A STUDY ON THE DEMOGRAPHIC CHARACTERISTICS AND THE SPECTRUM OF CT FINDINGS IN ADULT PATIENTS WITH OBSTRUCTIVE JAUNDICE; WITH ULTRASOUND AND HISTOPATHOLOGICAL CORRELATION AT THE KENYATTA NATIONAL HOSPITAL

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A RESEARCH DISSERTATION SUBMITTED IN PARTIAL FULFILMENT FOR THE AWARD OF MASTER OF MEDICINE IN DIAGNOSTIC IMAGING AND RADIATION MEDICINE, FACULTY OF HEALTH SCIENCES, UNIVERSITY OF NAIROBI.

DECLARATION

I, **Dr. Okode Neema,** declare that the work contained herein is my original idea and has not been presented in any other university or institution of higher learning to the best of my knowledge.

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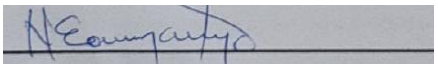
Signature:  **Date: 30th October, 2023**

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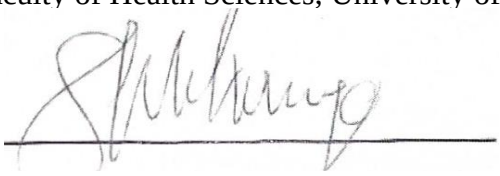
Signature:  **Date: 30th October, 2023**

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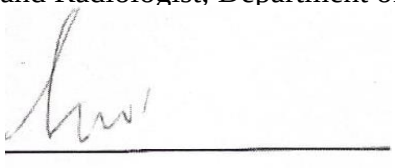
Signature:  **Date: 30th October, 2023**

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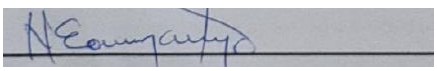
Signature:  **Date: 30th October,2023**

DEPARTMENTAL APPROVAL

This dissertation has been presented and approved by the Department of Diagnostic Radiology and Radiation Medicine.

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DEDICATION

To my husband **Daniel**, who has been my rock through this whole journey; and our kids, **Femi** and **Maya**, who have been understanding and accommodating during this time.

ACKNOWLEDGEMENT

My sincere thanks are first and foremost due to God Almighty for his protection and direction. I sincerely appreciate the invaluable advice and guidance provided by my supervisors, Drs. Gladys Mwango and Beatrice Mugi and from the beginning of the proposal until the conclusion of the study, I am grateful for your unceasing support. To all my Kenyatta National Hospital coworkers who helped me in whatever way they could throughout my research.

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LIST OF ABBREVIATIONS AND ACRONYMS

ACS-	American College of Surgeons
ALP-	Alkaline Phosphatase
ASE-	Association of Surgical Education
CA 19-9-	Carbohydrate Antigen 19-9
CBD-	Common Bile Duct
CECT-	Contrast Enhanced Computed Tomography
CHD-	Common hepatic duct
CT-	Computed Tomography
GGT-	Gamma-Glutamyl Transferase
KNH-	Kenyatta National Hospital
LHD-	Left hepatic duct
MDCT-	Multidetector Computed Tomography
MRCP-	Magnetic Resonance Cholangiopancreatography
MRI-	Magnetic Resonance Imaging
PSC-	Primary Sclerosing Cholangitis
RHD-	Right hepatic duct
SPSS-	Statistical Package for Social Sciences
US-	Ultrasound

ABSTRACT

Background: Hepatobiliary disease is a major cause of morbidity and mortality worldwide. Biliary obstruction presenting clinically as obstructive jaundice has been identified as a major complication of these diseases. In the United States (2018), biliary obstruction had an incidence of approximately 5 cases per 1000 people. According to the Health Information Department at the Kenyatta National Hospital (2016-2020), obstructive jaundice contributed to 1.5% of all surgical admissions, 25% of all adult hepatobiliary diseases, and a 30% case fatality rate. Obstructive jaundice is caused by various conditions, including gallstones, strictures, pancreatic mass lesions, hepatic and biliary tree malignancies. Cross-sectional imaging has proven helpful in the detection of such lesions. There is limited data on the disease burden and the imaging characteristics of the different causes of obstructive jaundice in the region. Therefore, this study proposes to determine the demographic distribution and the spectrum of diseases causing obstructive jaundice using CT imaging at the Kenyatta National Hospital.

Objective: To evaluate the spectrum, frequency, age, and sex distribution of conditions causing obstructive jaundice using CT scanning, to compare these findings with ultrasound findings and to correlate the imaging findings with histopathology results.

Materials and Methods: An analytical cross-sectional study that was conducted over a period of one year from January 2022 to December 2022 at the Radiology department of the Kenyatta National Hospital. Using a purposive sampling technique, 31 patients with clinical and/or ultrasound features of obstructive jaundice were recruited. They were subjected to CT scanning of the hepatobiliary system using the triple phase protocol. A review of the images was done in the respective reporting rooms and the findings were verified by a consultant radiologist. In liaison with the surgical, Interventional Radiology and Pathology departments, follow up of the histopathology results was done. The demographic data and the spectrum of findings at CT and histopathology were keyed in Microsoft Excel and imported to IBM SPSS version 23.0 for analysis.

Results: The distribution of ages ranged from 25 to 76 years. The mean age was 54.32 +/-14.1 years. The median age was 54 with an interquartile range of 43.0-68.0). 18 participants were female and 13 were male. 100% of the patients were of the black race. The most common age group belonged to the 60-69 and 40-49 age groups, at 25.8% respectively. Ultrasonography detected an obstruction in 77.4% of the cases. CT detected an obstruction in 100% of the patients. 30 patients had malignant disease and 1 had benign disease. The most frequent diagnosis given at CT evaluation was pancreatic adenocarcinoma at 32.3%,

cholangiocarcinoma at 19.4%, periampullary tumors at 12.9%, gallbladder carcinoma at 6.5%, and choledocholithiasis at 3.2%, among other diagnoses. 58.1% of the patients had an obstruction at the distal CBD level, followed by hilar level (29%), and proximal CBD level (12.9%). Histopathology confirmed malignant disease in 30 patients, with a male to female ratio of 1:1.8. only 1 female patient had benign disease (choledocholithiasis). With a P value of 0.235 no significant difference was seen in the prevalence of obstructive jaundice between the males and females. At histopathology, 41.9% of the patients had pancreatic adenocarcinoma, 16.1% had cholangiocarcinoma and metastatic disease respectively, 9.7% had gallbladder adenocarcinoma, 6.5% had periampullary carcinoma, 3.2% had choledocholithiasis, among other diagnoses. 90% of patients with malignant histopathology was in the >40 years age groups and a single patient with benign disease was in the <40 years age groups. When compared to histopathology as a gold standard, CT correctly diagnosed the specific causes of obstruction in 90.3% of the patients. The level and type of obstruction were correctly determined in 100% of the patients. With a P value of 0.285, there was no significant difference between CT and histopathology as diagnostic tests.

Conclusion: Obstructive jaundice is more common in our setting, with the most prevalent causes being malignant disease. CT correctly diagnosed the specific cause, the level and type of obstruction in most of the patients, making it an ideal diagnostic work up tool in evaluating the spectrum and frequency of conditions in obstructive jaundice.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background Information

Jaundice is defined as a condition in which the skin, sclera, and mucous membranes turn yellow due to increased levels of serum bilirubin > 2.5mg/dl(1). Obstructive jaundice is seen when there is blockage of the biliary or pancreatic ducts thus preventing the normal drainage of bile from the liver to the duodenum. This causes an increase in already conjugated bilirubin with a direct hyperbilirubinemia of >50% of the total bilirubin levels (2).

Obstructive jaundice is a common surgical problem that may lead to various local and systemic complications. These may include liver dysfunction, cardiovascular suppression, malnutrition, renal failure, bleeding tendencies, and immune suppression. All these complications lead to increased morbidity and mortality. Thus, there is a need for early identification and proper management of such patients. The condition carries a significant disease burden worldwide. According to the World Health Organization (WHO) world health rankings data in 2018, hepatobiliary-related diseases are ranked 21 in Kenya and 118 worldwide. With an age-adjusted death rate of 11.47 per 100000(3).

Computed Tomography (CT) imaging is now readily available in Kenya. The Ministry of Health and the County governments have worked together to provide radiology services to Kenyans. Through the Managed Equipment Services (MES) project of 2016, 52 county hospitals were equipped with radiology equipment including CT scans. In another project done in 2020, the Kenya government together with strategic partners, Neusoft and Megascope, helped acquire additional CT machines for 37 counties. Included in the project was a diagnostic facility within the Kenyatta National Hospital (KNH) that connected all the 37 Neusoft CT scans through teleradiology, thus improving the quality and duration of service delivery to patients throughout the country.

CT imaging technology has undergone significant improvement over the past two decades. MDCT with intravenous injection of iodinated contrast media has allowed for rapid multiphasic image acquisition with high-quality 3D reconstructions that can delineate up to the third-order biliary radicals. The thin slice images, high resolution, single breath holds, and coronal reconstructions are ideal in depicting dilated biliary ducts. CT has also been helpful in the evaluation of hepatic masses and is currently the workhorse for the detection of pancreatic lesions (4).

Obstructive jaundice can be caused by a variety of benign or malignant diseases. Choledocholithiasis, biliary strictures, pancreatitis, and parasite infections are examples of benign causes. Pancreatic cancer, cholangiocarcinoma, hepatic, and periampullary tumors are some of the malignant causes. The incidence of these disorders varies according to age and gender.

In our setup, malignancy has been identified as the commonest cause of biliary obstruction, with a higher predisposition for men and older patients in their fifth and sixth decades (5). Benign causes like choledocholithiasis impact 1-15% of cholelithiasis patients, and the incidence rises with age. It occurs more frequently in females who carry higher risk factors for gall stone development. These include obesity, high calorie diet, pregnancy, and rapid weight loss.

With the diverse range of diseases seen in biliary obstruction, this study aimed at determining the spectrum of these diseases in the Kenyan African population using CT as a diagnostic tool and correlating the CT findings to ultrasound and histopathology.

2.0 CHAPTER TWO: LITERATURE REVIEW

From a historical perspective, Whipple, an American surgeon was the first person to describe obstructive jaundice in 1935. He also invented the concept of preoperative biliary drainage also known as Whipple's procedure (6). Various radiological studies have been done to determine the epidemiology, spectrum, and pattern of conditions that are encountered in biliary obstruction in the adult population. Demographic distribution significantly determines the causes of obstructive jaundice. This includes age, sex, and race-related demographics.

2.1 Sex and Age Distribution in Obstructive Jaundice

2.1.1 Sex Distribution and Obstructive Jaundice

Majority of the studies done locally have identified a female sex predilection towards obstructive jaundice. In a prospective and retrospective study on the value of magnetic resonance cholangiopancreatography (MRCP) in obstructive jaundice (2011), Dr. Ngololo found a female predominance of 56.2% (5) of the study's participants. Using ultrasonography in evaluating some aspects of obstructive jaundice at the Kenyatta National Hospital (1988), Dr. Okoth et al (7) identified a female sex majority of 11 cases compared to 9 male cases out of the 20 patients that were recruited in his study.

Chalya et al. (8) identified a female to male ratio of 1.3:1 in the East African region of Tanzania (2011) when analyzing the etiological spectrum of the disease using ultrasonography (8). Internationally, with a M:F ratio of 1:1.6 and employing computed tomography and ultrasound as diagnostic methods, Padmalatha et al. (2007) also found a female predominance (9). In a retrospective case series study in Saudi Arabia (2018) by Alrashed et al (10), females accounted for 72% of the cases compared to males at 28%.

Differing from the studies above, male predominance has been identified in several studies. Khan et al did a prospective observational study in India (2019) that showed a male predominance of 55.72% (11).

From the studies above, we can deduce that sex predilection varies geographically and relies on the specific causes of obstructive jaundice.

2.1.2 Age Distribution and Obstructive Jaundice

In 2015, Mathew et al assessed the value of computed tomography in obstructive jaundice and found a majority age distribution in the 41-50 age group (12). (9)Dr. Ngololo, Dr. Chalya et al, and Alrashed et al (5,8,10) identified a mean age distribution of 53.3, 58.64, and 43.9 years respectively. Padmalatha et al (9) found a majority distribution in the 41–50-year age group.

These studies establish that obstructive jaundice rises with advanced age, mainly affecting patients in their fifth and sixth decades.

2.2 Race-related Demographics and Obstructive Jaundice

Race and ethnicity have also been recognized as important determinants in the development of obstructive jaundice. Choledocholithiasis is the commonest benign cause of obstructive jaundice, it shows significant variability in terms of racial and ethnic distribution. Everhart (13) conducted a study in America to find out the relationship between ethnicity and gallstones. Among the women, the risk of gallbladder disease was highest among the American Indians, followed by Hispanics, non-Hispanic whites, and non-Hispanic blacks. Men showed lower risk in all ethnic groups and similar prevalence between the different ethnicities. Asians and Africans have decreased risk compared to persons of Hispanic and Northern European origin.

2.3 Malignant and Benign disease in Obstructive Jaundice

2.3.1 Malignant Disease in Obstructive Jaundice

In the studies done in Kenya, malignant disease was identified to be a majority contributor to the disease. Dr. Ngololo et al found that the leading cause of obstruction was tumors (53%), this was followed by calculi (20%) and strictures (17%)(5). Dr. Okoth et al (7)also found a malignant disease predominance, with pancreatic cancer contributing to 55% of cases, gall stones (10%), hepatocellular cancer (10%), and gall bladder cancer (10%). Chalya et al (8) in Tanzania found that 58.6% of the cases had a malignant cause of disease.

In Pakistan, Siddique et al (14) evaluated the etiological spectrum of obstructive jaundice through history, physical Exam, US, CT, MRCP, and Biochemical tests. Malignant causes of obstructive accounted for 56.66%, and benign causes 43.33%.

Sex distribution of malignant disease varies with the specific causes of obstruction. A female predominance in malignant disease has been identified in several studies. Chalya et al (8) found that malignant disease was more common in females. However, Mathew et al (12) found a male preponderance of 63.6% in malignant disease.

Advanced age is a common risk factor in the development of malignant disease. Padmalatha et al (9) found a majority distribution in the (41–50-year) age group. Khan et al (9)found a majority age distribution in the (>65 years and 55–65-years age groups). In his study, Mathew et al (12)found that 90% of all the patients with malignant disease were > 40 years old.

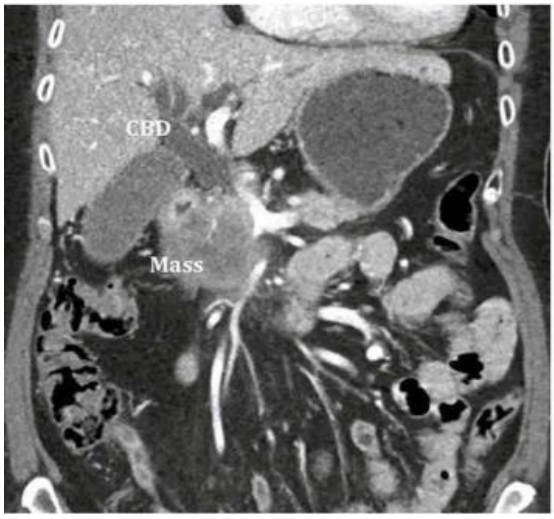
2.3.1.1 Malignant Causes of Obstructive Jaundice

Cancer is identified as the third leading cause of death in Kenya, with the annual incidence rate rising from 37000 to 47,887 as of 2018 (15). In Studies done locally and in other parts of the world, pancreatic cancer has been identified as the principal cause of malignant biliary obstruction.

When assessing malignant lesions, CT imaging can characterize lesions in terms of, confirming the diagnosis, localizing the lesion, staging the tumor, determining resectability, and advising the surgeon preoperatively of relevant anatomic variants.

2.3.1.2 Pancreatic Cancer

Pancreatic cancer is the ninth most common and fourth most common cause of cancer-related death in the US. It has a low incidence rate but a high mortality rate. 90-95% of cases are adenocarcinomas (16). When discovered, the disease is usually too advanced for surgical resection. A study conducted by Korir in Nairobi (17) found that pancreatic cancer had an incidence of 4.1/100,000. Roy et al (18) did a cross-sectional observational study in Bangladesh to determine the etiological spectrum of obstructive jaundice in a tertiary care hospital. They collected data from history, physical exams, liver function tests, US, and CT. Based on the results 58% had malignant causes and 42% benign. They also found a predominance of pancreatic cancer among the malignant causes at 30% followed by gall bladder cancer at 16%. While assessing the indicative findings of pancreatic cancer in prediagnostic CT, Ahn (19) could infer that focal hypoattenuation, pancreatic duct dilatation with/without interruption, and distal parenchymal atrophy were the most useful findings for detecting pancreatic cancer.

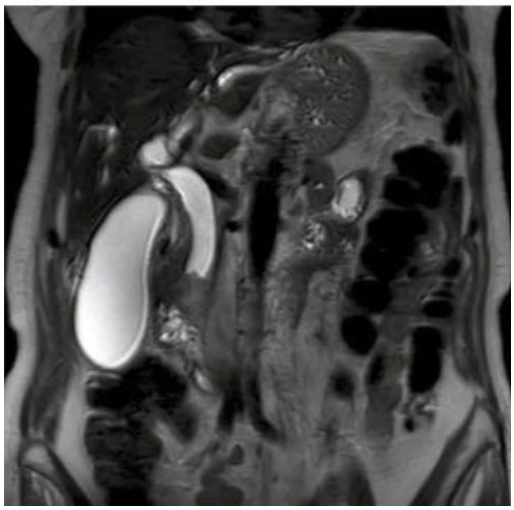


Source: Viesca & Arvanitakis (2019) (20)(20)

Figure 1:showing a pancreatic head carcinoma with proximal CBD dilatation.

2.3.1.3 Cholangiocarcinoma

Cholangiocarcinoma is the second most common primary hepatic cancer. It is often encountered in advanced stages in the context of obstructive jaundice (21). In 2009, Chung et al (22) was able to assess the varying appearances of cholangiocarcinoma on imaging. On CT imaging, mass-forming intrahepatic cholangiocarcinoma appeared as homogenous low-attenuation mass lesions with irregular peripheral enhancement and were sometimes associated with capsular retraction, satellite nodules, and peripheral intrahepatic duct dilatation. Peri ductal infiltrating cholangiocarcinoma appeared as ductal ectasia or narrowing without mass formation. The ducts also demonstrated increased enhancement. Intraductal cholangiocarcinoma had varying imaging patterns including ductal ectasia, strictures, and intraductal polypoid mass lesions.



Source: Viesca & Arvanitakis (2019) (20).

Figure 2:Showing a distal CBD cholangiocarcinoma with proximal CBD dilatation.

2.3.1.4 Periampullary Tumors

Periampullary tumors arise 2cm within the ampulla of vater. The four main types of tumors include pancreatic cancer of the head or uncinate process, extrahepatic cholangiocarcinoma of the distal CBD, ampullary tumors, and periampullary duodenal cancer. These are highly malignant tumors and present in late stages leading to poor prognosis. In a study done in 2018 by Hashemzadeh et al, MDCT showed a high sensitivity of 100%, specificity of 16.7%, and accuracy of 84.4% in the preoperative evaluation of periampullary tumors(23).

2.3.2 Benign Disease in Obstructive Jaundice

Unlike the other African studies, in South Africa, Di Bisceglie et al (24) was able to identify that chronic pancreatitis and malignant obstruction occurred in almost equivalent frequency. Chronic pancreatitis was the leading cause (33.8%), malignant obstruction (32.1%), intrahepatic obstruction (16.1%), gall stones (7.1%), sclerosing cholangitis (5.4%), miscellaneous (5.4%).

Mathew et al (12) also found that benign causes accounted for 56% of the causes while malignant causes were 44%. As far as individual causes were concerned the major cause was choledocholithiasis 22% followed by pancreatic head carcinoma 20% and cholangiocarcinoma 18%. 50 people were studied, males and females were similar in number.

Gracanin et al (25) conducted a study to determine the etiology and epidemiology of obstructive jaundice in Continental Croatia using endoscopic retrograde cholangiopancreatography (ERCP). The most common cause was gallstones (54.1%). Primary and secondary malignant causes accounted for (29.8%) of the cases, with the most common cause of malignant obstructive jaundice being pancreatic cancer (11.5%).

Benign disease like choledocholithiasis have been shown to demonstrate female predominance. Dr. Ngololo and Mathew et al found 84.6% and 90.9% female predominance respectively among female patients (5,12).

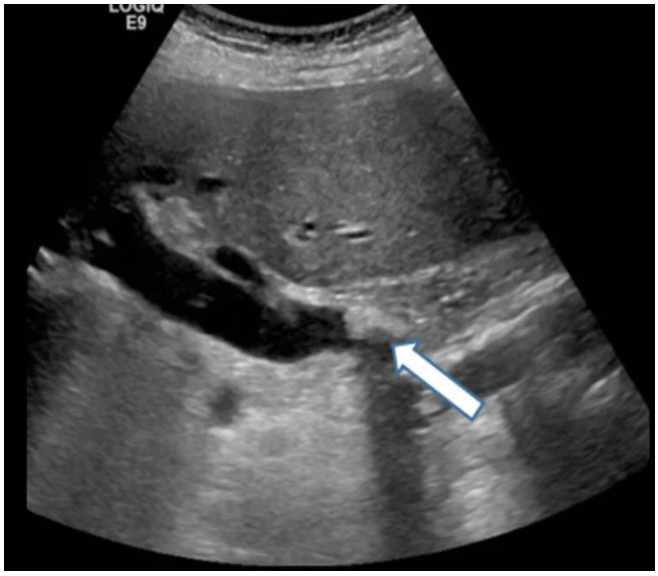
Benign disease distribution is commoner in the younger age groups. In a prospective interventional study Gulab et al (26) concluded that benign disease was more common in the <40-year age groups, while malignant disease affected the >40-year-old age groups. Mathew et al identified that most of the patients with choledocholithiasis were in the age range of 21-40 years (12).

2.3.3 Causes of Benign Disease in Obstructive Jaundice

2.3.3.1 Choledocholithiasis

Choledocholithiasis is the commonest cause of benign obstructive jaundice. It is seen in 6-12% of patients undergoing cholecystectomy. In a study done in 1987, Baron (27) evaluated the specificity of previously suggested CT criteria for diagnosing CBD stones. CT scans of 38 patients were compared with scans of 32 with carcinoma obstructing the CBD and 28 non-obstructed patients. CBD stone was directly visualized as a target sign or densely calcified structure in 76% of the patients with stones, one with carcinoma showed a similar target sign. A rim sign in the distal CBD was seen in 16% of patients with stones compared to 38% in

carcinoma and 54% in non-obstructed patients. Irregular intraluminal densities were seen in 11% of patients with stones compared to 25% with carcinoma and 32% in non-obstructed patients. Abrupt CBD termination without a mass was seen in 13% of patients with stones compared to 31% in patients with carcinoma. Therefore, CT was considered accurate in detecting CBD stones.



Source: Murphy et al. (2020) (28)

Figure 3:showing a sagittal ultrasound with a stone in the distal CBD. There is posterior acoustic shadowing with proximal CBD dilatation.

2.3.3.2 Biliary Strictures

Biliary strictures are secondary to a variety of benign and malignant causes, with the most common benign causes being attributed to iatrogenic causes (post-liver transplant or cholecystectomy). In 2007, Saluja et al (29) conducted a study in India to differentiate between malignant and benign causes of hilar strictures. Of the 58 patients, 34 had benign and 24 had malignant etiology. The mean age of benign patients was 38 years compared with 54 years for malignant biliary strictures. CT imaging features are dependent on the primary cause of the stricture.

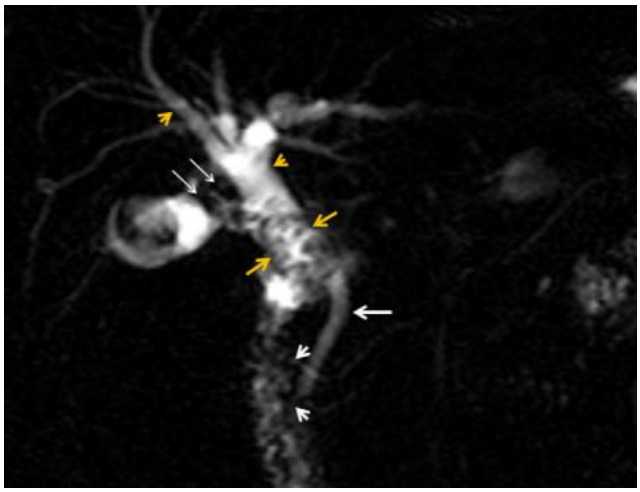
2.3.3.3 Primary Sclerosing Cholangitis

Primary sclerosing cholangitis is a chronic progressive cholestatic hepatic disease that has been described as the hepatobiliary manifestation of ulcerative colitis(30). Rahn et al(31) assessed the CT appearance of 10 patients with radiological and biopsy-proven findings consistent with sclerosing cholangitis. 9 patients had PSC. The diagnostic findings included thickening and luminal narrowing of the bile ducts. In each of the 10 cases, a similar pattern of dilatation was

identified on CT imaging. 7 of the 10 cases were associated with inflammatory bowel disease. Beaded appearance of the intrahepatic ducts was seen in all the cases. Gross dilatation of the extrahepatic ducts was not seen in any of the 10 cases. single ducts were sometimes serpiginous in the course with different extents of dilatation. The images showed no evidence of intrahepatic masses to explain biliary duct dilatation. In chronic advanced disease, CT showed features of cirrhosis and venous collaterals in 3 of the patients, indicating portal hypertension. 1 patient had gall bladder involvement with luminal narrowing and GB wall thickening.

2.3.3.4 Mirizzi Syndrome

Mirizzi syndrome is a complication of persistent cholelithiasis and occurs in 1% of patients with cholelithiasis(32,33). The typical features are dilatation of the common hepatic duct, gallstone impaction in the cystic duct, and normal duct width below the stone. Christopher Becker et al (1983) used US and CT to diagnose Mirizzi syndrome preoperatively. He deduced that the syndrome does not always have typical features, and sonography and CT are the primary imaging tests. Direct cholangiography was found to be important in cholecystobiliary fistulae secondary to stone penetration (34).



Source: Gupta and Garg (2012). (35)

Figure 4: MRCP showing large calculus in the cystic duct eroding into the CHD (yellow arrows). Multiple calculi are seen (thin white arrows), the CHD, RHD, LHD are mildly dilated (yellow arrowheads), the CBD is normal in caliber (white arrow), incidental pancreatic divisum. (White arrow heads).

2.3.3.5 Pancreatitis

Acute and chronic pancreatitis have both been identified as causes of obstructive jaundice. In 2004, Satomi Kawamoto et al used CT to assess 5 patients with lymphoplasmacytic sclerosing pancreatitis in biliary obstruction. The CT scans showed enlargement of the pancreatic head, 2

of the cases demonstrated diffuse and 3 had focal pancreatic head enlargement. The gland appeared featureless in involved regions with effacement of its normal lobular appearance. There was no segmental variation of contrast enhancement within the gland. Thickening and contrast enhancement of the CBD was seen in 4 cases and the gallbladder wall in 3 cases. These findings were pathologically correlated with inflammatory infiltrate of the CBD in 3 cases and the gall bladder in 1 case. Pancreatic duct dilatation was not seen in any patient (36).

2.3.3.6 Parasitic Infections

Parasitic infections are uncommon causes of obstructive jaundice. Ascaris lumbricoides is a prevalent parasitic infection in developing countries. The worm migrates from the small bowel through the duodenal ampulla into the biliary tree causing an obstruction.

Hydatid cyst is caused by Echinococcus Granulosus. Partial obstruction may result from rupture of the cyst into the biliary tree. Villain-Gonzalez et al. (37) found that this complication was seen in 5-25% of cases. Primary hydatid cyst has also been described as a cause, but it is extremely rare. Hydatid disease should be included in the differentials of pancreatic cystic lesions (38).

2.4 Computed Tomography (CT) In Obstructive Jaundice

When assessing biliary obstruction, the main role of CT imaging is to determine the presence of an obstruction, the level of the obstruction, the presence of biliary duct dilatation, the possibility of a surgical resection, the approaches that can be used for palliative stenting, and to differentiate between benign and malignant causes.

On assessing the usefulness of CT in obstructive jaundice in 2014, Singh et al(39) compared the diagnostic accuracy of MRI/MRCP to US/CT. with a sample size of 50 patients, all the patients underwent ultrasound evaluation with a 1-5Mhz curvilinear probe, followed by a multi-slice contrast-enhanced CT (Siemens) with collimation of 2mm and MRI/MRCP.ERCP, PTC, histology, and anatomo-pathologic findings were used as gold standards. The diagnostic accuracy of benign vs malignant disease was found to be 98% & 98% respectively in MRCP. CT accuracy was 82.86% and 91.4%. ultrasound accuracy was 88% and 88% respectively. In the diagnosis of benign disease MRCP was 100% sensitive, US 80.77%, CT 54.55% respectively. In the diagnosis of malignant disease, MRCP had 95.83%, US 79.17%, and CT 91.67% sensitivity. They concluded that MRCP was superior to ultrasound and CT scans.

Ahmetoglu et al. (40) evaluated the value of MDCT cholangiography with volume rendering for the assessment of biliary duct obstruction. A sample size of 34 patients with laboratory

features of obstructive jaundice was used. The Somatom Plus 4, volume zoom siemens machine was used. The following parameters were implemented, Slice width 1.25mm, collimation 4.1mm, reconstruction interval 1mm, a current of 120mAs, and voltage of 140Kv. These results were compared to ERCP and PTC findings. It showed a sensitivity of 93% and a specificity of 89% in biliary stone pathology. Sensitivity and specificity of 94% in patients with malignant biliary obstruction. The accuracy for the diagnosis of the cause of obstruction was 83.3%. They concluded that MDCT cholangiography with volume rendering had high sensitivity and specificity for diagnosing obstructive jaundice.

These studies have shown good sensitivity, specificity, and accuracy levels in the detection of various diseases in obstructive jaundice. In the study by Amandeep Singh et al., CT showed a moderate sensitivity of 54.55% in detecting benign lesions. However, it performs better in identifying malignant mass lesions, with a sensitivity of 91.67%. The study by Ahmetoglu (40) showed that MDCT, with its technological advancements, significantly improved its accuracy in detecting the cause and level of obstruction. However, MRCP was still considered the gold standard.

2.5 Diagnosis in Obstructive Jaundice

According to the American college of surgeons (ACS) division of education and the association of surgical education (ASE) guidelines, history, physical examination, laboratory tests, and imaging studies serve as a basis for patient diagnosis in obstructive jaundice(2). In 2006, Anderson et al(41) found that history, physical examination, and laboratory tests demonstrated a 90% accuracy in identifying patients with extrahepatic obstructive jaundice. However, confirmation of the level and cause of obstruction using various imaging modalities are required.

2.6 Study Justification

In the previous two decades, CT has advanced tremendously in technology, and it is now rapid, non-invasive, inexpensive, and readily available for patients. In the study conducted by Mathew et al (12), CT was reported to have a high diagnostic accuracy of 96% in detecting lesions in biliary obstruction. As a result, image quality and patient service delivery have both improved. Because hepatobiliary illness is one of the leading causes of morbidity and mortality in Kenya, there was a need to utilize CT in our setup to determine the disease spectrum based on age, sex, and frequency distribution. This study's strength was improved by comparing the CT findings to ultrasonography and correlating with histopathology. Based on local studies,

Ultrasound and MRCP had been employed as diagnostic methods to determine the spectrum of disease in obstructive jaundice at the Kenyatta National Hospital. To my knowledge, no CT imaging studies have been conducted. This research was conducted to empower radiologists and give them a better grasp of the illness spectrum and distribution; as well as a better understanding on the value of CT in evaluating hepatobiliary disease. This will eventually aid in the improvement of patient care and outcomes.

2.7 Research Question

What is the spectrum, frequency, age, and sex distribution of CT findings in adults with obstructive jaundice at the Kenyatta National Hospital?

2.8 Specific objectives

a) To determine the spectrum of findings at CT in obstructive jaundice patients.
b) To determine the frequency, age, and sex distribution of the various causes of obstructive jaundice using CT scanning.
c) To compare the CT findings of obstructive jaundice with ultrasound findings.
d) To correlate the CT findings of obstructive jaundice with histopathology.

3.0 CHAPTER THREE: METHODS AND MATERIALS

3.1 Ethical Considerations

Permission was sought from the KNH administration to conduct the study. Ethical guidelines were employed in line with the World Medical Association Declaration of Helsinki. The name, religion, and ethnicity were not documented. Only the CT number was used for confidentiality. No additional cost was incurred by the participants in the study.

3.2 Safety Measures

Due to the COVID-19 pandemic era, safety measures were undertaken during the period of the study to prevent the spread of the virus. The machines were thoroughly cleaned between each suspected patient visit. Hand washing and use of masks before, during and after the scanning procedure. The practice of social distancing between the patients and the hospital personnel. The scanning time was limited for suspected or confirmed COVID-19 cases.

3.3 Study Design

An analytical cross-sectional study.

3.4 Study Duration

Over a period of one year from January 2022 to December 2022.

3.5 Study Area Description

The study was conducted at the Radiology department of the Kenyatta National Hospital. A total of 31 patients with clinical and/or ultrasound features of obstructive jaundice were recruited for the study. They were subjected to CT scanning using the triple phase protocol. Two CT machines were utilized for the study, the 64 slice NeuVizIn and Siemens Brilliance 128 slice machines.

The Siemens and Neusoft scans were conducted at the Radiology Department in the Accident and Emergency building and the KNH Diagnostic and Reporting Center building, respectively. A review of the images was done in the respective reporting rooms and the findings were verified by a consultant radiologist. In liaison with the surgical, Interventional Radiology and Pathology departments, follow up of histopathology specimens was done. The samples were obtained within a one-month window period from the onset of radiological diagnosis.

3.6 Study Population

The study population consisted of patients with obstructive jaundice sent to KNH Radiology Department for CT scan evaluation of the hepatobiliary system.

3.7 Sample Size Determination

Sample size will be calculated using Fisher's formula.

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

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 2%)

d= desired precision (0.05)

$$\frac{1.96^2 \text{ X } 0.02\ (1-0.02)}{0.05^2} = 30.11$$

A sample size of 31 patients was used for the study.

3.8 Recruitment and Consenting Procedures

Patients who met the criteria were recruited from the Radiology Department in the Kenyatta National Hospital. Participation was voluntary. They were provided with consent forms. The participants were informed in a language that they understood. Patients' contact information was provided on the consent forms if they wished to.

3.9 Inclusion Criteria

a) All adult patients who had a clinical diagnosis of obstructive jaundice.
b) All adult patients who had ultrasound features of obstructive jaundice.
c) All obstructive jaundice patients that were referred to the KNH radiology department for CT scan evaluation of the hepatobiliary system.
d) All patients that consented to participate in the study.

3.10 Exclusion criteria

a) Patients who declined participation in the study.
b) Patients aged less than 18 years.

c) Patients with contraindications to CT scanning, such as hypersensitivity to contrast agents and kidney dysfunction with an estimated glomerular filtration rate of <30ml/min/1.73m^2.

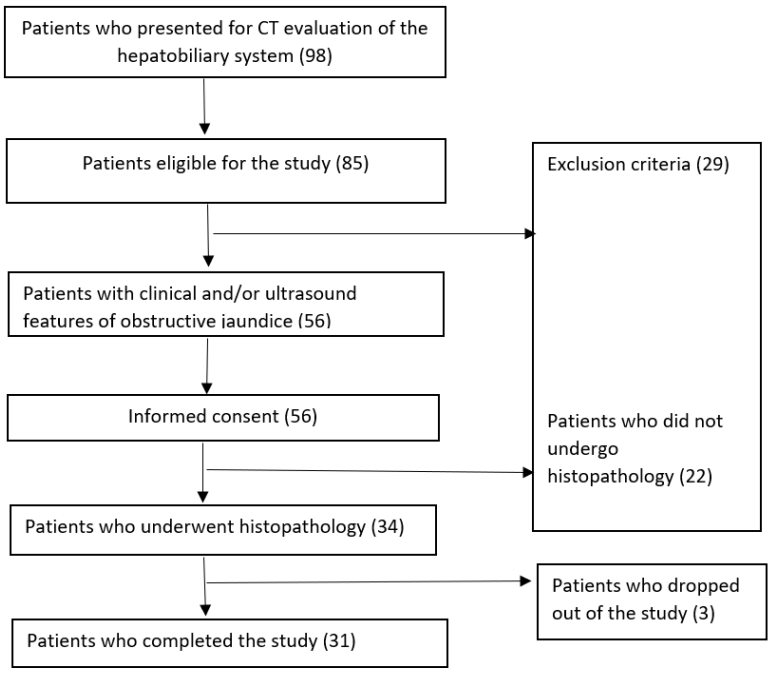


Figure 5:Flow chart for patient selection

3.11 Data Collection Procedures

The patients were recruited based on a clinical diagnosis and/or ultrasound features of obstructive jaundice. The main ultrasound features being dilated intrahepatic >3mm and/or extrahepatic ducts >4mm. As such ultrasound was used as a screening method. Other positive ultrasonographic imaging findings relating to biliary obstruction included mass lesions, hypoechoic masses mostly seen in pancreatic head cancer, heterogeneous masses commonly seen in cholangiocarcinoma and posterior acoustic shadowing seen in choledocholithiasis.

The patient's history, laboratory investigations and ultrasound findings were recorded on the data collection tool. CT scans were performed using the two available machines in KNH (64 slice NeuVizIn and the Siemens Brilliance 128 slice machines).

The principal investigator reviewed the CT images on the console. The pre- and post-contrast images were evaluated. The pre contrast images were evaluated for dilated intrahepatic ducts of >3mm and extrahepatic ducts with a CHD measuring >4mm and the CBD measuring >8mm

in diameter, target sign, filling defects within the biliary ducts for (strictures, choledocholithiasis), hyperattenuating lesions within the ducts (stones), benign and malignant masses arising within or around the dilated ducts. The post-contrast studies were evaluated for enhancement pattern of hepatobiliary and pancreatic structures, there was assessment of the margins of mass lesions, enhancement pattern of the lesions, mass effect, lymph node evaluation, vascular encasement, presence of metastasis, and possibility of resection.

The cause and level of obstruction were determined. A final diagnosis was made by the principal investigator. The findings were verified by a consultant radiologist. In liaison with the surgical, Interventional Radiology and Pathology departments, follow up of histopathology specimens was done. The samples were obtained within a one-month window period from the onset of radiological diagnosis. The specimens were obtained from surgical procedures such as ERCP, endoscopic ultrasound, open and laparoscopic surgeries. Interventional Radiology procedures included PTC (percutaneous transhepatic cholangiography), ultrasound and CT guided biopsies. These samples were sent to the Kenyatta National Hospital laboratory. The average turn-around time for histopathology results was approximately two weeks.

The radiological diagnoses made at CT were compared to ultrasound and correlated to histopathology findings.

3.12 Quality Assurance

The patient fasted for 6 hours before the procedure. Studies were done using the two CT machines in KNH, the 64 slice NeuVizIn and Siemens Brilliance 128 slice machines. Oral negative contrast (water) was administered 15 minutes before the procedure and on the table. Plain abdominal CT images were obtained at 120Kv and 200mAs to determine the reference Hounsfield units. This also helped in evaluating any calcium-containing biliary calculi. The current dose (mAs) varied with the patient's body weight.

The IV contrast agent was administered, Omnipaque 350mg/ml, a low osmolar non-ionic water soluble contrast agent, was used for abdominal CT imaging. Visipaque 350mg/ml an iso-osmolar non-ionic contrast agent that is ideally used for renal imaging, was the one available in KNH during part of the period of the study and it was also used for abdominal imaging. The contrast media were administered as a 70-80ml bolus at a rate of 4-5ml/sec, the dose was adjusted to body weight at 0.4-0.5gI/kg. The bolus was followed by a saline chaser at a rate of 4-5ml/sec. A multiphasic approach (triple phase) was utilized.

The images were acquired at the late arterial phase (35 sec), early portal venous phase (75 sec) and delayed phase (180sec) using bolus tracking. Studies were devoid of artifacts. All the

images were reviewed independently by the two supervisors in this study who are qualified consultant radiologists at the University of Nairobi and the Kenyatta National Hospital. They were blinded to the histopathological findings.

3.13 Data Management

The data was checked for completeness and free of error before entry into a Microsoft Excel 2017 Software, and later it was exported to the Statistical package for social sciences (SPSS) version 23.0 for analysis. Demographic, clinical, and laboratory characteristics (categorical data) was presented as frequencies and percentages, and the continuous data was presented as means with standard deviations or as median with interquartile range. The various hepatobiliary and pancreatic CT findings as well as their various causes were presented as frequencies and percentages. Chi-square tests were used to compare the CT findings to ultrasound findings and correlated to histopathology. All statistical tests were considered significant where the p-value was < 0.05.

3.14 Dissemination of Study Results

The research findings will be disseminated through the Department of Diagnostic Imaging and Radiation medicine, The University of Nairobi, and published in peer-reviewed journals.

4.0 CHAPTER FOUR: RESULTS

4.1 Demographic Distribution of The Participants

A total of 31 participants were recruited. The distribution of ages ranged from 25 to 76 years. The mean age was 54.32 +/-14.1 years. The median age was 54 with an interquartile range of 43.0-68.0), as shown in figures 6 and 7 below. 18 patients were female (58.1%) and 13 were male (41.9%). The male-to-female ratio was 1:1.4. Most patients belonged to the 60-69 and 40-49-year age groups at 25.8%, respectively. This was followed by the 50-59 (19.4%) and 70-79 (16.1%) year age groups. The 20-29 and 30-39 age groups shared equal frequency at 6.5% each.

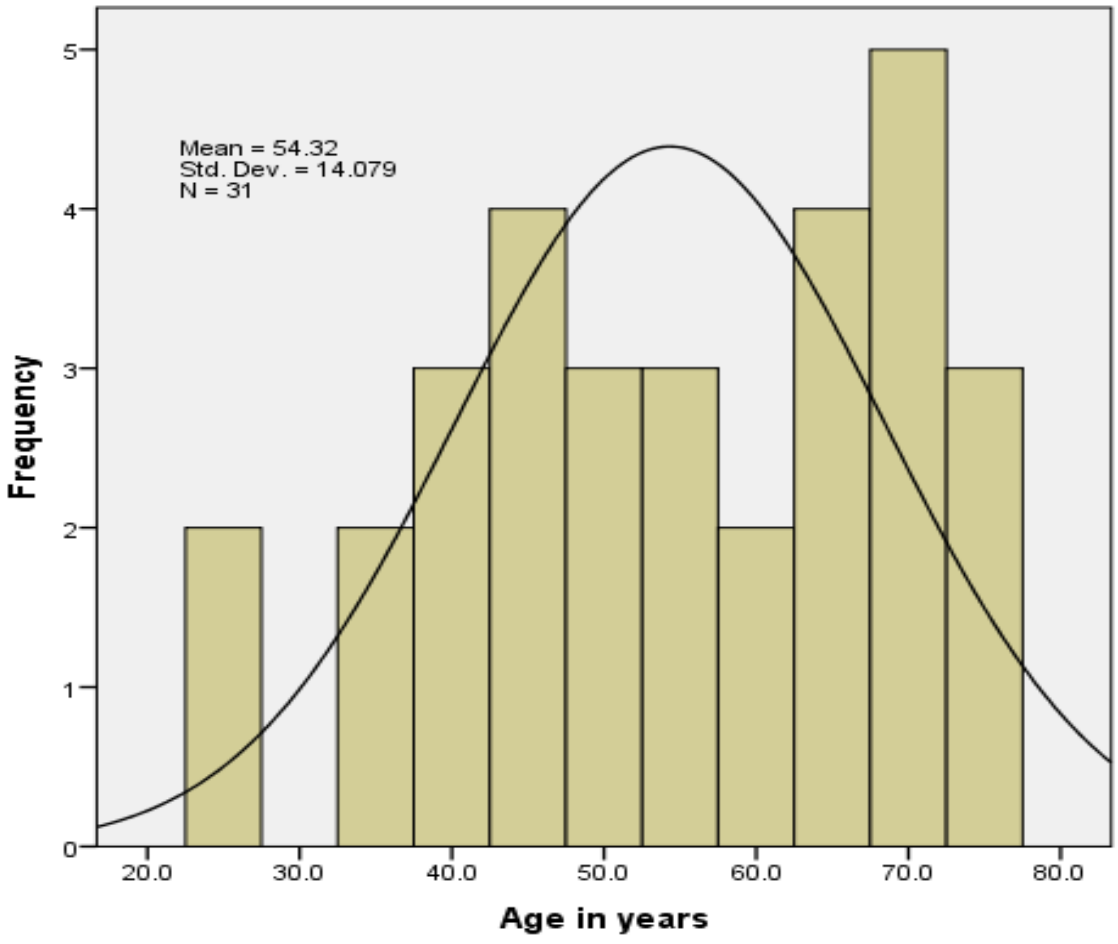


Figure 6:Age distribution (n=31)

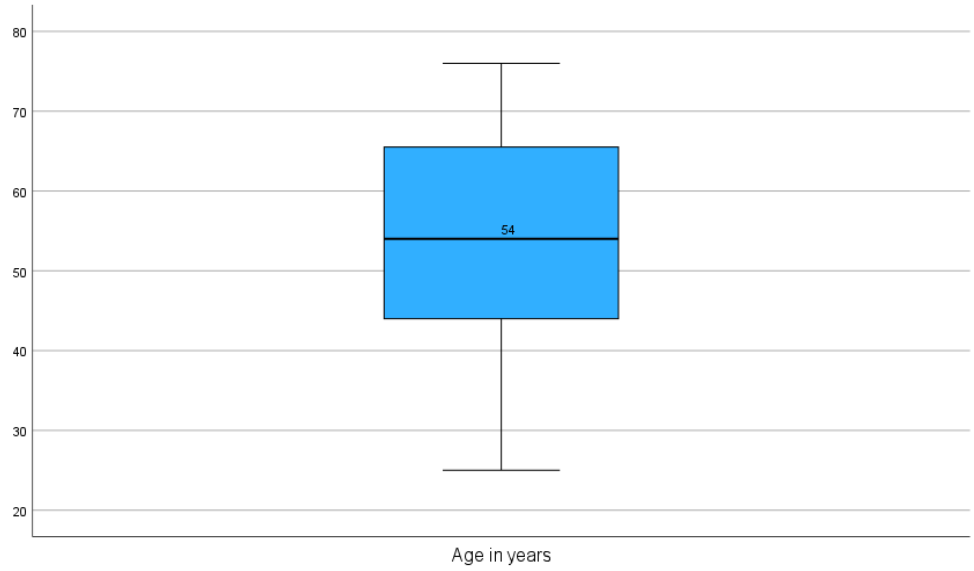


Figure 7:Box plot showing age distribution (n=31)

4.2 Ultrasound Features

Ultrasonography detected the presence of an obstruction in 77.4% of the cases. The most prevalent ultrasound finding was dilated intrahepatic ducts in 61.3% of the patients. This was followed by dilated extrahepatic ducts and hepatomegaly at 16.1% respectively. Table 1 below shows the other ultrasound features.

Table 1:Ultrasound Features (n=31)

Features	Frequency	Percentage
Dilated intrahepatic ducts	19	61.3
Dilated extrahepatic ducts	5	16.1
Hepatomegaly	5	16.1
Biliary sludge	2	6.5
Ill-defined pancreatic head mass	2	6.5
Ascites	2	6.5
Gall bladder mass	1	3.2
Features of hepatitis	1	3.2
Hypoechoic liver masses	2	6.5
Markedly contracted gallbladder	1	3.2

4.3 Spectrum of CT Findings

4.3.1 CT Diagnosis

At CT, 30 (96.8%) out of the 31 cases had suspected features of malignant disease, and only 1 case (3.2%) had a diagnosis of benign disease (choledocholithiasis). Pancreatic adenocarcinoma (32.3%) was the most common diagnosis given at CT. This was followed by cholangiocarcinoma (19.4%), periampullary tumors (9.7%), metastatic disease (9.7%), and gallbladder carcinoma (6.5%). Several cases were given a differential diagnosis based on the findings found at CT imaging review, as shown in table 2 below.

Table 2:CT diagnosis (n=31)

Features	**Frequency**	**Percentage**
Pancreatic head adenocarcinoma	10	32.3
Cholangiocarcinoma	6	19.4
Periampullary tumour	4	12.9
Gall bladder carcinoma	2	6.5
Choledocholithiasis	1	3.2
Cholangiocarcinoma/gall bladder carcinoma	2	6.5
Distal CBD stricture/ampullary mass	1	3.2
Focal pancreatitis/pancreatic adenocarcinoma	1	3.2
Intrahepatic metastatic lesion with unknown primary	1	3.2
Hepatic metastasis with primary ovarian malignancy	1	3.2
Hepatic metastasis with primary breast malignancy	1	3.2
Periampullary mass/ Gall bladder carcinoma	1	3.2
Total	31	100

4.3.2 Level of Obstruction

In the CT images the most frequent level of obstruction was at the distal CBD (58.1%), followed by hilar level (29%), and proximal CBD (12.9%) as seen in table 3 below.

Table 3:Level of obstruction (n=31)

Level	Frequency	Percent
Distal CBD	18	58.1
Hilar	9	29.0
Proximal CBD	4	12.9
Total	**31**	**100.0**

4.4 Duct Characteristics

The results are shown in Table 4 below on the pre-contrast characteristics of the ducts. Many of the cases (87%) demonstrated intrahepatic duct dilatation, followed by extrahepatic duct dilatation (71%) and double duct sign (41.9%). Intraductal masses were observed in 9.7% of the patients, and biliary duct wall thickening and strictures were seen in 6.5%. All the intraductal masses demonstrated heterogeneous post-contrast enhancement in the arterial and portal venous phases.

Table 4: Duct characteristics (n=31)

Characteristic	Frequency	Percent
Extrahepatic duct dilatation	22	71
Intrahepatic duct dilatation	27	87
Intraductal stone	1	3.2
Intraductal mass	3	9.7
Biliary duct wall thickening	2	6.5
Biliary strictures	2	6.5
Double duct sign	13	41.9

4.5 Pre-Contrast Characteristics (Mass Lesions)

As shown in Table 5 below, 30 (90.7%) of the 31 patients had mass lesions. All lesions demonstrated irregular shapes with ill-defined margins (90.3%). 60% of the masses demonstrated sizes of >4cm in at least one of the dimensions. 80% of the masses were single, with 3.3% of the masses demonstrating the presence of calcification. 86.7% had solid components, while 13.3% had mixed solid and cystic components.

Table 5: Pre-Contrast characteristics of mass lesions (n=30)

Variable		Frequency	Percent	Other Features
Margins- Well-defined/ Ill-defined	Well defined	2	6.5	-
	Ill-defined	28	90.3	-
	No Mass	1	3.2	
Shape	Regular shape	-	-	-
	Irregular shape	30	100.0	-
Size	Size (<4cm)	12	40.0	-
	Size (>4cm)	18	60.0	-
Single/ Multiple	Single	24	80.0	
	Multiple	6	20.0	
Calcifications	Yes	1	3.3	GB mass
	No	29	96.7	-
Solid/ Cystic/ Mixed	Solid	26	86.7	-
	Cystic	0	0	-
	Mixed	4	13.3	-

4.6 Post-Contrast Characteristics (Mass Lesions)

Most mass lesions (93.3%) demonstrated heterogenous enhancement in the late arterial and Portal venous phases, while 6.7% had a peripheral rim enhancement that was well demonstrated in the arterial phase.

4.7 Histopathological Diagnosis

As shown in Table 6 below, the histopathological diagnosis confirmed that 96.7% had a malignant disease and 3.3% had a benign disease. The M: F ratio of malignant disease was 1:1.8. Only one female patient had a benign disease. The most prevalent disease was pancreatic adenocarcinoma at 41.9%, followed by cholangiocarcinoma and metastatic disease at 16.1%, respectively, gall bladder carcinoma at 9.7%, and periampullary carcinoma at 6.5%, among other diagnoses.

Table 6:Histopathological diagnosis (n=31)

Histopathology diagnosis	Frequency	percent
Pancreatic adenocarcinoma	13	41.9
Cholangiocarcinoma	5	16.1
Adenocarcinoma of gallbladder	3	9.7
Periampullary carcinoma	2	6.5
Choledocholithiasis	1	3.2
Pancreatic neuroendocrine adenocarcinoma	1	3.2
Malignant CBD stricture	1	3.2
Metastatic carcinoma with unspecified primaries	2	6.5
Metastatic fibrous histiocytoma	1	3.2
Metastatic invasive ductal carcinoma of the breast	1	3.2
Metastatic bilateral ovarian serous adenocarcinoma with omental and hepatic disease	1	3.2
Total	**31**	**100.0**

4.6 Histology by Sex Distribution

The P value was 0.235. Therefore, no significant difference was seen in the prevalence of obstructive jaundice between males and females. However, as shown in figure 8 below, female preponderance was seen in the cases of gall bladder carcinoma, periampullary carcinoma, choledocholithiasis, and pancreatic neuroendocrine carcinoma.

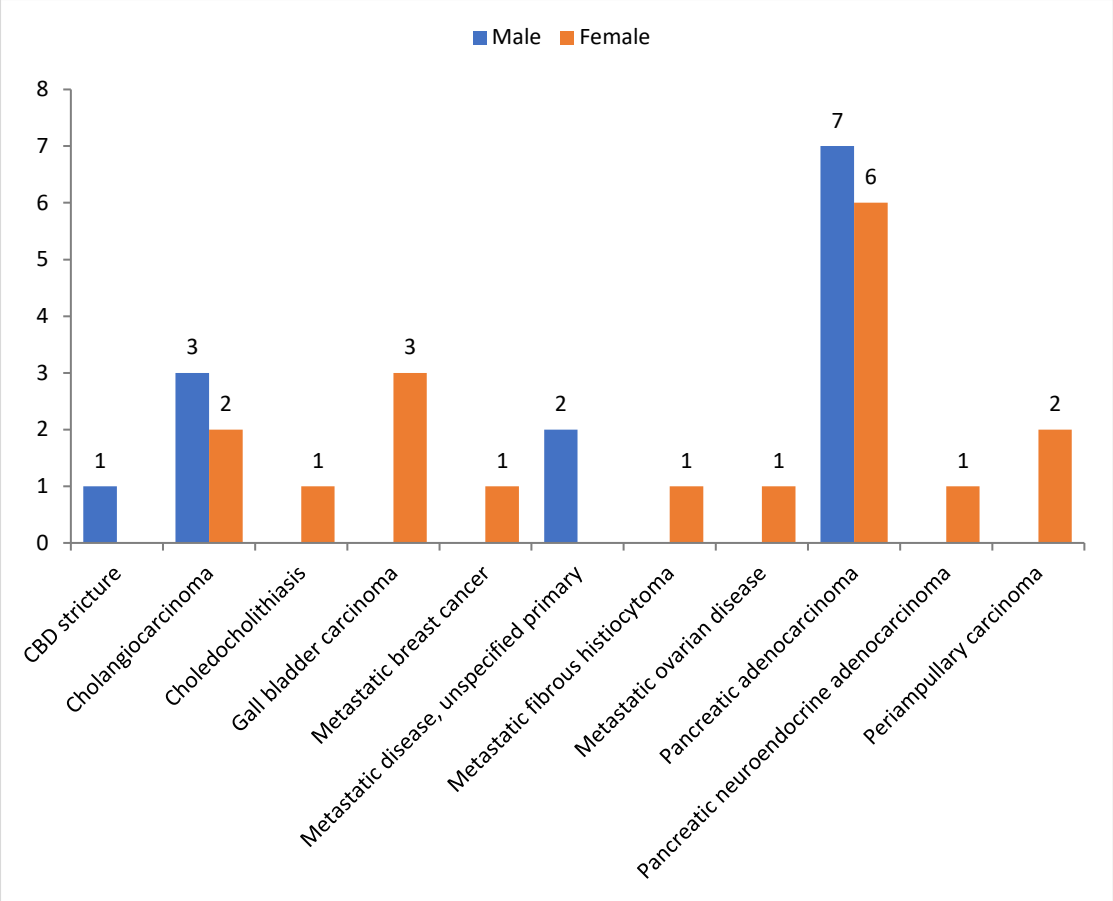


Figure 8:Histology and sex distribution (n=31)

4.7 Histology by Age Group

90% of patients with malignant disease were >40 years. 100% of patients with benign disease were < 40 years. As in figure 9 below, pancreatic adenocarcinoma showed a majority predominance in the 60-69 and 40-49 age groups. Cholangiocarcinoma was common in the 40-49 age group with an almost equivalent distribution in the other age groups. Choledocholithiasis was seen in the 20-29 age group.

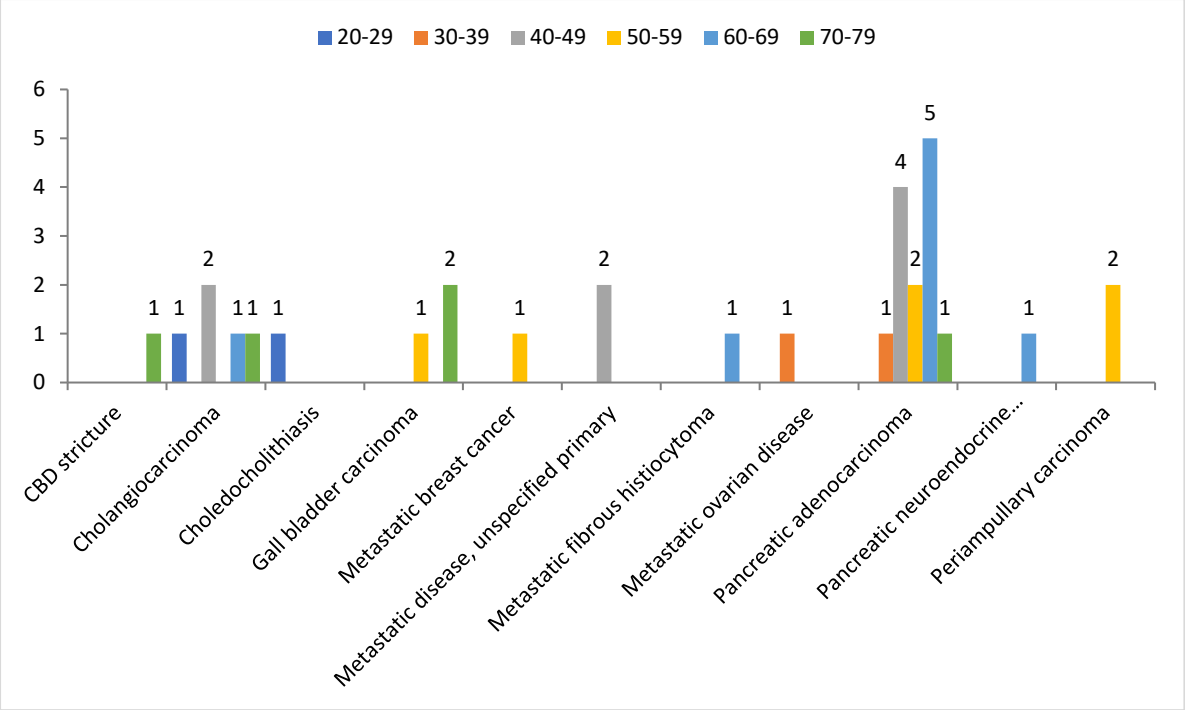


Figure 9:Histology and age distribution (n=31)

4.8 Correlation of CT and Histopathology

As shown in table 7 below, when correlated to histopathology as the gold standard, CT correctly diagnosed the specific obstruction causes in 90.3% of the cases. The level and type of obstruction were correctly determined in 100% of the cases.

Table 7:Correlation of CT and histopathology (n=31)

Diagnosis	**Histopathology**	**CT**	**P Value**
Pancreatic adenocarcinoma	13 (41.9)	14 (45.1)	
Cholangiocarcinoma	5 (16.1)	6 (19.4)	0.285
Gallbladder carcinoma	3 (9.7)	4 (12.9)	
Periampullary carcinoma	2 (6.5)	2 (6.5)	
Metastatic disease, Unspecified primary	2 (6.5)	1 (3.2)	
Metastatic ovarian disease	1 (3.2)	1 (3.2)	
Metastatic breast cancer	1 (3.2)	1(3.2)	
Metastatic fibrous histiocytoma	1 (3.2)	0	
Pancreatic neuroendocrine carcinoma	1 (3.2)	0	
Malignant CBD stricture	1 (3.2)	1 (3.2)	
Choledocholithiasis	1 (3.2)	1 (3.2)	

There was a misdiagnosis rate of 9.7%, with metastatic disease demonstrating the highest misdiagnosis rate at 40% (2 out of 5) as shown in table 8 below. Using the Wilcoxon ranking test (P value= 0.285), there was no significant difference between the two diagnostic tests.

Table 8:CT misdiagnosis (n=3)

Diagnosis at CT	**Diagnosis at histopathology**	**Wilcoxon ranking test**
Pancreatic adenocarcinoma	Periampullary carcinoma	0.285
Periampullary mass	Metastatic fibrous histiocytoma	
cholangiocarcinoma	Metastatic disease with unknown primary	

4.9 Illustration of Sample Cases

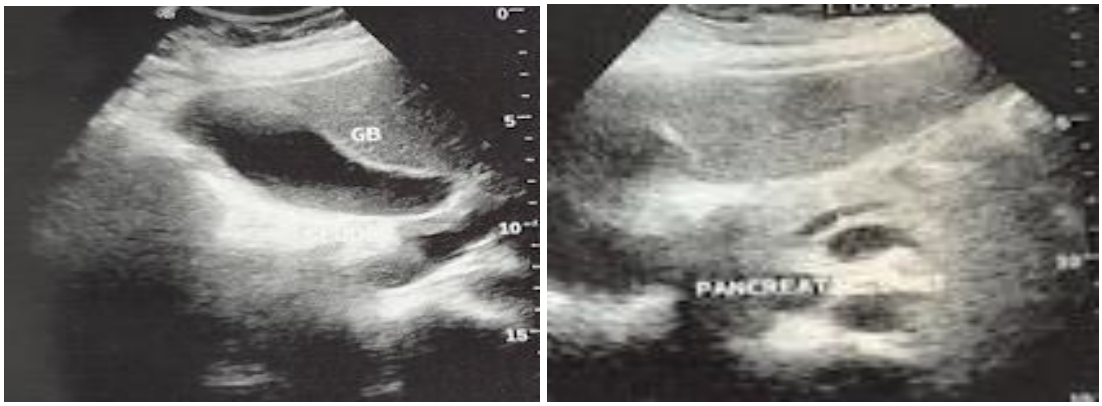


Figure 10: Image Shows a 50-year-old female with ultrasound features of gall bladder sludge and a dilated main pancreatic duct.

Figure 11:Image shows an axial CT of the same patient in image 1 during the late arterial phase with a prominent and heterogeneously enhancing mass at the region of the pancreatic head; a CT diagnosis of pancreatic adenocarcinoma was given. However, histology confirmed it to be periampullary carcinoma

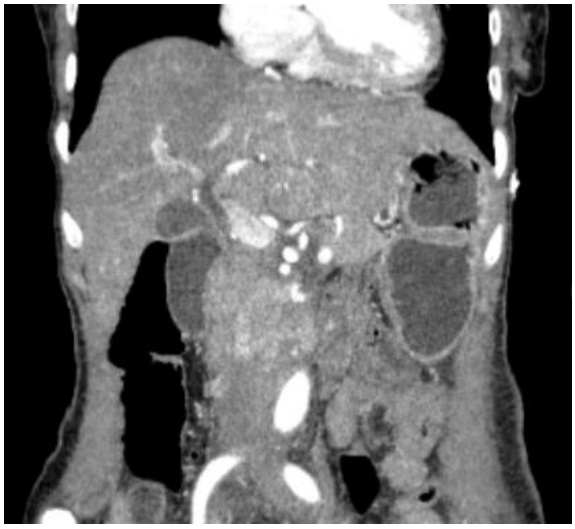


Figure 12: Image shows a **coronal reconstruction image in the late arterial phase of a 59-year-old woman with a large pancreatic head adenocarcinoma obstructing the distal common bile duct with upstream dilatation. There was a 180-degree encasement of the superior mesenteric artery.**

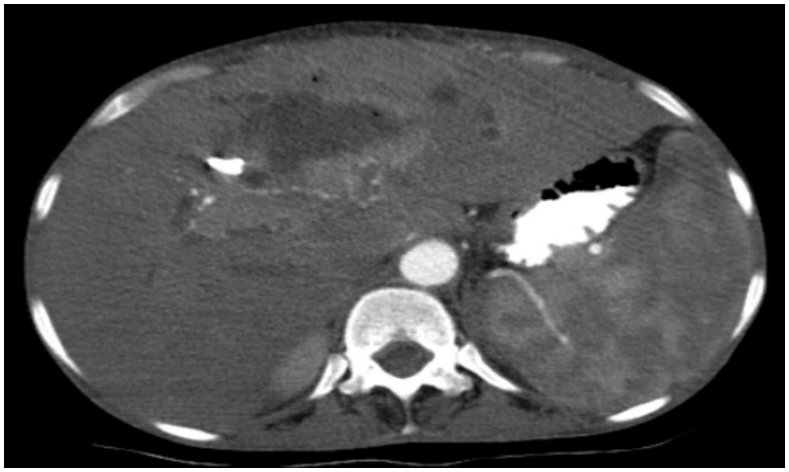


Figure 13:Image shows an axial CT image during the late arterial phase, in a 76-year-old female shows a heterogeneously enhancing intrahepatic segment 4 mass and dilated biliary radicals. CT and histopathology confirmed it to be a cholangiocarcinoma. A misplaced biliary stent is seen in situ.

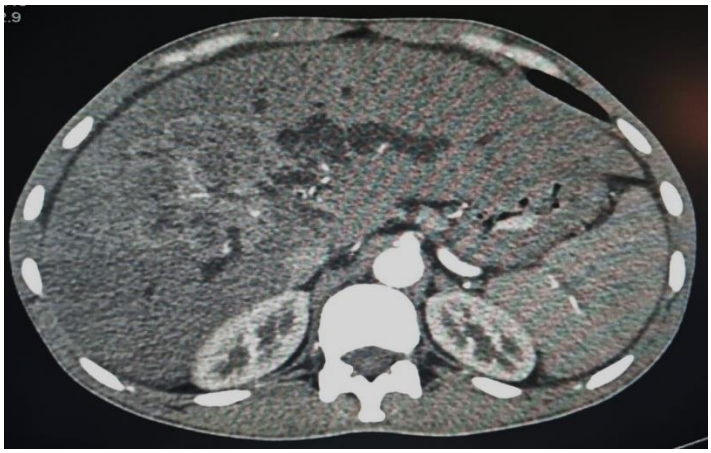


Figure 14:Image shows An axial CT image of a 43-year-old male that showed a peripherally enhancing mass with CT features of cholangiocarcinoma; histopathology confirmed it to be a metastatic adenocarcinoma.

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

This study was to determine the demographic distribution of patients with obstructive jaundice at Kenyatta National Hospital. The minimum age was 25 years, and the maximum was 76 years, with a mean age distribution of 54.32+/-14.1 years. These findings are in agreement with those of Dr. Ngololo and Padmalatha et al(5,9) which found a mean age distribution of 53.3 and 46 years, respectively. In this study, the majority of the patients were in the 60-69 and 40-49-year age groups at 25.8% respectively, which agrees with the Padmalatha and Khan et al studies in India(9,11) that found a majority age distribution of 41–50-year and 55-65 age groups, respectively. This study found a female predominance of 58.1% which also agrees with Dr. Ngololo and Padmalatha et al studies, that found a 56.2% and 62% female predominance, respectively (5,9).

In our study, ultrasonography detected the presence of an obstruction in 77.4% of the cases, which disagrees with the Indian study by Kaushal et al(43) that found a 100% detection rate. We also determined that dilated intrahepatic ducts were the commonest finding at ultrasound evaluation (61.3%); this is in contrary to Chalya et al in Tanzania (8) who found that extrahepatic ductal dilatation was the commonest finding at 78.9%. These findings are attributed to patients' bowel gas and body habitus as well as operator dependence.

Our study has established that most patients had malignant disease at 96.8% and benign disease at 3.2%, with a female predominance of 56.7% and 100% respectively in both disease categories. This is similar to the findings by Chalya et al(8) who found a malignant disease predominance at 58.6% compared to benign disease at 41.4%, with a female predominance ratio of 2.5:1 in malignant disease and 1.4:1 in benign disease. A study from India by Mathew et al(12) differs from these findings, with benign disease being the most common cause of obstruction at 56%.

Our study has demonstrated that pancreatic ductal adenocarcinoma was the commonest cause of malignant obstruction at 46.1%. There was no significant difference in prevalence of the disease between males and females with a male-to-female ratio of 1.2:1. This agrees with the Indian study by Gulab et al (26) which found a pancreatic cancer predominance of 47.36%.

In our study, metastatic disease and cholangiocarcinoma have been found to be major causes of obstruction at 16.1% at equal frequency, coming second to pancreatic cancer. This agrees with Mathew et al(12) who also utilized MDCT and histopathology and found

cholangiocarcinoma to be the second most common cause of malignant obstructive jaundice at 18%. However, no cases of metastatic disease were identified in his study. Ahmed et al in Egypt (2020)(44) identified only 2.9% of cases of malignant metastatic nodes as primary causes of obstruction.

In our study, gallbladder carcinoma, periampullary carcinoma, and pancreatic neuroendocrine adenocarcinoma demonstrated a female predominance. Kaushal et al(43) also identified a female predominance of gallbladder carcinoma in his study. This study has also shown that malignant disease was more common in the older age groups (> 40 years), which conforms with the findings by padmalatha et al(9).

In our study, there was a 100% female predominance of benign disease (choledocholithiasis). This agrees with the Mathew et al(12) study which found a 90.9% distribution of choledocholithiasis among female patients. We established that benign disease was seen in the younger age group of 20-29; Gulab et al(26) study also found that benign disease was more common in <40-year age groups.

In this study, when correlated to histopathology as the gold standard, CT correctly diagnosed the specific obstruction causes in 90% of the cases. There was 100% detection rate in identifying the level and type of obstruction. This is comparable to the Al pedrosa et al study in Spain(45) at 94% and Mathew et al study in India(12) at 96.7% in identifying the causes of obstruction. Mathew et al found 100% sensitivity in determining the level and type of obstruction.

This study identified a CT misdiagnosis rate of 9.7% (3 out of 31) in identifying the cause of obstruction. Metastatic disease demonstrated the highest misdiagnosis rate at 40% (2 out of 5). The P value of 0.285 showed no significant difference between CT and histopathology as diagnostic tools. This agrees with the Mathew et al study(12) whereby CT incorrectly diagnosed 2 out of 50 patients, one case of lower CBD cholangiocarcinoma was misdiagnosed as a benign stricture, and distal CBD sludge was misdiagnosed as a CBD calculus. In his study, CT demonstrated an accuracy of 96% in determining the cause of obstruction.

5.2 Conclusions

This study has determined a female and older age groups' predominance in obstructive jaundice. Malignant disease was common in the older age groups >40 years, and benign disease was common in the younger age groups <40 years. The study further showed that malignant disease was the most common cause of obstructive jaundice, with pancreatic adenocarcinoma being the commonest malignant cause of obstruction. Contrary to previous studies, our study has identified metastatic disease as a significant cause of obstruction. However, it demonstrated the highest rate of misdiagnosis. This highlights the need for proper imaging protocols and histopathology to characterize and diagnose obstructive jaundice lesions. Choledocholithiasis was found to be the only cause of benign disease. Findings from this study show that CT is useful in characterizing lesions and determining the level and type of obstruction and that CT is superior to ultrasonography in determining the cause of biliary obstruction.

5.3 Study Limitations

A limited number of patients were recruited for the study. This was attributed to a lower number of patients undergoing tissue biopsies, mainly due to financial constraints, loss to follow-up, and lack of equipment such as biopsy kits at the Interventional Radiology department. A purposive sampling technique was utilized in this study. Therefore, a selection bias was encountered. Only the patients with eventual positive diagnoses at histopathology were recruited for the study.

A predominance of malignant disease was encountered, which was attributed to Kenyatta National Hospital being a tertiary center for managing cancer patients. Due to the small sample size, there was a limited representation of uncommon diseases such as parasitic infections, primary sclerosing cholangitis, hydatid disease, and pancreatitis. Ultrasound imaging is operator dependent. Therefore, images acquired by other personnel may not have been optimal for comparison to CT and histopathology. There needed to be a proper PACS system, which resulted in delayed access to patients' reports and images.

5.4 Recommendations

A larger study should be done for a more generalizable conclusion on the spectrum of CT findings in obstructive jaundice. Proper PACS system is recommended to allow for faster follow-up and data collection of patients from the point of clinical diagnosis to histopathology and treatment.

The radiology department should continue adopting the pre- and post-contrast image acquisition protocol from this study. For accurate assessment of lesions, bolus tracking with the triple phase technique at the late arterial (35 sec), portal venous (75 sec), and delayed (180 sec) phases are advised. Nonionic water soluble IV contrast should be delivered at a rate of 4-5ml/sec at a dosage of 0.4-0.5gI/kg. Neutral oral contrast (water) is recommended to clearly delineate the bowel. 1 mm-thick axial slices and isotropic datasets should be used for sagittal and coronal reconstruction.

REFERENCES

1. Addley J, Mitchell RM. Advances in the investigation of obstructive jaundice. Vol. 14, Current Gastroenterology Reports. 2012. p. 511–9.
2. Coucke EM, Akbar H, Kahloon A, et al. Biliary Obstruction [Updated 2021 Sep 28]. In: StatPearls [Internet]/ Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539698/.
3. World health statistics 2018: monitoring health for the SDGs, sustainable development goals. Geneva: World Health Organization; 2018.
4. obstructive jaundice modalities.
5. John DR, Ngololo M. THE VALUE OF MAGNETIC RESONANCE CHOLANGIOPANCREATOGRAPHY IN OBSTRUCTIVE JAUNDICE. A RETROSPECTIVE AND PROSPECTIVE STUDY AT KENYATTA NATIONAL HOSPITAL A DISSERTATION SUBMITTED IN PART FULFILMENT FOR THE DEGREE OF MASTER OF MEDICINE IN DIAGNOSTIC RADIOLOGY SUPERVISOR DR. ALFRED ODHIAMBO MBChB, M.MED (NBI) CONSULTANT RADIOLOGIST AND SENIOR LECTURER DEPARTMENT OF DIAGNOSTIC IMAGING AND RADIATION MEDICINE UNIVERSITY OF NAIROBI mm UNIVERSITY OF NAIROBI MEDICAL LIBRARY.
6. Peters JH, Ohio LC, Carey F. Historical Review of Pancreaticoduodenectomy.
7. Okoth FA, Ogutu EO, Lule GN, Wambugu MN. Some aspects of obstructive jaundice at Kenyatta National Hospital. East Afr Med J. 1989 Sep;66(9):594–7.
8. Chalya PL, Kanumba ES, McHembe M. Etiological spectrum and treatment outcome of Obstructive jaundice at a university teaching hospital in northwestern Tanzania: A diagnostic and therapeutic challenges. BMC Res Notes. 2011;4.
9. M P, O J, J A. RADIOLOGICAL EVALUATION OF OBSTRUCTIVE JAUNDICE BY ULTRASOUND AND CT. Journal of Evidence Based Medicine and Healthcare. 2015 Oct 28;2:7829–46.
10. Alrashed FM, Almalki Ahmed Y, Alflan A, Alzahrani M, Alrashed Fatima M, Alshahrani Saeed A, et al. PHARMACEUTICAL SCIENCES OBSTRUCTIVE JAUNDICE: INCIDENCE, ETIOLOGY AND MANAGEMENT IN ASEER REGION, SAUDI ARABIA. IAJPS [Internet]. 2018(12):17102–9. Available from: http://www.iajps.com

11. Khan ZA. Clinical profile of patients with obstructive jaundice: a surgeon's perspectives. International Surgery Journal. 2019 May 28;6(6):1876.
12. Mathew RP, Moorkath A, Basti RS, Suresh HB. Value and accuracy of multidetector computed tomography in obstructive jaundice. Pol J Radiol. 2016 Jun 28;81:303–9.
13. Everhart JE. Gallstones and ethnicity in the Americas. J Assoc Acad Minor Phys. 2001 Jul;12(3):137–43.
14. Siddique K, Ali Q, Mirza S, Jamil A, Ehsan A, Latif S, et al. EVALUATION OF THE AETIOLOGICAL SPECTRUM OF OBSTRUCTIVE JAUNDICE [Internet]. Vol. 20, J Ayub Med Coll Abbottabad. 2008. Available from: http://www.ayubmed.edu.pk/JAMC/PAST/20-4/Khurram.pdf
15. Kenya-Cancer-Policy-2020.
16. Joshi A, Rajpal K, Kakadiya K, Bansal A. Role of CT and MRCP in Evaluation of Biliary Tract Obstruction. Vol. 2, Current Radiology Reports. Springer New York LLC; 2014.
17. Korir A, Okerosi N, Ronoh V, Mutuma G, Parkin M. Incidence of cancer in Nairobi, Kenya (2004-2008). Vol. 137, International Journal of Cancer. Wiley-Liss Inc.; 2015. p. 2053–9.
18. Bimal Chandra Roy B, Abu Hanifa M, Shafiul Alam M, Naher S, Sarkar P. Global Journal of Medical Research: I Surgeries and Cardiovascular System Etiological Spectrum of Obstructive Jaundice in a Tertiary Care Hospital. 2015;
19. Ahn SS, Kim MJ, Choi JY, Hong HS, Chung YE, Lim JS. Indicative findings of pancreatic cancer in prediagnostic CT. Vol. 19, European Radiology. 2009. p. 2448–55.
20. Viesca MFY, Arvanitakis M. Early diagnosis and management of malignant distal biliary obstruction: A review on current recommendations and guidelines. Vol. 12, Clinical and Experimental Gastroenterology. Dove Medical Press Ltd; 2019. p. 415–32.
21. Gravito-Soares E, Gravito-Soares M, Figueiredo P, Tomé L. A Rare Clinical Presentation of Cholangiocarcinoma. Case Rep Gastrointest Med. 2017;2017:1–4.
22. Chung YE, Kim MJ, Park YN, Choi JY, Pyo JY, Kim YC, et al. Varying appearances of cholangiocarcinoma: Radiologic-pathologic correlation. Radiographics. 2009 May;29(3):683–700.
23. Hashemzadeh S, Mehrafsa B, Kakaei F, Javadrashid R, Golshan R, Seifar F, et al. Diagnostic Accuracy of a 64-Slice Multi-Detector CT Scan in the Preoperative Evaluation of Periampullary Neoplasms. J Clin Med. 2018 Apr 27;7(5):91.
24. di Bisceglie AM, Oettle GJ, Hodkinson HJ, Segal I. Obstructive Jaundice in the South African Black Population. J Clin Gastroenterol [Internet]. 1986;8(5). Available from:

https://journals.lww.com/jcge/Fulltext/1986/10000/Obstructive_Jaundice_in_the_South_African_Black.9.aspx

25. Gracanin AG, Kujundzić M, Petrovecki M, Romić Z, Rahelić D. Etiology and epidemiology of obstructive jaundice in Continental Croatia. Coll Antropol. 2013 Mar;37(1):131–3.
26. Gulab Dhar Yadav, Anju Yadav, Shraddha Verma, Mohammad Tahir Hussain. Clinical profile, management, and outcome of obstructive jaundice patient at a tertiary care center: A prospective study. Asian J Med Sci. 2022 May 3;13(5):94–9.
27. Baron RL. Common Bile Duct Stones: Reassessment of Criteria for CT Diagnosis'.
28. Murphy MC, Gibney B, Gillespie C, Hynes J, Bolster F. Gallstones top to toe: what the radiologist needs to know. Vol. 11, Insights into Imaging. Springer; 2020.
29. Saluja SS, Sharma R, Pal S, Sahni P, Chattopadhyay TK. Differentiation between benign and malignant hilar obstructions using laboratory and radiological investigations: A prospective study. HPB. 2007;9(5):373–82.
30. Hirschfield GM, Karlsen TH, Lindor KD, Adams DH. Primary sclerosing cholangitis. In: The Lancet. Elsevier B.V.; 2013. p. 1587–99.
31. Rahn NH, Koehler1 RE, Weyman2 PJ, Truss3 CD, Sagel2 SS, Stanley1 RJ. CT Appearance of Scierosing Cholangitis [Internet]. Available from: www.ajronline.org
32. Safioleas M, Stamatakos M, Safioleas P, Smyrnis A, Revenas C, Safioleas C. Mirizzi Syndrome: An unexpected problem of cholelithiasis. Our experience with 27 cases. Vol. 5, International Seminars in Surgical Oncology. 2008.
33. Yun EJ, Choi CS, Yoon DY, Seo YL, Chang SK, Kim JS, et al. Combination of Magnetic Resonance Cholangiopancreatography and Computed Tomography for Preoperative Diagnosis of the Mirizzi Syndrome [Internet]. Available from: www.jcat.org
34. Becker1 CD, Hasslerr H, Terrier1 F, Becker CD. Preoperative Diagnosis of the Mirizzi Syndrome: Limitations of Sonography and Computed Tomography [Internet]. Available from: www.ajronline.org
35. Gupta M, Garg D. Mirizzi syndrome: recognition on magnetic resonce cholangiopancreatography. Clinical Gastroentorology and Hepatology. 2012 Dec 1:10(12):A32.
36. Kawamoto S, Siegelman SS, Hruban RH, et al. Lymphoplasnocytic sclerosing pancreatitis with obstructive jaundice: CT and pathology features. American Journal of Roentgenology. 2004 Oct;183(4):915-21.

37. Villán-González A, Pérez-Pariente JM, Barreiro-Alonso E. Obstructive jaundice secondary to a hepatic hydatid cyst. Revista Espanola de Enfermedades Digestivas. 2018;110(11):741–2.
38. Jai SR, Hattabi K el, Bensardi F, Chehab F, Khaiz D, Bouzidi A. Primary Hydatid Cyst of the Pancreas Causing Obstructive Jaundice [Internet]. Vol. 13, The Saudi Journal of Gastroenterology. 2007. Available from: http://www.saudijgastro.com
39. Singh A, Mann HS, Thukral CL, Singh NR. Diagnostic accuracy of MRCP as compared to ultrasound/CT in patients with obstructive jaundice. Journal of Clinical and Diagnostic Research. 2014 Mar 15;8(3):103–7.
40. Ahmetoglu A, Kosucu P, Kul S. et al. MDCT cholangiography with volume rendering for the assessment of patients with biliary obstruction. American Journal of Roentgenology. 2004 Nov;183(5):103-7.
41. Anderson SW, Lucy BC, Varghese JC, et al. Accuracy of MDCT in the diagnosis of choledocholithiasis. American Journal of Roentgenology,]. 2006 Jul;187(1):174-80.
42. Pringle K, Ahmed I. Obstructive jaundice and its management. BMJ learning module [Internet]. Available from: https://www.researchgate.net/publication/249962774
43. Yadav RK, Kaushal V, Griwan MS, Garg P, Popli P, Maken S, et al. Ultrasonography and computed tomography evaluation in patients of obstructive jaundice. Asian Oceanian Journal of Radiology. 2000 Jan 1;5:138–43.
44. Alsowey AM, Salem AF, Amin MI. Validity of MDCT cholangiography in differentiating benign and malignant biliary obstruction. Egyptian Journal of Radiology and Nuclear Medicine [Internet]. 2021;52(1):104. Available from: https://doi.org/10.1186/s43055-021-00468-3
45. Pedrosa CS, Casanova R, Lezana AH, Fernandez MC. Computed Tomography in Obstructive Jaundice Part II: The Cause of Obstruction1.

APPENDICES

Appendix A: Data Collection Form

Title: obstructive jaundice: spectrum of CT findings in patients with obstructive jaundice at the Kenyatta National Hospital.

Resident: Dr. Neema Anyango Okode

DATA COLLECTION TOOL

Study Number: CT number: Age: Sex: Comorbid conditions:

CLINICAL PRESENTATION

PRESENTING COMPLAINT	YES
Jaundice	
Pruritus	
Pale stools	
Dark urine	
others	

LABORATORY MARKERS

RAISED PARAMETER	YES	NO
Direct bilirubin		
ALP		
GGT		
AST		
ALT		
Prolonged prothrombin time		
CA 19-9		

CT FINDINGS

SITE OF OBSTRUCTION	Tick
Hepatic ducts	
Cystic duct	
Proximal CBD	
Mid-CBD	
Distal CBD	
Pancreatic duct	

LEVEL OF OBSTRUCTION	Tick	
Hilar/ perihilar		
Proximal CBD		
Mid-CBD		
Distal CBD		

PRE-CONTRAST CHARACTERISTICS (DUCTS)

CHARACTERISTIC	YES	NO
Extrahepatic ducts dilatation		
Intrahepatic ducts dilatation		
Intraductal stone		
Target sign		
Rim sign		
Intraductal mass		
Biliary duct wall thickening		
Biliary strictures		
Double duct sign		

POST-CONTRAST CHARACTERISTICS (DUCTS)

Homogenous enhancement		
Heterogenous enhancement		
none		

PRE-CONTRAST CHARACTERISTICS (MASS LESIONS)

CHARACTERISTIC	YES	NO
Well defined		
Ill-defined		
Regular margins		
Irregular margins		
Size (<4cm)		
Size (>4cm)		
single		
multiple		
calcifications		
solid		
cystic		
mixed		

POST-CONTRAST CHARACTERISTICS (MASS LESIONS)

CHARACTERISTIC	YES	NO
Homogenous enhancement		
Heterogenous enhancement		
Rim enhancement		
None		

FINAL DIAGNOSIS WITH COMMENTS/REMARKS.

ULTRASOUND FINDINGS

ULTRASOUND FINDINGS	REMARKS

HISTOPATHOLOGY FINDINGS	REMARKS

Appendix B: Consent Information Document

PARTICIPANT INFORMATION AND CONSENT FORM SAMPLE ADULT CONSENT FOR ENROLLMENT IN THE STUDY

(To be administered in English and Kiswahili translation)

Title of Study: SPECTRUM OF CT FINDINGS IN PATIENTS WITH OBSTRUCTIVE JAUNDICE AT THE KENYATTA NATIONAL HOSPITAL

Principal Investigator and institutional affiliation: DR. OKODE A. NEEMA, RESIDENT AT UNIVERSITY OF NAIROBI, DEPARTMENT OF DIAGNOSTIC IMAGING AND RADIATION MEDICINE

Introduction:

I would like to tell you about a study being conducted by the above listed researcher. The purpose of this consent form is to give you the information you will need to help you decide whether 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 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 have been sent for computed tomography (CT) imaging and have the clinical and laboratory features of obstructive jaundice. The purpose of the interview is to find out your age, sex, and relevant clinical history that

appertains to a diagnosis of obstructive jaundice. Participants in this research study will undergo CT abdominal imaging with the recommended hepatobiliary protocol. The images will be reviewed, and the results compared to US and histopathology findings. This will help in confirming the diagnoses. There will be approximately 30 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 10 minutes. After the interview has finished, I will request to review your CT images. I will also follow up with ultrasound imaging findings and histopathology. 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 getting further clarification or more information if required.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional, and physical risks. Efforts 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 our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be 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. 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, discussing your diagnosis and treatment may be stressful. In case of any psychological 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 counselling and more information concerning your diagnosis. Also, the information you provide will help us better understand the use of CT in investigating obstructive jaundice. This information is a contribution to science and will help

us understand the distribution of disease in your condition. This in the long run benefits you and other patients' management.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

No additional costs will be incurred.

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.

WHAT IF YOU HAVE QUESTIONS IN THE 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 following persons.

Secretary, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

Supervisor: Dr. Gladys Mwango, Telephone number +254720127553

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

Appendix C: 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 at any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my 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 provide contact information for follow-up: Yes /No

Participant printed name: _____

Contact (mobile number): _____

Participant signature / Thumb stamp _____ Date _____

Name of Parent/Guardian providing consent for a minor: _____

Signature: _____ 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: DR. OKODE A. NEEMA Date: _____

Signature

_____ Role in the study: Principal investigator.

For more information contact Dr. Okode Neema at 0708518133 from 8am to 5pm, on all weekdays.

Appendix D: Fomu ya Idhinii ya Kushiriki Katika Utafiti

Kichwa cha Utafiti: KUKAGUA KIASI CHA WAGONJWA WENYE UGONJWA WA MANJANO INAYOSABABISHWA NA VIZUIZI MWILINI KWA KUTUMIA WA CT (Computed Tomography)

Mpelelezi mkuu na ushirika wa kitaasisi: DR. OKODE A. NEEMA, MWANAFUNZI WA SHAHADA YA UZAMILI KATIKA RADIOLOGY. CHUO KIKUU CHA NAIROBI, IDARA YA RADIOLOGY

Ningependa kukuambia juu ya utafiti unao fanywa na mtafiti aliye orodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa habari utahitaji kukusaidia kuamua kama utashiriki katika utafiti. Jisikie huru kuuliza maswali yoyote juu ya madhumuni ya utafiti, ni nini kitatokea ikiwa utashiriki katika utafiti, hatari nafaida zinazowezekana, haki yako kama kujitolea, na kitu kingine chochote kuhusu utafiti au fomu hiia mbayohaijwazi. Wakati tumejibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kuwa kwenye masomo au la. Utaratibu huu unaitwa 'ridhaa iliyo na habari'. Mara tu utakapo elewa na kukubali kuwa katika masomo, nitakuomba utie saini jina lako kwenye fomu hii.

Unapaswa kuelewa kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu:

i) Uamuzi wako wa kushiriki ni hiari kabisa

ii) Unaweza kujiondoa kutoka kwa masomo wakati wowote bila kutoa sababu ya kujiondoa kwako

iii) Kukataa kushiriki katika utafiti hautaathiri huduma unayostahiki katika kituo hiki cha afya au vifaa vingine.

Tutakupa nakala ya fomu hii kwa rekodi zako.

Naweza kuendelea? NDIO/ LA

Utafiti huu umedhibitishwa na Itifaki ya Kamatiya Maadiliya Kitaifaya Kenya ya Chuo Kikuu cha Maadili na Utafiti cha Nairobi.

HILI NDANI YA KUFUNDA HILI?

Watafiti waliotajwa hapo juu wanahoji watu ambao wanahitaji kufanyiwa picha za CT na wamekuwa na dalili na majibu ya maadara yanayo ambatana na ugonjwa wa maanjano inayo sababishwa na vizuizi mwilini. Madhumuni ya mahojiano ni kujua umri wako na jinsia yako. Washiriki wa utafiti huu pia watafanya utafiti wa picha zao za CT ya tumbo kupitia pendekezo na itafiki za CT katika hospitali kuu ya kenyatta. Hakuna uchunguzi wa ziada au vipimo

vitakavyo hitajika. Kutakuwa na washiriki takriban 30 katika utafiti huu waliochaguliwa kwa nasibu. Tunaomba idhini yako kufikiria kushiriki katika utafiti huu.

NINI KITAKUWAJE KAMA UTAONA KUWA KATIKA FUNDO HILI LA UTAFITI?

Ikiwa unakubali kushiriki katika utafiti huu, mambo yafuatayo yatatokea: Utahojiwa na mahojiano aliyefunzwa katika eneo la kibinafsi ambapo unahisi vizuri kujibu maswali. Mahojiano yatadumu takriban dakika 10. Baada ya mahojiano kumaliza, nitaomba kupitia picha zako za tumbo za CT. Pia nitauliza ripoti zako za ultrasound na histopathology kuhakikisha matokeo yaliyopatikana kwenye CT. Tutauliza nambari ya simu ambapo tunaweza kuwasiliana nawe ikiwani lazima. Ikiwa unakubali kutoa habari yako ya mawasiliano, itatumiwa tu na watu wanao fanyakazi kwa utafiti huu na hautashirikiwa na wengine. Sababu ambazo tunaweza kuhitaji kuwasiliana nawe ni pamoja nakupata ufafanuzi zaidi au habari zaidi ikiwa inahitajika.

JE KUNA HAKUNA ATHARI ZAIDI, DHAMBI ZA KIUMBUSHO ZINAZOONEKANA NA DUNIA hii?

Utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihemkona za mwili. Jaribio linapaswa kuwekwa kila wakati ili kupunguza hatari. Hatari moja ya uwezekano wa kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unachotwambia kama siri iwezekanavyo. Tutatumia nambari yakukutambulisha katika hifadhidata ya kompyuta iliyo lindwa na nywila na tutaweka rekodi zetu zote za karatasi katika baraza la mawaziri lililofungwa. Walakini, hakuna mfumo wakulinda usiri wako unaweza kuwa salama kabisa, kwa hivyo bado inawezekana kwamba mtu angegundua kuwa ulikuwa kwenye utafiti huu na anaweza kupata habari juu yako. Pia, kujibu maswali katika mahojiano inaweza kuwa mbaya kwako. Ikiwa kuna maswali ambayo hutaki kujibu, unaweza kuyaruka. Una haki ya kukataa mahojiano au maswali yoyote yaliyo ulizwa wakati wamahojiano. Tutafanya kila tuwezalo kuhakikisha kuwa hii inafanywa kwa faragha. Kwa kuongezea, wafanyikazi wote wa masomo na mahojiano ni wataalamu walio na mafunzo maalum katika mitihani / mahojiano haya. Pia, kujadili juu ya utambuzi wa ugonjwa wa manjano unaosababishwa na vizuizi mwilini na matibabu inaweza kuwa ya kusisitiza. Katika kesi ya shida yoyote ya kisaikolojia inayohusiana na utafitihuu, wasiliana na wafanyi kazi wa utafiti mara moja kwa nambari iliyotolewa mwishoni mwa waraka huu. Wafanyi kazi wa masomo watakutendea kwa hali ndogo au kukuelekeza wakati inahitajika.

Je! Kuna faida zozote za kupata ndani ya masomo haya? Unaweza kufaidika kwa kupokea ushauri wa bure habari Zaidi juu ya utambuzi wako. Pia, habari unayo toa itatusaidia kuelewa kiasi cha wagonjwa wenye wana ugonjwa wa manjano kwa kutumia CT.

KUWA KUJIFUNZA KWENYE FUNDI HILO KULIWEZA KUFANYA CHOCHOTE?
Habari hii nimchango kwa sayansi nautasidia kwa matibabu ya wagonjwa.

Uamuzi wako wakushiriki katika utafiti niwahiari. Uko huru kukataa kushiriki katika masomo na unaweza kujiondoa kutoka kwa masomo wakati wowote bila dhulma au upotezaji wa faida yoyote.
NINI KAMA UNA MASWALI KWA FEDHA?
Hakuna gharama za ziadazitakazopatikana.
NINI KUNA KESHO ZAKO ZAIDI?
Ikiwa una maswali zaidi au wasiwasi juuya kushiriki katika utafitihuu, tafadhali piga simu au tuma ujumbe wamaandishi kwa wafanyi kazi wautafiti kwa nambari iliyotolewa chini ya ukurasa huu.
Kwa habari Zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na watu wafuatao.
Katibu, Hospitali ya Kitaifa ya Kitaifaya Chuo Kikuu cha maadili cha Kenya na Kamati ya Utafiti ya Nambari ya 2726300 Ext. 44102 barua pepe uonknh_erc@uonbi.ac.ke.
Msimamizi: Dr. Gladys Mwango, Nambayasimu +254720127553
Wafanyi kazi wamasomo wata kulipa kwa malipo yako kwa nambari hizi ikiwa simu niya mawasiliano yanayo husiana na masomo.

Kichwa Cha utafiti: KUKAGUA KIASI CHA WAGONJWA WENYE UGONJWA WA MANJANO INAYOSABABISHWA NA VIZUIZI MWILINI KWA KUTUMIA WA CT (Computed Tomography)
Jina la Mtafitu: Dr. Okode Neema, mwanafunziwa Shahada ya Uzamili Katika Radiology Chuo Kikuu cha Nairobi, Idara ya Radiology.

Mimi nina thibitisha kuwa nimesoma na kuelewa au nimeelezewa na kuelewa hati ya ‘’Consent Information Document’’ kwa ajili ya utafiti huu. Nimepewa fursa ya kuuliza maswali ambayo majibu yao yamekuwa yakutosha. Ninaelewa kuwa ushirika wangu niwa hiari na kwamba sijalazimishwa kushiriki. Naelewa kwamba naweza kukataa bila yakutoa sababu yoyote, bila ya huduma ya matibabu yangu au haki za kisheria kuathirika. Nina elewa kwamba sitapokea fidia yoyote, fedha au vinginevyo, nasitapokea matibabu yoyote ya upendeleo, zawadi au tuzo, kwa ajili ya kushirika katika utafiti huu. Ninaelewa kwamba taarifa yangu binafsi itakuwa siri, lakini kwamba yoyote husika matibabu, habari kuhusu matokeo ya uchunguzi wangu na taarifa

zilizo kusanywa itakuwa itapatikana kwa mtafiti, na inaweza kuangaliwa na wasimamizi wake.

Mimi nawapa ruhusa yakuwa na upatikanajiwa habari hii.

Ninatoa idhini yakushiriki katika utafiti huu Ndio/ La

Ninatoa idhini yakuwapa nambari zangu za simu: Ndio/ La

Jina la mshiriki: _____

Nambari ya simu_____

Sahihi/muhuri wa kidole: _____ Tarehe: _____

Jina la mzazi/ mlezi anaye toa idhini kwa mshiriki ambaye ni mdogo: _____

Sahihi/muhuri waki dole: _____ Tarehe: _____

Jina la mtafiti: DR. OKODE NEEMA Tarehe: _____

Sahihi: _____

Kwa maelezo zaidi wasilianana Dr. Okode Neema kwa nambari ya simu 0708518133 kutoka saa mbili asubuhi mpaka saa kumi na moja jioni, siku za wiki

Appendix E: Ethical Review Application Form

This form must be attached to every proposal forwarded to PU- Ethics Review Committee

Part A (TO BE FILLED FOR EACH PROPOSAL)

Title: _____

_____

_____

Institution: _____

Research Programme if any _____

Field of Study _____

Name of Principal

Investigator(s): _____

Contact phone number for Principal Investigator:

_____

E-mail address for Principal Investigator:

_____

Study Implementation County(s):

_____

Expected source of funding:

_____

Total amount of funds needed:

_____

Declaration: I _____ (full names)

Being the principal investigator for this study declare that:

(a) If any changes to this proposal or procedure be desired, the changes shall be requested to the PU - Ethics Review Committee and effected only after written approval by the PU – ERC

(b) The following investigators will participate in this study and are bound by (a) above.

NOTE: THE TABLE BELOW MUST BE FILLED AND SIGNED BY CO-INVESTIGATORS BEFORE REVIEW

Name/ institution	Telephone	Email contact	Signature

Signature _____ Date _____

(Principal Investigator)

PART B (TO BE FILLED AFTER PU – ERC APPROVAL)

Proposal number and date: _____

This proposal Yes No

1) Has been reviewed by the PU-Ethics Review Committee

2) Has been approved by the PU-Ethics Review Committee

Date Sign

3) Has been deferred by the PU-Ethics Review Committee Date Sign

Any other information

_____

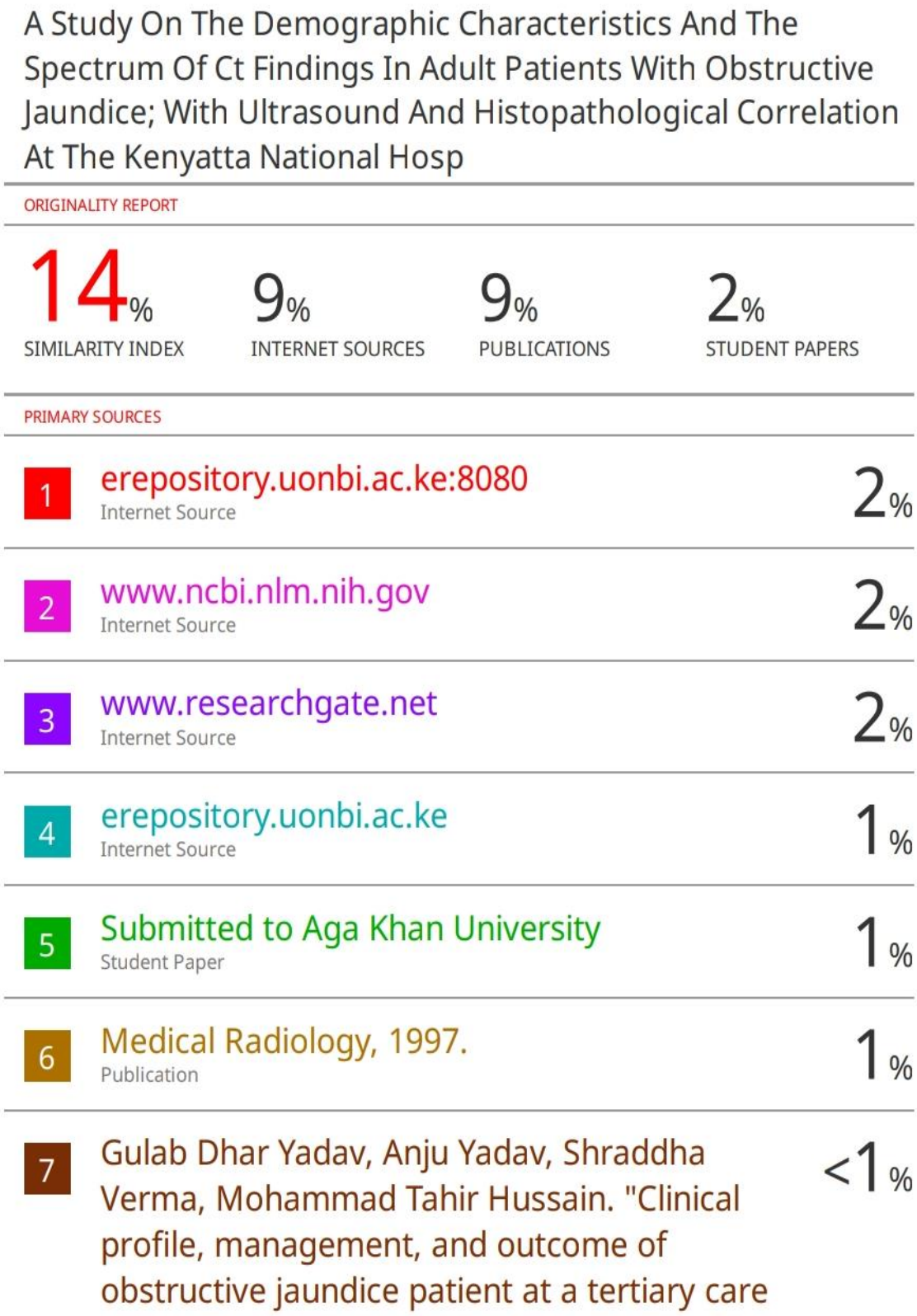
_____

___

Notes: The signed form must be submitted to PU – ERC with 2 copies of the proposal to be reviewed for submission alongside the CVs of PI and the collaborators, the layman summary and receipt of review fees.

Appendix F: KNH/UoN-ERC Letter of Approval

Appendix G: Certificate of Plagiarism



A Study On The Demographic Characteristics And The Spectrum Of Ct Findings In Adult Patients With Obstructive Jaundice; With Ultrasound And Histopathological Correlation At The Kenyatta National Hosp

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