

Key Finding

Strict ICHD criteria may undercount clinically meaningful migraine days due to missing associated symptoms; probable migraine improves alignment with patient-report

Background

- Migraine days in trials are defined using ICHD-3 criteria applied to diary data or via patient self-report
- Patient-reported migraine days often do not align with ICHD-based definitions
- Discrepancies may reflect patient-ICHD algorithm differences, not reporting error
- Patient impression may identify migraine-linked headaches and treatment response
- This has implications for interpretation of clinical trial endpoints
- Study Objective: Examine differences between self-reported and ICHD-derived migraine days

Methods

Study Design and Data Collection

- MiCOAS longitudinal observational study (3 cohorts)
- Daily diaries (28–56 days) and weekly/biweekly assessments

Participants and Definitions

- Inclusion: >14 daily assessments; >2 migraine days
 - N = 1,008; 28,788 diary days
- Self reported: “Did you have a migraine day” (yes/no)
- ICHD-derived: ICHD-3 criteria applied to symptom responses

Analysis

- Descriptive Statistics: n, %, IQR
- Agreement: kappa coefficients (κ)
- Conditional Analysis: Self-reported migraine days not meeting strict ICHD criteria

When Patient Experience and Diagnostic Criteria Diverge: Insights from the MiCOAS Study on Migraine Day Classification

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Results

Sample Characteristics

- The analysis sample consisted of N = 1,008 participants with a total of 28,788 diary days (Table)
- Participants had a median (25th, 75th percentile) of 27(24, 28) daily assessments and had 10 (7, 16) self-reported and 5 (2, 10) ICHD-derived migraine days

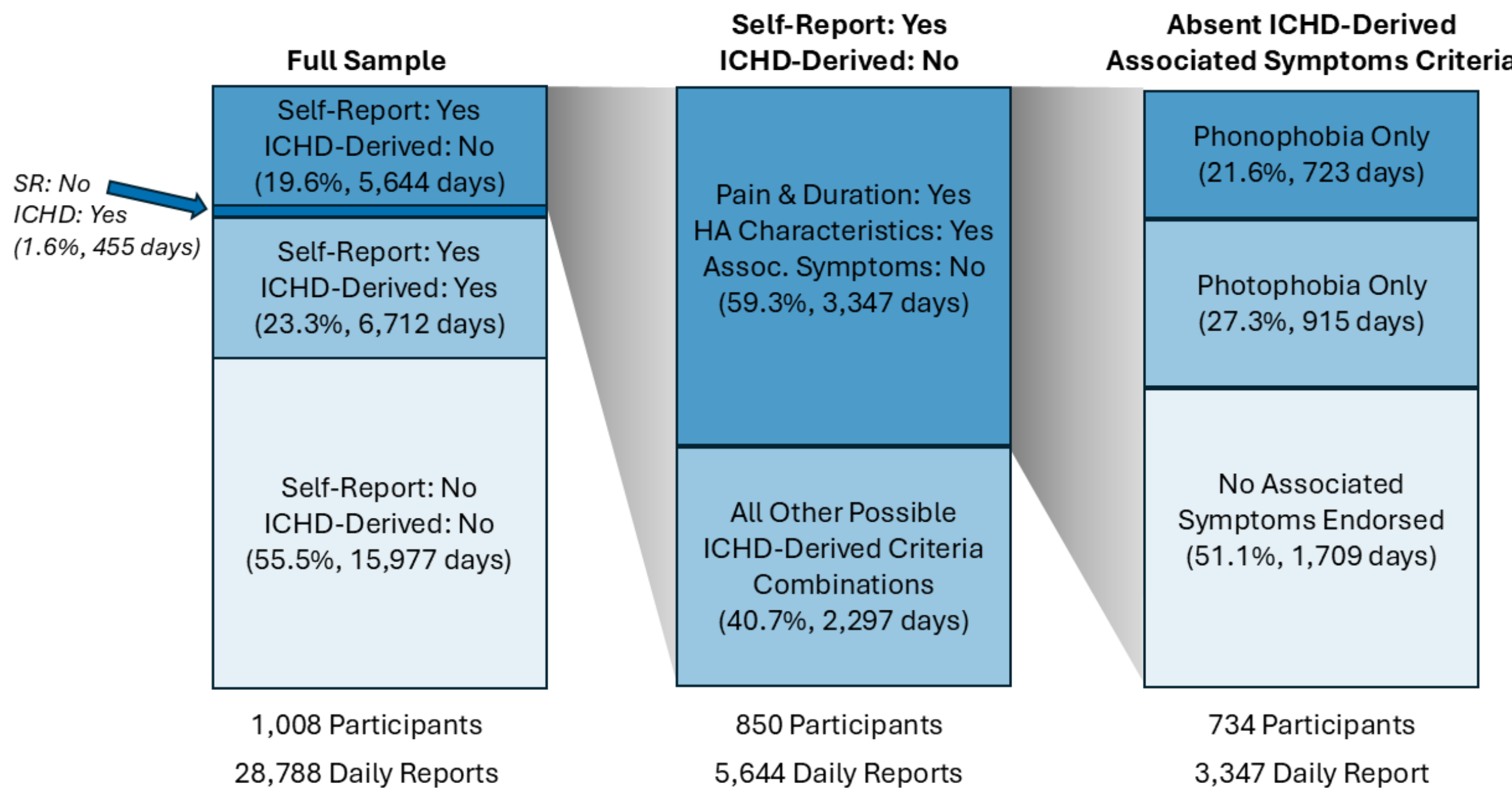
Table. Background characteristics for analysis sample

N = 1,008	
Age (years), mean (SD)	38.67 (10.85)
Sex, n(%)	
Female	801 (79.5%)
Male	201 (19.9%)
Unknown	6 (0.6%)
Race, n(%)	
Black or African American	153 (15.2%)
White	774 (76.8%)
Other	81 (8.0%)
Monthly Headache Days (years), mean (SD)	13.37 (6.53)
Acute Medication Use, n(%)	
Yes	956 (95.1%)
No	49 (4.9%)
Preventive Medication Use, n(%)	
Yes	677 (67.3%)
No	329 (32.7%)

Agreement

- Moderate agreement between self-reported and ICHD-derived migraine days
 - Median κ = 0.54 (IQR = 0.54)
- Across 28,788 person-days:
 - 55.5% classified as both non-migraine by both methods
 - 23.3% classified as both migraine by both methods
- **Discordance in 19.6% of days** (n = 5,644) (Figure)
 - Majority: self-reported migraine days not meeting ICHD criteria

Figure. Self-report vs ICHD-derived migraine days discordance



Exploring Discordance

- Among discordant days:
 - **59.3% failed associated-symptom criteria only**
 - **51.1%: no associated symptoms**
 - 27.3%: photophobia only
 - 21.6%: phonophobia only
- Agreement improved under alternative definitions:
 - Probable migraine day: Median κ = 0.76 (IQR = 0.38)
 - ICHD + acute medication use: Median κ = 0.70 (IQR = 0.43)

Discussion

- Differences between migraine day definitions likely reflect symptom interpretation, not error
- Strict enforcement of ICHD-3 criteria may miss clinically meaningful migraine-like experiences
- Patient-report aligns with clinically relevant migraine
- Day-level misclassification may bias monthly migraine day endpoints and treatment effects

Unique Insights

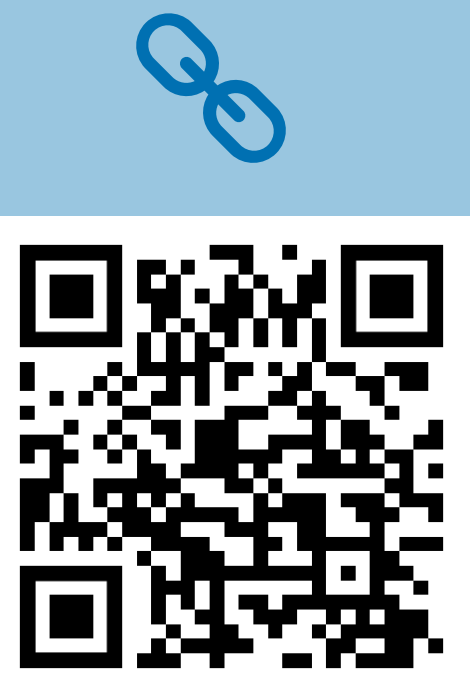
- ☐ Discordance is phenotype-driven, not noise
- ☐ ICHD criteria may under-detect mild or incomplete migraine days
- ☐ Missing associated symptoms, not core pain features, drive misalignment

Applied Takeaways

- ✓ Incorporate probable migraine into outcome definitions
- ✓ Interpret diary-based endpoints with symptom flexibility
- ✓ Prioritize patient-reported experience alongside clinical criteria

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