EXPLANTATION OF PFO CLOSURE DEVICES: A MULTICENTER SURVEY

Objective To examine the frequency and causes of surgical explantation of PFO closure devices.

Background Patent Foramen Ovale (PFO) has been linked with cryptogenic strokes, recurrent transient neurologic deficits, sleep apnea, decompression illness, and migraines. Approximately 20% of adults are suspected to have a PFO, and 8,000 PFO closure procedures are performed each year utilizing various devices. Several randomized trials are in progress to determine if PFO closure is preferable to medical management in the treatment of patients with cryptogenic strokes or migraine. The majority of PFO closures are performed off-label as there is no FDA approval for use of any device to close a PFO. As data accumulates on the benefits of PFO devices, it is also important to examine complications that may occur. There have been isolated reports of patients that needed to have their device removed. Because extraction of a PFO device requires open heart surgery, it would be useful to determine the relative frequency of this unfortunate event.

Methods & Results We performed a database review to identify the frequency and causes of PFO device explantation, examining 18 high-volume PFO closure centers from Europe and the United States. Of the 13,736 percutaneous PFO device implantations performed over the past 9 years at these 18 institutions, 37 (0.27% (95% CI, .21% - .39%)) devices required surgical removal. There were a wide range of causes cited for these removals. The most common cause for explantation was chest pain (n=13), often times determined to be secondary to nickel allergy to the PFO device. Other causes for removal included persistence of a residual shunt (12), the presence of thrombus on the device (4), pericardial effusion (2), perforation of the atrium or aortic root (2), recurrent strokes (1), the development of endocarditis (1), and other reasons (2).

Conclusion The vast majority of PFO closure procedures are performed safely with minimal complications. However, there is a small (0.27%) incidence of severe complications associated with PFO closure that may require surgical removal. In addition, the frequency of surgical explantation is device dependent; some of these devices seem to be safer than others.