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ORIGINAL ARTICLE

The Dysphagia in Stroke Protocol Reduces Aspiration Pneumonia in Patients with Dysphagia Following Acute Stroke: a Clinical Audit

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Abstract

Cough reflex testing has been evaluated as a component of the clinical swallowing assessment as a means of identifying patients at risk of aspiration during swallowing. A previous study by our research group found good sensitivity and specificity of the cough reflex test for identifying patients at risk of aspiration post-stroke, yet its use did not decrease pneumonia rates, contrary to previous reports. The aim of this study was to expand on our earlier work by implementing a clinical management protocol incorporating cough reflex testing within the same healthcare setting and compare patient outcomes to those from the original study and to evaluate clinical outcomes in patients with acute stroke who were managed using the Dysphagia in Stroke Protocol (DiSP). Secondarily, to compare those outcomes to historical data prior to implementation of the DiSP. This clinical audit measured outcomes from 284 patients with acute stroke managed per the DiSP, which guides use of videofluoroscopic swallowing study and patient management based on clinical exam with cough reflex testing. Data from our previous trial were included for comparison of pre- and post-DiSP patient outcomes. Data collection took place between November 2012 and April 2016 at four urban hospitals within New Zealand. Following implementation of the DiSP, the rate of aspiration pneumonia (10%) was substantially lower than the pre-DiSP rate (28%), with no pneumonia readmissions within 3 months. Pneumonia-related mortality was unchanged. By 3 months, 81% of the patients were on a normal diet and 67% had returned home, compared to pre-DiSP outcomes of 55% and 55% respectively. Previous work has suggested that simply implementing cough reflex testing in dysphagia management may not be sufficient to improve patient outcomes. The present study adds to this picture by suggesting that the true variable of influence may be the way in which the results of the test are applied to patient care. There is a strong case to support the use of a structured protocol if cough reflex testing is to be implemented in clinical practice.

Keywords Aspiration pneumonia · Dysphagia · Deglutition · Clinical protocol

Introduction

Swallowing impairment (dysphagia) following stroke represents a substantial health issue. Up to 70% of patients with stroke will be diagnosed with dysphagia [1], with aspiration of pharyngeal contents occurring in up to half [2]. Aspiration is a leading cause of pneumonia and has an odds ratio for death of 4.4 [3]. Clinical identification of aspiration is unreliable [4–6], complicated by 'silent aspiration', defined as aspiration in the absence of a protective coughing response. Silent aspiration affects between 42% and 67% of patients [6, 7].

While over 35 published dysphagia screening tools exist, few meet the criteria of reliability, validity and ease-of-use. Of those that do, none satisfactorily consider silent aspiration. For example, the Modified Mann Assessment of Swallowing Ability [8] and the Emergency Physician Dysphagia Screening [9] tools evaluate voluntary, but not reflexive, cough. The Barnes Jewish Hospital Stroke Dysphagia Screen [10], Toronto Bedside Swallowing Screening Test [11], Yale Swallow Protocol [12] and the 3-ounce water swallow test [13] account for overt aspiration, yet a patient with silent aspiration could conceivably pass these screening procedures if post-swallow vocal quality was clear.

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In response to this issue, several research groups have investigated the effectiveness of cough reflex testing (CRT) to identify patients with silent aspiration [14–19]. This test involves inhalation of a tussive agent delivered via nebulised air. Absence of coughing suggests an impairment of laryngeal sensorimotor response. For detecting silent aspiration, CRT has a reported sensitivity between 0.70 and 0.87 [15, 18, 20, 21] and specificity 0.65 to 0.89 [15, 18, 20, 21]. A study by Guillén-Solà et al. [19] is an exception, with sensitivity at 0.19. Methodological limitations, including possible selection bias and the use of pulse oximetry to determine study inclusion, may explain this finding.

Addington et al. [14] reported lower pneumonia rates using CRT when using a fairly rigid protocol for allowing post-testing oral intake; however, administering CRT via a mouthpiece excluded patients who could not achieve a lip seal. Our research group followed with a randomised controlled trial of CRT administered via facemask for post-stroke dysphagia assessment [17]. In this study, clinicians were encouraged to incorporate findings from CRT into clinical decision making; however, no structured protocol was in place. Sensitivity and specificity for detecting aspiration were 71% and 60%, respectively [18]. Despite this, Miles et al. [17] found no reduction in pneumonia or mortality among patients who received CRT. Heavy reliance on clinician judgement in the absence of a management protocol may have accounted for these results [17]. This prompted careful consideration of how CRT should be translated into clinical routine and the development of a standardised management protocol: the Dysphagia in Stroke Protocol (DiSP). The present study sought to evaluate the effects of the DiSP on clinical outcomes in patients with acute stroke in the same healthcare setting as the Miles et al. [17] study, and compare the outcomes to our historical data.

Methods

The DiSP was incorporated into clinical routine in the same metropolitan hospital that was previously involved in a clinical trial of CRT, published as Miles et al. [17]. Because CRT was already firmly established at this hospital, a controlled trial was not possible. For this reason, an observational study of the DiSP was undertaken as a step in this translational research programme. An a priori sample size of 284 participants was calculated for an estimated effect size of 0.4 and 90% statistical power ($p < .05$). Data collection took place between November 2012 and April 2016 at four urban hospitals within New Zealand. Patients with acute stroke who were referred for swallowing evaluation were prospectively recruited (for recruitment details, see Fig. 1). Patients referred for palliative swallowing advice were excluded. Appropriate ethical approval was received and all patients provided informed consent or consent by proxy.

The DiSP is conceptualised in Fig. 2. Training to the protocol consisted of 8 h of formal training on CRT procedures/interpretation, as well as written protocols and procedural management flowcharts. Clinicians of all experience levels performed the DiSP, provided they were competent in performing/interpreting instrumental and clinical swallowing assessments.

CRT is a validated tool and is utilised in the DiSP as per published methods [17]. Citric acid diluted in 0.9% sodium chloride is prepared at two doses: 0.8 mol/L at which 90% of healthy adults cough [22] and 1.2 mol/L at which 96% of people can no longer suppress coughing [22]. Citric acid is delivered via a facemask (Hudson Micro Mist Nebuliser Standard Connector & Adult Mask, Hudson RCI, NC, USA) during tidal breathing. The facemask is connected to a Turboneb 2 Nebuliser (Clement Clarke International Limited, Harlow, UK) with an obstructed flow rate of 6.6 L/min. Initially, a placebo dose of 0.9% sodium chloride is presented to acclimate the patient to the presentation of nebulised air. Citric acid (0.8 mol/L) is then presented for up to 15 s with the instruction: 'Breathe normally through your mouth. Cough if you need to'. During this time, coughing presence/absence and a subjective judgement of coughing strength (strong/weak) are noted. The test is performed up to three times at this dose, with at least 30 s between presentations to prevent tachyphylaxis. Two or more consecutive 'strong' coughs (C2 response threshold) triggered on two out of three trials is considered a positive response. The patient is then instructed to 'Try not to cough' while receiving the same dose. If the patient suppresses coughing on two out of three trials, the test is repeated using the higher dose (1.2 mol/L). A patient passes the CRT if they cough strongly to 0.8 mol/L citric acid and cannot suppress coughing at either 0.8 or 1.2 mol/L. A patient fails the CRT if they cough weakly to 0.8 mol/L or can suppress coughing at 1.2 mol/L.

As per the DiSP, patients who passed the CRT proceeded to an evaluation of oral intake, with subsequent management decisions determined by the SLP and multi-disciplinary team. Patients who failed the CRT remained non-oral and were immediately referred for a videofluoroscopic swallowing study (VFSS).

Following the VFSS, oral intake recommendations were determined by the patient's response to aspiration. Patients who silently aspirated remained non-oral with alternative nutrition/hydration provided until recovery of the cough reflex or resolution of aspiration (as determined by repeat CRT/VFSS). Patients who aspirated with an ineffective cough remained non-oral for the aspirated texture. Patients who did not aspirate, or who aspirated with an effective cough were recommended an appropriate diet.

The following outcomes were measured at 3 months post-stroke: development of AP, mortality, length of hospital stay, post-stroke domicile and readmission to hospital with

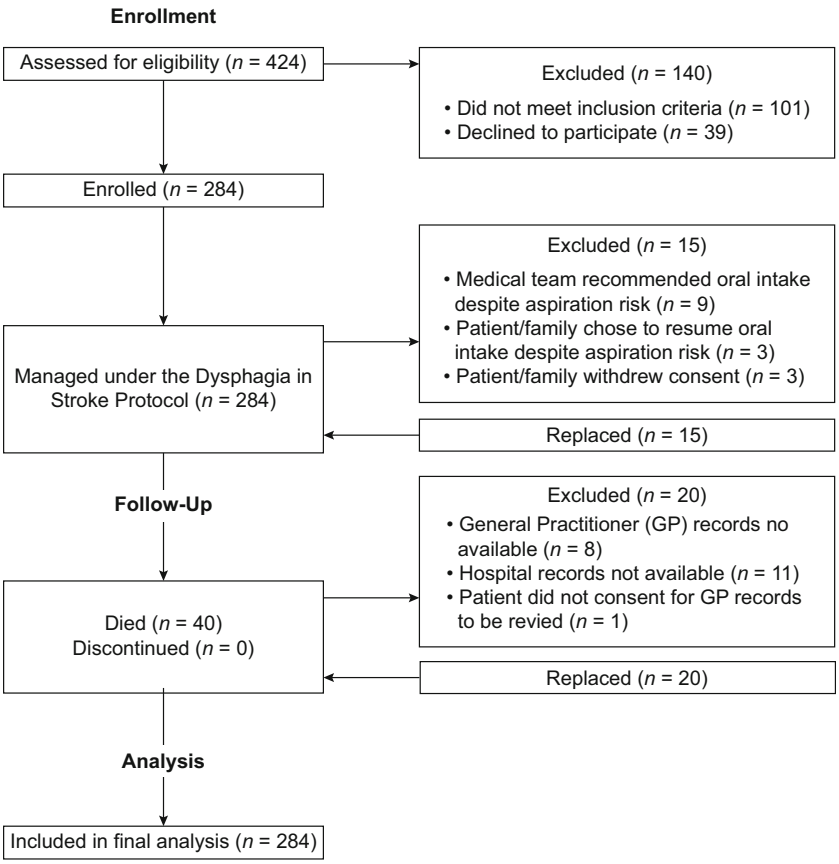

Fig. 1 Details of study recruitment. CRT, cough reflex test

pneumonia. Clinical decision parameters were also examined, including referral for VFSS and diet recommendations. The diagnosis of AP was based on the presence of three or more of the following: fever (> 38 °C), abnormal chest examination (tachypnea [> 22 breaths/min], tachycardia, inspiratory crackles, bronchial breathing), productive coughing with purulent sputum, abnormal chest X-ray, arterial hypoxemia (PO_2 < 70 mmHg) and detection of a relevant pathogen (positive gram stain and culture) [23]. Diets were categorised as tube-fed with no/minimal oral intake, modified oral diet ± supplemental tube feeding, or normal.

Statistical analyses were completed using SPSS (IBM Corp. Released 2015. IBM SPSS Statistics for Mac, Version 23.0. Armonk, NY, USA). Patient outcomes were evaluated with descriptive statistics. Comparative descriptive statistics are also presented from an historical cohort of 148 patients from four metropolitan hospitals—including the hospital from the present study—who had recruited patients to a previous trial of CRT [17]. Historical patients underwent identical clinical evaluations to patients in the present audit, with the exception that decisions regarding swallowing management were left to the discretion of the clinician in the absence of a protocol. Bivariate statistics were used to determine which factors were associated with three functional outcomes (dependant variables): AP, mortality, and AP-related mortality. Only those variables with a significance of $p < .05$ were included in multivariate logistic regression models to predict the probability of specific factors being associated with functional outcomes while controlling for the other variables, including demographics and clinical decisions as reported in Table 2. Statistical significance was set at the .05 level. Adjusted odds ratios (OR) and associated 95% confidence intervals were used to quantify the relationships.

Results

Outcomes from 284 patients were collected. Baseline demographic and clinical features of the patients are shown in Table 1. Clinical outcomes are shown in Table 2. Comparisons to historical data are displayed in Table 3.

The rate of AP was 10%, substantially lower than the previously reported rate of 28% [17]. AP was not associated with passing or failing the CRT ($p = .98$). Patient mortality was slightly lower (14%) compared to that of historical figures (16%). Advanced age (OR = 1.07, 95% CI 1.00–1.13, $b = .06$, $p = .05$) and increased number of days on the acute ward (OR = 1.21, 95% CI 1.06–1.40, $b = .19$, $p = .004$) significantly predicted mortality. Pneumonia-related mortality was 6%, similar to that of historical figures (5%). No variables in

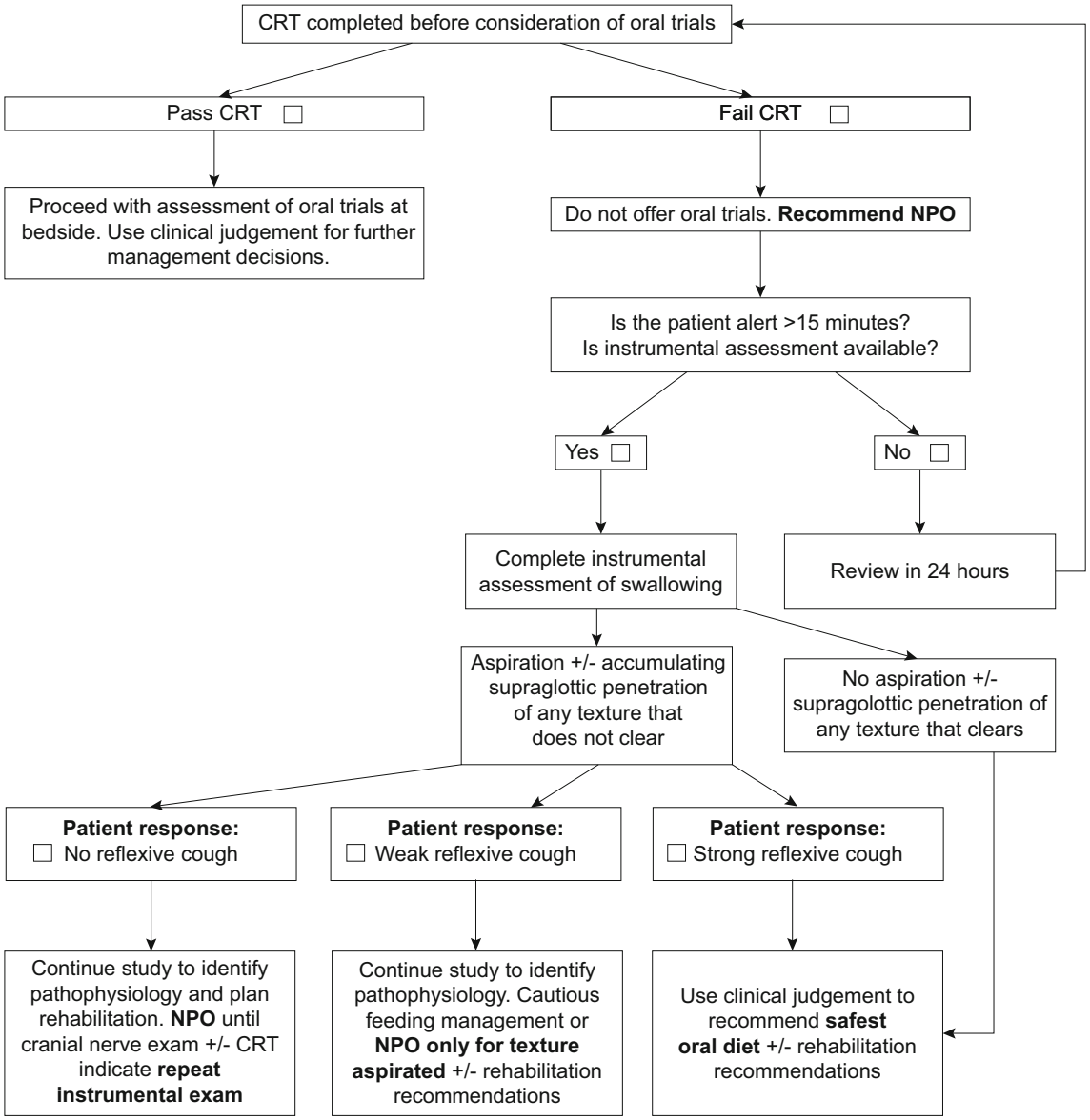

Fig. 2 The Dysphagia in Stroke Protocol. CRT, cough reflex test; NPO, nil per orem

the regression model emerged as significantly associated with pneumonia-related mortality.

Patients' swallowing was assessed within 1 day (on average) of admission to hospital. The majority of patients (64%) immediately resumed oral intake with 32% resuming a normal diet. The DiSP delayed the resumption of normal oral intake for nine patients (3%) for an average of 1.4 days, during which time enteral hydration and administration of medication via alternative routes was provided. Five patients (2%) who passed the CRT and were recommended a normal diet developed AP.

Nearly one-third (31%) of patients were referred for instrumental assessment of swallowing. This figure is substantially greater than that of historical data (18%). The average wait time for VFSS was 2 days (SE = 0.46) for DiSP patients, compared to 9 days (SE = 1.67) for historical patients [$t(30) = 3.57$, $p = .001$, $r = .55$]. The referral rate for VFSS following a failed CRT was 95% for DiSP patients, compared to 46% that for historical patients. Following a passed CRT, the referral rate was 16% for DiSP patients, compared to 8% that for historical patients.

Patients spent fewer days on an acute stroke ward [$\bar{x}$ = 6 days] compared to historical patients [$\bar{x}$ = 9 days]. Similarly, patients also spent fewer days in hospital (acute + rehabilitation [$\bar{x}$ = 24 days]) compared to historical patients [$\bar{x}$ = 32 days]. Patients who died during hospitalisation were excluded from LOS analysis ($n = 14$). No DiSP patients were readmitted to hospital with AP during the audit, compared to a historical 5% readmission rate over the same length of time.

At 3 months, only a single patient was tube-fed (0.5%). The majority of patients (81%) were on a normal diet, with 19% on a modified oral diet. Patients who had died ($n = 40$) or who were lost to follow-up ($n = 29$) were excluded from this analysis. By contrast, three historical patients (2%) were tube-fed,

Table 1 Patient demographics

Demographics	DiSP ($n = 284$)	Historical ($n = 148$)
Age	Mean 76 years (SD = 12)	Mean 76 years (SD = 15)
Male	143 (50%)	78 (53%)
Ethnicity		
Caucasian	260 (92%)	111 (75%)
New Zealand Maori	8 (3%)	16 (11%)
Pacific Islander	7 (2%)	13 (9%)
Other	11 (4%)	8 (5%)
Comorbidities		
Previous stroke	82 (29%)	44 (30%)
Respiratory comorbidities	52 (18%)	15 (10%)
Cardiac comorbidities	155 (55%)	103 (70%)
Site of lesion		
Supratentorial	241 (85%)	128 (86%)
Infratentorial	30 (11%)	11 (7%)
Mixed	4 (1%)	1 (1%)
Not reported	9 (3%)	8 (5%)
Laterality of lesion		
Left	116 (41%)	69 (47%)
Right	138 (49%)	64 (43%)
Bilateral	16 (6%)	15 (10%)
Not reported	14 (5%)	0 (0%)
Independence upon admission		
Nursing home or hospital	31 (11%)	20 (14%)
Home	253 (89%)	128 (86%)
Response to initial cough reflex test		
Strong coughing (pass)	206 (73%)	91 (61%)
Weak coughing (fail)	40 (14%)	31 (22%)
Absent coughing (fail)	38 (13%)	26 (18%)
Diet following initial assessment		
Non-oral	103 (36%)	43 (29%)
Modified oral	90 (32%)	83 (56%)
Normal oral	91 (32%)	22 (15%)

DiSP Dysphagia in Stroke Protocol, *SD* standard deviation

55% were on a normal diet and 43% were on a modified oral diet.

By 3 months, 145 patients (67%) had returned to their own home, 62 patients (29%) were in a nursing home and 8 patients (4%) remained in hospital. By comparison, 71 patients (55%) in the historical group had returned to their own home by 3 months, 16 patients (13%) were in a nursing and 41 patients (32%) remained in hospital.

Discussion

This translational research programme has provided valuable information regarding the implementation of a novel test into clinical routines. We initially hypothesised that incorporating CRT into clinical routine would improve clinicians' ability to identify patients at risk for aspiration, change clinical decision-making regarding the reinstitution of oral intake and ultimately result in lower rates of aspiration pneumonia. Results from our first randomised controlled trial of CRT [17] in acute stroke suggested that this was not the case, and that rates of aspiration pneumonia were very high. We learned anecdotally from this study that clinicians tended to rely on established practice patterns rather than CRT findings when making clinical decisions.

This prompted careful reconsideration of how CRT should be incorporated into clinical care, and the development of a prescriptive, formal management protocol (the DiSP). The present study assessed the change in clinical outcomes following the implementation of the DiSP in patients with acute stroke. The DiSP provided a decision-making pathway based

Table 2 Factors associated with aspiration pneumonia, mortality and pneumonia-related mortality among DiSP-managed patients

	Aspiration pneumonia			Mortality			Pneumonia-related mortality		
	p value	Adjusted OR	95% CI for OR	*p* value	Adjusted OR	95% CI for OR	*p* value	Adjusted OR	95% CI for OR
Age	.45	1.02	0.97–1.07	.05*	1.07	1.00–1.13	.19	1.06	0.97–1.16
Comorbidities									
Previous stroke	.61	0.75	0.24–2.42	.48	1.47	0.50–4.32	.31	0.32	0.04–2.89
Respiratory comorbidities	.02*	3.65	1.24–10.72	.93	0.94	0.23–3.83	.99	0.00	0.00–0.00
Cardiac comorbidities	.69	1.21	0.47–3.15	.85	0.90	0.30–2.74	.29	0.42	0.08–2.10
Lesion site									
Supratentorial vs. mixed	.87	0.83	0.08–8.57	.18	0.19	0.02–2.12	.39	0.24	0.01–6.10
Infratentorial vs. mixed	.34	0.28	0.02–3.57	.12	0.13	0.01–1.72	.35	0.19	0.01–6.39
Not reported vs. mixed	.89	1.23	0.07–22.45	.69	0.57	0.34–9.50	.70	0.48	0.01–20.31
Response to initial CRT									
Absent cough vs. strong cough	.86	0.85	0.16–4.66	.72	1.41	0.22–9.18	.82	1.41	0.07–27.46
Weak cough vs. strong cough	.94	0.94	0.20–4.47	.68	0.68	0.11–4.37	.84	1.32	0.10–18.15
Diet following initial assessment									
Non-oral vs. normal	.39	1.93	0.43–8.69	.23	3.46	0.46–26.23	.54	2.55	0.13–52.03
Modified oral vs. normal	.88	1.10	0.30–4.05	.12	3.69	.71–19.13	.30	3.47	.33–37.02
Number of days in acute ward[a]	.27	1.08	0.95–1.22	.004*	1.21	1.06–1.37	.76	1.03	.84–1.27
Number of days in hospital (acute + rehabilitation)[a]	< .001*	1.03	1.01–1.04	.75	1.00	0.98–1.03	.99	1.00	0.97–1.03

DiSP Dysphagia in Stroke Protocol, *OR* odds ratio, *CI* confidence interval

*$p < .05$

[a] Excluding patients who had died or were lost to follow-up

Table 3 Comparison of outcomes between DiSP patients and non-protocol-managed (historical) patients

	DiSP group ($n = 284$)	Historical group ($n = 148$)	*p* value
Lost to follow-up	29 (10%)	2 (1.4%)	< .001
Aspiration pneumonia	29 (10%)	41 (28%)	.03
Mortality	40 (14%)	23 (16%)	.37
Pneumonia-related mortality	17 (6%)	7 (5%)	.50
Number of days in acute ward (mean)[a]	6	9	< .001
Number of days in hospital (acute + rehabilitation, mean)[a]	24	32	< .001
Received an instrumental swallowing assessment	88 (31%)	27 (18%)	.005
Readmission to hospital for pneumonia	0 (0%)	7 (5%)	.001
Domicile at 3 months post-stroke[ba]			
Hospital	8 (4%)	41 (32%)	< .001
Nursing home	62 (29%)	16 (13%)	< .001
Home	145 (67%)	71 (55%)	.17
Diet at 3 months post-assessment[a]			
Tube-fed (percutaneous endoscopic gastrostomy tube)	1 (0.5%)	3 (2%)	.15
Modified oral diet	40 (19%)	52 (42%)	< .001
Normal diet	172 (81%)	68 (55%)	< .001

DiSP Dysphagia in Stroke Protocol

[a] Excluding patients who had died or were lost to follow-up

[b] Excluding patients who were not living in their own home pre-stroke

on patients' risk of aspiration as measured using CRT, and response to aspiration as visualised using VFSS. This audit indicates that clinicians were guided towards management decisions that ultimately reduced the rate of AP. This suggests that, although CRT can provide information about aspiration risk, a framework is required for clinicians to incorporate that information into their decision-making.

Findings support previous reports of reduced AP when clinical decision-making pathways are in place for dysphagia screening [24–27] and management [14, 28]. The effectiveness of such pathways may result from the elimination of bias imposed by clinical judgement. The advantage of the DiSP over other published protocols is that it specifically evaluates silent aspiration risk.

DiSP patients experienced substantially lower rates of AP and fewer pneumonia-related readmissions than historical patients. Despite this, only a modest reduction in mortality was observed in those who developed pneumonia. Although the DiSP may help to reduce the incidence of morbidity, once a patient becomes unwell, other healthcare issues and comorbidities determine mortality. To reduce pneumonia-related mortality, additional measures relating to the most vulnerable patients may need investigation. One example is oral hygiene status. AP was not associated with passing/failing the CRT, reinforcing that the appropriate management of patients with aspiration—both silent and overt—is more important than simply identifying potential aspirators.

The DiSP is not considered a screening tool for nurses, as the interpretation of instrumental swallowing assessments is beyond the scope of nursing. However, CRT could be incorporated into existing nurse-led dysphagia screenings as a way of identifying patients who would be appropriate for management under the DiSP.

The DiSP may benefit healthcare providers by reducing pneumonia-related costs. CRT costs less than $6.28 USD per test (cost of face mask, tubing and sterile citric acid) plus a one-off cost of $211 USD per nebuliser. There are increased costs associated with videofluoroscopy; however, a recent cost-analysis model in an acute stroke setting [29] suggests a universal VFSS policy is more cost effective than clinical examination alone/clinical examination plus VFSS. While a policy of universal VFSS for all stroke patients is unlikely to be feasible in many stroke units due to resource limitations, the DiSP offers an alternative by identifying patients who may benefit the most from VFSS, and providing a structured approach to post-VFSS management. These are important implications for the healthcare dollar. Post-stroke pneumonia is associated with a $27,633 USD per patient increase in the cost of care [30]. Extrapolating the results from this study and our earlier study to 100 patients, use of the DiSP would prevent 18 incidents of pneumonia, at a cost savings of $497,394 USD, or $4973.94 per patient. However, the DiSP also increased the rate of VFSS, costing on average $337 USD per patient. Again considering 100 patients, use of the DiSP would result in 13 additional VFSSs, at a total cost of $4381, or an additional $43.81 per patient. Weighing CRT and VFSS costs against the savings associated with reduced AP, overall, there are potential savings of $4923.85 per patient when the DiSP is implemented. A detailed study is needed to confirm the cost-benefit ratio of implementing the DiSP compared with a policy of universal VFSS plus a structured management approach.

This study is not without limitations. First, drawing comparisons to a historical control group adds a clear potential for bias. It is possible that other changes in medical practice (both individual and departmental) account for some of the improved outcomes. However, the major conclusions of the study remain valid because no changes in departmental stroke protocols were implemented during the period between the historical data collection and the present audit, apart from implementation of the DiSP. The design of the present study was unavoidable, given that CRT was firmly established at the study location and valued by clinicians. It is likely that including control patients would have introduced clinician bias, invalidating the results. Future studies that include an active control group are required to draw definitive conclusions about the effectiveness of the DiSP. A second limitation is that the DiSP relies not only on clinicians' to identify presence/absence of cough, but also a clinical judgement of cough strength. Prior research suggests that clinical reliability for this judgement is not strong [31]. This requires further assessment. Additionally, AP is multifactorial and eliminating it requires a multi-faceted approach. Future work may consider including other risk factors for AP, such as poor oral hygiene, mobility and stroke severity. Analysis of stroke severity was not possible in the present study due to inconsistent reporting in patients' medical records, but it recommended for future work in this area.

Summary

Translational research, by definition, involves transitioning novel approaches from the laboratory into the clinical realm in order to improve patient outcomes. This report documents the successful translation of CRT into clinical practice in a setting with a historically high rate of AP. We first showed that the inclusion of CRT alone to identify patients at risk of silent aspiration did not improve patient outcomes [17]. The current study demonstrated that the implementation of a dysphagia protocol based on CRT guided clinicians towards optimal management decisions and resulted in long-term benefit for patients with stroke. A rigorous, randomised controlled trial in a health setting naive to CRT is required to confirm these results, and is a suggested next step in this line of research. Future studies should also continue to refine dysphagia protocols with the view to reducing AP after stroke.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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