup>d</sup> Myriah Elletson<sup>d</sup> Martin W. Bergmann, MD,<sup>e</sup> Boris Schmidt, MD,<sup>f</sup> and Jacqueline Saw, MD, FRCPC<sup>g</sup> *Rochester, Minneapolis, MN; New York, NY; Stanford, CA; Hamburg, Frankfurt, Germany; and British Columbia, Canada*

**Background** Oral anticoagulants (OACs) reduce stroke risks with nonvalvular atrial fibrillation (AF); however, they are underused because of absolute or relative contraindications due to real or perceived risk of bleeding. Although left atrial appendage closure is increasingly performed in OAC-ineligible patients, this has not been studied in a randomized controlled trial.

**Study objectives** The ASAP-TOO study is designed to establish the safety and effectiveness of the Watchman left atrial appendage closure device in patients with nonvalvular AF who are deemed ineligible for OAC. The primary effectiveness end point is the time to first occurrence of ischemic stroke or systemic embolism. The primary safety end point includes all-cause death, ischemic stroke, systemic embolism, or device- or procedural-related event requiring open cardiac surgery or major endovascular intervention.

**Study design** This is a multinational, multicenter prospective randomized trial. Patients meeting the inclusion criteria with CHA<sub>2</sub>DS<sub>2</sub>-VASc score  $\geq$  2 and who are deemed by 2 study physicians to be unsuitable for OAC will be randomized in a 2:1 allocation ratio to Watchman versus control. Control patients will be prescribed single antiplatelet therapy or no therapy at the discretion of the study physician. Up to 888 randomized subjects will be enrolled from up to 100 global investigational sites. Both device group and control patients will have follow-up visits at 3, 6, and 12 months and then every 6 months through 60 months.

**Summary** This trial will assess the safety and efficacy of Watchman in this challenging population of high-stroke risk AF patients. (Am Heart J 2017;189:68-74.)

# Non-inferiority comparison with NOACs

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*Am Heart J.* 2017 Jan;183:108-114. doi: 10.1016/j.ahj.2016.10.003. Epub 2016 Oct 11.

## Interventional left atrial appendage closure vs novel anticoagulation agents in patients with atrial fibrillation indicated for long-term anticoagulation (PRAGUE-17 study).

[Osmancik P<sup>1</sup>](#), [Tousek P<sup>2</sup>](#), [Herman D<sup>2</sup>](#), [Neuzil P<sup>3</sup>](#), [Hala P<sup>3</sup>](#), [Stasek J<sup>4</sup>](#), [Haman L<sup>4</sup>](#), [Kala P<sup>5</sup>](#), [Poloczek M<sup>5</sup>](#), [Branny M<sup>6</sup>](#), [Chovancik J<sup>6</sup>](#), [Cervinka P<sup>7</sup>](#), [Holy J<sup>7</sup>](#), [Vancura V<sup>8</sup>](#), [Rokyta R<sup>8</sup>](#), [Taborsky M<sup>9</sup>](#), [Kovarnik T<sup>10</sup>](#), [Zemanek D<sup>10</sup>](#), [Peichl P<sup>11</sup>](#), [Haskova S<sup>12</sup>](#), [Jarkovsky J<sup>12</sup>](#), [Widimsky P<sup>2</sup>](#), [PRAGUE-17 Investigators](#).

### Author information

#### Abstract

Atrial fibrillation (AF), with a prevalence of 1% to 2%, is the most common cardiac arrhythmia. Without antithrombotic treatment, the annual risk of a cardioembolic event is 5% to 6%. The source of a cardioembolic event is a thrombus, which is usually formed in the left atrial appendage (LAA). Prevention of cardioembolic events involves treatment with anticoagulant drugs: either vitamin K antagonists or, recently, novel oral anticoagulants (NOAC). The other (nonpharmacologic) option for the prevention of a cardioembolic event involves interventional occlusion of the LAA.

**OBJECTIVE:** To determine whether percutaneous LAA occlusion is noninferior to treatment with NOAC in AF patients indicated for long-term systemic anticoagulation.

**STUDY DESIGN:** The trial will be a prospective, multicenter, randomized noninferiority trial comparing 2 treatment strategies in moderate to high-risk AF patients (ie, patients with history of significant bleeding, or history of cardiovascular event(s), or a with CHA<sub>2</sub>DS<sub>2</sub>-VASc  $\geq 3$  and HAS-BLED score  $\geq 2$ ). Patients will be randomized into a percutaneous LAA occlusion (group A) or a NOAC treatment (group B) in a 1:1 ratio; the randomization was done using Web-based randomization software. A total of 396 study participants (198 patients in each group) will be enrolled in the study. The primary end point will be the occurrence of any of the following events within 24 months after randomization: stroke or transient ischemic attack (any type), systemic cardioembolic event, clinically significant bleeding, cardiovascular death, or a significant periprocedural or device-related complications.

**CONCLUSION:** The PRAGUE-17 trial will determine if LAA occlusion is noninferior to treatment with NOAC in moderate- to high-risk AF patients.

# Comparison between different devices

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*Catheter Cardiovasc Interv.* 2017 Mar 1;89(4):763-772. doi: 10.1002/ccd.26678. Epub 2016 Aug 27.

## Left atrial appendage closure: A single center experience and comparison of two contemporary devices.

[Figini F<sup>1,2</sup>](#), [Mazzone P<sup>1</sup>](#), [Regazzoli D<sup>1</sup>](#), [Porata G<sup>1</sup>](#), [Ruparelia N<sup>1,2,3</sup>](#), [Giannini F<sup>1,2</sup>](#), [Stella S<sup>1</sup>](#), [Ancona F<sup>1</sup>](#), [Agricola E<sup>1</sup>](#), [Sora N<sup>1</sup>](#), [Marzi A<sup>1</sup>](#), [Aurelio A<sup>1</sup>](#), [Trevisi N<sup>1</sup>](#), [Della Bella P<sup>1</sup>](#), [Colombo A<sup>1,2</sup>](#), [Montorfano M<sup>1</sup>](#).

### ⊕ Author information

#### Abstract

**OBJECTIVES:** To compare indications and clinical outcomes of two contemporary left atrial appendage (LAA) percutaneous closure systems in a "real-world" population.

**BACKGROUND:** Percutaneous LAA occlusion is an emerging therapeutic option for stroke prevention in atrial fibrillation. Some questions however remain unanswered, such as the applicability of results of randomized trials to current clinical practice. Moreover, currently available devices have never been directly compared.

**METHODS:** We retrospectively analyzed consecutive patients who underwent LAA closure at San Raffaele Hospital, Milan, Italy between 2009 and 2015. Clinical indications and device selection were left to operators' decision; routine clinical and transesophageal echocardiography (TEE) follow-up was performed.

**RESULTS:** One-hundred and sixty-five patients were included in the study, of which 99 were treated with the Amplatzer Cardiac Plug (ACP) and 66 with the Watchman system. During the follow-up period (median 15 months, interquartile range 6-26 months) five patients died. The incidence of ischemic events was low, with one patient suffering a transient ischemic attack and no episodes recorded of definitive strokes. Twenty-six leaks  $\geq 1$  mm were detected (23%); leaks were less common with the ACP and with periprocedural three-dimensional TEE evaluation, but were not found to correlate with clinical events. Clinical outcomes were comparable between the two devices.

**CONCLUSIONS:** Our data show excellent safety and efficacy of LAA closure, irrespectively of the device utilized, in a population at high ischemic and hemorrhagic risk. The use of ACP and 3D-TEE minimized the incidence of residual leaks; however, the clinical relevance of small peri-device flow warrants further investigation. © 2016 Wiley Periodicals, Inc.

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**KEYWORDS:** antithrombotic agents; atrial fibrillation; stroke

# Comparison between different devices



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## AMPLATZER™ Amulet™ LAA Occluder Trial (Amulet IDE)

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02879448

[Recruitment Status](#) ⓘ : Recruiting

[First Posted](#) ⓘ : August 25, 2016

[Last Update Posted](#) ⓘ : March 22, 2018

See [Contacts and Locations](#)

## Study Description

Go to

### Brief Summary:

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

# Comparison between different devices



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## COMITATO ETICO

Milano, 26/03/2018

Gent. mo Dott. Patrizio Mazzone  
OSR

E pc St. Jude Medical  
Dott. Valeria Prandoni, [valeria.prandoni@abbott.com](mailto:valeria.prandoni@abbott.com)

**Oggetto:** Presa d'atto relativa allo studio avente per titolo:  
"Studio randomizzato e controllato sull'occlusore dell'auricolare atriale sinistra Amplatzer Amulet".

**Codice protocollo:** CIP 10114 (AMULET IDE)  
**Eudract:** NA  
**Numero del registro dei pareri del CE:** 45/2018

## verificato che

detto protocollo sarà condotto in conformità ai principi etici che traggono la loro origine dalla Dichiarazione di Helsinki, nel rispetto della Good Clinical Practice e delle disposizioni normative applicabili

**esprime parere favorevole**

# Post procedural antithrombotic therapy

## EWOLUTION – OAT at Follow-Up

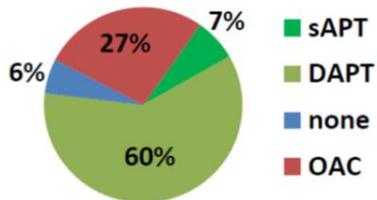
Pts with known medication: N = 997



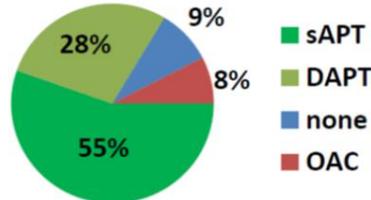
Pts without FU information: N = 52

Pts with first medication discontinuation info: N = 945

Post-implant



After first discontinuation



OAC drop within 3 mo  
DAPT drop within 6 mo

Watchman

## Antiplatelet and Anticoagulant therapy (1-3 months F/U)

	Baseline N = 1073	Discharge N = 1058	1-3 Month F/U N = 719
None	40.6%	14.7%	6.5%
Single Antiplatelet	20.5%	23.8%	31.3%
Dual Antiplatelet	14.4%	41.8%	45.6%
(N)OAC only	15.8%	7.3%	4.7%
(N)OAC plus Single Antiplatelet	1.5%	1.9%	1.3%
Triple Therapy	0.7%	2.2%	2.4%

Amplatzer



# Conclusions

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Left atrial appendage closure is:

- Safe: incidence of adverse events is low, and it is decreasing further with increased operator experience
- Efficacy: non inferior to OAC (warfarin) in terms of reduction of ischemic events and superior in terms of hemorrhagic events in the long term

# Conclusions

---

The growing number of studies and data available in literature suggests that indications can be extended to the following groups of patients :

- In patients at risk of stroke with contraindication to anticoagulant therapy
- In patients with ischemic events despite anticoagulant therapy
- In patients with a high hemorrhagic risk

# Conclusions

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- In patients with advanced renal failure/dialysis
- In patients who need dual antiplatelet therapy (PTCA)
- In patients who prefer to undergo the procedure
- In fragile patients
- In patients with a low compliance to OAC/NOACs

# Conclusions

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What we still need is data on...

- Comparison with NOACs
- Comparison between different devices
- Long-term follow-up in patients with contraindications to NOACs
- Optimal medical therapy after the procedure: Single antiplatelet therapy? DAPT? No therapy?

# Thank you for your attention!



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