Complications following transcatheter ASD closure with the Amplatzer septal occluder

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The aim of this study is to report complications of transcatheter ASD closure using the Amplatzer Septal Occluder (ASO) (St Jude Medical).
From December 1999 to October 2013, 750 patients underwent ASD closure with the ASO. Closure was mostly realized under general anaesthesia and transoesophageal echocardiography control.
Choice of the device diameter was established after balloon sizing and calculation of the stretched diameter.
Mean age of the patients was 31.9 ± 22 years (0.5 month – 84 years). The stretched diameter was 22.5 ± 6.6 mm (5 - 40 mm) and device dimension 22 ± 6.7 mm (4 – 40 mm). Duration of the procedure was 41 ± 15 minutes (10 – 120 minutes) and fluoroscopic time 7.63 ± 6.65 minutes (1 - 92 minutes).
Dose of radiation was 18.7 ± 22 Gy.cm² (median 12 Gy.cm²).
Implantation succeeded in 96.3 % of pts and failure was mainly related to deficient rim. No device related death was noticed. Embolization occurred in 4 pts (0.5 %): 1 in the aorta, 1 in the left ventricle, and 2 in the pulmonary artery. All but one underwent surgical extraction and ASD closure.
The patient with aortic embolization had percutaneous device extraction and underwent subsequently successful implantation with a larger device. No patient required blood transfusion for any groin hematoma. One patient without aortic rim had hemopericardium one month after implantation; this was corrected by drainage without any recurrence and ASD full occlusion was noticed on Doppler control. No late complication was observed. The rate of full occlusion on Doppler control is more than 90 %, and the remainings have trivial shunt.
Transcatheter ASD occlusion with the Amplatzer Septal Occluder is a safe and effective procedure. The rate of immediate complication is very low with a need of surgery in less than 0.4 % of patients. No device related late complications were reported up to 14 years after implantation. The risk of aortic perforation in absence of anterior rim (noticed in about 20 % of pts) is trivial and not a real limitation in clinical practice.