

Beyond Frequency Alone – Exploring What Meaningful Improvement Means in the Treatment of Migraine: Focus Groups in Patients and Health Care Providers

Patricia Sacco,¹ Shweta Shah,² Laurin Jackson,¹ Mark Price,¹ Mark Bensink,² Carolyn Bernstein³

¹Research Triangle Institute, Raleigh, NC, USA; ²Amgen Inc., Thousand Oaks, CA, USA; ³Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

INTRODUCTION

- Although several prophylactic migraine treatments exist, treatment guidelines do not recommend a single, first-line-treatment
 - Choice of treatment is based on patient symptoms, needs, and the presence of comorbid conditions and concomitant medications^{1,2}
 - Reducing monthly migraine days may be an important goal (50% used as a benchmark), but other factors must also be considered³
- Patients with chronic migraine experience substantially greater impact on daily activities compared with patients with episodic migraine, with higher direct medical costs, greater overall health care resource utilization, reduced health-related quality of life, and higher rates of comorbidities^{4,5}
- Meaningful symptom and functional improvements may be defined differently for these groups
- There is growing interest in defining meaningful attributes of care and symptom and functional improvements, which are critical factors that influence acute and preventive treatment decision-making

OBJECTIVE

- To understand what aspects of symptom and functional improvement are most meaningful to patients with migraine and physicians who care for patients with migraine

METHODS

- Study Design**
- A focus group study was conducted in October 2019 at a qualitative research facility in Raleigh, North Carolina, USA
 - A convenience sample of patients and health care providers (HCPs) were recruited for a total of three focus groups
 - The focus groups were moderated by experienced qualitative researchers using a semi-structured discussion guide
 - Participants were asked to respond to a series of discussion topics using a standard methods that elicited both spontaneous responses and responses to direct probes
 - All interviews were audio-recorded

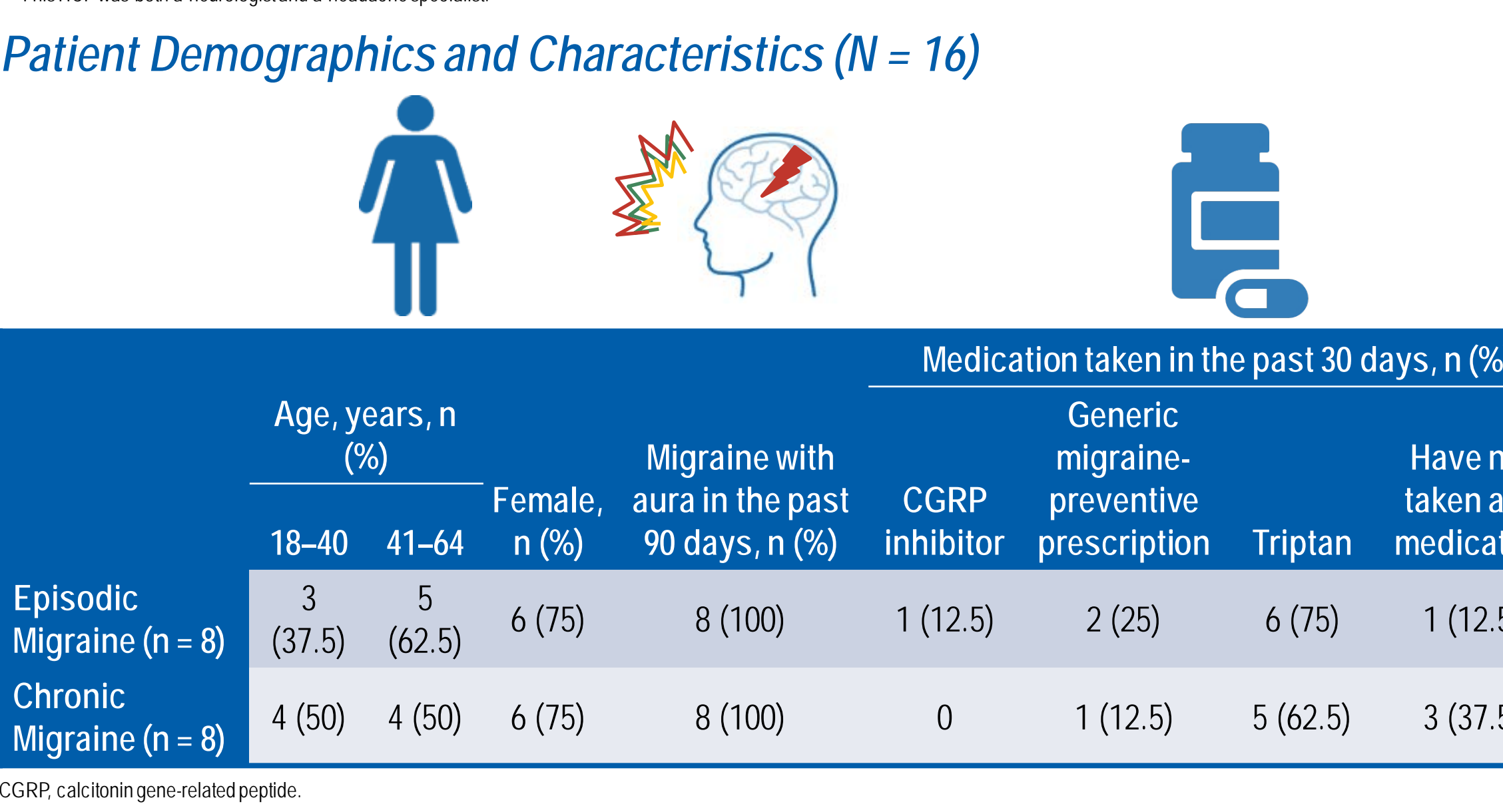
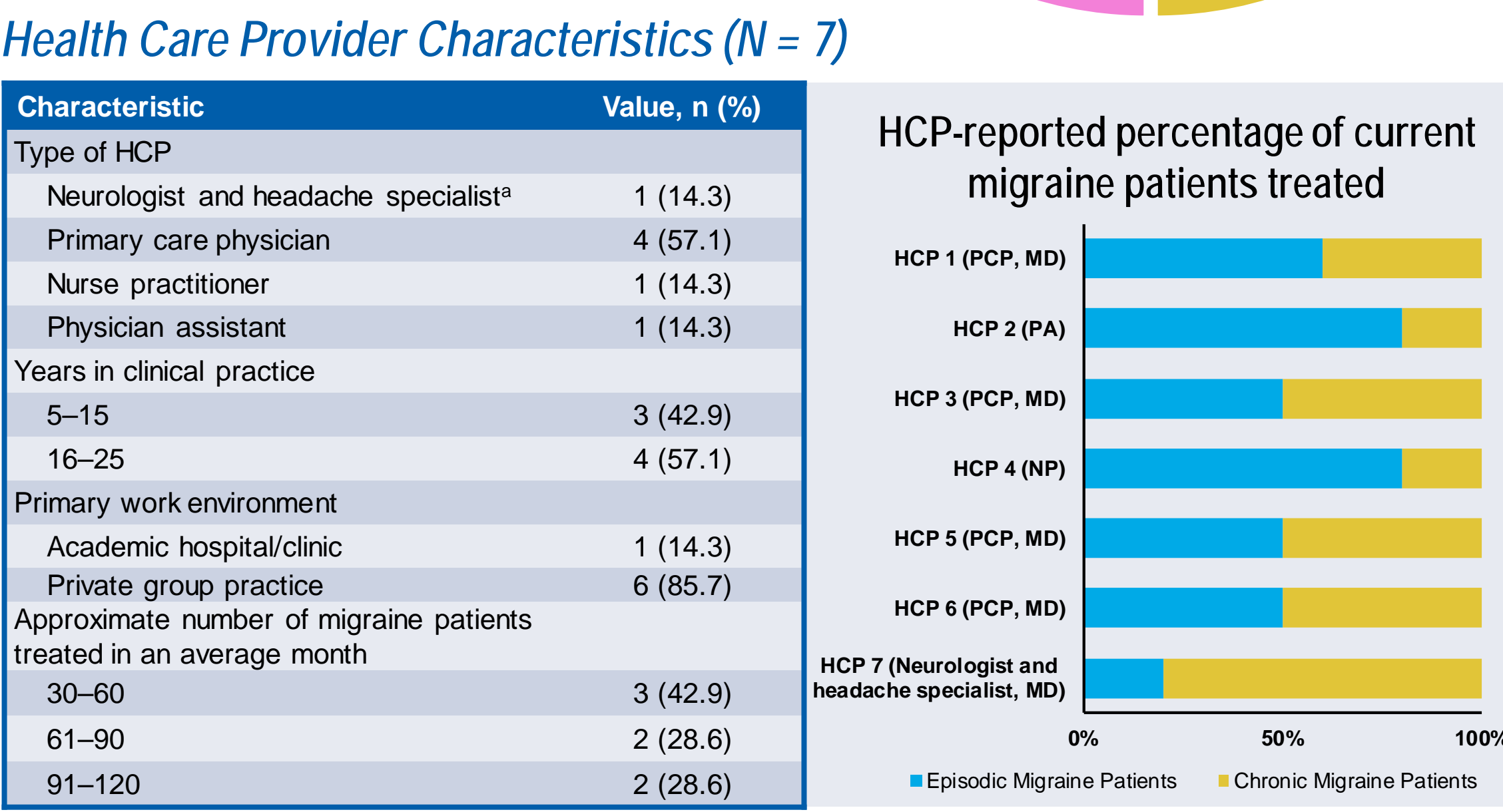
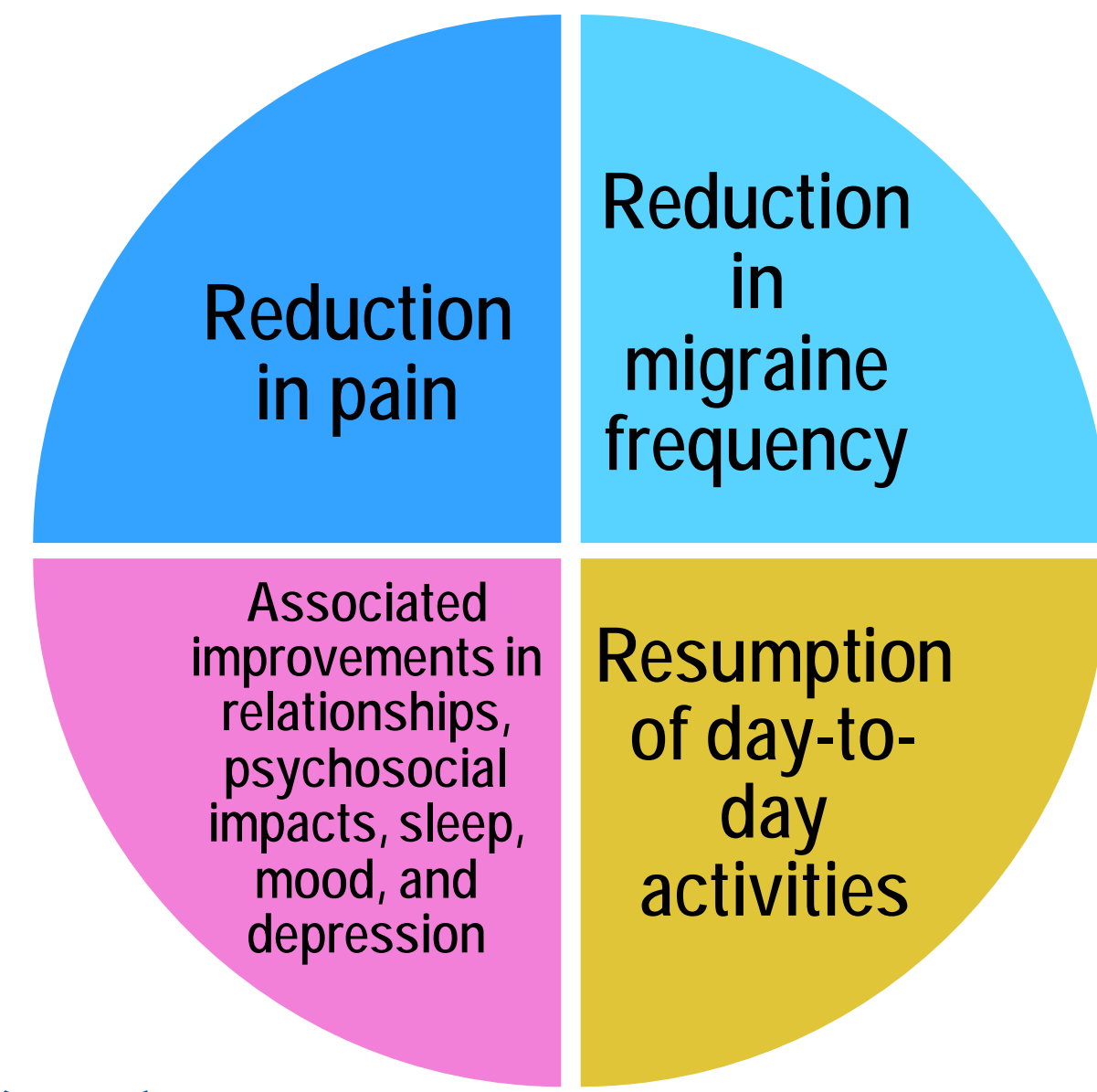
Study Participants

- Health care provider focus group (n = 6 to 8)**
 - ≥ 5 years clinical experience
 - Currently treating ≥ 30 migraine patients per month in the US
 - 60-minute focus group discussion
- Episodic migraine patient focus group (n = 6 to 8)**
 - 18–64 years of age
 - 4–14 headache days per month for the past 3 months
 - 90-minute focus group discussion
- Chronic migraine patient focus group (n = 6 to 8)**
 - 18–64 years of age
 - ≥ 15 headache days per month for the past 3 months
 - 90-minute focus group discussion

- Qualitative analysis of field notes and audio recordings involved identification, characterization, and summarization of patterns found in focus group data
 - Dominant trends from each focus group were used to define themes or patterns in participants' observations and experiences

RESULTS

HCPs and patients agreed on important measures of meaningful improvement



- HCPs expressed that it is difficult to manage treatment with nonspecific therapies used for migraine and help patients remain compliant with these medications due to side effects and lack of tolerability
- Side effects from standard therapies, such as tingling, nervousness, drowsiness, fatigue, nausea, cardiovascular problems, and brain fog, can be as debilitating as the migraine itself for some patients

Verbatim Patient Statements About Experiences With Migraine

Episodic Migraine Patients (n = 8)

- "Pain is like a hammer pounding on my head."
- "stabbing from inside my head."
- "After a migraine, I cannot hold a conversation and have to cancel social plans. I have to go home from work. Medicine puts me out of commission, not the migraine."
- "I force myself to do things like going to a concert because I don't want to interfere with taking my wife away from socializing. I feel antisocial and have anxiety and worry about when I'll have a migraine."
- "Success with treatment would be able to continue activities after taking medication."
- "Medication prevents me from doing other things 100% of the time."

Chronic Migraine Patients (n = 8)

- "eye twitching, floaters, ringing in my ear which travels around my head," ...has "had a constant headache for 4 months."
- "I walk the floor when I have a migraine. I can't put my head down and [have to] put pressure on my head"
- "I may take an hour to 1 and ½ hours to lay down after a migraine, and I take a lot of time off work. It is difficult to interact with coworkers."
- "My kids say I am antisocial and irritable. I have to save my vacation days for sick time."
- "I don't like to remember to take medication. An ideal medication could be implanted under the skin with no side effects."
- "Ideal medication would work in 30 minutes to get rid of the pain, would not have brain fog, and would not affect mood."

Symptoms

Impact on Daily Activities

Experience with migraine treatment

Qualities of an Ideal Migraine Medication Identified by HCPs and Patients

Quality	NP	PA	PCP	Neurologist	EM Patients	CM Patients
Efficacy: speed of action	X	X	X	X	X	X
Efficacy: improves functioning/return to normal activities	X	X	X	X	X	X
Efficacy: durability of effect			X		X	
Efficacy: completely relieves pain	X	X	X	X	X	X
Efficacy: prevents migraine, reduces frequency						X
Safety: no side effects and long-term safety			X	X	X	X
Safety: no rebound headache				X	X	
Safety: no drug interactions	X					

- Both patient groups highlighted that they would be able to resume their daily activities more quickly if they had relief of migraine symptoms, which would subsequently benefit their day-to-day, social, and leisure activities

CONCLUSIONS

- Resumption of day-to-day activities and subsequent impacts on social/emotional function following treatment are aspects of meaningful improvement reported by migraine patients and HCPs
- HCPs discussed reductions in pain and migraine frequency to achieve these improvements, while patients highlighted broader symptom relief, including relief from treatment-related side effects
- Many factors beyond frequency reduction alone are important to patients and HCPs and therefore critical to consider when managing migraine and making migraine treatment decisions

LIMITATIONS

- Selection bias is inherent in qualitative research and study participants comprised a convenience sample and were recruited from one qualitative research facility
- The experiences of patients with migraine and HCPs who are willing to participate in a focus group may be systematically different from those who do not wish to participate in a focus group
- Qualitative analyses did not include formal coding or thematic analysis

REFERENCES

- Evers S, et al. *Eur J Neurol*. 2009;16(9):968-981.
- Silberstein SD, et al. *Neurology*. 2012;78(17):1337-1345.
- American Headache Society (AHS). *Headache*. 2019;59:1-18.
- Stokes M, et al. *Headache*. 2011;51:1058-1077.
- Wang S.J, et al. *Cephalalgia*. 2013;33:171-181.

DISCLOSURES

- PS: Employee of RTI Health Solutions which was contracted by Amgen for this analysis
- SS: Employee and stockholder of Amgen
- LJ: Employee of RTI Health Solutions which was contracted by Amgen for this analysis
- MP: Employee of RTI Health Solutions which was contracted by Amgen for this analysis
- MB: Employee and stockholder of Amgen
- CB: performed this work as a paid consultant in collaboration with Amgen. She is an Associate Neurologist at BWH and an Assistant Professor of Neurology at Harvard Medical School

This study was funded by Amgen Inc.; erenumab is codeveloped by Amgen and Novartis.

ACKNOWLEDGMENTS

- Medical writing support for this poster was funded by Amgen Inc. and was provided by Allison Gillies, PhD, of Complete Healthcare Communications, LLC (North Wales, PA), an ICON plc company
- The final responsibility for the content lies with the authors