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Original Article

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Efficacy and Safety of 20% Albumin Compared to Plasmalyte in Reversing Sepsis-Related Hypotension in Cirrhotic Patients

Chetan Goyal[1], Deepa Agarwal[2]*

[1]Assistant Professor, Department of Anesthesia, Pacific Institute of Medical Sciences, Umarda, Udaipur, Rajasthan, India
[2]Assistant Professor, Department of Anesthesia, Pacific Medical College and Hospital, Bhilon ka Bedla, N.H. 27, Pratap Pura, Girwa, Udaipur, Rajasthan, India

***Address for Correspondence:** Dr. Deepa Agarwal, Assistant Professor, Department of Anesthesia, Pacific Medical College and Hospital, Bhilon ka Bedla, N.H. 27, Pratap Pura, Girwa, Udaipur, Rajasthan, India
E-mail: agarwal.deepa19@gmail.com

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ABSTRACT

Background: Sepsis-related hypotension in cirrhotic patients presents unique tasks due to altered hemodynamic and fluid shifts. While albumin is frequently used for volume resuscitation, evidence comparing hyperoncotic albumin to balanced crystalloids like Plasmalyte in this specific population is limited.

Methods: A prospective, randomised, open-label, controlled trial was conducted at a tertiary care hospital in Udaipur, Rajasthan. Sixty adult patients (30 per group) with cirrhosis and sepsis-associated hypotension were randomised to receive either 20% albumin or Plasmalyte according to sepsis guidelines. The primary outcome was reversal of hypotension within 6 hours. Secondary outcomes included norepinephrine requirements, lactate clearance, incidence of pulmonary oedema, renal disfunction, allergic reactions, in-hospital mortality, and 7-day survival.

Results: Baseline characteristics were similar between groups. Hypotension reversal within 6 hours occurred in 80% of the albumin group versus 50% of the Plasmalyte group (p=0.01). Median time to achieve MAP ≥65 mmHg was shorter in the albumin group (3.2 [2.5–4.0] vs. 5.6 [4.8–6.5] hours; p<0.001). The albumin group required suggestively lower norepinephrine doses (0.06±0.02 vs. 0.12±0.04 µg/kg/min; p=0.002) and had better lactate clearance at 6 and 24 hours (p=0.003 and 0.001, respectively). Pulmonary oedema (10% vs. 3.3%, p=0.61), worsening renal function (6.7% vs. 10%, p=0.64), and in-hospital death (20% vs. 26.7%, p=0.54) were not suggestively different between groups.

Conclusions: In cirrhotic patients with sepsis-related hypotension, 20% albumin was superior to Plasmalyte in accomplishing early hemodynamic stabilisation and reducing vasopressor requirements. However, this did not translate into improved short-term survival or lower complication rates. Additional large-scale trials are necessary to define the optimal role of albumin in this population.

Key-words: Sepsis, cirrhosis, Hypotension, albumin, Plasmalyte, Fluid resuscitation, Vasopressors, Lactate clearance

INTRODUCTION

Sepsis and septic shock constitute important causes of illness and death in patients with cirrhosis, with systemic inflammation, circulatory dysfunction, and multi-organ failure occurring frequently [1]. In cirrhotic patients, these risks are compounded by portal hypertension, hypoalbuminemia, immune dysregulation, and increased vascular permeability, predisposing them to hypotension and acute kidney injury during sepsis. For such individuals, quick restoration of mean arterial pressure ≥ 65 mmHg and tissue perfusion via fluid resuscitation is a foundation of initial management.

Balanced crystalloid solutions such as Plasmacytes are frequently considered first-line due to favourable electrolyte composition and lower cost. However, colloid fluids like albumin, the natural plasma protein, offer both oncotic pressure support and potential non-oncotic benefits such as antioxidant, endothelial-stabilising, and immune-modulatory effects [2]. Particularly, in cirrhosis, albumin has proven utility for specific indications, including spontaneous bacterial peritonitis, hepatorenal

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syndrome, and post-paracentesis circulatory dysfunction. Numerous meta-analyses in sepsis have explored whether albumin confers superiority over crystalloids. Xu *et al.* found no overall mortality benefit with albumin versus saline in adult severe sepsis or septic shock patients [2]. Similarly, a larger Cochrane-style systematic review including 15 RCTs through 2014 concluded that albumin did not significantly reduce mortality compared to crystalloid fluids (RR ≈ 0.94) and crystalloid should be first-line on account of cost and safety considerations [3].

However, meta-analytical subgroup analyses suggest nuance: albumin may confer benefit in septic shock specifically. One meta-analysis of ~5,124 septic patients (3,482 with septic shock) demonstrated that albumin, particularly 20% hyperoncotic solutions, was associated with significantly reduced 90-day death, compared to balanced crystalloids [4]. A separate trial sequential analysis found no conclusive mortality benefit, though the information size was limited, prompting calls for further RCTs in targeted populations [5].

Building on this, the ALPS trial directly compared 20% albumin versus Plasmacytes in cirrhotic patients presenting with sepsis-induced hypotension. Fifty patients randomised to receive 20% albumin (0.5–1.0 g/kg over 3 hours) were compared with fifty receiving Plasmacytes (30 mL/kg over 3 hours). Baseline MAP, arterial lactate, and SOFA scores were comparable between groups. The trial found that 62% of patients in the albumin arm achieved MAP≥65 mmHg at 3 hours versus only 22% in the Plasmacytes group ($p<0.001$). Albumin also produced faster lactate clearance ($p=0.03$) and a tendency toward delayed and reduced need for dialysis, though there was no significant difference in 28-day mortality (58% vs 62%, $p=0.57$). Importantly, treatment with 20% albumin had to be discontinued in 22% of patients due to pulmonary difficulties, whereas none were discontinued in the Plasmacytes arm safety apprehensions in this high-risk population.

Thus, the ALPS trial suggests that hyperoncotic albumin can restore blood pressure and improve perfusion parameters more rapidly than balanced crystalloid in cirrhotic septic patients, though without a clear survival benefit and with increased risk of pulmonary morbidity requiring close monitoring. These results are consistent with broader observations: while albumin's pressure-raising and lactate-clearing properties may be physiologically advantageous, its high cost and risk profile, in particular, pulmonary oedema, limit its indiscriminate use in sepsis [6,7].

In cirrhosis specifically, the physiologic rationale for albumin is stronger than in sepsis alone: dysfunctional endogenous albumin, impaired vascular tone, hypoalbuminemia and portal hypertension can render colloid more effective in volume support and host-modulatory resilience. However, most RCTs and meta-analyses until ALPS have either excluded cirrhotic or had underpowered subgroups, making dedicated evidence such as ALPS essential [8,9].

Applying such evidence to a setting like Udaipur, Rajasthan, requires consideration of local resources, patient population characteristics, and the feasibility of monitoring for complications like pulmonary oedema [10]. While Plasmacytes remains inexpensive, safe, and effective for most cirrhotic septic patients, the evidence from ALPS supports selective early use of 20% albumin in those with refractory hypotension, provided intensive monitoring is available [11].

In summary, current literature up to 2024 indicates that 20% albumin is more effective than Plasmacytes in achieving rapid hemodynamic stabilisation in cirrhotic patients with sepsis-related hypotension, but does not improve short-term mortality and carries measurable safety risks. Additional larger multicentric trials are necessary to clarify being impact, optimal dosing, and subgroup selection, especially across diverse healthcare situations [12].

MATERIALS AND METHODS

Study Design and Setting- This study was designed as a prospective, randomised, open-label, controlled clinical trial conducted at a tertiary care teaching hospital in Udaipur, Rajasthan. The primary aim was to evaluate and compare the efficacy and safety of 20% human albumin versus Plasmalyte, an isotonic balanced crystalloid solution, in reversing sepsis-related hypotension in adult patients diagnosed with liver cirrhosis. Informed consent was obtained from all participants or their legal representatives before enrolment.

Participant Selection- Adults aged between 18 and 70 years were included if they had a confirmed diagnosis of liver cirrhosis based on clinical features, biochemical parameters. Eligible patients were also required to present with sepsis and associated hypotension, defined

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as a mean arterial pressure below 65 mmHg despite receiving initial fluid resuscitation of at least 30 mL/kg crystalloid.

Patients were excluded from participation if they had any of the following conditions:

- ✓ Active upper or lower gastrointestinal bleeding at presentation
- ✓ Acute-on-chronic liver failure requiring emergent liver transplantation
- ✓ Diagnosed cardiomyopathy with left ventricular ejection fraction less than 40%
- ✓ Known hypersensitivity to albumin or components of the investigational fluid
- ✓ Terminal illness or end-stage organ failure unrelated to liver disease
- ✓ Pregnant or lactating women

Randomisation and Interventions- After eligibility confirmation, patients were randomised in a 1:1 ratio into two treatment arms using a computer-generated random allocation sequence. Allocation concealment was ensured using sequentially numbered, sealed opaque envelopes handled by an independent investigator not involved in patient care. Group A (Albumin Group): Patients received intravenous 20% human albumin solution at a dose of 1.5 g/kg body weight infused over 3 hours on Day 1. A second dose of 1 g/kg was administered on Day 3 if clinically indicated based on persistent hemodynamic instability or hypoalbuminemia. Group B (Plasmalyte Group): Patients received Plasmalyte by the standard protocol for fluid resuscitation in sepsis, typically starting at 30 mL/kg over the first 3 hours, titrated based on clinical response and fluid status. In both groups, additional care, including antibiotic therapy, source control, vasopressor support, oxygen supplementation or ventilatory assistance, and renal replacement therapy if required, was administered following the current Surviving Sepsis Campaign guidelines. Vasopressor support was initiated for MAP <65 mmHg despite adequate fluid loading.

Outcome Measures

- ✓ The primary outcome of the study was the successful reversal of hypotension, defined as achieving a MAP of ≥65 mmHg within 6 hours of fluid intervention without the requirement for vasopressors.
- ✓ Total vasopressor requirement
- ✓ Changes in serum lactate levels measured at baseline, 6 hours, and 24 hours
- ✓ Incidence of pulmonary oedema, diagnosed clinically and confirmed radiologically
- ✓ In-hospital mortality and 7-day survival rate post-enrolment
- ✓ Occurrence of adverse events such as new-onset renal dysfunction or allergic reactions attributable to fluid therapy

Sample Size Estimation- The sample size was calculated to detect a minimum expected difference of 20% in the primary outcome between the two groups, with a power of 80% and a two-sided alpha level of 0.05. Based on this estimation, a total of 60 patients were required for the study.

Statistical Analysis- Data were entered into a secure database and analysed using IBM SPSS Statistics. Normality was tested with the Kolmogorov–Smirnov test. Normally distributed variables were expressed as mean±SD and compared with the Student's *t*-test, while non-normal data were shown as median (IQR) and analysed using the Mann–Whitney U test. Categorical variables were presented as frequencies (%) and compared using the Chi-square or Fisher's exact test. Relative risk with 95% CI was calculated where relevant. A p-value<0.05 was considered statistically significant. Subgroup analyses were performed by baseline serum albumin, MELD score, and vasopressor use.

RESULTS

The mean age of patients in the albumin group was 52.4±9.6 years, while it was 51.7±8.9 years in the Plasmalyte group (p=0.73), showing no significant difference. Both groups had a predominance of male patients, with 70% in the albumin group and 66.7% in the Plasmalyte group (p=0.78). The Model for End-Stage Liver Disease scores were also comparable, with a mean score of 18.2±4.1 in the albumin group and 17.8±3.9 in the Plasmalyte group (p=0.64), suggesting similar severity of underlying liver disease. Hemodynamic and biochemical parameters at baseline were balanced between the groups. The mean baseline mean arterial pressure was 58.3±5.2 mmHg in the albumin group compared to 57.9±6.1 mmHg in the Plasmalyte group (p=0.81), indicating equivalent degrees of hypotension

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before intervention. The baseline serum lactate levels, an important marker of tissue hypoperfusion and sepsis severity, were 4.2±1.1 mmol/L in the albumin group and 4.0±1.2 mmol/L in the Plasmalyte group (p=0.57), with no statistically significant difference. Similarly, baseline serum creatinine levels were nearly identical between the groups (1.5±0.4 mg/dL vs. 1.6±0.5 mg/dL, p=0.49), indicating comparable renal function before fluid resuscitation (Table 1).

Table 1: Baseline Characteristics of Study Participants

Parameter	Albumin Group (n=30)	Plasmalyte Group (n=30)	p-value
Age (years)	52.4±9.6	51.7±8.9	0.73
Male sex (%)	21 (70%)	20 (66.7%)	0.78
MELD score	18.2±4.1	17.8±3.9	0.64
Baseline MAP (mmHg)	58.3±5.2	57.9±6.1	0.81
Serum lactate (mmol/L)	4.2±1.1	4.0±1.2	0.57
Baseline creatinine (mg/dL)	1.5±0.4	1.6±0.5	0.49

Hypotension reversal within 6 hours of intervention was achieved in 80% of patients in the albumin group compared to only 50% in the Plasmalyte group (p=0.01), indicating superior efficacy of albumin in early hemodynamic stabilisation. Similarly, the median time to achieve a MAP of ≥65 mmHg was significantly shorter in the albumin group at 3.2 hours (interquartile range: 2.5–4.0 hours) compared to 5.6 hours (IQR: 4.8–6.5 hours) in the Plasmalyte group (p<0.001). The total norepinephrine requirement, measured as the mean dose administered, was significantly lower in the albumin group (0.06±0.02 µg/kg/min) compared to the Plasmalyte group (0.12±0.04 µg/kg/min; p=0.002), suggesting that albumin reduced the need for vasopressor support. Serum lactate levels, an indicator of tissue hypoperfusion and severity of sepsis, were also consistently lower in the albumin group. At 6 hours post-intervention, serum lactate levels were 2.9±0.8 mmol/L in the albumin group compared to 3.7±1.0 mmol/L in the Plasmalyte group (p=0.003). This movement persisted for 24 hours, with the albumin group showing a mean serum lactate of 1.8±0.6 mmol/L compared to 2.6±0.9 mmol/L in the Plasmalyte group (p=0.001) (Table 2).

Table 2: Primary and Secondary Outcomes

Outcome	Albumin Group (n=30)	Plasmalyte Group (n=30)	p-value
Hypotension reversal within 6 hrs (%)	24 (80%)	15 (50%)	0.01*
Median time to MAP ≥65 mmHg (hrs)	3.2 (2.5–4.0)	5.6 (4.8–6.5)	<0.001*
Total norepinephrine dose (µg/kg/min)	0.06±0.02	0.12±0.04	0.002*
Serum lactate at 6 hrs (mmol/L)	2.9±0.8	3.7±1.0	0.003*
Serum lactate at 24 hrs (mmol/L)	1.8±0.6	2.6±0.9	0.001*

The comparison of safety and outcome parameters between the two study groups showed no statistically significant differences. Pulmonary oedema, a known potential complication of albumin therapy, was observed in 10% of patients in the albumin group compared to 3.3% in the Plasmalyte group (p=0.61). Although numerically higher in the albumin group, this difference did not reach statistical significance.

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Worsening renal function occurred in 6.7% of patients in the albumin group and 10% in the Plasmalyte group (p=0.64), again showing no significant difference. No allergic reactions were reported in either group. In-hospital mortality was 20% in the albumin group and 26.7% in the Plasmalyte group (p=0.54), indicating no statistically significant survival advantage with either fluid strategy. Similarly, the 7-day survival rates were comparable, with 80% survival in the albumin group and 73.3% in the Plasmalyte group (p=0.54). These results suggest that while albumin improved early hemodynamic parameters and lactate clearance, these benefits did not translate into a statistically significant difference in short-term survival or incidence of major complications when compared to Plasmalyte (Table 3).

Table 3: Safety Outcomes and Mortality

Parameter	Albumin Group (n=30)	Plasmalyte Group (n=30)	p-value
Pulmonary oedema (%)	3 (10%)	1 (3.3%)	0.61
Worsening renal function (%)	2 (6.7%)	3 (10%)	0.64
Allergic reaction (%)	0	0	–
In-hospital mortality (%)	6 (20%)	8 (26.7%)	0.54
7-day survival (%)	24 (80%)	22 (73.3%)	0.54

DISCUSSION

This analysis synthesises evidence on adult cirrhotic patients with sepsis-induced hypotension, focusing on the efficacy and safety of hyperoncotic albumin versus balanced crystalloid solutions. The ALPS trial, involving cirrhotic patients randomized to 0.5–1 g/kg of 20% albumin versus Plasmalyte over three hours, established suggestively higher rates of hypotension reversal at 3 hours in the albumin group (62% vs. 22%, p<0.001), as well as more rapid lactate clearance and reduced need for dialysis initiation. However, no mortality difference at 28 days was observed, and pulmonary complications leading to albumin discontinuation occurred in approximately 22% of albumin-treated patients [13].

The FRISC trial, using 5% albumin vs 0.9% saline in 308 cirrhotic septic patients, also found superior reversal of hypotension at both 1 and 3 hours, improved heart rate and lactate clearance, and a higher short-term survival at one week. This suggests that even iso-oncotic albumin discusses hemodynamic and perfusion advantages versus saline in this situation [14].

In dissimilarity, broader non-cirrhotic sepsis studies such as the ALBIOS trial, SAFE, and EARSS, which largely excluded cirrhotic patients, found no overall death benefit with albumin compared to crystalloids. However, subgroup analyses in septic shock hinted at modest death reductions with 20% albumin.

Similarly, a meta-analysis of over 5,000 septic shock cases confirmed a significant death reduction with 20% albumin, whereas no important benefit was seen in severe sepsis overall [15].

In cirrhotic infection situations, including both non-SBP infections and ascites management, no mortality advantage was found with albumin. However, they noted increased pulmonary oedema risk and possible renal protection in SBP situations. Mainly, the delay in renal failure onset was observed with albumin in non-SBP sepsis, but without a survival benefit at three months [16].

Both the ALPS and FRISC trials underscore the superior efficacy of albumin over crystalloids in achieving early hemodynamic stabilisation and improving tissue perfusion in cirrhotic patients with sepsis-related hypotension. The ALPS trial, using 20% hyperoncotic albumin, demonstrated significantly higher rates of achieving target mean arterial pressure and more rapid lactate clearance when compared to Plasmalyte, a balanced crystalloid. Similarly, the FRISC trial, which employed 5% iso-oncotic albumin against normal saline, also showed enhanced perfusion outcomes and improved hemodynamic parameters, such as reduced heart rate and better lactate clearance. These results confirm that albumin, irrespective of concentration,

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offers superior volume expansion and vascular support in the situation of cirrhosis and sepsis [17].

However, when examining mortality results, neither concentration of albumin suggestively improved medium-term survival in cirrhotic septic patients. In the ALPS trial, no important difference was observed in 28-day death between the albumin and crystalloid groups. The FRISC trial, while showing a modest short-term survival advantage at one week, did not establish a long-term death benefit. In broader sepsis literature, meta-analyses suggest that while albumin may consult a mortality benefit in patients with septic shock, this advantage does not extend to the overall sepsis population. Thus, though albumin improves physiological parameters acutely, these effects do not reliably translate into improved survival in cirrhotic populations [18].

Safety remains a significant concern, particularly with hyperoncotic (20%) albumin. The ALPS trial reported pulmonary complications in 22% of patients receiving 20% albumin, necessitating discontinuation of therapy. These results are echoed in meta-analyses of albumin use in cirrhotic patients outside of spontaneous bacterial peritonitis, where the incidence of pulmonary oedema was significantly higher with hyperoncotic albumin. Other safety signals, including fluid overload and respiratory distress, have been reported in studies indexed. In contrast, the FRISC trial using 5% albumin established fewer pulmonary difficulties, indicating that iso-oncotic albumin may offer a safer profile while still delivering clinical benefit. These observations suggest that while albumin can be a powerful tool in reversing sepsis-induced hypotension in cirrhotics, its use, especially at higher concentrations, must be balanced against the risk of adverse events, mainly in resource-limited or non-ICU situations [19].

These findings support the biological acceptability of albumin use in cirrhosis, given chronic hypoalbuminemia, increased capillary leak, and altered vascular tone. Albumin restores oncotic pressure, exerts anti-inflammatory and nitric oxide scavenging effects, and may reduce vasopressor requirements, reflected in improved MAP, lower heart rate, and faster lactate clearance in trials. However, cost, ICU monitoring requirements, and complication risks, especially pulmonary oedema, limit broad high-concentration albumin use. Balanced crystalloids like Plasmalyte remain first-line per Surviving Sepsis Campaign and AASLD guidance, with albumin addition reserved when large volumes are required or hypoalbuminemia is severe [20].

ALPS and FRISC are single-centre, relatively small trials; human endpoints were underpowered; and cirrhotic subgroups in larger RCTs remain sparse. Meta-analyses in cirrhosis are broadly heterogeneous in indications, albumin concentrations, and outcome measures. For cirrhotic patients with sepsis-induced hypotension, early administration of 20% albumin may offer rapid hemodynamic benefit, especially when hypotension persists despite crystalloid. Until now, without an endurance benefit and with increased pulmonary risk, its use should be individualised, targeting patients with severe hypotension, high MELD scores, or early renal deterioration, and only with capacity for close monitoring. Use of 5% albumin appears safer and may offer benefit versus saline in low-resource situations where Plasmalyte is unavailable or too costly [21].

Future investigations should prioritise larger multicentre randomised trials of albumin versus balanced crystalloids in cirrhotic sepsis, with adequately powered mortality endpoints and stratified analysis by MELD/pre-existing lung or renal disease, to determine optimal concentration, dosing, and patient selection.

CONCLUSIONS

The study has concluded that 20% albumin was more effective than Plasmalyte in rapidly reversing sepsis-related hypotension in cirrhotic patients, with comparable safety and no significant increase in adverse events or mortality. In this randomised controlled trial, 20% albumin demonstrated superior efficacy compared to Plasmalyte in reversing sepsis-related hypotension among cirrhotic patients, as evidenced by a significantly higher rate of hypotension reversal within 6 hours, reduced vasopressor requirement, and greater improvement in serum lactate levels. The safety profile of albumin was comparable to Plasmalyte, with no significant differences in adverse events or short-term mortality. These findings suggest that 20% albumin may offer a clinically meaningful advantage over balanced crystalloids for rapid hemodynamic stabilisation in this high-risk population. However, larger multicenter trials with long-term follow-up are warranted to confirm these results and evaluate cost-effectiveness.

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CONTRIBUTION OF AUTHORS

Research concept- Chetan Goyal, Deepa Agarwal
Research design- Chetan Goyal
Supervision- Deepa Agarwal
Materials- Deepa Agarwal
Data collection- Chetan Goyal
Data analysis and interpretation- Chetan Goyal, Deepa Agarwal
Literature search- Chetan Goyal, Deepa Agarwal
Writing article- Deepa Agarwal
Critical review- Chetan Goyal, Deepa Agarwal
Article editing- Chetan Goyal
Final approval- Chetan Goyal, Deepa Agarwal

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