



## CADTH Therapeutic Review Project in Brief

# New Oral Anticoagulants for the Prevention of Thromboembolic Events in Patients with Atrial Fibrillation

### Condition

Atrial fibrillation — also referred to as AFib or AF— is the most common abnormal heart rhythm, affecting 350,000 Canadians. It can lead to serious complications, such as stroke and other blood clots.

### Drugs

Anticoagulant drugs make the blood less likely to form clots. Warfarin has been the mainstay of anticoagulant therapy for more than 60 years. New oral anticoagulants include dabigatran (Pradax), rivaroxaban (Xarelto), and apixaban<sup>1</sup> (Eliquis).

### Issues

Warfarin is effective in preventing strokes and other blood clots in patients with AFib, but there are some challenges with warfarin therapy. Warfarin doses must be personalized, and regular blood tests are needed to ensure correct dosing.

New oral anticoagulants are given in fixed doses, so routine blood tests and personalized dosing are not needed.

### Methods

An expert committee made recommendations on new oral anticoagulants. The recommendations were based on a systematic review and network meta-analysis of the clinical evidence of these drugs, as well as an economic analysis of their cost-effectiveness.

<sup>1</sup> At the time of this report, apixaban was not approved by Health Canada for the prevention of stroke and systemic embolism in patients with non-valvular AF.

### Key Messages

Warfarin is the recommended first-line therapy for preventing stroke in patients with atrial fibrillation.

- Warfarin is proven to be a safe, effective, and cost-effective first choice for therapy.
- Many patients taking warfarin do well on the medication. For these patients, there is no evidence to support switching therapies.

New oral anticoagulants are a second-line option for some patients with non-valvular atrial fibrillation not doing well on warfarin.

- Although they are as effective at preventing stroke as warfarin, the newer drugs are more expensive and little is known about their long-term safety.

If a new oral anticoagulant is prescribed, patients must be monitored.

- Regular assessments of adherence to treatment, kidney function, drug interactions, and bleeding risk are necessary.
- If bleeding occurs, there is no antidote or proven management strategy.

### Research Results

Compared with warfarin, the benefits of new oral anticoagulants are small. The estimated number of patients who would avoid a stroke or other blood clot if treated with a new drug rather than warfarin was 2 to 6 people for every 1,000 patients treated per year.

Bleeding risks for patients treated with the newer drugs compared with warfarin were similar overall, with a modest decrease in intracranial bleeding and a small increase in gastrointestinal bleeding. A systematic review showed that there is no reversal agent or proven management strategy if bleeding occurs with the new drugs. The cost-effectiveness of the new drugs was uncertain.

*DISCLAIMER: The information in this Project in Brief is intended to help health care decision-makers, patients, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. The information in this Project in Brief should not be used as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process nor is it intended to replace professional medical advice. While CADTH has taken care in the preparation of the Project in Brief to ensure that its contents are accurate, complete, and up-to-date, CADTH does not make any guarantee to that effect. CADTH is not responsible for any errors or omissions or injury, loss, or damage arising from or as a result of the use (or misuse) of any information contained in or implied by the information in this Project in Brief.*

*CADTH takes sole responsibility for the final form and content of this Project in Brief. The statements, conclusions, and views expressed herein do not necessarily represent the view of Health Canada or any provincial or territorial government. Production of this Project in Brief is made possible through a financial contribution from Health Canada.*