EuroPCR Interventions for structural heart disease Euro15A-OP333

One year clinical comparison of Amplatzer and Occlutech occluders for percutaneous closure of patent foramen ovale

Gaspardone A.[1], Trabattoni D.[2], Gioffrè G.[1], Giardina A.[1], Fabiocchi F.[2], De Santis A.[1], Montorsi P.[2], Iamele M.[1], Calligaris G.[2], D'errico F.[1], Bartorelli A.[2], Sgueglia G.A.[1]

1. Sant'Eugenio Hospital, Rome, Italy; 2. Centro Cardiologico Monzino, Milan, Italy

Aims: To compare the acute and long-term results of patent foramen ovale closure with two occluder devices based on different technologies.

Methods and results: Overall, 363 consecutive patients (48±13 years, 219 women) undergoing percutaneous closure of patent foramen ovale with either the Amplatzer PFO Occluder (n=165) or the Occlutech Figulla Flex (n=198) were enrolled in a multicentre, prospective, registry. All patients were followed-up with contrast transthoracic echocardiogram and clinical evaluation at 24 hours, 6 months and 12 months after the procedure. At baseline, a right-to-left shunt > grade 1 was detected in 82% of patients and atrial septal aneurysm was present in 100 of them. A high procedural and technical success was observed in both groups and no differences were recorded in patent foramen ovale closure efficacy. Despite a trend toward a higher incidence of acute residual shunt immediately after device deployment among patients treated with the Occlutech device, a residual right-to left shunt > grade 1 was observed in 4% of all patients, independently of the device implanted to close the patent foramen ovale. The only difference reported with Occlutech was a significantly lower rate of atrial fibrillation and supraventricular arrhythmias compared to Amplatzer (16.9% vs. 9.0%, p=0.02).

Conclusions: According to this multicentre study, percutaneous closure of patent foramen ovale with the Occlutech Figulla Flex device appears as safe and effective as with the well-established Amplatzer PFO Occluder.