Comparison of patient identification methodologies in chronic inflammatory demyelinating polyneuropathy using United States administrative claims data

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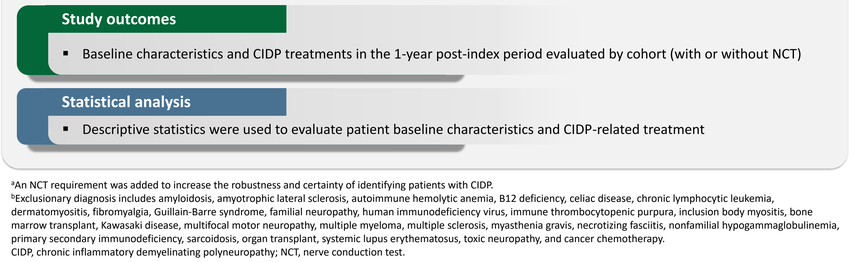
Introduction and Purpose

- Chronic inflammatory demyelinating polyneuropathy (CIDP) is an immune-mediated disorder of the peripheral nervous system characterized by sensory loss, progressive limb weakness, and fatigue.[1,2]
- The annual prevalence of CIDP is 8.9 per 100,000 persons in the United States (US), with the disease primarily affecting males between 40 and 60 years of age.[3]
- Despite the development of diagnostic criteria,[4] there is no gold standard test for CIDP, leading to common misdiagnosis that can result in substantial physical, emotional, and financial burden on both the patient and society.[4-6]
- The complexities of diagnosing CIDP experienced in clinical practice are also reflected in real-world data, resulting in potentially misrepresentative cohort selection.[7] There is limited knowledge on additional criteria for identification of patients with CIDP in claims data, other than relying on diagnostic codes.
- The objective of this research was to explore patient identification methods for CIDP in claims data to better align with diagnostic processes in clinical practice.

Methods

- The study was undertaken as represented in **Figure 1**, to identify key clinico-diagnostic characteristics to enable selection of the relevant patient population.

Figure 1. Study methodology



[a]Nerve conduction abnormalities suggestive of demyelination are one of the most important electrodiagnostic criteria for CIDP.[7,9] The NCT is the cornerstone diagnostic assessment for confirming CIDP and strengthens the diagnostic certainty of true CIDP in certain patient subgroups. Therefore, NCT was included as patient eligibility criteria to increase the robustness and certainty of identifying patients with CIDP.
CIDP, chronic inflammatory demyelinating polyneuropathy; ICD, International Classification of Diseases; US, United States.

- In step 3, inclusion of an NCT was selected as a potential patient eligibility criterium to increase the robustness and certainty of identifying patients with CIDP, based on literature and expert consensus that this is a cornerstone diagnostic assessment for confirming CIDP (**Figure 1**).
- In step 4, the hypothesis was tested in a retrospective cohort study conducted using Komodo Health (a US-based claims database containing complete medical and prescription claims information from 150 payers across all geographic regions in the US from January 2016 to December 2020).[10]

- The details of study design are presented in **Figure 2**. To assess the impact of NCT requirement, 2 cohorts were identified:
  - Patients selected with NCT requirement (≥1 NCT present either after the index date and before another CIDP diagnosis, or ≤90 days before the index date)
  - Patients selected without NCT requirement

Figure 2. Study design

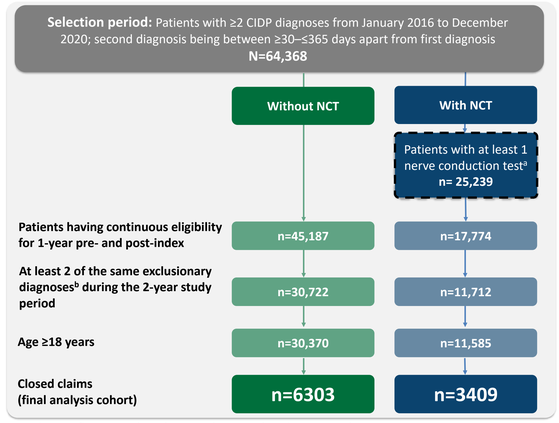
[a]An NCT requirement was added to increase the robustness and certainty of identifying patients with CIDP.
[b]Exclusionary diagnosis includes amyloidosis, amyotrophic lateral sclerosis, autoimmune hemolytic anemia, B12 deficiency, celiac disease, chronic lymphocytic leukemia, dermatomyositis, fibromyalgia, Guillain-Barre syndrome, familial neuropathy, human immunodeficiency virus, immune thrombocytopenic purpura, inclusion body myositis, bone marrow transplant, Kawasaki disease, multifocal motor neuropathy, multiple myeloma, multiple sclerosis, myasthenia gravis, necrotizing fasciitis, nonfamilial hypogammaglobulinemia, primary secondary immunodeficiency, sarcoidosis, organ transplant, systemic lupus erythematosus, toxic neuropathy, and cancer chemotherapy.
CIDP, chronic inflammatory demyelinating polyneuropathy; NCT, nerve conduction test.

Results

Study cohorts and baseline characteristics

- Among the dataset, 6303 patients with CIDP were identified with conventional inclusion criteria (without NCT requirement). In contrast, 3409 patients with CIDP were identified who fulfilled the NCT requirement (**Figure 3**).

Figure 3. Patient selection



CIDP, chronic inflammatory demyelinating polyneuropathy; NCT, nerve conduction test.
[a]An NCT requirement was added to increase the robustness and certainty of identifying patients with CIDP.
[b]Exclusionary diagnosis defined in study design.

- Baseline demographics and clinical characteristics were similar across both cohorts (**Table 1**).
- A larger proportion of patients with NCT were using steroids at baseline compared to those selected without the NCT requirement.
- Overall, at baseline, more patients with NCT underwent laboratory testing compared to those without NCT.

Table 1. Baseline demographics and clinical characteristics

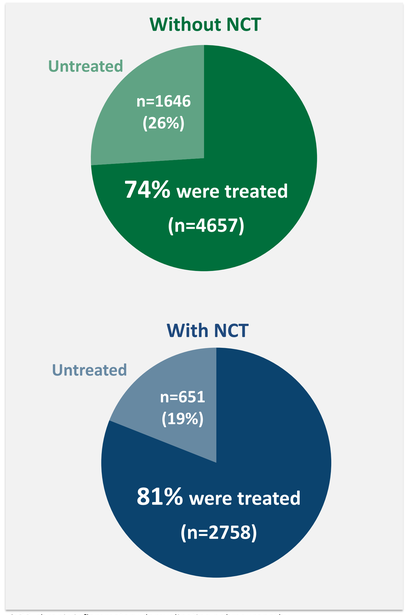
	Without NCT (N=6303)	With NCT (N=3409)
Age, years, mean (SD)	60.7 (14.2)	59.4 (13.9)
Gender, n (%)		
Male	3686 (58)	2055 (60)
Female	2617 (42)	1354 (40)
Race and ethnicity, n (%)		
Non-Hispanic Caucasian	2478 (39)	1405 (41)
Hispanic	590 (9)	292 (8)
Non-Hispanic African American	290 (5)	162 (5)
Non-Hispanic Asian	59 (1)	25 (1)
Other/unknown	2886 (46)	1525 (45)
CCI, mean (SD)	2.0 (2.2)	2.0 (2.2)
Insurance, n (%)		
Commercial	2835 (45)	1680 (49)
Medicare	1987 (32)	934 (27)
Medicaid	845 (13)	460 (13)
Others[a]	636 (10)	335 (10)
Comorbidities, n (%)		
Diabetes without chronic complication	1906 (30)	1054 (31)
CPD[b]	1355 (21)	753 (22)
Diabetes with chronic complication	1242 (20)	720 (21)
Peripheral vascular disease	921 (15)	514 (15)
Cerebrovascular disease	907 (14)	519 (15)
Renal disease	573 (9)	282 (8)
CHF	632 (10)	341 (10)
Any malignancy[c]	603 (10)	313 (9)
Treatments used 1 year prior to index, n (%)		
Steroids	2069 (33)	1287 (38)
IVIg/IVIg or SCIg with combinations	933 (15)	521 (15)
IVIg or SCIg	356 (6)	136 (4)
Other combinations/treatments	241 (4)	120 (4)
IVIg	271 (4)	119 (3)
NSIST	87 (1)	33 (1)
PLEX	18 (0)	4 (0)
Biologics	9 (0)	2 (0)
Laboratory values, n (%)		
CBC	4579 (73)	2636 (77)
Comprehensive blood panel	4189 (66)	2482 (73)
HbA1C	3146 (50)	1930 (57)
CT	2034 (32)	1195 (35)
MRI	1676 (27)	1206 (35)
Serum Ig	1310 (21)	879 (26)
Lumbar-spinal puncture tests	694 (11)	482 (14)
Urine protein	521 (8)	347 (10)
Nerve biopsy	70 (1)	37 (1)

[a]Including self-insured, other/unknown, dual-eligible, or Tricare/Veterans Affairs.
[b]Including bronchitis, emphysema, asthma, chronic obstructive pulmonary disease, bronchiectasis, pneumoconiosis, and chronic drug-induced interstitial lung disorders.
[c]Including lymphoma and leukemia, except malignant neoplasm of skin.
CBC, complete blood count; CCI, Charlson Comorbidity Index; CHF, congestive heart failure; CPD, chronic pulmonary disease; CT, computerized tomography; HbA1C, glycated hemoglobin; Ig, immunoglobulin; IVIg, intravenous immunoglobulin; MRI, magnetic resonance imaging; NCT, nerve conduction test; NSIST, nonsteroidal immunosuppressive treatment; PLEX, plasma exchange; SCIg, subcutaneous immunoglobulin; SD, standard deviation.

CIDP treatment utilization during 1 year post-index

- Across both cohorts, the majority of patients used at least 1 CIDP treatment during 1 year post-index. A considerably larger proportion of patients were untreated in the cohort without NCT versus with NCT (26% vs 19%; **Figure 4**).

Figure 4. Patients treated versus untreated for CIDP during 1 year post-index

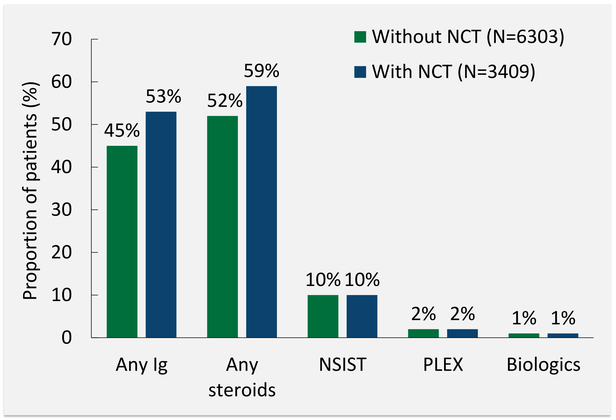


CIDP, chronic inflammatory demyelinating polyneuropathy; NCT, nerve conduction test.

- Among patients who received at least 1 CIDP treatment during 1-year post-index date, immunoglobulin (Ig) and steroids were the most common.
- The proportions of patients receiving Ig (**Figure 5A**) and steroids (**Figure 5B**) were higher among those who had an NCT versus without NCT.

Figure 5. Proportion of patients who utilized CIDP treatment at least once during 1 year post-index

(A) Proportion of patients who utilized each CIDP treatment class at least once during 1 year post-index



Ig, immunoglobulin; NCT, nerve conduction test; NSIST, nonsteroidal immunosuppressive treatment; PLEX, plasma exchange.

(B) Proportion of patients who utilized steroids at least once during 1 year post-index

IV, intravenous; NCT, nerve conduction test.

Conclusions

- **In this analysis based on a US claims database, a patient cohort with a greater certainty of CIDP diagnosis was identified with the addition of the NCT requirement.**
- **CIDP treatment patterns during 1 year post-index date suggest that a greater proportion of patients with a true CIDP diagnosis may be receiving treatment in 1 year post-index, compared with results observed using patient selection solely based on diagnostic codes.**
- **In future studies utilizing real-world datasets across therapeutic areas, including disease-specific clinical diagnostic procedures may be critical to identify relevant study cohorts with increased robustness.**

Limitations

- Retrospective datasets are limited in capture of key clinical parameters, such as disease severity, that may also help to better identify patients with CIDP.
- As the study population was selected from a US-based dataset, the study findings may not be generalizable to patients from other geographical regions.

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