PICS-AICS
Pediatric and Adult Interventional Cardiac Symposium
MIAMI
LOEWS MIAMI BEACH HOTEL
JANUARY 19-22, 2013
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MID-TERM RESULTS OF PERCUTANEOUS CLOSURE OF ATRIAL SEPTAL DEFECT AND PATENT FORAMEN OVALE USING THE OCCLUTECH FIGULLA® FLEX I/II CLOSURE DEVICE. MULTICENTER ITALIAN EXPERIENCE

E. Onorato[1 2] , V. Ambrosini[1] , B. Missiroli[3], C. Zimbalatti[3], R.A. Osanna[4] , A. Pitì[2] , P. Rubino[1]

[1] Division of Invasive Cardiology, Casa di Cura "Montevergine", Mercogliano (Avellino)
[2] Division of Invasive Cardiology, Humanitas Gavazzeni Clinic, Bergamo
[3] Emodinamica e Cardiologia Interventistica, S.Anna Hospital, Catanzaro
[4] U.O. Cardiologia Emodinamica, Azienda Ospedaliera Regionale San Carlo, Potenza

Purpose: To assess the safety and efficay of percutaneous closure of atrial septal defect (ASD) and patent foramen ovale (PFO) with or without atrial septal aneurysm (ASA) using the novel Occlutech Figulla® Flex I/II ASD/PFO Closure Device .

Methods: Between April 2010 and September 2012, we performed transcatheter ASD and PFO closure in 224 consecutive symptomatic patients (pts). Twenty six ASDs (female/male=2,3/1; mean age 40±18 years,range 14-65) and one hundred ninety eight PFOs (female/male=2,9/1; mean age 48±15 years, range 12-75) were included. Pts were pre-procedurally submitted to cardiological/neurological examination including contrast transthoracic/transesophageal echocardiography (cTTE/cTEE), brain CT/NMR imaging and contrast-enhanced transcranial Doppler (cTCD). Indication for ASD closure was significant left-to-right shunt associated with RV overload and mild to moderate pulmonary artery hypertension. 11 ASDs (47,8%) were more than 30 mm in diameter. Closure of PFO was clinically indicated for secondary prevention in pts with previous cryptogenic cerebrovascular events due to presumed paradoxical embolism. Pre-procedurally thromboembolic events were: 107 ischemic stroke (54,8%), 88 transient ischemic attack (41,5%). Atrial septal aneurysm was observed in 35 pts (17,1%); a prominent redundant Eustachian valve was present in 25 pts (12,2%). Thrombophylic disorders were present in 10 pts (5,5%). 40 pts were aura migraineurs (19,6%). Primary prevention of cerebrovascular accidents was done in three professional scuba divers with multiple episodes of decompression sickness with large right-to-left shunt (RLS) via PFO. All procedures were performed with local anesthesia under fluoroscopic guidance and rotational intracardiac echocardiography (Ultra-ICE) alone. Clopidogrel was recommended for 2 months and aspirin for at least 6 months after ASD/PFO closure.

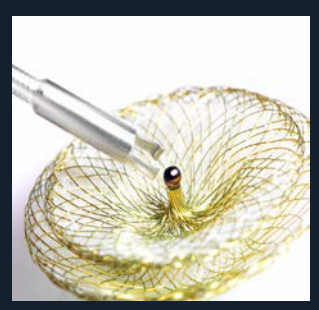
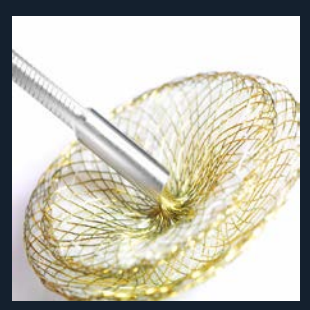
RESULTS: Device implantation was successful in all pts, except one. The in-hospital complications were: self-limited supraventricular arrhythmia in 25 pts (11,1%); new onset transient atrial fibrillation in 1 pt (0,4%) ; minimal groin hematoma in 15 pts (6,6%); mild pericardial effusion which appeared not to be related to the procedure in 1 pt (0,4%); massive coronary air embolism with prolonged inferior ST segment elevation and transient cardiac arrest successfully resuscitated without further sequelae in 1 pt (0,4%). cTTE/cTEE and cTCD 6 months after PFO closure (n= 105) revealed four moderate residual shunts with unclear clinical relevance (3,8%). Nonetheless, in two cases a second device implantation has been successfully performed with abolition of the residual RLS. In the ASD group (n= 18), one mild to moderate residual shunt was observed four months after implantation of a 39 mm device. No device malfunction, erosion, valvular regurgitation or thrombus formation occurred so far.

Occlutech Figulla® Flex I/II Devices Technology

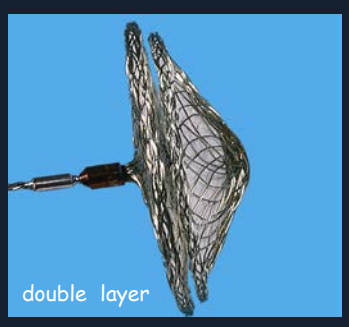

Figulla® Flex I ASD Occluder

Figulla® Flex II ASD

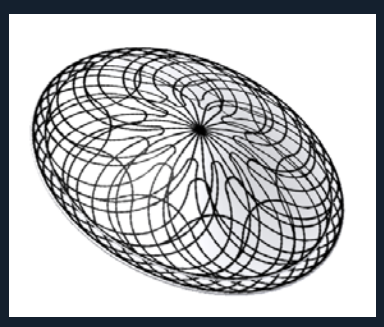
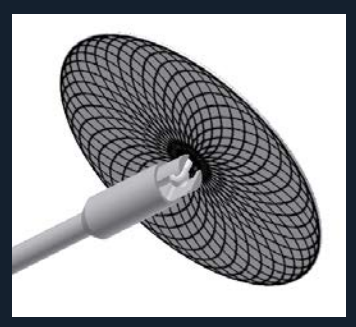
Figulla® Flex II - Close up

Figulla® Flex II ASD Occluder connecting to Pusher



Figulla® Flex I PFO Occluder

Figulla® Flex II PFO Occluder

New Flex Delivery System

Conclusions: Catheter ASD/PFO closure using Occlutech Figulla® Flex I/II devices appear to be easy, safe and effective, ensuring high closure rate and low complication rate. Mid-term follow-up results appear favorable with respect to recurrent thromboembolic events. Further studies with adequate follow-up are warranted to confirm long-term efficacy.