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Original Research Paper

An observational study of ivig in view of efficay in guillain barre syndrome

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ABSTRACT:
Background[(1)]: Guillain-Barré syndrome is an inflammatory polyradiculoneuropathy characterized by rapidly evolving weakness and areflexia, reaching nadir within 4 weeks. In Guillain-Barré syndrome, the body's immune system attacks part of the peripheral nervous system. This can result in muscle weakness and loss of sensation in both upper and lower limbs. In this condition the immune system produces harmful antibodies that attack the nerves. The most effective treatment for Guillain-Barré syndrome is intravenous immunoglobulin, that is obtained from human plasma that is pooled from 3000-10,000 donors, it is widely used in the treatment of auto-immune neuromuscular diseases. **Methods**: This is a prospective observational research study to find out the efficacy outcomes of the drug intravenous immunoglobulin in guillain barre syndrome. **Results**: Among the patients who were treated with IVIG, 88%, had a good outcome i.e., symptoms are decreased and,10% (21) has poor outcome i.e., some of them symptoms are persistant. Among 50 patients most of the patients i.e., 25 (50%) have shown symptomatic relief on Day 5 least patients 5 (10%) patients on Day7. Among 50 patients, 43 patients have a muscle power >= 4 They constitute 86% of the total patients registered, we also noticed that the predominant treatment that are exhibiting therapeutic achievements were IVIg. **Conclusion**: This study on state of the drug IVIg given in the condition of guillain barre syndrome condition has shown the therapeutic efficacy prominently for 5 consecutive days which is given in parentral route as matter of fact to meet the disease condition and prevent its progression. Most of the patients have shown symptomatic relief on Day 5 of IVIg treatment, majority of the patients have progressed immensely obtaining great results, and the patients have a muscle power >= 4, which shows greater recovery of the patients with IVIg treatment.

Keywords: Guillain-Barré syndrome, IVIg, immunoglobulin

INTRODUCTION:[(2) (3)]

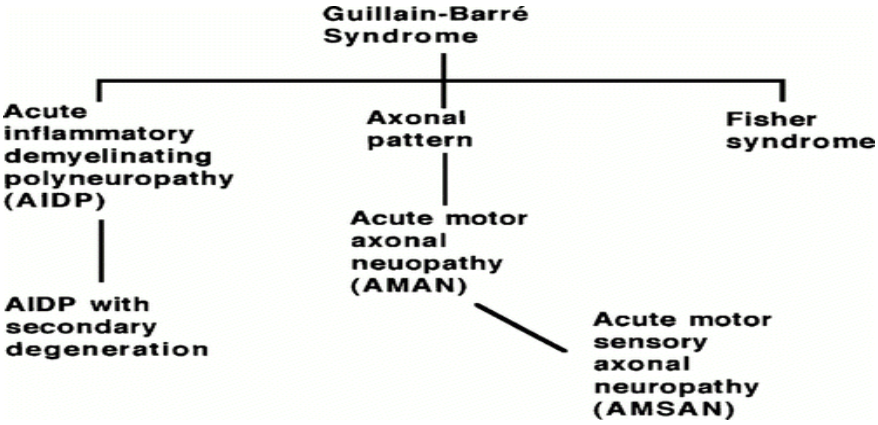
GBS is an inflammatory polyradiculoneuropathy characterized by rapidly evolving weakness and areflexia, reaching nadir within 4 weeks. In Guillain-Barré syndrome, the body's immune system attacks part of the peripheral nervous system. The syndrome can affect the nerves that control muscle movement as well as those that transmit pain, temperature and touch sensations. This can result in muscle weakness and loss of sensation in the legs and/or arms. It is a rare condition, and while it is more common in adults and in males, people of all ages can be affected. Approximately 10-15% of patients with GBS require assistance with long-term residual disability, requiring a prolonged hospital stay and extended time of rehabilitation. Campylobacter jejuni, cytomegalovirus (cmv), mycoplasma pneumonia, epstein-barr virus, and influenza virus are just a few of the several antecedent illnesses that have been identified. Patients are usually able to identify the precise day that their sensory and motor problems are started.

Symptoms:[(4)]

- Symmetrical limb weakness-proximal,distal
- Cranial nerve palsies-iii,vii,ix,xii
- Pain

- Numbness
- abnormal vasomotor tone causing venous pooling and facial flushing

The types are given below:



Pathogenesis:[5][6]

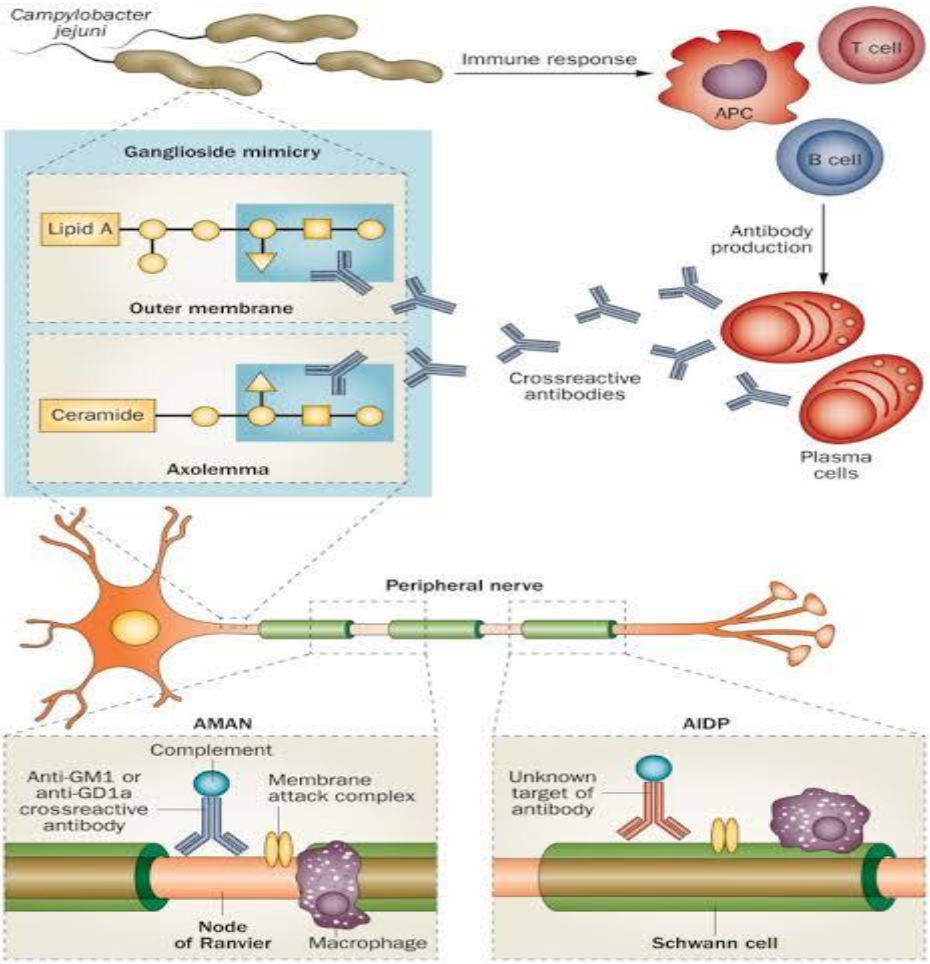


Fig:1 types of GBS

AIDP (acute inflammatory demyelinating polyneuropathy):

There is lymphocytic mononuclear cell infiltration and severe macrophage-associated segmental demyelination at the nerve roots and proximal nerve segments in the acute inflammatory demyelinating polyneuropathy version of GBS (AIDP)the model of GBS that is brought on by a fusion of antibodies to myelin glycolipids and T-cell-mediated immunity to myelin proteins, provides a significant amount of the evidence for disease pathophysiology.

AMAN (acute motor axonal neuropathy):

AMAN is characterised by sparing of the dorsal nerve roots, dorsal root ganglia, and peripheral sensory nerves and a lack of lymphocytic infiltrate. The expansion of the node of Ranvier and complement-mediated macrophage recruitment to the nodal area are the two initial changes. The most proximal nerve terminals may be influenced by axonal degeneration, according to the proposed explanation. Based on the substantial association between C. jejuni infection and AMAN, molecular mimicry is suggested as the pathogenetic mechanism of AMAN. Cross-reacting antibodies come from the lipopolysaccharide capsule of the C. jejuni sharing epitopes with GM1 and GD1a and cause the nerve damage.

AMSAN (acute motor sensory axonal neuropathy):

Initially, these individuals will experience acute widespread weakness. Repeated electrophysiological tests reveal diminished or nonexistent CMAP and SNAP amplitudes, quickly resulting in a total loss of electrical excitability. Patients subsequently displayed a delayed and mediocre recovery. Motor and sensory axons had suffered severe degeneration.The pathophysiology of AMSAN shares similarities with AMAN in terms of the pattern of perinodal space invasion by macrophages. The dorsal and ventral roots are both damaged in AMSAN, which is a differentiation.

Miller fisher syndrome:

Some C. jejuni strains that develop a unique pattern of antibodies to GQ1bganglioside are the origin of the MFS pattern. The antibodies detect epitopes that are only expressed in purkinji cells, dorsal-root ganglion cells, and the nodal areas of oculomotor nerves.Consequently they experience from ataxia, areflexia, and ophthalmoplegia.

the treatment working mode in GBS, during mild condition IVIg is given for 4 weeks and the condition is treated, there by its not resurfaced again. IVIg involves enzymatic treatment, fractionation, and chromatography to remove impurities, and is frequently stabilised with sugars or amino acids to inhibit aggregation. To render hepatitis, retroviruses, and other viral and bacterial dormant.

Risk factors:[7]

- recent history of infection and surgery
- cranial nerve impairement
- alcohol consumption

Diagnosis:[8][9]

- physical examination
- laboratory findings
- nerve conduction studies
- spinal tap
- electromyography(EMG)[10]

Treatment; [12]

Plasma exchange: [9]

Plasmapheresis, or plasma exchange, was the first efficient GBS therapy option (PE). In order to remove immune complexes and potential autoantibodies, centrifugal blood separators are used to split the plasma from the blood. To make up for the lost protein concentration, the plasma is then injected into the reservoir into the subject along with a 5% albumin solution. Compared to plasma exchange, intravenous immunoglobulin is slightly safer and considerably simpler to administer. Intravenous immunoglobulin combined to plasma exchange is not more effective than either alone.

IVIg[11]: Human plasma extracted from 3,000 to 10,000 donors is used to synthesize IVIg. IVIg has a complex mechanism of action that includes modulating Fc receptor expression and function, interfering with complement activation and the cytokine network, generating anti-idiotypic antibodies, and modifying T-cell and B-cell activation, differentiation, and effector functions. Such a wide spectrum of activities reflects the roles played by circulating immunoglobulins in the upkeep of immunological homeostasis and self-tolerance in healthy person.

METHODOLOGY:

Study-place: Department of neurology at Government General Hospital, Guntur,AP
Period of study: 6 months (September – February)
Study-design: Observational Prospective study
Sample size: 50

Inclusion criteria:

1. Age between 15-60 yrs.
2. Both male and female patients with GBS and are receiving IVIg.

Exclusion Criteria:

1. Pregnancy
2. Age below 15yrs

3. Other neurological complications

Study procedure:
This study will be conducted after getting approval from the Institutional Human Ethics committee and informed consent form from patients. The patients will be screened based on Inclusion and Exclusion criteria. Patients who satisfy Inclusion criteria will be included in the study. After including subjects into the study, the data will be collected by using variety of scales namely, Hughes scale for assessing functional status of patients with GBS and Egris scale to predict the risk of respiratory insufficiency for in the designed validated data collection form.

Plan of work PHASE I:
➢ Identification of scope of work
➢ Literature review.
➢ Protocol preparation.
➢ Preparation of patient consent form.
➢ Ethical committee approval.

PHASE II:
➢ Selection of subjects for the study based on inclusion and exclusion criteria.
➢ Taking informed consents.
➢ Collection of demographics

PHASE III:
➢ Follow -up of subjects.
➢ Interpretation and Tabulation of the oriented data

PHASE IV:
➢ Tabulated data will be statistically analyzed using Microsoft excel and Statistics i.e., t-test and ANOVA test
➢ Discussion and conclusion of the study
➢ Submission of dissertation

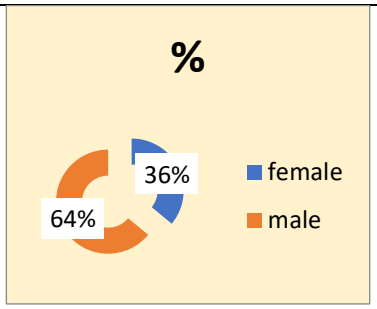
DATA TOOLS USED:
1. Patient consent form
2. Patient data collection form
3. Hughes scale and Egris scale

STATISTICAL ANALYSIS:
At the end of the study, all the data obtained were analyzed by using statistical method mean, standard deviation and ANOVA test, T-test, Chi-square test of the data was calculated and report.

RESULTS:

Graphs:1&2
Table 01: Distribution of subjects based on Gender

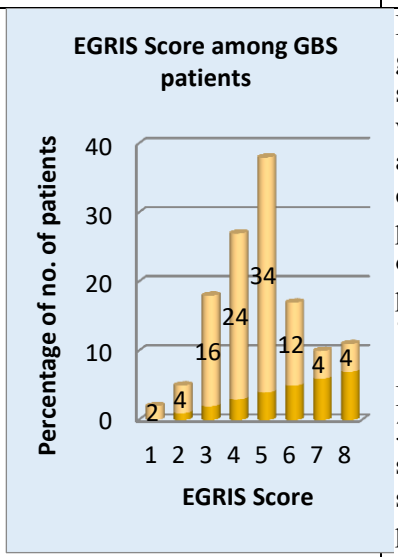
S.no	Gender	No. of patients(n=50)	% of no. of patients (%)
1.	Male	32	64
2.	Female	18	36



patients are divided into two groups i.e., Male and Female and their percentages were calculated. Among 50 patients, 32 (64%) are male patients and 18(36%) are female patients. The least number of patients are Females. This shows Male has predominance.

comparison of egris score among gbs patients

S.no	Egris score	No. of patients (n=50)	% of no.of patients(%)
1.	0	3	6
2.	1	4	8
3.	2	7	14
4.	3	11	22
5.	4	16	32
6.	5	6	12

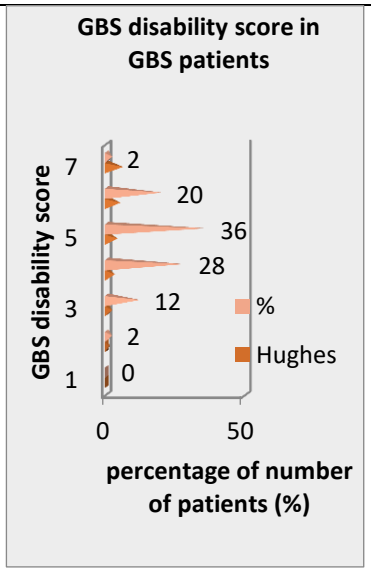


Patients are classified into 8 groups based on EGRIS scores i.e.,disability score with 0, 1, 2, 3, 4, 5, 6, 7 and percentages were calculated. Among 50 patients maximum number of patients i.e., 16 (32%) of patients have Egris score '4'. Least number of patient 1 (2%) have Egris score'6'. Egris score '0' is present in 3 patients (6%), score '1' seen in 4 (8%) of patients , score 2 seen in 7 (14%) patients, score 3 seen in 11 (22%) patients, score '5' seen in 6 (12%) of patients and score 7 seen in 2 (4%)

7.	**6**	**1**	2		of patients.
8.	**7**	**2**	4		

Graphs:3&4
Comparison of GBS disability score among patients

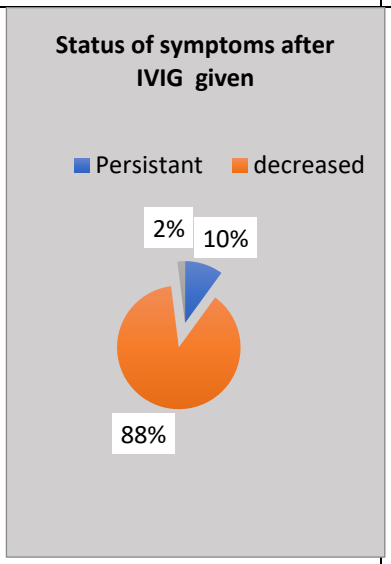
s.no	gbs disability score	No. of patients(n=50)	% of no.of patients(%)
1.	0	0	0
2.	1	1	2
3.	2	6	12
4.	3	14	28
5.	4	18	36
6.	5	9	18
7.	6	2	4



Patients are classified into 7 groups based on GBS disability scores i.e.,disability score with 0, 1, 2, 3, 4, 5, 6 and percentages were calculated. Among 50 patients maximum number of patients i.e., 18 (36%) of patients have GBS disability score '4'. Least number of patient 1 (2%) have GBS disability score '1'. GBS disability score '0' is present in no one. GBS disability score '2' seen in 6 (12%) of patients , GBS disability score '3'seen in 14(28%) patients, score '5'seen in 9 (18%) patients, GBS disability score '6' seen in 2 (4%) of patients.

Comparison of Status of the symptoms after IVIG treatment

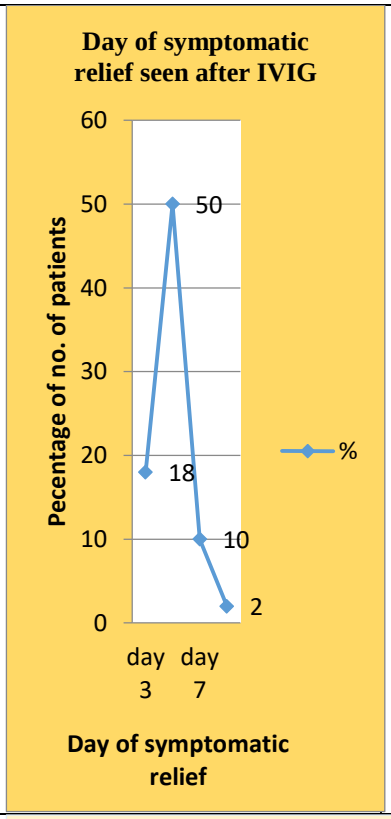
no	symptoms	No. of patients (n=50)	% of no.of patients(%)
1.	Decreased	44	88
2.	Persistent	5	10
3.	Death	1	2



After IVIG treatment, based on the symptoms decreased, persistent , death patients are divided into 3 groups and percentages are calculated. Among 50 patients most of the patients i.e., 44 (88%) symptoms are decreased, only 5 (10%) of patients symptoms are persistent and 1(2%) of the patient is dead.

Graphs:5&6
Comparison of the day on which symptomatic relief seen in GBS patients

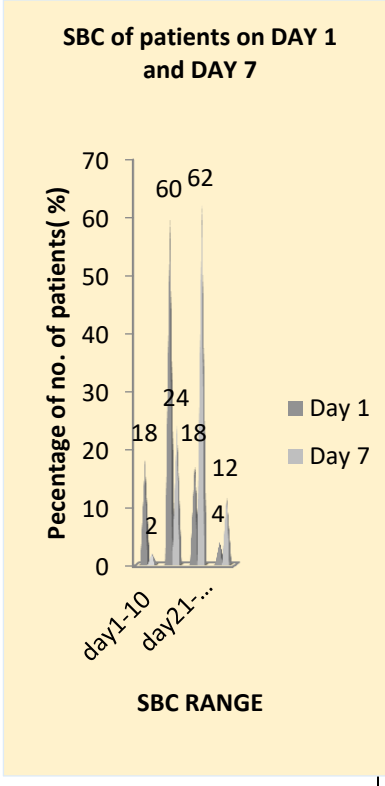
s.no	day of symptomatic relief	No. of patients (n=50)	% of no.of patients(%)
1.	Day 3	19	38
2.	Day 5	25	50
3.	Day 7	5	10
4.	No relief seen	1	2



Patients were divided into four groups based on Day of relief seen after IVIG treatment i.e., on Day 3, Day 5, Day 7 and no relief seen and percentages were calculated. Among 50 patients most of the patients i.e., 25 (50%) have shown symptomatic relief on Day 5 of IVIG treatment , 19 (38%) of patients on Day 3, 5 (10%) patients on Day 7 and 1 patient doesn't show any response.

Comparison of SBC on Day 1 and Day 7

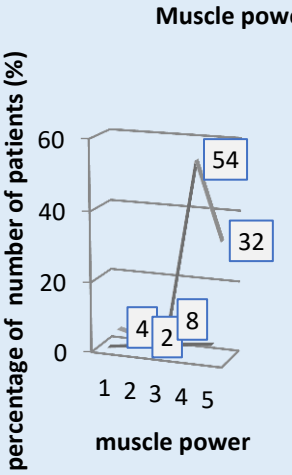
s.no	SBC range	No. of pts on Day 1	%of no. of pts on day 1	No. of pts on Day 7	%of no. of pts on Day 7
1.	0-10	8	16	1	2
2.	11-20	30	60	12	24
3.	21-30	9	18	31	62
4.	31-40	3	6	6	12



In a study population patients were divided into 4 groups according to their SBC range i.e., 0-10, 11-20, 21-30, 31-40 SBC scores were taken on Day 1 and Day 7 and percentages were calculated. Among 50 patients of GBS Single breath count was taken on Day 1 and Day 7.Day 1 results includes 8 (16%) patients had a SBC of 0-10, 30(60%) patients had a SBC of 11-20, 9(18%) patients had a SBC of 21-30 and 3(6%) patients had SBC of 31-40 Day 7 results includes 1(2%)patient has SBC of 0-10, 12 (24%) patients had SBC of 11-20, 31(62%) patients had SBC of 21-30, 6 (12%) patients had SBC of 31-40.

Graph:7
comparison of muscle power among GBS patients

s.no	muscle power	no.of patients (n=50)	%of no.of patient (%)
1.	1	2	4
2.	2	1	2
3.	3	4	8
4.	4	27	54
5.	5	16	32



Patients are classified into 5 groups based on muscle power of patients i.e.,muscle power with 1, 2, 3, 4, 5 and percentages were calculated. Among 50 patients maximum number of patients i.e., 27 (54%) of patients have muscle power '4'. Least number of patient 1 (2%) have muscle power '2'. muscle power '1' seen in 2 (4%) of patients , muscle power '3'seen in 4(8%) patients, score '5'seen in 16 (32%) patients.

DISCUSSION:

Several studies have shown a slight male preponderance for GBS. As our results of graph no]1 occupancy of sex ratio male ratio is greater than female ratio preponderance (64% vs 36%) with a male: female ratio of 2:1 with history of autoimmune diseases and various infections may lead to GBS 43 patients were admitted with admission disability score of ≥ 3 in GBS disability scale. They constituted 86% of the total patients registered. Mean values is 3.5 P(t<=t)0.07013241. patients were admitted with admission EGRIS score of ≥ 4 in EGRIS scale. They constituted 82% of the total patients registered. Mean value is 4 P(t<=t)0.0121367 Among the patients who were treated with IVIG, 88%, had a good outcome i.e., symptoms are decreased and, 10% (21) has poor outcome i.e., some of them symptoms are persistant. Among 50 patients most of the patients Fig no. 18 i.e., 25 (50%) have shown symptomatic relief on Day 5 least patients 5 (10%) patients on Day 7. Mean value is 25 P(t<=t)0.039598. Among 50 patients, 43 patients have a muscle power >= 4 They constitute 86% of the total patients registered. Mean value is 25 P (t<=t)0.398598. Only 1 death are recorded in our study, which constituted 2% of the total admissions.

In our study comparison of SBC on graph no 6 among patients was done between Day 1 and Day 7. most of the patients i.e., 30(60%) patients had a SBC of 11-20, and least patients has 3(6%) patients had SBC of 31-40 on Day 1. Day 7 results includes 31(62%) patients had SBC of 21-30. Increased SBC range was observed in Day 7 when compared to Day 1

CONCLUSION:

This study on state of the drug IVIg given in the condition of Guillain Barre Syndrome condition has shown the therapeutic efficacy prominently it has been given for 5 consecutive days and the effect is shown after the following days, the drug is given in parentral route as matter of fact to meet the disease condition and prevent its progression,of the disease, it is first analyzed in the study and the assess whether the patient require mechanical ventilation or if he is under respiratory distress. There was a raise in SBC on day 7 who has low SBC on day 1. Most of the patients i.e., 25 (50%) have shown symptomatic relief on Day 5 of IVIG treatment, Most of the patients i.e.,88% (44), had a good outcome i.e., symptoms are decreased among 50 of admitted patients. Most of the patients i.e., 43 patients have a muscle power >= 4, which shows greater recovery of the patients with IVIG treatment.

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