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Efficacy of palmitoylethanolamide in patients with painful neuropathy. A clinical and neurophysiological open study. Preliminary results.

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Introduction: Recent studies suggest that inflammation and mast cell activity play a crucial role in the pathophysiology of neuropathic pain. Palmitoylethanolamide is a recently developed drug that inhibits mast cell activity (Fig.1).

Methods: To assess the efficacy of palmitoylethanolamide in painful neuropathy we plan to collect 30 drug naïve patients with painful neuropathy or non-responders to other drugs. To date we clinically investigated sensory disturbances and pain with an 11-point numerical rating scale (NRS) in 27 patients before and after treatment with palmitoylethanolamide. In all patients we investigated non-nociceptive fibres function by nerve conduction study (NCS) and nociceptive fibres function by laser evoked potentials (LEPs) (Fig.2).

Results: After treatment the amplitude of ulnar and sural sensory nerve action potential was higher ($P = 0.039$ and $P = 0.045$ respectively) and pain rating lower ($P < 0.001$). The changes of hand and foot LEP amplitudes also reached statistical relevance ($P = 0.045$ and $P = 0.04$ respectively) (Fig.3). The mean value of the afferent pathway-related neural responses after treatment was significantly higher than that before (sensory index) (Fig.4).

Discussion: Our preliminary findings indicate that palmitoylethanolamide may improve nerve function and reduce neuropathic pain. These findings indicate the need for a randomized controlled trial to assess the effectiveness of palmitoylethanolamide.

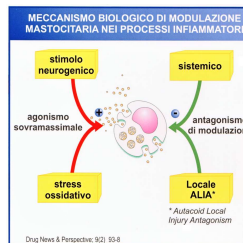


Fig. 1 Biological mechanism of mast cell modulation in inflammatory processes.

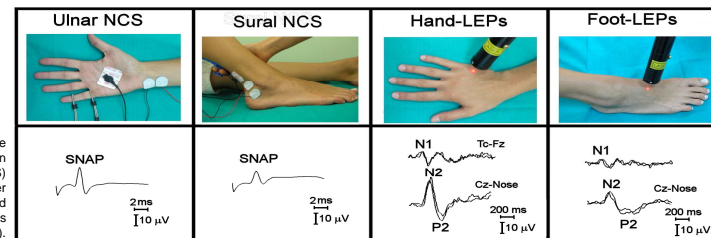


Fig. 2 Nerve Conduction Study (NCS) and Laser Evoked Potentials (LEPs).

Sensory Index Change

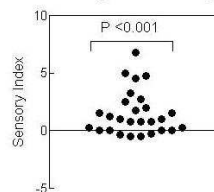


Fig. 4 Sensory index change after treatment.

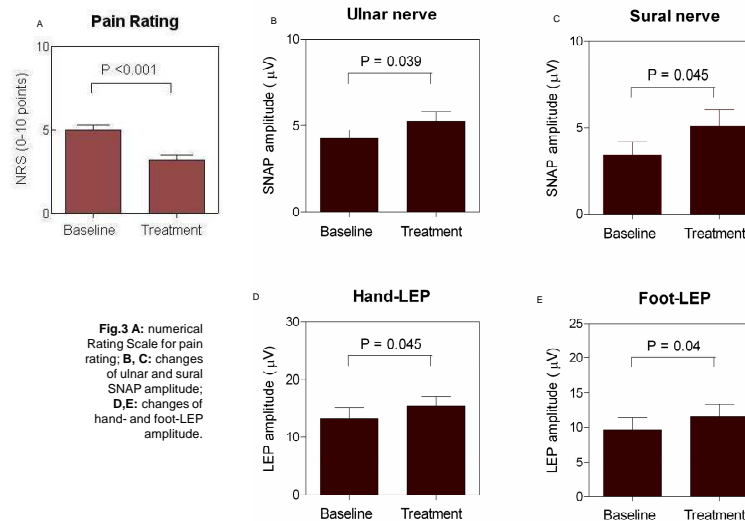


Fig. 3 A: numerical Rating Scale for pain rating; B, C: changes of ulnar and sural SNAP amplitude; D, E: changes of hand- and foot-LEP amplitude.

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