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Therapeutic Plasma Exchange in Neurological Disorders: Experience at Referral Neuroscience Hospital in Bangladesh

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Abstract

Background: Therapeutic Plasma Exchange (TPE) is a very effective modality of treatment for many of the immune-mediated neurological disorders. **Objective:** The aim of study was to evaluate demographics, indications, adverse reactions and outcome of TPE in patients with neurological disorders. **Methodology:** This prospective study was conducted in the Department of Transfusion Medicine at National Institute of Neurosciences and Hospital (NINS), Dhaka from January 2023 to December 2023 for a period of one year. All the available data were systematically recorded and these were variables of demographics, clinical indications, numbers of sessions, volume of exchanged plasma, clinical response and complications during or after the procedure. **Results:** A total number of 110 patients with different neurological disorders had undergone 362 sessions of TPE among which 71 (64.5%) were male. The mean age, number of TPE session and volume of plasma exchange were 33.6±12.3 years (Range 15 to 71), 3.8±1.1 (Range 2 to 7), 2105±320mL (Range 1400 to 3200) respectively. Guillain-Barre Syndrome (GBS) (n=68, 61.8%) was the most common indication of TPE followed by Myasthenia gravis (MG) (n=18, 16.4%). In 362 sessions of TPE, overall incidence of adverse reaction was in 47(12.98%). Allergic reaction (n=15, 4.14%) and hypotension (n=9, 2.48%) were most commonly reported. Reactions were mild and were reversed by bed side managements. **Conclusion:** A variety of neurological disorders require TPE as a treatment option, with Guillain-Barré Syndrome and Myasthenia gravis being the most common cases in our setting. *[Journal of National Institute of Neurosciences Bangladesh, July 2024;10(2):77-82]*

Keywords: Therapeutic plasma exchange; Neurological disorder; Guillain Barre Syndrome; Myasthenia gravis

Introduction

Therapeutic plasma exchange (TPE) is an extracorporeal blood purification technique that reduces the amount of circulating autoantibodies, alloantibodies, immune complexes and monoclonal proteins by centrifugation and replacement of patient's plasma[1]. The fluid volume removed must be replaced to avoid volume depletion. Albumin, saline, or combination of the albumin and saline are used as a substitution fluid[2]. TPE was first employed in 1952 in patients with multiple myeloma to control hyperviscosity. By the 1970s TPE had evolved as a treatment modality in a number of neurological disorders in which autoimmunity plays a major role including myasthenia gravis, Guillain-Barré syndrome (GBS) and chronic inflammatory demyelinating polyneuropathy (CIDP)[3,4].

The most common term is plasmapheresis, which technically means removal of plasma only, for the proper term, "plasma exchange", which technically refers to both removal of plasma and its replacement[5]. In the literature, these terms are used interchangeably. During plasmapheresis, blood is initially taken out of the body

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through a needle or previously implanted catheter[6]. Plasma is then removed from the blood by a cell separator. Three procedures are commonly used to separate the plasma from the blood cells: discontinuous flow centrifugation, continuous flow centrifugation and plasma filtration[7]. After plasma separation, the blood cells are returned to the person undergoing treatment, while the plasma is discarded and the patient receives replacement donor plasma, albumin, or a combination of albumin and saline (usually 70% albumin and 30% saline). An anticoagulant usually citrate is given to the patient during the procedure[7].

A variety of possible mechanisms for the actions of TPE has been proposed, including removal of antibody, alloantibody, immune complexes, monoclonal protein, toxin or cytokine(s), replenishment of a specific plasma factor, and, lastly, the placebo effect[8]. For most neurologic diseases, patient improvement is associated with a drop in antibody titers as a result of TPE. It should be noted that, other mechanisms may exist[9]. Though plasmapheresis is helpful in certain medical conditions, like any other therapy, there are potential risks and complications. Insertion of a rather large intravenous catheter can lead to bleeding, pneumothorax, thrombosis (in case of CV line), and thrombophlebitis[10]. Citrate is infused while the blood is running through the circuit. It is an effective anticoagulant that binds to calcium in the blood. This can lead to life-threateningly hypocalcemia[6]. Other complications include hypotension, potential exposure to blood products, with risk of transfusion reactions or transfusion transmitted diseases, suppression of the patient's immune system, bleeding or hematoma from needle placement.

Neurological disorders encompass a range of conditions that can result in substantial physical, cognitive, and emotional impairments[11]. Some of the most prevalent neurological disorders include autoimmune conditions such as Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), multiple sclerosis, ADEM, autoimmune encephalitis (AIE) as well as neuromuscular disorders like myasthenia gravis[12-13]. The aim of study was to evaluate demographics, indications, adverse reactions and outcome of TPE in patients with neurological disorders.

Methodology

Study Settings and Population: This single centre, single arm prospective cohort study was conducted in the Department of Transfusion Medicine at National Institute of Neurosciences and Hospital (NINS), Dhaka, Bangladesh from January 2023 to December 2023 for a period of one year. All patients who received TPE as a treatment during hospitalization were included in this study.

Study Procedure: All patients were admitted in ward/cabin/HDU/ ICU of NINS. They were brought into Transfusion Medicine department in the morning before starting procedure. Patient with respiratory failure were supported by portable ventilator. After completion of procedure, they were shifted to their respected department

Preparation before Plasmapheresis: At the beginning, following parameters were checked and appropriate steps were taken to correct them like CBC, SGPT, serum creatinine, serum calcium, serum magnesium, serum total protein, serum albumin, serum electrolytes, RBS, ECG, blood grouping and screening and vital parameters. After each session necessary investigations were done like CBC, serum calcium, serum albumin, serum total protein.

Procedure of Plasmapheresis: TPE was performed with 1 to 1.2 volume plasma exchange with continuous flow (Fresenius Kabi/ Optia / Cobe Spectra) machine, with intermittent flow (Haemanetics) machines by using double/try lumen femoral dialysis catheter. TPE was done by alternate day basis for 8 to 10 days. Acid Citrate Dextrose (ACD) is used for anticoagulation. Isotonic saline, fresh frozen plasma (FFP), 5% albumin were used as a replacement fluid. During procedure haemodynamic parameters were closely monitored and adverse reactions were treated accordingly. To avoid citrate toxicity 10 ml of 10% calcium gluconate was used. Before giving FFP, antihistamine injection (pheniramine meliate) was given routinely.

Statistical Analysis: All the available data were systematically recorded and these were variables of demographics, clinical indications, numbers of sessions, volume of exchanged plasma, clinical response and complications during or after the procedure. Quantitative data was expressed as mean and standard deviation and as numbers (%) for categorical data. Statistical analyses of the results were obtained by using window-based computer software devised with Statistical Packages for Social Sciences (SPSS-22).

Ethical Consideration:

Results

A total of 110 patients received plasma exchange during the study period. Among 110 patients. 71(64.5%) were male and 39(35.5%) were female. Age ranging from 15 to 71 years, mean age was 33.6±12.3years. Total 362 sessions of TPE were done in 110 patients. TPE

sessions range from 2 to 7 with a mean of 3.8±1.1 sessions per patient. The volume of plasma exchange ranges from1400 to 3200 ml with a mean of 2105±320mL per patient. (Table 1) Mean time duration of each session was 110±7.2 minutes (range- 90 to 120 minutes) in continuous flow machine and 201±12.2 minutes (range- 180 to 240 minutes) in intermittent flow machine (Table 1).

Table 1: Demographic and Therapeutic Plasma Exchange Characteristics

Characteristics	Values
Mean Age with SD (Years)	33.6±12.3
Gender	
• Male	71(64.5%)
• Female	39(35.5%)
Number of TPE session (mean±SD)	3.8±1.1
Volume of Plasma Exchange in ml (mean±SD)	2105±320
Duration of each session (in minutes)	
• Continuous flow machine (mean±SD)	110± 7.2
• Intermittent flow machine. (mean±SD)	201±12.2

Indications for TPE were different neurological disorders in these 110 patients. Guillain-Barre Syndrome (GBS) (n=68, 61.8%) was the most common indication of TPE followed by Myasthenia gravis (MG) (n=18, 16.4%). (Figure 1) CIDP (n=7, 6.4%) was the third most common indication of TPE. Among the others, we encountered NMO spectrum disorder (n=5, 4.5%), acute disseminated encephalomyelitis (ADEM) (n=4, 3.6%), autoimmune encephalitis (AIE) (n=3, 2.7%). Total 5 (2.5%) cases were non neurological (Figure I).

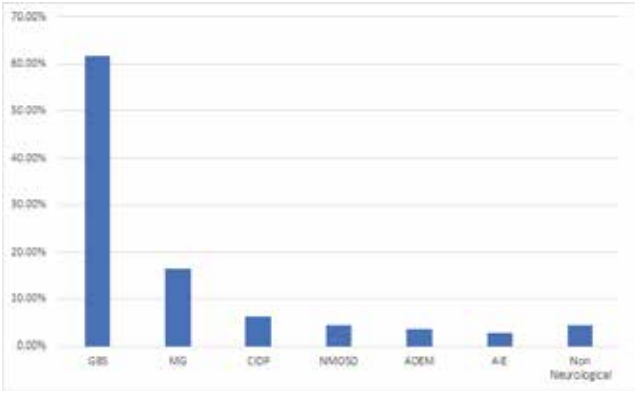

Figure I: Indication of Therapeutic Plasma Exchange (ADEM= Acute disseminated encephalomyelitis, AIE = Autoimmune encephalitis, CIDP= Chronic Inflammatory Demyelinating Polyneuropathy, GBS = Guillain-Barre Syndrome, MG= Myasthenia gravis, NMOSD= NMO spectrum disorder,)

In 362 sessions of TPE, overall incidence of adverse reaction was in 47(12.98%). (Table 2) Allergic reaction was the commonest side effect. Allergy was noticed in 15(4.14%) cases. Hypotension (n=8, 2.48%) was the second most adverse reaction. Pyrexia was reported in 8(2.21%) cases. We encountered 7(1.93%) catheter related problem. Hypocalcemia occurred in 4(1.1%) cases, vasovagal attack in 2(0.54%) cases. 2(0.54%) patients complained of nausea and vomiting (Table 2). Reactions were mild and were reversed by bed side managements. 2(0.54%) patients died; but death was unrelated to TPE. The most common adverse effect was mild allergy (n=15, 4.14%). Allergic reactions were observed despite of giving antihistamine IM routinely prior to the procedure. Itching, rash or urticaria was noticed. All of them needed additional antihistamine. 1 patient received injection hydrocortisone in a single bolus due to severe allergy with urticaria. TPE cycles were completed successfully. Hypotension was defined as fall of mean arterial blood pressure (BP) more than 20 mm Hg from baseline. Whenever hypotension was noticed, procedure was stopped temporarily for a few minutes, injection hydrocortisone 200 mg given IV- and 500-ml normal saline was given IV running. These measures were sufficient to stabilize blood pressure in most cases. In 1 patient, institution of pressor dopamine was needed. TPE cycles were completed after restoring normal blood pressure. During 8(2.21%) procedures, body temperature was increased. Fever subsided after using paracetamol. Despite of giving calcium on routine basis in each procedure, 4(1.1%) cases developed hypocalcemia. Additional injectable 10% calcium gluconate were needed to correct hypocalcemia. Catheter related problem observed in 7(1.93%) patients resulted from complete or partial occlusion of femoral catheter and catheter site infection. Catheter had to be replaced in these cases. Two patients vomited for one episode. Injecton ondansetron IV was given in these 2 patients and they settled down. Patients also reported

Table 2: Adverse reactions following Therapeutic Plasma Exchange

Adverse Effect	Frequency	Percent
Allergic reaction	15	4.1
Hypotension	9	2.5
Pyrexia	8	2.2
Catheter related problem	7	1.9
Hypocalcemia	4	1.1
Vomiting	2	0.5
Vasovagal attack	2	0.5
Total	**47**	**13.0**

symptoms like restlessness, sweating, heart burn, discomfort, parasthesia. Their complaints were mild and subsided spontaneously without any medication. Two patients died but not due to TPE (Table 2).

Discussion

TPE has significantly reduced the morbidity and mortality of patients with various diseases. The low risk to benefit ratio encouraged its use in many different conditions, with mostly excellent therapeutic results[14-15]. Our study provides a crucial information regarding TPE in the management of neurological disorders at our tertiary care hospital in Bangladesh. We observed a diverse array of neurological conditions, with Guillain-Barre syndrome emerging as the most common disorder accounting for 61.8% of the cases.

Several major randomized-controlled trials have shown Therapeutic Plasma Exchange (TPE) as an effective treatment modality in Guillain-Barre Syndrome (GBS) patients[16]. The treatment modality also has a strong level of established effectivity according to the American Academy of Neurology (AAN) and American Society for Apheresis (ASFA) guidelines[17-18]. Our study showed 61.8% of our patients underwent Therapeutic Plasma Exchange for the treatment of Guillain Barre Syndrome while studies at other international centers mention the percentage to be 34.0% and 66.0% cases[19-20].

The effectivity of TPE in patients with CIDP was documented in a randomized double-blind placebo-controlled trial[21-22]. Around two-thirds of patients suffer a relapse after plasma exchange and hence require a maintenance form of plasma exchange or other long-term immune modulatory medications[23]. Our study showed about 6.4% patients underwent plasma exchange therapy for the treatment of Chronic Inflammatory Demyelinating Polyneuropathy while studies at other international centers mentioned the percentage around 4.3 to 11 cases[19].

There are multiple studies mentioning the beneficial effect of Therapeutic Plasma Exchange (TPE) in Myasthenia Gravis patients[24-25]. Some studies label TPE and intravenous immunoglobulin to be equally efficacious, while other studies suggest TPE to be more effective, with significant improvement in respiratory function.[23] Our study revealed that about 16.4% of our patients underwent TPE for the treatment of Myasthenic crisis while studies at other international centers mentioned the percentage around 15.3 to 21 cases[19-20].

ADEM patients presented to us with an altered mental status and encephalopathy which progressed to coma; however, other patients can also present with hemiparesis, quadriparesis, and ataxia as well[26]. We treated the patient initially with intravenous methylprednisolone. Therapeutic Plasma Exchange (TPE) sessions of the patient were started if there was no improvement with steroid. In a case series, some patients with ADEM who did not respond to corticosteroids improved significantly with TPE[27]. Our study showed about 3.6% of our patients underwent TPE for the treatment of Acute Disseminated Encephalomyelitis while studies at other international centers mentioned the percentage around 1.09 and 3.17 cases[19].

Neuromyelitis Optica Spectrum Disorder (NMOSD) patients presented with spinal cord syndrome, brain stem syndrome, optic neuritis. The patients initially received intravenous methylprednisolone, which was followed by Therapeutic Plasma Exchange (TPE) in refractory cases. Studies have shown that early TPE in such patients can yield positive results in terms of recovery[28-30]. Our study revealed that 4.5% of study group comprised of Neuromyelitis Optica Spectrum Disorder (NMOSD) patients, while the same figure in international studies is around 3.17% cases[20].

There is evidence about the usefulness of Therapeutic Plasma Exchange (TPE) in Multiple Sclerosis (MS) patients. There were no patients with Multiple Sclerosis treated within our study. However, it is around 3.17% in international studies[20]. We had 3 patients with autoimmune encephalitis (AIE). The patients were treated with Methylprednisolone initially, which was followed by Therapeutic Plasma Exchange (TPE) in refractory cases. All patients showed some improvement. Our study showed that about 3.4% of our patient group underwent TPE for the treatment of autoimmune encephalitis (AIE), while studies at other international centers mentioned the percentage to be around 2.3% cases[19].

There was no procedure related mortality in our study though several investigators have reported deaths associated with TPE. The incidence of death associated with PE has been estimated to 0.05% cases[31]. The incidence of severe, life-threatening complications was estimated at 0.025 to 4.75% of procedures[32]. In this study, the most common adverse effect was allergy (n=15, 4.14%). It was mild in most cases and severe in 1 case. Allergic reactions were observed despite of giving antihistamine IM routinely prior to the procedure. Itching, rash or urticaria was noticed. All of them needed additional antihistamine. One patient

received injection hydrocortisone in a single bolus. All TPE cycles were completed successfully. Gafoor et al reported 2.2% episode of allergic reaction during TPE in a tertiary care hospital in South India[33].

Hypotension is one of the most common cardiovascular complications of plasma exchange[34]. In this study there was fall in the arterial blood pressure in 9(2.48%) cases. Temporary cessation of the procedure, injection hydrocortisone 200 mg and 500 ml normal saline were sufficient to stabilize blood pressure in 8 cases. In 1 patient, dopamine was needed. The all 4 TPE cycles were completed after restoring normal blood pressure. The usual incidence of TPE related hypotension is 2.6% to 8.1% cases[35].

In this study, pyrexia occurred in 8(2.21%) cases. Fever subsided after using paracetamol. TPE sessions were completed successfully. Catheter related problem was observed in 7(1.93%) patients resulted from complete or partial occlusion of femoral catheter. In all patients, catheter had to be replaced. Gafoor et al reported 7.0% incidence of access related problems during TPE. Due to access problem, 4 to 5% of PE may have to be terminated[36].

Nausea has been reported during as many as 15.0% cases and paresthesia in 9.0% cases of exchanges utilizing concentrated citrate solution such as ACD-A36 solution[36], These symptoms can be partly avoided by adding calcium to the replacement fluids, slowing the infusion of citrated blood, or by using anticoagulant solutions with a lower concentration of citrate[37]. In this study regular parenteral replacement of calcium was responsible for a low incidence of hypocalcemia (n=4, 1.1%). None of the patients experienced severe hypocalcemia with the development of cardiac arrhythmia.

Conclusion

TPE is an effective treatment modality that can be used in the management of many different autoimmune neurological diseases. We observed a diverse array of neurological conditions, with Guillain-Barre syndrome as the most common disorder. TPE is a safe therapeutic procedure with acceptable mild adverse reactions.

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None

Conflict of interest
Other than technical and logistic support from the scientific partner the investigators did not have any conflict of interest in any means.

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Contribution to authors
Hassan MS, Islam MA, Uddin MN conceived and designed the study, analyzed the data, interpreted the results, and wrote up the draft manuscript. Islam S, Fatema K, Sonia SF involved in the manuscript review and editing. Mehrab R, Yusuf A, Ferdous Ara conceived and manuscript writing. All authors read and approved the final manuscript.

Data Availability
Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate
Ethical approval for the study was obtained from the Institutional Review Board. As this was a prospective study the written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

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