

CUMULATIVE RESEARCH DATA REPORT

ELECTROANALGESIC TREATMENT AND CHRONIC HEADACHE PAIN

MIGRAINE • CLUSTER • TENSION

342 Patient Summarization Report

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ABSTRACT:

342 patients presenting with primary chronic headache pain including severe migraine, cluster, tension, and post-traumatic syndrome were administered specific-parameter electrical current (electroceutical treatment) and reported 74% subjective pain relief. Electroceutical procedural treatment involved electrical fields from the Stimulatory Class and from the Multi-facilitory Class of electroceuticals as described by the Clinical Electromedical Research Academy (CERA). The clinical study also included comparisons of headache therapy, including the combination of pharmacological therapy with electroceutical treatment.

Keywords: chronic headache pain; electroceutical treatment; Stimulatory Class; Multi-facilitory Class; Clinical electromedical Research Academy (CERA)

INTRODUCTION:

The complaint of headache pain is heard daily by most all clinical practitioners, and much confusion exists as to its true etiology, pathophysiology, mechanisms, and best treatment.

Numerous theories of the etiology, mechanism, and treatment of headache remain controversial. Hypocrites wrote about migraine and its aura over 2400 years ago, and the controversy as to its being vascular or neurological remains unresolved. Treatment, therefore, has also remained ambiguous.

Management of the headache patient involves more than finding an effective medication: Indeed, as many of these disorders persist for years, preventing or aborting attacks is much more desirable over the long term. This summarized report represents a type-specific approach in headache management using bioelectric treatment, and is intended as a means of minimizing the need for potentially addicting pharmaceuticals.

Vascular headaches termed "migraine" have been classified as classic and common migraine, hemiplegic migraine, ophthalmoplegic migraine, cluster headaches, and toxic headaches among other terms. In essence, the differentiation between classic or common migraine depends on whether there is an aura phase in the headache.

The precise diagnosis of migraine must be confirmed by a meticulous history because the ensuing examination and laboratory confirmation is usually non-confirmatory. The main purpose of a complete neurological examination and laboratory radiologic studies is to reveal other organic pathology that resembles a migrainous headache. The diagnosis of migraine should never be made unless:

1. There have been 5 or 6 similar attacks
2. An attack lasts at least 4 hours
3. The headache is unilateral (hemicranial)
4. There are elicitable symptoms (not necessarily aura)
5. There is no organic pathology

Migraine attacks tend to occur two to four times a month and typically upon arising or in early morning. They rarely awaken the patient.

PROVOCATIVE FACTORS AND SUBSTANCES:

Migraine Headaches can be elicited, provoked, or aggravated by changes in the patient's environment such as menstruation, sexual activity, minor head trauma, emotional stress, and even weather changes. Medications and certain food substances also influence migraine. Alcoholic beverages, processed foods containing nitrates, MSG, hard cheeses, nuts, herring, chocolate, yogurt, and caffeine are all known to provoke migraine attack.

Cluster headaches, in contrast to classical migraine, occur primarily in males at a ratio of approximately 5:1. Onset is typically in the late twenties, but has reported in children as young as 1 year and persons as old as 70 years.

In its classic form, the headaches come in clusters, one or two per year, each lasting 2 to 3 months. Periodicity is the most striking characteristic of cluster headaches.

Cluster headaches have no aura, either visual or neurological, and no prodrome. The headache begins abruptly and builds up to a climax in 10 to 15 minutes. The typical cluster headache is unilateral, but it may change sides from one attack to another.

The pain is usually described as "excruciating" but unlike migraine, is rarely termed "throbbing." The pain usually lasts 45 minutes to 1 hour and often the patient will report that the eyeball feels as if it's being pushed out of its socket. Typically the pain pattern affects the 1st and 2nd branch of the trigeminal nerve.

For a specific diagnosis of classic cluster headache the episodes (1) must occur for periods lasting 7 days to 1 year, and (2) be separated by pain-free periods of time lasting 14 days or more. It should also be noted that approximately 80% of all patients are heavy smokers and have a history of excessive use of alcohol. Typically, cluster headache patients are described as ambitious, proficient, goal-oriented, compulsive, but insecure in personality. This A-type personality together with the potential for substance abuse and medication addition (ergotamine, analgesics, etc.) makes treatment normally difficult.

Areas of ischemia of the involved supraorbital area, depicted by thermograph have been reported and assumed to be pathognomonic of cluster headaches. The fact that cluster headaches can be precipitated by the ingestion of alcohol, histamine, and nitroglycerin – all vasodilators, implies vasodilation as the etiological basis of this headache. An increase in temporal artery pulsation is associated with cluster headache, indicating an increase in extracranial blood flow following the onset of pain. This suggests a primary neurological rather than a primary vascular etiology.

Tension headache is defined as an ache or sensation of tightness, pressure, or constriction, widely varied in intensity, frequency, and duration: long-lasting, and commonly suboccipital, associated with sustained contraction of skeletal muscles, usually as a part of the individual's reaction to "life-stress."

When tension headaches are combined with a vascular type of headache they are termed "combined headaches," which are essentially "combinations of vascular headache of the migraine type and muscle contraction headache," both prominently coexisting in an attack.

TREATMENT PRINCIPLE:

The mechanisms of action and clinical application of electroceutical treatment of headache pain are reviewed. The proper use of clinical electroceutical medicine (specific-parameters of electrical current) directs the clinician to choose the best "electroceutical class" pursuant to the bio-physiological effects desired based upon differential diagnosis. At present, research conducted by the Clinical Electromedical Research Academy (CERA) has created two specific electroceutical classifications:

Stimulatory Class: "Bio-physiological effects induced by repeated synchronous action potentials in excitable cells - membrane depolarization and repolarization activity."

Multi-facilitory Class: "Bio-physiological effects induced *without* action potentials – effects are achieved via multiple mechanisms of action."

Mechanisms of Multi-facilitory (Mf) Effects:

- Cellular Oscillo/Torsional Response
- Sustained Reactive Depolarization
- Second-Messenger Formation
- Imitation of Hormone/Ligand Activity

The electroceutical treatment is administered via specially designed anatomical electrodes. Mild, controlled electric pulses are introduced within the patient's comfort range and specific parameters allow either topical or endogenous treatment.

With electroceutical treatment, five mechanisms of action have been identified in the mitigation or resolution of headache pain: From the *Stimulatory Class (St)*, two (2) mechanisms are known and from the *Multi-facilitory Class (Mf)*, three (3) mechanisms are currently known:

1. (St) - Counter-irritation via sensory nerve fiber stimulation which interferes with local pain perception in the CNS.
2. (St) - Bioactive neuropeptide release; cell receptor uptake of endorphin, enkephalin, etc. inhibits pain impulses in the CNS.
3. (Mf) - The cellular oscillo/torsional response balances metabolite (pain and inflammation mediators) concentration differences - pH normalization.
4. (Mf) - Second-messenger formation (cyclic AMP) directs cell-specific activity toward membrane repair - inhibiting arachidonic acid and subsequent prostaglandin (pain mediator) cascade.
5. (Mf) - Application of specific exogenous Mf stimulus, which falls within the absolute refractory period of the cell membrane, induces sustained reactive depolarization across multiple nodes of Ranvier (neuron blockade = vasoconstriction).

MATERIALS AND METHODS:

The summarization study consisted of patients visiting one of six participating clinics. Patients were invited to participate in the study provided they had previously undergone conventional therapy without significant pain relief and were willing to discontinue pharmacological agents during the trial period of thirty (30) days.

Pharmacological agents included; ergotamines and related alkaloids, acetaminophen, isometheptene mucate (Midrin), aspirin, NSAIDs, phenothiazines, anti-depressants, etc.

During the thirty day clinical trial period, fourteen (14) specific-parameter bioelectric treatments were administered from a special, programmed electroceutical medical device. Electroceutical treatment parameters providing specific, desired physiological effects for headache pain management were selected by the research advisors and member clinicians of the Clinical Electromedical Research Academy (CERA).

After receiving appropriate informed consent, patients all initially received treatment daily for the first week, then three (3) times weekly for the next three (3) weeks for a total of fourteen (14) treatments.

The effectiveness of each treatment was quantified using the 10cm visual analog scale marked at one end with “no-pain” and the other end with “worst possible pain.” Patients were instructed to mark their appropriate pain level 15-minutes prior to treatment and 15-minutes following treatment. Using special headache electrodes, the areas most affected by pain were treated, i.e. occipital joint, high nape of neck, frontal, temporal, and myofascial. Percentage of pain relief in duration of hours was also calculated.

RESULTS:

Of the original 350 patients, 342 completed the trial period and 8 patients were eliminated due to non-compliance. 254 (74%) of the patients reported significant improvement or no subjective headache pain, including no daily reoccurrence of migraine or cluster-type headache pain after the initial week of daily treatment. 52 (15%) of the patients reported only minimal mitigation of headache pain. 33 (10%) of the patients reported no subjective improvement and 3 (1%) of the patients reported an increase in headache pain or a movement of pain sensation to another anatomical area, which was described (at least) as severe as the original pain.

At the end of the trial period, patients without “significant” improvement were told to resume their previous pharmacological treatment in combination with bioelectric treatment for five (5) to ten (10) additional treatments administered daily.

Treatment success percentage (significant relief or no pain) increased to 93%. Interestingly, this high percentage of treatment success continued at 93% even at a 50% reduction in pharmacological agent dosage.

SUMMARY:

We have discussed the application of specific-parameter electric pulses (electroceutical medicine) for the treatment of acute and chronic headache pain. Although there is still much to research in this area, it is presumed that these successful results were obtained by influencing the levels of neuro-modulators (endorphin, dynorphin, enkephalin, etc.) and of second-messenger formation (cyclic AMP), which probably normalized inter-cellular response and communication. Each patient received specific electric impulses from both classifications of electroceuticals - *Stimulatory Class and Multi-facilitory Class*, automatically alternated by the electroceutical medical device. The alternation of treatment seems to normalize the proper balance between vascular vasodilatation and vasoconstriction.

Although significant, acceptable results were achieved without oral medication, it is our opinion that a combination (matrix-approach) of specific bioelectric pulses administered with the proper pharmacological agents (even at substantially lower and less toxic dosage) would provide optimum treatment results.

No adverse reactions were noted with any of the patients during the initial treatment trial period with electroceutical energy only. It was also noted that the normally occurring side effects of pharmacological treatment appeared to be reduced when combined with electroceutical treatment.

We believe that there is enough evidence to encourage the use of specific-parameter, automatically alternated electroceutical medicine) alone or the combination (matrix-approach) of electroceutical energy and specific pharmaceuticals (at lowered, less toxic dosage) in the mitigation or resolution of headache pain and concomitant symptoms. Finally, we believe that these approaches have placed us on the threshold of discovery; it is time to apply our growing knowledge in all clinical settings.

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