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Accuracy of non-invasive diagnosis of esophageal varices among cirrhotic patients in a low-income setting

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ABSTRACT

Cirrhosis is a chronic liver disease that is frequently complicated by increased portal venous pressure and the formation of EV. The most common clinical manifestation of portal hypertension is esophageal varices, and ruptured varices are the most fatal complication of portal hypertension. The diagnosis and follow-up of esophageal varices is done by Esophagogastroduodenoscopy, but in most developing countries, the follow-up of cirrhotic patients by gastrointestinal endoscopy remains a challenge.

Objective: Assessment of diagnostic accuracy of noninvasive tests as predictors of esophageal varices among cirrhotic patients at University of Gondar comprehensive Hospital.

Method: Institution based cross-sectional study was conducted among cirrhotic patients from March 2022–October 2022. All study participants underwent screening for Esophageal Varices, Spleen Diameter, Platelet count and Platelet count/spleen diameter ratio. Data were analyzed using SPSS version 26. ROC curves were plotted for Spleen Diameter, Platelet count and Platelet count/spleen diameter ratio with specific cutoffs determined. Diagnostic performance was assessed using ROC curve. The diagnostic thresholds were specified with their sensitivity, specificity, positive predictive value, negative predictive value positive and negative likelihood ratios.

Result: A total of 206 patients were included. The mean age was 41.84 year and SD of (41.84 ± 12.398). About 79.4 % percent were males. Endoscopy confirmed esophageal varices were present in 176(85.4 %) cases. Sixty-seven percent of cases had decompensated cirrhosis (Child-Pugh class B&C). The platelet count to spleen diameter ratio less than 818 had a PPV of 94.7 % (AUROC = 0.835), while spleen diameter greater than 145 mm had 93.7 % PPV (AUROC = 0.783). At a platelet count cutoff <121,000/mm3, the PPV was 95.1 % (AUROC = 0.818).

Conclusion: In this study, platelet count, spleen diameter, and PC/SD all performed well for EV diagnostics, with PC/SD outperforming the others. This finding supports the use of these noninvasive indicators for the diagnosis and implementation of prophylactic treatment foe esophageal varices in health institutions where gastrointestinal endoscopy is unavailable.

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1. Introduction

Cirrhosis of the liver is a chronic liver disease that is frequently complicated by increased portal venous pressure and the formation of esophageal varices (EV). Cirrhosis of the liver is responsible for approximately 90 % of cases of portal hypertension in Western countries, whereas Schistosomiasis is the leading cause in other countries [1].

The most common clinical manifestation of portal hypertension is esophageal varices, and ruptured varices are the most fatal complication of portal hypertension. Varices usually form when portal pressure exceeds 10 mm Hg and bleed when it exceeds 12 mm Hg [2].

Every year, 5 % of new cases of esophageal varices are diagnosed, with nearly 5–10 % of these patients progressing from small varices to large varices. Approximately one-third of patients with compensated cirrhosis and up to 60 % of patients with portal hypertension develop EV [3,4].

Patients with advanced chronic liver disease typically undergo an upper endoscopy to screen for esophagogastric varices. However, upper endoscopy is not recommended for patients with liver stiffness $<$20 KPa and platelet count $>150 \times 10^9$/L as there is a low probability of high-risk varices and patients should be followed up by yearly repetition of transient elastography and platelet count. Patients with high-risk varices should receive primary prophylaxis with either nonselective beta-blockers or endoscopic band ligation [5,6].

Considering the high prevalence of EV among cirrhotic patients, using an accurate and specific means to noninvasively diagnose EV would most likely increase the cost/benefit of empiric treatment by reducing the number of patients who receive avoidable treatment and increasing the number of properly treated patients [2,6].

Performing an endoscopic evaluation of all cirrhotic patients for screening may not be easily available and affordable, especially in resource-limited countries like Ethiopia. A cost-effective method of screening would be possible if cirrhotic patients could be identified for varices based on non-invasive clinical and biochemical variables.

A Platelet count-to-spleen diameter ratio (PSDR), platelet count, and spleen diameter have been suggested as possible non-invasive screening tools of EV as they are relatively simple and less expensive. These methods can be used for initiation of treatment with non-selective beta blocker and patient follow up, as well as prioritizing for endoscopy in resource constraint areas.

However, there is a paucity of published data regarding the role of those noninvasive methods on predicting EV in Ethiopia. For this reason, this study was designed to assess the utility of non-invasive screening tools of esophageal varices among cirrhotic patients at Gondar University comprehensive hospital, North West Ethiopia.

2. Method

2.1. Study area and period

The study was conducted at University of Gondar Comprehensive Hospital. Patients with a diagnosis of any liver disease have follow up at the gastroenterology clinic and are always seen by members of the gastroenterology unit. The study was conducted from March 2022 to October 2022.

2.2. Study design

Institution based, prospective cross-sectional, validation study was conducted.

2.3. Participants

The confidentiality of information that was collected during the investigation was protected by assigning an anonymity number to each investigation sheet. In addition, an authorization was requested and obtained in advance from the administrative and medical authorities of university of Gondar. Based on this a total of 206 cirrhotic patients, aged $\geq$18, who were having follow up at Gondar University hospital, gastroenterology clinic were recruited consecutively. All patients who were willing to undergo for biochemical assessments, abdominal U/S and upper GI endoscopy were included in the study. All those who had a history of spleen resection, a known concomitant hematological disease that affects spleen size and benign diseases that affect spleen size (cysts $>$1 cm) were excluded. Similarly, all those who had any kind of intervention for esophageal varices were also excluded.

2.4. Laboratory assays

The laboratory analysis was performed by two BSc laboratory technicians after collecting 5 ml of blood in two test tubes. The hemoglobin and platelet counts were analyzed using a fully automated hematology analyzer, Beckman Coulter DXH 800 machine using the flow cytometry technique. The liver enzymes and bilirubin level were determined by using Cobas chemistry analyzer.

2.5. Imaging modalities

Screening for EGD is done by senior members of gastroenterology unit by using “Olympus” brand video endoscope. Abdominal ultrasound was performed by experienced radiologists by using 3D ultrasound machine.

2.6. Statistical analysis

After data was collected using a structured questionnaire and entered into Epi data version 4.6, it was exported to SPSS version 26 for cleaning and analysis. Continuous variables were summarized using mean and standard deviation (SD), while categorical variables were summarized using frequency and percentages.

Receiver operating characteristic (ROC) curves were plotted for (PC; SD; PC/SD) and cutoff values were determined using the Youden index, and each data was compared for diagnostic accuracy using the ROC curves with each group of esophageal varices detected by endoscopy. The diagnostic thresholds were specified with their sensitivity, specificity, positive predictive value, negative predictive value and positive and negative likelihood ratios.

2.7. Operational definition

Cirrhosis: diagnosis of cirrhosis was based on combination of clinical, biochemical and ultrasound. Ultrasound diagnosis of cirrhosis was based on: the presence of a heterogeneous liver with homogeneous nodules, enlargement of the Spiegel's lobe, dilation of the portal vein and crenellated contours of the liver.

Severity of cirrhosis was assessed using child pugh score as class A: score 5–6, class B: score 7–9, class C:score 10–15 [7].

Splenic diameter: The diameter of the spleen corresponded to the largest diameter taken from inferior most tips to highest point along the diaphragm, crossing through the splenic hilum enlargement of the Spiegel's lobe, dilation of the portal vein and crenellated contours of the liver and was expressed in millimeters (mm) [8].

Esophageal Varices: Presence of varices on endoscopic examination and was classified as no varices and with varices and graded according to the Paris classification as follows [9].

- ➢ Grade I: varicose veins disappear on insufflations; -
- ➢ Grade II: varicose veins that do not disappear on insufflation but not confluent; -
- ➢ Grade III: varicose veins that do not disappear on insufflation and confluent.

Grade III was considered to be large OV/high risk varices and grades I and II were considered to be small varicose veins [9].

Table 1
Sociodemographic, clinical, laboratory Endoscopy and abdominal ultrasound baseline characteristics of patients with cirrhosis at UoG hospital, 2022.

Sociodemographic	Categories	Frequency/mean and SD
Age	years	41.84(±12.398)
	Male	164(79.6 %)
Sex	Female	42(20.4 %)
Clinical parameters		
comorbidities	None	178 (86.4 %)
	CHF	3(1.5 %)
	Hypertension	14(6.8 %)
	DM	5(2.4 %)
	HIV	1(0.5 %)
	CKD	4(1.9 %)
	Bronchiectasis	1(0.5 %)
Ascites	Yes	153(74.3 %)
	No	53(25.7 %)
jaundice	Yes	64(31.1 %)
	No	142(68.9 %)
child Pugh score	A	68(33 %))
	B	85(41.3 %)
	C	53(25.7 %)
Laboratory parameters		
serum Albumin	mg/dl	2.99(±0.78)
total bilirubin	mg/dl	1.59 (±1.46)
Alanine transaminase	IU/L	40.55 (±30.78)
Aspartate aminotransferase	IU/L	51.6 (63.48)
Hemoglobin	g/dl	10.81 (±3.26)
platelet count	/mm3	89,350 (±59780.37)
Endoscopy and ultrasound parameters		
Esophageal varices	Yes	176((85.4 %)
	No	30 (14.6 %)
	small varices	89 (50.6 %)
Grade of EV	large varices	87 (49.45 %)
spleen diameter	Mm	186.24(±38.81)

3. Results

A total of 206 patients with cirrhosis were included in this study. The mean and standard deviation of the participants' ages were 41.84 (12.398) years. The vast majority of participants (79.4 %) were men. About 13.6 % of study participants had comorbidities, with hypertension being the most common (6.8 %), followed by diabetes (2.4 %). Ascites was identified in 153 (74.3 %) of the patients, and jaundice was observed in 64 (31.1 %) of the patients. The severity of cirrhosis was assessed using the Child Turcotte Pugh (CTP) score; 25.7 % of patients had advanced disease (class C), while 33 % had class A (see Table 1).

Baseline laboratory parameters revealed mean serum albumin 2.99(0.78), total bilirubin 1.59(1.46), hemoglobin 10.81(3.26), and platelet count 89,350(59780.37).

The baseline upper gastrointestinal endoscopy and abdominal ultrasound revealed that 176 (85.4 %) of the participants had esophageal varices, with 87 (49.45 %) having large varices. In this study, the mean and standard deviation of spleen diameter was 186.24(38.81) (see Table 1).

The most common causes of cirrhosis were found to be hepatitis B infection and hepato-splenic schistosomiasis, each accounting for 26 % of cases (Fig. 1).

3.1. Non-invasive predictors of esophageal varices

The ROC curve was used to evaluate the performance of spleen diameter, platelet count, and PC/SD in the diagnosis of EV in all stages of cirrhosis patients. The spleen diameter predicted 93.7 % of the EV (AUROC = 0.783) with a threshold of >145 mm. For the diagnosis of EV, a platelet count of ≤121,000 has a PPV of 95.1 % and an NPV of 50 % (AUROC = 0.818) (Table 2 and Fig. 2).

In this study, PC/SD 818 had a sensitivity of 92.1 % and a specificity of 70 % with an AUROC of 0.835 for the diagnosis of EV. All three parameters were statistical significance (See Table 2 and Fig. 2).

3.2. Subgroup analysis of non-invasive predictors of esophageal varices

In this study, subgroup analyses for compensated cirrhosis, small varices, large varices, and child pugh C patients were performed using ROC curve. The spleen diameter with a threshold of >150 mm predicted 95.8 % of the EV in compensated cirrhosis (AUROC = 0.868). A platelet count of ≤118,000 revealed a PPV of 96.6 % and NPV of 62 % (AUROC = 0.88) whereas, PC/SD ≤ 713 had a sensitivity of 89.1 % and a specificity of 86.3 % (AUROC = 0.888) in diagnosing EV (See Table 3 and Fig. 3).

The performance for patients with child Pugh C was assessed and revealed 100 % specificity and 40 % sensitivity at a PC/SD threshold of >538. SD was having a sensitivity of 88 % and a specificity of 66.67 % at a cut off value of 230 (See Table 3 and Fig. 4).

PC/SD with a threshold of ≤881 had an AUROC of 0.817 for small varices, platelet count with a threshold of ≤121,000 revealed an AUROC of 0.81, and SD with a threshold of >145 revealed an AUROC of 0.764 (See Table 4 and Fig. 5).

For large esophageal varices, PC/SD with cutoff value of ≤877 revealed a PPV of 94.7 %, PC with cutoff value of ≤121,000 revealed

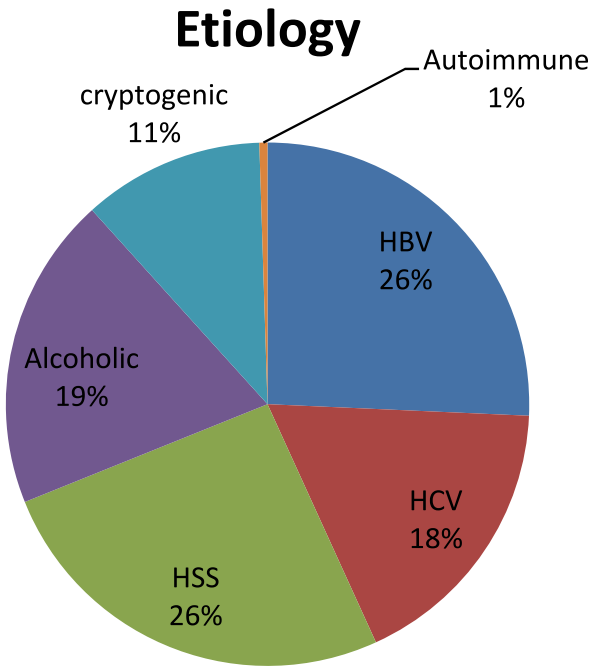

Fig. 1. Distribution of Causes of Cirrhosis among study participants at UoG hospital, 2022.

Table 2
Showing SD, PC, and PC/SD performance in the diagnosis of esophageal varices in cirrhotic patients at UoG hospital, 2022.

	AUC	*P*-value	Cutoff value	sensitivity	specificity	PPV	+LR	NPV	-LR
PC/SD	0.835	<0.0001	≤818	92.10 %	70 %	94.70 %	2.96	60 %	0.16
Platelet count	0.818	<0.0001	≤121,000	87.50 %	73.30 %	95.10 %	3.28	50 %	0.17
spleen diameter	0.783	<0.0001	>145 mm	93.20 %	63.33	93.70 %	2.54	61.30 %	0.1

AUC: area under the curve, PC/SD: platelet to spleen diameter ratio, PPV: positive predictive value, NPV: negative predictive value, +LR: positive likelihood ratio, -LR: negative likelihood ratio.

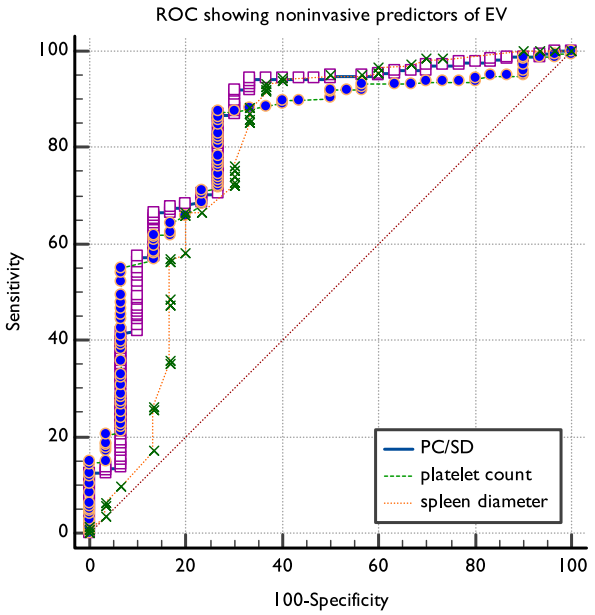

Fig. 2. ROC showing non-invasive predictors of EV among all sages of cirrhosis at UOG hospital, 2022.

Table: 3
SD, PC, and PC/SD performance in the diagnosis of esophageal varices in cirrhotic patients with compensated and child pugh C patients at UoG hospital, 2022.

	AUC	*P*-value	Cutoff value	sensitivity	specificity	PPV	+LR	NPV	-LR
compensated cirrhosis									
PC/SD	0.888	<0.0001	≤713	89.13 %	86.36 %	97.40 %	6.54	58 %	0.13
Platelet count	0.88	<0.0001	≤118,000	91.3	81.82 %	96.60 %	5.02	62 %	0.11
spleen diameter	0.868	<0.0001	>150 mm	91.30 %	77.27 %	95.80 %	4.02	61.10 %	0.11
Child Pugh C									
PC/SD	0.567	0.6872	>538	40	100.00 %	100 %	1.1	22.7 %	0.6
Platelet count	0.51	0.9563	≤39,000	20	100.00 %	100 %	0.9	18.1 %	0.8
spleen diameter	0.743	0.1909	≤230	88	66.67 %	93.7 %	2.64	49.5 %	0.18

AUC: area under the curve, PC/SD: platelet to spleen diameter ratio, PPV: positive predictive value, NPV: negative predictive value, +LR: positive likelihood ratio, -LR: negative likelihood ratio.

a PPV of 94.8 %, and SD with cutoff value of >145 mm revealed a NPV of 76 % (See Table 4).

4. Discussion

In this study, we have tried to assess the diagnostic performance of noninvasive predictors of esophageal varices among cirrhotic patients.

In this study, the optimal cutoff value for PC/SD ratio was ≤818, which revealed a sensitivity and specificity of 92.05 % and 60 %, respectively (AUC: 0.835) for all stages of cirrhosis. This cutoff value was less than what was used by Giannini et al.'s (≤909), but with a comparable outcome of 91.5 % sensitivity and 67.0 % specificity (AUC = 0.860) [10]. Another study which was done in china also used a PSDR<909 as a cutoff value, yielding a positive predictive value of 73 % and a negative predictive value of 88 % [11]. On the other hand, a study done in India reported that a cut-off value of 1014 was found to have higher positive and negative predictive values

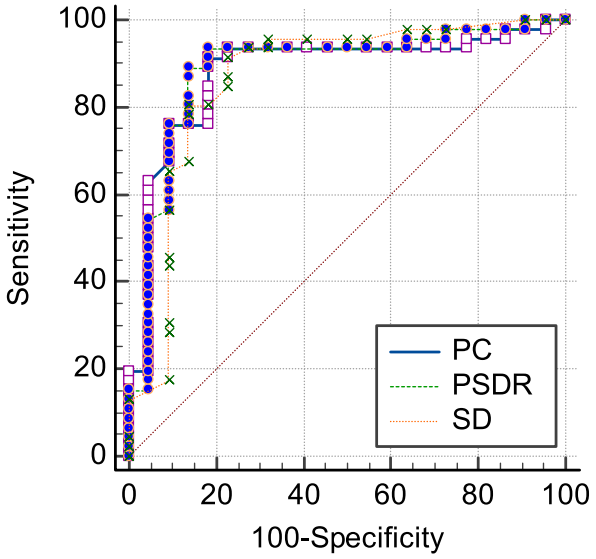

Fig. 3. ROC curve showing non-invasive predictors of EV among compensated cirrhosis at UOG hospital, 2022.

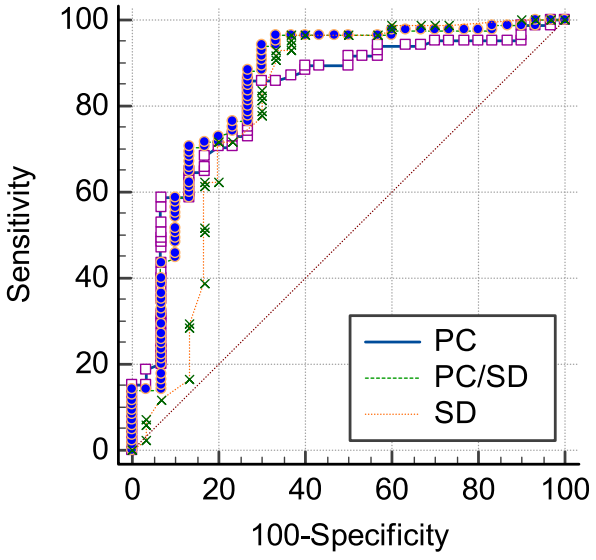

Fig. 4. ROC showing non-invasive predictors of EV among cirrhosis patients with child pugh C at UOG hospital, 2022.

Table 4
SD, PC, and PC/SD performance in the diagnosis of large and small esophageal varices at UoG hospital, 2022.

	AUC	*P*-value	Cutoff value	sensitivity	specificity	PPV	+LR	NPV	-LR
large EV									
PC/SD	0.853	<0.0001	≤877	94.12 %	70.00 %	94.70 %	3.17	68 %	0.08
Platelet count	0.825	<0.0001	≤121,000	85.88 %	73.33 %	94.80 %	3.22	47.70 %	0.18
spleen diameter	0.802	<0.0001	>145	96.47 %	63.33 %	93.70 %	2.63	76.00 %	0.05
small EV									
PC/SD	0.817	<0.0001	≤877	94.12 %	70 %	94.70 %	3.17	67.70 %	0.08
Platelet count	0.81	<0.0001	≤121,000	85.88 %	73.33 %	94.80 %	3.22	47.70 %	0.19
spleen diameter	0.764	<0.0001	>145	96.47 %	63.33 %	93.70 %	2.63	76 %	0.05

AUC: area under the curve, PC/SD: platelet to spleen diameter ratio, PPV: positive predictive value, NPV: negative predictive value, +LR: positive likelihood ratio, -LR: negative likelihood ratio.

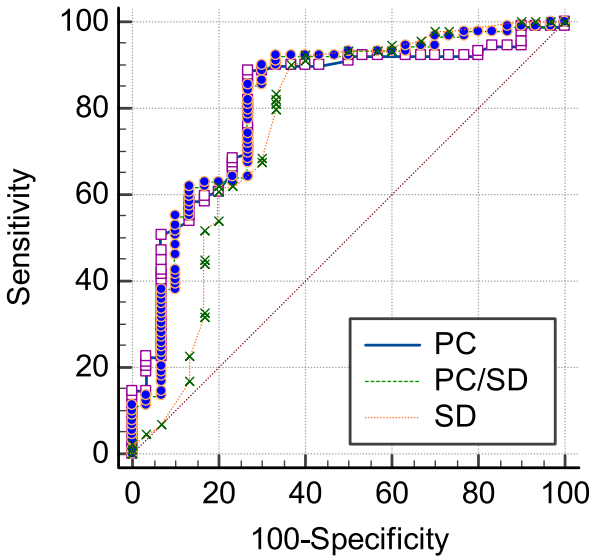

Fig. 5. ROC showing non-invasive predictors of EV among cirrhosis patients with small varices at UOG hospital, 2022.

of 95.4 % and 95.1 %, respectively, which had better NPV than the finding in our study. A PC/SD cutoff value of 830.8 predicted a sensitivity of 76.9 % and specificity of 74.2 % in a Chilean study, which was less than our finding [12]. According to a report from Egypt, an optimal cutoff value for PC/SD of 939.7 provided 100 % sensitivity and a specificity of 95.6 %, which was better in diagnostic accuracy than the findings of our study [13].

For compensated cirrhosis, the PSDR at a cutoff value of ≤713 predicted sensitivity and sensitivity of 89.13 % and specificity 86.36 % respectively (AUORC = 0.888) which is comparable to the finding from patients at all stages of cirrhosis in this study. A recent meta-analysis also reported, the use of platelet count to spleen diameter ratio with a cutoff value of 909 yielded AUORC of 0.88 which is comparable to our study [14]. In our study, the PC/SD ratio was determined separately for small and large varices and revealed AUORC of 0.817 and 0.853, respectively, which is consistent with research done in the United States, which revealed AUORC of 0.83 however the accuracy of PC/SD ratio was better in our study than study done in Ivory Coast, where the best cutoff for diagnosing large OV was 818, with AUORC of 0.654 [15]. Another study conducted in Italy, with a threshold of <736 revealed yielded a sensitivity of 38 % and specificity of 40 % for predicting large varices, which is lower than the sensitivity and specificity found in our study [16].

PC/SD performance for child pugh C patients was also conducted, and at a threshold of >538 we found a specificity of 100 % and sensitivity of 22.7 %. This finding had a lower sensitivity compared to similar studies done in Saudi Arabia, which showed 95 % sensitivity. This difference could be due to the fact that our study included only two patients without varices from a total of 54 patients [17]. Moreover this difference could also be due to distinct genetic characteristics within the study's source populations (European, Asian, African, and American), different stages of patient presentation, and variation in the etiology of the causative agent.

When PC/SD Compared to spleen diameter and platelet count, our study found that PC/SD had highest accuracy (77.8 %–88.3 %) for diagnosing all stages of cirrhosis and varices of any size which is consistent with other similar studies [11,18].

In our study, platelet count ≤121,000 had a sensitivity and specificity of 87.5 % and 73.3 %, respectively (AUC 0.818), for compensated cirrhosis with best cutoff value ≤ 118,000 revealed sensitivity and specificity of 91.3 % and 81.8 %, respectively whereas for large varices with cutoff value ≤ 121,000 revealed specificity of 85.8 % and specificity of 73.3 %. Study groups with small varices, with best cutoff value of ≤121,000 had sensitivity of 88.7 % and specificity of 73.3 %. The findings were found to be comparable among all group of patients in this study. This rate of prediction is comparable to that reported from Italy where the sensitivity was in the range of (63–77 %) while the specificity was (69–88 %), using a cutoff point of 140,000 for patients with liver cirrhosis and 150,000 for those with splenic vein thrombosis [19]. However, our study's sensitivity and specificity were higher than those found in a study from western Tanzania, where a cutoff value of ≤98,000 yielded sensitivity and specificity of 59.1 % and 54.8 %, respectively [20]. This difference could be attributed to variation in etiology, advanced disease at presentation, and cutoff value used is also different in the current study.

In this study splenomegaly also had a good predictive ability (AUC: 0.783) at a cutoff point of >145 mm, yielded a sensitivity of 93.2 % and a specificity of 63.3 % among all cirrhotic patients. A cutoff value of >150 mm has a sensitivity of 91.3 % and a specificity of 77.2 % for compensated cirrhosis patients, Sensitivity of 96.4 % and specificity of 63.3 % were obtained for large EV with best cutoff value > 145 mm, whereas sensitivity of 89.8 % and specificity of 63.3 % were found for small varices with best cutoff value > 145 mm. When compared among subgroups, PC/SD has greater accuracy for predicting large varices in our study. For instance a study conducted in Tanzania with cutoff of 152 mm, revealed a sensitivity of 65.9 % and a specificity of 65.2 %, with comparable specificity and low sensitivity than our study [20]. A SD cutoff value of >102 mm yielded a sensitivity of 86 % and a specificity of 75 % in an Ivory Coast study which is consistent to our study [21]. This study predicted better than those reported in South Carolina where splenomegaly was found to have a sensitivity and specificity of 75 and 57 % respectively in predicting esophageal varices in the United States

[22], which is comparable to a recent meta-analysis review by Thomopoulos and colleagues (sensitivity:75–91 %; specificity: 46–62 %) [11]. This disparity may be due to differences in disease severity and etiology among study populations.

4.1. Limitation of the study

The diagnosis of cirrhosis in this study was not based on histopathologic findings of liver biopsy which is considered as the gold standard. Inter-observer variations might also affect the reports of ultrasound findings.

5. Conclusion and recommendation

Platelet count, spleen diameter, and PC/SD all performed well for EV diagnosis in this study, with better diagnostic performance seen for PC/SD. Even though the performance of those non-invasive parameters cannot completely replace the paramount importance of endoscopy, PC/SD could still guide physicians to initiate prophylactic treatment for EV in health facilities where gastrointestinal endoscopy is not available, especially considering the high mortality of this complication.

Competing interests' declaration

None of the authors received any form of financial or non-financial benefits from the submitted work.

Ethical approval

Ethical clearance was obtained from research and ethical review committee of University of Gondar, college of medicine and health science with ethical approval number Ref no. 1600/2022. Verbal and written consent from each study subjects was obtained, information's were secured after detail explanation about the main purpose of the study. Confidentiality of the information was assured by omitting names of the study subjects from the questionnaire and efforts were made to maintain privacy of the respondents during the interview time.

Data access

All authors were given full access to all of the data in this manuscript and will take responsibility for the integrity and accuracy of the data and its analysis.

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Data availability statement

The minimal anonymized dataset is uploaded with the manuscript.

CRediT authorship contribution statement

Haile Tesfaye Gebregziabher: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Workagegnehu Hailu:** Writing – review & editing, Writing – original draft, Supervision, Methodology. **Zinahbzu Abay:** Writing – review & editing, Writing – original draft. **Segenet Bizuneh:** Writing – review & editing, Writing – original draft, Supervision. **Meiraf Daniel Meshesha:** Writing – review & editing, Formal analysis.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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