SHORT TERM CLINICAL AND TECHNICAL OUTCOMES OF PERCUTANEOUS TRANSHEPATIC CHOLANGIOGRAPHY AND BILIARY DRAINAGE, FOR THE MANAGEMENT OF BILIARY OBSTRUCTION IN KENYATTA NATIONAL HOSPITAL

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DECLARATION

I declare that this thesis is my original work and has not been presented anywhere else for academic purposes.

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ABBREVIATIONS AND ACRONYMS

aPTT- Activated partial thromboplastin time

BD- Biliary Drainage

CBD- Common bile duct

CHD- Common hepatic duct

CT- Computed Tomography

ERCP- Endoscopic Retrograde Cholangiopancreatography

GB- Gall bladder

HB- Haemoglobin

HIV- Human Immunodeficiency virus

INR- International Normalised Ratio

IR- Interventional Radiology

IRC- Interventional Radiology Clinic

KNH- Kenyatta National Hospital

LHD- Left hepatic duct

PLT- Platelets

PTBD- Percutaneous Transhepatic Biliary Drainage

PTC- Percutaneous Transhepatic Cholangiography

PTI- Prothrombin Time Index

RASD- Right anterior Sectoral Duct

RHD- Right Hepatic duct

RPSD- Right posterior Sectoral Duct

ABSTRACT

Background: Obstructive jaundice is a common presentation in patients referred to the Interventional Radiology (IR) unit in Kenyatta National Hospital (KNH). It is a significant cause of morbidity in patients suffering from various hepatobiliary diseases. Percutaneous relief of the biliary obstruction through percutaneous transhepatic cholangiography (PTC) and biliary drainage (BD) leads to clinical improvement in quality of life. However, percutaneous external biliary drainage, can also lead to increased morbidity and mortality in some patients. Despite the use of PTBD locally, there is paucity of data regarding its clinical and technical success rates and associated complications.

Objective: This study sought to evaluate the technical and clinical success rates of PTBD procedure and determine the short-term clinical outcomes of patients undergoing PTBD at KNH.

Methodology: This was a retrospective and prospective cross-sectional study. Retrospective data on PTBD clinical outcomes was abstracted from patient files from 12 months prior to this study. Same data was prospectively gathered from patients' files for 3 months until the sample size was achieved. The study was undertaken at the KNH radiology department on patients undergoing PTBD over the study period. A preformed data collection sheet was used to capture relevant information. Analysis was done using IBM Statistical Package for Social Sciences (SPSS) (Version 27.0). for descriptive analysis, mean and corresponding standard deviation or median and corresponding interquartile range were used for normally distributed and skewed continuous data respectively. For categorical data, frequency and percentage was used. Paired sample t test and Wilcox ranked test were used to determine if the changes in laboratory parameters pre and post intervention were statistically significant

study findings will be presented in descriptive text, charts, tables, and percentages. Descriptive statistics will be used for the analysis. Frequencies and percentages will be used to analyse categorical variable data such as presenting complaints, complications, management outcomes and symptoms. For continuous variables such as haemoglobin level and age, mean and standard deviation will be used if the data will be normally distributed.

Results: The mean age of the patients who underwent PTBD was 56 (SD=13.6) years. A total of 14 (26.9%) had Hillar mass and Klatskin tumour, 12 (23.1%) had Pancreatic head carcinoma, 11 (21.2%) cholangiocarcinoma, and 5 (7.7%) strictures 5 (9.6%) had metastasis, and 5 (9.6%) had gall bladder carcinoma or mass. All 52 patients had yellowness of eyes, 43

(82.7%) had pruritus, and 18 (34.6%) abdominal pains. Biliary drainage was technically successful in 51 (98.1%) of the cases. The clinical success rate was 81.6%. A Wilcoxon signed-rank test showed that the intervention resulted in statistically significant reduction in total bilirubin (Z = -6.033, P-value<0.001) and direct bilirubin (Z = -5.799, P-value<0.001). The immediate post-procedure complications included 2 (3.8%) cases of septic shock, 2 (3.8%) cases of vessel puncture, 2 (3.8%) cases of bleeding through the tube, 1(1.9%) case of tumoral bleeding and 1 (1.9%) case of death. One-month post-procedure, 5 (9.6%) cases of catheter dislodgement, 5 (9.6|%) cases of Peri tubal discomfort/pain, 2(3.8%) cases of peri-tubal leakage, 2 (3.8%) cases of peri tubal infection and 2 (3.8%) cases of cholangitis were reported.

Conclusion: PTBD is a highly effective and safe approach to biliary drainage with high clinical and technical success rates as was the case in this study and most previous studies in other settings. While there were minimal complication rates among the patients who underwent the procedure in this study, the commonly observed complications could be treated conservatively.

CHAPTER ONE: INTRODUCTION

1.1 Background information

Obstructive jaundice is a common presentation among patients presenting at the KNH IR clinic. It occurs because of obstruction or blockage to normal biliary flow. Biliary obstruction has many causes, both benign and malignant, including cholangiocarcinoma, other primary hepatic tumours, gall bladder masses, pancreatic head masses, calculi, benign strictures, cholangitis and duodenal tumours.

Patients presenting at KNH with obstructive jaundice tend to come in advanced stages of disease where curative surgery is not possible, and palliation is the mainstay of management. They usually present with features of liver failure, pruritis, weight loss, poor feeding, features of cholangitis or sepsis and even hepatic encephalopathy. PTC and BD are performed to bring an improvement in quality of life, and possibly improve the clinical state in preparation for palliative chemotherapy (1). Once performed, patients who go on to receive chemotherapy show improved median survival rates (2).

The mainstay of treatment of biliary system obstruction is relief of the dilatation to decompress the system, and where possible, develop a communication between the biliary system and the bowel, thereby enabling the return of physiological bile flow. This can be done via operative or biliary bypass surgery, endoscopic bypass via ERCP or percutaneously via PTBD.

Each of these methods has benefits and drawbacks. Although operative biliary bypass is the method of choice for treatment, non-operative palliation may be desirable for selected patients (3). Management of the biliary dilatation percutaneously also decreases pain, jaundice and incidence of cholangitis. Biliary drainage also helps improve liver function prior to surgery or neoadjuvant chemotherapy.

There has been fast progression of medical imaging technology to include minimally invasive interventional treatment paradigms into clinical patient care. In our setting, interventional radiology (IR) procedures are seeing a rapid progression in patient numbers, more so in the management of obstructive jaundice. These procedures can be lifesaving especially in those with inoperable tumours, sepsis and significant comorbidities, that would make these patients poor surgical candidates. Despite the advantages, PTBD can also be associated with morbidity and mortality.

Percutaneous transhepatic biliary drainage (PTBD) for the management of obstructive jaundice has become a safe and effective technique. It is an effective method in relieving both distal and proximal biliary obstruction. The metallic self-expandable stents that are used in PTBD and stenting have also proved superior to the plastic stents used during ERCP (4).

No study has been done regarding PTBD clinical and technical outcomes in this country so far. PTBD worldwide, has been shown to be invaluable in treatment of non-resectable causes of obstructive jaundice. The cost of the procedure as well as the lack of adequate numbers of trained IR in Kenya, has been prohibitive in getting these services to deserving patients. The same situation is seen in similar developing countries like Ghana (5).

This study aims to evaluate the short term clinical and technical outcomes of PTBD, as well as determine the factors influencing clinical and technical outcomes in patients undergoing PTC and BD in Kenyatta National Hospital. The study outcome will be useful in influencing the expansion of treatment protocols for obstructive jaundice within the country, to include PTBD within the treatment pathways for appropriate candidates.

1.2 Study Justification

Obstructive jaundice is a common presentation of patients presenting at the IRC and surgical clinics at KNH. No study has been done in Kenya outlining the technical or clinical outcomes

of PTBD for those patients with obstructive jaundice managed by percutaneous biliary drainage. PTBD is a rapidly upcoming means of treatment used in managing patients with biliary obstruction in Kenya, particularly the malignant type, especially because most patients present late or at advanced stages of disease, when the malignancy is no longer amenable to surgery. This study will influence policy regarding management of obstructive jaundice since PTBD reduces hospital stay and costs incurred by surgery, is tolerated well by patients, reduces mortality and morbidity and improves quality of life especially in advanced disease.

1.3 Research question

What are the technical and short-term clinical outcomes of patients undergoing PTBD?

1.4 Objectives

1.4.1 Broad objective

To determine the short term clinical and technical outcomes of PTBD at KNH.

1.4.2 Specific objectives

1. To describe the demographics and aetiology of biliary obstruction and the presenting symptoms in patients presenting at KNH for PTBD between 2021 and 2022.
2. To describe the short-term clinical outcomes of PTBD procedure done at KNH between 2021 and 2022.
3. To describe the technical outcomes of PTBD procedure done at KNH between 2021 and 2022.
4. To describe the short-term complications experienced by patients after PTBD in KNH between 2021 and 2022.

CHAPTER TWO: LITERATURE REVIEW

Hepatic anatomy

The liver is divided into 8 anatomical and functional segments. This is according to the Couinard classification. Each segment is defined by its drainage to its own hepatic vein and bile duct. The segment is also supplied by its own hepatic portal vein (6). Segment 1 or the caudate lobe is different anatomically from other segments. This is because of its situation between the ligamentum venosum fissure and the inferior vena cava.

The liver and its 8 segments are divided into the right hepatic and left hepatic lobes. The middle hepatic vein is responsible for this division into the right and left liver lobes.

The right liver lobe comprises of segments V-VIII. These are further classified into the superior segments and inferior segments by the right portal vein. The superior segments are segments VII and VIII and the inferior segments are segments V and VI. The segments are even further classified as anterior or posterior. They are divided by a coronal oblique plane called the Cantlie's line containing the right hepatic vein. The anterior segments are V and VIII whereas the posterior segments are VI and VII.

The left lobe of the liver is comprised of segments II-IV. The umbilical fissure as well as the falciform ligament divide it into the lateral segments (segments II and III) and a single medial segment (IV or quadrate lobe). Segment II and III are divided by the left hepatic vein. Segment II is found posterosuperior to the vein while segment III is located antero-inferior to it (6).

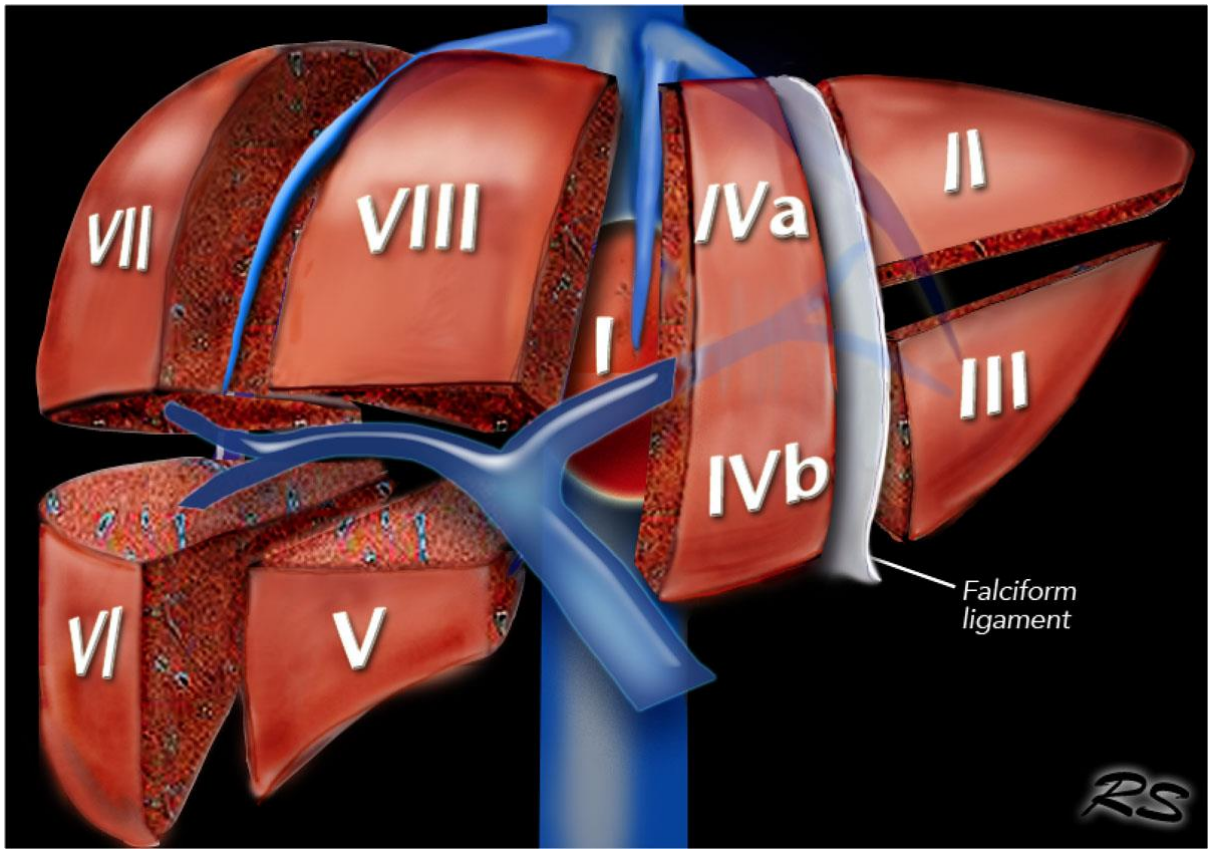


Figure 1: Couinard segmental anatomy of the liver[1]

Biliary tree anatomy

The biliary drainage system runs along the portal venous system. In addition to the hepatic artery, these three structures form the hepatic triad.

The right lobe of the liver is drained by the right hepatic bile duct (RHD). The right anterior sectoral bile duct (RASD) drains segments V and VIII. The right posterior sectoral (RPSD) bile duct drains segment VI and VII. The RASD and the RPSD then join to form the RHD. The left lobe of the liver is also drained by the left hepatic duct. This is formed by a draining duct from segment II and III each and one or more from segment IV. The common hepatic duct is formed by confluence of the right and left bile ducts. Segment 1 (caudate lobe) is anatomically distinct, therefore it drains into both the right and left bile ducts.

[1] https://radiologyassistant.nl/abdomen/biliary-system/biliary-duct-pathology (accessed on 27/12/2021)

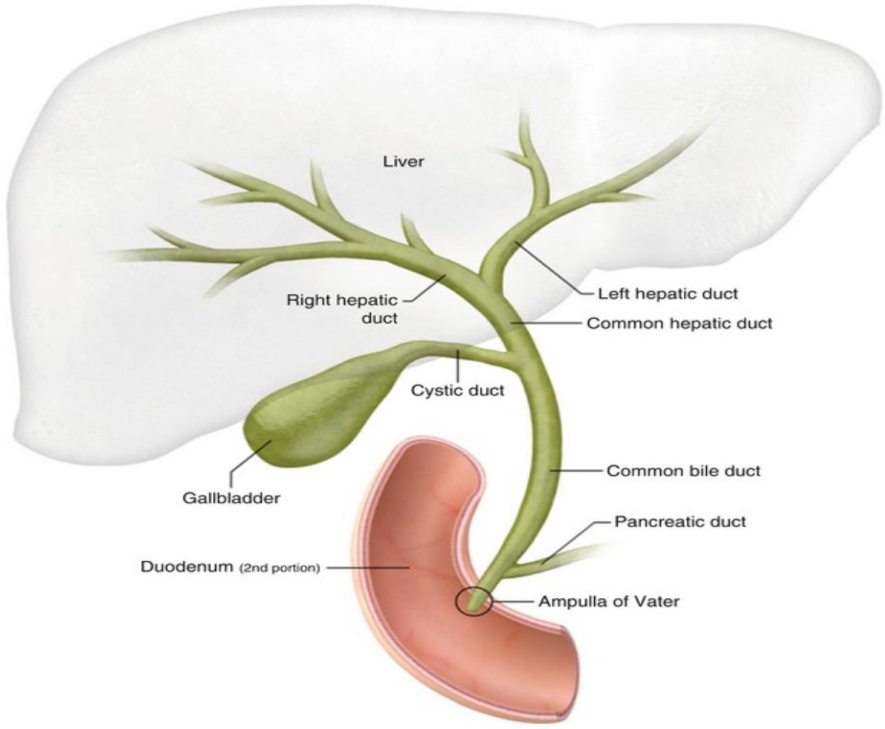


Figure 2: Pictorial diagram showing biliary anatomy[2]

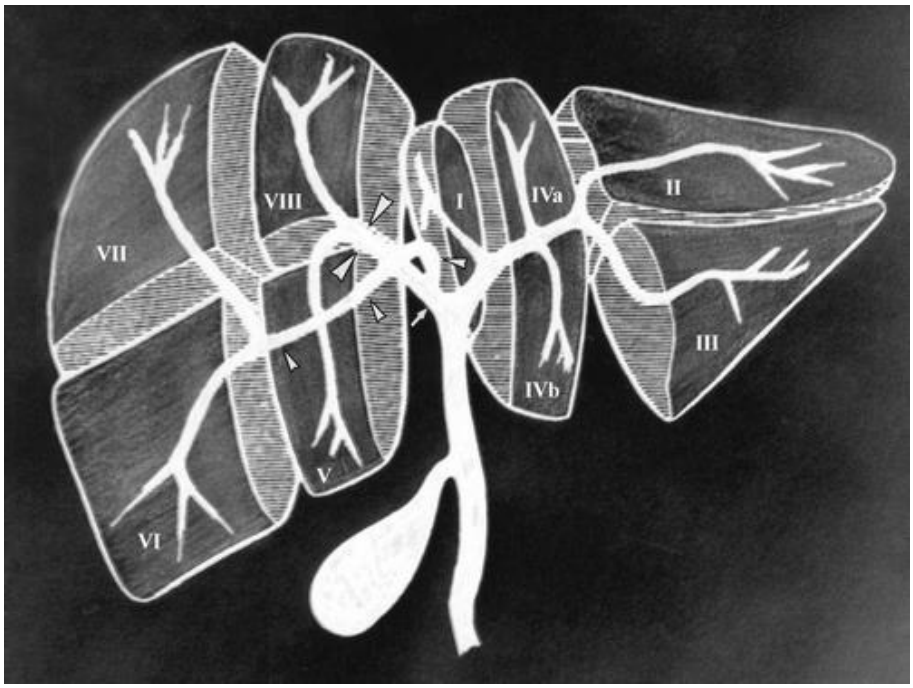


Figure 3: Normal hepatic biliary segmental anatomy (Couinard), and normal fusion of cystic duct with common hepatic duct. Note the small arrowheads show normal confluence of right posterior duct and right anterior duct.[3]

[2] https://radiologykey.com/the-biliary-tree/ (accessed on 27/12/2021)
[3] https://www.ajronline.org/doi/pdfplus/10.2214/ajr.177.2.1770389 (accessed on 27/12/2021)

The cystic duct, whose origin is from the gall bladder, joins the common hepatic duct (CHD) to form the common bile duct (CBD). The normal CBD measures 6 mm in diameter.

The CBD then follows an inferior course to joins the pancreatic duct which together, then form the ampulla of Vater. The ampulla of Vater, through the major duodenal papilla, then enters the 2nd part of the duodenum.

Normal variant biliary tree anatomy

The normal biliary tree anatomy as described above is demonstrated in 58-60% of the population (6). Variants are therefore quite common and include accessory bile ducts (aberrant ducts). These are demonstrated in approximately 2 % of the population.

Accessory/aberrant ducts drain individual liver segments into the CHD, CBD, cystic duct or even GB. They are found more commonly in the right hepatic lobe. However, they may also be seen from the caudate and left lobe.

The RPSD shows the most common variant anatomy. It can drain into LHD in (~15%) or drain into the anterior (not posterior) aspect of RASD (~12%).

RASD can also drain into LHD in ~6% of the population. A "triple confluence" is made up of RPSD, RASD and LHD united at a confluence to form CHD. It is seen in ~11% of patients.

An aberrant hepatic duct is typically an RPSD which is draining into CHD. Low insertion of the RHD into the CHD is rare and is seen in ~2% of the population.

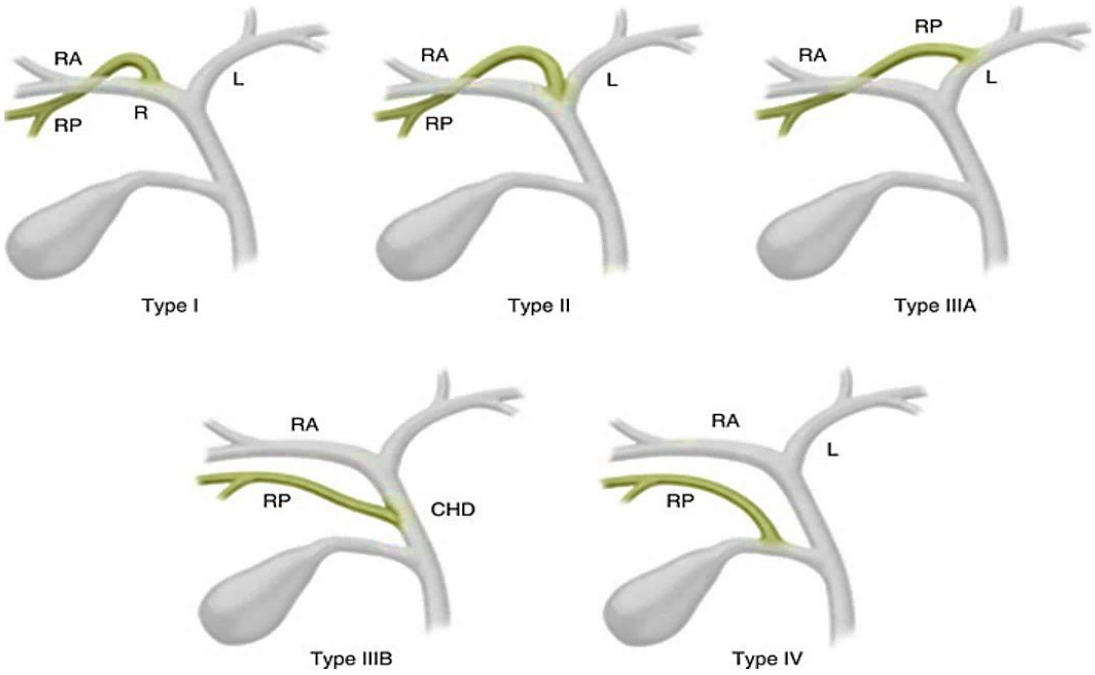


Figure 4: Biliary variants[4]

Causes of obstructive jaundice/biliary obstruction

These are broadly classified into benign and malignant causes. They include:

Benign causes:

- Benign strictures e.g., primary sclerosing cholangitis.
- Cholangitis
- Choledocholithiasis
- Extrinsic compression e.g., from benign intrahepatic tumour, choledochal cysts, pancreatic pseudocysts, bilomas.

Malignant causes:

- Cholangiocarcinoma

[4] https://radiologykey.com/the-biliary-tree/ (accessed on 27/12/2021)

- Infiltration by other malignancies e.g., Gall bladder carcinoma, hepatocellular carcinoma, pancreatic head carcinoma, metastases.
- Extrinsic compression e.g., from metastatic adenopathy

Percutaneous transhepatic cholangiography and biliary drainage (PTBD)

This is an interventional radiology procedure that is performed by a radiologist for diagnostic and/or therapeutic purposes. It is performed by accessing the biliary tree percutaneously through a needle puncture at the skin and then shortly after that via a catheter introduced into the biliary system. The procedure is performed under imaging guidance using ultrasound initially for gaining access, and then fluoroscopy for the rest of the procedure.

Indications for PTBD include:

- Relieving obstructed biliary ducts due to calculi, cholangitis, tumour or extrinsic compression.
- Antegrade biliary stenting for biliary obstruction after relieving the biliary dilatation.
- Management of cholangitis
- Percutaneous access for minimally invasive biliary procedures e.g., percutaneous stone removal.
- Management of biliary leaks/fistulas
- As an access for other biliary interventions e.g., balloon dilatation of biliary strictures, placement of brachytherapy.

Relative contraindications include:

- Ascites
- Coagulopathy
- Multifocal biliary ductal dilatation

Absolute contraindications are few:

- Uncorrectable coagulopathy.
- Lack of a safe access

Pre-procedural evaluation

Involves evaluation of several parameters:

- Previous imaging- to evaluate for presence and pattern of biliary obstruction, to plan on access and trajectory of the PTC, evaluate for adjacent structures
- Laboratory work up:
    - Haemoglobin (Hb) >10g/Dl
    - Platelets (PLT) >50000/ml
    - Liver function tests (LFT)
    - Activated Partial thromboplastin time (aPTT) < 50 secs
    - International Normalised Ratio (INR) <1.5
- Obtaining informed consent

Procedure

The procedure is usually performed under no or minimal sedation, or conscious sedation, except for uncooperative patients who require moderate sedation or general anaesthesia. An initial pre-procedure ultrasound of the liver is done to determine access site. Doppler ultrasound is utilised to differentiate bile ducts and blood vessels. The skin is then cleaned and draped under the standard surgical skin cleaning procedures.

Local anaesthesia is given under ultrasound guidance at the expected puncture site to the skin and subcutaneous tissue up to the liver capsule under ultrasound guidance, and a skin nick made with a small blade size 11/15.

Using a 21G Chiba needle or micro puncture needle, the skin and liver are punctured under ultrasound guidance. A peripheral bile duct is then punctured using ultrasound guidance. The stylet is removed, and once bile is seen flowing out of the needle, contrast is given via the micro puncture needle, and a cholangiogram is done to confirm that the needle is placed within the biliary system. A 0.018' nitinol micro guidewire is then advanced into the bile ducts and the needle removed over it.

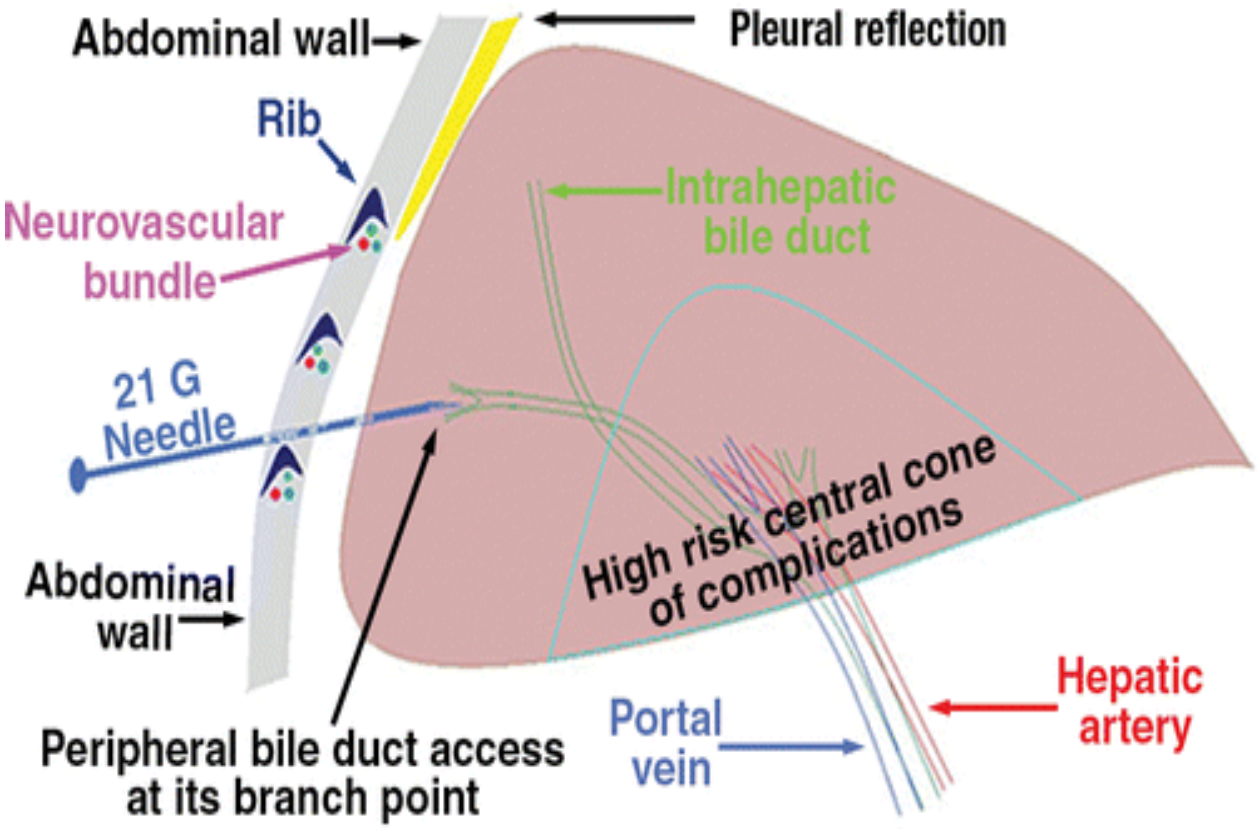


Figure 5: Coronal illustration of the right-sided biliary access technique in accessing a peripheral bile duct. The needle is traversing the soft tissues above the upper border of the rib but below the pleural reflection.[5]

Serial dilatation is done with the assembled dilators and then a 0.035 standard Teflon guide wire is advanced under fluoroscopic guidance into the confluence of the RH and LHD or CHD.

[5] https://www.researchgate.net/profile/Karthikeyan-Damodharan/publication/314972115/figure/fig2/AS:731798682214400@1551485810123/Coronal-projection-illustration-of-the-technique-used-to-access-a-peripheral-bile-duct_W640.jpg

Once the position is confirmed, an 8F or 10F biliary drainage tube is inserted over the wire and position confirmed on fluoroscopy. If an endo-exo or internal-external drain is required, a 0.035 or 0.038 hydrophilic wire is advanced through the dilator into the CBD, and up to the duodenum, under fluoroscopic guidance. A 40 cm 8F/10F drain is then advanced under fluoroscopic guidance with its end holes placed in the duodenum and the proximal side holes located above the level of obstruction, usually at the hilum. Final cholangiogram is then done using contrast injection through the newly placed biliary drain. The biliary drain or tube is secured to the skin using a suture and dressing done. The drainage tubes are attached to an external bag where the bile will drain.

Complications

These occur more commonly in patients with minimally dilated or undilated bile ducts due to the complexity or difficulty of cannulating the ducts. They can be summarised as being due to the access, catheter, or stent, or due to vascular and non-vascular complications, as listed below.

Complications Associated with Biliary Interventional Procedures

Access-related complications
Pain
Pleural space transgression
Subcapsular hematoma
Inadvertent arterial access
Inadvertent extrahepatic bile duct access
Bile duct perforation
Ascites and bowel interposition in right upper quadrant
Nonvascular complications
Bile leakage
Acute pancreatitis
Biloma and/or abscess
Cholangitis
Vascular or bleeding complications
Pseudoaneurysm
Bilioarterial fistula
Bilioportal vein fistula
Catheter erosion into inferior vena cava
Catheter-related complications
Fracture
Obstruction
Dislodgement
Buckling
Stent-related complications
Obstruction
Migration
Disjunction
Fracture
Balloon ruptured by stent struts

Figure 6: Complications of PTBD[6]

[6] https://pubs.rsna.org/doi/pdf/10.1148/rg.2017160159

LITERATURE REVIEW

Obstructive jaundice is a rising cause of mortality and morbidity worldwide, more so the malignant type. The same situation is seen in Kenya, where most patients present at the late stages of the disease, especially for malignant obstructive jaundice, due to the asymptomatic nature of the causative malignancy in the early stages.

Biliary obstruction can be relieved surgically, via ERCP or percutaneously via PTC and external BD. PTBD is rapidly evolving as one of the major treatment options for our patients due to the late stage at which patients present. No clinical study has been done in our population to evaluate the clinical or technical outcomes in these patients.

No clinical study has been done in our population to evaluate the clinical or technical outcomes in these patients.

In 1987 to 1988, a study carried out at the Kenyatta National Hospital (KNH) by Okoth et al found that pancreatic head carcinoma accounted for 55% of cases of biliary obstruction. This was followed by gallstones at 10% and hepatocellular carcinoma at 10%, and gall bladder tumours at 10% (7). However, this was a limited study which was screening for causes of biliary obstruction on ultrasound. Another study by Bitta et al in 2009, evaluating causes of malignant obstructive jaundice at KNH, found that the leading cause was carcinoma of the head of the pancreas at 65%, followed by cholangiocarcinoma at 21% and peri-ampullary tumours at 14% (8).

According to the Eldoret Cancer Registry, 3 in 5 patients annually present with cholangiocarcinoma, similar to the incidence of gall bladder carcinoma (9).

There has been fast progression of medical imaging technology to include minimally invasive interventional treatment paradigms into clinical patient care. In our setting, interventional radiology (IR) procedures are seeing a rapid progression in patient numbers, more so in the

management of obstructive jaundice. These procedures can be lifesaving especially in patients with inoperable tumours, sepsis and significant comorbidities making them poor surgical candidates. Despite their advantages, they can also be associated with morbidity and mortality.

Percutaneous transhepatic biliary drainage (PTBD) for the management of obstructive jaundice has become a safe and effective technique. It is an effective method in relieving both distal and proximal biliary obstruction. The metallic self-expandable stents that are used in PTBD and stenting have also proved superior to the plastic stents used during ERCP (4).

Khara et al has described the definition of proximal and distal biliary obstruction by consensus where the upper/sub-hepatic CBD is termed as "proximal CBD" and the lower/pre-ampullary portion termed as "distal CBD" (10).

In a multicentre study done in England between 2001 and 2014 of 16 822 patients, evaluating causes of poor outcomes after PTBD for inoperable pancreatobiliary tumors, the median age of the patients was 72, ranging between 19–104 years. Majority of the patients (58%) had pancreatic cancer while 30% had biliary tract cancer (1). In-hospital mortality as well as 30-day mortality were 15.3% and 23.1% respectively. The factors they found associated with the 30-day mortality included advanced age (≥81 years), other co-existing co-morbidities, pre-existing abnormal renal function, non-pancreatic cancers and male sex (1).

In several study series, the technical success or outcome is >90% whereas the clinical success or outcome is >75%. A number of complications have also been seen post procedure, with short term mortality shown being <2% in these series. Most of these complications demonstrated after the procedure are mild and can be treated conservatively (4).

30-day mortality after PTBD has however, been shown to be higher at >10% in many other series. This is thought to be due to the underlying diseases that most patients already have or

due to the advanced stage of disease. Recurrent jaundice post PTBD and stenting is seen in approximately 10–30% and will require re-intervention (4).

In a comparative study by Mortele et al, where clinical and technical outcomes were compared between PTBD and ERCP in patients with gall bladder carcinoma, PTBD was found to have slightly better clinical and technical success rates with lower complication rates than ERCP (6).

Another single centre study done in China between 2008 and 2009, evaluating the factors affecting the short-term prognosis of PTBD for malignant obstructive jaundice, showed that pre-operative cholangitis, Child Pugh Grade > 11, elevated Creatinine >115, low haemoglobin levels, high TBIL carried a poorer prognosis in the first 30 days after intervention (11).

A more recent study between 2017 and 2019, done by Pankaj et al in a single centre in India, review of 90 patients who underwent PTBD was done. Here, they found older age and female sex as well as non-dilated ductal system, as the main risks for adverse events. Gallbladder carcinoma was their highest underlying cause for biliary obstruction (12). Their technical success rate was 91.2% with no procedure related mortalities.

Percutaneous biliary interventions, according to Weber et al, are associated with rates of complication between 3% to 10% and procedural mortality rates ranging from 0.1% to 0.8% (13). The guidelines published by the Society of Interventional Radiology recommend that the practice of PTBD should be reviewed if these rates are surpassed.

According to Venkatanarasimha et al, the complications of PTBD interventions are wide-ranging from mild complications like discomfort at the access site to life-threatening conditions like vascular complications. These life-threatening complications are relatively uncommon. Most of these complications are self-limiting (14).

Clinical and technical outcomes

Zhang et al, in their study evaluating clinical and technical outcomes after percutaneous biliary drainage, described a successful technical outcome as correct placement of the biliary drain with subsequent active drainage of bile. They described a successful clinical outcome as a reduction of >20% in the serum bilirubin levels done 7 days after the procedure (15). Kumar et al, in evaluating for recovery of liver function after biliary drainage percutaneously, found that although bilirubin levels were shown to decrease after the procedure, certain other factors influenced the rate of decrease. These factors included the duration of biliary obstruction, the degree of hepatic parenchymal disease or tumour extent, the initial serum bilirubin levels and the presence of biliary sepsis. These factors were found to delay the rate of reduction of bilirubin levels, thought to be due to their association with ongoing hepatocyte impairment (16).

No study has been done regarding PTBD clinical and technical outcomes in this country. PTBD worldwide, has been shown to be invaluable in treatment of non-resectable causes of obstructive jaundice. The cost of the procedure as well as the lack of adequate numbers of trained IR in Kenya, has been prohibitive in getting these services to deserving patients. The same situation is seen in similar developing countries like Ghana (5).

This study aims to show technical and clinical success rates from PTBD with the objective of influencing policy decisions regarding mainstreaming PTBD procedures in management of obstructive jaundice, to improve quality of life and support or permit palliative or definitive surgical or oncological management.

Technical outcomes are described as measures of technical success while performing a procedure and can be influenced by the skill of the interventional radiologist, patient factors and the anatomical and technical difficulties in carrying out the procedure.

The correct placement of the catheter into the biliary system, and drainage of bile, shall be an indication of technical success in this study. Inability to cannulate the biliary system or place the drain in the correct position will be termed as technical failure. Any complications arising from the attempt to cannulate the biliary ducts will be documented.

Clinical outcomes are described as measures of changes of the patients' symptomatology, improving or worsening health condition, quality of life and presence of complications after a procedure. In this study, we shall evaluate the percentage reduction in bilirubin levels in the intermediate short term and the document the changes in symptomatology.

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study design

This was a retrospective and prospective cross-sectional study. Retrospective data on PTBD clinical outcomes was abstracted from patient files from 12 months prior to this study. We prospectively collected the same data from patient files for 3 months until the sample size was achieved. We used a combination of retrospective and prospective approaches in data collection due to time constrains within this fellowship. We abstracted data from files of patients undergoing PTBD from January 2021 to June 2022. Data abstraction from the files was done over a period of 6 months from March to June 2022.

3.2 Study setting

The procedure was carried out at the KNH radiology department, IR unit. Patient recruitment was done at the IR clinic (IRC) and department of radiology in KNH and be selected according to the inclusion criteria. The IRC was held once a week, on a weekday morning and it receives approximately 25-40 patients for varied patients referred from different areas. Approximately 1-2 patients are seen at IRC every week for management of obstructive jaundice through PTBD procedure. At least 1 in-hospital or in-patient consultation per week, for the same procedure, was also received at the IR department. The patients were reviewed by the interventional radiologist or the fellow in IR, and appropriate pre-procedure laboratory work-up was ordered and previous images reviewed to determine suitability and preparedness for the procedure. Once fully prepared, the patient was scheduled for the PTBD procedure at the IR department. Informed consent was sought for the procedure, and in very sick patients, assent was given by the guardian. The procedure was carried out within the radiology department on KNH, at the IR unit.

The IR unit had one procedure room where PTBD procedures were carried out. At least 8-13 procedures were carried out daily in the unit except on clinic days. The unit had one fluoroscopy or angiography machine and two ultrasound machines within it. The IR machines employed for PTBD procedures specifically at KNH are a Phillips MD Eleva angiography machine manufactured by Phillips Medical Systems taking fluoroscopic images at 2 frames per second and a Philips ultrasound machine.

The procedures were carried out by the interventional radiologists or IR fellows with supervision by the IR consultants. They were assisted by a nurse and radiographer. Approximately one to two PTBD procedures were carried out every week at the unit.

3.3 Study population

The population included patients attending KNH IR and surgical clinics and radiology department and in-patients who have biliary obstruction managed through PTBD. They had to meet the inclusion criteria.

The patients who meet the inclusion criteria were asked for consent for their inclusion into the study. Their demographic data and clinical and technical data was collected as per the data collection form. All PTBD procedures and the imaging was evaluated by the principal researcher in consultation with a consultant interventional radiologist at the study site workstation. Two research assistants were recruited and trained to carry out image collection and data tabulation. Clinical records were tracked, and telephone interviews employed where necessary to check for short interval clinical outcomes.

3.4 Eligibility criteria

3.4.1 Inclusion criteria

All patients who had primarily undergone PTBD at KNH during the study period and consented to the study.

3.4.2 Exclusion criteria

1. Patients who had already undergone successful biliary stenting through ERCP.
2. Patients who already have previously inserted indwelling biliary drains.

3.5 Sample size determination

A minimum sample size of 47 patients was sufficient to estimate the clinical and technical outcomes of PTBD among a finite population of patients seeking this procedure at the KNH Interventional Radiology Unit with 95% confidence (± 10%). Since the proportion of PTBD outcomes had not been estimated before in Kenya, or a similar context, we selected a conservative proportion of 50%, which yielded the highest population for cross sectional studies estimating proportions. From medical records in the Interventional Radiology Department at KNH, PTBD was conducted on an average of 90 patients per year. We anticipate a similar population of patients over the 18-month study period within which we abstracted the data in PTBD outcomes. We abstracted data from files of patients undergoing PTBD from January 2021 to June 2022. Data abstraction from the files was done over a period of 6 months from March to June 2022.

The following principle was applied to get the sample size formula (17).

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

Where:

n’ = Sample size with finite population correction

N= Population size at the KNH Interventional Radiology Department of 90 patients per year.

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

P = Conservative proportion of PTBD outcomes (50%)

α = Precision with a 95% confidence interval which gives a margin of error of 0.1.

$$n' = \frac{90 * (1.96)^2 * 0.5(1-0.5)}{(0.1)^2 (90-1) + (1.96)^2 * 0.5(1-0.5)}$$

$$= \frac{345.6 * 0.25}{0.89 + 0.96}$$

$$= \frac{86.4}{1.85}$$

n' = 47 patients

3.6 Sampling procedure

We used consecutive sampling method for all patients who have undergone PTBD at KNH and meet the inclusion criteria until the desired sample size was achieved.

3.7 Data collection

Files and medical records of all the patients who underwent PTBD at the facility over the 12 months before the inception of the study and upto 6 months after the inception of the study, were retrieved from IRC, records department and radiology department at Kenyatta National hospital. The process of retrieving these files was done by the principal investigator. The required data was then extracted from the files/medical records into the hard copy data extraction form by the principal investigator. Technical and clinical success was evaluated from the files and medical records in the immediate and intermediate periods after the procedure.

Data collection was done according to the specific objectives as outlined.

Objective 1: To describe the demographic features of the patients undergoing PTBD at KNH, classify the pattern of diseases causing biliary obstruction in these patients and describe the presenting symptoms and laboratory work up

- Age
- Sex
- Residence
- Presenting symptoms
- Any imaging done and level of biliary obstruction.
- Cause of biliary obstruction
- Pre-procedure laboratory work-up

Objective 1 was presented as follows:

Patient characteristics		n (%)
Sex	Male	n (%)
	Female	n (%)
Age c	Mean	SD
Any imaging done	Ultrasound	n (%)
	CT	n (%)
	MRI	n (%)
Level of obstruction on imaging	Proximal	n (%)
	Distal	n (%)
Cause of biliary obstruction	Cholangiocarcinoma	n (%)
	Hepatocellular carcinoma	n (%)
	Gall bladder carcinoma	n (%)
	Pancreatic carcinoma	n (%)
	Benign biliary stricture	n (%)
	CBD calculi	n (%)
	Ampullary or periampullary carcinoma	n (%)

	Metastatic disease Other/unknown	n (%) n (%)
Laboratory work up	Mean	 Sd

Table 1: Patient demographics and presenting symptoms, diagnosis and laboratory work-up

Objective 2: To describe the clinical outcomes of PTBD:

Clinical outcomes were described according to the changes in symptomatology within the immediate and first 30 days after the procedure.

Symptoms	Improvement (n=%)	worsening	No change
Nausea			
Vomiting			
Yellowness of eyes			
Pruritis			
Inability to feed			
Fever			
Ability to feed			

Table 2: Clinical outcomes depicted by change in symptomatology in the immediate and intermediate period after the procedure

Objective 3: To describe the technical outcomes of PTBD:

Technical outcomes will be described in terms of technical success where an biliary drain is successfully inserted, or failure, where the biliary drain was not inserted successfully, and the reasons why.

- Success rate
- Technical complications

Technical success	**N (%)**		**n (%)**
YES	%	Unisectoral external PTBD	n (%)

		Multisectoral external PTBD	n (%)
		Internal-external PTBD	n (%)
NO	%	**Technical complication, if any:**	
		Difficult cannulation-minimally dilated ducts	n (%)
		Patient condition-tachypnea, dysnoea	n (%)
		Vessel puncture	n (%)
		Bowel or other organ puncture	n (%)
		Pneumothorax	n (%)

Table 3: Technical outcomes of PTBD: technical success rates and causes of technical failure

Objective 4: To determine post procedure immediate and intermediate (first 30 days) complications experienced by patients after undergoing PTBD:

- List any immediate post procedure (within 24 hours)
- List any intermediate complications (within 1 month)

Time duration	Complication	n (%)
Immediate	Sepsis/septic shock	n (%)
	Tube dislodgement	n (%)
	Non-functioning tube/blocked tube	n (%)
	Intra-peritoneal bile leak	n (%)
	Worsening level of consciousness	n (%)

	Death	n (%)
Intermediate	Tube dislodgement	n (%)
	Tube blockage/non-functioning tube	n (%)
	Peri-tubal leak	n (%)
	Peri-tubal discomfort or pain	n (%)

Table 4: Immediate and intermediate post procedure complications of PTBD

3.8 Data management

Raw data from the patient files was verified by the principal investigator to check for errors or omissions made while abstracting the data. Abstracted data was in the safe custody of the principal investigator who filed them in a locked cabinet. Data coding was also done to ensure that data entries were in the right format and also minimized incomplete data entries. Data collected in this study was stored in a password-protected computer and backed up in a secure Data Cloud Service. Each patient entry was under the unique study number so as to protect the privacy of the study participants.

3.9 Data analysis

Abstracted data from patient files was entered into a Microsoft Excel™ Database and then exported into a Statistical Package for Social Scientists version 22 (SPSS, Chicago) software, which was used for data analysis. The mean and standard deviation was used to summarise continuous variables. In case the variable data was not normally distributed, median, and corresponding interquartile range was used. Categorical data was analysed using frequencies and percentages. To determine the association between pre and post intervention laboratory parametor values, pared sample t test or the non parametric form Wilcoxon signed-rank test were used to determine if there was any significant differences. A p value of <0.05 was considered statistically significant.

The results are presented in form of tables, figures (pie charts and bar charts), images and prose format.

3.10 Quality control

All the patient files with clinical notes and procedure images was evaluated by the principal researcher in consultation with a consultant interventional radiologist in the study site.

3.11 Ethical considerations

The study was carried out once approval is given by the KNH/UoN ethics committee. Participation in the study was voluntary. Consent was both verbal and written. Waiver of consent was sought where necessary for example in the unconscious or acutely confused patients, when the guardian was not available.

There was no additional expenses incurred nor was any unique risk experienced by participating in this study. There was no victimization or preferential treatment experienced due to refusal to participate or acceptance of participation in the study.

Sensitive patient information obtained from participants was kept confidential and no names was recorded in the study data collection sheet.

All patient records were anonymised and coded with serial numbers. Only Xray numbers were recorded. A participant link log was retained separately by the principal investigator in the event of retrieval of patient records. All study materials were kept under lock and key with only specific study personnel allowed to access study materials. The ALARA principle in keeping radiation exposure to as low as reasonably achievable was followed for all patients.

Copies of the study were given to the University of Nairobi and Kenyatta National Hospital for future reference and to facilitate policy change and improvements in patient management. .

3.12 Study dissemination

The information on the clinical and technical outcomes of PTBD in Kenyatta National Hospital was determined. This information was disseminated through a thesis report, manuscripts and conference presentation to relevant stakeholders with the intention of impacting policy in management of biliary obstruction.

CHAPTER FOUR: RESULTS

4.1 Patient characteristics

4.1.1 Socio-demographic characteristics

The mean age of the patients was 56 (SD=13.6) years, with the youngest being 28 years and eldest being 86 years **(Figure 1).**

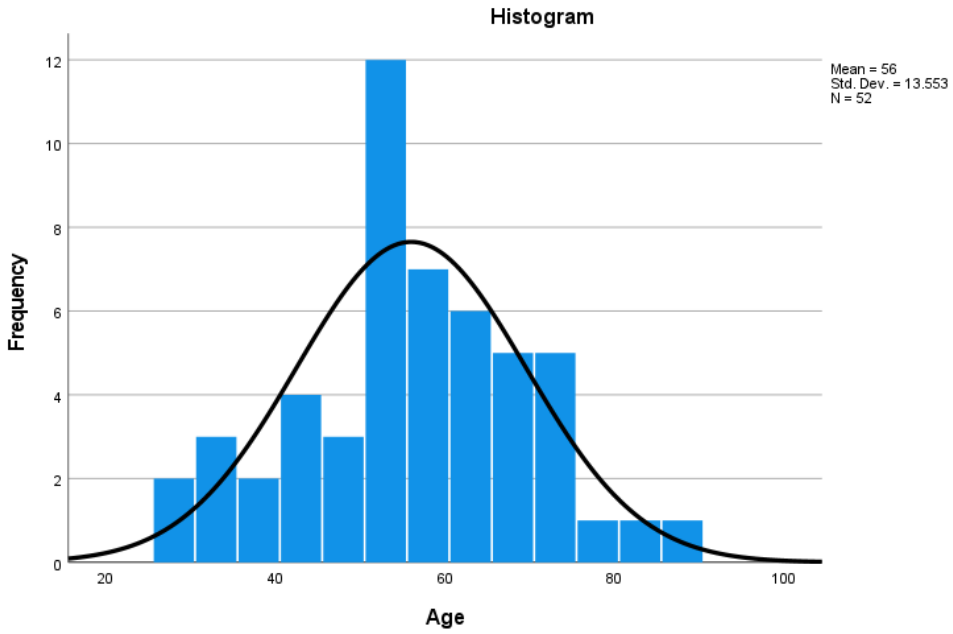


Figure 7: Patients' age distribution

More than half, 29 (55.8%) were females while the rest were males**. (Figure 2).**

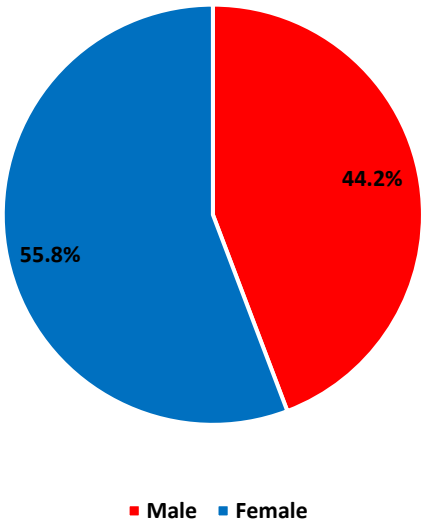


Figure 8: Sex distribution

The participants county of residence is shown in table below. A quarter, 13 (25.0%) were from Murang'a county, 12 (23.1%) Nairobi County, and 5 (9.6%) Kiambu county. **(Table 1).**

Table 5: Patients' County of residence

County	Frequency (n)	Percent (%)
Busia	1	1.9
Isiolo	1	1.9
Kakamega	1	1.9
Kiambu	5	9.6
Kirinyaga	1	1.9
Kisii	2	3.8
Kitui	2	3.8
Machakos	3	5.8
Makueni	1	1.9
Meru	2	3.8
Murang'a	13	25.0
Nairobi	12	23.1
Nakuru	1	1.9
Narok	1	1.9
Nyandarua	1	1.9
Nyeri	3	5.8
Uasin Gishu	1	1.9
West Pokot	1	1.9
Total	52	100.0

4.1.2 Aetiology of biliary obstruction and the presenting symptoms in patients

Among the patients, 25 (48.1%) had Klatskin tumor and cholangiocarcinoma, 12 (23.1%) had Pancreatic head carcinoma, and 5 (7.7%) strictures including post-surgical stricture, post hepaticojejunostomy surgical stricture, stricture of unknown cause, and distal CBD stricture. 5 (9.6%) had metastasis including metastatic liver disease (1), metastatic gastric carcinoma (1), breast cancer (1) and cervical cancer (2). Another 5 (9.6%) had gall bladder carcinoma or mass. All 52 patients had yellowness of eyes, 43 (82.7%) had pruritus, 18 (34.6%) abdominal pains, 12 (23.1%) weight loss, 9(17.3%) vomiting, 7 (13.5%) nausea, 7 (13.5%) feeding inability, 5 (9.6%) abdominal swelling and 4 (7.7%) fever. **(Table 2).**

Table 6: Aetiology of biliary obstruction and the presenting symptoms in patients

Diagnosis and symptoms pre intervention	Frequency (n)	Percent (%)
Patient diagnosis		
Metastasis	5	9.6
Cholangiocarcinoma	25	48.6
Choledocholithiasis	2	3.8
Gall bladder carcinoma or mass	5	9.6
Pancreatic head carcinoma	12	23.1
Periampullary carcinoma	1	1.9
Post hepaticojejunostomy	2	3.8
Stricture	5	9.6
Symptoms pre intervention		
Nausea	7	13.5
Vomiting	9	17.3
Yellowness of eyes	52	100
Pruritus	43	82.7
Weight loss	12	23.1
Inability to feed	7	13.5
Fever	4	7.7

Abdominal swelling	5	9.6
Abdominal pain	18	34.6

*Some participants had more than one diagnosis.

Out of the 52 patients presenting for PTBD, 8 (15.4%) had a history of an unsuccessful ERCP. 44 (84.6%) of the patients had not had any attempt at ERCP prior to presenting for PTBD. **(Figure 3).**

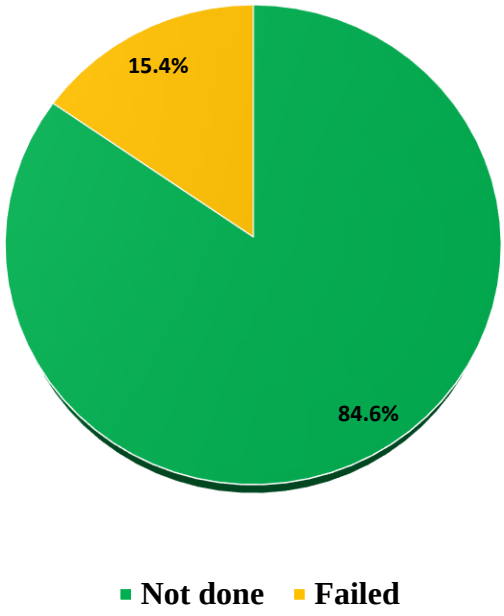


Figure 9: ERCP

4.1.3 Previous pre-procedure imaging

MRI had been done in 34 (65.4%) patients, CT scan in 24 (46.2%) and ultrasound in 7(13.5%). Most patients came with at least more than one imaging modality done.

On the pre-procedural imaging, distal obstruction was found in 14 (26.9%) of the patients whereas 36 (69.2%) of the patients had proximal obstruction. **(Table 3).**

Table 7: Imaging and obstructions

Imaging and obstructions	Frequency (n)	Percent (%)
Previous imaging availed		
Ultrasound	7	13.5
CT Scan	24	46.2
MRI	34	65.4
Obstruction on previous imaging		
Distal obstruction	14	26.9
Proximal obstruction	36	69.2
None	2	3.8

4.1.5 Comorbidities

Only 20 (38.4%) of the patients had comorbidities.

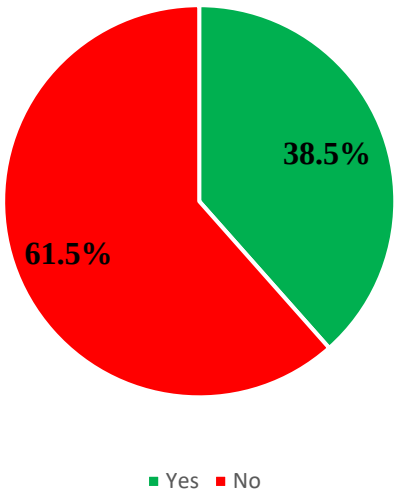


Figure 10: Presence of comorbidities

Among the 20 (38.4%) patients who had comorbidities, 7 (13.5%) had other malignancies, 5 (9.6%) hypertension, 4 (7.7%) diabetes, 2(3.8%) HIV/AIDS, 1 (1.9%) kidney disease and 1 (1.9%) pulmonary disease.

The rest, 32 (61.5%), had no comorbidities.

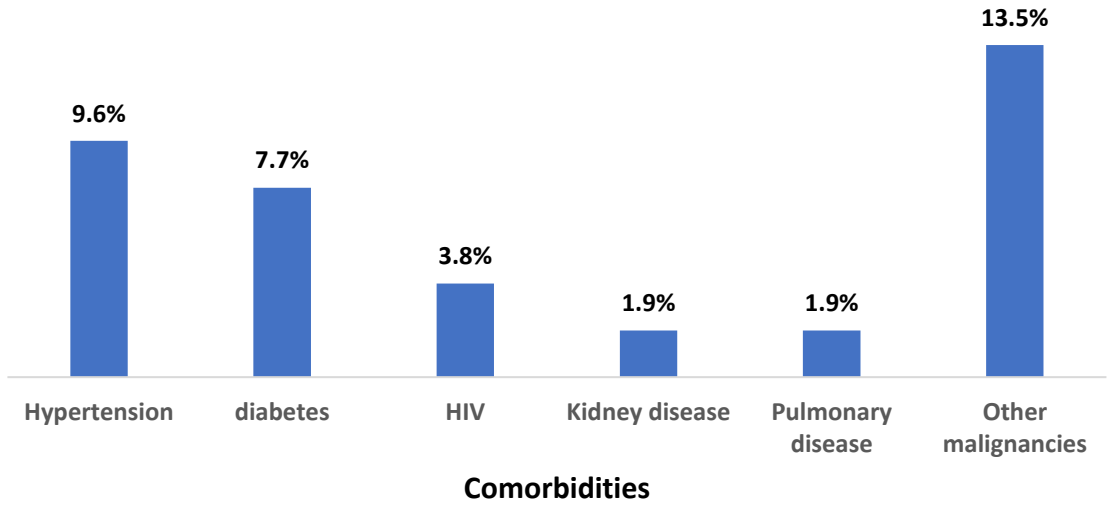


Figure 11: Comorbidities in patients

4.2 Clinical outcomes and success rate

4.2.1 Pre intervention Laboratory parameters

The mean haemoglobin pre intervention was 11.9 (SD=1.9) while mean white blood cells (WBC) was 10.2 (SD=4) and the median platelets levels was 388.0 (IQR=280.8-487.5). The median total bilirubin and direct bilirubin was 377.0 (IQR=238.3-455.0) and 200.0 (IQR=133.0-260.0), respectively.

The median Gamma-glutamyl Transferase (GGT), Alkaline phosphatase (ALP), International Normalized Ratio (INR) and Prothrombin Time Index (PTI) was 305.5 (IQR=169.8- 817.5), 510.5 (IQR=379.3-658.5), 1.2 (IQR=1.1-1.5) and 86.0 (IQR=70.0-93.9) respectively. **(Table 5).**

Table 8: Laboratory parameters

Lab parameter	Mean (SD)	Median (IQR	Range
Haemoglobin	11.9 (1.9)	11.9 (11.0-12.9)	16.0-7.6
White blood cells	10.2 (4.6)	9.8 (7.0-11.4)	27.0-3.9
Platelets	385.3 (144.6)	388.0 (280.8-487.5)	747- 200
Total bilirubin	373.5 (183.2)	377.0 (238.3-455.0)	771-61.7
Direct bilirubin	199.3 (91.1)	200.0 (133.0-260.0)	416-30

Gamma-glutamyl Transferase (GGT)	515.4 (488.6)	305.5 (169.8- 817.5)	1848-21
Alkaline phosphatase (ALP)	610.3 (364.1)	510.5 (379.3-658.5)	2031-226
International Normalized Ratio (INR)	1.3 (0.4)	1.2 (1.1-1.5)	2.5-0.8
Prothrombin Time Index (PTI)	81.5 (16.9)	86.0 (70.0-93.9)	109-43

4.2.2 Post procedure laboratory parameters

One month post procedure, the mean WBC was 9.2 (SD=2.8%). The median total bilirubin and direct bilirubin were 107.0 (IQR=54.6-190.0) and 65.0 (IQR=33.0-120.5), respectively (**Table 8).**

Table 9: Post procedure laboratory parameters

Parameter	Mean (SD)	Median (IQR)	Range
Total Bilirubin	128.7 (90.3)	107.0 (54.6-190.0)	410.0-18.8
Direct bilirubin	83.5 (64.6)	65.0 (33.0-120.5)	298.0-7.5
White blood cells (WBC)	9.2 (2.8)	9.2 (7.9-11.1)	16.8-3.5

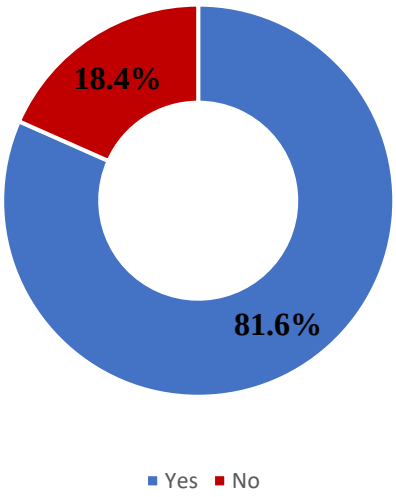
4.2.3 Clinical Success Rate

Post intervention, there was improvement in 4 (66.7%) of the 6 nausea cases while there was no change in the remaining 2 (33.3%) cases. Among the 16 cases with vomiting, there was improvement in 8 (50.0%), worsening in 5 (31.3%) and no change in 3 (18.8%). Among the 45 with yellowness of eyes, there was improvement in 40 (88.9%). Among the 40 who had pruritus, there was improvement in 35 (87.5%), while among the 15 with weight loss, improvement was noted in 12 (80.0%). Most, 5(83.3%) of the 6 who had feeding inability improved. Improvement was also noted in 3 (37.5%) of the 8 who had fever. **(Table 9).**

Table 10: Symptoms post intervention

Symptoms post intervention	Frequency (n)	Percent (%)
Nausea (n=6)		
Improved	4	66.7
No change	2	33.3
Vomiting (n=16)		
Improved	8	50.0
No change	3	18.8
Worsened	5	31.3
Yellowness of eyes (n-45)		
Improved	40	88.9
No change	5	11.1
Pruritus (n=40)		
Improved	35	87.5
No change	5	12.5
Weight loss (n=15)		
Improved	12	80.0
No change	3	20.0
Feeding inability (n=6)		
Improved	5	83.3
No change	1	16.7
Fever (n=8)		
Improved	3	37.5
No change	1	12.5
Worsened	4	50.0

The overall clinical success rate among the patients was 81.6%.



4.2.4 Changes in laboratory parameters pre to post intervention

The paired WBC mean difference pre and post procedure was not statistically significant; t(48)=0.73, P-value=0.472, and the effect size was very small , Cohen's d=0.104. **(Table 10).**

Table 11: Paired sample t test showing changes in laboratory parameters pre to post intervention

Paired sample t test	Paired Differences Mean (SD)	95% CI of the Difference	T	df	P-value. (2-tailed)	Cohen's d
Total bilirubin - Total Bilirubin One Month Post Procedure	243.8 (168.2)	195.5-292.1	10.1	48	<0.001	1.450
Direct bilirubin - Direct Bilirubin One Month Post Procedure	115.6 (87.4)	90.5- 140.7	9.3	48	<0.001	1.323
WBC- WBC One Month Post Procedure	0.46 (4.4)	-.81-1.7	.73	48	0.472	0.104

A Wilcoxon signed-rank test showed that the intervention resulted in statistically significant reduction in total bilirubin (Z = -6.033, P-value<0.001) and direct bilirubin (Z = -5.799, P-value<0.001). **(Table 11).**

Table 12: Wilcoxon Signed Ranks Test showing changes in median laboratory parameters pre to post intervention

Wilcoxon Signed Ranks Test	Median	Z	P value
Total bilirubin one month post procedure – total bilirubin	377.0 (238.3-455.0) 107.0 (54.6-190.0)	-6.033	<0.001
Direct bilirubin one month post procedure – direct bilirubin	200.0 (133.0-260.0) 65.0 (33.0-120.5)	-5.799	<0.001
WBC one month post procedure - WBC	9.8 (7.0-11.4 9.2 (7.9-11.1)	-0.580	0.562

4.3 The technical outcomes of PTBD procedure

Biliary drainage was technically successful in 51 (98.1%) of the 52 cases.

Of the 51 successful cases, an external drainage approach was used in 28 (54.9%), with a primary endo-external approach used in 16 (31.4%) and primary biliary stenting done in 7 patients (13.7%). For the 28 external drainage accesses, left access was used in 18 (64.3%) and right access in 10 (35.7%). For the 16 endo-external access, a left access was used in 9 (56.3%), right access in 6 (37.5%) and both right and left access in 1 (6.2%). For the 7 who got primarily stented, left access was used in 4 (57.1%), right access in 2 (28.6%) and both left and right access in 1 (14.3%). **(Table 6).**

Table 13: Technical outcomes of PTBD procedure

Biliary drainage	Frequency (n)	Percent (%)
Success of biliary drainage (N=52)		
Successful	51	98.1
Failed	1	1.9
Approach to successful drainage (n=51)		
Endo-external	16	31.4
External	28	54.9
Stent	7	13.7
Access side		
External drainage access (n=28)		
Right access	10	35.7
Left access	18	64.3
Endo-external access (n=16)		
Right access	6	37.5
Left access	9	56.3
Both	1	6.2
Stent (n=7)		
Right access	2	28.6
Left access	4	57.1
Both	1	14.3

In the 1 patient where there was technical failure (inability to insert a biliary drain or stent), the reason was multiple unsuccessful punctures due to the patients condition (dyspnoea).

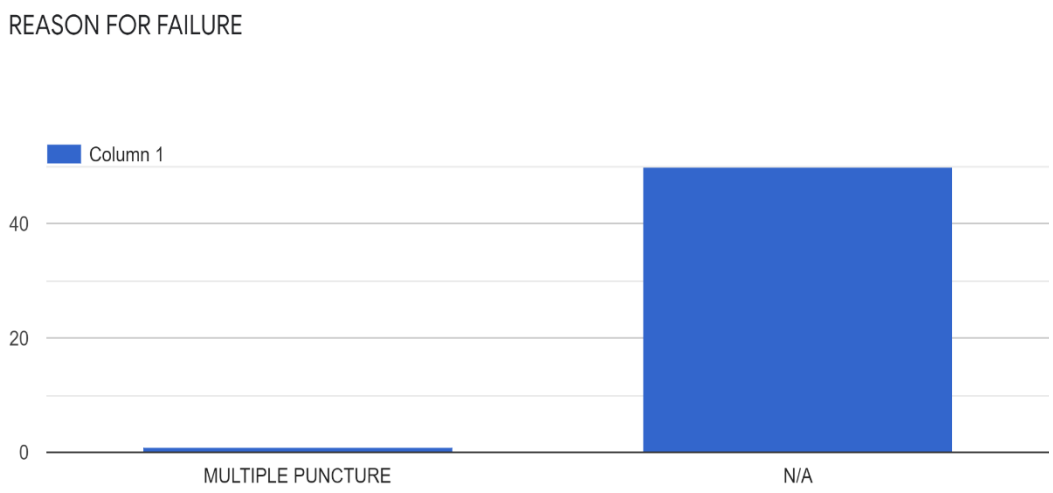


Figure 4: Reason for technical failure

4.4 Immediate/short-term post procedure complications

The immediate post procedure complications were seen in 6 (11.5 %) patients out of the 52. These included 2 (3.8%) cases of septic shock, 2 (3.8%) cases of bleeding through the tube, 1(1.9%) case of tumoral bleeding and 1 (1.9%) case of death.

Short term post procedure complications at one month after the procedure, were seen in 16 patients (30.6%). Of these, 5 (9.6%) had catheter dislodgement, 5 (9.6|%) had peri tubal discomfort/pain, 2(3.8%) had peri-tubal leakage, 2 (3.8%) had peri tubal infection and 2 (3.8%) cases developed cholangitis**. (Table 7).**

Table 14: Immediate/short-term post procedure complications

Complications	**Frequency (n)**	**Percent (%)**
Immediate complications		
Septic shock/sepsis	2	3.8
Pneumothrorax	0	0
Other organ puncture	0	0
Peritoneal bile leak	0	0
Tube dislodgement	0	0
Tube blockage	0	0
Death	1	1.9
Tumoral bleeding	1	1.9

Bleeding through the tube	2	3.8
Complications one month post procedure		
Catheter blockage	0	0
Catheter dislodgement	5	9.6
Peri tubal leakage	2	3.8
Peritubal discomfort/pain	5	9.6
Peritubal infection	2	3.8
Cholangitis	2	3.8

4.5 Images

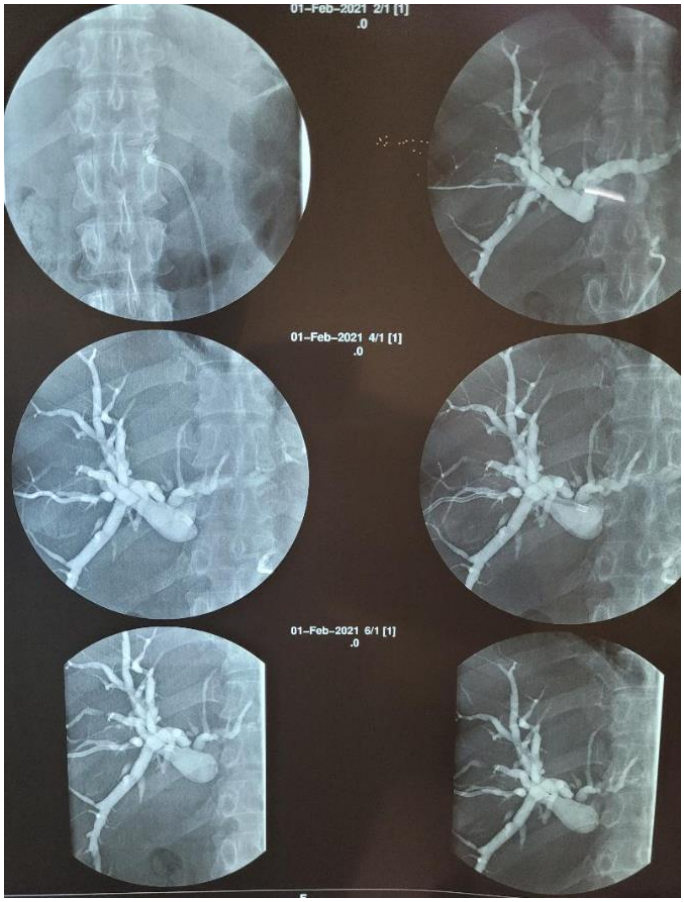


Figure 12: Patient with a hilar cholangiocarcinoma. An ascites drain had been inserted prior to the procedure. Access was from a right approach. Cholangiogram from a catheter inserted showed communication of the right and life hepatic ducts with no contrast seen

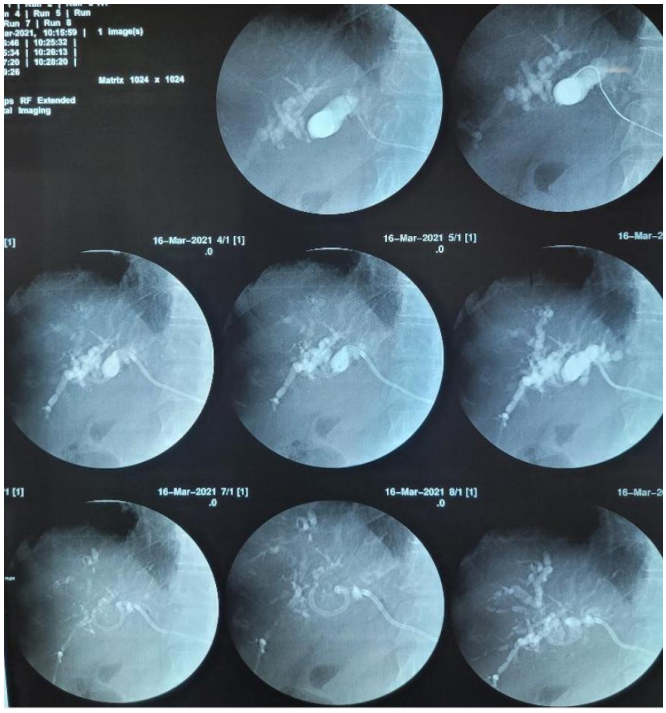


Figure 13: Patient with a hilar cholangiocarcinoma. Access was from the left. Eternal biliary drain was inserted and final cholangiograms showed delayed filling of the right hepatic ducts with contrast. Decision was made to leave a left external biliary drain in and review cholangiograms at a later date for right hepatic biliary drainage after the inflammation subsides.

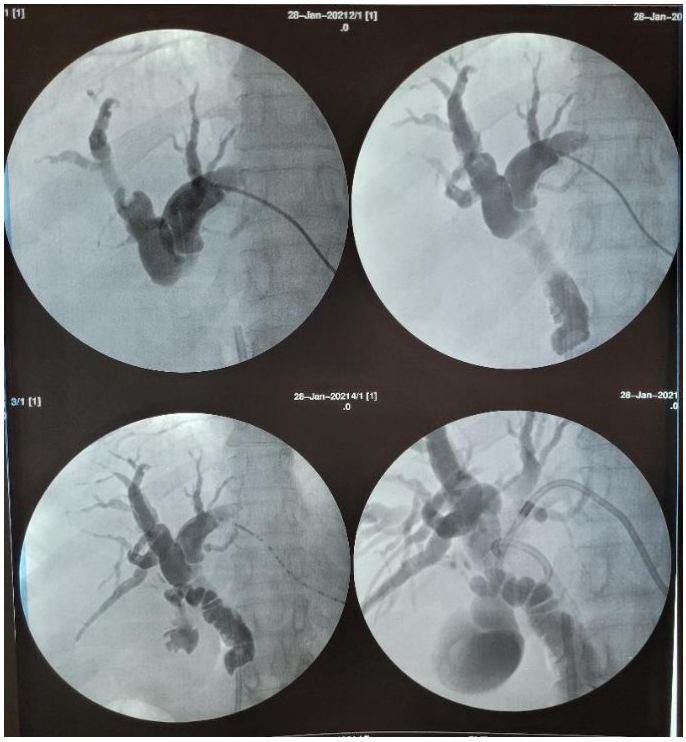


Figure 14: Patient who developed biliary obstruction at the anastomotic site, following a cholecystectomy and hepaticojejunostomy for cholelithiasis and choledocholithiasis. The access was made from the left, and cholangiogram done showed a short segment tight stricture at the anastomotic site. Access was finally made into the jejunum and an internal-external drain left insitu

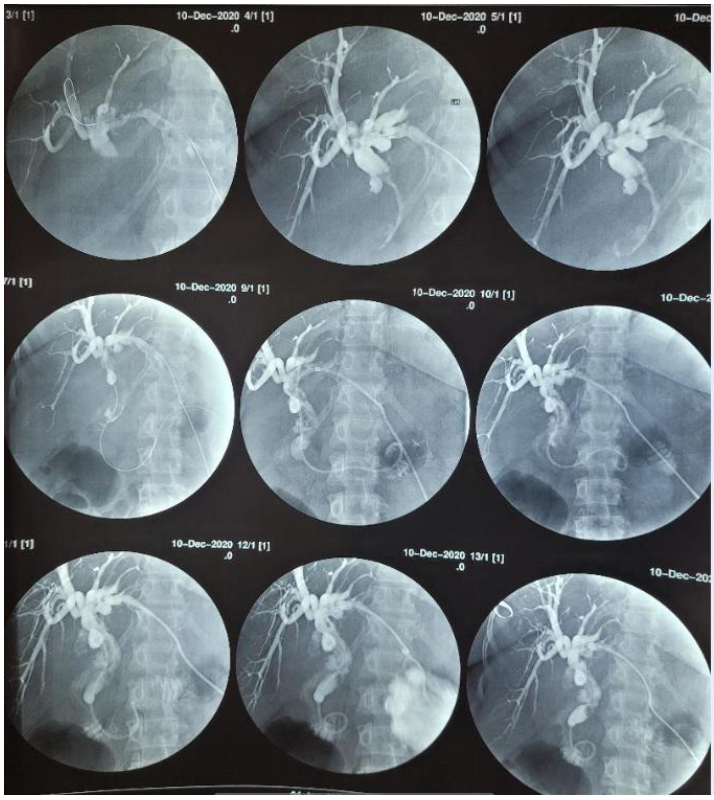


Figure 15: Patient with hilar cholangiocarcinoma. Left biliary access was made and internal-external biliary drain inserted.

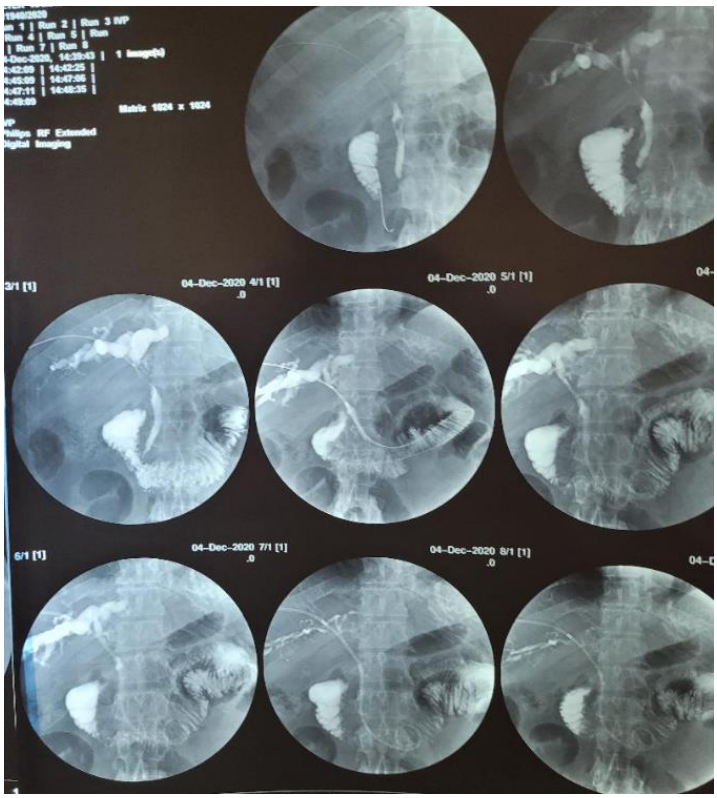


Figure 16: Patient with CHD/CBD stricture due to cholangiocarcinoma. An internal-external biliary drain was inserted from a right sided access.

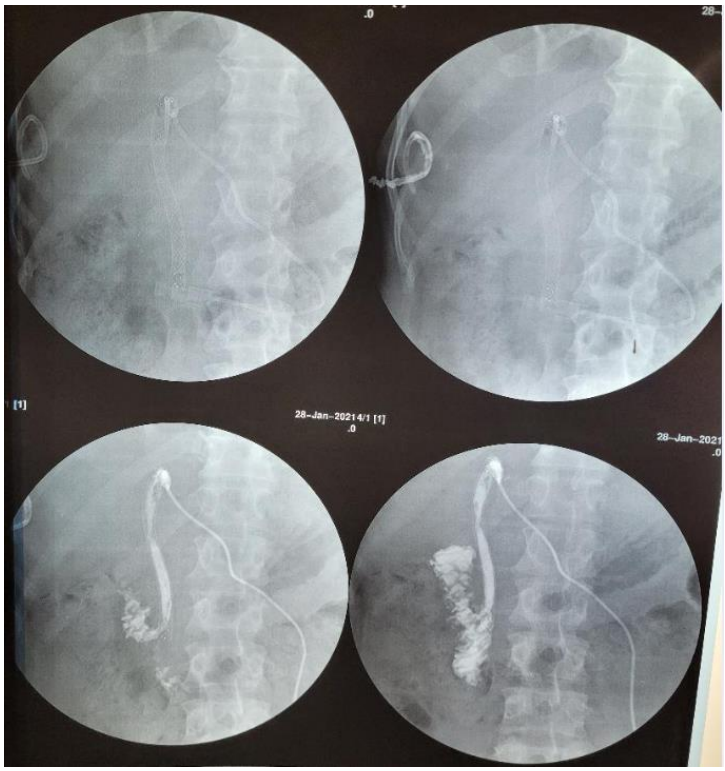


Figure 17: Patient presented with peritubal bile leakage from the right sided external biliary drain. She also had a left sided biliary safety catheter after inserting a biliary stent from a left access. Scout images of a cholangiogram showed a dislodged blocked right biliary external drain which was then removed. Left sided cholangiogram via the safety catheter showed a widely patent stent.

CHAPTER FIVE: DISCUSSION

5.1 Summary of findings

This is among the few studies examining the outcomes and complications of patients undergoing PTBD in the Kenyan setting. The PTBD procedure is considered the gold standard treatment for patients where ERCP is not possible or has been unsuccessful (18).

In this study, the mean age of the patients who underwent PTBD was 56 (SD=13.6) years. More than half, 29 (55.8%), were females. A total of 25 (48.6 %) had cholangiocarcinoma, 12 (23.1%) had Pancreatic head carcinoma, and 5 (7.7%) strictures 5 (9.6%) had metastasis, and 5 (9.6%) had gall bladder carcinoma or mass. All 52 patients had yellowness of eyes, 43 (82.7%) had pruritus, 18 (34.6%) abdominal pains, 12 (23.1%) weight loss, 9(17.3%) vomiting, 7 (13.5%) nausea, 7 (13.5%) feeding inability, 5 (9.6%) abdominal swelling and 4 (7.7%) fever. Biliary drainage was technically successful in 51 (98.1%) of the cases. The immediate post-procedure complications included 2 (3.8%) cases of septic shock, 2 (3.8%) cases of bleeding through the tube, 1(1.9%) case of tumoral bleeding and 1 (1.9%) case of death. One-month post-procedure, 5 (9.6%) cases of catheter dislodgement, 5 (9.6|%) cases of Peri tubal discomfort/pain, 2(3.8%) cases of peri-tubal leakage, 2 (3.8%) cases of peri tubal infection and 2 (3.8%) cases of cholangitis were reported. There was an improvement in 4 (66.7%) of the six nausea cases post-intervention, while there were no changes in the remaining 2 (33.3%) cases. Among the 16 cases of vomiting, there was an improvement in 8 (50.0%), worsening in 5 (31.3%) and no change in 3 (18.8%). Among the 45 with yellowness of eyes, there was an improvement in 40 (88.9%). Among the 40 who had pruritus, there was an improvement in 35 (87.5%), while among the 15 with weight loss, improvement was noted in 12 (80.0%): most, 5(83.3%) of the six who had feeding inability improved. Improvement was also noted in 3 (37.5%) of the eight who had a fever. The clinical success rate in the study was 81.6%. A Wilcoxon signed-rank test showed that the intervention resulted in statistically significant reduction in total bilirubin ($Z = -6.033$, P-value<0.001) and direct bilirubin ($Z = -5.799$, P-value<0.001).

5.2 Patients' characteristics

The mean age of the participants was 56 years, an indicator that the biliary obstruction resulting in PTBD was more common among the middle-aged to elderly in the Kenyan population. However, these patients were younger than the UK population undergoing a similar procedure where the median age of 72 (age range 19–104) years was reported (1). More than half (55.8%) were females. However, the gender difference was not significant.

Most of the patients were from Nairobi or counties from the former central province bordering Nairobi, including Kiambu and Murang'a. This reflects the main catchment area of KNH, where the majority of the patients visiting the facility come from, as it is close to these counties. Hence this may not necessarily indicate the high prevalence of biliary obstruction among patients in these areas but reflect the facilities' catchment regions. It is also an indicator of access, considering the distance from the counties where most of the patients came to KNH compared to other counties in the country. It may also however, give an indication of the patterns of this disease countrywide, since KNH is a tertiary facility and the primary referral centre for such management.

5.3 Aetiology of biliary obstruction and the presenting symptoms in patients

Neoplasms have been noted to be the most common cause of biliary obstruction. With carcinomas like Cholangiocarcinomas, gallbladder carcinomas, pancreatic tumours and metastatic tumours such as cervical and breast cancers being common aetiology of biliary obstruction (19), as was the case in this study.

Generally, the causes of biliary obstruction are classified into benign and malignant causes. Common benign cause includes choledocholithiasis, post-surgery or cholecystectomy stricture, inflammatory, stricture formation secondary to pancreatitis and idiopathic causes. On the other hand, malignant causes consist of cholangiocarcinoma, which is the leading cause, gall bladder carcinoma, pancreatic carcinoma, and metastasis (20). Concurrent to this study's findings, a study in Poland found pancreatic head tumours (43%) and cholangiocarcinoma (17.7%) were the main indications for PTBD (21). Also related to this study's findings, where Hilar mass and Klatskin tumour/cholangiocarcinoma (48.6 %) and pancreatic head carcinoma (21.2%) were the main malignant cause of biliary obstruction, a study conducted in India found cholangiocarcinoma (62%) to be the most common malignant cause of biliary obstruction (20).

Nausea or vomiting, yellowness of the eyes, pruritus, fever, pain, weight loss, loss of appetite and tiredness and fatigue are common symptoms in patients with biliary obstruction (4). In this study, all patients had yellowness of eyes while 82.7% had pruritis. These two are the commonly reported symptoms in patients with biliary obstruction as was the case in a study in India where 88% of the patients had deep yellow eyes (22).

5.6 Technical success rate

In this study, the technical success rate of PTBD was 98.1%. This is similar to other previous studies where a high technical success rate of the procedure was noted. With increased expertise and better instrumentation, a PTBD success rate of approximately 95% with fewer complications has been reported. The likelihood of complications can be reduced further by minimising biliary manipulation and ensuring optimal antibiotic coverage (23).

In concurrence with the findings of this study, a study in Germany among patients who underwent PTBD reported a 96% technical success rate (24). Similarly, in the study by Tapping and colleagues, PTBD's high technical success rate of 99% was found (25). In a related study in Poland, PTBD was successful in 90.7% of the cases (21). This is in agreement with the projected PTBD success rate as per the CIRSE guidelines (26). Similarly, other previous studies have reported the high technical success rates including 100% in the study by Inal and colleagues (27).

5.4 Clinical success rate

Generally, abnormally high levels of bilirubin and ALP are common in patients with biliary obstruction, as was the case in a study conducted in India (28). There was a significant reduction in total bilirubin and direct bilirubin levels post-intervention compared to pre-PTBD intervention. This is consistent with what has been found in previous studies. In a study in Croatia, the mean total bilirubin aspartate aminotransferase, alanine aminotransferase, gamma-glutamyl transferase, and alkaline phosphatase significantly reduced post-procedure (29), an indicator of its high clinical success rates. The same was found in a study in Poland that reported a reduction in these laboratory parameters after the PTBD procedure (5), as was the case with (30-32). This is an indicator of PTBD's ability to alleviate jaundice symptoms based on the bilirubin levels' significant reduction post-procedure (21). However, in our study, the changes in other laboratory parameters apart from total and direct bilirubin and WBC could not be determined due to the lack of post-intervention data on the other parameters.

In this study, the clinical success rate was 81.6%. This was comparable to what has been found in previous studies. A study by Becker et al (33) and Dinkel et al., (34) reported a clinical success rate of 77%. A clinical success rate of 88% was found in the study by Inal and colleagues (27), 91% in the studies by Roeren et al. (35) and Lee et al. (36) , 96% in the study by Indar and colleagues (37) and 98% in the study by Kaskarelis1999 and colleagues (38).

5.5 Immediate and short-term post procedure complications

There were a few post-procedure complications in this study, including tumoral bleeding, septic shock, catheter dislodgement, peri tubal pain/discomfort, peri tubal leakages, peri tubal infection, cholangitis and one case of death. Most of the complications were noted to be mild and tube-related and infection-related. The few associated complications are an indicator of the procedure's effectiveness and safety. However, further evaluation through randomised studies is the most appropriate in providing an accurate picture of the complication associated with the procedure.

Similar to this study, where there were few complications, in the study done in the UK, only 5.9% of the patients who underwent PTBD had complications one-week post-procedure, while only 20% had complications three months post-procedure. In this study, infection was the common complication in 2.4% of the patients within the first week and 9% of the patients within a month post-PTBD. These infections include cholangitis in 3.9% of the cases, sepsis in 3.9% and unspecified site bacterial infection in 0.8% (1). This relates well with findings in our study, where 3.8% of the cases had cholangitis, and 3.8% had peri tubal infections

In the study in the UK, 2.9% had stent displacement or blockage within a mean of 6.3 months (1), unlike in this study where a higher proportion of one-month post-procedure catheter dislodgement (9.6%) was seen with no cases of tubal blockage reported. However, in this study, the patients have only followed up one-month post-procedure; hence not possible to determine long term complications post-procedure.

Unlike the few complications noted in this study one-month post-PTBD, previous studies in other settings have reported high proportions of complications within this period. In the study by Turan and colleagues, the one-month complication rate was 62.8%, with infectious complications occurring in 40.6% of the cases and non-infectious complications occurring in 34.7% of the cases (39). Other previous studies reported infectious complication rates of up to 17% (1, 25, 40, 41). A previous Dutch study showed that infectious complications were common in patients with malignant biliary obstruction, often drainage-related and occur more often after PTBD (42).

While in this study, only one case of mortality was reported 30 days post-procedure, in the study by Turan and colleagues, all-cause mortality was 17.2% one-month post-procedure, with more than half of the mortality cases being due to the underlying malignancy and not related to the procedure while 8.2% of the mortality were thought to be directly related to the

procedure, occurring during the management of the procedure-related complications like sepsis or bacteraemia (39).

In a related study by (Knap et al. 2015), mortality was (7.53%). Several other studies reported higher all-cause mortality rates 30 days to post PTBD, ranging from 10-23.1% (1, 40, 44, 45).

However, as was the case in this study, we have other studies where low mortality was reported, as was the case in the study by Weber *et al*.(13), where 3 (0.7%) patients died after the PTBD procedure and in Yee *et al*. (50) where 1.9% mortality was reported.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

PTBD is a highly effective and safe approach to biliary drainage with high clinical and technical success rates as was the case in this study and most previous studies in other settings.

It decreases jaundice and relieves most symptoms associated with biliary obstruction. Our results show that PTBD is useful for relief of the symptoms and proves to be an essential alternative to ECRP, in case of ECRP failure. While there were minimal complication rates among the patients who underwent the procedure in this study, the short follow up period made it difficult to determine the long-term impact on survival rates.

Technical success rates were high, concurrent with other studies in other parts of the world. This indicates that technical skills in this part of the world are comparable to other areas.

The commonly observed complications in this study were predominantly mild and mostly tube related. Most of there could be treated conservatively. The mortality rate associated to the procedure was low with only one case reported, which was due to the underlying disease.

6.2 Recommendations

1. Studies with large sample sizes are needed to determine the prevalence of complications in patients undergoing PTBD locally. Randomised controlled trials are needed to determine the actual likely risk of complications and mortality and the efficacy of the PTBD intervention.
2. Studies covering the different facilities in the country are needed to determine the national estimates of the success rates and complications associated with PTBD in Kenya.
3. PTBD remains important in biliary tract obstructive disease and especially where ERCP is technically not successful, where there is proximal obstruction or altered surgical anatomy post surgical intervention. It should therefore be recognized and incorporated in the standard care protocols for these patients.
4. There is a need for long term follow up of patients who undergo PTBD in order to determine its associated long-term complications.
5. There is need to evaluate post procedure tube care in our setting to reduce incidences of peritubal infections.

6.3 Limitations

This was a one facility study covering a short period; hence a small sample size does not represent the country's patient population undergoing PTBD in Kenya.

The study was cross-sectional; hence not possible to infer causation and determine between the outcome and exposure, which occurred before the other.

The symptoms assessment was subjective; hence no accurate measure of the clinical success rate of the PTBD procedure in the study. However, the laboratory parameters measure to address this shortfall.

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APPENDIXES

Appendix 1a: Informed Consent Form

Study title: Short term clinical and technical outcomes of percutaneous transhepatic cholangiography and biliary drainage, for the management of biliary obstruction in Kenyatta National Hospital.

Principal investigator: Dr. Maina Wangari

Introduction

My name is Dr. Felista Wangari, a Interventional Radiology fellow in the department of Diagnostic Imaging and Radiation Medicine at the University of Nairobi.

Investigator's statement

I am carrying out a study on short term clinical and technical outcomes of percutaneous transhepatic cholangiography and biliary drainage, for the management of biliary obstruction. This is a form of treatment to relieve the biliary obstruction that has caused you to present in hospital.

I would like to recruit you/ your patient in this study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about what we will ask you to do, the risks, the benefits and your rights as a volunteer, or anything about the research or in this form that is not clear. When all your questions have been answered, you can decide if you want to be in this study or not. This process is called "seeking informed consent".

Confidentiality

Information obtained from you will be treated with confidentiality. Only your hospital number will be used. The investigator, institutional review board of Kenyatta National Hospital and University of Nairobi Ethics and Research Committee only will have access to information about you. The information about you will be identified by the study code number and will not be linked to your name in any records. Your name will not be used in any published reports about this study.

Purpose, benefits and risks

This study aims at determining the short-term outcomes after performing the percutaneous biliary drainage procedure. This is for purposes of improving patient experiences as far as clinical outcomes and our technical challenges during the procedures. There are no additional

risks that you will be exposed to by participating in this study. You will not receive any monetary compensation for participating in the study. Participating in this study will not be of direct benefit to you.

The researcher will only review images of the investigations ordered by the attending clinicians and any procedure arising from such review will be for the benefit of the patients and not the researcher.

Voluntary participation

Patient participation is voluntary. Refusal to answer any of the questions asked above at any time will not result in loss of benefit or penalty. Should you choose to withdraw from the study, you will receive the standard treatment entitled to you. You have a right to decline or withdraw from the study. *The researcher will have no financial or material gain. There will be no reimbursement for participation in the study.*

Whom to contact

If you have any questions regarding the study, feel free to contact the chief researcher:

Dr Wangari Maina

Tel: 0722 633148

P.O.Box 61915-00200 Email: feli_maina@yahoo.com

Supervisor: Dr Chacha

Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi

Supervisor: Dr Mugambi

Kenyatta National Hospital, Interventional Radiology Unit

This study has been approved by the Kenyatta National Hospital / University of Nairobi Ethics and Research Committee, and any questions and issues regarding the study could be addressed to:

The Chairperson, KNH/UON –ERC

Hospital Road along Ngong Road

P.O Box 20793, Nairobi

Tel.2726300 Ext 44102

Email: uonknh_erc@uonbi.ac.ke Website: www.uonbi.ac.ke

Please confirm that you have agreed to participate in this study by signing the consent form provided to you.

CONSENT FORM.

Subject's statement (Individual patient consent form)

I……. of……
consent to take part in this research, after having read the explanation form and having the study purpose explained to me by the researcher. My participation is voluntarily given.
I also understand that no harm shall come to me, and no treatment will be denied to me should I choose to withdraw from the study,

Signature of Participant……Or Thumbprint…….

X-Ray Number: …… Date……

Researcher's Statement

I, the undersigned, have fully explained the relevant details of this research study to the participant. The participant has understood what the research study entails and has willingly given consent. I confirm that no coercion or inducement for participation was undertaken.

Researcher: I certify that the patient has understood and consented participation in the study.

Dr. Felista Wangari 0722 633148

P.O.Box 61915-00200 Email: feli_maina@yahoo.com

Signature…….

Date…….....

Appendix 1b: Fomu Ya Kufafanua Utafiti

Mtafiti: Daktari Felista Wangari

Jina langu ni Daktari Felista Wangari, mwanafunzi katika chuo cha udaktari, Chuo Kikuu cha Nairobi. Ninafanya utafiti kuhusu matokeo yanayopatikana baada ya wagonjwa kufanyiwa aina ya matibabu ya kupatia nyongo njia ya kupita nje ya mwili wakati wanaugua shida inayozuia nyongo kupita njia yake ya kawaida. Hii ni aina ya matibabu ambayo hayahitaji upasuaji.

Haki zako zitalindwa, habari utakayotoa au ile itakayopatikana kukuhusu, itakuwa siri wakati wote na itatumika katika utafiti huu tu.

Ni muhimu kuelewa ya kwamba ushiriki ni wakujitolea, sio lazima kushiriki katika huu utafiti, na pia waweza kubadili nia yako wakati wowote kuhusu kuendelea kushiriki, bila ya kuathiri huduma zako za kiafya.

Ukiwa na maswali kuhusu utafiti huu, unaweza kuwasiliana na mtafiti mkuu kwa kutumia anwani ifuatayo:

Dr.xxxx Telephone: 0722 633148

Sanduku la Posta: 61915-00200 Barua pepe: feli_maina@yahoo.com

Msimamizi mkuu: Dr Chacha

Department of Diagnostic Imaging and Radiation Medicine,

University of Nairobi

Msimamizi: Dr Mugambi

Kenyatta National Hospital

Interventional Radiology Unit

Utafiti huu umepewa idhini na hospitali ya Kenyatta pamoja na chuo kikuu cha Nairobi. Maswali yanaweza kuelekezwa kwao katila anwani ifuatayo:

Mwenyekiti, KNH/UON –ERC

Hospital Road along Ngong Road

P.O Box 20793, Nairobi Tel.2726300 Ext 44102

Email: uonknh_erc@uonbi.ac.ke Website: www.uonbi.ac.ke

Tafadhali tia sahihi yako kwa fomu ya idhini kudhibitisha kuwa umekubali kuwa mshiriki katika utafiti huu.

Idhini ya kushiriki katika utafiti

Mimi……wa……..nimekubali kushiriki katika utafiti unaoendelea katika hospitali hii ya Kenyatta. Nimejisomea fomu ya kufafanua utafiti huu na nikaelezwa umuhimu wa utafiti huu.

Nimeelewa ya kwamba sitadhulumiwa wala kunyimwa matibabu kamili nikiaamua kujiondoa kwa utafiti. Nimekubali kwamba nimeelezewa kikamilifu kuhusu utafiti huu na nakubali kushiriki.

Nambari ya Xray: _____ Sahihi: _____ Tarehe:_____

Sahihi ya muhusika……AU kidole……

Tarehe……

Kiapo cha mtafiti

Naapa ya kwamba nimeelezea mgonjwa/ mzazi wa mgonjwa manufaa na madhara yote yanayohusu kusajiliwa katika utafiti huu. Mgonjwa/ mzazi ameelewa yote yanayohitajika na yanayohusu utafiti huu na usajili wake. Idhini yake imepewa kwa hiari yake bila kulazimishwa au kuahidiwa pesa, zawadi au matibabu ya ziada.

Sahihi ya mtafiti…….....

Tarehe……

Appendix 2: Data Collection Tool

Xray No.:

Age:

Male/female:

Residence:

Diagnosis and staging if any:

Comorbidities: (Please state if Diabetes, Hypertension, Stroke, HIV etc)

1. **Presenting complaints:**

Symptoms	Yes	No
Nausea		
Vomiting		
Yellowness of eyes		
Pruritis		
Weight loss		
Inability to feed		
Fever		
Others		

Previous imaging and findings:

Previous imaging available	YES	NO	Level of obstruction- PROXIMAL OR DISTAL
Ultrasound			
CT			
MRI			

NB- Proximal obstruction- at the hilum, CHD, sub-hepatic CBD and intra-hepatic ducts

Distal obstruction- at the lower CBD and peri-ampullary region

Lab work up:

Lab test	Parameter		YES	NO	VALUE
Full hemogram	**HB**	**>10 g/dL**			
		<10 g/dL			
	WBC	**Normal**			
		Elevated			
	Platelets	**Normal**			
		Elevated			
Liver function tests	**TBIL**	**Normal**			
		Elevated			
	DBIL	**Normal**			
		Elevated			
	GGT	**Normal**			
		elevated			
	ALP	**Normal**			
		elevated			
INR		**Normal**			
		Prolonged			
PTI		**Normal**			
		Prolonged			

Known cause of obstructive jaundice:

YES-

NO-

If yes, cause _____

2. **Procedure done:**

Successful: yes_____ no_____

If yes,

External biliary drain inserted-unisectoral – YES/NO

- or multisectoral)- YES/NO

External-internal drainage tube inserted- YES/NO

If NO, Technical difficulties if any:

Multiple punctures-

Patient condition e.g dysnoea, tachypnoea-

Cannulation of the hepatic artery or portal vein-

Puncture of bowel or other organ

Others-

3. Clinical outcomes at one month:

Serum bilirubin levels:

TBIL- _____

DBIL- _____

WBC- _____

Symptoms if any, at one month:

Is there any improvement or reduction in symptoms: YES / NO

Symptoms	Improvement	Worsening	No change
Nausea			
Vomiting			
Yellowness of eyes			
Pruritis			
Weight loss			
Inability to feed			
Fever			
Others			

4. Immediate complications- Intra-procedural upto 24 hours

Complication	YES	NO

Sepsis/septic shock		
Vessel puncture		
Pneumothorax		
Bowel or other organ puncture		
Peritoneal bile leak		
Tube dislodgement, blockage		
Death		

Intermediate complications- At one month-

(Includes persistent blocked catheter, pulled-out tube or peri-tubal leak, peri-procedural discomfort and morbidity)

Complication	YES	NO
Blocked catheter or non-functional tube		
Catheter/tube dislodgement		
Peri-tubal leakage		
Peri-tubal discomfort or pain		

Appendix 3: Ethical Approval