INDICATIONS, INCIDENCE AND RISK FACTORS OF EARLY COMPLICATIONS OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY AS SEEN IN KENYATTA NATIONAL HOSPITAL

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M.B.Ch. B (U.o.N)

A DISSERTATION SUBMITTED IN PART FULFILLMENT FOR THE AWARD OF MASTER OF MEDICINE IN GENERAL SURGERY OF THE UNIVERSITY OF NAIROBI.

DECLARATION

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

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The research proposal has been presented at the surgical departmental meeting and is hereby approved for presentation to the Kenyatta National Hospital Ethics and Research Committee**.**

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Chairman,
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DEDICATION

To my wife Wanjiku Karogo and our children Liam Mwangi and Nyakio Nyambura you are my inspiration and thank you for the patients.

To my Mum and siblings thank you for the continued support.

To my late father Wilson Mwangi thank you for inspiring me to be the best I can.

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ABBREVIATIONS

KNH-	Kenyatta National Hospital
UON-	University of Nairobi
ERCP-	Endoscopic Retrograde Cholangiopancreatography
CT scan-	Computed Tomography Scan
MRCP-	Magnetic n Endoscopy
SOD-	Sphincter of Oddi Dysfunction
SPPS-	Statistical Package for Social Sciences
ERC-	Ethics and Research Committee

ABSTRACT

Background

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a common procedure in any general surgical service with both diagnostic and therapeutic indications. Complications associated with this procedure are either early or late and include pancreatitis, infections, bleeding and perforations. Despite this being a part of the surgical armamentarium at the Kenyatta National Hospital (KNH), there is paucity of data on the associated early complications.

Objective

To describe the indication, incidents and factors associated with early complications of ERCP in KNH.

Study Design

This was a prospective observational study.

Study Setting

Kenyatta National Hospital endoscopy unit, general surgical and medical wards.

Methodology

All patients who were undergoing ERCP in the endoscopy unit were recruited by consecutive sampling. Informed consent was obtained from the patients. The patients were followed up for the first 72 hours after ERCP had been performed in both medical and surgical wards and the various complications documented by both clinical examination and laboratory tests.

Data Management and Analysis

A structured data collection sheet was used to collect data. The data was entered in the SPSS version 21.0 for analysis and presented in pie charts, tables and graphs format. P value and 95% confidence interval was used to determine statistical significance. Incidence of complications was calculated and presented as frequencies and proportions. The association between age, gender, length and indication of procedure was compared using chi square.

Results

Ninety nine (99) patients were recruited of which ninety eight (98) completed the follow up. The most common clinical indication for ERCP was obstructive jaundice (96.9%) while the most common radiological indication for ERCP was choledocholithiasis (33%). The overall rate of complication was 22.7%, with acute pancreatitis and cholangitis being 12.4% each and bleeding 6%. No patient developed perforation as a complication. Women were found to

have more complications as compared to men as well as older people as compared to younger patients.

Out of the patients who had undergone prior ERCP only three (3) developed complications as compared to nineteen (19) who developed complications and had not undergone prior ERCP.

Conclusion

Obstructive jaundice still remains to be the most common clinical indication for ERCP while pancreatitis and cholangitis still remain to be the leading complications post ERCP. Female gender still is a risk factor for developing complications given that most patients are females. However younger age, longer procedure time and prior ERCP are not predisposing factors to developing complications.

1.0 CHAPTER ONE: INTRODUCTION

Endoscopic Retrograde Cholangiopancreatography (ERCP) is a minimally invasive procedure which is commonly performed in the endoscopy unit, for diagnostic or therapeutic purposes. It involves use of a special endoscope called duodenoscope with a side view camera that helps to visualize the major and minor papillae of the duodenum. The major papilla contains the ampulla of Vater where the biliary and pancreatic duct open. Once the major papilla is identified, cannulation and opacification with dye of the biliary tree or pancreatic duct is done and visualized using fluoroscopy. Once the pathology is identified a therapeutic procedure can be performed. In cases where the therapeutic procedure cannot be performed the diagnosis helps to plan for a more definitive procedure or palliative care(1). Compared to other diagnostic studies of the biliary and pancreatic ducts namely, Ultrasound, Magnetic Resonance Cholangiopancreatography (MRCP), Computed Tomography Scan (CT scan), Percutaneous Transhepatic Cholangiopancreatography(PTC) and biliary scintigraphy ERCP has revolutionized the management of diseases of the pancreas and biliary tree as it offers both diagnostic and therapeutic capabilities at the same sitting(1).

KNH is the only public facility in Kenya which is offering ERCP. Currently 250 ERCPs are being done yearly in the KNH endoscopy unit which is an increase from when we began a few years ago. This number is expected to rise in the coming years in KNH as more gastroenterologists' surgeons and physicians are training on how to do ERCPs in the KNH endoscopy unit which is a World Health Organization recognized Endoscopy Training center. More public and private facilities are expected to offer ERCP as more people gain expertise on the procedure.

Further gastrointestinal diseases remain the most common presentation among both in and outpatient as seen in any surgical services(2,3). Biliary and pancreatic diseases form a good percentage of these diseases and these diseases can be benign or malignant presenting with obstructive jaundice as the most common presentation. The benign diseases include choledocholithiasis, biliary injuries following laparoscopic cholecystectomy and biliary strictures while malignant ones include cancer head of pancreas, Cholangiocarcinoma, Periampullary tumors which usually present late as seen in other centers in the world(4). A majority of these patients will be very sick at presentation and will need a procedure which can be diagnostic and therapeutic. Following diagnostic imaging, a good percentage of these patients are sent for ERCP which offers both diagnostic and therapeutic solution to these

patients which can be done at the same sitting. In some cases, such as with periampullary tumors, diagnostic imaging is inconclusive making ERCP superior as it allows biopsy of pathologies seen during the procedure which are sent for histology for definitive diagnosis.

Complications which arise after ERCP has been done have been documented in various established centers in the world. These complications can either be early or late, with the early complications occurring during the first 72hrs after the procedure and late occurring 72 hours after the procedure(5). The early complications include pancreatitis, septic complications, bleeding and perforations. If unnoticed they contribute to significant morbidity, mortality, increased length of hospital stay, and cost of treatment(6). Currently we have no data on the complications of ERCP whether early or late in our KNH. This study will not only help in improving post ERCP care, but it will also help in improving training of residents, qualified surgeons and physician gastroenterologists and development of local protocols for handling of pancreatic and biliary diseases.

2.0 CHAPTER TWO: LITERATURE REVIEW

Endoscopic Retrograde Cholangiopancreatography(ERCP) is a minimally invasive endoscopic procedure performed for both biliary and pancreatic diseases first described in 1968 which was first used for diagnosis only(1). Further advancements in technology in 1974 saw ERCP offer sphincterotomy which was the beginning of therapeutic procedures done during ERCP.(1) Since then ERCP has proven to be superior to other examinations such as ultrasound, CT scan, MRCP, PTC, biliary scintigraphy, of the hepatobiliary and pancreatic diseases as it offers both diagnostic and therapeutic procedures at the same sitting. ERCP uses a special endoscope called a duodenoscope which is made up of flexible fiberoptic cables which allows it to maneuver all the way to the duodenum and has a side view camera and a working port. The fiberoptic scope is connected to a high-resolution screen which helps the gastroenterologist visualize what he or she is doing and the working port allows introduction of various instruments to aid in completion of the procedure.

Once the duodenoscope is introduced and maneuvered through the upper GIT to the second part of the duodenum, the major papilla which contains the ampulla of Vater where the common bile duct and pancreatic duct open is visualized and inspected for any pathology before it is cannulated. When pathology is present on the papilla, biopsies are taken before cannulation. Using the working port on the duodenoscope the biliary and/or the pancreatic ducts are cannulated and opacified with contrast material to provide diagnostic information by use of fluoroscopy. Other diagnostic advances used in conjunction with ERCP are, brush cytology, biopsy, intraductal ultrasound, cholangioscopy and pancreatoscopy.(1) Therapeutic maneuvers performed during ERCP include endoscopic sphincterotomy with or without stent placement, removal of choledocholithiasis, and other ancillary techniques for the treatment of pancreatic and biliary duct disease.

(1) Globally ERCP is performed on patients with both benign and malignant diseases, with benign being choledocholithiasis, pancreatic duct stones, benign biliary stricture and malignant being malignant biliary strictures, cancer head of pancreas, periampullary tumors. This are the same indications we are seeing locally, and ERCP has gone a long way in improving care in patients with these conditions. Patient preparation is key before the procedure to avert any morbidity or mortality. Adequate fluid hydration, Preoperative lab

investigations; total blood count, liver function tests, urea electrolyte and creatinine and international normalized ratio (INR) are checked and when in acceptable ranges then ERCP is planned. The patient is finally starved for 6hrs prior to the procedure to allow gastric emptying for good visualization during the procedure. Despite these adequate preparation various complications have been known to occur which contribute to morbidity, mortality, long duration of hospital stay and increased cost of health care.

These complications which occur after ERCP has been done, are known to either be early or late. The early complications seen in the first 72hrs being, pancreatitis, septic complications, perforations and bleeding while late complications are seen after 72hrs. World over in advanced centers complication rates are recorded and this has been used to improve practice. Overall complication rates as seen by Andriulli et al at 6.85%, szarzy et al 6.89% with difficult cases contributing to higher rates of complications as described in the HOUSE classification.(7) There is paucity of data in our endoscopy unit in Kenyatta National Hospital since we started doing ERCP on complications whether early or late.

2.1 Acute Pancreatitis

Acute pancreatitis is the most common complication of ERCP. Consensus of post ERCP pancreatitis by Cotton and agreed by Revised European Society of Gastrointestinal Endoscopy Guidelines 2014 and American society of gastrointestinal endoscopy guidelines, consists of the following criteria; serum amylase at least 3 times above normal limit 24hrs post procedure, new abdominal pain consistent with pancreatitis and symptoms enough to require hospital stay or extend the length of hospital stay, and/or abdominal computer tomography scan consistent with diagnosis of acute pancreatitis.(8)

Severity will either be mild, moderate or severe**,** with mild and moderate being seen in 95-99% of patients and severe being 1-5%. Mild includes serum amylase more than 3 times of the upper limit, 24hrs after ERCP and prolonged hospital stay by 2-3 days. Moderate includes serum amylase more than 3 times of the upper limit and hospitalization of 4-10 days. Severe includes hospitalization of more than 10 days, hemorrhagic pancreatitis, phlegmon, or pseudocyst which require percutaneous drainage or surgery.(9). Its incidence is reported to be about 3.46% by Andriulli et al in a multicenter study in 2007(8) .Pathophysiology is multifactorial which is a combination of chemical, thermal, mechanical, enzymatic,

hydrostatic overfilling of the pancreatic duct by contrast.(10) Contrast agent causes chemical pancreatitis. Mechanical injury is the most common cause, which results from prolonged manipulation of the papillary orifice, repeated manipulation of the pancreatic duct leading to obstruction and impaired pancreatic emptying. Thermal injury occurs from electrocautery of the pancreatic duct which results in edema leading to obstruction with impaired pancreatic emptying. Hydrostatic injury occurs from over injection of dye into the pancreatic duct results into ductal and acini injury. Bacteria from the intestines introduced during cannulation of the papillary orifice through bacterial toxins have also been shown to contribute by activation of immune cells which release cytokines. This results in pancreatic cell damage.(5,6)

All of the above mechanisms finally lead to impaired pancreatic emptying activation of the enzymes from the inactive to the active from, leading to auto-digestion of the pancreatic parenchyma. Risk factors shown to be associated with post ERCP pancreatitis as demonstrated by freeman et al include young age, previous post ERCP pancreatitis, normal bilirubin, pancreatic duct injection, balloon dilation of biliary sphincter, suspected Sphincter of Oddi dysfunction, precut sphincterotomy, pancreatic sphincterotomy.(5,6)

2.3 Septic Complications

Infections account for 1.4% with cholangitis and cholecystitis being the most common as reported by Andriulli et al in 2007(8).

Ascending cholangitis is the most common septic complication, which presents 24-72 hours post ERCP. It results from biliary stasis and infection in the biliary tract, which can either be because of incomplete or failed drainage of an infected or obstructed biliary system.(5,6) Bacteria is introduced in the biliary system either by hematogenous spread, from the enteric system by the endoscope or in the past poorly disinfected endoscopes were implicated but with improved disinfection methods that has reduced. Clinical presentation includes; fever, right upper quadrant pain and jaundice which is the Charcot's triad. A patient can also develop suppurative cholangitis which leads to confusion and hypotension in addition to the Charcot's triad making it Reynold's pentad.

Sever cases may be associated with a hepatic abscess. Complications are graded as mild, moderate or severe. Mild is temperatures above 38^{o} c for 24 to 48 hours. Moderate is febrile illness requiring more than three days of hospitalization, endoscopic or percutaneous

intervention, Severe is patient in septic shock or requiring surgery. Risk factors include use of percutaneous endoscopy, use of stents in malignant strictures, jaundice, failed or incomplete biliary drainage.(5,6).

Acute cholecystitis develops from introduction of nonsterile contrast into a poorly emptying gall bladder or mechanical or inflammatory obstruction of the cystic duct by an endoprosthesis, malignancy or gallstones. It is reported to be the second most common septic complication after cholangitis(8). Clinical presentation includes; Nausea, vomiting, fever, tenderness localized in the right upper quadrant. Thickened gallbladder wall and pericholecystic fluid collection on ultrasonography or CT scan. Risk include, use of self-expandable metal stents which are covered obstructing the cystic duct, presence of stones in the gallbladder, filling of gallbladder with contrast during examination.(5,6)

Pancreatic infections are uncommon, but it results from, seeding of bacteria from contaminated equipment or an infected pseudocyst due to contamination following pancreatic duct injection or stone removal.

Bacterial peritonitis is rare but common in post ERCP patients as compared to other endoscopic procedures.

2.4 Bleeding

Bleeding usually occurs after sphincterotomy in therapeutic compared to diagnostic ERCPs, except if one gets sporadic Malory Weis tears or minor submucosal hemorrhages after manipulation of papilla especially in patients with periampullary tumors or bleeding diathesis. Andirulli et al found an incidence of 1.34%(8) with, half of the bleeding occurs after sphincterotomy while the other half occurs between 24hrs and several days after the sphincterotomy. Severity of bleeding is mild moderate or severe. Mild bleeding is not only visible endoscopically, but also a hemoglobin drop of less than 3g/dl or no need for transfusion. Moderate bleeding which needs transfusion of 4 units or less with no intervention needed either angiographic or surgery. Severe bleeding will require transfusion of 5 units or more, or may need angiographic or surgical intervention.(5)Risk factors for bleeding include sphincterotomy, use of anticoagulants within 72hrs after procedure, coagulopathies, cholangitis, papillary stenosis.(5,6)

2.5 Perforations

The incidence of ERCP related perforations is placed at 0.6%(8) by Andirulli et al with a mortality rate of 9.9%. They result from; direct perforation by the endoscope, extension of sphincterotomy cut into the duodenum, guidewire perforations and stent migration.(5) Undiagnosed or delay in diagnosis of perforations causes significant mortality. Most perforations are noted during ERCP while others are picked by clinical signs, physical signs and fluoroscopic findings. CT scan of the abdomen is also very sensitive in detection of perforations. Classification according to Stapfer includes, lateral duodenal wall perforations caused by the endoscope, periampullary perforations of medial duodenal wall perforations caused by sphincterotomy, distal bile duct or pancreatic duct injury related to wire or basket, retroperitoneal air alone.(5,11)Risk factors for perforations include female gender 1.7% vs male gender 0.9%, patients above 40 years, sphincter of oddi dysfunction, longer duration of procedure, difficult cannulation, intramural injection of contrast media, sphincterotomy, biliary stricture dilation.(5,6)

Szary et al found pancreatitis to be the most common complication with a range of 1-15%, infections accounted for 1.4%, hemorrhage 2%, perforations less than 1%. Female sex, younger age, increased procedure time, suspected sphincter of oddi dysfunction(SOD), history of prior post ERCP pancreatitis(PEP) were found to be associated with more complications(6).

Saito et al looking at complication of one stage endoscopic stone removal, found incidence of pancreatitis was 4.6%.(12)Hui et al in a multicenter study involving 101 patients found pancreatitis can occur despite precut sphincterotomy or placement of a prophylactic pancreatic stent for prevention of PEP. Two patients developed perforations, Two patients developed hemorrhage(9).American society for gastroenterological endoscopy guidelines found the incidence of pancreatitis to be at 9.7% with precut sphincterotomy, difficult cannulation and endoscopic large balloon dilation of intact sphincter being risk factors.

Hemorrhage 0.3 to 2% with sphincterotomy, coagulopathy, cholangitis and use of anticoagulants as risk factors. Infections at 0.3-5% with stent placement, incomplete drainage and previous failed procedures as risk factors. Perforations 0.06-0.8% with altered anatomy, longer duration of procedure, precut papillotomy sphincter of Oddi dysfunction, biliary

sphincter dilation, older patient and female sex as risk factors.(5)Osman et al in a general surgical referral center in turkey managed 54 patients who had undergone ERCP in different centers 29 female and 26 male who had complications as follows 21(38.8%) pancreatitis, 15(27.7%) perforations, 11(20%) infections and 7(12%) hemorrhage(13). Srivatava et al in a retrospective study between 2007 and 2012 found perforations to be 171 (1.5%) of the ERCPS performed. Age above 40, females gender and sphincterotomy were risk factors while completion of the intended procedure was associated with good outcomes(14). Ambrus et al found the overall incidence of complications to be 8.2%;pancreatitis 2.7%, bleeding 1.5%, cholangitis 4.5% in patients who underwent ERCP after liver transplant in a surgical unit in Copenhagen(15). Olosson et al found an overall complication rate of 12.6% with pancreatitis at 4.6%, infections 0.8% and bleeding at 2.5%. Patients found to have complicated pathologies and poor physiological status contributing to a higher HOUSE score had higher rates of complication as compared to lower HOUSE scores.(7)

3.0 CHAPTER THREE: STUDY JUSTIFICATION & METHODOLOGY

Biliary and pancreatic diseases are common, with a lot of late presentations seen in our setup. ERCP is increasingly being used to offer minimally invasive diagnostic and therapeutic solutions for these diseases. This study seeks to describe the early complications within the first 72hrs after ERCP in KNH which have been shown to contribute to significant morbidity and mortality, which can be prevented if complications are picked and managed early. This will go a long way in helping to improve practice of endoscopy and patient care in Kenyatta National Hospital. This will also improve training protocols for residents and surgeons in our center in Kenyatta National Hospital.

3.1 Main Objective

To determine the indications, incidence and factors associated with early complications of Endoscopic Retrograde Cholangiography in Kenyatta National Hospital.

3.2 Specific Objectives

a) To determine the indications of ERCP..

b) To determine the incidence of early complications after ERCP .

c) To determine the factors associated with early complications of ERCP.

3.2 Methodology

3.2.1 Study Design

This was a prospective observational study which was conducted in the KNH endoscopy unit and the patients followed up in the various general surgical(5A,5B,5D) and medical ward(7D) for the first 72hrs after the procedure.

3.2.2 Study Population

Patients who underwent ERCP in the endoscopy suite and consented to participate in the study were followed up in the medical and surgical wards for the first 72 hours in KNH.

3.2.3 Study Area

The study area was in the KNH Endoscopy unit and patients followed up in the gastroenterology medical ward(7D) and general surgical wards (5A,5B and 5D). KNH is the largest referral center and receives patients from all over the country. Currently KNH endoscopy unit is the only public facility offering ERCP and receives patients from all over

the country and therefore serves as a good sampling site.

3.3 Study Procedure

3.3.1 Enrollment

All patients who were undergoing ERCP in the endoscopy unit were recruited through a face to face interview after giving informed consent and before the procedure. The procedure was conducted by a qualified gastroenterologist physician or surgeon. The relevant clinical data for this study was extracted from the patients file; laboratory work ups, anesthetic charts and procedure/operative notes.

3.3.2 Follow up after the procedure

All patients who underwent ERCP were admitted for observation for a minimum of 72hrs.The patient were followed in the wards for up to 72hrs where clinical information and laboratory data relevant for this study was noted and recorded. Any recorded complication from the attending physician was noted and recorded.

3.3.3 Inclusion Criteria

a) All patients who underwent ERCP in the endoscopy unit and followed up in the medical and general surgical wards in KNH.

b) Patients above 18 years.

3.3.4 Exclusion Criteria

a) Patients who did not consent to participating in the study.

3.3.5 Method

Consecutive sampling of patients who came for ERCP was used. All patients who fulfilled the criteria were included in the study. Written consent was obtained from the patient. A preformed data sheet was used to collect data before ERCP and filled in within 72hrs after intervention.

3.4 Sample Size Determination

Sample size was calculated using the Fischer's formula;(16)

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

Where,

n = Desired sample size

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

P = expected true proportion (estimated at 6.9%, from a systematic review conducted by Andriulli et al (2007) of prospective studies conducted between January 1997- May 2006 in different centers. Andriulli et al found 6.9% to be the complication rate of ERCP.)(8)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.069(1 - 0.069)}{0.05^2} = 99$$

3.5 Data Collection and Management

3.5.1 Data Collection

3.5.1.1 Enrollment

Recruitment included all patients undergoing ERCP in KNH through consecutive sampling. All patients who underwent ERCP admitted through the endoscopy unit, or admitted in the medical and general surgical wards and diagnosed with conditions requiring ERCP were recruited. Recruitment was verbal, and participants were duly informed of the nature and purpose of the study. All patients who agreed to participate in the study, written informed consent was obtained and they were subsequently enrolled in the study. Data was collected by the principle researcher and research assistant using a data collection sheet. Data collection included age, gender, clinical or radiological diagnosis prior to ERCP, diagnosis at ERCP, time taken to do the procedure.

3.5.1.2 Follow up

Clinical examination findings for the first 72 hours and laboratory result findings of hemogram and amylase at 48hrs after ERCP were collected. Sensitization of consultants in the endoscopy unit and residents in medical and surgical wards was done through conveniently placed notices.

3.5.1.3 Data Handling

The research assistant was a medical officer who was taken through the data collection tool to familiarize with it and have the abstraction process. The data was entered into a Microsoft excel spreadsheet with encrypted password protection known to the principle researcher and assistant

3.5.1.4 Data Analysis

The data was entered, cleaned and analyzed using statistical package for social sciences (SPSS) for windows version 21. Demographic data, clinical data, indications for ERCP and early complications of ERCP was analyzed and presented as frequencies and proportions for categorical data and mean and median for continuous data. Chi-square test was used to determine the association between factors affecting early complications and early complications of ERCP. The P-value <0.05 was considered statistically significant.

3.6 Ethical Considerations

The study was commenced upon approval by the department of surgery, UoN and KNH Ethics and Research committee. The researcher also obtained permission from KNH administration

A pre-consent counselling of all patients was carried out, after which an informed consent was obtained from each of the participant prior to enrollment in the study.

Those who decline participation were not denied the treatment they deserve because of their decision not to participate.

There was no extra cost incurred for participating in the study. All data was recorded in MS Excel data sheets that was saved under password protection only accessed by personnel involved in the project. Confidentiality and privacy were observed, and the data sheets were destroyed upon completion of the study.

3.7 Study Results Dissemination

The researcher shared the results of the study with clinicians both from KNH and UoN in the endoscopy unit, surgical and medical wards for the purpose of improving care of patients. The results will also be published online for access to anyone who might require them. This was done with consent from KNH research department.

3.8 Study Limitations

The researcher had no control over the years of experience of the clinician doing the ERCP but tried to pick patients who underwent ERCP under a consultant gastroenterologist.

4.0 CHAPTER FOUR: RESULTS

4.1 Demographic Characteristics

During the study period ninety-eight (98) patients were successfully recruited into the study. However, over the study period one (1) patient dropped out due to incomplete data. we were therefore left with 97 patients who completed the follow up process.

Of the ninety-seven patients who were analyzed, a majority of them fell within the age group of fifty-one to sixty years (51-60) years with a mean age of fifty-two point seven (52.7). the age range of the patients under the study was 15years and 92 years (figure 1).

A majority of the patients fifty-nine (60.8%) recruited in the study were females while thirty-eight (39.2%) were males (figure 2).

AGE

Mean=52.7±16.34yrs, max=92, min=15yrs

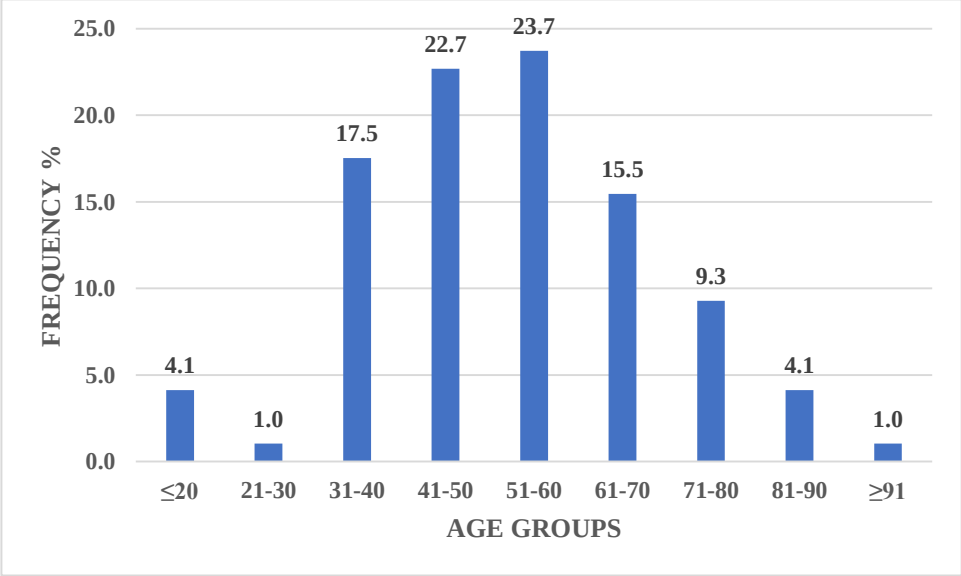

Figure 1 Distribution by Age

Females=59(60.8%)

Males =38(39.2%)

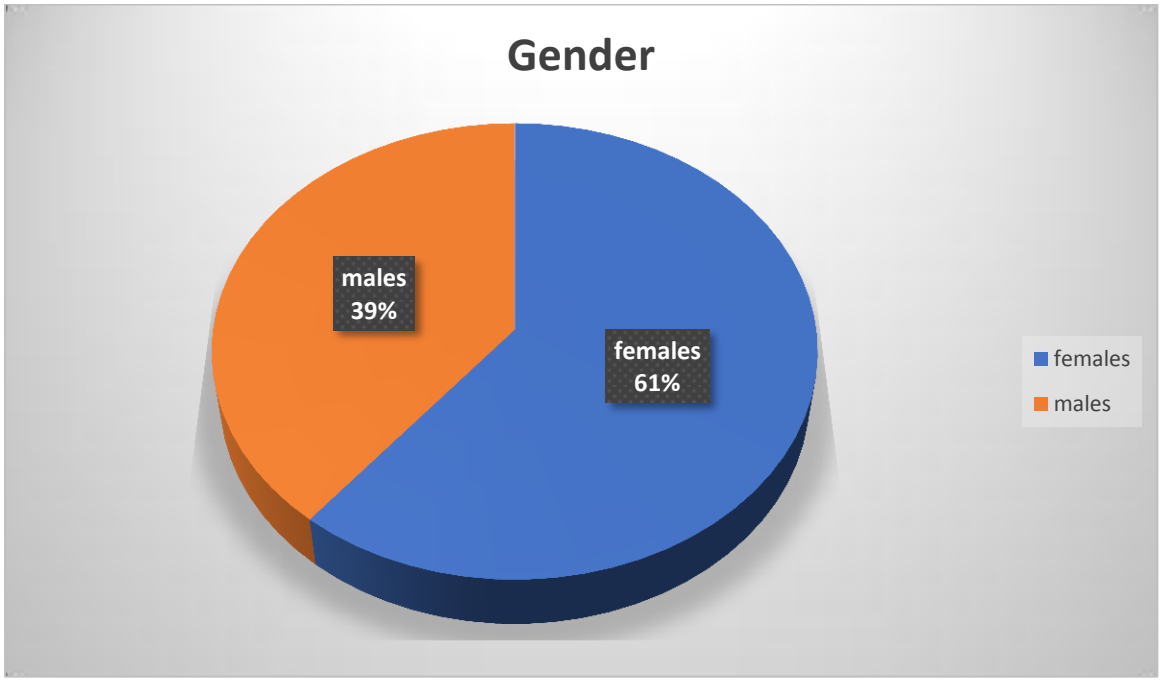

Figure 2 Distribution by Gender

4.2 The Mode of Presentation

At the time of admission, the most frequent clinical indication for ERCP was obstructive jaundice, 94(96.9%), while the most common radiological indication of ERCP was choledocholithiasis (33%). Seventy-nine (81.4%) of the study population had no comorbidities while sixteen (18.6%) of patients had comorbidities. Only 16(16.5%) of the study population had had a previous ERCP.

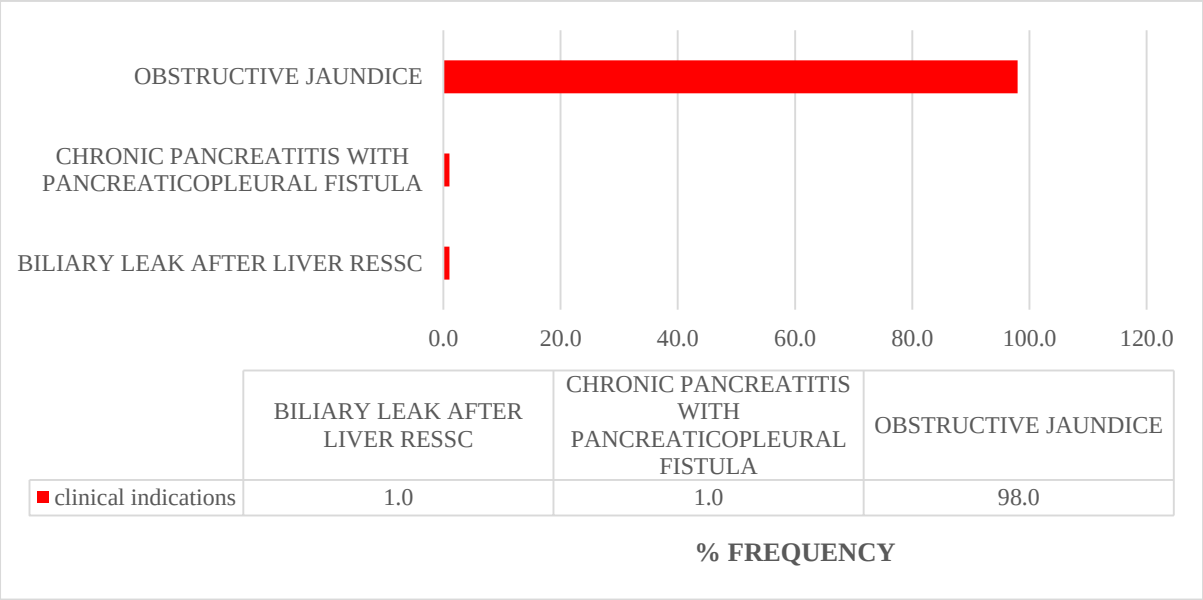

Figure 3 Clinical Indications of ERCP

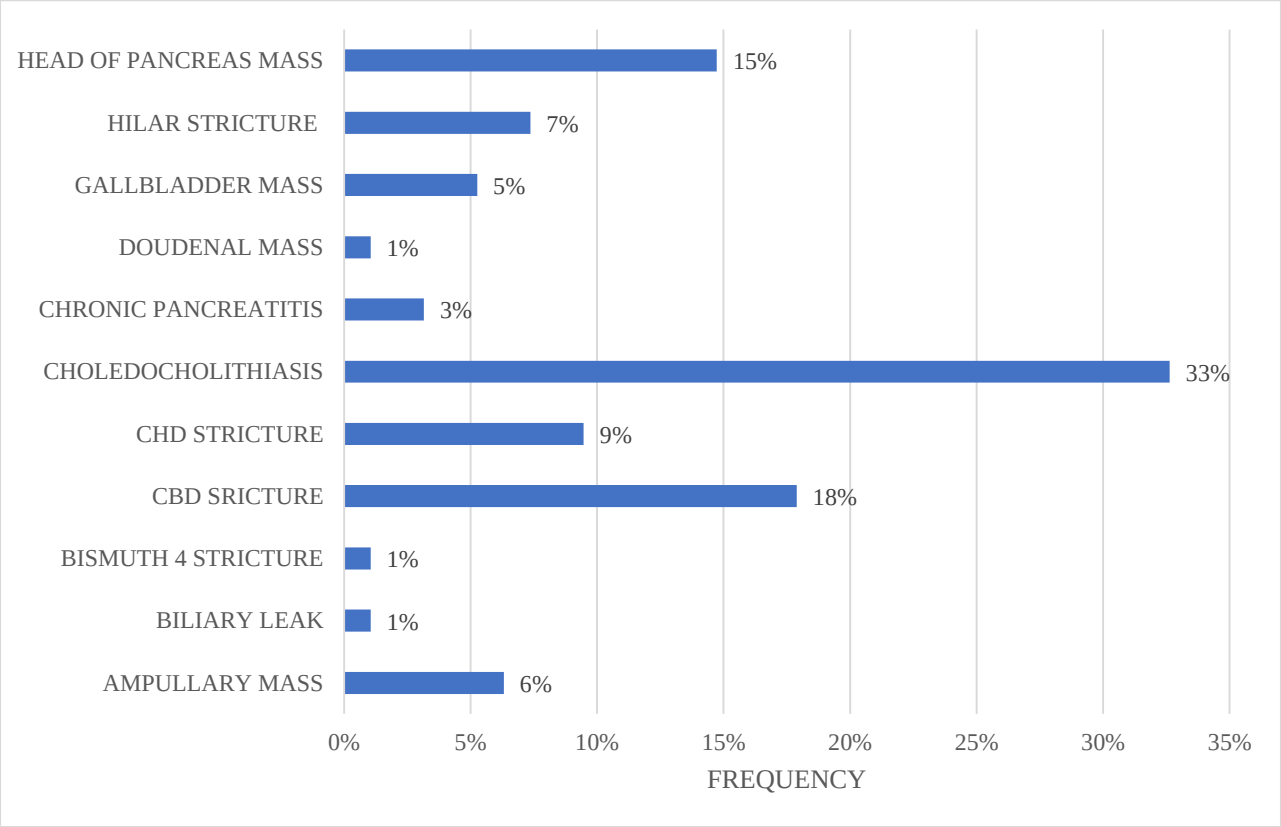

Figure 4 Radiological Indications of ERCP

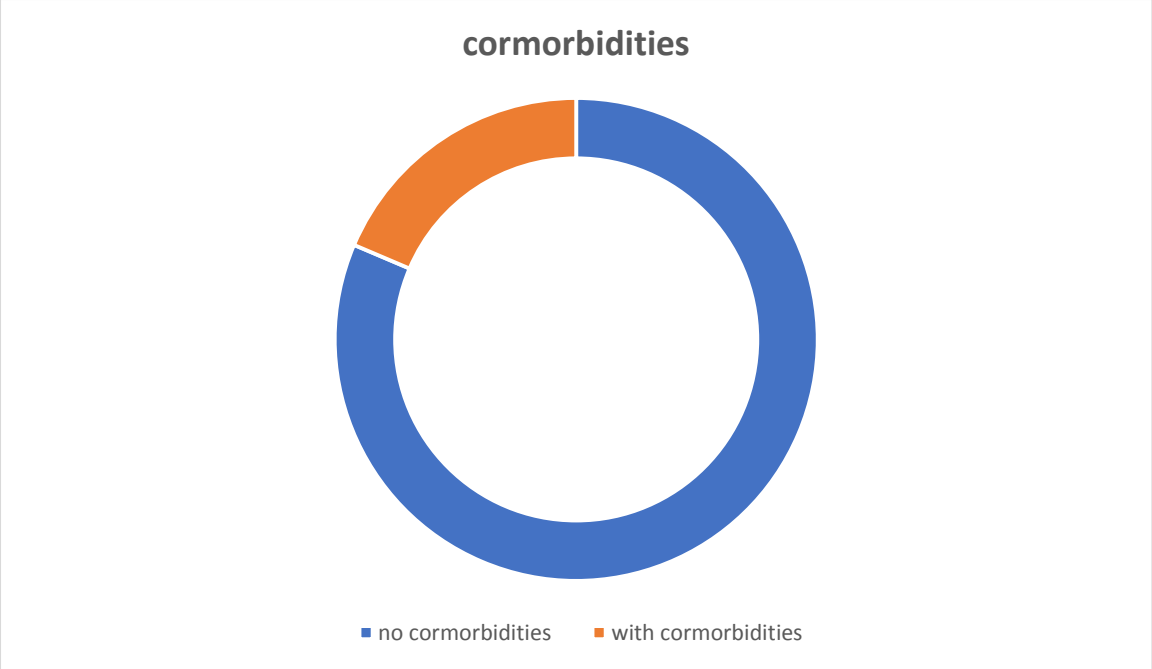

Figure 5 Cormorbidities

4.3 Complications

The Median duration time of ERCP was=90mins (IQR: 60-120mins). Twenty-two (22.7%) of all participants had at least one complication. Only 3(3.1%) of our participants died while on follow up in the study. The most common complications were pancreatitis (12.4%) and cholangitis (12.4%), some patients had more than one complication. It is worth noting that all the ERCPs were done by qualified gastroenterologists. However, none of the complications were statistically significant in relation to the variables of age, gender, duration of procedure, comorbidities or prior ERCP

Table 1 Summary of complications post ERCP

COMPLICATION	MILD (%)	MODERATE (%)	SEVERE (%)	TOTAL (%)
Pancreatitis	8(8.2)	1(1)	3(3.1)	12(12.4)
cholangitis	8(8.2)	1(1)	3(3.1)	12(12.4)
Bleeding	5(5.2)	0	1(1)	6(6.2)
perforation	0	0	0	0

Table 2 Correlation of Pancreatitis and Risk Factors

VARIABLE	PANCREATITIS		P-VALUE
	NO	YES	
AGE			
≤20	4	0	
21-30	1	0	
31-40	15	2	
41-50	21	1	
51-60	21	2	0.34
61-70	11	4	
71-80	6	3	
81-90	4	0	
≥91	1	0	
GENDER			1.00
Male	33	5	
female	52	7	
COMORBIDITY			0.21
Yes	16	0	
No	69	2	
DURATION (mean)	97.9±37.5	90.9±32.1	0.52

None of the variables were significantly related to development of pancreatitis post ERCP

Table 3 Correlation of Cholangitis with risk factors

VARIABLE	CHOLANGITIS		P-VALUE
	NO	YES	
AGE			0.94
≤20	4	0	
21-30	1	0	
31-40	16	1	
41-50	19	3	
51-60	20	3	
61-70	12	3	
71-80	8	1	
81-90	4	0	
≥91	1	0	
GENDER			1.00
Male	34	4	
female	52	7	
COMORBIDITY			1.00
Yes	14	2	
No	72	9	
DURATION (mean)	98.3±37.4	88.2±32.5	0.36

None of the variables were significantly related to development of cholangitis post ERCP

Table 4 Correlation of Bleeding with Risk Factors

VARIABLE	BLEEDING		P-VALUE
	NO	YES	
AGE			1.00
≤20	4	0	
21-30	1	0	
31-40	16	1	
41-50	20	2	
51-60	21	2	
61-70	14	1	
71-80	9	0	
81-90	4	0	
≥91	1	0	
GENDER			0.4
Male	37	1	
female	54	5	
COMORBIDITY			0.36
Yes	16	0	
No	75	6	
DURATION (mean)	98.0±37	83.3±37	0.32

None of the variables were significantly related to development of bleeding post ERCP.

Table 5 Correlation of Prior ERCP with Complications

PRIOR ERCP	COMPLICATION		TOTAL	P-VALUE
	Yes	No		
Yes	3	13	**19**	1.00
No	19	62	**81**	
TOTAL	**22**	**75**	**100**	

Prior ERCP was not significant in terms of developing complications.

5.0 CHAPTER FIVE: DISCUSSION

5.1 Indications for ERCP

Globally the indications for ERPC are choledocholithiasis, pancreatic duct stones, benign biliary strictures for benign conditions and malignant biliary strictures, head of pancreas tumors, periampullary tumors for malignant conditions. A majority of these conditions will present with obstructive jaundice as the most common clinical presentation. Our study established that the most common clinical indication for ERCP in KNH was found to be obstructive jaundice at 96.9%, chronic pancreatitis, biliary leak post-surgery were found to account for 1% each. The most common radiological indication for ERCP was choledocholithiasis at 38%. CBD stricture 18%, mass head of pancreas 15%, CHD stricture 9%, hilar stricture 7%, ampullary mass 6%, gallbladder mass 5%, chronic pancreatitis 3%, duodenal mass 1%, and biliary leak 1% which was similar to the global indications(1). However, we were not able to conclude weather the strictures found were benign or malignant because of lack of brush cytology equipment and FNA needles.

5.2 Incidence of Complications

Our study findings established an overall complication rate of 22.1% which is different from Andriuli et al 6.85% and szary et al 6.89%. The most common complications were found to be pancreatitis 12.4% and cholangitis 12.4% respectfully which is different from other studies which state that pancreatitis 3.46% is the most common complication and cholangitis 1.4% following as the second most common complication(6,8). Mild pancreatitis accounted for a majority of the patients with pancreatitis 8.1%, while moderated and severe accounted for the other number 1% and 3.1% respectively. Mild cholangitis accounted for the majority of the patients with cholangitis 8.1% while moderate and severe formed the other number 1% and 3.1% respectfully. Bleeding accounted for 6% with mild accounting for 5.2% and severe1% respectfully which was noted 24hrs after ERCP compared to what Andriuli et al found that half of the bleeding is noted immediately after the sphincterotomy and the other half 24hrs after the procedure. None of the patients who participated in the study developed a perforation which is different from the other studies done where bleeding accounted for 0.6%. The discrepancy in our findings could be attributed to the fact that the number of patients in our study which was low compared to the other studies.

5.3 Factors Associated with Complications

We looked at five factors to determine their significance on complications post ERCP. Age, Gender, prior ERCP, time taken to do the procedure and comorbidities.

Our study revealed the number of people who developed a higher number of complications were females; pancreatitis, females 7 compared to 5 males, cholangitis 7 males compared to 4 females, bleeding 5 females compared to 1 male. No patient had perforation as complications. These findings were similar to what szary et al found that females were predisposed to higher rate of complications.

Older age 61-70 grouped people were found to have higher rate of complications with pancreatitis 4, cholangitis 3 and bleeding 2 as compared to younger age groups who had pancreatitis 2, cholangitis 1, and bleeding 1 respectively. This was different from what szary et al found where younger people were more predisposed to complications.

Our study revealed that people who had comorbidities were not predisposed to having complications as compared to people who did not have comorbidities. The average time for doing ERCP was 90 minutes and longer procedure time (>90 minutes) did not predispose the patient to having any complications.

Patients who had had prior ERCP done, were not at a higher risk of developing complications as compared to patient who were having the procedure for the first time. Out of the patients who had complications 3 had had prior ERCP while 19 had not had prior ERCP.

Three out of the 98 patients died. The first one had had was a female who developed acute severe pancreatitis, acute severe cholangitis and severe bleeding, after a successful ERCP and did not have any comorbidities. The second patient was a male who developed severe bleeding after a successful ERCP. The third patient had severe cholangitis which later tipped the patient in sepsis he had a heart condition and was on anticoagulants.

5.4 Conclusion

The commonest clinical and radiological indication for ERCP was obstructive jaundice and choledocholithiasis respectively, and more females developed complications as compared to males. Overall the early post ERCP complication rate was 22.1% with the commonest complications being acute pancreatitis and acute cholangitis. There was no statistical difference in the patients who developed complications and those who did not develop complications in terms of age, gender, length of procedure and prior ERCP.

5.5 Recommendations

ERCP has advanced a lot with use of endoscopic ultrasound and newer techniques of getting tissue specimens for more accurate diagnosis especially that of strictures and masses.

There is need to employ this newer technique so that we improve our diagnostic capacity and intervention as well. More people should also be trained in this field as it is proving to provide alternative minimally invasive solutions which can be lifesaving to patients who are very ill to undergo extensive open procedures.

A large high powered study should be performed to look into detail the early post ERCP complications and it is the hope of the researcher that this will be a catalyst to future studied in this field.

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STUDY BUDGET

BUDGET ITEM	**AMOUNT (KSHS.)**
Research fee for KNH-ERC	1,500
Statistician consultation fee	30,000
Stationery;(a) Printing (b) Photocopying (c) Binding (d) Pens Labs; 1. Complete blood count@500 2. Amylase @400	5,000 2,000 10,000 500 49,500 39,600
Research assistants fee @15,000 each (one assistants)	15,000
Contingency fund	10,000
Total	**163,000**

TIMELINES

ACTIVITY	**AUG 2018 – JAN 2019**	**FEB- – JULY 2019**	**JULY- NOV 2019**	**NOV – NOV 2019**	**DEC 2019**
PROPOSAL DEVELOPMENT					
ETHICAL APPROVAL					
DATA COLLECTION					
DATA ANALYSIS					
PRESENTATION AND SUBMISSION					

APPENDICES

Appendix I: Statement of Consent

Participant Information and Consent Form

For Enrollment in the Study

(To be administered in English or any other appropriate language e.g Kiswahili translation)

Title of Study: **Indications, Incidence and Risk factors of Early Complications of Endoscopic Retrograde Cholangiopancreatography as seen in KNH.**

Principal Investigator\and institutional affiliation:

Dr. Karogo I. Mwangi.

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

Co-Investigators and institutional affiliation:

1. Professor P.L.W Ndaguatha
   MBChB(U.o.N), M.Med (Surgery)(U.o.N), F.C.S(ECSA), Fellow of Urology(U.K).
   Department of Surgery, School of Medicine, University of Nairobi
   P.O. Box 19676 KNH, Nairobi 00202

2. Dr Nyaim Opot
   MBChB (U.o.N), M.Med Surgery (U.o.N), F.C.S (ECSA)
   Department of Surgery, School of Medicine, University of Nairobi
   P.O. Box 19676 KNH, Nairobi 00202

3. Dr. Shahbal Swaleh
   MBchB(UoN), MMED surgery(U.o.N)
   Department of surgery, school of medicine, University of Nairobi
   P.O BOX 19676 KNH, Nairobi 00202

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

What Is This Study About?

The researchers listed above are interviewing individuals who are undergoing endoscopic retrograde cholangiopancreatography. The purpose of the study is to find out the early complication of endoscopic retrograde cholangiopancreatography. Participants in this research study will be asked questions about past medical illnesses, the current condition they are being treated for. Abdominal pain, nausea and fever 24hrs after the procedure and a physical examination. Participants will also have the choice to undergo test such as blood tests, Ultrasound scan and CT scans.

There will be approximately 99 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

What Will Happen If You Decide To Be In This Research Study?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 15 minutes. The interview will cover topics such as age, sex and the problem your doctor is about to treat you for.

After the interview has finished, we will follow you through the procedure and record the preparation done to you, monitoring during the procedure and the final outcome of the procedure. We will follow you up in the ward for 72hrs and record any complications which might occur. However, we will not participate per se in your treatment and we will only be observers. The information recorded will help the doctors to improve treatment offered at the unit. This information will be strictly confidential to the researcher only. No names or any information that can trace you in anyway will be recorded.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: explaining to you about the outcome of your procedure and any additional treatment that maybe required.

Are There Any Risks, Harms Discomforts Associated with This Study?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

It may be embarrassing for you to have a physical examination. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. Also, the first few hours after the procedure may be stressful (e.g event recalls).

You may feel some discomfort when recovering from the procedure because of the manipulation which will be done and you may have a small bruise or swelling in your mouth. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

Are There Any Benefits Being In This Study?

You may benefit by receiving free laboratory testing, counselling. We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand the early complications after ERCP has been done. This information is a contribution to science and developing protocol for patient cares.

Will Being In This Study Cost You Anything?

You will only incur the cost of treatment with no additional costs.

Will You Get Refund For Any Money Spent As Part Of This Study?

None.

What If You Have Questions In Future?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

What Are Your Other Choices?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

Consent Form (Statement of Consent)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to have data preserved for later study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ Date: _____

Signature

_____

Role in the study: _____ [i.e. study staff who explained informed consent form.] For more information contact _____ at _____ from

_____ to _____

Witness Printed Name (If witness is necessary, A witness is a person mutually acceptable to both

the researcher and participant)

Name _____ Contact information _____ Signature

/Thumb stamp: _____ Date; _____

Appendix II: Fomu Ya Idhini

Sehemu ya kwanza : Maelezo ya Daktari mtafiti.

Mimi ni Dkt Karogo Mwangi, kutoka shule ya Elimu ya Afya idara ya upasuaji Chuo Kikuu cha Nairobi. Ninafanya utafiti kuhusu matibabu inayotekelezwa kwa njia ya vifaa vya endoscopy badala ya upasuaji. Unapo kubali kusajiriwa katika utafiti huu, tutakuuliza maswali kuhusu tatizo unalotibiwa na daktari. Tena tutafuatilia matibabu utakayo tibiwa na kurekodi namna ya matibabu hadi yatakapo malizika. Ni vyema kukujulisha kuwa mtafiti hatahusika kwa kukutibu bali atayafuatilia matibabu kwa kurekodi. Habari zote zitakazokusanywa zitashughulikiwa kwa siri na hazitasambazwa ila tu kwa ruhusa kutoka kwa mkurugenzi mkuu wa utafiti wa chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta. Matokeo ya utafiti huu utawasaidia madaktari kuendeleza matibabu haya kwa ufanisi zaidi na kwa kuendeleza elimu.

Kuhusika kwako, mwanao au jamaa wako kwenye utafiti huu hakuna malipo yoyote ila ni kwa hiari yako mwenyewe na pia unaweza kujiondoa kushiriki katika utafiti wakati wowote bila kuhatarisha matibabu ya mwanao/jamaa wako katika Hospitali Kuu ya Kenyatta. Naomba mimi ama wasaidizi wangu katika utafiti wakuulize maswali ambayo yatajibiwa kwa fomu maalum. Habari yote ambayo utatuarifu ni ya siri kati yako nasi watafiti na haitaenezwa kwa watu wengine. Jina la mwanao/jamaa wako halitaandikwa kwenye fomu yoyote wala kwenye vipimo vyovyote.

Unaweza kuuliza maswali yeyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu kwa mtafiti mkuu ama mkuu wa idara ya upasuaji katika chuo kikuu cha Nairobi ama walimu wasimamizi wa utafiti ukitumia nambari za simu zifuatazo;

- Katibu wa utafiti, Hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi. Sanduku la Posta 20723 KNH, Nairobi 00202. Nambari ya simu 726300-9.

Walimu wakuu wa Chuo kikuu cha Nairobi:

1. **Professor P.L.W. Ndaguatha**
   MBChB(U.o.N), M.Med(Surgery)(U.oN), F.C.S (ECSA), Fellow of Urology(U.K)
   Sanduku la Posta 19676 KNH, Nairobi 00202.
2. **Dkt Nyaim Opot,**
   MBChB (U.o.N), M.Med Surgery (U.o.N), F.C.S (ECSA)
   Sanduku la Posta 19676 KNH, Nairobi 00202.

3. **Dkt Shahbal Swaleh**
   MBchB(U.o.N), MMED surgery(U.o.N)
   Sanduku la Posta 19676 KNH, Nairobi 00202

Mtafiti

Dkt Karogo Mwangi.

Idara ya Upasuaji ya Shule ya Afya – Chuo kikuu cha Nairobi,

Sanduku la Posta 36153 00200.

Numbari ya simu: 0721419494

Sehemu ya pili – Idhini ya mgonjwa.

Mimi (Jina)…… nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Karogo Mwangi kutokana na hali ambayo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu yangu au mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na hata madaktari wenyewe na kwa kuendeleza elimu.

Kidole cha gumba kwa Yule asiyeelewa Kuandika

Sahihi/ama alama ya kidole cha gumba katika sanduku ……..

Tarehe…….. Siku/Mwezi/Mwaka

Jina la shahidi……

Sahihi…….

Tarehe……(Siku/Mwezi/Mwaka)

Sehemu ya tatu – Dhibitisho la mtafiti

Hii nikuidhinisha ya kwamba nimemueleza msimamizi wa mshiriki(mgonjwa) kwenye utafiti kuhusu utafiti huu na pia nimempa nafasi yakuuliza maswali. Nimemueleza yafuatayo;

- Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.
- Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.
- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayoyapata katika hospital kuu ya Kenyatta.
- Habari ambazo atapeana hazita tangazwa hadharani bila ruhusa kutoka kwake (mshiriki) na pia kutoka kwa mdhamini mkuu wa utafiti wa hospital kuu ya Kenyatta na chuo kikuu cha matibabu.

Jina la anayesimamia mshiriki ……

Sahihi……

Tarehe……

Appendix III: Data Collection Form

Serial No ……

1. Patient's gender ……..
2. Patient's Age …….
3. What is the Clinical diagnosis?

   ……

   ……..…

   …….
4. What is the patient's Pathological or radiological diagnosis?

   ……

   ……

   …….
5. Does the patient have any of the following co-morbidities? Answer is yes or no.
   - diabetes……..
   - hypertension…….
   - Asthma…….
   - renal disease……..
   - lung disease……
   - use of anticoagulants…….
   - heart disease……..
   - Liver disease……..
   - prior ERCP performed; yes……. No…..
6. Investigations before ERCP
   - What is the INR? …..
   - What is the White cell count? …….
   - What is the Level of total bilirubin? ……..
   - What is the Level of direct bilirubin? ……
   - What is the Albumin level? …….
   - What is the Urea level? ……..
   - What is the Creatinine level? ……..

7. What fluids were given during the procedure?
    - Ringers lactate…….
    - Normal saline……..
    - Dextrose……..
    - Others(specify)……
8. What per rectal Analgesia was given after ERCP in miligrams?
    - Indomethacine …….
    - Diclofenac……
    - Others(specify)……..
9. What was the indication of ERCP?

    Diagnostic…… Therapeutic…….
10. What was the length of the Procedure?

    Starting time…… stopping time……
11. Was cannulation successful?

    Yes…… No…….
12. Which procedure was done on the biliary or pancreatic duct?
    - Use of guidewire after dye cholangiogram; Yes…… No……..
    - Sphincterotomy……
    - Sphincteroplasty……
    - Stent placement; Yes….. No…..
    - what kind of stent plastic…. Metallic…..
    - Brush cytology……..
13. What was the diagnosis at ERCP?

    ……

    …….

14. What was the Outcome of ERCP?

    Successful…… Not Successful……

Complications

	Day 1		**Day 2**		**Day 3**	
COMPLICATION	Yes	No	Yes	No	Yes	No
Epigastric pain						
Right upper quadrant pain						
Abdominal tenderness						
Jaundice						
Fever						
Nausea						
Vomiting						
Confusion						
Blood pressure						
Temperature						
Days of hospitalization						
Level of amylase at 48hrs						
Level of white blood cells at 48hrs						

Appendix IV: KNH/UON-ERC Letter of Approval

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/282

18 July, 2019

Dr. Isaac Karogo Mwangi
Reg. No.H58/74458/2014
Dept.of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 18 JUL 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Dear Dr. Mwangi

RESEARCH PROPOSAL: INDICATORS, INCIDENCE AND RISK FACTORS OF EARLY COMPLICATIONS OF ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATORGRAPHY AS SEEN IN KENYATTA NATIONAL HOSPITAL (P188/03/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 18th July 2019 – 17th July 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF.M.L. CHINDIA
SECRETARY, KNH-UoN ERC

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The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine,UON
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