



Albumin Therapy for Advanced Liver Disease: New Data from the EASL Congress 2026

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Meeting Summary

The role of human albumin therapy in the management of advanced liver disease is not yet fully established across all settings and remains a topic of debate. The significant and complicated burden of the disease, coupled with limited therapeutic options, presents ongoing challenges. At the European Association for the Study of the Liver (EASL) Congress 2026, studies in patient populations worldwide delivered new insights to add to the debate on the use of human albumin therapy at the most severe end of the liver disease spectrum. This article reviews a selection of the latest data, evaluating long-term albumin therapy for decompensated cirrhosis, as well as Phase III study evidence on the use of therapeutic plasma exchange (TPE) for acute-on-chronic liver failure (ACLF).

Long-Term Albumin Therapy for Decompensated Cirrhosis

Real-World Data From an Australian Cohort

In the largest real-world cohort study of albumin therapy outside Europe, Sood et al.¹ (investigator-initiated study, sponsored by CSL Ltd, Melbourne, Australia) retrospectively examined the safety and efficacy data for long-term (6-month), outpatient use of human albumin in the routine clinical setting in Australia. Taken from a larger cost-comparison study (described in the following section), patient cohort data were derived from 11 centres in Australia,² and included patients with decompensated cirrhosis who had received regular albumin treatment. Patients with a transjugular intrahepatic portosystemic shunt, transplant, or portal vein thrombosis were excluded. The cohort included 134 patients, the majority of whom had cirrhosis due to alcohol-related liver disease (64.2%) or steatotic liver disease (34.3%). Most patients had ascites (93.3%), and 17 patients (12.7%) had a recent history of hepatocellular carcinoma. Human albumin (20% concentrated; CSL Ltd, Melbourne, Australia) was given at a mean dose of 40 g, across a total of 2,298 infusions (median: 19 infusions/patient). Data were assessed across a 6-month assessment window from treatment initiation, with patients censored at 6 months, liver transplant, or death.

Clinical outcomes were available for 105/134 patients (29 excluded: death, n=21, or transplant, n=8, prior to 6 months). Long-term albumin therapy was associated with a 17.3% decrease in the use of diuretics (from 91.8% to 74.5% of patients), a statistically significant improvement in the severity of ascites ($p<0.0001$),¹ and an accompanying decrease in the proportion of patients requiring outpatient paracentesis (from 67.9% to 44.8% of patients). There was also a significant increase in median serum albumin from 30 g/L to 35 g/L ($p<0.0001$), and a numerical improvement in disease severity (Model for End-Stage Liver Disease [MELD-Na] score: 19 to 17; $p=0.08$). Recompensation was reported as 'rare',

and seven patients (5%) were referred for transjugular intrahepatic portosystemic shunt. Notably, 94 patients (70%) remained on therapy at 6 months, and the plan was for most patients (78/105; 74%) to continue albumin therapy beyond 6 months. In terms of safety, deaths that occurred prior to 6 months occurred at a median of 118 days after starting therapy, with most (17/21) being liver-related. Across the long-term treatment period, there were only two minor complications associated with infusion (nausea and painful cannulation).

While a real-world study lacks the controlled environment of a randomised trial, it provides valuable insight into the use of albumin therapy across the wide and complex range of patients with decompensated cirrhosis who are treated in routine clinical practice. Expanding the existing evidence base beyond Europe, these data represent a relatively large sample of approximately 2,300 infusions of human albumin in a severely affected, predominantly palliative, baseline population. Long-term outpatient albumin therapy was associated with clinically meaningful improvements in ascites alongside a reduced requirement for paracentesis, and no safety concerns were identified. The investigators conclude that long-term albumin therapy is a 'pragmatic strategy' to lower demand on healthcare resources and benefit patients with substantial disease burden in routine clinical practice.

Real-World Cost-Comparison Study

Looking to examine the wider healthcare impact of long-term albumin therapy, this retrospective Australian study by Sood et al.² (investigator-initiated study, sponsored by CSL Ltd, Melbourne, Australia) investigated healthcare utilisation and costs across 6 months of treatment. The analysis was based on a cohort of 134 patients with decompensated cirrhosis from 11 treatment centres in Australia (as described in the study above),¹ and compared with a historical cohort of 140 patients who did not receive albumin treatment, but who were matched for age, gender, and disease severity (median MELD-Na: 19.0 albumin versus 17.8 control; $p=0.07$). Cost estimates

for albumin, day unit infusion, outpatient paracentesis, and inpatient/emergency admissions were predetermined. Patients in the albumin group received 2,298 infusions in total (mean: 40 g/session) across the 6-month period.

After 6 months of albumin therapy, more patients experienced improvement in ascites severity (57.1%), as compared with controls (26.7%; risk ratio: 2.14; $p < 0.0001$). This correlated with a significant reduction in paracentesis: 405 in the albumin group (median: 0 per 100 patient days [ptd]), compared with 763 in the control group (median: 2.7 per 100 ptd; $p < 0.0001$). There was no difference between the groups in mortality rate (16.4% albumin versus 23.6% control; $p = 0.67$), although investigators noted a divergence in the Kaplan–Meier curve appearing at 6 months. Liver transplants occurred in more albumin-treated patients (eight patients; 6.0%) than control patients (two patients; 1.4%; $p = 0.045$). In terms of healthcare utilisation, the groups did not differ in the number of hospital admissions, nor in length of stay. Despite the additional drug and administration costs of albumin treatment itself, the total healthcare costs across 6 months were numerically lower in the albumin-treated group (4,643,788 AUD compared with 5,761,856 AUD in the control group), with the median cost per patient/100 ptd being similar: 12,627 AUD (interquartile range: 7,459–28,369 AUD) in the albumin group, and 12,966 AUD (interquartile range: 5,127–33,389 AUD) in the control group ($p = 0.72$).

Thus, based on a retrospective analysis and compared with a historical control cohort, findings from this large, real-world study suggest that, at 6 months, long-term albumin therapy delivered improvements in the control of ascites, reducing the need for paracentesis, without increasing overall healthcare costs for patients with decompensated cirrhosis. The study authors conclude that albumin treatment may offer a cost-neutral approach (at least) to generating clinically meaningful outcomes for patients with decompensated cirrhosis.

Do Clinical Data Support a Change in Practice?

The use of long-term albumin as a disease-modifying therapy to target mortality rates and prevent cirrhosis-related complications is an area of active debate, due to conflicting evidence from clinical trials. To re-evaluate this situation, Kim et al.³ performed a systematic literature review and meta-analysis (study funded by Grifols Worldwide Operations) of all published clinical trials from 1995 to the present, plus congress abstracts from 2022–2025, to capture the most recent published data. Studies were eligible for inclusion if they included adults with cirrhosis and ascites, compared long-term albumin therapy with placebo or standard medical treatment (SMT) for ≥ 4 weeks, and reported mortality rates over ≥ 12 months.

Seven of the 22 available studies met the eligibility criteria, including a total of 1,431 patients. Across the seven studies, patients treated with albumin showed a significant reduction in 12–36-month mortality (primary endpoint; random effects model) compared with the control (SMT/placebo) group (odds ratio [OR]: 0.66; 95% CI: 0.47–0.93; $p = 0.02$).³ Patients receiving long-term albumin therapy also had significantly lower odds of developing ascites (OR: 0.30; 95% CI: 0.16–0.54; $p < 0.0001$), refractory ascites (OR: 0.52; 95% CI: 0.33–0.81; $p < 0.01$), hepatic encephalopathy (OR: 0.62; 95% CI: 0.41–0.95; $p = 0.03$), renal dysfunction (OR: 0.45; 95% CI: 0.21–0.97; $p = 0.04$), or spontaneous bacterial peritonitis (OR: 0.30; 95% CI: 0.16–0.54; $p < 0.0001$) at ≥ 12 months' follow-up, which were all examined as secondary endpoints.³ There were no significant differences between the albumin and control groups in the secondary endpoints of hyponatraemia (OR: 0.62; 95% CI: 0.36–1.06; $p = 0.08$), or gastrointestinal bleeding (OR: 1.15; 95% CI: 0.60–2.23; $p = 0.67$) at ≥ 12 months' follow-up.

Meta-analyses have inherent limitations, and there was heterogeneity in outcome definitions across studies, with variable sample sizes across the different analyses due to all endpoints not being included in all the studies. In addition, any differences in patient inclusion criteria, albumin dosing/

regimen, and means of follow-up between the individual studies may add further variation. However, using this approach also facilitated the evaluation of albumin therapy in a large, pooled population of approximately 1,500 patients. The meta-analysis was supportive of a role for long-term albumin therapy as a disease-modifying intervention for patients with decompensated cirrhosis, being associated with significant reductions in mortality and key cirrhosis-related complications. The study authors advise that further research is needed to define those patients who will respond best to this therapeutic strategy, and to optimise protocols and enable individualised treatment plans.

Predicting Clinical Response: Post-hoc Analysis of the ANSWER Study

As noted in the previous poster, identifying those patients who are likely to benefit most from long-term albumin therapy is currently a key topic of discussion. The ANSWER study was a Phase IV, open-label, randomised, multicentre, Italian trial (investigator-initiated study, funded by the Italian Medicines Agency, Rome, Italy), which demonstrated that long-term albumin administration prolongs overall survival and reduces cirrhosis-related complications in patients with decompensated cirrhosis.^{4,5} In a post-hoc analysis of the ANSWER study, Pompili et al.⁶ examined the association between serum albumin levels at baseline and clinical response to albumin therapy (18-month mortality; Fine-Gray model adjusted for age, viral aetiology, Child-Pugh score, and MELD-Na), alongside an exploratory analysis to examine treatment effect by different baseline serum albumin thresholds (from 2.5 to 4.2 g/dL). The study included 431 patients with cirrhosis and uncomplicated Grade 2/3 ascites who were randomised to SMT or SMT+albumin therapy (40 g weekly, maintenance dose), for up to 18 months, with 18-month survival as the primary endpoint and cirrhosis-related complications as secondary endpoints. The two treatment groups were stratified by baseline serum albumin concentration, and similar numbers of patients discontinued the study early in the SMT+albumin and SMT treatment arms (42 versus 41 patients, respectively).

The model revealed that the SMT+albumin treatment effect (survival benefit) was linked to lower baseline serum albumin values. A baseline serum albumin cut-off of 3.2 g/dL was associated with the greatest survival benefit (confirmed by internal validation via bootstrap analysis). In patients with baseline serum albumin ≤ 3.2 g/dL ($n=275$; 64%), the 18-month survival rate was significantly higher in the SMT+albumin subgroup, compared with the subgroup receiving SMT alone (hazard ratio [HR]: 0.47; 95% CI: 0.29–0.77; $p=0.002$). In patients with serum albumin >3.2 g/dL, the mortality rate was low in both subgroups (HR: 1.04; 95% CI: 0.41–2.63; $p=0.93$). The incidence of paracentesis, cirrhosis-related complications, and hospital admissions was also significantly improved (lower) in the SMT+albumin subgroup compared with the SMT subgroup across all the baseline albumin strata.

Thus, findings from this post-hoc investigation indicate that addition of long-term albumin therapy to SMT provides advantages independent of baseline serum albumin levels, reducing cirrhosis-related complications and paracentesis; but appears to provide additional benefit in terms of mortality only in patients with mild-to-moderate hypoalbuminaemia (i.e., ≤ 3.2 g/dL at baseline). While the post-hoc, exploratory nature of the study is recognised, investigators note that costs and logistical issues currently restrict the widespread use of long-term albumin therapy and suggest that this evidence may help prioritise its use when resources are constrained. This could direct treatment towards patients who are most likely to gain a survival benefit, and so create more individualised treatment plans.

TPE in ACLF

The Phase III, Multicentre APACHE Study

In an oral presentation at EASL 2026,⁷ Javier Fernández, EF CLIF, EASL-CLIF Consortium and Grifols Chair; Hospital Clínic, IDIBAPS and CIBERehd, Barcelona, Spain, outlined

the results of the landmark APACHE study (sponsored by Instituto Grifols, S.A., Barcelona, Spain), evaluating the efficacy and safety of high-volume plasma exchange with 5% albumin replacement (PE-A5%; Albutein 5%®, Grifols, Barcelona, Spain) in patients with ACLF. Following on from the promising findings of a pilot study,⁸ APACHE was a Phase III, multicentre, randomised, controlled, parallel-group, open-label trial performed at 29 sites in nine countries across Europe and North America. In total, 274 patients who had been hospitalised with ACLF (Grades 1b–3a; 55% Grade 2) were randomised to receive SMT+PE-A5% (n=135; 4–9 sessions; median: 4 sessions of PE-A5%) or SMT (n=139). The primary endpoint was 90-day survival, censored at the point of liver transplant. Overall, the number of patients who terminated the study prior to 90 days was similar in the two treatment groups: 99 patients in the SMT+PE-A5% group (including 40 deaths, 30 transplants), and 110 patients from the SMT group (including 56 deaths, 18 transplants).

SMT+PE-A5% was associated with a significant increase in 90-day survival rate without prior liver transplant, compared with SMT alone (HR: 0.65; 95% CI: 0.45–0.94; p=0.021; primary endpoint).⁷ The 90-day survival benefit was most prominent in patients with ACLF Grade 2 (HR: 0.55 [95% CI: 0.34–0.90]) (Grade 1b HR: 0.73 [95% CI: 0.27–2.02]; Grade 3a (HR: 0.83 [95% CI: 0.43–1.59]) (exploratory subgroup analysis). The 28-day survival rate also approached significance, with an HR of 0.67 (95% CI: 0.44–1.01; p=0.06). While the 90-day transplant-free survival rate was similar between groups (HR: 0.83; 95% CI: 0.62–1.12; p=0.22), this was based upon 51 deaths and 36 transplants (total n=87) in the SMT+PE-A5% group, compared with 69 deaths and 20 transplants in the SMT group (total n=89). The study authors suggest that these findings point towards PE-A5% acting mainly as a bridge to liver transplant.

Total treatment-emergent adverse events (TEAE) were more frequent in the SMT+PE-A5% group (85.2% patients) than in the SMT group (71.9% patients), which the authors note is consistent with the known side effects of plasma exchange.

However, despite differences in the overall rate of TEAEs, the number of deaths due to TEAEs was similar between groups (SMT+PE-A5%: 7.0% of patients; SMT: 7.2% of patients), as was the rate of study withdrawal due to TEAEs (7.0% versus 5.0%, respectively). In addition, adverse reactions or suspected adverse reactions due to PE-A5% were reported in only <5% of patients, with no new safety concerns raised.

The study authors suggest that SMT+PE-A5% demonstrates a favourable benefit–risk profile in the treatment of patients with ACLF, significantly increasing 90-day survival compared with SMT alone, mainly in patients with less severe forms of ACLF (Grade 2), and with TEAEs reflecting known risks. It is noted that for non-clinical reasons, study enrolment was terminated early, when only 274 (72%) of the 370-participant target had been enrolled, which may have affected the power of the planned statistical tests. However, the study remains a pivotal controlled Phase III study, gaining evidence from a large patient population across multiple centres worldwide.

Single-Centre Study in India

Data were presented from another large-scale study examining the use of TPE for ACLF in a single centre in India. In this open-label, parallel group, randomised controlled study (investigator-initiated study at the All India Institute of Medical Sciences, New Delhi, India), Biswas et al.⁹ examined the impact of TPE on the survival of patients with ACLF (Grades 1–3b), in comparison with SMT.^{9,10} The study enrolled 194 patients who were randomised 1:1 to receive SMT+TPE (5 sessions) or SMT alone. At baseline, most patients had Grade 2 ACLF (64.5%), there was a median of two organ failures per patient, and alcohol use was the most common aetiology of liver disease (67.5%). Just over half of patients completed all five sessions of TPE (56/97 patients; 57.7%), with haemodynamic instability being the leading cause of discontinuation of TPE (18/41 patients; 43.9%). The formulation of TPE/albumin dose is not reported.

The all-cause 28-day mortality rate (primary endpoint) was significantly lower in the SMT+TPE group than in the SMT group (44.3% versus 63.9%; $p=0.006$). However, the 90-day mortality rate (secondary endpoint) was similar in both groups (SMT-TPE 66% versus SMT 69.1%; $p=0.64$). These findings were independent of the severity of disease (ACLF Grades 1–3) or alcohol/non-alcohol aetiology (subgroup analyses). At Day 7, organ failure (hepatic and coagulopathy) was resolved in more patients treated with SMT+TPE than with SMT alone (hepatic: 35.5% versus 25.7%, $p=0.013$; coagulation: 48% versus 22%, $p=0.001$). There were also greater reductions in serum bilirubin, international normalised ratio, and plasma ammonia in the SMT+TPE group, and lower prognostic scores (MELD and Chronic Liver Failure-Consortium [CLIF-C] ACLF) for mortality risk at Day 7, compared with SMT alone. In addition, more patients receiving TPE had resolution of systemic inflammatory response syndrome (20.8% versus 8%; $p=0.039$), with a greater decline in serum levels of 25 cytokines from baseline to Day 5 versus the SMT group (proof-of-principle study). Regarding safety, dyselectrolytaemia and shivering were the most common complications after TPE, and, at Day 7, there was a higher incidence of new-onset infections in the TPE group than in patients receiving SMT alone (21.7% versus 11.8%; $p=0.062$).

While highlighting the benefit of TPE on 28-day mortality rates and resolution of organ failure in patients with ACLF, the authors noted that this did not extend to a benefit in 90-day mortality. They also cited concerns over safety outcomes (infections and fluid and electrolyte imbalances) and expressed concern over tolerability in this critically ill patient group.

Clinical Implications

The decompensated phase of cirrhosis is characterised by the emergence of serious clinical signs such as ascites and bleeding, heralding accelerated disease progression towards liver transplant or death.¹¹ Strategies to prevent disease progression

involve suppression of causative factors (e.g., alcohol, hepatitis infection), and targeting key pathogenic events.¹¹ However, evidence for the effectiveness of these two approaches across the patient spectrum is limited. Long-term albumin therapy has been proposed as a strategy to improve pathogenic abnormalities in systemic circulatory function, but existing clinical data on its use are conflicting.¹¹ As a result, the current EASL treatment guidelines do not recommend albumin therapy for decompensated cirrhosis, stating that further clinical evidence is required.¹¹

Thus, the latest study findings presented at EASL 2026 contribute valuable evidence to the ongoing discussion on the role of albumin therapy for decompensated cirrhosis. The abstracts reviewed in this article demonstrate the survival benefits of long-term albumin therapy in real-world and post-hoc clinical analyses, strengthened by a meta-analysis of seven individual clinical studies that support a role for long-term albumin therapy as a disease-modifying intervention.^{1–3,6} Alongside the improved mortality rate (versus SMT), the studies indicate that albumin therapy may produce improvements in disease severity and cirrhosis-related complications, including a lower incidence of ascites (often associated with reduced survival) and the accompanying need for paracentesis. There is also preliminary evidence that patients with less severe disease may benefit most in terms of survival outcome, presenting the opportunity for a more individualised treatment approach.⁶ The abstracts present safety findings in less detail, though they clearly state that no new safety concerns were identified.

Two of the abstracts considered the impact of costs on the use of long-term albumin therapy.^{2,6} Pompili et al.⁶ suggested that the direct drug and administration costs present a barrier to wider uptake, while Sood et al.² showed that albumin is a cost-neutral (and potentially cost-saving) therapy, linked to its efficacy in reducing the need for paracentesis and hospital admission. Therefore, further research into the health economics of albumin therapy across different settings may serve to

educate healthcare authorities around the cost-benefit balance of treatment. In addition, identifying the specific subgroups of patients who benefit most from albumin therapy may not only improve patient outcomes, but also favour the efficient and cost-effective use of healthcare resources.

ACLF is a severe form of decompensated cirrhosis associated with organ failure and a high risk of mortality in the short-term.¹² Liver transplant is the only life-saving treatment for ACLF, and there is a need for therapies that can quickly stabilise patients prior to transplantation.¹² At EASL 2026, data presented from two prospective studies augmented the evidence base for using TPE in ACLF.^{7,9} Both studies indicated that TPE can improve short-term survival in patients with ACLF, and data from the pivotal, multicentre APACHE trial supported the use of TPE as a 'bridge to liver transplant' with higher 90-day survival rates and more liver transplants than in patients receiving SMT alone. However, there were conflicting opinions on the safety of TPE. The APACHE investigators presented a favourable benefit-risk profile for TPE, while in the single-centre study, Biswas et al.⁹ conclude that tolerability (related to infections, electrolyte disturbance, and catheter-related complications) is a limiting factor in this critically ill patient population.

The role of albumin in these settings remains under discussion and is not fully established across all treatment scenarios.

However, there is an urgent need to address the high disease burden and meet the clinical challenges of acute treatment or prevention of complications in chronic liver disease. Taking account of the latest data in decision-making processes and guidelines, with contributions from clinical and routine practice settings worldwide, is key to keeping the debate moving forward and optimising patient outcomes.

Conclusion

The combined data from prospective, retrospective, and meta-analysis studies presented at EASL 2026 contribute to the evolving evidence base for the use of human albumin therapy in severe liver disease. The studies are supportive of potential benefits in survival, ascites control, liver-related complications, healthcare utilisation, and costs, while remaining mindful of safety concerns for this critically ill population. As the studies display different advantages and limitations in the information they deliver, with heterogeneity in designs and settings, their collective findings cannot be considered definitive. However, new and emerging evidence is necessary to inform the future management of advanced liver disease, shaping treatment strategies, and identifying those patients most likely to benefit from therapy.

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