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> [J Pain Res.](#) 2019 May 20;12:1577-1604. doi: 10.2147/JPR.S192174. eCollection 2019.

Effectiveness and Tolerability of THC:CBD Oromucosal Spray as Add-On Measure in Patients With Severe Chronic Pain: Analysis of 12-week Open-Label Real-World Data Provided by the German Pain e-Registry

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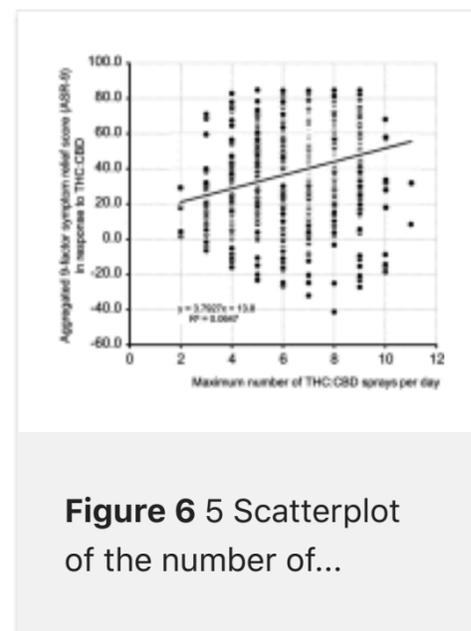
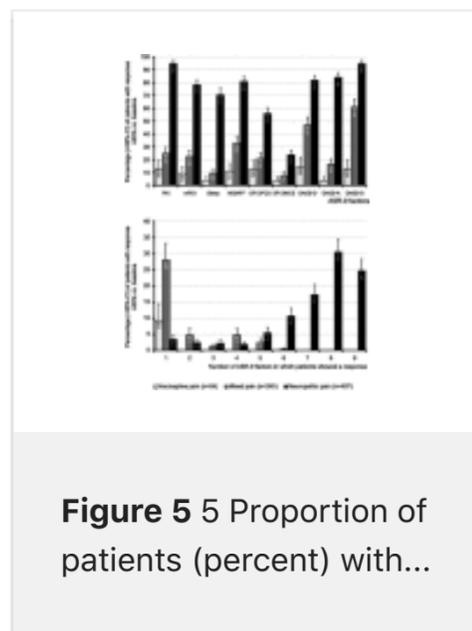
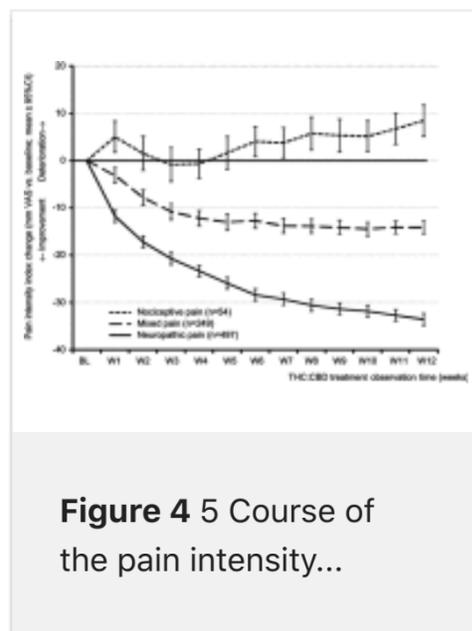
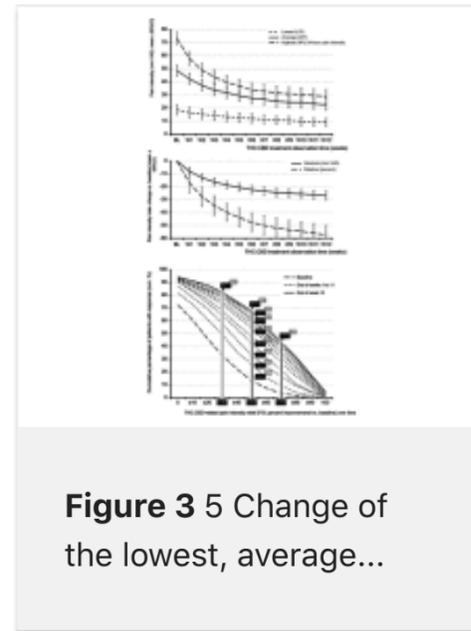
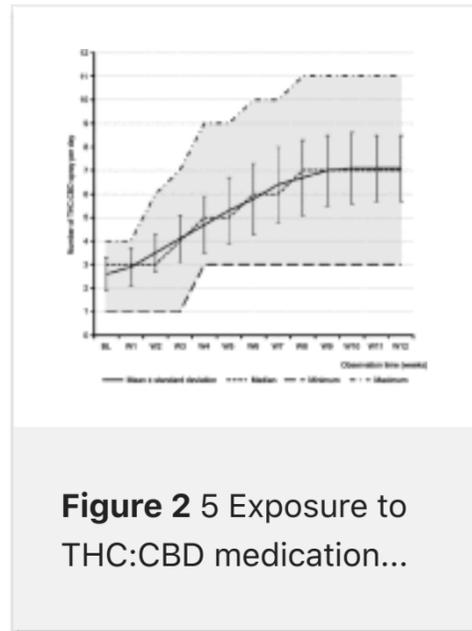
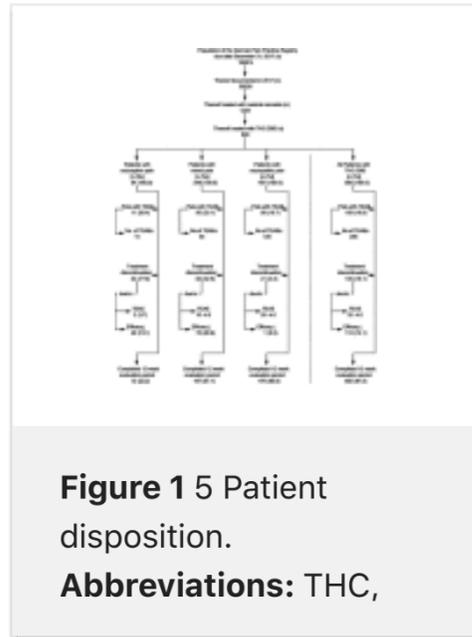
Abstract

Objective: To evaluate effectiveness, tolerability and safety of an oromucosal spray containing Δ^9 -tetrahydrocannabinol (THC) and cannabidiol (CBD), as add-on treatment in patients with severe chronic pain (SCP). **Methods:** Exploratory analysis of anonymized 12-week routine/open-label data provided by the German Pain e-Registry (GPR) on adult SCP patients treated with THC:CBD oromucosal spray in 2017. **Results:** Among those 30.228 cases documented in the GPR in 2017, 800 (2.6%; 57% female, mean \pm SD age: 46.3 \pm 9.7 years) received a treatment with THC:CBD. All patients fulfilled the legislative preconditions for a treatment with cannabis as medicine as defined by the German Act Amending Narcotics and Other Regulations. THC:CBD-treatment was followed by an aggregated nine-factor symptom relief (ASR-9) improvement at end of week 12 vs baseline of 39.0 \pm 26.5% (95%-CI: 36.9-41.1, median: 42, range -41 to 85). A full ASR-9 response (ie, a 50%-improvement in all 9 factors) was found for 123 patients (15.4%), while 488 patients (56.0%) presented with an \geq 50% improvement in at least 5 of 9 ASR factors. With a 54.9 \pm 17.2% (median: 56%, range: -6 to 85) improvement was significantly superior in the neuropathic pain subgroup (n=497, 62.1%) vs those with mixed (n=249, 31.1%; ASR-9: 18.2 \pm 12.0, median: 19, range: -12 to 42%) or nociceptive pain (n=54, 6.8%; ASR-9: -11.9 \pm 10.5, median: -11, range: -41% to 12%; p <0.001 for each). 159 patients (19.9%) reported at least one of 206 TEAEs, most of them of mild intensity (n=81.6%). Most frequently reported TEAEs were increased appetite (n=50, 6.3%) and dysgeusia

(n=23, 2.9%). TEAE-related discontinuations were reported for 32 patients (4.0%). 113 (14.1%) patients discontinued due to inadequate pain relief, most of them with nociceptive pain (n=40, 74.1%), least with neuropathic pain (n=1, 0.2%; $p<0.001$). **Conclusion:** THC:CBD oromucosal spray proved to be an effective and well-tolerated add-on treatment for patients with elsewhere refractory chronic pain - especially of neuropathic origin.

Keywords: German pain e-Registry; THC:CBD spray; add-on treatment; neuropathic pain; retrospective analysis; severe chronic pain.

Figures



All figures (11)

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