

Neuromuscular Electrical Stimulation (NMES) to the Laryngeal Elevator Musculature Compared to Traditional Dysphagia Therapy Without NMES:

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INTRODUCTION

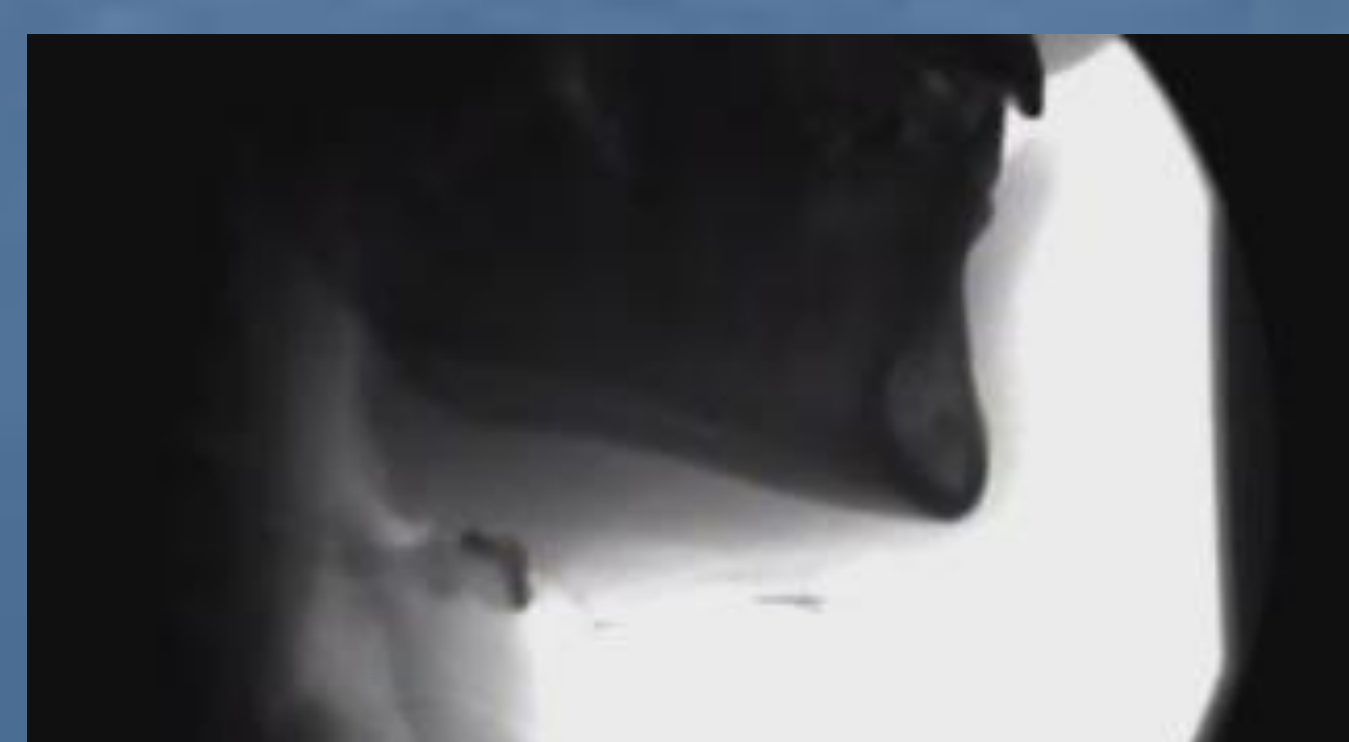
The purpose of this study was to evaluate the safety and efficacy of a very specific therapeutic NMES protocol for use in patients with impaired laryngeal elevation causing dysphagia and to compare this therapy option to a similar group of patients receiving only traditional dysphagia therapy .

SUBJECTS

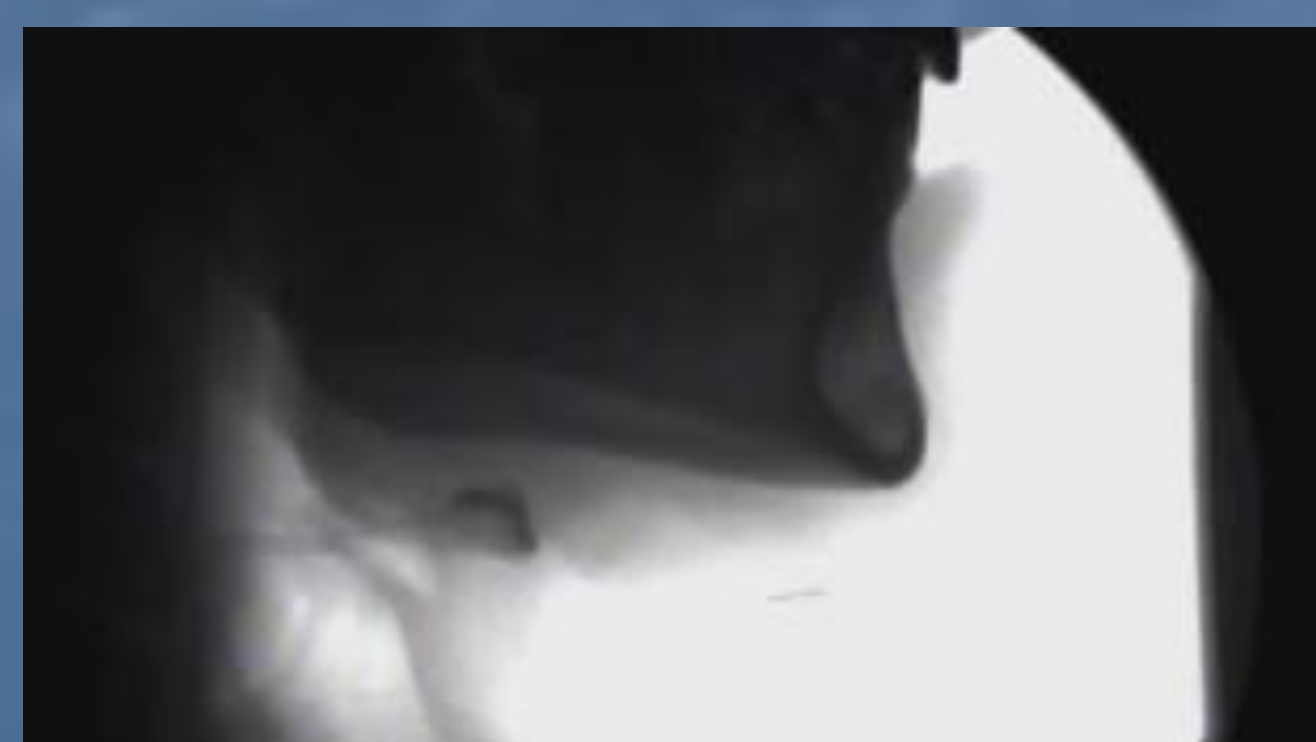
The patients evaluated were obtained from multiple long term care facilities in Texas. Group 1 included patients receiving at least 20 therapy days of the NMES protocol as well as traditional therapy (78 patients). Group 2 included patients receiving traditional dysphagia therapy only as would have been performed prior to any NMES modality training or for patients who refused the NMES therapy protocol (46 patients).

METHODS

A total of 124 patients were evaluated by modified barium fluoroscopic swallow study by a trained licensed speech language pathologist and were found to have impaired laryngeal elevation as a primary or secondary dysfunction causing aspiration or risk of aspiration to the degree that diet changes were necessary. A swallow severity scale was established to determine the diet after the initial diagnosis of dysphagia under fluoroscopy. The subset of patients who were able to tolerate at least 20 days of traditional dysphagia therapy while also using the NMES protocol established were included in the analysis as patients having successful completion of the protocol. A comparison was made from a total of 46 patients who received only the traditional dysphagia therapy but whose chart reviews noted these patients exhibited dysphagia with decreased laryngeal elevation as diagnosed from modified barium swallow study under fluoroscopy. These charts were evaluated as to the number of patients who had an improved swallow severity scale.



Larynx at rest



Laryngeal elevation with Rx³ESP electrical stimulation treatment

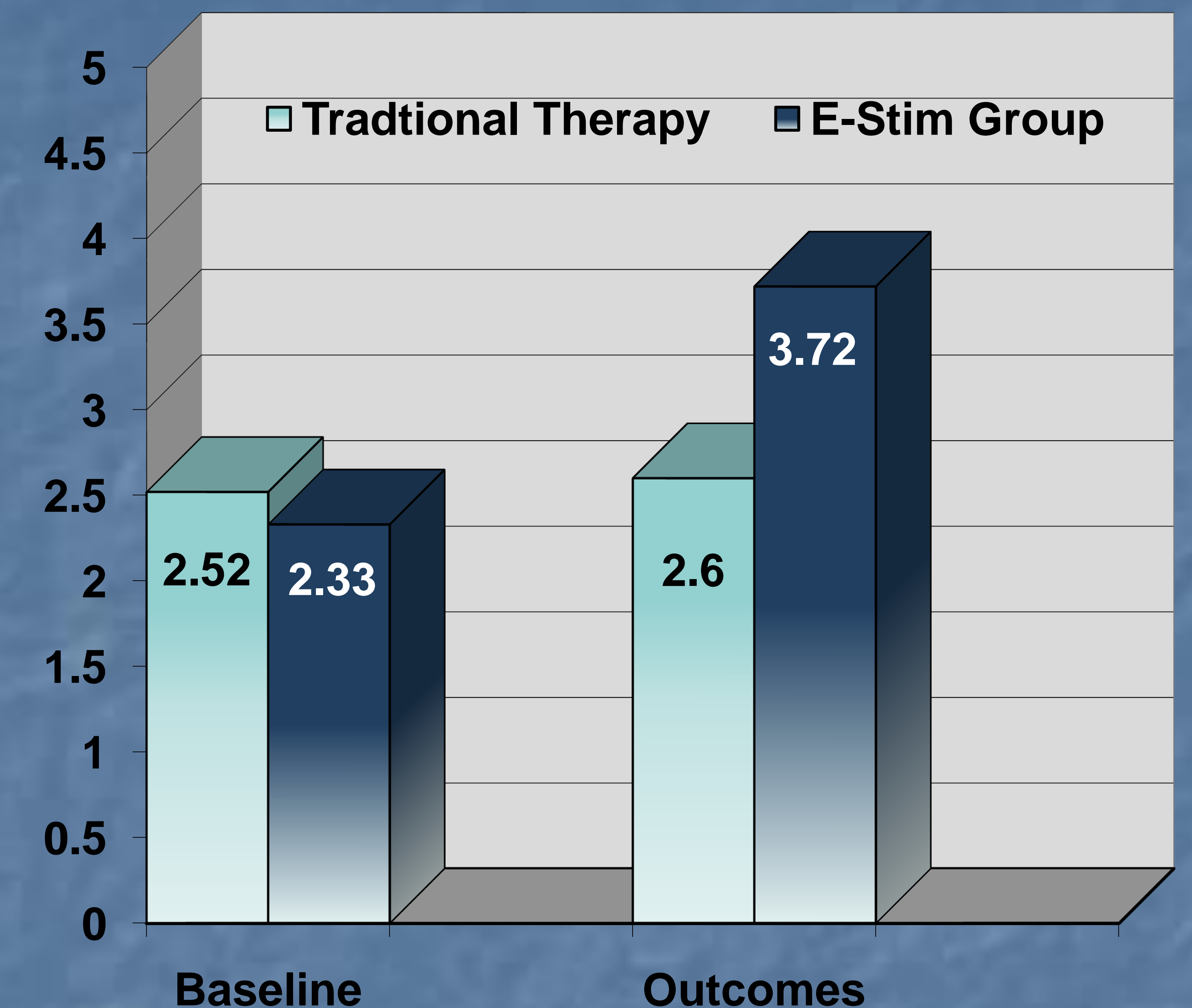
SWALLOW SCALE

0. NPO
1. Therapeutic intake only
2. Pleasure feedings only, unsupervised > 2-3 times per day
3. Modified diet of either thickened liquids, puree or mechanical soft with strategies (3 meals/day)
4. Strategies only, no alternate method of intake
5. Normal swallow function

RESULTS

Patients in the Group 1 subgroup receiving at least 20 days of the NMES protocol improved their swallow severity scale scores from an average of 2.33 to an average of 3.72. Patients in Group 2 receiving only traditional therapy improved their swallow severity scale scores from an average of 2.52 to an average of 2.60. Not all of the Group 2 traditional therapy patients were able to achieve a period of at least 20 days of therapy. The average number of therapy visits in the NMES subgroup was 36.79 (range of 20-91). The average number of therapy days in the traditional study group was 19 days (range: 8-44). In this study, 75% of the patients who received at least 20 days of the NMES protocol had a diet upgrade (58/78), while 25% of the patients did not improve in diet upgrades (20/78). It should be noted that 4 patients were already at a high swallow rating prior to beginning therapy (mechanical soft with thin liquids) and, therefore, did not have much room to improve. In the traditional therapy arm of this review 10% of patients improved to achieve a diet upgrade, 80% of the patients did not improve to a diet upgrade and 10% of the patients had a decline in ability.

There were no significant adverse events that occurred during this study period. There were some patients who refused therapy both with the NMES as well as the traditional methods. Some patients were discharged back to a hospital with ongoing medical illnesses which were not attributed to either therapy group. All of these patients did not meet the intent to treat criteria of 20 days of the NMES therapy protocol.



Means and Standard Deviations on the Swallow Severity Scale at Pre- and Post-Testing

Group	Pre-test	Post-test
Treatment n = 78	2.35 _a (1.31)	3.72 _b (1.53)
Control n = 46	2.59 _a (1.13)	2.61 _a (1.33)

Note: Standard deviations in parentheses. Differing subscripts indicate statistically significant differences.

DISCUSSION

The results of this clinical trial suggest that patients who present with dysphagia due in part to diminished laryngeal elevation and receive NMES to the laryngeal elevators as an adjunct to traditional methods of therapy improved in diet upgrades and swallow function at a higher percentage compared to those patients who did not receive the NMES protocol. There was also more than 5,814 therapy visits using this protocol in this study which would suggest that it is a safe adjunct to include in treating pharyngeal dysphagia with impaired laryngeal elevation.