Section: General Medicine

Original Research Article

APRI SCORE AND FIB-4 INDEX AS NON-INVASIVE PREDICTORS OF ESOPHAGEAL VARICES IN LIVER CIRRHOSIS

T. Sowjanya Lakshmi[1], Rahul Conjeevaram[2], Maganti Yamuna[3], Jyothi Conjeevaram[4], Padamtinti Anurag Rao[5]

[1]*Assistant Professor, Department of General Medicine, Narayana Medical College and Hospital, Nellore, India.*
[2]*Assistant Professor, Department of General Medicine, Narayana Medical College and Hospital, Nellore, India.*
[3]*Assistant Professor, Department of General Medicine, Narayana Medical College and Hospital, Nellore, India.*
[4]*Professor and HOD, Department of Community Medicine, Narayana Medical College and Hospital, Nellore, India.*
[5]*Postgraduate 3rd year, Department of General Medicine, Narayana Medical college and Hospital, Nellore, India.*

Received *: 15/01/2026*
Received in revised form *: 02/03/2026*
Accepted *: 19/03/2026*

Corresponding Author:
Dr. Padamtinti Anurag Rao,
Postgraduate 3rdyear, Department of General Medicine, Narayana Medical college and Hospital, Nellore, India.
Email:anuragrao1065@gmail.com

DOI: 10.70034/ijmedph.2026.2.3

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (2); 14-20

ABSTRACT

Background: Cirrhosis leads to portal hypertension and life-threatening complications like esophageal variceal bleeding. While endoscopy is the gold standard for diagnosis, its invasive nature and cost, necessitate reliable non-invasive predictors.

Aim: To evaluate the Aspartate Aminotransferase to Platelet Ratio Index (APRI) score and Fibrosis-4 (FIB-4) as non-invasive predictors of esophageal varices in liver cirrhosis.

Materials and Methods: This observational study at Narayana Medical College Hospital (January–July 2024) included 105 cirrhotic patients. APRI and FIB-4 scores were calculated and compared against endoscopic findings.

Results: Esophageal varices were present in 65.7% of patients. An APRI cut-off of ≥ 0.9 demonstrated 74.5% sensitivity, 61.1% specificity, and a significant association with high-risk varices (p = 0.0005).Binary logistic regression analysis revealed that patients with an APRI score of ≥ 0.9 had nearly five times the odds of harbouring high-risk varices compared to patients with an APRI score < 0.9 (OR = 4.59; 95% CI: 2.00–10.58; p = 0.0003). A FIB-4 cut-off of ≥ 2.78 showed higher sensitivity (82.3%) but lower specificity (40.7%), with a significant association (p = 0.0174).Patients with a FIB-4 score ≥ 2.78 had more than five times the odds of having esophageal varices compared to patients with a score below the 2.78 threshold (Odds Ratio [OR] = 5.31; 95% Confidence Interval [CI], 2.15 – 13.10; p < 0.001).

Conclusion: Both indices are valuable tools for risk stratification. APRI serves as a reliable positive predictor for identifying high-risk varices, while FIB-4's high sensitivity makes it an effective primary screening tool to rule out severe disease in resource-limited settings

Keywords: APRI, FIB-4, Esophageal varices, Non invasive predictor, Cirrhosis.

INTRODUCTION

Cirrhosis is defined as a histological development of regenerative nodules which are surrounded by fibrotic bands as a result of chronic liver injury leading to development of portal hypertension and various complications including end stage liver disease.[1]Chronic liver disease and cirrhosis are major global health related concerns, constituting among the top 10 leading causes of death in Africa, Southeast Asia, Europe and the Eastern Mediterranean in 2023.[2]Southeast Asia region had the highest number of incident cases, deaths and disability-adjusted life-years (DALYs) attributing to cirrhosis and other chronic liver diseases.[3]

Cirrhosis is divided into compensated and decompensated stages, with differentiating clinical features and prognosis. In the compensated stage,

patients have few or no symptoms because the liver is still functioning sufficiently, even in the presence of significant fibrotic tissue. The compensated liver disease patient has a median survival of approximately 6.5 years. In decompensated cirrhosis, the liver is extensively damaged leading to poor function of the liver, and patients in this stage will eventually develop serious life-threatening complications including esophageal variceal bleeding and hepatic encephalopathy(HE). The median survival of patients with this stage of cirrhosis is approximately 2.5 years.[4]

The combination of damaged hepatic sinusoids and imbalance between vasodilator and vasoconstrictor agents results in increased intrahepatic vascular resistance in cirrhosis leading to portal hypertension(PH).[5]It is responsible for the classical complications of cirrhosis, such as gastroesophageal varices and bleeding, ascites, hepatorenal syndrome (HRS), hepatic encephalopathy(HE), and altered liver metabolism. Early identification and management of these complications are vital to improve patient outcomes and survival.[6]Clinically significant portal hypertension (CSPH) occurs when the hepatic venous pressure gradient (HVPG) exceeds 10 mmHg.[7]

One of the life-threatening complications of decompensated cirrhosis is variceal hemorrhage. According to American Association for the Study of Liver Diseases(AASLD), screening endoscopy is advised to determine the presence and grading of varices for which will require treatment with non-selective betablockers (NSBB) or endoscopic variceal ligation (EVL).[8]Variceal hemorrhage occurs at a rate around 10-15% per year. Progression from small to large sized varices occurs at rate of 10-12% per year. The mortality of variceal hemorrhage ranges between 15% and 25% in the first six weeks.[9] This accounts for the need ofendoscopy to detectthe presence of esophageal varices necessary to decrease the mortality in patients with decompensated liver disease.

Endoscopy remains the gold standard procedure for diagnosing oesophageal varices despite its association with risks attributable to invasive procedures such as infection, bleeding, and perforation.[10] In resource limited setting areas, due to limited availability of endoscopic equipment with trained health care personnel, non-invasive indicators for identification of esophageal varices such as Aspartate Aminotransferase to Platelet Ratio Index (APRI) and Fibrosis-4 (FIB-4) index can be used to identify the need of further endoscopic assessment in particular set of cirrhotic patients.

Aim and objectives

Aim

To assess APRI and FIB-4 index as non-invasive predictors of esophageal varices in liver cirrhosis.

Objectives

1. To compare APRI score, FIB-4 index, and presence of esophageal varices in liver cirrhosis.
2. To study the sensitivity, specificity, negative predictive value, positive predictive value, area under curve of APRI score, FIB-4 index in identifying the esophageal varices in liver cirrhosis.
3. To study the association between APRI score, FIB-4 index and severity of esophageal varices in liver cirrhosis.

MATERIALS AND METHODS

Study design:

This is an observational epidemiological study of cirrhotic patients admitted to medical ward and intensive care unit (ICU) in Narayana Medical College Hospital, Nellore for a period of January to July 2024.

Inclusion Criteria

1. Patients aged above 18years who are diagnosed with cirrhosis of liver admitted to medical wardsand ICU.

Exclusion Criteria

1. Patients under 18years of age
2. Patients who are not willing to participate in the study
3. Pregnant women
4. Patients who were already on beta blocker therapy, those who had undergone endoscopic treatments (sclerotherapy/band ligation
5. Patients who underwent previous surgeries for portal hypertension or trans-jugular intrahepatic portosystemic shunting.
6. Patients living with HIV
7. Patients on immunosuppressive medication
8. Patients with portal or splenic vein thrombosis

Study Procedure

Study was conducted after obtaining the institutional ethics committee approval.

A written informed consent was obtained from all the patients participating in the study. In cases where patient is unconscious, the consent was obtained from next responsible attendants.

After taking informed consent, all the study participants were subjected to detailed history.All the patients in the study underwent relevant investigations including complete hemogram, renal function tests, liver function tests including transaminases, ascitic fluid analysis is recorded in patients with ascites, ultrasonography of abdomen was done to determine the presence of cirrhosis.All the participants underwent upper gastrointestinal endoscopy for detection and grading of varices, portal hypertensive gastropathy.

Calculation of APRI

APRI score is calculated based on the following formula,[11]

APRI = AST/upper limit of normal × 100/PLT 10^9/L

Calculation of FIB-4 index:

Based on the following formula,[12]

FIB-4 =Age(years)x AST

PLT 10^9/L x √ALT

Diagnosis of cirrhosis of liver:

Liver biopsy being the gold standard for diagnosis of cirrhotic liver, ultrasonography is used often as first line investigation to detect cirrhosis as it is non-invasive and widely available. B-mode ultrasound was used to confirm the diagnosis of cirrhosis of the liver based on US scoring system (USSS). These findings are comparable to liver stiffness measurement (LSM) in the diagnosis of cirrhosis and predicting fibrosis.[13]

Esophageal varices

The identification of esophageal varices, gastric varices and portal hypertensive gastropathy was done by using upper gastrointestinal endoscopy. The grading of esophageal varices was done based on AASLD practice guidelines, which classifies esophageal varices less than 5mm as small and esophageal varices > 5mm as large[8].

Treatment

All patients were given standard-of-care treatment according to the BavenoVII guidelines[7]

Statistical Analysis

Data management and statistical analysis were performed using [Insert Software Name, e.g., SPSS version 26.0]. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages.Chi-square Test was used to determine the association between categorical risk groups (dichotomized APRI and FIB-4 scores) and the severity of esophageal varices (low-risk vs. high-risk).A p-value of < 0.05 was considered statistically significant for all analyses. Receiver Operating Characteristic (ROC) analysis was performed to quantify the discriminative ability of APRI and FIB-4 across continuous thresholds. The Area Under the Curve (AUC) was used to compare the overall performance of the two indices. Binary Logistic Regression was conducted using APRI and FIB-4. Odds Ratios (OR) with 95% Confidence Intervals (CI) were calculated to determine the increase in the likelihood of high-risk esophageal varices.

RESULTS

During the study period, 126 patients were screened.Of these,105 patients were included in the study. The reasons for exclusion were age <18 years(n=4), patients already underwent endoscopic treatment(n=12), patients with HIV(n=2), patients with splenic veinthrombosis(n=3).

Of the 105 patients in the study, 93(88.6%) were male and 12(11.4%) were female (Figure 1). Mean age of the patients in our study was 52.5±12.7 years with minimum and maximum age being 24 and 89 respectively.33(31.4%) patients were suffering from diabetes whereas72(68.6%) patients were found to be non-diabetic. Nine patients (8.6%) were hypertensive and 96 patients (91.4%) were non hypertensive. History of alcoholism was observed in 63(60%) of patients and no such history in 42(40%) of the study subjects. Based on aetiology, 89 patients have alcohol use disorder, 6 patients have hepatitis B, 2 patients have hepatitis C, 8 patients have Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) (Figure 2). In the study population, 69 patients (65.7%)were found to be having esophageal varicesand 36 patients (34.3%)did not have esophageal varices. In 69 patients with esophageal varices, 18(17.1%) were having small varicesand 51(48.6%) were having large esophageal varices. [Figure 3]

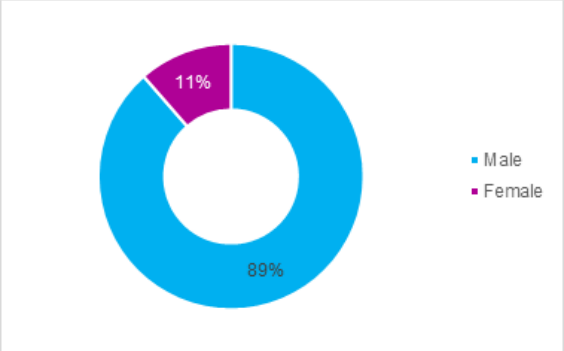

Figure 1: Gender distribution

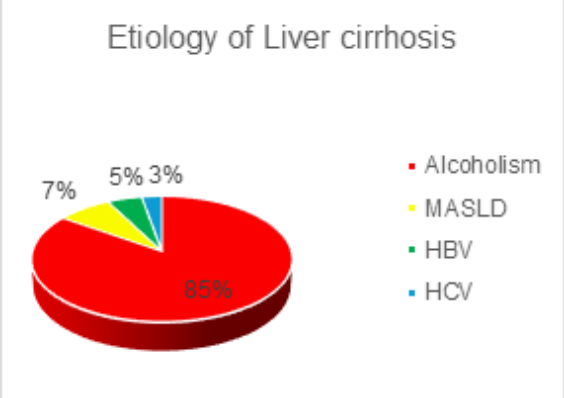

Figure 2: Etiological distribution of liver cirrhosis

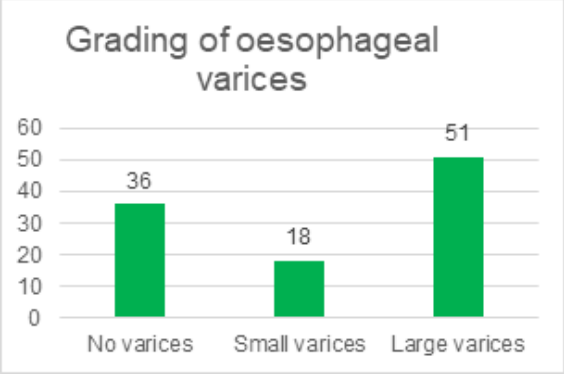

Figure 3: Grading of esophageal varices

In our study, APRI score of less than 0.9 was noted in 49(46.7%) patients and score of0.9and above was noted in 56(53.3%) patients.FIB-4 index of less than

2.78 was noted in 29(27.6%) patients and the index of 2.78 and more was noted in 76(72.4%) patients.

Association between APRI Score and Esophageal Varices Severity:

To evaluate the clinical utility of the APRI in predicting the severity of esophageal varices, patients were stratified into two risk categories based on their variceal grading: low-risk (no varices and small varices) and high-risk (large varices). When evaluating APRI as a categorical variable utilizing a predefined cut-off of 0.9, a statistically significant association with the presence of high-risk esophageal varices was observed (p = 0.0005).

Diagnostic Performance of APRI (Cut-off ≥ 0.9):

The diagnostic validity of using an APRI cut-off of ≥ 0.9 to predict high-risk esophageal varices was assessed. At this threshold, the APRI score demonstrated a sensitivity of 74.5% (95% CI: 61.1%–84.5%) and a specificity of 61.1% (95% CI: 47.8%–73.0%).The positive predictive value (PPV) and negative predictive value (NPV) were 64.4% (95% CI: 51.7%–75.4%) and 71.7% (95% CI: 57.5%–82.7%), respectively. The overall diagnostic accuracy of the APRI score at this cut-off was 67.6% (95% CI: 58.2%–75.8%).

Receiver Operating Characteristic (ROC) Analysis

To further quantify the overall discriminative ability of the APRI score across all possible thresholds, a ROC analysis was performed. The AUC was 0.712 (95% CI: 0.607–0.806), indicating APRI has a moderateand statistically significant ability to discriminate between patients with low-risk and high-risk esophageal varices. [Figure 4]

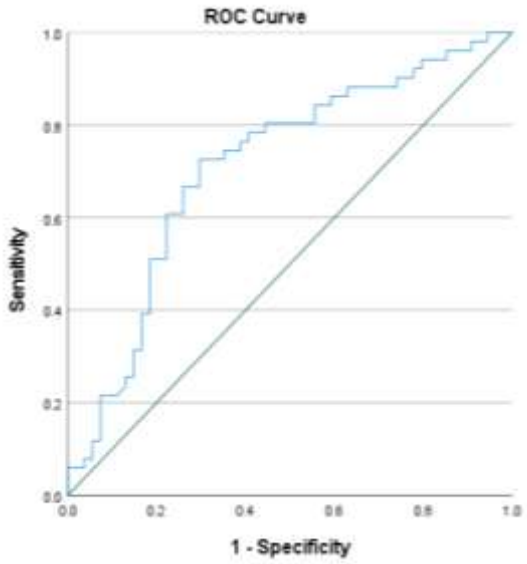

Figure 4: ROC curve of APRI score

Logistic Regression and Likelihood Ratios:

Binary logistic regression analysis revealed that patients with an APRI score of ≥ 0.9 had nearly five times the odds of harbouring high-risk varices compared to patients with an APRI score < 0.9 (OR = 4.59; 95% CI: 2.00–10.58; p = 0.0003).

Furthermore, likelihood ratios were calculated based on the dichotomized APRI threshold (<0.9 vs. ≥ 0.9). The Positive Likelihood Ratio (PLR) was 1.92 (95% CI: 1.32 – 2.78) and the Negative Likelihood Ratio (NLR) was 0.42 (95% CI: 0.25 – 0.70).

Association between FIB-4 scoreand Esophageal Varices Severity:

To determine the utility of theFIB-4 index in predicting the severity of esophageal varices, patients were classified into two groups based on endoscopic findings: low-risk (no varices and small varices) and high-risk (large varices). The FIB-4 score was evaluated using a predetermined clinical cut-off of 2.78, categorizing patients into a negative/low-risk group (FIB-4 < 2.78) and a positive/high-risk group (FIB-4 ≥ 2.78). A Chi-square test of independence demonstrated a statistically significant association between a FIB-4 score of ≥ 2.78 and the presence of high-risk esophageal varices (p = 0.0174).

Diagnostic Performance of FIB-4 (Cut-off ≥ 2.78):

The diagnostic performance of the FIB-4 score at the ≥ 2.78 threshold for identifying high-risk esophageal varices was evaluated. At this cut-off, the FIB-4 score yielded a high sensitivity of 82.35% (95% CI: 69.75% – 90.43%), though specificity was lower at 40.74% (95% CI: 28.68% – 54.03%). The PPV was 56.76% (95% CI: 45.41% – 67.43%), and the Negative Predictive Value NPV was 70.97% (95% CI: 53.41% – 83.90%). The overall diagnostic accuracy of the test at this threshold was 60.95% (95% CI: 51.39% – 69.74%).

Receiver Operating Characteristic (ROC) Analysis:

To assess the overall discriminative capacity of the FIB-4 score across all continuous thresholds, an ROC curve was generated. The analysis yielded AUC of 0.702. This indicates that the FIB-4 score has a fair and clinically meaningful ability to discriminate between patients with high-risk varices and those with low-risk varices. [Figure 5]

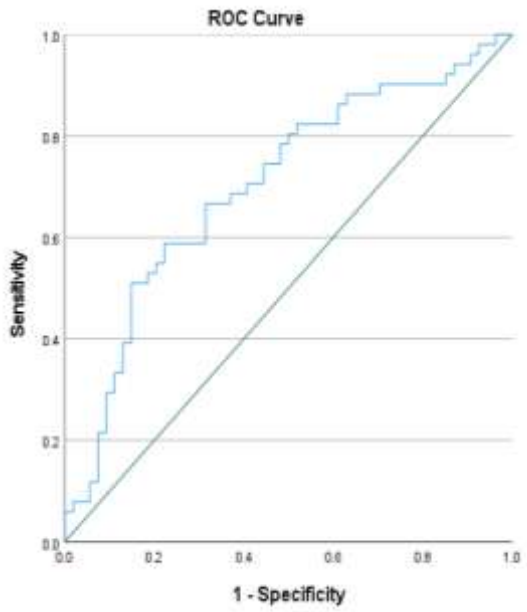

Figure 5: ROC curve of FIB-4 Index

A binary logistic regression analysis was performed to quantify this association. The analysis demonstrated that a FIB-4 score ≥ 2.78 is a significant independent predictor for the presence of esophageal varices. Patients with a FIB-4 score ≥ 2.78 had more than five times the odds of having esophageal varices compared to patients with a score below the 2.78 threshold (Odds Ratio [OR] = 5.31; 95% Confidence Interval [CI], 2.15 – 13.10; p < 0.001).

Furthermore, Likelihood Ratios (LR) were calculated for the dichotomized FIB-4 score. The PLR was 1.39 (95% CI: 1.08 – 1.79). The NLR was 0.43 (95% CI: 0.22 – 0.85), suggesting that a FIB-4 score < 2.78 moderately decreases the likelihood of high-risk varices, offering some utility in ruling out severe variceal disease before undergoing endoscopic assessment.

Performance of APRI score and FIB-4 index as non-invasive prediction of esophageal varices is represented in Table 1.

Logistic Regression and Likelihood Ratios:

Table 1: Performance of Non-invasive Markers for Prediction of Esophageal Varices

Parameters	APRI	FIB-4
Sensitivity (%)	74.5	82.3
Specificity (%)	61.1	40.7
PPV (%)	64.4	56.7
NPV (%)	71.7	70.9
Diagnostic accuracy (%)	67.6	60.9
AUC	0.712	0.70
Odds ratio (OR)	1.46	1.16
Positive Likelihood Ratio	1.92	1.39
Negative Likelihood Ratio	0.42	0.43

Area under the curve (AUC) obtained from the receiver operating characteristic; PPV: positive predictive value; NPV: negative predictive value; APRI: AST-to-platelet-ratio index; FIB-4: fibrosis-4-index.

DISCUSSION

One of the challenges in managing liver cirrhosis is the timely identification of esophageal varices to prevent life-threatening variceal haemorrhage. Due to the invasive nature, cost and need for trained personnel for gold standard method of oesophagogastroscopy, need for simple, non-invasive laboratory-based indices like APRI score and FIB-4 index could serve as reliable predictors for esophageal varices.

In our study of 105 patients, 93(88.6%) were male and 12(11.4%) were female similar as a study conducted in Lucknow by Rapellyetal,[14] where 82%(n = 89) were male and 18% were female (n = 20). The mean age of the patients in our study was 52.5 years with standard deviation of 12.7 years where as in a study conducted in Nagpur by Kothari etal.[15]showed the mean age of 43.77±9.95 years.

In the present study, diagnosis of esophageal varices was done according to AASLD guidelines.65.7% patients had esophageal varices, of which 17.1% patients had small varices and 48.6% were found to have large varices; 34.3% study subjects did not have esophageal varices on endoscopy.In a study conducted in 2017 by Kraja et al,[12] on predictors of esophageal varicesand variceal bleeding in liver cirrhosis patients was reported that 31.7% had small varices, 21.6% had large varices, and 18.7% had no varices.

Comparison of APRI Performance

In our study, an APRI cut-off of ≥0.9 yielded a sensitivity of 74.5% and specificity of 61.1%, positive predictive value of 64.4%, negative predictive value of 71.7%, diagnostic accuracy of67.6% in predicting esophageal varices. This is very similar to the work of Loaeza-del-Castillo et al., who found that an APRI score > 1.1 had a high negative predictive value for excluding the presence of varices, suggesting that patients below this threshold might safely defer screening endoscopy.[16]

Furthermore, a meta-analysis by Deng et al. involving 1,488 patients reported a pooled AUC of 0.60–0.70 for APRI in predicting esophageal varices, which is slightly lower than our observed AUC of 0.712.[17]This is consistent with a recent 2023 study by Kumar et al., which reported an

AUROC of 0.699 for APRI in predicting esophageal varices at a cut-off of > 0.9. Their study also noted a sensitivity of 85.3%, reinforcing that APRI is a robust marker across different Indian patient populations.[18]

In this study,a highly statistically significant association between an APRI score of ≥0.9 and high-risk esophageal varices (p =0.0005) which is very similar to study conducted in north India (p < 0.001) indicating the patients with high APRI score are more likely having esophageal varices.[19]

Our study utilized binary logistic regression analysis revealed that patients with an APRI score of ≥ 0.9 had nearly five times the odds of harbouring high-risk varices compared to patients with an APRI score < 0.9 (OR = 4.59; 95% CI: 2.00–10.58; p = 0.0003). Furthermore, likelihood ratios were calculated based on the dichotomized APRI threshold (< 0.9 vs. ≥ 0.9). ThePLR was 1.92 (95% CI: 1.32 – 2.78), indicating a moderate shift in post-test probability, and the NLR was 0.42 (95% CI: 0.25 – 0.70). In Kothari's central Indian cohort focusing on alcoholic cirrhosis, the Odds Ratio for APRI was found to be 3.07(CI:1.62-5.80), PLR of 1.81 and NLR of 0.46.[15]In a study conducted in Surat, India,the odds ratio for APRI ≥ 1.1 predicting esophageal varices was15.05 (95 % CI:4.07-55.7), signifying that patients with elevated APRI were about fifteen times more likely to have varices.[19]

Comparison of FIB-4 Performance

The FIB-4 index (at a cut-off of≥2.78) showed a higher sensitivity of 82.3% but a significantly lower specificity of 40.7% and an NPV of 70.9%. This high sensitivity makes FIB-4 an excellent screening tool, making it is unlikely to miss a patient with high-risk varices,but the low specificity suggests a high rate of false positives where patients might still undergo unnecessary endoscopies.The relatively high NPV makes it a good screening tool for ruling out esophageal varices.

Our results for FIB-4 (Sensitivity 82.3%, Specificity 40.7% at a cut-off of 2.78) highlight a common trend in hepatology research. Kim et al. evaluated FIB-4 in patients with liver cirrhosis and reported that FIB-4 is an excellent predictor of advanced fibrosis, its specificity for esophageal varices specifically tends to be lower than for liver stiffness itself.[20]Our findings for FIB-4 (Sensitivity-82.3%, AUC-0.702) are supported by recent data from Naveen et al. (2024–2025), whose observational study concluded that the FIB-4 index is a highly reliable predictor of esophageal varices. They reported sensitivity of 96.6%,specificity of 75% and AUC = 0.987 for FIB-4 cut-off of 3.3 for diagnosing esophageal varices.[21]The sensitivity we observed at 2.78 suggests our threshold is ideal for primary screening in a busy hospital setting to ensure no high-risk patient is missed for endoscopy rather than the higher threshold values of 3.3 as FIB-4 index.

Our study showed an OR = 5.31; 95% CI, (2.15 – 13.10); p < 0.001), which indicates that patients with a FIB-4 score ≥ 2.78 had more than five times the odds of having esophageal varices compared to patients with a score below the 2.78 threshold. The PLR was 1.39 (95% CI: 1.08 – 1.79), indicating that a FIB-4 score ≥ 2.78 slightly increases the probability of high-risk varices being present. The NLR was 0.43 (95% CI: 0.22 – 0.85), suggesting that a FIB-4 score < 2.78 moderately decreases the likelihood of high-risk varices, offering some utility in ruling out severe variceal disease before undergoing endoscopic assessment. In Kothari et al. the odds ratio was 3.92 (CI: 2.04-7.55), LR+ of 1.81 and LR- of 0.46.[15]

CONCLUSION

Our study demonstrates that APRI and FIB-4 index are valuable, non-invasive clinical tools for predicting the presence and severity of esophageal varices in patients diagnosed with liver cirrhosis.

With a cut-off of ≥ 0.9, APRI provided a balanced diagnostic performance (Accuracy: 67.6%) and a statistically significant association with high-risk varices (p=0.0003) indicating it as a reliable positive predictor in predicting presence of esophageal varicesin cirrhotic patients in our cohort.At a cut-off of ≥ 2.78, FIB-4 demonstrated high sensitivity (82.35%), making it an effective screening tool to ensure high-risk patients are not missed, although its lower specificity (40.74%) may lead to a higher rate of false positives.Both tests had a relatively high NPV which is useful in ruling out a patient with esophageal varices.

Given the high cost and invasive nature of endoscopy, these markers offer a practical alternative for risk stratification, especially in resource-limited settings. Based on the results of this study, we recommend the use of APRI as a primary tool for identifying high-risk varices, while FIB-4 can be used to rule out severe disease in primary care.

Limitations

The study was conducted at a single tertiary care hospital in South India hence findings may reflect local demographic and etiological trends and might not be fully generalizable to the entire Indian population. A significant majority of our patients (85%) had alcoholic liver disease. Since alcohol consumption directly influences AST levels, the performance of APRI and FIB-4 might differ in populations where viral hepatitis (HBV/HCV) or MASLD are the predominant causes of cirrhosis.The histological gold standard of liver biopsy was not performed due to its invasive nature and risk of complications in cirrhotic patients where clinical standards like ultrasonography and endoscopy are used for diagnosing liver cirrhosis.This was an observational study at a single point in time. A longitudinal study would be required to determine if changes in APRI and FIB-4 over time can predict the progression of varices or the risk of an initial bleeding episode. Exclusion of

patients with previous endoscopic therapy or sclerotherapy have eliminated severe cases, potentially underestimating predictive range of APRI score.

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