Real-World Observations on Symptom Response and Tolerability of Intravenous Immunoglobulin in Patients with Inflammatory Myopathies through a Nurse-Led Outcomes Monitoring Program in a Home Infusion Setting

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CSI CLINICAL SPECIALTY INFUSIONS

BACKGROUND

Home infusion is an alternative site of care for rheumatology patients requiring the administration of medications, like immunoglobulin (Ig) therapy in a setting outside of a hospital, medical facility or outpatient infusion center.

This service is supported by specialty pharmacies and home infusion companies with care provided by professionals who have obtained additional training.[1,2]

Administering infusions in the home setting reduces time away from everyday activities, such as work and school, offering a safe and effective alternative to traditional infusion settings, as well as offering potential cost savings.[3,4]

The range of treatments offered in the home setting continues to increase, as quality of life benefits and improved clinical outcomes continue to be demonstrated.[5]

Idiopathic inflammatory myopathies (IIM) are autoimmune diseases typically characterized by muscle weakness. Intravenous Immunoglobulin (IVIg) is an effective immunomodulatory therapy in patients with refractory IIM[6,7,8]. However, data is limited regarding trajectory of patient reported symptom response and tolerability of IVIg among patients with IIM.

PURPOSE

This study aims to report the symptom change and treatment tolerance of IVIg naïve adults with IIM through implementation of a structured outcomes monitoring program within a home infusion and specialty pharmacy model.

METHODS

As part of the proprietary CSI Pharmacy Clinical Outcomes 360℠ program, offered by a national home infusion and specialty pharmacy, a clinical care and patient-reported outcomes monitoring program was developed by a multidisciplinary team within the IIM patient population.

Patients with confirmed IIM diagnosis who were IVIg treatment naïve and had ≥2 IVIg infusions, were recruited between 5/2024–8/2025.

Patients also responded to anchor questions regarding their symptoms.

All data was collected by home infusion nurses prior to each IVIg infusion and adverse drug reactions (ADRs) were identified through pharmacist-led patient interviews and review of nursing infusion documentation.

Descriptive statistical analyses were conducted to summarize key findings.

DISCUSSION

IVIg appears safe and beneficial for IIM patients receiving home therapy.

Nearly half reported symptom improvement within one month, with continued benefits over multiple infusions.

The monitoring program provided valuable insights into IVIg treatment response, reinforcing its safety and tolerability.

No severe ADRs occurred and mild side effects were reported within expected incidence rates.

RESULTS

The program integrated clinical safety assessments and structured collection of patient symptoms via Health Assessment Questionnaire (HAQ), Patient Global Disease Activity (PTGD), Patient-Reported Outcomes Measurement Information System (PROMIS®) Physical Function (v2, 8b), Fatigue (v1, 7a), and Pain Interference (v1.1; 6a), and Brief Pain Inventory (BPI) as well as anchor questions regarding their symptoms.

Figure 1a. Patient Demographics

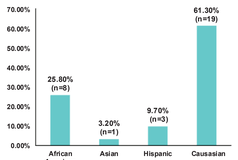


Figure 1b. Patient Demographics

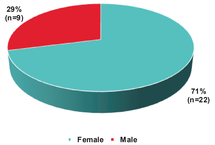


Figure 1c. Patient Demographics

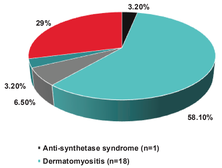


Table 1. Patient Demographics

Variable	Home Infusion IVIg Therapy Patients (n =31) n (%)
Age, Median (Range)	
Median (Range)	47 (11-80)
11-17	1 (3.2%)
18-44	9 (29%)
45-64	10 (32.3%)
65-74	8 (25.8%)
>75	3 (9.7%)
# of Visits	
Total	193
Median (Range)	4 (2-12)
1	31 (100%)
2	31 (100%)
3	27 (87.1%)
4	23 (74.2%)
5	22 (71%)
6	19 (61.3%)
7	11 (35.5%)
8	8 (25.8%)
9	8 (25.8%)
10	7 (22.6%)
11	3 (9.7%)
12	3 (9.7%)
Length of Diagnosis to 1st Infusion of IVIg Treatment, (Years)	
Median (Range)	1 (<1 - 40)
0-4	19 (61.3%)
5-9	5 (16.1%)
10-14	3 (9.7%)
15-19	2 (6.5%)
30-34	1 (3.2%)
35-40	1 (3.2%)
Disease Characteristics Present	
Muscle	28 (90.3%)
Muscle Weakness	28 (90.3%)
Muscle Pain	22 (71.0%)
Joint	20 (64.5%)
Joint Pain	18 (58.1%)
Joint Swelling	16 (51.6%)
Skin	21 (67.7%)
Rash	20 (64.5%)
Blood Circulation	6 (19.4%)
Raynaud Phenomenon	6 (19.4%)
Lung	17 (54.8%)
Difficulty Breathing	18 (58.1%)
Pulmonary Arterial Hypertension	2 (6.5%)
Oxygen Use at Home	1 (3.2%)
Interstitial Lung Disease/Pulmonary Fibrosis	2 (6.5%)

Figure 2. Patient Global Disease Activity

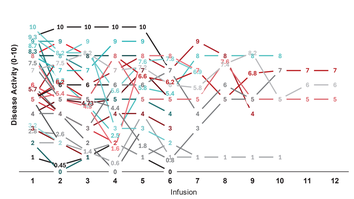


Figure 3. Health Assessment Questionnaire

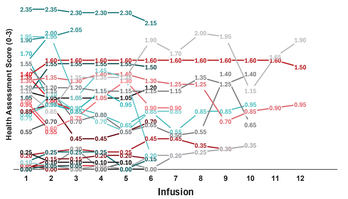


Figure 4. BPI Pain Severity

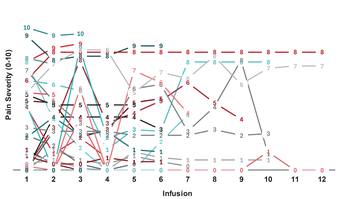


Table 2. Adverse Drug Reactions During IVIg Infusions

Adverse Reactions	1st IVIg	2nd IVIg	3rd IVIg	4th IVIg	5th IVIg	6th IVIg	7th IVIg	8th IVIg	9th IVIg	10th IVIg	11th IVIg	12th IVIg	Totals
Mild													
Headache	12	11	4	1	2	2	1		1	4	2	2	42
Fever	2	2		1			1		1			1	8
Nausea	3	3				1							7
Rash	2		1				1	1		2			7
Body Aches	1	1	1			1				2			6
Tingling	2	2	1									1	6
Dizziness	1	1								2			4
Itching	1	1	1			2							5
Chills	1	2		2									5
Fatigue	1	2											3
Diarrhea	2				1								3
Pain		1				1							2
Insomnia					1	1							2
Swelling				1									1

*23 out of 31 patients reported at least 1 ADR during an IVIg infusion

Figure 5. PROMIS Fatigue

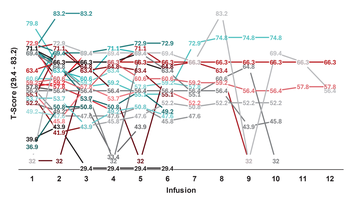


Figure 6. PROMIS Pain Interference

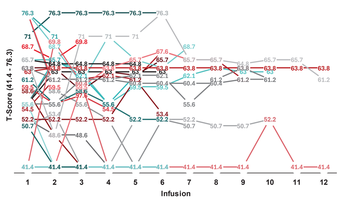


Figure 7. PROMIS Physical Function

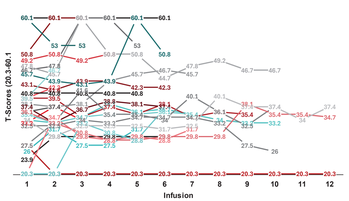


Figure 8. Median Creatine Kinase (CK) Levels (Visits 1-9)

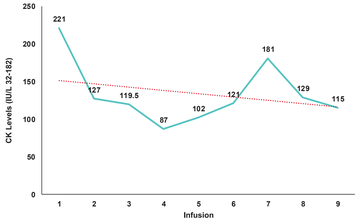
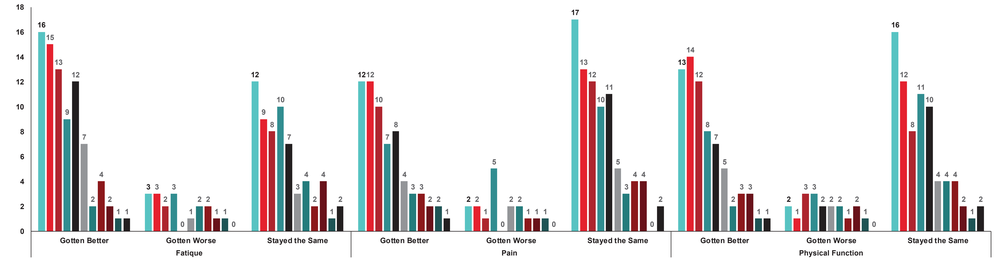


Figure 9. Symptoms Based Anchor Response Questions



CONCLUSION

This study demonstrated IVIg-naïve IIM patients can be effectively monitored through a nurse-led, structured outcomes program which could represent a scalable approach for managing complex immunotherapy in decentralized environments.

Approximately half of the patients reported improvement after one IVIg infusion.

Symptomatic improvement and lack of serious ADRs suggest that IVIg is well tolerated and may offer meaningful benefits to patients with IIM.

Further studies with larger sample sizes and extended follow-up intervals are necessary to assess long-term efficacy and tolerability.

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The authors have no conflicts of interest or disclosures to report related to this project.

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