Reducing the Impact of Headache and Allodynia Score in Chronic Migraine: An Exploratory Analysis from the Real-World Effectiveness of Anti-CGRP Monoclonal Antibodies Compared to Onabotulinum Toxin A (RAMO) Study

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Supplementary material S1. STROBE Checklist

Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title Page
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	9
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	9-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	9-10
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	9-10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9-10

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9-10
		(*b*) Describe any methods used to examine subgroups and interactions	9-10
		(*c*) Explain how missing data were addressed	9-10
		(*d*) If applicable, explain how loss to follow-up was addressed	NA
		(*e*) Describe any sensitivity analyses	9-10
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3-4, Table 1, Table 2, Table 3
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	4, Table 1
		(b) Indicate number of participants with missing data for each variable of interest	All Tables
		(c) Summarise follow-up time (eg, average and total amount)	4, Figure 1, Table 2
Outcome data	15*	Report numbers of outcome events or summary measures over time	5-6, Table 2, Table 3
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6, Table 2
		(*b*) Report category boundaries when continuous variables were categorized	6, Table 2
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-7, Table 2, Table 3, Table S1
Discussion			
Key results	18	Summarise key results with reference to study objectives	7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7-8
Generalisability	21	Discuss the generalisability (external validity) of the study results	7-8

Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10

Table S1. ASC-12 sensitivity analysis					
	Anti-CGRP mAbs	**BoNT-A**	**p-value**	**Adjusted MD (95%CI)**	**p-value**
ASC-12 ≥ 3 points (mild allodynia)					
Baseline ASC-12			**0.0012**	NA	NA
Mean (SD)	12.5 (3.8)	7.5 (3.7)			
Median (IQR)	14 (8 to 15)	7 (4.5 to 10)			
	n=10	n=36			
6 months CFB			**0.0202**	-6.1 (-11.8 to -0.4)	**0.036**
Mean (SD)	-5.8 (5.9)	-1.2 (4.4)			
Median (IQR)	-4 (-8 to -3)	-1 (-4.5 to 0.5)			
	n=9	n=36			
12 months CFB			**0.0083**	-5.5 (-11.0 to 0.1)	0.052
Mean (SD)	-6.7 (5.2)	-1.8 (4.0)			
Median (IQR)	-6 (-8 to -4)	-2 (-3 to 2)			
	n=9	n=29			
ASC-12 ≥ 6 points (moderate allodynia)					
Baseline ASC-12			**0.0143**	NA	NA
Mean (SD)	12.5 (3.8)	9.16 (3.2)			
Median (IQR)	14 (8 to 15)	8 (7 to 11)			
	n=10	n=25			
6 months CFB			0.0919	-5.8 (-12.7 to 1.1)	0.096
Mean (SD)	-5.8 (5.8)	-2.0 (4.5)			
Median (IQR)	-4 (-8 to -3)	-2 (-5 to 1)			
	n=9	n=25			
12 months CFB			**0.0455**	-6.7 (-13.0 to -0.5)	**0.037**
Mean (SD)	-6.7 (5.2)	-2.6 (4.4)			
Median (IQR)	-6 (-8 to -4)	-2 (-6 to 0)			
	n=9	n=21			
ASC-12 > 9 points (severe allodynia)					
Baseline ASC-12			0.1639	NA	NA
Mean (SD)	14.4 (2.6)	12.5 (2.1)			
Median (IQR)	14 (14 to 15)	12 (11 to 14)			
	n=7	n=10			
6 months CFB			**0.0100**	Not estimable	NA
Mean (SD)	-6.3 (6.3)	-0.8 (4.0)			
Median (IQR)	-4 (-6 to -3)	-1 (-2 to 1)			
	n=6	n=10			
12 months CFB			0.6822	Not estimable	NA
Mean (SD)	-6.3 (6.0)	-4.5 (4.8)			
Median (IQR)	-5 (-7 to -2)	-3.5 (-8 to -2)			
	n=7	n=8			

Abbreviations: 95%CI=95% confidence interval; ANOVA=analysis of variance; ASC-12=allodynia symptoms checklist; BoNT-A=Onabotulinumtoxin-A; CGRP=calcitonin gene related protein; HIT-6=headache impact test; IQR=interquartile range; mAbs=monoclonal antibodies; MD=mean difference; NA=not applicable; OR=odds ratio; SD=standard deviation.

Unadjusted comparisons performed by means of the Wilcoxon rank-sum test. Adjusted analysis was performed with an ANOVA model with significantly different baseline variables entered as covariates to estimate MD with 95%CI for continuous variables.