NICE Bites

Dabigatran etexilate and rivaroxaban for the prevention of stroke and systemic embolism in atrial fibrillation

NICE TA249, TA256; 2012

Dabigatran etexilate and rivaroxaban are oral anticoagulants. They are recommended as an option for the prevention of stroke and systemic embolism in people with non-valvular atrial fibrillation with one or more of the following risk factors according to the licensed indication:

**Dabigatran etexilate**
- age ≥ 75 years
- age ≥ 65 years with one of the following: diabetes mellitus, coronary artery disease or hypertension
- left ventricular ejection fraction below 40%
- symptomatic heart failure of New York Heart Association (NYHA) class 2 or above
- previous stroke, transient ischaemic attack or systemic embolism

**Rivaroxaban**
- age ≥ 75 years
- diabetes mellitus
- congestive heart failure
- hypertension
- previous stroke or transient ischaemic attack

The decision about whether to start treatment should be made after an informed discussion between the clinician and the person about the risks and benefits of these anticoagulants compared with warfarin. For people who are taking warfarin, the potential risks and benefits of switching should be considered in light of their level of international normalised ratio (INR) control.

*See Summary of Product Characteristics for full prescribing information

Fingolimod for the treatment of highly active relapsing-remitting multiple sclerosis

NICE TA254; 2012

Fingolimod* is recommended as an option for the treatment of highly active relapsing–remitting multiple sclerosis in adults, only if:
- they have an unchanged or increased relapse rate, or ongoing severe relapses compared with the previous year despite treatment with beta interferon, **AND**
- the manufacturer provides fingolimod with the discount agreed as part of the patient access scheme.

*See Summary of Product Characteristics for full prescribing information
Acute upper gastrointestinal bleeding: management

NICE CG141; 2012

This guideline covers the management of acute upper gastrointestinal bleeding in adults and young people ≥16 years.

Definition of terms

INR international normalised ratio
GI gastrointestinal
NSAID non-steroidal anti-inflammatory drug
PPI proton pump inhibitor
TIPS transjugular intrahepatic portosystemic shunts

Risk assessment

- For all patients with acute upper GI bleeding use the following risk assessment scores:
  - Blatchford score at first assessment, AND
  - full Rockall score after endoscopy.
- Consider early discharge for patients with a pre-endoscopy Blatchford score of 0.

Treatment and management

Resuscitation

- Give patients with massive bleeding a transfusion with blood, platelets and clotting factors in line with local protocols.
- Base decisions on blood transfusion on the full clinical picture, recognising that over-transfusion may be as damaging as under-transfusion.
- Do NOT offer platelet transfusion to patients who are not actively bleeding and are haemodynamically stable.
- Give platelet transfusion to patients who are actively bleeding and have a platelet count of < 50 x 10^9/litre.
- Give fresh frozen plasma to patients who have either:
  - a fibrinogen level of < 1g/litre, OR
  - a prothrombin time (INR) or activated partial thromboplastin time >1.5 times normal.
- Give prothrombin complex concentrate to patients who are taking warfarin and actively bleeding.
- Treat patients who are taking warfarin and whose upper GI bleeding has stopped in line with local warfarin protocols.
- Do NOT use recombinant factor VIIa except when all other methods have failed.

Endoscopy

- Offer endoscopy:
  - immediately after resuscitation to all patients with severe acute upper GI bleeding,
  - within 24 hours of admission to all other patients.
- Do NOT use adrenaline as monotherapy for the endoscopic treatment of non-variceal upper GI bleeding. Use one of the following:
  - a mechanical method (e.g. clips) with or without adrenaline,
  - thermal coagulation with adrenaline,
  - fibrin or thrombin with adrenaline.

Treatment after first or failed endoscopic treatment

- Consider a repeat endoscopy, with treatment as appropriate, for all patients at high risk of re-bleeding, particularly if there is doubt about adequate haemostasis at the first endoscopy.
- Offer a repeat endoscopy to patients who re-bleed with a view to further endoscopic treatment or emergency surgery.
- Offer interventional radiology to unstable patients who re-bleed after endoscopic treatment. If not promptly available then refer urgently for surgery.

Management of variceal bleeding

- Give terlipressin* to patients with suspected variceal bleeding.
- Stop treatment after definitive haemostasis has been achieved or after five days.***
- Give prophylactic antibiotics at presentation.***

Oesophageal varices

- Use band ligation.
- Consider TIPS if bleeding from oesophageal varices is not controlled by band ligation.

Gastric varices

- Offer endoscopic injection of N-butyl-2-cyanoacrylate to patients with upper GI bleeding from gastric varices.
- Insert TIPS if bleeding from gastric varices is not controlled by endoscopic injection of N-butyl-2-cyanoacrylate.

Preventing bleeding in acutely ill patients in critical care

- Give acid suppression therapy (H2-receptor antagonist or PPI) for primary prevention of upper GI bleeding in acutely ill patients admitted to critical care. If possible, use the oral form of the drug.
- Review the ongoing need for acid suppression drugs when they recover or are discharged from critical care.

*See Summary of Product Characteristics (SPC) for full prescribing information.

**The terlipressin SPC states a maximum duration of treatment of 72 hours (3 days). Obtain and document informed consent.

***NICE did not make a specific recommendation on this but the Guideline Development Group noted that current practice is to prescribe broad spectrum antibiotics for approximately five days.

Prescribing

Acid suppression therapy

- Do NOT offer PPIs or H2-receptor antagonists before endoscopy to patients with suspected non-variceal upper GI bleeding.
- Give PPIs to patients with non-variceal upper GI bleeding and stigmata of recent haemorrhage shown at endoscopy.

Patients on NSAIDs, aspirin or clopidogrel

- Continue low-dose aspirin for secondary prevention of vascular events in patients with upper GI bleeding in whom haemostasis has been achieved.
- Stop other NSAIDs (including cyclooxygenase-2 inhibitors) during the acute phase in patients presenting with upper GI bleeding.
- Discuss the risks and benefits of continuing clopidogrel (or any other thienopyridine antiplatelet agent) in patients with upper GI bleeding with the appropriate specialist (for example, a cardiologist or a stroke specialist) and with the patient.

Supporting documents

NICE has published a clinical guideline on acutely ill patients in hospital.

Implementation tools and resources

Visit the NICE Pathway: Acute upper GI bleeding

This bulletin summarises key prescribing points from NICE guidance. Please refer to the full guidance at www.nice.org.uk for further detail.

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