NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Rivaroxaban, Treatment of DVT or PE

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Lead Author:	Catherine Bagot
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Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

RIVAROXABAN FOR THE TREATMENT AND PREVENTION OF RECURRENCE OF DEEP VEIN THROMBOSIS AND/OR PULMONARY EMBOLISM

INTRODUCTION:

Rivaroxaban is an oral anticoagulant that has been approved for the treatment and prevention of recurrence of deep vein thrombosis (DVT) and/or pulmonary embolism (PE). Apixaban remains the anticoagulant of choice in this patient group in NHSGGC. However occasionally rivaroxaban may be the preferred option due to previous intolerance to apixaban (thought unlikely to be related to drug class), or recognised benefit of once daily dosing.

INCLUSION CRITERIA:

- Age >18 years
- New diagnosis of acute DVT and/or PE
- Secondary prevention of DVT and/or PE
- Unsuitable for treatment with apixaban e.g. intolerance of apixaban, recognised benefit of once daily dosing

EXCLUSION CRITERIA:

- Creatinine clearance < 15ml/min
- Pregnant or breast feeding women
- Liver disease associated with cirrhosis and/or coagulopathy
- Patients with VTE and active cancer (when LMWH is the preferred anticoagulant)
- Concurrent use of the following medications:
  - Triazole and imidazole antifungals (except fluconazole)
  - Protease inhibitors
  - Strong CYP3A4 inducers e.g. rifampicin, phenytoin, carbamazepine
- Patients considered at increased risk of bleeding who would be unsuitable for any form of therapeutic anticoagulation

DOSING:

1. Prescribe LMWH (dalteparin) until DVT/PE diagnosis confirmed.
2. Once DVT/PE confirmed, stop LMWH and give 1st dose rivaroxaban 22-24 hours following the last dose of LMWH
3. Day 1-21: rivaroxaban 15mg twice daily.
4. Day 22: reduce dose to 20mg once daily (also see note 7).
5. For patients continuing with long term anticoagulation, the rivaroxaban dose can be reduced to 10mg once daily after receiving at least 3 months therapeutic anticoagulation following an acute DVT/PE.
6. Rivaroxaban tablets should be taken along with a meal.
7. Use rivaroxaban with caution when creatinine clearance is 15-29ml/min, and if patient perceived to have a high bleeding risk reduce once daily dose to 15mg from day 22 onwards. If patient requires long term anticoagulation reduce dose to 10mg from 3 months onwards.

PATIENT EDUCATION:

The risk of major bleeding associated with the use of rivaroxaban may be less than that associated with warfarin, but is not zero risk. Patients must therefore be fully counselled as follows:

Patients must:

- inform their dentist or surgeon that they are taking rivaroxaban
- seek medical attention if they experience symptoms of bleeding
- be advised that missed doses of rivaroxaban will increase the risk of further venous thrombosis and that strict compliance with the medication is essential

A DOAC Patient Information Booklet for NHS GCC patients is under development and should be used to assist in the counselling process when available.

DISCHARGE ARRANGEMENTS:

- The initial 21 days of treatment (at a dose of 15mg twice daily) should be supplied from hospital pharmacy
- The patient should be issued with a 'Rivaroxaban Patient Alert Card'. A 'DOAC Patient Information Booklet and Alert Card' for NHS GGC patients is under development and should be issued to patients when available.
- The GP immediate discharge letter should be accompanied by a completed 'Rivaroxaban Treatment Discharge Letter' detailing the date to start once daily dosing and subsequent stop date
- An anticoagulant clinic appointment is NOT required

DISCHARGE INFORMATION FOR GENERAL PRACTITIONERS OF PATIENTS COMMENCED ON RIVAROXABAN

Date: ...../...../.....

Patient details:

TREATMENT WITH RIVAROXABAN

The above patient has been commenced on rivaroxaban for the treatment of an acute Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism. Rivaroxaban is an oral anticoagulant and, like warfarin, is associated with an increased risk of bleeding, but unlike warfarin, does not require any monitoring of its anticoagulant effect (indeed routine coagulation screen tests are relatively insensitive and unsuitable for measuring rivaroxaban's anticoagulant effect) Therefore, this patient does not need to attend an anticoagulant clinic.

Treatment dose and duration:

- The patient has been supplied with the first three weeks of treatment (at a dose of 15mg twice daily) from the hospital pharmacy
- You are being asked to prescribe the remainder of the course at the dose indicated below for the stated treatment period

ACTIONS FOR GP:

1. **Prescribe rivaroxaban .....mg once daily to commence on ...../...../.....**
2. **The intended duration of rivaroxaban for this patient is: .....months/indefinite [delete as appropriate].**
3. **Therefore on: ...../...../..... discontinue the treatment or, reduce rivaroxaban dose to 10mg once daily long term [delete as appropriate].**

Cautions and contraindications:

- Rivaroxaban should not be used in patients with severe renal (creatinine clearance <15ml/min) or severe liver impairment. Caution is required if creatinine clearance is 15 – 29 ml/min.
- Its effect is altered by the concurrent use of triazole and imidazole antifungals (except fluconazole), protease inhibitors and strong CYP3A4 inducers e.g. rifampicin, phenytoin, carbamazepine.
- If the patient develops severe renal or liver impairment during the course of treatment with rivaroxaban, or must commence one of the above drugs, then the ongoing anticoagulation management of the patient should be discussed with a haematologist.
- If the patient develops any bleeding symptoms during the course of treatment with rivaroxaban, then the patient should be discussed with your local haematologist. The half-life of rivaroxaban is 5-13 hours (i.e. shorter than warfarin), however there is no readily available reversing agent.

Patient education and counselling points:

- Inform the patient that should they require a dental or surgical procedure, they must inform the dentist or surgeon that they are currently using rivaroxaban
- Inform the patient to seek medical attention if they experience symptoms of bleeding
- If the patient sustains a significant injury, particularly involving the head, then they must be advised to seek medical attention, either in primary care or with emergency services, depending on the severity of the injury.

Further information:

If you have any questions regarding this medication, please do not hesitate to contact the clinical team or hospital pharmacy that initiated this medication.

Many thanks for your ongoing supervision of this patient's anticoagulation.