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Midterm follow-up after interventional closure of atrial septal defects using the Solysafe septal occluder

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Objective: The Solysafe septal occluders (Swissimplant ®) is a self-centering device for interventional closure of secundum type atrial septal defects and patent foramen ovale which was first successfully implanted in 2005. Individual reports of wire fractures terminated the distribution and implantation of Solysafe septal occluders (SSO) in August 2010. Therefore, we contacted and evaluated all patients who underwent interventional closure of an atrial septal defect using this device at our institution.
Methods: From 7/2008 to 7/2010 interventional closure of an atrial septal defect using a SSO was performed in 23 patients (18 females, 5 males). Mean age at the procedure was 8.0 years (2.9 to 16.2 years), the native defect size was mean 11mm (5 to 16mm) measured by transesophageal echocardiography. SSO types 15, 20, and 25 were used in 7, 13, and 3 patients, respectively. No SSO types 30 or 35 were used. Between 09/2010 and 12/2010 all patients were re-evaluated carefully. In addition to transthoracal echocardiography and electrocardiogram the integrity of the wire frame was controlled by fluoroscopy.
Results: Mean 389 days (69 to 799 days) after the interventional procedure all patients were asymptomatic. Echocardiography revealed a flat device in all patients without residual shunt. No wire fractures were detected by fluoroscopy.
Conclusion: Thorough check-up revealed no wire fracture or other device related problems in our patients treated with SSO types 15 to 25. However, mean follow-up was only 1 year. Maybe larger devices or devices implanted in persistent foramen ovale are more susceptible to the reported wire fractures. Further careful follow-up evaluation is necessary.