NHS FORTH VALLEY

Rivaroxaban for Stroke Prevention in Atrial Fibrillation

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Consultation and Change Record

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Consultation Process:	Thrombosis Interest Group, NHS Forth Valley Area Drug and Therapeutics Committee, NHS Forth Valley
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Change Record

Date	Author	Change	Version
11 Oct 12	Dr R Neilson	Change to dose modification in renal impairment to use eGFR as measure of renal function.	1.1
20 Mar 12	Dr R Neilson	1) Modification of doses in renal impairment 2) Minor textual changes	1.2

Indications

Rivaroxaban is licensed for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack.

Rivaroxaban is accepted for use by the SMC in patients who:

1) Have poor INR control despite evidence that they are complying with a coumarin anticoagulant . Poor control is defined as an INR in target range in <60% of INR tests.
2) In patients who are allergic to or unable to tolerate coumarin anticoagulants.

Rivaroxaban is a new drug where there is relatively limited experience in its use. Some recent medicine releases have revealed hitherto unrecognised side effects.

Dosing

The recommended dose of rivaroxaban in non-valvular AF is 20mg once daily.

Missed Dose
If a dose is missed the patient should take rivaroxaban immediately and continue on the following day with the once daily intake as recommended. The dose should not be doubled up within the same day to make up for a missed dose.

Renal Impairment
Mild renal impairment (eGFR 30 – 59ml/min) – No dose adjustment

Moderate renal impairment (eGFR 15-29ml/min) dose - 15 mg once daily

Severe renal impairment (eGFR of <15ml/min) - Rivaroxaban should not be prescribed.

Converting from Warfarin to Rivaroxaban

For patients requiring rivaroxaban therapy for the prevention of stroke and systemic embolisation, warfarin should be stopped and rivaroxaban therapy initiated when the INR is ≤ 3.0.

Converting from Clexane to Rivaroxaban

Rivaroxaban should be started 0-2 hours before the next scheduled administration of clexane.

INR MEASUREMENT IS NOT APPROPRIATE TO MEASURE THE ANTICOAGULANT ACTIVITY OF RIVAROXABAN AND THEREFORE SHOULD NOT BE USED FOR THIS PURPOSE.

Treatment with rivaroxaban does not require routine coagulation monitoring.

Populations at Potentially Higher Risk of Bleeding

Patients with renal impairment – See above

Patients with hepatic impairment – Rivaroxaban is contraindicated in patients with a coagulopathy related to hepatic disease and a relevant bleeding risk, including cirrhosis (Child Pugh B+C)

Patients on other medicinal products
Rivaroxaban should not be prescribed with azole-antimycotics such as ketoconazole, itraconazole, voriconazole and posaconazole.

Care should be taken with drugs that affect haemostasis such as NSAIDs, aspirin and other antithrombotic agents or platelet aggregation inhibitors.

Perioperative Management

If an invasive procedure or surgical intervention is required rivaroxaban should be stopped at least 24 hours prior to the intervention if possible. If the procedure cannot be delayed the increased risk of bleeding due to rivaroxaban should be assessed against the urgency of the intervention.

Rivaroxaban should be restarted as soon as possible after the invasive procedure or surgical intervention provided the clinical situation allows and adequate haemostasis has been achieved.

Overdose

Due to limited absorption a ceiling effect with no further increase in plasma exposure is expected at ingested doses of rivaroxaban of 50mg and above. Activated charcoal may be used to reduce absorption if clinically indicated. Due to high plasma protein binding rivaroxaban is not considered dialysable.

How to Manage Bleeding Complications

If a patient taking rivaroxaban develop bleeding problems treatment should be discontinued until the bleeding resolves. Potential interventions include:

- Symptomatic treatment ie mechanical compression, surgical intervention, fluid replacement
- Blood and/or blood component therapy
- In life threatening bleeding in a patient taking rivaroxaban that is not controlled by the above measures the use of the Prothrombin Complex Concentrate (PCC) Beriplex can be considered. There is currently very limited clinical experience with the use of these products in patients receiving rivaroxaban.

IN THE CASE OF MAJOR BLEEDING ON RIVAROXABAN THE PATIENT SHOULD BE DISCUSSED WITH THE DUTY CONSULTANT HAEMATOLOGIST.

FURTHER ADVICE CAN BE OBTAINED FROM DR RODERICK NEILSON, CONSULTANT HAEMATOLOGIST AT 01324 567084

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