Safety Profile of 5% Albumin Versus Fresh Frozen Plasma in Therapeutic Plasma Exchange for Guillain-Barré Syndrome

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ABSTRACT

Background: Therapeutic plasma exchange (TPE) is an established treatment for Guillain-Barré syndrome (GBS). Although generally safe, mild complications may occur. Fresh frozen plasma (FFP) and 5% albumin are commonly used replacement fluids, and their comparative safety remains clinically important. **Objective:** To compare the safety profile of 5% albumin and fresh frozen plasma as replacement fluids during therapeutic plasma exchange in patients with Guillain-Barré syndrome. **Methods & Materials:** This comparative cross-sectional study was conducted at BSMMU and NINS, Dhaka, from October 2021 to September 2022. Eighteen GBS patients undergoing TPE were equally divided into FFP and 5% albumin groups. A total of 90 TPE sessions were analyzed for immediate complications, including fever, allergic reactions, hypotension, and symptomatic hypocalcemia. Data were analyzed using SPSS version 22, with $p < 0.05$ considered significant. **Results:** Baseline demographic and anthropometric characteristics were comparable between groups ($p > 0.05$). Fever occurred in 2.2% of albumin sessions versus 8.9% of FFP sessions. Allergic reactions were observed in 2.2% and 6.7%, hypotension in 2.2% and 11.1%, and symptomatic hypocalcemia in 4.4% and 11.1% of sessions in the albumin and FFP groups, respectively. Although complications were numerically higher in the FFP group, differences were not statistically significant ($p > 0.05$). **Conclusion:** Both replacement fluids were generally safe during TPE in GBS patients; however, 5% albumin showed relatively fewer immediate complications than fresh frozen plasma.

Keywords: *Therapeutic plasma exchange; Guillain-Barré syndrome; fresh frozen plasma; 5% albumin.*

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INTRODUCTION

Therapeutic plasma exchange (TPE) is an established extracorporeal blood purification technique in which a patient's plasma is selectively removed and replaced with an appropriate substitution fluid to eliminate circulating pathogenic substances [1]. The procedure is a specialized form of apheresis, derived from the Greek term *aphaeresis*, meaning "to take away," and refers to the separation and removal of specific blood components while returning the remaining constituents to the circulation [2]. Over the past several decades, advances in apheresis technology and plasma separation techniques have markedly improved the safety, efficiency, and clinical applicability of TPE across a wide range of immune-mediated and hematological disorders [3].

The modern concept of apheresis evolved from early efforts in plasma fractionation during the mid-20th century. Initial developments were driven by the need for safer plasma-derived therapeutic agents, particularly during wartime, when transfusion-transmitted hepatitis posed a major risk [4]. Subsequent refinements in centrifugation and membrane separation technologies enabled the transition of apheresis from a donor-based plasma collection method to a therapeutic intervention [5]. Since the introduction of membrane-based plasma separators in the late 1970s, TPE has become an integral component of therapy for several neurological, immunological, and metabolic diseases [2].

Guillain-Barré syndrome (GBS) is one of the most important neurological indications for TPE. GBS is an acute, immune-mediated polyradiculoneuropathy characterized by rapidly progressive, usually symmetrical weakness and diminished or absent deep tendon reflexes [6]. The disease spectrum includes several subtypes, of which acute inflammatory demyelinating polyradiculoneuropathy (AIDP) accounts for the majority of cases worldwide. Other recognized variants include acute motor axonal neuropathy, acute motor-sensory axonal neuropathy, Miller Fisher syndrome, and acute autonomic neuropathy [7]. Disease progression typically occurs over hours to weeks, and severe cases may involve respiratory and autonomic dysfunction requiring intensive care support.

Although spontaneous recovery occurs in many patients, GBS remains associated with considerable morbidity and mortality. Approximately 20–30% of patients require mechanical ventilation during the acute phase, and persistent neurological disability occurs in up to 20% of survivors [8]. The disorder is often preceded by infection or immune stimulation, leading to an aberrant autoimmune response against peripheral nerve components. Molecular mimicry between microbial antigens and nerve gangliosides has been strongly implicated, particularly in axonal variants and Miller Fisher syndrome [9].

Intravenous immunoglobulin (IVIG) and TPE are the two established disease-modifying therapies for GBS. Randomized controlled trials and meta-analyses have demonstrated that TPE improves outcomes in both mildly and severely affected patients, particularly when initiated within the first seven days of symptom onset [8,10].

The therapeutic benefit of TPE is attributed to the removal of circulating autoantibodies, immune complexes, complement components, and pro-inflammatory mediators involved in nerve injury [1].

Various replacement fluids have been used during TPE, including 5% albumin, fresh frozen plasma (FFP), and albumin combined with synthetic colloids. Among these, 5% albumin and FFP are the most commonly used replacement fluids in many low- and middle-income countries. While both fluids effectively maintain intravascular volume, they differ substantially in composition and safety profiles. FFP contains coagulation factors and plasma proteins but carries risks of allergic reactions, transfusion-transmitted infections, transfusion-related acute lung injury, and circulatory overload [11]. In contrast, 5% albumin is associated with a lower risk of immunologic reactions but may predispose patients to hypotension and electrolyte disturbances, particularly hypocalcemia [12].

Although the overall morbidity associated with TPE has declined significantly with technological advancements, procedure-related complications still occur in approximately 4–6% of procedures. Common adverse events include hypotension, hypocalcemia, allergic reactions, fever, nausea, vomiting, paresthesia, and vascular access-related complications. The contribution of replacement fluid type to these adverse events remains a clinically important consideration, particularly in resource-limited settings where standardized protocols may vary [11,13]. The present study aims to evaluate and compare the safety profile of 5% albumin versus fresh frozen plasma as replacement fluids during therapeutic plasma exchange in patients with Guillain-Barré syndrome.

OBJECTIVES

The objective of this study was to compare the safety profile of 5% albumin and fresh frozen plasma as replacement fluids during therapeutic plasma exchange in patients with Guillain-Barré syndrome.

METHODS & MATERIALS

The comparative cross-sectional study was conducted in the Department of Transfusion Medicine, Bangabandhu Sheikh Mujib Medical University, and the Department of Transfusion Medicine, National Institute of Neuroscience and Hospital, Dhaka, Bangladesh. The study was carried out over twelve months from October 2021 to September 2022.

Sample Selection

Inclusion criteria

- Age between 18 and 65 years
- Both male and female patients
- Diagnosis of Guillain-Barré syndrome confirmed by nerve conduction study

Exclusion criteria

- Age below 18 years or above 65 years
- Prior treatment with intravenous immunoglobulin (IVIG)
- History of severe allergic reactions to blood or blood products
- Ongoing immunosuppressive therapy

Data Collection Procedure

A total of 20 patients were initially enrolled, of whom 18 completed the study protocol and were included in the final analysis. Participants were allocated into two groups based on the order of enrollment into the TPE procedure. Patients with odd serial numbers received 5% albumin as the replacement fluid, while those with even serial numbers received fresh frozen plasma. Accordingly, patients were divided into Group I (FFP) and Group II (5% albumin). Therapeutic plasma exchange was performed using a Haemonetics MCS+ intermittent flow cell separator (Haemonetics Corporation, Braintree, Massachusetts, USA), which employs a single venous access with a closed apheresis system. All procedures were conducted strictly according to the standard operating procedures of the Transfusion Medicine Departments of both centers.

The plasma volume exchanged during each session ranged from 1.0 to 1.5 times the calculated plasma volume, approximately 45 mL/kg body weight. Acid citrate dextrose solution A (ACD-A) was used as the anticoagulant according to session requirements. To prevent citrate-induced hypocalcemia, calcium gluconate (10%, 10 mL) was administered prophylactically at a rate of one ampoule for every 1000 mL of plasma exchanged. Each patient underwent between one and five sessions of therapeutic plasma exchange based on clinical indication, and for the purpose of analysis, each session was considered as a single observational unit.

Fresh frozen plasma used during the procedures was screened for hepatitis B virus, hepatitis C virus, human immunodeficiency virus, malaria, and syphilis and selected according to standard donor eligibility criteria. Five percent albumin was administered according to institutional protocol. Baseline data including age, gender, education level, monthly income, and blood group were recorded prior to the procedure. Vital signs, including pulse and blood pressure, serum calcium levels, and previous history of allergic reactions were documented before initiation of each session and monitored throughout the procedure.

The primary outcome measures were procedure-related adverse events, which included fever, allergic reactions such as itching, rash, or urticaria, hypotension defined as systolic blood pressure below 90 mmHg, and symptomatic hypocalcemia manifested by perioral or digital paresthesia, nausea, or vomiting. These events were recorded separately for each group during every therapeutic plasma exchange session with the assistance of clinicians, nurses, and apheresis technologists.

Participants or their legal guardians provided written informed consent prior to enrollment. They were informed about the purpose of the study, the voluntary nature of participation, and the confidentiality of their data, which were used solely for research purposes without personal identifiers. Sociodemographic information was collected using a semi-structured questionnaire through face-to-face interviews, and for illiterate participants, relevant information was obtained from medical records. Additional clinical and procedural data were collected through direct observation during the therapeutic plasma exchange sessions.

Ethical Considerations

Ethical approval was obtained from the Ethical Review Committee of Bangabandhu Sheikh Mujib Medical University and National institute of neuroscience and hospital. Informed consent was taken from patients or their legal guardians before enrollment. Confidentiality of patient information was strictly maintained and data were used solely for research purposes.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, version 22. Quantitative variables were expressed as mean ± standard deviation and compared using the unpaired t-test, while qualitative variables were presented as frequencies and percentages and analyzed using the Chi-square test. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table I shows the distribution of the study population according to demographic characteristics. It was observed that more than half (55.6%) of patients belonged to age was ≤30 years in Albumin and 6(66.7%) in FFP. The mean age was 35.4±14.44 years in Albumin and 27.33±9.55 years in FFP. More than two third (66.7%) of patients were female in both groups. More than two third (66.7%) of patients came from rural area in

Albumin and 4(44.4%) in FFP. More than two third (77.8%) of patients were educated in Albumin and 8(88.9%) in FFP. Majority (88.9%) of patients came from lower income family in Albumin and 6 (66.7%) in FFP. The differences of demographic characteristics were not statistically significant (p>0.05) between Albumin and FFP.

Table I
Distribution of the study population according to demographic characteristics (*n*=18)

Characteristics		Albumin (n=9)		FFP (n=9)		P-value
		n	%	n	%	
Age in year	≤30	5	55.6	6		[a]0.181[ns]
	>30	4	44.4	3		
	Mean ± SD	35.4±14.44		27.33±9.55		
	Range (min-max)	18-55				
Gender	Male	6	66.7	6	66.7	[b]1.00[ns]
	Female	3	33.3	3	33.3	
Residence	Urban	6	66.7	4	44.4	[b]0.342[ns]
	Rural	3	33.3	5	55.6	
Education	Illiterate	2	22.2	1	11.1	[b]0.527[ns]
	Educated	7	77.8	8	88.9	
Monthly income	Low income	8	88.9	6	66.7	[b]0.256[ns]
	High income	1	11.1	3	33.3	

ns= not significant; [a]p value reached from Unpaired-t test; [b]p value reached from Chi-square test

Table II shows the distribution of the study population according to anthropometric characteristics. The mean height was 160.33±7.23 cm in Albumin and 157.33±12.53 cm in FFP. The mean height was 59±12.37 kg in Albumin and 58.22±13.37 kg in FFP. The mean body surface area (B.S.A) was 1.61±0.2 m^2 in Albumin and 1.59±0.24 m^2 in FFP. The differences of anthropometric characteristics were not statistically significant (p>0.05) between Albumin and FFP.

Table II
Distribution of the study population according to anthropometric characteristics (*n*=18)

Anthropometric characteristics	Albumin (n=9)	FFP (n=9)	P-value
	Mean±SD	Mean±SD	
Height (cm)	160.33±7.23	157.33±12.53	0.542[ns]
Weight (kg)	59±12.37	58.22±13.37	0.899[ns]
Body Surface Area (B.S.A) m^2	1.61±0.2	1.59±0.24	0.850[ns]

ns= not significant; [a]p value reached from Unpaired-t test

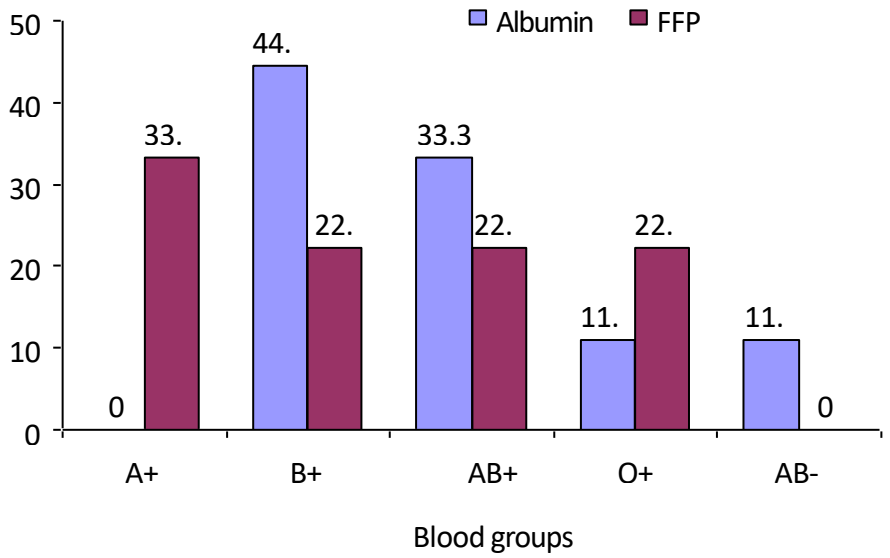

Figure 1 Bar diagram shows the blood groups of study population

Figure 1 shows the distribution of ABO blood groups among the study population. In the Albumin group, the most common blood group was A (44.4%), followed by B (33.3%), while AB and O were each 11.1%. In the FFP group, blood group O was most common (33.3%), followed by A, B, and AB (22.2% each). Overall, the blood group distribution was relatively comparable between the two groups.

Table III shows Types of fluid with complications. Fever had found 1(2.2%) session in albumin and 4(8.9%) sessions in FFP. One (2.2%) of session had allergic reaction in albumin and 3(6.7%) sessions in FFP. One (2.2%) of session had hypotension in albumin and 5(11.1%) sessions in FFP. Two (4.4%) of sessions had symptomatic hypocalcemia in albumin and 5(11.1%) sessions in FFP. The differences of complications were not statistically significant (p>0.05) between albumin and FFP.

Table III
Types of fluid with complications (Total sessions = 90)

Complications		Albumin (n = 45 sessions)		FFP (n = 45 sessions)		P-value
		n	%	n	%	
Fever	Present	5	55.6	6		[a]0.181[ns]
	Absent	4	44.4	3		
Allergic reaction	Present	6	66.7	6	66.7	[b]1.00[ns]
	Absent	3	33.3	3	33.3	
Hypotension	Present	6	66.7	4	44.4	[b]0.342[ns]
	Absent	3	33.3	5	55.6	
Symptomatic hypocalcemia	Present	2	22.2	1	11.1	[b]0.527[ns]
	Absent	7	77.8	8	88.9	

ns= not significant; p value reached from Fisher's exact test

DISCUSSION

This comparative cross-sectional study was conducted to evaluate and compare the frequency of immediate procedure-related complications during therapeutic plasma exchange (TPE) using 5% albumin and fresh frozen plasma (FFP) as replacement fluids in patients with Guillain-Barré syndrome (GBS). A total of 18 patients were included, equally divided into two groups, and 90 TPE sessions were analyzed to assess safety outcomes. The baseline demographic and anthropometric characteristics were comparable between the two groups. In the present study, more than half of the patients in both groups were aged ≤30 years, with mean ages of 35.4 ± 14.44 years in the albumin group and 27.33 ± 9.55 years in the FFP group. Although some studies have reported a higher mean age among GBS patients (Gashti et al., 2018; Rahmanian et al., 2018) [14,15], the age distribution in the current study reflects the variability of GBS across age groups. Guillain-Barré syndrome can occur at any age, although the risk increases with advancing age (van Doorn et al., 2008) [6]. In contrast to the established male predominance described in the literature, the present study observed a female predominance in both groups; however, this difference was not statistically significant and may be attributed to the small sample size. Sociodemographic variables, including residence, education, and monthly income, were also similar between groups, indicating homogeneity and reducing the likelihood of confounding due to baseline imbalance. Anthropometric parameters such as height, weight, and body surface area did not differ significantly between the two groups, supporting comparability prior to intervention. The primary objective of the study was to evaluate immediate complications associated with different replacement fluids during TPE. A total of 90 TPE sessions were analyzed (45 sessions per group), and complications were assessed per session. Overall, complications were numerically more frequent in the FFP group compared to the albumin group, although these differences did not reach statistical significance. Fever occurred in 2.2% of sessions in the albumin group compared to 8.9% in the FFP group. Allergic reactions were observed in 2.2% of albumin sessions and 6.7% of FFP sessions. Hypotension developed in 2.2% of albumin sessions compared to 11.1% of FFP sessions. Similarly, symptomatic hypocalcemia occurred in 4.4% of albumin sessions and 11.1% of FFP sessions. Although none of these differences were statistically significant, the trend consistently favored 5% albumin in terms of lower complication frequency. These findings are consistent with previously published literature indicating that FFP is associated with a higher incidence of allergic and transfusion-related reactions. Stoian et al. (2021) reported that allergic reactions such as chills, fever, rash, and hypotension are more common when plasma is used as replacement fluid [16]. Basic-Jukic et al. (2005) also documented a significantly higher incidence of allergic reactions among patients receiving FFP [17]. Liumbruno et al. (2009) highlighted that FFP carries risks of transfusion-related acute lung injury, circulatory overload, febrile reactions, and infectious transmission [18]. In contrast, albumin replacement is generally associated with fewer immunologic complications, although mild reactions may still occur (Roy et al., 2015) [19]. Hypocalcemia is a known complication of TPE due to citrate anticoagulation, which binds ionized calcium. Song et al. (2004) reported hypocalcemia as the most frequent complication during plasma exchange procedures. In the present study, prophylactic calcium supplementation was administered routinely, which may explain the relatively low frequency of symptomatic hypocalcemia in both groups [20].

Hypotension is another recognized complication of TPE and may result from rapid plasma removal or fluid shifts. McLeod et al. (2010) described hypotension as a common adverse event related to both the procedure and replacement fluid [21]. Although hypotension was more frequent in the FFP group in the current study, the difference was not statistically significant. Importantly, the absence of statistically significant differences between groups may be attributed to the small sample size and relatively low event rates. Nevertheless, the consistent numerical trend toward higher complication rates with FFP suggests that 5% albumin may offer a comparatively safer profile in terms of immediate procedural tolerance. Overall, both replacement fluids demonstrated acceptable safety profiles during therapeutic plasma exchange in patients with Guillain-Barré syndrome. However, the observed trend toward fewer complications with 5% albumin supports its consideration as a preferred replacement fluid when clinically appropriate, particularly in settings where minimizing transfusion-related reactions is desirable.

CONCLUSION

Therapeutic plasma exchange is a safe and well-tolerated treatment modality for patients with Guillain-Barré syndrome. In this comparative study evaluating the safety profile of 5% albumin and fresh frozen plasma as replacement fluids during therapeutic plasma exchange, procedure-related complications such as fever, allergic reactions, hypotension, and symptomatic hypocalcemia were observed in both groups. Although these adverse events occurred more frequently in the FFP group, the differences were not statistically significant.

Overall, both 5% albumin and fresh frozen plasma demonstrated acceptable safety profiles. However, the consistent trend toward a lower frequency of complications in the albumin group suggests that 5% albumin may be a comparatively safer and better-tolerated replacement fluid during therapeutic plasma exchange in patients with Guillain-Barré syndrome. Larger studies are recommended to further validate these findings and establish definitive clinical recommendations.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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