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St. Paul's Hospital Millennium Medical College

ADMISSION PATTERN, CLINICAL PROFILE AND TREATMENT OUTCOME OF BILIARY
STONE DISEASE AT SAINT PAUL'S HOSPITAL, ADDIS ABEBA ETHIOPIA: A TWO
YEARS RETROSPECTIVE REVIEW STUDY

By: Dr Frew Ameha (Principal investigator)

September, 2018

ADDISABABA, ETHIOPIA

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GENERAL SURGERY

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Abstract

Background: More than 95% of biliary tract affections are due to gallstone disease. Open cholecystectomy used to be the standard procedure for treatment of cholelithiasis until the introduction of laparoscopic cholecystectomy which is now the gold standard for treating gallstone disease in the developed world. Nevertheless, open Cholecystectomy is still widely practiced in the developing world [4]. Mortality rates, Morbidity rate and length of hospital stay were all significantly associated with age, admission pattern, and disease status [16].

Objectives: To determine the admission pattern, clinical profiles and treatment outcomes of biliary stone disease at SPHMMC Addis Ababa, Ethiopia.

Methods: A retrospective review of patient chart and operation logbook was done in the period of January 2015 to December 2017 in St Paul's hospital, Addis Ababa, Ethiopia. Data was analyzed by SPSS statistical software. Pearson's chi-square test was used for statistical analysis. P-value <0.05 was considered significant

Result: A total of 316 patients were included in the study. 266 (84.2%) were female and 50 (15.8%) were male with female to male ratio of 5:1. The mean age of diagnosis is 41.19 years. Elective and emergency admissions is 301 (95.3%) and 50 (4.7%) respectively. The commonest admission diagnosis is Symptomatic Cholelithiasis 232 (73.4%) followed by CBD stone 38 (12.0%), Resolving Cholecystitis 24 (7.6%), Resolving Cholangitis 11 (3.5%), Chronic Cholecystitis 5 (1.6%), Asymptomatic Cholelithiasis 3 (0.9%), Gangrenous/Perforated GB 3 (0.9%). The overall Morbidity rate and the incidence rate of bile duct injuries were 11 (3.5%), and 5 (1.6%) respectively. The overall Mortality rate was 3 (0.9%).

Conclusion: Open cholecystectomy and CBD exploration with choledochoduodenostomy are the two most commonly done procedure for management for biliary stone disease with slightly higher rate of morbidity and mortality rate. There is higher incidence rate of bile duct injury. Morbidity rate has clinically significant association with age, admission diagnosis and the type of procedure done. Residents skills and experience should be given emphasis as the higher rate of Bile duct injury occurred in the hand of the residents.

Key words: Biliary stone disease, Open cholecystectomy, Laparoscopic cholecystectomy, CBD Exploration

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Abbreviation and Acronyms

ACC	Acute calculus cholecystitis
AC	Acute cholecystitis
RCT	Randomized control trial
SPHMMC	St Paul's Hospital Millennium Medical College
SPSS	Statistical Package for Social Science
NSAID	Non-steroidal anti-inflammatory drug
ERCP	Endoscopic retrograde cholangiopancreatography
NPO	Nothing per os
CBD	Common bile duct
GSD	Gall stone disease
CD	Choledochoduodenostomy
GUH	Gondar University Hospital
GI	Gastrointestinal
GB	Gall Bladder
TAH	Tikur Anbessa Hospital
MOF	Multiorgan Failure

CHAPTER-1: Introduction

1.1 Background

Gallstone is one of the most common digestive surgical disorders worldwide. Gall stone diseases are among the most common gastrointestinal surgical illness requiring hospitalization. More than 95% of biliary tract affections are due to gallstone disease. Among biliary tract diseases, cholelithiasis is the leading cause of inpatient admissions for gastrointestinal problems. Up to 90 percent of gallstones are cholesterol or mixed gallstones. The remaining 10 percent of gallstones are pigmented stones, which have less than 20 percent cholesterol [21].

Cholelithiasis is a disease associated with multiple risk factors. One of the main risk factors for developing the disease is female sex. It is four times higher in women than in men. Common bile duct stones (choledocholithiasis) may form de novo in bile ducts (primary, 5 percent of common bile duct stones) or migrate to the common bile duct from the gallbladder (secondary, 95 percent of common bile duct stones). Primary common bile duct stones are more common in Asian populations because of the increased prevalence of flukes and parasitic infections, such as clonorchiasis, fascioliasis and ascariasis.

Patients with gallstones can be grouped into symptomatic and asymptomatic. The vast majority of patients with gallstones are asymptomatic. The natural history of GSD, according to some studies, indicates 70% remain symptom free. A primary symptom of gallstones is repeated attacks of pain, often referred to as biliary colic. The pain is usually in the right upper quadrant or epigastric area. Symptomatic gallstones typically manifest with right upper quadrant abdominal pain, often accompanied by nausea and vomiting. On examination, there is pain to palpation in the right upper quadrant (Murphy's sign). Recurrent symptoms and gallstones on an ultrasound make the diagnosis of symptomatic cholelithiasis. Complications of gall stone disease include acute cholecystitis, choledocholithiasis with or without acute cholangitis, and gallstone pancreatitis, biliary obstruction, gallbladder empyema or perforation.

The mainstay of treatment for gallstone diseases is laparoscopic cholecystectomy, which is the most commonly used modality of treatment in the developed world. Prophylactic cholecystectomy for silent gallstones is not warranted. Cholecystectomy is one of the most common major abdominal surgical procedures performed in western countries. Open cholecystectomy used to be the standard procedure for treatment of cholelithiasis until Laparoscopic Cholecystectomy was introduced in 1991.

Laparoscopic cholecystectomy has now become the gold standard for treating gall stone disease in the developed world. Most people requiring a laparoscopic cholecystectomy are experiencing choledocholithiasis (gallstones in the bile duct), cholelithiasis (cholesterol stones), or acute cholecystitis (inflammation of the gallbladder wall) [19]. Nevertheless, open Cholecystectomy is still widely practiced in the developing world [4]. Although the development of postoperative wound infection or biliary fistula significantly prolonged length of stay and increased cost, neither was associated with a significant increase in mortality during that admission. While the absolute number of patients with central nervous system complications, intraoperative hemorrhage,

postoperative cardiac complications, intraoperative hemorrhage, postoperative cardiac complications, or shock was relatively small, each of these problems was associated with a significant risk of death [16].

Common bile duct stones can accompany acute cholecystitis in up to 10% of cases. These stones can be removed endoscopically before or after cholecystectomy, or surgically at the time of laparoscopic or open cholecystectomy. Conservative management is also one option for acute cholecystitis. Death following cholecystectomy is rare, but post-operative complications may cause severe morbidity. Mortality rate, length of hospital stay, and charges were all significantly associated with age, admission status (elective, urgent, or emergent), and disease status [16].

The goals of treatment of choledocholithiasis are to remove the stones from the biliary tree and to decompress the biliary tree urgently if bacterial cholangitis is present. Acute cholangitis is a clinical syndrome characterized by fever, jaundice, and abdominal pain that develops as a result of stasis and infection in the biliary tract.

Although the prevalence of cholelithiasis is said to be low in developing world compared to that of the westerners, it still contributes significant proportion of General Surgeon's operation in the developing country [4]. The prevalence of the condition is said to be low in Africa and other developing countries. Gallstone disease is supposed to be an uncommon disease in tropical Africa. In sub-Saharan Africa countries the prevalence of gallstone disease is estimated to be less than 5% however its incidence is still low in African countries when compared to the Western countries. Nowadays the disease is more frequently reported in Africa [1].

1.2 Statement of the Problem

Although considered a worldwide medical problem there is a wide variation in the magnitude of gallstone disease in different geographic areas. Annually 600,000 cholecystectomies are done in the American adult population. However, the true magnitude is not known as most of the patients are asymptomatic. The magnitude of gallstone disease is said to be lower in Asia and Africa than in the western world. The prevalence of GSD is about 10% in its adult population. In Western Europe the prevalence ranges from 5.9% to 21.9% with the highest prevalence seen in Norway, Sweden, Germany and the lowest in Italy. It has been demonstrated that prevalence of GSD increases with age. In the USA 20% of those 40 years and older and 30% of those above 70 years old have biliary stone with female to male ratio of 4:1. The lowest prevalence is found in Asian and African countries. The reported prevalence in Asia ranges from 4.35-10.7% [1].

In Africa, the prevalence of GSD was reported from few countries. For instance, in a group of antenatal women, the prevalence was 2.1% in Nigeria, 4% in Tunisia, 5.2% in Sudan and 10% in black women (above 50 years) of Soweto [2]. Nonetheless this may change with the changing lifestyle and dietary habits which increase the risk of developing gallstone disease. A study done in Gondar University Hospital, northwest Ethiopia, found that the overall hospital prevalence of cholelithiasis among individuals above 14 years of age was found to be 5.2% in patients presenting for ultrasound examination suggesting that cholelithiasis is not an uncommon disease in our country [2]. Another study done in one of the referral hospitals in central Ethiopia showed that, on average, 71 patients were operated on for gallstone disease each year. A study done at Tikur Anbessa Hospital in Addis Ababa reported an average of 78 cholelithiasis cases each year among 747 patients surgically treated for gallbladder disease, suggesting that it is a reasonably common disease [1]. The prevalence has similar pattern to some African and Asian studies but still much lower than those in Europe and America. The proportion of asymptomatic cholelithiasis was almost 50% of the cholelithiasis detected [2].

A research done on surgical Management of Common Bile Duct Stones at Saint Paul's Hospital, Addis Ababa, Ethiopia showed Choledocholithiasis comprised 7% of all cholelithiasis. The CBD stones are, in most instances secondary to gallstone. Primary choledocholithiasis are found under some circumstances. The high female preponderance observed in study which is a known fact and is in relation with other studies. Patients with a mean age of 49 years were younger than found in most studies. The finding of right upper quadrant pain and Jaundice as leading symptoms is in line with other studies. Similarly Icterus and right upper quadrant tenderness were the frequently identified signs. Ultrasonography is said to be unreliable in the detection of stone in the common bile duct. In this study ultrasound peaked 58 % of the choledochal stone [18].

1.3 Significance of the study

Gallstone disease is a worldwide disease and it remains to be one of the most common health problems leading to surgical intervention. Although the prevalence of cholelithiasis is said to be low in developing world compared to that of the westerners, it still contributes significant proportion of General Surgeon's operation in the developing country [4]. Nowadays the disease is more frequently reported in Africa [1]. In sub-Saharan Africa the prevalence of gallstone disease is estimated at less than 5%, while its incidence is still low in African countries as compared to the Western countries.

Cholelithiasis was the most common cause of admission to Tikur Anbessa Hospital, Addis Ababa, Ethiopia making 10.3% all admission and 25.9% of all GI admission [4]. A study done at department of radiology, Gondar university hospital, Ethiopia showed prevalence of cholelithiasis among patients clinically suspected to have cholelithiasis was 27.2%. Of the 68 patients with cholelithiasis, 22.1% had evidences of complication; 5 (7.4%) choledocholithiasis, 3 (4.4%) acute cholecystitis, 4 (5.9%) chronic cholecystitis, 2 with gallbladder (GB) hydrops and one patient with porcelain GB [2].

The overall mortality rate of open cholecystectomy was 0.17% and the incidence rate of bile duct injuries was approximately 0.2%. The mortality rate was 0.03% in patients younger than 65 years of age and 0.5% in those older than 65 years of age. Mortality rate, length of hospital stay, and charges were all significantly correlated with age, admission status (elective, urgent, or emergent), and disease status.

There is a limited previously done study on biliary stone disease despite it being significant burden in our hospital surgical department so this study will be a baseline study in terms of epidemiological and clinical result for further study in our hospital and the country. The primary aim of the current study, therefore, is determine the admission pattern and clinical profile of biliary stone disease and its complication at SPHMMC, Addis Ababa, Ethiopia. The study will also evaluate the treatment options and treatment outcome of biliary stone disease in terms of hospital stay, intraoperative complication and morbidity and mortality.

CHAPTER-2: Litrecture review

A research done by Mizan K. and Fasika A. at ayder referral hospital studied a total of 225 patients. The age group 30-49 years comprised one-half of the patients and over two-thirds (71.6%) of the patients were female. Abdominal pain was the predominant complaint, including right upper quadrant pain (74.7%), epigastric pain (20%), and left upper quadrant pain (4.9%). About one-third (34.7%) had radiation of the pain to the back and 15.6% to the shoulders. Fatty meal was identified as an exacerbating factor in 62.2% of the patients. One hundred and eighty-four patients were operated on; laparoscopy was done in 30.2%, and open cholecystectomy in 51.6%. Only two patients had a complicated immediate post-operative course. This study concluded that gallstone disease is not uncommon in the northern part of Ethiopia. The pattern and clinical profile of the disease is not different from what has been reported from other parts of Ethiopia and the rest of Africa. Well-designed epidemiological studies are required to determine the risk factors, the types of stones, the diagnostic value of radiological examination and the efficacy of laparoscopic management of gallstone disease [1].

A research done by Adem A et on Pattern of surgical admissions to Tikur Anbessa Hospital, Addis Ababa, Ethiopia, three-year retrospective analysis was undertaken of all surgical admissions to Tikur Anbessa Hospital (TAH) between September 1994 and August 1997. There was a total of 5,353 surgical admissions of which 3,968 (74.100) were elective cases. The overall male to female ratio was 1.7:1. Gastrointestinal and genitourinary conditions accounted for 62% of elective cases, while for emergencies, gastrointestinal and neuro-surgical patients constituted 75.8% of admissions. Cholelithiasis (10.3%), multinodular goitre (6.1%), benign prostatic hypertrophy (BPH) (5.3%) and gastric outlet obstruction (4.8%) made up 26.7% of all surgical admissions. The overall mortality was 8%, being higher for emergencies (21.10/0) than for elective surgery 4%). Gastrointestinal (GI) and neurosurgical conditions accounted for 71.2% of all deaths. Neurosurgical emergencies had the highest mortality rate (36.80) [3].

Should Delayed Cholecystectomy Following Acute Calculous Cholecystitis Be Discouraged in a Resource-restricted Setting? These researches showed that twenty of 25 patients undergoing delayed cholecystectomy had a laparoscopic approach as compared to 12 of 43 patients in the early cholecystectomy group. The mean time to delayed cholecystectomy following conservative management was 173 days. During this waiting period, 18 of 59 (30.5%) patients had a significant episode related to cholelithiasis, warranting either a visit to the emergency room and/or hospital admission. These significant attacks included 14 episodes of biliary colic, 11 episodes of acute cholecystitis, two episodes of acute pancreatitis and one episode of choledocholithiasis. There was no associated mortality related to these attacks.

Since the establishment of laparoscopic cholecystectomy as the standard of care for elective gall bladder surgery, attention has turned to its use in the acute setting. The advantage of shorter hospital stay has been established while concerns regarding increased complication rates and conversion rates have been dispelled by randomized controlled trials and meta-analyses. In addition, up to 20% of patients will fail conservative management and up to 25% of patients will relapse while awaiting definitive surgery, contributing to morbidity and increased costs and

further favoring early cholecystectomy. The overwhelming evidence has resulted in guidelines recommending early cholecystectomy as preferable in the management of mild ACC.

Despite the evidence, the global uptake of early cholecystectomy is low. In the United Kingdom, only 11% of surgeons routinely treated patients with early cholecystectomy. In Japan, even following the institution of the Tokyo Guidelines, only 41.7% to 62.3% of surgeons opted for early cholecystectomy. These results are consistent with these study findings, which demonstrate that conservative management followed by delayed cholecystectomy is the most common management approach for patients with mild ACC at our institution.

This study demonstrated that despite conservative management being an effective option for the management of mild ACC, this approach is not innocuous. Compared to current evidence, the surgical wait time was at the higher end of the currently reported range, resulting in a large proportion of patients experiencing relapse while awaiting surgery. Furthermore, the risk of significant interval attacks requiring readmission or intervention fell within the reported ranges of 14.0% to 35% previously published. This results not only in morbidity, but increased over all costs which is a significant issue in an already resource-restricted setting [6].

The study done by R.S Date on review of the management of gallstone disease and its complications during pregnancy comparing conservative with surgical management of cholecystitis showed no significant difference in incidence of preterm delivery (3.5% vs 6.0%, $P = .33$) or fetal mortality (2.2% vs 1.2%, $P = .57$). There was no maternal or fetal mortality in 20 reports of laparoscopic cholecystectomy and 9 reports of endoscopic retrograde cholangiopancreatography, thus indicating their safety when performed with necessary precautions. Laparoscopic cholecystectomy is a safe procedure in all trimesters. In 12 reports of gallstone pancreatitis, fetal mortality was 8.0% versus 2.6% ($P = .28$) in conservative and surgical groups, respectively, suggesting the need for earlier surgical intervention [20].

Open cholecystectomy a contemporary analysis of 42,474 patients by Roslyn analyzed a total of 42,474, which represents approximately 8% of all patients undergoing cholecystectomy in the United States in any recent 12-month period. The overall mortality rate was 0.17% and the incidence rate of bile duct injuries was approximately 0.2%. The mortality rate was 0.03% in patients younger than 65 years of age and 0.5% in those older than 65 years of age. Mortality rate, length of hospital stay, and charges were all significantly correlated with age, admission status (elective, urgent, or emergent), and disease status. These data indicate that open cholecystectomy currently is a very safe, effective treatment for cholelithiasis and is being performed with near zero mortality. The ultimate role of laparoscopic cholecystectomy needs to be defined in the context of current and contemporary data regarding open cholecystectomy [16].

Timing of Cholecystectomy for Acute Calculous Cholecystitis a research by Claudio Papi showed that cumulative operative and perioperative mortality and morbidity were 0.9% and 17.8%, respectively, for open cholecystectomy and 0% and 13.1%, respectively, for laparoscopic cholecystectomy. The pooled RD for operative complications in early surgery was 1.37% for open cholecystectomy and 3.11% for laparoscopic cholecystectomy. In laparoscopic cholecystectomy the cumulative conversion rate to open cholecystectomy was 21.5%. The pooled RD for

conversion rate in early laparoscopic cholecystectomy was -7.99%. Total hospital stay was significantly shorter in the early surgery group. More than 20% of patients referred to delayed surgery fail to respond to conservative management or suffer recurrent cholecystitis in the interval period. Early operation (open or laparoscopic) does not carry a higher risk of mortality and morbidity compared to delayed operation and should be the preferred surgical approach for patients with acute calculus cholecystitis [7]

Cholecystitis: the Ethiopian experience, a report of 712 operated cases from one of the referral hospitals showed that the male to female ratios for elective and emergency admissions were 1:5 and 1:2.4, respectively. The mean age was 42.7 years. Acute cholecystitis accounted for 10.6% of the 712 cases. There were a total of 666 (93.5%) calculus and 46 (6.5%) acalculus cases. Empyema was seen in 77 (10.8%) patients and hydrops of the gallbladder in 35 (4.9%). Iatrogenic Common Bile Duct (CBD) injury was found to be more of a problem of the contracted gallbladder. In this study severe complications like gangrenous gallbladder, perforated gallbladder, suppurative cholangitis and subhepatic abscess were found more in males than in females. Calculus cholecystitis was found to be a common disease in Ethiopia, and that its features and prevalence as well as sex predilection compare well with reports from other areas. However the findings in this report were found to be different from the reports of the rest of the African Continent [8].

Gallstone disease in a teaching hospital, Addis Ababa: a 5-year retrospective review study was undertaken in 747 patients surgically treated for gallbladder disease in the period 1995-99 in Tikur Anbessa Hospital, Addis Ababa. There are not many studies of gallbladder disease in Africa. The disease appears to be not uncommon in Ethiopia. The sex ratio (M: F) was 1:5, narrower ratio in complicated cholelithiasis. The mean age was 42 years. About 80% of patients were in the age group between 30 and 60 years. The median duration of symptoms at admission was 2 years. Abdominal pain, in 96% of cases situated in the right upper quadrant and usually aching type, was the most frequent presenting symptom; RUQ tenderness was the most common sign. Clinically, 29.4% of patients were categorized obese. Gallstone detection rate by ultrasound was about 96% but cholecystitis appeared to be overlooked. At operation, about 77% of cases had features of chronic cholecystitis, 2% acalculous cholecystitis. Majority of the stones were grossly cholesterol stones. Cholecystectomy was performed in 99% of cases, most often through the oblique subcostal and transverse routes. The overall in-hospital mortality rate was 0.4%. Nearly 87% of cases had postoperative course without incident. The etiologic factors and the type of gallstones, we believe, are not different from that of the developed world. Cholecystectomy is a safe and most effective procedure that provides ultimate cure for symptomatic gallstone disease [9].

A retrospective observational study done by Assefa Getachew at the department of radiology, Gondar university hospital from September 2004 to January 2006 among a total of 1603 study subjects, the proportion of patients with cholelithiasis was 5.2%. Of the patients with gallstone disease 55 were females and 28 were males with a ratio of 2:1. The prevalence of cholelithiasis in the age group 35-64 was 7.3%, 10.1% for females and 4.8 % for males. The ratio of symptomatic to asymptomatic cholelithiasis was 1:1 (34/34). The prevalence of cholelithiasis among patients clinically suspected to have cholelithiasis was 27.2%. Of the 68 patients with cholelithiasis, 22.1% had evidences of complication; 5 (7.4%) choledocholithiasis, 3 (4.4%) acute cholecystitis, 4

(5.9%) chronic cholecystitis, 2 with gallbladder (GB) hydrops and one patient with porcelain GB. The prevalence of cholelithiasis (5.2%) in Gondar university hospital suggesting that cholelithiasis is not an uncommon disease in the area. A further community based and multi centered study is recommended to determine the prevalence of gallstone disease in Ethiopia [2].

Outcome of surgical management of choledocholithiasis in St. Paul Teaching Hospital, Addis Ababa, Ethiopia. In this study a total of 1230 underwent open cholecystectomy over 5 year period of which 98 patients were found to have choledocholithiasis constituting 7%. Of the 98 patients who underwent common bile duct (CBD) exploration, the records of 78 patients were found and made the basis of this analysis. Fifty-nine (75.6%) patients were females and 19(24.4%) were males, with a male to female ratio 1: 3. The mean age was 49.15 years. The most common symptoms were right upper quadrant pain and jaundice. The most frequent physical findings was right upper quadrant tenderness. Choledocholithotomy with T-tube insertion was done in 39 patients, side to side choledochoduodenostomy in 34 patients, and hepaticojejunostomy in 5 patients. Twenty-four (71.6%) choledochoduodenostomy patients were discharged in less than ten days after operation while 36(87.1%) of those with T-tube were discharged after 10 days ($p<0.019$). The re-operation rate was 12.8% for the T-tube insertion group and 2.9% for choledochoduodenostomy patients. There were 3(8.8%) deaths in the former and 1(2.9%) in the group of choledochoduodenostomy. The overall complication rate was 11 (30.6%) for the T-tube insertion and 3 (8.8%) for the choledochoduodenostomy. Choledochoduodenostomy is a better option than Choledocholithotomy with T-tube insertion in the treatment of choledocholithiasis in African setting. We recommend choledochoduodenostomy (CD) for multiple CBD calculi, big calculi in the CBD, much dilated CBD ($>2\text{cm}$), primary CBD stones, hepatic stones, recurrent stones, and elderly patients where the size of the CBD is 15mm and above [4].

Gallstone disease in an Ethiopian referral hospital, a research done by Kefene H evaluated sixty-four patients suspected radiologically to have gallstone disease for clinical symptoms, physical findings and laboratory abnormalities. Fifty-three of them had ultrasound examination which confirmed the diagnosis in 52 (98.1%). An attempt was also made to identify possible predisposing factors. Sixty of these patients underwent cholecystectomies, with common duct exploration in 10 of them. On visual assessment at surgery, 96.6% of the stones were thought to be cholesterol in type. [10].

CHAPTER -3: Objectives

3.1 General Objective

To determine the admission pattern, clinical profile and treatment outcome of biliary stone disease at SPHMMC, Addis Ababa, Ethiopia

3.2 Specific Objectives

- To Assess the socio demographic distribution of biliary stone disease
- To determine the admission pattern of biliary stone disease and its complications
- To determine the clinical profile of biliary stone disease
- To identify the treatment options and treatment outcome of biliary stone disease

CHAPTER-4: Methods and Materials

4.1 Study area and period

The study was conducted at St Paul's Hospital Millennium Medical College, located in Addis Ababa, Ethiopia, which is the second big hospital in AA which serves as a referral center for patients from Addis Ababa and all over the country. Data was collected from operation logbook from January 2015-December 2017.

4.2 Study design

Retrospective cross sectional study was conducted with the evaluation of patient chart.

4.3 Population

4.3.1 Source population

All patients who were admitted to SPHMMC, department of surgery from January 2015–December 2017.

4.3.2 Study population

All patients who were admitted to SPHMMC with the diagnosis of biliary stone disease and its complication during the study period.

4.3.3 Inclusion criteria

All patients admitted and treated with open or laparoscopic cholecystectomy or CBD explorations for diagnosis biliary stone disease and its complication at St. Paul's Hospital Millennium medical college, Addis Ababa, Ethiopia during the study period.

4.3.4 Exclusion criteria

Patients aged <14 years

Incomplete medical charts

Open or laparoscopic Cholecystectomy and CBD Exploration done for other biliary pathology

4.4 Sample size and sampling technique

4.4.1 Sample size

The sample size was calculated using a single population proportion formula by assumed p (0.5) proportion of biliary stone disease since prevalence of biliary stone disease was unknown. Other assumptions made during the sample size calculation was 5% marginal error (d) and confidence interval of 95% ($z_{\alpha/2} = 1.96$). Based on these assumptions, the sample size calculated was as follow:

$$n = \frac{z_{\alpha/2}^2 \cdot P(1-P)}{D^2} \quad n = \frac{1.96^2 \times 0.5(1-0.5)}{0.05^2} \quad n = 385$$

Where; n is the minimum sample size required

P is an estimate of the prevalence of biliary stone disease

$(Z_{\alpha/2})^2$ -is the standard normal variable at $(1-\alpha)$ % confidence level and α is mostly 0.05 i.e. with 95% confidence interval.

d-is the margin of error to be tolerated (5%)

The final sample (n) required for this study in particular was 390.

4.4.2 Sampling technique

Convenience sampling method was used for sampling

4.5 Variable

4.5.1 Dependent variable

Hospital stay

Bile duct injury

Morbidity rate

Mortality rate

4.5.2 Independent variable

Age

Sex

Comorbidity

Clinical profile/presentations

Admission pattern (Emergency/Elective)

Admission diagnosis

Procedure done and Procedure done by (Resident or Consultant)

4.6 Data Collection Technique and procedure

4.6.1 Data collection tools

Data were collected by using English version checklist prepared in order to conduct necessary information from the operation log book.

4.6.2 Recruitment and training of data collectors

A structured pre-tested data collection format was used and data were collected by reviewing the charts of the patients by trained nurses and medical interns.

4.6.3 Data collection technique

The charts of all patients admitted with the diagnosis of biliary stone disease and its complication in the study period were obtained from the operation log book, monthly Morbidity & mortality registry and nursing documentations. Data collection included patient socio demographics,

admission pattern, clinical presentations, admission diagnosis, hospital stay, morbidity and mortality, procedure done and procedure done by.

4.7 Data management

Data were stored in a secured place to maintain confidentiality. Back-up of the data were stored in different areas not to lose the data.

4.8 Data processing and analysis

The collected data was cleaned, coded and entered into EPI-INFO version 7.2.2.0 and exported to SPSS version 20 for analysis. Descriptive statistics like frequency, mean/median, standard deviation and percentage were used. The results were summarized using graphs, charts and tables. The interpretation of data using summaries was done according to the main finding in the study objective.

All results was expressed as mean $\pm$ standard deviation. The effects of outcome modifiers on morbidity and mortality rates were determined using analysis of variances and logistic regression models. Differences were considered to be significant at the 1% probability level. Explanatory variables with level of significance less than 0.05 was used to select independent variables appeared on bivariate analysis for fit for the final multiple logistic regression model. Variables appeared on multiple logistic regressions with p-value less than 0.05 were declared as statistically significant.

4.9 Data Quality Control

Quality assurance measures were undertaken during checklist designing, data collection and data management process. Validity of the checklist was maintained by using questionnaire adopted from different literatures that were used by other researchers. The instrument was pre-tested by administering it to a small group of charts (5 % of the total sample) with characteristics similar to those of the intended charts before the actual application for the study and appropriate adjustment and correction was under taken. Data from a pre-test finding were excluded from the actual data. The principal investigator reviewed the checklist on daily basis for completeness and consistency. Data edition was done on the same day. Cleaning and exploration of outlier responses was done after data entry and during analysis.

4.10 Ethical consideration

Ethical clearance was obtained from the Research & Publication Committee (RPC) of the Department of surgery, SPHMMC. Confidentiality of information collected from charts was respected and only used for this study purpose.

4.11 Dissemination of the results

The final result was presented to SPHMMC, department of surgery as a fulfillment for post-graduation study and other bodies who need the research accordingly.

4.12 Operational Definition

Mortality: -In hospital death of patients admitted and operated for biliary stone disease

Morbidity: - In hospital complication of patient admitted and operated biliary stone disease

Length of stay: - The total number of in hospital stay days of patient with biliary stone disease and its complication.

4.13 Conceptual frame work

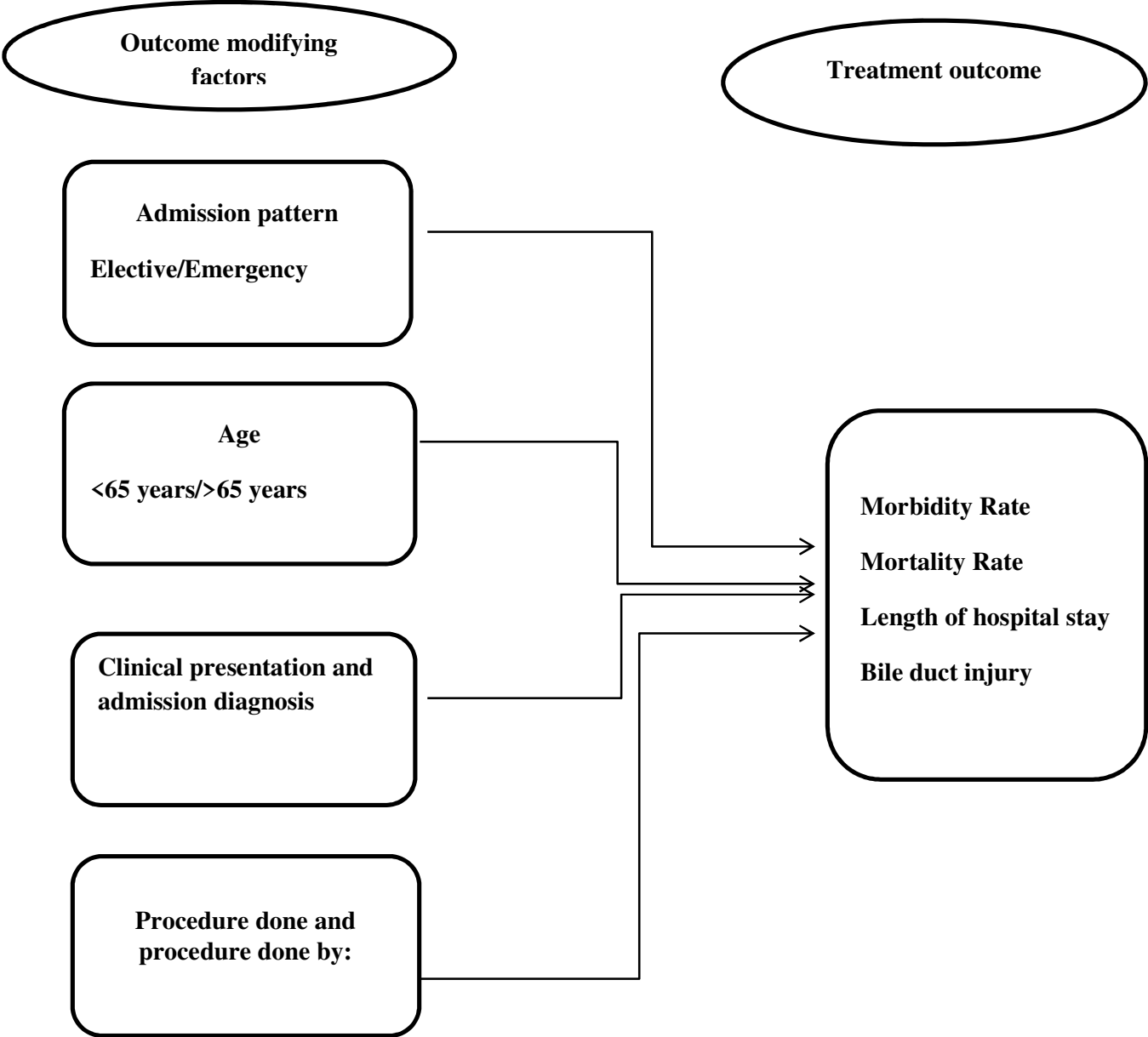


Figure 1: Conceptual framework of the stud

CHAPTER-5: Results

A total of 316 patients were included in the study. 266 (84.2%) were female and 50 (15.8%) were male with male to female ratio of 5:1. The mean age of diagnosis of biliary stone disease is 41.19(18-80 Range, SD of 12.72) years.

Table 1: Frequency of biliary stone disease with age group and sex of patient.

Age	F	M	Total
15-24	18 (6%)	2 (1%)	20 (6%)
25-34	72 (23%)	12 (4%)	84 (27%)
35-44	80 (25%)	18 (6%)	98 (31%)
45-54	51 (16%)	8 (3%)	59 (19%)
55-64	31 (10%)	3 (1%)	34 (11%)
65-74	12 (4%)	6 (2%)	18 (6%)
75-85	2 (1%)	1 (0%)	3 (1%)
Total	266 (84.2%)	50 (15.8%)	316 (100%)

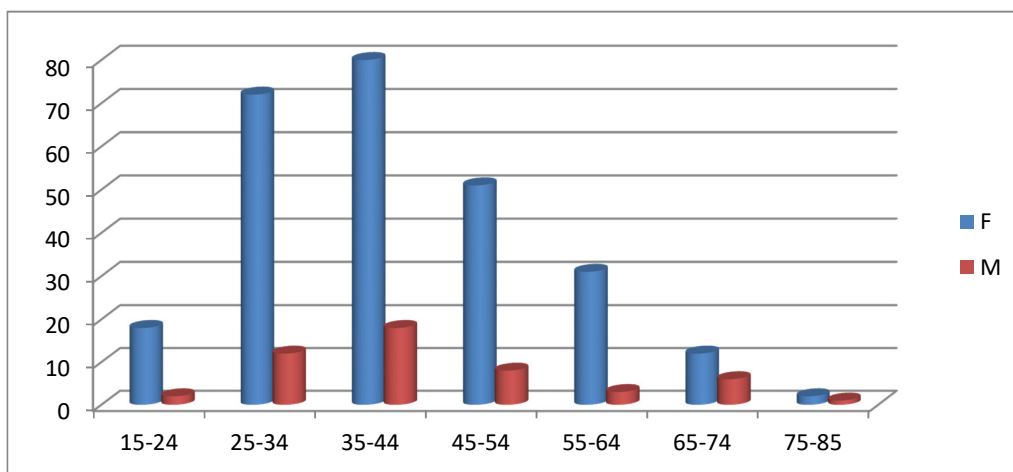


Figure 2: Frequency of biliary stone disease with age group and sex of patient.

Of all patients 188 (59.5%) patients were from Addis Ababa, 105 (33.2%) were from Oromia, 12 (3.8%) were from Amhara, 6 (1.9) were from SNNPR region and 5 (1.6%) from others. Overall 272 (86.1%) were from Urban area and 44 (13.9%) were from Rural area. The comorbidity identified were hypertension 34 (10.8%), DM 16 (5.1%), RVI 14 (4.4%), bronchial Asthma 6 (1.9%), dyslipidaemia 1(0.3%) and heart Failure 1 (0.3%).

Table 2: Addresses

Address	Frequency	Percent	Valid Percent	Cumulative Percent
AA	188	59.5	59.5	59.5
Oromia	105	33.2	33.2	92.7
Amhara	12	3.8	3.8	96.5
SNNPR	6	1.9	1.9	98.4
Others	5	1.6	1.6	100.0
Total	316	100.0	100.0	

The clinical presentation is RUQ/ Epigastric Pain 313 (99.1%), Nausea 224 (70.9%), Vomiting 191 (60.4%), Fat Intolerance 126 (39.9%), Fever 40 (12.7%), Jaundice 40 (12.7%), Urine and stool colour change 22 (7%), RUQ Tenderness 11 (3.5%), Hypotension/Shock 5 (1.6%) and Mental change 5 (1.6%).

Table 3:- Clinical presentations

	Frequency	Percent
RUQ Abdominal pain	313	99.1
Nausea	224	70.9
Vomiting	191	60.4
Fever	40	12.7
Fat Intolerance	126	39.9
Jaundice	40	12.7
RUQ Tenderness	11	3.5
Urine & Stool Colour Change	22	7.0
Hypotension/Shock	5	1.6
Lethargic	5	1.6

The mean duration of symptoms is 12.29 (0-72 Range, SD of 14.45) months. Elective admission accounts for 301 (95.3%) and emergency admission accounts for 50 (4.7%). The commonest admission diagnosis was Symptomatic Cholelithiasis 232 (73.4%) followed by Common bile duct stone 38 (12.0%), Resolving cholecystitis 24 (7.6%), Resolving cholangitis 11 (3.5%), Chronic cholecystitis 5 (1.6%), Asymptomatic Cholelithiasis 3 (0.9%), Gangrenous/perforated GB 3 (0.9%).

Table 4: Admission pattern

Admission	Frequency	Percent	Percent
Elective	301	95.3	95.3
Emergency	15	4.7	4.7
Total	316	100.0	100.0

Table 5: Admission diagnosis

Admission Diagnosis	Frequency	Percent	Percent
Symptomatic Cholelithiasis	232	73.4	73.4
Resolving Cholangitis	11	3.5	3.5
Resolving Cholecystitis	24	7.6	7.6
Perforated/Gangrenous GB	3	0.9	0.9
Asymptomatic Cholelithiasis	3	0.9	0.9
CBD Stone	38	12.0	12.0
Chronic cholecystitis	5	1.6	1.6
Total	316	100.0	100.0

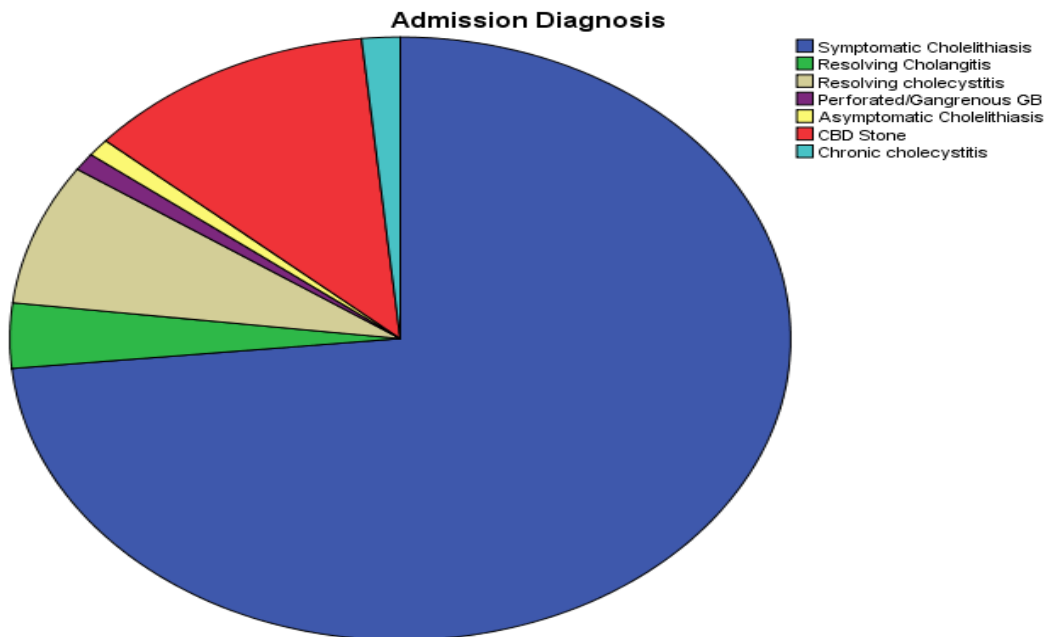


Figure 3: Admission diagnosis

Table 6: Distribution of biliary stone disease with the age grouping

Age	Asymptomatic Cholelithiasis	CBD Stone	Chronic cholecystitis	Perforated/Ga ngrenous GB	Resolving Cholangitis	Resolving cholecystiti s	Symptomatic Cholelithiasis	Total
15-24	0	4	0	0	1	1	14	20
25-34	2	13	3	0	0	7	59	84
35-44	1	8	1	0	4	9	75	98
45-54	0	4	1	0	2	2	50	59
55-64	0	7	0	1	0	2	24	34
65-74	0	0	0	2	4	2	10	18
75-85	0	2	0	0	0	1	0	3
Sex	0	0	0	0	0	0	0	0
F	3	26	2	1	5	20	209	266
M	0	12	3	2	6	4	23	50
Total	3	38	5	3	11	24	232	316

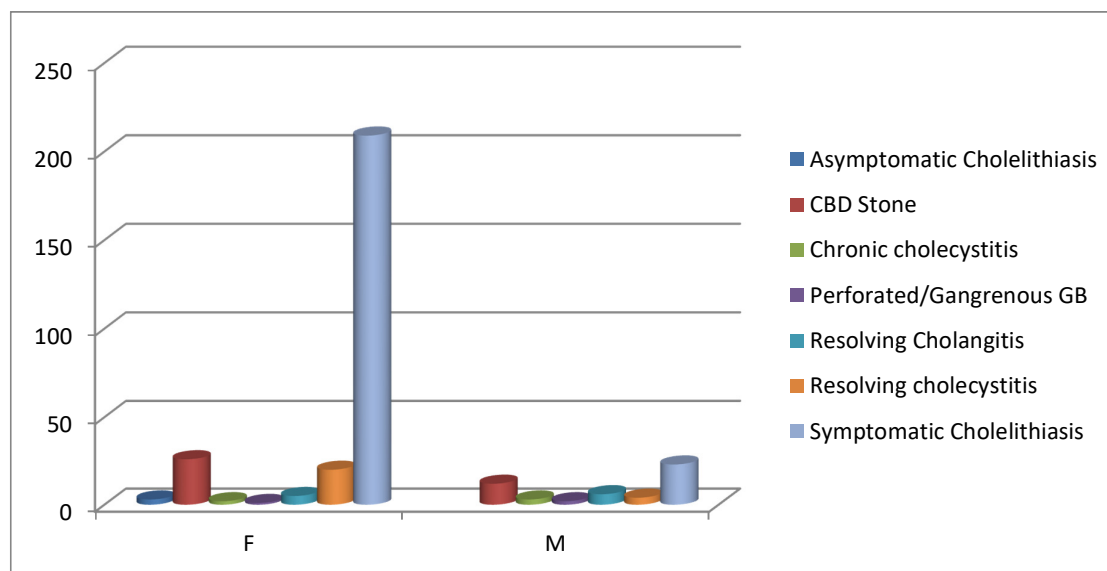


Figure 4:- Distribution of biliary stone disease with the age grouping and sex of a patients.

The procedure performed were open cholecystectomy 257 (81.33%), CBD exploration 49 (15.50%), laparoscopic cholecystectomy 9 (2.85%), partial cholecystectomy 1 (0.32%). CBD exploration were done for patients with diagnosis of CBD stone and Resolving cholangitis. CBD exploration were done with choledochoduodenostomy 32 (10.1%), choledochojejunostomy plus Browns anastomosis 7 (2.2%), through the cystic duct 4 (1.3%), Primary Closure 4 (1.3%), Roux-en-y Hepaticojejunostomy 1(0.32%) and T tube 1 (0.32%).

The mean duration of surgery is 70.33 (20-210 range, SD of 34.69) mins. The mean pre OP, post OP and the total hospital is 5.47 (0-20 range, SD 4.06), 3.47 (1-24 range, SD 3.06) and 8.96 (2-37 range, SD 5.89) days respectively. The Morbidity rate is 11 (3.5%). The post operative complications found were HAP 5 (1.6%), Post Op Collection 5 (1.6%), SSI 4 (1.3%). The incidence rate of bile duct injuries was 5 (1.6%). Drainage was left in 59 patients (18.7%). The Mortality was 3 (0.9%) of which MOF accounts for 1 death (0.3%) and AMI accounts for 2 (0.6%).

Table 7: Descriptive of age, duration of symptom, duration of surgery, hospital stay(pre, post and total).

	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Age	62	18	80	41.19	12.719	161.763
Duration of Surgery	190	20	210	70.33	34.686	1203.143
Duration of symptoms	72.00	.00	72.00	12.2983	14.44665	208.706
Post OP Saty	23	1	24	3.49	3.064	9.387
Pre OP Stay	25	0	25	5.47	4.066	16.530
Total Hospital saty	35	2	37	8.96	5.886	34.646

Table 8:- Frequency of Morbidity, Mortality and CBD injury with the age group.

Age	Morbidity		Total	Mortality		Total	Bile duct injury		Total
	NO	Yes		NO	YES		NO	YES	
15-24	20	0	20	20	0	20	20	0	20
25-34	82	2	84	84	0	84	83	1	84
35-44	95	3	98	97	1	98	96	2	98
45-54	58	1	59	59	0	59	57	2	59
55-64	33	1	34	34	0	34	34	0	34
65-74	13	3	18	16	2	18	18	0	18
75-85	2	1	3	3	0	3	3	0	3
Total	303	11	316	313	3	316	311	5	316

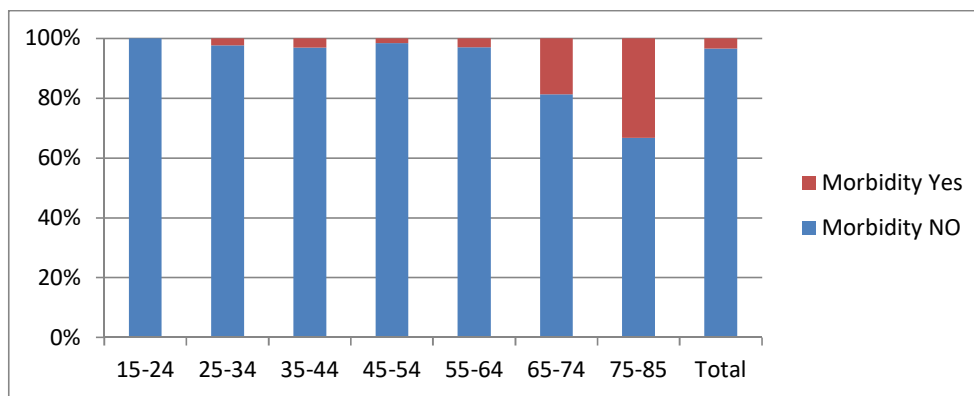


Figure 5: Age group with morbidity

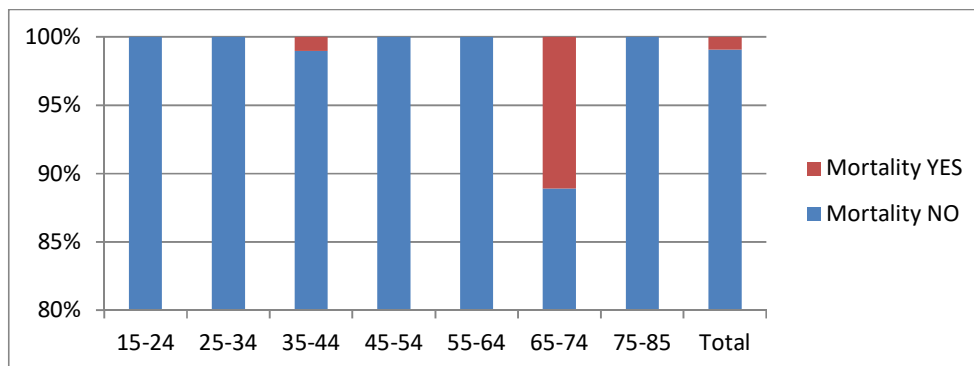


Figure 6: Age group with mortality

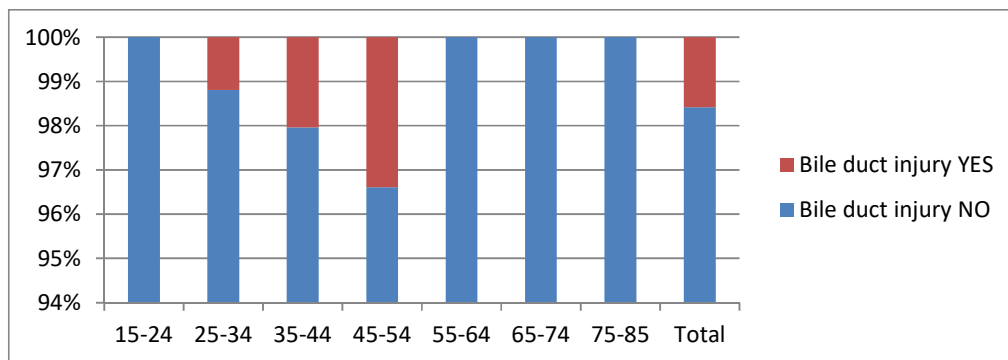


Figure 7: Age group with bile duct injur

CHAPTER-6: DISCUSSION

One third of patients admitted with biliary stone disease were at the age range of 35-44 years which is a younger age group. The Male female ration of 1:5 is silimlay with other researchs and also mean age of disgnosis and duration of symptom is comparable with other researchs[1]. There is statistically significant association between age and morbidity rate (Pvalue<0.001).

11(3.5%) patients had obstructive jaundice among 38 patients admitted with the diagnosis of CBD stone. 11 (3.5%) patient had GB Empyema among 24 patients admitted with a diagnosis of Resolving Cholecystitis. GB Hydrops was seen in 3(0.9%) among patients admitted with a diagnosis of Symptomatic Cholelithiasis. The choledochcholelithiasis was seen in 49 patients including patients with Resolving cholangitis accounting around 15.5% of all cholelithiasis. There is statistically significant association between admisssion diagnosis and morbidity (P value 0.044). The Mortality was 3 (0.9%) which is slightly higher than compared to what is mentioned in literatures[16].

Open cholecystectomy was done by residents starting from 2nd year resident and most procedure were done by senior resident next to consultant. Most of open cholecystectomy were done senior residents next to consultant and almost all bile duct injury occurred in the hand of a residents. The incidence rate of bile duct injuries was 5 (1.6%) which is higher than other mentioned in literatures[16].

Almost all CBD exploration done were by consultant. There is statistically significant association between the type of procedure done and post operative hospital stay (P value<0.001).The major operative compliation observed in this study is comparable and similar to the other study done which is slightly higher. There is statistically significant association between the type of procedure done and morbidity rate(P value<0.001). The Morbidity rate is 11 (3.5%) which is higher than overall in-hospital mortality rate mentioned in other study[9].

CHAPTER -7: Conclusions and Recommendations

7.1 Conclusions

Open cholecystectomy and CBD exploration with choledochoduodenostomy are the two most commonly done procedure for management for biliary stone disease with slightly higher rate of morbidity and mortality rate. There is higher incidence rate of bile duct injury. Morbidity rate has clinically significant association with age, admission diagnosis and the type of procedure done

7.2 Recommendations

Farther community based study should be undertaken to determine the risk factors and prevalence of biliary stone diseases in our setup and our country. Residents skills and experience should be given emphasis as the higher rate of Bile duct injury occurred in the hand of the residents.

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Annex-I

DATA COLLECTION FORMAT

Card Number.....

Age.....

15-24 B. 25-34 C. 35-44 D. 45-64 E. 65-74 G. 75-85

Sex A. Male B. Female

Address

A. Addis Ababa B. Oromia C. Amhara D. SNNPR E. Tigray F. Others

5. Comorbidity

A. DM B. Hypertension C. Renal failure D. Heart failure E. Immune suppression/RVI

F. Liver failure/cirrhosis G. Hyper lipidemia H. NO

6. Obesity

A. 18.5-24.5 B. 25-29.9 C. >30 D. NA

7. If female, 1. Pregnancy A. YES B. NO C. NA

2. Parity A. 1 B. 2 C.3 D.4 E.5 F.>5 G. Nulipara
H. NA

3. OCP A.YES B. NO C.NA

8. Admission

A. Emergency B. Elective

9. Duration of symptoms.....days.....months.....years.

10. Clinical profile/presentations

A. Abdominal pain B. Nausea/Vomiting C. Fever D. RUQ/Abdominal Tenderness

E. Jaundice F. Shock/Hypotension G. Mental status change/Lethargic

11. Admission Pattern

A. Symptomatic Cholelithiasis B. Resolving Cholecystitis C. CBD Stone D. Acalculous Cholecystitis

E. Resolving Cholangitis F. GB Empyema G. Emphysematous Cholecystitis H. Asymptomatic Cholelithiasis I. Chronic Cholecystitis J. Gangrenous/Perforated GB

12. Intraoperative complication

A. Duration of surgery.....

B. Blood loss.....

C. Drainage use.....

E. Bile duct injury.....

13. Morbidity A. HAP B. AMI C. PTE/DVT D. SSI E. NO F. Post OP Collection

14. Mortality A. Yes B. NO

C.	If	Yes,	Cause	Of
Death.....				

15. Hospital stays 1. Pre op stays.....days

2. Post op stays.....days

3. Total hospital stays.....days

16. Procedure done

A. Open cholecystectomy B. CBD exploration C. Laparoscopic cholecystectomy D. Partial cholecystectomy

17. Procedure done by

A. R1+Senioer B. R2 +Seniors C. R3 + Senior D R4 + Senior E. Consultant

Annex-II
Declaration

I, the undersigned declare that this thesis is my original work, has not been presented for a degree in this or any other University and that all sources of materials used for the thesis have been fully acknowledged.

Name: _____

Signature: _____

Name of the institution: _____

Date of submission: _____

This thesis has been submitted with my approval as University advisor

Name and signature of the first advisor

Name and signature of the second advisor