





The Safety of Oral Rehydration Solution Jelly for Water and Electrolyte Intake in Patients with Dysphagia

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Purpose: Oral rehydration solutions (ORSs) are effective in replacing fluids and electrolytes and are widely used. OS-1 Jelly (Otsuka Pharmaceutical Factory, Tokushima, Japan) is a jelly drink corresponding to code 2-1 of the 2021 Japanese Dysphagia Diet. Although jelly drinks are less likely to be aspirated than liquids, their physical properties vary depending on the product. Therefore, the severity of dysphagia may affect intake status. This study aimed to investigate the association between the intake status of ORS jelly and swallowing function.

Patients and Methods: Thirty-six patients with dysphagia who required videoendoscopic swallowing evaluation at our university hospital were enrolled. Videoendoscopic swallowing evaluation was performed, and each participant swallowed 5 mL of OS-1 Jelly or thickened water modified to International Dysphagia Diet Standardization Initiative (IDDSI) level 2 three times. Statistical analysis was performed to determine the difference in the number of swallows, time until the swallowing reflex, position for inducing the swallowing reflex, presence of pharyngeal residue, penetration, or aspiration between ORS jelly and thickened water.

Results: The time until the swallowing reflex was induced and the position of the swallowing reflex triggered were significantly earlier for ORS jelly ($p=0.012$, $p=0.001$). The incidence of pharyngeal residue was significantly lower with ORS jelly ($p=0.002$). The Penetration-Aspiration Scale score was similar for both samples ($p=0.062$), and no aspiration was observed in either sample.

Conclusion: Patients with dysphagia who can swallow thickened water modified to IDDSI level 2 can consume ORS jelly. ORS jelly, which requires no thickening and can be easily and safely consumed, is effective for water and electrolyte intake in patients with dysphagia.

Keywords: oral rehydration solutions, swallowing function, fluid intake, electrolyte supply

Introduction

Patients with dysphagia are at risk of malnutrition and dehydration due to decreased food and fluid intake that accompanies disability.^{1,2} Changes related to aging also decrease the body water content and further increase the risk of dehydration.³ When this condition is combined with infections and changes in living conditions, such as isolation, it can lead to severe dehydration, which is life-threatening for patients with dysphagia and older adults. Efficient fluid and electrolyte supplementation are recommended to prevent dehydration. In cases of dehydration accompanied by vomiting or diarrhea, it is necessary to easily and quickly supply lost fluids and electrolytes.⁴ Especially for patients with dysphagia who do not receive tube feeding, it is necessary to not only consume water but to do so more effectively with as little volume as possible. Oral rehydration solutions (ORSs) are used to address these issues,^{5,6} which are advantageous because of the rapid absorption of fluids and electrolytes in the small intestine.^{7,8} However, although ORSs are beneficial for supplying fluids and electrolytes, aspiration and other problems must be considered when using liquids

in patients with dysphagia. Therefore, a jelly-type ORS was developed. However, it has not been verified whether ORS jelly can be safely consumed by patients with dysphagia. Therefore, this study aimed to verify whether ORS jelly, which is effective for the supply of fluids and electrolytes, can be safely consumed by patients with dysphagia.

Materials and Methods

Participants

This was a human observational study that conforms to the general principles outlined in the Declaration of Helsinki and the STROBE guidelines. The study included 36 patients diagnosed with dysphagia based on videoendoscopic evaluation (VE). They received visiting or outpatient care at our university hospital between February and December 2021 and who required VE. Assigned dentists explained the study to their patients when performing the VE and recruited participants. The inclusion criteria were a dysphagia diagnosis, oral intake ability, and ability to follow the instructions. The study protocol was approved by the institutional review board of Tokyo Medical and Dental University (approval number: D2020-065). Individuals were excluded if they were considered difficult to examine due to frequent severe aspiration, had unstable general condition such as poor consciousness or poor respiratory status, and did not consent to the study. Informed written consent for the study was obtained from all subjects.

ORS Jelly Used in the Study

OS-1 Jelly (OS-1 Jelly; Otsuka Pharmaceutical Factory, Tokushima, Japan, country of manufacture: Japan) now commercially available was used as the test food. The ingredients are dextrose, salt/citric acid (Na), gelling agent (polysaccharide thickener), potassium chloride, sodium phosphate, magnesium chloride, sweetener (sucralose, acesulfame potassium), and flavor. The nutritional values are energy, 20 kcal; water, 195.0 g; protein, 0.0 g; fat, 0.0 g; and carbohydrate, 5.0 g per 200 g. OS-1 Jelly has a mixed texture of liquid and jelly. The physical properties are as follows: cohesion, 0.75; hardness, 294 N/m²; and adhesiveness, 19 J/m³.

Data Collection

All participants consumed thickened water and ORS jelly to determine any differences in swallowing dynamics between the two groups. Participants first ingested either thickened water or ORS jelly, followed by another sample. The envelope method was used to determine which sample was ingested first. The order in which the samples were consumed was not disclosed to the participants, and they were randomly assigned in equal numbers. Thickened water was prepared by adding 1 g of food thickener (Toromi-up perfect, The Nisshin OilliO Group, Tokyo, Japan, country of manufacture: Japan) to 100 mL of water and mixing it well to obtain the viscosity of the International Dysphagia Diet Standardization Initiative (IDDSI) Framework level 2 (mildly thick). The ingredients of the food thickener are dextrin, polysaccharide thickener, sodium gluconate, and magnesium chloride. Since ORS jelly is semi-transparent in color, both samples were colored blue with food coloring. Each sample was refrigerated to approximately 10°C.

The participants' age, sex, primary disease of dysphagia, and Dysphagia Severity Scale (DSS)⁹ and Functional Oral Intake Scale (FOIS)¹⁰ scores were extracted from their medical records.

VE was performed to evaluate swallowing function when the participants consumed thickened water and ORS jelly. A fiberoptic endoscope (Pentax Japan, Tokyo, Japan) was inserted through the participant's nose in the sitting position. After 5 mL of each sample was placed into the mouth, the participants were instructed to swallow. The trial was repeated three times. The number of swallows, time until the swallowing reflex was induced, position of the bolus that triggered the swallowing reflex, pharyngeal residue in the vallecula and pyriform sinuses, and presence of aspiration or penetration were evaluated from the VE images.

Number of Swallows

Whiteout observed during swallowing in the VE was defined as swallowing. The number of swallows for each trial was measured for each sample, and the median of the three trials was calculated.

Time Until the Swallowing Reflex Was Induced

The time between placing the test sample in the participant's mouth and the first swallow was measured. The mean value of the trials was used as the time until the swallowing reflex was induced.

Position of the Bolus That Triggered the Swallowing Reflex

The position of the bolus that triggered the swallowing reflex was observed in the VE. Referring to previous reports, we classified the location of the bolus into three areas: oral cavity (unable to identify the tip of the bolus), posterior oral cavity to the vallecula, and posterior vallecula to the pyriform sinuses.¹¹

Pharyngeal Residue in the Vallecula and Pyriform Sinuses

Pharyngeal residues were evaluated using the 5-point Yale Pharyngeal Residue Severity Rating Scale, which ranges from 1 (none) to 5 (severe).¹²

Presence of Aspiration or Penetration

Aspiration and penetration were evaluated using an 8-point scale (1: no penetration and aspiration, contrast does not enter the airway; 8: aspiration, contrast passes glottis, visible subglottic residue, absent patient response) using the Penetration-Aspiration Scale (PAS).¹³ Although the PAS was designed for videofluoroscopy, a previous study has shown high inter- and intrater reliability of the PAS with the application of VE.¹⁴

All VE imaging evaluations were performed by a single dentist specializing in dysphagia rehabilitation. The dentist has performed VE for over 5 years. Another dentist was present at the VE and was in charge of the randomization. It was impossible for the assessor to identify whether thickened water or ORS jelly was consumed based on imaging. The lowest score of the three trials for each sample was used in the evaluation of the position that triggered the swallowing reflex, Yale Pharyngeal Residue Severity Rating Scale, and PAS.

Data Analysis

The required sample size was calculated using G*power 3.1 (Heinrich Heine University, Duesseldorf, Germany). A minimum of 34 participants were required (power: 0.8, effect size: 0.5). Statistical analysis was performed using Wilcoxon's signed-rank test to compare the two samples for differences in the number of swallows, the time until the swallow reflex was induced, the position of the bolus that triggered the swallowing reflex, pharyngeal residue, and aspiration/penetration. The significance level was set at 5%, and the data were analyzed using SPSS version 25.0 (IBM, Armonk, NY).

Results

Participant Characteristics

Data from all participants were analyzed. The participants' characteristics are shown in Table 1. The 36 participants included 15 males and 21 females, with a median age of 80 years (39–92 years). Cerebrovascular disease (33.3%) was the most common primary cause of dysphagia, followed by disuse syndrome (19.5%).

The DSS of the participants ranged from 3 to 6, and the percentage of patients who aspirated (DSS 3 and 4) was 38.9%. The remaining participants were classified as having oral or minimal problems. The FOIS of the participants ranged from 2 to 6, and 19.4% of the participants were tube-fed (FOIS 2 and 3). The others only ate orally (Table 2).

Comparison of Swallowing Dynamics Between Thickened Water and ORS Jelly

Table 3 shows the results of the swallowing dynamics analysis of thickened water and ORS jelly. No significant difference was found in the number of swallows between the thickened water and ORS jelly ($p=0.364$).

The time until swallowing reflex was significantly earlier for the ORS jelly than for the thickened water, and the swallowing reflex occurred more proximal to the oral cavity for the ORS jelly (time until swallowing reflex, $p<0.001$; position of the bolus that triggered swallowing reflex, $p=0.043$) (Figure 1). The incidence of pharyngeal residue was

Table 1 Patient Characteristics (N=36)

Sex	
Male, n (%)	15 (41.6)
Female, n (%)	21 (58.4)
Age, median (range)	80 (39–92)
Primary Disease of Dysphagia, n (%)	
Cerebrovascular disease	12 (33.3)
Disuse syndrome	7 (19.5)
Postoperative oral cancer	6 (16.7)
Dementia	5 (13.9)
Respiratory disease	3 (8.3)
Others	3 (8.3)

Table 2 Dysphagia Severity Scale and Functional Oral Intake Scale Scores

Dysphagia Severity Scale, n (%)		Functional Oral Intake Scale, n (%)	
1	0 (0)	1	0 (0)
2	0 (0)	2	3 (8.3)
3	4 (11.1)	3	4 (11.1)
4	10 (27.8)	4	4 (11.1)
5	8 (22.2)	5	8 (22.2)
6	14 (38.9)	6	17 (47.3)
7	0 (0)	7	0 (0)

Notes: Dysphagia Severity Scale: 1, saliva aspiration; 2, food aspiration; 3, water aspiration; 4, occasional aspiration; 5, oral problems; 6, minimal problems; 7, within normal limits. Functional Oral Intake Scale: 1, no oral intake; 2, tube-dependent with minimal/inconsistent oral intake; 3, tube supplements with consistent oral intake; 4, total oral intake of a single consistency; 5, total oral intake of multiple consistencies requiring special preparation; 6, total oral intake with no special preparation, but with specific food limitations; 7, total oral intake with no restrictions.

Table 3 Comparison of Thickened Water and Oral Rehydration Solution Jelly

	Thickened Water (Median, Range)	OS-1 Jelly (Median, Range)	p value
Number of swallows	2 (1–5)	1.75 (1–5)	0.364
Time until swallowing reflex (s)	1.12 (0.4–5.8)	0.83 (0.3–4.2)	<0.001*
Position of the bolus that triggered the swallowing reflex	2 (2–3)	2 (1–3)	0.043*
Pharyngeal residue	2 (1–5)	2 (1–4)	0.048*
Penetration-Aspiration Scale score	1 (1–4)	1 (1–4)	0.260

Notes: * $p < 0.05$. Position of the bolus that triggered the swallowing reflex: 1, in the oral cavity; 2, from the distal part of the oral cavity to the vallecula of the epiglottis; 3, from the distal part of the vallecula of the epiglottis to the pyriform sinus. Pharyngeal residue: 1, none; 2, trace; 3, mild (less than one-quarter); 4, moderate (less than half); 5, severe (more than half). Penetration-Aspiration Scale: 1, none (material does not enter the airway); 2, material enters the airway, remains above the vocal folds, and is ejected from the airway; 3, material enters the airway, remains above the vocal folds, and is not ejected from the airway; 4, material enters the airway, contacts the vocal folds, and is ejected from the airway.

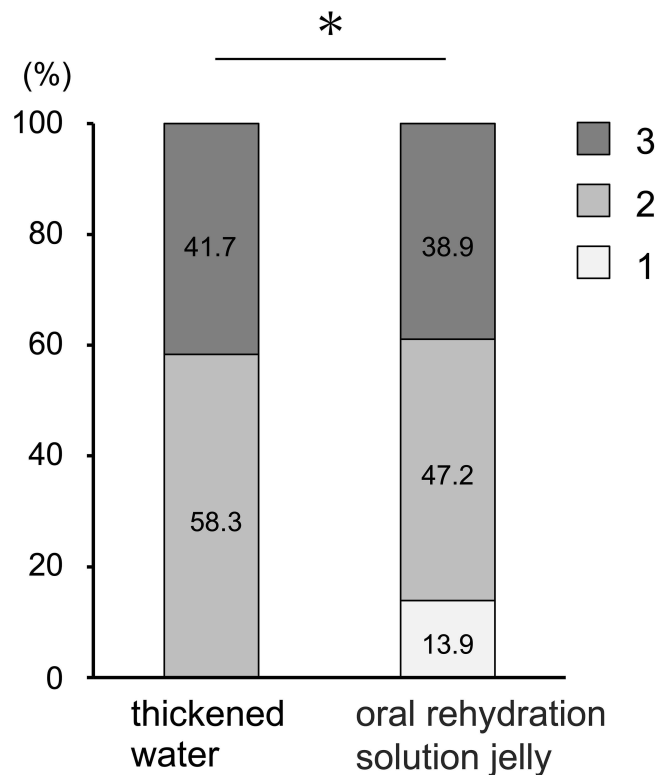


Figure 1 Distribution of the position of the tip of the food bolus just before swallowing thickened water or oral rehydration solution (ORS) jelly. In the case of thickened water, the swallowing reflex was most frequently induced in the area between the distal part of the oral cavity and the vallecula of the epiglottis. With the ORS jelly, the same tendency was observed. However, some jelly was partially retained in the oral cavity ($p < 0.05$). 1: in the oral cavity, 2: from the distal part of the oral cavity to the vallecula of the epiglottis, 3: from the distal part of the vallecula of the epiglottis to the pyriform sinus. * $p < 0.05$.

significantly lower with ORS jelly (2 [1–4]) than with thickened water (2 [1–5]) ($p = 0.002$) (Figure 2). The PAS score was similar for ORS jelly (1 [1–4]) and thickened water (1 [1–4]) ($p = 0.260$) (Figure 3).

Discussion

The physical properties of thickened water are generally evaluated based on viscosity (cP or Pa·s). The physical properties of ORS jelly were evaluated based on hardness, adhesiveness, and cohesiveness. ORS jelly has a mixed texture of liquid and jelly and is heterogeneous. If the viscosity of a liquid is low, it is more difficult for a patient with dysphagia to consume, and the risk of aspiration increases.¹⁵ However, it was not possible to compare the ORS jelly and thickened water using the same index because the physical properties of the two are different. Therefore, in the present study, we evaluated swallowing dynamics, such as the number of swallows, time until the swallowing reflex, and position of the bolus that triggered swallowing reflex using VE in patients with dysphagia. In addition, pharyngeal residue and the presence of aspiration or penetration were compared between ORS jelly and thickened water as indicators of safety. These clinical evaluations were the methods used in a previous study to assess food safety,¹⁶ and we consider that these evaluations were valid methods to assess the safety of ORS jelly for patients with dysphagia.

Regarding the ingredients of the ORS jelly, a gelling agent (polysaccharide thickener) forms the basis of the jelly. Polysaccharide thickeners, such as pectin, xanthan gum, and guar gum, are water-soluble polymers (polysaccharides) that are viscous and gelatinous when dissolved in water. Therefore, OS-1 Jelly does not contain gelatin. Since the dissolving temperature of polysaccharides is approximately 70–90°C, they do not dissolve at body temperature when ingested. In other words, the physical properties of OS-1 Jelly do not change in the oral cavity or pharynx the way that gelatin jelly does.

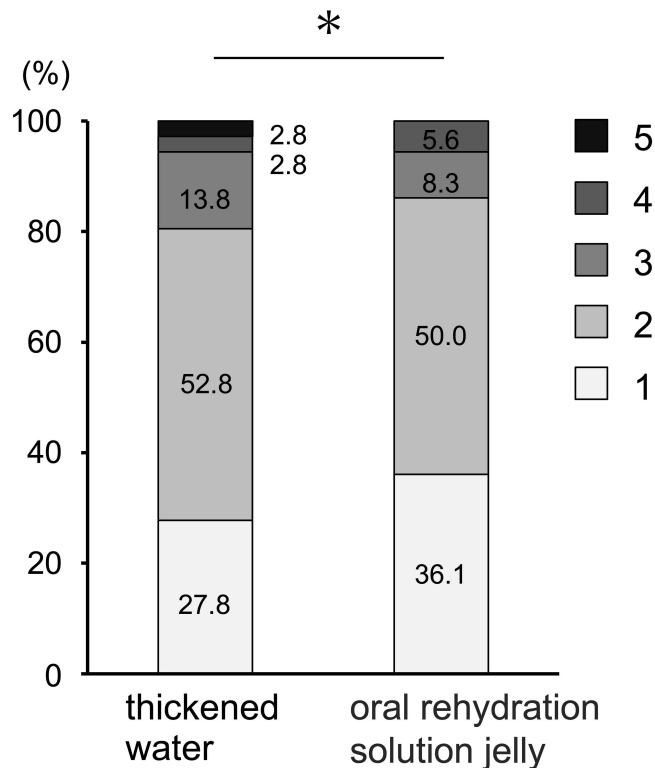


Figure 2 Pharyngeal residue after swallowing. The thickened water group included one patient (2.8%) with a score of 5 (more than half remained in the pharynx after swallowing), whereas the oral rehydration solution jelly group included patients with scores ranging from 1–4 ($p < 0.05$), with no patient scoring 5. Yale Pharyngeal Residue Severity Rating Scale: 1, none; 2, trace; 3, mild (less than one-quarter); 4, moderate (less than half); and 5, severe (more than half). * $p < 0.05$.

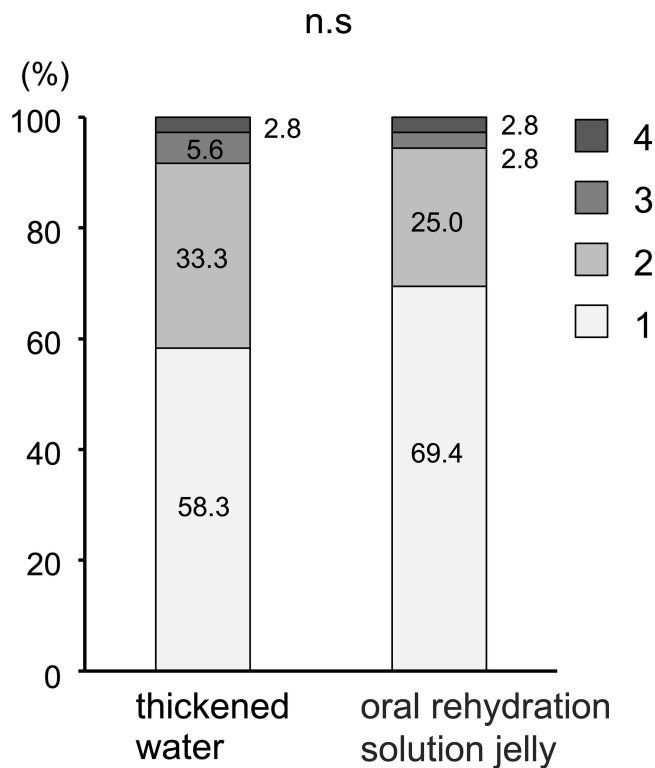


Figure 3 Penetration-Aspiration Scale results. Thickened water and oral rehydration solution jelly showed no aspiration, and 41.7% and 30.6% (total of those with a score 2 or above), respectively, showed penetration ($p = 0.062$). 1, none (material does not enter the airway); 2, material enters the airway, remains above the vocal folds, and is ejected from the airway; 3, material enters the airway, remains above the vocal folds, and is not ejected from the airway; 4, material enters the airway, contracts the vocal folds, and is ejected from the airway. **Abbreviations:** n.s., not significant.

The position of the bolus before swallowing is influenced by chewing and the physical properties of the food being consumed.¹⁷ The time to swallowing reflex was significantly earlier for the ORS jelly than for the thickened water, and the swallowing reflex occurred more proximally in the oral cavity. If the food bolus flows into the hypopharynx before the swallowing reflex occurs, the risk of pre-swallowing aspiration increases because swallowing fails to occur in time. Therefore, we consider the risk of aspiration to be smaller if the swallowing reflex is triggered at the time a food bolus is present in the proximal oral cavity, especially for fluid foods. In addition, patients with dysphagia are likely to aspirate biphasic foods that are a mixture of solids and liquids. From the results of this study, we could say that ORS jelly has good cohesion between the jelly and water and does not possess the physical properties of a biphasic food; thus, the risk of only the liquid flowing into the pharynx first is lower. On the other hand, there may be a prolonged oral transit time in patients with dysphagia whose swallowing function is decreased, especially postoperative patients such as those after oral cancer surgery, which results in a longer delivery period of the food bolus from the oral cavity to the pharynx.¹⁸ A part of the food bolus reaches the hypopharynx before swallowing, and the food bolus remains stored in the hypopharynx until further food transportation is completed and the swallow reflex is induced. When ORS jelly is used in clinical practice, attention should be paid to patients with a prolonged oral transit time, such as those with poor oral function due to disease or oral cancer surgery.

The pharyngeal residue score after swallowing ORS jelly was significantly lower than that after swallowing thickened water. Of all the participants, one (2.8%) had a score of 5 (more than half remained in the pharynx after swallowing) when consuming thickened water. However, the same subject had a score of 4 (less than half remained in the pharynx after swallowing) when consuming ORS jelly. The physical properties of the food and patients' oral and pharyngeal functions affect the residue after swallowing. The adhesive property is related to residuals in the pharynx after swallowing; the higher the adhesiveness, the more likely the residuals are to remain.¹⁹ Since the adhesive property of ORS jelly is very low (19 J/m^3), the amount of pharyngeal residue was significantly lower than that of thickened water in this study. All subjects consumed thickened water and ORS jelly orally on the same day. Therefore, there was no difference in swallowing function, such as pharyngeal contraction, laryngeal elevation, or opening of the esophagus. It is possible that the gel-like texture with low adhesiveness, texture (tactile sensation), and taste (gustatory sensation) also affected swallowing function.

The PAS scores were almost similar for thickened water and ORS jelly, and no aspiration was observed in either sample. Nevertheless, there were 15 cases (41.7%) of penetration with thickened water and 11 cases (30.6%) with ORS jelly; thus, complete safety of the ORS jelly cannot be guaranteed for all patients with dysphagia. However, these participants had penetration with thickened water but not with ORS, or had penetration with both. Therefore, the results suggest that patients with dysphagia who can consume thickened water may have a low risk of aspiration when they consume commercially available ORS jelly without adding food thickener. However, it should be carefully noted that since OS-1 Jelly is a mixture of water and crushed jelly in the pouch, the physical properties may not be uniform if it is not well mixed.

There are some limitations to this study. First, patients with more varied levels of dysphagia are needed to assess in detail the swallowing function and condition of patients who can safely consume ORS jelly. Second, patients with dysphagia were given thickened water and ORS jelly orally and were compared to determine whether there were differences in swallowing dynamics. In principle, thickened water is tasteless and odorless, although there may be some change in taste depending on the adjustment of the food thickener. In contrast, ORS jelly has a slightly salty taste, but it is less salty than the drink type. Nevertheless, when observing swallowing dynamics, the influence of taste could not be completely eliminated. Third, OS-1 Jelly is a product of a Japanese company; therefore, it may be difficult to obtain in some countries.

Conclusion

In patients with dysphagia, the time until the swallowing reflex was induced and the position of food bolus that triggered swallowing reflex were significantly earlier for ORS jelly than for thickened water. Pharyngeal residues were significantly lower with ORS jelly than with thickened water. Furthermore, aspiration or penetration was observed at the same level. Although ORS jelly requires uniform mixing before intake owing to the physical properties of fluid and jelly, the

results suggest that patients with dysphagia who can swallow thickened liquid modified to IDDSI level 2 may have a low risk of aspiration even if they consume ORS jelly as is.

Abbreviations

DSS, Dysphagia Severity Scale; FOIS, Functional Oral Intake Scale; IDDSI, International Dysphagia Diet Standardization Initiative; ORS, oral rehydration solution; PAS, Penetration-Aspiration Scale; VE, videoendoscopic evaluation.

Data Sharing Statement

The datasets generated and analyzed during the current study are not publicly available due to their containing information that could compromise the privacy of the participants but are available from the corresponding author on reasonable request.

Consent for Publication

Written informed consent for publication of their details was obtained from the study participant.

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OS-1 is the registered trademark of Otsuka Pharmaceutical Factory, Inc. in Japan and other countries.

Author Contributions

All authors contributed to the study conception and design. Conceptualization: Kazuharu Nakagawa; Methodology: Kazuharu Nakagawa; Project Administration: Kazuharu Nakagawa and Kanako Yoshimi; Investigation: Akira Yoshizawa and Kota Aritaki; Data Curation: Kazuharu Nakagawa; Formal analysis: Kazuharu Nakagawa; Visualization: Kazuharu Nakagawa and Kanako Yoshimi; Writing-original draft presentation: Kazuharu Nakagawa and Kanako Yoshimi; Writing-review and editing: Kanako Yoshimi, Kohei Yamaguchi and Ayako Nakane; Supervision: Haruka Tohara. All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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