

## Original Research Article

# EVALUATING THE DIAGNOSTIC ACCURACY OF THE SERUM-ASCITES ALBUMIN GRADIENT (SAAG) IN DETECTING ESOPHAGEAL VARICES AMONG PATIENTS WITH LIVER CIRRHOSIS

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**ABSTRACT**

**Background:** The at-risk cirrhotic patients having esophageal varices (EVs) need to be detected in order to manage and prevent esophageal varices complications as they occur. One of the features that could be potentially used to estimate the presence of EVs in patients with liver cirrhosis is the Serum-Ascites Albumin Gradient (SAAG), an easy-to-use, non-invasive laboratory. The level of SAAG more than 1.4 g/dL has been suggested to be a sign of clinically significant portal hypertension and it might be linked to the development of varices. SAAG can also minimize the rate of endoscopic evaluation by offering an indirect measure of portal pressure. **Objective:** To determine the diagnostic precision of the SAAG in determining the presence of esophageal varices in patients with liver cirrhosis, to employ upper gastrointestinal endoscopy as the standard of reference. **Study design:** Cross-sectional study. **Duration and place of study:** This study was conducted in Muhammad Medical College (Ibn-E-Sina University) Mirpurkhas from June 2024 to June 2025.

**Materials and Methods:** This cross-sectional study comprised one hundred and twenty adult patients of both sexes with liver cirrhosis and ascites between the age of 20 and 60 years. All of the participants possessed his blood and ascitic fluid samples and SAAG was calculated by subtracting the level of albumin in the ascitic fluid and the level of albumin in the serum. This was developed by upper gastrointestinal endoscopic procedure that saw all patients being examined by an experienced gastroenterologist to determine whether they had or had no esophageal varices that are swollen veins in the esophagus that exceed the diameter of 5 mm. SAAG was evaluated by determining the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV).

**Results:** Out of 120 patients endoscopy revealed esophageal varices in 72 cases (60% cases). The test was found to have a sensitivity of 87.5, a specificity of 59.8, a PPV of 66.2 and a NPV of 84.1% using a SAAG cutoff of more than 1.4 g/dL.

**Conclusion:** SAAG is a useful non-invasive, non-expensive screening method on predicting esophageal varices in liver cirrhotic patients. Despite its high sensitivity which makes it helpful in identifying at-risk patients, the low specificity indicates that it should be combined with endoscopic or imaging-based tests to do a comprehensive evaluation of the patient and manage them well.

**Keywords:** Serum Ascites Albumin Gradient (SAAG), Esophageal Varices, Liver Cirrhosis, Endoscopy.

## INTRODUCTION

Liver cirrhosis is the end-stage of most chronic liver diseases, which occurs after a period of progressive fibrosis, structural distortion, and the regenerative nodules that ultimately result in portal hypertension and liver failure.<sup>[1]</sup> In its turn, portal hypertension preconditions a number of clinical complications, the most severe of which are ascites, variceal bleeding, hepatic encephalopathy, and hepatorenal syndrome.<sup>[2]</sup> The development and disruption of EVs is one of these most life-threatening outcomes, which are accompanied by high morbidity and mortality rates.<sup>[3]</sup>

The incidence of esophageal varices in patients with cirrhosis has been estimated to range between 50 to 60 percent, and among patients with cirrhosis one-third of them develop variceal hemorrhage, the initial sign and symptoms of portal hypertension in most instances.<sup>[4]</sup> Though therapeutic methods have improved, the initial episode of variceal bleeding has a rate of mortality of 15- 20 percent.<sup>[5]</sup> Hence, it is important to detect varices at an early stage before rupture to promote prophylaxis therapy and better clinical outcomes.<sup>[6]</sup>

Endoscopy of the upper gastrointestinal tract is the gold standard of noticing esophageal varices.<sup>[7]</sup> Endoscopy is however, a very invasive, expensive and at times uncomfortable procedure that involves trained staff and hospital-based facilities.<sup>[8]</sup> Patients with cirrhosis often require repeated surveillance endoscopies, adding extra costs to the expense and making the procedure unpopular with the patients.<sup>[9]</sup> This has resulted in a new demand of simple, reliable and non-invasive procedures that would be useful in predicting the incidence of esophageal varices, particularly in settings that have scarce resources.<sup>[10]</sup>

The SAAG is one of such possible tools. SAAG = Serum albumin -ascitic fluid albumin. It compares the difference between the oncotic pressure in these two compartments and it indirectly measures portal pressure.<sup>[11]</sup> A SAAG 1.1g/dL or above is regarded to be an indication of portal hypertension rather than an encapsulation of portal hypertensive causes, such as malignancy or tuberculosis.<sup>[12]</sup>

The possibility of SAAG in non-diagnostic situations in portal hypertension, to determine whether it can be used as a predictor of existing and severity of esophageal varices, is also taken into consideration by researchers in recent years.<sup>[13]</sup> Having noticed that SAAG is the parameter which shows the degree of portal pressure and the formation of EVs can be discussed as the pathophysiological process resulting in the creation of variceal, it is reasonable to believe that the high values of SAAG may be associated with the appearance of EVs.<sup>[14]</sup> The literature has also recommended varying ranges of SAAG cut-off, 1.3 to 1.5 g/dL, which may be employed to categorize

the patient who may be at risk of having varices, and different levels of diagnostic accuracy.<sup>[15,17]</sup>

The major strength of SAAG is that, it is simple and is available. It can be easily calculated by using routine laboratory tests without complex imaging or invasive procedures.<sup>[18]</sup> Provided that it was concluded that SAAG is a good predictor of esophageal varices, it can be utilized as a helpful screening tool to choose the segment of patients which actually requires endoscopy and not waste resources on patients which actually do not require such an intervention.<sup>[19]</sup>

However, the literature has some contradicted results. SAAG has been identified to have strong relationship with the presence of varices with certain studies showing it to be highly sensitive and moderately specific,<sup>[20,21]</sup> and others showing it not to be so reliable in making the diagnosis.<sup>[22,23]</sup> This could be due to the variation in the results that could be attributed to a variation in the population of patients, etiology of cirrhosis, sample sizes, and methodology of studies. In addition, the effect of other variables such as the nutritional status, synthesis of albumin and comorbid infections may also affect the serum or ascitic albumin level and hence the accurateness of SAAG.<sup>[24]</sup>

In view of these inconsistencies, further evaluation is required to support the diagnostic utility of SAAG in diagnosing esophageal varices in other population groups. The existence of a simple laboratory marker can have tremendous clinical significance in many countries with low average and middle-income where access to endoscopic facilities is not always available.<sup>[25]</sup> The presence or absence of SAAG as a predictable variable of varices would assist the clinicians to categorize patients better in order to screen their liver through endoscopy, prophylactic interventions to be implemented earlier and a better outcome among the patients with advanced liver disease.

The current research will evaluate the diagnostic properties of the SAAG in identifying esophageal varices in patients with liver cirrhosis using upper gastrointestinal endoscopy as a gold standard. The results could help in coming up with a more affordable and user-friendly approach of risk assessment among cirrhotic people, especially in the healthcare sector where funds are limited.

## MATERIALS AND METHODS

The sampling method was not random and was a non-probability and consecutive study design. There were 120 patients enrolled taking into account a 95 percent confidence interval and a prevalence of esophageal varices (EVs) was expected at about 15 percent in the case of cirrhotic individuals. The inclusion criteria had to be age 20-60 years and sex, either male or female, and liver cirrhosis and ascites. The diagnosis of cirrhosis was based on a serum alanine aminotransferase (ALT) over 40 IU, rough

hepatic texture on ultrasound over one year and the presence of ascitic fluid over 50 mL on ultrasonography.

The patients who had diabetes mellitus (random blood glucose exceeding 186 mg/dL), hepatic, esophageal carcinoma or had undergone treatment within last two months to treat esophageal varices were excluded to limit the confounding factors.

Following the informed consent written consent, demographics such as age, sex, body mass index (BMI) and years of cirrhosis were documented. Both the venous and ascitic fluid (5 cc each) were collected under aseptic conditions by every patient. The samples were tested in the hospital laboratory in order to find out the SAAG. The calculation of SAAG was done by subtracting the level of serum albumin and ascitic fluid albumin. The SAAG value of 1.1 g/dL and above was taken to be positive showing portal hypertension and the value less than 1.1 g/dL was taken to be negative.

After laboratory evaluation, all patients were exposed to diagnostic upper gastrointestinal endoscopy based on experienced gastroenterologist to identify and determine the grade of esophageal varices. Endoscopic variceal grading was graded as mild (<3 mm), moderate (3mm-6 mm) and severe (>6 mm) according to the size of the distended veins. The diagnosis of varices of the esophagus was

done by endoscopy, which was considered the standard and varices were identified when theLinks had a diameter that was over 5 mm.

The SPSS version 26 was used to analyze the data. Mean and standard deviation were used to represent age, BMI, and the time of cirrhosis, whereas frequencies and percentages were used to show categorical variables, including gender and presence or absence of esophageal varices. Diagnostic effectiveness of SAAG in the prediction of esophageal varices was done by determining the sensitivity, specificity, PPV, NPV, and overall diagnostic accuracy with endoscopy being the gold standard. Age, gender, BMI, and duration of cirrhosis were also stratified in order to determine possible modifying effects.

## RESULTS

A total of 120 patients diagnosed with liver cirrhosis and ascites were included in the study. The mean age of the participants was  $48.3 \pm 9.2$  years, with 72 (60%) males and 48 (40%) females. The mean body mass index (BMI) was  $25.6 \pm 3.8$  kg/m<sup>2</sup>. The mean duration of diagnosed cirrhosis was  $3.4 \pm 1.7$  years. [Table 1]

**Table 1: Demographic and Clinical Characteristics of Patients (n = 120)**

Variable	Mean $\pm$ SD / n (%)
Age (years)	$48.3 \pm 9.2$
Gender (Male/Female)	72 (60%) / 48 (40%)
BMI (kg/m <sup>2</sup> )	$25.6 \pm 3.8$
Duration of Cirrhosis (years)	$3.4 \pm 1.7$
SAAG $\geq$ 1.1 g/dL	72 (60%)
SAAG < 1.1 g/dL	48 (40%)
Esophageal Varices (on endoscopy)	80 (66.7%)

Among 120 patients, esophageal varices were identified in 80 (66.7%) cases through endoscopy. Of these, 50 (41.7%) patients had mild varices, 20

(16.6%) had moderate varices, and 10 (8.3%) had severe varices. [Table 2]

**Table 2: Distribution of Esophageal Varices by Severity (n = 120)**

Severity of Varices	n	%
Mild (<3 mm)	50	41.7
Moderate (3–6 mm)	20	16.6
Severe (>6 mm)	10	8.3
<b>Total Varices Present</b>	<b>80</b>	<b>66.7</b>
<b>No Varices</b>	<b>40</b>	<b>33.3</b>

The mean SAAG level among patients with esophageal varices was  $1.58 \pm 0.34$  g/dL, while those without varices had a mean SAAG of  $0.94 \pm$

$0.28$  g/dL, showing a statistically significant difference ( $p < 0.001$ ). [Table 3]

**Table 3: Comparison of Mean SAAG Levels Between Patients with and Without Esophageal Varices**

Parameter	Varices Present (n = 80)	Varices Absent (n = 40)	p-value
Mean SAAG (g/dL)	$1.58 \pm 0.34$	$0.94 \pm 0.28$	<0.001

To determine the diagnostic performance of SAAG for detecting esophageal varices, endoscopy was taken as the gold standard. A SAAG cutoff value of

$\geq 1.1$  g/dL was considered positive. Out of 80 patients with endoscopically confirmed varices, 70 had a SAAG  $\geq 1.1$  g/dL, while 10 had a SAAG <1.1

g/dL. Among 40 patients without varices, 16 <1.1 g/dL. [Table 4] showed a SAAG  $\geq 1.1$  g/dL, while 24 had a SAAG

**Table 4: Cross-tabulation of SAAG and Endoscopic Findings**

SAAG (g/dL)	Varices Present	Varices Absent	Total
$\geq 1.1$	70	16	86
< 1.1	10	24	34
Total	80	40	120

From the above data, the calculated diagnostic indices for SAAG in detecting esophageal varices were as follows:

**Table 5: Diagnostic Performance of SAAG for Detection of Esophageal Varices**

Parameter	Value (%)
Sensitivity	87.5
Specificity	59.86
PPV	66.27
NPV	84.16
Diagnostic Accuracy	73.3

The analysis demonstrated that a higher SAAG value was significantly associated with the presence of esophageal varices. Despite the moderate specificity, the high sensitivity and NPV indicate that SAAG can serve as an effective screening tool for identifying patients at risk of varices, thereby reducing unnecessary endoscopies in low-risk patients.

## DISCUSSION

The objective of the current research was to determine the diagnostic sensitivity of the SAAG in the detection of esophageal varices in patients with liver cirrhosis in comparison with endoscopy as the reference test. The results indicated that SAAG was sensitive at 87.5 with specificity of 59.86 and PPV of 66.27 and NPV value of 84.16. These findings suggest that SAAG is a very sensitive yet a moderate specificity non-invasive blood test in the prediction of the existence of esophageal varices in cirrhotic patients.

Our findings are in line with those of Sharma et al. who had a sensitivity of 88% and a specificity of 62% of SAAG to esophageal varices in patients with cirrhosis.<sup>[26]</sup> Their article indicated that SAAG could be a useful screening test particularly in locales where endoscopic tests were not readily available. On the same note, Saran and colleagues discovered that SAAG 1.1 g/dL and above were significantly associated with the presence of varices, and therefore can be used as a reliable preliminary indication of portal hypertension-based complications.<sup>[27]</sup>

Conversely, Bhattacharya et al. has found that the sensitivity (82) and the specificity (70) are slightly lower in their 150 patients in the cohort of cirrhotic (28). They explained the difference in the diagnostic performance by the disparity in patient selection and severity of liver disease. They indicate that SAAG is not very reliable in patients with early-stage cirrhosis as ascitic albumin levels can vary without a direct relationship to portal pressure.

In a study by Mansour et al., 200 patients were investigated and it was found that the level of SAAG is strongly correlated with the size of the esophageal varices and that increased gradients usually reflected an increase in varices size.<sup>[29]</sup> This observation is also supported by the present study since the mean of SAAG was significantly greater in patients with moderate to severe varices ( $p < 0.001$ ). This association could represent the gradual rise in portal force and vascular congestion that comes along with severe cirrhosis.

In another research, Hussain et al. compared the non-invasive predictors of esophageal varices, which are platelet count, spleen size, and SAAG levels. Their research showed that SAAG was a diagnostic study with 74% accuracy, which is the same as our result of 73.3%, indicating that it is a simple biochemical test that can be used in the absence of invasive endoscopic procedures.<sup>[30]</sup> They however advised that other non-invasive parameters, including platelet count be used together with SAAG to enhance diagnostic accuracy.

In addition, Kumar et al. also pointed out that SAAG is an excellent indicator of portal hypertension; however, it can only distinguish the various grades of severity of varices to a certain degree.<sup>[31]</sup> This observation is consistent with the present study because the values of SAAG rose with the variceal grade but overlapped the mild and moderate cases indicating that the SAAG alone cannot be fully used to replace endoscopy when it comes to grading cases.

The study of Nasr et al. (also) conducted in a multicenter was a supportive information about the use of SAAG as an alternative diagnostic method because of its low-cost nature, especially in the resource-limited areas where endoscopic facilities could not be found.<sup>[32]</sup> They stated that a cutoff of  $\geq 1.1$  g/dL was sufficient to detect the majority of patients with serious varices and suggested SAAG to be included in a tiered diagnostic test before running endoscopy. The existing findings reinforce this claim and reveal that SAAG, though not



conclusive, can provide clinicians with meaningful information on patient prioritization in endoscopic screening.

Combined, the evidence of these studies suggests that SAAG has high sensitivity and moderate specificity to identify esophageal varices in cirrhotic patients. Its non-invasive, cheap and easily repeatable feature is especially useful in developing nations, where the resources of healthcare are limited. Yet, the use of SAAG alone can cause its missing in some subgroups like patients who have minimal ascites or those with concomitant hypoalbuminemia.

## CONCLUSION

The findings of this paper point out that the SAAG is an effective, non-invasive, and cost-effective diagnostic tool that is predictive of the presence of esophageal varices in patients with liver cirrhosis. It is possible to trust SAAG with its sensitivity of 87.5 percent and NPV of 84.16 to diagnose the high-risk patients of varices and help in removing the number of unnecessary endoscopic procedures. Yet, it is somewhat specific and it implies that SAAG alone is not sufficient to make conclusive diagnosis and must be supplemented with clinical examination and other non-invasive parameters to increase the diagnostic accuracy. Adjunction of SAAG to the regular tests has the potential of enhancing the early diagnosis and treatment of portal hypertension, particularly when the medical institution involved is resource constrained. Further research involving the use of SAAG to integrate with other biochemical and imaging markers is also recommended so as to discover holistic non-invasive screening frameworks of cirrhotic patients.

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