

Cognitive Interference in Migraine: Results of the MiCOAS Qualitative Study

Maya Tuchman Gerstein, DrPH, MPH

American Headache Society Annual Conference

June, 2021

Additional Authors: R.J. Wirth, PhD, Alyssa Uzumcu, BA, Kelly P. McCarrier, PhD, MPH, Alexis Cooke, PhD, Nancy Toubia, MPH, Dawn C. Buse, PhD, Carrie R. Houts, PhD, James S. McGinley, PhD, Richard B. Lipton, MD

MiCOAS™



PHARMERIT
AN OPEN HEALTH COMPANY



Vector Psychometric Group, LLC

Disclosures

- This presentation was supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award (UG3FD006795) totaling \$1,286,743 with 100 percent funded by FDA/HHS. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government

Acknowledgements

- The authors would like to thank Katie Golden for her work as a MICOAS advisor and CHAMP for advertising for study participation and assisting in recruitment

Learning Objectives

1. Upon completion, participants will be able to recognize migraine-related impacts to sustained attention, executive function, language/speech, and memory as reported by patients in qualitative interviews
2. Upon completion, participants will be able to distinguish patient-reported experiences with migraine-related cognitive interference across pre-headache, headache, post-headache, and inter-ictal periods
3. Upon completion, participants will be able to describe the patient-reported burden of cognitive deficit co-occurrence among persons living with migraine disease

Background and Objectives

- The Migraine Clinical Outcome Assessment System (MiCOAS) is a multi-stage FDA grant focused on integrating patient input into clinical trial outcomes
- Little previous research has been conducted to understand the prevalence and burden of migraine-related cognitive interference
- Study aim: Capture patient perspectives on migraine-related cognitive changes during and between migraine attacks
 - Essential first step in the development of a core set of patient-centric COAs in migraine

Methods:

Recruitment, Sampling, Data Collection, Analysis

- N=428 eligible individuals screened and consented through online platform distributed via the Coalition for Headache and Migraine Patients (CHAMP)
- Iterative purposeful sampling targeted variation and representation in study sample
- A total of N=40 semi-structured interviews were conducted in 8 sampling waves
 - n=20 episodic migraine (EM); n=20 chronic migraine (CM)
- Hybrid deductive/inductive approach to transcript coding
 - Saturation of concepts achieved (84% of cognitive interference codes identified within first 30% of interviews [Wave 3])
- Concept frequencies utilized as a starting point for analysis
- Thematic content analysis to identify key patterns and recurrent themes

Select Characteristics of Interview Sample

Variable	Category	Total Interview Sample (N=40)
Gender, n (%)	Women	31 (77.5)
	Men	7 (17.5)
	Trans Man	1 (2.5)
	Genderqueer/Gender Non-Binary	1 (2.5)
Race*, n (%)	American Indian or Alaskan Native	4 (10.0)
	Asian	3 (7.5)
	Black or African American	9 (22.5)
	Native Hawaiian or Other Pacific Islander	1 (2.5)
	White	27 (67.5)
	Other	1 (2.5)
	Prefer not to answer	1 (2.5)
Ethnicity, n (%)	Hispanic	9 (22.5)
	Non-Hispanic	31 (77.5)
Education, n(%)	Grade 12 or GED equivalent	3 (7.5)
	Associates degree, technical school, or trade apprenticeship	8 (20.0)
	Some college (No degree awarded)	10 (25.0)
	College Degree (BA, BS, or similar)	11 (27.5)
	Advanced or graduate/post-graduate degree (PhD, MD, JD, PharmD, or similar)	8 (20.0)
	Prefer not to answer	-
Household Income, n (%)	Under \$12,999	2 (5.0)
	\$13,000 to \$21,999	6 (15.0)
	\$22,000 to \$49,999	10 (25.0)
	\$50,000 to \$74,999	6 (15.0)
	\$75,000 to \$99,999	4 (10.0)
	\$100,000 and over	8 (20.0)
	Prefer not to answer	4 (10.0)
Average Number of Headache Days per Month, n (%)	0-1	-
	2-3	6 (15.0)
	4-7	8 (20.0)
	8-14	6 (15.0)
	15-23	18 (45.0)
	24 or more	2 (5.0)

*Total percent exceeds 100 because participants were able to identify with more than one race category

Cognitive Interference: Concept Frequencies

Frequency of migraine related cognitive changes reported by interview participants (N=40) across pre-headache, headache, post-headache, and inter-ictal phases of their typical migraine attacks

Cognitive Interference	Pre-Headache	Headache	Post-Headache	Inter-Ictal
Trouble with concentration/focus	25	25	11	0
Confusion/disorientation	4	3	2	0
Avoid making decisions	17	18	6	0
Fogginess	18	9	17	0
Losing words/speech	24	12	9	2
Memory	12	15	11	12
General	3	5	7	9
Learning	9	7	5	6
Retrieval/recall	3	10	4	1
Slurred words/speech	1	3	0	0
Difficulty processing information	14	11	7	1

- Cognitive changes often manifest in pre-headache, carry into headache, and may resolve or linger during the post-headache period
- Pain during headache may dominate experience, use up attentional resources, and thus, reduce “bandwidth” to focus on/identify cognitive changes

00-12: I have no activities, no talking. I'm just laying there, I'm in pain. It's not - nothing else is happening. Everything is focused on my body and how it's reacting to it.

Co-Occurrence of Cognitive Deficits

Proportion of participants (N=40) reporting occurrence and co-occurrence of migraine-related cognitive interference features across pre-headache, headache, post-headache, and inter-ictal phases

# of Endorsed CI Features	Pre-headache	Headache	Post-headache	Inter-ictal
0	10.0%	12.5%	32.5%	67.5%
1	10.0%	7.5%	22.5%	22.5%
2	22.5%	22.5%	20.0%	5.0%
3	15.0%	22.5%	7.5%	5.0%
4	20.0%	10.0%	7.5%	0.0%
5	15.0%	15.0%	5.0%	0.0%
6	7.5%	5.0%	5.0%	0.0%
7	0.0%	0.0%	0.0%	0.0%
8	0.0%	2.5%	0.0%	0.0%
9	0.0%	2.5%	0.0%	0.0%

- Vast majority of participants endorsed two to five cognitive features during pre-headache/headache
 - Co-occurrence of cognitive deficits during these phases may be common
- In contrast, among participants reporting cognitive interference during post-headache/inter-ictal periods, most endorsed only one or two cognitive features

Cognitive Interference: Key Findings

Key Finding	Exemplary Quote
<ul style="list-style-type: none"> • Impairments to 1) receptive language, 2) language production, and/or 3) speech production reported by majority of participants (29/40; 72.5%) 	<p>00-06: <i>It's like the connection between knowing what I'm trying to say and my mouth is just broken. Which is really frustrating, and that ends up just making things worse, because then I frustrate myself, and the frustration makes the pain worse. [pre-headache]</i></p>
<ul style="list-style-type: none"> • Changes in ability to sustain attention include fogginess, confusion/disorientation, and trouble maintaining concentration/focus 	<p>00-18: <i>Sometimes it really - I just say that I'm thinking through cotton or that my brain feels foggy. [pre-headache]</i></p>
<ul style="list-style-type: none"> • Deficits in executive function include difficulty making decisions and processing information 	<p>00-27: <i>When - I've had my husband basically forcibly take me to the emergency room when it was bad enough. He'd ask me, do you want to go to the emergency room, and I can't even decide yes or no. [headache]</i></p>
<ul style="list-style-type: none"> • Issues with memory (i.e., learning, retrieval/recall) cited across all phases of attack and as a key cognitive impact in the inter-ictal period 	<p>00-01: <i>Well, you don't notice it until there's a need for something, where you - if, that day after the migraine, there's a need for that memory, even if it's short-term memory, and you can't access it, then it's very noticeable - something that happened two days before the migraine and it's not immediately available, but you sort of know it...That's uncomfortable. [inter-ictal]</i></p>
<ul style="list-style-type: none"> • Variable relationship between pain and cognitive interference 	<p>00-14: <i>It's gotten more back - it was I would say more back to normal because I didn't have that pain that would distract my focus, take away from my focus...definitely my focus came back together because I didn't have that intense pain. [post-headache]</i></p> <p>00-41: <i>I'll still have brain fog. I actually will still have brain fog for days. And I won't realize it until later. I could be completely fine, have ba - brain fog and work on my report, like my budget or whatever, and come back a couple days later without brain fog and be like, OK, that makes no sense. I don't know why I did that. I must have had brain fog.[post-headache]</i></p>

Conclusions and Study Limitations

- Cognitive interference is a common burden for people with migraine disease
 - 36 out of 40 (90%) participants reported one or more cognitive feature during pre-headache
 - 35 out of 40 (87.5%) participants reported one or more cognitive feature during headache
 - 27 out of 40 (67.5%) participants reported one or more cognitive feature during post-headache
 - 13 out of 40 (32.5%) participants reported one or more cognitive feature during interictal period
- Cognitive interference during and between migraine attacks impacts function
- Findings highlight the importance of assessing cognitive-related outcomes in this population
- Study assessed subjective cognition (i.e., patient self-report) and used participants' perceptions of cognitive change to drive categorization of cognitive impacts/features