Société Française de NeuroModulation | INS French Chapter

Neuromodulation Trigémino-Cervico-Vagale dans le Diabète de type 2

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Combined minimally invasive vagal cranial nerve and trigeminocervical complex peripheral nerve stimulation produces prolonged improvement of severe painful peripheral neuropathy and hyperglycemia in type 2 diabetes

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INTRODUCTION

Neuropathie périphérique diabétique (DPN), complication du diabète sucré

1. Résultat de la défaillance bioénergétique + réduction d'expression du facteur de croissance endothélial vasculaire A (VEGF-A)
2. **persiste malgré un contrôle glycémique optimal**
3. **nécessité de traiter la cause du dysfonctionnement métabolique lipidique**

Comparing Percutaneous Electrical Neuro-Stimulation with Placebo in the Management of Diabetic Peripheral Neuropathic Pain

Poster NANS 2019

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Abstract

Painful diabetic neuropathy is a common phenotype of peripheral neuropathy due to diabetes, affecting up to a third of the general diabetic population. The aim of this study was to evaluate the efficacy of auricular percutaneous electrical neuro-stimulation (PENS) in treating and relieving patients suffering from painful complications of diabetes.

A double-blind, randomized, placebo-controlled longitudinal trial enrolled 89 subjects with pain due to peripheral neuropathy caused by type 2 diabetes mellitus. Patients with pain duration of 4 months involving the lower extremities were randomly assigned to receive either standard (A) or variable-frequency (B) auricular PENS treatment, or a sham device, for 12 weeks, on a week-on week-off basis. Visual analogue scale (VAS) on 10 cm was used to assess pain, while severity of peripheral neuropathy was estimated through the vibration perception test (VPT) and the overall neuropathy limitation scale (ONLS). Insomnia and anxiety/mood severities were appraised by means of, respectively, the insomnia severity index (ISI) and the Hamilton anxiety rating scale (HAS). These 5 measures were repeated each week, alternating between installation and removal of the treatment device. Patients were encouraged to come back and complete the 6 treatments. Parameters of diabetic control were gauged at the first and last visit.

Population size dwindled from initial 89 to 63 subjects remaining after 12 weeks (21 with A, 22 with B). VAS, VPT, ONLS and HAS measures decreased with statistical significance for all 43 individuals in comparison with 20 placebo-treated patients (p-value $\ll 0.001$). Pain scores were found to linearly reduce with time from 7.1 ± 0.6 to 6.5 ± 1.0 over the complete study period with placebo, whereas neurostimulation allowed reductions from 7.2 ± 1.0 to 4.5 ± 1.0. Moderate pain VAS drops were found to be accompanied by drastic plunges in VPT. Study subjects were further sieved according to the decrease of blood glucose measures. Patients who demonstrated good glycemic control (16 out of 43) had quadratic reductions in pain with treatments A and B, from 7.5 ± 0.9 to 4.1 ± 0.6, and from 7.1 ± 1.5 to 5.2 ± 0.7, respectively. Glycemia also determined the decline of anxiety scores. Furthermore, ISI exhibited overall significant decrease ($p \ll 0.001$) for PENS groups in comparison with a raise of insomnia values for the control group. Analgesic requirements decreased by 80% for both treatment groups and only by 7% with placebo. No adverse events were found.

Active PENS treatments improved the neuropathic pain symptoms in all patients who completed the 12 weeks. Their resilience in participating may explain this success. In addition to decreased extremity pain, PENS improved physical activity, sense of well-being, and sleep quality while reducing the need for analgesics.

Keywords:
Diabetic Neuropathy, Painful, Percutaneous Electrical Neuromodulation; MeSH IDs D003919, D004561

We used First Relief™ (DyAnsys Inc., San Mateo, CA), a miniaturized PENS device (measuring about 6 x 2 cm) designed to administer intermittent electrical auricular neurostimulation via selectively placed needles in ambulant patients (Figure 1).

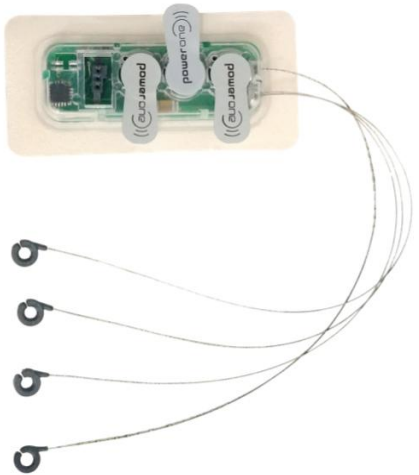

Figure 1: PENS battery-operated device with three electrodes.

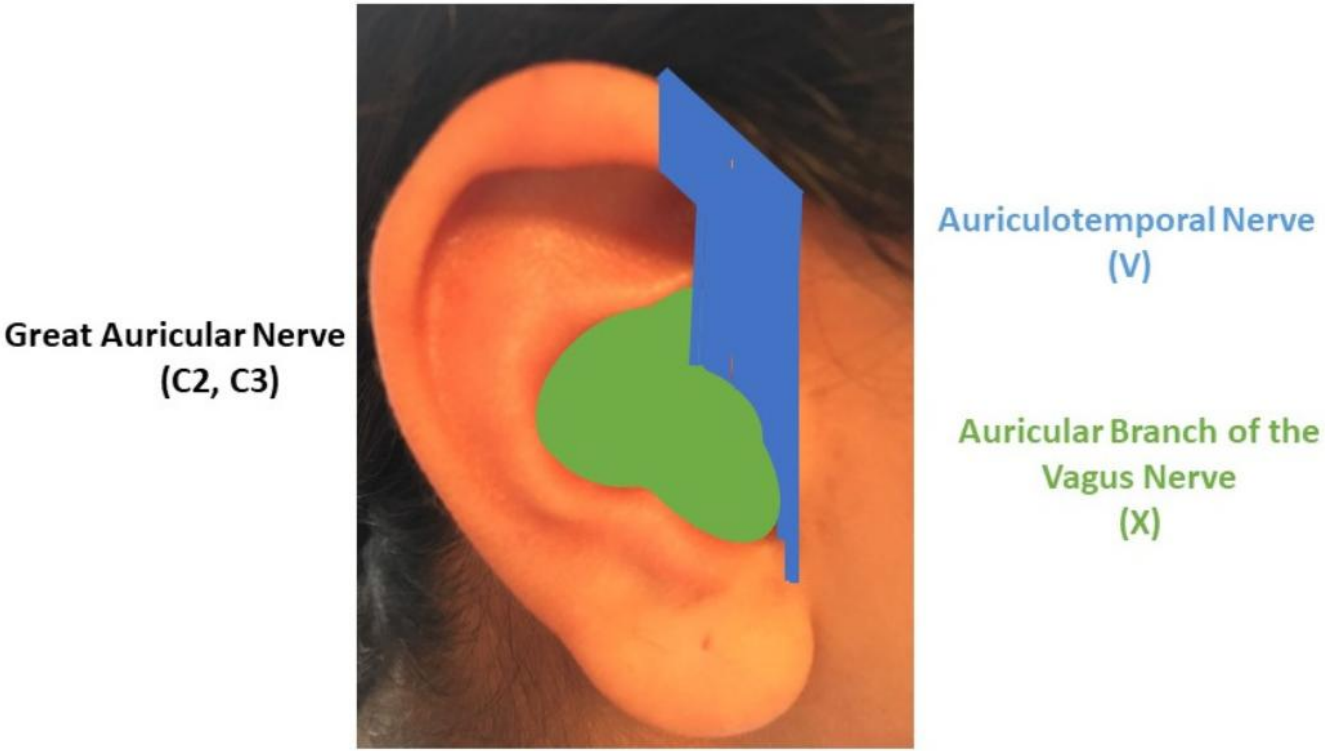

Figure 2. Delineation of three strategic areas for non-invasive neuromodulation on the lateral side of the auricle: the green area is mainly supplied by the Auricular Branch of the Vagus Nerve (X); the blue area is mainly supplied by the Auriculotemopral nerve, a branch of the trigeminal nerve (V); the largest remaining area is mainly supplied by the Great Auricular Nerve (C2, C3). Inspired by Peuker and Filler, 2002. Copyright Dr. Rangon.

METHODES

- **83 patients** Native Americans (91 initiaux, 8 perdus de vue) avec Diabète de type 2 + DPN sévère

- **Stimulation combinée minimale-invasive : appareil NS 100**, Neurosolutions100 Inc Dallas, TX (USA), **implanté dans l'oreille**
- **nerf vague (aVNS) + complexe trigéminocervical (TCC)** + soins de routine

- **Stimulation pendant 19 jours puis explantation**
- **Les scores numériques de douleur (NRS) et les niveaux moyens de glycémie** ont été mesurés **30, 60 et 90 jours après l'explantation**

NS 100, Neurosolutions100 Inc Dallas, TX (USA)

FIGURE 1
Patient Programming Technical Unit (PTU, Neurosolutions100 Inc., Dallas, TX, USA). Real time, closed loop, neural impedance drop feedback and alternating fixed and sweep wave current/power density patterns are proprietary precision neural localization and electrical field programming software platforms required to objectively identify, implant and program the NS100 Vagal and Trigeminocervical complex peripheral nerve stimulating device.

Douleur RESULTATS Glycémie

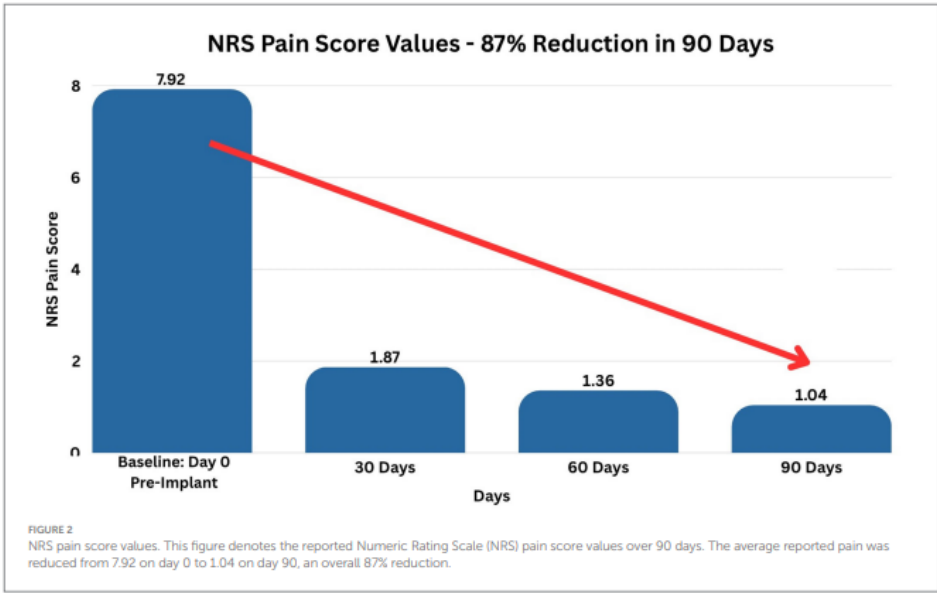

FIGURE 2
NRS pain score values. This figure denotes the reported Numeric Rating Scale (NRS) pain score values over 90 days. The average reported pain was reduced from 7.92 on day 0 to 1.04 on day 90, an overall 87% reduction.

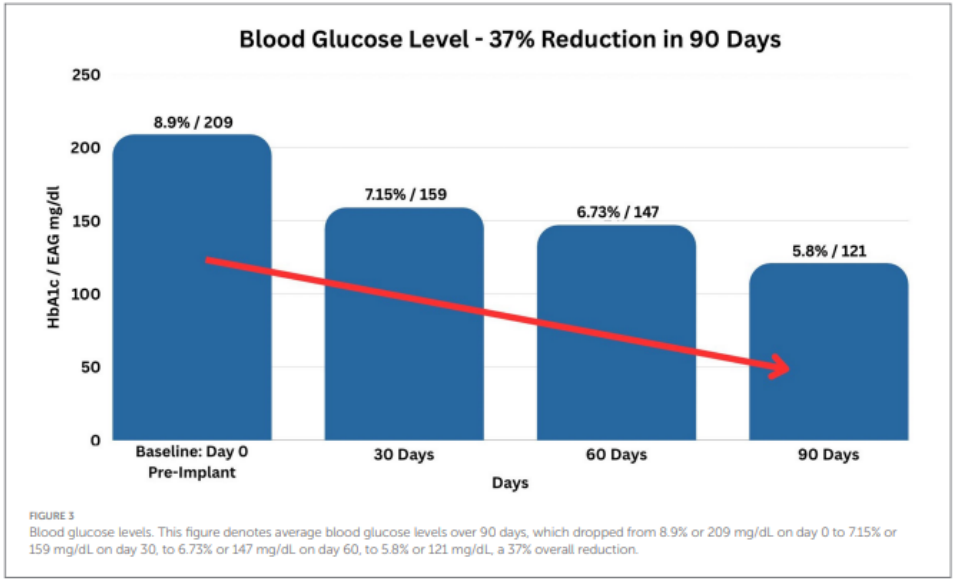

FIGURE 3
Blood glucose levels. This figure denotes average blood glucose levels over 90 days, which dropped from 8.9% or 209 mg/dL on day 0 to 7.15% or 159 mg/dL on day 30, to 6.73% or 147 mg/dL on day 60, to 5.8% or 121 mg/dL, a 37% overall reduction.

Après SEULEMENT 19 jours de traitement!

CONCLUSIONS

La stimulation combinée minimale-invasive des nerfs périphériques aVNS et TCC semble être à la fois:

1) une thérapie prometteuse à court terme pour la DPN :

Son efficacité surpasse ceux obtenus avec la VNS cervicale seule

2) une alternative non pharmacologique potentielle pour la gestion du diabète de type 2

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