The Walton Centre NHS
NHS Foundation Trust

Excellence in Neuroscience

DABIGATRAN REVERSAL WITH IDARUCIZUMAB GUIDELINE

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Guideline for the issue and management of dabigatran reversal agent idarucizumab (Praxbind)

Introduction

Dabigatran is one of a group of direct oral anticoagulants (DOAC) licensed for use in atrial fibrillation and venous thromboembolism. Dabigatran has a plasma half life of 12-15 hours and is primarily renally cleared so adequate diuresis must be maintained in order to promote adequate drug clearance.

There is a licensed product for the reversal of this agent in an emergency situation called idarucizimab or Praxbind®.

Idarucizumab is a specific reversal agent for dabigatran. It is a humanized monoclonal antibody fragment (Fab) that binds to dabigatran with very high affinity, approximately 300-fold more potent than the binding affinity of dabigatran for thrombin. Idarucizumab potently and specifically binds to dabigatran and its metabolites and neutralises their anticoagulant effect.

Idarucizumab is licensed for use in patients who have been treated with dabigatran and require rapid reversal of the anticoagulant effects in the following situations:

- For emergency surgery/urgent procedures
- In life-threatening or uncontrolled bleeding

A single dose of idarucizumab will be held in the transfusion laboratory. Its use will require authorisation by a Consultant Haematologist.

Requesting idarucizamab

Where possible, establish the time of the last dose of dabigatran and contact the on-call Haematologist at Liverpool University Hospital Foundation Trust to get authorisation for Idarucizamab (Praxbind®).

The following information will be required:

- Confirmation that the DOAC taken was definitely dabigatran. This reversal agent has no effect upon apixaban, rivaroxaban or edoxaban.
- Time of last dabigatran dose.
- Nature of haemorrhage/requirement for emergency surgery

Ensure bloods have been sent for:

- FBC, U&Es, LFTs
- Clotting including PT, APTT, INR, fibrinogen and thrombin time
- Group and save/cross match
- Ring the laboratory [redacted] and request dabigatran drug level (drug level is a supplementary investigation and will not affect urgent management)

Dabigatran has a greater and more consistent effect upon the APTT rather than the PT although it may affect both. It is possible for a patient on a therapeutic dose of dabigatran to have a normal APTT.

Dose

Idarucizumab is supplied as a 2.5g/50ml solution for injection/infusion. An adult dose is 5g.

There is no dose adjustment required for renal impairment, hepatic impairment or in elderly patients aged 65 years or above.

The effect of reversal should last at least 24 hours. If re-bleeding occurs, there is the potential to give a second dose following discussion with a consultant Haematologist

Administration

The 5g dose should be given IV as two consecutive 2.5g infusions, each over 5-10 minutes or as a bolus injection by injecting both 2.5g vials consecutively one after another via syringe, each over 3-5 minutes.

A pre-existing IV line may be used for administration; flush with sterile 0.9% NaCl solution prior to infusion

No other infusion should be administered in parallel via the same IV access.

Additional Management Strategies

- Ensure adequate fluid input to maintain good urine output (dabigatran is renally excreted)
- Consider oral activated charcoal if dabigatran ingestion is less than 2 hours ago
- Consider hemodialysis, especially if the patient is in renal failure
- Blood product replacement to maintain
    - Hb > 80g/L
    - Platelets >100x10^9/L
- Fibrinogen > 2g/L
- PT/APTT < 1.5 x normal range
- Maintenance of
    - Temperature >36^{o}C
    - Ionised Ca^{2+} >1mmol/L
    - Serum Potassium < 4.5mmol/L

Reintroduction of dabigatran therapy

Dabigatran can be re-initiated 24 hours after administration of idarucizumab, if the patient is clinically stable and adequate haemostasis has been achieved.

After administration of idarucizumab, other antithrombotic therapy (e.g. low-molecular weight heparin) can be started at any time, if the patient is clinically stable and adequate haemostasis has been achieved.