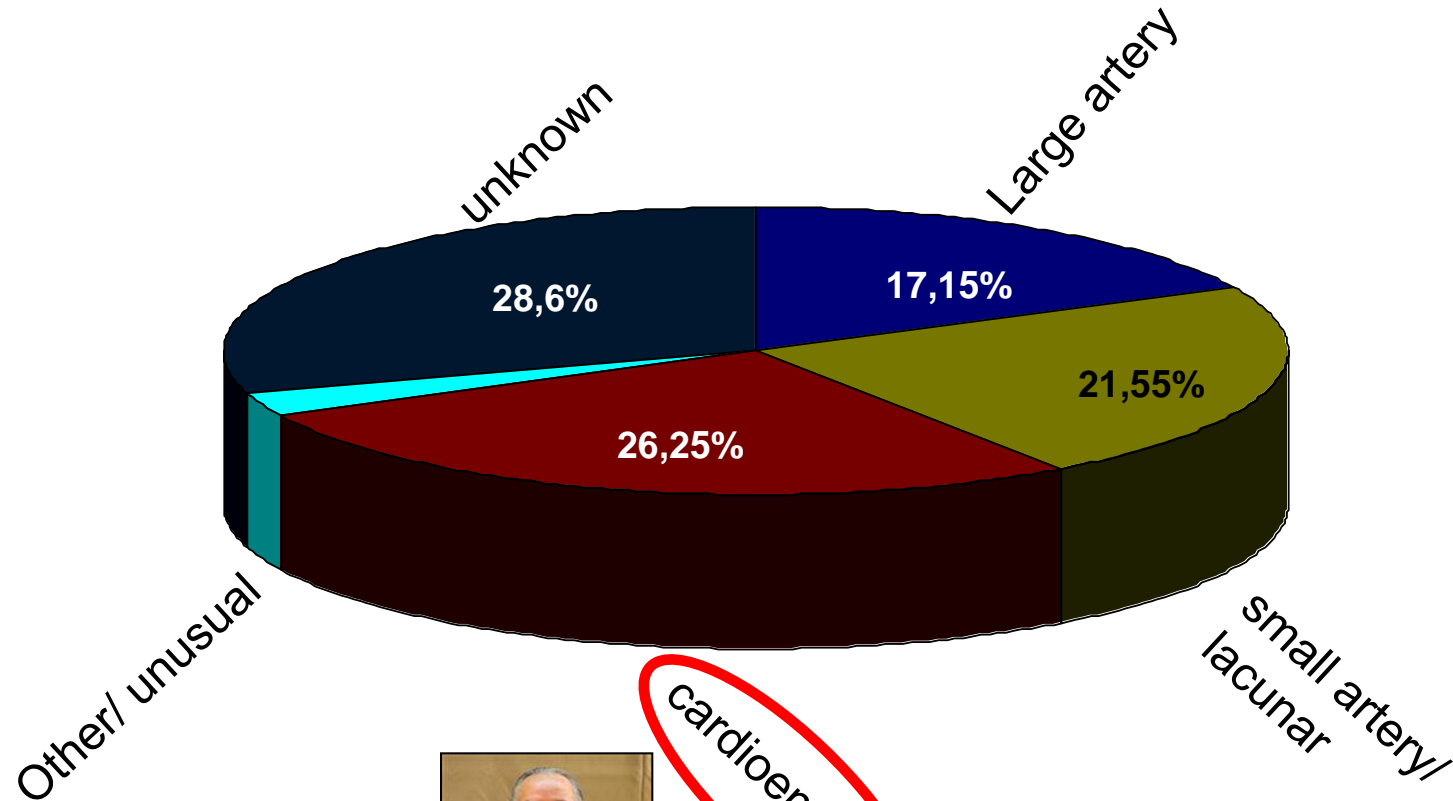


# **Left Atrial Appendage Closure - Alternative Therapy for Stroke Prevention in Atrial Fibrillation**

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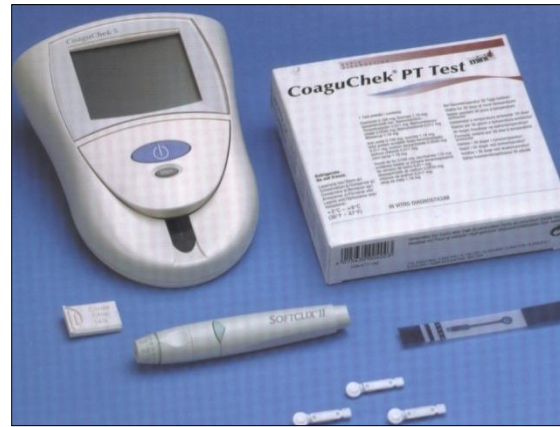


# Characteristics of stroke





# PT-INR control



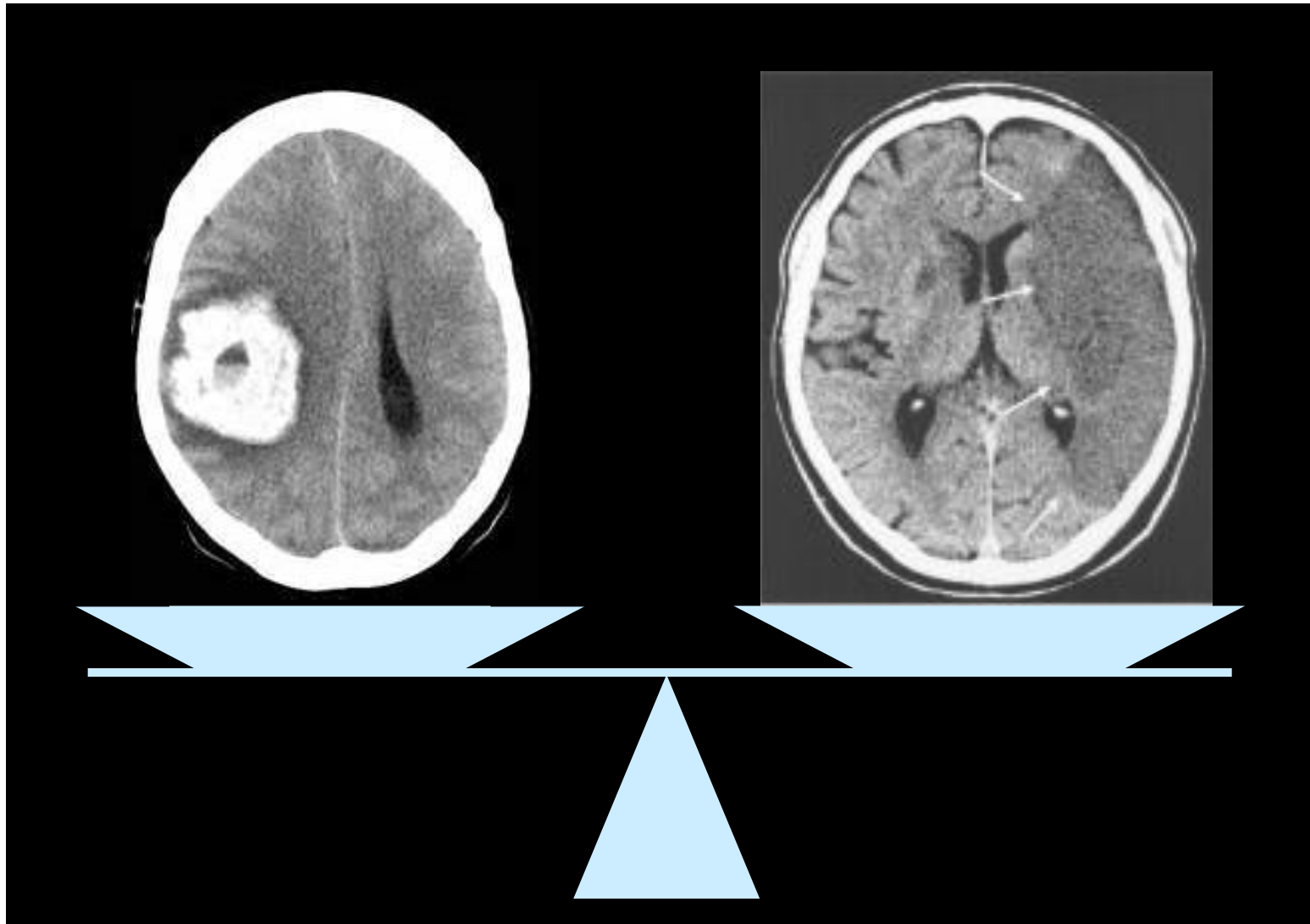
# Food limitation



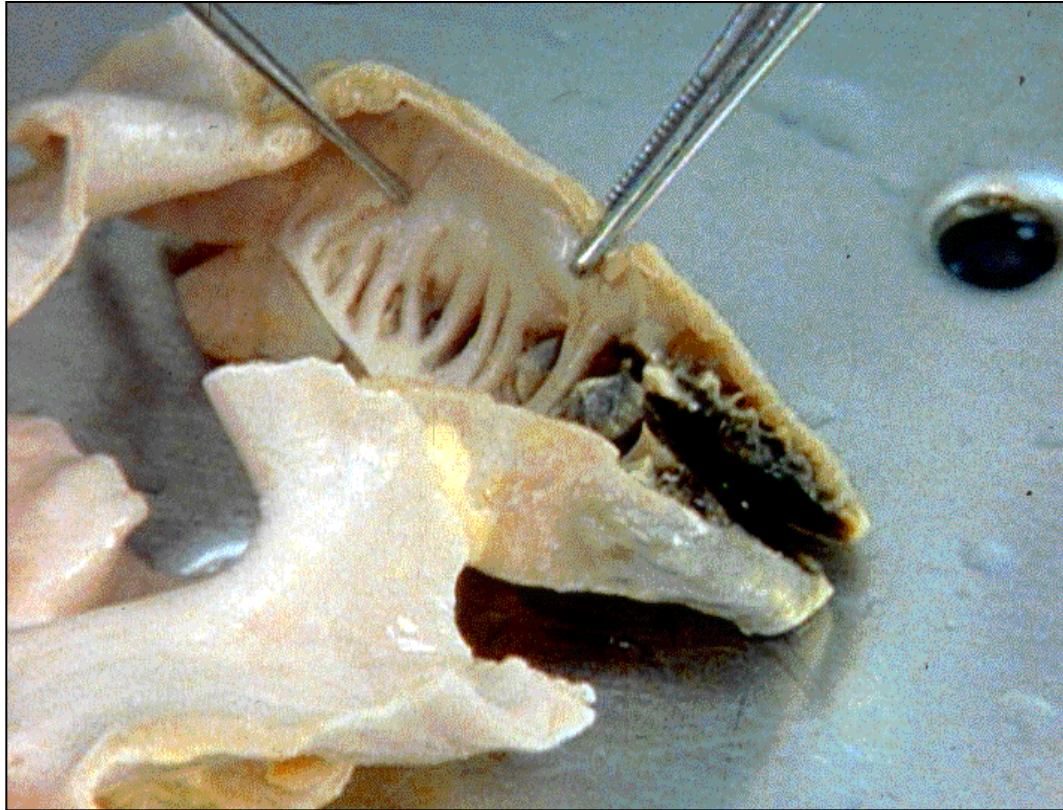
# Drug interaction



# Balance between RISK and BENEFIT...



# Surgical LAA excision/ occlusion



Go et al. JAMA 2001;285:1270-75

Almahameed et al. J Cardiovasc Electrophysiol. 2007;18:364-6

# LAA closure device in Europe

ACP Device



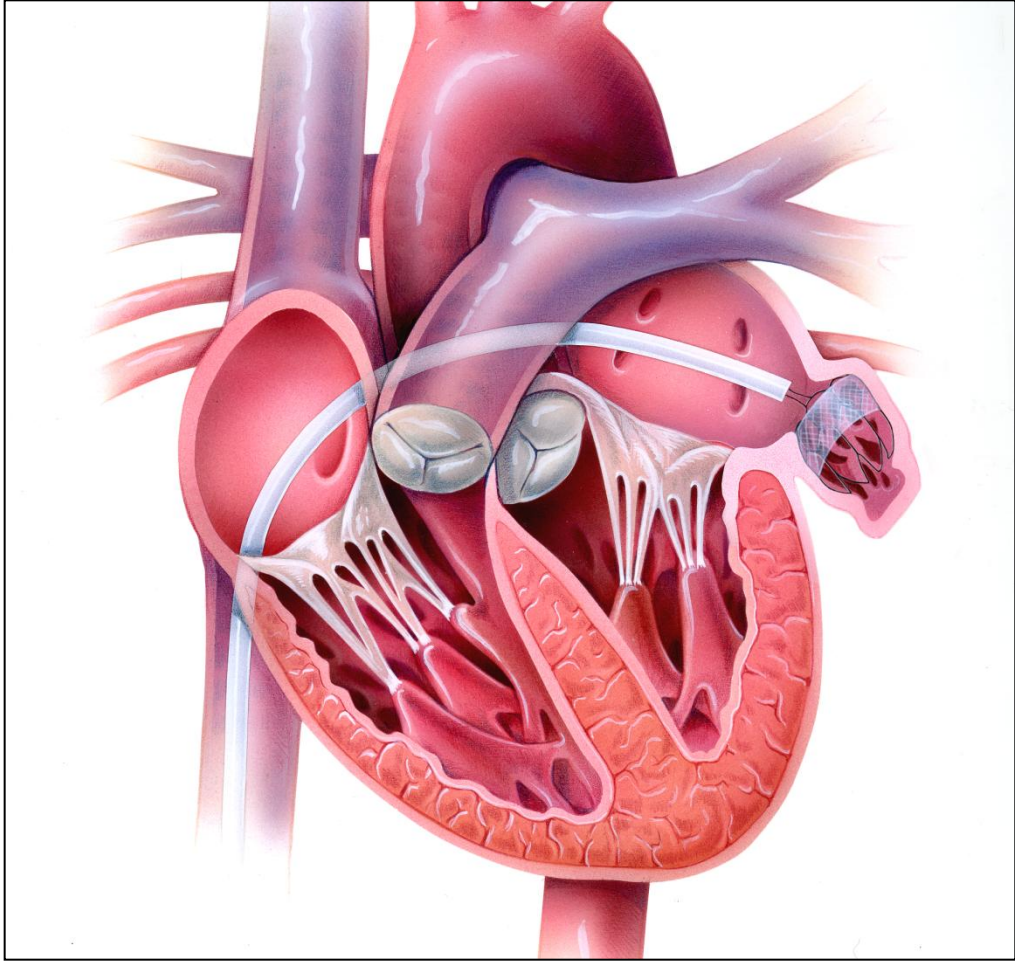
AMPLATZER® Cardiac Plug  
© AGA Medical Corporation

No randomized data

Watchman Device



Evidence based therapy

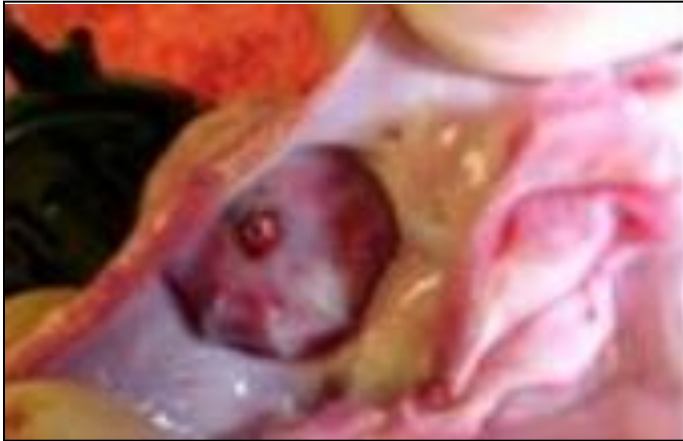






# Healing process

Canine Model: 30-day



Canine Model: 45-day



Human Pathology:  
9-month post-implant (non-device related)



# Watchman device evidence

STUDY	PATIENTS	SITES	COMMENTS
<b>Pilot</b> ✓	66	8 (4 US, 4 EU)	<ul style="list-style-type: none"> <li>318 patient years of follow-up</li> <li>30 patients with 5+ years of follow-up</li> <li>Enrollment complete, continue to follow patients on annual basis</li> </ul>
<b>PROTECT AF</b> ✓	800	59 (55 US, 4 EU)	<ul style="list-style-type: none"> <li>1,500 patient years of follow-up</li> <li>27 months average follow-up per patient</li> <li>Enrollment complete, continue to follow patients for 5 years</li> </ul>
<b>Continued Access Registry (CAP)</b> ✓	566	26 (24 US, 2 EU)	<ul style="list-style-type: none"> <li>Significantly improved safety results</li> <li>Enrollment complete, continue to follow patients for 5 years</li> </ul>
<b>ASAP</b> ✓	150	4 (4 EU)	<ul style="list-style-type: none"> <li>Treat patients contra-indicated for warfarin</li> <li>Last patient in Nov, 24th 2011</li> <li>Patients will be followed for 2 years</li> </ul>
<b>EVOLVE</b> ✓	69	3 (3 EU)	<ul style="list-style-type: none"> <li>Evaluate next generation WATCHMAN</li> <li>Enrollment is complete, will follow patients for 1 year</li> </ul>
<b>PREVAIL -ongoing-</b>	245	≤50	<ul style="list-style-type: none"> <li>Same endpoints as PROTECT AF</li> <li>Revised inclusion/exclusion criteria</li> <li>Initial enrollment November 2010</li> <li>Enrollment up to 400 randomized, anticipated enrollment completion March, 2012</li> </ul>
<b>Total</b>	1,896		

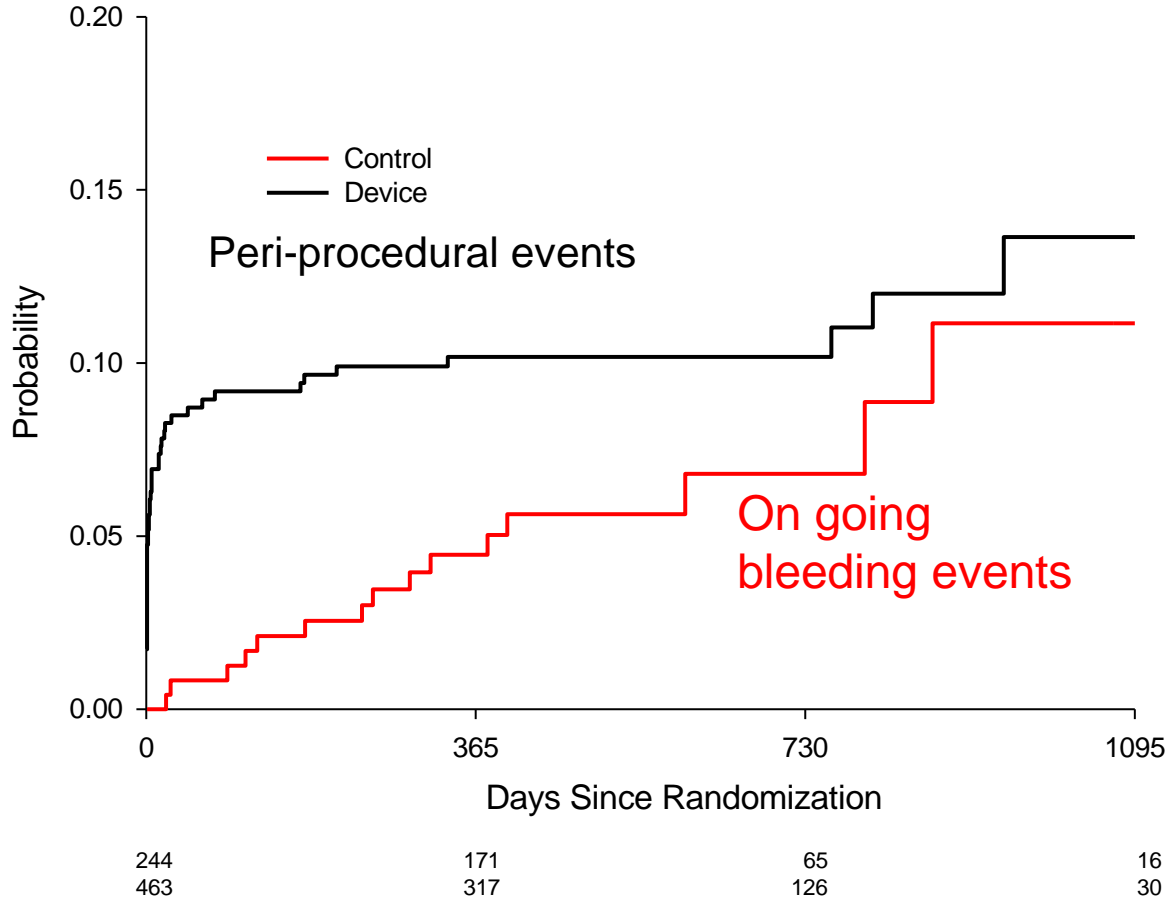
# PROTECT AF

Event	Watchman Group (n = 463)		Warfarin Group (n = 244)		Rate Ratio (Watchman/Warfarin) (95% CrI)	Posterior Probabilities	
	Events/ Patient-Years	Observed Rate (Events per 100 Patient-Years) (95% CrI)	Events/ Patient-Years	Observed Rate (Events per 100 Patient-Years) (95% CrI)		Non- inferiority	Superiority
Primary Efficacy Endpoint	39/1720.2	2.3 (1.7, 3.2)	34/900.8	3.8 (2.5, 4.9)	0.60 (0.41, 1.05)	>0.999	0.960
Stroke	26/1720.7	1.5 (1.0, 2.2)	20/900.9	2.2 (1.3, 3.1)	0.68 (0.42, 1.37)	0.999	0.825
Ischemic Stroke	24/1720.8	1.4 (0.9, 2.1)	10/904.2	1.1 (0.5, 1.7)	1.26 (0.72, 3.28)	0.780	0.147
Hemorrhagic Stroke	3/1774.2	0.2 (0.0, 0.4)	10/916.2	1.1 (0.5, 1.8)	0.15 (0.03, 0.49)	>0.999	0.999
Systemic Embolization	3/1773.6	0.2 (0.0, 0.4)	0/919.5	0.0	NA	-	-
Cardiovascular Death	17/1774.3	1.0 (0.6, 1.5)	22/919.4	2.4 (1.4, 3.4)	0.40 (0.23, 0.82)	>0.999	0.995

# PROTECT AF – Primary Safety Endpoint

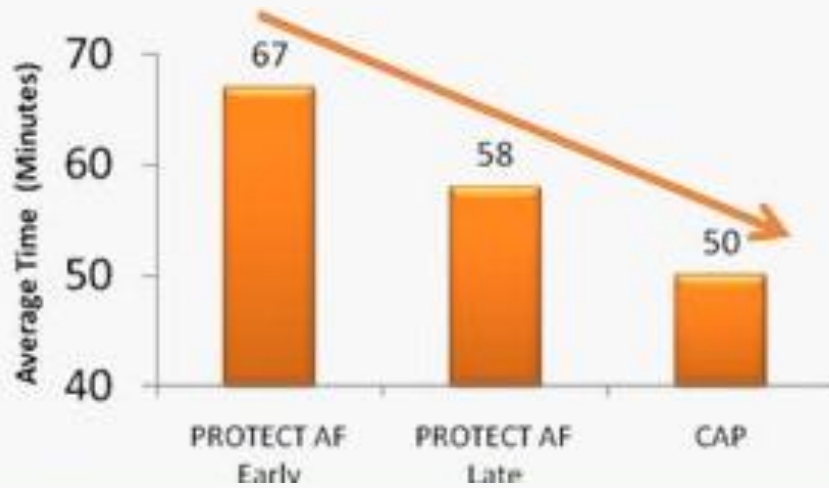
- Device embolization, major bleedings, pericardial effusion-

Primary Safety Endpoint

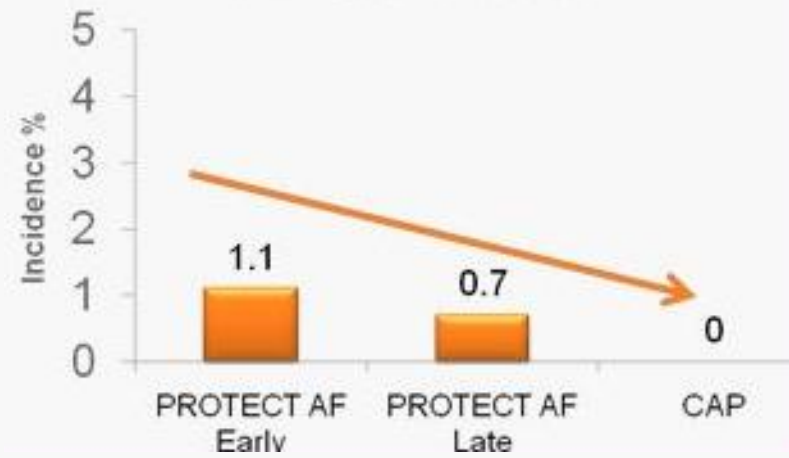


Event Description	WATCHMAN N (% of 463)	
	Pericardial Effusion	21
Ischemic Stroke	5	1.1%
Device Embolization	1	0.2%
Major Bleeding	5	1.1%
Other	2	0.4%
<b>Total</b>	<b>34</b>	<b>7.3%</b>

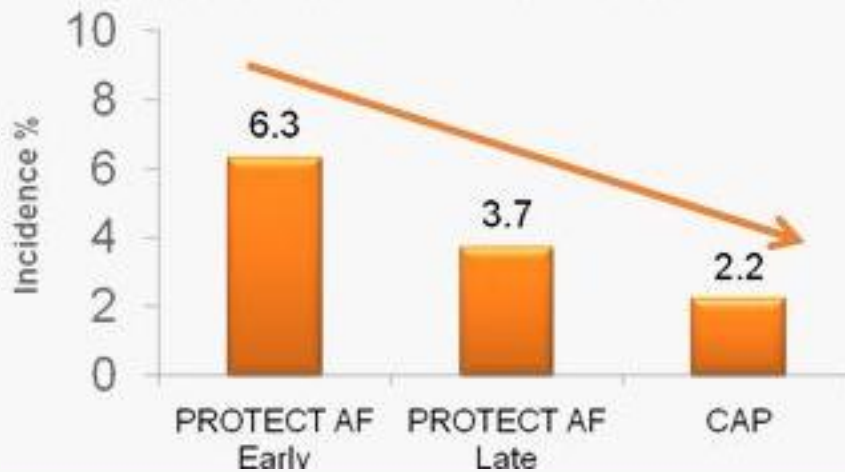
## Procedure time



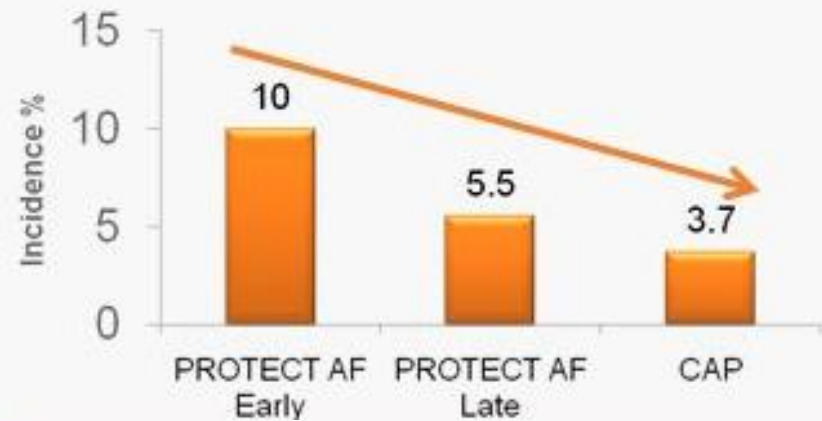
## Procedure related stroke



## Serious pericardial effusion\*

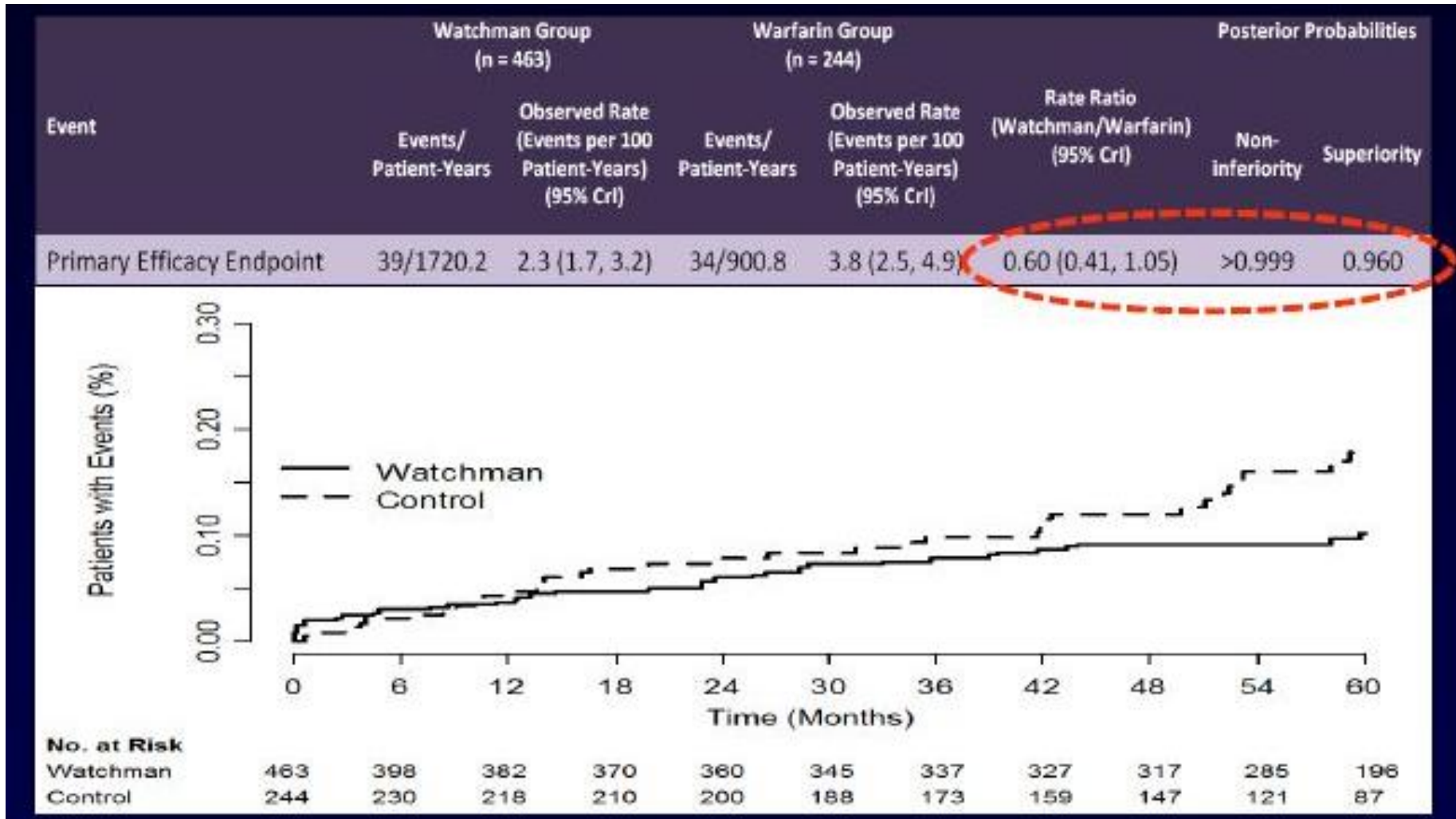


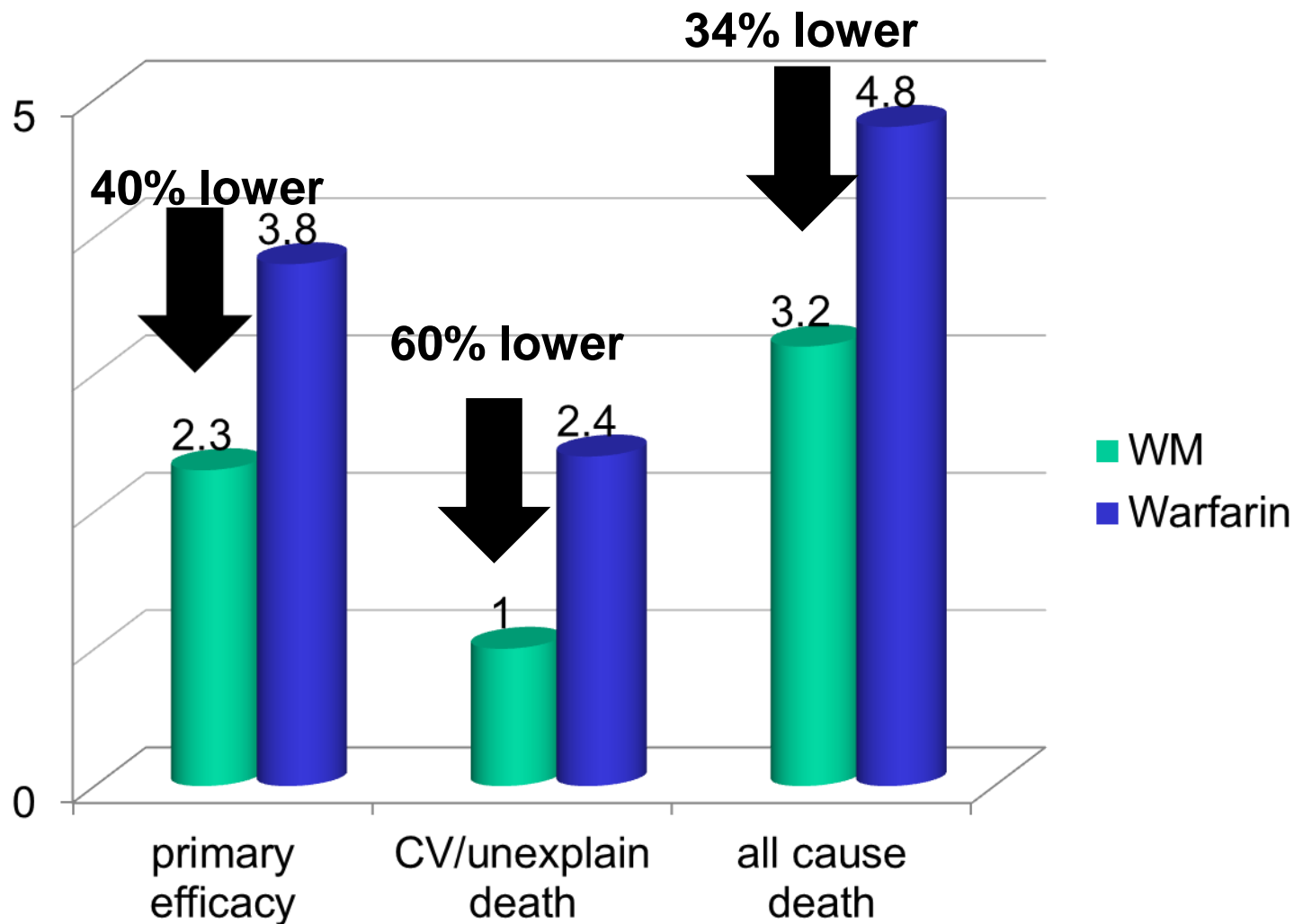
## Procedure related adverse event\*



\* : occurred within 7 days

# PROTECT AF 4-year superiority





# PROTECT AF 4-year superiority



# Watchman vs. Warfarin PROTECT AF + CAP

study	CHADS <sub>2</sub> (mean±SD)	Ischemic stroke	Hemorrhagic stroke
PROTECT AF+CAP	2.3±1.2	1.26/100pt-y	0.11/100pt-y
RE-LY (warfarin arm)	2.1±1.1	1.2%	0.38%
ROCKET AF (warfarin arm)	3.46±0.96	1.42/100pt-y	0.44/100pt-y
ARISTOTLE (warfarin arm)	2.1±1.1	1.05%	0.47%

## **Left Atrial Appendage Closure With the Watchman Device in Patients With a Contraindication for Oral Anticoagulation**

The ASAP Study (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology)

Vivek Y. Reddy, MD,\* Sven Möbius-Winkler, MD,† Marc A. Miller, MD,\* Petr Neuzil, MD, PhD,‡  
Gerhard Schuler, MD,† Jens Wiebe, MD,§ Peter Sick, MD,|| Horst Sievert, MD§

*New York, New York; Leipzig, Frankfurt, and Regensburg, Germany; and Prague, Czech Republic*

# DRUG

Dabigatran- twice daily dose  
compliance is required

NOAC effect is not reversible  
if bleeding develops

Short-term risk

Local solution

20% discontinue

After successful implant,  
87% can discontinue OAC

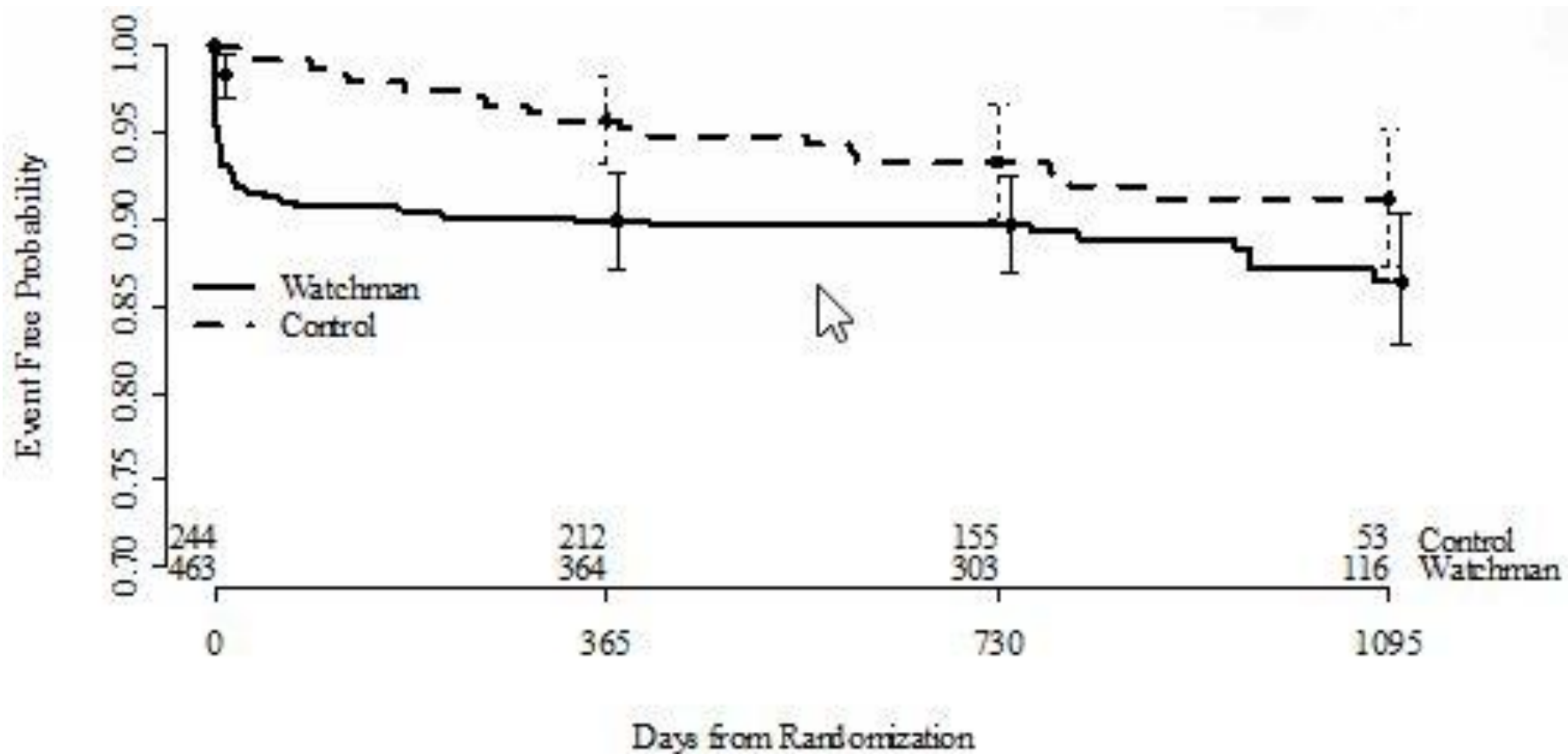
Systemic solution

Long-term risk

Risk of bleeding is limited  
in procedure/periprocedure

No on-going activity is needed  
to maintain benefit of LAA closure

# DEVICE



多謝♥