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Late complications after Interventional Closure of Atrial Septal Defect with the Solysafe® Septal Occluder

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Prospective mono-center study for interventional closure of atrial septum defect, secundum type (ASD) by Solysafe® Septal Occluder (SSO) was performed in our institution, with one year follow-up. Patients were re-examined after implantation of a SSO, because of device fracture (DF) diagnosed in one patient.

Objectives: To evaluate long term results of ASD closure by SSO and potential complications, such as: device deformation (DD), device fracture (DF), wire embolization (WE), device thrombosis (DT), and others.

Methods: Extended follow-up examination was performed in all patients after SSO, including transthoracic echocardiography (TTE), standardized fluoroscopy (sF) and in pts with complications transesophageal echocardiography (TEE) as well.

Results: Between 09/2006 and 04/2008 57 pts have undergone SSO due to ASD. Median age was 15.9 years (4.5-53). Complete follow up was available in 49 pts (85.96%). Only one patient was symptomatic. Median follow-up was 3.2 years (2.25-3.7). Patients were divided in three groups: Group A- 12 pts with small SSO (15mm), Group B- 25 pts with medium size SSO (20 and 25mm) and Group C- 12 pts large SSO (30 and 35mm). Complications were diagnosed in 15/49 (30.6%) pts. Patients from Group A have not had any complication until now. In Group B 2/25 (8%) pts had DD and 1/25 (4%) pts had DF. In Group C 3/12 (25%) had DD and 9/12 (75%) pts had DF, from whom WE was disclosed in 3 (left atrium, right ventricle and right pulmonary artery) and DT in one. There is a significant correlation between size of SSO and the complication rate. All complications, except DT were diagnosed only by sF, while TTE was normal. Massive DT was diagnosed by TTE and confirmed by TEE. Surgical removal of SSO was performed in 3 pts with DF and DT. Unfortunately, one patient died after surgery due to massive pulmonary embolism, but there is no hard evidence to blame it to the device.

Conclusions: The incidence of complications after ASD closure by SSO is extremely high, particularly in pts with large SSO. sF is imperative for accurate diagnosis of DF and WE. Close monitoring is necessary for all pts with SSO.