P.E.N.S.-STUDY

(PENS EFFICACY ON NEUROPATIC SYMPTOMS – STUDY)

PRELIMINARY DATA

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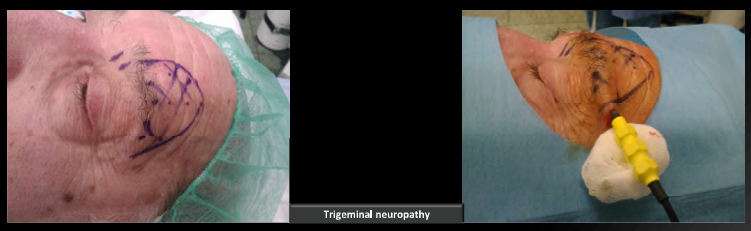
Introduction.

It is challenging to treat a well-recognized neuropathic pain in patients with allodynia and hyperalgesic localized areas. The use of analgesic drugs, such as opiates, is not free of risks, in the absence of proven effectiveness.

The availability of a new device with limited invasiveness for Percutaneous Electrical Nerve Stimulation (PENS), could provide a modern chance for the treatment of chronic neuropathic non-cancer pain. Aim of this observational and multicentric study is to validate the effectiveness of such treatment in a selected population of patients.



Trigeminal neuropathy

Methods.

Typology: observational prospective clinical study involving 10 italian Pain Centers, each one planned to enroll 15 patients with an active, well-circumscribed, severe (Numerical Rating Scale, NRS ≥ 7) neuropathic non-cancer pain, or a pain syndrome with a predominant neuropathic component, lasting for at least three months and resistant to common therapies.

Exclusion criteria are current infections, coagulopathy or anticoagulant therapies, psychiatric disorders.

The enrolled patients will be divided in two groups according to the probe placement:

Group A (PENS along the course of the responsible nerve)

Group B (PENS along the major axis of the circumscribed allodynic hyperalgesic area).

The effectiveness of PENS therapy will be evaluated according to the NRS, the NPS (Neuropathic Pain Scale), the EuroQol as measure of health outcome, at the following times:

T0 (basal);

T1, sixty minutes after treatment

T2, one week after treatment

T3, one months after treatment

T4, three months after treatment

T5, six months after treatment.

All the data have been statistically analyzed according two-way ANOVA test, a $p<0.05$ was considered significant.

	T0	T1	T2	T3	T4	T5
NRS	8,17±1,6	2,9±2,5	4,21±2,7	4,22±2,7	4,83±2,7	4,66±3,1
NPS	6,48±2,5		2,85±1,9	2,69±1,8	2,87±1,8	3,24±2,08
N°PTS	51	51	46	29	24	12

Tab1 (NRS and NPS trends, all patients)

	T0	T1	T2	T3	T4	T5
NRS	8,33±1,1	3,18±2,93	4,25±2,49	4,50±2,90	5,33±2,74	4,66±3,1
NPS	5,82±2,4		2,41±1,87	2,87±2,09	3,32±1,8	3,24±2,08

Tab 2 (NRS and NPS trends, 12 patients with complete follow-up)
NRS T0>T5 p= 0,0018 ; NPS T0>T5 p=0,0023

Results.

From december 2011 to may 2012, 51 patients, 22 males and 29 females, medium age 62.2 +/- 15.1yrs, were enrolled by 5 Pain Centers. Occipital neuralgia, trigeminal neuralgia, scar pain and other neurological pain conditions, appear to be the most frequently treated pain syndromes, with a mean duration over 30 months. No complications have occurred during the treatments except for two small hematomas in the injection site.

Only 12 patients have completed the follow-up, while 24 patiens are still at three months and 29 at one month.

Trends of NRS and NPS scores of all patients are reported in table 1, while data reported on table 2 relate only to the 12 fully controlled patients. At admission NRS and NPS scores were 8,17 and 6,48 respectively. All the patients evaluated after one month from the treatment show a considerable decrease of the two scores. In the 12 patients who have completed the observation period, NRS and NPS show a significant decrease that lasts until the sixth month. Euroqol's value has improved from 0.3 to 0.6. Eight out of the fully controlled patients have reported a satisfactory agreement with the treatment.

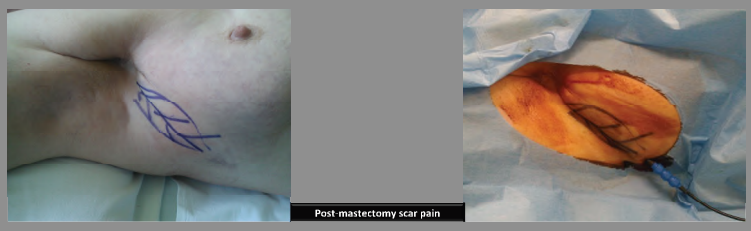
Cluster Headache

Discussion and conclusions.

This work represents the first observational, prospective, multicenter study with the aim to validate a new minimally invasive therapy (PENS) in patients with neuropathic non-cancer pain, who have received no benefit from previous pharmacological therapies.

Preliminary data seem to show the effectiveness of PENS for the treatment of these challenging pain syndromes, without significant adverse events. PENS has been effective both immediately and after one month, but notably the reduction of the perceived pain remains satisfactory (43% and 39% for NRS and NPS respectively) in the subgroup of patients who have completed the follow-up. It is possible to argue that PENS therapy would allow a long-term benefit, and the improved Euroqol at the sixth month after treatment, is in agreement with this argumentation.

Given the still small number of patients enrolled, equal to 1/3 of provided, more detailed analyses on the overall efficiency of PENS treatment for pathology and subgroups, are not yet possible and we need to complete the study in order to evaluate this approach on a broader population of patients.



Post-mastectomy scar pain

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