Poster #TH 183

Contemporary Prospective Understanding of Migraine Real-world Evidence (CAPTURE): Baseline Patient-Reported Outcomes

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OBJECTIVE

Describe results of an interim analysis of baseline patient-reported outcome (PRO) data for CAPTURE participants enrolled as of December 2023

CONCLUSIONS

Baseline PROs in CAPTURE suggest greater disease burden from migraine among participants with higher MHD frequency

CAPTURE will provide critical global data on the longitudinal course of migraine and the associated burden over time

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INTRODUCTION

- Longitudinal evidence describing symptom frequency, patient-reported outcomes (PROs), and contemporary treatment patterns in migraine is currently lacking,[1] which limits understanding of the disease and can negatively impact health care stakeholders' ability to treat proactively
- Limitations in this area of research include the use of cross-sectional study designs, limited consideration of migraine frequency, narrow geographical samples, no assessments of health care resource utilization, and little or no data describing treatment patterns
- CAPTURE is an international, prospective study that aims to enhance the understanding of longitudinal disease burden and treatment patterns among people living with migraine, stratified by headache frequency
  - We present an interim analysis of baseline PRO data for CAPTURE participants enrolled as of December 2023

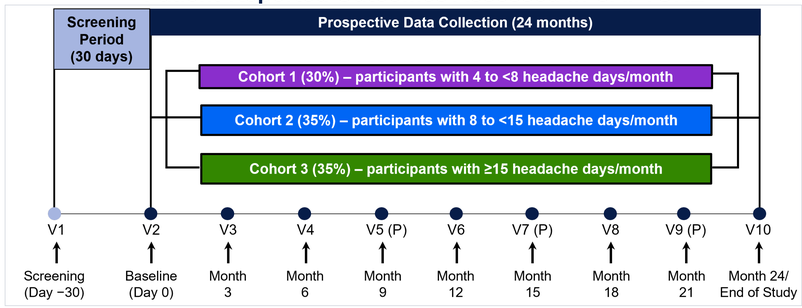
Patient-Reported Outcomes Assessed in CAPTURE

• Migraine Disability Assessment Scale (**MIDAS**)[2]	• Migraine-Specific Quality of Life questionnaire v2.1 (**MSQ v2.1**)[3]	• Work Productivity and Activity Impairment Questionnaire: Migraine (**WPAI: Migraine**)[4]	• 6-item Headache Impact Test (**HIT-6**)[5]
• Patient Global Impression–Severity (**PGI-S**)[6]	• Hospital Anxiety and Depression Scale (**HADS**)[7]	• Migraine Interictal Burden Scale (**MIBS-4**)[8]	

METHODS

- CAPTURE is a 2-year, international, prospective, longitudinal study of adults with migraine, conducted at headache specialty centers and community sites with a target enrollment population of 2000 participants
- Data sources include electronic health records, physician/patient surveys, medical chart review, and participant eDiary
- Study population will include adults diagnosed with migraine for ≥1 year, age <50 years at onset, taking ≥1 medication indicated for migraine, and ≥4 MHDs in the 3 months before screening
- Approximately 2000 participants are planned to enrol in the study of which 163 participants are already enrolled in Canada
- Study endpoints will include changes from baseline in monthly headache days (MHDs), monthly migraine days (MMDs), acute medication use days, and PROs across the study period and durations of current and subsequent migraine treatment use
- Baseline demographics, clinical characteristics, and PROs were analyzed descriptively

Patient-Reported Outcomes Assessed in CAPTURE



P, phone call; V, visit. Visits are clinic visits unless otherwise noted. Participants are to complete a daily headache diary for 30 days prior to visits 2–10.

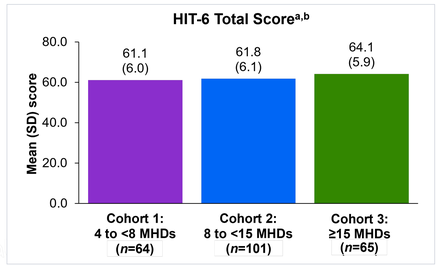
RESULTS

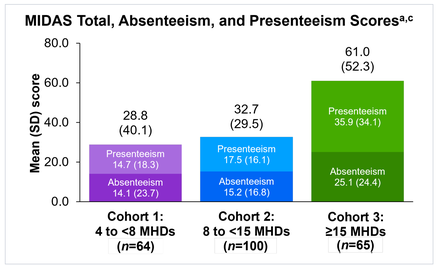
Baseline Demographic Characteristics

	Cohort 1: 4 to <8 MHDs (*n*=68)	Cohort 2: 8 to <15 MHDs (*n*=104)	Cohort 3: ≥15 MHDs (*n*=67)
Age, mean (SD), years	42.3 (12.5)	42.6 (12.7)	40.8 (12.4)
Sex, *n* (%)[a]			
Female	52 (77.6)	87 (86.1)	57 (91.9)
Male	15 (22.4)	14 (13.9)	5 (8.1)
Missing	1	3	5
Race[a]			
White	64 (95.5)	102 (100.0)	62 (96.9)
Black or African American	1 (1.5)	0	0
Asian	2 (3.0)	0	0
American Indian or Alaska Native	0	0	2 (3.1)
Missing	1	2	3
Region, *n* (%)			
Canada	15 (22.1)	23 (22.1)	14 (20.9)
Europe	53 (77.9)	80 (76.9)	53 (79.1)
South America	0	1 (1.0)	0

MHD, monthly headache day; SD, standard deviation.[a] Percentages calculated using nonmissing values.

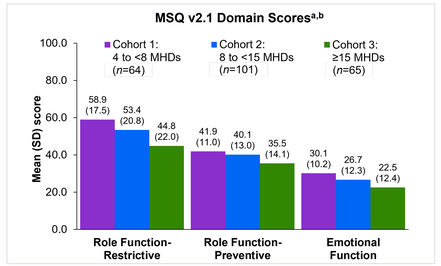
- Mean scores on patient-reported assessment of headache impact (HIT-6) were severe for all cohorts
- Mean scores on patient-reported assessment of migraine-related disability (MIDAS) were substantially higher for participants in cohort 3 (≥15 MHDs) than for those in cohorts 1 and 2

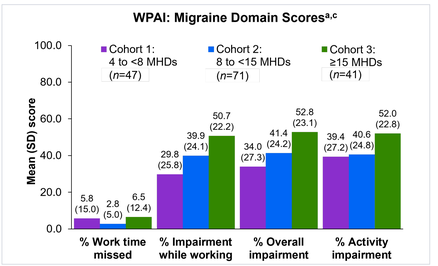




HIT-6, 6-item Headache Impact Test; MHD, monthly headache day; MIDAS, Migraine Disability Assessment Scale; SD, standard deviation.
[a] Ns represent numbers of participants with data available for analysis.
[b] HIT-6 score ranges from 36–78 (≤49, little or no impact; 50–55, some impact; 56–59, substantial impact; 60–78, severe impact).
[c] MIDAS scores represent the number of days of work/school, household work, and family/social/leisure activities missed (MIDAS items 1, 3, and 5, defined as absenteeism for this analysis) and the number of days when productivity at work/school, household work, and family/social/leisure activities was reduced by at least half (MIDAS items 2 and 4, defined as presenteeism for this analysis) in the past 3 months. Participants who did not perform a given activity in the past 3 months were asked to answer "zero."

- There was a trend toward lower patient-reported quality of life (MSQ v2.1) with higher MHD frequency
- There was a trend toward higher patient-reported productivity loss and activity impairment (WPAI: Migraine) with higher MHD frequency





EF, emotional function; MHD, monthly headache day; MSQ v2.1, Migraine-Specific Quality-of-Life questionnaire v2.1; RFP, Role Function–Preventive; RFR, Role Function–Restrictive; WPAI: Migraine, Work Productivity and Activity Impairment Questionnaire: Migraine.
[a] Ns represent numbers of participants with data available for analysis. Only participants who reported full- or part-time employment are included in WPAI analyses. The ns for WPAI: Migraine Activity Impairment are: cohort 1, n=64; cohort 2, n=101; cohort 3, n=65.
[b] MSQ v2.1 domain scores range from 0–100; higher scores indicate better quality of life.
[c] WPAI: Migraine domain scores represent percent time missed or impaired in the past 7 days.

- Mean scores on patient-reported assessments of anxiety/depression symptoms (HADS), interictal burden (MIBS-4), and migraine symptom severity (PGI-S) tended to increase with higher MHD frequency

Baseline PRO Measures: HADS, MIBS-4, and PGI-S

	Cohort 1: 4 to <8 MHDs (*n*=64)[a]	Cohort 2: 8 to <15 MHDs (*n*=101)[a]	Cohort 3: ≥15 MHDs (*n*=65)[a]
HADS total score[b]	11.2 (6.7)	12.4 (6.8)	14.7 (8.7)
Anxiety	6.7 (3.9)	7.3 (4.1)	8.0 (4.7)
Depression	4.5 (3.4)	5.0 (3.5)	6.7 (4.9)
MIBS-4[c]	4.5 (2.9)	5.4 (3.6)	6.2 (3.7)
PGI-S[d]	1.6 (0.8)	1.8 (0.8)	2.2 (0.7)

[a] Ns represent numbers of participants available for analysis.
[b] HADS total score ranges from 0–42 (21 points per subscale: 0–7, symptoms absent; 8–10, borderline; ≥11, symptoms present).
[c] MIBS-4 score ranges from 0–12 (0, no interictal burden in the past 4 weeks; 1–2, mild; 3–4, moderate; ≥5, severe).
[d] PGI-S score ranges from 0 (no migraine symptoms over the past 7 days) to 5 (very severe migraine symptoms over the past 7 days).
HADS, Hospital Anxiety and Depression Scale; MHD, monthly headache day; MIBS-4, Migraine Interictal Burden Scale; PGI-S, Patient Global Impression–Severity; SD, standard deviation.