

Real-World Data on the Effect of Repeated Treatment with High-Concentration Capsaicin Patch on Pain Intensity, Psychological Distress, and Concurrent Medication Use in Peripheral Neuropathic Pain Following Postoperative or Posttraumatic Nerve Injury

Michael A. Überall¹, Mariëlle Eerdeken², Sylvia Engelen², Rita Freitas², Myriam Heine², Tamara Quandel²

¹IFNAP - Privates Institut für Neurologische Wissenschaften, DGS-Exzellenzzentrum für Versorgungsforschung, Nürnberg, Deutschland; ²Grünenthal Pharma GmbH, Deutschland

Background & Aims

Peripheral neuropathic pain due to nerve injury (PNI) occurs after surgical procedures or traumatic events. Its symptoms include allodynia, shooting pains, sensory deficits, and altered sensations which substantially impact patients' daily activities and emotional well-being. Standard treatments such as antidepressants, anticonvulsants, and opioids, often provide only partial pain relief and may be accompanied by systemic adverse effects. The current analysis focusses on the impact of high concentration (179 mg) capsaicin patch (HCCP) on neuropathic pain, affective distress, and concomitant use of pain medication in clinical practice.

Methods

This is a retrospective cohort study of data from the German pain e-Registry. Patients with PNI, at least one HCCP treatment and 12-months of follow-up were included. Assessment at baseline and after each HCCP treatment included the average 24-hour pain intensity (API), Depression Anxiety and Stress Symptoms (DASS-21) questionnaire and change in concomitant pain medication. The sleep item of the modified pain disability index (mPDI-sleep) was used to measure impairment of sleep.

Results

All 499 patients underwent one HCCP treatment, with 402, 264, and 135 patients receiving a second, third, and fourth treatment respectively. The median age of the patients was 57 years, and the median duration of pain was 4 years (Table 1).

The mean API score (100-mm VAS) decreased from 53.8 at baseline to 21.5 after 4 treatments (Figure 1A) with the proportion of patients experiencing severe pain (API score > 50) dropping from 49.1% to 5.2% (data not shown), while the proportion of responders ($\geq 30\%$ / $\geq 50\%$) increased with successive treatments (Figure 1B). The sleep disturbance score (100-mm VAS) followed a similar pattern to mean pain intensity, decreasing from a baseline mean of 54.4 to 20.3 after 4 HCCP treatments (data not shown).

Table 1: Demographic and baseline data of PNI patients (n=499) at the start of therapy

Age (years) mean [median] (SD)	57.1 [57] (13.6)
Female (%)	62.5
Mean body mass index (BMI, kg/m ²) mean [median] (SD)	27.0 [26.5] (5.5)
Pain duration (years), mean [median] (SD)	4.7 [4] (3.6)
Current pain intensity (CPI, mm VAS), mean [median] (SD)	56.7 [59] (21.2)
Average 24-hour pain intensity (API, mm VAS), mean [median] (SD)	53.8 [50] (15.4)
Number of previous neuropathic pain treatments [(co-)analgesics], mean [median] (SD)	7.7 [7] (2.3)
Number of current neuropathic pain treatments [(co-)analgesics], mean [median] (SD)	4.1 [4] (1.7)
Number of physician specialties involved in neuropathic pain management, mean [median] (SD)	7.0 [7] (1.5)

Following 4 HCCP treatments, mean DASS-21 scores (0 to 21) for depression, anxiety, and stress decreased from 7.5, 5.0, and 9.6 at baseline to 5.0, 3.1, and 5.3 after 4 treatments respectively (Figure 1C). Consequently, the proportion of patients with strong/severe symptoms decreased from 26.6%, 26.0%, and 29.0% at baseline to 11.8%, 8.1%, and 6.7% respectively (Figure 1D).

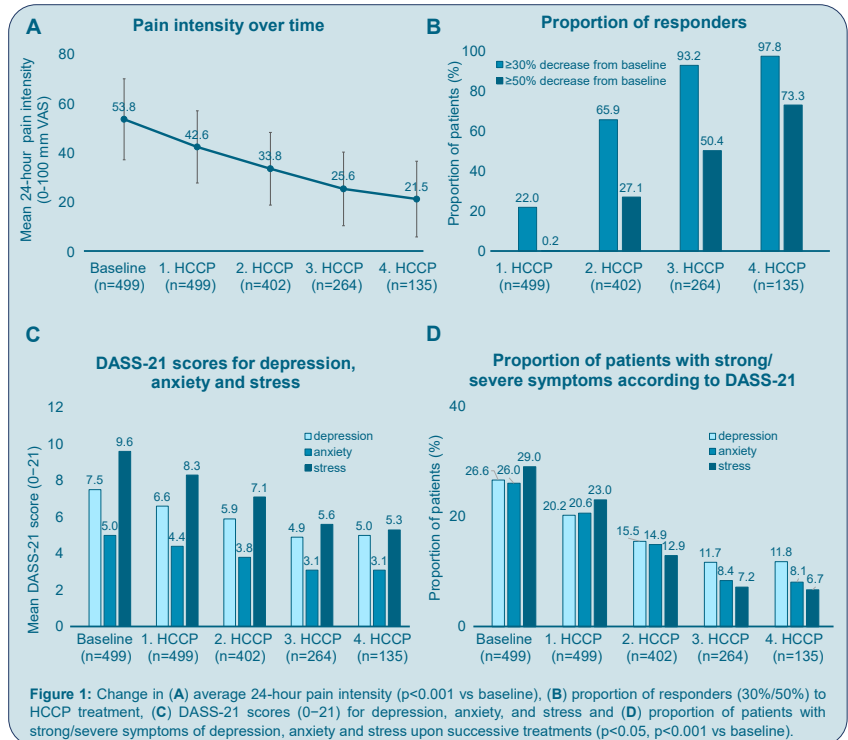


Figure 1: Change in (A) average 24-hour pain intensity ($p < 0.001$ vs baseline), (B) proportion of responders (30%/50%) to HCCP treatment, (C) DASS-21 scores (0-21) for depression, anxiety, and stress and (D) proportion of patients with strong/severe symptoms of depression, anxiety and stress upon successive treatments ($p < 0.05$, $p < 0.001$ vs baseline).

The median number of concomitant pain medications decreased from four at baseline to two in patients who had received all four treatments. While all patients were initially taking concomitant pain medication, this number declined with the progression of HCCP treatments. Importantly, the proportion of patients taking antiepileptics, antidepressants and strong opioids decreased from initially 66.7, 89.6 and 65.1% to 37.0, 42.2 and 27.4% respectively (Figure 2).

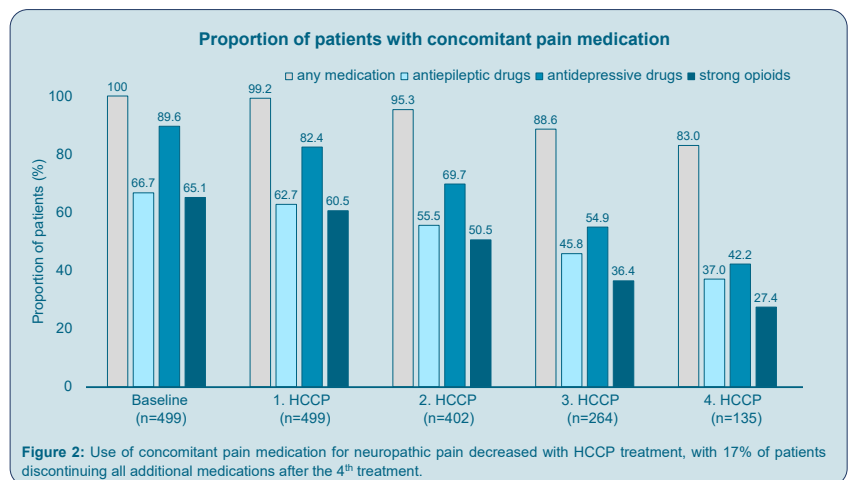


Figure 2: Use of concomitant pain medication for neuropathic pain decreased with HCCP treatment, with 17% of patients discontinuing all additional medications after the 4th treatment.

Conclusion

In clinical practice, PNI patients receiving repeated treatment with HCCP show progressive and sustained improvements in pain reduction, sleep impairment and affective distress, and a decrease in the use of concurrent pain medication.

Conflict of interest: Michael A. Überall is Director of IFNAP and Managing Director of O. Meany-MDPM GmbH, which is responsible for the concept, development and provision of the PraxisRegister Schmerz. Mariëlle Eerdeken, Sylvia Engelen, Myriam Heine and Tamara Quandel are employees of Grünenthal GmbH. Rita Freitas is employed by Grünenthal S.A., Portugal. The study was conducted with the support of Grünenthal GmbH.