

INP104 Reduces ED And Urgent Care Visits Among Patients With Episodic Migraine

Carrie Dougherty, MD
Department of Neurology
Georgetown University Hospital



BACKGROUND

- Migraine is associated with high rates of emergency department (ED) and urgent care (UC) visits
- Despite use of triptans and other acute treatments for migraine, many patients do not achieve adequate relief
- Of those presenting to the ED, a small portion are admitted for inpatient treatment. The average charge for an inpatient admission for migraine in 2012 was \$21,576 per patient in the U.S.¹
- Patients with migraine had annual direct costs that were \$6,500 higher than individuals without migraine²
- INP104 is a novel, self-administered drug-device combination product using a Precision Olfactory Delivery (I123 POD®) device to target delivery of dihydroergotamine mesylate to the upper nasal space

OBJECTIVE

To estimate the effect of INP104 on healthcare resource use among patients with episodic migraine in the phase 3 STOP 301 clinical study

METHODS

Phase 3, multicenter, 24-week, open-label STOP 301 study of INP104 enrolled patients with a documented diagnosis of migraine and at least two attacks/month during the previous six months (NCT03557333)

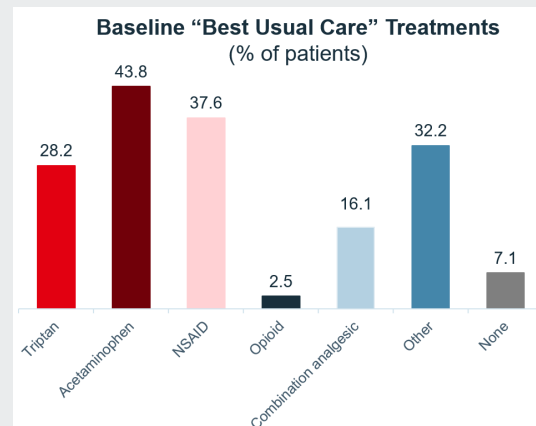
- Self-reported HCRU data for the 12-month baseline period on “best usual care” was compared to data from the eDiary while on treatment with INP104
- Data were analyzed for the 354 patients who received at least one dose of INP104
- Exposure-adjusted event rates were calculated to account for varying treatment exposure times

RESULTS

Table 1. Demographic Characteristics

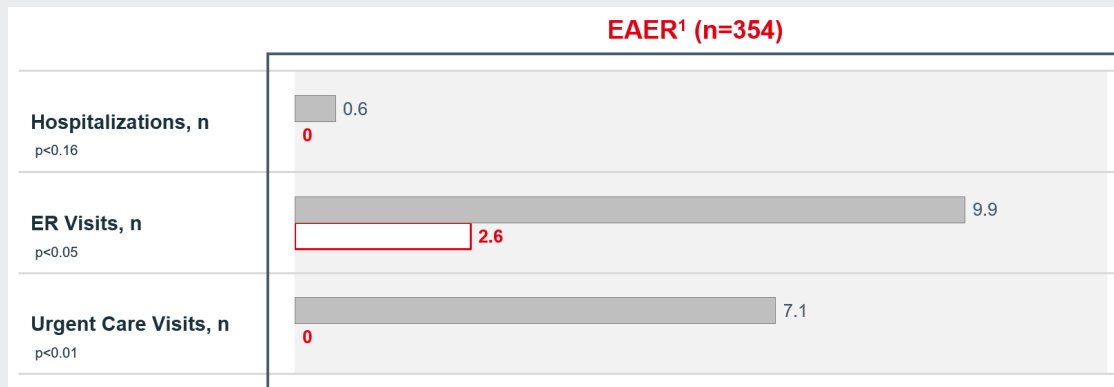
Demographic Characteristics	
Number of patients	354
Female (n, %)	304 (86)
Age (mean, SD)	41.3 ± 11.12
Baseline migraine in 28-day screening period	4.6
Maximum severity of headache: severe	65.3%

Figure 1. Baseline Treatments



Patients could be on multiple treatments at baseline, hence total number of Best Usual Care treatments exceeded 100%

Figure 2. HCRU: Exposure-Adjusted Event Rate Treatment on INP104 vs. Best Usual Care



¹EAER (exposure-adjusted event rate) is a standardized way to annualize events, such as hospitalizations, ER visits and urgent care visits, in a population with variable exposure durations to INP104 compared to the number of events in the 12 months prior to treatment with INP104. For subjects with multiple occurrences of each specific event, each occurrence was counted. Paired t-tests assessed the significance of changes in HCRU

CONCLUSION & DISCUSSION

- This is the first phase 3 study in acute migraine, to our knowledge, to collect and report HCRU data.
- In patients with acute migraine presenting to the ED, IV DHE mesylate has an established role as an effective agent to treat intractable symptoms. However, the ED is not an optimal setting of care to treat migraine as it is a recurring disorder which is better treated in an outpatient setting with continuity of care.
- This study is limited in that the clinical care provided by the study protocol may have reduced healthcare seeking behavior relative to the real-world setting.
- Data collected on unplanned physician/clinic visits was deemed unreliable due to the recall bias.
- Treatment with INP104 significantly reduced the utilization of ED, UC visits over 24-weeks compared to the period on best usual care. Cost savings associated with this reduction in healthcare utilization will be the subject of future analyses.

REFERENCES

1. Law HZ, Chung MH, Nissan G, Janis JE, Amiriak B. Hospital Burden of Migraine in United States Adults: A 15-year National Inpatient Sample Analysis. *Plast Reconstr Surg Glob Open*. 2020 Apr 23;8(4):e2790.
2. Bonafede M, Sapra S, Shah N, Tepper S, Cappell K, Desai P. Direct and Indirect Healthcare Resource Utilization and Costs Among Migraine Patients in the United States. *Headache*. 2018 May;58(5):700-714.

Audio recording for AAN 2021 (max 3-5 minutes)

Impact of INP104 on Healthcare Resource Use Among Patients in STOP 301

- Thank you for joining us today to discuss this analysis of the Impact of INP104 on Healthcare Resource Use Among Patients in the STOP 301 study
- Migraine is associated with high rates of emergency department and urgent care visits
- And despite use of triptans and other treatments for acute migraine, many patients do not achieve adequate relief prompting them to go to Urgent Care Centers or the ED
- Some who present at the ED are admitted for inpatient care
- All of these settings of care are sub-optimal for patients, and are expensive to the healthcare system
- INP104 is a novel, self-administered drug-device combination product using a Precision Olfactory Delivery (POD®) device to target delivery of dihydroergotamine mesylate to the upper nasal space. Impel NeuroPharma has an NDA currently under review by the FDA for the acute treatment of migraine
- In the STOP 301 study, patients with a history of 2 or more migraines per month, but excluding those with chronic migraine, were offered INP104 in addition to any preventative they were already taking
- The objective of this analysis was to determine the effect of INP104 over 24 weeks on the rates of ED, UC and hospitalization compared to best usual care
- We analyzed the data for the 354 patients who received at least one dose of INP104 in the STOP 301 study and calculated exposure-adjusted event rates to account for varying treatment exposure times
- Exposure-adjusted event rates account for the varying duration on therapy across patients in the study and is a commonly utilized health outcomes metric
- The event rate for hospitalization, ED visits and UC visits were lower while on INP104 in this study compared to the event rate while on best usual care prior to study
- The rate of hospitalization was zero on INP104 versus 0.6 on best usual care
- ED visits were reduced from a rate of 9.9 to 2.6
- And urgent care visits went from 7.1 to zero
- One limitation of our study worth noting is that the care given in a clinical trial setting may not reflect healthcare seeking behavior seen in the real world
- In conclusion, the ED and urgent care centers are not the optimal setting of care to treat migraine as it is a recurring disorder which is better treated in an outpatient setting with continuity of care
- INP104 can be self-administered at home which may lead to reductions in healthcare encounters in these settings which will be of benefit to patients, providers (in ED and UC settings) and payors