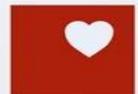


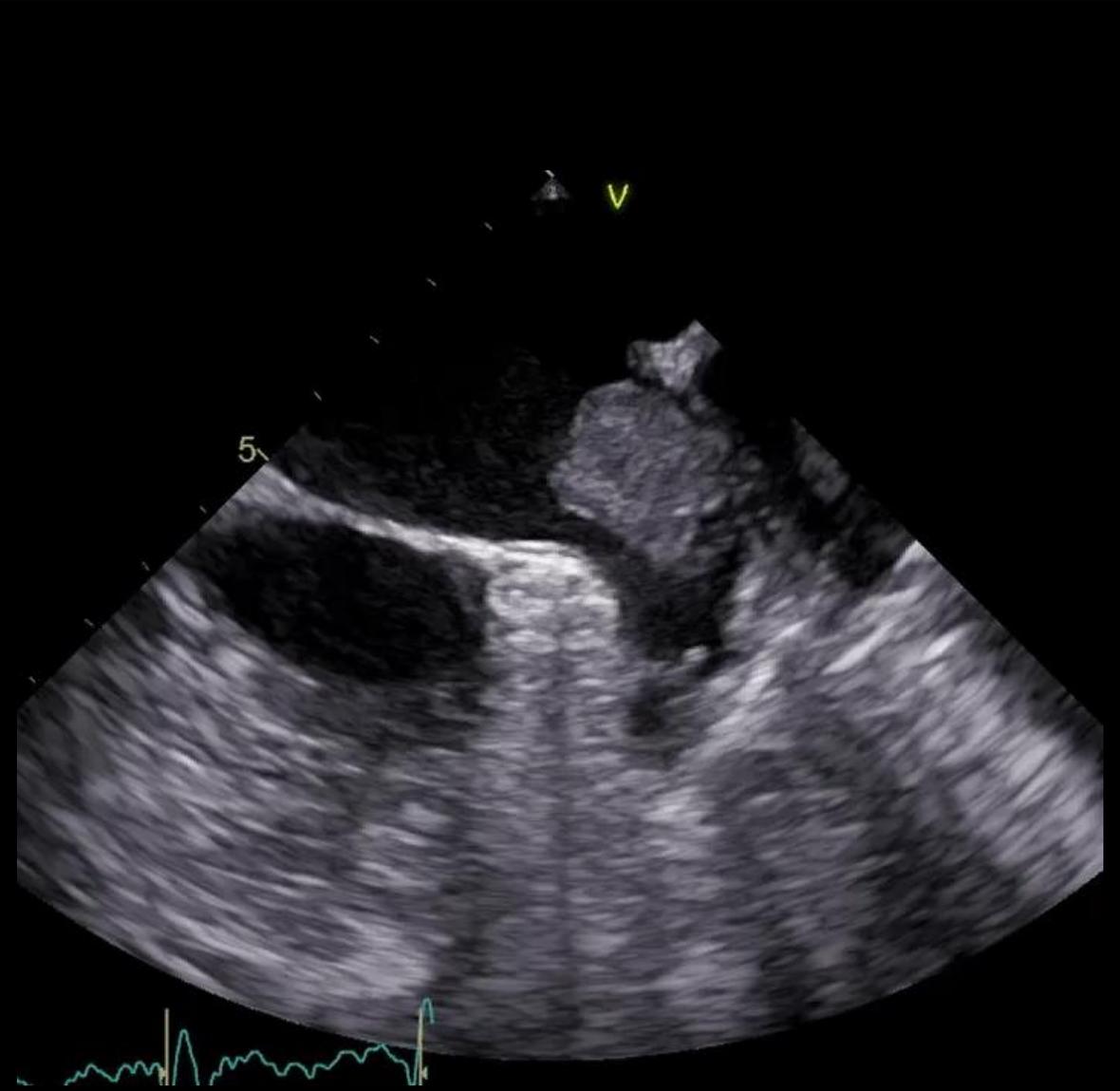
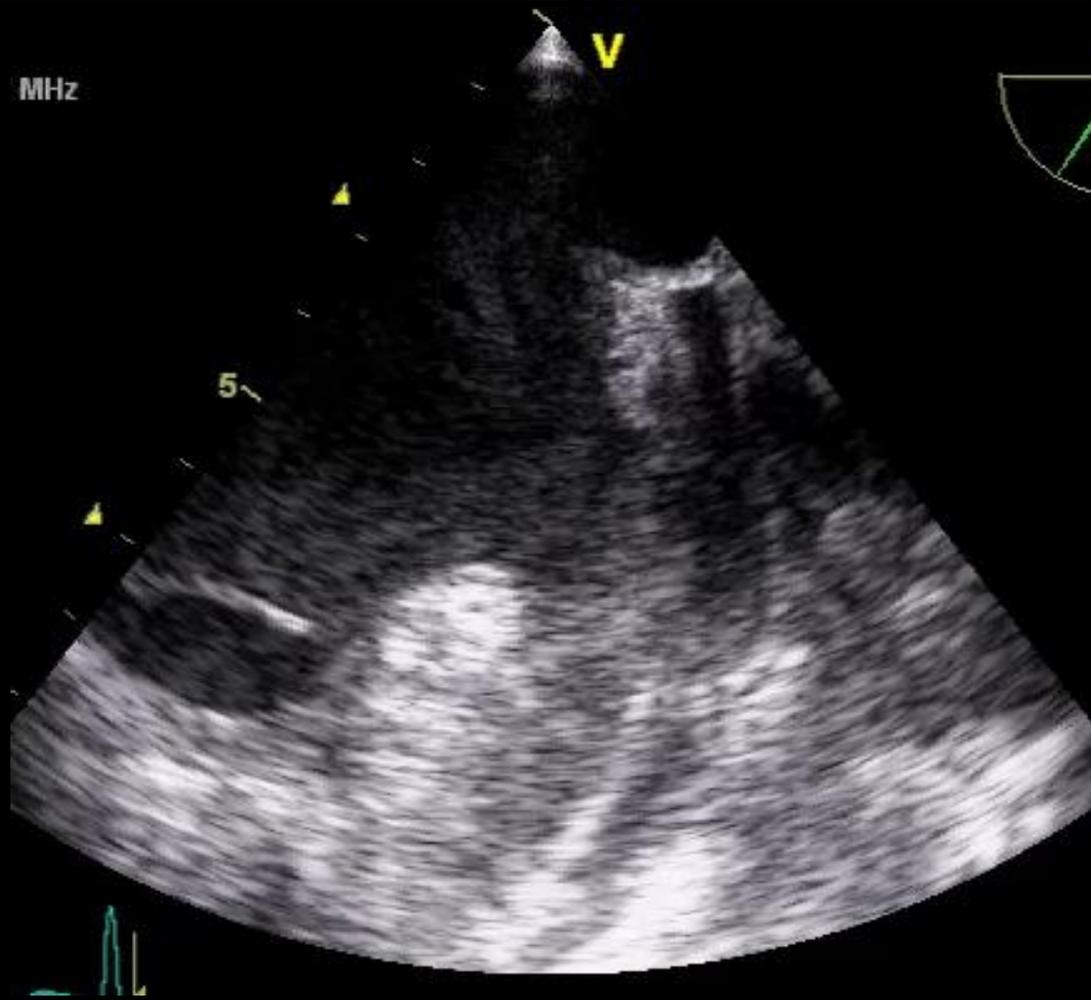
# Jak jsem na tom s uzávěry ouška levé síně?

Co je nového v arytmologii v našich krajích?  
Symposium firmy Cardion

Petr Peichl, Klinika kardiologie IKEM



# Sludge/trombus v oušku LS



# Antikoagulační léčba

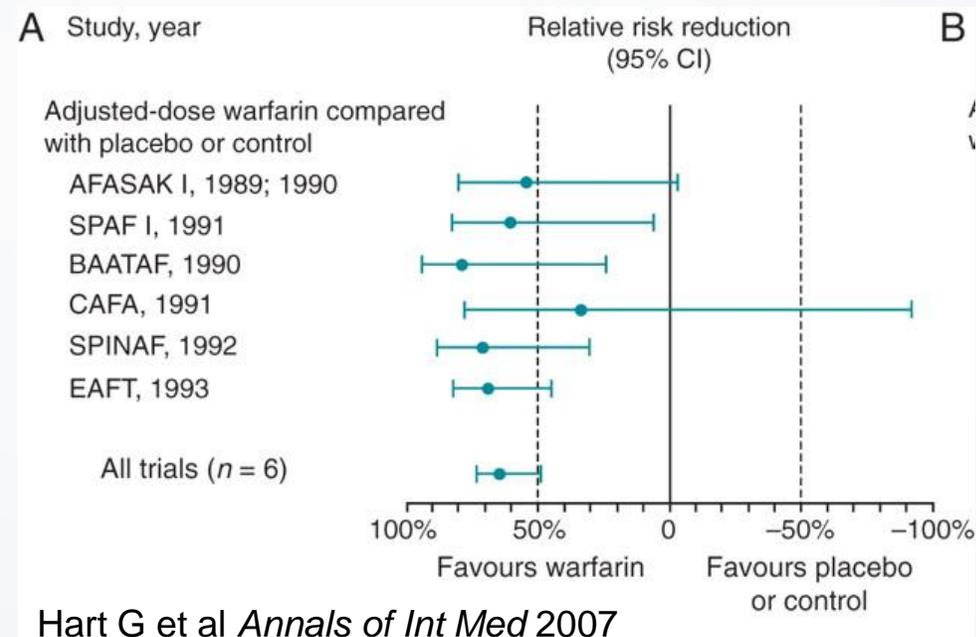
## Hart G et al *Annals of Int Med* 2007

Metaanalýza studií srovnající warfarin s kontrolami či placebem

- Redukce rizika CMP o 64%
- Redukce riziko mortality o 26%

## Ale...

- ... musí být užívána doživotně
- ... zvyšuje riziko krvácení, které se dále zvyšuje s věkem
- U některých pacientů musí v určité fázi být antikoagulační léčba přerušena



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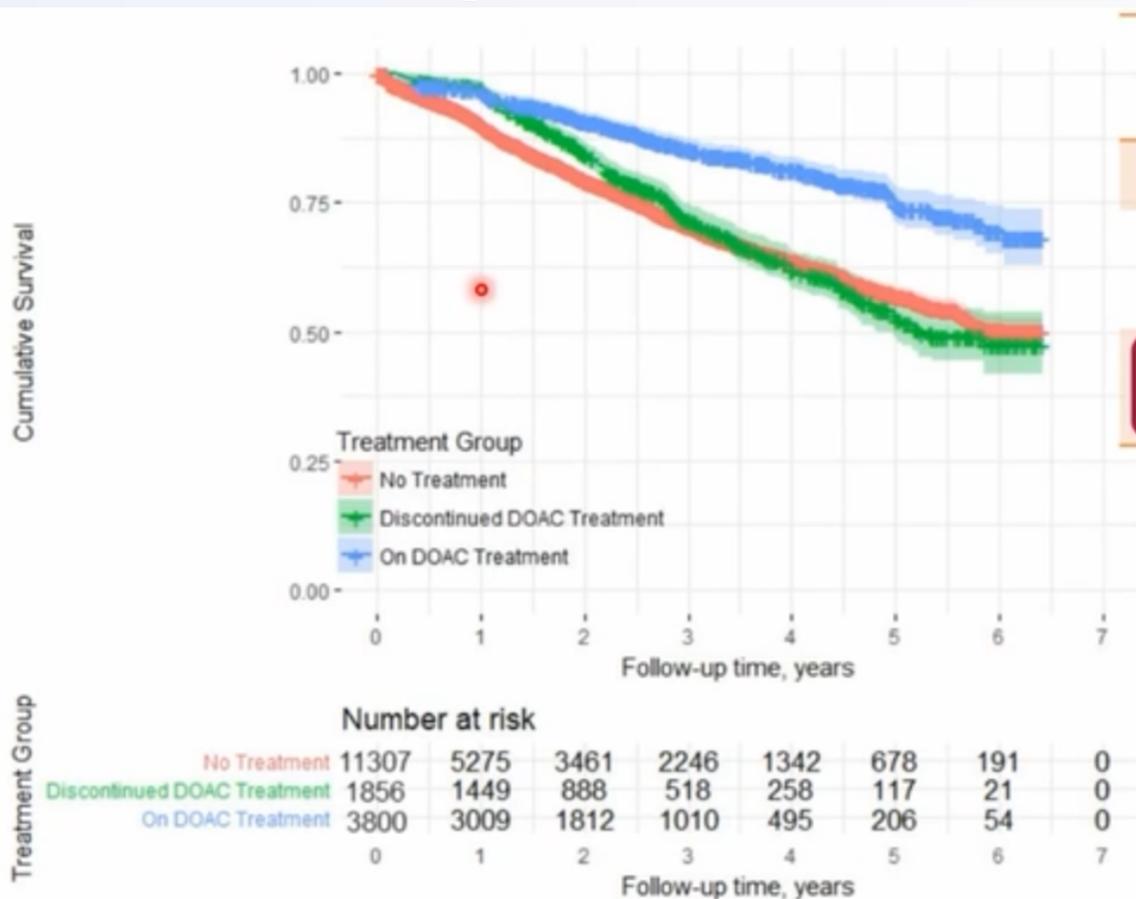
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# Adherence k NOAK a mortalita

## Data od pacientů s nově diagnostikovanou FiS



|                        | DOAC             | No Anticoagulant  | P-Value |
|------------------------|------------------|-------------------|---------|
| Population             | Deaths/100pt-yrs | Deaths/ 100pt-yrs |         |
| Continuous treatment   | 5.3              | 11.1              | < 0.001 |
| Discontinued treatment | 12.1             | 11.1              | 0.60    |

Results showed that continuous DOAC treatment yielded significant reductions in mortality, however, there was **no significant difference in mortality** between patients who **discontinued DOAC treatment** and those who received **no therapy**

# Percutaneous LAAC

# SURGICAL LAAC

## „BALL“ - TYPE

Watchman



WaveCrest



Watchman FLX Pro



## „DISC“ - TYPE

Amplatzer



LAMBRE



Amulet



Omega



## Suture

Lariat



In development

CLAAS

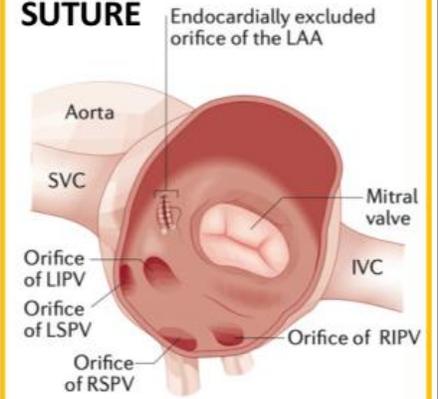


LAMINAR



## S-LAAC

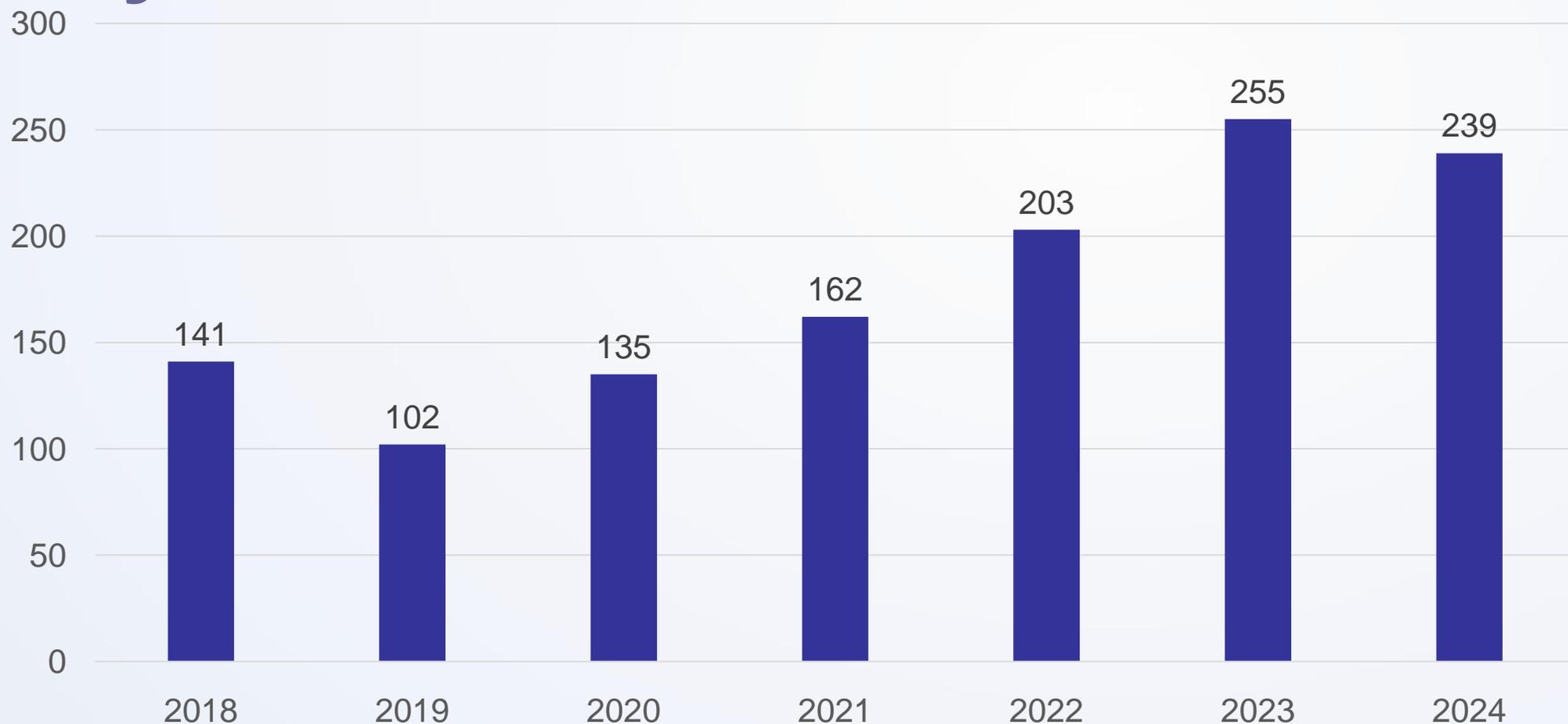
SUTURE



ATRICLIP



# Počty katetrizačních uzávěrů oušek v ČR

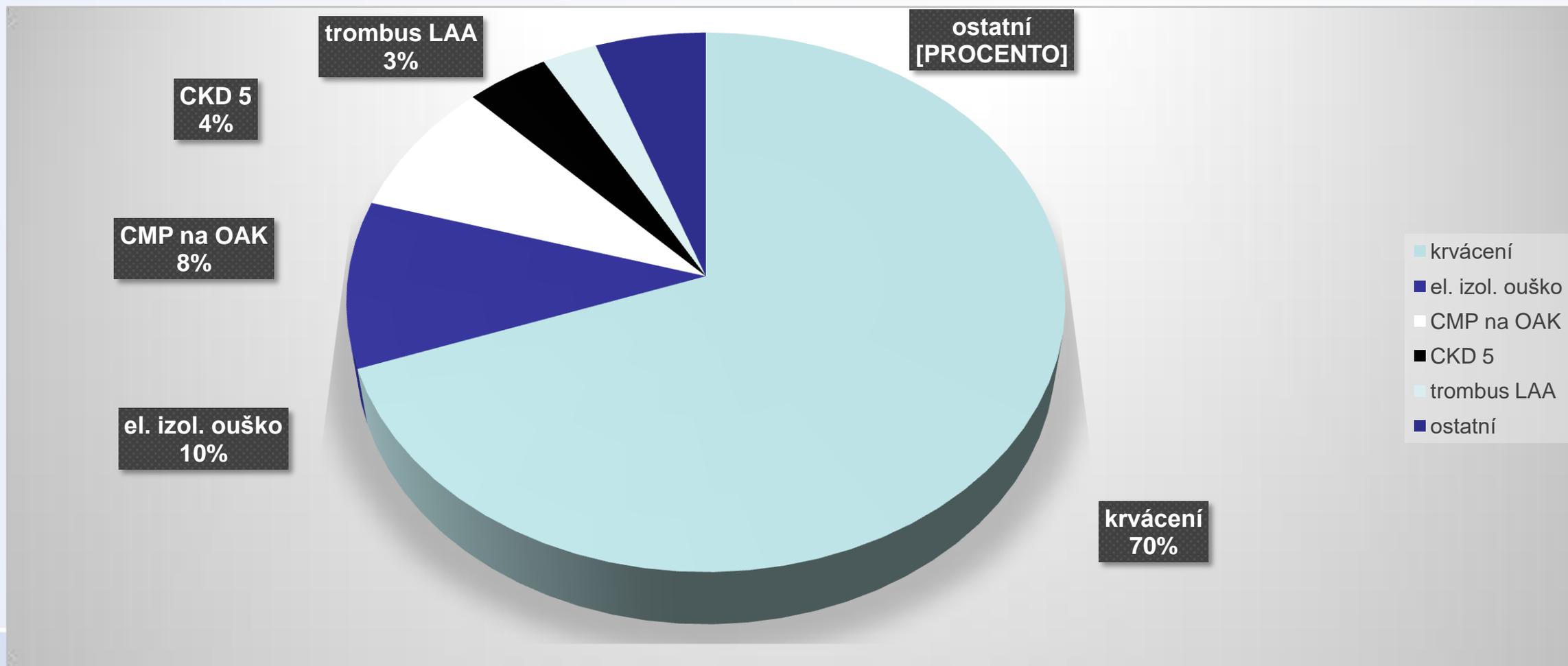


Zdroj: data od distributora

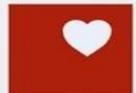


# Indikace k LAAO v IKEM (2014-2024)

n=284

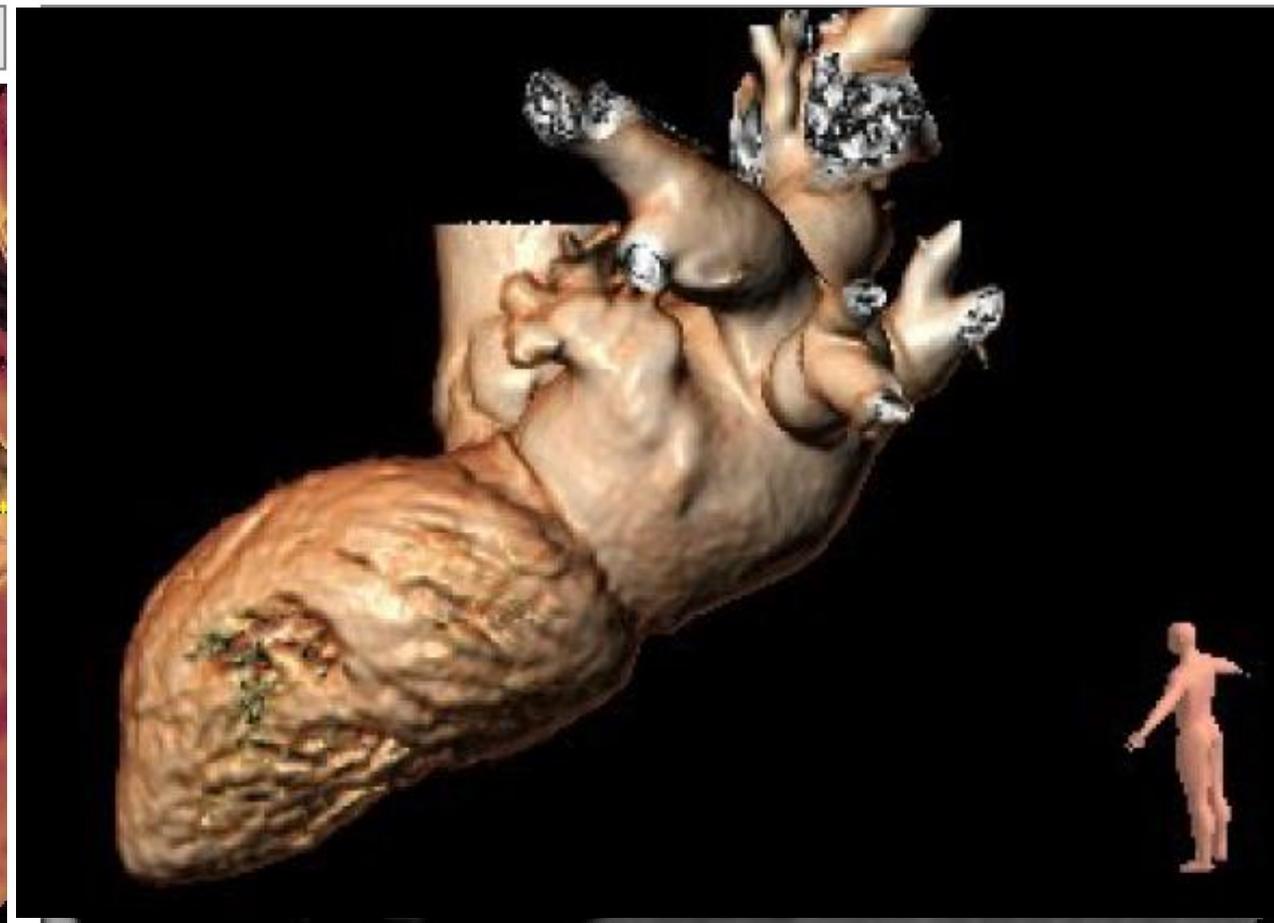
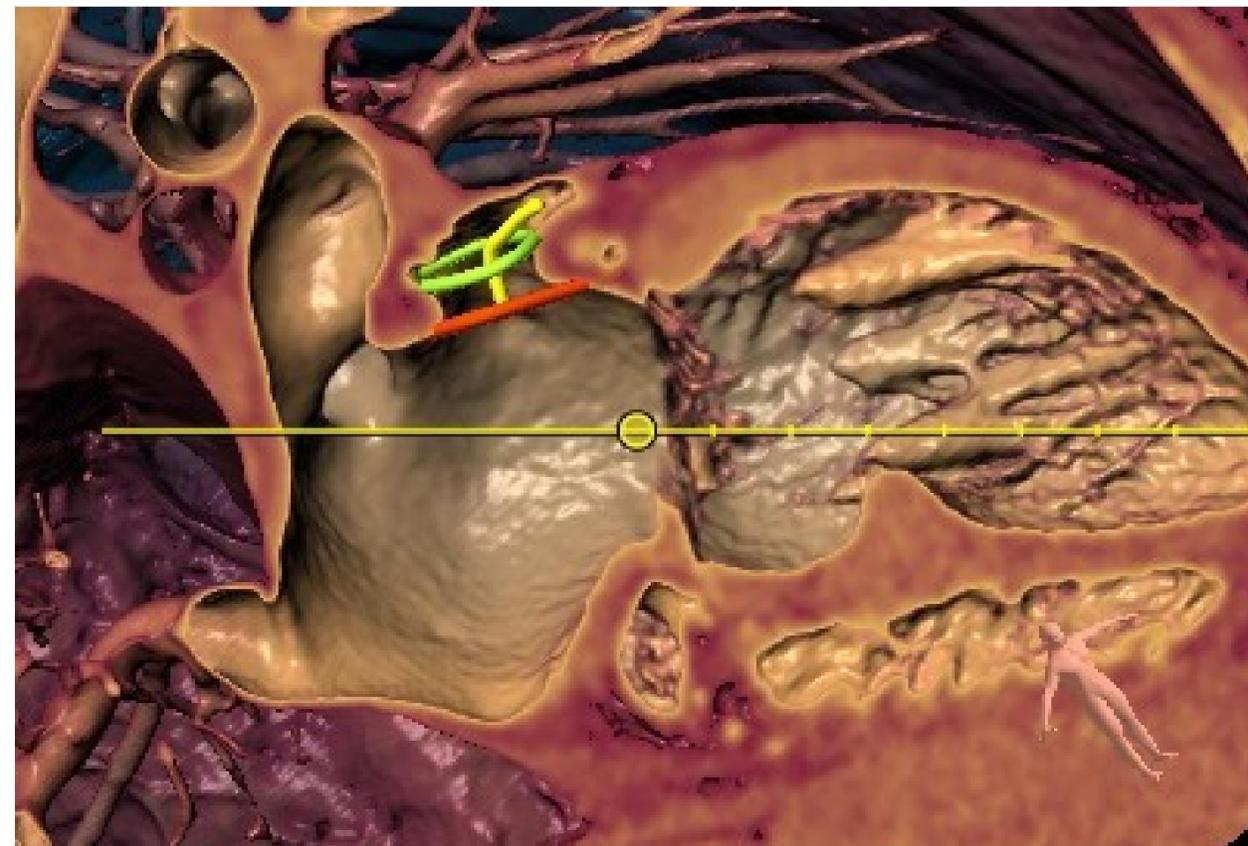


# Jak se okluze ouška provádí?

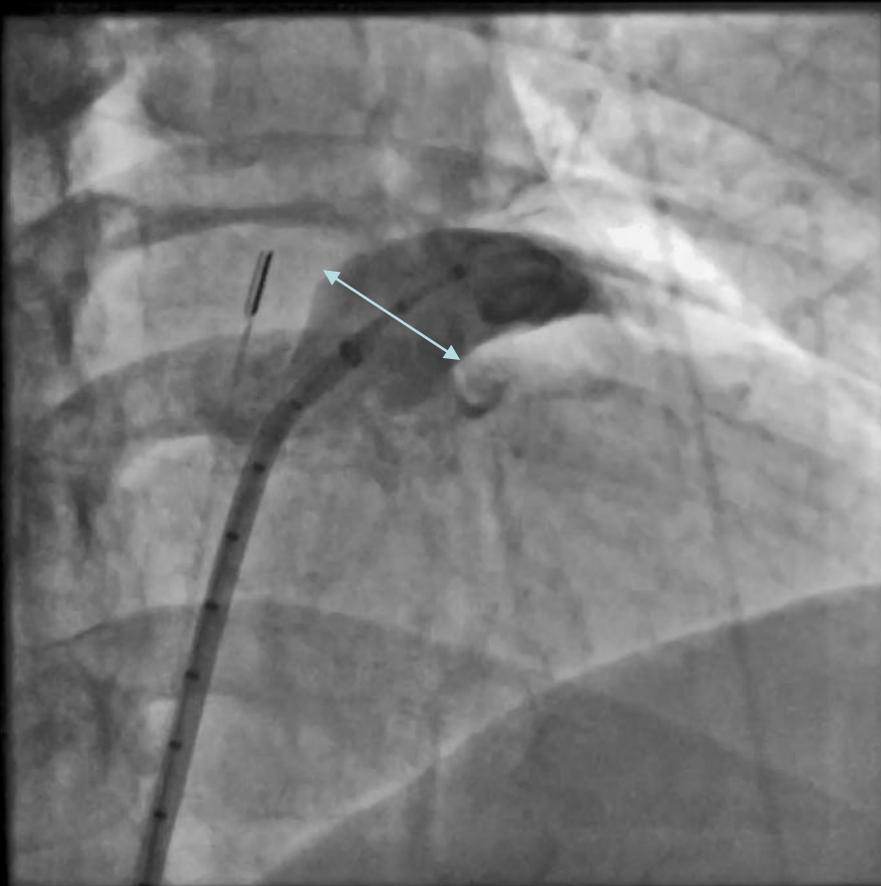


# Sizing - Trimensio

LAA 3D reconstruction



# Sizing...



RAO Cran 20



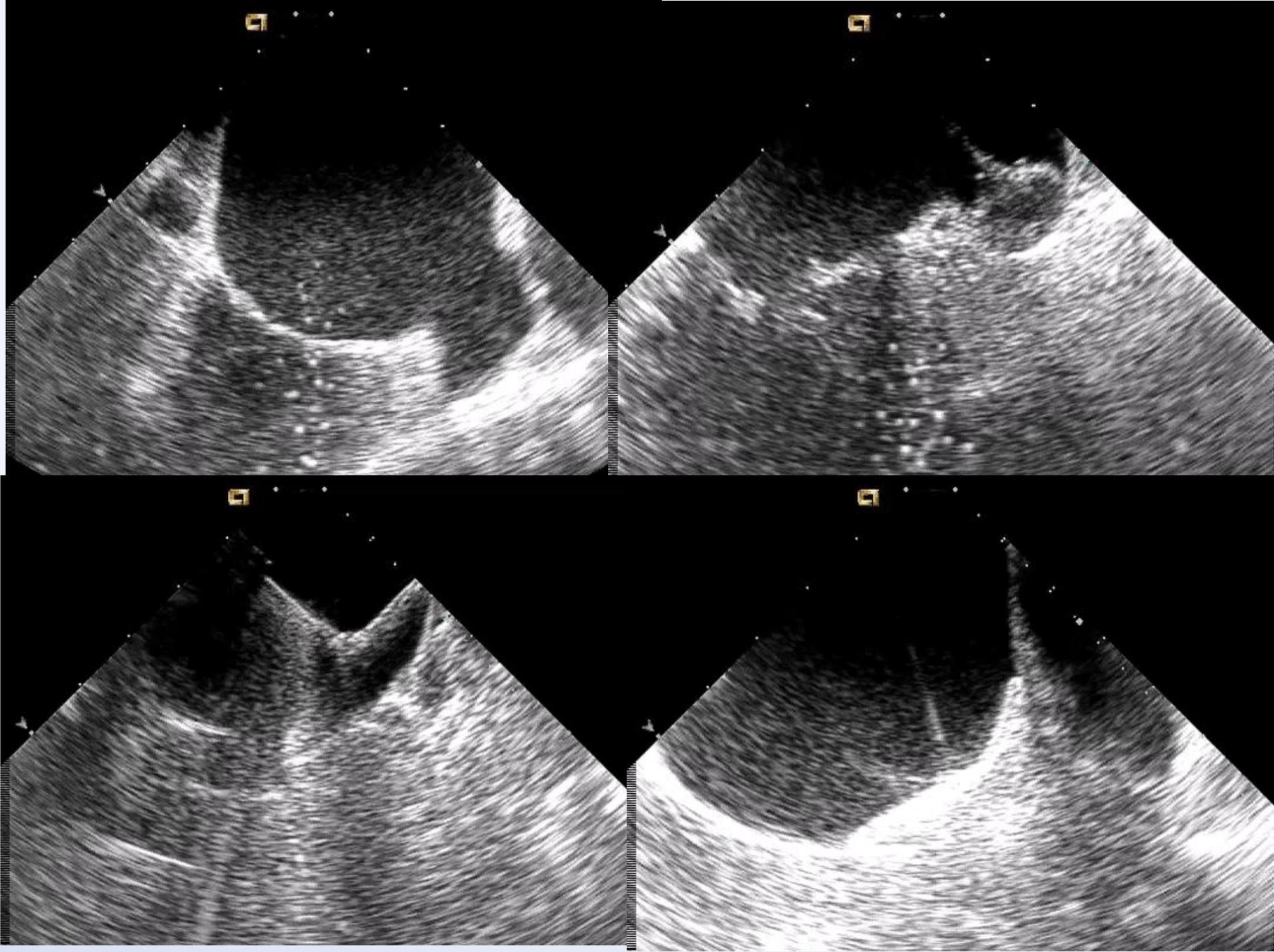
RAO Cau 20

Selection of device = maximal diameter + 3-5mm

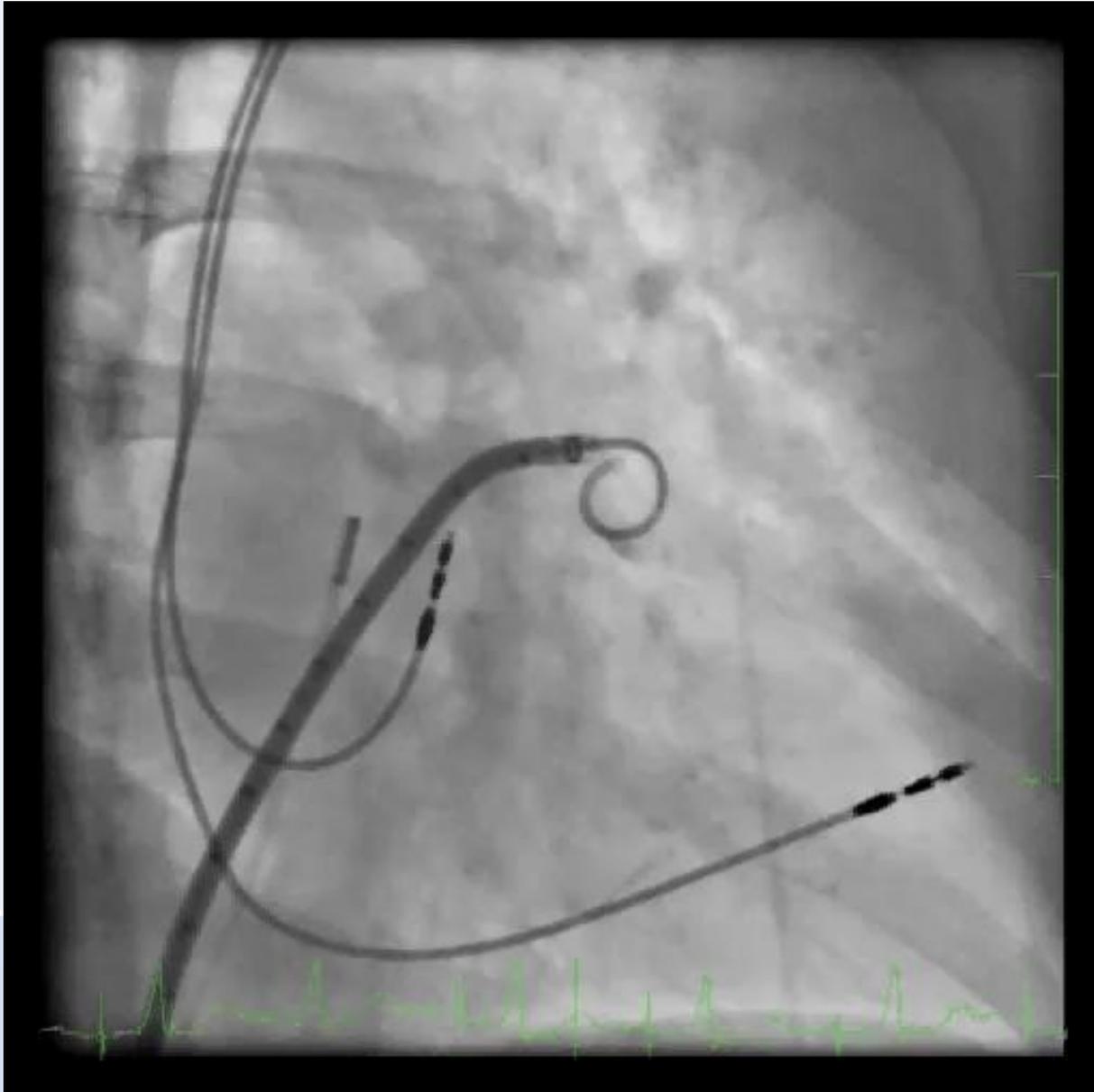
# CARPENTER WORKFLOW

- 1) MEASURE TWICE
- 2) CUT ONCE
- 3) FORCE IT TO FIT

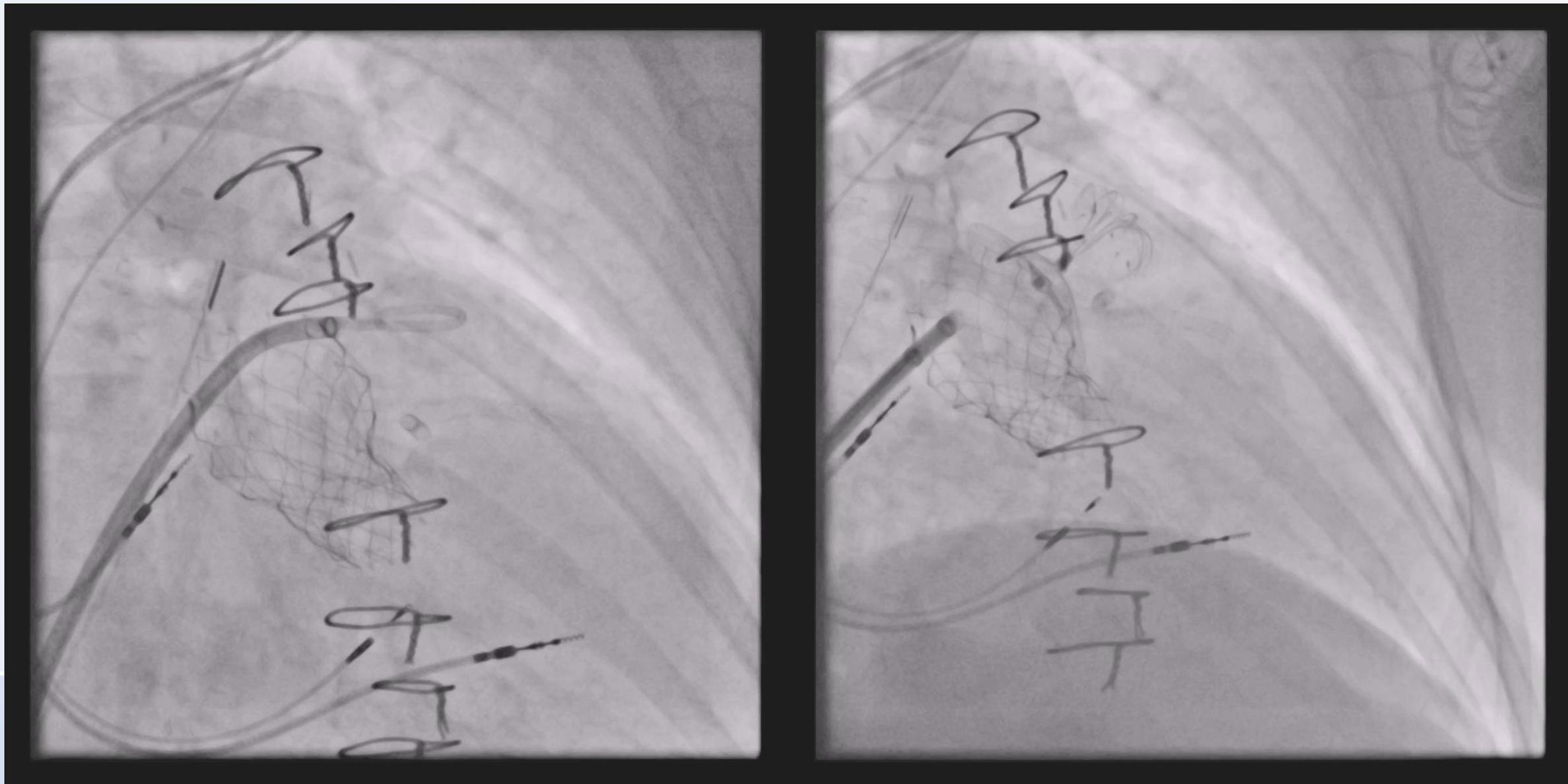




# Implantace Amulet

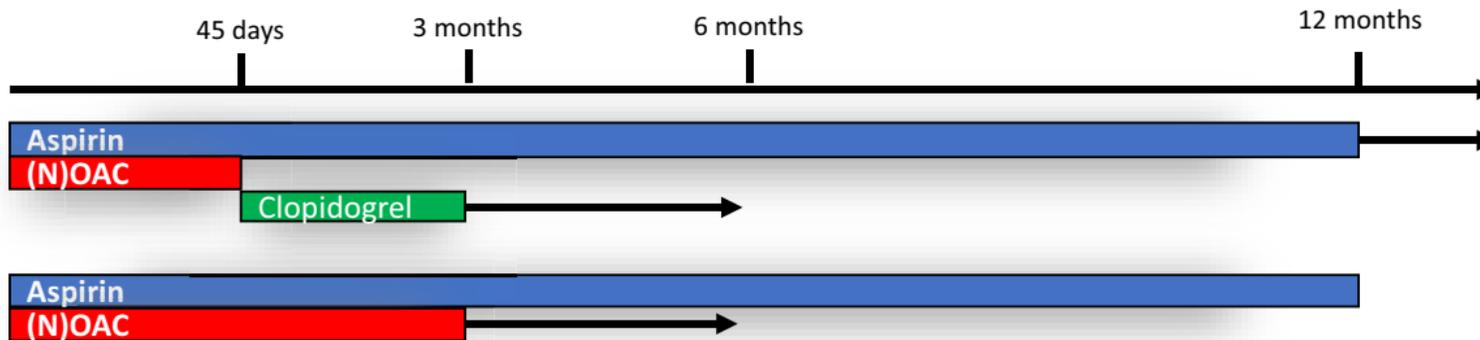


# Implantace Lambre

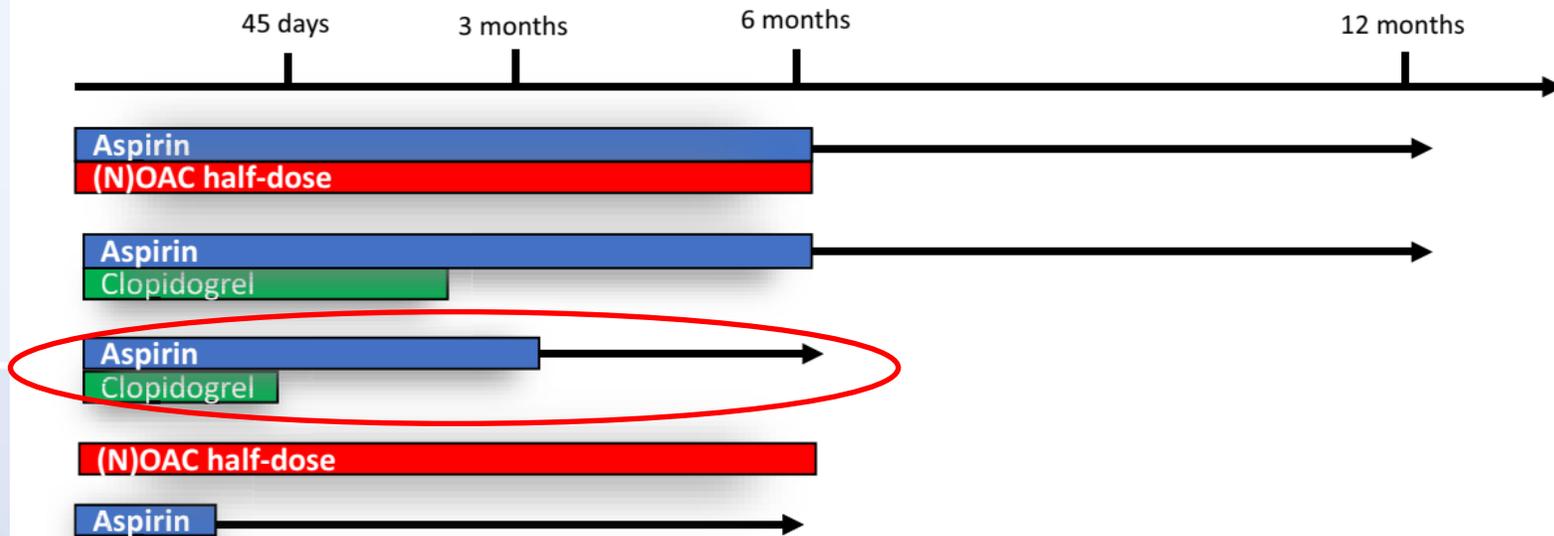


# Schéma antitrombotické léčby po implantaci

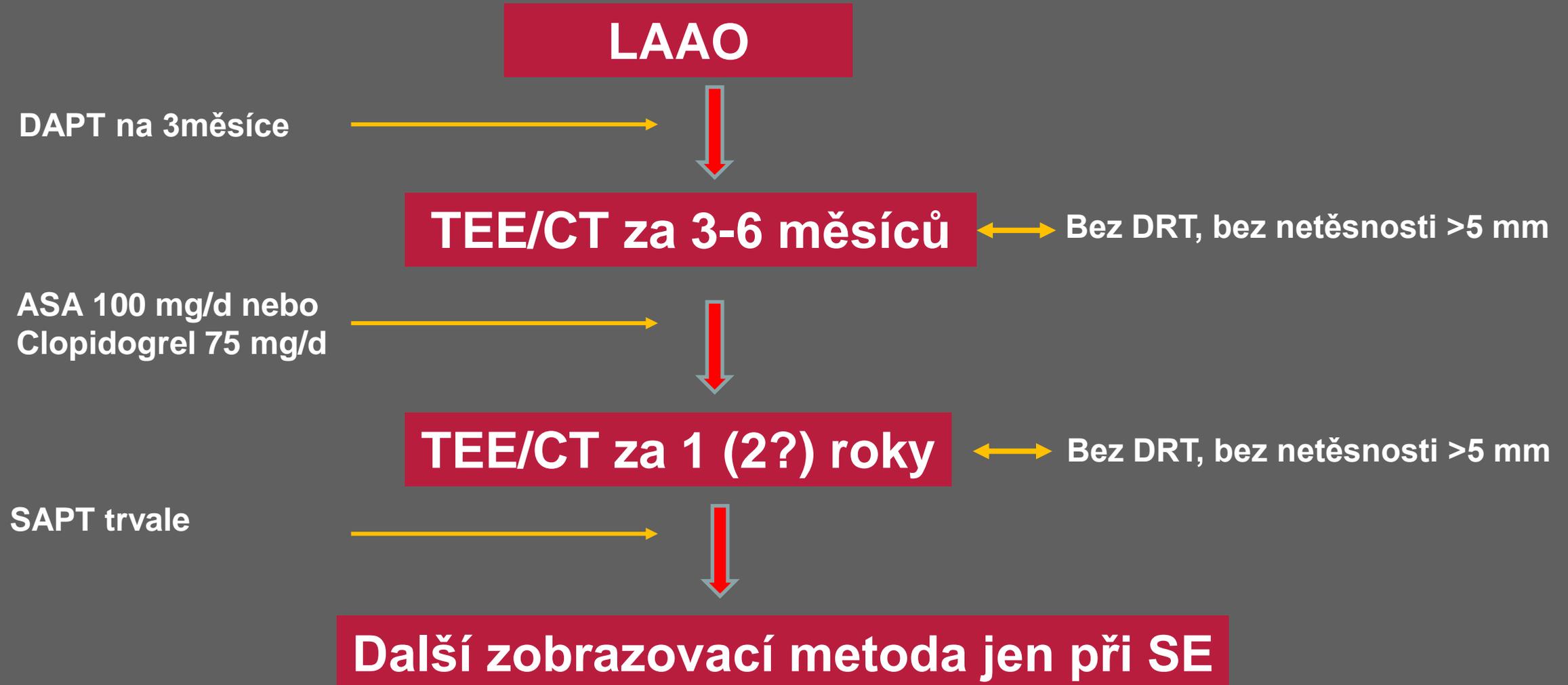
Patients eligible for Short-term anticoagulation  
Post-procedural anti-thrombotic therapy



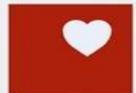
Patients non-eligible for Short-term anticoagulation  
Post-procedural anti-thrombotic therapy



# Schéma sledování po LAAO v IKEM

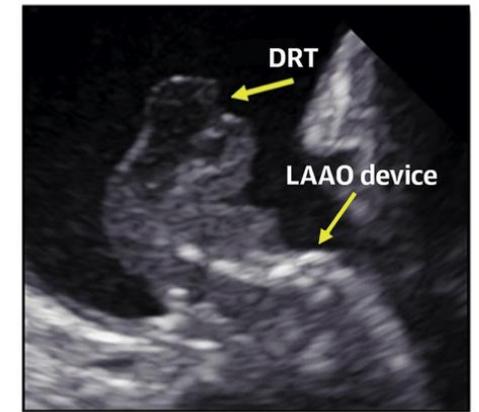
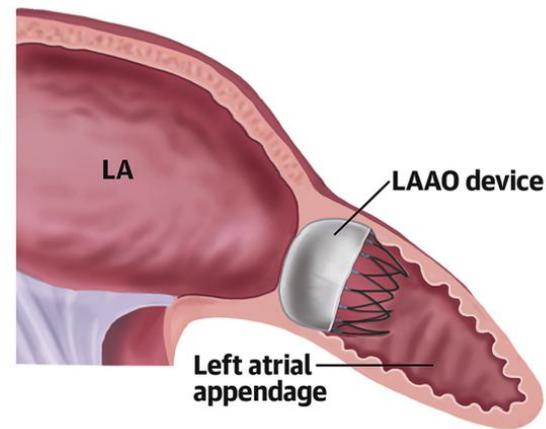


# Periprocedurální komplikace uzávěru ouška LS



# Device related thrombosis

- Objevuje se u 3-4% pacientů po implantaci okluderu
- Analýza 771 pts
- DRT asociovaná byla s vyšším výskytem CMP, systémové embolizace či úmrtí (OR 2.37)
- Při multivariantní analýze byla DRT asociovaná s:
  - Sklonem k hyperkoagulaci
  - Perikardiálním výpotkem
  - Renální insuficiencí
  - Distální implantací (>10mm hranu plicních žil)
  - Perzistující FiS
- Žádná asociace s typem OAK/APT při dimisi



## Major Risk Factors

- Iatrogenic pericardial effusion
- Hypercoagulable state

## Minor Risk Factors

- Deep LAAO implant (>10mm from pulmonary ridge)
- Renal insufficiency
- Non-paroxysmal AF

1 major risk factor

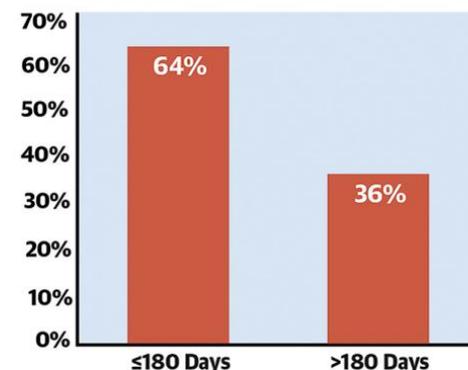
OR

2 minor risk factors

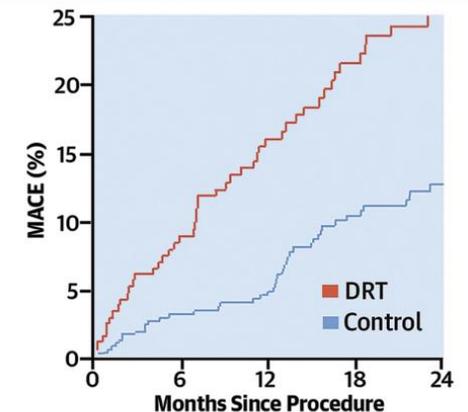
2.1-fold

Risk of Device Related Thrombus (DRT)

## Timing of DRT Diagnosis Post LAAO

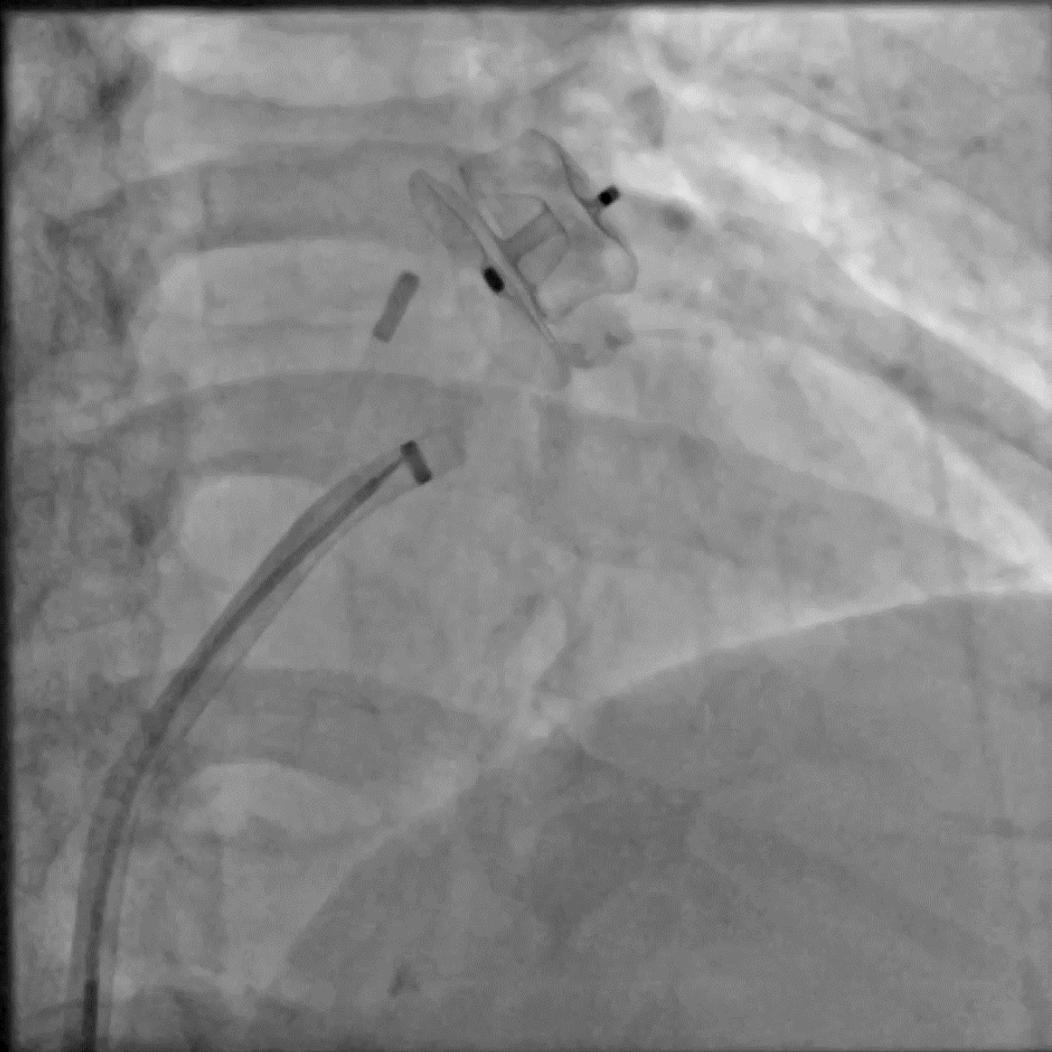


## Outcomes of LAAO



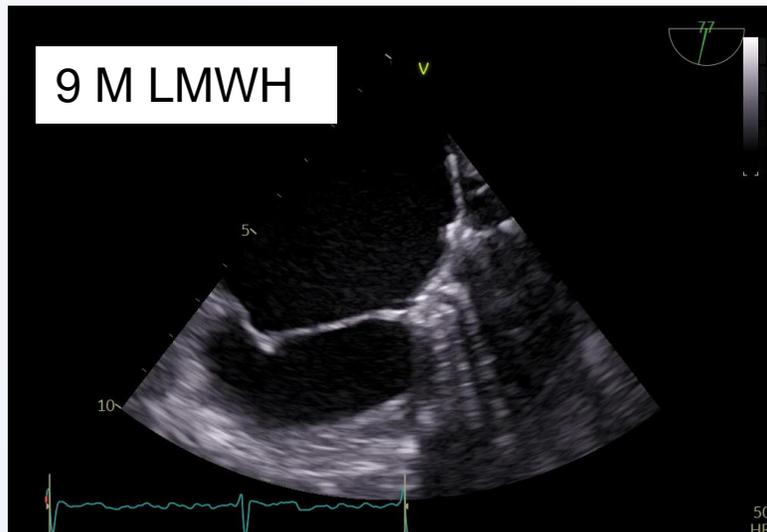
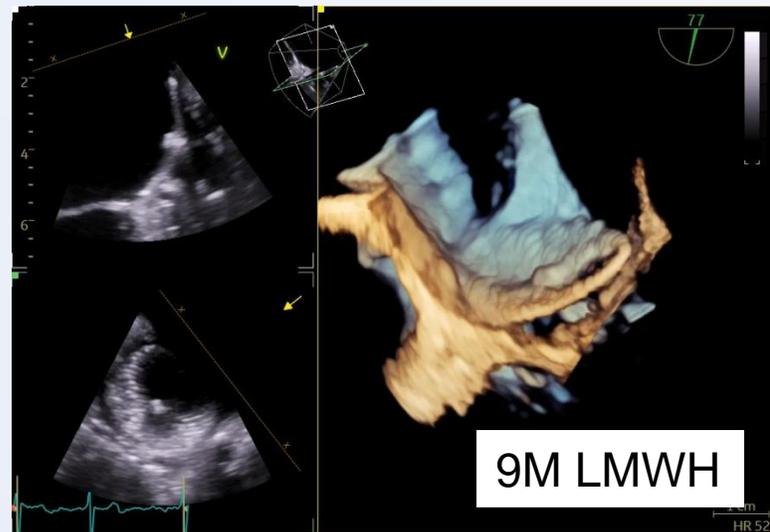
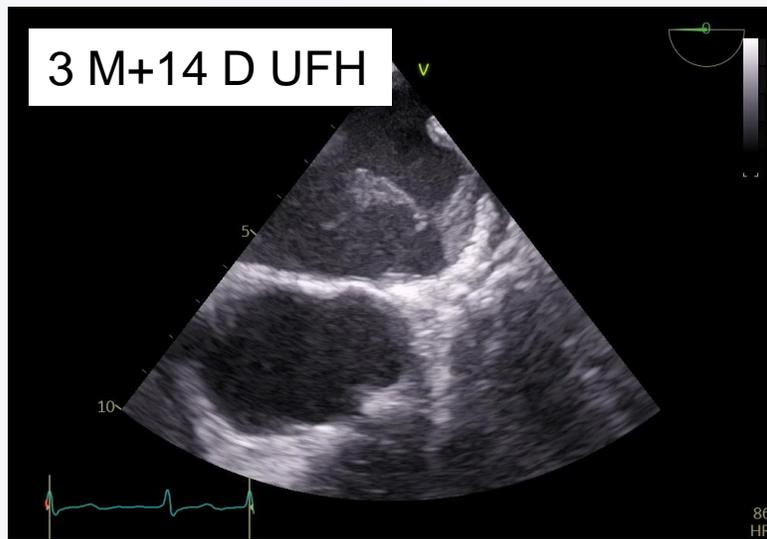
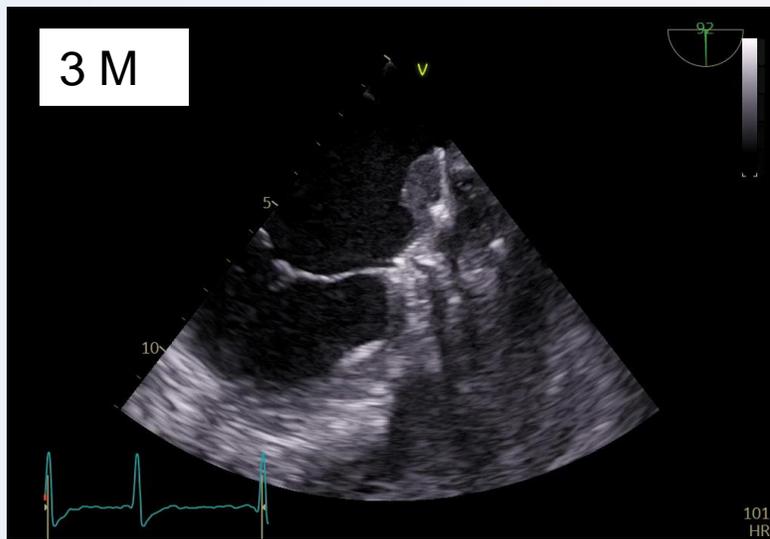
# Undersizing is also not optimal

**Suboptimal position of occluder**

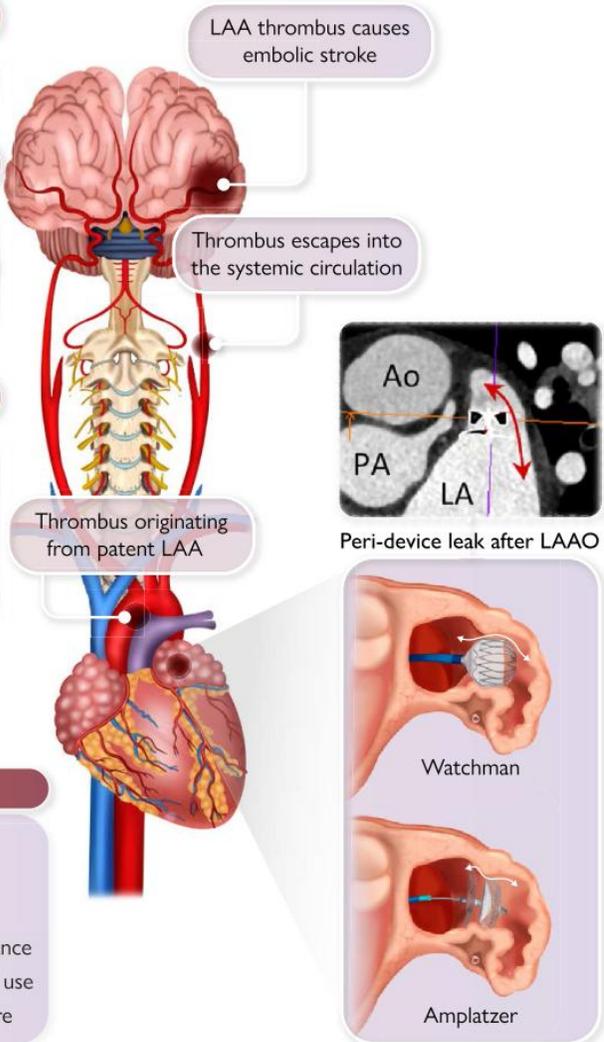
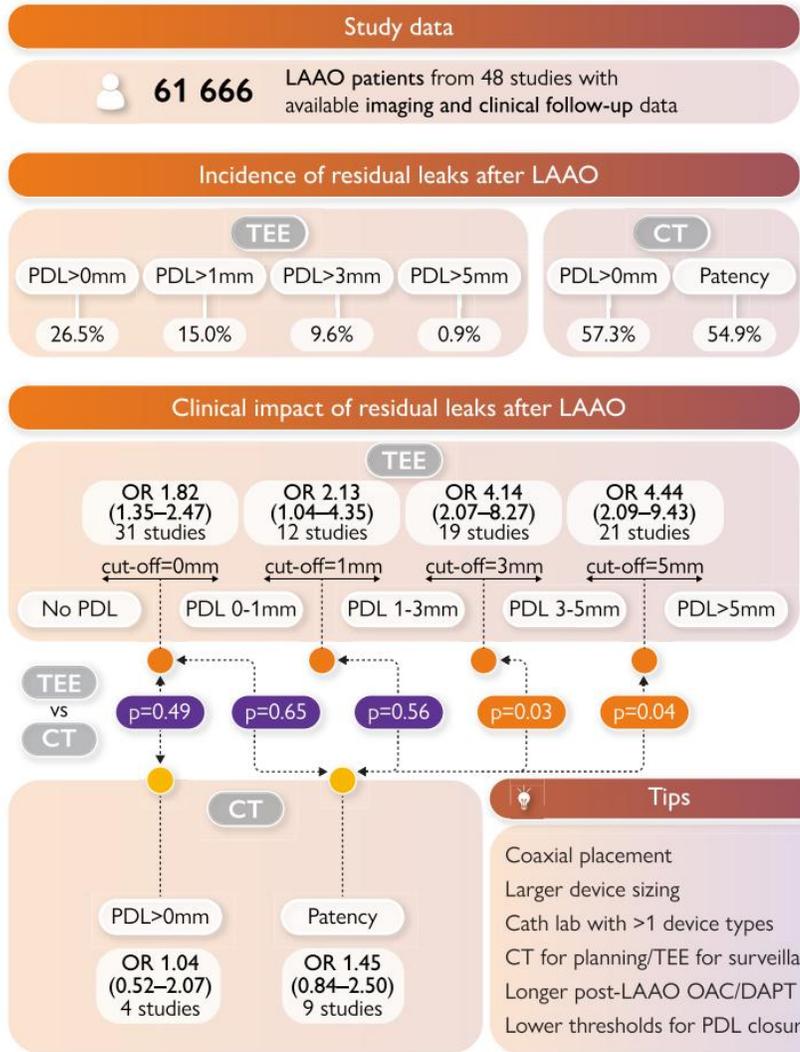


# Thrombus on occluder at 3months TEE on DAPT





# Peridevice leaks (PDL)

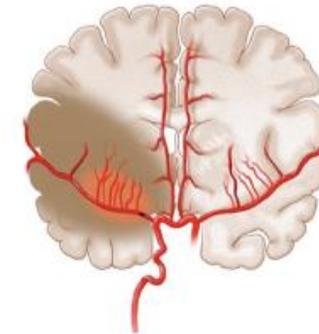
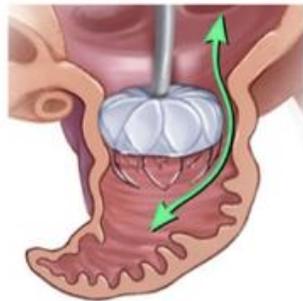
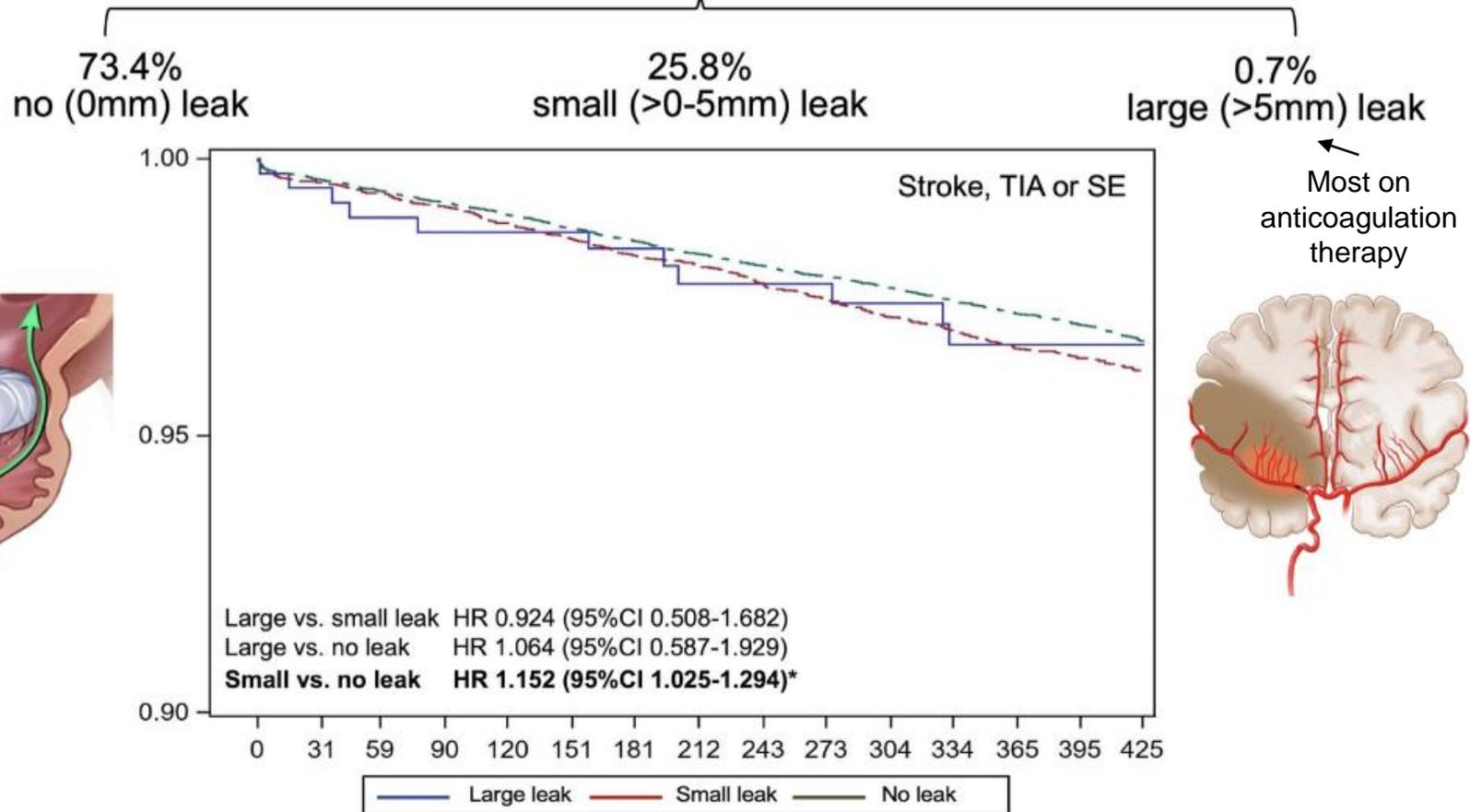


- Přítomnost PDL asociována s vyšší:
  - Rizikem TE (pOR 2.04)
  - Krvácením (pOR 1.12)
  - Mortalitou (pOR 1.16)
- Velikost reziduálního leaku okolo okludéru zvyšuje riziko tromboembolismu
- TEE lepší než CT v predikci rizika

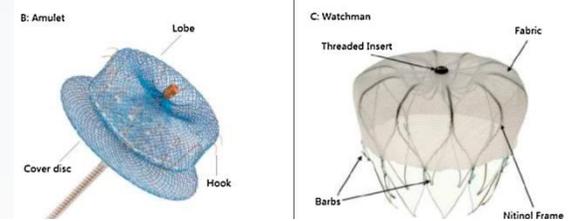
# Peridevice leaks

## Association of Peri-Device Leak with Thromboembolic Events after LAAO

51,333 Patients Underwent LAAO



# Amulet IDE Trial



- Prospektivní, randomizovaná, multicentrická studie porovnávající bezpečnost a účinnost LAAC uzávěrem Amulet a Watchman

- 1878 pac. randomizováno 1/1

## ÚSPĚŠNOST UZÁVĚRU (A vs. W):

98,4% vs. 96,4%

## KOMPLIKACE

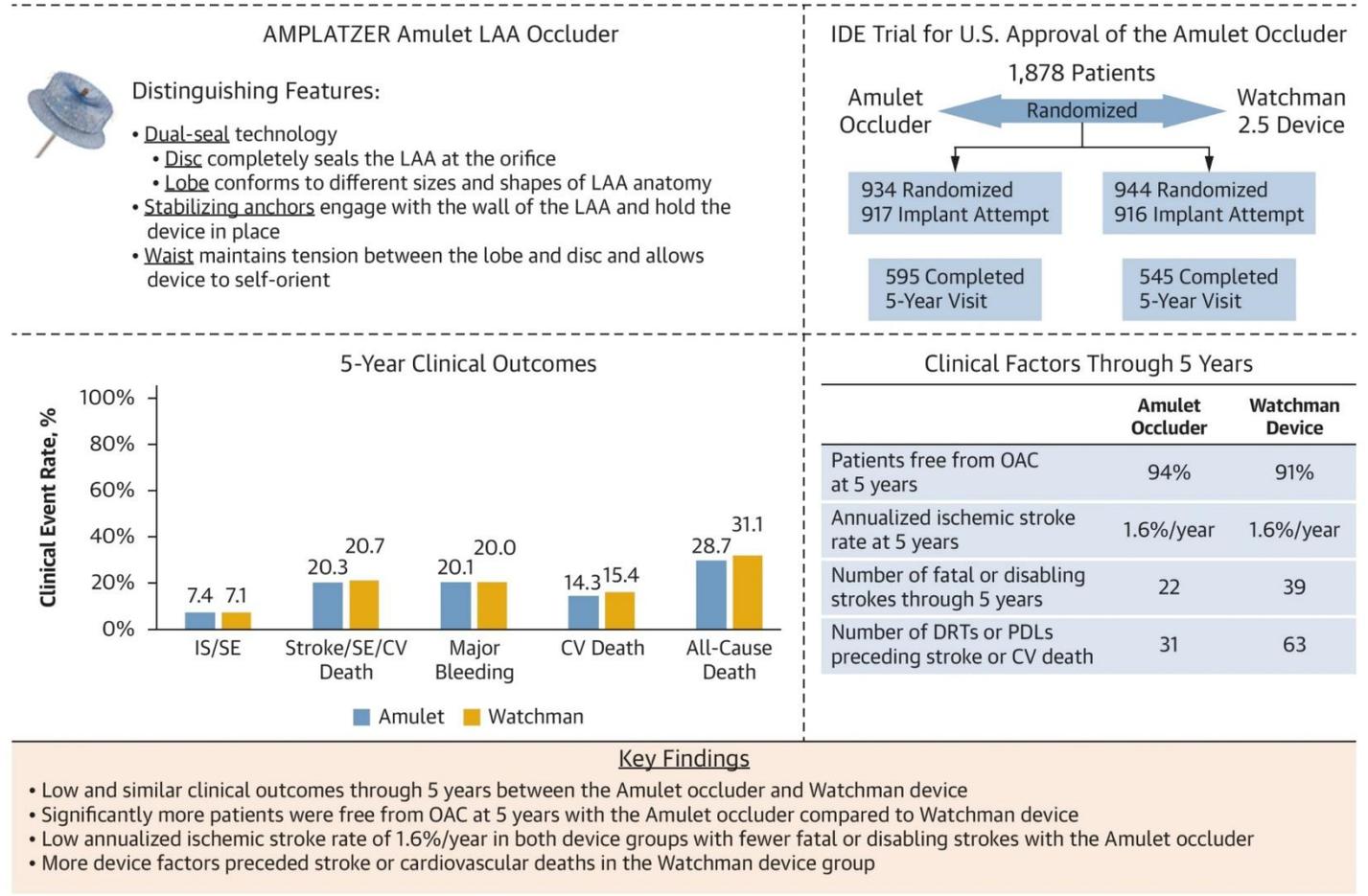
4,5% Amulet vs. 2,5% Watchman FLX  
(především dáno ↑ perikard. výpotek, nutnosti chirurgie či úmrtí = 0)

## PERI-DEVICE LEAK (> 3 mm)

**Akutně:** 11% Amulet, 26% Watchman FLX

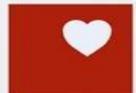
**1 rok:** 9% Amulet, 22% Watchman FLX

5-Year Results From the Randomized Amulet IDE Trial



# Současné zdroje informací o klinickém efektu LAAO

- Prospektivní observační registry
- Prospektivní randomizované studie

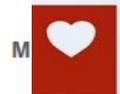
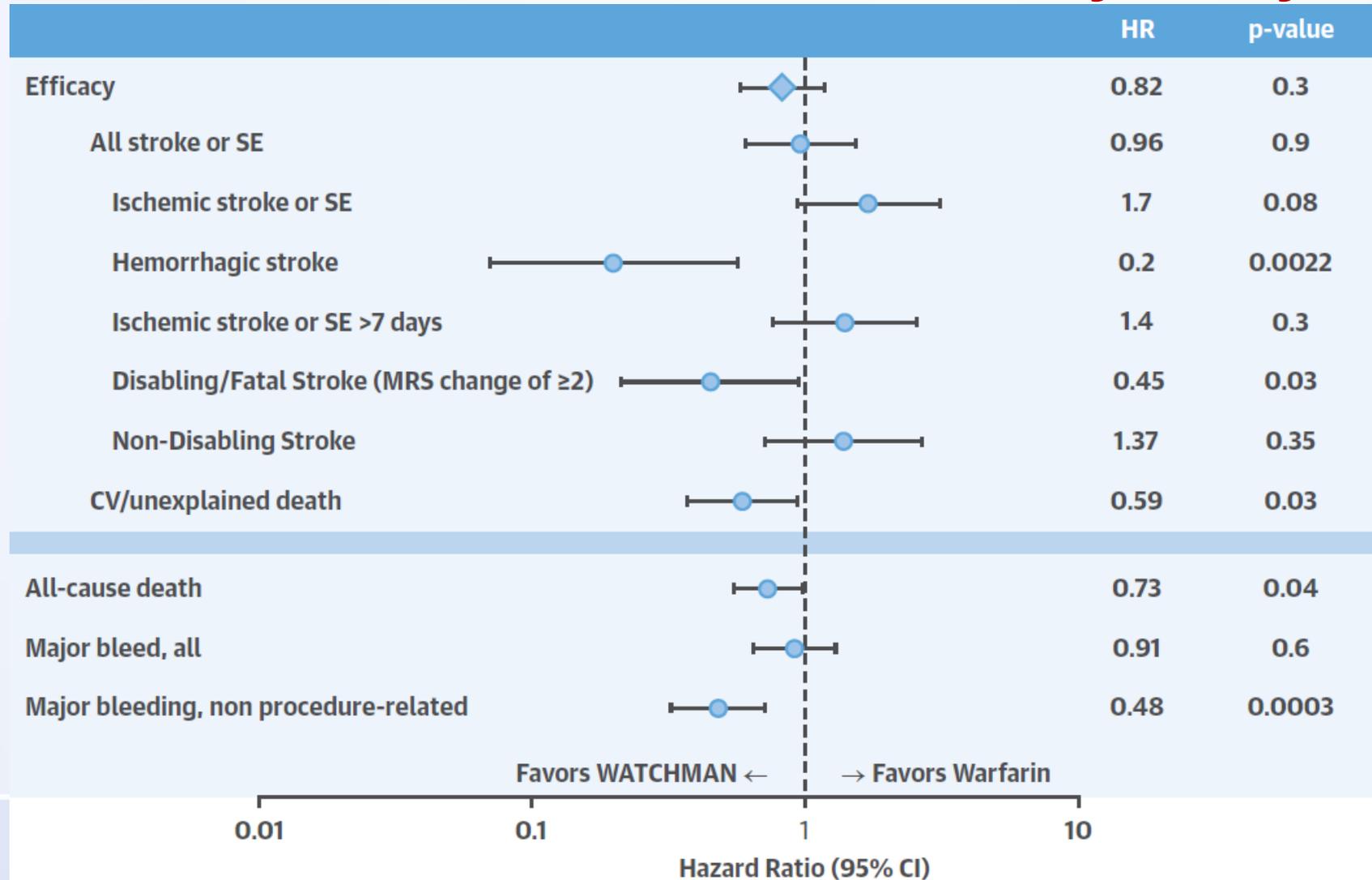


# Prospektivní registry LAAO

| Registry                          | Number of patients  | Device  | CHA <sub>2</sub> DS <sub>2</sub> -VASc score | HAS-BLED score | Results   |
|-----------------------------------|---|---|--|----------------|---|
| EWOLUTION<br>(NCT01972282)        | 1025<br>Voluntary single-arm, prospective, non-randomized registry                    | Watchman                                      | 4.6  | 2.4            | (1) Successful implantation: 98.5%<br>(2) Peri-procedural SAE rate within 7 days: 2.8%<br>(3) Stroke reduction: 83% (compared with calculated risk)<br>(4) Reduction of stroke/TIA/systemic embolism: 80% (compared with calculated risk)   |
| Amplatzer Amulet<br>(NCT02447081) | 1088<br>Voluntary single-arm, prospective, non-randomized registry<br>Independent CEC | Amulet  | 4.2  | 3.3            | (1) Successful implantation: 99.1%<br>(2) Peri-procedural SAE rate within 7 days: 3.2%<br>(3) Stroke reduction 67% (compared with calculated risk)<br>(4) Reduction in severe bleeding: 3.2%<br>(5) 1-year mortality: 8.4%  |
| LAARGE<br>(NCT02230748)           | 643<br>Voluntary single-arm, prospective, non-randomized registry                     | Watchman,<br>Amplatzer cardiac plug<br>Amulet | 4.7  | 4              | (1) Successful implantation: 98.5%<br>(2) MACCE rate hospital stay: .5%<br>(3) No difference in stroke (.4 vs. 1.1 vs. 0%) or severe bleeding (.7 vs. .0 vs. 3.1%) in patients with LVEF >55%, 36%–55%, and ≤ 35%   |
| LISA (NCT03666780)                | 500<br>Voluntary single-arm, prospective, non-randomized registry                     | LAmbre  | NA   | NA             | NA  |
| FLAAC-2<br>(NCT03434015)          | 1020<br>Voluntary single-arm, prospective, non-randomized registry                    | Watchman,<br>Amplatzer cardiac plug<br>Amulet | NA   | NA             | NA  |
| PINNACLE FLX<br>(NCT02702271)     | 400<br>Voluntary single-arm, prospective, non-randomized registry, independent CEC    | Watchman FLX                                  | 4.2  | 2.0            | (1) Successful implantation: 98.8%<br>(2) Peri-procedural SAE rate within 7 days: .5%<br>(3) All-cause death: .5% (45 days), 6.6% (6 months)<br>(4) All stroke: .7% (45 days), 2.6% (6 months)<br>(5) Pericardial effusion: .7% (45 days), 1.0% (6 months)<br>(6) Major bleeding: 3.0% (45 days), 7.9% (6 months) |

# Randomizované studie

## PROTECT-AF a PREVAIL: 5-leté výsledky



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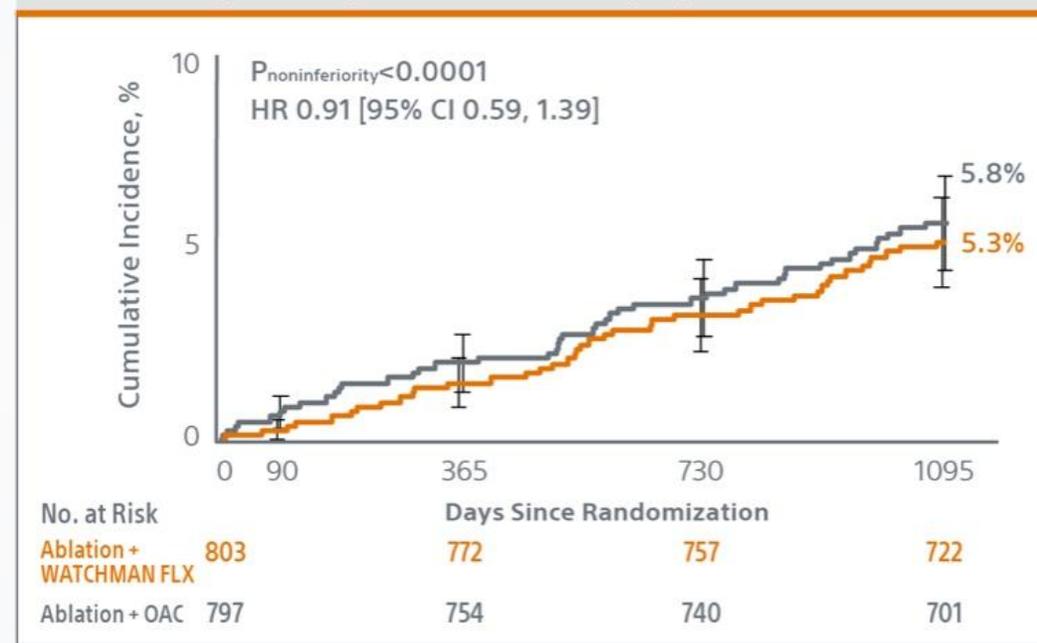
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# OPTION trial

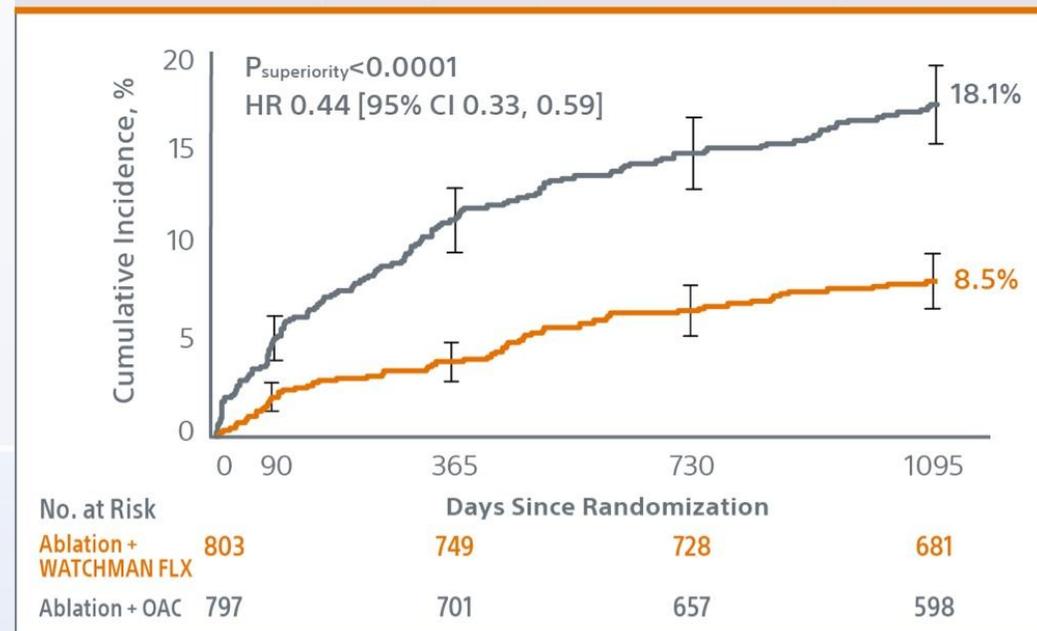
- Multicentrická randomizovaná studie srovnávající u pacientů podstupujících ablací FiS
  - NOAK
  - Uzávěr ouška (Watchman FLX)
    - Konkomitantní 41%, sekvenčně 59%
- 1,600 pts randomizováno 1:1
- Úspěšný uzávěr u 98.8% pts
- Noninferiorita v kompozitním primárním endpointu
- Superiora v bezpečnostním endpointu
  - krvácení mimo vlastní výkon

Wazni O NEJM 2024

## Primary Efficacy: Stroke, Mortality, Systemic Embolism



## Primary Safety: Non-procedural Bleeding

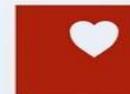


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# Indikace k uzávěru ouška



# 2024 ESC AF Guidelines

## **Recommendation Table 10** — Recommendations for percutaneous left atrial appendage occlusion (see also Evidence Table 10)

| Recommendation   | Class <sup>a</sup> | Level <sup>b</sup> |
|--|--------------------|--------------------|
| Percutaneous LAA occlusion may be considered in patients with AF and contraindications for long-term anticoagulant treatment to prevent ischaemic stroke and thromboembolism. <sup>372,376,386,387</sup> | <b>IIb</b>         | <b>C</b>           |

© ESC 2024

# ACC/HRS 2023 Guidelines

## Recommendations for Percutaneous LAAC

|    |      |   |
|----|------|---|
| 2a | B-NR | In patients with AF, a moderate to high risk of stroke (CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥2), and <u>a <b>contraindication to long-term oral anticoagulation</b></u> due to a nonreversible cause, pLAAO) is reasonable.  |
| 2b | B    | In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on OAC, pLAAO may be a <u>reasonable alternative OAC</u> based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for OAC is more extensive. |

## Recommendations for Cardiac Surgery—LAA Exclusion/Excision

|    |   |   |
|----|---|---|
| 1  | A | In patients with AF undergoing cardiac surgery with a CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥2 or equivalent stroke risk, surgical LAA exclusion, in addition to continued anticoagulation, is indicated to reduce the risk of stroke and systemic embolism.               |
| 1  | A | In patients with AF undergoing cardiac surgery and LAA exclusion, a surgical technique resulting in absence of flow across the suture line and a stump of <1 cm as determined by intraoperative transoesophageal echocardiography should be used.                                 |
| 2b | A | In patients with AF undergoing cardiac surgery with CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥2 or equivalent stroke risk, the benefit of surgical LAA exclusion in the absence of continued anticoagulation to reduce the risk of stroke and systemic embolism is uncertain. |

# Běžící randomizované studie

## CATALYST: Amplatzer Amulet LAAO vs. NOAC

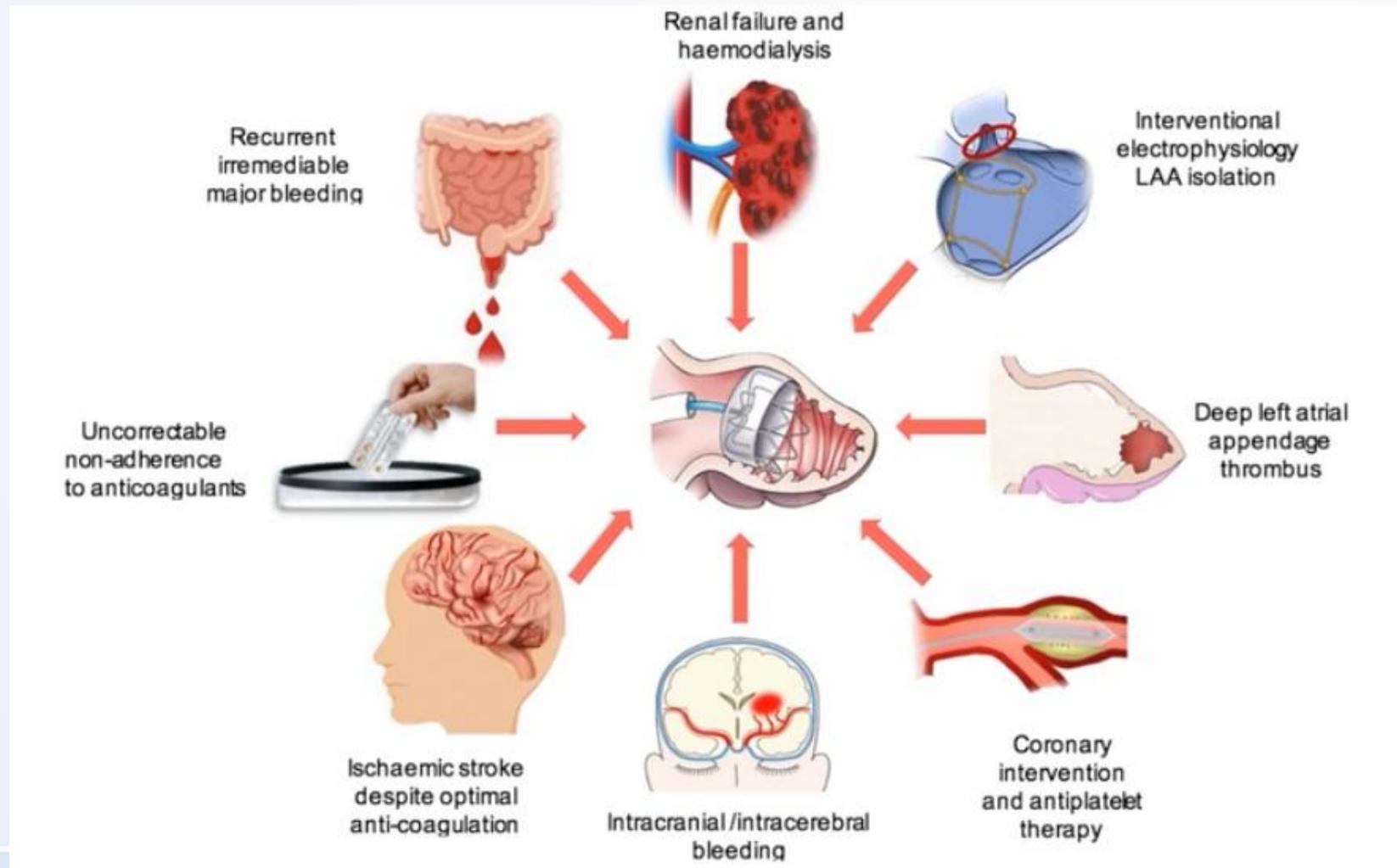
- Prospektivní randomizovaná studie porovnávající LAAC (Amulet) vs. NOAC
- Vstupní kritéria: FS, CHA<sub>2</sub>DS<sub>2</sub>VASC  $\geq$  3
- Primární endpoint
  - 1) ischemická CMP, systémová embolizace, CV mortalita (non-inferiorita)
  - 2) klinicky významné krvácení (superiorita)
- Plánováno zařadit 2650 pacientů (478 pac.k 25.10.2021), očekávané výsledky 12/2024

## CHAMPION-AF: Watchman FLX vs. contemporary OAC

- Prospektivní randomizovaná studie porovnávající LAAC (Watchman FLX) vs. NOAC
- Vstupní kritéria: FS, CHA<sub>2</sub>DS<sub>2</sub>VASC  $\geq$  3
- Primární endpoint
  - 1) ischemická CMP, SE a CV mortalita (non-inferiorita)
  - 2) non-procedurální klinicky významné krvácení (superiorita)
- Plánováno zařadit 3000 pacientů, očekávané výsledky 12/2027



# Stále více indikací k uzávěru LAA?



# Další běžící randomizované studie

- **Vysoké riziko krvácení** (LAAO vs best medical care)
  - CLOSURE-AF, COMPARE LAAO
- **Post-intracerebrální krvácení** (LAAC vs best medical care)
  - CLEARANCE, STROKECLOSE
- **Post-ischemické CMP** (LAAO vs NOAK)
  - OCCLUSION-AF
- **Pacienti v terminální renálním selhání** (LAAO vs best m care)
  - LAA-Kidney



# Uzávěr ouška levé síně

## PRO

- Doživotní protekce
- 20 let zkušeností
- Nízké riziko TE
- Nízké riziko krvácení
- Nízké riziko výkonu



## PROTI

- Periprocedurální riziko
- Riziko DRT
- Peridevice leaks
- Oproti NOAK méně dat z RT
- Cost-effectiveness

# Děkuji za pozornost

