GI Haemorrhage Study

Study protocol

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Introduction

Gastrointestinal Haemorrhage (GIH) is a common cause of hospital admission (incidence 100/100,000 adults annually) and death. The overall in-hospital mortality is 10% and is attributed to a combination of advanced age, multiple co-morbidities, and high transfusion requirements, rather than exsanguination. When GIH complicates other severe illnesses, the mortality is much higher (26% vs 7%) [1]. Upper GIH is 4 times commoner than lower GIH. 9000 UK patients die annually from upper GIH alone [1]. Evidence of widespread variation in the availability of services was published in 2010 [2].

Whilst UK overall mortality rates have improved from 14% to 10% in the past 20 years, other European countries have improved to 7% [1,3,4]. A USA study in 2009, showed significantly excess mortality at weekends [5]: findings that are likely to be replicated in the UK.

GIH is managed by both medical and surgical teams and requires a multidisciplinary approach. Management differs between upper and lower GIH. Upper GIH is managed by supportive therapy, pharmacologically, endoscopic treatment, interventional radiology (embolisation), and open surgery. Lower GIH is managed by supportive therapy, diagnostic and interventional radiology or open surgery.

Each unit of blood transfusion increases the chance of death (coagulopathy/multi-organ failure). Rapid definitive treatment reduces mortality but depends on appropriate staff and resources being available [6].

CT scanners are now highly sensitive at localising acute GIH. Extensive evidence demonstrates the benefit of utilising this non-invasive technique but its use out of hours is unknown [7].

When endoscopic treatment fails, embolisation has the same therapeutic success as surgery but with lower mortality and morbidity [8]. It is currently underutilised [1]. The reasons are probably multi-factorial with factors including non-inclusion on care-pathways, education and lack of 24 hour availability (perceived and real).

[1] Hearnshaw SA, Logan RF, Lowe D, Travis SP, Murphy MF, Palmer KR. Acute upper gastrointestinal bleeding in the UK: patient characteristics, diagnoses and outcomes in the 2007 UK audit. Gut. 2011; 60(10):1327-1335

[2] Scope for Improvement: a toolkit for a safer Upper Gastrointestinal bleeding (UGIB) service: Academy of Medical Royal Colleges October 2010.

[3] Rockall TA, Logan RF, Devlin HB, Northfield TC. Incidence of and mortality from acute upper gastrointestinal haemorrhage in the United Kingdom. Steering Committee and members of the National Audit of Acute Upper Gastrointestinal Haemorrhage. BMJ 1995;311(6999):222-6

[4] Fiore, Frédéric Di; Lecleire, Stéphane; Merle, Véronique; et al.Changes in characteristics and outcome of acute upper gastrointestinal haemorrhage: a comparison of epidemiology and practices between 1996 and 2000 in a multicentre French study European Journal of Gastroenterology & Hepatology:June 2005 - Volume 17 - Issue 6 - pp 641-647

[5] Ananthakrishnan AN, McGinely EL, Saeia K. Outcomes of Weekend admissions for upper gastrointestinal hemorrhage: A Nationwide analysis
Clinical Gastroenterology and Hepatology (2009)Vol 7, Issue 3, 296-302

[6] Schenker MP, Duszak R, Soulen M, et al: Upper gastrointestinal haemorrhage and transcatheter embolotherapy: clinical and technical factors impacting success and survival. J Vasc Interv Radiol 12:1263-1271, 2001

[7] Geffroy Y, Rodallec MH, Boulay-Coletta I et al. Multidetector CT Angiography in Acute Gastrointestinal Bleeding: Why, When, and How. RadioGraphics 2011; 31:35

[8] Mirsadraee S, Tirukonda P, Nicholson A, Everett SM, McPherson SJ
Embolization for non-variceal upper gastrointestinal tract haemorrhage: a systematic review. Clin Radiol. 2011 Jun;66(6):500-9

[9] British Society of Gastroenterology. UK Comparative Audit of Upper Gastrointestinal Bleeding and the Use of Blood. Available at: http://www.bsg.org.uk/pdf_word_docs/blood_audit_report_07.pdf [accessed 27 Sept 2012]

Guidelines and standards

Scottish Intercollegiate Guidelines Network [SIGN] Guideline No. 105, Management of acute upper and lower gastrointestinal bleeding ISBN 978 1 905813 37 7, 2008

NICE Clinical Guideline 141 Acute Upper Gastrointestinal Bleeding - Management 2012

Following NICE CG141
National costing report: acute upper gastrointestinal bleeding was produced in June 2012. http://www.nice.org.uk/nicemedia/live/13762/59577/59577.pdf

Supporting bodies

Royal College of Radiologists /British Society of Interventional Radiologists, British Society of Gastroenterology, Association of Coloproctology, The Joint Advisory Group on Gastrointestinal Endoscopy, The Association of Upper Gastrointestinal Surgeons, The Royal College of Physicians.

Aims and Objectives

Aim

To identify the remediable factors in the quality of care provided to patients treated for GI haemorrhage.

Objectives

Based on the issues raised by the expert group, the objectives of this study are to collect information on the following:

- The quality of assessment including risk stratification and early warning scores
- Referral pathways: including who the patient is admitted under/transferred to
- Delays in treatment
    - Endoscopy, CT, interventional radiology, surgery
- Inequalities in treatment
    - Secondary vs tertiary
    - Geographical
- Assess the use of escalated care and anaesthetic support for interventions.
- Identify futile/inappropriate interventions

Methodology

Population/Inclusions

Patients aged 16 years or older that were coded for a diagnosis of GI haemorrhage and admitted to hospital between 1st January 2013 and 30th April 2013 inclusive. The included ICD10 codes are:

I85.0	Oesophageal varices with bleeding
K92.0	Haematemesis
K92.1	Melaena
K92.2	Gastrointestinal haemorrhage, unspecified gastrointestinal bleeding
K25.0	Gastric ulcer, acute with haemorrhage
K25.2	Gastric ulcer, acute with both haemorrhage and perforation
K26.0	Duodenal ulcer, acute with haemorrhage

K26.2	Duodenal ulcer, acute with both haemorrhage and perforation
K27.0	Peptic ulcer, site unspecified, acute with haemorrhage
K27.2	Peptic ulcer, site unspecified, acute with both haemorrhage and perforation
K28.0	Gastrojejunal ulcer, acute with haemorrhage
K28.2	Gastrojejunal ulcer, acute with both haemorrhage and perforation
K29.0	Acute haemorrhagic gastritis

Exclusions

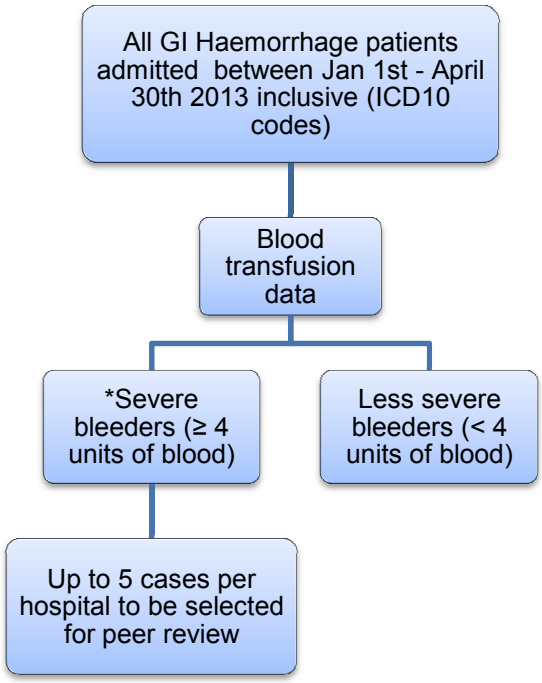
Patients admitted as a day case will be excluded from the study.

Case identification

Local Reporters will be asked to complete a predefined spreadsheet listing all patients that meet the inclusion criteria. Details on any procedures performed (OPCS codes) and the amount of blood, if any, transfused will also be collected along with details of the discharging clinician. The blood data will be used as an indicator of the more severe bleeders.

Since both lower and upper GI haemorrhage patients will be included, information on all diagnosis codes will be collected to help determine the likely source (lower or upper) of bleeding. This will enable the biased sampling of cases so sufficient 'severe' lower GI bleeders are included in the peer review sample.

It may be necessary to verify the severity of bleeding and type of GI bleed (lower or upper) with the clinician questionnaire, prior to requesting photocopied casenote extracts for the peer review sample.



* The number of units of blood that is used to determine the group of 'severe bleeders' is subject to change

Figure 1

Sample size

A sample size of approximately 500 patients will be selected from the 'severe bleeding group' (see figure 1) for clinician questionnaire dissemination and case note review. The number of cases included will be limited to a maximum of five per hospital.

Method of data collection

Spreadsheet

As above, cases will be identified using a data collection spreadsheet. This will identify all patients meeting the study inclusion criteria, and include the patient's NHS number, date of birth, diagnosis codes (ICD10), procedure codes (OPCS), blood transfusion data, admission and discharge dates and the name of the discharging consultant.

Clinical questionnaire

A questionnaire will be sent to the consultant who was responsible for the patient's care at the time of discharge. This will collect data around the objectives listed above.

Casenotes

Photocopies of the case notes of each included patient will be requested at the time of questionnaire dissemination. A list detailing the required case note extracts will be included with each questionnaire.

Organisational questionnaire

An organisational questionnaire collecting information regarding facilities, equipment, policies and guidelines relevant to the management of patients with a GI haemorrhage will be sent to the NCEPOD Local Reporter. We ask that the Local Reporter liaise with the relevant person(s) that can accurately complete the questionnaire.

Participating sites

Data will be collected from all hospitals in England, Wales, Northern Ireland, the Channel Islands and the Isle of Man. Scotland is not included but Scotland will be made aware of the work through links with the Scottish Audit of Surgical Mortality, with whom NCEPOD has excellent links. Data will be collected from NHS and large independent sector hospital groups, as well as many of the smaller private hospitals.

Pilot Study

A pilot study will be undertaken prior to ensure the data collection methods and questionnaires are robust.

Review of cases and analysis

Advisor group

A multidisciplinary advisory group will be recruited to review the data and to provide expert opinion on the process of care and management of patients who been diagnosed with a GIH.

Assessment form

For each case included in the peer review the Advisors will be asked to complete a questionnaire outlining details of the case and giving their opinion on the quality of care provided to the patient.

Analysis

Questionnaire data will be electronically scanned into a preset database. Data will be analysed quantitatively and qualitatively

Confidentiality and data protection

Once the data have been extracted by the NCEPOD researchers, the questionnaires and casenotes will be anonymised to remove patient identifiers prior to review by the Advisory Group.

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 251 approval has been obtained to perform this study without the use of patient consent.

Dissemination

On completion of this study a report will be published and widely disseminated.

Timescale