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A Comparative Study of Therapeutic Effects of Plasma Exchange and Intravenous Immunoglobulins in Guillain Barre Syndrome

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Abstract

***Background:** Guillain-Barré Syndrome (GBS), a rare but significant cause of acute flaccid paralysis, exhibits diverse clinical presentations ranging from symmetrical limb weakness to cranial nerve involvement and autonomic dysfunction. Therapeutic options include plasma exchange (PE) and intravenous immunoglobulin (IVIg), both shown to improve outcomes. However, limited data exist on the comparative effectiveness and outcomes of these therapies in the Indian population.*

***Materials and Methods:** This retrospective, observational study was conducted at a tertiary care hospital in South Gujarat from July 2020 to February 2023. A total of 100 patients diagnosed with GBS were included, 50 each in the PE and IVIg groups. Data was collected using medical records, with clinical and diagnostic evaluations based on the Brighton Criteria. Outcomes were assessed using the Hughes Disability Scale. Statistical analyses were performed using Epi Info software.*

***Results:** The cohort comprised of 65% males, with a mean age of 31.5 ± 4.1 years in the IVIg group and 36.0 ± 2.8 years in the PE group. Demyelinating neuropathy was the most common subtype (68%). At four weeks post-therapy, the PE group demonstrated significantly better improvement in disability scores (mean 1.31 ± 0.16 versus 2.29 ± 0.27, p = 0.001) and a shorter weaning duration from mechanical ventilation (19.1 ± 3.5 days versus 37.7 ± 5.8 days, p = 0.04). Mortality was significantly lower in the PE group (8% versus 32%, p = 0.003).*

***Conclusion:** PE outperformed IVIg in improving functional outcomes and reducing mortality in GBS patients. These findings underscore the need for evidence-based allocation of resources, particularly in resource-constrained settings.*

***Key words:** Guillain-Barré Syndrome (GBS), Plasma Exchange (PE), Intravenous Immunoglobulin (IVIg), Acute Flaccid Paralysis, Disability Outcomes.*

Introduction

Guillain-Barré Syndrome (GBS) is a leading cause of acute flaccid paralysis, presenting with symmetrical limb weakness and hypo- or areflexia, typically progressing to maximum severity within four weeks[1]. Sensory symptoms, such as paraesthesia and numbness, generally follow a symmetrical distal pattern. The most prevalent subtypes of GBS include acute inflammatory demyelinating polyneuropathy (AIDP) and acute motor axonal neuropathy (AMAN), with Miller Fisher syndrome (MFS), characterised by ophthalmoplegia, ataxia, and areflexia, being a less common variant[2]. The clinical course and outcomes of GBS can vary widely[2].

GBS is a rare condition, with an incidence ranging from 0.81 to 1.89 (median 1.11) per 100,000 person-years. It is more common in men than women (3:2 ratio). Global incidence rates vary, from as low as 0.40 per 100,000 person-years in Brazil to as high as 2.5 per 100,000 person-years in regions like Curaçao and Bangladesh. The disease is less frequent in children (0.34 - 1.34 per 100,000 person-years) and becomes more prevalent with age[2].

In India, there is limited data on the population-level burden of GBS. Small case series indicate GBS as a significant cause of non-poliomyelitis acute flaccid paralysis (AFP), including fatal cases[3]. However, it remains uncertain whether axonal subtypes like AMAN are more common than AIDP, as observed in other developing nations[4].

Clinically, GBS patients often develop cranial nerve involvement, particularly facial or pharyngeal weakness. The characteristic ascending flaccid paralysis evolves over days to weeks. Autonomic dysfunction is common, manifesting as wide blood pressure fluctuations, postural hypotension, and cardiac arrhythmias. Approximately one-third of hospitalised patients require ventilatory support due to respiratory failure and oropharyngeal weakness, making early management critical. Immunologically, GBS involves endoneurial inflammation of spinal nerve roots and distal nerve segments[5].

Antecedent infections, such as upper respiratory tract infections, often precede GBS onset by 10 - 14 days[5].

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Identified triggers include *Campylobacter jejuni* gastroenteritis, cytomegalovirus, *Mycoplasma pneumoniae*, Epstein-Barr virus, and influenza[6]. Diagnosis is supported by cerebrospinal fluid (CSF) analysis and electrodiagnostic testing, although both may appear normal in the early stages. AIDP remains the most prevalent form, accounting for 70 - 90% of cases, with variants like AMAN, acute motor sensory axonal neuropathy (AMSAN), and MFS also observed. Seasonal variations, influenced by infection patterns have been reported, with peaks in summer in Asian countries[7].

Management of GBS involves therapeutic plasma exchange (TPE) and intravenous immunoglobulin (IVIg), both effective when initiated early[8,9]. IVIg is often preferred due to fewer complications but comes with higher costs. Supportive care, including physical therapy, plays an integral role in reducing complications such as respiratory issues, deep vein thrombosis, and delayed mobility[10].

Plasma exchange (PE), proven effective within four weeks of onset, typically involves four sessions (50 mL/kg/session) using fresh frozen plasma or albumin-saline mixtures. IVIg, administered at 0.4 g/kg/day for five days, shows comparable efficacy to PE when given within two weeks of symptom onset[9]. Given the socio-economic constraints of patients in India, particularly those from middle- and lower-income groups, the high cost of treatment poses a significant burden. Prolonged ventilatory support further increases the risk of complications like ventilator-associated pneumonia and sepsis, emphasizing the need for comprehensive ICU management[11].

This study aims to provide insights into the burden, management, and outcomes of GBS, addressing gaps in knowledge to improve clinical and public health strategies.

Material and Methods

Study Setting

The study was conducted at a tertiary care hospital in South Gujarat, affiliated with a government medical college.

Study Design

This was a retrospective, observational study.

Study Population

The study included all confirmed cases of Guillain-Barré Syndrome (GBS) admitted to the Department of General Medicine at the tertiary care hospital.

Inclusion Criteria

- Patients aged >18 years.
- All diagnosed cases of GBS admitted to the tertiary care hospital.

Exclusion Criteria

- Myopathies due to electrolyte imbalance.
- Paralysis resulting from vascular causes.

Sampling Technique

Convenience sampling was used.

Sample Size

The sample size was calculated using OpenEpi software with a 95% confidence interval and 80% power. Based on the mean ICU stay duration reported by Charra B *et al*[12], which was 38.2 ± 7.6 days for the IVIg group and 52.4 ± 5.3 days for the PE group, the minimum required sample size was determined to be 50 patients in each group.

Study Period

The study was conducted from July 2020 to February 2023.

Data Collection

Ethical clearance was obtained from the Institutional Ethics Committee (IEC) before initiating the study. Data were collected retrospectively from patient records using a predesigned proforma. Patients with neurological weakness were evaluated, and treatments with plasma exchange (PE) or intravenous immunoglobulin (IVIg) were assigned. Morbidity and therapeutic outcomes were assessed through clinical, cerebrospinal fluid (CSF), and electrophysiological evaluations. CSF analysis in 60 patients identified albumin-cytological dissociation, while electrophysiological studies distinguished neuropathic subtypes.

Diagnostic Criteria

The Brighton Diagnostic Criteria for Guillain-Barré Syndrome (GBS) was applied, including symmetrical flaccid weakness, decreased reflexes, monophasic onset (12 hours - 28 days), elevated CSF protein, supportive nerve conduction studies, and exclusion of alternative diagnoses.

Outcome Assessment

Patient outcomes were evaluated using the Hughes Disability Scale (0 - 6), ranging from normal function (0) to death (6).

Data Analysis

Data were entered into Microsoft Excel version 2023 (Microsoft Corporation, Redmond, Washington, United

States) and analysed using Epi Info 7.2 software. Descriptive statistics and inferential statistics were appropriately used to summarize the findings.

Ethical Considerations

Ethical clearance was obtained from the IEC, and the study was conducted in accordance with the ethical guidelines. Confidentiality was strictly maintained, and patient information was used solely for study purposes.

Results

The study included 100 participants with Guillain-Barré Syndrome (GBS)

Table I: Age and gender distribution of study participants (N = 100).

Variable	Participants Receiving IVIg Therapy (n=50)	Participants Receiving Palsma Exchange Therapy (n=50)	Total
Age (years)			
18 - 30	18 (36%)	14 (28%)	32
31 - 60	32 (64%)	36 (72%)	68
Mean ± SD	31.5 ± 4.1	36.0 ± 2.8	
Gender			
Male	32 (64%)	33 (66%)	65
Female	18 (36%)	17 (34%)	35

Table I presents the demographic distribution of the study participants. The cohort was divided into two treatment groups: intravenous immunoglobulin (IVIg) therapy (n = 50) and plasma exchange (PE) therapy (n = 50). In terms of age, most participants were aged 31 - 60 years, comprising 68% of the total population. The mean age for the IVIg group was 31.5 ± 4.1 years, while the PE group had a mean age of 36.0 ± 2.8 years. Regarding gender, males predominated in both groups, making up 64% in the IVIg group and 66% in the PE group, resulting in an overall male-to-female ratio of 65:35.

Table II: Clinical presentation, HIV status, and CSF analysis of study participants.

Category	Number	Percentage (%)
Clinical feature (N = 100)		
Acute onset flaccid paralysis	100	100
Hyporeflexia/Areflexia	100	100
Bilateral symmetrical or asymmetrical weakness	100	100
History of fever	50	50
Bowel and bladder involvement	0	0
History of trauma	0	0
Sensory involvement	10	10
History of unknown substance poisoning	2	2
Drug history	0	0
Precipitating event (GIT/Respiratory)	80	80
HIV status (N = 100)		
HIV Positive	10	10
HIV Negative	90	90
Cerebrospinal Fluid (CSF) Analysis (N = 60)		
Albumin-cytological dissociation	22	37
No albumin-cytological dissociation	38	63

Table II summarises the clinical features, HIV status, and cerebrospinal fluid (CSF) analysis of the participants. All 100 participants exhibited acute-onset flaccid paralysis, hyporeflexia/areflexia, and bilateral weakness. Fifty per cent of participants had a history of fever, and 80% experienced a precipitating event, such as gastrointestinal or respiratory infections. Sensory involvement was observed in 10%, while 2% had a history of unknown substance poisoning. No participants reported trauma or bowel/bladder involvement. HIV testing revealed 10% positivity, and CSF analysis performed in 60 participants showed albumin-cytological dissociation in 37%, while 63% lacked this finding.

Table III: Laboratory parameters and Nerve conduction velocity (NCV).

Laboratory Parameters (N = 60)			
Parameter	**Feature**	**Number**	**Percentage (%)**
WBC	Within normal range	17	28
	Leukocytosis	43	72
Serum Protein	Within normal range	49	82
	Hypoproteinaemia	11	18
Nerve Conduction Velocity (NCV) Findings (N = 100)			
Neuropathy Type		**Number**	**Percentage (%)**
Axonal Neuropathy		20	20
Demyelinating Neuropathy		68	68
Mixed Neuropathy		12	12

Table III provides an overview of laboratory parameters and nerve conduction velocity (NCV) findings in the participants. Among the 60 participants assessed, leukocytosis was observed in 72%, and hypoproteinaemia was seen in 18%. NCV findings revealed that 68% of participants had demyelinating neuropathy, 20% had axonal neuropathy, and 12% exhibited mixed neuropathy, indicating a diverse range of neuropathic patterns.

Table IV: Disability grade, mechanical ventilation, and hospitalisation.

Disability Grade (Mean ± SD)				
Time-point	**IVIg (n = 50)**	**Plasma Exchange (PE) (n = 50)**	**P-Value**	**95% CI**
At presentation	4.06 ± 0.11	4.2 ± 0.07	0.23	(-0.17 to -0.10)
Immediate post-therapy	3.27 ± 0.16	3.02 ± 0.09	0.06	(0.22 to 0.28)
After 4 weeks	2.29 ± 0.27	1.31 ± 0.16	0.001	(0.92 to 1.02)
Mechanical Ventilation Requirement (N=100)				
Ventilation Status	**IVIg (n = 50)**	**PE (n = 50)**		**P-Value**
Required	38 (76%)	32 (64%)		0.9
Not Required	12 (24%)	18 (36%)		
Hospitalisation Duration (Days)				
Duration	**IVIg (n = 50)**	**PE (n = 50)**		**P-Value**
1–30 days	13	21		0.22
31–60 days	29	24		
>60 days	8	5		
Weaning from Mechanical Ventilation (Days)				
Treatment	**Mean ± SD**		**P-Value**	**95% CI**
IVIg	37.7 ± 5.8		0.04	(-19.7 to -17.4)
PE	19.1 ± 3.5			

Table IV outlines the disability grade, mechanical ventilation requirements, and hospitalisation duration across the two treatment groups. Disability grades at presentation showed no significant difference between the groups (p = 0.23). However, significant improvement was observed at four weeks post-treatment, with the PE group showing a lower disability grade (mean of 1.31 ± 0.16) compared to the IVIg group (mean of 2.29 ± 0.27, p = 0.001). Mechanical ventilation was required for 76% of IVIg patients and 64% of PE patients, with a significantly shorter weaning duration for the PE group (mean of 19.1 ± 3.5 days versus 37.7 ± 5.8 days for IVIg, p = 0.04). Hospitalisation duration was similar between the two groups (p = 0.22).

Table V: Treatment outcome and mortality.

Outcome of Treatment (N = 100)				
Outcome	**IVIg (n=50)**	**PE (n = 50)**	**P-Value**	
Death	16 (32%)	4 (8%)	0.003	
Treated	34 (68%)	46 (92%)		
Comparative Analysis of Disability Grades				
Timepoint	**IVIg (n = 50)**	**PE (n = 50)**	**P-Value**	**95% CI**
At presentation	4.06 ± 0.11	4.2 ± 0.07	0.23	(-0.17 to -0.10)
Immediate post-therapy	3.27 ± 0.16	3.02 ± 0.09	0.06	(0.22 to 0.28)
After 4 weeks	2.29 ± 0.27	1.31 ± 0.16	0.001	(0.92 to 1.02)

Table V presents the treatment outcomes and mortality rates between the two groups. The mortality rate in the IVIg group was significantly higher (32%) compared to the PE group (8%, p = 0.003). The PE group also had a higher proportion of patients treated successfully (92%) compared to the IVIg group (68%). Additionally, disability grades at different time points indicated a more favourable outcome in the PE group, with significantly lower disability scores at four weeks post-treatment (p = 0.001).

Discussion

This retrospective study analysed 100 confirmed cases of Guillain-Barré Syndrome (GBS) admitted to a tertiary care hospital in South Gujarat, India, from July 2020 to February 2023. The primary objective was to evaluate the therapeutic effects of plasma exchange (PE) and intravenous immunoglobulin (IVIg) in treating GBS. Fifty participants were treated with IVIg and the remaining 50 with PE.

Age Distribution

The mean age of participants in the IVIg group was 31.5 years, and for the PE group, it was 36 years. This difference was not statistically significant. These findings align with studies conducted by Charra *et al*[12], where the mean ages for IVIg and PE groups were 37.4 and 30.7 years.

Gender Ratio

The male-to-female ratio in this study was 1:0.6 in the IVIg group and 1:0.5 in the PE group. These ratios are consistent with findings reported by Sonawale *et al*[11] and Kishore *et al*[13], which reported male-to-female ratios of 1:0.6 for both treatment modalities.

Clinical Presentation

All participants in both groups exhibited acute onset flaccid paralysis, hyporeflexia/areflexia, and bilateral symmetric weakness. Sensory involvement was noted in 10% of cases. Precipitating events, predominantly gastrointestinal and respiratory infections, were reported in 80% of cases. These findings are similar to those of Charra *et al*[12], who observed flaccid paralysis, hyporeflexia/areflexia, and bilateral symmetric weakness in all patients, with sensory involvement in 46% and gastrointestinal or respiratory infections in 51.2%.

Cerebrospinal Fluid Analysis

Albuminocytological dissociation was observed in 37% of participants in this study, compared to 85% reported by Sonawale *et al*[11]. Hypoproteinaemia and leukocytosis were noted in 34% and 63% of participants, respectively.

Disability Grade Improvement

The mean disability grade at presentation was 4.06 in the IVIg group and 4.2 in the PE group, with no statistically significant difference. However, after 4 weeks of therapy, the mean disability grade improved significantly in both groups, with values of 2.29 for IVIg and 1.31 for PE. This indicates that while both treatments are effective, PE showed marginally superior results. These findings are consistent with Kishore *et al*[13] and Leonhard *et al*[14], who reported similar trends in disability grade improvement.

Nerve Conduction Studies

In this study, demyelinating neuropathy was the most common finding on nerve conduction velocity (NCV) studies, observed in 68% of participants, followed by axonal neuropathy (20%) and mixed neuropathy (12%). These findings align with the studies by Rath *et al*[15].

Duration of Mechanical Ventilation Weaning

The mean duration of weaning off mechanical ventilation was significantly longer in the IVIg group (37.7 days) compared to the PE group (19.1 days). This result is similar to the findings of previously done study results by Elahi *et al*[16].

Outcome and Mortality

The mortality rate in this study was significantly higher in the IVIg group (32%) compared to the PE group (8%). This difference is consistent with findings from El-Bayoumi *et al*[17], which reported mortality rates of 18.7% and 14.2% for IVIg and PE groups, respectively, in mechanically ventilated children with GBS.

Limitations

This study being a retrospective study, it relies on previously recorded data, which may introduce information bias and limit the scope of analysis. Additionally, the sample size is relatively small, emphasizing the need for future multicentric studies with larger cohorts to improve generalisability.

Conclusion

The findings of this study reinforce the effectiveness of both IVIg and PE in managing GBS, with PE showing marginally better outcomes in terms of disability grade improvement, shorter mechanical ventilation duration, and lower mortality rates. These results contribute to the growing body of evidence supporting the use of plasma exchange as a preferred therapeutic modality in certain cases of GBS.

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