

UPDATED CRITERIA FOR CLOSURE OF PATENT FORAMEN OVALE IN PATIENTS WITH CRYPTOGENIC STROKE - ARE THEY ALSO VALID FOR PILOTS?

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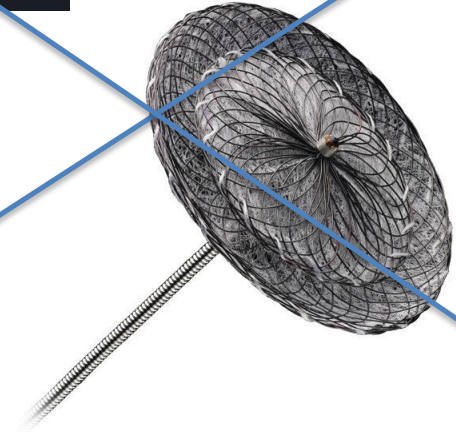


SHARING THE SKY SAFELY

11.-15. NOVEMBER 2018, BANGKOK, THAILAND



AMPLATZER™ PFO OCCLUDER

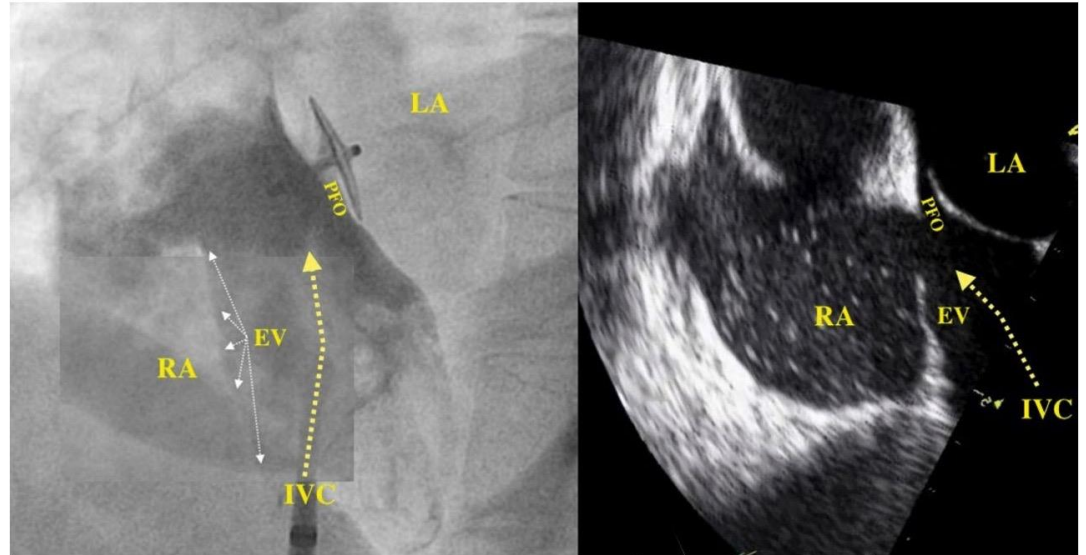


Disclosures: No conflicts of interest



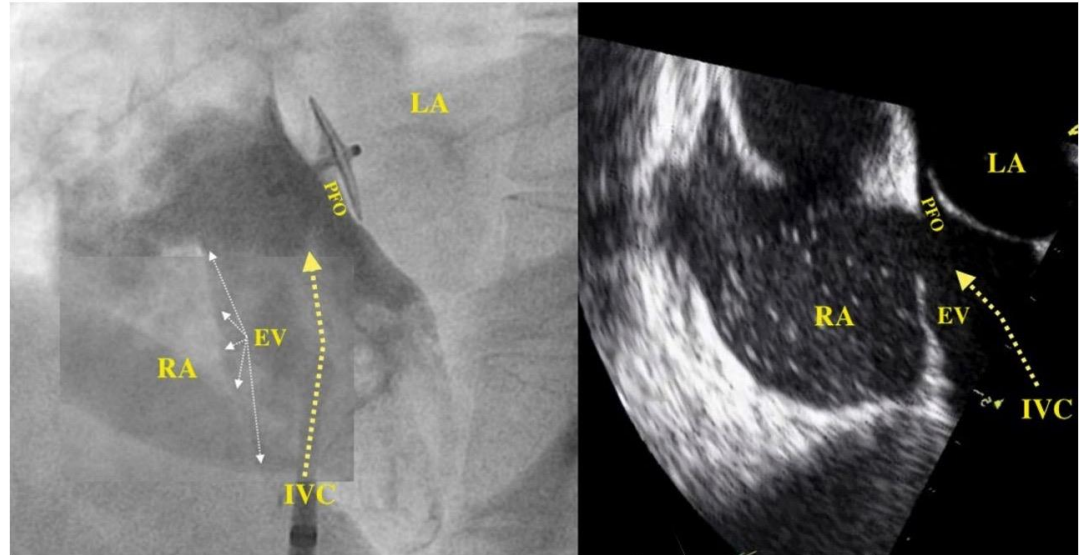
Updated criteria for closure of patent foramen ovale in patients with cryptogenic stroke - Are they also valid for pilots?

- Case report, part I
- The problem
- State of the art 2018
- Case report, part II
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Applicant for an initial EASA-class 2-Medical, 54 yrs. male

- 18.03.2018 First AME consultation: Because of a transient ischemic attack in the past und the presence of a patent foramen ovale (PFO) referral of the medical documents to a cardiological expert of Swiss CAA.
- Medical history: 02.12.2014 Hospitalisation in a medium sized hospital because of a transient left sensory hemisyndrome lasting about 2 ½ hours. - In the previous medical history: No special event.
- Chemist, nonsmoker, married, one child. - Mother and brother have hereditary thrombophilia.



- Examinations:
 - Normal results for ... (multiple examinations).
 - Ultrasound arteria cerebri media: under Valsalva right to left shunt.
 - Transesophageal echocardiography: PFO with spontaneous left to right shunt.
 - Thrombophilia? Yes, mild form.

- Diagnoses:
 - Probable transient ischaemic attack (TIA)
 - PFO
 - cardiovascular risk factors: none
 - mild hereditary thrombophilia

- Follow up:
 - Annual cardiological examinations at that hospital.
 - Treatment with Aspirin 100 mg daily.

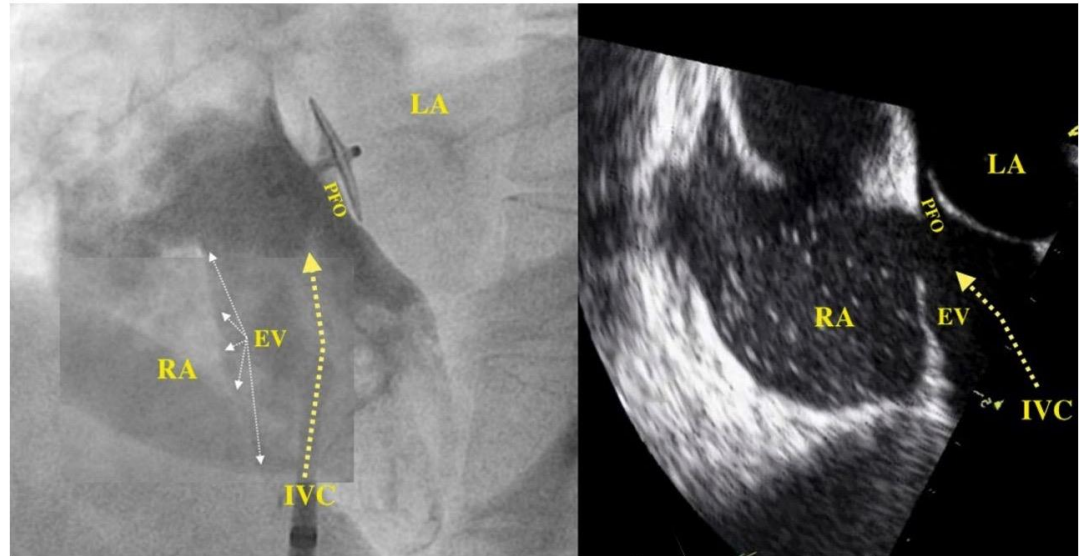
- 03/2018 Considerations/opinion of the cardiological expert of Swiss CAA for decision fitness to fly:

- Cryptogenic stroke and PFO:
 - Just to continue with aspirin-treatment?
 - Closure of the PFO?



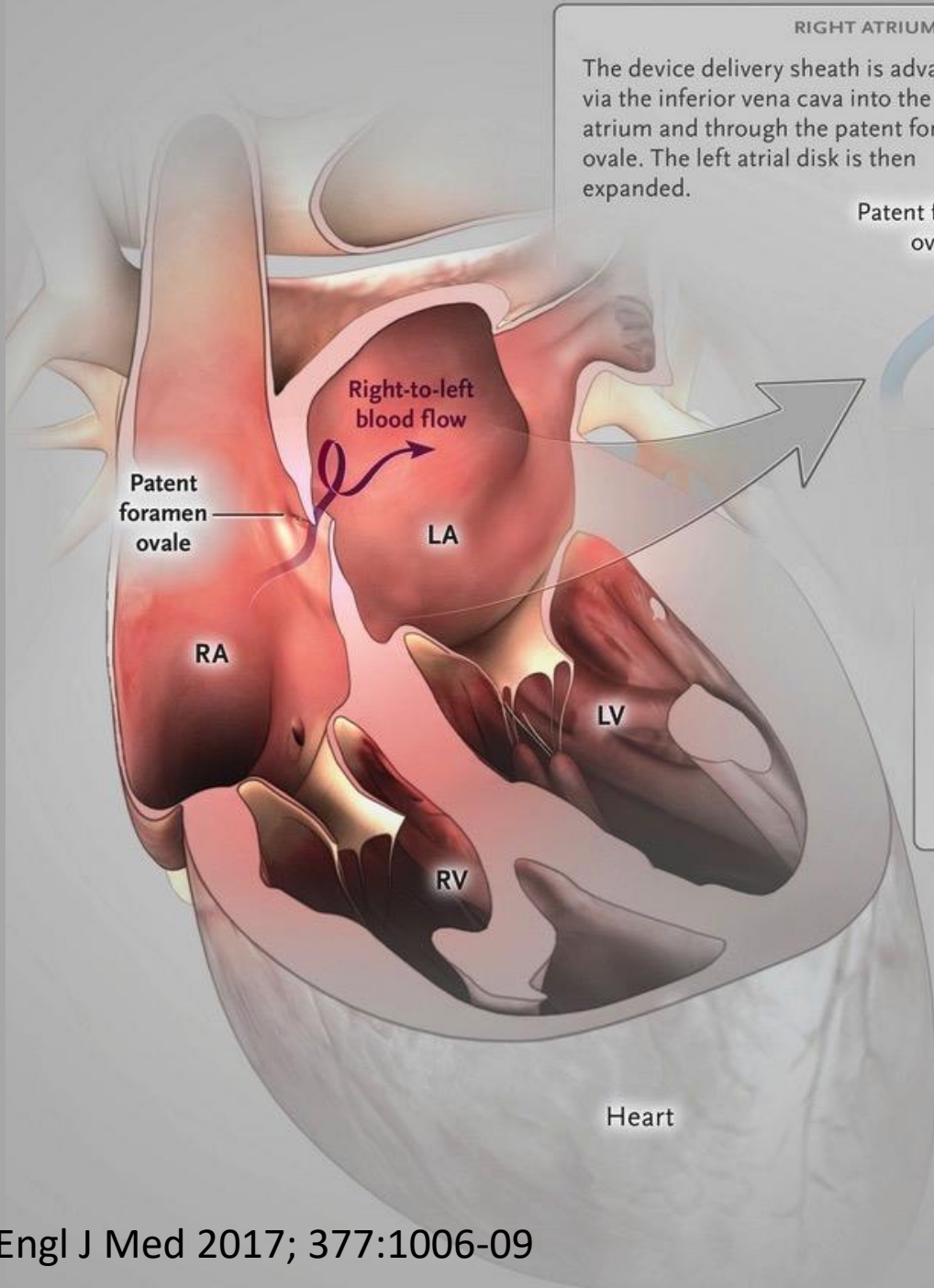
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- Cryptogenic stroke and PFO:
 - Longterm treatment with thrombocyte aggregation inhibitor or anticoagulation?
 - Closure of the PFO?





A

RIGHT ATRIUM

LEFT ATRIUM

The device delivery sheath is advanced via the inferior vena cava into the right atrium and through the patent foramen ovale. The left atrial disk is then expanded.

Patent foramen ovale

Atrial septum

Amplatzer PFO occluder expanded

B

The left atrial disk is retracted against the septal wall, and the delivery sheath is pulled back into the right atrium, where the right atrial disk is deployed.

Delivery sheath

RIGHT ATRIUM

C

The device is fully expanded, closing the patent foramen ovale. The delivery sheath is removed.

Waist

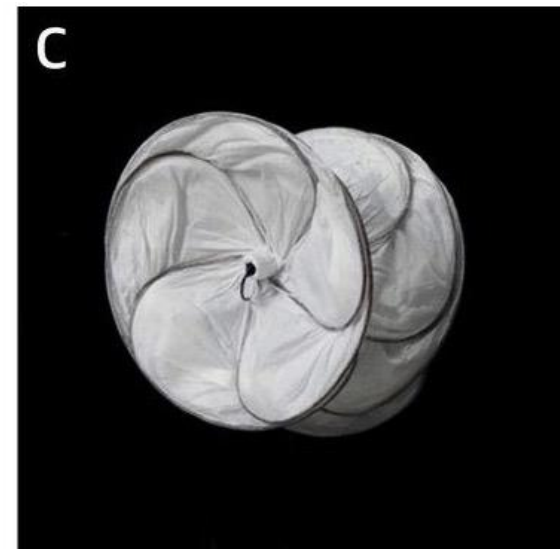
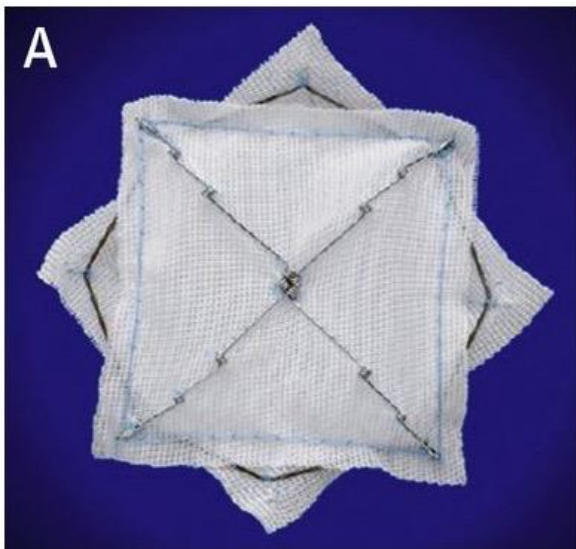
Right atrial disk

Left atrial disk

PFO:

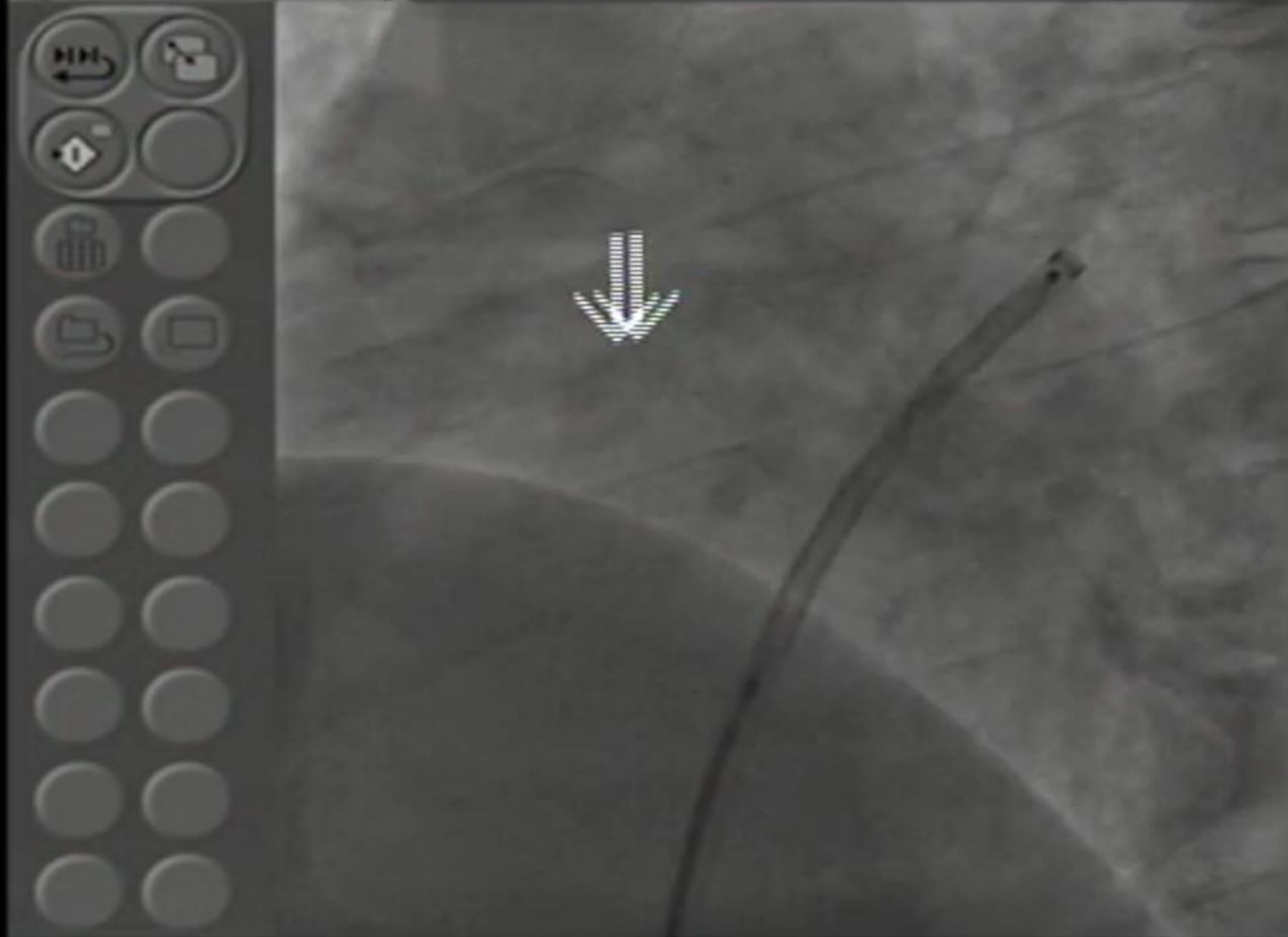
- Prevalence of PFO: 20% to 25% in the adult population.
- 40% to 50% of patients suffering a cryptogenic stroke have a PFO.
- Because of this high prevalence of PFO in the general population, it is difficult to prove a causal relationship between PFO and stroke by paradoxical embolism.
- Should a PFO in patients with cryptogenic stroke be closed percutaneously?





PFO occluders used in randomised clinical trials. (A) STARFlex PFO device (CLOSURE). (B) Amplatzer PFO occluder (RESPECT trial). (C) Gore Cardioform septal occluder (Gore REDUCE trial).

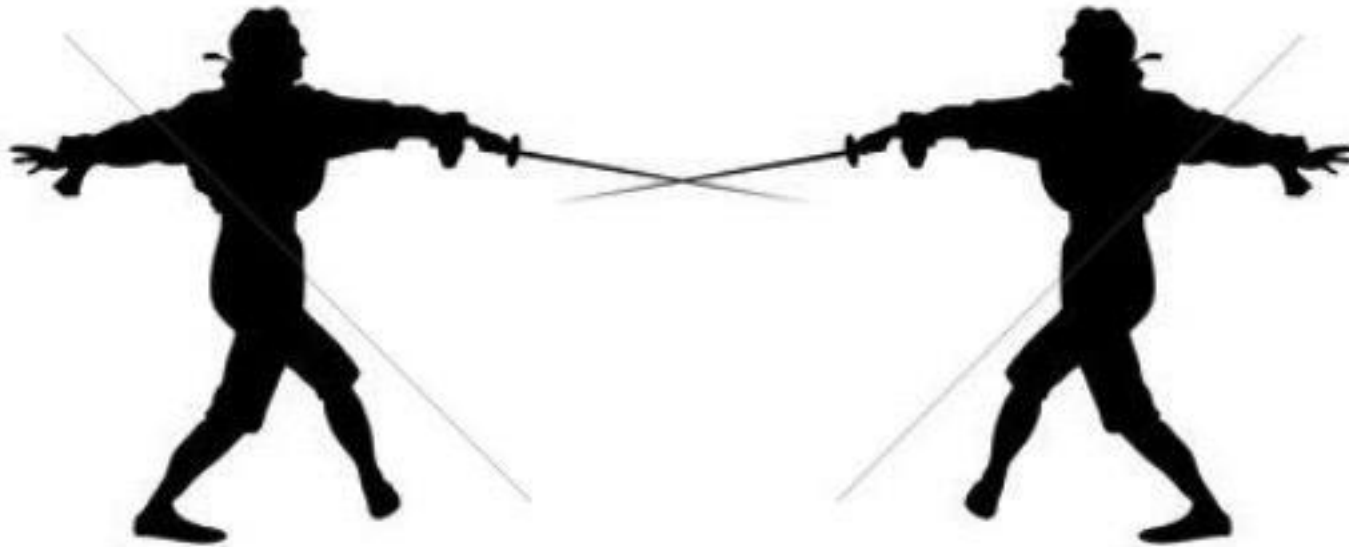




Neurologist

and

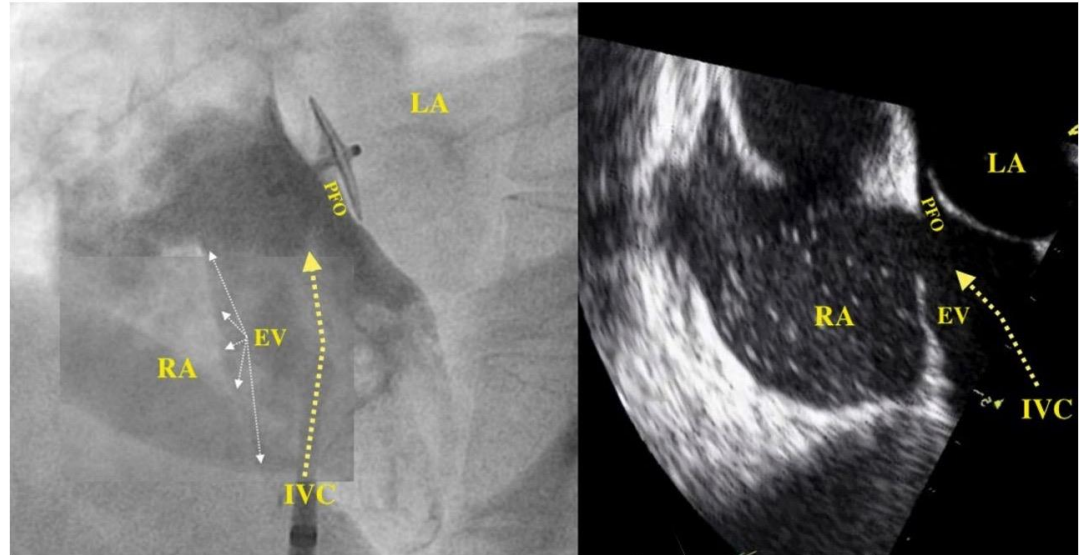
Cardiologist



- Percutaneous closure of PFO has been debated for more than a decade in ischemic stroke of unknown etiology, and no significant benefit has been demonstrated until recently.

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ORIGINAL ARTICLES

Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke

J.-L. Mas and Others

CLOSE

1011-1021 **FREE** CME

Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke

J.L. Saver and Others

RESPECT longterm

1022-1032 **FREE**

Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke

L. Søndergaard and Others

REDUCE

TABLE 1 Clinical Trials Randomizing Cryptogenic Stroke Patients to Percutaneous PFO Closure or Medical Therapy

Randomized Clinical Trial (Ref. #)	Cohort (Number of Patients)	Device Arm	Medical Arm	Follow-Up	Primary Outcome	Results
CLOSURE I (20)	Cryptogenic stroke or TIA + PFO; age 18–60 yrs (909)	PFO closure + aspirin and warfarin for 1 month, then aspirin for 2 yrs	Aspirin, warfarin or both	2 yrs	Composite of stroke, TIA, early death from any etiology and late neurological death	PFO closure did not significantly reduce recurrent stroke or TIA compared with medical therapy
PC (23)	Cryptogenic stroke, TIA or peripheral embolism + PFO; age <60 yrs (414)	PFO closure + aspirin for 5–6 months + clopidogrel or ticlopidine for 1–6 months	Antiplatelet or antithrombotic therapy	Mean 4 yrs	Composite of death, nonfatal stroke, TIA, or peripheral embolism	PFO closure did not significantly reduce recurrent embolic events or death compared with medical therapy
RESPECT (27) (extended follow-up)	Cryptogenic stroke + PFO; age 18–60 yrs (980)	PFO closure + aspirin and clopidogrel for 1 month, then aspirin for 5 months	Aspirin, warfarin, clopidogrel or aspirin + extended release dipyridamole	Median 5.9 yrs	Composite of recurrent nonfatal and fatal stroke and early death	PFO closure reduced recurrent stroke events compared with medical therapy
CLOSE (40)	Cryptogenic stroke + PFO with large shunt or atrial septal aneurysm; age 16–60 yrs (663)	PFO closure + aspirin and clopidogrel for 3 months, then single antiplatelet therapy	Aspirin, clopidogrel, or aspirin + extended-release dipyridamole or vitamin K antagonist or direct oral anticoagulant	Mean 5.3 ± 2.0 yrs	Fatal or nonfatal stroke	PFO closure reduced recurrent stroke events compared with medical therapy
Gore REDUCE (41)	Cryptogenic stroke + PFO; age 18–59 yrs (664)	PFO closure + aspirin, aspirin and dipyridamole, or clopidogrel	Aspirin, aspirin and dipyridamole, or clopidogrel	Median 3.2 yrs	Freedom from stroke; incidence of new brain infarct on MRI	PFO closure reduced recurrent stroke events and new brain infarcts on MRI compared with medical therapy

MRI = magnetic resonance imaging; PFO = patent foramen ovale; TIA = transient ischemic attack.

SAFETY OF PERCUTANEOUS PFO CLOSURE

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REVIEW TOPIC OF THE WEEK

Cryptogenic Stroke and Patent Foramen Ovale



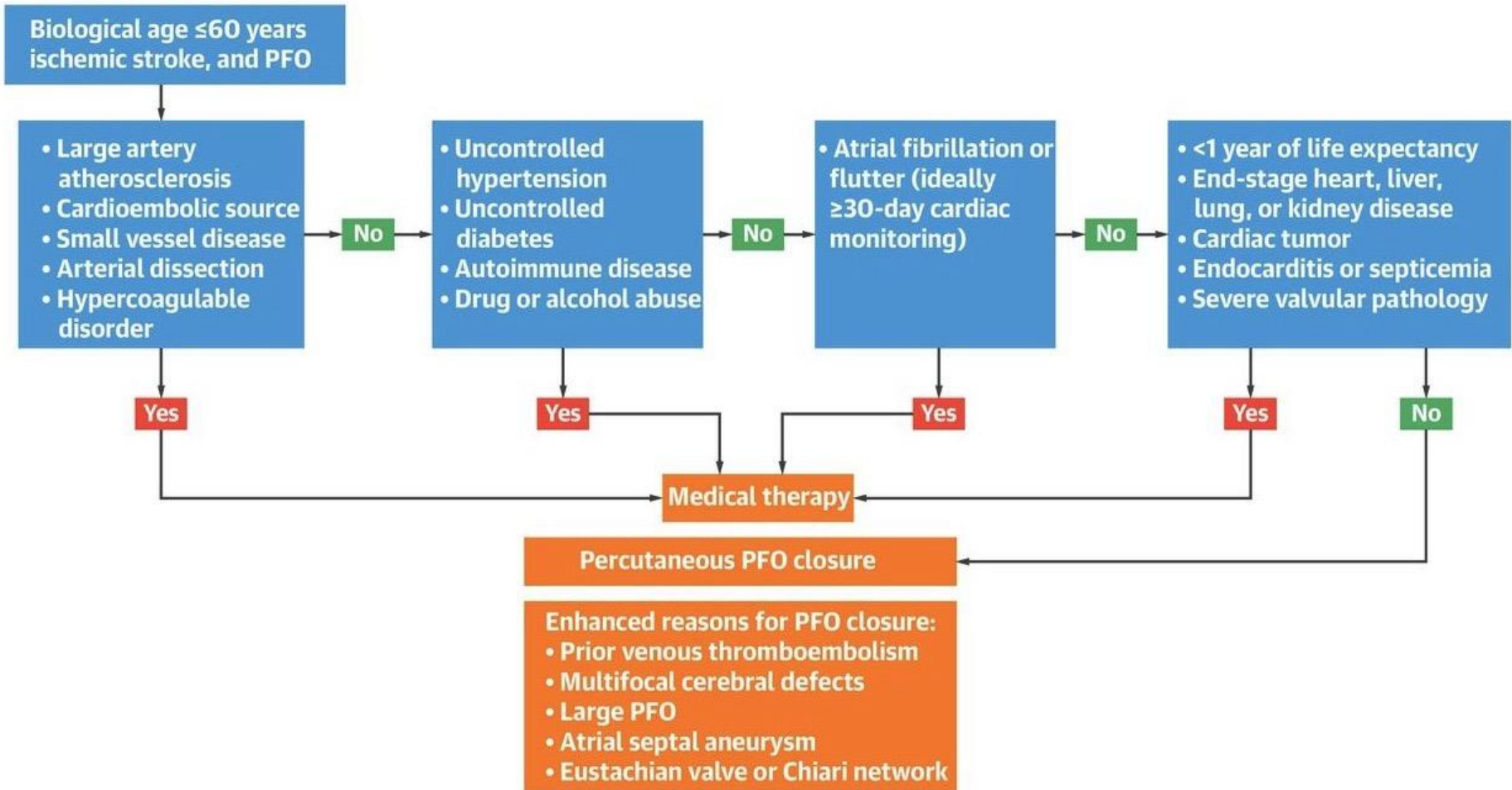
Mohammad K. Mojadidi, MD,^a Muhammad O. Zaman, MD,^a Islam Y. Elgendy, MD,^a Ahmed N. Mahmoud, MD,^a Nimesh K. Patel, MD,^b Nayan Agarwal, MD,^c Jonathan M. Tobis, MD,^d Bernhard Meier, MD^e

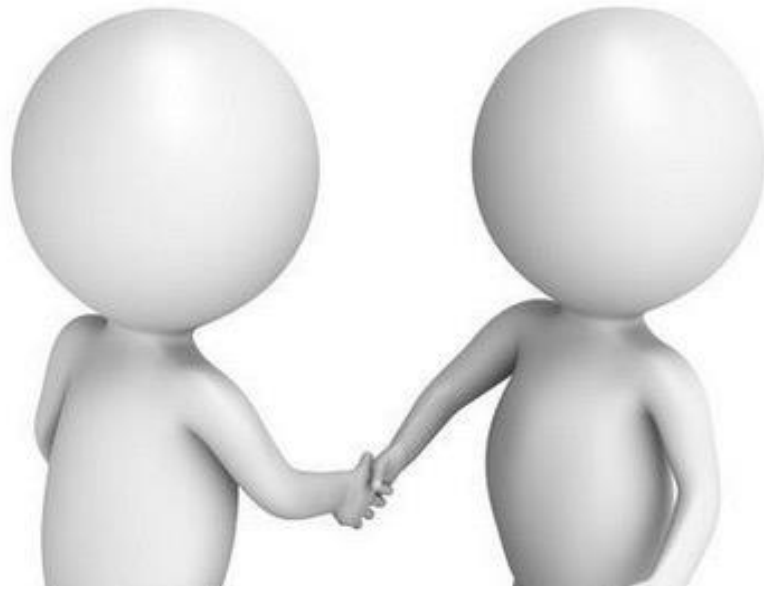
ABSTRACT

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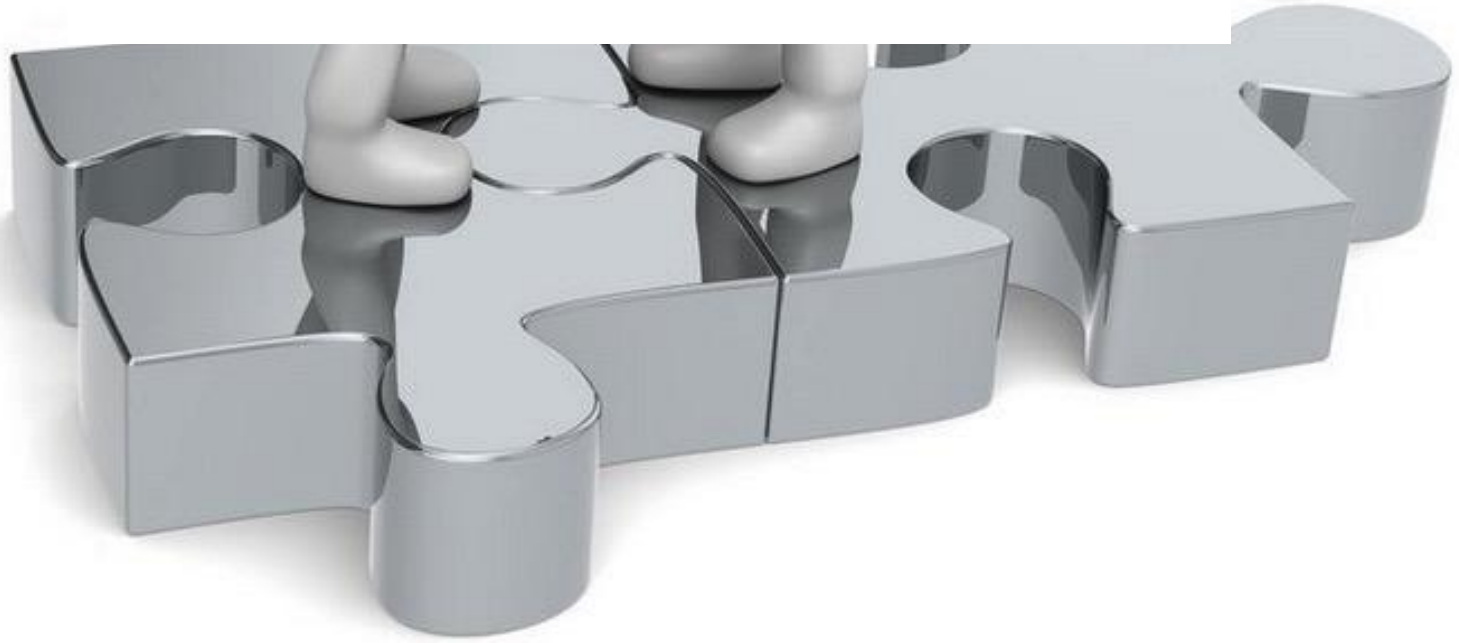
The long-term follow-up data from the RESPECT trial and 2 new randomized trials (CLOSE and REDUCE) have clarified these findings. They showed that with good patient selection, transcatheter PFO closure significantly reduces the risk of recurrent stroke compared with medical therapy in patients with cryptogenic stroke, with no increased risk of serious adverse events or influence on major bleeding. (J Am Coll Cardiol 2018;71:1035-43) © 2018 by the American College of Cardiology Foundation.

CENTRAL ILLUSTRATION: Evidence-Based Algorithm for PFO Closure in Ischemic Stroke Patients for Highest Clinical Yield, Based on Randomized Trials



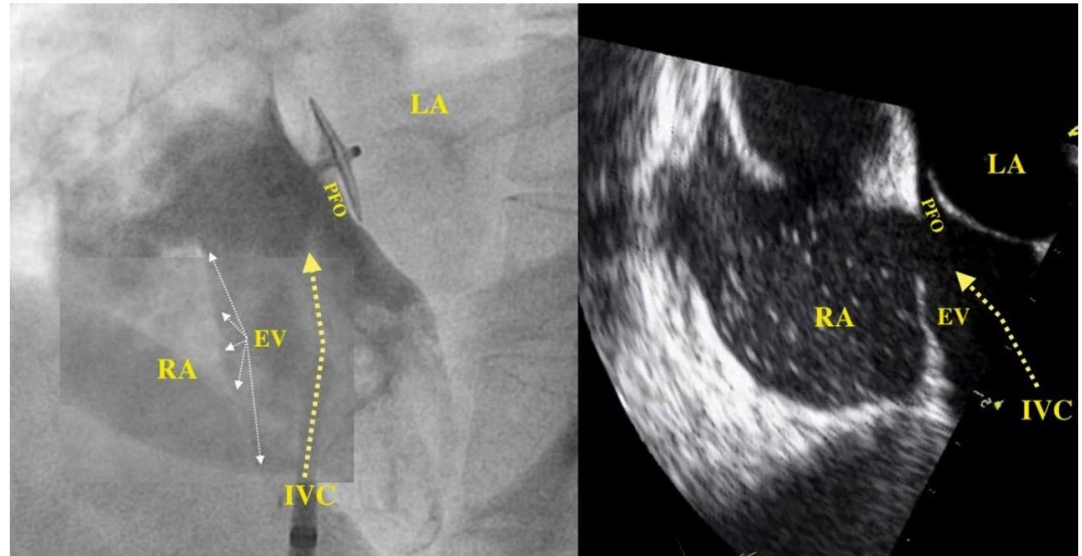


Neurologist and Cardiologist



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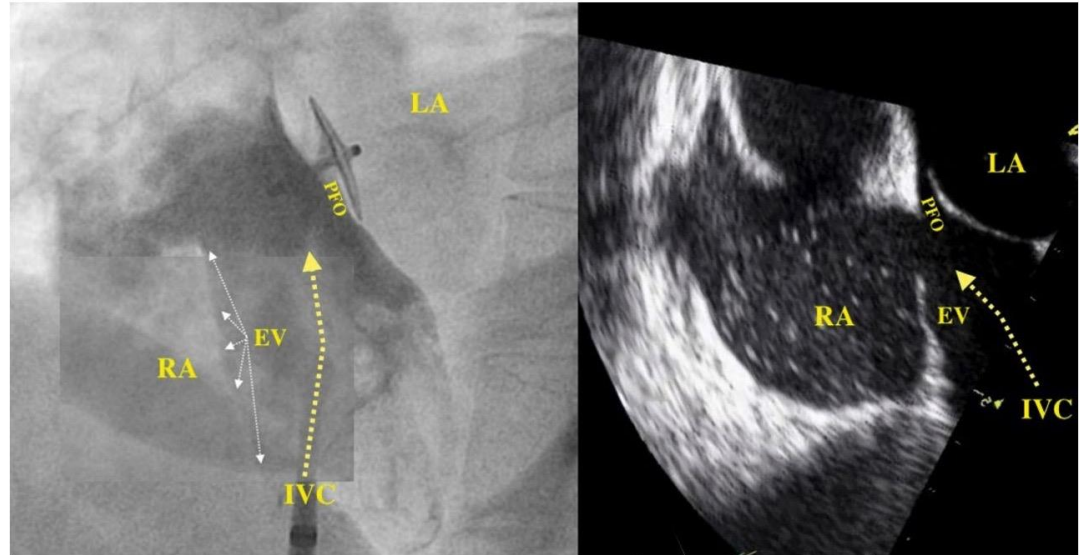


- 31.05.2018: Reevaluation: PFO Grade II-III and known mild hereditary thrombophilia.
- 02.07.2018: Closure of the PFO (Amplatzer PFO-device), Clopidogrel for three months and Aspirin for six months or longer (thrombophilia).
- 15.08.2018: Control examination including echocardiography: good result, no complication.
- 16.08.2018: Fit to fly for EASA-class 2-Medical without restriction. Control in one year.



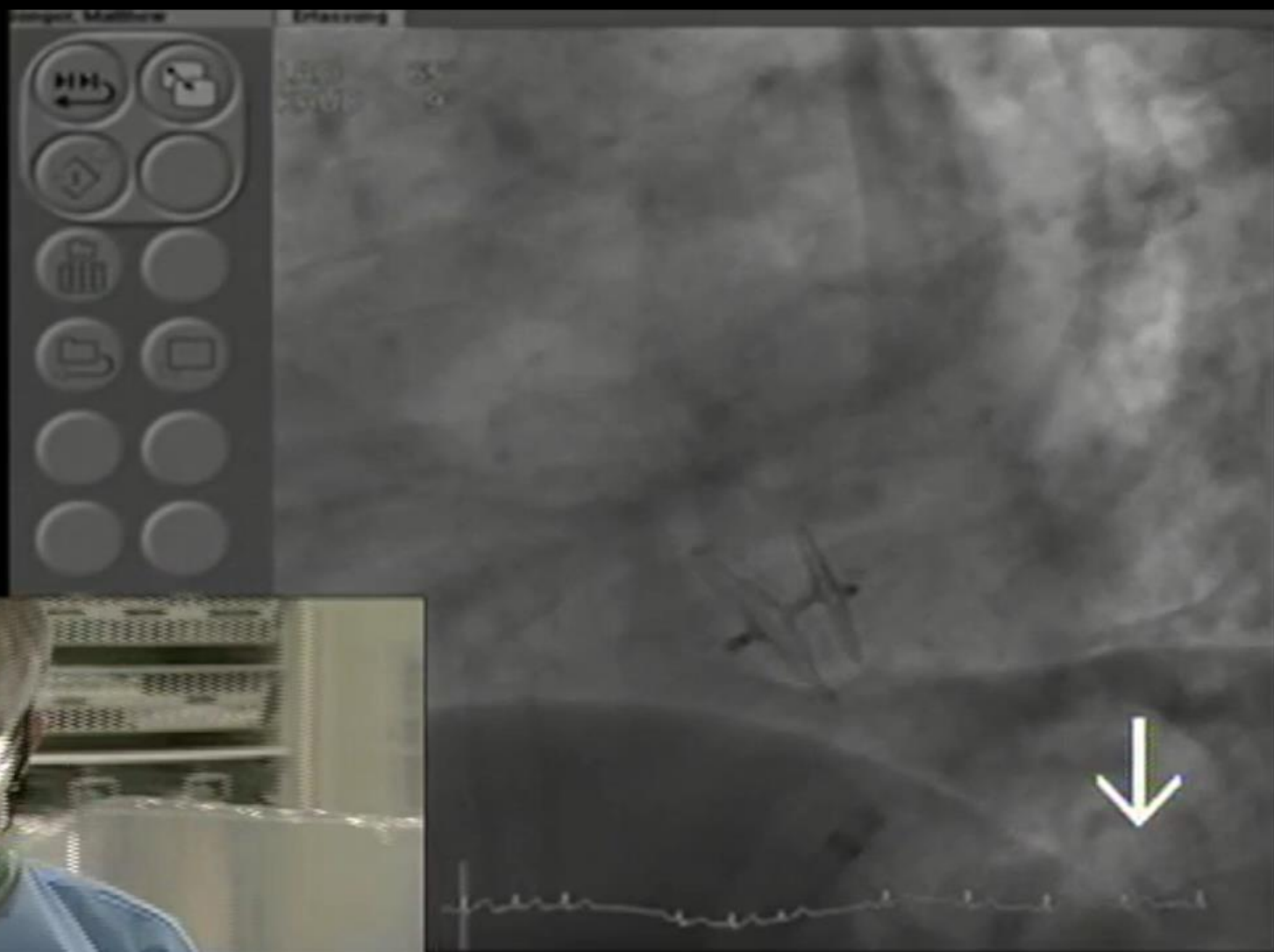
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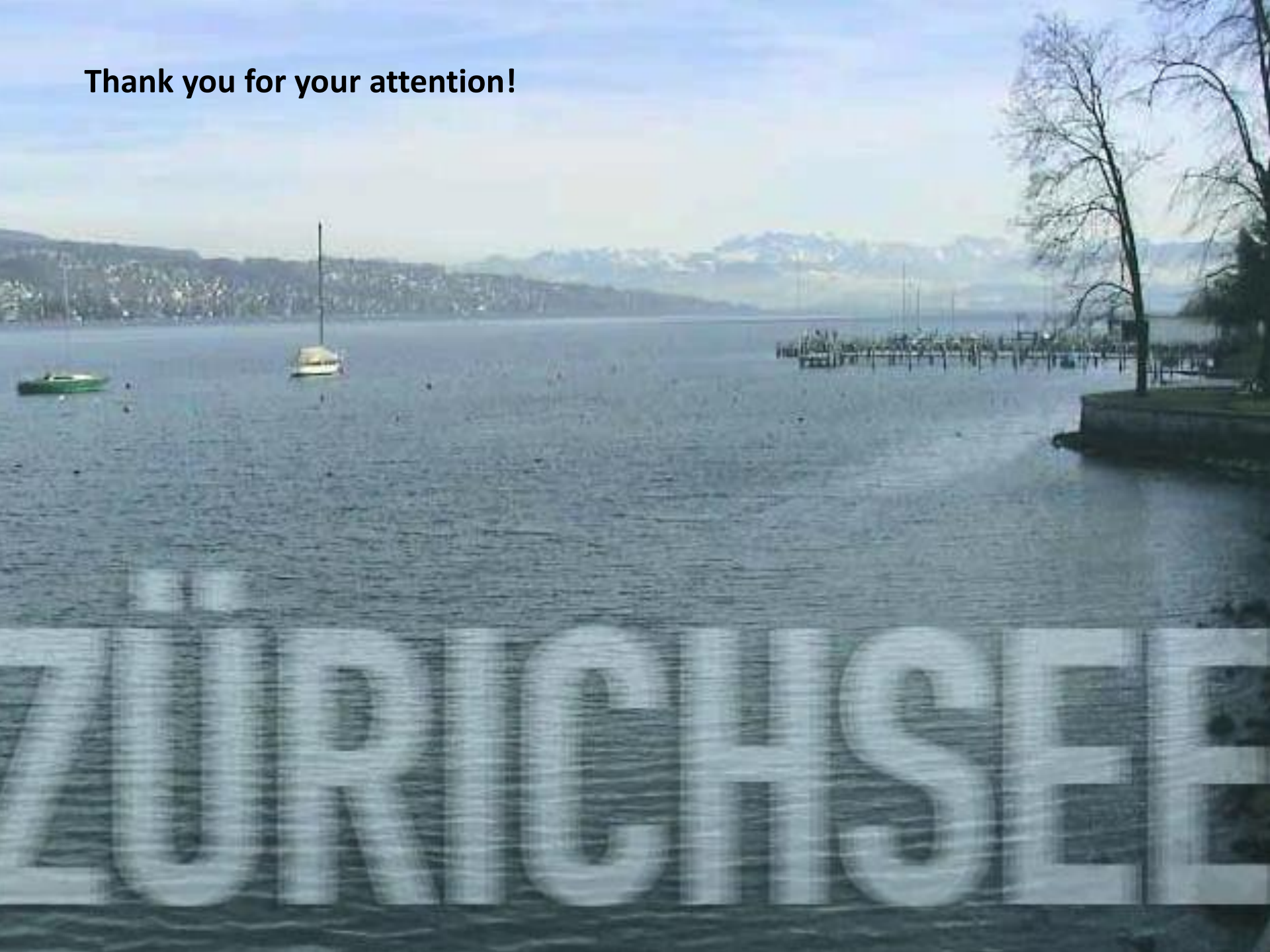


- Newest scientific data show that percutaneous closure of PFO is beneficial and safe for a defined class of patients with cryptogenic stroke.
- Fitness to fly must not be limited per se in pilots undergoing this procedure.





Thank you for your attention!



ZÜRICHSEE