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Longterm follow up of interventional closure of atrial septal defect using the Solysafe™ Septal Occluder

Knirsch W. (1,3), Quandt D. (1,3), Christmann M (1,3), Hübler M. (2,3), Kretschmar O. (1,3)
Paediatric Cardiology (1), Congenital Cardiovascular Surgery (2), Children's Research Center (3), University Children's Hospital, Paediatric Heart Center, Zurich, Switzerland

Objective: Since August 2010 distribution and sale of the Solysafe Septal Occluder (SSO) is stopped for interventional closure of atrial septal defect (ASD II) due to reported wire fractures. Longterm follow up data are lacking. Methods: We analysed the incidence of irregularities associated with SSO during longterm follow up until December 2015 by fluoroscopic assessments as recommended by the company. Results: SSO was successfully implanted in 51 children (male 24) at an age (mean±SD) of 8.0±4.6 (range 1.6-17.8) years and a body weight of 29.1±18.1 kg (9.5-86) with a SSO size of 15mm (n=28), 20mm (n=13), 25mm (n=8), and 30mm (n=2). During longterm follow up all patients were clinically asymptomatic. Fluoroscopy showed after 4.8±1.6 years in 17 patients (33.3%) irregularities, i.e. fractures or dehiscences, not determined by echo before. In eight patients (15.7%) we found single or multiple dehiscences of wire loops disconnected from the central pin, and in nine (17.6%) patients single or multiple fractures. Dehiscence was only found in children with 15mm devices (n=8), while the risk of fractures increased with SSO size (15mm size, 7.1%, 20mm, 15.4%, 25mm, 37.5%, 30mm, 100%). The yearly risk of irregularities increases after implantation (3rd year, 5.9%, 4th, 6.3%, 5th, 6.7%, 6th, 7.5%, 7th, 10.5%). The integrity of the device was not altered in 50 patients (98%), despite one patient with three fractures of wire loops on both sides of the device and embolized wire fragments to both pulmonary arteries detected two years after implantation. The fractured wire ends sticked out of the septum and injured anterior mitral leaflet, therefore, cardiac surgery was performed with complete explantation of the device and successful mitral valve repair and uneventful postoperative course.
Conclusions: During longterm follow up the rate of irregularities with fractured or dehiscent wire loops of implanted SSO is high, and progresses continuously, and requires regular fluoroscopic controls. Larger size of SSO is a risk factor for fractures. Despite radiological irregularities the integrity and stability of most of the devices were not affected due to a firm and adequately thick coat of scar tissue, which hopefully will ensure longterm safety for the patients.