

Seeking care, diagnosis, and acute prescription for migraine among those with headache-related disability: Results of the OVERCOME study

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BACKGROUND

- Individuals with migraine and associated disability may face barriers to getting appropriate care
- The journey to potentially effective acute treatment for migraine includes at least 3 conditional steps:
 - Consulting a healthcare professional
 - Receiving an accurate diagnosis
 - Getting a recommended^a acute medication for migraine
- Previous efforts to identify barriers to consulting, diagnosis, and treatment did not consider acute care across both episodic and chronic migraine and occurred in a healthcare environment not reflective of current treatment options^{1,2}
- OVERCOME, a web-based survey conducted in a representative US sample, provides a contemporary view of the migraine healthcare landscape, ranging from those with very low-frequency episodic migraine to those with chronic migraine

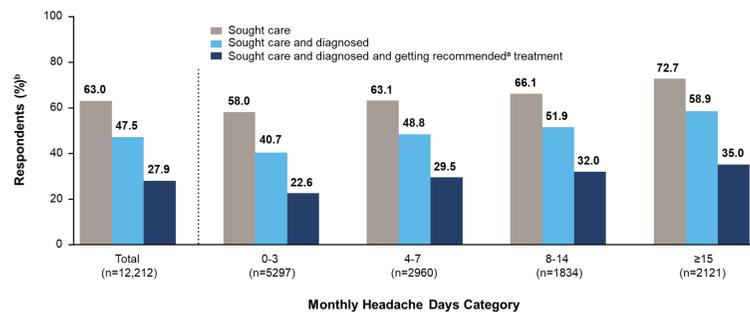
OBJECTIVES

- The objectives of this analysis of the OVERCOME study were to:
 - Determine the proportion of people with migraine and associated disability who traverse each of these steps
 - Compare individuals at each step on sociodemographic features, migraine-related characteristics, and healthcare utilization for migraine

^aNon-opioid acute oral/intranasal/subcutaneous/patch medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine (Marmura MJ, et al. *Headache*. 2015;55:3-20). Medications include acetaminophen, ergots, non-steroidal anti-inflammatory drugs, triptans, antiemetics, intravenous magnesium sulphate, and isometheptene, and combinations of acetaminophen/aspirin/caffeine, sumatriptan/naproxen, codeine/acetaminophen, and tramadol/acetaminophen.
 OVERCOME=Observational survey of the Epidemiology, Treatment, and Care Of Migraine.
 1. Dodick DW, et al. *Headache*. 2016;56:821-834. 2. Lipton RB, et al. *Headache*. 2013;53:81-92.

KEY RESULTS

Proportion Seeking Care, Diagnosed With Migraine, and Getting Recommended^a Acute Medication for Migraine Among Respondents With Headache-Related Disability (MIDAS ≥6)



^aNon-opioid acute oral/intranasal/subcutaneous/patch medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine (Marmura MJ, et al. *Headache*. 2015;55:3-20). Medications include acetaminophen, dihydroergotamine, aspirin, diclofenac, ibuprofen, naproxen, all triptans, combination sumatriptan/naproxen, combination acetaminophen/aspirin/caffeine, combination ergotamine/caffeine, flurbiprofen, ketoprofen, and isometheptene.
^bPercentages in each column reflect the % relative to the total n below that column.
 MIDAS=Migraine Disability Assessment.

Significant Unmet Needs Were Observed Regardless of Where Care Was Sought; However, Respondents Seeking Care at ED/UC/Retail Were Least Likely to Receive Optimal Care

Place Care Sought	Sought Care		Migraine Diagnosis Among Those Who Sought Care		Getting Recommended ^a Acute Medication Among Those Diagnosed	
	No (n=4517)	Yes (n=7695)	No (n=1893)	Yes (n=5802)	No (n=2401)	Yes (n=3401)
None, %	100	0	N/A	N/A	N/A	N/A
ED/UC/Retail, %	N/A	100	35.4	64.9	40.8	23.7
Primary care, %	N/A	100	26.6	73.4	36.3	37.1
Specialist, %	N/A	100	19.5	80.5	24.3	56.2

^aNon-opioid acute prescription medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine (Marmura MJ, et al. *Headache*. 2015;55:3-20). Recommended treatments include acetaminophen, ergots, non-steroidal anti-inflammatory drugs, triptans, antiemetics, intravenous magnesium sulphate, and isometheptene, and combinations of acetaminophen/aspirin/caffeine, sumatriptan/naproxen, codeine/acetaminophen, and tramadol/acetaminophen.
 ED/UC/Retail=Emergency Department OR Urgent Care OR Retail Clinic (where retail refers to a clinic located in a pharmacy or retail store); N/A=Not applicable; Primary care=Primary care provider, family medicine, or internist (not a specialist); Specialist=Neurologist, pain specialist, or headache specialist.

CONCLUSIONS

- Only a small proportion (27.9%) of those with headache-related disability traverse all 3 steps to getting recommended^a acute medication for migraine
- Having health insurance and having severe migraine-related disability were positively related to traversing each step
- Seeking care in an Emergency Department/Urgent Care/Retail Clinic only is less likely to lead to appropriate diagnosis and/or receiving recommended acute medications relative to seeking care in a specialist or primary care setting
- These findings highlight the ongoing unmet needs regardless of monthly headache days and where patients seek care

^aNon-opioid acute oral/intranasal/subcutaneous/patch medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine (Marmura MJ, et al. *Headache*. 2015;55:3-20). Medications include acetaminophen, dihydroergotamine, aspirin, diclofenac, ibuprofen, naproxen, all triptans, combination sumatriptan/naproxen, combination acetaminophen/aspirin/caffeine, combination ergotamine/caffeine, flurbiprofen, ketoprofen, and isometheptene.

Methods

Study Design

- Data were obtained from a web-based survey conducted in a representative US sample
 - These data are from the Cohort 1, Wave 1 (baseline) survey conducted in Q4 2018

Respondent Population (N=21,143)

- Reported having a headache or migraine attack in the past 12 months
- Met criteria for migraine based on:
 - Validated AMS/AMPP migraine diagnostic screener¹ using modified ICHD-3 criteria (94% of sample) AND/OR
 - Self-report of migraine diagnosis by an HCP (61% of sample)

Population for This Analysis

- Respondents with at least mild migraine-related disability (MIDAS ≥6; N=12,212 or 57.8% of total respondents)
- Population subgroups
 - Sought care (Yes/No) – based on having sought care for migraine at a specialist, primary care, or ED/UC/Retail Clinic over the past 12 months
 - Migraine diagnosis (Yes/No) – based on report of having been diagnosed by an HCP
 - Getting recommended acute treatment (Yes/No) – based on non-opioid acute oral/intranasal/subcutaneous/patch medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine²
 - Monthly headache days category (0-3, 4-7, 8-14, ≥15) – based on monthly headache day average over the past 90 days

Recommended Acute Medications²

- Non-opioid acute oral/intranasal/subcutaneous/patch medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine
- Medications include acetaminophen, DHE, aspirin, diclofenac, ibuprofen, naproxen, all triptans, combination sumatriptan/naproxen, combination acetaminophen/aspirin/caffeine, combination ergotamine/caffeine, flurbiprofen, ketoprofen, and isometheptene

Survey Instruments

- MIDAS: assesses days with migraine-related disability across 5 areas over the past 3 months (90 days).³ Scores of 6-10 are indicative of mild disability, 11-20 are indicative of moderate disability, and >21 are indicative of severe migraine-related disability
- ASC-12: assesses presence and severity of cutaneous allodynia symptoms during migraine attacks⁴ – 12-item checklist with scores ranging from 0 to 24; higher scores indicate greater severity of cutaneous allodynia
- MSSS: assesses migraine symptom severity⁵ – assesses 7 headache features with scores ranging from 0 to 21; higher scores indicate greater severity
- mTOQ-4: assesses acute treatment optimization⁶ – 4 items and scores ranging from 0 to 8, with scores <6 indicating poor/very poor acute treatment optimization
- MSQ-RFR: assesses a domain of migraine-specific quality of life⁷ – comprises 7 items; raw domain scores are summed and transformed to a 0-100 scale, with higher scores indicating better quality of life
- Pain severity: self-reported average migraine pain severity measured using a 0-10 Likert-type scale, with anchors of 0 “No pain at all” and 10 “Pain as bad as it could be”

Statistical Methods

- The data are presented as frequency counts with percentages or means and standard deviations
- t test (continuous variables) or chi-square test (categorical variables), for total respondents and stratified by monthly headache days category, evaluated differences between groups at each step (p<0.05)

Disclosures:

Susan Hutchinson has served on advisory committees, advisory boards, review panels, or speaker bureaus for Alder, Allergan, Amgen, Avanir, Biohaven, electroCore, Eli Lilly and Company, Promius, Supernus, Teva Pharmaceuticals, and Theranica Pharmaceutical, as well as speaking and teaching for Promius. Dawn C. Buse has received funding for “other activities” from Allergan, Amgen, Avanir, Biohaven, Eli Lilly and Company, and Promius, and has served on the board or editorial board of *Current Pain and Headache Reports*. Michael L. Reed or his employer (Vedanta) has received funding for “other activities” from Allergan, Amgen, Dr. Reddy’s Laboratories, Eli Lilly and Company, GlaxoSmithKline, Merck & Co., Inc., National Headache Foundation, and Novartis. Sait Ashina has received consulting fees from Allergan, Amgen, Biohaven, Eli Lilly and Company, Novartis, Percept, Satsuma, Supernus, and Theranica Pharmaceutical. Richard B. Lipton has received funding from Alder Biopharmaceuticals, Allergan, American Academy of Neurology (other activities), American Headache Society, Amgen, Autonomic Technologies (speaking and teaching), Avanir, Biohaven, Boston Scientific, Dr. Reddy’s Laboratories, electroCore, Eli Lilly and Company, eNeura Therapeutics, GlaxoSmithKline, Headache (other activities) (personal fees), Informa (speaking and teaching), Merck & Co. Inc., Migraine Research Foundation, National Headache Foundation, Neurology (board membership), NIA (other activities), NINDS (other activities), Novartis (speaking and teaching) (other activities) (personal fees), Permex, Teva Pharmaceuticals, Vedanta, and Wolff’s Headache 7th and 8th Edition, Oxford University Press, 2009. Robert A. Nicholson, Bert B. Vargas, Karen Saaman, Anthony J. Zagar, Yongin Kim, and Eric M. Pearlman are employees of and own shares in Eli Lilly and Company. Medical writing assistance was provided by Tania Dickson, PhD, CMPP, of ProScribe – Envision Pharma Group, and was funded by Eli Lilly and Company.
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Results

Differences in Sociodemographic Factors for Care-Seeking, Diagnosis, and Getting Recommended^a Acute Medication for Migraine

Variable	Sought Care			Migraine Diagnosis Among Those Who Sought Care			Getting Recommended ^a Acute Treatment Among Those Diagnosed		
	No (n=4517)	Yes (n=7695)	p-Value	No (n=1893)	Yes (n=5802)	p-Value	No (n=2401)	Yes (n=3401)	p-Value
Mean age, years	39.6	40.7	<0.001	40.6	40.7	0.788	40.2	41.1	0.021
Female, %	80.4	75.2	<0.001	70.2	76.8	<0.001	78.1	75.9	0.047
Hispanic, %	9.5	12.1	<0.001	13.1	11.8	0.267	11.1	12.3	0.328
White, %	86.3	80.6	<0.001	78.4	81.4	0.006	83.0	80.2	0.002
Have health insurance, %	80.4	89.0	<0.001	87.7	89.4	0.046	85.7	92.0	<0.001
College degree or higher, %	32.4	32.8	0.618	31.2	33.4	0.080	28.7	36.6	<0.001
Employed full-time, %	41.0	44.1	<0.001	43.8	44.2	0.772	38.1	48.5	<0.001

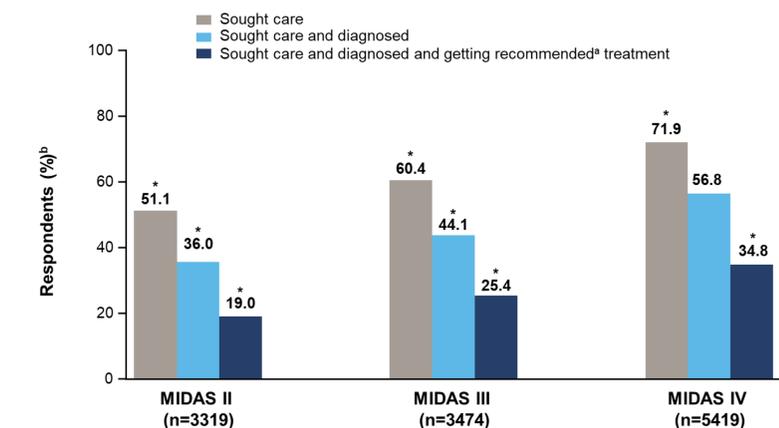
^aNon-opioid acute oral/intranasal/subcutaneous/patch medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine (Marmura MJ, et al. *Headache*. 2015;55:3-20). Medications include acetaminophen, dihydroergotamine, aspirin, diclofenac, ibuprofen, naproxen, all triptans, combination sumatriptan/naproxen, combination acetaminophen/aspirin/caffeine, combination ergotamine/caffeine, flurbiprofen, ketoprofen, and isometheptene.
 Note: Items in **BOLD** represent significant differences between Yes vs. No for traversing each step.

Differences in Migraine-Related Factors for Care-Seeking, Diagnosis, and Getting Recommended^a Acute Medication for Migraine

Variable	Sought Care			Migraine Diagnosis Among Those Who Sought Care			Getting Recommended ^a Acute Treatment Among Those Diagnosed		
	No (n=4517)	Yes (n=7695)	p-Value	No (n=1893)	Yes (n=5802)	p-Value	No (n=2401)	Yes (n=3401)	p-Value
Pain severity, mean	7.2	7.7	<0.001	7.1	7.9	<0.001	7.8	8.0	<0.001
ASC-12, mean	3.7	5.4	<0.001	4.9	5.6	<0.001	5.2	5.8	<0.001
MSSS, mean	17.2	17.8	<0.001	16.8	18.2	<0.001	18	18.3	<0.001
mTOQ-4 Poor/very poor optimization, %	54.1	63.0	<0.001	57.4	64.8	<0.001	66.7	63.5	<0.001
MSQ-RFR, mean	50.7	43.5	<0.001	49.4	41.6	<0.001	41.9	41.4	0.354

^aNon-opioid acute oral/intranasal/subcutaneous/patch medication identified as having Level A/B evidence in the American Headache Society 2015 guidelines for acute treatment of migraine (Marmura MJ, et al. *Headache*. 2015;55:3-20). Medications include acetaminophen, dihydroergotamine, aspirin, diclofenac, ibuprofen, naproxen, all triptans, combination sumatriptan/naproxen, combination acetaminophen/aspirin/caffeine, combination ergotamine/caffeine, flurbiprofen, ketoprofen, and isometheptene.
 Note: Items in **BOLD** represent significant difference between Yes vs. No for traversing each step.
 ASC-12=12-Item Allodynia Symptom Checklist with scores ranging from 0 to 24; MSQ-RFR=Migraine-Specific Quality-of-Life Questionnaire Role Function-Restrictive comprising 7 items. Raw domain scores are summed and transformed to a 0-100 scale, with higher scores indicating better quality of life; MSSS=Migraine Symptom Severity Scale, assesses 7 headache features with scores ranging from 0 to 21; mTOQ-4=Migraine Treatment Optimization Questionnaire (4-item), assesses 4 items and scores range from 0 to 8, with scores <6 indicating poor/very poor acute treatment optimization; Pain severity=Self-reported average migraine pain severity measured using a 0-10 Likert-type scale, with anchors of 0 “No pain at all” and 10 “Pain as bad as it could be.”

Higher Rates of Diagnosis and Getting Recommended Acute Medications for Migraine Were Observed With Increasing Migraine-Related Disability



*p<0.05 Yes vs. No for traversing each step.
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^bPercentages in each column reflect the % relative to the total n below that column.
 MIDAS=Migraine Disability Assessment; MIDAS II=Mild migraine-related disability; MIDAS III=Moderate migraine-related disability; MIDAS IV=Severe migraine-related disability.

Abbreviations

AMS/AMPP=American Migraine Study/American Migraine Prevalence and Prevention study; ASC-12=12-item Allodynia Symptom Checklist; DHE=Dihydroergotamine; ED=Emergency Department; HCP=Healthcare provider; ICHD-3=International Classification of Headache Disorders-3; MIDAS=Migraine Disability Assessment; MSQ-RFR=Migraine-Specific Quality-of-Life Questionnaire Role Function-Restrictive; MSSS=Migraine Symptom Severity Scale; mTOQ-4=Migraine Treatment Optimization Questionnaire (4-item); OVERCOME=Observational survey of the Epidemiology, Treatment, and Care Of Migraine; UC=Urgent Care.

