International Headache Society
IHC 2025
Sep 10 - 13 2025
São Paulo | Brazil

A Prospective, Open-label Long term efficacy and tolerability study of combination treatment of Botulinum toxin and Greater Occipital Nerve Blocks in Resistant Migraine

Mahak Golani[1], Manju Yadav[1], Arijit Pal[1], Sanjay Rao Kordcal[1], Debashish Chowdhury[1]

1. Neurology, Govind Ballabh Pant Institute of Postgraduate Medical Education and Research (GIPMER), New Delhi, India

INTRODUCTION AND AIM

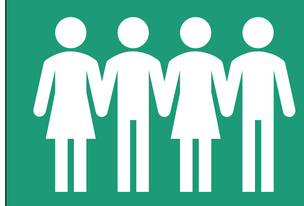
- Resistant migraines are difficult to treat. Currently anti-CGRP monoclonal antibodies (anti-CGRP-mAbs) with or without Botulinum toxin-A (BoT-A) are used based on expert opinion.[1] However, these combination treatments are very costly and are prohibitive for patients living in LMIC. We aimed to study a cheaper alternative option for RM patients.
- **AIM:** To study the efficacy and tolerability of combination treatment of Botulinum toxin (BoT-A) and Greater Occipital Nerve Block (GONB) in patients with Resistant Migraine (RM).

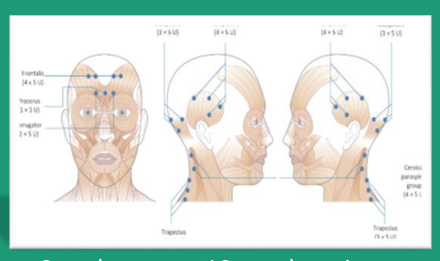
METHODOLOGY

Open-label design

RM diagnosed by modified EHF 2020 criteria

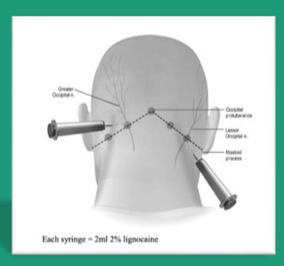
1. Failure of 3 or more drug classes with established evidence for migraine prevention given at appropriate dose and duration (no anti-CGRP-mAbs used because of non-availability)
2. Migraine diagnosed by ICHD-3 with debilitating headaches more than 8 days/month for 3months





3 cycles every 12 weeks using PREEMPT paradigm

+



Bilateral GONB (2% 2ml lidocaine) injected 4-weekly for 9 cycles

Efficacy and safety assessed → at 36 weeks

OUTCOME

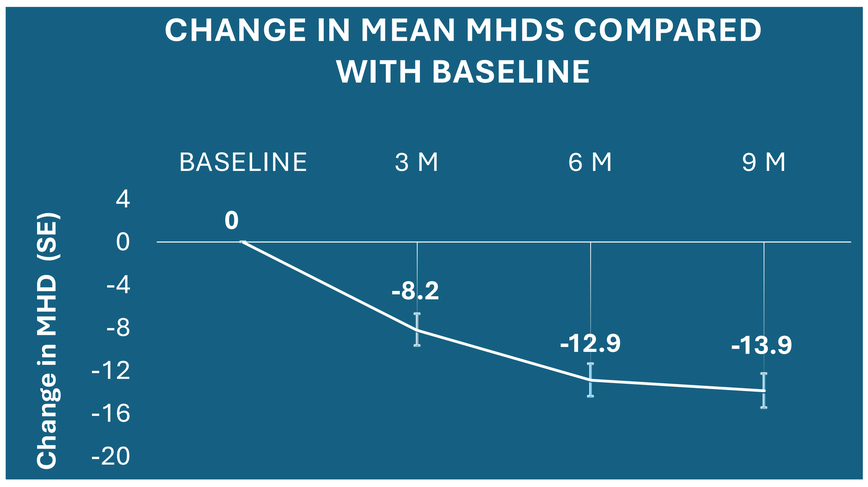
PRIMARY	**Mean change in monthly headache days (MHD) at 36 weeks from baseline**
KEY SECONDARY	**Mean change in monthly migraine days (MMD)** **50% responder rate at 36 weeks from baseline**
OTHER SECONDARY ENDPOINTS	**Mean changes in VAS score, HIT-6 score, acute medication treatment (AMT) days and PHQ-9 score from baseline.**

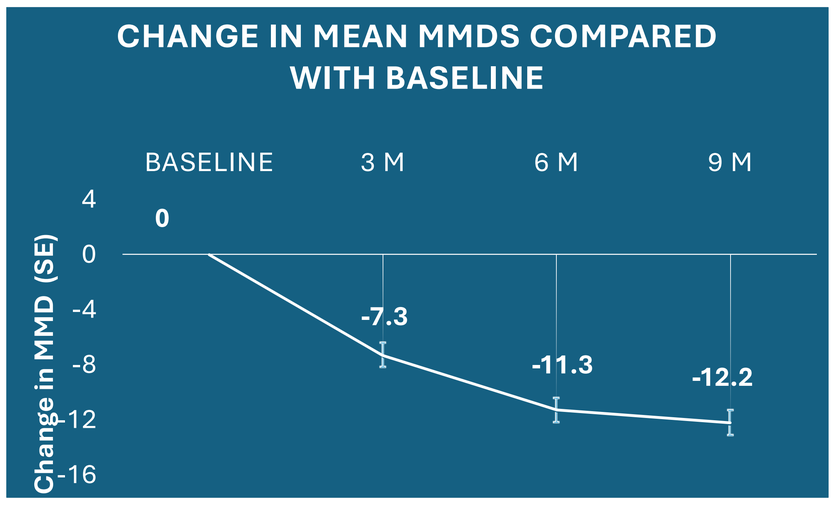
Efficacy analysis was done using linear generalized mixed model for repetitive measures using baseline as covariate. The level of significance was set at $p<0.05$.

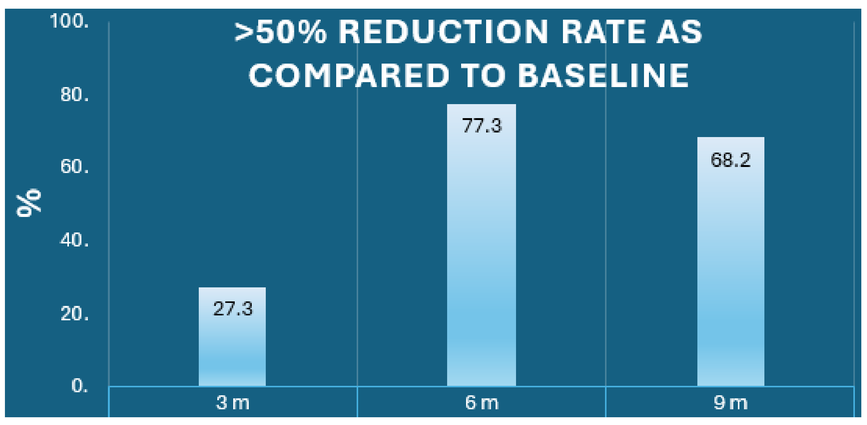
RESULTS

22 Patients (18 female, 4 male)

Baseline Characteristics	
Mean Age	29.7 ± 10.6 years
Mean duration of RM	8.0 ± 6.2 years
Failed preventive medications	3.7 ± 1.1
MHD	25.0 ± 4.2
MMD	19.0 ± 4.6
VAS score	8.2 ± 0.9
HIT 6 score	67.3 ± 5.8
AMT	29.9 ± 13.8
PHQ9	13.2 ± 4.1







Adverse event	No. of patients
Local site pain	8
Local site bleeding	6
Local site swelling	6
Local site numbness	3

Failed preventive drugs

Propranolol, Flunarizine, Topiramate, Amitriptyline, Divalproex, BoT-A, GONB

Other secondary endpoints (mean changes compared with baseline; all $p<0.05$)

Headache intensity (VAS): -2.4 Acute migraine treatment days: -12.2 days

Depression scores (patient health Questionnaire-9):-7.1 Headache disability (HIT– 6): -20.5

CONCLUSIONS

1. The combination treatment of BoT-A and GONB in patients with RM over 9 months was efficacious and well tolerated.
2. The efficacy started within 3 months of initiation and was sustained up to 9 months.
3. This combination treatment in view of cheaper cost and easy accessibility may be a good alternative for treating RM.
4. A randomised controlled trial is warranted.

***REFERENCES**: Ornello R, Andreou AP, De Matteis E, Jürgens TP, Minen MT, Sacco S. Resistant and refractory migraine: clinical presentation, pathophysiology, and management. EBioMedicine. 2024; 99:104943.