AMERICAN ACADEMY OF NEUROLOGY®

Migraine prevention with a supraorbital transcutaneous stimulator

A randomized controlled trial

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Abstract

Objective: To assess efficacy and safety of trigeminal neurostimulation with a supraorbital transcutaneous stimulator (Cefaly, STX-Med., Herstal, Belgium) in migraine prevention.

Methods: This was a double-blinded, randomized, sham-controlled trial conducted at 5 Belgian tertiary headache clinics. After a 1-month run-in, patients with at least 2 migraine attacks/month were randomized 1:1 to verum or sham stimulation, and applied the stimulator daily for 20 minutes during 3 months. Primary outcome measures were change in monthly migraine days and 50% responder rate.

Results: Sixty-seven patients were randomized and included in the intention-to-treat analysis. Between run-in and third month of treatment, the mean number of migraine days decreased significantly in the verum (6.94 vs 4.88; p = 0.023), but not in the sham group (6.54 vs 6.22; p = 0.608). The 50% responder rate was significantly greater (p = 0.023) in the verum (38.1%) than in the sham group (12.1%). Monthly migraine attacks (p = 0.044), monthly headache days (p = 0.041), and monthly acute antimigraine drug intake (p = 0.007) were also significantly reduced in the verum but not in the sham group. There were no adverse events in either group.

Conclusions: Supraorbital transcutaneous stimulation with the device used in this trial is effective and safe as a preventive therapy for migraine. The therapeutic gain (26%) is within the range of those reported for other preventive drug and nondrug antimigraine treatments.

Classification of evidence: This study provides Class III evidence that treatment with a supraorbital transcutaneous stimulator is effective and safe as a preventive therapy for migraine.

Neurology February 19, 2013 80:697-704

Received April 23, 2012.
Accepted October 4, 2012.