Effectiveness and safety of monoclonal antibodies for migraine prevention after two and a half years of clinical experience

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BACKGROUND AND IMPORTANCE

Erenumab, galcanezumab and fremanezumab were approved in 2019 for migraine crisis prevention. Efficacy and safety were demonstrated in three-months lasting clinical trials. At present, long-term effectiveness and safety can be analyzed.

AIM AND OBJECTIVES

To evaluate the effectiveness and safety of monoclonal antibodies (mAb) utilized in migraine after two-and-a-half years of clinical use.

MATERIALS AND METHODS

Prospective, observational study conducted in a tertiary hospital (December-2019 to June-2022). Data were obtained from patients' medical records (approved by our Ethics Committee). Effectiveness and tolerance are evaluated 3 months after initiation:

- ✓ **Response** [decrease in headache and/or migraine days per month ≥50% compared to baseline and/or a significant improvement in quality of life (measured by HIT-6 and MIDAS scales] (and proper tolerance): maintained up to 12 months.
- ✓ **Partial response** (decrease ≤50%) or adverse effects (AE): change to another mAb with different mechanism of action.
- ✓ **Lack of response** (decrease ≤25%): treatment suspended.

*If response is achieved during the last months, the mAb can be maintained for another year.

RESULTS

✓253 patients initiated treatment with a mAb. 69% (n:175) completed 12 months with effectiveness (responders) and 31% (n:78) stopped at third-month evaluation (PR/LR patients and AE-suffering patients), 42 of which changed to a second mAb. Ending reasons were: PR/LR (n:52), PR/LR and AE (n:9), AE (n:8) and others not related to the treatment (n:9).

✓After completing 12 months, 140 patients stopped the treatment; 25 maintained it for another treatment-course, some of which have already started a third course (median duration: 23 [17-37]), and 10 switched to a second mAb.

✓**Safety**: 33% (n:83) reported at least one AE during the treatment with the first and/or second mAb, being the reason for discontinuation in 7% (n:17) of patients (due to vertigo and constipation, mainly). Most frequent AE: vertigo/dizziness (17%, n:45), constipation (13%, n:33) and skin rashes after injection (4%, n:11).

CONCLUSION AND RELEVANCE

Anti-CGRP mAb are effective and safe treatments that improve migraine suffering patients' quality of life. A significant percentage of patients completes the treatment-course and only 7% of patients discontinues the mAb due to intolerance.

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