Uzávěr ouška levé síně – málo využívaná, avšak efektivní prevence ischemických i krvácivých příhod

B. Janek, Klinika kardiologie IKEM
XXVI. Výroční sjezd ČKS
Brno 7.5.2018

INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICÍNY
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Nevalvulární fibrilace síní

- Bez nutnosti antikoagulační terapie jen „nízce rizikoví“ CHA_2DS_2-VASc skóre = 1-2
- U ostatních VKA (Warfarin)
- ASA i DAPT nedostatečné k prevenci + riziko krvácení nezanedbatelné (ne menší než VKA?)
- INR 2-3
- Pravidelné kontroly
- NOAC (v ČR s omezeními)

Riziková stratifikace – skórování rizika CMP CHA_2DS_2-VASc

- **C**ongestive HF/LV dysfunkce 1
- **H**ypertenze 1
- **A**ge (věk) ≥75 let 2
- **D**iabetes 1
- **S**troke (CMP) 2
- **V**askulární postižení 1
- **A**ge (věk) 65-74 1
- **S**ex **c**ategory (ženské pohlaví) 1

- 90% všech trombů pochází z ouška levé síně

Riziková stratifikace – skórování rizika krvácení HAS-BLED

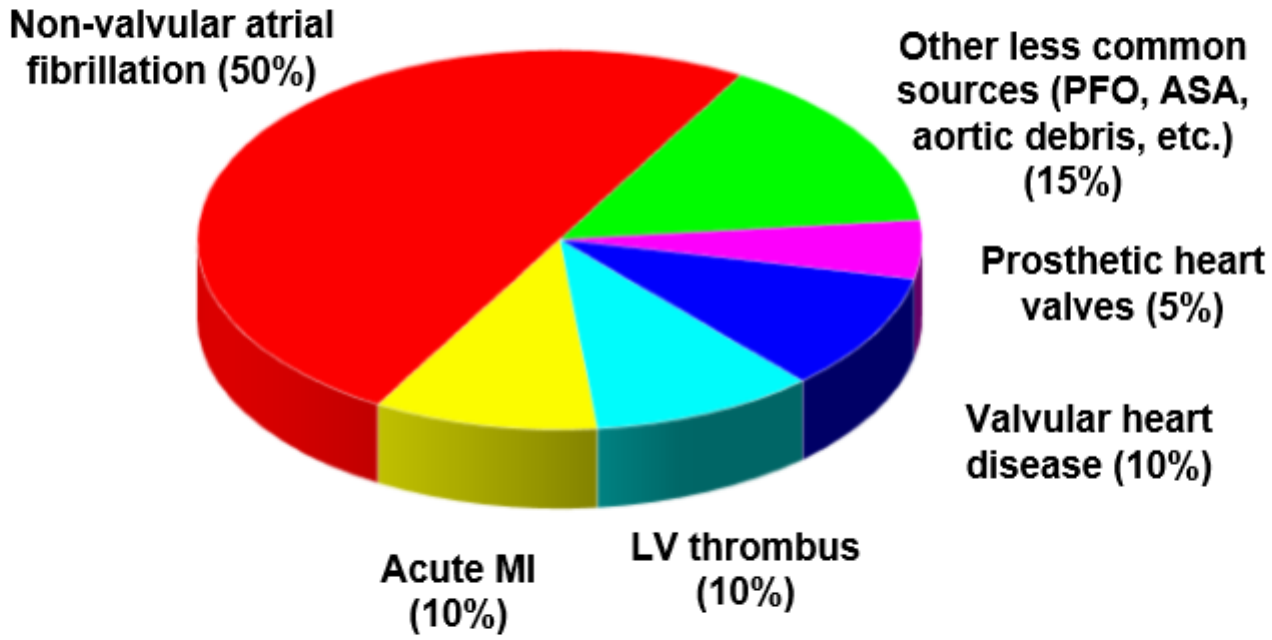
- **H**ypertenze
- **A**bnormální renální/jaterní funkce
- **S**troke (CMP)
- **B**leeding history
- **L**abilní INR
- **E**ldery (věk nad 65 l., „chatrnost“)
- **D**rugs/alkohol (ASA, NSAID..)

Krvácivé komplikace

- Mozkové krvácení
- Subdurální krvácení
- Intraokulární krvácení
- Rekurentní pulmonální
- GIT krvácení (nekorigovatelné)

- Špatná kompliance/nemožnost kontrol
- Opakované pády

Stroke and Non Valvular Atrial Fibrillation



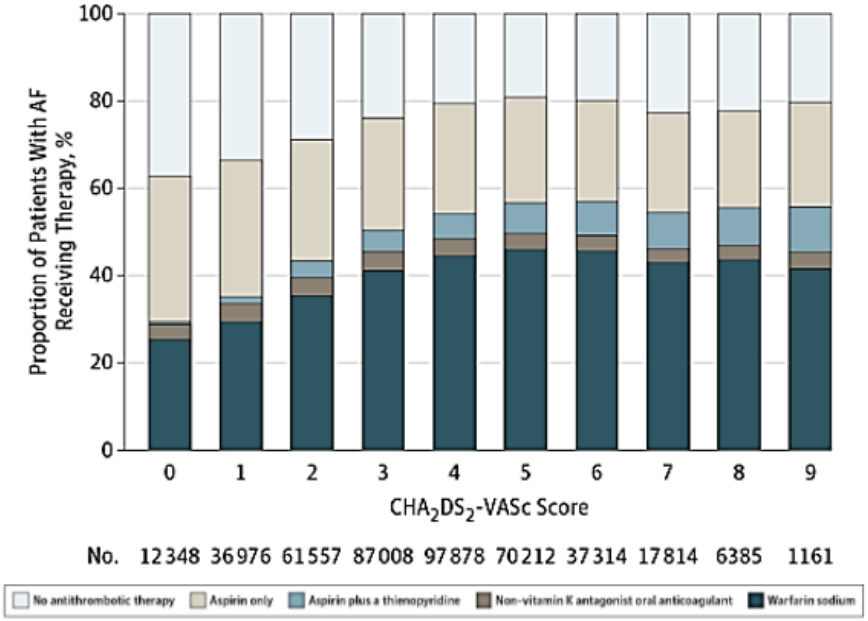
Cerebral Embolism Task Force. Arch Neurol 1986

Oral Anticoagulation is Standard of Care, but Not Ideal for All

NCDR Pinnacle Registry

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Use of OACs in AF Patients peaks at ~50%, use declines with increasing risk



Warfarin

- Bleeding risk
- Daily regimen
- High non-adherence rates
- Regular INR monitoring
- Food and drug interaction issues
- Complicates surgical procedures

Novel Oral Anticoagulants

- Bleeding risk
- Daily or 2x/daily regimen
- High non-adherence rates
- Complicates surgical procedures
- Limited reversal agents
- High cost

Registry 429□17 AFpatients
2008 -2012

1. Hsu, J et al. *JAMA Cardiol*. Published online March 16, 2016. doi:10.1001/jamacardio.2015.0374

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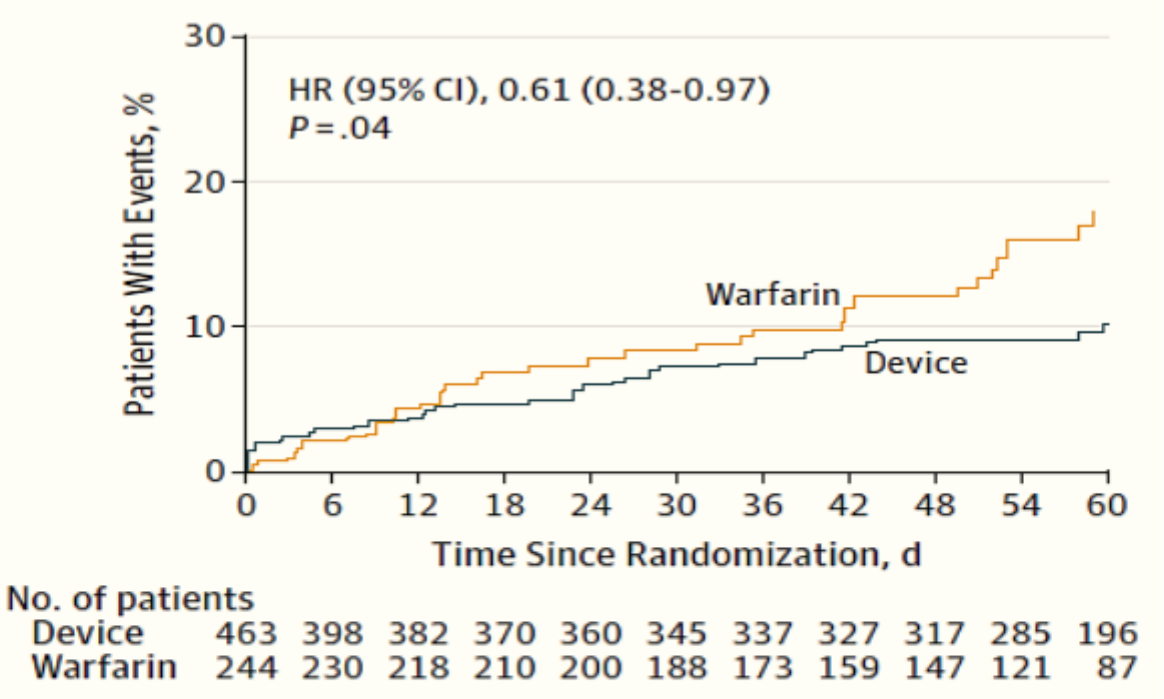
PROTECT-AF 4 Years:
Primary Efficacy endpoint

Event	Device Group (n = 463)		Warfarin Group (n = 244)		Device/Warfarin Rate Ratio (95% Credible Interval)	Posterior Probabilities, %	
	Events/Patient-Years	Observed Rate[a]	Events/Patient-Years	Observed Rate[a]		Noninferiority	Superiority
Primary efficacy end point[b]	39/1720.2	2.3 (1.7-3.2)	34/900.8	3.8 (2.5-4.9)	0.60 (0.41-1.05)	>99	96



a. Events per 100 patient-years (95% credible interval); b .Composite of stroke, systemic embolization, or cardiovascular/unexplained death

For Bayesian analysis, a posterior probability of 97.5% represents non-inferiority; ≥95% represents superiority.

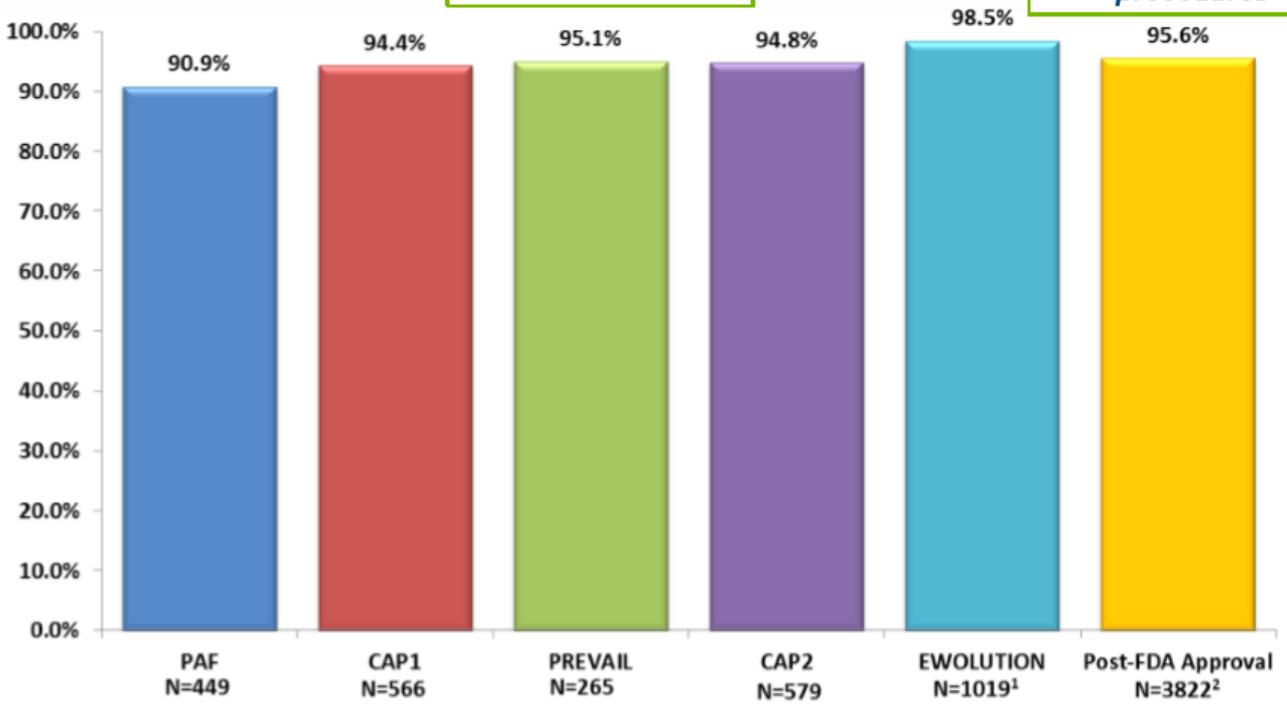
Reddy, VY et al. JAMA. 2014; 312(19)

Procedural Success

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

~50% new operators

~70% new operators performed 50% of procedures



Implant success defined as deployment and release of the device into the LAA; no leak ≥ 5 mm

* The EWOLUTION Registry is a European prospective registry which reflects CE Mark indications for use which differ from the FDA indications for use.

1 Boersma, L.et al. *EHJ* 2016;37(31): 2465.; 2 Reddy VY, Holmes DR, et al. JACC 2016; 69(3): 253-261.

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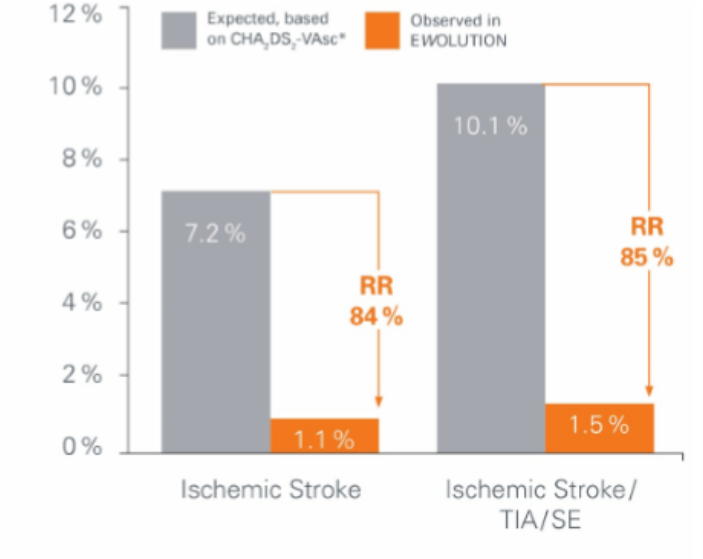
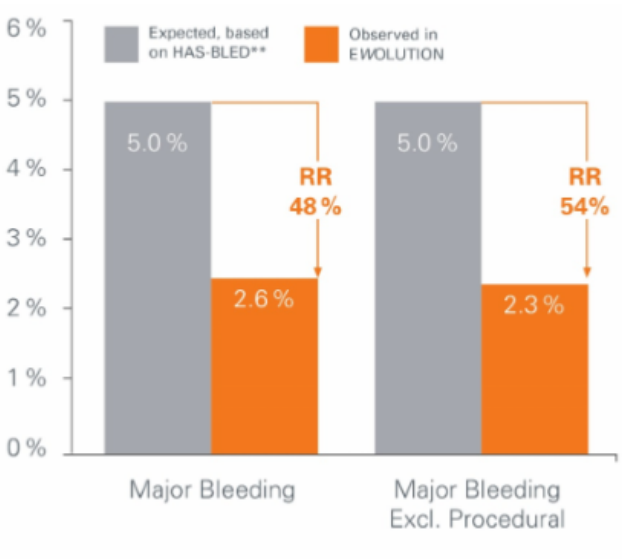
Effectiveness in Ischemic Stroke and Bleeding Rate Reduction – Annual Rates[1]





* Effectiveness in stroke reduction vs. estimated in the absence of therapy for comparable CHA_2DS_2-VASc scores based on Friberg et al. EHJ 2012.
** Effectiveness in bleeding reduction vs. estimated under VKA therapy for comparable HAS-BLED scores based on Lip et al. JACC 2011.

EWOLUTION

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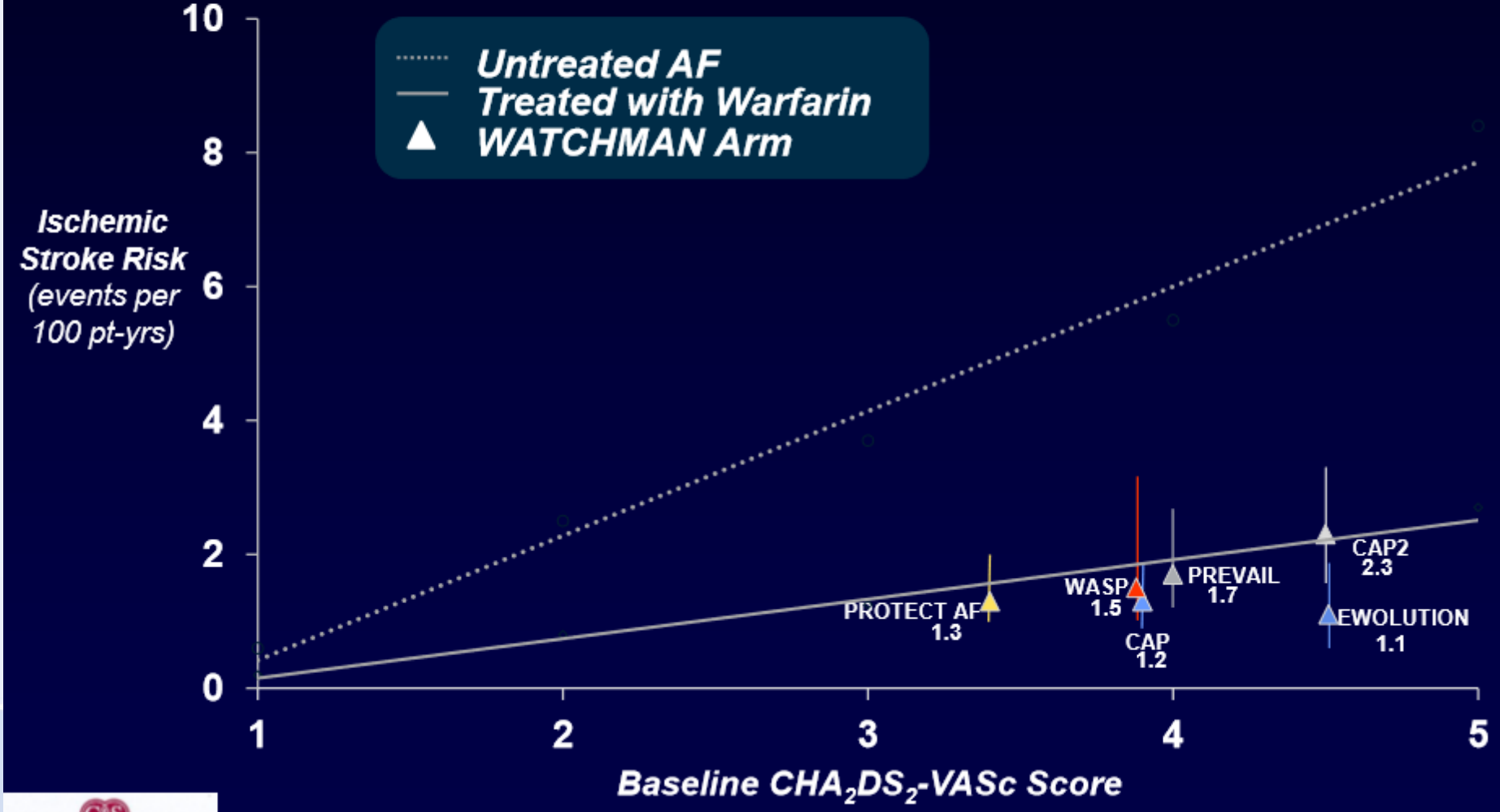
IKEM

Results

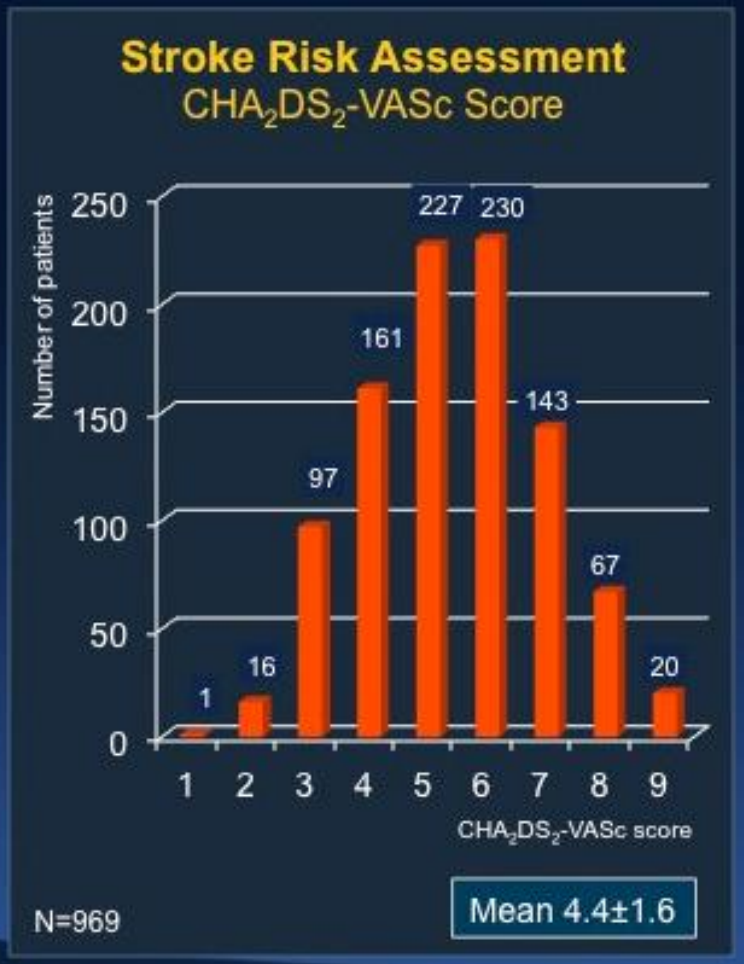
WATCHMAN Comparable to Warfarin for Ischemic Stroke

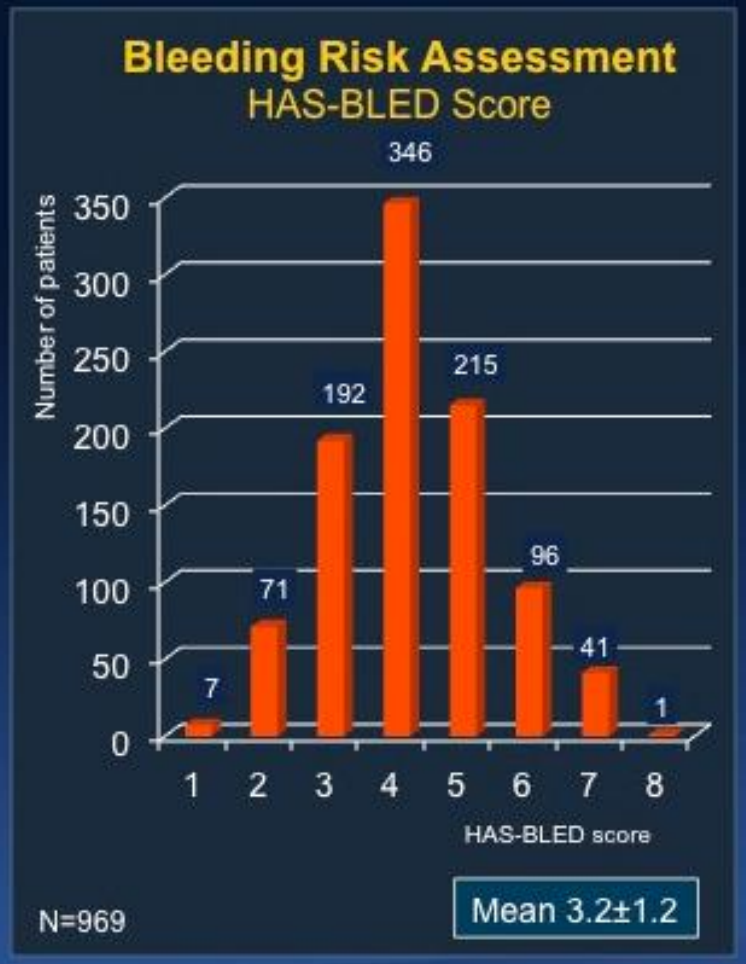


CEDARS-SINAI MEDICAL CENTER

EWOLUTION: Boersma Lva et al Heart Rhythm 2017;doi-10.1016/j.hrthm.2017.05.038; WASP: Philips K, et al.Journal of Arrhythmia (in press).

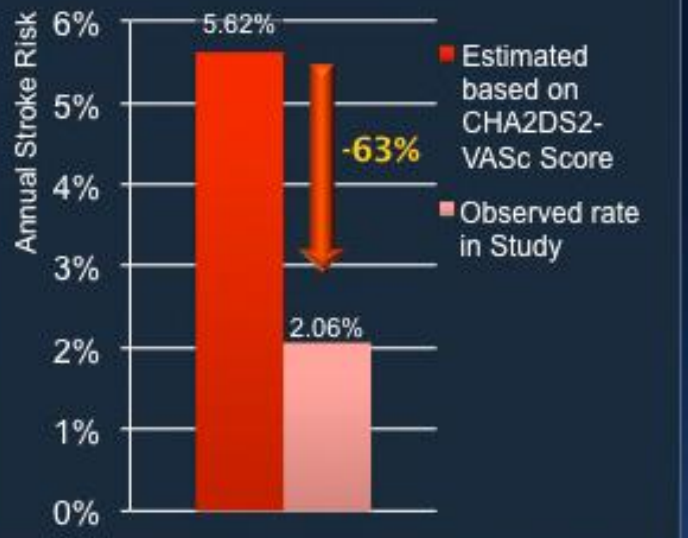
Risk assessment





Results

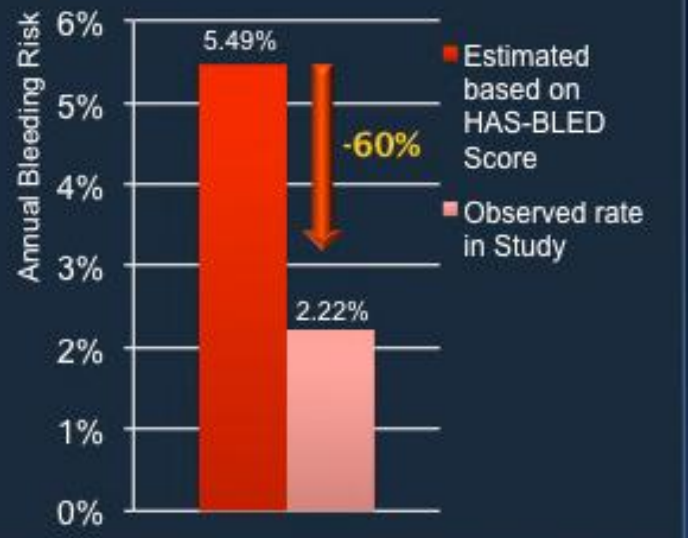
Effectiveness in Stroke Reduction vs estimated



Total Patients	Total Patient Years	CHA_2DS_2-VASc score
928	1216.2	4.41

Estimated Stroke Rate per $CHA2DS_2$-VASc	Actual Annual Stroke Rate (N strokes + TIA)
5.62%	2.06% (25)

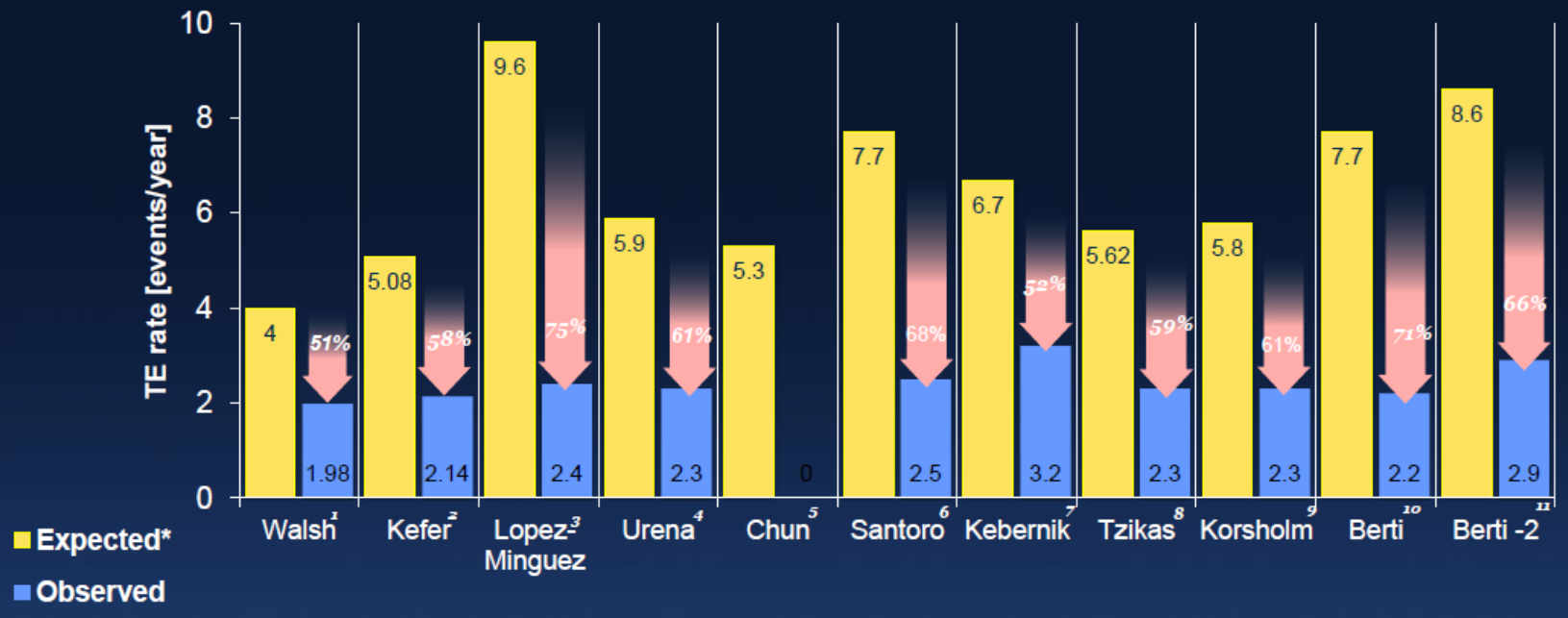
Effectiveness in Bleeding Reduction vs estimated



Total Patients	Total Patient Years	HAS-BLED score
928	1216.2	3.18

Estimated Bleeding Rate per HAS-BLED	Actual Annual Bleeding Rate (N major bleeds)
5.49%	2.22% (27)

Expected and observed stroke rates in AMPLATZER™ LAA Occluders



Patients	204	75	158	52	40	128	89	1001	107	110	542
Patient years	101	75	290	87	NR	238	93	1349	265	264	896
Strokes/TIAs	2	2	7	2	0	5	3	31	6	6	16
TEreduction [%]	51%	58%	75%	61%	N/A	68%	52%	59%	61%	71%	66%

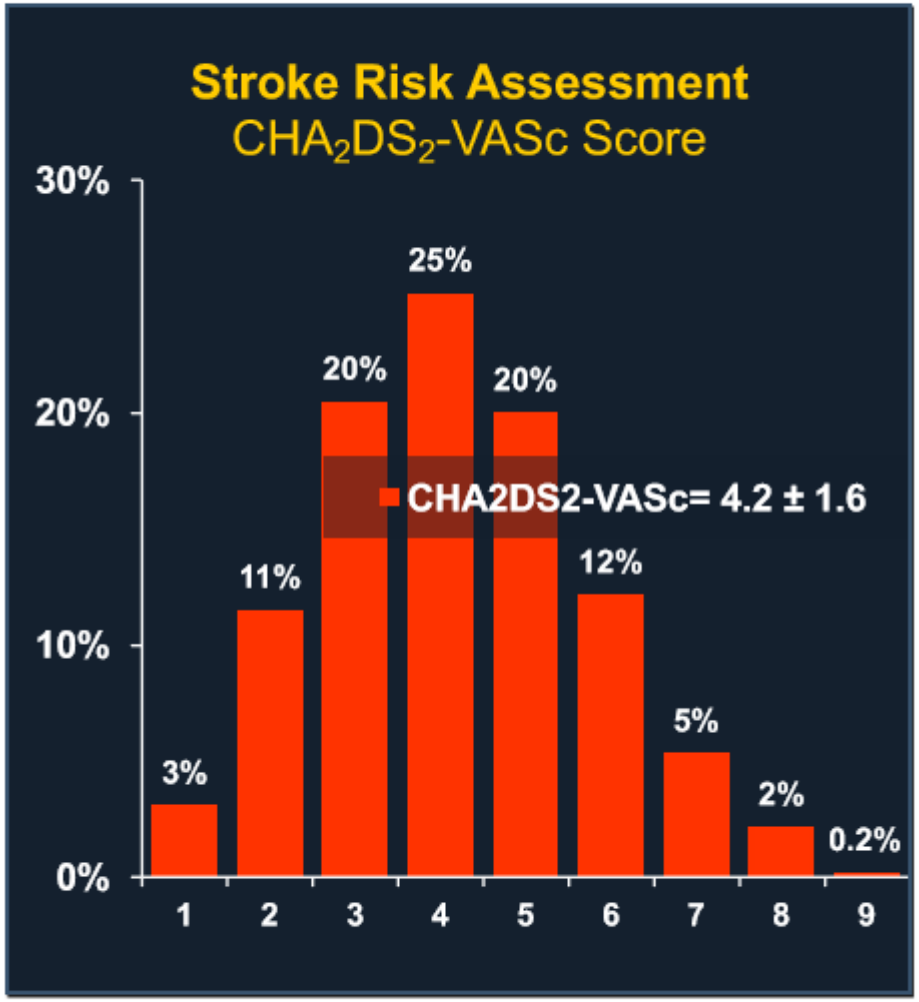
1. Walsh et al. Presented at EuroPCR, Paris. 2012
2. Kefer, J. et al. Acta Cardiolog. 201368(6); 551-558
3. López-Mínguez et al. Heart. 2015;101:877–883.
4. Urena et al. JACC Cardiovascular Interventions, 2013. 62, 96-102.
5.Chun et al. Heart Rhythm, 2013 10, 1792-1799.
6. Santoro et al. EuroIntervention, 2016. 11(10), 1188-1194
7. Kebernik et al. Cardiology and Therapy, 2015. 4(2), 167-177.
8. Tzikas et al. EuroIntervention, 2016. 11(10), 1170-1179.
9. Korsholm et al. EuroIntervention. 2017;12:2075-2082.
10 Berti et al. Heart. 2016;102:1969-1973.
11. Berti et al., Int J Cardiol. 2017 Jul 16. pii: S0167-5273(17).

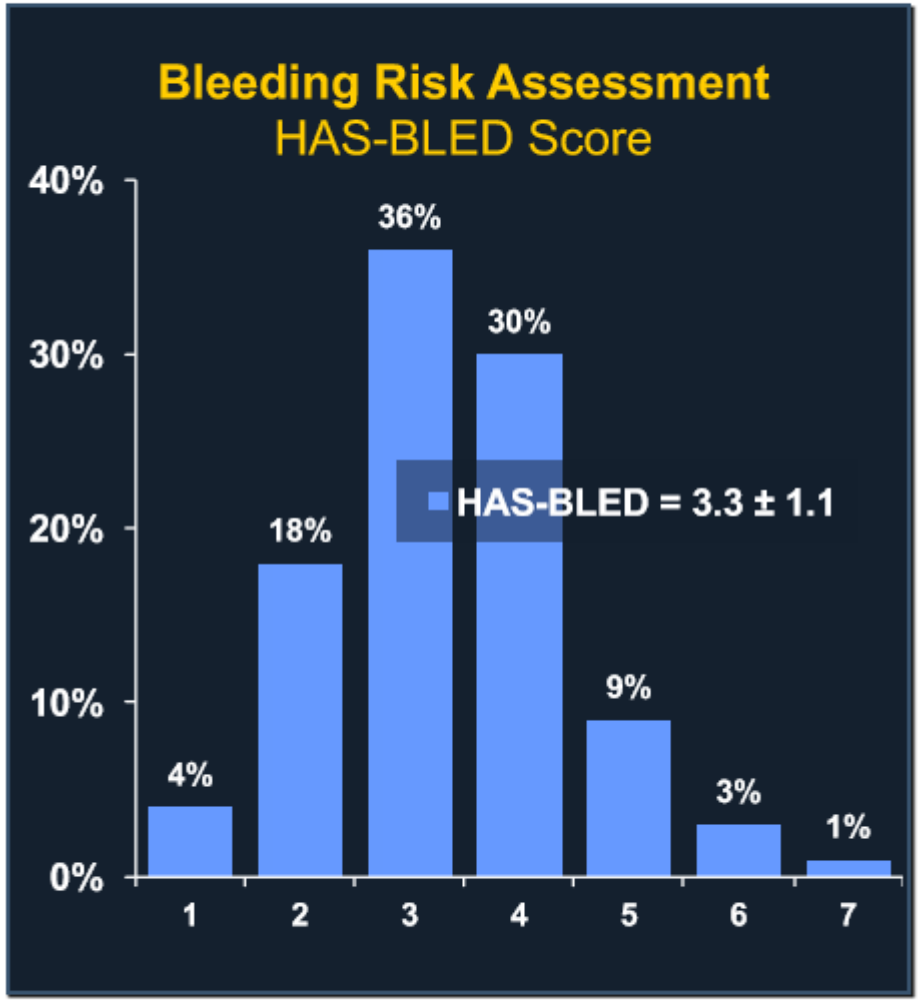
Results: Patient Population

	Mean ± SD or % n=1071*
Age (years)	75 ± 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_2DS_2-VASc Score $\geq$ 4	65%
HAS-BLED $\geq$ 3	58%

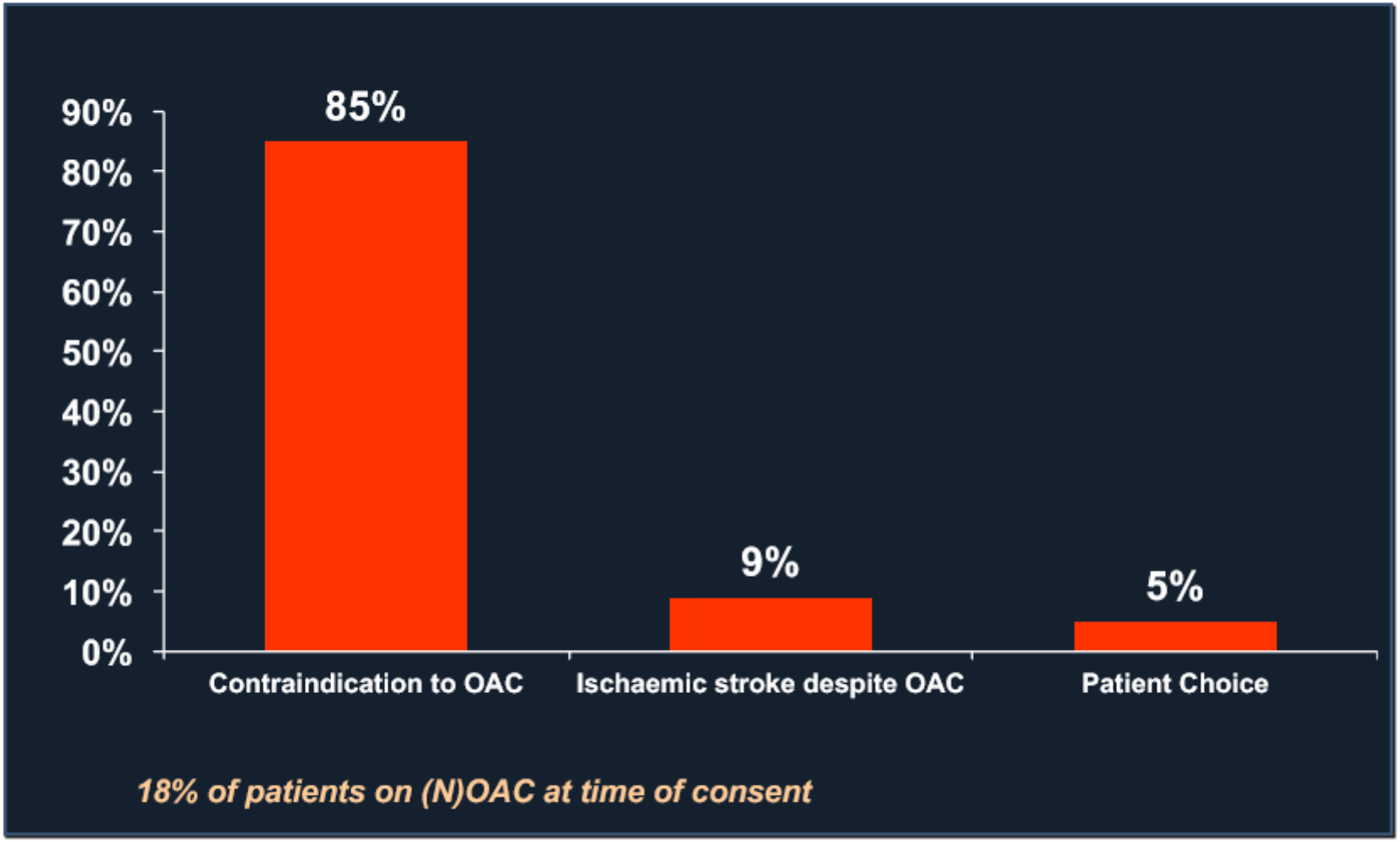
*Baseline data unavailable in 2 patients

Stroke and Bleeding Risk





Results: Indication for Procedure



Implant Procedure

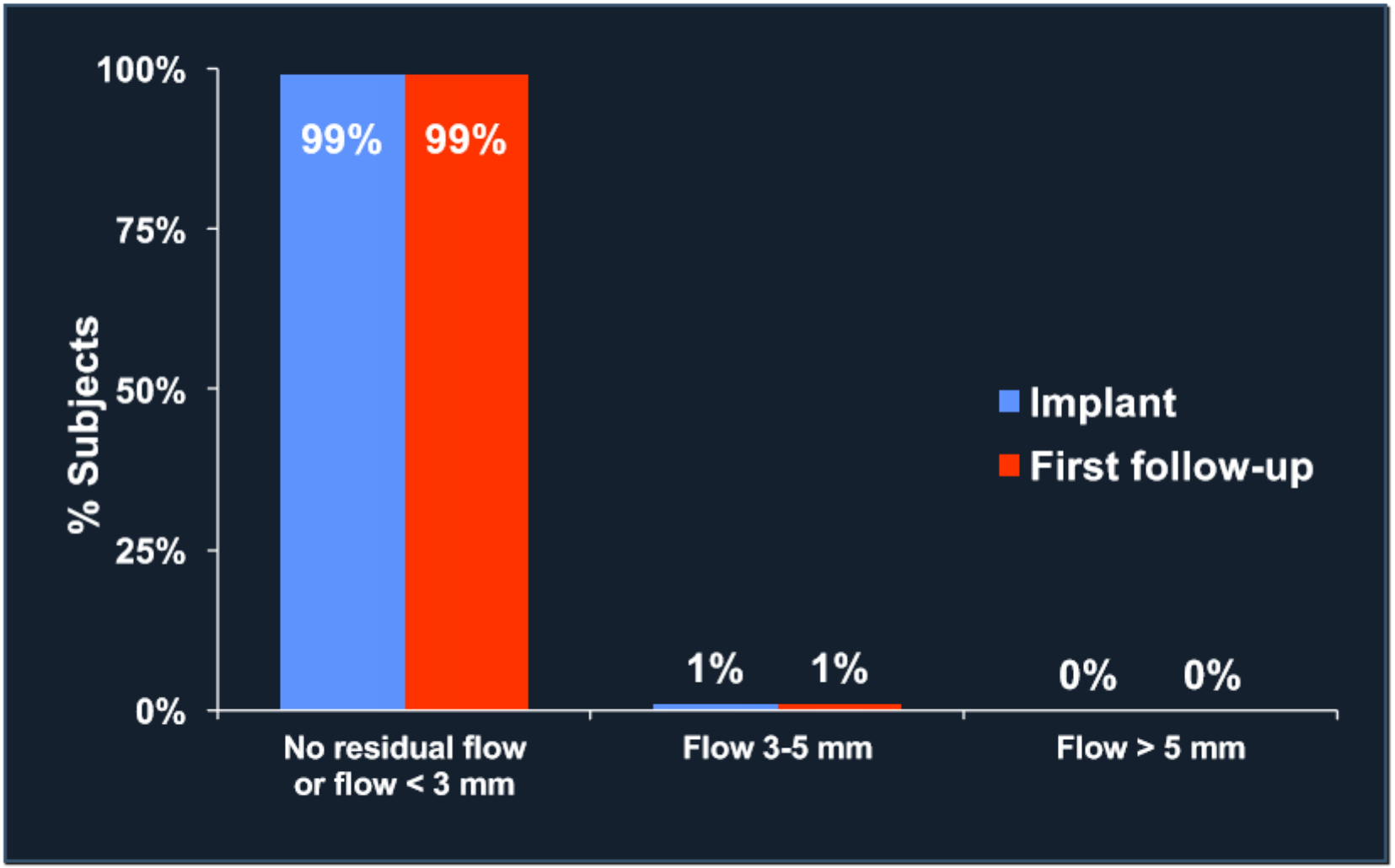
Imaging modality	% (n)
Intracardiac echo	10% (107)
Transoesophageal echo	90% (966)

Device Selection	% (n)
First device selected implanted	93% (995)

Major Adverse Events

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

TEE verified LAA Closure Rate



Independent Echo Core lab utilized for analysis

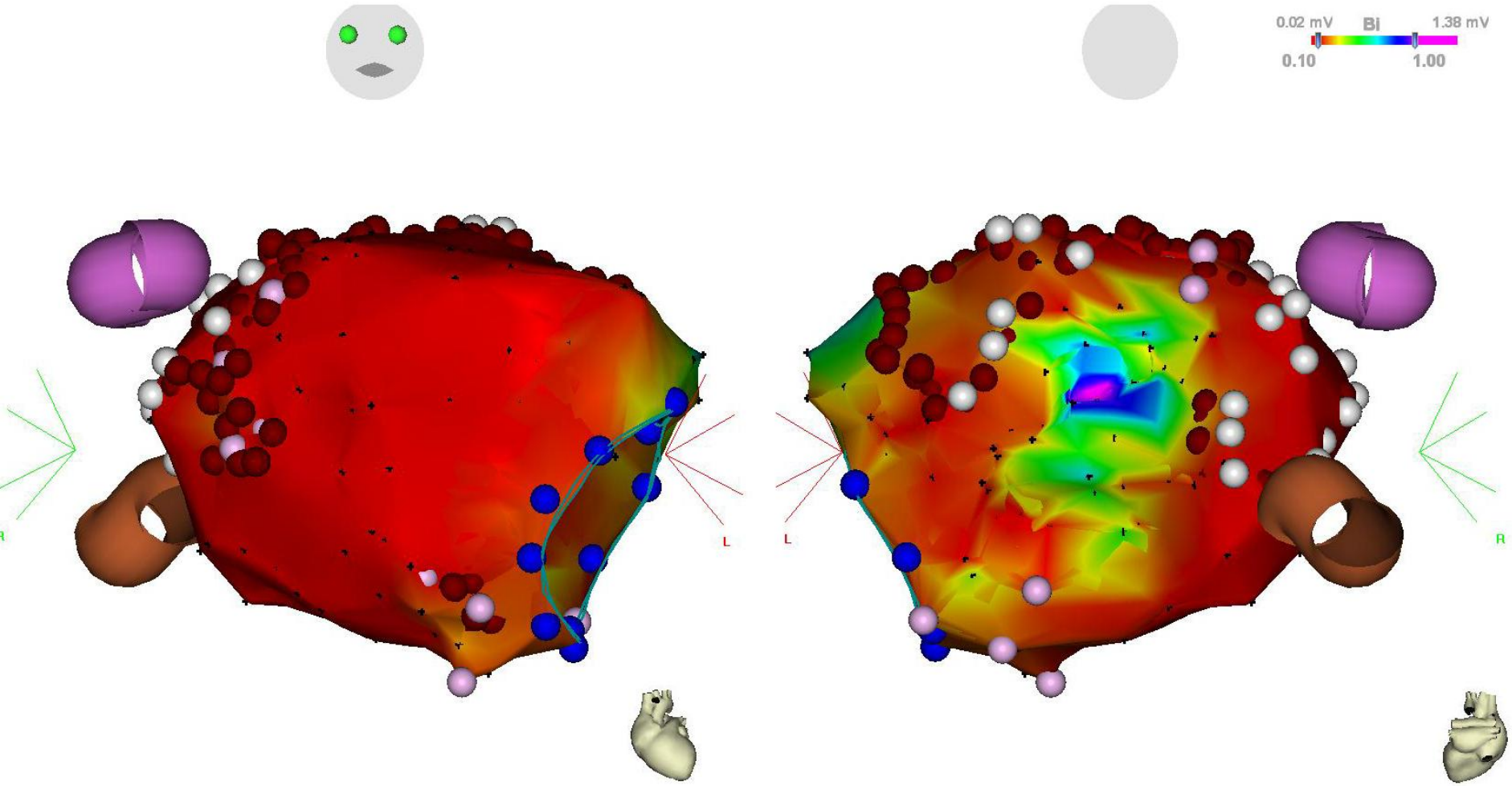
Safety Comparison

	Watchman EWOLUTION[1] 1025 pts	Amplatzer Amulet Amulet Registry[2] 1088 pts
Implant Success	98.5%	99.0%
LAA Closure Rate (1-3 months)	99.3% < 5mm	99.6% < 3mm
Device or Procedure-Related Complications	2.7%	3.2%
Early Mortality	0.7%	0.2%

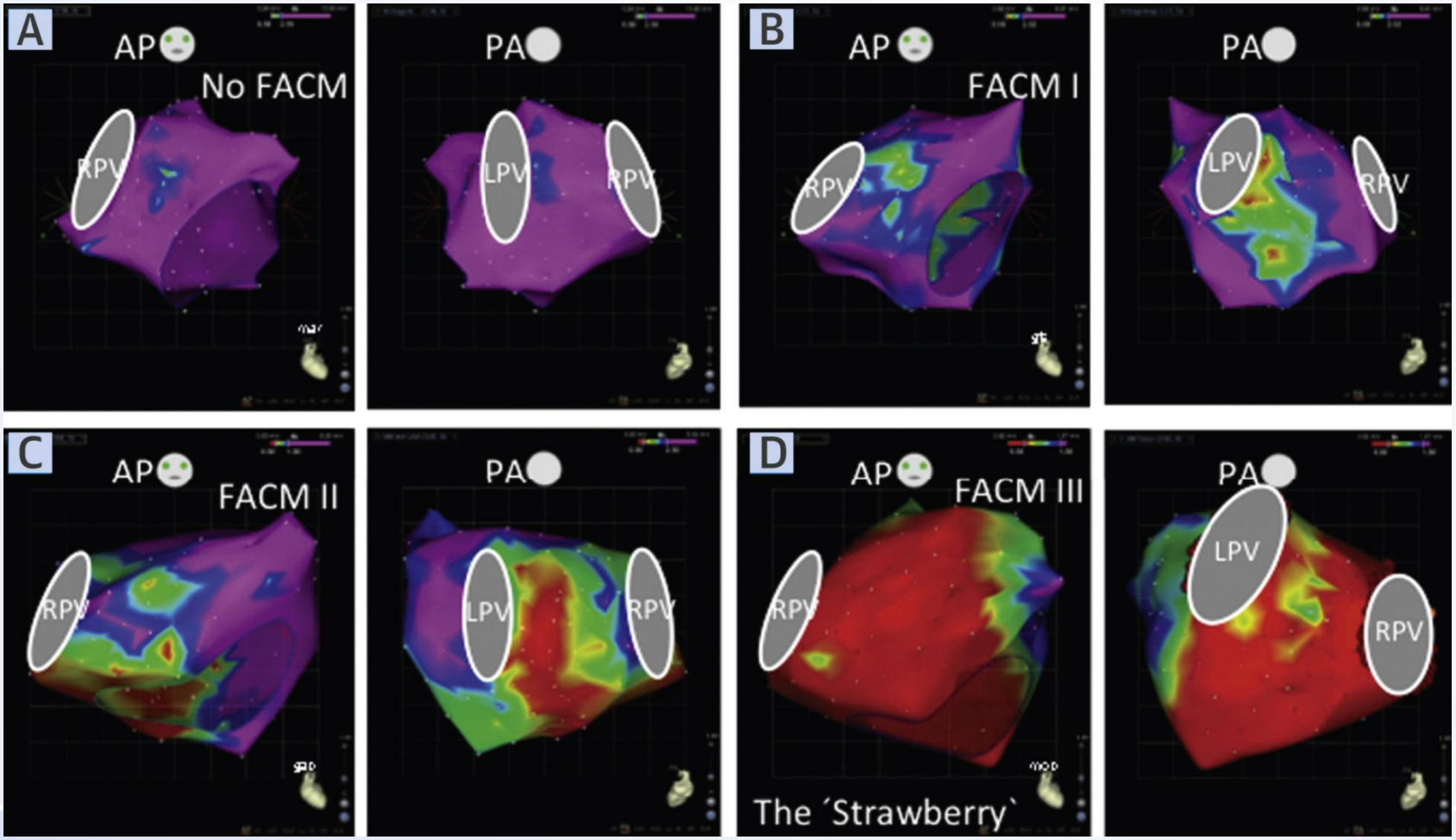
[1] Boersma et al. *Eur Heart J*. 2016
[2] Landmesser et al. *Eurointerv*. 2017

- 51-letá žena
- hypertense
- 10-letá anamnéza paroxysmální FiS
- 2011 implantatace 2D PM
- ECHO: LAVI 39.5 cm3/m2
- 01/2015 ablace persistentní FiS
  - časná rekurence, trvání Fis 1 rok

Pulmonary vein isolation



Fibrotic atrial cardiomyopathy



Kottkamp H JACC 2015

Recordings of the LAA in the end of the procedure

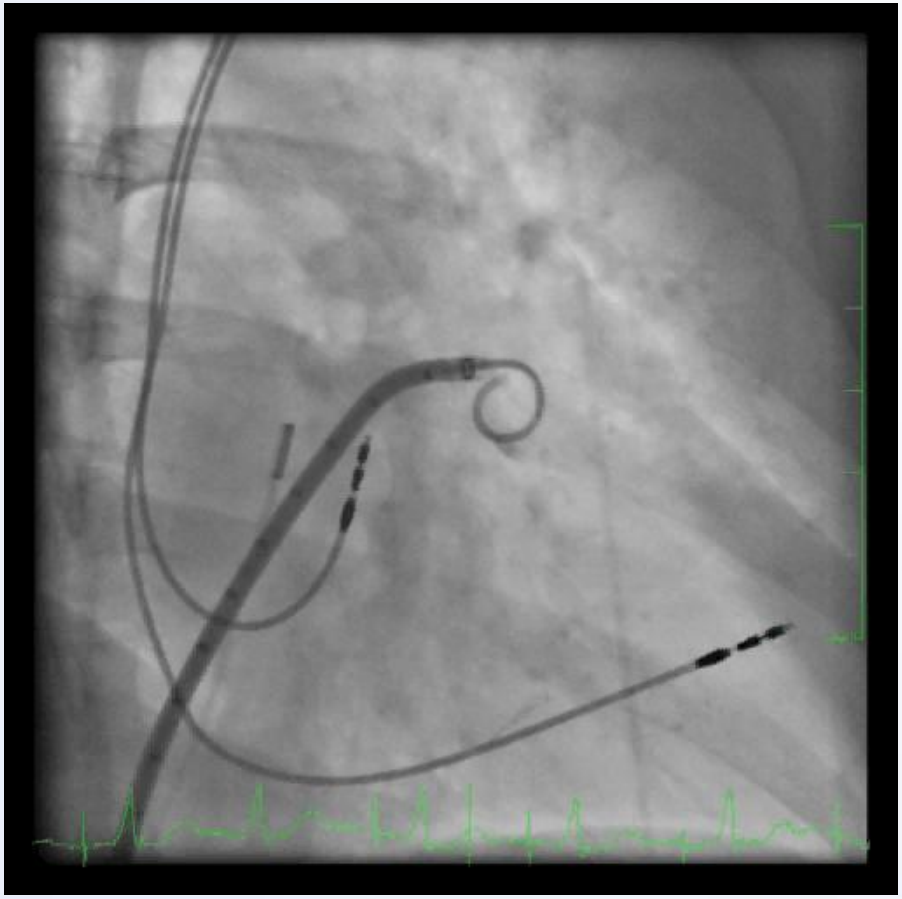
Osud po IPŽ

- Dimise na Xareltu
- 2 týdny po ablaci utrpěla iCMP – okluze ACM l. sin. – léčena mechanickou trombektomií
- TEE – LAA bez trombu, mírná dilatace LS - LAVi 39.5 cm^3/m^2
- Rekurence FiS/SVT v paměti PM

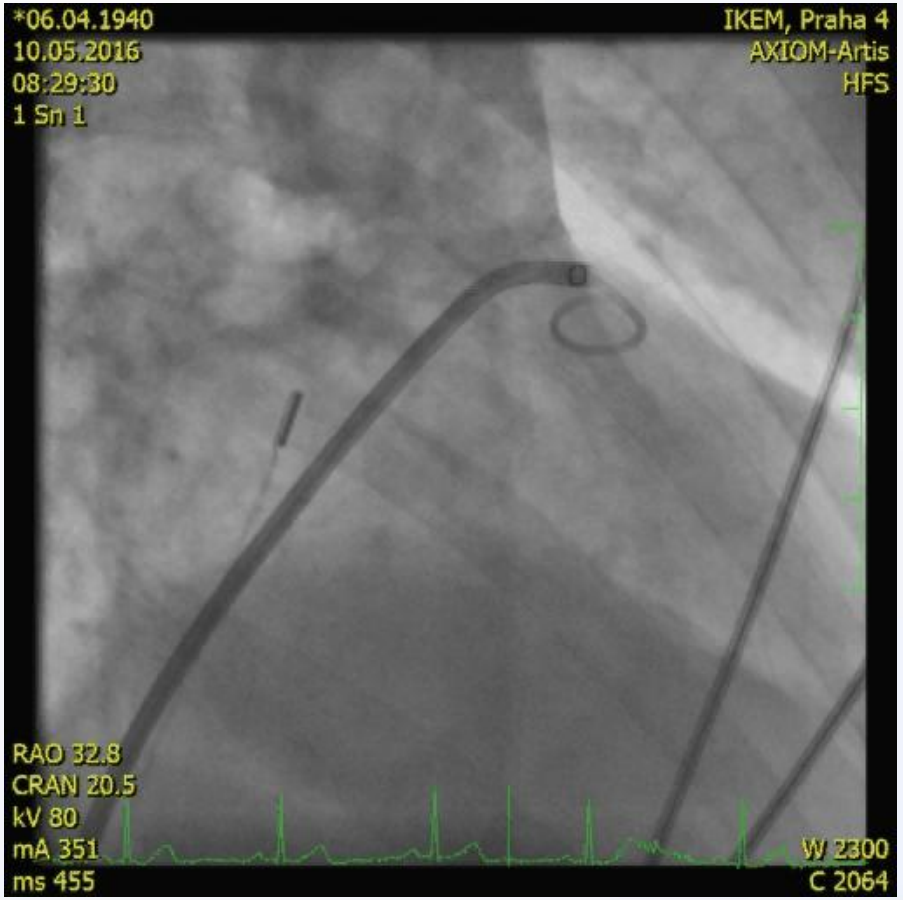
Strategie výkonu

Pac. No	Celková anestezie	TRA pigtail Ao	TEE na punkci IAS	TEE guiding	ICE na punkci IAS	ICE guiding
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						

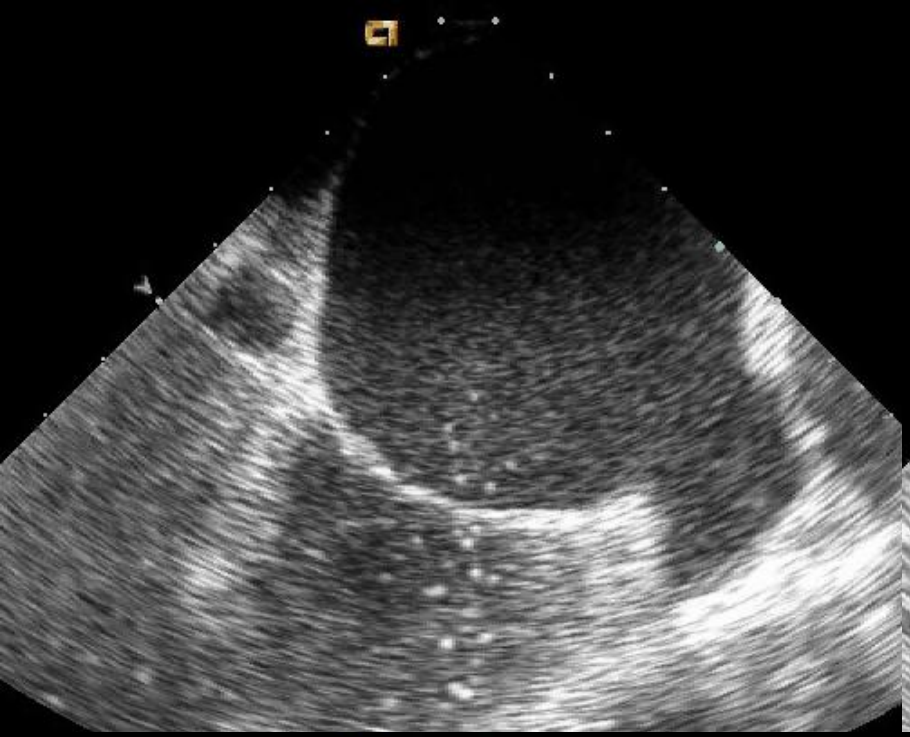
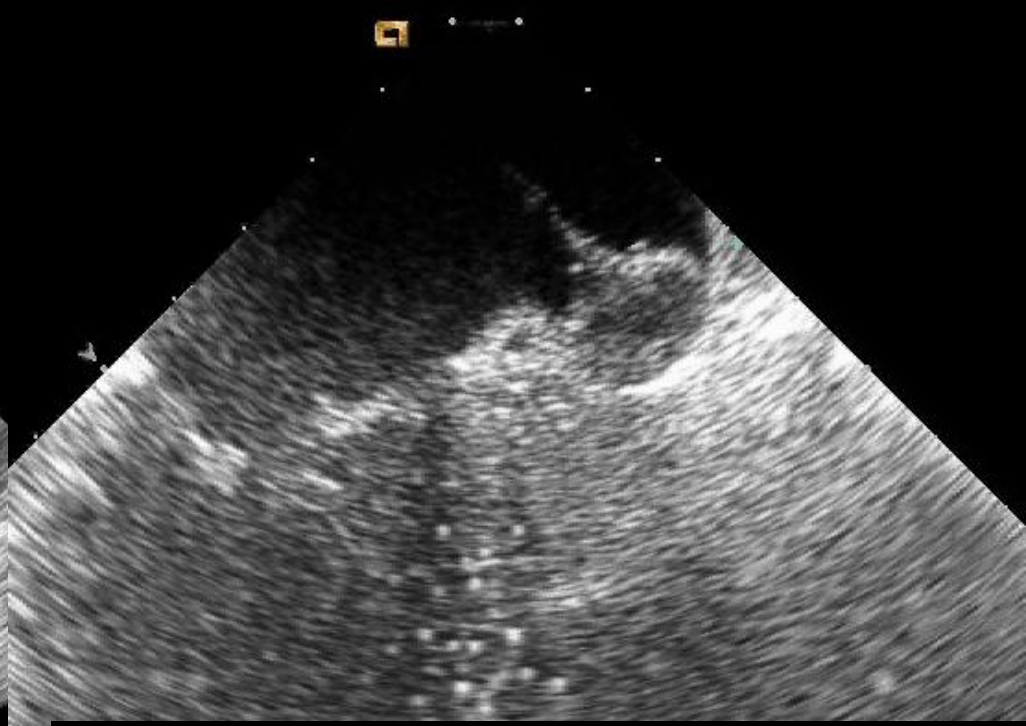
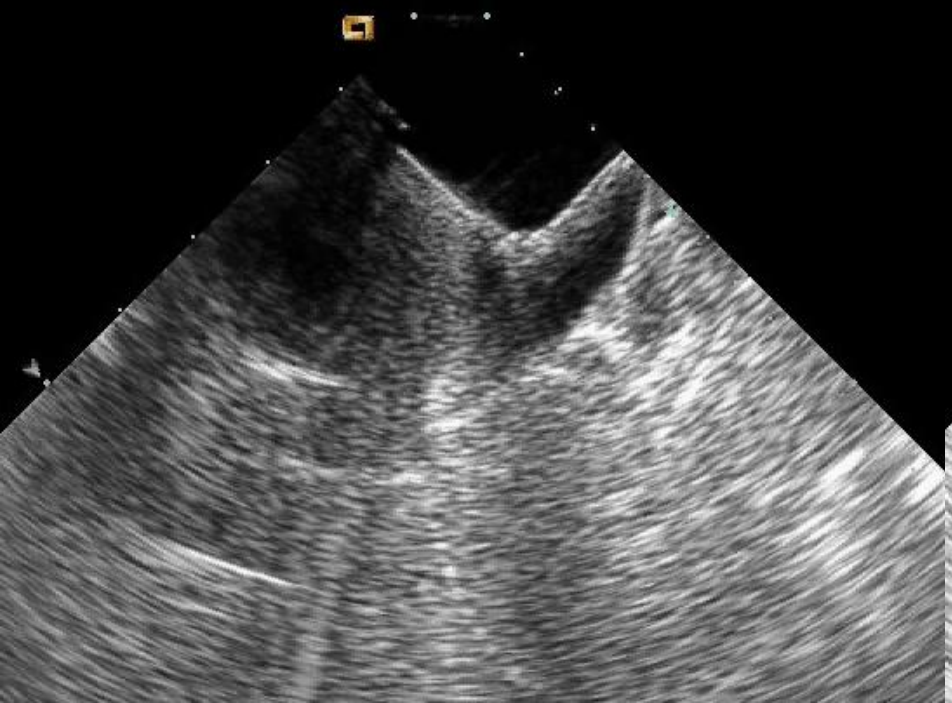
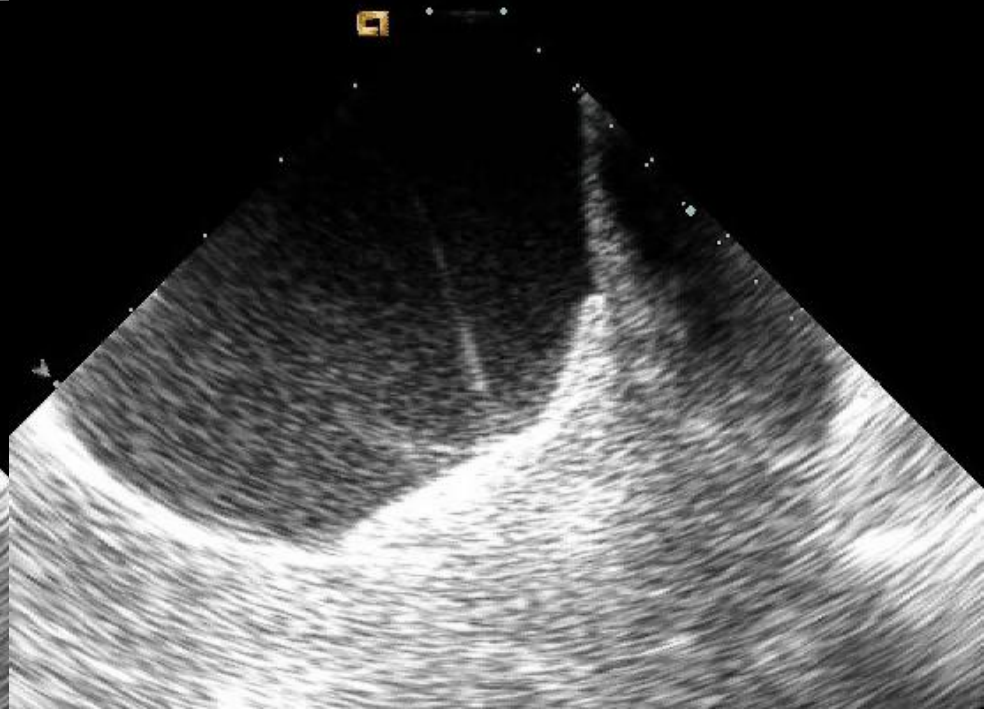
LAA angiography and occlusion

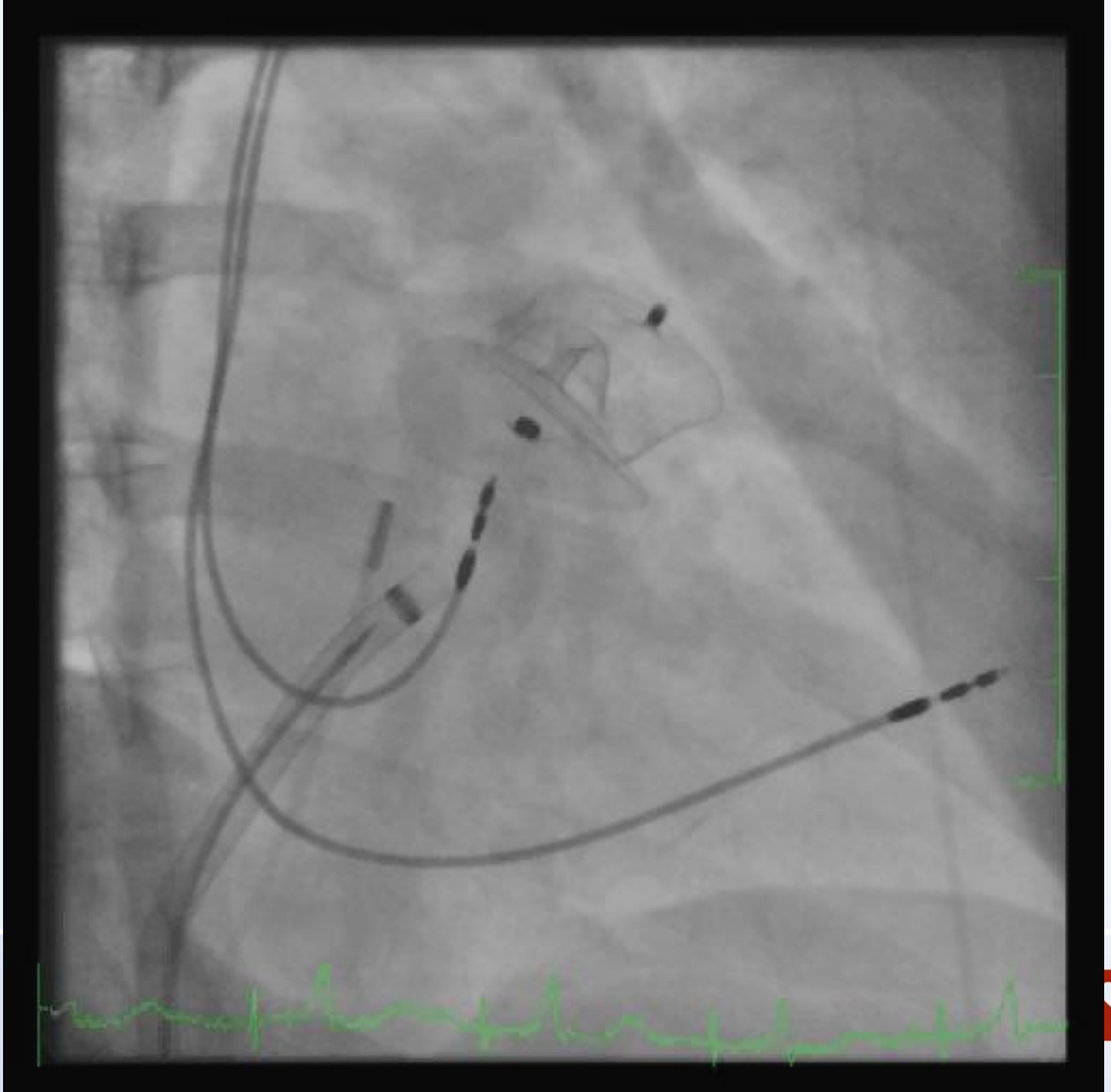


Absence of any contraction despite absence of arrhythmia!



Normal contraction of LAA in different patient



Závěry I

- Polovina, v tom nejrizikovější nemocní, není chráněna proti riziku systémového tromboembolismu, především ischemické CMP
- Řada adekvátně léčených nemocných s FiS je ohrožena krvácivými komplikacemi léčby
- Uzávěr ouška levé síně je vysoce úspěšný v prevenci systémové embolie/krvácení
- Úspěšnost procedury blízko 100%

Závěry II

- Popisujeme případ fibrotické myopatie LS nejasné etiologie, která vedla k dysfunkci ouška LS analogické stavu elektrické izolace ouška LS
- Tento stav je spojen s vysokým rizikem tromboembolických komplikací
- Katetrizační uzávěr ouška LS má potenciál snížit toto riziko