International Journal of Research in Medical Sciences
Kiran NC et al. Int J Res Med Sci. 2026 Jan;14(1):130-134
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20254371

Original Research Article

Diagnostic accuracy of serum-ascites albumin gradient in esophageal varices in cirrhosis

Kiran N. C.[1]*, Manisha Bais Thakur[1], Anita Rani[2]

[1]Department of Medicine, Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi, India
[2]Department of Biochemistry, Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi, India

Received: 05 November 2025
Accepted: 11 December 2025

***Correspondence:**
Dr. Kiran N. C.,
E-mail: knc867@gmail.com

ABSTRACT

Background: Chronic liver disease (CLD) is the major global health concern. Portal hypertension leads to Esophageal Varices (EVs), when bleeds have a high mortality rate. Early diagnosis and treatment of EVs improves patient outcome and decrease mortality. The serum ascites albumin gradient (SAAG) has been used as a biomarker for detecting portal hypertension. In this study, we aimed to assess the diagnostic accuracy of SAAG in predicting EVs in cirrhotic patients.
Methods: This was an observational cross-sectional study, conducted at Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi. 75 cirrhotic patients were enrolled, SAAG was calculated and Upper GI Endoscopy was performed to screen for EVs. Diagnostic performance of SAAG was assessed using specificity, sensitivity, positive predictive value, negative predictive value and receiver operating characteristic curve (PPV, NPV and ROC) analysis.
Results: The patient demographics showed a predominance of males (82.67%) with alcohol being the main cause of CLD. A strong positive correlation was found between SAAG and EVs grade. SAAG value of >1.4g/dl predicted varices with a sensitivity of 93.65%, specificity of 100%, AUC of 0.968 (p value <0.0001) and diagnostic accuracy of 94.67%. SAAG value of >1.8g/dl predicted high-risk varices with a sensitivity of 100%, specificity of 88.68% (p value <0.0001), AUC of 0.992, PPV of 78.6% (95%CI:59.0-91.7%) and diagnostic accuracy of 92.00%.
Conclusions: The study shows that SAAG is a reliable marker for predicting EVs in cirrhotic patients and can be used for early identification of at-risk patients, facilitate in timely and effective management to prevent serious complications.

Keywords: Albumin, Cirrhosis, CLD, Diagnostic accuracy, Endoscopy esophageal varices, Grades of EV, Portal hypertension, SAAG, Variceal rupture

INTRODUCTION

Liver diseases are gaining recognition as a public health priority within India as it led to 18.3% of the two million worldwide deaths related to liver disease in 2015 and ranks as the ninth most common cause of fatality in India, registering 19.6 deaths per 100,000 individuals according to 2019.[1,2]

Cirrhosis is characterised by widespread fibrous scarring of the liver, which replaces the normal liver structure with nodular formations.[3] The prevalence of cirrhosis, on the rise due to increased alcohol use, obesity, and metabolic diseases, leading to MAFLD and chronic hepatitis.

Cirrhosis leads to increase in the hepatic venous pressure gradient (HVPG) which, when exceeds 5 mmHg, referred to as portal hypertension (PHT).[4] Esophageal varices are the collaterals between Portal and systemic venous circulation formed in the submucosa of the lower esophagus as a consequence of PHT. Upon diagnosis, around 30% of patients with cirrhosis have EVs, increasing to 90% after about ten years. Bleeding from EVs has a mortality rate of at least 20% at six weeks.[5] For patients having a HVPG exceeding 20 mmHg, the

mortality rate within 30 days is significantly high, at 20% w, in comparison with those with lower pressure, who are at higher risk for recurrent bleeding within the first week of admission or of failure to control bleeding (83% vs. 29%) and have a higher 1-year mortality rate (64% vs. 20%).[6]

Upper GI Endoscopy is the only gold standard modality established to know the oesophageal varices; it should be done as early as possible to detect varices and prevent bleeding, but its limitations are it is relatively expensive, invasive, requires technical expertise and is unavailable everywhere.

The serum-ascites albumin gradient (SAAG) is a minimally invasive method that is precise and has already been described in the classification of ascitic fluid based on the absence or presence of PHT.[5] SAAG may be regarded as an indirect indicator for identifying EVs and is beneficial in areas where human and material resources for conducting UGE are limited. This study aimed to determine the diagnostic accuracy of SAAG in predicting EVs in cirrhotic patients.

METHODS

The study was conducted in the Department of General Medicine (VMMC and Safdarjung Hospital, New Delhi) from 2022-2024, Observational Cross-sectional Study The study included 75 subjects. The study was approved by Institutional Ethical committee.

Inclusion criteria

All the subjects above the age of 18 years with a diagnosis of cirrhosis ultrasonically.

Exclusion criteria

Subjects with congestive heart failure, hepatocellular carcinoma/any other malignancies, chronic kidney disease and nephrotic syndrome, abdominal tuberculosis, pregnancy, malnutrition were excluded.

Study process

As per inclusion criteria, all the subjects had undergone Ultrasound and CLD was diagnosed. A detailed history was taken, and physical examinations were done. CBC, LFT, KFT, viral markers, PT-INR, urine routine and microscopy was done. Under aseptic precaution, ascitic fluid was tapped and sent for cytology, biochemistry, ascitic albumin. SAAG was calculated, and all the subjects underwent upper GI endoscopy during the hospital stay. Varices were graded as per BEPPU classification.[7]

Endoscopy was done for the patient who meets the inclusion criteria by a single endoscopist.

Statistical analysis

The categorical variables were described by counts and percentages (%), while the quantitative data were described using means ± standard deviation (SD), along with medians and the interquartile range (IQR) defined by the 25th and 75th percentiles. The normality of the data was assessed using Shapiro-Wilk test. For quantitative variables, associations were analysed using the independent t-test. Fisher's exact test was used for qualitative variables because at least one cell had an expected value of less than 5.

Univariate and multivariate logistic regression analyses were conducted to find significant risk factors for varices. The ROC curve was used to determine the optimal cut-off point, as well as the sensitivity, specificity, PPV and NPV value of the SAAG in predicting the presence and grade of varices. The Spearman's correlation coefficient was used to determine the correlations between the grade of EVs and SAAG, Child-Turcotte-Pugh (CTP) score, and Model for End-Stage Liver Disease (MELD) score. A p-value of <0.05 was considered statistically significant.

RESULTS

Our study included 75 patients who met the inclusion and exclusion criteria. The diagnostic accuracy of SAAG in EVs in cirrhosis was determined. Of 75 patients, 62 (82.67%) were male, and 13 (17.33%) were female.

Baseline characteristics

The mean age of the study patients was 46.05±8.8 yrs, the most represented age group of 41 to 50 years (45.33%). Alcohol is the most common aetiology of CLD in our study, which was 56.00%; Hepatitis B, Hepatitis C, MASH, Autoimmune and other causes constituted the rest, 44.00% (18.67%, 10.67, 9.33% and 2.67%, respectively). Mean value ± SD of serum albumin and Ascitic fluid albumin was 2.76±0.46 and 1.01±0.53 (Table 1). Among 75 patients, 21.33% cases had SAAG of 1.1 to 1.49 g/dl, 53.33% cases had SAAG of 1.5 to 1.99 g/dl and 25.33% cases had SAAG of ≥2g/dl. Mean±SD SAAG is 1.74±0.33 g/dl (Table 2).

Of the patients, 82.67% belonged to CTP class C, 14.67% were Class B, and 2.67% were Class A. The mean MELD score among the study subjects was 16.56±3.32, with a median (25^{th} -75^{th} percentile) of 16 (15-18) (Table 3).

Among 75 patients, 33 (44.00%) patients have Grade F2 EVs, 22 (29.33%) Grade F3 EVs, 8 (10.67%) Grade F1 EVs and 12 (16.00%) had no varices (Table 3). Of those, 88.89% of patients with EVs belonged to CTP Class C, 9.52% belonged to CTP Class B, and only 1.59% belonged to Class A (Table 4).

In a patient with SAAG 1.1-1.49g/dl, only 6.35% of patients had EVs as compared to patients with SAAG

values of 1.5-1.99g/dl and >2g/dl; all patients had EVs. Mean±SD SAAG was higher in patients with esophageal varices (1.83±0.28g/dl vs. 1.3±0.09g/dl, p<0.0001) (Table 5).

Table 1: Basic characteristics of patients.

Variable	Total, %
Age	46.05±8.8
Gender	
Female	17.33
Male	82.67
Etiology	
Alcohol	56.00
Hepatitis B	18.67
Hepatitis C	10.67
MASH related	9.33
Autoimmune	2.67
Other	2.67
Investigation	
Hemoglobin (g/dl)	9.72±1.91
Total leucocyte count (cells/mm^3)	6772±1599.37
Platelet count (cells/µl)	73337.33±35781.12
Total bilirubin (mg/dl)	5.25±2.74
AST (U/l)	119.69±82.87
ALT (U/l)	59.19±37.15
ALP (U/l)	152.6±53.25
PT (seconds)	15.82±3.55
INR	1.41±0.64
Total serum protein (g/dl)	6.69±0.99
Albumin (g/dl)	2.76±0.46
Ascitic fluid sugar (mg/dl)	101.83±31.42
Ascitic albumin (g/dl)	1.01±0.53

ALP- Alkaline Phosphatase; ALT- Alanine Transaminase; AST- Asparatate Transaminase; MASH-Metabolic dysfunction associated Steatohepatitis; PT- Prothrombin Time

Table 2: SAAG range and percentage of patients.

SAAG	Percentage
1.1 to 1.49 g/dl	21.33
1.5 to 1.99 g/dl	53.33
>=2 g/dl	25.33
Mean±SD	1.74±0.33
Median (25th -75th percentile)	1.8 (1.55-1.95)
Range	1.2-2.4

SD- Standard Deviation

The AUROC curve (AUC 0.968; 95% CI: 0.931 to 1.000) indicates, SAAG is the significant predictor of varices at the cut-off point of >1.4 g/dl with the AUROC of 0.968 for correctly predicting the presence of varices. It shows that, of the patients with varices, 93.65% had SAAG >1.4 g/dl. SAAG >1.4 g/dl, had 100.00% probability of the presence of varices; if SAAG <=1.4 g/dl, there was a 75.00% chance of no varices (Table 6).

Table 3: CTP and MELD profile of patients.

Variable	Mean±SD	Median (25th -75th percentile)	Range
CTP score	10.32±1.2	10 (10-11)	6-13
MELD score	16.56±3.32	16 (15-18)	9-33
CTP class	**Frequency**	**Percentage**	
A	2	2.67	
B	11	14.67	
C	62	82.67	
Total	75	100.00	

Table 4: EVs grade and frequency.

UGIE: EVs grade	Frequency	Percentage
No varices	12	16.00
F1	8	10.67
F2	33	44.00
F3	22	29.33
Total	75	100.00

Table 5: Distribution EVs according to SAAG.

SAAG (g/dL)	Total pt	Absence of EVs (n=12)	Presence of EVs (n=63)	P value
1.1 to 1.49	16 (21.33)	12 (100)	4 (6.35)	<0.0001*
1.5 to 1.99	40 (53.33)	0 (0)	40 (63.49)	
>=2	19 (25.33)	0 (0)	19 (30.16)	
Mean±SD	1.74±0.33	1.3±0.09	1.83±0.28	<0.0001†
Median	1.8 (1.55-1.95)	1.3 (1.2-1.4)	1.8 (1.6-2)	
Range	1.2-2.4	1.2-1.4	1.2-2.4	

†Independent t-test, *Fisher's exact test

Table 6: Diagnostic performance of SAAG >1.4 g/dL.

Variables	Values
Area under the ROC curve (AUC)	0.968
Standard error	0.0192
95% Confidence interval	0.931 to 1.000
P value	<0.0001
Cut off	>1.4 g/dl
Sensitivity (95% CI)	93.65 (84.5-98.2)
Specificity (95% CI)	100 (73.5-100.0)
PPV (95% CI)	100 (93.9-100.0)
NPV (95% CI)	75 (47.6-92.7)
Diagnostic accuracy, %	94.67

An AUROC curve (AUC 0.992; 95% CI: 0.982 to 1.000) indicates SAAG was the significant predictor of Grade III varices at the cut-off point of >1.8 g/dl, with the AUROC of 0.992 for correctly predicting Grade III varices. If SAAG >1.8 g/dl, there was a 78.60% probability of Grade III varices; if SAAG <=1.8 g/dl, then there was a 100.00% chance of no Grade III varices (Table 7).

Table 7: Diagnostic performance of SAAG >1.8 g/dL.

Variables	Values
Area under ROC curve (AUC)	0.992
Standard error	0.00519
95% Confidence interval	0.982 to 1.000
P value	<0.0001
Cut off	>1.8 g/dl
Sensitivity (95% CI)	100 (84.6 - 100.0)
Specificity (95% CI)	88.68 (77.0 - 95.7)
PPV (95% CI)	78.6 (59.0 - 91.7)
NPV (95% CI)	100 (92.5 - 100.0)
Diagnostic accuracy, %	92.00

NPV- Negative Predictive Value; PPV- Positive Predictive Value

Univariate regression showed, SAAG: 1.5 to 1.99 g/dl, >=2 g/dl were significant risk factors of varices. With the increase in SAAG and CTP score, the risk of varices significantly increases with odds ratio of 155572 (231.312 to 104631975) and 1.772 (1.07 to 2.935), respectively.

Patients with SAAG: 1.5 to 1.99 g/dl, >=2 g/dl had significantly high risk of varices with odds ratio of 225.255 (10.826 to 4686.707), 108.322 (4.947 to 2371.913) respectively.

On performing multivariate regression, SAAG: 1.5 to 1.99 g/dl, >=2 g/dl are significant independent risk factors of varices after adjusting for confounding factors. Patients with SAAG: 1.5 to 1.99 g/dl, >=2 g/dl has a significantly high risk of varices with an adjusted odds ratio of 228.306 (10.401 to 5011.503), 109.718 (4.769 to 2524.13) respectively.

DISCUSSION

Cirrhosis, a major health issue globally, is on the rise due to increased alcohol use, obesity, and metabolic diseases. In India, it's the ninth leading cause of death due to CLD. Portal hypertension from cirrhosis can lead to severe complications like ascites and esophageal varices, the latter increasing bleeding risks and mortality. It's essential to detect varices early to decrease the risk of bleeding, but the cost and technical expertise limit its availability. Many studies have suggested the serum-ascites albumin gradient (SAAG) as an accessible alternative method for assessing portal hypertension and predicting esophageal varices.

In our study, out of 75 cirrhosis patients, 62 (82.67%) are male, and 13 (17.33%) are female with the mean age of the study subjects 46.05±8.8 years, and median age of 47 years.

In our study, alcohol is the most common aetiology of CLD, which is 42 (56.00%). Hepatitis B, Hepatitis C, NASH, Autoimmune and other causes constituted the rest 44.00% (18.67%, 10.67, 9.33% and 2.67%, respectively). Alcohol, Hepatitis B and C constituted about 85.34% of CLD. The drinking habits of our society can explain the male predominance in our study.

In our study, the mean value of serum albumin level is 2.76±0.46 g/dl, and ascitic albumin is 1.01±0.53 g/dl (range 0.3-2.6). SAAG value of 1.5 to 1.99 g/dl is seen in 40 (53.33%) of our patients, SAAG of ≥2 g/dl in 25.33% (19 patients) and SAAG of 1.1 to 1.49 g/dl 16 (21.33%). In our study, the mean±SD SAAG is 1.74±0.33 g/dl, with a median (25^{th} -75^{th} percentile) of 1.8 (1.55-1.95) g/dl.

In our study, Grade F1 EVs is present in 8 (10.67%), Grade F2 EVs in 33 (44.00%), Grade F3 EVs in 22 (29.33%) and no varices in 12 (16.00%). In our study majority of the patients has Grade F2 EVs (44%), which is similar to study done by Thong VD who had reported 41.2% with Grade F2, 35.0% with grade 1,16.3% with Grade 3 esophageal varices (EVs) and 7.5% without varices.[8]

In our study, the majority of 62 (82.67%) cases have CTP class C, 11 (14.67%) cases have class B, and only 2 (2.67%) cases have class A. The mean MELD score among the study subjects was 16.56±3.32, with a median (25^{th} - 75^{th} percentile) of 16 (15-18).

As our centre is a tertiary referral centre, the majority of our patients has severe cirrhosis CTP class C. In our study, we found a significant, strong positive correlation between SAAG (g/dl) and Esophageal varices grade, with a coefficient of 0.912. Only 25 % of patients with SAAG levels of 1.1 to 1.49g/dl have EVs, in contrast to all 100% of patients with SAAG levels of 1.5 to 1.99g/dl and >2g/dl have EVs. A multivariate regression analysis revealed that a SAAG of 1.5 to 1.99 g/dL and a SAAG of 2 g/dL or higher were significant independent risk factors for varices. The adjusted odds ratios for these factors were 228.306 (with a 95% confidence interval of 10.401 to 5011.503) and 109.718 (with a 95% confidence interval of 4.769 to 2524.13), respectively, with p values of 0.001 and 0.003.

In our study, a SAAG value of >1.4 g/dL predicted varices, with a sensitivity of 93.65% (95% CI: 84.5 - 98.2%) and a specificity of 100% (95% CI: 73.5 - 100.0%) and AUC 0.968. The p-value is <0.0001 with a diagnostic accuracy of 94.67%, which is similar to a study by Gamal S. El Deeb, in which an SAAG value of >1.4g/dl predicted EVs with a sensitivity of 97.70% and specificity of 89.47% (p<0.001).[9]

In a study by Thong VD, a SAAG > 1.75 g/dl showed EVs with 78.4% sensitivity and 83.3% specificity.[6] In a study by Chaurasia et al, an SAAG value of >1.70 was associated with esophageal varices (EVs), while in the study by Alam SM, it was SAAG >2.0 g/dL.[10,11]

In our study, a SAAG value of >1.8g/dL predicted high-grade varices with a sensitivity of 100% (95% CI: 84.6 - 100.0%) and a specificity of 88.68% (95% CI: 77.0 - 95.7%), with p value of <0.0001 and area under the

ROC curve (AUC) of 0.992, with a positive predictive value (PPV) of 78.6% (95% CI: 59.0 - 91.7%) and a diagnostic accuracy of 92.00% which is similar to study done by Vo Duy Thong who also showed that SAAG ≥ 1.8 are at higher risk for large EVs.

Based on our study results, we can suggest that, in cirrhotic patient SAAG >1.4g/dl predicts presence of EVs and SAAG >1.8g/dl have high chances of high-grade EVs; hence, they should undergo upper GI endoscopy to prevent the risk of bleeding and decrease mortality.

CONCLUSION

The study shows that SAAG is a reliable marker for predicting EVs in cirrhotic patients and can be used for early identification of at-risk patients, facilitate in timely and effective management to prevent serious complications.

ACKNOWLEDGEMENTS

Authors would like to thank the Department of Medicine, VMMC and Safdarjung Hospital, New Delhi, for their continuous guidance and support throughout the course of this stud.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kiran NC, Thakur MB, Rani A. Diagnostic accuracy of serum-ascites albumin gradient in esophageal varices in cirrhosis. Int J Res Med Sci 2026;14:130-4.