Selective Outpatient Management of Upper Gastrointestinal Bleeding in the Elderly: Results from the *SOME* Bleeding Study

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To determine whether elderly patients with upper gastrointestinal bleeding could be safely managed as outpatients, 84 patients (65 years and older) were studied over a 23-month period. Urgent outpatient endoscopy was performed and clinical as well as endoscopic criteria were applied to determine the need for hospital admission. Patients with endoscopic findings that indicated a low risk for rebleeding were not admitted if they lacked one major or three minor predefined clinical criteria. All enrollees were monitored with hematocrit determination and clinical assessments for 4 weeks after discharge from the clinic or hospital. Twenty-four (29%) patients were treated as outpatients; none rebled. In contrast, seven (12%) of the 60 inpatients had one or more rebleeding episodes (p = 0.002). Bleeding from peptic ulcer disease was associated with use of nonsteroidal anti-inflammatory medications in 81% of patients. We conclude that selective outpatient management of elderly patients with upper gastrointestinal bleeding can be done safely and can potentially reduce health care expenditures.

Upper gastrointestinal bleeding (UGIB) is a common disorder that customarily requires inpatient hospital care. Yearly admission rates have been estimated to be 150 per 100,000-population (1). The health care expenditure for the treatment of UGIB has been estimated to exceed $2.5 billion a year in the United States alone (2). This figure will likely increase as the elderly live longer. Peptic ulcer disease (PUD) will continue to be a major health problem for this segment of the population due to the high frequency of *Helicobacter pylori* infection in patients over 60 years of age (3) and the frequent consumption of nonsteroidal antiinflammatory drugs (NSAIDs) by the elderly (4). Since elderly patients have an increased morbidity and mortality due to UGIB (5-8), outpatient management of this disorder represents a particular challenge in this group. Theoretically, outpatient management can be achieved by the development of appropriate practice guidelines that take into account endoscopic features predicting the likelihood of recurrent hemorrhage or the possible need for surgery, as well as clinical features predicting good clinical outcomes.

It has been suggested that patients with low-risk endoscopic findings can be discharged immediately after stabilization without compromising the quality of care (9). Several studies have utilized endoscopic and clinical criteria to select patients with UGIB for outpatient management (10-12). None of these studies, however, has specifically addressed UGIB in the elderly. We, therefore, chose to study the selective outpatient management of UGIB in the elderly based upon the hypothetical consideration that a set of clinical and endoscopic criteria could be developed that would allow us to provide more appropriate utilization of healthcare resources and prevent unnecessary hospitalization.

Materials and Methods

Study Design

Patients were referred to members of the gastroenterology section by Ochsner emergency department staff and primary care physicians at Ochsner Clinic's main campus and satellite clinics. All patients 65 years of age or older with UGIB who were participants in a managed care contract between the Health Care Financing Administration and both the Ochsner Clinic and Ochsner Foundation Hospital were eligible for the study. Patient enrollment began in December 1995 and terminated on November 1997.

Patients were evaluated by members of the Section on Gastroenterology within 2 hours of presentation to the Ochsner Clinic or the Emergency Department of the Ochsner Foundation Hospital. Each patient was seen by a GI subspecialty resident and staff physician fully acquainted with the predefined criteria for admission to the hospital or intensive care unit (ICU) and discharge from the outpatient setting. For the purposes of the study, UGIB was defined as the presence of hematemesis or melena within the preceding week, or a decrease in hematocrit of 5% or more in association with orthostasis or hypotension. Orthostasis was defined as a rise in pulse ≥15 beats per minute or a fall in systolic blood pressure of ≥15 mHg from supine to erect position. Patients with orthostasis were given 1 L of normal saline intravenously over 1 hour and reassessed (see Figure 1). Persistent orthostasis required admission to the ICU. In all other instances, every effort was made to evaluate patients with upper endoscopy (EGD) while they were still outpatients. The results of the EGD were graded as low-, moderate-, and high-risk for rebleeding according to the criteria defined in Table 1. Patients with high-risk lesions required admission to the ICU; individuals with moderate-risk lesions required admission to a 23-hour observation unit or were directly admitted to the hospital ward as deemed medically necessary. In all other instances, comorbid illnesses and the need for social support were recorded to determine whether outpatient management was safe and feasible for each individual. These factors were classified as major and minor clinical criteria for admission (see Table 2). Patients with low-risk endoscopic findings required admission to a 23-hour observation unit if they had one major or three minor clinical criteria for admission. Patients with low-risk endoscopic lesions and no clinical criteria for admission were managed as outpatients (Figure 1). A questionnaire including socio-demographic data, a listing of any significant comorbid illnesses, prior history of UGIB, and risk factors for peptic ulcer disease, including a detailed history of NSAID use was filled out on all patients during the initial assessment immediately prior to endoscopy.
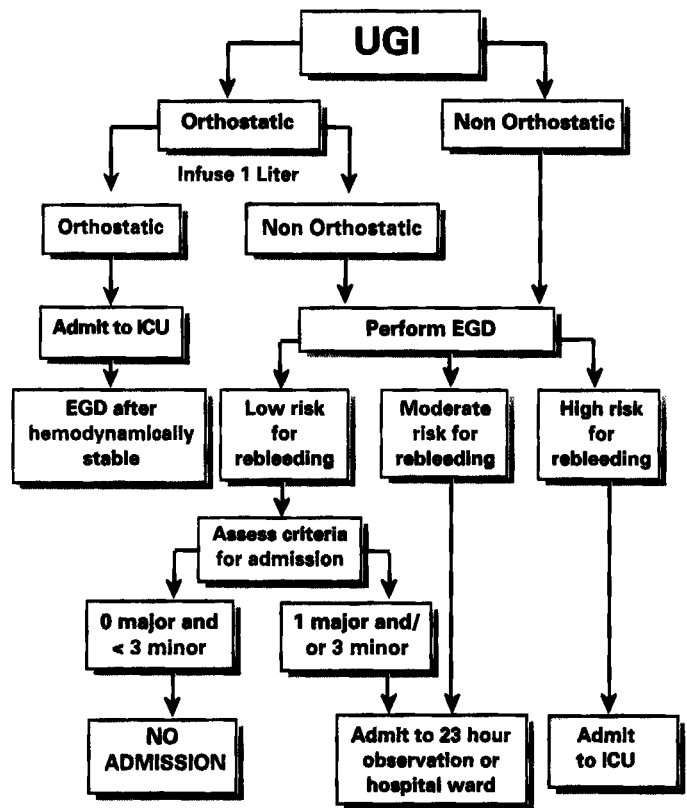

Fig 3. Etiology of peptic ulcer disease in prospectively studied patients. NS = normal saline.

Table 1. Risk of Rebleeding from Different Endoscopic Lesions*
Low Risk White base ulcer <1.5 cm in diameter Erosive mucosal disease (esophagus, stomach, or duodenum) Non bleeding Mallory Weiss tear Portal hypertensive gastropathy
Moderate Risk Ulcer >1.5 cm in diameter Ulcer with pigmanted flat spot Ulcer with non bleeding visible vessel that the endoscopist felt was adequately treated Ulcer with adherent clot after agressive washing for 5 minutes Blood in stomach, no source found
High Risk Actively bleeding ulcer or Mallory tear Ulcer with non bleeding visible vessel unable to treat endoscopically Ulcer >5 cm in diameter and/or >1 cm depth Ulcer on posterior wall of duodenum Dieulafoy's lesion
*Based on references 14 and 15

Table 2. Criteria for Admission.

Major Criteria for Admission
  Severe cardiac disease/ recent MI
  Severe respiratory failure
  Decompensated cirrhosis
  Severe coagulopathy (INR ≥ 1.5)
  Poor social support
  Requires blood transfusion
  Recent cerebrovascular accident

Minor Criteria for Admission
  Mild/moderate cardiac disease
  Obstructive pulmonary disease requiring medication
  Age >75 years
  Compensated cirrhosis
  Chronic renal failure, dialysis dependent
  Mild coagulopathy (INR <1.5)
  Remote cerebrovascular accident
  Poor nutritional status

INF = International normalization ratio
MI = Myocardial infarction

Table 3. Follow-Up Evaluations for Prospective Protocol after Discharge from the Clinic or Hospital

Presence of
  1. Melena
  2. Bright red or maroon stools
  3. Hematemsis
  4. Dizziness, lightheadedness, or syncope
  5. Palpitations

Use of
  6. Iron supplementation
  7. Other medications
  8. Over-the-counter nonsteroidal anti-inflammatory
    medications
      Type
      Dose and frequency of use
      Reason for use

Laboratory data
  9. Hemoglobin and hemocrit at discharge, 1 week,
    and 4 weeks after discharge

Table 4. Comparison of the Inpatient and Outpatient Groups

Value	Outpatient	Inpatient	P
Patient Number	24	60	
Mean Age (yr)	74	74	.71†
Median Age (yr)	72	73	
Age Range (yr)	65-91	65-89	
Female	6 (25%)	27 (45%)	
Male	18 (75%)	33 (55%)	0.09
Prior History of PUD	10 (42%)	25 (42%)	1.00
Prior History of UGIB	8 (33%)	15 (25%)	0.44
Ethanol Use*	2 (8%)	4 (7%)	0.79
Tobacco Use	3 (13%)	11 (18%)	0.52
Presenting Symptoms			
Melena	18 (75%)	43 (72%)	0.76
Weakness	2 (8%)	22 (38%)	0.009‡
Hematemesis	10 (42%)	14 (23%)	0.09
Orthostasis	3 (13%)	19 (32%)	0.07
Abdominal Pain	5 (21%)	13 (22%)	0.93
Syncope	0	6 (10%)	0.12
Hematochezia	0	5 (8%)	0.18
Dyspepsia	1 (4%)	3 (5%)	0.67
Bleeding Lesions			
Peptic Ulcer	11 (46%)	46 (77%)	0.006‡
Mucosal Erosions	6 (25%)	3 (3%)	0.01§
Tumor	0	3 (5%)	0.34
Mallory-Weiss Tear	2 (8%)	2 (3%)	0.32
Dieulafoy	0	2 (3%)	0.51
Grade IV Esophagitis	2 (8%)	1 (2%)	0.19
Esophageal Ulcer	1 (4%)	1 (2%)	0.49
Arteriovenous Malformation	0	1 (2%)	0.71
Portal Gastropathy	1 (4%)	0	0.28
No Lesion Found	1 (4%)	1 (2%)	0.49

*Daily consumption > 60 grams/day; †Student's t test; ‡Chi-square; §Fisher's exact test; PUD=peptic ulcer disease; UGIB=upper gastrointestinal bleeding

We attempted to determine the cause of mucosal injury in our patient population by testing all patients with PUD or erosive mucosal disease for *H.pylori* with the Clo test (Tri-Med Specialties Inc., Overland Park, KS) and with Pyloritek (SerimTM Research Corporation, Elkhart, IN) after June 1997.

In instances where the physician performing the endoscopy decided not to obtain mucosal biopsies, serum samples were evaluated for IgG antibody to *H. pylori* by enzyme-linked immunoassay (Wampole Laboratories, Cranbury, NJ).

Patients with PUD or erosive mucosal disease who were taking NSAIDs other than aspirin for cardiac prophylaxis were instructed to discontinue these medications and, if necessary, use non-ulcerogenic pain medications such as acetaminophen. Upon discharge from the clinic, emergency room, or hospital, the study nurse contacted each patient by telephone and recorded data pertaining to clinical evidence of rebleeding (see Table 3). The survey was conducted at 2 days, 1 week, and 3 weeks after discharge. Four weeks after discharge, each patient was interviewed and examined by a physician investigator. Each patient had a hemoglobin and hematocrit determination upon discharge and at the end of the first and fourth week post discharge.

Data Analysis

Continuous variables were evaluated by Student's t test, whereas categorical variables were evaluated by X^2 or Fisher's exact test whenever appropriate. The X^2 test for Goodness of Fit was applied to the relative risk of rebleeding according to the disposition status as follows: no admission, admission to 23-hour observation or hospital ward, and admission to the intensive care unit (13).

Results

In the 23-month period from December 1995 to November 1997, 84 Medicare-contracted patients were enrolled in this prospective study. For purposes of this study, we excluded three patients who were under the age of 65.

Twenty-four patients (29%) were managed as outpatients. Eighteen of the 24 patients (75%) had melena and 10 (42%) had hematemesis upon initial presentation. The mean duration of bleeding before endoscopy was 2.3 days (range 0 to 10 days). The requirements for outpatient management were met by 22 (92%) of these patients. One of the patients who received outpatient management without meeting the criteria had a history of severe cardiac disease and the other individual was on warfarin with an international normalization ratio of 2.0. Both of these individuals, however, had low-risk endoscopy findings (gastric erosions and non-bleeding Mallory-Weiss tear, respectively). In addition, a patient who required blood transfusion and met all other criteria for outpatient management was transfused in the emergency room. Each of these patients had no further bleeding. Hematocrits increased a mean of 0.4% and 2.0% at 1 and 4 weeks from discharge, respectively, in patients who were managed as outpatients. There were no clinical episodes of rebleeding during the 30-day follow-up period.

During the study period, 60 patients (71%) were admitted to the hospital. The mean length of stay for these patients was 2.0 days. Sixteen subjects (27%) were hospitalized for less than

24 hours and 15 (25%) were directly admitted to an intensive care unit. Admission was required, according to our criteria, in 93% of these patients. In retrospect, four patients could have been managed as outpatients and were directly admitted to the hospital by a primary care physician without prior consultation by the gastroenterology section. Two of these patients were discharged on the same day they were admitted and neither rebled. Four of the admitted patients (7.0%) (two with gastric ulcers, one with duodenal ulcer, and one with Dieulafoy's lesion) rebled during hospitalization. Within 1 month of discharge, rebleeding occurred in four patients (7%), including one patient who rebled during the index hospitalization. Two patients initially presented with gastric ulcers; one had a Dieulafoy's lesion; and the remaining individual had grade IV esophagitis. As can be seen in Figure 2, the frequency of repeat bleeding either during or after the index hospitalization was highest in patients admitted to the intensive care unit, intermediate in patients admitted to a 23-hour observation or hospital ward, and lowest (0 of 24) in those for whom hospitalization was not deemed necessary (p = 0.002).

Table 4 compares the outpatient and inpatient populations. Inpatients were significantly more likely to bleed from peptic ulcer disease (p = 0.006) and less likely to have mucosal erosions alone (p = 0.01) as a cause of bleeding. Inpatients were also more likely to complain of weakness upon initial presentation (p = 0.009).
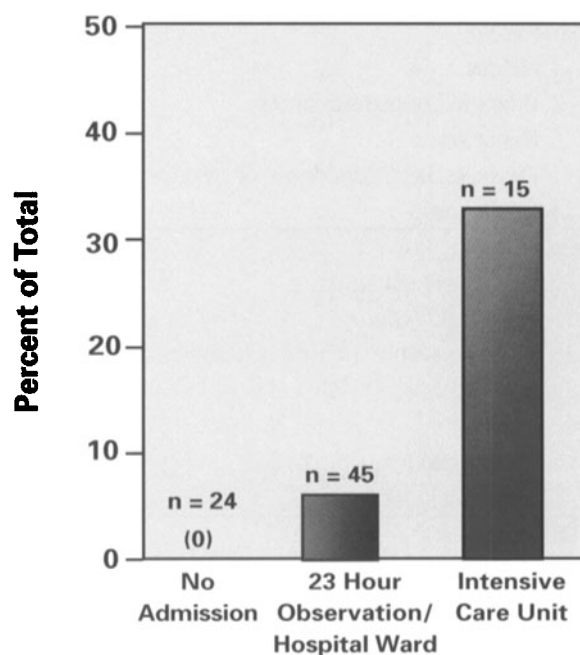

Fig 2. Frequency of rebleeding according to admission status os patients. n = total number of patients in each group. The difference between rate of bleeding in the no-admission group and the other groups was statistically significant at p = 0.002 by X^2 test for Goodness of Fit.
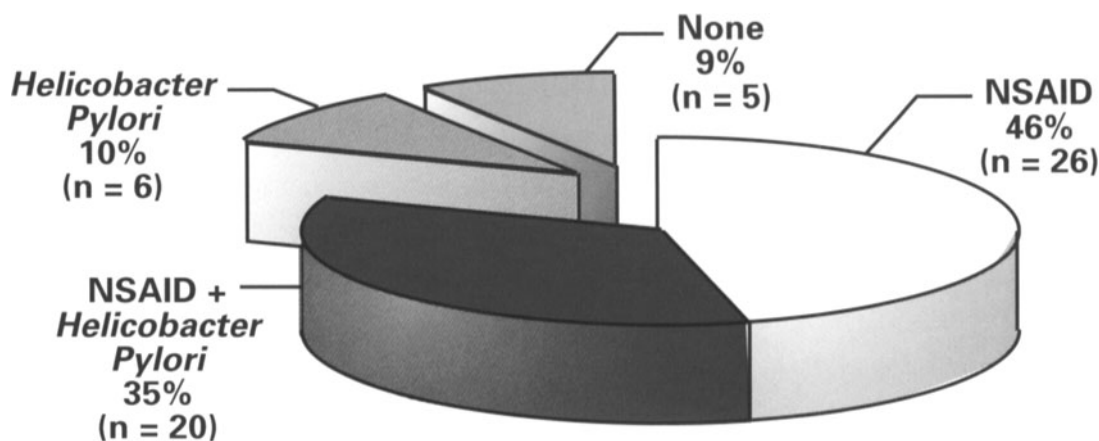
Fig 3. Etiology of peptic ulcer disease in prospectively studied patients.

Peptic ulcer disease was the source of bleeding in 57 (68%) of the patients in the prospective study. NSAIDs were the most common cause of PUD in this population (Figure 3), having been used by 63 patients (75%) in the entire population and 46 (55%) with a history of PUD. Over-the-counter NSAIDs accounted for the overwhelming majority of instances (60 patients or 95%). Only eight patients (13%) were using NSAIDs prescribed by their physicians, and five of these individuals were additionally consuming over-the-counter NSAIDs. Only one of the chronic NSAID users was taking misoprostol at the time of UGIB. Thirteen patients had a history of bleeding due to PUD. Nonetheless, six (46%) were consuming NSAIDs at the time of their current episode of bleeding. Information about the reason for utilization of NSAIDs was available in 73 patients (87%). Fifty-four of the 73 patients (74%) were taking NSAIDs: aspirin alone in 21 (29%), other NSAIDs alone in 20 (27%), or a combination of aspirin and other NSAIDs in 13 (16%). The most frequent reasons given for NSAID use in the 54 patients were musculoskeletal pain (69%), aspirin for cardiac prophylaxis (14%), and chronic headache (11%).

Discussion

The current study demonstrates that it is safe to manage stable elderly patients with UGIB as outpatients as long as there are no significant comorbid illnesses and low-risk endoscopic findings. The determination of low-, moderate-, and high-risk for repeat bleeding or requirement for surgery has been defined in the literature for peptic ulcer disease (14) and other types of mucosal lesions. To determine the need for admission, we used previously published endoscopic criteria and evaluated each patient for comorbid illnesses that could potentially have an impact on morbidity or mortality from UGIB. The prognostic information provided by prompt endoscopic examination obviated the need for inpatient observation in hemodynamically stable patients with low-risk lesions. Of note, our group of outpatients experienced no further episodes of bleeding. In contrast, seven patients who were admitted (12%) rebled either during the hospital stay or within 1 month of discharge (p =0.002). Outpatients in this study had a lower transfusion requirement than inpatients because the need for transfusion was a criteria for admission. However, further experience since the study's completion indicate that a minor transfusion requirement may also be managed safely for outpatients, provided the other criteria are met. Our estimate of the frequency of outpatient management is, therefore, probably conservative. It should be noted that the close follow-up in our protocol, involving regular determination of hematocrit and hemoglobin levels, helped ensure that no patients had subclinical episodes of rebleeding.

It is important to emphasize that before the implementation of our study, these elderly patients would have been managed as inpatients at our institution. Moreover, many

institutions are likely to employ conservative policies of admission for elderly patients with UGIB because of reports of increased risk of mortality in this population (5-8). This has led some authors to advocate admission to an ICU when minor UGIB occurs in an elderly patient (15).

The establishment of practice guidelines based on endoscopic and clinical data for the treatment of patients with UGIB improves the efficiency of hospital resource utilization and reduces health care expenditures. In fact, upon completion of the study, consultation with the Hospital Financial Analysis Section was sought in order to compare the average costs and charges for patients who were managed on an outpatient basis with those admitted to a 23-hour observation unit. This analysis revealed a 63% reduction in the average cost of care and a 59% reduction in average charges when patients were treated in the outpatient setting (data not shown). Dramatic cost savings have recently been delineated in another study of upper gastrointestinal bleeding in which patients were endoscoped either in the emergency room or electively after admission (17). In that study, the median true costs were $3,323 for the control group that received elective upper endoscopy and $1,974 for the urgent endoscopy group, nearly half of whom were assigned outpatient care.

As anticipated, PUD and mucosal erosions were the most common cause of bleeding in our elderly patients. Somewhat surprising, however, was the high frequency of NSAID use in this population. Bleeding from PUD was linked to NSAIDs, either alone or in combination with *H. pylori* infection, in 46 of 57 cases (81%). The high frequency of NSAID use in this group of elderly patients with bleeding from PUD is higher than that published in other studies, which range from 13.2% to 70% (18-20). In one study pertinent to the elderly population, the prevalence of NSAID use in patients >60 years of age with bleeding from PUD was 35% (18). The current study demonstrates that 95% of our patients with bleeding from PUD due to NSAIDs acquired these agents over-the-counter. This raises important questions about the level of information that elderly patients have about the dangers of consuming NSAIDs on a regular basis.

Selective outpatient management of UGIB in the elderly can be done safely. Our endoscopic and clinical criteria for admission to the hospital successfully predicted those patients who were prone to rebleed and may have a need for further therapy. Particularly impressive was the inordinately high frequency of NSAID-induced bleeding in our population. A greater effort needs to be made to educate patients, particularly those who are elderly, about the inherent dangers of over-the-counter NSAIDs, as well as those prescribed by their physician.

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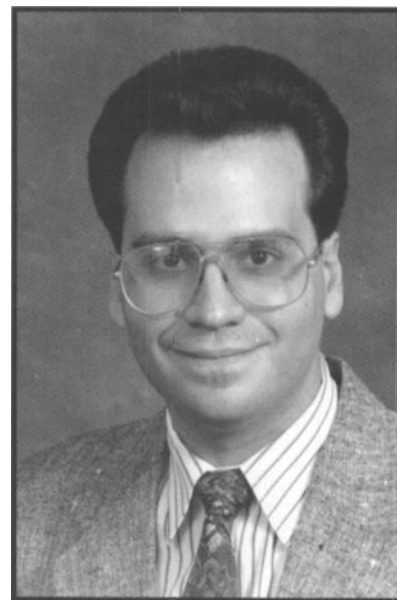
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