We find the results of Krumbsdorf et al. (1) to be of interest in its detail of the natural course of unusual device-related, large-burden thrombus in the now uncommon setting of protamine use. We consider other associative relationships, as well as the editorial recommendations of Moore and Levi (2), to be unsubstantiated. Clinicians should not base management decisions in patients with PFO and stroke on such anecdotal and highly selected data. We await the results of ongoing and future randomized clinical trials to address these concerns.

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REFERENCES


Incidence and Clinical Course of Thrombus Formation on Atrial Septal Defect and Patent Foramen Ovale Closure Devices

Krumbsdorf et al. (1) present impressive data concerning the risk of thrombus formation on closure devices for atrial septal defects (ASDs) and patent foramen ovale (PFO) in 1,000 consecutive patients.

The vast majority of these patients were treated in the Bethanien-Hospital where we worked together with Dr. Sievert from July 1995 until he left our institution in June 2003. Until October 27, 2000, we shared the scientific database for all patients who had received an atrial septal implant. Therefore, we would like to add some information on two of our patients who were apparently included in the series of Krumbsdorf et al. (1).

One PFO patient with an Amplatzer (AGA Medical Corp., Golden Valley, Minnesota) occluder developed thrombus on the left atrial disk of the device, which was detected by transesophageal echocardiography (TEE) five weeks after implantation (implanted January 26, 2000; TEE date March 1, 2000). With heparinization and anticoagulation, the further course was uneventful.

Another PFO patient suffered two strokes 5.7 years after implantation of a Buttoned device (Custom Medical Devices, Amarillo, Texas). The TEE revealed a 10 × 7-mm thrombus on the left atrial disk of the occluder (implantation date March 4, 1996; TEE date November 16, 2001). The thrombus resolved after heparinization and anticoagulation, and the further clinical course was uneventful. The latter event was published as a case report (2).

We believe that these data might be clinically relevant, not only because thrombus formation may occur early after implantation of an Amplatzer device, but more importantly, even after more than five years following defect closure. Therefore, all investigators involved in the field of interventional ASD closure have the obligation to follow their (own) patients for an unlimited period of time.

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REPLY

We greatly appreciate the comments and suggestions by Drs. Landzberg and colleagues, Massimo and colleagues, Jux and Bertram, and Schräder regarding our recent paper (1).

First, we absolutely share the opinion of Landzberg and colleagues that randomized trials are superior to nonrandomized trials! Conversely, nonrandomized trials are better than no trials at all! And before a randomized trial can be initiated we have to have an idea about what we are looking for and what the incidence of a specific event like thrombus formation might be. Dr. Landzberg and his colleagues know very well how difficult it is to conduct a randomized trial in catheter closure of intracardiac defects. Although the first transcatheter atrial septal defect (ASD) closure was performed more than 25 years ago, until today no randomized trial has ever been started.