drug trials; 2) to identify trials that specifically examined the impact of treatment on patient-reported anxiety, depression and sleep disturbance, as these common comorbid symptoms are associated with poorer health status in people with epilepsy; and, 3) to identify which measures/domains were most responsive to change. METHODS: A review of 41 adult epilepsy trials examining the impact of an oral antiepileptic drug on patient-reported assessments of anxiety, depression, well-being, sleep, function and treatment satisfaction. Studies were identified through searches in MEDLINE, the Cochrane Central Register of Controlled Trials and reference lists of published articles. RESULTS: The most common types of PROs comprised epilepsy-specific measures assessing multiple domains of functioning and well-being (used in 30 studies) and generic measures assessing anxiety/depression and other emotions (used in 21 studies). There was limited detection of treatment effect on scales assessing anxiety/depression and emotional well-being. Scales assessing perceptions of emotional well-being were more likely to show significant differences than measures assessing symptom severity. Patients were not required to have clinically significant anxiety/depression to participate. It is possible that patients entered trials with symptoms in the normal range, leaving no room to show improvement; that treatment did not worsen symptoms; or, that instruments were not responsive. Findings were mixed regarding other specific health status domains. Patients receiving active treatments typically reported significantly higher levels of satisfaction than those receiving placebo. Only 2 trials identified that assessed patient-reported sleep, but both showed significant differences on specific domains. CONCLUSION: Anxiety and depression were among the most common PROs assessed, but there was limited detection of treatment effect. Trial selection criteria complicate interpretation of findings. Patient-reported sleep outcomes were rarely studied, but deserve more attention in adult epilepsy drug trials.

LONGITUDINAL PATIENT-REPORTED OUTCOMES (PRO) IN SUBJECTS WITH REFRACTORY PAIN ASSOCIATED TO TRIGEMINAL NEURALGIA: A POST-HOC ANALYSIS OF A 12-WEEK PROSPECTIVE STUDY IN PRIMARY CARE SETTING (PCS) UNDER ROUTINE MEDICAL PRACTICE

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OBJECTIVES: To analyze longitudinal PRO measurements evolution after treating refractory pain due to Trigeminal Neuralgia in Primary Care Setting (PCS) during 12-weeks under routine medical practice. METHODS: Sub-analysis of a sample of patients above 18 years, with 6-month chronic pain due to trigeminal neuralgia refractory to, at least, one previous analgesic [previous mean (SD) number of drugs was 2.2 (1.2), with a 36.3% on one-drug only], included in a prospective, naturalist, 12-weeks two-visit study on refractory peripheral Neuropathic pain. PRO measurements included pain severity by McGill-pain scale (included 50%-reduction responder rate and days with no/mild pain), anxiety and depression symptoms (HAD scale), sleep disturbances (MOS-sleep), disability (Sheehan scale), and quality-adjusted-life-year (QALY) gain (EQ-5D). Paired non-parametric and t-tests were applied. RESULTS: Ninety-one patients were analyzed: 45% switched to pregabalin as a monotherapy, 37% received pregabalin as add-on therapy, and in 18% previous treatment was replaced by a regimen not including pregabalin. After 12 weeks of therapy, significant reduction in last-week mean pain severity [-35.0 (23.9) mm, p < 0.0001, 53.9% responders] and percentage of subjects declaring the pain as severe or worst from 60.5% to 10.5% (p < 0.0001), was accompanied by reductions in total disability score [-8.2 (6.0) pts, p < 0.0001], depression symptoms score [-3.8 (4.2) pts, p < 0.0001], anxiety symptoms score [-3.4 (3.3) pts, p < 0.0001], and summary-index sleep problems scoring [-16.5 (18.4), p < 0.0001], while treatment increased the quarterly mean number of days with no/mild pain [+32.3 (28.9) days, p < 0.0001], the average number of sleeping-hours per night [+0.8 (1.3), p < 0.0001], and produced a QALY gain of 0.0317 (0.0385). CONCLUSION: A therapy mix of painful trigeminal neuralgia mostly based on pregabalin (82% of cases) was associated with a significant longitudinal improvement in patient-reported-outcomes including severity of pain, symptoms of depression and anxiety, disability, sleep disturbance and quality-adjusted-life-year gain.