# Real-World Study on Treatment Patterns and Economic Burden of Diabetic Peripheral Neuropathic Pain in China

RWD216

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## 1. BACKGROUND

- **Diabetic Peripheral Neuropathy (DPN)** is a common complication of **Diabetes Mellitus(DM)**, with **Diabetic Peripheral Neuropathic Pain (DPNP)** being a major form, affecting 28% of individuals with DM in the USA[1,2], 6% to 34% in Europe[3], and 28% to 37% in Japan[4-6].
- Patients with DPNP experience **abnormal sensations, numbness,** and **pain below the knee**, often accompanied by **sleep disturbances** and **a reduced quality of life**.
- Despite the significant burden of DPNP, research regarding its treatment patterns and economic impact in China remains sparse.

## 2. OBJECTIVES

- A retrospective cohort study was conducted to examine treatment patterns and the economic burden associated with DPNP in Tianjin, China.

## 3. METHODS

✓ **Data Source:** "Healthcare Big Data Super Platform," which integrates information from 43 tertiary hospitals and 39 secondary hospitals in Tianjin, China.

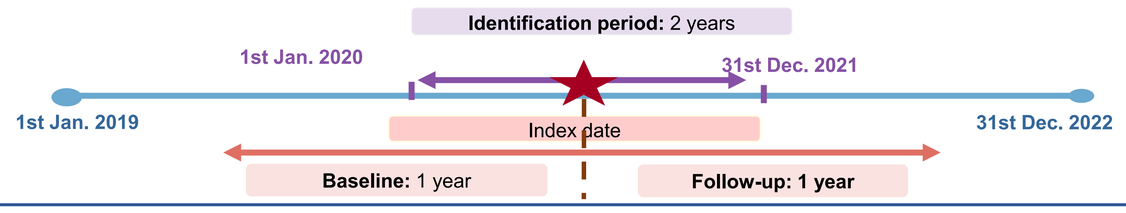
✓ **Study population:** DPN patients identified **between 1st Jan. 2020, and 31st Dec. 2021**, were classified into DPNP and non-painful DPN groups (Fig1). **The entry for the DPNP cohort** was determined by the first diagnosis or prescription of guideline-recommended DPNP medications, with **non-painful DPN patients being age- and sex-matched.**

✓ **Pharmacological Treatment of DPNP: Guideline-recommended DPNP medications in China** include **Anticonvulsants** (Pregabalin, Gabapentin), **Antidepressants** (Duloxetine, Venlafaxine, Amitriptyline), **Analgesics** (Tramadol, Morphine), and **Topicals** (Capsaicin, Lidocaine).

- **Discontinuation** is defined as a gap of more than 180 days between prescriptions.

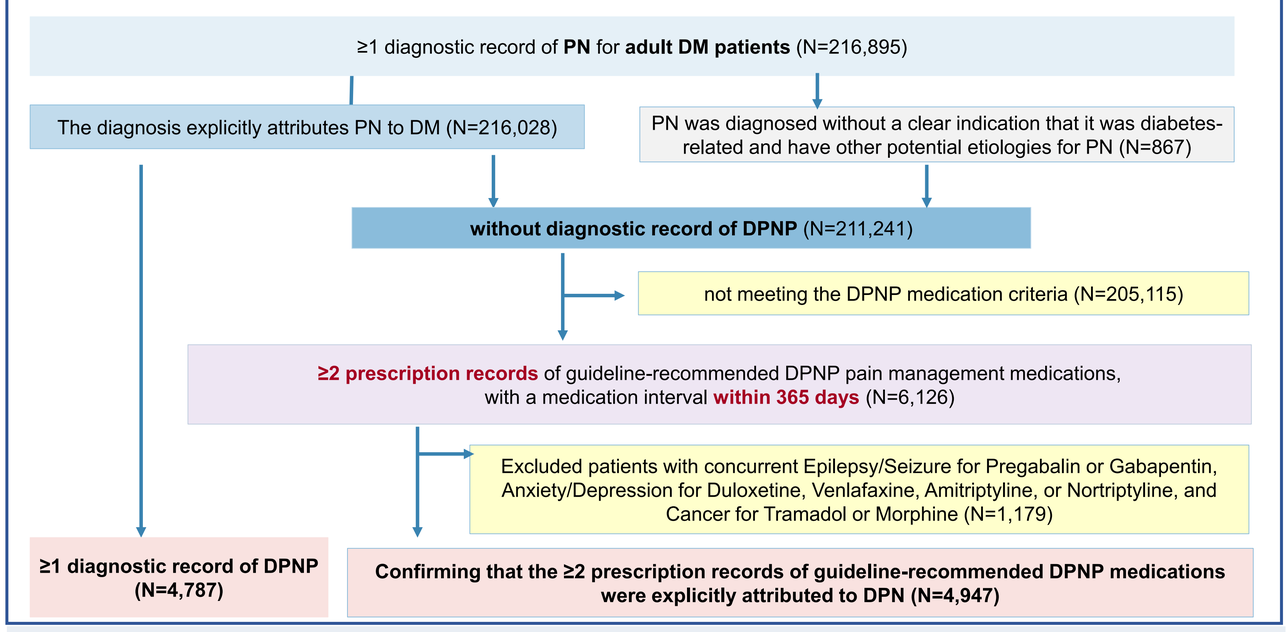
✓ **Statistical Methods:** Statistical comparisons were conducted using the Chi-square or Fisher's exact test for categorical variables, and the independent samples t-test or Mann–Whitney U test for continuous variables, based on data distribution. P values were reported without adjustment for multiple testing.

**Fig.1 Overview of the study period**




✓ A total of **216,895** diabetic patients with ≥1 confirmed diagnosis of PN were included. Among them, **216,028** had diagnostic records explicitly attributing PN to DM. The remaining **867** patients had PN diagnoses without explicit linkage to DM and have other potential etiologies for PN. As the diagnosis records alone did not confirm diabetes as the cause, classification required additional review of repeated use of DPN-related analgesics.

**Fig.2 Inclusion and Exclusion of DPNP Population Based on Diagnostic/Prescription Records**




✓ **DPNP Cohort (N=9,734):** including 4,787 with ≥1 DPNP diagnosis and 4,947 meeting prescription-based criteria. Patients with comorbidities potentially affecting medication use (e.g., epilepsy, anxiety, depression, cancer) were excluded (N=1,179).

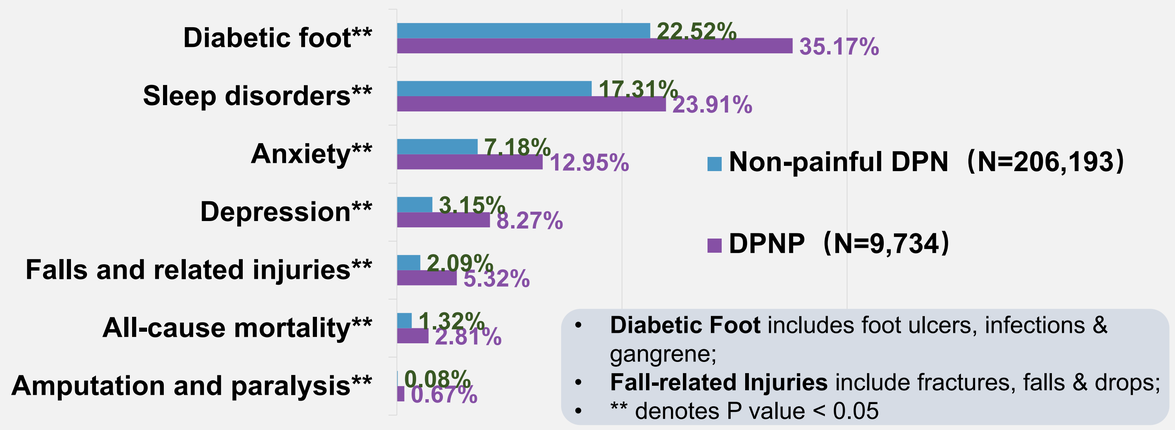
✓ **Non-painful DPN cohort (N=206,194):** These patients met the criteria of having ≥1 diagnostic record of PN among adult DM patients (N=216,895), but were not classified as DPNP (N=9,734), nor did they belong to the group whose PN diagnosis lacked clear attribution to diabetes and had other potential etiologies (N=867).

## 4. RESULTS

| Baseline Characteristics | DPNP | Non-painful DPN |
|---|---|---|
| **Gender [n(%)]** | | |
| Male | 5,109 (52.49%) | 98,281 (47.66%) |
| Female | 4,625 (47.51%) | 107,912 (52.34%) |
| **Age at Enrollment [mean (sd)] **** | 63.51 (15.37) | 62.81 (10.92) |
| **Hospital Level at Enrollment [n(%)]**** | | |
| Tertiary | 7,588 (77.95%) | 144,789 (70.22%) |
| Secondary | 2,146 (22.05%) | 61,404 (29.78%) |
| **Admission Path at Enrollment [n (%)] **** | | |
| Outpatient | 6,001 (61.65%) | 172,559 (83.69%) |
| Inpatient | 3,733 (38.35%) | 33,634 (16.31%) |
| **CCI [mean(sd)]** | 1.62 (1.51) | 1.67 (1.11) |

CCI: Charlson Comorbidity Index; ** denotes P value < 0.05

**Fig.3 The incidence of clinical prognostic events during the follow-up period**




**DPNP Treatment Patterns (9,699 Patients with Prescription Records)**

- **Anticonvulsants** were the most commonly used medication class, with 30.72% of patients (2,980 individuals), primarily **Pregabalin** (18.74%) and **Gabapentin** (16.04%). Most patients had a short duration of **Pregabalin** use, with 63.30% using it for 0-14 days, 27.69% for 15-29 days,.
- **Topicals** were used by 28.14% of patients (2,729), with **Lidocaine formulations** being the most common (27.91%).
- **Analgesics** were used by 23.00% of patients (2,231), with **Tramadol** being the most prescribed (21.67%).
- **Antidepressants** were used by 7.97% of patients (773), with **Duloxetine** (4.59%) and **Venlafaxine** (3.50%) being the most prescribed.

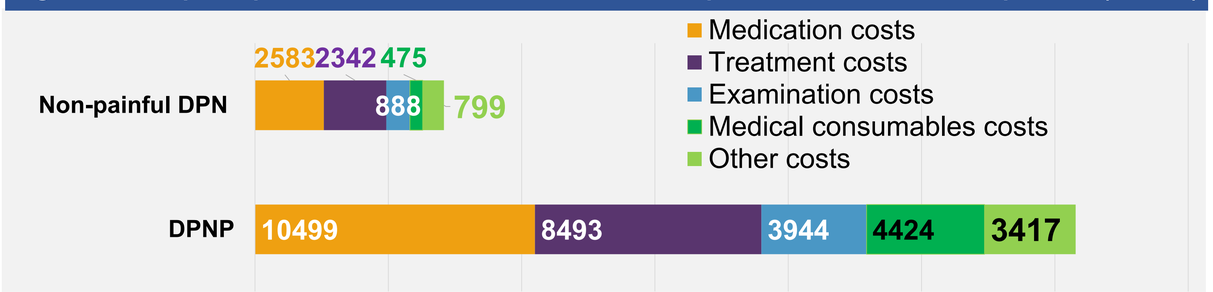
**All-cause healthcare resource utilization during the follow-up period (1 year):**

- **Outpatient Care:** DPNP patients had more outpatient visits (25.20 vs. 18.32, P < 0.05), with 97.78% receiving care, compared to 94.64% in the non-painful DPN group (P < 0.05).
- **Inpatient Care:** DPNP patients had a significantly higher hospitalization incidence (40.08% vs. 21.14%) and, on average, more hospitalizations (0.78 vs. 0.34) and longer stays (8.99 vs. 3.23 days) during the 1-year follow-up (P < 0.05).

**All-cause healthcare costs during the follow-up period (1 year):**

- DPNP patients had higher total per capita costs than non-DPNP patients (CN¥48,689.80 vs. CN¥24,883.37; P < 0.05), including hospitalization (CN¥30,776.30 vs. CN¥7,085.81) and outpatient costs (CN¥13,524.19 vs. CN¥9,315.27).
- Total costs encompassed inpatient and outpatient expenses, including medications.

**Fig. 4 Annual per capita all-cause direct medical costs for inpatient care and their composition (in CN ¥)**




## 5. CONCLUSION

- Compared to non-painful DPN, DPNP patients in Tianjin, China have worse outcomes and higher healthcare utilization and costs, especially hospitalizations.

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## Reference

[1] Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic neuropathy: a position statement by the American Diabetes Association. Diabetes Care. 2017;40:136–154.
[2] Gregg EW, Gu Q, Williams D, et al. Prevalence of lower extremity diseases associated with normal glucose levels, impaired fasting glucose, and diabetes among U.S. adults aged 40 or older. Diabetes Res Clin Pract. 2007;77:485–488.
[3] Alleman CJ, Westerhout KY, Hensen M, et al. Humanistic and economic burden of painful diabetic peripheral neuropathy in Europe: a review of the literature. Diabetes Res Clin Pract. 2015;109:215–225
[4] Satoh J, Baba M, Yagihashi S, et al. Frequency of diabetic polyneuropathy (DPN) and clinical significance of Achilles tendon reflex in diagnosis of DPN. J Japan Diabetes Soc. 2007;50:799–806.
[5] Goto Y. Research about diabetic neuropathy. J Jpn Physicians Assoc. 2002;17:125–138.
[6] Yokoyama H, Tsuji T, Hayashi S, Kabata D, Shintani A. Factors associated with diabetic polyneuropathy-related sensory symptoms and signs in patients with polyneuropathy: a cross-sectional Japanese study (JDDM 52) using a non-linear model. J Diabetes Investig. 2020;11:450–457.