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The influence of size, specific gravity, and head position on the swallowing of solid preparations

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ABSTRACT

Aim: To clarify the influence of size and specific gravity of solid preparations, and the position of healthy volunteers when swallowing, for the purpose of practical use in patient consultation regarding the taking of medicines.
Materials and methods: The paper reports three studies. Volunteers were asked to swallow four different capsules (A, large and heavy; B, large and light; C, small and heavy; D, small and light) in Study 1, two preparations with different positions (upright, horizontal, and chin-down) in Study 2, and two preparations before and after anesthetization of the bilateral lingual and inferior alveolar nerve in Study 3. The oral transit time (OTT) and pharyngeal transit time (PTT) were evaluated with videofluoroscopy.
Results: The mean OTT became longer in the order of C, D, B, A. The mean PTT showed no statistically significant differences. The swallowing preference of the four preparations ranked by the subjects showed that difference in size but not the difference in specific gravity is a significant factor. In the chin-down position, OTT was shorter for two preparations, compared with the other two positions. The mean OTT for both the A and B preparations was significantly longer after the bilateral lingual and inferior alveolar nerves were anesthetized.
Conclusion: When swallowing solid preparations, a consideration of size and the position will enable ease of swallowing of medicines. This would especially be the case when delivery of the medicines to be taken by the aged suffering from oral hypoesthesia caused by an underlying disease.

1. Introduction

There are patient complaints of difficulties in swallowing tablets and capsules. In particular, elderly patients express such complaints, and perceptions of swallowing difficulty may be caused by one or more of the following factors, considering both patients and drug preparations. One of the problems for patients is that taking tablets and capsules is different from ingestion of solid foods, because patients are required to swallow without chewing, making the mechanism of swallowing medications without mastication different from that of swallowing solid food [1]. It is reported that transport of chewed solid food from the oral cavity to the pharynx is actively driven by tongue-palate contact and does not depend on gravity [2]. The other factor may be deterioration in the swallowing function in the elderly [3,4]. Further, dry swallowing has been shown to take longer than wet swallowing, and the duration of both kinds of swallowing increases with age [5,6]. Other factors are volume of water ingested when swallowing medicines [7], the posture/position [8], and gravity [2]. Further, psychological stress may be a factor in swallowing difficulty. Problems with medicine preparations include the fact that tablets and capsules may behave differently in the mouth when they are administered with water, because the specific gravity of most tablets is above that of water and that of medications in capsules is below specific gravity. Further, Overgaard et al. have discussed the size, shape, color, and surfaces of preparations [9], Hey et al. the size, shape and weight of preparations [10], and Channer and Virjee the size and shape [11]. The various findings will be discussed in detail. Here it is reported that capsules were easier to swallow than tablets, and that the difficulty in swallowing increases with the size of the capsules or tablets to be swallowed [9]. Differences in the specific gravity of solid preparations was reported as an important factor in swallowing by Kahrilas et al. [7], while Johnsson et al. [8] found that the specific gravity of the bolus did not influence oral and pharyngeal transport in healthy volunteers. There have been no reports of a correlation between size and specific gravity of solid preparations or head position, and swallowing.

Before starting this survey, the authors had interviewed 240 out-patients of dental clinics about medications. About 40% of these patients answered that they had felt difficulty in taking

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medications. Asked in which posture they would take a capsule, 47.2% answered upright, 51.5% horizontal, and 1.3% reported the chin-down position [12]. These results suggested the need for a more detailed survey of the relationship between swallowing solid medications and head position.

Based on these findings, the investigators here hypothesized that the size and specific gravity of solid preparations as well as head position affect the perceived ease of swallowing of solid preparations. It was also hypothesized that loss of tongue sensation induced by local anesthesia may affect the swallowing sequence of the solid preparations. To clarify the influence of size and specific gravity on the swallowing of solid preparations, the head position and effects of local anesthesia, the oral transit time (OTT), and pharyngeal transit time (PTT) of capsules, and the perceived degrees of difficulty in swallowing capsules of different weights and specific gravities were investigated.

2. Materials and methods

2.1. Study design/subjects

To address the purpose of the research, the investigators designed and implemented three experimental studies.

2.1.1. Study 1: size and specific gravity

The subjects swallowed four different preparations in capsules in a set order of A, B, C, and D (further details below) in the horizontal position, and this was repeated three times for each preparation.

2.1.2. Study 2: head positions

The subjects swallowed two preparations A and B in 3 different head positions – upright, horizontal, and chin-down, and this was repeated three times. We defined chin-up or head back position as upright in this study. According to Logemann [13], the chin-up posture is used to drain food from the oral cavity using gravity. It is helpful to patients with reduced tongue control. If the clinician is concerned about airway protection when the patient's head is tilted back, the patient may be taught supraglottic swallowing. Then we defined the three head positions: the head facing up ("upright" in the following from Johnsson [8] and Palmer [2]), the head facing forward ("horizontal" in the following from Johnsson), and the head facing down ("chin-down" in the following from Logemann).

2.1.3. Study 3: influence of local anesthesia

The subjects swallowed preparations A and B in the horizontal head position, and this was repeated three times. Then, local anesthesia of the bilateral lingual and inferior alveolar nerve was administered by injection of 2 ml of 2% lidocaine (Xylocaine, AstraZeneca, Osaka, Japan); next, one of the authors established the absence of sensation on the dorsal surface of the tongue by touching it with a pair of tweezers, and additional lidocaine was administered where sensation remained. Following the confirmation of absence of sensation, the subjects were asked to swallow preparations A and B in the horizontal head position, in the same order as in the first stage of the study.

2.1.3.1. Solid preparations. Four solid preparations, capsules, were used in the studies (Table 1). The capsules contained lactose and to vary the specific gravity also barium sulfate (Baritop P) capsules were hard gelatin-type J. P. No.1-size (19 mm × 7 mm, volume 0.60 ml) for preparations A and B, and J.P. No.4-size (9 mm × 4 mm, volume 0.24 ml) for preparations C and D. The A preparation was a large, heavy capsule equivalent to a large tablet; B was like a large and light capsule; C was a small and heavy tablet; and D was like a small and light capsule (Table 1).

2.1.3.2. Subjects. The study population comprised healthy volunteers recruited among dentists and pharmacists at Hokkaido University Hospital, and students of the schools of pharmacy at 3 universities—Hokkaido University, Hokkaido Pharmaceutical University, and the Health Sciences University of Hokkaido—with the studies conducted between July 2001 and November 2009. To be included in the study, volunteers were required to give informed consent in writing, with regard to the videofluoroscopic examination.

The participants had no history of swallowing difficulties, changes of voice, or neurologic diseases, major illnesses, or head and neck surgery. Ethical approval was secured from the Hokkaido University Ethics Committee.

2.2. Variables

The dependent factors were the OTT and PTT. The objects were the four preparations (A, B, C, and D) in Study 1, three head positions (upright, horizontal, and chin-down) in Study 2, and the absence or presence of local anesthesia in Study 3. In each study, the OTT and PTT were evaluated as the primary outcomes. The OTT and PTT were evaluated with videofluoroscopic examinations. The secondary outcome was a rating of the swallowing preferences by the subjects themselves for the capsules in Study 1.

At the end of the Study 1 procedures, the subjects were asked to rank the order of ease of swallowing of the preparations (self-rating in the ease of swallowing).

2.3. Data collection

The subjects swallowed the capsules described above in the same order, while seated, and the capsule swallowing was repeated 3 times. Each preparation was taken separately as a single bolus with 30 ml of water.

A videofluoroscopic examination of the swallowing was performed during the swallowing in lateral projection. The videofluoroscopy started just before a capsule entered the mouth and ended after the capsule had been fully swallowed, and transported to the esophagus. The results of the oral and pharyngeal swallowing were recorded on videotape and converted to digital data. The OTT and the PTT were determined using Premiere (ver.5.0, Adobe Systems Incorporated, San Jose, CA, USA) software. One of the authors examined the OTT and PTT throughout the study. The OTT is defined as the length of time between a capsule entering the mouth and reaching the margin of the mandibular bone, and the recorded time was an average of the three trials. The PTT is defined as the length of time between a capsule passing the margin of the mandibular bone and the rear tip of the capsule passing the pharynx, thus fully entering the esophagus. This was also averaged over the three trials. At the end of Study 1, the subjects were asked to rank the ease of swallowing of the preparations ingested (self-rating).

2.4. Data analysis

The statistical analysis was performed using ANOVA, and $p < 0.05$ was considered to be statistically significant.

3. Results

Fifty-four healthy volunteers were enrolled in the three studies. Twenty-five volunteers (20 male and 5 female) aged between 22 and 37 were the subjects of Study 1. Nineteen volunteers (12 male and 7 female) aged between 21 and 43 were the subjects of Study 2. Ten volunteers (all male) aged between 24 and 32 were the subjects of Study 3.

Table 1
Solid preparations tested in the present study.

Preparation	A Large and heavy	B Large and light	C Small and heavy	D Small and light
Contents (mg)	742.3	339.4	320.5	134.2
Barium sulfate	742.3	169.7	320.5	67.1
Lactose	–	169.7	–	67.1
Gravity (mg)	815.1	412.2	358.5	172.2
Specific gravity	1.37	0.69	1.52	0.73

Table 2
Oral transit time (OTT), pharyngeal transit time (PTT) and self-rating of swallowing for four preparations (mean ± SE).

Preparation	A	B	C	D
Number of subjects	2	1	15	6
OTT (s)	2.29 ± 0.32	2.23 ± 0.27	1.97 ± 0.31[a]	1.98 ± 0.26[b]
PTT (s)	1.10 ± 0.01	1.10 ± 0.01	1.10 ± 0.01	1.10 ± 0.01

Number of subjects: number of subjects who ranked the preparation as easiest to swallow. One subject was excluded from the table, because this subject could not recognize differences in the specific gravities of the preparations.
[a] OTT A and C, $p = 0.031$.
[b] OTT B and D, $p = 0.039$.

Table 3
Oral transit time (OTT), pharyngeal transit time (PTT) for the three head positions (mean ± SE).

Head position	OTT (s)		PTT (s)	
	Preparation			
	A	B	A	B
Upright	1.14 ± 0.27	1.24 ± 0.25	0.12 ± 0.02	0.11 ± 0.02
Horizontal	1.32 ± 0.19	1.46 ± 0.24	0.09 ± 0.01	0.09 ± 0.01
Chin-down	0.96 ± 0.10[a]	0.95 ± 0.12	0.10 ± 0.01[b]	0.10 ± 0.02

In oral transit time for preparation A, statistically significant difference between the chin-down and horizontal positions ($p = 0.025$).
[a] OTT A, horizontal and chin-down, $p = 0.025$. In the pharyngeal transit time for preparation A, there were statistically significant differences between the chin-down and upright head positions ($p = 0.02$).
[b] PTT A, upright and chin-down, $p = 0.02$.

3.1. Study 1: influence of size and specific gravity

3.1.1. OTT and PTT

The mean OTT was longer in the order of preparations C, D, B, and A. The smaller capsules showed shorter OTT than the larger capsules (C and D vs. A and B), and the OTT for the smaller capsules was shorter than the large capsules with the same specific gravity ($p < 0.05$). Capsules with the low specific gravity showed shorter OTT (difference not statistically significant) when in the form of large capsules. The mean PTT showed no statistically significant differences among all four preparations (Table 2).

3.1.2. Self-rating

The order of the ease of swallowing for the four preparations ranked by the subjects when ingesting in the horizontal head position are shown in Table 2. These results show that preparations C and D (small capsules) were easier for the subjects to swallow than preparations A and B (large capsules). The ease of swallowing order for the four preparations ranked by subjects coincided correlated with the OTT values but not with the PTT values. One subject did not recognize differences in the specific gravity of the preparations of A vs. B, or C vs. D. We excluded this subject from the data in Table 2.

3.2. Study 2: influence of head position

3.2.1. OTT and PTT

The OTT of preparations A and B were shorter in the chin-down position than in the horizontal and upright positions (Table 3). Moreover, the OTT of preparation A in the chin-down position was statistically significantly shorter than that in the horizontal head position ($p < 0.05$).

The PTT of the chin-down and upright positions for preparation A were also statistically significantly different ($p < 0.05$). There were numerical differences in the PTT among head positions and between preparations, but these differences were smaller than those of the OTT durations.

Table 4
Oral (OTT) and pharyngeal transit times (PTT) before and after the bilateral lingual and alveolar nerves were anesthetized (mean ± SE).

Before and after	OTT (s)		PTT (s)	
	Preparation			
	A	B	A	B
Before	0.96 ± 0.17[a]	1.06 ± 0.14[a]	0.18 ± 0.03[a]	0.22 ± 0.03
After	4.17 ± 1.72	2.99 ± 1.02	0.26 ± 0.03	0.28 ± 0.05

[a] Before and after the anesthesia, OTT for preparation A ($p = 0.038$) and B ($p = 0.031$), and PTT for preparation A ($p = 0.018$) showed statistically significant differences.

3.3. Study 3: influence of local anesthesia

3.3.1. OTT and PTT

The mean OTT was statistically significantly longer after the anesthesia, both for preparations A and B. After the bilateral lingual and inferior alveolar nerves were anesthetized ($p < 0.05$), the mean OTT for preparation A was prolonged more than that of preparation B, when compared with the differences before the anesthesia. The mean OTT for preparation A was 4.3 times longer after the anesthesia (0.96 vs. 4.17 s), and for preparation B the duration was 2.8 times longer (1.06 vs. 2.99 s) after the bilateral lingual and inferior alveolar nerves were anesthetized (Table 4). There were large individual differences in OTT pre- and post-anesthesia for both preparations A and B. The differences in the PTT values for both preparations A and B were smaller than those in the OTT values.

4. Discussion

It has been reported that the preparations were to be taken with a minimum of 10 ml of water [14], or around of volume of water would be appropriate. However, we observed capsules adhering to the esophageal membrane at the level of the carina in a preliminary study. Then we decided the swallowing volume of water defined as 30 ml is sufficient, as 10–20 ml of fluid is necessary to induce peristalsis. In the study here, subjects have to drink water repeatedly, three or four times, once for each preparation.

The results show that size and specific gravity of the swallowed capsules may affect the OTT. The ease of swallowing order for the four preparations as ranked by the subjects correlated approximately with the OTT values but not with the PTT values. Both the heavy and light capsules showed shorter OTT and PTT in the chin-down position. The mean OTT was statistically significantly longer after the bilateral lingual and inferior nerves were anesthetized.

The results of the present study show that swallowing tends to be easier with small than with large capsules. For the influence of the size and specific gravity of the capsules in Study 1, it was conjectured that with capsules of the same size, those with higher specific gravity would be easier to swallow than those with lower specific gravity. Also, that if the capsules have the same specific gravity, a smaller capsule would be easier to swallow than a larger one. We surmised that capsules with higher specific gravity would sink into the liquid swallowed with the capsule and be transported to the pharynx with the liquid. It was further conjectured that capsules with lower specific gravity would float on the water swallowed with the capsule while the capsule remained in the mouth. This was assumed to be a cause of the longer OTT.

The swallowing preferences of the subjects showed that 21 subjects preferred small capsules and 17 subjects preferred heavy capsules. At the beginning of this study, it was surmised that both the size and specific gravity may affect the order of preference of swallowing, and that the influence of the size may be stronger than that of the specific gravity. Actually the result of the swallowing preference of the four preparations ranked by the subjects showed that the difference in size, but not the difference in specific gravity is a significant factor. This result is supported in the Johnsson report that the specific gravity of the bolus did not influence the oral and pharyngeal transport in healthy volunteers [8]. Also the swallowing preference in size was reflected in the results of OTT. The results suggest that the OTT may be used to establish swallowing preferences in patients. There are reports of the relationship between the preference for solid preparations in swallowing and OTT [10], here it was concluded that preferences are affected by the shape and size of the solid preparations.

The results of the study here are consistent with these reports: that is, the small, heavy preparation was ranked as the easiest to swallow, and has a shorter OTT.

Study 2 was aimed at evaluating factors affecting swallowing solid preparations. We surmised that if there was a relationship between swallowing and head position when swallowing preparations A and B, which were evaluated as difficult to swallow by the self-rating in Study 1, it could point to ways to swallow large capsules more easily. There are also pharmaceutical cases in which large capsules are filled with large volumes of active ingredients or excipients. However, patients sometimes take these preparations for their medication. With regard to the head position when swallowing, the chin-down head position showed shorter OTT for both preparations A and B. There were differences in the PTT among head positions and between preparations, but these differences were smaller than those of the OTT. Therefore, it may be recommended that heavy or light capsules be swallowed with the head in the chin-down position. The OTT of the large, light capsule was significantly shorter in the chin-down position than in the other two positions. This may be explained by the location of the capsule floating in the water in the mouth ingested with the capsule, because the light capsule tends to locate near the pharynx in the chin-down position, and supplementary movements facing the chin-down or horizontal position may affect swallowing. Some of the subjects, when swallowing in the horizontal head position swallow the preparations with supplementary movement such as drawing in the chin.

It was initially surmised that OTT is an indicator for the preference and/or ease of swallowing. If subjects are not able to transport preparations into the pharynx and keep the preparations, rolling in the mouth, the OTT will become longer. According to Logemann [13], the chin-up posture is used to drain food form the oral cavity using gravity. It is helpful to patients with reduced tongue control. If the clinician is concerned about airway protection when the patient's head is tilted back, the patient may be taught the supraglottic swallow.

As shown in Tables 2 and 3, there were differences in the OTT in Study 1 (A: 2.29 ± 0.32, B: 2.23 ± 0.27) and Study 2 (A: 1.32 ± 0.19, B: 1.46 ± 0.24). In the Study 1, OTT for A preparation became longer in 4 out of 25 subjects and also that for B preparation became longer in 3 out of 25 subjects compared with the mean OTT in each preparation. These outliers were rejected by test of rejection of Smirnoff. In this study we did not permit subjects to move their head up or down freely but to keep the head facing forward. Then it resulted in the differences between Study 1 and Study 2.

The aim of Study 3 was to determine the influence of local anesthesia on the OTT and PTT. Here sensory suppression was assumed to show which part of the swallowing process is affected by oral disturbances. It was speculated that the sensory suppression would further assist in a better understanding of swallowing difficulties. In this study, the swallowing in the oral phase took more time because of the sensory suppression by the topical anesthesia and the OTT was prolonged. The swallowing in the pharyngeal phase was less affected by the anesthesia than the swallowing in the oral phase. According to the report of Tei et al. [15], anesthesia of the lingual nerve simultaneously affects the inferior alveolar nerve. Consequently, both the mucosa of the dorsal surface of the tongue, and the mucosa of the lower lip, lower gingival mucosa, and periodontal ligament of premolars and molars are anesthetized. By the anesthetic injection, the sensory inputs from the mouth were reduced and the sensory feedback systems of the mastication were confused and had been disrupted. The prolongation of the oral containment time and total sequence duration, and the increase in total number of chews and swallows shown in the study clearly demonstrate that mastication after anesthesia is altered. The soft palate was not influenced by the sensory suppression. Based on this we surmised that the resulting total swallowing sequence is similar to that of elderly

with swallowing impairment due to underlying diseases such as neuromuscular diseases or cerebral infarction. Moreover, OTT is prolonged by the effect of sensory suppression. The results showed this to result in much longer OTT both for preparations A and B. It is considered that sandwiching of objects such as food between the hard palate and dorsum of the tongue when swallowing makes a closed space and produces a negative pressure, helping to push the object into the esophagus. The role of the mechanical receptor in the sensory nerve is to sense whether both the hard palate and the dorsum of the tongue are closed or not [16]. In the present study, the blocking of the bilateral lingual and inferior nerves may be assumed to modify the mechanics of the interaction between the tongue and the hard palate. The altered relationship between the tongue and the hard palate then induces the lengthening of the OTT, and the lengthening of the OTT caused by the oral sensory disturbance made it difficult for subjects to swallow.

The total swallowing sequence with the nerves anesthetized like in Study 3 here is similar to the situation in elderly patients with swallowing impairment due to some underlying ailment. In the case of patients who suffer from disorders in the oral area or oral phase, it may be recommended for such patients to be administered smaller capsules. If there is a need to ingest large capsules, a chin-down position with supplementary movements may be helpful to them.

5. Conclusions

We have observed capsules adhering to the esophageal membrane at the level of the carina in some subjects in the preliminary study: a situation which raises the risk of ulceration, perforation, or stricture. A low specific gravity capsule could become trapped in the pyriform fossa and cause dysphagia. Care is necessary when considering the size of solid preparations and an appropriate head position is also crucial for aged people with oral hypoesthesia caused by an underlying complaint.

Further investigation is needed to clarify more details of the factors that enable the swallowing of solid preparations simply and without discomfort. We hope that the findings in the present study will be helpful for patient consultation with regard to taking medicines appropriately in clinical use.

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