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Usability of intranasal drug delivery devices: Children and their Parents

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Abstract
Recently, the use of over the counter (OTC) drugs are highly recommended. However the usability of packages and devices has not been well studied. We conducted usability tests with 20 children and 20 adults.
Five commonly used OTC intranasal drug delivery devices, one group of devices containing 30 ml liquid (A, B, C) and the other containing 15 ml (D, E), were tested. To evaluate the usability of nasal devices, 5 scoring choices were selected by the subjects for opening caps, stability of holding with fingers, and ease of pushing levers. Some 7-year old children could not hold and push devices A and B.
Parents chose smaller devices (D, E) for their children. All parents assessed that it was necessary to see the actual devices when they choose nasal devices for their children. The study of usability for OTC drugs and devices is an important issue for safe medication.

Keywords: intranasal drug, device, package, children, usability

1. Introduction
In Japan, national medical expenses in 2015 exceeded 42 trillion yen and were 7.96% of the gross domestic product (GDP) [1]. The increasing elderly population is leading to increased medical expenditures [2]. Thus, there is the need to develop and provide more sophisticated community based medical service in Japan [3]. For appropriate self-medication from children to the elderly in the community setting, we have to seriously consider safety in use including clear labeling and high usability of drug packaging and medical care devices [4]. From a risk management point of view, the role of packaging and devices is important as reflected in the many guidelines and regulations in the United States and other countries [4, 5]. Particularly, over the counter (OTC) drugs provided by community pharmacists require high levels of safety for all users including the elderly and children [6]. Since users tend to buy OTC drugs based on their impression of packaging, design of packaging and devices with better usability is also essential [7]. If usability is poor, it directly affects adherence and thus usefulness of drugs [8]. There is the rule that children from 7 years old are allowed to use nasal devices [9]. However, there is no data on usability by children in Japan. This study analyzed usability of nasal drugs, which are always used with devices, by children ages 7 to 10 and adults, and the dynamic characteristic of nasal drug delivery devices. Children in this age group are independent users of nasal drug delivery devices for common diseases such as allergic disorders.

2. Materials and methods
We conducted the study on nasal drugs for adults and children with consent (by the parents for 7 to 10-year-old children). Because general consumers were the target subjects, we excluded adults who the parents of children in the study and medical personnel including doctors, nurses and pharmacists. The investigation was conducted by interviewing subjects regarding their impressions of the packaging, the intranasal drug delivery devices and their characteristics".

2.1 Nasal drug delivery devices
The nasal drug delivery devices used in this study are available for over the counter (OTC) drugs in general drugstores for alleviation of acute nasal inflammation and allergic rhinitis for adults and children seven years old or older. The five types of nasal drug delivery devices used in the study were all fixed-quantity mist-type devices (device A–E). Five commonly used OTC devices were selected; each device had a different body shape and caps. There were two groups, one containing 30 ml liquid (A, B, C), and the other containing 15 ml (D, E). The nasal drug delivery devices and packaging used in this study are shown in Figs.1 and 2.

Table 1

Device	Dose (ml)	Distance from bottom to lever top (cm) (show"*")	Lever shape
A	30	8.0	Circle
B	30	7.8	Wing shape
C	30	7.2	Wing shape
D	15	6.4	Circle
E	15	6.4	Circle

Fig 1: Classification of the nasal drug delivery devices

The packages were processed to not show trademarks or manufacturer names.

Fig 2: Package of the nasal drug delivery devices

2.2 Evaluation items (healthy adults)

To evaluate usability of nasal device, we used the 8 item questionnaire listed below.

1. Which packages do you want to purchase for your own use? (A–E)
2. Ease of opening cap (difficult, quite difficult, normal, quite easy, easy)
3. Stability of holding with fingers (inferior, slightly inferior, normal, slightly superior, superior)
4. Ease of pushing lever (difficult, quite difficult, normal, quite easy, easy)
5. Overall evaluation (inferior, slightly inferior, normal, slightly superior, superior)
6. Which devices do you want to purchase for your own use? (A–E)
7. Which devices do you want to purchase for use by your child? (A–E)
8. After you used an actual device, would you want to purchase it again? (Yes/ No)

2.3 Evaluation item (7–10-year-old children)

To evaluate usability of nasal device, we used the 7 item questionnaire listed below.

1. Ease of opening cap (difficult, quite difficult, normal, quite easy, easy)
2. Stability of holding with fingers (inferior, slightly inferior, normal, slightly superior, superior)
3. Ease of pushing lever (difficult, quite difficult, normal, quite easy, easy) (1-3: same evaluation items as items 2–4 for healthy adults)
4. Which device do you want to use the most? (A–E)
5. Can you open the cap? (Yes/No)
6. Can you hold with your fingers? (Yes/No)
7. Can you push the lever? (Yes/No)

2.4 Measurement of finger strength required to push for a dose

Using a FGP-100 digital force gauge (Nidec-Shimpo Corporation, Kyoto, Japan), each nasal-spray preparation was covered with a test tube, set in a stand, and pressed from the upper side for measurement. Measurement was performed 10 times, and the mean ± S.D. was calculated.

3. Results & Discussion

Subjects include twenty children (7–10 years old), and their parents. All subjects were healthy, and there were no subjects with finger paralysis or low vision.

Of the adult subjects, 45.0% chose D and 25.0% chose E, both were smaller packages and devices (Fig. 3).

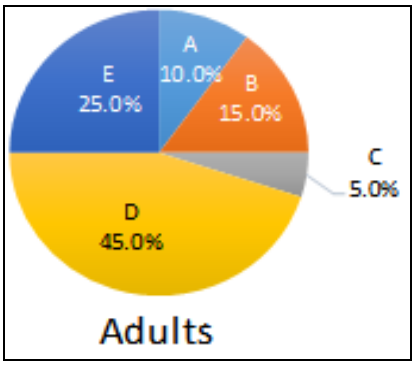

Fig 3: Which packages do you want to purchase for your use?

Three children aged 7 could not grasp or push devices A and B. On the other hand, two children could not open the cap of device C because it was too hard.

Table 2: Device operation of the children (the number of people)

Can you opening of the cap?					
	A	B	C	D	E
Yes	20	20	18	20	20
No	0	0	2	0	0
Can you hold it with your fingers?					
	A	B	C	D	E
Yes	17	17	10	10	10
No	3	3	0	0	0
Can you push the lever?					
	A	B	C	D	E
Yes	17	17	10	10	10
No	3	3	0	0	0

For cap opening, there were many answers that it was too hard to open device C for both adults and children. However, for devices B, there were many answers by children that it was easy to open but many adults answered it was hard to open.

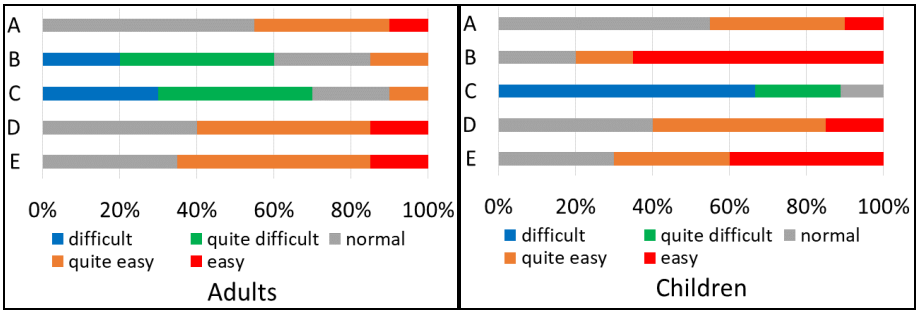

Fig 4: Ease of opening cap.

For stability of holding with fingers, among children, devices that were long from bottom to top (A, B) had lower evaluation scores than the other devices. There were similar results for adults.

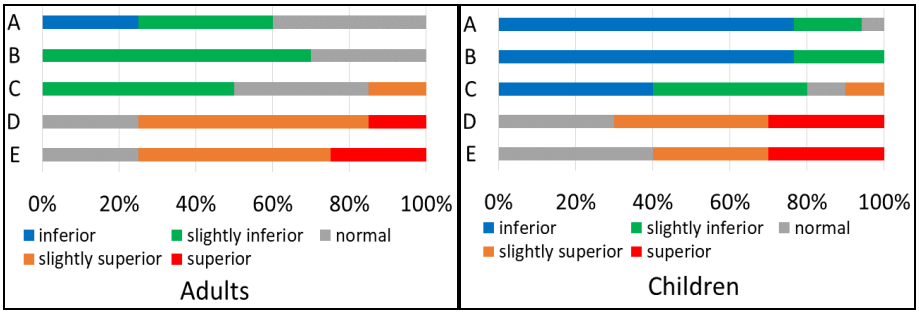

Fig 5: Stability of holding with fingers.

For ease of pushing levers for devices that are long from bottom to top (A, B, C), about 80% of children answered it was difficult or quite difficult. On the other hand, for A, more than 40% of adults answered it was easy and quite easy.

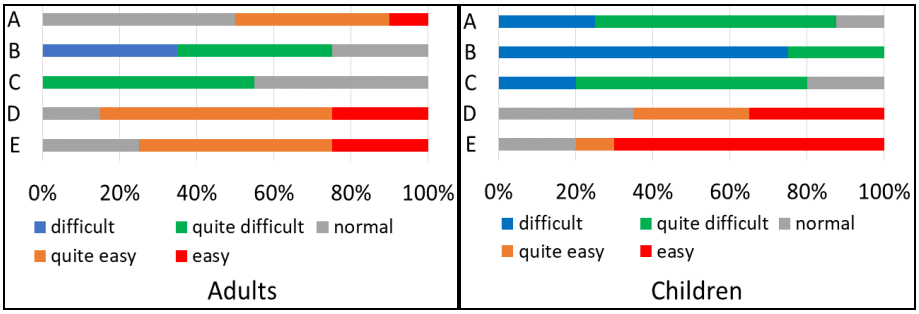

Fig 6: Ease of pushing lever.

As for overall judgment of the adults, they tended to choose smaller devices (D, E).

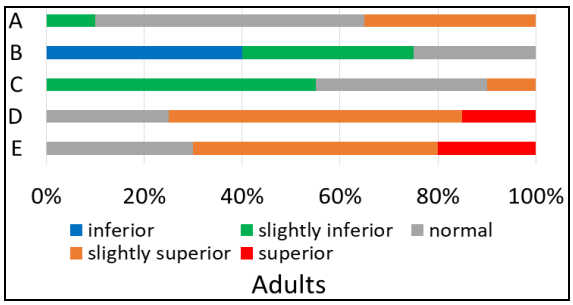

Fig 7: Overall evaluation.

As for the preference for devices among adults and children, they tended to choose smaller devices (D, E). Parents also chose devices for their children that were smaller devices (D, E) (Figures 8–10).

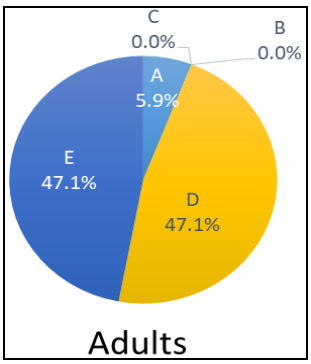

Fig 8: Which devices do you want to purchase when you use it by yourself?

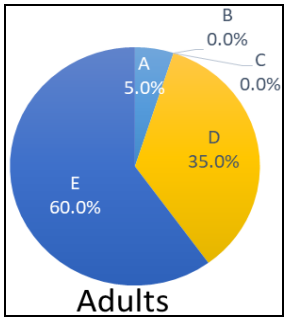

Fig 9: Which devices do you want to purchase when your child uses it?

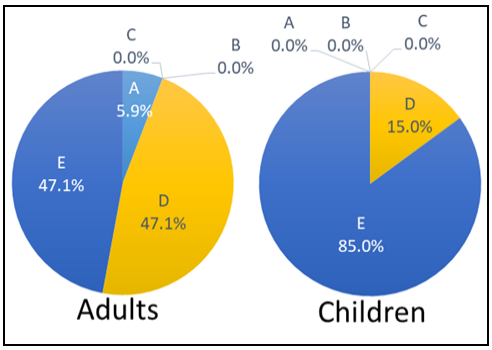

Fig 10: Which devices do you want to use most?

All 20 adults replied "yes" to the question "After you saw the actual device, did you want to purchase it?"
We show the free comments in Table.2.

Table 3: Free comments

Device	Free comments
A	Size is big. So it is hard to grasp slightly.
B	Size is big. So it is hard to grasp. Cap is small. It is hard to push. The form of the lever is unfavorable.
C	Size is big. A cap is hard.
D	Ordinary Easy to use Small
E	Small Because a cap is big, it is easy to open out. It is easy to push it.

We show the results of the measurements of finger strength required to push for a dose in Figure 11. The force required for the nasal drug delivery devices varied among the devices from 12.7 N (D) to 31.4 N (B). The finger strength required to push for a dose for A was significantly higher than that for all other devices. The strength required for B was significantly higher than for A, C and E (Fig. 11).

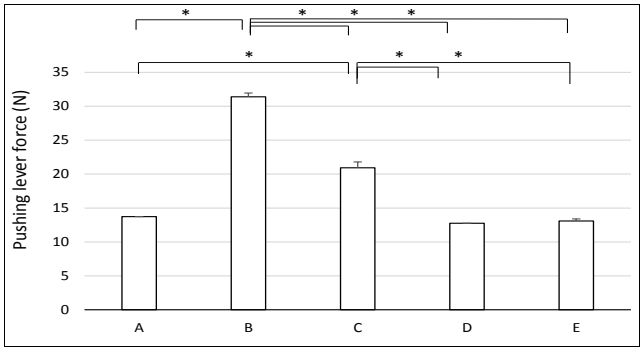

Fig 11: Comparison of lever pushing force required for A–E (n=3). *$p < 0.001$ (Tukey Kramer HSD Test)

Usability of devices affects availability to patients availability and could influence adherence [8, 10-13]. This result suggests that both children and their parents chose devices that have a short distance from bottom to top and require low finger strength to push for a dose.

4. Conclusions

The usability of nasal drug delivery devices for children and adults, and the differences between children and adults were evaluated in this study. Both children and adults tended to choose smaller devices with low finger strength required to push for a dose. Thus, our results regarding usability suggest that human ergonomic factors such as size of hands is closely related usability of devices. It is suggested that the trial-use of devices is important. Some additional instruction for children could be useful for appropriate use of nasal drugs by children.

5. References

1. Estimates of National Medical Care Expenditure, FY Ministry of Health, Labour and Welfare, Japan, 2015. http://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/15/dl/kekka.pdf, 23 Sep. 2017.
2. Health, Labour and Welfare White Paper, Ministry of Health, Labour and Welfare, Japan, 2015. http://www.mhlw.go.jp/wp/hakusyo/kousei/16/dl/1-04_02.pdf, 23 Sep. 2017.
3. Report of the National Council on Social Security System Reform (The Prime Minister in Action) JAPAN, 2013. http://www8.cao.go.jp/shoushi/shoushika/meeting/taskforce_2nd/k_1/pdf/s9-1.pdf#search=%27%E7%A4%BE%E4%BC%9A%E4%BF%9D%E9%9A%9C%E5%88%B6%E5%BA%A6%E6%94%B9%E9%9D%A9%E5%9B%BD%E6%B0%91%E4%BC%9A%E8%AD%B0%E5%A0%B1%E5%91%8A%E6%9B%B8%27, 23 Sep. 2017.
4. Kiyomi Sadamoto, Mikio Murata, Kiyoshi Kubota. Life and Medication– Needs for Packaging and Devices–, International journal of pharmacy and pharmaceutical research. 2016; 8(1):232-243.
5. FDA. Guidance for Industry "Container Closure Systems for Packaging Human Drugs and Biologics.
6. Manako Hanya, Akiyo Shibata, Hiroyuki Kamei, Kazuhisa Matsuba, Masahiro Asai, Masayoshi Taniyama. Analysis of Pharmacist Communication with Patients in Triaging OTC Drugs, Jpn. J Pharm. Health Care Sci. 2007; 33(8):693-701.
7. Evaluation of Users' Attention to the Labeling Information of Over-the-counter Medicines using Eye-tracker, Japan Society of Kansei Engineering 2012; 11(1):69-78.
8. Lars Osterberg MD, Terrence Blaschke MD. Adherence to Medication, N Engl J Med. 2005; 353:487-497.
9. Pharmaceutical Administration and Regulations in Japan Regulatory Information Task Force Japan Pharmaceutical Manufacturers Association, Japan, 2015. http://www.jpma.or.jp/english/parj/pdf/2015.pdf, 23 Sep. 2017.
10. Yuko Wada, Shyoko Ami, Mitsuru Nozawa, Miho Goto, Ken-ichi Shimokawa, Fumiyoshi Ishii. Generic selection criteria for safety and patient benefit [V]: Comparing the

pharmaceutical properties and patient usability of original and generic nasal spray containing ketotifen fumarate, Drug Discoveries & Therapeutics. 2016; 10(2):88-92.
11. Spector SL, Kinsman R, Mawhinney H, *et al.* Compliance of patients with asthma with an experimental aerosolized medication: implications for controlled clinical trials, J Allergy Clin Immunol. 1986; 77:65-70.
12. Norell SE. Monitoring compliance with pilocarpine therapy. Am J Ophthalmology. 1981; 92:727-731.
13. Kass MA, Meltzer DW, Gordon M. A miniature compliance monitor for eyedrop medication, Arch Ophthalmology. 1984; 102:1550-1554.