Dysphagia

THE POTENTIAL IMPACT OF VITALSTIM® THERAPY ON HEALTHCARE COSTS: A White Paper

VitalStim Therapy has significant potential to dramatically impact the health care costs arising from oropharyngeal dysphagia. The magnitude of this potential can best be understood in the context of the prevalence of this common condition (see Part 1), and the high costs associated with this disorder (see Part 2). This white paper details all of these issues, and also summarizes scientific research on VitalStim Therapy (see Part 3).

Contents

This white paper presents the following critical information relevant to understanding the potential impact of VitalStim Therapy on the nation's healthcare budget:

Part 1 – Oropharyngeal Dysphagia: Prevalence, Mortality and Complications presents a comprehensive summary of what is currently known about the prevalence of dysphagia and its complications, especially among the elderly.

Part 2 – The Potential Impact of VitalStim Therapy on Healthcare Costs reviews information about costs associated with dysphagia and this neuromuscular electrical stimulation (NMES) device's potential impact on the nation's healthcare budget for the treatment of dysphagia.

Part 3 – Scientific Research on VitalStim Therapy provides a comprehensive summary of the scientific background regarding VitalStim Therapy's safety and long-term effectiveness accepted by the FDA when it cleared VitalStim Therapy in 2002 as the only NMES device for use in the treatment of dysphagia. The paper also discusses scientific research that is currently underway.

Appendix A – VitalStim Therapy has been Found to be Safe provides scientific data about the safety of VitalStim Therapy.

Part 1: Dysphagia – Prevalence, Mortality and Complications

Part 1 of this white paper synthesizes a wide variety of data about the prevalence of dysphagia, its mortality, and its complications, especially among the elderly.

Overall Prevalence: Dysphagia is not a medical disease, per se, but a symptom or side effect of various neurological, structural, or cognitive conditions or deficits. It may be the result of head and neck trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, and encephalopathies. Patients with dysphagia can be at risk for aspiration pneumonia, dehydration, malnutrition, failure to thrive, and even death.

> "
> ...over 15 million adult Americans are affected by this condition...
>
> ...one in every 17 Americans will develop some form of dysphagia at some point in their lifetime...
> "

Just how prevalent is this little-known condition that seriously impacts the nation's healthcare budget? Recall that over 15 million adult Americans are affected by this condition, with over a million people being newly diagnosed every year.

Indeed, one in every 17 Americans will develop some form of dysphagia at some point in their lifetime.

Specific Conditions: Dysphagia is experienced by as many as 50 to 75 percent of stroke patients. This condition is responsible for the majority of respiratory infections in stroke patients.

It is estimated that 60 to 70 percent of patients who undergo radiation therapy for head and neck cancer experience dysphagia. And the rapid rise of esophageal cancer has also increased the prevalence of this condition.

In degenerative neurological diseases, such as Parkinson's Disease, Multiple Sclerosis, Cerebral Palsy, myasthenia gravis, ALS (amyotrophic lateral sclerosis or Lou Gehrig's disease) and others, estimates of dysphagia's prevalence run as high as 90 percent, according to the US Department of Health and Human Services.

Mortality Data: The mortality statistics from dysphagia-related causes are staggering: approximately 60,000 people annually die from complications or consequences of swallowing disorders. This represents more deaths than from liver disease, kidney disease, and HIV-AIDS combined, based on Centers for Disease Control (CDC) data. What's more, the number of deaths that can be directly or indirectly attributed to swallowing disorders is nearly equal to the number of deaths due to diabetes – the sixth leading cause of death in the U.S. – according to the CDC.

Dysphagia and the Elderly

Dysphagia is especially common among the elderly. Studies suggest that up to 75 percent of nursing home residents experience some degree of dysphagia, and that as many as half of all Americans over 60 will experience dysphagia at some point after that age.

As their condition becomes more severe, a significant number of dysphagia sufferers develop a need for a feeding tube (percutaneous endoscopic gastrostomy or PEG). Other sufferers require PEG tube feeding immediately or soon after the event that causes their dysphagia (e.g., stroke, head and neck cancer).

According to data cited in a Veteran's Administration (VA) report, aspiration pneumonia is a leading cause of death among the elderly, and has been reported as a growing cause of hospital admissions in that population segment. Pneumonia – a large percentage of which arises from dysphagia – is the fifth leading cause of death of Americans over the age of 65, and the third leading cause of death in those over 85. A CMS study reported that hospitalizations because of aspiration pneumonia nearly doubled in the 1990s, while the incidence of other types of pneumonia decreased. Even healthy elders are more at risk for aspiration caused by change in the swallowing mechanism as a function of aging, even in people free of disease.

Dysphagia's Impact on Quality of Life (QOL)

Quality of life is seriously affected by dysphagia. Many dysphagia patients experience social isolation because they are unable to eat with family and friends. The loss of swallowing can also lead to severe depression due to the interruption of patients' normal ways of life.

Complications of Dysphagia

In addition to aspiration pneumonia, dysphagia also predisposes patients to many other serious health consequences – complications such as choking; bronchospasm; exacerbation of chronic lung disease; an increased infection rate; life-threatening dehydration; death from asphyxia; and chronic malnutrition that often leads to significant weight loss, muscle wasting, physical debilitation, and even death. In head and neck cancer patients, dysphagia can often lead to poor wound healing and reduced tolerance to medical treatments.

	Cohort A	Cohort B
Complications	**Stroke patients w/ PEG tube and dysphagia**	**Stroke patients w/o PEG tube and w/o dysphagia**
N (%) deaths 4 quarters after index quarter	356 (66%)	10,796 (36%)
N (%) patients with aspiration pneumonia admissions	90 (17%)	795 (3%)
N (%) patients with sepsis admissions	71 (13%)	1,196 (4%)
N (%) patients with decubitus ulcers	111 (20%)	2,962 (10%)

An analysis of Medicare records for stroke patients shows that stroke patients who have severe dysphagia are twice as likely to die within the year (66% of severe dysphagic stroke patients versus 36% of non-dysphagic stroke patients), are almost six times as likely to be readmitted for aspiration pneumonia (17% vs. 3%), are more than three times as likely to be readmitted for infections (13% vs. 4%), and are twice as likely to develop decubitus ulcers (20% vs. 10%). Each of these complications brings with it significant additional medical problems and attendant higher overall healthcare costs. Covance 2005. VitalStim Therapy Payer and Inpatient Rehabilitation Facility Economic Model.

Part 2: The Potential Impact of VitalStim Therapy on Healthcare Costs

Part 2 of this white paper brings together information about the cost of dysphagia and the potential impact that effective dysphagia management including NMES could have in helping to reduce the nation's healthcare expenditure.

VitalStim Therapy's Potential Impact on Healthcare Costs

As the only electrical stimulation therapy cleared by the FDA for treatment of dysphagia, this innovative treatment modality has proven to be an effective means of reducing costs arising from dysphagia. Its impact is felt in three separate ways:

- correcting dysphagia at early stages of the condition
- preventing its progression to the point where the patient may require a feeding tube
- enabling many patients on tubes to return to normal or partly-normal eating.

> *"...VitalStim Therapy offers a realistic opportunity to drastically reduce healthcare costs for dysphagia."*

Complications commonly result from dysphagia can significantly increase the cost of a patient's care. Based on statistics on the efficacy of treatment to date, VitalStim Therapy can be expected to reduce the incidence of the following:

- hospital readmissions
- emergency room visits
- extended hospital stays
- the need for expensive respiratory and nutritional support
- the necessity for long-term institutional care
- a tracheostomy for breathing (in the most severe cases)
- PEG tube

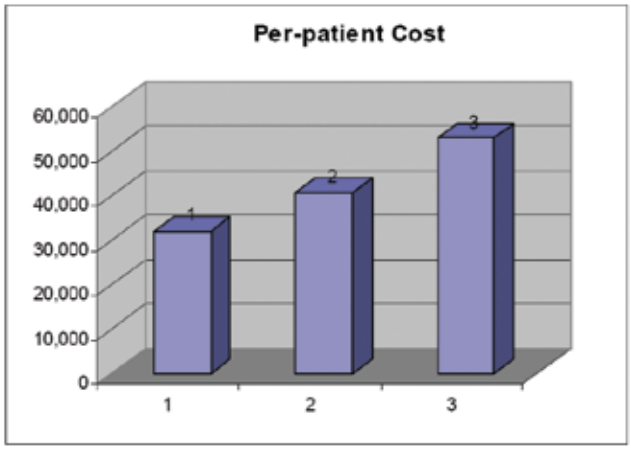
Thus, VitalStim Therapy offers a realistic opportunity to drastically reduce healthcare costs for dysphagia. The treatment provides substantial savings for patients, insurers, and healthcare providers, and offers the potential of significant cost savings to Medicare. Patients who undergo VitalStim Therapy have moved from PEG-tube feeding to successful swallowing in an average of 14 one-hour sessions.

Dysphagia Cost Factors – Feeding (PEG) Tubes

Feeding tubes are an expensive form of therapy. The annual healthcare costs associated with PEG tubes are reported to average over $31,000 per patient per year. The average daily cost of PEG-tube feeding is close to $90.

In 2003, the total annual cost to Medicare just for enteral feeding supplies was more than $670 million. This figure represents almost 6% of the total Medicare budget for DME supplies for that year. Including the monies spent in hospitals, the total cost of dysphagia to the healthcare system is well over $1 billion annually, and rising rapidly.

Further, according to a recently published study, the prevalence of feeding tube usage is rising steadily. And with the U.S. population aging rapidly, and life expectancy increasing, both the number of people requiring PEG tubes, and the length of time elderly patients will be on a tube, are certain to rise at an increasing rate.



1. Annual Medicare expenditure for stroke patient without dysphagia $ 32,093
2. Annual Medicare expenditure for stroke patient with mild dysphagia $ 40,712
3. Annual Medicare expenditure for stroke patient with severe dysphagia (with a PEG tube) $ 52,966

VitalStim Therapy's Potential Cost Impact in Stroke Survivors

According to data submitted to, and accepted by, the FDA, VitalStim Therapy can return stroke victims to normal or near-normal swallowing function before they progress to the point where they need a feeding tube. There are also many reported instances of patients on feeding tubes who have been able to restore their swallowing function to the point where the tube is no longer required for them to receive adequate nutrition.

An analysis of Medicare Standard Analytic files reveals that Medicare spending per stroke patient is increased by as much as $20,000 per year when that patient has dysphagia. This increase is due to dysphagic patients having more incidents of aspiration pneumonia, septicemia and other complications related to dehydration and malnutrition. Considering the total number of dysphagic patients, the annual price tag to the healthcare industry is close to $3 billion. (Covance 2005)

Part 3: Scientific Research on VitalStim Therapy

Part 3 of this white paper provides the scientific background regarding VitalStim Therapy's long-term effectiveness and safety, based on the study that was accepted by the FDA when it cleared VitalStim Therapy in 2002 as the only NMES device for use in the treatment of dysphagia.

> *"...Medicare spending per stroke patient is increased by as much as $20,000 per year when that patient has dysphagia"*

The FDA Study

VitalStim Therapy's clearance by the FDA was based on a long-term study of nearly 900 patients, both in-patient and outpatient, which included direct comparison of electrical stimulation using VitalStim Therapy with thermal stimulation, a traditional approach to treating dysphagia.

VitalStim Therapy's Efficacy

Overall Efficacy: Based on this direct comparison study, electrical stimulation proved to be significantly more effective in restoring swallowing function – measurable improvement was noted in over 98% of patients studied, compared with less than 33% of the patients receiving thermal stimulation.

Efficacy in Severe Cases of Dysphagia: VitalStim Therapy's success rate in restoring patients' swallowing function past the point of their requiring a feeding tube (Percutaneous Endoscopic Gastrostomy or PEG) was 97.5%, versus 39% for thermal application. Further, in well over one-third of these severe dysphagia cases, VitalStim Therapy was able to restore the patient's swallowing function completely, while not a single patient was restored to full swallowing function by means of thermal application.

Efficacy was Independent of Cause of Dysphagia: VitalStim Therapy was effective independently of the cause of a patient's dysphagia, including such common causes as stroke, head or neck cancer, degenerative neurological conditions (e.g., Parkinson's Disease, Multiple Sclerosis) and respiratory conditions.

Efficacy was Independent of Patient Age or Gender: VitalStim Therapy proved effective across the full spectrum of age groups and in both sexes – the success rate in patients over 80 years old was comparable to that in patients 51-80 years old, as was the success rate in children aged 1-4 and even in infants.

VitalStim Therapy's Efficacy (cont.)

Efficacy was Independent of Patients' Co-morbidities: VitalStim Therapy was also effective independently of any other health problems (co-morbidities) that were unrelated to patients' dysphagia, such as diabetes, hypertension, coronary artery disease or chronic obstructive pulmonary disease (COPD).

Efficacy was Independent of How Long Patients' Dysphagia Had Been Present:
VitalStim Therapy's effectiveness was independent of the time between the onset of dysphagia and treatment – it was just as effective in patients who had suffered from dysphagia for over 6 months as in those who'd only recently developed the condition. In fact, VitalStim Therapy even worked in patients who had endured swallowing impairment for as long as 40 years. Long-term sufferers (over 6 months) required more treatments than short-term sufferers (an average of over 8 treatments versus an average of 5).

> "The study also showed that VitalStim Therapy is a safe application of electrial stimulation..."

VitalStim Therapy's Long-Term Effectiveness

Follow-Up Study Showed That VitalStim Therapy's Effects Last: The lasting effectiveness of VitalStim Therapy was demonstrated in a 3-year follow-up study (also submitted to the FDA), which showed that:

- the improvement in swallow function achieved by this therapy persisted for up to 3 years after treatment, and
- the superior results of electrical stimulation over thermal stimulation are maintained long-term.

Forthcoming Research on VitalStim Therapy

Many Studies Underway: VitalStim Therapy is actively facilitating scientific research and providing outcome data for peer-review analysis. Multiple studies are currently underway or being submitted for publication.

Appendix A.: VitalStim Therapy has been Found to be Safe

VitalStim Therapy's clearance by the FDA was based on a long-term, randomized, study of nearly 900 patients, both in-patient and outpatient, which included direct comparison of electrical stimulation using VitalStim Therapy with thermal application, the previous leading traditional treatment.

In this long-term study, the VitalStim Therapy treatment program was found to be a safe application of electrical stimulation for the treatment of dysphagia:

- During a period of over 5 years, more than 4,500 individual applications of electrical stimulation were administered to nearly 900 patients without negative side-effects.
- There was not a single occurrence of laryngospasm, trismus, change in pulse oximetry or changes in heart rhythm or blood pressure.
- These are important results, since there have been discussions in the scientific literature about such potential risks of the application of electrical stimulation to the head and neck.
- A number of steps were taken in the VitalStim Therapy study to eliminate such side effects, for example:
    - Electrodes were placed so as to minimize side-effects. For instance, they were placed so as to avoid the carotid body*.
    - Lower voltage and lower current were used than the voltage and current delivered by many other forms of standard neuromuscular stimulation.
- In addition, no problems were observed in patients who had pacemakers.

Only one problematic issue was observed; this was an occasional occurrence of skin irritation as a result of tape used to secure the stimulation electrodes to the anterior portion of the neck.

* The carotid body is a chemoreceptor located near the bifurcations of the carotid arteries that monitors changes in the oxygen content of the blood and helps control respiratory activity.

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