

THE PHARMA INNOVATION

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

Kiyomi Sadamoto^{1*}, Masaru Mizoguchi², Takahiro Yamanouchi², Shuji Morimoto³, Kiyoshi Kubota⁴

1. Kiyomi Sadamoto; Professor M.D., Ph.D. Department of Clinical Science, Faculty of Pharmaceutical Sciences, Toho University, Miyama 2-2-1, Funabashi, Chiba 274-8510, Japan. Phone/FAX: +81-47-472-1171, E-mail:sadamoto@phar.toho-u.ac.jp
2. Masaru Mizoguchi, Takahiro Yamanouchi; Researcher Department of Clinical Science, Faculty of Pharmaceutical Sciences, Toho University, Miyama 2-2-1, Funabashi, Chiba 274-8510, Japan. Phone/FAX: +81-47-472-1171
3. Shuji Morimoto; Morimoto-Pharma Co., Ltd, President CEO Morimoto-Pharm Co.Ltd 1-25 Matsugaoka Senriyama Suitashi Osaka Japan 565-0843
4. Kiyoshi Kubota; Daiichi-Sankyo Co., Ltd. Chief Researcher, Packaging Research Group 1-12-1 Shinomiya, Hiratsuka, Kanagawa Japan 254-0014

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.

Corresponding Author's Contact information:

Kiyomi Sadamoto*

Department of Clinical Science, Faculty of Pharmaceutical Sciences, Toho University, Miyama 2-2-1, Funabashi, Chiba 274-8510, Japan

E-mail: sadamoto@phar.toho-u.ac.jp

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.

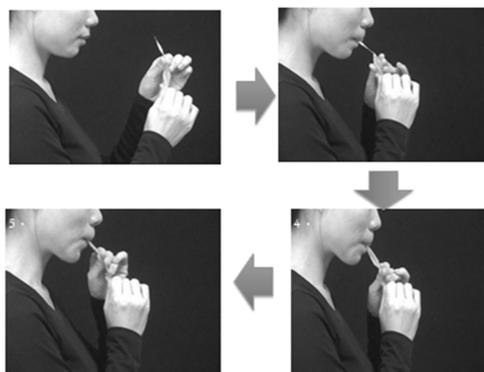
The study was conducted in a small room with three people present: the administrator, the participant, and an observer. The administrator explained the details of study, scored the HDS-R, and measured pinch-power. The HDS-R score and pinch-power were used as objective scales to assess cognitive impairment 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

NRS	Breaking Film	Pushing Gel	Preference for a GT
0	Cannot open	Cannot push out	Do not like it at all/never want to use it
1 2	Extremely hard to open	Very difficult to push out	Clearly unfavorable
3 4	Relatively difficult to open	Relatively difficult to push out	Slightly unfavorable
5 6	No problem opening	No problem pushing out	The same as the prescribed tablet usually used.
7 8	Relatively easy to open	Relatively easy to push out	Slightly preferable
9 10	Very easy to open	Very easy to push out	Clearly preferable/want to use it all the time

Figure 2. Instructions for using a GT



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.

Table 2. Participant profiles and scores for pinching power and HDS-R

	All Patients	Patients in Elderly Care Home	Outpatients in Clinic
Number	35	12	23
Males/females	10/25	1/11	9/14
Age, y	76.6±7.9	82.2±8.9	73.7±5.6
HDS-R	25.7±3.8	22.8±4.6	27.0±2.4
Pinch power (kgf)	4.7±2.3	2.7±2.3	5.8±1.3

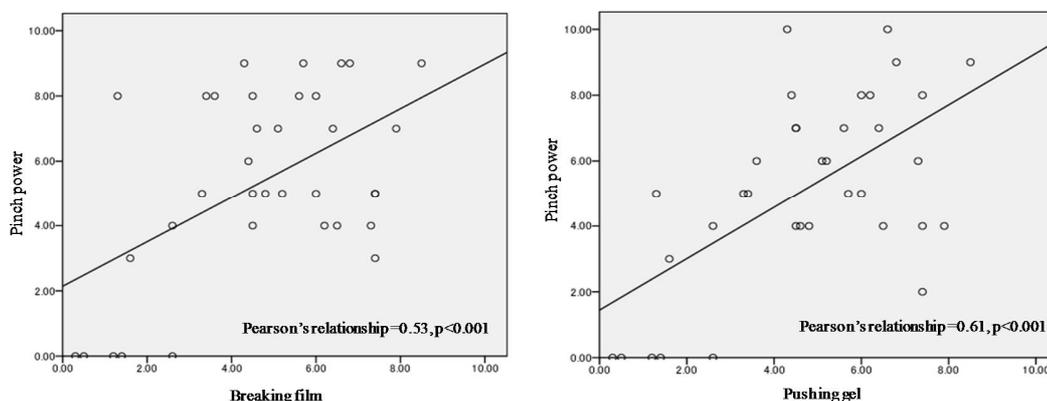
HDS-R, Hasegawa Dementia Scale Revised: best 30, under 20 suspect dementia

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:

1. Sadamoto K, Mizoguchi M, Yamanouchi T, Kinoshita N, Saeki T, How many elderly patients with handicaps can distinguish these eye drops? *J Packaging Tech* 2010; 19 (5): 383-6.
2. Itoh K, Tsuruya R, Shimoyama T, Watanabe H, Miyazaki S, D'Emanuele A, et al. In situ gelling xyloglucan/alginate liquid formulation for oral sustained drug delivery to dysphagic patients, *Drug Dev Ind Pharm* 2010; 36: 449-55.
3. Ministry of Health, Labour and Welfare, Japan. The project to collect and analyze hiyari-hatto cases. Ministry of Health, Labour and Welfare, Tokyo 2010.
4. Gurwitz JH, Field TS, Harrold LR, Rothschild J, Debellis K, Seger AC, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting, *JAM* 2003; 289(9): 1107-6.
5. Kastrissios H, Blaschke TF, Medication compliance as a feature in drug development, *Ann Rev Pharmacol Toxicol* 1997; 37: 451-75.
6. Hikota E, Takahashi M, Yanagawa C, Onagi A, Shibata I, Sadamoto K, Assessment of difficulty in opening power and granule medication packages – patient-friendly packages needs for those with low manual dexterity, *Jpn J Pharm Health Care Sci* 2007; 33 (10): 840-6.
7. Hunkeler EM, Meresman JF, Hargreaves WA, Fireman B, Berman WH, Kirsch AJ et al. Efficacy of nurse telehealth care and peer support in augmenting treatment of depression in primary care, *Arch Fam Med* 2009; 9: 700-8.
8. Miyazaki S, Takahashi A, Itoh K, Ishitani M, Dairaku M, Togashi M, et al. Preparation and evaluation of gel formulations for oral sustained delivery to dysphasic patients, *Drug Dev Ind Pharm* 2009; 35: 780-7.
9. Itoh K, Hatakeyama T, Shimoyama T, Miyazaki S, D'Emanuele A, Attwood D, In situ gelling formulation based on methylcellulose/pectin system for oral-sustained drug delivery to dysphagic patients, *Drug Dev Ind Pharm* 2011; 15: 790-797.
10. Miyazaki S, Ishitani M, Takahashi A, Shimoyama T, Itoh K, Attwood D, Carrageenan gels for oral sustained delivery of acetaminophen to dysphagic patients, *Biol Pharm Bull* 2011; 34: 164-6.
11. Cramer JA. Enhancing patient compliance in the elderly: role of packaging aids and monitoring, *Drugs & Aging* 1998; 12 (1): 7-15.
12. Coleman EA, Smith JD, Raha D, Min SJ, Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med* 2005; 165: 1842-1847.
13. Hughes CM, Medication non-adherence in the elderly: how big is the problem? *Drugs & Aging* 2004; 21 (12): 793-811.
14. Sadamoto K, Mission of drug packaging, *J Packaging Tech* 2011; 20 (4): 257-61.
15. Avorn J, Including elderly people in clinical trials: Better information could improve the effectiveness and safety of drug use *BMJ* 1997; 315: 1033.