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Influencing the practice and outcome in acute upper gastrointestinal haemorrhage

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Abstract

***Aims*—To assess changes in practice and outcome in acute upper gastrointestinal haemorrhage following the feedback of data, the reemphasis of national guidelines, and specific recommendations following an initial survey.**

***Design*—A prospective, multicentre, audit cycle. Forty five hospitals from three health regions participed in two phases of the audit cycle.**

***Patients*—Phase I: 2332 patients with acute upper gastrointestinal haemorrhage; phase II: 1625 patients with upper gastrointestinal haemorrhage.**

***Methods*—Patients were evaluated with respect to management (with reference to the recommendations in the national guidelines), mortality, and length of hospital stay.**

***Results*—Following the distribution of data from the first phase of the National Audit and the formulation of specific recommendations for improving practice, the proportion of hospitals with local guidelines or protocols for the management of upper gastrointestinal haemorrhage rose from 71% (32/45) to 91% (41/45); 12 of the 32 hospitals with guidelines during the first phase revised their guidelines following the initial survey. There was a small but significant increase in the proportion of all patients who underwent endoscopy (from 81% to 86%), the proportion who underwent endoscopy within 24 hours of admission (from 50% to 56%), and the use of central venous pressure monitoring in patients with organ failure requiring blood transfusion or those with profound shock (from 30% to 43%). There was, however, no change in the use of high dependency beds or joint medical/surgical management in high risk cases. There was no significant change in crude or risk standardised mortality (13.4% in the first phase and 14.4% in the second phase).**

***Conclusions*—Although many of the participating hospitals have made efforts to improve practice by producing or updating guidelines or protocols, there has been only a small demonstrable change in some areas of practice during the National Audit. The failure to detect any improvement in mortality may reflect this lack of change of practice, but may also reflect the fact that a large proportion of the deaths in this unselected study are not preventable; only a very large study could hope to demonstrate a significant change out of the context of a clinical trial.**

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Observation of clinical practice represents a large proportion of the total published research into upper gastrointestinal bleeding. Studies have used a variety of methodologies. Firstly, one off surveys of clinical practice and outcome carried out on a hospital basis have added to an understanding of the risk factors for gastrointestinal bleeding, as well as describing current practice in a particular institution. When conducted in a defined population they have also served to describe the epidemiology.[1] Secondly, there have been retrospective[2] and prospective[3] surveys over long periods of time that have allowed outcome to be assessed in relation to documented changes in practice. Schiller *et al*[2] looked at management and outcome in three consecutive quinquennia but were unable to demonstrate any improvement in outcome in terms of mortality despite apparent changes in diagnostic and surgical practice. Hunt,[3] on the other hand, in a prospective study over six years, showed quite convincingly that a prospective system of management with a dedicated unit and established protocols for resuscitation, rapid endoscopy, and surgical intervention was associated with steadily improved mortality in three consecutive two year periods. Thirdly, surveys have been undertaken and the findings compared with previously published data in the same districts[4] or with other entirely separate studies.[5]

These studies unfortunately suffer from the inevitable variation in methodology which makes comparisons difficult and unreliable, especially when prospective studies are compared with retrospective studies. Furthermore, most of these studies are far too small for anything but very large differences to be regarded as other than chance phenomena. Fourthly, studies that more closely represent true audit have undertaken an initial retrospective survey to quantify and qualify the management and outcome and have followed this with a prospective analysis to determine the impact of specific alterations in practice.[6] These studies also suffer from the necessity to compare retrospective and prospective data and still require the equality of case mix to be established, but do have constancy of definitions, criteria, and population.

This report compares two large prospective studies using identical methodologies in the same population. Having performed an initial audit, we undertook a process of active feedback of data and guideline dissemination; and made specific recommendations for improving practice on a multicentre basis. We examined the impact of this process by means of a second National Audit of acute upper gastrointestinal haemorrhage, thus closing the audit cycle.

Subjects, Methods and Definitions

AUDIT

The method of case identification and data collection has already been described.[7 8] All patients aged 16 and over, fulfilling our definition of acute upper gastrointestinal haemorrhage, were recruited to the study. Patients were identified prospectively and detailed standardised questionnaires were completed by medical staff involved with the management of each case. An identical methodology was used during the second phase of the study. The first phase spanned a four month period in 1993 (from June to September or from July to October) and the second phase spanned a three month period from May to July 1994, allowing at least a six month period between the two phases of the study. In total 2332 cases were identified during the first phase at the 45 hospitals that repeated the audit cycle. During the second phase, 1625 cases were identified.

Definitions and criteria used in the study have been published previously.[7]

MEASURES TAKEN BETWEEN THE TWO PHASES OF THE AUDIT

In October 1993, following the initial audit, bound copies of the national guidelines[9] were sent to physicians, surgeons, and geriatricians that had been identified as being regularly involved in the management of acute upper gastrointestinal haemorrhage. During January 1994 a meeting was convened in each of the health regions involved, and the findings of the National Audit were presented in relation to the national guidelines. In February 1994, copies of an analysis of the data were sent to each participating audit unit, each lead clinician, and each audit chairman, as well as other involved personnel. The format of this document allowed each unit to extract its own data using confidential codes, and to compare it with other units and the overall results. This book was accompanied by a series of recommendations which are outlined below, as well as an encouragement to present and discuss the results locally at audit meetings, grand rounds, or other forums. The period of time between the dissemination of the national guidelines and the second phase was therefore six or seven months; the time between the feedback of individualised data and the second phase was three months. Information regarding structural facilities and changes undertaken between the two studies was supplied by a consultant gastroenterologist at each hospital.

RECOMMENDATIONS MADE

- Hospitals without widely available local guidelines or protocols for the management of acute upper gastrointestinal haemorrhage should produce these with reference to the national guidelines and the structural facilities available.
- Patients presenting with acute upper gastrointestinal haemorrhage should undergo endoscopy within 24 hours of admission. High risk patients should undergo endoscopy within 12 hours following resuscitation.
- Patients with lesions amenable to endoscopic haemostatic therapy should receive this treatment at the time of the initial endoscopy in order to reduce the rate of further haemorrhage with its associated increase in mortality. This refers in particular to peptic ulcers with visible vessels and oesophageal varices.
- Patients with organ failure at presentation requiring blood transfusion, and patients presenting with severe hypotension suggestive of major blood volume loss, should have a central venous pressure line as part of their management in order to monitor the transfusion of fluids and give an early indication of continued or recurrent haemorrhage
- Patients presenting with acute upper gastrointestinal haemorrhage who are therapeutically anticoagulated or who have established liver disease should have a test of blood coagulation performed urgently in order to establish the presence of over anticoagulation or potentially correctable coagulopathy.
- Patients who are at particular high risk of further haemorrhage and death should be managed in beds allocated to the care of high dependency patients.
- Patients at high risk of rebleeding and death should be jointly managed from the outset by physicians and surgeons. In patients requiring potential surgical intervention and in particular those aged over 60 and who have a further haemorrhage, a consultant surgeon should be involved in the decision to operate.

Results

Forty five hospitals took part in both phases of the audit cycle. The first phase identified 2332 patients over a four month period and the second phase identified 1625 patients over a three month period. The patients were carefully assessed to establish whether the case mix was similar in each group, so that valid comparisons of management and outcome could be made. Table 1 shows the similarity between the two groups with regard to epidemiological and other risk factors that contribute to the case mix. In addition, the distribution of risk scores[10] was similar in both phases of the study. No significant differences between the two groups by any of these parameters was evident.

PROTOCOLS AND GUIDELINES

During the first phase of the audit, 32/45 (71%) of the hospitals already had some form of local guidelines or protocols for the management of admissions with acute upper gastrointestinal bleeding, although these varied considerably in format, content, and availability to junior staff. Following the feedback of data from phase I, 12 of the 32 hospitals revised or updated their guidelines. Of the 13 hospitals without any guidelines originally, five had developed and disseminated new guidelines, four had adopted the "national guidelines" for use locally, one had plans to develop them in the near future, and three had taken no action in this regard. In summary, during the second phase of the study the proportion of hospitals with guidelines had risen from 71% to 91%, and 38% of the hospitals with guidelines had revised them. Prior to the start of the second phase of data collection, 43 of the 45 hospitals had undertaken both local presentation and discussion of the results in a variety of forums.

TABLE 1 *Characteristics of sample populations in phase I and II*

	Phase I	*Phase II*
Number of cases	2332	1625
Inpatients/transfers	15.9% (371)	16.4% (266)
Age		
Mean	66	66
Median	71	71
Range	16–103	17–103
% >80 years	27.2% (634)	28.6% (464)
Sex (male)	57.0% (1327)	57.5% (934)
Blood pressure <100 mm Hg on admission	11.2% (256/2293)*	11.8% (191/1613)*
Co-morbidity at presentation		
Any major co-morbidity	59.1% (1378)	59.4% (965)
Malignancy	8.2% (191)	8.9% (145)
Organ failure	15.2% (354)	15.9% (259)
Diagnosis		
None made	23.2% (542)	23.0% (374)
Peptic ulcer	36.1% (842)	36.4% (592)
Upper GI malignancy	4.0% (93)	4.1% (67)
Varices	4.6% (108)	4.9% (80)
Mallory-Weiss tear	5.1% (119)	6.0% (98)
Oesophagitis	10.3% (241)	11.0% (179)
Erosive disease	10.3% (240)	10.9% (177)
Other	6.3% (147)	3.6% (58)
Blood transfusion		
Mean	2.9 units	2.8 units
Median	2.0 units	2.0 units
Rebleeding	15.4% (354/2297)*	16.2% (260/1605)*
Risk score		
0	14.7% (343)	15.7% (255)
1	13.5% (314)	12.6% (205)
2	17.2% (401)	16.2% (263)
3	22.1% (515)	19.5% (317)
4	21.0% (489)	22.6% (368)
5	7.6% (177)	8.7% (141)
6+	4.0% (93)	4.7% (76)

*Denominator is less than total number of cases because of missing values. GI, gastrointestinal.

TABLE 2 *Endoscopic practice*

	Phase I	*Phase II*
Number of patients	2332	1625
Exclusions	122 (5.2%)	132 (8.1%)
Patients analysed	2210	1493
Total undergoing endoscopy during admission	1800/2210 (81.4%)	1271/1493 (85.1%)*
Total undergoing endoscopy within 24 hours	1108/2210 (50.1%)	836/1493 (56.0%)†
Total number of higher risk patients endoscoped within 12 hours (initial risk score >2)[10]	277/1194 (23.2%)	198 / 802 (24.7%)
Total number of patients with varices or peptic ulcers with visible/spurting vessels	190	146
Patients receiving treatment at initial endoscopy	136/190 (72.3%) +7 subsequently Total = 143 (75.2%)	105/146 (71.9%) +7 subsequently Total = 112 (76.7%)

*Increase, 3.7% (95% confidence interval 1.3% to 6.1%).
†Increase, 5.9% (95% confidence interval 2.6% to 9.1%).

TABLE 3 *Other aspects of management*

	Phase I	*Phase II*
Central venous pressure monitoring		
All patients	287/2332 (12.3%)	298/1625 (18.3%)*
High risk patients presenting with a systolic BP <70 or patients with concomitant cardiorespiratory disease and requiring blood transfusion	126/421 (29.9%)	129/299 (43.4%)†
Test of coagulation		
All patients	1294/2332 (55.5%)	1055/1625 (64.9%)‡
Patients with liver disease	124/139 (89.2%)	127/149 (85.2%)
Anticoagulated patients	111/135 (82.2%)	70/81 (86.4%)
Use of high dependency facility		
All patients	203/2322 (8.7%)	146/1625 (9.0%)
High risk (initial risk score >2)[10]	127/1274 (10.0%)	94/ 902 (10.5%)

*Increase, 6.0% (95% confidence interval (CI) 3.7% to 8.3%); †increase, 13.2% (95% CI 6.1% to 20.3%); ‡increase, 9.4% (95% CI 6.4% to 12.5%).
BP, blood pressure.

USE OF DIAGNOSTIC AND THERAPEUTIC ENDOSCOPY

Four aspects of endoscopic practice were studied: proportion of all patients undergoing endoscopy; time between presentation and endoscopy; time between presentation and endoscopy in high risk patients; and use of endoscopic therapy in amenable lesions, namely oesophageal varices and peptic ulcers with visible or spurting vessels.

Some groups of patients were excluded from the analysis of endoscopic intervention. These included patients that did not undergo gastroscopy for the following reasons: patients specifically categorised as terminal care patients; patients who refused or whose family refused to consent to endoscopy; patients self discharging prior to endoscopy being undertaken; patients requiring direct and urgent surgical intervention because of rapid exsanguination; patients with a specific contraindication to endoscopy; and patients who died rapidly on admission. By these criteria, 122 patients were excluded from phase I and 132 from phase II.

Table 2 shows that in phase I, 81.4% of all patients underwent endoscopy at some time during admission, compared with 85.1% in phase II. The number of patients undergoing endoscopy within 24 hours rose from 50.1% in phase I to 56.0% in phase II. The number of acutely admitted high risk patients, defined as having a risk score of greater than 2,[10] undergoing endoscopy within 12 hours was 23.2% in phase I and 24.7% in phase II.

A total of 190/2210 (9%) phase I and 146/1493 (10%) phase II patients had either endoscopically diagnosed peptic ulcer disease with a visible or spurting vessel recorded, or bleeding oesophageal varices visible at endoscopy. Of this group, 72.3% phase I patients received endoscopic therapy in a variety of forms at the time of the initial endoscopy. A further 2.9% had therapy instituted at a subsequent endoscopy because of continued or recurrent bleeding. In phase II, the proportion of these cases receiving therapy was 71.9% at the initial endoscopy, with a further 4.8% subsequently. Although small, both the rise in the total number of patients undergoing endoscopy

TABLE 4 *Surgical practice*

	Phase I	*Phase II*
Operative rate		
For bleeding	134 (5.7%)	82 (5.0%)
For malignancy	18 (0.8%)	12 (0.7%)
For other reason (e.g. peritonitis)	29 (1.2%)	17 (1.0%)
Total	181/2332 (7.8%)	111/1625 (6.8%)
Operator (all patients operated)		
Consultant	91/181 (51.3%)	56/111 (50.5%)
Unsupervised registrar	36/181 (19.9%)	22/111 (19.8%)
Involvement of surgical team in management		
All patients	905/2332 (38.8%)	621/1625 (38.2%)
Over 60 and rebleed	186/270 (68.9%)	125/197 (63.5%)
Shocked, >4units transfused and rebleed	48/61 (78.3%)	34/44 (77.3%)
Risk >2	543/1274 (42.6%)	377/902 (40.2%)
Consultant informed prior to operation	149/181 (87.6%)	93/111 (85.3%)
Consultant examination prior to operation	102/181 (59.3%)	69/111 (64.5%)

TABLE 5 *Outcomes*

	Phase I	*Phase II*
Days in hospital (acute cases)		
Mean	8.9	8.1
Median	6	5
Days in hospital (low risk: score <2)		
Mean	5.6	5.5
Median	4	4
Surgical intervention for acute bleeding	134/2332 (5.7%)	82/1625 (5.0%)
Crude mortality	13.4% (308/2301)	14.4% (231/1615)
Risk standardised mortality ratio	Reference = 100	0.96 (0.84–1.09)
Surgical mortality	35/134 (26.3%)	17/82 (21.3%)

and the proportion who underwent endoscopy within 24 hours were statistically significant.

ADMISSION WARD, INVESTIGATION, AND USE OF CENTRAL VENOUS PRESURE MONITORING

All participating hospitals had access to intensive therapy unit beds. Ten of the 45 had in addition access to high dependency beds or special gastrointestinal bleed facilities. For this analysis, we have included as a high dependency bed, any of the following: intensive therapy unit, high dependency unit, coronary care unit, gastrointestinal unit (including liver units), and emergency admission units, all of which would be expected to have more intensive nursing and monitoring facilities than would normally be found on a general ward. Of all patients admitted during the first phase, 203/2332 (8.7%) were managed in a high dependency facility compared with 146/1625 (9.0%) during the second phase (table 3). For high risk patients with a risk score of more than 2, 127/1274 (10.0%) during the first phase and 95/902 (10.5%) during the second phase were managed in these units.

For all patients, the use of central venous monitoring rose from 12.3% (287/2332) to 18.5% (298/1625). The use of central venous pressure lines in patients presenting with profound shock (systolic blood pressure <70 mm Hg) or who had organ failure at presentation and required blood transfusion, rose from 126/421 (29.9%) to 129/299 (43.4%) in the second phase (an increase of 13.2%; 95% confidence intervals 6.1% to 20.3%).

The investigation, in the acute phase, of blood coagulation rose overall from 1294/2332 (55.5%) to 1055/1625 (64.9%). However, in patients with known liver disease or who were therapeutically anticoagulated, there was no change from 235/274 (85.8%) to 197/230 (85.6%).

SURGICAL PRACTICE AND INTERVENTION

There was no significant change in the degree of surgical involvement either overall or in the specific high risk categories. The actual rate of surgical intervention was higher in the high risk subgroups specified in table 4, being 21.1% (phase I) and 19.3% (phase II) higher in these high risk groups than the overall rate in patients over the age of 60 who rebled; and 31.1% (phase I) and 22.7% (phase II) higher in those with shock on admission, high transfusion requirements, and rebleeding more than four times. These rates were between four and five times higher than the overall rate. The role of the consultant in the decision to operate by examining the patient preoperatively did rise slightly from 59% to 65%, but not significantly so. Twenty per cent of operations were still undertaken by unsupervised registrars.

OUTCOME

Table 5 shows crude and risk adjusted mortality for all patients, length of hospital stay for acute admissions and low risk cases, surgical intervention, and surgical mortality. There were no statistically significant differences in crude or risk adjusted mortality in any of these subgroups. The mean and median hospital stay for acute admissions was less in the second phase by a factor of about one day. This was not, however, the case in the low risk groups (who might most safely benefit from early discharge). This finding may reflect the increase in early endoscopy described above.

Discussion

We conclude that as a result of this audit process, action has been taken by many of the participating hospitals to improve management by producing or updating local guidelines or protocols. In addition some units were able, within the relatively short time frame of the study, to introduce structural changes in order to facilitate improvements in care in relation to the national guidelines. Overall, some small but statistically significant changes have taken place in terms of the extent and rapidity of diagnostic endoscopy undertaken and in the use of central venous pressure monitoring for patients presenting with organ failure and requiring blood transfusion or presenting with profound shock. However, there was no measurable improvement in some important aspects of care such as the use of high dependency beds; the investigation of clotting function in those at high risk of clotting abnormalities; combined medical-surgical management of high risk cases; consultant surgical involvement in the decision to operate; and endoscopic therapy in cases of haemorrhage from varices or peptic ulcers with visible vessels (even when patients going directly to surgery are excluded). There was no change in mortality.

Our inability to stimulate major improvements in practice is disappointing, and may have several reasons. Firstly, the multicentre nature of this study means that any changes in

structure or practice are not uniform. Benefits at some centres may therefore be obscured by the lack of change at other sites. Secondly, structure and process varied considerably between units at the starting point, as teaching hospitals with established gastrointestinal bleeding units as well as district general hospitals with single handed gastroenterologists were included in the study. Thirdly, the time interval between the feedback of data and the second phase of data collection may have been insufficient for structural changes, such as the institution of improved endoscopy services for acute upper gastrointestinal bleeds and high dependency beds, to have been implemented. Nor indeed may the finances be available for such changes over a short period.

Large scale behavioural changes as well as structural changes are likely to take a considerable period of time, and it may be that only an increased awareness of the situation can be achieved within a short time frame. However, the few specific areas we have reported on were deliberately chosen because they could relatively easily be incorporated into existing practices without any major structural changes being made, as they mostly consisted of simple management issues.

The inability to demonstrate an improvement in mortality is disappointing but perhaps not surprising for several reasons. Firstly, several studies of the current epidemiology of upper gastrointestinal haemorrhage (including this one) suggest that the number of preventable deaths may be quite small.[8] Secondly, the size of the change in practice that we have observed would not be expected to result in a significant change in outcome in a study of this size. As a result very much larger studies would be required to demonstrate statistical differences in mortality.

Mortality is however not the sole outcome measure. There is evidence,[6] which is supported by data from this study,[11] that a proportion of patients can be identified and managed as outpatients or with limited admission and early discharge, with considerable resource savings. The median time spent in hospital for this very low risk group was four days in both phases of the audit. The implementation of early discharge policies does, however, necessitate a rapid diagnostic endoscopic service in order to identify these cases.

Can audit influence practice and outcome? The effect of feedback of information on clinical practice is integral to discussion of the usefulness and effectiveness of clinical practice guidelines and audit in influencing practice and outcome. A review of 36 studies of intervention using the feedback of statistical data concluded that feedback of data is necessary but not sufficient in the process of maintaining high quality clinical care.[12] On the basis of limited evidence, active feedback appears better than passive, targeting the decision makers who have already agreed to review their practice; information feedback presented close to the time of decision making is likely to be most effective. The optimal mode of presentation is as yet unclear.

Theoretical resistance to the implementation of guidelines, such as the stifling of clinical freedom and innovation, the formalisation of unsound practice, standardisation of practice around the average, and the legal implications continue to be put forward,[13] but there is also a substantial weight of opinion in their favour.[14 15] The arguments against their introduction seem to confuse their purpose with that of protocols (which have a different role) and imply that all clinicians treating common conditions are sufficiently expert in that field to be allowed complete freedom of action. At consultant level, specialisation has not advanced so far that all common conditions are managed by specialists in that field, and it is certainly true that not all acute upper gastrointestinal bleeds are managed by gastroenterologists. It has been shown in other areas of clinical medicine such as the management of asthma,[16] that while the specialists in the field tend to follow the recommendations of guidelines (perhaps because of a knowledge of the research on which they are based), many generalists do not. In addition, the structure of health care in the UK means that most acute conditions are managed, at least initially, by junior staff in training. It should be recognised that guidelines have an important educational role in an environment where it is impossible for clinicians continually to keep abreast of all the published literature in each of the fields to which they are exposed in everyday practice.

There was a large active component to the dissemination of this data, by the use of regional presentations, the targeting of consultants (specialist and non-specialist) with national guidelines and recommendations, as well as the feedback of confidential comparative data in numerical and graphical formats. In addition, local discussion of the results and their implication was encouraged, as was the development or revision of local guidelines or protocols with reference to the national publication with its emphasis on local ownership. The issue of informing and educating the junior staff was tackled locally by the lead consultants and audit departments in the form of local audit meetings, either as a special event or as part of a routine audit programme, and often on more than one occasion.

Producing and disseminating guidelines is one step in attempting to remove unacceptable management practices and ensure that practices of established benefit (from clinical trial evidence) are not ignored. One of the criticisms of guidelines is that they have usually failed in their ultimate aim of improving practice and outcome; the reasons for this are probably complex. Tactics that have proved most successful to the implementation of change have been the use of financial or contractual inducements, neither of which have been a feature of this study. Having gone through a period of substantial national guideline production, the next challenge is to find methods that will result not only in the acceptance and promotion of guidelines, but a measurable change in practice in line with their recommendations.

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