*A Study to Evaluate Serum - Ascites Albumin Gradient (SAAG)
and Ascitic Fluid Total Protein (AFTP) in Case of Portal
Hypertension and Non-Portal Hypertension Ascites Cases
at a Tertiary Level Hospital and Research Institute*

Section A-Research paper

A STUDY TO EVALUATE SERUM - ASCITES ALBUMIN GRADIENT (SAAG) AND ASCITIC FLUID TOTAL PROTEIN (AFTP) IN CASE OF PORTAL HYPERTENSION AND NON-PORTAL HYPERTENSION ASCITES CASES AT A TERTIARY LEVEL HOSPITAL AND RESEARCH INSTITUTE

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Abstract

Background: Ascites can be because of portal hypertension or non-portal hypertension causes. We studied the role of serum ascites albumin gradient and the ascitic fluid total protein in case of portal hypertension and non-portal hypertension ascites. We conducted this study to evaluate the efficacy of SAAG and AFTP in the portal hypertension and non-portal hypertension related ascites.

Methods: This was a single centre hospital-based cross-sectional study conducted in patients admitted to the Krishna hospital under medicine wards and ICU over a period of 18 months from October 2020 to March 2022. 90 cases of ascites were studied in detail for clinical signs and symptoms, type of ascites, relation of SAAG and AFTP in ascites.

Results: The mean age of the patients was 51.74 ±10.76 years. Out of 90 patients 76.67% were males. The majority of patients presented with abdominal distension, 88 (97.78%) cases followed by swelling of limbs in 62 (68.89%). Most common sign was ascites seen in all cases (100%), followed by splenomegaly in 62 cases (65.56%) and pedal oedema in 54 cases (60%). We had 14 cases with SAAG of <1.1 gm% (15.56%) and we had 76 cases with SAAG of ≥1.1 gm% (84.44%). It was observed that majority of patients with SAAG ≥1.1 gm% had portal hypertension related ascites (64 out of 65 patients) with statistically significant relation. (P<0.001) The sensitivity, specificity and accuracy of SAAG was 98.46%, 52% and 92.86% respectively. Positive predictive value of SAAG was 84.21% and Negative predictive value of SAAG was 92.86%. On comparison, we found that the SAAG had better sensitivity of 98.46%, specificity of 52% and accuracy of 85.56% to diagnose it as compared to AFTP with sensitivity of 78.63%, specificity of 42.09% and accuracy of 65.63%.

Conclusion: Our study concludes that SAAG can easily predict portal hypertension related ascites, with SAAG of ≥1.1 gm% having sensitivity and accuracy of 98.46% and 92.86% respectively.

Keywords: serum - ascites albumin gradient (SAAG), ascitic fluid total protein (AFTP), portal hypertension, non-portal hypertension, ascites.

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1. Introduction

Ascites is defined as the accumulation of fluid within peritoneal cavity. Careful history taking and clinical examination can provide clue to the etiology of ascites. In addition to peritoneal pathology, which is not connected to portal hypertension, more than 80% of cases of ascites are caused by portal hypertension, primarily as a result of cirrhosis. Because the methods of evaluation and administration for these two groups differ, this categorization is crucial. [1]

In past portal hypertension ascites was many times distinguished from non-portal hypertension causes by checking whether fluid is of transudative or exudative nature. This concept assumed that in portal hypertension, protein poor ascitic fluid transudates from the normal peritoneal surface, whereas in ascites associated with peritoneal diseases protein rich ascitic fluid exudates from the peritoneal surface. Ascitic fluid is termed transudate if AFTP (ascitic fluid total protein) is <2.5g/dl. [1]

Ascites may be due to Portal Hypertension (E.g.-Cirrhosis) or causes due to disease of the peritoneum unrelated to portal hypertension (E.g.-Tubercular peritonitis, peritoneal carcinomatosis). The pathophysiology of ascitic fluid development is poorly understood and cannot be fully understood by the previous classification of exudative and transudative ascites based on Ascitic fluid total protein (AFTP). [2]

Clinical situations have made it difficult, particularly in cases of cardiac ascites, malignant ascites, and mixed ascites, such as cirrhotic patients with spontaneous bacterial peritonitis, cirrhotic patients receiving prolonged diuretic therapy, and ascites in the abdomen. In order to categorise ascites into two groups, a new method called SAAG [Serum Ascites Albumin Gradient] has been created – High SAAG ascites with SAAG ≥1.1 g/dl in cases with the portal hypertension and the Low SAAG ascites with SAAG <1.1 g/dl in cases with ascites, that is unrelated to portal hypertension.[3-5]

SAAG reflects the oncotic pressure exerted by serum albumin over ascitic fluid albumin which truly equals the high hydrostatic pressure gradient between the portal bed and the ascitic fluid. Therefore, the difference between the serum and the ascitic fluid albumin concentrations correlates directly with portal pressure. [6-7] SAAG classification is much more physiologic and correlates well with the pathogenesis even in patients on diuretic, cardiac ascites and mixed ascites. Various studies have shown superiority of SAAG in classifying ascites compared to transudate-exudate concept.[8-10]

Now ascites due to the malignancies are on rise and difficult to diagnose by the routine ascitic fluid analysis. Although SAAG accurately differentiate ascites due to the portal hypertension from other causes, but the SAAG is not able to differentiate between malignant ascites and tuberculous ascites as both of them are having low SAAG (<1.1 gm%).[11] Fluid cytology has quite low sensitivity for the malignancy as the differentiation between reactive atypical mesothelial cells and malignant cells is sometimes difficult. [12,13]

Thus there is a need for this study to know the serum ascites albumin gradient and the ascitic fluid total protein in case of portal hypertension and non-portal hypertension ascites. We conducted this study to evaluate the efficacy of SAAG and AFTP to differentiate between the portal hypertension and non-portal hypertension related ascites.

2. Methodology:

This was a single centre hospital-based cross-sectional study conducted in patients admitted to the Krishna hospital under medicine wards and ICU over a period of 18 months from October 2020 to March 2022. The sample size was 90 cases.

According to Shankar Suman et al,[14] the sensitivity of SAAG is 94% and specificity is 90%. The sensitivity of AFTP is 78% and specificity is 50%. The prevalence of ascites in case of cirrhosis is 50%. Hence, we chose-

p= 50%
z= standard constant value at 95 CI=1.96
Sensitivity=94%.
d=absolute precision=0.07
$N \geq Z^2$ Sensitivity (1- Sensitivity) $/d^2$ P
N =1.96*1.96*0.94*(1-0.94)/0.07*0.07*0.5
Thus,

Sample Size = N = 88
Rounding it up to 90, so we included a total of 90 cases in our study.

Patients visiting Medicine Department OPD and admitted in the wards of Medicine department in Krishna Hospital, A tertiary care hospital and a teaching institute Karad, Maharashtra were studied. Patients with ascites proved by ultrasound above age of 18 years who gave a written informed consent were included in the study. Patients with hepatic encephalopathy and acute gastro- intestinal bleeding and patients with blunt injury abdomen were excluded.

90 patients with ascites were subjected to detailed history and thorough clinical examination and detailed investigations were done.

Ethical approval:

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Ethical clearance for the study was taken from institutional ethical committee after discussion of the study protocol with committee.

Statistical Analysis:
Data was collected using a semi-structured pre-tested questionnaire, data Collected was entered in Microsoft Excel. Data is represented in frequencies and percentages, charts and graphs. Mean and standard deviation of quantitative variables is shown. Appropriate statistical tests are applied using SPSS software version 21 for analysis. Chi square test is used for association and student's t-test is used for comparison wherever applicable. Other statistical tests are used as per study requirements. P value < 0.05 is taken as statistical significance.

Reference Citing:
Vancouver system of listing and citing of references is used. As per this system, the references are numbered and listed consecutively in the order in which they are first cited in the text.

Observations and Results:
90 cases of ascites were studied in detail. It was observed that majority of patients were in age group 51-60 years (35.56%) followed by 41-50 years (26.67%). More than 60 years were 18 cases (20%) and 13 were 31 to 40 years (14.44%), 3 cases were less than 30 years (3.33%). The mean age of the patients was 51.74 ±10.76 years.

Out of 90 patients 76.67% were males and 23.33% females. Male to female ratio was 3.29: 1.

Table 1) Distribution of patients according to Clinical features: Symptoms & Signs:

Clinical features: Symptoms	No. of Patients (n=90)	Percentage*
Abdominal distension	88	97.78%
Swelling of limbs	62	68.89%
Breathlessness	45	50.00%
Fever	18	20.00%
Jaundice	39	43.33%
H/O Blood transfusion	12	13.33%
Alcoholic	59	65.56%
Signs		
Ascites	90	100%
Splenomegaly	62	65.56%
Pedal Oedema	54	60.00%
Pallor	48	53.33%
Icterus	46	51.11%
Hepatomegaly	33	36.67%

*(Multiple Responses Present)

The above table described distribution of patients according to clinical features of symptoms and signs. It was observed that majority of patients presented with abdominal distension, 88 (97.78%) cases followed by swelling of limbs in 62 (68.89%), breathlessness in 45 (50%). Majority of patients were chronic alcoholic, 59 cases (65.56%).

Most common sign was ascites seen in all cases (100%), followed by splenomegaly in 62 cases (65.56%), pedal oedema in 54 cases (60%), pallor in 48 cases (53.33%) and icterus in 46 cases (51.11%) and hepatomegaly in 33 cases (36.67%).

Out of 90 cases, we had 65 cases with ascites related to portal hypertension (72.22%) rest 25 cases didn't have portal hypertension (27.78%). Significant difference was seen in the presence and absence of portal hypertension related ascites wise distribution of the study participants (p<0.001).

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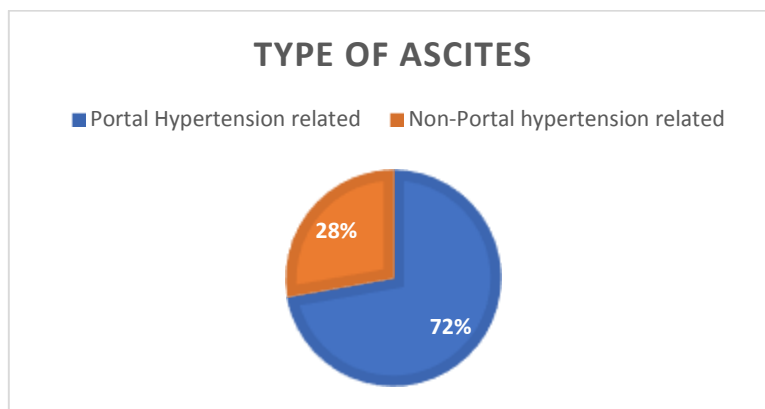
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Fig 1) Distribution of patients according to portal hypertension related ascites

We observed that 86 cases survived after treatment (95.56%) while the rest 4 died (4.44%). Significant difference was seen in the outcome of the study participants (p<0.001).

SAAG was studied in the study participants, we had 14 cases with SAAG of <1.1 gm% (15.56%) and we had 76 cases with SAAG of ≥1.1 gm% (84.44%). Significant difference was seen in the distribution of the study participants with the SAAG values <1.1 gm% and ≥1.1 gm% (p<0.001).

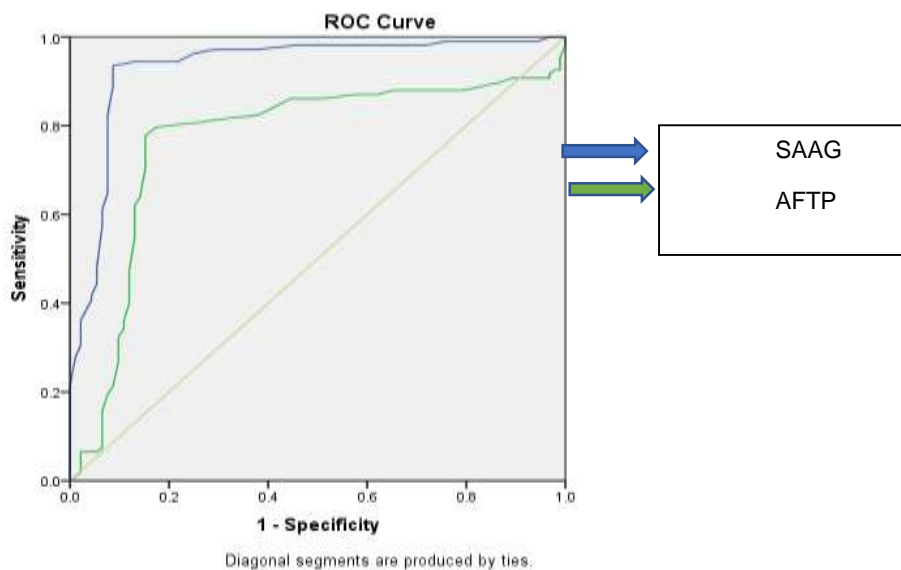Table 2) Relation of SAAG and portal hypertension related ascites

SAAG	Portal hypertension related ascites	Non-portal hypertension related ascites	P value
≥1.1 gm%	64	12	
<1.1 gm%	01	13	<0.0001 (S)
Total	65	25	

The above table describes relation of SAAG and portal hypertension related ascites. It was observed that majority of patients with SAAG ≥1.1 gm% had portal hypertension related ascites (64 out of 65 patients) with statistically significant relation.

(P<0.001) The sensitivity, specificity and accuracy of SAAG was 98.46%, 52% and 92.86% respectively. Positive predictive value of SAAG was 84.21% and Negative predictive value of SAAG was 92.86%.

Figure 2: ROC analysis of efficacy of SAAG and AFTP to diagnose ascites due to portal hypertension

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ROC Analysis	SAAG	AFTP
Sensitivity	**98.46%**	**78.63%**
Specificity	**52.00%**	**42.09%**
Accuracy	**85.56%**	**65.63%**

When we compared SAAG and AFTP to diagnose portal versus non portal hypertension related ascites, we found that the SAAG had better sensitivity of 98.46%, specificity of 52% and accuracy of 85.56% to diagnose it as compared to AFTP with sensitivity of 78.63%, specificity of 42.09% and accuracy of 65.63%.

3. Discussion

Ascites is a lethal presentation, with myriad of cause behind. This presentation is common all over the world in medical practice. Its early detection is required to ensure effective management without any complications. The present cross-sectional study carried out at tertiary institute to determine study serum ascites albumin gradient (SAAG) and ascitic fluid total protein (AFTP) in case of portal hypertension and non-portal hypertension ascites.

Age Distribution
In the present study, it was observed that majority of patients were in age group 51-60 years (35.56%) followed by 41-50 years (26.67%). More than 60 years were 18 cases (20%) and 13 were 31 to 40 years (14.44%), 3 cases were less than 30 years (3.33%) The mean age of the patients was 51.74 ±10.76 years.

Rinku Joshi et al [15] studied clinical profile of ascites observed mean age of the patients studied was 54.89 ± 12.99 years with the minimum being 16 years and maximum being 82 years. This finding was similar to present study. Nakhale BD et al [16] in a study on clinical profile and comparison of SAAG with ascites fluid total protein (AFTP) in cases of ascites observed mean age of diagnosis of ascites was 42.41 ±7.72 years and maximum cases in 30-49 years age group. The earlier studies of Khan FY et al [17] shows mean age of 52.9±14.8 years and Khan FY et al [17] shows age of 50.7±15.8 years. This finding was in accordance to present study.

Gender Distribution
In the present study, out of 90 patients 76.67% were males and 23.33% females. Male to female ratio was 3.29: 1.
Nakhale BD et al [16] in a study on clinical profile and comparison of SAAG with ascites fluid total protein (AFTP) in cases of ascites observed 74% were male and 26% were female with male: female ratio 2.84:1. Rinku Joshi et al [15] studied clinical profile of ascites observed 28 (24.6%) were females,

while the rest 86 (75.4%) were males. Suresh Saravanakumar et al [18] in a study on diagnostic accuracy of serum ascites albumin gradient observed majority of their participants were males (88%) as compared to females of 12%. Shanker Suman et al [14] in their study on ascites by observed out of 100 patients of ascites who participated in their study 80 (80%) were males and 20 (20%) were female. These finding were in accordance to present study.

Clinical profile
In the present study, distribution of patients according to clinical profile showed that majority of patients presented with abdominal distension, 88 (97.78%) cases followed by swelling of limbs in 62 (68.89%), breathlessness in 45 (50%). Majority of patients were chronic alcoholic, 59 cases (65.56%). most common sign was ascites seen in all cases (100%), followed by splenomegaly in 62 cases (65.56%), pedal oedema in 54 cases (60%), pallor in 48 cases (53.33%) and icterus in 46 cases (51.11%) and hepatomegaly in 33 cases (36.67%).

Similarly, in Nakhale BD et al [16] study majority of patients had abdominal distension (100%), dyspnea (58%) abdominal pain (35%), 15 cases had altered consciousness (encephalopathy), 8 cases presented with hematemesis. Icterus was present in 30 cases and edema feet in 38. Fever was present in 10 (16%) cases.

Rinku Joshi et al [15] studied clinical profile of ascites observed most common clinical feature being distension (74, 64.9%) followed by anorexia (53, 46.4%).

Distribution of patients according to portal hypertension related ascites
In the present study, out of 90 cases, 65 cases with ascites related to portal hypertension (72.22%) rest 25 cases didn't have portal hypertension (27.78%). Significant difference was seen in the presence and absence of portal hypertension related ascites wise distribution of the study participants (p<0.001).

Nakhale BD et al [16] in a study on clinical profile and comparison of SAAG with ascites fluid total protein (AFTP) in cases of ascites observed 78% patients with portal hypertension with ascites. Shanker Suman et al [14] in a study on ascites by estimating Serum Ascites Albumin Gradient (SAAG) and Serum Ascites Cholesterol Gradient (SACG) observed out of 100 patients of ascites, 72 (72%) had portal hypertension related ascites and 28 (28%) had non- portal-hypertension related ascites. This

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finding was in accordance to present study. AK Seth et al [19] in a study on diagnostic accuracy of serum ascites albumin gradient observed majority of the study subjects were with portal hypertension related ascites. (94.28%)

Distribution of patients according to outcome
In the present study, observed that 86 cases survived after treatment (95.56%) while the rest 4 died (4.44%). Significant difference was seen in the outcome of the study participants (p<0.001).
Touhidur Rahman et al [20] in a study on outcome of the patients with ascites observed 9% patients of this study died during hospital stay.

Distribution of patients according to SAAG
In the present study, SAAG was studied in the study participants, we had 14 cases with SAAG of <1.1 gm% (15.56%) and we had 76 cases with SAAG of ≥1.1 gm% (84.44%). Significant difference was seen in the distribution of the study participants with the SAAG values <1.1 gm% and ≥1.1 gm% (p<0.001).
Beside present study, Marshal et al, [21] in Goyal et al. [9] Kajani et al [22] also found similar results.

Relation of SAAG and portal hypertension related ascites
The described relation of SAAG and portal hypertension related ascites. It was observed that majority of patients with SAAG ≥1.1 gm% had portal hypertension related ascites (64 out of 65 patients) with statistically significant relation. (P<0.001) The sensitivity and accuracy of SAAG was 98.46% and 85.56% respectively.
Similarly, in Nakhale BD et al [16] study mean SAAG portal hypertension related etiology was 2.05±0.5

gm/dl and in normal portal pressure related it was 0.72±0.19 gm/dl, this difference was statistically highly significant. (P<0.05) Sensitivity of 92.31% by SAAG in differentiating etiology of ascites related to portal hypertension.
Kanvy BA et al [23] in Saudi Arabia, two other parameters i.e. ascitic fluid lactic dehydrogenase and ascitic to serum ratio of total protein, in addition to SAAG and AFTP were compared. Among all the four highest positive and negative predictive values (80% 98%) against that of ascitic fluid total protein (68% 96%).
M. Beg et al [24] observed the diagnostic accuracy and sensitivity of SAAG were 96% respective values 68% and 66% of AFTP. In the other study, conducted by Gupta R et al [10] Gastroenterology and Pathology, M.L.N Medical college, Allahabad, observed that the diagnostic accuracies of AFTP and SAAG were found to be 88% respectively.
Runyon et al [25] conducted a study among 901 patients in the University of Iowa, Iowa city in the year 1992. The diagnostic accuracy of SAAG and ascitic fluid total protein was 96.7% and 55.6% respectively. In another study conducted among 51 patients by Akriviadis EA et al [26] in the University of Thressaloniki, Hippocratical Hospital, Greece the diagnostic accuracy of SAAG was found to be 98% when compared to 52%-80%.
This shows, serum ascites albumin gradient (SAAG) is the single best test against ascitic fluid total protein (AFTP), in the differential diagnosis of ascites. The serum ascites albumin gradient (cut off value 1.1gm/dl) is a better indicator of portal hypertension than the traditional parameter of ascitic fluid total protein AFTP concentration.

Table 3: Comparison of the present study with other similar studies

Reference	Author (Year)	Study type	Sample Size	Interpretation
77	Beg M Et al [24] (2001)	Comparative study	100	Found that both SAAG and AFTP predicted ascites cases properly with sensitivity of SAAG 94.73% and of AFTP 65.62%
87	Nakhale BD et al [16] (2016)	Comparative Study	100	Clinical profile and comparison of SAAG with ascites fluid total protein (AFTP) in cases of ascites at a tertiary referral hospital in Maharashtra was compared. The SAAG had a sensitivity of 92.31% while the AFTP had a sensitivity of 83.54%
88	Khan FY et al [17] (2007)	Descriptive, prospective study	104	Liver cirrhosis is the main cause of ascites. SAAG is a better distinguishing marker for separating ascites related to portal hypertension

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Reference	Author (Year)	Study type	Sample Size	Interpretation
				from other causes of ascites without portal hypertension. In patients with low gradient ascites, ascitic fluid glucose and LDH level are useful indicators for separating tuberculous from malignant ascites. SAAG had better sensitivity of 98.02% than 83.54% of AFTP to diagnose ascites.
93	Malabu UH Et al [27] (2006)	Prospective Study	90	Albumin gradient was compared with the usual parameters of ascitic fluid analysis in the differential diagnosis of ascites. They observed that the efficiency of the biochemical parameters in correctly diagnosing patients with ascites caused by liver cirrhosis and those due to tuberculous peritonitis or malignancies was highest for albumin gradient 180 IU/L (77%), ascitic fluid total protein >3.0 g/dL (73%), ascitic fluid to serum lactic dehydrogenase ratio >0.6 (70%) and ascitic fluid to serum total protein ratio >0.5 (63%).
94	Rodríguez et al. [28] (2014)	Observational and retrospective study	116	61 (52%) had ascites due to portal hypertension from liver cirrhosis, and 55 (48%) of ascites due to NO HTP. The sensitivity and specificity for GASA was 93% and 47% respectively, for PTLA was 80% and 89% respectively, for CAA was 85% and 87% respectively and for the IPAS was 83% and 80% respectively. The area under the ROC curve for GASA was 0.70, ATPL was 0.84, IPAS was 0.81 and CAA was 0.86, we found statistically significant differences between GASA compared to the other three parameters ($p<0.01$).
95	Gogoi P et al [29] (2018)	Prospective study	100	Evaluated Serum/Ascites Albumin Gradient (SAAG), as being a Very Cost Effective and Reliable First-Line Diagnostic Parameter in the Differential Diagnosis of Ascites in a tertiary care centre of North-East India. They found that the SAAG had a sensitivity of 95% while the AFTP had a sensitivity of 61.66% to diagnose ascites in portal hypertension cases.
-	**Present study (2022)**	Cross Sectional study	90	We found that majority of the ascites cases in our study are due to portal hypertension. There were 4 deaths in our study (mortality 4.44%). Majority of the cases had SAAG of ≥1.1 gm%. Our study concludes that SAAG can easily predict portal hypertension related ascites, with SAAG of ≥1.1 gm% having sensitivity and accuracy of 98.46% and 92.86% respectively.

4. Conclusion

We observed the importance of SAAG evaluation in ascites cases. We found that majority of the ascites cases in our study are due to portal hypertension. There were 4 deaths in our study (mortality 4.44%). Majority of the cases had SAAG of ≥1.1 gm%. Our study concludes that SAAG can

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easily predict portal hypertension related ascites, with SAAG of ≥1.1 gm% having sensitivity and accuracy of 98.46% and 92.86% respectively. We conclude that SAAG should be calculated in every patient with Ascites and it should be used as a prognostic indicator.

Conflict of interest: None

Source of Funding: This was a self-funded study.

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