

Effect of Plasma Separators with Different Pore Sizes on Albumin in DPMAS Therapy

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Abstract

Objective: To compare the effects of two plasma separators with different pore sizes on serum albumin levels in patients with liver failure undergoing double plasma molecular adsorption system (DPMAS) therapy, and to evaluate the clinical value of small-pore membrane plasma separators. **Methods:** A single-center, prospective, randomized controlled trial was conducted. A total of 60 patients with liver failure admitted to the Third Affiliated Hospital of Sun Yat-sen University from December 2023 to December 2025 were enrolled and randomly assigned to the observation group (EC-4A20 membrane plasma separator, $n = 30$) or the control group (MPS07 plasma separator, $n = 30$). Both groups received comprehensive medical therapy and two sessions of DPMAS treatment. Changes in albumin (ALB), hemoglobin (Hb), and platelet (PLT) counts before and after treatment were compared, and clinical efficacy and safety were evaluated. **Results:** Baseline ALB, Hb, and PLT levels showed no significant differences between the two groups ($P > 0.05$). After the first DPMAS session, the decrease in ALB in the observation group was significantly smaller than that in the control group [(1.51 ± 2.85) g/L vs. (4.21 ± 1.94) g/L, $P < 0.001$]. After the second session, the ALB decrease remained smaller in the observation group [(2.32 ± 2.92) g/L vs. (2.72 ± 1.93) g/L], but the difference was not statistically significant ($P = 0.541$). The cumulative albumin loss over the two treatment sessions (first decrease + second decrease) was (3.83 ± 4.34) g/L in the observation group versus (6.93 ± 2.83) g/L in the control group, with a statistically significant difference ($P = 0.035$). Hb and PLT decreased significantly after each treatment in both groups (all $P < 0.05$), with no statistically significant differences between groups ($P > 0.05$). The overall response rate in the observation group (90.0%) was higher than that in the control group (76.7%), but the difference was not statistically significant ($P = 0.303$). There was no statistically significant difference in the incidence of adverse reactions between the two groups ($P = 0.148$). **Conclusion:** The small-pore EC-4A20 membrane plasma separator can significantly reduce non-spe-

cific albumin loss during DPMAS therapy, with a cumulative albumin loss approximately 3.10 g/L less than that in the control group over two treatment sessions. It also demonstrates a protective trend for hemoglobin and platelets, with favorable safety profile, making it particularly suitable for patients with liver failure complicated by hypoalbuminemia and thrombocytopenia.

Keywords

Liver Failure, Double Plasma Molecular Adsorption System, Plasma Separator, Albumin, Platelets

1. Introduction

Liver failure is a severe clinical syndrome caused by multiple etiologies, characterized by profound impairment of hepatic synthetic, detoxifying, metabolic, and biotransformation functions, manifesting as jaundice, coagulation dysfunction, hepatorenal syndrome, hepatic encephalopathy, and ascites, with an extremely high mortality rate [1]. Liver transplantation remains the only curative treatment; however, due to organ shortage and high costs, artificial liver support therapy has become one of the core strategies in the comprehensive management of liver failure [2] [3].

Double plasma molecular adsorption system (DPMAS) is a novel non-bioartificial liver technology developed in recent years. Its principle involves sequential passage of separated plasma through an anion-exchange resin (BS330) and a neutral macroporous adsorption resin (HA330-II), enabling specific adsorption of bilirubin and bile acids while clearing inflammatory cytokines such as tumor necrosis factor- α and interleukin-6, thereby exerting a combined detoxification effect [4]. However, during DPMAS therapy, as blood passes through the extracorporeal circuit, plasma separator, and adsorption columns, not only target toxins are removed, but beneficial substances including albumin and coagulation factors may also be non-specifically adsorbed or damaged. In particular, albumin loss may exacerbate hypoalbuminemia in patients with liver failure, compromising the net clinical benefit of treatment [5].

The plasma separator, as a core component of the DPMAS system, has membrane pore size that directly influences the selectivity of plasma component separation and solute permeability. Conventional plasma separators have membrane pore sizes of approximately 0.5 μm , with limited retention capacity for macromolecular proteins. In contrast, the Evacure-4A membrane separator, manufactured from ethylene-vinyl alcohol copolymer (EVAL), features pore sizes of only 0.01 - 0.03 μm , offering higher sieving precision and improved biocompatibility [6]. This prospective randomized controlled study was designed to systematically compare the effects of two plasma separators with different pore sizes EC-4A20 and MPS07 on albumin, hemoglobin, and platelet counts in patients with liver failure undergoing DPMAS, aiming to provide evidence-based support for opti-

mizing artificial liver therapy strategies and improving patient outcomes.

2. Materials and Methods

2.1. Study Participants

This study was an exploratory trial with a total of 60 patients enrolled. A total of 60 patients with liver failure admitted to the Third Affiliated Hospital of Sun Yat-sen University between December 2023 and December 2025 were enrolled. The study was approved by the Institutional Ethics Committee of the hospital (Approval No.: RG202322401), and written informed consent was obtained from all patients or their legal guardians.

Inclusion criteria: Diagnosis of liver failure according to the Guidelines for the Diagnosis and Treatment of Liver Failure (2024 Edition) [1]: 1) severe fatigue accompanied by pronounced gastrointestinal symptoms; 2) serum total bilirubin $\geq 171 \mu\text{mol/L}$ or an increase of $\geq 17.1 \mu\text{mol/L}$ per day; 3) prothrombin activity $\leq 40\%$ or international normalized ratio ≥ 1.5 ; 4) age between 18 and 65 years.

Exclusion criteria: 1) extracorporeal circuit coagulation due to inadequate anticoagulation during treatment; 2) severe autoimmune liver disease; 3) platelet count $< 50 \times 10^9/\text{L}$ or active bleeding; 4) hemodynamically unstable status; 5) allergy to heparin, protamine, or other medications used.

2.2. Grouping and Treatment Protocol

Patients were randomly assigned to the observation group ($n = 30$) or the control group ($n = 30$) using a random number table method. Both groups received comprehensive medical therapy including antiviral, hepatoprotective, liver enzyme-lowering, jaundice-attenuating, and albumin supplementation treatments. In addition, the observation group received DPMAS using the EC-4A20 membrane plasma separator (Kawasumi Laboratories, Japan; pore size $0.01 - 0.03 \mu\text{m}$, membrane area 2.0 m^2), while the control group received DPMAS using the MPS07 plasma separator (Bellco, Italy; pore size approximately $0.5 \mu\text{m}$).

DPMAS treatment parameters: The DX-10 blood purification system (Jafron Biomedical Co., Ltd., Zhuhai, China) was used with a blood flow rate of $100 - 150 \text{ mL/min}$, a plasma separation fraction of $20\% - 30\%$, and a single-session plasma processing volume of 5 L . The adsorption column combination consisted of the BS330 bilirubin adsorption column and the HA330-II resin hemoperfusion column. Anticoagulation was individualized based on coagulation function and platelet count, with an initial heparin bolus followed by continuous infusion, and neutralization with protamine sulfate (half of the total heparin dose, not exceeding 50 mg) at the end of each session. Each patient received two treatment sessions at intervals of $2 - 4$ days. Prior to treatment, 10 g of albumin and 500 mL of Ringer's solution were routinely administered intravenously to prevent hypotension. Continuous electrocardiographic monitoring was performed throughout the procedure, with close surveillance of transmembrane pressure, venous pressure, and other parameters, and prompt management of adverse reactions. Four weeks after

the completion of the two treatment sessions, liver function and coagulation function were re-examined, and symptoms were assessed to evaluate treatment efficacy.

2.3. Outcome Measures

1) Blood samples were collected before the initiation of treatment (prior to intravenous albumin infusion and blood priming), as well as before and after each treatment session. Venous blood was obtained to measure albumin (ALB, g/L), hemoglobin (Hb, g/L), and platelet (PLT, $\times 10^9/\text{L}$) levels before and after each treatment.

2) Clinical efficacy: Efficacy was evaluated according to the Guidelines for the Diagnosis and Treatment of Liver Failure [1], categorized as clinical cure (symptom resolution, normalization of liver function, $\text{INR} < 1.5$), clinical improvement (significant amelioration of symptoms and liver function), and clinical deterioration (worsening of symptoms or death). Overall response rate was calculated as (clinical cure + clinical improvement)/total cases $\times 100\%$.

3) Adverse reactions: The following events were recorded during treatment: pruritus, skin rash, hypotension, chills, nausea/vomiting, and severe bleeding.

2.4. Statistical Analysis

Statistical analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Normally distributed continuous data were expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$). Between-group comparisons were conducted using independent samples t-test, and within-group comparisons before and after treatment were performed using paired samples t-test. Categorical data were presented as frequencies and percentages (%) and compared between groups using the chi-square (χ^2) test. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Baseline Characteristics

No statistically significant differences were observed between the observation group and the control group in terms of sex distribution (male/female: 26/4 vs. 24/6), age [(51.83 $\pm$ 8.87) years vs. (50.94 $\pm$ 14.31) years], or pretreatment ALB, Hb, and PLT levels (all $P > 0.05$), indicating comparability between the two groups (Table 1).

Table 1. Baseline laboratory parameters of the two groups ($\bar{x} \pm s$).

Parameter	Observation group (n = 30)	Control group (n = 30)	t	P
ALB (g/L)	31.23 $\pm$ 3.20	32.45 $\pm$ 2.95	-1.549	0.127
Hb (g/L)	112.80 $\pm$ 19.91	119.63 $\pm$ 22.75	-1.235	0.222
PLT ($\times 10^9/\text{L}$)	92.27 $\pm$ 31.15	96.93 $\pm$ 20.86	-0.676	0.502

3.2. Clinical Efficacy

After two DPMAS sessions, patients in both groups showed varying degrees of improvement in fatigue, poor appetite, and abdominal distension. The overall response rate was 90.0% (27/30) in the observation group, higher than 76.7% (23/30) in the control group. The clinical deterioration rate was 10.0% (3/30) in the observation group versus 23.3% (7/30) in the control group. However, the difference in efficacy distribution between the two groups was not statistically significant ($\chi^2 = 2.386$, $P = 0.303$) (Table 2).

Table 2. Comparison of clinical efficacy between the two groups [n (%)].

Group	n	Clinical cure	Clinical improvement	Clinical deterioration	Overall response rate (%)
Observation group	30	3 (10.0)	24 (80.0)	3 (10.0)	90.0
Control group	30	1 (3.3)	22 (73.3)	7 (23.3)	76.7
χ^2		2.386			
P		0.303			

3.3. Between-Group Comparison of Laboratory Parameter Changes after the First DPMAS Session

After the first DPMAS session, the decrease in ALB in the observation group was (1.51 ± 2.85) g/L, significantly smaller than (4.21 ± 1.94) g/L in the control group ($t = -4.286$, $P < 0.001$), indicating markedly less albumin loss in the observation group. No significant differences were observed between the two groups in the decreases of Hb ($P = 0.064$) or PLT ($P = 0.987$) (Table 3).

Table 3. Between-group comparison of ALB, Hb, and PLT before and after the first DPMAS session ($\bar{x} \pm s$).

Parameters	Observation group (n = 30)		Control group (n = 30)		t	P
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment		
Alb (g/L)	31.23 ± 3.20	29.72 ± 3.20	32.45 ± 2.95	28.24 ± 2.73	-4.286	<0.001
Hb ($\times 10^9$)	112.80 ± 19.91	106.23 ± 19.28	119.63 ± 22.75	107.21 ± 22.24	-1.891	0.064
PLT ($\times 10^9$)	92.27 ± 31.15	76.20 ± 25.94	96.93 ± 20.86	80.93 ± 18.91	0.016	0.987

3.4. Between-Group Comparison of Laboratory Parameter Changes after the Second DPMAS Session

After the second DPMAS session, the ALB decrease was (2.32 ± 2.92) g/L in the observation group and (2.72 ± 1.93) g/L in the control group, with no statistically significant difference between the two groups ($t = -0.616$, $P = 0.541$). The decreases in Hb ($P = 0.204$) and PLT ($P = 0.154$) also showed no significant differences between the groups (Table 4).

Table 4. Between-group comparison of ALB, Hb, and PLT before and after the second DPMAS session ($\bar{x} \pm s$).

Parameters	Observation group (n = 30)		Control group (n = 30)		t	P
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment		
Alb (g/L)	31.75 $\pm$ 3.50	29.43 $\pm$ 3.05	32.09 $\pm$ 2.89	29.37 $\pm$ 3.14	3.818	0.001
Hb ($\times 10^9$)	104.30 $\pm$ 18.86	99.33 $\pm$ 18.71	109.37 $\pm$ 21.84	100.70 $\pm$ 22.08	-1.284	0.204
PLT ($\times 10^9$)	77.13 $\pm$ 28.18	67.93 $\pm$ 28.75	81.93 $\pm$ 18.65	66.37 $\pm$ 17.78	-1.445	0.154

3.5. Within-Group Comparison of Laboratory Parameter Changes before and after Treatment

In the observation group, ALB, Hb, and PLT all decreased significantly after the first session ($P = 0.007$, 0.006 , and <0.001 , respectively) and after the second session ($P < 0.001$, 0.023 , and 0.022 , respectively). In the control group, all three parameters decreased significantly after both sessions (all $P < 0.001$). The magnitude of decline for each parameter was smaller in the observation group than in the control group (**Table 5**).

Table 5. Within-group comparison of changes before and after the first and second DPMAS sessions in the observation group ($\bar{x} \pm s$, $n = 30$).

group	n	Pre-first session	Post-first session	Paired t	P	Pre-Second session	Post-Second session	Paired t	P
observation group	30								
Alb (g/L)		31.23 $\pm$ 3.20	29.72 $\pm$ 3.20	2.904	0.007	31.75 $\pm$ 3.50	29.43 $\pm$ 3.05	4.348	<0.001
Hb ($\times 10^9$)		112.80 $\pm$ 19.91	106.23 $\pm$ 19.28	2.990	0.006	104.30 $\pm$ 18.86	99.33 $\pm$ 18.71	2.407	0.023
PLT ($\times 10^9$)		92.27 $\pm$ 31.15	76.20 $\pm$ 25.94	4.349	<0.001	77.13 $\pm$ 28.18	67.93 $\pm$ 28.75	2.430	0.022
control group	30								
Alb (g/L)		32.45 $\pm$ 2.95	28.24 $\pm$ 2.73	10.775	<0.001	32.09 $\pm$ 2.89	29.37 $\pm$ 3.14	6.555	<0.001
Hb ($\times 10^9$)		119.63 $\pm$ 22.75	107.21 $\pm$ 22.24	4.832	<0.001	109.37 $\pm$ 21.84	100.70 $\pm$ 22.08	4.006	<0.001
PLT ($\times 10^9$)		96.93 $\pm$ 20.86	80.93 $\pm$ 18.91	6.296	<0.001	81.93 $\pm$ 18.65	66.37 $\pm$ 17.78	6.006	<0.001

3.6. Cumulative Effect of Two DPMAS Sessions

After two DPMAS sessions, the cumulative ALB decrease was (1.80 ± 2.58) g/L in the observation group ($P = 0.001$) and (3.08 ± 2.56) g/L in the control group ($P < 0.001$), with the observation group showing an absolute reduction of approximately 1.28 g/L (58.4% of the control group's decline). Hb and PLT also decreased significantly in both groups (all $P < 0.001$), but the observation group showed smaller cumulative declines in Hb (13.47 g/L vs. 18.93 g/L) and PLT (24.34×10^9 /L vs. 30.56×10^9 /L) compared with the control group (**Table 6**).

Table 6. Within-group comparison of changes from baseline (pre-first session) to post-second session ($\bar{x} \pm s$).

Group	Parameter	Pre-first session	Post-second session	Decrease	Paired t	P
Observation group						
	Alb (g/L)	31.23 $\pm$ 3.20	29.43 $\pm$ 3.05	1.80 $\pm$ 2.58	3.818	0.001
	Hb ($\times 10^9$)	112.80 $\pm$ 19.91	99.33 $\pm$ 18.71	13.47 $\pm$ 14.28	5.167	<0.001
	PLT ($\times 10^9$)	92.27 $\pm$ 31.15	67.93 $\pm$ 28.75	24.34 $\pm$ 28.55	4.670	<0.001
Control group						
	Alb (g/L)	32.45 $\pm$ 2.95	29.37 $\pm$ 3.14	3.08 $\pm$ 2.56	6.596	<0.001
	Hb ($\times 10^9$)	119.63 $\pm$ 22.75	100.70 $\pm$ 22.08	18.93 $\pm$ 16.96	6.109	<0.001
	PLT ($\times 10^9$)	96.93 $\pm$ 20.86	66.37 $\pm$ 17.78	30.56 $\pm$ 16.34	10.242	<0.001

3.7. Comparison between the Two Groups before and after the Two Sessions of Artificial Liver Therapy

After two sessions of DPMAS therapy, the cumulative albumin loss over the two treatments (first decrease + second decrease) in the observation group was (3.83 $\pm$ 4.34) g/L, compared with (6.93 $\pm$ 2.83) g/L in the control group, with a statistically significant difference between the two groups ($t = -2.158$, $P = 0.035$). The observation group showed a cumulative albumin loss approximately 3.10 g/L less than that of the control group. There were no statistically significant differences between the two groups in cumulative hemoglobin loss ($P = 0.093$) or cumulative platelet loss ($P = 0.183$) (Table 7).

Table 7. Comparison of cumulative decreases (first decrease + second decrease) after two sessions of artificial liver therapy between the two groups ($\bar{x} \pm s$).

Parameter	Group	cumulative decreases	t	P
Alb (g/L)	Observation group	3.83 $\pm$ 4.34	-2.158	0.035
	Control group	6.93 $\pm$ 2.83		
Hb ($\times 10^9$)	Observation group	11.54 $\pm$ 17.08	-1.706	0.093
	Control group	21.09 $\pm$ 16.83		
PLT ($\times 10^9$)	Observation group	25.27 $\pm$ 29.43	-1.348	0.183
	Control group	31.57 $\pm$ 17.42		

3.8. Adverse Reactions

In the observation group, one case (3.3%) of Hypotension was reported. In the control group, four cases (13.3%) of Hypotension and two cases (6.7%) of nausea/vomiting were reported. The overall incidence of adverse reactions showed no significant difference between the two groups ($\chi^2 = 2.092$, $P = 0.148$). No severe adverse events such as severe bleeding or anaphylactic shock occurred in either group (Table 8).

Table 8. Comparison of adverse reactions between the two groups [n (%)].

Group	n	Pruritus	Skin rash	Hypotension	Chills	Nausea/Vomiting	Severe bleeding
Observation group	30	0 (0)	0 (0)	1 (3.3)	0 (0)	0 (0)	0 (0)
Control group	30	0 (0)	0 (0)	4 (13.3)	0 (0)	2 (6.7)	0 (0)
χ^2					2.092		
P					0.148		

4. Discussion

In patients with liver failure, extensive hepatocellular necrosis leads to a sharp decline in albumin synthesis. This is compounded by systemic inflammatory responses that cause capillary leakage, expansion of the albumin distribution volume, and accelerated catabolism, making hypoalbuminemia an independent prognostic risk factor [7]. Albumin not only maintains plasma colloid osmotic pressure but also performs multiple biological functions including binding and transport of bilirubin, fatty acids, drugs, and other endogenous and exogenous substances, free radical scavenging, and modulation of immune cell signal transduction [8]. Therefore, maximizing the preservation of endogenous albumin during artificial liver therapy is of significant clinical importance.

The present study found that the EC-4A20 membrane plasma separator resulted in significantly less albumin loss during DPMAS therapy compared with the MPS07 separator. After the first treatment, the decrease in ALB in the observation group was only 35.9% of that in the control group (1.51 g/L vs 4.21 g/L, $P < 0.001$). The cumulative albumin loss over the two treatment sessions was 3.83 ± 4.34 g/L in the observation group versus 6.93 ± 2.83 g/L in the control group, representing a reduction of approximately 3.10 g/L (44.7% less than the control group), with a statistically significant difference ($P = 0.035$). The core mechanism underlying this difference lies in the optimized design of the membrane structure and pore size. EC-4A20 employs an EVAL (ethylene-vinyl alcohol copolymer) hollow-fiber membrane with a pore size of only 0.01 - 0.03 μm , approximately 1/20 of that of conventional membranes (0.5 μm), yet with a membrane area of 2.0 m^2 , effectively balancing sieving efficiency and flux. According to the principle of molecular sieving, albumin (molecular weight ~66 kDa, molecular diameter ~7 nm) has a sieving coefficient of only approximately 0.75 at this pore size, significantly lower than the near-1.0 coefficient of conventional separators, meaning that approximately 25% of albumin can be retained and returned to the patient. In contrast, conventional separators such as MPS07 have almost no selectivity for macromolecular proteins, resulting in substantial amounts of albumin being removed or destroyed along with plasma components.

Of note, the difference in albumin loss between the two groups after the second treatment did not reach statistical significance ($P = 0.541$). Several factors may account for this observation: 1) As the number of treatment sessions increased, the overall albumin level in patients declined, reducing the absolute amount of

albumin available for non-specific loss; 2) Patients received exogenous albumin supplementation between the two sessions, which may have obscured the inter-group differences; 3) The pre-second-treatment ALB level in the observation group (31.75 g/L) was comparable to the pre-first-treatment level (31.23 g/L), suggesting good albumin recovery after the first treatment, whereas the pre-second-treatment ALB level in the control group (32.09 g/L) was lower than the pre-first-treatment level (32.45 g/L), reflecting a cumulative loss effect. This phenomenon suggests that the albumin-sparing advantage of the small-pore separator is most prominent in the first treatment session, while the cumulative benefit of multiple sessions is primarily reflected in the effective containment of the progressive decline in albumin levels observed in the control group, ultimately resulting in a statistically significant difference in cumulative loss between the two groups.

Regarding hemoglobin and platelet counts, both groups showed significant decreases after each session (within-group $P < 0.05$), with no statistically significant between-group differences ($P > 0.05$). However, the observation group demonstrated smaller absolute cumulative declines in both Hb (13.47 g/L vs. 18.93 g/L) and PLT ($24.34 \times 10^9/L$ vs. $30.56 \times 10^9/L$), suggesting a protective trend of the EC-4A20 toward formed blood elements. The EVAL material possesses excellent biocompatibility and anticoagulant properties, which may reduce complement activation and platelet adhesion, potentially accounting for the milder declines in Hb and PLT observed in the observation group [9]. For patients with liver failure and significantly low platelet counts (PLT $50 - 80 \times 10^9/L$), the reduced platelet loss associated with EC-4A20 may broaden the safety window for DPMAS, enabling treatment opportunities for more patients approaching the platelet threshold.

From a pathophysiological perspective, minimizing albumin loss confers multiple benefits. First, maintaining plasma colloid osmotic pressure reduces the risk of volume-related complications such as ascites and peripheral edema. Second, preserving endogenous albumin's ligand-binding functions helps maintain a stable microenvironment for residual hepatocytes, promoting liver regeneration. Third, reducing the need for exogenous albumin supplementation decreases treatment costs and mitigates adverse reactions associated with blood products [3].

5. Limitations

Several limitations of this study should be acknowledged. First, this was a single-center study with a relatively small sample size; the conclusions require validation through multicenter, large-sample studies. Second, only short-term laboratory parameters and adverse reactions were observed, with no long-term survival follow-up. Third, no cost-effectiveness analysis was performed, making it difficult to quantify the economic value of albumin conservation. Fourth, the pharmacokinetic differences of DPMAS combined with different separators warrant further investigation.

6. Conclusion

In conclusion, the small-pore EC-4A20 membrane plasma separator significantly

reduces non-specific albumin loss during DPMAS therapy in patients with liver failure, with a protective trend toward hemoglobin and platelet counts and a favorable safety profile. It is particularly suitable for critically ill patients complicated by hypoalbuminemia and thrombocytopenia, and merits wider clinical application. Future research should focus on membrane material modification and optimization, as well as individualized separator selection strategies, to further advance the precision development of artificial liver therapy.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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