

Transcutaneous Neuromuscular Electrical Stimulation (VitalStim) Curative Therapy for Severe Dysphagia: Myth or Reality?

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Objectives: VitalStim therapy was approved by the US Food and Drug Administration in 2001 for the treatment of dysphagia through the application of neuromuscular electrical stimulation to cervical swallowing muscles. This approval was based upon submission of data on more than 800 patients who received this therapy collected by the principal developer and patent-holder of the device. The therapy is marketed as successful in restoring long-term swallowing function in 97.5% of dysphagic patients past the point of requiring a feeding tube and as significantly better than existing therapies. More than 2,500 speech-language pathologists have taken the certification course, and thousands of devices have been sold. To date, however, aside from the developer's own studies, there are no peer-reviewed publications supporting these claims. We sought to evaluate the effectiveness of VitalStim therapy in a heterogeneous group of dysphagic patients.

Methods: We performed a retrospective analysis of 18 patients who received this therapy at an urban tertiary referral center. All patients underwent pretherapy evaluation by speech-language pathologists, including modified barium swallow and/or functional endoscopic evaluation of swallowing and clinical evaluation of swallowing that included assessment of laryngeal elevation, diet tolerance, and swallowing delay, and were then assigned an overall dysphagia severity score. After therapy, all patients underwent the same assessments. Twelve of the 18 also underwent a functional swallowing telephone survey months (range, 1 to 21 months) after their therapy to assess whether the improvement was worthwhile and sustained.

Results: Eleven of the 18 patients (61%) demonstrated some improvement in their swallowing. Six of the 18 patients (33%) were improved enough to no longer require a feeding tube. However, of the 5 patients categorized as having "severe dysphagia" before therapy, only 2 showed any improvement, and these patients still required a feeding tube for adequate nutrition. Telephone surveys did confirm that those who improved with their therapy seemed to maintain their progress and that most patients were satisfied with their therapy.

Conclusions: VitalStim therapy seems to help those with mild to moderate dysphagia. However, the patients with the most severe dysphagia in our study did not gain independence from their feeding tubes. The authors conclude that VitalStim therapy clearly has a place in the management of dysphagia, but that the most severely afflicted are unlikely to gain dramatic improvement.

Key Words: aspiration, dysphagia, neuromuscular electrical stimulation, VitalStim therapy.