PRACTICE OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAGHY IN KENYATTA NATIONAL HOSPITAL

By: Dr. Sajni. H. Pabari

MBChB (University of Nairobi)

A proposal submitted in part fulfillment of the degree of Master of Medicine, Internal Medicine

Department of Clinical Medicine and Therapeutics,

University of Nairobi

DECLARATION

This research proposal is my original work as a requirement for the degree of Masters of Medicine in Internal medicine and has not been presented for a degree to any other university.

Signature ……. Date……11/8/2022…….

PRINCIPAL INVESTIGATOR

Dr. Sajni. H. Pabari

MBcHB (University of Nairobi)

RESIDENT, DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS

SUPERVISORS:

This study has been submitted with the approval from my supervisors**:**

Professor Elly Otieno Ogutu

Consultant Physician, Gastroenterologist and Associate Professor

Department of Clinical Medicine & Therapeutics

University of Nairobi

Signed……. Date……12/8/2022……

Professor Erastus Amayo

Consultant Physician, Neurologist and Professor

Department of Clinical Medicine & Therapeutics

University of Nairobi

Signed……..Date……12/8/2022…….

Dr. Andrew Odhiambo

Consultant Physician, Medical Oncologist and Lecturer

Department of Clinical Medicine & Therapeutics

University of Nairobi

Signed…… …. Date……12/8/2022……

DEDICATION

I would like to dedicate this work to my loving parents, Mr. and Mrs. Pabari and sister Roshni.

ACKNOWLEDGEMENT

I would like to give my appreciation to the following people:

Firstly, Almighty God, for always being my guiding light without whom none of this would be possible,

My family, for the undying support. I thank you for helping me materialize every dream of mine and being my backbone through the whole process.

My supervisors for their invaluable guidance and time,

My colleagues for their never-ending encouragement,

My statistician and research assistant for their assistance,

And lastly my friends for their moral support and understanding.

TABLE OF CONTENTS:

LIST OF ABBREVIATIONS:..... VII

LIST OF FIGURES AND TABLES: IX

1.0 ABSTRACT: 1

2.0. INTRODUCTION AND LITERATURE REVIEW:.....2

2.1. THE PROCEDURE:.....3
2.2. INDICATIONS FOR ERCP:.....3
2.2.1. BILIARY INDICATIONS: 4
2.2.2. PANCREATIC INDICATIONS:..... 8
2.3. COMPLICATIONS OF ERCP: 10
2.4. INVESTIGATIONS DONE PRIOR TO ERCP: 13

3.0 JUSTIFICATION: 16

4.0 STUDY QUESTION:.....17

5.0 STUDY OBJECTIVES:.....18

5.1. PRIMARY OBJECTIVES: 18

6.0 METHODOLOGY: 19

6.1 STUDY SITE:.....19
6.2 STUDY DESIGN:.....19
6.3 STUDY POPULATION:.....19
6.4 SAMPLE SIZE:.....20
6.5 SAMPLING METHOD: 20
6.6. INCLUSION AND EXCLUSION CRITERIA: 21
6.6.1 INCLUSION CRITERIA: 21
6.6.2 EXCLUSION CRITERIA:..... 21
6.7 STUDY FEASIBILITY:.....21
6.8 STUDY PROCEDURE & METHODS:.....22
6.8.1 RECRUITMENT:..... 22
6.8.3 STUDY ADMINSTRATION AND QUALITY ASSURANCE:..... 24
6.9 RESEARCH PARAMETERS:.....24
6.9.1 DEFINITION OF RESEARCH VARIABLES: 24
6.10 RESEARCH LIMITATIONS:.....28

7.0 DATA MANAGEMENT: 29

8.0 ETHICAL CONSIDERATIONS: 30

9.0 TIMELINE CHART: 31

10.0 BUDGET: 32

11.0 DUMMY TABLES: 33

12.0 REFERRENCES: 37

APPENDIX: 40

APPENDIX 1: STUDY PROFORMA.....40

LIST OF ABBREVIATIONS:

ERCP – Endoscopic Retrograde Cholangiopancreatography

CT SCAN – Computed Topography Scan

MRCP – Magnetic Resonance Cholangiopancreatography

KNH – Kenyatta National Hospital

USA – United States of America

PD – Pancreatic Duct

CBD – Common Bile Duct

ASGE – American Society of Gastroenterology

ESGE – European Society of Gastroenterology

IV – Intravenous

SOD – Sphincter of Oddi

SoM – Sphincter of Oddi Manometry

FCSEMS – Fully Covered Self-Expandable Metal Stent

PSC – Primary Sclerosing Cholangitis

e.g. – For Example

AP – Acute Pancreatitis

AIP – Autoimmune Pancreatitis

IgG4 – Immunoglobulin G4

CP – Chronic Pancreatitis

EUS – Endoscopic Ultrasound

ESWL – Extracorporeal Shock Wave Lithotripsy

PEP – Post ERCP Pancreatitis

Hb – Hemoglobin

i.e. – That is

LIST OF FIGURES AND TABLES:

FIGURE 1 – BISMUTH CLASSIFICATION OF PERIHILAR TUMORS 10

FIGURE 2 – RECRUITMENT FLOW CHART 27

TABLE 1 – TIMELINE CHART 32

TABLE 2 - BUDGET 33

1.0 ABSTRACT:

Background: Endoscopic Retrograde Cholangiopancreatography has been a major evolution in the field of Gastroenterology for the management of pancreato – biliary disorders. It is now used primarily as a therapeutic tool due to the advent of less invasive imaging modalities. ERCPs have been done in Kenya for the last two decades, however, we do not have comprehensive published data for the same.

Objectives: The primary objectives of this study are to describe the indications, findings, interventions performed and complications of ERCP done in Kenyatta National Hospital Endoscopy Unit and to document which pre-procedural imaging was done prior to the ERCP procedure.

Study Design: Audit of Endoscopic Retrograde Cholangiopancreatography done at the Kenyatta National Hospital Endoscopy Unit.

Setting: The study will be carried out in the Endoscopy Unit of Kenyatta National Hospital.

Methodology and study period: All ERCPs performed between August, 2014 and December, 2019 fulfilling the inclusion criteria will be included in the study. Patient information will be retrieved from patient files and recorded in specified study pro – forma.

Population: All ERCPs performed on patients at the KNH endoscopy Unit between August,2014 and December,2019

Data Management: Data will be entered and managed in Microsoft Access data base. At the end of data entry cleaning will be performed and the data exported into SPSS version 23.0 statistical software for analysis. Descriptive statistics will be used for demographic and clinical characteristics. ERCP indications, findings, interventions and complications will be summarized and presented as percentages with 95% confidence intervals. In addition, pre-procedural imaging done before ERCP procedure will be determined and presented as proportions of the studied population.

2.0. INTRODUCTION AND LITERTURE REVIEW:

ERCP was introduced in 1968, initially as a diagnostic tool but has since evolved to be utilized mainly as a therapeutic intervention. Diagnosis has mainly been taken over by less invasive procedures such as abdominal ultrasound, computed topography (CT) scan, endoscopic ultrasound and magnetic resonance cholangiopancreatography (MRCP). (1)

In the last 5 decades ERCP has greatly advanced to become the established therapeutic gold standard for management of obstructive biliary and pancreatic diseases in the developed world. However, in developing countries like our own, ERCP had not gained its audience up until the last 2 decades. It was first done in Kenyatta National Hospital Endoscopy Unit in 2014. Before then we relied on open surgery for management of simple pancreato-biliary conditions that could easily be treated with the minimally invasive ERCP procedure, further on increasing morbidity and mortality especially in poor surgical candidates(2).

In Kenya we do not have any comprehensive published data for the same, however unpublished data indicate 200 – 300 cases are done every year in the private sector. (3)

ERCP is technically more demanding and time consuming than other endoscopic procedures. Therefore, requiring adequate patient co-operation, preparation and user expertise.(1)

2.1. THE PROCEDURE:

Patient preparation with adequate clinical, laboratory and non-invasive workup is done. Once patient is declared a suitable candidate for the procedure, informed consent is obtained. Patients are usually fasted for at least 6 hours prior to the procedure to allow adequate gastric emptying for clear visualization and to reduce risk of aspiration. Adequate sedation is given during the procedure and patient is placed in prone, supine or left lateral decubitus position.

A side-viewing duodenoscope is then passed through the mouth and stomach to the duodenum. The major duodenal papillae (ampulla of Vater) is identified and checked for any abnormality. This gives access to ventral pancreatic duct (PD) and common bile duct (CBD). The minor duodenal papilla is then checked for any abnormality. It is the opening of the accessory pancreatic duct and is cannulated in patients with pancreatic divisum.(4,5)

To visualize the biliary and pancreatic systems adequately, successful cannulation of the desired duct is necessary, with experienced endoscopists achieving an overall success rate of 94% (11,16). There are various biliary cannulation techniques available including sphincterotome, guide- wire assisted, contrast-assisted or a combination of the three. (1)

After successful cannulation, contrast is injected and a cholangiogram or pancreatogram is fluoroscopically obtained. Once the underlying abnormality is viewed, specific accessory equipment can be passed through the scope for appropriate therapeutic interventions.(4)

2.2. INDICATIONS AND INTERVENTIONS OF ERCP:

Indications can be broadly classified into:

- Biliary – malignant and non-malignant causes
- Pancreatic – malignant and non-malignant causes

2.2.1. BILIARY INDICATIONS AND INTERVENTIONS:

Choledocholithiasis:

Choledocholithiasis was the first and most common therapeutic use of ERCP. Allowing both stone clearance and drainage of bile, it has been the gold standard for management of bile duct stones for the last 3 decades. (1,6–9) Whether symptomatic or not, the ESGE recommends ERCP for all CBD stones. (10)

For ascending cholangitis not responsive to medical therapy, immediate ERCP has shown most benefit and for those patients responding to intravenous (IV) hydration and antibiotics, ERCP is recommended within 24 – 48hours. For those patients undergoing urgent ERCP procedures, the aim of the procure is for biliary drainage rather than stone extraction. (10)

If ERCP is being planned with a laparoscopic cholecystectomy, then sequencing of the two procedures can be ERCP pre-operatively, intra-operatively or post-operatively, none proven to be superior than the other. However, each has its own risk profile. Pre-operative ERCP carries risk of interval migration of gall stones before the surgery and exposure of patients to ERCP complications. Intra- operative ERCP requires two specialists unless the surgeon is able to perform the ERCP himself. There is a chance of technical failure in post-operative ERCP necessitating repeat surgery for duct exploration and clearance. If preoperative ERCP is done, laparoscopic surgery should be followed up within 2 weeks to avoid cholecystitis, biliary colic, recurrence of bile stones, biliary pancreatitis and higher conversion rates to open cholecystectomy.(10,11) In 2014, Wanis et al., stated the role of ERCP for choledocholithiasis without cholangitis in patients who are poor surgical candidates for various reasons. Another study done by Lai et al. showed markedly reduced mortality rates with ERCP compared to surgical drainage, with further studies showing increasing morbidity and mortality with delaying ERCP in severe ascending cholangitis.(1) An adequate outlet is required for stone removal, this is provided by electrocautery through the SOD to gain access to the bile and pancreatic ducts.(10) Sphincterotomy on its own reduces the rate of recurrence of biliary symptoms to 20.2% compared to 11% in cholecystectomy patients as shown by a study done by Pereira-Lima et al.(1) Balloon or basket catheters, both equally efficacious can be used for stone removal with complete extraction seen in up to 91.3% as shown by a study done at a Finnish hospital in 2012. In

the event of incomplete stone removal, the ESGE recommends insertion of stents which reduces stone volume and load by 44 – 96%. Plastic stents are usually used for choledocholithiasis as they are cheaper and have reduced stent migration as compared to metal stents. Stone removal can then be reattempted after 3 - 6months. Difficult stone, (defined by stone characteristics, i.e., diameter(>1.5cm), number, shape or location and anatomical factors, i.e., sigmoid shape CBD, CBD strictures, short distal CBD and narrow CBD angle) are usually not cleared with routine interventions and may therefore require large balloon dilation, mechanical lithotripsy or cholangioscopy-assisted electrohydraulic/laser lithotripsy. Papillary balloon dilation is usually reserved for patients with coagulation disorders or abnormal anatomy with stones less than 8mm due to poor outcome and need for further intervention. (6,8)

Biliary Strictures:

Biliary strictures can be caused by inflammation (– recurrent cholangitis, primary sclerosing cholangitis), malignancy, postoperative (- post-biliary reconstruction, post-cholecystectomy), trauma, post-radiation, infections and ischemia. A suspicion of biliary stricture is derived clinically after which imaging using MRCP or CT scan is done to elicit the cause of the obstruction. ERCP is then the gold standard therapeutic intervention used to determine the tissue diagnosis and appearance of the stricture. (1,12)

According to a study done by Wanis et al., brushing and cytology is done for strictures with a 100% specificity and 50% sensitivity. Stenting is done to reduce risk of cholangitis and may be needed for up to a year in benign strictures and indefinitely for malignant strictures. Stenting has a long-term re-stenosis rate of about 20% - 62% as shown in a study done by Draganov et al. compared to surgery which also carries a morbidity rate of 33.3% and mortality rate of 1.3%. Multiple stents are used for benign strictures and 3monthly repeat ERCP is done while increasing the number of stents with each procedure for up to 1 year.(1) A large study done by Deviere et al. showed increase success rate, easier insertion and reduction in need of repeat stent insertions with fully covered self-expandable metal stent (FCSEMS).(12)

Dominant stricture is a narrowing with residual diameter of <1.5mm in the CBD, or <1mm in the hepatic duct. They mainly occur in patients with primary sclerosing cholangitis

(PSC) and pose a high risk for progression to cholangiocarcinoma. Therefore, extensive imaging, laboratory work up and ERCP for biopsy and brushing and eventually stenting to relieve symptoms once malignancy has been ruled out are needed. Stenting carries a risk of bacterial cholangitis, hence, endoscopic dilation with or without stenting is recommended as the first therapeutic choice by the American Association for the Study of Liver Diseases guidelines for management of strictures in PSC.(1) Dilation can be done with hydrostatic balloons or graduated catheters and can be performed for dominant strictures, postoperative strictures and strictures resulting from choledocholithiasis.(13)

Biliary Leak:

Biliary leaks are seen post cholecystectomy and can arise from the cystic duct, bile duct or duct of Luschka. They are classified as low grade – require complete filling of intrahepatic ducts to demonstrate contrast leak, or high grade – obviously evident before intrahepatic opacification. Success rates for bile leak endoscopic intervention ranges from 80-100%.(13) Bile leak is often associated with strictures that are recognized intraoperatively or early in the postoperative period, while ischemia and subsequent fibrosis is seen in those presenting late.

Sphincterotomy is done to decompress the bile duct and stenting done to maintain patency for 4 – 6 weeks. (13)

Sphincter of Oddi Dysfunction:

The Rome III revision of Milwaukee Biliary Group classifications categorizes biliary SOD into 3; Type I which is characterized by biliary-type pain, abnormal aminotransferases, bilirubin, or alkaline phosphatase (over 2 times normal values) documented on 2 or more occasions and a dilated bile duct (>8 mm on US). Endoscopic sphincterotomy will offer resolution in 90% of cases and therefore sphincter of Oddi manometry (SOM) is unnecessary. Type II SOD is characterized by biliary-type pain and one of the previously mentioned laboratory or imaging abnormalities. SOM is recommended to determine the diagnosis and select patients likely to benefit from endoscopic therapy. The EPISOD trial done by Cotton et al showed that Type III SOD does not exist.(13)

Cholangiocarcinoma:

ERCP is primarily for palliative purpose in cholangiocarcinoma. Majority of patients present with unresectable disease. (1) Decision between surgical or endoscopic approach depends on the location of the tumor, i.e., hilar vs non-hilar tumors. Surgical resection is recommended for Bismuth I lesions without metastatic disease. (14)

Type	Bismuth-Corlette Classification of Perihilar Tumors
I	Tumor involves common hepatic duct
II	Tumor involves bifurcation of the common hepatic duct
IIIa	Tumor involves the right hepatic duct
IIIb	Tumor involves the left hepatic duct
IV	Tumor involves both right and left hepatic ducts

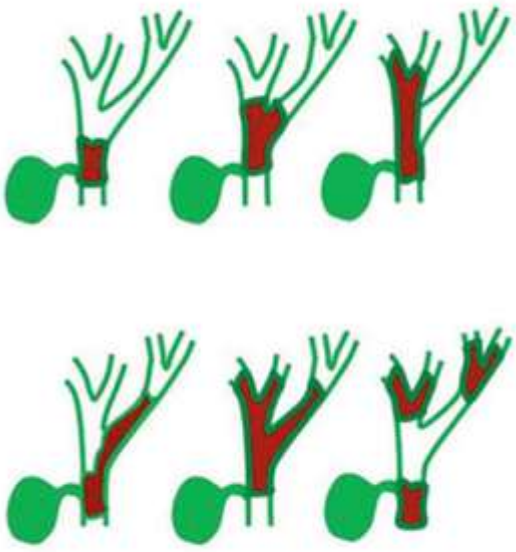

Figure 1 - Bismuth Classification of Perihilar Tumors

50% of the liver needs to be drained to relieve jaundice and unilateral or bilateral stenting of Klatskin tumor depends on bismuth classification. Apart from a select group of patients (cholangitis, chronic jaundice, poor nutritional state and renal dysfunction), pre-operative biliary decompression for resectable tumors has shown no additional benefit. Brushing and biopsy for cytology and histology to confirm diagnosis of cholangiocarcinoma with sensitivity ranging from 18-60% is also done. (1,14)

Ampullary Tumors:

Obstructive jaundice, recurrent cholangitis and dilated pancreatic and biliary ducts (double duct sign) all the way to the level of the papilla raise a suspicion of ampullary tumor.(14) ERCP is done for both staging and therapeutic purposes.(1)

Post-ampullectomy stenting of the pancreatic duct is done to reduce the risk of pancreatitis and biliary stenting may be necessary as a palliative measure in unresectable tumors. Brushing and cytology is done for cytological and histological studies.(1)

2.2.2. PANCREATIC INDICATIONS AND INTERVENTIONS:

Acute Pancreatitis:

Acute pancreatitis (AP) is a common indication for ERCP. 80% of cases of AP can be diagnosed with history, examination, laboratory and imaging studies. An index episode of unexplained or idiopathic pancreatitis comprises the remaining 20%.

Causes of AP include gallstones, alcohol, microlithiasis, pancreatic divisum, autoimmune pancreatitis (AIP) and SOD dysfunction. For gallstones, ERCP is only indicated for gallstones causing impaction and biliary pancreatitis. For patients with an index episode of unexplained acute pancreatitis, ERCP is not the recommended procedure of choice, it is done for treatment of abnormalities found via less invasive procedures, or when those procedures fail to establish a diagnosis in recurrent episodes of acute pancreatitis where it has a sensitivity between 38-79%.(1,15)

Sphincter of Oddi Dysfunction:

The sphincter of Oddi is made up of 3 sphincters; the biliary, pancreatic and common sphincters. Classification is by The Rome III revision of Milwaukee Biliary Group (discussed under biliary SOD above). Depending on the pressures in the common sphincter, a biliary sphincterotomy cutting through the biliary and common sphincter may be adequate to significantly reduce the pressures at the pancreatic sphincters. Manometry is usually done for type 2 SOD, and treatment is dependent on the manometry findings. Pancreatic sphincterotomy is usually reserved for those unresponsive to biliary sphincterotomy alone. Minimal difference in preventing recurrent episodes of pancreatitis was found in patients with pancreatic SOD managed with combined biliary and pancreatic

sphincterotomies (52.8%) vs biliary sphincterotomy alone (51.5%). Manometry and sphincterotomy is not recommended for type 3 SOD as evidenced by a randomized multicenter trial done by Cotton et al.(15)

Autoimmune Pancreatitis:

Autoimmune pancreatitis (AIP) is a cause of chronic pancreatitis but can also precipitate an acute episode. The 2 types of AIP include; type I (lymphoplasmacytic sclerosing pancreatitis) which is seen in older patients and mainly mediated by immunoglobin G4 (IgG4), while type II (idiopathic duct-centric pancreatitis) is seen in younger patients and mainly mediated by granulocyte epithelial cells. Due to geographical differences in the role of ERCP for AIP, the International Consensus Diagnostic Criteria for AIP recommend use of ERCP when CT scan findings are not typical for AIP and IgG4 associated biliary strictures not responsive to corticosteroid treatment. Biopsy is taken for IgG4 staining and ruling out malignant process with a sensitivity of up to 80% and specificity between 89% to 100% for diagnosing AIP.(15)

Chronic Pancreatitis:

Chronic Pancreatitis (CP) is an inflammatory process involving destruction of pancreatic parenchyma and ducts together with irreversible fibrosis. ERCP is used in patients with abdominal pain caused by ductal hypertension due to PD strictures and stones. ERCP has a sensitivity of 71-93%, and a specificity of 89-100% in the diagnosis of CP. ERCP visualizes ductal but not parenchymal changes seen in CP and it may not be able to distinguish between CP and age or alcohol related changes. Therefore, it is primarily reserved for therapeutic purposes.(1,15)

Pancreatic Duct Strictures:

Pancreatic Duct (PD) strictures maybe due to chronic inflammation and fibrosis in CP or malignant causes. ERCP is done for drainage of the main PD to relieve symptoms. Brushings are taken for cytology to evaluate for malignancy. Dilation is usually done with stenting to reduce abdominal pain in 65-84% of patients. Recurrent stent changes may be necessary due to stent blockages. There are no studies to compare use of single versus multiple stents. Use of FCSEMS for PD strictures is yet to be clearly established.

Recurrence of strictures was only seen in 10.5% of patients with CP in a study done by Costamagna et al. (1,15)

Pancreatic Duct Stones:

PD stones are a common cause of AP or CP. PD strictures complicate the ERCP intervention for PD stones. ERCP has significant long-term benefit with reduced morbidity and mortality compared to that seen in pancreatic surgery. Endotherapy which involves pancreatic sphincterotomy, stone extraction, dilation and stenting is done. May require prior extracorporeal shock wave lithotripsy (ESWL). The ESGE recommends ESWL followed by ERCP for obstructive radiopaque stones ≥5mm in the main PD. Short term pain improvement was seen in 77-100% while long term statistics ranged between 54% and 86% as demonstrated by several trials. However, the same has not been reflected by several other studies which have even demonstrated superiority of pancreatic surgery over endoscopic management. 37% patients experienced complete resolution of pain with surgery vs 14% in patients undergoing ERCP in a randomized trial by Dite et al..(1,15)

Other Pancreatic Indications:

PD leaks, pseudocysts and walled off necrosis which can be caused by trauma, iatrogenic injuries, AP and CP. Stenting and sphincterotomy is used for communicating and incomplete PD leaks with success rates of around 60%. Necrosectomy is used for walled off necrosis together with transmural drainage with resolution rates of 91%.(1,15)

Pancreatic divisum is a failure of fusion of the dorsal and ventral pancreatic ducts, occurring in around 7% of the population. Papillotomy of the minor papilla is performed to prevent further attacks of pancreatitis due to pancreatic divisum with a success rate of around 60%.(15)

2.3. COMPLICATIONS OF ERCP:

Pancreatitis:

Post ERCP pancreatitis (PEP) is the commonest complication of ERCP occurring in 1-14% of cases with the majority being mild. (8,16–18) In 1991, Cotton et. al classified PEP as mild, moderate and severe. Mild PEP was defined by the presence of clinical pancreatitis, amylase >3x the normal at 24hours post procedure and requiring extension of planned admission to 2 – 3 days. Moderate PEP is defined by pancreatitis necessitating

admission for 4 – 10 days. Severe PEP is defined as hospital admission for >10days, OR, development of infection, pseudocyst, hemorrhagic pancreatitis, phlegmon, OR, requiring percutaneous drainage or surgery.(19) The Revised Atlanta Classification, though not specific to PEP, includes organ failure, so that mild pancreatitis has no organ failure, local or systemic complications, moderate pancreatitis is defined as organ failure resolving in 48hours and/or local or systemic complications without persistent organ failure and severe pancreatitis as persistent single or multiple organ failure beyond 48 hours.(20)

Risk factors for PEP include prior PEP or recurrent pancreatitis, SOD, female sex, young age, normal bilirubin levels, difficult cannulation, repeated guidewire cannulation of the PD, unintended repeated injection of contrast into the PD, papillectomy, PD cannulation, failure to clear duct stones, end stage renal disease, operator experience, case volume and trainee participation. Several risk reduction recommendations have been given; using ERCP for therapeutic purposes only, prophylactic PD stenting for high risk patients, delayed removal of pancreatic stents for 7 – 10 days, administration of rectal non-steroidal anti-inflammatory drugs e.g. indomethacin and aggressive IV hydration.(19,21)

Infectious complications:

Infectious complications include cholangitis, cholecystitis and duodenoscope related infection.(8,19) Cholangitis is the commonest infectious complication seen in 0.5 – 3% of cases. Risk factors for cholangitis include stenting of malignant strictures, combined percutaneous endoscopic procedures, failed biliary access or drainage, previous stenting, and stent obstruction or migration. Preventive measures that can be applied are antibiotic prophylaxis in selected patients, proper ERCP technique, biliary stenting for incomplete stone removal, appropriate stent selection and timely stent changes.(19)

Cholecystitis seen in around 0.5% of cases occurs in the event of contamination of the gall bladder by nonsterile contrast material.(19,22) Risk factors include cholelithiasis and use of FCSEMS for malignant obstruction. Treatment options include surgery and percutaneous cholecystectomy.(19)

Duodenoscope related infections are very rare but important to note due to transmission of highly pathogenic bacteria including carbapenem-resistant Enterobacteriaceae. They occur due to in-efficient cleaning of the scope, especially in centers where re-usable scopes are

being used. Several equipment processing techniques have shown infection prevention, however the best is yet to be determined. (19)

Hemorrhage:

Bleeding is a potential serious complication of ERCP with sphincterotomy. It is classified as immediate (i.e., occurring intra-procedure or soon after the procedure) or delayed (hours – weeks post-ERCP) or can also be classified as significant or nonsignificant as seen by overt bleeding, hemoglobin (Hb) changes and need for transfusion. Cotton et al graded bleeding as mild if Hb dropped by <3[g/dl] without need for transfusion, moderate if ≤4 units of blood is transfused without need of angiographic or surgical intervention and severe as transfusion of ≥5 units or need for surgical or angiographic intervention.

Sphincterotomies, either biliary and/or pancreatic are the commonest cause of bleeding comprising 0.3 -2% of peri-procedural complications. Rarely, injury to the spleen, liver, vasculature or a pseudoaneurysm can lead to bleeding.(19) According to a study done by Freeman et al., significant bleeding ranged between 1.2 – 2%, out of which 0.6% was mild, 0.9% moderate and 0.5% severe.(22)

Risk factors of hemorrhage derived from studies done by Freeman et al, Masci et al and other meta-analysis include coagulopathy, anticoagulation in the last 3 days, incidence of observed intra-procedural bleeding, precut sphincterotomy, stenosis of papillary orifice and pure-cut current compared to mixed current has higher bleeding risk.(19,22)

Perforation:

Perforation is a serious complication of ERCP and if left undiagnosed has a mortality rate ranging from 8% to 23% due to secondary sepsis and multi-organ failure. Can occur due to the endoscope puncturing the duodenal lumen leading to intraperitoneal perforation, extension of sphincterotomy incision past the intramural section of the bile or pancreatic ducts resulting in retroperitoneal seepage or extramural migration of guidewires or stents. Risk factors include; patient factors such as female sex, older age, suspected SOD, abnormal anatomy e.g. gastrectomy and procedural factors such as intramural contrast injection, increased procedure time, difficult cannulation, dilation of biliary strictures, sphincterotomy and precut papillotomy, inadequate experience of operator, endoscopic papillary large balloon dilation (although less than sphincterotomy alone).(19)

Cardiopulmonary Complications:

Cardiopulmonary complications range between 2.1% to 5.3%, and are often sedation related. Mortality from cardiopulmonary events approximates 0.07%. They include cardiac arrhythmias, aspiration, drop in oxygen saturation or hypotension and air or venous embolism. The adverse events are not clearly defined and hence not standardized where mild episodes of hypoxia or drop in blood pressure may not be recorded. Use of different sedation and prone position has been associated with fewer complications.(19)

Others:

Several other ERCP related adverse effects have been reported. They include stent obstruction and/or migration, pneumothorax +/- pneumoperitoneum, splenic injury, subscapular hepatic hematoma, impaction of a retrieval basket around a bile duct stone and hypersensitivity to contrast.(19)

2.4. INVESTIGATIONS DONE PRIOR TO ERCP:

ERCP is generally being used for therapeutic purposes solely, as less invasive imaging modalities have come to use for diagnostic purposes. These include magnetic resonance cholangiopancreatography (MRCP), computed topography (CT) scans, endoscopic ultrasound (EUS) and plain abdominal ultrasound. These imaging modalities are a useful guide to plan further investigation and therapeutic ERCP.

MRCP provides useful information on the diagnosis, nature, extent and accessibility of the abnormality seen. Advantages of MRCP include; no associated morbidity or mortality, patient preparation is not needed, sedation is usually not required, can be done even in those unfit for ERCP and apart from claustrophobia has not significant adverse effects.(23) Several randomized trials and meta-analysis have shown reduced need for repeat ERCP procedures in patients who have pre-ERCP MRCPs done, similar accuracy between the 2 investigations in detecting extrahepatic cholangiocarcinoma versus benign biliary strictures and MRCP being highly sensitive and specific for diagnosis of biliary strictures post liver transplant.(12)

However, in the case of choledocholithiasis, ASGE recommends use of ERCP without MRCP in high-risk patients. This reduced hospital stay, prevented delay to ERCP and excessive radiological and hospital charges to the patient. High risk is defined as ascending

cholangitis seen clinically, bilirubin more than 4[mg/dl]and CBD stone on ultrasound OR CBD dilation more than 6mm with an intact bladder and bilirubin of 1.8 – 4[mg/dl].(24)

CT scans and ultrasound have been available a long time before MRCP. Diagnostic accuracy of CT scans for both benign and malignant lesions of the pancreato-biliary system ranges between 82% and 91%, respectively, while that of ultrasound is around 88% for both. This is lower than the 98% diagnostic accuracy of MRCP for both benign and malignant lesions.(25)

For benign lesions MRCP has a sensitivity of 100%, whereas ultrasound stands at 80.77% and CT scan at 54.55%. Whereas for malignant disease, CT scan has a sensitivity of 91.67% compared to ultrasound at 79.17%, and MRCP being the most sensitive at 95.83%. (25)

Ultrasound is a useful modality to diagnose biliary dilatation and select patients that require MRCP. Its main advantage being no adverse effects, easy accessibility, speed, ease of performance, low cost and no radiation exposure. However, it has several setbacks including it being user dependent, difficult to perform in obese patients and poor visualization in the presence of excessive bowel gas shadows. (25)

CT scan although a useful and modestly sensitive and specific modality, has largely been over taken by MRCP due to its higher diagnostic accuracy without need of contrast injection yet being non-invasive. However, where MRCP is not available CT scan provides invaluable information prior to ERCP. (24)

EUS combines ultrasound with an endoscope to view the upper gastrointestinal tract. It is an invasive procedure that allows diagnosis and biopsy of the visualized lesion. Its advantages include allowance for FNA and biopsy, injection therapy, drainage of pancreatic pseudocyst, use in patients in whom MRCP is contraindicated due to metal implants and cost – effectiveness compared to ERCP. However, it also has disadvantages such as being user dependent, risk of infection, pancreatitis and perforation amongst others. EUS when compared to MRCP has shown similar sensitivity and specificity as compared to MRCP for diagnosis of choledocholithiasis. However, ERCP remains the gold standard for therapeutic management of bile stones.(26) For pancreatic tumors EUS has a sensitivity

of 96% while together with FNA the sensitivity is 85% and specificity of 98%. For benign pancreatic disease it is used as an adjunct to other imaging modalities rather being the sole diagnostic procedure.(27)

3.0 JUSTIFICATION:

Several studies world over describe the practices of ERCP in various facilities. ERCP procedures have been done at the endoscopy unit in KNH since 2014. Despite increasing use and training of ERCP in our setup, we do not have comprehensive published local data on the same since then.

In Kenya approximately 500 to 600 ERCPs are performed annually. This study will help determine the indications, findings and complication of the ERCP procedure in our population.

The study will form a basis of good clinical practice and policy making of ERCP procedures in our country.

4.0 STUDY QUESTION:

What are the practices of Endoscopic Retrograde Cholangiopancreatography at Kenyatta National Hospital Endoscopy Unit?

5.0 STUDY OBJECTIVES:

5.1. PRIMARY OBJECTIVES:

1. To describe the indications, findings and interventions performed during ERCP procedures done in KNH Endoscopy Unit.
2. To determine the incidence and type of complications of ERCP done in KNH endoscopy Unit.
3. To document which pre-procedural imaging was carried out prior to the ERCP procedure.

6.0 METHODOLOGY:

6.1 STUDY SITE:

This audit will be done at Kenyatta National Hospital Endoscopy Unit.

6.2 STUDY DESIGN:

An audit of Endoscopic Retrograde Cholangiopancreatography done at the Kenyatta National Hospital Endoscopy Unit.

6.3 STUDY POPULATION:

All ERCPs performed on patients at the KNH endoscopy Unit between August,2014 and December,2019.

6.4 SAMPLE SIZE:

Being an audit, all consecutive files of ERCP patients for the 6-year study period will be used for data collection.

A minimum sample size was calculated as follows:

According to health records estimates in KNH, 700 patients underwent ERCP in in the 6-year period of interest. A representative sample will be drawn from this finite population and sample size will be determined as follows:

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

Where

n' = sample size with finite population correction,

N = size of the target population = 700

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated proportion of patients with the most common indication of ERCP – CBD stones from previous studies = 37% (16)

d = margin of error = 5%

$$= \frac{700 \times 1.96^2 \times 0.37 \times 0.63}{0.05^2\,(700-1) + 1.96^2 \times 0.37 \times 0.63}$$

n = 237

A minimum of 237 patient files will be sampled for this study.

6.5 SAMPLING METHOD:

All patient files from August,2014 to December,2019 who underwent ERCP procedure at the KNH Endoscopy Unit fulfilling the inclusion criteria will be used for data collection.

6.6. INCLUSION AND EXCLUSION CRITERIA:

6.6.1 INCLUSION CRITERIA:

All files with ERCP procedure performed in them at the Endoscopy Unit in KNH.

6.6.2 EXCLUSION CRITERIA:

ERCPs without an I.P number or incomplete I.P numbers recorded in the endoscopy register at the Endoscopy Unit in KNH will not be used for data collection.

6.7 STUDY FEASIBILITY:

KNH is the largest referral and teaching hospital in the country. Being one of the busiest, it's Endoscopy Unit runs between 8am and 5pm for elective procedures and 24 hours for emergencies. It is run by a team of trained gastroenterologists, general surgeons, nurses and support staff. Being a training facility; many procedures are also performed by trainees under supervision. Follow up is then undertaken at the once weekly gastroenterology clinic. Approximately 700 ERCPs were performed in the aforementioned 6 years. Around 10 files can be reviewed daily in a 5hour period, equating to 70 days of data collection. Hiring research assistants will help shorten this duration.

6.8 STUDY PROCEDURE & METHODS:

6.8.1 RECRUITMENT:

The investigator and research assistant will retrieve the I.P numbers of all ERCPs done between August,2014 and December,2019 from the register in the Endoscopy Unit at KNH. With the help of records officers, they will then retrieve the files of the same patients. All patients will then be coded with unique identification numbers to maintain patient confidentiality. Each ERCP procedure will then be sub – coded to enable identification of repeat procedures (≥ 2 ERCPs) done on the same patient. To ensure completeness in data collection all consecutive ERCPs found in the collected files will be used for data collection whether recorded in the endoscopy register or not.

The investigators will collect relevant socio-demographic i.e., gender, age and residence and clinical-pathological i.e., indications, findings, interventions, complications and pre-procedural imaging data using a pre-specified study pro-forma.

Missing files will be recorded as so and will not be included in the final data analysis. Secondary sources of data collection such as the nursing cardex will be sought for files with absent/incomplete procedure notes for completeness of data.

All data collected will be stored in a password protected laptop computer which will be in the sole custody of the primary investigator.

During the entire process of data collection and analysis, measures to prevent spread of the COVID – 19 virus by use of adequate sanitization, face masks and appropriate social distancing will be put in place.

6.8.2 RECRUITMENT FLOW CHART:

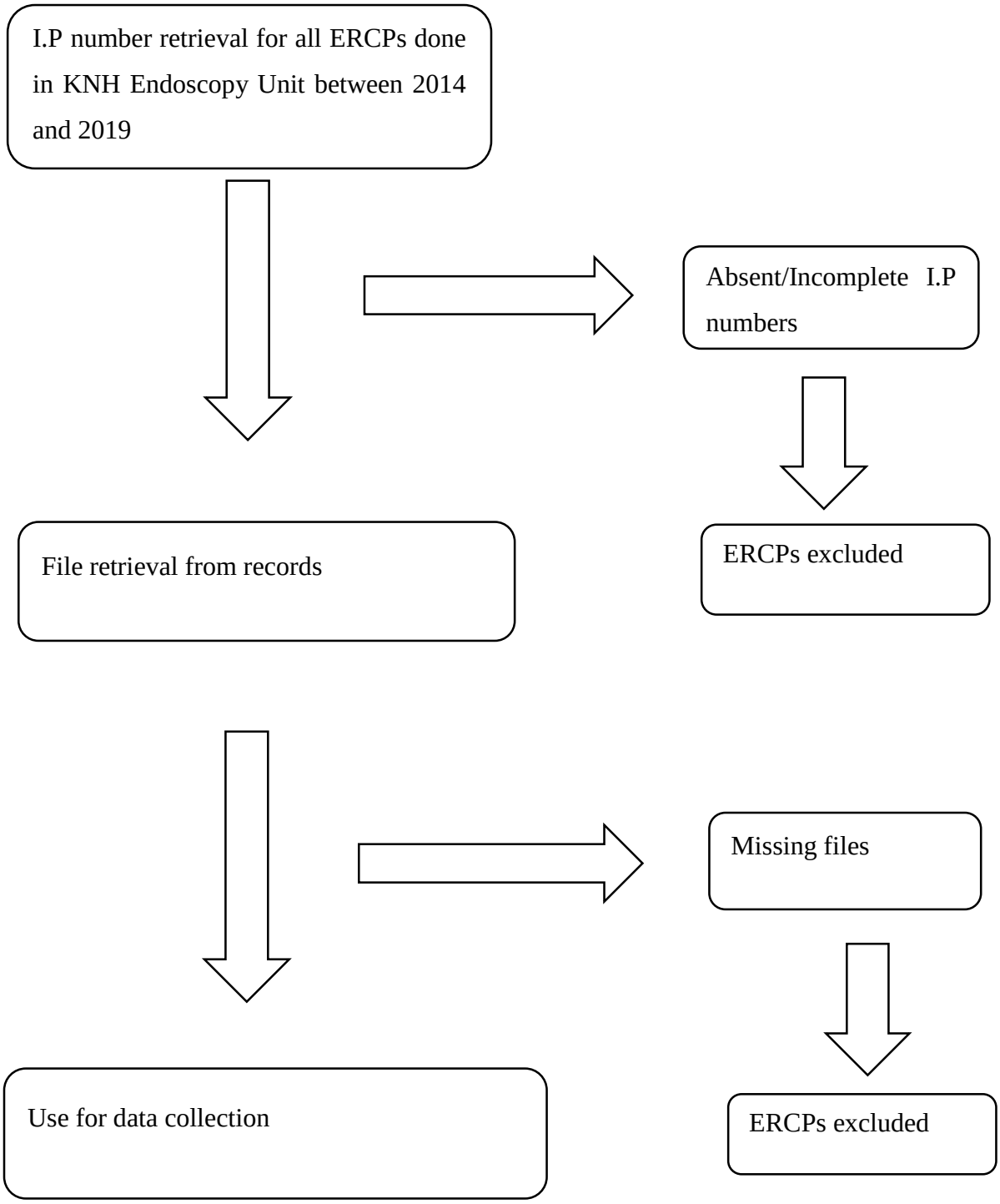

Figure 2: Recruitment Flow Chart

6.8.3 STUDY ADMINSTRATION AND QUALITY ASSURANCE:

The research assistant will be trained and supervised for assurance of accurate and time-efficient data collection. All data collected will be counter checked by the principal investigator to avoid errors. The entire process of proposal development to statistical analysis and book presentation will be done under the guidance of the supervisors and statistician.

6.9 RESEARCH PARAMETERS:

a. Socio – demographic data:
    - Sex
    - Age
    - Residence
    - Co-morbidities
b. Clinical-pathologic data:
    - Indication
    - Successful Cannulation
    - Findings
    - Interventions performed
    - Complications
    - Anesthesia administered
c. Imaging:
    - Pre- procedural non-invasive imaging done

6.9.1 DEFINITION OF RESEARCH VARIABLES:

1.Indications:

This is the reason patient is referred for ERCP.

2. Findings:

Findings are the macroscopic observations made by the endoscopist during the ERCP procedure.

3. Interventions performed:

These are what the endoscopist performs during the ERCP procedure in an attempt to gain therapeutic outcome.

4. Complications:

Complications are unfavorable/unwanted outcomes of the ERCP procedure occurring during, immediately after or up to 4weeks post ERCP.

a) Pancreatitis:

   Pancreatitis will be defined as;

   - Mild – clinical pancreatitis, amylase >3x the normal at 24hours post ERCP and requiring/extension of planned admission to 2 – 3 days.
   - Moderate - pancreatitis necessitating admission for 4 – 20 days.
   - Severe – hospital admission for >10days, OR, development of infection, pseudocyst, hemorrhagic pancreatitis, phlegmon, OR, requiring percutaneous drainage or surgery.

b) Infection:

   The Tokyo guidelines 2007 will be used to define ERCP related infections.

   - Cholangitis will be defined as:
     - Presence of fever >38^{o}C, chills, abdominal pain and jaundice, OR
     - Laboratory evidence of biliary obstruction and inflammation, OR
     - Imaging evidence of biliary obstruction, AND
     - No evidence of acute cholangitis in the one week before the ERCP procedure.
   - Cholecystitis will be defined as:
     - Patient with any 1 of; murphy's sign positive, a mass, pain or tenderness over the right upper quadrant, AND

- One of; fever, elevated white blood cells, elevated C-reactive protein.

- Bacteremia will be defined as:
  - Presence of fever, chill, AND
  - Positive bacterial blood cultures post – ERCP.

c) Hemorrhage:

Hemorrhage will be defined as per Cotton et al as:

- Mild – drop in Hb of <3[g/dl] without need for transfusion
- Moderate - ≤4 units of blood transfused without need of angiographic or surgical intervention.
- Severe - ≥5 units of blood transfusion, OR surgical/angiographic intervention needed.

d) Perforation:

Perforation is the puncturing of viscus by the duodenoscope or accessory equipment used during the ERCP procedure.

e) Cardiopulmonary complications:

- Hypotension:

  Will be defined as a drop in blood pressure at any time during the ERCP procedure below a systolic pressure of 90mmHg and diastolic pressure of 60mmHg.

- Hypoxia:

  Will be defined as a drop in oxygen saturation below 90% at any point during the ERCP procedure.

- Arrythmias:

  Will be defined as any new change in heart rate pattern at any point during the ERCP procedure.

- Air embolism:

  Will be defined as unwanted entry of air into the vasculature during the ERCP procedure, suspected with sudden deterioration in vital signs.

5. Anesthesia:

Will be defined as whether any anesthesia was offered to the patient during the procedure and if yes, then type of the anesthesia.

6.10 RESEARCH LIMITATIONS:

Being a retrospective study, incomplete recording of patient details in the endoscopy registrar may lead to error in data collection.

7.0 DATA MANAGEMENT:

Data will be entered and managed in Microsoft Access data base. At the end of data entry cleaning will be performed and the data exported into SPSS version 23.0 statistical software for analysis. Descriptive statistics will be used for demographic and clinical characteristics. ERCP indications, findings, interventions and complications will be summarized and presented as percentages with 95% confidence intervals. In addition, pre-procedural imaging done before ERCP procedure will be determined and presented as proportions of the studied population.

8.0 ETHICAL CONSIDERATIONS:

Data collection will commence after ethical approval is given by the department of clinical medicine and therapeutics of the University of Nairobi and Kenyatta National Hospital research and ethics committee.

Absolute confidentiality will be maintained. The primary investigator will be the sole holder of all data collected which will be stored in a password protected laptop computer.

All data will be re-coded using unique identifier number which will be used in the data collection forms and later for data analysis.

Data obtained will only be presented after approval from the supervisors and institution of the study.

Data collected will not be used for any other purpose apart from fulfilment of the objectives of this study.

9.0 TIMELINE CHART:

Activity:	Proposed time:
Literature Review	January – February, 2020
Protocol Development	March – November, 2020
Protocol Presentation	December, 2020
KNH Ethical Approval	January - February, 2020
Data Collection	March - April, 2020
Data Analysis	May, 2020
Dissertation write-up	June, 2021
Result Presentation	June, 2021
Corrections and handing in of final report	July, 2021

Table 1: Timeline Chart

10.0 BUDGET:

ITEM	COST (kshs)
Stationery and Printing	35,000
Research assistant	30,000
Statistician	35,000
Subtotal	100,000
Contingency	10,000
Total	110,000

Table 2: Budget

11.0 DUMMY TABLES:

Table 1: Patients characteristics:

Variable	Frequency (%)
Mean age (SD)	
Gender Male Female	
Comorbidities Hypertension Diabetes Malignancy Other None	

Table 2: Indications:

Variable	Frequency (%)	95% CI
Biliary indications CBD stones Biliary strictures Acute cholangitis Stent exchange Biliary tumor Hilar Non-hilar Ampullary tumor Biliary leak Bile duct obstruction or jaundice without accurate diagnosis Sphincter Oddi dysfunction Cholangioscopy		
Pancreatic indications Carcinoma of pancreas Recurrent pancreatitis workup Chronic pancreatitis Pancreatic duct stones Pancreatic duct stricture Pain Pancreatic leak Pancreatic pseudocyst Pancreatic divisum Pancreatic Carcinoma		
Miscellaneous		

Extra biliary malignancy causing biliary obstruction Others		

Table 3: Pre-ERCP imaging:

Variable	Frequency (%)
Pre-ERCP imaging Ultrasound CT scan MRCP Other Not known	

Table 4: Procedure:

Variable	Frequency (%)
Completed ERCP:	
Failed cannulation: Anatomical variation Tight stricture Difficult procedure	
Failure to visualize ampulla	
Abandoned due to peri – procedural complication	
Incomplete ERCP	

Table 5: Findings of ERCP:

Variable	Frequency (%)
Findings Normal ERCP with no intervention CBD stricture: Benign: Malignant: Failure to remove stone Completely Partially Procedure abandoned due to peri-procedural complication	

Table 6: Interventions of ERCP:

Variable	Frequency (%)
Biliary interventions	
Conventional sphincterotomy	
Pre – cut sphincterotomy	
Balloon extraction of CBD stones	
Basket extraction of CBD stones	
Sphincterotomy, incomplete duct clearance and biliary stenting	
Endoscopic large balloon papillary dilation	
Mechanical lithotripsy	
Sphincterotomy and stenting	
Stent insertion	
Biliary stent exchange	
Stent removal	
Stent type:	
Plastic stent	
Fully covered self-expandable metal stent	
Uncovered metal stent	
Pancreatic interventions	
Major papilla pancreatic sphincterotomy	
Pancreatic sphincterotomy (major papilla) and stenting	
Pancreatic duct stone clearance	
Pseudocyst drainage	
Minor papilla sphincterotomy	
Minor papilla stenting	
Miscellaneous	
Biopsy	
Brushing	
Histology report	
Yes	
No	

Table 7: Peri-procedural complications:

Variable	Frequency (%)
Pancreatitis	
Mild	
Moderate	
Severe	
Not defined	
Infectious	
Cholangitis	
Cholecystitis	
Bacteremia	
Other	
Hemorrhage	
Mild	
Moderate	
Severe	
Not defined	
Perforation	
Cardiopulmonary	
Hypotension (bp <90/60mmhg)	
Hypoxia (spo2 < 90%)	
Arrythmias	
Air embolism	
Death	

12.0 REFERRENCES:

1. N Wanis K. Endoscopic Retrograde Cholangiopancreatography: A Review of Technique and Clinical Indications. J Gastrointest Dig Syst [Internet]. 2014 [cited 2020 Mar 3];04(04). Available from: http://omicsonline.org/open-access/endoscopic-retrograde-cholangiopancreatography-a-review-of-technique-and-clinical-indications-2161-069X.1000208.php?aid=30068

2. Okello Michael, Tumusiime Gerald, Nabimanya Viola, Baguma Steven, Ocama Ponsiano. Pioneering endoscopic retrograde cholangiopancreatography in a Sub Saharan African hospital: A case series - ScienceDirect [Internet]. [cited 2020 Mar 22]. Available from: https://www.sciencedirect.com/science/article/pii/S2405857218300597

3. Coelho-Prabhu N, Shah ND, Van Houten H, Kamath PS, Baron TH. Endoscopic retrograde cholangiopancreatography: utilisation and outcomes in a 10-year population-based cohort. BMJ Open. 2013;3(5):e002689.

4. Boškoski I, Tringali A, Costamagna G. Teaching endoscopic retrograde cholangiopancreatography cannulation. Transl Gastroenterol Hepatol. 2019 May;4:30–30.

5. Testoni PA, Mariani A. Minor Papilla Cannulation and Sphincterotomy | Abdominal Key [Internet]. [cited 2020 May 11]. Available from: https://abdominalkey.com/minor-papilla-cannulation-and-sphincterotomy/

6. Gurung R, Purbey B, Koju R, Bedi T. Endoscopic Retrograde Cholangiopancreatography at Dhulikhel hospital: Outcome Analysis. Kathmandu Univ Med J. 2015 Oct 12;12(1):55–9.

7. Alvi AH, Chachar AZK, Parvaiz R. A 4 year ERCP Profile of Tertiary Care Hospital: Indications and Diagnosis. :4.

8. Siiki A, Tamminen A, Tomminen T, Kuusanmäki P. ERCP Procedures in a Finnish Community Hospital: A Retrospective Analysis of 1207 Cases. Scand J Surg. 2012 Mar;101(1):45–50.

9. John A, Mattar K, John AS, Khairat M, Al Kaabi S. Therapeutic biliary and pancreatic endoscopy in Qatar- a five year retrospective audit. Qatar Med J. 2012 Dec;2012(2):8.

10. Manes G, Paspatis G, Aabakken L, Anderloni A, Arvanitakis M, Ah-Soune P, et al. Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy. 2019 May;51(05):472–91.

11. Maple JT, Ikenberry SO, Anderson MA, Appalaneni V, Decker GA, Early D, et al. The role of endoscopy in the management of choledocholithiasis. Gastrointest Endosc. 2011 Oct;74(4):731–44.

12. Hu B, Sun B, Cai Q, Wong Lau JY, Ma S, Itoi T, et al. Asia-Pacific consensus guidelines for endoscopic management of benign biliary strictures. Gastrointest Endosc. 2017 Jul;86(1):44–58.

13. Chathadi KV, Chandrasekhara V, Acosta RD, Decker GA, Early DS, Eloubeidi MA, et al. The role of ERCP in benign diseases of the biliary tract. Gastrointest Endosc. 2015 Apr;81(4):795–803.

14. Anderson MA, Appalaneni V, Ben-Menachem T, Decker GA, Early DS, Evans JA, et al. The role of endoscopy in the evaluation and treatment of patients with biliary neoplasia. Gastrointest Endosc. 2013 Feb;77(2):167–74.

15. Chandrasekhara V, Chathadi KV, Acosta RD, Decker GA, Early DS, Eloubeidi MA, et al. The role of endoscopy in benign pancreatic disease. Gastrointest Endosc. 2015 Aug;82(2):203–14.

16. Qadir A, Khalid M, Younis I, Salamat A. OUTCOME OF ERCP (ENDOSCOPIC RETROGRADE CHOLANGIO-PANCREATOGRAPHY) IN MILITARY HOSPITAL RAWALPINDI. Prof Med J. 2019 Jul 10;26(07):1062–6.

17. Chatterjee S, Rees C, Dwarakanath A, Barton R, MacDonald C, Greenaway J, et al. Endoscopic retrograde cholangio-pancreatography practice in district general hospitals in North East England: a Northern Regional Endoscopy Group (NREG) study. J R Coll Physicians Edinb. 2011 Jun 1;41(2):109–13.

18. El Nakeeb A, El Hanafy E, Salah T, Atef E, Hamed H, Sultan AM, et al. Post-endoscopic retrograde cholangiopancreatography pancreatitis: Risk factors and predictors of severity. World J Gastrointest Endosc. 2016;8(19):709.

19. Chandrasekhara V, Khashab MA, Muthusamy VR, Acosta RD, Agrawal D, Bruining DH, et al. Adverse events associated with ERCP. Gastrointest Endosc. 2017 Jan;85(1):32–47.

20. Banks PA, Bollen TL, Dervenis C, Gooszen HG, Johnson CD, Sarr MG, et al. Classification of acute pancreatitis—2012: revision of the Atlanta classification and definitions by international consensus. Gut. 2013 Jan;62(1):102–11.

21. Dumonceau J-M, Kapral C, Aabakken L, Papanikolaou IS, Tringali A, Vanbiervliet G, et al. ERCP-related adverse events: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy. 2020 Feb;52(02):127–49.

22. Freeman ML, Herman ME, Ryan ME. Complications of Endoscopic Biliary Sphincterotomy. N Engl J Med. 1996;10.

23. Eva C Kaltenthaler, Stephen J Walters, Jim Chilcott. MRCP compared to diagnostic ERCP for diagnosis when biliary obstruction is suspected: a systematic review [Internet]. [cited 2020 Mar 24]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1579209/

24. Anand G, Patel YA, Yeh H-C, Khashab MA, Lennon AM, Shin EJ, et al. Factors and Outcomes Associated with MRCP Use prior to ERCP in Patients at High Risk for Choledocholithiasis. Can J Gastroenterol Hepatol. 2016;2016:1–6.

25. Singh A, Singh Mann H, Thukral Lal C, Singh Rajan N. Diagnostic Accuracy of MRCP as Compared to Ultrasound/CT in Patients with Obstructive Jaundice [Internet]. [cited 2020 Mar 25]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4003596/

26. Giljaca V, Gurusamy KS, Takwoingi Y, Higgie D, Poropat G, Štimac D, et al. Endoscopic ultrasound versus magnetic resonance cholangiopancreatography for common bile duct stones. Cochrane Hepato-Biliary Group, editor. Cochrane Database Syst Rev [Internet]. 2015 Feb 26 [cited 2020 May 12]; Available from: http://doi.wiley.com/10.1002/14651858.CD011549

27. Chung A, Kwan V. Endoscopic ultrasound: an overview of its role in current clinical practice. Australas J Ultrasound Med. 2009 May;12(2):21–9.

APPENDIX:

APPENDIX 1: STUDY PROFORMA

STUDY TITLE: PRACTICE OF ENDOSCOPY IN KENYATTA NATIONAL HOSPITAL

(TICK WHERE APPROPRIATE)

STUDY ID NUMBER:

DATE OF ERCP:

INCOMPLETE/MISSSING PROCEDURE NOTES:

REFERRAL:

YES:

IF YES, FROM:

NO:

INPATIENT :

OUTPATIENT :

SECTION 1 : SOCIODEMOGRAPHIC INFORMATION :

AGE:

SEX:

MALE:

FEMALE:

RESIDENCE:

SECTION 2: PAST MEDICAL HISTORY:

COMORBIDITIES:

HYPERTENSION:

DIABETES:

MALIGNANCY:

IF YES, SPECIFY:

OTHER:

NONE:

SECTION 3: INDICATION:

BILLIARY INDICATIONS:

OBSTRUCTIVE JAUNDICE:

CBD STONES:

BILIARY STRICTURES:

ACUTE CHOLANGITIS:

STENT EXCHANGE:

BILLIARY TUMOR:

HILAR:

COMMON BILE DUCT – NON – HILAR:

AMPULARY TUMOR:

BILLIARY LEAK:

BILE DUCT OBSTRUCTION/DILATION WITHOUT ACCURATE DIAGNOSIS:

SPHINCTER OF ODDI DYSFUNCTION:

STENT INSERTION:

STENT REMOVAL:

CHOLANGIOSCOPY:

OTHER:

PANCREATIC INDICATIONS:

CARCINOMA HEAD OF PANCREAS:

SYMTOMATIC CHRONIC PANCREATITIS WITH PAIN:

PANCREATIC DUCT STONES:

PANCREATIC DUCT STRICTURE:

PANCREATIC DUCT LEAK:

PANCREATIC PSEUDOCYST:

PANCREATIC DIVISUM:

OTHER:

MISCELLANEOUS:

EXTRA BILIARY MALIGNANCY CAUSING BILIARY OBSTRUCTION:

OTHERS:

SECTION 4: PRE-ERCP IMAGING:

ULTRASOUND:

CT SCAN:

MRCP:

EUS:

OTHER:

NOT KNOWN:

SECTION 5: ANESTHESIA:

WAS ANAETHESIA GIVEN:

YES:

NO:

NOT KNOWN:

IF YES:

SEDATION:(SPECIFIC DRUG)

PARALYSIS:(SPECIFIC DRUG)

BOTH:(SPECIFIC DRUGS)

SECTION 6: PROCEDURE:

COMPLETED ERCP:

YES:

NO:

IF NO:

FAILED CANULATION SECONDARY TO:

ANATOMICAL VARIATION:

TIGHT STRICTURE:

DIFFICULT PROCEDURE:

OTHERS:

FAILURE TO VISUALIZE AMPULLA:

ABANDONED DUE TO PERI-PROCEDURAL COMPLICATION:

OTHERS:

SECTION 7: FINDINGS OF ERCP:

SELECT ONE FROM SECTION 3 ABOVE:

OTHERS:

NORMAL ERCP WITH NO INTERVENTION:

BLOCKED STENT:

CBD STRICTURE:

BENIGN:

MALIGNANT:

FAILURE TO REMOVE STONE:

COMPLETELY:

PARTIALLY:

OTHER:

SECTION 8: ERCP INTERVENTION PERFORMED:

BILIARY INTERVENTIONS:

CONVENTIONAL SPHINCTEROTOMY:

PRE – CUT SPHINCTEROTOMY:

BALLOON EXTRACTION OF CBD STONES:

BASKET EXTRACTION OF CBD STONES:

SPHINCTEROTOMY, INCOMPLETE DUCT CLEARANCE AND BILIARY STENTING:

ENDOSCOPIC LARGE BALLOON PAPILLARY DILATION:

MECHANICAL LITHOTRIPSY:

SPHINCTEROTOMY AND STENTING:

STENT INSERTION:

BILIARY STENT EXCHANGE:

STENT REMOVAL:

IF STENTING DONE:

PLASTIC:

METAL:

FULLY COVERED SELF EXPANDING METAL STENT:

UNCOVERED METAL STENT:

CHOLANGIOSCOPY:

OTHER:

<u>PANCREATIC INTERVENTIONS:</u>

MAJOR PAPILLA PANCREATIC SPHINCTEROTOMY:

PANCREATIC SPHINCTEROTOMY (Major papilla) AND STENTING:

PANCREATIC DUCT STONE CLEARANCE:

PSEDOCYST DRAINAGE:

MINOR PAPILLA SPHINCTEROTOMY:

MINOR PAPILLA STENTING:

MISCELLANEOUS:

BIOPSY:

BRUSHING:

HISTOLOGY REPORT:

YES:

(if yes give report)

NO:

SECTION 9: COMPLICATIONS:

NONE:

PANCREATITIS:

YES:

NO:

IF YES:

MILD:

MODERATE:

SEVERE:

NOT DEFINED:

INFECTIOUS:

YES:

NO:

IF YES:

CHOLANGITIS:

CHOLECYSTITIS:

BACTEREMIA:

OTHER:

HEMORRHAGE:

YES:

NO:

IF YES:

MILD:

MODERATE:

SEVERE:

NOT DEFINED:

PERFORATION:

YES:

NO:

CARDIOPULAMONARY:

YES:

NO:

IF YES:

HYPOTENSION (BP <90/60mmHg):

HYPOXIA (SPO2 < 90%):

ARRYTHMIAS:

AIR EMBOLISM:

DEATH:

OTHER: