ARRHYTHMIAS

Changes to recommendations for stroke prevention in AF

Early autumn in the northern hemisphere was marked by major changes to official recommendations for management of patients with atrial fibrillation (AF). The European Society of Cardiology has produced new guidelines on AF management, which will have a substantial impact on clinical practice in Europe. Additionally, on the other side of the Atlantic Ocean, an FDA advisory panel has responded to findings of the RE-LY trial by unanimously recommending approval of dabigatran for stroke prevention in patients with this arrhythmia.

Amongst many noteworthy updates to the European guidelines on AF management is the recommendation to use a modified CHADS₂ score to determine which patients with AF need anticoagulation. “Newer stratification methods like CHA₂DS₂-VASc seem to offer more comprehensive stroke risk stratification,” explains Gregory Lip, an author of the new guidelines. “[CHA₂DS₂-VASc helps] to identify the ‘truly low

risk’ category of patients who do not need antithrombotic therapy ... and reduces the number of people classified into the ‘intermediate risk’ group.”

Meanwhile, in the USA, an FDA advisory panel voted unanimously on 20 September to recommend approval of dabigatran in the prevention of stroke in patients with AF. The decision was made on the basis of the RE-LY trial—which demonstrated that the oral direct thrombin inhibitor dabigatran is at least as good as warfarin at reducing stroke risk in patients with AF over 2 years—and came 3 weeks after a new prespecified analysis of the study was published online.

In the new analysis, the RE-LY study results were adjusted for each center’s average time in therapeutic range (INR 2.0–3.0) for its warfarin-treated patients. As RE-LY investigator Lars Wallentin explains, “in any prospective randomized trial comparing [another anticoagulant with] warfarin, the outcome will be dependent on the quality of INR control in the control group.” The investigators

found that the dabigatran-associated reduction in total stroke risk was apparent regardless of the quality of INR control in the warfarin-treated patients at the prescribing clinic.

The RE-LY trial and the associated recommendation by the FDA advisory panel is likely to impact greatly on clinicians’ prescribing practices, owing to the extensive monitoring required with warfarin use. However, as highlighted by many clinicians in their discussion of the FDA advisory panel’s decision on www.theheart.org, this impact will be tempered somewhat by the much higher cost of dabigatran.

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Original articles The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology. Guidelines for the management of atrial fibrillation. *Eur. Heart J.* 31, 2369–2429 (2010) | Wallentin, L. *et al.* Efficacy and safety of dabigatran compared with warfarin at different levels of international normalised ratio control for stroke prevention in atrial fibrillation: an analysis of the RE-LY trial. *Lancet* 376, 975–983 (2010)