

Effectiveness of an upper-gastrointestinal haemorrhage unit: a prospective analysis of 900 consecutive cases using the Rockall score as a method of risk standardisation

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Objectives To assess the effectiveness of a centralised upper-gastrointestinal haemorrhage (UGIH) unit.

Methods The UK Audit of acute UGIH resulted in the formulation of a simple numerical scoring system. The Rockall score categorises patients by risk factors for death and allows case-mix comparisons. A total of 900 consecutive patients admitted to a UGIH unit between October 1995 and July 1998 were analysed prospectively. Patients were given an initial Rockall score and, if endoscopy was performed, a complete score. This method of risk stratification allowed the proportion of deaths (in our study) to be compared with the National Audit using risk standardised mortality ratios.

Results The distribution of both initial and final Rockall scores was significantly higher in our study than in the National Audit. A total of 73 (8.1%) patients died, compared with the National Audit mortality of 14%. Risk-standardised mortality ratios using both initial and complete Rockall scores were significantly lower in our study when

compared with those in the National Audit.

Conclusion A specialised UGIH unit is associated with a lower proportion of deaths from UGIH, despite comprising a greater number of high-risk patients than the National Audit. This lower mortality therefore cannot be attributed to a more favourable case mix and demonstrates that further improvements in mortality for UGIH can be made. *Eur J Gastroenterol Hepatol* 16:487–494 © 2004 Lippincott Williams & Wilkins

European Journal of Gastroenterology & Hepatology 2004, 16:487–494

Keywords: upper-gastrointestinal haemorrhage, Rockall score

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Received 14 May 2003

Accepted 22 September 2003

Introduction

Acute upper-gastrointestinal haemorrhage (UGIH) is a common reason for emergency hospital admission, with an internationally observed incidence between 50 and 150 per 100 000 adults per year [1–3]. The mortality of UGIH has been reported to vary from 2.4 to 14% [2–8].

There have been considerable advances in medical treatment and novel endoscopic intervention in UGIH. Although this has led to a reduction in rebleeding rates, these interventions have had only a modest effect on mortality [7,9–13]. This is attributed to the increasing number of elderly patients admitted with UGIH, who may have significant comorbidity [2,7,14].

Previous investigators have suggested that organisational factors such as early endoscopy, speciality-based management, and the use of predetermined care protocols may also have an impact on the mortality of patients with UGIH [15–17]. The management of UGIH varies internationally, not just from one country

to another but also from academic centres to district hospitals [4–6,18]. In North America, it is possible for patients with UGIH to be admitted directly to a medical intensive care unit (ICU) [19]. This type of unit is comparable to high-dependency units in the UK. This has significant resource implications and is not the current practice in the UK [20]. However, admission to a general medical ward is far from optimal. A pragmatic approach is the provision of a centralised UGIH unit. This would cost less but potentially optimises the care of patients with UGIH [21]. This is analogous to a coronary care unit. The evidence to support an improvement in mortality is conflicting [6,21–25]. It is difficult to draw conclusions from these reports because of the differences in case mix.

The risk of rebleeding or death in patients with UGIH may be estimated by stratified scoring systems [14,26]. Rockall *et al.* [27] devised a numerical scoring system that categorised patients by risk factors for death (Table 1) and allowed case-mix comparisons. The Rockall score was created following the largest epi-

Table 1 The Rockall risk scoring system for upper-gastrointestinal haemorrhage

Component	Score			
	0	1	2	3
Age (years)	< 60	60–79	≥ 80	
Pulse rate (beat/min)	< 100	≥ 100		
SBP (mmHg)	≥ 100	≥ 100	< 100	
Comorbidity	None	None	IHD, cardiac failure, any other major comorbidity	Renal failure, liver failure or disseminated malignancy
Diagnosis	Mallory–Weiss lesions or no lesion, no SRH	All other diagnoses	Malignant lesions of the upper-gastrointestinal tract	
Stigmata of recent haemorrhage	No stigmata or dark spot in ulcer base		Any other signs	

IHD, ischaemic heart disease; SBP, systolic blood pressure; SRH, stigmata of recent haemorrhage.

demographical study of UGIH in the UK. The National Audit for UGIH was a multicentre study involving 4185 adult cases of UGIH from 74 hospitals [2]. Subsequently, a second cohort of 1625 patients was tested for applicability of the scoring system. The Rockall score demonstrated a reproducible prediction of mortality [27]. Although alternative scoring systems have been described [28–30], Rockall's is the only score to have been validated internationally (externally) by other investigators [14,26,31–34]. The Forrest classification differs from the Rockall score as it is based purely on endoscopic findings and pertains only to rebleeding [8,35]. Thus, this would not be the appropriate choice of scoring system when trying to assess the benefit of a bleed unit in terms of mortality.

This study aims to assess the effectiveness of a centralised UGIH unit in the management of acute UGIH by using the Rockall score to allow for case-mix comparisons.

Patients and methods

Patients and organisation of upper-gastrointestinal haemorrhage unit

Data were collected prospectively on 900 consecutive patients admitted with suspected UGIH between October 1995 and July 1998. All patients with suspected upper-gastrointestinal bleeding referred to the hospital or who had bled within the hospital were admitted to a centralised UGIH unit. This was a universally agreed management protocol within the hospital. We further ensured that all patients with UGIH were included within the study by using identification discharge codes. This is the same system that was used in the original Rockall study and has been validated by other investigators [2,36]. The UGIH unit was part of the gastroenterology ward, where there was existing nursing expertise in the management of major gastrointestinal haemorrhage from oesophageal varices. All patients had a history of haematemesis or melaena. A nurse was assigned specifically to the unit with responsibility for implementation of the unit protocol and data collection.

Patient outcomes were entered prospectively into a dedicated UGIH database in a manner identical to that used in the National Audit [2]. Patients consented to have their clinical data stored on a dedicated database for the purposes of audit. Written guidelines were produced for the management of upper-gastrointestinal bleeding, based on recommendations published by the British Society of Gastroenterology, the Royal College of Physicians and the Royal College of Surgeons [20]. Consultants (with or without the support of a specialist registrar) from the gastroenterology unit were designated to provide a 24-h on-call service. This involved continuously available specialist clinical advice, immediate endoscopy (if haemodynamically unstable), and a minimum clinical input of a daily ward round. Nursing staff monitored patients for signs of recurrent/active bleeding by assessing haemodynamic parameters at least hourly. A change in the clinical status triggered further review by a gastroenterologist. We do not routinely insert nasogastric tubes or arterial or central venous lines. However, central access may be obtained in the presence of significant UGIH, in keeping with UK guidelines [20]. There is a 24-h on-call vascular radiology service available, including arteriography/embolisation therapy.

Gastroscopy was performed by a consultant or a supervised specialist registrar (usually within 24 h). However, if the registrar was experienced, then he or she could undertake the procedure independently, with consultant supervision available immediately on request. The registrars involved in the on-call service had all completed a minimum of 2 years of gastroenterology training before rotating to the post at the Royal Hallamshire Hospital. They had undertaken more than 1000 gastroscopies, of which approximately 5–10% were therapeutic.

Following endoscopy, we did not operate a specific policy of early discharge according to a low Rockall score (as suggested previously by other investigators [37]). Although we would recommend that patients

with a low Rockall score would be suitable for discharge, this was ultimately left to the discretion of the referring consultant. The logistics of our unit involve shared care between the gastroenterologist and admitting consultant throughout the patient's stay on the bleed unit, but thereafter the patient would again be under the care of the initial referring consultant. In specific cases where the primary problem was deemed to be of a significant gastroenterological cause, we would offer to take over the care of these individual cases.

Ethical approval was not required, since the database was established through the Royal Hallamshire Audit Group.

Management of upper-gastrointestinal haemorrhage

Duodenal and gastric ulcers with stigmata of recent haemorrhage (visible or spurting vessel, adherent clot) were injected with 1:100 000 adrenaline. Thereafter, we used an oral proton pump inhibitor. Eradication therapy for *Helicobacter pylori* was considered at a later date. Any patient on non-steroidal anti-inflammatory drugs or anticoagulants prior to admission would have these discontinued.

All patients with suspected varices received a 50- μ g intravenous bolus of octreotide on admission, followed by an infusion of 1 mg of octreotide in 55 ml of normal saline at a rate of 3 ml/h. This infusion was continued for 5–7 days or until the patient was no longer passing melaena. At endoscopy, if stigmata of recent haemorrhage were seen, then varices were injected with ethanolamine. Other therapeutic options such as Minnesota tubes were used as appropriate at the discretion of the endoscopist on-call. Patients were referred for, and underwent, surgery according to published guidelines [20].

Rockall scores

Patients were stratified for risk according to the criteria identified by Rockall *et al.* [27]. An initial score of 0–2 was considered low risk, 3–5 as medium risk and 6–7 as high risk. We subdivided patients into three groups because previous studies (and the original Rockall study) have attributed risk according to this manner [21,27,33,34,37]. For example, other investigators have demonstrated that patients with a complete score of 7 or above have a worse outcome [21,33,34]. Also, a complete score of 2 or less has been shown to have a low risk of rebleeding [37]. This subdivision of scores was based on our review of the current literature and advice from our statistical support (Statistical Services Unit, University of Sheffield). All patients who underwent upper-gastrointestinal endoscopy were also given a complete score with the addition of endoscopic diagnosis and stigmata of recent bleeding. A complete score

of 0–3 was considered as low risk, 4–6 as medium risk and 7 or more as high risk (Table 1).

For patients with oesophageal varices, we also calculated the Child–Pugh score to observe whether there was a correlation between this and the Rockall score. These data have already been published, revealing that the Rockall score was as predictive of rebleeding and mortality as was the Child–Pugh score [34].

Statistics

Rockall score distribution, both before and on completion of endoscopy, was compared in our cohort of patients with data from the National Audit using chi-squared testing. Crude and risk-standardised mortality ratios (SMRs) and 95% confidence intervals (CIs) were calculated, both for overall mortality and for each risk group [38]. In both cases, expected values were those from the National Audit [2]. Although the definition of SMR is a ratio of rate estimated between a cohort and the reference population, we have used the indirect method of standardisation for our data. We believe that using the National Audit as the reference population rate is a reasonable substitute for the general population, particularly as this is the largest body of data estimating incidence and mortality of UGIH in the UK. Thus, in our study the SMR is the ratio of the observed cases (in our own data) compared with the number of expected cases (the National Audit) [38].

Lengths of follow-up (exposure) in the National Audit group and our study are identical. Both studies reported proportion of deaths in in-patients [2].

The Statistical Services Unit, University of Sheffield, provided statistical support.

Results

Demographics

A total of 900 patients (491 males, 409 female) were considered to have had UGIH. Age distribution was as follows: 371 (41.2%) patients under 60 years, 163 (18.1%) aged 60–69 years, 164 (18.2%) aged 70–79 years, and 202 (22.4%) patients over the age of 80 years. The demographics of this population sample are similar to those of the National Audit [2]. In addition, any significant difference between the two cohorts would be corrected for, since age is an independent risk factor and is integral to the Rockall score.

During the study period (October 1995 to July 1998), there were 14 patients who were admitted directly to the ICU (with unrelated primary pathology) and then had a secondary diagnosis of UGIH. These cases were excluded from our analyses. There were no cases of terminally ill patients in whom intervention was deemed inappropriate.

The median duration of stay for the whole cohort was 4 days (range 1–44 days). The median duration of stay for patients with a variceal bleed was 6 days (range 2–44 days). However, this did not achieve statistical significance when compared with the rest of the group ($P = 0.08$). Patients with a variceal bleed often require a longer period of admission due to concomitant significant liver disease.

Endoscopy

Gastroscopy was performed in 841 (93.4%) patients within 24 h of admission to the unit.

Endoscopic diagnoses are given in Table 2. An ulcer was visualised in 278 patients (136 gastric, 121 duodenal, 21 oesophageal), of which 127 (45.7%) had stigmata of recent haemorrhage [27]. Endoscopic injection therapy was performed in 77.3% ($n = 157$) of patients with varices and 39.2% ($n = 109$) for bleeding peptic ulcers. The cohort of patients who had endoscopic injection therapy for peptic ulcer disease ($n = 109$) were those who had major stigmata of recent haemorrhage, i.e. a spurting vessel, adherent clot or visible vessel. The high rate of detection of stigmata of recent haemorrhage could be a reflection of early endoscopy, as described previously by many investigators [16].

Rebleeding and transfusion requirements

The rebleed rate was 20.1% (56 patients) in patients with cratered ulcers. A total of 213 patients had variceal bleeds, with a rebleed rate of 18.3% (39 patients).

Table 2 Endoscopic findings for the 841 patients who underwent gastroscopy

Diagnosis*	<i>n</i>	%
Oesophageal varices	203	24.1
Oesophagitis	126	15.0
Cratered duodenal ulcer	98	11.7
Cratered gastric ulcer(s)	88	10.5
Normal	71	8.4
Not endoscoped	59	7.0
Superficial gastric ulcer(s)	48	5.7
Gastritis	38	4.5
Bleeding ?cause	30	3.6
Mallory–Weiss tear	26	3.1
Superficial duodenal ulcer	23	2.7
Duodenitis	22	2.6
Oesophageal ulcer	21	2.5
Gastric varices	10	1.2
Gastropathy	9	1.1
Unable to intubate	5	0.6
Gastric carcinoma	5	0.6
Arteriovenous malformation	5	0.6
Gastric polyp	4	0.5
Gastric nodule	4	0.5
Gastric outflow obstruction	3	0.4
Duodenal polyp/tumour	2	0.2
Oesophageal polyp	2	0.2
Oesophageal carcinoma	1	0.1
Haemobilia	1	0.1

*There were 904 diagnoses, since 63 cases had dual pathology.

For patients with peptic ulcer, their transfusion requirements ranged from 0 to 16 units (1 unit = 300 ml). The median transfusion requirement was 3 units. For patients with variceal haemorrhage, their transfusion requirements ranged from 1 to 23 units. The median transfusion requirement was 4 units.

Surgery

A total of 58 patients (6.4%) with UGIH refractory to medical therapy required surgical intervention. The overall operative mortality was 13.8% ($n = 8$). Of those undergoing surgery, the most common reason was ulcer disease ($n = 35$), for which the operative mortality was 8.6% ($n = 3$). Other causes are given in Table 3.

Standardised mortality ratios and causes of death

Both initial and complete scores were significantly higher than those in the National Audit ($P < 0.001$). The median initial score both for the National Audit and for the Royal Hallamshire bleed unit was 3. The median complete score for the National Audit was 4, compared with 5 for the Royal Hallamshire bleed unit (Fig. 1). In our group the proportion of deaths was 73 (8.1%), while in the National Audit the observed proportion of deaths was 14%, giving a crude mortality ratio of 0.58 (95% CI 0.45–0.71). The proportion of deaths in patients with ulcer disease was 9.4% (26/278) and in patients with oesophageal varices 11.7% (23/197). The observed mortality for patients with peptic ulcer disease in the National Audit was 12% and with varices 23% [2].

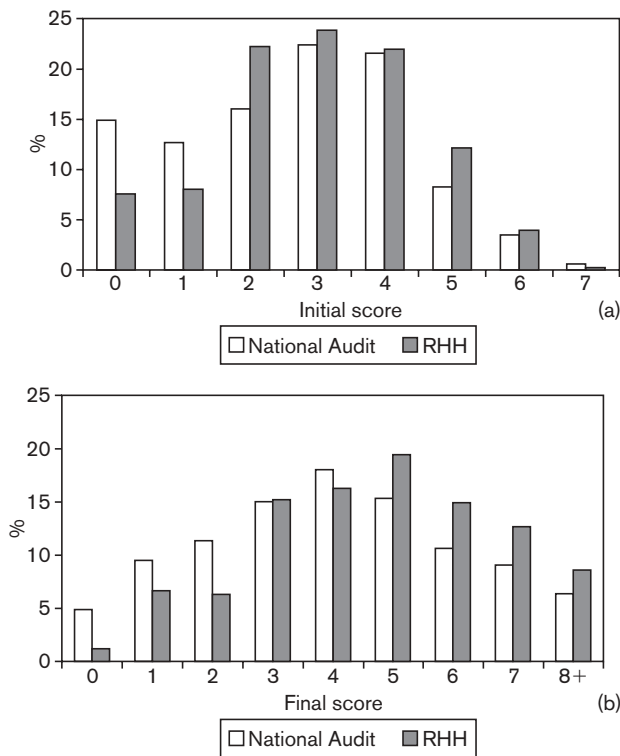
More importantly, the SMRs were significantly lower in our centralised unit for both initial (SMR 0.53, 95% CI 0.41–0.65) and final scores (SMR 0.63, 95% CI 0.48–0.78) (Fig. 2).

Using the initial scores, SMR was 0.60 (95% CI 0.12–1.08) for the low-risk group ($n = 340$), 0.52 (95% CI 0.36–0.65) for the medium-risk group ($n = 522$) and

Table 3 Diagnosis of patients requiring surgical intervention for upper-gastrointestinal haemorrhage

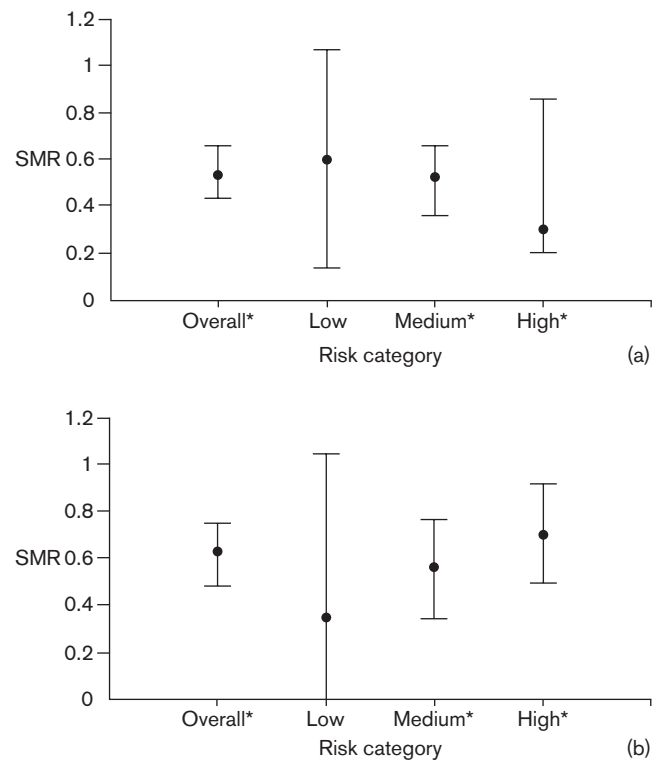
Operative diagnosis ($n = 58$)	<i>n</i>
Peptic ulcer	35
Carcinoma of stomach	7
Arteriovenous malformation	5
Varices	2
No cause found	2
<i>Stromal tumour:</i>	
Stomach	1
Small bowel	1
<i>Secondary deposit from:</i>	
Ovarian cancer	1
Colonic cancer	1
Pancreatic cancer	1
Haemobilia	1
Small-bowel ischaemia	1

Fig. 1



Comparison of (a) initial and (b) complete Rockall scores between the National Audit and the Royal Hallamshire Hospital (RHH) bleed unit.

Fig. 2



Comparison of standardised mortality ratios (SMRs) between the National Audit and the Royal Hallamshire Hospital bleed unit: (a) initial scores; (b) complete scores. * $P < 0.001$.

0.30 (95% CI 0.20–0.86) in the high-risk group ($n = 38$).

Using the complete scores, SMR was 0.35 (95% CI 0.00–1.04) for the low-risk group ($n = 246$), 0.56 (95% CI 0.34–0.78) for the medium-risk group ($n = 424$) and 0.70 (95% CI 0.49–0.91) in the high-risk group ($n = 178$) (Fig. 2).

Of the 73 patients who died, the mean age was 67 years, the mean initial score was 4.6, and the mean final score was 7.2. Seven patients died before endoscopy and could not be allocated a final score. All of these patients suffered cardiac arrest whilst being resuscitated. The primary cause of death was noted as ischaemic heart disease (4/7), cerebrovascular disease (1/7), uncontrolled haemorrhage (1/7) and renal failure (1/7). Causes of death for the whole cohort are outlined in Table 4.

Discussion

This study demonstrates a risk-adjusted mortality that is lower than that described in the National Audit and suggests that, contrary to previous observations, further

Table 4 Cause of death in patients with upper-gastrointestinal haemorrhage

Cause of death	<i>n</i>
Uncontrolled haemorrhage	16
Decompensated liver disease	17
Hepato-renal failure	8
Carcinomatosis	8
Ischaemic heart disease/cardiac failure	6
Pneumonia	6
Cerebrovascular disease	3
Peritonitis	3
Renal failure	2
Multiorgan failure	2
Pulmonary embolus	2

reductions in mortality can be achieved. The recognition of case mix as affecting the outcome in patients with UGIH is described well, particularly when considering age and comorbidity [14,24–26,31–34]. We observed a lower proportion of deaths in a large cohort of patients admitted to our specialised UGIH unit. By applying the Rockall scoring system to our data, and then comparing our data with those of the National Audit, we have demonstrated that our findings are independent of case mix.

Limitations of study

Our study differed from the National Audit in two respects. First, the Rockall scores in our cohort were significantly higher than those of the National Audit. This may be related to the higher proportion of patients with oesophageal varices in our series, since we provide a tertiary service for patients with oesophageal varices. This subgroup of patients with UGIH may have higher Rockall scores. There may be an improved outcome for variceal bleeding in a tertiary centre, and it is possible that this could bias our results [11,13]. Our observed mortality for patients with oesophageal varices was 11.7%, and the rebleeding rate was 18.3%. This compares favourably against the observed mortality for variceal patients in the National Audit (180/4185 of overall cohort), which was 23% [2]. We have confirmed recently the validity of the Rockall scoring system for patients with both oesophageal varices and peptic ulcers, so this is accounted for in the analysis [34]. We do not believe that an improved outcome within this subgroup of patients influences the results more than any other subgroup diagnosis, as case-mix adjustment is integral to the scoring system. In addition, varices represent only 24.1% of our cohort. Given that the mortality of variceal bleeding is reported to be higher than that of non-variceal bleeding, one may even expect this to negatively bias our results [8,11,13].

The second difference was our substantially higher rate of endoscopy (93.4%) compared with the National Audit (70.9%). This may account for our higher complete scores, as patients who were not endoscoped within the National Audit could have been too unfit for the procedure and thus no data would have been available for complete scores. This would lead to patients at greatest risk being excluded from the National Audit analysis if they died before endoscopy. We may have therefore underestimated the benefit of the UGIH unit.

We were unable to demonstrate an improvement in the proportion of deaths in the low-risk group, as the confidence interval only just crosses 1. This may be expected, as the benefit would be hardest to show within the low-risk group.

Previous investigators assessing the value of a centralised approach to bleeding have provided conflicting results. Kapur and colleagues [24] reported no difference in mortality when auditing UGIH in Gwent before and after the creation of a dedicated bleed unit. However, this was a smaller cohort ($n = 524$) with lower Rockall scores than our study. Although they applied Rockall scores to their cohort, they did not calculate SMRs, so no statistical comparisons could be made. Recently, Sandel and colleagues [25] suggested that the differences in mortality between patients admitted with

UGIH to general medical wards by comparison with gastroenterology could be attributed to case mix. This Dutch group observed that the comorbidity was greater in patients under the care of general medical firms. However, this study was smaller ($n = 322$), was retrospective, and sampled only a proportion of patients with UGIH during their study period. For comparisons between general medical and gastroenterology patients, they included only those patients admitted to hospital with UGIH. Thus, potentially the sickest group – patients who bled within the hospital and are usually transferred to the UGIH unit – were excluded from analysis. This highlights a further advantage of a UGIH unit, in that accurate data collection is greatly facilitated. Only 14 cases of UGIH were excluded from our study; these were all ICU patients with a secondary diagnosis of UGIH. Given the small number of patients (14/914 taken as a fraction of the whole study population), we would not expect the exclusion of this group to affect our results. In addition, case-mix adjustment has been an integral part of the evaluation. Finally, Sandel and colleagues [25] did not specify what specialist services were provided on their gastroenterology ward and whether they had the facilities that are available in a UGIH unit, e.g. 24-h on-call with immediate access to endoscopy, if indicated.

Sclerotherapy for the management of variceal haemorrhage has recently been superseded by banding [11,13]. Although it is now our practice to perform variceal banding preferentially to sclerotherapy, this was not the case during the timeframe of this study (October 1995 to July 1998). Preliminary reports of endoscopic combination therapy (adrenaline plus a further endoscopic intervention, e.g. endoclips) and intravenous omeprazole have shown a reduced risk of rebleeding in peptic ulcer disease [7,8,12]. Had we been using these novel modalities, then we may have reduced the rebleeding rates in our study and perhaps have had a modest effect on the proportion of deaths. However, this could have created a bias in our results by further improving our mortality in comparison with the National Audit. Data from the National Audit were collected from June to October 1993 [2]. During this period, the optimal management of UGIH would have been identical to our study. Thus, the absence of these novel modalities makes the two groups of patients more comparable. The similarity in therapeutic and endoscopic intervention between the two cohorts would suggest that the improved outcome is due to the creation of a dedicated UGIH unit.

Why should there be an improvement in the proportion of observed deaths with the creation of a centralised UGIH unit? A number of factors may be implicated, including rapid assessment, resuscitation and prompt endoscopy, appropriate use of endoscopic intervention,

early identification of rebleeding, and appropriate timing of surgery [15–17]. We cannot determine which of these has been most important, but all are facilitated by the creation of a specialist area allowing joint medical–surgical evaluation, implementation of predefined protocols, and monitoring by specialist nursing staff. We would suggest that it is the framework of a UGIH unit that creates an environment where patients are managed optimally.

Following the initial National Audit, Rockall *et al.* prospectively re-evaluated changes in practice and the mortality in patients with UGIH [39]. Specific recommendations were outlined to participating hospitals, re-emphasising the national guidelines. Despite this, Rockall *et al.* were unable to demonstrate an improvement in mortality [39]. Their suggestion was that only finite benefits could be derived because of the progressively elderly population with greater comorbidity. Although many of the hospitals had implemented protocols, their 24-h endoscopy rate was still only 56% and there was no observed difference in the use of high-dependency beds or joint medical and surgical care. This would substantiate our own data and imply that the creation of a centralised UGIH unit would improve mortality in the management of UGIH. Such centralised units have been described in district general hospitals and teaching hospital settings [6,21–25], but local arrangements to provide appropriate cover have to be made, involving medical and surgical endoscopists. Approximately 50% of the on-call service was undertaken by consultant staff ‘first on’. Having demonstrated a benefit, a case for adequate medical support has to be made. In addition, a centralised unit is considered to be potentially cost-effective [25].

Conclusion

The value of a centralised UGIH unit is analogous to the historical debate on the effectiveness of coronary care units in reducing mortality after acute myocardial infarction. Although a joint working party of the Royal College of Physicians and the British Cardiac Society recommended ‘that some form of specialized accommodation for the care of patients after cardiac infarction is essential’ [40], some published studies refuted this [41,42]. The ability to draw meaningful conclusions from such studies was hampered by case mix. This issue was only resolved by Chapman [43] using a prognostic index scoring system that corrected for variations in case mix and demonstrated a uniform reduction in mortality in this disease-specific situation.

In conclusion, our study is the first to correct for any influence of case mix and patient selection in the outcome of patients with acute UGIH. We observed a significantly lower proportion of deaths in patients admitted to a centralised unit, despite having a greater

number of patients with comorbid disease. We believe that all patients presenting with acute UGIH are managed optimally on a dedicated UGIH unit. However, validation of our observation is required by further prospective studies. Future investigators would also have to correct for case mix.

Acknowledgements

We are grateful to our nursing colleagues who have been involved in the running of the unit, including I. Epworth, J. Jones and C. Gummer who contributed to data collection and co-ordination of the unit during this study. In addition, we would wish to thank surgical and medical colleagues, in particular R. Davies and A. Majeed who were involved in the on-call rota.

Conflict of interest

None declared.

Authors' contributions

Alan Lobo, Simon Jones and Dermot Gleeson conceived and designed the study. Elaine McFarlane, Alan Johnson, Dermot Gleeson and Alan Lobo acted as clinical investigators. David Sanders, Mike Perry and Simon Jones interpreted the data and co-wrote the manuscript. David Sanders, Elaine McFarlane, Alan Johnson, Dermot Gleeson and Alan Lobo revised the drafts as well as the final version of the manuscript. David Sanders is the study guarantor.

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