

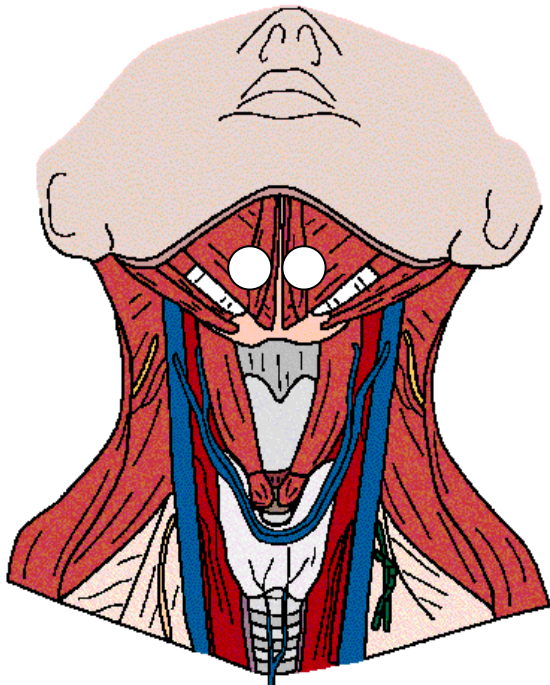


The Biber Protocol ®

POLICIES AND PROCEDURES

NMES ELECTRODE PLACEMENT

- Submental region – stimulating the suprahyoid muscles.
- Bipolar placement above the hyoid beneath the mandible on anterior digastric muscles with overlapping margins to mylohyoid.
- The electrodes should **NEVER** touch.



Neuromuscular Electrical Stimulation for Dysphagia: Indications, Contraindications and Precautions

Indications:

Patients, both pediatric and adult, with pharyngeal dysphagia, are eligible for neuromuscular electrical stimulation (NMES)

This treatment is most appropriate but not limited to patients with dysphagia as a result of stroke, post radiation/chemo treatment, neuromuscular disease, head injury and head and neck surgery.

Neuromuscular Electrical Stimulation is used for the purpose of muscle re-education, increasing ROM and retarding disuse atrophy of the muscles of the swallowing process.

Contraindications:

Never use NMES on a patient with a defibrillator.

Cautions:

Patients with a pacemaker will undergo interrogation testing by the pacemaker representative to determine if interference with pacemaker function exists. Cardiologist will be contacted for verbal approval.

Any patient who is unable to demonstrate ability to express pain or discomfort i.e. verbal, non-verbal, gestural, eye contact, facial grimacing, torquing of body etc. will not be able to participate.

Patients with a seizure disorder may participate if seizures are controlled by medication. It is advisable to speak with the neurologist before proceeding.

Neuromuscular Electrical Stimulation for Dysphagia: Indications, Contraindications and Precautions cont.

Any metal implants located in proximity to electrode placement should not cause adverse effects however the patient may experience some sensation in the area. If so, the patient will decide to continue or terminate treatment.

Any patient with any other implanted electronic devices such as cochlear implants, vagal nerve stimulation, deep brain stimulation etc may not be a candidate and the implanting surgeon should be contacted to discuss possible interference issues.

Precautions:

Isolated cases of skin rash or hypersensitivity may occur at the site of electrode placement and may be reduced through the use of application of emollient.

Sensitivity to tape may be observed and can be reduced by using hypoallergenic tape or a cloth headband.

Patients with sensory nerve damage or overall reduced sensory awareness should be monitored carefully and amplitude should be kept at lowest levels possible providing physiological responses are optimal. Skill and caution should be utilized when dealing with patients with sensory integration issues.

Techniques and knowledge commonly used in treating this disorder should be applied. The use of sub-sensory levels with gradual increase in amplitude over time may be appropriate but not without careful attention to potential adverse effects.

Uniformity of conductivity should be monitored at all times for all patients to avoid skin irritation.

NMES Procedure:

- ▶ Clean area of electrode site with water if needed, apply prep pad if you choose
- ▶ Place tape over electrodes while electrodes are still on plastic
- ▶ Apply electrodes to patient using tape
- ▶ Electrodes should be close together but never touching.
- ▶ Placement is directly under the chin, in the fleshy area, not on the mandible and not on the neck.
- ▶ The electrode leads (the cords that connect to the machine) should be pointing down towards the neck
- ▶ Place a cloth headband on to secure electrodes
- ▶ Connect the electrodes to the device.
- ▶ Turn the device on.
- ▶ Using the toggle switch, very slowly, increase the amplitude.
- ▶ Ask the patient to tell you when they first feel the sensation
- ▶ Once the patient has acknowledged the sensation explain that you will continue to increase the amplitude until it is "strong but comfortable"
- ▶ Continue to increase the amplitude very slowly
- ▶ Stop increasing the amplitude when patient notifies you or if you note discomfort
- ▶ Assess for movement. You should feel a pulling upward or outward of the muscles under the chin.
- ▶ Instruct the patient to swallow every time the stimulation occurs.
- ▶ The swallow should be exactly timed with the stimulation.
- ▶ Treatment time varies from 15 to 30 minutes depending on patient's tolerance and goals of treatment.

Steps for using NMES with Pacemaker

WARNING: Do not use NMES with a defibrillator

1. Contact the cardiologist. Introduce your self and explain that you are seeing his/her patient for dysphagia and would like to utilize NMES with placement in the submental region only, at a frequency of 50 Hz and a phase duration that may range from 130 usec to 400 usec. Tell them you will be setting up an appointment with the pacemaker rep for interrogation and to check for interference. The MD may say that is unnecessary and give you permission to proceed in which case just ask if he/she would mind sending a script that states "ok to proceed with NMES". If they want you to proceed with the testing then continue with the following steps.
2. All patients have a pacemaker card. On the back of the card is a 1 800 number for the company. Call the company, tell them where your facility is located and ask for the rep for that area to contact you regarding your patient. If they ask why, explain it is for an interrogation and interference test.
3. When the rep contacts you explain that you want to use NMES your patient and tell them you have spoken with the cardiologist and you would like to see what their availability is to come by and do an interrogation and test for interference. This is a free service; there is no cost to you or the patient. It is a part of their job. They are often in the area seeing patients; in the OR or in doctor's offices.
4. When the rep comes they will set the patient up and interrogate the pacemaker. Meantime you can have the patient with electrodes in place ready to go. The rep will place a magnet over the pacer, this will prevent a shock from occurring but still allows the pacer to function. Explain to the patient you want to go as high as you can so that you are confident that no matter what the level, there will not be a problem.
5. Set the device with the standard parameters unless they are a head and neck cancer patient (higher phase duration) and try to get them to the max amplitude. Explain it may be uncomfortable but it will only be for 5-10 sec. All patients typically tolerate the max amplitude with this explanation.
6. Turn the stim on and go up to the max. The rep will have a digital display that will tell you if there is interference. If there is, then you know not to proceed and no harm done. If there isn't then ask for a printout of the graph and you and the rep sign it. Write the date and the parameters used and document in chart as well. For ex: Guidant rep Mary smith provided pacemaker interrogation and interference testing for NMES in the submental region for potential treatment of dysphagia. Equipment tested at a frequency of 50 Hz, phase duration of 180 usec in the submental region with no interference noted.
7. Send a copy of your findings to the cardiologist, keep a copy in your chart and proceed with treatment.

Electrical Stimulation and Cancer UPDATE

The most recent evidence demonstrates a clear acceptance within the scientific community that not only is NMES *not* a risk but rather a clear benefit.

1. J Surg Oncol. 2016 Jul;114(1):27-31. doi: 10.1002/jso.24265. Epub 2016 May 4. Neuromuscular electrical stimulation improves radiation-induced fibrosis through Tgf-B1/MyoD homeostasis in head and neck cancer. Peng G1, Masood K2, Gantz O1, Sinha U1.

The study includes 30 patients with pre and post intraoperative muscle biopsy for evidence of fibrotic tissue and uses NMES combined with traditional dysphagia therapy with statistically significant benefit.

2. Head Neck. Oct 2012; 34(10): 1428–1433.

Murine model of neuromuscular electrical stimulation on squamous cell carcinoma: Potential implications for dysphagia therapy

Gary Linkov, BS,¹ Ryan C. Branski, PhD,² Milan Amin, MD,² Natalya Chernichenko, MD,¹ Chun-Hao Chen, MD,¹ Gad Alon, PhD,³ Susan Langmore, PhD,⁴ Richard J. Wong, MD,¹ and Dennis H. Kraus, MD^{1,*}

Background

Dysphagia is a potential consequence of treatment for head and neck cancer. Neuromuscular electrical stimulation (NMES) has evolved as a treatment option, with the goal of improved swallow function in patients with chronic dysphagia. However, the effects of NMES on tumorigenicity are unknown and often confound the initiation of this therapy, potentially limiting its efficacy in treating patients with head and neck cancer.

Methods

Squamous cell carcinoma was grown in the flank of athymic, nude mice. Mice were randomized into treatment and control groups; the experimental group received daily NMES directly to the flank for 8 days.

Electrical Stimulation and Cancer UPDATE (Cont)

Results

Tumor volumes, recorded on days 0, 3, 7, and 10, demonstrated no significant differences between groups on each day of measurement. Immunohistochemical analysis of apoptosis, proliferation, and vascularization also failed to demonstrate statistically significant differences between treated and untreated groups.

Conclusions

NMES does not promote the growth of underlying tumor in our model. These data may provide preliminary evidence that applying electrical stimulation over the muscles of the anterior neck does not increase the risk of tumorigenicity. Early initiation of NMES in this challenging population may be feasible from an oncologic standpoint.

3. Okino M, Mohri H

First Department of Surgery, Yamaguchi University School of Medicine.

Japanese Journal of Cancer Research : Gann [1987, 78(12):1319-1321] Type: Journal Article

Application of a high-voltage electrical impulse (5 kV/cm, 2 msec) after bleomycin administration resulted in a significant size decrease of subcutaneously inoculated AH-109A hepatocellular carcinoma in Donryu rats. The tumor size decreased to an average of 17% of the initial mass 4 days after the treatment. Neither the high-voltage electrical impulse nor bleomycin administration alone showed an inhibitory effect on the tumor growth. **It was concluded that the concomitant use of a high-voltage electrical impulse and an anticancer drug has the potential to be applicable for cancer treatment.**

4. Tumor Growth Retardation, Cure, and Induction of Antitumor Immunity in B16 Melanoma-bearing Mice by Low Electric Field-enhanced Chemotherapy

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Electrical Stimulation and Cancer UPDATE (Cont)

Purpose: The exposure of cells in vitro to trains of low voltage-pulsed electric fields in the range of 20–100 V/cm was previously shown to induce an efficient uptake of macromolecules with molecular weight in the range of Mr 300–2,000,000 via an endocytic-like process. This study examines the antitumor effectiveness of treatment based on similar exposure of solid tumors in mice to low electric fields (LEFs) in the presence of chemotherapeutic agents.

Experimental Design: LEF was applied to ~5 mm in diameter (60–70 mm³) s.c. B16-F10.9 melanoma tumors by percutaneously placed electrodes after intratumoral injection of either cis- platinum(II) diamminedichloride, Taxol, 5-fluorouracil, or bleomycin.

Results: Significant eradication of primary tumors, prolongation of survival, and complete cure of some of the C57Bl/6 mice from both primary tumors and metastases were achieved using this technique with cis-platinum(II) diamminedichloride, bleomycin, and Taxol (13.5, 8, and 26% cure rate, respectively). Mice cured by LEF-enhanced chemotherapy and challenged with a tumorigenic dose of B16-F10.9 cells lived significantly longer than first time inoculated ones, and 23.5% of the challenged mice did not develop tumors at all. Spleen cells from the cured mice that were inoculated together with B16-F10.9 cells inhibited the primary tumor growth in intact mice. Histological analysis of tumor sections of LEF-enhanced chemotherapy-treated mice revealed multiple necrotic areas, apoptosis, and massive infiltrates of T lymphocytes and macrophages. **Low voltage electrochemotherapy with Taxol was shown to be more effective than surgical removal of the tumor with Taxol.**

Conclusions: These findings indicate that LEF-enhanced chemotherapy is an effective treatment of animals bearing metastatic melanoma.

Parameter Definitions & When to Change Parameters

1. Pulse Duration

Definition: The elapsed time from initiation of each pulse until its end within a waveform. Electrical current departs from 0 and ends when it returns to 0. Sometimes it is referred to as pulse width (i.e. the amount or width of the pulse contained within each waveform).

When to Change: Lower the phase duration if the subject complains of discomfort at an amplitude level below 15 and there is no contraction.

Why? Higher phase duration is more likely to stimulate pain fibers and lowering it will allow for an increase in amplitude which will allow for an increased chance of achieving a contraction.

Remember that there is an inverse relationship between amplitude and phase duration.

Lower it to 135usec.

When to change: Increase the pulse duration if the patient is at the highest amplitude level and still doesn't have a contraction and is still quite comfortable.

2. Contraction Time

Definition: The length of time the electrical stimulation is on including ramp up.

When to Change: If the subject is unable to complete the swallow in the time allotted. Increase the contraction time to match the amount of time it takes.

3. Relaxation Time

Definition: The amount of "rest" time. The stimulus is off. There is no electrical current during this time.

When to Change: If the subject complains that they feel "rushed" in between swallows or seem to fatigue. Increase to allow more rest time but make sure you adjust for a longer treatment time if they can not complete at least 50 swallows.

4. Treatment Time

Definition: The total time allotted for a single treatment. Normally set for 30 minutes.

When to change: When the subject c/o fatigue or you have limited time with the patient.

5. Frequency

Definition: The number of pulse per second

When to change: Usually set at 50hz for swallowing and 30z for facial stimulation. Not typical to change frequency. Remember a frequency too high will fatigue the muscle and a frequency too low will result in a twitch.

6. Amplitude

Definition: the total area contained in the waveform representing the magnitude/ height/maximum value of current. It is directly tied to the number of motor units recruited.

When to change: The patient is always in control of how strong the amplitude is.

Tips for increasing amplitude if needed to achieve a contraction:

1. Explain to the patient that it needs to be strong enough to move the muscle but not so strong to be uncomfortable
2. Allow the patient time to acclimate and see if they can tolerate an increase after 5-10 minutes
3. Lower the pulse duration

Recommended Reading on Electrotherapy

Alon, G. Principles of Electrical Stimulation In: Nelson, KM, Hayes, KW and Currier, DP (eds): Clinical Electrotherapy, 3rd ed. Connecticut: Appleton and Large, 1997 pp 55-139.

Dellito, A and Synder-Mackler, L. (1990) Two Theories of Muscle Strength Augmentation Using Percutaneous Electrical Stimulation. Physical Therapy, 70, (3), 158-164.

Doucet, B. M., Lam, A., & Griffin, L. (2012). Neuromuscular Electrical Stimulation for Skeletal Muscle Function. *The Yale Journal of Biology and Medicine*, 85(2), 201–215.

Baker, L., Parker, K., and Sanderson, D. (1983) Neuromuscular Electrical Stimulation for the Head-Injured Patient. Physical Therapy, 63, (12), 1967-1974.

Galnz, M., Klawansky, S, Stason, W, Berkley, C, and Chambers, TC. (1996) Functional Electrostimulation in Post Stroke Rehabilitation: A Meta-Analysis of the Randomized Controlled Trials. Physical Medicine and Rehabilitation, 77, 549-553.

Electrical Stimulation: Enhancement of Muscle Function, An American Physical Therapy Association Anthology 1993. (Available through APTA website)

Robinson, Andrew J; Lynn Snyder-Mackler (2007-09-01). *Clinical Electrophysiology: Electrotherapy and Electrophysiologic Testing* (Third ed.). Lippincott Williams & Wilkins.

Watson, Tim. 2008 Electrotherapy: Evidence Based Practice, 12 edition, Churchill Livingstone Elsevier

Also check out electrotherapy.org and read section on Key concepts in Electrotherapy