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Rivaroxaban

Rivaroxaban is currently one of four nonvitamin K antagonist oral anticoagulants which may be prescribed for people with atrial fibrillation (AF). This sheet covers considerations for those who have been offered this drug.

AF and stroke risk

People who have AF are at higher risk of clots forming in the heart. If these clots travel through the bloodstream to the brain then this may cause a stroke.

AF-related strokes are often more serious than other strokes. This is because the large clots which form in the heart can cause more damage resulting in more disability.

To reduce the risk of stroke an anticoagulant is often prescribed. An anticoagulant lengthens the time a clot takes to form by just enough to address 80% reduction in risk of stroke.

Until recently warfarin was the most commonly prescribed anticoagulant and is a very effective medication, dramatically reducing the risk of stroke. Warfarin requires regular monitoring as its effectiveness can vary due to lifestyle, dietary intake, general health and other prescribed medications. Monitoring involves frequent blood tests to check international normalised ratio (INR) levels. The result determines the dose of warfarin.

In recent years further anticoagulants have been developed. These are the Direct Oral Anticoagulants (DOACs), and include apixaban, dabigatran and edoxaban. Unlike warfarin, they do not require blood tests as they are unaffected by dietary intake, lifestyle or general health. DOACs also interact less with other medications. The DOACs are as effective as warfarin in preventing an AF-related stroke.

How does it work?

In May 2012, the National Institute for Health and Care Excellence (NICE) published a recommendation for rivaroxaban as a possible treatment to reduce the risk of stroke in AF patients who are already assessed as being at increased risk of stroke and systemic embolism.

The clotting of the blood is a complex process as blood should clot rapidly when required but also remain fluid at other times. The process is often referred to as the 'clotting cascade' by clinicians. This term is used to explain how the stimulation to form a clot triggers a series of steps before producing the blood enzyme thrombin. The enzyme thrombin changes the soluble protein fibrinogen to the insoluble protein fibrin. Clots are made of fibrin.

Rivaroxaban is an anticoagulant drug that helps to prevent blood from clotting. It does this by interfering with a substance in the body (Factor Xa, 'ten A') that is involved in the development of blood clots. Unlike warfarin, it does not require regular INR monitoring.

Rivaroxaban is licensed in the UK for use in non (metallic) valvular AF patients to reduce the increased risk of stroke caused by AF. Rivaroxaban is approved for other indications including reducing the risk of clots in adults who have hip or knee replacement surgery, and treating thrombosis due to a clot formation in the body (e.g. the leg).

Dose

For stroke prevention in AF, rivaroxaban is administered at a fixed dose of 20mg once daily although the dose may need to be reduced if kidney function is impaired. If your kidney function is impaired, you have low body weight or you are taking other medication that affects the amount of rivaroxaban required to be effective, you may be



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offered a lower dose of 15mg once daily. Talk to your doctor who will advise on the best dose for you.

Rivaroxaban should be taken once a day with your main meal so that it will be completely absorbed.

Before starting treatment, your doctor should talk with you about the risks and benefits of rivaroxaban compared with other alternatives such as warfarin. If you are already taking warfarin, you and your doctor should take into account how well your INR is controlled when deciding whether to switch to rivaroxaban.

Remember to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription as some medicines can increase or reduce the effect of rivaroxaban.

You should also remember to inform dentists or surgeons before any treatments or procedures are undertaken as changes to medication may need to be made.

What is the evidence?

A large randomised, double-blind trial of over 14,000 patients across 45 countries, compared rivaroxaban with warfarin which aimed for an INR of two-three; a measure of how long it takes blood to clot. People recruited in the study had AF with a prior stroke or AF with at least two risk factors such as diabetes mellitus, heart failure and hypertension. Rivaroxaban was found to have similar efficacy to warfarin for stroke prevention.

What about the potential side effects?

Like all medicines, rivaroxaban can cause side effects, although not everybody gets them. As with other anti-clotting drugs, rivaroxaban can cause bleeding which may potentially be life threatening. However, the risk is relatively low. Bleeding was the

most common adverse event reported by patients treated with rivaroxaban in the major clinical trial for preventing AF induced strokes. In that trial, rivaroxaban's risk of major bleeding was similar to that of warfarin; however, it caused less bleeding into the brain and more bleeding into the stomach and intestines.

What should I do if I miss a dose?

If you remember on the same day, take the tablet immediately and then take your usual dose the next day.

If you remember the next day or later, take your usual dose for that day. NEVER double the prescribed dose in a single day. It is very important to take the tablets exactly as directed. Never take larger or more frequent doses.

What to do if you notice bleeding

Like all medicines, anticoagulants have side effects. The most serious side effect of anticoagulants is bleeding.

You should contact your GP urgently or attend the emergency department if you experience any of the following:

- Nose bleeds that last more than 10 minutes
- Blood in your vomit or sputum
- Passing blood when you go to the toilet – either in your urine or faeces
- Passing black coloured faeces
- Severe or spontaneous bruising
- Unusual headaches

For further information on anticoagulants, please see AF Association's Preventing AF-related stroke: anticoagulation booklet.

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