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ORIGINAL ARTICLE

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Clinical Use and Adverse Reactions of Intravenous Immunoglobulin in Filipino Patients in a Tertiary Hospital in Baguio City, Philippines

Vernadette A. Landayan, MD and Karol Anne B. Camonayan-Flor, MD, FPCP, DPSAAI

Department of Internal Medicine, Baguio General Hospital and Medical Center, Benguet, Philippines

Correspondence to:
Vernadette A. Landayan, MD
Department of Internal Medicine, Baguio General Hospital and Medical Center
Gov. Pack Rd., Baguio, 2600 Benguet, Philippines
Tel. No.: (074) 442 7933
E-mail: vlandayan.md@gmail.com
ORCiD: https://orcid.org/0009-0001-0210-5119

ABSTRACT

Background: Intravenous immunoglobulin (IVIG) is a pooled antibody, and a biological agent used to manage various diseases including autoimmune, infectious, and inflammatory states. Intravenous immunoglobulin (IVIg) use is growing dramatically internationally due to the increasing numbers of acute and chronic conditions that may benefit from IVIg. It is generally considered a safe therapy, with adverse reactions rarely encountered, occurring in 10-30% of patients. Most of these adverse effects (AEs) associated with IVIg administration are mild and transient.

Methodology: This descriptive study included adult patients who received IVIG from October 1, 2014, to October 31, 2024. Frequencies and percentages were used to describe the clinico-demographic profile of patients, the indications for IVIG infusion, the adverse reactions observed, and the clinical outcome.

Results and Discussion: A total of 131 patients (51 males, 80 females) received IVIG infusions. Twenty-eight percent (n = 37) experienced adverse reactions. The most common indication was Guillain-Barre Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP) (29.7%), followed by Myasthenia Gravis (25%), and Autoimmune Encephalitis (25%) for Autoimmune diseases, and COVID-19 (4.5%), followed by Septic shock (1.5%) for non-autoimmune diseases. Difficulty of breathing was the most common adverse reaction (n = 14, 10.7%), followed by fever (n = 10, 7.6%) and chest pain (n = 3, 2.2%). Other adverse reactions were headache (n = 2, 1.5%), lightheadedness (n = 1, 0.7%), tachycardia (n = 1, 0.7%), abdominal pain (n = 1, 0.7%), nausea (n = 1, 0.7%), vomiting (n = 1, 0.7%), diarrhea (n = 1, 0.7%), epistaxis (n = 1, 0.7%), and cardiac arrest (n = 1, 0.7%). The majority of patients given IVIG were discharged improved (n = 102, 77.9%), while 5.3% were discharged against medical advice, and 22 patients (16.8 %) died.

Conclusion: The common indications for IVIG among autoimmune diseases are Guillain-Barré Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP), Myasthenia Gravis, Autoimmune Encephalitis, Systemic Lupus Erythematosus (SLE) and Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP). For non-autoimmune diseases, the leading indications are COVID-19 and Septic Shock. The most frequently encountered adverse reaction was difficulty of breathing, followed by fever, chest pain and headache. The most severe adverse event was cardiac arrest. Less common adverse reactions included lightheadedness, tachycardia, abdominal pain, nausea, vomiting, diarrhea, and epistaxis.

Keywords: Intravenous Immunoglobulin (IVIG), adverse effects, indications, adult patients, Filipino

INTRODUCTION

Intravenous immunoglobulin (IVIG) is used in different disease entities. Since its discovery as an effective treatment more than thirty years ago, it has been administered as an immunomodulatory therapy in autoimmune and inflammatory diseases.[1] In recent years, the list of possible indications for IVIG has grown rapidly. During the COVID-19 pandemic, IVIG has been used as an adjunct therapy through three different mechanisms: control of cytokine storm, viral neutralization, and restoration of immune dysregulation. During this period, there was a notable increase in the use of IVIG in our locality, both as primary treatment, as well as an adjunct to the standard treatment for certain diseases. IVIG is generally considered a safe therapy, with adverse reactions occurring in approximately 10-30% of patients.

Based on extensive research using Google scholar, PubMed and NCBI, only one study on adverse reactions of IVIG in the Philippines has been published.[2] There is a lack of local data IVIG indications and associated adverse reactions. Knowledge of the common side effects is essential for institutions to manage potential adverse reactions effectively, and for patients to recognize risks and minimize harm during treatment. Early identification of adverse reactions allows timely interventions to prevent complications. Furthermore, this study aims to provide baseline and local data on the clinical use of IVIG, both as a primary treatment, and an adjunct treatment.

OBJECTIVES

The general objective of this study is to determine the indications for prescribing IVIG and the adverse reactions among adult patients admitted at Baguio General Hospital and Medical Center, who received IVIG infusions from October 2014 to October 2024.

Specific objectives

1. To describe clinico-demographic profile of patients given IVIG at Baguio General Hospital and Medical Center from October 2014 to October 2024, in terms of
   A. Age
   B. Sex
   C. Presence of comorbidities
   D. History of allergic reaction to other drugs
   E. Previous use of IVIG
2. To determine specific indications of IVIG, in terms of
   A. Nature of disease
      i. Autoimmune disease
      ii. Non-autoimmune disease
   B. Treatment role
      i. Primary treatment
      ii. Adjunct treatment
3. To determine the adverse reactions of patients given IVIG, according to
   A. Organ-specific or systemic
   B. Immediate or delayed
4. To determine the outcomes of patients given IVIG
   A. Discharged improved
   B. Mortality, all cause

METHODOLOGY

Study design

This was a descriptive study utilizing patients' records and data through chart review. The research was approved by the Technical Review Board (TRB) and the Ethics Review Committee (ERC) of BGHMC where the study was also was conducted.

Study participants

The general population of this study included all patients aged 19 years old and above who were admitted to Baguio General Hospital and Medical Center from October 1, 2014, to October 31, 2024, particularly the Internal Medicine and Neuroscience Department, who received at least one IVIG infusion and those who received a 5-day course of IVIG. Excluded from the study were pediatric patients, patients who have an incomplete chart and those patients who bought the IVIG outside of BGHMC Pharmacy.

In concordance with international recommendations, a frequency of 62% was applied.[3] A sample size of 362 was determined using OpenEpi. However, based on actual census from the Pharmacy of BGHMC, only 139 patients received IVIG from October 2014 to October 2024. Thus, total enumeration was done and all of these patients were included in the study. Although Gamma-I.V. and Immunorel were the two IVIG brands available during the study period, the specific brand administered was not accounted for, which constitutes a limitation of the study.

Data collection

The complete list of patients who received IVIG between October 2014 to October 2024 was obtained from the Pharmacy Department. With the approval of the Data Privacy Officer, the patient charts from the Medical Records and EMR were reviewed. For patients who experienced adverse reactions, data regarding the specific type of reaction; time interval between IVIG infusion and onset of symptoms were gathered through the Data Abstraction Form, summarized, and encoded in Microsoft Excel.

Statistical analysis

Descriptive statistics was utilized in this study. Microsoft Excel 2019 analyzed the data. Frequencies and percentages were used to describe the clinico-demographic profile of patients who received IVIG infusion, its indications, the

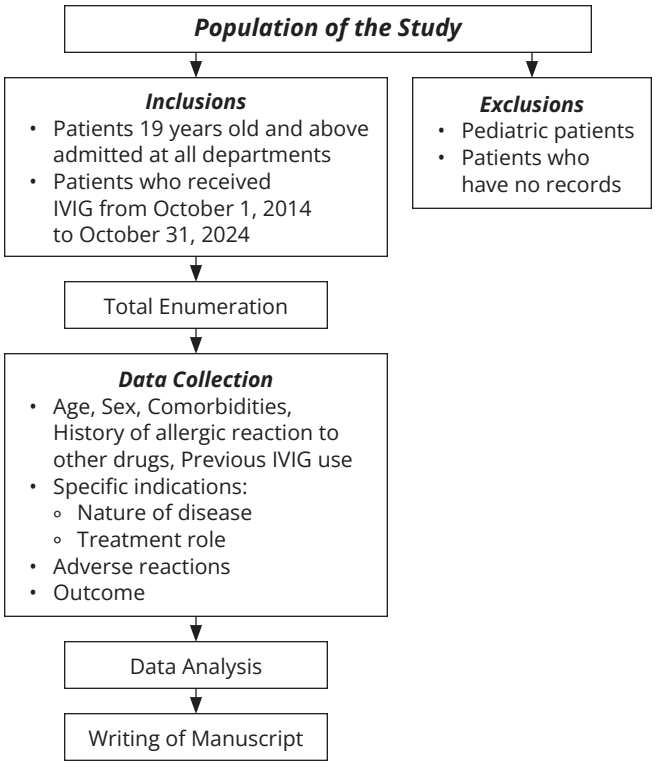

Figure 1. Algorithm of the study.

adverse reactions following infusion and the outcomes of these patients.

RESULTS

According to the census of the Pharmacy of Baguio General Hospital and Medical Center, 139 adult patients received IVIG from October 1, 2014 – October 31, 2024. Among these, there were 8 patients whose medical records were untraceable; hence, the remaining 131 patients were included in the final study.

The baseline clinical and demographic characteristics, including prior history of allergic reaction to other drugs and previous history of IVIG use are summarized in Table 1. The mean age was 38.90 years; 51 (38.9%) were males and 80 (61.1%) were females. Hypertension (19%), Diabetes mellitus (6.8%), and cardiovascular diseases (6.8%) were among the top three comorbidities, while 44.2% had none. Most patients had no prior allergic reaction to other drugs (98.5%) and no previous IVIG exposure (93.2%); 9 patients (6.8%) had a previous history of IVIG use.

For autoimmune diseases, Guillain-Barre Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP) was the most common indication for prescribing IVIG (n = 39, 29.7%). This is followed Myasthenia Gravis (25%) and Autoimmune Encephalitis (25%), and both Systemic Lupus Erythematosus (10%) and Chronic Inflammatory Demyelinating Polyneuropathy (10%). Among non-autoimmune diseases, the most common indication was COVID-19 (4.5%), followed by Septic shock (1.5%), Toxic Epidermal Necrolysis (TEN) (0.7%), SJS-TEN (0.7%), and Hemophagocytic Lymphohistiocytosis.

As shown in Table 2B most patients received IVIG as primary treatment (74.8%), while 25.2% of patients received it as an adjunct to the standard treatment.

Table 1. Clinicodemographic characteristics and outcomes of sample population

	Frequency (n)	Percentage (%)
Age		
19-29	47	35.8
30-49	51	38.9
50-69	27	20.6
70 and above	6	4.7
Sex		
Male	51	38.9
Female	80	61.1
Comorbidity		
Hypertension	25	19.0
Cardiovascular Disease	9	6.8
Diabetes Mellitus	9	6.8
Thyroid disorder	4	3.0
Cerebrovascular Disease	4	3.0
Malignancy (Breast cancer, Urinary bladder mass)	4	3.0
Hepatitis	3	2.2
Psychiatric disorder	3	2.2
Pregnancy	3	2.2
Rheumatic Heart Disease	2	1.5
Chronic Kidney Disease	2	1.5
Pulmonary Tuberculosis	2	1.5
Valvular Heart Disease	2	1.5
Asthma	2	1.5
Dyslipidemia	1	0.7
Autoimmune Kidney Disease	1	0.7
Cholelithiasis	1	0.7
Benign Paroxysmal Positional Vertigo	1	0.7
Chronic Obstructive Pulmonary Disease	0	0.0
Others: Tubuloovarian abscess, Ovarian Dermoid cyst, Alcoholic liver disease, Alcohol dependence	4	3.0
None	58	44.2
History of allergic reaction to other drugs		
With history	2	1.5
Without history	129	98.5
Previous use of IVIG		
With previous use	9	6.8
Without previous use	122	93.2

Adverse reactions occurred in 37 (28%) patients during IVIG infusions. One patient had difficulty breathing and desaturating during infusion, then went into cardiac arrest, which lead to the discontinuation of IVIG. The top 3 adverse reactions were difficulty of breathing, fever and chest pain (Table 3). All adverse reactions occurred immediately during infusion and within the 5-day period when IVIG was administered. There were no reported delayed reactions. However, the specific time interval between IVIG administration and the development of adverse effects was not evaluated, which is a limitation of this study.

The majority of patients were discharged improved (n = 102, 77.8%) (Table 4). Seven patients (5.3%) were discharged against medical advice. Among autoimmune diseases, Guillain-Barré Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP) remains to have the highest mortality rate (3.8%). However, in terms of mortality rate per disease entity, GBS accounts for 12.8%. One patient with GBS received IVIG on two separate occasions, 1 year apart. The patient was discharged after the first course; but succumbed to death on the second course due to complications from GBS. Systemic lupus erythematosus ranks as the second most common cause

Table 2A. Specific indications for IVIG

	Frequency (N)	Percentage (%)
Autoimmune		
Guillain-Barré Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP)	39	29.7
Myasthenia Gravis	25	19.0
Autoimmune Encephalitis	25	19.0
Systemic Lupus Erythematosus (SLE)	10	7.6
Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)	10	7.6
Multiple sclerosis (MS)	4	3.0
Antiphospholipid syndrome (APS)	2	1.5
Subacute Inflammatory Demyelinating Polyneuropathy	1	0.7
Immune thrombocytopenic purpura (ITP)	1	0.7
Cervical Myelopathy To consider Clinically isolated syndrome	1	0.7
Neuromyelitis optica spectrum	1	0.7
Autoimmune Hemolytic Anemia	1	0.7
Non-autoimmune		
COVID-19	6	4.5
Septic Shock	2	1.5
Toxic Epidermal Necrolysis (TEN)	1	0.7
SJS-TEN	1	0.7
Hemophagocytic Lymphohistiocytosis, Myelodysplastic syndrome	1	0.7

Table 2B. Specific indications for and frequency of prescribing IVIG according to treatment role

Treatment role	Frequency (N)	Percentage (%)
Primary treatment	98	74.8
Adjunct treatment	33	25.2

Table 3. Adverse reactions in patients who received IVIG infusion

	Frequency (N)	Percentage (%)
Systemic reactions		
Fever	10	7.6
Organ specific reactions		
Neurologic		
Headache	2	1.5
Lightheadedness	1	0.7
Migraine	0	0.0
Loss of consciousness	0	0.0
Respiratory		
Difficulty of breathing	14	10.7
Cough	0	0.0
Bronchospasm	0	0.0
Pleural effusion	0	0.0
TRALI	0	0.0
Cardiovascular		
Hypotension	0	0.0
Hypertension	0	0.0
Tachycardia	1	0.7
Chest pain	3	2.2
Arrhythmia	0	0.0
Myocardial infarction		
Cardiac arrest	1	0.7
Gastrointestinal		
Abdominal pain	1	0.7
Nausea	1	0.7
Vomiting	1	0.7
Cramping	0	0.0
Diarrhea	1	0.7
Cutaneous		
Urticaria	0	0.0
Nonspecific maculopapular eruption	0	0.0
Pruritus	0	0.0
Hematologic		
Epistaxis	1	0.7
Thrombotic phenomena	0	0.0
Neutropenia	0	0.0
Renal		
Tubular damage	0	0.0
Renal failure	0	0.0

Table 4. Outcomes of patients prescribed with IVIG

	Frequency (N)	Percentage (%)
Outcomes		
Discharged	102	77.9
DAMA	7	5.3
Mortality, all-cause	22	16.8
	All patients given IVIG (n = 131) N (%)	**Patients per specific indications for giving IVIG (N,%)**
Autoimmune		
Guillian-Barré Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP)	5 (3.8%)	5 (12.8%)
Systemic Lupus Erythematosus (SLE)	4 (3.0%)	4 (40.0%)
Myasthenia Gravis	3 (2.2%)	3 (12.0%)
Autoimmune Encephalitis	3 (2.2%)	3 (12.0%)
Neuromyelitis Optica Spectrum	1 (0.7%)	1 (100%)
Autoimmune Hemolytic Anemia	1 (0.7%)	1 (100%)
Non-autoimmune		
COVID-19	2 (1.5%)	2 (33.3%)
Septic shock	2 (1.5%)	2 (100%)
Hemophagocytic Lymphohistiocytosis, Myelodysplastic syndrome	1 (0.7%)	1 (100%)

of mortality in terms of frequency (n = 4, 3%). In terms of mortality per disease entity, SLE has a mortality rate as high as 40%. This may be due to IVIG being given as adjunctive therapy for refractory cases. Neuromyelitis optica spectrum and Autoimmune hemolytic anemia shared the highest mortality rate at 100%, with both having 100% mortality rate.

Among non-autoimmune diseases, all patients with Septic shock and Hemophagocytic Lymphohistiocytosis who received IVIG died. While the all caused mortality rate of patients with COVID 19 was reported to be at 33.3%.

DISCUSSION

Intravenous immunoglobulin (IVIG) is a pooled antibody preparation used to manage various immunodeficiency states and a plethora of other conditions, including autoimmune, infectious, and inflammatory states. Initially used as a replacement therapy for immunodeficiency diseases, IVIg is now widely applied in autoimmune and inflammatory diseases with the ultimate goal of normalizing a compromised immune system. IVIg has two dosing schedules, (i) low dose or "replacement" therapy, used in patients with primary and selected secondary immunodeficiencies characterized by absent or deficient antibody production. These indications include, for example, hypogammaglobulinemia, B cell chronic lymphocytic leukemia, acute graft-versus-host disease (GVHD) after bone marrow transplantation, children with HIV, and Wiskott–Aldrich syndrome and, (ii) high dose or "immunomodulatory/anti-inflammatory therapy", indicated for conditions such as Kawasaki disease (KD), idiopathic thrombocytopenic purpura (ITP), and Guillain–Barré syndrome. The US FDA has approved IVIG for the treatment of primary immunodeficiencies, immune thrombocytopenic purpura, Kawasaki disease, bone marrow transplantation in patients aged over 20 years, chronic B-cell lymphocytic leukemia, and pediatric AIDS.[4] The most common clinical indications for IVIg in adults requiring ICU admission and supported by clinical practice guidelines are Guillain-Barré syndrome, myasthenia gravis and Lambert-Eaton myasthenic syndrome, inflammatory myopathies, and primary or secondary immunodeficiency diseases complicated by severe bacterial sepsis. In line with previous studies, this study found Guillain-Barré Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP) to be the most common indication (29.7%), followed by Myasthenia Gravis (25%) and Autoimmune Encephalitis (25%). IVIg has been utilized in neurologic, dermatologic, or infection-related disease.[5] Emerging indications include necrotizing fasciitis, toxic epidermal necrolysis/Stevens-Johnson syndrome, and toxic shock syndrome.[6] In this study, two patients given IVIG for SJS-TEN. Researchers and clinicians have investigated the potential role of IVIG during the COVID-19 pandemic particularly in severe or complicated cases. The so-called 'cytokine storm' is recognized as the pathogenic basis of severe disease and represents a target for treatment with corticosteroids, immunotherapies, and intravenous immunoglobulin (IVIg). Globally, most of the published studies have reported good clinical responses, demonstrated by the resolution of lung lesions, normalization of oxygen saturation and key laboratory parameters, and overall improvement in clinical status.[7]

When patients are carefully selected and IVIG is properly administered, side effects are rarely encountered (occurring in 10–30% of patients). Most are mild and transient. To minimize the side effects, IVIG is recommended at doses not higher than 0.4 g/kg body weight given over a 5-day schedule for 1 month in conditions such as polymyositis and scleroderma.[8,9]

Adverse reactions to IVIG can be classified as systemic or organ specific. A systemic reaction leads to constitutional symptoms (such as fatigue, malaise, fever, flushing, chills, anorexia, myalgia/ arthralgia, "flu-like" symptoms, and anaphylactoid symptoms. While organ-specific reactions include Neurologic, Respiratory, Cardiovascular, Gastrointestinal, Renal, Cutaneous, and Hematologic systems. Overall, mild-to-moderate reactions occur in 5% to 15% of infusions.[10] Mild reactions do not require cessation

of therapy, are not associated with significant vital sign changes, and respond promptly to symptomatic therapy. Severe reactions occur in less than 1% of patients. Adverse reactions may be classified as immediate (occurring during the infusion itself) or delayed (occurring after the infusion has ceased). These adverse events may be due to the relative "impurity" of the commercial preparations, or the undesirable effects of its active component (IgG). According to literatures, the most common adverse effects occur soon after infusions and can include headache, flushing, chills, myalgia, wheezing, tachycardia, lower back pain, nausea, and hypotension. The most common organ-specific IVIG reactions are neurologic, with headache being the most commonly reported symptom, occurring in 5% to 20% of infusions and up to one-third or more of patients overall.[11] In this study, the most frequently observed adverse effect was difficulty of breathing, accounting for 10.7 of patients%.

In the study titled "Adverse Events of Intravenous Immunoglobulin Infusions: A Ten-Year Retrospective Study," Palabrica et al. reported that 32% of the 77 patients who received intravenous immunoglobulin (IVIG) infusions experienced adverse reactions. Pediatric patients comprised 52% of the study population. The most common indication was Kawasaki disease (85.7%) followed by immunodeficiency disorders (7.8%).[2] The top 3 adverse effects were fever (11%), skin rash(8%) and chills (7%). The most common adverse reactions to IVIG usually occurred in the first 30 min of administration and observed in approximately 5% of infusions. These include fever, chills, mild nausea and/or vomiting, backache, abdominal pain, myalgia, headache, and even some vasomotor and cardiovascular manifestations marked by changes in blood pressure and tachycardia. Interventions done include slowing infusion rate and administering medications such as paracetamol, antihistamines, and corticosteroids. Oxygen and intravenous fluid hydration were also given in some cases. In this study, the patient's outcome was not assessed.

The discharge rate of patients with Guillain-Barré Syndrome (GBS) varies based on factors such as disease severity, timeliness and effectiveness of treatment, and the patient's overall health. A study by Kushner et al. reported that 81.8% of patients with GBS were discharged from the hospital.[12] It also showed that 87.2% of patients with GBS were discharged improved, which is consistent with previous studies. Similarly, most patients with autoimmune encephalitis show significant improvement, with 80.95% discharged improved. [13] In this study, discharge rate was 88%. For chronic inflammatory demyelinating polyneuropathy (CIDP), treatment outcomes and prognosis depend on the clinical phenotype. However, patients with typical CIDP generally experience favorable long-term outcomes, in about 90% of cases despite a 50% relapse rate. In this study, all CIDP patients (100%), were discharged improved, with no notable relapse observed.

Regarding non-autoimmune conditions, Patel et al. reported that 65.2% of hospitalized COVID-19 patients were discharged, while 33.6% required home healthcare upon discharge.[14] In contrast, this study showed 33.3% mortality rate among COVID-19 patients given IVIG. This is contrary to previously published papers that reported favorable outcomes with IVIG in COVID-19 patients. This could be due to the severity and complications of COVID-19 when these patients received the IVIG. Regarding sepsis and septic shock, a separate study found that 52.6% of patients discharged after sepsis were able to return home,[15] while other studies showed a mortality rate of 30-40%. In this study, the recorded mortality rate for Septic shock patients given IVIG is 100%. This may be attributed to the complications of septic shock. Although intravenous immunoglobulin (IVIG) has been explored as a treatment for sepsis, its clinical effectiveness remains uncertain. Some studies suggest a potential reduction in sepsis-related mortality with IVIG use, but the findings are inconsistent due to significant variability in study quality and dosing regimens. Reflecting this uncertainty, the 2016 Surviving Sepsis Campaign advised against routine IVIG use in sepsis, citing low-certainty evidence and high heterogeneity among studies. However, it emphasized the need for large, multicenter trials to better assess the potential benefits of IVIG in sepsis treatment.[16]

The mortality rate for patients with autoimmune diseases varies depending on the specific condition and other clinical factors. Among immune-mediated neuropathy, Guillain–Barré syndrome (GBS) is the most common, with an incidence rate of 0.59 - 2.35 per 100,000 persons worldwide, while the reported mortality rate of GBS has ranged from 3% to 13%. In this study, a comparable result was observed, with the recorded mortality rate of GBS patients at 12.8%. The most common causes of death in patients with GBS are respiratory and cardiovascular complications.[17] The mortality rates of Autoimmune encephalitis, chronic inflammatory demyelinating polyneuropathy (CIDP), and Myasthenia Gravis in Myasthenic crisis were 6%–19%,[18] 3.3-11%,[19] and 1.5%.[20] respectively. This study represents the general population with a mortality rate of 12% for patients with Autoimmune encephalitis, and 12% for Myasthenia Gravis. However, in this study, no mortalities were reported among patients with CIDP.

The strength of this study is its large sample size (n = 131). The limitation of this study, on the other hand, is the difficulty in identifying whether the adverse reactions were secondary to IVIG or due to the multiple medications given during IVIG administration.

CONCLUSION AND RECOMMENDATIONS

The common indications for IVIG among autoimmune diseases are Guillain-Barré Syndrome / Acute Inflammatory Demyelinating Polyneuropathy (AIDP), Myasthenia Gravis, Autoimmune Encephalitis, Systemic Lupus Erythematosus (SLE) and Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP). Among non-autoimmune diseases, the most common are COVID-19 and Septic Shock. The most commonly observed adverse reaction was difficulty of breathing, followed by fever, chest pain and headache. The most severe event was cardiac arrest. While less common reactions included lightheadedness, tachycardia, abdominal pain, nausea, vomiting, diarrhea, and epistaxis. The results of this study can have significant implications for patients, doctors, and allergologists because it directly impacts treatment safety, efficacy, and patient outcomes.

This study could be strengthened by including the dosage of IVIG given per patient and its correlation with the incidence of adverse effects, as well as the specific time frame of appearance of adverse reactions after IVIG administration. Moreover, further research is recommended on interventions following the appearance of adverse reactions, which may guide allergologists and clinicians to develop pre-medication strategies and choose safer alternatives for patients at-risk. Continued investigation on IVIG related adverse events enhances patient safety, improves therapeutic success rates, and contributes to the medical community's understanding of immunotherapy. It also promotes innovation in drug formulations and delivery methods, making IVIG therapy safer and more effective for diverse patient populations.

Statement of Authorship

All authors certified fulfilment of ICMJE authorship criteria.

Author Disclosure

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