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Relative Incidence of Thrombus Formation on the CardioSEAL and 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 August 2003, 68 patients (50 PFO, 13 ASD and 5 fenestrated septum) were treated successfully with the Amplatzer device (19 septal and 18 PFO occluders) or the CardioSEAL device (30). Antiplatelet medication (aspirin and clopidogrel) was prescribed for 6 months after the procedure. Fifty-two patients had transesophageal echocardiography (TEE) one month after device implantation (26±9 days).

Results: No patient suffered a thromboembolic episode during the 30 month follow-up period. TEE revealed that thrombus formation occurred more frequently on the CardioSEAL device (5/23, 22%) than on the Amplatzer device (0/27, 0%) (p=0.02). The presence of thrombus on the device in the follow-up period was defined as a new hypoechogenic nonplanar, partially mobile structure. Although thrombus disappeared or 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.