

Safety and Efficacy of the Aspire2 Device

CONCLUSION:

The Aspire² Device delivers neuromuscular electrical stimulation (NMES) with adjustable parameters as well as provides surface electromyography sEMG and biofeedback. Patients receiving therapy for dysphagia with this device appear to benefit not only in the improvement of swallow function but also in the prevention of and/or reduction of risk for aspiration pneumonia. The Aspire² is both a safe and efficacious treatment option for both adults and children suffering from dysphagia.

OBJECTIVES:

The objective of this study was to analyze the efficacy and safety of the Aspire² device in group of patients with known dysphagia and high risk for aspiration pneumonia.

METHODS:

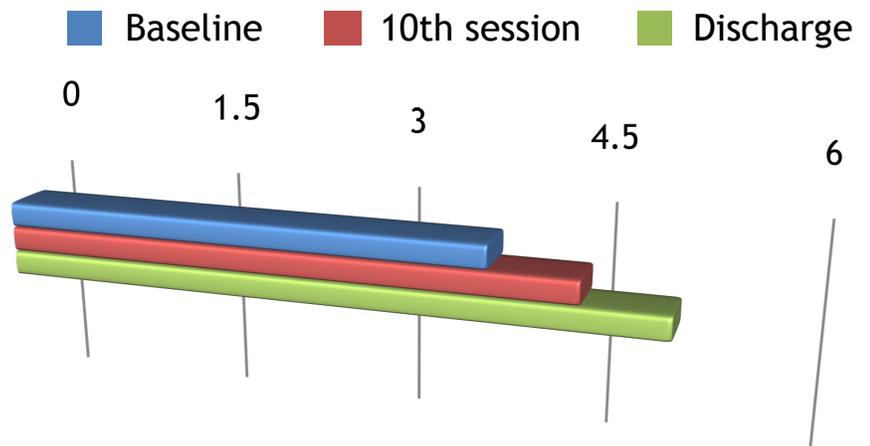
A retrospective review of patient database of both adults and children from March 18, 2015 through November 30, 2015 was performed at the Aspire Center for Health + Wellness in NYC across three locations. All patients had received therapy for dysphagia using the Aspire² Device. Response to therapy was calculated using the ASHA normed and validated National Outcome Measurement Scale (NOMS) as well as reported and verified incidences of aspiration pneumonia.

RESULTS:

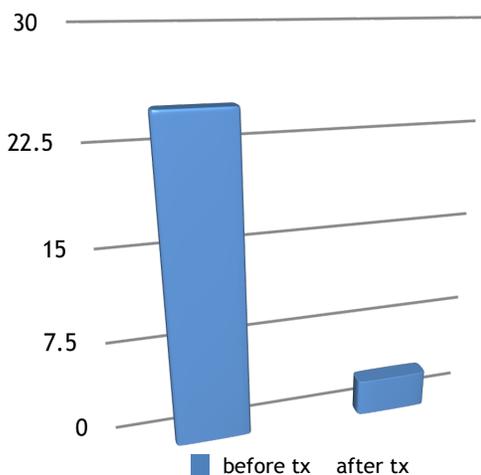
A total of 81 patients were included in this study; 61 males and 20 females of which 75 were adults and 6 were children. Etiologies included MS (54), CVA (6), PD (8), TBI (6), HNC (3), CP(3) and DS (1).

The average baseline NOMS score was 3.76 with a follow up at 10 sessions at 4.41 and a discharge score of 5.04 with an average gain of 1.28. Patients received an average of 18 thirty minute treatment sessions.

NOMS Scores



Incidence of Aspiration Pneumonia Before and After Treatment with Aspire2



There were a total of 25 incidences of aspiration pneumonia at the onset of therapy which was reduced to only 3 incidences at the end of therapy. The 3 incidences of aspiration pneumonia were attributed to 1 new onset CVA and 2 significant exacerbations of MS symptoms. There were no adverse effects associated with the use of the Aspire² device.

ASHA NOMS Swallowing Scale

Swallowing

Note: In Levels 3–5, some patients may meet only one of the “and/or” criteria listed. If you have difficulty deciding on the most appropriate level for an individual, use dietary level as the most important criterion if the dietary level is the result of swallow function rather than dentition only. Dietary levels at FCM Levels 6 and 7 should be judged only on swallow function, and any influence of poor dentition should be disregarded.

LEVEL 1: Individual is not able to swallow anything safely by mouth. All nutrition and hydration is received through non-oral means (e.g., nasogastric tube, PEG).

LEVEL 2: Individual is not able to swallow safely by mouth for nutrition and hydration, but may take some consistency with consistent maximal cues in therapy only. Alternative method of feeding required.

LEVEL 3: Alternative method of feeding required as individual takes less than 50% of nutrition and hydration by mouth, and/or swallowing is safe with consistent use of moderate cues to use compensatory strategies and/or requires maximum diet restriction.

LEVEL 4: Swallowing is safe, but usually requires moderate cues to use compensatory strategies, and/or the individual has moderate diet restrictions and/or still requires tube feeding and/or oral supplements.

LEVEL 5: Swallowing is safe with minimal diet restriction and/or occasionally requires minimal cueing to use compensatory strategies. The individual may occasionally self-cue. All nutrition and hydration needs are met by mouth at mealtime.

LEVEL 6: Swallowing is safe, and the individual eats and drinks independently and may rarely require minimal cueing. The individual usually self-cues when difficulty occurs. May need to avoid specific food items (e.g., popcorn and nuts), or require additional time (due to dysphagia).

LEVEL 7: The individual’s ability to eat independently is not limited by swallow function. Swallowing would be safe and efficient for all consistencies. Compensatory strategies are effectively used when needed.

Diet levels/restrictions are defined on the next page. Your facility’s levels may not exactly match these, but please use these levels as a guide in scoring this FCM.

Swallowing FCM continued

Swallowing: Dietary Levels/Restrictions

Maximum restrictions: Diet is two or more levels below a regular diet status in solid and liquid consistency.

Moderate restrictions: Diet is two or more levels below a regular diet status in either solid or liquid consistency (but not both), OR diet is one level below in both solid *and* liquid consistency.

Minimum restrictions: Diet is one level below a regular diet status in solid *or* liquid consistency.

Solids

Regular: No restrictions.

Reduced one level: Meats are cooked until soft, with no tough or stringy foods. Might include meats like meat loaf, baked fish, and soft chicken. Vegetables are cooked soft.

Reduced two levels: Meats are chopped or ground. Vegetables are of one consistency (e.g., soufflé, baked potato) or are mashed with a fork.

Reduced three levels: Meats and vegetables are pureed.

Liquids

Regular: Thin liquids; no restrictions.

Reduced one level: Nectar, syrup; mildly thick.

Reduced two levels: Honey; moderately thick.

Reduced three levels: Pudding; extra thick

ASHA. (2003). National Outcomes Measurement System (NOMS): Adult Speech-Language Pathology User's Guide.