

## Effects of Tablet Size and Head Posture on Drug Swallowing: A Preliminary Examination Using Endoscopy in Healthy Subjects

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Tablet size and head posture have been reported to affect swallowing of medications, but no previous studies have evaluated their effects in detail. Our aim was to investigate for the first time the effect of tablet size and head posture on drug swallowing by endoscopic evaluation in healthy subjects. Round tablets (7, 10, 12, and 14 mm in diameter) were swallowed by 15 healthy adults with an endoscope inserted in the neutral, head flexion, and head extension positions. Evaluation of swallowing difficulty using a numeric rating scale (NRS), presence or absence of pharyngeal residue and its location, and tablet oral transit time (TOTT) were recorded. In the neutral position, the NRS score was higher with the 14 mm tablets than with the 7 mm tablets. The TOTT with the 7 mm tablets was significantly shorter in the head extension than in the neutral position. Swallowing difficulty increased when the tablet diameter was more than 7 mm. Residues were found in the epiglottis, pyriform sinus, and tongue base. These findings suggest that head extension shortens the TOTT and assists oral-pharyngeal transport.

**Key words:** tablet size, head posture, swallowing, endoscopy, pharyngeal residue

**A**mong orally administered drugs, tablets are the most popular because they are easier to handle and more portable than syrups and capsules [1]. However, difficulty in swallowing drugs is observed in 10-40% of healthy subjects and in a greater percentage of elderly people with dysphagia, leading to a reduction in adherence to medications [2].

Tablet size affects the ease of picking up and swallowing of the tablets [1]. When the tablet is too small, it is difficult to pick up, and when it is too large, it is difficult to swallow [1]. Oshima *et al.* compared the ease of picking up and swallowing placebo tablets between 132 healthy elderly people and 102 healthy university

students by unaided visual observation of the tablets [3]. They concluded that tablets  $\leq 8$  mm in diameter are easy to swallow, and tablet sizes  $\geq 7$  mm are easy to pick up [3]. Kurata *et al.* performed a subjective sensory evaluation of the difficulty of picking up and swallowing an orally disintegrating placebo tablet in 84 people aged  $\geq 65$  years [1]. They found that 76% of the participants had difficulty in swallowing a tablet with a diameter of 15 mm. They also found that a 13 mm diameter tablet is easier to pick up than an 8 mm diameter tablet [1]. Schiele *et al.* conducted a questionnaire survey of 11 general practitioners and 1,051 patients taking medication [4]. They reported that 37.4% of the patients complained of difficulty when taking the drug, and that 70.4% of the attending physicians were not aware of

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such difficulty. Difficulty in swallowing was reported with round tablets with an average diameter of  $8.7 \pm 2.0$  mm, whereas no difficulty was reported with tablets with an average size of  $8.1 \pm 1.7$  mm [4]. The evaluations in these studies were based on participants' impressions when looking at the tablet and their subjective impressions after swallowing. No studies have objectively evaluated tablet swallowing using video-endoscopy (VE) or video-fluorography (VF) in healthy subjects. In addition, no studies have objectively evaluated swallowing function when tablets are taken with different head postures [2,4,5]. The purpose of this study was to investigate the effects of tablet size and head posture on drug swallowing using subjective and objective evaluation methods in healthy subjects.

## Materials and Methods

This study was conducted in accordance with the Declaration of Helsinki. This study was approved by the Kanagawa Dental University Research Ethics Review Committee (approval number: 585) and registered in the UMIN Clinical Trial Registration (number: UMIN ID R000044760; registered February 17, 2020). We explained the study procedures and ethical matters to the participants, and written informed consent was obtained from all participants.

**Determination of water volume when taking medications.** Six participants swallowed a commercially available placebo tablet with a diameter of 7 mm (Placeplus<sup>®</sup>; Placebo Pharmaceutical, Shiga, Japan). Participants swallowed a total of 5 tablets using a total of 5 volumes of water in randomized order: 5 mL, 10 mL, 15 mL, 20 mL, or 30 mL. The difficulty of swallowing the tablet in each trial was recorded by visual analog scale (VAS) as a subjective evaluation. The suitable water volume for taking tablets was set based on the ease of taking tablets; the head was in a neutral position for this series of trials.

**Preparation of tablets to be taken.** The tablets used were prepared according to the pharmacist instructions. A hot hand press analog HHT-1<sup>®</sup> (AS ONE, Osaka, Japan) was used to produce tablets with different diameters. The composition was 99.0% crystalline cellulose and 1.0% sodium stearate. Table 1 shows the diameter, thickness, and weight of each tablet.

**Participants and measurements.** The study included 15 healthy adults with no clinical dysphagia.

The participants' age, sex, height, and usual head posture (neutral, head flexion, or head extension) while taking medications were recorded. Four types of tablets (A, B, C, and D) with different diameters were administered to the participants in each of the three positions (12 trials for each participant). The neutral, head flexion, and head extension positions were determined using Mizuno's method [6]. The head angle was  $60^\circ$  in the head flexion position,  $90^\circ$  in the neutral position, and  $120^\circ$  in the head extension position with reference to the Frankfurt plane, which is the line connecting the external ear canal and the acromion when sitting (Fig.1). The participant sat in a wheelchair (KAJ202SB-42; Kawamura Cycle, Hyogo, Japan) with feet on the floor, the head supported with a wheelchair pillow (Kurumaisuyou-antoudai; Nihon ISK, Ibaraki, Japan), and a cushion to maintain the neck angle during swallowing. The plain water used for swallowing tablets was colored with green dye (Shokuyou-Shikiso: green; Kyouritsu Shokuhin, Tokyo) so it could be observed with an endoscope. A predetermined amount of the colored water was placed into a catheter-tip type syringe (Terumo Syringe<sup>®</sup>, 50 mL, catheter-tip type; Terumo Corporation, Tokyo) and an assistant directly injected it into the oral cavity while maintaining the swallowing position. The subject was instructed to swallow immediately after the tablet was put into the oral cavity. Before the measurement, the participants took placebos (Placeplus<sup>®</sup>) in both the head

Table 1 Tablet characteristics

type	diameter (mm)	thickness (mm)	weight (mg)
A	7	4	180
B	10	4	350
C	12	4	450
D	14	4	600

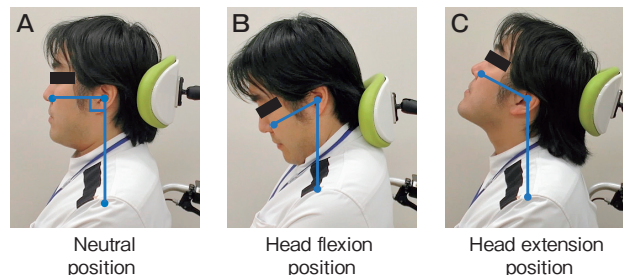


Fig. 1 Head position when swallowing tablets. A, Neutral position; B, Head flexion position; C, Head extension position.

flexion and head extension positions for training.

A laryngoscope (ENT-30PC, 3.2 mm diameter; Machida Seisakusho, Chiba, Japan) was used for the swallowing test and was inserted nasally after applying a lubricant (K-Y jelly; Reckitt Benckiser, Slough, England) to the shaft of the endoscope. VE images were obtained using a light source (RLED30; Machida Seisakusho), monitor (LCD-GC252SXB; I-O Data Device, Ishikawa, Japan), and video recording system (CA22WP; Machida Seisakusho). After inserting the endoscope, participants swallowed only the determined amount of water in the neutral position as a control during the first procedure. In the second procedure, participants took a tablet of each diameter in a neutral head position with an amount of plain water determined by randomized order (4 times in total). The same trials were then performed in the head flexion and head extension positions. For each participant, the order of the four differently sized tablets (tablets A to D) was randomized by a computer. The subject and the monitor showing VE images were recorded simultaneously by a video camera (GZ-RY980; JVC Kenwood, Kanagawa, Japan).

The subjective estimation of swallowing difficulty was expressed using the numeric rating scale (NRS) [7]. In addition, the occurrence of gag reflex and residue in the oral cavity were recorded. After the examination, the recorded VE image was investigated, and the tablet oral transit time (TOTT) (starting when the tablet entered the oral cavity, to when swallowing occurred, then whiteout at the point of maximal pharyngeal contraction) was measured. The occurrence of cough reflex during swallowing, presence or absence of residue in the pharynx, and location of residue were recorded.

**Statistical analysis.** The results are shown as the median (interquartile range). The Friedman test was used for the comparison of tablet diameter by NRS and TOTT in each posture and the comparison of the posture by NRS and TOTT for each tablet diameter. The Mann-Whitney *U* Test and Kruskal-Wallis test were used for comparison of three or more groups, and the Bonferroni test was performed in a *post-hoc* analysis. Cochran's Q test was used to compare the occurrence of pharyngeal residue to the difference in tablet diameter in each posture, and to compare the location of the residue in the pharynx to the difference in posture for each tablet diameter, and the Bonferroni test was used in a *post-hoc* analysis. SPSS Statistics 26 (IBM Japan, Tokyo,

Japan) was used for statistical analysis.

Based on a previous study, the required number of cases for 80% power was calculated to be 13, considering an  $\alpha$  error of 5% and a  $\beta$  error of 20% [8]. G\*Power 3.1 (Kiel University, Kiel, Germany) was used for calculating sample size. Assuming a dropout rate of 20%, 15 patients were finally considered as the required number of cases.

## Results

**Background of subjects.** The study included 15 healthy adults (11 men and 4 women) with a median (interquartile range) age of 32 (29-35) years and a height of 168 (163-171) cm. The usual head posture while taking tablets was the extended position in 11 participants (73.3%) and the neutral position in 4 participants (26.7%).

**Determination of water intake when taking medication.** Table 2 shows the VAS scores reflecting the ease of taking the placebo for each tested amount of drinking water. A VAS value of 50 is considered the middle score, at which a placebo tablet (diameter of 7 mm) can be taken normally. The median VAS value of 15 mL water was 49.5, and that of 20 mL was 15.5, indicating a reduction in VAS with increasing water volume. Based on the above results, 15 mL was considered the appropriate amount of water when taking tablets in this study.

**Performance status.** In 180 trials, NRS and TOTT were measurable in all tests. The pharyngeal residue in 2 cases could not be confirmed after swallowing due to cough reflex (tablet diameters of 10 mm and 12 mm in the head extension position). In 5 cases, a tablet could not be delivered to the pharynx and remained in the oral cavity. In addition, in 3 cases, the tablet returned to the oral cavity after being transferred to the pharynx.

**NRS.** Figures 2 and 3 show the NRS results for tablet swallowing. The median NRS score for swallowing 15 mL of water alone was 1 (0-3). In all treatments,

**Table 2** VAS in determining water intake

	5 mL	10 mL	15 mL	20 mL	30 mL
Max	100	80	70	52	35
Min	79	5	8	6	0
Median	93.5	67	49.5	15.5	17

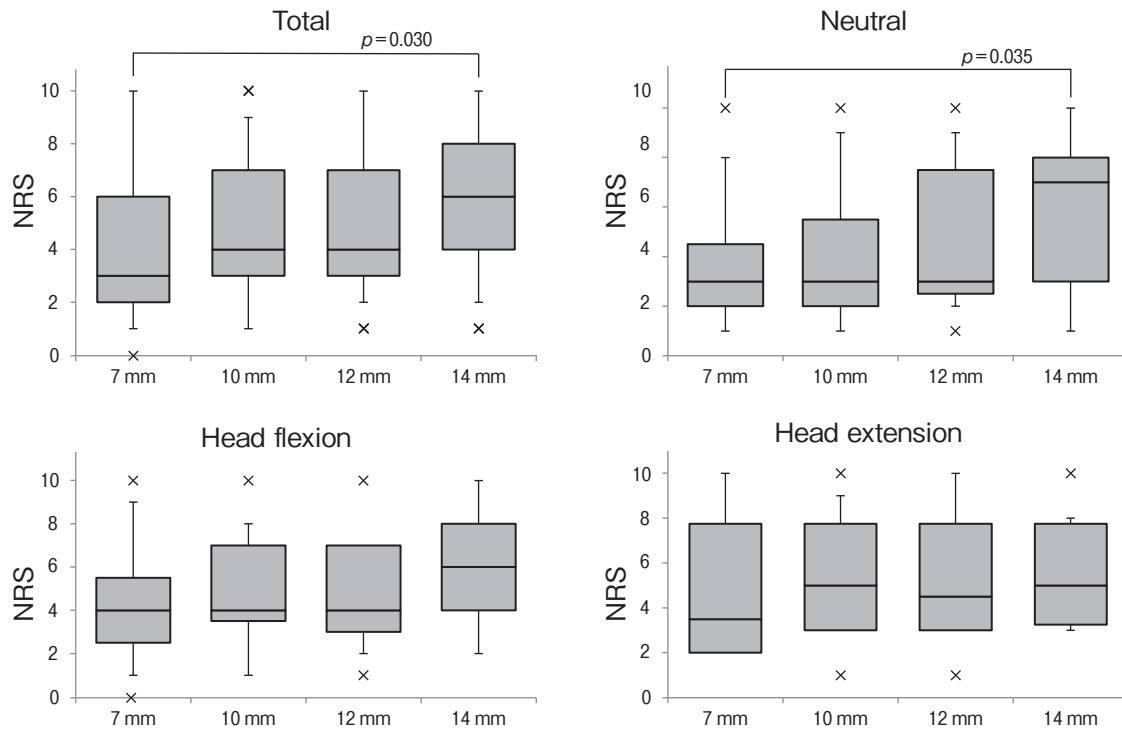


Fig. 2 Comparison of NRS between tablet diameters. Box and whisker plots of the NRS for each of four tablet diameters: 7 mm, 10 mm, 12 mm and 14 mm.

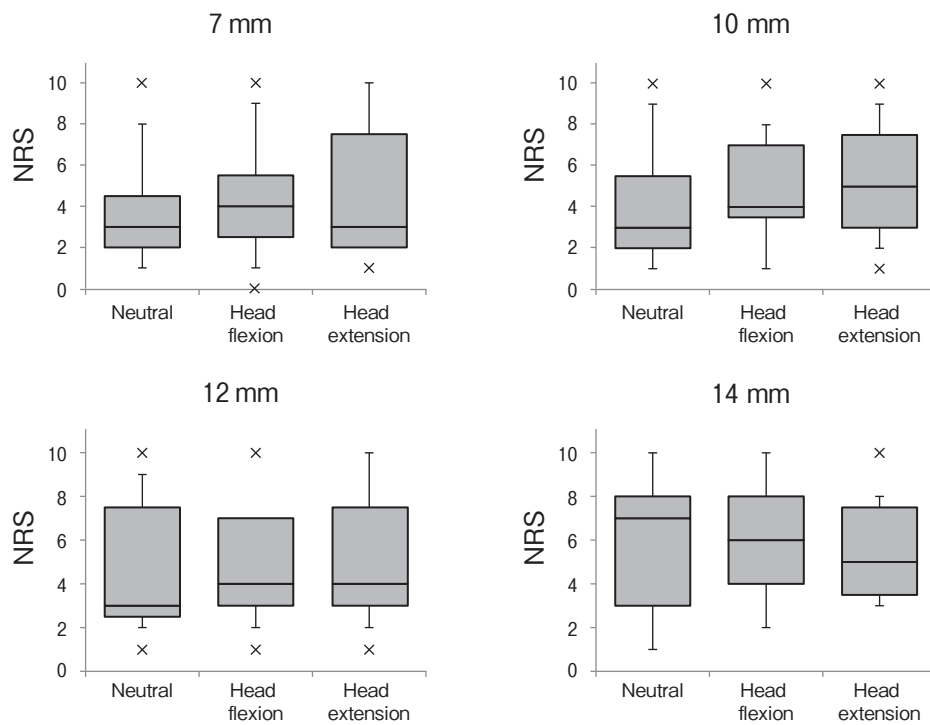


Fig. 3 Comparison of NRS between postures. Box and whisker plots of the NRS for each of three postures: the neutral position, head flexion position and head extension position.

the NRS score was significantly different among the 4 groups of tablet diameters ( $p=0.047$ ), and multiple comparisons showed significantly different NRS scores between 7 mm and 14 mm (overall) ( $p=0.030$ ) (Fig. 2). In the neutral position, a significant difference in NRS scores was found between the four groups ( $p=0.0067$ ). In multiple comparisons, a significant difference in NRS scores was found between 7 mm and 14 mm in the neutral position ( $p=0.035$ ), but no difference was observed in the other postures (Fig. 2). Comparison of NRS scores among postures showed no significant difference for each tablet diameter (Fig. 3).

**TOTT.** The TOTT results when swallowing tablets are shown in Figures 4 and 5. No significant difference was observed in the comparison of TOTT among tablet diameters in each posture (Fig. 4). The comparison between the postures at each tablet diameter showed a significant difference in TOTT among the three groups ( $p=0.032$ ). Multiple comparisons showed a significant difference in TOTT between the neutral and head extension positions with 7 mm tablets ( $p=0.032$ ) (Fig. 5).

**Pharyngeal residue.** Table 3 shows the findings in regard to residue within the pharynx. Pharyngeal

residual tablet was observed in 23 of 180 cases (12.8%). No significant difference was found between the tablet diameter and head posture with regard to the occurrence of residue in the pharynx. Based on the VE images, the pharyngeal residue was located in the epiglottic vallecula (VAL), pyriform sinus (PS), and tongue base (TB) (Fig. 6). Residues were observed in 14 cases (7.8%) in the VAL, 7 cases (3.9%) in the PS, and 2 cases (0.1%) in the TB. Residues in the VAL were observed in all postures, but residues in the PS were not found in the neutral position. The median NRS score (interquartile range) was significantly higher when pharyngeal residue was present than when pharyngeal residue was absent, *i.e.*, 7 (5-9) vs. 4 (2-7), respectively ( $p=0.00004$ ).

### Discussion

This study showed that the NRS score increased in proportion to an increase in tablet diameter. In particular, a tablet with 14 mm diameter was more difficult to swallow than a tablet with 7 mm diameter in the neutral position. TOTT was significantly shortened in the head extension position when a tablet of 7 mm diameter was

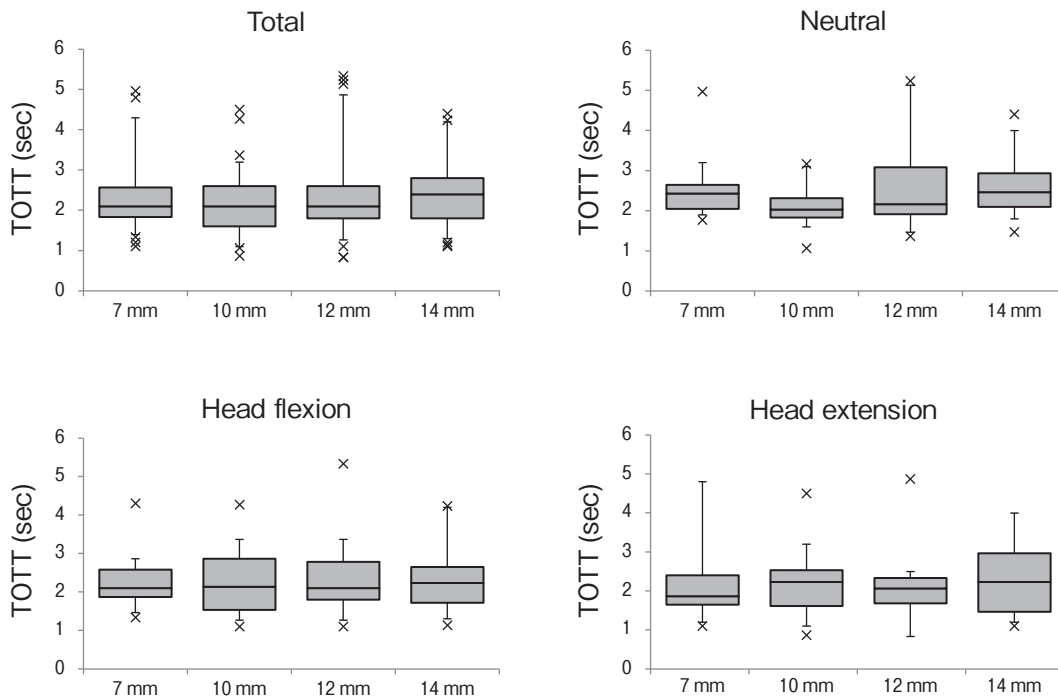


Fig. 4 Comparison of TOTT between tablet diameters. Box and whisker plots of the TOTT for each of four tablet diameters: 7 mm, 10 mm, 12 mm and 14 mm.

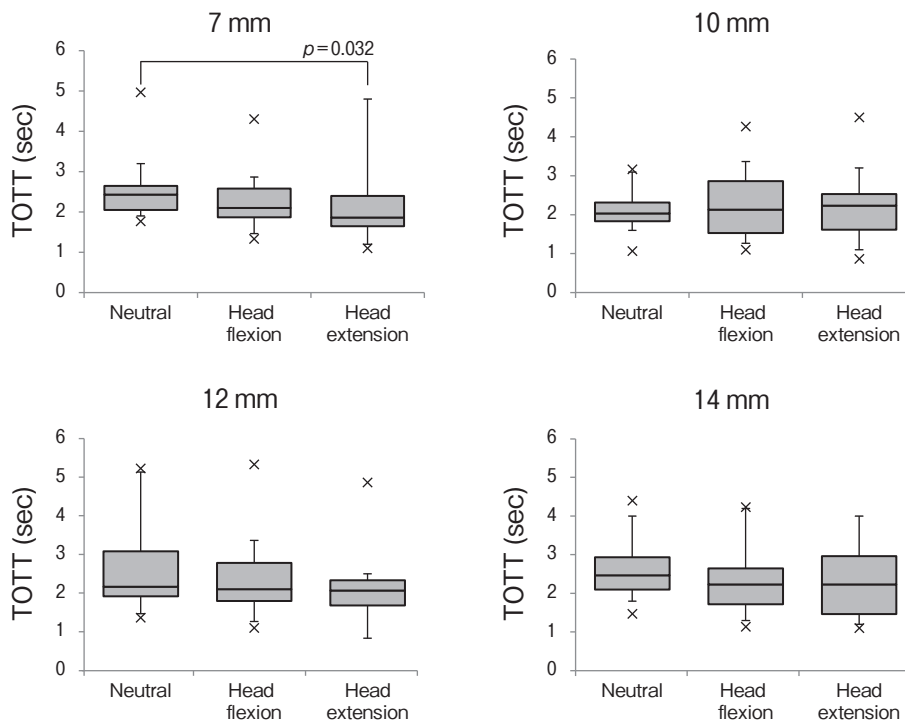


Fig. 5 Comparison of TOTT between postures. Box and whisker plots of the TOTT for each of three postures: the neutral position, head flexion position and head extension position.

Table 3 Pharyngeal residue

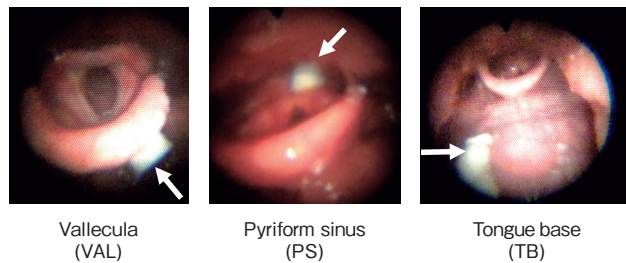
		7 mm	10 mm	12 mm	14 mm	total
Pharyngeal residue	Neutral	3	1	2	2	8
	Head flexion	2	2	1	3	8
	Head extension	1	3	2	1	7
	Total	6	6	5	6	23
Vallecula	Neutral	3	1	2	2	8
	Head flexion	1	1	0	0	2
	Head extension	1	1	1	1	4
	Total	5	3	3	3	14
Pyriform sinus	Neutral	0	0	0	0	0
	Head flexion	1	1	1	2	5
	Head extension	0	2	0	0	2
	Total	1	3	1	2	7
Tongue base	Neutral	0	0	0	0	0
	Head flexion	0	0	0	1	1
	Head extension	0	0	1	0	1
	Total	0	0	1	1	2

swallowed. Residues in the pharynx were observed in the VAL, PS, and TB.

Two patient studies have reported the objective eval-

uation of tablet swallowing using VE examination. Mann and Cray evaluated the swallowing of normal and orally disintegrating tablets (ODTs) in 36 patients





**Fig. 6** Location of pharyngeal residual tablet. Endoscopic images of the pharynx immediately after tablet swallowing. The white arrow indicates the position of the residual tablet.

with dysphagia [9]. When swallowing a normal tablet as compared to an ODT, significantly greater surface electromyographic amplitude and longer total swallowing time were observed. Buhmann *et al.* evaluated swallowing function by swallowing endoscopy in 118 patients with Parkinson's disease (PD) and 32 healthy subjects [10]. They found that 28% of PD patients and 16% of controls showed substantial impairment in the ability to swallow medication. However, problems in the study included tablets dissolving in the pharynx or oral cavity, coughing, and the need to drink water repeatedly after swallowing the tablets.

The evaluation measures of our study were the NRS score after swallowing as a subjective evaluation, TOT as an objective evaluation, and pharyngeal residue. The NRS can capture detailed subjective changes. It is useful to convey subjective numerical evaluation results in a short time after swallowing, when the endoscope is inserted nasally. Total time to swallow (TTS), measured as the time from when an oropharyngeal tablet is placed on the tongue until the time it disappears, has previously been used as an objective evaluation of the tablet swallowing time [9]. TTS captures the total time of swallowing—including the preparation, oral, and pharyngeal stages—as well as the additional swallowing period when the tablet remains in the pharynx [9]. In this case, the presence or absence of residue in the pharynx greatly affects the results, masking the differences in time between the 5 swallowing stages. Similar to TTS, TOT starts when the tablet is placed in the oral cavity, but unlike in TTS, TOT ends when whiteout is observed with the endoscope. Whiteout with VE is a phenomenon that occurs when the soft palate or the base of the tongue is elevated approximately 0.02 sec after the swallowing reflex is triggered [11]. Therefore, whiteout could be used as a standard

point when the pharyngeal swallowing reflex begins. In other words, TOT is an index that is not affected by the time change due to residue in the oral cavity and pharynx after the swallowing reflex. TOT reflects the temporal effects on the movement of tablets in the oral cavity and the movement from the oral cavity to the pharynx due to changes in tablet diameter and posture during swallowing.

A previous study reported that a tablet diameter of 7 mm or more is “easy to pinch” and is desirable [3]. On the other hand, in the same study about 70% of healthy elderly people found it difficult to swallow a 10 mm tablet, suggesting that swallowing becomes difficult when the tablet is large [3]. In this study, we included healthy adults and allowed them to swallow tablets of diameter 7 mm, 10 mm, 12 mm, and 14 mm. The NRS score tended to gradually increase as the tablet diameter increased, and a significant difference was observed between 7 mm and 14 mm in the neutral head position of swallowing (Fig. 2). The difficulty in swallowing increased as the tablet diameter increased, which is the same result as in the previous report [3].

On the other hand, no significant difference was found in TOT or the frequency of pharyngeal residue, as the present study included young adults who had a swallowing function tolerance (“reserve”). Hence, tablet diameter may not have affected these factors [12]. In other words, young adults have more than the minimum necessary swallowing function; therefore, they can cope with inadequate bolus formation during the preparatory stage. In addition, young adults have longer hyoid bones, greater laryngeal elevation, and a larger amount of movement than the elderly [12]. On the other hand, there is little “reserve” in the elderly; therefore, if the study was conducted in the same settings for the elderly, a significant difference in TOT and pharyngeal residue may have been observed.

With regard to the relationship between posture and NRS, a significant difference was found between the tablet diameters of 7 mm and 14 mm in the neutral head position, but no significant difference was noted in NRS according to tablet diameter in the head flexion and head extension positions (Fig. 2). However, when the tablet diameters were 7, 10, and 12 mm, the median NRS was 3 in the neutral head position and 4 to 5 in the head flexion and extension positions, thus suggesting that the head flexion and extension positions might have been set at different angles from the usual

head postures during tablet intake for each subject.

The results showed that the TOTT in the head extension position was significantly shorter than that in the neutral head position when swallowing a 7 mm tablet. Forough *et al.* stated that when a person who has no dysphagia complains of difficulty in swallowing when taking medication, it is best to start with posture adjustment, which does not require invasive or special preparation [2]. Kaplan *et al.* compared the medication-swallowing status in the neutral, chin-up, chin down, and lateral rotation positions and stated that the neutral and chin down positions are the preferred postures for taking drugs [5]. Schiele *et al.* introduced the pop-bottle method with head extension movement and lean-forward with head flexion movement when taking drugs [13]. Calvo *et al.* used the chin-up posture as a compensatory procedure in patients with oral disorders but no laryngo-pharyngeal disorders, such as those with postoperative tongue cancer and cerebrovascular disorders with motor paralysis confined to the hypoglossal nerve [14]. In this method, gravity assists the feeding movement from the oral cavity to the pharynx, which is normally performed by tongue movement [14].

When we investigated the usual head posture for taking tablets, 73.3% of participants used the neutral position, 26.7% used the head extension position, and none used the head flexion position. The head extension compensation method was performed for tablet swallowing in approximately 25% of healthy subjects. It can be inferred that it is more difficult to transport the tablet from the oral cavity to the pharynx than the food bolus; thus, the compensatory method is conventionally performed. This result shows that TOTT was shorter in the head extension than in the neutral head position when swallowing a 7 mm tablet, which is considered to be the result of gravity-assisted oropharyngeal transport. The advantage of head extension was limited to tablets of 7 mm diameter or less, because the difference in posture showed no effect while swallowing tablets with a diameter of 10 mm or more. In addition, the head extension swallowing method is not recommended for patients with pharyngeal dysphagia because it requires sufficient swallowing function tolerance ("reserve") [12].

In this endoscopic evaluation, we found variations in the location of pharyngeal residual tablet, such as the VAL, PS, and TB. A previous study using VE for

patients with PD has shown that tablets become stuck in the epiglottis or that disintegrated tablets remain [8]. Our present study is the first to show by means of endoscopic images that residual tablet remained in the PS and TB after swallowing (Fig. 6). Previously, the PS and VAL have been reported as the sites of frequent pharyngeal food residue [12]. The mechanism differs depending on the location of residue. VAL residue increases when epiglottic anatomical morphology and/or epiglottic inversion is weakened due to reduced hyoid elevation [15]. PS residue is said to be caused by a decrease in pharyngeal contraction force or a decrease in the amount of upper esophageal opening [15]. TB residue increases when the propulsive force of the tongue weakens [15]. In the present study, although we found no significant difference between the frequency of PS residue and that of TB residue, there was little residue on the VAL in the head flexion position. It has been reported that in head flexion, the distance between the epiglottis and the TB is shortened and the space in the VAL is narrowed, so that the VAL residue is likely reduced [16]. On the other hand, in our series there were many residues in the PS in the head extension position and no residue on the PS in the neutral head position. Residue in the PS may increase because the epiglottic pressure increases, but the hypopharyngeal contraction pressure decreases in the chin tuck position [17]. In addition, both head flexion and extension positions shorten the opening time of the upper esophageal sphincter [18]. The neutral head position may result in good clearance of the PS. Although the location of the pharyngeal residual tablet changed with the change in swallowing posture, the frequency of occurrence of pharyngeal residue did not change. It is traditionally considered that posture adjustment is useful for assisting swallowing function [19], but changing the swallowing posture is not always effective to avoid pharyngeal residual tablet.

The limitations of the present study are as follows. First, in order to investigate the effect of tablet diameter on swallowing function, a cylindrical tablet was made with a tableting machine, but many tablets on the market are shaped as ordinary R and two-stage R tablets without corners [20]. The corners may cause more friction with the oropharyngeal mucosa than the regular tablets. Buhmann *et al.* examined the effect of tablet coating and reported that a coated tablet is easier to swallow than a non-coated tablet even if it is large [10].



Thus the reduction of friction by tablet coating may greatly affect the ease of swallowing. However, the effect of tablet shape on swallowing function is still unknown.

Secondly, we performed a video-endoscopic swallowing study as an objective evaluation of swallowing function, but the presence of the endoscope inserted through the nose promotes discomfort during swallowing and may affect the NRS. The median (interquartile range) NRS score when swallowing 15 mL of water after endoscopic insertion was 1 (0-3); thus, the NRS result during tablet swallowing should be adjusted by subtracting the discomfort from endoscopic insertion. In addition, fixation of the head using a wheelchair pillow might have caused tension in the neck during swallowing, which could have affected the NRS.

Finally, although the water amount required for tablet swallowing was determined with the head in the neutral position, the appropriate water amount may differ if the head is in the flexion or extension position. In future studies, the appropriate amount of water should be confirmed even in head flexion and extension in order to improve the validity of the study.

In conclusion, when the tablet diameter was increased to more than 7 mm, our participants found the tablet difficult to swallow, and the head extension position shortened the tablet oral transit time and assisted the oral-pharyngeal transfer of the tablet. Based on the above results, it will be most convenient for a person without dysphagia to swallow a 7 mm diameter tablet in a head extension position. However, depending on the patient's posture, the tablets may remain not only in the VAL but also in the PS and TB. In the elderly and in patients with dysphagia, depending on the type of impaired swallowing, adjusting the tablet mold may be considered necessary.

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