LETTER FROM THE EDITOR IN CHIEF

Dear Reader,

In my March Letter from the Editor in Chief, I wrote about the increased interest in the field of stroke prevention for patients with atrial fibrillation (AF). An important development occurred since that letter, which is the FDA approval of the Watchman left atrial appendage closure device.

The approval of the Watchman device represents a major breakthrough in the treatment of AF. The device is the first and only approved non-pharmacological alternative to Warfarin for stroke prevention in patients with non-valvular AF. The approval was based on data from well-designed multicenter randomized clinical trials. The most important of these studies is PROTECT AF, which demonstrated the superiority of this device compared to Warfarin for preventing the combined outcome of stroke, systemic embolism, and cardiovascular death. In addition the study showed superiority of the Watchman for reducing cardiovascular and all-cause mortality. Moreover data from subsequent studies using the Watchman device, such as the PROTECT AF CAP, PREVAIL, and PREVAIL CAP, demonstrated that the implantation procedure can be performed with a relatively low risk of complications. Patients with AF and an appropriate rationale for not taking Warfarin have now an approved non-pharmacologic alternative.

Drug treatment with Warfarin is associated with significant management issues, such as an unpredictable dose response necessitating dose adjustments, frequent laboratory monitoring and multiple interactions with other drugs. Over the past few years the management of patients with non-valvular AF who are suitable to take Warfarin has been greatly facilitated by the availability of alternative therapies. The Watchman device is the latest addition to other options which include four novel anticoagulants: Dabigatran, Rivaroxaban, Apixaban, and Edoxaban; all of which have been studied in landmark clinical studies. However none of these treatments provides an approved therapy for patients with bleeding and contraindication to Warfarin. Stroke prevention in patients with AF and inability to take Warfarin continues to be very challenging. Bleeding remains a major reason for withdrawal of anticoagulation with the novel anticoagulants. The implantation of the Watchman device requires short term anticoagulation after the procedure which may not be possible in many patients. As a result there is a significant need to find a solution for this group of patients and I believe that the initiation of clinical studies aiming to test the safety and efficacy of left atrial occlusion devices in patients with contraindications to anticoagulation is of utmost importance. Designing such studies will be challenging because of the lack of an approved treatment that can be used in randomized studies.

In summary the approval of the Watchman device represents a major step forward in our ability to reduce the risk of stroke associated with AF. Additional clinical studies are needed to expand the treatment indications and allow this procedure to a wider population.

Warm regards,

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