Idea for Unit-Dose Packaging in Japan

-How to organize good adherence for elderly patients-

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Abstract: Elder patients with complex diseases need to take a large number of medicines. Therefore, the unit-dose heat-sealing film (for tablets and capsules) is used to help people take medicines in Japan. However, there are still some problems with unit-dose packaging, such as low adherence, difficulty opening and the issue of the large amount of waste involved. In this study, we evaluated the conventional unit-dose packaging and developed it which suit for Japanese patients and medical service. We made a prototype of the new unit-dose packaging and evaluated usability of this one in medication through comparison with conventional unit-dose heat-sealing film. This was a prospective, controlled 2 week trial conducted in 20 elder patients. According to the questionnaire, Almost patients satisfied with the new packaging due to ease of choosing right unit which should take. Furthermore, the number of remained medicine in the study group is less than the control group. The control group generated larger amount of trash than the study group. The new unit-dose packaging reduced omission of a medication and amount of trash. Moreover, the questionnaire represents that the new packaging is easier to use than existing one.

Keywords: unit-dose; usability; adherence; packaging

1. Introduction

Japan has the most rapidly aging population in the world, and 25 % of the population will be 65 or older by 2013 [1]. Elderly patients with complex diseases need to take a large number of medicines while also expe-riencing declines in the cognitive and physical abilities required for medication management, leading to in-creased risk of medication errors and low compliance [2-3]. Therefore, the unit-dose heat-sealing film (for tablets and capsules) is used to help people take medicines in Japan. However, there are still some problems with unit-dose packaging, such as low adherence, difficulty of opening and the issue of the large amount of waste involved. On the other hand, practical problems are still unclear, because there have been few studies focusing on these problems. In this study, we developed a prototype of a new unit-dose package which could be suitable for Japanese patients, and evaluated it through a series of clinical experiments.

2. Method

2.1. Comparison between Japanese and British Unit-dose Packaging Characteristics

We compared some Japanese conventional, heat-sealing film unit-dose packaging (Fig1) with some English unit-dose packaging (Fig2). Although there are many kinds of unit-dose packaging all over the world, most of them are similar with the exception of the Japanese packaging. So, we chose a British one as a representative sample of foreign package.

2.2. Developing a Prototype for New Unit-dose Packaging

We made a prototype for new unit-dose packaging. Characteristics of Japanese and English unit-dose packaging were reflected in the prototype. The prototype was made in cooperation with a drug packaging company in Japan, Kanae Co.,Ltd. .

Size (one unit): 80×70mm
Firm material: Polyethylene and cellophane
Firm thickness: 40μm
Weight (one unit): 0.5g
Described items: Patient name, Date, Drug name, Timing of doses

Figure 1. A Japanese unit-dose package

2.3. Commissioning Test

This was a prospective, controlled 2-week trial evaluating the usability of the prototype packaging with medication, through comparison with a Japanese conventional unit-dose package. In August 2010, at a same clinic, patients who were over 60 years old, self-

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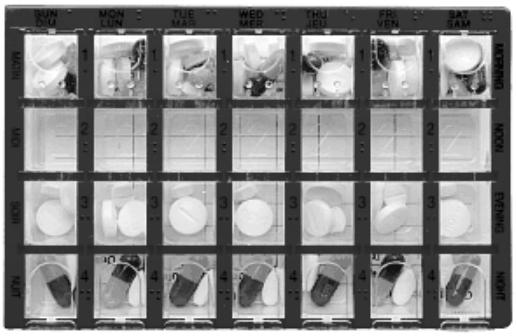
managing medication and taking doses (tablets and/or capsules) at several times were enrolled in this study (n=10). Their drugs were packed in the prototype and the conventional unit-dose packaging respectively; participants took medicine from each packaging. They took medication using the prototype for one week, and after this period they filled out a questionnaire, comprising



Size: 160×100×25mm
Weight: 145g
Described items: Timing of doses, Points system, Day of the week

Figure 2. An English unit-dose package "DOSETT®"

questions on the usability of the prototype. For the following week, they took medication using the conventional packaging and filled out a questionnaire about the conventional one. The questionnaire consisted of 6 questions, Drug administration, Portability, Opening the packaging, Readability of lettering, Amount of waste, Size of packaging. These were estimated on a zero-to-ten scale (0 being the worst, 10 the best). They also completed a medication error checking sheet when they forgot or mistook their medication for those 2 weeks. At their next visit to the clinic, they handed in the completed questionnaires and the used prototype packaging.

3. Results

3.1. Comparison between Japanese and British Unit-dose Packaging Characteristics

Comparison between Japanese and English unit-dose packaging shows that common features and many differences existed between Japanese and English packaging and medical situations. Common features were the improvement of medication adherence, such as facilitating and confirming drug administration, preventing the loss of drugs and the swallowing of drugs with the blister pack (in Japan, most tablets and capsules are packed in blister packs, thus some elderly patients take a drug without stripping off the packaging). Differences were found in several respects (Table 1). In particular, the greatest difference was on the point of preventing medication errors.

3.2. Developing a Prototype for New Unit-dose Packaging

The comparison indicated that with the Japanese unit-dose package it is difficult to confirm medication that has not been taken and there is tendency to produce large amount of waste. Considering these factors, the prototype was a calendar style multi unit-dose packaging, like the English packaging (Fig.3). There were some published controlled studies of the use of calendar blister package as compliance aids [4-5]. In addition, from a hygiene viewpoint, the tray dispensed drugs were heat-sealed with aluminum 20μm/PP.

Table 1. Differences between Japanese and English unit-dose packaging

	Japanese unit-dose packaging	British unit-dose packaging
Confirming whether drugs are taken or not	Difficult	Easy
Consideration of physically challenged patients	Not equipped	Equipped (some have points system)
Identifying contents	Easy	Not easy
Amount of waste	Large	Small (Some are reusable)
Dispensing fee for unit-dose	Yes	No
Child resistant function	Not equipped	Equipped

3.3. Commissioning Test

According to the result of the questionnaire, all participants were satisfied with the new packaging because of the ease of choosing the correct unit that should be taken and of confirming whether or not they took the medication. Concerning the amount of waste, it was estimated that the new package would produce less waste than the conventional one. With regard to portability, the conventional package was evaluated as better than the new packaging. In total for the six categories, the new packaging scored higher than the conventional packaging. In addition, most of the participants gave positive answers to the question as to whether they would like to use the new unit-dose packaging. For the other questions, no differences were found.

4. Discussion

Through the commissioning tests, the new unit-dose packaging was mainly appreciated by subjects. Few participants said that taking medication using the new

packaging is more pleasant than with the conventional one because he could confirm his missed dose and was motivated to manage administration. Regarding portability, results indicate that subjects who were employed and had to carry their drugs around disliked the new packaging due to its indivisibility into one unit

Size
(folded): 150×200×15mm
Weight: 35.9g
Tray material: Polypropylene (thickness: 600μm)
Cover material: Cardboard
How to open: Push through aluminum with finger
Described items: Patient name, Date, Day of the week, Drug information

Figure 3. Detail of the prototype unit-dose packaging

and bulkiness. Concerning capacity of one unit and lettering size, the size of the prototype is the minimum, thus we cannot make it smaller than it is now. For these reasons, the conventional unit-dose packaging should continue to be used by patients who are working outside the home and have a high potential for self-management. About waste, subjects regarded the prototype as less wasteful packaging. In this trial, we made the cover of the prototype with cardboard. If we adopted plastic materials for the cover, the part wasted would only be the tray and we could thus reduce wastage.

5. Conclusion

This study suggests that the new unit-dose packaging has the potential to improve adherence and could replace the Japanese conventional unit-dose packaging in some cases. However, further research is needed to assess its effectiveness. We plan to improve this packaging to provide a style more suitable for medication in Japanese.

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