CLINICAL PROFILE OF PATIENTS WITH CHRONIC LIVER DISEASE AND THE PREDICTORS OF HOSPITAL MORTALITY AT MUHIMBILI NATIONAL HOSPITAL

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CLINICAL PROFILE OF PATIENTS WITH CHRONIC LIVER DISEASE AND THE PREDICTORS OF HOSPITAL MORTALITY AT MNH

BY

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CERTIFICATION

The undersigned certify that he has read and hereby recommend for examination of Dissertation entitled*:* **"*Clinical Profile of Patients with Chronic Liver Disease and The Predictors of Hospital Mortality at MNH: A Cross-sectional Study"***in partial fulfillment of the requirements for the degree of Master of Medicine (General Surgery) of Muhimbili University of Health and Allied Sciences.

……

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Date……

DECLARATION AND COPYRIGHT

I, **Hibaaq Mohamoud Ahmed**, declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

Signature……. Date…….

ACKNOWLEDGEMENTS

To Almighty God for making everything possible.

Much appreciation should go to my supervisor Dr. Ally Hamisi Mwanga for his tireless guidance, support and making me believe, this seemingly impossible work can be done, and truly the dream has become true.

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DEDICATION

This work is dedicated to my dear Mom and husband, for their er support, and care during the whole period of my studies.

ABSTRACT

Background: Chronic liver disease (CLD) is the term used to describe disordered liver function for 6 or more months. It results from progressive destruction and regeneration of liver parenchyma and encompasses a variety of liver pathologies leading to cirrhosis and hepatocellular carcinoma. Commonest cause of CLD is viral hepatitis (HBV AND HCV) and alcohol misuse. It develops gradually with imprecise clinical presentation and as a result lead to late diagnosis. Therefore, initial presentation with clinically decompensated liver disease is common.

Objective: To describe patient characteristics and predictors of hospital mortality.

Patients and methods: A cross-sectional hospital-based study conducted for a period of 6 months starting from November 2020 to April 2021, the study population comprised of consenting adults with clinical and radiological evidence of chronic liver disease. Semi-structured interviews were designed to obtain information, association was tested using chi-square with a P value of 0.05 accepted for significance.

Results: There were 123 patients with chronic liver disease in this study. Mean age of respondents was 48± 14 years with a male to female ratio of 2.6:1. Majority of patients had HBV infection, 56% had cirrhosis, HCC 29%, and cirrhosis with HCC 15%. Subjects had a mean MELD score of 15.6±8.7 and most patients were in Child Turcotte Pugh score class B and C. Having MELD between 9-19 and higher or Child Turcotte Pugh class B and C was associated with increased in-hospital mortality.

Conclusion: Majority of subjects had a HBV infection, as per clinical profile most presented with decompensated liver function, from our results MELD and Child Pugh could predict mortality and patients that will benefit of liver transplant.

TABLES OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

List of Abbreviations

ALF	Acute Liver Failure
ALD	Alcoholic liver Disease
AIH	Autoimmune Hepatitis
CLD	Chronic Liver Disease
CTP	Child–Turcotte–Pugh
ESLD	End Stage Liver Disease
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HE	Hepatic Encephalopathy
HCC	Hepatocellular Carcinoma
INR	International Normalization Ratio
MELD	Model for End stage Liver Disease
UNOS	United network of organ sharing
MNH	Muhimbili National Hospital
MUHAS	Muhimblili University of Health and Allied Science
NASH	Non-Alcoholic Steatohepatitis
PBC	Primary Biliary Cirrhosis
PSC	Primary Sclerosing Cholangitis
TIPS	Trans-jugular intra-hepatic Portosystemic shunt
WHO	World Health Organization
PHTN	Portal hypertension
HVPG	Hepatic venous gradient
AST	Aspartate transaminase
ALT	Alanine transaminase
PPV	positive predictive value
AASLD	American Association for the Study of Liver Diseases

Definition of Terms

Clinical profile is the summary of patient presentation including history, physical examination, and risk factors. It is designed to support seamless collaboration and documentation for patient workflow.

Chronic liver disease is a progressive deterioration of liver function over 6 months with a continuous inflammation, destruction and regeneration of liver parenchyma and incorporates a wide range of liver pathologies including: cirrhosis and hepatocellular carcinoma.

CHAPTER ONE

1.0 INTRODUCTION:

The liver is a crucial organ in the human body that has a major role in synthesis, metabolism, and detoxification of potentially toxic by-product metabolic substances. With its unique physiology and anatomy this organ is susceptible to various injuries and systemic disorders. Liver diseases have a worldwide distribution with different geographical locations and usually asymptomatic presentation(1).

Despite the high global prevalence of viral hepatitis affecting all geographical regions the middle- and low-income countries are disproportionally affected. Viral hepatitis related deaths reported in 2015 were 1.34 million with the commonest being Hepatitis B Virus (HBV) at 66% and Hepatitis C Virus (HCV)at 30% with a higher burden reported in Asia and Sub-Saharan Africa(2).

Liver diseases are responsible for 2 million deaths per year worldwide, in which cirrhosis accounts for 1 million due to viral hepatitis and hepatocellular carcinoma (HCC). Cirrhosis and HCC are the 11^{th} and 19^{th} leading cause of death worldwide respectively. Cirrhosis and viral hepatitis specifically HBV and HCV are independent risk factors for the development of HCC and cholangiocarcinoma(3).

The Global Burden of Diseases study in 2010 showed that in sub-Saharan Africa cirrhosis mortality doubled between 1980 and 2010 from (53,000-103,000 deaths). There were various underlying causes of cirrhosis, the common ones included HBV (34%), alcohol (18%) HCV (17%) and unknown in (31%). With HBV, HCV, and Alcohol also accounting for 47%, 23% and 20% respectively of hepatocellular carcinoma (HCC)(4).

In Acute Liver Failure (ALF) and chronic end-stage liver disease (ESLD), liver transplant has become a lifesaving procedure, being the 2^{nd} most common solid organ transplant less than 10% of people have the access globally(5).

This study highlighted clinical profile of patients with CLD, and predictors of hospital mortality at Muhimbili National Hospital.

CHAPTER TWO

2.0 LITERATURE REVIEW

Chronic liver disease is a progressive disease which develops over months, years, or decades. Frequently, CLD results from cirrhosis, a state in which scar tissue substitutes normal healthy liver tissue.

2.1 Aetiology of CLD

The causes of cirrhosis are HBV, HCV, Alcoholic liver disease (ALD), Non-alcoholic steatohepatitis disease (NASH), Autoimmune hepatitis (AIH), primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC) and inherited metabolic disorders including haemochromatosis and Wilson disease (6).

The World Health Organisation (WHO) reported in the global hepatitis report in 2015, the prevalence of hepatitis B virus in the general population was 3.5% with the highest prevalence reported in Africa and the western pacific region accounting 6.1% and 6.2% respectively. The WHO also reported 1% of the world's population were living with hepatitis C virus, with the European and Mediterranean regions more affected compared to other regions. It was also reported that the incidence of HCV in United States of America is significantly increased between the years 2010-2014(7).

A descriptive study done in Dar Es Salaam, Tanzania by Wolfgang et al Between July 2012 and February 2013 reported a total of 106 patients were clinically diagnosed with liver cirrhosis, a large proportion (48%) of these patients were positive for HBsAg. Females accounted for (55%) and had a higher proportion of patients with HBsAg positive as compared to males (45%) (9). In a mini review done by Kilonzo S et al reported the sero prevalence of HBV infection was 6% in the general population of Dar Es Salaam, the rate had increased compared to previous studies that reported 4.4%(8).

Alcohol associated liver or alcoholic liver (ALD) diseases are related to alcohol intake practices with highest regions of alcohol use disorders in USA, European and western pacific regions. 50% of cirrhosis related deaths were attributed by alcohol intake worldwide (9).

In a cross-sectional study done in Uganda at Mulago hospital to determine prevalence of alcohol use, misuse and ALD. 10% of the study participants and 48% of those classified

with alcohol misuse met the definition of ALD with a significant greater proportion of male gender 65%(10).

Non-alcoholic fatty liver disease (NAFLD) became a public health alarm after becoming one of the important causes of chronic liver disease, NAFLD consists of two separate conditions with one being steatosis which is accumulation of fat in the cells without inflammation and the other one steato-hepatitis (NASH) causing inflammation and fibrosis of liver cells. This condition increased with the increase of the prevalence of overweight and obesity, the global prevalence of NAFLD 25.2% with a prevalence above 30%in the middle east and south America among patients underwent biopsy and the prevalence of NASH was 59%(2).

In a cross-sectional study conducted at MUHAS, Dar es Salaam, 432 outpatients attending internal medicine clinic were enrolled to study prevalence of fatty liver disease among patients presented with liver disease, the prevalence of fatty liver disease reported was 13.9%, the independent factors were diabetes mellitus, male gender, obesity, high triglyceride and low HDL(11).

Auto-immune liver diseases, including autoimmune hepatitis, primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), the epidemiological data of this condition is obtained mostly from western world and fewer data from Asia. In a non-systematic comprehensive review done in Nigeria concluded there is only case few case series reported but no hospital-based study or epidemiological survey investigating these conditions so far(12).

Metabolic liver diseases are a heterogeneous group of diseases that in adults include hemochromatosis, Wilson's disease, and alpha 1-antitrypsin deficiency as the most frequent metabolic causes of liver cirrhosis(13).

Hepatocellular carcinoma: 70-80% of HCC results from the background of chronic liver inflammation, the mechanism is thought to be the cycle of chronic inflammation with regenerative proliferation. The most common pre-malignant lesion is considered liver cirrhosis(14).

Unexplained chronic hepatitis(cryptogenic hepatitis) is a disease that presents with hepatitis, cirrhosis and develop HCC despite behaving similar to CLD its unexplained by

clinical, laboratory and histological findings, its reported to have a global prevalence of 5%(15).

Fitz maurice et al reported that HCC became the sixth most common cancer universally in 2015 where 854,000 of new cases were diagnosed. HCC is the 5th leading common cancer on average and 8th among women with 1 in 45 men and 1 in 113 women of the affected population under 79 years of age. This has the greatest impact on resource-limited countries as the 4th leading cause of cancer is HCC, and 1st cancer-related mortality in 2015(16).

In a retrospective hospital-based study done in Nigeria by Nwokediuko et al, described cirrhosis and HCC accounting for approximately two-thirds of admissions related to liver, 60% of chronic liver diseases had HBV infection(1).

2.2 CLD presentations

Most of the chronic liver disease develops gradually with imprecise clinical presentation and as a result lead to late diagnosis. A significant proportion of patients with chronic liver disease are asymptomatic and remain undiagnosed only to be found at autopsy. At first the patients might experience non-specific fatigue, weakness, loss of appetite with nausea and weight loss. However, patients come late to a hospital with advanced decompensated stage (12). initial presentation with clinically decompensated liver is common and is characterized by the presence of complications such as ascites, variceal haemorrhage, or hepatic encephalopathy (13).

Ascites

This is the accumulation of fluid in the peritoneal cavity, commonest cause is liver cirrhosis nonetheless can be caused by other intraperitoneal and extraperitoneal conditions. It's associated with poor prognosis 15% of patients die within 1 year while 44% die in 5 years (17). Elfaki et al in Sudan reported in a retrospective hospital-based study, the most common complication of cirrhosis is ascites in which the mainstay of treatment is restriction of oral sodium intake in the diet and promotion of sodium excretion by diuretics(18).

Patients with refractory ascites there is option to insert indwelling catheter but has increased risk of infection(19).

Variceal Haemorrhage

These are dilated submucosal veins, which occur at the areas of portosystemic collaterals and form after pre-existing vascular channels are dilated by portal hypertension (PHT), most commonly at the distal part of the oesophagus. Invasive way to measure the portal pressure is to monitor the hepatic venous pressure gradient (HVPG) in vascular/hemodynamic lab, approximately one third of cirrhotic patients will have PHT; HVPG>5mmHg defines PHT. Clinically significant presentation of PHT develop when HVPG is >10mmHg. Management of bleeding varices includes resuscitation of the patient, pharmacotherapy and endoscopic treatment, however with recurrent bleeding refractory to above interventions there comes the role of surgery with careful selection of patients, these surgical options to relief PHT are Oesophageal devascularization with or without splenectomy, non-selective shunts ,selective shunts and liver transplantation (20).

Hepatic encephalopathy

this a neuro-psychiatric symptom resulting from mental and neuromotor dysfunction, usually develops gradually and starts with altered sleep pattern progressing to lethargy, stupor, and coma. In patients with cirrhosis this condition is associated with triggering factors, such as infection, medications and electrolyte imbalance(21).

Hepato-renal syndrome

Acute renal impairment occurs in advanced liver disease, this develops as consequence of PHTN which predisposes to splanchnic vasodilation, nitric oxide is the main vasodilator nevertheless others are present in lesser extent e.g., carbon monoxide, glucagon, vasodilator peptides. Cardiac contractility increases to balance however at late stage the cardiac output may decrease due to development of cirrhotic cardiomyopathy(22).

Bleeding

Patients may present with bleeding tendency; this is caused by decreased synthesis of procoagulant factors due to loss of ability of the liver production. Bleeding can also be caused by thrombocytopenia which is attributed by several factors including sequestration of platelets in the spleen, bone marrow suppression due to HCV and interferon based antiretroviral therapy(23).

Hepatocellular carcinoma (HCC)

HCC develops in background of CLD and is the commonest indication of surgery in CLD, depending on several factors such as size and stage of tumour, functional liver reserve and performance status of the patient, liver resection and transplant are the principal treatment options(24).

2.3 Predictors of mortality

Scoring models have been used, to assess the severity of the disease. The first one was the Child–Turcotte–Pugh (CTP) score which is based on laboratory findings of bilirubin level, prothrombin time, and albumin, also the assessment of presence or severity of encephalopathy and ascites. The drawback of this model is the subjective assessment of ascites and encephalopathy by the attending physician (25).

Another model the model of end stage liver disease MELD score was developed to replace CTP, it has objective parameters namely creatinine, bilirubin, and prothrombin time. This model is useful to assess the prediction of 3-month mortality for patients waiting for liver transplant and selection of patients with end stage liver disease for liver transplant. MELD score is calculated using the following formula MELD = 3.8[Ln serum bilirubin (mg/dL)] + 11.2[Ln INR] + 9.6[Ln serum creatinine (mg/dL)] + 6.4, the score is reported as a whole number so the result of equation above is rounded. The MELD score in the beginning was developed to assess the prognosis of patients before undergoing trans jugular intrahepatic portosystemic shunt (TIPS), although CTP score has a subjective parameters it's still useful and has a n advantage of easier calculation compared to MELD score (13). Both scores are interpreted as in the following tables.

CTP score	adding points of 5 categories below		
CTP class	Class A 5-6 points	Class B 7-9 points	Class C 10-15 points
	1 point	2 points	3 points
Albumin(g/dl)	>3.5	2.8-3.5	<2.8
Bilirubin(mg/dl)	<2	2-3	>3
INR	<1.7	1.7-2.3	>2.3
Ascites	None	Slight	Moderate
Encephalopathy	None	Grade 1or 2	Grade 3 or 4

Meld score	3-month mortality
40 or more	71.3% mortality
30-39	52.6% mortality
20-29	19.6% mortality
10-19	6.0% mortality
<9	1.9% mortality

Angermayr et al in CTP Vs MELD in predicting survival in patients undergoing TIPS reported differentiating CTP class A or B were less sensitive predicting the survival rate among patients with cirrhosis(26). However, Alassan et al in Abidjan Ivory Coast, found that CTP score >8 had a high positive predictive value (PPV) for in-hospital mortality where this study the prediction accuracy of CTP score was not different in comparison with MELD score(27).

Austrian consensus paper issued by Austrian Society of Gastroenterology and Hepatology in cooperation with the Austrian Society for Transplantation, Transfusion and Genetics in February 2016 recommended liver transplantation for patients with liver cirrhosis and a Child–Pugh score B/C or a MELD score of ≥15(13).

Wiesner et al in 3-month mortality prospective study of adults in the waiting list of united network of organ sharing (UNOS), who had mean MELD of 28,18.3 for patients listed in as status 2A and 2B respectively, the mortality was greater in patients with higher MELD score (e.g., MELD score 9 experienced 1.9% mortality compared to MELD 40 who experienced 71.3% mortality)(28).

The American Association for the Study of Liver Diseases (AASLD) guidelines endorsed that a patient with a CTP score ≥ 7 and a MELD score 10 or higher be referred for organ transplant(29). Other prognostic factors include gender and age, Patrizia et al reported pre-menopausal women progress slowly to chronic liver disease, this is proved clinically to be due to oestrogen level that decreases rate of liver fibrosis, also older age has a risk developing non-alcoholic steatohepatitis, osteoporosis, and worse response to antiviral therapy (30).

Currently when there are no obtainable medical and surgical treatment options for ALF and chronic ESLD, liver transplantation become a lifesaving option for patients. More than

80% of transplants are due to cirrhosis, the other indications of liver transplant vary geographically(13).

2.4 Problem statement

Liver diseases are an important and largely neglected health issue in low- and middle-income countries. Chronic liver diseases are associated with significant morbidity and mortality. Critical care and early liver transplant in end stages of liver disease before multi-organ failure may improve the outcome of patients. However, in our setting information are critically lacking about patients suffering from CLD and need of various surgical interventions including liver transplant.

2.5 Study Rationale

The study will generate knowledge on the morbidity of liver diseases in our setting which is currently limited. This will stimulate further research on the subject. Information collected from this study will add knowledge on chronic liver diseases and will be utilized in improving patient's surgical care.

2.6 Research questions

What are the patient characteristics and predictors of hospital mortality at MNH?

2.7 Objectives

2.7.1 Broad objective

To describe the clinical profile of patients with chronic liver disease and predictors of hospital mortality at MNH November 2020- April 2021

2.7.2 Specific objective:

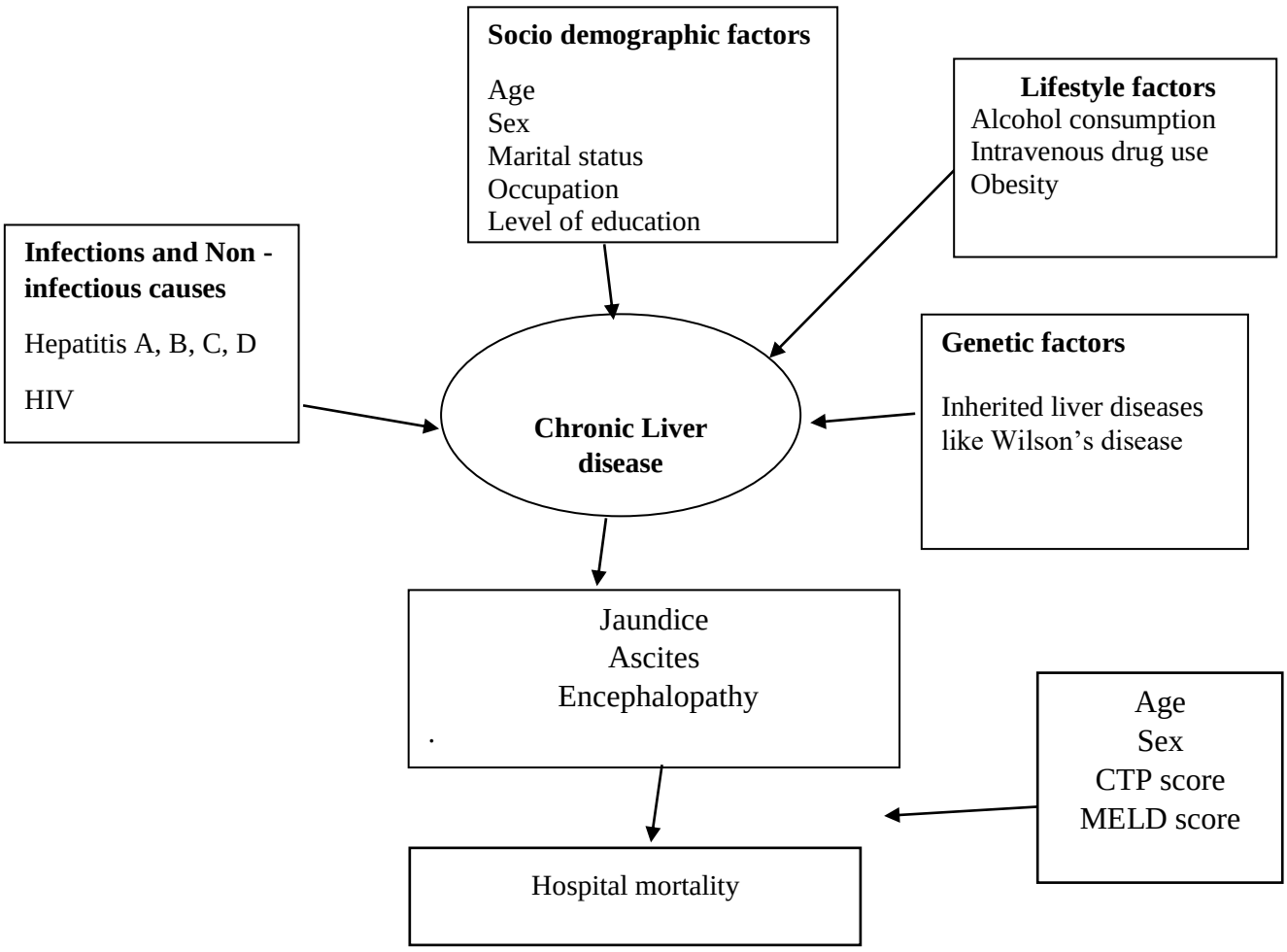
2.8 Objectives

1. To describe the clinical profile of patients with chronic liver disease at MNH
2. To describe the aetiology of chronic liver diseases, at MNH
3. To identify predictors of hospital mortality among patients with chronic liver disease at MNH.

2.9 Conceptual framework

The conceptual framework shows the relationships between the different risk factors and chronic liver disease. They include the socio demographic factors like age, sex, lifestyle factors like alcohol consumption, smoking, obesity; Infectious and non-infectious causes like Hepatitis, HIV, tumours, hypertension; genetic factors like family history of liver disease, gene mutations. The consequences of CLD may include encephalopathy, disseminated intravascular coagulation, and at worst death as illustrated (Figure1)

Figure 1 Conceptual framework



CHAPTER THREE

3.0 Methodology

3.1 Study design

This was hospital based cross-sectional study.

3.2 Study period

The study was carried out between from November 2020 to April 2021.

3.3 Study population

All patients with chronic liver disease who were admitted at surgical and medical wards at Muhimbili National hospital during the study period.

3.4 Study area and period

This study was conducted in the adult medical and surgical units at Muhimbili National Hospital. It is in Dar Es Salaam, Tanzania, the city with a population of 4.7 million people, and is the largest hospital in Tanzania. This hospital serves as the national referral hospital and the main teaching hospital of Muhimbili University of Health and Allied sciences (MUHAS). It has an estimated 1,500 beds of whom about 170 beds are occupied by both medical gastroenterology and surgical units. The wards are run by nurses, physicians, doctors, surgeons, and consultants. The surgical units are divided according to their areas of specialization which are Gastroenterology and General Surgery, Thoracic and General Surgery, Urology, Paediatric Surgery and Plastic and Reconstructive Surgery Unit. Chronic liver disease patients are managed at the gastroenterology and surgical units at MNH. On average, these two units admit 30 patients with CLD per month. The gastroenterology unit runs the hepatic clinic outpatient services once a week. The surgical unit performs resection of any liver masses among CLD patients per month if amenable to surgery to prolong life. There are no liver transplant services available at MNH with patients referred overseas.

3.5 Sampling technique

Consecutive sampling was used, visiting respective wards whereby all eligible subjects meeting the inclusion criteria were selected until required sample size was achieved.

3.6 Eligibility criteria

3.6.1 Inclusion criteria

All patients admitted with primary chronic liver disease were included defined as

I. The presence of clinical features suggestive of decompensated liver disease viz. ascites, jaundice, and/or hepatic encephalopathy; for more than 6 months.
II. Radiological imaging showing liver pathology and or biochemical evidence of deranged liver function.

3.6.2 Exclusion criteria

The following patients were excluded:

I. Chronic liver disease caused by secondary liver cancer
II. Liver dysfunction secondary to comorbidities viz. congestive cardiac failure, biliary obstruction, and septicaemia.

3.7 Sample size calculation

The sample size was determined by using the Kish and Leslie sample size formula.

$N=Z^2XP(1-P)/e^2$ where

N=calculated sample size,

Z= Z value for the standard normal curve at 0.05

P=Proportion of patients with CLD admitted at MNH

e=margin of error

As the prevalence of the disease is unknown in our setting, we considered to put the proportion at 50%.

Z=1.96, e=0.05, P=0.50

Substituting

$N=1.96^2x\ 0.50(1-0.50)/\ (0.05^2)$

N=385.

The proposed study was carried out over a period of 6 months. An estimated number of patients admitted with CLD over the six-month period was180.

Using the sample size for a finite population,

that N(adj) = (Nxn)/(N+n).

Where N=is the calculated sample size and n is the finite population size.

N(adj)=(385x230)/ (385+230)

N(adj)=122

The minimal sample size calculated was 122 participants, this study recruited 123 participants.

3.8 Sampling technique

Consecutive sampling was used to enrol participants into the study until the sample size was attained.

3.9 Study procedures of data collection

Prospective participants were approached from the gastroenterology and surgical units. The study procedures were explained to them, and voluntary written informed consent was obtained in a private environment. The principal investigator and a study research assistant administered the semi structured questionnaire to collect the data. The questionnaire consisted of socio-demographic, past medical and surgical history, clinical characteristics, laboratory, and radiological investigations. The data collected by the researcher assistant was cross checked daily by the principal investigator for consistency, completeness, and logic. Any edits or amendments were made before storage of the data collection tools.

All patients with suspected diagnosis of CLD were assessed by proper history, physical examination and by ultrasound examination/CT scan

The diagnosis of CLD was suspected when the following features were present

I. Physical examination with nodular liver on palpation
II. Signs of portal hypertension including ascites, splenomegaly, spider naevi, and bleeding varices
III. Deranged liver function test with or without jaundice

The gold standard for diagnosis of CLD is biopsy but it's not routinely done, non-invasive imaging with ultrasound, CT or MRI is currently recommended.

A cirrhotic score table was obtained from Nishuira T et al which validated these parameters with histological findings(31), when hypoechogenic lesion detected with ultrasound American Association for the Study of Liver Diseases (AASLD) recommends additional imaging with CT or MRI is necessary to demonstrate arterial wash in and venous wash out(32).

variables	Score 0	Score 1	Score 2
Liver parenchymal echotexture	Homogenous/fine	Course	Highly non-homogenous/course
Liver surface	Smooth	Irregular	nodular
Liver edge	Sharp(acute)	Blunted	Rounded
Liver size	Normal	Enlarged (>15cm mid-clavicular line)	Shrunken (<10cm mid-clavicular line)
Portal vein diameter	Normal	Dilated (>13mm)	
Spleen size	Normal	Enlarged (>13cm)	

3.10 Study variables

Dependent variable: Chronic liver disease was defined as presence of signs and symptoms of liver disease for 6 months with radiological finding of liver pathology and or biochemical evidence of deranged liver function.

3.11 Independent variables:

Demographic characteristics: age, sex, level of education, occupation

Past medical history and clinical characteristic: Duration of illness, history of alcohol consumption, history of smoking, presence of ascites, presence of bleeding, history of Hepatitis B vaccination, history of blood transfusion and intravenous drug injection, MELD score, Child Pugh score.

Radiological and laboratory investigations: Ultrasound scan and CT scan findings, biopsy findings, Total bilirubin levels, total ALT, AST, Urea, Sodium, International normalized ratio (INR), potassium, Creatinine, serum albumin levels.

3.12 Data management and analysis

Data collected was checked for quality and coding was done prior to data entry. Data were coded, cleaned, and analyzed using Statistical Package for Social Sciences version 25

(SPSS Inc., Chicago, IL, USA). **Objective 1:** The patient characteristics was summarized as means and standard deviations for continuous variables while proportions were used for categorical variables. **Objective 2**: The aetiology of CLD in the study participants was summarized as means and standard deviations for continuous variables while proportions were used for categorical variables.

Objective 3: MELD score was calculated for every enrolled participant using MELD = 3.8[Ln serum bilirubin (mg/dL)] + 11.2[Ln INR] + 9.6[Ln serum creatinine (mg/dL)] + 6.4, CTP also calculated using the following parameters hepatic encephalopathy, ascites, total bilirubin, albumin, and INR. X^2 was done to predict factors associated with hospital mortality.

3.13 Ethical consideration

Ethical clearance was obtained from the MUHAS Institution Review Board (IRB) and permission for the study was obtained from Muhimbili National Hospital administration. Written informed consent was obtained from all the patients with confidentiality assurance given. Withdrawal right from the study was respected. Privacy of the participants was protected by using study identification numbers instead of participants' names during data collection.

CHAPTER FOUR

4.0 RESULTS

Socio-demographic Characteristics

Of the 123 patients 89(72.4%) were males, the ages of patients ranged from 25-77 with mean age of 48years (SD ± 14years). Most patients received formal education 94(76.4%). Thirty-seven patients (30.1%) had history alcohol consumption and 26(21.1%) were current consumers whereas 11(9%) were past consumers. Thirty three (26.8%) were employed (Table 1).

Table 1. Socio-demographic characteristics of the participants

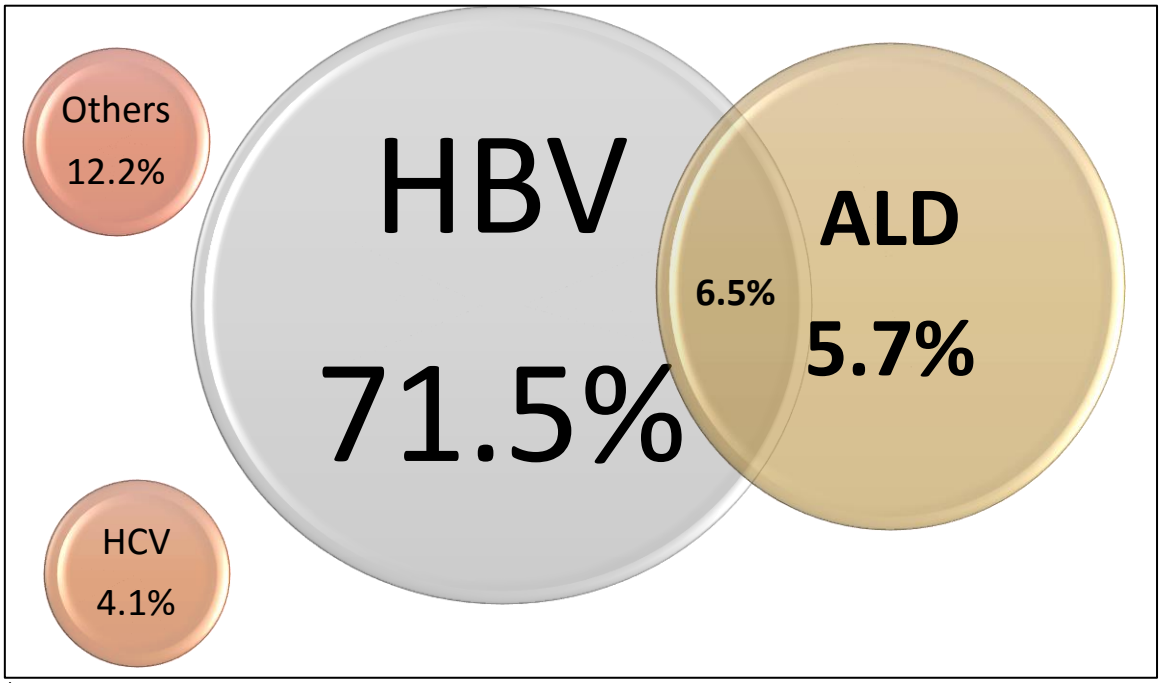
Variable	Frequency (n)	Percent (%)
Age		
18 – 35	29	23.6
36 – 45	28	22.8
46 – 60	35	28.5
>60	31	25.2
sex		
Male	89	72.4
Female	34	27.6
Education level		
No formal education	29	23.6
Primary	46	37.4
O – level	28	22.8
A – level	9	7.3
University	11	8.9
Occupation		
Employed	33	26.8
Unemployed	24	19.5
Retired	6	4.9
Self employed	26	21.1
Farmer	28	22.8
Student	6	4.9
Alcohol consumption		
Current consumer	26	21.1
Past consumer	11	9
Never consumed	86	69.9
*Herbal medicine use**	77	62.6

*Herbal medicine use for treatment

Aetiology of Chronic Liver Disease

Aetiological risk factors were, HBV infection 88 (71.5%), (HCV) infection 5(4.1%), 7(5.7%) had alcoholic liver disease and 8 (6.5%) had concomitant ALD with HBV infection (figure 2)

Figure 2. Aetiology of chronic liver Disease

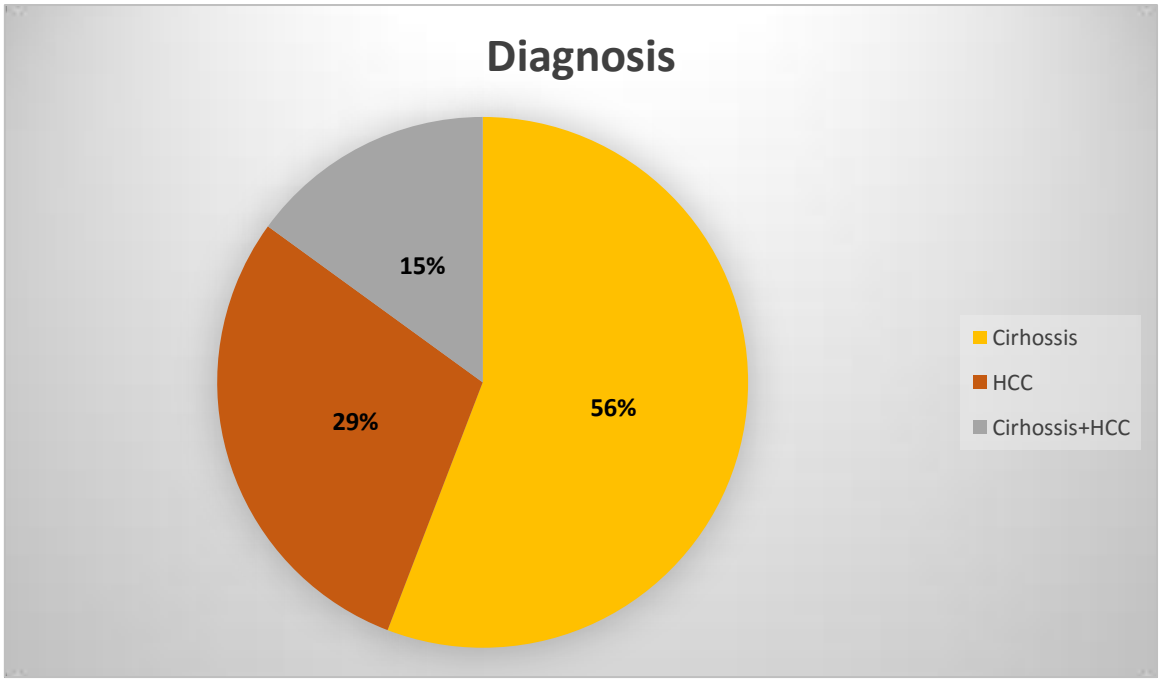


*Hepatitis serology missing in 2 patients.

Type of chronic liver disease

Cirrhosis was present in 67(56%) with chronic liver disease, while HCC accounted for 35 (29%) and cirrhosis with HCC for 18(15%). (Figure 3)

Figure 3. Forms of chronic liver Disease

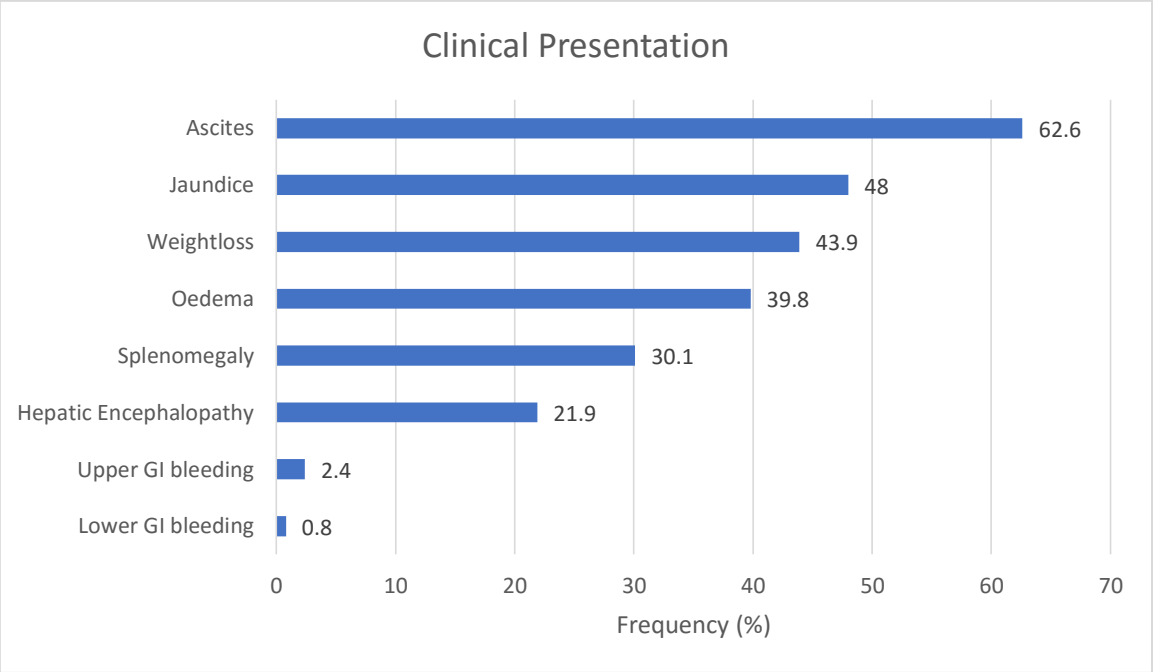


*3 no images to confirm diagnosis.

Clinical presentation

Majority of patients showed features of hepatic decompensation at initial hospitalization. Most of the patients had an ascites 77(62.6%), jaundice 59(48%), splenomegaly 37(30.1%), and hepatic encephalopathy in 27 (21.9%). Lower limb edema was reported in 49(39.8%) patients, 54(43.9%) patients had experienced anorexia and 54(43.9%) had weight loss. Few subjects 3 (2.4%) had a blood transfusion following bleeding esophageal varices whereas 1 patient had upper and lower GI bleeding simultaneously. (Figure4)

Figure 4. Clinical presentation



MELD/Child-Pugh Score of patients

Most subjects had a MELD score between 9-19, 71(60.7%), while the rest were as follows <9 21 (17.9%), 20-29 12 (9.4%), 30-39 12 (10.3%) and 2 (1.7%) subjects scored more than 40. The mean MELD score was 15.6 (±8.7).

Using the Child-Pugh score, most patients were class B and C were 42(37.5%) and 40(35.7%) respectively, while 30 (26.8%) patients were Class A. (Table 2)

Table 2. MELD/CTP SCORE

Variable	Frequency	Percent (%)
Meld[a]		
<9	21	17.9
9-19	71	60.7
20-29	11	9.4
30-39	12	10.3
>40	2	1.7
CTP[b]		2
Class A	30	26.8
Class B	42	37.5
Class C	40	35.7

[a] 6 missing values in MELD.

[b] 11 missing in CTP.

Age, Sex and Aetiology in relation to hospital mortality

Mortality increased with increasing age and was highest among over 60 years (41.9%, p=0.11), more males (31.5%) died as compared to females (17.6%) however, the difference was not statistically different. Viral and alcohol related causes had a similar survival rate at 23.7% and 28.6% respectively, patients with unknown aetiology had mortality of (53.8%), however the difference was not statistically significant (p=0.14) all aetiologies had a similar survival rate except with the unknown aetiology group with a mortality of 7(53.8%). (Table 3)

Table 3. Ages/Sex/Aetiology Vs Hospital

Age	**Alive**	**Died**	**P value**
18-35	24(82.8%)	5(17.2%)	
36-45	19(67.9%)	9(32.1%)	
46-60	28(80%)	7(20%)	0.11
>60	18(58.1%)	13(41.9%)	
Sex			
Male	61(68.5%)	28(31.5%)	
Female	28(82.4%)	6(17.6%)	0.17
Aetiology of CLD			
Viral related	71(76.3%)	22(23.7%)	
Alcohol related	5(71.4%)	2(28.6%)	0.14*
Viral + alcohol related	6(75%)	2(25%)	
Others	6(46.2)	7(53.8)	

*Fishers exact

MELD/CPT score in relation to Hospital mortality

A MELD score was calculated for the patients based on total bilirubin, creatinine, and INR. Hospital mortality was greater on higher MELD score no death was observed in patients with score<9, those with scores 9-19, 20-29, 30-39, >40 had a mortality of 16(22.5%), 7(63.6%), 9(75%), 1(50%) respectively with P-value of ≤ 0.001. Patients were also scored using the Child- Pugh score based on bilirubin, albumin, INR, ascites, and hepatic encephalopathy.

Mortality was mostly observed in patients with CPT class C 24(60%) and to lesser extent on those in class B 8(19%), while class A had no mortality with a p-value of 0.001. (Table 4)

Table 4. Hospital Mortality Vs MELD/CTP

MELD	**Alive**	**Dead**	**p-value**
<9	21 (100%)	0 (0%)	
9-19	55 (77.5%)	16 (22.5%)	
20-29	4 (36.4%)	7 (63.6%)	
30-39	3 (25%)	9 (75%)	<0.001*
>40	1 (50%)	1 (50%)	
CTP			
Class A	30(100%)	0(0%)	
Class B	34(81%)	8(19%)	
Class C	16(40%)	24(60%)	<0.001*

*****Fishers exact

CHAPTER FIVE

5.0 DISCUSSION

Chronic liver disease has not been extensively studied in the Tanzania context despite the long history of treating patients with CLD. The study has dissected the clinical presentation of patients and severity of CLD.

The current study has shown males are affected more with CLD; male female ratio was 2.6:1 with mean age of 48 years. Male gender appears to be a risk factor for chronic liver disease, similar studies reported male predominance (33)(34)(35) this could be explained by behavioural difference between the two genders, men consumed more alcohol and had a higher prevalence of viral hepatitis.

HBV was the commonest risk factor of CLD, followed by alcohol and HCV, nevertheless, there were a significant proportion of patients with unknown underlying aetiology. This is similar to other studies who pointed high prevalence of HBV in Africa, in Dar Es Salaam as it increased from 4.4-6%, also recently lancet stated high prevalence of chronic hepatitis in pregnant women in sub-Saharan Africa which increases the risk of vertical transmission (36)(37). This is important to highlight for HBV which currently is part expanded program of immunization since 2002, study done about vaccine coverage among health care workers at Muhimbili national hospital revealed low coverage(38) while those patients with un explained risk factors need further workup to point out most associated risk factors, this limited by investigation spectrum which is not broad at MNH.

Chronic liver disease is known to presents with vague symptoms hence a delay in presentation witnessed in our study, most of the presentations listed in this study were those of decompensated liver disease in almost all the patients, which means patients sought hospital treatment when alarm symptoms were seen and use of traditional herbal medicine by majority of patients.

Commonest presentations were ascites, jaundice, oedema, and weight loss. Ascites accounted for the greatest proportion, ranging from slight to massive ascites this is a similar finding reported in other studies (18)(39). Although hepatic encephalopathy represents a potentially reversible condition and was present to lesser extent, but it was associated with poor prognosis Twenty one of twenty-seven patients died despite the resuscitative measures. Bleeding varices was the least common presentation although the rate of variceal haemorrhage is 5-15% per year(40).

There are several prognostic predictors including age, sex, aetiology of CLD, MELD and CTP scores. In this study age, sex and aetiology did not significantly influence hospital mortality while MELD and CTP score were more predictive. MELD and CTP scores are used to categorize patients according to severity of liver diseases, currently MELD score is used to predict 3-month mortality and selection of patients for liver transplant, In this study mean MELD score was 15.6 (±8.7), higher MELD score was associated with increased in-hospital mortality, also 33% of patients had MELD of greater than 17 while 60% were in CTP class B and C which makes these patients a candidate for liver transplant. In addition, elevated MELD scores imply hepatorenal syndrome, which is life-threatening condition for patients with CLD. Most patients consumed traditional herbal medicine which is known to have a toxic effect on the renal and liver function. It was also observed that, CTP class C and class B, predicted greater hospital mortality compared to class A where there was no death was observed.

The higher scores in MELD and CTP predicting mortality were correlated with severity of liver dysfunction patients presented with and both were similar in prediction. Several studies reported similar to this[27](39). Although Angermyer et al had a conflicting findings highlighting the superiority of MELD score[26], in his study both scores were able to predict survival, but the advantage of MELD was ability to stratify patients according to their individual risk.

CHAPTER SIX

6.0 Conclusion

Majority of subjects had a HBV infection, as per clinical profile most presented with decompensated liver function, from our results MELD and Child Pugh could predict mortality, identify the severity of CLD patients receiving treatment at MNH. With this finding every point time there is a great proportion of patients that will benefit of liver transplant.

6.1 Recommendations

1. Longitudinal studies (prospective or retrospective cohort) are recommended for long term follow up of the patients.
2. Primary health facilities should be built capacity of diagnosing chronic liver disease to enable early diagnosis and referral to tertiary facilities.
3. To enforce surgical interventions for chronic liver disease including future establishment of liver transplant.

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APPENDICES

APPENDIX I: INFORMED CONSENT FORM

INTRODUCTION

You are invited to participate in a study on "
CLINICAL PROFILE OF PATIENTS WITH CHRONIC LIVER DISEASE AND THE PREDICTORS OF HOSPITAL MORTALITY AT MUHIMBILI NATIONAL HOSPITAL". You have been asked to participate in this study as you have symptoms of liver disease. Please read this form and should you have questions please ask before agreeing to participate in the study.

The purpose of the research is to assess severity of the disease of chronic liver disease. This study will help to understand the impact of the disease and the information obtained will be used for patient care.

Your participation in this research is entirely voluntary. Whether you choose to participate or not in the study you will continue receiving services at the health facilities with no change. You may change your mind later and stop participating even if you agreed earlier. You have the right to withdrawal from the study at any time if you decide to do so and you do not have to give reason.

CONFIDENTIALITY

In this study all information will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. We will disclose research results to you and the attending doctor.

RISKS

By participating in this research, you will not be subject to any risk.

BENEFITS

There will be no direct benefits to you from this study. However, information obtained from this study may be of benefit to the community because it will highlight further treatments needed.

Contacts and Questions

This study is headed by Dr. Hibaaq Mohamoud, MUHAS (Study investigator).

You may ask any question you have now. If you will have questions later, or in the event of study related injury you are encouraged to contact her at:

Dr. Hibaaq Mohamoud,

Tel: +255 692955077

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in this study.

NAME……

Participant's name

NAME……SIGNATURE…….

DATE……

Witness

KISWAHILI FOMU YA RIDHAA

Unaalikwa kushiriki kwenye utafiti kuhusu: hali ya ugonjwa sugu wa ini na uhitaji wa upandikizwaji katika hospitali ya taifa Muhimbili

Unaalikwa kushiriki katika utafiti huu kwasababu una dalili za ugonjwa wa ini. Tafadhali soma fomu hii na ikiwa una maswali tafadhali uliza kabla ya kukubali kushiriki katika utafiti.

Madhumuni ya utafiti huu ni kutathmini ukali wa ugonjwa sugu wa ini. Utafiti huu utasaidia kuelewa athari za ugonjwa huu na uhitaji la usimamizi bora wa ugonjwa.

Ushiriki wako katika utafiti huu ni wa hiari kabisa. Ikiwa utachagua kushiriki au sio kwenye utafiti utaendelea kupata huduma kwenye vituo vya afya bila mabadiliko. Unaweza kubadilisha mawazo yako baadaye na kuacha kushiriki hata kama ulikubali mapema. Una haki ya kujiondoa kwenye utafiti wakati wowote ikiwa utaamua kufanya hivyo na sio lazima usipe sababu.

KUFANIKIWA

Katika utafiti huu habari zote zitahifadhiwa katika eneo salama linalopatikana tu kwa watu walioidhinishwa. Haitakuwa na majina ya watu au habari yoyote ambayo itawatambulisha. Tutakuelezea wewe na daktari anayekuhudhuria matokeo ya utafiti.

ATHARI

Katika kushiriki katika utafiti huu, hautakuwa chini ya hatari yoyote.

FAIDA

Hautakuwa na faida za moja kwa moja kutoka kwa utafiti huu. Lakini habari zitakazopatikana kutoka kwa utafiti huu inaweza kuwa ya faida kwa jamii kwa sababu itaonyesha kama matibabu zaidi inahitajika.

Mawasiliano na Maswali

Utafiti huu unaongozwa na Dk. Hibaaq Mohamoud, MUHAS (Mchunguzi wa Utafiti).

Unaweza kuuliza swali lolote unalo sasa. Ikiwa utakuwa na maswali baadaye, au baadae unaweza kuwasiliana naye kwa:

Dr. Hibaaq Mohamoud,
Tel: +255 692955077
TAMKO LA RIDHAA

Nimesoma habari hapo juu. Nimeuliza maswali na nimepokea majibu. Mimi idhini ya kushiriki katika utafiti huu.

JINA …… SAHEHE…….

Jina la Mshiriki

JINA…….. SAHEHE……. TAREHE……

Jina la shahidi

APPENDIX II: questionnaire

(To be filled while enrolling a patient for the first time into the study)

IDENTIFICATION PARTICULARS

1. Serial Number ……
2. Clinic Number ……

Date Registered in GE Dept. (dd/mm/yy) ……

DEMOGRAPHIC DETAILS

Name of the patient

Age (Completed years) ……

Gender (Male, Female) ……

7. Permanent Address:

8. Telephone number: …….
9. Referred from: …….
   Self -referral …….
10. Educational qualification
    No formal education ☐ Primary ☐ -level ☐ evel ☐
    University ☐

LIEFESTYLE INFORMATION

11. Do you smoke

No ☐ Yes ☐ past smoker- ☐

12. If Yes, number smoked ……

23. Do you drink alcohol?

No ☐ Yes ☐ Past consumer ☐

24. If Yes, amount (gms) consumed ……

25. Main type of alcohol consumed ……

28. Have you been vaccinated for HBV?

1. Yes

2. No

29. If yes at what age ……. years

30. Any history of blood transfusion

1. Yes

2. No

32. Any history of intravenous drug use

1. Yes

2. No

33. If yes for how long …… years

34. herbal medicine use

1. Yes

2. No

Part 2: history and examination

DURATION OF COMPLAINTS IN MONTHS

38. Duration of Complaints of Jaundice……..

39. Duration of complaints of Weight loss…….

40. Duration of complaints of Pain …….

41. Duration of complaints of Abdominal mass …….

42. Duration of complaints of Abdominal distension …….

43. Duration of complaints of Fever ……

44. Duration of complaints of UGI bleed ……

45. Duration of complaints of LGI bleed ……

46. Duration of complaints of Edema ……

47. Duration of complaints of Anorexia …….

PAST HISTORY (No- Yes-

48. H/o Bleeding …….

49. Jaundice ……

50. H/o Prolonged Illness ……

51. H/o Encephalopathy ……

52. H/o Surgery. ……

53. H/o Abdominal distension ……

54. H/o Other Complaints (specify) ……

55. Family history of any liver disease……

56. H/o Diabetes…….

CLINICAL EXAMINATION

57. Temperature------- C0

58. Weight---------kg

59. Height---------cm

60. BP----------mmHG

61. LN palpable 1. Yes 2. No

62. LL oedema 1. Yes 2. No

63. Jaundice 1. Yes 2. No

64. Finger clubbing 1. Yes 2. No

65. Palma erythema 1. Yes 2. No

66. Flapping tremors 1. Yes 2. No

67. Dupuytrens contracture 1. Yes 2. No

68. Spider naevi 1. Yes 2. No

69. Scratch marks 1. Yes 2. No

70. Caput medusa 1. Yes 2. No

71. Spleen palpable 1 Yes 2. No

72. Liver palpable 1. Yes 2. No

1. Liver span ……. cm

2. Tenderness 1. Yes 2. No

3. Surface – 1. Smooth…… 2. Rough…. 3.Nodular…...

4. Ascites 1. Yes 2. No

73. Respiratory examination

1. RR------/min

2. Pleural effusion 1. Yes 2.N0

4. Crackles 1. Yes 2. No

74. CVS

1. HR-------/min

2. Cardiomegaly 1. Yes 2. No

3. Pericardial effusion 1. Yes 2.No

4. Valvular heart disease 1. Yes 2.No

75. CNS examination

1. Consciousness GCS-------/15

2. Memory: 1. Intact 2. Impaired

3. Hepatic encephalopathy Grade…….

Part 3: investigations

76. HBS antigen + (by ELISA) …….

77. Anti HBc positivity ……

78. Anti-HCV Positivity (by ELISA)

…….

79. Co-infection of HIV (by ELISA)

…….

80. AST……

81. ALT ……

82. GGT…….

83. ALP…….

SPECIFIC DETAILS ABOUT LIVER DISEASE

84. CHILD/MELD score details

a. Encephalopathy stage (0 if No encephalopathy) ……..

b. Ascites (Absent Mild, responsive Moderate to severe)

c. Serum Bilirubin (mg/dl) ……

d. Prothrombin time (INR) ……

e. Serum creatinine (mg/dL) ……

f. Serum Albumin (mg/dL) ……

85. Image findings (USS, CT scan)

1. cirrhosis
2. cirrhosis + HCC
3. HCC

HOSPITALIZATION DETAILS

87. Duration of hospital stay (days) ……

88. Discharge status Alive- ☐ Died- ☐

89. If died

a. Variceal bleeding……..

b. Hepato-renal syndrome…….

c. Hepatic encephalopathy……

d. Sepsis……

e. HCC causing liver failure…….

f. Other (specify) …….

Date of death (dd/mm/yy) ……

78. If discharged, status (Recovered- ☐ No change- ☐

Complication specify…….

Signature of the PI: ……

Date:……..