GIB6: A REGIONAL TRAINEE-LED AUDIT INTO PATIENT CARE AND OUTCOMES FOLLOWING ACUTE UPPER GASTROINTESTINAL BLEEDING

BACKGROUND

Trainee-led networks

Our colleagues in anaesthetics and surgery have lead the way with establishing and developing trainee-led collaborative networks. These networks support trainees to run effective multi-site audit and quality improvement projects, to develop their academic and research skills, and to collaborate with trainees of all grades, consultants and allied professions around the country. More recently, these projects have included national audit projects, several RCTs with the backing of prestigious funders, and collaboration internationally. There is huge potential within the UK gastroenterology and hepatology community!

The Midlands has pioneered trainee-led collaborative networks in Gastroenterology. The West Midlands Research in Gastroenterology Group (WMRiG) was established in March 2015. The Gastroenterology Audit and Research Group (the GARNet) was launched in November 2016 in the East Midlands. Trainee networks are a great way to meet and work with friends and colleagues; to deliver projects on a larger scale with more power, to complete the cycle and share learning and improvements as doctors rotate in their training programmes, and so with greater potential for making an impact and benefiting our patients; and, to fulfil curriculum competencies in research and audit, including for annual appraisals. The British Society of Gastroenterology (BSG) are supporting and promoting trainee-led networks.

Acute upper gastrointestinal bleeding (AUGIB)

Gastrointestinal bleeding (GIB) is a common medical emergency, with approximately one presentation every six minutes in the UK.[1,2] The optimal management of AUGIB and the quality of care our patients receive are important to us all as gastroenterology registrars, and relevant across multiple specialties and grades at essentially every acute hospital in the UK. Overall mortality in was 14% in 1993[3] and 10% in 2007.[4] Subsequently, several UK relevant guidelines were published which emphasise effective early management and timely endoscopy as important process goals to reduce mortality and morbidity.[5-7] The 2015 NCEPOD enquiry into high risk GIB highlighted variations in practice and raised concerns regarding suboptimal care.[1] In 2016, a GARNet trainee-led audit across nine hospitals in the East Midlands identified continuing variations in performance against guidelines and delays to endoscopy.[8]

Our two trainee-led networks, the GARNet and WMRiG, are collaborating to create an audit and quality improvement cycle in order to evaluate and improve the care of patients with AUGIB. This project is supported by the national digestive diseases charity Core and the BSG, through their Trainee Research Network Awards programme under the title "*About bleeding time: driving improvements in the quality of care received by patients with AUGIB using the GIB6 care bundle*".

The GIB6 concept (Figure 1) was initially developed by Prof Sauid Ishaq (based on his work as national advisor to the NCEPOD gastrointestinal haemorrhage study) and Dr Keith Siau on behalf of the Russell's Hall GIB steering group. The bundle was originally constructed following thematic analysis of key early interventions in AUGIB, with multidisciplinary participation from consultant representatives from acute care, emergency medicine, critical care and general surgery. The underpinning rationale behind GIB6 is to generate a care bundle with timeline, which could be applied within the first 24 hours of presentation, in order to improve outcomes. The proposed model consisted of 6 time-dependent domains (all beginning with R), each with corresponding items aligned with national quality standards and linked with good clinical practice.[9] This project will refine the GIB6 bundle and prepare for its implementation.

PROJECT AIMS

1. To utilise and develop the GARNet and WMRiG networks in the shared purpose of evaluating and improving the care of patients with AUGIB across the Midlands, through audit against national quality standards and assessment of patient and process outcomes.

2. To rigorously refine the GI bleed care bundle (GIB6) and prepare it for implementation.

This is a cross-regional project, jointly designed and delivered. The regional team are grateful to colleagues across our networks for their feedback and support in refining and delivering the project. The GARNet will lead on our first aim and WMRiG will lead on our second aim, working with the GIB steering group and consultants and colleagues across the region and nationally.

Additional aim

To set up a framework for change and identify potential barriers to successful implementation, by:

- engaging patients and the public through Core to establish their priorities in GI bleeding and identify patient-reported outcomes;
- engaging doctors and other health care professionals at participating sites across the Midlands to identify any shortfalls in service provision and to propose potential solutions;
- utilising regional quality improvement resources (HEE networks and the improvement academy) and the RCP Quality Improvement Hub;
- engaging with senior clinicians and experts within gastroenterology, cross-specialty and nationally.

MEASURES OF SUCCESS

1. The delivery of UK gastroenterology's first multi-region trainee-led audit and quality improvement project.

2. The production of a GI bleed care bundle, refined through a Delphi consensus process of expert review and with input from trainees, that is ready for wider implementation.

Other benefits of this audit:

- to involve many gastroenterology trainees and consultants across the Midlands in the shared goal of evaluating and improving the care of their patients with GI bleeding;
- to enable actively involved trainees to demonstrate competence in audit and quality improvement projects, as required annually by the Gastroenterology ARCP Decision Aid;
- to enable each Trust to demonstrate audit and action plans to improve care against national quality standards, which is required of all accredited endoscopy units;
- to enable the GARNet to complete an audit cycle of East Midlands sites (first run in November 2016).

AUDIT CRITERIA AND STANDARDS – *SEE APPENDIX FOR SUMMARY AND REFERENCES*

The key audit criteria and standards are the National Institute of Health and Care Excellence (NICE) QS38 Quality Standards. These are used by the Joint Advisory Group on gastrointestinal endoscopy (the JAG) to assess endoscopy units for accreditation against their Global Rating Scale (GRS) Standards, and were recommended by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report. Reference will also be made to other selected recommendations from the NCEPOD report and the European Society of Gastrointestinal Endoscopy (ESGE) guidelines.

In addition, we will collect data on:

- patient outcomes, namely re-bleeding, unplanned re-admission and mortality;
- process outcomes related to the time from patient presentation to endoscopy, to better understand any delays in timely endoscopy;
- selected aspects of the GIB6 bundle, to better understand their utility and usability.

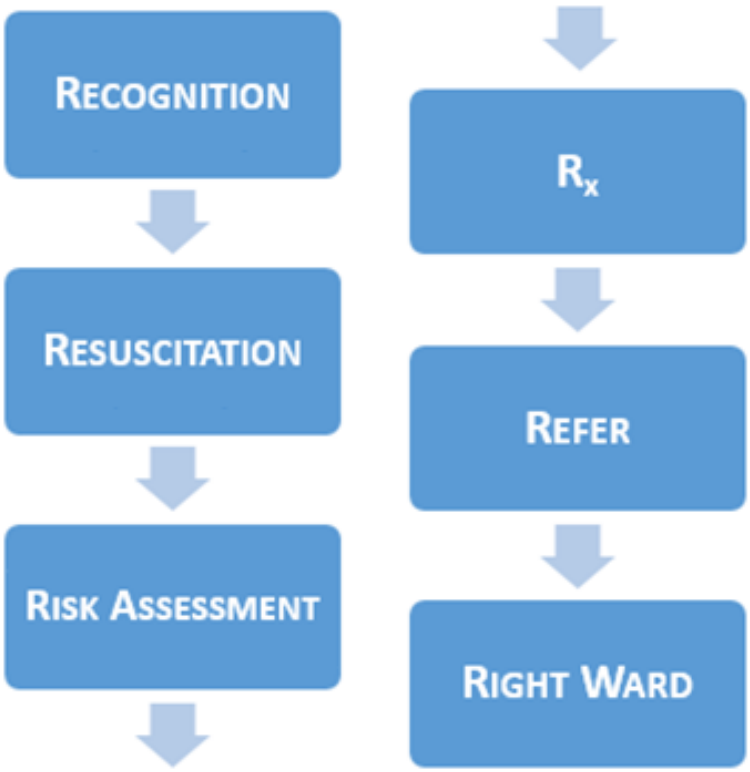

Figure 1: Domains within GIB6.

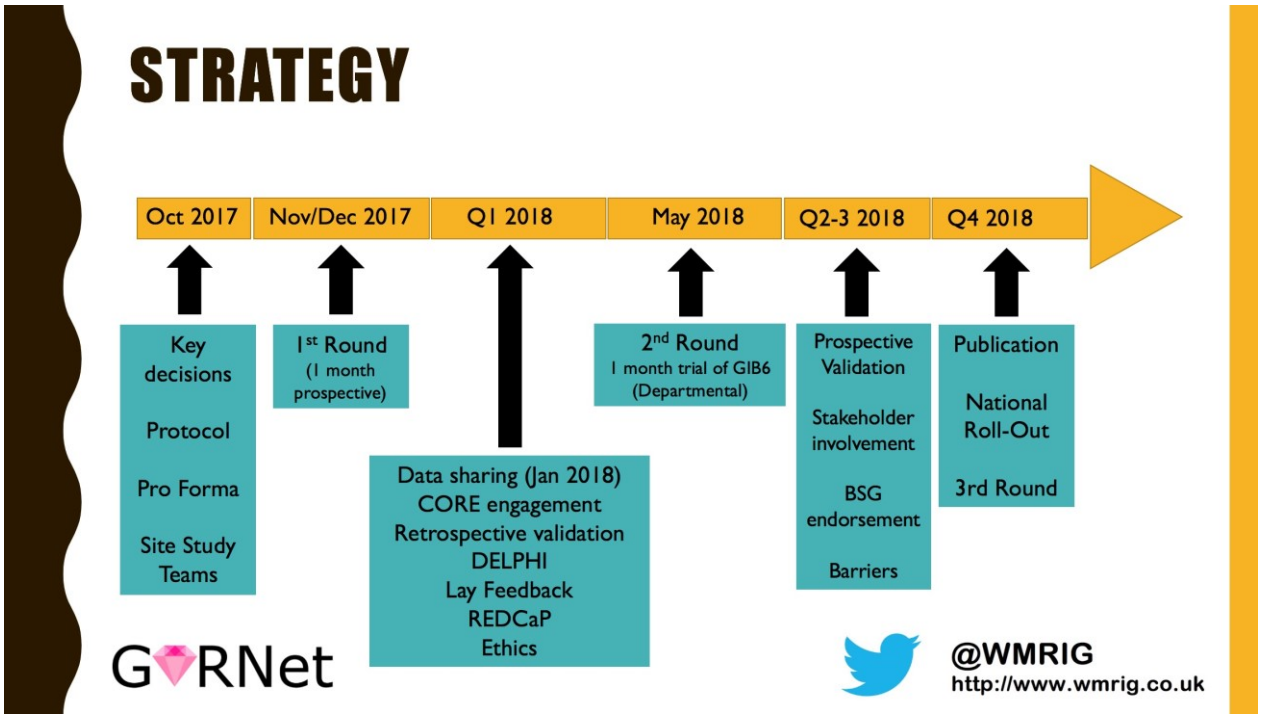

Figure 2: Strategic roadmap for GIB6.

The final elements and timeline are likely to be further refined following feedback from trainees and others, and review of audit data and local quality improvement proposals. Note that 1st Round, 2nd Round and 3rd Round refer to the planned audit and re-audit cycles.

AUDIT PROTOCOL

Study Design

- Prospective cross-regional multi-centre audit and quality improvement project.

Inclusion Criteria

- Patients aged 16 and older (in line with NICE QS38 and CG141, though who are under adult services).
- Admitted in a consecutive 30-day window in November and December 2017, with the target period of Wednesday 1st to Thursday 30th November 2017 inclusive (staggered starts possible for feasibility).
- In whom a clinical diagnosis is made of possible acute upper gastrointestinal bleeding (AUGIB).
- And an in-patient gastroscopy is undertaken during the index admission to investigate ± treat bleeding.

Exclusion Criteria

- Patients under the care of services for children and young people.
- Patients who undergo gastroscopy in the site study window but were admitted prior to this window.
- Existing inpatients who develop AUGIB.
- Presentation with bright red rectal bleeding and low shock index (≤1).
- Indication for endoscopy documented as vomiting or other symptom complex, rather than as the investigation and treatment of suspected AUGIB.
- Low-risk patients discharged for outpatient endoscopy.
- Endoscopy was not undertaken (e.g. in frail older people who have non-interventional management).

Note: these criteria were selected to reflect the 2016 East Midlands protocol and to simplify the audit for this cycle, though some of these other groups may be included in future audit rounds.

Timeframe

- Thirty-day window to prospectively identify patients who meet the inclusion and exclusion criteria.
- Data collected from relevant hospital records at the point of discharge, death or 8 days after endoscopy.
- Subsequent collection of patient outcomes extending to 30 days (and future time points if possible).
- Complete any local and regional data validation and review in December 2017 and January 2018.
- Updates on progress will be presented at East Midlands and West Midlands training days.
- Receive final anonymised data for all sites with 30 day outcomes before the 31st January 2018.
- Return of site-specific report for each participating hospital by the end of February 2018, alongside non-attributed regional data for benchmarking.
- Cross-regional meeting planned for March 2018

Study Team

Each participating site must have a Study Team. This must include: at least one Site Project Lead and a Site Consultant. This may include: additional Site Project Lead for larger sites (projected size >20 patients in collection period), Site Project Investigators and Site Project Contributors. The specific roles are detailed in the descriptions that follow.

- Site Project Lead(s) – liaising with the local Clinical Governance and Audit department (and informing their clinical audit and governance lead and clinical service lead as necessary, particularly where these individuals are not also taking on the role of Site Consultant), advertising and promoting projects at the local site level, co-ordinating and managing data collection, ensuring secure data collection and anonymization of all data prior to sharing, presenting the results at local level, developing local suggestions for improving quality of care.
- Site Consultant, who takes institutional responsibility for oversight – supporting the Site Project Lead(s) in their role, advertising and promoting projects at the local site level and particularly with the consultant body and management, contributing to the discussion of results and quality improvement plans at local level.

- Site Project Investigator(s) – significantly involved in the Project, above and beyond data collection, such as leading a team of Site Project Contributors or making an extensive contribution to patient identification and/or data collection.
- Site Project Contributor(s) – involved with patient identification and/or data collection.
- Regional Project Leads – devising the proposal and protocol, applying for grants or funding as required, managing and co-ordinating the conduct of the Project across region(s), collating and analysing the study data, presenting the data at regional or national level, submitting any resulting articles for publication.

Patient List, Proforma and Data Collection

- All sites will use a common audit template and the Regional Leads are keen to develop this and future templates through feedback from trainees. Additional data may be collected for local use at the discretion of each site's Study Team. To support feasibility and delivery, the project team understand that it may not be possible to collect every data point for every patient at each site (e.g. where there is no record of the date/time of an endoscopy request).
- Data collection will be the responsibility of the Site Project Lead of each participating site. Participation in the project WhatsApp group is encouraged, to support a coherent approach to data collection and validation, and to enable timely response to any queries by the Regional Project Leads.
- It is strongly encouraged that other colleagues are included in the site Study Teams, including junior doctors in Core Medical Training and the Foundation Programme where possible, though it is important that the Site Project Lead and other registrars support them in this role (e.g. when certain terms may be less familiar, such as reporting of endoscopic findings, stigmata of recent haemorrhage, and therapies).
- The patient list for each site, with patient identifiers and the audit reference number for that site, will be collected in a separate file stored in a secure location on a Trust-specific computer. The Site Project Lead should ensure that this file is suitably password protected and accessible only to their Study Team.
- The audit proforma will include the audit reference number for each patient but no other patient identifiable information, such that in effect only unlinked anonymised data are available in the audit proforma and no patient will be identifiable. This file will also be stored in a secure location on a Trust-specific computer. In line with established practice for previous regional and national trainee-led projects involving multiple sites, all data must be anonymised prior to sharing. The Site Project Lead(s), in liaison with the Site Consultant and others such as the local Caldicott Guardian as necessary, should ensure that data intended for sharing is fully anonymised and only shared via secure channels such as NHS mail or REDCap.
- Site-specific results will not be presented publicly with attribution to any particular sites, but each site will be given their own results. These can then be presented locally by the site Study Team and local colleagues, alongside the overall results to enable regional benchmarking.

Dissemination Plan

- Presentation and discussion of results at local meetings (e.g. governance, endoscopy, grand round etc.).
- Engagement with quality improvement experts and patient advocacy groups.
- Submission and presentation at specialty meetings (Midland Gastroenterological Society, British Society of Gastroenterology and United European Gastroenterology Week) and relevant general meetings (e.g. Society for Acute Medicine and regional Royal College of Physicians meetings).
- Preparation of a report and associated output for Core and the BSG.
- Publication in a relevant journal upon completion of the quality improvement cycle. Authorship will reflect the collaborative nature of this project and the trainee-led networks involved, whilst ensuring (1) that every person who contributes to the Study Team at reported sites will be citable individually by name, and (2) recognising particular contributions of regional leads and others to design, delivery, analysis and write up. Output specific to GIB6 refinement will follow separate authorship rules.
- Development of regional guidelines, e.g. combined UGI and LGI document (as per NCEPOD).

Governance Perspectives

- The study has been approved by the East and West Midlands Gastroenterology Training Programme Directors. Whilst this project is not research, we advise for all Site Project Leads to undergo certification in Good Clinical Practice (GCP) to familiarise themselves with best practice in data collection. Training is available for free via http://www.wmrig.co.uk or https://www.thegarnet.org/nihr-crn, and can be used as evidence of research involvement at ARCP and for participation in Clinical Research Network studies.
- The project must be registered at each site as a clinical audit (or re-audit, as applicable).
- Formal ethics approval is not required as the data collected will be used to inform local practice and not used to make generalisable inferences, as per the HRA Decision Tool "is my study research?".
- Identification of eligible patients and data collection may begin if verbal approval from the Site Consultant is provided, prior to receiving formal audit/governance department approval. However, this approval will be required before data can be anonymised and shared.

APPENDIX: SUMMARY OF KEY AUDIT CRITERIA AND STANDARDS

National Institute for Health and Care Excellence (NICE) QS38 (July 2013)[5]

1. People with AUGIB receive a risk assessment using a validated risk score.

Numerator – the number of people in the denominator who receive a risk assessment using a validated risk score (*note*: NICE suggest a Glasgow Blatchford score at first assessment and a full Rockall score after endoscopy).
Denominator – the number of people with AUGIB (*note*: the first audit cycle has a more restricted denominator).

2. People with severe AUGIB who are haemodynamically unstable are given an endoscopy within 2 hours of optimal resuscitation.

Numerator – the number of people in the denominator who receive endoscopy within 2 hours of optimal resuscitation (clinical judgement should be used to determine whether people who are haemodynamically unstable have achieved their optimal level of resuscitation).
Denominator – the number of people with severe AUGIB who are haemodynamically unstable (active bleeding whose blood pressure or pulse cannot be normalised or who need rapid intravenous fluids to maintain haemodynamic stability).
Note: the 2-hour window was set by expert consensus, whereas other experts consider that endoscopy within 2-6 hours of presentation is an appropriate process target to represent a similar quality measure outcome (and NICE have used 4 hours).

3. People admitted to hospital with AUGIB who are haemodynamically stable are given an endoscopy within 24 hours of admission.

Numerator – the number of people in the denominator who receive endoscopy within 24 hours of admission (*note*: in this audit admission is considered to be the time of presentation to hospital for those admitted with AUGIB).
Denominator – the number of people admitted to hospital with AUGIB who are haemodynamically stable (have stabilised blood pressure and pulse).

4. People with non-variceal AUGIB and stigmata of recent haemorrhage are offered endoscopic treatments

Numerator – the number of people in the denominator who receive endoscopic treatments (combination or a mechanical method). *Note*: where possible we will aim to collect data on therapy/therapies used including the volume of adrenaline.
Denominator – the number of people with non-variceal AUGIB and stigmata of recent haemorrhage.

5. People with non-variceal AUGIB who continue to bleed or re-bleed after endoscopic treatment and who are haemodynamically unstable are given interventional radiology treatment.

Numerator – the number of people in the denominator who receive interventional radiology treatment (embolisation).
Denominator – the number of people with non-variceal AUGIB (from the stomach or duodenum) who continue to bleed or re-bleed after endoscopic treatment and who are haemodynamically unstable. *Note*: re-bleed, to be assessed at 48h and 7d, may need defining[10]; we will also record the number of people who receive surgical intervention, where this occurs.

6. People with suspected or confirmed variceal AUGIB are given antibiotic therapy at presentation.

Numerator – the number of people in the denominator who receive antibiotic therapy at presentation.
Denominator – the number of people with suspected or confirmed variceal AUGIB at presentation.
Note: we will also audit the use of terlipressin (or similar) for confirmed variceal AUGIB.

7. People with AUGIB from oesophageal varices are given band ligation.

Numerator – the number of people in the denominator who receive band ligation.
Denominator – the number of people with AUGIB from oesophageal varices.

8. People with AUGIB from gastric varices are given an endoscopic injection of N-butyl-2-cyanoacrylate.

Numerator – the number of people in the denominator who receive endoscopic injection of N-butyl-2-cyanoacrylate. *Note*: this definition is taken to include thrombin.
Denominator – the number of people with AUGIB from gastric varices.

9. People with uncontrolled AUGIB from varices are given TIPS.

Numerator – the number of people in the denominator who receive TIPS (transjugular intrahepatic portosystemic shunts).
Denominator – the number of people with uncontrolled AUGIB from varices (oesophageal/gastric). *Note*: record care transfers.

10. People with AUGIB who take aspirin for secondary prevention of vascular events and in whom haemostasis has been achieved are advised to continue on low-dose aspirin.

Numerator – the number of people in the denominator who are advised to continue on low-dose aspirin.
Denominator – the number of people with AUGIB who take aspirin for secondary prevention of vascular events and in whom haemostasis has been achieved.

Joint Advisory Group on gastrointestinal endoscopy (the JAG) Global Rating Scale (GRS) measures most applicable to this project (April 2016)

No	Measure	Level	Guidance (*note*: summarised)
2.6	Over 50% of patients admitted with AUGIB who are haemodynamically stable receive endoscopy within 24 hours of admission.	C	NICE has a set of quality statements to support an AUGIB quality standard. The quality standard defines clinical best practice for AUGIB and should be read in full.
2.8	A process is in place for identifying and reviewing all deaths occurring within 30 days of an endoscopic procedure and all unplanned admissions within 8 days of an endoscopic procedure.	B	The endoscopy service is expected to review all safety matters including 30-day mortality and 8-day readmissions at agreed intervals (monthly, quarterly).
2.11	Over 75% of patients admitted with AUGIB who are haemodynamically stable receive endoscopy within 24 hours of admission.	B	*as per 2.6*
2.12	The service is compliant with over 50% of the quality measures in the 2013 NICE guidelines for AUGIB.	B	NICE has a set of quality statements to support an AUGIB quality standard. The majority of these measures can be achieved by the endoscopy service itself, although some will need the co-operation of other departments e.g. critical care or radiology. These should be incorporated into local hospital practices in order to support the best outcome for the patient with AUGIB.
2.13	The service has an action plan to address areas where it is unable to currently meet the quality measures in the 2013 NICE guidelines for AUGIB.	B	*as per 2.6*

APPENDIX: SUMMARY OF SELECTED ADDITIONAL CRITERIA AND STANDARDS

National Confidential Enquiry into Patient Outcome and Death (NCEPOD): Time to Get Control? (2015)[1]

R6: All patients who present with a major upper or lower GI bleed, either on admission or as an inpatient, should be discussed with the duty or on-call (out-of-hours) consultant responsible for major GI bleeds, within one hour of the diagnosis of a major bleed.
R8: As previously stated by NICE (QS38), all patients with a GI bleed and haemodynamic instability should have 24/7 access to an OGD within two hours of optimal resuscitation.
R9: Endoscopy lists should be organised to ensure that GI bleed emergencies can be prioritised and all acute patients with GI bleeding have their endoscopy within 24 hours.
R12: All patients with a GI bleed must have a clearly documented re-bleed plan agreed at the time of each diagnostic or therapeutic intervention.
R13: Resuscitation and airway support during endoscopy and interventional radiology procedures should be equivalent to facilities during emergency surgery. Unstable patients should have anaesthetic and/or critical care support.
R20: All deaths from major GI bleeds within 30 days of admission should undergo combined multidisciplinary peer review to identify remediable factors in patient care.
R21: The NICE Clinical Guideline (CG141) and Quality Standards (QS38) for AUGIB should be adhered to.
R25: The JAG should consider including access to and delivery of 24/7 endoscopy for GI bleeding in their Global Rating Scale.

European Society of Gastrointestinal Endoscopy (ESGE) 2015[7]

MR2: ESGE recommends a restrictive red blood cell transfusion strategy that aims for a target haemoglobin between 70 g/L and 90 g/L. A higher target haemoglobin should be considered in patients with significant co-morbidity (e.g. ischaemic cardiovascular disease) (strong recommendation, moderate quality evidence).

Note: this audit will collect data on haemoglobin at discharge as a simple though imperfect surrogate measure of transfusion practice, and on the discharge prescription of oral or intravenous iron supplementation.[9]

MR6: ESGE recommends intravenous erythromycin (single dose, 250 mg given 30–120 minutes prior to OGD) in patients with clinically severe or ongoing active AUGIB. In selected patients, pre-endoscopic infusion of erythromycin significantly improves endoscopic visualization, reduces the need for second-look endoscopy, decreases the number of units of blood transfused, and reduces duration of hospital stay (strong recommendation, high quality evidence).

MR12: ESGE recommends PPI therapy for patients who receive endoscopic haemostasis and for patients with adherent clot not receiving endoscopic haemostasis. PPI therapy should be high dose and administered as an intravenous bolus followed by continuous infusion (80 mg then 8 mg/hour) for 72 hours post endoscopy (strong recommendation, high quality evidence).

MR15:

- ESGE recommends restarting anticoagulant therapy following non-variceal AUGIB in patients with an indication for long-term anticoagulation. The timing for resumption of anticoagulation should be assessed on a patient-by-patient basis. Resuming warfarin between 7 and 15 days following the bleeding event appears safe and effective in preventing thromboembolic complications for most patients. Earlier resumption, within the first 7 days, may be indicated for patients at high thrombotic risk (strong recommendation, moderate quality evidence).
- In patients receiving low-dose aspirin for secondary cardiovascular prophylaxis who develop peptic ulcer bleeding, ESGE recommends aspirin be resumed immediately following index endoscopy if the risk of re-bleeding is low (e. g. Forrest IIc/III). In patients with high risk peptic ulcer (Forrest Ia to IIb), early reintroduction of aspirin by day 3 after index endoscopy is recommended, provided that adequate haemostasis has been established (strong recommendation, moderate quality evidence).

Note: ESGE make other recommendations for: low-dose aspirin for primary cardiovascular prophylaxis, dual antiplatelet therapy and PPI co-therapy, which are omitted from this audit.

REFERENCES

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