THE PATTERN OF PRESENTATION, CURRENT MANAGEMENT AND COMPLICATIONS IN PATIENTS AGED 13 YEARS AND ABOVE WITH GALLSTONE DISEASE AS SEEN AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

I declare that the dissertation is my original work and has not been presented for a degree in any other university.

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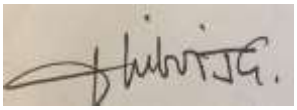
SIGNATURE……  **…… DATE ……**28/04/2020**……**

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DEDICATION.

This research work is dedicated to all my teachers in surgery, colleagues, and patients for making this study possible. I also wish to dedicate it to my beloved family and friends who have supported me in one way or another towards the accomplishment of this great research project.

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LIST OF ABBREVIATIONS

GSD- GALLSTONE DISEASE

BMI- BODY MASS INDEX

MRCP- MAGNETIC RESONANCE CHOLANGIO-PANCREATOGRAPHY

EUS- ENDOSCOPIC ULTRASOUND

CT- COMPUTED TOMOGRAPHY

SOPC- SURGICAL OUTPATIENT CLINIC

KNH- KENYATTA NATIONAL HOSPITAL

CBD- COMMON BILE DUCT

GGT: GAMMA GLUTAMYL TRANSFERASE

LCBDE: LAPAROSCOPIC COMMON BILE DUCT EXPLORATION

OPERATIONAL DEFINITION OF TERMS

Gallstone: this is solid masses formed from bile precipitates

Gallstone disease: calculous disease of the biliary tract that are direct results of gallstones

Cholelithiasis: the presence of gallstones which are concretions that form in the biliary tract, usually in the gallbladder.

Choledocholithiasis: the presence of one or more gallstones in the common bile duct

Diagnosis of gallstone disease: abdominal ultrasound and liver function test are the important initial tests that should be done when there is clinical suspicion of gallstone disease e.g., abdominal pain, jaundice, or fever. However, LFTs are not reliable and may be normal in the presence of symptomatic disease.

Differential diagnosis of gallstone disease: the following are the disease entities that may mimics gallstone, they include:

- Acute pancreatitis
- Appendicitis
- Bile duct strictures
- Bile duct tumors
- Cholangiocarcinoma
- Cholecystitis
- Gallbladder cancer
- Pancreatic cancer
- Peptic ulcer disease

ABSTRACT

Background: Gallstone disease is a worldwide problem and is a common cause of hospitalization leading to surgical intervention. The prevalence of gallstone in Africa was considered low but has been on the rise due to changes in dietary habits, obesity, sedentary lifestyle, and drugs. The exact etiology of the disease is unknown. The exact pattern of presentation is also not documented.

Objectives: To determine the current pattern of presentation, management, and complications of gallstone disease in patients as seen at the Kenyatta National Hospital.

Methodology: The study design is a prospective descriptive study.

Study setting: Accident and emergency unit, surgical and medical wards, critical care units and theatres for Kenyatta National Hospital

Study Population**:** All male and female patients (above the age of 13 years) undergoing treatment for gallstone disease at accident and emergency department, surgical outpatient clinics and the general surgical and medical wards in the Kenyatta National Hospital

Study design: The study design is a prospective descriptive study.

Data Collection: A structured questionnaire that is self-administered with open and close-ended questions, and including participants' biodata, comorbidities, symptomatology, laboratory investigations, imaging modalities, management options, and complications was used in this study.

Data Management and Analysis: Statistical analysis was done only on fully completed questionnaires. Descriptive statistics such as frequencies and percentages were used to describe the prevalence, pattern of presentation, and complications of gallstone disease.

Study utility: The drive of conducting the study was to determining the current pattern of presentation, management, complications, of gallstone disease as seen in the KNH. Information derived from this study will help policymakers to draft guidelines in the management of gallbladder disease at the KNH which may be replicated countrywide.

1.0: INTRODUCTION

1.1: Background of the study

Gallstone disease is a global health burden that results in significant morbidity and mortality constituting a significant economic burden in the developed world(1). It was previously considered sporadic in sub-Saharan Africa but its prevalence has been increasing in many countries(2). Gallstones have been part of human pathology since ancient times and are linked to dietary habits, environmental conditions, and genetic predisposition(3). Gallstones are classified into pigment, cholesterol, and rare stones. This classification is based on the predominant chemical composition and gross appearance of the stone(4).

Gallstones are a prevalent condition in the general population, more than 75% are asymptomatic. Asymptomatic gallstones are at a lower risk of symptom development and about 10-20% usually develop to symptomatic within 5 and 20 years of diagnosis respectively, hence the symptomatic gallstones' average development risk is 2.0 – 2.6% per year(5). It is prudent therefore to clearly define exactly the signs and symptoms which are peculiar to the gallstone disease(6). 77% of the pain experienced in patients with gallstone disease occur in the evenings or at night and distributed in the whole of the right upper quadrant which is experienced more in women than in men(6). In a large cohort Scandinavian study, uncomplicated gallstone disease presented with occasional abdominal and biliary pain, in the setting of complications, the stones were mostly associated with cholecystitis and common bile duct stones(7).Gallstone related pain has a particular pattern of presentation in many of the patients; in the Italian MICOL study, the following salient features had a considerable association to gallstones: no heartburn presence combined with right hypochondrium or epigastric pain with pain radiating to the shoulders. Pain in the upper abdomen was understood to be the most common symptom(5). The symptomatic gallstones diagnosis is based mainly on the history of a right upper quadrant and epigastric pains and the incidence of gallstones which in most cases is confirmed radiologically but can imitate that of numerous other disorders due to its location. This is referred to as non-specific. On some occasions, there is disagreement concerning whether indigestion symptoms are as a result or provoked by gallstones(6).

Three conditions must be present to cause the formation of gallstones, these are bile supersaturation to accelerate cholesterol crystal precipitation. The other conditions are nucleation and hypomotility- this means cholesterol crystals must remain in the gallbladder long enough to form into stones(8). Crystal growth to cause gallstones formation is as a result gallbladder m3ucin hypersecretion and formation of gel with unfinished gall bladder removal. Indication for disparities in gall stone occurrence rates among diverse geographical and populations based on diversity, family, and other studies support a genetic susceptibility strongly, to cholesterol gallstones formation in humans(4,8). There are multiple risk factors associated with gallstone disease which are shown in table 1.1.

These are classified as either modifiable or non-modifiable risk factors(9). Risk factors that are Non-modifiable involve female gender, ethnicity, family history, genetic predisposition, and increasing age. Modifiable risk factors include metabolic syndrome, sedentary lifestyle, rapid weight loss, pregnancy, high fat diet, cirrhosis, and Crohn's disease.

There is a significant correlation between gallstones and nephrolithiasis. Both renal stone disease and gallstone disease have been related to several diseases variety such as insulin resistance diabetes, metabolic dyslipidemia, syndrome, hypertension, obesity, and gout(9,10). In recent Atherosclerosis Risk in Communities (ARIC) study, individuals having gallstones history were 54% likely to equally report a nephrolithiasis history after adjusting for body size, age, gender, and other factors(11).

Table 1: Risk factors for developing gallstones(adapted from Stinton et al)(9).

Non-modifiable	**risk factors** **Modifiable risk factors**
Family history	Metabolic syndrome (obesity, dyslipidemia, Diabetes Mellitus)
Genetic predisposition	Sedentary lifestyle
Female gender	Rapid weight loss
Ethnicity	Pregnancy
Increasing age	High-fat diet
	Cirrhosis
	Crohn’s disease

Ethnic background plays an important part in gallstone disease prevalence and the type of stone that forms(9,12). Cholesterol gallstones are more prevalent in the western world developed countries; In Asia bile ducts brown pigment is the most prevalent. Cholelithiasis cases are highly reported in North American Indians with the affliction of 64.1% for women and 29.5% for men(9). Sub-Saharan Black Africans record the lowest prevalence (<5%)(13). Obesity is a familiar gallstones risk factor. The increased risk magnitude and the incidence rate of symptomatic gallstones, however, have not been quantified well, majorly among the highest risk most obese people. Women embarking on programs of rapid weight loss with diets of very low calories are relatively at a higher risk of lithogenesis(14). . The gallstone formation and diabetes mellitus association are regularly confounded by co-factors such as BMI, age, and a gallstone disease family history(15). Furthermore, cholesterol gallstone formation has no clear biological basis. Instead, abdominal obesity, diabetes, and gallstone appear to be related through metabolic syndrome(16). High estrogen levels in pregnancy lead to more cholesterol secretion and formation of supersaturated bile. Increased progesterone levels decrease gallbladder motility which results in increased gallbladder volume and bile stasis. All these changes increase gallstone formation. Increased parity probably increases the risk of GS by repeatedly exposing a woman to the above-mentioned physiological changes(17,18).

The outcome of this study will add significant data in regards to the pattern of presentation, current management and complications in patients being managed for gallstone disease at the Kenyatta National Hospital. Extrapolation of this data will help Kenyatta National Hospital and other major facilities in drafting protocols that aid in the management plans and devising ways of reducing the pre-operative and post-operative complications of gallstone disease.

2.0: LITERATURE REVIEW

Gallstone disease has a worldwide prevalence. However, its occurrence (19)(Sun, Tang, & Jiang, 2009)has a regional variation(22). The occurrence of gallstone disease in western countries has been reported in the ranges of 7.9% in men and 16.6% in women on approximate. It varies from 3% to 15% approximately in Asia, in Africans, it is almost absent (less than 5%) (13) and in China, it varies from 4.21% to 11%(19). The gallstone disease occurrence is equally large in some ethnic groups, e.g. in Pima Indian men and women it is 73%; 29.5% of American Indian men and 64.1% of American Indian women(20,21). South America Indians has an equal high occurrence of gallbladder disease. In Chile, the distinctive Mapuche Indians reveal more incidence of gallbladder disease; 49.4% and 12.6% in women and men respectively(>60% women in their fifties)(22). In the perception of medical economic, the major reason for hospitalization is gallstone disease and forms a huge burden in the US and Western countries(19).

A statistics based on population, relying on an all-inclusive survey in the US indicates that 262,411 hospitalizations happened in 2000 for cholecystitis, though there was a predictable 778,632 outpatient visits(16). Luckily, cholecystitis has comparatively low mortality at 0.6%. The rate of admission and operation in hospitals for cholelithiasis has increased in developed countries since 1950(16).

Gallstone prevalence in Europe is comparable to that in the USA with the mean European prevalence at 18.5% (23). Gallstone disease prevalence and incidence accurate data are not available for every country in Europe; from Italy and Scandinavia, there originate most studies. The gallstone disease median prevalence varies from 5.9% to 21.9%(24,25). The lowest prevalence of 5.9% was reported in Italy while the highest of 21.9% was recorded in a Norwegian study that sampled a total of 2464 individuals between the ages of 20 and 70 years(24,26). In a population study on the occurrence of gallstone disease in Sirmione an Italian town, examined by ultrasonography, the prevalence was 6.7% and 14.6% in men and women respectively ranging 18 to 65 years in age with the general frequency of 11% (27). In a different study in Italy assessing the gallstone disease incidence and risk factors. The MICOL project cross-sectional study based on a population that started in 1985 and protracted to 1988 and intended to acquire the distribution of gallstone disease overview in Italy rendering to

different regions and ages(28). 9611 patients were enrolled by six centers throughout Italy(5477 and 4134 for males and females respectively aged 30-79 years), with 9517 involved into the analysis: 424 patients (4.4%) had G.D and 61 (0.6%) had cholecystectomies resulting to a cumulative occurrence of 0.67% in a year (0.66% in males, 0.81% in females)(29). In a study to estimate the prevalence of GD in an adult living population in the city of Stockholm in Sweden, the overall prevalence of gallstone disease was 15%. This was done in age groups between 40 to 60 years in both sexes(25).

In South American studies, Peru showed an overall prevalence of 14.3% with females having a higher preponderance of 16.0% and a male prevalence of 10.7%(30). In a study on cholelithiasis in Buenos Aires in Argentina, the prevalence of gallstones was found to be 21.9%. A significant relation was realized amid cholelithiasis and body mass index, age, family history, and female gender (31). In another study to assess gallstone disease prevalence in Argentina, a random sample of the Rosario city population was studied. The study showed an overall prevalence of 20.5% (23.8% in women and 15.5% in men)(32).

In an Asian study in Taiwan, the incidence of gallstone disease in a prospective cross-sectional study on vegetarian Taiwanese population was found to be 8.2%(33), though previous studies in Taiwan had shown an overall prevalence of 4.3%- 16.6%(34). A study in China's Xinjiang region on the prevalence and gallstones disease risk factors among Uighur and population. The prevalence rate was significantly higher in the Uighur population with an overall rate of 11.1-15.5%(35). The general gallstones disease incidence in Okinawa Japan was 3.2%. prevalence was found to be increasing with age at 11.4% at 70 years of age and higher in the female population at 4% and male at 2.5%(36).

In another Japanese study gallbladder stones occur concurrently in 67% of CBD stones, though, the CBD stones prevalence in gallbladder stones is 15%(37). Primary hepatolithiasis and choledocholithiasis seem to be much common in countries of East Asian than in Western societies, where, secondary to gallbladder stones traversing through the cystic duct, are the bile duct stones(37).

A cohort study over 15 years duration about gallstone disease in a rural Bangladeshi community was 5.4%(38). this was higher than rates in some other Asian countries like

Japan(36) and Thailand. In India, a community-based study in the city of Chandigarh on the epidemiology of gallstone disease has shown a prevalence rate of 3.1% with a higher female rate of 4.2% and male 1.88%. gallstones were diagnosed with 64.9% of the symptomatic patient(39). A recent study in Saudi Arabia on the prevalence and R.F for G.D has indicated a prevalence rate of 8.6%(40). This prevalence was lower than another study conducted in the same country where the overall prevalence of gallstones was 11.7%.

In the African context, cholelithiasis and cholecystitis were thought to be rare in Africa. This is in sharp contrast to the high gallstone frequency in western Europe and the US(2). A five-year prospective study at the University of Ilorin teaching hospital, Nigeria from 1997-2001. The number of cholecystectomies for cholelithiasis and cholecystitis was rising every year throughout the study. The increase in gallbladder disease is probably as a result of changing dietary habits. Another study at the University of Ibadan on Ultrasound prevalence of gallstone disease in diabetic patients had shown a prevalence of 17.5%(41). The study has concluded that there exists a strong correlation between obesity and GSD. So, increasing age in the presence of diabetes certainly doubles the incidence and went ahead to recommend an ultrasound scan of the biliary system as part of baseline investigative modalities in diabetics.

In Ghana, a study on the incidence of gallstone disease in people that are undertaking abdominal ultrasound at the Komfo Anokye Teaching Hospital, Kumasi, Ghana between 2009 to 2012 was 5.9%. Increasing sex, age, and family history considerably affect the occurrence(42)

A study of gallstone disease among black South Africans has suggested that gallstone is rare in Africa(43). The review was done in Baragwanath Hospital and the University of Witwatersrand over a three-year duration. A total of 118 cholecystectomies were done from 1983-1985 with an overall mortality of 10%. However, the mortality rate for the under 60-year-old group was 3.2% compared with 21% for over 60 years old. The above reports suggest that gallstone disease is rare in Africa. It must be noted that the incidence of cholecystectomy is only a crude indication of gallstone prevalence since the majority of stones are silent.

An epidemiological study in Gondar University in Ethiopia, the prevalence of cholelithiasis was 5.2%. with male to female ratio of 2:1, 6.8% for females, and 3.6% for males. In this study, there was an increasing prevalence with increasing age(44).

A study of the Masai population in East Africa found that although the kilojoule content of their diet was composed of 65% fat, atherosclerotic and gallstone disease was very rare(21).

Similar studies done on the Masai in Kenya by Mann et al had concluded that the likelihood that inhabitation of cholesterol endogenous synthesis with large milk intake and hence reduce Cholesterol serum levels. This hypocholesteremia and trend for further fall in level with more intake of milk can be ascribed to a synthesis suppression triggered by inhibitor present in milk somewhat by the surfactant presence or absence in the diet(45).

In Kenya, although there is a significant body of knowledge about gallbladder disease, a lot of information about the pattern of presentations, management and complications are yet to be known. A retrospective review of laparoscopic cholecystectomy at the KNH and three selected private hospitals from January 2001 to December 2010 by Jani PG and Gill H showed a female preponderance 77.5% and 40% of patients less than 40years of age, with 77.5% of the patients operated undergoing laparoscopic cholecystectomy and 24.15% underwent open cholecystectomy. This is by far in contrast to the Western studies where Laparoscopic cholecystectomy is done for much elderly population(46). A retrospective study by Awason N. Charles recorded a total of 53 cases. This accounted for 0.6% of all general and urological operation in the duration between 1982 to 1986 and concluded gallstone to be uncommon in the Kenyan society(47). Koech David Kimutai had shown the prevalence to be 18.02 per year and recurrent episodes of right upper quadrant pain as the commonest mode of presentation (93.4%)(48). There is a significant knowledge gap in the prevalence and pattern of presentation of gallbladder disease in Africa and particularly in Kenya. There is a general increase in the risk factors such as obesity, sedentary lifestyle, and western diets adopted by Kenyans changes the narrative that gallstone disease is still a rare disease in Africa(2).

The majority of the Individuals having gallbladder stones do not exhibit symptoms relating to the stones. In prior studies, there was a try to relate abdominal symptoms to the occurrence of gallstones. About two-thirds of stones were found to be asymptomatic(49,50). A small

percentage of up to 4% develop symptoms annually and up to 10% become symptomatic after 5 years of follow up (49).

In males with gallstone disease, a sole predictor of biliary pain was age increase (major pain in the right hypochondrium). Whereas, in females, body mass index had also an association with pain (majorly in the epigastrium). No relation was revealed between comorbidities and GD(29). Gallstone causes pain in many ways. Intermittent obstruction of the cystic duct may cause biliary pain which is the commonest presentation of GS(51). It typically is either epigastric or right upper quadrant pain that can be related to nausea and vomiting. This may last for some hours or may persist for more than 24 hours(51).

Inflammation of the gallbladder because of infection arising from an obstructed cystic duct is referred to as acute cholecystitis. In this condition, patients may have a fever in addition to biliary pain. Cholecystitis is often preceded by one or more prior episodes of biliary pain which may be confirmed on history taking(51).

The main diagnostic modality for diagnosing gallstones is an abdominal ultrasound scan, this is relatively cheap, accurate, and readily available. It has a sensitivity of more than 95%for stones larger than 2mm and specificity of more than 95% in the case stones yield acoustic shadows(52). A study on the utility of ultrasonography and Computed tomography for the examination of the acute biliary disease has warranted ultrasound as the initial imaging study for assessment in patients alleged of having G.D and acute cholecystitis. Ultrasound was found to be highly sensitive and accurate for the diagnosis of cholelithiasis and acute cholecystitis(53). The study does not recommend the utility of CT scan as the preliminary study for evaluation of suspected case of Gallstone Disease, Rather CT scan may be suitably utilized for evaluation in patients having a wider differential diagnosis, a known history of a chronic biliary disease or with puzzling clinical signs and symptoms(53). In another study on evidence-based present practices of surgery in calculous G.D, ultrasound was favored over CT scan in the diagnosis of alleged G.D as greater than 60% of gallstones are not radiopaque(54). similarly, a CT scan is less sensitive in the diagnosis of calculous cholecystitis. More than 50% of patients with clinical signs of pancreatitis or common bile duct stones do not have gallstones detected on CT scan; subsequent ultrasound identifies gallstones in almost 90% of this patient (54).

However, CT scan plays a pivotal role in conditions that ultrasound findings are equivocal. It is also very valuable in the examination of alleged complications of ACP emphysematous cholecystitis and gallbladder perforation and gallstone ileus(55).

Nevertheless, ultrasonography may miss bile duct stones in up to 50% of the cases. These are with alike sensitivity and specificity diagnosed by magnetic resonance cholangiopancreatography(MRCP), and by endoscopic ultrasound(EUS)(51). MRCP is rapid and non-invasive and shows immense biliary tract anatomical detail. It is therefore useful where choledocholithiasis is suspected(51,56).

In a retrospective study in Turku University Central Hospital in Finland to examine the cause of extrahepatic cholestasis, involving dilated bile ducts and triggered by bile duct stone or a stricture, malignancy-related structure. Plasma bilirubin established to be the best liver function test in malignant bile duct stricture patient differentiation from those having bile duct stones. Serum bilirubin was found to be significantly higher in malignant stricture than those with stones in comparison to alkaline phosphatase, alanine aminotransferase, and gamma-glutamyl transferase(57).

In terms of tumor markers, serum carbohydrate antigen 19-9 (CA19-9) is majorly utilized for the diagnosis and prognostic pancreatobiliary neoplasms evaluation. A CA19-9 level of >100 U/mL most likely shows the presence of the malignant disease, majorly pancreatic cancer early stages. The pancreatic cancer specificity of CA19- 9 level >1,000 U/mL was 99%. Though, a high CA19-9 level of >1,000 U/mL was often found in some benign diseases, like common bile duct stones, acute pancreatitis, diabetes, acute cholangitis, and liver cirrhosis(58)

Choledocholithiasis and cholangitis seem to negatively affect the specificity of CA 19-9 in the evaluation of suspected pancreatic cancer and should always consider benign causes in the differential diagnosis even in the case of extremely high levels of CA 19-9 as simply managing these benign causes can result in a dramatic response in a relatively short period (59)

Asymptomatic GS does not need any intervention except in some unique patients at risk of complications or malignancy such as those with porcelain gallbladder, immunosuppressed patients, elderly, and diabetics.

Non-surgical treatment of gallstones involves bile acid utilization for oral dissolution. It has led to the dissolution of gallstone successfully in a population of patients extremely limited. Approximately 25% of these patients recur and are only indicated for unfit patients or patients that are not willing to undergo surgery(60).

The symptomatic gallstone disease choice of treatment is laparoscopic cholecystectomy(51). Laparoscopic cholecystectomy (LC) is less invasive, has a shorter hospital, and shorter time frame until return to normal activities than is associated with open cholecystectomy (OC) which is associated with more hospital stay. In addition to that, laparoscopic cholecystectomy is likely to be associated with less morbidity, and a shortened convalescence period(61).

The other significant advantages of laparoscopic cholecystectomy over open cholecystectomy include less postoperative pain, better cosmetic outcomes, earlier return of bowel function, earlier return to full activity, and reduced overall cost(46). However, laparoscopic cholecystectomy did not have a considerable difference from open cholecystectomy concerning mortality, operative time, and some complications like bile duct injuries(62).

The commonest complications of gallstone disease include acute cholecystitis, acute obstructive cholangitis secondary to choledocholithiasis, and gallstone pancreatitis. Others include biliary fistula, and gallstone ileus(63).

The common gallstone associated complications which include acute cholecystitis and choledocholithiasis involve treating patients medically with intravenous fluids, antibiotics, and analgesics for acute cholecystitis until the gallbladder inflammation is fixed and then elective cholecystectomy is planned. critically ill patients with critical cholecystitis and risk of other complications should be treated with intravenous fluids, antibiotics, and analgesics. percutaneous cholecystostomy needs to be considered in the case it fails(64).

For choledocholithiasis, treatment involves removal and clearance of gallbladder and retained gallbladder stones. Multicenter results, prospective, single-stage, and random comparison of the trials of laparoscopic cholecystectomy and extraction of laparoscopic stone with preoperative endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic cholecystectomy confirmed procedures similarly were effective common bile duct stones clearance. Nevertheless, the single-stage procedure has been gaining ground of late

owing to the reduced mean hospital stay, fewer risks of anesthesia(65). The single stage comprises laparoscopic common duct exploration (LCBDE) and laparoscopic cholecystectomy carried out at the same sitting. This single-stage procedure was also advocated by the British Society of Gastroenterologist and encouraged surgeons to train in LCBDE(66).

The operative modality for gallstone disease is cholecystectomy which can either be open cholecystectomy or laparoscopic cholecystectomy. Both open and laparoscopic cholecystectomy is highly safe, and efficient procedures for the treatment of symptomatic gallstones.

Complications following open cholecystectomy are mainly limited to elderly patients with co-morbid conditions and complicated biliary tract disease(67). Operative cholangiography has a protective effect on complications of cholecystectomy. In comparison to open cholecystectomy, laparoscopic cholecystectomy carries a nearly two times higher risk of major bile duct injuries, vascular and bowel complications(68).

Open cholecystectomy has been a safe, effective, and standardized treatment for patients with symptomatic cholelithiasis before the advent of laparoscopic cholecystectomy which has become the gold standard therapy for symptomatic gallstones(67). Most complications of open cholecystectomy are non-biliary and not related specifically to the procedure with most of the adverse outcomes being limited to elderly patients with co-morbid conditions and complicated biliary disease. Fever and acute urinary tract infections are the most frequent complications. Other complications that were noted included include wound dehiscence and surgical site infections(67).

Laparoscopic cholecystectomy is accepted as the gold standard procedure in the treatment of chronic symptomatic calculous cholecystitis. Studies have shown it to be a safe and effective procedure, especially when performed by an experienced surgeon. Most documented studies are showing its complication rates to be less than 3%. The common complications associated with the procedure include bile duct injury, bile leak, retained CBD stone, gallbladder perforation, injury to the hollow organs, intraoperative and postoperative bleeding, and wound infection(69).

3.0: PROBLEM STATEMENT

Gallstone disease is a worldwide condition which remains to be one of the most common health problems with a significant economic burden. The disease is more common in the western world(44). The prevalence has been on the rise in the African continent due to changes in lifestyle like dietary changes, sedentary lifestyle, and in some instances family history. It is one of the conditions that result in hospital admissions leading to surgical intervention. Surgical management varies from simple cholecystectomy or cholecystectomy with common bile duct exploration. The gold standard of surgical care is laparoscopic cholecystectomy which has become the standard of care in the Kenyatta National hospital and many other facilities in the country(46). There are many complications associated with open and laparoscopic cholecystectomy which are investigated in this particular study. There are no clear-cut studies carried out in our set up on the pattern of presentation, management options available for gallstone disease, and the complications expected which could be categorized as preoperative and postoperative(67).

4.0: CONCEPTUAL FRAMEWORK

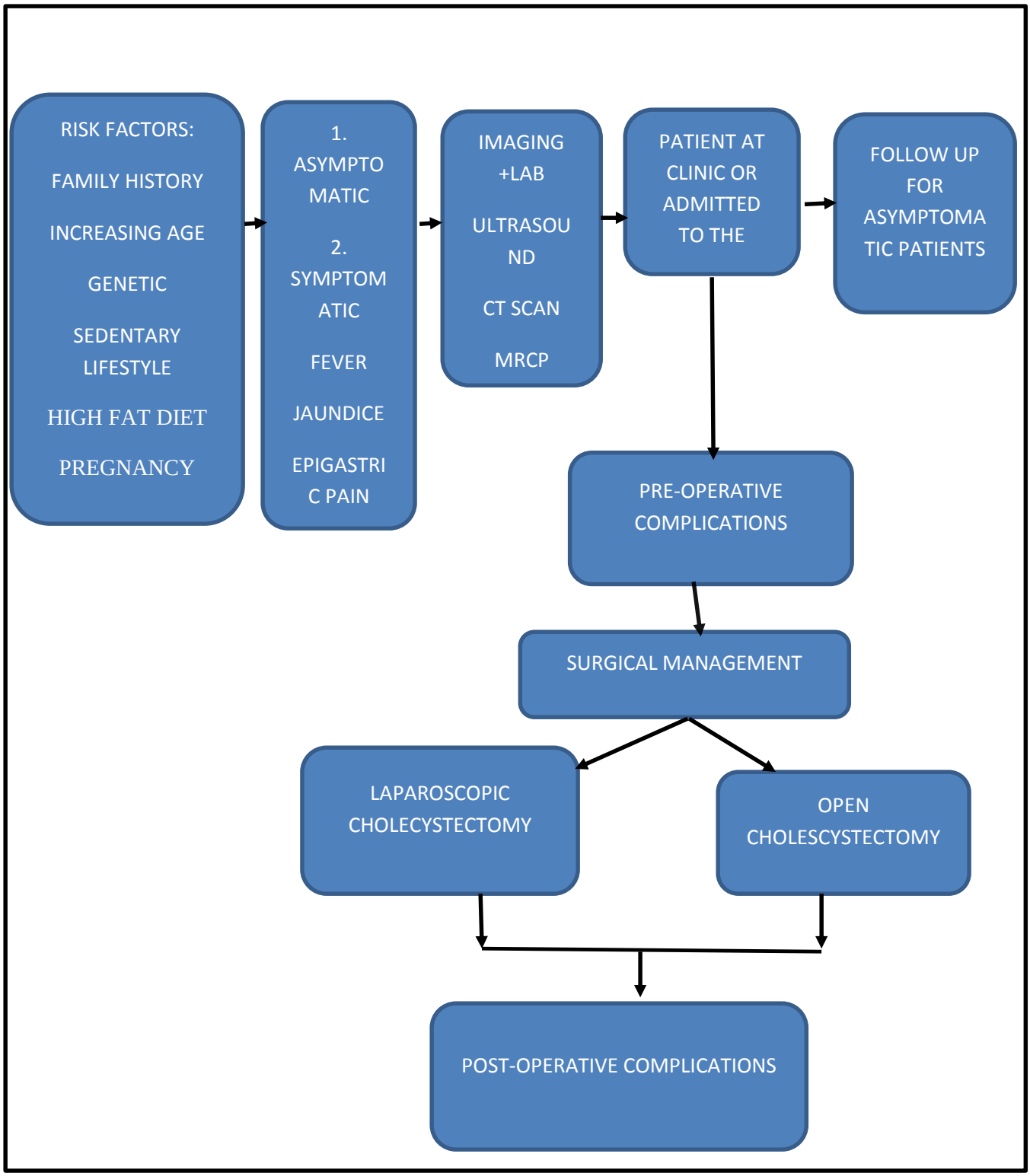

Figure 1: Conceptual Framework

5.0: STUDY JUSTIFICATION

Gallstone disease was previously considered rare in sub-Saharan Africa. In recent times there was a rise in the prevalence rate due to changes in lifestyle habits like dietary modifications, physical inactivity, and increased incidences of obesity and hyperlipidemia(70). The burden of the cases of gallstone disease at the Kenyatta National Hospital has been increasing by the years since it is the biggest referral facility in the country. There is a paucity of well-documented data on the pattern of presentation, management options, and complications of gallstone disease at the facility. The utility of this study is to design clear guidelines in the mode of presentations, management protocols which are either non-surgical and surgical and complications associated with gallstones.

6.0: STUDY QUESTION

What is the current pattern of presentation, management, and complications in adult patients at the Kenyatta National Hospital?

7.0: STUDY OBJECTIVES

7.1: Broad objectives

To determine the pattern of presentation, current management, and complications in patients aged more than 13 years with gallstone disease as seen at the KNH.

7.2: Specific objectives

1. To determine the pattern of presentation of gallstone disease in KNH
2. To determine the management options used for gallstone at KNH
3. To determine the complications of gallstone disease which are preoperative and postoperative.

8.0: MATERIALS AND METHODS

8.1: STUDY DESIGN

This was a prospective descriptive study.

8.2: STUDY SETTING

The study was conducted at the KNH surgical outpatient clinic, surgical and medical wards, endoscopy units, and KNH private wing. KNH is at the apex of the public health care system in Kenya with a capacity of 2000 beds. It is the largest referral hospital in the region and has the highest number of hepatobiliary surgeons in the country making most patients with gallstone seek treatment there. The standard of care for the patients with gallstone disease is laparoscopic cholecystectomy which is a specialized procedure that is not performed in most centers in the country.

8.3: STUDY POPULATION

This included all adults (males and females aged 13 years and above) undergoing treatment for gallstone disease at the KNH Surgical outpatient clinics, accident, and emergency or admitted at the general surgical or medical wards.

8.4: SAMPLE SIZE DETERMINATION AND FORMULAR

Sample size was be calculated using the following formula(71,72)

$$\boldsymbol{n = \frac{Z^2 P(1-P)}{d^2}}$$

Where;

n= sample size with finite population correction

Z = Z statistic for a level of confidence, 95%

P=expected proportion= 5.2%(44)

d=precision, set at 5%

Substituting in our formula gives a sample size of 76 participants.

8.5: SAMPLING PROCEDURE

The principal researcher and the two research assistants recruited patients into the study from the accident and emergency, the surgical outpatient clinics, medical and surgical wards. In-

patient follow ups were conducted until the date of discharge or until 30 days elapsed or whichever came first.

8.6: RECRUITMENT AND CONSENTING PROCEDURES

8.6.1: INCLUSION CRITERIA

1. All male and female patients (13years or more) who were confirmed cases of gallstone disease by ultrasound undergoing treatment at the surgical outpatient clinic or admitted at the general surgical wards at the KNH for the same condition were included in the study.
2. All patients with ultrasound, CT Scan or MRCP that confirmed the diagnosis of gallstone disease were recruited into the study.

   NB) Patients were required to come with laboratory results either in the first visit or in the subsequent visits.

8.6.2: EXCLUSION CRITERIA

1. Patients under the age of 13 years
2. Patients who did not consent for the study.
3. Patients suspected of gallstone disease not confirmed by ultrasound.

8.7: STUDY VARIABLES

The study variables that were documented in this study included:

1. Independent variables- age, sex, BMI, serum lipid profile, alkaline phosphatase, and total bilirubin
2. Dependent variables- presence or absence of gallstone, previous history of cholecystectomy, diabetics, pregnancy, and ethnic background or region of origin.

8.9: DATA COLLECTION PROCEDURE

A structured self-administered questionnaire, specifically designed for this study was used. It consisted of both open and closed-ended questions. A research assistant was recruited into the study for data collection. The research assistant is a resident in the department of general surgery who is based at the Kenyatta National Hospital. Data collection was done from the first visit and documented. The complications of gallstone disease were assessed from the first visit to the clinic or admission for patients pre-operatively. For those patients who underwent

cholecystectomy either laparoscopically or open technique were followed up for 30 days since there are complications of cholecystectomy that have delayed onset.

8.10: DATA ANALYSIS AND PRESENTATION

Filled data sheets were stored in a secured locker only accessible to the principal researcher. Filled and completed data sheets were entered into a password coded Microsoft excel/spreadsheets and thereafter the data was exported to Statistical Package for Social Sciences version 23.0 that were used for the analysis. Backup of data in the password coded software were done daily. Data was presented in tables, charts, and graphs. Categorical data was also presented as frequencies and percentages while continuous variables such as ages was summarized using mean and median.

8.11: ETHICAL CONSIDERATIONS

Ethical approval was obtained from the KNH Ethics and Research Committee before carrying out the study. Permission was sort from the KNH administration before recruiting patients into the study. Patients were recruited into the study after obtaining voluntary verbal and written informed consent. The benefits of participating in the study was explained to the patients and thereafter the decision to participate was made voluntarily to them. Declining to participate was not going to disadvantage them in any way. The participants and the administration were thus reassured that mitigation measures against the spread of COVID-19 were undertaken during the duration of data collection so that the patients and staff are safe from the Novel coronavirus disease infection as follows:

- All patients had their temperatures taken before getting into the clinic or the ward.
- All patients had face masks on during visits to the clinic and all consultations and interview.
- Social distancing was maintained at all times during the study.
- Hand sanitizers were placed in the waiting bay and in the examination room to ensure patients sanitize their hands.
- Both the researcher and the assistant who are resident doctors working in the general surgery department wore surgical masks throughout the exercise
- The researcher and the assistant ensured hand sanitization was done before and after the examination of patients.

9.0: RESULTS

The results of the characteristics of the patients indicate that 67 (82.7%) were female, while the males were 14 (17.3%). Female to male ratio was 4.78:1. The results are as shown on Table 1.0.

Characteristics of the Patients

Table 1.0: Sex distribution of patients with gallstone disease

Gender	Frequency (n=81)	Percentage (%)
Male	14	17.3
Female	67	82.7

Table 2.0: Age distribution of patients with gallstones

Age	Frequency (n=81)	Percentage (%)
13-20	1	1.2
21-30	8	9.9
31-40	17	21.0
41-50	20	24.7
51-60	20	24.7
61-70	8	9.9
Above 70	7	8.6

Table 2 shows age distribution of the patients with gallstone disease as ranging from 13-78 years. Majority of patients were aged between 31-60 years (70.3%) while gallstone was less common in age groups below 30 years (11.1%) and above the age of 60 years (18.6%). The youngest patient was age 13 years while the oldest was 78years.

Table 3.0: Body mass index of patients with gallstones

BMI	Frequency (n=81)	Percentage (%)
<18.5	1	1.2
18.5-24.9	32	39.5
25.0-29.9	19	23.5
30.0-34.9	18	22.2
>=35	11	13.6

39.5% of patients with gallstone disease had a normal body mass index while 23.5% were overweight and 22.2% had grade 1 obesity and 13.6% had grade 2 obesity and morbid obesity as shown on table 3 above.

Table 4.0: Geographical distribution of patients with gallstones by region

Residence		
Nairobi	59	72.8
Central	15	18.5
Eastern	4	4.9
Rift valley	2	2.5
Western	1	1.2

Majority of patients with gallstone seen at Kenyatta national hospital resided in Nairobi city (72.8%), while 18.5% are residing in the central region, 4.9% from eastern, 2.5% from the rift valley and western 1.2%.

Table 5.0: Geographical distribution of patients with gallstones by county

	Frequency (n=81)	Percentage (%)
Baringo	1	1.2
Bomet	1	1.2
Bungoma	2	2.5
Homabay	1	1.2
Kajiado	2	2.5
Kakamega	3	3.7
Kericho	1	1.2
Kiambu	14	17.3
Kirinyaga	4	4.9
Kisii	1	1.2
Kisumu	2	2.5
Kitui	2	2.5
Laikipia	1	1.2
Machakos	12	14.8
Marsabit	1	1.2
Meru	1	1.2
Murang'a	7	8.6
Nairobi	11	13.6
Nakuru	1	1.2
Nyandarua	1	1.2
Nyeri	9	11.1
Siaya	1	1.2
Taita Taveta	2	2.5

In terms of regional distribution by county, majority of the patients came from Kiambu county (17.3%), followed by Machakos (14.8%), Nairobi (13.6%), Nyeri (11.1%) while the least numbers were recorded from the counties of Siaya, Meru, Laikipia, Bomet, Baringo, Nakuru and Marsabit at 1.2% as shown in Table 5.

Familial history of gallstones was present in only 6 (7.4%) of the patients, while majority had no family history of gallstones as shown on table 6.0.

In terms of comorbidities, 12 (14.8%) patients had hypertension, 11 (13.6%) had hypertension co-existing with diabetes, and 7 (8.6%) had diabetes only. Majority of the patients with gallstones had no co-existence with diabetes or hypertension 63% as shown in table 7.0.

Table 6.0: Family history of gallstones

Family history of gall stones	Frequency (n=81)	Percentage
Yes	6	7.4
No	75	92.6

Table 7.0: Presence of comorbidity

Comorbidity	Frequency(n=81)	Percentage
Diabetes	7	8.6
Diabetes/Hypertension	11	13.6
Hypertension	12	14.8
None	51	63.0

On the signs, 70 (65.4%) of all the patients had tenderness in the right upper quadrant, which was followed by 24 (22.4%) of the patients having a positive Murphy's sign, and only 2 (1.9%) had a palpable gall bladder. Around 11(10.3%) of the patients had no demonstratable signs of gallstone disease.

The symptom most exhibited was pain in the RUQ with 67 (82.7%) of the patients, followed by pain in the epigastrium with 64 (79.0%) patients, 24 (29.6%) patients had presented with nausea and vomiting, 6 (7.4%) patients with fever, and 9 (11.1%) patients who were asymptomatic. The results are as shown on Table 8.

Table 8.0: Results

Signs		
Tenderness in RUQ	70	65.4
Murphy's sign positive	24	22.4
Palpable gall bladder	2	1.9
None	11	10.3
Symptoms		
Asymptomatic	9	11.1
Pain in the epigastrium	64	79.0
Pain in the RUQ	67	82.7
Nausea and vomiting	24	29.6
Fever	6	7.4

Majority of the patients had normal clinical parameters for Bilirubin (54, 66.7%), ALP (51, 63.0%), ALT (56, 69.1%), and for AST (56, 69.1%), but of significance is that majority of the patients had raised GGT (57, 70.4%).

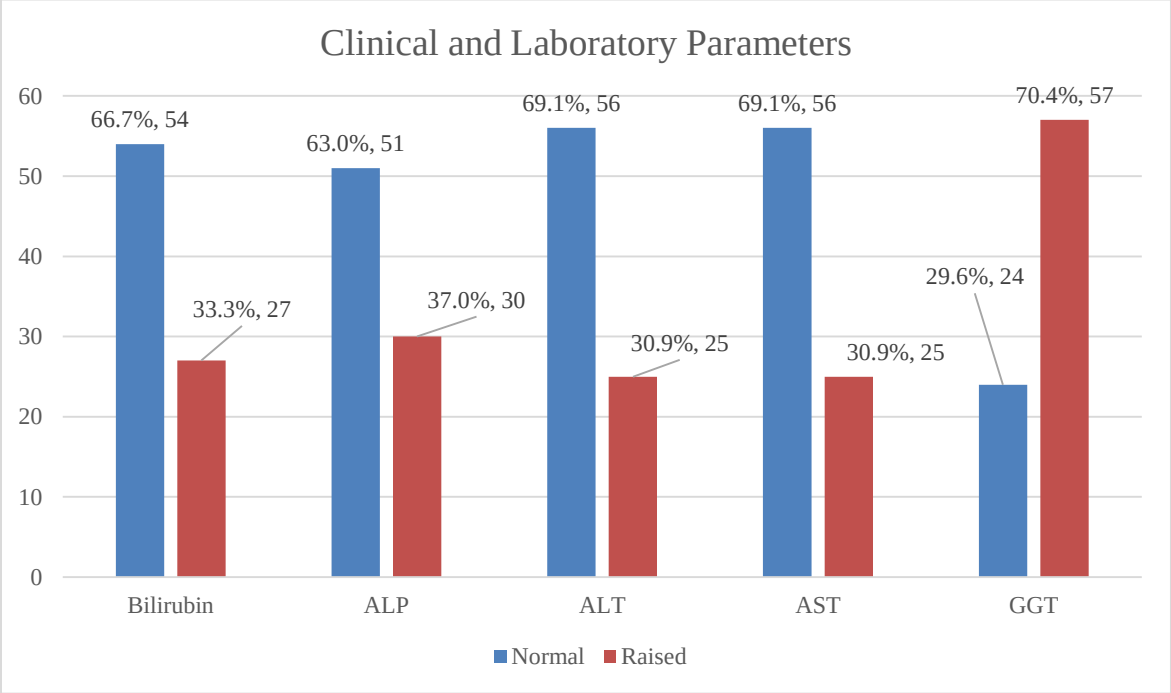

Figure 1: Clinical and Laboratory Parameters

There were 46 (56.8%) of the patients who had Ultrasound, this was followed by 17 (21.0%) who took an ultrasound and CT scan, the patients who did CT scan only were 7(8.6%), MRCP only were 4(4.9%), Ultrasound and MRCP 3(3.7%) The patients who combined Ultrasound, MRCP and CT scan were 2(2.5%) while those who did MRCP, and CT scan were 2(2.5%). This is shown in table 9.

Table 9.0: Imaging Options

	Frequency (n=81)	Percentage
US only	46	56.8
US and CT scan	17	21.0
CT scan only	7	8.6
MRCP only	4	4.9
US and MRCP	3	3.7
US, MRCP and CT scan	2	2.5
CT scan and MRCP	2	2.5

On the imaging findings, 72 (88.9%) of the patients the gall bladder was seen, 50 (61.7%) patients had gallstones seen, and only 2 (2.5%) their gall bladder was not visualized.

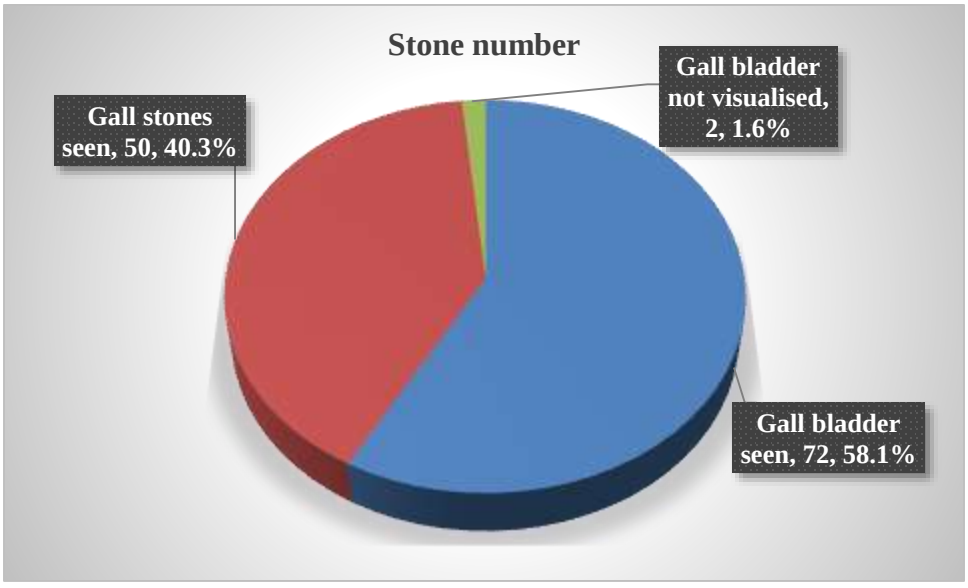

Figure 2.0: Imaging Findings

The findings for the number of stones, the results indicate that 58 (71.6%) had multiple while only 23 (28.4%) had single. This is as shown by Figure 3.0

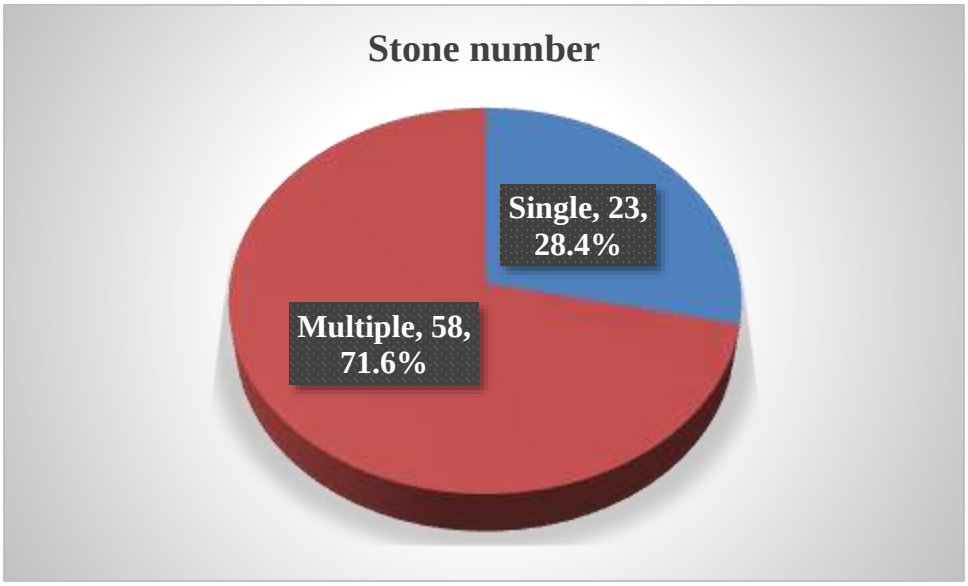

Figure 3.0: Stone number

The findings for the site of the gall stones indicate that 71 (87.7%) were at the gall bladder while 9 (11.1%) were at the biliary tree, and only 1 (1.2%) was at the gall bladder/biliary tree. This is as shown by Figure 4.0

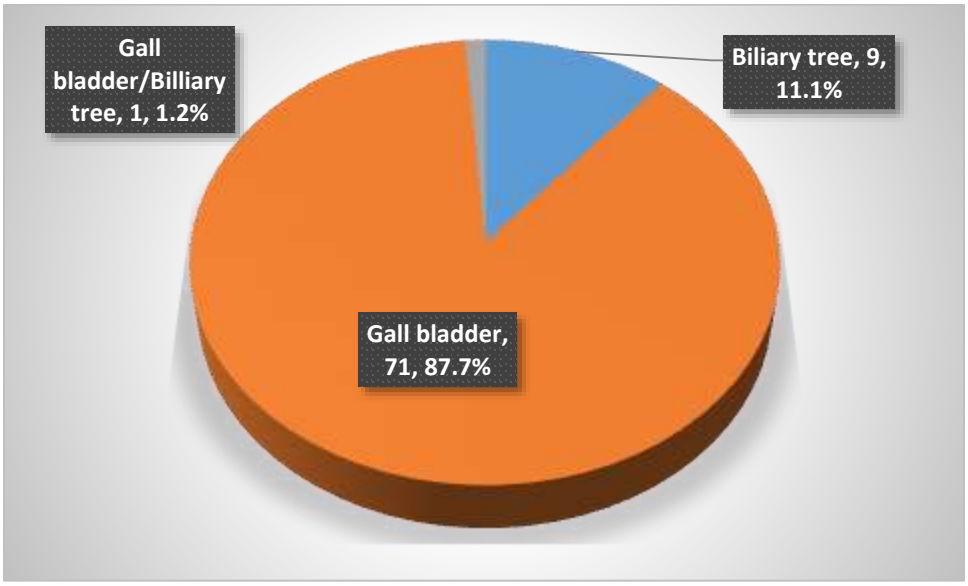

Figure 4.0: Gall stone site

Management options for the patients included surgical with 62 (76.5%), and non-surgical option with 19 (23.5%) patients only. For those who had the surgical option, 58 (93.5%) had a laparoscopic cholecystectomy, while 4 (6.5%) had an open cholecystectomy. The results are as shown on Table 10.0.

Table 10.0: Management of gallstone disease

Management option	**Frequency (n=81)**	**Percentage**
Surgical	62	76.5
Non-surgical	19	23.5
Surgical option, *(n=62)*		
Laparoscopic cholecystectomy	58	93.5
Open cholecystectomy	4	6.5

Table 11.0: Complications

Associated with gall stones		
Cholangitis	3	3.7
Cholecystitis	10	12.3
Choledocholithiasis	18	22.2
Pancreatitis	3	3.7
None	47	58.0
Associated with cholecystectomy		
Biliary leaks	1	1.2
Bleeding	1	1.2
CBD injury	3	3.7
None	76	93.8

Results of the complications indicated that 58% of patients had no complications preoperatively while 42.0% of all the patients had complications associated with gall stones, the most common complication associated with gall stones was Choledocholithiasis (18, 22.2%), this is followed by cholecystitis (10,12.3%), pancreatitis and cholangitis were both reported at 3.7%.

Post-operative complications were minimal since 93.8% of patients had no complications while only 6.2% of all the patients had complications associated with cholecystectomy with 3.7% of the patients reported to have common bile duct injury, while biliary leak and bleeding was reported 1.2% each. This is as shown on Table 11.0.

10.0: DISCUSSION

This was a prospective study on the pattern of presentation, management and complications in patients aged 13 years and above with gallstone disease as seen at the Kenyatta National Hospital. In the study, a total of 81 patients were reviewed with 82.7% of the patients being of female gender. The female to male ratio was 4.78:1, this ratio with significant female preponderance was comparable to two other Kenyan previous studies by Jani(46)et al and Awason Charles(47) studies with female to male ratios of 4:1 and 4.3:1 respectively. Majority of the patients were aged between 31-60 years (70.3%). This was similar to previous studies in Kenya by Jani(46) et al which cumulatively found 80% of the patient to be between 21 to 60 years. A similar study by David Koech(48) found the peak age between 30-60 years to be 70.4%(47,48).

Only 39.5% of the patients sampled had a normal body mass index, 23.5% were overweight, 22.2% had class 1 obesity and 13.6% had class 2 and class 3 obesity. Since majority of the patients in the study had deranged body mass index, this is in concordance with three population screening surveys in Italy, Denmark and the United States that showed a positive association between body mass index and gallstone disease in women(19). However, there was no positive association between body mass index and gallstone disease. A possible reason for this finding may be that body mass index is not a suitable standard of obesity in men.

In terms of geographical distribution, majority of the patients with gallstone disease seen at the KNH resided in the city of Nairobi (72.8). on the basis of the home county, majority of the patients came from Kiambu (17.3%) followed by Machakos with 14.8%. This distribution can be attributed to higher population in Nairobi and its environs where people are likely influenced by western diet with high cholesterol. This pattern was also observed in previous studies by Awason (1988) (47) and Koech (2002)(48).

Family history was only present in 6% of the patients in this study. This was in contrast to a study done in India on the high prevalence of gallstones in the 1st degree relatives of gallstone patients which has shown up to five times increased risk of developing gallstones in relatives of gallstone patients at 37%(73).

Majority of the patients (63%) reviewed in the study had no co-existence with diabetes or hypertension. However,14.8% of the patients had hypertension, while 13.6% had hypertension co-existing with diabetes and 8.6% had diabetes only. Previous population
Studies have shown inconsistent associations of diabetes mellitus with gallstone disease(19). An Italian study conducted in Rome had shown that diabetes was associated with increased risk of gallstone disease in men and women separately while a study of Hispanic Americans found a positive association between diabetes and gallstone disease in women but not in men(19).

The most common symptoms presented by most patients were pain in the right upper quadrant (82.7%) followed by epigastric pain at 79.0% while the most common signs were tenderness in the right upper quadrant (65.4%) followed by positive Murphy's sign (22.4%). This is similar to a study done in Belgium on the burden of gallstone disease in Europe which stated that right upper quadrant pain is the most typical symptom suggesting gallstone disease(26). Around 10.3% of the patients had no demonstratable signs and symptoms of gallstone disease. This picture is not consistent to most studies which demonstrated that more than 70% of gallstones are asymptomatic(49). A higher number of patients evaluated in this study were symptomatic. This findings were consistent with an epidemiological study done in Gondar University Hospital in Ethiopia(44).

All the patients recruited in the study had undergone liver functions test and most of the parameters were normal with bilirubin raised at (33.7%), alkaline phosphatase (37%), alanine aminotransferase and aspartate aminotransferase both at (30.1%). The most notable laboratory picture was significantly elevated gamma-glutamyl transferase which was raised in 70.4% of the patients. This findings were similar to a study in Pakistan on the role of liver function test in symptomatic cholelithiasis(23) which concluded that routine liver function tests in pre-operative assessment of uncomplicated symptomatic cholelithiasis usually comes out normal and it is not a good predictive marker of for the detection of common bile duct calculi.

The most important imaging modality for the diagnosis of gallstone disease in this study was abdominal ultrasound which was done in 83% of the patients with 56% undergoing ultrasound only. This was similar to the findings in the study by Koech David (2002)(48) and Jani(46) et

al. 21% ultrasound and CT scan, 3.7% ultrasound and MRCP and finally 2.5% underwent ultrasound, CT and MRCP. From this investigation we have noted that there is a wide range of imaging options at the Kenyatta National Hospital and most patients come to hospital when there have underwent quite a number of investigations in terms of ultrasound, CT scan, MRCP, ERCP and PTC. Most of the stones were found in the gallbladder (87.7%) and most were multiple stones (71.6%).

In terms of management, most of the patients were managed by surgical options (76.5%) while 23.5% of the patients underwent non-surgical means. Laparoscopic cholecystectomy was the main surgical option available at the Kenyatta National Hospital at 93.5%. this is significant improvement from Koech David(48)study where laparoscopic cholecystectomy was 24.1% of all the cholecystectomies where open was 75.1%. This has indicated a significant shift from open to laparoscopic cholecystectomy at the KNH. This is in concordance with the global trends where laparoscopic cholecystectomy is adopted as the standard of care for symptomatic cholelithiasis as evidenced by Cochrane review of laparoscopic versus open cholecystectomy for patients with cholecystolithiasis(62). This is due to shorter hospital stay and convalescence period in the laparoscopic cholecystectomy.

42% of the patients in the study had pre-operative complications with the commonest being choledocholithiasis (22.2%), followed by cholecystitis (12.3%) and with pancreatitis and cholangitis both at 3.7%. In the post-operative setting, 6.2% of the patients developed complications associated with cholecystectomy with bile duct injury at 3.7%, with biliary leak and bleeding at 1.2%. This is in contrast to Jani (46)study with superficial surgical infection as the commonest complications. In this particular study, there were no cases of SSI, this could be due to low cases of open cholecystectomy.

11.0: CONCLUSIONS

- There is female preponderance for gallstones with 82.7% of the patients being females
- The ratio of female to male was 4.78:1
- Peak incidence was between 31-60years which was 70.3% of the patients
- Majority of the patients had deranged body mass index at 60.5%
- Most of the patients live in heavily populated urban areas like Nairobi and its environs
- This study and other studies had shown an inconsistent association between gallstones and chronic disease like diabetes and hypertension
- The most common clinical manifestations were right upper quadrant and epigastric pains, this was followed by positive Murphy's sign
- Preoperative liver function test in uncomplicated cholelithiasis is usually normal and is not a good predictive for the detection of common bile duct calculi
- The most important modality for diagnosis of gallstone is ultrasound with most stones found in the gallbladder (87.7%).
- Majority of the patient were managed surgically (76.5%) and laparoscopic cholecystectomy was the standard of care (93.5%) at the Kenyatta National Hospital.
- 42% of the patients had preoperative complications with the commonest being choledocholithiasis.
- Majority of the patient who underwent cholecystectomy had no complications with only 6.2% of the patients developing complications associated with the procedure.

12.0: RECOMMENDATIONS

- Further study with a larger sample size is recommended to evaluate the exact prevalence of gallstone disease at the Kenyatta National Hospital and enumerate the risk factors owing to the high number of cases.
- Ultrasound is the gold standard for the diagnosis of gallstone disease. Most patients are over investigated with CT scan and MRCP. MRCP should only be done in suspected gallbladder stones.
- Though laparoscopic cholecystectomy is the standard of care at the Kenyatta National Hospital, many hospitals in the counties still lack this service. Training of more laparoscopic surgeons is recommended.

13.0: STUDY TIMELINES

Table 2: Study Timelines

Activity	January-February	March-May	June – August	September-November	December-January	February
Proposal development	■					
Ethical approval		■				
Data collection			■			
Data analysis				■		
Result writes up					■	
Result presentation						■

14.0: STUDY BUDGET

Table 3: Study Budget

Item	Unit Cost (Ksh)	Units	Total Cost (Ksh)
Statistician consultation fees and research assistants	20, 000		50,000
Research Fee (ERC)	2,000	1	2,000
Printing	20,000	1	20,000
Photocopy and Binding	20000	3	20,000
Flash Drives and Stationery	5000	2	10,000
Communication/ Airtime	1000	2	2,000
Laboratory workup (Liver function tests)	1200	76	91200
Statistician/ Data Analysis	40,000	1	40,000
Internet	50,000		50,000
Miscellaneous	10,000	1	10,000
Total Cost			**295,200**

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16.0: ANNEXES

Annex 1: Consent Form

CONSENT FORM

This informed consent has three sections

I. Information sheet (to share information about the research with you)

II. Certificate of consent (for signatures if you agree to take part)

III. Statement by the researcher

SECTION ONE: INFORMATION SHEET

STUDY TITLE: TO DETERMINE THE PATTERN OF PRESENTATION, CURRENT MANAGEMENT AND COMPLICATIONS IN PATIENTS WITH GALLSTONE DISEASE AS SEEN AT THE KENYATTA NATIONAL HOSPITAL

Principal Investigator: Dr. Abdi Osman Mohamud

Supervisors: Dr. Elly Nyaim Opot and Dr. Kennedy Ondede

Institution: Department of Surgery, School of Medicine, University of Nairobi.

STATEMENT BY INVESTIGATOR:

Introduction:

My name is Dr. Abdi Osman Mohamud, I am a postgraduate student at the University of Nairobi, Department of Surgery. I am carrying out a study to determine the pattern of presentation, current management, and complications in patients as seen at the Kenyatta National Hospital. This will encompass patients seen in the out-patient clinics, accident and emergency department and wards for adult patients.

I am inviting you to participate in this study.

The purpose of this consent form is to enable you to decide whether or not to participate in this exercise. I reiterate that you are free to participate in this study immediately or later upon reflection. You are free to consult any other party with whom you are comfortable regarding your participation.

The study has been approved by the KNH/UoN Ethics and Research Committee and as per procedure has been assigned protocol number viz: _____.

The investigator or assistant investigator will be available to answer any questions that may arise in the course of filling out the consent form and/or thereafter.

If you agree to participate, you will be asked to provide personal information and other details about your condition. All the information that is collected will be kept confidential and no one apart from the investigators will access it. The information packet will be assigned a unique number and your name will not appear anywhere. There is no additional cost for participating in this study.

If you choose to take part in this study, it will be out of your own free will and you will not be denied medical care in case you decline participation. You may withdraw your participation at any time without any consequence.

The participant's involvement in this research will be through an interview, clinical evaluation, and examination of the patient's clinical record. The data collected will be used for research purposes only.

BRIEF DESCRIPTION OF THE STUDY

Gallstone disease is increasingly becoming common in the African population due to changes in lifestyle. The bulk and the burden of the patients seen at the Kenyatta National Hospital is increasing by the years. The study aims to evaluate the pattern of presentation. Treatment modalities and possible complications of gallstones disease. The data will help policymakers in the hospital to plan an elaborate management plan and limit the complications.

PARTICIPATION IN THE STUDY

Participation is voluntary and without coercion. The questionnaire will capture information about the medical condition that the patient presents. These patients are the ones seen in the surgical outpatient clinic or admitted in the surgical wards.

RISKS AND HARMS ASSOCIATED WITH THE STUDY

No risk or harm will come to you by participating in this study. No personal information will be collected and data collected will remain anonymous and will not be traced back to you.

BENEFITS OF PARTICIPATING IN THIS STUDY

The information you provide will help us better understand how the patients coming with gallstones present, the treatment options available to us, and the possible complications associated with the condition.

QUESTIONS AND CHOICES:

If you have any questions, you can contact the primary investigator on the phone number and email address provided on the bottom of this page, you are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of benefits.

SECTION TWO: CERTIFICATE OF CONSENT

PARTICIPANTS STATEMENT:

I have read this form or had the information read to me. I have had my queries addressed in a language that I understand. The risks and benefits of participating in this study have been explained to me. I understand that participation in this study is voluntary and I am free to withdraw at any time.

I agree with my free will and volition and without any coercion to participate in this study.

_____

Signature/thumbprint of the patient

Date_____

Day/Month/ Year

STATEMENT BY THE WITNESS IF THE PARTICIPANT IS ILLITERATE OR INCAPACITATED

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given the consent freely,

_____

Name of Witness

_____

Signature of Witness

Date_____

Day/Month/ Year

SECTION THREE: STATEMENT BY RESEARCHER

I have accurately read out the information sheet to the participant to the best of my ability and made sure of the following:

· That the participant's consent has been given voluntarily and without duress. · That all the information gathered will be treated with confidentiality. That refusal to participate or withdrawal from the study will not in any way compromise the quality of care and treatment given to the patient. That the result of the study might be published to enhance the knowledge of the subject of research. That I have answered all the questions asked by the participant to the best of my knowledge and ability.

_____

Name of the researcher taking consent

_____

Signature of the researcher taking consent

_____

Date (Day/Month/Year)

Who should you contact?

If you have any questions to ask in the course of the research, you may contact any of the following:

1.Principal researcher:

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   MBCHB, MMED SURGERY (UON)
   Department of Surgery, General Surgeon and Hepatobiliary Surgeon, Kenyatta National Hospital.

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4. Secretary, UON/KNH-ERC

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Tel: 020-726300-9

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Annex 2: Swahili Consent form

FOMU YA MAKUBALIANO YA KUSHIRIKI KATIKA UTAFITI

Fomu hii ya makubaliano ina sehemu tatu

I. Ukurasa wa habari (maelezo yanayokuhusu katika utafiti huu) II. Fomu ya makubaliano (ambapo utahitajika kuweka sahihi kuidhinisha ushiriki wako)

III. Ujumbe kutoka kwa mtafiti

SEHEMU YA KWANZA: UKURASA WA HABARI

SWALA LA UTAFITI

Kutambua kiwango cha ugonjwa, mtirirko wa ishara na dalili pamoja na athari tata za ugonjwa wa mawe katika mfuko wa nyongo kwa wagonjwa wanaotibiwa katika hospitali ya taifa kenyatta

UJUMBE KUTOKA KWA MTAFITI

Jina langu ni daktari Abdi Osman Mohamud, ni mwanafunzi wa shahada ya uzamili katika tiba ya upasuaji chuo kikuu cha Nairobi. Ninafanya utafiti kutambua kiwango, mtirirko wa dalili na ishara na athari tata wa ugonjwa wa mawe katika mfuko wa nyongo kwa wagonjwa wanaotibiwa katika hospitali kuu ya kenyatta. Utafiti huu unalenga wagonjwa wanaonwa katika kliniki, idara ya dharura na katika wodi za watu wazima za upasuaji za kenyatta.

Nakualika kushiriki katika tafiti hii.

Lengo kuu la fomu hii ya idhini ni kukuwezesha wewe kuamua kushiriki au kutoshiriki katika zoezi hili. Nasisitiza kuwa una uhuru wa kushiriki katika tafiti hii iwe sasa au hata baada ya kutafakari na pia una uhuru wa kuomba ushauri au kushauriana na mtu mwingine juu ya ushiriki wako katika zoezi hili

Utafiti huu umeidhinishwa na kamati ya maadili na tafiti ya KNH/UON na kama ilivyo taratibu imepewa nambari ya protokali.....

Mtafiti au mtafiti msaidizi atakuwa tayari kujibu maswali yoyote yatakayojitokeza katika ujazaji fomu hii ya idhini

Endapo utaridhia kushiriki katika tafiti hii utaombwa kutoa taarifa zako binafsi na taarifa za hali yako ya ugonjwa. Taarifa hizi zitakusanywa na kuhifadhiwa katika usiri na watafiti ndo wenye mamlaka ya kuvitazama.

Taarifa hızı zitapewa nambari maalumu na majina yak hayataonekana tena popote. Hakuna gharama zozote za ziada utakazoingia katika kushiriki tafiti hii.

Ushiriki wako katika tafiti hii ni wa hiari na endapo hutoshirirki utaendelea kupata huduma za tiba kama kawaida. Pia una uhuru wa kujitoa kwa muda wowote bila shida ama hasara yoyote.

Mshiriki kataika tafiti hii atahojiwa na kufanyiwa tathmini ya hali ya ugonjwa na pia kutizama kumbukumbu za tiba. Tarifa hili zitakusanya kwa ajili ya tafiti na si vinginevyo

MUHTASARI WA TAFITI HUSIKA

Ugonjwa wa mawe katika mfuko wa nyongo unazidi kuongezeka katika jamii ya waafrika na hii ni kutokana na mabadiliko ya kitabia na maisha. Kuna ongezeko ya baadhi ya wagonjwa wanaougua ugonjwa ya mawe ya mfuko wa nyongo katika hospitali kuu ya Kenyatta na nchi kwa ujumla. Madhumuni kuu la kufanya tafiti kutambua kiwango, mtirirko wa dalili na ishara na athari tata wa ugonjwa wa mawe katika mfuko wa nyongo kwa wagonjwa wanaotibiwa katika hospitali kuu ya kenyatta.

KUSHIRIKI KATIKA UTAFITI:

Ukikubali kushiriki katika utafiti huu utapatiwa fomu ya kujaza. Fomu hii inahusu ujuzi na mtazamo wa kifaa hiki na mazuizi ya utumizi. Nitanukuu shida ya kiafya uliyo nayo pamoja na shida au madhara yanoyoambatana na utumizi huu.

HATARI YA KUSHIRIKI KATIKA UTAFITI:

Hakuna hatari au madhara yoyote utakayoyapata kwa kushiriki katika utafiti huu. Hakuna maelezo ya kibinafsi ambayo tutayanukuu. Maelezo utakayo tupatia yatahifadhiwa kwa siri na hayawezi kufuatiliwa kwako baadaye.

FAIDA YA KUSHIRIKI KATIKA UTAFITI:

Ujumbe utakaotupatia utasidia kuelewa zaidi Kutambua kiwango cha ugonjwa, mtirirko wa ishara na dalili pamoja na athari tata za ugonjwa wa mawe katika mfuko wa nyongo kwa wagonjwa wanaotibiwa katika hospitali ya taifa kenyatta. Shida zikiwepo tutaweza kuingilia kati mapema tweze kuuia madhara.

MASWALI NA MACHAGUZI:

Iwapo una maswali yoyote, unaweza kuwasiliana na mtafiti mkuu kupitia nambari ya simu ya rununu na pia kwa barua pepe zilizoko mwisho wa ukurasa huu. Uamuzi wako wa kushiriki katika utafiti huu ni kwa hiari yako. Una uhuru wa kususia kushiriki na una haki ya kujiondoa wakati wowote uamuapo bila kupoteza haki na faida yako.

SEHEMU YA PILI: FOMU YA MAKUBALIANO

UJUMBE KUTOKA KWA MSHIRIKA:

Nimesoma fomu hii ya makubaliano kwa kina au nimesomewa fomu hii. Maswali yangu yamejibiwa kwa lugha ambayo naelewa. Nimeelezwa kwa kina, madhara na faida ya kushiriki katika utafiti huu. Naelewa kwamba kushiriki kwangu katika utafiti huu ni kwa hiari yangu na nina uhuru wa kujiondoa wakati wowote.

_____

Sahihi/Alama ya kidole cha mshirika

_____

Date (Siku/Mwezi/ Mwaka)

UJUMBE KUTOKA KWA SHAHIDI IWAPO MSHIRIKA HAJUI KUSOMA, KUANDIKA AMA HAJIWEZI:

Nimeshuhudia mtafiti akisoma ujumbe huu kwa kina kwa mshirika, na kwamba mshirika imepewa nafasi ya kuuliza maswali. Nathibitisha ya kwamba mshirika amepeana idhini kwa hiari yake.

_____

Jina la Shahidi

_____

Sahihi ya Shahidi

_____

Tarehe (Siku/Mwezi/ Mwaka)

SEHEMU YA TATU: UHUMBE KUTOKA KWA MTAFITI:

Nathibitisha kuwa nimemweleza kwa kina mshiriki kuhusu utafiti huu na naamini ya kwamba mshiriki ameelewa na amekubali kwa hiari yake kutia sahihi makubaliano haya. Nimemueleza yafuatayo:

1. Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo. 2. Kwamba kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe. 3. Kwamba anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayoyapata katika hospitali kuu ya Kenyatta 4. Kwamba habari ambazo atapeana hazita tanganzwa hadharani bila ruhusa kutoka kwake (mshiriki) 5. Kwamba nimejibu maswali yote aliyo nayo mshiriki kinagaubaga.

_____

Jina la mtafiti au msimamizi wake

_____

Sahihi ya mtafiti au msimamizi wake

_____

Tarehe (Siku/Mwezi/Mwaka)

Kwa maelezo zaidi, wasiliana na:

1.Mtafiti mkuu

Dkt. Abdi Osman Mohamud

Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu Cha Nairobi

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Dk Nirav Chauhan

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3.wasimamizi

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4.Katibu, UON/KNH,

SLP 20723-00202

KNH, Nairobi.

Simu: 020-726300-9

Barua Pepe: KNHpan@Ken.Healthnet.org

Annex 3: Assent Form

This consent form is for patients under the age of 18 years. It is an assent explanation and parental consent form.

Study title**: THE PATTERN OF PRESENTATION, THE CURRENT MANAGEMENT, AND COMPLICATIONS IN PATIENTS WITH GALLSTONE DISEASE AS SEEN AT THE KENYATTA NATIONAL HOSPITAL**

Study site: Kenyatta National Hospital

My name is Dr. Abdi Osman Mohamud, a postgraduate student in general surgery, Department of Surgery at the University of Nairobi. I am conducting a study on the pattern of presentation, current management, and complications of patients with gallstone disease that are seen at the Kenyatta National Hospital. The data will help the policymakers in the hospital to plan elaborate management protocols of the patients with gallstones and limit its complications.

Participation in this study is voluntary and there are no monetary benefits from participation in the study. Once the study is completed, we write a report about what was learned. The report will not include your name or mention that you were in the study.

You don't have to be in this study if you do not want to be. If you decide to discontinue after we begin, that is okay. Your parents or legal guardians will also know about the study.

If you decided that you want to be in the study, please write your name and sign

Name……

Signature……

Date…….

Annex 4: DATA COLLECTION TOOL (QUESTIONNAIRE)

STUDY SERIAL NUMBER……. INPATIENT NUMBER…….

PART 1: DEMOGRAPHIC DATA

Sex: male ☐ female ☐

Age: 13-20 ☐ 21-30 ☐ 31-40 ☐ 41-50 ☐ 51-60 ☐ 61-70 ☐ above 70

Residence: Nairobi ☐

Central ☐

Eastern ☐

N/Eastern ☐

Rift Valley m ☐

Western ☐

Nyanza ☐

Coast ☐

Home county - 1-47 ☐

BMI: <18.5 ☐ 18.5-24.9 ☐ 25.0-29.9 ☐ 30-34.9 ☐ >35 ☐

Family history of gallstones: Yes ☐ No ☐

Comorbidities: Diabetes Mellitus ☐ Hypertension ☐ Others ☐

PART 2: SYMPTOMATOLOGY

SIGNS: Tenderness in the right hypochondrium ☐

Murphy's sign positive ☐

Palpable gallbladder ☐

Jaundice ☐

Others (specify) ☐

SYMPTOMS: Asymptomatic ☐

Pain in the right hypochondrium ☐

Pain in the epigastrium ☐

Nausea and vomiting ☐

Fever ☐

PART 3: LABORATORY INVESTIGATIONS

Liver function test:

Bilirubin levels: Normal ☐ raised ☐

Alkaline phosphatase: Normal ☐ raised ☐

Alanine aminotransferase: Normal ☐ raised ☐

Aspartate aminotransferase: Normal ☐ raised ☐

GGT Normal ☐ raised ☐

PART 4: IMAGING MODALITIES

Ultrasound ☐ CT Scan ☐ MRCP ☐ Others(specify) ☐

ULTRASOUND FINDINGS:

Gallbladder not visualized ☐ Gallbladder seen ☐

Gallstones seen ☐ gallstones not seen ☐

Gallstone site: Gallbladder ☐ Biliary tree ☐

Number of gallstones: Single ☐ multiple ☐

PART 4: MANAGEMENT

Management options:

Non-surgical ☐ Surgical ☐

Surgical options: Open cholecystectomy ☐ Laparoscopic cholecystectomy ☐

PART 5: COMPLICATIONS:

ASSOCIATED WITH GALLSTONES

Cholecystitis ☐ Cholangitis ☐ Pancreatitis ☐

Choledocholithiasis ☐ Others (specify) ☐

ASSOCIATED WITH CHOLECYSTECTOMY

Bleeding ☐ Biliary leaks ☐ CBD injury ☐ SSI ☐

Other(specify) ☐