

Effectiveness of High Concentration (179 mg) Capsaicin Patch in Reducing Pain and Improving Quality of Life in Peripheral Neuropathic Pain Following Postsurgical or Posttraumatic Nerve Injury: A 12-Month Real-World Study

Michael A. Überall¹, Mariëlle Eerdeken², Sylvia Engelen², Rita Freitas³, Myriam Heine², Tamara Quandel²

¹IFNAP – Privates Institut für Neurologische Wissenschaften, DGS-Exzellenzzentrum für Versorgungsforschung, Nuremberg, Germany; ²Grünenthal Pharma GmbH, Germany; ³Grünenthal S.A. Portugal

Introduction and Purpose

Peripheral neuropathic pain due to nerve injury (PNI) from surgery or trauma severely impacts patients' quality of life (QoL) and emotional well-being. This study aimed to evaluate the effects of repeated treatments with high concentration (179 mg) capsaicin patch (HCCP) on pain intensity, sleep, and various aspects of QoL in a real-world clinical setting.

Methods

Data of patients with various peripheral neuropathic pain etiologies who underwent 1 to 4 HCCP treatments and had ≥ 12 months of follow-up were extracted from the German Pain eRegistry (n=2,574). The current analysis specifically focused on patients with PNI (n=499). Patients were stratified according to the number of HCCP treatments received (1, 2, 3, or 4). Assessments were conducted at the start of the HCCP therapy (baseline) and at month 3, 6, 9, and 12 (at the time of potential repeated HCCP treatments), and included: average 24-hour pain intensity (API), 24-hour pain intensity index (PIX: mean of lowest, average, and highest 24-hour pain intensities), sleep disturbance (modified Pain Disability Index [mPDI], sleep item), physical and mental QoL (Veterans RAND-12, VR-12), overall well-being (Marburg Questionnaire on Habitual Health Findings, MQHFF), pain-related disability (von Korff, days absent from usual activities in the past three months), and tolerability.

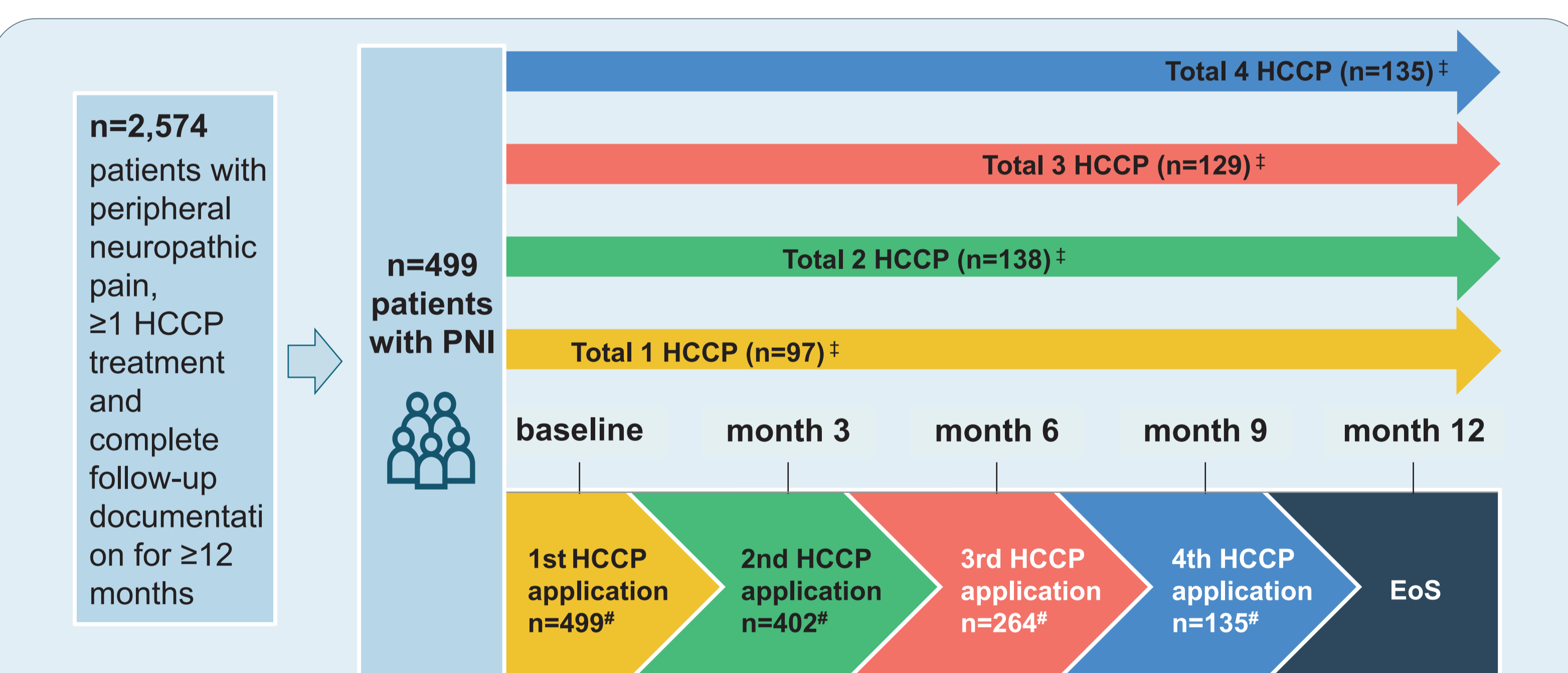


Figure 1: Study design. Assessments were made prior to the first HCCP treatment (baseline) and after each HCCP treatment or immediately before the next treatment at 3-month intervals. Patients who discontinued treatment were evaluated within ± 2 weeks of the anticipated time of treatment.

#) Number of patients receiving a 1st, 2nd, 3rd, and 4th treatment. †) number of patients with a total of 1, 2, 3 and 4 treatments, respectively, during the observation period (12 months). EoS: End of Study (month 12); HCCP: high concentration capsaicin patch; PNI: peripheral nerve injury.

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
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)
Average 24-hour pain intensity (API, mm VAS), mean [median] (SD)	53.8 [50] (15.4)
No. of previous neuropathic pain treatments ([co-]analgesics), mean [median] (SD)	7.7 [7] (2.3)
No. of current neuropathic pain treatments at baseline ([co-]analgesics), mean [median] (SD)	4.1 [4] (1.7)
No. of physician specialties involved in neuropathic pain management, mean [median] (SD)	7.0 [7] (1.5)

PNI, peripheral nerve injury; SD, standard deviation; VAS, visual analogue scale

Results

This analysis included 499 patients (Table 1), with 97, 138, 129, and 135 receiving 1, 2, 3, and 4 HCCP treatments, respectively. PIX scores significantly decreased after the first treatment across all groups. The scores further declined progressively in patients who continued HCCP and increased in those who discontinued treatments (Figure 2A). The same trend was seen in the proportion of patients achieving a $\geq 30\%$ reduction in 24-hour API (Figure 2B). Important improvements with each additional treatment were also observed in sleep quality (mPDI), overall well-being (MQHFF), physical (PCS) and mental (MCS) QoL scores (VR-12) as well as a reduction in number of days that daily activities could not be performed (Figure 2C–G). Notably, all measures deteriorated three months after treatment has been stopped. Changes from baseline to the fourth treatment were as follows (mean \pm SD): PIX (mm on visual analogue scale [VAS]): 53.2 \pm 13.6 to 29.1 \pm 12.0, API (mm VAS): 53.7 \pm 16.4 to 21.5 \pm 15.3, MQHFF: 9.7 \pm 6.9 to 15.7 \pm 11.7, mPDI (mm VAS): 49.6 \pm 22.2 to 20.3 \pm 16.7, VR12-PCS: 29.5 \pm 8.2 to 37.0 \pm 11.3, VR12-MCS: 41.6 \pm 13.1 to 52.1 \pm 17.5, von Korff (days absent from usual activities in the past three months): 51.3 \pm 35.4 days to 27.1 \pm 24.5 days. The tolerability profile only featured application-site reactions (data not shown).

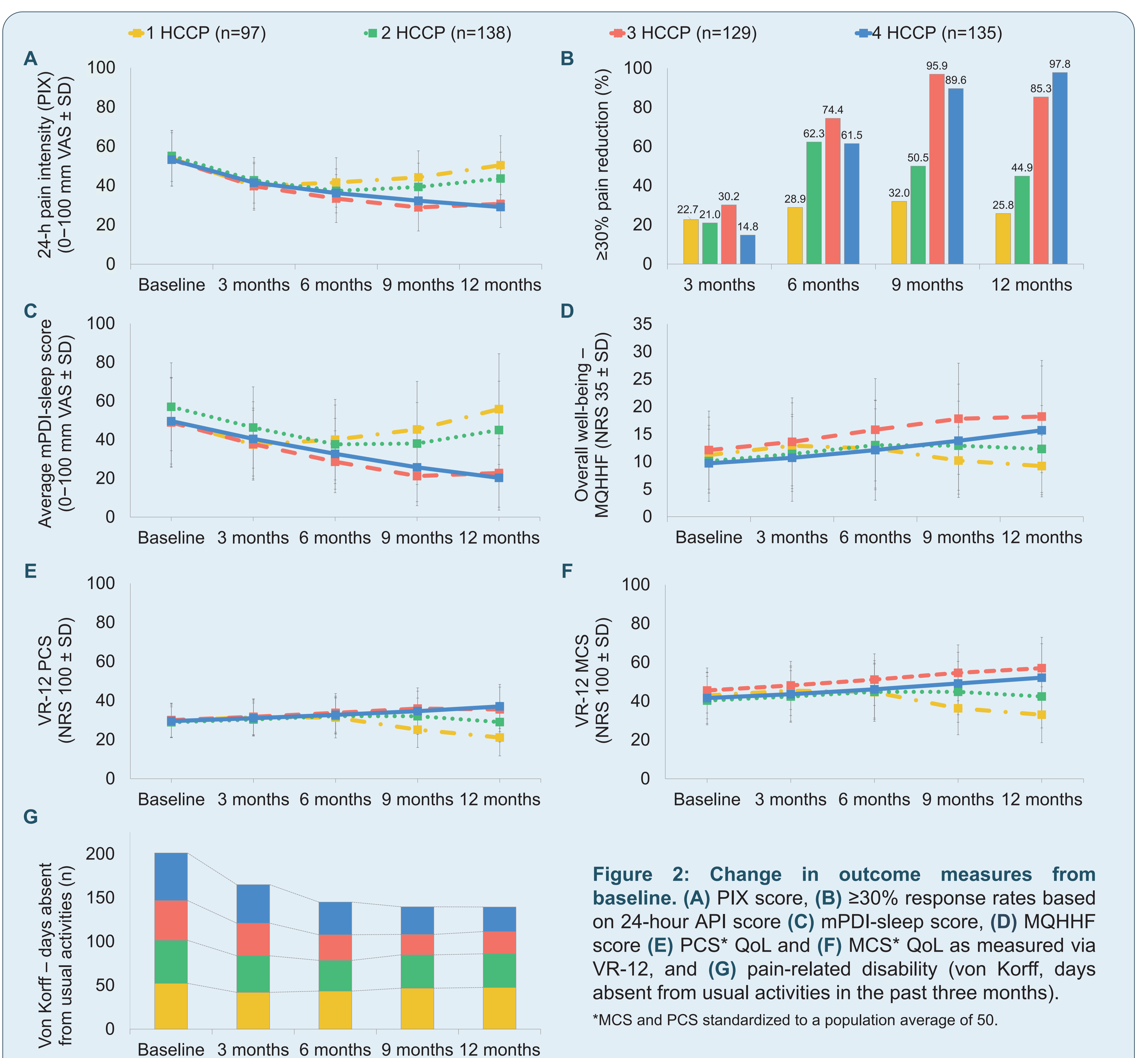


Figure 2: Change in outcome measures from baseline. (A) PIX score, (B) $\geq 30\%$ response rates based on 24-hour API score (C) mPDI-sleep score, (D) MQHFF score (E) PCS* QoL and (F) MCS* QoL as measured via VR-12, and (G) pain-related disability (von Korff, days absent from usual activities in the past three months).

*MCS and PCS standardized to a population average of 50.

Conclusions

Treatment of PNI patients with HCCP resulted in significant improvements in pain intensity, sleep disturbance, and both physical and mental QoL. These benefits contributed to an overall enhancement in well-being and daily functioning. Progressive improvement was observed with each treatment but diminished when treatment was discontinued, highlighting the importance of repeated treatment for optimal clinical benefit.