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Full title of the research	Major Causes and Factors associated the outcome of patients with Upper GI bleeding in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia: Institution Based Prospective cohort study
Duration of the project	January- October 2023
Study area	Addis Ababa, Ethiopia
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We the undersigned are the principal investigator and the advisors for this study. We declare that this proposal is our original work.

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List of Acronyms

EGD - Esophagogastroduodenoscopy

UGIB – Upper gastrointestinal bleeding

LGIB – Lower gastrointestinal bleeding

PUD – Peptic ulcer disease

GERD – Gastrointestinal reflux disease

Hgb – Hemoglobin

HCT – Hematocrit

DM – Diabetes mellitus

MELD – Model for end stage liver disease

ALBI – Albumin bilirubin score

TASH – Tikur Anbessa Specialized Hospital

CPS - Child Pugh Score

PRBC – Packed Red blood cells

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Abstract

Background: Upper gastrointestinal bleeding refers to blood loss within the intraluminal gastrointestinal tract from any location between the upper esophagus to the duodenum at the level of the ligament of Treitz. Bleeding from the upper gastrointestinal tract is approximately five times more common than from the lower gastrointestinal tract. The incidence of upper GI bleeding ranges from 50 to 150/100,000 population annually, and as many as 70% of acute upper GI bleeding episodes occur in patients older than 60 years. This study aimed to assess the Rebleeding and Death at 30 days of the patient's outcome with those upper GI bleeding in TASH, Addis Ababa, Ethiopia.

Method: The study was an institution-based prospective cohort study. A total of 123 patients who had upper GI bleeding were enrolled in this study, and associated factors studied. Data samples were collected from the study participants, together with associated sociodemographic, endoscopic findings, lab profiles, potential risk factors, and other important questionnaires**,** at the TASH GI Clinic endoscopy unit from January 2023 to September 2023.

Result: The mean age of participants with GIB was 41.28 ± 16.352 (range 13–84 years). About 67 (54.5%) of patients were under 40 years of age. Out of 123 patients admitted with upper GI bleeding, 73 (58.5%) of them stayed in hospital for less than 3 days, rebleeding at 30 days occurred in 21 (17.1%) of patients, and death at 30 days occurred in 17 (13.8%).

Conclusion: In this study, the mortality rate at 30 days was high about 13.8% and in 17.1% of patients, rebleeding occurred within 30 days. Variceal bleeding was found the most common cause of upper gastrointestinal bleeding accounting for 53.7% of patients.

Key words: Death at 30 days, Upper GI bleeding, Endoscopy, Rebleeding at 30 days.

1. Introduction

1.1. Background

Upper gastrointestinal bleeding refers to blood loss within the intraluminal gastrointestinal tract from any location between the upper esophagus to the duodenum at the level of the ligament of Treitz (1). It is a common medical emergency associated with significant morbidity and mortality (2). Overt upper gastrointestinal bleeding (UGIB) is defined as bleeding proximal to the ligament of Treitz with symptoms of hematemesis, melena, or occasionally hematochezia (3,4). Bleeding from the upper gastrointestinal tract is approximately five times more common than lower gastrointestinal tract (5).

The incidence of upper GI bleeding ranges from 50 to 150/100,000 population annually, and as many as 70% of acute upper GI bleeding episodes occur in patients older than 60 years (2). The incidence of UGIB increases with age probably because of the increased consumption of nonsteroidal anti-inflammatory drugs (NSAIDs) (6). Older age is associated with an increased rate of comorbidity, greater medication use, and atypical clinical presentations. The aging of the population makes the evaluation and management of gastrointestinal bleeding in the elderly a special and increasingly common clinical challenge (7). The main risk factors for upper gastrointestinal bleeding are Age more than sixty years old, concurrent diseases, coagulation problems, NSAIDs. Aspirin, selective serotonin reuptake inhibitors and other anti-platelet and anticoagulant medications and Helicobacter pylori infection (8). In patients with cardiovascular and renal disease, UGIB tends to be more severe and has greater morbidity (9).

Causes of UGI bleed have been classified into variceal (e.g., esophageal and gastric varices) and non-variceal (e.g., peptic ulcer, erosive gastroduodenitis, reflux esophagitis, tumor, vascular ectasia, etc.). This classification is important as the two have different management protocols and prognosis (10). Helicobacter pylori (H. pylori) infection and the use of nonsteroidal anti-inflammatory drugs (NSAIDs) are two of the major risk factors for peptic ulcers and ulcer complications (5).

Peptic ulcer disease is the most common cause of hemorrhage across the years followed by gastritis and esophagitis with variceal bleeding being an uncommon cause of UGIB in the Western data (6). Varices accounted for one third of those hospitalized for UGIB, closely behind peptic ulcer disease (6). Use of NSAIDs or ASA is reported in more than half of the patients with ulcer bleeding

(6,11). Variceal bleed is the major cause of upper gastrointestinal bleeding in cirrhotic patients, accounting for up to 70% of cases (6).

While population-based studies on the incidence of upper GI Bleeding is lacking in Africa, several hospital-based studies show that among the common causes of UGIB, Variceal bleeding holds the leading place accounting for 45-70% of cases. In contrast to Western data, in several studies from sub-Saharan Africa, mortality from upper GI bleeding is quite high, ranging from 6 to 33%, including studies from our country (12–15).

The first line investigation for evaluation of upper GI bleeding is endoscopy (16). Endoscopy for diagnosis of cause of upper GI bleed has a sensitivity of 92–98% and specificity of 100% (17).

It is generally recommended that patients admitted to or under observation in hospital for UGIB undergo endoscopy within 24 hours of presentation (18–21). Early endoscopy helps in establishment of an accurate diagnosis, provides prognostic information diagnosis of certain lesions and to guide care and thereby reduce rebleeding, requirement for transfusion, the need for surgery, costs and duration of hospitalization (22). Most importantly, endoscopic therapy is also used to stop bleeding from specific disease processes. Optimum resuscitation including appropriate blood transfusion must however, be done before endoscopy is undertaken (16).

The last two decades have witnessed major advances in upper gastrointestinal hemorrhage management, including the discovery of Helicobacter pylori, the widespread use of proton pump inhibitors, and the development of novel endoscopic and radiologic hemostatic techniques. At the same time, there has been widespread use of antiplatelet drugs and anticoagulants, in addition to an epidemic of obesity, all of which are risk factors for variceal and non-variceal upper gastrointestinal hemorrhage (4).

The mortality rate for all of the different etiologic categories of non-variceal upper gastrointestinal hemorrhage declined over the last three decades (23). Yet, no mortality difference was reported for esophageal variceal hemorrhage over time (4,23). Despite the advances in the treatment of UGIB, 4-19% of affected patients have a poor prognosis, such as rebleeding or death in low- and middle-income countries (24).

Risk stratification in patients with UGIB is essential for optimal management of bleeders, both for triage of those at high risk to inpatient care and for identification of patients at low risk of adverse outcome who can be safely managed as outpatients. A number of prognostic clinical factors have

been shown to be independently associated with the risk of 30-day mortality after acute UGI bleeding (25–27).

A primary goal of the initial assessment is to determine whether the patient requires urgent intervention (e.g., endoscopic, surgical, transfusion) or can undergo delayed endoscopy or even be discharged to outpatient management (22). Although numerous factors from the patient history, physical examination, and initial tests have been examined for an association with a need for intervention, no single factor is sufficiently predictive of UGIB severity to be used for triage (28). The Blatchford score (29) and the Clinical Rockall score (30) have been examined in several studies and may determine the need for urgent endoscopy. In elderly patients with upper gastrointestinal bleeding, the Rockall score is clinically more useful for predicting mortality and rebleeding than the Glasgow–Blatchford and AIMS65 scores; however, for predicting duration of hospitalization and the need for blood transfusion, the Glasgow–Blatchford score is superior to the Rockall (31).

Endoscopy in patients with UGIB is effective in diagnosing and treating most causes of UGIB and is associated with a reduction in blood transfusion requirements and length of intensive care unit/total hospital stay. Early endoscopy (within 24 hours of hospital admission) has a greater impact than delayed endoscopy on length of hospital stays and requirements for blood transfusion. In appropriate settings, endoscopy can be used to assess the need for inpatient admission (28,32).

Risk factors for mortality in UGIB patients include advanced age, low hemoglobin level, low systolic blood pressure, blood in a gastric aspirate, presence of severe co-morbidity (neoplasia, cirrhosis), worsening health status (American Society of Anesthesiology classification 3 or 4), rebleeding, hypoalbuminemia, elevated creatinine, elevated serum aminotransferase level, onset of bleeding during hospital admission, and active bleeding or other stigmata of recent hemorrhage at the time of endoscopy (25,33). In the presence of any of these prognosticators, emergency physicians as well as managing gastroenterologists should pursue a high level of care to prevent death, because about 30% of deaths occur within the first 24 hour of admission to hospital, and part of this mortality within the first 8 hours (25,33–36).

Hypertension, ascites, multiple EV columns, EV higher grade, presence of gastric varices and associated respiratory disorder are independent factors found to be associated with recurrence of bleeding in variceal group (12,37).

Rebleeding in UGIB is substantial, ranging from 7–16%, despite endoscopic therapy. It is especially high in variceal bleeding (25–29%) and peptic ulcer bleeding (20– 22%). Rebleeding is an important risk factor and prevention of rebleeding may be one of the factors that can influence mortality. The mortality rate in patients with recurrent bleeding is quite high, between 30 and 37% (3,4).

In Ethiopia, there has not been a population-based study about the prevalence of upper GI bleeding. Facilities providing endoscopy are mostly limited to the capital and major cities in some parts of the country. In one study from the capital city, among 1,769 therapeutic endoscopies done in a private center over 8 years, about 76% of the therapeutic endoscopic interventions were for upper GI bleeding patients showing the high prevalence of the problem in our country.(38) A high mortality rate of 17.2% has been reported in another tertiary hospital in Addis Ababa from a retrospective study (14).

However, there is no published prospective study evaluating the mortality rate and factors affecting mortality in patients presenting with upper GI Bleeding. Knowledge about those factors associated with favorable or adverse outcomes in our patient population will help improve in risk stratification and formulating locally relevant management protocols.

1.2. Significance of the study

Early identification of the patients with factors associated with increased mortality during an acute UGIB episode may be beneficial for patients' risk stratification. Patients at high-risk will require hospital admission, rapid resuscitation, close observation, and prompt endoscopic intervention, while the low-risk ones can be discharged early and managed on an outpatient basis, thus decreasing costs and optimizing utilization of the limited resources available in emergency departments. Such decisions are better guided based on locally identified risk stratification models that depend on prospective studies in our local population.

We identified two previous retrospective facility-based studies reporting on high magnitude and mortality rates associated with UGIB among patient seen in endoscopy centers in Addis Ababa. To our knowledge, our current study is the first prospective study which aims to identify the causes of acute UGIB and their outcome and to determine the factors associated with increased mortality and re-bleeding in patients presenting with UGIB to TASH endoscopy unit during the study period. The findings of the study will generate evidence on the risk factors associated with rebleeding and mortality among our study population.

2. Literature Review

Acute upper gastrointestinal bleeding remains a common emergency situation and an important cause of morbidity and mortality. One of the earliest population-based studies showed the annual incidence of hospitalization for acute GI bleeding was 102.0 per 100,000 population (35). It is still a frequent gastrointestinal emergency accounting for > 250,000 hospitalizations in the USA. Several recent population-based epidemiological surveys evaluating cause and outcome of upper gastrointestinal bleeding have reported the crude incidence rates of acute UGIB with large variation. The incidence of UGIB in the west of Scotland is at the higher rate of 172/100 000 adults. The incidence in Denmark and The Netherlands is at the lower end, respectively 37 and 48/100 000 adults. Differences in incidence might be explained by the different populations, including differences in cause of bleeding, use of medications, endoscopic and pharmaceutical management and outcome. Different selection criteria, for example, exclusion of in-hospital patients might lead to selection bias in estimating incidence and population. Despite these differences, the incidence varies between 50 and 150 hospital admissions per 100 000 adults per year and tends to remain constant in the Western literatures (6,23,35,39). Although there are no population based prevalence studies in Africa, Kiringa et al., identified the prevalence of UGIB symptoms in 20.3% among the patients they screened in a single center in Uganda (40).

There is such a pronounced increase in incidence of UGIB with age. Blatchford et al., showed that the incidence sharply rose with age, being almost 6-times higher among those over 75 years of age. Other surveys confirmed this striking rise of incidence of acute UGIB with age (6,23,41). Studies have also shown that the percentage of elderly patients with UGIB has increased from 46.1% to 63.2%, while the increase for those over the age of 80 years was from 6.3% to 24.5% probably because of increasing life expectancy (23,42).

The commonest etiologies of UGIB are different in the different regions of the world. Peptic ulcers account for approximately one third of patients with UGIB hospitalizations in the U.S. while varices are uncommon cause of UGIB following ulcer bleeding and esophagitis(11).

In a large single-center US study of patients hospitalized with UGIB, ulcers account for approximately one third of patients with UGIB hospitalizations, with a modest decline of incidence about 10% over the last 20 years accounted for by a decline in bleeding duodenal ulcers. Varices continue to be a common cause of UGIB at urban hospitals serving a lower socioeconomic status population, accounting for one third of patients hospitalized with UGIB(11).

The most common cause of UGIB is also peptic ulcer in European studies. An increase in the diagnosis rate of gastric ulcer with a simultaneous decrease of duodenal ulcer as a cause of bleeding has been observed. Erosive lesions of the stomach or duodenum and varices were found as the next most frequent causes of acute bleeding (23).

Portal hypertension, on the other hand, is reported as the most common cause of upper GI bleeding in the population in the low- and middle- income countries, with the most common endoscopic lesions reported being esophageal varices, followed by gastric erosion/gastritis, and duodenal ulcer (36,43).

A recent study done in 2021 from India showed variceal bleed is the commonest cause of upper GI bleeding in their patients. The majority of patients belonged to the age group of 31-40 years, which is quite young population demography of upper GI bleeders compared to the European and Western data (5,23).

In another prospective study from India analyzing the clinical and endoscopic profile and mortality pattern, the most common cause of UGIB was portal hypertension related (Esophageal and gastric varices) seen in 56% of patients, peptic ulcer-related bleed was seen in only 15% patients, gastric erosions were responsible for bleed in 12% patients, gastric malignancy accounted for 4.5% of cases. Dieulafoy's lesion was responsible for bleed in 2% cases and 2% had Duodenal polyp(44).

Studies in Africa report variceal bleeding as the commonest cause of UGIB. In a prospective, cohort study aimed at identifying the major causes of upper gastrointestinal bleeding and the magnitude of mortality, rebleeding and readmission in a tertiary level hospital in Tanzania, the most common cause of upper GI bleeding was esophageal varices, found in 57% of patients. PUD accounted for 18% of cases and gastritis for 10.4% (33).

In a retrospective analysis of patients with UGIB over 5 years in Uganda, Esophageal varices accounted for 40.6% of all causes of UGIB, followed by Esophagitis and Gastritis and Peptic ulcer disease was only 6.2% (15). The epidemiology of gastrointestinal bleeding in Egypt, Malawi and Uganda is similar to studies from East and West Africa with esophageal varices the predominant cause of upper gastrointestinal bleeds (13,15,37). Esophageal varices are the commonest cause of upper gastrointestinal bleeding in this environment due to the high endemic nature of Hepatitis B infection and hepatosplenic schistosomiasis in the area (15).

There is wide variation in mortality rate reported by different centers for acute upper gastrointestinal bleeding worldwide. Comparison of mortality rate is difficult because of variation

in study methods, definitions and inclusion criteria. The severity of acute UGIB at presentation may generally vary widely (41).

Age is a major determinant of the outcome of patients with UGIB. In addition to its incidence, the population mortality of UGIB also increases sharply with increasing age. An even 100-times greater mortality rate among those over 75 years of age than among those 15–29 years of age was found in Scotland (41).

There is also a distinct difference in mortality among in-hospital patients who present with UGIB and emergency admissions. In epidemiological surveys, mortality in in-hospital patients is significantly higher compared to that of the emergency admissions and out-patients (45). Rockall et al., in a large study in 74 hospitals in England, reported a wide variance in mortality from 0% to 29%. Mortality was 33% for the inpatient group compared with 11% for emergency admissions (35).

Co-morbidity also plays a major role in the high mortality rate among these in-hospital patients. Paspatis et al., showed that in the absence of any comorbidity death rate significantly decreased among upper GI bleeders to the level that no death occurred in those with no comorbidity in their study. Malignancy and organ failure were associated with the poorest outcome in these patients with mortality rate of up to 33% (45). In an early study from U.K., mortality in patients younger than 60 years and without concomitant disease at presentation was very low while 83% of the deaths among the emergency admissions were associated with one or more major comorbidities mainly malignancy, organ failure (cardiac, renal, or hepatic), and respiratory disease. Their study showed a clear non-linear relation between age and mortality for emergency admissions because of acute UGIB although age is not an entirely independent risk factor because of its association with comorbidity (35).

In a study done in Iran in 2016, overall mortality of patients with UGIB was 23.2%. The most important independent prognostic predictors of mortality were older age. Mortality increased >50 fold for people aged 85 years and more compared with those under 40 years and the diagnosis of esophageal and gastric/duodenal malignancies as well as esophageal varices with p-value <0.01. In addition, they found significantly higher rebleeding rates in older patients and those with diagnosis of malignancy (p-value <0.01) (34).

Many other factors have also been found to be strongly associated with poor prognosis of UGIB patients. Varices were associated with increased mortality in a large single center in the U.S. The

overall in-hospital mortality for all patients was reported to be 6.7%. They reported that varices were significantly associated with in-hospital mortality (OR; 1.55). Patients with hematemesis showed increased risk of rebleeding requiring repeat endoscopy and a trend toward an increased in-hospital mortality (OR; 1.53 and 1.4 respectively) (11).

Mortality from nonvariceal UGIB is reported in the range of 5–10% in a large Italian study and they identified a number of prognostic clinical factors independently associated with the risk of 30-day mortality after an acute UGI bleed. The most relevant predictors were advanced age, liver cirrhosis, chronic renal failure and advanced neoplasia, and the low hemoglobin level at presentation. Independent predictors of 30-day mortality in their study included advanced age (over 80 yr.) (OR 4.7), low hemoglobin levels at presentation (<7 g/dL) (OR 4.7), presence of severe comorbidity (renal failure (OR 5.2), neoplasia (OR 9.8), liver cirrhosis (OR 11), and worsening health status (ASA class 1 or 2 vs ASA class 3 or 4 (OR 3.3 and 7.2)). Thirty-day mortality was 15.2% in patients with recurrent bleeding and recurrent bleeders accounted for 10.9% of the total patients deceased (OR 4.12). Diastolic pressure <70 mmHg (OR 2.46), concomitant use of nitrates (OR 1.82), systolic pressure <115 mmHg (OR 1.78), hematemesis (OR 1.66), and active bleeding at endoscopy (OR 1.30) were all clinically relevant factors affecting 30-day outcomes (25).

In a study published in 2022 comparing between variceal and nonvariceal gastrointestinal bleeding, severe anemia doubled the risk of rebleeding (Odds ratio; 2; 95% CI 1.13–3.52). In non-variceal UGIB, severe anemia increased the risk of death in non-variceal hemorrhages by 4 times (OR = 4; 95% CI 2.1–6.75); hemorrhagic shock increased the risk of death by 3.4 times (OR = 3.4; 95% CI 1.34–6.5); antiplatelet agents, anticoagulants, and NSAIDs increased the risk of death by 3.5-, 2 and 1.7 times respectively (OR = 3.5). In variceal bleeds, the presence of gastric varices increased the risk of rebleeding 3.3 times (OR = 3.3; 95% CI 1.96–5.63), the presence of grade III esophageal varices increased the risk of rebleeding by 2.25 times (OR = 2.25; 95% CI 1.36–3.72), severe anemia increased the risk of rebleeding 2 times (OR = 2; 95% CI 1.12–2.83), and age > 60 years increased the risk of bleeding 1.6 times (OR = 1.6; 95% CI 1.3–3.43). Severe anemia may increase the risk of death from upper variceal hemorrhage 19 times (OR = 19; 95% CI 7.6–23.5); Child-Pugh C class increased the mortality risk by 5.6 times (OR = 5.6; 95% CI 2.91–10.8) (46).

In an observational clinical cohort study conducted in Syria in 2022, the mortality rate of patients with ulcer bleeding was found to be 7.8% and 6.6% patients suffered rebleeding within 30 days.

They found that age, NSAIDs, altered mental capacity, Forrest classification (Ia, Ib, and IIa), and requirement of multiple blood transfusion were associated with a higher risk of rebleeding ($p = 0.003$) (47).

In another study assessing poor outcomes in acute UGIB, they found that stigmata of recent hemorrhage (OR; 5.28) , APACHE II score >10 (OR; 3.11) and finding of Esophageal varices (OR; 3.85) were independently associated with in-hospital mortality, rebleeding and need for urgent surgery (48).

In contrast to the Western data, mortality rates in African studies are high. A prospective study from Tanzania reported that mortality rate was 33.5% and was significantly higher in patients with high white blood cell count (HR 2.45, p=0.011), raised serum alanine aminotransferase (HR 4.22, p=0.016), raised serum total bilirubin (HR 5.79, p=0.008) and lack of an endoscopy (HR 4.40, p <0.001). Rebleeding was reported in 7.1% (33). Similarly, lack of endoscopy was associated with the high mortality in Malawi. The majority of the bleeders died while waiting to undergo endoscopy (66.7%) (13).

In another prospective study, Age > 40 years was a significant independent predictor of mortality (OR = 7.00 (95% CI 1.7–29.2). Having a high clinical Rockall score of ≥ 4 was a significant independent predictor of mortality (OR = 6.4 (95% CI 1.8–22.8) (24).

A prospective follow-up study done in Egypt in 1,000 patients with upper GI bleeding reported that recurrence of bleeding occurred in 19.4% of variceal group in comparison to 6.1% of non-variceal group, while mortality was found in 4.3% of variceal group in comparison to 1.5% of non-variceal group. The mortality rate is lower than what most of the African studies reported(12,15,33). Independent predictors of complications were Child Pugh class, MELD and ALBI scores (odds ratio; 5.63 and 2.11 respectively) beside the presence of HCC (OR 4.89). Mortality predictors were PRBC units transfused (OR; 1.11, Child Pugh class (OR; 5.1) MELD (OR; 1.27) scores, and presence of HCC (OR; 6.62) (37).

Retrospective review of endoscopic findings in Nigeria also reported about 45% patients were found to have variceal bleeding and the mortality rate was near 18% which were all patients with variceal bleeding (49). In cirrhotic with upper GI bleeding, Child–Pugh score C (OR:6.99; 95% CI = 2.58–18.95), and development of either hepatorenal syndrome (OR: 16.5;95% CI = 7.02–38.9) or hepatic encephalopathy (OR: 2.38; 95% CI = 1.25–4.5) were independent predictors of mortality in a large prospective study (42).

In a recent population-based study in US, UGIB mortality has decreased from 4.7% in 1989 to 2.1% in 2009. In-hospital mortality decreased among patients with non-variceal UGIH from 4.5% in 1989 to 2.1% in 2009. For variceal UGIH, mortality decreased from 10.7% in 1989 to 5.3% in 1999 then slightly increased to 5.6% in 2009 (3). The reason is that the last two decades have witnessed major advances in upper gastrointestinal hemorrhage preventive and treatment modalities, including the discovery of Helicobacter pylori, the widespread use of proton pump inhibitors, and the development of novel endoscopic and radiologic hemostatic techniques (4).

In a European study done on patients with UGIB, the overall mortality was reduced from 5.2% to 3.1% in the last decade but the difference is not statistically significant. In patients with peptic ulcer bleeding, a similar trend was observed, from 3.3% to 2.4%. Emergency surgery requirement has also decreased from 10.6% to 3.6% within less than 2 decades difference. They suggested is that the use of defined protocols and combined surgical and medical management have reduced mortality in their units. These low mortality rates have also been attributed to close monitoring of patients with acute upper GI bleeding, medico-surgical collaboration, and the widespread availability of therapeutic endoscopy (23,42).

When we see studies from our country, there are retrospective studies focusing on the etiology but studies on the outcomes of UGIB and factors affecting are generally lacking. An unpublished retrospective study done by Bereket et.al., in Tikur Anbessa Specialized hospital, which is the largest tertiary hospital in Ethiopia reported the commonest endoscopic finding seen in patients with UGIB was esophageal varices which is seen in 33.7% of patients followed by duodenal ulcer seen in 19.8% of patients. Delay of intervention beyond 24 hours and presence of comorbidities were significantly associated with a trend to increased length of stay as well as in hospital complications.

Another cross-sectional retrospective study done in Addis Ababa tertiary hospital reported that varices is the most common cause of UGIB seen in 46.1%, followed by peptic ulcer disease 24.2%, esophagitis 3.9%, gastritis 6.3% (8), duodenitis 3.1% and malignancy 4.7%. 7.8% had both varices and ulcer. The proportion of death in this study was 17.2% which is comparable to most of the Sub-Saharan studies' reports(14).

2.1. Conceptual Framework

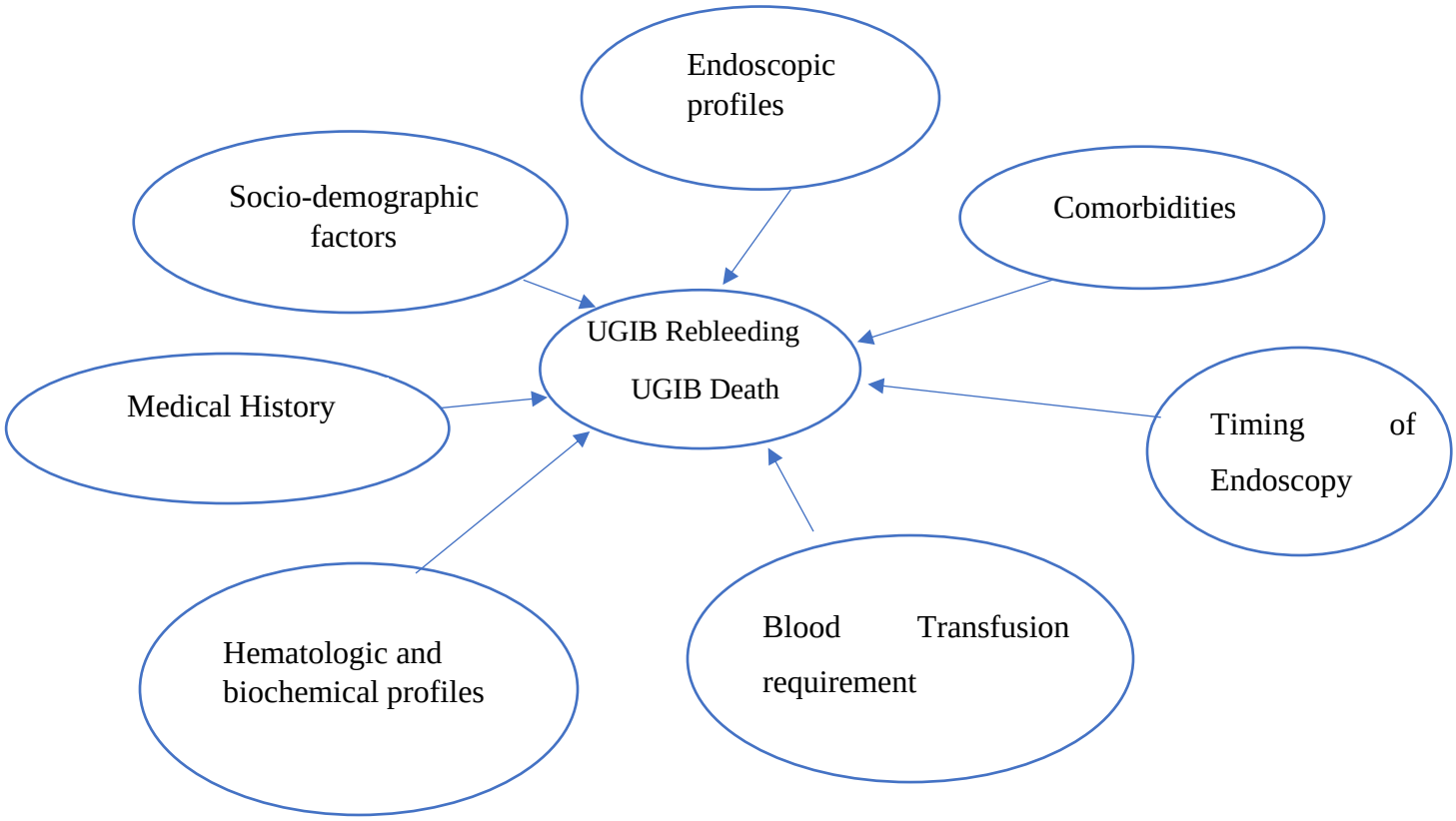

Figure 1: Conceptual framework for major causes and factors associated with outcomes of patients presenting with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023.

3. Objectives

3.1. General objective

- To assess the major causes and factors associated with outcomes of patients presenting with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023.

3.2. Specific objectives

- To determine the common causes of upper GI bleeding in patients undergoing endoscopy in TASH, Addis Ababa, Ethiopia, 2023.
- To determine the 30 days rebleeding rate among patients presenting with UGIB in TASH, Addis Ababa, Ethiopia, 2023.
- To determine the 30-days mortality rate among patients presenting with UGIB in TASH, Addis Ababa, Ethiopia, 2023.
- To determine the factors associated with the rebleeding at 30 days of patients with UGIB in TASH, Addis Ababa, Ethiopia, 2023.
- To determine the factors associated with the death at 30 days of patients with UGIB in TASH, Addis Ababa, Ethiopia, 2023.

4. Methodology

4.1. Study design

The study was an institution-based prospective cohort study to be conducted at TASH GI clinic endoscopy unit from January 2023 to October 2023 GC.

4.2. Study setting

The research was conducted at Tikur Anbessa Specialized Hospital (TASH). TASH is located in the capital city, Addis Ababa, and it is the largest and pioneering teaching referral Hospital in Ethiopia. TASH endoscopy unit is one of the World Gastroenterology organization training centers located in east Africa. The Gastroenterology unit provides both outpatient clinic service, diagnostic as well as therapeutic endoscopic services and inpatient service for admitted patients. It is one of the two hospitals training postgraduate gastroenterology fellows in Ethiopia.

4.3. Study population

The study population were all patients undergoing UGI endoscopy for an indication of Upper GI Bleeding in TASH endoscopy unit from January 2023 to October 2023.

4.4. Sample size and Sampling technique

The required sample size for the study was 106 by using population proportion formula assuming CI of 95% and precision of 0.1, confidence level of 95%, α 0.05 and adjusting for estimated 10% drop out rate.

n = N*X / (X + N – 1), where, $X = Z\alpha/22 *p*(1-p) / d^2$

P is the is the (estimated) proportion of the population, 50% (lack of previous similar study) $n=Z^2* p(1-p)/d^2$

The sampling technique was non-probability method in which all patients presenting with upper GI bleeding in the specified study period was recruited to the study. One month follow up on outcomes was done in person at GI clinic or via phone calls. However, all patients with upper GI Bleeding presenting during the study period was included even if the actual number is more than 106 to increase the power of study.

4.5. Inclusion criteria

Patients was included in the study if they are aged 13 years or older and had clinical evidence of acute upper gastrointestinal bleeding on admission, a history of having experienced such a bleed up to 10 days before the date of admission, or clinical evidence of acute upper gastrointestinal

bleeding while an established inpatient for any other reason and are willing to participate in the study and sign consent form.

4.6. Exclusion criteria

Patients with no upper GI lesion identified on initial endoscopy to explain the suspected UGIB).

Patients with upper GI bleeding who are not willing to sign consent to be part of the study.

Missing data, dropout and lost to follow-up.

4.7. Study Variables

4.7.1. Dependent variables

- UGIB
- Re-bleeding
- Mortality

4.7.2. Independent variables

- Socio-demographic factors:
    - Age, sex, marital status, place of residence, occupation, education and risk factors including smoking, NSAIDs use, alcohol use, anticoagulant use, steroid use.
- Medical History (Prior UGIB, Liver disease, and Clinical presentation)
- Hematologic and biochemical profiles of study subjects (Hgb, PLT, Urea, Creatinine, AST, ALT, ALP, PT, PTT, INR, Albumin and Bilirubin)
- Comorbidities (HTN, DM, IHD, CKD, Stroke…)
- Endoscopic profiles of subjects
- Timing of Endoscopy
- Blood Transfusion requirement
- Length of stay in-hospital

4.8. Operational definitions

Upper gastrointestinal bleeding: Gastrointestinal bleeding in the upper gastrointestinal tract, defined by clinical manifestations of hematemesis, melena or hematochezia or as bleeding arising from esophagus, stomach, or duodenum diagnosed during endoscopy.

Endoscopic evaluation of the bleeding lesion in case of peptic ulcer is defined according to the FORREST Classification (50) as following: FI – Active bleeding (FIa – arterial, spurting hemorrhage, FIb – oozing hemorrhage), FII – Stigmata of recent hemorrhage (FIIa – Visible vessel, FIIb – Adherent clot, FIIc –Dark base - hematin covered lesion, FIII –Lesions without active bleeding.

Patients who had variceal type of upper GI bleeding are classified endoscopically according to the severity of bleeding into three grades of esophageal varices and Sarin classification(51) of gastric varices is used. [Grade 1= Small, straight esophageal varices Grade 2= Enlarged, tortuous esophageal varices that occupy <1/3 of lumen, Grade 3= Large, coil shaped esophageal varices occupying >1/3 of the lumen]

Rebleeding is defined as fresh hematemesis, melena or both with either shock (pulse rate >110 beats/min and systolic blood pressure <90 mmHg) or a decrease in hemoglobin concentration of at least 2 g/dl (1.2 mmol/L) during the study period, with confirmation of recurrent bleeding by endoscopy or surgery, recurring within 10 days of the presenting bleed.

Continued bleeding is defined as signs of bleeding as continuing for more than 24 hours. High pulse and low blood pressure without other obvious cause, further hematemesis, passage of fresh melaena, falling hemoglobin concentration-more than could be explained by hemodilution.

4.9. Data collection Procedures

4.9.1. Data collection and instruments

Structured questionnaire was used to reach the objectives. Data collection was done by trained data collectors who are physicians working in the respective unit. The PI was overseeing the data collection process.

Data on demographic profile, etiological spectrum, clinical presentation, endoscopic findings, treatment modalities, and clinical outcome was collected from the patients themselves or their attendants, endoscopy report and patient laboratory data on electronic medical records. Information on demographic characteristics, endoscopic findings, medical and/or surgical management and clinical outcome (transfusion requirements, rebleeding rate, mortality) of all patients were recorded in a preformed structured questionnaire.

The required information about each patient was recorded using a structured questionnaire. The form was divided into multiple sections. Section one/Personal and demographic information: age, gender, marital status, address, average income, and habits. Section two/Medical history: Risk factors, Medication history, laboratory test results, vitals, physical findings and biomarkers. Section three/Patients' clinical presentation: Presented signs and symptoms that were associated with the upper gastrointestinal bleeding (like melena, hematemesis, epigastric pain etc.), the onset of bleeding, results of the endoscopy, laboratory results (blood hemoglobin/hematocrit, CBC, blood electrolyte, X-ray results, blood group and urinary test results, ultrasound test results to investigate the liver and Portal vein etc.).

4.9.2. Data quality measurements

Questionnaire was prepared in English version adopted and modified from different literatures to address the objectives of this study. Training was given to data collectors. The data collectors were the investigator, and trained physicians at ER and endoscopy unit. Follow up and supervision was done by the principal investigator. In order to check if the questionnaire was clear and addressing the objective, questionnaire was pre-tested on a 5% of samples. The collected data was checked for completeness before execution of any data entry process.

4.10. Data management and analysis

After checking for completeness, data was entered to SPSS version 26. Both descriptive and analytic statistics was performed using SPSS software version 26. Descriptive data were generated for independent and dependent variables. All categorical data were expressed as proportions, whereas all continuous data were expressed as mean± standard deviations. A binary logistic regression analysis model was used to identify factors associated with outcomes variables (rebleeding and death at 30 days). Those variables with a p-value ≤ 0.200 in the bivariate logistic regression were entered into a multivariate logistic regression analysis. A multivariate logistic regression model was used to identify the association of independent variables and the outcomes variables (rebleeding and death at 30 days). In multivariable logistic regression analysis, the statistical significance of associations between independent variables and the outcomes variables (rebleeding and death at 30 days) was determined using odds ratios with a 95% confidence interval and p-values < 0.05.

4.11. Ethical Consideration

Ethical clearance was obtained from institutional review board of college of Health sciences, Addis Ababa University. Written informed consent was obtained from each patient. All data collected were maintained confidential.

4.12. Dissemination of Results

The results of the study will be presented to Addis Ababa University, college of medicine and health science and department of Internal Medicine. The finding of this research will be disseminated to Hospitals and affiliated Universities in the country. Thereafter, the manuscript will be sent for publication on peer-reviewed journal.

5. Results

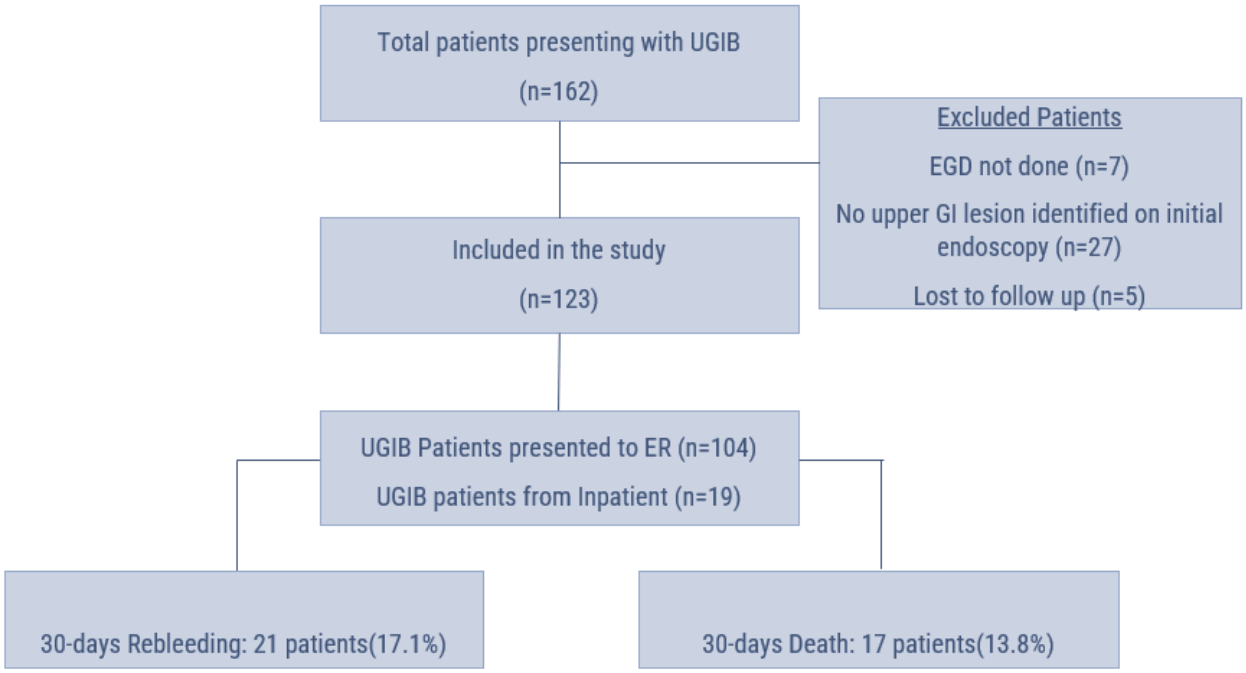

Figure 2: STROBE Flow Diagram

5.1. Sociodemographic characteristics of the patients

Out of 123 patients with upper GI bleeding (UGIB) enrolled in this study, 73.2% (n = 90) were male and 26.8% (n = 33) being female. The average age of participant with GIB was 41.28 ± 16.352 (range 13–84 years). About 67 (54.5%) of patients were under 40 years of age. Out of 123 patients, 104 (84.5%) patients were from outpatient while 19 patients presented from inpatient ward. More than half (69%) were married and 35 (28.5%) were single. About 44% patients were from Addis Ababa, 31.7% were from Oromiya and 8.9% patients came from SNNPR. The average monthly income was 1709 ETB (±1719.73) (**Table 1**).

Table 1: Sociodemographic characteristics of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Variables	Category	Frequency (n)	Percent (%)
Age	≤ 40 years	67	54.5
	41-60 years	39	31.7
	> 60 years	17	13.8
Gender	Male	90	73.2
	Female	33	26.8
Residency	Addis Ababa	54	43.9
	Oromia	39	31.7
	SNNPR	11	8.9
	Amhara	7	5.7
	Others*	12	9.7
Marital Status	Married	85	69.1
	Single	35	28.5
	Divorced	2	1.6
	Widowed	1	.8
Employment	Yes	83	67.5
	No	40	32.5
Monthly Income	< 1709 ETB	70	56.9
(Mean=1709.35±1719.73)	> 1709 ETB	53	43.1

* Tigray, Harar, Gambella

5.2. Risk factors for Upper GI bleeding

During the study period, the most common risk factors were assessed among the upper GI bleeding patients included in this study. Out of these risk factors, forty-three (35%) had history of intake alcohol occasionally and eighteen (14.6%) were regularly taking alcohol, 30 patients (24.4%) were smokers, 15 (12.2%) were infected with hepatitis B infection and 7 (5.7%) were Hepatitis C antibody positive. Among the study population, a recent history of drug consumption at the time

of presentation was documented in upper GI bleeders, mostly used were NSAIDS drugs (Diclofenac/Ibuprofen) in 26 (21.1%), and 10 (8.1%) were taking anti-platelet drugs and 7.8% patients were on anticoagulants (warfarin (5.6%), Rivaroxaban, 2.2%). 17 (13.8%) patients had previous history of PUD. Stool Antigen for Helicobacter pylori was positive in 8.1% of patients and 13% of patients had previous history of upper GI bleeding (**Table 2**).

Table 2: Risk factors of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Risk Factors		Frequency (n)	Percent (%)
Frequency of Alcohol use	Never	61	49.6
	Occasional	43	35.0
	Regular	18	14.6
	Ex-alcoholic	1	0.8
Smoking History		30	24.4
Anti-Platelet Drugs Use		10	8.1
Anti-coagulants Drugs use		9	7.3
NSAIDS Drugs Use		26	21.1
HBV Status	Positive	15	12.2
HCV Status	Positive	7	5.7
H. Pylori Test results	Positive	10	8.1
Prior PUD History	Yes	35	28.5
Previous UGIB History	Yes	17	13.8

5.3. Clinical presentation

The most common clinical presentation among UGIB patients in this study was hematemesis and melena. The majority (72, 58.5%) of the patients had both hematemesis and melena, 30 (24.4%) of the patients presented with melena only, and only 21 (17.1%) patients presented with hematemesis only. Thirty-four (27.6%) of all patients (PR > 100) were tachycardic while 39 (31.7%) had systolic BP < 100mmHg (**Figure 1**).

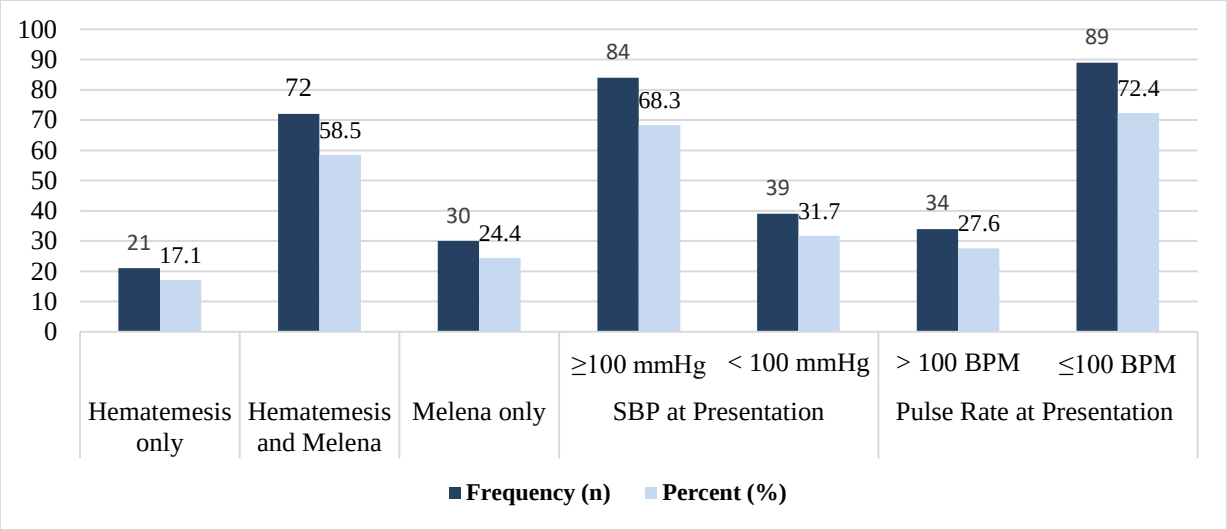

Figure 3: Clinical presentation of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

5.4. Comorbidities among those patients having upper GI bleeding

A total of forty-nine patients (39.8%) had one or more comorbidities. The most common comorbidity in this study was Malignancy 13 (26.5%) followed by hypertension 8(16.3%), Diabetes 7(14.3%). Both HTN+DM were 6 (12.4%) patients (**Table 3**).

Table 3: Comorbidities of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Variables	Category	Frequency (n)	Percent (%)
Comorbidity	Yes	49	39.8
Types of Comorbidities (n= 49)	Malignancy	13	26.5
	HTN	8	16.3
	DM	7	14.3
	HTN+DM	6	12.4
	Cardiac VHD/IHD	5	10.2
	Ischemic Stroke	5	10.2
	RVI	3	6.1
	Asthma	1	2.0
	CKD	1	2.0

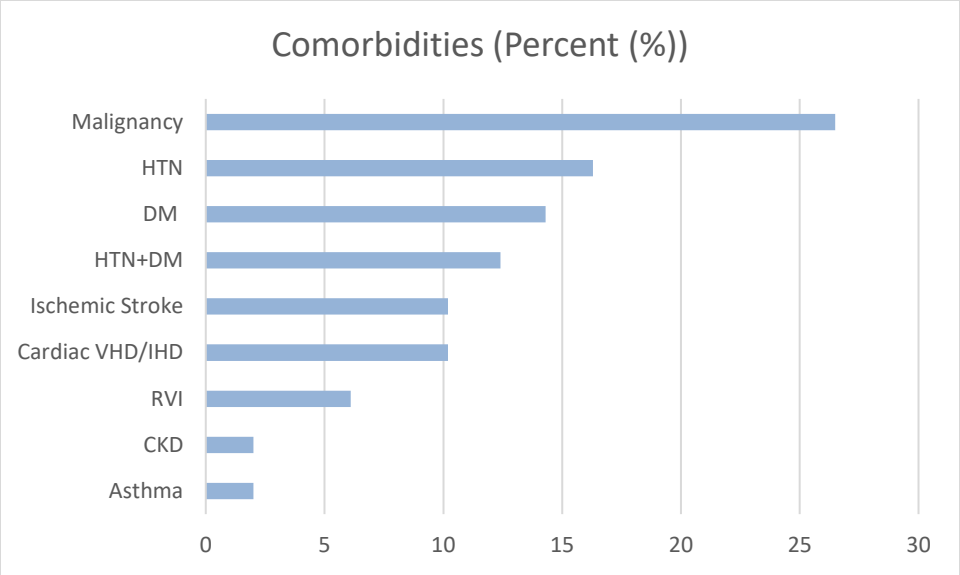

Figure 4: Types of Comorbidities of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=49).

5.5. Laboratory profiles

Laboratory profiles of the patients were examined. A hemoglobin (Hb) was done in 123 patients, and 51 (41.5%) of the patients in the study had a Hb < 8 g/dl, thus classifying them as having severe anemia. The platelet count was found ≤ 150,000 in 59 (48.0%) of these patients, thus had thrombocytopenia. The liver enzymes and renal function test were done and ALT > 40 were 13.0%, AST >38 was 26.8%, and ALP >129 were 14.6%, and the renal function test with creatinine > 1.1 and urea >45 was 10.6% (**Table 4**).

Table 4: Laboratory profiles of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Variables	Category		Frequency (n)	Percent (%)
CBC	**WBC**	< 4000	32	26.0
		4000-10,000	63	51.2
		> 10,000	28	22.8
	Hgb level	< 8	51	41.5
		8-10	41	33.3
		10-12	17	13.8
		> 12	14	11.4
	Platelet	≤ 150,000	59	48.0
		>150,000	64	52.0
LFT	**ALT**	≤ 40	107	87.0
		> 40	16	13.0
	AST	≤ 38	90	73.2
		> 38	33	26.8
	ALP	≤ 129	105	85.4
		> 129	18	14.6
	T. Bil	≤ 1.3	96	78.0
		> 1.3	24	19.5
	INR	≤ 1.4	95	77.2
		> 1.4	13	10.6
		Test not done	15	12.2
	Albumin	≥ 3.5	38	30.9
		< 3.5	58	47.2
		Test not done	27	22.0
RFT	**Creatinine**	≤ 1.1	110	89.4
		> 1.1	13	10.6
	Urea	≤ 45	110	89.4
		> 45	13	10.6

5.6. Endoscopic profile

In this study, we investigated endoscopic procedures, and 20 (16.3%) of the patients were recorded as EV, DU, or GU, 17 (13.8%) were EV + PHG, and 15 (12.2%) were EV + GOV-2. Of the total endoscopic findings, 66 (53.7%) Variceal bleeding and 48 (39.0%) cases of non-variceal bleeding were reported (see Table 5).

Table 5: Endoscopic profiles of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Variables	**Category**	**Frequency (n)**	**Percent (%)**
Endoscopic finding	EV	20	16.3
	EV +GOV-1	15	12.2
	EV + GOV-2	4	3.3
	EV + PHG	17	13.8
	IGV-1	3	2.4
	DU or GU	20	16.3
	Gastropathy	9	7.3
	GERD	10	8.1
	Mallory Weiss Tear	1	.8
	EV+GOV-1+GOV-2	3	2.4
	EV+DU	4	3.3
	Gastric Mass	9	7.3
	Others*	8	6.5
Forrest (n=24)	Forrest 3	19	15.4
	Forrest 2C	5	4.1
Endoscopic Findings	Variceal Bleeding	66	53.7
	Non-Variceal Bleeding	48	39.0
	Malignancy	9	7.3
Endoscopy Done By	Fellow	107	87.0
	Senior	16	13.0

** – Dielafoy's lesion, duodenopathy, Angioectasia, Hemobilia, caustic stricture*

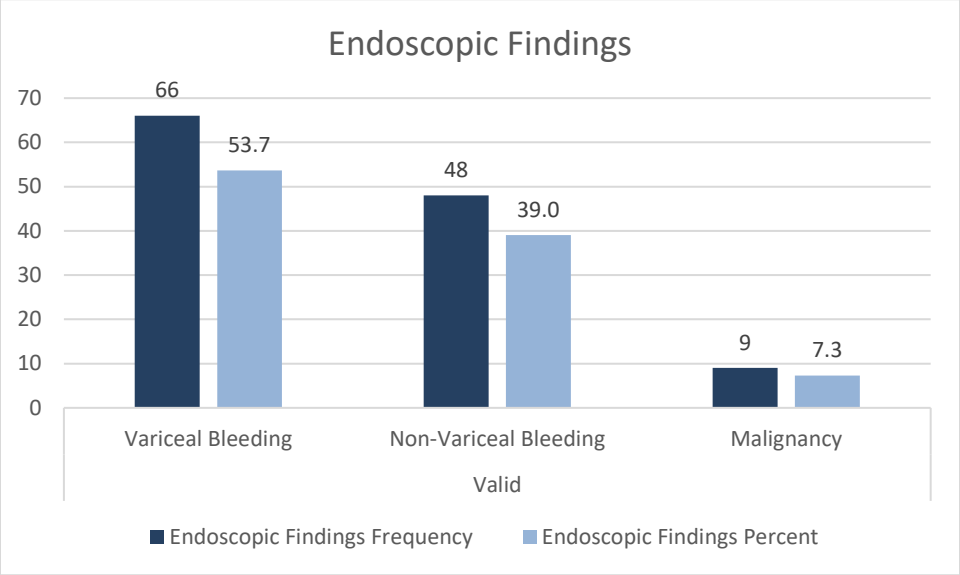

Figure 5:Endoscopic findings of patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123)

5.7. Ultrasonographic Features

All 123 (100%) patients had abdominal ultrasounds performed. Out of the total ultrasonographic characteristics reported, 62 (50.4%) have evidence of portal HTN, 50 (40.7%) had cirrhosis, 15 (12.2%) had periportal fibrosis and 16 (13%) had Portal vein thrombosis found on ultrasound (See Figure 2). In patients with portal hypertension, chronic viral hepatitis account for the majority of the cases in 22 patients (35.5%), followed by hepatosplenic schistosomiasis evidenced by peri-portal fibrosis on ultrasound in 15(24.2%) patients, alcoholic liver disease in 9(14.5%) and autoimmune liver disease in 5(8.1%) patients. Cryptogenic cirrhosis accounted for 11 (17.7%) of the cases (See Table 6).

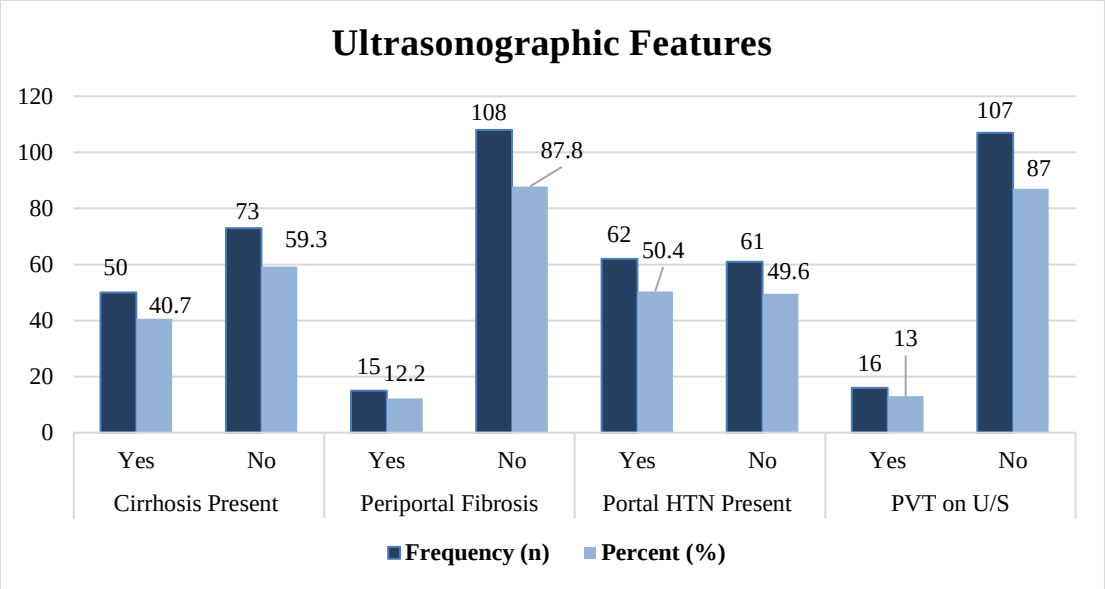

Figure 6: Ultrasonographic features of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Table 6: Etiology of portal HTN related upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=62).

Etiology	**Number (%)**
Hepatitis B	15(24.2%)
Hepatitis C	7(11.3%)
Schistosomiasis	15(24.2%)
Alcoholic liver disease	9(14.5%)
Autoimmune liver disease	5(8.1%)
Cryptogenic cirrhosis	11(17.7%)

5.8. Management of patients with Upper GI Bleeding

Out of the total 123 patients, fifty-eight patients (47.2%) of the patients, endoscopy was done within 12-24 hours of presentation. Endoscopic intervention was done 53(43.1%) with endoscopic band ligation being the most commonly done intervention in 97% of cases with alcohol and adrenaline injection and hemoclip application done for 3% patients. Out of the patients for whom endoscopic intervention was not done, 60 (85.7%) of patients were intervention not required whereas in 10 (14.3%) facility was not available. 58 (47.1%) patients required blood transfusion

required, with 24(19.5%) of the patients requiring 3-5 units of RBC during hospital stay (**Table 7**).

Table 7: Management of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Variables	Category	Frequency (n)	Percent (%)
Timing of Endoscopy	< 12 Hrs	12	9.7
	12-24 Hrs	58	47.2
	> 24 Hrs	53	43.1
Endoscopic Intervention Done	Yes	53	43.1
	No	70	56.9
Reason Intervention Not done (n=70)	Intervention Not Required	60	85.7
	Facility Not Available	10	14.3
Blood Transfusion Required	Yes	58	47.1
	No	65	52.8
Number of PRBC Transfused	Not transfused	65	52.8
	< 3 units PRBC	34	27.7
	3-5 units PRBC	24	19.5

5.9. Outcomes of the patients with Upper GI Bleeding

Of the total patients who underwent endoscopy for upper GI bleeding, in 98.4% (n=121) of them the bleeding were controlled. Out of 123 patients presenting with upper GI bleeding, rebleeding at 30 days occurred in 17.1% (n=21) of patients, death at 30 days occurred in 13.8% (n=17) and 58.5% (n=73) them stayed in hospital for less than 3 days (**Figure 4**).

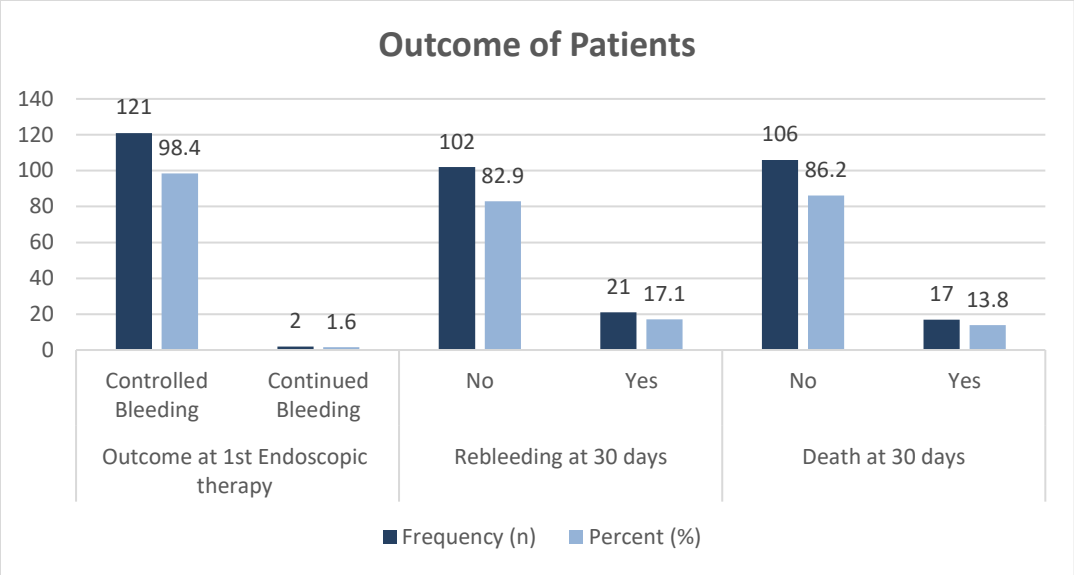

Figure 7:Outcome of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

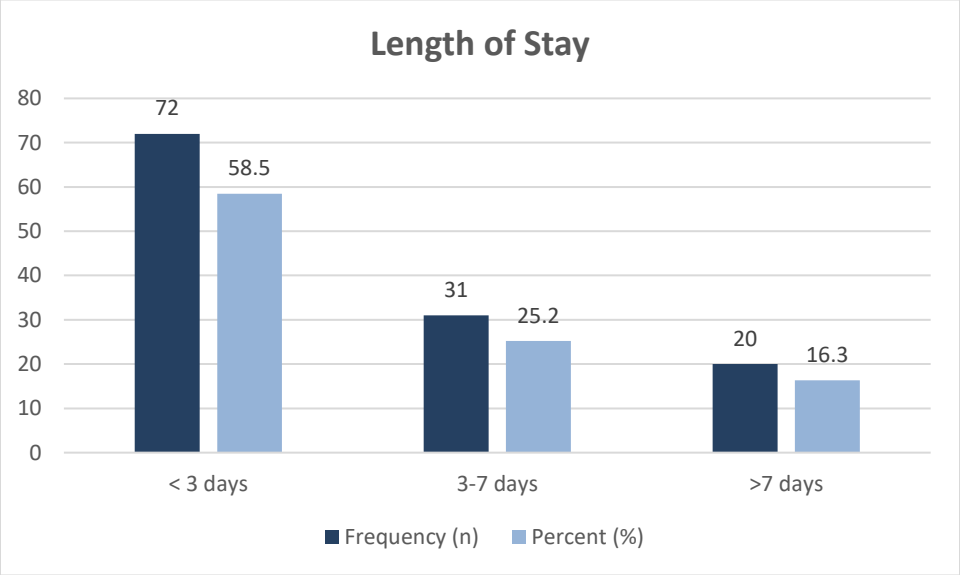

Figure 8: Length of stay in hospital of patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

5.10. Factors Associated with Rebleeding at 30 days

In bivariate analysis, the variables previous UGIB history, systolic BP at presentation, alanine aminotransferase (ALT), total bilirubin, presence of cirrhosis, presence of portal HTN, endoscopic intervention done, blood transfusion required and length of stay at hospital were associated with

rebleeding at 30 days among patients with upper GI bleeding. In multiple logistic regression analysis, variables systolic BP at presentation, alanine aminotransferase (ALT), presence of portal HTN and blood transfusion required were significantly associated with rebleeding at 30 days at a 95% confidence interval among patients with upper GI bleeding.

Patients who had systolic BP < 100 mmHg at presentation were 4.95 times more likely to have rebleeding at 30 days compared to those who had systolic BP ≥100 mmHg at presentation (AOR: 4.95, 95%CI: 0.95, 25.63), p=0.047). Patients who had elevated liver enzyme alanine aminotransferase (ALT) > 40 were 6.25 times more likely to have rebleeding at 30 days compared to those who had liver function test with alanine aminotransferase (ALT) ≤ 40 (AOR: 6.25, 95%CI: 1.08, 36.14), p=0.041). Patients who did not have portal HTN were 92% less likely to have rebleeding at 30 days compared to those who had portal HTN (AOR: 0.08, 95%CI: 0.01, 0.94), p=0.045). Patients who did not required blood transfusion were 81% less likely to have rebleeding at 30 days compared to those who required blood transfusion (AOR: 0.19, 95%CI: 0.04, 0.85), p=0.030) (**Table 8**).

Table 8: Factors associated with rebleeding at 30 days of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Variables	**Category**	**Rebleeding**		**COR (95%CI)**	**AOR (95%CI)**	**p-value**
		No	**Yes**			
Previous UGIB history	Yes	11	6	1	1	
	No	91	15	0.30 (0.09, 0.94)	1.18 (0.19, 7.35)	0.858
Systolic BP at presentation	≥100 mmHg	75	9	1	1	
	< 100 mmHg	27	12	3.70 (1.40, 9.77)	**4.95 (0.95, 25.63)**	**0.047**
ALT	≤ 40	92	15	1	1	
	> 40	10	6	3.68 (1.17, 11.62)	**6.25 (1.08, 36.14)**	**0.041**
T. Bilirubin	≤ 1.3	83	13	1	1	
	> 1.3	17	7	2.63 (0.91, 7.56)	0.76 (0.16, 3.73)	0.734
Cirrhosis Present	Yes	38	12	1	1	
	No	64	9	0.45 (0.17, 1.16)	0.99 (0.09, 10.75)	0.992
Portal HTN present	Yes	47	15	1	1	
	No	55	6	0.34 (0.12, 1.95)	**0.08 (0.01, 0.94)**	**0.045**

Endoscopic Intervention Done	Yes	41	12	1	1	
	No	61	9	0.50 (0.19, 1.30)	3.64 (0.44, 30.52)	0.233
Blood Transfusion Requirement	Yes	38	17	1	1	
	No	64	4	0.14 (0.04, 0.45)	**0.19 (0.04, 0.85)**	**0.030**
Length of stay at hospital	< 3 days	64	8	1	1	
	3-7 days	25	6	1.92 (0.60, 6.09)	0.52 (0.08, 3.09)	0.468
	> 7 days	13	7	4.31 (1.33, 13.97)	1.36 (0.22, 8.51)	0.743

p-value < 0.05 was considered as statistically significant; COR: Crude odds ratio; AOR: Adjusted odds ratio; CI: Confidence interval; HTN: Hypertension; UGIB: Upper GI Bleeding; BP: blood pressure; ALT: Alanine Aminotransferase; T. Bilirubin: total bilirubin.

5.11. Factors Associated with Death at 30 days

In bivariate analysis, the variables age, previous UGIB history, systolic BP at presentation, pulse rate at presentation, blood urea level, endoscopic findings, timing of endoscopy, blood transfusion required and length of stay at hospital were associated with death at 30 days among patients with upper GI bleeding. In multiple logistic regression analysis, age, pulse rate at presentation, timing of endoscopy and length of stay at hospital were significantly associated with death at 30 days at a 95% confidence interval among patients with upper GI bleeding.

Patients who had age > 60 years were 16.83 times more likely to die at 30 days compared to those whose age ≤ 40 years (AOR: 16.83, 95%CI: 2.37, 114.37), p=0.018). Patients who had pulse rate ≤ 100 BPM at presentation were 99% less likely to die at 30 days compared to those who had pulse rate > 100 BPM at presentation (AOR: 0.01, 95%CI: 0.00, 0.39), p=0.013). Patients who got endoscopy between 12-24 hours after admission were 96% less likely to die at 30 days compared to those who got endoscopy less than 12 hours (AOR: 0.04, 95%CI: 0.01, 0.77), p=0.033). Patients who had hospital stay of > 7 days were 54.90 times more likely to die at 30 days compared to those who hospital stay of < 3 days (AOR: 54.90, 95%CI: 1.47, 212.78), p=0.032) (**Table 9**).

Table 9: Factors associated with death at 30 days of the patients with upper GI bleeding in TASH, Addis Ababa, Ethiopia, 2023, (n=123).

Variables	**Category**	**Death**		**COR (95%CI)**	**AOR (95%CI)**	**p-value**
		No	**Yes**			
Age	≤ 40 years	60	7	1	1	

	41-60 years	34	5	1.26 (0.37, 4.28)	0.53 (0.04,7.48)	0.640
	> 60 years	12	5	3.57 (0.97, 13.16)	**16.83 (2.37, 114.37)**	**0.018**
Previous UGIB Hx	Yes	12	5	1	1	
	No	94	12	0.31 (0.09, 1.02)	4.87 (0.28, 85.62)	0.313
Systolic BP at presentation	≥100 mmHg	77	7	1	1	
	< 100 mmHg	29	10	3.79 (1.32, 10.91)	0.16 (0.02, 1.80)	0.139
Pulse rate at presentation	> 100 BPM	21	13	1	1	
	≤100 BPM	85	4	0.08 (0.02, 0.26)	**0.01 (0.00, 0.39)**	**0.013**
Urea	≤ 45	98	12	1	1	
	> 45	8	5	5.10 (1.44, 18.14)	3.59 (0.15, 86.99)	0.432
Endoscopic Findings	Variceal Bleeding	57	9	1	1	
	Non-Variceal Bleeding	45	3	0.42 (0.11, 1.65)	0.09 (0.01, 2.07)	0.131
	Malignancy	4	5	7.91 (1.78, 35.16)	2.41 (0.06, 103.19)	0.647
Timing of Endoscopy	< 12 Hrs.	7	5	1	1	
	12-24 Hrs.	51	7	0.19 (0.05, 0.77)	**0.04 (0.01, 0.77)**	**0.033**
	> 24 Hrs.	48	5	0.15 (0.03, 0.64)	0.05 (0 .01, 1.37)	0.076
Blood Transfusion Required	Yes	39	16	1	1	
	No	67	1	0.04 (0.01, 0.29)	1.49 (0.08, 28.40)	0.791
Length of stay at hospital	< 3 days	71	1	1	1	
	3-7 days	22	9	29.05 (3.48, 24.13)	11.87 (0.35, 39.71)	0.167
	> 7 days	13	7	38.23 (4.33, 33.22)	**54.90 (1.47, 212.78)**	**0.032**

p-value < 0.05 was considered as statistically significant; COR: Crude odds ratio; AOR: Adjusted odds ratio; CI: Confidence interval; UGIB: Upper GI Bleeding; BP: blood pressure

6. Discussion

Upper GI bleeding is one of the common reasons for patients to visit our hospital and for gastroenterologist consultation in Tikur Anbessa specialized hospital. This study is one of the few prospective studies conducted on etiology, clinical profile and outcomes and factors associated with outcomes of patients with UGIB in Ethiopia. In our study, 73.2% of upper GI bleeding patients were male. Such male predominance was reported in other studies from Africa and from the Middle East countries as well as from a retrospective study in Ethiopia which reported a significant male preponderance(5,14,33,34,37,40,47,49).

The average age of participant with GIB was 41 years (range 13–84 years). About 67 (54.5%) of patients were young, under 40 years of age. This is consistent with other studies in Africa and other developing countries(5,10,14,24,40). However, it is lower than the age reported in the developed world and could reflect difference in etiology of UGIB and the higher life expectancy in the west(25).

About 30% of our study patients had recent history of NSAIDs or Anti-platelet drug use which is lower than the studies reported in Europe(25,34) but comparable from a study from Bangladesh who reported that about 29% of their patients had use of NSAIDs or anti-platelet drugs((10)). Alcohol intake was seen in our study population in 50% cases which is higher than reported in India, which has similar socio-demographics as our country (5). Smoking was reported in our study in 24% of patients and is similar to that reported in Bangladesh((10)). Stool H.*pylori* test was positive in 50% of patients with ulcer bleeding in our study which is lower than that reported from a retrospective study at a different institution in our country (57%) of ulcer bleeding patients had stool H.*pylor*i positive((14)). Hematemesis and melena were the most common clinical presentation in our study followed by melena only in 24% of the patients. This is similar to other studies done in Africa and Asia(10,24,43). About 30% of the patients had deranged vital signs with tachycardia >100 BPM or systolic BP < 100, a finding seen in other similar studies from India((52)).

40% of the patients in our study have co-morbidities, most of which is HTN and diabetes, which together account for 55% of the comorbidities in our study which is comparable to a study from Ethiopia in another tertiary referral institution where they reported co-morbidities in 57.8% of their study UGIB patients. Malignancy accounts for about 27% of the co-morbidities, which is equivalent to that seen in our study. This is in contrast with other studies with the same socio-

demographic make-up of population with reported co-morbidities of less than 20% ((10,52)) These are quite high considering the young age demography of our study group. This might be explained by the referral bias as our institution is one of the few tertiary referral centers in the country for both endoscopy services as well as oncology treatment center.

Regarding laboratory abnormalities seen in this study low hemoglobin less than 8 g/dl was seen in 45% of patients in our study, which defines severe anemia which is lower than reported in Tanzania where 60% their study patients had Hgb<8g/dl((24)). Transfusion of blood was given to 47% of patients in our study and this is comparable to a retrospective study done in a referral center in Ethiopia where 48% of their patients with UGIB required transfusion((14)).

In this study, variceal bleeding is the most common cause of bleeding seen on endoscopy accounting for 54% of cases followed by ulcer bleeding which is about 16% bleeding cases. This is also the case in most studies from Africa and India where variceal bleeding and portal hypertensive bleeding accounts for most of the upper GI bleeding. This might be because of the shared socio-demographic characteristics including the prevalence of viral hepatitis and schistosomiasis in the areas((5,14,33,36,43,44)). This is in contrast to the high prevalence of ulcer bleeding in high income countries((6)). Most of the patients had grade 3 esophageal varices from the esophageal varices group and the majority of the ulcer bleeders had Forrest class III ulcers.

Ultrasonography was done for all 123 patients in our study. Portal hypertension was the most common finding on ultrasound which was found in 50.4% of our patients which corresponds with the finding of variceal bleeding on endoscopy. This is lower than that seen in Tanzania (30%) and India where 47% patients had portal hypertension and 43% had cirrhosis((5,33)). The cause of portal hypertension was viral hepatitis in 35.5% of the patients, 24.2% was due to hepatosplenic schistosomiasis evidenced by peri-portal fibrosis on ultrasound. This is similar to a retrospective study done in our country where they reported chronic viral hepatitis in 36.5% of patients with portal hypertension((14)). Alcoholic cirrhosis accounts for 14.5% of the portal hypertension, followed by autoimmune liver disease seen in 8.1% patients. This is in contrast to reports from India where most of the portal hypertension is due to alcoholic liver disease((43,44)).

Guidelines recommends that following hemodynamic resuscitation, early (≤24 hours) upper GI endoscopy should be performed(28,32). In our study endoscopy was done within 24 hous in 58% patients. While this is a higher number than a study from another tertiary referral center reported

in our country and from another study from Africa where about 17% patients received early endoscopy (<24 hours)((14,24)). 43% of patients received interventional endoscopic treatment which is higher than that reported in other African studies where 74% patients with variceal bleeding were managed medically only((14)).

Mortality is dependent on the study population, and inclusion and exclusion criteria used. In our study, death at 30 days occurred in 13.8% of the patients. This is lower than that reported from Africa as well as India who have mortality reports from 16.7% in Uganda to 24% in Iran((14,24,34,40,44)). There are reports of lower mortality from India with report of 8.6% mortality as well as in Egypt with reported mortality of 8.7%((36,52)).

Factors associated with death at 30 days in our study on multivariate analysis include elderly with age >60 years, hemodynamic instability with PR>100, longer length of stay in-hospital and urgent endoscopy. Similarly, age >60 years is reported as a factor for mortality from studies in Africa as well as other countries((24,34,47)). Higher mortality in patients with hemodynamic instability has been shown in different studies including from a retrospective study done in our country((14)) and patients benefit from early adequate resuscitation prior to endoscopy to improve survival((28,32)).

Studies showed that the mortality of UGIB is higher in patients who had co-morbid illnesses(43,44). In our study only 12.2% of patients with comorbidities died. This may be due to small sample size and lack of wide spread population screening for common comorbid illness and hence the presence of undiagnosed comorbidities.

Patients with longer length of stay in hospital are more likely to develop complications as well as hospital acquired infections contributing to increased mortality as these patients are more likely to be immunosuppressed from their underlying comorbid disease conditions.

Rebleeding at 30 days occurred in 17% of the patients in our study this is quite high compared to other studies with reported rebleeding rate of 3.4% to 11.9%((34,52)).

Low systolic BP, elevated alanine transaminase level, the presence of portal hypertension and multiple blood transfusion requirement were significantly associated with rebleeding at 30 days in our study. Studies from India had reported similar significant mortality associated with the presence of portal hypertension, with hemodynamic instability and requirement of multiple transfusions((52)).

7. Conclusion and Recommendations

7.1. Conclusion

In this study, the majority of patients belonged to the age under 40 years, with a male predilection. Variceal bleed was the commonest cause of upper GI bleeding in our patients. The overall 30-days mortality is 13.8% and 30-days re-bleeding rate is 17% with the majority of patients length of stay in hospital less than three days. Patients with acute UGIB require early and more aggressive intervention.

7.2. Strength

As to the investigator's knowledge, this is the first prospective study done on outcomes of upper GI bleeding in Ethiopia.

It is done at the endoscopy training center accredited by WGO.

7.3. Limitation of the study

This is a single centered hospital based prospective study

7.4. Recommendations

We recommend a large scale multicenter national study to study the morbidity and mortality of GI bleeding and policy makers should give priority for GI bleeding including development of guidelines, expand endoscopic service and scale up of treatment centers.

Future studies should also focus on evaluating how to improve access to UGI endoscopy so as to improve outcomes.

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Annex:

Questionnaire

Questionnaire to assess: Major Causes and Factors affecting the outcome of patients with Upper GI bleeding in Tikur Anbessa specialized hospital.

Institution Based Prospective cohort study

Code _____

MRN_____

Study site_____

PART I: SOCIODEMOGRAPHIC CHARACTERSTICS

1. Age in years _____

2. Address

A. Addis Ababa B. Oromia C. Amhara D. SNNPR E. Tigray F. Others (specify)_____

3. Marital status

A- Single B- Married C- Divorced / Separated

4. Employments

A- Yes B- No

5. Average monthly income (birr) _____

PART II. RISK FACTORS

1. How often do you drink Alcohol?

A. Regular Alcoholic B. Occasional C. Ex-alcoholic D. Never

2.Smoking history (Do you smoke?)

A. Never B. Former C. Current D. Unknown

3. Do you take any Antiplatelet drugs?

A. Aspirin B. Clopidogrel C. No use

4. Do you take Anticoagulants?

A. Warfarin B. Others (specify)_____ C. None

5. Do you take NSAIDS? A. Diclofenac B. Ibuprofen C. Others (Specify)_____ D. None

6. Any known Viral Hepatitis?

A. Hepatitis B B. Hepatitis C C. Others/specify_____

7. Helicobacter Pylori tested? A. Positive B. Negative C. Not determined

8. Do you have Prior chronic Liver Disease? A. Yes B. No

9. Do you have Prior PUD history? A. Yes B. No

10. Do you have Previous history of UGIB?

PART III. CLINICAL PRESENTATION

1. Hematemesis only A. Yes B. No
2. Melena only A. Yes B. No
3. Hematemesis and Melena A. Yes B. No
4 Hematochezia only A. Yes B. No
5. Anemia only A. Yes B. No
6. Syncope A. Present B. Absent
7. Systolic Blood pressure at presentation A. >/- 100mmHg B. <100mmHg
8. Pulse rate at presentation A. >100 BPM B. </-100 BPM

PART IV COMORBIDITIES

1. HTN A. Yes B. No

2. Diabetes A. T1DM B. T2DM C. No Diabetes

3. IHD A. Yes B. No

4. Stroke A. Ischemic stroke B. Hemorrhagic stroke C. No

5. COPD A. Yes B. No

6. Asthma A. Yes B. No

7 CKD A. Yes B. No

8. Known Malignancy A. Yes B. No

PART V: LABORATORY PROFILES

CBC	WBC	< 10,000 >10,000
	Hgb level	< 7g/dl 8-10 g/dl 10-12g/dl > 12g/dl
	Platelet	< 150,000 >150,000
LFT	ALT	Normal Increased ( )
	AST	Normal Increased ( )
	ALP	Normal Increased ( )
	T. Bil	Normal Increased ( )
	INR	Normal Prolonged( )
	Albumin	Normal Decreased ( )
RFT	Creatinine	Normal Increased ( )
	Urea	Normal ( ) Increased ( )

PART 6. ENDOSCOPIC PROFILES

1. Gastric Ulcer	1.Yes (Specify Forrest class) _____	2.No	
2. Duodenal Ulcer	1.Yes (Specify Forrest class) _____	2.No	
3. Esophageal varices	1.Yes (Specify Grade) _____	2. No	
4. Gastric Varices	1.Yes (Specify Sarin class) _____	2.No	
5. Gastro esophageal varices	1.Yes(specify)_____	2.No	
6. Portal-hypertensive gastropathy	1.Yes	2.No	
7. Gastric Cancer	1.Yes	2.No	
8. Esophageal Cancer	1.Yes	2.No	
9. Mallory Weiss tear	1.Yes	2.No	
10. GERD	1.Yes (Specify LA-Grade)	2.No	
11. Others	1.Yes (Specify)_____	2.No	
12.. Endoscopy done by	1. Senior	2. Fellow	

PART 7. ULTRASONOGRAPHIC FEATURES

1. Features of Cirrhosis	1.Yes (specify)	2.No	
2. Periportal Fibrosis	1.Yes	2.No	
3. Splenomegaly	1.Yes	2.No	
4. Features of portal HTN	1.Yes (specify)	2.No	
5. Other Findings			

PART 8. MANAGEMENT

1.	Conservative management (Medical management) only	1. Yes 2. No	
2.	Endoscopy done how many hours after admission	1. < 6 hrs 2. 6-12 hours 3. Between 12 and 24 hours 4. Greater than 24 hours	
3.	Reason Endoscopic treatment not given	1. Endoscopic treatment not required (clean based etc.…) 2. Facility not available (band or sclerosant)	
4.	Endoscopic Treatment done	1. Epinephrine Injection 2. Sclerotherapy 3. Band ligation 4. Heat therapy (Monopolar, Bipolar)	
5	Blood Transfusion	1. Red cell transfusion(quantify) ____ 2. Platelet transfusion(quantify)_____ 3. FFP transfusion(quantify)_____ 4. No blood products given	
6	Helicobacter pylori	1. Tested (Result) ……. 2. Not tested	

PART IX. OUTCOMES

1.	Outcomes (at first endoscopic therapy)	1.Controlled bleeding 2.Continued bleeding 3.Required intubation	
2.	Complications During hospitalization	1.Rebleeding 2.AKI 3.Encephalopathy	

		4.Infection(specify)_____ 5.Death 6. Not hospitalized	
3.	Outcome at 30 days	1. Death 2. Alive, Rebleeding – Mention time of Rebleeding 3. Alive, No Rebleeding	
4.	Length of stay in hospital	_____(In days)	

Consent form for patients

This questionnaire is to be filled by a health professional.

Dear Participant, my name is Dr Blen W/Giorgis. I am an internist who is on a Sub specialty training in Gastroenterology and hepatology at Addis Ababa University, school of medicine department of Internal medicine.

I am conducting a research project titled: Major Causes and Factors affecting the outcome of patients with Upper GI bleeding in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia.

Your participation in this research is entirely voluntary. I am grateful that you are willing to give information about your health condition which will only take about 15 minutes. This research is being done to predict factors affecting the outcome of patients with upper GI bleeding in Ethiopia and improve patient care subsequently based on the findings of the research.
By participating in the study, you are contributing to the betterment of the national health status as the information you give will be compiled and used in the policy making, Guideline development and further research.

All the information you provide us will be kept confidential and your name will be coded in number. There is no harm associated with the study and you have the right to decline involvement in the study or withdraw your consent at any point during the interview.

I would like to kindly ask you to give as a genuine response and sign in the space provided below to describe that you willingly decided to participate in the study.

Signature of participant: _____ Date: _____

Signature of the interviewer: _____ Date: _____

Information to data collector

Dear data collector, please make sure that the data is complete and any questions that you may have can be raised using the following address.

Mob: (+251) 911-97-77-04

Email: meetblen2010@gmail.com