

Real-world evidence on HRQoL of therapy-resistant migraine patients undergoing preventive treatment in an ambulatory care setting

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Migraine significantly impacts patients' lives

Migraine is associated with a high burden of disease and significantly reduces health-related quality of life (HRQoL). Generating evidence of relevant clinician- and patient-reported outcomes (PROs) for different treatments, especially preventive ones, therefore, is an essential prerequisite for advancing personalized care paths.

Novel preventive drug treatments may improve HRQoL

The objective of this study was to analyze the HRQoL and relevant clinical performance parameters in patients diagnosed with a therapy-resistant migraine who were receiving different types of preventive substances including monoclonal antibodies in a real-world ambulatory care setting.

Design/Methods

Study Design: A single-center retrospective observational study compared an intervention and control group diagnosed with a therapy-resistant migraine over 1 month in a specialized neurology care center.

Drug treatment: The intervention group received different types of monoclonal antibodies, whereas the control group received no medication or other types of preventive substances.

Instruments: Using the web-based software Heartbeat Pro, patients filled out questionnaires at two time points: baseline (T0) and 1 month follow-up (T1). Real-world evidence data was collected including medical history data as well as validated PROs like the disease-specific Migraine Disability Assessment (MIDAS), the generic EQ-5D-5L-VAS and the 7-domain score PROMIS-29 instruments.

Statistical analysis:

- We calculated the relative difference in the number of migraine days between T0 and T1 and classified them along a 1/3 quantile distribution. Subsequently, the relationship between improvement and treatment was plotted by an association plot showing the Pearson residuals and p-value.
- Data were submitted to a logistic regression predicting the migraine days' improvement by treatment and a linear mixed regression grouped by patient ID over time predicting the HRQoL measured by EQ5DVAS score (rating from 0-100 reflecting the patient's subjective quality of life).
- Spearman correlation was used to analyze the relationship between the 7-domain score PROMIS-29 and the migraine days as well as the MIDAS score.

Monoclonal antibodies reduce the number of migraine days

The majority of the study population in both groups was female aged between 51 and 60 years old and diagnosed with a chronic migraine (Table 1). The leading comorbidity in both groups was depression (~19%), followed by high blood pressure (~13%) and lung disease (~11%); ~28% of the migraine patients had no comorbid condition (Figure 1).

Table 1. Sample characteristics stratified by treatment

Treatment	N	monoclonal, N = 82 [†]	non-monoclonal, N = 21 [†]
Sex	103		
female	68 (83%)	15 (71%)	
male	14 (17%)	6 (29%)	
Diagnosis	103		
chronic migraine	65 (79%)	15 (71%)	
episodic migraine	17 (21%)	6 (29%)	
Smoking status	103		
No	51 (62%)	11 (52%)	
Smoked in the past	8 (9.8%)	3 (14%)	
Unknown	16 (20%)	5 (24%)	
Yes	7 (8.5%)	2 (9.5%)	
Age group	103		
<40	13 (16%)	4 (19%)	
>60	9 (11%)	4 (19%)	
40-50	23 (28%)	4 (19%)	
51-60	37 (45%)	9 (43%)	
[†] n (%)			

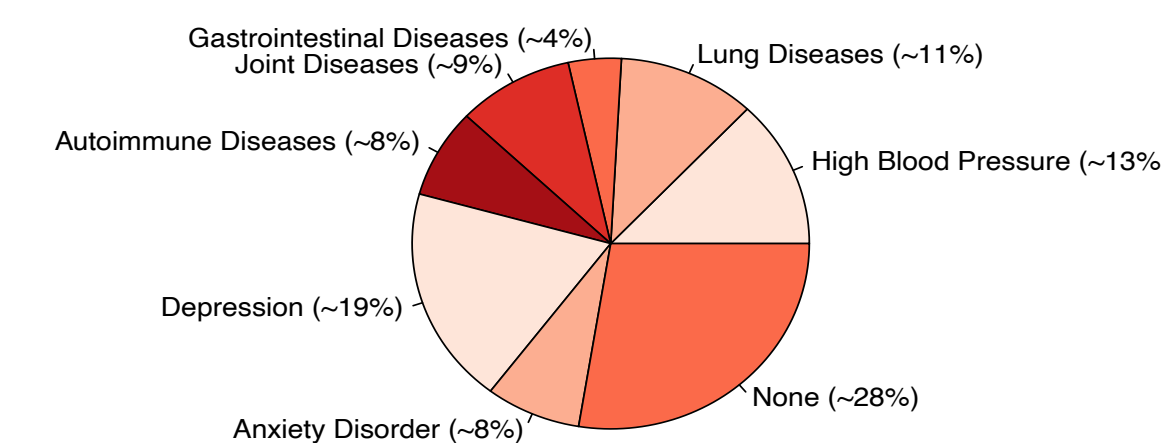


Figure 1. Comorbidities in migraine patient sample

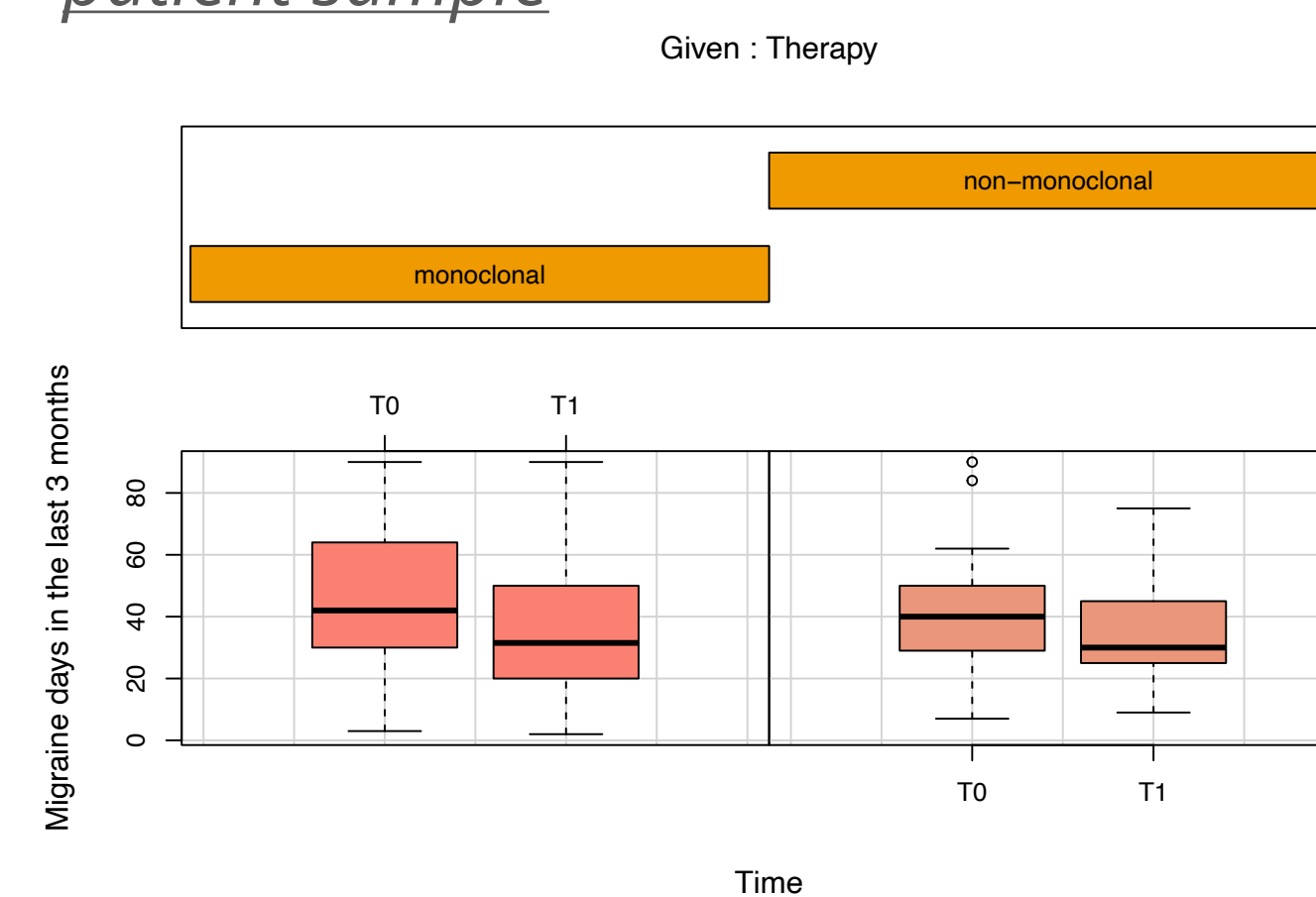


Figure 2. Number of migraine days at T0 and T1 grouped by treatment

75% of the intervention group reported to have 64 days of migraine at T0 and less than 49 days after one month of treatment equaling a decrease of 15 days. In comparison, 75% of the control group reported less than 50 days at T0 and finished with less than 45 days at T1 (decrease by 5 days). Thus, the number of migraine days decreased more in the intervention group (Figure 2).



Figure 3. Relationship between treatment and categorized by relative difference in migraine days after one month

"Worsening or low to no improvement" corresponds to (-0.0208,5] relative change in migraine days. Medium improvement reflects (-0.333,-0.0208] decrease in migraine days and high improvement to [-0.967,-0.333]. The intervention group, therefore, is overrepresented in the medium/high improvement category. However, the calculated Pearson residuals are non-significant with a p-value > 0.05 (Figure 3).

Table 2. Logistic regression of improvement in number of migraine days and linear mixed regression of quality of life predicted by treatment and/or time

Characteristic	Improvement of migraine days after 1 month		Quality of life (EQ-5D-VAS)	
	OR [†]	95% CI [†]	Beta	95% CI [†]
Therapy				
monoclonal	—	—	—	—
non-monoclonal	0.41	0.16, 1.02	-4.4	-14, 5.8
(Intercept)			57 ***	52, 62
Time				
T0			—	—
T1			7.9 ***	3.4, 12

[†]OR = Odds Ratio, CI = Confidence Interval p-values: * < 0.05, ** < 0.01, *** < 0.001

The logistic regression showed that the intervention group was ~2.4 times more likely to show improvement in the number of migraine days ($p = 0.056$). The subjective quality of life measurement, however, significantly increased by 7.9 score points after 1 month (Table 2).

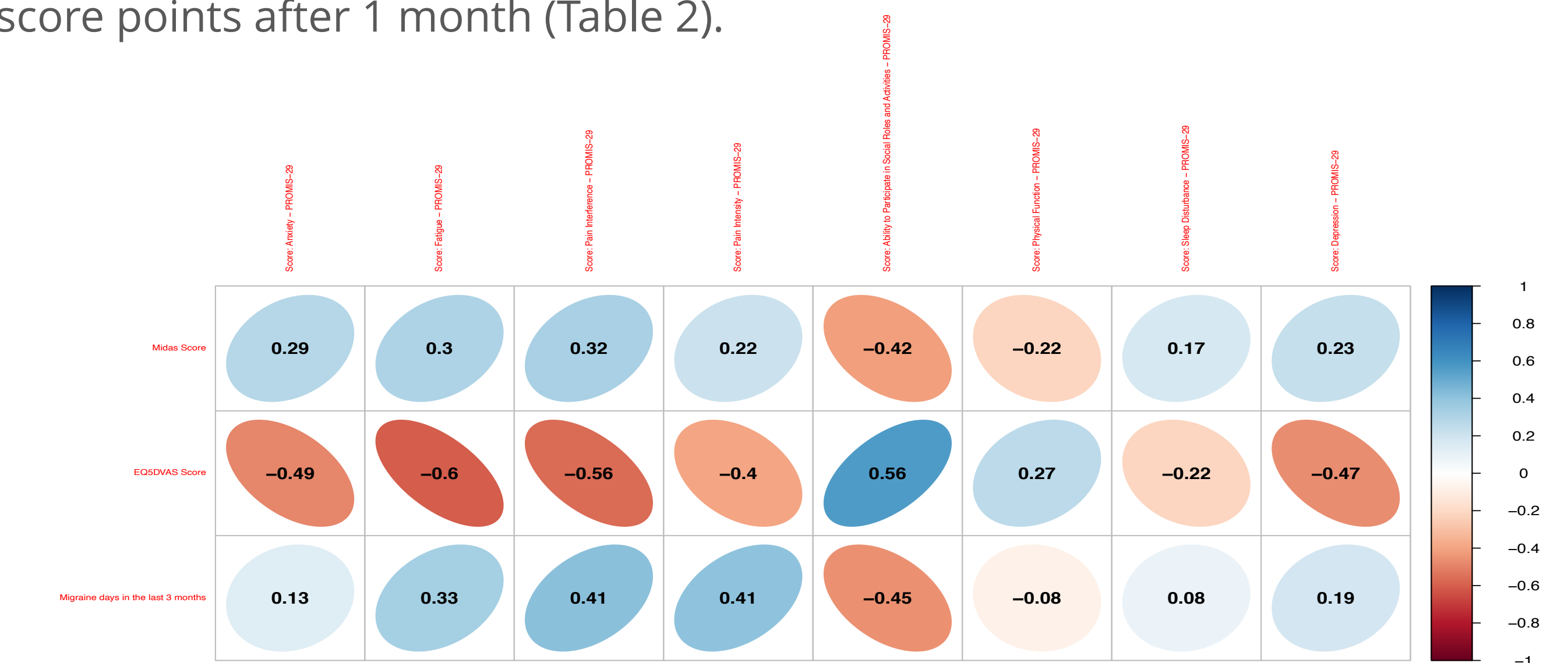


Figure 4. Spearman correlation between EQ5DVAS score, MIDAS score and migraine days in the last 3 months with the 7-domain PROMIS-29 scores

Number of migraine days in the last 3 months and the MIDAS score positively correlated with the PROMIS-domains of pain interference as well as pain intensity and negatively correlated with the ability to participate in social activities. Overall, a positive effect on some domains of the PROMIS-29 is associated with a reduced number of migraine days and an increased EQ5DVAS score (Figure 4).

Novel drug treatments can improve HRQoL

Patients receiving a preventive treatment with monoclonal antibodies experienced a decrease in migraine days and showed an improvement in certain PROMs, demonstrating that preventive migraine treatment in an ambulatory setting can be beneficial for the HRQoL and general clinical performance.

Outlook

The real-world evidence showed that treating migraine patients with monoclonal antibodies is associated with a reduced number of migraine days. To further validate the results, increasing the sample size of the control group as well as observing patients for a longer period of time would be beneficial.