ENDOVASCULAR CLOSURE OF PATENT FORAMEN OVALE IN CRYPTOGENIC STROKE: INCIDENCE OF RECURRENCES IN A PROLONGED FOLLOW UP

D.GIOBBE*, A.BALDUCCI *, G.PAGLIA*, M.L.GIOBBE, P. SCACCIATELLA**, M.GIORGI**,I. MEYNET**

** Neurosciences Dpt ** Cardiothoracic Dpt. A.O.U. Città della Salute e della Scienza Turin*

OBJECTIVE: to report the results of the percutaneous closure(PC) in a cohort of selected 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: 258 patients, 154 males 104 females, mean age 48 yrs, admitted to Molinette Hospital from 2005 to 2015, were subjected to clinical evaluation, lab tests including a coagulopathy screening, cerebral imaging, duplex scanner (intracranial,neck and lower limbs), transthoracic (TTE) and transesophageal (TEE) echocardiography, Holter ECG. Platelet inhibitors were employed pre and post closure. The procedure, performed under fluoroscopic and echocardiographic drive, had a mean duration of 45'. An Amplatzer PFO-occluder was positioned in 96% of cases. The follow up included a clinical re-evaluation at 1 and 6 months and subsequently every 6 months, a TTE at 1 month, a TEE at 6 months

RESULTS: The PC 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 nor hemorrhagic events were identified. During the follow up (mean duration 40,3 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. After 12 metanalyses, concerning the same 3 randomized trials (CLOSURE I, PC and RESPECT), which arrived to opposite conclusions, very recently the first pooled analysis of individual participant data showed that closure reduced recurrent stroke and had a statistically significant effect on the composite endpoint stroke/TIA/death in adjusted but not unadjusted analyses

CONCLUSIONS: In our group percutaneous closure of PFO proved safe and effective in a prolonged follow up. It seems noteworthy that both the TIA-Stroke annual Recurrence Rate (RR) and the stroke annual RR (0,35% and 0,12% respectively) are 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 remarkable too the incidence of atrial fibrillation (1,8% in the follow up) results less increased than previously described.

STUDY SAMPLE

258 pts (154 M, 104 F)
Mean age 48,4 (± 13 yr) s)
Cryptogenic stroke (183 or TIA (75)*
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: 205 pts
Eustachian valve: 54 pts
Previous ischemic events: 27 pts
Hypercogulable state: 49 pts (20 MTHFR mutations, 27 hyperhomocysteinemia, 2 Leyden mutation, 2 S protein deficiency, 2 prothrombin mutation)
DVT: 12 pts
Shunt at rest: 193 pts (36 large)
Large shunt after Valsalva: 166 pts

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: 108 pts (42%)
Hypercholesterolemia: 70 pts (27%)
Coagulopathy: 49 pts (19%)
Smoke: 41 pts (16%)
Diabetes M: 21 pts (8%)
Family Susceptibility: 21 pts (8%)
Previous or present DVT: 13 pts (5%)
Estroprogestinic therapy: 8 pts (3%)

COAGULATION STUDY FINDINGS

MTHFR mutations:	20 pts (8%)
Hyperhomocysteinemia:	27 pts (10%)
Protein S deficiency:	2 pt (0,8%)
Factor V mutation:	2 pt (0,8%)
Factor V mutation:	2 pt (0,8%)

TEE FINDINGS

Shunt	at rest	after Valsalva
Mild/Mod	156	91
Large	36	167

PERCUTANEOUS CLOSURE

TIA/Stroke proc. time: 3,9 months ± 2,63
Fluoroscopic guidance (radioscopy time 6,3 ± 4')+ TEE guidance
Local anesthesia: 211 cases (82%)
General anesthesia: 47 cases (18%)
Device type: Amplatzer PFO occluder in 247 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: 1,9% (1 TIA,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 (0,8%)
After Valsalva	3 pts (1,2%)
Residual small shunt	
At rest	3 pts (1,2%)
After Valsalva	11pts (4,3%)

REFERENCES *1 Rengifo-Moreno et al PFO transcatether closure vs medical therapy on recurrent vascular events: asystematic review and meta-analysis of RCTs* ***Eur Heart J 2013;34:3342-52***
2 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.***
3 Kent D et al Device Closure of Patent Foramen Ovale After Stroke Pooled Analysis of Completed Randomized Trials ***J Am Coll Cardiol 2016;67:907-17***

Sin
XLVII CONGRESSO NAZIONALE
22-25 OTTOBRE 2016 – VENEZIA
WebPoster