"Enhancing Drug Adherence and Patient Outcomes: The Role of SCIg Pump Selection in Subcutaneous Immunoglobulin Therapy for Primary Immunodeficiency Disease"

Brent Rutland, MPH, MBA, Jasmin Bosshard, MS and Carleton Southworth, MS
KORU Medical Systems

Aim

This paper aims to give an overview and an evaluation of adherence to therapy rates of PID patients who receive exclusively SCIg treatment with using a mechanical pump in the underlying observation period.

Introduction

Primary immunodeficiency disease (PID) requires lifelong replacement therapy with immunoglobulin (IG) to reduce infection risk and maintain health. Without lifelong immunoglobulin therapy, PID patients are subject to elevated risk of serious infections and death. Administration routes include intravenous (IV) and subcutaneous (SC) delivery. Recent literature indicated that there is a trend toward SC delivery over IV delivery.

Subcutaneous immunoglobulin therapy is easier to administer at home than IV immunoglobulin therapy. Moreover, the adverse event rate associated with SC therapy is superior to the adverse event rate (and severity) associated with IV therapy. In addition, patients typically score higher on quality-of-life measures with SC when compared to IV therapy. Convenience, the ability to self-schedule, and the ability to avoid travel and to avoid school or work interference are often cited as reasons for preferring SC to IV therapy.

Study Overview

No prescribed therapy is likely to be efficacious where compliance is poor. Compliance to the prescribed subcutaneous immunoglobulin (SCIg) therapy protocol is vital to ensure better long-term outcomes for patients with PID. Accordingly, information regarding patient compliance to SC therapy is needed. This study is designed to address this information gap.

Methodology

A Specialty Pharmacy captured drug receipts for 23,955 US patients receiving immunoglobulin therapy, for a wide variety of indications. Of these, 11,213 were PID patients. PID patients included icd_10_1 codes from D80.0 through 83.9. Administration modes included SCIg or IVIg therapy. Data were collected from January 2019 to July 2023.

Data captured included a unique patient identifier, demographics (including age and gender), diagnoses, administration routes, drug delivery dates, and pump devices used. The prescribed dose and dose frequency were also captured. Mean volume of drug was also captured for some patients. Where applicable, means and standard deviations were tabulated.

This analysis focuses on PID patients receiving SCIg therapy, that used Koru pumps (FREEDOM60® and FreedomEdge) exclusively. Short-term compliance to SCIg therapy was calculated using drug shipment delivery dates.

Results

Among the observed patients, 6,553 (58.4%) received exclusive SCIg therapy. Of these SCIg patients, 3,787 (57.8%) had documented pump information.

The most common diagnoses were (1) Common variable immunodeficiency, unspecified (ICD D83.9, 31.4%) and (2) Nonfamilial hypogammaglobulinemia (ICD D80.1, 29.2%). All other ICD codes represented less than 10% of included patients.

ICD 10 Code / Diagnosis			
Description (SHORT DESCRIPTION (VALID ICD-10 FY2024*))	**ICD 10**	**Count**	**%**
Hereditary hypogammaglobinemia	D80.0	52	1.7
Nonfamilial hypogammaglobinemia	D80.1	890	29.2
Selective deficiency of immunoglobulin A [IgA]	D80.2	13	0.4
Selective deficiency of immunoglobulin G [IgG] subclasses	D80.3	209	6.9
Selective deficiency of immunoglobulin M [IgM]	D80.4	21	0.7
Immunodeficiency with increased immunoglobulin M [IgM]	D80.5	13	0.4
Antibody defic w near-norm immunoglob or w hyperimmunoglob	D80.6	297	9.7
Transient hypogammaglobulinemia of infancy	D80.7	2	0.1
Other immunodeficiencies with predominantly antibody defects	D80.8	58	1.9
Immunodeficiency with predominantly antibody defects, unsp	D80.9	32	1.1
Severe combined immunodeficiency with reticular dysgenesis	D81.0	1	0.0
Severe combined immunodeficiency w low T- and B-cell numbers	D81.1	3	0.1
Severe combined immunodeficiency w low or normal B-cell numbers	D81.2	1	0.0
Other combined immunodeficiencies	D81.89	7	0.2
Combined immunodeficiency, unspecified	D81.9	24	0.8
Di George's syndrome	D82.1	2	0.1
Hyperimmunoglobulin E [IgE] syndrome	D82.4	1	0.0
Immunodeficiency associated with oth major defects	D82.8	1	0.0
Com variab immunodef w predom abnlt of B-cell nums & functn	D83.0	181	5.9
Com variab immunodef w predom immunoreg T-cell disorders	D83.1	5	0.2
Common variable immunodef w autoantibodies to B- or T-cells	D83.2	8	0.3
Other common variable immunodeficiencies	D83.8	269	8.8
Common variable immunodeficiency, unspecified	D83.9	957	91.4

Mean age was 50.1 years. Mean time on therapy was 983 days. Age range was 1 to 80+ years. Deliveries of SC therapy grew steadily from 2019 through 2023.

Demographics	
N	3,047
Mean Age, Years (Std. Dev.)	50.1 (21.0)
Gender F/M/U	2,144/ 902/ 1
F: Mean Age, Years (Std. Dev.)	54.3 (19.2)
M: Mean Age, Years (Std. Dev.)	40.2 (24.4)

Patients using the studied pumps refilled their SCIg prescription every 31.4 days on average. Each delivery was validated prior to shipment by the patient or their caregiver. Considering the Gregorian calendar's mean month length of 30.44 days, short-term adherence to SCIg therapy with the studied pump was calculated at 97%.

Frequencies of Delivery	
N (Receipts, Patients > 2)	79,794 / 3,021
Mean Number of deliveries per patient (Range)	26.4 (1;100)
Mean Time between two deliveries, Days (Std. Dev.)	31.4 (9.4)

Number of Deliveries, Mean Frequency (Days)			
Total Deliveries	**Days**	**Patients**	**%**
1 - 9	32.8	632	20.7
10 - 19	32.2	665	21.8
20 - 39	31.5	1065	35.0
40 - 59	29.6	580	19.0
60 - 79	27.2	103	3.4
80 - 100	16.8	2	0.1

Discussion

This study provides data on short-term adherence to treatment with SCIg. The large dataset suggests that patients and caregivers accept this treatment. Previous studies show that patients prefer SCIg over IV and that the switch improves quality of life. The study's limitations include limited variables and lack of clinical performance and adverse event analysis. However, previous data support switching to SCIg due to its favorable adverse event profile and patient preference for home administration, improving quality of life. PID patients on IV therapy could benefit from switching to SCIg.

Conclusion

This study showed that a significant portion of patients received SCIg therapy using the pump of study, indicating the vital role of these pumps in supporting SCIg therapy. SCIg patients with PID refilled their prescriptions every 31.4 days on average. Short-term adherence to SCIg therapy with the studied pump was calculated at 97%, indicating high compliance. These findings suggest that pumps effectively support SCIg therapy and contribute to high compliance rates.