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Therapeutic plasma exchange using apheresis: Clinical experience and outcomes in neurological and non-neurological cases at a tertiary care center in western India

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Abstract:

INTRODUCTION: Therapeutic plasma exchange (TPE) is a procedure used to treat various neurological and non-neurological disorders by removing and replacing a patient's plasma to eliminate disease-causing substances. Here, we present our experience using TPE to treat various diseases with an apheresis machine.

AIM: To evaluate the safety and efficacy of TPE as a treatment modality in various patients with neurological and non-neurological diseases admitted in tertiary care center in western India.

METHODOLOGY: A retrospective analysis of 152 TPE procedures was conducted over 3 years (April 2021–April 2024) in a Western Indian tertiary care hospital. The study involved 39 patients aged 7–72 years. Clinical improvement was assessed through relevant investigations before, during, and after TPE procedures.

RESULTS: Thirty-nine patients were studied, with Guillain–Barre Syndrome (GBS) being the most common indication for TPE, followed by acute liver failure (ALF) and myasthenia gravis (MG). Clinical improvement was seen in 76.19% (16/21) of GBS patients, 12.5 (1/8) of ALF, and 100% (5/5) of MG patients. 13/18 (72.22%) patients in the neurological category showed complete recovery even after replacement of 0.5–0.9 plasma volume ($n = 18$). The adverse reaction rate for TPE was 5.92% (9 events in 152 cycles), most common being allergic reactions and paresthesia.

CONCLUSION: TPE is safe and efficient treatment modality for the treatment of neurological and non-neurological diseases. Our experience highlights TPE's safety and efficacy. One group in the neurological category showed improvement even with low-volume exchanges (0.5–0.9 PV). Further research is required to enhance the understanding and use of TPE in patient care.

Keywords:

Acute liver failure, adverse events, Guillain–Barre syndrome, myasthenia gravis, myositis, plasma volume, therapeutic plasma exchange

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Introduction

Therapeutic plasma exchange (TPE), is a procedure in which plasma and its soluble constituents are removed from

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the body in exchange for a replacement fluid (albumin or plasma).^[1] Earliest application of TPE was seen in 1950, treating hyperviscosity syndrome in Waldenström macroglobulinemia.^[2–4] TPE removes harmful blood substances

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such as monoclonal paraproteins and autoantibodies and replaces missing plasma components.^[5] TPE has been used as therapeutic modality in various groups of disorders including neurological and non-neurological systems. The American Society for Apheresis (ASFA) categorizes TPE indications in guidelines on the use of therapeutic apheresis in clinical practice, 9th special issue.^[6] TPE can be performed using centrifugal (apheresis machines) or membrane filtration (renal replacement equipment) technology.^[7]

TPE operates through two primary mechanisms:

1. Removing harmful plasma substances:
Abnormal antibodies (e.g., immunoglobulin G [IgG] in myasthenia gravis [MG] and Guillain-Barré Syndrome [GBS], immunoglobulin M [IgM] in Waldenström macroglobulinemia).
2. Replenishing deficient plasma components:
Example: ADAMTS13 enzyme in thrombotic thrombocytopenic purpura.

In essence, TPE eliminates excess harmful substances or supplements beneficial plasma components. Efficient TPE removal requires substances with high molecular weight, mainly plasma-based rather than in tissues, long half-life, and slow production rate.^[8]

Removal of pathogenic substance by TPE is based on half-life and distribution volume of the substance. The first session removes 65%–70% of intravascular targets, with subsequent sessions less effective due to tissue redistribution. IgG and IgM removal rates differ based on their compartmentalization. ASFA 2023 guidelines recommend exchanging 1.0–1.5 times plasma volume (PV) per session, with frequency varying by disease type and severity.^[6,8]

Complications of TPE include allergic reactions, bleeding disorders, electrolyte imbalances, thrombophlebitis, citrate toxicity causing paresthesia/cramps, hypocalcemia, and hypotension.^[9]

Limited research exists on use of centrifugation-based TPE as treatment modality for various diseases in Western India's population.

Aim and objective

Our study evaluated the use of recently introduced TPE with centrifugation technology at our center, focusing on various aspects of this treatment modality, such as demographic data, indications for TPE, PV replaced, clinical outcome, efficacy, effect on hematological parameters, and complications across various patient groups. The analysis followed the ASFA guidelines.

Methodology

A retrospective study was conducted on 39 patients and 152 TPE cycles in a tertiary care hospital from April 2021 to April 2024 (3 years).

Inclusion criteria

1. Patients who gave consent to undergo TPE
2. Confirmed diagnosis of neurological or non-neurological condition
3. Patient in any age group and weight above 35 kg and hematocrit above 24
4. Hemodynamically stable patients
5. Valid request from clinicians.

Exclusion criteria

1. Hemodynamically unstable vitals
2. Patients receiving another primary therapy for treatment, such as immunoglobulins, steroids, and immunosuppressive therapy.

Therapeutic plasma exchange procedure details

All TPE procedures were performed using Haemonetics MCS+ cell separator after obtaining informed consent and after detailed clinical evaluation of the patient. Procedures were performed bedside in the ward or in the ICU, supervised by specialists, with continuous monitoring of vital signs.

A dual-lumen central venous catheter was placed in the subclavian or internal jugular vein to get venous access. Anticoagulant ACD-A was used at a 1:9–1:14 ratio to whole blood. Draw cycle speed was 60–100 ml/min, return cycle speed was 80–110 ml/min, and PV removed per cycle was 100–150 ml, adjusted for platelet count. 0.5–1.5 PVs were removed per session. Total blood volume (TBV) was calculated using Nadler's formula.^[10] PV was calculated using formula: $PV = TBV \times (1 - \text{Hematocrit})$. The number and frequency of sessions varied based on the disease, treatment response, and clinician's decision.

The replacement fluid used was fresh frozen plasma and 5% albumin. 10 ml of 10% calcium gluconate was administered per 1000 ml of plasma removed to prevent citrate toxicity.

Clinical improvement assessment criteria

GBS, myositis, autoimmune neuropathy, and chronic inflammatory demyelinating polyneuropathy (CIDP): Improvement in muscle power is assessed pre- and post-TPE using Medical Research Council Scale.

MG: Improvement in breathing ability and weaning off ventilatory support. Improvement in dysphagia.

Liver disorder: Decrease in total bilirubin level, improvement in jaundice, and correction in INR.

Complications and adverse reactions were closely monitored during and after the procedure.

Statistical analysis

All information was recorded in a Microsoft Excel data spreadsheet for further analysis. Paired *t*-test was used to assess statistical significance wherever needed.

Results

A total of 152 TPE procedures performed on 39 patients were analyzed.

Among these patients, 26 (66.67%) were male, and 13 (33.33%) were female. The age range of the patients was 7–72 years (average age 54.18 years).

Each patient underwent average of 3.89 TPE procedures during their treatment course.

One to 1.5 PV replacement was attempted in the patients. However, it could be achieved in 13 patients (13/39; 33.33%). Most of the patients (26/39; 66.66%) could not achieve this PV replacement either due to clinical recovery (15/26; 57.69%), clinically ordered by treating physician (8/26; 30.76%) or untimely cessation of procedure due to adverse reactions (3/26; 11.53%).

Patients were categorized into neurological and non-neurological groups. Most TPE procedures – 76.9% (30/39 patients) were performed

on the neurological group, with the remaining 23.1% (9/39 patients) in the non-neurological group [Table 1].

As per the ASFA guidelines of 2023, 30 patients (76.9%) fell under Category I. One patient (2.56%) was categorized as Category II. Five patients (12.82%) were classified as Category III, and two patients (5.12%) were placed in Category IV [Table 2].

In the neurological group of 30 patients undergoing TPE, 21 were diagnosed with GBS, 5 with MG, and 2 with myositis. In addition, there was 1 patient each diagnosed with CIDP and autoimmune neuropathy [Table 1].

Non-neurological group ($n = 9$) consisted of 8 patients with acute liver failure (ALF) secondary to various causes and 1 patient of early allograft dysfunction secondary to liver transplant [Graph 1].

Among 21 GBS patients, 16 fully recovered (R), with muscle power increasing from Grade I/II to Grade V (movement against moderate resistance over full range of motion).

In 5 not recovered (NR) patients, 3 patients showed only partial recovery, with muscle power up to Grade III, and 2 patients showed no improvement. These patients (NR) required additional treatments such as IvIg, rituximab, and methyl prednisolone. TPE was started after more than 25 days from symptom onset in NR patients.

Among 21 GBS patients, 8 had demyelinating neuropathy, 5 had axonal neuropathy, and 5 had mixed (axonal + demyelinating) neuropathy. Complete

Table 1: Category of patients undergoing therapeutic plasma exchange procedures

Diagnosis	Neurological group ($n=30$)					Nonneurological Group ($n=9$)	
	GBS	Myasthenia gravis	Myositis	Autoimmune neuropathy	CIDP	Acute liver failure	EAD in liver transplant
Number of patients	21	5	2	1	1	8	1

CIDP=Chronic inflammatory demyelinating polyneuropathy, GBS=Guillain-Barre syndrome, EAD=Early allograft dysfunction

Table 2: Distribution of therapeutic plasma exchange patients

Clinical condition	ASFA category	Number of patients	Gender	Age, mean (range)	Average TPE sessions ($n=152$)
GBS	I	21	Male - 16 Female - 5	55.1 (28–77)	4.1
MG	I	5	Male - 1 Female - 4	54.4 (36–70)	4.6
Myositis	IV	2	Male - 2	67.5	4.5
Autoimmune neuropathy	II	1	Male - 1	61	5
CIDP	I	1	Male - 1	52	5
ALF	I, III	8	Male - 4 Female - 4	47.3 (7–70)	2.5
EAD in liver transplant	III	1	Male - 1	61	3

CIDP=Chronic inflammatory demyelinating polyneuropathy, GBS=Guillain-Barre syndrome, EAD=Early allograft dysfunction, TPE=Therapeutic plasma exchange, ASFA=American Society for Apheresis, ALF=Acute liver failure, MG=Myasthenia gravis

recovery occurred in 6 of 8 (75%) with demyelinating neuropathy, 2 of 5 (40%) with axonal neuropathy, and all 5 (100%) with mixed neuropathy after prescribed TPE treatment [Table 3].

All 5 MG patients required ventilatory support before TPE. After TPE, 4 patients were fully recovered, weaned off the ventilator, and showed improvement in dysphagia. One patient was weaned off from ventilator and was discharged with BiPAP support for palliative care due to associated lung cancer. Hence, all 5 (100%) patients were considered as recovered from symptoms of myasthenia gravis.

Two Myositis patients and one CIDP patient showed complete improvement. One autoimmune neuropathy patient showed no improvement.

Among 30 neurological patients, 1–1.5 PV could be achieved in 12 patients, and 0.5–0.9 PV could be achieved in 18 patients [Table 4].

In 1–1.5 PV replacement category, 83.33% (10/12) neurological patients got recovered, whereas in 0.5–0.9 PV replacement category, 72.33% (13/18) neurological patients got recovered [Graph 2].

In 8 patients of ALF, only 0.5–0.8 PV replacement could be achieved. Average bilirubin decrease in these patients was 5.52 mg/dl. 7/8 patients of ALF showed no clinical improvement. In 1 post-liver transplant patient, 21.28 mg/dl bilirubin drop was seen after 3 TPE cycles and 1.2 PV replacement.

Overall pattern of clinical improvement in study cases is as shown in Table 5. Platelet count was decreased by 25%,

and hemoglobin was decreased by 0.26 gm% post-TPE. No blood transfusions or electrolyte replacements were needed during or after TPE cycles. The average TPE cycle time was 171 min.

6/39 patients experienced adverse events (9 events in 152 TPE cycles; 5.92%). Adverse events observed as shown in Table 6. No hemodynamic changes occurred during any of the TPE cycles.

9/39 patients (23.07%) received 35 TPE cycles in general ward, completing treatment without major complications.

Discussion

We present a series of 39 cases who underwent 152 TPE procedures at tertiary care hospital in Western

Table 3: Guillain-Barre syndrome variants in the study

	Demyelinating	Axonal	Mixed (demyelinating + axonal)
Number of patients	8	5	5
Recovered patients	6	2	5
Percentage recovery	75	40	100

Table 4: Comparison between recovery rates of neurological patients as per plasma volume replaced

PV	Total neurological patients	Recovered neurological patients	Recovery (%)
1–1.5	12	10	83.33
0.5–0.9	18	13	72.22

$P=0.7915$ (>0.05). No difference between recovery rates in both the categories. PV=Plasma volume

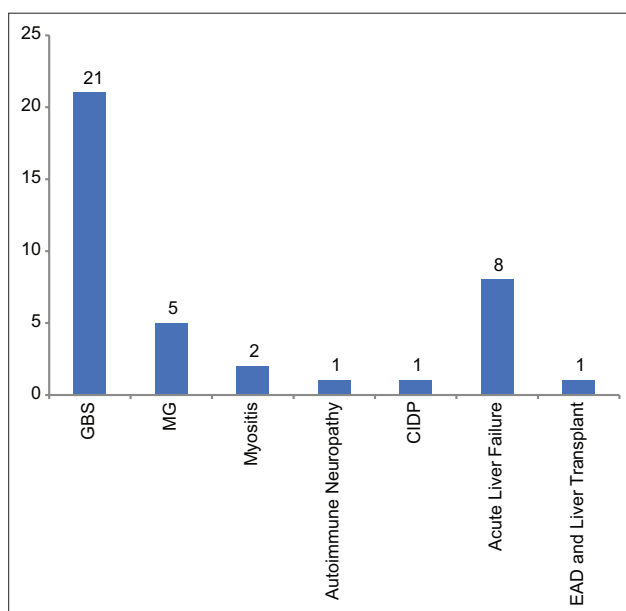
Table 5: Overall pattern of clinical improvement in study cases

Disease	Total patients	Completely recovered	Response rate
GBS	21	16	76.19
MG	5	5	100
Myositis	2	2	100
CIDP	1	1	100
Autoimmune-neuropathy	1	0	0
ALF	8	1	12.5
EAD in liver-transplant	1	1	100

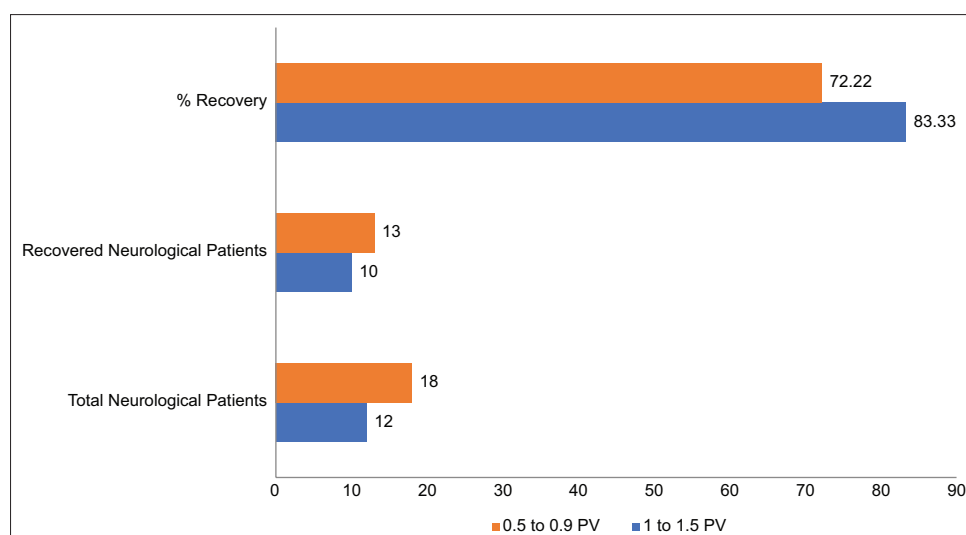
CIDP=Chronic inflammatory demyelinating polyneuropathy, EAD=Early allograft dysfunction, ALF=Acute liver failure, GBS=Guillain-Barre syndrome, MG=Myasthenia gravis

Table 6: Adverse reactions during therapeutic plasma exchange treatment

Nature of adverse events	Number of patients
Allergic	4
Paresthesia	3
Exacerbation of underlying cardiac event	2
Total	9



Graph 1: Patients enrolled in study



Graph 2: Recovery rate as per plasma volume replaced

India using centrifugation technology over period of 3 years for various neurological and non-neurological diseases.

Neurological category

Neurological disorders made up the majority (76.9%) of TPE patients, reflecting TPE's established role in treating immune-mediated neurological conditions.^[8,9,11] GBS was the most common indication (21/30, 70%). GBS is mentioned as category I indication in the ASFA guidelines. TPE is also considered as first-line therapy in GBS in most of the published studies.^[6,9] Most GBS patients (16/21; 76.2%) in our study showed clinical improvement, with increased muscle strength increasing after TPE. These results support previous studies showing TPE's efficacy in GBS, especially when started within 7 days of symptom onset.^[11] Early intervention with TPE is important as 3 of 21 GBS patients who did not respond well had TPE initiated after 25 days from symptom onset.

TPE offers a cost-effective alternative for the treatment of GBS that is as equally effective as immunoglobulin (IVIg). This was emphasized in a study by Hughes involving 383 patients, where treatments included plasma exchange, IVIg, or plasma exchange followed by IVIg. The study showed similar outcomes across all three groups after 4 weeks and during the 48-week follow-up period.^[12] In our study, 16 GBS patients (76.19%) did not require second line of treatment after TPE.

In this study, demyelinating and mixed (demyelinating and axonal) variants of GBS showed complete remission in 75% and 100% of patients, respectively. Bobati and Naik discussed that the axonal variant of GBS demonstrated significant clinical improvement with TPE compared to IVIg.^[13]

TPE was successfully used for MG treatment by Pinching and Peters in 1976 for the first time.^[14] Kumar *et al.* demonstrated TPE's effectiveness in improving short-term outcomes for MG patients in crisis or experiencing exacerbations despite steroids and immunosuppressants.^[15] Gajdos *et al.*, in a meta-analysis, concluded that TPE offers short-term benefits, particularly during myasthenic crises.^[16] In our study, TPE yielded favorable outcomes in all 5 MG patients (successful weaning from ventilatory assistance and improvement in dysphagia).

Two myositis patients and one patient with CIDP showed complete clinical improvement. Le Guern and Guillevin recommended TPE as a preferred treatment for refractory and acute inflammatory myopathies, often in combination with immunosuppression or anti-B-lymphocyte therapy.^[17] The ASFA guidelines from 2023 classify CIDP as a Category I indication for TPE.^[6]

Some neurological patients in our study showed clinical recovery with lower PV replacement (0.5–0.9 PV replacement) or fewer TPE cycles than recommended.

In the group receiving lower plasma volume replacement (0.5–0.9 PV; $n = 18$), neurological recovery was observed in 72.2% of patients (13/18), whereas the higher plasma volume replacement group (1–1.5 PV; $n = 12$) demonstrated a recovery rate of 83.3% (10/12) [Table-4]. The difference between recovery rates in these two groups was not statistically significant ($P = 0.7915$ [>0.05]). Bauer *et al.*'s review of studies from Germany, India, and Bangladesh supports the practice of using 0.4–1 PV in TPE for neurological disorders with good outcomes.^[8] Lower PV exchanges reduce risk of transfusion-transmitted diseases, and it offers a cost-effective therapy in developing countries like India. It also minimizes the

removal of essential primary medications (e.g., rituximab, caplacizumab, antibiotics, anticoagulants, etc.).^[8] In a feasibility study on 20 GBS patients done by Islam *et al.*, the authors concluded that small volume plasma exchange (SVPE) can be considered as a potential alternative low-cost treatment for the patients with GBS in resource-poor settings, and SVPE also helps to prevent central line-associated bloodstream infections.^[18] Our study does not statistically support use of low-volume plasma exchange as a clinically more efficacious treatment option as compared to 1–1.5 PV replacement. However, at $P = 0.7915$ (>0.05), we fail to reject the null hypothesis that response rates in both low volume plasma exchange category and 1–1.5 volume exchange category are same.

It is observed that statistically equal clinical recovery in neurological patients was seen when low-volume plasma exchange was done as compared to 1–1.5 PV exchange. However, a study on a larger sample size is recommended to prove use of low-volume plasma exchange for the treatment of neurological disorders.

Non-neurological category

In 8 ALF patients, 0.4–0.8 PV (low PV) was replaced using TPE. Total bilirubin was reduced by an average of 5.52 mg/dL, and coagulation parameters improved, though overall clinical improvement was modest. One patient with early allograft rejection postliver transplant received 1.2 PV TPE, leading to a 21.28 mg/dL decrease in bilirubin and satisfactory clinical improvement. These results confirm TPE's role in removing albumin-bound and unbound toxins and supporting liver function in ALF. Larsen *et al.*'s randomized trial showed improved transplant-free survival with high volume TPE (HV-TPE) compared to standard therapy.^[19]

Chris-Olaiya *et al.* summarized the benefits of high-volume TPE (HV-TPE) in ALF in their review.^[20] The authors highlighted that at HV-TPE (plasma replacement at 15% of ideal body weight) can remove 90%–98% of toxins from the intravascular space, contributing to its beneficial effects. The authors suggest HV-TPE may be more effective than standard-volume TPE in managing ALF.

Hematological parameters

Platelet count was decreased by 25% and hemoglobin was decreased by 0.26 gm% post-TPE in our study. This did not trigger transfusion of any blood component nor change the course of treatment. Very minimal changes in platelet and hemoglobin levels are seen post-TPE procedures using centrifugation technology in published data.^[21]

Adverse reactions

We observed 9 adverse reactions in 152 cycles (5.92%), with allergic reactions and paresthesia being the

most common. The reactions were resolved with immediate interventions. Importantly, there were no major hemodynamic changes or significant electrolyte imbalances observed during the study period, indicating the overall safety and tolerability of TPE with centrifugation technology in our patient population as compared to other published studies where TPE done by membranous principle triggered severe complications leading to termination of TPE session.^[9,21]

In our study, 9 patients (23.07%) received TPE treatment (total 35 TPE cycles) in general ward and completed the recommended cycles without major adverse events. This highlights the safety of the TPE using centrifugation technology. Fu *et al.* also demonstrated the feasibility of performing TPE (245 procedures in 55 patients) in nonacute setups for neurology patients. They concluded that TPE in semicritical neurology patients in basic nonacute settings was safe with predictable complications, reducing the need for critical care services.^[22]

Key observations and recommendations of our study

1. Early Intervention with TPE in neurological patients can potentiate faster recovery
2. Low volume plasma exchange showed similar outcomes as compared to conventional 1–1.5 PV exchange in the neurological category. A study on a larger sample size is recommended to have better statistical significance
3. High volume plasma exchange is necessary to expect better clinical outcome in liver failure cases
4. The hemoglobin levels and platelet counts were not decreased below the levels which triggered therapeutic transfusions
5. The TPE by centrifugation observed very limited complications, and hemodynamic stability was maintained.

Conclusion

Our study provides valuable insights into the clinical experience and outcomes of TPE using centrifugation technology in a tertiary care setting. The study demonstrated efficacy of TPE in both neurological and non-neurological conditions, with favorable clinical outcomes and a manageable safety profile. Benefits of lesser volume of plasma exchange (<1 PV) shall be evaluated in future as a cost-effective treatment alternative in resource-poor setting where treating neurological cases with 1–1.5 PV exchange is not possible.

Limitations and future directions

Our retrospective study with small sample size limits generalizability. Future research needs larger,

prospective, multicenter studies to validate findings, optimize TPE strategies, and compare with other treatments.

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Conflicts of interest

There are no conflicts of interest.

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