The Safety and Efficacy of Subcutaneous Immunoglobulin for Treatment Naïve Primary Immunodeficient Patients

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Background

Primary immunodeficiency (PI) is a group of over 400 conditions in which parts of the immune system are absent or dysfunctional. Patients with PI are at risk of severe, life-threatening infections that can lead to organ damage and decreased quality of life.

Immunoglobulin (Ig) replacement therapy is a safe and effective treatment for patients with PI and can be administered subcutaneously (SCIg) or intravenously (IVIg) based on patient specific factors. Guidelines for management of PI support serum immunoglobulin G (IgG) levels ≥ 500 mg/dL to protect against infections.[1] Historically, patients starting Ig replacement therapy require a loading dose of IVIg before transitioning to SCIg maintenance doses to achieve stable serum levels.[2]

Purpose

The purpose of this study is to determine the efficacy and safety of subcutaneous SCIg as an at-home maintenance regimen for patients with PI who are naive to Ig replacement therapy.

Methods

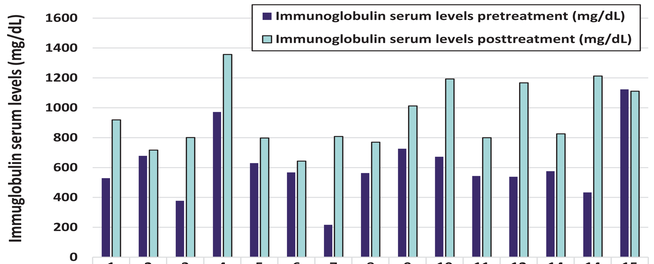
This retrospective chart review included PI patients initiated on SCIg therapy weekly maintenance doses between March 01, 2020, and July 31, 2022. In the study, no patients received a loading dose of SCIg or IVIg. The primary outcome was IgG serum levels ≥ 500 mg/dL and the occurrence of infection as documented in electronic medication records.

Data on antibiotic use for infection treatment, hospitalizations, and adverse events were collected and analyzed using descriptive statistics (frequency and percentage). Exclusion criteria included patients who had previously received Ig therapy (IVIg, SCIg).

Table 1: Summary of Patient Population

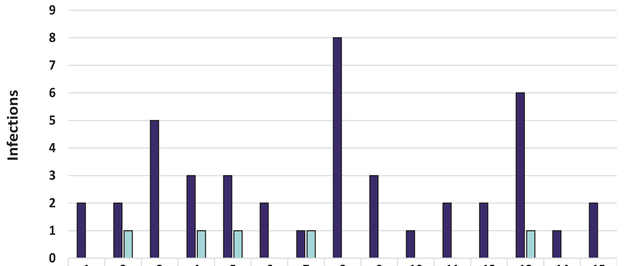
Gender (n= 15)	
Female	9 (60%)
Male	6 (40%)
Age Range (years) (n= 15)	
0-20	4 (26%)
20-40	3 (20%)
40-60	4 (26%)
60-80	4 (26%)
Diagnosis (n=15)	
Antibody immunodeficiency	4 (26%)
Common variable immunodeficiency	4 (26%)
X-linked agammaglobulinemia	2 (13%)
Selective deficiency of IgG	2 (13%)
NEMO deficiency	1 (6%)
Nonfamilial hypogammaglobulinemia	1 (6%)
Specific antibody deficiency	1 (6%)

Figure 1: Pre-treatment vs Post-treatment Immunoglobulin Serum Levels



Patients	1	2	3	4	5	6	7	8	9	10	11	12	14	14	15
Immunoglobulin serum levels pretreatment (mg/dL)	529	678	378	972	630	567	217	563	726	672	543	538	576	433	1123
Immunoglobulin serum levels posttreatment (mg/dL)	919	717	801	1357	798	643	808	770	1012	1193	800	1167	826	1212	1111

Figure 2: Pre-treatment vs Post-treatment Infections Per Year



Patients	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Pretreatment infections per year	2	2	5	3	3	2	1	8	3	1	2	2	6	1	2
Posttreatment infections per year	0	1	0	1	1	0	1	0	0	0	0	0	1	0	0

Results

Charts of 15 patients aged 6 to 72 years old were assessed *(Table 1)*. Fifteen patients received a 20% SCIg product at a mean maintenance dose of 503.6 mg/kg/month (range, 3 to 20 grams). Mean pre-treatment IgG serum levels were 610 mg/dL (range, 217 mg/dL-1123 mg/dL) *(Figure 1)*. Seven patients required a dose increase 3-6 months after start of care (SOC). Mean posttreatment IgG serum levels were 1018 mg/dL (range, 717 mg/dL-1772 mg/dL) *(Figure 1)* which were collected on average are 11 months after SOC.

There were 43 pretreatment infections and 5 posttreatment infections per year which required antibiotic therapy *(Figure 2)*. Infections documented were sinusitis, pneumonia, and otitis media. During the study period, there were two hospitalizations due to infection (pneumonia and a urinary tract infection). Four patients experienced local site reactions (nodules and/or mild pain), a known side effect of SCIg. One patient developed a needle phobia; however, no adverse reactions lead to the discontinuation of treatment.

Discussion

During the study period, fifteen patients achieved IgG levels > 500 mg/dL. Fourteen patients experienced a decrease in infections after initiating SCIg. Limitations of this study include a small sample size and reliance of electronic documentation on occurrence of infections and adverse event data.

Conclusions

There is limited data regarding initiation of SCIg at a maintenance dose without prior immunoglobulin therapy in patients with PI. SCIg offered at a maintenance dose may be a safe and effective initial therapy in PI patients who are treatment naïve as shown by a decrease in infections and increased clinical response in this study.

References

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[2] Kobrynski L. Subcutaneous immunoglobulin therapy: a new option for patients with primary immunodeficiency diseases. Biologics. 2012;6:277-87. doi: 10.2147/BTT.S25188. Epub 2012 Aug 24. PMID: 22956859; PMCID: PMC3430092

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Ashlee BeGell; Matthew Morris; Maria Giannakos; Julia Huebner. Nothing to disclose.