

STS101 Use Reduces Migraine Frequency Over Time

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Introduction

- Dihydroergotamine (DHE) mesylate is a recommended first-line treatment option for the acute treatment of moderate or severe migraine attacks, with or without aura.¹
- DHE has long been speculated to have benefits beyond the acute resolution of symptoms during a migraine attack, and repeated use may have prolonged or preventive benefits.^{2,3}
- STS101 (ATZUMI™) is an FDA-approved drug-device combination of a DHE mesylate powder formulation prefilled in a single-use delivery device for nasal administration (**Figure 1**).⁴
- STS101 provides rapid DHE absorption, with plasma concentrations of DHE over the 2 hours following administration (AUC_{0-2h}) more than twofold greater than those following administration of DHE liquid nasal sprays.^{4,6}
- The ASCEND study primarily assessed the safety and tolerability of STS101 5.2 mg in the acute treatment of migraine attacks with or without aura over 12 months. The secondary objective was to describe the effectiveness of STS101 over 12 months.

Objective

- To evaluate the frequency of treated migraine attacks in study participants who used STS101 over a full year

Methods

Study Design and Treatment Intervention

- ASCEND was a multi-center, multi-dose, open-label, 12-month study of STS101 in adults aged 18–65 years with migraine (NCT04406649).
- After establishing eligibility, the participants could self-administer STS101 5.2 mg as needed (PRN) for up to 2 doses within 24 hours to treat a single migraine attack, and up to 12 doses/ month for 12 months.

Participants

- Study participants must have had ≥1-year history of migraine (with or without aura) according to the International Classification of Headache Disorders, 3rd edition,⁷ including:
 - Migraine onset before age of 50 years
 - 4–12 migraine attacks/month in each of the 3 months prior to screening
 - <15 headache days/month in each of the 3 months prior to screening
- Exclusion criteria included diagnosis of non-migraine headache, history of cerebrovascular disease, and ≥2 cardiovascular risk factors.

- Participants must have had an intact nasal mucosa at baseline (i.e., no ulceration or bleeding; no or mild erythema, swelling, or rhinorrhea).
- Migraine frequency data were analyzed in a cohort of participants who completed 12 months of study participation and used either the first or final version of the STS101 device on average ≥2 times per month.

Outcomes and Analyses

- All migraine attacks were to be treated with STS101 and were recorded and qualified in an eDiary including, pain severity and the presence of other cardinal migraine symptoms.
 - Cardinal migraine symptoms were defined as nausea, photophobia, and phonophobia.
- Participant data were stratified into 3 strata, defined by the frequency of treated attacks in the first study month.
 - 1–2 Attacks
 - 3–4 Attacks
 - ≥5 Attacks
- Descriptive statistics were used to analyze the data.

Results

- A total of 176 participants were included in the analysis and treated 6,907 migraine attacks over 12 months with the monthly frequency of treated attacks ranging between 419 and 692 (**Table 1**).
- Participants who treated an average of 6, attacks in Month 1 experienced nearly 3 fewer treated attacks by Month 11, and those who completed the study reported 4 fewer attacks in the final month (**Figure 2**).
- Figure 3** shows that 79% of participants who treated ≥5 attacks in Month 1 shifted to a lower attack frequency stratum by Month 11—48.7% moved down one stratum and 30.3% moved down two.
- Majority of participants (58.9%) who treated 3–4 attacks in Month 1 shifted to a lower attack frequency stratum, treating 1–2 attacks at Month 11.

Figure 1. STS101 Administration

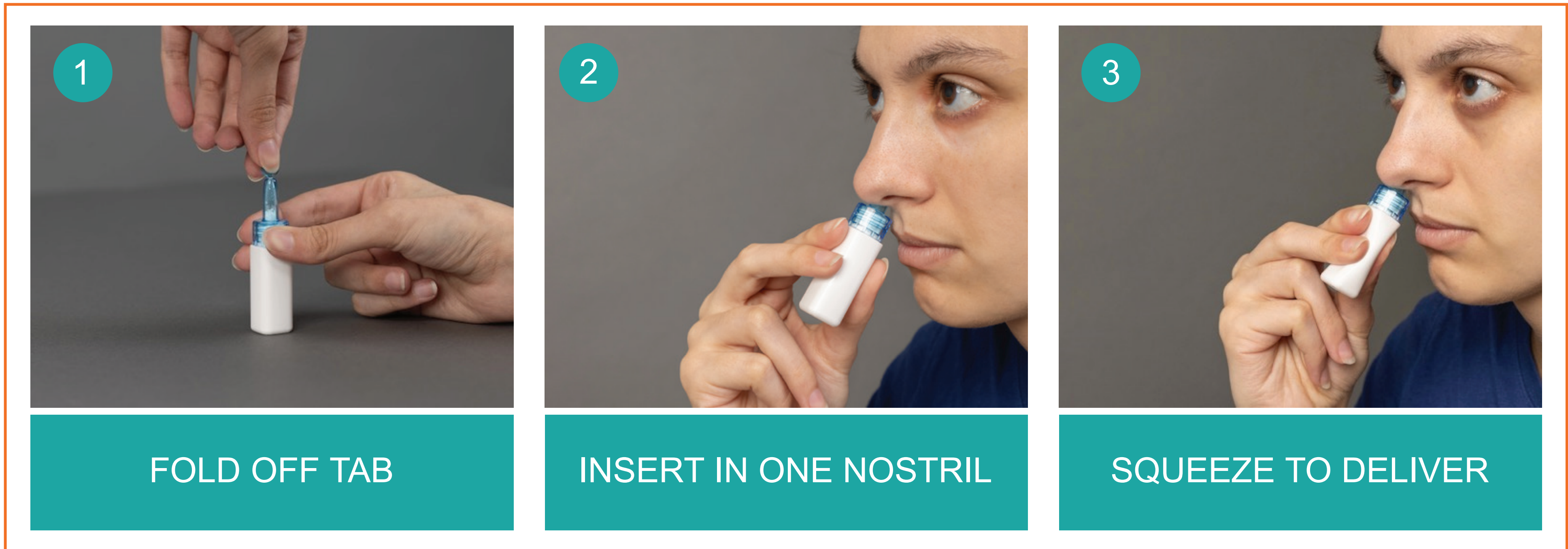


Table 1. Baseline Demographics and Migraine Characteristics

12-Month Exposure Population, N=176	
Mean (SD) age, years	42.2 (10.82)
Sex, n (%)	
Female	158 (89.9%)
Ethnicity, n (%)	
Hispanic or Latino	99 (56.3%)
Race, n (%)	
White	166 (94.3%)
Body mass index (kg/m ²), mean (SD)	27.3 (4.68)
Years since onset, mean (SD)	18.3 (11.87)
Typical migraine symptoms, n (%)	
Aura	77 (43.8%)
Nausea	150 (85.2%)
Photophobia	176 (100.0%)
Phonophobia	170 (96.6%)
Allodynia	56 (31.8%)

SD, standard deviation.

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Disclosures

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Figure 2. Mean Number of Treated Attacks in Participants by Month 1 Frequency Data

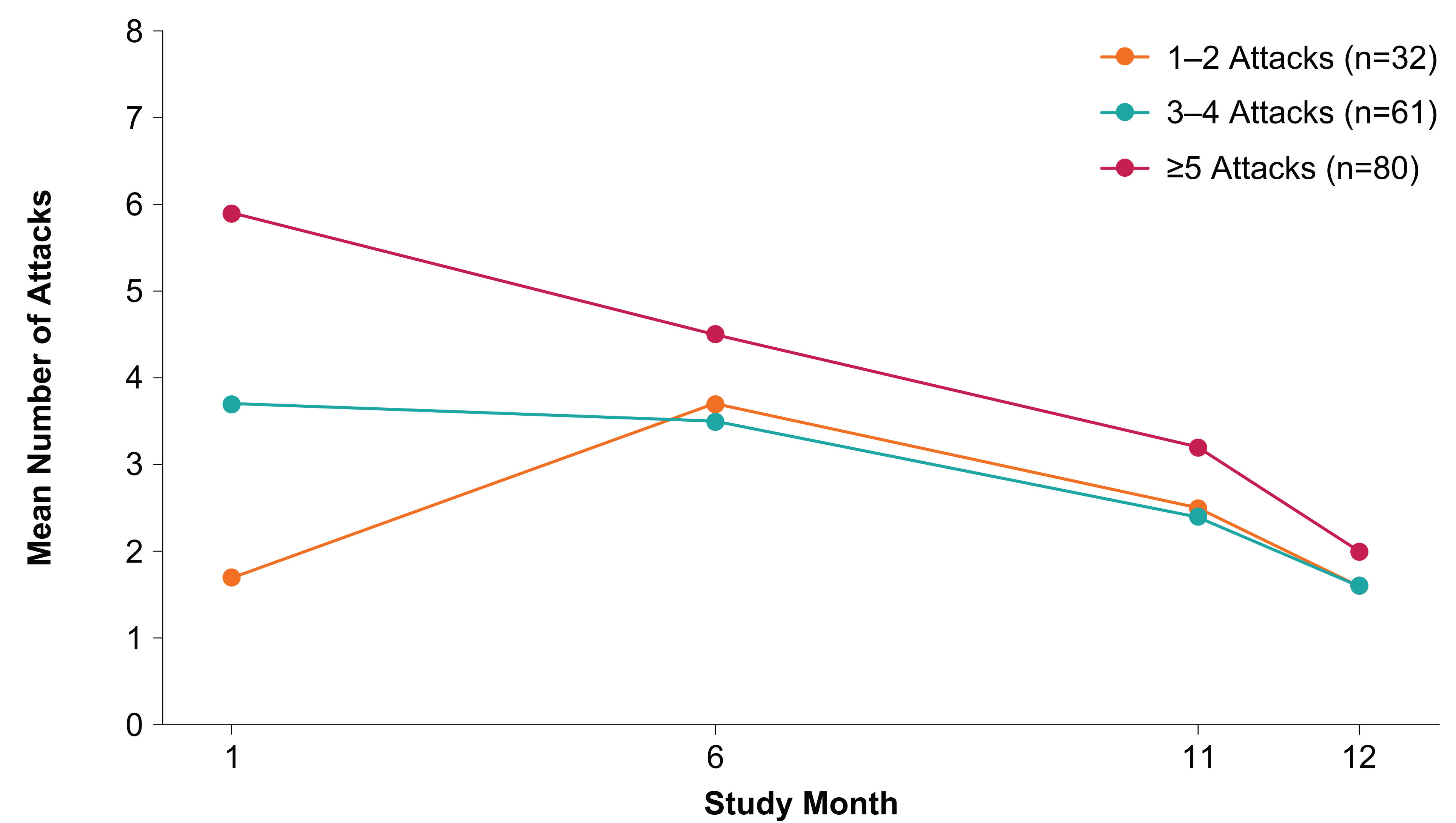
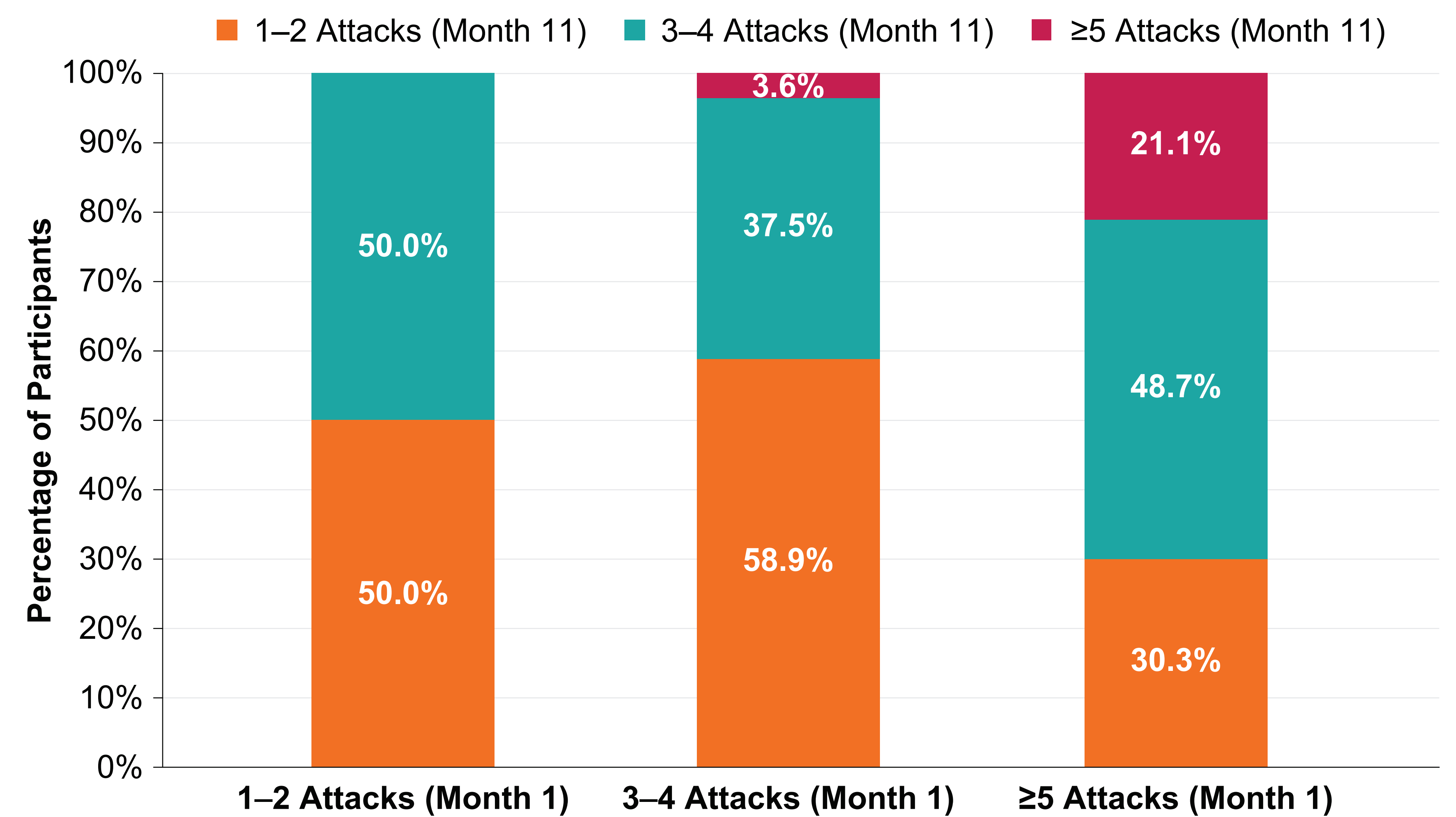


Figure 3. Shift in Monthly Migraine Attack Frequency From Month 1 to Month 11



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