Title

Relative incidence of thrombus formation on the CardioSEAL and the amplatzer interatrial closure devices

Journal

AMERICAN JOURNAL OF CARDIOLOGY, 92(6A)

ISSN

0002-9149

Authors

Anzai, H
Child, J
Natterson, B
et al.

Publication Date

2003

TCT-387

Relative Incidence of Thrombus Formation on the CardioSEAL and the Amplatzer Interatrial Closure Devices. *H. Anzai, J. Child, B. Natterson, J. Krivokapich, J.M. Tobis. University of California, Los Angeles Center for Health Sciences, Los Angeles, California, USA.*

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 between the 2 US Food and Drug Administration-approved devices at 1 month after implant.

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 (AGA Medical Corporation, Golden Valley, MN) was used in 26 patients (13 septal and 13 PFO occluders) and the CardioSEAL device (Nitinol Medical Technologies, Inc., Boston, MA) was used in 30 patients. Antiplatelet medication (aspirin and clopidogrel) was prescribed for 6 months after the procedure. A month after device implantation (27 ± 9 days), 43 patients had transesophageal echocardiography.

Results: No patient had a thromboembolic episode during the 2-year follow-up period. Transesophageal echocardiography revealed that thrombus formation occurred more frequently on the CardioSEAL device (5 of 23, 22%) than on the Amplatzer device (0 of 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 after additional warfarin therapy in 3 patients, 1 patient had surgical explantation of the device because of 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 1 month after insertion than the Amplatzer device. Most patients with thrombus on the device had a benign clinical course because of thrombus resolution after anticoagulation therapy. However, the high incidence of thrombus after implantation could explain the presence of recurrent embolic events observed in prior clinical trials.