

Nurses' practice related to administration of intravenous albumin therapy among patients with chronic liver disease, with a view to develop a standard operating procedure based on the deficiencies in the nurses' practice

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Abstract: *Background :* Human serum albumin is a common colloid used for volume expansion, albumin replacement and plasmapheresis. anaphylactic reaction to colloids are uncommon, and hypersensitivity reaction to HSA are even rarer. The application of a nursing care protocol in case of an adverse reaction to albumin can help in early management of the reaction and can improve practice linked to albumin therapy and raising nursing standards. **Objective-**To assess the Nurses' Practice related to administration of IV albumin therapy among patients with Chronic Liver Disease, with a view to develop a Standard Operating procedure based on the deficiencies in the Nurses' Practice. **Methods :** Using a quantitative approach, an observational study was conducted. The total enumeration sampling technique was used to enrol 336 patients and 91 nurses who were directly involved in the patient care and administering IV albumin therapy. An observation checklist was prepared for nursing practice also for patients to assess the frequency of adverse reaction. **Result :** Nurse' mean practice score is 75.00. The highest possible score was 100, with the lowest score was 0, in terms of administration of albumin therapy, 28.57% nurses had poor practice, whereas 40.65% had average practice, only 6.59% of nurses had very good practice and 24.17% had a good practice. **Conclusion :** The standard operating procedure was developed that will enhance the nurses' practice and lead to early identification of adverse reaction.

Key Words: Nurses', Albumin Therapy, Chronic Liver. Standard Operating Procedure.

1. INTRODUCTION

The most abundant plasma protein in the body, human serum albumin, regulates plasma oncotic pressure and fluid distribution between bodily compartments. This pleiotropic molecule influences systemic and redox homeostasis, immunological and inflammatory responses, bacterial translocation, pro-inflammatory cytokine production, protein transport, and medication pharmacokinetics and administration thanks to its unusual molecular structure. Albumin is a protein made by the liver and circulated in the bloodstream. Human plasma proteins are used to make medicinal albumin. This medication increases plasma volume or albumin levels in the blood [1].

Drugs, metal cations, gases, poorly water-soluble compounds (bile salts, cholesterol, fatty acids, bilirubin, and so on), hormones (steroids, thyroxin), and other substances are all transported by albumin [2]. Decompensated cirrhosis is characterized by the development of clinical complications resulting from portal hypertension and liver failure. Such complications are responsible for most of the deaths among patients with cirrhosis [3].

The application of a nursing care protocol in the case of an adverse reaction to albumin can lead to early management of the reaction and improve nursing practise linked to albumin therapy, raising nursing standards.

2. LITERATURE REVIEW

A study was conducted with an aim to assess the evaluation of human albumin pattern, the method was carried out between December 2014 to December 2015, using pre-designed forms covering demographic data and clinical and laboratory information. A total 202 patient were selected with the mean age of 55.9±20.5 years, including 53% male

patients. The highest prescription percentages were for patients with the diagnosis of Gastrointestinal Cancers (10.9%) while most of the patients were admitted in burn ward (16.3%), and concluded that low percentage of acceptable prescription which highlights the necessity for reviewing and supervising the utilization of albumin [4].

Immediate hypersensitivity reactions to human serum albumin in a child undergoing plasmapheresis was the subject of a case report. Plasmapheresis with albumin as the replacement fluid was used to treat a 10-year-old kid with chronic inflammatory demyelinating polyneuropathy. He had a significant allergic reaction with symptoms of respiratory, gastrointestinal, and cutaneous irritation. They also discovered that human serum albumin skin testing was positive and caused objective systemic symptoms, indicating an acute hypersensitive reaction to HSA. And they conclude that, while colloids are a rare source of acute hypersensitivity reactions, if not diagnosed and treated rapidly, they can induce severe and potentially fatal reactions [5].

A study is conducted to evaluate the effect of a nurse-led albumin infusion service that greatly lowers the requirement for therapeutic paracentesis in the outpatient day procedure. The goal was to track the uptake and impact of this service on therapeutic paracentesis day procedure admissions during the previous two years. Patients with cirrhosis and ascites hospitalized under gastroenterology to the day procedure ward for either therapeutic paracentesis of at least 1 L of intravenous albumin infusions between October 1, 2017, and September 30, 2019, were included in their study. For every 2 L of ascites drained, 100 mL of 20% concentrated albumin was given, or 2 100 mL per albumin admission, according to usual protocol. Linear regression was used in the statistical analysis, with a <0.05 deemed significant. A review of hospital coding was conducted to ensure that there was no rise in in-patient admissions. Over the course of two years, 460 distinct patient experiences were documented for 28 patients. Every six months, a median of 12.5 patients (range, 10–17) were admitted to the day procedure facility for paracentesis or albumin infusions. During each 6-month period, the average number of paracentesis admissions per patient dropped. While admissions for albumin infusions per patient significantly increased, from 1.2 to 10.1 ($r^2 = 0.93$, $P = 0.04$), neither the average volume of ascites drained with each paracentesis ($r^2 = 0.51$, $P = 0.29$) nor the overall albumin volume per patient ($r^2 = 0.81$, $P = 0.10$) significantly changed during the study period ($r^2 = 0.84$, $P = 0.10$). Overall, inpatient admissions with ascites did not rise during the two years, with a progressive decrease from 30 to 25 every six months ($P = 0.29$). [6]

3. OBJECTIVES

Primary objective

1. To assess the practice related to the administration of IV albumin therapy among the nurses.
2. To determine the frequency of adverse reactions among chronic liver disease patients following IV albumin therapy.

Secondary Objective:

1. To find the association between nurses practice with their demographic characteristics.
2. To find the association between adverse reactions with the demographic and clinical variables of chronic liver disease patients.
3. To develop standard operating procedure based on the deficiencies in the administration of intravenous albumin therapy.

4. METHODOLOGY

Approach and Design: Quantitative Research design, Observation method.

Study Variable: Nurses' Practice related to I/V albumin therapy, Adverse reaction to I/V albumin therapy.

Setting: All General wards, private wards, emergency and albumin day care of Institute of Liver and Biliary Sciences, New Delhi.

Sample and sample size: Nurses who were administering albumin therapy (sample size-91), All patients with chronic liver disease receiving albumin therapy (sample size-336).

Inclusion criteria: All the Nurses working in the wards during the data collection time period, also the patients admitted in the wards and fulfilling the Child-Turcotte Pugh class-A and class-B.

Exclusion criteria: Nurses who are not directly involved and on leaves and patients who are unconscious or critically ill, and Child Turcotte Pugh- Class-C.

The study is based on the nurses' practice in the administration of Intravenous albumin therapy with chronic liver disease patients, the researcher develops a conceptual framework for the study on Ernestine Wiedenbach's Prescriptive theory.

Tools for data collection :

Tool-1 Structured questionnaire to assess the socio-demographic data for nurses.

Tool-2 Observation checklist to assess nurses practice related to administration of albumin therapy

Tool-3: Structured questionnaire to assess the socio-demographic and clinical variables of patients.

Section-A: Structured questionnaire for demographic variable

Section-B: Structured questionnaire for Clinical Variable

Tool-4 Observation checklist to assess the adverse drug reaction on patients due to intravenous albumin

5. Method of Data collection : For the final study, the data was collected from the month of 1st November 2021 to 4th December 2021 at general wards of ILBS. Observation was made on nurses practice, and events of albumin transfusion in the clinical areas of ILBS. After ethical approval and permission from the concerned authority and content validity for the tools from the seven experts was obtained. The purpose of the study was explained to the participants. The researcher introduced herself to nurses and patients and provided them participants information sheet and obtained informed written consent. Nurses who agreed to participate, were observed individually. Nurses were observed for the nurses practice related to intravenous albumin therapy using Practice checklist. The nurses practice of all the nurses in the selected wards were observed. The nurses practice was observed once for each nurse. The principal investigator took the demographic, clinical and baseline data of all the patients before transfusion of albumin therapy. All the patients receiving the albumin therapy were also observed for any adverse reaction using checklist for adverse reactions using patients' medical and nursing records. In case of development of adverse reactions in those patients, on whom the nurse's practice was being observed, the principal investigator stopped the albumin transfusion (in case it was not stopped by the assigned nurse) that patient does not develop any serious event. So, total nurses who were administering albumin therapy were 91 who fulfilled the inclusion criteria and agreed. In terms of patient who were receiving albumin therapy were 336 and in terms of events, total 400 events of albumin therapy were observed.

6. RESULTS:

6.1 Demographic characteristics of the Nurses administering IV albumin therapy

Data is tabulated and analysed to obtain frequency and percentage distribution of demographic characteristics of nurses. The findings related to (Age, gender, educational qualification, clinical experience, has administered albumin earlier, last administration of albumin, and received any prior training related to albumin therapy. It is found that nearly half of the nurses, 44 (48.4%), were in the age group of 24 to 30 years, 29 (31.9%) in the age group of 31 to 35 years, 16 (17.6%) in the age group of 36 to 40 years, and 2 (02.2%) in the age group of 41 to 45 years. There were 47 (51.6%) male nurses and 44 (48.4%) female nurses. The majority of the nurses were GNM qualified 66 (70.3%) and the rest 25 (27.4%) were B.Sc. or post-basic B.Sc Nursing. Half of the nurses, 46 (50.5%), had 6-10 years of clinical experience, 39 (42.9%) had 6-10 years of clinical experience, and only 6 (6.6%) had 11 to 15 years of clinical experience. All of the nurses have given albumin before, within the previous week. None of the nurses had any prior experience with albumin therapy. 48 (52.7%) nurses were allocated two to three patients each shift, while 43 (47.3%) nurses were assigned more than three patients per shift.

6.2 Description of demographic characteristics, the clinical variable of chronic liver disease patients receiving IV albumin therapy.

3 (0.9 percent) of patients were from the age group of 18 to 30 years, 115 (34.2%) years Patients were from the age group of 31 to 40 years, 112 (33.3 percent) were from the age group of 41 to 50 years, 81 (24.1 percent) 51 to 60 years, 25 (7.4 percent) of patients were from the age group of 61 to 70 years old, 211 (66.8 percent) of patients were male, 125 (37.2 percent) of patients were female regarding hospitalization for the management of the liver disease, 39 (11.6 percent) of patients were hospitalized the first time, 174 (51.8 percent) of patients hospitalized 2-3 times, 80 (23.8%) patients were hospitalized 4-6 times, and 43 (12.8 percent) patients were hospitalized more than 6 times, 324 (96.4 percent) had received albumin earlier and 12 (3.6 percent) patients did not receive any albumin therapy earlier. None of the patients any had a history of allergic reactions.

6.3 Demographic characteristics of CLD patients receiving albumin therapy

143 people (42.6%) were diagnosed with CLD ethanol. AIH was diagnosed in 84 (25.0%) people, while NASH was found in 83 (24.7%). CLD-HBV linked was detected in 26 people (7.7%). The bulk of the patients 325 (96.7 percent) presented with ascites. 193 (59.3%) of these patients had grade-I ascites, 74 (22.7%) had grade-II ascites, and 58 (17.8%) had grade-III ascites. Among all the patients, 330 (98.2%) had hypalbuminaemia as a reason for albumin transfusion, while 6 (1.8%) reported graft failure as an indication for albumin transfusion. Significant

abdominal drainage was an indication for albumin transfusion in 91 (27.1%) of patients, and large-volume paracentesis was an indication for albumin transfusion in 197 (58.6%). Only 7 (2.0%) of the patients required albumin transfusion due to shock. Almost 321 (95.5%) of patients spent 1 to 7 days in the hospital, 11 (3.3%) spent 8 to 14 days in the hospital, and only 4 (1.2%) of patients spent 15 to 21 days in the hospital.

6.4 Frequency and percentage distribution of practice scores of nurses

Table 1 Frequency and percentage distribution of nurses by the level of practice of nurses

n= 91

Practice Score	Frequency (f)	Percentage (%)
>90 Very Good	6	6.59%
80-89% Good	22	24.17%
70-79% Average	37	40.65%
<70% Poor	26	28.57%

Maximum Possible score = 100

Minimum Possible Score = 0

Table- 2 Domain wise Mean Percentage of Practice Score of Nurses.

n= 91

Domain	No of items	Mean Percentage	Rank
Pre-Procedure practice	16	77.81	II
During Procedure practice	14	58.39	III
Post-Procedure practice	8	78.96	I

Maximum Possible Score= 100

Minimum Possible Score= 0

The data in table 2, shows that the lowest mean percentage of practice score of Nurses was 58.39 in the domain of nurses' practice During the procedure checklist, this was followed by the mean percentage practice score of 77.81 percent in the domain of Pre-Procedural Practice, the mean percentage of post-procedure practice score was 78.96 and the domain of post-procedure checklist ranked under I.

Table-3 Adverse reaction related to albumin therapy in chronic liver disease patients.

n= 400

Variable	Frequency (f)	Percentage (%)
Tachycardia	2	0.5%
Difficulty in breathing	8	2.0%
Decrease oxygen	2	0.5%
Fever developed after transfusion	2	0.5%
Nausea	1	0.2%
Itching	1	0.2%
Onset of symptoms related to adverse reaction		
Within 1-3 min	8	2.0%
Within 4-6 min	1	0.2%

This table depicts, 2(0.5 percent) of patients had tachycardia after albumin transfusion. 8 (2.0 percent) of patients had difficulty in breathing after albumin transfusion. 2 (0.5%) of patients observed that and after confirming saturation level by pulse-oximeter they had decrease in saturation after albumin transfusion. 2 (0.5 percent) of patients had developed fever after albumin transfusion, 1(0.2%) of patients complain of Nausea feeling after albumin transfusion and one of the patients complains of itching all over the body after the albumin transfusion, 8 (2.0 percent) of patients

complaints of adverse reaction after 1-3 min, 1 (0.2 percent) complains of adverse reaction regarding albumin after 4-6 min.

Table-4 Association between the nurse's practice scores related to administration of intravenous albumin and the nurses' demographic characteristics.

n= 91

Variable	Practice score (Mean±SD)	F/t	MD	df	p-value
Age in years					
24-30	71.30±5.63	F= 8.34		90	0.000**
31-35	77.86±7.91				
36-40	80.19±9.02				
41-45	73.00±9.89				
Gender					
Male	76.17±8.33	t= 1.46	2.44	89	0.14
Female	73.73±7.46				
Education					
G.N.M	74.45±6.23	t= 1.039	1.94	89	0.30
B.Sc.	76.40±9.13				
Experience					
Less than 5	71.15±6.23	F= 9.35		90	0.000**
6-10	77.89±8.19				
11-15	77.67±6.68				
Patients assigned in a shift					
Two or three	75.31±7.93	t= 0.40	0.68	89	0.68
More than three	74.63±8.10				

P<0.001** Highly Significant

One-way ANOVA or student t-test is applied to find the association between mean practice score and demographic variable.

Table-5 Association between adverse reaction of albumin among chronic liver disease patient with their demographic variable

n=400

Variable	Albumin Reaction		Fisher exact test/ χ^2	p-value
	Present	Absent		
AGE in years				
20-30	0 (0.0)	3(0.7)	Fisher exact test=2.56	0.64
31-40	5 (1.2)	134(33.5)		
41-50	2 (0.5)	136(34.0)		
51-60	2 (0.5)	89(22.2)		
61-70	0(0.0)	29(7.2)		
Gender				
Male	3(0.7)	261(65.2)	$\chi^2=4.37$	0.03*
Female	6(1.5)	130(32.5)		

Number of times hospitalized for liver disease.				
first time				
2-3 times	0(0.0)	43(10.7)	Fisher exact test=1.64	0.67
4-6 times	5(1.2)	212(53.0)		
More than 6 times	2(0.5)	91(22.7)		
	2(0.5)	45(11.2)		
Have you received albumin therapy earlier?				
Yes	1(0.2)	387(96.7)	$\chi^2=233.4$	0.000**
No	8(2.0)	4(1.1)		

p<0.0001** Highly Significant

The data given in Table 5 shows the findings related to the association between adverse reactions & selected demographic variables.

Fisher exact test is applied for demographic and adverse reactions; the p-value is not found significant in any. It can be thus interpreted that there is no significant relationship between adverse drug reactions and Age, no of times of hospitalization.

Chi square of 4.37 is computed and p value (0.03) at the level of 0.05 significance, shows a statistically significant difference in gender of the patient. Second chi square (233.4) at p value (0.000) was highly significant in have you received albumin.

Hence, the null hypothesis H_2 is rejected. It can be interpreted that there is a significant association between adverse reactions in albumin therapy in gender and have you ever received albumin therapy earlier.

Table-6 Association between the adverse reaction of albumin among chronic liver disease patients with their selected clinical variable.

Variable	Albumin Reaction		Fisher exact test/ χ^2	p-value
	Present	Absent		
Diagnosis of the patient				
CLD ethanol	3(46.0)	184(46.0)	Fisher exact test=3.26	0.37
AIH	4(1.0)	88(22.0)		
NASH	1(0.2)	93(23.2)		
CLD-HBV	1(0.2)	26(6.5)		
Presence of Ascites #(n=389)	9(2.3)	380(97.6)	$\chi^2=0.26$	1.00
Grade #(n=389)				
Grade-I	1(0.2)	251(64.5)	Fisher exact test=22.5	0.000**
Grade-II	0(0.0)	75(19.2)		
Grade- III	8(2.0)	54(13.8)		

n=400

Liver failure				
Absent	6(1.5)	65(16.9)	$\chi^2=3.74$	0.05
Present	3(0.7)	326(81.5)		
Duration of hospitalization				
1-7 days	9(2.2)	376(94)	Fisher exact test=0.90	1.00
8-14 days	--	11(2.7)		
15-21 days	--	4(1.0)		

Grade of Ascites is calculated out of patients with ascites (n=389)

CLD- chronic liver disease, AIH- Autoimmune hepatitis, NASH- Non-alcoholic steatohepatitis, HBV- Hepatitis B virus.

p<0.001* Highly Significant

Fisher exact test and chi square is applied for clinical variables and adverse reactions the p-value is not found to be significant in any.

There is significant association in grade of ascites and adverse reaction, data showed that p-value (0.000) which is found significant in grade III ascites with fisher exact value of 22.5.

It can be thus interpreted that there is no significant relationship between adverse reactions in terms of diagnosis, presence of ascites and in any other indication of albumin i.e., liver failure and duration of hospital stay. But there is a significant association between grade III ascites with p-value (0.000).

Therefore, null hypothesis H_2 is rejected for grade III ascites. It can be interpreted that there is significant association between adverse reaction in albumin therapy and the grade of ascites. The patient who is with grade III ascites are at a higher risk of developing albumin adverse reactions.

7. DISCUSSION: The result of the present study showed that the mean percentage practice score of nurses who were administering I/V albumin therapy to the patients was 75.00 percent $\pm$ 8. 0. [7], concluded that the mean transfusion practice score is 10.25 percentage $\pm$ 1.92. Another study concluded [8] indicates that nurses had average to poor practice in the administration of IV albumin therapy and shows that two-thirds of respondents (66.1%) had an unsatisfactory level of IV albumin therapy practice whereas only (33.9%) of the respondents had satisfactory in their practice in relation to IV therapy

8. CONCLUSION: It is concluded that nurses' working in wards had average to poor practice in administration of IV albumin therapy. The nurses practice was found significantly associated with age and clinical experience of the nurses. As practice is inadequate, repeated and focused training of nurses is very important to enable retention of knowledge and practice. In addition, adverse reaction related to albumin therapy that were reported are shortness of breath, tachycardia, itching, fever and nausea. There was no case of death probably attributed to albumin, that was reported. The standard operating procedure based on the deficiencies was developed that will enhance the nurses practice and lead to early identification of adverse events.

9. LIMITATIONS:

- A standardized tool could not be located by the investigator, so the investigator developed the tool for the study.
- The nurses practice after the implementation of SOP for albumin therapy was not assessed.
- Study was limited to only the general wards and semi-private and private wards of the selected hospital.

10. RECOMMENDATIONS:

- A survey can be conducted to assess the knowledge regarding albumin therapy.
- A similar study can be done to assess the effectiveness of the standard operating procedure of IV albumin therapy among nurses.
- A similar study can be done on the nurses to check the pre and post-test knowledge.

- A similar study can be done through standardized tools.
- Association of adverse reaction with other relevant factor like fluid overload, electrolyte balance can be sought.

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