VERY LOW RECURRENCE RATE IN PATIENTS AFFECTED BY CRYPTOGENIC STROKE, PFO AND HIGH RISK ASSOCIATED CONDITIONS WHEN SUBJECTED TO PERCUTANEOUS CLOSURE: THE DATA OF THE MOLINETTE HOSPITAL REGISTRY

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Objective: to report the results of the transcatether closure(TC) in patients affected by cryptogenic cerebral ischemic events (CCIE), Patent Foramen Ovale (PFO) and associated high risk conditions such as interatrial septal aneurysm, hypercogulable state, deep venous thrombosis, multiple ischemic events, large shunt or shunt at rest.

***Patients and methods**: 231* patients, 138 males 93 females, mean age 49 yrs, admitted to Molinette Hospital from 2005 to 2014, were subjected to neurological and cardiological evaluation, lab tests including a thorough screening for coagulopathy, cerebral MR or CT, duplex scanner (neck and lower limbs), transcranial doppler, transthoracic (TTE) and transesophageal (TEE) echocardiography. Antiplatelet agents were employed before and after closure. The procedure, performed under fluoroscopic and echocardiographic drive, had a mean duration of 45'. An Amplatzer PFO-occluder was positioned in 95% of cases. The follow up included a cardiological and neurological re-evaluation at 1 and 6 months and subsequently every 6 months, a TTE at 1 month, a TEE at 6 months.

Results The TC closure success rate was 100%. In the periprocedural time a transient paroxistic atrial arrythmia was observed in 4 pts and 1 TIA occurred; no residual large shunts or hemorrhagic events were identified. During the follow up (mean duration 32,9 months) 9 small and 3 severe residual shunts were identified, 1 stroke and 1 TIA, 5 transient arrhythmias and an interatrial sept erosion occurred, 3 pts underwent surgery.

DISCUSSION TC closure of PFO is a very debated topic. Recently 5 metanalyses, concerning the same 3 randomized trials (CLOSURE I, PC and RESPECT), arrived to opposite conclusions. It must be considered that in CLOSURE I Trial (909 out of 2303 patients considered in the metanalyses) 87 centres enrolled 909 patients in 5 years (2/y/centre), which suggests a certain degree of inexperience and that the CardioSEAL STARflex was employed, a first generation device burdened by frequent complications

CONCLUSIONS: In our group endovascular closure of PFO proved safe and effective in the short and mid term. It seems promising the TIA-Stroke annual Recurrence Rate (RR) is 0,47% and the stroke annual RR is 0,16%, considerably lower than reported in literature. (Mas 4,8 and 3,8%, Nedeltchev 9,9% CCIE, Anzola 8,2% CCIE, Almekhlafi 4 and 1,6%, the FORI Study 4,2 and 3,4%, Closure I 3%). It is noteworthy too the incidence of atrial fibrillation (1,8% in the follow up) results less increased than previously described.

STUDY SAMPLE

231 pts (138 M, 93 F)
Mean age 48,9 (± 13 yr) s)
Cryptogenic stroke (163 or TIA (68)*
PFO
Associated conditions (ASA, Eustachian valve, hypercoagulable state, previous DVT, previous ischemic events, shunt at rest, large shunt after Valsalva)

*No definite cause, large artery(>50% stenosis-dissection of cerebroafferent vessels), lacunar and cardioembolic (AF, recent MI, mitral-aortic valve path, dilated cardiomyopathy, left atrial or ventricular thrombus, akinetic left ventricular segment) strokes excluded

HIGH RECURRENCE RISK ASSOCIATED CONDITIONS

ASA: 183 pts
Eustachian valve: 48 pts
Previous ischemic events: 24 pts
Hypercogulable state: 44 pts (18 MTHFR mutations, 24 hyperhomocysteinemia, 2 Leyden mutation, 2 S protein deficiency, 2 prothrombin mutation)
DVT: 11 pts
Shunt at rest: 172 pts (32 large)
Large shunt after Valsalva: 148pts

PREPROCEDURE EXAMINATIONS AND THERAPY

Cardiological and neurological evaluation (with vascular risk factor assessment
Lab tests with coagulation study
Brain CT or MR
Color Coded Sonography of extracranial arteries and of lower extremity veins
Transcranial Color Coded Sonography
TTE and TEE with contrast medium
Preclosure therapy: antiplatelet agents

FOLLOW UP

Cardiological and neurological examination + Transthoracic Echocardiography 1 month after closure
Cardiological and neurological re-examination every 6 months
Transesophageal Echocardiography 6 months after procedure
Transthoracic Echocardiography after 1 year and subsequently every year if shunt persistence
Postclosure therapy:
ASA + Clopidogrel for 3 months
ASA for other 3 months
ASA subsequently only if shunt persistence

VASCULAR RISK FACTORS

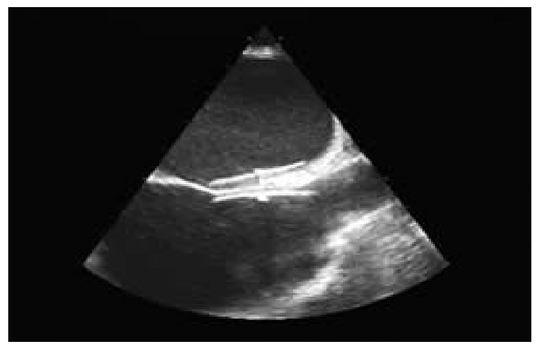
Hypertension: 97 pts (42%)
Hypercholesterolemia: 63 pts (27%)
Coagulopathy: 44 pts (19%)
Smoke: 37 pts (16%)
Diabetes M: 18 pts (8%)
Family Susceptibility: 18 pts (8%)
Previous or present DVT: 11 pts (5%)
Estroprogestinic therapy: 7 pts (3%)

COAGULATION STUDY FINDINGS

MTHFR mutations:	18 pts (8%)
Hyperhomocysteinemia:	24 pts (10%)
Protein S deficiency:	2 pt (0,9%)
Factor V mutation:	2 pt (0,9%)
Factor V mutation:	2 pt (0,9%)

TEE FINDINGS

Shunt	at rest	after Valsalva
Mild/Mod	139	82
Large	32	149



PERCUTANEOUS CLOSURE

TIA/Stroke proc. time: 3,9 months ± 2,63
Fluoroscopic guidance (radioscopy time 6,3 ± 4')+ TEE guidance
Local anesthesia: 189 cases (82%)
General anesthesia: 42 cases (18%)
Device type: Amplatzer PFO occluder in 220 pts, Intrasept in 9, Premere in 2

PROCEDURAL RESULTS

Mean procedural time (door to door) 46±11' (range 20-90')
Mean fluoroscopy time 6,3 ± 4'(range 2-22)
Lenght of stay: 3,5 ± 1,1 days
Procedural success: 100%
Major complications: 0%
Minor complications: 2,2% (4 AF and 1 flutter)

FOLLOW UP GEN. AND NEUROL. ADVERSE EVENTS

Deaths	0
Ischemic recurrencies	2 (1Stroke1 TIA)

FOLLOW UP CARDIOLOGICAL ADVERSE EVENTS

Ventricular tachicardia	0
Device Embolization	0
Malpositioning	0
Cardiac perforation	0
Pericardic Effusion	0
Thrombus Formation	0
Aortic Erosion	0
IAS Erosion (inf edge of the device)	1
Transient Atrial Fibrillation	5

FOLLOW UP SHUNT EVOLUTION

Residual large shunt (in 2 percutaneous closure repeated)	
At rest	2 pts (1%)
After Valsalva	3 pts (1,5%)
Residual small shunt	
At rest	3 pts (1,5%)
After Valsalva	10 pts (4,3%)

References *1 Rengifo-Moreno et al PFO transcatether closure vs medical therapy on recurrent vascular events: asystematic review and meta-analysisof RCTs* ***Eur Heart J 2013;34:3342-52***
2 Pickett Ca et al Percutaneous Closure versus Medical Therapy Alone for Cryptogenic Stroke Patients with a Patent Foramen Ovale: Meta-Analysis of Randomized Controlled Trials ***(Tex Heart Inst J 2014;41(4):357-67)***
3 Spencer F.A. et al Systematic review of percutaneous closure versus medical therapy in patients with cryptogenic stroke and patent foramen ovale ***BMJ Open 2014;4:e004282.***

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