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Decrease in VAS Score Following Placement of a Percutaneous Peri-Auricular Peripheral Nerve Field Stimulator

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Abstract A cohort of 20 chronic pain patients in three separate clinics underwent a series of four one-week peri-auricular percutaneous nerve field stimulation (PENFS) treatments. A 65% improvement in VAS score was observed.

Keywords Chronic pain, Percutaneous peripheral nerve fields stimulator

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1. Methods and Materials

During June, July and August 2014, in three separate Midwest centers, a cohort of 20 patients experiencing unremitting multiyear chronic pain underwent a series of four one-week for peri-auricular percutaneous peripheral nerve field stimulation (PENFS) treatments. Subject patients were selected sequentially.

2. Inclusion and Exclusion Criteria

a. Inclusion Criteria-

- Have consistent, daily pain (greater than 4 on the VAS for 30 days in a row)
- The skin of the ear at the site of the Neuro-Stim System implantation must be intact and free of infection.
- The participant must have vital signs (HR/breathing/ blood pressure) within stable acceptable medical limits
- Does not have any type of on - demand implantable electric devices
- Does not have a history of seizures
- Is not pregnant (will be evaluated by asking verbally)
- Is willing to participate and understand/sign the patient consent

b. Exclusion Criteria-

- Has intermittent, non daily pain
- Does not have at least one external ear
- The skin of the external ear is not intact or is infected.
- Have inconsistent vital signs (fluctuating, extremely low blood pressure, tachycardia, etc)
- Wear any type of implanted electrical device such as a brain shunt, vagal stimulator, pace maker, spinal pain pump, etc.
- Has a history of seizures
- Is pregnant
- Is unwilling to voluntarily participate
- Hemophilia
- Psoriasis vulgaris

The devices used for the percutaneous peripheral nerve field stimulation were Neuro-Stim System (NSS ©) manufactured by Key Electronics, Jeffersonville, IN. (Figure 1)

Figure 1. NSS as received from manufacturer

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The kit consists of the following:

1. EAD (External Auricular Device) which is an FDA cleared neuromodulating generator targeting acute and chronic pain with a frequency of 1-10 Hz, pulse width of 1 ms, Amplitude of 3,.2 v, Impulse of 100 mw, Interval of 2 sec, Length of stimulation of 120 hrs., Duty cycle of 2 hrs.on / 2 hrs. off.
2. A wire harness, which consists of three 4-pin arrays and one single pin ground wire connected by wire leads to a connector which attaches to the generator.
3. A transilluminater designed to help visualize and isolate targeted neurovascular bundles.
4. Tweezers
5. Steri-Strip© liquid adhesive to help adhere the electrode arrays and single pin ground wire to the skin to help assure proper energy transfer
6. A surgical marking pen
7. Oval bandages to help hold the arrays and ground pin in place
8. Tegaderm bandages to help affix the wires (if needed)
9. Alcohol pad to disinfect the skin at the implantation sites.

The EAD generator is cleared for a targeted population of acute and chronic pain. These devices are designed to stimulate the neurovascular bundles of peripheral branches of the cranial nerves found in the peri-auricular area (external ear) including the vagus (X), trigeminal (V) facial (VII), hypoglossal (XI) and occipital nerves and branches of the posterior auricular and superficial temporal arteries. (Figure 2)

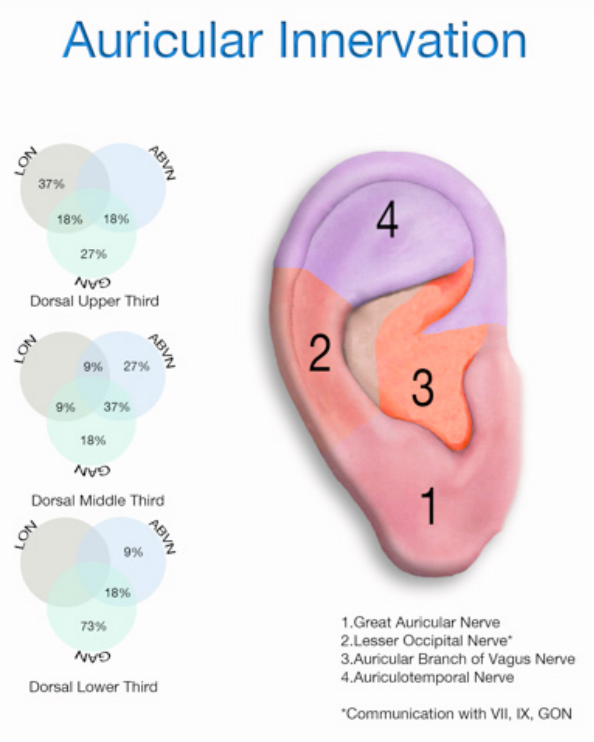

Figure 2. Cranial nerve distribution in ear

3. Procedure

Vital signs were recorded, and pre-treatment pain levels were self-reported by the patient and recorded using the VAS pain scale.

Patients were placed in a supine position, and observing sterile technique the peri-auricular area was cleansed with a 70% solution of isopropyl alcohol, and evaluated by IHS's (Innovative Health Solutions) patent pending technique of trans-illumination to visualize and isolate the neuro-vascular bundles associated with the terminal afferent branches of the targeted cranial neurovasccular bundles nerves. The targeted areas were marked with a provided surgical pen on the ventral and dorsal.

Steri-Strip© liquid adhesive was placed over the marked areas [1] The percutaneous electrodes were then implanted within one mm of the previously identified neuro-vascular bundles and secured with the provided oval bandages. The electrode harness was inserted into the solid-state integrated circuit generator. The generator with connected harness was attached behind the ear with the attached double-sided surgical tape by removing the tape backing and pressing firmly onto the skin for 15 seconds. (Figure 3)

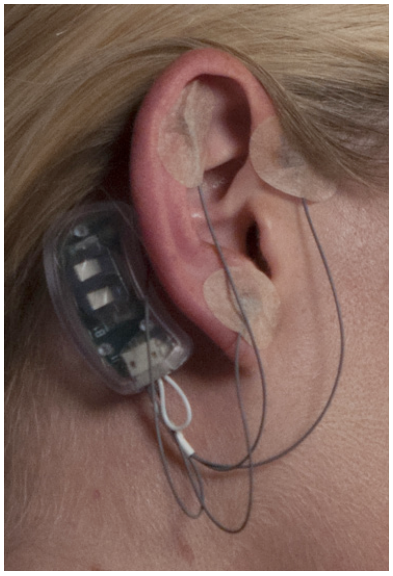

Figure 3. NSS in place on patient

The patients remained supine and were observed for an additional 30 minutes, being evaluated for any adverse reactions.

At the end of that time VAS scores were again collected and recorded as per protocol.

4. Report of Findings

Description of cohort:

- n = 20
- M = 6
- F = 14
- Average age 60.1

- Age range 29-81
- Average starting VAS 7.36
- Average ending VAS 2.65
- Average improvement in VAS: 4.71
- Average percentage improvement in VAS: 65%

5. Adverse Reactions

Potential overall risks/ discomforts involved are very minimal – Rare (event rate 1% - < 5%).

The risks/discomforts may involve:

- Discomfort upon insertion of the electrodes for < 5 minutes - Rare (event rate 1% - < 5%)
- Discomfort at the lead placement site > 5 minutes – none observed
- Bleeding at the electrode site if the neurovascular bundle is penetrated - Rare (none observed)
- Localized discomfort if the electrodes should become dislodged during the wearing of the device - Rare (none observed)
- Localized dermatitis - Rare (none observed)
- Drop in blood pressure - Rare (event rate 1% - < 5%)
- Syncope (fainting) - Rare (none observed)

Potential adverse effects to supporting personnel

Skin piercing with percutaneous needles - Rare (none observed)

Table 1

Ave. age	60.1		60.1	
	Pre	Post		
Total VAS	152	53	152	53
Cohort average initial VAS	7.6		7.6	
Cohort average final VAS	2.65		2.65	
cohort average VAS improvement	4.95		4.95	
cohort average % VAS improvement	65		65	
F>M 14/6				
F average initial VAS	7.92			
F average final VAS	2.78			
F average % improvement	64.89			
M average initial VAS	7.16			
M average final VAS	2.33			
M average % improvement	67.45			

6. Discussion

Woolf, Wallace, Clauw, Melzack, and many others have repeatedly demonstrated the association of chronic pain conditions with central sensitization, autonomic dysfunction, disturbances in serotonin function, decreases in endogenous opioid production, and persistent inflammation of microglia. In addition, neuropsychiatric dysfunction is a common comorbid presentation in these patients. In this complex and integrated milieu, we are left to evaluate subjective pain and function levels as a measure of our outcomes. Recognizing full well the significant impact of the factors above, and multiple others, upon the neuromatrix we have set out to measure changes in VAS scores subsequent to the placement of a series of percutaneous peripheral nerve field stimulators. [2-22]

The clinical application and efficacy of percutaneous electrical neural stimulation has been accepted throughout the physician community [23], has been verified for use in many acute and chronic pain conditions [24] and also been reported as an analgesic complementary therapy for the management of pain secondary to bony metastasis [25].

This procedure distinguished from manual acupuncture [21], electrical acupuncture and/ or TENS [26, 27] although the physiological results may be similar [28].

As opposed to acupuncture, the location of PENS needles is determined by neurological and vascular proximity rather than theories of energy flow or reflex points. [26, 29] Percutaneous electrical neural stimulation therefore provides in-direct stimulation to the nerves [30] via a battery-operated pulse generator which delivers current that can be varied in form, intensity, frequency, and is differentiated by " the use of fine needles inserted through the skin to stimulate peripheral sensory nerves" [31].

The reduction in symptoms of such systemic disorders such as fibromyalgia, knee pain, lower back pain, inflammation, edema/ ischemia are thought to be from the effect on the mid brain, endorphin production, and stimulation of spinal and peripheral inhibitory pain mechanisms via direct neurovascular stimulation and reduction of sympathetic fibers in the arterial walls. The NSS neurostimulation system allows for direct, physician applied, ambulatory, continual treatment.

The use of electrical stimulation has been indicated for reducing the need for analgesic drugs such as NSAIDS, and central acting Opioids [32]. This may also help alleviate the dependencies, addictions, and other common complications found with opioid use such as immunosupression, constipation, and hyperalgesia. [30, 33-35]

Reduction of pain and the reduced use of opioids may reduce the length of post operative hospital stays and therefore should be explored for reducing the chance of HAI's (hospital acquired infections) [30, 36].

Phillips, et al compared findings from a group of publications as did The University of Birmingham, Alabama and noted the following results with peripheral electrical neural stimulation [27, 37]:

1. A reduction in VAS and other pain scores compared to sham needle placement and placebo in tension, migraine, and post traumatic headache [38]
2. Decrease in frequency of Sciatica pain [39]
3. Decrease post herpetic and diabetic neuralgia [40]
3. A decrease in the use of oral analgesics (both opioid and non opioid)
4. An increase in physical activity
5. Improvement quality of sleep. [41, 42]

The NSS is the first device specifically designed to provide ambulatory, percutaneous neuromodulating nerve field stimulation in the peri-auricular area utilizing the technique and concept of visualizing and targeting auricular neurovascular bundles. The 120 hr treatment (in two hour cycles) helps provide neurovascular stimulation over a much extended time compared to other PENFS techniques.

All participants of the study reported use of prescribed central acting opioids (CAO) throughout their course of treatment and none reported satisfactory resolution of their pain. Long term efficacy of CAO in the control of chronic non- cancer pain is questionable and should be approached cautiously by both user and prescribers. FDA REMs guidelines have been established for evaluating the use of extended release and long acting opioids often used for the treatment of chronic pain. [43]

The patient population for this clinical report of findings was not controlled for any specific pain entity but rather was included into the study based upon the inclusion and exclusion criteria as outlined specifically daily, consistent pain. This population is very broad in scope and therefore does not further define efficacy of the NSS for a specific use. Since the EAD generator itself is FDA cleared for a targeted population of acute and chronic pain the clinical evidence in this ROF is therefore supportive of the FDA clearance.

Of further significance was the lack of any unacceptable clinical complications such as dermatitis, infections, bleeding at the site of implantation, drop in blood pressure, or syncope. None were reported at any of the three clinical sites. There was also no reports of injury (skin piercing) or otherwise of any of the participating clinicians. This presents a strong indication of clinical safety. The FDA clearance for the device has been placed in the “minimal risk” category and is further substantiated by this clinical report of findings.

7. Conclusions

Initial clinical report of findings at three independent sites indicate the use of Neuro-Stim System (NSS) peri-auricular percutaneous electrical nerve field stimulation - PENFS) appears to be an effective, minimal-risk, non-narcotic alternative for reducing chronic pain. While further double blind and long-term studies are needed the initial findings indicate a significant reduction in patient reported pain. Because of the efficacy and minimal risk, the Neuro-Stim System (peri-auricular PENFS) should considered the by clinicians as a non-narcotic adjunct for chronic pain control.

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