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Greater Occipital Nerve BLOCK with and without steroids FOR Chronic Migraine (GONBLOCK-FOR-CM): A Randomized Double-Blind Placebo-Controlled Study

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BACKGROUND

Chronic migraine (CM) is disabling with limited affordable preventives. Greater occipital nerve block (GONB) modulate the pain pathway through trigemino-cervical complex and offers a safe, low-cost option. However, long-term efficacy evidence is lacking, warranting randomized controlled evaluation.

OBJECTIVE

To study the efficacy and tolerability of GONB using methylprednisolone (MPS) plus lidocaine, lidocaine alone and placebo in patients with CM.

METHODOLOGY

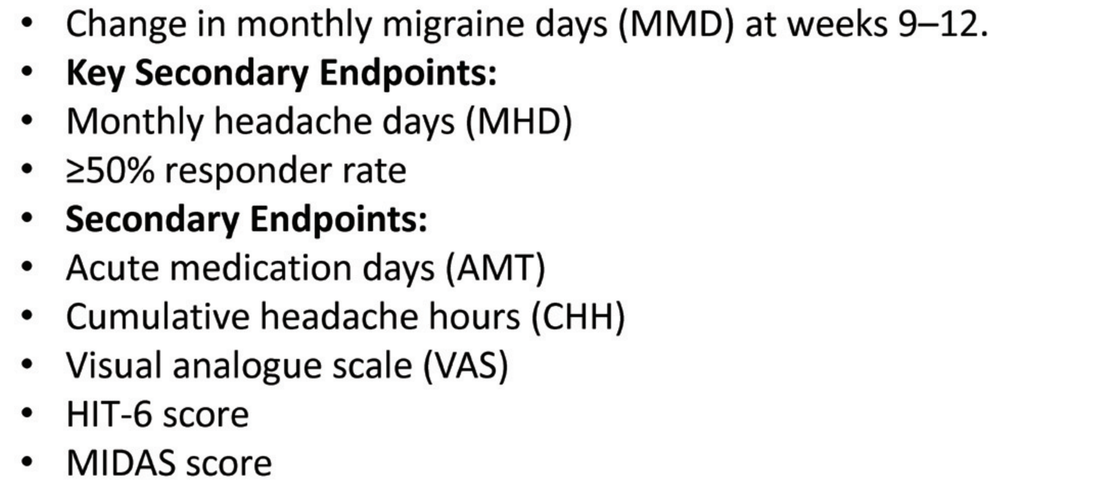
Design: Randomized, double-blind, placebo-controlled trial.
Patients: Adults (18–65 yrs) with CM (ICHD-3).
Randomization (1:1:1):

- **MPS 80mg + Lidocaine 2% (2ml each, total 4ml)**
- **Lidocaine 2% (2ml) + NS 2ml**
- **NS 4ml (Placebo)**

Administration: Bilateral GONB every 4 weeks for 12 weeks.
Blinding and masking: Active and placebo injections looked exactly similar. All received prior lignocaine jelly at the injection sites to mask the effect of numbness.
Endpoints:

- **Primary Endpoint:**
- Change in monthly migraine days (MMD) at weeks 9–12.
- **Key Secondary Endpoints:**
- Monthly headache days (MHD)
- ≥50% responder rate
- **Secondary Endpoints:**
- Acute medication days (AMT)
- Cumulative headache hours (CHH)
- Visual analogue scale (VAS)
- HIT-6 score
- MIDAS score
- MSQOL score
- CGI-S score
- CGI-I score
- Adverse events

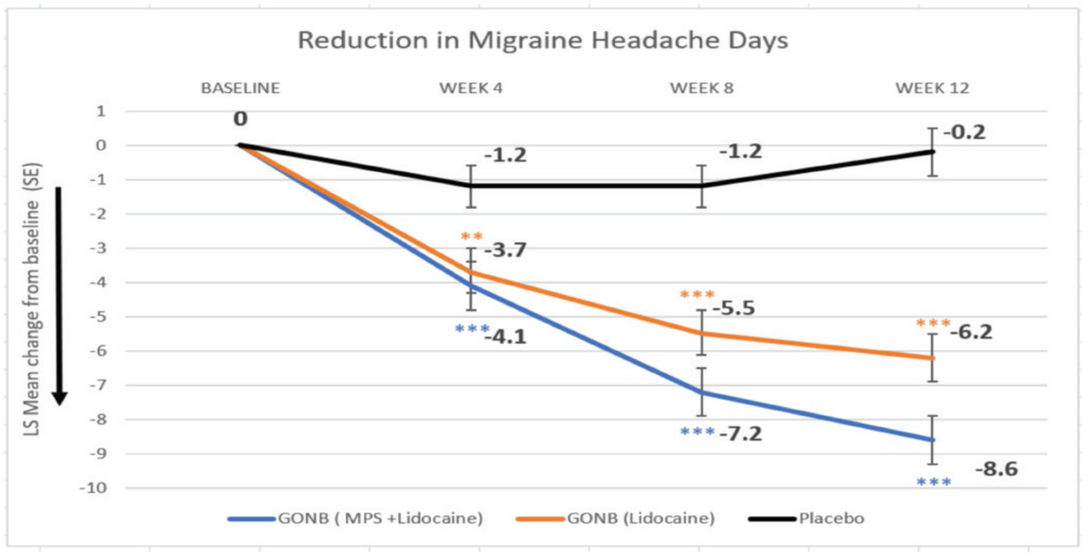
Statistical Analysis: Linear mixed-effects model, $p < 0.05$.
Clinical Trials Registry of India (CTRI 2023/04/051913)



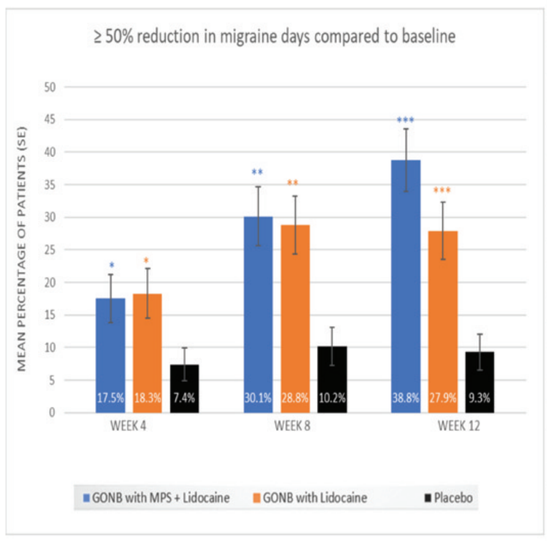
RESULTS

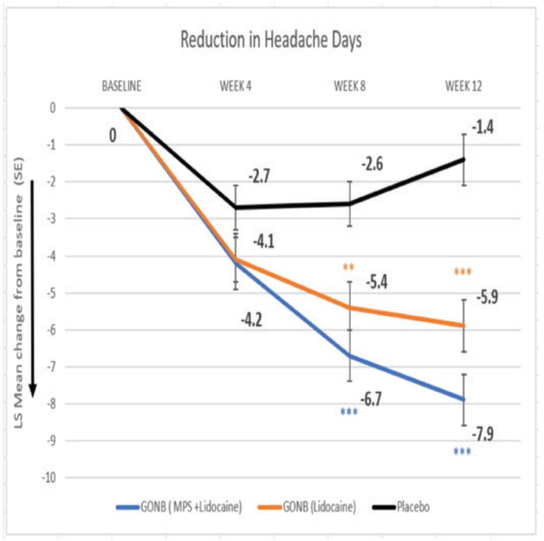
A total of 332 patients were randomized of which 315 were included in efficacy analysis. Baseline demographic and headache characteristics of the three groups were comparable. The baseline MMD are:

- Group receiving MPS plus lidocaine: 22.3 ± 5.3
- Group receiving lidocaine alone: 20.9 ± 6.4
- Group receiving placebo 20.2 ± 6.6
- **Primary Endpoint:**



- **Key Secondary Endpoints:**





- **Secondary Endpoints :**

All secondary endpoints showed significant improvements in both the active treatment groups over placebo ($p<0.05$).
Adverse events were mostly mild and transient across groups: local bleeding, swelling, dizziness, syncope, alopecia, neck pain, and rare local site reactions.
No serious adverse events occurred, confirming safety.

CONCLUSIONS

GONB using either MPS plus lidocaine or lidocaine alone significantly reduced MMD and MHD in patients with CM compared with placebo at 12 weeks. GONB using MPS plus lidocaine had additional benefit in reducing MMD as compared to GONB without MPS. GONB was safe and well-tolerated.