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Risk Factors Associated with Outcomes in Patients Undergoing Plasmapheresis: A Retrospective Study

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ABSTRACT

Plasmapheresis is an effective therapeutic modality for autoimmune and neurological disorders; however, it may be associated with certain clinical complications. Identifying risk factors associated with patient outcomes is essential for enhancing safety and quality of care. This study aimed to determine the factors associated with in-hospital mortality in patients undergoing plasmapheresis. This retrospective study included 200 hospitalized patients who underwent plasmapheresis between 2014 and 2021 at our institution. The primary outcome was in-hospital mortality. Demographic, laboratory, and clinical data were extracted from the patients' medical records. Statistical analyses were performed using univariate and multivariate Cox regression models in STATA (version 25). The mean age of the patients was 42.3 years, and 58.5% were female. Overall, 14.5% of the patients died during hospitalization. Findings revealed that age >40 years (p=0.014), Covid-19 infection (p< 0.001), low calcium levels (p =0.047), number of treatment sessions (p=0.009), use of fresh frozen plasma (FFP) (p=0.020), and administration of normal saline (p=0.005) were significantly associated with an increased risk of mortality. In conclusion, several clinical and laboratory factors were associated with mortality in patients who underwent plasmapheresis. Careful monitoring of electrolytes, appropriate adjustment of treatment sessions, and optimal fluid management may improve the outcomes. The findings of this study can inform therapeutic decision-making and enhance the quality of patient care.

Keywords: Plasmapheresis; Risk factors; Mortality; Clinical outcomes

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Introduction

Plasmapheresis, also known as therapeutic plasma exchange (TPE), is a plasma purification technique that removes antibodies, immune complexes, and inflammatory mediators from circulation. It is used to treat autoimmune and neurological disorders, as well as critical conditions such as sepsis [1]. Although some studies have demonstrated that TPE may reduce

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short-term mortality in patients with sepsis-induced organ failure, the evidence remains inconsistent [2, 3].

In a recent systematic review and meta-analysis, it was demonstrated that adding TPE to standard therapy in critically ill septic patients was associated with improved short-term survival [2]. Nevertheless, the safety of this procedure remains a major concern, particularly regarding hypotension during the process and citrate toxicity, which may lead to hypocalcemia [4, 5]. A multicenter study of patients admitted to intensive care units reported multiple complications following TPE, including hospital-acquired infections, with prolonged ICU stay and mechanical ventilation identified as strong predictors of infection [6].

Moreover, in patients with immune disorders, such as anti-glomerular basement membrane disease, combined strategies of plasmapheresis and immunosuppressive therapy may improve prognosis; however, the risk of infection and other procedure-related complications must be carefully considered. [7]. Recent data also indicate that when TPE is applied with high plasma exchange volumes, particularly in cases of acute liver failure, complications such as alkalosis, hypotension, and hypocalcemia are common [8]. Recent observational studies have also investigated predictors of response to plasma exchange; for instance, baseline serum antibody dilution prior to TPE may be an important predictor of procedural success [9]. Conversely, in patients with COVID-19, several meta-analyses have demonstrated that TPE can significantly reduce mortality, although the risk of complications, such as infection and electrolyte imbalance, remains a concern [10, 11].

More recent studies have indicated that the number of sessions, volume of plasma exchanged, and timing of the intervention may influence clinical outcomes [12]. In addition, some data indicate that major bleeding events related to TPE, such as those occurring after initiation of the procedure, can reduce patient survival and should be regarded as significant risk factors [13].

Another study focusing on safety reported that in a multicenter cohort, definitive complications such as metabolic acidosis, severe hypotension, and hypocalcemia occurred in patients who underwent high-volume plasma exchange [8]. Similarly, research on patients with autoimmune diseases indicated that common adverse events of TPE included first-day anxiety, citrate-induced hypocalcemia, and decreased albumin levels during subsequent days [14]. Therefore, the precise identification of clinical and laboratory risk factors associated with mortality in patients undergoing plasmapheresis, particularly those admitted to intensive care units, is of critical importance [15].

Given this scientific gap, the present study was designed to investigate the risk factors associated with patient outcomes following plasmapheresis using real-world data from hospitalized patients at Shahid Rahimi Hospital in Khorramabad between 2014 and 2021. The findings of this study may contribute to enhancing patient safety, improving nursing performance, and developing standardized care strategies in clinical settings.

Materials and Methods

Study design

This retrospective observational study included 200 hospitalized patients who underwent therapeutic plasma exchange (TPE) in the intensive care units of Shahid Rahimi Hospital, Khorramabad, Iran, between 2014 and 2021. Fifteen medical records were excluded because of incomplete data. The inclusion criteria comprised receipt of at least one session of TPE and availability of complete clinical and laboratory records. Patients with missing key information, including primary outcomes, laboratory results, or essential clinical data, were excluded from the analysis and a brief comparison between the retained and excluded cases was performed to minimize the risk of selection bias.

Variables

The primary outcome of the study was in-hospital mortality. Independent variables included age, sex, underlying disease, number of plasmapheresis sessions, volume and type of replacement fluids (normal saline, FFP), serum calcium level, and other laboratory parameters recorded at the last session prior to the outcome. Hypocalcemia was defined as a serum calcium level < 8.5 mg/dl. All other variables were defined and coded according to established clinical and laboratory standards.

Data Collection

The primary outcome of this study was in-hospital mortality. The independent variables included age, sex, underlying disease, number of plasmapheresis sessions, volume and type of replacement fluids (normal saline, FFP), serum calcium level, and other laboratory parameters recorded at the last session prior to the outcome. Hypocalcemia was defined as a serum calcium level < 8.5 mg/dl. All other variables were defined and coded according to the established clinical and laboratory standards.

Statistical Analysis

Data analysis was performed using Stata software version 25. Initially, descriptive statistics were generated for the demographic and clinical variables. Subsequently, univariate Cox regression was applied

to examine the association between each variable and primary outcomes. Variables with $P < 0.1$ were entered into the multivariate model, and $P < 0.05$ was considered statistically significant in the final analysis. Percentages are reported with one decimal place and without spacing (e.g., 58.5%). All results are presented with appropriate references and adherence to academic writing standards.

Results

In this study, 200 patients (across 1,040 plasmapheresis sessions) were evaluated for the study. As shown in Table 1, most patients who underwent plasmapheresis were female (58.5%). Most patients were married (61.5%), and the largest proportion had an educational level below the high school level (47.5%). In addition, more than half of the study population (52.5%) was younger than 40 years.

Table 2 shows the distribution of patient outcomes following plasmapheresis. Among the evaluated patients, 29 (14.5%) died, 139 (69.5%) experienced partial recovery, and 6 (3.0%) were referred to other hospitals. In addition, 15 records were excluded from the analysis because of incomplete data. The primary outcome of the study was in-hospital mortality, which was observed in 29 patients (14.5%).

In the Cox regression analysis, age > 40 years, low calcium level, number of plasmapheresis sessions, and the use of FFP and normal saline were significantly associated with an increased mortality risk. Other demographic factors, such as gender, marital status, and educational level, were not statistically significant. Likewise, variables including PTT level, amount of albumin administered, use of anticoagulant drugs, serum albumin level, and CRP level showed no significant association with mortality. Variables with $P < 0.1$ in the univariate analysis were included in the multivariate model. As shown in Table 3, each retained variable was independently associated with the mortality risk. Multivariate Cox regression analysis demonstrated that age > 40 years was significantly associated with an increased risk of death (HR = 3.54; P = 0.042). In contrast, normal saline use was significantly associated with a reduced risk of death (HR = 0.92; P = 0.025). Other variables, including gender, number of plasmapheresis sessions, and number of FFP units, did not show independent significant effects.

Table 1. Demographic characteristics of patients undergoing plasmapheresis at Shahid Rahimi Educational and Medical Center, Khorramabad (2014–2021)

Variable		Number	percentage
Sex	Male	83	41.5
	Female	117	58.5
Marital status	Single	60	30.0
	Married	123	61.5
	Widowed	17	8.5
Education	Below high school	95	47.5
	High school diploma and above	62	31.0
	Unknown	43	21.5
Age	≤ 40 years	105	52.5
	> 40 years	95	47.5

Table 2. Types of patient outcomes following plasmapheresis at Shahid Rahimi Educational and Medical Center, Khorramabad (2014–2021)

Outcome	Number	Percentage
Partial recovery	139	69.5
Death (in-hospital)	29	14.5
Unspecified	10	5.0
Discontinued by personal request	9	4.5
Full recovery	7	3.5
Referred to other centers	6	3.0

Table 3. Results of multivariate Cox regression analysis of patients undergoing plasmapheresis at Shahid Rahimi Educational and Medical Center, Khorramabad (2014–2021)

Variable	Hazard Ratio (95% CI)	P value
Age (> 40 years)	3.543 (1.046–12.00)	0.042
Sex	3.470 (0.385–31.260)	0.267
Number of TPE sessions	1.035 (0.802–1.336)	0.790
Number of FFP units	0.981 (0.950–1.012)	0.231
Normal saline use	0.919 (0.853–0.989)	0.025

Discussion

The findings of this study demonstrated that several clinical factors, including older age, COVID-19 infection, reduced calcium levels, a higher number of plasmapheresis sessions, and the type of replacement fluid, were associated with an increased risk of mortality. These results are supported by the evidence in the existing literature. For instance, a recent meta-analysis reported that TPE significantly reduced mortality in patients with sepsis [16]. A review of critically ill patients also indicated that plasma exchange may modulate the immune response by removing cytokines [17].

In patients with COVID-19, multiple studies and meta-analyses have shown that TPE may reduce mortality [18]. This finding is consistent with our results and suggests a potential mechanism involving cytokine clearance and the modulation of the inflammatory response.

However, some studies have reported that plasma exchange may be associated with increased complications or prolonged hospitalization in patients with higher SOFA or APACHE II scores [19]. This highlights the importance of appropriate patient selection and close monitoring during TPE. Comparative studies between TPE and other blood purification techniques, such as CPFA, have indicated that not all methods exert similar effects on mortality, and technical differences may influence patient outcomes [20].

Our study had several limitations, including its retrospective, single-center design; potential selection bias; exclusion of incomplete records; limited availability of certain disease severity indices; and possibility of confounding variables. For instance, patients who received specific replacement fluids or more sessions may have been more critically ill at the baseline [21].

Based on these findings, it is recommended that high-risk patients (older age, COVID-19 infection, low calcium levels) undergo closer monitoring during TPE and that the choice of replacement fluid and number of sessions be made with greater caution [22]. Furthermore, training nurses and healthcare staff is essential to improve the management of high-risk patients and prevent complications [23].

Prospective studies and large clinical trials are necessary to determine the true effect of TPE in different patient populations, particularly to evaluate the role of replacement fluids, optimal number of sessions, and interactions with comorbid conditions [24–25].

Conclusion

This study demonstrated that several clinical and laboratory variables, including age, COVID-19 infection, calcium level, number of sessions, and type of replacement fluid, were associated with patient outcomes following plasmapheresis. These findings emphasize that identifying high-risk patients and modifying treatment protocols may help reduce mortality and improve the quality of care.

The results also highlight the importance of close patient monitoring, appropriate selection of replacement fluids and treatment sessions, and nurse training for the optimal management of high-risk patients. The study limitations, including its retrospective design, single-center setting, and exclusion of incomplete records, should be considered when interpreting the findings.

Therefore, future studies with stronger designs, including prospective investigations and randomized clinical trials, are recommended to evaluate the effectiveness of TPE in different patient populations and determine the best therapeutic strategies.

Authorship contribution statement

F GH and K H conceptualized and designed the study. PK and RM conducted validation, analysis, and investigation. FG managed resources, data curation, and visualization. FG drafted the manuscript, while K H, P K, and R M reviewed and edited it. KH supervised and administered the project.

Ethical Consideration

The study was approved by the Ethics Committee of Lorestan University of Medical Sciences (code: IR.LUMS.REC.1401.187). All data were analyzed confidentially, with no possibility of identifying individual patients.

Declaration of Competing Interest

The authors have no conflict of interests related to this article

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Declaration of Generative AI

The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript, nor for the creation of tables, or their corresponding captions.

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