

# Left Atrial Appendage Closure 2014

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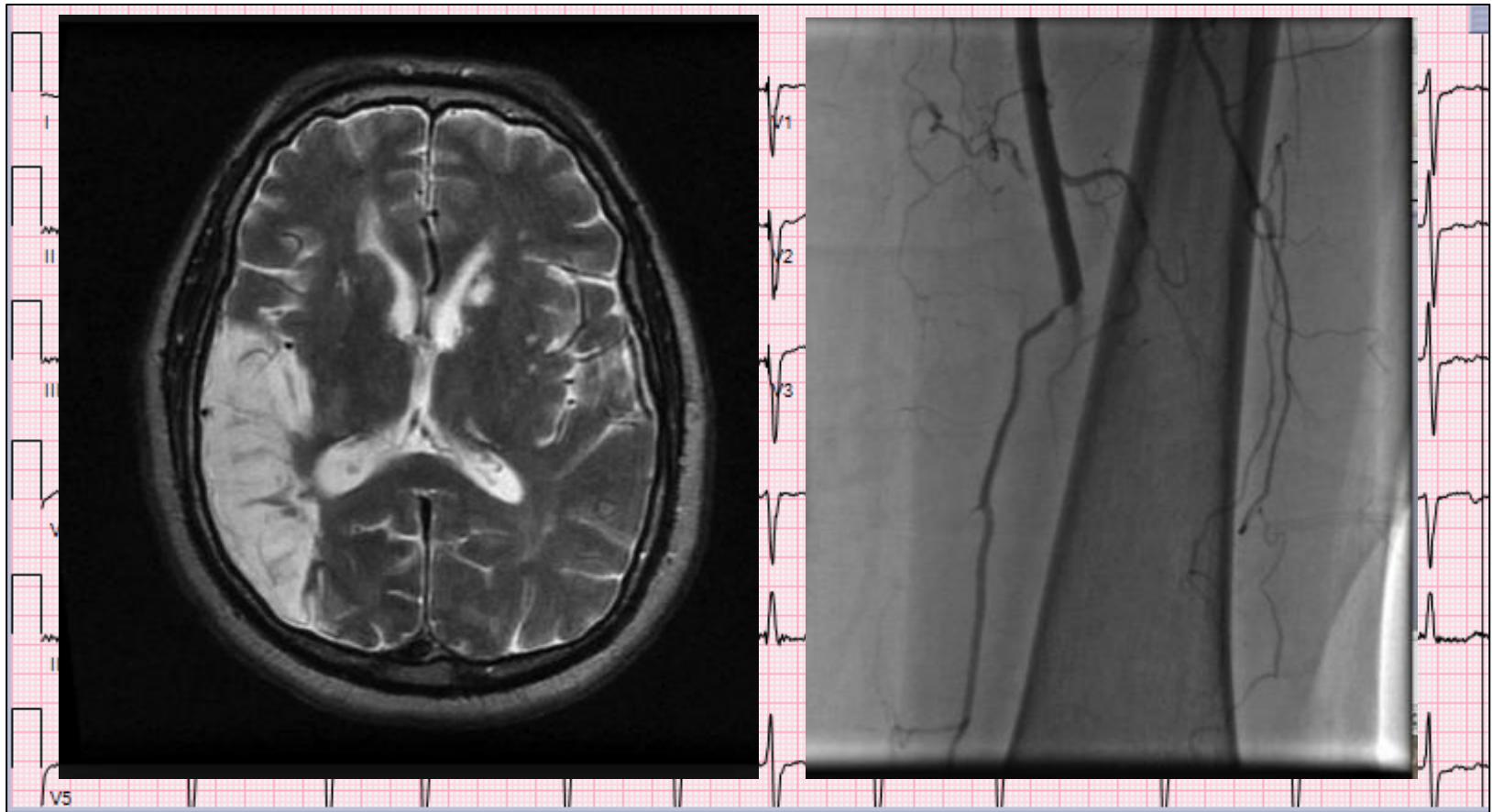
Division of Cardiology

University of Texas Health Sciences Center

San Antonio, Texas

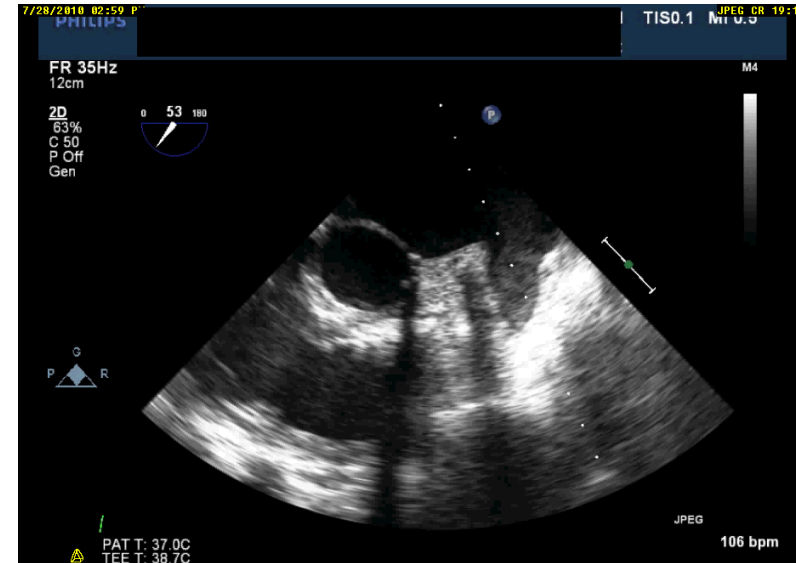
# Disclosures

- › Speakers Bureau for Edwards Lifesciences
- › Consultant for NAVIGATE CSI



# Atrial Fibrillation Epidemiology

- › 2010 Global Estimates
  - 20.9 million men
  - 12.6 million women
- › 2010 US Prevalence
  - ~2.7-6.1 million
    - Expected to grow to ~5.6-12 million (2050)
- › 23.5% of strokes 80-89 years
- › > 75,000 strokes/year due to AF



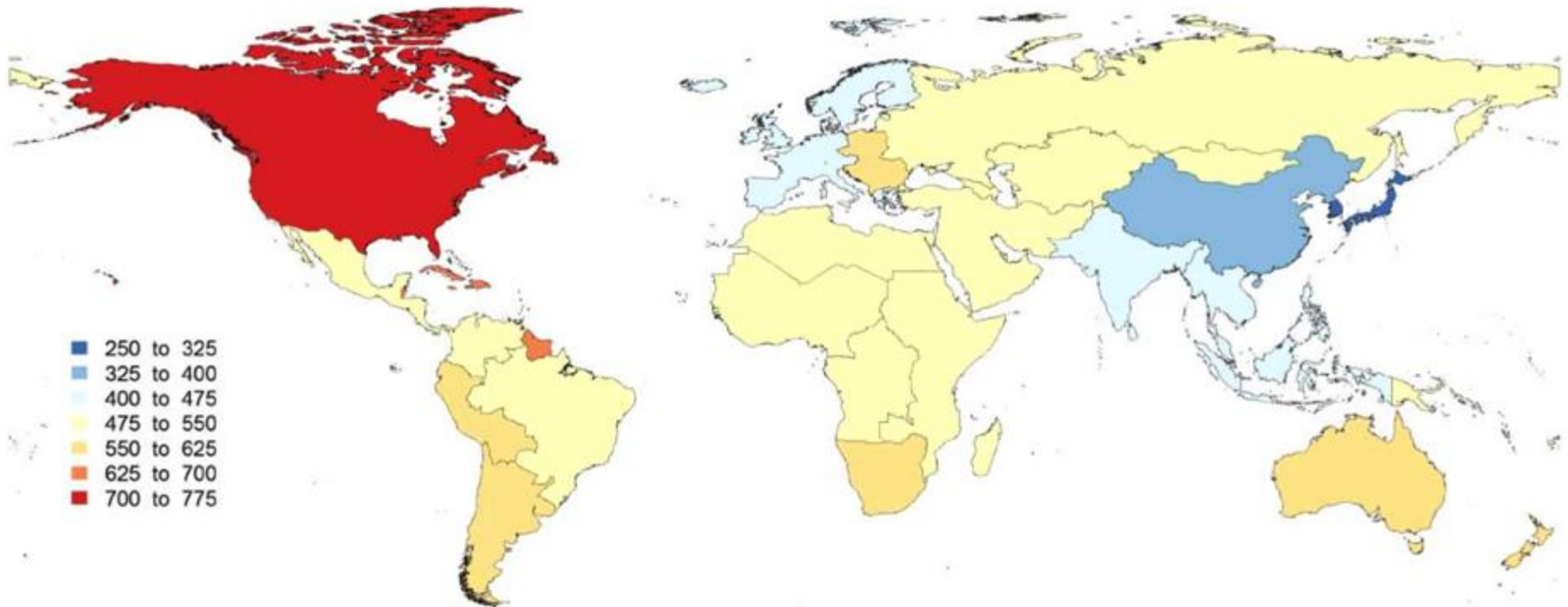
Go, A.S. Circulation 2014; 129:e29-e292.

Chugh S. et al. Circulation 2014;129:837-847.

Furie, KL et al. Stroke 2011;42:227-276.

# Atrial Fibrillation Global Impact

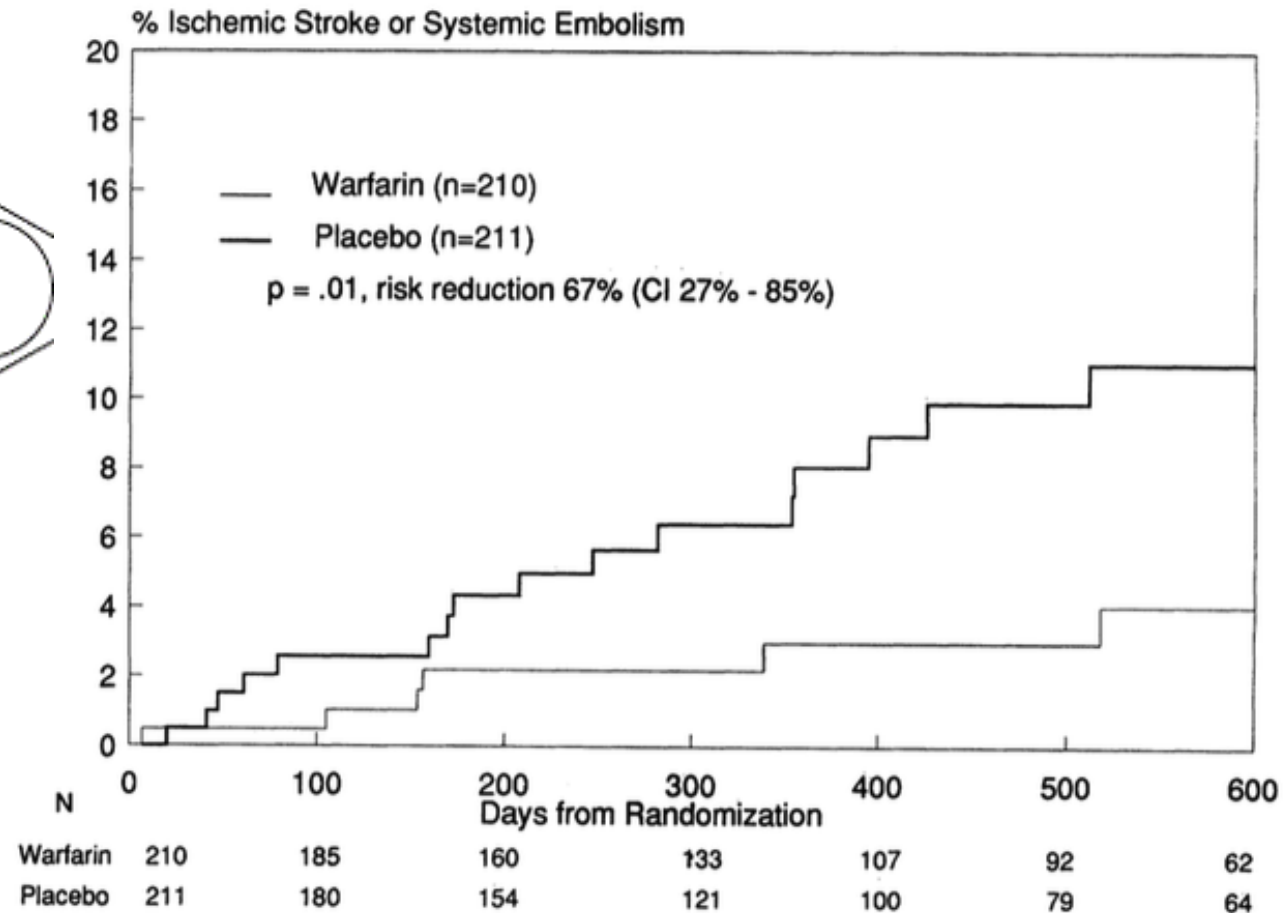
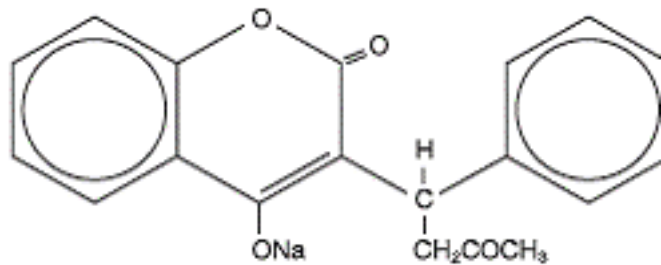
Prevalence of atrial fibrillation and flutter (per 100,000) by region, 2010



Chugh S. et al. Circulation 2014;129:837-847.

# VKA

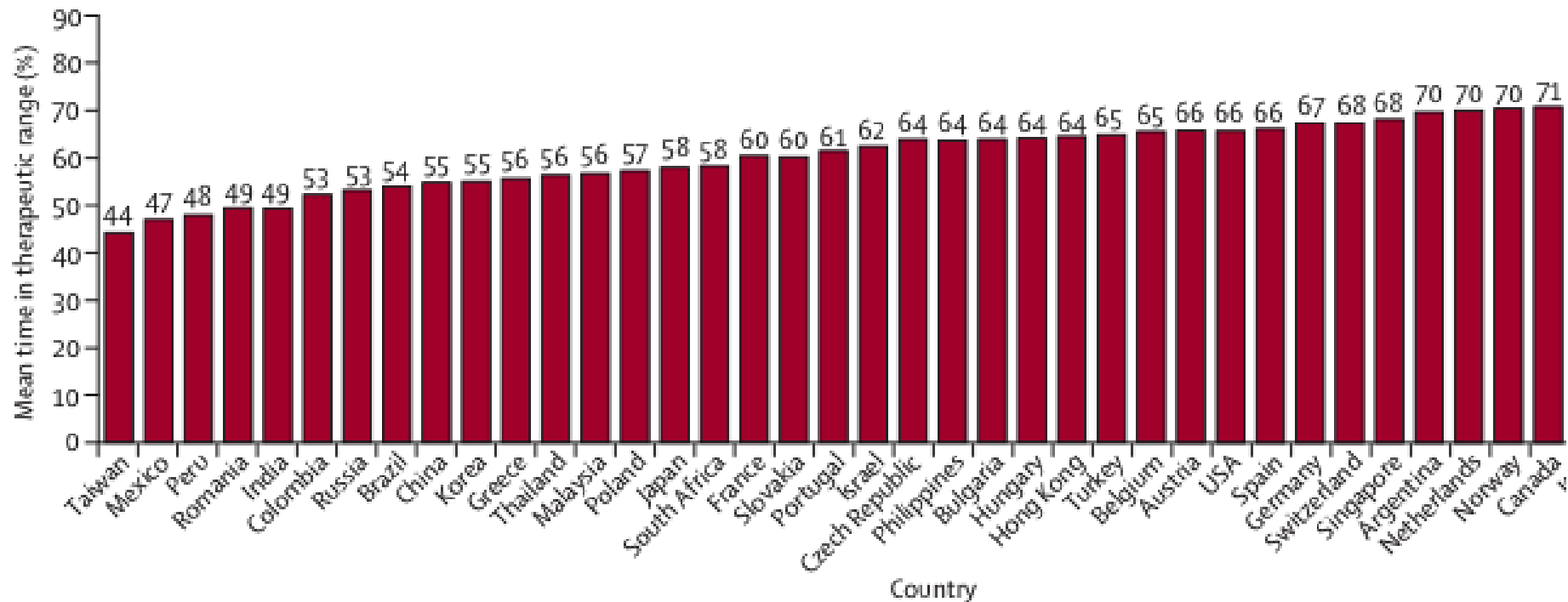
## 67% reduction in embolic events



Wolf, PA et al. Circulation 1991;84:527-539.

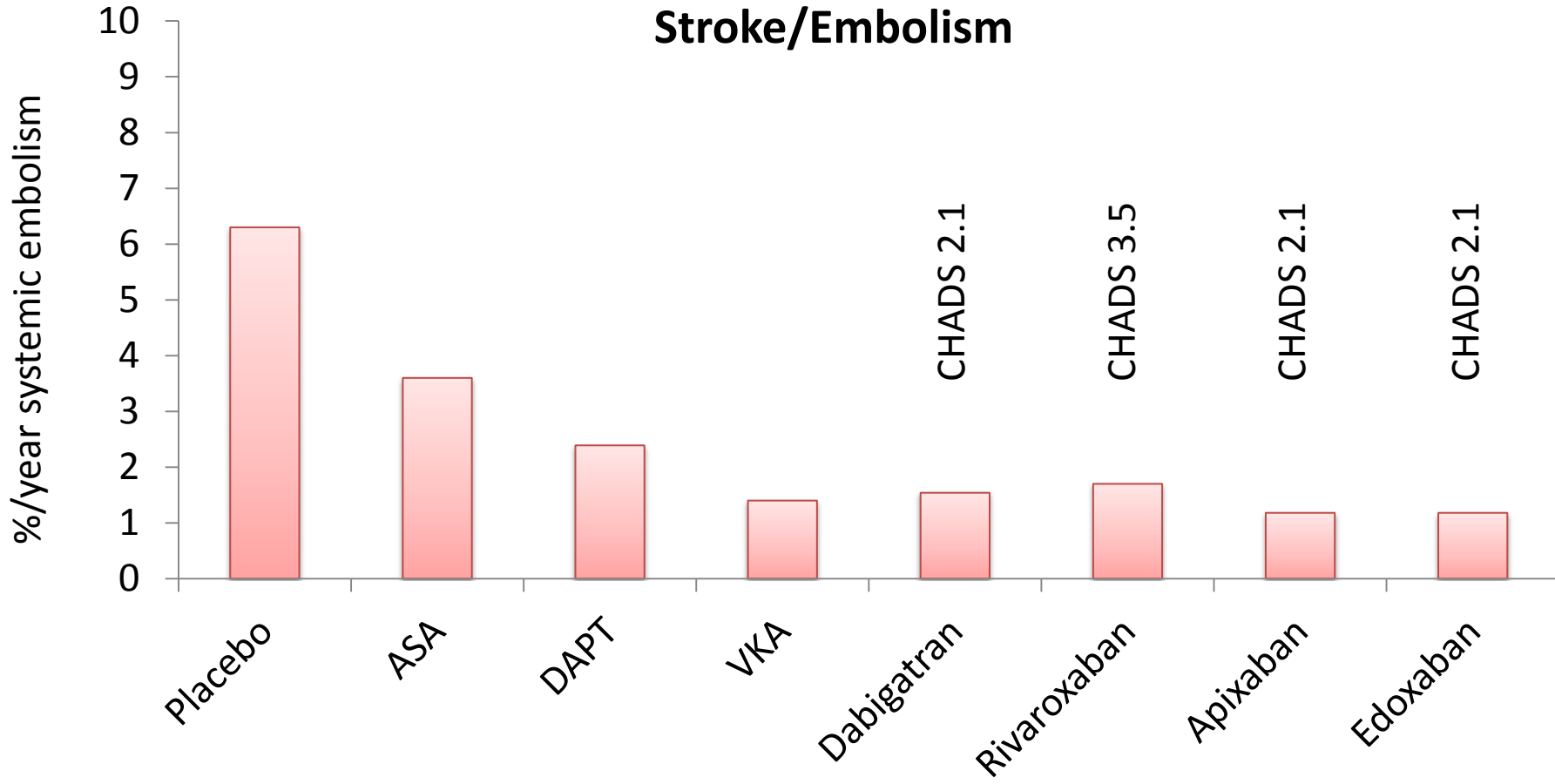
# Mean Time in Therapeutic Range

## RE-LY



Wallein, L et al. Lancet 2010; 376:975-983.

# Rates of Stroke According to Treatment

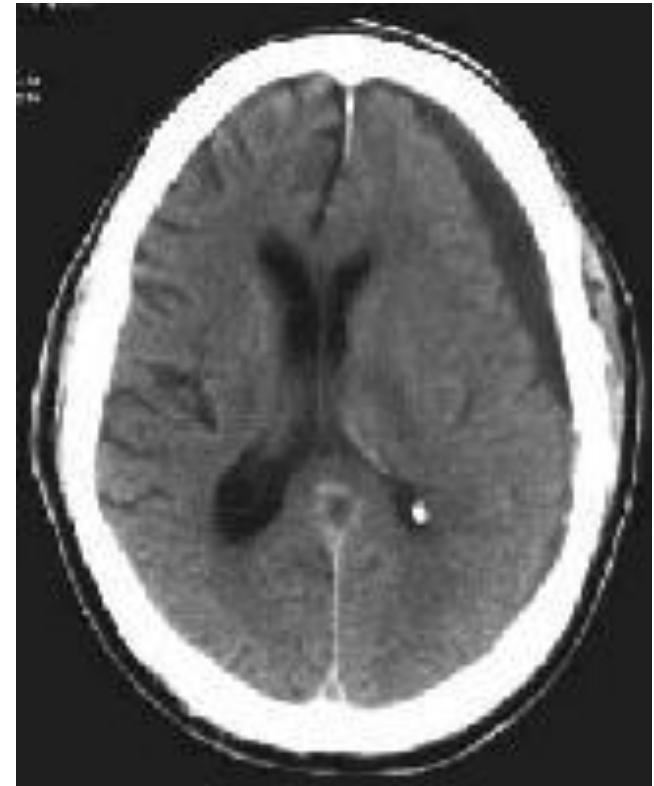


SPAF I, ROCKET-AF  
ACTIVE-W, ARISTOTLE  
RE-LY, APPRAISE-2



# Elderly Falls

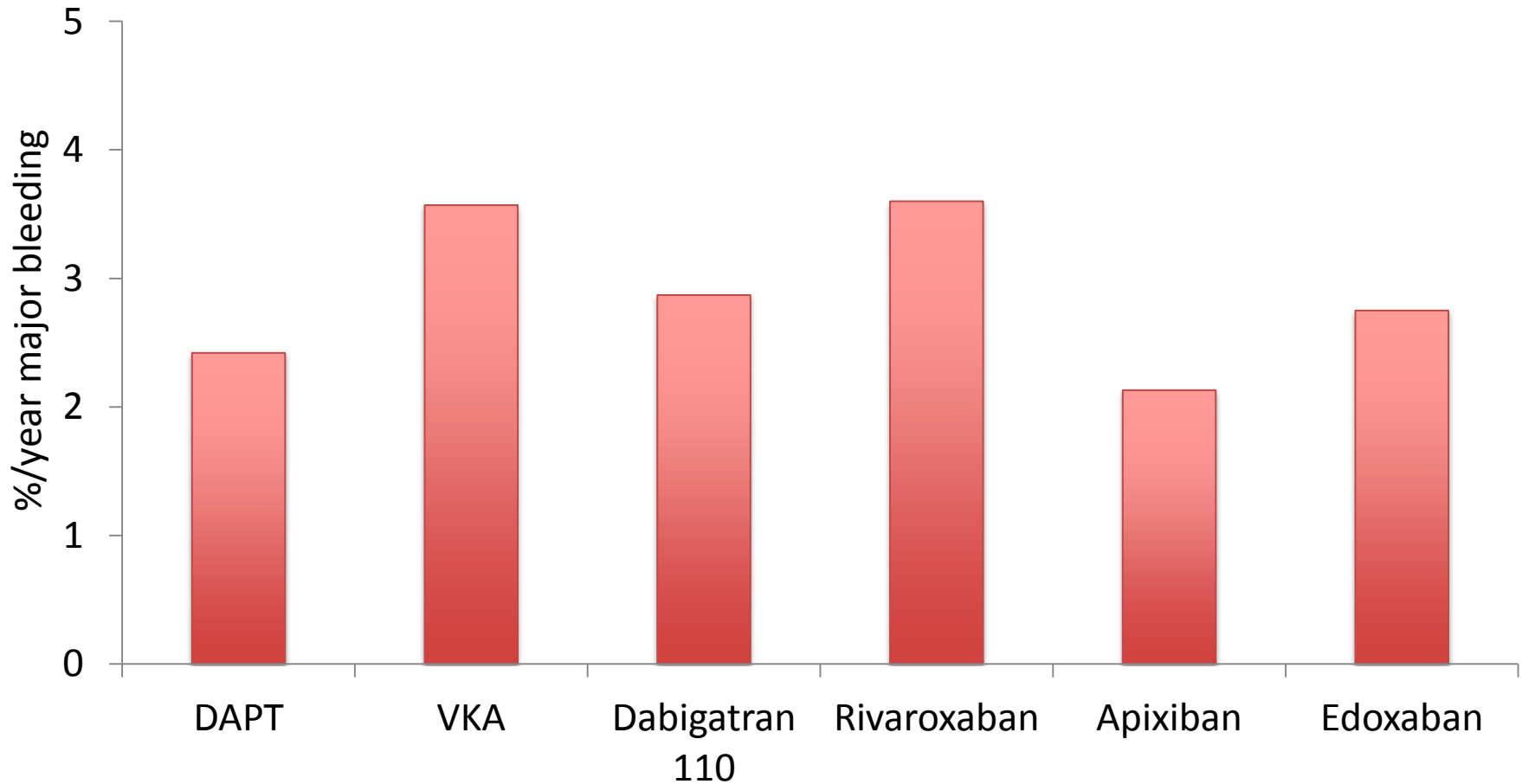
- › 2012
  - 2.4 million non-fatal falls among older adults treated in ER
    - 722,000 pts hospitalized
- › 2011
  - 22,900 older adults died of fall injuries



CDC

[Web-based Injury Statistics Query and Reporting System \(WISQARS\)](#)

# Major Bleeding According to Treatment

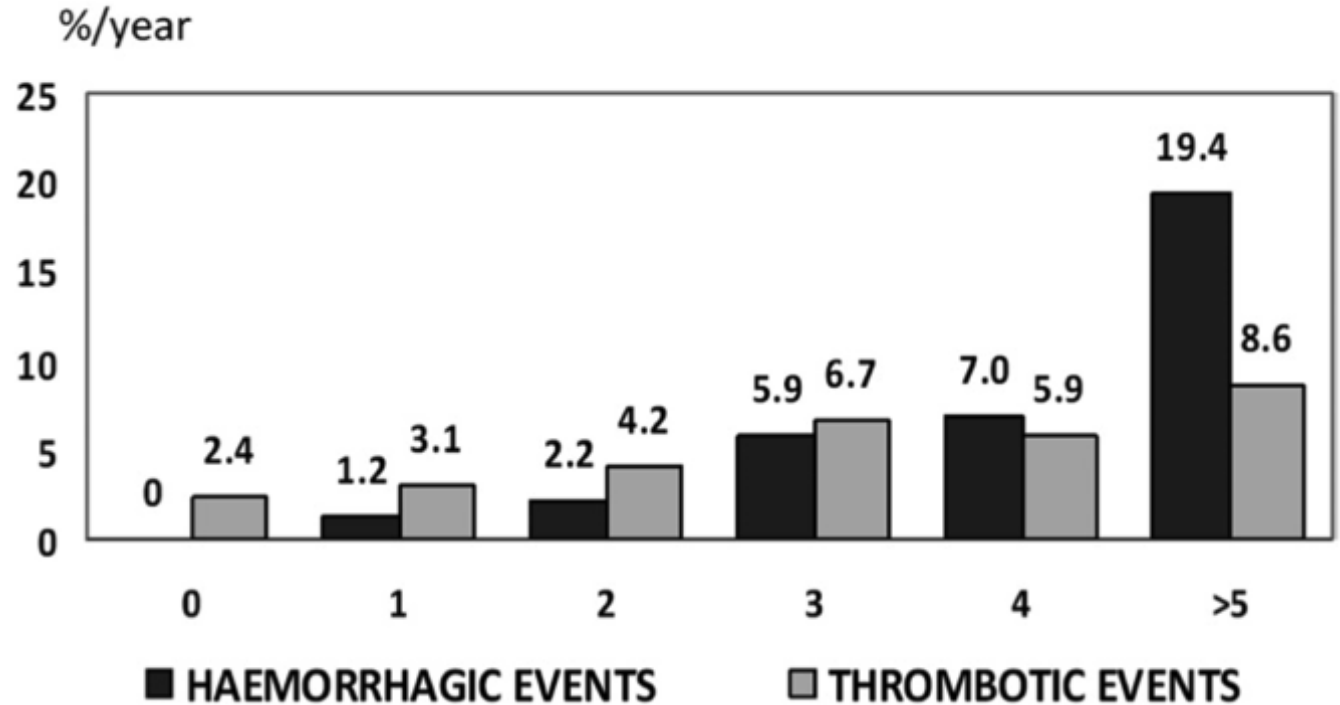


ROCKET-AF  
ACTIVE-W, ARISTOTLE  
RE-LY, APPRAISE-2

# HAS-BLED

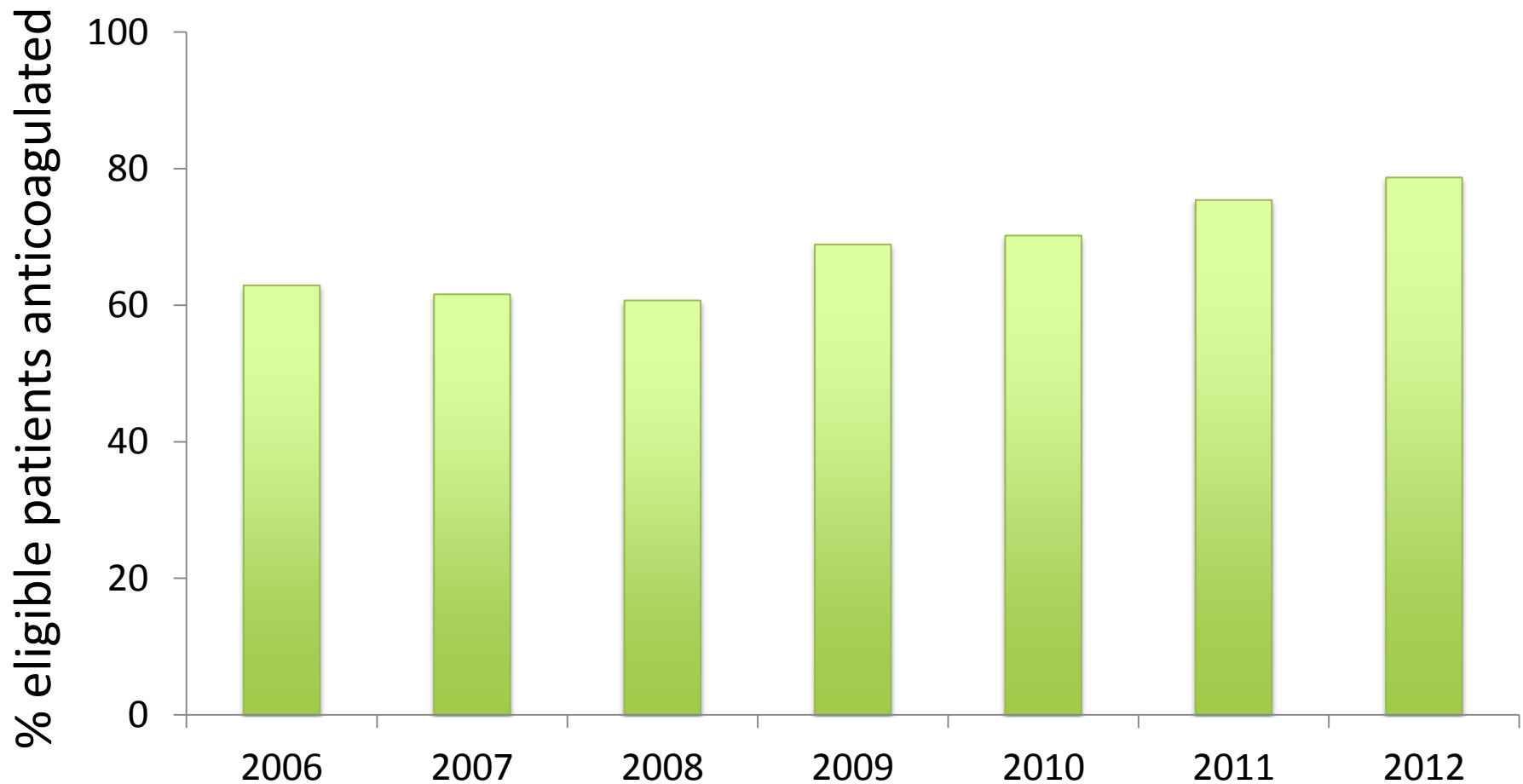
## Predictive of Bleeding

<b>Hypertension</b>
Abn Renal/liver
Stroke
Bleeding history
Labile INR
Elderly
Drug/ETOH



Gallego P et al. Circ Arrhythm Electrophysiol  
2012;5:312-318.

# Proportion of atrial fibrillation Anticoagulated (%)

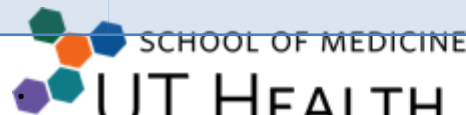


Go, A.S. Circulation 2014; 129:e29-e292.

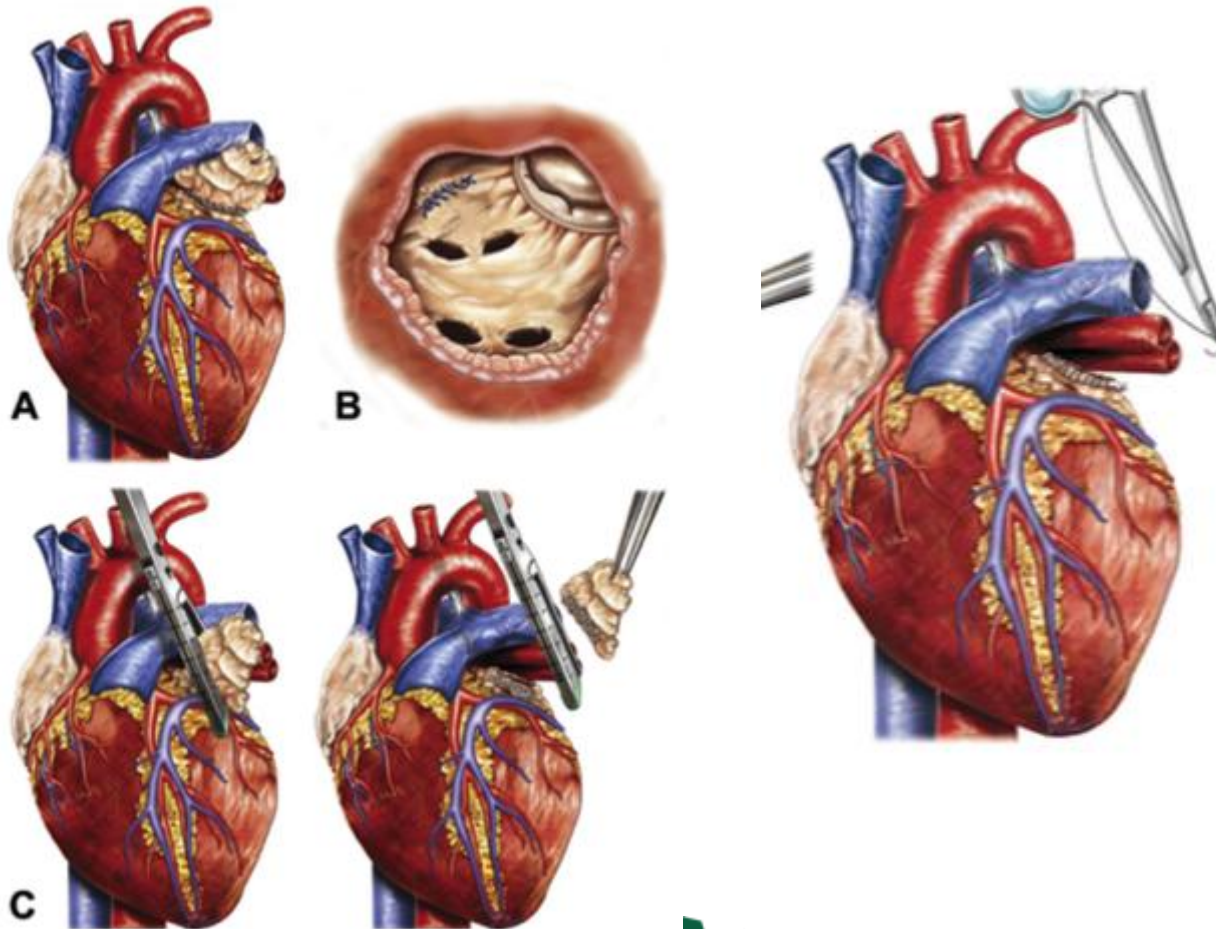
# Atrial Appendage Role in Stroke (total 91% in LAA)

	LAA thrombi	%	Left atrium	%
Stoddard, JACC '95	66	99%	1	1.5%
Manning, Circulation '94	34	97%	1	2.9%
Aberg, Acta Med. Scan. '69	35	74%	12	25.5%
Tsai, JFMA '90	2	50%	2	50%
Klein Int J. Card. Imag. '93	12	92%	1	7.7%
Manning, Circulation '94	8	73%	2	27.3%
Klein, Circulation '94	19	95%	0	0%
Leung, JACC '94	19	100%	0	0%
Hart, Stroke '94	6	100%	0	0%

Blackshear, JL et al. Ann Thorac Surg;61:755-9.



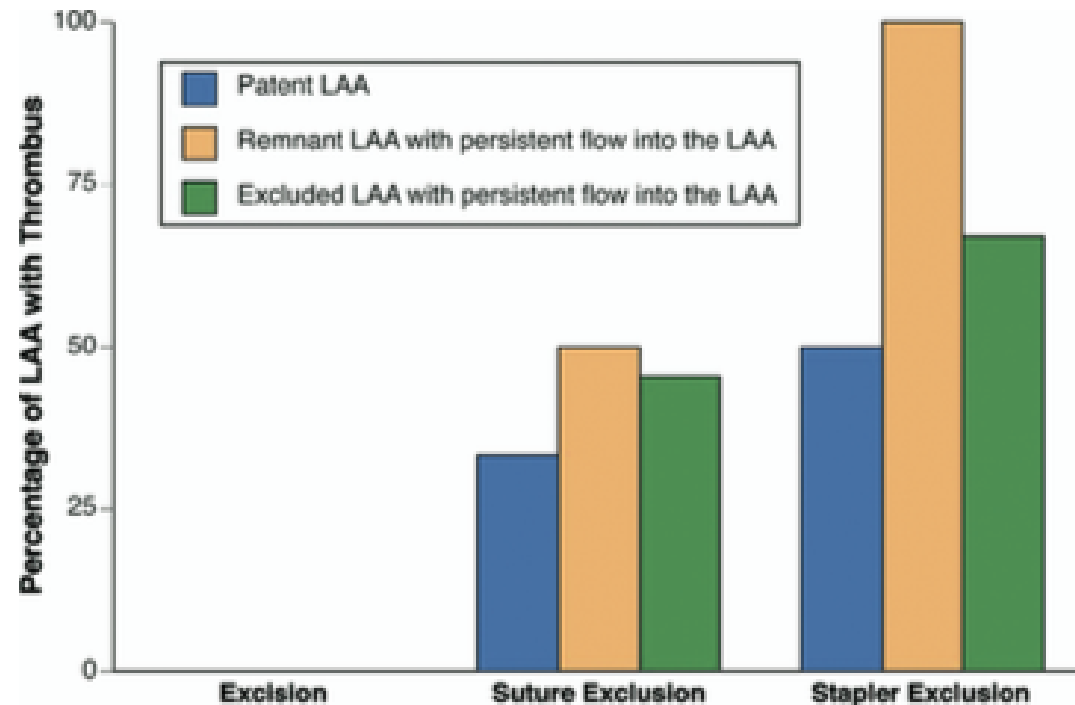
# LAA Surgical Closure



Chatterjee, S. et al. Ann Thorac Surg  
2011;92:2283-92.

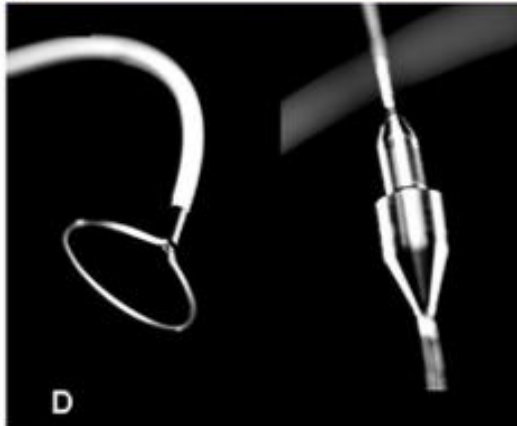
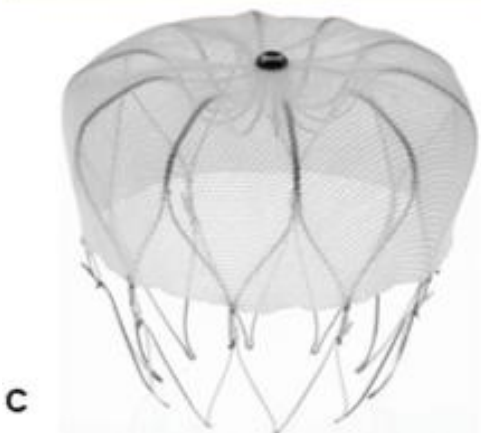
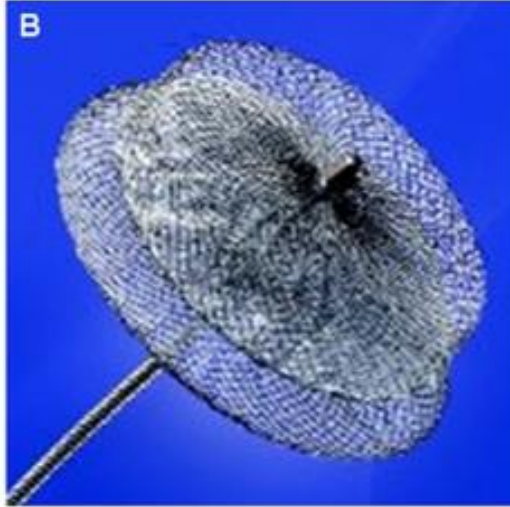
# Surgical Exclusion Limited Success

- › 2,546 pts total
- › 137 post-exclusion TEE
  - 40% success
- › Remaining patent LAA
  - 41% with thrombus



Kanderian AS et al. JACC 2008;52:924-9.

# LAA Closure Percutaneous Devices



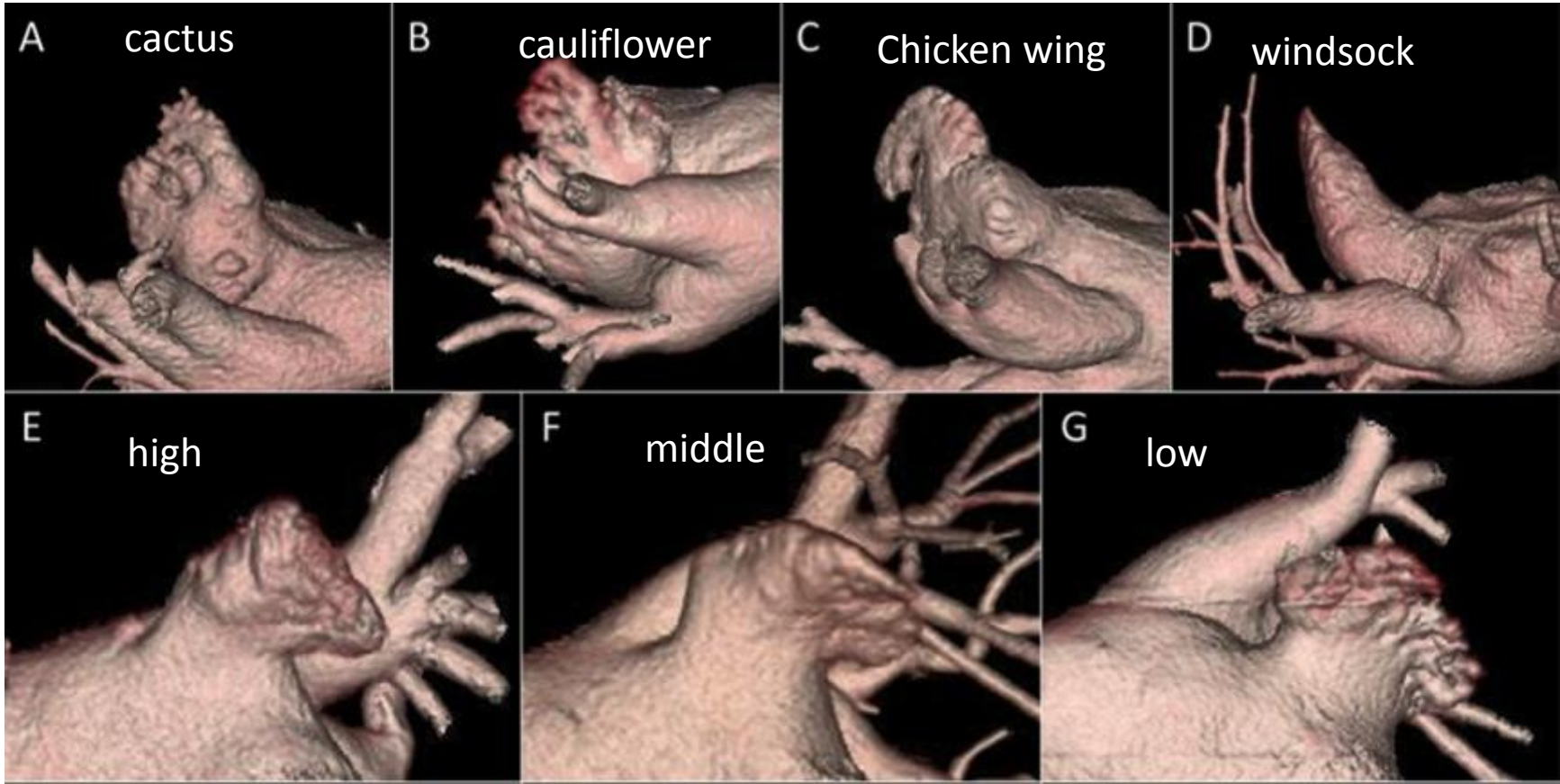
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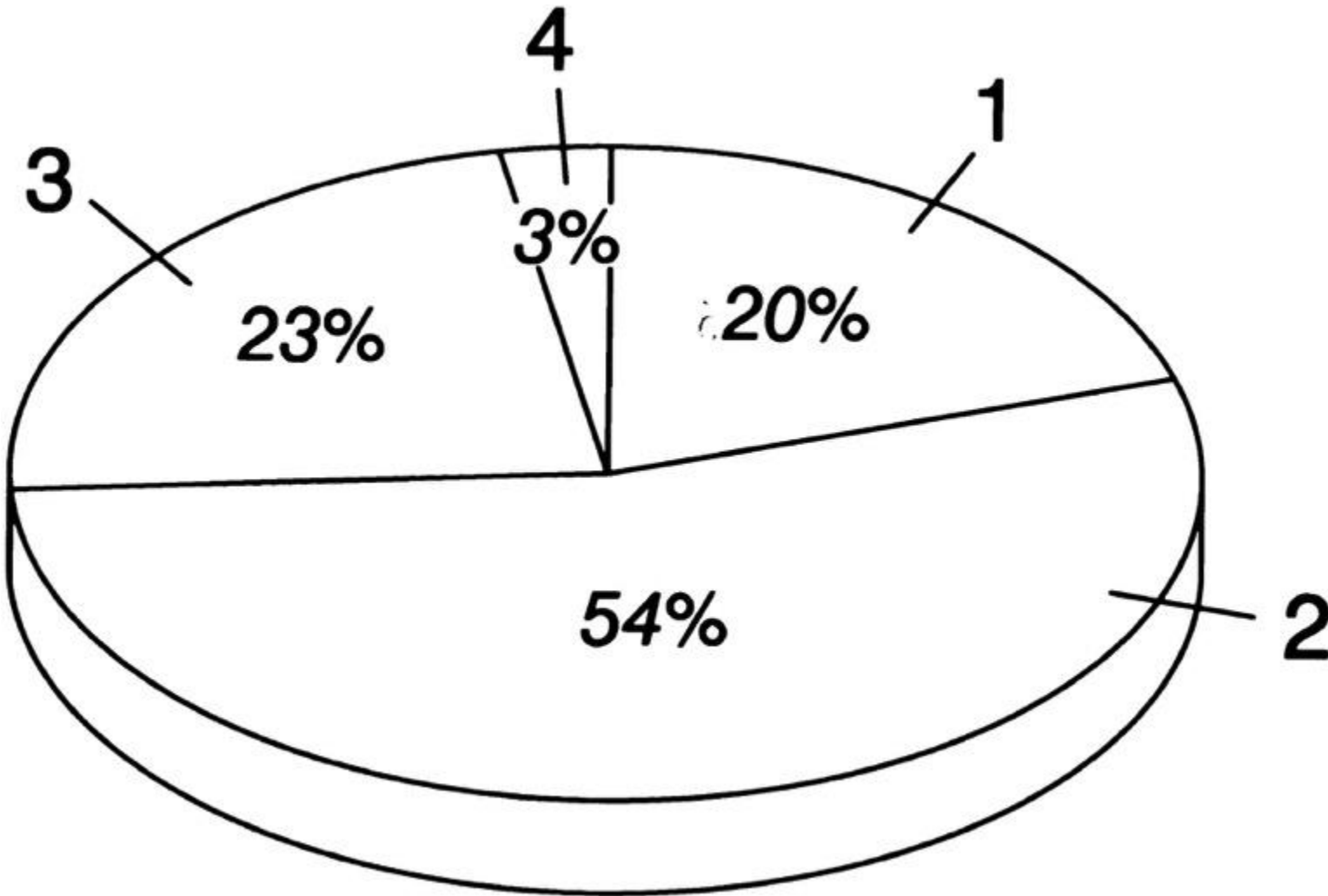
Chatterjee, S. et al. Ann Thorac Surg  
2011;92:2283-92.  
Lam S et al. CCI 2014.



# Left atrial appendage anatomy



Distribution of number of lobes (1 to 4) of left atrial appendage.



Veinot J P et al. Circulation. 1997;96:3112-3115



# LAA occlusion

## PLAATO

### › PLAATO

- Self expanding nitinol frame
  - ePTFE covering
- Initial 15/15 device success
  - 1 hemopericardium
- Follow up
  - 1 Month TEE
    - No leak
    - No thrombus
    - Good healing
- Not Commercially Available

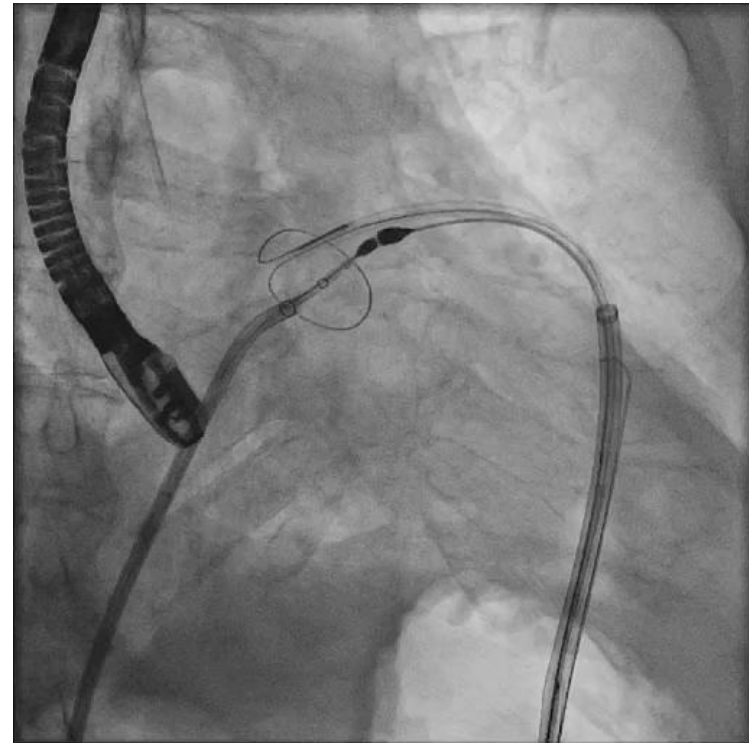


Sievert, H et al. Circulation 2002;105:1887-9.

# LARIAT

## A Complex Procedure

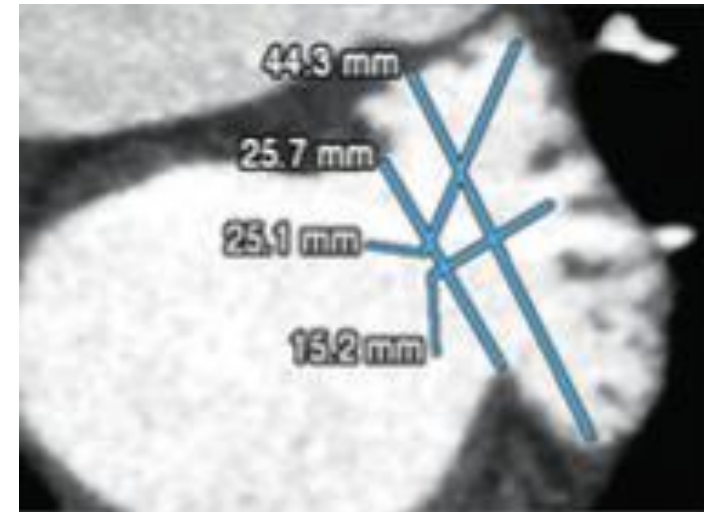
- › Dry Pericardial Access
- › Transseptal Access
- › Endocardial Magnet Placement
- › Epicardial Magnet-Magnet connection
- › Snaring of the LAA
- › Confirmation of Closure



# LARIAT

## Exclusions

- › LAA width 40 mm
- › Superiorly oriented LAA with the apex directed behind the pulmonary trunk
- › Bi-lobed or multi-lobed LAA in which lobes are oriented in different planes exceeding 40 mm
- › Posteriorly rotated heart



# LARIAT

## Early US Experience

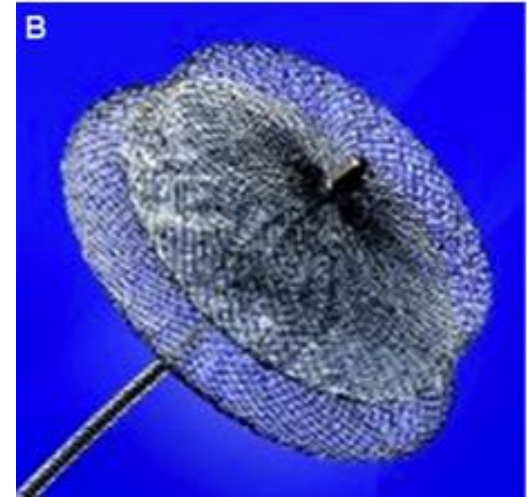
› N=154

- Procedural Success 86%
- Major Complications 10.0%
  - Major Bleeding 9.1%
  - Significant pericardial effusions 10.4%
  - Death/MI/stroke 2.9% (median 112 days)
  - 2 RV perforations
  - 1 LAA perforation
- Follow up TEE (n=63)
  - 3 thrombi (4.8%)
  - 13 residual leak (20%)
  - Complete closure in 79%



# Amplatzer Cardiac Plug

- › Self-expanding nitinol mesh
  - Distal lobe
  - Proximal disk
  - Sewn polyester patch



# Amplatzer Cardiac Plug

	<b>N</b>	<b>Follow Up</b>	<b>Safety</b>	<b>Efficacy</b>
Park et al.	143	24 hr	Procedural comp. 7%	N/A
Urena et al.	52	20 ± 5 mo	Procedural comp. 5.8%	CV death 1.9% Stroke 1.9%
Meerkin et al.	100	In-hospital	Procedure comp. 1.0%	N/A
Lam et al.	20	12.7 ± 3.1 mo	Procedure comp. 10%	Stroke 0
Chun et al.	40	1 yr	Procedure comp. 5%	Death 5% Stroke 0
Guerios et al.	86	25.9 patient y	Procedure comp. 5.6%	Death 3.5% Stroke 0
Horstmann et al.	20	13.6 ± 8.2	Procedure comp. 0%	Stroke 0
Kefer et al.	90	1 yr	Procedure comp. 9.3%	Death 5.3% Stroke 2.1%
Streb et al.	21	In-hospital	Procedure comp. 14%	N/A



# Amplatzer Cardiac Plug Device Thrombosis

## › Device thrombosis rate

- Up to 17.6% (6/34)
  - Independent risk factors
    - CHADS2/CHADS2-Vasc
    - LVEF
    - Platelet count

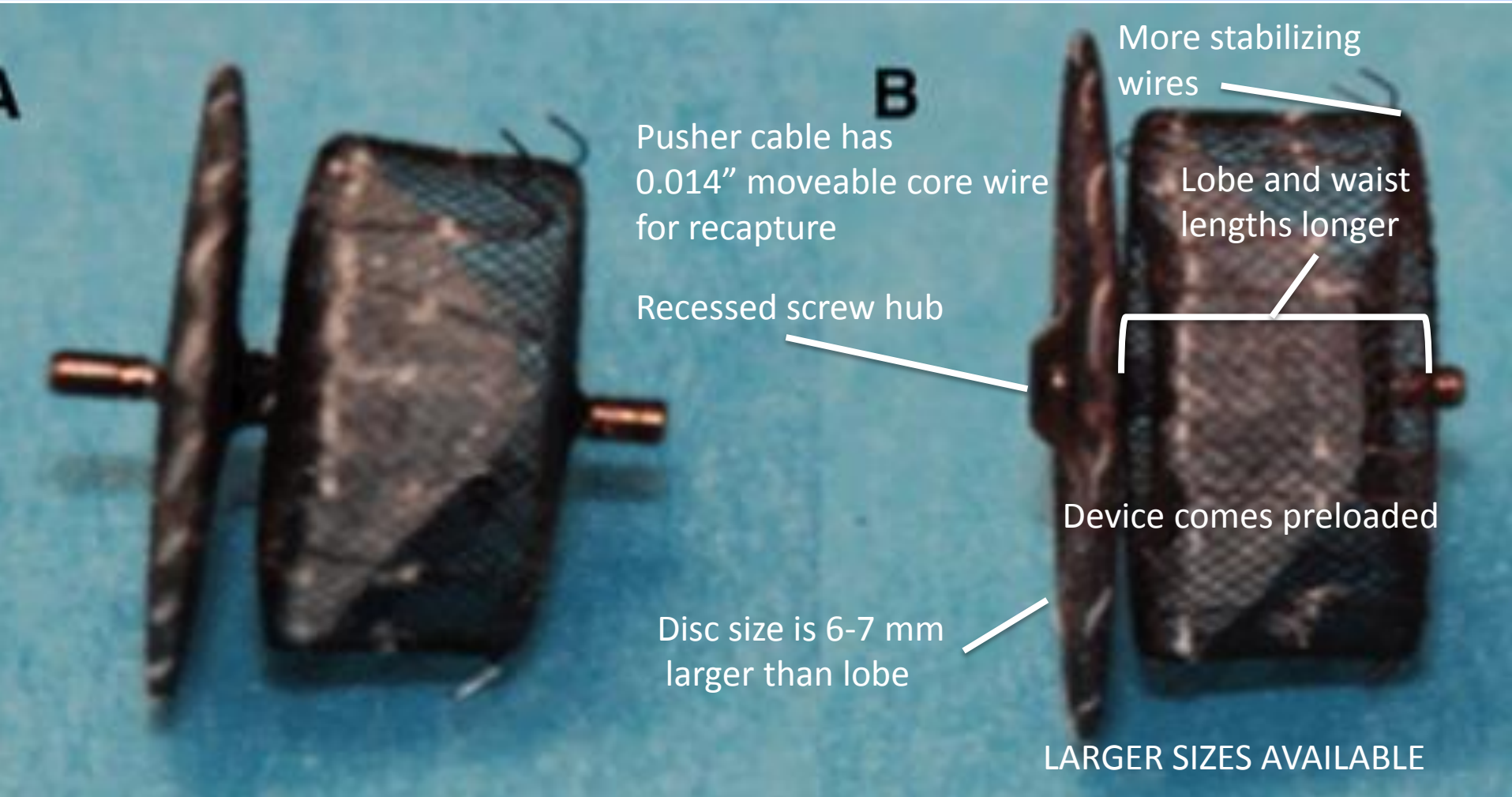
## › Canine studies

- Incomplete neo-endocardial coverage
  - Inferior margin
  - End-screw hub



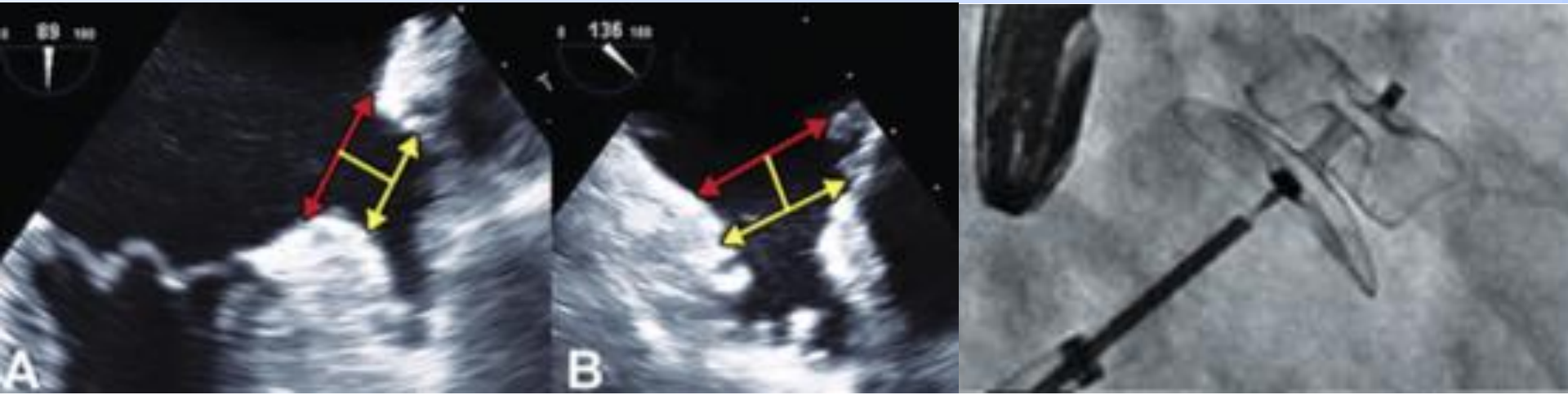
Kar S et al. JACC Intv. 2014;7:801-7.  
Plicht et al. JACC Intv. 2013;6:606-13.

# Amplatzer Amulet



# AMULET

## Small studies



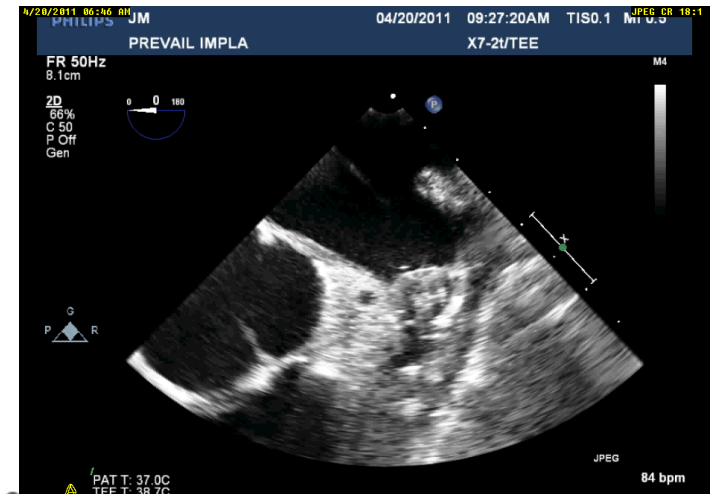
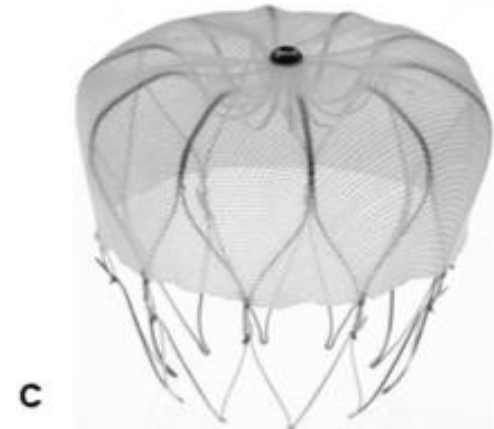
Author	N	Success	Embol.	P. effusion	Stroke	MI
Lam et al.	17	100%	0	1	0	0
Frexia et al.	25	96%	0	0	0	0

1/25 device thrombosis when not compliant with DAPT

Lam S et al. CCI 2014  
 Frexia, X et la. IJC 2014; 174:492-496.

# WATCHMAN DEVICE

- › Self-expanding nitinol frame
  - Fixation barbs
  - Permeable polyester fabric cover
- › 21, 24, 27, 30, 33 mm



# WATCHMAN PROTECT-AF

	<b>Watchman</b>	<b>Control</b>	<b>RR</b>
Combined efficacy endpoint	3.0%	4.9%	0.62 (0.35-1.25)
All Stroke	2.3%	3.2%	0.71 (0.35-1.64)
Ischemic Stroke	2.2%	1.6%	1.34 (0.60-4.29)
Hemorrhagic Stroke	0.1%	1.6%	0.69 (0.00-0.45)
Safety EP	7.4 %	4.4%	1.69 (1.01-3.19)

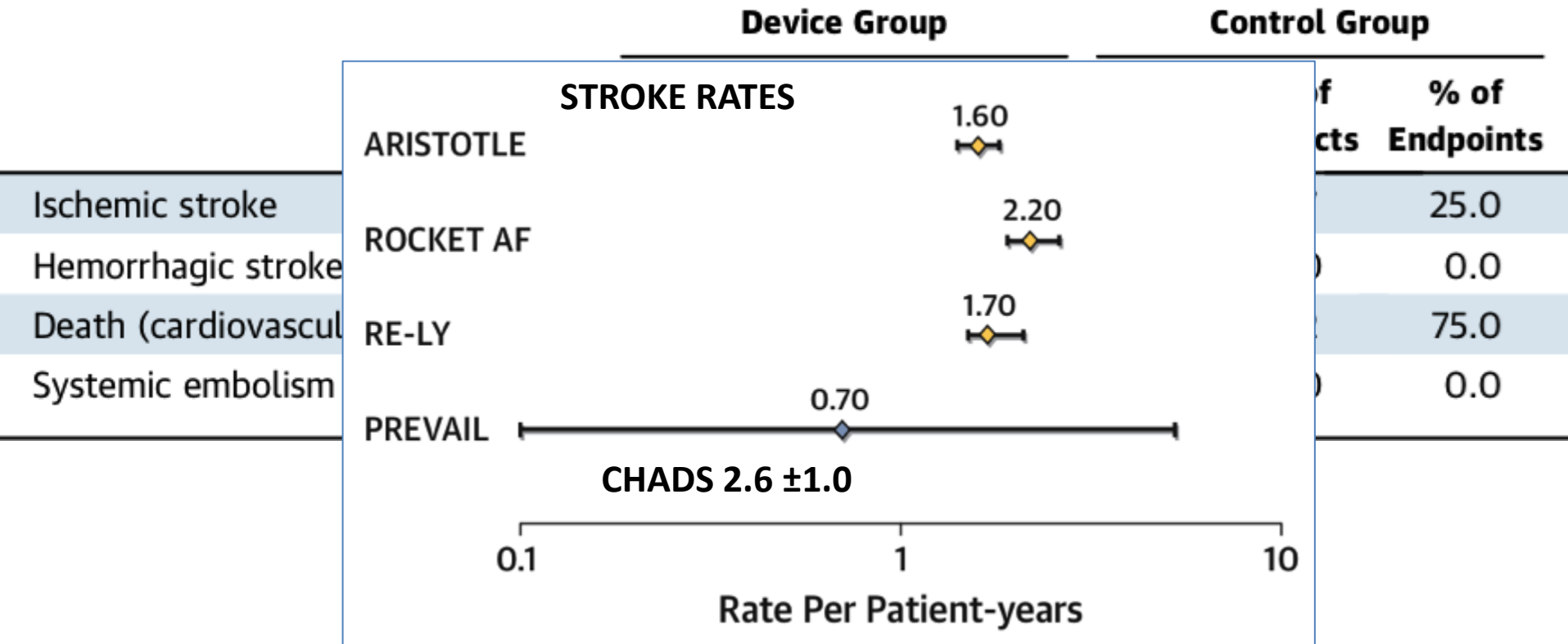
Holmes, DR et al. Lancet 2009; 374:534-42.

# WATCHMAN PROTECT-AF

	Intervention (n=463)	Control (n=244)
Serious pericardial effusion*	22 (4.8%)	0
Major bleeding†	16 (3.5%)	10 (4.1%)
Procedure-related ischaemic stroke	5 (1.1%)	0
Device embolisation	3 (0.6%)	0
Haemorrhagic stroke‡	1 (0.2%)	6 (2.5%)
Other§	2 (0.4%)	0

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

# WATCHMAN PREVAIL



Holmes, DR et al. JACC 2014;64:1-12.

# WATCHMAN Safety

	<b>PROTECT AF</b>	<b>CAP</b>	<b>PREVAIL</b>	<b>p Value</b>
Implant success	90.9	94.3	95.1	0.04
All 7-day procedural complications	8.7	4.2	4.5	0.004
Pericardial effusion requiring surgery	1.6	0.2	0.4	0.03
Pericardial effusion with pericardiocentesis	2.4	1.2	1.5	0.318
Procedure-related strokes	1.1	0.0	0.7	0.02
Device embolization	0.4	0.2	0.7	0.368

Holmes, DR et al. JACC 2014;64:1-12.



# WATCHMAN Leaks

## TEE evaluations

### Flow around device filter

Yes

No

Unable to evaluate

Field not completed

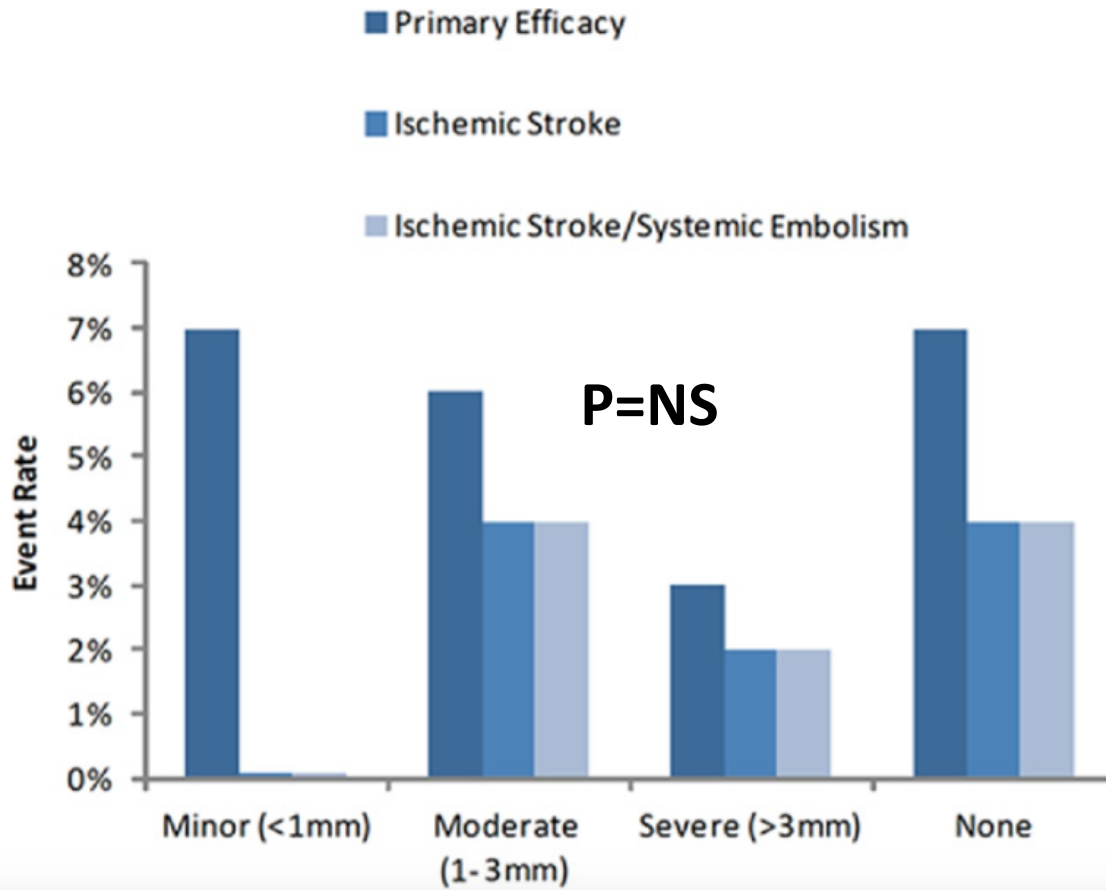
### If leak present

#### Flow severity (%)

Minor <1 mm

Moderate 1-3 mm

Major >3 mm



p Value

0.001

0.275

Viles-Gonzalez J et al. JACC 2012; 59:923-9.



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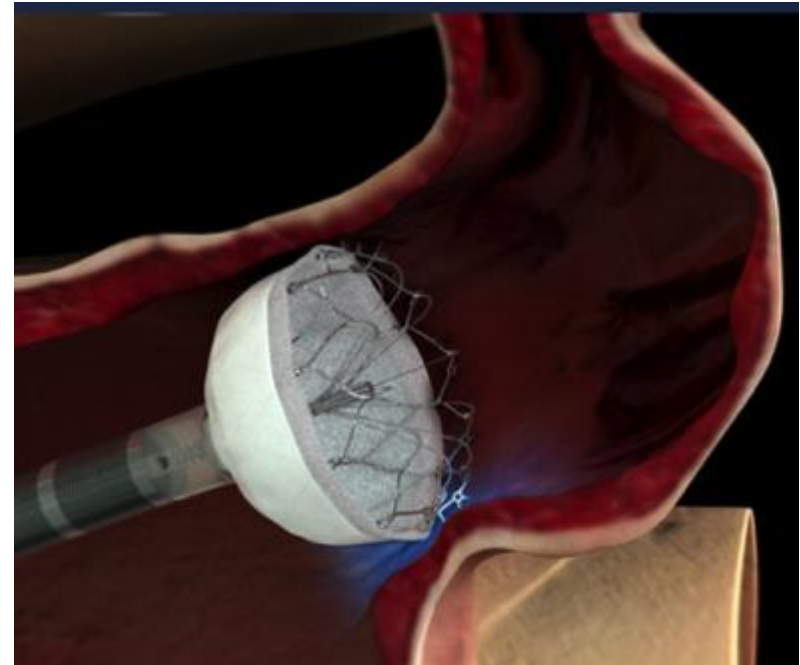
# Coherex LAA occluder

## › Device

- Microtine anchors
- ePTFE occluder material
- 22, 28, 32 mm

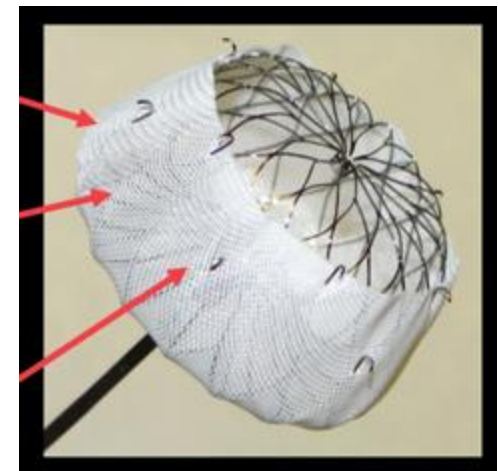
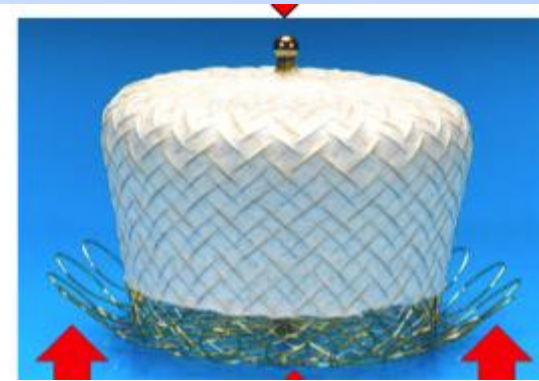
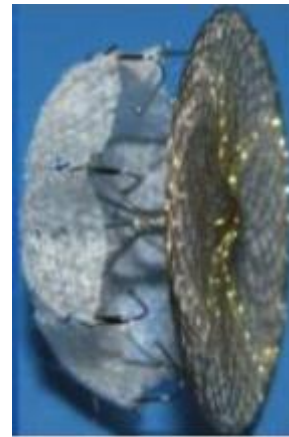
## › First in Man Trial

- N=73
  - 97% success
  - MAE 4.1%
    - 2 pericardial effusions
    - 1 major bleed requiring transfusion



# LAA Occluder Devices

- › Occulotech LAA Occluder
  - Nanospun polyurethane occluder
  - Loops
  - Flexible ball/forcep
- › Lifetech LAMBRE occluder
  - PET membrane
  - Double membrane design
  - barbs
  - FIM
    - 60/60 success
    - 3.3% MAE
- › Watchman FLX
  - 10-20% reduction in length
  - 80% more struts
    - conformability

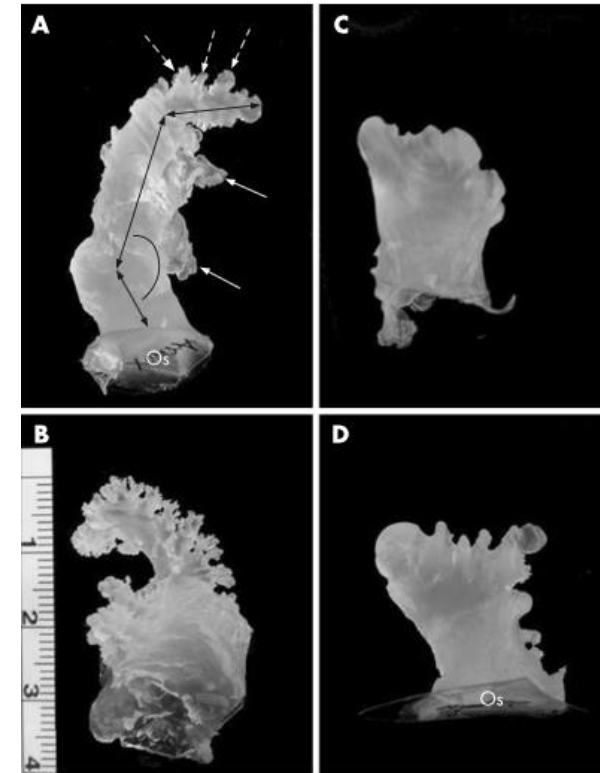


Malik et al. TCT 2014  
Sievert H et al TCT 2014

<b>PLAATO</b>	<b>Appriva Medical</b>	<b>Single-lobe, nitinol cage, ePTFE, hooks</b>	<b>NA</b>
WATCHMAN	Boston Scientific	Single-lobe, nitinol frame; PET membrane, hooks	CE mark
ACP	St. Jude	Lobe and disk, polyester mesh, nitinol mesh, stabilizing wires	CE mark
Amulet	St. Jude	Lobe and disk, polyester mesh, nitinol mesh, stabilizing wires	CE mark
WaveCrest	Coherex	Single-lobe, nitinol frame, ePTFE membrane, polyurethane foam, anchors	Trial
LAA occluder	Occulotech	Single-lobe, nitinol wire mesh, nanomaterial covering	Trial
Sideris Transcatheter Patch	Custom Medical Devices	Frameless detachable latex balloon covered with polyurethane	Trial
LAmbre	Lifetech	Lobe and disk, nitinol, PET membrane, distal barbs	Trial
Pfm	Pfm Medical	Dual disk (proximal disk, distal anchor, middle connector)	Pre-clinical
Ultrasept	Cardia	Lobe/disk, nitinol frame, Ivalon cover	Trial

# Summary

- › Unmet need for stroke prophylaxis
  - VKA variable efficacy
  - Poor candidate for anti-coagulation abundant
- › LAA anatomy highly variable
  - Rigorous anatomic screening
- › Occluder Devices
  - May require short term anticoagulation
  - DAPT if comfortable
  - Large device leaks may allow thrombus formation
- › LARIAT
  - Procedural risks present- steep learning curve
- › Availability of multiple devices
  - May require tailored approach for specific anatomy



# 감사합니다.



# Atrial Fibrillation Increasing Rates

**Table 2. Estimated Age-Adjusted Incidence Rates with 95% Uncertainty Intervals of Atrial Fibrillation (per 100 000 Person-years) for Men and Women**

	1990	2010
<b>Men</b>		
Global, all ages	60.7 (49.2–78.5)	77.5 (65.2–95.4)
Age ≥35 y	141.0 (114.6–182.6)	181.2 (152.6–222.8)
Developed countries	78.4 (67.5–91.9)	123.4 (107.6–141.5)
Developing countries	50.0 (33.8–76.8)	53.8 (38.7–79.8)
<b>Women</b>		
Global, all ages	43.8 (35.9–55.0)	59.5 (49.9–74.9)
Age ≥35 y	102.0 (83.9–127.9)	139.7 (117.1–175.3)
Developed countries	52.8 (45.0–62.9)	90.4 (77.8–104.5)
Developing countries	36.0 (24.5–54.7)	40.0 (27.2–62.6)

Chugh S. et al. Circulation 2014;129:837-847.

# Appendage Excision

## Limited Success

First Author, Year	Country	No. Studied	Method of Closure	Closure Success Rate, <sup>a</sup> %	Effect of LAA Closure on Stroke Prevention
Johnson, 2000 [25]	USA	437	Excision	100	Positive
Katz, 2000 [30]	USA	50	Endocardial suture	64	None
Garcia-Fernandez, 2003 [31]	Spain	205	Endocardial suture	90	Positive
Bando, 2003 [38]	Japan	812	Endocardial suture	Not measured	Negative
Blackshear, 2003 [45]	USA	15	Thoracoscopic epicardial pursestring	93 <sup>b</sup>	Positive
Pennec, 2003 [40]	France	30	Endocardial	70–80	Negative
			Excision	100	Positive
Schneider, 2005 [41]	Germany	6	Endocardial suture	17	Negative
Healey, 2005 [28]	Canada	77	Epicardial suture	45	Positive
			Stapler	72	
Kanderian, 2008 [29]	USA	137	Excision	73 (20% stapler)	Positive trend
			Suture exclusion	23	
			Stapler	0	
Bakhtiary, 2008 [33]	Germany	259	Clamp and epicardial suture	100 <sup>b</sup>	Positive

Chatterjee, S. et al. Ann Thorac Surg 2011;92:2283-92.