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Evaluation of Role of Prophylactic Swallowing Rehabilitation in Chemoradiotherapy for Advanced Head and Neck Cancer Using Novel Software Analysis of Videofluorography Images

Hiromi FURUIE*), Takao HAMAMOTO, Nobuyuki CHIKUIE, Takashi KONO, Takayuki TARUYA, Takashi ISHINO, Tsutomu UEDA, and Sachio TAKENO

Department of Otorhinolaryngology, Head and Neck Surgery, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

ABSTRACT

Concurrent chemoradiotherapy (CRT) for head and neck cancer (HNC) is associated with substantial side effects, most notably those related to swallowing function. Recently, early implementation of protective exercises has been recommended as an important intervention in patients treated with chemoradiotherapy. Several studies, including randomized controlled trials, have evaluated prophylactic swallowing exercises and swallowing outcomes. Although several clinical outcome measures to assess the severity of swallowing dysfunction are available, they are indirect measures. Videofluorography is the most popular and efficient examination that visually demonstrates the dynamic state of swallowing. This study aimed to determine whether prophylactic swallowing rehabilitation provided to HNC patients receiving CRT would result in better swallowing outcomes. Thirty patients were enrolled in this study. Fifteen patients (the control group) received swallowing rehabilitation after CRT on demand, and the other 15 (the rehabilitation group) received prophylactic swallowing rehabilitation from the beginning. Swallowing motion was evaluated with motion analysis software. There were statistically significant differences in hyoid bone displacement, duration of swallowing onset, larynx elevation time, and total swallowing time between the control and rehabilitation groups. Based on the results of this study, prophylactic swallowing rehabilitation seems to reduce the extent and severity of the functional problems that occur after CRT.

Key words: *Head and neck cancer*, *swallowing*, *fluorography*, *rehabilitation*

INTRODUCTION

Concurrent chemoradiotherapy (CRT) has become the standard therapy for advanced head and neck squamous cell carcinoma. However, CRT has adverse effects on many functions of the upper respiratory and digestive systems. Dysphagia is a common and potentially serious complication that results in life-threatening adverse effects, such as aspiration pneumonia. Swallowing dysfunction is closely related to poor quality-of-life (QOL), even if the structures of the pharynx and larynx are preserved[1,3,19]. Previously, post-treatment rehabilitation for swallowing dysfunction was conducted, however, with limited success, and has not proven to be satisfactory for promoting swallowing function[15,20]. Since it is generally agreed that prolonged disuse of the pharynx and larynx causes detrimental effects on swallowing function in patients with head and neck cancer (HNC)[12], the potential benefits of prophylactic swallowing interventions have recently garnered interest[7,9,18]. Several studies have reported that conducting swallowing rehabilitation during pre- or early post-treatment periods could reduce the incidence of dysphagia in patients treated with CRT. Some of these studies suggest that patients who completed successful swallowing rehabilitation tended to have a better diet within a shorter period of time and experienced more weight gain, shorter duration of gastrostomy tube use, and higher quality of life[4,7,9,18]. However, many of these studies had a weak study design, and some systematic reviews performed on these studies pointed out certain limitations because the exercise protocols used in these studies were highly variable[2,17]. It should also be noted that few studies have found the same positive effects while using the same methods of evaluation. Moreover, a recent study failed to find an improvement in swallowing function with prophylactic swallowing rehabilitation[8].

Due to the conflicting results in the available literature, further research is warranted to investigate the potential benefits of prophylactic swallowing rehabilitation in patients with HNC who are scheduled to undergo CRT. This study aimed to determine whether prophylactic swallowing rehabilitation for HNC patients under-

* Corresponding author: Hiromi Furuie
Department of Otolaryngology, Hiroshima University, Kasumi 1-2-3, Minami-ku, Hiroshima 734-8551, Japan
Tel: 81-82-257-5252, Fax: 81-82-257-5254, E-mail: d115632@hiroshima-u.ac.jp

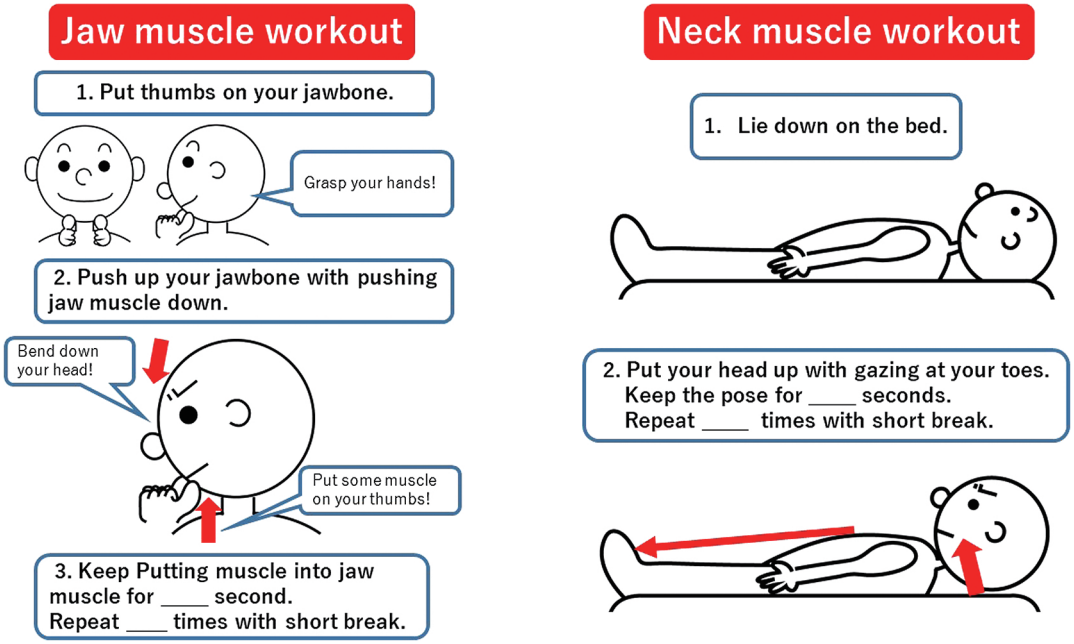

Figure 1 Briefing paper explaining the prophylactic swallowing rehabilitation protocol. The pictures and indications show the methods of prophylactic swallowing rehabilitation. Initially, speech therapists and/or expert nurses instructed the patients on how to perform the swallowing rehabilitation using this briefing paper.

going CRT would lead to better swallowing outcomes and, to investigate the utility of software analysis for evaluation of swallowing function.

MATERIALS AND METHODS

Patients

This was a retrospective cohort study. As we have recently started prophylactic swallowing rehabilitation for HNC patients treated with CRT, we compared the patients who received prophylactic swallowing rehabilitation from the beginning with those who received the rehabilitation on demand. Patients with advanced squamous cell carcinoma of the head and neck who were treated at Hiroshima University Hospital from 2016 to 2017 with CRT primarily for the larynx field were included in this study. We reviewed the patients' medical records retrospectively. Patients with a previous history of HNC treatment or tracheostomy, and those who had swallowing dysfunction from the beginning were excluded from the study. All patients received 80–100 mg/m^2 of cisplatin on days 1, 22, and 43 if acceptable. All patients were administered intensity-modulated radiotherapy (IMRT) of 70 Gy in 35 fractions over 7 weeks concurrently with chemotherapy. After recruitment, the patients were divided into a rehabilitation group and non rehabilitation group. The 15 patients in the control group received the swallowing rehabilitation after CRT on demand, while the 15 in the rehabilitation group received prophylactic swallowing rehabilitation from the beginning.

Prophylactic swallowing rehabilitation

Before starting CRT, the patients were taught about the methods of prophylactic swallowing rehabilitation with reference to the briefing paper and a self-assessment sheet was circulated to evaluate the degree of performed rehabilitation. The prophylactic swallowing rehabilitation included mouth stretching and opening exercise, neck stretch, vocal exercise, cough exercise, and Shakers exercise (Figure 1). Initially, speech therapists and/or expert nurses instructed the patients on how to perform the swallowing exercise, after which the patients performed the exercises themselves. The patients mentioned the number of times each exercise was performed in the self-assessment sheet.

On demand swallowing rehabilitation

During CRT or after CRT period, some patients who had difficulty swallowing or risk of aspiration received swallowing rehabilitation, similar to prophylactic swallowing rehabilitation contents. The patients who had no trouble in swallowing had received no rehabilitation instruction.

Evaluation of swallowing function

For all patients, videofluorography (VF) was performed at the beginning of the treatment and after completion of CRT when the patients restarted oral intake (80 mA, 65 kV, 80 msec/Fr, SONIALVISION G-4; Shimadzu, Tokyo, Japan).

The VF images were analyzed with 2D motion analysis software (Dipp-Motion V; DITECT, Tokyo, Japan) for spatial and temporal interpretation. For this purpose, the coordinate origin was set at the top edge of the fifth cervical spine. The vertical line was fixed from the fifth to second cervical spine with the horizontal line set on the origin. Furthermore, 5 points were fixed as reference points: hyoid bone, tongue base, epiglottic vallecula, arytenoid edge, and post-cricoid cartilage. The motion of the

Table 1 Penetration-Aspiration Scale scores.

Score	Description
1	No contrast enters the airway.
2	Contrast enters the airway, remains **above the vocal folds**, and **is ejected** from the airway (not seen in the airway at the end of the swallow).
3	Contrast enters the airway, remains **above the vocal folds**, **and is not ejected** from the airway (is seen in airway after the swallow).
4	Contrast enters the airway, **contacts the vocal folds**, and **is ejected** from the airway.
5	Contrast enters the airway, **contacts the vocal folds**, and **is not ejected** from the airway.
6	Contrast enters the airway, **crosses the plane of the vocal folds**, and **is ejected** from the airway.
7	Contrast enters the airway, **crosses the plane of the vocal folds**, and **is not ejected** from the airway despite effort.
8	Contrast enters the airway, **crosses the plane of the vocal folds**, and **is not ejected** from the airway and there is **no response** to aspiration.

Table 2 Bolus residue scale scores.

Score	Description
1	No residue.
2	Residue in the valleculae.
3	Residue in the posterior pharyngeal wall or piriform sinus.
4	Residue in the valleculae and posterior pharyngeal wall or piriform sinus.
5	Residue in the posterior pharyngeal wall and piriform sinus.
6	Residue in the valleculae and posterior pharyngeal wall and piriform sinus.

hyoid bone was plotted using the software, and the position of the hyoid bone, its maximum elevated position, the distance moved, and the speed of its movement were analyzed, as reported in a previous study[6]. The length of hyoid bone movement was measured relative to a coin with 23.5 mm diameter and located on the examining table in an erect position. Additionally, we calculated the change in the size of the pharynx cavity, using the planar dimension circle around the set points and cervical spine line. As part of swallowing motion analysis, we measured the duration of swallowing onset, larynx elevation time, and total swallowing time using motion analysis graphics (Figure 2). Additionally, each VF movie was scored using the Penetration-Aspiration Scale (PAS)[11] (Table 1) and Bolus Residue Scale(BRS)[13] (Table 2). After CRT, the Functional Oral Intake Scale (FIOS) scores[10] (Table 3) were evaluated.

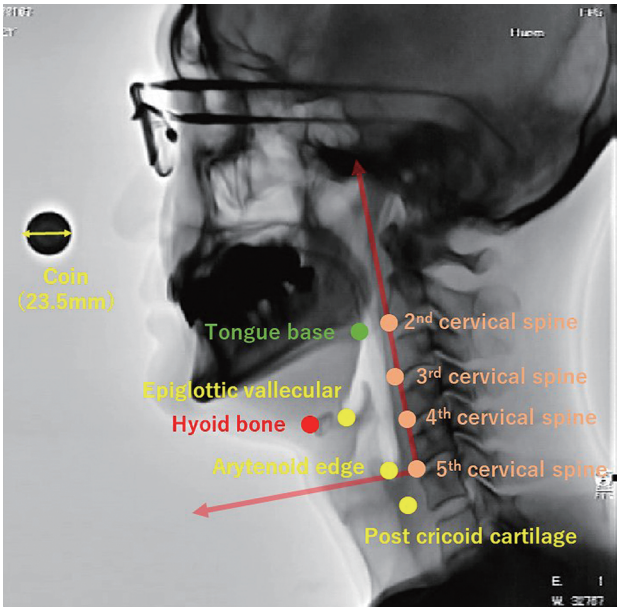

Figure 2 Analysis set point on fluorography image. For motion analysis of fluorography images, the coordinate origin was set at the top edge of the 5th cervical spine. The vertical line was set from the 5th to 2nd cervical spine, with the horizontal line set on the origin. The other 5 points were reference points: hyoid bone, tongue base, epiglottic vallecula, arytenoid edge, and post-cricoid cartilage.

Statistics

All statistical analyses were conducted using JMP v13.0 (SAS Institute Inc.). Regarding the comparison of patient characteristics, each data point was statistically analyzed by chi-squared test. Regarding the position of the hyoid bone, its maximum elevated position, the distance moved, the speed of its movement, the size of the pharynx cavity, the duration of swallowing onset, larynx elevation time, and total swallowing time, pre and post CRT data were statistically analyzed by paired t-test for the rehabilitation and control groups. A p value was analyzed as an average of the difference between pre and post CRT of each group. Regarding PAS, BRS, and FIOS, the score of each group was statistically analyzed by Student's t-test. A p value < 0.05 was considered a statistically significant difference.

RESULTS

Thirty patients were enrolled in this study. There were no significant differences between the rehabilitation group and the control group in terms of age, sex, primary tumor site, TNM clinical stage, or treatment regimen (Table 4).

There was no remarkable change in the position of the

Table 3 Functional Oral Intake Scale scores.

Score	Description
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.

Table 4 Patient characteristics.

Charactrestic	Total Sample	Intervention	Control
Age (mean year)	67 (50–79)	62 (50–78)	69（56–79)
Sex (Male, Female)	M 28, F 2	M 14, F 1	M 14, F 1
Hypopharynx	12	5	7
Oropharynx	9	5	4
Larynx	5	4	1
Glossa	2	1	1
Tumor Stage (2/3/4)	6/7/19	2/4/11	4/3/8
CDDP cycles (2/3)	12/17	8/7	5/10

hyoid bone, its maximum elevated position, its speed of motion, and the size of the pharynx cavity between the pre CRT and post CRT. There were also no statistically significant differences between the rehabilitation and control groups in terms of the position of the hyoid bone ($p = 0.544$), its maximum elevated position ($p = 0.345$), its speed of motion ($p = 0.364$), and the size of the pharynx cavity ($p = 0.553$)(Figure 3). In the rehabilitation group, the average of hyoid bone displacement was increased, and swallowing onset duration, larynx elevation time, and swallowing time were not postponed between pre and post CRT. In the control group, the average of hyoid bone displacement was decreased, and swallowing onset duration and swallowing time were postponed between pre and post CRT. There were statistically significant differences between the rehabilitation and control groups in hyoid bone displacement ($p = 0.0212$), the duration of swallowing onset ($p = 0.002$), larynx elevation time ($p = 0.0212$), and total swallowing time ($p = 0.002$) and hence better swallowing function (Figure 4, 5). Although the differences between groups in PAS ($p = 0.1543$), BRS ($p = 0.1081$), and FIOS ($p = 0.1783$) scores were not significant, the rehabilitation group tended to have better scores and hence better swallowing function (Figure 6).

DISCUSSION

A number of studies have shown that CRT for the head and neck region has a negative effect on swallowing function[5,9,21,22]. The primary adverse effects of CRT affect the key anatomical areas and may weaken tongue base movement, prolong pharyngeal transit time, reduce elevation of the larynx, reduce laryngeal closure and epiglottis inversion, and alter tissue integrity, thereby leading to fibrosis. Fibrosis affects both oral and pharyngeal muscles, contributing to reduced mobilization of muscles and structures during swallowing. These adverse changes contribute to a high rate of aspiration, resulting in the need for alternative methods of nutrition and disuse of the swallowing muscles. The consequent lack of masticatory and pharyngeal muscle activity is an additional reason for the delay in post-treatment swallowing recovery. The importance of continuing with even limited oral intake during treatment has been highlighted in the literature. Therefore, the importance of continued rehabilitation throughout the treatment and post-treatment periods to maintain swallowing function is self-evident[16]. The concept of exercises to reduce swallowing-related morbidity has been explored in several recent studies[3,19,20]. Early implementation of protective exercises has been highlighted as an important intervention for patients undergoing organ-preservation protocols for a number of years, given the known impact of CRT on swallowing function[2,7,9,18]. However, it is only recently that the potential benefit of prophylactic swallowing rehabilitation for HNC patients treated with CRT has begun to be investigated[2,14,18]. Despite the limited evidence for the beneficial effects of prophylactic swallowing rehabilitation on swallowing function in this patient population, these exercise programs have become an important component of the management strategy for patients undergoing organ-preservation treatments.

To date, several published studies, including randomized controlled trials, have evaluated prophylactic swallowing exercises and related swallowing outcomes. Kotz et al. reported that patients who performed prophylactic swallowing exercises had improved swallowing function, as evaluated with the FOIS-score after CRT[23]. Carnaby et al. also evaluated the efficacy of swallowing exercise during CRT with a randomized controlled trial that showed a significant benefit in terms of the Mann Assessment of Swallowing Ability score[18]. Kulbersh et al. also reported an improvement in the M.D. Anderson Dysphagia Inven-

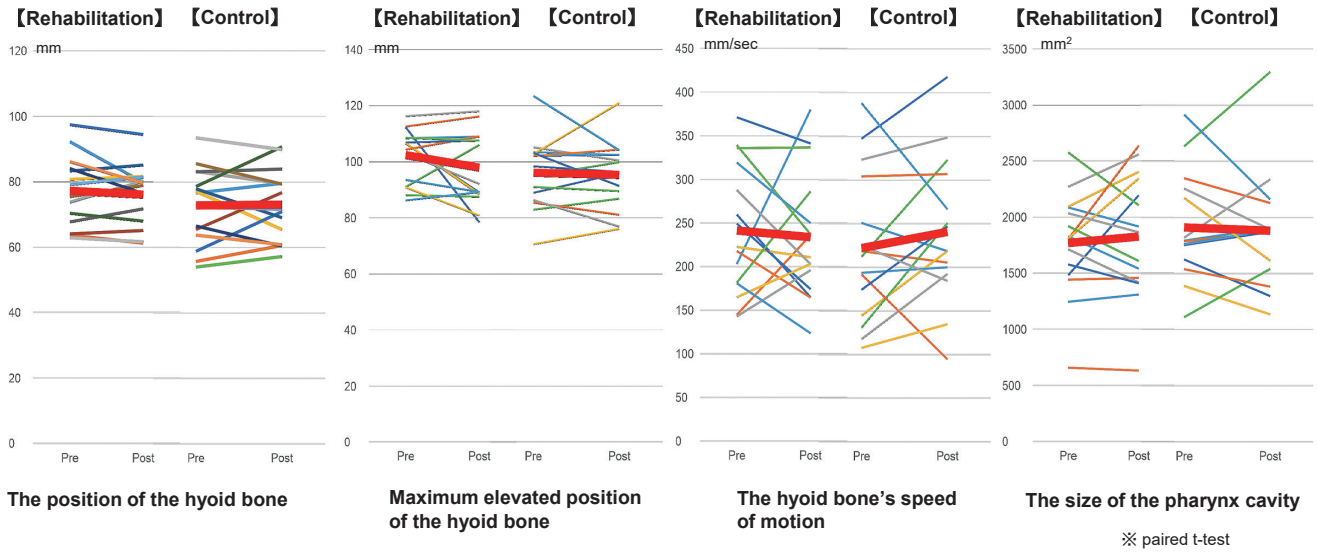

Figure 3 Comparisons of the position of the hyoid bone, maximum elevated position of the hyoid bone, the hyoid bone's speed of motion, and the size of the larynx cavity onset between the rehabilitation group and the control group. Each colored line indicates the change from pre-CRT (left side) to post-CRT (right side) and the average data are shown with the heavy red line. There were no remarkable changes in the position of the hyoid bone, its maximum elevated position, its speed of motion, and the size of the pharynx cavity between pre-CRT and post CRT. CRT: chemoradiotherapy.

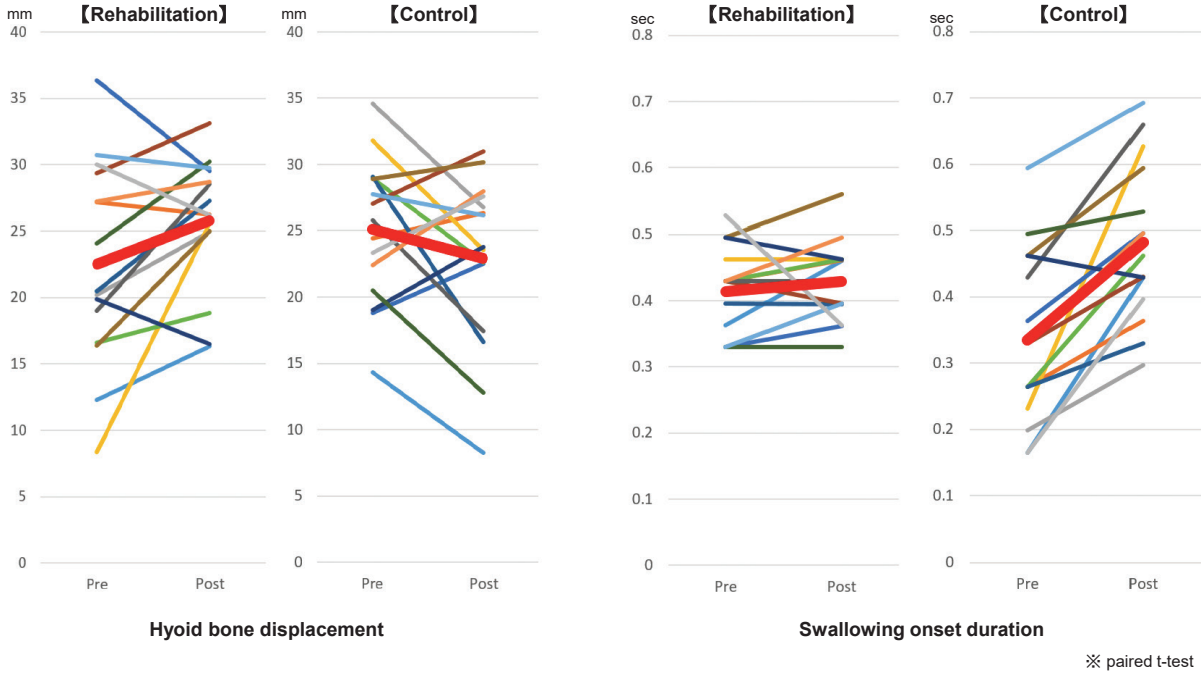

Figure 4 Comparisons of hyoid bone displacement and duration of swallowing onset between the rehabilitation group and the control group. In the rehabilitation group, the distance moved by the hyoid bone increased, indicating improvement in hyoid bone movability after CRT. In the control group, the duration of swallowing onset increased, indicating weakening of swallowing onset after CRT. CRT: chemoradiotherapy.

tory quality-of-life score[9]. Although several clinical outcome measures are available to assess the severity of swallowing dysfunction, these are indirect measures, and as such, VF is the most popular and efficient examination that visually demonstrates the dynamic state of swallowing. Even though PAS is a popular scoring system for swallowing based on VF, there are no methods that directly evaluate swallowing function.

Fortunately, with recent advancements in image analysis software, precise analysis of swallowing motion can be performed using computers. Ohba et al. evaluated VF movies of post-CRT HNC patients using motion analysis software and demonstrated the benefit of prophylactic swallowing exercise[6]. We used the image analyze software, similar to previous studies, to measure the swallowing function with special focus on the movement of the hyoid bone.

In this study, we found that patients who were provided prophylactic swallowing rehabilitation from the beginning of CRT had significantly improved hyoid bone movement, swallowing onset duration, larynx elevation time, and total swallowing time. Additionally, the PAS,

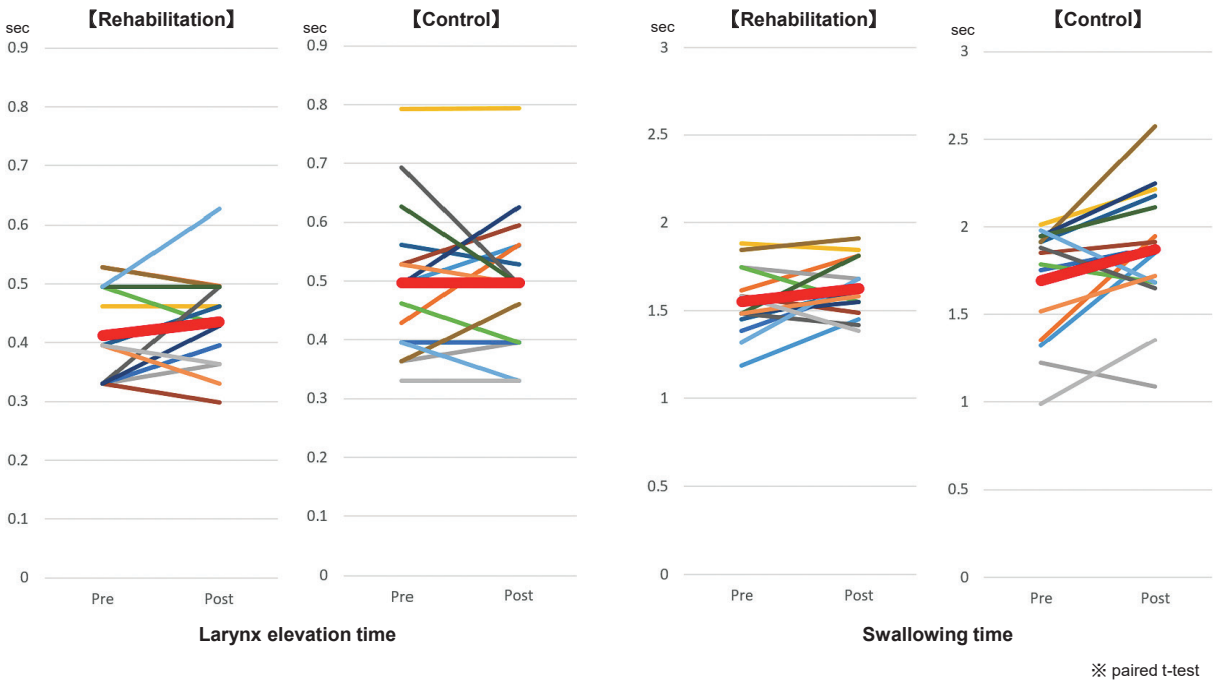

Figure 5 Comparisons of larynx elevation time and swallowing time between the rehabilitation group and the control group. In the rehabilitation group, the larynx elevation time slightly increased, indicating improvement in larynx movability after CRT. In the control group, the swallowing time increased, indicating weakening of swallowing movement after CRT. CRT: chemoradiotherapy.

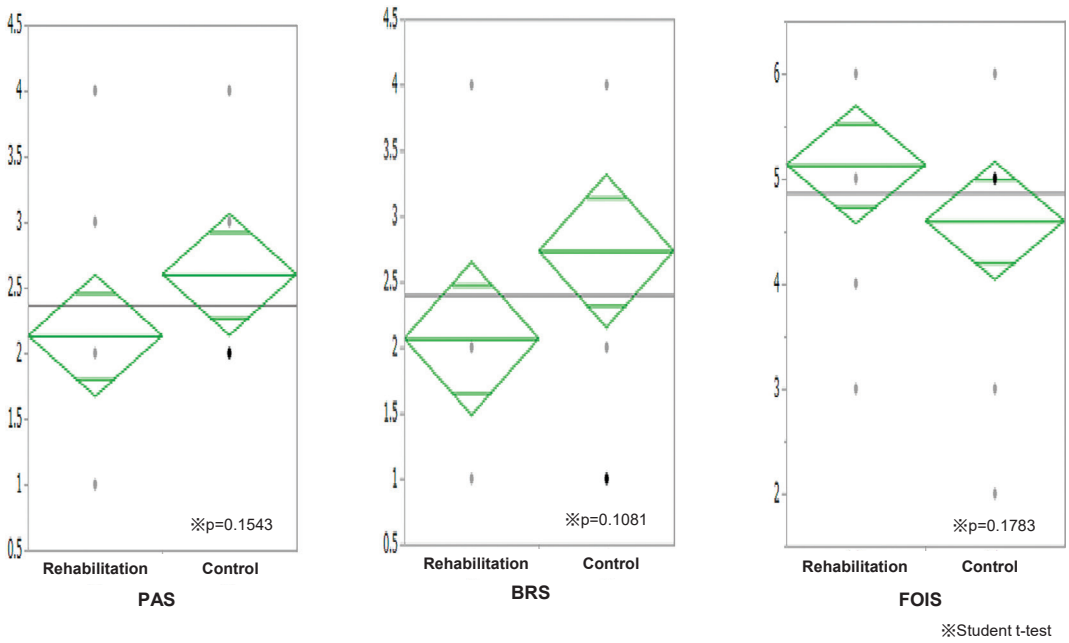

Figure 6 Comparisons of Penetration-Aspiration Scale, Bolus Residue Scale, and Functional Oral Intake Scale, scores between the rehabilitation group and the control group. Diamonds indicate the average value of the distribution. The top and bottom points of the diamond indicate the 95% confidence interval. The center line indicates the total average value and the short line on each side indicates the 25th and 75th percentile quarter ranges. The rehabilitation group showed better swallowing function, as the average distributions of the PAS, BRS, and FOIS scores were higher in the rehabilitation group.

BRS, and FOIS scores were better in the rehabilitation group, though the difference was not statistically significant. We recognized that hyoid bone displacement might represent swallowing functional movement relevant to larynx elevation time and total swallowing time. We also recognized that the swallowing onset time might represent the sense of pharyngeal reflex relevant to total swallowing time.

Although the PAS, BRS, and FOIS have been designed to be simple, in the interest of brevity, the scores may differ slightly depending on the grader. In contrast, software analysis provides accurate results and has high repeatability, hence, it is more useful for detecting significant differences. Our results, similar to those of previous studies, indicate the benefit of prophylactic swallowing rehabilitation and the possibility that software analysis can be used to evaluate swallowing function.

Nonetheless, some limitations to our study deserve

mention. We configured the assessment time to after completion of CRT when patients restart oral intake. The assessment timing was a little earlier, as worst swallowing dysfunction occurs 3 months post-CRT[24]. However, to truly benefit, rehabilitation group should continue exercise for a while with self-initiated motivation. Second, this was not a prospective and randomized study. As each patient has distinct primary and regional malignant development, background, and motivation for rehabilitation, these differences created barriers in matching background of the patients to perform a prospective and randomized study. Third, the sample size was small. Although locally advanced HNC are relatively rare malignancies, a larger sample size may have enabled us to predict which patients would have been more likely to benefit from prophylactic swallowing rehabilitation. It would also help us answer the important question of how much and how often do the exercises need to be performed to be effective.

DISCUSSION

Based on the results obtained in this study, it is not possible to conclude that pretreatment exercises are efficacious in preventing swallowing problems, but they seem to indicate that software analysis of videofluorography images can be used to evaluate swallowing function. These issues exemplify the need for further studies designed to examine appropriate prophylactic swallowing exercises implemented with adequate frequency, intensity, and long-term practice for maximum functional gain and recovery in this patient population.

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Conflict of interest

None of the authors have any conflict of interest to declare in relation to this study.

Ethical Approval

All procedures performed in this study involving medical information of human participants were in accordance with the current version of the Declaration of Helsinki. The study protocol was approved by the Human Ethics Review Committee of Hiroshima University Hospital (E-503).

Informed Consent

Informed consent was obtained from all individual participants included in this study.

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