Opioid Usage Among Patients With Diabetic Peripheral Neuropathy (DPN) – US Claims Database Analysis

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BACKGROUND

- The International Association for the Study of Pain defines peripheral neuropathic pain in patients suffering from diabetes as "pain arising as a direct consequence of abnormalities in the peripheral somatosensory system in people with diabetes"[1, 2]
- First-line therapies include tricyclic antidepressants, serotonin-norepinephrine reuptake inhibitors (like duloxetine), and anticonvulsants (like pregabalin and gabapentin). However, a majority of patients using these treatments experience side effects.[3,4] Some common side effects include dizziness, somnolence, nausea, headache, blurred vision, and dry mouth
- There is clinical evidence that supports the use of opioids in the management of diabetic peripheral neuropathy (DPN)[5]
- Although there are a number of treatment options available for symptomatic DPN patients, pain management is inadequate[3]

OBJECTIVE

- The objective of the analysis was to evaluate usage of Schedule II, III, and IV opioids among commercially insured US patients with DPN

METHODS

- Patients aged ≥18 years with a diagnosis of DPN between January 1, 2009 and December 31, 2009 were identified in the Pharmetrics database. The date of the first DPN diagnosis for a patient during this period was termed as the Baseline Date for the patient
- The DPN cohort was defined using ICD-9 codes 250.6X and 357.2
- Patients with ≥12 months of continuous enrollment before and after their Baseline Date were included
- Patients were classified as opioid naive (ON) and opioid experienced (OE) based on whether they had filled a prescription for any opioids during the 6 months prior to the Baseline Date
- Opioid treatment was classified based on Schedule (Schedule II and III/IV) and long acting (L) versus short acting (S)
- An analysis of patient demographics, co-diagnosis, and Schedule II and III/IV opioid use in the full cohort and in the ON and OE patients over a 12-month follow-up from Baseline Date was carried out (**Table 1**)

Table 1. Definitions and Rules Used in the Analysis

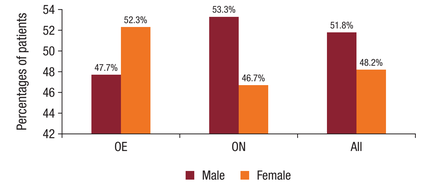
1. Classification as ON or OE was based on whether the patient had taken any opioid during the 6 months prior to the Baseline Date.
2. Discontinuation of treatment was defined as the first discontinuation post-initiation during the 12-month follow-up period.
3. Complete treatment discontinuation was defined as the last discontinuation in the 12-month follow-up period.
4. Patients who continued on the opioid beyond 12 months were censored.

ON, opioid naive; OE, opioid experienced.

RESULTS

Baseline Characteristics

- Of the 56,244 patients identified with DPN in the database, about half were in the 45 to 64 years age group; mean age was 64.26 (standard deviation ± 13.31) years. 52% of the patients were male and 27% of the patients were OE (**Figure 1**)

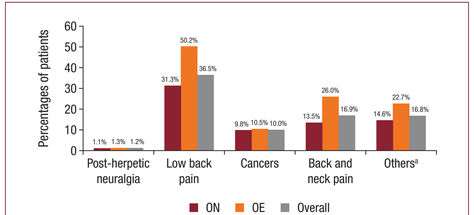


OE, opioid experienced; ON, opioid naive.

Figure 1. Gender distribution of OE patients, ON patients, and the overall cohort.

Co-diagnoses

- 49.6% of patients had ≥1 pain co-diagnosis (**Figure 2**)
- OE patients were more likely to have a pain-related co-diagnosis
- 36.5% of patients had ≥1 co-diagnosis of low back pain (50.2% among OE and 31.3% among ON), while 16.9% had ≥1 diagnosis of back and neck pain with a neuropathic component during the 1-year follow-up period post Baseline Date

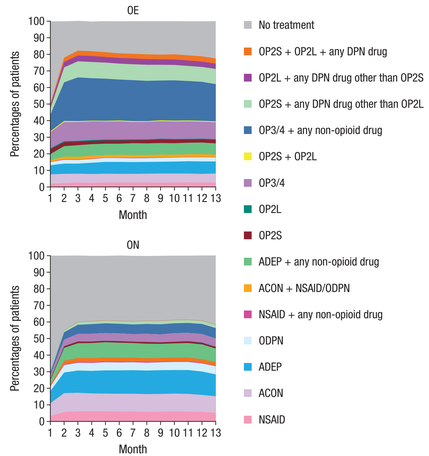


ON, opioid naive; OE, opioid experienced.
[a]Other co-morbidities include atypical facial or phantom limb pain, trigeminal neuralgia, reflex sympathetic dystrophy, nerve root and plexus disorders, inflammatory and toxic neuropathy, and other disorders of soft tissues.

Figure 2. Co-diagnoses in the ON and OE patients.

Choice of Treatment Regimens

- 59% (N = 33,333) of the sample were exposed to a DPN-related treatment during the 12-month follow-up. The corresponding percentages for ON and OE patients were 47% and 91%, respectively
- At baseline, 61% of these patients were not being treated for pain (70% for ON vs 50% for OE)
- While the number of treated patients increased by 25% among ON-treated patients in the month after the Baseline Date, it increased by 28% in OE-treated patients during that time period
- 65% of DPN-treated patients were exposed to opioids, primarily Schedule III/IV
- OE patients were more likely to use opioids than ON patients (85% in OE vs 50% in ON patients). This was true both for Schedule II opioids and Schedule III/IV opioids
- Antidepressants were the dominant drug regimen in ON patients, while Schedule III/IV opioids (as monotherapy and in combination) were most often prescribed to OE patients (**Figure 3**)

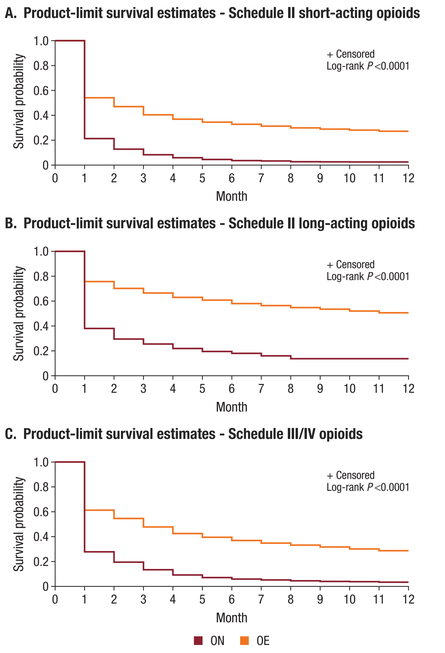


OE, opioid experienced; ON, opioid naive; OP2S, Schedule II short-acting opioids; OP2L, Schedule II long-acting opioids; DPN, diabetic peripheral neuropathy; OP3/4, Schedule III/IV opioids; ADEP, antidepressants; ACON, anticonvulsants; NSAID, non-steroidal anti-inflammatory drug; ODPN, other diabetic peripheral neuropathy.

Figure 3. Distribution of patients by treatment regimen applicable in each calendar month post Baseline Date.

Treatment Persistence

- OE patients had longer persistency with opioids
- Median time to discontinuation (**Figure 4**) was:
  - 3 months in OE patients and 2 months in ON patients for Schedule II short-acting opioids
  - >12 months in OE patients and 2 months in ON patients for Schedule II long-acting opioids
  - 4 months in OE patients and 2 months in ON patients for Schedule III/IV opioids



ON, opioid naive; OE, opioid experienced.

Figure 4. Kaplan-Meier plot for discontinuation of (A) Schedule II short-acting opioids, (B) Schedule II long-acting opioids, and (C) Schedule III/IV opioids.

- Median time to discontinuation for Schedule II short-acting opioids and Schedule III/IV opioids was 2 months as compared to Schedule II long-acting opioids, which was 10 months (**Figure 5**)

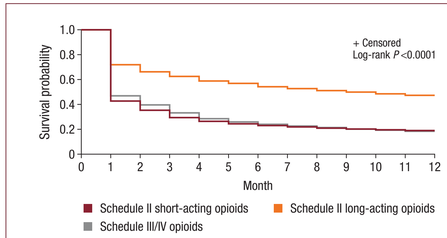


Figure 5. Kaplan-Meier plot to compare discontinuation of Schedule II short-acting, Schedule II long-acting, and Schedule III/IV opioids.

CONCLUSIONS

- **At baseline, nearly 61% of DPN-treated patients did not receive any of the specified DPN treatments**
- **The high use of opioids in the management of DPN was seen, particularly among OE patients**
- **Opioid persistency was higher among OE patients**
- **A noticeable proportion of DPN patients have a pain co-diagnosis, particularly among OE patients, signifying the need for treatments that can effectively manage DPN as well as other pain conditions**

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Disclosures

K. Hill, S. Merchant, and M. Mehra are employees of Janssen Global Services, LLC.

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