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Midterm follow up of interventional closure of atrial septal defect using the Solysafe™ Septal Occluder – Diagnostic impact of fluoroscopy for complication management

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Objective: In August 2010 sales and distribution of the Solysafe Septal Occluder has been immediately stopped for interventional closure of secundum type atrial septal defects (ASD II) because of frequent reports of wire fractures. Therefore, we analysed the incidence of irregularities associated with implanted occluders during midterm follow up.
Methods: We evaluated the midterm follow up of all patients after implantation of Solysafe Septal Occluder focussing on the results of fluoroscopic assessments as recommended by the company.
Results: Between April 2007 and June 2010 in 51 pediatric patients (male:female = 24:27) at an age (mean±SD) of 8.0±4.6 years (range 1.6-17.8 years) and a body weight of 29.1±18.1 kg (9.5-86) Solysafe Septal Occluder were successfully implanted. ASD II presented as solitary defects (n=39), two defects (n=11), or multiple defects (n=1) with a significant left to right shunt Qp to Qs 1.7±0.7 (1.0-4.0), native resp. balloon stretched size of 10.0±3.9 mm (5-20) resp. 12.5±4.7 mm (6.5-23) determined by transesophageal echocardiography. During midterm follow-up of 2.1±0.9 years (0.5-3.7) patients were clinically asymptomatic and echocardiography revealed a complete closure rate of 94.9% (48 of 51 patients). Fluoroscopy showed in two patients (3.9%) new complications, not determined by echo before: In one patient (age 7.9 years, 25mm device, no residual shunt) fixed fracture of one wire loop not leaving the plane of the atrial septum, in the second patient (age 5.0 years, 30mm device, residual shunt) multiple fractures of wire loops on both sides of the device, with embolization of wire fragments to left and right pulmonary artery. Due to fractured wire ends sticking out of the septum and by this injuring the anterior mitral leaflet, cardiac surgery was performed with complete explantation of the device and successful mitral valve repair and uneventful postoperative course.
Conclusions: Despite low periprocedural complication rate, during midterm follow-up the rate of fractured wire loops of Solysafe Septal Occluder should lead to regular fluoroscopic controls at least every year as recommended by the company. Large size of the occluder and residual shunts were risk factors for complications in our cohort.