

VitalStim® Therapy

Fact Based Talking Points on VitalStim Therapy



Dysphagia, or difficulty with swallowing, is a sorely neglected medical disorder that impacts as many as 15 million Americans, with approximately one million people annually receiving a new diagnosis of the condition.

VitalStim'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 with thermal application, the previous leading traditional treatment.

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

VitalStim Therapy is a Safe Therapy

- VitalStim Therapy at the writing of this document is the only Powered Muscle Stimulator that is cleared by the FDA for application over the throat. According to the Guidance Document for Powered Muscle Stimulator 510(k) published by the FDA in June 1999 the FDA provides the following labeling as a Warning regarding the application of traditional NMES (Powered Muscle Stimulator) on or over the throat.

“
VitalStim Therapy’s clearance by the FDA was based on a long-term, randomized, study of nearly 900 patients. 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.
”

- ❑ Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- ❑ Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

- 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 oxymetry, 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 study to eliminate adverse effects; for example:
 - ❑ Electrodes 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.

The VitalStim® Therapy FDA Study was a Randomized Study

Concerns have been raised about whether the VitalStim FDA Study was truly a randomized study, and on this score there has been a certain amount of confusion among practitioners. This Fact Sheet has been developed to set the record straight for clinicians and other healthcare practitioners by showing in a clear but thorough manner why this study was, in fact, a randomized, well-designed study.

One reason for confusion is simply that the subject of randomization in experimental studies in healthcare is a highly complex field, connecting to both statistical analysis and the design of scientific experiments.

The VitalStim FDA Study was designed to gather data to answer the question of whether an electrical-stimulation therapy protocol could be more efficacious than thermal stimulation, by comparing two groups of dysphagia patients who had been randomly selected, as well as shown to be similar in regard to such critical study attributes as age, severity of dysphagia, and comorbidities.

Why is randomization such an important aspect of experimental design? For three reasons: First, it increases the likelihood that a sample of patients selected for a study reflects the entire broad population of possible patients, which would validate that the study results apply across this broad spectrum, not just to the narrow universe from which the study authors selected their subjects. It gives practitioners a scientific basis on which to generalize results from the experimental environment to their own clinical setting.

The second reason why randomization is so critical relates to “experimenter bias.” There is a large amount of literature on experimenter bias which indicates just how easily even the most well-intentioned author can, inadvertently or unwittingly, introduce bias into an experimental study by an unintentionally-skewed selection of study subjects. Such bias skews results and diminishes the credibility of a study. Randomization minimizes experimenter bias in the selection of study subjects.

Third, since the study compared the efficacy of two alternative modalities for dysphagia, without an assurance of random selection of each of the two groups studied, there would be little credibility to conclusions about the effectiveness of one treatment vis-à-vis the other – the differential results might be easily explained away by the failure to randomly select the two groups and show they were relevantly similar.

The VitalStim FDA Study was conducted in a clinic setting. In such settings, one well-established method of achieving randomization in subject selection is to include in the study a consecutive series of clinic patients who present for treatment over a period of time, until the intended number of subjects is reached. So if we are looking to include 200 subjects in our study, we include every subject (who meets the study conditions) who presents for treatment (say) starting at 9 am Monday morning, until the 200th person at 2:55 pm Wednesday.

VitalStim® Therapy Talking Points

Why is this method thought likely to generate a random selection? Because consecutive patients walking into a clinic over a period of time are not being pre-selected by anyone, and therefore are extremely likely to be typical of the entire population – and not just of clinic patients, but of the whole universe of (say) dysphagia sufferers. And because they are self-presenting, there is no experimenter bias in the choice of subjects (in effect, no one selects the particular subjects).

Since the VitalStim study was designed to compare a group of dysphagia sufferers treated with electrical stimulation (ES) with a group treated with thermal stimulation (TS), two separate groups were chosen in this random manner.

Now, even with such a random selection process, there is always the small but real chance that the two groups “randomly” selected may turn out to NOT be equivalent in regard to critical study variables, which in this case included age, severity of dysphagia, and comorbidities. After all, there is a minute but real possibility that 70% of the people who walked into the clinic on Monday through Wednesday and wound up in the ES group, were under 45 years of age and suffered only mild dysphagia. And there’s an equally small (but real) chance that all those placed into the TS group (people who walked in on Thursday and Friday, say), were over 68 years of age and had more severe cases. This could, theoretically, have happened.

So while it is extremely likely that using a “consecutive patients” technique to select the two study groups virtually assures us we have randomization, and thereby have similar groups, no method can provide a 100% guarantee of this.

Therefore, to ensure that our randomization process was achieving its intended result, we went further and actually compared the populations in the two groups to eliminate this unlikely possibility that the two randomly selected groups were not truly similar. Once we knew that they were similar, we could assert with total confidence that if any differential results arose in the study, they were caused solely by the treatment, and were not due to dissimilarities between the two study groups. We wanted to be sure we were comparing apples to apples, not to oranges.

These facts show why it is neither fair nor accurate to criticize the FDA-approved study (or the Freed et al. (2001) paper) as not involving randomization.

Look at it this way: If there had been a deficiency in regard to randomization, it would have to have had some sort of consequence – there would have been some sort bias that affected – or could have affected – the outcomes of the study. For instance, consider these very legitimate questions:

- Did the electrotherapy patients selected have less severe dysphagia than the thermal stimulation patients?
- Were the electrotherapy patients younger than the thermal stimulation patients?
- Did the electrotherapy patients have fewer co-morbid conditions than the thermal stimulation patients?

If the answer to any of these questions was “Yes,” then criticism of the study’s randomization might well be valid. For instance, if the electrotherapy patients were in better condition than the thermal stimulation patients, then it could have been their condition, not the treatment, that was responsible for the differential response to treatment.

But in fact, the answer to all of these questions is “No.” The electrotherapy patient group and the thermal stimulation patient group were so similar in all critical respects, that they confirm the study’s claim to be based on randomization, since the two study groups were truly similar with respect to age, extent of dysphagia, and co-morbid conditions.

VitalStim® Therapy Can Reduce Health Care Costs

In addition to its documented therapeutic efficacy for dysphagia and its well-established safety record, VitalStim® Therapy has significant potential to dramatically impact the staggering health care costs arising from this quite common condition. This potential can best be understood against the background of the prevalence of dysphagia and the high costs associated with this condition.

Dysphagia Background: Prevalence & Complications

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 (difficulty in swallowing), 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, including 50 to 75 percent of stroke patients; dysphagia 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 dysphagia.

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

Dysphagia is especially common among the elderly; for instance, 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.

VitalStim® Therapy Talking Points

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., a stroke).

According to data cited in a VA report,^(b) 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 hospitalization 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.

“
...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...
”

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; severe 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.

One must realize just how profoundly patients' quality of life is affected by dysphagia. Many of these 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.

Dysphagia Background: Cost Factors

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 for outpatients was more than \$670 million. This figure represents almost 6% of the total Medicare budget for that year. Including the monies spent in hospitals, the total cost of dysphagia to the healthcare system is well over \$1 billion dollars 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.

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 CDC data. What's more, the number of deaths that can be directly or indirectly attributed to swallowing disorders approximates the number due to diabetes – the sixth leading cause of death in the U.S. – according to the CDC.(c)

VitalStim Therapy's Impact

VitalStim Therapy can make a substantial contribution to today's urgent efforts to reduce healthcare costs. This innovative treatment modality has proven to be an effective means of reducing the astronomical costs arising from dysphagia; it impacts dysphagia in three separate ways:

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

The following commonly result from the complications of dysphagia – and all of them dramatically increase the cost of a patient's care. By correcting the condition, reducing its complications, or reversing dysphagia, VitalStim® Therapy can be expected to reduce the incidence of all of the following among dysphagia sufferers:

- 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)
- percutaneous endoscopic gastronomy (PEG) tube.

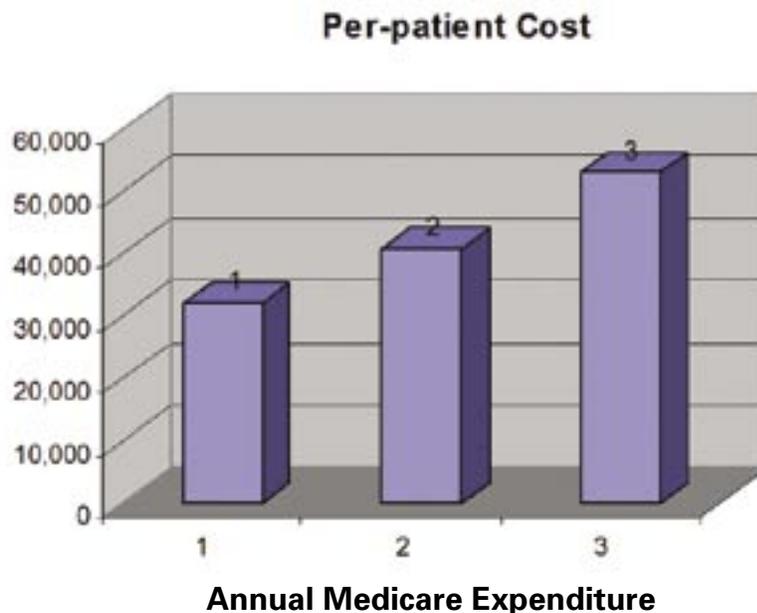
“
*...VitalStim
Therapy
offers a realistic
opportunity to
drastically reduce
healthcare costs
for dysphagia.*
”

VitalStim® Therapy Talking Points

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.

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 when that patient has dysphagia by as much as \$20,000 per year. 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 dollars.



- | | |
|--|-----------|
| 1. Stroke patient without dysphagia | \$ 32,093 |
| 2. Stroke patient with mild dysphagia | \$ 40,712 |
| 3. Stroke patient with severe dysphagia
(with a PEG tube) | \$ 52,966 |

Cost Implications of VitalStim® Therapy in Stroke Patients with Dysphagia

A third-party study has concluded that the proper management of dysphagia in stroke patients is likely to significantly reduce the direct and indirect medical costs incurred due to dysphagia and its associated complications.

Incidence:

Of the approximately 700,000 new stroke patients in the US annually, 39% have mild to moderate levels of dysphagia, and 19% have severe dysphagia. Complications of dysphagia include aspiration pneumonia, septicemia, choking, chronic malnutrition, life-threatening dehydration, infection, and possibly death.

Objective:

To estimate the budgetary impact of including the VitalStim® Therapy System in the treatment approach for stroke patients with dysphagia.

Assumptions:

- The elimination of complications of dysphagia from stroke patients offers the potential for significant cost savings.
- The VitalStim® Therapy System is a proven successful therapeutic intervention for treating dysphagia, which has been used in more than 25,000 patients.

Methodology:

Using retrospective Medicare claims data, an economic model was developed to estimate potential cost savings that may be generated as a result of implementing VitalStim® Therapy. The data was drawn from the 2000 and 2001 Medicare Standard Analytic Files (SAF).

The Three Cohorts:

Based on Medicare data, stroke patients were classified into three cohorts, defined as follows:

- *Severe dysphagia patients* were defined as dysphagia patients who were placed on a percutaneous endoscopic feeding gastronomy (PEG) tube
- *Mild-to-moderate dysphagia patients* were defined as dysphagia patients who were not placed on a PEG tube
- Stroke patients *without* any diagnosis of dysphagia.

VitalStim® Therapy Talking Points

Key Conclusions:

- Dysphagia among stroke patients contributes significantly to patient morbidity and therefore to increased costs both for healthcare providers and for payers.
- On an annualized basis, average per-patient payments by Medicare for stroke patients with dysphagia versus stroke patients without dysphagia differed significantly. In the year following initial hospitalization, cost differentials for the three stroke patient cohorts were as follows:
 - ❑ \$44,980 for stroke patients with severe dysphagia (63% higher than for the patients without dysphagia)
 - ❑ \$34,402 for stroke patients with mild-to-moderate dysphagia (25% higher than for the patients without dysphagia)
 - ❑ \$27,535 for stroke patients without dysphagia.
- Improved management of dysphagia will yield significant cost savings; incontrovertible statistics on the success rates of treating dysphagia with VitalStim® Therapy point the way for future cost savings across all care settings.
- These financial figures demonstrate that a successful dysphagia management approach, especially one including VitalStim® Therapy, offers the US health care system an opportunity for significant cost savings; specifically:
 - ❑ Each stroke patient with mild-to-moderate dysphagia who can be kept from requiring a PEG tube, represents a potential annual cost savings of up to \$10,578.
 - ❑ From the payer perspective, use of this dysphagia treatment approach for all stroke patients would result in a per-stroke patient annual cost savings of \$2,892. For a commercial plan with 2 million enrollees, this translates into a total cost savings of approximately \$14 million per year.
 - ❑ Based on expected VitalStim® Therapy success rates, use of the VitalStim® Therapy dysphagia treatment approach in a typical 60-bed inpatient rehabilitation facility would result in a cost savings of \$2,799 per patient stay; for such a facility, this translates into an annual cost savings of \$681,462.
- Significant differences were found in the incidence of complications in the three cohorts in the year after the stroke event, as follows:
 - ❑ the incidence of aspiration pneumonia among patients with severe dysphagia was almost 6 times as high as among patients without dysphagia
 - ❑ the incidence of septicemia among patients with severe dysphagia was more than 4 times as high as among patients without dysphagia
- Thus, an approach that keeps stroke patients in the mild-to-moderate category from requiring PEG tubes significantly reduces the incidence of complications and their associated morbidity in stroke patients.

Covance 2005. VitalStim Therapy Payer and Inpatient Rehabilitation Facility Economic Model.

(a) Department of Health and Human Services Food and Drug Administration (DHHS). (2001). *Freed bioelectric: Dysphagia treatment device*. Retrieved June 1, 2004 from www.fda.gov

(b) JoAnne Robbins, PhD, Guest Editorial: The current state of clinical geriatric dysphagia research. At: <http://www.vard.org/jour/02/39/4/guested.htm>

(c) National Center for Health Statistics: Deaths/Mortality (2002). At <http://www.cdc.gov/nchs/fastats/deaths.htm>



VITALSTIM[®]
THERAPY
BY CHATTANOOGA GROUP

1-800-506-1130
+1-423-870-7200
vitalstimtherapy.com