PO-283: Adverse events leading to discontinuation of galcanezumab in Real Wold Evidence (RWE) in 1056 patients with migraine (Galca-Only Consortium).

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OBJETIVE

Anti-calcitonin gene-related peptide monoclonal antibodies are generally well tolerated, with few adverse effects and in most cases, mild in nature. We aim to describe the frequency of adverse events leading to discontinuation in a large series of patients treated with galcanezumab in a real world setting.

METHODS

Galca-Only Consortium is a multicenter ambisective cohort study. From November 15, 2019, to January 31, 2022, all consecutive patients with chronic migraine or high-frequency episodic migraine with prior failure to three or more migraine preventive drugs, treated with galcanezumab were included.
Patients were systematically assessed by headache experts and followed up quarterly for 12 months. A series of variables were gathered, related to patients' demographics, comorbidities, migraine diagnosis and situation and migraine burden. Response to treatment was according to the 50% responder rate (R50), defined as the proportion of patients with who achieved a reduction of at least 50% in the number of headache days per month (HDM), compared to the baseline period.
During the entire study period, 12 months, the proportion of patients who discontinued galcanezumab due to adverse effects, in the opinion of the responsible physician, was assessed. Adverse events were classified according to the reported symptoms.

RESULTS

During the study period, 70/1056 (6.6%) patients discontinued galcanezumab due to adverse events. A total of 90 adverse events were reported, summarized in the table.
Patients presenting adverse events leading to discontinuation did no differ in age, gender, years of migraine disease, HIT6 at baseline, compared to the rest of the patients.
There were differences in the proportion of patients with chronic migraines (92.9% vs 75.2%, p=0.001), number of headache days per month at baseline (30 [25-39] vs 20 [14-30] p=0.0.001) and frequency of comorbidities, such as mood disorders (58.3% vs 31.6%), fibromyalgia (21.7% vs 10.7%, p=0-001), or other chronic pain (41.7% vs 18.4%, p=0.001), respectively.

Table1. *Discontinuation of Galcanezumab due to Adverse events (n=90) in 70 patients00*

	N (%)
Vertigo/Dizziness	31 (2.9)
Constipation	13 (1.2)
Local cutaneous pain o rash	9 (0.9)
Fatigue, drowsiness	9 (0.9)
Generalized cutaneous rash	7 (0.7)
Blood pressure instability	5 (0.3)
Diarrhea, nausea, abdominal pain	4 (0.5)
Generalized pain	3 (0.3)
Others	9 (0.9)

CONCLUSION

Galcanezumab discontinuation due to treatment emergent adverse effects in patients with migraine in a real world setting was infrequent. Half of them are due to dizziness or constipation.