

EFFECTIVENESS AND SAFETY OF MONTHLY VERSUS QUARTERLY FREMANEZUMAB FOR MIGRAINE PREVENTION: A 12 MONTHS ITALIAN, MULTICENTER, REAL-LIFE STUDY

A. Antoniazzi[1], E. Ratto[1], I. Cetta[1], A. Visentini[1|2], L. Consuma[1|2], F. Genovese[1|2], L. Zanandrea[1|2], C. Lovati[3], S. Cevoli[4], V. Favoni[4], F. Vernieri[5|6], C. Altamura[5|6], B. Colombo[1], M. Filippi[1|2], R. Messina[1|2]

[1]Headache Center, Neurology Unit, IRCCS San Raffaele Scientific Institute, Milan, Italy; [2]Vita-Salute San Raffaele University, Milan, Italy; [3]Headache Center, L. Sacco University Hospital, Milan, Italy; [4]IRCCS Istituto delle Scienze Neurologiche di Bologna, Italy; [5]Unit of Headache and Neurosonology, Department of Medicine and Surgery, University Campus Bio-Medico di Roma, Italy; [6]Fondazione Policlinico Universitario Campus Bio-Medico, Rome, Italy

Background. Fremanezumab, an anti-CGRP monoclonal antibody, is available as either a 225 mg monthy injection or a 675 mg quartery injection for migraine prevention. Both regimens were effective in randomized controlled trials, but real world evidence is lacking. Our purpose was assessing whether the two regimens have comparable efficacy and tolerability.

Methods. This is a prospective observational study involving four Italian headache centers. Eligible patients were assigned to the monthly or quarterly regimen based on their preference. Patient characteristics were collected at baseline, and then reassessed at 3, 6 and 12 months after starting fremanezumab. We collected data about monthly headache days (MHD), monthly migraine days (MMD), acute medication days (AMD), acute medication pills (AMP) and adverse events (AE). Migraine disability assessment score (MIDAS), Headache Impact Test (HIT-6), Allodynia Symptoms Checklist (ASC12) were completed at each timepoint.

Results. Two-hundred twenty-two patients chose monthly administration and 165 patients chose quarterly administration. Data were available for 347 patients at 3 months, for 377 patients at 6 months and for 298 patients at 12 months. Patients in the monthly group were 80,8% female and had a median age of 49 (IQR 38-58), 57,1% had episodic migraine with 15 (IQR 11-23) MHD and 15 (IQR 10-20) MMD at baseline. Patients in the quarterly group were 79,8% female and had a median age of 51 (IQR 41-58), 66.3% had episodic migraine with 16 (IQR 12-25) MHD and 15 (IQR 10-20) MMD at baseline. There was no significant difference at baseline between the two groups. Both regimens proved effective and safe, with no difference between the two groups at each timepoint in responder rates and AE. Both groups showed similar reductions in MHD, MMD, AMD and AMP, as well as in MIDAS and HIT-6 scores.

Conclusions. Our data confirm the effectiveness of fremanezumab in improving both frequency of headache and disability metrics in migraine patients, along its general safety and tolerability. Choice of monthly or quarterly administration does not appear to influence any outcome measure, and should therefore be individualized based mainly on patients preference and ease of administration.