minimal side effects / acceptable side effect profile, effective medication, and tolerability.

Conclusions

Most patients in Germany are treated with acute medications only, although many experience headache frequencies indicating prevention eligibility. Notably, patients with chronic headache frequency (15 + HD) have low preventive treatment use and high combination OTC and acute prescription use. Considerable impairment in work productivity and daily activity was observed across all headache frequency groups.

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Baseline demographics and disease characteristics of patients with episodic cluster headache: results from a phase 3 clinical trial

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The Journal of Headache and Pain 2018, **19(Suppl 1):**P113

Background: Cluster headache (CH) is a disabling primary headache disorder characterized by episodic attacks of intense unilateral headache with autonomic symptoms and/or restlessness or agitation. Patients with episodic CH (approximately 85.0% of CH patients) have cluster periods typically lasting 2-12 weeks and differ diagnostically from chronic CH patients based on duration of remissions. Increased blood levels of calcitonin gene-related peptide (CGRP) have been associated with CH, making CGRP a potential therapeutic target. The objective of this study was to assess the efficacy and safety of galcanezumab, a CGRP monoclonal antibody, in patients with episodic CH. In this abstract, we report on baseline demographics and disease characteristics of these patients.

Methods: This phase 3, randomized, double-blind, placebo-controlled study enrolled patients aged 18-65 years who met International Classification of Headache Disorders, 3rd edition, beta version diagnostic criteria for episodic CH and had a prior history of a cluster period that lasted ≥6 weeks. During the prospective baseline, patients were required to have a total of ≥4 attacks, with an attack frequency of at least one attack every other day but ≤8 attacks/day. Certain concomitant abortive (but not preventive) treatments were allowed. Eligible patients were randomized to galcanezumab 300 mg or placebo administered subcutaneously once monthly for 2 months. Analyses were conducted on an intent-to-treat population.

Results: A total of 106 patients were randomized and treated with galcanezumab 300 mg (N=49) or placebo (N=57). Overall, the patient population was predominately male (83.0%) and white (84.9%), with a mean age of 46.4 years and the majority from Europe (66.0%). Mean duration of CH illness was 16.8 years. Lifetime suicidal ideation and suicidal behavior before screening was reported by 13.2% and 0.9% of patients, respectively. Current tobacco and nicotine combined use was reported by 53.8% of patients, while 26.4% reported prior use. The most common pre-existing conditions were insomnia (10.4%), gastroesophageal reflux disease (10.4%), and hypercholesterolemia (7.6%). During the prospective baseline period, patients had an average of 17.5 CH attacks per week. Average pain severity of the CH attack was 2.5 on a 5-point scale (moderate to severe). The average weekly total of CH attack duration was 15.5 hours. The proportion of patients using oxygen and/or subcutaneous sumatriptan during the prospective baseline period was 45.3% and 56.6%, respectively.

Conclusion: These data build upon the existing data to provide descriptive characteristics of the episodic CH population.

Ethics approval

The study was approved by a central Ethics Review Board and registered on ClinTrials.gov (NCT02397473).

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PrevenBox: Evaluation of concomitant use of preventive medications with OnabotulinumtoxinA in migraine

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The Journal of Headache and Pain 2018, **19(Suppl 1):**P114

Background: OnabotulinumtoxinA is an effective, tolerable and safe preventive treatment for chronic migraine (CM). Other than a reduction in headache frequency or disability, in CM the withdrawal of concomitant preventive medication indicates treatment effectiveness and quality of life improvement.

Objective: To characterize the change in the use of oral preventive medication after treatment with OnabotulinumtoxinA in patients with migraine.

Methods: This is a multicentre study. We consecutively included patients with migraine (ICHD-3) that were on preventive treatment with OnabotulinumtoxinA. We retrospectively collected demographic data, diagnosis of migraine, frequency and intensity changes, number of cycle and OnabotulinumtoxinA dose. In addition, we listed the initial and current preventive treatment (number of drugs and group) and the number and cycle of medications withdrawn. We performed a univariate and logistic regression analysis.

Results: We included 542 patients: 87.6% women, mean age 47.6 ± 11.7 years. A 89.3% had chronic migraine and 10.8% had high frequency episodic migraine. The mean reduction in frequency after treatment was 13.4±8.2 headache days/month. At baseline, a 91.3% took other preventives and during treatment with OnabotulinumtoxinA a 58.6% withdrew at least one drug, 25.8% stopped completely all oral preventive drugs. Factors associated with withdrawal were: being male, having >50% response in frequency and intensity, the number of infiltrations and a shorter chronification period until the first OnabotulinumtoxinA administration ($p < 0.05$). The multivariate analysis showed that a better response in intensity (OR:1.8 [1.4-2.2], $p<0.001$), a greater number of infiltrations (OR:1.1 [1.0-1.2], $p<0.001$) and a shorter chronification period (OR:0.994 [0.992-0.997], $p<0.001$) were predictors of withdrawal. The ROC curve, showed that 6 OnabotulinumtoxinA cycles was the cut-off point that better predicted oral preventive medication withdrawal ($p < 0.001$).

Conclusions: Treatment with OnabotulinumtoxinA reduces the use of other preventive medications for migraine. The highest probability of withdrawal occurs after 6 cycles of treatment.