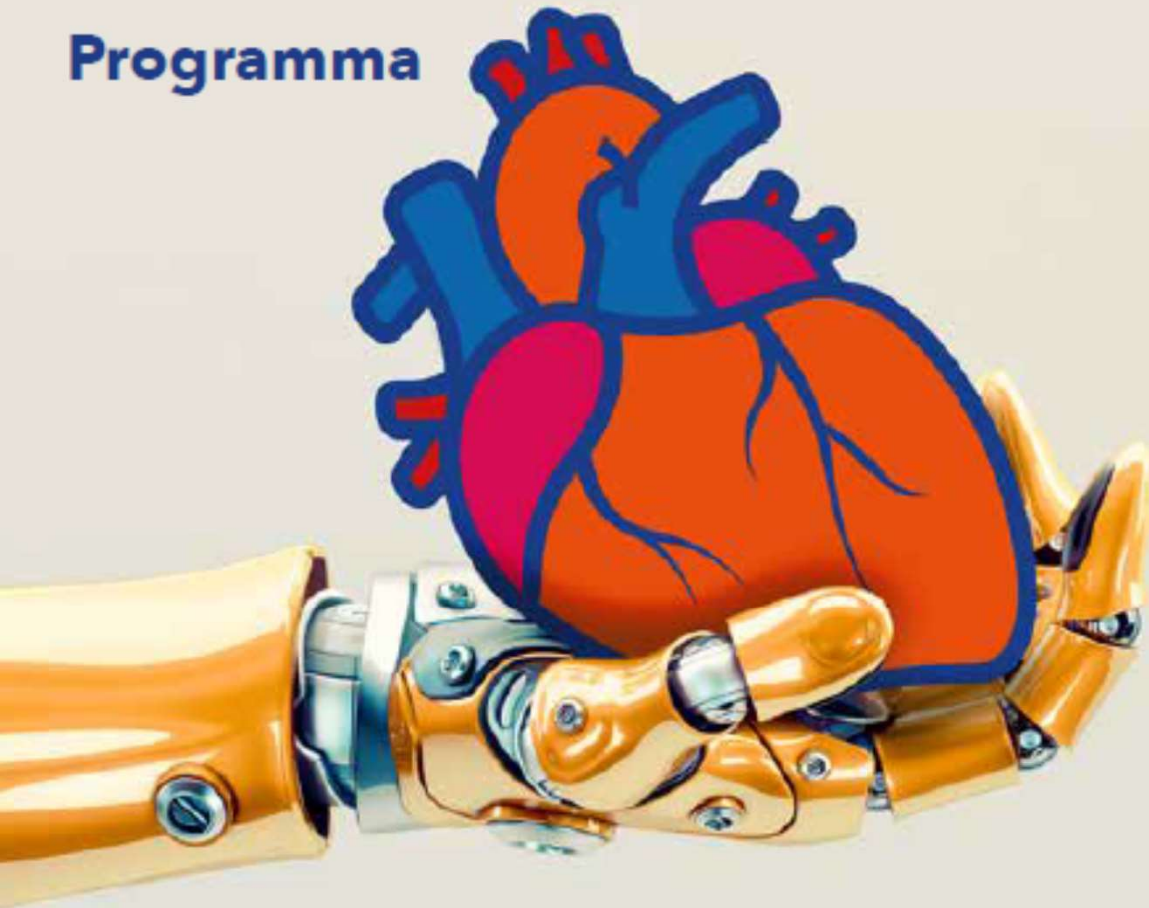


CardioLucca

Heart Brings Heart 2023

Programma

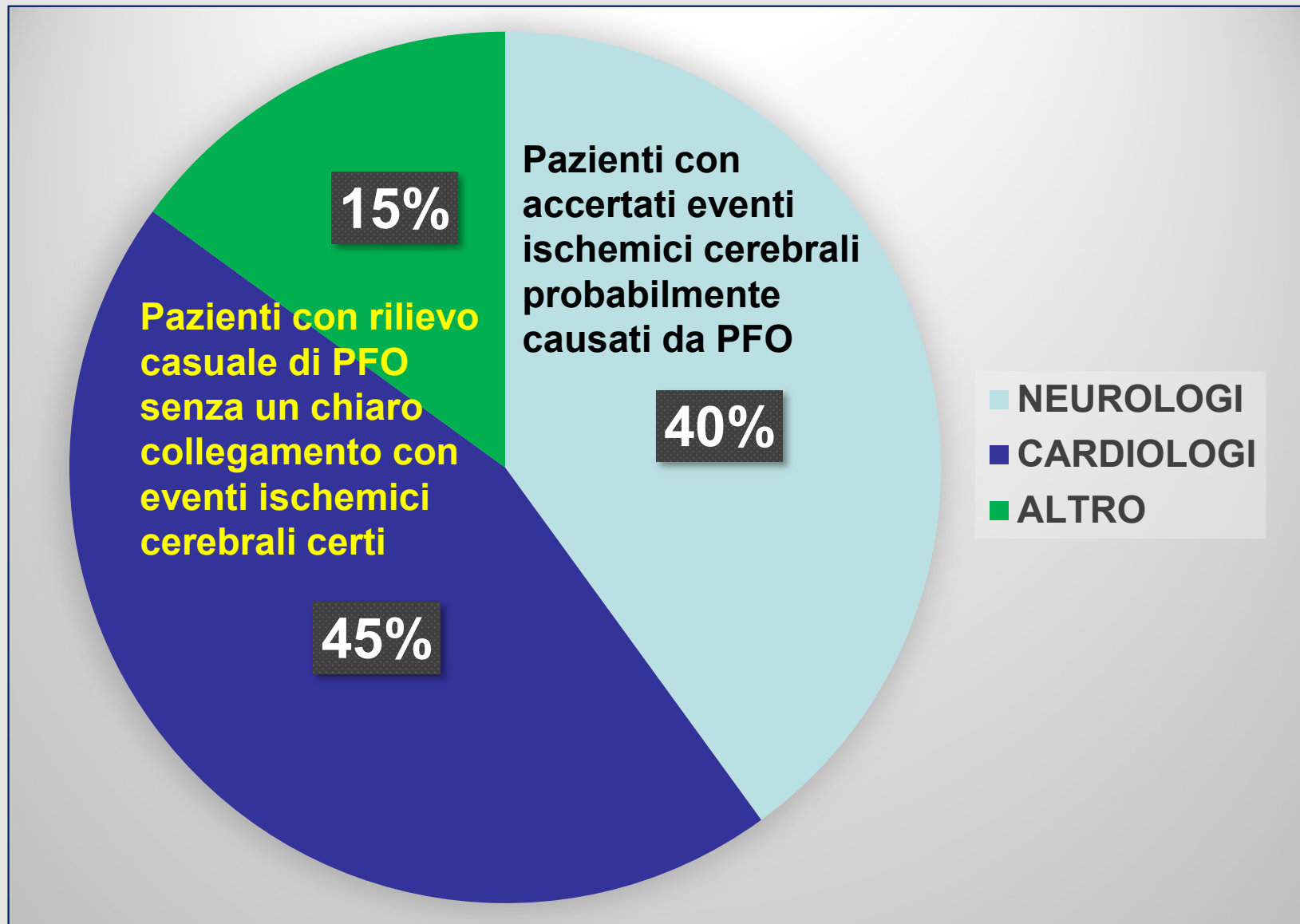


Lucca, 22-24 Giugno 2023
Centro Congressi Auditorium San Francesco

Management terapeutico dopo diagnosi di PFO

Achille Gaspardone
Ospedale Sant'Eugenio - Roma

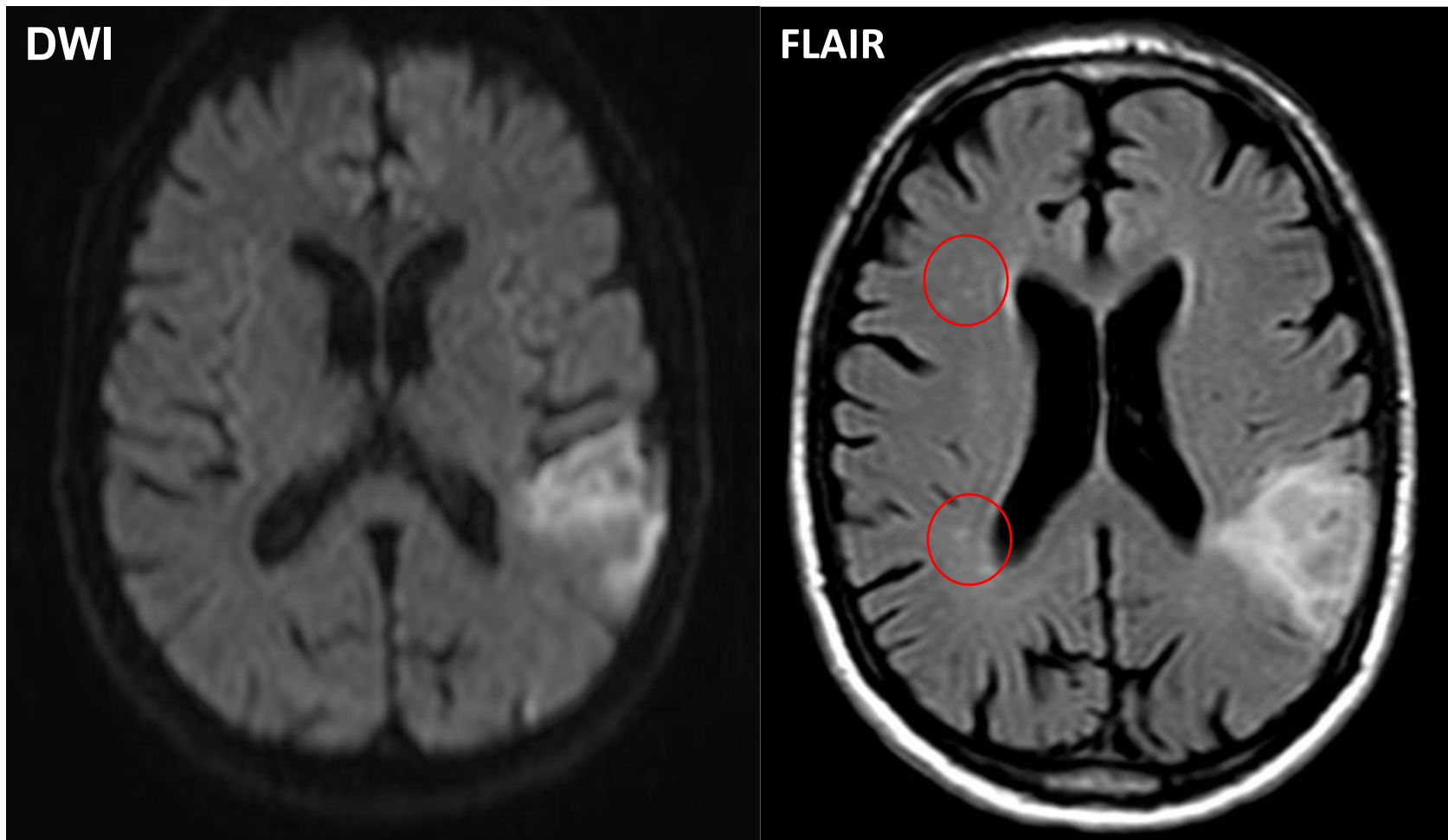
Provenienza dei pazienti con diagnosi di Pervietà della Fossa Ovale



Database Ospedale Sant'Eugenio (2234 pazienti dal 2002 al 2023)

Step 1: Neurological evaluation

Clinical neurological evaluation. Brain MRI with neuroradiological evaluation with particular attention to thromboembolic pathogenesis of brain lesions.

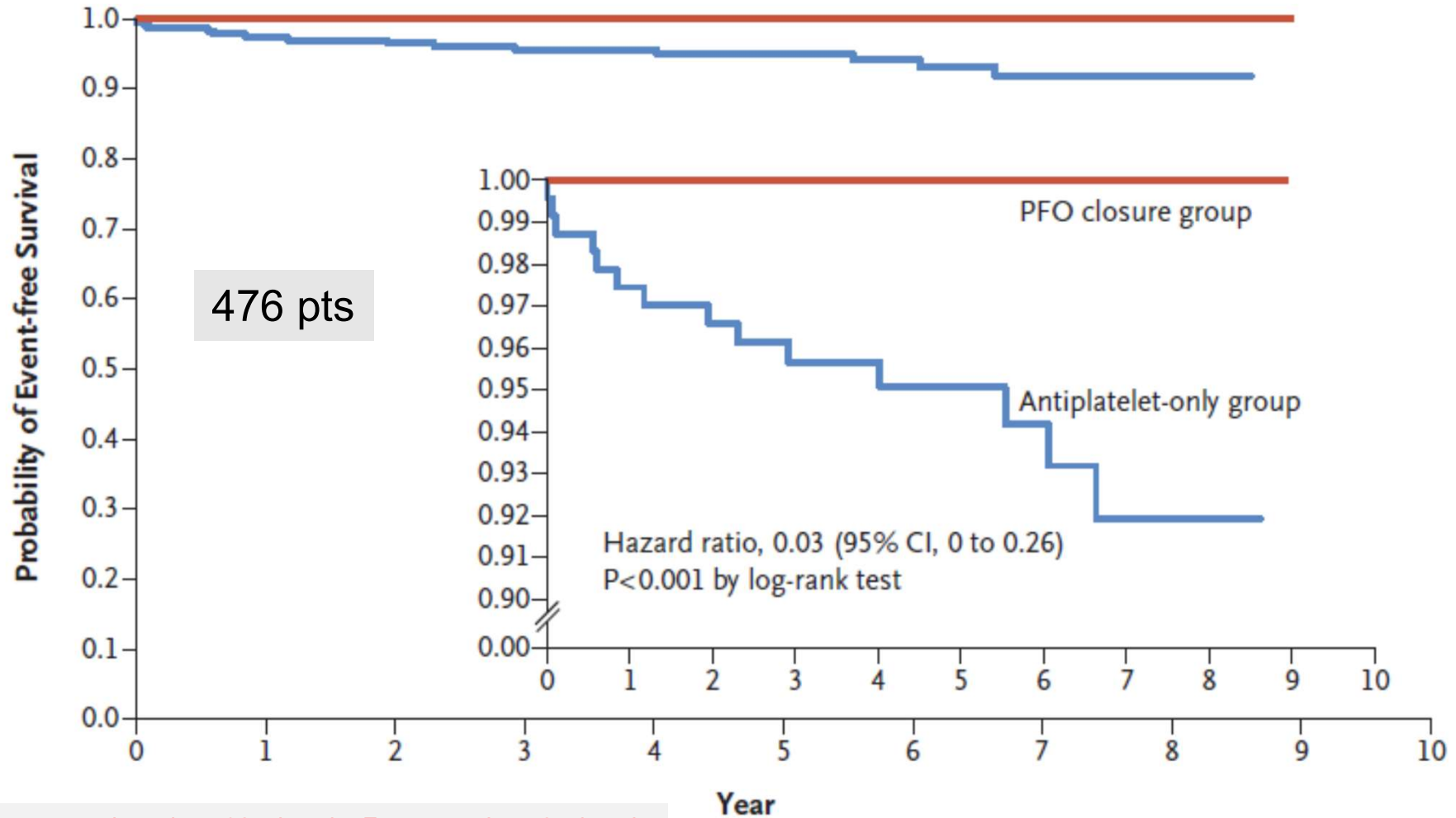


Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke

CLOSE

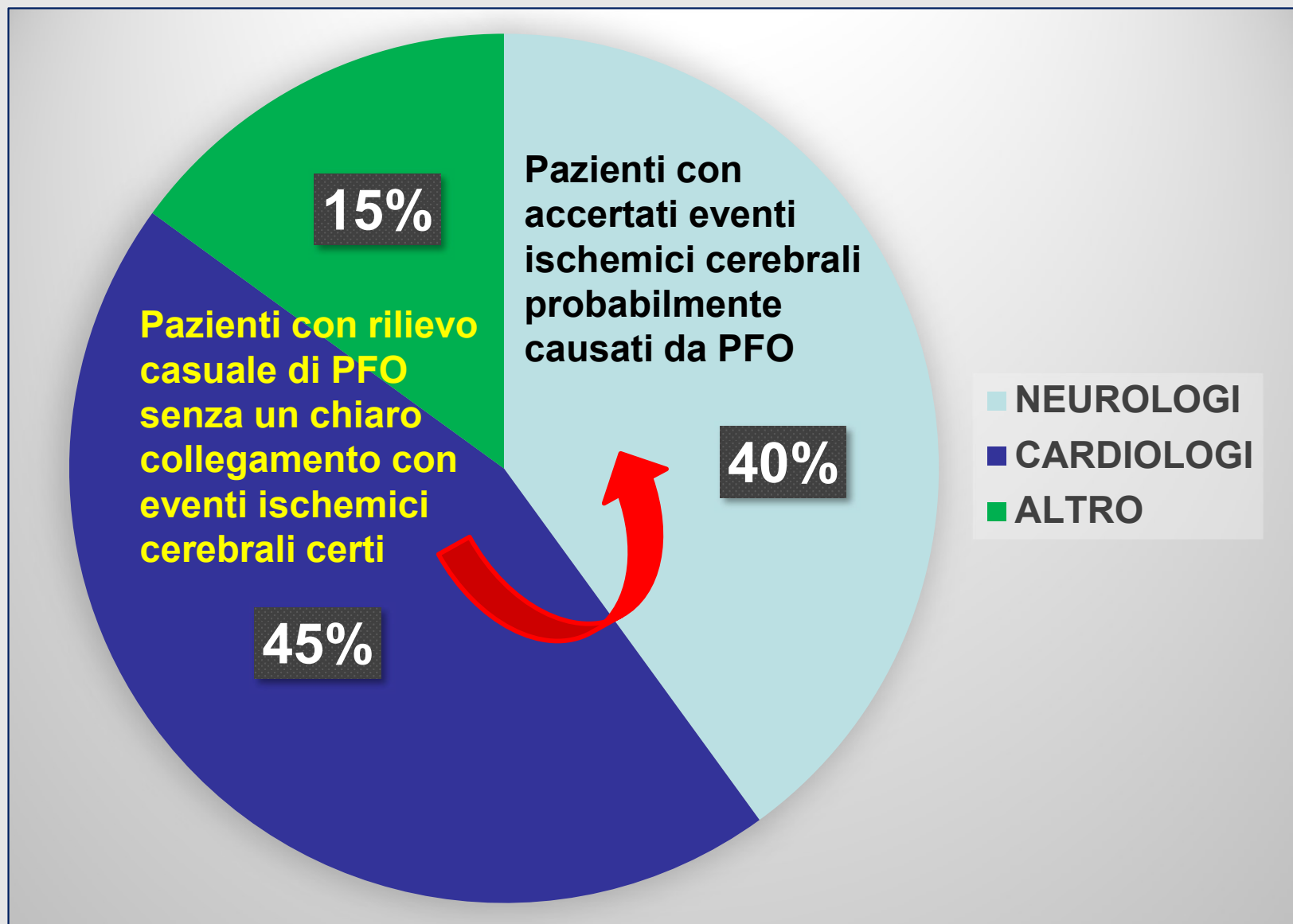


JL Mas



The trial was conducted at 32 sites in France and at 2 sites in Germany from December 2007 through December 2016.

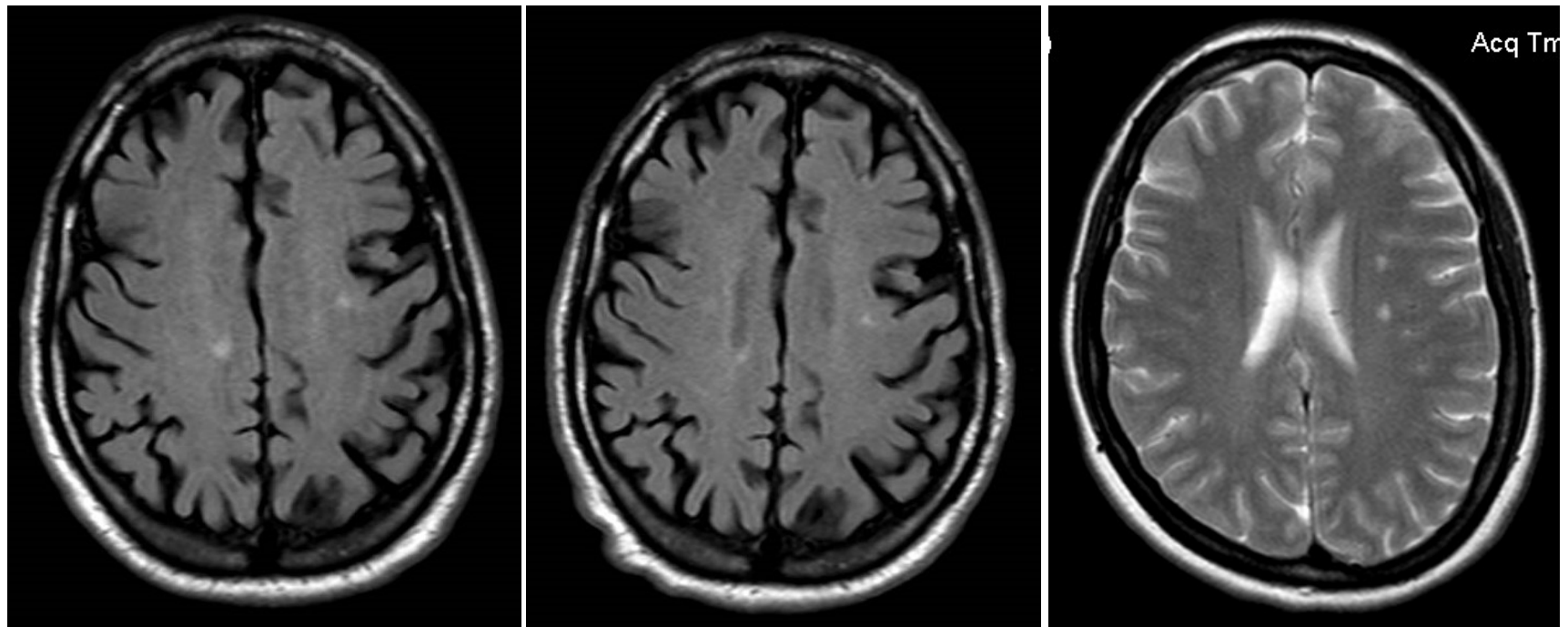
Provenienza dei pazienti con diagnosi di Pervietà della Fossa Ovale

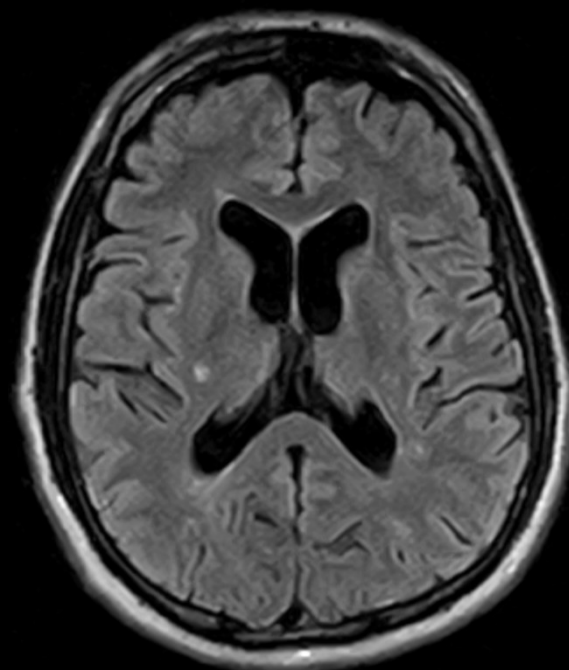
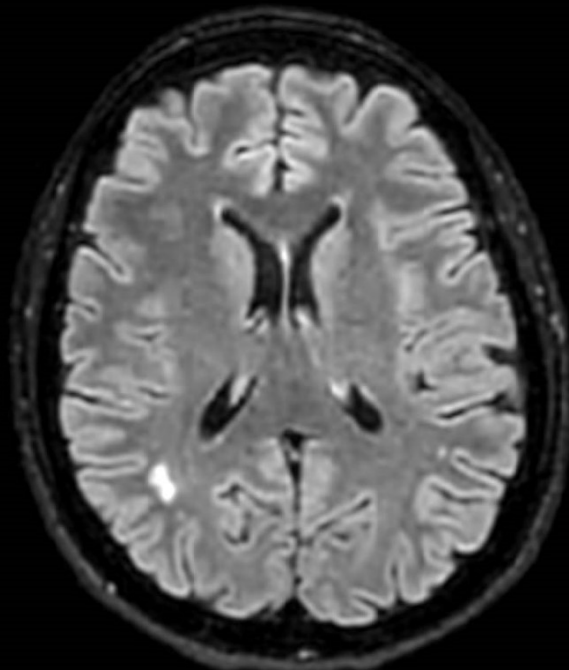
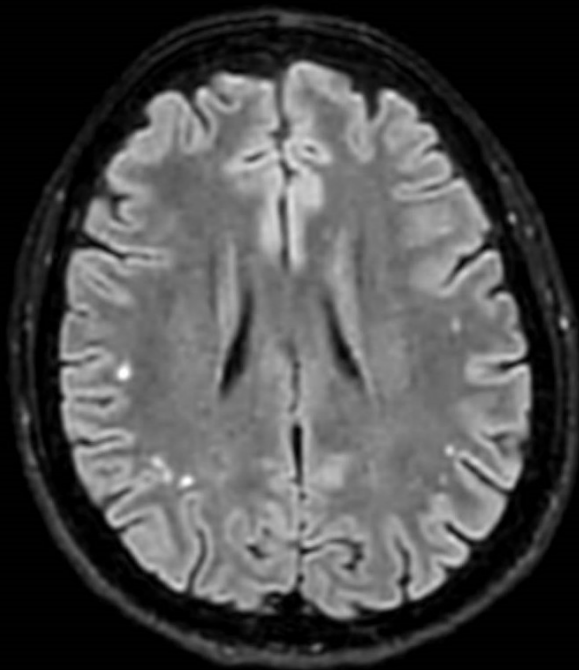


Database Ospedale Sant'Eugenio (2234 pazienti dal 2002 al 2023)

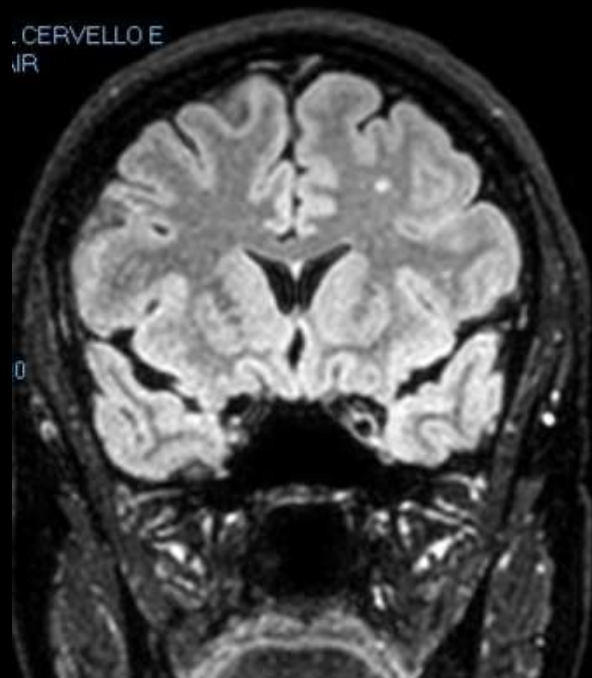
Step 1: Neurological evaluation

Clinical neurological evaluation. Brain MRI with neuroradiological evaluation with particular attention to thromboembolic pathogenesis of brain lesions.





. CERVELLO E
JR

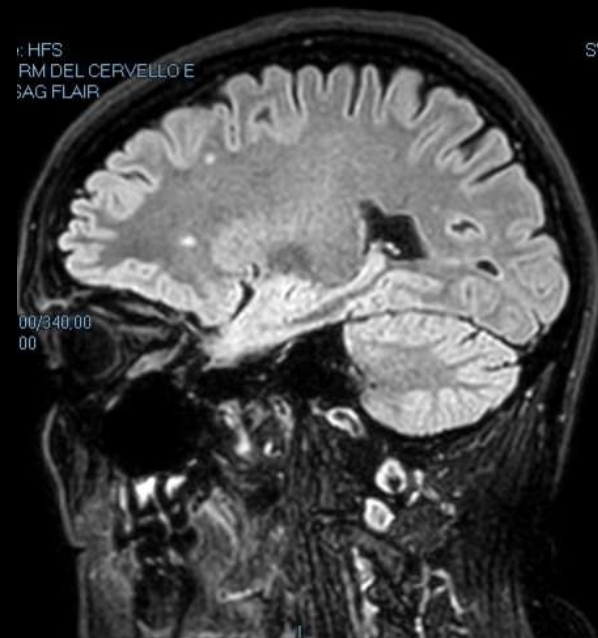


CERVELLO E



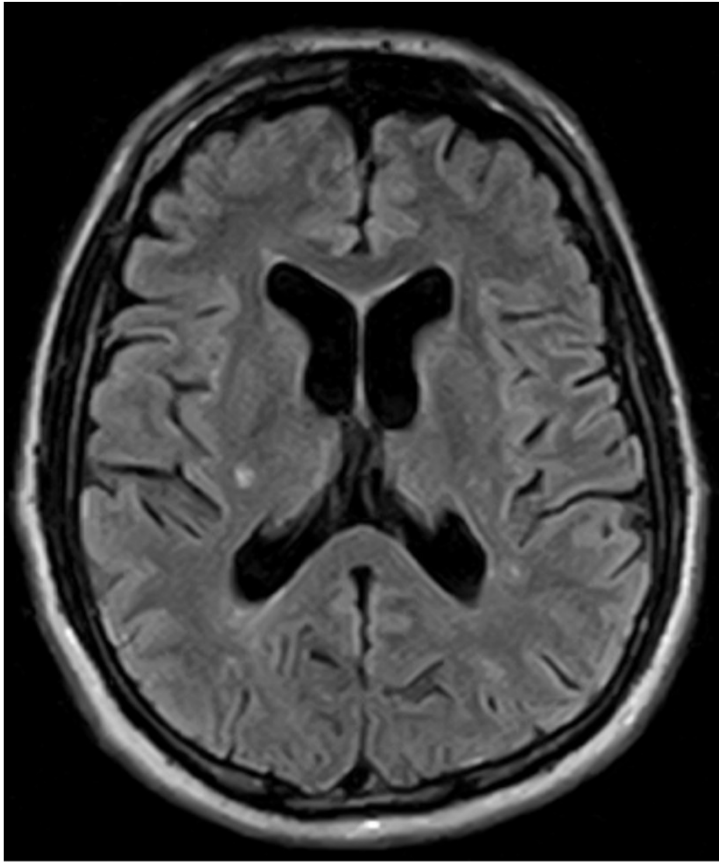
r. HFS
RM DEL CERVELLO E
3AG FLAIR

SW



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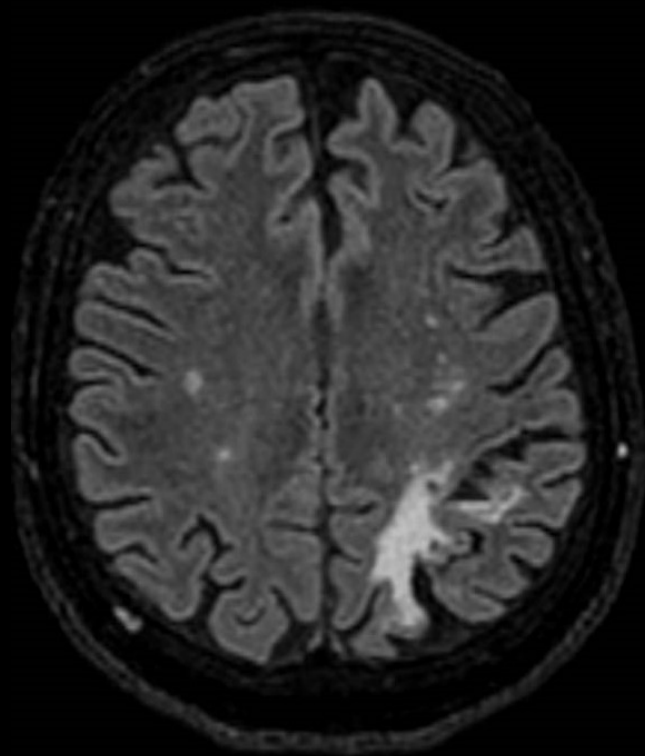
Valutazione neuroradiologica



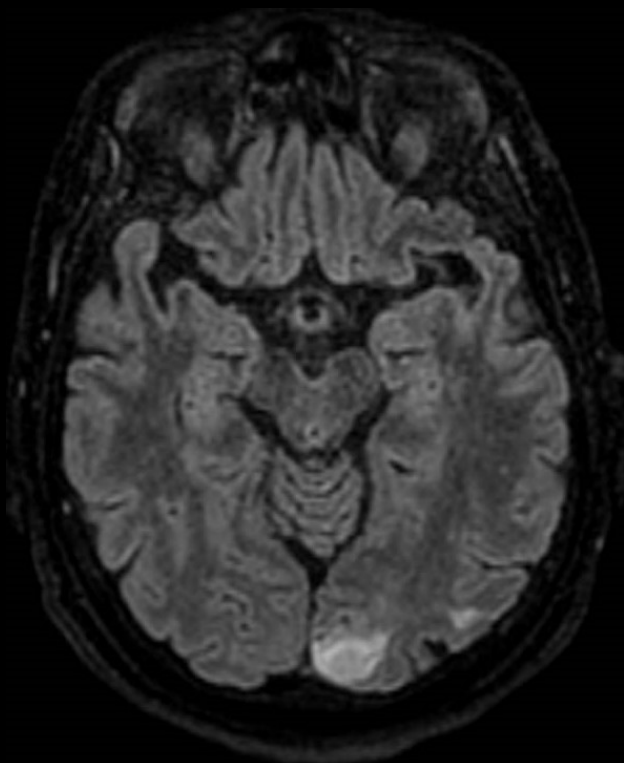
?

1. Emicrania (lesioni iuxtacorticali)
2. Ipertensione (lesioni profonde)
3. Sclerosi Multipla (corpo calloso e verticali)
4. Vasculite ($\Delta\Delta$ captazione del mdc)

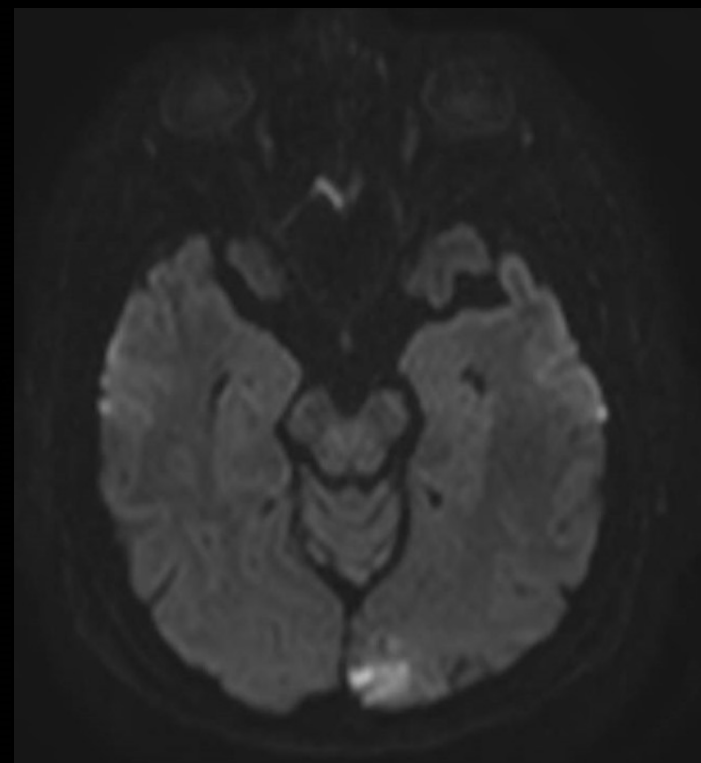
Emicrania & Ictus



FLAIR ASSIALE

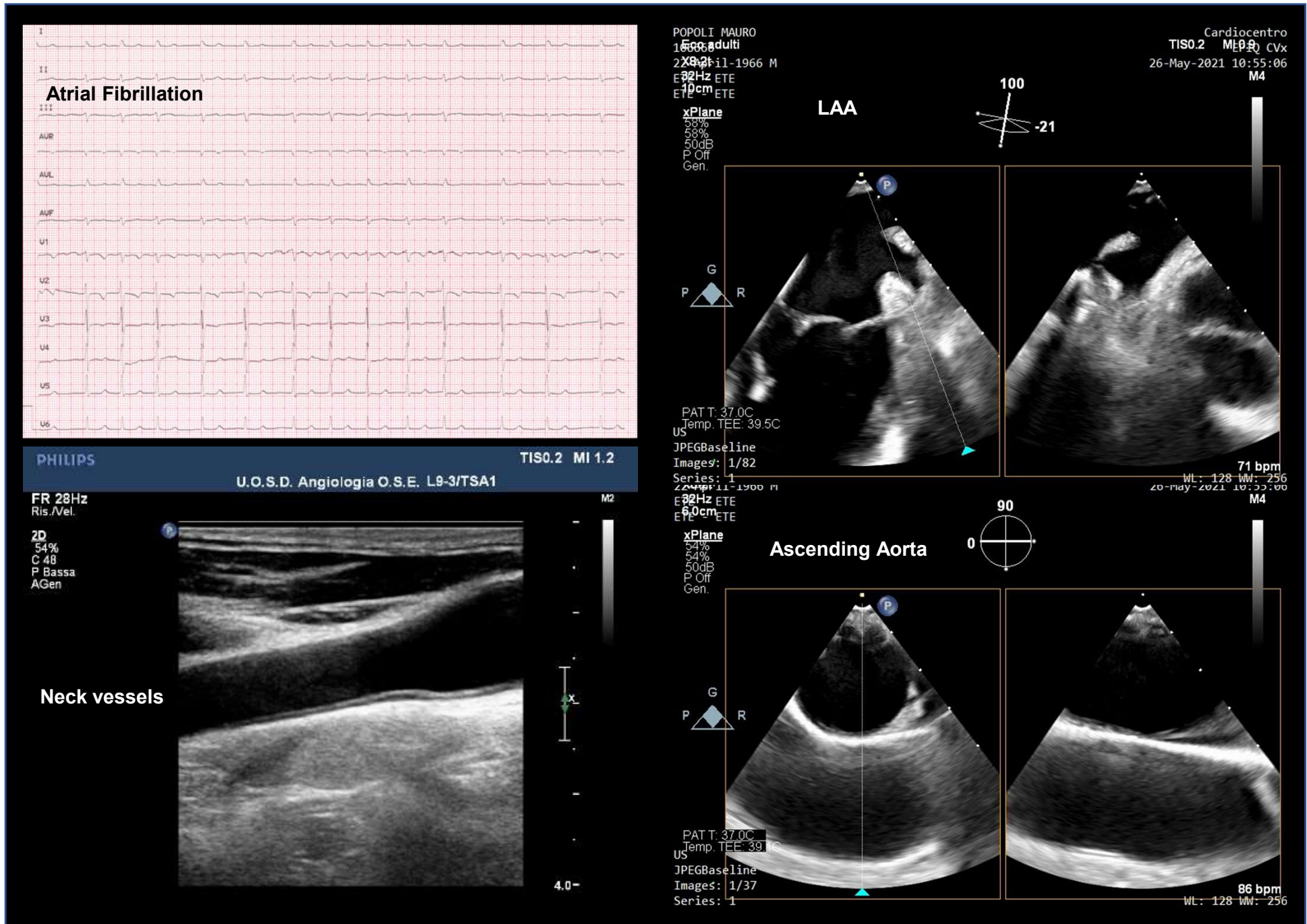


FLAIR ASSIALE



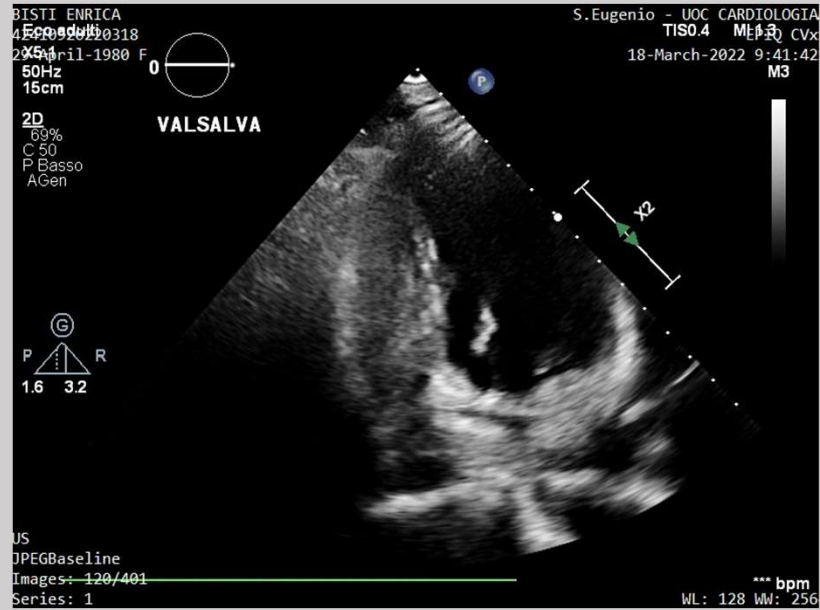
DWI sb 1000

Step 2: Rule out alternative embolic sources

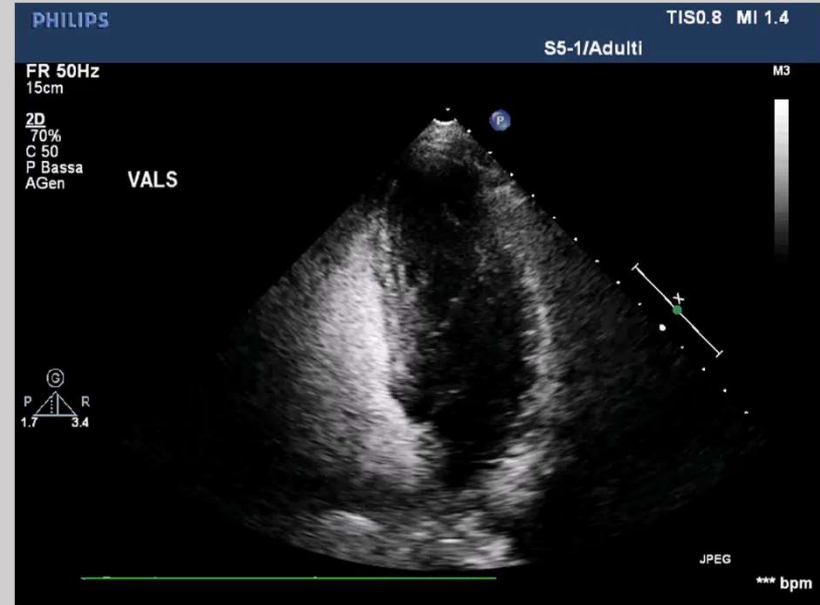


Step 3: TTE RL shunt grading

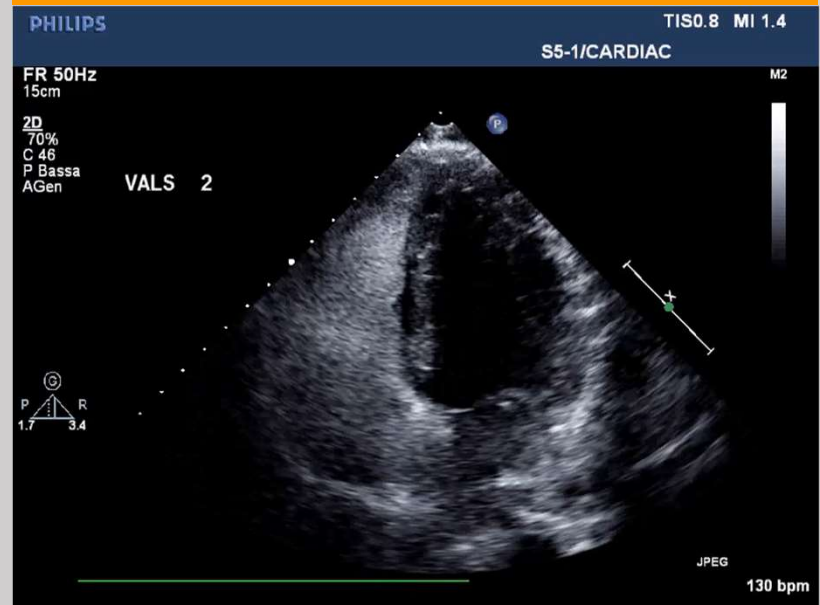
Grade 0



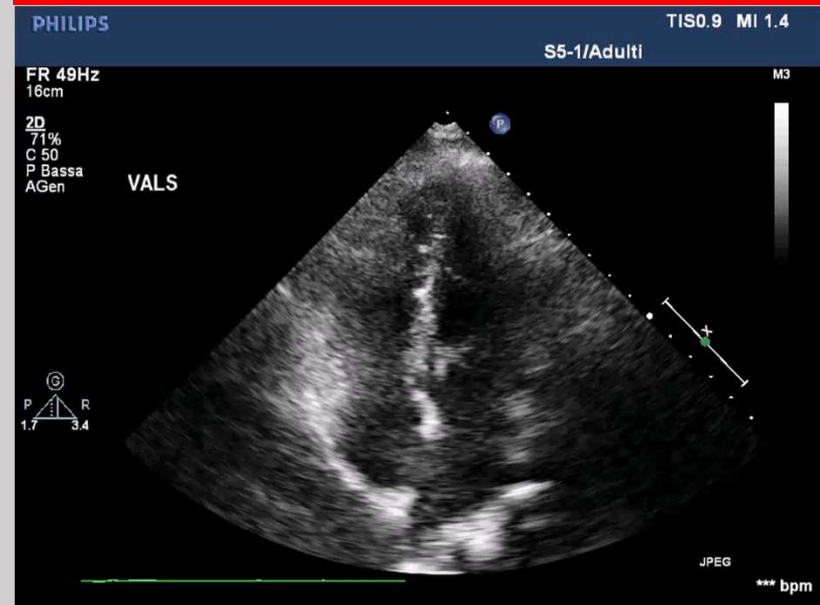
Grade 1



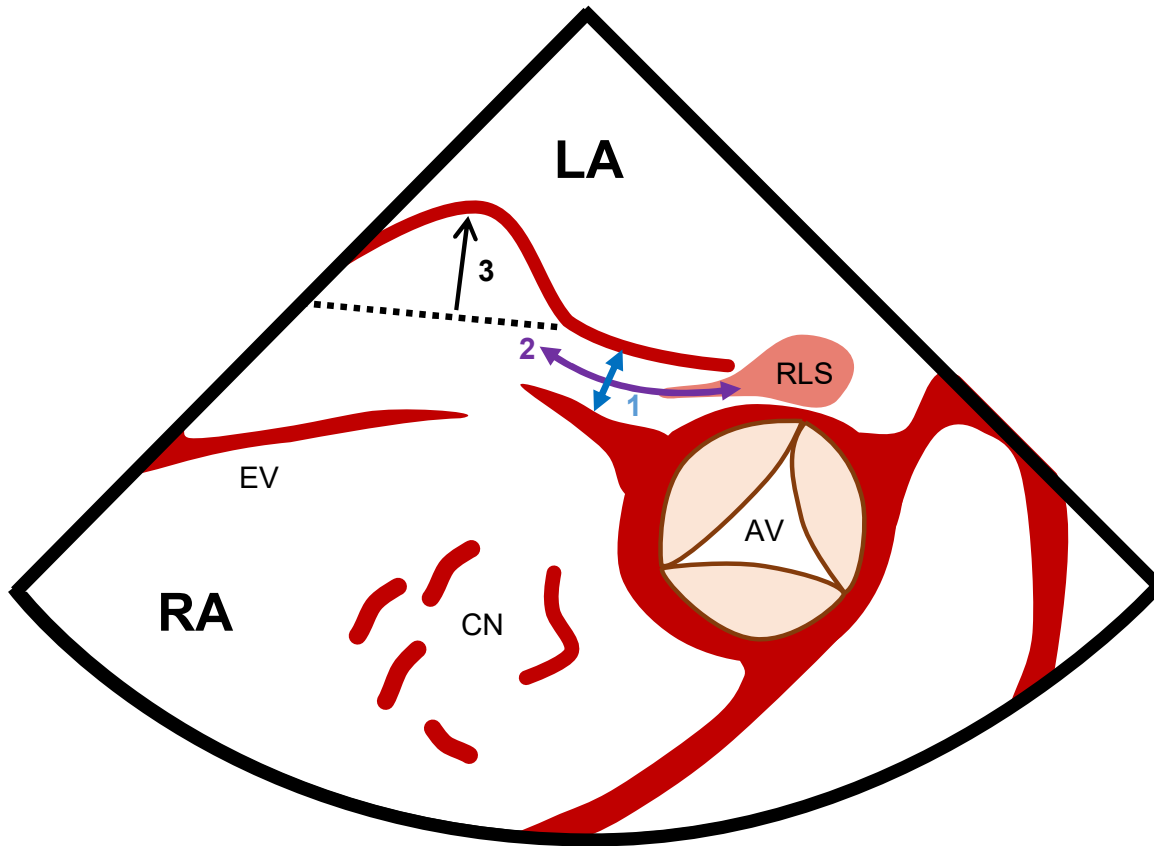
Grade 2



Grade 3



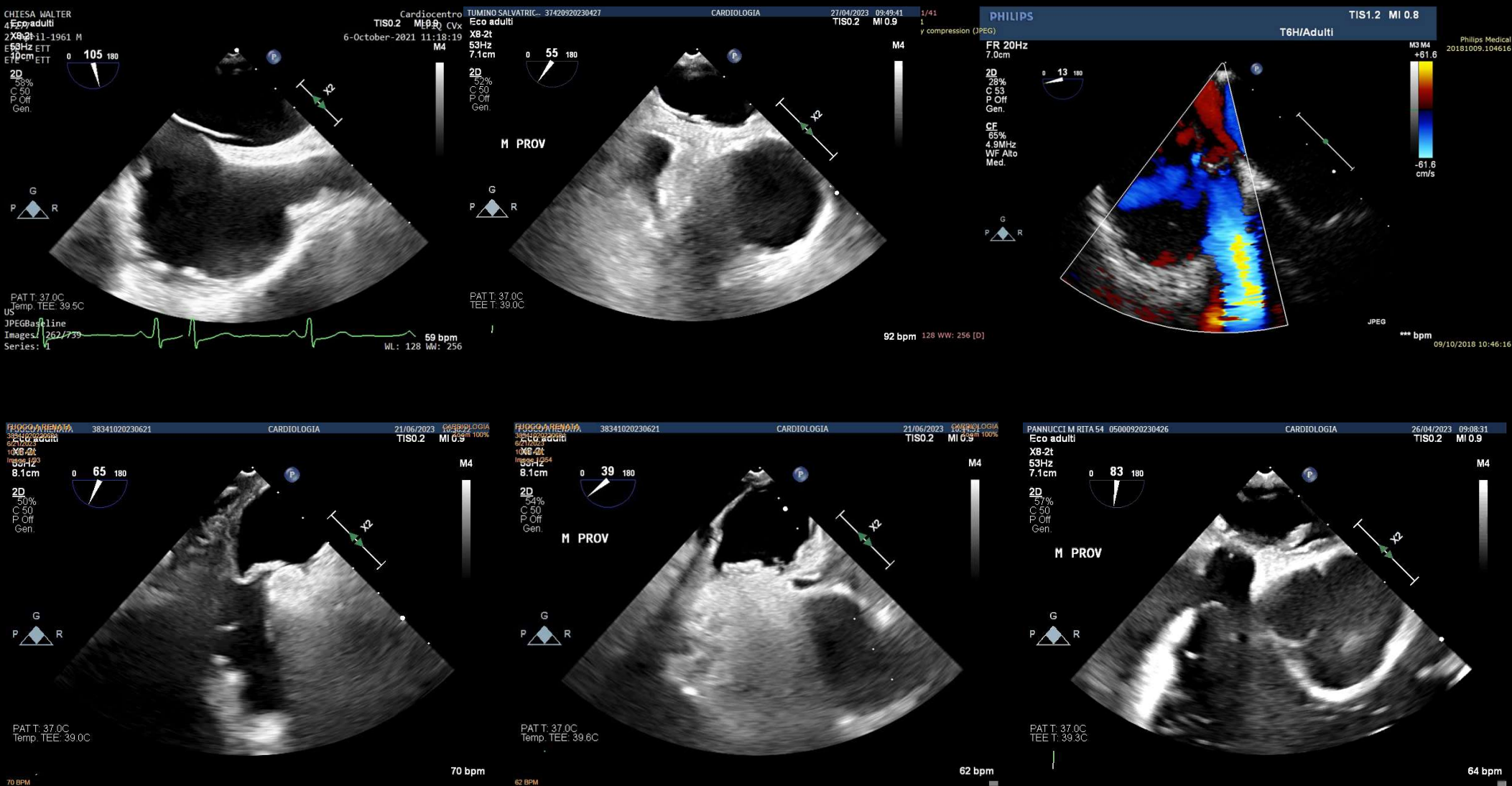
Transesophageal PFO Evaluation



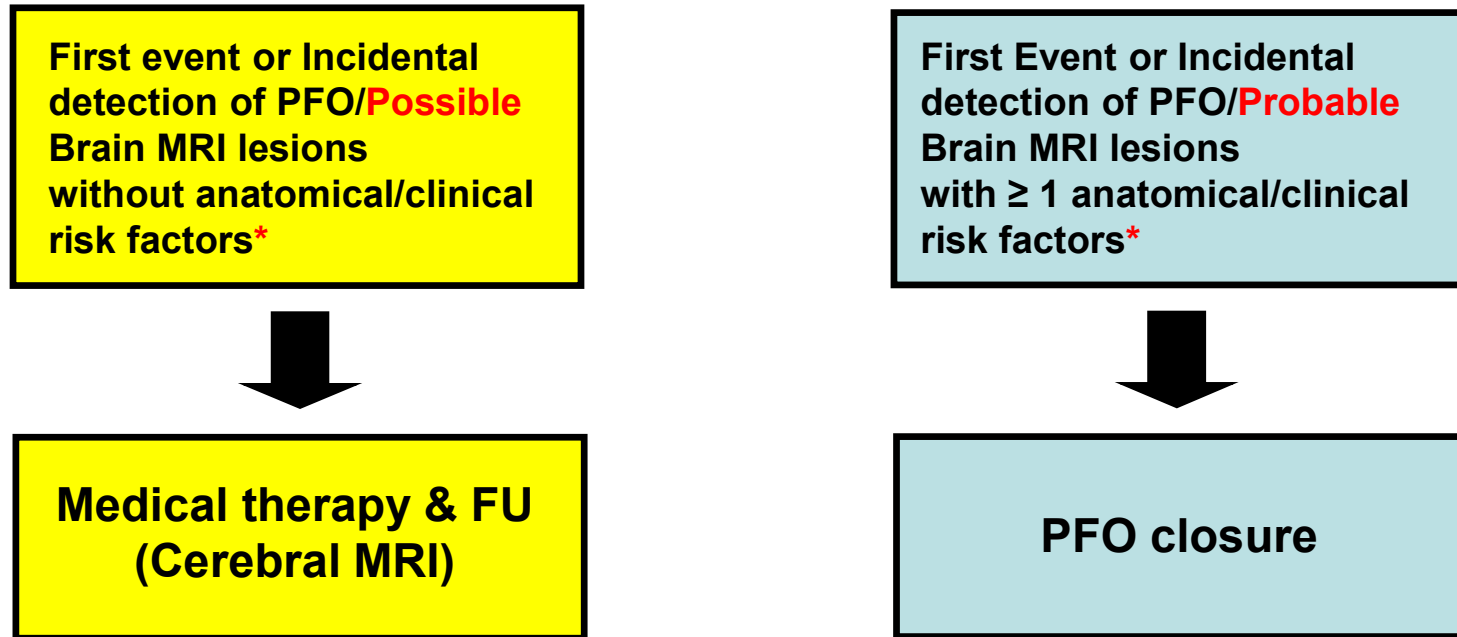
1. Basal RL & LR shunt (color)
2. RL shunt grading with Valsalva
3. SS & SP length²
4. SS/SP min & max overlapping
5. PFO max width¹
6. Aneurysm (max excursion)³
7. Eustachian Valve
8. Chiari net
9. Fenestrations
10. Interatrial septum length

N.B. All measurements in short-axis and long-axis views

Anatomical Risk Features



Management after Diagnosis of PFO



Anatomical risk factors***

- Atrial septal aneurysm >10 mm
- Large PFO (>4 mm)
- Basal R-L shunt and/or ≥ grade 2
- Eustachian valve >10 mm
- Chiari network
- L-R basal shunt
- Multiple ischemic lesions at MR

Clinical risk factors*

- Young age < 60 yrs
- RoPE Score ≥ 7 (62% PFO-attributable fraction)
- History of DVT/PE and/or Thrombophilia
- Valsalva-associated (diving) embolic event
- Ischemic event on arousal (OSAS)/migraine
- Long travel/immobilization associated event
- Stroke/TIA & simultaneous systemic/pulmonary embolism

Suture vs Device PFO closure

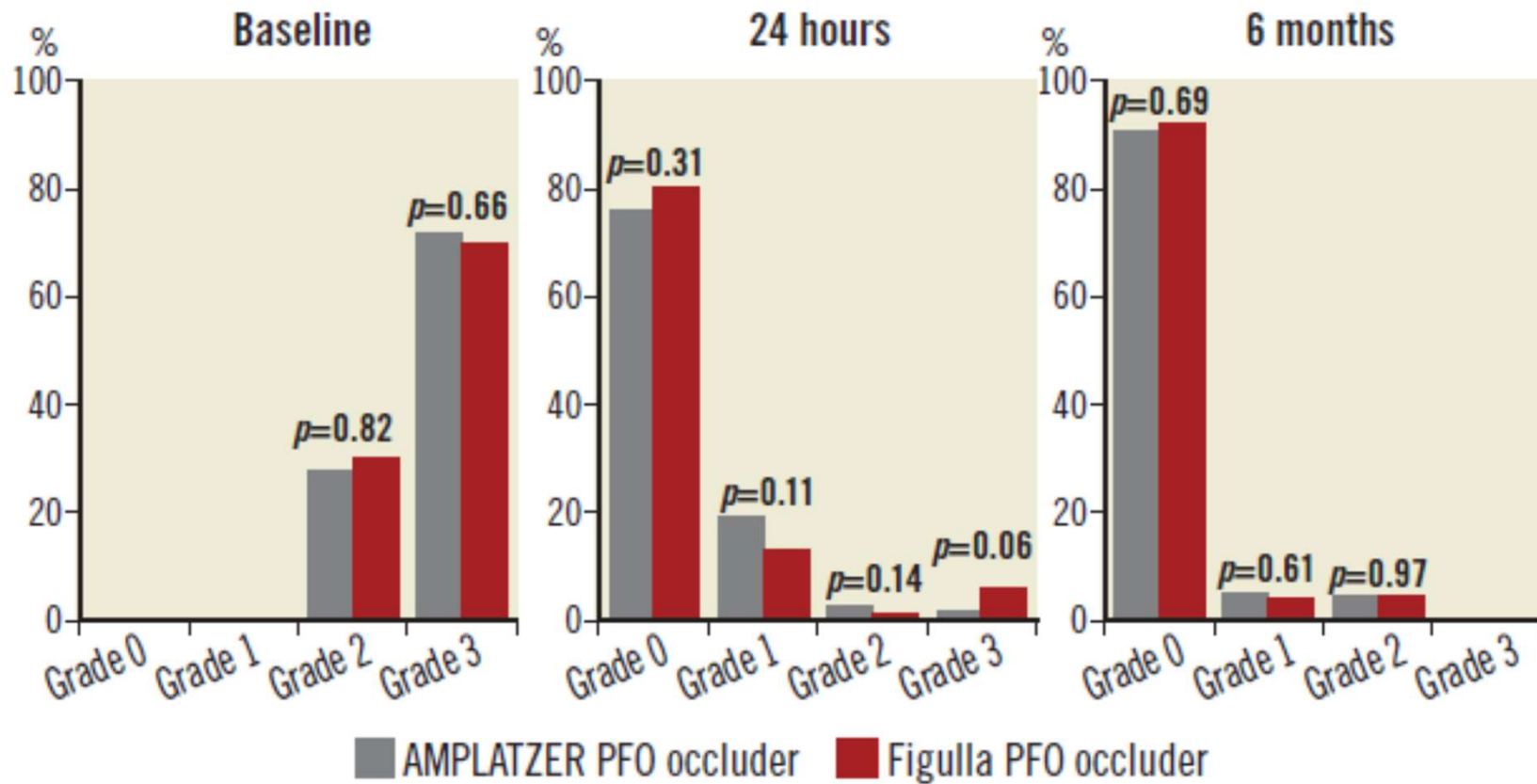
Suture

Umbrella device

Left atrial side view

17074 Heartstitch Newhope St, Fountain Valley, CA 92708, USA
FIM 2008; CE Mark 2012; Commercial release Nov 2015; Italy use May 2016

AMPLATZER versus Figulla occluder for transcatheter patent foramen ovale closure



Patent foramen ovale occluders safety in Clinical Trials and Real-World

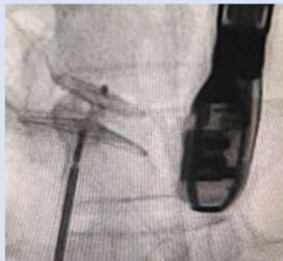
Major device/procedure-related adverse events

CLINICAL TRIALS	REDUCE	23.1%
	PC	21.1%
	CLOSURE	16.9%
	CLOSE	5.9%
	RESPECT	4.2%

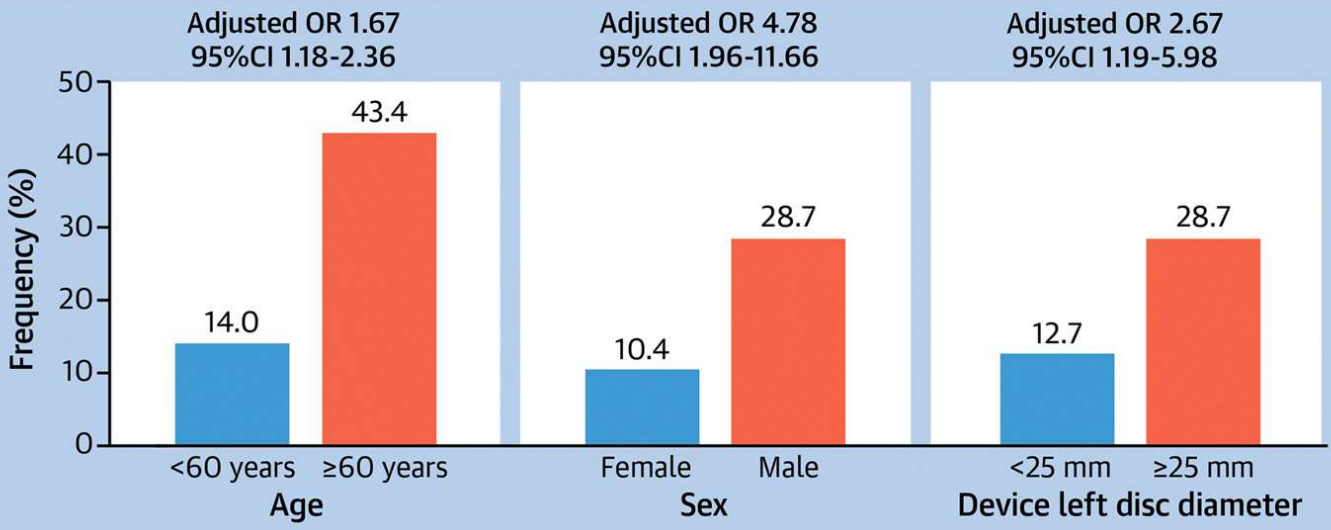
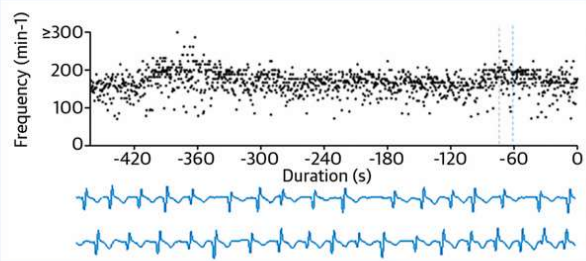
Risk of adverse outcomes among 1887 patients undergoing percutaneous PFO closure after an ischemic cerebral event (administrative claim data)

REAL-WORLD	Total adverse outcomes	7.0% (95% CI 5.9%–8.2%)
	Atrial fibrillation/flutter	3.7% (95% CI 2.9%–4.6%)
	Vascular complications	3.0% (95% CI 2.3%–3.9%)
	Haematoma/haemorrhage	2.7% (95% CI 2.0%–3.5%)
	Cardiac tamponade/perforation	0.5% (95% CI 0.2%–0.9%)
	Death	0.3% (95% CI 0.1%–0.6%)
	Pneumothorax/haemothorax	0.1% (95% CI 0.0%–0.3%)

Supraventricular Arrhythmia Following Patent Foramen Ovale Percutaneous Closure



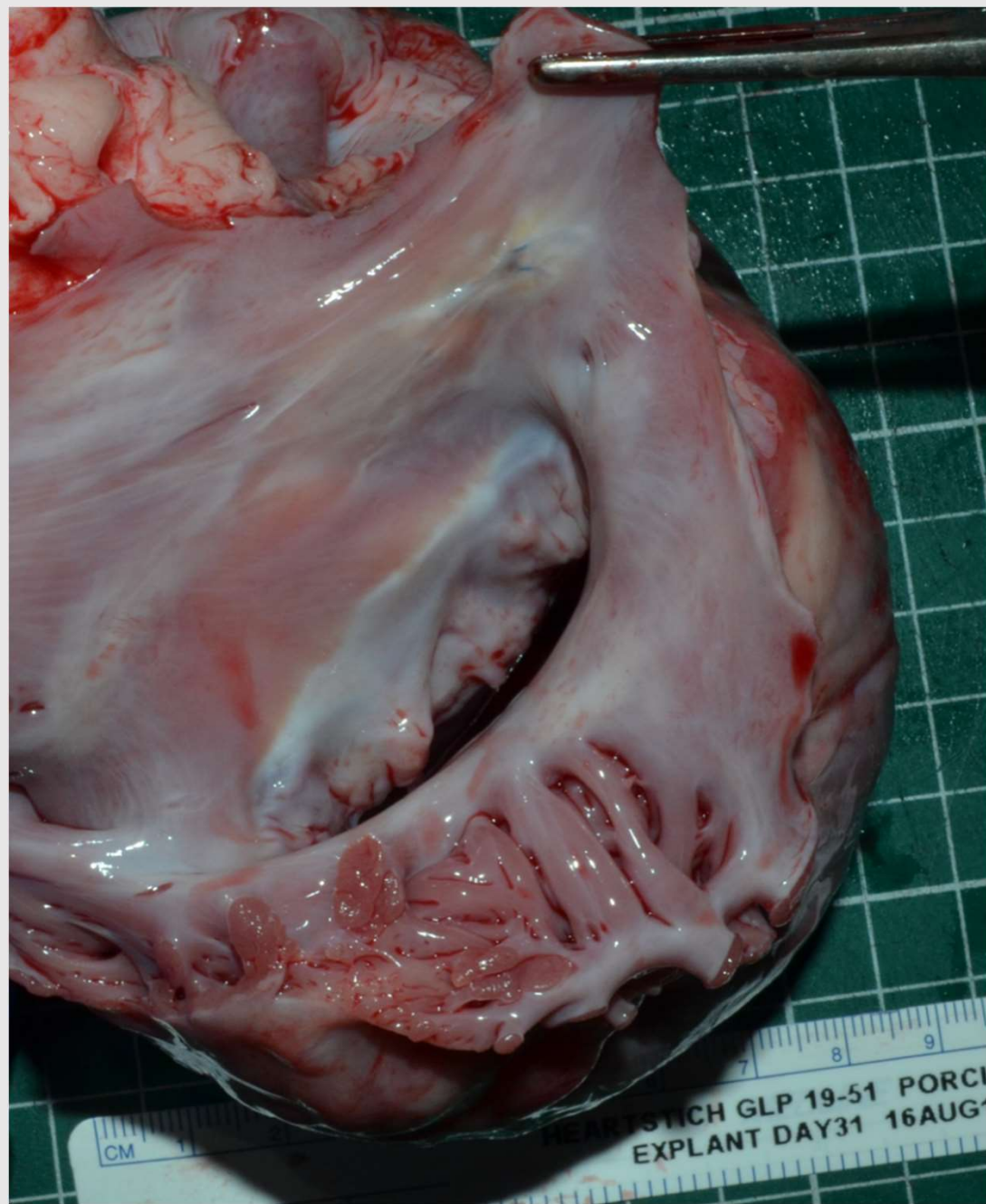
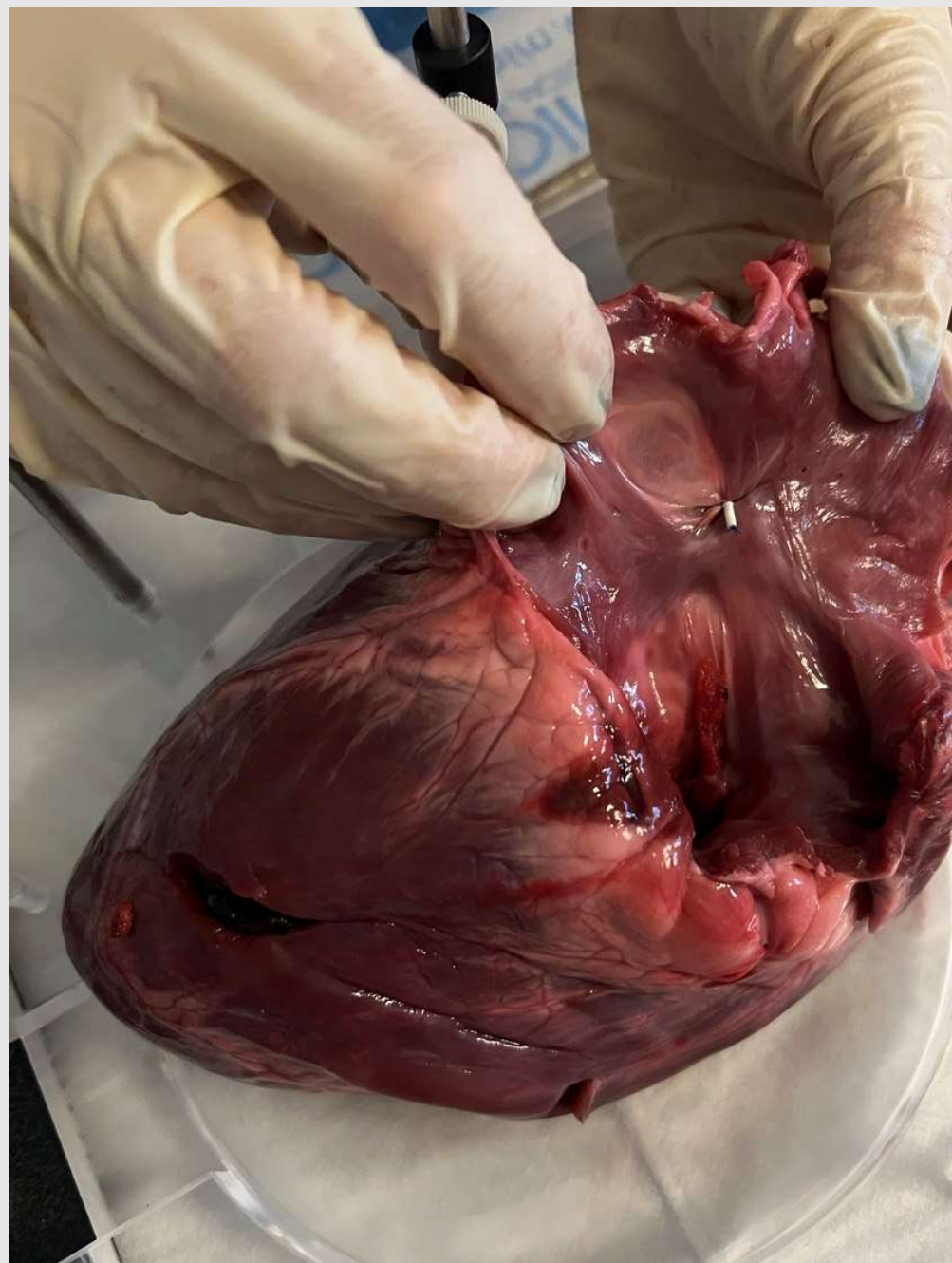
- Overall: 20.9% (225 pts)**
- Intrahospital postprocedural: 4.4%
 - External loop recorder-monitored patients: 9.9% **<55 yrs (4 weeks)**
 - Implantable loop recorder-monitored patients: 28.9% **≥55 yrs**



Guedeney P et al, JACC Intv 2022

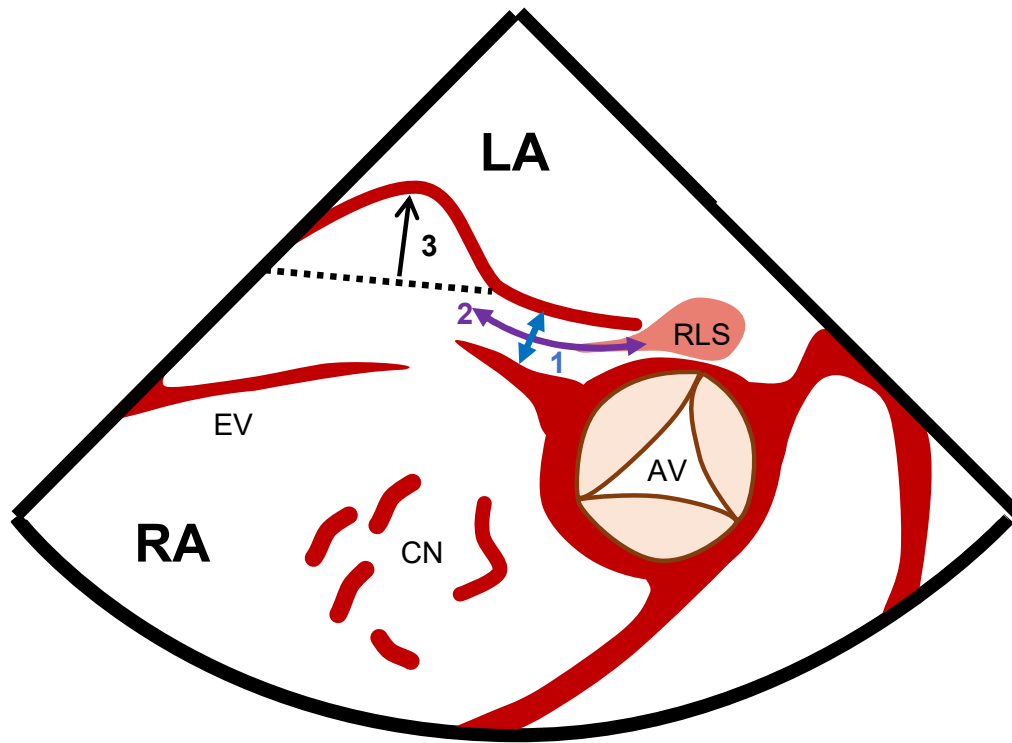
Suture: Advantages Over Occluder Devices

- No permanent prosthetic DEVICE (“deviceless” procedure)
- No obstruction/encumbrance of the atrial chambers
- No risk of migration/embolization/erosion/perforation
- No effect on atrial geometry and functionality
- No limitations for future left heart procedures (MVP, AFA, LAAC)
- No allergenic risk (no metallic alloy)
- No need of long term anti-coagulation/antiplatelet rx
- No risk of left side air embolism during the procedure
- No need of intra-procedural TE or IC echo monitoring
- No need of anesthesiological support (local anesthesia)
- No induction of supraventricular arrhythmias (atrial fibrillation)
- Easily repeatable if initial attempt is unsuccessful
- Safer than traditional devices



Porcine exp model (7/2019). 31 days explant suture endothelization. Right atrial view

Predictors of Residual Right-to-Left Shunt after suturing*



TEE short axis view

1. Tunnel Width (maxTW)
2. Septa Overlap (minSO)

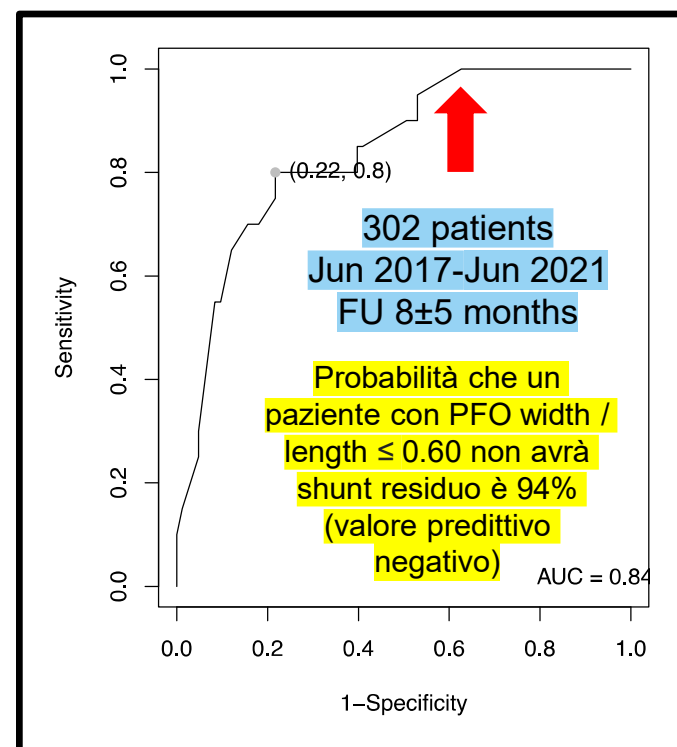
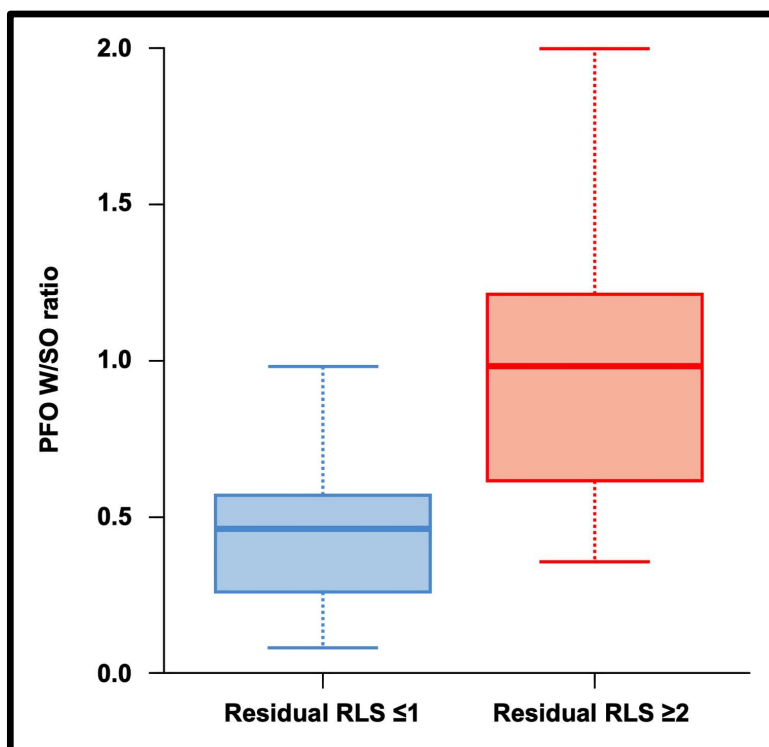
Calculations** (in mm)

A. $\text{maxTW}/\text{minSO}$

* Using one stitch only; ** All measures in short and bicaval TEE views

Predictors of Residual Right-to-Left Shunt*

New variable	RLS ≤ 1 (n = 242)	RLS ≥ 2 (n = 60)	Odds ratio (95% CI)	p value	AUC	Cut-off value	Sens (95% CI)	Spec (95% CI)	PPV (95% CI)	NPV (95% CI)
PFO width / PFO length	0.50 \pm 0.28	0.97 \pm 0.42	48.1 (9.3 – 352.2)	< 0.001	0.84 (0.75 – 0.93)	0.61	0.80 (0.63 – 0.98)	0.78 (0.69 – 0.87)	0.47 (0.30 – 0.64)	0.94 (0.89 – 0.99)



* Using one stitch only. Cath Cardiovasc Int (in press)

NobleStitch EL STITCH Trial is a PFO Comparative Trial (STITCH)

Study Design

Go to ▼

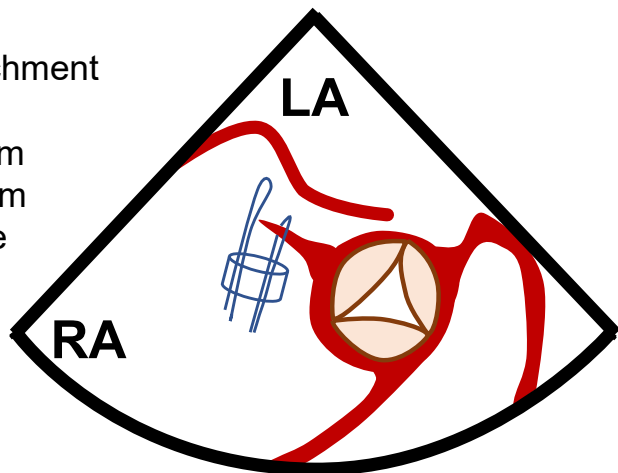
Study Type ⓘ : Interventional (Clinical Trial)
Estimated Enrollment ⓘ : 640 participants
Allocation : Non-Randomized
Intervention Model : Parallel Assignment
Intervention Model Description : A 640 participants indicated for percutaneous transcatheter closure of a PFO to reduce risk of recurrent Ischemic Stroke; between ages 18 - 60 years, who have had a Cryptogenic Stroke due to Paradoxical Embolism To be conducted both in the USA and the European Union.
Masking : None (Open Label)
Primary Purpose : Treatment
Official Title : STITCH - Prospective Multi Center Comparative Parallel Concurrent Study of the NobleStitch EL Compared to FDA Approved Amplatzer Occluder Device for Closure of Patent Foramen Ovale to Prevent Recurrent Ischemic Stroke
Actual Study Start Date ⓘ : December 1, 2020
Estimated Primary Completion Date ⓘ : December 31, 2021
Estimated Study Completion Date ⓘ : April 30, 2026

Suture vs Device PFO Closure

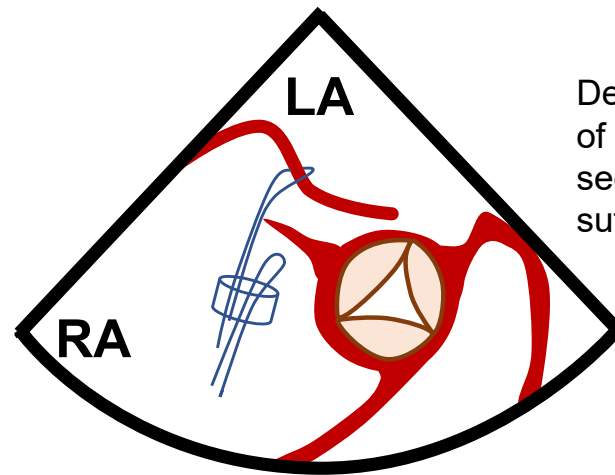
Traditional “*amplatziform*” devices currently guarantee the best efficacy in terms of abolition of the shunt, but they are not free from complications (even serious) and drawbacks. In favorable anatomies, direct suture offers objective advantages and can be the first choice closure technique.

Mechanisms of late suture failure and residual shunt

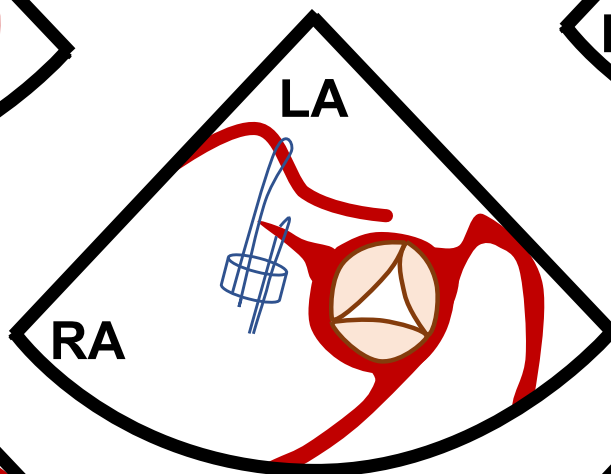
Detachment
of the
septum
primum
suture



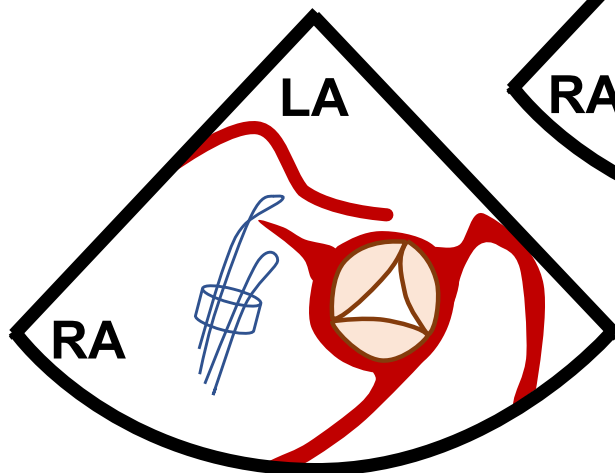
Detachment
of the septum
secundum
suture



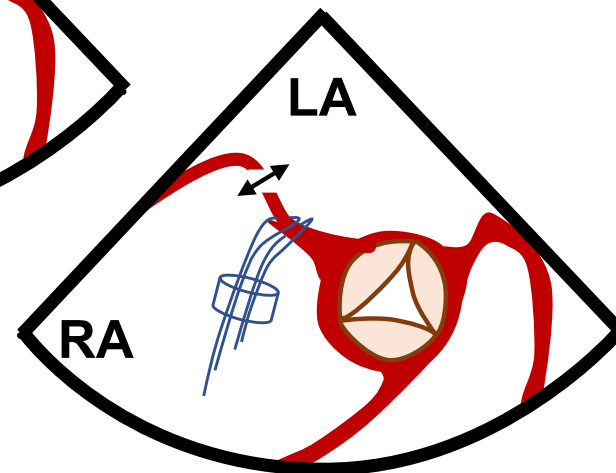
Loosening of a suture



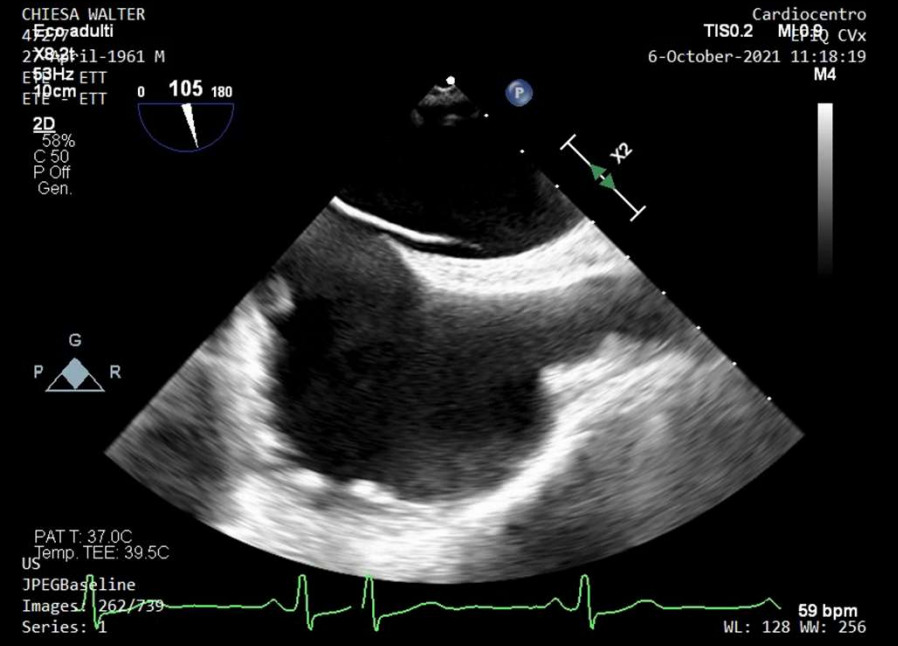
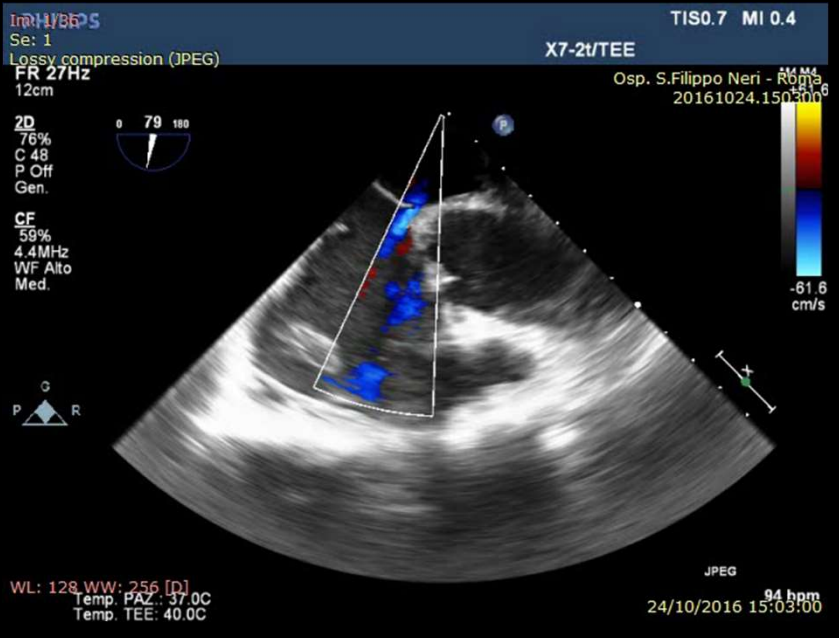
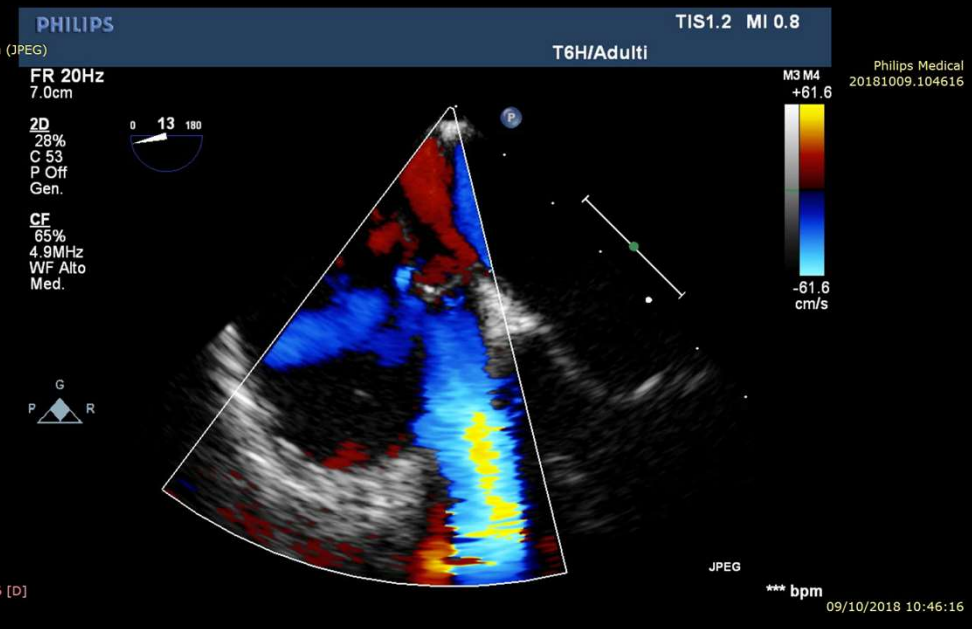
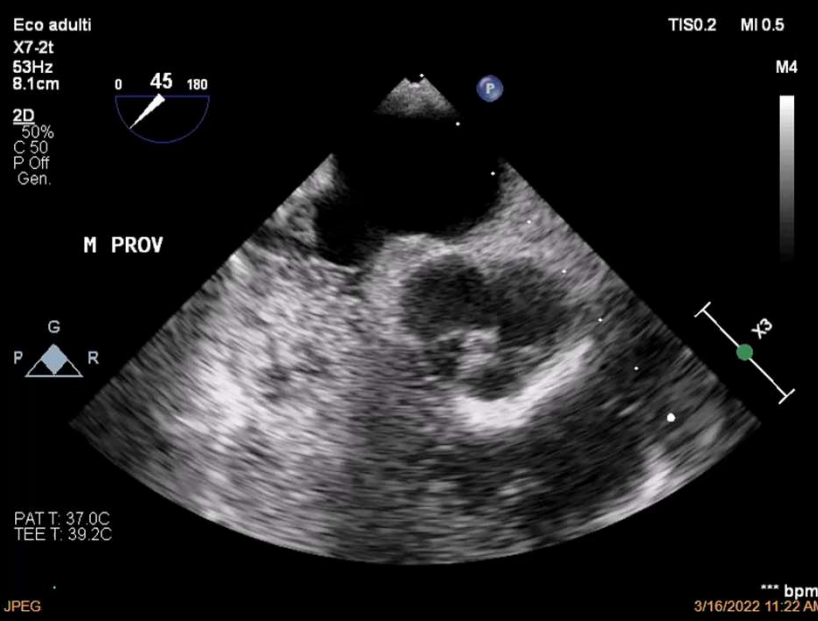
Detachment
of the
septum
primum
and
secundum
sutures and
kwiknot
embolization



Creation of
an pre-
procedural
undetected
fenestration
by stretching
the septum
primum



Step 3: TEE evaluation



Eco adulti

X8-2t
53Hz
7.1cm



2D
52%
C 50
P Off
Gen.

BASALE



PAT T: 37.0C
TEE T: 38.9C

89 bpm

Eco adulti

X8-2t
53Hz
7.1cm



2D
52%
C 50
P Off
Gen.

M PROV



PAT T: 37.0C
TEE T: 39.0C

92 bpm

TEE

X7-2t
53Hz
12cm



2D
54%
C 48
P Off
Gen.

BASALE



PAT T: 37.0C
TEE T: 39.3C

77 bpm

TISO.2 MI 0.5

M4

Eco adulti

X8-2t
53Hz
7.1cm



2D
57%
C 50
P Off
Gen.

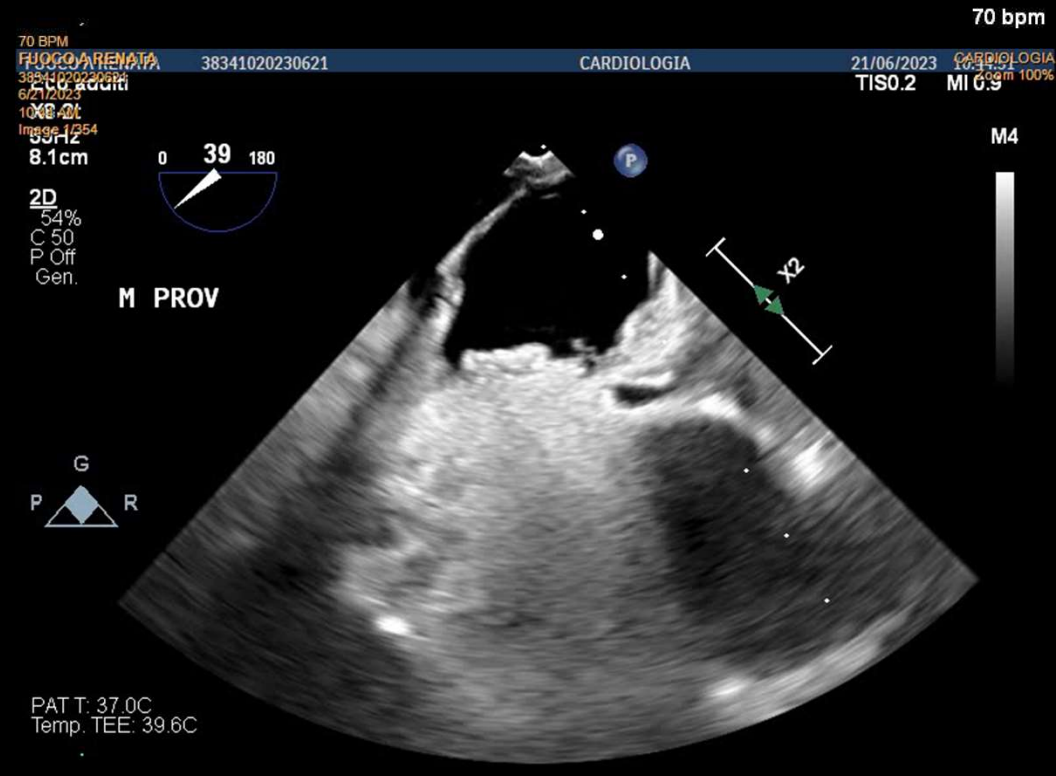
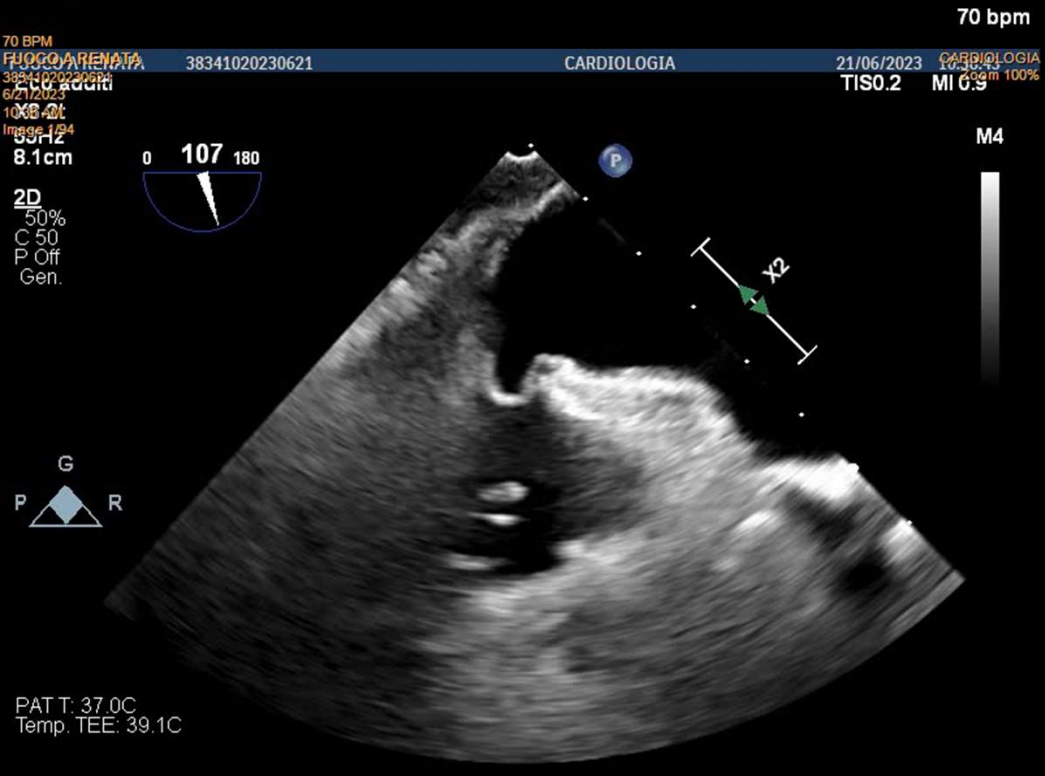
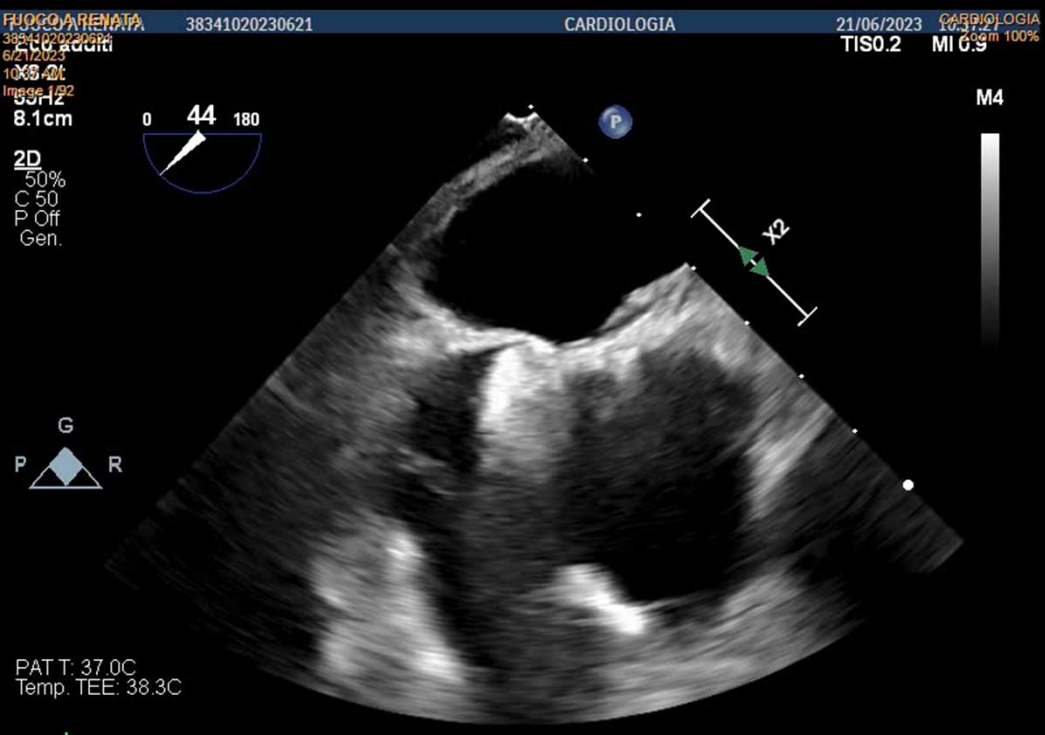
M PROV



PAT T: 37.0C
TEE T: 39.3C

64 bpm

M4



71 BPM

62 BPM