PROCEDURAL RESULTS AND CLINICAL OUTCOME OF TRANSCATHETER PERCUTANEOUS CLOSURE OF PATENT FORAMEN OVALE WITH NEW ULTRASEPT OCCLUDER DEVICE: A SINGLE CENTER EXPERIENCE.

Emanuela de Cillis MD, PhD; Alessandro Santo Bortone MD, PhD.

Institute of Cardiac Surgery, Department of Emergency and Organs Transplantation, University of Bari, Bari, Italy.

Corresponding Author:

Emanuela de Cillis MD, PhD
Institute of Cardiac Surgery – University of Bari - Italy
Phone and fax: +39 080 5592 192
Email: e.decillis@cardiochir.uniba.it

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Introduction: Cryptogenic stroke remains the final diagnosis in 40% of ischemic acute cerebrovascular events. Stroke is the leading cause of disability and the third leading cause of death in the developed Countries. Cardiogenic stroke may be provoked by various factors, but involvement of patent foramen ovale (PFO), especially when associated with atrial septal aneurysm (ASA) is among the most frequently suspected and is complex to investigate. Identifying the causes of neurologic ischemic syndromes is essential to any strategy intended to prevent the catastrophic consequences of cerebral infarction. Furthermore, it is important to offer increasingly safer and less invasive therapeutic opportunities for patients to minimize treatment burden and allow for timely rehabilitation. Our experience suggests that percutaneous treatment of PFO meets these criteria and appears safe and beneficial for secondary prevention of recurring acute cerebrovascular events.

A principal determinant of success in the percutaneous closure of PFO is the choice of an appropriate device; as the actual effectiveness of each particular style occluder is likely to depend

on the differing defect anatomies encountered. Among commercially available occluder devices, the generation six "Atriasept" Cardia device and generation seven "Ultrasept" Cardia device (CARDIA Inc. Eagan, MN, USA), show additional novel improvements in safety and performance. The aim of our study is to evaluate and report the experience of our Institution regarding the use of these devices in terms of procedural safety and efficacy, anatomical assessment utilizing intra-cardiac echocardiography and fluoroscopy, and eventual clinical outcomes.

Ultrasept is the seventh generation Cardia device, a double rounded occluder in which the right atrial struts and end caps (Atriasept) have been completely replaced with a second rounded sail. This new design has no pointed arms or rough saw blade style edges and presents a fully smooth and rounded profile thus improving and maximizing safety. Wire shaping is accomplished with 19 stranded woven nitinol elements that maximize fatigue resistance while maintaining an appropriate tension. The forerunner to these devices was the company's widely used Intrasept device which was the first occluder device for treatment of PFO designed to employ a novel articulating sail concept.

Material and methods: From November 2008 to July 2011, 29 consecutive patients (19 females, 10 males; average age 46 yrs, range 14-66 yrs), admitted with diagnosis of recurrent ischemic neurologic events confirmed by cerebral imaging, underwent percutaneous closure of PFO using Cardia Atriasept and Ultrasept devices. In the last 5 consecutive treated patients the Cardia seventh generation Ultrasept device was used. In accordance with our protocol, transesophageal echocardiography (TEE) in conjunction with Transcranial Doppler (TCD) evaluation was used in determining a diagnosis of PFO in symptomatic patients. In all patients, a permanent moderate to severe right-to-left shunt was found. PFO length generally ranged from 6mm to 14mm with type II tunnel morphology most prevalent. In general, Ultrasept and Atriasept devices were selected for use in a wide variety of defect anatomies including patients presenting a very thick septum secundum and complex connections between the two septae. In these difficult anatomical conditions both the

Atriasept and Ultrasept devices were able to be implanted quite easily. Both devices were also implanted regularly in patients with PFO type I tunnel morphology and ASA without difficulty as well.

All procedures were performed using intracardiac echocardiography (ICE) (Acunav 8Fr, Acuson Siemens) guidance under local anesthesia with mild conscious sedation. Total procedure duration was less than 20 minutes in all patients. Bilateral venous access was gained via right and left femoral veins and the PFO was catheterized using a multipurpose catheter under ICE guidance. All patients received 100 IU/Kg heparin i.v. at the time of the procedure and antibiotic prophylaxis. All 29 treated patients were studied during the follow-up period with clinical neurologic evaluations (Rankin modified scale) and TCD microbubble tests during basal conditions and after Valsalva manoeuvre at 6 months. Transthoracic echocardiography was performed at 1, 6 and 12 months. If a moderate shunt (> 10 micro bubbles) were detected at 6 month follow-up, transesophageal echocardiography would also be performed. Protocol defined follow-up was 100% complete in all treated patients.

Results: Successful device deployment was achieved in 100% of patients without any intra or periprocedural major complications. Only 1 patient presented a short term supra-ventricular arrhythmia (atrial fibrillation) within the first hour after implantation of a 30mm Atriasept occluder which spontaneously resolved three hours later. All patients were discharged within 3 days in good overall conditions and were prescribed a double antiplatelet regimen for 3-6 months. During the follow-up period, no arrythmogenic events occurred.

The follow-up was complete in 100% of cases (range 2- 32 months). At two years follow-up, there were no recurrent episodes of stroke and/or TIA as documented by nuclear magnetic resonance (NMR) and neurological examination, and no recurrence of acute cerebrovascular events was

observed. Significantly, at 6 months follow-up, all patients who received an Ultrasept or Atriasept device resulted negative for TCD micro embolic signals (<5-10 HITS) confirming optimal sealing of the implanted device and lack of any residual shunting. TTE evaluations at 1, 6 and 12 months further showed optimal sealing of all devices without any signs of erosion, malposition, dislodgement, incomplete closure or thrombus formation around the device.

Discussion and Conclusions: Our experience suggests that percutaneous closure of PFO with the Cardia Atriasept device, and in particular with the new version Ultrasept device, appears safe and beneficial for prevention of clinical recurrence of acute cerebrovascular events. A principal determinant of procedural success is the choice of an appropriate device for the specific defect morphology encountered, and the effectiveness of commercially available occluder devices is likely to depend on differing anatomies. Our experience suggests that the Atriasept/Ultrasept devices, due in part to their high flexibility, easy loading and extremely low profile, showed excellent performance in differing anatomical configurations of interatrial septum making them particularly suitable for a wide variety of defect morphologies; including thicker septae of up to 1cm in our study. The present report shows that in comparison to our extensive use of legacy devices (Amplatzer PFO occluder etc.), a reasonably comparable to superior outcome was obtained with our use of the Atriasept, and in particular the new Ultrasept occluder devices, warranting further studies with a larger patient population.

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