

## Original Article

**Diagnostic accuracy of serum - ascites albumin gradient (SAAG) for detection of esophageal varices in patients with liver cirrhosis**

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**Abstract:**

**Introduction:** Identifying patients with compensated cirrhosis who are at risk of developing esophageal varices (EVs) is crucial for effective management. The Serum Ascites Albumin Gradient (SAAG) is a non-invasive laboratory tool that can predict the presence of EVs in cirrhotic patients, with a cutoff value of  $>1.4$  g/dL indicating the need for clinical attention. SAAG can potentially reduce the need for repeated upper endoscopies.

**Objective:** To evaluate the diagnostic accuracy of SAAG in diagnosing esophageal varices in patients with cirrhosis, using endoscopy as the gold standard.

**Materials and Methods:** This cross-sectional study was conducted between April 2023 and October 2023 at the North Medical Ward, Department of Medicine, Mayo Hospital, Lahore. A total of 270 patients with cirrhosis and ascites (age 20-60 years) from both the genders were enrolled using non-probability consecutive sampling. 5cc blood and ascitic fluid samples were collected and sent to the hospital's laboratory for SAAG assessment. Patients underwent endoscopy to determine the presence of EVs, with varices considered present if the esophageal veins measured  $>5$  mm in diameter.

**Results:** The diagnostic performance of SAAG in detecting EVs was evaluated, with sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) calculated. The results showed that SAAG had a sensitivity of 87.5%, specificity of 59.86%, PPV of 66.27%, and NPV of 84.16%.

**Conclusion:** SAAG is a non-invasive, cost-effective tool with high sensitivity but low specificity for diagnosing esophageal varices in cirrhotic patients. Therefore, while SAAG can help reduce the frequency of endoscopy, it should be used in conjunction with other diagnostic methods for more accurate patient management.

**Key Words:** Serum ascites albumin gradient (SAAG), Esophageal Varices, Liver Cirrhosis, Endoscopy

**How to Cite this:**

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**Introduction:**

Progressive liver dysfunction is a hallmark of liver cirrhosis. In the early stages, the liver retains its ability to compensate for normal functions, and with timely diagnosis and treatment, liver function can be sustained for a longer period. However, in the advanced stages of cirrhosis, patients may experience several complications, one of which is gastrointestinal bleeding.<sup>1</sup>

A significant complication of cirrhosis is the development of esophageal varices (EV), with a bleeding risk ranging between 25% and 35%.<sup>2</sup>

Approximately 30-40% of patients with compensated cirrhosis (Child-Pugh class A) present with EV, while this figure increases to 60-85% in patients with decompensated cirrhosis (Child-Pugh classes B and C).<sup>3</sup> Overall, about 50-60% of cirrhosis patients will eventually develop EV.<sup>4</sup> A study conducted in Pakistan found that 14.6% of cirrhotic patients had EV.<sup>5</sup> Identifying patients at risk for EV is crucial in managing cirrhosis effectively.<sup>6</sup>

Non-invasive methods are now available for assessing EV, including scoring systems based

on laboratory investigations, which help minimize the need for repeated endoscopies.<sup>7</sup> The Serum Ascites Albumin Concentration Gradient (SAAG), which is derived from the comparison of albumin levels in ascitic fluid and serum, serves as a useful tool. A high SAAG score ( $>1.1$  g/dL) typically indicates portal hypertension, a leading cause of EV.<sup>8</sup> The incidence of EV can thus be evaluated through a high SAAG score, reducing the necessity for endoscopic procedures.<sup>9</sup> The sensitivity and specificity of the SAAG for detecting EV are reported to be 91% and 50%, respectively, with a positive predictive value (PPV) of 91%, a negative predictive value (NPV) of 50%, and an overall accuracy of 85%.<sup>10</sup> A study by Patel et al. demonstrated a sensitivity of 95.2% and specificity of 44.4%. Another study found a sensitivity of 100%, specificity of 23.1%, PPV of 89.7%, NPV of 100%, and accuracy of 90%.<sup>11</sup>

Endoscopic evaluation of patients at risk for EV also carries the potential risk of exposing individuals to transmissible infections such as hepatitis B and C.<sup>12</sup> As a result, SAAG can be a useful alternative to invasive endoscopic procedures for diagnosing EV. Although the literature has highlighted SAAG's potential as a non-invasive diagnostic tool, its diagnostic accuracy for identifying EV remains a topic of debate.<sup>12</sup>

The goal of this study is to assess the diagnostic accuracy of SAAG for identifying EV in cirrhotic patients, using endoscopy as the gold standard. Endoscopy remains the routine method for diagnosing EVs, but there is an increasing need for non-invasive diagnostic approaches to reduce patient risk, particularly in cases where esophageal bleeding is not present.

### Material and Methods:

This cross-sectional study was conducted over six months (April 9, 2023, to October 9, 2023) at Mayo Hospital Lahore, utilizing a non-probability, consecutive sampling technique. A total of 270 patients were enrolled, with a 95% confidence interval and an expected prevalence of esophageal varices (EV) of 14.5% in cirrhotic patients. The patients were aged 20-60 years, from either gender, with cirrhosis (defined by ALT  $>40$  IU, coarse liver on ultrasound for  $>1$  year, and ascites  $>50$  mL on ultrasound), and ascites. SAAG was considered

positive if the serum ascites albumin concentration gradient (SAAG) was  $\geq 1.1$  g/dL and negative if  $<1.1$  g/dL. Endoscopy was used as the gold standard for diagnosing EVs, defined as positive if esophageal veins were  $>50\%$  larger than normal. All the diabetic patients (blood sugar  $>186$  mg/dL), those with liver or esophageal carcinoma or those who received EV treatment within the last two months were excluded from the study.

A written informed consent was obtained from all participants. Demographic data (age, sex, BMI, duration of cirrhosis) was recorded and a 5cc venous blood and ascitic fluid samples were collected for SAAG analysis. The blood samples were processed in the hospital's laboratory and EV status was determined based on the SAAG result. Patients also underwent endoscopy, which classified varices as mild ( $<3$  mm), moderate (3–6 mm), or severe ( $>6$  mm) based on direct visualization.

Data analysis was performed using SPSS version 22. Descriptive statistics (mean, standard deviation) were calculated for quantitative variables (age, BMI, duration of cirrhosis). Frequency and percentage were determined for categorical variables (gender, EV status). Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy of SAAG were calculated using endoscopy as the gold standard. Stratified analyses by age, gender, BMI, and cirrhosis duration were also performed.

### Results:

Mean age of patients included in this study was  $39.24 \pm 11.57$  years. Among patients 137(50.7%) were male and 133(49.3%) were females. As per body mass index criteria 96(35.6%) patients body mass index was normal. As per SAAG findings 169(62.6%) patients were positive for esophageal varices. As per endoscopic findings 128(47.4%) patients were positive for esophageal varices. Diagnose accuracy parameters calculation showed that sensitivity and specificity of SAAG was 87.5% and 59.86% respectively. PPV and NPV for SAAG was 66.27% and 84.16% respectively (**Table-1**). An increasing trend was seen in specificity as increase in age. In younger age groups specificity of SAAG was lower as compared to elderly age group patients. However, for sensitivity opposite

trend was seen. In younger age group sensitivity was higher as that of elderly age group patients (**Table-2**). Among male patients sensitivity and specificity of SAAG was 86.67% and 54.55% and among female patients it was 88.24% and 66.15% respectively (**Table-3**). Among obese patients sensitivity (83.72%) and specificity (57.45%) of SAAG was lower as that of patients with normal body mass index [Sensitivity: 93.48% & Specificity: 56%] and overweight patients [Sensitivity: 84.62% & Specificity: 66.67%] (**Table-4**). Patients with duration of cirrhosis as 2-3(years) among them sensitivity and specificity of SAAG was 86.11% and 55.13% respectively. While patients with duration of cirrhosis as 4-5(years) among them sensitivity and specificity of SAAG was 89.29% and 65.63% respectively (**Table-5**).

*Table-1: Diagnostic Accuracy of SAAG taking Endoscopy as Gold Standard for diagnosis of esophageal varices in patients with liver cirrhosis*

SAAG	Endoscopy		Total
	Positive	Negative	
Positive	112(87.5%)	57(40.1%)	169
Negative	16(12.5%)	85(59.9%)	101
Total	128	142	270

**Sensitivity**=87.5% (80.66, 92.16)

**Specificity**=59.86% (51.64, 67.56)

**Positive Predictive value**=66.27% (58.85, 72.97)

**Negative Predictive value**=84.16% (75.81, 90.01)

**Diagnostic accuracy**=72.96% (67.37, 77.91)

*Table-2: Diagnostic Accuracy of SAAG taking Endoscopy as Gold Standard stratified for age for diagnosis of esophageal varices in patients with liver cirrhosis*

SAAG		Endoscopy		Total
		Positive	Negative	
20-30	Positive	28(93.3%)	24(49%)	52
	Negative	2(6.7%)	25(51%)	27
31-40	Positive	32(91.4%)	12(37.5%)	44
	Negative	3(8.6%)	20(62.5%)	23
>40	Positive	52(82.5%)	21(34.4%)	73
	Negative	11(17.5%)	40(65.6%)	51

	20-30	31-40	>40
Sensitivity	93.33%	91.43%	82.54%
Specificity	51.02%	62.5%	65.57%
PPV	53.85%	72.73%	71.23%
NPV	92.59%	86.96%	78.43%
DA	67.09%	77.61%	74.19%

*Table-3: Diagnostic Accuracy of SAAG taking Endoscopy as Gold Standard stratified for Gender for diagnosis of esophageal varices in patients with liver cirrhosis*

		Endoscopy		Total
		Positive	Negative	
Male	Positive	52(86.7%)	35(45.5%)	87
	Negative	8(13.3%)	42(54.5%)	50
Female	Positive	60(88.2%)	22(33.8%)	82
	Negative	8(11.8%)	43(66.2%)	51

	Male	Female
Sensitivity	86.67%	88.24%
Specificity	54.55%	66.15%
PPV	59.77%	73.17%
NPV	84%	84.31%
DA	68.61%	77.44%

*Table-4: Diagnostic Accuracy of SAAG taking Endoscopy as Gold Standard stratified for body mass index for diagnosis of esophageal varices in patients with liver cirrhosis.*

		Endoscopy		Total
		Positive	Negative	
Normal	Positive	43(93.5%)	22(44%)	65
	Negative	3(6.5%)	28(56%)	31
Overweight	Positive	33(84.6%)	15(33.3%)	48
	Negative	6(15.4%)	30(66.7%)	36
Obese	Positive	36(83.7%)	20(42.6%)	56
	Negative	7(16.3%)	27(57.4%)	34

	Normal	Overweight	Obese
Sensitivity	93.48%	84.62%	83.72%
Specificity	56%	66.67%	57.45%
PPV	66.15%	68.75%	64.29%
NPV	90.32%	83.33%	79.41%
DA	73.96%	75%	70%

*Table-5: Diagnostic Accuracy of SAAG taking Endoscopy as Gold Standard stratified for duration of Cirrhosis for diagnosis of esophageal varices in patients with liver cirrhosis.*

Endoscopy				Total
	Positive	Negative		
2-3 years	Positive	62(86.1%)	35(44.9%)	97
	Negative	10(13.9%)	43(55.1%)	53
4-5 years	Positive	50(89.3%)	22(34.4%)	72
	Negative	6(10.7%)	42(65.6%)	48

	2-3	4-5
Sensitivity	86.11%	89.29%
Specificity	55.13%	65.63%
PPV	63.92%	69.44%
NPV	81.13%	87.5%
DA	70%	76.67%

## Discussion:

The risk of bleeding from esophageal varices (EV) is a critical concern in patients with cirrhosis and portal hypertension. Several diagnostic tools, including ultrasound and biochemical tests, help assess this risk. One key biochemical measure is the Serum Ascites Albumin Gradient (SAAG), a reliable indicator of portal hypertension. A SAAG value greater than or equal to 1.1 g/dL typically indicates portal hypertension, whereas values lower than 1.1 g/dL suggest non-portal hypertensive causes of ascites. Correcting SAAG levels may reduce the risk of bleeding from varices by identifying and managing portal hypertension effectively.<sup>13</sup>

Several studies have highlighted the role of SAAG in assessing EV in cirrhotic patients. Eldeeb GS et al. demonstrated that SAAG had a sensitivity of 87.5%, specificity of 59.86%, positive predictive value (PPV) of 66.27%, and negative predictive value (NPV) of 84.16%.<sup>14</sup> Another study, conducted by Sharma et al. in India reported a SAAG sensitivity of 81% and a specificity of 100%.<sup>15</sup> However, the discrepancy in SAAG levels observed in this study, when compared to its sensitivity, was in contrast with the findings from other studies, suggesting a potential issue in standardization or population differences. In addition, a study

by Das BB reported a SAAG sensitivity of 91% and specificity of 50%, with an overall accuracy of 85%, a PPV of 91%, and an NPV of 50%.<sup>16</sup> Similarly, Chaurasia AK found a sensitivity of 95.2% and specificity of 44.4%<sup>17</sup> and Kumar S reported a sensitivity of 100% and a specificity of 23.1%, with a PPV of 89.7% and an NPV of 100%.<sup>18</sup> A common trend in these studies is the higher sensitivity of SAAG, coupled with lower specificity, which indicates that SAAG is more reliable in detecting patients at risk of variceal bleeding but may result in false positives. This variation in diagnostic performance across studies could be attributed to differences in sample size, sample selection criteria, and the cut-off points used for SAAG.

SAAG also serves to determine the severity of portal hypertension. A higher SAAG ( $\geq 1.1$  g/dL) indicates significant portal hypertension, while a lower SAAG ( $< 1.1$  g/dL) suggests the absence of portal hypertension.<sup>19,20</sup> The threshold of 1.1 g/dL is crucial as it provides clinicians with an indication of whether further investigation, such as endoscopy, is warranted to assess EV risk.

Endoscopy remains the gold standard for diagnosing EV, gastric varices, and portal hypertensive gastropathy.<sup>21</sup> However, SAAG provides a valuable alternative for evaluating portal hypertension and estimating the risk of variceal bleeding. Using SAAG as a screening tool could help identify patients who may not require immediate endoscopic evaluation, potentially reducing healthcare costs, minimizing patient discomfort, and alleviating the burden on endoscopy units.<sup>22,23</sup> By using SAAG to stratify patients based on their risk, healthcare systems could optimize the allocation of resources, ensuring that high-risk patients receive timely intervention while low-risk patients are spared unnecessary procedures.

## CONCLUSION:

The results of this study indicate that the Serum Ascites Albumin Gradient (SAAG) demonstrates high sensitivity but low specificity in diagnosing esophageal varices in cirrhotic patients. Hence, SAAG is an important non-invasive screening tool to detect EV in selected group of patients to avoid undergoing unnecessary endoscopic procedure.

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#### **Author's Contribution:**

**DN:** Conceived and designed the study, involved in data collection, performed statistical analysis and writing the manuscript.

**MSA, IUH, AAK, SH, MKY:** Collected the data, critical review and preparation of manuscript.

All authors have read, approved the final manuscript and are responsible for the integrity of the study.