Evaluation of Leucocyte Esterase Reagent Strip Test for Rapid Diagnosis of Spontaneous Bacterial Peritonitis in Adult Cirrhotic Patients: A Hospital Based Cross Sectional Study, Addis Ababa, Ethiopia, 2021.

A Thesis submitted to the Departemnt of Internal Medicine, Collage of Health Sceinces, Addis Ababa University, in partial fulfilment of the speciality certificate in Internal Medicine.

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I the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project *and for the provision of required progress reports as per terms and conditions of the research publications office in effect at the time of grant is forwarded as the result of this application.* I will provide timely progress report to my advisors and seek the necessary advice and approval from my primary advisor in the course of the research.

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Acronyms and Abbreviations

AAU:	Addis Ababa University
AF:	Acetic fluid
AIH:	Autoimmune hepatitis
ALD:	Alcoholic liver disease
AMC:	Adera Medical Center
AOR**:**	Adjusted Odds Ratio
BB:	Beta-bleckers
BP:	Blood Pressure
CI**:**	Confidence Interval
CLD:	Chronic liver disease
Cmm:	Cells/millimeter^3
CNNA:	Culture negative neutrocytic acites
COR**:**	Crude Odds Ratio
CTP:	Child pugh score
DM:	Diabetes mellitus
E.coli:	Escherichia coli
EV:	Esophageal varices
HBV:	Hepatitis B virus
HCC:	Hepatocellular cancer
HCV:	Hepatitis C virus
HE:	Hepatic encephalopathy
HIV/AIDS:	Human Immune deficiency Virus/Acquired Immune Deficiency Syndrome
HTN:	Hypertension
ICP:	Increased intracranial pressure
LDOR:	Log Diagnostic Odds Ratio
LERS:	Leucocyte Esterase Reagent Strip
MAFLD:	Metabolic associated fatty liver disease
MmHg:	Millimetres of Mercury
MOF:	Multi organ failure
NPP:	Negative predictive value
P:	Prevalence
PMN:	Polymorph nuclear cells
PPV:	Positive predictive value
SBP:	Spontaneous bacterial peritonitis
Sn:	Sensitivity
Sp:	Specificity
TASH:	Tikur Anbessa Specialized Hospital
UGIB:	Upper gastrointestinal bleeding
Y12HMC:	Yekatit 12 Hospital Medical Collage

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Abstract

Introduction: *Chronic liver disease is characterized by fibrosis and architectural distortion of the liver. Spontaneous Bacterial Peritonitis is the most common and fatal complication of liver cirrhosis. The standard diagnostic modality of SBP is costly, laborious, and most of all time consuming for resource limited set up. Hence, it is crucial to find an alternative easy, inexpensive and rapid diagnostic modality.*

Objective*: To evaluate the use of leucocyte esterase reagent strip test in diagnosis of SBP among cirrhotic patients in two public and one private hospital in Addis Ababa, Ethiopia, 2021.*

Methodology*: A facility based cross sectional study was conducted from August 15 to September 30, 2021 among adult cirrhotic patients at public and private health centre, Addis Ababa, Ethiopia. Data was collected through self-administered questionnaire and medical records. All patients had undergone paracentesis, and the ascetic fluid was processed for PMN, LERS and culture. The collected data was entered to SPSS version 26.0. Descriptive statistics was presented using tables and figures. Sensitivity, Specificity, PPV and NPP of LERS was calculated and association was assessed using Binary Logistic Regression where P-value and 95% CI for odds ratio are used for testing significance and interpretation of results.*

Result: *Out of 94 study participants, 74 were males and the mean age was* 47.2 ± 9.4*. The commonest cause of cirrhosis was HBV (36.2%) followed by ALD (26.6%) and HCV (21.3%). More than half (51) of the patients had CTP B, and 42 CTP C. Electrolyte disturbance, HE, and HRS were identified at a rate of 71.4%, 64.8% and 53.8% respectively. Of the 16 patients who died 11 were secondary to sepsis. SBP was diagnosed in 56 patients by ascetic fluid PMN count as compared to 51 detected by LERS test and 2 by ascetic fluid culture. At a cut off of* 2^+*, sensitivity, specificity, PPV, and NPV were 81.8%, 94.6%, 94.7%, and 81.4%. In comparison, at cut off level of* 3^+*; sensitivity, specificity, PPV and NPV were 60%, 97.2, 92.3%, and 81.4% respectively. The overall accuracy of the test was 88.3% and the LDOR was 70.*

Conclusion*: Our study demonstrated that LERS test is a simple, inexpensive, accessible, and sensitive alternative rapid screening tool for diagnose of SBP.*

Budget: *Overall, a total of 80,500 Ethiopian Birr was utilized to accomplish the thesis work.*

Key words*: SBP, CLD, cirrhosis, Leukocyte esterase reagent strip, ascetic fluid analysis*

1. Introduction

1.1 Background

1.1.1 Chronic Liver Disease

1.1.1.1 Definition and Epidemiology

Chronic liver disease/CLD/ is an end result of a variety of liver diseases characterized by fibrosis and architectural distortion of the liver with the formation of degenerative nodules with varied clinical manifestations and complications lasting for more than 6 months[1].In 2017, 1.32 million deaths worldwide were directly due to cirrhosis[2]. Cirrhosis is the leading cause of mortality and morbidity across the world. It is the 11th leading cause of death and 15th leading cause of morbidity, accounting for 2.2% of deaths and 1.5% of disability-adjusted life years worldwide in 2016[3]. Though, the mortality rate varies across regions overall mortality is decreasing worldwide as a result of effective vaccination and treatment given for patients with viral hepatitis[4]. Currently, the absolute number of CLD cases at any stage of the disease is estimated at 1.5 billion worldwide[5]. In Ethiopia, chronic liver disease is the 7th cause of death, accounting for 24 deaths per 100,000 populations in 2019[6].

1.1.1.2 Causes of Cirrhosis

Historically, viral hepatitis has been the leading aetiology for CLD[5]. However, improved preventive strategies and treatment have led to improving CLD trends. Meanwhile, alcohol consumption and obesity are increasing key liver disease risk factors[4]. Globally, the proportion of cirrhosis caused by hepatitis B virus (HBV) is 3.6%, hepatitis C virus (HCV) is 2.5%, alcoholic liver disease(ALD) is 8%, and non-alcoholic fatty liver disease(NAFLD) accounts for 25%[7].Other liver diseases, including primary biliary cirrhosis, primary sclerosing cholangitis, Wilson's disease and autoimmune hepatitis, account for 1% of cases[8]. According to a systematic review and meta-analysis done in Ethiopia, the three most common aetiologies identified were; HBV(40%), ALD(17%) and HCV(15%)[9].

1.1.1.3 Diagnosis of Cirrhosis

Early diagnosis and treatment of the CLD will help in stabilization and reversal of the disease. The work up of cirrhotic patients is based on clinical presentation, imaging techniques and chemistries that help in identification of the aetiology, assess severity, select treatment modality and prognostication[10].

1.1.1.4 Complications of Cirrhosis

Major complications of cirrhosis include spontaneous bacterial peritonitis(SBP), hepatic encephalopathy(HE), portal hypertension, variceal bleeding(EV), and hepatorenal

syndrome(HRS)[10]. Spontaneous bacterial peritonitis, hepatic encephalopathy and Upper GI bleeding are the commonest complications of CLD that often warrant hospital admission[1]. A retrospective study from Germany including 236 patients demonstrated that 45% of them were in a decompensated stage at the time of presentation. In the subgroup analysis the most common complication was EV (60%), followed by ascites (49%),HE(25%), HRS(18%) and pleural effusion(14%)[11].A hospital based study in Ethiopia documented the most common initial presentation of cirrhotic patients to be ascites (87.7%). The other complications were; HE(42%), SBP(25%), and UGI bleeding(24.1%)[12].

1.1.2 Spontaneous Bacterial Peritonitis

1.1.2.1 Definition and Epidemiology

Spontaneous bacterial peritonitis/SBP/ is the most common and fatal complication of liver cirrhosis and is defined as the infection of ascetic fluid /AF/ in the absence of a contiguous source of infection and/or an intra-abdominal and potentially surgically treated inflammatory focus such as perforation or inflammation of intra peritoneal organs.[13] The prevalence of SBP reaches to 30% in hospitalized cirrhotic patients and 1.5-3.5% in outpatient[14]. Around 50% of SBP episodes are present at the time of hospital admission; others are acquired after hospital stay[15].

1.1.2.2 Risk factors and Etiology

Significant proportion of cirrhotic patients will have SBP at the time of admission[15]. The major risk factors that increase the likelihood of developing SBP are stage of the disease, previous diagnosis of SBP and upper GI bleeding, low ascetic fluid protein, and high serum bilirubin[10]. The commonest organisms isolated in patients with SBP include E.coli, Gram positive cocci /mainly Streptococcus species/, Enterococci and Acinetobacter species account for 70% of all cases of SBP[14, 16, 17].A Nigerian study that assessed the causative agents of SBP, 93% had monomicrobial infection with E.coli accounting for 70%, followed by Klebsiella and Streptococcal species[18].

1.1.1.3 Clinical Presentation

Patient with SBP may have clinical features of abdominal pain, abdominal distension, fever, vomiting or diarrhoea with examination findings of abdominal tenderness and laboratory findings of altered white blood cell count/WBC/, worsening of liver function and renal function tests[10]. Abdominal paracentesis is considered necessary for all patients with ascites

on admission to the hospital or during hospital stay when they develop hepatic encephalopathy, upper gastrointestinal bleeding, renal impairment or signs of sepsis.[14, 19]

1.1.1.4 Diagnosis

The diagnosis of SBP is considered when the polymorph nuclear /PMN/ cell count is ≥ 250/mm^{3}and ascetic fluid culture positivity is proven[20]. The ascitic fluid culture is positive in less than 40% of cases even in best setups. Currently, it is universally accepted that ascetic fluid cell count > 500/ mm^3 and PMN ≥ 250/mm^3, irrespective of AF culture result, as best surrogate marker of diagnosing SBP[14]. Culture negative neutrocytic ascites (CNNA) is diagnosed when the ascitic fluid culture didn't grow any bacteria but PMN count is 250/cmm or more[20]. It has been shown that early paracentesis has a tendency to reduce mortality in hospitalized patients (5.5% Vs 7.5%) compared to those with delayed paracentesis[21].

The leukocyte esterase reagent strips/LERS/ test are designed for use in urine, identifying leukocytes by detecting their esterase activity via a colorimetric reaction[14, 22]. Leukocyte esterase test was one of the components assessed for the presence of urinary tract infection by urinalysis /dipstick test/ in addition to other nine parameters.

The principle of LERS test is based on the esterase activity of the leukocytes. A pyrrole esterified with an amino acid is used as the substrate; hydrolysis of the ester, releases the pyrrole which in turn reacts with diazonium salt yielding a violet or purple dye in relevant pad of the strip[23]. The test has been used to diagnose infection in different body fluids other than urine[24]. The LERS has grading scales which different form one another based on the type of strip test used. These grades are; grade 0 for trace, grade 1^+: 70 leukocytes/cmm, grade 2^+: 125 cells/cmm and grade 3^+: 500 cells/cmm[25].

Thought, use of LERS test for the diagnosis of SBP in cirrhotic patients is not included in the current guidelines because of its lower sensitivity, different studies are being done to assess its accuracy[3, 20].

1.1.1.5 Treatment and Prognosis

The survival of patient with SBP rests primarily on prompt diagnosis and early initiation of treatment. Antibiotics are the main stay of treatment which are started empirically and modified based on patient's risk factors and ascitic fluid culture result. The commonly used antibiotics are cephalosporin, beta-lactams, carbapenems and vancomycin[10]. The mortality of untreated SBP was high/>80%/ when first described but it has been reduced to less than

20% with early diagnosis and treatment[13, 14]. Therefore, early diagnosis and aggressive antibiotic therapy is crucial for survival.

1.2 Rationale

In a significant proportion of patients the clinical manifestation of SBP either can be subtle or patients can be asymptomatic for which the diagnosis requires high index of suspicion[14]. In this case we rely on laboratory parameters such as AF analysis. The presence of AF culture is confirmatory but not a prerequisite for initiation of early treatment[10, 20].

An ascitic fluid cell count is done either manually or in automated manner using spectrophotometer. Both methods are costly, laborious, require skill, widely unavailable and most of all time consuming[26]. It takes several hours to get the results to the hands of the primary physician because of busy working hours, limited supply of resources and limited number of liver disease expertise[26]. The delay of investigation, in turn translate to the delayed management initiation and eventually mortality To tackle this problem, leukocyte esterase reagent strip test have been proposed and studied for two decade now especially in emergency set up where early diagnosis is important[26-28].

1.3 Significance of the Study

The leucocyte esterase strip test is one of the crucial tests used as surrogate marker for SBP diagnosis[14]. The clinical use of leukocyte esterase test for rapid diagnosis of SBP is not validated due to its observer subjectivity and different test kits[29]. In developing countries like ours CLD patients with SBP have high mortality mainly because of the unavailability of the standard investigation modalities like AF analysis and culture. The assumption of a simpler, cost effective and timely test to diagnose SBP and early management initiation will improve survival and health care service in patient with cirrhosis. The limited evidences in our continent, and lack in Sub-Saharan African region, where larger proportion of CLD patients exist, makes the diagnosis and clinical practice difficult[30]. The aim of this study is to evaluate leucocyte esterase strip test to rapidly diagnose SBP among cirrhotic patients in resource limited setup like Ethiopia.

2 Literature review

Considering the increase in number of patients with cirrhosis globally and locally with its complications, there are several studies done on the issue. The majority of data that are available compare leucocyte esterase reagent strip test to manual or automated AF cell count and few comparisons with ascetic fluid culture.

A study from European and American centre on rapid diagnosis of SBP with leukocyte esterase strips done compared to manual cell count and AF culture in 2005 showed a sensitivity, specificity and positive and negative predictive value of the MultistixSG 10 reagent strips were 86%, 100%, 100%,and 99% in France and 83%, 96%, 83%, and 96% in USA respectively. In comparison a France study depicted the same result with sensitivity, specificity and positive and negative predictive value of 89%, 100%, 100% and 99%, respectively[19, 31].

In 2010, a study from India on Evaluation of leucocyte esterase reagent strip test for the rapid bedside diagnosis of spontaneous bacterial peritonitis revealed the more stringent purple color /Grade 3^{+}/ cut off to diagnose SBP had a sensitivity of 92% and specificity of 100%. Similarly in a Pakistanian study done in the same year showed the sensitivity and specificity were 92% and 95% respectively[28, 32].

A systematic review of seventeen studies done in UK revealed the leucocyte esterase strips were found to have sensitivity ranging from 45-100%, specificity ranging from 81-100%, PPV ranging from 42-100% and NPV ranging from 87-100%[33].

An observational study from India in 2020 on accuracy of LERS test for rapid bedside screening of SBP revealed at cut off 2+; sensitivity to diagnose SBP was 100%, with specificity of 94%, PPV being 57%and NPV 94% with a negative test result excluding SBP with a high degree of certainty[34].

A cross sectional study from Iran which compared nitrite and leukocyte esterase test with urine culture, found the sensitivity of dipstick test to be 72%, specificity, NPP, PPV of 79.4%, 72% and 94.3%[35].

A recent systematic review and meta-analysis, including 31 studies and 4446 patients, compared the performance of four LERS tests in detection of SBP. The study has demonstrated the summary sensitivity of Aution sticks, Combur, Meltistix and Periscreen was 0.962, 0.892, 0.806, and 0.939, respectively and summary specificity of Aution sticks,

Combur, Meltistix and Periscreen was 0.940, 0.922, 0.922, and 0.672, respectively. The level of heterogeneity was low to considerable throughout for summary sensitivity but moderate to considerably high for summary specificity of the tests[29].

Regarding Cost, an accuracy and cost-effectiveness study in Brazil showed accuracy of 95% and a significant cost reduction of reagent strips compared with cell count and differential[36].

3. Objective

3.1 General Objective

- ✓ To evaluate the use of leucocyte esterase reagent strip test as a rapid diagnostic tool of SBP among cirrhotic patients attending Tertiary Government and Private Health Facilities, Addis Ababa, Ethiopia, 2021.

3.2 Specific Objectives

- ✓ To compare the sensitivity and specificity of leucocyte esterase test with spectrophotometric analysis of ascetic fluid for the diagnosis of SBP
- ✓ To compare PPV and NPV of leucocyte esterase test with ascetic fluid PMN for the diagnosis of SBP
- ✓ To assess the accuracy and LDOR of leucocyte esterase reagent strip test
- ✓ To compare the cost effectiveness of LERS to PMN analysis and culture

4. Method

4.1 Study area and period

The study was conducted in two public hospitals, TASH and Yekatit 12 HMC, in Addis Ababa, the capital of Ethiopia. These hospitals are two of the tertiary hospitals with largest GI units giving care to several cirrhotic patients in an inpatient and outpatient settings. Adera Medical Centre is the largest GI private centre with significant number of cirrhotic patients in Addis Ababa.

The study was conducted from August 15, 2021 – November 30, 2021 among adult cirrhotic patients at TASH, Yekatit 12 HMC and AMC in Addis Ababa, Ethiopia.

4.2 Study design

A facility based cross sectional study was conducted at TASH, Yekatit 12 HMC and Adera Medical Centre from August 15, 2021 – November 30, 2021.

4.3 Study population

The study population were all adult cirrhotic patients meeting the inclusion criteria who are hospitalized to GI units of TASH, Yekatit 12 HMC and Adera medical center from August 15, 2021 – November 30, 2021.

4.4 Inclusion Criteria and exclusion criteria

Inclusion criteria

- Adult cirrhotic patients being followed at the GI referral clinics with clinical features suggestive of SBP
- Adult cirrhotic patients admitted to the hospitals with clinical features and diagnosis of hepatic encephalopathy (HE), oesophageal variceal bleeding (EV) and ascites.

Exclusion Criteria

- Adult cirrhotic patients admitted to the hospitals with contraindication for paracentesis.
- Patients with clinical and imaging evidence suggestive of secondary causes of peritonitis
- Adult cirrhotic patients who received antibiotic treatment at the time of admission.

- Adult cirrhotic patients admitted to the hospitals who are mentally unstable and critically ill /patients diagnosed with acute fulminant liver failure, higher grade HE and terminally sick or HCC/.
- Adult cirrhotic patients who fail to consent for participation in the study

4.5 Sample size determination and procedure

At TASH, the minimum patients and Maximum patients seen in a single month was 3 and 10 respectively in the past 1 year.

At Yekatit 12 HMC, the minimum and maximum patients seen in a single month was 7 and 19 respectively.

At Adera Medical centre, the minimum patients and maximum patients seen in a single was month 15 and 35 respectively.

Taking these real data in to account, the minimum number of patients seen in the 3 hospitals together is 25 and the maximum is 64 per month.

So the minimum number of sample size required was **83** with 10% non-respondent rate of patients with cirrhosis over three months.

4.6 Study Variables

Dependent Variables:

- SBP in adult cirrhotic patients admitted and/or on follow up at GI referral clinics

Independent Variables:

- Demographic and Socioeconomic factor
    - Age,
    - Gender,
    - Ethnicity,
    - Marital status
    - Educational factors
    - Economic status
    - Chronic illness
- Behavioural factors
    - Alcohol ingestion
    - Chat ingestion

        - Salt intake
- SBP related risk factors
    - Cause of cirrhosis
    - Stage of cirrhosis
    - Treatment for causative agent
    - Previous SBP, UGI bleeding or HE diagnosis
    - Prophylaxis for SBP and UGI bleeding
    - Complications of cirrhosis
    - Outcome of patients
    - Cause of death
    - Ascitic fluid PMN
    - Ascitic fluid culture
    - Ascitic fluid protein
    - Ascitic fluid SAAG

4.7 Operational definition:

- CLD/Cirrhosis diagnosis is made by clinical, laboratory and radiologic evidence [20]
    - Clinical evidence of patients presenting with stigmata of CLD
    - Laboratory evidence including thrombocytopenia, abnormal liver enzymes
    - Imaging evidence of nodular liver with coarse echo texture and blunted edges, portal vein diameter ≥ 13mm, splenomegaly, ascites and collateral veins
- SBP diagnosed by AF Polymorph nuclear (PMN) cell count is 250 or greater and/or culture positivity[20].
- Culture negative neutrocytic ascites (CNNA) is diagnosed when the ascetic fluid culture didn't grow any bacteria but PMN count is 250/cmm or more[20].
- Ascetic fluid protein is < 2.5 g/dl in cirrhotic patients[20].
- Serum albumin ascetic gradient (SAAG) is ≥ 1.1g/dl in patients' cirrhosis[20].
- Hypotension is defined as low blood pressure of < 90/60 or presence of postural hypotension with clinical features[37].
- Hypertension is defined as raised blood pressure of ≥ 140/80 measured in two occasions four to six hours apart[37].
- Diabetes Mellitus is diagnosed when the FBS ≥ 126, HgA1C ≥ 6.5 and RBS ≥ 300 with poly symptoms[38].

- Alcohol consumption is defined as consumption of 2 standard drink for men and 1 standard drink for women for more days of the week[39, 40].
- Moderate salt restriction for cirrhotic patients is less than 8g of dietary salt per day[20].
- Child Pugh (CTP) score is used to assess the severity of cirrhosis and uses parameters such as ascites and encephalopathy grading with bilirubin, albumin and prothrombin time[10].
- Income classification[41]
    - Low income – less than 1046 USD annually.
    - Middle income – 1046 – 12695 USD annually.
    - High income - greater than 12,695 USD annually.

4.8. Methodology

4.8.1. Data collection and procedure

Data was collected using a self-administered structured questionnaire and medical record in GI units of TASH, Yekatit 12 HMC and AMC. The questionnaire was initially prepared in English version and translated to Amharic language.

To insure data quality, training was given to three professional nurses before data collection and pre-test was conducted on 5% of randomly selected adult cirrhotic patients Bed side measurements of blood pressure and random blood glucose was taken by the trained professional nurses.

A diagnostic ascetic fluid paracentesis was performed under strict aseptic technique precautions by physician. Ascetic fluid of 10 ml with two test tubes were collected for routine microscopy and biochemistry and at the same time tested using Labo-Quick Multistix 10 SG LERS test[42]. The strips were read visually and the strips were disposed immediately. The strips were held close to the bottle label and matched carefully in 2 minutes for optimal result according to the information provided on the strip leaflet. Another 50 ml of ascetic fluid is sent for culture. The ascetic fluid cell count and culture was performed in a single laboratory for all samples.

4.8.2. Data management and Statistical analysis

The collected data was checked for its completeness, compiled, coded, entered and cleaned on Epi Info and SPSS version 26.0 was used for analysis.

Descriptive statistics will be presented with frequency tables and graphs. Association between SBP and other complications of cirrhosis and related factors will be assessed using Binary Logistic Regression with Odds ratio and 95% CI will be used for testing significance and interpretation of results. Multinomial Logistic Regression was used to assess the association between LERS and ascetic fluid PMN and culture result.

4.9 Ethical consideration

Ethical consideration and permission was obtained from Internal medicine department, AAU. Participants will be kept anonymous by excluding their names or identification numbers in the study. Written consent was obtained from individual respondents. The right of the respondents to refuse answer for few or all of the questions and undergo the procedure was respected.

5. Result

Out of the 102 patients, only 94 patients were analysed. Of the 8 patients that were excluded 3 patients had HCC without cirrhosis, 2 patients were already on antibiotics, 2 patients had Disseminated Tuberculosis and 1 patient had malignant ascites secondary to Cholangiocarcinoma with liver metastasis.

A total of 94 study participants (100% response rate) were included in the study. The majority of the respondents were male 74(78.7%). The overall age range was between 16 and 72 years with the mean age $\pm SD$ of 47.2 ± 9.4. The majority of respondents (36.2%) were between the age category of 31-45 years. The majority of the study participants were from Addis Ababa (51%) and married (55.3%). Of all the patients, 41.5% of them attended primary education and more than half (63.8%) had low income.

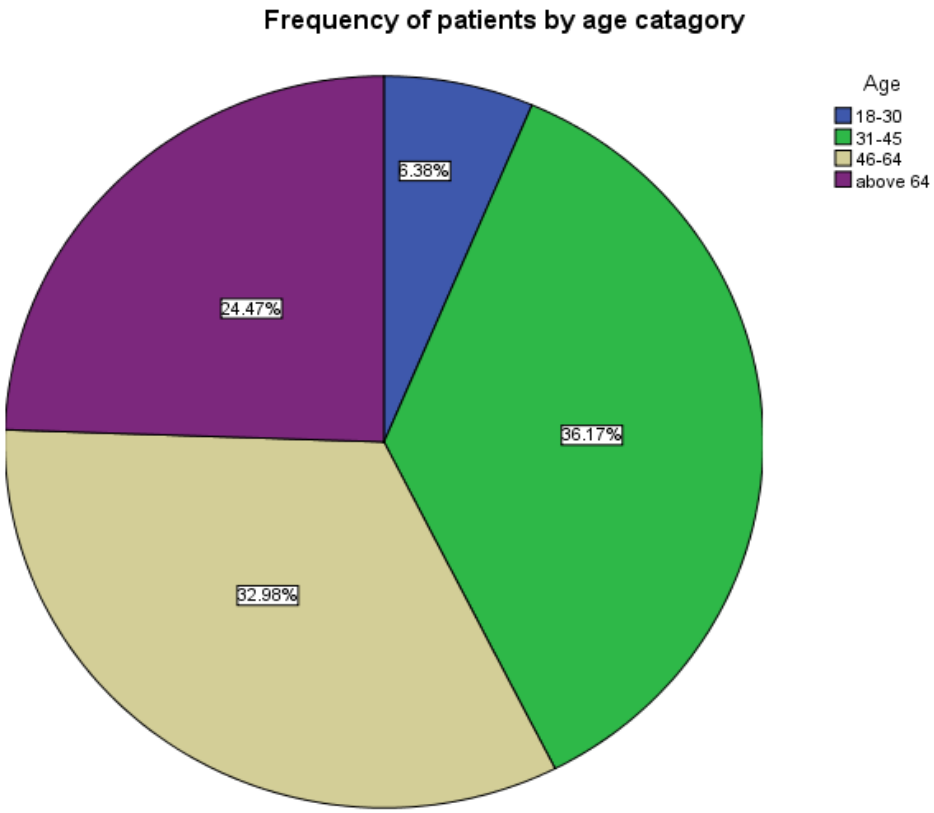

Figure 1: Frequency of patients by age category, Addis Ababa, Ethiopia, 2021.

Table 1: Socio demographic characteristics of adult cirrhotic patients in Addis Ababa, Ethiopia, 2021 (n= 94).

Variable	Number(percent)
Gender	
Male	74(78.4)
Female	20(21.6)
Ethnicity	
Addis Ababa	48(51.1)
Oromia	23(24.5)
Amhara	9(9.6)
Tigray	3(3.2)
SNNPR	7(7.4)
Somalia	2(2.1)
Afar	1(1.1)
Others	1(1.1)
Marital status	
Single	18(19.1)
Married	52(53.3)
Divorced	9(9.6)
Widowed	15(16)
Educational level	
Uneducated	20(21.3)

Primary education	39(41.5)
Secondary education	28(29.8)
Tertiary graduate and above	7(7.4)
Total yearly income	
Low income	60(63.8)
Middle income	33(35.1)
High income	1(1.1)

Of the total 94 participants, more than one third (39%) subjects had chronic illness and of which twelve (12.8%) of them had Diabetes Mellitus, eleven (11.7%) had hypertension and seven patients both. Sixteen patients (17%), and fifteen (16%) of the respondents had a habit of alcohol drinking and chat chewing, respectively. Of those study subjects who have significant alcohol consumption, half of them (8.5%) continued to drink after diagnosis. Regarding dietary habit, 61.5% of the respondents continued to use additional salt to their diet after the diagnosis of cirrhosis.

Table 2: Behavioral characteristics of adult cirrhotic patients in Addis Ababa, Ethiopia, 2021 (n= 94).

Variables	Number(Percent)
Chronic illness	
No chronic illness	57(60.6)
DM	12(12.8)
HTN	11(11.7)
Both	7(7.4)
HIV	3(3.2)
Cardiac illness	3(3.2)

Others	1(1.1)
Chat chewing	
Yes, daily	1(1.1)
Yes, sometimes	14(14.9)
No, never	79(84.0)
Significant alcohol ingestion	
Yes	16(17.0)
No	78(82.9)
Alcohol intake after the diagnosis of cirrhosis	
Yes	8(8.5)
No	86(91.5)
Salt consumption	
The normal amount , 8g/day	24(61.5)
Less than normal amount< 6g/day	15(38.4)

Fifty five (58.5%) of the patients were index cases with first diagnosis and twenty nine (30.9%) of them within one year of diagnosis. HBV was the most common cause of cirrhosis (36.2%) followed by Alcohol (26.6%) and HCV (21.3%). Of the 20 patients who have HCV infection as a cause of cirrhosis 5 (25%) of them had concomitant diabetes. Fifty one patients (54.3%) had CTP score of B cirrhosis, and forty two (45.7%) had CTP score of C , while none were CTP A. Concerning current treatment , most patients were treated with BB(78.7%), diuretics(66%) and lactulose(42.6%). Sixty nine (73.4%) patients were BB for on prophylaxis upper GI bleeding during follow up compared to only seven (7.4%) patients on SBP prophylaxis. Based on bed side measurements, twelve (12.7%) patients had raised BP and fifteen (16%) patients had raised RBS. Of the 94 study participants, ninety one (96.8%) of them had complications of cirrhosis. The complications electrolyte disturbance, HE, and HRS were identified at a rate of 71.4%, 64.8% and 53.8% respectively. Cephalosporin (87.2%) was the frequently used antibiotics to treat SBP, initiated within 6 hours (59.6%) of patients' admission, and ascetic fluid analysis result was ready within 12 hours (68.1%) in

most cases. Regarding outcome of patients, seventy four (78.4%) of them improved and sixteen (17%) died with commonest cause of death being refractory septic shock with multi organ failure (68.7%)(Table 3).

Table 3: Clinical characteristics of adult cirrhotic patients in Addis Ababa, Ethiopia, 2021(n= 94).

Variable	Number(Percent)
Duration of diagnosis of cirrhosis	
Index(first presentation)	55(58.5)
< 1 year	29(30.9)
1-5 years	9(9.6)
5- 10 years	1(1.1)
Treatment type	
BB	74(78.7)
Diuretics (Furosemide and spironolactone)	62(66.0)
Lactulose	40(42,6)
Antiviral therapy	36(38.3)
Rehabilitation therapy including ALD	10(10.6)
Steroid and immunosuppressive	7(7.4)
Use of Prophylaxis	
EV	75(79.8)
SBP	7(7.4)

Both	1(1.1)
None	11(11.7)
BP	
<90/<60	3(3.2)
90-120/60-80	79(84.0)
130-140/80-90	8(8.5)
>140/>90	4(4.3)
RBS	
< 70 mg/dl	2(2.1)
70 - 300 mg/dl	77(81.9)
>300 mg/dl	15(16.0)
Complications of cirrhosis	
Electrolyte disturbance,	65(71.4)
HRS	59(64.8)
HE,	49(53.8)
UGI bleeding,	23(25.3)
HCC	16(17.6)
Coagulopathy	5(5.5)
Antibiotics initiated for SBP	
Cephalosporin	82(87.2)

Carbapenem	11(11.7)
Floroquinolone	1(1.1)
Time of initiation of antibiotics after SBP diagnosis	
Within 6 hours	56(59.6)
Within 12 hours	29(30.9)
Within 24 hours	9(9.6)
Time of Ascetic fluid analysis result after admission	
Within 6 hours	14(14.9)
6.3)Within 12 hours	64(68.1)
Within 24 hours	16(17.0)
Outcome of the patient	
Improved,	74(78.7)
Worsened,	4(4.3)
Died	16(17.0)
Cause of death	
Refractory septic shock with MOF	11(68.7)
HE with increase ICP	4(25.0)
UGI bleeding	1(6.3)

Ascetic fluid analysis PMN count and culture were positive in fifty six (total of 92) and two (out of 72) patients respectively. Out of the total 92 ascetic fluid analysis, 43 patients had LERS 0 and 1^{+} result though comparing with ascetic fluid PMN 8 patients had SBP.

However, none of these patients had ascetic fluid culture positivity. Whereas when LERS grade of 2^{+} was taking to account; out of 51patients, 2 patients were without SBP and all were CNNA. While in the 3^{+} range; 11 out of 13 patients had CNNA and 12 had SBP(Table 4).

We will assess the performance of LERS test against PMN at a cut off value of 2^{++}. At a cut off of 2^{+}, sensitivity to diagnose SBP was 81.4%; specificity of 94.6%, PPV being 94.7%, and NPV of 81.2%. In comparison, at cut off level of 3^{+}; sensitivity decreased to 60%, specificity increased to 97.2%, PPV of 92.3% and NPV of 81.4%.

Taking ascetic fluid culture result in to count, 2 of 51 patients had culture positivity (SBP) at LERS cut off level of 2^{+} or more, compared to none at LERS cut off level of 1^{+} or less. The positive ascetic fluid culture grew E. coli resistant to Augmentin and Ceftriaxone but sensitive to Cefepime, Ceftazidime ,Vancomycin and Meropenum.

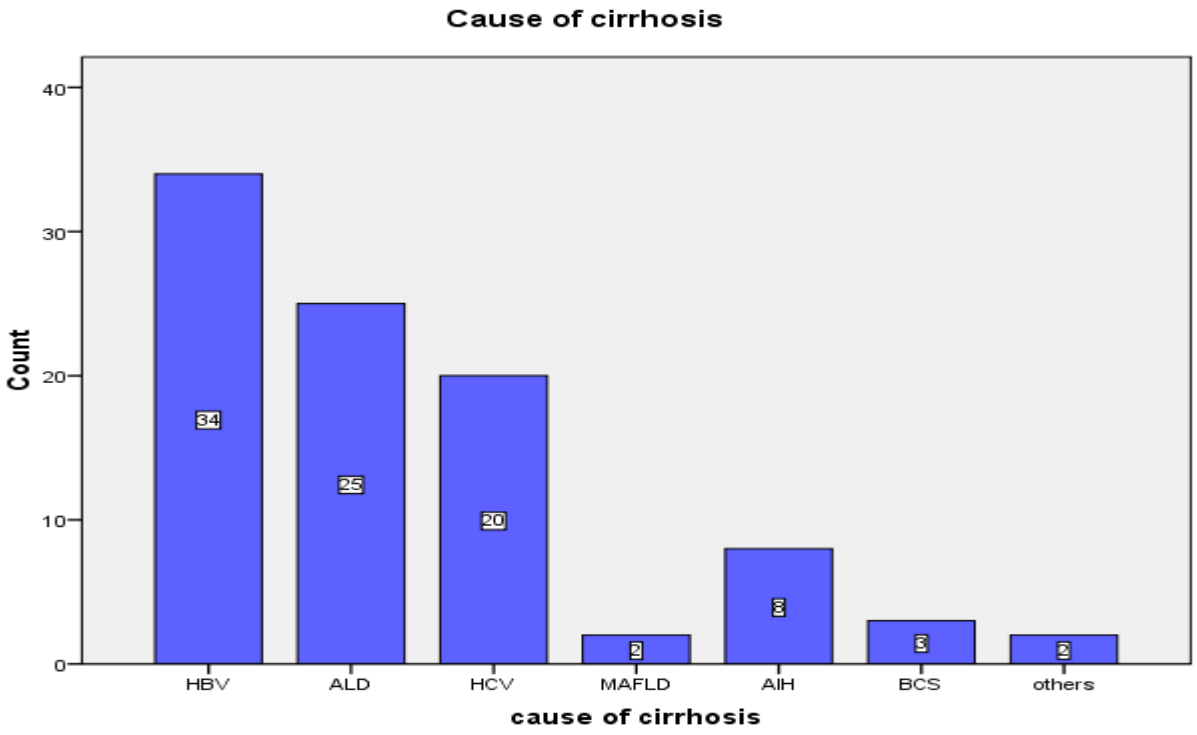

Figure 2: Cause of cirrhosis, Addis Ababa, Ethiopia, 2021.

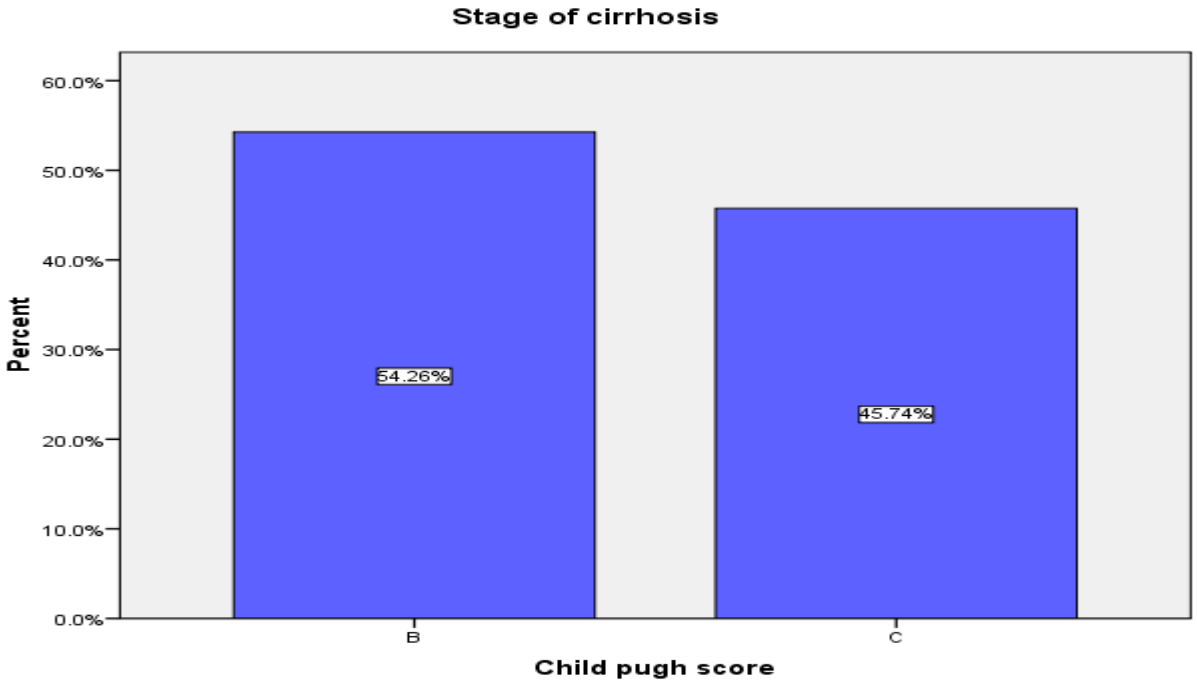

Figure 3: Stage of cirrhosis, Addis Ababa, Ethiopia, 2021

Table 4: Associations between AF PMN, culture and LERS among adult cirrhotic patients in Addis Ababa, Ethiopia, 2021 (n= 94).

Observed	Predicted LERS			
AF PMN				
	0	1+	2+	3+
SBP (≥250)	0	8	36	12
No SBP(<250)	18	17	2	1

Table 4A: Number of patients with AF PMN and LERS among adult cirrhotic patients in Addis Ababa, Ethiopia, 2021 (n= 94).

AF LERS	AF PMN			
	SBP(≥250)	No SBP (<250)	Percentage correct	AOR 95% CI
Positive (2+and 3+)	48	3	94.1	0.651 (0.487-0.972)
Negative(0 and 1+)	8	35	81.4	0.207 (0.171-0.679)

Table 4B: Associations between AF PMN and LERS among adult cirrhotic patients in Addis Ababa, Ethiopia, 2021 (n= 94).

AF LERS	AF Culture			
	Negative	Positive	Percentage correct	AOR 95% CI
Positive (2+and 3+)	51	0	100.0	0.41 (0.33-0.44)
Negative(0 and 1+)	41	2	4.7	0.171 (0.207-0.679)

Table 4C: Associations between AF Culture and LERS among adult cirrhotic patients in Addis Ababa, Ethiopia, 2021 (n= 94).

AF PMN	AF LERS		
	O and 1+	2+	3+
SBP	8	36	12
% within SBP	18.2%	81.8%	60.0%
% within LERS	18.6%	94.7%	92.3%
No SBP	35	2	1
% within SBP	94.6%	5.4%	97.2%
% within LERS	81.4%	5.3%	81.4%

Table 4D: Associations between AF PMN and LERS at cut off 2+ and 3+ among adult cirrhotic patients in Addis Ababa, Ethiopia, 2021 (n= 94).

6. Discussion

Our study on clinical characteristics of cirrhotic patients showed the most common cause of cirrhosis to be HCV (36.2%), ALD (26.6%) and HCV (21.3%). Though, NAFLD is the leading cause of cirrhosis worldwide, a systematic review and meta-analysis done previously in Ethiopia identified HBV(40%), ALD(17%) and HCV(15%) to be the leading causes of cirrhosis[7, 9]. In the current study, 54.3% of patients had CTP score of B cirrhosis, and (45.7%) had CTP C, as opposed to a study from Germany, 55% had CTP A, 30% CTP B and 15% CTP C. These finding can be explained by the late presentation and delayed diagnosis of patients in our country. The frequently observed complications of cirrhosis were electrolyte disturbance (71.4%), HE (64.8%), and HRS (53.8%). A study from the same country demonstrated ascites(60%), EV(49%), HE(25%), HRS(18%) and pleural effusion(14%) to be the leading complication of cirrhosis; in contrary to a study from India with coagulopathy(83%), EV(81%), ascites (64%), HE (51%) and SBP(12.5%) being the usual complications.[11, 43]. More than one third (39) of patients who were on follow up were consuming more than 8g of salt per day and of the 20 patients who were on follow-up for ALD, only half (10 patients) have been linked to rehabilitation therapy. These findings emphasize on the lack of multidisciplinary team involvement in patient's care and poor patients' adherence to life style modification measures, in addition to limited number of rehabilitation centres in the country.

The study demonstrated, 56 out of 94 patients were diagnosed with SBP using PMN. In 60% of patients who had SBP, antibiotic was initiated within 6 hours (more in private set up than in public centres). In those patients, Ascetic fluid cell count result was collected after the initiation of antibiotics. This finding of ours strengthens the need for rapid and cheaper alternative for the diagnosis of SBP, as it has been demonstrated by other studies as well[44]. 7 of the 29 patients who were on follow-up for cirrhosis had previous diagnosis of SBP. All patients had ascetic fluid protein and SAAG result less than 2.5g/dl and greater than 1.1g/dl, respectively. Regarding the outcome of SBP patients, 16 of the patients died. The commonest cause of mortality in our study was Sepsis (68.7%), in the majority GI focus (63.6%) was discriminated. However, One Indian study showed the leading cause of mortality in cirrhotic patients to be worsening HE (50%) followed by UGI bleed and sepsis/40].

Out of the 38 patients who had no SBP based on PMN, 8 of them had LERS positivity at cut off level of 2^{+} and above. Of the 51 patients who had SBP based on AF PMN, only 3 patients had negative LERS with cut off level 1^{+} or below. These indicated lower false positivity level of LERS at higher cut off value. 2 of the three patients, who had no SBP but LERS cut off value $^{2++}$, had haemorrhagic ascetic fluid with concomitant HCC.

Only 2 patients had SBP(E.coli identified) diagnosed by Ascetic fluid culture out of 72 patients. However, Standard text books have indicated the level of ascetic fluid culture positivity to be close to 40%, in comparison to the study from Pakistan that revealed 44 SBP patients with culture positivity of 187 patients[10, 45]. The high CNNA level observed in our study can be as a result of the delayed laboratory inoculation of the culture bottles and low colony count of the monomicrobial infections despite the advanced stage of the cirrhosis[46, 47].

Our study showed, LERS can be helpful in screening for SBP. At a cut off level of 2^{+}, the sensitivity and specificity was 81.8% and 94.6% respectively. Compared to cut off level of 3^{+} the sensitivity decreased to 60% and specificity increase to 97.2%. While the PPV at cut off level of 2^{+} was 94.7%, decreasing to 92.3% at cut off of 3^{+}. However, the NPV (81.4%) remained similar despite the cut off value. The overall accuracy of the test was 88.3% and the LDOR was 70. The results were maintained in the three centres where the study was performed.. Lower cut off level of LERS have demonstrated higher sensitivity which will help in identifying and treating patients suspected of having SBP. Similarly, early diagnosis and initiation of treatment will decrease the high mortality rate associated with delay in diagnosis.

Our results are similar to studies done in different parts of the world. One study performed 100 paracentesis and ascetic fluid was analysed using two different LER strips. Of which 9 patients had SBP based on PMN count and positive ascetic fluid culture, and 5 were CNNA. The study demonstrated, the sensitivity, specificity, NPV and PPV of the tests to be 89%, 100%, 100%, and 99%. And the results of the two strips to be concordant[48].

Another study of 94 patients, diagnosed 52 patients with SBP by manual count. The overall sensitivity of LERS was 92% , with specificity of 95%, PPV of 96% and NPV of 90%[27].

In study done to assess the usefulness of urine strip test in rapid diagnosis of SBP, among 75 patients 18 of the patients had SBP. At a cut off value of 2^{+} or more, the sensitivity,

specificity, PPV and NPV were all 100%. However, at a cut of 3^+ the sensitivity, specificity, PPV and NPV were 67%, 100%, 100% and 89% respectively[26].

A recent observational study that assessed the accuracy of LERS test for rapid bedside screening of SBP, SBP was diagnosed in 17 of 64 patients. At cut off of 2^+, sensitivity to diagnose SBP was 100%, specificity of 94%, PPV being 57%, and NPV of 94%.Whereas at cut off 3^+, sensitivity decreased to 76%, while specificity increased to 100%; PPV of 100% and NPV of 93.7%. The study also showed the overall accuracy at 2^+ and 3^+ was respectively 94.5% and 93.75%[49].

The above results were reciprocated in a study done to evaluate the LERS in the diagnosis of SBP in150 cirrhotic children among which 41 patients were diagnosed to have SBP. The sensitivity and specificity of LERS according to PMN were 87.8% and 91.4% respectively. Comparing LERS with AF culture results were 88.23% sensitive and 77.44% specific. The efficacy of LERS in diagnosing SBP, according to PMN and culture results were 90.6% and 78.6% [50].

In view of our result and those of other studies, the leukocyte esterase reagent test can be used as a rapid diagnostic tool for screening suspected patients of SBP. The higher NPV of the test in the studies emphasize their use in emergency units and low resource set up where other means of diagnostic evaluation result takes hours to be collected. In this set ups, the early diagnoses of SBP will save lives and resources.

Though, our study represents the only data from Sub-Saharan Africa, it has relatively small sample size and the calorimetric reading can be subjective. These data will require confirmation in further studies with larger sample size, at multiple centres and more detailed analysis of ascetic fluid properties including (PH, osmolality).

LERS test kit can be found at any pharmaceutical companies and online shopping sites. LERS is cost effective as compared to AF analysis and culture. It is ten and twenty times less costly as compared to AF PMN and culture respectively.

7. Conclusion

Our study demonstrated that LERS test is a rapid, accessible, affordable screenimg tool for the diagnosis of SBP with over all good sensitivity and specificity. The bedside test is important in diagnosing SBP in developing countries like Ethiopia where Sepsis following SBP is the leading cause of death in cirrhotic patients.

8. Strength and Limitation

Strength

- The study population was selected randomly from adults cirrhotic patients admitted to inpatient department in the three GI units in the study period fulfilling the exclusion criteria. As a result it minimizes selection bias.
- The study was conducted in multicentre (three GI centres) and ascetic fluid PMN and culture was done in a single laboratory which increased the accuracy of the test.
- Training was given to the professional nurses and physicians who collected the data and performed the paracentesis and LERS test in order to decrease inter-observer variability.
- The Laboratories used calibrated measurement instrument approved by ISO.

Limitation

- The study will have limitations, mainly related to the cross-sectional nature of the analyses, which prevents from making any conclusions regarding causality.
- Although the study included all cirrhotic patients admitted to the GI unit at the study period, the sample size was relatively small. Therefore, individuals selected (study population) might be with a different distribution of metabolic and endocrine complications, compared to the general patients' population.

9. Plan for dissemination

After completion of the study, the final result will be submitted to Department of Internal medicine in AAU, Yekatit 12 HMC, Adera Medical Center, Ethiopian Public Health Institute, Addis Ababa Health Bureau and Ministry of Health, so that the paper might serve as an input for changing practice and advance future studies in the area. We will also try to get the results of the study published in reputable medical journals to create awareness on the issue and possibly encourage further research work on the topic.

10. Budget analysis

Table 5: Budget breakdown for personnel, stationary, logistic and procedure expenses for the project, Addis Ababa, 2021.

A. Personnel Cost

For training					
Title	**No. of participants**	**Qualification**	**No. of days**	**Per diem (ETB)**	**Total (ETB)**
Data collectors	3	MD	1	300.00	900.00
Sub total					**900.00**
For data collection					
Title	**No. of participants**	**Qualification**	**Sample size**	**Per diem (ETB)**	**Total (ETB)**
Data collectors	3	MD	102	100.00	10,200.00
Sub total					**10,200.00**

B. Stationary and Logistics

Item	**Quantity**	**Unit Price (ETB)**	**Total (ETB)**
Written consent form and Data entry paper	102 copies x(3 pages)	1.00	306 .00
Print & binding (proposal & thesis)	10 copies x(50 pages)	2.00	1000.00
Pen	5	8.00	40.00
Pencil	5	4.00	20.00
Eraser	5	8.00	40.00
Note pad	5	25.00	125.00
Mobile card	5	100	500.00
Sub total			**1,725.00**

C. Procedure cost

Item	**Quantity**	**Unit Price**	**Total cost**
LERS	**2 pack**	**1050**	**2,100.00**
AF analysis	**102**	**200**	**20,400.00**
AF Culture	**81**	**500**	**40,500.00**
Sub total			**63,000.00**

D. Budget Summary

Item	**Total Cost (ETB)**
Personnel cost	11,100.00
Stationary & logistics	1,725.00
Procedure cost	63,000.00
Sub-total	75,825.00
Contingency 6%	4,675.00
Total Cost of the Project	**80,500.00**

11. Work plan

Serial no.	Activity	Responsible body	Sept.-Dec.	Jan.-Mar.	Apr - May.	June	July – Sep.	Oct.-Nov.	Dec. 2021	Feb. 2022
1	Topic selection	Primary investigator								
2	Proposal writing And Editing	Primary investigator and Advisors								
3	Submission of the final proposal	Primary investigator								
4	Pretesting the questionnaire	Primary investigator								
5	Data collection	Primary investigator and professional nurses								
6	Data coding, entry & cleaning	Primary investigator								
7	Data analysis	Primary investigator and Advisors								
8	Thesis writing & 1st draft submission	Primary investigator and Advisors								
9	Reporting the final work	Primary investigator								
10	Thesis presentation and publishing	Primary Investigator								

Figure 4: Guant chart of work plan

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Annex

Annex I.A : Information sheet in English

Respondent's Codenumber

Comparing bedside leucocyte esterase strip test with Spectrophotometric analysis and ascetic fluid culture result to rapidly diagnose Spontaneous bacterial peritonitis among adult Cirrhotic patients at TikurAnbessa specialized hospital, Yekatit 12 hospital medical college and Adera medical center in Addis Ababa, Ethiopia.

I am a speciality student of internal medicine department of AAU. I would like to request your participation in this study that will involve asking you some questions and conducting some tests. Before we proceed, I will request you to listen carefully to what I am going to read to you about the Purpose of this study and what it involves and tell me whether you are willing to participate in this research or not.

Annex II.A: Consent form in English

Consentform

The purpose of this study to compare the diagnosis of SBP using LERS test with that of standard AF analysis and culture result in cirrhotic admitted patients

The survey is made up of two parts:-

1. We ask you some questions that have been found to be associated with the disease.
2. We will take your measurements such as weight, height and blood pressure.

We would like to do paracentesis and do laboratory investigations from the sample. We would like to assure you that the information obtained will be strictly for our research use.

You will be informed of the test results and if diagnosed with any of the diseases mentioned then treatment will be initiated as soon as possible. Your name will not be used in our report and the information obtained will not be used in any way that will identify you. The interview is voluntary. Your participation/ non-participation, or refusal to answer questions will have no effect now or in the future on services that you or any member of your family may receive from the hospital.

Do you volunteer to participate?

Yes……..

No……..

Name …….

Signature …….

Phone number ……..

Annex III, A-Questioner in English

Sample of English Questionnaire to be used in the research

Step 1 Demographic and Socioeconomic Information of Respondent			
no	Questions	Alternative Choices for Response	Code
1	Sex	1.Male	
		2.Female	
2	Age(enter number)	1. 18-30 2. 31-45 3. 46- 64 4. ≥65	
3	Ethinic origin of the patient	1. Addis Ababa 2. Oromia 3. Amhara 4. Tigray 5. SNNPR 6. Somalia 7. Afar 8. Other, Specifiy……..	
4	Marital status	1. Never married 2. Married 3. Divorced 4. Widowed	
5	Educational level	1. Uneducated 2. Primary education 3. Secondary education 4. Tertiary graduate and above	
6	Total yearly income	1. Low income 2. Middle income 3. High income	
7	Do you have any known chronic illness?	1. DM 2. HTN	

		3. Both 4. HIV 5. Cardiac illness 6. None 7. Other, Specify……..	
Step 2 Behavioural information and Feeding Practice			
8	Do you chew chat?	1. Yes daily 2. Yes, sometimes 3. No, not at all	
9	Have you ever taken any type of alcohol drink regularly above the standard? beer, wine, spirit, tela, tej…	1. Yes, I have 2. No, I have never	
10	If yes to question number 9, then for how long did you drink alcohol?	1. <1 year 2. 1- 5 years 3. 5 - 10 years 4. >10 years	
11	Did you take any alcohol drink after the diagnosis of CLD`?	1. Yes 2. No	
12	How much of salt do you consume in your everyday meal?	1. I don' t use salt at all 2. The normal amount , 3g/day 3. Less than normal amount< 2g/day	
Step 3 SBP related information			
13	How long has it been since the diagnosis of cirrhosis?	1. Index(first presentation) 2. < 1 year 3. 1-5 years 4. 5- 10 years 5. >10 years	
14	How long as it been since	1. Index(first presentation)	

	started on medication?	2. < 1 year 3. 1-5 years 4. 5 - 10years 5. >10 years	
15	Cause of cirrhosis?	1. HBV 2. HCV 3. ALD 4. MAFLD 5. AIH 6. others	
16	Treatment type?	1. Diuretics (Furosemide and spironolactone) 2. BB 3. Antiviral therapy 4. Lactulose 5. Rehabilitation therapy including ALD 6. Steroid and immunosuppressive	
17	Use of Prophylaxis?	1. SBP 2. EV 3. Both 4. None	
Step 4 Bed side Measurements and Laboratory investigations			
18	Blood pressure measured 2 times 4-6 hrs apart	1. <90/<60 2. 90-120/60-80 3. 130-140/80-90 4. >140/>90	
19	Random blood sugar	1. < 70 mg/dl 2. 70 - 300 mg/dl 3. >300 mg/dl	
20	Ascetic fluid analysis PMN	1. < 250 cells/ml 2. ≥ 250 cells/ml	

21	Ascetic fluid analysis protein	1. <2.5 g/dl 2. ≥2.5 g/dl	
22	SAAG(serum to Ascetic fluid albumin gradient)	1. ≥ 1.1 g/dl 2. < 1.1g/dl	
23	Ascetic fluid culture(if done)	1. Organism identified 2. Not identified	
24	LERS test	1. Negative (0) or trace 2. +1 3. +2 4. +3	
25	Child pugh score	1. A 2. B 3. C	
26	Other complications	1. UGI bleeding, 2. HE, 3. Electrolyte disturbance, 4. HRS, HPS, 5. HCC 6. Coagulopathy	
27	Antibiotics initiated for SBP	1. Cephalosporins and B -lactam 2. Floroquinolones 3. Carbapenems 4. Other, specify …….	
28	Time of initiation of antibiotics after SBP diagnosis	1. Within 6 hrs 2. Within 12 hrs 3. Within 24 hrs 4. After 24 hours	
29	Time of Ascitic fluid analysis result after admission	1. Within 6 hrs 2. Within 12 hrs 3. Within 24 hrs 4. After 24 hours	
30	Outcome of the patient	1. Improved, 2. worsened,	

		3. same , 4. died	
31	If patient dies, cause of death	1. Hypoglycaemia 2. UGI bleeding 3. Refractory septic shock with MOF 4. HE with Increased ICP 5. Other, specifiy…….	

Annex I, B- Information sheet in Amharic

Annex II, B- Consent form in Amharic

Annex III, B-Questioner in Amharic

አማርኛ መጠይቅ

መለያ ቁጥር

እኔ ዶ/ር ሰብሪና አህመድ የተባልኩ የጥቁር አንበሳ የውስጥ ደዌ ህክምና ክፍል ተማሪ ስሆን ይህ ጥናት ለድህረ ምረቃ የመመረቂያ ፅሁፍ ለማቅረብ የተዘጋጀ ነው፡፡ የዚህ ጥናት ዓላማ በጥቁር አንበሳ ሆስፒታል፣ የካ/12/ሆ እና በአደራ የህክምና ማዕከል ውስጥ ተኝተው በሚታከሙ የጉበት በሽተኞችን የጉበት በሽታ ስፋትና ስርጭት እንዲሁም የተጓዳኝ በሽታዎችን ለማወቅ ነው፡፡ ለዚህም ይረዳ ዘንድ መጠይቁ ስለ ጉበት በሽታና ተጓዳኝ ችግሮችን፣ የደም ግፊትና ስኳር ልኬት እንዲሁም የደምና የሰውነት ፈሳሽ ምርመራን ይጨምራል፡፡ የመመረቂያ ፅሁፍ ከየትኛውም የመንግስት ወይም የግል ድርጅት ጫና ውጪ በመሆኑ ነፃ ሆነው መጠይቁን በመሙላት እንዲተባበሩኝ በትህትና እጠይቃለሁ፡፡

ይህ ጥናት የግለሰቡ /የግለሰቧ ስም የማይጠቀም በመሆኑ በፍፁም ፈቃደኝነት ላይ የተመሰረተ ነው፡፡ በመጠይቁ አለመሳተፍ ምንም ዓይነት ችግር የማያስከትል መሆኑን እንድትረዱልኝ እፈልጋለሁ፡፡ ይህ ጥናት ከእርሶ አልፎ ለአገሪቷ የጠና ዘርፍ ከፍተኛ ግብዓት ሆኖ እንዲያገለግል የእርሶ ተሳትፎ ወሳኝነት አለው፡፡

በዚህ ጥናት ለመሳተፍ ይስማማሉ/ህ/ሽ

እስማማለሁ:.....

አልስማማም:.....

ፊርማ .....

ስልክ ቁጥር.....

1. የማህበራዊ እና የኢኮኖሚያ ጥያቄዎች

2. እድሜ	
3. ፆታ	ወንድ ☐ ሴት ☐
4.የትውልድ ቦታ	1. አዲስ አበባ 2. ኦሮሚያ 3. ትግራይ 4. አማራ 5. ደቡብ ህ/ቤ/ክ 6. ሶማሊያ 7. አፋር 8. ሌሎች ….
5. የጋብቻ ሁኔታ	1. ያላገባ 2. ያገባ 3. ሚስት/ባል የሞተባት/በት 4. የተፋታ
6. የትምህርት ደረጃ	1. ቀለም ያልቆጠረ 2. አንደኛ ደረጃ የተማረ 3. ሁለተኛ ደረጃ የተማረ 4. ሦስተኛ ደረጃና ከዚያ በላይ
7. የገቢ ሁኔታ	1. ዝቅተኛ ገቢ 2. መካከለኛ ገቢ 3. ከፍተኛ ገቢ
8. ተጓደኛ በሽታ	1. ስኳር 2. ደምግፊት 3. ስኳር እና ደምግፊት 4. ኤች አይ ቪ ኤድስ 5. የልብ በሽታ 6. ተጓዳኝ በሽታ የሌለው 7. ሌሎች….

2. የስነ ባህሪ እና አመጋገብ ጥያቄዎች

8. ጫት መቃም	1- ሁሌ እቅማለሁ 2- አንዳንዴ

	3- ቅሜ አላውቅም
9. በየቀኑ 2-3 መለኪያ አልኮል ትጠጣለህ/ሽ	1- አዎ 2- አልጠጣም
10. የጉበት በሽታ እንዳለህ ከተነገረህ/ሽ በኋላ ጠጥተሽ/ህ ታውቃለህ/ሽ	1- አዎ 2- የለም

3.ከጉበት በሽታ ጋር ተያያዥነት ያላቸው ጥያቄዎች

11. በቀን ምን ያህል ጨው ተትጠቀማለህ/ሽ	1- ምንም አልጠቀምም 2- ተጨማሪ ምግብ ላይ አልጠቀምም 3- አብሮ ከተፈጨው ውጪ ተጨማሪ እጠቀማለሁ
12. የጉበት በሽታ እንዳለብህ ካወክ/ሽ ስንት ጊዜ ሆነ	1. ለመጀመሪያ ጊዜ 2. ከአንድ ዓመት በታች 3. ከ1-5 ዓመት 4. 5-10 ዓመት
13. የጉበት በሽታ መንስኤ	1.የጉበት ቫይረስ B “HBV” 2. የጉበት ቫይረስ C “HCV” 3. አልኮል 4. AIH 5.MAFLD ከተጓዳኝ በሽታዎች ጋር የተገናኘ 6. ሌሎች…
14. የምትጠቀማቸው መድሃኒቶች (ከአንድ በላይ መምረጥ ይቻላል)	1. “Diuretics”- የሰውነት ውሃ ለመቀነስ የሚረዱ 2. ደም እንዳይደማ የሚረዱ “BB” 3. የጉበት ቫይረስ መድሃኒት 4. ሰገራ ለማውጣት የሚረዱ 5. አልኮል ለማቆም የሚረዱ 6. የሰውነት መከላከል
15. የጨጓራ መድማትን /እንፈክሽን ለመከላከል የምትወስደው /ጂው መድሃኒት አለ?	1. አዎ 2. የለም
16. የጥያቄ ቁጥር 15 መልስ አዎ ከሆነ የትኛውን?	1. የኢንፈክሽን መከላከያ 2. የመድማት መከላከያ 3. ሁለቱንም 4. የቱንም

17. ከዚህ በፊት ከጉበት በሽታ ጋር በተያያዘ የትኛው አሞት ያውቃል?	1. የጨጓራ መድማት 2. የሆድ ውስጥ ኢንፌክሽን 3. አቅል መሳት
18. የጉበት በሽታው ደረጃ	1. CTP A 2. CTP B 3. CTP C
19. ከጉበት በሽታ ጋር በተያያዘ ያለ ተጨማሪ በሽታ	1. ከጨጓራ ደም መድማት 2. አቅል መሳት (ንቃተ ህሊና መቀነስ) 3. የሰውነት ንጥረ ነገሮች መዛባት 4. የኩላሊት በሽታ 5. የጉበት እጢ /ካንሰር/ 6. ከሌሎች የሰውነት ክፍሎች ደም መድማት
20. የትኞቹን መድሃኒቶች ለሆድ ውስጥ ኢንፌክሽን ተጠቀሙ?	1. Ceplalosporsin 2. Floroquinolone 3. Carbapenem 4. ሌሎች …
21. የሆድ ውስጥ ኢንፌክሽን መድሃኒት በስንት ሰዓት ሆስፒታል ከደረሱ ተጀመረ	1. በ6 ሰዓት ውስጥ 2. በ12 ሰዓት ውስጥ 3. በ24 ሰዓት ውስጥ 4. ከ24 ሰዓት በኋላ
22. የሆድ ወስጥ ኢንፌክሽንን የሚያሳየው የላብራቶሪ ምርመራ ውጤት በስንት ሰዓት ውስጥ ደረሰ?	1. በ6 ሰዓት ውስጥ 2. በ12 ሰዓት ውስጥ 3. በ24 ሰዓት ውስጥ 4. ከ24 ሰዓት በኋላ
23. ከዚህ ቀደም የጨጓራ መድማት ነበረ?	1. አዎ 2. የለም

4.የላብራቶሪ ምርመራዎች

24. ከዚህ ቀደም የሆድ ውስጥ ኢንፌክሽን ነበረ?	1. አዎ 2. 2. የለም
25. ከዚህ ቀደም የንቃተ ህሊና መቀነስና ራስ መሳት ነበረ?	1. አዎ 2. የለም

26.የበሽተኛው ውጤት (ለውጥ) ከህክምና በኋላ	1. አገገመ 2. ባሰበት 3. ለውጥ የለውም 4. ሞተ
26. በሽተኛውን ለሞት ያበቃው ምክንያት	1. የተባባሰ ኢንፌክሽን (Refractory septic shock) 2. የንቃተ ህሊና መቀነስና የጭንቅላት ማበጥ (HE with increased ICP) 3. የጨጓራ ደም መፍሰስ (UGI Bleeding) 4. ሌሎች
27. የደም ግፊት	1. 90/60-80 2. 90-120/60-90 3. 130-140/80-90 4. >140/>90
28. የስኳር ልኬት (RBS)	1. <70 ሚ/ግ /ዲ.ኤል 2. 90-10/60-80 3. 130-140/80-90 4. >140/>90
29. የሆድ ውስጥ ፈሳሽ የሴል ቁጥር	1. <250 ሴል /ኤም.ኤል 2. ≥250
30. የሆድ ውስጥ ፈሳሽ ፕሮቲን ቁጥር	1. <2.5 ግ/ዲ.ኤል 2. 2.5>ግ/ዲ.ኤል
31. የሆድ ውስጥ ፈሳሽ SAAG	1. ≥1.1 ግ/ዲ.ኤል 2. < 1.1.