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Original article

Clinical decision-making using an assessment protocol of swallowing function after aspiration pneumonia: a comparative retrospective study

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Abstract

Objective: Aspiration pneumonia is a challenge in Japan, with many elderly citizens; however, there are insufficient experts on swallowing. Non-expert doctors may suspend oral intake for an overly long period because of the fear of further aspiration. We devised and modified an assessment protocol for swallowing function with reference to the Japanese and American practical guidelines for dysphagia. This study aimed to demonstrate clinical decision-making using the protocol by reporting the results of decisions on the safe and timely restart of adequate food intake for patients with aspiration pneumonia.

Patients and Methods: This comparative retrospective study included 101 patients hospitalized with aspiration pneumonia between April 2015 and November 2017. We compared the parameters of patients for whom decisions on resumption of oral intake were aided by our protocol against those of patients from the previous year when the protocol was not used. We counted the days until either resumption of oral intake or events of aspiration/choking.

Results: The duration of days until oral intake in the two groups was 1.64 ± 2.34 days in the protocol group (56 patients) and 2.09 ± 2.30 days in the control group (45 patients) (P=0.52). The adverse events of aspiration/choking were less frequent in the protocol group (5 vs. 15, odds ratio (OR) 0.32, P<0.001) as compared to the control group. The protocol group showed a significant reduction in aspiration/choking (OR 0.19, P<0.01).

Conclusion: Clinical decision-making based on the protocol seems to help non-expert doctors make informed decisions regarding resuming oral intake after aspiration pneumonia.

Key words: aspiration pneumonia, dysphagia, swallowing function, geriatric, deglutition

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Introduction

The incidence of aspiration pneumonia (AP) has reportedly increased in Japan, where there are many elderly citizens. Impaired swallowing associated with elderly patients may lead to oral and/or gastric contents entering the lungs, which may especially occur in those with an ineffective cough reflex[1]. Various studies have reported that 5–15% of the community-acquired pneumonia cases have AP[2, 3]. In Japan, AP is common in hospitalized pneumonia, and its incidence in community-acquired pneumonia has been reported to be 60.1%[4]. In a randomized study, supplemental nutrition plus daily oral cleaning was associated with a reduction in the frequency of pneumonia[5]. A focus on oral hygiene has yielded an inconsistent benefit; possibly owing to the issues of study design[6]. Oral rather than tube feeding is preferred, particularly in those who have experienced a stroke, for rehabilitative reasons[1]. Oral feeding may be achieved using a mechanical soft diet with thickened liquids rather than pureed food and thin liquids. Nutritional

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rehabilitation with swallowing exercises and early mobilization may prevent the recurrence of AP in patients with dysphagia[7].

The importance of comprehensive intervention following the clinical pathway of eating and swallowing disorders in elderly patients with dementia was noted in a retrospective historically controlled study[8].

Older adults unable to consume food orally and those with AP have been reported to have a poor clinical course[9]. The adverse effects of delayed resumption of oral intake include prolonged treatment duration and a decline in swallowing ability. In facilities where swallowing experts are insufficient, non-expert doctors may suspend oral intake for an overly long period[9]. Others may have inadequately restarted food intake for fear of further aspiration or choking.

The number of speech therapists in Japan, for example, 21.5 per 100,000 individuals in 2016, is much fewer than that in the United States (53.9 per 100,000 individuals)[10]. Therefore, non-expert physicians have been used in Japan to assess the swallowing function of elderly individuals, including those after AP, aiming to restart oral intake.

We used a protocol for swallowing function (Figure 1) based on existing assessment protocols, the Japanese practical guidelines for dysphagia 2015[11] and American Speech-Language-Hearing Association recommendations for screening of swallowing that could be used by non-experts[12].

This comparative retrospective study aimed to compare the performance of patients for whom clinical decision-making was based on the protocol versus those for whom the protocol was not used. We examined whether the protocol could be used by doctors without specific expertise in swallowing to determine the safe and timely restart of adequate food intake for patients with AP.

Patients and Methods

Design and setting

This was a comparative retrospective study of adult patients (≥18 years) with AP who were admitted to the Department of General Internal Medicine, Akashi Medical Center between April 2015 and November 2017. We compared patients for whom the decision to resume oral intake was based on a protocol and those for whom it was not used. The protocol (Figure 1) was developed through repeated discussions by the Nutrition Support Team, which included a certified expert nurse in dysphagia nursing, based on existing assessment protocols for swallowing function, the Japanese practical guidelines for dysphagia 2015[11] and American Speech-Language-Hearing Association recommendations for screening of swallowing that could be used by non-experts[12]. This protocol included repetitive saliva swallowing test (RSST), modified water swallowing test (MWST), and food testing. The RSST measured the number of repeatable

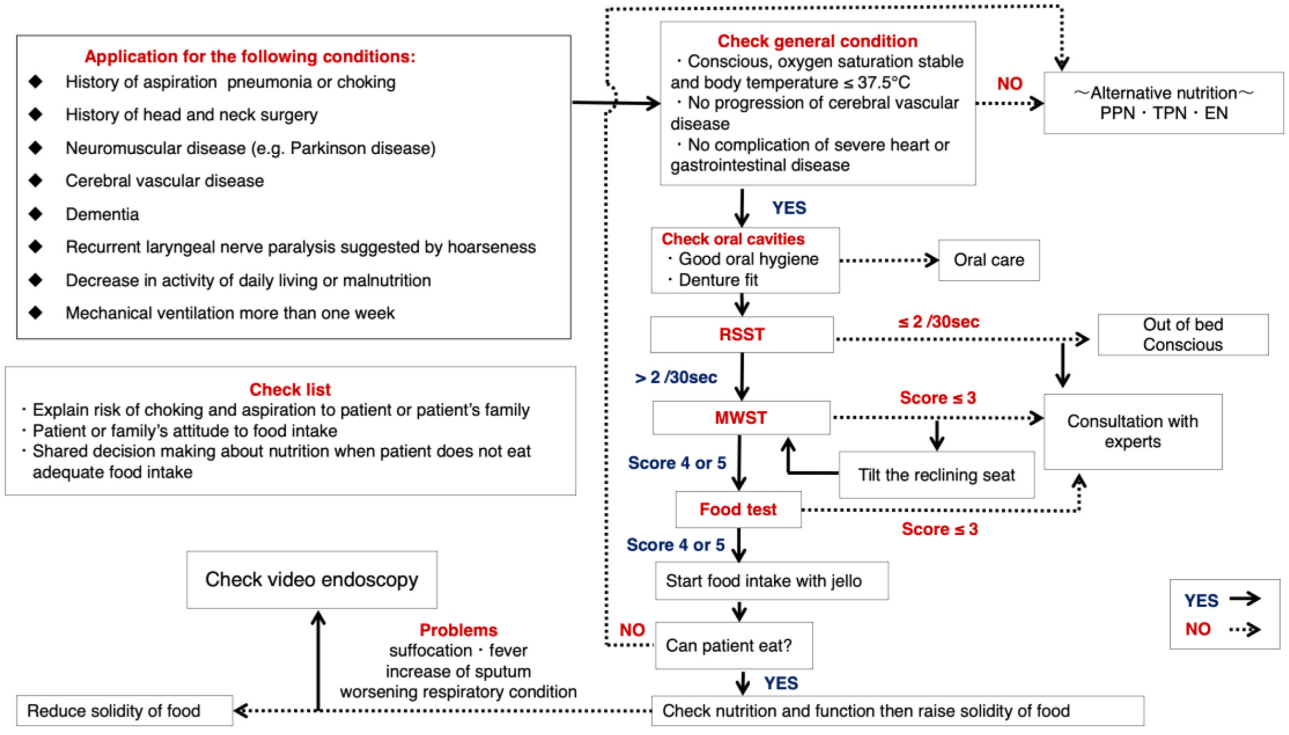

Figure 1 Assessment protocol for swallowing function. PPN: peripheral parenteral nutrition; TPN: total parenteral nutrition; EN: enteral nutrition.

swallows in 30 s. Three swallows within 30 s were used as the cutoff value for screening. The MWST involved 3 mL of water placed under the tongue, and the patient was asked to swallow. It was scored between 1 and 5, with a score of 4 used as a cut-off value, with higher values being considered favorable. The food test involved 4 g of jello placed on top of the tongue, and the patient was asked to swallow. It was also scored between 1 and 5, with a score of 4 being used as a cut-off value, with higher scores again being considered favorable.

AP was diagnosed according to the following criteria[13, 14]: 1) presence of a new gravity-dependent infiltrate on chest radiography or computed tomography; 2) presence of two or more of the following: leukocytosis, fever, purulent sputum, or high C-reactive protein (CRP) level; 3) positivity for dysphagia in a simple screening, which included water swallowing or food test administered by nurses. The excluded patients were those who were unable to eat owing to severe dysphagia according to the assessment by an expert nurse, those dependent on artificial nutrition (gastrostomy or total parenteral nutrition), and those who died during hospitalization. The participants were divided into control (N=45) and protocol (N=56) groups. The control group comprised patients before we began using the protocol (between April 2015 and September 2016), while the protocol group comprised patients after we began using the protocol between October 2016 and November 2017.

Data collection

We recorded the patients' backgrounds and confounders at hospital admission. We selected parameters associated with pneumonia prognosis and eating function, including age, sex, the concentration of blood urea nitrogen, oxygen saturation, consciousness, and systolic blood pressure[15]. Other factors considered to be associated with prognosis and outcomes were collected from previous reports. High CRP concentration has been reported as a poor prognostic factor[16], similar to nutritional status[17]. Low white blood cell and lymphocyte counts, indicating bacterial infection and poor immunity, were also considered poor prognostic factors[18]. High and low body temperatures have also been reported with inflammation[19]. Denture use is reportedly associated with a swallowing disability[18]. According to nursing and healthcare-associated pneumonia guidelines, antibacterial agents[20] associated with failure of initial treatment and the presence of healthcare-associated pneumonia risk factors were also considered to affect prognosis[21]. The swallowing difficulty was assessed using the seven-point Functional Oral Intake Scale (FOIS)[22], wherein the highest score indicated normal swallowing ability (score 1: nothing by mouth, 2: tube dependent with minimal attempts of food or liquid, 3: tube dependent with consistent oral intake of food or liquid, 4: total oral diet of a single consistency, 5: total oral diet with multiple consistencies but requiring special preparation or compensations; 6: total oral diet with multiple consistencies without special preparation but with specific food limitations, 7: total oral diet with no restrictions). Data were collected and examined by two physicians (Y.K. and N.I.).

Outcome measures

The duration of hospitalization and number of calories of nutrition intake (days 1 to 7, and then on day 14) were counted, and patient swallowing function with FOIS was scored. The number of days until oral intake or adverse events (aspiration and/or choking) were also compared between the groups. This retrospective cohort study was based on medical records.

Statistical analysis

In this study, we evaluated the reduction in AP incidence by introducing a swallowing function evaluation program. Fisher's exact test was used to evaluate the incidence of AP, and the odds ratio (OR) and 95% confidence interval were calculated as the effect size of the swallowing function evaluation program for AP. Multiple logistic analysis was used to adjust for the influence of background factors. The backward stepwise method was used for variable selection, and the model with the smallest Bayesian information criterion was selected.

The number of days until the start of solid meals was graphically illustrated using empirical cumulative distribution function plots and compared using the Kolmogorov–Smirnov test. Statistical analyses were conducted using R (version 3.5.1; The R Foundation for Statistical Computing, Vienna, Austria).

Ethical approval and registration

The study design was registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) Clinical Trial (UMIN trial ID: UMIN 000039492) (UMIN-CTR URL: http://www.umin.ac.jp/ctr/index.htm). This study was approved by the Akashi Medical Center Research Ethics Committee and conducted in accordance with the Declaration of Helsinki. Informed consent was obtained in the form of an opt-out on the website.

Results

AP was confirmed in 101 patients (control group, 45; protocol group, 56). The mean ages of the patients were 82.9 ± 14.0 years in the control group and 82.75 ± 12.4 years in the protocol group. The patient characteristics are shown in Table 1. Adverse events of aspiration or choking were notably less frequent in the protocol group (five events, 8.9%) than in the control group (16 events, 35.5%) (OR 0.32,

Table 1 Patient backgrounds and parameters obtained at hospital admission

	All (N=101)	Control (N=45)	Protocol (N=56)
Age, years	82.8 (13.1)[a]	82.9 (14.0)	82.8 (12.5)
Sex, Female	34 (33.7%)[b]	12 (26.7)	22 (39.3)
BMI, kg/m^2	18.9 (3.4)	18.7 (3.0)	19.0 (3.8)
WBC, mm^2	10,790 (4,964)	10,823 (4,619)	10,762 (5,266)
CRP, mg/dL	6.0 (6.13)	6.5 (6.5)	5.6 (5.8)
BUN, mg/dL	22.5 (10.4)	21.8 (9.1)	23.1 (11.4)
Alb, g/dL	3.2 (0.6)	3.1 (0.7)	3.2 (0.6)
Hb, g/dL	12.0 (2.0)	12.1 (2.1)	11.8 (1.9)
TLC, mm^2	1,030 (547)	1,043 (634)	1,028 (472)
BT, °C	37.6 (1.0)	37.5 (0.8)	37.7 (0.8)
Systolic blood pressure, mmHg	125 (25.3)	123 (26.0)	127 (25.0)
Consciousness; Confused	17 (16.8%)	6 (13.3%)	11 (19.6%)
Denture; Used	48 (47.5%)	15 (33.3%)	33 (58.9%)
Initial antibacterial agent			
β-Lactamase inhibitor combined with penicillins	67 (66.3%)	28 (62.2%)	39 (69.6%)
Cephalosporins	16 (15.8%)	5 (11.1%)	11 (19.6%)
Others	18 (17.8%)	12 (26.7%)	6 (10.7%)
Oxygen administration to maintain $SpO_2 \geq 90\%$	48 (47.5%)	25 (55.6%)	23 (41.1%)
Reason for aspiration			
Stroke	36 (35.6%)	16 (35.6%)	20 (35.7%)
Neuromuscular disease	12 (11.9%)	5 (11.1%)	7 (12.5%)
Dementia	39 (38.6%)	17 (37.8%)	22 (39.3%)
Others	26 (25.7%)	9 (20.0%)	17 (30.4%)
FOIS			
Level 4	12 (11.9%)	7 (15.6%)	5 (8.9%)
Level 5	9 (8.9%)	4 (8.9%)	5 (8.9%)
Level 6	25 (24.8%)	8 (17.8%)	17 (30.4%)
Level 7	54 (53.5%)	26 (57.8%)	28 (50.0%)
Severity score			
0	3 (3.0%)	1 (2.2%)	2 (3.6%)
1	34 (33.7%)	11 (24.4%)	23 (41.1%)
2	44 (43.6%)	22 (48.9%)	22 (39.3%)
3	13 (12.9%)	7 (15.6%)	6 (10.7%)
4	5 (5.0%)	3 (6.7%)	2 (3.6%)
5	2 (2.0%)	1 (2.2%)	1 (1.8%)
Severity score average	1.89 (0.979)	2.07 (0.986)	1.75 (0.958)

[a]Continuous data are shown by means, standard deviations, and ranges. [b]Categorical variables are reported as numbers and percentages. BMI: body mass index; WBC: white blood cell counts; CRP: C-reactive protein; BUN: blood urea nitrogen; Alb: albumin; Hb: hemoglobin; TLC: total lymphocyte count; BT: body temperature; FOIS: functional oral intake scale.

P<0.001). There was a similarity between the two groups. Duration of days until oral intake resumption in the two groups was 1.64 ± 2.34 days in the protocol group and 2.09 ± 2.30 days in the control group (P=0.521) (Figure 2). After adjustment for multiple logistic analysis, the protocol group had a significantly lower number of adverse events such as aspiration or choking (OR 0.19, P=0.0048) (Table 2) than the control group. The duration of hospitalization was 15.8 ± 10.3 in the control group and 16.2 ± 11.26 in the protocol group (P=0.95) (Figure 3). The number of calories of nutritional intake (days 1 to 7 and 14, P=0.252) and change in FOIS (P=0.834) were similar between the groups (Figure 4).

Discussion

In this retrospective study, aspiration and choking decreased significantly when the protocol was used to determine whether to restart oral intake. However, the number of days until initiation of oral intake and change in FOIS were not significantly different.

Our protocol (Figure 1) included RSST, MWST, and food testing. RSST reported a sensitivity of 0.98 and a specificity of 0.66 in screening aspiration[23]. The reported sensitivity and specificity of MWST were 0.70 and specificity 0.88, respectively. The sensitivity of the food test was 0.72 and specificity was 0.62[24]. Combined MWST and food test

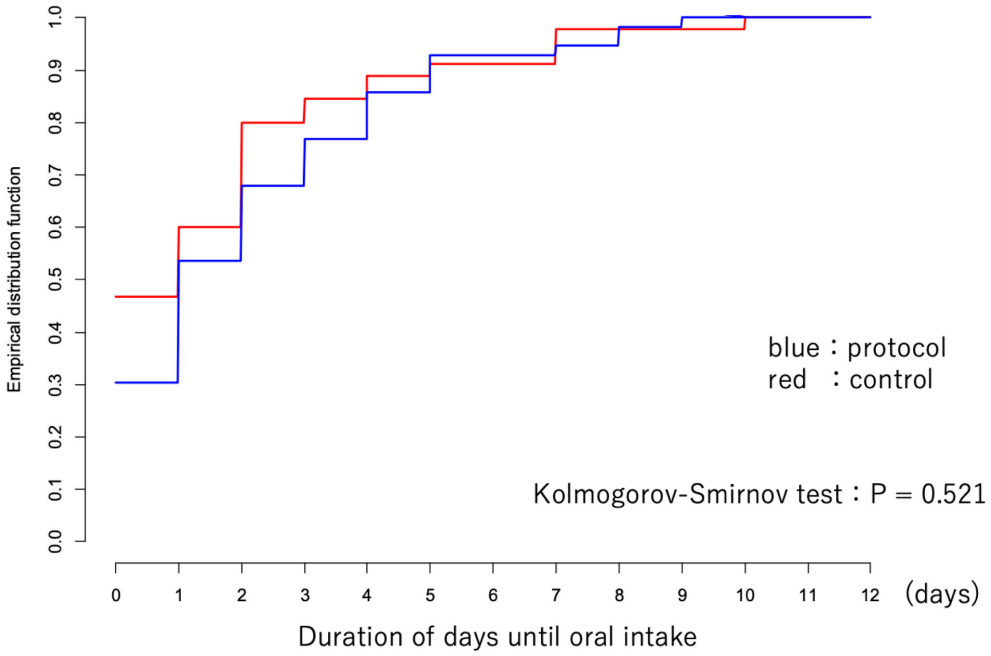

Figure 2 Comparison of the accumulative curve of the duration of days until oral intake in the two groups. The duration is 1.64 ± 2.34 and 2.09 ± 2.30 days in the intervention and control groups, respectively.

Table 2 Adverse events of aspiration or choking are less frequent in the protocol group (five events) than that in the control group (16 events) (odds ratio [OR] 0.32, *P*=0.150)

Factor	Multivariate analysis		Stepwaise method	
	Odds ratio	*P*-value	Odds ratio	*P*-value
Intervention	0.32 (0.07–1.52)	0.15	0.19 (0.06–0.61)	0.0048
Age	0.61 (0.09–4.22)	0.61	–	–
Alb	0.31 (0.05–1.83)	0.20	–	–
BMI	0.30 (0.06–1.51)	0.14	–	–
BUN	3.31 (0.68–16.00)	0.14	–	–
CRP	0.00 (0.00–Inf)	0.99	–	–
FOIS	1.11 (0.23–5.38)	0.90	–	–
Hb	1.60 (0.24–10.80)	0.63	–	–
LIN	1.26 (0.13–12.50)	0.84	–	–
WBC	0.89 (0.18–4.54)	0.89	–	–
Other	0.22 (0.02–1.90)	0.17	–	–
Consciousness	0.07 (0.00–1.36)	0.08	–	–
Denture	0.36 (0.07–1.99)	0.24	–	–
Systolic blood pressure	5.92 (0.19–181.00)	0.31	–	–
Oxygen administration to maintain $SpO_2 \geq 90\%$	1.02 (0.23–4.48)	0.98	–	–
Neuromascula	4.18 (0.46–37.70)	0.20	–	–
Sex	0.50 (0.08–3.25)	0.47	–	–
Body Tempreture	0.25 (0.04–1.62)	0.15	–	–
Dementia	1.38 (0.30–6.39)	0.68	–	–
Stroke	1.75 (0.38–8.21)	0.48	–	–

After adjustment of multiple logistic analyses, the protocol group significantly reduced adverse events of aspiration or choking in the intervention group (OR 0.19, 95% confidence interval [CI] 0.06-0.61; *P*=0.0048).

Alb: albumin; BMI: body mass index; BUN: blood urea nitrogen; CRP: C-reactive protein; FOIS: functional oral intake scale; Hb: hemoglobin; TLC: total lymphocyte count; WBC: white blood cell counts.

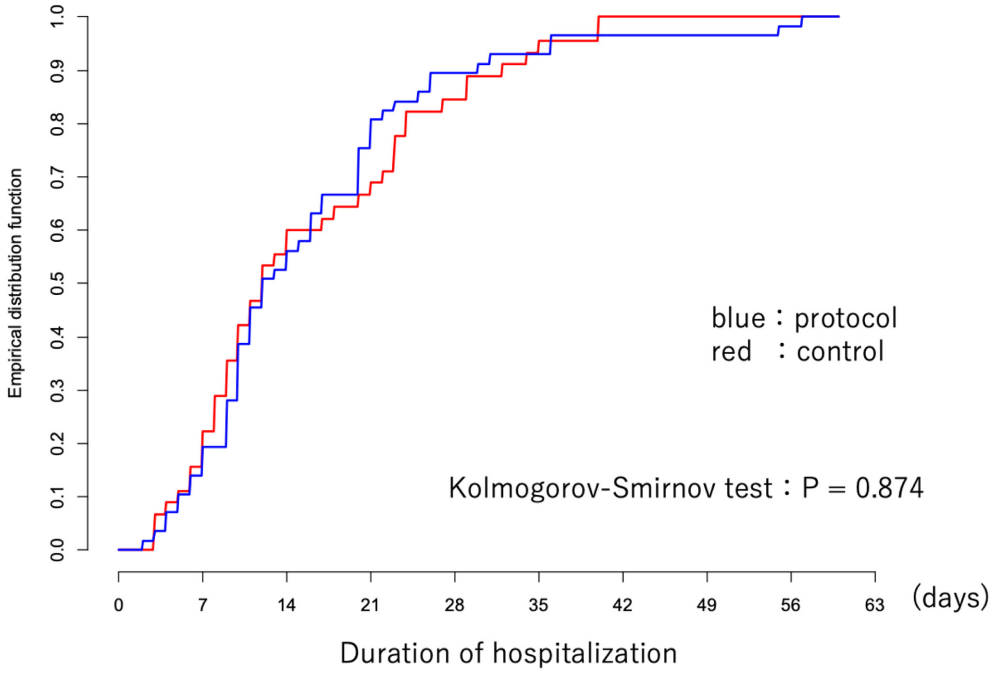

Figure 3 Comparison of the accumulative curve of the duration of hospitalization in the two groups. Duration of hospitalization is 15.8 ± 10.3 in the control group and 16.2 ± 11.26 in the intervention (protocol) group.

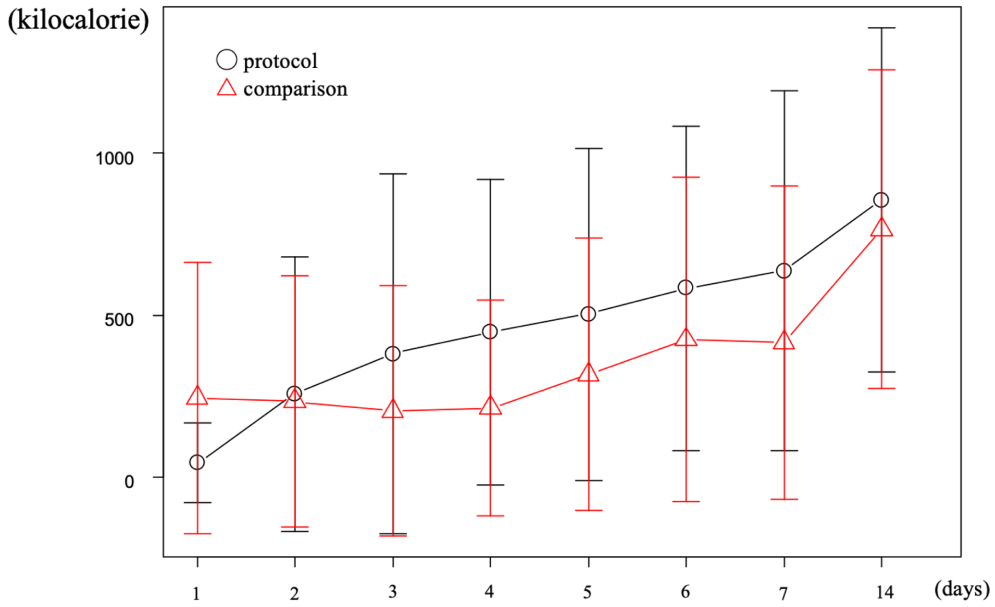

Figure 4 Results of repeated measured ANOVA for the amount of the calories of nutrition intake (day 1 to 7 and then day 14). *P*-value for ANOVA: *P*=0.252 (interaction test: *P*=0.536). ANOVA: analysis of variance.

had a reported sensitivity of 0.90 and specificity of 0.56[25]. We intend this protocol (Figure 1) to be used by non-expert physicians to quickly assess their ability to restart oral intake of adequate food. Our results showed a reduced risk of adverse events of aspiration and/or choking, suggesting that the protocol could be used to guide non-experts in determining when to restart oral intake appropriately.

There was no significant difference in the duration of days until initiation of oral intake, in the amount of calories of nutrition intake, or change in FOIS. Contrary to expectations, we did not observe a significant difference in the time taken to restart oral intake. However, when the protocol was

used, there were fewer incidences of aspiration and choking.

Recommendations for the prevention of AP after stroke or surgery have been reported[1]. After emergency intubation, antibiotic therapy for 24 h is recommended for comatose patients, and they should not have food for at least 8 h and not have clear liquids for at least 2 h before elective surgery and general anesthesia. For patients who have had a severe stroke, there have been various recommendations after extubation for patients requiring mechanical ventilation: swallowing evaluation, angiotensin-converting enzyme inhibitors for blood pressure control, and feeding in a semi-recumbent position.

Swallowing rehabilitation without oral nutrition was shown to improve the weaning rate from artificial nutrition in one report[26]. Early rehabilitative intervention by physical therapists improves the mortality rate[27]. The reduction of adverse events of aspiration/choking is considered to have a positive effect, as is the overall resumption of oral food intake.

Our study has several limitations. The participants were recruited from a single institution, which may reduce the generalizability of the data. The study site is an acute care hospital where there are comparatively few experts on swallowing function; therefore, our results may be considered a good representation of a hospital with limited access to experts. A second limitation is that our study was a comparative retrospective study, and the groups were compared historically over different durations. We cannot rule out bias concerning baseline characteristics and practice. However, after logistic regression analysis, the results of reducing the risk of aspiration and/or choking were similar. A third limitation is that the follow-up period was short; therefore, further studies will aim to better understand the long-term outcomes of clinical decision-making using the protocol. We cannot rule out the possibility that staff was paying attention to specific components of swallowing that may have affected the results, particularly in the differences or similarities between the groups.

Conclusion

Clinical decision-making using the protocol showed a reduction in further choking and/or aspiration in patients with AP. Therefore, this protocol was suggested for practical use by non-expert physicians in the treatment of patients with AP. Although the protocol is quite simple, the number of days until initiation of oral intake, change in FOIS, and amount of nutritional intake did not differ significantly between our patients who did and did not receive treatment in accordance with the protocol.

Conference presentation: We presented an earlier version of the manuscript as a poster at the Society of General Internal Medicine Annual Meeting in Denver in 2018.

Conflicts of interest: The authors declare no conflicts of interest in relation to this article.

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