

Cephalalgia

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not such that treatment choices should be based primarily on tolerability. They are better based on efficacy.

Chronic daily headache; migraine-prevention therapy and tension type headaches

PD.01

Chronic daily headache treated non-pharmaceutically with a nociceptive trigeminal inhibition dental splint

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Background The NTI (Nociceptive Trigeminal Inhibition) intraoral device is FDA approved for the prophylactic treatment of medically diagnosed migraine pain and is hypothesized to reduce noxious afferent activity through reduction of intensity of nocturnal hyperactive trigeminal motor activity (jaw clenching).

Methods 20 consecutive CDH patients, all who scored 'severe and disabling' on their HIT-6 questionnaire, were properly fitted with an NTI device and wore nightly for 9 months. HIT-6 questionnaires were complete at 4 weeks, 8 weeks, and 9 months following the initial fitting.

Results By the fourth week of nocturnal NTI use, nearly 75% reported significant positive improvements in their HIT-6 scores. By the second month, all HIT-6 scores had stabilized. Following seven months of continual nocturnal NTI use, 50% reported considerable improvement in the quality of their lives, with half of those reporting that their headaches no longer had any impact on their lives, while another reported experiencing only 'some' negative impact.

Conclusions The considerable long-term improvement on the lives of the majority of patients with severe and disabling intractable Chronic Daily Headache over a nine-month period, well after the cessation of placebo effect as a confounding factor, suggests that intense nocturnal jaw clenching and resultant nociceptive input to the trigeminal sensory nucleus should be considered as a perpetuating co-factor of CDH attack frequency and severity. An NTI device, provided by an experienced and knowledgeable practitioner, should be considered an important non-pharmacologic prescribed therapeutic option for improving the quality of life of severe headache patients.

PD.02

Comparison of botulinum toxin type A (BoNTA) and topiramate for the prophylactic treatment of chronic migraine: double-blind pilot study

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Background There is a need for effective prophylactic migraine therapy that has minimal side effects.

Objective Determine the effect of prophylactic treatment of botulinum toxin type A (BoNTA; BOTOX®) and topiramate

(Topamax®) on frequency and intensity of chronic migraine (CM) episodes.

Methods In this single-center, double-blind trial, patients received either BoNTA, maximum 200 U at baseline and month 3 (100 U fixed-site and 100 U follow-the-pain), +placebo topiramate, or topiramate, 4-week titration to 100 mg/day with option for additional 4-week titration to 200 mg/day, + placebo BoNTA (saline injections). The primary endpoint was treatment responder rate assessed using Physician Global Assessment (PGA) 9-point scale. Headache disability was measured using Headache Impact Test (HIT-6), headache diary, Migraine Disability Assessment (MIDAS), and Migraine Impact Questionnaire.

Results Of 60 patients randomized to treatment (mean age, 37 y; 90% female), 33 completed the study at 9.5 months (BoNTA, 18/30 [60%]; topiramate, 15/30 [50%]). In the topiramate group, 53.3% discontinued study because of adverse events (AEs) vs 25% in the BoNTA group. Between 68% and 82% of subjects reported some improvement at months 1, 3, 6, and 9 in PGA for both BoNTA and topiramate groups. No significant between-group differences were observed, except for marked improvement at month 9 (BoNTA, 27.3% vs topiramate, 60.9%, $P = 0.0234$, Chi-sq). In both groups, headache-days decreased and MIDAS and HIT-6 scores improved. 41 treatment-related AEs were reported in 18 BoNTA-treated subjects vs 87 in 25 topiramate-treated subjects.

Conclusions BoNTA and topiramate showed equivalent efficacy in the prophylactic treatment of CM. Patients receiving BoNTA had fewer AEs and discontinuations.

PD.03

Health-Related Quality of Life (HRQL) of patients eligible for prophylactic headache treatment with botulinum toxin type A (BoNTA) in the Program to Assess Headache Treatment Strategies (PATS)

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Objective PATS was conducted to assess the safety and effectiveness of BoNTA (BOTOX®: Allergan, Inc.) for headache (HA) prophylaxis in specialty care patients. Presented are baseline patient characteristics and their associations with indicators of HRQL.

Methods HRQL was assessed using the Headache Pain-Specific Quality of Life (HPSQL) questionnaire. Associations of HA diagnosis, frequency, and severity with HPSQL item and total scores were evaluated by ordered logistic regression.

Results 703 patients were enrolled. Nearly 66% had a chronic migraine diagnosis. Average HA frequency one month prior to enrollment was negatively related to HRQL with a 1-day increase in frequency associated with a greater likelihood of HA pain interfering with mood (4%, $p < 0.001$), recreational activities (4%, $p = 0.004$), or life enjoyment (4%, $p = 0.001$). Co-existing health conditions and HA severity were negatively associated with HRQL. Patients who reported severe

CHRONIC DAILY HEADACHE TREATED NON-PHARMACEUTICALLY WITH A NOCICEPTIVE TRIGEMINAL INHIBITION DENTAL SPLINT

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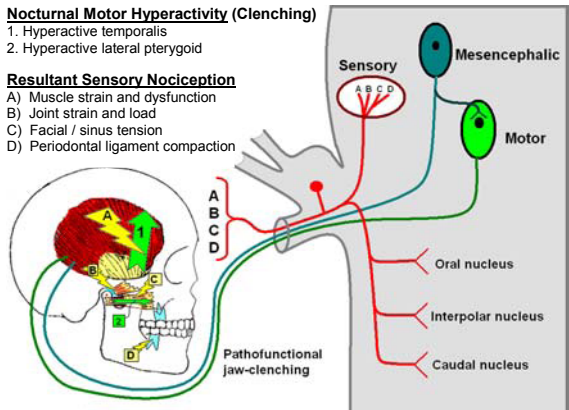
Background – The NTI (Nociceptive Trigeminal Inhibition) intraoral device is FDA approved for the prophylactic treatment of medically diagnosed migraine pain and is hypothesized to reduce noxious afferent activity through reduction of intensity of nocturnal hyperactive trigeminal motor activity (jaw clenching).

Nocturnal Motor Hyperactivity (Clenching)

1. Hyperactive temporalis
2. Hyperactive lateral pterygoid

Resultant Sensory Nociception

- A) Muscle strain and dysfunction
- B) Joint strain and load
- C) Facial / sinus tension
- D) Periodontal ligament compaction



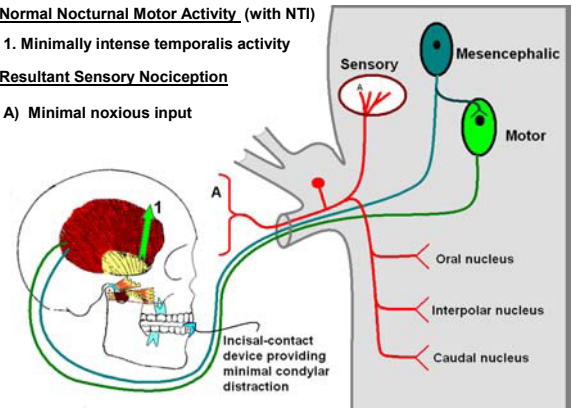
Molar and canine tooth contact allows for pathologic intensity of trigeminal motor hyperactivity (nocturnal jaw clenching)

Normal Nocturnal Motor Activity (with NTI)

1. Minimally intense temporalis activity

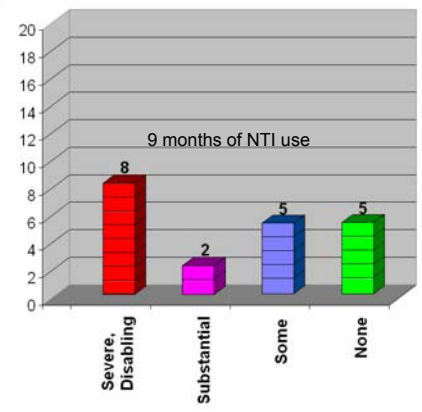
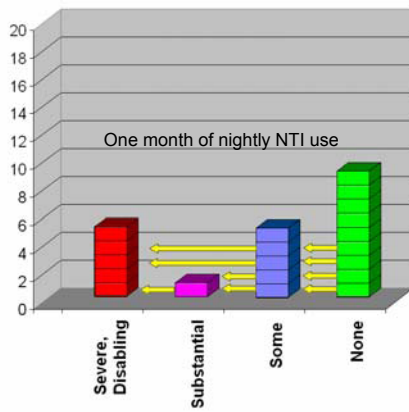
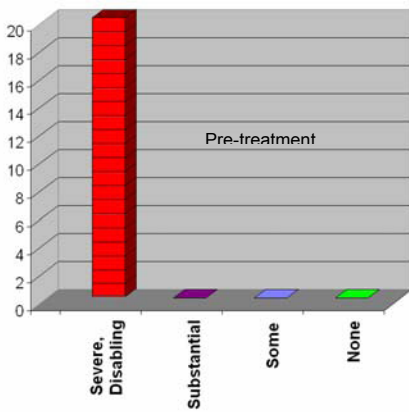
Resultant Sensory Nociception

- A) Minimal noxious input



Providing for only incisor-edge contact with an NTI device minimizes trigeminal nociception.

Methods - 20 consecutive CDH patients treated in a headache center, all who scored "severe and disabling" on their HIT-6 questionnaire despite maximal oral prophylactic medication, were properly fitted with an NTI device and wore nightly for 9 months. HIT-6 questionnaires were complete at 4 wks, 8 wks, and 9 months following the initial fitting.



Results – By the fourth week of nocturnal NTI use, nearly 75% reported significant positive improvements in their HIT-6 scores. By the second month, all HIT-6 scores had stabilized. Following seven months of continual nocturnal NTI use, 50% reported considerable improvement in the quality of their lives, with half of those reporting that their headaches no longer had any impact on their lives. 65% of subjects had a 71% average reduction in days per week of waking with a headache.

Conclusions – The considerable long-term improvement on the lives of the majority of patients with severe and disabling intractable Chronic Daily Headache over a nine-month period, well after the cessation of placebo effect as a confounding factor, suggests that intense nocturnal jaw clenching and resultant nociceptive input to the trigeminal sensory nucleus should be considered as a perpetuating co-factor of CDH attack frequency and severity. An NTI device, provided by an experienced and knowledgeable practitioner, should be considered an important non-pharmacologic prescribed therapeutic option for improving the quality of life of severe headache patients.

