LETTERS TO THE EDITOR

Risk of Thrombus Formation on Devices Used to Close Transcatheter Atrial Septal Defect and Patent Foramen Ovale

In a recent issue of the *Journal*, Krumsdorf et al. (1) discussed the incidence of thrombus formation on atrial septal defect (ASD) and patent foramen ovale (PFO) closure devices in 1,000 consecutive patients. The investigators report a group of 593 patients with PFO but only 235 patients had an embolic event. Closure of a PFO is usually indicated if there is a spontaneous or provokable right-to-left shunt during contrast transesophageal echocardiography (TEE) in a patient with clinic and/or radiologic evidence of an ischemic stroke, a transient ischemic attack, or an extracranial peripheral thromboembolic episode.

Most of the thrombi (14 out of 20) were detected at the four-week TEE study, but it is not clear whether the investigators excluded the presence of them immediately after the procedure. Krumsdorf et al. (1) described different protocols of anticoagulation during the procedure.

Regarding our experience (751 ASDs; 170 PFOs) we believe that the two most sensitive points are: 1) monitoring of the anticoagulation of the patient during the procedure using the activated clotting time, and 2) duration of antiplatelet therapy after transcatheter ASD closure.

This last point is not yet clarified; endothelialization of an ASD device is supposed to occur within a few months after implantation; this information is supported by animal studies (2). It is accepted that six months of antiaggregation (with one or two drugs) is a long enough period to prevent thrombus formation on the device (3,4).

The researchers found three thrombi at the six-month TEE; this might indicate that the endothelialization could not be completed at that time. Therefore, a longer period of antiplatelet therapy may be useful.

Chessa Massimo, MD, PhD
Butera Gianfranco, MD, PhD
Carminati Mario, MD
Pediatric Cardiology Department and GUCH Unit
IPSD
Via Morandi, 30
20097 San Donato Milanese
Milan
Italy
E-mail: massimo.chessa@lycos.com


REFERENCES


Thrombus Formation on Intracardiac Devices: A Complex Issue

Recently, Krumsdorf et al. (1) reported on the incidence and risk factors of thrombus formation on atrial septal defect (ASD) and patent foramen ovale (PFO) closure devices. Data provided in their study indicate that among other risk factors the device design and/or materials affect the risk of thrombus formation, being higher in CardioSEAL/STARFlex (NMT Medical, Boston, Massachusetts) and PFO-Star (Applied Biometrics Inc., Burnsville, Minnesota) compared to Amplatzer (AGA Medical Corp., Golden Valley, Minnesota) implants. However, other studies including comparable numbers of CardioSEAL/STARFlex devices (2) or even larger numbers of PFO-Star occluders (3) yielded much lower incidences of thrombus formation. Moreover, early thrombus formation on Amplatzer devices has also been documented and described in this Journal (2) and elsewhere (4,5). Therefore, we do not agree with the conclusion drawn by Moore and Levi (6) in their accompanying editorial that routine transesophageal echocardiography (TEE) surveillance in patients with Amplatzer septal occluders (in contrast to other devices) should not be recommended. In our opinion, all intracardiac devices should undergo a thorough and routine follow-up, including adequate imaging of the implanted devices (TEE).

With regard to the early thrombus formation, the editorial underemphasizes, the observation by Krumsdorf et al. (1) that 19 of 20 thrombi described were found in patients antagonized with protamine at the end of the implantation procedure. We would strongly advise against this unusual approach, and the investigators have in fact abandoned it with apparently better results in subsequent patients.

Using a multiple regression analysis, Krumsdorf et al. (1) found age not to be a risk factor for thrombus formation on atrial septal occluders. This may hold for their predominantly adult study population. In our combined experience of more than 200 ASD closures in children and adolescents using both the Amplatzer and CardioSEAL/STARFlex devices, we have not observed any thrombus formation. Furthermore, to the best of our knowledge, thrombus formation after ASD closure in children has not yet been described in the published reports.