

# The Effectiveness of NMES (VitalStim) Therapy in the Neonatal Population

- Randomized Control Double Blind Study, blind evaluator, with 2 year follow-up
- N=18, pilot study
- 9 controls 9 experimental with a cross-over "rescue" phase after 2 weeks available.
- 3 Sham units, 3 live units
- Inclusion criteria: medically compromised premature infants with significant decrease in medical stability during po attempts. (specific diagnoses and swallowing difficulties delineated out, significant pharyngeal difficulties was required)
- Swallow safety assessed by clinical evaluation and a radiographic swallow study with blind evaluator on study entry, at two week mark, and at study exit. Radiographic swallow studies were limited to study entry and repeated at study exit if penetration and/or aspiration were noted on initial swallow study. This was to limit radiation exposure.

## ***Results Summary:***

- ◆ After 2 weeks of therapy, the experimental group demonstrated a significantly higher % to full oral po's than the control group (both groups found to be significantly similar at start).
- ◆ Significant decrease in meeting need for GTT at end of 2 weeks than control group.
- ◆ 8/9 control patients passed into the rescue phase and all but one demonstrated significant improvement to avoid GTT within 2 week period.

## ***Oral feedings at 2 weeks (% to full volume):***

Control = 29%  
Experimental = 64%  
p = <0.001

## ***Met GTT criteria at 2 weeks:***

Control = 7/9  
Experimental = 1/9  
p = <0.004

## ***Safety of Swallowing at 2 weeks:***

Control = 2/17  
Experimental = 15/17

- ◆ Aspiration: At study entry 61% of patients aspirated, at study exit 0% aspirated regular consistency, and 29% aspirated on thin (breast milk) consistency.
- ◆ Spells with oral feedings: At study entry 83% of patient's demonstrated spells with oral feedings, at study exit 0% demonstrated spells (apneas and bradycardias during oral feedings)
- ◆ Multiple swallows needed to clear bolus: At study entry 83% demonstrated multiple swallows to clear bolus, at study exit 11% demonstrated multiple swallowing to clear bolus

Karin Mitchell, M.A., CCC-SLP, Kathy Ramirez, OTR/L, Maricela Robles, M.A., CCC-SLP, Jennifer Ahlswede, M.S., CCC-SLP, Dawn McKenna, M.A., OTR/L, Mitchell Katz, MD and John P. Cleary, MD

***Met GTT criteria following rescue phase:***

Control = 1/9

Experimental = 1/9

***No adverse response or injuries noted throughout the study***

***Follow-up over a 2 year period following discharge from NICU:***

15/18, (83%) subjects returned for periodic assessments. Revealed that ALL maintained safe swallowing skills over 2 year period

***◇ Summary:***

VitalStim treatment improved feeding volume and safety in this group of high risk neonates. Addition of VitalStim therapy to infants with delayed attainment of oral feedings and unsafe swallowing skills may reduce the need for GTT and prolonged hospitalizations.