CLINICAL PROFILE AND MANAGEMENT OUTCOME OF ACUTE CHOLANGITIS: A CROSSECTIONAL STUDY

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A thesis submitted to department of Surgery, School of Medicine, College of Medicine and Health Sciences, in partial fulfillment of the requirements for subspecialty certificate in Hepato-pancreaticobiliary surgery.

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July 2025

Addis Ababa, Ethiopia

DECLARATION

I, Dr.Gemeda Nebi, hereby declare that the work entitled `` Prevalence and factors associated with surgical site infection in patients undergoing hepato-pancreaticobiliary surgery: A Crossectional Multicentric Study, Addis Ababa`` is the result of my own work, and all sources or materials used for this thesis have been appropriately acknowledged. This thesis is submitted in partial fulfillment of the requirement for the award of a subspeciality certificate in Hepatopancreaticobiliary Surgery. It is an original work and this thesis has not been submitted to any other institution anywhere for the award of any academic promotion.

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Date of Submission, July,2025

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This is to certify the thesis prepared by Dr.Gemeda Nebi Edasu entitled`` Prevalence and factors associated with surgical site infection in patients undergoing hepato-pancreaticobiliary surgery: A Crossectional Multicentric Study, Addis Ababa`` and submitted in partial fulfillment of the requirement for the award of a subspeciality certificate in Hepatopancreaticobiliary Surgery complies with the regulations of the university and meets the accepted standards to originality and quality.

Advisor: **Dr. Zeki Abdurahman** Signature_____ Date_____

ABSTRACT

Background

Acute cholangitis (AC) is a life-threatening infection of the biliary system, most commonly caused by choledocholithiasis or malignant biliary obstruction. Despite advances in diagnostics and treatment, its burden in low-resource settings remains under-characterized.

Objective

This study aimed to evaluate the clinical profile, etiological factors, management practices, and outcomes of patients diagnosed with acute cholangitis over a five-year period at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia.

Methods

A retrospective hospital-based study was conducted involving 81 patients admitted with acute cholangitis from January 2020 to December 2024. Data were collected from medical records using a structured form and analyzed using SPSS version 25. Logistic and linear regression were performed to identify predictors of adverse outcomes and severity grading.

Results

The mean age of patients was 53.96 years; 56.8% were female. Choledocholithiasis and malignant obstruction were the most common etiologies of acute cholangitis attributing for 50.6% and 40.7% respectively. Jaundice (95.1%) and RUQ abdominal pain (71.6%) were the most frequent presenting symptoms. Only 18.5% fulfilled Charcot's triad. About 71.6% of patients had definite acute cholangitis while 28.4% had suspected acute cholangitis based on Tokyo Guidelines (TG13. About 85.2% of cases were successfully treated with medical management alone. About 39.5% of patients had unfavorable outcomes. Multivariate analysis identified age (**AOR: 4.7, 95% CI**: **1.04, 21.47; p=0.044**), presence of morbidity (**AOR: 4.7, 95% CI**: **1.05, 21.55; p=0.043**), TG13 Grade III (**AOR:3.1, 95% CI: 2.11, 8.36; p=0.024)** to be significantly associated with unfavorable outcome.

Conclusion

This study of acute cholangitis reveals a patient population with distinct demographic and etiological features, including a majority of female patients and a high rate of malignant obstruction (40.7%). The diagnostic utility of Charcot's triad was low (18.5%), while the Tokyo Guidelines (TG13) provided a definitive diagnosis in the majority of cases (71.6%). Current management, favoring open surgery (92.6%), is associated with negative outcomes, including prolonged hospital stays and high complication rates. These findings suggest that a shift toward minimally invasive techniques and adherence to the TG13 diagnostic criteria are necessary to improve patient outcomes.

Key Words: Acute ascending cholangitis, Ethiopia, clinical profile, management

Acknowledgement

I wish to express my sincere appreciation to the Department of Surgery, College of Health Sciences, Addis Ababa University, for facilitating this study and providing the necessary resources. Furthermore, my deepest thanks are reserved for my advisor, **Dr. Zeki Abdurahman,** for his unwavering support, guidance, and valuable feedback at every stage of this research. I am sincerely thankful to the study participants for their enthusiastic contributions.

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Abbreviation	Full Term
AC	Acute Cholangitis
TG13	Tokyo Guidelines 2013
TG18	Tokyo Guidelines 2018
ERCP	Endoscopic Retrograde Cholangiopancreatography
CBD	Common Bile Duct
RUQ	Right Upper Quadrant
ICU	Intensive Care Unit
WBC	White Blood Cell (Count)
PT	Prothrombin Time
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
ALP	Alkaline Phosphatase
TB	Total Bilirubin
DB	Direct Bilirubin
SPSS	Statistical Package for the Social Sciences
SD	Standard Deviation
CT	Computed Tomography
US	Ultrasound
MRCP	Magnetic Resonance Cholangiopancreatography
GI	Gastrointestinal
OPD	Outpatient Department
IQR	Interquartile Range
OR	Odds Ratio
CI	Confidence Interval
DR	Drainage
LFT	Liver Function Test

INTRODUCTION

1. Introduction

1.1 Background

Acute cholangitis is an acute inflammation and infection within the biliary tree, usually secondary to a mechanical obstruction such as choledocholithiasis, malignant biliary obstruction, benign strictures, ampullary or duodenal obstruction, and stent blockade. Or sphincter of Oddi dysfunction. It ranges in severity from a mild form, with fever and jaundice, to a severe form with septic shock(1). Persistent or partial obstruction to the biliary tree causes increased intraductal pressure, which eventually leads to the reflux of bacteria from duodenum to venous and lymphatic system. When bacteria translocate into the bloodstream, it precipitates septicemia, a systemic inflammatory response syndrome that represents a commonly fatal sequela of acute cholangitis(2, 3).

The causes of biliary tree obstruction in in greater than 85% is attributed to bile duct stones, malignancies and benign strictures(4-6). In the presence of obstruction, the bile is colonized and bacterial proliferates causing infection. The most common etiologies retrieved from bile and blood culture are E. coli, Klebsiella spp and Bacteroides spp (7, 8).

The triads of jaundice, fever and abdominal pain termed Charcoit`s triad was used for very long time to diagnose acute cholangitis. The triad remains pathognomonic for identifying cholangitis and carries a specificity of 85%, it yields a sensitivity of approximately 25% (9, 10). findings of hypotension and altered mental status are seen in only 5%–7% of cases, but typically represent more severe disease(11). Although fever in isolation exhibits a reported sensitivity ranging from 40% to 100% and abdominal pain alone demonstrates a sensitivity between 60% and 100%, these symptoms are limited by a lack of specificity (12).

But, in recent studies, its diagnostic sensitivity was found poor and it is no more used as diagnostic criteria. Since 2007, the Tokyo guideline has been used to diagnose, to classify and provide severity-based intervention worldwide. The guidelines were updated in 2013 and 2018, for better diagnostic sensitivity. Features of systemic inflammation, cholestasis and imaging findings were used in combination to diagnose AC in the guidelines. A definitive diagnosis of the

disease is made if a feature is found from systemic inflammation, cholestasis, and imaging. The diagnosis of suspected AC is made, if one item from systemic inflammation and one item from either cholestasis or imaging is present. The diagnostic sensitivity of TG13 is about 90% (13-15).

This infection of the bile duct can lead to severe complications, including sepsis, liver failure, prolonged hospital stays, and even death if not promptly diagnosed and treated. It is a rapidly progressive infection with mortality as high as 30%(16). The backbone of the treatment of acute cholangitis comprises prudent intravenous hydration and broad-spectrum antibiotic therapy. However, about 20% to 30% may fail to respond to medical management alone and require biliary drainage(17).

Globally, an annual incidence of 28 cases per 100 000 individuals(18). The incidence is higher in regions with a high prevalence of gallstone disease. The annual incidence rate of AC in the United States has been reported to range from 12 to 35 cases per 100 000 individuals, making it a relatively common cause of hospital admission(19). Up to 9% of patients admitted to hospital with gallstone disease have acute cholangitis. The median age ranges from 50-60 years and demonstrates a higher prevalence in males(13). Importantly, the underlying bacterial infection, serving as the essential trigger for acute cholangitis, can be exacerbated by numerous contributing factors(20).

Immunosuppression is a notable risk factor, as a weakened immune system can struggle to control bacterial populations within the biliary tract, resulting in overgrowth and possible infections. Invasive procedures in the biliary tract, such as endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography (PTC), can also introduce bacteria into the biliary system or cause trauma to the ducts, increasing the risk of infection(21). The incidence of acute cholangitis following ERCP is about 1% (22).

After proper physical examination, laboratory work up which includes CBC, LFTs, serum amylase, and lipase will be ordered if not already done while the patient was admitted. LFTs are important with serum pancreatic enzymes to exclude other causes or complications of cholangitis such as biliary or non-biliary pancreatitis. Bile and blood cultures are used for selecting appropriate antibiotics. If polymicrobial growth and polymicrobial sepsis are present, it may indicate a serious condition(23).

All patients with symptoms of acute cholangitis require imaging to establish the diagnosis and determine its severity, etiology, and extent. Abdominal ultrasound is usually the first imaging of choice. CT of the abdomen is usually performed to exclude other causes and to confirm a correct diagnosis especially if a malignant obstruction is suspected. It is used primarily for the evaluation of extrahepatic spread, to identify pericholedochal fistulas, and to delineate areas of fluid collection that may need drainage. MRCP is used when the diagnosis remains uncertain following US and CT. It is key to demarcate the level of obstruction(24).

Management of AC includes immediate resuscitation and stabilization of the patient, antibiotics, decompression of the biliary tree, and performance of definitive therapy. There is a consensus that patients with acute cholangitis should receive broad-spectrum antibiotics, and other measures should not be delayed while waiting for a definitive diagnosis. Organisms that produce common biliary tract infections are the main etiologic agents of AC: E.coli , Klebsiella, Enterobacter, and Bacteroides. Antibiotic coverage of the organisms obtained from cultures is crucial to achieving a good result in the management of patients for the most appropriate antibiotic treatment (25). The only way to downstage the severe AC is by biliary drainage with ERCP or PTC. ERCP is the first choice of biliary drainage in many cases. in patients with complications or persisting sepsis despite endoscopic intervention, PTC or operative biliary access is used(13, 23, 26, 27).

1.2 Statement of the problem

Acute cholangitis (AC), often referred to as ascending cholangitis, constitutes an urgent medical condition resulting from bacterial infection of the biliary system. (28). Choledocholithiasis, which obstructs the biliary tree, is the most significant risk factor for AC, representing almost 50% of cases(29). Malignant obstruction, which accounts for 10–30% of cases of AC, is the second most frequent cause of biliary obstruction(30).

The increased incidence of AC has been attributed by several factors such as aging populations with a higher prevalence of gallstones (the primary cause of biliary obstruction), and increased use of invasive biliary procedures. Acute cholangitis (AC) may also manifest as a post-procedural complication following endoscopic retrograde cholangiopancreatography (ERCP) for various biliary diseases, with incidence rate ranging from 0.5% to 2.4% (31, 32). The response to

medical therapy including antibiotics is very high if started timely. However, decompression may also be needed in many cases. surgical treatment is associated with significant mortality (10 %-40%) and disease severity (33, 34).

Accurate and up-to-date epidemiological data on in the AC are relatively scarce, mainly in the sub-Saharan African countries (31). The burden of acute cholangitis at Tikur Anbessa Specialized Hospital is notable due to the hospital's role as a tertiary referral center in Ethiopia. However, limited information exists on the clinical profile, management practices, and outcomes of patients treated for acute cholangitis.

Challenges such as delayed presentation, resource constraints, limited access to advanced diagnostic and therapeutic modalities, and variability in clinical management protocols may contribute to suboptimal outcomes. The lack of local data further hampers the development of context-specific strategies for improving care delivery. This retrospective study aims to analyze the clinical characteristics, etiologic factors, management approaches, and patient outcomes in cases of acute cholangitis at Tikur Anbessa Specialized Hospital.

1.3 Significance of the study

This study on the clinical profile and management of acute cholangitis holds significant importance for both clinical practice and public health by characterizing the clinical presentation and demographic features of patients with acute cholangitis, the study will provide insights into the local disease burden, risk factors, management pattern, outcome and trends specific to the studied population.

Identifying common symptoms, laboratory findings and imaging results associated with acute cholangitis will help clinicians improve diagnostic accuracy and reduce delays in initiating treatment, thereby improving patient outcomes. This can guide the development of standard treatment protocols tailored to the local healthcare context.

Data from this study can inform hospital administrators and policymakers about resource needs, such as improving access to diagnostic tools and therapeutic procedures, leading to better healthcare delivery for biliary tract diseases. The study will provide a baseline for further research into acute cholangitis and related biliary conditions, including other types of studies to test interventions or preventive measures.

By addressing these critical aspects, this study has the potential to enhance the quality of care for patients with acute cholangitis and contribute to evidence-based improvements in healthcare practices and policies.

2. Literature review

2.1 Pathophysiology and Etiologies of Acute cholangitis

Under normal circumstance the bile is sterile. This is kept by continuous flow of bile and the immunologic property of bile provided by IgA, mucous from biliary epithelium , bile salts, and tight junction between cholangiocytes and Kupffer cell (35). But, in the presence of biliary tree obstruction, these protective mechanisms are affected which can result in Acute cholangitis. For acute cholangitis to occur two important events must be present in majority of the cases. These are partial or complete obstruction to bile flow and bacterial proliferation in the normally sterile bile. The obstruction to bile flow causes abrupt increase in intraductal pressure. When the pressure in the ductal system is more than 20 cm of H_20, the bile will reflux into the venous and lymphatic system(8, 36, 37).

The organisms mostly found on blood or bile culture in different literatures are E.coli and Klebsiella spp. From a retrospective multicentric study, it was found that blood culture and bile culture were positive in 40 % and 83 % respectively. The agreement between the two was found in 31 % of the cases(8) . Other studies found different microorganisms across each TG13 severity grade with the aforementioned two microorganisms being the commonest in all the three severity grades. A study done in a tertiary center in South India on the profile and outcome of patients with acute cholangitis found Bile culture to be positive in 62.9%. In contrast, blood culture was positive in 15.7%. Bile cultures were predominantly polymicrobial compared to blood cultures (53.8 vs. 18%). Escherichia coli was the predominant isolate in blood and bile. Multidrug-resistant (MDR) organisms were seen in 79.5% of positive bile cultures (38).

The etiologies of acute cholangitis were found to be bile duct stones, different tumors, parasites, and benign biliary strictures(4, 5, 35, 36). A retrospective crossectional study of 6433 patients showed bile duct stone, tumors, and stent obstruction contributing to 61.0 %, 12.1% and 13.6% of cases of acute cholangitis respectively. This study found that about 41% of patients had a previous history of biliary procedures. Cholecystectomy (15%), biliary stent placement (15.2%), and biliary-enteric anastomosis (7.5%) were the most commonly found history(4).

The study done in a tertiary center in South India on profile and outcome of patients with acute cholangitis found that choledocholithiasis (54.3%), benign biliary stricture (28.6%), and malignancy (17.1%) were common etiological factors(6). Another retrospective study of 211

patients from Indonesia found almost similar result with stones, tumors and stricture being the commonest etiologic factors of acute cholangitis contributing to 68.25%, 30.33%, and 1.42 % respectively(39). A study by Seiki Kiriyama and colleagues of 6063 patients showed the disease to be commoner in males (59%) with mean age of 72.2± 13.6 years. Stones (60.3%), Malignancy (15.6%) , and stent obstruction (11%) were the most common etiologies of acute cholangitis in the study. The cause was unknown in 6.4% and other cause attributed for 11% combined in the study. The diagnostic rates of the TG13 criteria in patients with other or unknown etiologies were lower than those in patients with bile duct stones, malignancy and stent obstruction ($P < 0.01$)(40).

Naresh Agarwa and colleagues reviewed 175 cases of acute cholangitis and found about 15% cases having associated comorbidities. Diabetes mellitus (n = 10), hypertension (n = 12), coronary artery disease (n = 6), cerebrovascular accidents (n = 4), chronic obstructive pulmonary disease (n = 4) and pulmonary tuberculosis (n = 3) were the comorbidities found in the study(27).

2.2. Clinical profile of acute cholangitis

The incidence of AC has been observed increasing over time, which could be attributed to several factors such as improved diagnostic methods, aging populations with a higher prevalence of gallstones and Hepatopancreaticobiliary malignancies (the primary causes of biliary obstruction), and increased use of invasive biliary procedures. Unfortunately, accurate and up-to-date epidemiological data on AC is relatively scarce, mainly because of underdiagnosis and underreporting of the condition. This especially holds in middle and low-income countries like Ethiopia where diagnostic and therapeutic strategies remain available for a few economically able patients. The clinical presentation of acute cholangitis is variable. It depends on the duration of the presentation, disease severity, and patient demographics(8, 36, 37).

In many literatures acute cholangitis was found to be commoner in older males(4, 6, 23). The study from tertiary center from India found acute cholangitis in around 75% of cases. The mean age in the study was 51.7 ± 16 years(6). A study published by the Japanese Society of Hepatopancreaticobiliary surgery in 2017, found the mean age in TG13 grade I, grade II, and grade III to be 68.7 years, 76.3 years and 74.7 years respectively(40). The proportion of males in the study in each severity grading was 60% ,56.7 %, and 59.5% in grades I, II, and III

respectively(4). However, the review of 211 patients from Indosea showed acute cholangitis to be slightly commoner in females contributing for 51.6%(39).

Different attempts were made to increase diagnostic ability. One such attempt was the use of charcoit triads (fever, RUQ abdominal pain and jaundice) for diagnosing AC. The disease can progress to cause septic shock and change in mentation. The charcoit triads along with the latter two complications were called the Reynolds pentad. The charcoit triads have been in use for very long time for the diagnosis of Ac cholangitis, but its sensitivity and diagnostic rates largely remained very low though its specificity is high(14, 36). A review of 6063 patients by Kiriyama and colleagues showed that the rate of positivity of charcoit`s triad ranging from 14.2% in TG13 severity grade I to 27.4% in TG13 severity grade III. Over all the sign was positive in only 21.2 %(40). In a retrospective review of acute cholangitis patients, Charcot`s triad was more common in moderate to severe cholangitis. about 70% of patients with Charcot`s triad had moderate-to-severe cholangitis, while 6 (30%) patients had mild cholangitis(6).

Another important event in the diagnosis of AC is the establishment of Tokyo Guideline in 2007 which was revised in 2013 and 2018. The guideline is internationally used by clinicians to diagnose, and manage AC and its complications. This guideline was expected to be dynamic and change continually with advancements in technology and the latest understanding. Diagnosis, severity classification, therapeutic interventions and management algorithms were the central focus of the guidelines. The guidelines can differentiate the disease from acute cholecystitis or acute hepatitis with high sensitivity (87.6%) and high specificity (77.7%) (41). Kiriyama and colleagues, in their review, applied TG13 severity grading criteria retrospectively. They found that when the criteria are appropriately applied, it has about 90% sensitivity of diagnosing acute cholangitis. The result in the review showed that about 73.1% of patients met the criteria for definite Acute cholangitis where as 16.9% met the criteria for suspected acute cholangitis. About 10% met the criteria for neither definite or suspected acute cholangitis. Most of the patients (83.9%) who did not meet for diagnosis were mainly because of the absence of systemic inflammation. In this review, the proportion of patients in TG13 grade I, grade II, and grade III were 1=41.6% ,33.3%, and 25.1%(40). The study also showed that the diagnostic ability of TG13 increases with severity grading showing grade I severity to be lower than those in patients with other grades of severity.

Pedro França da Costa Soares and colleagues, in their review of 91 patients with obstructive jaundice, found that acute cholangitis was prevalent in the medical records of 9.9% of patients. However, with retrospective application of TG13 diagnostic criteria, the prevalence was actually 43%(7).

The TG13 severity grade was associated with some factors(4, 6, 39, 40). Prasanth Raghhupatruni and colleagues found that underlying chronic liver disease, high and very high Charlson comorbidity index (CCI), culture positivity, Hyperbilirubinemia > 6.3 mg/dl (p value< 0.001), ALP> 305.75 IU/L (p-value < 0.029), hypoalbuminemia < 2.8 mg/dl (p value< 0.001), INR > 1.2 (p-value< 0.039), and CRP>85.5 mg/L (p value< 0.001) were associated with moderate and severe acute cholangitis. another study by Kiriyama and colleagues found that the values of CCI, platelet, BUN, CR, and CRP increase with the increase in the severity grades of acute cholangitis(40).

The diagnosis and severity grading criteria as well are management recommendations are summarized in the following figures (41).

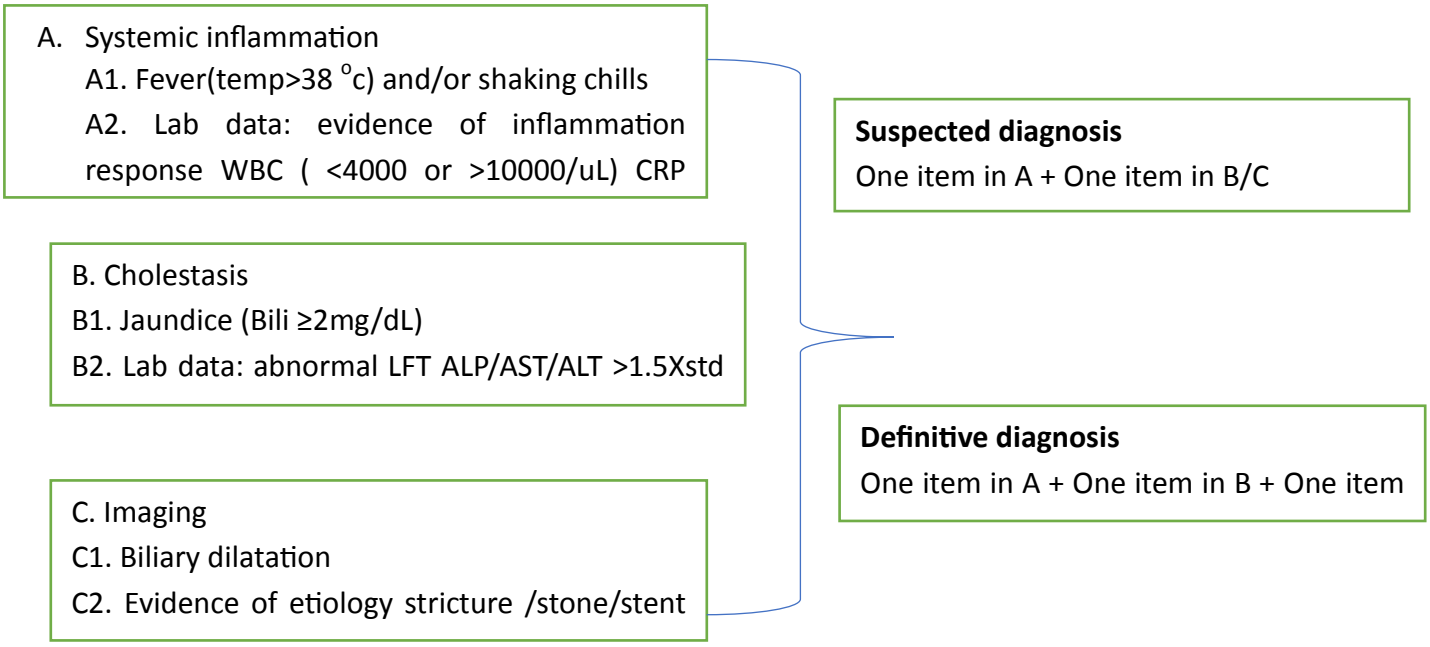


Figure 1. Suspected diagnosis and definitive diagnosis of acute cholangitis based on TG13(41)

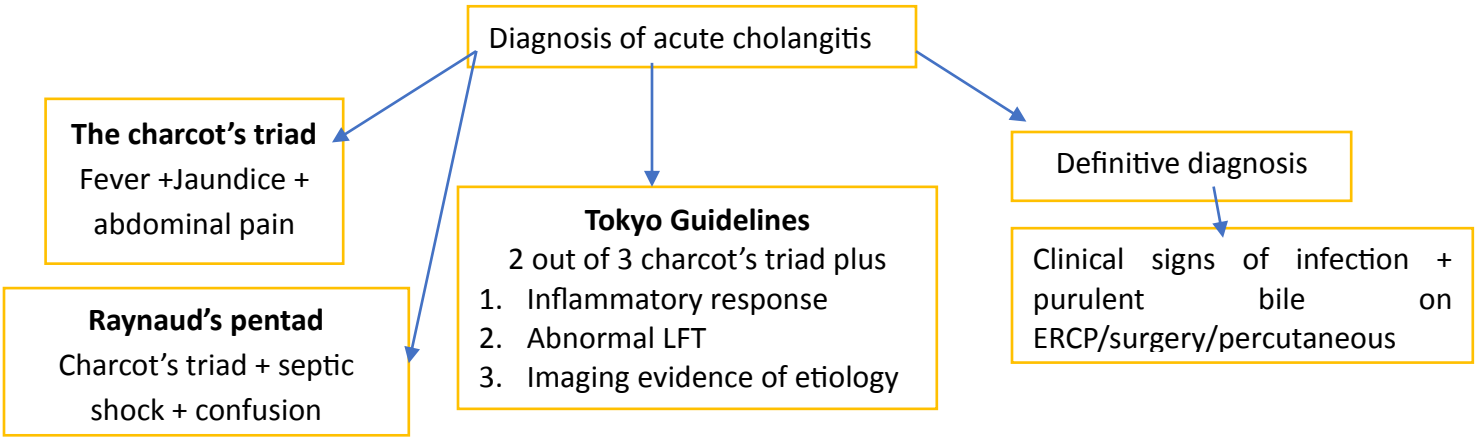


Figure 2. The different criteria for diagnosing of cholangitis(15).

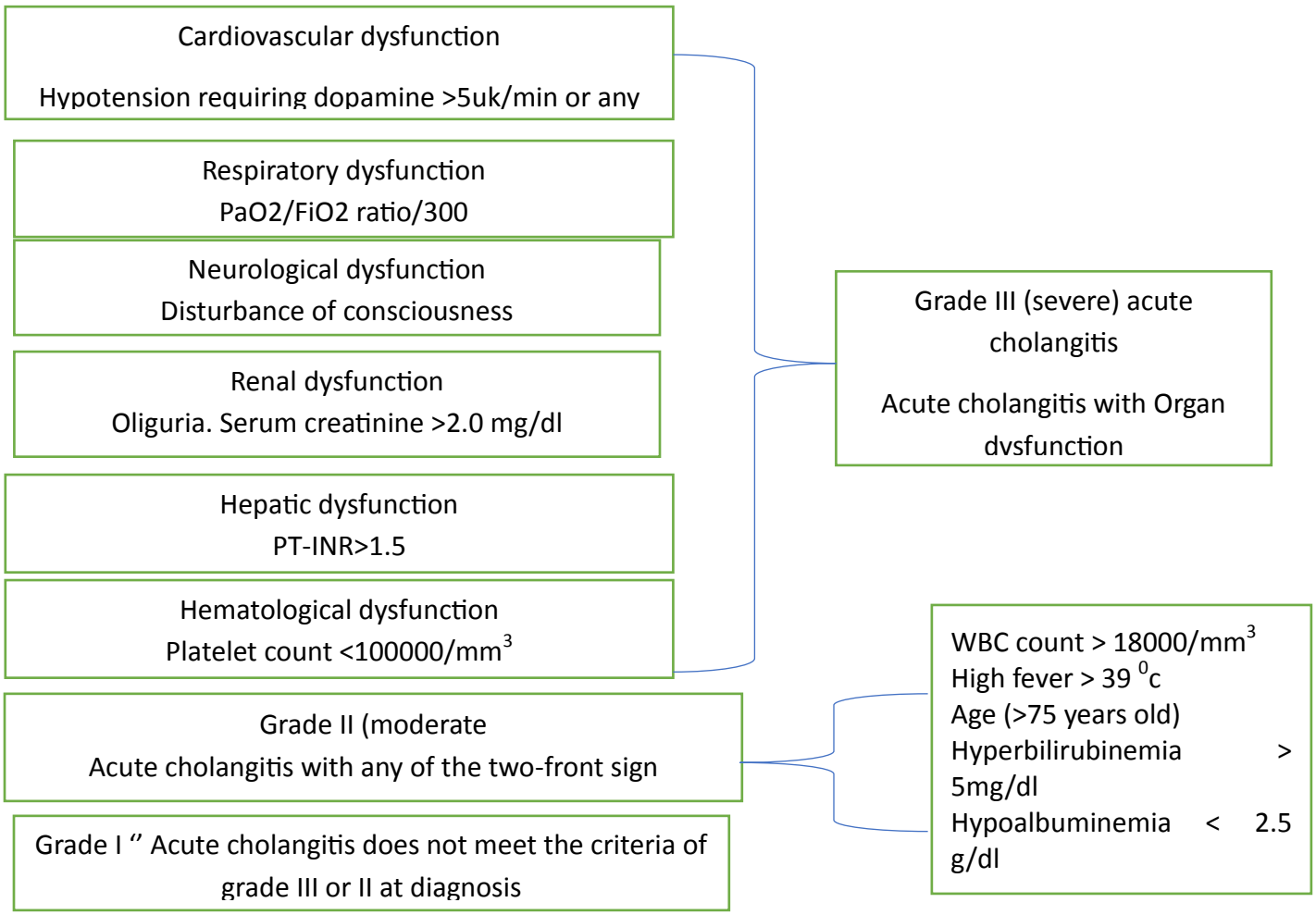


Figure 3. Severity grading of acute cholangitis in to grades I, II, III based on TG13(15).

2.3. Imaging

The imaging of patients with right upper quadrant abdominal pain usually starts with conventional abdominal ultrasound. The sensitivity of ultrasound in detecting choledocholithiasis depends on the diameter of common bile duct. The sensitivity is about 75% when CBD is dilated and about 50 % when CBD is normal in caliber. The sensitivity drops to for small stones or stones lodged near the ampulla where it is obscured by bowel gas(42, 43). In patients with acute cholangitis and unexplained or negative ultrasound findings, crossectional imaging should be done. Either CT-scan or MRCP should be done to detect the presence and site(s) of duct involvement(42). ERCP or PTC are usually reserved for biliary decompression based on location of obstruction, while ERCP or EUS aid tissue retrieval for biopsy(14, 37, 42). Kirimiya and colleagues found that positive imaging finding was affected by the etiology of obstruction. The positive finding was highest for bile duct stone (92.2%) followed by for malignancy (90.4%) and stent obstruction (85.8%). The presence of positive imaging finding was lowest when the etiology was unknown (50.8%)(40).

2.4 Management of acute cholangitis

Acute cholangitis is life threatening condition necessitating rapid identification and stabilization. According to the Tokyo Guidelines, a structured approach involving the assessment of vital signs and clinical status allows for stratification of severity and the initiation of timely intervention(13). Comprehensive assessment to identify all potential signs of sepsis and early signs of septic shock and immediate resuscitative measures is crucial (6, 36, 40).

All patients with cholangitis irrespective of the grade of cholangitis should receive antibiotic therapy and around 70% respond to medical therapy alone (44).

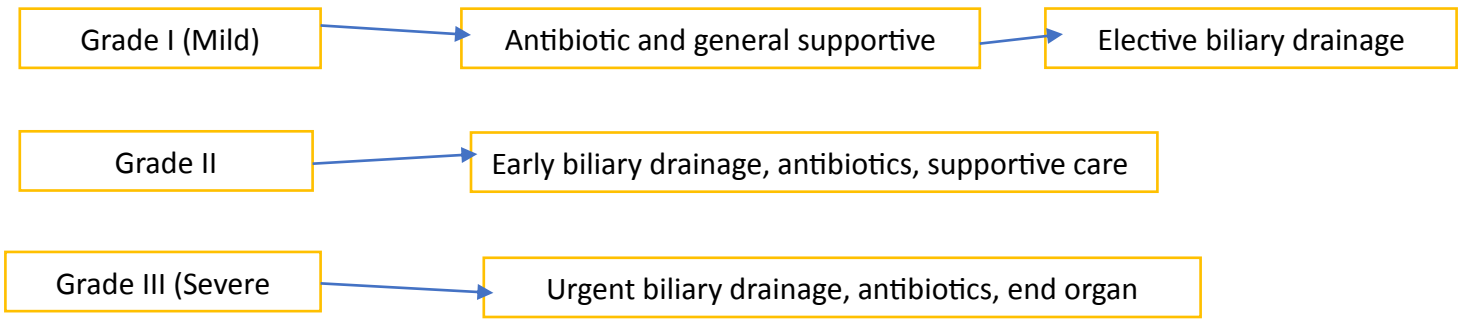


Figure 4.management regarding risk stratification based on TG13.

A review of 211 patients in Indonesia by Aries Budianto showed that the management of AC patients depends on TG13 severity grading. All patients received antibiotics regardless of the severity grading. In this study, 55.45% of patients only received antibiotics and supportive care. While 44.55 % needed external drainage (ED), cholecystectomy with common bile duct exploration (CECBD) or ERCP. External drainage was done for 10.9% of patients, and cholecystectomy and Common bile duct exploration was done for 31.28%. Bypass and ERCP were done for 1 and 4 patients respectively. It was also found that CECBD was associated with mortality in 12.07% of patients with Moderate cholangitis and 28.57 % of patients with severe cholangitis. Out of patients treated with ED, About 3 patients (15.7%) died (39).

Y. Tagashira, et al did a retrospective analysis of 573 patients with acute cholangitis in Tokyo and found that about 23.2% of patients received inadequate initial antibiotic therapy and one patient (0.8%) did not receive antibiotics. The majority of patients (79.1) had undergone ERCP therapy. Though many patients had ERCP, it did not confer any benefit in terms of reduced mortality rate in the final model despite being a statistically significant variable in univariate analysis in the study(45).

Prasanth Raghhupatruni, et al analyzed the management approach of 70 patients with acute cholangitis and found that all patients underwent ERCP regardless of the grade. About 95% of patients had biliary stenting done after ERCP. All patients who did not have stenting were cases of mild AC. Endoscopic drainage failed in about 6% of patients and later underwent PTBD and repeat ERCP.

A study done on Endoscopic operation of acute cholangitis in elderly Cases revealed that endoscopic biliary drainage was achieved in 172 cases (nobiliary drain 56 group Ⅰ, 24 group Ⅱ, stent 64 group Ⅰ, 28 group Ⅱ) without any significant age- related difference in the success rate. Abdominal pain, fever, hypotension, altered sensorium, peritonism and renal failure improved after median time of 5 d in 120 cases in group Ⅰ (2- 15 d) compared to 10 d in 47 cases of group Ⅱ (3- 20 d). Normalization of leucocyte count was seen after a median time of 7 d (3- 20 d) in 120 cases in group Ⅰ compared to 15 d (5- 26 d) in 47 cases in group Ⅱ. Five cases (melanoma gallbladder n = 3, CBD stones, n = 2) failed in the group Ⅱ and they had experienced biliary drainage after failure of response to conservative operation for 72 h. There

was increased mortality in cases in group Ⅱ despite successful biliary drainage (0/120 vs 5/ 52). Length of hospital stay was longer in group Ⅱ cases(16.4 ± 5.6, 7- 30 d) than in group Ⅰ cases(8.2 ± 2.4, 7- 20 d)(49).(46).

The outcome and prognosis of acute cholangitis were tried to be predicted by some researchers. The outcome variables in different studies used are persistent organ failure, admission to ICU, in-hospital stay, and 30-day mortality(4-6). JEAN F. and colleagues found failure of response to initial medical therapy (p-value < 0.001), renal failure (p value< 0.001), associated liver abscess (p value < 0.001), age ≥ 50 years (p- value < 0.05), female sex (p-value < 0.05), high malignant biliary stricture (p-value < 0.05), and acute cholangitis following PTC (p-value <0.05) to be associated with adverse treatment outcome. Patients responding immediately to antibiotic therapy (n = 389) were associated with a mortality of 1.5%, whereas those that did not respond (n =60) were associated with a mortality of 62%(5). One study showed CCI score > (AOR 4.12; 95% CI 1.18-14.38) , bilirubin > 2. 5mg/dl (AOR 3.39; 95% CI 1.46-7.89), septic shock within 48 h of the first positive blood culture (AOR 3.34; 95% CI 1.42-7.89) neoplastic obstruction or unsuitable initial anti-microbial therapy as predictors of adverse outcome(45). Another study found bilirubin> 10mg/dl , hypoalbuminemia (alb< 2.8g/dl) , INR > 1.5 , ALP > 305.75 IU/L, and CRP> 5mg/dl as predictors of adverse outcomes(6)

2.5 Conceptual framework

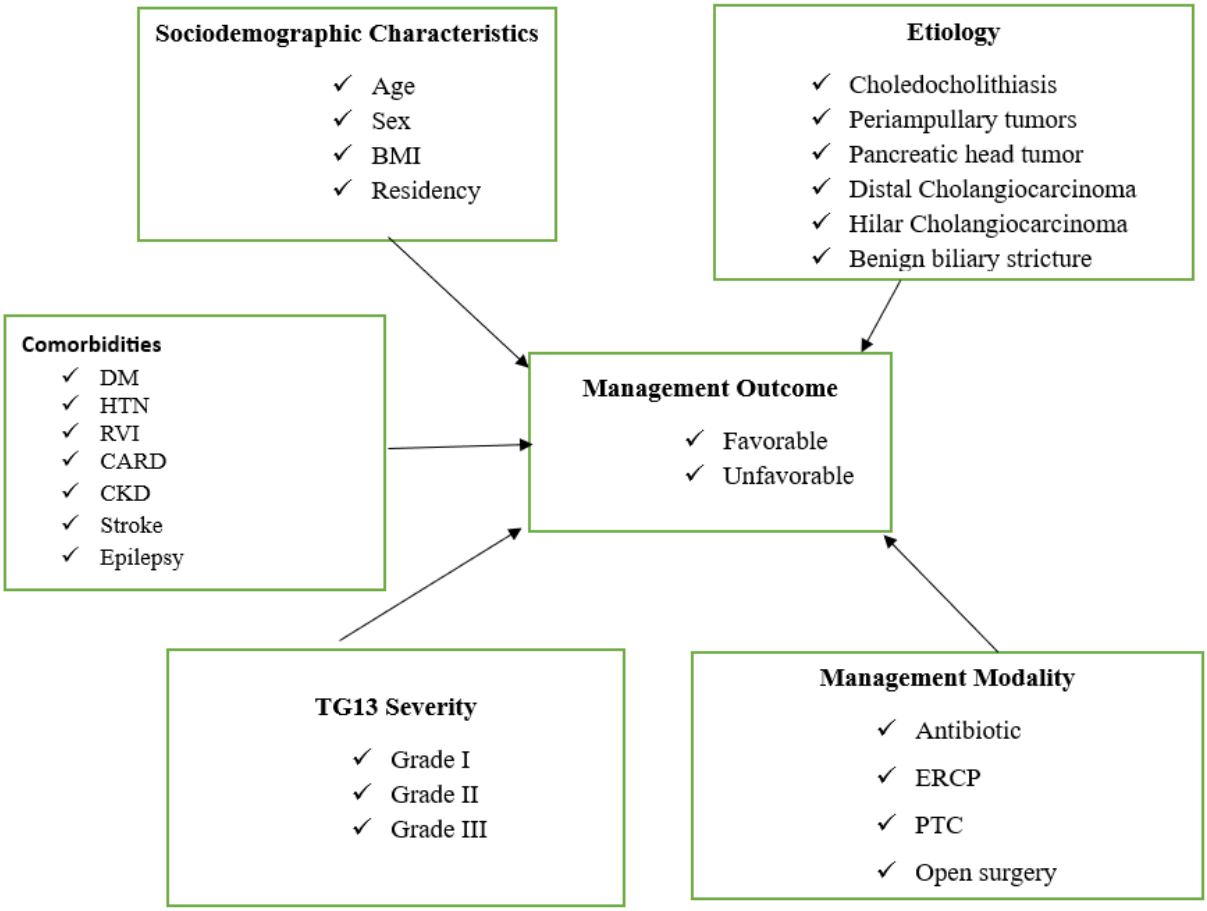


Figure 5. The conceptual framework adapted from literatures for clinical profile and management of patients treated for acute cholangitis at TASH, Addis Ababa, Ethiopia, July 2025.

3. Objective

3.1 General objective

To describe the clinical profile, management, and outcomes of patients with acute cholangitis at Tikur Anbessa Specialized Hospital.

3.2 specific objective

To describe the clinical profile of patients admitted with acute cholangitis at Tikur Anbessa Specialized Hospital.

To identify the management modalities of acute cholangitis at Tikur Anbessa Specialized Hospital.

To determine the management outcome of patient treated for acute cholangitis at Tikur Anbessa Specialized Hospital.

4.Methods

4.1 Study Area and Period

This study was conducted at Tikur Anbessa Specialized Hospital (TASH), located in Addis Ababa, Ethiopia. As the nation's largest tertiary care facility and the principal teaching hospital for numerous medical disciplines, TASH functions as the primary referral center for the most complex medical and surgical cases from across the country.

The hospital is a leading center for Hepatopancreaticobiliary (HPB) services, delivered through a dedicated HPB unit within the Department of Surgery. During the study period, this specialist unit was staffed by five supervising HPB surgeons and five HPB fellows. The concentration of specialist expertise, advanced diagnostic and therapeutic capabilities, and a high-volume, diverse patient caseload makes TASH a uniquely suitable setting for a detailed investigation into the clinical profile and management of acute cholangitis.

The study period encompassed a five-year retrospective review of patient data from January 1, 2020, to December 31, 2024. This timeframe was purposefully selected to ensure a sufficiently large and representative sample size for robust analysis and to provide a contemporary snapshot of the diagnostic approaches, management trends, and patient outcomes related to acute cholangitis at the institution.

4.2 Study Design

Institutional based crossectional study was conducted. Data was obtained from the medical records of patients (chart) diagnosed with acute cholangitis

4.3 Source Population

All adult patients who received a diagnosis of acute cholangitis at Tikur Anbessa Specialized Hospital within the designated five-year study period (January 2020, to December 2024).

4.4 Study Population

All patients admitted to the surgical wards of Tikur Anbessa Specialized Hospital with a primary diagnosis of acute cholangitis during the study period and who fulfilled all pre-defined inclusion criteria while meeting none of the exclusion criteria.

4.5 Inclusion and Exclusion Criteria

4.5.1 Inclusion criteria

All adults above the age of 18 years admitted to the surgical ward at TASH for acute cholangitis in the study period.

4.5.2 Exclusion criteria

Patients with incomplete medical records

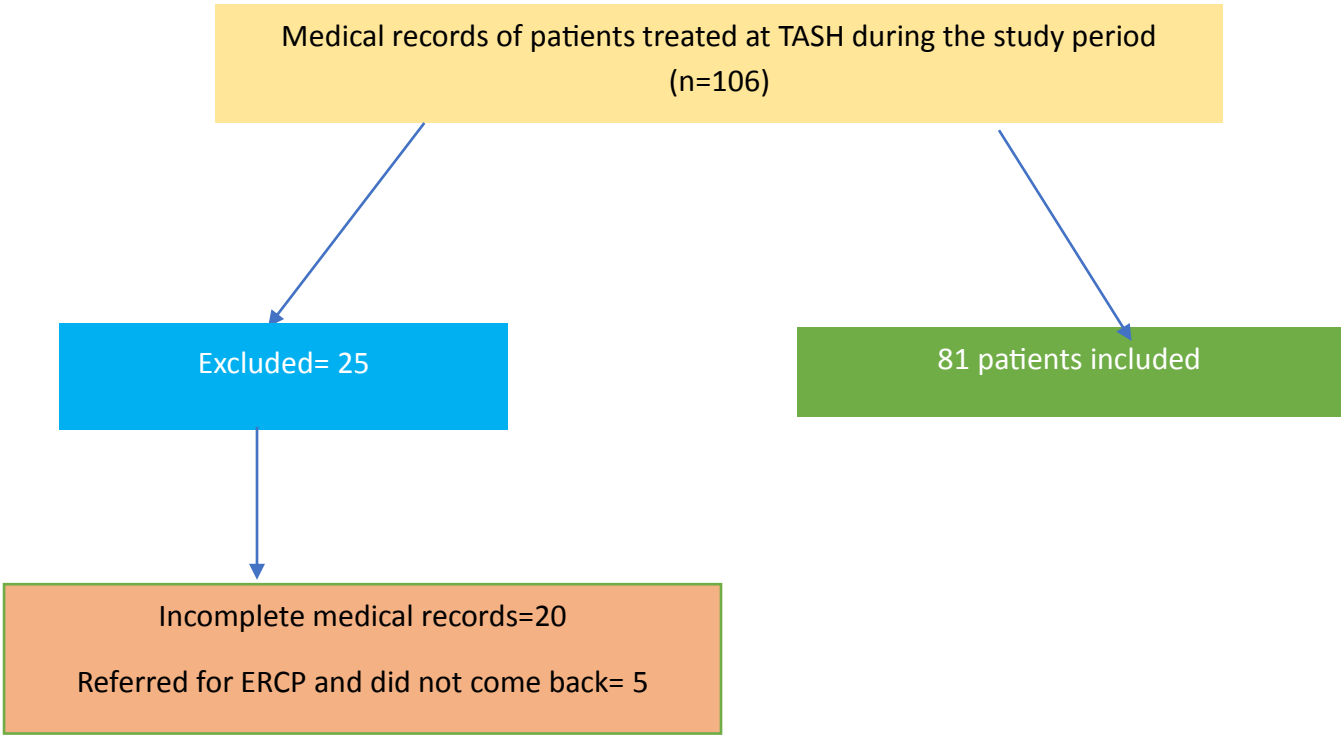
Patients who were transferred to other facilities before completing treatment and did not come back for follow-up.

Patients who did not complete the treatment

Patients with concurrent acute abdominal conditions (e.g., acute pancreatitis) that could confound the diagnosis or management of acute cholangitis

4.6 Sample Size Determination and sampling procedure

All consecutive medical records of patients with diagnosis of acute cholangitis and admitted to surgical ward during the study and who fulfilled the inclusion criteria were included.



4.8 Study Variables

4.8.1 Dependent Variable

Management outcome (Favorable vs unfavorable)

4.8.2 Independent Variables

- ✓ Sociodemographic characteristics (age,sex,BMI, residence)
- ✓ Comorbidity (DM,HTN,Cardiac Diseases, CKD, Stroke)
- ✓ Etiology (Choledocholithiasis, Periampullary tumors, Pancreatic head tumor, Distal Cholangiocarcinoma, Hilar Cholangiocarcinoma, Benign biliary stricture)
- ✓ TG13 diagnosis and severity (Grades I, II, III)
- ✓ Modality of Management (Antibiotics, ERCP, PTC or Surgery)

4.9 Operational definition

Persistent organ-failure-Organ failure persisting greater than 48 hours

Definitive acute cholangitis – cases having systemic inflammation + evidence of cholestasis + imaging evidence of biliary obstruction.

Suspected acute cholangitis- cases having systemic inflammation + evidence of cholestasis or imaging evidence of biliary obstruction

Mild acute cholangitis: - Disease with criteria of neither moderate nor severe AC

Moderate acute cholangitis: If any of the following is present: WBC count > 12000/$mm^{3\ or}$ < 4000 /mm3, high fever > 39 ^{0}c, age (>75 years old), hyperbilirubinemia > 5mg/dl, hypoalbuminemia < 2.5 g/dl.

Severe acute cholangitis: - Patients having any organ failure

Prolonged hospital stays: hospital stays greater than 75^{th} percentile(47)

Favorable outcome- if the patient has no prolonged hospital stay, liver abscess, ICU admission, in-hospital mortality, persistent organ failure, or 30-day mortality

Unfavorable outcome- patient having any of the above parameters (prolonged hospital stay, liver abscess, ICU admission, in-hospital mortality, persistent organ failure or 30-day mortality.

Clinical improvement- Clinical improvement is a positive response to initial therapy for acute cholangitis. It is defined by resolving fever, normalizing inflammatory markers (WBC, CRP), and decreasing bilirubin/liver enzymes.

4.10 Data Collection Methods

Data was collected by two trained Nurses (BSc) working at the surgical ward of TASH using pretested data collection tool prepared by the principal investigator. One surgical resident supervisor and two BSc nurse was assigned for the data collection process, training was given to the data collectors by the principal investigator for two days on the objective of the study, how to fill and collect the relevant data using the data collection sheet. The Principal Investigator was continuously supervising the data collectors. Socio-demographic and other patient-related factors were extracted from patient medical charts. The patient card number were obtained from surgery department and Operation Room HMIS register. All patient card was collected from card office. Patient data from time of discharge to one month after discharge.

4.11 Data Quality Control Measures

The data collecting sheet was adopted from previous research's done on similar title and checked for internal consistency capable of yielding the required data for the study and some modifications were done. Training was given for data collectors. The principal investigator was also supervising the data collection process. Pretest was done in 5% of the cases of the questionnaire with the same study area by the principal investigator. The collected data were checked for completeness consistency and clarity.

4.12 Data Processing and Analysis

Collected data were checked for completeness, consistency, clarity, and missed values and was entered into EPI-info version 4.6. Then cleaned and coded data was exported to SPSS version 25 for data management and further statistical analysis. The collected data in relation to option of management and associated factors. Frequency counts were performed to assess completeness of all variables. 95% confidence intervals were used to Correlates outcome variable with its independent variable. All tests were two sided and statistical significances were set at p-value < 0.05.

4.13 Ethical Considerations

The proposal was submitted to my advisors for feedback and approval before conducting the study then ethical approval was requested from surgery department research and ethical review committee and formal letter of permission was obtained from the department. Permission was obtained to the outpatient department to get the patient's chart. The information collected from the study subjects was kept confidential and it was used only for the study.

4.14 Dissemination plan and use of findings

The results of this study will be disseminated through both institutional and academic channels.

Upon completion, a comprehensive final report will be submitted to the Department of Surgery at Tikur Anbessa Specialized Hospital. The findings will also be formally presented to departmental staff to inform local clinical practice and guide potential quality improvement initiatives.

Furthermore, a manuscript detailing the study's methodology, results, and implications will be prepared and submitted for publication in a reputable, peer-reviewed medical journal. This will ensure that the findings contribute to the broader scientific literature on the management of acute cholangitis, particularly within resource-limited settings.

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5.RESULT

5.1 Socio-Demographic Characteristics

A total of 81 patients diagnosed with acute cholangitis meeting the inclusion criteria were enrolled. The mean age was 53.96 ±14.47 years (range: 22–81), with the majority aged 41–60 years (37.0%). Females comprised 56.8% of the cohort. Most patients (64.2%) resided in urban areas. Comorbidities were present in 28.4% of patients, with hypertension (14.8%%), diabetes mellitus (16%%), and Cardiac diseases (5%) being the most prevalent. See Table 1 below.

Table 1. Sociodemographic characteristics and Comorbidities, Addis Ababa,2025

Variable	Total (%)	Retrospective severity grade of acute cholangitis		
		I(%)	II(%)	III(%)
Age in years				
21-40	21(25.9)	17(20.1)	3(3.7)	1(1.2)
41-60	30(37)	18(23.5)	10(12.3)	2(2.5)
>60	**30(37)**	**14(17.3)**	**6(26.7)**	**10(16.7)**
Gender				
Male	35(43.2)	19(23.5)	8(9.9)	8(9.9)
Female	46(56.8)	30(37)	11(13.5)	5(6.2)
Residency				
Urban	**52(64.2)**	**32(39.5)**	**12(14.9)**	**8(9.8)**
Rural	29(35.8)	17(20.98)	7(8.6)	5(6.2)
Comorbidity				
Yes	**23(28.4)**	**3(3.7)**	**13(16)**	**7(8.6)**
No	58(71.6)	46(56.8)	6(7.4)	7 (8.6%)
List of comorbid disease (n=23)				
Chronic Kidney disease	2(2.5%)		1	1
Asthma	1(1.2%)		1	
Cardiac disease	4(5%)		3	1
DM	13(16%)	2	8	3
COPD	1(1.2%)		1	
Hypertension	12(14.8%)	2	5	5
Epilepsy	2(2.5%)		1	1
Stroke	1(1.2%)		1	
HIV	1(1.2%)		1	

5.2 Etiologies of Acute Cholangitis

The etiological spectrum of acute cholangitis in this cohort was broadly classified into benign and malignant origins. Benign causes accounted for the majority (59.3%) of cases, with **choledocholithiasis** identified as the most prevalent etiology, present in **50.6%** of patients. Malignant causes constituted **40.7%** of cases, predominantly periampullary carcinoma, pancreatic head tumors, and cholangiocarcinoma affecting various segments of the biliary tract. See Figure 6 below.

A prior history of biliary tract disease or intervention was documented in **12.3%** of patients, most commonly **cholecystectomy**, followed by bile duct strictures and previous episodes of acute cholangitis or cholecystitis. See table 2 below.

Table 2:Etiologies of Acute Cholangitis, Addis Ababa, 2025

Previous history of biliary disease	Total (%)	Grade I	Grade II	Grade III
Yes	10(12.3)	4(8.2)	2(10.5)	4(30.8)
No	71(87.7)	45(91.8)	17(89.5)	9(69.2)
Types of biliary disease (n=10)				
Acute Cholangitis	2(20)	2	0	0
Acute cholecystitis	1(10)	1	00	0
Bile duct stricture	4(40)	1	1	2
Cholecystectomy	3(30)	1	2	0
Etiology of Acute Cholangitis				
Benign	48(59.3)	32(65.3)	10(52.6)	6(46.2)
Malignant	33(40.7)	17(34.7)	9(47.4)	7(53.8)

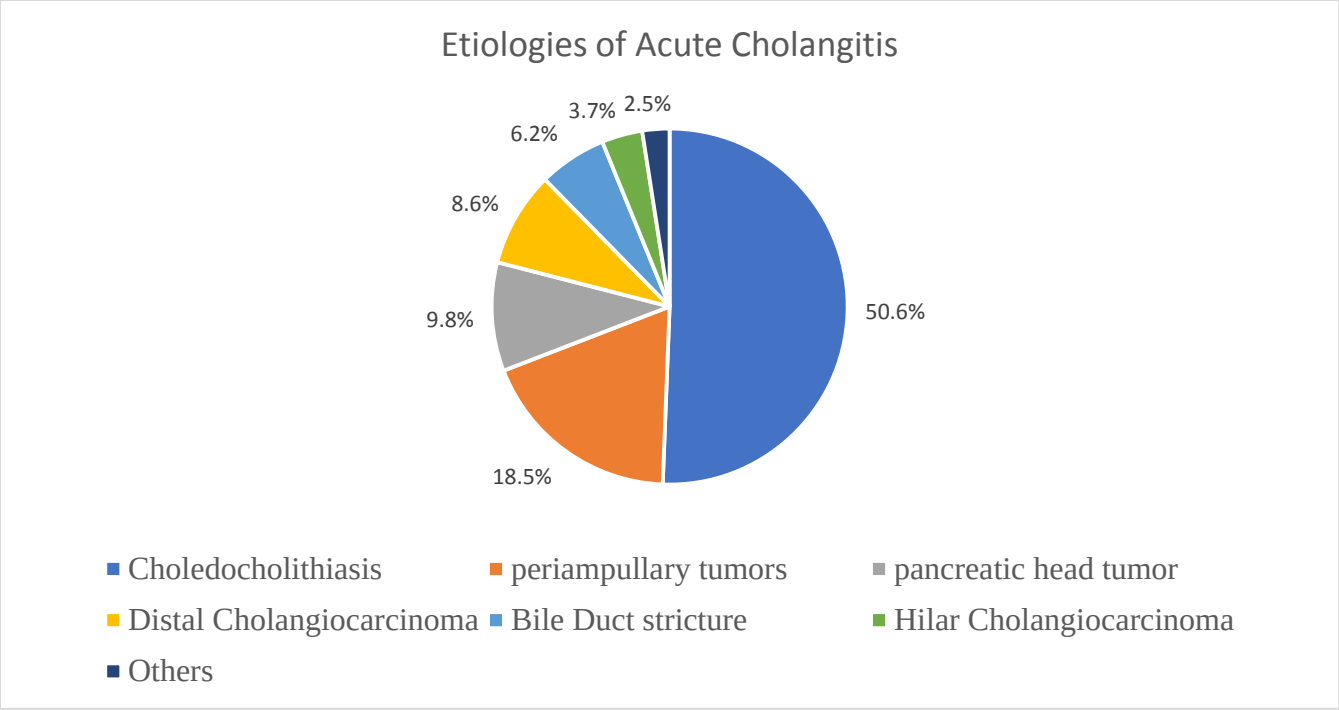

Figure 6: Etiologies of Acute Cholangitis

5.3 Clinical Presentation of the study participants

The mean duration of hospital stay was 17.14 days, ranging from 3 to 58 days. A hospital stay of 23 days or more, corresponding to the 75th percentile, was considered prolonged and observed in 25.9% of patients. Jaundice was the most frequently reported presenting symptom, occurring in 95.1% of patients. Other common symptoms included right upper quadrant abdominal pain (71.6%), vomiting (56.8%), loss of appetite (56.8%), and dark-colored urine (61.7%). Less commonly reported symptoms were pruritus, generalized itching, and altered mental status. Charcot's triad was present in 18.5%, while Reynold's pentad was observed in a single patient. See table below.

Table 3:Clinical Presentation of patients, Addis Ababa, 2025

Variable	Total (%)	Retrospective severity grade of acute cholangitis		
		I(%)	II(%)	III(%)
Presenting symptoms				
Jaundice	77(95.1)	52(67.5)	19(24.7)	6(7.8)
Fever	25(30.9)	18(72)	3(12)	4(16)
Right upper quadrant pain	58(71.6)	40(69)	15(25.9)	3(5.2)
Dark urine colour	50(61.7)	34(68)	14(28)	2(4)
Vomiting	46(56.8)	26(56.5)	16(34.8)	4(8.7)
Nausea	34(42)	17(50)	13(38.2)	4(11.8)
Pruritus	11(13.6)	6(54.5)	2(18.2)	3(27.3)
Pale and clay colour stool	27(33)	18(66.7)	7(25.9)	2(7.4)
Loss of appetites	46(56.8)	29(63)	13(28.3)	4(8.7)
Weight loss	24(29.6)	13(54.2)	8(33.3)	3(12.5)
Itching loss	13(16)	12(92.3)	1(7.7)	0
Chills or rigor	7(8.6)	4(57.1)	3(42.9)	0
Others	6(7.4)	4 (4.9)	1	1
Pulse rate per minute				
60-100	67(82.7)	48(71.6)	16(23.9)	3(4.5)
>100	14(17.3)	6(42.9)	5(35.7)	3(21.4)
Blood pressure				
Normotensive	67(82.7)	48(71.6)	17(25.4)	2(3)
Hypotensive	7(8.6)	1(14.3)	2(28.6)	4(57.1)
Hypertensive	7(8.6)	5(71.4)	2(28.6)	0
Temperature				
35.6-37.2	56(69.1)	36(44.4)	18(22.2)	2(2.5)
>37.2	25(30.9)	18(22.2)	3(3.7)	4(4.9)
Oxygen saturation				
<90	19(23.5)	12(63.2)	4(21.1)	3(15.8)
>90	62(76.5)	42(67.7)	17(27.4)	3(4.8)
Abdominal tenderness				
Yes	42(51.9)	25(59.5)	14(33.3)	3(7.1)
No	39(48.1)	29(74.4)	7(17.9)	3(7.7)
Charcot` Triad				
Yes	15	11(73.3)	2(13.3)	2(13.3)
No	66	43(65.2)	19(28.8)	4(6.1)
Reynold`s Pentad	1			1

5.4 Laboratory Results

The mean WBC count was 14,264/mm³, ranging from 2,930 to 114,000/mm³. The mean Hb was 12.43 g/dL. Values ranged from 7.2 to 20.5 g/dL. The mean platelet count was 322,099/mm³ while most patients (96.3%) had platelet counts >150,000/mm³. The mean total bilirubin was 12.3 mg/dL, ranging from 0.58 to 45.97 mg/dL. The mean direct bilirubin was 7.57 mg/dL. ALT ranged from 10 to 1,472 U/L, with a mean of 187 U/L. AST values showed wide variability, with a mean of 306.6 U/L and a maximum of 8,380 U/L. ALP ranged from 54 to 8,662 U/L, with a mean of 770 U/L. Serum albumin levels were available for all patients. The mean albumin level was 3.73 g/dL, with a range of 1.7–6.0 g/dL. About 42% of patients had albumin levels <3.5 g/dL, indicating potential hypoalbuminemia. See table below.

Table 4: Laboratory Results of study participants, Addis Ababa, 2025

Variable	Level	Total	Retrospective severity grade of acute cholangitis		
			I(%)	II(%)	III(%)
WBC/mm3	**<4000**	**4(4.9)**	**4(50)**	**2(50)**	**0**
	4000-12000	35(43.2)	33(94.3)	2(5.7)	0
	12000-18000	25(30.9)	16(64)	6(24)	3(12)
	>18000	17(21)	3(17.6)	11(64.7)	3(17.6)
Platelet count	100,000-150,000	3(3.7)	2(66.7)	0	1(33.3)
	≥150000	78(96.3)	52(66.7)	21(26.9)	5(6.4)
Total bilirubin	<5	32(39.5)	27(84.4)	2(6.3)	3(9.4)
	5-9.9	9(11.1)	5(55.6)	4(44.4)	0
	10-20	18(22.2)	9(50)	8(44.4)	1(5.6)
	>20	22(27.2)	13(59.1)	7(31.8)	2(9.1)
Direct bilirubin	<3	28(34.5)	23(82.1)	3(10.7)	2(7.1)
	3-7.99	18(22.2)	10(55.6)	7(39.9)	1(5.6)
	8-15	25(30.9)	16(64)	8(32)	1(4)
	≥15	10(12.3)	5(50)	3(30)	2(20)
ALT	Normal	21(25.9)	16(76.2)	3(14.3)	2(9.5)
	2folds	20(24.7)	14(70)	5(25)	1(5)
	3folds	18(22.2)	8(44.4)	9(50)	1(5.6)
	≥4folds	22(27.2)	16(72.7)	4(18.2)	2(9.1)
AST	Normal	14(17.3)	13(92.9)	1(7.1)	0
	2folds	18(22.2)	11(61.1)	6(33.3)	1(5.6)
	3folds	21(25.9)	12(57.1)	7(33.3)	2(9.5)
	≥4folds	28(34.6)	18(64.3)	7(25)	3(10.7)
ALP	Normal	22(27.2)	16(72.7)	5(22.7)	1(4.5)
	2folds	16(19.8)	7(43.8)	8(50)	1(6.3)
	3folds	6(7.4)	6(100)	0	0
	≥4folds	37(45.7)	25(67.6)	8(21.6)	4(10.8)
Albumin (g/dl)	**<2.5**	**11(13.6)**	**2(18.2)**	**6(54.5)**	**3(27.3)**
	2.5-3.5	23(28.4)	16(69.6)	5(21.7)	2(8.7)
	>3.5	47(58)	36(76.6)	10(21.3)	1(2.1)
Serum creatinine (mg/dl)	<2	76(93.8)	53(69.7)	21(27.6)	2(3.9)
	>2	5(6.2)	1(20)	0	4(80)
BUN (mg/dl)	<30	68(84)	44(64.7)	19(27.9)	5(7.4)
	>30	13(16)	10(76.9)	2(15.4)	2(7.7)
INR	**<1.5**	**70(86.4)**	**49(70)**	**19(27.1)**	**2(2.9)**
	1.5-2.0	6(7.4)	3(50)	1(16.7)	2(33.3)
	2.0-3.5	3(3.7)	1(33.3)	0	2(66.7)
	>3.5	2(2.5)	1(33.3)	1(50)	0
PT	<13	43(53.7)	28(65.1)	14(32.6)	1(2.3)
	>13	38(46.3)	26(68.4)	7(18.4)	5(13.2)
PTT	<35	64(79)	44(68.8)	16(25)	4(6.3)
	>35	17(21)	10(58.8)	5(29.4)	2(11.8)

5.5 Imaging Modalities

The imaging modalities used were abdominal ultrasound (US), computed tomography (CT) and Magnetic Resonance Cholangiopancreatography (MRCP). Abdominal Ultrasound was used as initial imaging modality in all the cases. About 81.5% of cases were further investigated with either CT-scan or MRCP. In about 85.2% both biliary dilatation and etiology of obstruction was detected.

Table 5. The imaging modalities and finding in patients managed for acute cholangitis at TASH, Addis Ababa, 2025

Variable	frequency	Percent
Imaging		
Abdominal Ultrasound only	**15**	18.5%
CT-scan	53	65.4%
MRCP	**15**	18.5%
Imaging Finding		
Biliary dilatation and Etiology of obstruction	**69**	85.2%
Biliary obstruction only	**12**	14.*%

5.6 Severity and Diagnosis of Acute Cholangitis

A significant majority of individuals presented with a confirmed diagnosis of acute cholangitis. The diagnostic breakdown revealed that 71.6% (58 patients) had definite acute cholangitis, while the remaining 28.4% (23 patients) were classified as having a suspected case.

The severity of the condition was assessed using the Tokyo Guidelines (TG13) grading system. This revealed that the largest proportion of patients, 60.5%, had Grade I (mild) acute cholangitis. Following this, 23.5% of patients were categorized as having Grade II (moderate) severity and 16% of the patient cohort were Grade III.

5.7 Management of Acute Cholangitis

Initial Management and Response

The most common initial intervention included fluid resuscitation, antibiotics, and pain management. All patients received ceftriaxone and metronidazole and resuscitation. Pain management was initiated for 57(70.4%). A majority were recorded (85.2%) to have improvement with initial therapy.

Emergency Bile drainage

Emergency drainage of bile was needed for 14.8% of patients in the form of ERCP, surgical drainage or PTC.

Table 7. Emergency Interventions

Type of Emergency Intervention	**n (out of 12)**
Surgical	6 (50.0%)
ERCP	4 (33.3%)
PTC	2 (16.7%)
Type of Emergency Surgical intervention	**n (out of 12)**
T-tube Drainage	1
CBDE + T-tube Drainage	3
Gastrojejunostomy+ cholecystojejunostomy	2

Definitive and palliative Management

Out of 81 patients, 69 (85.2%) required either definitive or palliative intervention. The most common procedures were Cholecystectomy with CBDE, Triple Bypass, Whipple`s procedure and Hepaticojejunostomy.

Table 8. Type of definitive management of patients

Type of Definitive Management	n	%
Cholecystectomy + CBDE	37	41.6%
Biliary-enteric bypass	23	23.6%
Whipple's procedure	9	12.5%
Cholecystectomy alone	4	5.5%
Hepaticojejunostomy	5	8.3%
Others (PTC, shunt)	2	8.3%

Outcome of management of Acute Cholangitis

About 60% of patients had favorable outcome. The remaining 40% either developed complications or had prolonged hospital stay (which was found to be >= 23 days in our study). Overall, 19.8% of patients developed complications. These include liver abscess, ICU admission, Persistent organ failure, hospital mortality, and 30-day mortality.

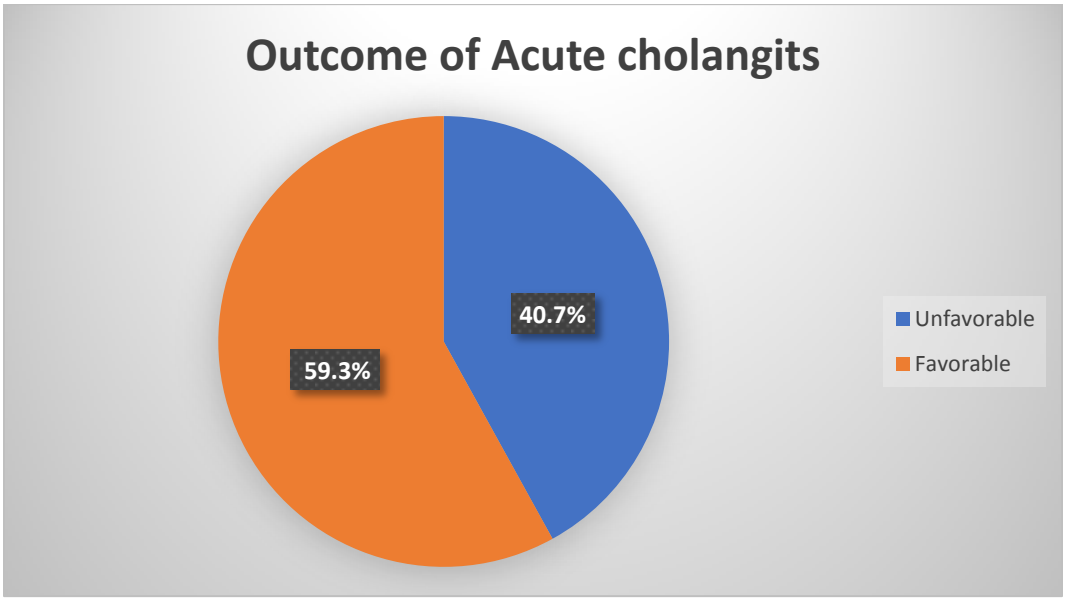

Figure 7: Management outcome of patients managed for acute cholangitis at TASH, Addis Ababa, Ethiopia,2025.

Table 9: Management outcome of patients managed for acute cholangitis at TASH, Addis Ababa, Ethiopia,2025.

Variable	Frequency	Percent (%)
Management outcomes of the patients		
Developed complications	16	19.7%
The list of complication (n=16)		
30-day Mortality	1	5.9%
ICU admission	5	29.4%
In hospital Mortality	2	11.8%
liver abscess	7	41.2
Persistent Organ Failure	1	5.9
Duration of hospital stay		
<23	62	76.5%
≥23	19	23.5%

Factors Associated with Adverse Outcome of Acute Cholangitis

Bivariate logistic regression analyses were conducted to explore the relationship between various demographic and clinical variables and adverse outcomes in patients with acute cholangitis. Initially, Bivariate logistic regression was run and a cut-off of 0.2 was used to screen for variables with potential association with adverse outcome of acute cholangitis. Variables that qualified were further entered into multivariable logistic regression.

Table 6. Univariate Analysis of Factors Associated with Outcomes of Acute Cholangitis TASH, Addis ,2026.

Variable	Outcome of Acute cholangitis		p-value	COR with 95%CI
	Unfavorable	Favorable		
Age in years				
21-40	4	17	1	
41-60	11	19	0.181	2.5(0.66, 9.19)
>60	17	13	0.010	**5.6(1.50, 20.53)**
Sex				
Male	15	20	1	
female	17	29	0.591	0.78(0.32, 1.92)
Residency				
Urban	18	34	1	
rural	14	15	0.130	1.8(0.69, 4.45)
Fever				
No	23	33	1	
yes	9	16	0.667	0.81(0.30, 2.14)
Loss of appetite				
No	8	27	1	

yes	24	22	0.009	**3.7(1.38, 9.79)**
Weight loss				
No	17	40	1	
yes	15	9	0.008	**3.9(1.44, 10.69)**
Comorbidity				
No	18	40	1	
yes	14	9	0.016	**3.4(1.27, 9.45)**
Total bilirubin				
<5	9	23	1	
5.9-9.99	3	6	0.762	1.3(0.26, 6.22)
10-20	9	9	0.126	2.6(0.77, 8.51)
>20	11	11	0.106	2.6(0.82, 7.97)
PTT				
<35	24	40	1	
>35	8	9	0.475	1.5(0.50, 4.36)
Albumin				
<2.5	7	4	0.060	3.7(0.95, 14.75)
2.5-2.5-3.5	10	13	0.345	1.6(0.59, 4.59)
>3.5	15	32	1	
Retrospective grading according to TG13				
Grade I	16	33	1	
Grade II	8	11	0.121	02.1(0.83, 5.15)
Grade III	8	5	0.040	**2.6(1.32, 6.45)**

A multivariate binary logistic regression analysis was conducted to identify independent predictors of unfavorable outcomes among patients with acute cholangitis. The analysis revealed three factors that were significantly associated with a higher risk of adverse events:

Patients older than 60 years were found to have a significantly higher risk of experiencing an unfavorable outcome compared to those aged 21-40. After adjusting for other variables, the odds of a poor outcome were 4.7 times greater in the older age group (Adjusted Odds Ratio [AOR]: 4.7; 95% Confidence Interval [CI]: 1.04–21.47; p=0.044).

The existence of underlying health conditions was also a powerful predictor. Patients with comorbidities had 4.7 times the odds of an unfavorable outcome compared to those without (AOR: 4.7; 95% CI: 1.05–21.55; p=0.043).

Patients classified with Grade III (severe) cholangitis had a 3.1-fold higher risk of an unfavorable outcome compared to those with Grade I (mild) disease (AOR: 3.1; 95% CI: 2.11–8.36; p=0.024).

Table 7:*The multivariate regression of association between Outcome of acute cholangitis independent variable among AC patient managed at TASH.*

Variable	Unfavorable outcome	P-Value	AOR with 95%CI
Age in years			
21-40	4	1	
41-60	11	0.638	1.4(0.31, 6.68)
>60	17	0.044	**4.7(1.04, 21.47)**
Residency			
Urban	18	1	
rural	14	0.676	0.76(0.21, 2.80)
Loss of appetite			
No	8	1	
yes	24	0.081	3.2(0.86, 11.68)
Weight loss			
No	17	1	
yes	15	0.162	0.35(0.08, 1.53)
Comorbidity			
No	18	1	
yes	14	0.043	**4.7(1.05, 21.55)**
Albumin			
<2.5	7	0.112	4.3(0.71, 25.56)
2.5-2.5-3.5	10	0.737	1.2(0.35, 4.46)
>3.5	15	1	
Retrospective severity grade			
Grade I	16	1	
Grade II	8	0.184	0.36(0.08, 1.63)
Grade III	8	0.024	**3.1(2.11, 8.36)**

6. DISCUSSION

A central finding of this research is the high degree of severity within the patient population. Nearly 40% of patients presented with moderate to severe (Grade II/III) cholangitis, with 16% having Grade III (severe) disease. This proportion of severe cases is notably high and reflects the institution's role as a national referral center (TASH), which naturally concentrates the most complex cases. This is consistent with findings from a large international multicenter study by Gomi et al., where 26.2% of patients were classified as Grade III, although this study was conducted in settings with more readily available resources. In contrast, a prospective study from a tertiary center in South India by Raghhupatruni et al. reported a lower Grade III prevalence of 5.7%, suggesting that regional differences and referral patterns significantly shape the patient populations seen.

The demographic profile of our cohort, with a mean age of 53.96 years and a high prevalence of comorbidities (28.4%), aligns with the established understanding that acute cholangitis is predominantly a disease of older, sicker patients. The multivariate analysis from this study powerfully demonstrates that both age > 60 years and the presence of comorbidities were independently associated with a 4.7-fold increase in the risk of an unfavorable outcome. This reinforces the findings of numerous international studies. The landmark multivariate analysis by Gigot et al. in 1989 identified advanced age and comorbid conditions like liver cirrhosis as significant predictors of mortality. More recently, the Tokyo Guidelines (TG13) incorporated age (≥75 years) as a criterion for moderate severity, acknowledging its impact on patient resilience and outcomes. Our study validates these international criteria in the local context, confirming that a patient's underlying physiological reserve is a critical determinant of their ability to survive the septic insult of severe cholangitis.

One of the most striking findings is the high prevalence of malignant causes of biliary obstruction (40.7%). This is a significant departure from many epidemiological reports where choledocholithiasis is the dominant etiology, often accounting for 60-80% of cases. For instance, the study by Raghhupatruni et al. found choledocholithiasis in 54.3% of cases and malignancy in only 17.1%. The high rate of malignancy in our cohort is almost certainly a reflection of referral bias. As the primary tertiary center, TASH receives patients with complex conditions, such as advanced pancreatobiliary cancers, who cannot be managed at regional hospitals. This finding is

remarkably similar to that of Akhtar et al., who conducted their study at a dedicated cancer hospital and reported an 86.9% rate of underlying malignancy in their cholangitis patients. This etiological profile is crucial, as malignant obstruction is an independent risk factor for poorer outcomes, a finding also noted by Gigot et al. Malignancy often implies a more complex and complete obstruction, higher rates of bacterial resistance, and a patient population that is generally older and frailer.

This research strongly reinforces the well-documented unreliability of classic clinical signs in diagnosing acute cholangitis. While jaundice was a near-universal finding (95.1%), the other components of Charcot's triad were far less common, with fever being recorded in only 30.9% of patients. Consequently, the full triad was present in just 18.5% of the cohort. This low sensitivity is consistent with a wide body of literature. A large review by Kiriyama et al. noted the sensitivity of Charcot's triad to be only 26.4%, although its specificity was high. The study by Soares et al. in Brazil also highlighted the discrepancy between the triad's classic status and its infrequent clinical presentation. Our findings serve as a critical reminder that the absence of fever or the complete triad should not lower the clinical suspicion for acute cholangitis, especially in elderly or immunocompromised patients who may not mount a robust febrile response.

Instead, this study supports the diagnostic paradigm of the Tokyo Guidelines, which places greater emphasis on a combination of systemic inflammation (indicated by laboratory markers), cholestasis (jaundice and liver enzyme elevation), and imaging findings. The high prevalence of key laboratory markers in our cohort—such as hyperbilirubinemia (60.5%) and markers of organ dysfunction like coagulopathy (INR >1.5 in 13.5%) and hypoalbuminemia (13.6%)—demonstrates their clinical utility not only for diagnosis but also for severity assessment, as these are core components of the TG13 severity grading criteria.

The management strategies employed at TASH reflect the significant challenges of providing care in a resource-limited environment. The finding that management relies heavily on open surgical procedures for both emergency biliary drainage and definitive treatment stands in stark contrast to the global standard of care, where endoscopic retrograde cholangiopancreatography (ERCP) is the first-line intervention. International guidelines and numerous studies, including the

work of Lai et al., have established that endoscopic drainage carries significantly lower morbidity and mortality rates compared to emergency surgery for severe cholangitis.

The reliance on surgery in our cohort is a direct indicator of limited access to advanced therapeutic endoscopy. This has profound implications for patient outcomes. Surgical intervention is more physiologically taxing, is associated with higher complication rates, and may lead to longer hospital stays. Furthermore, the time to definitive biliary drainage can be longer when relying on surgical pathways, and delays in biliary decompression are known to be associated with worse outcomes, including persistent organ failure and increased mortality. While our study did not specifically analyze the timing of intervention, the dominance of surgery suggests that achieving the recommended timelines for drainage in moderate (early) and severe (urgent) cholangitis is a major systemic challenge.

Perhaps the most robust finding of this research is the confirmation of age, comorbidity, and Grade III severity as powerful, independent predictors of unfavorable outcomes in a multivariate analysis. This is of paramount importance as it validates internationally derived risk stratification models in a local, resource-constrained African setting. The adjusted odds ratios were substantial and clinically significant, underscoring that these three factors are fundamental to the pathophysiology and clinical course of the disease, regardless of the healthcare environment.

These results are in strong agreement with both historical and contemporary literature. The seminal work by Gigot et al. identified similar factors, and the entire framework of the Tokyo Guidelines is built upon the principle that organ dysfunction (the definition of Grade III) is the primary determinant of immediate mortality risk. The study by Akhtar et al. also found in their multivariable analysis that only Tokyo severity grades II and III were significant factors associated with mortality. The convergence of our findings with these international studies confirms that a simple, rapid clinical assessment focusing on the patient's age, underlying health, and degree of organ failure is the most effective way to triage patients, predict their clinical course, and allocate potentially scarce resources to those at highest risk.

7. CONCLUSION

The demographic and etiological characteristics of the acute cholangitis cohort under investigation exhibit notable deviations from established international data, specifically a female predominance (56.8%) and a substantially higher incidence of malignant obstruction (40.7%).

The clinical utility of Charcot's triad for diagnosing acute cholangitis is demonstrably poor within this patient population, with a prevalence of only 18.5%. The Tokyo Guidelines (TG13) were found to be a more robust and reliable diagnostic tool, confirming a definite diagnosis in 70.4% of cases and proving essential for accurate classification.

The prevailing management strategy, which favors open surgical intervention (92.6%) over endoscopic drainage, is correlated with unfavorable clinical outcomes. This is evidenced by a prolonged mean hospital stay (17.14 days), prolonged hospital stays (23.5%) and a high complication rate (19.8%), indicating that current therapeutic practices contribute to significant patient morbidity and lag behind the standards of minimally invasive care.

8. RECOMMENDATIONS

Tokyo Guidelines (TG13) be formally adopted and integrated as the standard institutional protocol for the diagnosis and severity grading of all patients presenting with suspected acute cholangitis.

A strategic reallocation of resources is recommended to enhance the availability and utilization of endoscopic retrograde cholangiopancreatography (ERCP), establishing it as the first-line intervention for biliary drainage.

A protocol for systematic risk stratification should be implemented at the time of patient admission. This protocol should incorporate key prognostic markers identified in this study—notably hypoalbuminemia, elevated prothrombin time, and the presence of comorbidities—to enable the early identification of high-risk individuals who may require more aggressive monitoring and timely therapeutic intervention.

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ANNEX

ANNEX 1: DATA COLLECTION FORM

Title: Clinical profile and management of acute cholangitis: 5 years' experience at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia

Questionnaires

Part I. Demographics characteristics of the participants

1. Patient ID _____--
2. Age of the patient in years_____
3. Gender
    A. Male
    B. Female
4. BMI (if recorded) _____
5. Residency of the participants
    A. Urban
    B. Rural

Part II. Comorbidity

6. Comorbidity

A. Diabetes mellitus
B. Hypertension
C. Cardiac disease
D. Chronic kidney disease
E. Hepatitis B or C
F. Cirrhosis of the liver
G. Gallstones or previous biliary tract disease
H. Peptic ulcer disease
I. Pancreatitis

J. Chronic obstructive pulmonary disease (COPD)

K. Cancer

L. Other (specify): _____

7. previous history of biliary disease

A. Yes

B. No

8. If yes, the above question

A. Previous biliary enteric bypass

B. Previous abdominal surgery of cholecystectomy

C. Other, specify_____

Part III. Etiology of acute cholangitis related characteristics of the patient

9. Etiology of acute cholangitis? (Select all that apply):

A. Choledocholithiasis

B. Bile duct stricture

C. Pancreatitis

D. Primary sclerosing cholangitis

E. Parasitic infections

Part V. clinical presentation related characteristics of participants

10. Duration of symptoms?

A. Less than 24 hours

B. 1–3 days

C. 4–7 days

D. More than a week

11. List the types of symptoms the patient experienced (more than one answer possible)

    A. Fever

    B. Jaundice

    C. RUQ pain

    D. Mental status changes

    E. Low blood pressure or signs of shock?

    F. Nausea

    G. Vomiting

    H. Chills or rigor

    I. Dark-colored urine

    J. Pale or clay-colored stool

    K. Loss of appetite

    L. Others, specify

12. List the types of signs the patient experienced (more than one answer possible)

    A. BP_____

    B. PR_____

    C. Temperature_____

    D. RUQ tenderness

        1. Yes

        2. No

Part IV. laboratory finding related characteristics of the participants

13. complete blood count (CBC)

    A. White Blood Cell (WBC) count: _____/mm³

    B. Hemoglobin (Hb): _____ g/dL

    C. Platelet count: _____/mm³

14. Liver Function Tests (LFTs)

A. Total bilirubin: _____ mg/dL

B. Direct bilirubin: _____ mg/Dl

C. Alanine aminotransferase (ALT): _____ U/L

D. Aspartate aminotransferase (AST): _____ U/L

E. Alkaline phosphatase (ALP): _____ U/L

F. Gamma-glutamyl transferase (GGT): _____ U/L

15. Inflammatory Markers

A. C-reactive protein (CRP): _____ mg/L

B. Erythrocyte sedimentation rate (ESR): _____ mm/hr

C. Procalcitonin: _____ ng/mL

16. Renal Function Tests

A. Blood Urea Nitrogen (BUN): _____ mg/dL

B. Serum creatinine: _____ mg/dL

17. Coagulation Profile

A. Prothrombin Time (PT): _____

B. International Normalized Ratio (INR): _____

C. Activated Partial Thromboplastin Time (aPTT): _____

18. Electrolytes

A. Sodium (Na^+): _____ mmol/L

B. Potassium (K^+): _____ mmol/L

C. Chloride (Cl^-): _____ mmol/L

Part V. the culture related characteristics of the participants

19. Was a bile culture performed?

A. Yes

B. No

20. If yes, what was the source of the bile sample?

A. ERCP (Endoscopic Retrograde Cholangiopancreatography)

B. Percutaneous biliary drainage

C. Surgical bile drainage

D. Other (specify): _____

21. Were any microorganisms identified in the bile culture?

A. Yes

B. No

22. If yes, specify the microorganisms isolated (select all that apply):

A. Escherichia coli

B. Klebsiella species

C. Enterococcus species

D. Pseudomonas aeruginosa

E. Streptococcus species

F. Bacteroides species

G. Other (specify): _____

23. Was a blood culture performed?

A. Yes

B. No

24. Were any microorganisms identified in the blood culture?

A. Yes

B. No

25. If yes, specify the microorganisms isolated (select all that apply):

A. Escherichia coli

B. Klebsiella species

C. Enterococcus species

D. Pseudomonas aeruginosa

E. Streptococcus species

F. Bacteroides species

G. Other (specify): _____

26. Were sensitivity tests performed on the cultured microorganisms?

A. Yes

B. No

27. If yes, which antibiotics were tested for sensitivity?

A. Penicillin's

B. Cephalosporins

C. Carbapenems

D. Quinolones

E. metronidazole

F. Aminoglycosides

G. Other (specify): _____

Part VI. Tokyo guideline severity related characteristics of the participants

28. What is your retrospective TG13 diagnosis of the patient?

A. Definite AC

B. Suspected AC

C. Non-cholangitis

29. What is your current TG13 severity grading?

A. Grade I

B. Grade II

C. Grade III

30. Was the diagnosis recorded according to TG13 severity?

A. Grade I

B. Grade II

C. Grade III

Part VII. Imaging findings related characteristics of acute cholangitis

31. Which imaging modality was used for diagnosis? (Select all that apply)

A. Abdominal Ultrasound

B. Computed Tomography

C. Magnetic Resonance Imaging

D. Magnetic Resonance Cholangiopancreatography

E. Endoscopic Ultrasound

F. Endoscopic Retrograde Cholangiopancreatography

G. Other (specify): _____

32. Were any of the following findings present on ultrasound? (Select all that apply)

A. Choledocholithiasis

B. Periampullary tumors

C. High biliary malignancy

D. GB cancer

E. Benign biliary stricture

F. Others, specify

Part VX. Management modality related characteristics of the participants

33. What initial management was provided for acute cholangitis? (Select all that apply)

A. Fluid resuscitation

B. Antibiotic therapy

C. Pain management

D. Nutritional support

E. Other (specify): _____

34. Was an endoscopic procedure performed?

A. Yes

B. No

35. If yes, what type of endoscopic procedure was done? (Select all that apply)

A. Endoscopic Retrograde Cholangiopancreatography (ERCP)

B. Biliary stent placement

C. Other (specify): _____

36. Was surgical intervention required?

A. Yes

B. No

37. If yes, what type of surgery was performed?

A. T-tube biliary decompression

B. Biliary bypass surgery

C. Cholecystectomy with CBDE

D. Other (specify): _____

38. What was the indication for surgery?

A. Failed endoscopic intervention

B. Perforation or abscess

C. Recurrent cholangitis

D. Other (specify): _____

39. Was percutaneous drainage performed?

A. Yes

B. No

40. If yes, what type of procedure was done?

A. Percutaneous transhepatic biliary drainage (PTBD)

B. Percutaneous cholecystostomy

C. Other (specify): _____

41. Were vasopressors required to manage hemodynamic instability?

A. Yes

B. No

Part X. management outcome of the participants

42. What was the management outcome of the patients?

I. Improved and discharged

II. Developed complication

43. If the patient develop complication, specify the types of complication

A. Liver abscess

B. ICU admission

C. Presence of organ failure

D. In hospital mortality

44. Does the patient have 30-day mortality?

A. Yes

B. No

C. If yes, reason for mortality_____

45. duration of hospital stays in days_____