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Wire fractures in Solysafe® Septal Occluders - a single center experience

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Introduction: The Solysafe® Septal Occluder (SSO) is a relatively new device for interventional closure of patent foramina ovalia and secundum type atrial septal defects. In 08/2010, after initial unpublished reports on device fractures (DF), the manufacturer issued and "Urgent Field Safety Notice" prompting all medical care providers to reexamine all patients after implantation of a SSO (iSSO).
Objectives: To determine the incidence of DF after iSSO and to assess the spectrum of associated problems.
Methods: Prospective single center study. Extended follow-up examination including standardized fluoroscopy (sF) was performed in all patients after iSSO.
Results: Between 06/2005 and 07/2010, 111 patients had undergone iSSO at our institution. Median age and body weight were 50 years (9.3-79.6) and 75 kg (29-122), respectively. Indications for device implantation were 1) patent foramen ovale with a history of cryptogenic stroke (n=84; 76%) and 2) hemodynamically significant atrial septal defect of the secundum type (n=27; 24%). A total of 113 devices were implanted. Complete follow-up was available in 103 patients (92.8%). Median follow-up was 1.9 years (0-5.2). There were no new neurologic events or symptoms. The closure rate was 97.1%. DF was suspected by chest x-ray in one patient and documented in 10 patients by sF. In all patients with DF, damage to adjacent cardiac structures and intracardiac thrombi were ruled out by transesophageal echocardiography. The overall probability of freedom from device fracture was 82.3% after five years. There was no significant difference between the occluder sizes of 15-25 mm. The underlying cardiac lesion in all patients with DF was a patent foramen ovale ($p = 0.12$). In multivariate regression analysis, there was no significant influence of age, size, body weight or size at implantation. One patient had embolization of a device fragment to the right pulmonary artery. So far, all patients with DF were managed conservatively.
Conclusions: The incidence of DF after iSSO inacceptably high. sF is imperative for accurate diagnosis of DF. Further follow-up is needed to determine the risk for potential clinical hazards and to optimize management.