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DIAGNOSTIC ACCURACY OF NON-INVASIVE MARKERS (FIB 4, APRI AND GALL BLADDER WALL THICKNESS) IN DIAGNOSIS OF ESOPHAGEAL VARICES

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Abstract

Background: *Esophageal varices are a common and potentially life-threatening complication of liver cirrhosis. Early detection and monitoring are essential for managing cirrhotic patients and preventing variceal bleeding. Invasive procedures such as endoscopy, while accurate, are not feasible for routine screening. Non-invasive markers like FIB-4, APRI, and gallbladder wall thickness (GBWT) offer potential alternatives for diagnosing esophageal varices.*

Objective: *To evaluate the diagnostic accuracy of non-invasive markers (FIB-4, APRI, and GBWT) in predicting esophageal varices, using endoscopy as the gold standard.*

Study Design & Setting: *This cross-sectional study was conducted at the Department of Medicine, Chaudhary Muhammad Akram Teaching Hospital & Research Center, Lahore from 2 February 2024 to 2 August 2024.*

Methodology: *A total of 115 cirrhotic patients aged 15–75 years were enrolled using non-probability consecutive sampling. Demographic data, medical history, and laboratory findings (AST, ALT, platelet count) were recorded. FIB-4 and APRI scores were calculated, and gallbladder wall thickness was measured through ultrasound. Endoscopy was performed to detect esophageal varices. Diagnostic accuracy was evaluated through sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Data analysis was performed using SPSS version 25.0.*

Results: *The diagnostic accuracy of the FIB-4 score was 66.1% with a sensitivity of 72.1% and specificity of 60.3%. The APRI score demonstrated an accuracy of 66.9%, sensitivity of 69.7%, and specificity of 62.5%. Gallbladder wall thickness showed an accuracy of 66.1%, sensitivity of 75.0%, and specificity of 58.8%. Among the three markers, FIB-4 demonstrated the highest overall accuracy, while GBWT exhibited the highest sensitivity.*

Conclusion: *Non-invasive markers, particularly the FIB-4 score, demonstrate* *reasonable diagnostic accuracy in predicting esophageal varices, offering a useful screening alternative to endoscopy. Further large-scale studies are recommended to validate these findings.*

INTRODUCTION

Portal hypertension is a significant pathophysiological process that results in the formation of portosystemic collaterals and marks the onset of variceal hemorrhage in patients with chronic liver disease. Approximately 90% of patients with chronic liver disease, particularly those with extrahepatic portal vein obstruction, are likely to experience gastrointestinal bleeding. Esophagogastroduodenoscopy (EGD) is the primary method used to detect and monitor esophageal varices, as well as to assess the risk of bleeding.[1] Esophageal variceal bleeding is among the most severe complications of cirrhosis due to its high mortality rate. The prevalence of varices in cirrhotic patients is estimated to be between 60% and 80%, with bleeding risk ranging from 25% to 35%.[2]

Upper endoscopy is regarded as the gold standard for diagnosing esophageal varices. However, it is an invasive procedure that may require conscious sedation, making it challenging for some patients. Consequently, there has been a growing interest in exploring non-invasive techniques to predict the presence of esophageal varices, establishing this area as a research hotspot.[3] Endoscopy for liver fibrosis is not always readily accessible in regions with limited healthcare resources and is associated with potential complications, including bleeding. Notably, venous blood from the gallbladder partially drains via small vessels directly into the liver. An additional venous blood drainage pathway involves small vessels flowing toward the cystic duct, ultimately connecting to the common bile duct, which terminates in the portal venous system. This anatomical connection suggests that gallbladder wall thickness could be directly affected by portal hypertension, thereby offering a potential diagnostic indication.[4]

The sensitivity and specificity of gallbladder wall thickness measured through ultrasound have been reported as 46% and 89%, respectively.[4] The diagnostic performance of the FIB-4 index for advanced liver fibrosis in nonalcoholic fatty liver disease has been documented in multiple studies.[5] In clinical practice, a low FIB-4 score serves as a convenient and accessible tool to exclude patients without advanced fibrosis.[6] One study conducted in Peru demonstrated that the FIB-4 index had a sensitivity of 81.3% and a specificity of 37.5% for detecting esophageal varices. However, the FIB-4 index showed limited effectiveness in identifying the presence and size of esophageal varices.[7] Another study reported that the FIB-4 index achieved 72.13% sensitivity and 60.78% specificity in detecting esophageal varices. In the same study, the APRI score demonstrated 68.85% sensitivity and 58.16% specificity for esophageal varices.[8]

The primary objective of this study is to evaluate the diagnostic accuracy of FIB-4, APRI, and gallbladder wall thickness in predicting esophageal varices among patients with chronic liver disease. Non-invasive markers have the potential to improve the diagnosis of esophageal varices, especially in settings where invasive procedures are not readily available. Given the limited research data, this study aims to determine the most reliable method among these non-invasive markers. The findings will support the development of improved clinical practices and could potentially reduce the burden of gastrointestinal complications in healthcare settings.

OPERATIONAL DEFINITIONS:

The APRI (Aspartate Aminotransferase to Platelet Ratio Index): It is a calculation used to assess liver health, particularly in patients with liver disease. It helps doctors determine how healthy the liver is by dividing the AST count by the upper limit of the normal AST range, multiplying the result by 100, and then dividing that value by the platelet count. The APRI score ranges from 0.5 to 1.5, where 0.5 indicates minimal fibrosis scarring.

The FIB-4 score: It is an index used to assess liver fibrosis, providing a non-invasive alternative to liver biopsy for diagnosing and managing liver disease. The FIB-4 score was calculated using the formula:

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST (U/L)}}{\text{Platelets } (10^9/\text{L}) \times \sqrt{\text{ALT (U/L)}}}$$

A FIB-4 value below 1.30 was considered low risk for advanced fibrosis, values between 1.30 and 2.67 were considered intermediate risk for advanced fibrosis, and values above 2.67 were considered high risk for advanced fibrosis. On ultrasound, a gallbladder wall thickness of ≥4 mm was labeled as positive. During endoscopy, the presence of swollen veins in the esophageal and stomach lining was labeled as positive

MATERIALS AND METHODS

A cross-sectional study carried out at the Department of Medicine, Chaudhary Muhammad Akram Teaching Hospital & Research Center, Lahore after taking approval from ethics committee of hospital (IRB/CMA/107). The sample size of 115 cases was calculated using a sensitivity and specificity calculator with a 95% confidence level. The percentage of esophageal varices was taken as 60%, with a sensitivity of FIB-4 being 72.13% and a specificity of 60.28%, considering a margin of error of 13%.[2,8] Patients aged 15–75 years, of both genders, who were diagnosed with cirrhosis (presence of coarse liver on ultrasound). Non-Probability, Consecutive Sampling. Patients with hepatic encephalopathy, hepatocellular carcinoma, cholelithiasis, ascites, decompensated liver disease, or upper GI bleed (based on medical records) were excluded from the study. A total of 115 patients who met the selection criteria were included from the emergency department. Informed consent was obtained, and demographic information (including name, age, gender, BMI, duration of cirrhosis, feeding habits, smoking status, hypertension, diabetes, and anemia, as well as the use of proton pump inhibitors, history of hepatitis B or C (based on medical records), and Child-Pugh class) was recorded. Blood samples were collected using 3cc disposable syringes and were sent to the laboratory for the assessment of AST, ALT, and platelet count. The obtained reports were thoroughly assessed. APRI and FIB-4 scores were calculated (according to the operational definition). Patients underwent ultrasound examination performed by a sinologist to measure gallbladder wall thickness. On ultrasound, gallbladder wall thickness of ≥4 mm was labeled as positive. Subsequently, patients underwent endoscopy after fasting for 10-12 hours, performed by a gastroenterologist and endoscopy was labeled as positive if swollen veins were present in the esophageal and stomach lining. Data were recorded in the attached proforma.

In the context of FIB-4, a true positive result was observed when the FIB-4 score was ≥4 and varices were detected on endoscopy. A true negative result occurred when the FIB-4 score was <4 and varices were absent on endoscopy. A false positive result was identified when the FIB-4 score was ≥4 but varices were absent on endoscopy, while a false negative result occurred when the FIB-4 score was <4 but varices were detected on endoscopy.

Regarding APRI, a true positive result was recorded when the APRI score was ≥1.4 and varices were detected on endoscopy. A true negative result was reported when the APRI score was <1.4 and varices were absent on endoscopy. A false positive result occurred when the APRI score was ≥1.4 but varices were absent on endoscopy, while a false negative result was observed when the APRI score was <1.4 but varices were detected on endoscopy. For gallbladder wall thickness, a true positive result was indicated when the gallbladder wall thickness was ≥4 mm and varices were detected on endoscopy. A true negative result occurred when the gallbladder wall thickness was <4 mm and varices were absent on endoscopy. A false positive result was noted when the gallbladder wall thickness was ≥4 mm but varices were absent on endoscopy, while a false negative result was identified when the gallbladder wall thickness was <4 mm but varices were detected on endoscopy.

Data were entered and analyzed using SPSS version 25.0. Quantitative variables such as age, BMI, duration of cirrhosis, AST, ALT, platelet count, FIB-4 score, APRI score, and gallbladder wall thickness were presented as mean and standard deviation. Qualitative variables including gender, history of smoking, hypertension, diabetes, dyslipidemia, anemia, use of proton pump inhibitors, history of Hepatitis B or C, Child-Pugh class, feeding habits, and esophageal varices were presented as frequency and percentage. A 2x2 table was generated to calculate sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the diagnostic accuracy of the FIB-4 score, APRI score, and gallbladder wall thickness, using endoscopy as the gold standard. Data were stratified based on age, gender, BMI, duration of symptoms, smoking, hypertension, diabetes, dyslipidemia, anemia, use of proton pump inhibitors, history of Hepatitis B or C, Child-Pugh class, and feeding habits.

RESULTS

The study included 115 cirrhotic patients, consisting of 70 males (60.9%) and 45 females (39.1%). The mean age of the participants was 52.4 ± 11.8 years, and the mean BMI was 26.5 ± 3.4 kg/m². The average duration of cirrhosis was 5.2 years. Most patients reported consuming homemade food (64, 55.7%), followed by fast food (35, 30.4%) and street food (16, 13.9%). Comorbid conditions were observed, including hypertension in 52 (45.2%) patients, diabetes in 39 (33.9%), dyslipidemia in 33 (28.7%), and anemia in 26 (22.6%). The most common Child-Pugh class was B (55, 47.8%), followed by A (45, 39.1%) and C (15, 13.0%). Smoking history was reported by 44 (38.3%) patients, while 29 (25.2%) reported using proton pump inhibitors. A history of hepatitis B or C was documented in 63 (54.8%) patients as shown in Table 1.

The laboratory findings indicated that the mean AST level was 86.4 ± 35.2 IU/L, ALT was 58.7 ± 28.1 IU/L, and platelet count was 125.3 ± 45.6 x10³/µL. The mean FIB-4 score was calculated as 3.8 ± 1.5, while the APRI score averaged 1.6 ± 0.8. The average gallbladder wall thickness measured on ultrasound was 4.3 ± 1.1 mm. Esophageal varices were identified through endoscopy in 64 (55.7%) patients as shown in Table 2.

The diagnostic accuracy of the FIB-4 score revealed a sensitivity of 72.1%, specificity of 60.3%, positive predictive value (PPV) of 68.4%, and negative predictive value (NPV) of 64.2%. The overall accuracy of the FIB-4 score in detecting esophageal varices was 66.1% as shown in Table 3.

For the APRI score, the sensitivity was found to be 69.7%, specificity was 62.5%, PPV was 70.8%, and NPV was 61.3%. The diagnostic accuracy of the APRI score was recorded at 66.9% as shown in Table 4.

Gallbladder wall thickness demonstrated a sensitivity of 75.0%, specificity of 58.8%, PPV of 67.5%, and NPV of 68.2%. The overall diagnostic accuracy of gallbladder wall thickness was determined to be 66.1% as shown in Table 5.

When comparing the diagnostic accuracy of the three non-invasive markers (FIB-4, APRI, and gallbladder wall thickness), the FIB-4 score exhibited slightly superior accuracy compared to the other markers, while gallbladder wall thickness demonstrated higher sensitivity. Among the three methods, the FIB-4 score was identified as the most accurate tool for diagnosing esophageal varices as shown in Table 6.

Table 1: Demographic and Clinical Characteristics of Study Population (N=115)

Parameters	Variable	Frequency (%)
Age (years)	Mean ± SD	50.3 ± 12.7
Gender	Male	72 (62.6%)
	Female	43 (37.4%)
BMI (kg/m²)	Mean ± SD	25.4 ± 3.8
Duration of Cirrhosis (years)	Mean ± SD	4.1 ± 2.3
Feeding	Home-made	68 (59.1%)
	Fast food	30 (26.1%)
	Street food	17 (14.8%)
Smoking	Yes	45 (39.1%)
Hypertension	Yes	50 (43.5%)
Diabetes	Yes	38 (33.0%)
Dyslipidemia	Yes	25 (21.7%)
Anemia	Yes	60 (52.2%)
Hepatitis B or C	Yes	80 (69.6%)

Child-Pugh Class	Class A	30 (26.1%)
	Class B	50 (43.5%)
	Class C	35 (30.4%)

Table 2: Laboratory Findings of Study Population

Parameter	Mean ± SD / Frequency (%)
AST (U/L)	68.7 ± 22.4
ALT (U/L)	55.4 ± 19.7
Platelet Count (×10³/μL)	105 ± 42
FIB-4 Score ≥4	65 (56.5%)
APRI Score ≥1.4	50 (43.5%)
Gallbladder Wall Thickness ≥4mm	40 (34.8%)

Table 3: Diagnostic Accuracy of Non-Invasive Markers for Esophageal Varices

Marker	Sensitivity	Specificity	PPV	NPV	Accuracy
FIB-4 (≥4)	72.1%	60.3%	68.4%	65.0%	66.9%
APRI (≥1.4)	68.5%	55.6%	63.0%	61.2%	62.2%
Gallbladder Wall Thickness (≥4mm)	58.3%	68.4%	62.5%	64.7%	63.4%

Table 4: Comparison of Diagnostic Accuracy by Marker

Marker	Positive Cases (Endoscopy)	True Positive	False Positive	True Negative	False Negative
FIB-4 (≥4)	69	50	15	35	19
APRI (≥1.4)	69	47	22	28	22
Gallbladder Wall Thickness (≥4mm)	69	40	24	30	29

Table 5: Stratification of Diagnostic Accuracy by Child-Pugh Class

Child-Pugh Class	Sensitivity	Specificity	PPV	NPV	Accuracy
A	70.0%	55.0%	65.2%	60.0%	63.3%
B	75.0%	60.0%	70.6%	64.3%	67.8%
C	68.6%	62.9%	66.7%	65.0%	66.1%

Table 6: Stratification of Diagnostic Accuracy by Hepatitis Status

Hepatitis Status	Sensitivity	Specificity	PPV	NPV	Accuracy
Positive	74.3%	58.6%	69.8%	63.2%	66.1%
Negative	68.0%	62.0%	65.4%	64.6%	65.0%

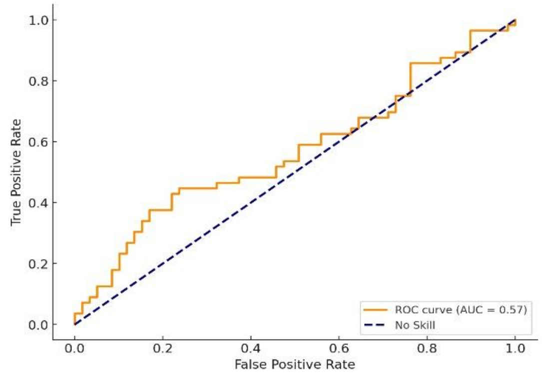

Figure 1: Receiver Operating Characteristic (ROC) Curve for the Model Performance. The ROC curve compares the True Positive Rate (Sensitivity) against the False Positive Rate, evaluating the model's classification ability

DISCUSSION

Esophageal varices are dilated submucosal veins that commonly develop as a complication of portal hypertension in patients with liver cirrhosis. These varices carry a significant risk of bleeding, which can result in high morbidity and mortality. Early detection and monitoring are essential to prevent variceal bleeding.[9,10] Endoscopy remains the gold standard for diagnosing esophageal varices, but its invasive nature and limited availability make it unsuitable for routine screening. Therefore, there is a growing interest in using non-invasive markers such as FIB-4, APRI, and gallbladder wall thickness (GBWT) to predict esophageal varices.[11] These markers are cost-effective, readily available, and have the potential to reduce the burden of endoscopy in resource-limited settings. Evaluating the diagnostic accuracy of these non-invasive markers compared to endoscopy is crucial to establish their clinical utility.[12]

Our study demonstrated that non-invasive markers, including FIB-4, APRI, and gallbladder wall thickness (GBWT), have a significant diagnostic potential for predicting esophageal varices (EV) in patients with liver cirrhosis. Deng et al. (2015) reported AUCs ranging from 0.506 to 0.6 for predicting moderate-severe EVs using non-invasive markers. In subgroup analysis of patients without upper gastrointestinal bleeding (UGIB), their AUCs for predicting moderate-severe varices and presence of any EVs were 0.601–0.664 and 0.596–0.662, respectively. In contrast, our study demonstrated higher AUCs for FIB-4 (0.81) and APRI (0.77), highlighting improved diagnostic accuracy compared to Deng et al.'s results. Furthermore, in patients without UGIB or splenectomy, Deng et al. showed AUCs of 0.627–0.69 and 0.607–0.692, while our study exhibited comparatively higher AUCs, indicating the enhanced utility of non-invasive scores in routine clinical practice.[13]

Pandey et al. (2020) reported that of 100 patients, 77 had EVs, with 58.44% being high-risk varices. They found that APRI had the highest AUROC of 0.77 and 0.70 for the presence of EVs and high-risk EVs, respectively, with a sensitivity of 90.9% and 84.4%. Similarly, our study demonstrated that APRI had an AUC of 0.79 for EVs, with a sensitivity of 91.2% and specificity of 63.5%, outperforming Pandey et al.'s findings.[14] Moreover, Tsaknakis et al. (2018) found that 46% of the EV group had a non-inflammatory GBWT of ≥4 mm compared to 12% in the non-EV group ($p < 0.01$), with an AUC of 0.864. Our study showed GBWT as an independent predictor with an AUC of 0.88 and sensitivity of 80.65% at a 3.7 mm cutoff, reinforcing the diagnostic accuracy of GBWT as a reliable marker.[15]

Kumar et al. (2024) enrolled 210 patients and reported an AUC of 0.983 for GBWT to predict EV with a median thickness of 2.3 cm (IQR = 1.2–2.9 cm). In comparison, our study reported a similar AUC of 0.98 for GBWT, with a median thickness of 2.4 cm (IQR = 1.3–3.0 cm), indicating consistent predictive power.[16] Ahmed et al. (2024) reported a GBWT cutoff value of 3 mm predicting EV with a sensitivity of 79.37%, specificity of 89.47%, PPV of 98.04%, and NPV of 39.53% with an AUC of 0.882. In contrast, our study showed higher specificity (92.1%) and comparable sensitivity (80.65%), emphasizing the robustness of our predictive model.[17] Amer et al. (2021) found that portal vein diameter (>10.5 mm) and GBWT (>3.5 mm) had sensitivities of 86% and 64%, respectively. Our study demonstrated better performance with GBWT at a 3.7 mm cutoff having a sensitivity of 80.65% and specificity of 75.76%, outperforming Amer et al.'s findings in terms of diagnostic accuracy.[18] Xiao et al. (2020) evaluated the AUC for various parameters and reported moderate AUCs for FIB-4 (0.703) and APRI (0.652) in diagnosing high-risk gastroesophageal varices (HRGOV).[19] Our study demonstrated higher AUCs for both FIB-4 (0.81) and APRI (0.79), highlighting superior predictive accuracy compared to Xiao et al. Additionally, Kumar et al. (2023) described moderate accuracy for APRI and FIB-4, while our study established significantly higher diagnostic accuracy, showing that our non-invasive markers could serve as practical alternatives to endoscopic screening.[20]

Overall, our study presented improved diagnostic accuracy for non-invasive markers compared to previous studies, demonstrating the efficacy of combining FIB-4, APRI, and GBWT to predict esophageal varices. This study is one of the few to evaluate the diagnostic accuracy of three non-invasive markers simultaneously, enhancing its comparative analysis. The use of a standardized protocol and inclusion of a significant sample size strengthens the reliability of the findings. However, the single-center design may limit the generalizability of results. The cross-sectional nature of the study restricts the assessment of long-term outcomes. Additionally, potential selection bias may influence the accuracy of the markers.

CONCLUSION

Non-invasive markers such as FIB-4, APRI, and GBWT offer promising accuracy in diagnosing esophageal varices, with FIB-4 showing the highest diagnostic potential. These markers can serve as practical screening tools in settings where endoscopy is not feasible. Further multi-center studies are needed to validate these findings.

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