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Effectiveness of Pregabalin and High Concentration Capsaicin Patch (179 mg) in Peripheral Neuropathic Pain: A Review of Studies ≥26 Weeks Duration

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Background

Peripheral neuropathic pain (PNP) is a chronic condition impacting quality of life that often requires long-term treatment. High concentration (179mg) capsaicin patch (HCCP) is a topical TRPV1 agonist providing neuropathic symptom relief for up to 3 months through defunctionalisation of nociceptors and nerve fibre regeneration with each treatment. This targeted analysis aimed to assess the effectiveness of HCCP and the standard of care pregabalin, in patients with PNP based on published studies of ≥26 weeks duration.

Methods

A systematic literature review was performed to identify relevant studies on PNP treatments (Embase, PubMed: Dec 2024). Studies including PNP patients (≥18 years) treated with pregabalin and/or HCCP, duration ≥26 weeks, were included in the analysis. Reduction in pain scores (any reported) and responder rates were analysed, and the feasibility of indirect comparisons was explored.

Results

Eight studies for HCCP and 5 for pregabalin met the inclusion criteria, both drugs were studied across a mixture of PNP aetiologies, including diabetic peripheral neuropathy, post herpetic neuralgia (both products) and post-surgical pain (HCCP). Most were real-world observational studies or open-label extensions of Ph3 studies. The only randomized controlled study in PNP >26 weeks found was for HCCP. Due to differences in study design, populations, and use of background treatments, a formal indirect comparison was not feasible. However, extracted data suggest that with pregabalin, analgesic effect is at best maintained in PNP over 26-52 weeks, and is strongly impacted by drug holidays, while HCCP effectiveness seems to increase with repeated treatment over similar periods.

Evidence Summary: Pregabalin

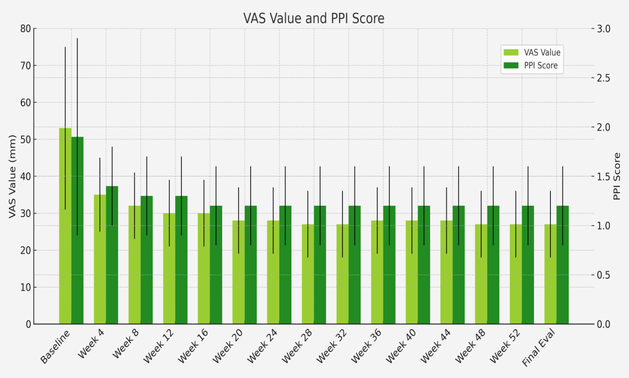


Figure 1. Pain scores in measured by Visual Analogue Scale (VAS) and Pain Perception Index (PPI) in pregabalin users with DPN.
Data taken from Satoh et al., 2011

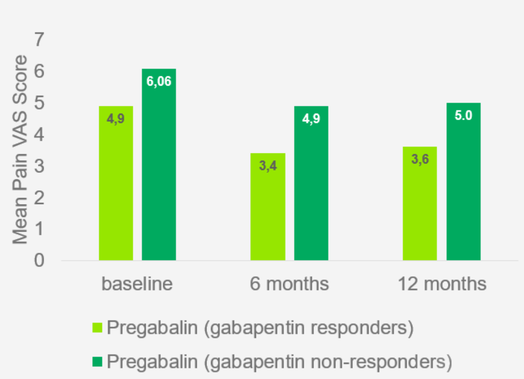
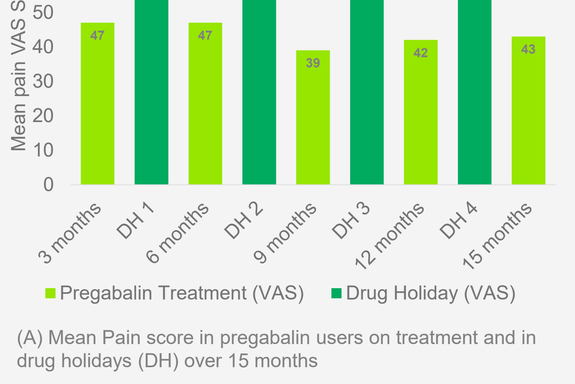
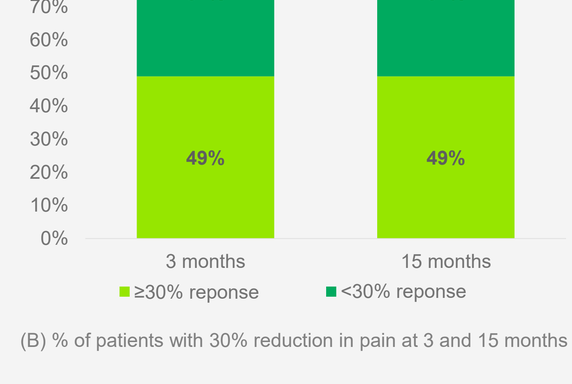


Figure 2. Pain scores in measured by VAS (0-10) in pregabalin users with DPN and other PNP aetiologies. Patients had been switched at baseline from gabapentin to pregabalin. Patients were split by prior response to gabapentin.
Data taken from Toth et al., 2010.





(A) Mean Pain score in pregabalin users on treatment and in drug holidays (DH) over 15 months

(B) % of patients with 30% reduction in pain at 3 and 15 months

Figure 3. (A) Pains scores in measured by VAS (0-10) in pregabalin users with DPN. Patients were treated with pregabalin, and given holidays every 3 months, those whose pain rebounded in the holiday were then re-treated with pregabalin.
(B) % of patients experiencing at least a 30% reduction in pain at 3 months and 15 months (excluding treatment holidays).
Data taken from Stacey et al., 2008.

Independent evidence summaries

Evidence Summary: HC Capsaicin Patch

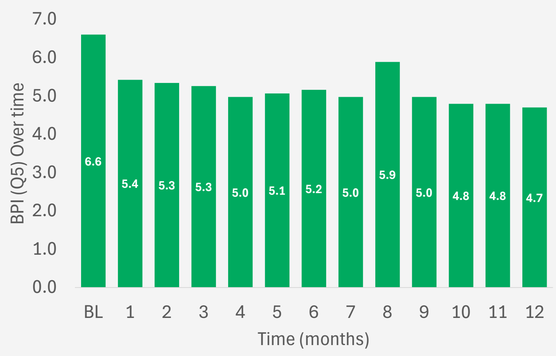


Figure A. Pain measured by BPI Average pain (Q5) in patients of all aetiologies (PHN, PNI, HIV-DSP and others) who received HCCP treatment
Data adapted from Galvez et al., 2016.

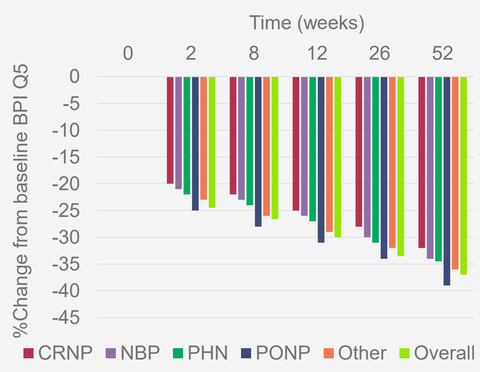


Figure B. Relative change (%) in pain measured by BPI Average pain (Q5) in patients with PNP who were using HCCP.
Data taken from Mankowski et al., 2017

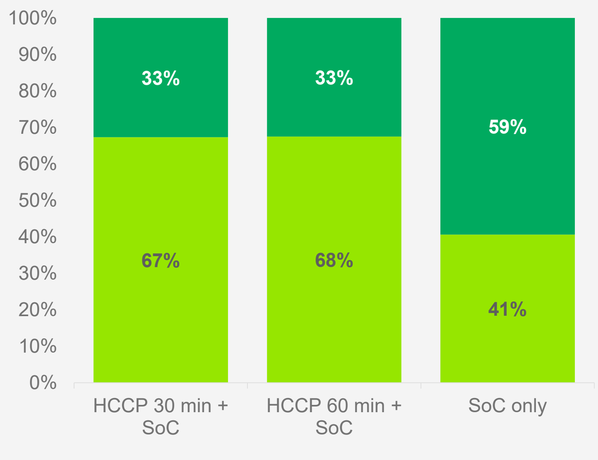


Figure C. Proportion of patients achieving ≥30% pain response at Month 12 in DPN patients.
Data taken from Vinik et al., 2019.

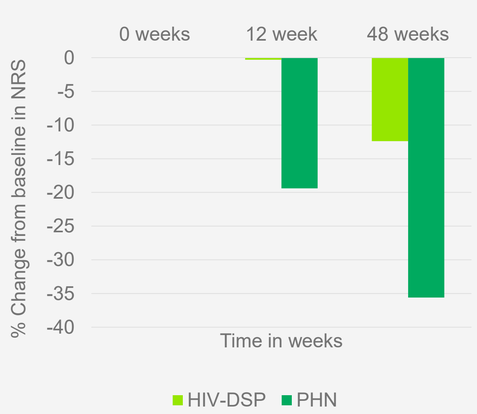


Figure D. Relative change in pain measured NRS (0-10) (Q5) in patients with PHN and HIV-DSP who were using HCCP. Data taken from Simpson et al., 2010

Conclusion

- Although limited by **study heterogeneity** and the **absence of a common comparator**, available data suggest **distinct effectiveness trajectories**: pregabalin shows **stable analgesic effects** at best, and is highly impacted by drug holidays. High concentration capsaicin patch treatment may offer **progressive benefit** with **repeated treatment**.
- **Long-term head-to-head trials** can better inform the distinct effectiveness trajectories in similar conditions.

List of identified studies (first author, year)

Pregabalin

Happich, 2014
Patel, 2014
Satoh, 2011
Stacey, 2008
Toth, 2010

High Concentration Capsaicin Patch

Bienfait, 2023
Dupoiron, 2022
Galvez, 2016
Kern, 2024
Mankowski, 2017
Schweitzer, 2014
Simpson, 2010
Treillet, 2022
Vinik, 2016/2019

Acronyms

PNP	Peripheral Neuropathic Pain
HCCP	High-Concentration Capsaicin Patch
BPI	Brief Pain Inventory
BPI-DN	Brief Pain Inventory – Diabetic Neuropathy version
CIPN	Chemotherapy-Induced Peripheral Neuropathy
CRNP	Cancer-Related Neuropathic Pain
DH	Drug Holidays
DPN	Diabetic Peripheral Neuropathy
DPNP	Diabetic Peripheral Neuropathic Pain
FU	Follow-Up
HIV-DSP	HIV-associated Distal Symmetrical Polyneuropathy
NBP	Neuropathic Back Pain
NR	Not reported
NRS	Numeric Rating Scale
OL	Open Label
Ph3	Phase 3 (clinical trial)
PHN	PostHerpetic Neuralgia
PNI	Peripheral Nerve Injury
PONP	Postoperative Neuropathic Pain
PPI	Pain Perception Index
PTNP	Post-Traumatic Neuropathic Pain
RCT	Randomized Controlled Trial
RIPN	Radiotherapy-Induced Peripheral Neuropathy
RWE	Real-World Evidence
VAS	Visual Analogue Scale

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