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Original Research Article.

An Observational Cohort Study on Prescription Patterns of Intravenous Albumin Use in Different Indications of Liver Disease

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ABSTRACT

Introduction: Albumin is administered 20% as a part of treatment in various indications associated with decompensated liver disease.

Methods: The study was conducted on patients over six months. Data were collected from 50 patients including males and females who are administered 20% albumin for liver cirrhosis. Disease severity before and after albumin infusion was calculated using prognostic tools like Child-Pugh and MELD-Na scoring system.

Results: Among 50 patients, a major percent of patients were found to be HRS (28%) for albumin infusion and few extended indications were noticed; Decompensated liver cirrhosis without any other complications (18%), HE (18%), Hyponatremia (16%). After albumin infusion for six months, prognostic tools (CPT and MELD-Na scores) and laboratory parameters (serum creatinine, serum sodium, serum albumin) were significantly improved with P-value less than 0.05.

Conclusion: Albumin usage has increased in some extended indications like decompensated liver cirrhosis without any other complications, hyponatremia, hepatic encephalopathy. Doses used in the present study were significantly less (when compared to standard doses as per the clinical guidelines) to minimize the adverse effects of albumin primarily pulmonary edema due to volume overload. Our study was consistent with the ANSWER trial where 20% albumin was used for the long term in decompensated liver cirrhosis.

Keywords: Hepatic encephalopathy, Hyponatremia, Hypoalbuminemia, Child-Pugh Turcotte, Model-End-Stage-Liver-Disease-Sodium, Albumin.

Abbreviations:

HRS: Hepato-Renal Syndrome; **HE:** Hepatic Encephalopathy; **SBP:** Spontaneous Bacterial Peritonitis; **HA:** Human Albumin; **CTP:** Child-Pugh Turcotte Score; **MELD-Na:** Model-End-Stage-Liver-Disease Sodium; **PPCD:** Post Paracentesis Circulatory Dysfunction; **CAD:** Coronary Artery Disease; **AKI:** Acute Kidney Injury; **CVA:** Cerebro-Vascular Accident; **COPD:** Chronic Obstructive Pulmonary Disease, **SMT:** Standard Medical Treatment; **AD:** Acute Decompensation; **ACLF:** Acute-On-Chronic-Liver-Failure, **DA:** During Admission; DD: During Discharge.

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INTRODUCTION

Cirrhosis is defined as the histological development of regenerative Hepato-cellular nodules surrounded by fibrous bands in response to chronic liver injury, which leads to portal hypertension and end-stage liver disease. In this condition, liver tissue is replaced with scar tissue and is damaged permanently.[1] The concentration of human serum albumin is 3.5-5 grams/deciliter, comprising approximately 50% of all the proteins in human plasma. So, it is specified as the most abundant protein in the plasma.[2,3] The circulatory half-life of albumin is approximately 16-18 hours, much lower than its total half-life which varies from 12.7 to 18.9 days in a young healthy adult.

Insulin, cortisol, and growth factor (hormonal components) are involved in the production of albumin and are inhibited by Interleukin-6 and Tumor-necrosis-factor alpha (inflammatory mediators).[2] Human serum albumin which is a plasma protein is well known for its versatile biological character as it gets distributed in fluid in distinct compartments of the body and controls plasma oncotic pressure.[4] Ascites is the most common complication of cirrhosis and is defined as the accumulation of fluid in the peritoneal cavity.[5] Spontaneous bacterial peritonitis is one of the most fatal complications in a patient with cirrhosis. It is defined as an infection of the ascitic fluid

with diverse symptomatology.[6] Hepato-renal syndrome is a reversible renal dysfunction in patients with cirrhosis. It is distinguished by reduced renal plasma flow and glomerular filtration rate and even in the absence of renal structural damage. The main indicator of HRS is severe renal vasoconstriction with absolute peripheral vasodilation. HRS is divided into 2 types. Type 1 HRS is the rapid deterioration of renal function where doubling of serum creatine to more than 2.5mg /dl and type 2 HRS is slowly progressive.[7] Hepatic encephalopathy is a reversible neuropsychiatric syndrome with altered consciousness in patients with advanced liver failure. It occurs mainly due to the buildup of neurotoxins like ammonia, amino acids, and fatty acids which are normally metabolized by the liver.[8] Hyponatremia Is one of the most common electrolyte abnormalities seen in hospitalized cirrhotic patients with ascites advanced liver cirrhosis and portal hypertension. Hyponatremia is suggested based on the serum sodium concentration of less than 130 meq/L.[9] Hypoalbuminemia is the condition where albumin levels below 3.4 grams/deciliter and is a predisposing factor for many of the complications and chronic liver disease.[10]

Albumin is prescribed in standard indications like Ascites, Spontaneous Bacterial Peritonitis, and Hepato-Renal Syndrome as per the clinical guidelines. Additionally, albumin is also prescribed in some extended indications like Hepatic Encephalopathy, and Hyponatremia ANSWER trial; is a multi-center study where albumin was given for decompensated liver cirrhosis patients with an advantage over the control group in terms of overall survival and acting as a disease-modifying treatment. The dose prescribed in the ANSWER trial was high which has been suggested to have caused pulmonary edema hence a decreased dose of albumin is prescribed to prevent the volume overload as per the study by saggar m shastry et.al.

METHODOLOGY

The study was conducted in the Gastroenterology department of Yashoda Hospital, Secunderabad, Telangana. It is a well-recognized and multi-specialty hospital, which caters to the needs of people from all over the country. Subjects in the study were cirrhotic patients with regular follow up. The purpose of the study is to evaluate the usage of albumin in various indications of liver cirrhosis.

Informed consent was obtained from all the patients.

The patient's disease severity before and after infusion of albumin was estimated with the help of laboratory parameters and a Model for End-stage liver disease (MELD) score and Child-Pugh (CPT) score. The present study is an observational cohort study conducted in the department of gastroenterology for six months. Liver disease patients were assigned for intravenous albumin infusion as a part of treatment. In and Outpatients of both sexes aged > 18 years who were diagnosed with liver disease were given intravenous albumin as a part of treatment. Patients below 18 years, Pregnant and lactating women are excluded and Patients with known hypersensitivity reactions to albumin and congestive heart failure were excluded. After taking permission from the institutional review board, Yashoda Hospital, the patients were explained about the study and procured informed consent. All the relevant patient data was collected. Each patient was then assessed by using the designed data collection forms. A suitable data collection form was designed to collect, document, and analyze the data. The data collection form includes demographic details of subjects (name, age, sex, etc.), previous medical history, diagnostic tests, laboratory investigations, drugs prescribed, social history, personal history, comorbidities, etiology for liver disease, and other relevant information. The data including demographics, past medical history, laboratory values, and other required data was collected from previous health records, laboratory investigations, and other relevant alternative sources. All the collected data were entered and saved in a suitably designed data collection form, developed for the study. A total of 50 patients including male and female were included in data collection accordingly after taking the informed consent form from each of them. By assessing laboratory parameters and disease severity assessment parameters, calculations were done. All 50 subjects were administered 20% albumin (20gms in 100 ml) every week over several months. Albumin was infused slowly over 2-3 hours.

Table 1: CPT scoring before albumin infusion

Score	Classification	Frequency	Percent
Child B	**Significant effect to functioning of liver**	21	42.0
Child C	**Severe liver disease**	29	58.0

Table 2: CPT scoring after albumin infusion

Score	Classification	Frequency	Percent
Child B	**Significant effect to functioning of liver**	23	46.0
Child C	**Severe liver disease**	27	54.0

Table 3: Paired T-test values for CPT scoring system before and after albumin infusion.

		Paired Differences		t	P value
		95% Confidence Interval of the Difference			
		Lower	Upper		
1	**Child Pugh_DA – Child Pugh_DD**	.0353	.5647	2.278	.027

Table 4: MELD-Na scores before albumin infusion

Score	Frequency	Percent
10-19	6	12.0
20-29	25	50.0
30-39	15	30.0
>40	4	8.0
Total	50	100.0

Table 5: MELD-Na scores after albumin infusion

Score	Frequency	Percent
<9	1	2.0
10-19	13	26.0
20-29	26	52.0
30-39	9	18.0
>40	1	2.0
Total	50	100.0

Table 6: Paired T-test values for MELD-Na scores before and after albumin infusion

		Paired Differences		t	P value
		95% Confidence Interval of the Difference			
		Lower	Upper		
1	MELD Na_DA – MELD Na_DD	2.0884	4.9916	4.901	0.000

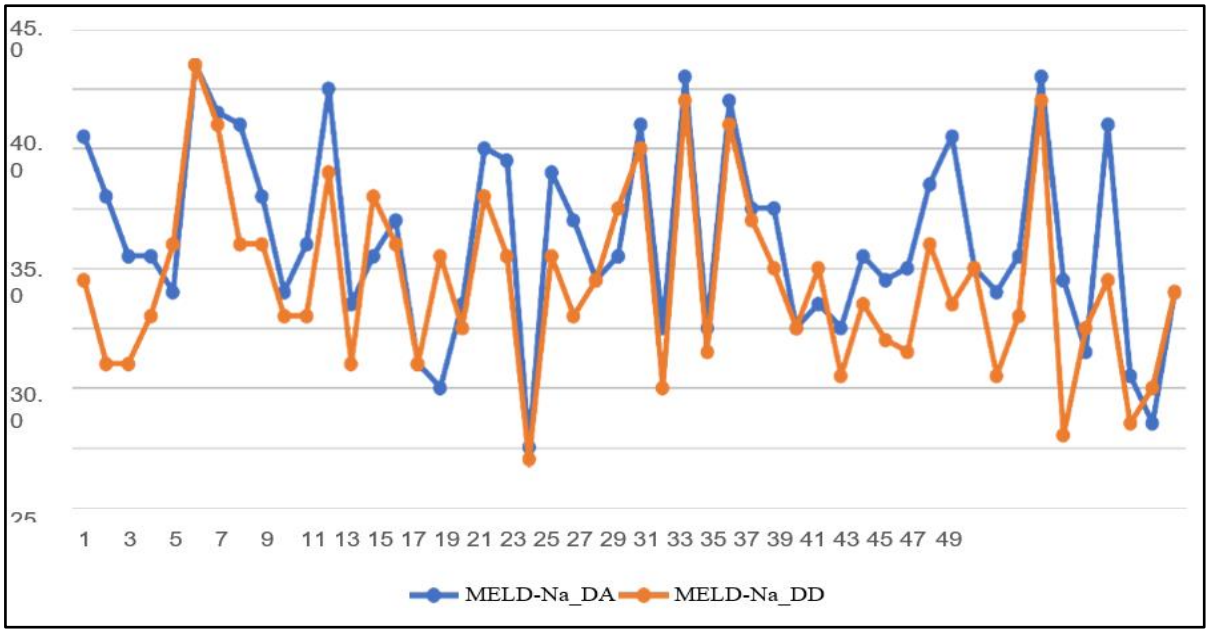

Fig 1: Co-relation MELD-Na scores before and after albumin infusion. Here the blue graph indicates MELD-Na score before albumin infusion and orange graph indicates MELD-Na score after albumin infusion.

Table 7: Distribution based on different indications of liver cirrhosis on albumin infusion

Indications	Frequency	Percentage
DCLD without any other complications	9	18.0
HRS	14	28.0
HE	9	18.0
SBP	3	6.0
Ascites	10	20.0
Hyponatremia	8	16.0

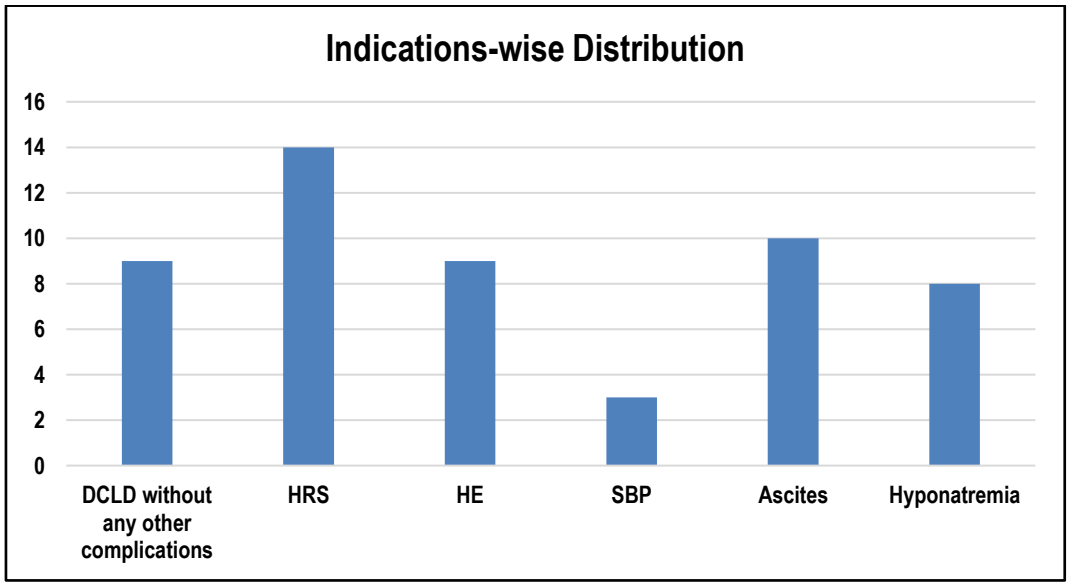

Fig 2: Indication-wise distribution as per albumin infusion.

Table 8: Paired t-Test values for creatinine and total bilirubin before and after albumin infusion

Laboratory parameters		Paired Differences		t	P-value
		95% Confidence Interval of the Difference			
		Lower	Upper		
1	Creatinine_DA - Creatinine_DD	.42551	.96169	5.199	0.000
2	T.bil_DA –T.bil_DD	-.6381	1.878	.990	0.327

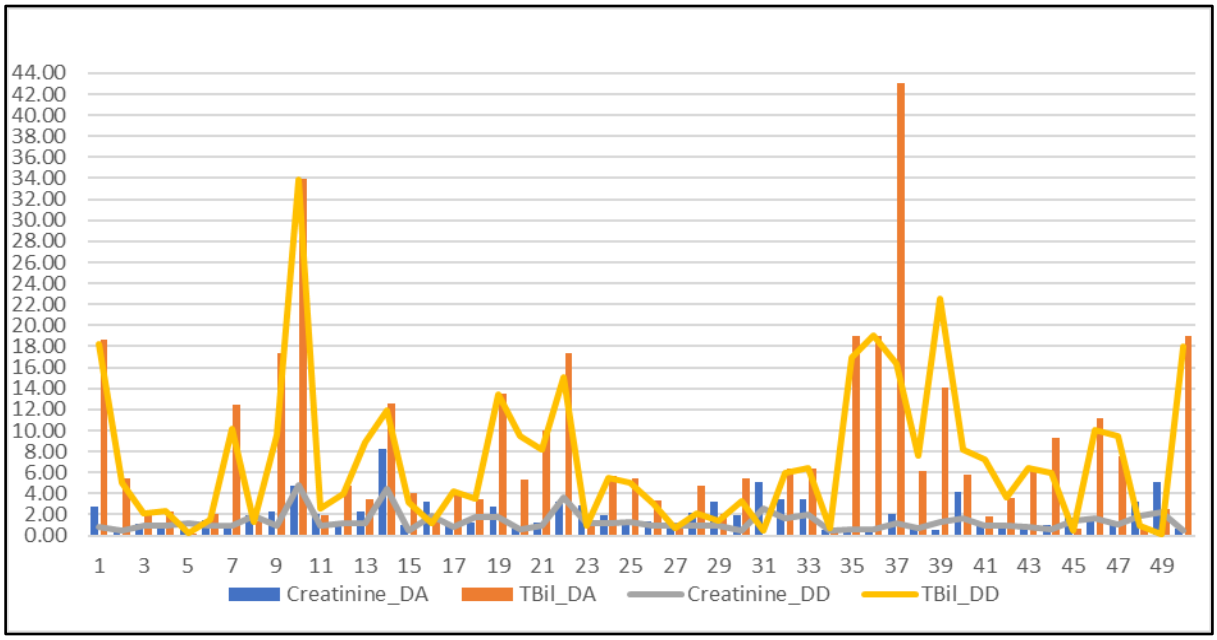

Fig 3: Co-relation between serum creatinine and serum albumin before and after albumin infusion. Here blue and orange bars indicate serum creatinine and total bilirubin before albumin infusion respectively. Gray and yellow graphs indicate serum creatinine and total bilirubin after albumin infusion.

Table 9: Paired t-Test values for serum albumin before and after albumin infusion

		Paired Differences		t	P value
		95% Confidence Interval of the Difference			
		Lower	Upper		
1	Albumin_DA - Albumin_DD	-.3306	-.1894	-7.405	.000

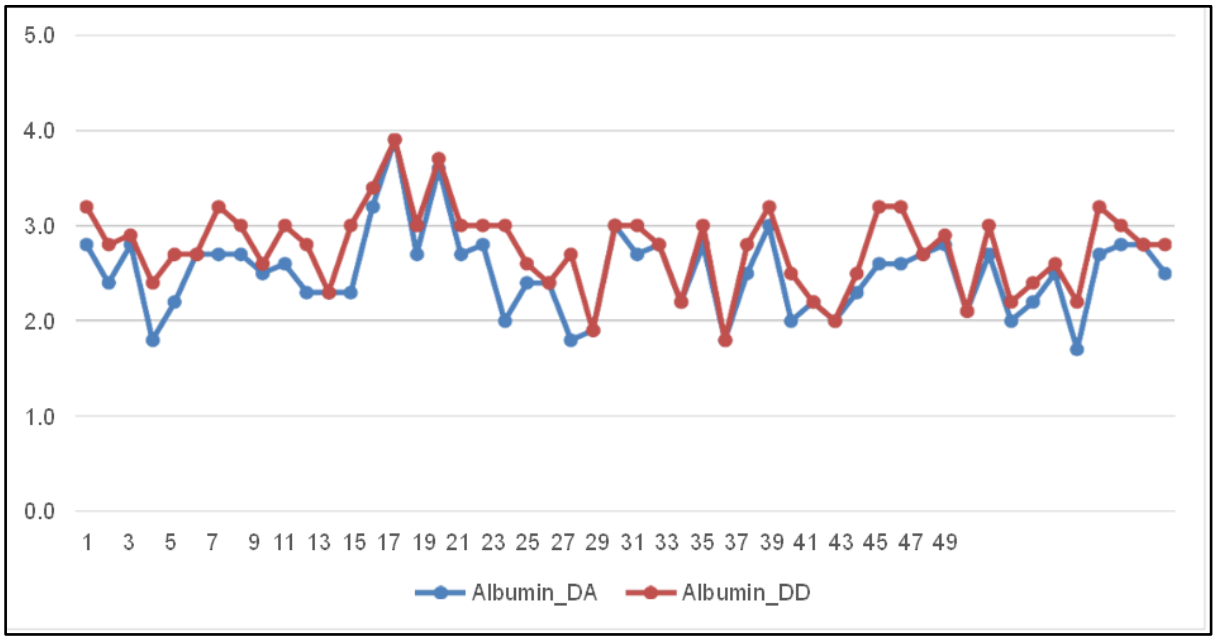

Fig 4: Co-relation between serum albumin before and after albumin infusion.
Here blue and red graphs indicate serum albumin levels before and after albumin infusion respectively.

Table 10: Paired t-Test values for serum sodium before and after albumin infusion

		Paired Differences		t	P value
		95% Confidence Interval of the Difference			
		Lower	Upper		
1	Sodium_DA - Sodium_DD	-6.8391	-2.8009	-4.797	.000

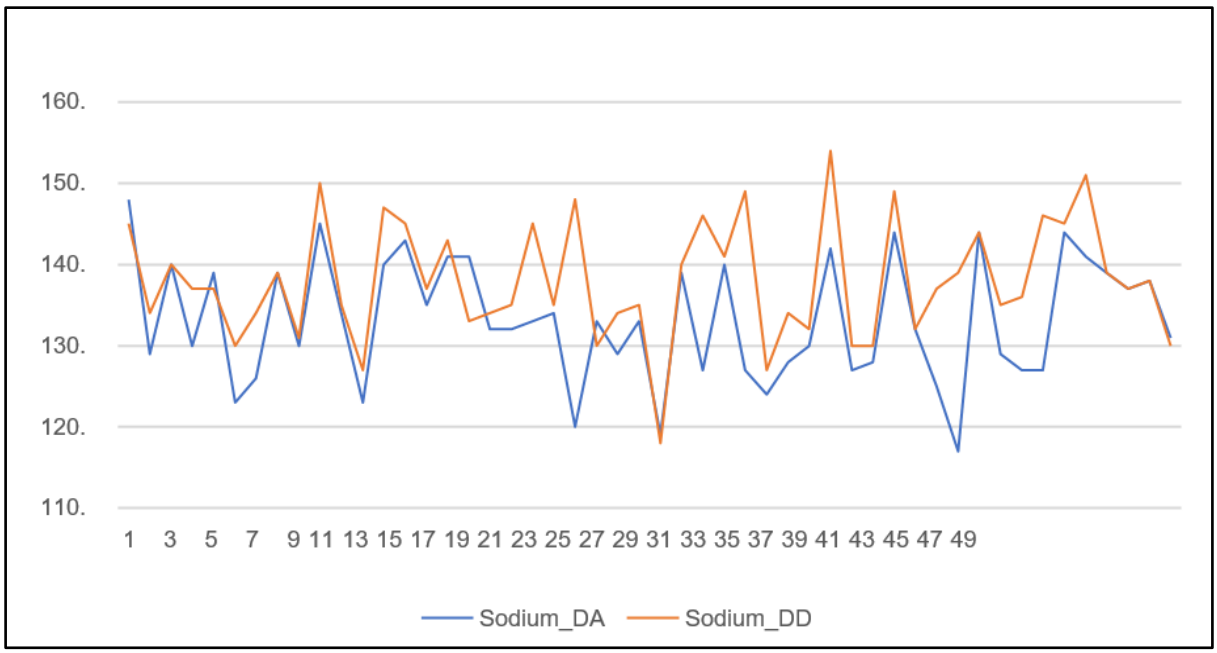

Fig 5: Co-relation between serum sodium before and after albumin infusion. Here blue and orange graphs indicate serum sodium levels before and after albumin infusion respectively.

Table 11: Paired t-Test values for hemoglobin before and after albumin infusion

	Paired Differences		t	P value
	95% Confidence Interval of the Difference			
	Lower	Upper		
Hb_DA-Hb_DD	-.0860	.8620	1.645	.106

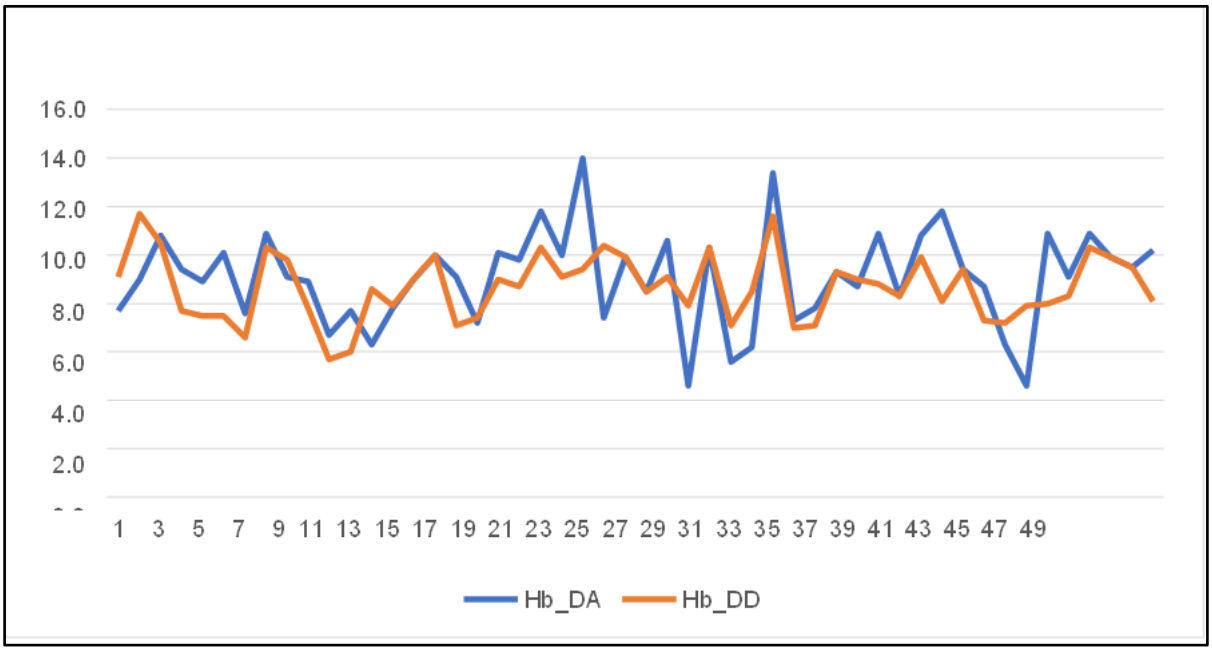

Fig 6: Hemoglobin levels before and after albumin infusion. Here blue and orange graphs indicate Hb levels before and after albumin infusion.

RESULTS

Age and gender-wise distribution: Among 50 patients 36% of patients were in the age group of 50-59 (n=18, 36%) followed by 40-49 (n=15, 30%), 60-69 (n=10, 20%), 30-39 (n=5, 10%), 70-79 (n=2, 4%); 94% (n=47) were men and 6% (n=3) women.

Etiology-wise distribution: Out of 50 patients, the etiology of the liver disease for the majority of the patients was found to be alcohol (n=44, 88%) followed by viral hepatitis (n=6, 12%), auto-immune (n=3, 6%), and fatty liver (n=1, 2%).

Comorbid-wise distribution of patients: It constituted Diabetes (n=21, 42%), followed by Hypertension (n=15, 30%), AKI (n=14, 28%), CAD (n=2, 4%), Hyperthyroidism (n=2, 4%), CVA (n=1, 2%), and COPD (n=1, 2%).

Distribution based on disease severity using the CPT scoring system: Patients with Child-Pugh C score were 58% and Child-Pugh B score was 42% before albumin infusion and none with Child-Pugh A (table 1). After albumin infusion, the Child-Pugh C score subjects decreased to 54% and the Child-Pugh B score to 46% with an improvement from Child-Pugh C to Child-Pugh B score. The p-value for the CPT scoring system before and after albumin infusion was 0.027 (table 3).

Distribution based on disease severity using the MELD-Na scoring system: Most had 20-29 (n=25, 50%), 30-39 (n=15, 30%), 10-19 (n=6, 12%), >40 (n=4, 8%) MELD-Na scoring system before albumin infusion (table 4). After albumin infusion the decreased; 20-29 (n=26, 52%), 10-19 (n=13, 26%), 30-39 (n=9, 18%), >40 (n=1, 2%), <9 (n=1, 2%) (table 5). It has been observed that after albumin infusion few patients MELD-Na score reduced to <9 and there is a decrease in the score of subjects who had high scores. The p-value for the MELD-Na scoring system is less than 0.05 (table 6 and figure 1).

Distribution based on indications for albumin: All the patients were divided based on their indications for albumin use and we found that albumin is also used in some extended indications HE (n=9, 18%), DCLD without any other complications (n=9, 18%), Hyponatremia (n=8, 16%) along with standard indications like HRS (n=14, 28%), SBP (n=3, 6%), Ascites (n=10, 20%). The majority of the patients were identified as HRS (n=14, 28%) for albumin use (table 7 and figure 2).

Distribution based on laboratory investigations (creatinine and total bilirubin) before and after albumin infusion: There is a significant difference between creatinine levels before and after the albumin infusion with a P-value less than 0.05 but there is an insignificant difference between total bilirubin levels before and after the albumin infusion with a P value 0.0327 (Table 8 and figure 3)

Distribution based on laboratory investigations (serum albumin) before and after albumin infusion: There is a significant difference between serum albumin levels before and after albumin infusion with a P value less than 0.05 (Table 9 and figure 4).

Distribution based on laboratory investigations (serum sodium) before and after albumin infusion: There is a significant difference between serum sodium levels before and after albumin levels with a P value less than 0.05 (Table 10 and figure 5)

Distribution based on laboratory investigations (Hemoglobin) before and after albumin infusion: There is a slight decrease in the Hemoglobin levels which was insignificant with a P-value of 0.106 (table 11 and figure 6)

Distribution based on survival rate: We have observed that, out of 50 subjects, patients who survived the treatment period were 84% (n=42).

DISCUSSION

IV infusion of albumin has been extensively used in decompensated liver cirrhosis, especially in patients with reported indications like Spontaneous bacterial peritonitis, Ascites, and Hepato-renal syndrome as per the clinical practice guidelines; also, it is used in some extended indications such as Hyponatremia, DCLD without any other complications and Hepatic encephalopathy as per the previous studies. ANSWER trial (2018) seems to have brought a new concept to clinical practice by

demonstrating better survival in the subjects who received albumin at regular intervals.

The primary objective of our study is to describe the trends of albumin usage in different indications of liver disease and our secondary objective is to evaluate the risk and benefits of 20% albumin use in different indications of liver cirrhosis, especially after the path-breaking beneficial results as seen in ANSWER trial.

In the present study, we observed 50 patients who were diagnosed with liver disease and assigned IV albumin as a part of the treatment. We noticed that most of the patients were in the age group of 50-59 (36%) followed by 40-49 (30%), 60-69 (20%), 30-39 (10%), and 70-79(4%).

Men were (47) 94% and the rest (3) were women (6%). David Mario Rodrigues et.al., in their study of 134 patients with cirrhosis representing a total of 100 patients who received IV albumin in which most of the patients were male71% (n=95) which is similar to our study.[11]

The etiology of liver disease for most of the patients in the study was ethanol-related with 88% (n=44) and the rest was virus related12% (n=6), auto-immune 6% (n=3), and NAFLD 2% (n=10). According to the study conducted by David Mario Rodrigues et al, the most common cause of cirrhosis was alcohol-related at 43% (n=57) followed by non-alcoholic fatty liver disease at 20% (n=27) and hepatitis at 16% (n=21) which is comparable to our study.[12]

Diabetes Mellitus 42% (n=21) and Hypertension 30% (n=15) are the most prevalent co-morbidities. Other co-morbid illnesses found in the study group were AKI 28% (n=14), Hypothyroidism 4% (n=9), CAD 4% (n=2), COPD 2% (n=1), and CVA 2% (n=1).

In our analysis, Child-Pugh and Meld-Na were used as prognostic tools for measuring the severity of liver disease. The patients with Child-Pugh C score were 58% (n=29), followed by Child-Pugh B at 42% (n=21), and none with Child-Pugh A. They were given an albumin infusion for six months. And after albumin infusion, Child-Pugh C score was 54% (n=27), followed by Child-Pugh B was 46% (n=23). There was a significant difference between the Child-Pugh score (before and after albumin infusion) with a p-value of 0.027 (<0.05). There was also a significant difference between the Meld Na scores (before and after infusion of albumin) with a p-value less than 0.05.

Albumin (20% in 100ml) is prescribed for evidence-based indications as per the clinical practice guidelines (Standford, EASL, AASLD). Major percent of patients were reported with HRS-28% (n=14) followed by Ascites-20% (n=10) and SBP-6% (n=3) in study group. Our findings were relevant to the survey conducted by Paolo Carcaceni et.al., where PPCP (98%), SBP (93%), and HRS (98%).[13]

Few extended indications are notified where albumin 20% in 100 ml has been used in Hepatic encephalopathy 18% (n=9), Decompensated liver cirrhosis without any complications 18% (n=9) [Analyzed significant increase in albumin levels after infusion; p<0.05], Hyponatremia 16% (n=8). [Analyzed by a significant increase in sodium level after infusion; p<0.05]. Our study was relevant to the previous studies carried out by Paola Carcaceni et.al., in his ANSWER trial, performed between SMT versus SMT plus HA described that incidence rate ratio and cumulative incidence of hepatic encephalopathy grade 3 or 4 along with other indications remarkably reduced by 30-60.5% in patients receiving SMT plus HA.[11] Louis China et al in their study of 79 patients (AD/ACLF) with albumin levels lower than 30g/liter, showed that 60% of patients attained their serum albumin levels.[14] Jas Mohan. S. Bajaj MD et al in their study performed on hospitalized patients with cirrhosis and hyponatremia received IV albumin had a significant correction of hyponatremia[15] respectively.

In our study of 50 patients on Albumin 20% infusion, the Creatinine and Total bilirubin values were noted before and after the infusion of albumin. There was a significant difference in creatinine with a p-value<0.05 but there was no significant difference in total bilirubin with p=0.327.

We observed in our study that there was a slight decrease in the hemoglobin level after the infusion of albumin 20%, probably as a result of increased fluid relocation to the intravenous compartment.[16]

Pulmonary edema was not observed in our study group given lower doses of albumin used. Pulmonary edema was observed in the other studies.[17]

The mortality rates throughout the study period were 16% (n=8) and the survival rate was 84% (n=42), and the complications of subjects were effectively reversed. The main observation in our study has been the liberal and increased usage of albumin in decompensated cirrhosis patients by the clinicians mainly being influenced by the ANSWER trial. The present study also documented a better result in subjects, though this is not a comparative study.

CONCLUSION

The current study was conducted to describe the trends of IV albumin use in different indications of liver disease where we observed that IV albumin was included as a part of the treatment regimen in the standard indications mentioned as per clinical guidelines i.e., HRS, SBP, and Ascites. Additionally, Albumin 20% IV infusion was also prescribed for some extended indications such as Hepatic encephalopathy, Hyponatremia, and DCLD without any other indications. An additional indication of decompensated liver disease based on the Answer trial is being used in clinical practice has been highlighted. There was a reduction in creatinine levels to its baseline and an increase in albumin and sodium concentration to their normal value and there was no pulmonary edema but there was a slight decrease in hemoglobin concentration after albumin infusion. The administered dose is less when compared to the dose that has been used in previous studies and clinical guidelines. It has been observed that if the standard dose of albumin was given there is a higher chance of pulmonary edema due to volume overload. Thus, based on the observational experience, the dose has been reduced in various indications. Here we conclude that with the use of albumin in various indications of liver disease the survival rate of patients was better and chances of a liver transplant may have been decreased. Furthermore, albumin is cost-effective in terms of lives saved. Therefore, albumin should be considered as a first-line treatment option in cirrhotic patients with decompensation, and the positive results of the ANSWER trial may find a way for clinical application.

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ETHICAL APPROVAL

Institutional Ethics Committee, Yashoda Academy of Medical Education and Research (IEC-YAMER).
Reg.No. ECR/49/Inst/AP/2013/RR-19.
DHR Reg.No. EC/NEW/INST/2020/1148. An informed consent form was taken from the patients.

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