Dosing, Side Effects, and Long-Term Outcomes for IVIg Use in Treatment of Neurological Conditions: Data from the Immunoglobulin Diagnosis, Evaluation, and Key Learnings (IDEaL) Patient Registry

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Introduction

Long-term outcomes and patient-reported quality-of-life assessments are not widely available for patients on immunoglobulin (Ig) therapy for various disease states. The IDEaL Patient Registry collects longitudinal information on patients receiving Ig therapy from Coram CVS/specialty infusion services in an alternate care setting, primarily in the home. Patients from our 140 investigators are eligible to enroll in the Registry. For this study, we examined the neurology patient population.

Methods

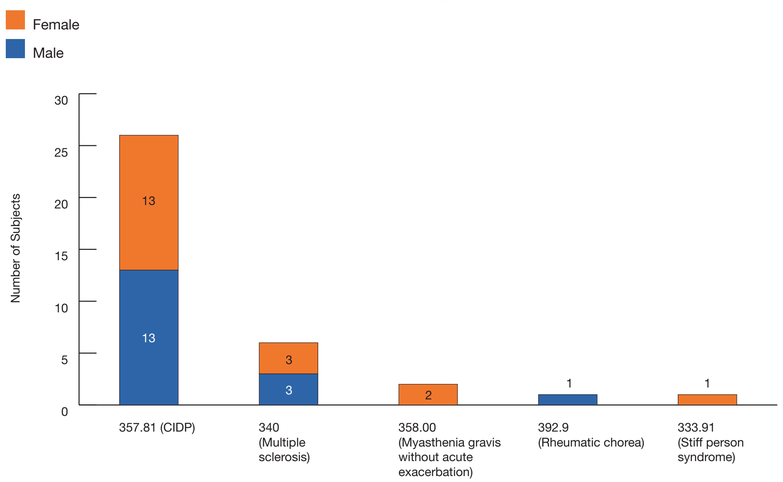
IRB approval was obtained, and informed consent was received from all patients. Information collected by Coram nurses and pharmacists was entered into the IDEaL database. Additionally, every six months, patients were asked to complete: an SF-36 questionnaire; a neuropathy symptom assessment including an overall disability sum score (ODSS) assessment and a visual analog scale (VAS) pain assessment; and a Life Quality Index Questionnaire (LQIQ).

Results

Patient Demographics and Diagnosis

As of spring 2015, the IDEaL Registry had 36 patients with neurological diagnoses enrolled. The majority of our patients (72%) were diagnosed with chronic inflammatory demyelinating polyneuropathy (CIDP), with other diagnoses including multiple sclerosis, myasthenia gravis, and stiff person syndrome. See Figure 1.

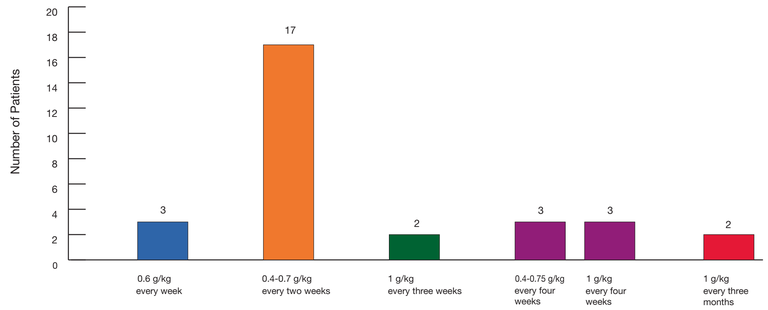
Figure 1. *Disease State and Gender Breakdown of Neurological Patients*



Dosing

IVIg dosing for these patients was extremely variable. For CIDP patients, we noted six distinct dosing patterns across 24 patients. The most common was 0.5 mg/kg every two weeks, equal to between 30–60 grams per infusion. See Figure 2.

Figure 2. *CIDP Dosing Schedules: Mg/kg and Frequency*



Pain and Disability Scores

Patient pain ratings for upper and lower extremity pain were assessed using a VAS scale. At both baseline and six-month time points, patients reported more pain in lower extremities than in upper extremities (baseline: 4.7 versus 2.1; six months: 3.7 versus 1.6). See Figure 3. Pain scores did show a trend toward decreasing while on treatment, though neither upper nor lower extremity changes reached significance (P=0.7 UE, P=0.5 LE).

Figure 3. *VAS Pain Scores: Upper and Lower Extremities*

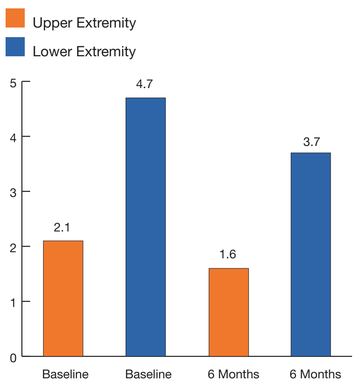
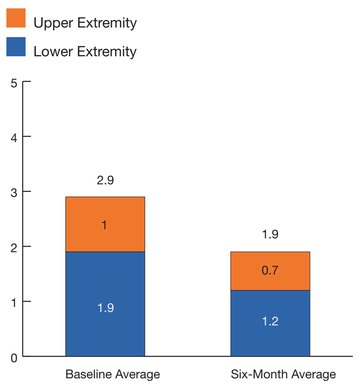


Figure 4. *ODSS Disability Scores: Baseline and Six-Month Upper and Lower Extremity Averages*



ODSS disability scores were also collected via patient report and scored at baseline and subsequent six-month intervals. At baseline, the UE disability score average was 1.0, and the LE score average was 1.9; the total ODSS average at baseline was 2.9. At the six-month follow-up time point, the ODSS UE average was 0.7, and the LE average was 1.2, for a total ODSS average of 1.9. See Figure 4. While not significant (P=0.35), there was a trend toward a lower disability index. Overall, we saw more patients with a higher degree of lower extremity disability than upper extremity disability, mirroring the VAS pain score distributions.

Health Status and Side Effects

Patients were asked to rate their current health compared to one year ago at six and 12 months post start of treatment. Overall, at both time points, the majority of patients reported improved health, or no declines in health (80% positive or no decline at six months, 100% positive or no decline at 12 months). See Figure 5.

The majority of patient monthly progress reports noted no side effects of IVIg administration (90%, 150/167). For those reporting side effects, among the most common were headaches and flu-like symptoms, which were reported in approximately 6% of monthly progress reports (10/167). Skin reactions, such as bruising and rash, were also documented in 3% of our monthly progress notes (5/167). See Figure 6.

Figure 5. *Health Transition Index: Health at Time Point Compared to One Year Prior*

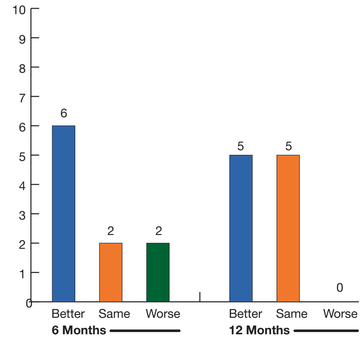
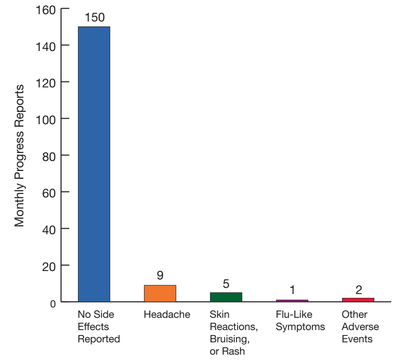


Figure 6. *Monthly Progress Reports: Side Effects*



Conclusions

- IVIg is used in the treatment of a variety of immune-mediated neurological conditions, but mostly in immune-mediated neuropathies, such as CIDP.
- IVIg dosing in CIDP patients is extremely variable, both in terms of grams as well as frequency of administration.
- In general, patients reported greater amounts of pain and disability in the lower extremities than in the upper extremities.
- During patients' first six months of IVIg treatment, both pain and disability scores showed a non-significant trend toward improvement.
- Quantitative scores showed a trend toward improvement, and patient self-reports showed that they felt their health was improving, or no longer declining, at both the six- and 12-month time points post start of infusion.
- Patients reported few side effects, and those that were reported were generally mild, such as headache and flu-like symptoms. No significant adverse events were reported in this cohort.

Overall, we noted that neurology patients receiving IVIg reported beneficial effects, and that side effects were not a significant issue. As the IDEaL Registry enrolls more neurology patients and follows them for longer time periods, we will be able to determine whether the positive treatment effect trends reach significance, and what the long-term outlook for these patients on IVIg treatment might be.