

Facts

- Atrial fibrillation is a major cause of stroke.
- Anti-coagulation is effective to prevent stroke for patients with atrial fibrillation.

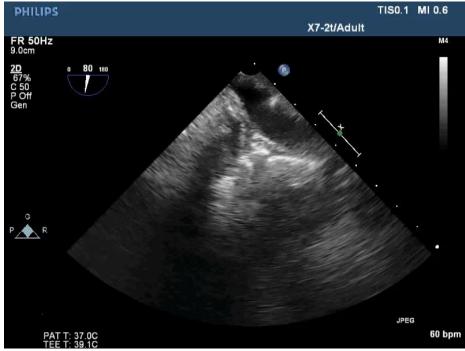
The key point is that they are not suitable for longterm use!!

- Any localized of general physical condition in which the hazard of hemorrhage might be greater than the potential clinical benefits of anticoagulation
- Any personal circumstance in which the hazard of hemorrhage might be greater than the potential clinical benefits of anticoagulation
- Pregnancy
- Hemorrhagic tendencies
- Blood dyscrasias
- Recent or contemplated surgery of central nervous system
- Recent or contemplated surgery of the eye
- Recent or contemplated traumatic surgery resulting in large open surfaces
- Gastrointestinal bleeding
- Genitourinary tract bleeding
- Respiratory tract bleeding
- Cerebrovascular hemorrhage
- Cerebral aneurysms
- Dissection aorta
- Pericarditis
- Pericardial effusion

- Bacterial endocarditis
- Threatened abortion
- Eclampsia
- Preeclampsia
- Inadequate laboratory facilities
- Unsupervised patients
- Senility
- Alcoholism
- Psychosis
- Lack of patient cooperation
- Spinal puncture
- Other diagnostic procedures with potential for uncontrollable bleeding
- Therapeutic procedures with potential for uncontrollable bleeding
- Major regional anesthesia
- Lumbar block anesthesia
- Malignant hypertension

All these patients had been excluded from the randomized NOAC trials





Anticoagulants- bleeding and inconvenience

- Anticoagulants are problematic in younger patients, because
 - They want to go skiing or bungee jumping.
- Anticoagulants are problematic in elderly patients, because
 - They have a higher bleeding risk.
 - They also want to go skiing or bungee jumping.

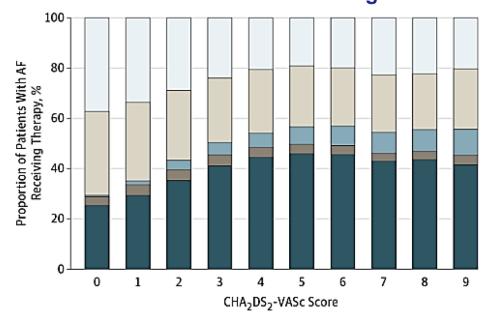






In real world, oral anticoagulation is continuously used in <50% of all AF patients

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



No. 12348 36976 61557 87008 97878 70212 37314 17814 6385 1161

No antithrombotic therapy Aspirin only Aspirin plus a thienopyridine Non-vitamin K antagonist oral anticoagulant Warfarin sodium

- American College of Cardiology
 National Cardiovascular Data Registry's
 PINNACLE (Pratice Innovation and
 Clinical Excellence) Registry
- 429 17 outpatients with AF
- Overall, OAC prescription prevalence did not exceed 50% even in higher-risk patients with a CHADS2 score exceeding 3 or a CHA2DS2-VASc score exceeding 4

Any treatment that provides continuous therapeutic effect and causes no bleeding?

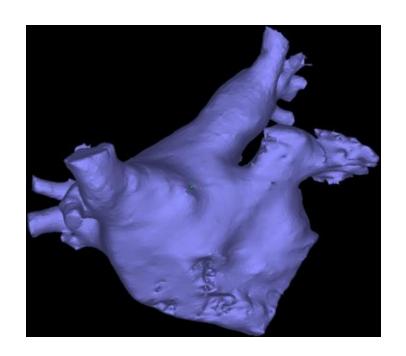


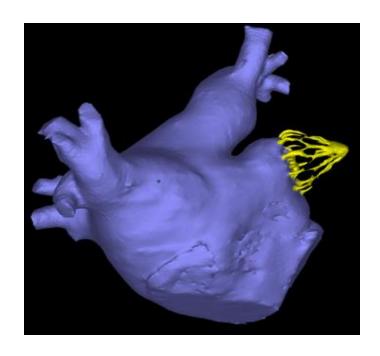
Most of the strokes in AF patients are caused by intracardiac thrombus.

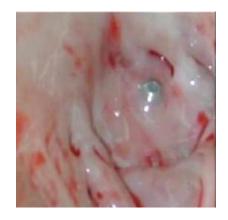
90% of intra-cardiac thrombus localizes in LAA.

Can we occlude or ligate the LAA to prevent stroke for our AF patients?

Percutaneously implant an occluder to occlude or close the LAA?









Percutaneous LAA Closure is now recommended in major AF treatment guidelines.



European Heart Journal doi:10.1093/eurheartj/ehw210 **ESC GUIDELINES**

2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS

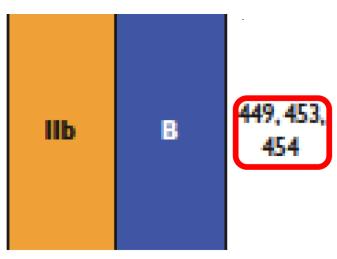
The Task Force for the management of atrial fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC

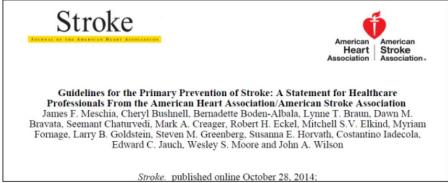
Endorsed by the European Stroke Organisation (ESO)

LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term anticoagulant treatment (e.g. those with a previous life-threatening bleed without a reversible cause).

Studies in non-Contraindicated patients



AHA/ASA guidelines for the primary prevention of stroke 2014



For patients with non-valvular AF, CHA_2DS_2 -VASc ≥ 2 and acceptably low risk of hemorrhagic complications, (N)OACs are recommended (Class I)

Closure of the LAA may be considered for high-risk patients with AF who are deemed unsuitable for anticoagulation

If performed at a center with low rates of periprocedural complications and the patient can tolerate the risk at least 45 d of postprocedural anticoagulation.

Class IIb; Level of Evidence B

http://stroke.ahajournals.org/content/early/2014/10/28/STR.000000000000046

Conclusion

- If your patient could not or do not want to take anticoagulant, do not forget there is another option, percutaneous LAAO implantation.
- Although we do not have large randomized clinical trials to support LAAO, we still have to make a decision.
- Using the limited data and common sense to judge. Just don't leave your patient untreated!!

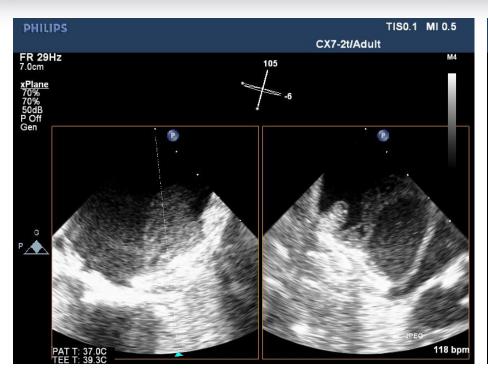
Argue 1: Stroke is a systemic disease LAAO is a local treatment

- Yes, LAAO is a local treatment, but this local treatment does reduce stroke risk by ~70%. A local factor may contribute to ~70% of the AF stroke risk.
- Yes, OAC is a systemic treatment, but it reduces stroke risk by also only ~70%. OAC is also not a 100% treatment (e.g. catheter ablation is a 100% treatment for PSVT).

Argue 2: AF is associated with systemic hypercoagulability which actually is the cause of stroke. LAA thrombus is just a bystander!!

- Yes, this hypothesis might be true. So we need to do LAAO and conduct LAAO clinical trials to see if this hypothesis is true or wrong!!
- The fact is that a local LAAO, similar to systemic OAC, reduces the risk of ischemic stroke in AF patients.
- So, getting rid of LAA thrombus does work!

Device Related Thrombus Keep on OAC





					-	
Purpose	Demonstrate safety and effectiveness compared to long-term Warfarin	Continued safety and effectiveness	Demonstrate safety compared to long-term Warfarin	Demonstrate safety and effectiveness in patients ineligible for Warfarin	All-comers registry Europe, middle East, and Russia	
Study design	2:1 randomized non-inferiority trial OAC eligible n = 463	Non-randomized, prospective OAC eligible n = 566	2:1 randomized non-inferiority trial, OAC eligible n = 269	Non-randomized; prospective, OAC ineligible n = 150	Non-randomized; prospective 73% OAC ineligible n = 1020	
Medical therapy	Warfarin plus ASA for 45 days, DAPT for 6 months, and ASA for life	Warfarin plus ASA for 45 days, DAPT for 6 months, and ASA for life	Warfarin plus ASA for 45 days, DAPT for 6 months, and ASA for life	DAPT for 6 months (clopidogrel + ASA) then ASA for life	Discretion of operator; 60% DAPT, 15% warfarin, 11% NOAC 3 months. ASA for life	
Results	non-inferiority to warfarin maintained at 5 years; trend for improved mortality	safety increases with operator experience and training; efficacy confirmed	safety issue from PROTECT-AF resolved; non-inferiority to warfarin not achieved: unexpected low event rate with warfarin	DAPT safe and effective for device thrombus prevention	Safety @ 3 months confirmed; 4.2% bleeding @ 3 months most relevant SAE procedure-related SAE similar to pulmonary vein isolation	
2019/4/16		2018 A	2018 AF Trends @andiovasc Med. 2017; 27(6): 435-46 72			

PREVAIL

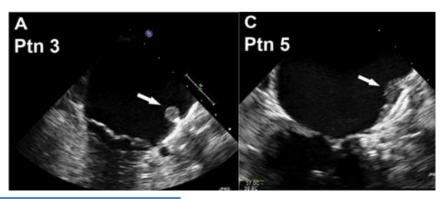
ASAP

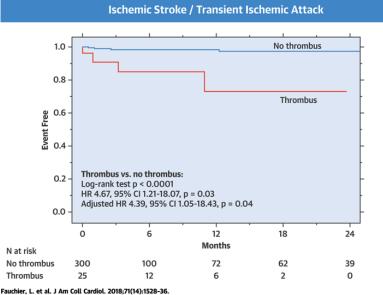
EWOLUTION

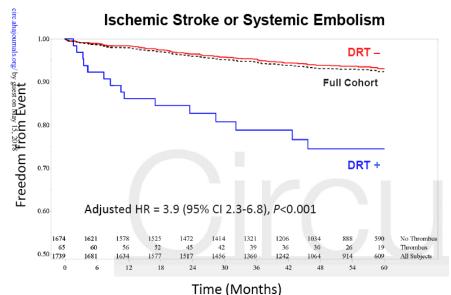
PROTECT AF

CAP

Argue 3: Thrombus on Device Device Related Thrombus (DRT)







JACC 2018

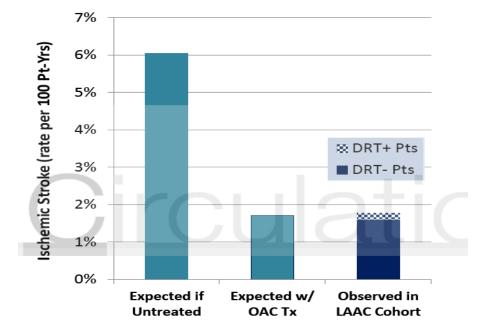
Circulation 2018

Device Related Thrombus (DRT)

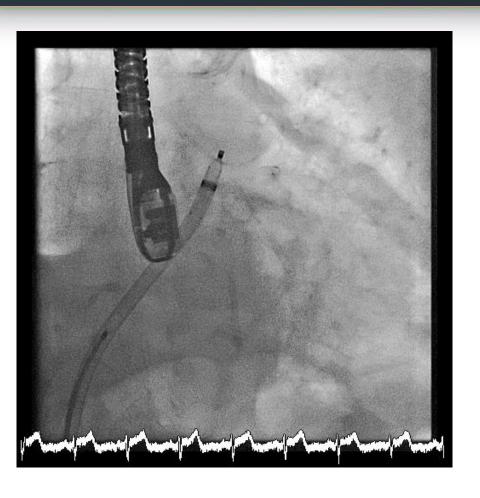
- DRT rate is 2%-8%, dependent on patient factors (uncontrollable), post-procedural anti-thrombotic regimen (controllable) and implantation skills (controllable).
- It is one of the complications of LAAO procedure.

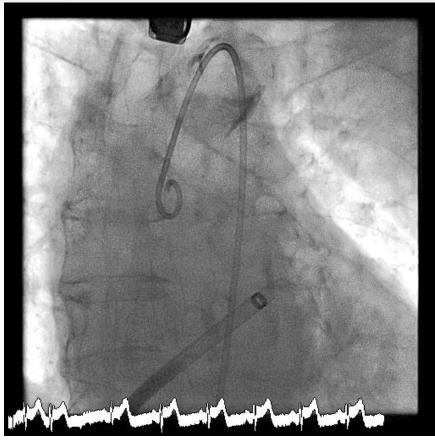
 But the ischemic stroke rate of treatment with LAAO, including those strokes related to DRT was still similar to that

of OAC.



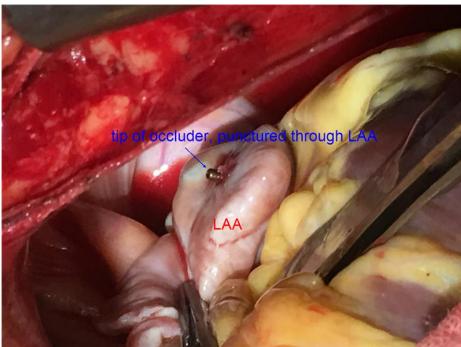
Air Embolism Suction out





LAA rupture, dye to pericardium ECMO, Emergent OP





Key point

- Transseptal puncture
 - 1. Electrocautery knife to transseptal needle
- Flushing by saline, keep adequact ACT
 - 1. Continue flushing, coopearation between operation and assistant
- As gentle as possible
 - 1. Careful look for LAA morphology LAA
 - 2. LAA as thin as paper



Anticoagulation just does not work long-term in selected AF patients!

Please don't forget there is another treatment option.

Thanks for your attention Comments or questions

