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Research Article

Adverse Reactions to Intravenous Immunoglobulin in Children with Primary Immunodeficiencies: A Single Center Experience

Fatih Karagözlü[1*], Murat Sütçü[2], Emine Manolya Kara[3], Ayper Somer[4]

[1] Department of Pediatrics, Düzce Atatürk City Hospital, Pediatric Cardiology, Düzce, Türkiye.
ror.org/026q76j62

[2] Department of Pediatrics, Division of Pediatric Infectious Diseases, Istinye University, Faculty of Medicine, İstanbul, Türkiye.
ror.org/03081nz23

[3] Department of Pediatrics, Division of Pediatric Infectious Diseases, Yeditepe University, Faculty of Medicine, İstanbul, Türkiye.
ror.org/025mx2575

[4] Department of Pediatrics, Division of Pediatric Infectious Diseases, İstanbul University, Faculty of Medicine, İstanbul, Türkiye.
ror.org/03a5qrr21

*Corresponding author:
dr.karagozlu@gmail.com

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ABSTRACT

Aim: This study evaluated the clinical outcomes of patients diagnosed with immunodeficiency who regularly received intravenous immunoglobulin therapy.

Material and Methods: This study was performed on 0-18-year-olds. 35 patients diagnosed with primary immunodeficiency were included in our study. Patients' data regarding gender, age, primary diagnosis, family history of immunodeficiency, consanguineous marriage, growth and developmental delay, lymphoid tissue involvement, systemic findings, infection frequency before and after intravenous immunoglobulin therapy, and the existence of hospitalization history were analyzed retrospectively.

Results: Thirteen (%37,1) female and 22 (%67,9) male patients were evaluated in this study. Twenty-one patients (%60) were diagnosed with common variable immunodeficiency, 6 were (%17,1) severe combined immunodeficiency, 3 were (%8,6) ataxia telangiectasia, 3 were (%8,6) hyper immunoglobulin M syndrome and 2 were (%5,7) Bruton agammaglobulinemia. All the patients (%100) had a history of hospitalization for recurrent infection. Before the immunoglobulin treatment, it was observed that one patient (%2,9) had 4-6 times, 15 patients (%42,9) had 7-10 times, and 19 patients (%54,3) had more than ten times history of infection per a year. However, after the immunoglobulin treatment, it has been observed that the infection frequency of all the patients (%100) was 1-3 times per year. Pretreatment median IgG values were 224 mg/dL (25-1339) and posttreatment 510 mg/dL (218-1568), who were entered into this study.

Conclusion: Early identification of PIDs before the emergence of serious infections is important for prognosis and providing timely genetic counseling to the family. Treatment with intravenous immunoglobulin therapy reduces recurrent infections, hospitalization, and morbidity.

Keywords: Immune deficiency, immunoglobulin therapy, IVIG, adverse reaction.

INTRODUCTION

The concept of passive immunization began in the 17th century when Lower and King conducted transfusion experiments, which Pepys described as "… mending of bad blood by borrowing from a better body" (1).

Bruton first identified the presence of patients with agammaglobulinemia and reported that immunoglobulin solutions previously developed by Cohn et al. (1) were beneficial when administered to agammaglobulinemia patients. However, he also observed that it caused anaphylaxis when administered intravenously.

Intravenous immunoglobulin (IVIG) treatment received FDA (Food Drug Administration) approval for the first time in 1981 in the United States of America, and its use was recommended primarily in the treatment of immune deficiencies with hypogammaglobulinemia (2).

Immunodeficiencies are divided into primary and secondary. Although there are many types of primary immunodeficiencies due to hereditary or congenital causes, approximately 70% of all patients have antibody production defects, so immunoglobulin replacement therapy provides first-line treatment in these patients. In secondary immunodeficiencies (chronic lymphoid leukemia, multiple myeloma, etc.), immunoglobulin replacement therapy is used at a similar dose and frequency as a preventive measure to reduce the risk of severe and recurrent infections due to decreased antibody production (3).

Adverse reactions to immunoglobulins may be local, systemic, specific to an organ (e.g., kidney, skin), or system (e.g., nervous system, hematologic system). Systemic adverse reactions may be early reactions occurring during the transfusion or within the first 6 hours (60% of adverse reactions); delayed reactions occurring between 6 hours and 1 week after the infusion (40% of adverse reactions); or late reactions occurring 1 week after the infusion. Late reactions may occur weeks or months after the infusion (4).

The clinical use of intravenous immunoglobulin therapy is increasing daily. This study investigated the efficacy of IVIG treatment, its side effects, and its effects on the frequency of infection in patients with immunodeficiency.

MATERIAL AND METHODS

The Local Research Ethics Committee approved the study, which was designed as a retrospective cross-sectional study at a single institution. The Istanbul University Istanbul Faculty of Medicine Ethics Committee approved the study (No: 2017/1103).

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The study included 35 children aged 0-18 diagnosed with immune deficiency and receiving regular IVIG treatment between 2010 and 2015 at the Department of Pediatric Infectious Diseases and Clinical Immunology, Istanbul University, Istanbul Faculty of Medicine. The patients were diagnosed according to the criteria of ESID (European Society for Immunodeficiency) and PAGID (Pan-American Group for Immunodeficiency).

Data from the patient files about gender, age, diagnosis, family history, growth-development retardation, lymphoid organ involvement, findings related to system involvement, frequency of infection before and after intravenous immunoglobulin treatment, history of hospitalization, initial and post-treatment immunoglobulin levels, hemoglobin, white blood cell and platelet values in complete blood counts at the time of admission were recorded retrospectively.

Side effects such as convulsions, vomiting, respiratory distress, fever, and headache were noted in patients during intravenous immunoglobulin infusion.

The SPSS (Statistical Package for Social Science) statistics program (version 21, Chicago) was used for statistical analyses. Qualitative measurements were given as numbers and percentages, and quantitative measurements were presented as mean ± standard deviation (with median, lower, and upper limits specified when necessary). Fisher's Exact test, Mann-Whitney test, and Pearson Chi-Square test were used to evaluate the data obtained in the study. $P<0.05$ in the tests was considered statistically significant.

RESULTS

Thirteen (37,1%) female and 22 (67,9%) male patients were evaluated in this study. Twenty-one patients (60%) were diagnosed with common variable immunodeficiency, 6 were (17,1%) severe combined immunodeficiency, 3 were (8,6%) ataxia telangiectasia, 3 were (8,6%) hyper immunoglobulin M syndrome, and 2 were (5,7%) Bruton agammaglobulinemia. (Figure 1).

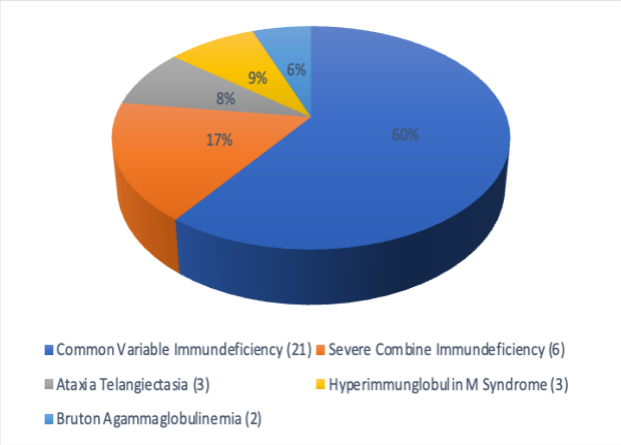


Figure 1. Distribution of cases by diagnosis.

There was a family history of immunodeficiency in 14 patients (40%) and consanguineous marriage in 25 patients (71.4%). Growth retardation was found in 25 (71.4%) of the cases. Physical examination revealed hepatomegaly in 6 (17.1%), splenomegaly in 5 (14.3%) and lymphadenopathy in 15 (42.9%) of 35 patients. In terms of system involvement, 11 (31.4%) had bronchiectasis, 1 (2.9%) had bone-joint involvement, 12 (34.3%) had gastrointestinal system involvement, 2 (5.9%) had endocrine system involvement, and in terms of neurologic involvement, 4 (11.4%) had ataxia and 1 (2.9%) had a history of meningitis. When evaluated in terms of symptoms at the time of first admission, 35 (100%) patients had a history of recurrent infections and hospitalization for this reason. Recurrent infections included upper respiratory tract infection in 16 (45.7%) patients, sinusitis/otitis in 8 (22.8%), pneumonia in 5 (14.3%), sepsis/meningitis in 3 (8.6%), and antibiotic use for more than two months in 3 (8.6%) patients (Table 1).

Table 1. The clinical outcomes of the patients.

Family history	
Family history of patients diagnosed with immunedeficiency	40% (n=14)
Consanguineous marriage	71.4% (n=25)
Physical examination	
Hepatomegaly	17.1% (n=6)
Splenomegaly	14.3% (n=5)
Lymphadenopathy	42.9% (n=15)
Growth retardation	71.4% (n=25)
System involvement	
Bronchiectasis	31.4% (n=11)
Bone-joint involvement	2.9% (n=1)
Gastrointestinal system involvement	34.3% (n=12)
Endocrine system involvement	5.9% (n=2)
Neurologic involvement	11.4% (n=4)
Recurrent infections	
Upper respiratory infection	45.7% (n=16)
Sinusitis/otitis	22.8% (n=8)
Pneumonia	14.3% (n=5)
Sepsis/meningitis	8.6% (n=3)

When the complete blood count parameters at hospital admission were evaluated, it was observed that 6 (17.1%) of 35 patients had leukopenia, 7 (20%) had neutropenia, 7 (20%) had lymphopenia, and 7 (20%) had anemia.

When evaluated in terms of the effectiveness of the treatment on the frequency of infection, 1 (2.9%) of 35 patients had a history of infection 4-6 times a year, 15 (42.9%) had a history of infection 7-10 times a year, and 19 (54.3%) had a history of infection more than ten times a year before intravenous immunoglobulin treatment. After treatment, the frequency of infection was 1-3 times a year in 35 patients (100%). There was a statistically significant decrease in the frequency of infection after intravenous immunoglobulin treatment ($p<0.001$) (Table 2).

Table 2. Immunoglobulin values pretreatment and posttreatment (mg/dL).

	Median
IgG (Pre-Treatment)	224
IgG (Post-Treatment)	510
p	<0,001

Immunoglobulin G values according to age were low in 31 (88.5%) patients before treatment. The median IgG values were 224 mg/dL. Immunoglobulin A values according to age were low in 10 (28.5%) patients. Median IgA values were 30 mg/dL (0-467). Immunoglobulin M values according to age were low in 15 (42.8%) and high in 3 (0.08%) patients. The median IgM values were 26 (5-1013). IgE elevation was present in 9 patients (25.7%). The median IgE values were 17 (1-6060) (Table 3).

Side effects observed within the first six hours of infusion were recorded in 4 cases (11.4%). Chills, headache, vomiting, convulsions, fever, and respiratory distress were prominent.

Table 3. Immunoglobulin values pretreatment (mg/dL).

	Median	Minimum	Maximum
IgG	224	25	1339
IgA	30	0	467
IgM	26	5	1013
IgE	17	1	6060

DISCUSSION

The incidence of patients diagnosed with primary immune deficiency varies between 1/10,000 and 1/100,000 in developed countries. Although the incidence of these diseases is not fully known in our country, where consanguineous marriages are common, it is expected that diseases with autosomal recessive transmission will be more common (5).

In our study, when 35 cases were followed up in 5 years (2010-2015) and evaluated with a primary immune deficiency diagnosis, the male gender distribution was 62.9%, which constituted most of the patients. In the study conducted by Yorulmaz et al. (6) in Konya, similar to our data, 61.4% of the patients with primary immune deficiency were male. In our study, 14 out of 35 cases (40%) had a family history of patients diagnosed with immune deficiency, and 25 (71.4%) had consanguineous marriage. The importance of a history of consanguineous marriage and genetic factors in the etiology of immune deficiency was emphasized. In the study conducted by Yorulmaz et al. (6), similar rates of consanguineous marriage were shown (37.5%). When the studies conducted in countries where consanguineous marriages are common were scanned from the literature, the rate of consanguineous marriage varied from 17.8% in China to 80% in Egypt (7,8).

There were signs of growth and developmental delay in 25 cases (71.4%). Hausser et al. (9) reported that growth and developmental delay were secondary to chronic diseases in seven out of 30 patients (23%). In another study conducted in our country, Yüksek et al. (10) found that the prevalence of growth and developmental delay in patients with primary immune deficiency was 78.8%, similar to our study. Growth and developmental delay are thought to be due to chronic diseases and infections.

In our study, 21 (60%) of 35 patients receiving regular intravenous immunoglobulin treatment had common variable immune deficiency, 6 (17.1%) had severe combined immune deficiency, 3 (8.6%) had ataxia telangiectasia, 3 (8.6%) had hyperimmunoglobulin M syndrome, and 2 (5.7%) had Bruton agammaglobulinemia. Patients diagnosed with transient hypogammaglobulinemia were excluded from the study because they did not receive regular intravenous immunoglobulin treatment. According to ESID data, the prevalence of significant diseases related to genotype in immune deficiencies is 11% for severe combined immune deficiency, 31% for common variable immune deficiency, 6.7% for transient hypogammaglobulinemia, 9% for IgA deficiency, 7% for phagocytic system disorder, and 1% for complement deficiencies (11). In a study conducted in our clinic, Sütçü et al. (12) showed that 54 (10.7%) of 507 patients with a history of recurrent infection were diagnosed with primary immune deficiency, 43 (80%) of these patients had primary antibody deficiency, 8 (14.8%) had combined immune deficiency, and 3 (5.5%) had congenital phagocytosis defects.

When evaluated in terms of system involvement, 11 (31.4%) of the cases had bronchiectasis, 1 (2.9%) had bone and joint involvement, 12 (34.3%) had gastrointestinal system involvement, 2 (5.9%) had endocrine system involvement, and 4 (11.4%) had ataxia, and 1 (2.9%) had a history of meningitis in terms of neurological involvement. The patient with a history of meningitis was diagnosed after being examined with suspicion of immune deficiency due to the disease he had. A history of meningitis should be evaluated as a clue to immune deficiency diseases.

Severe, recurrent lung infections can cause permanent dilatation and scarring of the bronchi, a chronic condition called bronchiectasis (13). Our study included bronchiectasis as a chronic complication in respiratory system involvement. In previous studies, bronchiectasis development was between 26% and 53%, similar to our cases (14,15).

In various publications, gastrointestinal system involvement is between 20% and 47% in patients with primary immune deficiency, most of which were evaluated as gastroenterological diseases. This was found to be consistent with our cases. However, since most patients with gastrointestinal symptoms are not investigated endoscopically, the true incidence is not known (16).

Central nervous system involvement is reported to be between 2% and 6% in the literature for meningitis development, and in our study, meningitis development was seen at lower rates. In publications, it has been stated that the most critical risk factor for meningitis development is delay in diagnosis and treatment (16).

Skeletal system infections were seen in 2.9% of our cases. Compared with the literature (1-7%), it was consistent with our cases (16). When evaluated in terms of hepatosplenomegaly, although there is no definitive data in the literature on primary immune deficiencies, it is between 6-17% in patients with common variable immune deficiency, 34-56% in chronic granulomatous disease, and when the two diseases were evaluated together, it was found to be 28% (17-19).

In our study, when the blood count parameters of the patients were evaluated at the time of admission, it was seen that 6 (17.1%) of 35 patients had leukopenia, 7 (20%) had neutropenia, 7 (20%) had lymphopenia, and 7 (20%) had anemia. In the study conducted by Yorulmaz et al. (6), these rates were determined as 4.7% lymphopenia, 4.7% neutropenia, and 31.3% anemia. In another study, in which

patients with suspected immune deficiency under the age of five were compared with patients with immune deficiency, lymphopenia was found to be 15%, and Neutropenia was found to be 10.6% in the immune deficiency group, while lymphopenia was found to be 4.4%, and neutropenia was found to be 2.6% in the other group (20). In the largest case series in England, hematological complications were reported in 39% of patients with common variable immune deficiency and 18% of patients with Bruton's disease. Lymphopenia was found in 21% of patients with common variable immunodeficiency and 11% of patients with Bruton's disease (16). Lymphopenia may be a clue to combined immunodeficiency; leukocytosis, leukocyte adhesion defect (LAD); thrombocytopenia, Wiskott-Aldrich syndrome and hyperimmunoglobulin M syndrome; neutropenia, some combined immunodeficiencies, X-linked agammaglobulinemia and congenital neutropenias; and eosinophilia, hyperimmunoglobulin E syndrome (12). Side effects were observed during infusion in 4 cases (11.4%). Compared with the literature, Struff et al. (21) evaluated 15,548 infusions administered to 1,705 patients in 72 centers with the same preparation and found systemic side effects were seen in 10 patients (0.6%). In a similar study, Brennan et al. (22) reported systemic reactions in 59 patients (13%) in 13,508 infusions administered to 459 patients in 4 centers. Another study by Nain et al. (23) reported systemic reactions in 18 patients (6,2%) in 290 infusions administered to 65. They noted that delayed headache was prevalent in 34% of patients (24). Systemic side effects have been reported at various rates (0.6%-26%) in the literature, and a similar rate (11.4%) was found in our study.

CONCLUSION

In conclusion, diagnosis of primary immune deficiency is important to have a family history and signs of frequent recurrent infections. Growth and developmental delays are frequently seen in these patients. Patients with a history of meningitis, in particular, should be screened for immune deficiency. Early diagnosis and treatment are very important due to the high mortality and morbidity rates due to chronic respiratory system, gastrointestinal system, and neurological system involvement, and the decrease in the frequency of infection with regular IVIG treatment. There are no common, definite, and serious side effects that limit its use, but caution should be taken in terms of possible side effects.

DECLARATIONS

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