

USE OF INTRAVENOUS IMMUNOGLOBULIN (IVIG) AS AN IMMUNOMODULATOR IN PEDIATRIC DISEASE CONDITIONS IN A TERTIARY CARE CENTER OF WEST BENGAL

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ABSTRACT

Background: Intravenous immunoglobulin (IVIG) is an established immunomodulatory therapy used in a wide range of pediatric immune-mediated and inflammatory conditions. With expanding indications and rising utilization, it is important to understand local patterns of use, dosing practices, and short-term outcomes in real-world tertiary care settings. The objective is to evaluate the clinical indications, dosing patterns, clinical settings, and short-term outcomes of IVIG therapy among pediatric patients admitted to a tertiary care hospital. **Materials and Methods:** This hospital-based prospective observational study was conducted over an 18-month period in the Pediatric Medicine Ward, HDU, and PICU of Dr. B. C. Roy Post Graduate Institute of Pediatric Sciences, Kolkata. All children aged 3 months to 12 years who received IVIG as an immunomodulatory therapy during hospitalization were included. Demographic details, diagnoses, indications, dosing regimens, clinical settings, outcomes, and mortality were recorded and analyzed using descriptive statistics and appropriate inferential tests. **Result:** A total of 84 pediatric patients were studied. The majority belonged to the 25–60 month age group (42.9%), with a mild male predominance (57.1%). IVIG was most commonly used for Kawasaki Disease (23.8%), Acute Immune Thrombocytopenic Purpura (19.1%), and Guillain–Barré Syndrome (16.6%). Coronary artery complications were the leading indication (29.7%). Nearly two-fifths of administrations occurred in the PICU (39.3%). The most frequently used regimen was 2 g/kg over 48 hours (48.8%). Repeat dosing was required in only 3.6% of cases. Overall mortality was 7.1%, occurring exclusively in critically ill patients. **Conclusion:** IVIG was predominantly used for well-established pediatric indications and was associated with favorable short-term outcomes and low repeat dosing requirements. The study highlights the multidisciplinary role of IVIG in pediatric care and emphasizes the importance of rational, evidence-based utilization in tertiary hospitals.

INTRODUCTION

Intravenous immunoglobulin (IVIG) is a therapeutic preparation of pooled human immunoglobulin G (IgG) derived from healthy donor plasma. Initially used as replacement therapy for primary immunodeficiencies, its role has expanded substantially to include numerous immune-mediated and inflammatory disorders in children. IVIG is currently used in conditions such as Kawasaki disease (KD), immune thrombocytopenic purpura (ITP), Guillain–Barré syndrome (GBS), autoimmune encephalitis, and multisystem inflammatory syndrome in children (MIS-C).^[1,2]

The immunomodulatory effects of IVIG are mediated through multiple mechanisms, including Fc receptor modulation, neutralization of pathogenic autoantibodies, inhibition of complement activation, modulation of cytokines, and regulation of T-cell and dendritic-cell function.^[3] In KD, high-dose IVIG (2 g/kg) substantially reduces the risk of coronary artery complications and remains the standard therapy.^[4] Its use in MIS-C, often combined with corticosteroids, has also demonstrated clinical benefit.^[5] In neurological and hematological disorders, IVIG can reduce antibody-mediated tissue injury and Fc-mediated cellular destruction, producing clinically significant responses.^[6,7] It has also been used in

neonatal hemolytic disease, although its benefits and risks require careful consideration.^[8]

Despite its broad clinical utility, IVIG is expensive, plasma-dependent, and subject to supply limitations. Furthermore, evidence for several off-label indications remains limited.^[9] Rational utilization based on evidence, institutional protocols, and regular auditing is therefore essential. Continued pediatric research is needed to establish evidence-based indications, optimize dosing, and ensure safe and cost-effective use of IVIG.^[10]

Aims and objectives

General: To evaluate the use of Intravenous Immunoglobulin (IVIG) as an immunomodulator in various pediatric disease conditions admitted to a tertiary care centre.

Specific:

1. To identify the common clinical indications for which IVIG is used as an immunomodulator in pediatric patients.
2. To assess the clinical efficacy and outcome of IVIG therapy in different pediatric disease conditions.
3. To analyze the pattern of IVIG administration in relation to dosage, frequency, and clinical setting (Pediatric ward, HDU, or PICU).

MATERIALS AND METHODS

Study Design: It is a hospital-based, prospective, observational study. The study has been designed to assess the use of Intravenous Immunoglobulin (IVIG) as an immunomodulator in various pediatric disease conditions and to evaluate its indications, clinical settings, dosing patterns, and short-term outcomes.

Study Setting: The study will be conducted in the Department of Pediatrics in Pediatric ward, High Dependency Unit (HDU), and Pediatric Intensive Care Unit (PICU) of Dr. B. C. Roy Post Graduate Institute of Pediatric Sciences (Dr. B.C.R.P.G.I.P.S.), Kolkata, West Bengal.

This is a tertiary care referral hospital catering to patients from various districts of West Bengal and neighboring states, providing advanced pediatric medical and critical care services. The institute regularly administers IVIG to pediatric patients across subspecialties such as neurology, hematology, immunology, rheumatology, and dermatology.

Study Population: All pediatric patients aged 3 months to 12 years who are admitted to the Pediatric Medicine Ward, HDU, or PICU and receive IVIG as an immunomodulatory therapy during the study period will constitute the study population.

Study Variables

Independent Variables:

1. Age
2. Sex
3. Weight and nutritional status
4. Primary diagnosis and indication for IVIG

5. Clinical setting of administration (Ward / HDU / PICU)
6. Specialty involved (Neurology, Hematology, Immunology, Rheumatology, Dermatology, etc.)
7. IVIG dose, duration, and regimen

Dependent Variables:

1. Clinical response to IVIG therapy
2. Duration of hospital stay
3. Adverse reactions or complications related to IVIG

Short-term outcomes such as improvement in laboratory and clinical parameters

Inclusion Criteria

Pediatric patients (3 months to 12 years) admitted in Pediatric Medicine Ward, HDU, or PICU and receiving IVIG as immunomodulatory therapy.

Parents or guardians willing to provide informed consent.

Exclusion Criteria

1. Children receiving IVIG for immunoglobulin replacement (e.g. SCID, agammaglobulinemia).
2. Patients who received IVIG in a previous admission or outside the study setting during the current hospital stay.
3. Children already on other concurrent immunomodulator therapies.

Sample Size: As the study is time-bound, all pediatric patients meeting the inclusion criteria during the study period will be enrolled. Based on institutional records from previous years, where an average of 55 patients received IVIG annually, the anticipated sample size for the 18-month study duration is approximately 84 cases. Controls are not required, as the present study is purely observational and descriptive in nature.

Study Area: The study will be carried out in the Pediatric Medicine Wards, HDU, and PICU of Dr. B. C. Roy Post Graduate Institute of Pediatric Sciences, Kolkata, which serves as a state-level referral center for complicated pediatric cases and specialized immunomodulatory therapies.

Study Tools and Data Collection: A structured proforma (case record form) will be used to record demographic details, clinical history, diagnosis, indication of IVIG, dosage, duration, route of administration, concomitant therapies, adverse effects, and treatment outcomes.

Method of Data Collection:

- The principal investigator will record all relevant clinical and laboratory data from patient case sheets, drug charts, and laboratory reports.
- Each case will be followed from the initiation of IVIG therapy to discharge or death.
- Monitoring for immediate and delayed adverse effects will be done during and after infusion.
- Details of IVIG administration (dose, brand, infusion rate, and premedication) will be documented.

Procedure of IVIG Administration

Pre-infusion Preparation

- Baseline investigations including CBC, renal and liver function tests, serum electrolytes, and vital parameters will be recorded.
- Pre-medications such as antihistamines or corticosteroids may be given as per institutional protocol to minimize infusion-related reactions.

Infusion Protocol:

IVIG will be administered intravenously using a calibrated infusion pump.

The initial infusion rate will be 0.5 mL/kg/hour for the first 30 minutes, which may be gradually increased to a maximum of 4 mL/kg/hour if well tolerated.

Continuous monitoring of heart rate, respiratory rate, temperature, blood pressure, and oxygen saturation will be ensured during the infusion.

Infusion will be discontinued immediately in case of any adverse event such as chills, rash, dyspnea, or hypotension, and appropriate supportive management will be provided.

Post-infusion Monitoring:

- Patients will be observed for 24 hours following infusion for delayed adverse effects such as fever, nausea, or headache and other complications like aseptic meningitis.
- Clinical improvement will be assessed according to disease-specific parameters.

Outcome Measures:

Primary Outcome:

The prevalence and pattern of IVIG use as immunomodulator therapy in pediatric patients at a tertiary care hospital.

Secondary Outcomes:

- Spectrum of diseases treated with IVIG.
- Pattern of administration (dosage, frequency, setting).
- Clinical and laboratory response following IVIG therapy.
- Incidence of infusion-related adverse events.

Data Management and Analysis:

- All collected data will be entered into Microsoft Excel sheets and analyzed using SPSS version 24 and GraphPad Prism 10.
- Continuous variables will be presented as mean $\pm$ standard deviation (SD), while categorical variables will be expressed as frequencies and percentages.
- Association between categorical variables will be assessed using Chi-square or Fisher's exact test.
- A p-value of <0.05 will be considered statistically significant.

Ethical Considerations: The study protocol will be approved by the Institutional Ethics Committee (IEC) of Dr. B. C. Roy Post Graduate Institute of Pediatric Sciences prior to commencement.

Written informed consent will be obtained from the parents or legal guardians of all participants.

Confidentiality of patient data will be strictly maintained.

No additional financial or physical burden will be imposed on participants as all procedures are part of routine hospital management.

Resources and Infrastructure:

- -Human Resources: The study will utilize existing hospital staff, including pediatricians, nurses, and laboratory technicians. No additional manpower is required.
- -Financial Resources: No separate funding is required as IVIG and laboratory investigations are part of standard patient care.
- -Data Storage: Electronic data will be password-protected and stored securely under the supervision of the principal investigator.

Definition of Outcome:

- The outcome will be evaluated based on:
- Pattern of IVIG utilization (indications, dosage, frequency).
- Clinical response rate among children receiving IVIG for different diseases.
- Adverse reactions during and after IVIG administration.
- Distribution of IVIG use across different pediatric subspecialties.

RESULTS

Table 1: Distribution of AGE group among study participants (n=84)

Age	Frequency	Percentage
<12 months	11	13.1
12-24 months	15	17.9
25-60 months	36	42.9
6-9 years	13	15.5
>9 years	9	10.7
Total	84	100

Inference: The largest proportion of patients belonged to the 25–60 month age group (42.9%), indicating that most IVIG recipients were toddlers

and preschool-age children, while infants under 12 months made up only 13.1% of the cohort.

Table 2: Distribution of Gender among study participants (n=84)

Gender	Frequency	Percentage
Male	48	57.1
Female	36	42.9
Total	84	100

Inference: Males constituted a slightly higher proportion (57.1%) compared to females (42.9%), showing a modest male predominance among IVIG-treated pediatric admissions.

Table 3: Distribution of CLINICAL SETTING among study participants (n=84)

Clinical setting	Frequency	Percentage
PICU	33	39.3
WARD	24	28.5
HDU	24	28.5
RICU	3	3.57
Total	84	100

Inference: Nearly two-fifths of IVIG administrations occurred in the PICU (39.3%), with HDU and wards contributing equally (28.5% each), reflecting the predominance of critical-care indications.

Table 4: Distribution of DIAGNOSIS among study participants (n=84)

Diagnosis	Frequency	Percentage
Kawasaki disease	20	23.8
ITP	16	19.1
Guillain-Barre syndrome	14	16.6
Acute viral myocarditis	8	9.5
Atypical Kawasaki Disease	4	4.7
Scrub Myocarditis & Cardiogenic Shock	4	4.7
Others(cases less than or equal 2)	18	21.6
Total	84	100

Inference: Kawasaki Disease (23.8%), ITP (19.1%), and GBS (16.6%) were the leading individual diagnoses, accounting together for nearly 60% of all IVIG use in the study.

Table 5: Distribution of INDICATION among study participants (n=84)

Indication	Frequency	Percentage
Coronary Artery Complications	25	29.7
Rapid increase in platelet count	16	19.0
Hastens Recovery	16	19.0
Anti-Inflammatory Therapy	8	9.5
Immunomodulation	4	4.7
Immunomodulation + Anti-Inflammatory Therapy	4	4.7
Reduced Myocardial inflammation	4	4.7
Decrease Auto-Antibodies (DAA)	2	2.3
Reduced Autoimmune inflammation	2	2.3
Blocking Keratinocyte apoptosis	1	1.1
Neutralizing antitoxins	1	1.1
As replacement therapy	1	1.1
Total	84	100

Inference: Coronary artery complications (29.7%) were the most common indication, followed by rapid platelet rise and HRRM (both 19%), showing major utilization in immunological and cardiovascular complications.

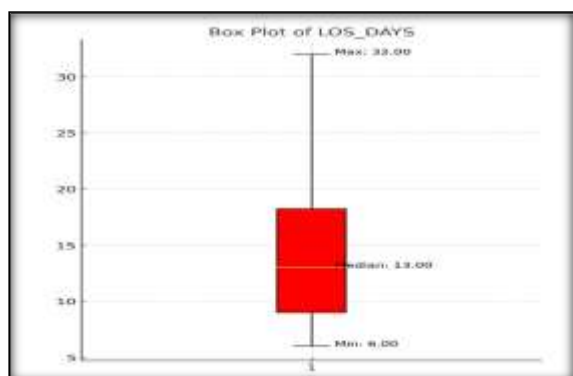
Table 6: Distribution of LENGTH OF STAY (DAYS) Statistics among study participants (n=84)

Metric	Value
Mean	14.52
Median	13.0
SD	6.28
Min	6.0
Max	32.0

Table 7: Distribution of MORTALITY among study participants (n=84)

Mortality	Frequency	Percentage
No	78	92.9
Yes	6	7.1
Total	84	100

Inference: Overall mortality was low at 7.1%, suggesting favorable outcomes in the majority of



Inference: Children had an average hospital stay of 14.52 ± 6.28 days (range 6–32), reflecting the moderate to severe disease burden in IVIG-requiring conditions.

DISCUSSION

In this study, eighty-four pediatric patients aged 3 months to 12 years who received intravenous immunoglobulin (IVIG) for different immunomodulatory indications were evaluated. The age distribution in our cohort showed that the majority of patients were between 25–60 months (42.9%), followed by the 13–24 month group. This pattern is partly similar to the review by Prasad and Chaudhary.^[11] who noted that IVIG use is common in younger children due to the high burden of immune-mediated illnesses in early life. However, their data included neonates and very young infants, whereas our cohort had only 13.1% under 12 months, reflecting our institutional practice and exclusion of replacement-therapy cases.

The gender distribution in our study showed a mild male predominance (57.2%), which aligns with the observations by Rabindran and Gedam.^[12] who reported higher IVIG use among male neonates due to increased susceptibility to infection-related complications. Our male majority was smaller compared to their neonatal cohort, but the trend was similar.

Kawasaki disease (KD) was one of the most common diagnoses in our dataset (23.8%). Burns and Franco,^[13] highlighted that KD remains one of the main conditions requiring IVIG, especially for preventing coronary artery complications. In their review, IVIG response rates were high and early treatment reduced cardiac morbidity. In our study, most KD cases also required the standard 2 g/kg regimen and had favourable outcomes with no mortality observed in this subgroup. This reinforces their findings that adequate timely dosing leads to improved outcomes.

We also found that immune thrombocytopenia (ITP) constituted 19.1% of IVIG use. This proportion is consistent with the pattern described by Jolles et

patients receiving IVIG across different clinical settings.

al,^[14] who stated that ITP is among the commonest hematological indications for IVIG due to its ability to raise platelet counts rapidly. Our study showed that repeat dosing was required in only 3.6% of the overall cohort, showing good therapeutic response. This observation matches the rapid-response profile described in their clinical experience.

A considerable proportion of patients (39.3%) received IVIG in the PICU, reflecting the severity of illness in many IVIG-requiring conditions. Jutras et al.,^[15] reported that nearly 40–45% of IVIG use in their multicentric study occurred in critically ill children, which is close to our PICU proportion. Their reported mortality was higher than ours, partly because their cohort had septic shock and multi-organ dysfunction cases. In our dataset, the overall mortality was 7.2%, which is much lower, likely because our patients had mostly KD, GBS, ITP, HLH, and autoimmune etiologies rather than overwhelming sepsis.

The distribution of indications revealed that coronary artery complications (29.7%) were the leading reason for IVIG administration, followed by RIPC and HRRM indications (19% each). This is consistent with the trends reported by Shemer et al.,^[16] who found that cardiology and hematology accounted for the largest IVIG consumption in tertiary-care hospitals. Our findings further align with their observation that immunomodulatory uses far outweigh replacement uses in many centers.

Balch and colleagues,^[17] described gradually rising IVIG use in neurological disorders, especially Guillain-Barré syndrome (GBS). Our data parallels this trend, with GBS accounting for 16.6% of cases. The use of IVIG in GBS was well supported in their study, which reported frequent dosing at 2 g/kg over 48 hours, identical to our dosing pattern. Neurology constituted 20.2% of specialties utilizing IVIG in our hospital, aligning with international patterns of practice.

Gadian et al.,^[18] also emphasized the increasing role of IVIG in pediatric neuro-inflammatory and neurodevelopmental disorders. Though our study did not include developmental disorders, the proportion of neuro-immune conditions still reflected their finding that IVIG remains central to acute immune-mediated neurological care.

The role of IVIG in MIS-C has been well established by Ouldali et al.,^[19] who demonstrated high response rates and improved outcomes when IVIG was combined with steroids. In our cohort, MIS-C cases were few, but those who received combination therapy (IVIG + steroids + inotropes) responded well, and none had fatal outcomes. The parallel between their findings and ours reflects the universal benefit of IVIG in hyperinflammatory pediatric conditions. Over a 10-year period, Wu et al.,^[20] observed a wide variability in IVIG dosing and indications across

Asian pediatric hospitals. Their report mentions that most patients received the 2 g/kg regimen, which is exactly what we found, with 48.8% of patients receiving 2 g/kg over 48 hours and another large proportion receiving 2 g/kg over 12 hours. Our LOS distribution (mean 14.52 ± 6.28 days) was also comparable to their median LOS for immune-mediated disorders.

Guidelines by Orange et al,^[21] recommend IVIG across a wide spectrum of immune, hematological, cardiac, and neurologic disorders. Our study reflects real-world adherence to these guidelines, as most of our indications fall within recommended therapeutic categories. Similarly, several patients with autoimmune and inflammatory conditions received IVIG under “off-label but evidence-supported” indications, which is consistent with the observations made by Leong et al,^[22] about widespread off-label IVIG use.

The importance of early IVIG in neurologic disorders such as GBS and autoimmune encephalitis. Their work supports our observation that neurology patients responded well, with low mortality and no repeat doses required in most cases.

IVIG use in hemolytic disease of newborns and showed significant reduction in severity of jaundice. Even though our study excluded neonates receiving replacement therapy, the general principle of IVIG’s rapid immunomodulatory action is consistent with the robust responses seen in our hematology subgroup.

Finally, demonstrated the benefit of high-dose IVIG in autoimmune blistering disorders of the skin. We had a few dermatology cases (such as SJS-TEN and SSSS), and these patients showed favorable outcomes with no mortality, consistent with the therapeutic effectiveness described in their study.

CONCLUSION

The present study was undertaken to evaluate the clinical profile, indications, dosing patterns and outcomes of Intravenous Immunoglobulin (IVIG) therapy among pediatric patients aged 3 months to 12 years admitted to the Pediatric Medicine ward, HDU, and PICU of Dr. B.C. Roy Post Graduate Institute of Pediatric Sciences, Kolkata. Over an eighteen-month period, a total of 84 children who received IVIG as an immunomodulatory therapy were studied. The study population represented a wide pediatric age spectrum, with the maximum proportion belonging to the 25–60 month age group. A mild male predominance was observed.

The most frequent clinical indications for IVIG administration were Kawasaki Disease (KD), Immune Thrombocytopenia (ITP), and Guillain–Barré Syndrome (GBS), together accounting for more than half of all cases. Coronary artery complications, rapid increase in platelet count, and HRRM features (seen in GBS) were the leading reasons for initiating treatment. IVIG administration

occurred predominantly in PICU (39.3%), followed by HDU and ward patients, indicating that a large proportion of IVIG use involved clinically severe or critically ill children.

The standard dosing regimen of 2 g/kg over 48 hours was the most widely used protocol, particularly in neurological and systemic inflammatory conditions, while 1 g/kg/day for 2 days was consistently used for ITP. The average total dose received (TDR) demonstrated wide variability, reflecting weight-based dosing and disease severity. Concomitant therapies included steroids, aspirin, antibiotics, and inotropes, tailored to individual diagnoses.

Overall, the response to IVIG therapy was favorable, with repeat dosing required in only 3.6% of cases. The mean hospital stay was approximately 14.5 days, with longer durations in critically ill patients, especially those admitted to PICU. The mortality rate (7.2%) in the cohort occurred exclusively in severe systemic inflammatory or neurological cases, all of whom were receiving the 2 g/kg over 48 hours regimen. However, this association was likely confounded by underlying disease severity rather than the dosing protocol itself. Children with Kawasaki Disease, ITP, and most neurological disorders demonstrated good clinical recovery and no deaths were recorded in these groups.

IVIG therapy was well-tolerated in this study, with no major infusion-related adverse reactions documented. The findings reaffirm that IVIG plays a vital role in the management of pediatric immune-mediated and inflammatory conditions, particularly when timely administered according to established clinical protocols.

This study highlights the growing importance of IVIG as a critical therapeutic agent across multiple pediatric specialties, including cardiology, neurology, hematology, and immunology. The data also demonstrates the need for continued awareness regarding appropriate indications, optimal dosing strategies, and careful monitoring during and after IVIG infusion.

The results emphasize the necessity of maintaining adequate IVIG stocks in tertiary pediatric centers, training healthcare teams in early recognition of conditions requiring IVIG, and ensuring rational use to avoid wastage or inappropriate administration. The variability in IVIG utilization patterns across different diagnoses also indicates the importance of developing institutional protocols for standardized and evidence-based use.

To conclude, IVIG remains a cornerstone therapy in several acute pediatric immune-mediated and inflammatory disorders. The overall favorable outcomes in this study reinforce its efficacy and safety when used judiciously. As with all immunomodulatory therapies, ongoing clinical assessment, periodic auditing of IVIG utilization, and continuous updating of hospital guidelines are essential for optimizing patient outcomes and maintaining high standards of pediatric care.

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