



St. Paul Hospital Millennium Medical College

Graduate Study Program

**Pattern and factor associated with management outcome of patients with
Common bile duct stone at tertiary care hospital, Addis Ababa Ethiopia.**

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October 2022



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Common Bile Duct stone at a tertiary care hospital. Addis Ababa, Ethiopia**

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**A final thesis submitted to the Department of Surgery, for Partial fulfillment of
specialty certificate in General Surgery, St.PaulHospital Millennium Medical
College.**

Addis Ababa, Ethiopia

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Full title of research project	Pattern and factors associated with management outcome of patients with CBD stone at a tertiary care hospital.
Duration of the project	January 2022-November 2022
Study area	St.Paul Hospital MMC ,Addis Ababa ,Ethiopia
Total cost of the project	55,909
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Abstract.

Back ground :-Gall stone disease is one of the most common afflictions of the digestive tract and common bile duct stones are found in 6% to 12% of patients with stones in the gallbladder.common bile duct stones can be suspected pre-operatively by symptoms or signs of jaundice, pancreatitis, or cholangitis, or by derangement in liver function tests, or on imaging showing duct dilation or actual ductal stones. Diseases related to gall stone and common bile duct stones are among one of the burdens to the health care system in developing countries including Ethiopia.

Objective :-to assess the pattern and factors associated with management outcome of patients treated for Common Bile duct stone disease in St.Paul hospital MMCSeptember 01/2010-august 30/2013 E.C

Methods

A retrospective cross sectional study was conducted. The study period was from January 2022-november 2022 at St.Paul hospital MMC.Data was collected from patient record using structured questionnaire by residents. After checking the completeness of data, it was analyzed using SPSS version 26.

Result. A total of 97 patients treated for Common Bile duct stone disease in St.Paul hospital MMC from September 01/2010-august 30/2013 E.C included in the study, among which 41 (42.3 %) patients were male and 56(57.7%)were female, with female to male ratio of 1.4:1.The mean age of the participants was 48.86.The most common complaint during initial visit was right upper quadrant pain in 89.7% of patients followed by yellowish discoloration of the eye in 70.1% of patients.Cholecystectomy, choledocholithotomy, side to side choledochoduodenostomy was the most common procedure done in 78(80.4%)of patients. Postoperative complication occurred in 20(20.6%)of patients and 5(5.15%)patients was taken to the OR for re-exploration.The most common complication was surgical site infection, including post operative collection, which occurred in 11(11.3%)of patients.

Conclusion :-Cholecystectomy, choledocholithotomy and side to side choledochoduodenostomy was the most common procedure done and has successful outcome and its a better option of management in resource limited setting.

Key words.CBDstone ,overall complication ,choledochoduodenostomy

Acknowledgements

- I would like to thank God for everything, I acknowledge all authors who availed their published article free of charge for my literature review.
- My advisors Dr. ShankoGebruand Dr. HenokTeshome ,I would like to thank them for their guidance,tireless efforts and encouragement in the accomplishment of this research. I am grateful that St.Paul Hospital MMC has sponsored this research project.

Acronyms and Abbreviations

CBD	Common bile duct
CI	Confidence Interval
ERCP	Endoscopic retrograde cholangiopancreatography
HIV	Human immunodeficiency virus
GBD	Gall bladder disease
GI	Gastrointestinal
MMC	Millennium medical collage
MD	Medical doctor
MRCP	Magnetic resonance cholangiopancreatography
NHANES	National Health and Nutrition Examination Survey
OPD	Outpatient department
OR	Odds Ratio
TASH	TikurAnbesa specialized hospital
UK	United kingdom
US	ultrasound
ZMH	Zewditumetasebiya Hospital

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1. Introduction

1.1 Background

Choledocholithiasis is identified in 10% to 18% of patients undergoing cholecystectomy, either preoperatively, intraoperatively, or postoperatively(1). The majority of cases of choledocholithiasis are secondary, the result of stones that originally formed in the gallbladder(2). Chemically, these stones tend to be cholesterol or black-pigment stones(3). Primary choledocholithiasis, 10% to 15% of cases (with a higher incidence in Asian countries), results from the formation of stones within the common bile duct(4). They are predominantly brown pigment (calcium bilirubin) stones. Primary stones occur in patients with congenital absence of the gallbladder and in those whose CBD had been cleared at the time of prior cholecystectomy(3).

Common bile duct stones can be suspected pre-operatively by symptoms or signs of jaundice, pancreatitis, or cholangitis, or by derangement in liver function tests, or on imaging showing duct dilation or actual ductal stones. Chronic obstruction can result in hepatic abscess, secondary biliary cirrhosis, and portal hypertension. In people without jaundice, with normal duct size on trans abdominal ultrasound, the prevalence of common bile duct stones at the time of cholecystectomy is less than 5%(5,6).

Transabdominal ultrasound and ERC are the most common preoperative imaging modalities with endoscopic ultrasound, MRCP, and HCT emerging as potentially more accurate and less invasive tools(7). Many common duct stones are clinically silent and may be identified only during cholangiography if it is performed routinely during cholecystectomy. Without pain or an abnormal liver function panel, a setting in which selective cholangiography is not performed, 1% to 2% of patients after cholecystectomy will present with a retained stone. When it is performed routinely, intraoperative cholangiography identifies choledocholithiasis in approximately 10% of asymptomatic patients, suggesting that most choledocholithiasis remains clinically silent(8,9).

Open common bile duct exploration was the only treatment for bile duct stones until endoscopic retrograde cholangiopancreatography (ERCP) was introduced in 1974(10), because of lack of expertise and necessary equipments open CBD exploration is still the widely practiced method of CBD stone management in Ethiopia.

The ideal treatment for common bile duct stones is still controversial. The options are that of surgical treatment alone (open or laparoscopic surgery) or a combination of endoscopy with surgical treatment (pre-, intra- or post laparoscopic cholecystectomy ERCP) to clear the common bile duct stones.

With current practice in Ethiopia ,Choledochoduodenostomy is a better option than CholedocholithotomywithT-tube insertion in the treatment of choledocholithiasis(11). it's not easy to find a lot of studies in the pattern and outcome of different means of managements in CBD stone in ethiopia. The aim of this study is to assess the clinical pattern andfactors associated with surgical outcome of patients with CBD stone.

1.2. Statement of the problem

The prevalence of gallbladder cholelithiasis is roughly 20.5 million (6.3 million men and 14.2 million women) in the United States whereas in Europe it is reported to vary between 5.9% and 21.9% of the general population, of this 11% to 21% of patients with cholelithiasis also have concomitant common bile duct stones (CBDS) at the time of surgery(12). Healthcare costs associated with the diagnosis and treatment of biliary tract stones typically exceed those for any other disease of the digestive tract. When we see the experience in our country there are studies that suggest around 7%- 12.5% rate of CBD exploration among cholecystectomy patients(11,13).

The prevalence of gallbladder stones in the general population in western and eastern is up to 20%; of these patients, up to 20% have synchronous CBDS which are asymptomatic in up to half of these latter cases. These data mean that up to 2% of the general population may have unknown CBDStone during their life-span; CBDStone may cause potentially life-threatening complications, such as acute cholangitis or acute pancreatitis, and therefore should be diagnosed and treated(12).

Over the past two decades, the advancement in laparoscopic and endoscopic techniques has almost made open biliary surgery obsolete. Notwithstanding this, due to lack of training as well as equipment, many surgeons in the developing world including Africa are commonly required to perform open cholecystectomy and CBD exploration for choledocholithiasis(16).

However, laparoscopy and ERCP are not consistently available in less developed countries, including Ethiopia. Most cases of symptomatic cholelithiasis or CBD stones are managed by open cholecystectomy and/or open surgical exploration of the CBD(17).

1.3 Significance of the study

Gallstones occur in approximately 15% of the general population . In people who have cholecystectomy for gallbladder stones, approximately 10% to 18% also have common bile duct stones(1).Diseases related to gall stone and CBD stones are among one of the burden to the health care system in developing countries including Ethiopia.Despite the significant nature of the disease entity and the everlasting challenge in management of patients with gall stone disease and CBD stone there are no significant number of study that shows the true nature of the disease as well the outcome of the surgical management of this patients in Ethiopia .this study aims to close the gap with respect to the pattern and outcome of surgical management of CBD stone and to provide the surgeon with the necessary information on subsequent surgical management of such patients so that informed decision will be taken based on research based study from our own experience.

2.literature review.

Gallstones are among the most common gastrointestinal illness requiring hospitalization and frequently occur in young, otherwise healthy people with a prevalence of 11% to 36% in autopsy reports(18). In particular, it is believed that gallstones may be caused by a combination of factors including heredity, obesity, and the ability of the gallbladder to contract (motility). Gallstones are categorized into *cholesterol stones* that are mostly hardened cholesterol and account for approximately 80% of the calculi, and *pigment stones* made of bilirubin that account for the remainder of 20%. Pigment stones are further categorized into black and brown pigment stones(19).

Most common bile duct stones form initially in the gallbladder and migrate through the cystic duct into the common bile duct. These stones are identified as secondary calculi to distinguish them from primary common bile duct stones, which form within the biliary tract. The primary stones are associated with biliary stasis and infection and are more commonly seen in Asian populations. The causes of biliary stasis that lead to the development of primary stones include biliary stricture, papillary stenosis, tumors, or other (secondary) stones(18).

A retrospective study from TASH on pattern of admission to the surgical department of TikurAnbessa hospital (TAH) revealed that cholelithiasis and its complications accounted for 10% of the whole admission and 25.9% of GI conditions. On another study from TikurAnbessa hospital revealed that CBD stone was found in 8% of 745 patients who underwent Cholecystectomy for cholelithiasis(11) but study from Japan indicates that incidence of choledocholithiasis is even higher occurring in 18.5% of patients operated for cholelithiasis. according to A three yr retrospective a study conducted at st.paul MMC 1230 patients underwent surgery for cholelithiasis among which 98(7%) had choledocholithiasis. Fifty-nine (75.6%) patients were females and 19(24.4%) were males, with a female to male ratio of 3.1:1. The mean age was 49 years with range of 16 to 87(11).

Another study at France also showed among 579 patients operated for CBD stone 386 were women (67%) and 193 were men (33%)(20). Inflammatory, infective, and congenital typical presentations of choledocholithiasis include biliary colic, jaundice, cholangitis, and pancreatitis. Of these, pain from biliary colic tends to be the most common symptomatic manifestation of CBD

stones. In many cases, the intermittent obstruction and passage of CBD stones will result in fluctuating elevation of bilirubin and liver function enzyme(4).

According to a 5-year period review in united kingdom between January 2008 and January 2013, 216 patients underwent surgical CBDExploration , of whom 152 (70%) were female. Patients' age ranged from 14 to 92 years. One hundred and nineteen of the 216 (55%) were performed as part of an emergency admission. Reasons for presentation were biliary colic 119 (54%), acute cholecystitis 32 (15%), acute pancreatitis 23 (11%), cholangitis 21 (10%), and jaundice 17 (8%). All but two patients (1%) had abnormal liver function tests and 184/216 (85%) patients had their CBD stones diagnosed radiologically preoperatively. In the remaining 32 patients CBD stones were detected by intraoperative cholangiography (IOC)(21).this findings are also similar to the study done on France ,prospective study on 20 yrsexperience in Francewhich showed Biliary colic or complications were present in the history of 555 patients (96%). Four hundred one (69%) had histories of biliary symptoms suggestive of CBD stones (prolonged acute biliary pain and/or acute cholangitis and/or jaundice and/or cholestasis) (20).

According to study conducted at St.paul MMC The most common presenting symptoms of CBD stone were right upper quadrant pain, jaundice, fat indigestion in 76 (97.4%), 51(65.4%), 39(50%) of the cases respectively. Right upper quadrant tenderness and icterus were the most frequent physical signs observed in 58(74.4%) and 41(52.6%) respectively. The laboratory serum bilirubin and transaminase levels along with ultrasound of the abdomen were the diagnostic aid used apart from history and physical findings(11).

Open cholecystectomy and bile duct exploration were performed commonly as the standard treatment for patients with choledocholithiasis for many years with good success and low rates of morbidity and mortality. During this era of open operative interventions which was performed by duodenotomy and sphincterotomy or bilioenteric anastomosis, the percentage of retained stones was only 1% to 3%, but from 20 yrs retrospective study from France showed reoperation rate 12 % (in the 1st decade)for residual stone(4,20).

In the last several decades, however, there has been a shift away from routine open cholecystectomy and CBD exploration with improvements in noninvasive imaging and increasing sophistication of percutaneous and endoscopic interventions. Surveys of general surgeons practicing in a rural area of the United States demonstrated that the preferred approach

to choledocholithiasis was ERCP (75%), followed by laparoscopic (21%) and open (4%) exploration(4).

The lack of sophisticated instruments and expertise in the field make open CBD exploration the preferred approach in many developing countries including Ethiopia.

A recent extensive literature review of 16 published randomized trials comparing the results of choledocholithiasis management by open surgery, laparoscopy and various endoscopic-laparoscopic protocols, did not show any significant differences concerning overall mortality and morbidity, ranging from 0%-3% and 13%-20%, respectively. Nevertheless, the cumulative rate of retained stones was significantly lower after open surgery (6%) than after two-step protocols (including laparoscopic cholecystectomy and ERC + endoscopic sphincterotomy regardless of the sequence of procedures - 16%)(12).

According to a 5-year review results of bile duct exploration in an Upper GI unit in UK total of 93/216 (43%) Open CBDE Explorations and 123 Laparoscopic CBDE Explorations (57%) were performed. Of the total 157 choledochotomies (open and laparoscopic) performed, 109 (69%) were closed primarily with sutures and 41 (26%) over a T-tube; 4 patients were converted to a hepatic-jejunostomy and 3 to a choledochoduodenostomy. An overall ductal clearance rate of 87% (187/216) was achieved; 90% for Open CBDE Explorations with 9/93 (10%) retained stones but the study in France from 20 yrs experience in open CBD exploration showed retained stones was found in only 1% of patients in the 2nd decade of the study(20,21).

The same study showed bile leaks requiring intervention occurred in 8 (4%) patients (4 in each of the Laparoscopic CBDE Exploration and Open CBDE Explorations groups). Overall complications inclusive of retained stones occurred in 81/216 (38%) patients, 41/93 (44%) after Open CBDE Exploration and 40/123 (32%) after Laparoscopic CBDE Exploration, the procedure related complications rates fall to 32/93 (34%) after Open CBDE Exploration and 20/123 (16%) after Laparoscopic CBDE Exploration(21).

From a 20 yrs experience prospective study at France, CBD exploration was done in 579 patients and Complications related to biliary drainage tubes occurred in 18 patients, or 5% of those with tubes, mostly in the first decade, they included external bile leakage. Postoperative acute pancreatitis developed in 1 patient. Ten patients (2%) required early reoperation for wound

and biliary complications, intraperitoneal bleeding, and bleeding ulcer. Reoperations for biliary complications included 2 relaparotomies for intraperitoneal bile leak following removal of the tube, 2 for dislodgement, and 1 for rupture of the tube(20).

According to the study performed at St. Paul MMC Choledochotomy with T-tube drainage and choledochoduodenostomy were the two frequently performed procedures. Although it seems that bigger duct size might have pressed to do choledochoduodenostomy the distribution is not significantly different. The postoperative stay was significantly delayed for the choledochotomy and T-tube drainage group. Re-exploration rate was also more in the T-tube drainage group. On follow up three of the T-tube drainage and one of the choledochoduodenostomy patients got complicated which deserved re-exploration which is not statistically significant. This observation definitely favors Choledochoduodenostomy for surgical management of properly selected cases of common bile duct stones. This study has shown that side-to-side CD is a better alternative procedure with less early and late complication. They recommend it for multiple CBD calculi, much dilated CBD (2cm), big stone in the CBD, Hepatic stone, recurrent stone, Primary CBD stone and elderly patients where the size of CBD is 15mm and above(11).

3. Objectives

3.1 General Objective:

To determine the pattern and factors associated with management outcome of patients with CBD stone disease in St. Paul's MMC from September 01/ 2010-august- 30/2013 E.C

3.2 specific objectives

1. to identify the common clinical presentation of a patient with CBD stone
2. to assess the management outcome of a patient with CBD stone.
3. To determine factors affecting the management outcome of CBD stone patients

4. Methods

4.1 study setting

This study was conducted at St. Paul's millennium medical college which is located at the capital city of Ethiopia. The hospital has inpatient capacity of more than 700 beds and an average of 1200 emergency and outpatient clients are seen daily in the hospital prior to the covid 19 pandemic.

The department of surgery at St. Paul's hospital MMC comprises general surgery and subspecialty service. It gives subspecialty service in cardiothoracic surgery with 02 surgeons, hepatobiliary surgery with 02 surgeons and three fellows, pediatrics surgery with three surgeons, uro-surgery with 05 surgeons, endocrine and breast surgery with two surgeons, transplant surgery with 04 surgeons. Surgical inpatient service has 40 adult and 20 pediatrics beds with 06 OR tables.

4.2 study period.

The study was conducted from January 2022-november2022.

4.3 study design

Hospital based cross –sectional study was conducted.

4.4 study population

4.4.1 source population

The source population were all patients who were admitted in St.paul Hospital MMC department of surgery during study period, from September 01/2010-august 30/2013E.C

4.4.2 study population

The study population were all patients who were admitted and operated to St. paul hospital MMC surgical ward with the diagnosis of CBD stone and all patients diagnosed to have CBD stone intra-operatively in the study period from September 01/ 2010-august 30/2013 E.C.

4.4.3 Inclusion criteria

All patients operated at St. paul hospital MMC surgical ward with diagnosis of CBD stone after proper clinical and imaging evaluation as well all patients diagnosed to have CBD stone intra-operatively was included in the study.

4.4.4 Exclusion criteria

All patients who are operated somewhere else and admitted posts operatively and all patients with incomplete chart recordings were excluded from the study.

4.5 Sample size and procedure

The sample size was calculated using a single population proportion formula taking 8% CBD exploration from study done at st.paul hospital MMC

$$n = \frac{z^2 p(1 - p)}{e^2}$$

n = the required sample size

p = proportion of patients who underwent CBD exploration for biliary lithiasis.

$Z_{\alpha/2}$ = the critical value at 95% confidence level = 1.96

e = precision (margin of error) = 5%

Accordingly,

$$n = \frac{(1.96)^2 * 0.08(1 - .08)}{0.05^2}$$

$$n = \frac{(1.96)^2 * 0.08(.92)}{0.05^2}$$

$$n = 113$$

Adding non response rate of 10% the final sample size were 124. From these 97 patients fulfilling the inclusion criteria has been included in the study. The response rate in the study was 85.8%.

4.6 Study variables

❖ Dependent variables

-management outcome(smooth pos -op course, complicated post-op course ,died)

❖ Independent variable

-Age

-Sex

-mode of presentation (elective vs. emergency)

-duration of illness

-intra-operative local adhesion

-presence of co-morbid illness

-size and number of stone

-CBD diameter

-type of surgery

-Length of post op stay.

-serum bilirubin

-previous management for acute complications biliary stone disease

4.7 Data Collection and Procedures

CBD stone patients' chart was traced from OR registration log book and HMIS records. Data was collected from patient card using structured questionnaire by residents.

4.9 Data Quality Control and Management

The data collection instrument was pretested on 10 % of CBD stone patients prior to actual data collection to check missed information so as to make possible amendments. Selection and training of data collector was done. Checking for completeness and consistency of collected data at the end of each day was done throughout data collection period.

4.10 .Data Analysis Plan and Procedures

Each questionnaire was checked for completeness, and missed values. Descriptive statistics of numeric variables was presented in means and standard deviations. Categorical variables was presented using frequency and percentage. Data was analyzed using SPSS version 26. Odds ratio was calculated to assess the strength of association between outcome variable and explanatory variables. All tests considered a significance level of $p < 0.05$.

4.11 Ethical Consideration

Ethical clearance was obtained from the institute of research board, St. Pual hospital MMC. After the permission letter received from St. Pual hospital MMC the study was conducted. This study was justifiable by its potential benefit, including contribution to knowledge and understanding, social welfare and individual well-being. This project was supported by current literature and previous studies.

4.12 Dissemination of Results

After analyzing data, conclusion and recommendation was made and the result was submitted to St. Pual's Hospital MMC, department of surgery.

5. Result.

5.1 Socio demographic characteristics of CBD stone patients.

A total of 97 patients who were surgically managed for diagnosis of CBD stone disease full filling the inclusion criteria were included in this study. Of the study sample 41 (42.3 %) patients were male and 56(57.7 %) were female, with female to male ratio of 1.4:1. The mean age of the participants was 48.86(SD of 15.58) years and the range was from 18-89. Among the total number of patients 38(39.2%) were in 21-40 years of age followed by 33(34%) patients in 41-60yrs of age.(table 1)

Table 1. Socio demographic characteristics of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variable	Frequency(n=97)	Percent (%)
Age	<20	1
	21-40	38
	41-60	33
	61 and above	25
Sex.	Male	41
	Female	56

5.2 clinical presentations of CBD stone patients

The mean duration of illness is 9 months(SD of 20.7) and it ranges from 10 days to 120 months. According to their initial evaluation 34(35.1%) patients present at emergency base while 63(64.9%) of patients present as outpatient. The most common complaint during initial visit was right upper quadrant pain in 89.7 % (87) of patients followed by yellowish discoloration of the eye in 70.1%(68)of patients while 32%(31)of patients has previous management for acute complications of biliary stone disease. Among this patients (N=31 48.3%) 15 had previous management for ascending cholangitis and 14(45.1%)of patients has previous history of cholecystectomy while 1(0.0322%)patient had both. Co morbid illness was identified in 21(21.64%) patients with 8(8.4%) of patients have HTN while 5(5.15%) patients have RVI. During the initial presentation 12(12.4%) of patients were hypertensive, 8(8.2%)were tachycardic

and 6(6.2%)of them were febrile. The most common physical finding documented was icteric sclera in 59(73.8%) of patients followed by RUQ tenderness in 55(68.8%) of patients. (Table 2)

Table 2 clinical presentation of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variables	Frequency	Percent
Clinical presentation		
RUQ or epigastric pain	87	89.7%
yellowish discoloration of the eye	68	70.1%
cola colored urine	38	39.2%
stool color change (clay colored stool)	22	22.7%
itching	19	19.6%
nausea and/or vomiting present	38	39.2%
fever, chills or rigor	25	25.8%
previous management for acute complications of biliary stone disease	31	32.0%
previous management for acute complications of biliary stone disease		
Ascending cholangitis	15	15.46%
cholecystectomy	14	14.43%
cholecystectomy + lavage for postop collection	1	1.03%
Cholecystectomy, Ascending Cholangitis	1	1.03%
Variable	Frequency	Percent
Co morbid illness		

HTN	8	8.24
HIV	5	5.15
HTN +cardiac	2	2.06
Others	5	5.15

Physical finding

Icteric sclera	59	60.8%
RUQ tenderness	55	56.7%
palpable gall bladder	1	1.03%

*others DM,Goiter,psychiatry,asthma,HTN+DM each accounting one.

5.3 laboratory findings of CBD stone patients

During laboratory evaluation of the initial visit 22(22.6) of patients had elevated WBC,SGOT was raised in 54(55.6%) ,SGPT raised in 60(61.8%) and ALP was documented to be done in 91 patients and was raised in70(76.9% n=91)of patients .Total and direct bilirubin was documented to be done in 84 patients and was raised in 74(88.1% n=84) and 72(85.7% n=84) of patients respectively.(table 3)

Table 3 laboratory findings of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variable	Frequency	Percent
White blood cell count		
<11,000	75	77.3
11,000 - 15,000	11	11.3
>15,000	11	11.3
SGOT		
Normal	42	43.3
<2x increment	9	9.3
2 - 5 x increment	29	29.9

>5x increment	16	16.5
SGPT		
Normal	37	38.1
<2x increment	12	12.4
2 - 5 x increment	28	28.9
>5x increment	20	20.6
ALP		
Normal	21	21.6
<2x increment	15	15.5
2 - 5 x increment	27	27.8
>5x increment	28	28.9
Not available	6	6.2
TOTAL Bilirubin		
Normal	10	11.9
<2x increment	19	22.6
2 - 5 x increment	26	30.9
>5x increment	29	34.5
Not available	13	13.4
Direct bilirubin		
Normal	12	14.3
<2x increment	19	22.6
2 - 5 x increment	18	21.4
>5x increment	35	41.6
Not available	13	13.4

5.4 Diagnostic imaging findings of CBD stone patients

At the initial evaluation of imaging in 80(82.5%)patients U/S was used to diagnose stone in CBD while in 17(17.2%)of patients CT or MRI was used for diagnosis of stone in the CBD while in 35(36.1%)patients CT scan and in 39(40.2%) MRCP was used as confirmatory imaging. Among the imaging findings CBD or HD was documented to be dilated in 91(93.8%)of patients and in 55(56.7%)of patients the size of CBD was documented to be b/n 1-2cm.when we see the stone size 26(26.8%)of patients had documented stone size of 1-2 cm while 24(24.7%) patients had documented stone size of <1cm and in 55(56.7%)of patients there were concomitant gall bladder stone.(table 4)

Table 4 imaging findings of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variable	Frequency	Percent
Method of stone detection		
Stone detected on U/S	80	82.5
Stone Detected on CT	35	36.1
Stone detected ion MRCP	39	40.2
CBD dilation		
Yes	91	93.8
No	6	6.2
Size of CBD		
<1cm	6	6.2
1-2cm	55	56.7
>2cm	19	19.6
Not documented	17	17.5
Variable	Frequency	Percent
Size of stone		
<1cm	24	24.7
1-2 cm	26	26.8
>2cm	17	17.5
Not documented	30	30.9
Concomitant gall bladder stone		

Yes	55	56.7
No	28	28.6
Absent gall bladder(previous cholecystectomy	14	5.2

5.5 preoperative and intraoperative course of patients who has been explored for CBD stone disease.

Among the 97 patients 95(97.9%)of patients were explored on elective base while 2(2.1%)were explored on emergency base. Vitamin k was documented to be given preoperative for 53(54.6)of patients, in which the minimum number of days given were 01day and maximum of 7 days with a mean number of days given being 3.74days(SD 1.63).Intraoperatively CBD was found to be dilated in 78(80.4)of patients and 48(49.5%)of patients had local adhesion during exploration. During choledochotomy 48 (49.5%) of patients has multiple stone while 35(36.1%) of patients had single stone in 4(4.1%)of patients only sludge was found in dilated CBD and in 10(10.3%) of patients no stone was identified.Cholecystectomy, choledocholithotomy and side to side choledochoduodenostomy was the most common procedure done in 78(80.4%)of patients,in 5(5.3%) of patients only cholecystectomy was done because the CBD was not dilated and there was no stone found intraoperatively,while ERCP was done in 2(2.1%)patients.Intraop accident was recorded in one patient where there was absent gallbladder and difficulty in identifying the CBD in which case further exploration was differed .Drainage was left in 85(87.6%)of patients.the mean length of procedure was 120.5min with SD (42.14) and with a minimum of 30min and maximum of 210 min .(table 5)

Table 5 preoperative and intraoperative course of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variable	Frequency	Percent
Mode of exploration		
Emergency	2	2.1
Elective	95	97.9
Vitamin k given		
Yes	53	54.6
No	15	15.5
Not mentioned	29	29.9
Intraoperative dilated CBD		
Yes	78	80.4
No	19	19.6
Local adhesion		
Yes	48	49.5
No	49	50.5
Intraoperative finding of stone		
Single	35	36.1
Multiple	48	49.5
sludge	4	4.1
Stone not found	10	10.3
Type of procedure		
Cholecystectomy, choledocholithotomy, side to side	78	80.4
choledochoduodenostomy		
Cholecystectomy, choledocholithotomy, end to side	3	3.1
choledochoduodenostomy		
cholecystectomy, choledocholithotomy, roux- en-y hepaticojejunostomy	3	3.1
Cholecystectomy	5	5.2
Cholecystectomy choledocholithotomy, choledochoduodenostomy	2	2.1

ERCP	2	2.1
Other*	4	4.1
Drainage left.		
Yes	85	87.6
No	12	12.4
Others*hepaticoduodenostomy, cholecystectomy cholidocholithotomy,and T-tube closure,laparotomy alone,cholecystectomy ,hepaticoduodenostomy		

6.postoperative outcome of patients with CBD stone disease.

The total hospital stay ranged from 4days-40 days with mean stay of 13.74days (SD 6.24)among which 38(39.2%)of patients stayed for 11-15days.postoperatively patients stayed from2-25days with mean postoperative stay of 6.73days SD (3.57).among this 53(54.6%)of patients had post operative stay of 6-10days ,35(36.1%)patients had postoperative stay of <5days ,6(6.2)patients had post operative stay of 11-15 days while 3(3.1%)patients had >15 days of post operative stay.

Postoperative complication occurred in 20(20.6%)of patients and 5(5.15%)patients was taken to the OR for re-exploration.the most common complication was surgical site infection which occurred in 11(11.3%)of patients among which 5(5.2%)patients developed SSSI while deep SSI and post op collection occurred in 3(3.1%)of patients, HAP occurred in 3(3.1%)of patients.Among the 5 re-laparotomy the 1st two was for anastomotic leak,the 2nd was for small bowel volvulus ,3rd was a patient with post op collection with 1st part duodenal perforation and the 4th for complete wound dehiscence.on discharge 94 (96.9%)of patients were discharged improved while 2(2.1%)patients were discharged with same condition with the compliant of intermittent abdominal pain.on follow up out of 68 patients who were jaundiced preoperatively 66(97%)of them had improvement in their jaundice while all patients who had post operative documentation on follow up had their itching resolved. The mean follow up period was 3.867month (SD 5.41) ,the minimum follow up period being 2weeks and maximum period of 36month.during follow up 8(8.24%)of patients was found to have complication,among this two patients had SSI on early post operative follow up period, two patients had CBD stricture and

among this two, one of them had ascending cholangitis.the remaining complications were incisional hernia,liver abscess,abdominal wall abscess and retained stone .finally based on the early and pos operative follow up course there was no death documented on any of the patients included on this study and the mortality rate according to this study was zero.(table 6)

Fig.2 post operative complications of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97

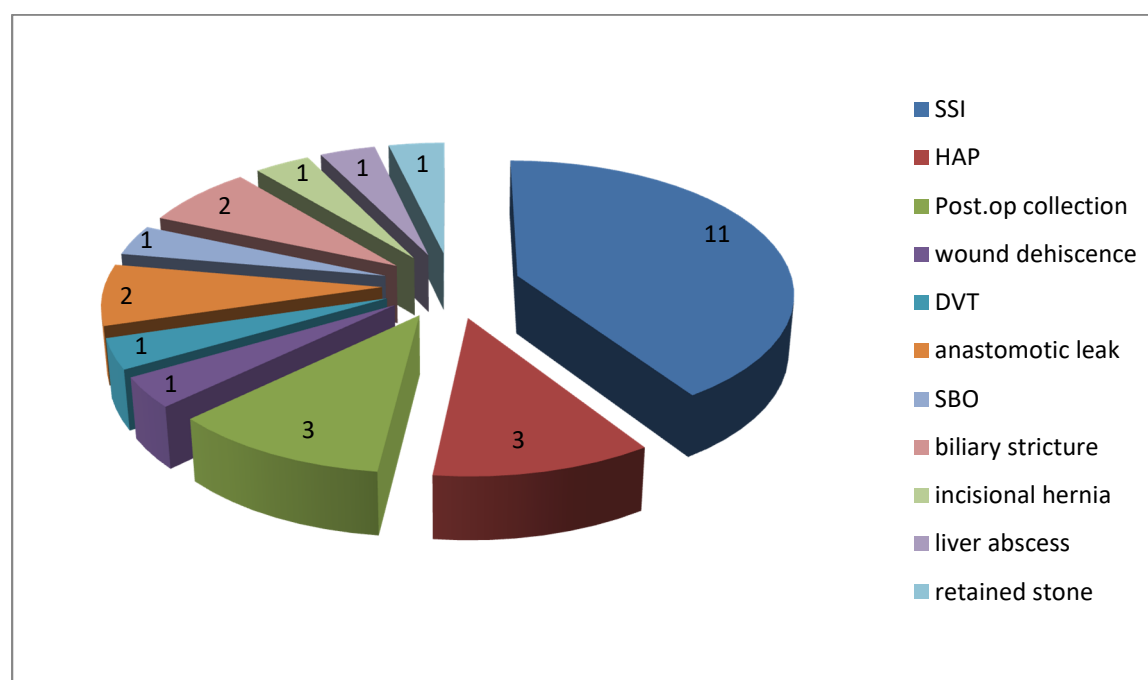


Table 6 post operative course of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variable	Frequency	Percent
Post op stay		
<5days	35	36.1
6-10days	53	54.6

11-15	6	6.2
>15days	3	3.1
Total hospital stay		
<5days	5	5.2
6-10days	25	25.8
11-15days	38	39.2
>15days	29	29.9
Post op complication		
Yes	20	20.6
No	78	80.4
Type of complication		
SSI	11	11.3
HAP	3	3.1
Biliary stricture	2	2.06
Anastomotic leak	2	2.06
complete Wound dehiscence	1	1.03
DVT	1	1.03
SBO 2ndry to volvulus	1	1.03
Liver abscess	1	1.03
Incisional hernia	1	1.03
Retained stone.	1	1.03

5.7 factors associated with management outcome of patients with CBD Stone disease.

In a binary logistic regression showed that intra-operative local adhesion ,CBD diameter ,SGPT and SGOT were associated with over all postoperative complication of surgical management of CBD stone at p-value less than 0.25.Among this the binary logistic regression also showed that intra-operative local adhesion and CBD diameter were significantly associated with over all postoperative complication of surgical management of CBD stone at p-value less than 0.05.

According to the result of binary regression patients with intra-operative local adhesion has 75% decreased risk of overall post operative complication (P value 0.016, OR = 0.250 (95% CI 0.081, 0.773)) table 7.

In addition, those variables significantly associated with overall postoperative complication of management of CBD stone disease at p-value of less than 0.25 were candidates for Multivariable logistic regression analysis.

Multivariable logistic regression model showed that only diameter of CBD was significantly associated with overall postoperative complication of management of CBD stone disease, with p-value less than 0.05 and 95% confidence interval. The preoperatively recorded diameter of CBD was significantly associated with the overall complication of management of CBD, in which patients with larger diameter of CBD has 85% (P value = 0.031, OR .149 (95% CI .027, .837)) decrease in risk of overall post operative complication. In this analysis the recorded preoperative CBD diameter was further categorized as diameter of <1cm, 1-2cm and >2cm but doesn't show association up on categorization Table 8.

It was also shown that Postoperative complication was significantly associated with prolonged post operative stay, in which patients with postoperative complication has significant risk of prolonged post op course (P value < 0.005 OR = 1.488 (95% CI 1.192, 1.858)).

Table seven :- binary logistic regression result of intra-op local adhesion with overall post-operative complication of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variable	Over all Complication		OR(95%CI)	P.value
	Yes	no		
Intra-operative local adhesion				
Yes	5	35	0.25(0.081,0.773)	0.016
No	15	28		

Table eight :- Multiple logistic regression of patients surgically managed for CBD stone at SPHMMC from September 01/2010-august 30/2013 E.C (N=97)

Variable	Sig.	OR	95% Confidence Interval for Exp(B)	
			Lower bound	Upper bound.
Total hospital stay	.228	.514	.174	1.517
Post operative stay	.823	.880	.289	2.681
SGPT	.241	1.408	.794	2.497
Intra operative local adhesion	.071	.245	.053	1.130
CBD diameter	.031	.149	.027	.837

6. Discussion

Diseases related to gall stone and CBD stones are among one of the burden to the health care system in developing countries including Ethiopia. In general population, 11% to 21% of patients with cholelithiasis also have concomitant common bile duct stones (CBDS) at the time of surgery(12). Open cholecystectomy and bile duct exploration were performed commonly as the standard treatment for patients with choledocholithiasis for many years with good success and low rates of morbidity and mortality(4).

According to this study The mean age of the participants was 48.86 with the range of 18-89. Among the total number of patients 38(39.2%) were in 21-40 years of age followed by 33(34%) patients in 41-60 yrs of age, this figure is comparable to the 5-year period review in united kingdom between January 2008 and January 2013, where the age range was from 14-92(21). A clinical based retrospective analysis done at SPHHMMC between January 1st 1994 to December 30 1999 showed the mean age was 49 years with range of 16 to 87, which is similar to the current study(11).

Based on this study among those 97 patients 41 (42.3 %) patients were male and 56(57.7 %) were female, which gives a female to male ratio of 1.4:1. study at France showed among 579 patients operated for CBD stone 386 were women (67%) and 193 were men (33%) with female to male ratio of 2:1, the study at SPHHMMC also showed a higher female to male ratio of 3.1:1. based on this data the proportion of male patients undergoing CBD exploration is higher than previously mentioned literatures(11,20).

Based on this study, according to their initial evaluation 34(35.1%) patients present at emergency base while 63(64.9%) of patients present as outpatient but only 2(2.1%) patients were their CBD explored on emergency base while according to 5-year period review in united kingdom One hundred and nineteen of 216 (55%) were performed as part of an emergency admission showing very low rate of emergency CBD exploration compared to the west despite significant proportion of patients presenting at emergency base(21). This study also showed that The most common complaint during initial visit was right upper quadrant pain in 89.7%(87) of patients followed by yellowish discoloration of the eye in 70.1%(68) of patients while 32%(31) of patients has previous management for acute complications of biliary stone disease. Among this patients (N=31 48.3%) 15 had previous management for ascending cholangitis and 14(45.1%) of patients has previous history of cholecystectomy. According to different studies done (5-year period review in united kingdom between January 2008 and January 2013, prospective study on 20 yrs experience in

France, study conducted at St. Paul MMC) the clinical presentations were similar with the most common presenting symptoms of CBD stone being right upper quadrant pain, except the review in United Kingdom found out that only 8% of patients presented with jaundice, which is significantly lower than found on this study where 70.1% of patients had history of jaundice and this could be associated with the fact that most of the patients in the west have early diagnosis because of routine imaging evaluation for minor abdominal complaints. (11,20,21).

This study also found out that during laboratory evaluation of the initial visit 22 (22.6%) of patients had elevated WBC, SGOT was raised in 54 (55.6%), SGPT raised in 60 (61.8%) and ALP was raised in 70 (76.9% n=91) of patients. Total and direct bilirubin was raised in 74 (88.4% n=84) and 72 (85.7% n=84) of patients respectively and along with this lab results at the initial evaluation of imaging in 80 (82.5%) patients U/S was used to diagnose stone in CBD while in 17 (17.2%) of patients CT or MRI was used for diagnosis of stone in the CBD while in 35 (36.1%) patients CT scan and in 39 (40.2%) MRCP was used as confirmatory imaging. This result was supported by a study done on Management of Common Bile Duct Stone on April 2006 which showed Trans abdominal ultrasound is commonly used diagnostic modality. The same study also points out that ERC with endoscopic ultrasound are becoming preoperative imaging modalities with MRCP, and HCT emerging as potentially more accurate and less invasive tools (22). In our study even if we found that 35 (36.1%) of patients had stone detected on CT while 39 (40.2%) patients had stone detected on MRCP which showed a potential for usage of these emerging modalities, the use of ERCP and endoscopic U/S for preoperative evaluation is quite low which is possibly attributed to the lack of equipment and trained expertise.

According to this study Among the 97 patients 95 (97.9%) of patients were explored on elective basis while 2 (2.1%) were explored on emergency basis and Vitamin K was documented to be given preoperatively for 53 (54.6%) of patients. Intraoperatively CBD was found to be dilated in 78 (80.4%) of patients and 48 (49.5%) of patients had local adhesions during exploration. During cholecystectomy 48 (49.5%) of patients had multiple stones while 35 (36.1%) of patients had single stone. Cholecystectomy, choledocholithotomy and side to side choledochoduodenostomy was the most common procedure done in 78 (80.4%) of patients, while only two patients had their stone explored through ERCP. According to a paper on Traditional surgical management of common bile duct stones: A prospective study during a 20-year experience Open cholecystectomy and bile duct exploration were performed commonly as the standard treatment for patients with

choledocholithiasis for many years with good success and low rates of morbidity and mortality. During this era of open operative interventions it was performed by duodenotomy and sphincterotomy or bilioenteric anastomosis²². The five year review conducted at SPHMMC 15 yrs back also showed that Choledochotomy with T-tube drainage and Choledochoduodenostomy were the two frequently performed procedures.

Over the past two decades, the advancement in laparoscopic and endoscopic techniques has almost made open biliary surgery obsolete. Notwithstanding this, According to a paper on Open common bile duct exploration without T-tube insertion – two decade experience from a limited resource setting in the Caribbean due to lack of training as well as equipment, many surgeons in the developing world are commonly required to perform open cholecystectomy and CBD exploration for choledocholithiasis, which was the same to the finding in our study.

Currently there are multiple centers in Ethiopia where laparoscopic cholecystectomy being practiced routinely including our center of study during the study period, despite many literatures supporting the choice of laparoscopic CBD exploration over open CBD exploration none of the patients in our study has undergone laparoscopic CBD exploration.

When we see the post operative outcome of patients in our study, the total hospital stay ranged from 4 days-40 days with mean stay of 13.74 days among which 38 (39.2%) of patients stayed for 11-15 days and postoperatively patients stayed from 2-25 days with mean postoperative stay of 6.73 and. among this 53 (54.6%) of patients had post operative stay of 6-10 days while 35 (36.1%) patients had postoperative stay of <5 days. Postop complication occurred in 20 (20.6%) of patients and 5 (5.15%) patients was taken to the OR for re-exploration among this two of the patients had anastomotic leak. The most common complication was surgical site infection including post op collection, which occurred in 11 (11.3%) of patients, while HAP occurred in 3 (3.1%) of patients. According to a 5-year review results of bile duct exploration in an Upper GI unit in UK Overall complications inclusive of retained stones occurred 41/93 (44%) after Open CBD Exploration with the procedure related complications rates fall to 32/93 (34%) which was significantly higher than the finding in our study. The same study showed bile leaks requiring intervention occurred in 4 (4.3%) patients while a paper From a 20 yrs experience prospective study at France, CBD exploration was done in 579 patients, and Ten patients (2%) required early reoperation for wound and biliary complications, intraperitoneal bleeding, and bleeding ulcer. Reoperations for biliary complications included 2 relaparotomies for intraperitoneal bile leak following removal of the tube, 2 for dislodgement, and 1 for rupture of the tube, the study at

ST.paul MMC also showed Re-exploration rate was also more in the T-tube drainage group than choledochoduodenostomy(11,20,21).

According to the data from our study the rate of re-exploration and anastomotic biliary leak rates are comparable to the above mentioned studies . This study showed that diameter of CBD was significantly associated with overall postoperative complication of management of CBD stone disease(p-value 0.031) in which patients with larger diameter of CBD has 85% (OR .149(95% CI .027,.837))decrease in risk of overall post operative complication.

6.1Limitation of the study

The study has some limitations. this study is conducted in single institution in brief period so the result might not be applicable to other settings in the country and also since the study was done retrospectively from patient recordings there might be a limitation on data quality.

7.conclusion.

Cholecystectomy, choledocholithotomy and side to side choledochoduodenostomy was the most common procedure done and has successful outcome with increasing CBD size where complication rate was significantly decreased. It's a better option of management in resource limited setting. Intraoperatively stone was found in 79 (81.4%) of patients with 49.5% of which was multiple stone and postoperatively only one patient had retained stone ,because of the lack of follow up imaging in most of patients it was difficult to know the stone clearance rate of the current method of procedures which are used in the study setting.

The most common post operative complication was SSI followed by HAP and postoperative collection which has resulted in prolonged post operative length of hospital stay.with follow up of standard protocols on surgical aseptic technique the rate of SSI can be decreased.

8. Recommendations

With the results of this study we recommend Cholecystectomy, choledocholithotomy and side to side choledochoduodenostomy as good option of management for CBD stone disease in resource limited setting in patients with larger diameter of CBD.

The most common method of CBD stone management based on this study was open CBD exploration with billiary enteric anastomosis which is highly invasive procedure, with the current trend of less invasive or minimally invasive option of management the practice towards the new era of development can be adapted.

Proper and updated preoperative evaluation, adequate documentation on patient evaluation ,intraoperative findings and follow up course ,special attention on post operative follow up specially on laboratory and imaging evaluation.

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10. Annexes

Questionnaire form: CBD stone

1. s.no 2. age _____ 3. sex a. male b. female

4. presentation I. a. emergency b. elective c. intra-operative

II. duration of illness _____

5. complaints

a. RUQ or epigastric abdominal pain

b. yellowish discoloration of the eye

c. urine color change (cola colored urine)

d. stool color change (clay colored stool)

e. itching

f. fever, chills or rigors

g. previous management for acute complications biliary stone disease

h. presence of co-morbid illness

i. others (specify)

6. vital sign

i. BP.

a. in normal range b. hypertensive c. hypotensive

ii. PR.

a. In normal range b. tachycardic

ii. T0

a. in normal range b. febrile

7. icterus

a. yes b. no

8. RUQ tenderness

a. yes b. no

9. Palpable gall bladder

10.lab.results

I.CBC(leukocytosis) _____

II. Liver enzymes

- a. SGOT_____
- b. SGPT_____
- c. ALP_____

III. Total Bilirubin_____

Direct Bilurubin_____

IV.pancreatic enzymes

- a. normal
- b. elevated

11.imagings

I. Diagnosis of CBD stone was made by and write the findings for each

a.Usd_____

b. CT _____

C. MRCP_____

II. how much was the diameter of CBD_____

III.Intraoperatively due to _____ (palpable stone, dilated biliary tree, or pre OP suspicion)

IV. Concomitant gall bladder stone

- a.yes
- b.no

12. management

I.type of exploration

- a. emergency
- b.elective

II.Vitamin K - Given for _____ days or Not mentioned _____

III.inra-op finding _____

IV.type of procedure

- a. Cholecystectomy ,choledocholithotomy ,side to side choledochoduodenostomy
- b. Cholecystectomy ,choledocholithotomy ,end to side choledochoduodenostomy
- c. Cholecystectomy ,choledocholithotomy,roux-en-y choledochojejunostomy
- d. Cholecystectomy ,choledocholithotomy,roux-en-y hepaticojejunostomy
- e. Cholecystectomy ,cheledocholithotomy,T-tube closure.

f. Others (specify)_____

V.. surgery time_____

VI.intra op accident _____

VII.if yes how was it managed_____

VIII.drainage left

A.yes B.no

12.postop course

I.how long was hospital stay_____

II.post op complication

a.yes b.no

III .if yes mention the type of complication

How is the complication managed _____

If the complication is death reason for death_____

IV.re-exploration

a.yes b.no

V.if yes mention the intra-op finding, reason and the type of procedure done

VI.Post OP liver function test write the numbers____

VII.Post OP improvement in symptoms Itching, Jaundice....

13. Out-patient follow up

I. complication picked during follow up

a.yes b.no

II.if yes mention the type of complication_____

III.How is the complication managed _____.

IV.How long is the patient followed as an out patient _____.

V.long term improvements in symptoms ...

