Interventional ASD-closure with the occlutech devices in 1333 patients: First results of the IRFACODE – registry

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Introduction The Occlutech ASD device series show an improved device design and gained CE mark in 2007; larger follow-up outcome series are however missing.

Methods Retrospective analysis of the feasibility, safety, results and follow-up of ASD-closure with these devices over a 5 year period in 16 centers from 11 countries.

Patients In 1333 patients (female 67,4%) successful (96,2%) ASD closure was performed, mean age was 29 years (range 4 months – 83 years), weight 51,8 kg (range 4 – 175 kg), length 148,5 cm, (range 43 – 195 cm). 15,9% of the defects showed no and 33,2% only a deficient aortic rim (total 49,1%), in 12,8% there was more than one defect, a septum aneurysm in 19,4%. Implantation was performed with TTE only in 19,4%, with TOE guidance in 80,8% and with ICE in 6,9%, mean device size was 21 mm, the devices used were OSO 48%, Flex I 41% and Flex II 17,9%.

Results Immediate closure was achieved in 78,6%, at discharge 82,5%, 95% at 6 and 95,8% at 12 months. The overall complication rate was only 6,3% (including 23 new onset arrhythmias, 19 new onset migraine, 2 TIA); significant complications (n=7, =0,5%) were device embolization in 4 patients (3 without balloon sizing), 3 AV-blocks (total=7, <0,01%) and no erosion or death.

Conclusion Interventional closure of ASDs using the Occlutech ASD devices is feasible in a large variety of patients and safe with only a minimal risk of side effects and especially without aortic erosions despite a large percentage of defects with no or only deficient aortic rim.

Conflict of interest NAH is proctor for ASD closure, the other authors declare no conflict of interest.