

Efficacy and safety of catheter closure of atrial septal defects using the Amplatzer versus the Cocoon septal occluder. A Multicenter Randomized Study

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Introduction: Transcatheter closure of atrial septal defect (ASD) using the Amplatzer Septal occluder (ASO) has become the procedure of choice in most cardiac centers. However, despite its technical simplicity the procedure is still associated with complications which, although very rare, are potentially life-threatening. The Cocoon septal occluder (CSO) is an improved ASO with certain design features (Nanoplatinum coating, softness) that may potentially reduce the risk of device related erosions and nickel allergic reactions. We design a randomized controlled study to prospectively compare the efficacy and safety of these two devices.

Methods: 636 patients (median age 14.5 years) from 4 major centers in Greece and Romania were randomly assigned in a 1:1 ratio to catheter ASD closure using the ASO (group 1) and CSO (group 2), respectively. The procedure was guided by fluoroscopy and 2D and 3D transesophageal echocardiography.

Results: Mean echocardiographic ASD diameter was 21 ± 7 mm (range 14-35 mm), and 22 ± 6 mm (range 12-34 mm) in group 1 and group 2, respectively. Mean device diameter was 24 ± 9 mm (range 17-40 mm) and 22 ± 8 mm (range 14 – 38 mm) in group 1 and group 2, respectively. The device was permanently implanted in 310 (98%) and 309(97%) patients of the group 1 and group 2, respectively. Follow-up (FU) ranged from 6- 48 months. Complete ASD occlusion at 1 month FU was 99% in both groups of patients. One device erosion (required surgical removal of the device) and 3 severe skin allergic reaction (AR) that required chronic treatment with cortisone were observed in one and 3 patients, respectively, of group 1. No device erosions or ARs were observed in group 2. Device embolization due to insufficient septal rims was observed in 3 and 4 patients of group 1 and group 2, respectively. No other major complication occurred in both groups of patients. **Conclusions:** The ASO is a safe and effective in the great majority of cases. The CSO is a safe and effective device that adds to our armamentarium for as much safer catheter ASD closure. Further studies with a larger patient population are needed to confirm our results.