NMES for Dysphagia: What it is, What it is not....

Dysphagia

- Estimated 15 million adult patients in USA
- Frequently occurring condition in many disease states
- CVA is most frequent diagnosis

Undiagnosed and untreated

Patients with confirmed diagnosis of dysphagia
- Undiagnosed: 64%
- Diagnosed: 36%

Patients who believe their swallowing problem can be treated
- Believe it can’t be treated: 61%
- Believe it can be treated: 39%

100% = 360 patients with known complaints of dysphagia

**Dysphagia due to stroke**

- Majority of dysphagic patients are cortical or brainstem stroke patients
- Dysphagia generally resolves in majority of cortical stroke patients within 6 months
- Brainstem stroke causes more severe and permanent dysphagia due to damage to cranial nerve nuclei
- Medical priority in treating dysphagia:
  - Prevent dehydration and malnutrition
  - Avoid development of aspiration pneumonia

**Swallow dysfunctions in CVA**

- Swallow system is impaired as a result of multiple contributing factors:
  - Decreased neural drive to swallowing musculature
  - Insufficient sensory feedback for efficient motor control
  - Muscle atrophy as a result of disuse
  - Myofascial restrictions as a result of disuse

**Disuse atrophy**

- Dysphagia is associated with disuse atrophy, especially of fast-twitch, type II muscle fibers
- Patients elicit spontaneous swallows with less frequency than non-dysphagic counterparts
- Individuals with compromised health and those of advanced age are most susceptible to disuse atrophy
- Significant atrophy is evident as soon as 72 hours post-stroke
- Atrophy is reversible with exercise


Swallow dysfunctions in CVA

- Management strategies often reinforce underlying impairments
  - Patients are often taught compensatory swallowing techniques (e.g., turning head or tucking chin when swallowing) to improve swallow safety but at the expense of normal swallow dynamics
  - Diets are often modified to a consistency requiring slower contractions
  - Diets are often limited to a quantity and consistency that limits aspiration but decreases oral intake

Burden of illness

Occurrence of complications 1 year post stroke in patients with severe dysphagia and a PEG compared to patients without dysphagia. (CMS data file analysis)

Limited treatment options

<table>
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<tr>
<th>Compensation (mainstay of current management)</th>
<th>Therapy</th>
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<tr>
<td>Head turn</td>
<td>Biofeedback (sEMG, pressure)</td>
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<tr>
<td>Chin tuck</td>
<td>Effortful swallow</td>
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<td>Modified diet</td>
<td>Oromotor exercise</td>
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<td>Supraglottic swallow</td>
<td>Thermotactile stim</td>
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<td>Medical management</td>
<td>Mendelsohn, Masako, Shaker</td>
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<td>PEG</td>
<td>Electrotherapy (recent addition = VitalStim)</td>
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<td>Medication – anti-reflux, botox, etc.</td>
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<td>Surgery – dilatation, myotomy, etc</td>
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Conventional treatments and management strategies have little supporting evidence. Data demonstrate that:
- Management strategies are effective at limiting aspiration but not at improving swallowing.
- Feeding tubes do not reduce aspiration nor occurrence of aspiration pneumonia.
- Feeding strategies (tubes, diet modifications, etc.) do not improve hydration.

Predictors of aspiration pneumonia: how important is dysphagia?


Complications of PEG tubes

Cost of enteral tube feeding

Total annual cost to Medicare for enteral feeding supplies was more than $670 million (6% of annual DME budget).

Estimated cost of providing 1 year of feeding via PEG is $31,832. Main components of this cost include the initial PEG procedure, enteral formula and hospital charges for major complications.

What is VitalStim Therapy?

- Use of Neuromuscular Electrical Stimulation (NMES) to reeducate swallow
- Device and method cleared by the FDA in 2001 as safe and efficacious in treatment of dysphagia

Therapy adoption

- Therapists trained in use of VitalStim Therapy since 2003

Survey of SLP’s (users & non-users, n=2,000) shows that majority of users and patients report good satisfaction.

User & patient satisfaction

- 78% Therapist satisfaction
- 88% Patient satisfaction

**Safety of VitalStim**

- No adverse events were reported to FDA during pre-clearance clinical trial (n=892)
- No adverse events have been reported to manufacturer or to FDA since commercial launch in 2003

**What does it do?**

- Pulsed current depolarizes sensory and motor neurons transcutaneously
- Facilitates strengthening process of the swallowing muscles
- Increases sensory feedback and timing

**Which muscles can be reached?**

- Current flows between electrodes through the path of least resistance.
- Most muscles for swallowing can be easily reached, except for:
  - Palate
  - Superior Pharyngeal Constrictor
Typical treatment session

- Prepare skin, attach electrodes
- Stimulation remains on or 1 hour or as per patient tolerance
- During stimulation patient actively practices swallowing
- Progress patient with different foods/liquids as per tolerance

Typical treatment session

- Progression to therapeutic intensity
  - "Tingling"
  - "Vibration"
  - "Warm"
  - "Grabbing"

Limitations

- Denervated muscle does not respond to NMES
- Inability to elicit voluntary or reflexive swallow limits efficacy
- Structural abnormalities are not affected by NMES
Sample electrode placement

Different electrode placements target different muscle groups

Effects of NMES on muscle

- NMES + concurrent exercise has been shown to produce:
  - Increase in contractile proteins
  - Increase in aerobic enzymes
  - Increase in mitochondrial size and number
  - Increase in capillary density

Preferential type II recruitment

- Fast-twitch fibers (type II) abundant in swallowing muscles
- Type II more prone to disuse atrophy than slow twitch (type I)
- Normal recruitment order is reversed during NMES (type II first, then type I) facilitating swallow specific strengthening therapy
Facilitation of cortical plasticity

- Brain plasticity enables recovery of swallow function after CVA and occurs spontaneously
  - Since complications of dysphagia represent major health risk, acceleration of recovery is medical priority
- NMES facilitates cortical reorganization
  - Induces repetitive swallows
  - Produces sensory stimulation
  - Provides movement feedback
  - Promotes functional, task-specific use

Oh (2007): Cortical reorganization

- 8 dysphagic patients
  - 46-69 yo
  - 4 x CVA, 4 x brainstem CVA or cranial nerve lesion
- 10 NMES treatments using VS placements
- Outcome measures
  - Swallow function per MBS
  - Cortical mapping of maw left muscles per TMS
- Significant expansion of cortical map post-tx

Indications for VitalStim

- A patient is indicated for dysphagia therapy when they:
  - Show signs of, or are at risk for aspiration
  - and/or
  - Have difficulty managing their diet
**Possible signs of dysphagia**

- Coughing/clearing of throat after swallow
- Abnormal volitional cough
- Decreased voice quality (wet, hoarse, weak)
- Recurring chest infections
- Requires multiple swallows or special maneuvers to clear throat
- Difficulty completing a meal
- Feeling of food being stuck in the throat
- Requires diet to be modified (e.g., thickening, pureed food, soft solids)
- Difficulty initiating a swallow
- Spillage of food/liquid from lips and/or drooling

**Precautions, Contraindications**

- **Contraindicated**
  - Directly over active neoplasm or infection
  - Directly over carotid sinus

- **Caution**
  - Implanted electronics (cardiac demand pacemakers, ICDs, VNS)
  - Uncontrolled seizure disorder

**NMES in dysphagia treatment**

*Current state of research*
Studies to date

- 11 positive studies and 1 meta-analysis in print corroborate positive findings reported in the field
  - Use of NMES for dysphagia is safe
  - Improvement in swallow scores is directly associated with use of electrical stimulation
  - Use of NMES is finding widespread adoption among dysphagia therapists
  - Both therapists and patients are very satisfied with outcomes
  - NMES in conjunction with swallowing exercise is more effective than traditional treatment techniques alone
  - Use of NMES tends to decrease inpatient length of stay as a result of improved swallow function

Safety

- All studies tracked for the occurrence of adverse events and none were reported across all patient ages and diagnoses
  - No changes in pulse oxymetry readings, heart rate, or blood pressure (n=892)
  - No reports of laryngospasm, bradycardia or electromagnetic interference with cardiac pacemakers
  - No adverse events in the pediatric population

Efficacy

Meta-analysis of current data (total n=255) demonstrates significant treatment effect of ES added to standard treatment interventions

Freed M. Use of electric stimulation to restore swallow function. JDA (Baltimore) 1998
Christiansen M, Gynn J, Bash had J. Experience with transcutaneous electrical stimulation: A new treatment option for the management of pediatric dysphagia. JCSS. Charleston, 2003

Freed M. Use of NMES for dysphagia is safe than traditional treatment techniques alone

Swallowing + concurrent NMES

Swallowing + concurrent NMES

Inpatient use

- Treatment is safe and leads to improved swallow (Belafsky, et al, n=22)
- Treatment accelerates discharge (Blumenfeld et al, n=40)
- Mild (limited oral intake) to moderate (PEG fed with minimal oral intake) dysphagia patients benefit most with over 80% discontinuing PEG (Shaw et al, n=18)
NMES in chronic dysphagia

Sensory stim improved swallow safety in 75% of patients

Swallow safety on NIH-SSS

Score (lower = safer)


Thank you!