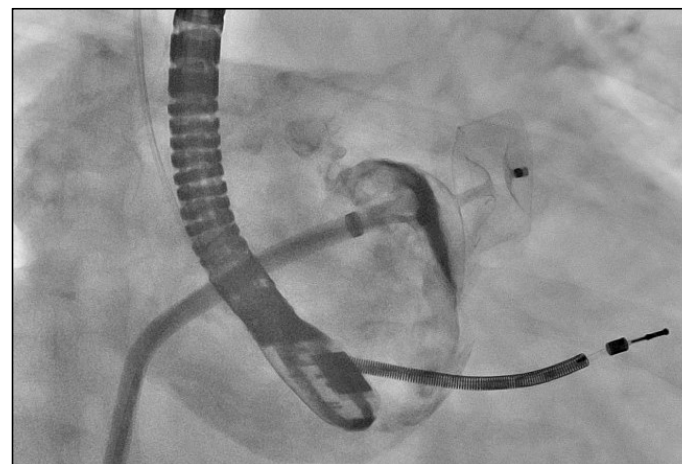


Hirnschlagprävention: Antikoagulation, Vorhofohrverschluss oder beides?

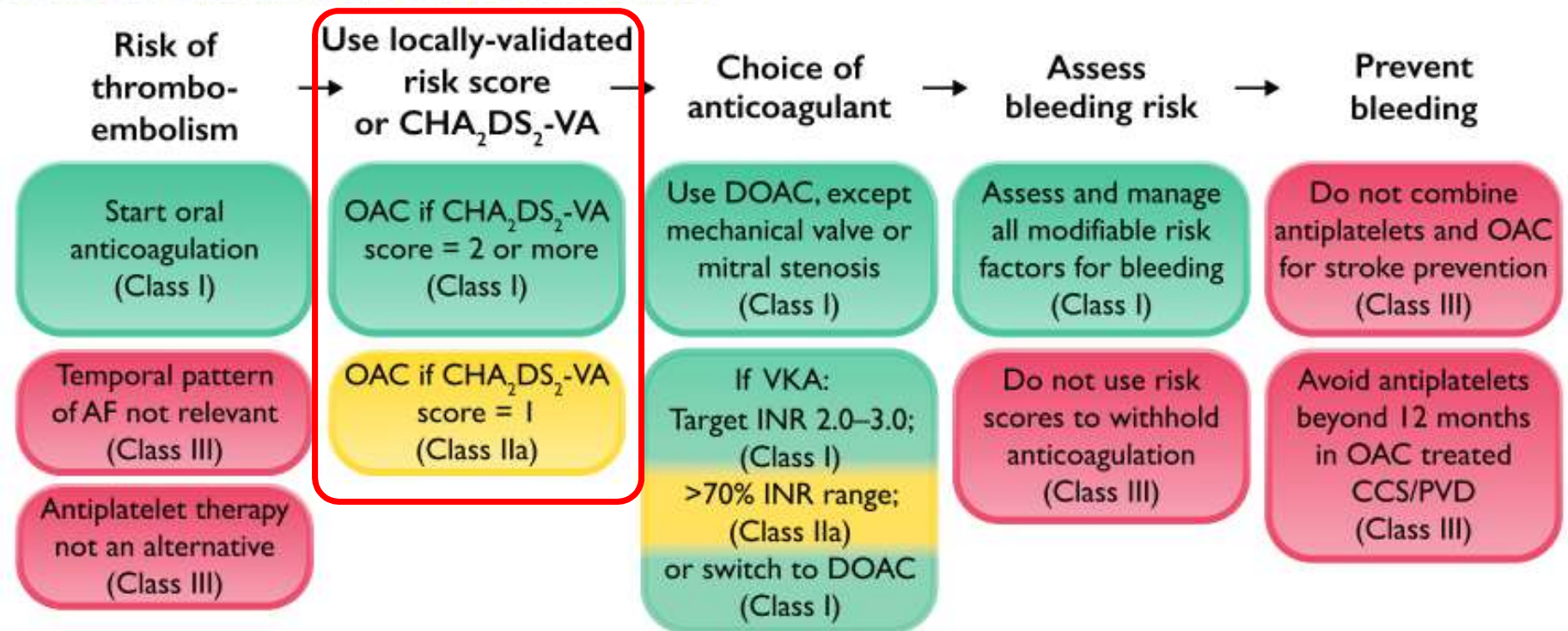
Prof. Laurent Roten
Rhythmologie / Elektrophysiologie



AF-CARE

CHA₂DS₂-VASc Score

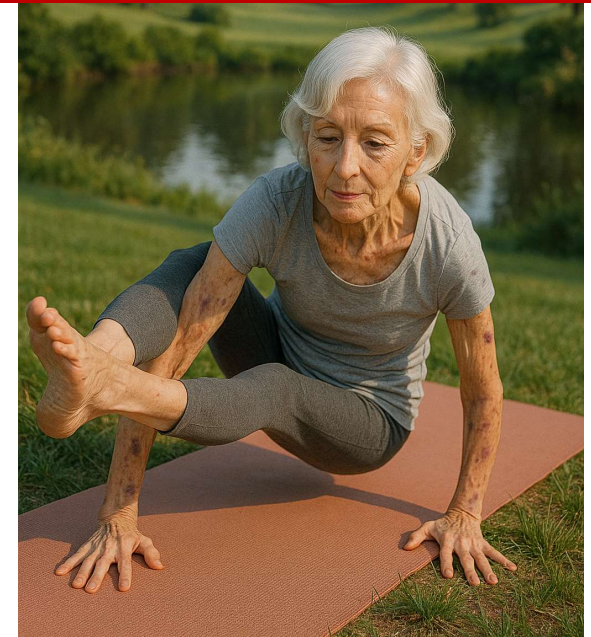
A Avoid stroke and thromboembolism



75-jährige ♀

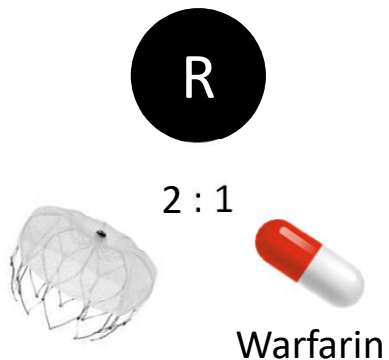
- Paroxysmales Vorhofflimmern
 - Erste Episode vor 3 Jahren
 - Ø 1 Episode alle 2 Monate,
 - EHRA Score 2a
- Arterielle Hypertonie
- CHA₂DS₂-VA Score 3
- LVEF normal; LAVI 36 mL/m²
- Amlodipin/Perindopril; DOAC; BB toleriert sie nicht
- Aktiver Lebensstil (Yoga 2x/Woche; Wandern)
- Ihr äusseres Erscheinungsbild ist ihr enorm wichtig

Doktor, ich bekomme sofort blaue Flecken, wenn ich irgendwo anstoße. Schauen Sie nur meine Unterarme! **Kann ich die Blutverdünnung nicht absetzen?**



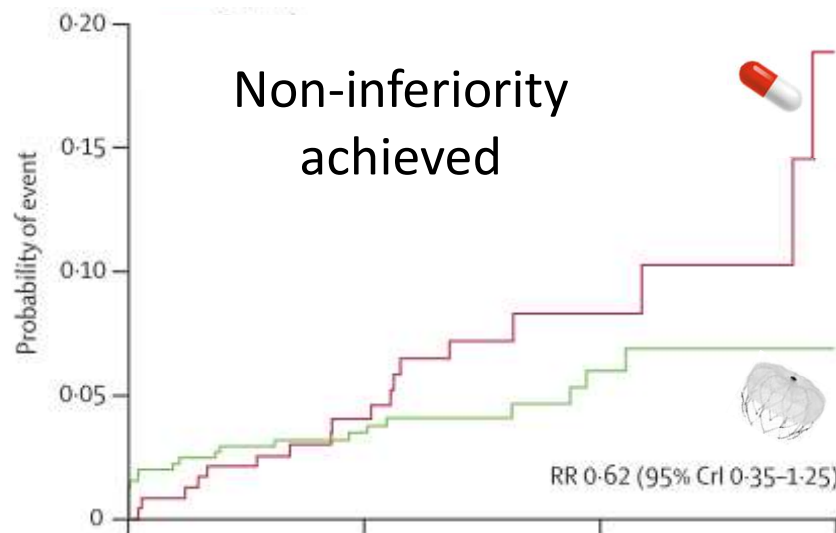
PROTECT AF RCT – Watchman vs. Warfarin

N=707
AF
CHADS₂ ≥1
No bleeding!



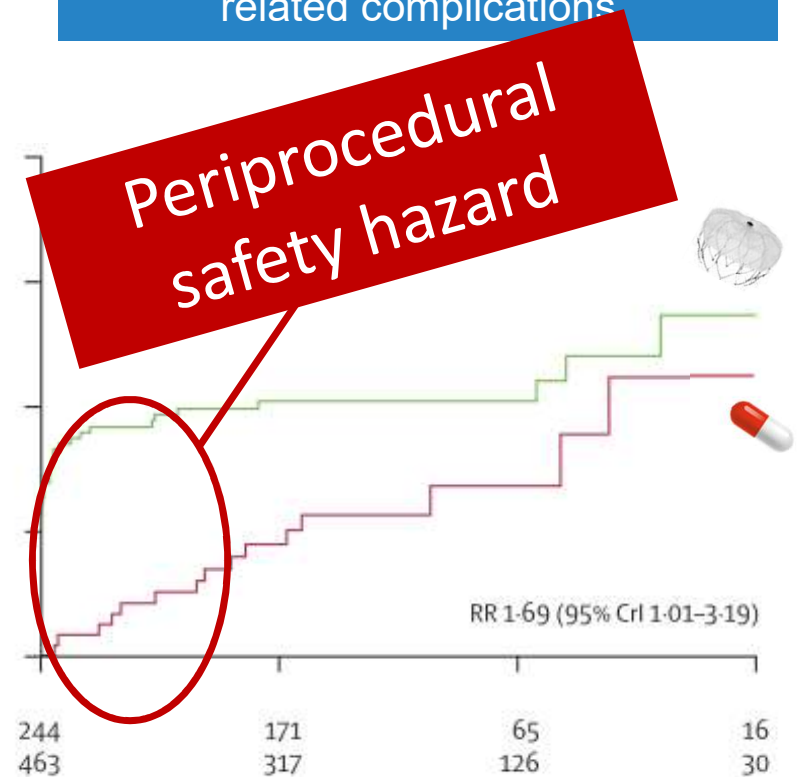
Device success 88%
(91% of attempted)

Primary Efficacy Endpoint
Stroke, systemic embolization or
cardiovascular death



Number at risk				
Control	244	174	67	17
Intervention	463	332	132	34

Primary Safety Endpoint
Major bleeding and procedure-
related complications



Number at risk				
Control	244	171	65	16
Intervention	463	317	126	30

PREVAIL RCT – Watchman vs. Warfarin

N=407
AF
CHADS₂≥2
No bleeding!



2 : 1



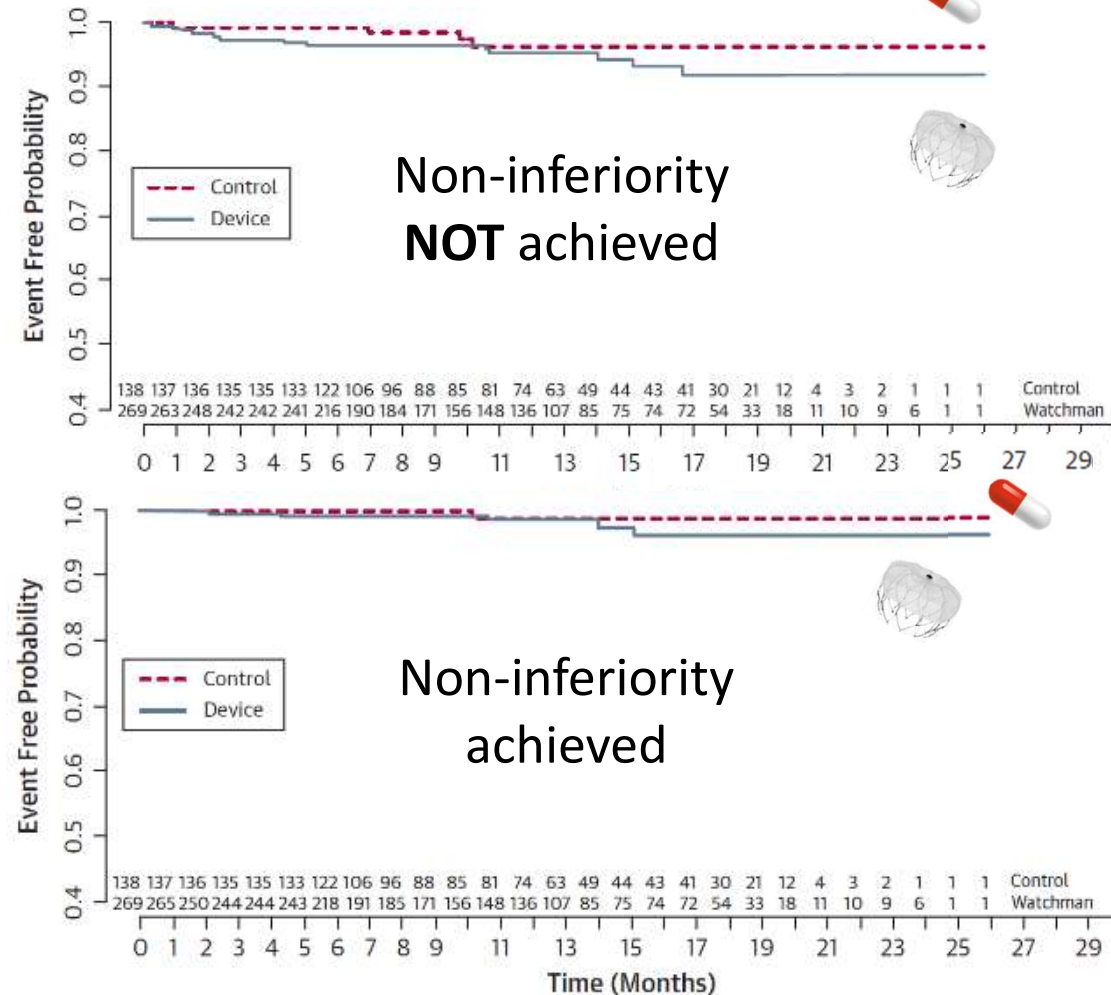
Warfarin

Device success 95%

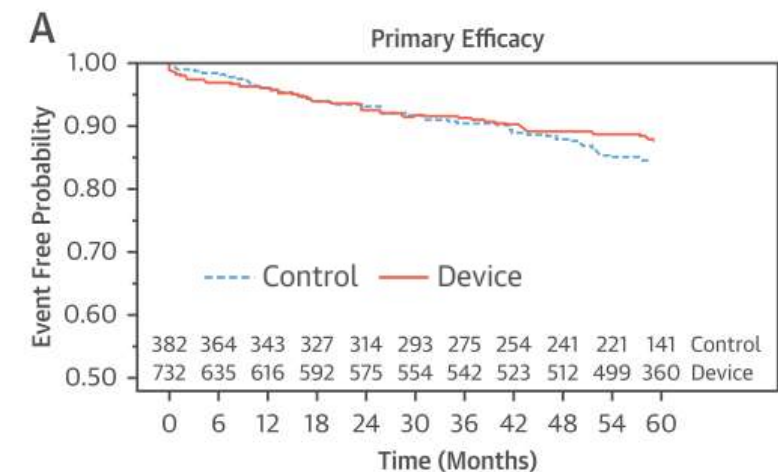
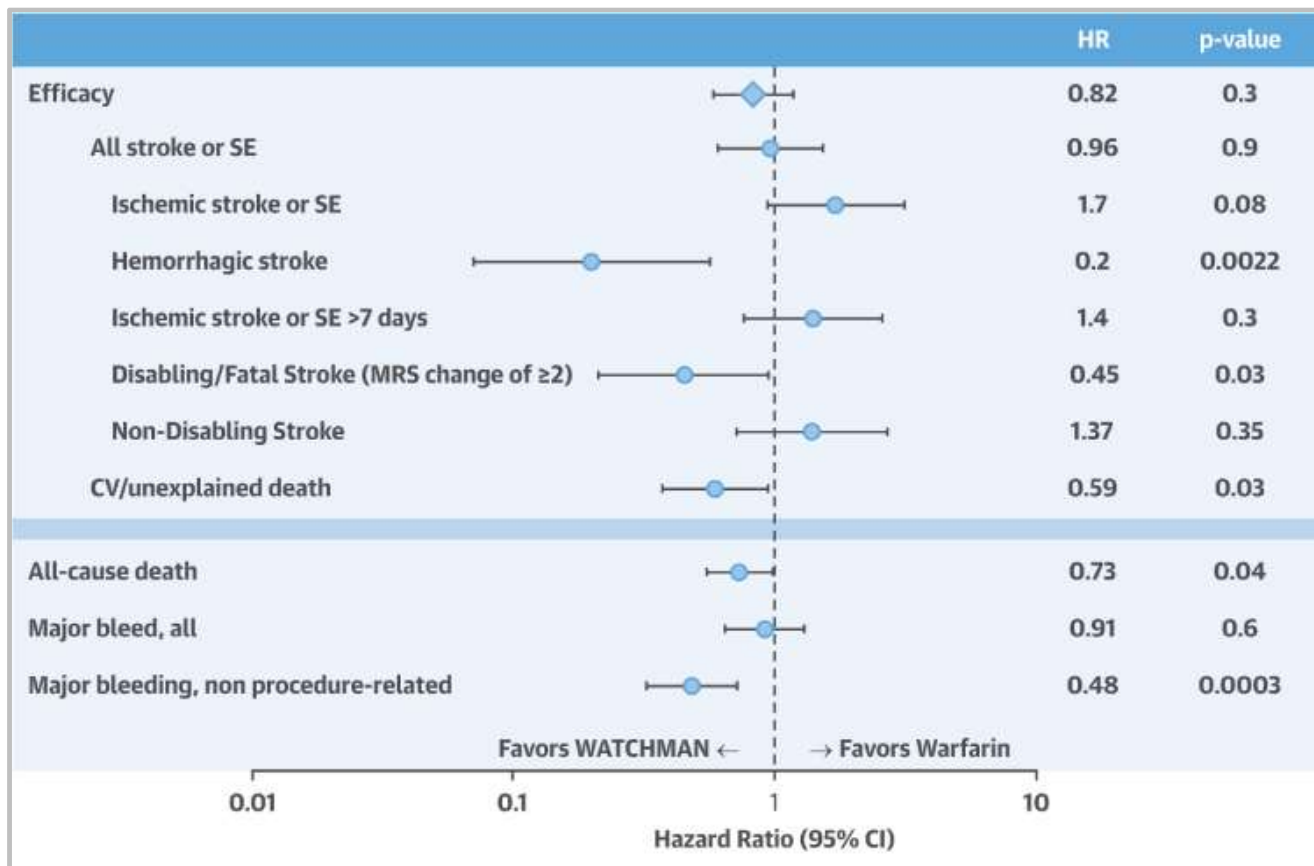
Primary safety endpoint
Device group
2.2%

**1st Co-Primary
Efficacy Endpoint**
Stroke, systemic
embolization or
cardiovascular death

**2nd Co-Primary
Endpoint**
Ischemic stroke or
systemic embolism
>7 days post
randomization



5-Year Patient-Level Meta-Analysis of PROTECT AF and PREVAIL



PRAGUE-17 – LAAO vs. DOAC

N=402

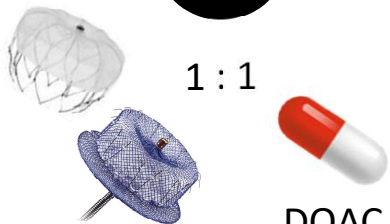
AF

CHA₂DS₂-VASc ≥3

Hx of bleeding/cardio-embolic event or high risk

R

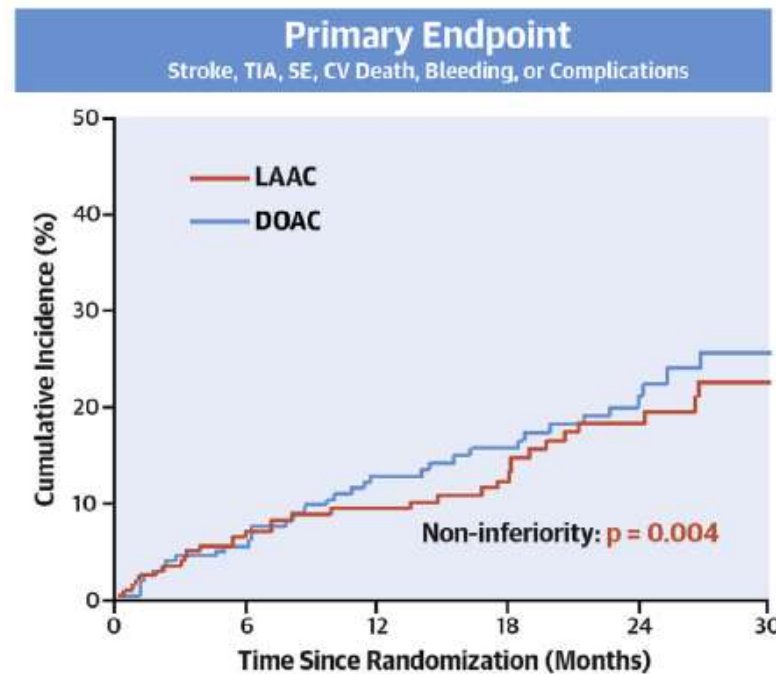
1 : 1



DOAC

96% Apixaban

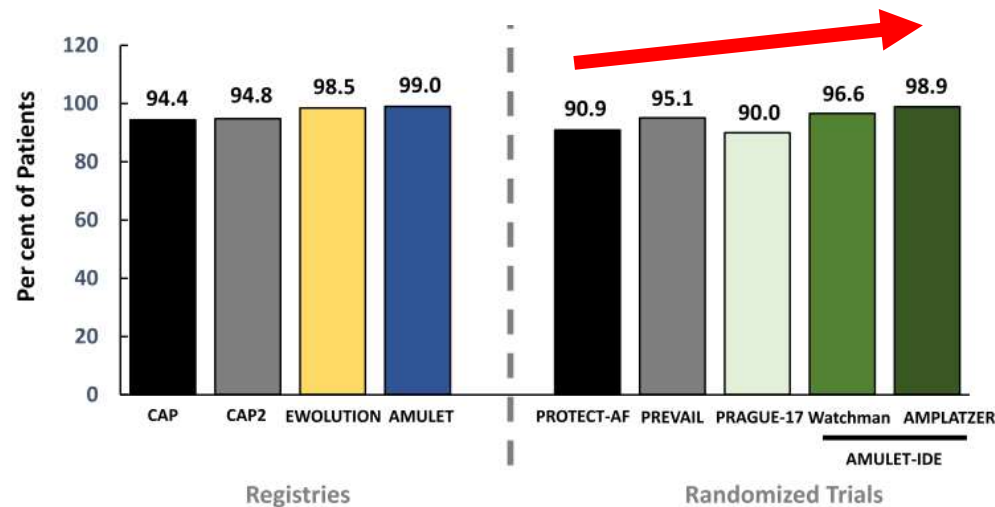
Device success 96.8%



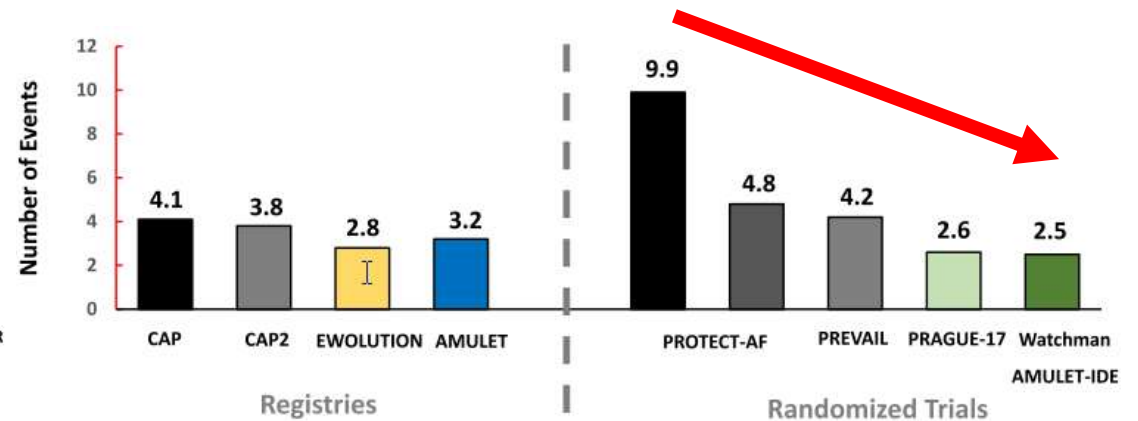
	sHR (95% CI)	p value
Primary Endpoint		
MITT	0.84 (0.53-1.31)	0.44
Per Protocol	0.82 (0.52-1.30)	0.40
On-Treatment	0.79 (0.49-1.25)	0.31
All-Stroke/TIA	1.00 (0.40-2.51)	0.99
CV Death	0.75 (0.34-1.62)	0.46
Major + NMCR Bleeding		
All	0.81 (0.44-1.52)	0.51
Nonprocedural	0.53 (0.26-1.06)	0.07

Erfolgs- & Komplikationsraten im Verlauf

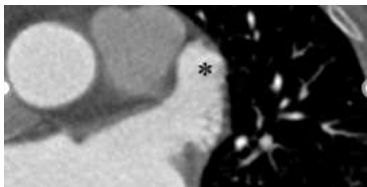
Implantationserfolg



Peri-prozedurale Komplikationen



Präprozedurales CT



Anästhesie, TEE/ICE



Neuere Devices



2024 ESC Guidelines on Atrial Fibrillation

Percutaneous LAA occlusion / Stand-alone endoscopic surgical closure of the LAA may be considered in patients with AF and contraindications for long-term anticoagulant treatment to prevent ischaemic stroke and thromboembolism.

IIb

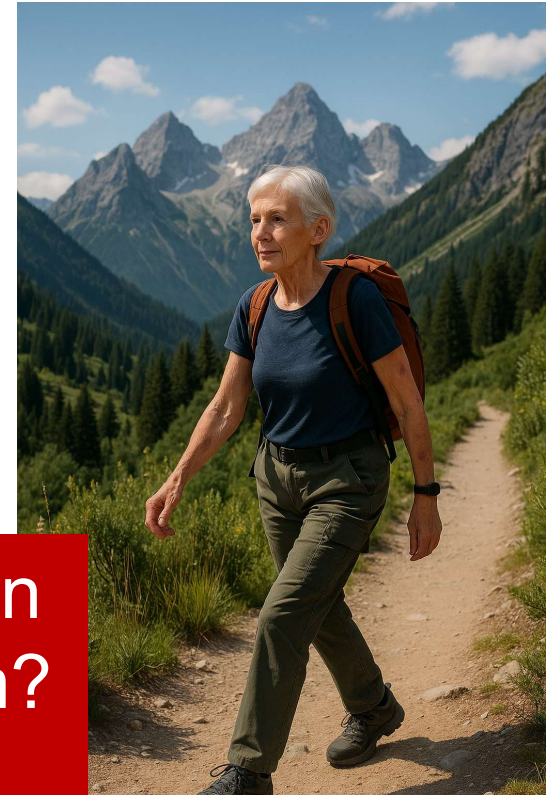
Study	Groups	Patient population	Number	FU	Completion
CHAMPION-AF NCT04394546	WATCHMAN ■ USZ	X Vorhofflimmern, oAK langfristig indiziert, kein Kontraindikationen	3000	3 Jahre	2027
CATALYST NCT04226547	Amulet ■ Inselspital ■ Stadtspital Triemli	Vorhofflimmern, oAK langfristig indiziert, kein Kontraindikationen	2650	2 Jahre	2030

76-jährige ♀

- Hat jetzt 1-2 Episoden von Vorhofflimmern pro Woche, Dauer bis 6h
- Yoga/Wandern geht dann nicht mehr!!!
- EHRA Score III

→ Indikation für Vorhofflimmerablation

Doktor, brauche ich dann noch die Antikoagulation? Oder können Sie das Vorhofohr verschliessen, wenn Sie schon dort sind?!



OAK nach Vorhofflimmernablation?



ESC

European Society
of CardiologyEuropace (2024) 26, 1–107
<https://doi.org/10.1093/europace/euae043>

EHRA DOCUMENT

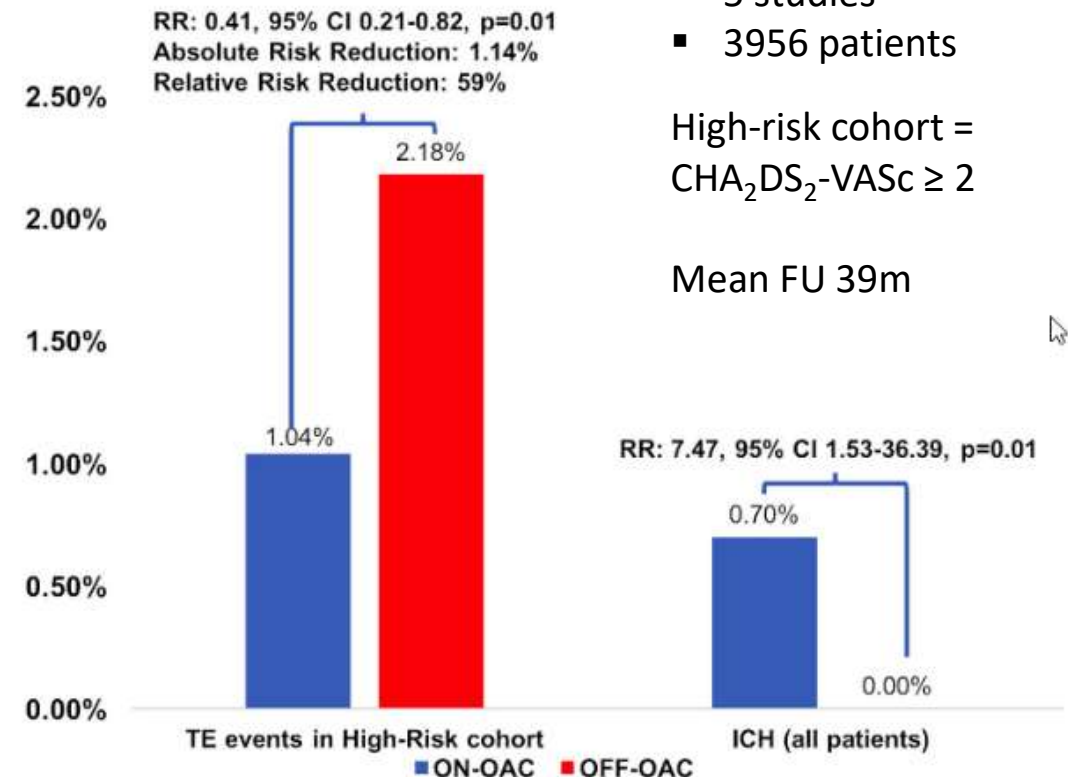


EHRA

European Heart
Rhythm Association

2024 European Heart Rhythm Association/ Heart Rhythm Society/Asia Pacific Heart Rhythm Society/Latin American Heart Rhythm Society expert consensus statement on catheter and surgical ablation of atrial fibrillation

In the absence of high-quality evidence, long-term anticoagulation after AF ablation in patients with CHA₂DS₂-VA score ≥ 2 is considered beneficial.



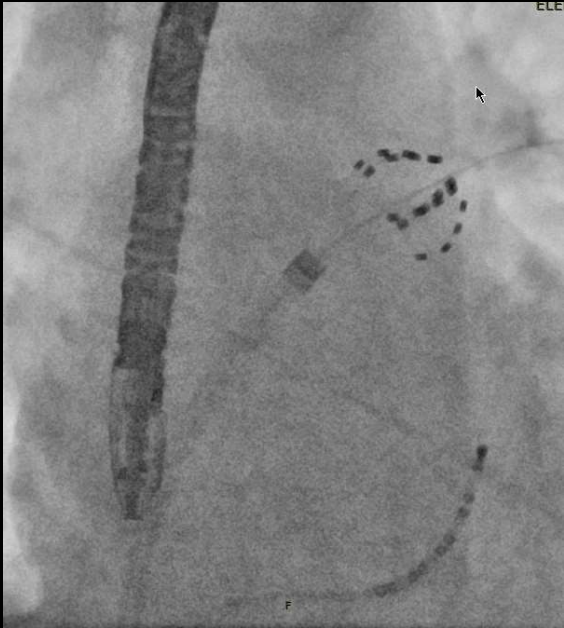
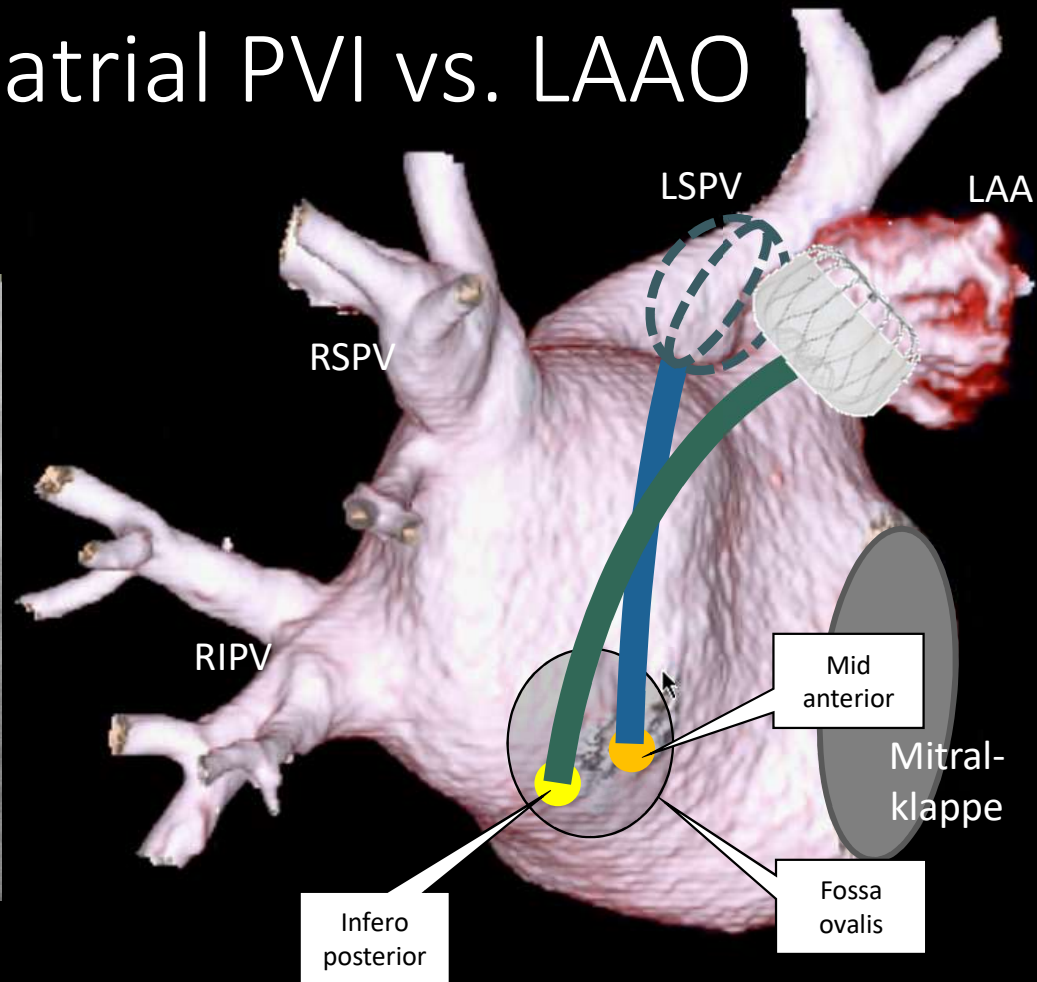
Systematic review

- 5 studies
- 3956 patients

High-risk cohort =
CHA₂DS₂-VASc ≥ 2

Mean FU 39m

Zugang linksatrial PVI vs. LAAO



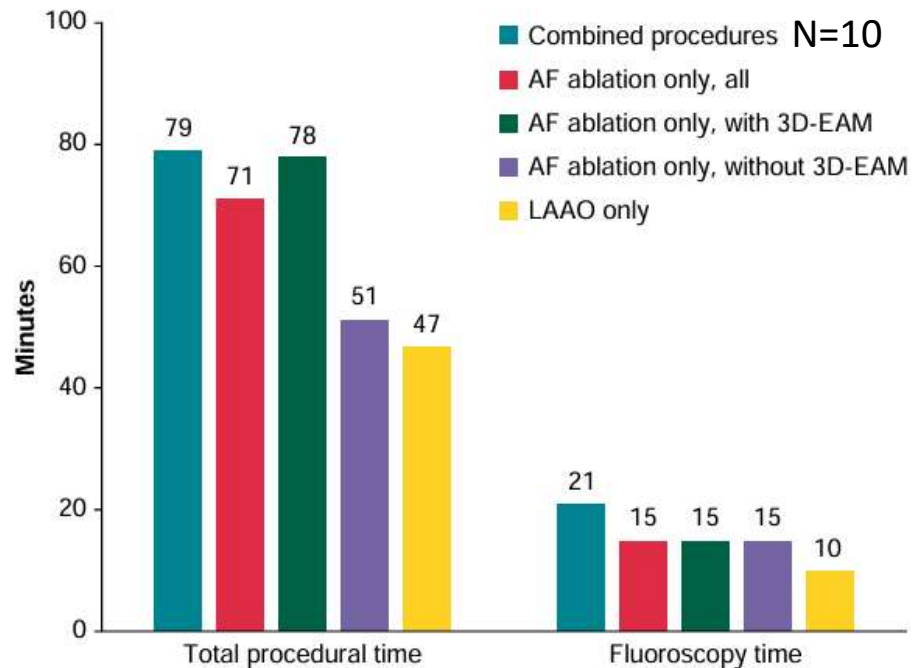
PVI (PFA) + LAAO – Erfahrungen in Bern

Single procedures
retrospective comparison, same operators, consistent technologies

AF ablation only
n = 207



LAAO only
n = 61



Procedural characteristics	Combined procedures <i>n</i> = 10	LAAO only <i>n</i> = 61
Total procedural time, min	79 (60–125)	47 (15–162)
Vein access to transseptal puncture, min	10 (2–27)	—
First to last PFA application, min	24 (17–43)	—
Transseptal puncture to last PFA application, min	38 (27–79)	—
Vein access to last PFA application, min	49 (34–93)	—
Last PFA application to occluder insertion, min	14 (10, 29)	—
LAA occluder insertion to release, min	5 (2–17)	—
Last PFA application to LAA occluder release, min	20 (15–37)	—
Fluoroscopy time, min	21 (15–26)	10 (3–50)
Radiation dose, cGy cm ²	1539 (191–10 323)	2476 (874–32 721)

OPTION Trial

N=1'600
AF ablation
CHA₂DS₂-VA ≥2

R

1 : 1

Concomitant
41%

Success
98.8%

3m OAC
12m ASS
(min.)

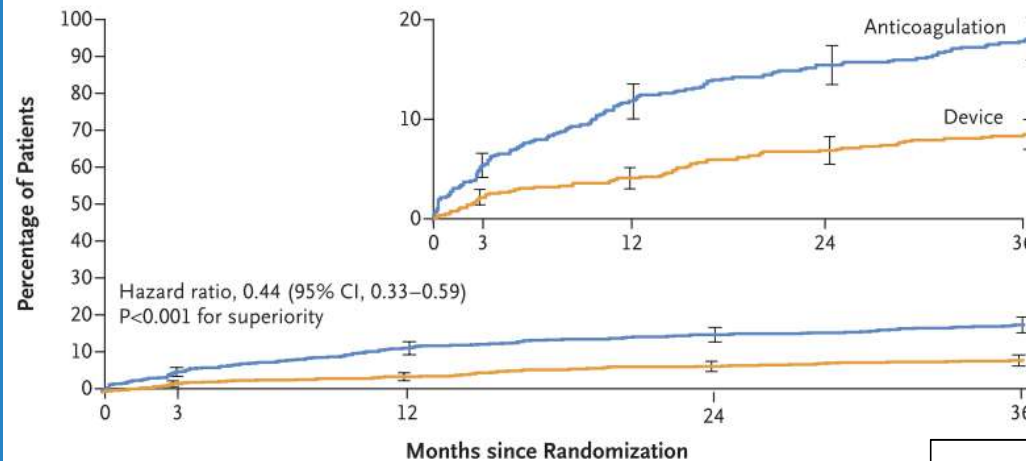
OAC for
study
duration

FU 3y

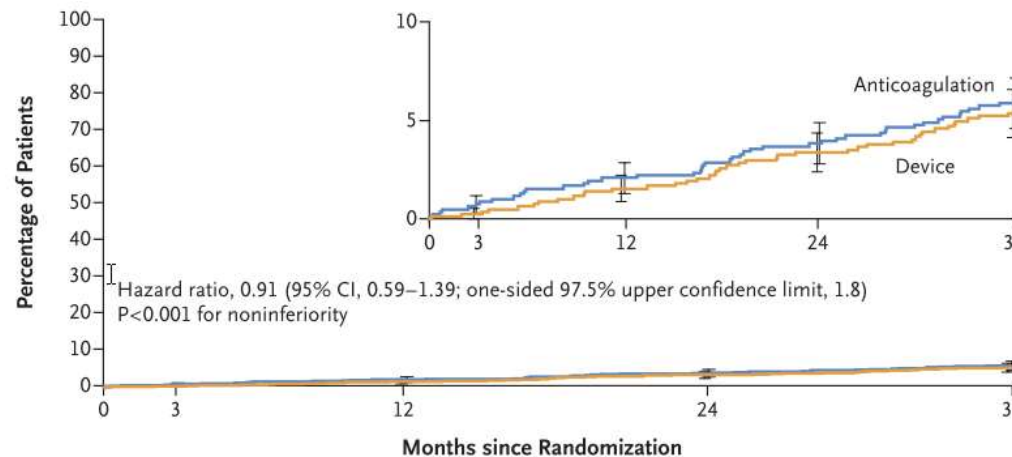
Primary Safety Endpoint

Non-procedure-related bleeding

Major bleeding and clinically relevant nonmajor bleeding



Death from any cause, stroke, or systemic embolism



1.17%/y

1.2%/y

Through 36m	Abl. + LAAO	Abl. + OAC
Stroke	1.6%	2.0%
TIA	1.6%	1.5%
SE	0.3%	0.1%
Death	3.8%	4.5%
CV death	2.0%	2.0%

OPTION Trial

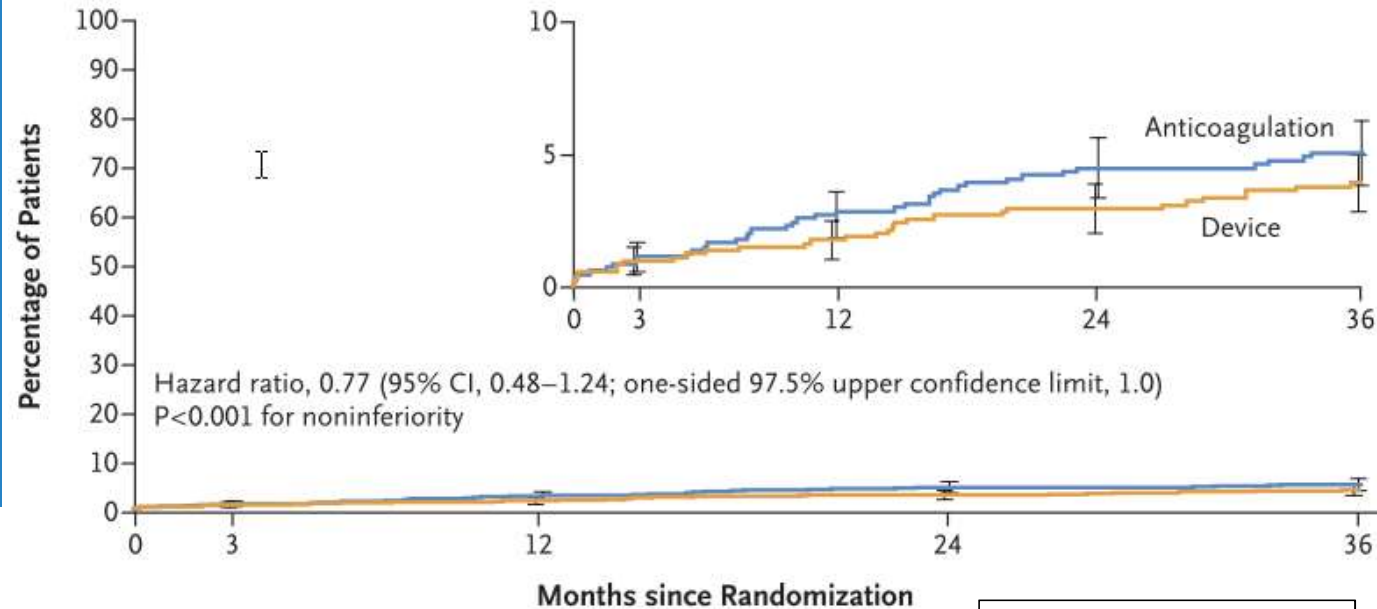
Device- or procedure-related
serious adverse events
22/783 (2.8%)

Within 10 days (22 pat./ 26 events)

- **4 bleeding events**
- 3 arrhythmias
- **3 pericardial effusions**
- **3 pseudoaneurysms**
- **2 air embolisms**
- 2 infections
- 2 pericarditis
- 1 chest pain
- 1 chronic kidney disease
- 1 elevated blood sugar
- 1 heart failure
- 1 odynophagia
- 1 pulmonary edema
- **LAAC in OAC group with groin hematoma**

Secondary Endpoint

Major bleeding, **including procedure-related bleeding**



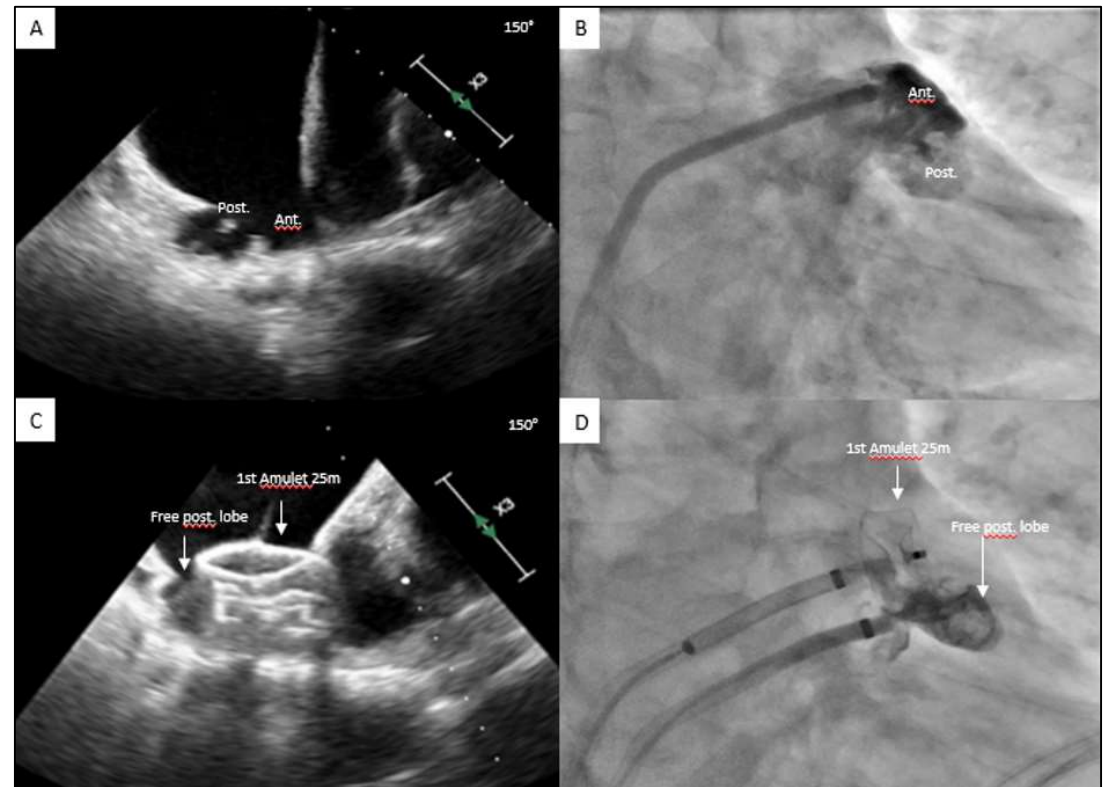
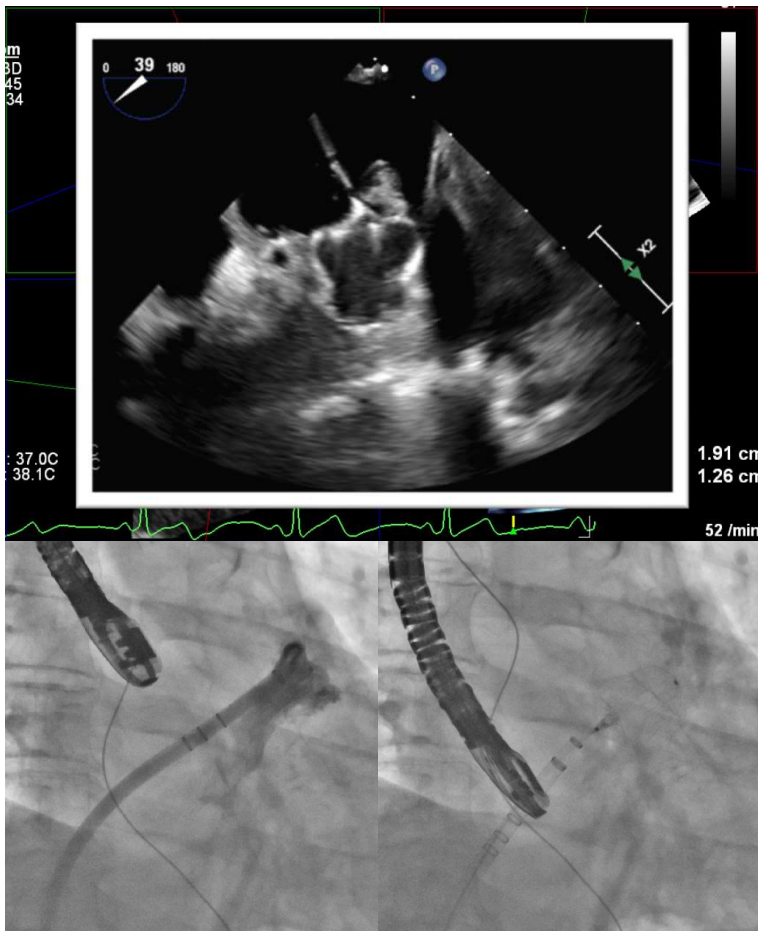
Non-procedure-related bleeding

Through 36m	Abl. +LAAO	Abl. +OAC
Major bleeding	23	33

- GI-bleeding (22)
- Hematuria (19)
- Epistaxis (19)
- Hematoma (11)
- Bruising (8)
- Oral bleeding (5)
- Lacerations (4)
- ...

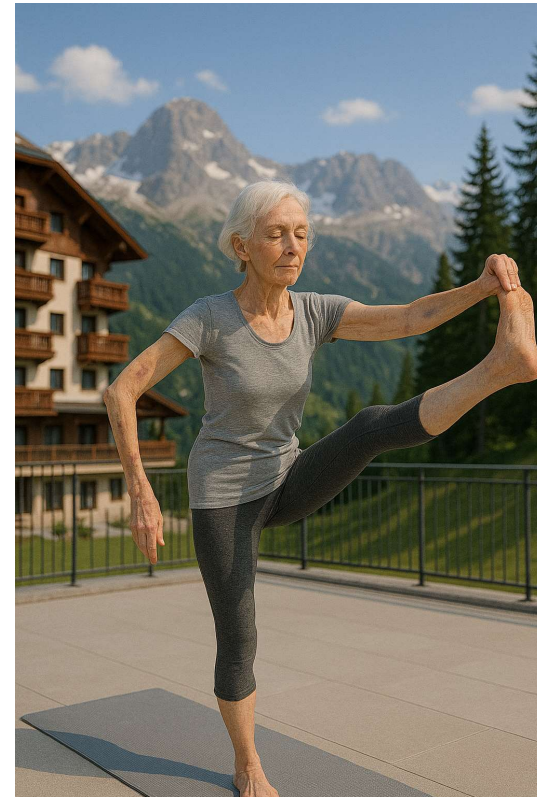
Gleichzeitige PVI + LAAO?

1. Wer benötigt nach (mutmasslich erfolgreicher) Vorhofflimmernablation noch eine antithrombotische Therapie?
2. Ist eine „*klinisch relevante, nicht schwerwiegende Blutung*“ relevant für die Patientin/den Patienten?
3. Wie hoch ist das (tatsächliche) prozedurale Risiko?



76-jährige ♀

- Aufgeboten für PVI+LAAO (bei geeigneter Anatomie) in 3 Monaten
- Ischämischer Schlaganfall mit plötzlich aufgetretener rechtsseitiger Schwäche und Sprachstörung
 - Verschluss der linken Arteria cerebri media (MCA)
 - Thrombolyse mit vollständiger Rückbildung
- Ablation abgesagt, sie kommt 2 Monate später in die Sprechstunde



**Doktor, ich habe die Blutverdünnung
zuverlässig eingenommen!
Jetzt was?!**

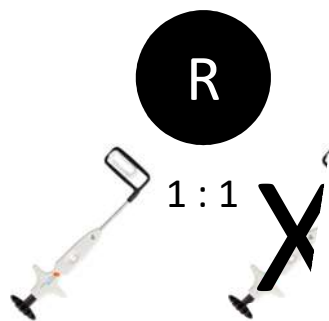
Thromboembolie trotz oraler Antikoagulation

Recommendation	Class ^a	Level ^b
A <u>thorough diagnostic work-up</u> should be considered in patients taking an oral anticoagulant and presenting with ischaemic stroke or thromboembolism to prevent recurrent events, including assessment of non-cardioembolic causes, vascular risk factors, dosage, and adherence. ^{356,357}	IIa	B
<u>Adding antiplatelet treatment</u> to anticoagulation is not recommended in patients with AF to prevent recurrent embolic stroke. ^{356,359}	III	B
<u>Switching from one DOAC to another</u> , or from a DOAC to a VKA, without a clear indication is not recommended in patients with AF to prevent recurrent embolic stroke. ^{252,356,359}	III	B

«Aside from thorough attention to underlying risk factors and co-morbidities, the approach to management of patients with a stroke despite OAC **remains a distinct challenge.**»

LAAOS

N=4'811
Vorhofflimmern
CHA₂DS₂-VASc ≥2
Herzchirurgie-Eingriff

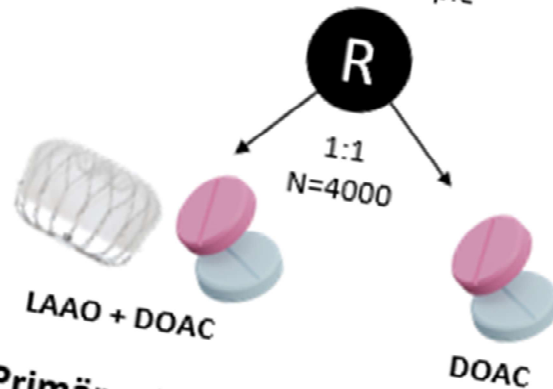


76.8% OAK
Nach 3 Jahren

ØFU 3.8y

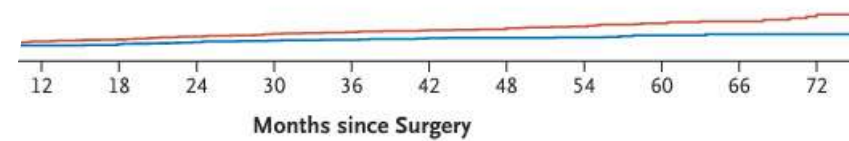
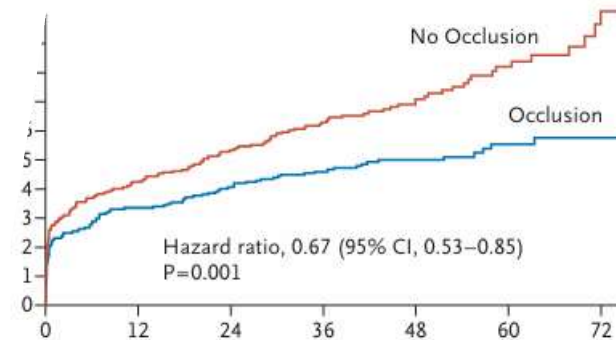
LAAOS-IV

Permanentes/persistierendes oder
paroxysmales (plus CVI) Vorhofflimmern
CHA₂DS₂-Vasc-Score ≥4
DOAC Therapie



Primärer Endpunkt
■ Ischämischer Hirnschlag/arterielle
Embolie

Primärer Endpunkt
Stroke oder systemische Embolie



Closure from within	939/1685 (55.7)
Closure from within	189/1685 (11.2)
Closure from within	255/1685 (15.1)
Closure from within	233/1685 (13.8)
Other approved techniques	69/1685 (4.1)

Ischämischer Hirnschlag trotz oAK?

Study	Groups	Patient population	Number	FU	Completion
OCCLUSION-AF NCT03642509	LAAO devices vs. DOACs	Vorhofflimmern und ischämischer Hirnschlag/TIA	750	5 Jahre	2030
ELAPSE NCT05976685	LAAO + DOAC vs. DOAC alone	Vorhofflimmern und ischämischer Hirnschlag trotz oAK	500-1000	4 Jahre	?

- Inselspital
- USB
- CHUV
- HUG
- KS St. Gallen
- KS Luzern
- Cardiocentro

 INSELGRUPPE

NEUROZENTRUM
Neurocentre | Neurocentro
Inselspital Universitätsspital Bern
Universitäre Psychiatrische Dienste Bern

Neurochirurgie
Neurologie
Neuropädiatrie
Neuroradiologie
Psychiatrie

**HERZ GEFÄSS
ZENTRUM**

Early closure of **L**eft atrial **A**ppendage for
Patients with atrial fibrillation and ischemic
Strok**E** despite anticoagulation therapy
- **ELAPSE**

Take Home Messages

- LAAO Thromboembolierisiko und Kontraindikation für OAK
- LAAO anstelle einer gut verträglichen OAK momentan nicht empfohlen (**CATALYST; CHAMPION-AF**)
- PVI + LAAO (bei günstiger Anatomie) als neue **Option**
- OAK + LAAO mögliche Strategie bei Hochrisikopatienten (**LAAOS IV; ELAPSE;** etc.)
- Ein chirurgischer LAA-Verschluss ist obligat bei Vorhofflimmern-Patienten anlässlich einer Herzchirurgie, wobei die OAK im Anschluss fortgesetzt werden sollte.