ORIGINAL ARTICLE

McNeill Dysphagia Therapy Program: A Case-Control Study

Giselle D. Carnaby-Mann, MPH, PhD, Michael A. Crary, PhD

ABSTRACT. Carnaby-Mann GD, Crary MA. McNeill Dysphagia Therapy Program: a case-control study. Arch Phys Med Rehabil 2010;91:743-9.

Objective: To compare the effectiveness of the McNeill Dysphagia Therapy Program, a systematic exercise-based rehabilitation framework for swallowing remediation, with traditional swallowing therapy techniques paired with surface electromyography (sEMG) biofeedback.

Design: Matched case-control study.

Setting: University medical center.

Participants: Dysphagic patients referred to an outpatient swallowing therapy service.

Interventions: Cases were individually matched to 2 separate controls for age, sex, and primary medical diagnosis (N=24). Cases were patients with dysphagia who entered the McNeill Dysphagia Therapy Program from September 2006 to October 2008. Controls entered a traditional swallowing therapy program augmented with sEMG biofeedback (traditional therapy with biofeedback group) from February 1994 to June 1999.

Main Outcome Measures: The primary outcome was the proportion of patients who improved clinical swallowing ability and functional oral intake. The secondary outcomes were the presence (or not) of tube feeding, physiologic change on instrumental swallowing studies, and occurrence of aspiration on posttreatment assessment.

Results: Case patients were more likely to demonstrate dysphagia recovery at posttreatment re-evaluation (adjusted odds ratio for dysphagia recovery=13.0 [95% CI, 1.27–63.89]; Mantel-Haenszel χ^2=6.7; P=.009; relative risk reduction=.69). Dysphagia was reduced by 69% in the McNeill Dysphagia Therapy Program treatment group compared with the traditional therapy with biofeedback group.

Conclusions: Both approaches facilitated improved swallowing function. The McNeill Dysphagia Therapy Program resulted in superior outcomes compared with traditional dysphagia therapy supplemented with sEMG biofeedback.

Key Words: Case-control studies; Electromyography; Rehabilitation.

THE PRIMARY GOAL of treatment for swallowing disorders is to improve the amount and variety of food and liquid swallowed orally while minimizing the risk of aspiration and related complications. Traditional approaches to dysphagia intervention include diet modification, compensation strategies, and direct swallowing exercises or maneuvers.[1] Each of these interventions intends to ensure the easiest, safest, and most effective method of swallowing. Approaches such as diet modification and postural compensations reflect a management strategy in that these approaches are not directed at changing (eg, improving) the function of the swallow mechanism. Approaches such as swallowing maneuvers and exercises aimed at the swallowing mechanism represent more direct attempts to improve swallow function by changing the pattern of swallowing.[1] Few studies have adequately evaluated these approaches, although several small studies have implied that application of swallow maneuvers and exercise may be effective at improving swallow function through positive change within the swallow mechanism.[2-7] Most studies have been retrospective analyses of outcome among single cases, small case series, or noncomparable groups.[2-7] In addition, limitations including selective assignment of subjects to treatment conditions, lack of blinding for outcome measurement, use of nonvalidated outcome measures, and incomplete follow-up have limited meaningful interpretation of data. Clinical research using matched control groups, blind outcome assessment, and validated assessment measures will add strength to the systematic evaluation of any dysphagia intervention strategy.[8,9]

One approach to dysphagia intervention that has been reported to result in positive clinical outcomes is the adjunctive application of sEMG biofeedback to various swallowing maneuvers. Bryant[10] first reported on the use of biofeedback in the treatment of dysphagia in 1991, noting that visual monitoring of the swallow signal was able to guide a patient's performance of swallowing techniques such as the effortful swallow and Mendelsohn maneuver. In this article, she reported improved swallow function in a single patient after 9 weeks of treatment. After this initial case report, several case series also demonstrated positive treatment outcomes using this strategy.[4,11-18] Despite treating a diverse range of patient etiologies (stroke, head/neck cancer, brainstem injury), all studies reported improved swallowing performance in patients with chronic swallowing difficulties after an intense intervention program of 10 to 15 sessions delivered over a period of 5 to 15 days.[4,11,12,15]

The McNeill Dysphagia Therapy Program is a systematic exercised-based therapy framework for the treatment of dysphagia in adults.[19] The McNeill Dysphagia Therapy Program focuses on progressive strengthening and coordination of swallowing in the context of functional swallow activities and the

List of Abbreviations

CI	confidence interval
FOIS	Functional Oral Intake Scale level
NMES	neuromuscular stimulation
OR	odds ratio
sEMG	surface electromyography

From the Departments of Behavioral Science and Community Health (Carnaby-Mann) and Communicative Disorders (Crary), University of Florida Health Center, University of Florida, Gainesville, FL.

Presented to the Dysphagia Research Society, March 5, 2009, New Orleans, LA.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

Reprint requests to Giselle D. Carnaby-Mann, MPH, PhD, Dept of Behavioral Science and Community Health, College of Public Health and Health Professions, University of Florida, 101 S Newel Dr, Gainesville, FL 32610, e-mail: *gmann@phhp.ufl.edu.*

0003-9993/10/9105-00612$36.00/0
doi:10.1016/j.apmr.2010.01.013

development of movement patterns and refinement of the coordination of the muscular components of the swallowing process. The McNeill Dysphagia Therapy Program uses the act of swallowing as an exercise incorporating a single swallowing technique (hard swallow) and a specific hierarchy of feeding tasks, which challenge a patient's swallowing system. The program provides detailed guidelines to the clinician to advance, maintain, or regress an individual patient based on the swallow performance of that patient. The basic details of the McNeill Dysphagia Therapy Program have been published in a previous case series study.[19] As the program advances, it increases demands on the system via progressively increasing resistive forces and alterations in velocity of movement, timing, and movement specificity of the swallowing activity. The main objective of the program is to rebuild functional patterns of swallowing movement. Our initial case series paired the McNeill Dysphagia Therapy Program with adjunctive NMES. In this current study, we compared the McNeill Dysphagia Therapy Program without NMES to traditional swallowing therapy augmented with sEMG biofeedback.

McNeill Dysphagia Therapy Program is similar to previous descriptions of traditional swallowing therapies with adjunctive sEMG biofeedback in frequency and total number of treatment sessions. The McNeill Dysphagia Therapy Program differs from more traditional approaches in that it follows a systematic exercise-based framework to advance safe oral intake and improve strength and coordination of the swallow mechanism. Given the surface similarities and differences between the McNeill Dysphagia Therapy Program and prior descriptions of traditional swallow maneuvers supplemented with sEMG biofeedback, the current study compared these 2 approaches on several common outcome measures in a matched case-control design. We hypothesized that because of the systematic application of exercise principles and the progressive introduction of increasingly resistive materials to swallow, the McNeill Dysphagia Therapy Program would result in superior clinical, functional, and physiological outcomes compared with traditional dysphagia therapy using swallow maneuvers taught with the use of adjunctive sEMG biofeedback.

METHODS

This study used a matched case control design. The application of the McNeill Dysphagia Therapy Program for swallowing rehabilitation was explored in 8 case subjects with chronic dysphagia matched to 16 control patients who had received traditional therapy with swallowing maneuvers taught with the adjunctive biofeedback (traditional therapy with biofeedback group). Patient details are summarized in table 1. Data for this study were retrospectively extracted from computerized existing datasets. Each case subject was individually matched to 2 separate controls for age, sex, and primary medical diagnosis. All treatment was conducted at the same academic hospital in the outpatient swallowing disorders clinic.

Case Subjects

Case patients were those who entered the McNeill Dysphagia Therapy Program from September 2006 to October 2008. All patients in this program presented to an academic outpatient swallowing clinic and were screened for inclusion in the program. Selection of participants was based on the following criteria: chronic impairment of swallowing (≥6 mo), age less than or equal to 90 years at onset of treatment, physician referral stating stable medical condition and ability to participate in an exercise-based treatment program, Mini-Mental State Examination[20] score greater than or equal to 23, significant limitation in functional oral intake of food and liquid (FOIS<5),[21] and biomechanical evidence of pharyngeal dysphagia per clinician judgment from videofluoroscopic examination. Biomechanical evidence of pharyngeal dysphagia was characterized by the presence of reduced hyolaryngeal elevation, reduced pharyngeal constriction, and/or reduced pharyngoesophageal segment opening. In addition, all case patients had failed to respond to a previous trial of traditional swallowing therapy. Similarly, no swallowing therapy was to have been provided to any patient within the preceding 3 months of participation in the treatment study. Finally, all patients enrolled in this study were willing and able to attend daily treatment sessions for up to 3 weeks.

Table 1: Group Characteristics

Variable	Case	Control	Significance
Sex (M:F)	2:6	4:12	Matched
Diagnosis			matched
H/N ca	6	12	
Neurologic	2	4	
Duration of dysphagia (mo)	45.1 (25.9)	13.87 (14.6)	$P<.002$*
Prior failed therapy (count)	8	5	$P<.001$†
MASA score, mean ± SD	156.6±13.5	157.9±10.6	NS
FOIS, median (range)	2 (1–4)	2 (1–4)	NS
Presence of gastrostomy tube (PEG-tube)	75% (6/8)	81% (13/16)	NS
Presence of aspiration	75% (6/8)	68% (11/16)	NS
Total no. of sessions, mean ± SD	12.37±2	19.68±3	NS

Abbreviations: F, female; H/N ca, head/neck cancer; M, male; MASA, Mann Assessment of Swallowing Ability; NS, not significant.
*Mann-Whitney *U* test.
†Chi-square test.

Control Subjects

The control subjects were also outpatients who had entered traditional therapy with biofeedback therapy from the same academic outpatient swallowing clinic from February 1994 to June 1999. Control subjects demonstrated the following criteria for entry into that program: chronic impairment of swallowing (≥6mo), age less than or equal to 90 years at onset of treatment, physician referral stating stable medical condition and ability to participate in an exercise-based treatment program, adequate cognitive function to facilitate participation in a therapy program, significant limitation in functional oral intake of food and liquid, and biomechanical evidence of pharyngeal dysphagia per clinician judgment from videofluoroscopic examination.

The local institutional review board approved the study.

Baseline Measures

Prior to initiation of the intervention, each subject (case and control) underwent a baseline evaluation to evaluate inclusion criteria and to obtain pretherapy outcome measures. As indicated under the previous section, Case Subjects, the FOIS was administered to ascertain the degree of functional limitation in oral intake of food/liquid.[21] This scale was also employed as an outcome assessment. Other baseline measures of outcome included clinical and instrumental swallowing evaluation. Clinical assessment of swallowing ability was completed using either the Clinical Dysphagia Examination for control subjects[22] or the Mann Assessment of Swallowing Ability[23] for case subjects. Psychometric properties of both examinations

have been previously published[23,24-27] (Mann Assessment of Swallowing Ability: sensitivity=73, specificity=89, positive likelihood ratio=6.6, negative likelihood ratio=.30; Clinical Dysphagia Examination: sensitivity=80, specificity=61, positive likelihood ratio=2.06, negative likelihood ratio=.33). Both clinical assessment protocols contained similar items, and thus assessments performed using the Clinical Dysphagia Examination were translated into Mann Assessment of Swallowing Ability scores to facilitate comparison. A comparison of translation between 2 raters demonstrated adequate representation validity (content validity ratio=.835[28]) and concurrent validity (Passing and Bablock regression coefficient[29] A=−7.4 (95% CI, −23.3–2.3), B=0.2 (95% CI, .143–.29) indicating acceptable agreement between assessment methods. In addition, strong concordance for this procedure was established (Kendall τ=.98). Instrumental swallowing evaluation was completed via a standard videofluoroscopic swallowing evaluation. Imaging studies were used to confirm the presence of pharyngeal dysphagia, identify the most appropriate food/liquid to be used in therapy, and/or document specific conditions and indicators of airway compromise for each subject. Both subject groups (case and control) used the same contrast materials and volumes in the instrumental study, including administration of 5-mL to 10-mL boluses of thin liquid, thick liquid, and pudding and a cracker, cup, or straw as was appropriate for each subject. Each subject was evaluated for movement characteristics during swallowing, residue after swallows, and any evidence of airway compromise (penetration into the endolarynx or aspiration into the subglottic trachea). Reliability of the videofluoroscopic evaluation procedure was established via a comparison of 2 independent reviewers. Specific information from these assessments (clinical signs of airway compromise, type and amount of material to initiate therapy) was provided to each treating clinician prior to the swallowing treatment.

Intervention: Cases

Treatment sessions for case subjects were conducted for 1 hour a day, 5 days a week for a maximum of 3 weeks or for 15 sessions. If the case subject reached an adequate level of functional oral intake (FOIS 6), treatment could be terminated before completing all 15 sessions.

Intervention: Controls

Control subjects also received treatment for 1 hour a day, 5 days a week. However, control subjects could be treated for shorter or longer periods if required. Two control subjects also received therapy on an alternating day schedule (n=3/wk).

Treatment Protocol: McNeill Dysphagia Therapy Program

All McNeill Dysphagia Therapy Program treatment sessions followed a standard protocol as previously described.[19] In this protocol, a single swallowing strategy was taught to the patient to facilitate swallowing attempts, the criteria and steps for advancement were predetermined, and the program hierarchically incorporated advancing steps of altered bolus volume, bolus consistency, eating rate, and amount of oral intake.

Treatment Protocol: Traditional Therapy With Biofeedback

Treatment with traditional therapy with biofeedback followed a sequence of electrode placement, determining a threshold for effort, instructing in a maneuver or compensation (most commonly the Mendelsohn maneuver or effortful/hard swallow), and recording progress on reaching the assigned sEMG threshold. A comparison of the 2 treatment approaches is presented in table 2.

Performance Monitoring

During both treatment programs, the treating clinicians recorded successful swallow attempts. Successful swallow attempts were characterized by the absence of expectoration or clinical signs of aspiration. In addition, the treating clinician recorded the bolus types attempted and events of coughing, throat clearing, expectoration, and/or other clinical signs of

Table 2: Comparison of Treatment Techniques

Variable	Trad/Bio (sEMG)	MDTP
Admission to program	No control of duration or severity of dysphagia prior to entry	Chronic dysphagia (≥6mo) Failed previous swallow therapy
Average no. of swallows/trial	4.6	10
Mean duration of session (min)	60	60
Mean no. of swallows/session	32	91
Length of program	4–5d/wk Average of 12.37 sessions	5d/wk Average of 19.68 sessions
Volumes trialed in Tx (mL)	1, 3, 5, 10, 20	5, 10
Bolus progression	Variable—no clear progression, increasing patient tolerance only	Organized bolus progression, standard criteria for progression
Monitoring variables		
Cough	Monitors cough, monitors sEMG threshold	Monitors clinical indicator of aspiration
Expectoration	Allows expectoration	Does not allow expectoration
Emphasis	Focus on the swallow maneuvers (eg, Mendelsohn, effortful swallow), sEMG threshold (μV)	Focus on swallow form, number of swallows (repetition), load (bolus type), frequency of swallows
Performance measure	Percentage of success reaching sEMG threshold	No evidence of clinical signs aspiration/expectoration (8/10) on swallow
Compensations	Allows/promotes use of chin tuck, head turn, and so forth	No maneuvers or compensations used
Home practice	Variable—not mandatory	Daily prescribed home practice
Termination criteria	No clear criteria	FOIS 6 or 15 sessions completed

Abbreviations: MDTP, McNeill Dysphagia Therapy Program; Trad/bio group, traditional therapy with biofeedback group; Tx, treatment.

struggle. In the traditional therapy with biofeedback subjects, success reaching the target sEMG threshold was also recorded.

Home Practice

Subjects in both treatment approaches were encouraged to complete dietary records of all food or liquid substances consumed at home. In the McNeill Dysphagia Therapy Program arm, the treating clinician collected dietary records at the beginning of each subsequent treatment session. These records were reviewed for patient compliance with the treatment protocol and to identify any difficulties with these materials that might have been encountered in the home environment. In the traditional therapy with biofeedback group, voluntary home practice was reviewed but was not mandatory and was not systematically incorporated into the treatment protocol.

Masking/Blinding

For the purpose of this study, an independent research assistant paired and matched the subjects by age, sex, and reported primary diagnosis without specific knowledge of the aims of this study. The data recorder and outcome assessors for this study were also blind to the case status of each subject. All swallowing therapy offered in both intervention groups (case and control) was administered independently by speech-language pathologists who conducted therapy sessions as per the defined treatment protocols.

Posttreatment Follow-Up

At the completion of the therapy period, all baseline evaluations were repeated to assess immediate posttreatment outcome. All subjects were evaluated clinically using the same scales used in the baseline assessment and underwent a repeat videofluoroscopic swallow examination. Data were complete for 100% of cases and controls.

Clinical Outcome of Treatment

The primary outcome measure for this study was the proportion of patients who improved in clinical swallowing ability and functional oral intake level after treatment. Dysphagia recovery was defined a priori as composite of FOIS greater than 5 and/or Mann Assessment of Swallowing Ability change greater than 10 points. This composite has been shown in previous studies to reflect meaningful clinical change in swallowing ability after dysphagia intervention.[19,21] Secondary outcome measures included the presence (or not) of tube feeding after treatment; descriptive change in swallow movements; and occurrence of residue, penetration, or aspiration observed on videofluorographic swallowing studies obtained before and after therapy.

Statistical Analysis

Group demographics were reviewed using descriptive methods. Primary statistical analysis considered the effect of treatment type on the resolution of dysphagia, defined by an FOIS greater than 5 and a greater than 10-point improvement in Mann Assessment of Swallowing Ability score. A matched pair analysis (Mantel-Haenszel adjusted OR[30]) was conducted on the primary and secondary dichotomous outcomes. Differences between performance noted on pretreatment and posttreatment evaluation for continuous measures were reviewed using *t* tests and nonparametric Mann-Whitney *U* tests for nonnormally distributed samples.

Rater reliability for videofluoroscopic analysis was conducted using responses from 2 blind reviewers on the VFE protocol[24] and analyzed using the weighted kappa for ordinal responses.[31]

RESULTS

Baseline Characteristics

Eight patients undergoing McNeill Dysphagia Therapy Program treatment were individually matched to 2 control subjects who had received traditional therapy with biofeedback therapy, resulting in 16 pairs. Eighteen subjects were men and 6 were women. The mean age ± SD of the group as a whole was 58.9±16.7 years (range, 20–70y). All the subjects were considered to have significant dysphagia (median FOIS level=2; range, 1–4) on enrollment in treatment, and all were cognitively able to participate in active swallowing rehabilitation. As a group, all subjects demonstrated complicated medical histories, with the most common precipitating diagnoses being head/neck cancer and stroke (see table 1). At baseline the groups (case and control) did not differ in dysphagia severity as determined by Mann Assessment of Swallowing Ability score or functional oral intake level as determined by the FOIS (see table 1). The mean duration of dysphagia (months) was significantly different between the case group and control subjects ($P<.002$), with the case subjects demonstrating a longer duration of dysphagia on average (45.1 vs 13.87mo). In addition, all of the case subjects had previously received and failed a trial of swallowing therapy, compared with only 5 of the control subjects ($P<.001$).

Outcomes

Clinical dysphagia assessment. The Mann Assessment of Swallowing Ability score differed significantly between the groups from pretreatment to posttreatment assessments ($P<.001$). The mean Mann Assessment of Swallowing Ability score increase ± SD for case subjects was 15.6±6.8, while mean Mann Assessment of Swallowing Ability score change ± SD for controls was 4.7±3.1 (table 3).

Change in functional oral intake [FOIS level]. A total of 21 (87%) of 24 patients increased the range and amount of materials they consumed orally. Case subjects significantly increased their FOIS compared with the control subjects ($P<.038$). Greater than 80% of case subjects raised their FOIS by 3 scale points after treatment. In addition, 66% of non-oral case patients increased oral intake to full oral feeding over the 3-week treatment period. In contrast, only 23% of non-oral control subjects improved to full oral intake.

Table 3: Treatment Outcomes

Outcome Measure	Case	Control	Significance
MASA score (mean ± SD)	175.6 (16.9)	164.2 (11.2)	$P<.001$*
Mean change in MASA score	15.6	4.7	
FOIS, median (range)	5 (2–6)	3 (1–6)	
mean change	3	1.62	$P<.038$†
Aspiration (count), pre/post	6/2	11/7	
Tube presence (count), pre/post	6/2	13/10	
Dysphagia presence (count), pre/post	8/6	16/13	

NOTE. Effect size comparison of group MASA change (Cohen *d*, 2.01 [0.8–3.18]); comparison of group FOIS change (Cohen *d*, .93 [.04–1.82]).
Abbreviation: MASA, Mann Assessment of Swallowing Ability.
**t* test, †Mann-Whitney *U* test.

Table 4: Dichotomous Outcomes Posttreatment

Variable	Adjusted OR (95% CI)	RRR	ARR	NNT	χ^2	Significance
Dysphagia recovery	13 (1.27–63.89)	.69	56%	1.7	6.7	$P \leq .009$
Aspiration	0.33 (0.14–0.52)	.50	25%	4.0	4.57	$P \leq .033$
Tube removal	5 (0.75–33.2)	.60	37%	2.6	4.5	$P \leq .034$

NOTE. Adjusted odds ratio = Mantel-Haenszel matched-pairs analysis.
Abbreviations: ARR, absolute risk reduction; NNT, number needed to treat; RRR, relative risk reduction.

Dysphagia Recovery

Nine of the 24 patients (37%) demonstrated resolution of dysphagia, defined as composite of FOIS greater than 5 and/or Mann Assessment of Swallowing Ability change greater than 10 points over the treatment period. Of these, 75% were case subjects compared with 12% of control subjects. Patients treated with the McNeill Dysphagia Therapy Program experienced a marked increase in the probability of recovery from dysphagia compared with those treated with the traditional/biofeedback therapy (OR=13; 95% CI, 1.27–63.89) (table 4). The relative risk reduction for dysphagia recovery was reduced by 69% in the McNeill Dysphagia Therapy Program group compared with the traditional therapy with biofeedback group. The absolute risk reduction demonstrated that for every 100 patients enrolled in the McNeill Dysphagia Therapy Program, 56 dysphagia cases would be rehabilitated. The number needed to treat to gain benefit with this approach was 1.7 (ie, for every 1.7 patients treated with the McNeill Dysphagia Therapy Program, 1 case of dysphagia would be averted).

Aspiration Reduction

Eight (47%) of 17 patients who aspirated on the pretherapy fluorographic evaluation did not aspirate on the posttherapy evaluation. Four (67%) of 6 case patients and 4 (36%) of 11 control patients eliminated aspiration on the posttherapy evaluation. Patients treated with the McNeill Dysphagia Therapy Program approach demonstrated a significant reduction in the presence of aspiration after treatment (OR=.33; 95% CI, .14–.52). The probability of continued aspiration if treated with the McNeill Dysphagia Therapy Program was 35% versus 62% if treated with the traditional therapy with biofeedback (see table 4).

Elimination of Tube Feeding

Seven (37%) of 19 patients were able to discontinue tube feeding after swallowing treatment. Four (67%) of 6 case patients and 3 (27%) of 11 control patients discontinued tube feeding after therapy. Participation in the McNeill Dysphagia Therapy Program group was associated with an increased probability of feeding tube removal (OR=5; 95% CI, .75–33.2). The probability of continued tube feeding if treated with the McNeill Dysphagia Therapy Program was 25% compared with 62% if treated with the traditional therapy with biofeedback approach (see table 4).

Change in Instrumental Swallowing Studies

Most patients (79%; 19/24) demonstrated change on videofluorographic swallowing examination after therapy. Only 5 patients (all within the control group) demonstrated no change on videofluorographic swallowing study. All case patients demonstrated change on the videofluorographic swallowing study. The most commonly reported changes included improved hyolaryngeal movement, reduced pharyngeal residue, increased movement of base of tongue movement, and reduced penetration and aspiration events. Interrater reliability between independent judges for videofluorographic analysis overall was very good (κ=.912; SE=.053).

Complications

Both the McNeill Dysphagia Therapy Program and traditional therapy with biofeedback protocols used were well tolerated by all the patients. No patient experienced any major swallowing-related medical complication over the treatment period. All patients in the McNeill Dysphagia Therapy Program group received posttreatment follow-up reassessment. Subjects in the traditional therapy with biofeedback group did not routinely return for follow-up appointments.

DISCUSSION

This study demonstrates that the McNeill Dysphagia Therapy Program produced superior outcomes compared with a matched group of subjects receiving traditional swallowing therapy taught with sEMG biofeedback in clinical and functional swallowing ability without significant complication. Few well controlled clinical treatment studies are currently published on swallowing therapy protocols. Available studies consistently report swallowing improvement after treatment. In concordance with these studies, our study has also demonstrated a positive effect on swallowing ability in both case and control subjects after treatment. The current study also demonstrated swallowing improvement from both interventions; however, improvement after the McNeill Dysphagia Therapy Program was superior in all measured outcomes to traditional maneuvers supplemented with sEMG biofeedback.

Many factors may account for the superior clinical and functional gains realized by the case subjects in this study. As evidenced from the treatment comparison depicted in table 2, the McNeill Dysphagia Therapy Program provides greater intensity and opportunity for practice of swallowing behaviors than the traditional therapy form. Specifically, the McNeill Dysphagia Therapy Program provides greater demand for number of swallows per bolus attempt, mean number of swallows a session, and mandatory home practice. Beyond this, the McNeill Dysphagia Therapy Program incorporates progressive strengthening, development of movement patterns, and refinement of coordination of the muscular components of the swallowing process. Compared to traditional therapy, these McNeill Dysphagia Therapy Program features offer a more systematic approach to swallowing rehabilitation founded in exercise physiology principles.

The traditional therapy with biofeedback approach performed in this study consisted of swallowing maneuvers (most commonly the Mendelsohn maneuver and the effortful swallow technique) and bolus attempts paired with surface electromyographic biofeedback. While this therapy format was considered at the time (1994–1999) to be progressive and intense, it is conceivable that practice patterns regarding the traditional therapy may have altered since its administration, resulting in a biased or inadequate comparator. However, in reviewing recent survey publications of dysphagia therapy practice patterns, this notion appears to be unsupported. In 2007, a descriptive survey of dysphagia practice patterns reported that most respondents (>480) conducted swallowing therapy using a combination of multiple techniques (>90% maneuvers).[32] Further, interventions lasted a mean of 1 hour, 3 times a week, for an average

of 11 to 15 sessions. In addition, limited criteria for the application of treatments, use of multiple combined maneuvers (eg, Mendelsohn, effortful swallow, thermal tactile stimulation), and lack of standardized follow-up of patients was common. Similarly, in a 2009 online survey of intervention by American Speech-Language-Hearing Association (ASHA) dysphagia interest group members (n=215)[33] and a systematic review of dysphagia treatment,[34] the Mendelsohn maneuver was reported as a primary treatment mode by greater than 90% of respondents. Moreover, this form of therapy produced a reported effect size of relative risk equal to 2.2 (95% CI, 1.4–3.5). Consequently, data currently available on dysphagia intervention practices appear consistent with the description of our traditional therapy with biofeedback group (see table 2).

The subjects (McNeill Dysphagia Therapy Program and control groups) in this study included patients with chronic dysphagia referred for outpatient dysphagia treatment. While this type of patient is typical of most outpatient dysphagia practices, it in no way denotes the type of patient that can be treated by the McNeill Dysphagia Therapy Program. Like most forms of dysphagia intervention, the McNeill Dysphagia Therapy Program can be used with patients demonstrating all severities of swallowing impairment who are deemed ready to undertake a trial of swallowing therapy. In the McNeill Dysphagia Therapy Program, several clinical indicators of dysphagia are used for decision-making within therapy sessions. Correspondingly, issues of cognitive capacity, airway competency, and motivation can be managed within the program, not unlike other swallowing intervention methods.[19]

Study Limitations

Case-control studies offer a degree of design control and are frequently used with rare clinical problems or limited observations; however, case-control designs are not without limitations. Case-control studies are valuable only if the case definition is precise and often raise issues of patient selection and comparability with other populations. However, they offer a practical and more rapid method of evaluating in a controlled manner information in support of a therapeutic strategy. Case-control studies represent a moderate level of evidence for treatment (3b),[35] and as such, we believe that this design is appropriate for the initial phases of scientific evaluation of the McNeill Dysphagia Therapy Program. Despite small samples, the large effect size from our primary outcomes suggests a meaningful clinical effect. Similarly, the consistency of results across several outcome measures (ie, all favoring the McNeill Dysphagia Therapy Program) supports a strong treatment effect.

Given the retrospective design employed, the impact of selection or recall bias cannot be excluded from this study.[36] However, data from both groups were collected independently and entered into independent datasets at the time of each subject's treatment. Likewise, the data extractor who matched the patients for age, sex, and primary diagnosis was blind to the aims and analysis of the study. Further, although control of confounders was achieved via the study design, simultaneous multivariate modeling was precluded because of sample size limitation. Finally, specific questions such as the particular characteristics of dysphagia that are modified by the McNeill Dysphagia Therapy Program and the impact of amount of treatment are important issues to address with future prospective clinical research efforts.

The strengths of this study include the standardization of treatment procedures and outcome assessment, blinding of data extraction, minimization of observer bias in outcome evaluation, 2:1 control to case matching, and the inclusion of multiple outcome measures that reduce the potential for the chance to influence the obtained outcomes. Moreover, the focus on a diverse sample of patients with chronic dysphagia (in both groups) who were not receiving additional treatments minimizes the influence of spontaneous recovery or cross-stimulation by co-occurring therapies and offers potential external generalization of this approach.

CONCLUSIONS

Results from this pair-matched case-control study of subjects treated with a novel and standardized intervention protocol suggest superior outcomes in clinical, functional, and physiological swallowing characteristics. Patients treated with the McNeill Dysphagia Therapy Program were 13 times more likely to improve their swallowing ability compared with a matched control. Case subjects treated with the McNeill Dysphagia Therapy Program demonstrated superior improvement to traditional techniques taught with adjunctive sEMG biofeedback across several clinical and functional swallowing measures after intervention. This controlled design constitutes preliminary evidence of treatment effectiveness using this new interventional protocol.

References

1. Logemann J. Evaluation and treatment of swallowing disorders. San Diego: College Hill Pr; 1983.
2. Logemann J, Kahrilas P. Relearning to swallow after stroke—application of maneuvers and indirect biofeedback: a case study. Neurology 1990;40:1136-8.
3. Neumann S. Swallowing therapy with neurologic patients: results of direct and indirect therapy methods in 66 patients suffering from neurological disorders. Dysphagia 1993;8:150-3.
4. Crary M. A direct intervention program for chronic neurogenic dysphagia secondary to brainstem stroke. Dysphagia 1995;10:6-18.
5. Crary MA, Baldwin BO. Surface electromyographic characteristics of swallowing in dysphagia secondary to brainstem stroke. Dysphagia 1997;12:180-7.
6. Horner J, Massey EW, Riski JE, Lathrop DL, Chase KN. Aspiration following stroke: clinical correlates and outcome. Neurology 1988;38:1359-62.
7. Odderson IR, Keaton JC, McKenna BS. Swallow management in patients on an acute stroke pathway: quality is cost effective. Arch Phys Med Rehabil 1995;76:1130-3.
8. Langemore S. Evaluation of oropharyngeal dysphagia: which diagnostic tool is superior? Curr Opin Otolaryngol Head Neck Surg 2003;11:485-9.
9. Robbins J, Butler SG, Daniels SK, et al. Swallowing and dysphagia rehabilitation: translating principles of neural plasticity into clinically oriented evidence. J Speech Lang Hear Res 2008;51: S276-300.
10. Bryant M. Biofeedback in the treatment of a selected dysphagic patient. Dysphagia 1991;6:140-4.
11. Huckabee M, Cannito M. Outcomes of swallowing rehabilitation in chronic brainstem dysphagia: a retrospective evaluation. Dysphagia 1999;14:93-109.
12. Crary MA, Carnaby-Mann GD, Groher ME, Helseth E. Functional benefits of dysphagia therapy using adjunctive sEMG biofeedback. Dysphagia 2004;19:160-4.
13. Crary MA, Carnaby-Mann GD, Groher ME. Biomechanical correlates of surface electromyography signals obtained during swallowing by healthy adults. J Speech Lang Hear Res 2006;49:186-93.
14. Crary MA, Carnaby-Mann GD, Groher ME. Identification of swallowing events from sEMG signals obtained from healthy adults. Dysphagia 2007;22:94-9. Epub 2007 Feb 9.

15. Haynes SN. Electromyographic biofeedback treatment of a woman with chronic dysphagia. Biofeedback Self Regul 1976;1: 121-6.
16. McKeown MJ, Torpey DC, Ghem WC. Non-invasive monitoring of functionally distinct muscle activations during swallowing. Clin Neurophysiol 2002;113:354-66.
17. Vaiman M, Eviatar E, Segal S. Surface electromyographic studies of swallowing in normal subjects: a review of 440 adults, report 2: quantitative data: amplitude measures. Otolaryngol Head Neck Surg 2004;131:773-80.
18. Vaiman M, Eviatar E, Segal S. Surface electromyographic studies of swallowing in normal subjects: a review of 440 adults, report 1: quantitative data: timing measures. Otolaryngol Head Neck Surg 2004;131:548-55.
19. Carnaby-Mann GD, Crary MA. Adjunctive neuromuscular electrical stimulation for treatment-refractory dysphagia. Ann Otol Rhinol Laryngol 2008;117:279-87.
20. Folstein MF, Folstein SE, McHugh PR. Mini-Mental State: a practical method for grading the state of patients for the clinician. J Psychiatr Res 1975;12:189-98.
21. Crary M, Carnaby-Mann G, Groher G. Initial psychometric assessment of a functional oral intake scale for dysphagia in stroke patients. Arch Phys Med Rehabil 2005;86:1516-20.
22. Crary MA, Gorham MM, Baldwin BO. Relationships between a clinical dysphagia examination (CDE) and fluorographic feeding recommendations [abstract]. Dysphagia 1998;13:124.
23. Mann GD. The Mann assessment of swallowing ability. Clifton Park: Singular Thompson Learning; 2002.
24. Mann G, Hankey G, Cameron D. Swallowing disorders following acute stroke: prevalence and diagnostic accuracy. Cerebrovasc Dis 2000;10:380-6.
25. Mann G, Hankey G. Initial clinical and demographic predictors of swallowing impairment following acute stroke. Dysphagia 2001; 16:208-15.
26. Carnaby-Mann G, Lenius K, Crary M. Update on assessment and management of dysphagia post stroke. Northeast Florida Med 2007;58:31-4.
27. Bours GJ, Speyer R, Lemmens J, Limburg M, deWit R. Bedside screening tests vs. videofluoroscopy or fiberoptic endoscopic evaluation of swallowing to detect dysphagia in patients with neurological disorders: systematic review. J Adv Nurs 2009;65:477-93.
28. Lawshe CH. A quantitative approach to content validity. Pers Psychol 1975;28:563-75.
29. Passing H, Bablock W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. J Clin Chem Clin Biochem 1983;21:709-20.
30. Breslow NE, Day NE. Statistical methods in cancer research, vol. I: the analysis of case-control studies. Lyon: International Agency for Research on Cancer; 1980.
31. Altman DG. Practical statistics for medical research. London: Chapman and Hall; 1991.
32. Crary M, Carnaby-Mann G, Faunce A. Electrical stimulation therapy for dysphagia: descriptive results of two surveys. Dysphagia 2007;22:165-73. Epub 2007 Feb 22.
33. Palmer A. Adult dysphagia rehabilitation survey. 2009. Available at: http://www.ohsu.edu/ent/gen/voice/adult_dysphagia_rehabilitation_survey. Accessed September 12, 2009.
34. Ashford J, McCabe D, Wheeler-Hegland K, et al. Evidence-based systematic review: oropharyngeal dysphagia behavioral treatments, part III—impact of dysphagia treatments on populations with neurological disorders. J Rehabil Res Dev 2009;46:195-204.
35. Oxford Centre for Evidence-Based Medicine. Levels of evidence and grades of recommendation. March 2009. Available at: http://www.cebm.net/index.aspx?o=1025. Accessed April 21, 2009.
36. Breslow N, Day N. Statistical methods in cancer research, volume I—the analysis of case-control studies. IARC Sci Publ 1980;32: 5-338.