

CEFALY®: A NOVEL DRUG-FREE APPROACH TO MIGRAINE PAIN RELIEF: A REVIEW

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ABSTRACT

Migraine headache is a debilitating disorder that affects millions of people in the United States and worldwide. Migraine management encompasses specific and nonspecific migraine therapeutics, including non opioid and opioid analgesics, triptans, and ergotamine's. There are many reasons why people cannot use drugs to treat their migraines as they may have trouble tolerating them, want to avoid their side effects, are allergic to them, are non-compliant, pregnant, or have some underlying medical condition that might worsen. Cefaly® happens to be pioneering electrotherapeutic device for effective treatment of migraine and has acquired ISO certification for the same.

Key words: Analgesics, Migraine, Therapeutics.

INTRODUCTION

Migraine is a debilitating neurological syndrome which leads to altered perceptions, headaches and nausea. It has worldwide prevalence of >12% as a standalone disorder and 2-3% as secondary/indirect condition. The other features accompanied with migraine involve nausea (90% of patients), vomiting (one third of patients), photophobia, phonophobia, osmophobia and final resort to a dark corner or room. Headache may be associated with blurred vision, nasal blockage, pallor or sweating, diarrhea and polyuria. Facial involvement includes swelling of the scalp and face, tenderness, throbbing/pulsating vein or artery in the temporal region, tender and taut neck region. Impaired concentration and mood along with feeling of faintness may occur.¹

Migraine has a female predilection, the debilitating pain lasts from 4 to 72 hours and due to the complex nature of the condition a long term management is challenging.² The goals of the management includes symptomatic relief from the acute pain with rapid intervention, avoid recurrence, return to normalcy, extended attack free periods and reduced use of medication in future.³

Self medications for headache may lead to habitual chronic headache with a daily recurrence and in the same way lead to 'transformed migraine' due to long term usage of migraine medications.⁴

Implantable neurostimulators (the current generator device) and electrodes over the spinal cord, peripheral nerves and skin work on the principle that they generate electrical impulses which causes the depolarizing nerves to elicit action potential.⁵

Neuro-stimulation as non pharmacologic management for analgesia has been used since long at leading physiotherapy centres worldwide and application of transcutaneous electrical nerve stimulation (TENS) has been proved scientifically for the same.⁶

Cefaly® a simple-to-use device based on the similar principle has taken the challenge to relieve patients from migraine and headache sans medications.

BASIC CONCEPT FOR PERIPHERAL NERVE STIMULATION

For episodic and chronic migraine, peripheral nerve stimulation (PNS) has emerged as a boon for their prevention and recurrences. With the advent of implantable devices, sub- or percutaneous, electrical stimulation of peripheral nerves branches are affected. The other option is transcutaneous stimulation by superficial skin electrodes attached to external neurostimulators. Although only in the most disabled migraine patient, invasive percutaneous PNS like occipital nerve stimulation (ONS) was limited to.⁷ In 1965 the gate control theory of pain was introduced that supports the concept of activation of A β fibers. It happens by innocuous stimuli of vibration and position that activate inhibitory interneurons within the substantial gelatinosa and subsequently influence the wide dynamic range neuron where both the large and small pain fibers synapse.

When activated the gate closes and inhibits the cephalad conduction of pain. The concept of early large fibre recruitment inhibiting small fibre

conduction remains the basis of the theory of electrical stimulation and pain inhibition. Electrical stimulation of A β fibre afferents within peripheral nervous system inhibits transmission of A δ and C fibers. Ell rich and Lamp showed the ability of PNS to suppress the somatosensory evoked potentials, and subjective complaints of pain associated with noxious laser induced nociception. The much lower sensory threshold of A β fibers allows selective activation of those fibers in sensory nerves without excitation of A δ or C fibers. Their study of direct stimulation of the nerve has shown motivating evidence for antinociceptive effects of PNS which has provided impetus to future studies on peripheral neuromodulation of pain. Peripheral nerve field stimulation (PNFS), may be an effective option for local generation of paresthesia. Peripheral nerve field stimulation (PNFS) causes activation of terminal sensory nerve fibers without muscle activation as the subcutaneous adipose tissue insulates the superficial muscle. The dense subcutaneous layer with terminal A β fibers and direct peripheral nerve stimulation confirms that the presence of electrical field depolarizes that terminal sensory afferents.⁸

WHAT IS CEFALY®

Cefaly® is a device that neuro-stimulates the skull. Initially, the pain relieving cranial neuro-stimulation was only possible by complex, bulky and expensive equipment as the bones of the skull and the sinuses are very sensitive.(Figure:1) Cefaly® is an innovative, handy, modern yet simple light weight economical device that alleviates the sufferings of migraine patients leading to non-pharmacologic and non-dependent good quality of future life.⁶ Cefaly® is the first cranial analgesic electrotherapeutic device to acquire ISO medical certification proven effective on migraine pain with no side effects. Cefaly® is based on TENS technology which is known for its safety hence it is unique in comparison to other methods of headache and migraine pain management.⁹



Fig. 1: Device Cefaly®

CEFALY®- THE DEVICE

It is manufactured by STX-Med in Herstal, Liege, Belgium and is a small, portable, battery-powered, prescription appliance that resembles a plastic headband worn across the forehead over the ears. The device needs to be positioned in the center of the forehead, above the eyes using self-adhesive electrode. (Figure: 2) A low intensity electric current is delivered onto the forehead and underlying tissues that stimulates branches of trigeminal nerves associated with migraine headaches. (Figure: 3). Clinically the device has been studied upon for over five years in various university pain clinics and laboratories and has been developed conforming to stringent compliance with ISO and IEC standards applicable to medical devices/equipment.¹⁰



Fig. 2: Position the device in the center of the forehead, just above the eyes, using a self-adhesive electrode.

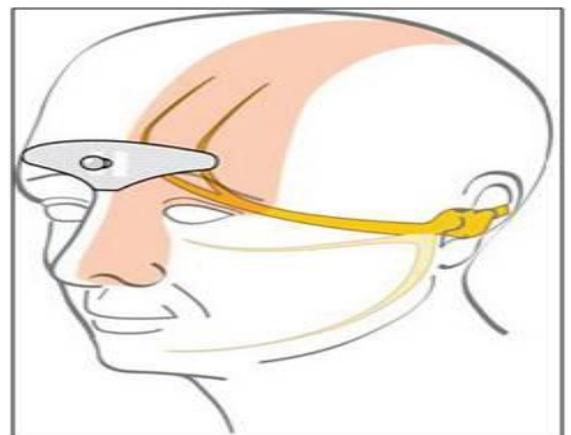


Fig. 3: The stimulation electrode placed on the forehead covers the supratrochlear and supraorbital nerves.

CEFALY® - Mechanism of action

Muscle and nerve cells respond well to electrical stimulus. Cefaly® specifically works upon the nerve cells and institutes painless electrical impulses on the specific nerves (branches of trigeminal nerve) that cause the migraine pain. The

trigeminal nerve carries information about touch, temperature, perception and pain from the face and scalp to the brainstem through an Endorphin-producing mechanism and the special design of the device caters to the bifurcation of trigeminal nerve hence acts on the crucial area of the aforementioned nerve. Cefaly® maintains a continuous flow between pain specific nerves and perfectly adapted electrical impulses it generates.

Cefaly® increases the production of endorphins and influx of touch sensitivity to the point that they do not leave any space for the influx of pain stimulus. Specific electrical impulses generated by this device stimulate the nerve fibers selectively and these impulses are imperceptible because they are generated slowly. The device has an electronic feedback mechanism that adjusts the electrical impulses i.e. it's customizable to one's comfort.¹⁰ Upon starting the device, the patient feels a tickling and tingling on the scalp and forehead, which indicates that the device is acting on the trigeminal nerve, the tingling becomes intense, and the entire forehead appears to be anaesthetized.

Various program settings are available for prevention and treatment of acute attacks:

1. **Treatment of Attack:** Program 1 is for acute episode to reduce the intensity of the pain in order to avoid taking medications. Irritation of sensitive intra-cranial structures above the tentorium cerebelli triggers pain across the surface of the anterior part of the head. It stimulates the sensitive A β nerve fibres in this region at high frequency and blocks the nociceptive fibres relieving the pain. The entire region of the first branch of the trigeminal (Willis ophthalmic nerve) nerve is thus subjected to the "gate control" mechanism. A powerful analgesic effect is obtained in the event of a migraine or tension headache. Cefaly® if used for 40 minutes blocks one in three attacks and reduces pain in 65% of cases.

2. **Prevention for Recurrence of Attack:** Program 2 program stimulates the A δ fibres which in turn at low frequency increases endorphin levels. The rise in endorphins reduces anxiety and stress, by altering trigger threshold for migraines and headaches, also reduces frequency of painful attacks. A session of 20 minutes is needed for a preventative effect. Patients have notice an improvement in 8 days.

3. **Anti-Stress Programme:** Anti-stress program requires two to three twenty-minute sessions per week.^{4,6} It produces general relaxation and a strong sense of well-being. Magis D et al assessed the patient's satisfaction and safety of this device on subjects who rented the device via Internet for 40 days, to assess transcutaneous supraorbital nerve stimulation tSNS in a large cohort of more than 2000

headache sufferers. The study concluded with remarks that transcutaneous supraorbital nerve stimulation (TSNS) is a safe and well-tolerated treatment that provides satisfaction to a majority of patients who tested it for 40 days.⁷

Schoenen J et al assessed the efficacy and safety of supraorbital transcutaneous neurostimulation (STNS) in migraine prophylaxis with the Cefaly® device in a multicentre, double-blind, randomized, sham-controlled trial. They concluded that STNS with the Cefaly® device is effective as a preventive therapy for migraine and the therapeutic gain (26%) is within the range of those reported for other preventive drug and non-drug anti-migraine treatments and the safety profile is excellent.¹¹

A clinical trial conducted in 5 Belgian university hospitals on 67 patients proved the efficacy of the Cefaly® compared to placebo for migraine prevention. At three months of treatment the 50% responder rate was significantly greater in the Cefaly® group (38, 1%) than in the placebo group (12, 1%). Seventy percents of patients declared they were satisfied or very satisfied with the Cefaly treatment. The drug consumption reduction is very impressive in the Cefaly® group (-37%) compared to the placebo group (+0.5%).⁶

REPLACEMENT OF ELECTRODES & BATTERIES

Replacement electrodes costs \$10 each and lasts for 20 uses. By storing in a zip pouch with alcohol-saturated cotton ball can increase up to 30 uses. Wiping the forehead with alcohol before applying the electrode prolongs the life of electrodes. Cefaly takes two AAA batteries. The batteries should be replaced once a month if the device is used for 20 minutes every day.

AVAILABILITY & PRICE

Cefaly device can be purchased at www.cefaly.us. The cost is US \$295 for the device. This price is comparable to the rest of the world, except from Costco Canada, where the device is US \$230 and six electrodes are \$33. Costco Canada does not ship to the U.S. and the company doesn't expect Costco to carry it in the U.S. Cefaly units with three program levels are for sale in Canada, Australia and Europe and patient don't need a prescription. The primary distributors will not send these devices to the U.S., but other websites might.¹²

INDICATIONS

Cefaly® is indicated for migraine with or without aura, stress and anxiety, tension headaches, cluster headaches, ophthalmic shingles, symptomatic frontal sinusitis, trigeminal neuralgia affecting Willis ophthalmic nerve.

CONTRAINDICATIONS

Cefaly® is contraindicated while driving, traumatic skull and facial injuries, allergies or rashes on forehead, Meniere's diseases and redness of the skin in the area around the electrode may persist for a few minutes after the session has ended.^{4,9}

CONCLUSION

Anti-migraine medications that are currently available are not well tolerated and are also moderately effective. Although the regular use of anti-migraine medications also contributes in the worsening of the disease and in the development in to chronic migraine. Cefaly® can be adopted as choice of treatment in migraine patients. The Cefaly® is an advanced, simple, light weight and comfortable device that offers non drug based and noninvasive treatment.

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