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Original Article

Efficacy of double filtration plasmapheresis combined with immunosuppressive agents in the treatment of severe lupus nephritis

Xia Lin, Xiaoyan Tang, Feng Su, Tingting Shi, Di Zeng, Shiping Liu

General Practice, Affiliated Hospital of North Sichuan Medical College, Nanchong 637000, Sichuan, China

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Abstract: Objective: To evaluate the efficacy of double filtration plasmapheresis combined with immunosuppressive agents in the treatment of severe lupus nephritis. Method: A retrospective analysis was conducted on the medical records of 102 cases of severe lupus nephritis treated between January 2021 and December 2022 in the General Practice Department at the Affiliated Hospital of North Sichuan Medical College. Patients who received immunosuppressive agents were included in the control group and those who received additional double filtration plasmapheresis were included in the observation group. Changes in liver and kidney function indicators, immune function indicators, disease activity, peripheral blood immunoglobulins, total albumin levels, gamma globulin levels, erythrocyte sedimentation rates (ESR), and inflammatory marker levels, and overall clinical efficacy were compared between the two groups. Results: After therapy, kidney function indicators in the observation group were lower than in the control group, while serum albumin (Alb), total albumin level, complement component 3 (C3) and C4 levels were higher (all $P<0.05$). Anti-double-stranded DNA antibody (ds-DNA) and white blood cell (WBC) counts in the observation group were also lower than those in the control group. Additionally, the systemic lupus erythematosus disease activity index (SLEDAI) scores, the levels of tumor necrosis factor-α (TNF-α), interleukin-6 (IL-6), C-reactive protein (CRP), and ESR were lower in the observation group than those in the control group (all $P<0.05$). The total clinical effective rate was higher in the observation group than in the control group ($P<0.05$). Conclusion: The combination of immunosuppressive agents with double filtration plasmapheresis in patients with severe lupus nephritis can significantly improve liver and kidney function, enhance immune function, and reduce inflammation, demonstrating good therapeutic effects and safety.

Keywords: Double filtration plasmapheresis, immunosuppressive agents, severe lupus nephritis, clinical efficacy, renal function, immunity function

Introduction

Severe lupus nephritis (LN) is a serious immune complex-mediated glomerulonephritis caused by systemic lupus erythematosus (SLE). LN affects 50% to 70% of SLE patients and is a major cause of mortality among these patients [1]. Lupus nephritis is a bilateral kidney immune disease with a high incidence in clinical practice, presenting primarily with hematuria, elevated blood pressure, renal failure, and proteinuria. Without timely and effective treatment, disease progression can increase the risk of adverse outcome [2].

Currently, immunosuppressive therapy like mycophenolate mofetil and cyclophosphamide combined with glucocorticoids is the primary approach to treat LN. Clinical studies have shown that [3] this treatment protocol can improve renal survival in LN patients. However, in severe cases, the condition can progress and worsen rapidly, making it challenging to control with hormone drugs and immunosuppressive agents in a short time.

Double filtration plasmapheresis, a selective plasmapheresis method, has gained wider application with advances in medical technology [4]. It can selectively remove large molecular substances from plasma [5], filtering out smaller components (e.g., albumin, small molecule proteins), and returning the processed plasma to the body, which helps eliminate pathogenic

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substances while minimizing the effect of therapeutic measures on normal compounds and electrolytes [6]. Clinical research has shown that [7] double filtration plasmapheresis yields favorable therapeutic outcomes in lupus nephritis patients. However, there is limited research on its combination with immunosuppressive agents.

This study aims to investigate the efficacy of immunosuppressive agents combined with double filtration plasmapheresis in treating patients with severe lupus nephritis.

Methods

Case selection

A retrospective analysis was conducted on the medical records of 102 cases with severe lupus nephritis admitted to General Practice Department at the Affiliated Hospital of North Sichuan Medical College between January 2021 and December 2022. Patients were grouped based on their treatment plans, with 51 cases each in the control group (immunosuppressive agents alone) and the observation group (immunosuppressive agents with double filtration plasmapheresis).

Inclusion criteria: (1) Patients met the diagnostic criteria for LN and severe lupus nephritis as established by the American Society of Rheumatology (1997 edition) [8]; (2) Presence of glomerular basement membrane thickening, with diffuse/staged deposition of subcutaneous immune complexes and evidence of renal tubular damage; (3) Patients with a disease activity index of 10 points or higher for severe lupus nephritis; and (4) Patients with abnormal renal function indicators.

Exclusion criteria: (1) Patients with nephritis caused by drug or hypertension-related factors; (2) Patients with abnormal coagulation function; (3) Patients with coexisting infectious diseases or serious organic diseases. This study was approved by the ethics committee of the Affiliated Hospital of North Sichuan Medical College.

Methods

All patients received glucocorticoid therapy with oral prednisone acetate upon admission. The initial dose was 0.5-1.0 mg/kg per day. After 28 consecutive days of medication, the daily dose was adjusted to 5-10 mg based on changes in the patients' condition, and maintained at this level. In addition, supportive treatment was provided, including gastric acid inhibitors, calcium supplements, and gastric mucosa protective drugs.

Control group: Patients were treated with oral mycophenolate mofetil, administered once daily at a dose of 1 g each time. The treatment continued for 6 months.

Observation group: Patients in this group were treated with double filtration plasmapheresis in addition to the above treatment. Under local anesthesia, internal jugular vein puncture was performed, and double-lumen tubes were inserted. Plasma separation was conducted using primary and secondary filters (EC50W and EC20W). Low molecular weight heparin and citric acid were administered for anti-coagulation to prolong the activated coagulation time. Under extracorporeal circulation, the whole blood was filtered at a rate of 120-150 ml/minute through EC50W, and the plasma was filtered through EC20W at a rate of 30-40 ml/minute, with filtered plasma subsequently returned to the body. Retained plasma components were circulated within EC20W at a rate of 60 ml/min. If the pressure before EC20W exceeded 150-160 mmHg, plasma separation was paused, and EC20W was flushed with 800 ml of physiological saline to clear retained plasma, discarding any residual component. Each session processed twice the volume of plasma, with a 20 g albumin supplement at a concentration of 5.7%-16.4%, administered once daily for 2 hours. Double filtration plasmapheresis was performed three times a week, with each patient receiving a total of two weeks of treatment.

Observation indicators

Primary outcomes: (1) Disease activity and erythrocyte sedimentation rate (ESR): Changes in disease activity and ESR were assessed in both groups before and after therapy. ESR was measured using the Weiss method, and the disease activity was evaluated using the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). SLEDAI scores were categorized as follows: inactive (<5 points), mild activity (5-9 points), moderate activity (10-14 points), and severe activity (≥15 points) [7]. (2) Immune index levels: Changes in immune index levels were analyzed by collecting blood samples before and after therapy. Anti-double-stranded

Table 1. Comparison of baseline data between the two groups

Group	Control group (n=51)	Observation group	X^2/t	P
Male	3	2	0.000	1.000
Age (years)	37.00±3.38	36.90±3.28	0.152	0.880
Complicated with hypertension (n)	4	6	0.443	0.505
Complicated with coronary heart disease (n)	7	5	0.378	0.539
Course of illness (months)	12.11±1.16	12.13±1.28	-0.083	0.934
Lee's pathological classification			0.405	0.810
III	16	17		
IV	16	18		
V	19	16		
Complication			0.147	0.929
Hemolytic uremic syndrome	4	3		
Thrombotic thrombocytopenic purpura	2	1		
Central system neuropathy	1	1		

DNA antibodies (ds-DNA) were measured using indirect immunofluorescence detection. The levels of complement component 3 (C3) and C4 were measured by immunoturbidimetry; and white blood cell (WBC) count was determined by microscope examination.

Secondary outcomes: (1) Liver and renal function indicators: Before and after the therapy, 2 ml of fasting venous blood was collected from the patients, centrifuged at 3500 r/min for 10 min (radius of 10 cm), and the serum was stored at -80°C. Midstream samples was also collected for testing. Blood creatinine (SCr) level and 24 h urine protein level were measured using a renal function tester; blood urea nitrogen (BUN) was assessed using the diacetyl monoxime method, and the serum albumin (Alb) level was measured by the bromocresol violet method. (2) Inflammatory index levels: Changes in inflammatory markers were recorded before and after treatment. C-reactive protein (CRP) levels were measured by dry immunochromatography with a fully automatic hypersensitive CRP analyzer. Interleukin-6 (IL-6) levels were measured by circulation-enhanced immunity with an immune analyzer, and tumor necrosis factor-α (TNF-α) was determined by immune scattering turbidimetry. (3) Clinical efficacy: Markedly Effective: Symptoms largely disappeared, serum albumin ≥35 g/L, urine protein ≤0.4 g/24 h, and normal SCr levels; Effective: Urine protein decreased to <3.5 g/24 h, with a ≥50% reduction from baseline, stable SCr, and serum albumin ≥30 g/L; Ineffective: Any of the above criteria were not met [9]. The total effective rate = markedly effective rate + effective rate. (4) Incidence of adverse reactions: Adverse reactions during treatment, including hypotension, diarrhea, nausea, and vomiting, were recorded.

Statistical treatment

Data collected in this study were standardized and analyzed using SPSS 20.0. Measured data were expressed as mean ± standard deviation ($\bar{x} \pm s$), and categorical data were expressed as percentages (%). Independent sample t-tests were used for comparison of measured data between the two groups, while chi-square tests were applied for categorical data. Statistical significance between groups was indicated by $P<0.05$.

Results

Comparison of baseline data between the two groups

The baseline data analysis (**Table 1**) revealed no significant differences between the two groups regarding gender, age, comorbidities, Lee's pathological classification, or complications (all $P<0.05$).

Comparison of liver and kidney function indicators between the two groups

As shown in **Table 2**, there were no significant differences in Alb, BUN, SCr or urinary protein levels between the two groups before treatment (all $P>0.05$). However, after therapy, the Alb levels in the observation group were signifi-

Table 2. Comparison of liver and kidney function indicators between the two groups

Group	Control group (n=51)		Observation group (n=51)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
BUN (mmol/L)	15.78±1.08	4.66±0.86*	15.86±1.13	4.00±0.56*,#
SCr (μ mol/L)	244.84±12.8	180.70±10.85*	244.84±12.89	170.64±8.34*,#
Urinary protein (g/h)	11.13±1.20	4.84±0.92*	11.15±1.41	4.01±0.31*,#

*P<0.05, compare to before treatment; #P<0.05, compare with control group. Alb: Albumin; BUN: Blood Urea Nitrogen; SCr: Serum Creatinine.

Table 3. Comparison of immune index levels compared between the 2 groups of severe lupus nephritis patients (n=51)

Group	Control group (n=51)		Observation group (n=51)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
ds-DNA (IU/L)	40.13±3.31	25.19±2.13	40.13±3.26	18.96±1.94*,#
WBC (10^9L^{-1})	12.27±1.18	11.03±0.77*	12.45±1.17	9.72±0.66*,#
C3 (g/L)	0.00±0.00	0.19±0.40*	0.03±0.19	0.90±0.30*,#
C4 (g/L)	0.00±0.00	0.20±0.30*	0.00±0.00	0.97±0.25*,#

*P<0.05, compared to before treatment; #P<0.05, compared to control group. ds-DNA: double-stranded DNA; WBC: white blood cells; C3: complement component 3; C4: complement component 4.

Table 4. Comparison of SLEDAI score and ESR between the two groups

Group	Control group (n=51)		Observation group (n=51)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
SLEDAI score (points)	18.86±2.07	10.03±0.19	13.92±2.16	7.15±0.36*,#
ESR (mm/h)	59.05±5.85	38.25±3.09*	59.43±5.92	29.27±1.47*,#

*P<0.05, compared to before treatment; #P<0.05, compared to control group. SLEDAI: Systemic lupus erythematosus disease activity index; ESR: erythrocyte sedimentation rates.

cantly higher than those in the control group, while BUN, SCr, and urinary protein levels were significantly lower in the observation group (all P<0.05).

Comparison of immune index levels between the two groups

As shown in **Table 3**, there were no significant differences in pre-treatment ds-DNA, complement C3, complement C4, or WBC levels between the two groups (all P>0.05). After therapy, compared to the control group, the levels of ds-DNA and WBC in the observation group were obviously lower, while the C3 and C4 levels were significantly higher (all P<0.05).

Comparison of disease activity and ESR scores between the two groups

As shown in **Table 4**, there were no significant differences in the SLEDAI score or ESR between the two groups before treatment (both P>0.05). After therapy, the levels of these two indicators in the observation group were lower compared to controls (both P<0.05).

Comparison of inflammatory marker levels between the two groups

As shown in **Table 5**, there were no significant differences in the levels of CRP, IL-6, or TNF-α between the two groups before therapy (all P>0.05); after the intervention, these inflammatory markers were significantly lower in the observation group compared to the control group (all P<0.05).

Comparison of clinical efficacy between the two groups

As shown in **Table 6**, the total clinical effective rate in the observation group was 92.16%, significantly higher than 76.47% in the control group (P<0.05).

Table 5. Comparison of inflammatory index levels between the two groups

Group	Control group (n=51)		Observation group (n=51)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
CRP (mg/L)	71.41±8.35	40.37±5.68	71.56±8.31	27.92±3.18*,#
TNF-α (ng/L)	1160.25±104.85	900.92±26.96*	1160.25±104.85	784.17±12.64*,#
IL-6 (ng/L)	105.29±9.59	80.27±6.44*	105.49±9.49	63.78±3.40*,#

*P<0.05, compared to before treatment; #P<0.05, compared to control group. CRP: C-reactive protein; TNF-α: tumor necrosis factor-α (TNF-α); IL-6: interleukin-6.

Table 6. Comparison of clinical efficacy between the two groups

Group	Control group (n=51)	Observation group (n=51)
Markedly effective	9	15
Effective	30	32
Invalid	12	4
Clinical total effective rate (%)	76.47	92.16
X^2/*P*-value	4.744/0.029	

Table 7. Comparison of adverse reaction frequency between the two groups

Group	Control group (n=51)	Observation group (n=51)
Hypotension	0	3
Nausea and vomiting	2	2
Diarrhea	1	1
Total (%)	5.88	11.76
X^2/*P*-value	1.087/0.295	

Comparison of incidence of adverse reactions between the two groups

As shown in **Table 7**, there were no significant differences in the frequency of adverse reactions between the two groups (5.88% vs. 11.76%, P=0.295).

Comparison of blood biochemical indicators between the two groups

After treatment, patients in the observation group exhibited a significant increase in serum albumin levels and a decrease in gamma globulin levels. Moreover, the patients in the observation group demonstrated a more distinct increase or decrease compared to those in the control group (all P<0.05) (**Figure 1**).

Comparison of immunoglobulin levels between the two groups

After treatment, the serum levels of IgG, IgA, and IgM decreased in both groups (all P<0.05), with the patients in the observation group showing a greater decrease compared to those in the control group (all P<0.05) (**Table 8**).

Discussion

Lupus nephritis (LN) is an immune-mediated disease resulting from a combination of multiple factors. As the condition progresses, the risk of impairment to other organ functions increases, and in severe cases, it can pose a life-threatening risk to patients [10]. Clinical statistics have shown [11] that about 70% of patients with severe LN experience active lupus, which raises the likelihood of acute kidney injury, and pathologic examination often reveals active lesions. Timely and accurate diagnosis and treatment are essential to control disease progression and reduce the risk of irreversible renal failure [12].

Plasma exchange is a therapeutic procedure in which plasma is separated from blood using a plasma separator and then processed through a secondary component separator with smaller membrane pores to remove high molecular weight proteins, such as pathogenic antibodies, while returning low molecular weight proteins such as albumin, along with a replacement solution, back into the body [13]. Plasma exchange includes simple plasma exchange and double filtration plasmapheresis (DFPP) [14]. DFPP, which has shown promising clinical results in the treatment of systemic diseases, uses plasma component separators with varying pore sizes to selectively remove large molecular weight proteins while retaining ben-

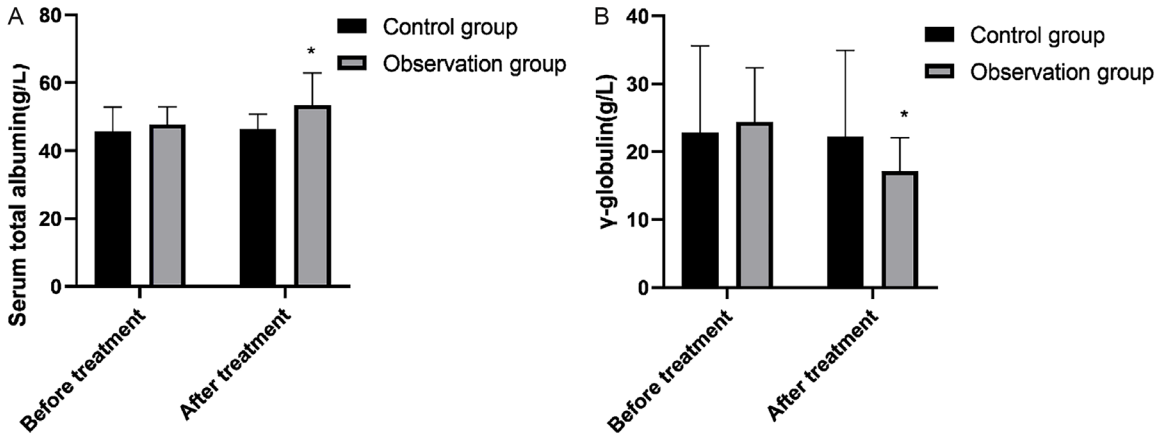

Figure 1. Comparison of serum biochemical indicator levels between the two groups before and after treatment. A: Serum albumin levels in the two groups. B: Gamma globulin levels in the two groups. *: Compared to control group, P<0.05.

Table 8. Comparison of serum immunoglobulin levels between the two groups

Group	Control group (n=51)		Observation group (n=51)	
	Before Treatment	After Treatment	Before Treatment	After Treatment
IgA (g/L)	2.47±1.16	2.31±1.18*	2.51±1.41	1.73±1.13*,#
IgG (g/L)	16.43±7.85	14.85±7.64*	16.60±7.80	11.22±6.97*,#
IgM (g/L)	1.03±0.37	0.72±0.49*	1.12±0.36	0.55±0.31*,#

*P<0.05, compared to before treatment; #P<0.05, compared to control group. IgA: immunoglobulin A; IgG: immunoglobulin G; IgM: immunoglobulin M.

eficial smaller proteins like albumin, which are then reintroduced into the body with a replacement solution. DFPP can quickly modulate the immune system by clearing pathogenic antibodies, restoring cellular immune function, and enhancing reticuloendothelial phagocytosis, providing swift symptomatic relief [15]. By effectively removing immune complexes, antibodies, and antigens from the patient's plasma, DFPP achieves therapeutic goals effectively. Literature reports indicate that after DFPP treatment for systemic lupus erythematosus (SLE), the negative conversion rates of Anti-Nuclear Antibodies and anti-dsDNA were 36.36% and 54.55%, respectively, aligning with the results of this study, and further demonstrating that DFPP's efficacy in clearing autoantibodies to treat SLE [16, 17]. After DFPP treatment, IgA, IgG, and IgM levels decreased, while albumin, C3, and C4 increased, indicating that DFPP not only removes serum immunoglobulins and immune complexes but also enhances treatment efficacy for SLE, consistent with previous studies [18]. In addition, DFPP acts quickly, leading to a rapid decrease in autoantibodies, minimizing immune complex formation, alleviating clinical symptoms, and providing rapid relief, in line with research reports [19].

Albumin is a key plasma protein synthesized by liver, playing a crucial role in maintaining blood osmotic pressure, transporting nutrients, and facilitating the removal of metabolic waste. BUN and SCr are protein metabolites and muscle metabolites, respectively. Currently, clinical evaluation of human liver and kidney function is mainly based on these indicators, along with urinary protein levels. Our results showed that the levels of liver and kidney function indicators in the observation group improved more significantly than those in the control group after therapy. This suggests that the combination of immunosuppressive agents and double filtration plasmapheresis technology can effectively improve the organ function in patients with severe lupus nephritis. We hypothesize that this improvement may result from double filtration plasmapheresis technology mimicking glomerular function by clearing immune complexes from the body. Additionally, the levels of coagulation-promoting factors and aggrega-

tion-promoting factors in LN patients are often increased, which exacerbates the disease. Double filtration plasmapheresis can reduce the fibrinogen and coagulation factor levels in the blood, providing a vital effect in controlling disease progression [20].

Lupus nephritis is a systemic immune disease that can impair renal function, with T cells playing a significant role in its onset and progression. Autoantibodies produced by B cells are dependent on T cell activity, and clinical studies [21, 22] have shown that the role of B lymphocytes in lupus nephritis development is heavily dependent on the inflammatory cytokines (such as CRP, IL-6, and TNF-α) they produce. In this study, post-treatment levels of inflammatory factors in the observation group were significantly lower than those of the control group, suggesting that combining immunosuppressive agents with double filtration plasmapheresis can effectively improve the inflammatory status in patients with severe lupus nephritis. We hypothesize that this effect may be due to double filtration plasmapheresis having a minimal effect on nutrients while effectively removing inflammatory factors and pathogenic substances from the blood, thereby reducing the inflammatory response and lowering inflammatory indicator levels in patients with LN [23, 24].

Previous studies report that DFPP treatment for SLE is relatively safe, with common complications including nausea, vomiting, diarrhea, and hypotension. These issues are related to the membrane material, while hypotension associated with protein leakage [25]. Active symptomatic treatment can effectively manage these complications. Meanwhile, this study found no significant difference in the incidence of adverse reactions between the two groups, further confirming the safety of DFPP in SLE treatment, similar to prior research findings [26].

Conclusion

For patients with severe lupus nephritis, combining immunosuppressive agents with double filtration plasmapheresis provides effective immune regulation, reduces inflammatory response, and improves renal function. This approach is beneficial for controlling disease progression and establishing favorable conditions for subsequent treatment.

Disclosure of conflict of interest

None.

Address correspondence to: Shiping Liu, General Practice, Affiliated Hospital of North Sichuan Medical College, No. 1 Maoyuan South Road, Shunqing District, Nanchong 637000, Sichuan, China. Tel: +86-13890786989; E-mail: Lx769256451@163.com

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