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# "A COMPARATIVE STUDY OF SERUM ASCITIC FLUID ALBUMIN GRADIENT WITH TOTAL PROTEIN IN ASCETIC FLUID IN HEPATIC AND NON-HEPATIC CAUSES OF ASCITES IN GOVERNMENT HOSPITAL, JAYANAGAR."

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#### ABSTRACT

#### **BACKGROUND:**

The traditional way of classification of ascites by AFTP offers little insight to the pathophysiology of ascites formation and it has further drawbacks. In order to overcome it the classification of ascites based on SAAG has emerged. Even SAAG also has some draw backs like non correlation with ascites due to non alcoholic cirrhosis and difficulty in identifying the ascites due to mixed etiology. So the study is conducted to compare the diagnostic accuracies of SAAG and AFTP in identifying the pathophysiology of ascites as both the method has drawbacks.

#### **METHODS:**

A total of hundred patients who were admitted with Ascites were included and ascitic fluid total protein and SAAG was calculated. They are classified on the basis of SAAG into High SAAG and low SAAG and on the basis of AFTP into Transudate and Exudate. After the etiology of ascites evaluated by various diagnostic procedures the sensitivity, specificity and diagnostic accuracy of SAAG and AFTP in identifying the pathophysiology of ascites calculated separately. The diagnostic accuracies of SAAG and AFTP compared statistically.

RESULTS: The sensitivity of SAAG was found to be 87.01% and that of AFTP was found to be 63.63%. The specificity of SAAG was found to be 82.60% and that of AFTP was found to be 56.41%. The diagnostic accuracy of SAAG was found to be 86% and that of AFTP was found to be 58%. The diagnostic accuracy of SAAG and AFTP for individual aetiologies of ascites were found and compared. SAAG was found to be superior to AFTP with a P value of <0.01. Which is statistically significant.

CONCLUSION: The sensitivity and specificity of SAAG and AFTP in identifying the pathophysiology of ascites in various hepatic and non-hepatic causes were studied and it was found that SAAG was superior to AFTP. The diagnostic accuracy of SAAG and AFTP was studied for individual etiologies of ascites and SAAG was found to be superior to AFTP and it was proved statistically significant.

KEYWORDS: ASCITES, SAAG, AFTP, CIRRHOSIS

#### **INTRODUCTION:**

Ascites is the pathologic accumulation of fluid within theperitoneal cavity. The word ascites is derived from the Greek word 'askos', which means a bag or sack. Ascitis occurs due to various disease from hepatic(cirrhosis, alcoholic hepatitis, budd chiaris syndrome) and extrahepatic sites (heart failure, nephritic syndromme, pancreatitis, myxedema, the peritonitis etc). Ascites is one of the most common problem seen in regular day to day practice by physicians which have been easily diagnosed by ascitic fluid analysis. The ascites is classified traditionally based on estimating the AFTP (ascitic fluid total protein) as 'exudative' and 'transudative' ascites. The ascitic fluid total protein is, more than or equal to 2.5 g/dl in exudative ascites and less than 2.5 g/dl intransudative ascites.

Serum-ascites albumin gradient (SAAG) is more useful in the classification of ascites. Classification by SAAG is under two categories: A high gradient ( $\geq 1.1 \text{ g/dl}$ ) in cases with portal hypertension either liver related or non-liver related and a low gradient (< 1.1 g/dl) indicates causes of ascites not associated with increased portal pressure such as: tuberculosis, pancreatitis, infections, serositis, various types of peritoneal cancers (peritoneal carcinomatosis) and pulmonary infarcts. The serum-ascites albumin gradient is calculated by subtracting the albumin concentration of ascitic fluid from the albumin concentration of serum obtained on the same day.

#### SAAG=Albumin serum- albumin ascitis

When AFTP is come to picture that has many pitfallsespecially in cases of cardiac ascites, cirrhotic patients on prolonged diuretictherapy<sup>3</sup> and in about 1/3rd patients of malignant ascites<sup>4</sup>, sometimes even in usualcirrhotic patients' ascitic fluid<sup>5</sup> and in SBP (spontaneous bacterial peritonitis)<sup>6</sup> whereit cannot identify the pathophysiology of ascitic fluid formation accurately. To overcome this issue another way(SAAG) of classification was introduced. Even the SAAG has drawbacks like difficulty in identifying ascites due to non-alcoholic cirrhosis 7. As both the methods AFTP and SAAG their own sets of drawbacks there is a need for a study to compare the diagnostic accuracy of SAAG and AFTP in identifying the pathophysiology causing ascites thereby helping in evaluating the etiological cause of ascites in various Hepatic and Non Hepatic conditions.

#### Aims and objectives

- 1. To differentiate ascites based on serum ascitic fluid albumin gradient as high gradient SAAG ascites (more than or equal to 1.1g/dl) and as Low gradient SAAG ascites of (<1.1g/dl)
- 2. To determine sensitivity and specificity of SAAG(serum ascitic fluid albumingradient) and that of AFTP (ascitic fluid total protein) in identifying thepathophysiology of ascites.
- 3. To compare the diagnostic accuracy of SAAG (Serum ascitic fluid albumingradient) with traditional marker AFTP (ascitic fluid total protein).

#### **Materials and methods**

A comparative prospective study done in 100 patient were admitted in department of general medicine in jaynagar general hospital ,banglore within a period of one year with ascitis,whose etiological diagnosis has not been established previously ,were studied. Written Informed consent was obtained from the patient in the language whichpatients could understand and the study was commenced after getting clearance from the hospital ethical committee.

On entry to the study, complete history and a thorough clinical examination was done for all the patients. Hundred patients who matched the set of criteria were included in this study. Ascitic fluid and blood sample were collected simultaneously and examined for ascitic fluid albumin, ascitic fluid total protein and serum albumin. The Bromo cresol green method<sup>8</sup> was used to calculate ascitic fluid albumin andserum albumin and Biuret method53 was used to measure ascitic fluid total protein onautomated chemistry analyser, Selectra-2. All the 100 patients underwent various other diagnostic investigations like ultra sound imaging and CT scan as of required and aetiology of the ascites were established. Then, the diagnostic accuracies of AFTP and SAAG were calculated and compared based on the already established diagnosis crieteria for selection of patient are as follows:-

INCL	LUSION	CRITERIA:
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$\square$ All patients with ascites due to any cause previously not established.
□ □ Patients with a normal coagulation profile
EXCLUSION CRITERIA:
□ □ patients with severe coagulopathy or with disseminated intravascular coagulation(DIC)
□ Ascitic patients with blunt injury to abdomen
☐ Ascitic patients with Hepatic encephalopathy or acute gastro intestinal bleeding.
☐ Ascitic patients on diuretic therapy before ascitic fluid analysis.

Abdominal paracentesis is done to collect the sample.

#### **Statistical Methods:**

Descriptive analysis and Inferential Statistical analysis has been carried out in this study. Results of continuous measurements are presented on Mean ±SD (Min-Max) and results of categorical measurements are presented in Numbers (%). Significance is assessed at 5 % level of significance.

The followingassumptions on data is made,

- 1. Dependent variables should be normally distributed,
- 2. Samples drawn from the population studied should be random, Cases of the samples studied should be independent. Analysis of variance (ANOVA) has been used to find the significance of study parameters between three or more groups of patients in the study, Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups in the study.

#### **Statistical software:**

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

#### **Results**

Among 100 patients 73% male and 27% female are participated in the study fulfilled inclusion criteria. Mean age group of patient was  $49.51\pm13.73$ . Theascites predominantly occurs in the age group 41-60years occupying about 59 percent of the total patients studied.most common cause seen is liver cirrhosis followed by congestive cardiac failure and the ascitis.from table no 1: shows liver cirrhosis is due to alcoholic condition was most common.from this table Mean serum albumin level (Mean  $\pm$  SD) is  $2.91\pm0.596$ , while mean ascetic fluid albumin is  $1.496\pm0.671$ .

Table no:1

Parameter Patient charecteristics			
Age (yrs), Mean ± S.D	49.51±13.73		
Age distribution			
< <u>20</u>	1		
$\frac{1}{21-30}$	7		
31-40	12		
41-50	31		
<u>51-60</u>	28		
61-70	17		
$\frac{31.75}{71-80}$	$\frac{1}{2}$		
>80	$\begin{bmatrix} \frac{1}{2} \end{bmatrix}$		
Gender (n, %)			
Male	73(73%)		
Female	27(27%)		
Etiology wise distribution (n %)	Male (n) Female (n) Total (%)		
AN & HYP	- 1 1 1		
CCF	10 3 13		
Liver Cirrhosis	48   12   60		
Hypothyroidism	1 1 2		
Liver metastasis	1 - 1		
Nephritic syndrome	$\begin{bmatrix} 1 \\ 2 \end{bmatrix}$ $\begin{bmatrix} 2 \\ 4 \end{bmatrix}$		
Peritoneal carcinomatosis	$\begin{bmatrix} 2 \\ 3 \end{bmatrix}$ $\begin{bmatrix} 6 \\ 6 \end{bmatrix}$		
Tb ascitis	8 5 13		
To applied			
Etiology of cirrhosis (n,%)			
Alcoholic cirrhosis	45(75%)		
Cryptogenic cirrhosis	4(6.66%)		
HBV(Cirrhosis)	11(18.33%)		
EXUDATE			
Peritoneal carcinomatosis	6		
TB ascites	13		
Liver metastasis	1		
Hypothyroidism	2		
TRANSUDATE			
Cirrhosis	60		
CCF	13		
Nephrotic syndrome	4		
AN & HTN	1		
Mean serum albumin level (Mean $\pm$ SD) 2.91 $\pm$ 0.596			
Mean ascitic fluid albumin (Mean $\pm$ SD) 1.496 $\pm$ 0.671			

Table no 2: no of patients and diagnostics parameter

•	AFTP		SAAG	
	Mean±sd (2.571±0.837)		Mean±sd (1.418±0.444)	
	<2.5 g/dl	±2.5 g/dl	<1.1	≥1.1
No of patients	52%	48%	29%	71%

From the above table it can clearly seen that in AFTP 52% people have <2.5g/dl and 48% have >2.5g/dl, While in SAAG 71% people  $\ge 1.1g/dl$ .

Table no 3:diagnostics based on etiology

Etiology	AFTP		P value	SAA	\G	p-value
	<2.5 g/dl	>2.5 g/dl		<1.1mg/dl	≥1.1mg/dl	
Liver Cirrhosis	37	23	<0.001***	8	52	<0.001***
Tb ascitis	4	9	<0.001***	12	1	0.337
CCF	4	9	0.001**	1	12	<0.001***
Nephritic syndrome	2	2	0.182	3	1	-
AN & HTN	1	4		1	-	-
Peritoneal carcinomatosis	1	5	0.004**	4	2	0.363
Hypothyroidism	2	7	<b>}</b>		2	-
Liver metastasis	1	-	-	-	1	
Total	52	48		29	71	

Table 4:Classification based on pathophysiology

Portal HTN	1 Jan 1	Without portal	NO(%)
	NO(%)	HTN	
Cirrhosis	60	Peritoneal	6
		carcinomatosis	
CCF	13	TB ascites	13
Liver metastasis	1	Nephrotic syndrome	4
Hypothyroidism	2		
AN & HTN	1		

Table no 5: Comparison of SAAG and AFTB for hepatic and non-hepatic etiology of ascites

Pathophysiology	SAAG		SAAG AFTB	
	<1.1mg/dl	≥1.1mg/dl	<2.5 g/dl	<2.5 g/dl
Non hepatic causes	21	18	14	25
Hepatic causes	8	53	38	23
Total cases	29	71	52	48

Table 6: Comparison of SAAG with portal hypertension

Pathophysiology	SAAG (≥1.1mg/dl)	SAAG (<1.1mg/dl)	
Portal hypertension	67(True positive)	10(False negative)	77
Without portal hypertension	4(false positive)	19(True negative)	23
	71	29	100

Specificity, sensitivity, positive predictive value, negative predictive value and diagnostic accuracy of SAAG is calculated from the table.

$$Specificity = = \frac{\text{true negative}}{\text{false positive+true negative}} = 82.60\%$$

Positive predictive value = 
$$\frac{\text{true positive}}{\text{true positive + false positive}} = 94.37\%$$

Diagnostic accuracy = 
$$\frac{100(\text{true Negative} + \text{true positive})}{\text{total no of cases}} = 86\%$$

Table 7: Comparison of AFTP with portal hypertension

Pathophysiology	AFTP≥2.5	AFTP<2.5	0
Exudates	14(True positive)	8(False negative)	22
Transudate	34(false positive)	44(True negative)	78
	48	52	100

Specificity, sensitivity, positive predictive value, negative predictive value and diagnostic accuracy of AFTP is calculated from the table.

**Sensitivity** = 
$$\frac{\text{true positive}}{\text{true positive+false negative}}$$
 = 63.63%

$$Specificity = \frac{\text{true negative}}{\text{false positive+true negative}} = 56.41\%$$

Positive predictive value = 
$$\frac{\text{true positive}}{\text{true positive} + \text{false positive}} = 29.16\%$$

Negative predictive value = 
$$\frac{\text{true Negative}}{\text{trueNegative+false Negative}} = 84.61\%$$

Diagnostic accuracy = 
$$\frac{100(\text{true Negative+true positive})}{\text{total no of cases}} = 58\%$$

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#### **Discussion**

The ascites is predominantly distributed among the age group of 41-60 yearsoccupying about 59 percent of the total population studied. The mean age group in thestudy was found to be 49.51±13.73 years. This is consistent with the findings of thevarious other studies done by Valdivia et al<sup>9</sup>, Younas et al<sup>10</sup>, Al-knawye et al<sup>11</sup>, KhanFy et al<sup>12</sup> and Jiang et al<sup>13</sup>. According to the studies conducted by Valdivia et al<sup>9</sup>, Beg M et al<sup>14</sup>, Shaikh etAl<sup>15</sup>, Younas et al<sup>10</sup> cirrhosis is found to be the most common cause of ascites as inthis study. The second most common cause of ascites in this study was found to betuberculosis and cardiac failure while that of Shaikh et al<sup>15</sup>, Younas et al<sup>10</sup> showedthat carcinomatosis was the second most common cause. The tuberculous ascites wasfound to be the second most common cause of ascites in the study conducted by Valdivia et al and Beg M et al<sup>14</sup>. However the etiological classification is based onthe hospital based studies and it represents only the tip of the iceberg seen in thegeneral population.

The mean serum albumin level in this study was found to be2.91 $\pm$ 0.596. this issimilar to the findings obtained by Santhosh Kumar et al<sup>23</sup> with mean serum albuminamong patient with ascites as 2.87  $\pm$  0.34.

The classification of ascites based on SAAG into high SAAG and low SAAGshowed that 71 % of the patients studied had high SAAG. This finding is consistentwith the findings of study by Shaikh et al<sup>15</sup> which had 85 % of the studied patient hadhigh SAAG suggesting that predominant cases of ascites have high SAAG and consequently portal hypertension. The SAAG value is high in most of the patients this can be attributed to the low mean serum albumin value. Among the patients with ascites having high SAAG the commonest etiologywas found to be cirrhosis with 60% and cardiac failure with 13%. This is similar tothat of finding obtained by khan et al<sup>12</sup> with cirrhosis as the major cause of ascites among high SAAG ascites. The second most common cause of high SAAG asciteswas found to be cardiac failure while in the study conducted by Khan et al<sup>12</sup> showed itwas massive hepatic metastasis.

The high SAAG value has correctly identified the pathophysiology of ascites asportal hypertension in 77% of ascites due to cirrhosis and is consistent withobservation of Beg M et al where it was about 92.59%. Among the ascites due tocardiac etiology the High SAAG value had identified about 92.31% as portalhypertension has its pathophysiology while the observations of Beg M et al showedthat it had identified 100%. The low SAAG value has correctly identified the pathophysiology of ascites as without portal hypertension in 92% of ascites due to Tuberculosis while that of Beg M et al was about 100%.

The incidence of cirrhosis is more in males when compared to females in ourstudy. About 73.3% are males while 26.6% are females. This can be explained because males outnumber females in alcohol consumption as observed by Jauhar etal<sup>22</sup> and further cirrhosis due to alcohol aetiology is the most common cause of cirrhosis in this study and it contributes about 75% of total cirrhosis. The diagnostic accuracy of SAAG and AFTP among the patients with ascites for evaluating the etiological causes of ascites is determined and was found to be 87.01%

and 63.63% respectively which showed that SAAG -Serum Ascitic Fluid AlbuminGradient is superior to AFTP in diagnosing the etiological cause of ascites. By Goyal AK et al<sup>16</sup>, Beg et al<sup>14</sup>, Runyon et al<sup>17</sup>, Laudanno et al<sup>18</sup>, Akriviadis et al<sup>19</sup>, Rana SV et al<sup>20</sup>, Younas et al<sup>10</sup>, Al-Knawye et al<sup>11</sup>shows similar evidence. The obtained P value was found to be <0.001 suggesting superiority of SAAG when compared to AFTP which is statistically significant.

Studies /	Place of study	SAAG %	AFTP%
Al-Knawye et al <sup>11</sup>	Saudi	91	84
Goyal AK et al <sup>16</sup>	India	97	72
Akriviadis et al <sup>19</sup>	Greece	98	52
Runyon et al <sup>17</sup>	America	96.7	55.6
Younas et al <sup>10</sup>	Pakistan	96	56
Rana SV et al <sup>20</sup>	India	86	72
Beg et al <sup>14</sup>	India	96	68

Das BB et al <sup>21</sup>	India	80	63
Present study	India	87	61

The sensitivity of SAAG and AFTP in this present study conducted was found to be 87.01% and 63.64% respectively. This results were consistent with the findings of studies conducted by Beg et al<sup>14</sup>, Rana SV et al<sup>20</sup> and Younas et al<sup>10</sup>.

The specificity of SAAG and AFTP in the present study was found to be 82.6% and 56.41 % respectively. This results were similar to that obtained by the studyconducted by younas et al<sup>10</sup>. This is contradictory to the findings ofstudy by Rana SV et al<sup>20</sup> where the specificity of AFTP was higher than that of SAAG. The specificity of AFTP was 88% while that of SAAG was 84%.

The positive predictive value (PPV) of SAAG and AFTP was found to be94.37 % and 29.16% respectively. This is consistent with the findings of study done by Khan Fy et al<sup>18</sup> and Younas et al<sup>10</sup>. The negative predictive value (NPV) of SAAG and AFTP was found to be 65.51 % and 85.61% respectively. This is consistent with the findings of study done byDas et al<sup>21</sup> with SAAG had negative predictive value of 85% while that of AFTP was 92%. The low negative predictive value of SAAG to AFTP is due to more false negatives of SAAG value.

#### Conclusion

The SAAG is found to be superior to the traditional method of classifying ascites based on AFTP in evaluating the etiology of ascites. The ascites is classified on the basis of SAAG value in to high SAAG and low SAAG. The sensitivity and Specificity of SAAG and that of AFTP in identifying the pathophysiology of ascites studied and found that SAAG had higher sensitivity and specificity compared to that of AFTP. The diagnostic accuracy of SAAG and AFTP was compared and SAAG was found to be superior to AFTP and it was proved statistically significant.

#### Limitations

The study has some limitations which are as follows:

- 1. The number of non-alcoholic cirrhosis involved in this study is very low only 15% of the total patient studied.
- 2. The sample size of this study is minimal.
- 3. The number of female patients included in the study is low compared to that of males.

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#### **Competing interests:**

No known competing interest to declare.

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