Effectiveness and tolerability of monoclonal antibodies targeting CGRP pathway for migraine prevention: Real-world data from the Migraine Registry (ReMig) in the Czech Republic

P039

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BACKGROUND

– Czech national registry of patients with migraine on biological therapy (ReMig) is a database containing information about patients diagnosed with migraine who are treated with anti-CGRP (Calcitonin Gene-Related Peptide) monoclonal antibodies at headache centres under the auspices of the Czech Headache Society (CzHS)
– Registry data are expected to lead to better understanding of patients' characteristics and to more effective treatment of migraine

OBJECTIVE

– First evaluation and cohort characteristics of patients with resistant episodic and chronic migraine treated with biological therapy in the real world, enrolled in the ReMig registry

METHODS

– The ReMig registry is a Czech registry of Migraine patients on biological therapy (SÚKL 210422007) which started in 2021
– It is a Phase 4, real-world, non-interventional multicentre prospective longitudinal study of migraine patients treated with all available CGRP monoclonal antibodies
– The following data is collected in ReMig registry: demographics, monthly migraine days (MMD), days of acute migraine medication, treatment persistence, safety, and patient questionnaires
– The analysed cohort consists of all patients who have a diagnosis of migraine and have at least one visit entered in the ReMig registry (i.e., have available biologic treatment data)
– The database lock point was on 21st of June 2023

RESULTS

– In addition to clinical data, patient questionnaires were prospectively collected within the ReMig registry; these results are included in poster ID P102

Patient characteristics

– At the database lock point (DLP), a total of 2,269 patients with available treatment data were recorded in the ReMig registry (**Table 1**)
– Positive family history of migraine was recorded in 64.6% of patients, most of the patients (60.1%) did not remember any migraine triggering event
  • 12.5% patients reported stress and 11.4% menarche as a migraine triggering event
– Before anti-CGRP treatment, 98.9% of patients were treated with antiseizure medication, 53.4% with calcium channel blockers and 45.5% with antidepressants
– Almost 60% of patients had at least one comorbidity (**Table 2**)
– Malignancies, eye diseases, urological/nephrological diseases and chronic infectious diseases were recorded in less than 5% of patients and are not included in the **Table 2**

Table 1. Baseline characteristics

Baseline characteristics[1)]	Total N = 2,269
Female	1,987 (87.6%)
Age at the DLP [years]	46.5 (±10.5)
Age at the time of diagnosis [years]	19.1 (±9.6)
Time from diagnosis [years]	27.4 (±12.2)
Time from diagnosis to 1st anti-CGRP treatment [years]	26.3 (±12.2)
Migraine diagnosis	
Chronic migraine (CM)	637 (28.1%)
Episodic migraine (EM)	1,632 (71.9%)
Baseline MMD	12.0 (±5.6)

1) Values are number and percentage or mean and standard deviation. DLP, database lock point; MMD, monthly migraine days.

Table 2. Comorbidities recorded in at least 5% of patients

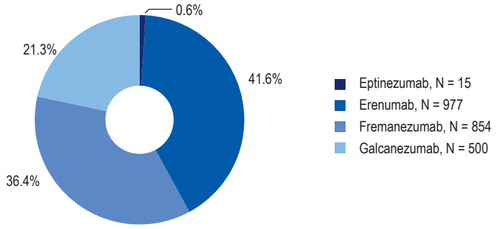
Comorbidities[1)]	Total N = 2,269
At least one	1,297 (57.2%)
Metabolic/endocrine diseases	404 (17.8%)
Cardiovascular disease	330 (14.5%)
Psychiatric disease	324 (14.3%)
Musculoskeletal diseases	257 (11.3%)
Other diseases	217 (9.6%)
Gastrointestinal and hepatic diseases	176 (7.8%)
Pulmonary diseases	139 (6.1%)
Neurological diseases	119 (5.2%)

1) Three patients' data were missing; comorbidities were multiple choice. Percentage was calculated from all analysed patients.

Anti-CGRP treatment

– In the **2,269** patients analysed, a total of 2,346 treatment series were recorded (**Figure 1**); 3.3% of patients had two or more treatment series
– The mean duration of anti-CGRP treatment was 12 months with maximum 2.5 years
– At the time of DLP, 253 (10.8%) of 2,346 treatments had been discontinued
  • The most common reason for discontinuation was lack of efficacy (66.4%) and adverse events (10.3%)

Figure 1. Type of anti-CGRP treatment



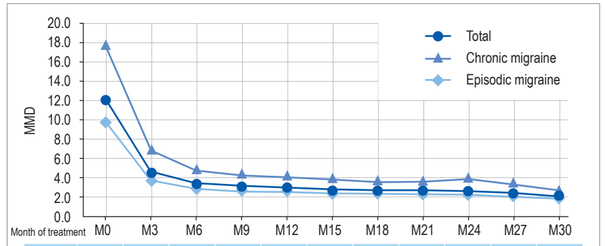
MMD

– Monthly migraine days (MMD) are collected in the ReMig registry at each visit, which takes place every 3 months (M0 = baseline, M3 = after 3 months of treatment, etc.)
– The baseline MMD was 12.0 for all analysed patients and decreased to 2.9 and 2.6 after 12 and 24 months of treatment (**Figure 2**)
– The proportion of patients with ≥50% improvement in MMD from baseline was 79.2% after 3 months and 96.9% after 24 months of anti-CGRP treatment (**Figure 3**)

Acute medication

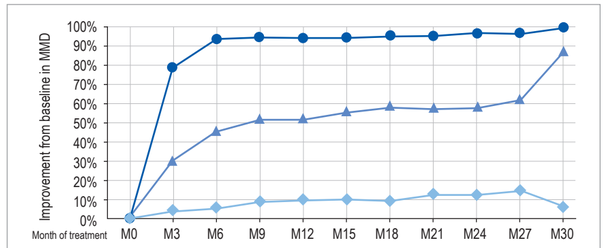
– A total of 2,298 patients (98.0%) required acute medication for migraine at the start of treatment
– The proportion of patients decreased during follow-up, with 901 patients (88.6%) after 12 months
– The mean number of days with the need for acute medication decreased during follow-up (**Figure 4**)

Figure 2. Mean MMD during anti-CGRP treatment



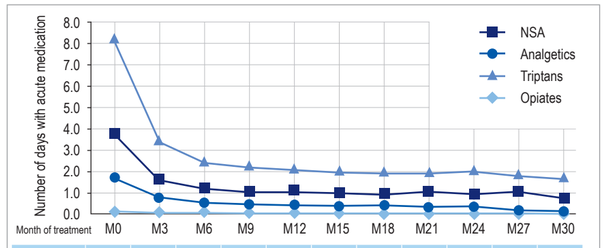
	M0	M3	M6	M9	M12	M15	M18	M21	M24	M27	M30
Total, N	2,346	1,909	1,558	1,273	1,017	787	591	401	228	103	16
CM, N	662	526	425	341	261	195	149	110	57	23	3
EM, N	1,684	1,383	1,133	932	756	592	442	291	171	80	13

Figure 3. Proportion of patients achieving ≥50%, ≥75% and 100% reduction in MMD from baseline



	M0	M3	M6	M9	M12	M15	M18	M21	M24	M27	M30
≥50%, N	1,512	1,460	1,207	962	744	564	383	221	100	16	
≥75%, N	576	707	658	526	440	344	230	132	64	14	
100%, N	79	86	112	101	77	55	52	28	15	1	

Figure 4. Mean number of days with acute medication on anti-CGRP treatment

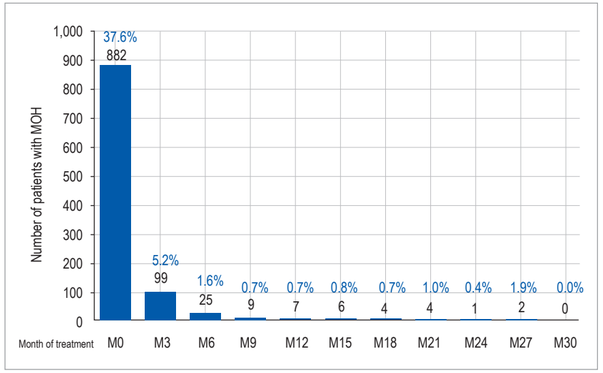


	M0	M3	M6	M9	M12	M15	M18	M21	M24	M27	M30
NSA, N	997	719	570	456	375	287	211	152	79	31	4
Analgetics, N	412	299	236	187	150	111	92	56	31	9	1
Triptans, N	1911	1422	1105	855	666	514	386	256	143	58	10
Opiates, N	10	4	3	3	2	3	1	0	0	0	0

MOH

– Medication overuse headache (MOH) decreased from 37.6% to 0.7% and 0.4% after 12 and 24 months of treatment (**Figure 5**)

Figure 5. Medication overuse headache during anti-CGRP treatment



Safety

– Of the 2,269 patients analysed, a total of 93 patients (4.1%) experienced ≥1 adverse event (AE)
– A total of 123 adverse events were recorded, 19 patients had >1 AE
  • In 2 patients (0.1%) the AE was serious

CONCLUSION

– The first results of registry confirm very good efficacy and tolerability of all CGRP antibodies
– The proportion of patients with ≥50% improvement in MMD from baseline was 79.2% after 3 months
– Further long-term prospective follow-up is expected to provide multi-year treatment success data, including further details and implications (e.g., effect of drug switching)
– Collecting data on the efficacy and tolerability of migraine treatment may contribute to its appropriate and safe administration, as well as to successful negotiations with government institutions and health insurance companies

The ReMig registry is supported by Hedalga foundation.
European Headache Congress (EHC), 6-9 December 2023, Barcelona, Spain.

What is impact of biological treatment on quality of life of patients with migraine: Real-world data from patient questionnaires in Migraine Registry (ReMig) in the Czech Republic

P102

Nežádal T[a], Doležal T[b], Pejřilová D[b], Turková B[b], Marková J[c], Bártková A[d], Klečka L[e] and ReMig study group

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BACKGROUND

– Czech national registry of patients with migraine on biological therapy (ReMig) is a database containing information about patients diagnosed with migraine who are treated with anti-CGRP (Calcitonin Gene-Related Peptide) monoclonal antibodies at headache centres under the auspices of the Czech Headache Society (CzHS)

OBJECTIVE

– Evaluation of work productivity, quality of life, impact of migraine on life and depression from patient questionnaires in patients enrolled in the ReMig registry

METHODS

– The ReMig registry is a Czech registry of Migraine patients on biological therapy (SÚKL 210422007) which started in 2021
– It is a Phase 4, real-world, non-interventional multicentre prospective longitudinal study of migraine patients treated with all available CGRP monoclonal antibodies
– The following data is collected in ReMig registry: demographics, monthly migraine days (MMD), days of acute migraine medication, treatment persistence and safety
– In addition to clinical data, patient questionnaires, specifically the WPAI, EQ-5D, HIT-6 and CUDOS, are prospectively collected within the ReMig registry
– Questionnaires were completed electronically by patients at the time of the follow-up visit to the physician every 3 months
– The database lock point was on 21st of June 2023

RESULTS

– In addition to patient questionnaires, patient clinical data were prospectively collected within the ReMig registry; these results are included in poster ID P039

Patient characteristics

– At the database lock point (DLP), a total of 2,269 patients and 2,346 treatment series were recorded in the ReMig registry
  • 87.6% were female patients, the mean age at the DLP was 46.5 years, the mean duration since diagnosis was 27.4 years
  • The mean baseline MMD was 12.0 and 71.9% had episodic migraine
  • The number of completed questionnaires was 727 at baseline, 452 after 12 months (M12) and 131 after 24 months (M24) of anti-CGRP treatment
– Visits are entered into the ReMig registry every 3 months (M0 = baseline, M3 = after 3 months, etc.)
– Description of the analysed cohort is part of poster ID P039

Work productivity

– Work productivity was assessed with the use of standardized Work Productivity and Activity Impairment (WPAI) questionnaire
  • The WPAI questionnaire ranges from 0 (or 0%, no limitation) to 100 (or 100%, complete limitation)
– For the employed patients, the mean absenteeism due to migraine was 11.6% and 2.7%, mean presenteeism was 49.6% and 15.6%, and mean overall work impairment was 52.7% and 16.5%, before and after 12 months of treatment, respectively (**Figure 1, Table 1**)
– The mean daily activity impairment evaluated in all patients was 58.2% at treatment initiation and 19.3% after 12 months of treatment

Figure 1. Work productivity questionnaire (WPAI) during anti-CGRP treatment

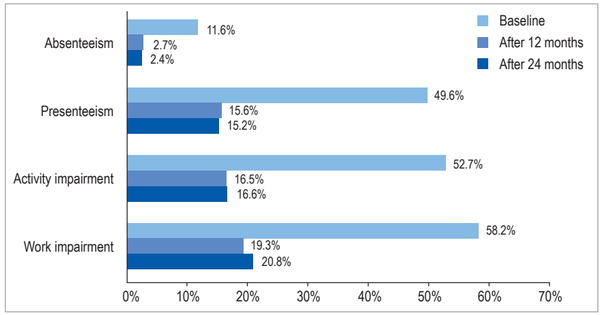


Table 1. Work productivity questionnaire (WPAI) during anti-CGRP treatment

WPAI[1)]	Absenteeism		Presenteeism		Work impairment		Activity impairment	
M0	552	11.6 (±20.4)	541	49.6 (±27.4)	541	52.7 (±28.4)	727	58.2 (±26.4)
M6	459	3.2 (±11.7)	456	19.3 (±24.4)	456	20.5 (±25.7)	582	23.3 (±26.7)
M12	353	2.7 (±12.0)	349	15.6 (±23.4)	349	16.5 (±24.3)	452	19.3 (±25.1)
M18	246	2.1 (±9.0)	245	15.1 (±20.9)	245	15.9 (±22.1)	297	19.7 (±24.1)
M24	104	2.4 (±8.3)	104	15.2 (±22.3)	104	16.6 (±23.9)	131	20.8 (±27.4)

1) Values are number of valid responses, mean and standard deviation (SD).

Quality of life

– The Quality of Life Questionnaire (EQ-5D) assesses 5 dimensions of quality of life: mobility, self-care, activities of daily living, pain/discomfort, and anxiety/depression
– A validated Czech version of the EQ-5D-3L questionnaire was used, and utilities were assessed using a British codebook (no Czech codebook exists yet)
  • A higher utility value corresponds to a higher quality of life, the maximum value is 1 (full health)
– The mean utility at baseline was 0.75 with median value of 0.80, and 0.88 after 12 months of treatment with median value of 1.00 (**Figure 2**)
– Patient-reported current health status on the visual analogue scale (VAS) was 64.6 and 78.2 before and after 12 months of biological treatment, respectively (**Table 2**)

Figure 2. Quality of life (EQ-5D) during anti-CGRP treatment

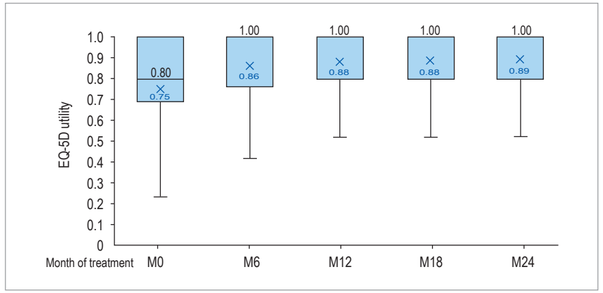


Table 2. EQ-5D visual analogue scale (VAS) during anti-CGRP treatment

EQ-5D VAS	N	Mean (±SD)
M0	727	64.6 (±23.2)
M6	582	75.6 (±23.5)
M12	452	78.2 (±22.2)
M18	297	77.5 (±22.1)
M24	131	77.0 (±23.2)

Impact of migraine on life

– The Headache Impact Questionnaire (HIT-6) assesses the impact of headaches on the ability to function at work, school, home, and social life
  • It ranges from 0 (no impact of migraine) to 78 (huge impact of migraine)
– At the start of biological treatment, 94.6% of patients experienced significant or huge impact of migraine on their lives; after 12 and 24 months of treatment, it was 48.0% and 42.0%, respectively (**Figure 3**)
– The mean value of HIT-6 was 65.4 and decreased to 54.9 after 12 months and 53.8 after 24 months of treatment (**Figure 4**)

Figure 3. Impact of migraine on life (HIT-6) during anti-CGRP treatment

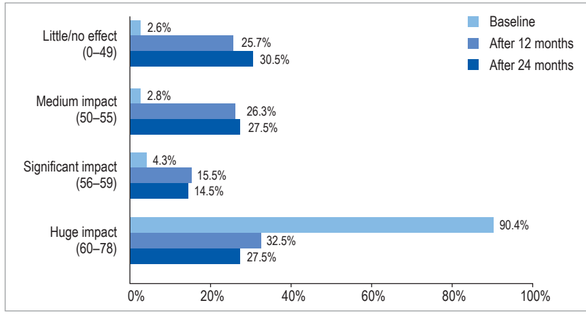
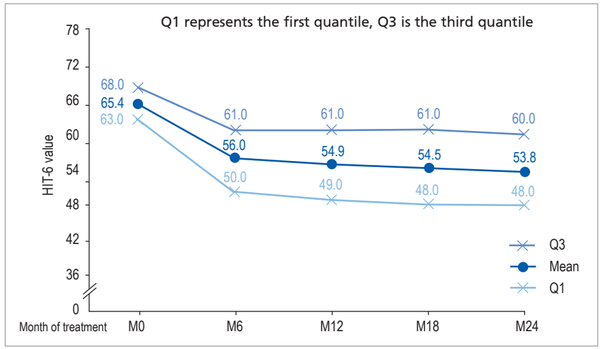


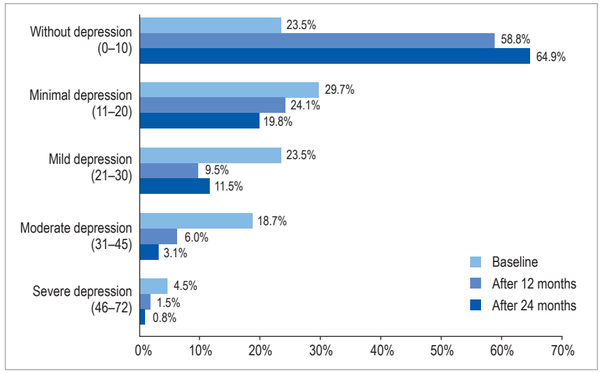
Figure 4. Impact of migraine on life (HIT-6) during anti-CGRP treatment



Depression

– The Clinically Useful Depression Outcome Scale (CUDOS) assesses patients' degree of depression in the past week, including the day the questionnaire was completed
  • The score ranges from 0 to 72, where a higher number indicates a higher degree of depression
– In total, only 23.5% of patients were free of depression when initiating biological treatment; after 12 and 24 months of treatment, the proportion without depressive symptoms increased to 58.8% after 12 months and 64.9% after 24 months of treatment (**Figure 5**)

Figure 5. Depression (CUDOS) during anti-CGRP treatment



CONCLUSION

– Patient questionnaires in ReMig registry contribute to clinical data by subjective patient assessment
– In addition to high efficacy and very good tolerability (poster ID P039), CGRP antibodies show substantial improvements in work productivity (WPAI), patient quality of life (EQ-5D), impact of headaches on patients' lives (HIT-6) and depression (CUDOS)
– During treatment with anti-CGRP antibodies, there was a significant improvement in work productivity and activities of daily living
– Psychiatric comorbidities are frequent in migraine, especially anxiety and depression. From the first years of the ReMig registry, the previously reported relief from depressive symptoms on CGRP antibody therapy is confirmed

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