

# Retrospective Evaluation of Therapeutic Plasma Exchange in Nephrology Clinic: A Single-Center Experience

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147

## ABSTRACT

**Objective:** The indication for use of therapeutic plasma exchange has been increasing in recent years. It is a method that contributes significantly to the reduction of mortality and morbidity with immunosuppressive treatments in many life-threatening diseases. The aim of this study is to examine, research, and develop therapeutic plasmapheresis procedures performed in a nephrology department.

**Methods:** In this study, we retrospectively reviewed the therapeutic plasma exchange procedures performed in our center. The demographic characteristics, clinical features, and laboratory results before and after the procedure of all patients were screened.

**Results:** A total of 67 patients (36 females, 31 males; mean age,  $45.73 \pm 15.89$  years) and 398 apheresis sessions were analyzed. The most common nephrological indication of the therapeutic plasma exchange was acute humoral rejection (40.3%). When the laboratory values of the patients before and after the procedure were examined, it was observed that there was a statistically significant decrease in creatinine and platelet values after the procedure and a significant increase in bicarbonate values. When therapeutic plasma exchange was performed for hemolytic uremic syndrome, it was found that there was a decrease in lactate dehydrogenase level and an increase in platelet count. Complications were detected in 2 of the patients during the procedure.

**Conclusion:** Therapeutic plasmapheresis exchange can be performed by many different indications in a nephrology department. Acute humoral rejection was the most common indication for plasmapheresis in our center. We think that the procedure performed with the right indications will contribute to better outcomes.

**Keywords:** Clinical nephrology, acute humoral rejection, therapeutic plasmapheresis exchange

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## INTRODUCTION

Therapeutic plasma exchange (TPE) is an extracorporeal treatment method and is based on the removal of the morbidity-causing component or pathogenic substance from the plasma. Therapeutic plasma exchange is divided into 2 main topics: cytappheresis and plasmapheresis. While cytappheresis is defined as the removal of abnormal or excessively increased blood cells, plasmapheresis is the removal of plasma and its replacement with a different fluid such as colloid or crystalloid. The

molecule to be removed can be immunoglobulins, auto-antibodies, immunocomplexes, antibodies, and toxins that are active in disease pathogenesis.<sup>1</sup>

Therapeutic plasma exchange can be done by several different methods. One of these methods is the centrifugal technique. In this method, the separation of blood into its components is based on the principle of separation of blood cells and plasma whose specific weights differ from each other with the effect of centrifugation.



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If blood is to be centrifuged in a tube, according to their specific weight, plasma, thrombocyte, mononuclear cell, granulocyte and erythrocyte are sorted from mild to heavy. The centrifugal method is essential in hematological treatments (cytapheresis).<sup>2,3</sup> In this method, there is no restriction on the weight of the molecule to be removed. The blood flow rate is approximately 90-150 mL/min and is lower than the filtration method. The most important disadvantage is that platelets can be reduced by 50%.<sup>4</sup> The second method is the filtration technique, and in this technique, blood components are separated from each other according to their size. In this method, a perforated membrane with pores of 0.2-0.5  $\mu\text{m}$  is generally used and the components are separated from each other according to the diameters of the pores in this membrane. The blood flow rate is approximately 90-200 mL/min. While it does not cause thrombocytopenia, high blood flow causes an increase in the risk of hemolysis.<sup>5,6</sup> The last technique is the method of separation by adsorption, in which the principle of affinity chromatography is used and specific harmful structures are taken out of the body. In this system, substances such as antigen, antibody, dextran sulfate, or heparin contained in a matrix bind specific structures in the blood and remove them. Different membranes are used for different clinical purposes such as hyperlipidemia, hyperbilirubinemia, and endotoxin removal.<sup>7</sup>

For the procedure to be beneficial, the substance to be removed must be large enough ( $>15\,000\text{ Da}$ ), have a long half-life, be acutely toxic, and be resistant to conventional therapy. Therefore, the process is used more frequently for the removal of high-molecular weight pathogenic antibodies such as IgG.<sup>8</sup> Therapeutic plasma exchange also increases endogenous excretion of circulating toxins by draining the reticuloendothelial system enhances cytotoxic therapy by stimulating lymphocyte clones and allows refeeding with large volumes of plasma without the risk of intravascular volume overload.<sup>9,10</sup> Therefore, TPE can be a definite treatment option depending on the underlying disease, or it can be used as a part of combination therapy.

As a general rule, large molecular weight substances create a state of equilibrium between the vascular space and the interstitium at a very slow rate. Therefore, the removal of any large molecular weight substance from plasma can be calculated

simply by first-order kinetics. When the plasma volume changes by 1 turn, the level of macromolecules in the plasma drops to 60%, while this decrease can be up to 75% when the plasma volume changes by 1.4 turn. The TPE program should be determined according to the pathological substance to be removed and the desired endpoint. The general recommendation is to make each change consist of 1-1.5 plasma volumes.<sup>11</sup>

The fluid loss created by the plasma exchange process is replaced with 3 types of fluids, namely albumin, fresh frozen plasma (FFP), and hydroxyethyl starch. Albumin is the standard replacement fluid currently used in most centers. The most important advantages are the absence of viral contamination risk and minimal risk of anaphylaxis, while its disadvantages are its ability to cause dilutional anemia and coagulopathy, the risk of hypotensive attacks due to the presence of prekallikrein activating factor, and it being an expensive product.<sup>12</sup> Since FFP provides a protein that inhibits platelet aggregation, it is preferred especially in thrombotic thrombocytopenic purpura and hemolytic uremic syndrome (HUS). While it is cheaper than albumin, the frequency of complications is higher. Hydroxyethyl starch can be used both in addition to albumin and alone. Although the most important advantage is its price, urticarial and pruritic attacks are more common. It can also cause coagulopathy and its elimination half-life is very long.<sup>11-13</sup>

Therapeutic plasma exchange is widely used in many neurological, hematological, immunological, and kidney diseases and also in cases such as hyperlipidemia and drug intoxications. According to the latest updated guidelines,<sup>14</sup> the therapeutic apheresis indications are grouped under 4 categories:

- Category I: Disorders for which apheresis is accepted as first-line therapy, either as a primary standalone treatment or in conjunction with other modes of treatment.
- Category II: Disorders for which apheresis is accepted as second-line therapy, either as a standalone treatment or in conjunction with other modes of treatment.
- Category III: The optimum role of apheresis therapy is not established. Decision-making should be individualized.
- Category IV: Disorders in which published evidence demonstrates or suggests apheresis to be ineffective or harmful. In these cases, apheresis treatment should only be done under approved research protocols.

In recent years, the frequency of TPE procedures has been increasing in the field of nephrology as in other fields. The indications and categories related to TPE in nephrology practice are summarized in Table 1.<sup>14</sup> As with other treatment modularities, some complications can be seen during the TPE procedure. However, complications rarely develop with the use of new-generation automatic apheresis devices used in recent years. In general, the incidence of complications is higher in patients in whom FFP is preferred as the replacement fluid. The most common complications are vasovagal and hypovolemic reactions,

## MAIN POINTS

- While the most common therapeutic plasma exchange indication in our center is acute humoral rejection, nephrological indications for apheresis are increasing.
- In our study, while there was no significant change in hemoglobin, pH, and ionized calcium values after the procedure, significant changes were observed in creatinine, bicarbonate, and thrombocyte values. Therefore, we think that better clinical responses can be obtained with the right indications.
- We observed that complications are not common with appropriate technique and follow-up.

**Table 1.** Indications for Therapeutic Plasmapheresis Exchange Therapy in Nephrology Practice

Disease	Category	Indication	Treatment	Replacement Fluids	Duration
Goodpasture syndrome	1	Alveolar hemorrhage, acute renal dysfunction in non-dialysis-dependent patients	With 4 L daily or every other day	Albumin, FFP	2-3 weeks
Cryoglobulinemia	1 or 2	RPGN, distal necrosis requiring amputation, or advanced neuropathy	1 plasma volume 3 days a week	Heated 5% human albumin	2-3 weeks
Crescentic glomerulonephritis	1	Patients with severe renal insufficiency, needing dialysis, and severe pulmonary hemorrhage	With 4 L daily or every other day	Albumin, FFP	2-3 weeks
Multiple myeloma	2	Cast nephropathy or monoclonal light chain height	5-7 sessions within 7-10 days	Albumin, FFP	Decided by the level of light chain.
Hyperviscosity syndrome	1	Severe neurological involvement such as stupor coma	1 plasma volume change per day	Albumin	Until symptoms disappear or serum viscosity returns to normal
Systemic lupus erythematosus	2	Patients with severe pulmonary hemorrhage or neurological involvement		Albumin, FFP	
Hemolytic uremic syndrome	1	All patients with suspected or diagnosed hemolytic uremic syndrome	1 plasma volume change per day	FFP	At least 7-10 days, until the platelet count returns to normal and hemolysis disappears
Rejection	1			Albumin, FFP	At least 4 sessions or until serum creatine level drops 20%-30%
Recurrent focal segmental glomerulosclerosis	1			Albumin, FFP	At least 10 days daily, then intermittently, usually continued for months

FFP, fresh frozen plasma; RPGN, rapidly progressive glomerulonephritis.

hypocalcemic reactions due to citrate toxicity, coagulation abnormalities, transfusion reactions, infection, drug removal, catheter-related problems, vascular access problems, air embolism, mechanical hemolysis, reduction in thrombocyte, lymphocyte numbers, and plasma proteins.<sup>15-17</sup> Procedure-related mortality is around 3-5 per 10 000 cases, and most of them are due to respiratory and cardiac causes. Especially the use of FFP as replacement fluid can cause cardiac deaths due to arrhythmia.<sup>18</sup> In the present study, we retrospectively examined the TPE procedures performed with nephrological indications in our clinic. We aimed to determine the indications of the procedure, its contribution to the treatment, and also its complications.

## METHODS

Ethical approval was obtained for the study (Date: 02.03.2018; approval number: 2018/1229). Written informed consent was obtained from all subjects included in the study.

A review of medical records (including information on age, sex, weight, height, disease duration, medications, and history of other diseases) was undertaken. The indication for the procedure, the type of replacement fluid used, the vascular access

used, the laboratory values before and after the procedure, and the complications that developed during the procedure were recorded. Control blood samples were taken 2 hours after the procedure.

Venous blood samples for biochemical analyses were drawn after at least 10 h of fasting early in the morning before taking any medication. Serum samples were used for detecting biochemical parameters, and whole blood samples were used to detect white cell and platelet counts. Serum creatinine levels were measured with Jaffe method.

## Statistical Analysis

Statistical Package for the Social Sciences version 21.0. (IBM SPSS Corp.; Armonk, NY, USA) was used to evaluate clinical and experimental data. Descriptive statistics for each variable were determined. The suitability of the variables to the normal distribution was examined. Paired samples *t*-test was used to examine the change of parameters showing normal distribution. The parameters that did not show a normal distribution were evaluated using the Wilcoxon test. A statistically significant difference was considered when the *P*-value < .05.

## RESULTS

A total of 67 patients (36 females, 31 males; mean age,  $45.73 \pm 15.89$  years) who underwent TPE with nephrological indication and 398 apheresis sessions were analyzed retrospectively. The apheresis indications and findings are shown in Table 2.

When the laboratory values of the patients before and after the procedure were compared, no significant changes were observed in the hemoglobin, pH, and ionized calcium values. While there was a statistically significant decrease in creatinine values after the procedure, there was a significant increase in bicarbonate and platelet values (Table 3).

In the subgroup analysis, an increase in platelet count and a decrease in lactate dehydrogenase values were found after the procedure in patients who underwent plasmapheresis with the diagnosis of the HUS. Complications were observed in 2 of our patients during the procedure. While an allergic reaction developed in 1 patient, respiratory arrest was observed in the other patient, which did not result in death and recovered rapidly. When the current status of these patients who presented with very severe symptoms was investigated after the plasmapheresis procedure, it was found that 70.1% of them were alive. (When the current status of these patients, who presented with very severe clinical symptoms after the plasmapheresis procedure, was examined, it was found that 70.1% of them were alive.)

## DISCUSSION

Therapeutic plasma exchange is the therapeutic apheresis technique used to remove large molecular weight substances from plasma, especially in hematological diseases. Today, the diseases treated with plasmapheresis are classified into 5 main categories: neurological, nephrological, hematological, immunological, and metabolic diseases.<sup>7</sup>

The nephrological indications of apheresis are increasing and the most common indication may differ between centers. Tamer et al,<sup>19</sup> reported in their study in 2017 that the most common indication was Goodpasture syndrome. On the other hand, in a study conducted among kidney diseases in 2019, rapidly progressive glomerulonephritis was found to be the most common indication with a rate of 36.2%.<sup>20</sup> In our study, 40.3% of the

**Table 2.** Apheresis Indications and Findings

Variables		n (%)
Gender	Male	31 (46.3)
	Female	36 (53.7)
Number of sessions	$5.94 \pm 4.664$ (mean $\pm$ SD)	5 (1-22) (Median)
Replacement fluid	Fresh frozen plasma	64 (95.5)
	Fresh frozen plasma and albumin	3 (4.5)
Vascular access	Antecubital vein	2 (3)
	Fistula	20 (30)
	Central venous catheter	45 (67)
Indication	Atypical hemolytic uremic syndrome	6 (9.0)
	Transplantation desensitization	1 (1.5)
	Focal segmental glomerulosclerosis	5 (7.5)
	Goodpasture syndrome	2 (3)
	Rapidly progressive glomerulonephritis	5 (7.5)
	Hemolytic uremic syndrome	3 (4.5)
	Mushroom intoxication	1 (1.5)
	Microscopic polyangiitis	2 (3.0)
	Acute humoral rejection	27 (40.3)
	Systemic lupus erythematosus	2 (3)
Complication	Wegener granulomatosis	13 (19.4)
	Allergic reaction	1 (1.5)
	Respiratory arrest	1 (1.5)
	None	65 (97.0)

patients constituted acute humoral rejection cases after kidney transplant, making it the most common nephrological indication group. The efficacy of plasmapheresis and sequential intravenous immunoglobulin (IVIG) therapy has been proven

**Table 3.** Changes in Patients' Laboratory Parameters After the Procedure

Parameter	Before (Mean $\pm$ SD)	After (Mean $\pm$ SD)	P
pH	$7.38 \pm 0.06$	$7.40 \pm 0.09$	.135
HCO <sub>3</sub> (mmol/L)	$20.18 \pm 4.88$	$23.59 \pm 4.79$	.002
Ionized calcium (mmol/L)	$0.93 \pm 0.21$	$1.10 \pm 0.63$	.969
Hemoglobin (g/dL)	$9.35 \pm 1.95$	$9.70 \pm 1.76$	.174
Platelet count (n/mm <sup>3</sup> )	137 (113)	175 (127.5) (niye +/-) yok(interquartile range olarak verildi)	.011
Creatinine (mg/dL)	$4.49 \pm 1.76$	$3.55 \pm 1.97$	.001

in acute humoral rejection after kidney transplantation.<sup>21</sup> White et al<sup>21</sup> demonstrated that plasmapheresis and sequential IVIG treatment provided graft survival in retrospective studies in patients with biopsy in patients with acute humoral rejection. In another study, the 1-year graft survival rate was reported to be 70% in patients with acute humoral rejection with plasmapheresis and IVIG treatment.<sup>22</sup>

Following acute humoral rejection, granulomatosis with polyangiitis, HUS, and focal segmental glomerulosclerosis (FSGS) were found as other frequent nephrological indications, respectively. The early removal of immune complexes and toxins rapidly interrupts the pathogenetic process and provides a more effective treatment than other therapeutic interventions. Although the literature on the efficacy of plasmapheresis treatment in thrombotic microangiopathic cases with predominant kidney involvement are contradictory, it is seen as a reasonable option considering the poor prognosis in adults.<sup>23-25</sup> Focal segmental glomerulosclerosis is a histological description of glomerular damage. Plasmapheresis is indicated for persistent proteinuria in the treatment of FSGS in native kidneys, despite steroid and other immunosuppressive therapy.<sup>25,26</sup> There are data on the positive effects of plasmapheresis treatment in cases of recurrent FSGS after kidney transplantation, and it is recommended with a category 1 indication in the 2016 American Society for Apheresis (ASFA) guideline.<sup>23,25,27,28</sup>

The number and frequency of plasmapheresis sessions are mostly determined empirically, according to the disease and the response received. Plasmapheresis is performed at intervals of 1 or a few days to ensure the balance between circulation and tissues. Generally, a total of 5-7 sessions are performed within 10-15 days. The most appropriate replacement schemes for different diseases are not fully known.<sup>29</sup> In 2003, Arslan et al<sup>30</sup> evaluated the patients who underwent plasmapheresis and reported that the average number of sessions was 4.5. In our study, a total of 398 apheresis sessions were performed in our center with different indications, and the average number of sessions was found to be 5.94.

In order to ensure adequate blood flow for plasmapheresis, femoral, subclavian or internal jugular vein catheterization or arteriovenous fistula should be created, taking into account the duration of the treatment. Temporary catheters are the commonly preferred as vascular access for the procedure.<sup>1</sup> In our study, a temporary central venous catheter was mostly used in accordance with the literature. In addition, we used arteriovenous fistula and antecubital vein as vascular access for the procedure (30% and 3%, respectively), and we did not encounter any complications related to catheterization in any of the patients.

The plasma volume to be used for TPE is generally 40 mL/kg. However, plasma volume; can also be calculated by the formula (patient weight × 70) × (1-hematocrit). 1-1.5 times the calculated plasma volume is used for TPE and is generally 3000-4500 mL.<sup>31</sup>

Four to five percent albumin solutions or FFP are preferred for replacement in most patients. In the case of using albumin, viral contamination and allergic reactions are not in question, but albumin use increases the cost. For this reason, FFP is more common in routine use. However, there may be differences between preferred replacement fluids according to experience and apheresis indication. In our center, FFP was used most frequently (95%) as the replacement fluid.

Plasmapheresis complication is associated with large vessel catheterization, coagulation disorders, septic complications due to impaired immunity due to removal of antibodies during the procedure, catheter-related infections, and transfusion of blood products. In addition, life-threatening hypotension, cardiac arrhythmias, and fluid-electrolyte imbalance can also develop. Mild symptoms such as urticaria, itching, limb paresthesias and pains, muscle contractions, dizziness, nausea, vomiting, fever, excitement, and seizures are more common.<sup>32</sup> In the study performed by Benítez et al.<sup>33</sup> complications during plasmapheresis were investigated and the most common complications were reported as hypocalcemia, hypotension, coagulopathy, hypokalemia, rash and procedure-related infection, and fever. In the present study, only 3% of our patients had complications during the procedure. Our study had some main limitations. First, the sample size was relatively small. Second, our study was designed retrospectively. Third, all of the patients enrolled in the study were Turkish. One should consider that our results cannot, therefore, be applied to all patients because of the differences between nationalities.

## CONCLUSION

In conclusion, in the present study, we demonstrated that TPE can be used with very different indications. While better clinical responses can be obtained with the right indication and technique, less frequent side effects are observed as the experience with the procedure increases.

**Ethics Committee Approval:** Ethics committee approval was received for this study from the ethics committee of Necmettin Erbakan University (Date: March 2, 2018, Decision No: 2018/1229).

**Informed Consent:** Written informed consent was obtained from all participants who participated in this study.

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