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Permanent carotid filter placement and atrial fibrillation: An alternative to anticoagulation or left atrial appendage exclusion?

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Preventing stroke is an important goal in the clinical management of patients with atrial fibrillation (AF). While oral anticoagulation (OAC) reduces the risk of ischemic stroke and systemic embolism, patients with AF may still have ischemic strokes despite taking OACs [1]. Additionally, there is a growing population of AF patients who are unable to take anticoagulants. In this issue of *Cardiovascular Revascularization Medicine*, Yodfat et al. [2] report the feasibility, safety, and efficacy of a novel common carotid artery (CCA) coil filter (Vine™; Javelin Medical Ltd., Israel) implant in pre-clinical testing.

The Vine™ is a permanent filter implanted in both CCAs for embolic stroke prevention in high-risk AF patients. This filter is made of superelastic nitinol wire with a circular cross-section that unfolds into a helix with supporting coils, a cone-shaped filter, and a linear stem across the carotid artery wall and internal and external anchors. It is designed to capture emboli traveling up the CCA, and prevent them from reaching the brain and causing a stroke. The Vine™ is inserted into the CCA lumen *via* a 24-guage needle under ultrasound guidance [2].

In this study, Yodfat et al. demonstrated the filter's efficacy *in vitro* in a pulsatile flow simulator using 1.2 mm nylon balls and thromboemboli, and *in vivo* in a sheep model demonstrating that the filter is safe, captures thromboemboli, and importantly the thromboemboli do not fragment upon capture [2]. The first in-human study with use of the Vine™ filter was also recently published – The CAPTURE Trial [3]. In this 3-center, nonrandomized clinical trial 25 AF patients were enrolled and 23 underwent successful bilateral CCA filter placement. At 6-months there were no device/procedure-related major adverse events, and asymptomatic thrombi were detected in 4 patients.

OAC remains the current mainstay of treatment for stroke prophylaxis in AF. Even though there is significant reduction of risk of stroke in patients with AF from anticoagulation with warfarin or non–vitamin K antagonist oral anticoagulants (NOACs), there is still an appreciable stroke risk during anticoagulant treatment, which approximates 1.7% per year for warfarin and 1.4% per year for NOACs [4]. These patients with AF who have an ischemic stroke or TIA despite anticoagulation therapy are at subsequent higher risk for further cerebral ischemic events [5]. Additionally, any temporary interruption of OAC for bleeding, urgent/elective surgery, or invasive procedure results in an increased risk of thromboembolism [6]. This underscores the importance of having alternative or adjunct treatment options for stroke prophylaxis in AF.

One such option is percutaneous left atrial appendage (LAA) occlusion. Among patients with AF, it is estimated that 90% of thrombi are located in the LAA [7], providing the rationale for LAA occlusion for patients too high risk for OAC. The WATCHMAN (Boston Scientific, Plymouth, MN) is the only LAA occlusion device approved by the United States Food and Drug Administration (FDA), and is a self-expandable nitinol cage, covered by a layer of permeable polyethylene terephthalate membrane, deployed in the LAA using a transseptal approach [8]. While LAA occlusion devices are effective in preventing stroke in patients intolerant to OAC, they do not prevent nonappendage origin emboli, and emboli originating outside of the heart, both of which would presumably be stopped by the Vine™ filter. Additionally, filter implantation is faster, much less invasive, performed by 1 operator, without general anesthesia, does not require transesophageal echocardiography, and does not have the rare catastrophic complications such as LAA perforation, tamponade, and death that can occur with LAA occlusion.

The concept of implanting a preventive device in a healthy vessel is not new. The Vine™ is similar in concept to inferior vena cava filters, which are often implanted in those at high risk for deep vein thrombosis or have a contraindication to anticoagulation in order to prevent downstream thromboemboli to the lungs. In the past the Diverter™ (MindGuard Ltd., Israel) was developed to filter embolic material flowing through the CCA preferentially into the external carotid artery. It consisted of a stent-like, self-expanding, tubular mesh placed in the CCA extending into the external carotid artery. Unfortunately, in the 3 patients implanted with the Diverter™, 2 had total occlusion and subtotal occlusion of the internal carotid artery at 7 and 14 months [9].

The Vine™ CCA filter is a promising technology. The filter can potentially be used in patients intolerant to OAC, as both data from sheep and the first in human experience showed safety with antiplatelet therapy alone [2,3], although long-term data are required. One of their patients had 2 posterior circulation strokes during the follow-up period [3], which highlights a limitation of the technology in that it provides no protection against posterior circulation embolic strokes as it does not protect the vertebral arteries. However, it should be noted that strokes involving the posterior circulation comprise only about 10% of strokes

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and are associated with significantly less morbidity and mortality [10,11]. Also unknown is if there is a thrombus burden on the filter that would impede blood flow into the carotids. Lastly, the CCA filter does not protect against small emboli slipping through the filtering portion. While these would likely result in subclinical strokes, there is correlation between new lesion volume and neurocognitive decline [12]. Taken together, OAC should likely still be recommended in patients with the CCA filter that can tolerate it.

Since the filter is completely retrievable within 4 h of insertion, it opens the possibility of its utility in cardiac interventions and surgeries that have increased risk of cardioembolic stroke, so long as filter retrieval is safe in the presence of captured thrombi. For example there is risk of stroke during open heart surgery from cerebral embolization of atheromatous debris from the aorta during surgical manipulation. The use of epiaortic filters and anaortic techniques have been used to minimize these risks; use of the CCA filter may be another viable option. Similarly, interventional cardiology procedures such as percutaneous aortic or mitral valve procedures, and percutaneous vein graft intervention can have an increased risk for stroke, and the CCA filter may help mitigate that risk. Currently transcatheter aortic valve implantation (TAVI) is the only interventional cardiology procedure with an FDA approved cerebral embolic protection device. The Claret (Claret Medical, Inc.; Santa Rosa, California, United States) is designed to capture debris dislodged during TAVI, and consists of a dual filter system deployed *via* the right radial or brachial approach to the brachiocephalic and left common carotid arteries [12]. Even in TAVI the CCA filter may be preferred because of its ease of placement, or in patients whose anatomy does not allow placement of the Claret device.

Many therapies for atrial fibrillation are aimed specifically at the heart, and we commend the authors for "looking outside the heart" in their development of the Vine™ CCA filter to prevent the most catastrophic consequences of AF. We look forward to the results of the CAPTURE 2 observational safety trial, and the planned randomized controlled trial comparing anticoagulation with anticoagulation plus bilateral CCA filters in AF stroke prevention.

Below is a headshot of the first author, Dr. Nachiket Patel.

Declaration of competing interest

No conflict of interest exists for the authors.

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