Letter by Karam and Marijon Regarding Article, “Atrial Fibrillation: Outpatient Presentation and Management”

To the Editor:

We read with great interest the article by Ezekowitz et al on outpatient presentation and management in the setting of atrial fibrillation. Management of atrial fibrillation on an outpatient basis should be encouraged. In the case of persistent AF presented by the authors, dronedarone was the antiarhythmic drug chosen for rhythm control, and started before cardioversion. Dronedarone is a new agent in the pharmacological arsenal for maintaining sinus rhythm. However, caution should be taken when prescribing dronedarone, particularly at this time, when the Permanent Atrial FibriLLAtion Outcome Study Using Dronedarone on Top of Standard Therapy (PALLAS) trial, which was testing the antiarrhythmic drug dronedarone in patients with permanent atrial fibrillation and at least another cardiovascular risk factor, was terminated because of a doubling in mortality in patients taking dronedarone.

Thanks to the large clinical development program including >10,000 patients, heart failure, gastrointestinal effects, non-significant rise in plasma creatinine, interaction with warfarin (increase in its anticoagulant effect), and moderate QT interval prolongation were initially identified as possible side effects of dronedarone. Besides, in January 2011, both American and European drug safety regulators advised health care professionals to consider the potential liver injury of dronedarone, and recommended close monitoring of liver function in these patients, especially in the first 6 months of treatment.

Following the presentation of PALLAS Study, the US Food and Drug Administration and the European Medicines Agency now have reviewed recommendations of the use of dronedarone. Particularly, the European Medicines Agency indicated that dronedarone should only be started by a specialist after other antiarrhythmic drugs have been considered, and it should not be used in patients with permanent atrial fibrillation, heart failure or left ventricular systolic dysfunction (impairment of the left side of the heart), and that such treatment should be restricted to patients with paroxysmal or persistent atrial fibrillation when sinus rhythm has been obtained. Finally, due to the low efficacy and potential morbidity, the Department of French Health and Social Security decided to stop the reimbursement of dronedarone, starting January 2012.

Disclosures

None.

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References

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