ELECTROCEUTICAL NEURON BLOCKADE

640 Patient Multi-Geographic Comparative Study

Richard Sorgnard, Ph.D. Pain Management
Leland Patterson, M.D., Neurology
Robert Schwartz, M.D., Physical Medicine
Michael Robertson, M.D., Anesthesiology
Samuel Goodloe, M.D., Anesthesiology
Simon Trueblood, M.D., Anesthesiology

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INTRODUCTION

Electroceutical neuron blockade is the procedure used to block the somatic or sympathetic nerve fibers. It is achieved by applying controlled-parameter electrical pulses via specifically designed electrodes placed on the skin. Electroceutical neuron blockade (ENB) can occur with a direct monophasic current (DC) to achieve cell membrane hyperpolarization (anodal block), a pure unmodulated medium frequency (Mf) to achieve sustained depolarization of the cell membrane, or a stimulatory class effect, interferential current (If) to achieve neuron function fatigue. The physics and theoretical framework underlying the different electrical currents used in the procedures will be reviewed.

Methods of measuring the extent of sympathetic blockade as well as clinical trials and patient observations using unmodulated medium frequency (Mf) to achieve electroceutical neuron blockade are also presented. Cumulative data from multiple study projects have shown that of the patients who underwent a series of electroceutical nerve blocks, 79% of them reported subjective relief from sympathetically-mediated pain after completing the treatment series.

DISCUSSION

The basic explanation of bioelectric physiology and the mechanism of action is the strength duration curve and its relation to the strength of an electrical pulse and the length of time it must be applied to tissue to produce a response. The strength duration curve shifts as a nerve becomes more or less excitable demonstrating that the more stable the nerve membrane is, the greater the stimulus required to depolarize it.

The affected nerve fiber and application of the electrical impulse determine the strength duration curve. There are required parameters that are reliant on the traits of the nerve fiber for an electrical pulse to be selectively applied to the specific type of nerve fiber. Electrical pulse considerations include pulse width, inter-pulse interval, frequency, current (or voltage), and waveform configuration. (The size, shape, and placement of specific electrodes, dosage, and impedance also are factors that affect the pulse).

Pulse charge is defined as the amount of electrical energy transferred to the tissue with each pulse phase. When pulse intensity and rate are constant, increased pulse duration will result in increased pulse charge and average current. Increasing the pulse duration recruits smaller diameter nerve fibers while not changing the depth of penetration. With constant pulse duration and rate, increased intensity (dosage) is associated with deeper penetration and recruitment of new and deeper nerve fibers.

DIRECT CURRENT - ANODAL BLOCK

If a direct-current monophasic waveform (DC) is utilized instead of a biphasic wave, it is possible to establish anelectrontonic potential outside the nerve fiber membrane to decrease nerve excitability. The result is an anodal blocking capability of that waveform.

Since electrode size, depth of penetration, and tissue impedance affect current (power) density, the smaller the electrode, the greater the density of current concentration at the electrode site. Current (power) density is less with larger distances between electrodes although penetration depth is greater. If larger inter-electrode distances are utilized, greater tissue impedance is experienced requiring a greater potential difference between electrodes to achieve an effective therapeutic current (power) density.

Using a small electrode at the anode and a much larger cathode increases the current (power) density under the anode. The radical size difference of the cathode causes the field from the anode to fan out in one place (e.g. perpendicular to it) rather than in planes of another direction.

Placing electrodes on opposing surfaces of the body with the anode over the sympathetic ganglia will affect the sympathetic chain. Electrode placement is important to assure that the concentration of the current is strong enough to influence the chain.

The amount of electrical current delivered to the nerve fiber determines the strength of the neuron blockade. In order for the pulse to cross through large impedance, a large potential difference is necessary. To accomplish the block without painful sensation during current flow, the duration of single stimuli is limited to less than 200 microseconds. This provides 50 to 100 times the duration of the pulse width during the interval between pulses when a frequency of 30-40 pulses per second (pps) is applied.

The physics of waveform morphology and electrical pulse density place restrictions on the pulse parameters. The electrical stimulus response relationship represented by the strength duration curve can be used to achieve anodal block without painful stimulus. If the sympathetic and C fibers are selectively influenced, then additional restrictions are placed on the pulse parameter. Nerve characteristics are no myelination, slower conduction, higher threshold, longer refractory period, and longer chronaxie values.

By studying the nerve characteristics and the strength duration curves, sympathetic, unmyelinated small-diameter C fibers can be selectively recruited by ascertaining pulses of relatively large amplitude, low frequency, and long duration; and adjusting parameters to a rate of about 30-40 pps, a pulse width of 100-200 microseconds, and typically higher amplitudes.

SUSTAINED DEPOLARIZATION-MEDIUM FREQUENCY (Mf) BLOCK

The undesired painful sensation normally associated with a direct current anodal block (previously described can be avoided while producing similar, desired therapeutic effects by utilizing the newer bio-electric technology: medium frequencies. Pure unmodulated medium frequency current is available in deeper tissues by crossing two identical pure sinusoidal medium-frequency currents with specific phase orientation. This results in a new current of summated therapeutic intensity, designated *Medium frequency-Depth (MfD)*, which can be unidirectionally directed into deeper tissue structures. Electrode size and placement assure proper penetration depth as a result of the lower skin impedance to MfD electroceutical impulses. An effective neuron block can occur through sustained depolarization of the cell membrane when a continuous refractory state is achieved (Wedensky inhibition).

To illustrate, skin and tissue layers act as capacitors. As the frequency decreases, the impedance of the capacitor increases. Since MfD, with its higher electrical pulse rate requires less energy to overcome the outer skin and tissue barriers, more bioelectric energy is available for deeper tissues.

When electrodes are placed on opposing surfaces of the body a vector of current is established assuring penetration depth. If an action potential arises, then the therapeutic current (power) density is adequate, proving the "all or nothing," law of excitation. Therefore, placing a smaller electrode over the affected sympathetic ganglia with a larger electrode placed on the opposing body surface increases the current (power) density at the ganglia where the block is desired.

The principals of cathodal closure (anelectrotonic inhibition) and anodal opening (catelectrotonic stimulation) state that pulsed currents with pulse rates up to approximately 100 pps stimulate. The frequency of a current can lead to occasional cathodal closure tetanus when it becomes high enough to fall within the absolute refractory period of the nerve. With MfD electroceutical application, all energy delivered falls within the absolute refractory period of the cell membrane. With proper dosage, this leads to the disappearance of all excitation and a continuous refractory state known at Wedensky inhibition.

NEURON FUNCTION FATIGUE

Static-field interferential treatment (If) was clinically introduced as a means of applying bioelectric energy of varied therapeutic pulse rates to human tissue. Two different pure unmodulated currents of medium frequencies were crossed to produce electrical interference. Thus, a new frequency of summated therapeutic dosage was created at any point within the body where these two currents (waves) joined or crossed each other. The pulse rate of the resulting wave equaled the difference between the crossing waves, e.g. 100 pps. The ability to control and move this static interference field was discovered and clinically proven by A. Hansjürgens, Ph.D. in the 1960's. Termed: dynamic interference current (If).

With this advanced technology, the frequencies of the two currents may now differ as much as 200 pps, and with dynamic interferential current (If), the higher middle-frequency permits lowered skin impedance to the current while at the same time the deeper tissues experience a lower pulse rate (0-200 pps) range. If the generating electrode of the current is varied, along with a crisscrossing of currents, a vector is obtained so as to ensure proper therapeutic dosage within the superposition of the fields.

The lower pulse rates achieved via dynamic interference fall outside of the absolute refractory period of the nerve. Therefore, action potentials are generated synchronous to the properly-dosed electromedical pulses. At specific pulse rates (above 30 pps), the repeated production of stimuli produces a loss of accommodation (neurotransmitter depletion) resulting in an eventual fatiguing effect on the nerve fiber.

METHODS OF MEASUREMENT

There are at least three major categories of independent tests that can be used to determine the presence of sympathetic blockade: tests of sympathetic function, blood flow, and pain. Within these three categories, there are at least 23 different studies that can be used. One of the oldest and most commonly used is the skin conductance response (SCR) test (also called impedance plethysmography [IPG] and rheography). This was previously called the sympatho-galvanic response test. The principle behind this test is the concept that a change in sympathetic activity is followed by a change in skin conductance that can be recorded with a simple electrocardiograph. Other common independent methods used today to assess sympathetic activity include thermography and pain score tests.

Before sympathetic blockade, skin blood flow is similar in contralateral limbs, and both limbs show a reduction in the height of the pulse wave in response to an ice challenge test. After sympathetic blockade, however, the affected limb shows a marked increase in the slope of the upward deflection of the pulse wave and an increase in height of the pulse wave. The blocked limb shows no change in response to an ice challenge test. IPG studies have also demonstrated that the recorded response to direct mechanical stimulation is attenuated after surgical section of unmyelinated sympathetic fibers.

Pain score tests are other readily available independent tests that can be used to assess the presence of a sympathetic block. Visual analog scales (a pain score test), for example, have been used to document the efficacy of electric sympathetic blocks. Published reports of studies using pain score tests have shown electroceutical neuron blockade to be effective in relieving sympathetically mediated pain for up to two years after the block, but more commonly for up to approximately 46 weeks.

MATERIALS AND METHODS (SUMMARIZATION)

An electroceutical neuron blockade device with MfD treatment current of 4000 pps to 20,000 pps and 8000 to 40,000 polarity reversals per second was utilized in clinical observation studies conducted to measure the efficacy of the medical device to achieve electrosympathetic analgesia. To assist in creating an average patient profile, summarized clinical observation data from diverse practices in different geographical locations was included: Pennsylvania, California, South Carolina, Florida, Nevada, and Texas. Six-hundred and forty (640) patients between 18 and 84 years of age presenting sympathetically-mediated, unresolved pain and/or edema with an average duration of two or more years were treated via the described electroceutical neuron blockade procedure. Diagnostic categories included pain after neck/back surgery, pre-surgery herniated discopathy, radioculopathy, vascular headache, Herpes Zoster neuralgia, and sympathetic dysfunction syndromes (i.e. Reflex Sympathetic Dystrophy, Raynauds, et cetera).

Before the electroceutical block procedure, all patients had failed to show a satisfactory response to surgical or non surgical interventions, including therapeutic exercise, manipulative technique, oral medication, trigger point injection, facet block, or epidural steroid injection. Physical examinations, medical histories, and diagnostic testing as necessary (electromyography, thermography, CAT scanning, myelography, magnetic resonance image testing, Minnesota Multiphasic Personality Inventory) were performed on patients involved in the studies. The procedure was explained to all patients and informed consent was obtained prior to the first treatment. To confirm the effectiveness of the sympathetic block, pain score scales (0-10) were used.

Electroceutical neuron blockade with a reported average success rate of 79% is compared to other invasive blockade procedures: Chemical block, Bier block, and Sympathectomy for severe intractable pain. Literature review analysis has shown average patient success percentages to be as follows:

- **Chemical block: 72% - 81%**
- **Bier block: 64% - 76%**
- **Sympathectomy: 74% - 87%**

It should be noted that the *surgical* procedures all carry technical complication capability (often requiring a recovery room setting) along with many possible undesired side effects, i.e., somatic paralysis, allergic reaction, vessel puncture, infection, etc.

There were no undesired or noted side effects reported with the electroceutical procedure except some slight superficial electrical burns under the small electrode in approximately 1% - 2% of the patients. It was found later that some of the cases with the slight electrical (power density) burns were attributed to a default in one of the clinic's electrical service (non-dedicated line).

The MfD bioelectric dosage utilized was the highest amperage "comfortably" tolerated by each patient during the 20-minute treatment. A small electrode was placed over the ganglia or nerve to which treatment was directed, and a second larger electrode placed on the opposing body surface.

Patients with an average of 25% subjective improvement from a trial block were then eligible for a therapeutic course (series) of treatments. After each treatment, the percentage of overall relief obtained was recorded. Pain score tests were repeated before the following day's treatment to assess the percentage of long-term relief obtained in comparison to baseline pain.

Seventy percent (70%) of the patients reported a 25% improvement after the trial block and were started on a follow-up series of treatments. Patient treatments were initially administered daily for at least the first week; and then, dependent upon results assessment and patient capability, were continued daily-to-three times weekly until resolution or response plateau. The total number of treatments given to each patient ranged from 2 to 42, but the average number of necessary treatments was 5. Overall, data summarization revealed that 79% of the patients who underwent the electroceutical neuron blockade procedure reported substantial improvement after the treatment series and en follow-up.

NOTE: Under normal vascular condition, no measurable changes in the sphygmoplethsmographic curve are typically seen during electroceutical sympathetic ganglion blockade. Conversely, if vascular lesions are present with defective circulation and loss of elasticity, a considerable improvement in the pulse volume and contractility will be detected.

CONCLUSION

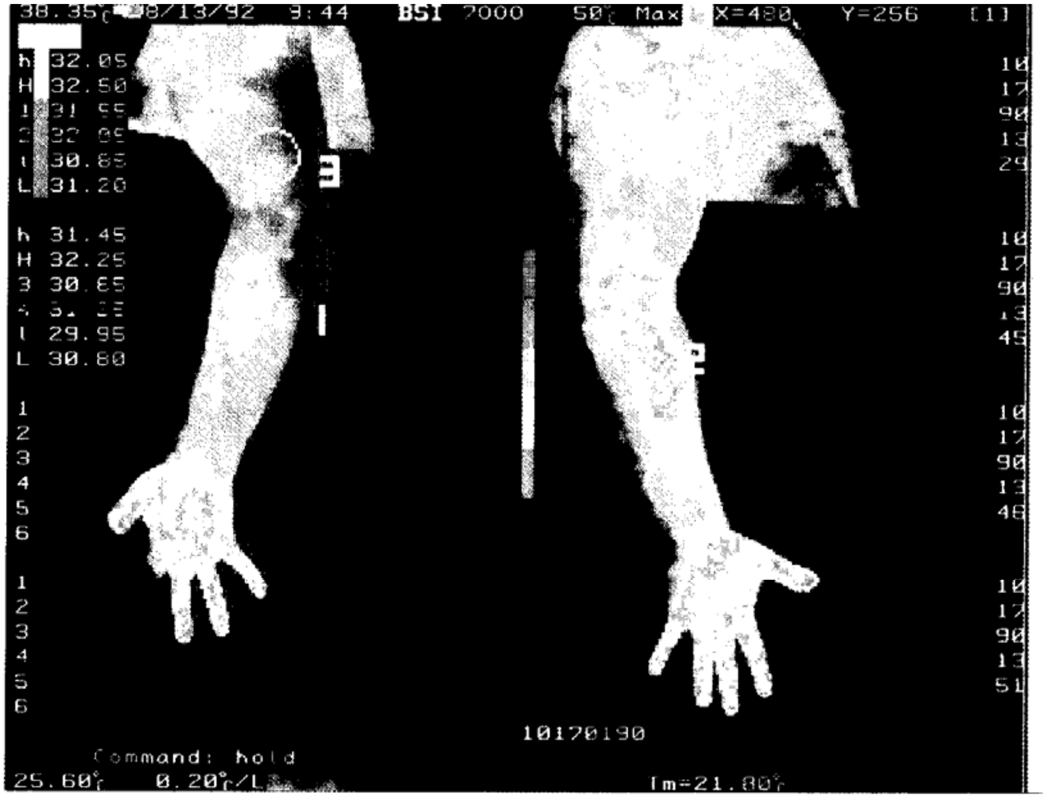
The physics behind electroceutical neuron blockade with direct current (DC), medium frequency (MfD) electroceutical parameters and dynamic interferential currents (If) have been reviewed.

In summary a direct current (DC) anodal neuron block occurs by producing sustained hyperpolarization of the cell membrane. Effective neuron blockade is achieved via medium frequency (MfD) by sustained depolarization of the cell membrane. Dynamic interferential current (If) neuron blockade occurs indirectly due to the neuron function fatigue principle.

Application of MfD electroceutical energy with a smaller electrode over the nerve or sympathetic ganglion to which treatment is directed and a larger electrode over the opposing body surface is a reliable method of achieving an electroceutical neuron block. Persistent sympathetically-mediated pain and edema relief can be achieved in approximately 79% of those who receive the treatment series.

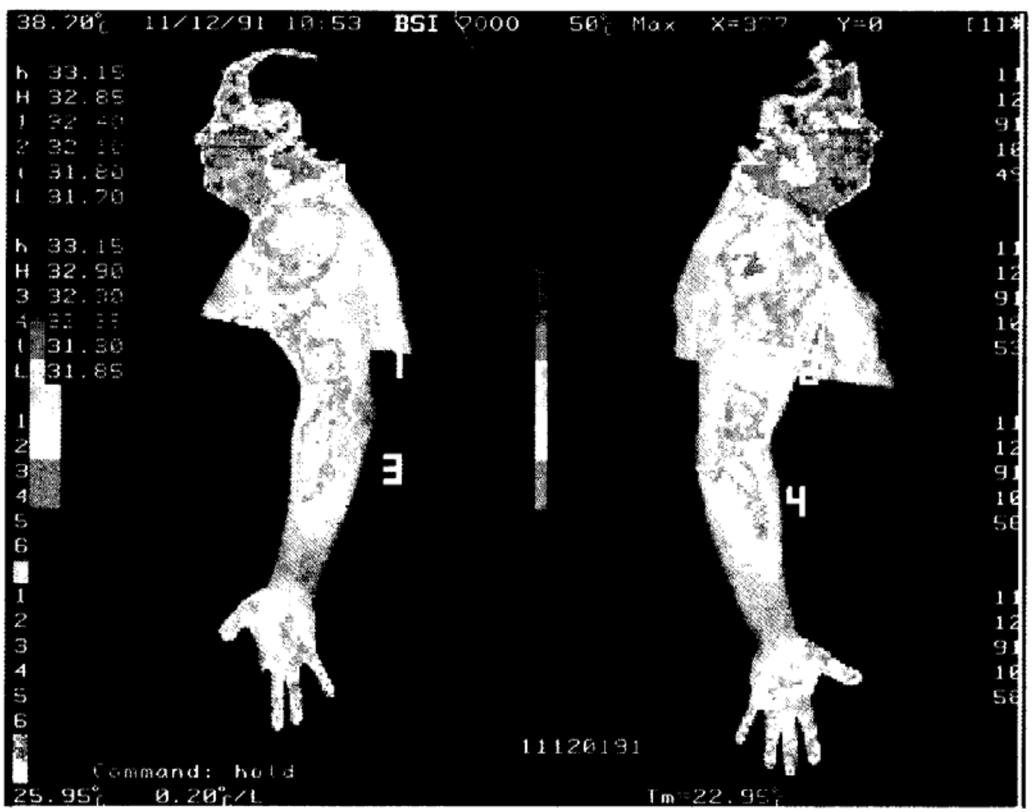
In addition to pain relief, other improvements were also noted. These include increased active movements of extremities, restoring sensory function of affected extremities, improved sleep, relief from muscle spasms, and overall improved health, mental status, and quality of life.

Our summarized data from geographically different patient studies suggests that electroceutical neuron blockade treatments are an effective modality for eliminating permanent partial disability, and enhancing quality of life and well being. **Compared with other methods of invasive treatments, the electroceutical neuron blockade has minimal adverse reaction, good compliance, and low cost characteristics that make it a valuable treatment approach.**



Prior to treatment, thermographic imaging indicates vascular abnormality due to temperature measurement differences. Following a series of 15 clinical bioelectric treatments, patient presented with normalized vasculature, balanced normal temperature measurement, and was clinically asymptomatic including the previous complaints of intermittent severe burning pain.

Follow-up at 9 months (at our request), patient underwent another thermography- results clearly show that vasculature and temperature regulation is still well within the normal range



EXAMPLES

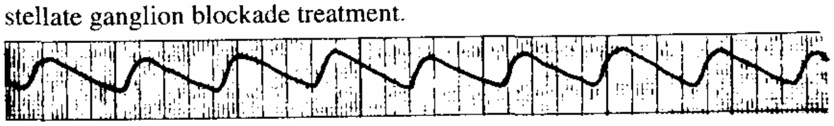
With a small electrode placed anatomically over the stellate ganglion, dosage was increased to "comfortable" patient tolerance (note: dosage was so adjusted that, through stimulation of the neighboring cervical plexus the scapula is raised and a slight turning of the head to the ipsilateral [stimulated] side occurs in the patient). At the same time, a photoelectric cell was attached to a finger of the same arm to record the sphygmoplethsmographic curve. In order to avoid fluctuations due to pressure, a pressure regulator was used to guarantee constant uniform pressure (approximately 50-l00g as described) between the receptor cell and distal phalanx of the finger, the control and observation of the volume curve performed by means of a photo-electric oscillographic monitor with simultaneous recording of the plethysmograhic curve by electrocardiograph.

Under normal vascular conditions no measurable changes in the sphygmoplethsmographic curve are typically seen during non-invasive ganglion blockade. Conversely, if vascular lesions are present with defective circulation and loss of elasticity, a considerable improvement in the pulse volume and contractility can be detected.

Example with six (6) curves recorded from the index finger of the left hand of a patient with Raynaud's disease (heavy smoker).

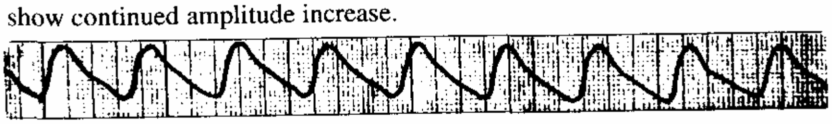
CURVE - 1 illustrates the shape of the uninfluenced basic curve with relatively low amplitude and no catacrotic/dicrotic peaks (defective elasticity)

CURVE - 2 illustrates only slight change after 1 minute ofnon-invasive stellate ganglion blockade treatment.



CURVE -3 illustrates continued increase in amplitude and suggestion of a dicroticism.

CURVE - 4 and CURVE - 5 after 6 and 7 minutes treatment respectively show continued amplitude increase.



CURVE - 6 after 8 minutes of treatment an improvement in circulation and elasticity has occurred which, in comparison to CURVE - 1 is absolutely unmistakable.

PROTOCOL SUGGESTIONS
Electroceutical Neuron Blockade Procedure

- Small electrode directly over nerve or ganglion to be blocked and large electrode on opposing body surface facilitating therapeutic dosage through target area.

- Electroceutical procedure frequency rate must be faster than the action potential production capability (within the absolute refractory period of the cell membrane), i.e. MfD at 4000 pulses per second (pps). Note: If neuron function fatigue effects are desired, use an electroceutical treatment frequency rate around 100 pps, i.e. interferential current (If) with proper frequency rate setting.

- Proper dosage and treatment procedures are not rigid in all cases, but are to be adjusted to the individual responsiveness of the patient. Dosage should be a high "comfortable" tolerance threshold, which may require a dosage increase during the procedure. The patient should never experience a stinging or burning sensation and should show no extreme muscular contraction. The dosage should be reduced for patients who are sensitive to electric sensations and prolonging treatment time can compensate this (under certain circumstances).

- In most cases, the clinical response to electroceutical blockade (after each treatment) is subtler than those normally accompanying chemical blockades. It must be noted, however, that there appears to be cumulative positive effects with subsequent electroceutical blocks versus an "accommodation" to subsequent chemical blocks. Overall patient success rates are nearly identical.

- For optimum response, electroceutical neuron blockade procedures should be performed 20-30 minutes daily for the first 5 days. If continued blockade treatment is advised, treatment may be altered to 3 times a week. Also, more conservative electromedical treatments for pain management may be performed alternately with the electroceutical blockade procedures

- Average treatment regime duration to asymptomatic patient discharge was 12-20 treatments, which included the electroceutical neuron block procedures and alternated electromedical treatments. In difficult, unresponsive cases, additional combined minimal pharmacotherapy was included.

- Electroceutical blockade procedures to larger (of deeper) nerves and ganglions require more caution while setting proper dosage levels as the required current (power) density could potentially create a superficial electrical burn. This can be avoided by using a small vacuum-type electrode over the target area. The vacuum pressure draws additional fluid to the target area (under the electrode) allowing better electric current distribution and penetration. If a small vacuum electrode is unavailable, use the next size larger electrode or lower the therapeutic dosage and lengthen the treatment time.

ELECTROCEUTICAL NEURON BLOCKADE SECONDARY TO FUNCTION FATIGUE

- Action potentials are generated synchronous to properly dosed electric impulses. By utilizing Stimulatory Class (St) treatment pulse rates above 30 pps and lower than 150 pps, nerve fatigue will occur after approximately 8 minutes of constant stimulation. Neuron function fatigue is accomplished by depleting normal, appropriate levels of synaptic neuro-transmitter substances (norepinephrine).

- Treatments should be performed daily to 3 times weekly with patient dosage setting generally lower than those used for the MfD electroceutical nerve blocks (previously described). Lower pulse rate function fatigue treatment is slightly less comfortable for the patient, especially at higher dosages. Treatment time should be kept at 15-20 minutes to avoid over-stimulation and possible post-treatment soreness (lactic acid).

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