GUEST EDITORIAL

Hazards of percutaneous PFO closure

Please see page 465 for the article by Christen et al. (doi:10.1016/j.euje.2005.08.002) to which this editorial pertains.

In 2004, an estimated 2000–3000 patients underwent percutaneous closure of a patent foramen ovale (PFO). Given the range of potential indications (such as prevention of cryptogenic stroke, decompression illness in divers, platypnea–orthodeoxia syndrome, and migraine headaches) and the perception of PFO closure being an easy and safe procedure, the number of patients with percutaneously implanted PFO closure devices will continue to grow.

The first attempt to percutaneously close an interatrial defect was undertaken in 1974 and reported by King and colleagues in 1976. In the following years, several different devices were developed and re-modified to facilitate this technique. It began with the Clamshell occluder from Rashkind, later modified into the CardioSEAL and then the StarFLEX device. Other models soon followed including the Buttoned device, the ASDOS device, the Monodisk, the Angel-Wings device, the Amplatzer ASD occluder and the Helex device. Although these devices were initially intended for atrial septal defect closure, they could also be used for closure of PFO, an idea first evoked by Bridges in 1992. Soon thereafter, devices dedicated exclusively for percutaneous PFO closure entered the market, namely the Amplatzer PFO occluder and the PFOStar (now Cardiastar) device.

Part of the reasoning to favour percutaneous PFO closure over open heart surgery promises a safer and of course, less invasive and painful procedure than surgery. The latter argument can be intuitively accepted, but what about the safety of the procedure and implanted devices? In 2003, Landzberg and colleagues reviewed the complication rate of percutaneous PFO closure subsuming 10 studies with overall 1355 patients and different closure devices. Major periprocedural complications (i.e. death, hemorrhage requiring blood transfusion, cardiac tamponade, need for surgical intervention, and fatal pulmonary emboli) occurred in 1.5% of patients, and minor complications (bleeding not requiring transfusion, transient atrial arrhythmias, device embolization with successful catheter retrieval, device arm fracture, symptomatic air embolism including transient ST-segment elevation, arteriovenous fistula formation and femoral hematoma at the entry side) occurred in 7.9% of the cases. This review included studies with "first generation" closure devices, requiring complex multistep implantation. Some of these earlier devices were not repositionable or retrievable and hence harbouring additional complications. With contemporary devices, the periprocedural complication rates are close to 1%. Hence, the periprocedural safety of percutaneous PFO closure seems to be acceptable.

However, one of the unknown issues using intracardiac devices is their long term risk. There are reports about thrombus formation, late embolization and erosion of cardiac structures leading to aorto-atrial fistulas or pericardial tamponade – as illustrated in the present article of Christen et al. Thrombus formation after device implantation has been extensively investigated and its prevalence has been reported to be around 2%. Most thrombi were detected within the first month after device implantation. These "early" thrombi were usually observed on transesophageal echo studies, but not on transthoracic imaging. The majority of these clots was seen on devices with uncoated metal arms (like the CardioSEAL and StarFLEX devices or the PFOStar device), but very rarely on the Amplatzer occluder with nitinol.
wire frame filled with polyester fabric or the Helex device, made of a nitinol wire frame covered with a membrane of polytetrafluoroethylene. Most of these small thrombi did not cause symptoms at the time of diagnosis and were only detected due to routine echocardiographic studies. Nevertheless, clinically important thrombi do occur with patients presenting with recurrent embolic events up to 6 years after the procedure. In cases of recurrent stroke or peripheral embolization after PFO closure, transesophageal echocardiography is necessary to visualize the device and its proper positioning as well as rule out thrombi adherent to the left atrial disk. In our personal experience, thrombi are seen more frequently in patients on oral anticoagulation during the first few months after device closure than in those on dual antiplatelet therapy (aspirin and clopidogrel) giving rise to a potential role for platelet adhesion as the triggering signal for thrombus formation in such scenarios.

Late dislodgement (i.e. after 4 weeks) of the PFO closure device is very uncommon. A correctly placed PFO closure device will straddle the thick muscular septum secundum with its two disks and have a stable position. Endothelium will overgrow the device and glue it to the interatrial septum. For the 2004–2005 period, the US Food and Drug Administration (FDA) reports so far only one case of embolization of an Amplatzer PFO occluder on its online information database, compared with more than 30 cases of embolized Amplatzer ASD occluders (used for atrial septal defect device closure).

Equally, erosion of cardiac structures has mainly been reported for ASD closure devices, especially the Amplatzer ASD occluder. The Amplatzer occluder with its nitinol wire frame is a relatively rigid device. This facilitates positioning and keeps it stable once implanted. The downside of this stability, however, is a potential for eroding and finally penetrating cardiac structures if the rim of one of its disks is rubbing against the atrial or aortic wall. The “culprit lesion” is usually created by the anterior—superior border of the device leading to right or left atrial perforation or aortic wall erosion — in cases where the device is splayed over the aortic root. It is obvious that patients with a deficient superior atrial septal rim or deficient aortic rim are at higher risk for cardiac perforation. Two out of every three patients with cardiac perforation due to device erosion will present within the first 3 days. In patients undergoing PFO closure, these issues fortunately seldom arise. However, in patients with a large atrial septal aneurysm, there is a tendency to use larger devices to “stabilize” the atrial septum and to assure that the whole PFO tunnel is covered by the closure disk — hence the risk of cardiac perforation might increase. The present report by Christen et al. nicely illustrates that cardiac perforation is not restricted to Amplatzer PFO occluders and can occur in an unpredictable manner. Fortunately, this is a very rare complication with an incidence of less than 0.1%. However, as the PFO device closure procedures rise so will likely the complication rates.

What is the echocardiographer’s role in the care of patients after percutaneous PFO closure? Because complications are rare, it is difficult to establish an evidence-based follow-up protocol. Taking into account that our interventional cardiologists mainly use the Amplatzer PFO occluder, transthoracic echocardiography is performed the day after the procedure or just prior to discharge to document proper device position and rule out early perforation. Transesophageal echocardiography is repeated 4–6 months after device implantation to exclude residual shunting (by colour Doppler and intravenous bubble contrast) and device adherent thrombi. Finally it is important to remember that complication can occur at any time and with any device. A high index of suspicion is necessary for early detection of both early and late complications of PFO device closures.

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