Clinical Guideline

NOAC DABIGATRAN (Pradaxa®) MANAGEMENT OF HAEMORRHAGE AND/OR EMERGENCY SURGERY

SETTING Trust-wide

FOR STAFF Medical staff

PATIENTS Adult patients requiring urgent surgical or invasive procedures who are taking Dabigatran

NOTE:

For Apixaban (Eliquis®), Edoxaban (Lixiana®), Rivaroxaban (Xarelto®) see separate guideline.
NOACs (Novel oral anticoagulants) direct Oral Anticoagulants (DOACS) – a quick guide apixaban (eliquis®), dabigatran (pradaxa®) & rivaroxaban (Xarelto®) see related guideline.

Background

Dabigatran is a direct oral anticoagulant (DOAC) also known as Non-vitamin K Oral Anticoagulant (NOAC), which works by inhibiting thrombin. It is currently used in prevention of thromboembolic stroke in patients with atrial fibrillation, for VTE prevention post elective hip or knee replacement and for treatment of VTE.

Patients on Dabigatran do not require routine monitoring but in therapeutic doses it will cause prolongation of standard clotting tests Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and Thrombin clotting Time (TT/TCT). If APTT and TT are normal it is highly unlikely that Dabigatran is contributing to bleeding.

Principles of Managing an emergency patient on Dabigatran

There is now a specific antidote to Dabigatran Idarucizumab* (Praxbind). This is licensed for management of critical bleeding and emergency surgery. This is stored in the emergency drugs fridge and the dose is 5g.

- Vitamin K and protamine will have NO EFFECT on bleeding.
- Fresh Frozen plasma is not recommended.
- Dabigatran will reach full therapeutic effect within two to three hours of the dose.
- The half-life of Dabigatran is dependent on renal function;

Renal Function (Creatinine Clearance)	Estimated half-life
>79ml/min	13 hours
50-79ml/min	15 hours
30-49ml/min	18 hours
<30ml/min	27 hours DRUG CONTRAINDICATED

- Repeated minor bleeding or a single major bleeding episode should prompt re-evaluation of the risks and benefits of the drug.
- If used within two hours of ingestion activated charcoal may be useful.

- **ASSESS PATIENT: Resuscitate.**
- Try and establish when last dose of drug was taken and document
- **Withhold Dabigatran**
- **Urgent bloods:** *(minimum required): FBC, renal function, clotting screen/fibrinogen, thrombin clotting time (TT/TCT), Urgent.*
- **Discuss with Haematology at an early stage if concerns** (On call bleep: [redacted], or via switch when out of hours)

Potentially clinically significant anticoagulant effect is **likely** to be present if last dose taken within 24 – 48hrs
Consider activated charcoal if ingestion <2 hours ago

Maintain BP and urine output

Is the patient actively bleeding?

Yes

No

Monitor.
See next page for surgery guidelines.

General measures: e.g. Mechanical compression/radiological intervention/endoscopy

Minor bleeding

Major Bleeding

Life threatening bleed

Bleeding remains mild or controlled?

No

Yes

Delay next dose or discontinue.

See next page for Surgery guidelines

Discuss with Haematology SpR for consideration of <u>Idarucizumab*</u>.
Bleep [redacted] or out of hours contact via UH Bristol switch
Consider Tranexamic acid 1g intravenously (avoid if renal tract bleeding)
Activate major haemorrhage protocol (as appropriate)
Supportive care aiming at maintaining
- Hb >7g/l
- Platelets >50x10^9/l (>100x10^9/l CNS bleeding)

Consider intervention to stop bleeding e.g. surgery/endoscopy
(All confirmed **<u>neurological bleeding</u>** should be discussed with Haematology & Neurosurgeons)

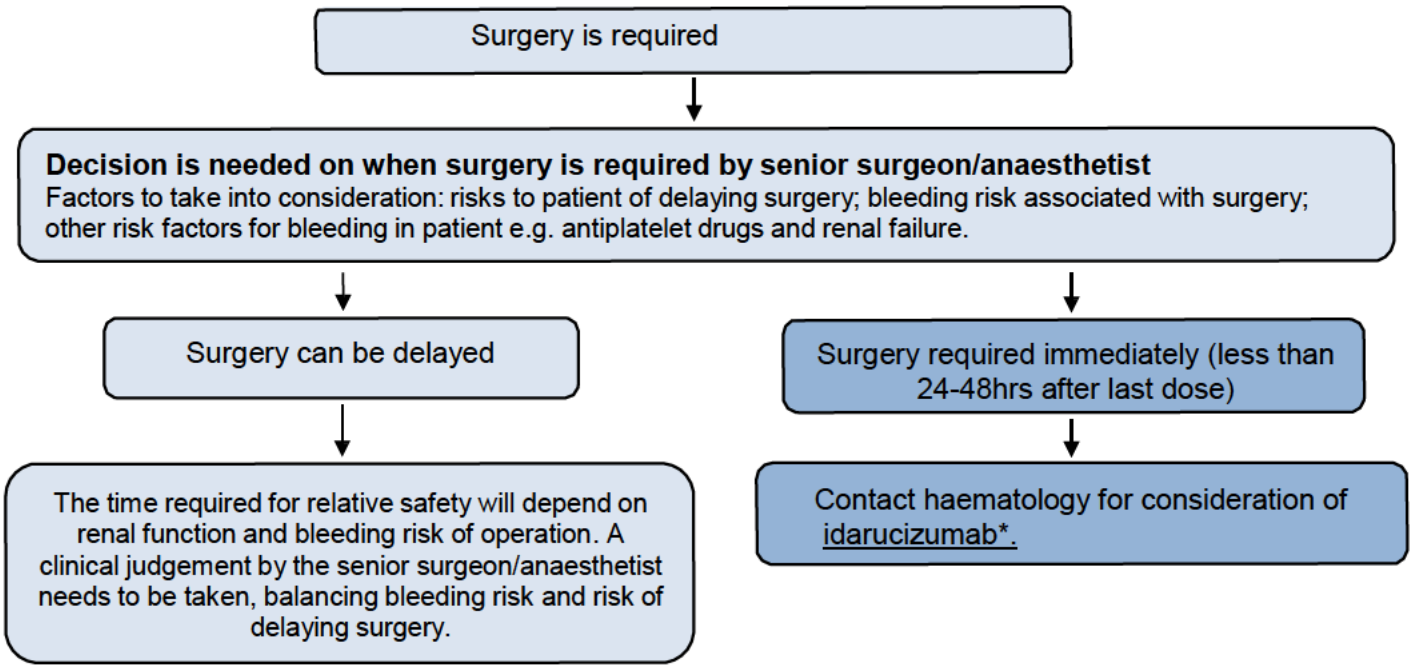
Clotting Screen
APTT and TT prolonged?

Yes

No

Dabigatran effect likely

Dabigatran effect unlikely



When to stop Dabigatran for elective surgery	
MAJOR SURGERY	**MINOR SURGERY** (low bleeding risk)
Creatinine Clearance > 79mls/min	
48 hours	24 hours
Creatinine Clearance 50-79mls/min	
72 hours	48 hours
Creatinine Clearance 20-49mls/min	
96 hours	>48 hours
Creatinine Clearance less than 30mls/min	
Drug Contraindicated. Seek Haematology advice.	

Regional anaesthesia: treat as for major surgery

If surgery is delayed more than 48 hours from last dose of Dabigatran, patient should be VTE risk assessed regularly and given standard VTE thromboprophylaxis with low molecular weight heparin if appropriate - assuming scheduling of surgery is not a contraindication

*** Idarucizumab is a specific reversal agent for Dabigatran.**

It is a monoclonal antibody that binds to the drug and facilitates removal from the circulation. It is licensed for management of urgent surgical procedures or in the event of life threatening bleeding in patients who have evidence of dabigatran effect – ie prolonged thrombin time. The dose is 5g (2x2.5g vials). The drug is available in the emergency drugs fridge.

Postoperative Management

Whilst an epidural is in situ anticoagulation is best managed with prophylactic low molecular weight heparin.

N.B. insertion and removal of the epidural catheter must be delayed by 12 hours after a prophylactic dose of Clexane and the dose of Clexane should be delayed by four hours after the removal of a catheter.

If dabigatran is inadvertently given while epidural catheter in situ, do not remove epidural catheter but refer to guide for withholding dabigatran prior to major surgery (min 48hrs – renal function dependent). Wait at least six to eight hours after catheter removal before giving next dose of dabigatran (24 hours if traumatic puncture).

Prophylactic anticoagulation may be required initially, especially if the patient is nil by mouth this may be best delivered using prophylactic low molecular weight heparin until the bleeding risk is satisfactory and/or the patient is able to tolerate oral medications.

Full dose anticoagulation should not be commenced until a minimum of 24 – 48 hours postoperatively. Do not recommence drug until haemostasis secured.

REFERENCES

Makris, M., Veen, J. J., Tait, C. R., Mumford, A. D., & Laffan, M. (2013). Guideline on the management of bleeding in patients on antithrombotic agents. British journal of haematology, 160(1), 35-46. http://onlinelibrary.wiley.com/doi/10.1111/bjh.12107/pdf

For summary product characteristics (SPCs) please see: https://www.medicines.org.uk/emc/

RELATED DOCUMENTS

Noac Apixaban Eliquis Or Rivaroxaban Xarelto Management Of Haemorrhage And Or Emergency Surgery

Noacs Doacs A Quick Guide Apixaban Eliquis Dabigatran Pradaxa And Rivaroxaban Xarelto

AUTHORISING BODY

Haematology Governance

SAFETY

Contact Adult Haematology Registrar bleep [redacted] (out of hours contact on call Adult Haematology registrar on call via UH Bristol switchboard)

QUERIES

Ward Pharmacists or Haematology Registrar as above