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Relative Incidence of Thrombus Formation on the CardioSEAL and the Amplatzer Interatrial Closure Devices

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Background: Transcatheter closure for atrial septal defect (ASD) and patent foramen ovale (PFO) is a promising alternative to surgical closure or anticoagulant therapy. A potential complication is thrombus formation on the device after implantation. This study compared the incidence of thrombus formation at one month post implant between the two FDA approved devices. Methods: From February 2001 through April 2003, 56 patients (42 PFO, 10 ASD and 4 fenestrated septum) were treated successfully with transcatheter closure devices. The Amplatzer device was used in 26 patients (13 septal and 13 PFO occluders) and the CardioSEAL device was used in 30patients. Antiplatelet medication (aspirin and clopidogrel) was prescribed for 6 months after the procedure. Forty-three patients had transesophageal echocardiography (TEE) one month after device implantation (27+/-9 days). Results: No patient suffered a thromboembolic episode during the two-year follow-up period. TEE revealed that thrombus formation occurred more frequently on the CardioSEAL device (5/23, 22%) than on the Amplatzer device (0/20, 0%) ($p<0.05$). Thrombus formed on the left atrial side in 4 patients and demonstrated a mobile pattern in 3 patients. Although thrombus disappeared or markedly diminished following additional warfarin therapy in 3 patients, one patient had surgical explantation of the device due to progressive increase in the size of thrombus with hypermobility despite additional therapy with warfarin and argatroban. Conclusion: The CardioSEAL device is more likely to have thrombus formation one month after insertion than the Amplatzer device. Most patients with thrombus on the device had a benign clinical course due to thrombus resolution following anticoagulation therapy. However, the high incidence of thrombus post implantation could explain the presence of recurrent embolic events observed in prior clinical trials.