▪ Headache Medicine 2026, Supplement ▪ p-ISSN 2178-7468, e-ISSN 2763-6178

Headache Medicine

ID: 348

Therapeutic profile and functional response to anti-CGRP monoclonal antibodies in patients with resistant migraine: a systematic literature review

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Introduction
Migraine is one of the leading causes of neurological disability worldwide, with a significant functional and socioeconomic impact. Resistant migraine is characterized by the persistence of symptoms after multiple failures of conventional therapies, which increases chronicity and disease burden. Monoclonal antibodies (mAbs) targeting Calcitonin Gene-Related Peptide (CGRP) promote direct modulation of this pathway. Assessment using patient-reported outcome instruments (PROMs), such as MIDAS and HIT-6, allows for the measurement of functional response and quality of life not exclusively identified by the reduction in monthly migraine days (MMDs).

Objective
To investigate the therapeutic profile and safety of anti-CGRP monoclonal antibodies in patients with resistant migraine.

Methods
This is a systematic review following the PRISMA guidelines. The search encompassed the PubMed, Cochrane Library, and Web of Science databases (2015-2026) using the descriptors "Monoclonal Antibodies," "Refractory Migraine," and "Quality of Life," analyzing the variables mean reduction in monthly migraine days (MMDs), functional disability (MIDAS and HIT-6 scores), quality of life (MSQ and EQ-5D-5L scores), and safety profile (incidence of adverse events and discontinuation rates). Statistical analysis was performed using R software, considering a significance level of $p<0.05$.

Results
124 articles were identified, with 22 eligible, of which 9 were included. Statistically significant reductions were observed in MMDs, with average drops between 8.2 and 12.1 days ($p<0.001$) and response rates (≥50% in MMDs) between 36.4% and 71%, demonstrating sustained benefits for up to 12 months. MIDAS scores showed drops above 60 points, with functional response (≥50% score) reaching 89.5%–100%. The HIT-6 scale also registered significant reductions ($p<0.001$), with drops of up to 12.1 points and clinically relevant improvements (≥6 points) in up to 66% of patients. mAbs demonstrated a greater magnitude of effect than botulinum toxin in outcomes such as MHD (-11.9 vs. -7.6) and MIDAS (-62.3 vs. -43.1). An improvement in quality of life (MSQ and EQ-5D-5L) was noted, with the health index rising from 0.61 to 0.72 after one year ($p<0.001$). The safety profile was favorable, with mostly mild adverse events such as administration reactions, constipation, fatigue, and nausea. Discontinuation rates due to ineffectiveness ranged from 7.3% to 11.6%, and discontinuations due to intolerance ranged from 1.5% to 3.3%.

Conclusion
Anti-CGRP mAbs demonstrate efficacy and safety in the prophylaxis of resistant migraine, promoting a sustained reduction in MMDs and improved quality of life. The MIDAS and HIT-6 scales demonstrate the recovery of functionality and patient satisfaction that isolated attack counting may underestimate. Furthermore, they show a greater magnitude of effect compared to botulinum toxin, a favorable safety profile, and low discontinuation rates.

Keywords:
Quality of life
Calcitonin gene-related peptide
Monoclonal antibodies
Refractory migraine

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