UNIVERSITY OF NAIROBI

# INCIDENCE AND OUTCOMES OF BILE DUCT INJURY FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY AT KENYATTA NATIONAL HOSPITAL

BY

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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN GENERAL SURGERY, UNIVERSITY OF NAIROBI

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## DECLARATION

I hereby declare that this dissertation is my original work and has not been presented for a degree or other awards in any other institution. Wherever another person's or institution's work is used, acknowledgment and referencing have been done.

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Principal Investigator

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## SUPERVISORS APPROVAL

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## DEPARTMENTAL APPROVAL

The dissertation proposal was submitted at the Department of Surgery dissertation clinic meeting held on 6th October 2022 at the University of Nairobi. Itwas subsequently approved by the Kenyatta National Hospital- University of Nairobi Ethics and Research Committee on 16th February 2023. This dissertation is hereby presented for examination with my approval as Chairman, Department of Surgery.

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## DEFINITION OF TERMS

**Bile duct injuries** Damage to the biliary tract occurring during cholecystectomy

**Laparoscopic cholecystectomy** Minimally invasive surgical removal of the gall bladder using abdominal port sites and a laparoscope

**Incidence**The number of new cases of injury occurring in a population over a particular period

**Outcomes** Results achieved after a surgical procedure as defined by morbidity and mortality

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# LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| BDI | Bile duct injury |
| CBD | Common Bile Duct |
| CHD | Common Hepatic Duct |
| CVS | Critical View of Safety |
| ERCP | Endoscopic retrograde cholangiopancreatography |
| GB | Gallbladder |
| HIDA | Hepatobiliary Iminodiacetic Acid |
| iOC | Intraoperative Cholangiography |
| KNH | Kenyatta National Hospital |
| LC | Laparoscopic Cholecystectomy |
| MRCP | Magnetic Resonance Cholangiopancreatography |
| OC | Open Cholecystectomy |
| PTC | Percutaneous Transhepatic Cholangiography |
| SSI | Surgical Site Infections |
| UON | University of Nairobi |

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## ABSTRACT

**Background**The increasing utilization of laparoscopic cholecystectomy has been linked with an increase in bile duct injuries, described as one of the direst complications following cholecystectomy. Bile duct injuries carry a significant postoperative morbidity and mortality rate with associated bearing on the reputation and mental health of the surgeon as well as a notable financial impact on healthcare structures. The timing of diagnosis and intervention taken have a noteworthy effect on long-term quality of life. The incidence of these injuries and outcomes of management initiated following their occurrence have not been documented locally.

**Objective** To establish theincidence and outcomes of bile duct injury following laparoscopic cholecystectomy at Kenyatta National Hospital (KNH).

**Methodology**This was a retrospective study of data gathered and stored in the KNH registry of laparoscopic cholecystectomies performed between January 2015 and December 2022.A total of 161 patients who had undergone laparoscopic cholecystectomy over the study period wereincluded. The data gathered included patients' demographic characteristics, indications for surgery, injury incidence, timing of diagnosis, and outcomes. Data was entered into SPSS version 26 for analysis. The data was analyzed for means and proportions. Association was established through chi-square and statistical significance analysis at a 95% interval level with a p-value of <0.05 being a significant difference. The results were presented in tables and graphs.

**Results** A total of 161 patients who underwent laparoscopic cholecystectomy were included in the study, with a median age of 41 years and female preponderance of 85.1%. 82.6% of patients had symptomatic cholelithiasis. The incidence of bile duct injury in patients undergoing laparoscopic cholecystectomy at KNH was 5% with 95% Confidence Interval [CI]: 2.2% to 9.6%. There was a significant difference in the duration of surgery among patients who had BDI (174 minutes) and those who did not have BDI (125.9minutes). 37.5% of the patients had an early diagnosis, 25% had an intermediate diagnosis and 37.5% had a delayed diagnosis. 50% of patients with BDI had Strasberg class A injury. All the patients who were diagnosed intraoperatively had primary repair and a mean length of stay of 7 days. Among those who were diagnosed post-operatively, the commonly presenting features included deranged LFTs (100%), jaundice (80%), and abdominal pain (60%), with 60% of these managed by ERCP with stenting. Delayed secondary repair over a T tube was associated with a bile leak, p 0.014. The mean length of hospital stay following management of postoperatively diagnosed BDI was 14 days.Surgical site infection was the most common complication after management of LC-BDI (25%). No mortalities were reported.

**Conclusion** A high index of suspicion in cases of altered anatomy and local inflammation and employing safe cholecystectomy strategies will likely reduce the incidence of injuries. Immediate repair of intraoperatively diagnosed bile duct injury is safe, has desirable long-term outcomes, and is associated with shorter hospital stays.

**Keywords** Laparoscopic cholecystectomy, bile duct injury, incidence, outcome

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# CHAPTER ONE

## 1.1 INTRODUCTION

Laparoscopic cholecystectomy (LC), since its introduction in the mid-1980s,has become the most commonly undertaken abdominal operative procedure in the United States (1), with approximately 830000 cholecystectomies done yearly and more than 90% of these performed laparoscopically (2). The benefits of LC have been well described internationally and locally. However, an increase in the rate of bile duct injuries(BDIs) as compared to the era of open cholecystectomy has also been demonstrated, with injuries to the biliary tree that happen duringlaparoscopic cholecystectomy being of a more severe nature than those seen in open gallbladder surgery.

BDIs are an uncommon but potentially debilitating complication of LC with noteworthy postoperative morbidity and mortality, impact on surgeon's practice, and notable financial burden on healthcare systems. Tornqvist et al described a BDI rate of 1.5% in LC (3) against rates of 0.1 to 0.2% seen during open cholecystectomy(49).In Kenya, Mahmoud in a study done at Kenyatta National Hospital(KNH) in 2021 showed a postoperative complication rate of 6.2% following cholecystectomies performed for gallstone disease, with common bile duct(CBD) injury seen in 3.7% and biliary leaks in 1.2% of all patients studied(4). This incidence rate of BDI injury in all cholecystectomies performed is significantly higher than rates seen internationally.

While there have great strides made in the field of laparoscopic surgery and laparoscopic cholecystectomy in particular, data are scarce on the incidence of bile duct injury following these procedures, as well as measures taken to address these injuries and outcomes following their occurrence. This study aims to identify the occurrence of these injuries, aid in the application of preventive measures, describe patient outcomes following the injuries, and minimize the morbidity and mortality associated with them.

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# CHAPTER TWO

## 2.1 LITERATURE REVIEW

**Introduction**

An increased incidence of bile duct injurieshas been seen with the increased utilization of laparoscopic cholecystectomy which has triggered global concern. Over the past three decades, their occurrence has been studied in several settings, with notable variations reported from one country to another.

One of the most severe complications of laparoscopic cholecystectomy is biliary tract injury. With an incidence of 1.5% as shown by Tornqvist et al(3), it is a rare event yet with the capacity for significant postoperative morbidity, an up to 3.5% chance of mortality, and notable impact on a surgical practitioner's standing in society and mental wellbeing. Additionally, 70 to 85% of cases occur during surgery and/or invasive investigations into the biliary tract. They more commonly occur during the early learning curve in a surgeon's laparoscopic career.

LC has been shown to have a higher BDI incidence compared to OC (5). A clear appreciation of the triangle of Calot along with its contents is essential for a safe cholecystectomy. Aberrant structures such as ducts and vessels are to be anticipated and safely navigated. Accessory hepatic ducts may be unknowingly ligated with resultant bile leaks following the surgery.

A prospective study at KNH by Mahmoud in 2021on gallstone disease of 76 patients showed that 93.5% of all cholecystectomies performed were laparoscopic(4), a notable increase from Kimutai in 2002 where LC accounted for only 24.1% of all the cholecystectomies(6). Mahmoud further indicated a postoperative complication rate of 6.2%.

**Anatomy and Physiology**

The extrahepatic biliary tract is a ductal system that directs bile from the liver into the second part of the duodenum. The gallbladder and its accompanying cystic duct arise as derivatives of the pars cystica, while the portion of the hepatic bud that lies proximal to pars cystica gives rise

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to the common bile duct. The CBD initially opens at the ventral aspect of the duodenum but is later found at the dorsomedial aspect of the developing duodenum.

The extrahepatic biliary tree consists of five parts namely the hepatic ducts (left and right), the common hepatic duct, the cystic duct, the gallbladder, and the bile duct. This system receives bile produced by the liver, transports it for storage and concentration in the gallbladder, and subsequently carries the bile to the duodenum on demand. The two hepatic ducts arise from the right and left hepatic lobes. The common hepatic duct is formed once they unite at the biliary confluence.

In approximately 15% of cases, accessory hepatic ducts exist that commonly emerge from the right side of the liver and have varied areas of opening including the CHD, the CBD, the cystic duct, or the gallbladder

The cystic duct unites with the CHD inferior to the porta hepatis and together form the common bile duct. This union occurs at an acute angle, the cystohepatic angle. The mucosa of the cystic duct projects into its lumen in a spiral arrangement forming the valves of Heister that maintain ductal patency. An important anatomical consideration is the parts of the CBD; these include the supraduodenal CBD- a 25mm portion locatedin front of the portal vein and with the hepatic artery to its left; retroduodenal- lies in close relation to the gastroduodenal artery and inferior vena cava; infraduodenal- this part runs within or on the pancreas, with the gastroduodenal artery to its left side, and the superior pancreaticoduodenal artery crossing over or behind the duct and intraduodenal- part of the CBD that runs in the duodenal wall together with the main pancreatic duct and unites with it forming the hepatopancreatic ampulla of Vater (7).

The intraduodenal CBD is surrounded by smooth muscle forming the sphincter choledochus that relaxes upon stimulation by cholecystokinin, allowing drainage of bile into the second part of the duodenum. The liver’s inferior surface, common hepatic duct, and cystic ducttogether form the cystohepatic triangle of Calot, which importantly contains the cystic and right hepatic arteries and lymph node of Lund. Accessory hepatic ducts are frequently found within the boundaries of the triangle as well(8).

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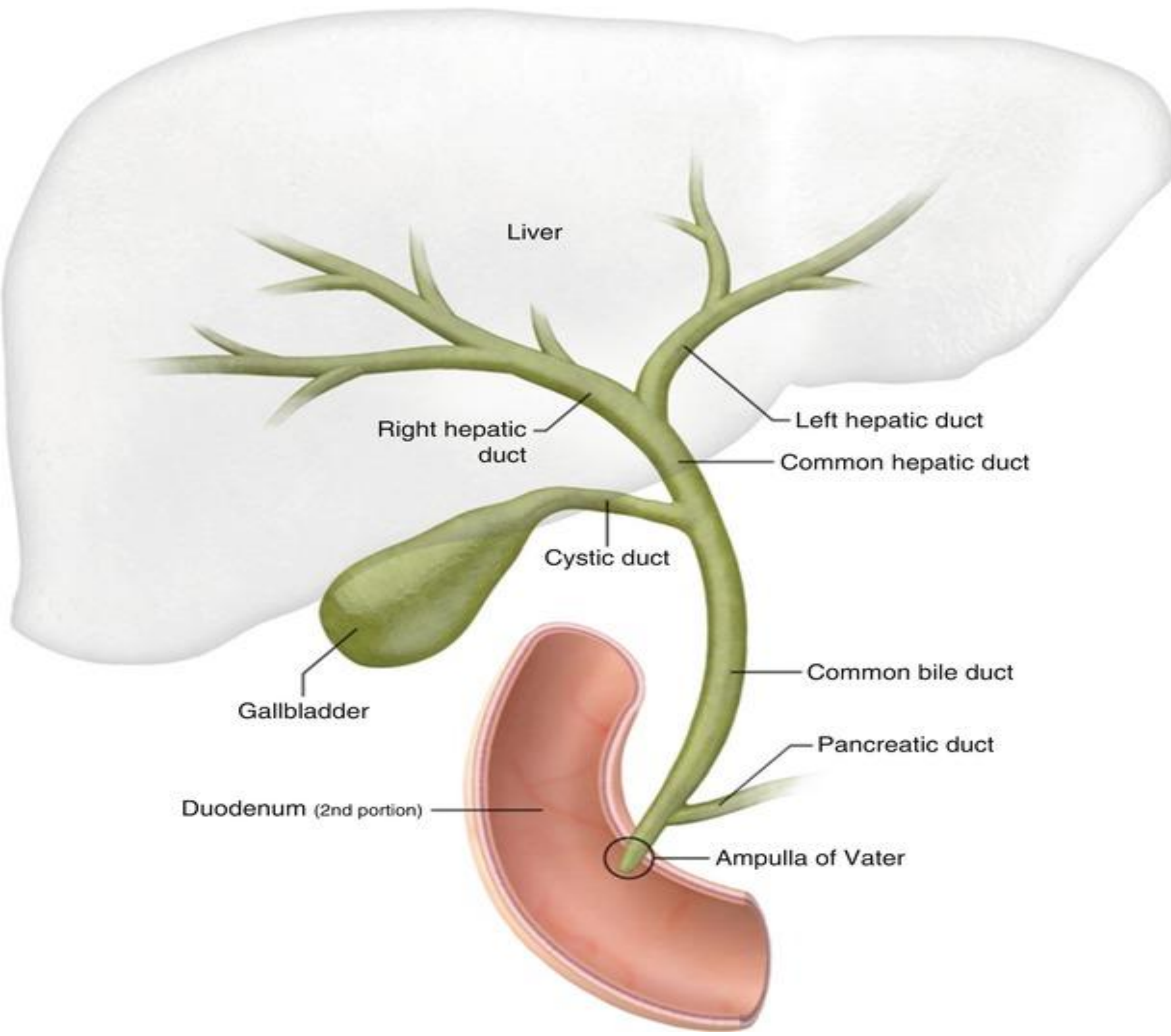
The autonomic nervous system, via the stimulation of splanchnic nerve efferent fibers, facilitates the relaxation of the gallbladder to allow the flow of bile into it for storage.

A patent CBD allows for the flow of bile from proximal ducts, that is the hepatic ducts and cystic duct, that direct bile from the more proximal intrahepatic biliary tree. Further enhancing this flow is the contraction of the GB and CBD sphincter relaxation, a process influenced by cholecystokinin hormone secreted by the mucosa of the duodenum to the presence of food in the duodenum. (8)



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**Laparoscopic Cholecystectomy**

Laparoscopic cholecystectomy involves the removal of the gallbladder in a minimally invasive surgical technique. Its safety and effectiveness have been seen in a majority of patients who have symptomatic gallbladder disease. The procedure usually involves about four 0.5-to-2.5-centimeter abdominal incisions, whose positions may vary between patients (9). On September 12$^{th}$, 1985, Dr E Muhe performed the first laparoscopic cholecystectomy, and that forever changed the approach to benign gallbladder disease management. Since then, it has increasingly become the procedure of choice for surgical management of a myriad of gallbladder diseases.

The procedure requiresconsiderable knowledge of the equipment necessary for laparoscopy. These apparatuses include video monitors, light sources, camera control units and telescopes, carbon dioxide insufflators, and suction-irrigation systems. In addition to these devices that allow the surgeon a clear view of the abdominal cavity, appliances such as a variety of trocars, graspers, electrosurgical devices, clip applicators, and dissecting forceps allow for access into the abdomen, dissection, manipulation, and safe undertaking of LC (51).

Of the 750,000 cholecystectomies currently carried out in the United States of America every year, 90% are laparoscopic cholecystectomies (10). A study done by Ahmed W in 2017 similarly showed that of the 830000 cholecystectomies annually done in the United States more than 90% were performed laparoscopically (2). With its well-documented advantages of reduced morbidity, enhanced postoperative recovery, minimal pain, and shortened hospital stay, LC is increasingly being employed worldwide by surgeons of varying levels of experience (11).

However, despite its noteworthyadvantages, laparoscopic cholecystectomy does have limitations including the steep learning curve that training surgeons have to go through, prolonged operating times with subsequent anesthetic complications, visceral and vascular injuries arising from the use of electrosurgical equipment, and complications arising from carbon dioxide insufflation (51)

Various techniques are employed in this procedure, with numerous different methods of laparoscopic cholecystectomy describedarisingfrompractitioners who develop modifications

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toimprove postoperative results. These modifications include a reduction in port number and/or size in comparison to the classically described standard LC (12).

Laparoscopic cholecystectomy, after rapidly substituting traditional cholecystectomy, is currently the procedure of choice for uncomplicated symptomatic gallstone disease, for select patients with uncomplicated acute cholecystitis and in cases of chronic cholecystitis (13).

Many African states are yet to fully embrace this surgical procedure. Adisa, Lawal, Orowolo, and Akinola observed that in many Nigerian public tertiary health facilities, laparoscopic cholecystectomy is not routinely performed. Notably, despite a limitation in the availability of resources, the outcomes of LC in the country were in keeping with experiences reported in other African nations (14).

In the 90's, laparoscopic surgery was pioneered in Kenya with LC being documented as the first laparoscopic procedure practiced in the country. Continued training of young general surgeons by experienced laparoscopy proficient surgeons has led to a noteworthy transition to LC. Evidence indicates that laparoscopic cholecystectomy cases have seen a demonstratable gradual rise from an average of 7 cases per month in 2000 to reaching a 22 procedure per month mark in 2001 just a year later (15). A prospective study by Mahmoud in 2021 showed that of 62 patients who had surgery for gallstone disease,laparoscopic cholecystectomy was performed in 93.5% of the cases. (4)

**Bile Duct Injury following Laparoscopic Cholecystectomy**

BDIs, ranging from minor accessory duct damage to major ductal injuries, are agrave complication of laparoscopic cholecystectomy with sequelae such as biliary strictures and secondary cirrhosis with long-term effects on a patient's health. Evidence indicates that delayed interventionin situations where complications arisemay lead to life-long disability (16).

A demonstrated increase in the incidence of iatrogenic bile duct injuries has been seen since the introduction of laparoscopic cholecystectomy, with various reports showing its occurrence has more than doubled. While its occurrence is on the increase, the heterogeneous referral of patients

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from multiple institutions to specialized centralized centers may lead to an underreported number of cases (17).

Despite the clear benefits of LC, it has been shown to result in significantly higher numbers of BDIs, with an incidence of 0.26 to 0.6% (18) and an incidence of up to four times greater than that seen in open cholecystectomy (19). Jaboska et al found an association between cholecystectomy and increased cases of these injuries. These injuries, with their notable impact on overall patient survival and quality of life,were reported at a 0.3%–0.7% incidence rate and resulted in frequent medico-legal charges being brought up against surgeons and institutions(20). With laparoscopic surgerycurrently the gold standard in symptomatic gallstone treatment, the incidence of iatrogenic BDI has increasedin numbers that have elicited concern (21).

A study done by Flum showed there was no increase in incidence for surgeries performed by newly practicing surgeons (1), with a 0.5% incidence of injury noted remaining relatively constant across all groups of surgeons. They are also shown to occur not due to a lack of skill or know-how on the part of the surgeon but more commonly due to a misunderstanding of the two-dimensional anatomy seen during laparoscopy (22).

Comprehensive knowledge of the anatomy of the biliary tract and vital surrounding structures enhances safety in laparoscopic surgery. This knowledge goes hand in hand with proper and meticulous surgical techniques. Gimenez et al showed that surgeons who are unable to correctly identify the markers of the critical view of safety report higher rates of BDI (26).

Amreek et al in a three-year retrospective study of 855 LCs found 9 instances of bile duct injury, representing 1.1% of total procedures performed with 2(0.2%) of the procedures completed laparoscopically and 7(22.5%) converted to open cholecystectomy (11). In a 10-year retrospective study done in Pakistan, CBD injuries during LC were the second most common complication (after hemorrhage) at 0.13% (23).

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Factors that have been seen to increase the occurrence of laparoscopic bile duct injuries include the presence of adhesions in the operating field, insufficient knowledge of biliary anatomy and aberrant ducts, surgeon inexperience, electrocautery use in close proximity to ducts, undue attempts at dissection orunforeseen excessive bleeding (24).

Nuzzo et al, in a retrospective survey undertaken at a university referral center in Rome, reported a 0.42% incidence with a hundred and thirty-five BDIs being identified (19). The incidents noted in the study included minor injuries (involving the cystic duct or small peripheral ducts) in 24.3% of cases (57 patients) and major injuries (to major ducts, the biliary confluence of the CBD) in 75.7% of cases (178 patients). It was also established that the incidence of BDI was increased in the settingof cholecystitis and decreased as surgical teams became more conversant with performing LCs. They further confirmed anincreased injury occurrence during laparoscopic cholecystectomy and highlighted the importance of correct surgical technique, the need for correct procedures, a multidisciplinary approach, and adequate surgical expertise to avoid BDI.

In Italy, Pesce, Palmucci, La Greca, and Puleo highlighted that withlaparoscopic cholecystectomy being a widely performed procedure, patient quality of life was significantly impacted by iatrogenic bile duct injuries that remained a considerable consequence of gastrointestinal surgery (25).

Perakis et al in a single center retrospective study involving 5456 laparoscopic cholecystectomy cases over 10 years identified five patients with biliary injuries which accounted for an overall incidence of 0.09%. All five cases were injuries involving major bile ductswith complete CBD or CHD transection. Intraoperative diagnosis was made in all cases with subsequent conversion to open cholecystectomy and repair undertaken. Despite this, a notably lengthy postoperative period of hospital stay, registered at an average of 38 days, was reported (13).

In 2020, a study by Soomro, Mangrio, Bherulal, and Rajper sought to establish the incidence of iatrogenic bile duct injury at a Pakistani Hospital afterboth open and laparoscopic cholecystectomy and their postoperative outcome over 2 years (24). The prospective study, monitored patients in the surgical ward and followed them up after they were sent home

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following removal of drains and in the outpatient department for 6 months. The results established that although there were no mortality outcomes, surgical site infections represented 15% of all the post-operative complications, bile leaks contributed to 10%, and recurrent cholangitis was seen in 5% of cases with the average 10-to-15-dayhospital stay reported.

Pottakkat et al evaluated a single-center experience of cholecystectomy-associated bile duct injuries in an Indian facility (17). The18-year retrospective study involved 5,782 cholecystectomy casesand found that 1% of the patients sustained BDI. 25 of these 57 patients (44%) had major injuries, 10 (18%) had minor BDI and the degree of injury was not classified in the remaining 22 (39%) patients.

As India rose to become a preferred destination for medical services, Perakis et al highlighted that with center experience, intraoperative diagnosis and management of a majority of the major BDIs can be undertaken.The attainment of favorable outcomescan then be accomplished by selecting and applying the best available intervention procedures for this group of patients (13).

A majority of African countries are yet to realize the benefits associated with LC due to a lack of experience among surgeons on the continent. In the West, an initialaversion to laparoscopic cholecystectomy due to a high possible incidence of bile duct injury has been seen to decrease as knowledge and experience on the detection and management of these debilitating complications has grown over time (14).

**Risk Factors for BDI**

Patient, surgeon, and equipment factors all play a role in the occurrence of BDIs. They include the presence of adhesions at the porta hepatis due to chronic cholecystitis, ongoing acute cholecystitis, variations in the anatomy of structures with aberrant duct and vessels, overeager electrocautery usage, undue upward fundal retraction, insufficient infundibular retraction and poor recognition of the biliary tree anatomy (24, 27). Others include excessive bleeding and subsequent attempts at aggressive control of bleeding that may be encountered during the surgery and surgeon inexperience with a majority of injuries seen during the early laparoscopic learning curve (28).

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**Presentation of BDIs**

The majority of BDIs will not be recognized during surgery, with only 25% picked up intraoperatively (early diagnosis), another 25% identified in the subsequent postoperative days via drains (Intermediate diagnosis), and more than half identified weeks, months, or years after the operation (delayed diagnosis). Presenting symptoms and signs are nonspecific and include vague abdominal pain that may occasionally be described as being in the right upper quadrant, nausea and vomiting, abdominal distension (due to bilious ascites), hotness of body with low-grade fever, and jaundice (29). Laboratory investigations will reveal leukocytosis with elevated liver enzymes and bilirubin levels. Markers of inflammation will also show increased levels, that is C reactive protein, serum lactate, and procalcitonin levels.

**Classification of BDIs**

While several classification systems have been developed, none is universally recognized, with each carrying various limitations (13). Several classification methods exist that have been developed over the past 4 decades, with more recent methods attempting to incorporate the many existing ones. Classifying these injuries not only serves the purpose of detailing their occurrence and extent but also facilitates proper planning with regard to the repair of the injury and patient prognosis following correction of the injury(25, 30).

The Bismuth classification, developed in 1982, defines injury concerning the biliary confluenceof right and left ducts and describes five types of strictures. Type 1 injuries involve the CBD and CHD more than 2cm from the confluence. Type 2 injuries are located less than 2 cm from the confluence. Type 3 and 4 injuries occur at the confluence, with an undamaged confluence in type 3 and a destroyed one in type 4 injuries. Type 5 injuries involve an aberrant right hepatic duct (31).

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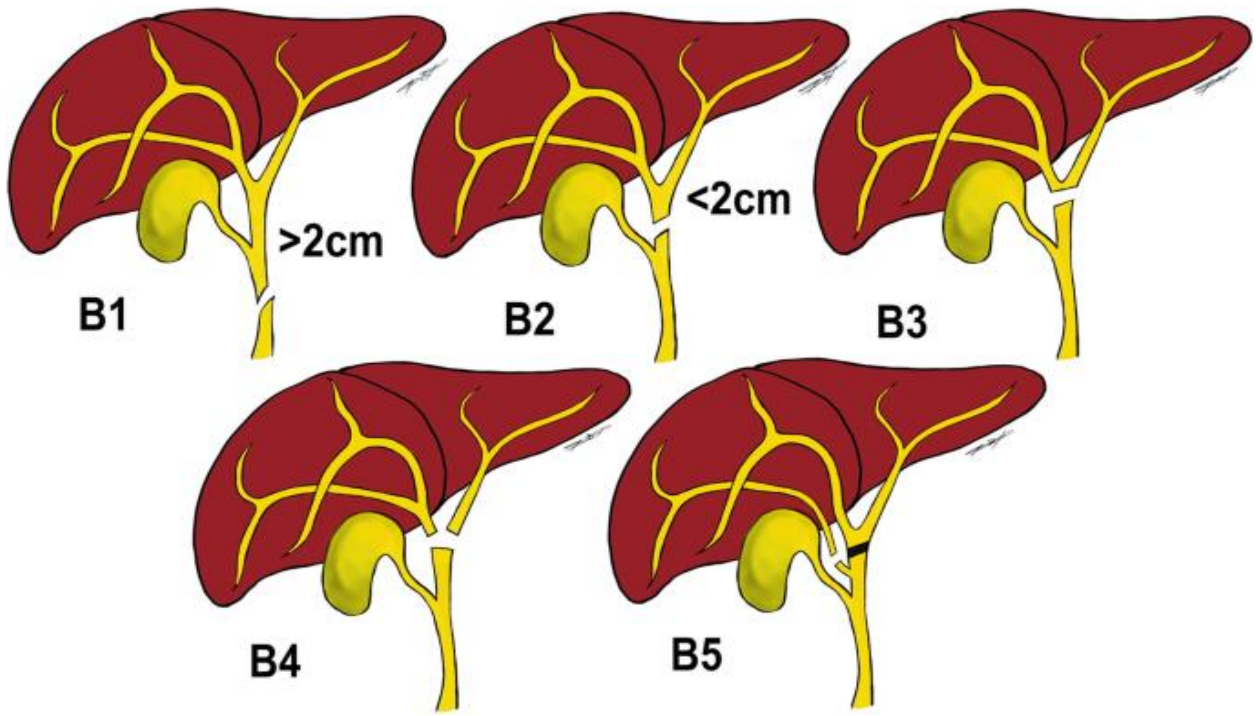


In 1995, following the increasing application of LC, the Strasberg classification (25) was developed to include the injuries observed during the procedures. This is the most commonly used classification system and allows for distinction between minor (A,B, C,D) and major (E1 to E5) injuries. Type A includes injuries to the cystic duct and liver bed ducts, type B injuries involve aberrant right hepatic duct occlusion, with transection of this aberrant duct classified as type C. Type D injuries are a lateral aspect CBD injury involving less than half of its circumference. Type E injuries involve the major ducts and incorporate the Bismuth classification.

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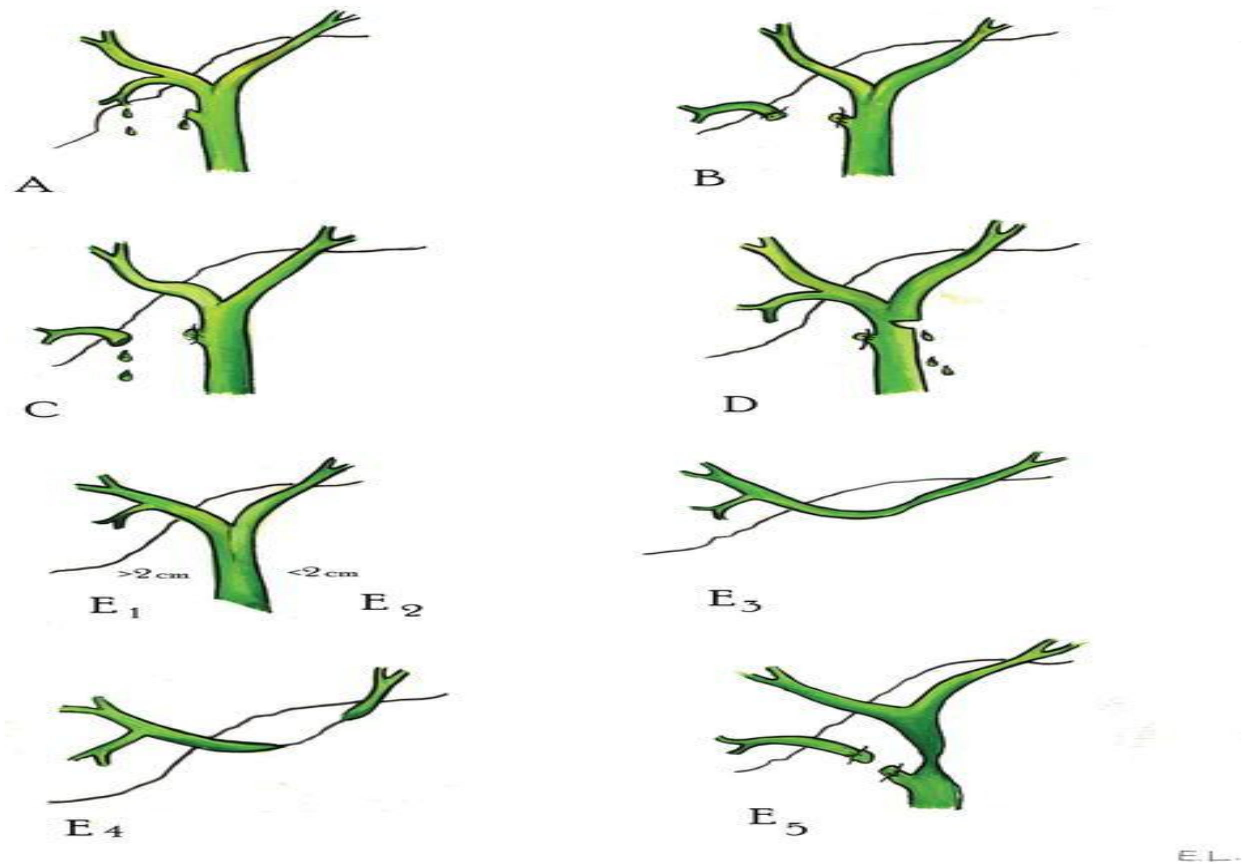


In the same year, McMahon defined a classification of injuries after LC which described minor injuries as lacerations at the cystic duct-CBD junction or lacerations involving less than 25% of the CBD's diameter. Major injuries are those involving lacerations or transections greater than 25% of the CBD or a noted CBD stricture postoperatively (25).

The Stewart Way classification includes both duct and vessel injuries and aims to describe the pattern and mechanism of an injury (22). Four classes are described. Class 1 injuries occur when the common bile duct is mistaken for the cystic duct but recognized before division or there is an inadvertent extension of the cholangiogram catheter incision into the CBD. Class 2 injuries arise with damage to the lateral aspect of the CBD by electrocautery or clips. Most common are class 3 injuries where the CBD is misjudged to be the cystic duct and completely transected. Class 4 injuries involve the right hepatic ductwith attendant right hepatic artery injury.

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The Anatomic, Time Of detection, Mechanism (ATOM) classification was developed in 2013 (32) and incorporates preexisting classification methods to standardize BDI description by defining the bile tree injury, coexisting vascular injury, time of injury recognition, and mechanism of injury.

**Safety in Cholecystectomy**

Strasberg in 1995 and later on Brunt in 2014 advocated for a six-strategy universal culture of safety to be employed by surgeons undertaking laparoscopic cholecystectomy to enhance safety in surgery, guide the budding surgeon, and augment the judgment and skill of an experienced surgeon to reduce the risk of biliary tract injuries, both during conventional and difficult or challenging procedures (25, 33). These strategies include:

1) Employing the Critical View of Safety by exposing the triangle of Calot, dissecting the lower one-third of GB to visualize the cystic plate and identifying that only two structures, these being the cystic artery and duct, enter the gallbladder;

2) Anticipating variations in anatomy for instance a shortened cystic duct or aberrant right hepatic duct in all LC procedures;

3) The use of imaging such as intraoperative cholangiography;

4) Planned intraoperative pauses by the surgical team to collectively confirm CVS has been achieved and identification of structures before their ligation(25);

5) Identifying when the CVS cannot be achieved making the procedure unsafe and opting for a bailout procedure such as subtotal cholecystectomy, cholecystostomy, or open cholecystectomy;

6) Seeking a second surgeon's input in situations where difficulty in proceeding with the procedure or defining structures with clarity is encountered (34).

**Prevention of BDI (22, 25, 36,47)**

Proper anatomical knowledge and a prior understanding of the possible difficulties that may be encountered given a patient's risk factors are important in preventing injury during LC. Several authors have described measures to be undertaken intraoperatively to minimize injuries. These include:

- Obtaining the Critical view of safety (CVS) by ensuring both cystic duct and artery are observed entering the gallbladder.

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- Carrying out dissection in an antegrade fashion.
- Identification of the important anatomical landmarks i.e.,Rouviere's sulcus and the Calot's node.
- Use of intraoperative cholangiography (35) and laparoscopic ultrasound.
- Performing a subtotal cholecystectomy to ensure safety is maintained in difficult dissections.
- Drainage procedure (cholecystostomy) where the GB cannot be removed.
- Timely conversion from a laparoscopic procedure to open cholecystectomy

Intraoperative cholangiography (iOC) is an imaging modality that, while not routinely employed, may be used during LC to define biliary anatomy and identify gallstones. It is advised in cases of suspected intraoperative BDI, unclear biliary treestructure, in cases of acute cholecystitis, and when the critical view of safety is not seen. In a study by Ludwig, the use of iOC was shown to decrease biliary tract injury (35).

On the other hand, proper reporting in the case of BDI noted intraoperatively is essential and recommendations by the WSES (46) include documentation of the

- Surgical indication,
- Identifiable landmarks and difficulties encountered,
- Biliary tree variations,
- Intraoperative findings,
- Duration of surgery,
- Switch to open procedure,
- Depiction of BDI with drain position (if placed) and
- Images if accessible

**Diagnosis of BDIs**

With more than two-thirds of bile duct injuries being identified postoperatively (37), a myriad of imaging techniques can be employed with differing degrees of accuracy when bile duct injury is suspected.

Ultrasonography is a noninvasive imaging modality that aids in the identification of ductal dilatation, intra-abdominal collections & associated vascular lesions (41).

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An abdominal CT scan will describe the findings as seen on ultrasound scans andfurther define the long-term effects of bile strictures with hepatic lobar atrophy and subsequent liver cirrhosis in the case of late diagnosis of BDI(38, 39,40).

Hepatobiliary Iminodiacetic Acid (HIDA) scan has the highest sensitivity for the detection of leaks and major ductal injuries. It identifies the relationship between leaks and accompanying abdominal fluid collections. With its utility of being a real-time imaging technique, it shows the route of bile flow from ongoing leaks (48).

Direct cholangiography with PTC and ERCP is both diagnostic (allowing for identification of continuing leaks) and therapeutic (facilitating biliary decompression and management of leaks using stents). On the other hand, MRCP carries the notable advantage of accuracy approaching 100% thereby allowing for a complete biliary tree evaluation, a detailed definition of the ductal system as well as detection and localization of ongoing leaks from sites of injury (41).

**Management of BDIs**

There are various measuresof intervention described for bile duct injuries that occur during laparoscopic cholecystectomy. Sicklick, Camp, Lillemore, Melton, Yeo, and Campbell in a 2005 retrospective study of 200 patients managed for major BDIs at the Johns Hopkins Department of Surgery (37) established that interventions undertaken included 9 cases of percutaneous drainage of pus collections (5.1%) and 4 cases of PTC with placement of stents (2.3%).

The various interventions also depend on the causes of bile duct injuries during LC. Nuzzo (19) at a university referral hospital in Rome highlighted that the most frequently reported cause of LC-associated BDIs is difficulty in identifying the components of the liver pedicle (36.8% of cases). Other causes includegallbladder inflammation (23.3%),variationsin normal anatomy (12.9%), improper electrocautery use (12.3%), undeterminederror in technique (9.8%), and problematichemorrhage control (4.9%).

Bile duct injuries remain a considerable burden for patients undergoing laparoscopic cholecystectomy, making the timing of interventions a crucial factor for better outcomes. Goykhman, Kory, and Small while evaluating the risk factors associated with failure of repairs after bile duct injury advised that early interventions are necessary for better outcomes. Of note,

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optimal timing of repair was not established for injuries that, after being initially unrecognized, presented days to months following LC (42).

Approximately 25% of BDIs are picked up intraoperatively and once recognized, conversion to open procedure is quickly undertaken and is not seen as a failure but rather wisdom on the part of the surgeon for the benefit of the patient (37). High rates of successful repairs are seen when injuries are corrected as soon as they occur and thus involvement of a hepatobiliary specialist or timely referral to specialized hepatobiliary centers, with multidisciplinary team involvement, is emphasized. In centers without a specialist, abdominal drain placement in the gallbladder fossa and referral within 48 hours of injury should be done. Minor injuries recognized intraoperatively can be repaired by a primary end-to-end anastomosis that approximates mucosa to mucosa, is tension-free, and is accompanied by abdominal drain placement. Wang highlights that major injuries such as CBD injury with bile leak and those involving loss of tissue are best managed at a specialized center where a Roux en Y hepaticojejunostomy with T tube placement is undertaken to reduce the risk of postoperative stricture formation. (44, 45)

Minor injuries diagnosed within 6 weeks of surgery are managed by drainage of collections and stent placement using ERCP while major injuries will require drainage, stenting, and secondary repair (hepaticojejunostomy) at approximately 6 to 8 weeks later once inflammation has resolved. Injuries diagnosed later than 6 weeks after the operation are significantly more complex to manage. Options of management may include drainage with stent placement and Roux en Y hepaticojejunostomy, liver resection in cases of liver atrophy or ductal stenosis, and/ or liver transplant where secondary biliary cirrhosis or sclerosing cholangitis has set in (45).

**Antibiotic Therapy**

No consensus exists at present on antibiotic use following BDI. The World Society of Emergency Surgery in 2020 recommended several guidelines to guide antibiotic therapy to complement source control measures instituted once injury is diagnosed(46). Broad-spectrum antibiotics are recommended for cases of suspected BDI with or without previous instrumentation into the biliary tract. For patients with a history of prior biliary infections or instrumentation, bile microscopy, culture, and sensitivity results will guide antibiotic therapy. In

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cases of major injury with associated biloma, fistulae, or peritonitis, piperacillin-tazobactam and carbapenems are recommended (46)

**Outcomes**

A retrospective review by Sahajpal et al of 69 patients reviewed complications seen following correction of laparoscopic cholecystectomy associated BDI,the relationship between time of repair and outcomes, and long-term impact (16). Short-term complications included cholangitis (10%), intraabdominalabscesses (4%), surgical site infection (4%), postoperativebleeding (3%)and gastrointestinal bleeding (1%). Long-term complications of note were bile duct strictures (14%) and incisional hernias (3%). The rate of mortality was at 1%. The results further suggested that long-term outcome is greatly determined by the timing of injury repair. Biliary strictures were more common for repairs undertaken in the intermediate period. Sahajpal concluded thatundertaking repairs in the immediate (0-72 hours) or delayed (6 weeks) periods after injury resulted in better outcomes.

Adisa, Lawal, Orowolo, and Akinola in 2011 evaluated the early LC outcome ata university hospital inIbadan, Nigeria. The prospective study, which followed selected patients from June 2009 through to December 2010, established a 2.4% incidence of BDI with the need for laparotomy for a patient on day 6 following a laparoscopic cholecystectomy where CBD injury was noted(14).

Pitt et al noted that bile leaks and bile duct injuries while mainly managed by endoscopists (40%) than surgeons (36%) showed significantly better success rates following surgical repair (88%) than in endoscopic management (76%) (50)

Jani and Gill in a 10-yearretrospective study from January 2001 to December 2010 undertaken at KNH reported a conversion rate of 5% for patients undergoing a laparoscopic cholecystectomy to open cholecystectomy. The results indicated that of these, five patients had variant anatomy and one patient had a bile leak. One patient was reported to have had a CBD injury with 3 patients being readmitted following LC. No mortality was reported during the study period. (15)

## 2.2 CONCEPTUAL FRAMEWORK

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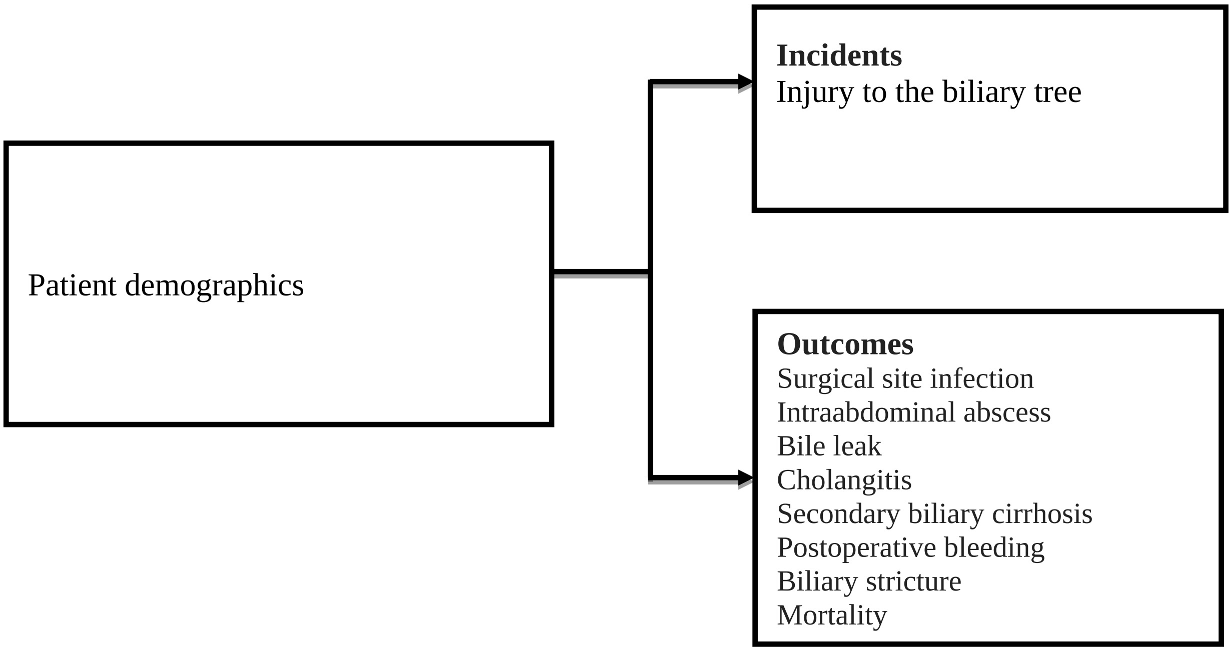
**Independent Variable** **Dependent Variables**

**Incidents and Outcomes of LC-BDI**




## 2.3 STATEMENT OF THE PROBLEM

Laparoscopic cholecystectomy hasreplacedopen cholecystectomy as the standard surgical interventionfor gallstones. It has throughout its history of application been associated with bile duct injuries, with an incidence of 0.4% to 1.5%. These injuries carry a significant risk of subsequent complications and non-negligible risk of mortality with implications on the patient, surgeon, and health care systems as a whole. The timing of their diagnosis and the treatment measures instituted thereafter greatly impact the success rates of their management., with early reconstruction shown to result in shorter hospital stays, reduced costs of care, and diminished burden of patients.

## 2.4STUDY JUSTIFICATION

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Significant progress has been realized globally in the utilization of laparoscopic cholecystectomy. However, bile duct injuries, with notably increased frequency than in the past, still represent a significant complication (19).

The past three decades have seen the increased application of laparoscopic cholecystectomy at KNH. With bile duct injuries being shown to be a severe complication of this procedure,it is crucial to establish their extent and outcomes in low-income countries such as Kenya and particularly KNH. Additionally, while there are local studies on gallstone disease that have noted the occurrence of BDIs; no studies on the incidence of LC-associated BDI and their outcomes exist. Determining the scale of these injuries is expected to improve the informed consent-taking process on the risks of BDI associated with LC, their detection, outcomes of management, and mitigate their impact on patient care.

## 2.5 STUDY QUESTIONS

1. What is the incidence of bile duct injury following laparoscopic cholecystectomy at Kenyatta National Hospital (KNH)?
2. What are the interventions for bile duct injury following laparoscopic cholecystectomy at Kenyatta National Hospital (KNH)?
3. What are the outcomes of bile duct injury following laparoscopic cholecystectomy at Kenyatta National Hospital (KNH)?
4. What is the relationship between interventions and outcomes of bile duct injury following laparoscopic cholecystectomy at Kenyatta National Hospital (KNH)?

## 2.6 STUDY OBJECTIVES

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**Broad objective**

To establish theincidence and outcomes of bile duct injury following laparoscopic cholecystectomy at Kenyatta National Hospital (KNH).

**Specific objectives**

1. Establishthe incidence of bile duct injuryin patients undergoing laparoscopic cholecystectomy at Kenyatta National Hospital (KNH).
2. Determine the interventions forlaparoscopic cholecystectomy-associatedbile duct injury at Kenyatta National Hospital (KNH)
3. Determine the complications of bile duct injury seen following laparoscopic cholecystectomy at Kenyatta National Hospital (KNH).
4. Determine the relationship between interventions and complications of laparoscopic cholecystectomy-associated bile duct injury at Kenyatta National Hospital (KNH).

# CHAPTER THREE: STUDY METHODOLOGY

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## 3.1 STUDY DESIGN

A retrospective cohort study over an eight (8) year period (January 2015 to December 2022).

## 3.2 STUDY SITE

The study wasundertaken at the KNH Medical Records Department.

Kenyatta National Hospital is a regional public referral facility for the Ministry of Health located in the Upper Hill area of Nairobi city, Kenya. It is a tertiary 1800-bed capacity facility with an active general surgical department that conducts laparoscopic procedures, including laparoscopic cholecystectomy.

The facility is well equipped with apparatus required for LC, including video monitors, light sources, telescopes, carbon dioxide insufflators, and suction-irrigation systems. These devices allow the surgeon a clear view of the abdominal cavity. In addition, appliances such as graspers, clip applicators, and dissecting forceps are at the surgeon's disposal.

The general surgical wards (5A,5B, and 5D) and private wards all conduct laparoscopic cholecystectomy surgery and have outpatient clinics that cater for the follow-up of these patients preoperatively as well as postoperatively. On average, 30 laparoscopic cholecystectomies were performed annually in the general surgical units of KNH between 2019 and 2022.

## 3.3 STUDY POPULATION

All patients who had undergone laparoscopic cholecystectomy in Kenyatta National Hospital from January 2015 to December 2022 and met the inclusion criteria.

## 3.4 ELIGIBILITY CRITERIA

**Inclusion Criteria**

- Clients on whom laparoscopic cholecystectomy was performed in KNH between January 2015and December 2022

**Exclusion Criteria**

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- Patients' files with missing data on demographics, bile duct injury, and/or outcomes.
- Patients referred from other facilities with bile duct injuries.

## 3.5 SAMPLE SIZE DETERMINATION

The Cochrane formula was used for sample size estimation

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

n–Desired sample size

Z -value from standard normal distribution corresponding to desired confidence level(1.96 for 95% CI)

P - Estimated incidence of BDI (4.9%, based on a prospective study by Mahmoud, 2021)

d - Level of precision desired (0.05)

$$n= \frac{1.96^2 (4.9) (1- 4.9)}{0.05^2}$$

Substituting into the formula, a sample size (n) of *72* persons was estimated. A minimum of 72 patients who had undergone laparoscopic cholecystectomy over the study period were sampled.

## 3.6 SAMPLING PROCEDURE

Records of patients were obtained from the KNH records department. Retrieval of files was done using the ICD 10 coding system and files were filtered to identify those which met the inclusion criteria. The files were then be checked for completeness and serial numbers assigned to each file to ensure anonymity.

## 3.7 VARIABLES

Independent Variable: The independent variables were the patient demographics.

Dependent Variable: The dependent variables were bile ductinjury incidence and outcomes.

## 3.8 DATA COLLECTION

Data collectioncommenced after getting approval for the study and a waiver of consent. Data was collected using a data abstraction tool. After obtaining permission to access the records, the researcher accessed patient files from the records departments as well as the theaters' procedure

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log. Using the inclusion criteria, the researcher identified those who qualified to be included in the study. The researchers' information did not include names but only medical records. The files with incomplete information werenot included in the study.

A data extraction checklist was used to collect both qualitative and quantitative information regarding demographic characteristics, laparoscopic cholecystectomy procedures, indications for surgery, the incidence of bile duct injuries, timing of diagnosis, and the outcomes of injuries.

## 3.9 TRAINING PROCEDURE

The principal researcher trained2 data collectors on the content of the data extraction checklist and the information to be collected. The training included the inclusion criteria for required data.

## 3.10 QUALITY ASSURANCE PROCEDURE

The researcherensured that integrity was observed in the data collection process and that the quality of data was maintained. The checklist was stored for references and confirmation of the clarity ofcollected data. Data suspected not to meet the required inclusion criteria and completeness was not included in the study.

## 3.11 DATA MANAGEMENT

Data was entered into an Excel sheet. Data cleaning was done by inspecting the entire checklist and those found incomplete were not included in the analysis. A standard entry of information was done to prevent duplication. The data was then entered into SPSS for effective storage and subsequent analysis.

## 3.12 DATA ANALYSIS

The collected data was entered into the Statistical Package for Social Sciences (SPSS) version 26 software for coding and analysis. The characteristics of patients undergoing laparoscopic cholecystectomy at KNH were analyzed for means and proportions. Association was established through chi-square and statistical significance analysis at a 95% interval level with a p-value of <0.05 being a significant difference. The results were presented in tables and graphs.

## 3.13 ETHICAL CONSIDERATION

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The study was submitted to the KNH/UON Ethics and Research Committee for ethical approval before data collection. This being a retrospective study based on patient records hence a low-risk study, waiver of consent was requested from ERC.

Institutional approval was obtained from the administration of Kenyatta National Hospital to allow access to patients' records.

The research was conducted as per University of Nairobi guidelines. The anonymity of the files selected was safeguarded by ensuring no patient names were included and serializingthe checklist used.

Data was stored at a place only accessible to the researcher and in a password-locked computer known only by the researcher to ensure confidentiality. Data was coded in a manner that its source was not identifiable to ensure anonymity. The files were searched for by the medical records staff and after abstracting the data the information was removed from the system.

## 3.14 STUDY LIMITATIONS

This study relied on secondary data collected for purposes other than research. Irrelevant and incomplete information was not included in the study. To overcome this, the researcher used only files that had complete data. Additionally, there was limited data published locally in this area of study. The researcher also reviewed any related evidence that had not been published yet to get a comprehensive outlook.

## 3.15 STUDY CLOSURE PLAN AND PROCEDURE

Following the acceptance of the research proposal, the researcher collected the proposed data and carried out an analysis. The researcher then provided the research findings to the research supervisor panel at the University of Nairobi and thereafter submitted a copy of the research findings to the relevant UON department as well as to the administration of Kenyatta National Hospital (KNH). The checklists of the extracted information will be kept for 5 years after which they will be destroyed. The researcher will share the information about the completion of the study and the deletion and destruction of the collected information to bring closure to the study.

# CHAPTER FOUR: RESULTS

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A total of 161 files of patients who underwent laparoscopic cholecystectomy (LC) between January 2015 to December 2022 were included in the study.

**Demographic characteristics of patients undergoing laparoscopic cholecystectomy**

The median age was 41 (Interquartile range [IQR]: 32 – 54) years with 52.2% (n =84) of the patients aged between 31 and 49 years. 85.1% (n =137) of patients were female, 54% (n =87) were residing outside Nairobi and 39.1% (n =63) were self-employed as shown in Table 1.

*Table 1: Demographic characteristics of patients undergoing LC at KNH*

| **Characteristics** | **Frequency** | **Percent** |
|---|---|---|
| **Age (Median, IQR) years** | 41(32 - 54) | |
| **Mean ±SD** | 42±14.2 | |
| <30 years | 26 | 16.1 |
| 31 - 49 years | 84 | 52.2 |
| 50 years and above | 51 | 31.7 |
| **Gender** | | |
| Male | 24 | 14.9 |
| Female | 137 | 85.1 |
| **Residence** | | |
| Within Nairobi | 74 | 46.0 |
| Outside Nairobi | 87 | 54.0 |
| **Employment status** | | |
| Employed | 41 | 25.5 |
| Self-employed | 63 | 39.1 |
| Student | 13 | 8.1 |
| Unemployed | 44 | 27.3 |

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**Diagnosis of patients undergoing laparoscopic cholecystectomy**

The findings showed that the majority of the patients 82.6%(n =133) had symptomatic cholelithiasis, 6.2%(n =10) had Chronic acalculous cholecystitis, 4.3%(n =7) had acute cholecystitis and 1.2%(n =2) had a gallbladder mass as shown in Figure 1.

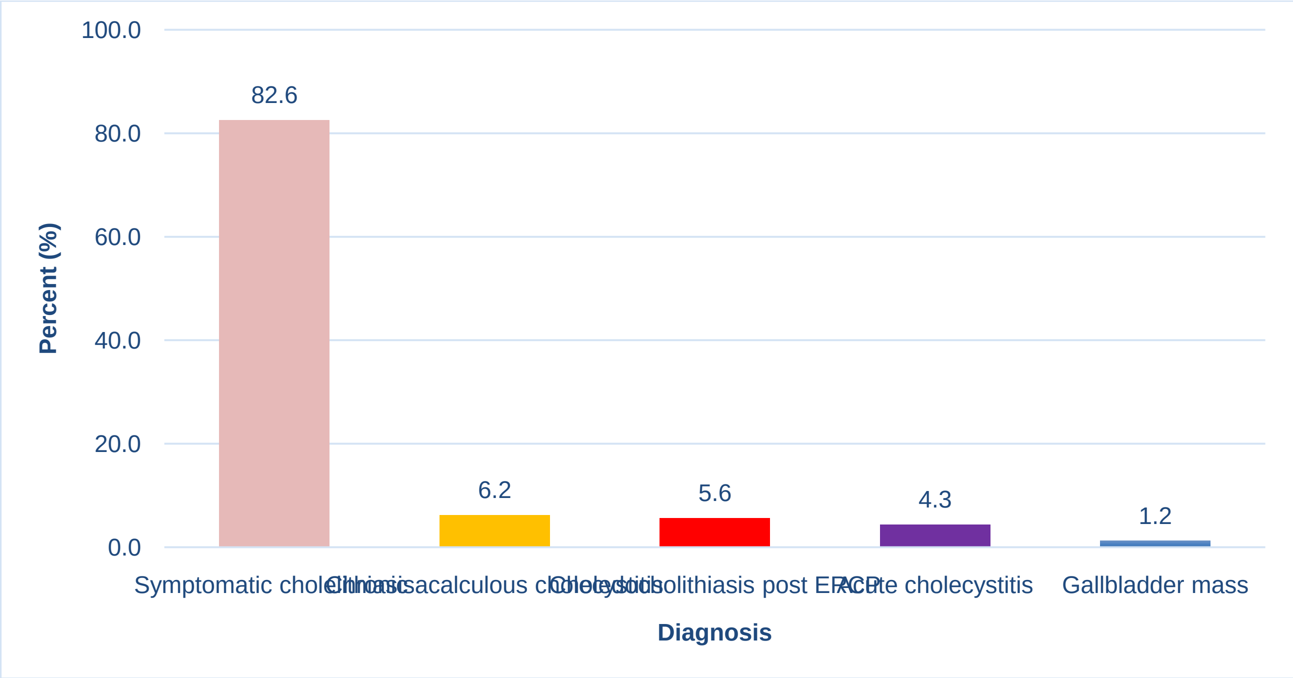


*Figure 1: Diagnosis of patients undergoing laparoscopic cholecystectomy at KNH*

**Perioperative characteristics of patients who underwent laparoscopic cholecystectomy**

The findings also showed that the median duration of surgery was 120 minutes (Interquartile Range [IQR]: 90 – 150 minutes) with 61.5% (n =99) of the surgeries taking ≤120 minutes. The median length of hospital stay was 4 (Interquartile range [IQR]: 3 – 5 ) days as shown in Table 2.

*Table 2: Peri-operative characteristics of patients who underwent LC at KNH*

| | Frequency | Percent |
|---|---|---|
| **Duration of surgery (Median, IQR)** | 120(90 - 150) | |
| **Mean ±SD** | 127.5±45.8 | |
| ≤120 minutes | 99 | 61.5 |
| >120 minutes | 62 | 38.5 |
| **Length of hospital stay (Median, IQR)** | 4(3 -5) | |
| **Mean ±SD** | 4.6±3.5 | |
| ≤7 days | 144 | 89.4 |
| >7 days | 17 | 10.6 |

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**Incidence of bile duct injury in patients undergoing laparoscopic cholecystectomy**

The incidence of bile duct injury in patients undergoing laparoscopic cholecystectomy at KNH was 5% with a 95% Confidence Interval [CI]: 2.2% to 9.6% as shown in Figure 2.

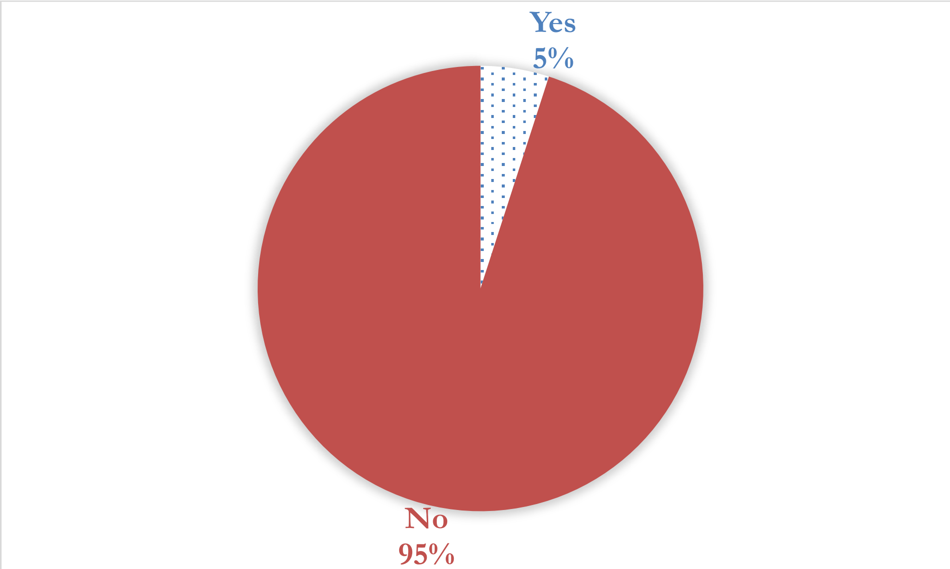


*Figure 2: The incidence of bile duct injury following laparoscopic cholecystectomy at KNH*

**Factors associated with bile duct injury following laparoscopic cholecystectomy**

The findings sought to investigate factors associated with bile duct injury following laparoscopic cholecystectomy and showed that there was a significant difference in duration of surgery among patients who had BDI, 174(SD±64.2) and those who did not have BDI, 125.9(SD±44.6) minutes.

*Table 3: Factors associated with BDI following laparoscopic cholecystectomy at KNH*

| **Variables** | **Presence of BDI** | | |
|---|---|---|---|
| | **Yes n (%) or Mean (SD)** | **No n (%) or Mean (SD)** | **P-value** |
| **Age (Mean ±SD) years** | 45.1±16.4 | 42.5±14.1 | 0.606* |
| **Duration of surgery (Mean ±SD) minutes** | 174±64.2 | 125.9±44.6 | **0.021*** |
| **Length of hospital (Mean ±SD) days** | 6.7±4.6 | 4.5±3.5 | 0.100* |
| **Gender** | | | 0.100** |
| Female | 7(5.1) | 130(94.9) | |
| Male | 1(4.2) | 23(95.8) | |
| **Diagnosis** | | | 0.151** |
| Symptomatic cholelithiasis | 6(4.5) | 127(95.5) | |
| Chronic acalculous cholecystitis | 0 | 10(100) | |
| Choledocholithiasis post ERCP | 2(22.2) | 7(77.8) | |
| Acute cholecystitis | 0 | 7(100) | |
| Gallbladder mass | 0 | 2(100) | |

*Independent t-test, ** Fischer's exact test

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**Time to diagnosis of bile duct injury**

In investigating the time of diagnosis of BDI, 37.5%(n =3) of the patients had an early diagnosis, 25%(n =2) had an intermediate diagnosis and 37.5%(n =3) had a delayed diagnosis as shown in Figure 3.

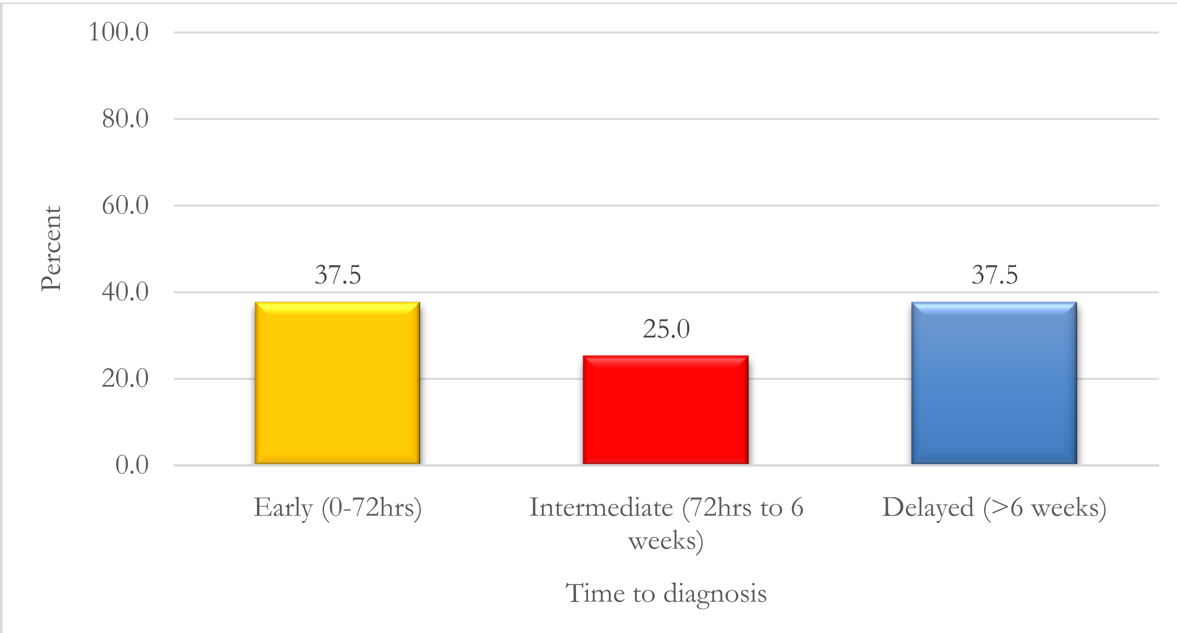


*Figure 3: Time to diagnosis of bile duct injury*

**Classification of bile duct injury**

BDIs were classified using the Strasberg Classification where half of the patients 50%(n =4) with BDI were classified as A as shown in Table 4.

*Table 4: Classification of bile duct injury using the Strasberg Classification*

| Classification | Frequency | Percent |
|---|---|---|
| **Minor** | | |
| A | 4 | 50.0 |
| D | 1 | 12.5 |
| **Major** | | |
| E2 | 1 | 12.5 |
| Not classified | 2 | 25.0 |

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**Findings for intraoperatively diagnosed bile duct injury**

Among the patients with BDI, 37.5%(n =3) of them were diagnosed intraoperatively, with all 3 being Strasberg A injuries. All of them had local inflammation as shown in Table 5.

*Table 5: The intraoperative findings among patients with bile duct injury (n =8)*

| | **Frequency** | **Percent** |
|---|---|---|
| Intraoperative findings described | 3 | 100 |
| Presence of local inflammation | 3 | 100 |
| Anatomical landmarks of the CVS unclear | 0 | |
| Anatomical variations of the biliary tract noted | 0 | |
| Intraoperative cholangiography performed | 0 | |
| Excessive bleeding | 0 | |
| Conversion to open procedure | 2 | 66.7 |
| Need for ICU admission | 0 | |

**Intervention and length of hospital stay of intraoperatively diagnosed BDI patients**

All the patients who were diagnosed intraoperatively had a primary repair and a mean length of stay of 7(Standard Deviation [SD]±2.4) as shown in Table 6.

*Table 6: The intervention and length of hospital stay of intraoperatively diagnosed BDI patients*

| | **Frequency** | **Percent** |
|---|---|---|
| **Intervention utilized** | | |
| Primary repair | 3 | 100 |
| Length of hospital stay (Mean, SD) days | 7±2.4 | |

**Findings among patients with post-operatively diagnosed BDI**

The findings established that among those diagnosed with BDI post-operatively, 60%(n =3) had delayed diagnosis while 40%(n =2) had intermediate diagnosis. The commonly presenting symptoms included deranged LFTs 100%(n =5), jaundice 80%(n =4) and abdominal pain 60%(n =3). Most of the patients 80%(n =4) were diagnosed using ERCP as shown in Table 7.

*Table 7: Findings among patients with post-operatively diagnosed bile duct injury*

| | **Frequency** | **Percent** |
|---|---|---|
| **Time of diagnosis** | | |
| Delayed diagnosis (>6 weeks) | 3 | 60.0 |
| Intermediate diagnosis (72hrs to 6 weeks) | 2 | 40.0 |
| **Presenting symptoms** | | |
| Nausea/vomiting | 2 | 40.0 |
| Jaundice | 4 | 80.0 |
| Abdominal pain | 3 | 60.0 |
| Deranged LFTs | 5 | 100.0 |

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| | | |
|---|---|---|
| Abdominal distension | 2 | 40.0 |
| **Diagnostic investigations** | | |
| Abdominal ultrasound | 1 | 20.0 |
| ERCP | 4 | 80.0 |
| MRI/MRCP | 3 | 60.0 |

**Interventions and length of hospital stay among post-operatively diagnosed BDI patients**

The findings revealed that 60%(n =3) of the patients were managed using ERCP with stenting, 20%(n =1) were managed using delayed secondary repair with biliodigestive anastomosis, and 20%(n =1) were managed by delayed secondary closure over T tube as shown in Figure 4. The mean length of hospital stay was 14 (SD±5.7) days with a minimum of seven days and a maximum of 21 days.

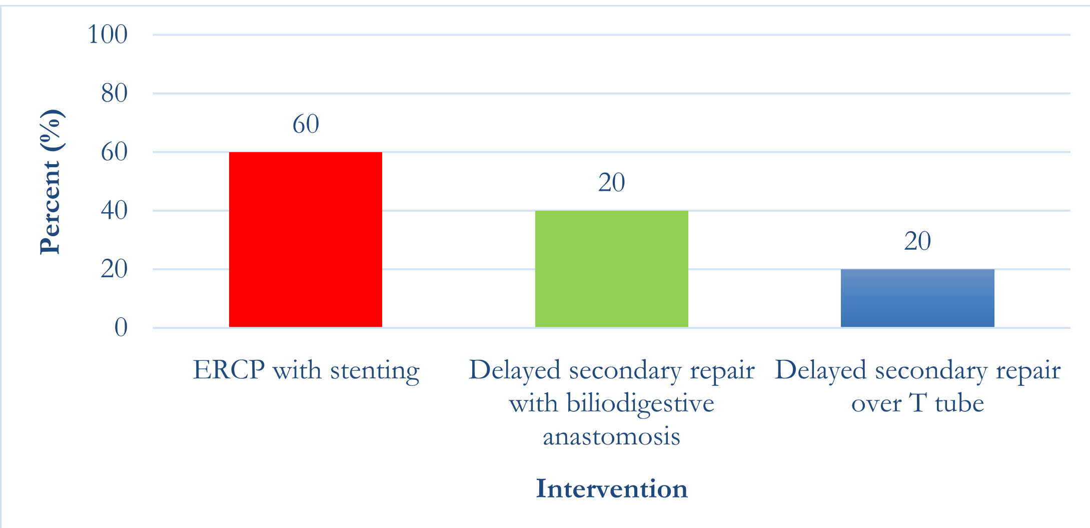


*Figure 4: The interventions among post-operatively diagnosed patients*

**Complications of bile duct injury seen following laparoscopic cholecystectomy**

The findings established that 50%(n =4) of the patients with BDI developed complications. The complications identified included surgical site infections 25%(n =2), bile leak 12.5%(n =1) and biliary structure 12.5%(n =1) as shown in Figure 5.

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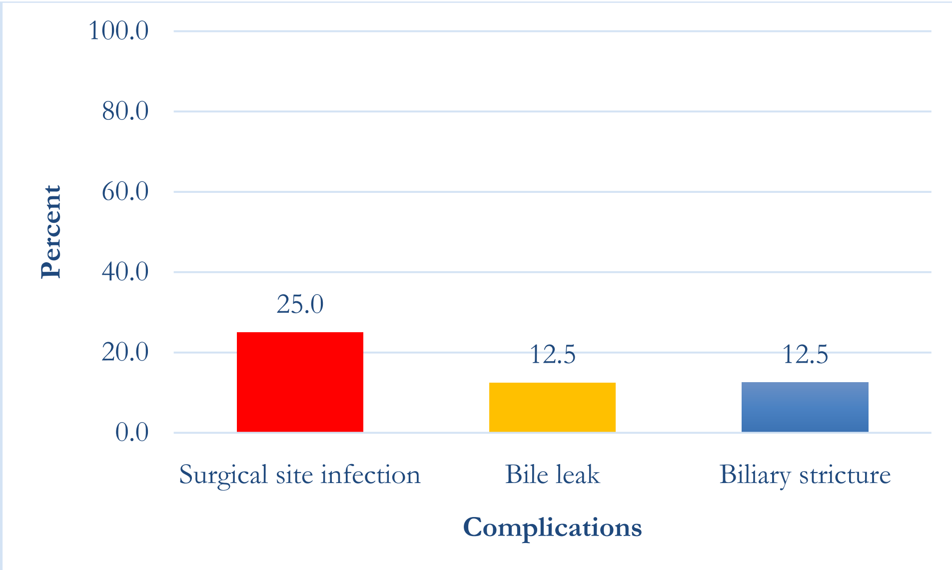


*Figure 5: The complications of bile duct injury seen following laparoscopic cholecystectomy*

**Relationship between interventions and surgical site infections (SSI)**

The findings established that there was no significant association between intervention and SSI among BDI patients following laparoscopic cholecystectomy (p = 0.543) as shown in Table 8.

*Table 8: The relationship between interventions and SSIin LC-associated BDI*

| | **Surgical site infection** | | **P-value** |
|---|---|---|---|
| | **Yes n(%)** | **No n(%)** | |
| **Intervention** | | | |
| ERCP with stenting | 1(50.0) | 4(66.7) | |
| Delayed secondary repair with biliodigestive anastomosis | 1(50.0) | 1(16.7) | 0.543 |
| Delayed secondary repair over T-tube | 0 | 1(16.7) | |

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**Relationship between interventions and bile leak**

The findings from Fischer's exact test established that there was a significant association between interventions and bile leak of laparoscopic cholecystectomy-associated bile duct injury (p =0.014). The patient who had a bile leak was managed using the delayed secondary repair over a T tube as shown in Table 9.

*Table 9: The relationship between interventions and bile leak in LC-associated BDI*

| | **Bile Leak** | | **P-value** |
|---|---|---|---|
| | **Yes n(%)** | **No n(%)** | |
| **Intervention** | | | |
| ERCP with stenting | 0 | 5(71.4) | |
| Delayed secondary repair with biliodigestive anastomosis | 0 | 2(28.6) | 0.014 |
| Delayed secondary repair over T-tube | 1(100) | 0 | |

**Relationship between interventions and biliary stricture**

The findings established that there was no significant association between intervention and biliary stricture of laparoscopic cholecystectomy-associated bile duct injury (p = 0.480) as shown in Table 10.

*Table 10: The relationship between interventions and biliary structure in LC-associated BDI*

| | **Biliary stricture** | | **P-value** |
|---|---|---|---|
| | **Yes n(%)** | **No n(%)** | |
| **Intervention** | | | |
| ERCP with stenting | 1(100) | 4(57.1) | |
| Delayed secondary repair with biliodigestive anastomosis | 0 | 2(28.6) | 0.480 |
| Delayed secondary repair over T-tube | 0 | 1(14.3) | |

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# CHAPTER FIVE: DISCUSSION

In this study, patients undergoing laparoscopic cholecystectomy had a female preponderance of 85.1% (M: F ratio of 1:5.7). This is attributed to a higher incidence of gallstone disease seen in women at KNH (4). The mean age of patients was 42 years. This is higher than in a study done by Jani (15) which showed a mean age of less than 40 years. This could be due to an increasing number of clients over the age of 40 years seeking healthcare services as well as increased life expectancy over the past 10 years. 46% of patients resided in Nairobi, likely due to the location of the study site within Nairobi county while the majority of patients were employed, owing to LC majorly being an elective procedure hence patients with formal employment and medical insurance being more likely to seek out the surgical service.

Symptomatic cholelithiasis (82.6%) was the most common indication for LC. This figure is lower than that seen by Jani where 97.5% of patients who had undergone cholecystectomy were found to have gallstones (15). These high figures in both studies can be explained by the increasingly sedentary lifestyle, incidence of obesity, and increasing age among the Kenyan population, all identified risk factors for cholelithiasis.

The mean duration of surgery was described as 127.5 minutes with a median hospital stay of 4 days. This is comparable to a study by Vaibhav(10), which described an average length of stay of 3.9 days for patients with acute cholecystitis who underwent laparoscopic cholecystectomy, and Adisa (14) where operation times ranged from 65 to 105 minutes with all patients being discharged by the second postoperative day. The longer average time of surgery in KNH may include both time for setup of laparoscopic equipment and anesthetic time, not giving a true picture of the duration of surgery whereas an increased hospital stay following what is an elective procedure arises since many patients tend to remain in the wards after being discharged as they wait for clearance from their medical insurer or are unable to clear their bills promptly.

In this retrospective study, we describe an incidence rate of 5%, accounting for a total of 8 biliary injuries among 161 patients who underwent laparoscopic cholecystectomy at KNH over eight years. This incidence rate is notably higher than that demonstrated by Tornqvist et al who

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described an incidence of 1.5% in LC against rates of 0.1 to 0.2% seen during open cholecystectomy (3). The rate is also higher than seen at several other centers internationally (13,17,19,23). Drawing from our findings, in 3 cases (37.5%) the presence of local inflammation is described, described a significant factor in the occurrence of injuries (19). Anatomical variations in the biliary tree, unsuitable surgical techniques, and attempts to control excessive bleeding may also result in injury (24,27,28). The high incidence may also be attributed to BDIs having been shown to occur more frequently early in the surgeon's training, with surgical trainee/resident-performed procedures being associated with a higher incidence of injuries due to the steep learning curve for LC(28,51).

In 6 cases where BDI occurred, patients were being managed for symptomatic cholelithiasis with 2 patients on management for choledocholithiasis post ERCP. None of the patients being followed up for cholecystitis sustained BDI. This contrasts with a study by Perakis et al where acute cholecystitis was found to correlate strongly with biliary injury during LC (13). In KNH, acute cholecystitis accounts for a very small number of patients undergoing LC (4.3%) compared to those presenting with symptomatic cholelithiasis (82.6%), hence more likely that injuries would occur in the larger number of patients with gallstone disease, some of whom had associated inflammatory changes.

Minor injuries accounted for 62.5% of LC-associated BDIs, with 60% of these being diagnosed intraoperatively. 1 case (12.5%) fits the description of a type E2 major injury. For patients who had postoperatively diagnosed major BDI, a mean stay of 14 days is shown. This notably differs from findings by Perakis where immediate reconstructive surgery for major (Strasberg E) injuries resulted in 60% of patients developing complications and an average hospital stay of 38 days (13). Immediate repair of major injuries is likely to result in postoperative complications due to the likelihood of unidentified ischemic injury and bile duct strictures that will occur during healing. It is therefore more prudent to divert the biliary system, allow for inflammation to resolve, and for areas of ischemia to become evident. This is further supported by David et al who recommended immediate repair of major bile duct injuries due to the increased risk of adverse outcomes in the postoperative period (45).

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In all cases of intraoperatively diagnosed BDI, a description of local inflammation was given. Anatomical variations and unclear landmarks were, however, not described/identified in any of the cases. Intraoperative cholangiography (iOC), a tenet for safe cholecystectomy, was not reported in any of the LC procedures undertaken at KNH. Its routine use is a cost-saving measure in complicated cases as it lowers the risk of injury(35) whereas other authors deem its use as unnecessary where an injury is obvious at the time of surgery (13). The lack of application of the universal culture of safety in KNH may be attributed to a lack of knowledge and standard practice of the same among surgeons and/or surgical trainees, most notably in the documentation of LC procedures.

Primary repair was undertaken in these cases of intraoperatively recognized BDI, 66 % of whom required conversion to open procedure. No complications were reported. Several authors argue comparably that BDIs recognized during LC should be operated on immediately and there is the best chance of successful outcome (44,45). This points to immediate repair when patients are in optimal physiological condition and contamination is absent, providing the best chance of good postoperative recovery, reduced hospital stay, and improved quality of life.

Among those who were diagnosed with BDI post-operatively, 60% had delayed diagnosis while 40% had intermediate diagnosis. Similar to findings by Lillemoe (29), deranged LTFs (100%), jaundice (80%), and abdominal pain (60%)) were the most commonly described signs and symptoms. Positive signs and symptoms, and deranged markers point to the vital role that clinical findings play in identifying the likelihood of injury in post-LC patients.

Following postoperative diagnosis of BDI, 60% of patients were managed by ERCP with stenting, 20% by biliodigestive anastomosis, and 20% by delayed secondary closure over T tube. Endoscopic intervention is shown to provide good outcomes in the management of BDIs both as a mode of management and as an adjunct to surgical intervention (41,45). The application of ERCP in KNH is vital in situations where the injury is diagnosed postoperatively and patient optimization is required before surgical reconstruction or as a definitive management option.

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Complications were noted in 50% of patients managed for BDI, with surgical site infections being the most commonly described at 25%. Findings by Soomro described surgical site infections representing 15% of all post-operative complications and recurrent cholangitis was seen in 5% of cases(24). In our study, SSIs accounted for the majority of complications with no cases of cholangitis following management of BDI reported. The occurrence of SSI following BDI may be attributed to bacterial contamination of the peritoneal cavity and surgical incision sites, which supports the recommendation for guided antibiotic therapy following injury (46). Similar to Jani's findings (15), no mortalities were reported.

No significant association was established between the time of diagnosis, intervention undertaken, and complications among patients with LC-associated BDIs. However, in the case of delayed secondary repair over a T tube for BDI diagnosed in the intermediate period, postoperative bile leak was seen to occur (P=0.014). Findings by Stewart (26) described a primary repair over a T tube being associated with unsatisfactory outcomes and the occurrence of biliary leakage. The occurrence of bile leak post-repair may be due to ongoing inflammation and ischemia following injury and/or tube displacement with continued leakage.

## CONCLUSION

An incidence of 5% for biliary duct injuries after LC at KNH is higher than the other centers. A high index of suspicion in cases of altered anatomy and local inflammation and employing safe cholecystectomy strategies especially the use of intraoperative cholangiography (when indicated) will likely reduce the incidence of injuries. There were no statistically significant differences between the timing of bile duct reconstruction and the postoperative outcomes. Immediate repair is safe, has good long-term outcomes, and is associated with shorter hospital stays.

## RECOMMENDATIONS

A multicenter study on laparoscopic cholecystectomy-associated BDI with a focus on patient and intraoperative factors, type of injuries, timing of interventions undertaken, and follow-up for complications over an extended period is recommended.

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# APPENDIX 1: DATA ABSTRACTION CHECKLIST

**INCIDENCE AND OUTCOMES OF BILE DUCT INJURY FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY AT KENYATTA NATIONAL HOSPITAL**

Study number………………………

1. **Patient Demographics**

a) Age……………… b) Sex M ☐ F ☐ c) BMI………………

d) Residence…………………………… e) Occupation…………………………

2. **Perioperative Details**

a) Date of admission…………………… b) Diagnosis…………………………….

c) Date of laparoscopic cholecystectomy………….. d) Duration of surgery(mins)……

e) Date of discharge…………………… f) Length of hospital stay (days)……………….

3. **PRESENCE OF BDI**(reported in operation notes/imaging reports/review notes)
   **Y** ☐ **N** ☐

4. **Time of Diagnosis**

a) Early (0-72hrs) ☐ b) Intermediate (72hrs to 6 weeks) ☐ c) Delayed (>6 weeks) ☐

5. **Classification of BDI (using the Strasberg Classification)**

a) Minor
A ☐ B ☐ C ☐ D ☐

b) Major
E1 ☐ E2 ☐ E3 ☐ E4 ☐ E5 ☐

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**6. Intraoperatively Diagnosed BDI**

a) Indication for surgery……………………………………..

b) Intraoperative findings described Y☐ N☐

c) Presence of local inflammation Y☐ N☐

d) Anatomical landmarks of the CVS unclear Y☐ N☐

e) Anatomical variations of the biliary tract noted Y☐ N☐

f) Intraoperative cholangiography performed Y☐ N☐

g) Excessive bleeding Y☐ N☐

h) Conversion to open procedure Y☐ N☐

i) Intervention taken:
Primary repair ☐ Primary biliodigestive anastomosis ☐ Percutaneous drainage ☐

j) Need for ICU admission Y☐ N☐ Indication………………………………

k) Length of hospital stay (days)………………………

**7. Postoperatively Diagnosed BDI**

a) Intermediate diagnosis (72hrs to 6 weeks) ☐ b) Delayed diagnosis (>6 weeks) ☐

c) Presenting symptoms:
Nausea/vomiting ☐ Jaundice ☐ Deranged LFTs ☐ Abdominal pain ☐
Fever ☐ Elevated CRP ☐ Abdominal distension ☐ Leukocytosis ☐

d) Diagnostic investigation done:
Abdominal ultrasound ☐ ERCP ☐ CT scan Abdomen ☐
PTC ☐ MRI/MRCP ☐

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e) Intervention taken:

Nonoperative management ☐ Percutaneous drainage ☐ ERCP with stenting ☐

Delayed secondary repair with biliodigestive anastomosis ☐ Liver resection ☐

f) Need for ICU admission Y☐ N☐ Indication…………………………………

g) Length of hospital stay (days)…………………………

**8. <u>Complications Post BDI Repair</u>**

a) Surgical site infection ☐ b) Intraabdominal collection/abscess ☐

c) Bile leak ☐ d) Postoperative bleeding ☐

e) Cholangitis ☐ f) Secondary biliary cirrhosis ☐

g) Biliary stricture ☐ h) Death ☐