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Critical Appraisal of a Treatment Publication: Electrical Stimulation for the Treatment of Dysphagia

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Well designed clinical investigation of treatment methods produce evidence that generalizes to the clinical setting, whether the authors' findings support or refute a method's benefits. Both the quality of the research and its findings deserve scrutiny by the consumers of the research to validate their adoption in clinical settings. Electrical stimulation for treatment of dysphagia is a controversial method that has received widespread attention with little peer reviewed analysis of its effectiveness. The following summary discusses the quality of the research and tests the authors' data for effect size (Sackett, Haynes, Guyatt, & Tugwell, 1991; Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000).

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Research Question

Do patients with stroke-related dysphagia demonstrate less severe aspiration and need for gastrostomy when treated with electrical stimulation therapy than they do with thermal-tactile stimulation therapy?

Patients, Eligibility, and Enrollment

Electrical stimulation (ES) has been investigated for use in neuromuscular rehabilitation and pain management. However, the authors did not provide a theoretical basis to explain the technique's hypothesized effect in treating dysphagia or provide the reader other rationale for comparing ES to other treatments. They compared the effectiveness of ES to that of thermal tactile stimulation in reducing severity of aspiration and subsequent need for gastrostomy. The study investigated two cohorts from a total of 110 patients with a history of "swallowing disorders caused by stroke." Patients were "alternately" assigned to one of the two treatment groups (electrical stimulation-ES, thermal stimulation-TS) at the time of enrollment. Though they state the study met the requirements of randomization, the authors did not randomly assign patients to groups. They reported assigning patients "much longer after stroke" to the ES group in part, because "most of these patients had already failed conventional therapy, which was the reason they were referred for the study" (p. 472). Co-morbid conditions of patients were fairly well distributed with the exception of "cancer," which was present in 25% of the TS group opposed to 10% of the ES group. Despite the evidence of relationships between oncologic treatment and certain types of cancer to dysphagia, details of cancer site, stage, and type and timing of ongoing or previous oncologic therapy were not reported, though they may have influenced the results for the TS group. Only 99 of the 110 patients enrolled were included in the analysis because 11 (10%) exited the protocol before completion for "unknown reasons," "transfer to other hospitals" (5 patients), and "drug toxicity" (6 patients). None of the patients who terminated the protocol early were included in the analysis, biasing the data in favor of those capable of completion and compromising "intention to treat"

requirements of randomized studies.

The selective assignment of patients to one group, failure to blind patients and investigators to group assignment or treatment, and failure to analyze all patients assigned to treatment compromise internal validity of the investigation, and unequal assignment of patients with cancer to the control (TS) group may have compromised its external validity. Truly randomized trials maintain the integrity of the enrolled subject pool to mitigate the effects of attrition.

Fluoroscopic Methods

Each patient underwent videotaped a pre- and post-treatment fluoroscopy that was analyzed by one of three different radiologists blinded to patient assignment to treatment groups. The radiologists' narratives were then sent to the speech-language pathologist who assigned a "swallow function score" based on the narrative. Thus, the clinician's ratings were biased by knowledge of the radiologists' interpretations. The authors present no information regarding training of raters in standard methods for fluoroscopic interpretations, reliability testing for judges' fluoroscopic data, development and standard methods of use of the 7-point scale used for assigning swallow function scores, or development testing of the scoring system's validity and reliability. Addressing the latter flaw, the authors state their scoring system "is no more subjective than the score validated and published by Rosenbek et al." (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996, p. 473). This comparison is unsupported, and the reader is encouraged to compare the present study with methods used by Rosenbek and colleagues (1996) to draw their own conclusions regarding this claim. The internal validity of the study was compromised by these methodological flaws. Other measures of dysphagia from the fluoroscopic tests, and more importantly, the nature of detected aspiration, were not reported. Hence, a theoretical basis explaining the hypothesized effects of the experimental treatment on airway protection was omitted, thus compromising external validity.

Treatment Protocol

Patients received one of two treatments (ES, TS) according to group assignment. Inpatients received one hour per day of the assigned treatment, and outpatients received one hour of treatment 3 days a week. All patients "received similar numbers of treatments" (5.5 for ES, 6.0 for TS) until "a swallow function score of at least 5 for inpatients and 6 for outpatients was achieved or the patient was discharged because of insurance constraints" p. 468). Though some discharged inpatients continued in the study as outpatients, it is not stated why some of them did not. Thermal stimulation was provided per published methods; however, dosage (number of repetitions per subject/session or for the group) or standardized techniques across subjects in the TS group were not reported. Thus, the reader and other investigators would be unable to precisely replicate the methods of this study. A significant flaw in this design is the comparison of ES to TS, the latter of which has been shown in numerous studies to produce only a transient reduction in duration of stage transition within seconds of stimulation in patients receiving extensive dosage and duration of treatment (Rosenbek et al., 1998). Owing to the absence of theoretical explanation for the effects of ES, the comparison of its effects to TS, which purports to cause specific and discrete effects, seems unsupported. Perhaps a more valid comparison might have been comparing ES to conventional therapy, consisting of combinations of procedures routinely used in clinics for similar patients.

The flaws in the treatment methods and protocol demonstrate unequal treatment availability to patients in the two groups, and comparison of the two methods to one another compromised the external validity of the study.

Follow Up

Follow-up data were collected by interview and medical record review of those readmitted to the research institution. There was no systematic method of data collection or analysis, and it is unclear if standard follow up procedures were performed with all patients. As a result, reported follow up information should be considered anecdotal.

Results

Although patients in each group improved significantly from their pre-treatment swallow function (ES $p<0.0001$, TS $p=0.0048$), significantly more ES patients improved than TS. The authors did not mention that the TS group showed highly significant improvement. This finding, even if anomalous, would be of interest to the reader. Effect size, binomial effects size display (BESD), and rate ratio calculations were performed using the authors' published data. The effect size for ES compared to TS was $r=.76$ (95% CI: .56-.96), a very large treatment effect. The rate ratio was 7.37 (ES using the authors' methods, is 7.37 times more likely to produce higher swallow function score than with TS performed as published). BESD showed that for every 100 similar patients treated, 88 would improve with ES and 12 would improve with TS. Raw data entered into the meta-analytic analysis of effect size appears in Table 1, and effect size summary appears in Table 2 (see page 14).

A second finding involved need for enteral support (swallow function score of 2 or higher achieved in patients with pre-treat-

ment scores of 0 or 1). Forty-one of the 43 severe ES patients and 15 of the 29 severe TS patients achieved a swallow function score of 2 or higher after treatment. Number needed to treat (NNT) calculations were performed to determine clinical predictive value of ES vs. TS. The NNT summary indicates that three patients from this population with swallow function scores of 0 or 1 would need to be treated using the authors' methods for one patient to "avoid a PEG" by achieving a score of 2 or higher after treatment (NNT=2.326, 95% CI: 2, 5). Again, a very large treatment effect is demonstrated in that successful outcome would likely occur in one of three cases, using the authors' reported enrollment and clinical methods. NNT summary information appears in Table 3.

Clinical Application of the Information

On the surface, the authors' reported conclusions are compellingly powerful. However, the reported methods contain significant threats to validity rendering the conclusions inapplicable to clinicians and patients for the reasons summarized above. As such, there is sufficient uncertainty regarding the conclusions of this method's generalizability to the clinical setting. Although electrical stimulation may be determined at some point to have merit in the management of neurogenic dysphagia, the present study does not substantiate its effectiveness. Given the widespread adoption of this method, further independent investigation of its effects is warranted.

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Table 1. *Raw data and significance (p) of comparisons as reported by authors**

Swallow Function Score	n	Mean ± SD (pre-treatment)	Mean ± SD (post-treatment)	p*
ES (treatment)	63	0.76 ±1.04	4.52 ±1.69	<0.0001*
TS (control)	36	0.75 ±1.20	1.39 ± 1.13	0.0048*
Between Group Difference (post-treatment scores)				<0.0001*

Table 2. *Effect size summary (standardized difference between groups)*

Effect Size	Pooled SD	Cohen's *d*	Effect Size *r*	95% CI	BESD+	BESD-	Rate Ratio
	1.333	2.347	.76	.56 -.96	88.06	11.94	7.373

Table 3. *Number needed to treat summary*

	Patients with pre-treatment score of 0,1	Patients With Post-Treatment Score ≥2	ARR	NNT	95% Confidence Interval (NNT)
TS	29	15	0.43	2.33	1.60-4.22
ES	46	43			