Innovative Tool for Taking Large Pills for the Elderly and Patients with Swallowing Difficulties

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Drugs provided with a jelly are reportedly easier for elderly patients to swallow. However, no innovative formulations have been developed that combine convenient packaging with a jelly (or gel). We attempted to develop an innovative packaging/jelly formulation to aid the swallowing of tablets among 35 people older than 65 years. More than 70% of study participants were able to swallow a large tablet easily with the new packaging/jelly formulation. Furthermore, more than 80% of participants preferred to use the new product when taking a large tablet or capsule daily. This new packaging/jelly formulation may lead to increased safety and improved compliance with drug therapy, as well as provide a new way of taking medication, not only among independent elderly patients, but also among highly dependent patients who experience difficulties swallowing.

**Keyword:** Innovative tool, pill, elderly, swallowing difficulties.

**Introduction:** Although there are differences in drug packaging/formulations in every country, risk management for drug taking is universal. Drug packaging that supports compliance with therapy is critical.[1] Because the life expectancy of Japanese people is the highest in the world, the number of elderly people in Japan is increasing.
Currently, subjects older than 65 years represent more than 23% of the Japanese population, and 86.2% of those older than 65 years use prescription drugs. At least 20% to 50% of elderly patients who use prescription drugs report some difficulties with taking drugs properly, including difficulties swallowing the pills.[2,3] In fact, recent reports have shown that accidents related to taking medications, particularly accidents related to difficulties associated with swallowing pills, are a common and serious problem.[4] It is clear that some type of supportive tool is needed that can help patients swallow pills.[5] This study examined the usefulness of a new gel-filled plastic film tube designed to make swallowing pills easier. Elderly participants used these packets to ingest large sugar tablets without water and evaluated the new packets.

Materials and methods

In November 2010, we conducted a study to evaluate the new gel packets, called Gel Together (GT) packets (Fig. 1) at the Sadamoto Clinic outpatient clinic and the Tachibana elderly care home located in Kanagawa, Japan. All of the participants who enrolled this study were older than 65 years. All had indicated that they understood the study after it was explained to them and provided informed consent to participate. The ethics committee at Sadamoto Clinic approved the study.

Figure 1. Picture of the GT (the white portion represents the tablet that needs to be swallowed)

The GT packets consist of two parts: an upper part containing a large lactic sugar powder tablet (18.2 mm long x 8.2 mm wide x 5.0 mm thick) and a bottom part containing a small amount (1.5 ml) of jelly (Fig. 1). This tablet was the same size as the biggest prescription tablet in Japan. As shown in Fig. 2, patients place the tablet-containing end of the GT in their mouth and squeeze the lower end containing the jelly/gel. This pressure causes the jelly to move toward the upper, tablet-containing end where it breaks a partition between the jelly- and tablet-containing compartments (Fig. 2). The jelly and tablet break a second partition and the tablet is pushed into the mouth.

The study comprised the following six steps:

Instructions on how to use a GT.

1. Measurement of pinch-power applied by participants using an Isoforce GT-300/305 (OG Giken KK, Okayama, Japan) machine.
2. Assessment of The Hasegawa Dementia Scale-Revised (HDS-R) by a medical doctor.
3. Pre-test: Trial involving pushing the gel from a packet into a cup.
4. Taking a tablet with a GT: Participants took tablets using a GT without water.
5. Evaluation of the GT by questionnaire.

The study was conducted in a small room with three people present: the administrator, the participant, and an observer. The administrator explained the details of study, scored the HDS-R, and measured pinch-power. The HDS-R score and pinch-power were used as objective scales to assess cognitive impairment and the ability to pinch open a packet, respectively. Participants then used a GT and answered a questionnaire at the end of the trial. The observer watched the participant during the trial and timed length of time required to understand the instructions regarding administration of the tablet and time required to take the tablet. The administrator and observer were same for each participant, and participants underwent the trial individually, one at a time. To rate the users’ subjective opinions of the gel packets, we used a 0-10 numerical rating scale (NRS), where 0 = the worst and 10 = the best (Table 1). Statistical analyses were performed using the Pearson correlation coefficient. Data were analyzed using SPSS for Windows®, version 17.0 (IBM Japan Ltd., Tokyo).

Table 1. Quantitative method for sensory test

<table>
<thead>
<tr>
<th>NRS</th>
<th>Breaking Film</th>
<th>Pushing Gel</th>
<th>Preference for a GT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Cannot open</td>
<td>Cannot push out</td>
<td>Do not like it at all/never want to use it</td>
</tr>
<tr>
<td>1</td>
<td>Extremely hard to open</td>
<td>Very difficult to push out</td>
<td>Clearly unfavorable</td>
</tr>
<tr>
<td>2</td>
<td>Relatively difficult to open</td>
<td>Relatively difficult to push out</td>
<td>Slightly unfavorable</td>
</tr>
<tr>
<td>3</td>
<td>No problem opening</td>
<td>No problem pushing out</td>
<td>The same as the prescribed tablet usually used.</td>
</tr>
<tr>
<td>4</td>
<td>Relatively easy to open</td>
<td>Relatively easy to push out</td>
<td>Slightly preferable</td>
</tr>
<tr>
<td>5</td>
<td>Very easy to open</td>
<td>Very easy to push out</td>
<td>Clearly preferable/want to use it all the time</td>
</tr>
</tbody>
</table>
Results

Table 2 shows participant profiles and scores for pinch power and HDS-R. Thirty-five participants were included in the study (23 outpatients and 12 patients in elderly care home). The mean age of subjects was 76.6±7.9 years, and the mean HDS-R score was 25.7±3.8 (best 30; under 20, suspect dementia). No patient had dysphagia. Twenty-eight patients (80%) reported experiencing choking when they ate or took medications, and all 35 reported that a big tablet was sometimes difficult to swallow. Table 3 shows participants’ understanding of the instructions for using the GT. Despite providing instructions for using the GT with a trial drug, about one quarter of patients were not successful at taking the drug. Table 3 shows participants’ evaluation of the procedure for taking a drug with the GT. About 23 patients (65.7%) were satisfied with the drug-taking procedure. However, among these 23 patients, 4 (16.7%) were not able to push the sugar pill completely into their mouth. Table 3 shows the NRS results for swallowing the sugar pill with the GT. Most patients provided a good evaluation of swallowing and indicated that they could not feel the tablet in their throat. Two thirds of patients were able to swallow the large placebo pill easily without any water in the first trial. Although one third of participants could not completely take pills with the GT, most of the patients who were unable to take the pills completely still provided a good evaluation of the GT. Good evaluations for taste and smell were also obtained. Despite the small amount of gel (1.5 mL) in the GT, two thirds of patients indicated that the volume of gel was adequate. The overall rating of the GT was 8.2±2.5, and 77.8% of patients preferred to use GT more than conventional pills (Table 3). Even among patients who failed to swallow the pill with the GT, most patients indicated that they still preferred to use the GT. Figure 3 demonstrates the correlation between pinch power and the technique required to use the GT. There was a strong relationship between pinch power and the method required to use the GT. A pinch power exceeding 2.6 kgf was correlated with ease of use of the GT.
Discussion

The administration of drugs using jelly to aid swallowing is already available for the elderly; however, no reports have been published to date regarding the use drug packaging combined with a jelly. Compared with younger people, the elderly tend to have chronic diseases and generally take more drugs more frequently than younger people; some of these tablets are relatively large. Indeed, the size of their medications may negatively affect compliance among elderly people with respect to their medical regimens. This lack of compliance not only makes it difficult to treat acute diseases, but it can complicate the management of chronic diseases. In addition, nurses, home care supporters, and family members often struggle to administer medicine to elderly patients,[6,7] and many elderly patients report difficulties with swallowing large tablets and capsules.[8,9] Some nurses and care supporters use jelly (or gel) to aid in the administration of drugs.[10-12]

Figure 3. Correlation between pinch power and actions when using a GT

This study of a new gel packet revealed that most patients did not experience any difficulties using the GT. In a previous study, despite receiving sufficient instruction regarding usage of a tool, only 30% or fewer of users were able to use the tool during the first try.[13,14] However, in this study, despite the fact that the GT differs from conventional drug packages, three quarters of participants could use the tool the first time they tried it. This means that participants understood the instructions and had the ability to use the GT. Based on HDS-R results, there was a low risk of dementia among study participants. This means that ordinary independent elderly subjects should be able to use a GT without difficulty. It is likely that the instructions will be even easier to understand if we take more time to demonstrate use of a GT, provide visual aids, and allow repeat trials.

In terms of pinch power, users with a pinch power greater than 2.6 kgf were able to push the gel out of the GT. Because most people have an average pinch power of 6 to 7 kgf,[15] the GT could be used by elderly persons with a lower-than-average pinch power.

In this study, all participants self-administered a large placebo tablet without water. This means that the GT can be used for patients who require less than average amounts of drinking water, patients who have difficulty drinking water, and
patients with aspiration pneumonia. In addition, evaluations of taste, smell, and gel quantity were all positive. GT packets may be helpful for patients with chronic swallowing and water-drinking problems. In addition, GT packets may be used by nurses or other supporters to help bedridden patients take their daily medications.

Conclusion

GT packets, a new packaging/jelly formulation, may lead to increased safety and improved compliance with drug therapy. In addition, it may provide a new way of taking medications, not only for independent elderly patients, but also for highly dependent patients who have difficulties swallowing.

REFERENCE: