

APRIL 2006

Technology Review



**VitalStim™
THERAPY
(REVOLUTIONARY
TREATMENT FOR
SWALLOWING
DISORDERS)**

HEALTH TECHNOLOGY ASSESSMENT UNIT
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH

Author:

Pn Mariammah Krishnasamy
Assistant Director
Health Technology Assessment Unit
Medical Development Division
Ministry of Health Malaysia

Reviewed by:

Datin Dr Rugayah Bakri
Head
Health Technology Assessment Unit
Medical Development Division
Ministry of Health Malaysia

1. INTRODUCTION

VitalStim therapy is a device used for patients suffering from a swallowing disorder called dysphagia. Possible causes of dysphagia are muscular dystrophy, brain injury, myasthenia gravis, amyotrophic lateral sclerosis, spinal cord injury, Parkinson's disease, multiple sclerosis, cerebral palsy, and Alzheimer's disease.

VitalStim therapy is non-invasive. The treatment uses controlled neuromuscular electrical stimulation to strengthen the muscles used in swallowing.

There is only one electrical stimulation device in the United States that is approved by the Food and Drug Administration (FDA) for the treatment of dysphagia. This device is marketed under the trade name VitalStim. VitalStim inventor Marcy Freed developed this dysphagia program after her persistence to pursue an idea she had about it for twenty years (Stern, 2003). In June 2001, the FDA approved the use of this external electrical stimulation for the treatment of swallow disorders in children and adults (FDA, 2001).

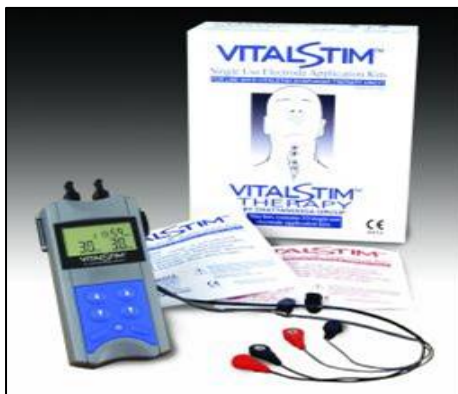
2. OBJECTIVE

To determine the safety, effectiveness and cost implications of VitalStim™

3. METHODOLOGY

The electronic databases of Pub Med, Ovid search engine, relevant databases such as Cochrane databases, Medline and Google were searched. The following were the key words used either singly or in combination: VitalStim, safety, effectiveness, cost, electrical stimulation, neuromuscular electrical stimulation, dysphagia, stroke, swallowing difficulty.

4. TECHNICAL FEATURES



Electrical muscle stimulators are devices used to repeatedly contract muscles by passing electrical currents through electrodes in contact with the body. The electrodes are attached to the stimulator device, which may be powered by battery or line voltage and controls the amount of energy flowing through the electrodes. This device has been

modified for the combination of electrical stimulation and traditional dysphagia techniques for muscles of swallowing.

The FDA has approved this device as Regulatory Class II. Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness. In the case of VitalStim, this means that the device must be prescribed by a physician and used by a licensed medical professional.

5. RESULTS AND DISCUSSION

5.1 Safety

The study conducted by Freed et al (2001) and a case study by Sabet et al (2005, Level 2), found that the usage of electrical stimulation for dysphagia is a safe technology.

A prospective study conducted by Leelamanit et al (2002, Level 8) revealed that the synchronized electrical stimulation has advantages of being non-invasive and actively assists in swallowing process. The synchronized feature of the synchronous electrical stimulator helps to restore normal swallowing mechanism and decreases the incidence of nasogastric tube insertion and gastrostomy.

There are some contradictions and warnings associated with this device (Center for Devices and Radiological Health, 2002.) These warnings include caution to be used when delivering the therapy to those with cardiac pacemakers.

Additional warnings include:

- a) The unknown effects of chronic electrical stimulation,
- b) The stimulation should not be applied over the carotid sinus nerves,
- c) Improper placement of the electrodes or improper use of recommended frequency, intensity and pulse, may cause laryngeal or pharyngeal spasm. A severe spasm of these muscles can close the airway or cause difficulty in breathing.
- e) Stimulation should not be applied on the chest because the introduction of electrical current into the heart may cause cardiac arrhythmias.
- f) The use of VitalStim Therapy is contraindicated with patients who are severely demented and exhibit non-stop verbalization. Constant verbalization could result in aspiration during trials of oral intake.

- g) VitalStim Therapy is contraindicated in patients with significant reflux due to use of a feeding tube. Such patients are prone to repeated cases of aspiration pneumonia, and the VitalStim device has not been studied in this population
- f) Use of the VitalStim device is contraindicated in patients with dysphagia due to drug toxicity because of the risk of aspiration during trials of oral intake.

5.2 Effectiveness

There is limited evidence available regarding the effectiveness of VitalStim. CIGNA Health Care agency indicated that the electrical Stimulation for dysphagia is considered as an experimental, investigational stage and the technology is unproven. (CIGNA Health Care, 2005).

A study by Suiter (2006, Level 8) showed that there was no significant gains in myoelectric activity of the sub mental muscles following Neuromuscular Electrical Stimulation. Therefore, the benefit of Neuromuscular Electrical Stimulation to the sub mental muscles with the goal of improving the pharyngeal swallow is not supported. Additional research investigating the duration of treatment as well as frequency and amplitude modulation of Neuromuscular Electrical Stimulation is needed to determine how it affects the biomechanical aspects of both the normal and disordered pharyngeal swallow.

On the other hand, Chetney & Waro (2004) evaluated the VitalStim device and found that it could be utilized by speech therapists in a home care setting. This article reflects the success in changing people's lives by helping them swallow again.

Freed et al (2001) reported that the electrical stimulation using VitalStim was 97% successful in improving or restoring a patient's ability to appropriately and adequately swallow. This study which was published in the May 2001 issue of Respiratory Care, eventually lead to the 2001 FDA approval of this device. The electrical stimulation appears to be effective treatment for dysphagia due to stroke and results in better swallowing function compared to the conventional, thermal-tactile stimulation (TS) treatment.

In another study by Leelamanit et al (2002), the authors tested whether the synchronous contraction of the thyrohyoid muscle by electrical stimulation during swallowing could improve dysphagia in 23 patients with a moderate to severe degree dysphagia who did not respond to medical treatment. Electrical stimulation therapy was given daily for 4 hours until the criteria for improved swallowing were fulfilled or other intervention was deemed necessary. Twenty of the patients showed marked improvement at the first course of treatment. The duration of the therapy varied from 2 to 4 days in patients with moderate dysphagia and from 3 to 30 days in patients with severe dysphagia. From the study the authors concluded that stimulating synchronous contraction of the thyrohyoid muscle by the electrical stimulator during swallowing improves dysphagia (resulting from reduced laryngeal elevation).

5.3 Cost

There is no evidence available regarding the cost-effectiveness of VitalStim.

The information on the cost of the device is obtained from the website of Vital Stim Therapy.

VitalStim therapy unit costs USD 1,595 per year and supplies are approximately USD 20 per treatment. There is also the cost of electrodes, which are approximately USD 20 per pack for one hour of electrical stimulation. Training to be certified in the technique is USD 895 (Career Improvement and Advancement Opportunities, 2004)

6. CONCLUSION

Neuromuscular Electrical stimulation for dysphagia is relatively a new technology. There is insufficient evidence supporting this technology, particularly on the dose and frequency of the application and types of patients. Furthermore, the device, Vital Stim is lacking in published, peer reviewed scientific literature to conclude that the electrical stimulation is effective in the treatment of dysphagia.

7. RECOMMENDATION

Better designed, randomized controlled trials are needed to demonstrate the clinical benefits of electrical stimulation for dysphagia.

8. REFERENCES

A: \ E. stem Therapy .htm.

A: \ Samaritan Regional Health System Press.htm

Chetney R, Waro K., Sentara Home Care Services, Chesapeake, VA 23320, USA. rchetne@Sentara.com, A new home health approach to swallowing disorders. Home Health Nurse. 2004 Oct; 22(10):703-7; quiz 708-9.

CIGNA Health Care, Dysphagia/ feeding therapy, 2005 (Third party payers).

Freed ML Freed L, Chatburn RL, Christian M. Respiratory Care Department, University Hospitals of Cleveland, 11100 Euclid Avenue, Cleveland OH 44106, USA. marcy.freed@uhhs.com, Electrical stimulation for swallowing disorders caused by stroke. Respir Care. 2001 May; 46(5):466-74.

Language pathologists, Occupational Therapies, Radiologist and other professionals involved in treating dysphagia. htm.

Laryngoscope. 2002 Dec; 112(12):2204-10. Synchronized electrical stimulation in treating pharyngeal dysphagia. Leelamanit V, Limsakul C, Geater A. Department of Otolaryngology, Faculty of Medicine, Prince of Songkla University, and Hatyai, Thailand.

Leelamanit, Vitoon MD; Limsakul, Chusak PhD; Geater, Alan PhD, Synchronized Electrical Stimulation in Treating Pharyngeal Dysphagia, [Independent Papers], The American Laryngological, Rhinological & Otological Society, Inc. Volume 112(12), December 2002, pp 2204-2210.

MA Crary and Giselle D. Carraby- Mann, Vital Stim Update Therapy, Published by Vital Stim Therapy, a Chattanooga Group product, Issue no. 4, January 2006. Clinical Research Focusing on Vital Stim Therapy.

Sabet, Farzad MD; Williams, Jeffrey MD; Tolat, Raj MD, Poster Board 110: Electrical Stimulation For Dysphagia: A Case Study And Review, [AAP Annual Meeting Abstracts: Abstracts of the Scientific Papers and Posters Presented at the Annual Meeting of the Association of Academic Physiatrists: Tucson, Arizona February 22-26, 2005: Poster Board Presentations], 2005 Lippincott Williams & Wilkins, Inc. Volume 84(3), March 2005, p 231.

Suiter DM, Leder SB, Ruark JL. School of Audiology and Speech-Language Pathology, The University of Memphis, 807 Jefferson Avenue, Memphis, Tennessee, USA, .Effects of Neuromuscular Electrical Stimulation on Submental Muscle Activity. Dysphagia. 2006 Mar 17; [Epub ahead of print].

www. fda.gov