New era for anticoagulant therapy highlighted in launch issue of Clinical Investigation

In a Guest Editorial published in the new publication Clinical Investigation, Dr Jeffrey Weitz and Dr John Eikelboom of McMaster University in Hamilton, Canada highlight the importance of the approval in October by the FDA of dabigatran etexilate (Pradaxa®, Boehringer Ingelheim). This new oral thrombin inhibitor provides an alternative to warfarin for long-term stroke prevention in patients with non-valvular atrial fibrillation.

Non-valvular atrial fibrillation is an increasingly common heart rhythm abnormality that is an important risk factor for stroke. Prophylactic anticoagulation with warfarin is commonly used to reduce the risk, but it is a notoriously difficult drug to administer. The appropriate warfarin dose varies from patient to patient reflecting, at least in part, the patient’s genetic profile, differences in the dietary intake of vitamin K and multiple drug interactions. Response to warfarin is so variable that frequent monitoring is necessary to ensure that the level of anticoagulation is therapeutic. Such monitoring is burdensome for patients and physicians alike, and costly for the healthcare system. Even when monitoring is performed, the level of anticoagulation is above or below the therapeutic range in at least half the patients, with consequent risk of bleeding or thrombosis. As a result, warfarin tends to be underused for stroke prevention in patients with atrial fibrillation.

The advent of dabigatran etexilate provides a solution in the form of an oral anticoagulant that can be given in a fixed dose and results in such a predictable level of anticoagulation that monitoring is unnecessary.

The advantages of dabigatran over warfarin include a rapid onset of action, predictable anticoagulant effect and low potential for interactions with food or other drugs. Dabigatran does require twice daily administration, and methods to monitor its anticoagulation effect are not yet well developed. The drug is also not suitable for those with severe renal impairment, and because there is no antidote, there is an increased risk of bleeding in patients requiring urgent procedures. Nevertheless, as the authors summarize, “The approval of dabigatran etexilate as an alternative to warfarin for stroke prevention in atrial fibrillation ushers in a new era for long-term anticoagulation.”

The approval of dabigatran etexilate is far from the end of the story. Several other new oral anticoagulants are in advanced stages of development for this indication. These agents, including rivaroxaban, apixaban and edoxaban, are oral factor Xa inhibitors and share many of the advantages of dabigatran etexilate over warfarin, and may have advantages over dabigatran itself. The authors look forward to the findings of clinical trials of these new approaches over the next two years and an expansion of options for stroke prevention in atrial fibrillation. They state, “We truly are at the dawn of a new era in long-term anticoagulation management.”

The Guest Editorial entitled New oral anticoagulants for stroke prevention in atrial fibrillation can be downloaded from the inaugural issue of Clinical Investigation, which is now available online at www.future-science.com/toc/cli/1/1. This new peer-reviewed, monthly publication is dedicated to the systematic coverage of the methodology, progress and outcomes of clinical
Clinical Investigation is dedicated to systematic coverage of the methodology, progress and outcomes of clinical trials. As a peer-reviewed, monthly publication, Clinical Investigation provides a forum for the rapid publication of original research and critically reviews the latest developments in medical research, from Phase I trials through to post-marketing studies and pharmacoeconomic research.

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