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Original Research Article

Evaluation of fluid-related adverse events during therapeutic plasma exchange in Guillain-Barré syndrome

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ABSTRACT

Background: Therapeutic plasma exchange (TPE) is used to treat moderate to severe Guillain-Barré syndrome (GBS), but it can cause fluid-related adverse events influenced by the type of replacement fluid, such as FFP or 5% albumin. Objectives were to evaluate and compare the frequency and severity of fluid-related adverse events during TPE in GBS patients receiving FFP or 5% albumin.
Methods: This cross-sectional study was conducted at BSMMU and NINS, Dhaka, from October 2021 to September 2022. Eighteen confirmed GBS patients undergoing TPE were equally divided into fresh frozen plasma (FFP) (n=9) and 5% albumin (n=9) groups, and 90 sessions were analyzed. Fluid-related adverse events were recorded and analyzed using SPSS version 22, with $p<0.05$ considered significant.
Results: A total of 22 adverse events were recorded (24.4% of sessions). Hypocalcemia was the most frequent complication (7.8%), followed by hypotension (6.7%), fever (5.6%), and allergic reactions (4.4%). Adverse events were numerically higher in the FFP group compared to the albumin group: fever (8.9% vs 2.2%), allergic reactions (6.7% vs 2.2%), hypotension (11.1% vs 2.2%), and hypocalcemia (11.1% vs 4.4%), though differences were not statistically significant ($p>0.05$). Most events were mild (72.7%), and no severe complications were observed.
Conclusions: Both FFP and 5% albumin were generally safe during TPE in GBS patients, though FFP showed a higher frequency of immediate fluid-related adverse events. Larger multicenter studies are needed to confirm these findings.

Keywords: Guillain-Barré syndrome, Therapeutic plasma exchange, Fresh frozen plasma, 5% albumin, Fluid-related adverse events

INTRODUCTION

Apheresis, derived from the Greek word aphaeresis meaning "a taking away," refers to an extracorporeal procedure in which blood components are separated, a specific constituent is removed, and the remaining components are returned to the individual's circulation. The modern era of apheresis began with the pioneering work of Edwin J. Cohn, who developed large-scale plasma

fractionation techniques during the mid-20th century.[1] His work, initially based on centrifugation methods for albumin purification, significantly improved the safety of plasma-derived products, particularly for injured soldiers, by reducing the risk of transfusion-transmitted infections (Hester). Subsequently, technological advances in the 1960s and 1970s, including continuous-flow cell separators and membrane-based plasma filters, enabled the development of TPE as a clinical modality.[2] Over time, refinements in plasma separation techniques have markedly reduced procedure-related morbidity.

TPE is performed either to collect specific blood components from donors or, more commonly in clinical practice, to remove pathogenic substances such as autoantibodies, immune complexes, or toxins from patients. TPE has become an established treatment option for several immune-mediated and neurological disorders, including GBS, Myasthenia gravis, chronic inflammatory demyelinating polyradiculoneuropathy, thyrotoxicosis, and acute liver failure (Padmanabhan et al).[3] Among these, GBS remains one of the most common indications for TPE in neurological practice.

GBS is an acute, immune-mediated polyradiculoneuropathy characterized by rapidly progressive, symmetrical limb weakness and diminished or absent deep tendon reflexes.[4] The most frequent subtype, acute inflammatory demyelinating polyradiculoneuropathy (AIDP), accounts for approximately 90% of cases in Western countries. Other recognized variants include acute motor axonal neuropathy (AMAN), acute motor-sensory axonal neuropathy (AMSAN), Miller Fisher syndrome, and acute autonomic neuropathy. Clinical progression typically occurs over 12 hours to 28 days, often reaching nadir within two to four weeks. Approximately 25% of patients develop respiratory failure requiring mechanical ventilation, and autonomic instability may result in life-threatening fluctuations in blood pressure and cardiac rhythm. Although many patients experience spontaneous recovery, up to 20% have persistent neurological deficits at one year, and mortality ranges from 3% to 5%.[6]

The pathogenesis of GBS is believed to involve molecular mimicry, in which antecedent infections trigger an aberrant autoimmune response directed against peripheral nerve components. Infection with *Campylobacter jejuni* is strongly associated with certain axonal variants, and outbreaks of Zika virus infection have also been linked with increased GBS incidence. Autoantibodies against gangliosides such as GM1 and GD1a are particularly implicated in AMAN and Miller Fisher syndrome subtypes. Given this immune-mediated mechanism, therapies targeting circulating antibodies-namely intravenous immunoglobulin (IVIG) and TPE-have become the cornerstone of treatment in moderately to severely affected patients.[7]

TPE exerts its therapeutic effect by removing circulating pathogenic antibodies, complement components, and inflammatory mediators. Evidence suggests that TPE is beneficial when initiated within the first seven days of symptom onset and is effective in both mildly and severely affected patients. Despite its clinical efficacy, TPE is not without risks. Although advancements in equipment and procedural protocols have substantially reduced complications over the past decade, immediate adverse events still occur in approximately 4-6% of procedures. Common complications include paresthesia, hypotension, hypocalcemia, allergic reactions, fever, shivering, nausea, vomiting, and vascular access problems.[8,9]

An important determinant of these complications is the type of replacement fluid used during TPE. Various fluids have been utilized, including 5% albumin, FFP, albumin combined with dextran 40, hydroxyethyl starch, or modified gelatin solutions. However, 5% albumin and FFP remain the most frequently used replacement fluids in many countries, including ours. While albumin is associated with fewer allergic and febrile reactions, FFP provides coagulation factors and may be preferred in specific clinical contexts. Differences in electrolyte composition, oncotic pressure, and immunogenic potential between these fluids may influence the incidence and severity of immediate adverse events.[10]

Given the increasing use of TPE in GBS and the potential impact of replacement fluid choice on patient safety, systematic evaluation of fluid-related adverse events is essential.

Therefore, this study aims to evaluate and compare fluid-related adverse events during TPE in patients with GBS, with particular emphasis on commonly used replacement fluids.

Objectives

The main objective was to evaluate the pattern, frequency, and severity of fluid-related adverse events occurring during therapeutic plasma exchange in patients with GBS.

METHODS

The 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.

Inclusion criteria

Patients diagnosed clinically and electrophysiologically with GBS, patients aged ≥18 years, patients who received TPE and patients who provided informed written consent (or consent from guardian where applicable) were included in the study.

Exclusion criteria

Patients with pre-existing severe cardiac, renal, or hepatic failure, patients with active systemic infection unrelated to GBS, patients with known hypersensitivity to plasma products or albumin and patients who did not complete at least one full TPE session were excluded from the study.

A total of 18 clinically and electrophysiologically confirmed cases of GBS who required TPE were enrolled purposively during the study period. These patients underwent a total of 90 TPE sessions. The participants were equally divided into two groups based on the type of replacement fluid used during the procedure. Group A received FFP as the replacement fluid, while group B received 5% albumin. Each group consisted of 9 patients, and 45 TPE sessions were analyzed in each group. TPE was performed using an automated apheresis machine according to standard institutional protocol. The volume of plasma exchanged per session was calculated based on body weight and hematocrit, generally targeting 1 to 1.5 plasma volumes per session. Acid citrate dextrose (ACD-A) was used as the anticoagulant. Each patient underwent multiple sessions, typically four to six, on alternate days depending on clinical condition and neurologist recommendation. Data were collected using a structured data collection sheet. Baseline demographic and clinical variables, including age, sex, body weight, and disease severity, were recorded. During each session, vital parameters such as blood pressure, pulse rate, respiratory rate, and oxygen saturation were monitored before, during, and after the procedure. Fluid-related adverse events including fever, allergic reactions (rash, urticaria, pruritus), hypotension, symptomatic hypocalcemia (perioral numbness, tingling, tetany), nausea, vomiting, and dyspnea were documented. Adverse events were categorized according to clinical severity and need for intervention. 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

All data were recorded systematically in preformed data collection form and quantitative data was expressed as mean and standard deviation and qualitative data was expressed as frequency distribution and percentage. Statistical analysis was carried out by using Statistical analysis was done by using SPSS (Statistical Package for Social Science) Version 22. A p-value of less than 0.05 was considered statistically significant. Confidentially was strictly maintained.

RESULTS

Table 1 shows the distribution of the study population according to demographic characteristics. The mean age was 35.4±14.44 years in the Albumin group and 27.33±9.55 years in the FFP group. In both groups, 6 (66.7%) patients were male and 3 (33.3%) were female. Regarding residence, 6 (66.7%) patients in the Albumin group and 4 (44.4%) in the FFP group were from urban areas, while 3 (33.3%) and 5 (55.6%) respectively were from rural areas. Most patients were educated, comprising 7 (77.8%) in the Albumin group and 8 (88.9%) in the FFP group. The majority of participants belonged to the low-income category, 8 (88.9%) in the albumin group and 6 (66.7%) in the FFP group. No statistically significant differences were observed between the two groups in terms of demographic characteristics (p>0.05).

Table 1: 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)	**Mean±SD**	35.4±14.44		27.33±9.55		[a]0.181[ns]
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 and [b]p value reached from Chi-square test

Table 2: Distribution of TPE sessions, (n=90).

Groups	N	Total sessions	Mean sessions
Albumin	9	45	5
FFP	9	45	5

Table 2 presents the distribution of TPE sessions in both groups. A total of 18 patients were included in the study, with 9 patients in each group. Each group underwent 45 TPE sessions, resulting in a total of ninety sessions. The mean number of sessions per patient was five in the both groups.

Table 3: Overall frequency of fluid-related adverse events (n=90 sessions).

Adverse event	N	Percentage (%)
Fever	5	5.6
Allergic reaction	4	4.4
Hypotension	6	6.7
Symptomatic hypocalcemia	7	7.8
Total adverse events	22	24.4

Table 3 demonstrates the overall frequency of fluid-related adverse events during the 90 TPE sessions. Fever occurred in 5 sessions (5.6%), allergic reaction in 4 sessions (4.4%), hypotension in 6 sessions (6.7%), and symptomatic hypocalcemia in 7 sessions (7.8%). In total, 22 adverse events were recorded, accounting for 24.4% of all TPE sessions.

Table 4: Comparison of fluid-related adverse events between albumin and FFP (Session-wise).

Complication	Albumin, (n=45)	FFP, (n=45)	P value
Fever	1 (2.2%)	4 (8.9%)	0.152
Allergic reaction	1 (2.2%)	3 (6.7%)	0.249
Hypotension	1 (2.2%)	5 (11.1%)	0.088
Hypocalcemia	2 (4.4%)	5 (11.1%)	0.161

Table 4 compares fluid-related adverse events between the albumin and FFP groups on a session-wise basis. Fever was observed in 1 (2.2%) session in the albumin group and 4 (8.9%) sessions in the FFP group. Allergic reactions occurred in 1 (2.2%) session in the albumin group and 3 (6.7%) sessions in the FFP group. Hypotension was reported in 1 (2.2%) session in the albumin group compared to 5 (11.1%) sessions in the FFP group. Symptomatic hypocalcemia occurred in 2 (4.4%) sessions in the albumin group and 5 (11.1%) sessions in the FFP group. Although the frequency of adverse events was numerically higher in the FFP group, the differences were not statistically significant ($p>0.05$).

Table 5: Severity grading of fluid-related adverse events, (n=22 events).

Severity grade	Albumin, (n=5 events)	FFP, (n=17 events)	Total
Mild	4	12	16 (72.7%)
Moderate	1	5	6 (27.3%)
Severe	0	0	0 (0%)

Table 5 illustrates the severity grading of fluid-related adverse events. Among the 22 recorded adverse events, 16 (72.7%) were mild and 6 (27.3%) were moderate in severity. No severe adverse events were observed in either group. In the Albumin group, 4 events were mild and 1 was moderate. In the FFP group, 12 events were mild and 5 were moderate. This indicates that the majority of complications were mild and manageable, and no life-threatening events occurred during the study period.

DISCUSSION

The present study was conducted to evaluate and compare fluid-related adverse events occurring during TPE in patients with GBS, particularly between FFP and 5% albumin as replacement fluids. A total of 18 patients undergoing TPE at Bangabandhu Sheikh Mujib Medical University (BSMMU) and the National Institute of Neurosciences and Hospital (NINS), Dhaka, were included. The study focused primarily on immediate procedure-related complications and their association with the type of replacement fluid used.

In this study, the mean age of patients was 35.4±14.44 years in the albumin group and 27.33±9.55 years in the FFP group. Although GBS can affect individuals of any age, its incidence increases with advancing age, and males are generally reported to be affected approximately 1.5 times more frequently than females.[4] However, in the present study, 66.7% of patients were male in both groups, showing no sex-based difference between the two arms. O'Brien et al reported that the majority of their patients were ≥40 years of age, whereas Rahmanian et al and Gashti et al documented higher mean ages compared to our population. The relatively younger mean age observed in this study may reflect local demographic patterns or referral characteristics.[11-13] No statistically significant differences were observed between the albumin and FFP groups regarding demographic or anthropometric variables, indicating that both groups were comparable at baseline.

With respect to overall complication frequency, fluid-related adverse events were observed in 24.4% of total TPE sessions. Hypocalcemia was the most frequent adverse event (7.8%), followed by hypotension (6.7%), fever (5.6%), and allergic reactions (4.4%). These findings are consistent with previous reports indicating that citrate-related hypocalcemia and allergic reactions are among the most common complications of TPE.[14] Song et al similarly reported hypocalcemia as the most frequent complication, occurring in 11.1 percent of the procedures, which is comparable to the higher rate observed in the FFP group in this study.[15]

When comparing replacement fluids, adverse events were numerically higher in the FFP group than in the albumin group. Fever occurred in 8.9% of FFP sessions compared to 2.2% with albumin. Allergic reactions were also more frequent with FFP (6.7%) than albumin (2.2%). Hypotension was observed in 11.1% of FFP sessions compared to 2.2% with albumin, and symptomatic hypocalcemia occurred in 11.1% of FFP sessions compared to 4.4% in albumin sessions. Although these differences did not reach statistical significance ($p>0.05$), likely due to small sample size, the trend suggests a higher incidence of complications with FFP.

These findings are supported by previous literature. Liumbruno et al reported that FFP is associated with allergic and anaphylactic reactions, febrile non-hemolytic transfusion reactions, transfusion-related acute lung injury (TRALI), and transfusion-associated circulatory overload.[16] Basic-Jukic et al observed a significantly higher incidence of allergic reactions in patients receiving FFP compared to albumin, with urticaria and hypotension being the most common manifestations.[17] Bell et al and Rock et al reported adverse event rates ranging from 34% to 45% in plasma exchange procedures using plasma products, particularly in thrombotic thrombocytopenic purpura (TTP) patients.[18,19] Reutter et al also documented allergic reactions in 65.8% of patients receiving plasma products, although the rate per plasma unit transfused was lower.[20]

In contrast, albumin is generally considered safer with respect to immunologic reactions, although it is not completely free of risk. Roy et al observed fewer allergic complications with albumin compared to FFP.[21] However, albumin may rarely cause allergic-type reactions due to trace plasma proteins or albumin polymers (Stafford et al).[22] Additionally, the use of angiotensin-converting enzyme inhibitors (ACEIs) prior to apheresis may increase the risk of bradykinin-mediated reactions, and withholding ACEIs before the procedure has been recommended.[23]

Severity grading in the present study demonstrated that 72.7% of adverse events were mild and 27.3% were moderate, with no severe complications observed in either group. This indicates that most fluid-related adverse events were manageable and did not necessitate termination of the procedure. These findings align with O'Brien et al who reported a 26% adverse event rate, most of which were mild and manageable. Similarly, McLeod et al emphasized that most TPE-related complications are transient and related to vascular access, anticoagulation, or replacement fluid.[14]

Overall, the present study demonstrates that while both albumin and FFP are effective replacement fluids during TPE in GBS patients, FFP appears to be associated with a higher frequency of immediate fluid-related adverse events. Although the differences were not statistically significant, likely due to limited sample size, the observed trend supports the consideration of albumin as a relatively safer replacement fluid in terms of immediate complications. Further large-scale studies are warranted to confirm these findings and provide more definitive comparative evidence.

Limitations

This study had a small sample size, which may have limited the ability to detect statistically significant differences between the albumin and FFP groups. Being conducted in two tertiary care centers, the findings may not be generalizable to other settings. Adverse events were analyzed on a session-wise basis without adjusting for repeated sessions in the same patient. Additionally, only immediate fluid-related complications were assessed, and long-term outcomes were not evaluated.

CONCLUSION

The present study evaluated fluid-related adverse events during therapeutic plasma exchange in patients with GBS and compared the safety profile of 5% albumin and FFP as replacement fluids. Although both fluids were generally safe and well tolerated, adverse events were observed more frequently in sessions where FFP was used compared to 5% albumin. The most common complications were symptomatic hypocalcemia and hypotension, followed by fever and allergic reactions.

Most adverse events were mild in severity, and no severe or life-threatening complications were recorded in either group. While the differences between the two replacement fluids were not statistically significant, the trend toward higher complication rates with FFP suggests that 5% albumin may be relatively safer in terms of immediate fluid-related adverse events. Larger, multicenter studies are recommended to confirm these findings and to provide stronger evidence for optimal replacement fluid selection during therapeutic plasma exchange in GBS.

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