Poster 113

Real-world Safety Assessment of Treatment of Chronic Inflammatory Demyelinating Polyneuropathy with Subcutaneous IgPro20

Victoria Divino,[1] Rajiv Mallick,[2] Betsy J. Lahue,[3] Katharine B. Coyle,[1] Yi Wang,[1] Mitch DeKoven,[1] Alphonse Hubsch[4]

1. IQVIA, Falls Church, VA, USA
2. CSL Behring, King of Prussia, PA, USA
3. Alkemi LLC, Manchester Center, VT, USA
4. CSL Behring, Bern, Switzerland

Introduction

- Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare disorder of the peripheral nervous system.[1]
- Intravenous immunoglobulin (IVIg) is recommended as a first-line treatment in CIDP.[2] Subcutaneous immunoglobulin (SCIg) is a recommended maintenance treatment.
- Hizentra® (Immune Globulin Subcutaneous [Human], 20% Liquid; IgPro20) was the first approved SCIg for CIDP maintenance therapy in the US.[3] In the Polyneuropathy and Treatment with Hizentra® study (PATH), IgPro20 was associated with a relatively low rate of adverse effects compared to IVIg.[4]
- Real-world data on safety outcomes in patients with CIDP treated with IgPro20 are limited.

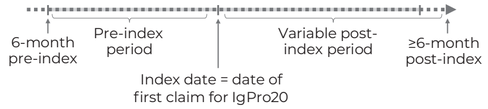
Objective

This study evaluated real-world safety outcomes in patients with CIDP treated with IgPro20 stratified by prior use of IVIg.

Methods

- A retrospective analysis was conducted using linked data in the US.
  - IQVIA's Professional Fee Claims (Dx), Longitudinal Prescription Claims (LRx), Hospital Charge Data Master (CDM), and Ambulatory EMR (AEMR) databases.
- Adults newly diagnosed with CIDP (ICD-9-CM 357.81; ICD-10-CM G61.81; SNOMED 128209004, 444728005, 230564004) from 1/2015 – 11/2021 were initially identified (date of first claim = *diagnosis date*).
  - Patients were required to have a second CIDP diagnosis ≥90 days after the diagnosis date.
  - Eligible patients initiated IgPro20 90-days prior to the diagnosis date or after (See **Figure 1**).
  - Patients had ≥1 post-index claim for IgPro20.

Figure 1. Study Design



6-month pre-index
- Pre-index period to assess patient demographics, clinical characteristics and safety events

Variable ≥6-month post-index
- Post-index period to assess safety events

SAFETY OUTCOMES

- Thirty safety outcomes (see **Table 2**), considered relevant from an immunoglobulin and/or infusion process perspective, were evaluated over the 6-month pre-index and available post-index (until first occurring of: IgPro20 discontinuation, switch, or end of the variable post-index).
- For each safety outcome, number of unique events per person-month was assessed.

ANALYSES

- Patients were stratified into two cohorts based on prior use of IVIg.
- Patient characteristics were compared between cohorts using Chi-square test and independent sample t-test.
- Within a cohort, event rate per person-month for each safety outcome was compared between the 6-month pre-index and the available post-index using univariate Poisson generalized estimating equation (GEE) models.
- p<0.05 was considered statistically significant.

Results

- The final sample comprised 203 patients initiating IgPro20. The majority (n=121; 59.6%) had prior IVIg use.
- Patients with prior IVIg use had lower mean age and Charlson Comorbidity Index (CCI) score, but higher proportion with neuropathic pain compared to those without prior IVIg use (see **Table 1**).

Table 1. Patient Characteristics

Characteristics	With prior IVIg (N=121)	Without prior IVIg (N=82)	p-value
Mean (SD) age, years	54.4 (14.9)	60.2 (18.0)	**0.0131**
Female, n (%)	70 (57.9)	47 (57.3)	0.9398
Medicare/Medicare Part D Payer, n (%)	16 (13.2)	29 (35.4)	**0.0002**
Neurology specialty at index, n (%)	30 (24.8)	22 (26.8)	0.7444
Mean (SD) CCI score	0.9 (1.6)	1.6 (2.3)	**0.0044**
Comorbidities of interest, n (%)			
Back pain	20 (16.5%)	20 (24.4%)	0.1671
Chronic acquired polyneuropathies	24 (19.8%)	18 (22.0%)	0.7149
Chronic pain	12 (9.9%)	8 (9.8%)	0.9698
Diabetic neuropathy	8 (6.6%)	6 (7.3%)	0.8457
Guillain-Barré syndrome	12 (9.9%)	6 (7.3%)	0.5225
Idiopathic small fiber neuropathy	6 (5.0%)	5 (6.1%)	0.7593
Neuropathic pain	105 (86.8%)	49 (59.8%)	**<0.0001**
Therapies of interest, n (%)			
Anti-convulsants	56 (46.3%)	40 (48.8%)	0.7263
Central muscle relaxants	20 (16.5%)	19 (23.2%)	0.2385
Corticosteroids	49 (40.5%)	30 (36.6%)	0.5750
NSAIDs	26 (21.5%)	17 (20.7%)	0.8971
Opioids	45 (37.2%)	34 (41.5%)	0.5400
Immunosuppressants[1]	55 (45.5%)	35 (42.7%)	0.6965
Plasma exchange	2 (1.7%)	2 (2.4%)	1.0000
Rituximab	1 (0.8%)	0 (0.0%)	1.0000

1. Azathioprine, corticosteroids, cyclophosphamide, cyclosporin, mycophenolate mofetil. All p<0.05 are in bold.
CCI, Charlson Comorbidity Index; IVIg, intravenous immunoglobulin; NSAIDs, nonsteroidal anti-inflammatory drugs; SD, standard deviation.

SAFETY EVENT RATES

- The event rate was statistically similar between the pre- and post-index periods for 26 out of 30 safety outcomes among patients with prior IVIg use, and for 28 out of 30 safety outcomes among patients without prior IVIg use (see **Table 2**).

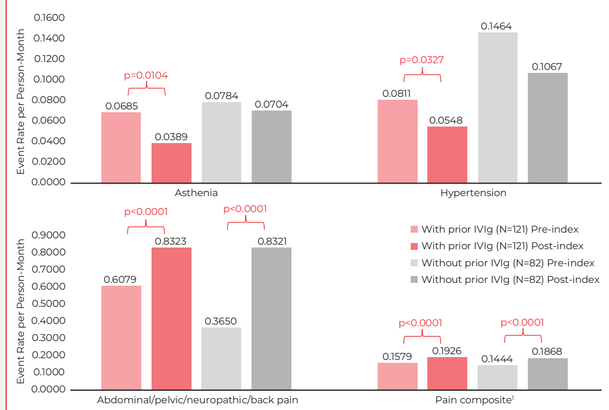
Table 2: Event Rate per Person-Month

Event	With prior IVIg (N=121)			Without prior IVIg (N=82)		
Characteristics	**p-value**	**Post-index**	**p-value**	**p-value**	**Post-index**	**p-value**
Infection composite	0.0405	0.0353	0.6176	0.0577	0.0728	0.3517
Abdominal infections	0.0028	0.0000	0.9914	0.0000	0.0146	0.9923
Cutaneous/mucosal infections	0.0112	0.0124	0.8611	0.0124	0.0097	0.7221
Lower RTI	0.0028	0.0053	0.4793	0.0041	0.0049	0.8774
Other bacterial diseases	0.0056	0.0035	0.5645	0.0062	0.0024	0.4173
Sepsis/blood stream infection/ local infection due to CVC	0.0014	0.0018	0.8669	0.0062	0.0024	0.4538
Upper RTI	0.0084	0.0141	0.3329	0.0124	0.0267	0.1358
UTI	0.0140	0.0053	0.0770	0.0268	0.0243	0.7965
TEE composite	0.0056	0.0035	0.6942	0.0206	0.0194	0.8437
DVT	0.0056	0.0035	0.6942	0.0041	0.0000	0.9914
PE	0.0014	0.0000	0.9907	0.0124	0.0097	0.7607
Stroke	0.0000	0.0000	—	0.0062	0.0097	0.3196
Thrombophlebitis	0.0014	0.0000	0.9907	0.0000	0.0000	—
Composite of Sepsis/blood stream infection/local infection due to CVC, and TEE composite	0.007	0.0053	0.7607	0.0227	0.0218	0.8668
Pain composite	0.1579	0.1926	**<0.0001**	0.1444	0.1868	**<0.0001**
Abdominal/pelvic/ neuropathic/ back pain	0.6079	0.8323	**<0.0001**	0.3650	0.8321	**<0.0001**
Arthritis/extremity pain	0.0671	0.0707	0.7752	0.1320	0.1286	0.8169
Headache/migraine	0.0307	0.0300	0.8488	0.0247	0.0243	0.9807
Pain (chest/throat)/other pain/ epigastric pain	0.0489	0.0353	0.3186	0.0412	0.0485	0.5822
Pain (chronic)	0.0210	0.0177	0.7510	0.0186	0.017	0.8421
Arthralgia	0.0363	0.0336	0.8361	0.0516	0.0412	0.3448
Aseptic meningitis	0.0000	0.0000	—	0.0000	0.0000	—
Asthenia	0.0685	0.0389	**0.0104**	0.0784	0.0704	0.7950
Chills	0.0028	0.0018	0.4876	0.0082	0.0049	0.3549
Hemolysis and hemolytic anemia	0.0000	0.0000	—	0.0062	0.0000	0.9929
Hypertension	0.0811	0.0548	**0.0327**	0.1464	0.1067	0.1288
Hyponatremia	0.0070	0.0035	0.2813	0.0062	0.0049	0.7742
Nausea	0.0070	0.0018	0.2094	0.0165	0.0097	0.3988
Osmotic nephrosis/acute renal failure/renal dysfunction	0.0168	0.0088	0.1501	0.0495	0.0509	0.9634
Rash	0.0056	0.0035	0.6015	0.0041	0.0000	0.9914

CVC, central venous catheter; DVT, deep vein thrombosis; PE, pulmonary embolism; RTI, respiratory tract infection; TEE, thromboembolic events; urinary tract infection

- For patients with prior IVIg use, a significant decrease in the event rate was observed for asthenia and hypertension (see **Figure 2**).
- For both cohorts, the event rate increased from pre- to post-index for abdominal/pelvic/ neuropathic/back pain and a composite pain outcome. Abdominal pain and musculoskeletal pain are known side effects of IgPro20

Figure 2. Event Rate per Person-Month



1. Includes: Abdominal/pelvic/neuropathic/back pain, arthritis/extremity pain, headache/migraine, pain (chest/throat)/ other pain/epigastric pain, pain (chronic), and arthralgia.

Conclusions

- **IgPro20 treatment in patients with CIDP is associated with stable safety outcomes for both patients switching from IVIg and for those new to immunoglobulin therapy.**
- **Findings were consistent with the known safety profile referenced in the current IgPro20 product label.**

References

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Presenter contact:
Christine.Curtis@cslbehring.com

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