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COMMENTARY

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The skinny on post-patent foramen ovale closure atrial fibrillation

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KEYWORDS
CERE—cerebrovascular disease, PFO—patent foramen ovale/atrial septal defect, STR— stroke, CHDA—congenital heart disease in adults

In the realm of percutaneous closure of patent foramen ovale (PFO) for a paradoxical embolic stroke, what is the clinical significance of developing atrial fibrillation (AF) post-device closure? The randomized clinical trials, which evaluated PFO closure to prevent recurrent stroke following a PFO-associated stroke, reported that the incidence of AF post-closure varied between 2% and 6%. These trials did not have routine electrocardiogram monitoring for extended periods of time either before or after PFO closure. The initial recognition of AF was subjective, dependent on the patient having symptoms, and alerting the physician.

In this issue of *Catheterization and Cardiovascular Interventions*, Robert Sommer's group at Columbia University describe their experience with a small percentage (5%) of their patients who received an implantable loop recorder.[1] The loop recorder was implanted before PFO closure to provide an extended monitoring period to exclude those who had preexisting paroxysmal atrial fibrillation. Of 761 patients that they treated over a 4-year period, 35 had a loop recorder that was inserted and remained in place for at least 1 month following PFO closure. Thirteen of these 35 people (37%) had evidence of post-closure AF, with 12 of 13 AF cases occurring within 4 weeks, and resolving within 12 weeks after device closure. These episodes were intermittent and transient, resolving either spontaneously or with electrical cardioversion (one case). None of the patients developed a recurrent stroke. The individuals who received a loop recorder were selected in part because of the perceived higher risk to develop AF in this patient subset. Patients who developed AF were older at the time of device closure than those loop recorder patients who did not develop AF (62 ± 11 vs. 52 ± 14 years, $p = 0.03$). The observation that 37% of patients with a loop recorder had some form of transient AF is concerning.

Our group reported that the frequency of AF depended on the device that was used.[2] In 320 patients, the Amplatzer device had a 0% prevalence and the Gore Cardioform device had a 13% prevalence of post-closure AF. The frequency of AF from the RESPECT Trial with the Amplatzer PFO Occluder was 4%. Our study did not use a loop recorder, so the true incidence was presumably underestimated. The current study used the Cardioform device predominantly, so a more accurate estimation of the frequency of AF for the Cardioform device may be somewhere between these reports of 13%–37%.

In one meta-analysis of all randomized trials of PFO closure for stroke and migraine, Elgendy et al.[3] reported that the incidence of stroke related to new-onset AF in the PFO closure group was 0.1% (5 out of 1841 patients). The current study by Sommers et al. reported no recurrent stroke in their patients who developed new-onset AF; thus, the risk of recurrent stroke due to post-closure AF appears to be quite low. Many operators elect to treat post-closure AF with short-term oral anticoagulation and antiarrhythmic therapy; in the clinical trials, most post-closure AF cases were not treated with long-term anticoagulation.[4] If we were to use a loop recorder in all cases, perhaps we would identify another 10% of patients who had asymptomatic AF. These hypothetical additional cases are not currently recognized in clinical practice; nevertheless, they did not cause a stroke, suggesting that post-closure AF is temporary and has a relatively good prognosis. Presumably, post-closure AF is due to inflammation induced by the newly implanted foreign material and the pressure exerted upon the atrial tissue by the closure device. The AF is transient, with a peak incidence of onset at 10–14 days, and diminishes over the next 6–8 weeks. We conclude from these observations that post-PFO closure AF is a nuisance to the patients who develop it and to their physicians who need to monitor it

and often treat it. But the risk of stroke due to transient AF is extremely low, as well as the risk of progression to persistent AF. Of all post-PFO closure AF cases, only 3.8% reportedly progress to permanent AF.[5] Thus, the concern for developing transient AF following PFO device closure is not an adequate reason not to have the PFO closed.

In a recent pooled analysis of the six major randomized clinical trials of PFO closure for stroke, the authors aimed to identify those patients who were most likely to benefit from PFO closure. They used the Risk of Paradoxical Embolism (RoPE) Score (a 10-point scoring system utilizing higher scores to reflect younger age and absence of vascular risk factors) and the PFO-Associated Stroke Causal Likelihood (PASCAL) Classification System; the latter combines the RoPE Score with echocardiographic features considered high-risk for PFO (large shunt or an atrial septal aneurysm) to classify individuals into three groups of causal relatedness: unlikely, possible, and probable.[4] This analysis identified 15% of patients from the studies who were "unlikely" to benefit from PFO closure in terms of preventing recurrent stroke. The "unlikely" to benefit group also had a higher incidence of post-closure AF, which occurred more than 45 days after closure. The AF in this subset is different from the benign transient AF that is described in the article by Sommer et al.; patients in this group were older with more risk factors for atherosclerosis (lower RoPE scores) and were thus more predisposed to developing AF. A PFO-occluding device may act as a trigger to increase the likelihood of developing AF in these already susceptible people. The point of the PASCAL system is to identify patients who are less likely to benefit and more likely to develop AF following PFO closure, with the recommendation to not close the PFO in this subset.

Sommer's group recommend that future studies of PFO closure should utilize an implantable loop recorder to determine the true prevalence of post-closure AF. But if the risk of recurrent stroke is so low, is a randomized clinical trial with a loop recorder implantation necessary?

CONFLICT OF INTEREST

Dr. Tobis has served as a consultant for St. Jude Medical (now Abbott) and W. L. Gore; has served as a proctor for Cardiac Dimensions; was a coinvestigator of the RESPECT trial; and was on the steering committee for the PREMIUM trial. The remaining author declares no conflict of interest.

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